Enabling The Diffusion of Disruptive Innovations in Medical Markets

Case of Iranian Cardiovascular Devices Market

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By

Mohammad Hajhashem

Manchester Business School

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Abstract

Following the studies of technology trajectories, Christiansen (1997) coined the concept of disruptive innovation to shed more light on the pattern of discontinuous innovations which were introducing new performance values to the market and mostly led to create a new market. Following his studies there have been a huge amount of scholars who have tried to elucidate the concept of disruptive innovations from different points of views. Among all of these studies, there are few researches about the dynamic of disruptive innovations diffusion in the market while most of the studies have focused on the concept itself.

According to Porter (2008) the dynamic of market competition has been totally changed over the past decade and survivance of incumbents in the market mostly depends on their capability to innovate disruptively and keep their dominancy by radical or incremental improvements. Considering the desire of incumbents to set a dominant position in today's fast growing markets, getting the ultimate benefits of disruptive innovations has become a disputable issue. Therefore, focusing on the dynamic of disruptive innovations, this research tries to elucidate the way that market leaders take an unknown potential disruptive innovation out of its dark corner during its infancy time, raise it and disrupt the mainstream market relying on it to establish a new market.

Focusing on the dynamic of innovation diffusion, this research has chosen the high-tech medical market of Iran as the main target of empirical field work. Novelty of this concept in medical markets and also appropriateness of invasive cardiovascular devices business in terms of great amount of disruptive innovation, make this case study appropriate for the purpose of this research. Therefore conducting a longitude case study of Iranian invasive cardiovascular market during the past 10 years, this research conducts 30 semi-structured interviews with the key decision makers of the four main incumbents of Iranian invasive cardiovascular market about launching new innovations including: Johnson and Johnson (Cordis), Abbott Laboratories, Boston Scientific and Medtronic. The findings of these interviews are supported by the results of archival researches for more validity and reliability. Finally these findings will get compared with the conceptual framework of research in the discussion chapter to modify the existing literatures and in some cases add some new theoretical notions to them.

The main contribution of this research is to identify the accelerating factors of disruptive innovation diffusion from, strategic, technological and cultural points of views. These findings can help practitioners to accelerate the diffusion rate of their disruptive innovations to disrupt the market earlier than the others and set their dominant position in the market as a market leader. Also it will provide an opportunity for the other scholars to build on more about the concept of disruptive innovation diffusion.

Declaration

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

Copyright statement

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List of Abbreviations

AMS: Bio-Absorbable Metal Stents

ANT: Actor Network Theory

BMS: Bear Metal Stent

CABG: Coronary Artery Bypass Graft

CAD : Coronary Artery Disease

CAM: Customers' Analysis Methods

CRM: Cardio Rhythm Management

CV: Cardiovascular

CVA: Cerebrovascular Accidents

DDRI: Disruptive Diffusion Regime of Innovation

DDVV: Design-Development-Verification-Validation

DES: Drug Eluting Stents

DHC: District Health Centers

DI : Disruptive Innovation

FDA: Food and Drug Administration

HDI: Human Development Indicators

HH: Health Houses

IA: Innovation Adoption

ICD: Implantable Cardioverter Defibrillators

IPR: Intellectual Property Right

IQ: Installation Qualification

LMR: Limit Market Release

MD: Medical Devices

MI: Myocardial Infarction

MMR: Mix Method Research

MOHME: Ministry of Health and Medical Education

NPD: New Product Development

OEM: Other Equipment Manufacturers

OQ: Operational Qualification

PCI: Percutaneous Coronary Intervention

PLC: Product Life Cycle

PMA: Pre-market clinical trial

PPQ: Product Performance Qualification

PQ: Performance Qualification

PTCA: Percutaneous Transluminal Coronary Angioplasty

RHC: Rural Health Centers

ROI: Return of Investment

S&T: Science and Technology

SBU: Strategic Business Unit

STP: Segmentation, Targeting, Positioning

TAM : Technology Acceptance Models

TB: Tuberculosis

TCC: The Currency Committee

TVR: Target Vessel Revascularization

UBD: Use By Date

UHC: Urban Health Centers

VAD: Ventricular Assist Devices

Chapter 1

[INTRODUCTION]

Introduction

Since it was coined by Christensen (1997), disruptive innovation (DI) has been analysed by many scholars, including Daneels (2002; 2004), Markides (2006), Druhel and Schmidt (2008) and Adner (2002), in order to provide a better understanding of the concept within scholarly literature. While most of these studies elaborated on the concept, few of them paid attention to efficient diffusion of DIs. This is the major reason for studying DI diffusion, since most scholars agree that market disruption is more dependent on diffusion mechanisms than technological advantages. DI basically depends on delivering new performance value to the market in a way that might alter the current performances (Droege and Johnson, 2010). Therefore, this research focuses on mechanisms of efficient DI diffusion while attempting to understand market dynamics during the process of market disruption in order to appreciate the key factors of successful market disruption in medical devices markets.

1.1 Societal and Scientific Relevance of this Research

According to the accelerated rate of knowledge production in the fifth generation of technological changes, high-tech businesses are growing faster than ever (Rothwell, 1994). As Schumpeter (1942) and Porter (2008) predicted, the nature of competition has been totally transformed and thousands of high-tech start-up businesses are currently growing all around the globe. As Mohr et al (2010) state, traditional production and marketing indicators are no longer the main leverage factors of competition. Today, incumbents concentrate on generating new innovations from the fast-growing technologies in their R&D divisions (Malerba, 2005). However, this is just the beginning of competition in high-tech markets. Perhaps the biggest challenge will be the waiting time on the marketplace. All incumbents and newcomers tend to enter the market with their new innovations aiming for dominancy in their market segments (Stremersch et al, 2010). Most competitors prefer their new innovations to be diffused in the market in a quick and sustainable manner.

Medical industries are some of the high-tech industries with the most investment in R&D. Most medical industries studies have been conducted based on healthcare innovations that are more concerned with service innovation than high-tech medical products. There is a specific body of literature on innovation diffusion in healthcare that builds upon various models (Neir et al, 2012). Healthcare is a particularly interesting domain within which to explore the development of technology for several reasons. Firstly, medical innovation frequently takes place in ways different from other fields. This is due to the emotional factors attached to the concept of health and illness and the political commitment to treat patients with the latest advances in medicine (Gelijns and Rosenberg, 1994). Nevertheless, there are two aspects to novel biomedical technologies. On one hand, they promise better health and improved quality of life. On the other, they are associated with higher costs of services. In the context of scarce resources and attempts to reduce expenditure, health policy and decision makers have to prioritize. As a result, some technologies diffuse while others do not (Gelijns and Zivin, 2001). Also, a perceived gap exists between 'best evidence' and 'evidence-based practice.' Technologies with reported clinical validity often fail to integrate into medical use, thus preventing patients from benefiting from scientific progress (Docteur and Oxley, 2003). This raises questions as to why clinical evidence alone is insufficient to 'push' innovation, and what other factors may exist that hinder the diffusion process. Coleman et al (1966) assert that healthcare is an interesting and complex domain, populated by a diverse set of groups of which the medical profession has retained primacy, particularly in the decisions to adopt an innovation at the local level. This is achieved mainly via inter-professional alliances and networks for change, which may facilitate or inhibit diffusion.

Therefore, considering the abovementioned gaps in diffusion of innovation in healthcare, this research will study discontinuous technological changes that lead to the next generation of medical technologies. Christensen (1997) named this 'disruptive innovation' (DI). Most of the studies on DIs have been conducted to clarify this concept. According to Machlup (1962), Rothwell (1994) and Van den Bulte (2000), the half-life[1] of high-tech products is decreasing in the fifth generation of

[1]The half-life of knowledge is the amount of time that has to elapse before half of the knowledge in a particular area is superseded or shown to be untrue. The concept is attributed to Fritz Machlup (1962).

technological development. In order to get the most benefit from the new generation of a high-tech product (technology cluster[2]), it must be diffused as soon as possible and settle the dominant designs and standards earlier than the other potential DIs in the market.

Therefore, due to the nature of high-tech industries, and the massive investments in medical innovations that necessitate the acceleration of the process of return of investment (ROI), this research will focus on the acceleration of the technology diffusion of DI in high-tech medical innovations.

The basic focus of this research is the dynamics of DIs in high-tech medical markets and the associated mechanisms that form this dynamic. While most previous DI studies have tried to shed more light on the concept of DI since Christensen (1997) (Droege and Johnson, 2010), this research focuses more on the competition of DI candidates to enter the market and disrupt the market sustainably. In other words, this research takes a step forward and discusses the dynamics of DI diffusion from infancy to demise. To take a fragile, unknown potential DI from its dark corner and disrupt the mainstream market, this research will focus on two main issues: dynamics of DI diffusion in medical markets and the mechanisms of market disruption.

However, the conceptual originality of this research is obtained from the researcher's point of view towards innovation diffusion studies. After further analysis of innovation diffusion models, we find that the literature on diffusion models can be divided into two categories according to the difference between research subjects and methods.

One is the macro-level mathematical model based on the overall statistical behaviour of potential adopters. The macro-model was first proposed by Bass (1967), of which the Bass model and its extended models are the main representatives. The mathematical model is the most mature diffusion model and is used widely; most diffusion models belong to this category. Through scholars' continuous expansion, such diffusion models have been used to study problems in various fields, such

[2] Rogers' (1995) definition of high-tech products.

as market mix strategies, competition, advertising, pricing, repeat purchase, technology substitution, etc.

The other is the social structure diffusion model, based on the individual decision-making behaviour of potential adopters. With the development of the computer, social structure models are increasingly used in innovation diffusion research. The basic idea of the micro-simulation model is to obtain the macro results by simulating the behaviour of the individual and interaction between individuals.

The research on adoption decision mainly studies the factors influencing individual adoption from the angle of the individual. Such research from the individual perspective compensates the lack of macro level perspective studies and considers individual heterogeneity and technology foresight.
While both macro and social structure models of innovation diffusion consider the economic issues as the main concern of diffusion curves, this research looks beyond the economical perspectives. Additionally, this research is methodologically unique, as will be discussed later. While most diffusion studies have tried to make a new economic model relying on quantitative methods, this research takes a market-level perspective and attempts to figure out the dynamic and enabling mechanisms of DI diffusion in medical markets.

1.2 Research Objectives and Questions

There is a large amount of literature about incremental and radical innovations diffusion by researchers such as Davis (1979), Mahajan et al (1993), Sultan et al (1990), Norton and Bass (1987), Mahajan and Muller (1979,1985, 1986,1994), Mahajan et al (1978, 1984, 1986, 1988, 1990), Bass and Bayus (1987) and Bass (1988) from the macro-level point of view, and Utterback (1978), Montaya-Weiss and Calantone (1994), Rogers (1985), Utterback and Abernathy (1975), Abernathy (1978), Anderson and Tushman (1990) from the social structure perspective.

However, considering the amount of literature, there remain gaps that this research intends to fill. Most of the existing research is about incremental and radical innovations rather than disruptive innovations. This is because most of the studies on DIs have attempted to elucidate the concept by generating an acceptable framework for this recently coined concept (Droege and Johnson, 2010). Secondly, as Zappa (2011) mentions, while most of the diffusion studies (even those on the social structure) concentrate on the diffusion curves and economic and marketing indicators of innovation diffusion, there are fewer studies considering the attached social contagion sense of new innovations in the process of diffusion.

Therefore, considering the importance of accelerating the diffusion of DIs in today's fast-growing economy, as well as surviving on the market, and regarding the gaps in existing literature relating to the transforming of an unknown potential DI candidate into a vigorous leading DI in a new generated market by itself, two research questions have been formulated:

1. How does a potential DI diffuse more quickly in medical markets achieving an earlier sales take-off and arriving at the consumer's critical mass as soon as possible?
    a. What are the main launching strategies by the market leaders to accelerate the diffusion rate of a new DI in medical markets?
    b. What are the enabling mechanisms of DI diffusions in medical markets

2. What is the dynamic path (Generation, market challenges, demise) of DI diffusions in the medical market?

Most of these questions target the main gaps in the interdisciplinary areas of knowledge between innovation diffusion studies and the DI field. The main purpose of this research is to study the way that medical market leaders choose to introduce a potential DI out of obscurity to establish a new market. In other words, while other scholars have attempted to shed light on the concept of DI, this

study goes one step further and discusses mastering disruptive innovations taking two leverages into account: accelerating the diffusion rate and facilitating the process of market disruption.

This research has several novel aspects to it. First of all the concept of mastering DIs is new. Secondly, emphasis on the social aspect of DI diffusion provides a comprehensive overview of the process of innovation diffusion. In addition, choosing medical industries as the main area for empirical study will provide specific originality in terms of findings, since there have been few such studies in the medical devices field. This is the first innovation study of this sector utilizing empirical research insights from Iran and neighbouring countries.

1.3 Research Methodology and Approach

This research looks at social phenomena from the point of view of critical realism. Critical realism attempts to find the mechanism behind an observed phenomenon to find truth (Bahskare, 2007). Additionally, this research aims to find the mechanism behind the diffusion of disruptive innovations in medical markets. As Bryman and Bell (2007) state, each qualitative or quantitative method should be supported by complementary documents in order to provide more reliable and valid findings. There are also other strategies to provide the research findings with more reliability and validity, such as applying mixed methods, using supportive documents, and making a chain of evidence to support the findings (Yin, 2003). There is also the triangulation strategy (Ryan et al, 2002), which addresses the research questions from complementary research methods (Bryman and Bell, 2007). In this respect, this study is a qualitative piece of research deriving benefit from triangulation and a chain of supportive documents to prove the findings valid and reliable.

Regarding the critical realistic point of view of this research, and based on the nature of the research questions, a longitudinal case study on the Iranian medical devices market over the past ten years was conducted in order to study the main incumbents' behaviour in bringing new disruptive innovation to the market and to follow its dynamic in the marketplace. After considering different medical fields,

the researcher decided to focus on the invasive cardiovascular (CV) devices industry, mainly because of the fast-growing nature and innovation of this field. Secondly, based on the archival research, CV diseases are the leading cause of death both in Iran and worldwide. Therefore, it seems reasonable to study the invasive CV devices market of Iran to identify the disruptive innovation cases on the market during the past ten years.

Therefore, this research concentrates on the DI roadmap by focusing on the dynamics of DIs in medical markets and enabling the mechanism of sustainable market disruption. This research includes a longitudinal case study of launched DIs in the Iranian CV devices market between 1998 and 2010. To collect the required data to address the research questions, in-depth elite interviewing, archival research and participative observation are applied. Since the majority of DIs on the Iranian CV market was launched by Cordis, Abbott Laboratories, Boston Scientific and Medtronic, the market dynamics have been investigated during the first round of interviews with the key decision makers of those companies. Supported by the findings of archival research into the sales reports and patent analysis, the case study was analysed by interviewees in the second round of interviews to examine the role of associated mechanisms in shaping the DI diffusion dynamic during the aforementioned time span. Finally, the findings of this phase will be analysed through template and discourse analysis backed by the findings of participative observation. The robust methodology of this study could be considered the most important contribution this research offers to the field of qualitative research. It is worth mentioning that theory building through case studies hasn't possessed a well-structured framework. This research offers a well-structured framework to generate generalizable theories out of case study research.

1.4 Introduction to Case Studies and Different Research Roles

According to the 2010 R&D scoreboard, the medical industry ranks number one in high-tech industry in terms of R&D expenditure. The high-tech medical devices industry is a new industry, which includes medical technology, nanotechnology, biotechnology and pharmacology. Therefore, one

aspect that makes this industry an appropriate candidate for this research is the novelty and originality of this medical domain. Because of the high rate of technological changes in medical industries and the significant amount of innovation in this industry, it seems appropriate to conduct this study in the context of medical industries. In other words, the technology-driven and R&D-oriented nature of the medical industry makes it suitable for this research.

High-tech medical innovations should be considered as bundled breakthrough technologies rather than simple products. However, the U.S. Food and Drug Administration (FDA) defines a medical device as *"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes*" (FDA, 2011). Since this research focuses on the concept of DI diffusion, it seems that the invasive CV devices market is suitable as the subject of fieldwork given the massive amount of DI in this segment during the past decade (as will be discussed in chapter four).

To understand the nature of DI diffusion in CV industries, this research will concentrate on the evolution of coronary artery disease (CAD) treatment over the last decade. In particular, the research will discuss the emergence of percutaneous transluminal coronary angioplasty (PTCA) as a procedure to disrupt the market of coronary artery bypass graft (CABG) and focus on the simultaneous co-evolution of relevant technologies and DI diffusion in the CAD treatment market in the Iranian healthcare system over the last decade. In fact, the research will discuss the evolution of PTCA and the first bare metal stent (BMS) used to facilitate the PTCA procedure. The market disruption of the second generation of stents (drug eluting stents, or DES) will also be scrutinized to figure out the dynamic and enabling mechanisms of DI diffusion in medical markets. In this respect, the interactions of the four main actors of the CAD treatment market of Iran (as mentioned earlier) and their launching

strategies will be analysed during the three areas of BMS, DES and bio-absorbable metal stents (AMS) on the Iranian CV market.

1.5 Structure of the Research and Thesis

This thesis contains eight chapters, each of which plays a particular role in defining, formulating, and addressing the research question to deliver the assumed contribution of this research. The research attempts to discuss the relevance and importance of DI diffusion on the medical market in chapter one. In chapter two, a significant amount of relevant literature will be discussed in order to build a reliable theoretical base to define the research questions based on the current gaps within this literature. Chapter two will offer hybrid and compiled models and creative frameworks to be used in data collection, classification and analysis in later chapters of this thesis. Chapter three covers the methodology and research design; this chapter will discuss the ontological and epistemological concerns of this research. Based on these concerns, the research strategy and design will be discussed in detail, taking into consideration the requirements set by the nature of the research questions. Data gathering, processing and analysing methods will highlight the methodological approaches of this research and, in the final part of chapter three, the main concerns of validity, reliability and generalizability of the findings through the offered research design will be discussed. As is shown in Figure 1.1, chapter four of this thesis essentially covers the industrial

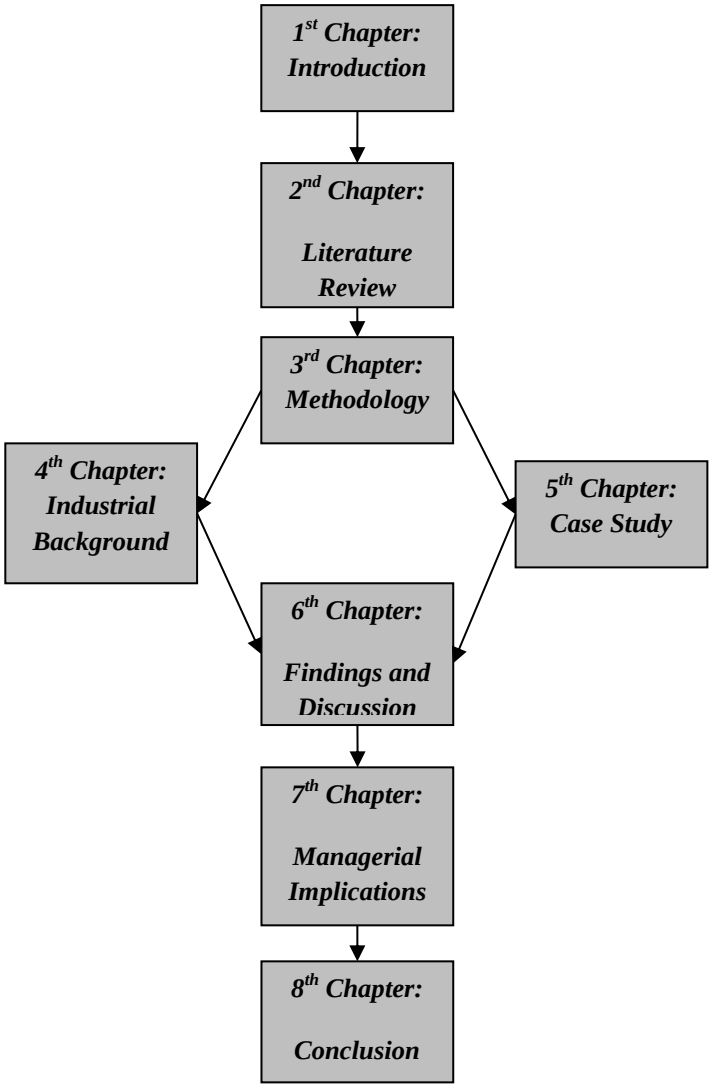


Figure 1.1 Thesis Structure

background of this thesis. Since the medical devices industry is the main context of this research, industry regulations, market structure and the primary engaged actors in the emergence and diffusion of medical innovations will be discussed within chapter four. In this chapter the context of medical devices will be narrowed down to the cardiovascular subdivision and focus will be placed on CAD treatment. Relevant technologies' trajectories, evolution of new innovations, market regulations, and the main actors within the market will be scrutinized, as will relevant jargons and technical terms to provide more understanding about the context of this research. Chapter five will present the case study of this research based on the data collected during the fieldwork. In fact, based on the interviews

with the key decision makers in the target companies and supportive documents of secondary data, the longitudinal case study of the Iranian CAD treatment market will be demonstrated in chapter five.

The findings from the longitudinal case study of this research will be categorised and presented within chapter six. The extracted findings from the longitudinal case study will be presented and compared with the previous findings in the field by other scholars and relevant discussions will take place to understand the similarity and discrepancies of the findings with the current literature. Finally within chapter eight, these discussions and findings will be summarized and set up to address the research. Also, the main contributions and the final proposed model of this research will be offered as the main conclusion of this research. It deserves mention that the managerial contributions of this research are presented as a separate section in chapter seven.

1.6 Anticipated Outcomes and Limitations

There are certain results that this research expects to achieve, and a number of limitations regarding its conduction. In terms of the expected outcomes of this research, the primary aim is to discuss the concept of DI in more detail and suggest a comprehensive framework to classify different types of DI based on the relevant literature. The second aim of the research is an introduction of a model to describe the social structure dynamic of DI diffusion in medical markets. Nevertheless, it is expected that relevant data will be obtained, upon the analysis of which the social structure model of enabling mechanisms of DI adoption in the medical market could be designed. In other words, this research will focus on the dynamic of DI diffusion in the medical market from the market's point of view, and attempt to understand the relevant mechanisms which shape such a dynamic to disrupt the mainstream market and open up a new one. However, the major outcome of this research will be a disruptive diffusion regime of innovation (DDRI), which will demonstrate the constant interaction of DI diffusion-enabling mechanisms to shape the dynamic of DI diffusion in the medical market. In fact,

DDRI could introduce a new innovation diffusion paradigm by which any revolutionary or non-revolutionary innovation could disrupt the mainstream market relying on DDRI.

However, there are limitations to conducting such research based on the mentioned research design. First of all, due to limitations of time, cost and relevance of context, focus must be given to the cardiovascular subdivision rather than the entire medical industry. Although other subdivisions might present different patterns of DI diffusion, due to the considerable amount of DIs in the cardiovascular subdivision and its significance in Iranian healthcare (as cardiovascular disease is the main cause of death in Iran), focus must be on this subdivision. Subsequently, other scholars could conduct the same research in other medical subdivisions and compare the results to provide a better understanding of DI diffusion in medical markets.

The scope of the research is limited geographically to the Iranian medical market. In fact, since the research design is based on a case study, it restricts the research territory, enabling an in-depth focus on the dynamic of DI diffusion in a medical market. In other words, according to the main objectives of this research and considering the limits of the chosen research design, focus may only be on the case of the Iranian medical market; other scholars could make further advances and conduct fieldwork in other countries.

Another limitation of this research arises from the number of DIs that it is possible to study in this thesis. In fact, since this research aims to understand the dynamic of DI diffusion in the market, a longitudinal case study will be conducted on ten years of the Iranian CAD treatment market. This specific time span limits the number of DIs to be studied in this research. Since this research possesses a qualitative view rather than quantitative one, the depth of information will be the main subject of concern, rather than the statistics of the research sample.

Finally, the sensitivity of healthcare and medical information does not invite disclosure. In other words, having access to the required data would require a significant amount of time and effort from two different aspects. Firstly, identifying the main actors within the Iranian cardiovascular market and access to the key decision makers of launching new innovation to conduct the interviews would

be difficult, if not impossible. Secondly, access to secondary data such as sales reports and pre-market trial results of some innovations during the last ten years is also necessary. Such access to this type of information seems to be quite limited.

The theoretical and industrial background of this research will be discussed in later chapters and will demonstrate the findings based on the abovementioned case study. Finally, the main discussion and conclusion will take place, and as well as addressing the research questions, further contributions of this research will be discussed.

2nd Chapter

[LITERATURE REVIEW]

Introduction

The focus of this research is the diffusion of disruptive innovations in medical markets, so the research questions will be defined based on the gaps in the relative literature. To understand the dynamic of the advanced technology in a given market, this chapter begins by looking at the literature of technology trajectories. Skimming the relative literature will narrow down the topic to the importance of discontinuous innovations, which will enable us to focus more on the dynamics of discontinuous innovations. Subsequently, after gaining a better understanding of the concepts of dominant design and the market challenges in crossing the chasm of the market's early majority and late majority, we will concentrate on the concept of disruptive innovation (DI), introduced by Christensen, as one of the most recent types of discontinuous innovation.

In fact, the review of DI literature published in the past decade will enable us to ascertain where gaps exist and further research needs to be conducted. However, since the diffusion of DI (dynamics and mechanisms) is the main concern of this research, the main body of innovation diffusion literature will be discussed to understand the social structure of innovation diffusion. Probing further into the history of innovation diffusion and focusing more on the systems of innovation studies, the research will introduce the social dynamic model of DI diffusion. Two objectives in developing this research model are 1) examining the research model of DI diffusion in the medical devices industry to determine the gaps in the literature and the case for modifying this model of diffusion dynamics; and 2) to focus more on enabling mechanisms of DI diffusion in medical markets. Most new product development (NPD) research has focused on the fuzzy front end[1] of innovation diffusion rather than offering specific diffusion strategies for new disruptive innovation. At the same time, marketing scholars have discussed product launch strategies at length, while diffusing new innovations (especially DIs) requires specific investigation, particularly since the nature of innovation is different and should be considered from an innovation diffusion point of view.

[1] According to Smith and Reinertsen (1991), the fuzzy front end is the earliest stage of the NPD process and roughly means all time and activity spent on discussing and developing an idea prior to the first official group meeting. In other words, the fuzzy front end is defined as that territory leading up to organizational-level absorption of the innovation process (Cohen and Levinthal, 1990).

The final section of this chapter will briefly introduce literature relating to the nature of medical innovations, since the main focus of this research is the medical markets.

2.1 Technology Trajectories and Innovation Dynamics

Innovation studies have resulted in a vast array of literature on the varieties and levels of innovation. Various scholars have found different patterns of technological changes to explain the emergence of different types of innovation. While Freeman and Soete (1997) consider innovation from an industrial perspective, Rothwell and Gardiner (1985) demonstrate it from a technological point of view. Drucker (1985) describes it as an entrepreneurial tool, and Porter (1990) deals with it as a main factor in competitive advantage. There is a direct correlation in the emergence of innovation with the interactive process of knowledge generation and application (Tidd and Bessant, 2009; Moor, 2006; Tödtling et al., 2009). According to the innovation system models (Lundvall, 1992; Nelson, 1993) and the innovation network researchers (Pawell and Gordal, 2005), innovations usually occur in constant relation to and interaction between business, science, and policy sectors.

Likewise, different levels of innovation, such as national, sectorial, and organizational, could be considered from different perspectives. For instance, while new product development (NPD) models such as the one illustrated in Figure 2.1 (Cooper and Kleinschmidt, 1993; Griffin, 1997; Hart, 1993; Hultink et al, 1997; Lilien and Yoon, 1989) focus on the generation of innovation mostly at a firm's level, S-Curve learning graphs, which have been used by many scholars such as Utterback and Abernathy (1975) and Abernathy (1978), are criticized by Sood and Tellis (2005). An example of such graphs can be seen in Figure 2.2, where Hinkes et al (2007) try to explain the concept of discontinuity between two generations of innovation. The incremental and radical innovations concept has been applied by many scholars in different applications. While Abernathy (1978) differentiates between incremental and radical innovations, Sahal (1981) discusses continuous and discontinuous technological changes. Tushman and Anderson (1986) call this *incremental and breakthrough innovation,* based on Abernathy and Clark's (1985) concept of conservative and radical innovation.

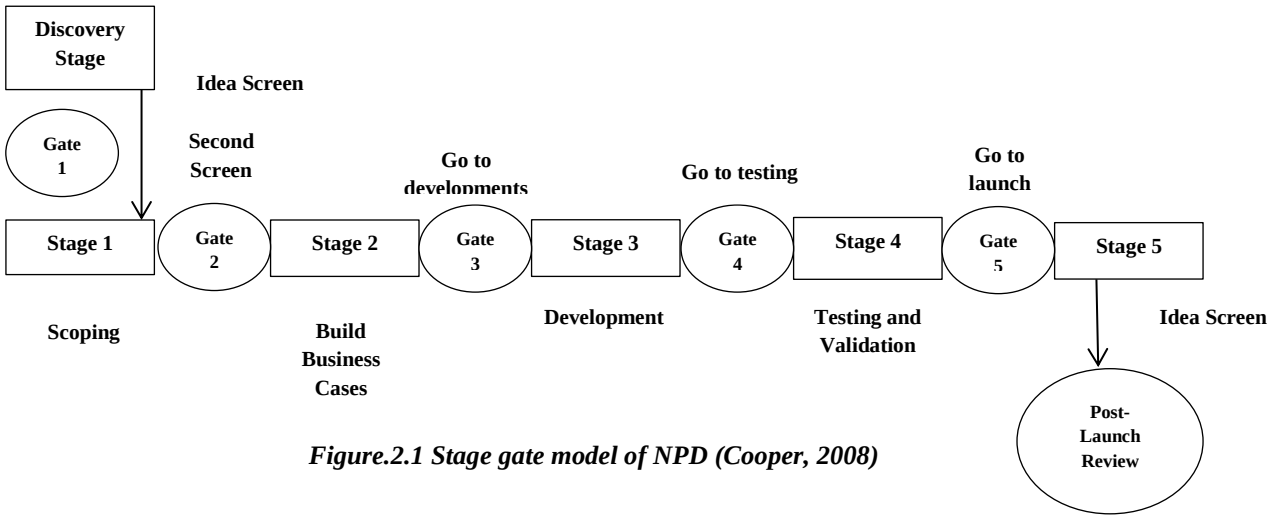


Figure.2.1 Stage gate model of NPD (Cooper, 2008)

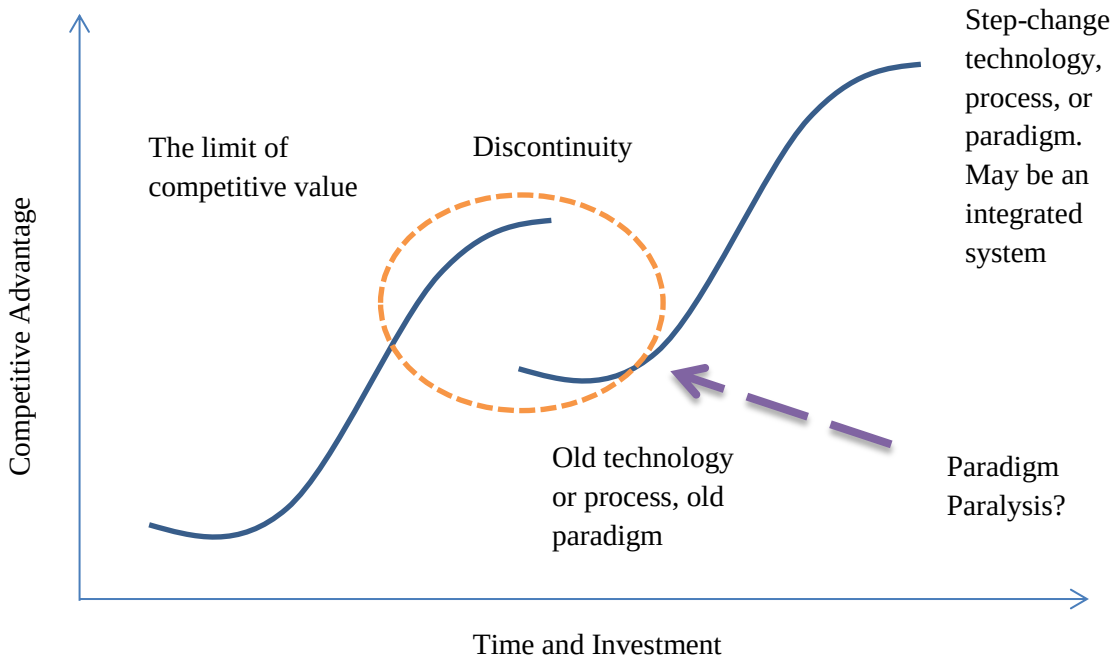


Figure2.2 S-Curve model of innovation (Hinks et al, 2007)

However, Henderson and Clark (1990) suggest this twofold classification might not describe some perspectives of industrial innovation processes properly, and propose the Henderson–Clark model of innovation depicted in Figure 2.3 (Henderson and Clark, 1990). In this model two other types of innovation have been added: modular, which has a greater impact on the component, and architectural, which has greater impact on the architecture of the components and their position to each other.

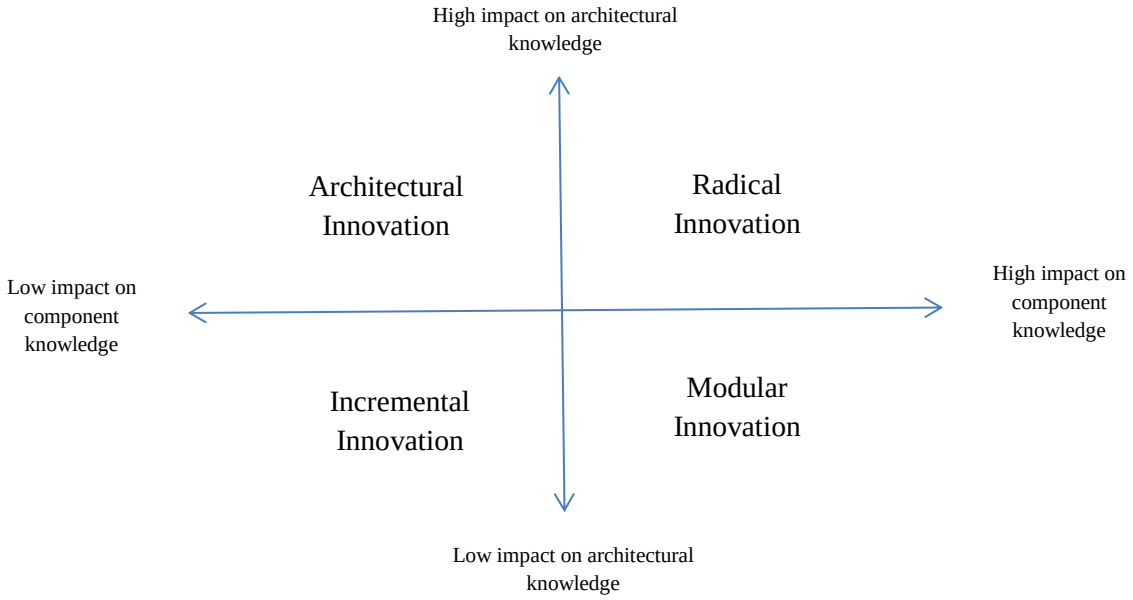


Figure.2.3 Clark-Henderson Model of Innovation (Clark and Henderson, 1990)

The *Dynamic Model of Innovation* by Utterback and Abernathy (Figure2.4) has been one of the most cited models of innovation, as it stresses the importance of dominant design and defining the technological changes by positioning dominant design within it (Utterback and Abernathy, 1975; Abernathy, 1978; Utterback, 1996). Christensen (1997) coined the term *disruptive innovation* for one of the recent innovation models. "Disruptive innovation is a powerful means of broadening and developing new markets and providing new functionality, which, in turn, may disrupt existing market linkages" (Christensen, 1997). The models in this research could be instrumental in elucidating the nature of technological changes to offer a better understanding of a post-disruption market economy.

The next section will discuss the dynamics of technological changes and the importance of dominant design in technological changes based on the dynamic model of innovation.

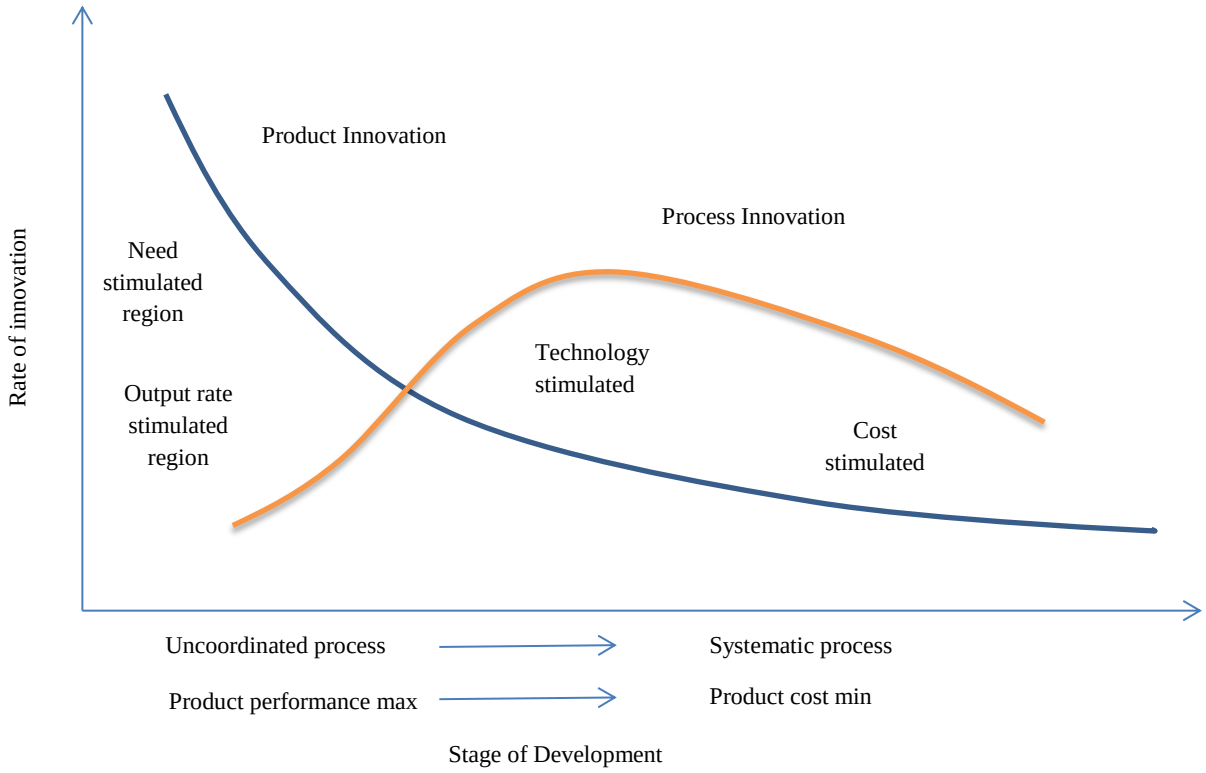


Figure.2.4 Dynamic Model of Innovation (Utterback and Abernathy, 1975)

Patterns of technological changes are a sequence of radical and incremental changes which are usually disrupted by discontinuity that leads to the next generation of technology (Rothwell and Gradiner, 1985; Tushman and Anderson, 1990) (Figure 2.5). Tidd and Bessant (2009) are of the opinion that technological changes usually occur in constant interaction with demand pull and supply push. Advanced or radical innovation usually takes place following new scientific knowledge generated by different scientific associations (most of which is based on the technology push nature of innovation), while incremental innovations usually take place in the on-going competition of incumbents within the business sector to satisfy market needs (Tushman and Anderson, 1990; Utterback and Abernathy, 1975; Tecee, 1986; Sahal, 1981; Abernathy, 1978). This continuous sequence of radical and incremental technological changes is usually disrupted by some technological discontinuity, as

illustrated in Figure 2.5 (Tushman and Anderson, 1990). This discontinuity could occur for a variety of reasons, such as the emergence of a new market, different national rules, and political reasons, among others (Tidd and Bessant, 2009).

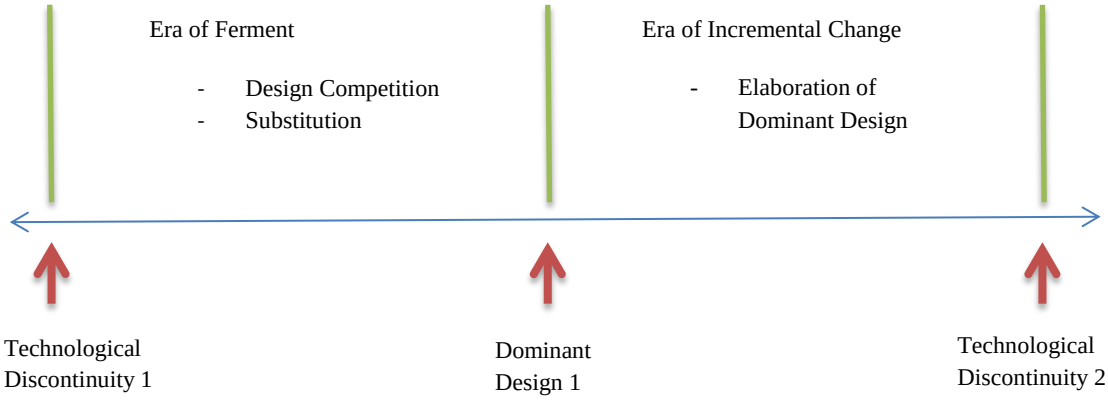


Figure 2.5 The Technology Cycle (Tushman and Anderson, 1990)

According to Tushman and Anderson (1990), technological discontinuity may be classified as competence-enhancing and competence-destroying, which implies the compatibility of the existing competence of a competitor with the essence of new market competition (Chiesa, 2001). Crawford (1994) mentions three levels of innovation: pioneering, adapting, and imitation. He discusses the rate of innovativeness, which Kleinschmidt and Cooper (1991) studied, coining the term *innovativeness ratio*.

Many scholars have studied the patterns of technological innovation, but Callahan's (2007) studies discuss more comprehensively the notion of dominant design in technological changes. Based on Callahan's (2007) studies and support from Anderson and Tushman (1990), this research will discuss the concept of dominant design and its position within different patterns of technological innovation, based on Utterback and Abernathy (1975), Abernathy (1978) and Abernathy and Clark (1985).

Utterback and Abernathy define innovation as the simultaneous process of product and process innovation classified into three continuous phases: fluid, transitional, and specific (Utterback and

Abernathy, 1975; Abernathy and Townsend, 1975). In the fluid phase, the rate of product change is higher than process innovation. In this phase radical innovations usually take place, and there are many different product designs, resulting in different market standards (Abernathy, 1978; Abernathy and Clark, 1985). There is no direct competition in this period, and the process is flexible and inefficient (Abernathy and Townsend, 1975).

The transitional phase is important due to the emergence of dominant design (Utterback, 1994). In this phase the major process changes and architectural innovations usually occur (Utterback and Abernathy, 1975). The number of competitors in the market will decline after the emergence of dominant design (Abernathy and Clark, 1985). The existence of dominant design in the market will affect the third phase (Abernathy and Clark, 1985). After issuing numerous product design standards in the market, most competitors cannot adapt to the new regulations and will inevitably vanish from the market (Utterback, 1996). Incremental innovations then generally occur in order to improve the performance of dominant design (Utterback and Abernathy, 1975). In this phase, efficiency of process is vital in order to improve the process productivity (Abernathy, 1978).

This stable market situation and incremental innovation could be challenged by new disruptive or architectural innovation that could lead to disruptive changes in the market structure and business model (Abernathy, 1978; Anderson and Tushman, 1990). Following these disruptive changes, a new generation of product will emerge in the new market structure based on the previous market situation (Utterback and Abernathy, 1975). This dynamic innovation model with fluid, transitional and specific phases will repeat itself, as it is the dynamic nature of industrial innovation that takes place in the technological context (Anderson and Tushman, 1990). Although this model has limitations, it seems appropriate for the purpose of this research. Next, a medical innovation model will be generated based on technological patterns of innovation and existing literature on medical innovations.

Dominant design has such a significant role in technological patterns that Anderson and Tushman (1990) claimed it as the second watershed after discontinuous disruption. Abernathy (1978) and Sahal (1981) mention that once a dominant design emerges, the rest of the technological progression

happens incrementally to increase the performance of dominant design. A great many scholars incorporate dominant designs into models of technological evolution.

This research will attempt to position the concept of dominant design within the notion of technological discontinuity. As Anderson and Tushman (1990) state, a technological discontinuity will not itself become a dominant design. Unlike the emergence of technological discontinuity as the first watershed in the technology cycle, the emergence of dominant design doesn't take place solely due to technological superiority (Teece, 1986); dominant designs reflect technical, social, and political constraints. Therefore, as Anderson and Tushman (1990) mention, a dominant design will not be located on the frontier of technical performance at the time it becomes dominant.

Therefore to illustrate the social and to some extent political constrains of setting a dominant design by disruptive innovations, we will first focus on the definition of disruptive innovations. Then to understand the social structure of disruptive innovation diffusion we will discuss the systems of innovations in the health sector and later on will concentrate on the relevant diffusion studies to provide more understanding around the dynamic and mechanisms of disruptive innovation diffusion in medical markets.

2.2 Towards Disruptive Innovations (DI)

Many scholars have focused on the continuous parts of technological cycles, and there are studies which have focused on discontinuous innovation. Robert and Veryzer's (1998) study is arguably one of the most prominent studies on discontinuous innovations. They state that "although many new-products professionals may harbour hopes of developing the next big thing in their respective industries, most product development efforts focused on incremental innovations" (Robert and Veyzer,1998; p 306). In this comment, Robert and Veryzer (1998) try to describe the differences between continuous and discontinues innovations. Discontinuous innovation is defined as a radical new product which leaps ahead of the competition in terms of customer familiarity and use. They position different types of innovation based on their continuity, as illustrated in Figure 2.6.

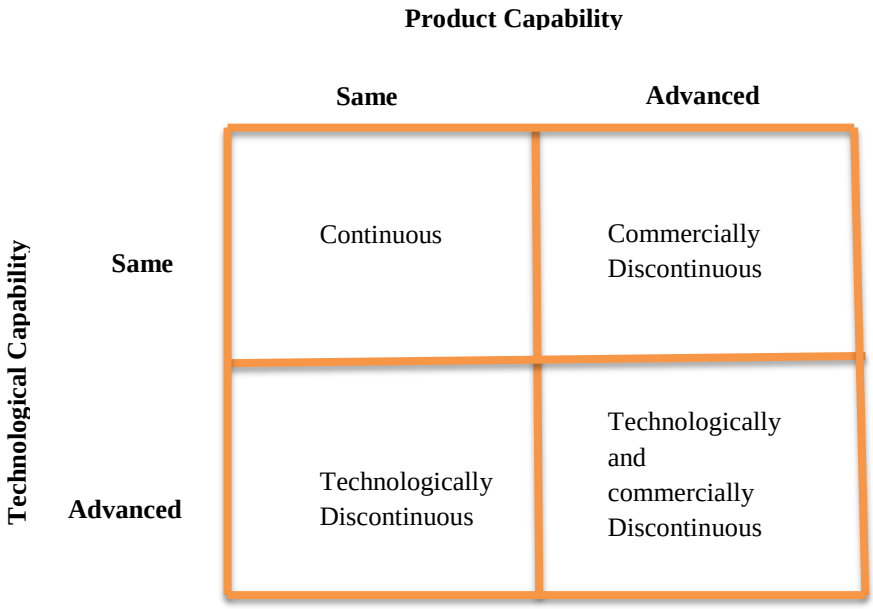


Figure 2.6. Types of Product Innovation (Robert and Veyzer, 1998)

This diagram illustrates continuity and discontinuity defined from both the technology and product capability perspectives. The only criticism of this notion is the idea of positioning radical innovations as a discontinuous change, which doesn't seem justified. According to Tushman and Anderson (1990), Utterback and Abernathy (1975), and Abernathy and Clark (1985), radical innovation usually occurs between two discontinuous changes of technology and usually before getting into dominant design (Figure 2.2). Positioning radical innovation into discontinuous categories leads to confusion between radical and disruptive innovation.

However, in solving this problem, Christensen (1997) arrived at a new definition of discontinuous innovation, or what he called *disruptive innovation*. "Disruptive innovation is a powerful means of broadening and developing new markets and providing new functionality, which, in turn, may disrupt existing market linkages" (Christensen, 1997; p 21). As shown in Figure 2.7, Christensen (1997) argues that by focusing on the high margin of the market (i.e. the top of the market pyramid, or the most demanding customers), incumbents often forget about the mainstream and low-end market needs.

By focusing on the high-end market, the needs of the mainstream market are overlooked (Christensen et al, 2000).

As Christensen et al (2000) state, these events make the market suitable for new entrants seeking to introduce their cheaper, simpler, and more convenient disruptive innovations to satisfy the mainstream market needs. This innovation then establishes a new generation of technology trends which could attain the dominant design position in the future (Moor, 2006).

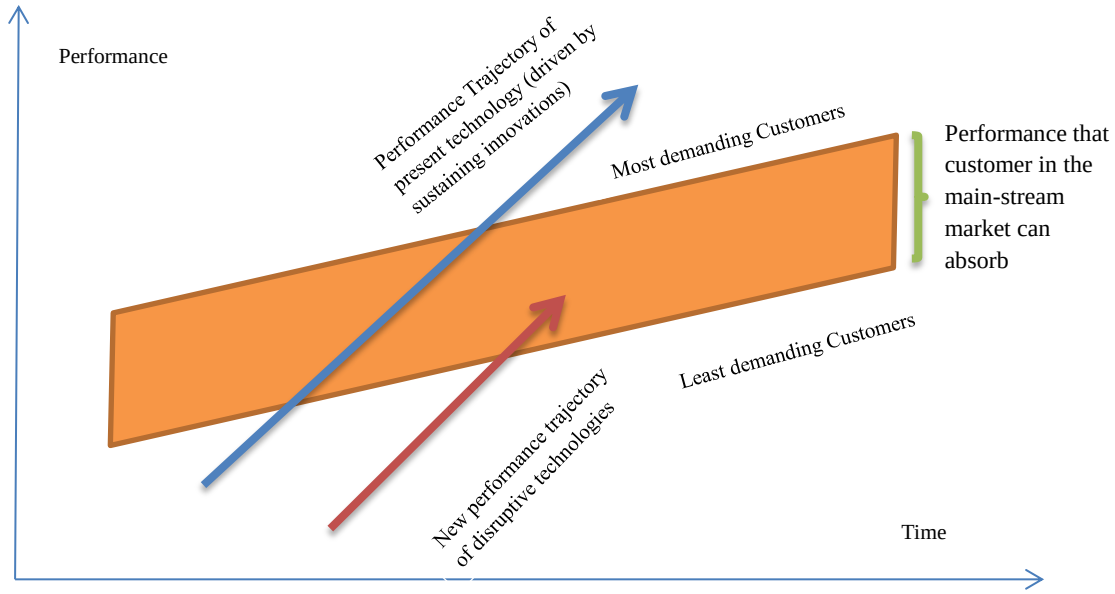


Figure 2.7 Disruptive Innovations (Christensen et al, 2000)

Although, Christensen (1997), Christensen et al (2000), and Christensen and Raynor (2003) issued and clarified this concept, there has been criticism of this definition and dispute over the concept.

One of the most constructive debates took place between Daneels (2002, 2004) and Christensen (1997, 2006) where Daneels (2002) argues that "Although disruptive technologies initially underperformed established ones in serving the mainstream market, they eventually displace the established technologies (p 1097)" In addition, Daneels (2004) adds that since disruptive innovations do not satisfy the mainstream market requirements in the initial emergence steps, incumbents consider it an inappropriate innovation.

The main issue of dispute surfaces when the initial disruptive innovation takes place in order to satisfy the needs of small niches in the market. Both innovators and some incumbents' R&D departments will improve the performance of this initial disruptive innovation in order to make it appropriate to satisfy the mainstream market requirements. According to Tushman and Anderson (1990) this is the ferment period[2] of the technology cycle preceding the dominant design position. Most incumbents underestimate the potential power of disruptive innovation to grab the market (Daneels, 2004). In the ferment period, new entrants will usually compete for the dominant position, while incumbents are engaged in improving their existing innovations to serve the high-end market (Daneels, 2002; Christensen and Raynor, 2003). The typical consequences are the following scenarios: If innovators have sufficient financial support to invest in their R&D departments, they will continue their innovation improvement efforts to attain the dominant position in the market (Adner, 2002). If unable to support their R&D endeavours, other incumbents will typically acquire new entrants and invest in their innovation if merited (Christensen and Raynor, 2003). Table 2.1 explains all the contributions to the concept of DI diffusion so far. Looking at these contributions will identify the gaps in the literature.

[2] The ferment period concept was first coined by Tushman and Anderson (1990) in order to describe the time span between the first technological discontinuity and the first dominant design. As they mentioned in their studies, the amount of competition and incumbents in the market is increasing in order to set the dominant design.

Authors	Research area	Main contribution to disruptive innovation studies
Utterback and Abernathy (1975)	Dynamic models of innovations	Dividing innovation process into three different phases: fluid, transition, and special, and positioning different types of innovation within it
Dosi et al (1982)	Technological innovations' trajectories	Declaring technological change trajectories and economics of technological changes
Tushman and Anderson (1990)	Technological discontinuity and dominant design: A cyclical model of technological changes	Discussing continuity and discontinuity, and positioning the importance of dominant design on it, and the notion of competency destroying and competency enhancing in discontinuous innovation
Robert and Veryzer (1998)	Discontinuous innovation and the NPD Process	Studying different types of innovation and positioning discontinuous innovations within them
Christensen (1997)	Innovators' dilemma: establishing the concept of disruptive innovation	Coining the concept of disruptive innovation and introducing this new concept to innovation literature
Chesbrough (2001)	Impact of technological changes on incumbents	Economics of incumbent after technological changes: adding further points to Dosi et al (1982)
Hart and Christensen (2002)	Driving innovation from the base of the pyramid	Diffusion of disruptive innovation from the base of the market pyramid.
Adner (2002)	Demand-based view of the emergence of competition	Introducing demand base view of disruptive technologies
Markides and Charitu (2003)	Responses to disruptive innovations	Talking about the incumbents' responses in the post-disruptive innovation period
Christensen and Raynor(2003)	Innovators' solution: more attention to technological point of view	Clarifying definition of disruptive innovation
Daneels (2004)	Criticising Christensen's initial concept of disruptive innovation	Issuing eight cardinal critiques of Christensen's perspective on the concept of disruptive innovation
Christensen(2006)	Completing the notion of disruptive technologies	Replying to Daneels' critiques of disruptive innovation
Markides (2006)	In need of a better theory	Classification of disruptive innovations into different categories for better understanding of disruptive innovation's concept
Moor (2006)	Marketing point of view toward technological changes	Looking at post-innovation period from marketing points of view
Schmidt and Druhel (2008)	Identifying a framework for disruptive innovation	Different classification of disruptive innovations based on encroachment models
Yu and Hang (2009)	Reflective studies of the field	Historical literature review about disruptive innovation and issuing questions for further research
Droege and Johnson (2010)	Limitation of disruptive innovations	Limitations and criticisms of disruptive innovation notions

Table 2.1 Contributions to the Concept of Disruptive Innovation

King and Tucci's (1999, 2002) findings are totally different from Christensen's (1997) notions. Also, Chesbrough (2003) indicates that the ferment period competition does not only include newcomers to the market. Market leaders with strategic plans for long-term survival are also included in the post-disruptive innovation competition. Moreover, King and Tucci (2002) argue that incumbents stand a good chance of winning over the competition and attaining the dominant design based on their accumulated experience in the market. The last statement by King and Tucci (2002) is different from those made by Christensen (1997) and Christensen et al (2000). Considering all of these notions, it is still debateable who the competitors of the ferment period in disruptive innovations are: incumbents, new entrants, or both (Droege and Johnson, 2010). Then as Droege and Johnson (2010) mention, the role and position of the main competitors to disrupt the market is still disputable and one of the main gaps of the literature which this research will try to address.

According to Markides (2006), one of the main gaps in the DI literature is the lack of specific criteria for disruptive innovations. Adner (2002) and Daneels (2004) mention that Christensen (1997) does not offer specific criteria to distinguish disruptive innovation from the others. Daneels (2004) sees this as "a technology that changes the bases of competition by changing the performance metrics along which firms compete" (p 247). Daneels (2004) also challenges the notion of market penetration from the low-end of the market. Although he does not refute the characteristics that Christensen et al (2000) mention about disruptive innovations, he believes that market penetration could begin from the mainstream market rather than the low-end market (or the base of the pyramid[3]). Actually, Table 2.2 points out the important criticisms and alternative explanations by the other scholars in their attempts to demystify the concept of DI.

[3] Hart and Christensen (2002) terminology

Authors	Classifications around disruptive innovations				
Utterback and Abernathy (1975) and Dosi et al (1982)	Continuous innovation		Discontinues innovation		
Tushman and Anderson (1990)	Competency enhancing		Competency destroying		
Christensen (1997)	Definition of disruptive innovation				
Daneels (2004)	Criticise Christensen's definition of disruptive innovation				
Markids (2006)	Business model innovations,		Product innovations	Technology innovations	
Schmidt and Druhel (2008)	High-end encroachment	Low-end encroachment	Fringe-market low-end encroachment	Detached-market low-end encroachment	Immediate low-end encroachment

Tabl 2.2 Different Classifications of Disruptive Innovation

Despite the widespread use of disruptive innovations by practitioners and academics, there are points needing clarification (Markides, 2006). Providing more clarification to the concept of disruptive innovations, Markides (2006) classifies them into three different categories: business models, new products, and technology innovations.

Markides and Geroski (2005) previously argued that Christensen's (1997) concept of DI does not distinguish between product, service, and business-model innovations, which lead to misunderstanding of the concept. Markides (2006) adds that these classifications are important since they arise in different ways (Charitou, 2001). New entrants have an advantage over the competition in attainting the dominant design position in technological disruption over product disruption because the ability to launch is considered the strength of incumbents based on their experience in the market (Markides, 2006).

The notion of first-mover advantages is mentioned by Christensen and Raynor (2003) as a competitive benefit for entrants new to the market after disruptive innovations. Markides and Geroski

(2005) refuted this idea by introducing the concept of late-mover[4] advantages, which points to the advantages incumbents have over their competition.

To sum up, most literature on disruptive innovation seeks to clarify the concept rather than the surrounding issues. Then in this research, while we are trying to provide more understanding around the social structure of DI diffusion, we will concentrate on the mentioned gaps within the current DI literature. We will then focus on the role of new entrants and incumbents to disrupt the mainstream market, possibility of the low-end vs high-end market disruption within the social structure of the healthcare systems and finally introduction of some criteria to distinguish DIs from the other types of innovation.

In the next section we will focus on the social structures within the healthcare systems to provide a better understanding about the dynamics of DI diffusion in social networks.

Attributes	**Radical innovation**	**Disruptive innovation**
Position of older technologies (Tushman and Anderson, 1990)	Do not be obsolete but in constant competition	Be totally obsolete and all the competition will take place in and around new technologies
Consequence of innovation	Attaining the dominant position in the market (Utterback, 1994) (Secondary dominant design)	Leading to the next generation of technologies, which means the start of another competition (Christensen, 1997) (Primary dominant Design)
Their position toward discontinuous innovation	Is the consequence of discontinuity (Tushman and Anderson, 1990)	The cause of discontinuity (Abernathy and Clark, 1984)
Leading to dominant design (Teece, 1986)	Directly	Indirectly
Their effect on current market competencies (Tushman and Anderson, 1990)	Competence-enhancing	Competence-destroying
Dominant origin (Utterback and Teece, 2005)	Mixture of needs and technologies	Technology driven and needs attention
Competition's actors (Markides , 2006)	More incumbents than new entrants	More new entrants than incumbents
Types of knowledge to generate an innovation (Tushman and Anderson, 1990)	Existing knowledge in the market	New, interdisciplinary knowledge as the result of R&D researchers

Table 2.3 Differences between Radical and Disruptive Innovations

[4] One of the most important dilemmas in DI diffusion is the benefits of first movers in the market over the late movers. It is still the subject of investigation as to one is more effective in market disruption. We will address this issue in further chapters.

2.3 Systems of innovation and Disruptive innovation

Studying and analysing transformation of entire economic sectors is one of the classical fields of innovation literature (Markard and Truffer, 2008). Dynamics of Disruptive Innovations are far more than just a technological innovation and changes in components of existing systems; they result in institutional changes, new socio-technical configurations, and new market structures. These changes make studying such transformations and the dynamics of the underlying innovations a demanding task. Nevertheless, innovation scholars have approached this topic from at least two different school of thoughts; the innovation systems perspective, and the transition school largely developed by Dutch researchers (Markard and Truffer, 2008).

As Adersen, Metcalf and Tether (2000) put it; Emergence of "systems of innovation" literature has probably been the most significant recent development in the study of innovation. In innovation systems literature, rooted in evolutionary economics, innovation is an interactive process among a wide variety of actors. A system of innovation approach stresses the importance of collective process, and dismisses the idea that firms innovate in isolation. It emphasizes the importance of feedback mechanisms as well as interactions among all actors (Hessels and van Lente, 2008). In the innovative process firms interact with other commercial as well as with non-commercial organizations. These organizations can be universities, research centres, financial institutions, and so on. It is under this approach, which learning is a key determinant of innovation, that a framework is created for terms such as Path-dependency, or Lock-in.

Systems of innovation studies are of the paramount important to conceptualize the process of change in the context of DI diffusion due to twofold reasons. Foremost as Daneels (2004) mentions, disruptive innovation is a retrospective concept since it cannot be called DI until the market disruption happens. Then DIs rooted in their past and are the creation of their diffusion dynamics. However, evidence to the vital role of the systems of innovations in this study arises from the path dependent nature of medical innovations. In other words, the health sector spans so many skill sets and knowledge bases. Within the health care sector there are a variety of actors like research hospitals,

medical practitioners, service providers, patients, and government agencies which play a crucial role in the health innovation and innovation diffusion (Consoli & Mina, 2008).

Innovation systems can be defined at different levels depending on the analysis. Historically the focus has been on two dimensions: geographical (National and Regional), or physical (Technological and Sectoral). Freeman (1987) study of Japanese national innovation system is being largely viewed as starting point of "System of Innovation" research. He and other pioneering authors, namely Lundvall (1992) and Nelson (1993), introduced and elaborated the concept of National Innovation Systems. Freeman (1987) defines national system of innovation as "networks of institutions, public or private, whose activities and interactions initiate, import, modify, and diffuse new technologies". Since then the concept has received significant attention within innovation community in academia as well as politicians, and has been extensively used by the OECD (Foxcon et al, 2005).

At other levels of aggregation innovation systems perspective has been applied; Regional Systems of Innovation (Cooke, 1996; Cooke et al., 1997; Braczyk et al, 1998; and De la Mothe and Paque, 1996); Technological Systems (Carlsson and Stankiewicz, 1991; Carlsson, 1995; 1997); and Sectoral Innovation Systems (Breschi and Malerba, 1997; Malerba, 2004) are the most cited ones (for an overview look at Chang and Chen, 2004; or Carlsson et al, 2002).

Sectoral innovation system is one of the most appropriate frameworks to understand the dynamics of DI diffusion, specifically in the medical devices context. Breschi and Malerba (1997) define sectoral innovation systems as the specific clusters of the firms, technologies, and industries involved in the generation and diffusion of new technologies and in the knowledge flows that take place amongst them. Then to understand the dynamic of DI diffusion to disrupt the mainstream market we should understand the sectoral innovation systems in the healthcare market. On the other hand, the main focus of innovation systems studies has historically been on the structure of the innovation systems at a snapshot within a time. Structure of a system includes (but not limited to) system borders, actors, institutions, and the networks of relations through which these are connected (Carlsson et al, 2002). This focus on structure has missed on the dynamics of innovation system (Hekkert et al, 2007).

Furthermore they all share the general purpose of innovation systems that is to develop, diffuse and use innovation (Edquist, 2005). As Markard and Truffer (2008) point out; systems are generally being characterized by their structure (system elements that interact with one another), and by their function (performing or achieving something). Structure of a system includes (but not limited to) system borders, actors, institutions, and the networks of relations through which these are connected (Carlsson et al, 2002).

Emergence of new innovations can be studied from multiple perspectives. Neo-classical economists look at the price and how it affects the technological choice within consumers. From a firm perspective, entrepreneurial act of an individual (firm) is at the centre of innovation and its diffusion (Jacobsson and Johnson, 2002). However, innovation and diffusion process is both a collective and individual act (Jacobsson and Bergek, 2011) and innovation system approach.

2.3.1 Sectoral Systems of Innovation and the health sector Economics

As we mentioned earlier, sectoral systems of innovation is defined by Malerba (2002, p. 250) as: "*A sectoral system of innovation and production is a set of new and established products for specific uses and the set of agents carrying out market and non-market interactions for the creation, production and sale of those products"*. According to Carlsson (2007), SI approach has attracted 6% of papers written on innovation systems. To better understand structure of SI, it is helpful if one analyses the boundaries, and the main elements.

According to the given definition, boundaries of SI approach are based on product types, enabling the system to encompass various technologies and transcend geographical borders (Coenen and Diaz Lopez, 2010). Malerba (2002) summarizes basic elements of SI as: products, agents, knowledge and learning processes, basic technologies, mechanisms of interactions, processes of competition and selection, and institutions. In his later work (2004) he reduces these elements to knowledge and technologies, actors and networks, institutions, and demand.

As Coenen and Diaz Lopez (2010) mention, mechanisms of interaction is the fundamental element of SI in dynamic sectors with a significant rate of innovation such as in the medical sector. This is one of the main reasons that this research is focused to understand the mechanisms of DI diffusions in the medical sectors besides the dynamics of it. Also in the next section we will try to provide more understanding around the nature of demand in the healthcare to describe the rich picture of SI in this sector.

In terms of dynamics of change, Sectoral Systems of Innovation (SSI) focuses on co-evolutionary processes, and incremental innovations within the system. Changes come about through co-evolution of the various elements in the system, and mainly are result of processes that cause path-dependency and susceptible for lock-in (Malerba, 2004). This approach has been criticized in the literature to fail in explaining how a new sectoral system emerges (Geels, 2005; Coenen and Diaz Lopez, 2010; Chang and Chen 2004). Malerba (2002) has also noted this shortcoming and called for further research on this topic which is the main purpose of this thesis. In other word, this research wants to elucidate the emergence of new SSI based on the diffusion of DI in medical markets.

2.3.2 Health Innovation Systems and the Nature of Demand

Healthcare market is different from other sectors in many aspects: the outcome of care is uncertain, large segments of the industry are dominated by non-profit providers, and payments are made by third parties such as the government and private insurers (Docteur and Oxley, 2003). In other word, the role of healthcare professionals, physicians, procurement teams, healthcare providers, medical and pharmaceutical companies and all over patients are absolutely complex in the health innovation systems (Pammolli et al, 2005). In fact, the role of the key decision makers, stakeholders and potential adopters are interchangeably overlapping and complicated which makes it difficult to understand the overall view of SSI in the healthcare sectors (Acemoglu and Finkelstein, 2005). Then, considering the view of Nelson and Sampat (2001), this research wants to look at the diffusion of DIs from social and institutional structures point of view. Considering this issue, Consoli and Mina

(2009) provide an intensive analysis of the health innovation systems which contributes significantly to understand the nature of demand in this sector. In their analysis, Consoli and Mina classify the medical innovation systems based on static and dynamic attributes of technologies and institutions within the system. While the static perspective on technologies and institutions indicates a snapshot overview on both factors as they have not been evolving and the relevant structures and cross-relations do not change over the time, the dynamic overview is significantly different. In fact while static studies on the medical innovations mostly focused on the health expenditure (Pammolli et al, 2005), reimbursement (Filekstein, 2005) and cost-effectiveness (Gruber and Phelps, 1997), other scholars such as Mckinlay (1981), Greer (1988) and Baker (1999) are considering the health innovation system as a linear model.

In fact, the innovation rate in medical technologies is remarkably high and the nature of innovation is changing radically. Scholars such as Mokyr (1998) discuss the demand-induced nature of medical innovations. In his "evolutionary theory of useful knowledge", Mokyr (1998) demonstrates that models of blind variation with selective retention (the models related to the Darwinian paradigm) are helpful for looking at the evolution of medical innovation. While Mokyr (1998) focuses on selective retention as an evolutionary innovation method, Ramlogan and Consoli (2008) believe that the history of medicine proves there are theoretical, methodological, and philosophical issues that affect selective retention of technologies preventing the selection of a specific route of investigation in a given medical field. They claim that medical innovation is a long-term learning process based on two conditions: growth in the ecology of forms of knowledge and the creation of coordination mechanisms within different forms of knowledge and different realms (Ramlogan and Consoli, 2008).

Within the technical and procedural understanding of knowledge, the growth of knowledge itself is a path-dependent process (Dosi, 1988). Langlois and Savage (2001) claim, based on Dosi's (1988) notion of the path-dependent nature of medical innovations, that the accumulation and recombination of compiled knowledge based on social understanding of the feedback's origin is the main concern of medical innovations. Likewise, Metcalfe et al (2005) state "medical innovations should be seen as trajectories of improvement sequences in which procedures are progressively refined and extended in

their scope of application"(p.1292). Mina et al (2007) also believe that the medical innovation process is neither random nor completely organized. Like Dosi (1988), Mina et al (2007) believe in medical innovation's path-dependent nature, which is restricted by peoples' perception of problems. Consequently, the trajectories of changes (sequence of innovative ideas) generate the accumulation of medical knowledge (Ramlogan and Consoli, 2008). Most innovation studies on medical technologies focus on the nature and evolution of medical technologies (Blume, 1992) and insist on the path-dependent and evolutionary nature of medical innovations.

Likewise, Ramlogan and Consoli (2007) demonstrate that while most of the medical innovation studies are focused on decisions to adopt existing technology, significant deal of literature seems to downplay the process that leads to the creation of new medical technologies. In fact, while most scholars in field of medical knowledge possess an evolutionary approach toward the medical innovations, they neglect the importance of disruptive and discontinuous changes in the medical knowledge trajectories. Therefore, the adoption of new medical innovation may be considered as a less mature area in medical device innovation and deserving of study.

Eventually, the existing literature mentions that the nature of medical innovation systems is non-linear, dynamic and complex and this research wants focus on the social structure of DI diffusion in the medical market. On the other hand the nature of demand in the medical innovation systems seems to be complicated too. Therefore, the non-linear nature of medical innovation systems and the complexities of the demand, necessitate further researches on the social structure of DI diffusion in medical markets due to the dynamic natures of both technology and institutions in cases of disruptive innovations.

Blume (1992) and Gelijns and Rosenberg (1994) extensively argued the interactive relations of a broad set of disciplines, agencies and institutions between firms, clinicians and academic scientists (Mina and Ramlogan, 2008). In fact, scholars have varied notions about the systems of innovations in medical devices sector. Rosenberg (1976) believes in the demand–intensive nature of medical innovation, which necessitates the existence of technological capabilities (Gelijns and Rosenberg,

1994). However, Mokyre (1998) claims that the cliché "necessity is the mother of innovation" is pointless. Medical innovations occur in an unstable situation as a consequence of frequent exogenous changes in pathogenic agents in a medical environment (Mokyr, 1998). Gelijns and Rosenberg (1994) add to Rosenberg's (1976) idea by asserting the importance of the biological-based demand of medical innovation rather than the social demand (Gelijns et al, 2001). Consequently, development of biological technology has a greater effect on medical innovations than do social needs (Mina et al, 2007).

Like Metcalfe and Ramlogan (2005) and Ramlogan et al (2007), Mokyr (1998) points to the weakness of the linear model of innovation in considering the feedback mechanism between phases of technology diffusion, technology adoption, technology application, applied research, and technology development. Linear models neglect the feedback between actual use and incremental changes which lead to potential improvement (Consoli et al, 2005).

Consoli and Mina (2009) point to the three important dimensions of medical innovation in the fifth generation of technology. Foremost is that the use of new medical technologies opens up previously available opportunities in the domain of practice. Metcalfe et al (2005) call this process technique and technology co-evolution, while Lucas (1988) implies it is a concept of learning by doing. Secondly, according to the recent open nature of medical innovation (Mina et al, 2007), imbedded knowledge gave added value to the innovation leading to the generation of the value-chain by merging imbedded knowledge with medical innovations. Finally, Consoli and Mina (2009) consider the importance of basic research and the medical practice feedback loop, the necessity of which has been discussed by scholars such as Langlois and Savage (2001).

Ramlogan and Consoli (2007), Malerba (2004), Nelson (2003) and Metcalfe et al (2005) believe that in order to understand the nature of medical innovation, emergence phase must be considered. Most of the sparse literature that considers the emergence of medical innovations directly, such as that of Ramlogan and Consoli (2007) and Consoli and Mina (2009), focuses on medical innovations

imbedded in healthcare innovations supporting medical service innovations rather than the technological aspects.

Consoli and Mina (2009) health innovation system describes the complex networks of the stakeholders, adopter, scientists, and healthcare professionals in much more details. However, since this research tends to focus on the social structure of DI diffusion, it seems to be necessary to slightly expand the health innovation system of Consoli and Mina (2009) on the service provision section to reflect the complexity of demand in more details. Then, to modify and expand the model to meet the requirements of innovation diffusion studies we will make some partial modifications on the health innovation system of Consoli and Mina (2009). Firstly, we will not consider the dynamics of medical innovations imbedded in the healthcare system when scholars such as Timerman and Berg (2003), Gejins and Rosenberg (2005), and Consoli et al (2005) consider the healthcare system one of the prominent actors in the medical innovation systems. The dynamic relationship between the development of scientific knowledge and applied techniques in clinical practice generates the innovation trends in medical technologies (Consoli, 2005). Therefore, the central role of hospitals as one of the most important references of active feedback should be considered in medical innovation systems (Murray, 2002). On the one hand, the divergent nature of objects and problems in medical knowledge (Fuch and Sox, 2001) leads to the unevenness of the nature of knowledge production in medical technologies (Gejins and Rosenberg, 2005). On the other hand, however, the collaboration of doctors, scientists, and hospitals is required to compensate for the unevenly compiled knowledge by mutual interaction of scientific knowledge and applied techniques (Consoli et al, 2005; Consoli, 2007).

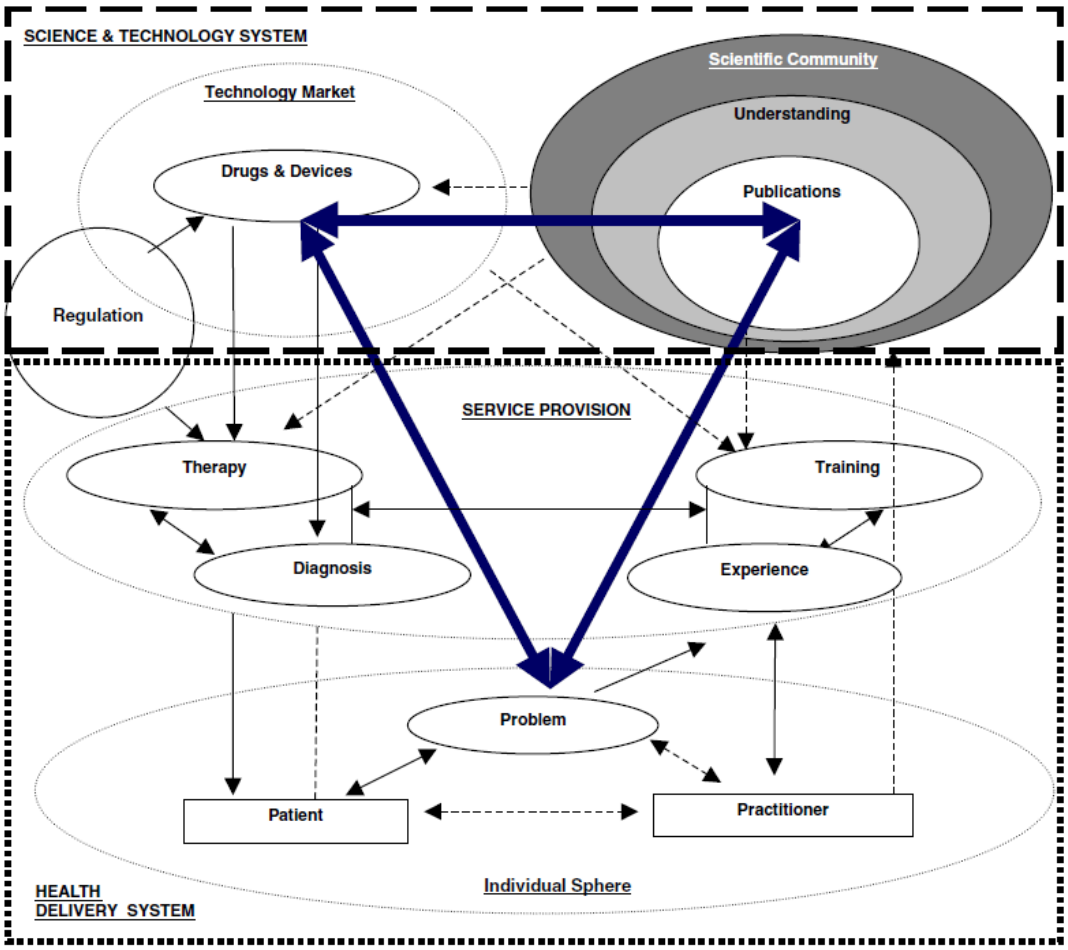


Figure2.8. Health Innovation Sytem (Consoli and Mina, 2009)

Secondly, according to Metcalfe (2001), another source of innovation other than the scientific community is R&D sections of medical technology firms. This could be also contributed by the R&D sections of adjacent medical technologies, according to the interdisciplinary nature of high-tech medical innovation in the fifth generation of technology (Mohr et al, 2009). Therefore, an interdisciplinary area resulting from the interaction between the scientific community and R&D sections of medical and non-medical corporations is potentially appropriate for generating new medical innovations. Chesbrough and Crowther (2006) add that by sharing their facilities and knowledge, different R&D sections and the scientific community will create synergic capabilities which are more capable, and which, according to Christensen (1998, 2006) and Danneels (2004), could lead to disruptive innovation and the creation of a new market. Also as it was mentioned before by Gelijns and Rosenberg (1994) the role of feedback mechanism should be emphasised in the health

innovation systems as we will try to enhance the level of feedback mechanisms in the medical innovation systems based on Djellal and Gallouj (2005) researches.

The result of this sequence could be valuable and added into the accumulated knowledge of the scientific community. This added experience will be examined and tested by scientists in different laboratories and hospitals and then shared as aggregated knowledge in medical technology's interdisciplinary area (Loasby, 2001).

Consequently, Figure 2.9 shows the multilateral feedback mechanism in the medical innovation systems. Then based on the small modifications and expansions on Consoli and Mina (2009) health innovation system, we present the medical innovation system in figure 2.9.

Also Kogut and Zinder (2003) emphasise the importance of a multilateral feedback mechanism in the medical innovation systems which Gejins and Rosenberg (2005) highlight as a constant interaction of knowledge and practice in the generation of medical innovations. Although this model is still crude and needs to be tested through different field work in this and other researches, but it can provide a reliable foundation for further researches and discussions.

In the next section, we will discuss the innovation diffusion literature to understand the dynamics and mechanisms of DI diffusion, based on the social structure within the health innovation systems and come up with the research model.

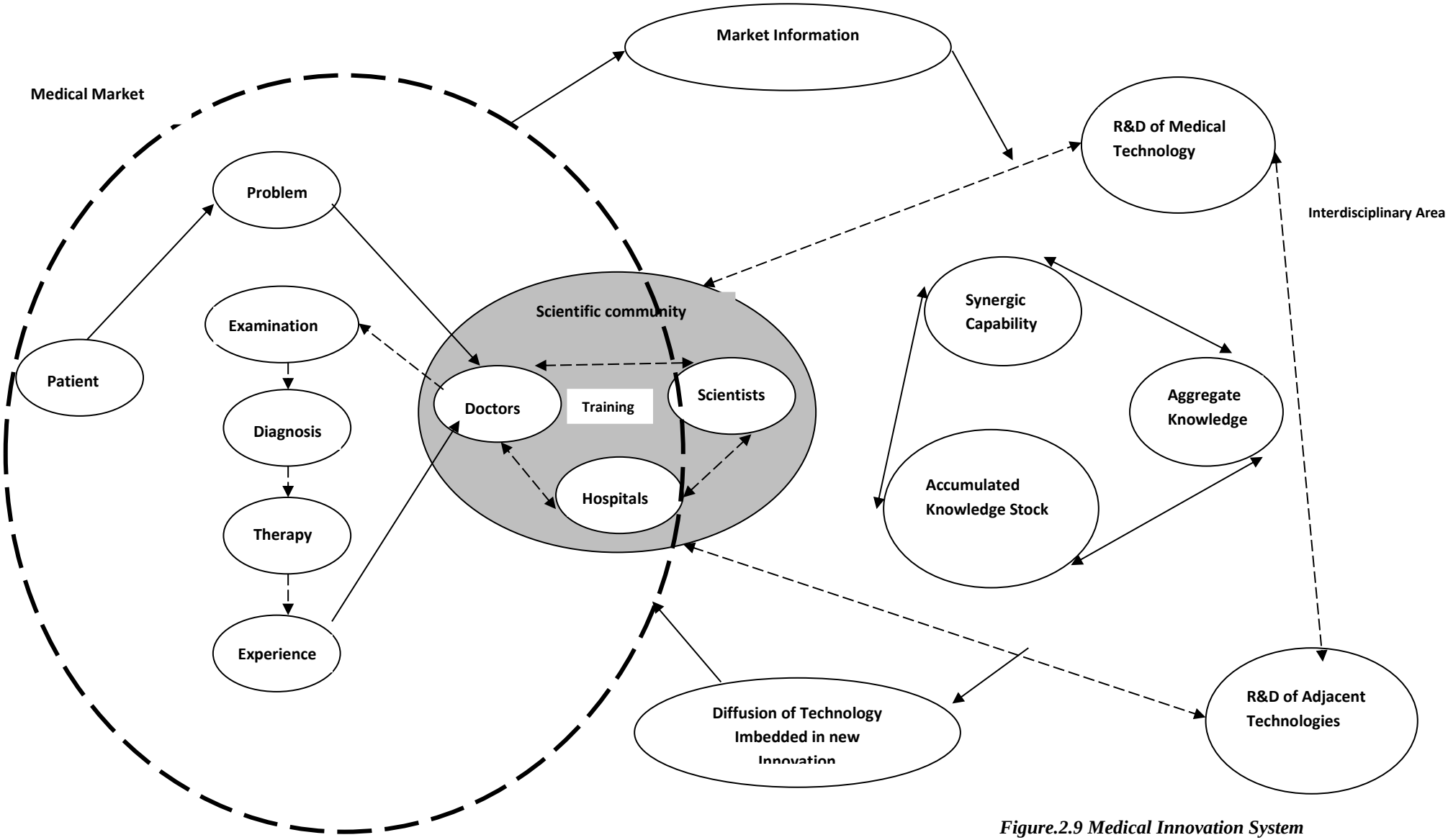


Figure.2.9 Medical Innovation System

2.4 Diffusion Models of Medical Innovations

The theory of innovation diffusion has increasingly become one of the most popular concepts for both marketing and innovation scholars .This theory has been discussed in different fields such as consumer durables, services, and pharmaceutical industries (Stremersch, 2009). This section will first focus on the evolution of diffusion models from Rogers' (1962) and Bass' (1969) studies up to the present time. Afterwards, the concept of sales take-off and vintage (Golder and Tellis, 1997) will be discussed, since the main concern of this research is to decrease the sales take-off time to accelerate the process of innovation diffusion (Golder and Tellis, 2004). This will be followed by a discussion of the acceleration of new product growth in the market (Stremersch et al, 2010), the dynamics of price elasticity during the product life cycle (Parker, 1992), and the important roles of influentials and imitators in the process of innovation diffusion (Mahajan and Joshi, 2007). Finally, we will state the effect of mainstream and emerging customers' orientation on the process of innovation diffusion (Daneels et al, 2011). The limits of innovation diffusion models will guide us through the further steps of research.

2.4.1 Dynamic of Innovation Diffusion and New Product Growth Models

With regard to Schumpeter's innovative theory in early twentieth century, most innovation diffusion studies began in the 1960s. Most scholars at that time were using the innovation diffusion theory in business studies about consumer behaviour, sales management, new product market analysis, and decision-making sciences. Many scholars have contributed to the concept of innovation diffusion. Perhaps we should call Rogers (1962) the co-founder of innovation diffusion studies (Shankar, 2008). Rogers defined diffusion of innovation as the process of spreading new innovation through the communication channels to the members of social networks over time (Rogers, 1985). He also mentioned five fundamental factors that affect the adoption of new innovation: relative advantage of new innovation, compatibility, simplicity, trialability and observability (Von Hipple, 1988).

Having a systematic review on the innovation diffusion literature, the major strands of the literature are seems to be on the first purchase diffusion models (such as Bass (1969), Dodds (1973), Tigert and Farivar (1981), Mahajan and Muller (1990), Easingwood, Mahajan and Muller (1983), Norton and Bass (1987), Bayus (1987), Gatington and Robertson (1989), and Sinha and Chandrashekharan (1992)), repeat purchase models (such as Lilien et al (1981), Rao and Yamad (1988) and Shankar et al (1998)), product life cycle (such as Redmond (1989), Golder and Tellis (1997), Agrawal and Bayus (2002), Tellis and Stremersch (2003), Tellis and Fornell (1988) and Shankar (2008)) , the role of marketing variables in diffusion (such as Horsky and Simon (1983), Horsky (1990), and Kalish (1985)) and some estimation models (including Urban et al (1990) and Twiss (1984)) .

In fact Bass (1969) coined the bass model of innovation diffusion by focusing on the timing of innovation adoption or initial purchase of new innovation. Based on his model so many other scholars such as Dodds (1973) and Tigert and Farivar (1981), tried to validate the forecasting capabilities of the Bass model. However, Mahajana and Muller (1990), focused on the shortcomings of the Rogers model of innovation diffusion and tried to combined the Bass and Rogers model to explain the process of innovation diffusion. In their criticisms of the Rogers diffusion model, Mahajan and Muller (1990) understood that unlike Roger's classification, adoption of new innovation doesn't follow a normal distribution patterns. They also figured out that, although Rogers model of innovation diffusion explain the social structure of innovation diffusion very well, the comparison across the various industries could result in totally different patten of innovation diffusion. The other studies by Norton and Bass (1987), Kim et al (2000) and Bayus (1987) were further attempts to the extension of the Bass diffusion model.

As we will explain further in this chapter, Gatingnon and Robertson (1989) focused on the effect of competition on the adoption of technological innovations by organizations which can be considered as one of the initial studies of technology diffusion among organization.

There have also been different studies on the effect of consumers' value perception of quality on the process of innovation diffusion, such as Zeithmal (1988), Ellen et al (1991), Moore and Benbasat (1991) and Fornell (1992). However, Chatman (1996) outlined the dynamics of insiders and outsiders in the process of innovation diffusion. There are also scholars who have conducted their studies of

innovation diffusion in the interdisciplinary fields of technology and social structures. For instance, while Souder and Sherman (1993) dedicated their studies to providing an overview of new product development process management, Montaya-Weiss and Calantone (1994) focused on the meta-analysis of new product development success drivers. One year later Brown and Eisenhardt (1995) modelled product development success factors from multiple actors' perspectives with regard to Montaya-Weiss and Calantone's (1994) comprehensive analysis. At the same time, Bauer (1995) elucidated the main reasons for the resistance against adopting new technologies. Reviewing their studies, Henard and Szymanski (2001) produced a new version of meta-analysis for new product development success drivers in 2001.

Understanding the development of new and incremental technology evolution, Song and Montaya-Weiss (1998) declared that the new product success drivers are different, depending on the level of product innovation. Their effort was one of the critical points in the history of innovation diffusion studies that guided other scholars to focus on the difference of various types of innovations.

Nevertheless, focusing on industrial networks, Shy (2001) and Hall and Khan (2003) attempted to shed more light on industrial networks and the affecting factors on adoption of new technology.

As it is evident from the history of innovation diffusion studies, there have been fewer studies on the social structure models of innovation diffusion in contrast to the significant number of studies on equation modelling strands of innovation diffusion. Also, even fewer studies have tried to classify the implications of successful diffusion based on the products' rates of innovation (Stremersch et al, 2010).

However, there have been some studies that focused on the concept of innovation diffusion from the consumers' point of view. These have mostly investigated subjects such as innovation adoption (IA) or technology acceptance models (TAM) (Shankar et al, 2003). As previously stated, a pioneering study in this field by Burt (1987) is concerned with the social contagion of innovation and how it affects the process of diffusion. In his paper, Burt is seeking to address an important question, which is related to the main concern of this research: Did the physicians resolve the uncertainty of adopting

the new drug through conversations with colleagues (cohesion)[5] or through their perception of the action proper for an occupant of their position in the social structure of colleagues (structural equivalence)[6]? Burt's later studies concluded four valuable findings: "(a) Contagion was not the dominant factor driving tetracycline's diffusion. Where there is evidence of contagion, there is evidence of personal preferences at work. (b) Where contagion occurred, its effect was through structural equivalence not cohesion. (c) Regardless of contagion, adoption was strongly determined by a physician's personal preferences, but these preferences did not dampen or enhance contagion. (d) There is no evidence of a physician's network position influencing his adoption when contagion is properly specified in terms of structural equivalence" (Burt, 1987). His findings emphasize the importance of social structures of target markets, which is the healthcare system in this research. Tornatzky and Klein (1982) also confirmed Rogers' (1962) findings of the relevant attributes of a well-diffused innovation: compatibility of the innovation to the market needs relevant advantage of innovation and its level of complexity. However, Rogers (1985) added the attributes of trialability and observablity to the conditions of efficient diffusion of innovation. Kalish (1985) suggested a framework based on Bass' (1969) model of innovation diffusion. He divided the process of innovation diffusion into two phases: awareness and adoption. He counts advertising and word of mouth as the main triggers of awareness, while adoption occurs when the perceived risk adjusted value of the product exceeds its selling price. On the other hand, following their previous studies, Bass and Norton (1987) generated a new model of innovation diffusion specifically concerning the adoption and substitution for successive generations of high-tech products. Also, Mahajan and Peterson (1987) solved the problem of the static ceiling of adopters in Bass' model of diffusion, and suggested their dynamic model of diffusion instead of the previous one. Apart from these studies on diffusion models, Howell and Higgins (1990) made a significant contribution to innovation adoption studies. Their model is shown in Figure 2.10. They investigated the personality characteristics, leadership

[5] The cohesion model focuses on socialization between the ego and alter ego. The more frequent and empathic the communication is between ego and alter ego, the more likely that the alter ego's adoption will trigger the ego's.

[6] The structural equivalence model highlights competition between ego and alter ego. This includes, in the extreme, the competition of people fighting one another for survival, but applies more generally to the competition of people merely using one another to evaluate their relative adequacy.

behaviours, and influence tactics of champions in technological innovations to find the implications of each factor. Following the adoption studies, Herbig and Palumbo (1994) investigated the effect of cultural contexts on the process of innovation adoption. Their conclusion includes a clear message: since the vast amount of social implications are embedded in the process of innovation diffusion, it follows totally different patterns on national, local and industry levels. In this respect, Valente (1996) mentions the effect of social networking on the acceleration of diffusion using the Hofsted (2001) classification of social groups. Also, Valente and Davis (1999) focused on the role of opinion leaders in social networks on the process of innovation diffusion, the idea that Van den Bulte (2006) termed the influence of influentials and imitators. Although this research is not intending to focus on the social aspect of innovation diffusion, since the topic itself is connected to social contagion, it may be necessary to consider some social backgrounds in order to provide a strategic framework of innovation diffusion.

Following the trend of innovation diffusion studies, Mahajan and Muller (1996), conducted a survey about the timing of innovation diffusion based on Bass' model of diffusion. They wanted to know if a firm should introduce a new generation immediately upon availability or delay introduction until the maturity stage of the preceding generation. The decision depends on a number of factors, including the relative size of the market potentials, gross profit margins, the diffusion and substitution parameters, and the discount factor of the firm.

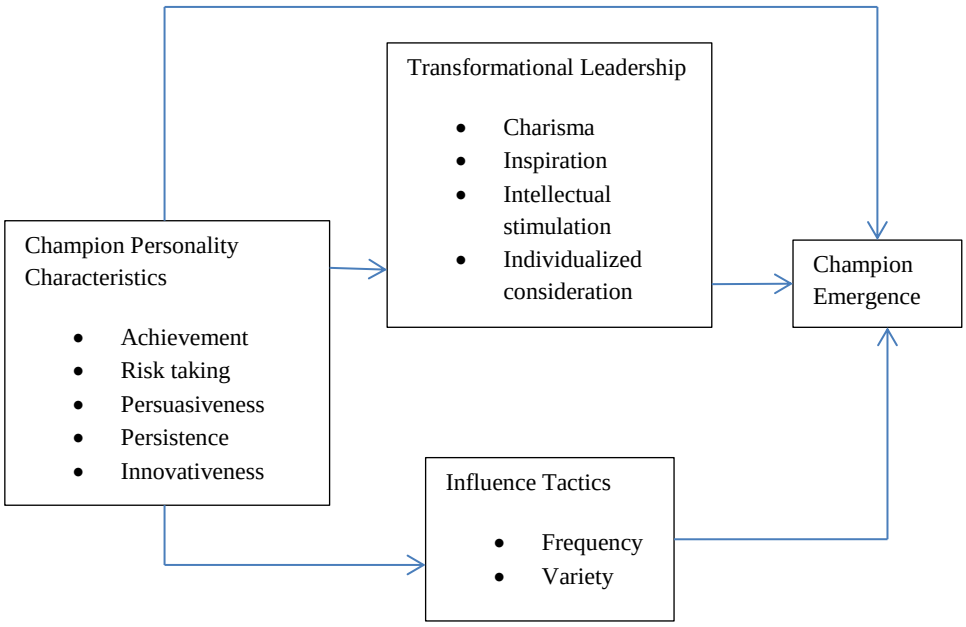


Figure.2.10 General Model of Champion Personality Characteristics, Transformational Leadership and Influence Tactics (Howell and Higgins, 1990)

On the other hand, perhaps, product life cycle (PLC) frameworks are one of the most appropriate classifications for studying innovation diffusion issues. Tellis et al, (2003) claim that PLC curves exhibit different growth patterns in each industry and are not as smooth as the classic-smooth adoption curves. As illustrated in Figure 2.11, Stremersch et al (2010) also state that in the initial stages of PLC, there are usually two different turning points: " 'take-off,' which occurs at the beginning, and 'saddle,' which occurs during early growth. The classic Bass model starts with spontaneous adoption by an initial group of adopters, but does not provide explanations for the mechanisms that lead to this initial adoption or take-off. Studies on take-off focus on this initial stage and explore the market's behaviour and the interface between adoption and the start of communication interactions" (Stremersch et al, 2010).

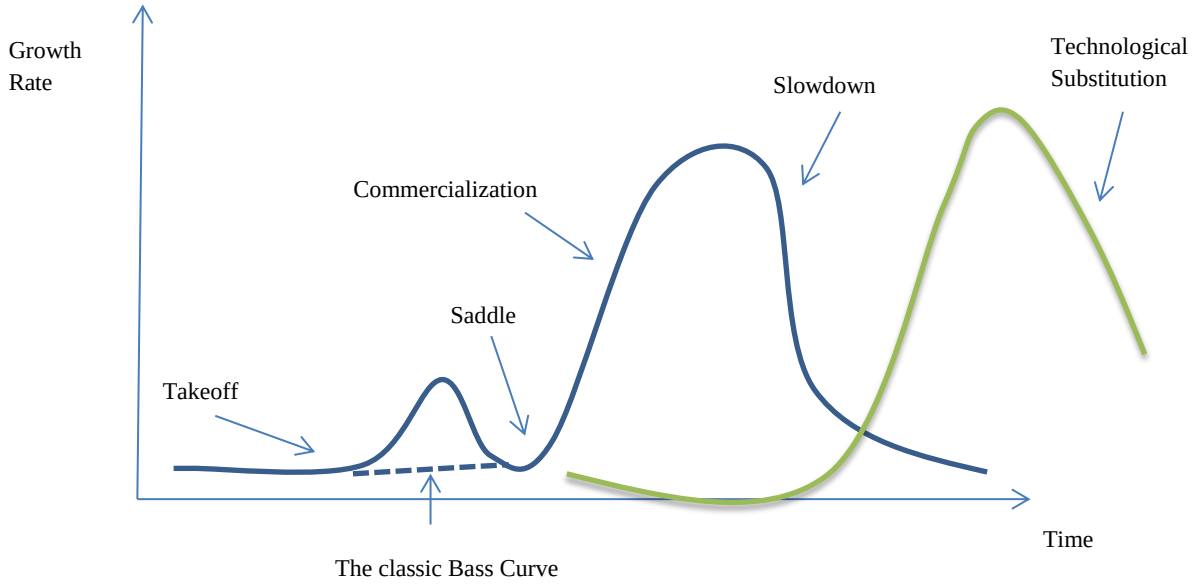


Fig. 2.11 Concept of Sales Take-off (Stremersch et al, 2010)

Golder and Tellis (1997) define take-off time as the time at which a dramatic increase in sales occurs that distinguishes the cut-off point between the introduction and growth stage of PLC (Golder and Tellis, 1997). They state that to get all the production, distribution and marketing done within the initial steps of PLC, it needs time to position the new product into its place successfully. Tellis et al (2003) mention that the main objective of take-off time is to accelerate the process to arrive at the dominant design position as soon as possible. There have been many studies on the factors affecting the shortening of take-off times. For instance, Tellis et al, (2003) consider price reduction, product category and cultural factors to be the main accelerators of the take-off process (Foster et al, 2004). This research aims to study the acceleration of the take-off process of disruptive innovations in the initial stages of diffusion; the accelerating factors inside (strategically) and outside the company (culturally) will be discussed later.

Although take-offs usually occur in the initial steps of innovation diffusion, sometimes in some markets a sudden decrease in sales is observed after the take-off time of innovation diffusion (Mahajan and Muller, 1998). This decrease in sales was observed first by Moore (1991), who described it as a chasm between the early and main market (Goldenberg et al, 2002). But Goldenberg

et al (2002) call this phenomenon *saddle*. Chandrshekharan and Tellis (2006) believe that the saddle phenomenon can be explained by the informational cascade theory.[7] Stremersch et al (2010) state that "Small shocks to the economic system such as a minor recession can temporarily decrease the adoption rate, and the decrease is magnified through the informational cascade" (Stremersch et al, 2010).

Goldenberg et al (2002) and Muller and Yogev (2006), believe there is another explanation for the saddle phenomenon, based on heterogeneity in the adopting population, which may consist of two different groups. They suggest that maybe the rates of innovation adoption are different in two groups, and, therefore, sales may show interim trough (Van de Bulte and Joshi, 2007).

Stremersch et al (2010) state that the innovation diffusion literature elucidates contradicting answers to the question of whether or not diffusion accelerates across the technology generations. Bass and Bass (2001) define the technology generation as a set of product brands and models that have similar functionality characteristics in customer perception. Other scholars, including Bass and Bass (2004), Kim et al (2000), Mahajan and Muller (1996), and Norton and Bass (1992, 1987), believe that growth parameters are constant across technology generations. But in an utter contradiction, still other scholars, such as Van den Bulte and Stremersch (2004, 2006) and Van den Bulte (2000, 2002), state that the overall pattern of diffusion of innovation accelerates over time. Stremersch et al (2010) state that "These two research streams form an intriguing paradox: It seems that, in the same economy, an acceleration of the diffusion of innovations over time should be reflected in an acceleration of diffusion of technology generations that succeed one other; however, the diffusion rates of sequential technology generations remain constant." A resolution to the paradox was suggested recently by Stremersch et al. (2010), who noted constant growth parameters across generations, but a shorter time to take-off for each successive generation. They investigated whether the faster take-off of successive generations is due to the passage of time or to a generational effect. They defined technology vintage as "the year in which the first model of a specific technology generation was launched commercially" (Peres et al, 2010).

[7] An information cascade has the potential to occur when people make decisions sequentially, with later people watching the actions of earlier people, and from these actions inferring something about what the earlier people know.

Also, Stremersch et al (2010) point out the paradox of new innovation growth across the technology generation. They state that a huge amount of literature presents the faster diffusion of recently introduced innovations than that of the older ones, while technology generation literature argues that the growth rate which is measured by the diffusion parameter remains constant across the technology generations (Stremersch et al, 2010). The results of their study show that "take-off acceleration is mostly driven by technology vintage (i.e., the passage of time) rather than generational shifts. Thus, time is a factor that accelerates early growth, but generational shifts do not (Peres et al, 2010).

Many discussions have taken place on the effect of vintage and generation on take-off time (Van den Bulte and Stremersch, 2008). For instance, Agarwal and Bayus (2002) point out the battles between competing products that set the dominant design in the market and establish new standards to industry. They mention that this is a challenge that subsequent generations may not face (Chandrashekharan and Tellis, 2008). At the same time, Kohli et al (1999) demonstrate the adoption efforts of consumers. They state that the earlier generations of products may require a more dramatic change in behaviour from consumers, as these products may be more novels (Kohli et al, 1999).

The above two issues affect the take-off acceleration across technology generations. But there are factors that will accelerate the takeoff process specifically during the technology vintage. For instance, Golder and Tellis (1997) believe that increasing the affordability of new innovation could lead to take-off acceleration. In this regard, Parker (1992) states that early market growth will be affected by price decline in necessity markets. Agarwal and Bayus, (2002) mention the importance of better communication and information channels to educate and inform potential customers of the benefits of new innovation.

Consequently, Golder and Tellis (1997) state that take-off acceleration does not necessarily imply a faster overall diffusion process. On the other hand, it seems based on the findings of Foster et al (2004) and Garber et al (2004) that the take-off time will be shortened across each subsequent technology generation. In other words, if a new generation takes longer to take off than the previous generation, it is a symptom of failure.

Therefore, stimulating take-off acceleration and avoiding saddles in the initial stages of PLC are the most important objectives in launching new innovation in the market. It seems this hasn't been studied sufficiently. This research aims to study this particular issue in disruptive innovations.

Mahajan et al, (2010) argue that the effect of social network structures on product growth is still a fundamental question. Although Van den Bulte and Buyts (2007) conducted empirical studies around this issue, the main theoretical points still beg to be studied (Mahajan et al, 2010). It seems that most researchers focused on the role of hubs or influentials in the overall growth process (Goldenberg et al, 2009). Mahajan et al, (2010) believe that the role of network structures in innovation diffusion has not grown much due to the lack of data.

Van den Bulte and Joshi (2007) suggest a theoretical framework of influential-imitator mixture. They discuss this looking from the social character point of view; influentials are autonomous and inner-directed, while imitators are other-directed, since they are looking for approval and directions. From the competition status angle, influentials have a high competitive status, while imitators have low statuses and mostly try to gain or maintain their status.

There have also been studies on the attributes of innovators and innovation itself that affect the diffusion of innovation. There have been some studies that categorise the effecting factors on innovation diffusion in different ways. One of the most renowned studies in this regard is Gatington and Robertson (1989). As shown in Figure 2.12, they defined a competitive behaviour paradigm for technology diffusion among the organizations.

Structural factors such as industry competitiveness, industry reputation, technology standardization, vertical coordination with customers, and resource commitments (including R&D allocations and marketing supports) are the main determinants of the innovators or supply-side competitive environment. The demand-side or the adopter-competitive environment is affected by structural factors such as industry heterogeneity, competitive intensity, demand uncertainty, and communication factors that include signal frequency and clarity, professionalization and cosmopolitanism.

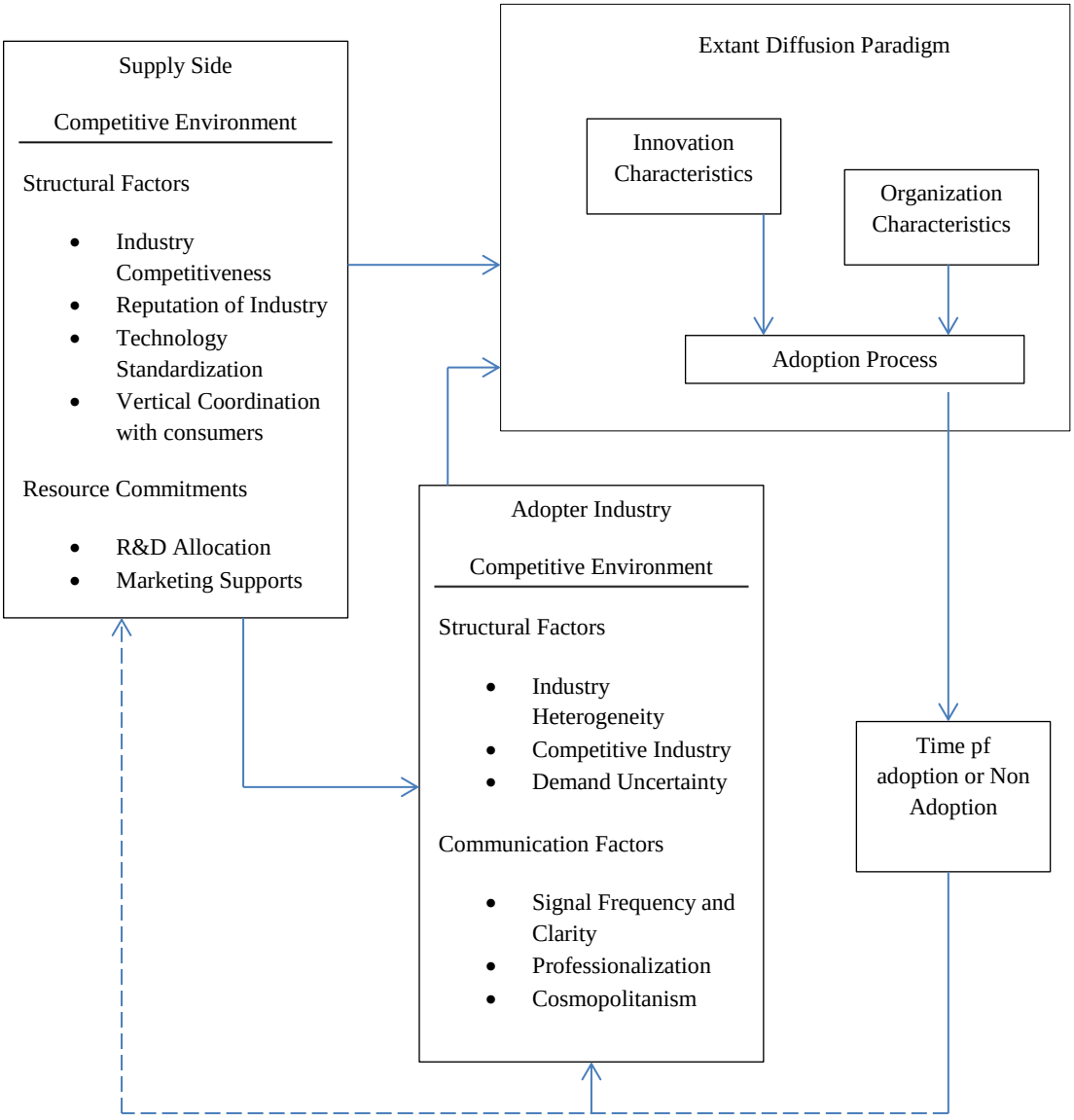


Figure 2.12 Gatington and Robertson (1989) Model of Innovation Diffusion

Nevertheless, there is another prominent classification of diffusion variables by Wejnert (2002), which is summarized in Table 2.4. She essentially grouped variables into three sections: characteristics on innovation, characteristics of innovators, and environmental context. How each characteristic is defined is depicted below. On the other hand, Peansupap and Walker (2005) state that the process of diffusion is the outcome of three factors: static factors of innovation diffusion, dynamic factors of change management, and the process of innovation implementation (Figure 2.13).

In their study on the diffusion of ICT innovation, they suggest different strategies to overcome the barriers to ICT diffusion.

Characteristics of Innovations	• Public versus private consequences • Benefits versus costs
Characteristics of Innovators	• Societal entity • Familiarity with the innovation • Status characteristics • Socioeconomic characteristics • Position in social networks • Personal characteristic
Environmental Context	• Geographical settings • Societal culture • Political conditions • Global uniformity

Table 2.4 Wejnert's (2002) Diffusion Framework

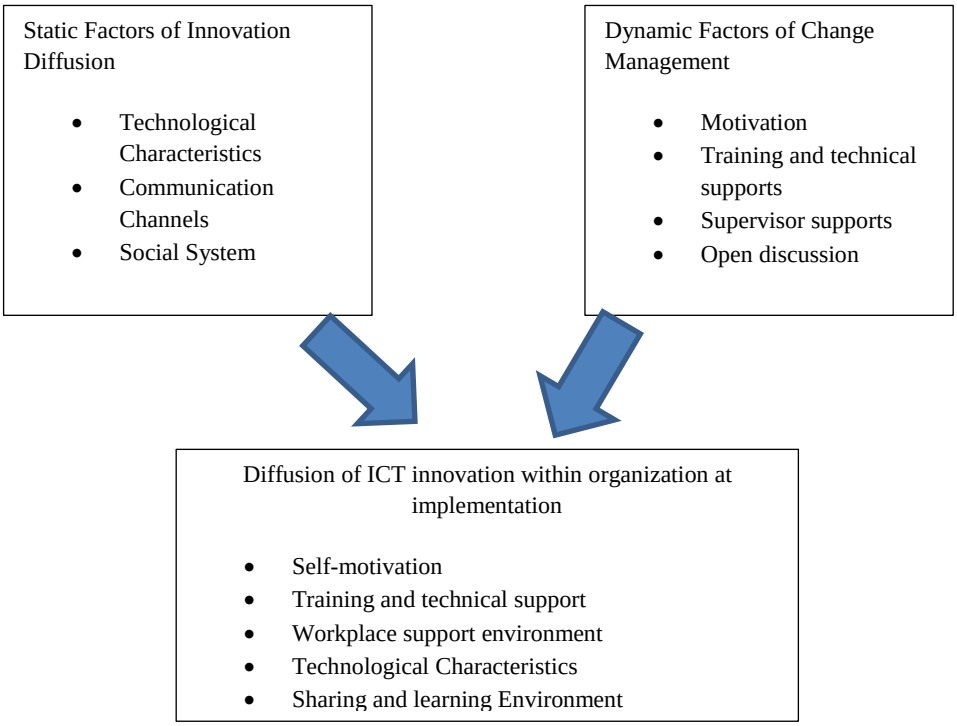


Figure 2.13 Peansupap and Walker's (2005) ICT Diffusion

To summarize the innovation diffusion studies we have included Table 2.5. Taking into account the various bodies of innovation diffusion studies, this research intends to generate a model that will explain the mechanism of diffusion of innovation underlying the dynamics of the market challenges. This model will later be applied to explain the diffusion of DI in medical markets and cover the gaps in current literature; we will outline the main questions of this research later.

Scholars		Area of research
Innovators and Innovation	Peansupap and Walker (2005) Wejnert (2002) Gatington and Robertson (1989)	Diffusion framework
Communication Channels	Alba and Hutchinson (1992)	Consumer knowledge constructs
	Zeithmal (1988), Ellen et al (1991), Moore and Benbasat (1991) and Fornell (1992)	Consumers' value perception of quality on the process of innovation diffusion
Process	Golder and Tellis (1997), Goldenberg et al (2002)	Take-off and saddles
	Moore (1991)	Crossing the chasm
	Chandrasekaran and Tellis (2006), Van de Bulte and Joshi, 2007	Informational cascade theory
	Bass and Bass (2001) , Bass and Bass (2004), Kim et al (2000), Mahajan and Muller (1996), Norton and Bass (1992, 1987) , Stremersch et al, 2010	Technology generations
	Rogers (1962)	General Model
	Abernathy and Utterback (1978)	Dominant design effect and the industrial substitution
	Maidique and Zirger (1984)	Drivers of product innovation success
	Stuart and Abetti (1987)	Predict the technology start-up companies' success rate
	Souder and Sherman(1993)	New products development process management
	Montaya-Weiss and Calantone (1994)	Meta-analysis of new product development success drivers
	Shankar et al, 2003	Technology acceptance models
	Tellis et al, (2003)	PLC curves are showing different growth pattern in each industry and are not as smooth as the classic-smooth adoption curves
Social Structures	Valente (1996)	Effect of social network on the acceleration of diffusion
	Valente and Davis (1999)	Opinion leaders in social networks

	Van den Bulte (2006)	Influence of influentials and imitators
	Mahajan et al, (2010), Van den Bulte and Joshi (2007)	Effect of social network structure on the product growth
	Richins and Bloch (1986)	Social structures of diffusion
	Burt (1987)	Examining the drivers of social contagion
	Shy (2001) and Hall and Khan (2003)	Understanding of industrial networks and the affecting factors on adoption of new technology
	Howell and Higgins (1990)	Investigated the personality characteristics, leadership behaviours, and influence tactics of champions of technological innovations
	Herbig and Palumbo (1994)	The effect of cultural contexts on the process of innovation adoption
Macro-level Studies (Diffusion Models)		
	Bass (1969)	Innovation diffusion of consumer-durable products
	Mahajan and Muller (1996)	The timing of innovation diffusion
	Kalish (1985)	Awareness and adoption, advertising and word of mouth as the main triggers of awareness, while adoption happens when the perceived risk adjusted value of the product exceeds its selling price
	Bass and Norton (1987)	New model of innovation diffusion of successive generations of high-tech products
	Mahajan and Peterson (1987)	Dynamic model diffusion

Table 2.5 Conducted Researches of the Dynamic of Innovation Diffusion

Reviewing social structure models of innovation studies in the previous section, the model below suggests a comprehensive outlook toward the dynamic of innovation diffusion from the social structure point of view, which this research will apply to study the dynamic of DI diffusion in medical markets. Based on Rogers' model of diffusion (1985), this model groups the main components of diffusion into three main categories:

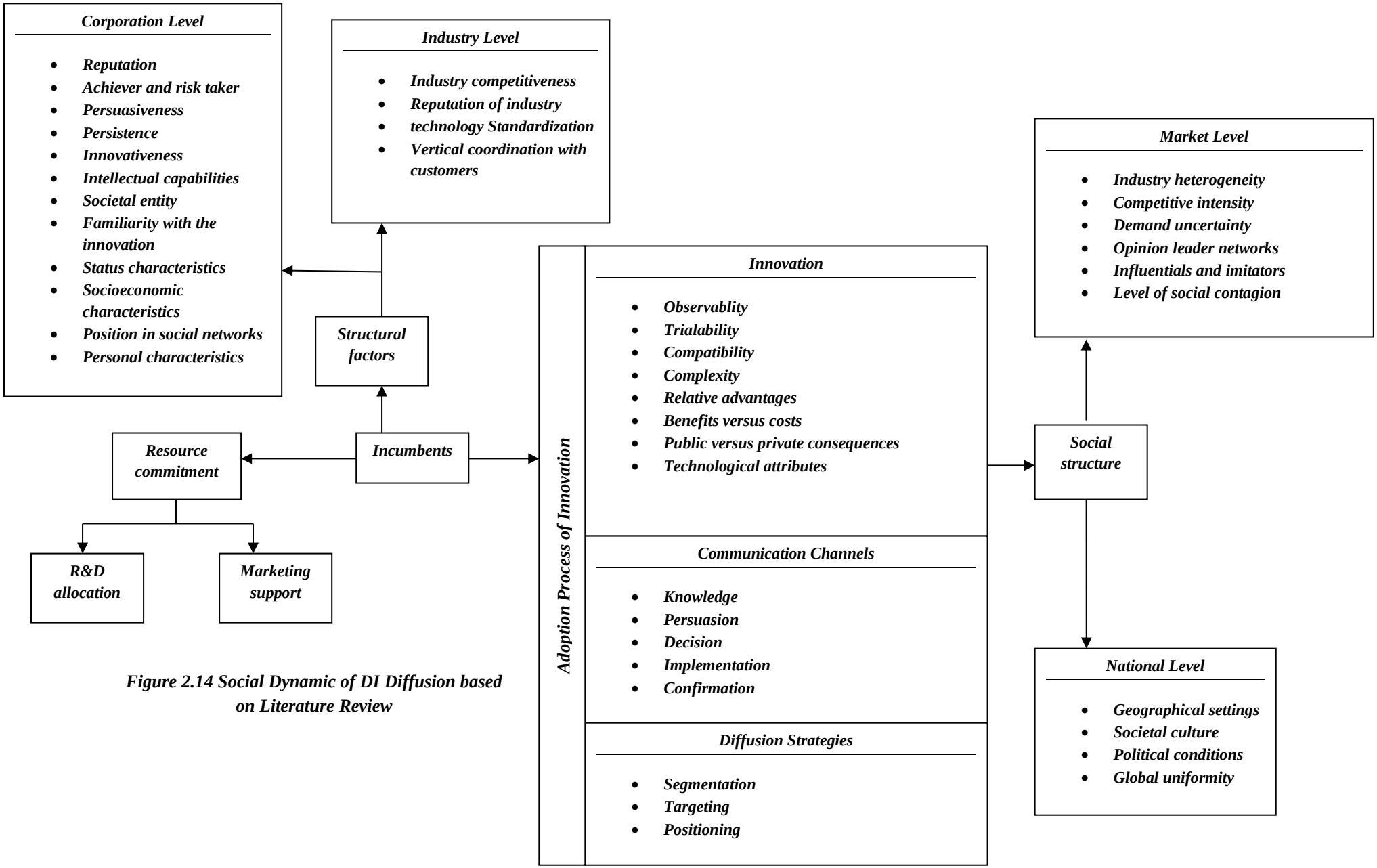


Figure 2.14 Social Dynamic of DI Diffusion based on Literature Review

1. The supply-side of innovation (incumbents' side or innovator's) based on the findings of Peansupap and Walker (2005) and Wejnert (2002) Gatington and Robertson (1989).
2. The process of adoption which is affected by the attributes of innovation, (Wejnert, 2002; Robertson and Gating, 1986; Rogers, 1985), the structure of communication channels (Zeithmal, 1988; Ellen et al, 1991; Moore and Benbasat, 1991; Fornell, 1992), and the diffusion strategies.
3. The demand-side of innovation (market or social structure) from both the market and local level points of view.

This research analyses the dynamic of DI diffusion in medical markets based on the research model in order to investigate the strength and weakness of the model in DI studies. In other words, this research attempts to modify the research model (which was generated from previous diffusion studies) to make it suitable to explain the dynamics of DI diffusion in medial markets.

However, there is another issue related to the research model around which this research seeks to extend the knowledge of DI diffusion. As is evident in Table 2.5, despite the many studies on different components of the innovation diffusion model, knowledge about diffusion strategies has not been developed adequately. One of the main reasons for this is the interdisciplinary nature of this topic. While marketing scholars consider innovation diffusion strategies from market penetration and new product development (NPD) points of view, innovation scholars focus more on the 'fuzzy front end' and the initial stages of NPDs (Von Hipple, 1985). Consequently, it seems there is a gap in the literature concerning the main strategies of innovation diffusion, which we call the mechanism of market disruption. Therefore, the second objective of this research is to figure out the main diffusion strategies of DI in order to accelerate the process of DI diffusion and facilitate the process of market disruption. In the next two sections each objective of the research will be discussed in more detail and the findings of the literature about the diffusion of DI in medical markets will be narrowed down further.

The main objectives of this research are supported by many rationales. While a significant number of scholars such as Davis (1989), Rogers (1962) and Shankar et al (2003) believe that the utility maximization behaviour of customers eventually leads them to replace old technology for new , Mac Vaugh and Schiavone (2010) refute this idea. Pointing out the sailing ship effect[8] (Gilfillan, 1935) they suggest that this replacement never happens automatically. Additionally, they cite three different levels of technology adoption: adoption of market or industry (macro-level), adoption of the networks inside the market (meso-level) and personal level of adoption (micro-level).

2.5. Diffusion of Disruptive Innovations in Medical Markets

Healthcare is one of the growing markets for new products and services. Since costs are rising, particularly in the developed world, the emergence and diffusion of disruptive innovations have become tremendously important in enabling the transition; less skilled people carry out more sophisticated performances in lower cost settings. In healthcare it is also important to overcome the barriers of treatment by new technologies. However, recently, diffusion of such new technologies has become a dilemma. As Williams et al (2008) mention, most of the problems occur because of the complexity of the actors within the healthcare innovation networks, including clinical professionals, the supply chain, reimbursement and regulatory agencies, and healthcare service providers. Therefore, generating a model to describe the diffusion of DI throughout the market could be quite valuable for both academics and practitioners. As Christensen et al (2000) argue DIs possesses three main attributes: they target non-consumers, they have a novel business model or value proposition, and they drive out the incumbent in a niche where they deliver equivalent quality at a lower price.

[8] The sailing ship example is recounted by Gilfillan (1935), who shows how the 'old' sailing ship was improved as steam ships emerged during the nineteenth century. Improvements concerned nearly all of the components and materials of the sailing ship, which was thus transformed from a basically wooden structure to a metallic one, whose carrying capability was massively improved. The basic point is thus:
"It is paradoxical, but on examination logical, that this noble flowering of the sailing ship, this apotheosis during her decline and just before extermination, was partly vouchsafed by her supplant, the steamer." (Gilfillan, 1935, p.156). What we are mainly interested in here is that sort of mechanism which implies intentional action pointing at improving the performance of an old technology, as stimulated by the emergence of a new one, devoted to supplying the same sort of operations or services. This mechanism is often referred to as the 'sailing ship effect' after Gilfillan's study on innovation in ships (Gilfillan, 1935)

Consequently, in this section the dynamic of DI diffusion in two phases will be discussed. Firstly, focus will be on the importance of DI diffusion and how it determines the process of market disruption. This will be followed by an examination of the differences of DI and disruptive technologies (DT) in order to suggest a research framework to categorize different types of DI and narrow down the research focus on healthcare markets.

As Lindsay and Hopkins (2010) mention in their studies, perhaps the Kimberly-Clark case study is the most well-known case of pure market disruption. As Christensen and Raynor (2003) state, disruptive innovations are being recognised for their diffusion methods. In other words, the diffusion process defines the disruptiveness of a given innovation regardless of the emergence situation (Markides, 2006; Daneels, 2004). Consequently, any radical, incremental, or revolutionary innovation could lead to the emergence of disruptive innovation when diffused through the market in a disruptive manner. For instance, The Kimberly–Clark Company disrupted the handkerchief market by introducing to the market facial tissues called Kleenex. Those facial tissues had, in fact, been consumed by Hollywood actors for a long time. Therefore, as we can see, the diffusion process plays the pivotal role in shaping a disruptive innovation. This is the reason that this research is focusing on the dynamic of diffusion of DIs. Sood and Tellis (2011) declare that although the emergence of an appropriate DI candidate is certainly important to disrupt the mainstream market, the main issue that distinguishes the actual DI from a potential one is the method of diffusion. Therefore, the first objective of this research is to unveil the diffusion dynamic of DI in medical industries. As mentioned previously, the complexity of the innovation networks in healthcare industries makes it valuable to focus on the diffusion of DI in this industry.

Technological change is critically important to a firm, since it has potential to make the assets, labour and intellectual capital of incumbents in the market totally obsolete (Sood and Tellis, 2011). It can also create entirely new markets, products, and customers, exploding demand (Govindarjan and Kopalle, 2006). On the other hand, it may open a new segment in the mainstream market (Christensen et al, 2000). Based on the definition of Sood and Tellis (2005; 2011) and Utterback and Acee (2005), we can consider three domains of disruption for a given disruptive innovation:

technology, firm, and demand disruption. As demonstrated in Figure 2.15, technology disruption takes place when a new technology crosses the dominant technology of the mainstream market in terms of its performance. In other words, technology disruption occurs when the performance of new technology surpasses the performance of the dominant one. At the next stage firm disruption will occur, which means the market share of a firm whose products get benefit from a new technology exceeds the market share of the largest firms in the mainstream market (Sood and Tellis, 2011). The third layer of disruption is demand disruption, which means that the total share of products in the market based on a new technology surpasses the market share of those products with the dominant technology.

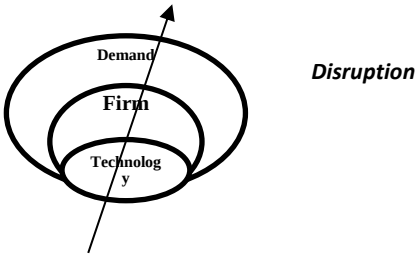


Figure 2.15 Three Layers of Market Disruption (Sood and Tellis, 2011)

There is a common mistake here that should be avoided: researchers confuse disruptive innovations (DI) and disruptive technologies (DT). Walsh and Linton (2000) define DT to be either a new combination of existing technologies, or new technologies whose application to problem areas or new commercialization challenges can cause major technology product paradigm shifts or create entirely new ones (Kostoff et al, 2003). In other words, Kondratieff (1935) and Schumpeter (1934) mention "long waves of technological change and the process of creative destruction caused by new technologies new skill sets either creating or redefining firms and existing markets".

DTs are scientific discoveries that break through the usual product/technology capabilities and provide a basis for a new competitive paradigm, while DIs are products, processes, or services that provide exponential improvement in the performance value perceived by the customer. In other words, perceived performance values play the most important role in the emergence of disruptive innovations. All the technical capabilities, designed services, and assigned attributes of innovations will be

perceived as new performance values by the market, and this is the main leverage of market disruption for the market incumbents. In fact, some scholars, such as Kichhoff and Walsh (2000), believe that considering the dynamic of disruptive innovations the well-managed organizations usually fail to recognize disruptive DTs. They believe that entrepreneurial firms with no established customer bases can take advantage of DIs to redefine the mainstream markets, while large firms are reluctant to cannibalize their own markets through the use of disruptive technology (Archer et al, 1999).

In contrast to sustaining technologies, which improve the performance of established products in the mainstream market, DTs often introduce new performance values not previously recognized by the mainstream market.

Consequently, based on the dynamic of technologies and DIs, we may consider various types of DIs in the market, as shown in Table 2.6. There are two ways to disrupt the mainstream market relying on sustaining technologies: market-pull DI and architectural DI. Market-pull DI occurs when an incumbent decides to use a sustaining technology in a new field or new market. It usually works by obtaining new applications from a sustaining technology in order to bring new performance values to the customers, or transferring the current performance values to new markets and new customers. A famous case of market-pull DI is Kimberly-Clark's Kleenex facial tissues. Market-pull DI mostly relies on low–end disruption and could disrupt the mainstream market focusing on new performance values for new customers in new markets (Lindsay and Hopkins, 2010).

Adner (2002) states that this sort of disruptive innovation possesses a new set of product attributes that underperformed in mainstream markets but introduced value for the customers outside the mainstream market. However, sometimes a given firm combines an array of sustaining technologies to produce a new innovation that can deliver new performance values to the customers, and, therefore, could disrupt the mainstream market. By doing this they usually create a new market that includes their current customers, and by disrupting the market from the low end they introduce new performance values to the market. Perhaps, as Abernathy and Clark (1985) and Henderson (2006)

mention, the case of Ford Automobile Manufacturing is one of most well-known cases of architectural DI.

However, DI relying on DT usually happens in three different ways in product markets. As Druhel and Schmidt (2008) state, either they may disrupt the market from the low end (price sensitive), or they may prefer to create a new market by disrupting the mainstream market from the high end (performance sensitive). They may also create a new segment in the mainstream market by introducing new performance values to a part of the market. In any case, DTs destruct the previous performance in the market by introducing new performance values. The dynamic of disruption in service markets is shown in Table 2.6.

As Table 2.6 illustrates, disruptive innovations relying on market pull, architectural innovations, and business model disruptive innovations could take place relying on sustaining technologies. In all three types of DI relying on sustaining technologies, disruption occurs by the creation of the new market alongside the current one. However, although they all encroach upon the market from the low end, with market pull DIs disruption occurs by showing the current performance values to new customers, while in architectural innovations new arrangements of a product's a component will deliver some new performance values to customers. Business model DIs also target new markets by delivering new sets of services to the customers to fill the current gaps, by delivering new services in more effective ways to the market. However, disruptive technologies could create a potential DI to disrupt the mainstream market from either the high or low end of the market. In some cases, disruptive technologies could enable the emergence of new services in the market. Disruptive technologies usually promise to deliver new performance values to the market.

DT		Product	Products					Services	
Sustaining technology	Performance Value	Existing	✓						
		New		✓				✓	
	Encroachment	Low end	✓	✓				✓	
		High end							
	Customers	Current		✓				✓	
		New	✓						
	Market	Existing							
		New	✓	✓				✓	
Disruptive technology	Performance Value	Existing							
		New			✓	✓	✓		✓
	Encroachment	Low end				✓			✓
		High end			✓		✓		
	Customers	Current			✓	✓	✓		✓
		New							
	Market	Existing					✓		
		New			✓	✓			✓
DI Types			Disruptive Innovation Market-Pull (Case of Kleenex)	Architectural Innovation (Case of Ford) Market -Pull	Disruptive Innovation from High End (iPhone) Tech-Push	Disruptive Innovation from Low End (Stents) Tech-push	Semi-Disruptive Innovation from High End (DES)	Disruptive Innovation by Business-Model (eBay)	Disruptive Innovation in Services Enabled by Technology

Table 2.6 Research Framework of DIs and DTs

Therefore, there are different types of DIs from various perspectives. However, this research focuses on the diffusion of DIs that occurs by the enforcement of DTs and mostly disrupts the market from the low end. In other words, this research aims to examine the suitability of the research model in order to explain the dynamic of DI diffusion in specific situations, as mentioned in the research framework.

2.6 Understanding the Enabling Mechanisms of DI Diffusion in Medical Markets

Engel (2011) points out the main challenge of market actors in bringing DIs to the market. He asks how a company that has the resources to bring new DI to the mainstream market and disrupt it can move quickly enough to forget about their current lucrative market and build a sustainable advantage based on the new potential market.

To address this question, Engel (2011) argues that large companies must understand the process of agile start-ups to figure out what makes them so effective. In fact, Engel (2011) considers the key to disrupting the mainstream markets is creating new performance values for customers. He states that focusing on customer development parallel to the product development process could disrupt the market. He believes that customer development would take place by investing more on launching teams and market information to make a customer base. This issue has been the main challenge of marketing scholars for a long time. However, this research looks at this issue from another perspective.

Much of the literature about innovation diffusion strategies has borrowed from marketing sciences (Muller et al, 2010). Much of the literature in this area is about issues such as NPD and launching strategies. There have been many studies by scholars such as Abbrat (1986), Kooper and Schmidt (1995), Easingwood (1989), Easingwood and Harrington (2002), Easingwood and Beard (1996), Easingwood et al (2006), Gulitinan (1999), and Hultink and Griffin (1998) about the launching strategies of new products. Most of them have looked at the issue from a marketing point of view. However, we know that innovation studies have their own implications that should be considered in

order to issue innovation diffusion strategies. This is particularly true regarding DIs, since the process of diffusion plays the most pivotal role in making a potential DI an actual one.

Consequently, this research develops a new strategic model for DI diffusion in industrial-consuming markets such as medical markets, based on a significant modification of NPD models in order to meet the requirements of innovation studies. Regarding this objective, the nature of current launching strategies of NPD paradigms will be touched upon, and an attempt will be made to find a strategic model of DI diffusion in medical markets.

As illustrated in Table 2.7, most scholars grouped new product launch strategies into three phases: market preparation, targeting and positioning, and execution (Easingwood et al, 2006). Market preparations usually include activities such as forming strategic alliance with the other actors in innovation network, supplying other equipment manufacturers (OEM), providing clear product information to the market, educating the market to understand new uses, and creating unique distribution channels (Easingwood, 1989; Easingwood and Harrington, 2002). However, as Christensen and Raynor (2003) and Govindarajan and Koppala (2006) argue, perhaps the most important strategy of the preparation phase is providing the diffusing pre-launch information to the market. As Easingwood et al (2006) state, this pre-launch information includes innovation and usage know-how, as well as creating a unique distribution channel. As Druhel and Schmidt (2008) state, a new business model could enhance the capability of market disruption significantly.

However, after preparing the market in a convincing manner, DI must be targeted and positioned into its appropriate segment of the market (Markides, 2006). Easingwood and Beard (1996) suggest that the main competitors target the high-value users and emphasize low price, technology superiority, and low risk to position and disrupt the market within the selected niche. Hultink and Griffin (1998) also suggest that perhaps holding different seminars and conferences for the target group could be a vital method to share the innovation's information with the market and select the target segment as a niche to disrupt the market.

Market Preparation

1. Form strategic alliance
2. Supply to OEMs to incorporate in other products
3. Provide clear product information to the market
4. Educate the market to understand new uses
5. Create unique distribution channels

Targeting and Positioning

1. Target high-value users
2. Emphasize low price
3. Emphasize technology superiority
4. Emphasize low risk
5. Offer different versions targeted at different buyers

Execution

1. Use opinion leaders
2. Have trial programs (e.g. demonstration)
3. Concentrate on niches
4. Cultivate a winner image
5. Focus on channel partners
6. Exploit technical alliance
7. Use reference sites

Table 2.7 Major Mechanisms to Disrupt the Mainstream Market

On the other hand, Niranjan et al (2012) believe that to position a DI well to disrupt the mainstream market, it needs to be executed effectively. Guiltinan (1999) states that the importance of opinion leaders (key physicians in a medical context) is significant in order to diffuse new innovation through their networks. Easingwood et al (2006) suggest other strategies such as conducting trial programs, concentrating on niches, and cultivating a winning image for a greater impact on the mainstream market. Reviewing the literature has shown, as Reinhardt and Gurtner (2011) have mentioned that the literature on diffusion strategies has not been well-understood, and more studies are necessary to understand the strategic model of DI diffusion in markets. Therefore, this research offers a new strategic model of DI diffusion in medical markets based on a revised version of launching strategies of the NPD paradigm.

Studies of diffusion models of DI in medical markets are significant in several respects. Foremost, medical innovations and healthcare markets are fundamentally different from similar fields. As Consoli et al (2007) mention, there are emotional factors attached to the concept of health and illness which makes medical innovation unique. Also, as Soleimani and Zenios (2011) state, the nature of medical innovation networks and the role of actors are tremendously complex and not comparable with the other markets. Therefore, medical markets have their own issues to be considered in diffusion studies of new DI innovations. However, as is mentioned in the WHO report (2010), there are two main characteristics a novel medical innovation should possess: a promise to improve the quality of treatment and the ability to reduce the high cost associated with new technologies.

Niranjan et al (2012) and Neir et al (2008) classify the main triggers of DI diffusion in medical industries based on the findings of Homer (1987) to understand the mechanism of DI diffusion in this respect. Basically, they divide the effecting factors on DI diffusion into endogenous and exogenous factors. Figure 2.16 shows the breakdown of endogenous factors into three areas, each of which reinforce the others in a feedback loop: use, evaluation and support. They mention that extent of use, purchaser fraction and new purchase decisions would form new purchases. On the other hand, they say that information plays a pivotal role in enhancing the level of adoption in medical markets (Kalish and Lilien, 1986). Markides and Charitue (2003) believe that promotional marketing and report publication would increase the level of information in medical markets. Therefore, the enhanced level of information and perceived average performance by customers will lead the market to accept the new product. The role of purchaser fraction in constructing the market's data base, which is simulated itself from the product availability in the market, should not be ignored (Dosi, 1986). However, primary growth in purchases, accumulated experience of users, and the amount of required experience for full skills shape the users' skills (Niranjan et al, 2012).

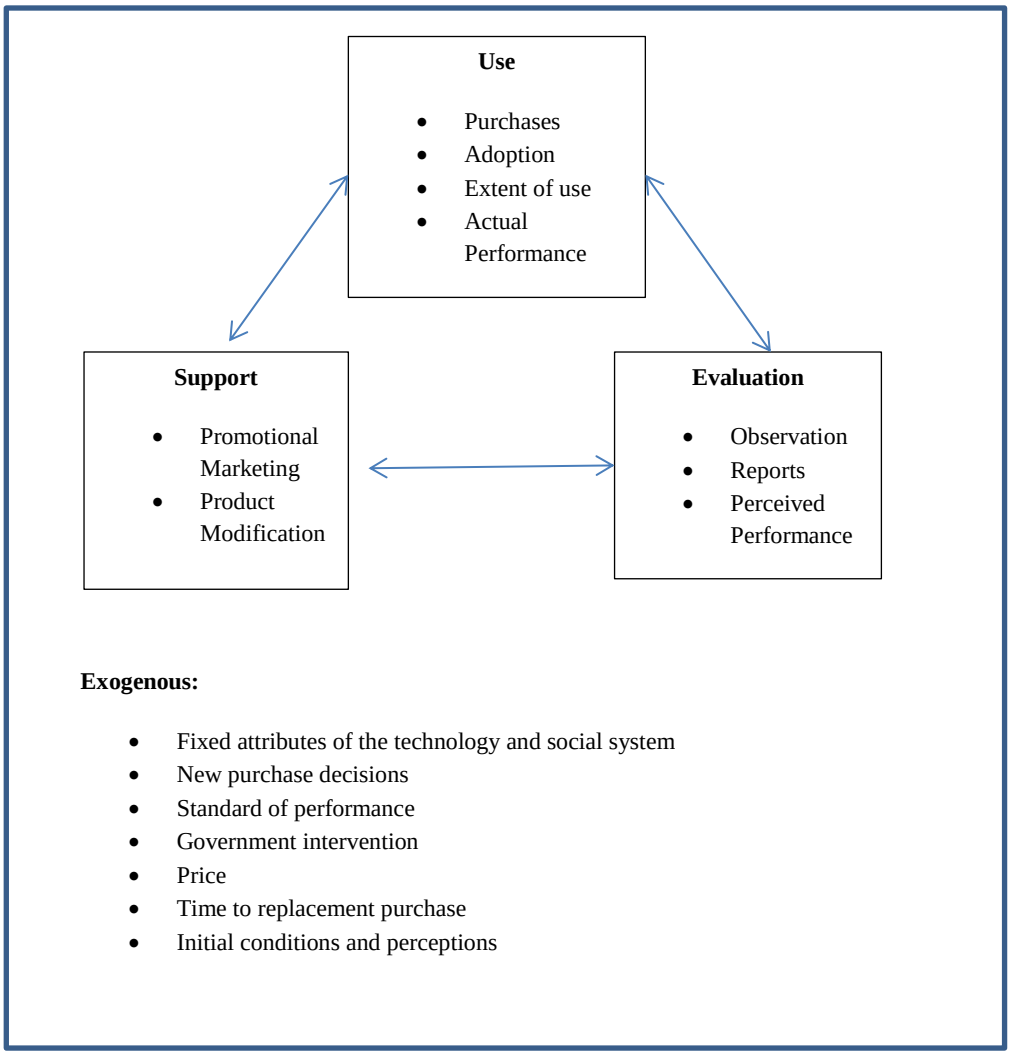


Figure 2.16 Interactive Mechanisms of DI Diffusions

Nevertheless, DI capabilities introduce actual performance to the market based on the users' skill and the extent of use in the market; perceived average performance will be generated and it will affect the market acceptance of DI itself (Homer, 1983). At the same time, there are other exogenous factors that affect the whole market in the same way, including the attributes of technology and social systems, standards of performance in medical practices, government interventions, reimbursement systems, and initial conditions and perceptions. The mechanism of DI diffusions in medical markets is summarized in Figure 2.17.

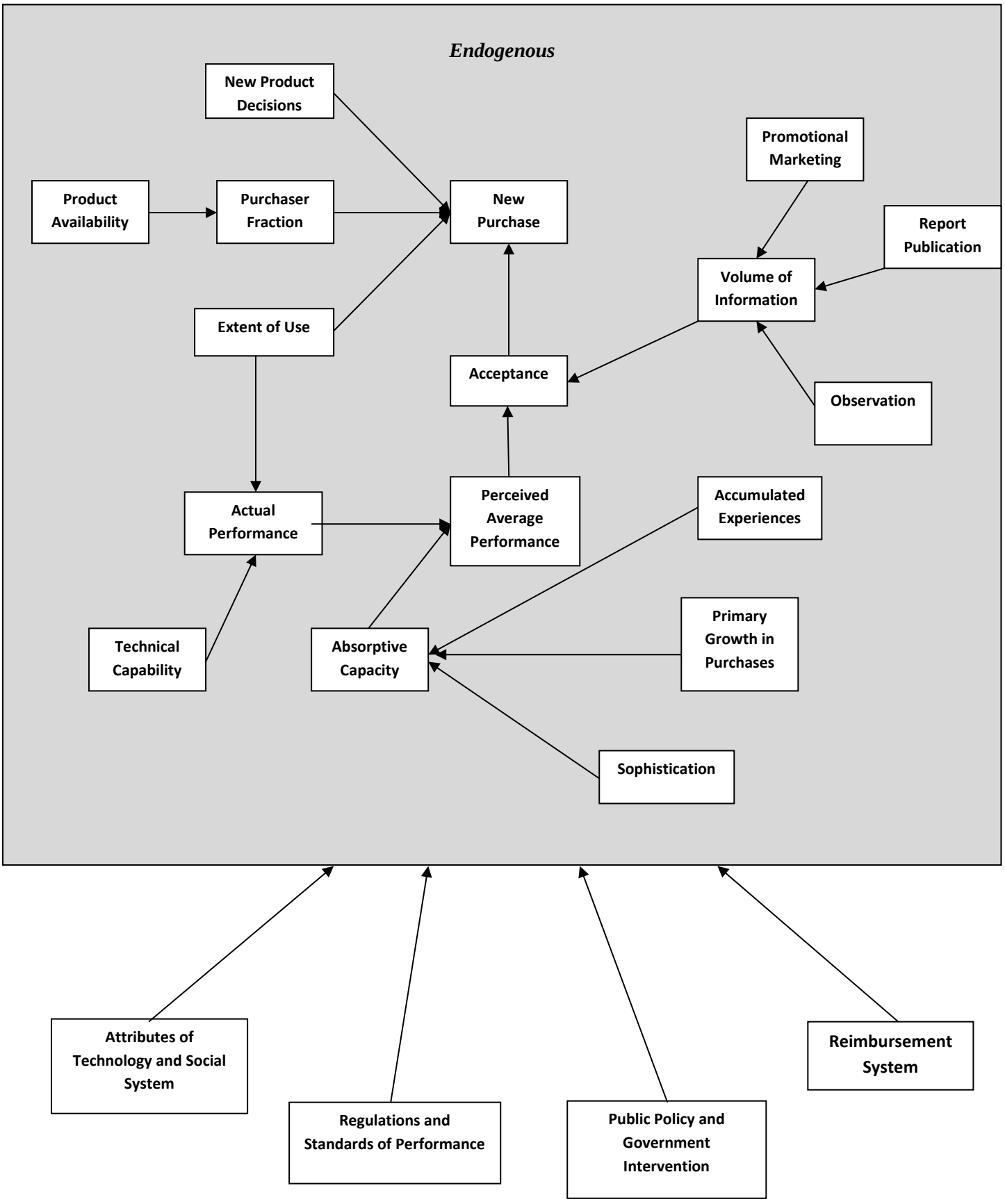


Figure 2.17 Model of Enabling Mechanism of DI Diffusion in Medical Markets

Conclusion

This chapter has discussed technology trajectories and emphasised the importance of discontinuous innovations and their need to be studied further. Focus has been on the concept of disruptive innovation (DI), and this concept was studied from different points of view. It was determined that although there has been much research on this topic the field of mechanisms and dynamics of DI need investigating more. The dynamic of DI diffusions based on the current literature were studied to create a model to be modified by the findings of this research. The mechanisms of DI diffusion were highlighted from strategic and adoption points of view. Consequently, a strategic model of DI diffusion was established; further modifications will be discussed in a later chapter. Finally, the discussion was narrowed down to the field of medical markets. The market and its implications on DI diffusions in medical markets were analysed by focusing on the nature of medical innovations and their probable performance values.

Consequently, three research models were introduced and will help in analysing the findings of the fieldwork. This process will contribute to the research objectives by enabling the modification of DI diffusion models in order to understand the mechanism and dynamics of DI diffusion in medical markets. This chapter has also provided frameworks to categorize the findings of this research based on the abovementioned literature. The next chapter will introduce an appropriate research design to satisfy the research objectives, followed by a fourth chapter offering more detail on the industry background.

3rd Chapter

[METHODOLGY]

Introduction

There are varying scholarly perspectives on choosing the appropriate research design. Some believe that the relationship between the nature of the research question and the methodologies' functionality is most important, while others insist on the applied methods in similar research (Cassell and Symon. 2004). It seems that these differences arise from the variety of epistemological and ontological perspectives.[1] While the first group believe in the existence of generative mechanism in the interpretive perspective, the second group consider the methods' rationale from a positivistic perspective.

This research will justify the methodology from both perspectives by giving priority to the proper methods for addressing research questions. This research will take a mixed method perspective for research design which arises from a critical realism[2] point of view. In order to construct a feasible research design based on the main goal for addressing the research question in a specific sector (medical devices) and in a specific market (Iranian), the case study method should be appropriate for looking at the concepts of post-disruptive innovation competition and diffusion acceleration from the firm perspective.

Based on the nature of the research questions, this research will use an explanatory-descriptive single case study. According to Ryan et al (2002), explanatory case studies attempt to explain the reasons for observed practices. Moreover, these scholars add that these types of case studies focus on the specific case which seems appropriate to contribute to the research. Explanatory case studies are usually applied in order to elucidate an important specific concept rather than to produce generalizations (Ryan et al. 2002).

[1] Fleetwood (2005) has a clarifying definition for research into epistemological and ontological issues. He defines ontology as a way of thinking about the world that influences the knowledge that can be known about it (epistemology). Accordingly, the way that this knowledge could be investigated includes methodology (Fleetwood, 2005).

[2] Likewise, to manipulate the problem of generalization in intensive research and the problem of research depth in extensive one , mix method could be considered as a solution ,entitle of critical realism to support both breadth and depth of research in business and management researches.

Explanatory case studies are usually classified within interpretive studies (Yin, 2003). This issue affects the role of theory and the nature of result generalization in a case study. In this type of case study, theories are applied to provide deeper understanding of the topic or to generate a framework in order to analyse the findings of research (they play this role in the literature review of this research). An explanatory case study insists on a theoretical generalization rather than a statistical one.[3]

Supporting case study findings forming a chain of evidence is needed to justify and confirm these findings (Yin, 2003). Accordingly, taking mix-method as its research design perspective, this research will design its methodology structure based on triangulation. Therefore, based on the explanatory-descriptive case study of the Iranian cardiovascular market during the last ten years, this research will include archival research, semi-structured interviews, and theoretical frameworks.

[3] Concerning generalisation, as Ryan et al. (2002) demonstrate, when research already has the knowledge of existing theories and applies it in the pattern modelling process the type of generalization cannot be related to the size of the studied sample. Likewise, the other researchers could examine the modified framework of this research and in turn try to modify it. This is the process of generating and modifying theories through various pieces of research (Lee et al, 2009). Thus, it seems that the findings of this research could be generalized for theoretical generalization of other research than simply statistical.

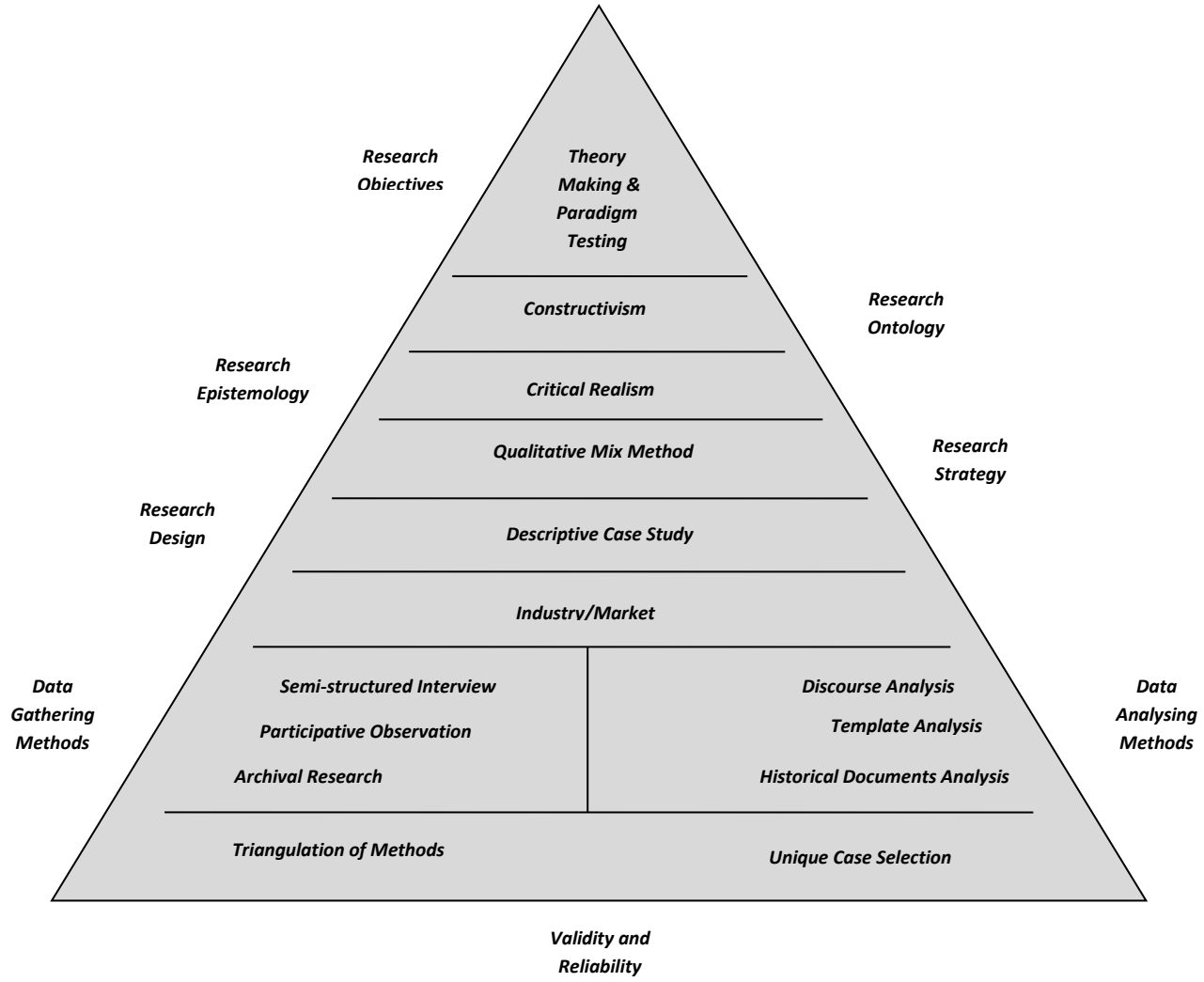


Figure 3.1. Methodology Chart of this Research

3.1 Scientific Position of the Research

Over time, and as early as the ancient Greeks, science has been looked upon constantly as one of the most venerable human endeavours. People with different levels of knowledge have confessed to the holy nature of science. A great number of philosophers have tried to describe the essence of knowledge and the structure of science. They have searched for different ways of achieving non-refutable knowledge. Most of them have attempted to depict the world's structures ontologically, and but have also demonstrated their epistemological point of view for discovering the truth (Sayer, 2000).

Fleetwood (2005) considers different levels of scientific claims: "*the way we think the world (ontology) influences: what we think can be known about it (epistemology): how we think it can be*

investigated (methodology) and the kind of theories and knowledge claims we think can be constructed about it" (Fleetwood and Ackroyd, 2005). On the one hand, possessing unclear ontology makes it almost impossible to achieve well-structured scientific outcomes. On the other hand, applying suitable ontology does not guarantee reliable scientific results. It does, however, at least facilitate the way in which to approach scientific truth. (Fleetwood and Ackroyd, 2005).

Historically, the evolution of epistemology could be identified by three major traditions in the philosophy of science (Sayer, 2000). Foremost is the classical empiricism represented by Hume and his followers, which indicated that the ultimate objects of knowledge are atomistic events. Science is considered as a type of atomistic or behavioural response to the drivers of given facts and their conjunctions (Archer et al. 1998). The second tradition, transcendental idealism, is mostly known through Kant's contribution. According to this view the world is a construction of human minds rather than something tangible to be experienced (Archer et al., 1998).

It seems that both of these traditions to some extent are radical and far from reality. Thus, critical realism emerged in order to provide a compromise between these two epistemological points of view. Ontologically, the most outstanding notion of critical realism is to consider the world independent from human thought and our knowledge about it (Sayer 2000). In other words, there is a reality independent of the human mind. The ultimate goal of natural and social science is to identify the real entities and describe their relationship both to nature and society. In fact, critical realism has emerged to surmount the weaknesses of both empiricism and idealism (Archer et al., 1998).

Introducing these initial principles and concepts of critical realism will help us to understand the comprehensive insights and potential capabilities of this doctrine to evaluate knowledge claims.

3.1.1 The Transitive and Intransitive Dimension of Knowledge

In order to explain the independence of the world from human knowledge, Bahskar (1998) distinguished two dimensions of knowledge: transitive and intransitive. The objects (a given phenomenon) that are being studied (both in social and natural science) are an intransitive part of

science, while rival theories and discourses about these phenomena include the transitive dimension of science (Sayer, 2000). This means that the intransitive dimension of science is the realm of actors and factors independent from human description. Indeed, because of the causal generative mechanism they could exist regardless of the existence of human beings. In other words, if the transitive dimension of science, including rival theories and various description changes, it doesn't necessarily mean that intransitive part and main concept will change at the same time (Bhaskar et al. 1998). For instance, Galileo challenged the pivotal position of the earth in the galaxy. This does not mean, however, that before or after his theory the position of the earth was different. Thus, refuting rival theories to approach reality does not mean a change in the essence of that reality since the essence of a reality is an intransitive part of science, and independent from human knowledge about it (Danermark et al., 1997).

3.1.2 Stratified Ontology of Critical Realism

In the realm of realism there are three different categories: empirical realism, which inclines more toward empiricist notions by focusing on experience as a way of approaching the reality, critical realism, and literary realism. These are distinguished from each other by the theory-laden nature of critical realism (Sayer, 2000). However, the most prominent difference between critical realism and the other types of realism is that "critical realism distinguishes not only between the world and our experience of it, but also between the real, the actual and the empirical layer of reality." In the real layer of reality, which could be social or natural, the main concern is about the existence of reality regardless of its empirical dimensions (Bhaskar et al., 1998). In other words, the "real" is the realm of objects, their structure, and their effect on the world, which is usually referred to as their causal power. In the transitive dimension of knowledge, understanding of these objects by identifying their structures and their powers is the main goal. Therefore, realists try to identify both necessity and possibility in the world. While "real" concerns the structure and power of a given object, the "actual" concerns "*what happens if and when those powers are activated to what they do and what eventuates when they do*" (Sayer, 2000). The third layer is called the empirical layer, which is also known as the realm of experience. In the case of an experiment for instance, observability could make us sure about

existence of objects, but the existence of an object is actually independent of our observation (Bhaskar et al., 1998). Collier (1994) claims that regarding unobservable entities we can refer to their observable affect, which can only be explained as a result of a specific entity.

Consequently, according to this stratification, realists claim that critical realism benefits from a stratified ontology rather than a flat one, and it is one of critical realism's advantages that it explain realities and evaluation of knowledge claims.

3.1.3 Anti–reductionist Nature of Critical Realism

Critical realism claims that the conjunction of two or more factors leads to the emergence of new phenomena, which have properties that are irreducible to those of their constituents (Archer et al., 1998). For instance, water is quite different from hydrogen and oxygen as its constituents. This means that the nature of critical realism is anti-reductionist, and due to this attribute, entities cannot be looked upon as a construction of their component (Danermark et al., 1997). However, this does not mean that they do not affect that entity; these constituents and their effects will be investigated by identifying the causal powers and generative mechanisms (this will be discussed later) (Sayer, 2000). For instance, in the social world people's roles and their identities are in constant relation with each other, and people's roles are defined by their relation to each other. Thus, all of the social facts, entities, and realities must be explained as a part of a larger system in constant relation to other components. Critical realism in social science refutes the idea of individualism[4] and supports the ideas of holism[5] and collectivism. Thus, critical realism accepts the systemic doctrine by refuting the reductionism discipline. According to Sayer (2000), a social system is "*Dependency and combination of causal effects of elements or aspects*". In this definition, social science is changeable in different times and spaces through the effect of different actors and factors, and critical realists intend to identify different patterns of causality.

[4] "Individualism is the doctrine that facts about societies are to be explained solely in terms of facts about individuals" (Archer and Bhaskar et al.,1998)

[5] "Holism is the notion that was generated by Emile Durkhim, and demonstrates that the properties of individuals are solely the function of their place in society". Stockman, N. (1983). Anti-positivist nature of science. Dordrecht, CIP.

3.1.4 Causality and the Concept of Generative Mechanism

"*One of the most distinctive features of realism is its analysis of causation, which rejects the standard Human secessionists view that it involves regularities among sequences of events*" (Bhaskar et al., 1998). Issues such as gathering data on regularities and repeated occurrences is misguided in critical realism. Instead of finding all the plausible causes and effects, critical realism suggests identifying causal generative mechanisms (Sayer, 2000). It is obvious that "*what causes something to happen has nothing to do with the number of times we have observed it happening*" (Archer et al., 1998). Therefore, in critical realism the notion of causation is not about a number of happenings as with the empiricist doctrine, but about causal mechanisms and happening conditions (Danermark et al., 1997). The famous example of black ravens demonstrates the differences between empiricism and critical realism causation. When empiricists look to repeated experience to prove the statement "all ravens are black," others, such as Popper, demonstrate the idea of falsification by finding at least one non-black raven to disprove such a statement. Realists attempt to find the generative mechanism that makes all ravens black. Thus, "generative mechanism" is the key concept of causation in critical realism, and it could be understood that realism causality is more about necessity than regularity of events.

Having discussed generative mechanisms, it is necessary to identify the structure and the nature of an object (Sayer, 2000). From the critical realism point of view, effects of events are results of a given generative mechanism that produces them by its causal power. Consistent regularities could just happen in closed system, while most of the natural and social systems are open (Bhaskar et al., 1998). In open systems a given generative mechanism could produce different events in different conditions, and different mechanisms could lead to the same result in various situations (Sayer, 2000). Therefore, having different objects and object structures with a great number of generative mechanisms in the natural and social world depicts a quiet complex pattern of causality with different structures and different mechanisms that could affect each other in order to produce a simple event (Sayer, 2000).

3.2 Evaluation of Knowledge Claims in the Social Sciences

Considering the evaluation of knowledge claims in natural science, perhaps the question may arise as to whether it is possible to use the same process and procedure to evaluate knowledge claims in social science or not. Bahskar (1979) in his book "The Possibility of Naturalism" insists on the anti–naturalistic essence of critical realism and demonstrates that there are other methods and procedures needed to evaluate knowledge claims in social science rather than naturalistic methods (Bhaskar et al., 1998). Outwaite (1998) considers three major concepts for refuting the possibility of naturalism in social critical realism: activity–dependent[6], concept-dependent,[7] and time–space invariant (Bhaskar et al. 1998). Social structures likely do not exist independently from the activities they are governed by and the agent's conception of what they are doing (Archer et al., 1998).

3.2.1 Structure, Agency and Reproduction

The pivotal notion of evaluating knowledge claims in social science arises from the relationship between structure and agency (Danermark, et al. 1997). Investigating this relationship and separating its constituents into necessary and contingency groups is critical to identify the reproduction process of structure (Sayer, 1992). Social structures never emerge automatically and are mostly generated by people's interaction in social systems. However, people do not reproduce social structure intentionally. For instance, people do not work in their profession to prove the importance of capitalism in the economy. In other words, actors are not merely programmed to reproduce structures (Sayer, 1992).

In social science, according to the critical realism discipline, "*while the elements of structures are necessarily related, it is contingent whether any structure as a unit exists*" (Bhaskar et al., 1998). It means that the relationship between structure and object, and also between object and its causal

[6] "Social structures, unlike natural structures, do not exist independently of the activities they govern" Archer, M., R. Bhaskar, et al. (1998). Realism and Morphogenesis. Critical Realism Essential Readings. M. Archer. London, Routledge**:** 356-382.

[7] "Social structures do not exist independently of the agents' conceptions of what they are doing in their activity"

powers and liabilities, are necessary, but the relations between causal powers and conditions (other causal powers) are contingent (Sayer, 2000).

In social sciences social forms and conditions are necessary for the existence of social agencies and social structures. As it previously mentioned, according to anti-reductionist notions of critical realism, societies are irreducible to their people (anti- individualism), but since "*the causal power of social forms is mediated through human agency*" (Sayer, 1992)the causal status of human agency must be vindicated by itself (Bhaskar et al., 1998).

There are different tendencies in social thought. Defining social structure and agency, Weberian Voluntarism[8] combines neo-Kantian notions with individualistic ideas. Nevertheless, in a different manner, Durkheimian Reification[9] mixes empiricist notions with collectivism in order to describe and evaluate knowledge claims in social science (Archer et al., 1998). Utilitarianism also applies empiricist notions to an epistemological point of view, but ontologically, as utilitarian's believe in individualism (Bhaskar et al., 1998). However, in a different attitude to two extreme sides of the continuum, Karl Marx considers the combination of realist ontology and relational sociology as a way to evaluate and describe the social sciences. Nevertheless, Marxism pinpoints the constant dialectical relation of agencies and structures in social science (Archer et al., 1998).

Ontological discussion of social science is an introduction to understanding how practical, social theories are made. According to critical realism's notion, practical social theories are the result of explanatory methodology, and at the same time explanatory methodology is made by social ontology (Archer, Bhaskar et al., 1998). In other words, according to their social ontology, critical realists try to identify the situation of social entities, such as actors, factors, and agencies in social systems. Then, drawing on explanatory methodologies, they seek to discover an assumed generative mechanism (Bhaskar et al., 1998). However, here there is a problem. As was mentioned in the discussion of the logic of scientific discovery in critical realism, after identifying social entities and the assumed

[8] "Social objects are seen as the results of intentional or meaningful human Behaviour." Archer, M., R. Bhaskar, et al. (1998). Societies. Critical Realism Essential Readings. R.Bahskar. London, Routledge**:** 206-257.
See above comments.

[9] "Social objects are seen as possessing a life of their own, external to and coercing the individual." Ibid.

generative mechanism, it should be examined by empirical testing in order to proof the reality. The question is how a generative mechanism should be examined in the social sciences.

The answer points out the main differences between the goal of knowledge claims in natural and social sciences. In natural sciences the aim of scientific claims is to find a generative mechanism in order to predict future events, but in social science it is generally impossible to predict the future (Ekstrom et al., 1997). As was mentioned earlier, social sciences are both concept and activity dependent at the same time. This means that there are great numbers of entities in social sciences in complex constant interactions with each other. Human agency has its own intention and conception about other social variables, and these are neither controllable or able to be manipulated (Sayer, 1992). Moreover, historical contingencies, different conditions, and social forms make social structures complex and morphogenesis (Bhaskar et al., 1998). Then, in order to morphogenesis nature of social sciences, the aim of scientific claims is to unveil a social generative mechanism to explain the cause of present events and consequences, rather than to predict the future (Bhaskar et al., 1998).

Consequently, in order to morphogenesis nature of social sciences and complexity of reality, critical realism attempts to unveil the real generative mechanism by focusing on events and consequences to find the causality and subsequently explain the reality (Danermark et al., 1997) . Therefore, this explanation could be considered a social theory, and also can be used to evaluate knowledge claims in the social sciences.

To identify a general mechanism in social sciences there are two major models that will be discussed in the next section. As a final point in this section, it deserves mentioning that natural theories are absolutely different from social theories in terms of universality. Natural theories are not time and space dependent, while social theories *are* time and space dependent.

3.2.2 Dialectical Nature of Social Science

Roy Bahskar in his book "Dialectic: The Pulse of Freedom" (1993) manipulates the notion of Marxism to explain the transcendental and morphogenetic nature of social science in critical realism.

According to Bahskar (1993), Marxism explicitly insists on the dialectical nature of science rather than the logical aspect of it (Archer et al., 1998). The concept of dialectics is a Hegelian heritage in social science. "*A dialectical conception, it might be said is a view that conceives of opposites as unity*" (Bhaskar et al., 1998). Hegel believed that there are great amount of contradictions within the entities that cause instant changes of reality. However, Hegel is referred to as an idealist, while Marx applied this idea and transformed it into a materialist dialectic rather than an idealist one (Motahhari, 1985). Karl Marx regards the dialectical nature of society as a collision or conflict between various generative mechanisms and their effect on each other (Bhaskar et al., 1998). This is the main reason that Marx argues for the dynamic nature of society as an open system. He considered a social generative mechanism as an object which social science tends to explain in order to change (Bhaskar et al., 1998). Thus, the concept of "constant social changes," which result from the collision of different generative mechanisms and their effects, is common to Marxist and critical realist notions. Therefore, Bahskar (1993) declares that the prefix 'critical' is well-positioned in critical realism mainly due to the aim of this philosophy to understand generative mechanisms to change the social system for better (Bhaskar et al., 1998). Basically, science aims to describe, explain, and predict the social issues (Sayer, 1992). Therefore, scientific theories must be descriptive, explanatory, and predictive. These analytical modes help science to "*characterize aspects of the single way in which scientific theories relate to their object*" (Sayer, 1992).

However, social science possesses evaluative and practical implications as well. Indeed, technology is the only practical and evaluative implication of social science (Bhaskar et al., 1998). However, Marx has added a prominent attribute to the concept of social science. He considers the idea of criticism as an important attribute of social science (Archer et al., 1998). For instance, Marx's social science is socialist by criticizing capitalism as the main object. With regards to Marx's contribution to social science, not only could various theories be related to one object (based on analytical modes of social science), but also, the relationship of theories to each other and their criticisms of each other could be assumed. This possibility, of course, makes social structure more complex (Motahhari, 1985). However, criticism and dialectical concerns could be found in Popper's discourses as well. Popper

defines dialectical notions by mentioning that thesis produces its anti-thesis, and both are in constant struggle with each other. This was termed ‘synthesis’by Popper. Also, Popper believes that synthesis could not happen unless all theories and knowledge claims are looked through a critical prism (Archer et al., 1998). Thus, analytical, practical, and critical implications of social science, and knowledge claims in the social sciences must be considered. Critical realism evaluates knowledge claims in social science based on these implications.

3.3 Implications of Critical Realism on Research Strategies in Management Studies

Having discussed critical realism, its principals, and the ways of producing and evaluating knowledge claims in both social and natural science, in this section the implications of critical realism in management and business studies will be discussed. Critical realism claims that in social science, events and consequences are the result of various generative mechanisms (Ekstrom et al., 1997). Moreover, these mechanisms are the outcomes of structures and constitutions of relevant objects. Regarding the causality of structures, mechanisms, and events, different types of research could be imagined according to Sayer (1992). Focusing on constant interaction of structures and mechanisms of causal powers, researchers use abstract research in title of idealism doctrine to find out imaginary generative mechanisms in social science (Sayer, 1992). Conversely, concentrating on series of actual events in concrete areas of causality, the researcher’s priority is extensive research (Danermark et al., 1997). Seeking regularities and common patterns within events and sequences in order to generalize the result is the main purpose of extensive research. This type of research makes a type of descriptive account as a representative generalization rather than explanatory presentation (Fleetwood and Ackroyd, 2005). Indeed, extensive research is close to the notion of classical empiricism, or at least empirical realism disciplines (Sayer, 1992).

Therefore, in business and management research, extensive researchers prefer to choose quantitative research strategies through large-scale survey of population or representative samples (Sayer, 1992). Quantitative methods in extensive research, representative samples, formal questionnaires, and also statistical analysis, such as variance or regression analysis, will be used in business and management

research (Sayer, 1992). Although there is some doubt as to their strengths in statistical generalization, "*extensive researches are not generalizable to the other populations at different time and places*" (Sayer, 1992).

If extensive research is considered as studying the breadth of causal powers (number of events and consequences), intensive research refers to in-depth studies of causal powers (Fleetwood and Ackroyd, 2005). Starting from structures and seeking to find the assumed generative mechanism by model - building is abstraction and transmission from mechanism to evidences and sequences, are concrete parts of causality in intensive researches (Sayer, 1992). Intensive research seeks to understand how processes work in a particular case and what the life cycles are of antecedents of events and consequences. In intensive research, the researcher wishes to unveil the real general mechanism through casual explanation of the production of certain objects or events (Fleetwood and Ackroyd, 2005).

The nature of intensive research uses qualitative methods as a research strategy. It seems that intensive research could be supported by critical realism. However, Fleetwood and Ackroyd (2005) strongly reject the structured classification of qualitative-quantitative research strategies in critical realism. They believe that both quantitative and qualitative methods could be used in business and management research in order to find the causal generative mechanism (Fleetwood and Ackroyd, 2005). They state that both the depth and breadth of research could be considered to find real causal mechanism. Therefore, in order to conduct business and management research, qualitative or mix methods could be used alongside an underlying critical realism discipline (Fleetwood and Ackroyd, 2005).

Consequently, as Bryman (2007) mentions, great numbers of business models use the critical realism doctrine to identify structures by defining effective entities and by describing their causal relations.

To sum up, it seems that critical realism, with its segmentation of knowledge into transitive and intransitive categories, and its stratification of reality, could solve the assumed pitfalls of both classical empiricism and transcendental idealism as research disciplines. Moreover, independency of

reality from existence encourages researchers to investigate, find, and modify different models in business and management in order to unveil generative mechanisms of different parts of society as an open system. Identifying social generative mechanisms in business and management research is intended to be explanative rather than predictive. Thus, different methods, such as case study (investigating one or more cases in order to identify generative mechanisms on special cases), interactive interviews, and ethnography are applied to qualitative research strategies. Likewise, as was mentioned earlier, in regard to manipulating the problem of generalization in intensive research and the problem of research depth in extensive projects, mix methods of qualitative–quantitative approaches could be considered as a solution. This would entitle critical realism to support both the breadth and depth of research in business and management.

3.4 Research Strategies

As has been mentioned in the previous chapter, in order to produce reliable and authenticated scientific findings, we need to consider both the depth and breadth of our analysis (Atkinson and Coffey, 1995). Therefore, considering critical realism as the main epistemological base of this research, and in order to provide some valid and reliable scientific claims from the research process, we need to proceed with mix method strategy (Bryman, 2009; Easton, 2002; Tashakkori and Teddlie, 2010). Tashakkori and Teddlie (2010) define mix method as follows: "*Mixed methods research is a research design with philosophical assumptions as well as methods of inquiry. As a methodology, it involves philosophical assumptions that guide the direction of the collection and analysis of data and the mixture of qualitative and quantitative data in a single study or series of studies. Its central premise is that the use of quantitative and qualitative approaches in combination provides a better understanding of research problems than either approach alone.*"

Cameron (2011) points to a framework in order to achieve a better understanding of mix method and the implications on business research. Following Mingers (2001), Tashakkori and Teddlie (2003), and Onwuegbuzie and Collins (2007), Cameron (2011) introduces the "5Ps" framework in order to

understand the impact of mix methods on the research process. These "Ps" can be found on Table 3.1.

Domain	***Description***
Paradigms P1	*Criticism:* From paradigmatic purists and claims of eclecticism. *Challenge:* Need to document and argue paradigmatic stance in MMR.
Pragmatism P2	*Criticism:* Epistemological relativism and short-sighted practicalism. *Challenge:* Become informed about the key debates and source MMR literature in the chosen field. Rigorously defend the stance and choices made at the interface between philosophy and methods
Praxis P3	*Criticism:* Problems related to methodological and data integration. *Challenge:* Informed choices, utilisation and application of MMR designs, methods and data analysis
Proficiency P4	*Criticism:* Superficial claims of utilising MM and the need to be proficient in both QUAL and QUANT methods. *Challenge:* Become skilled and competent in both chosen QUAL and QUANT methods and data analysis, as well as skilled and competent in mixed methods and integrated data analysis
Publishing P5	*Issues & challenges:* Political nature of reporting and publishing MMR in academic and discipline based literature such as disciplinary traditions, levels of acceptance of MMR within disciplines, and reporting MMR in its entirety given word length limitations.

Table 3.1. 5Ps Framework of Mix Method Research (MMR) Domains

Denzin and Lincoln (2008) describe a paradigm as such: "*The net that contains the researcher's epistemological, ontological, and methodological premises.*" Therefore, different epistemological, ontological, and methodological premises necessitate the application of particular research strategies to achieve the main objectives of those premises. As we mentioned earlier, this research adopts a critical realist paradigm for scientific claims, which vindicates the adoption of mix method in order to provide the research with more depth and breadth. Indeed, this is the main objective of the critical realism paradigm.

However, many scholars have called mix method the third movement of research methods (Tashakkori and Teddlie,2003; Cameron, 2008). Others believe that mix methods could be fitted in various research paradigms, and, therefore, refer to mix methods as a cease fire in the paradigm war. Another benefit of mix method is its practical approach to solving problems (Greene and Carcelli, 2003). In other words, most scholars consider mix method as a pragmatic method which bridges methodology and philosophical backgrounds of research. As Tashakkori and Teddlie (2010) claim, this pragmatism is the main advantage of mix method in generating new theories from practical fieldwork. Nevertheless, pragmatist perspectives to mix methods partly compromise the challenge between quantitative and qualitative struggles of research strategies (Silverman, 2000). Indeed, as the third generation of research strategies, mix method has eradicated the quantitative-qualitative classification of research design and relied on the nature of the research questions in order to provide more validity and reliability of findings; they focus more on a bundle of methods to produce more scientifically reliable results (Tashakkori and Teddlie, 2003; Onwuegbuzie and Collins, 2007; Cameron, 2011).

3.5 Research Design

So far the main considerations for choosing critical realism as a research paradigm and mix method as a research strategy has been discussed. At this point we need to define a well-structured research design in order to address the research questions and satisfy the main objectives of this research. There are two main objectives in this research: understanding the dynamic of DI diffusion in medical markets, and understanding strategic mechanisms of DI diffusion, in order to accelerate the process of diffusion. Indeed, on the one hand, most studies of innovation diffusion have been based around radical and incremental innovations, yet on the other hand, most DI studies are concerned with the emergence of DIs rather than their diffusion. This research seeks to fill this gap and investigate further the nature of DI diffusion in medical markets.

Looking at the research objectives philosophically, this research attempts to find the real generative mechanism of DI diffusion in order to disrupt the medical markets successfully, and to somehow

sustain this. This is the main reason that this research considers scientific claims from a critical realism point of view and adopts a mix method research strategy to study the phenomena both in depth and breadth at the same time.

Regarding the research questions there are some cardinal issues to consider in order to structure the research design: (a) the focus of the study is to answer "how" and "what" questions; (b) we cannot manipulate the behaviour of those involved in the study, by which we mean the actors in medical markets; (c) we wish to cover contextual conditions (medical markets) because we believe they are relevant to the phenomenon (DI diffusion) being studied; and (d) the boundaries are not clear between the phenomenon (DI diffusion) and context (medical markets). These are the main reasons that Yin (2009) suggests case study as the basis of research design. Baxter and Jake (2008) argue that sometimes it is impossible to picture a phenomenon regardless of the context. In this case perhaps case study is the most appropriate research design to find the generative mechanism. For instance, since the nature of medical markets are totally different from other markets (as was mentioned in the previous chapter), we need to investigate the concept of DI diffusion in the context of medical markets to find the main generative mechanism behind it.

Yin (2009) defines the case study as an empirical inquiry that investigates a contemporary phenomenon in depth and within its real life context, especially when the boundaries between phenomenon and context are not clearly evident. He adds that the case study is appropriate especially when the researcher has little control over events or when the focus is on a contemporary phenomenon. Meredith (1998) states that case studies could be appropriate for research design since the phenomenon can be investigated in its natural setting, and consequently, meaningful and relevant theories are generated from the understanding gained through actual practice.

3.5.1 Process of Theory Building from Case Studies

Bryman and Bell (2011), point to the two main processes of knowledge creation: induction and deduction. In this research considering inductive and deductive approaches will prepare a significant base for further activities of theory building or theory testing.

This research is following an inductive approach to designing the research strategies. It begins with observation of actors, factors, and their relationship in medical markets in order to deduce the main generative mechanisms of DI diffusion in these markets. Scrutinizing these mechanisms will help us to attain a better understanding of DI diffusion and its market dynamic. Therefore, by understanding these dynamics and mechanisms related to DI diffusion in medical markets this research will analyse the findings in order to produce the main patterns of DI diffusion in those markets, which will lead to some tentative hypotheses. Finally, in the discussion chapter we will compare those tentative hypotheses with the previous findings in the field by other scholars, in order to assess the validity and reliability of our findings and generate a more reliable theory (Farquhar, 2012).

3.5.2 Appropriate Types of Case Study for this Research and Prejudices against it

As it is shown in Table 3.2, there are different types of case study research, as Ryan et al (2008) mention. Based on these definitions, although this research is following a mix method strategy to design the research process, it has interpretive inclinations in doing so. The reason for this is well justified as follows. Based on Ryan et al's (2008) definitions, this research is looking at the world as a social construction. Therefore, the main task of case study in this research is to explain the mechanisms of the market. In other words, this research uses an explanatory case study in order to understand DI diffusion mechanisms and medical market patterns during the diffusion process. Nevertheless, the role of generated theories in such studies is to provide more explanation of phenomena rather than creating new hypotheses. However, the most important implication of explanatory case studies are their theoretical generalizability (Yin, 2003). In other words, the findings of this research may not be generalizable to all the cases, but they will create new theories that will be tested by other scholars in other fields and different time spans in order to test the findings of this

research. Therefore, although the findings of this research are not statistically generalizable they could be generalized theoretically.

Differences in Case Study Research		
Type of Research	Positive	Interpretive
View of the World	External and Objective	Social Construction
Types of Study	Exploratory	Explanatory
Nature of Explanation	Deductive	Pattern
Nature of Generalisation	Statistical	Theoretical
Role of Theory	Hypothesis Generation	Understanding

Table 3.2. Types of Case Studies (Ryan et al, 2008)

3.5.3 Actual Research structure in Practice

Basically, this research wishes to determine mechanisms and dynamics along with DI diffusion in medical markets. This research benefits from a longitudinal explanatory case study about the competition of the main market leaders in the Iranian cardiovascular devices market. Although we will discuss in detail later the main reasons for choosing the Iranian cardiovascular market as the main field for our case study, here we mention them briefly. Cardiovascular markets seem so appropriate for the main objectives of this research, since they are categorized within the high tech medical devices industry, and has experienced a huge amount of DI during the last ten years Examining the Food and Drug Administration of US (FDA) databases has shown us many DIs in this field. In addition, Iran seems to be an appropriate market since cardiovascular diseases are the main cause of

death in this country and in spite of the huge amount of economic sanctions on this country they are still the main market of cardiovascular devices in the Middle East (refer to the fourth chapter for more details).

Therefore, the research process begins with some archival research in both the FDA and the Ministry of Health and Medical Education (MOHME) databases in Iran to find out the main innovations launched in the Iranian medical market during the last ten years. Probing these cases the research distinguishes DI cases from the others based on the definition of DIs provided within the second chapter. Subsequently, after finding the main DI cases of the Iranian cardiovascular market, we take a further step and target the main incumbents of the market to study social structure of the market over the past ten years. Johnson and Johnson (Cordis), Medtronic, Boston Scientific and Abbott Laboratories are the main incumbents of the Iranian cardiovascular market during the last ten years. The triangulation of archival researches, semi-structured interviews and participative observations would provide more authenticated and reliable results during the fieldwork. Therefore, the researcher targets the key decision makers of the incumbent companies of the cardiovascular market in order to conduct semi-structured interviews with them.

Then, after conducting archival researches about the history of stenting in Iranian cardiovascular market in order to get a better understanding of the market's dynamics, in-depth semi-structured interviews are conducted in two separate rounds. As it shown in the table 3.3, during the first round of interviews with the key decision makers of launching stents in all the four major rival companies, they are asked about the history of stenting in Iran. Basically they have to explain who the main actors were in the BMS, DES and Post-DES era during the last 10 years and what were their main roles. Also they are questioned to provide further information about the incumbents' interactions in the market to establish their dominant positions in the market. Furthermore they have to mention how the relevant stenting capabilities were developed in each era and how reimbursement and healthcare systems affected the market dynamics.

Having all these information at hand and getting them confirmed with the findings of the prior archival researches, we would have an in-depth and comprehensive narrative about the dynamics of DI diffusion in the Iranian stenting market during the last 10 years. Then in the second round of the interviews, we would return to the interviewees and ask them to analyse the narrative to understand the main generative mechanisms behind the obtained narrative through the last round of interviews (which is confirmed with the findings of the antecedent archival researches).

Dynamics (Round 1)				
	Cordis	*Abbott*	*Boston*	*Medtronic*
BMS *DES* *Post- DES*	• *Personal information/ their roles in launching innovations* • *The history of stenting in Iran from 1998* • *How stenting capacities was developed in Iran* • *Who to convince/ how to convince* • *How this type of stents came to the Iranian market* • *What was the role of your company* • *How the competition was going on / who were the main competitors/ what they did?* • *The role of reimbursement and healthcare system*			
Mechanisms (Round 2)				
	Cordis	*Abbott*	*Boston*	*Medtronic*
BMS *DES* *Post- DES*	• *What product innovations?* • *To serve what needs of the market?* • *What was the premarket trial results?* • *Relative advantage and disengages compare to the other options* • *How to go from needs to demand* • *Launching team organization* • *Launching and diffusion strategies* • *Do you consider it success or failure? Why?* • *Competition strategies* • *What were the success and failure factors?*			

Table 3.3. The semi-structured interview's template

To help the interviewees to analyse the narrative more in depth during the second round of the interviews, we ask them some illustrative questions as mentioned in the table 3.3. In fact, we question

them about their company's innovations within each category of stents (BMS, DES and Post-DES stents), the relevant premarket trial results, the relative advantages and disadvantages of each innovation compare to the other existing options, their launching strategies, the launching team organization and their competition strategies. Finally we ask them if they consider the diffusion of each innovation successful and if so what they thing were the main success or failure factors.

It deserves mentioning that it is not an easy task, since it is almost impossible in Iran to gain access to these companies and ask them about their performance, since they consider this information top secret, classified information. In order to avoid any restricted sample selection bios, we will interview other doctors and nurses in order to make the findings more reliable. Indeed, interviewing thirty main decision makers in the Iranian cardiovascular industries, this research conducts a sort of semi-structured elite interview to understand more about the mechanism and dynamics of DI diffusion in medical markets.

Considering the issue of triangulation, this research benefits from an additional data collection method to provide further reliability of the findings. Participative observation is undertaken by attending many managerial meetings and strategic planning sessions of the main incumbents' companies. Additionally, other kinds of secondary data, such as sales reports, are gathered in order to compare the results of different applied strategies by the market incumbents during the last ten years.

Therefore, conducting these semi-structured elite interviews[10] alongside participative observations, and also comparing the findings from these methods to the findings of the archival research; this research offers a comprehensive map of DI diffusion in the medical devices market. The findings of the semi-structured elite interviews are analysed with discourse analysis method, while the findings of other methods are investigated by template analysis, and will be compared with the findings of the interviews. In addition, the findings of the archival researches will be applied in order to provide

[10] "Elite interviews are a key tool of qualitative analysis for political scientists, but they do present problems. In particular, interviewees can be awkward, obstructive, unforthcoming, or even deceitful. Likewise, the researcher will often not be able to interview all those he/she may wish to, resulting in gaps in the information gathered. However, what this type of interview does provide is an account by a major player in an event or issue of importance to the researcher's work. This allows the interviewer to understand the perceptions of that player and what may, or may not, have led that individual to think or act in the way s/he did" (Richards, 1996).

further understanding of the narrative in the case study chapter. The findings of the fieldwork will be analysed and compared with the findings of previous research in order to provide more validity and reliability to the research conclusions.

3.6 Data Gathering Methods

Using case study as the main research strategy provides the researcher with a variety of different choices for selecting methods both for data gathering and data analysing (Cassell and Symon, 2004). . According to Yin (2003), there are six different sources of evidence for data collection: documents, archival records, interviews, direct observations, participant observation, and physical artefacts. The necessity of more research validity has heightened the need for a chain of evidence by using multiple sources of evidence (Lewis and Richard, 2003). Hence, we will discuss some the methods used to collect and analyse the necessary data in regards to the research's main objectives.

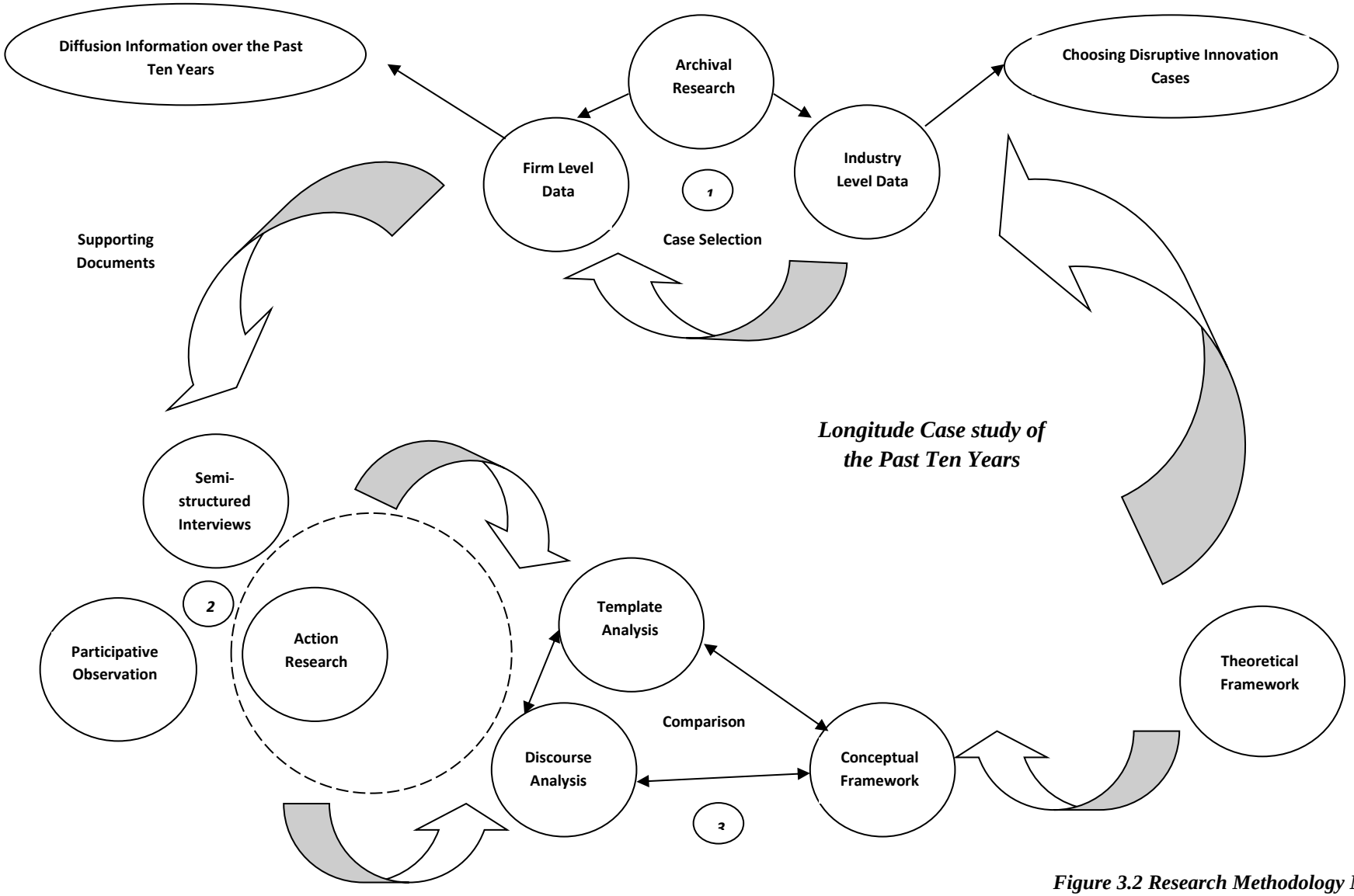


Figure 3.2 Research Methodology Model

3.6.1 Interview

Using these two types of method, both the historical and recent dimensions of research are covered. Qualitative interviewing is totally different from the structured interviewing in quantitative research (Bryman, 2007). The nature of the relationship between the interviewer and the interviewee is the key aspect of the qualitative research interview (Cassell and Symon, 2004). In qualitative interviews, the interviewee is not only considered as a sample component, but also has a participative role in the research. From the epistemological point of view, there are different disciplines with various ways of conduction. However, according to the general epistemological position of this research, it seems that the realist interview is a suitable option to conduct the interviews. In an obvious contradiction with phenomenological and social constructionist interviews, realist interviews assume that the accounts produced by participants during the interview make a direct connection with their real experience in the world outside of the interview (Cassell and Symon, 2004). Due to this assumption of realist interviews, it is preferable to compare the interview's findings with those obtained from other methods. For instance, archival studies in this research within the process of triangulation could be an appropriate combination of methods (Cassell and Symon, 2004).

3.6.2 Archival Research

Basically, archival research is performed by analyzing studies conducted by other researchers, or by examining historical records of organizations (Lewis and Richard, 2003). Some scholars consider archival research as a type of secondary data analysis, the data for which the researcher will probably not have been involved in the collection of, but uses directly in the process of data collection or scans to extract relative information to answer their research questions (Bryman, 2007).Technically there is a difference between qualitative and quantitative archival research, although both can concentrate on both recent or historical evidence (Miles and Huberman, 1994). Due to the research strategies, this research will focus on qualitative archival studies by studying historical documents of the main incumbent companies (such as sales reports), and study the recent perspectives through the interviews. From this research's epistemological point of view, archival research could be considered as a

continuing of the efforts of the interviewer to provide concrete evidence for the findings through the interview (Cassell and Symon, 2004). It deserves mentioning that using secondary data in archival research could save time and cost during the research process (Cassell and Symon, 2004).

3.6.3 Participative Observation

Compared to qualitative interviewing, participative observation and action research have some limitations which could be overcome by triangulation of these methods (Yardley, 2000). As Bryman and Bell (2011) state, by applying participative observation and action research it seems that the researcher could better position himself to gain a foothold on social reality in this way. In other words, the researcher could experience some issues that he/she would not with qualitative research. Moreover, he or she will participate in many of the same activities as the member of the social setting being studied (Bryman and Bell, 2011). However, the researcher may find some information that could not be obtained by conducting interviews. Since interviewing entails some kind of verbal communication, perhaps interviewees cannot truly reflect the situation as it is the real world. Therefore, triangulation of action research, participative observation, and archival research can assure us that we are viewing reality from different angles (Cassell and Symon, 2004). On the other hand, although qualitative interviewing will deliver a huge amount of information, interviewees will simply deliver their understanding of reality rather than the reality itself (Yardley, 2000). Therefore, it is the researcher's responsibility to confirm the findings of interviews by benefitting from participative observation and action research. This specific issue reflects the realist nature of this research.

3.7 Data Analysing Methods

Since the nature of the findings are mostly qualitative in this research (regardless of the findings of archival research), we need to explain how we intend to analyse the findings and what should be the main approach toward this. Basically, as Bryman and Bell (2011) state, there are three main approaches toward qualitative data analysis: analytic induction, grounded theory, and narrative analysis. In this research, based on the nature of the case study we will follow the recently coined approach of narrative analysis.

In order to analyse the narrative of this research we will build the narrative of the last ten years of the Iranian cardiovascular market based on the findings of semi-structured interviews, and enrich the story with the findings of archival research into the sales reports of the main incumbent companies of the field. Subsequently, by analysing this narrative in the findings chapter we will work out the main mechanism and dynamics of DI diffusion in medical markets. However, in analysing the findings of different collected data we will apply a particular strategy to each set data from different sources. We will use discourse analysis to extract more information from the semi-structured elite interviews' findings, and the findings of the action research and participative observation will be analysed with template analysis. Finally, the findings of the archival research will be analysed along with the narrative analysis in the case study chapter.

3.8 Reliability and Validity of the Findings

There are many different indexes that could evaluate the findings of a piece of research from a scientific point of view. According to Yin (2003), the findings of research should be valid, reliable, and generalizable. In qualitative research, validity refers to the presence of causal relationships between variables and results (Gibbert and Ruigrok, 2010). Mostly, this definition is applied to explanatory case studies, since the research is addressing the causal relationships in the context of a generative mechanism (Farquhar, 2012). As Eisenhardt (1989) mentions, a case study's validity should be attained through comparison with the relevant literature. In other words, emerging concepts and theory from case study research should be closely examined with the current literature, and the conflicts should be explored (Farquhar, 2012). In the discussion chapter all the findings of this research will be examined with concepts from the relevant literature and we will discuss the gaps based on facts and figures. Reliability is another factor which should be considered in regards to the quality of findings.

Based on the definition of Bryman and Bell (2011), the reliability of research has a close correlation with the consistency and stability of evidence. In other words, if another researcher repeated the

research in the same way, reliability confirms that he would get the same results (Silverman, 2000). Therefore, transparency and replication are two main pillars of reliability in case study research (Gibbert and Ruigrok, 2010). Transparency should be demonstrated through detailed documentation of the evidence and clear references to the findings of research. In this research we have quoted most of the transcripts directly in the findings section in order to provide the research with more transparency. Also, from a replication point of view, this research possesses a coherent research strategy which is in perfect compatibility with the research's epistemological and ontological backgrounds. Therefore, the research design and direct reflection of the evidence in this research satisfies the need for reliability of the findings.

Perhaps generalizability is the most disputable issue of the case study as a research design (Gibbert and Ruigrok, 2010). Most of the scholars with a quantitative attitude toward research believe that case study research is not sufficient proof of scientific studies (Bryman and Bell, 2011). They believe that the rate of objectivity is not satisfactory in such research, and the findings are not generalizable. To answer these critics it deserves mentioning that in this research we are not following a positivistic point of view, rather, the research possesses a critical realist attitude. Nevertheless, as Yin (2003) mentions, case studies never tend to generalise their findings to another situation. Therefore, they do not need to produce huge sample sizes. Since the main contribution of this research is theory building rather than testing a theory, and is an explanatory case study based on critical realist notions, we are not going to generalise the findings statistically. Rather, we will generalize the findings theoretically, as Miles and Huberman (1994) discuss. The findings of this research are theoretically generalizable, which means they could be examined by other scholars in different fields.

3.9 Statement of Originality of the Findings

We may consider the originality of the findings from different perspectives. This research seems to be unique in terms of topic. Indeed, while most of the previous studies on disruptive innovations have attempted to shed more light on the concept of DI since Christensen (1997) and Droege and Johnson

(2010), this research focuses more on the competition of potential DI candidates to get into the market and disrupt it prior to other competitors. In other words, this research takes a step forward and discusses the dynamic of disruptive innovation from infancy to demise. Taking a fragile, unknown, potential disruptive innovation from its dark corner and investigating how it disrupts the market, this research will focus on two main leverages: accelerating the diffusion and facilitating the disruption process.

From a diffusion point of view most of the macro-level studies have focused on following the patterns of innovation diffusion statistically, while the micro-level studies concentrate more on innovation adoption behaviour. Therefore, there is a significant gap in literature investigating the dynamic of DI diffusion. Consequently, this research contributes to the literature by elaborating on DI diffusion dynamics in medical markets, and as a result the enabling mechanisms of DI diffusion will be studied. Indeed, this research will modify the launching tactics of innovation to offer specific innovation diffusion mechanisms to disrupt the mainstream medical markets.

Additionally, the methodology and findings of this research seem to be original. Gaining access to the medical devices companies with high level security layers protecting their information, distinguishing the key decision makers of launching new innovations in each company, targeting them, and making appointments for interviews are the major obstacles that this research must overcome. The definition of 'case study' used in this research is original as well. The FDA list of launched medical innovations in Iran during the last ten years has been investigated in order to find the best examples of DI based on the definition of DI in the second chapter. Next, the actors involved in the process of market disruption were targeted in order to conduct elite interviews about the dynamics and mechanism of DI diffusion. To enrich the findings from interviews, some archival researches such as sales reports of the main incumbents from the last ten years have been analysed. Having access to the main incumbents of the Iranian medical devices market and investigating their undisclosed sales reports will provide the originality and authentication of the research findings.

3.10 Conclusion

To sum up, the major objective of this research is to investigate DI diffusion dynamics and the mechanism involved in this process. Therefore, the main methodological concern of the research is to create theories and test suggested paradigms based on long-term data from the field. Considering these concerns, and based on the main objectives of the research, the critical realist school of thought is adopted to form the scientific findings of this research. Additionally, a longitudinal case study of the Iranian cardiovascular devices market is chosen as the main body of the research design, and in order to provide more validity and reliability to the findings based on the mix method approach, the chain of evidence will be presented based on triangulation of different data collection methods.

Archival researches will be conducted on two different levels to meet the twofold objectives. At the industry level, archival researches (which will be presented in chapters four and five) tend to investigate relevant cases of DI in Iranian medical devices market to continue further researches based on their diffusion dynamics. However, at the firm-level archival researches main objective is to depict the diffusion curves of the selected DIs during the last ten years. In addition, thirty semi-structured elite interviews with key decision makers of the selected DI diffusion projects are conducted to understand the actual dynamics of DI diffusion and the relevant mechanism behind it. The notes of participative observations during the board meetings and the results of the observation of the organisations will add more value to the findings. Finally, the findings of semi-structured interviews will be analysed by discourse and template analysis, and the results will be compared with the findings of firm-level archival research to explain the generative mechanism of the diffusion patterns of selected DIs.

In the next two chapters (chapters four and five) industrial backgrounds of the research and the case study's main narrative will be discussed to provide further understanding of the field.

Chapter 4

[INDUSTRY BACKGROUND]

Introduction

This chapter provides the required industrial background to understand the case study and further medical jargons in this research. After giving some initial definitions related to medical devices industries, and some related facts, such as different classifications of medical devices, market size, and the main actors of the market, we will explain the process through which medical devices are developed. In the next section, we will concentrate on cardiovascular industries specifically, and demonstrate the history of catheterization and how it has contributed to the science and technology of cardiology during the last centuries. Subsequently, in the market level analysis we will discuss how the challenges of the major incumbents in the market shaped the dynamic of science and technologies to cure coronary acute disorder. Therefore, explaining the dynamic of the cardiovascular market and considering the major incumbents from the market point of view, we will conduct a retrospective analysis of their innovation trends in delivering coronary acute disorder treatment to unveil the main cases of disruptive innovation across the whole trajectory. Since the level of analysis in this research is the market, this chapter provides a comprehensive understanding of the medical devices industries and cardiovascular markets required to understand the major dynamics of the case study, which will be detailed in the fifth chapter. In addition, this chapter will provide concise information about the major incumbents of the cardiovascular market, which will be considered during the analysis chapter. Finally, the major contribution of this chapter to the research is to provide a rational procedure through which the case study will be formulated.

4.1 Medical Devices (MD) Industry

4.1.1 Typology of MD Industries

The medical devices industry is a fast growing one, which due to the advancement of interdisciplinary technologies is significantly dependent on R&D activities of the incumbents. Regarding the ample amount of innovations in this industry the definition and the boundaries of this realm has been expanded and emerged with many relevant interdisciplinary fields. The Food and Drug Association of the US (FDA) defines Medical devices as follows:

"An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

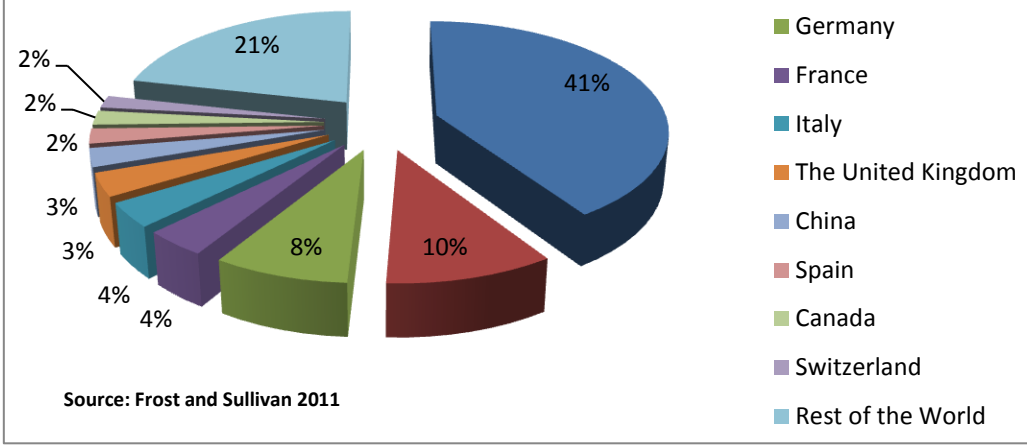
- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

This definition provides a clear distinction between a medical device and other FDA regulated products such as drugs (FDA declaration, 2011).

Frost and Sullivan's report (2011) mentions that the medical devices market value was worth around US$ 296.81 billion in 2010, and more than 40 % of it is possessed by the USA. Japan, Germany and France are following the USA on smaller scales, and the UK stands in sixth place after Italy, owning 3.4% of the global medical devices market (Figure 4.1)

Medical Devices Market: Per Cent Revenues by Geographical Region (World) , 2010

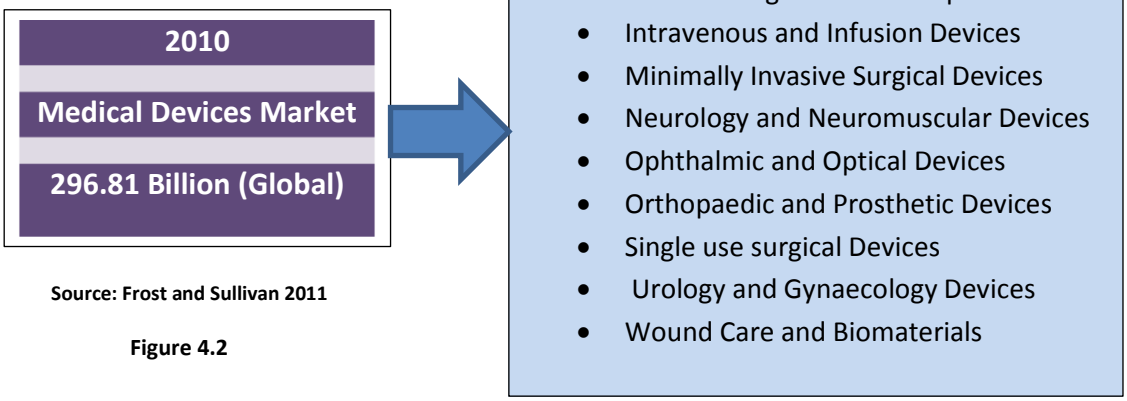
Figure 4.1



Source: Frost and Sullivan 2011

However, medical devices industries could be classified by the market segments or by the risk of appliance. They could also be catagorized by the usage purpose in different stages of medical conditions. Indeed, there are many different classifications of medical devices, as can be seen in figure 4.2 .

Medical Devices Market: Market Segmentation (World), 2010



Source: Frost and Sullivan 2011

Figure 4.2

Figure 4.3 shows the revenue distribution of medical devices fields. According to this graph, which is based on the Business Insight Report of 2011, the Cardiology and Thoracic surgery section earned around 55.80 billion US dollars in 2010. Indeed, cardiology and thoracic surgery possess more than 18 % of the medical devices market value. Besides orthopaedic and prosthetic apparatus, aesthetic and respiratory devices follow cardiology devices in terms of the medical devices market value.

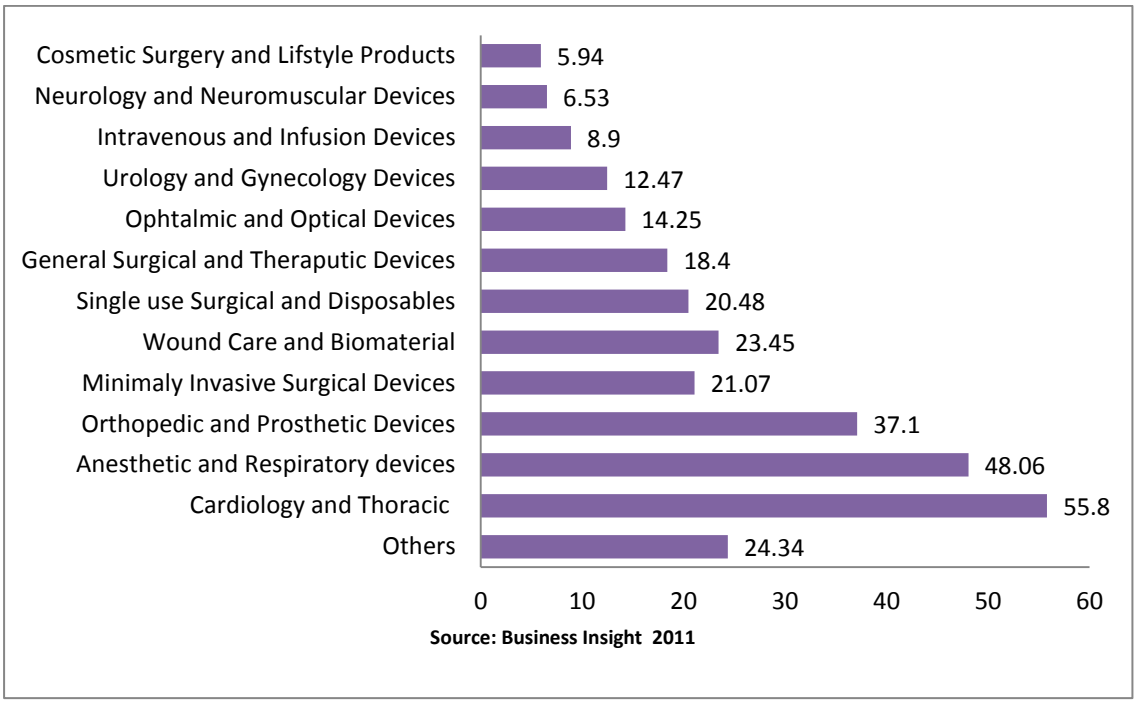


Figure 4.3 Medical Devices Market Total Revenue 2010

In addition, medical devices could be classified based on their contribution to the process of problem seeking, finding, and solving in the process of treatment. As Gejins and Rosenberg (2005) declare, considering the treatment process based on these three steps of problem solving would help specialists to categorize the medical devices based on their contributions. As can be seen from table 4.1, the process of examination, diagnosis, therapy, and surgery could be considered as the main pillars of these classifications. Nevertheless, medical devices could be categorized based on the risk of application. There are a mixture of factors, such as body internal-external implementation and mechanical-chemical effect on the patients, which may increase the risk of implementation.

Diagnostic Laboratory Devices: Microbiology Hood, Bacteriology culture incubator, Laboratory water bath, Analyzer system, Blood cells and the cell counter device laboratory, Photometers device (spectrometer material formed blood) Auto Analyzer, Special lab table, Laboratory medical diagnostic kits, Blood chemical analysis devices																					
Specialist Devices:																					
	Cardiothoracic and surgery	Colorectal surgery	Paediatric surgery	Plastic surgery	Vascular surgery	Transplant surgery	Trauma surgery	Breast surgery	Surgical oncology	Endocrine surgery	Skin surgery	Otolaryngology	Gynaecology	Oral and maxillofacial surgery	Orthopaedic surgery	Neurosurgery	Ophthalmology	Podiatric surgery	Urology	Dentistry	
Examination	**Examples:** Machine mercury barometer, Barometer system scorpion, Digital pressure gauge system, Medical thermometer, Mobile Medical, Flashlight, Ophthalmoscope, Otoscopy																				
Diagnose	**Examples:** X-ray diagnostic equipment, Ultrasonic Equipment (ultrasonic) (in radiology), Nuclear Medicine Equipment, Electrocardiogram, CT scan, Medical radiation equipment, Spiro meter, Audiometer																				
Therapy	**Examples:** Heart Stents, Joint implants, Cranioplasty implants,……, artificial heart valves, Spine implants																				
Surgery	**Examples:** Surgical Suction (vacuum), Electrocautery, specific device for each section																				
General Hospital Equipment: Trolley, Autoclave machine, Fore Machine, Examination bed, Monitor vital signs Medical lights, Electrocardiogram, Ventilator (Bennett), Laryngoscope, crusher equipment																					

Table 4.1 Classifications of Medical Devices based on their Contributions

Based on this definition the FDA has defined three classes of medical devices as detailed below:

Class I: General Controls

Class I devices are subject to the least regulatory control. "*General controls include provisions that relate to adulteration; misbranding; device registration and listing; premarket notification; banned devices; notification, including repair, replacement, or refund; records and reports; restricted devices; and good manufacturing practices*" (MD report of FDA, 2010). These devices are not supposed to be used in supporting or sustaining life or to be of substantial importance in preventing

impairment to human health, and they may not present a potential unreasonable risk of illness or injury (MD report of FDA, 2010).

Class II: General Controls with Special Controls

Class II devices are those for which general controls are required but not sufficient to assure safety and effectiveness. There are, however, some methods available to provide such assurances (USFDA, 2009). Class II devices need to pass some special controls in addition to general ones. "*Special controls may include special labelling requirements, mandatory performance standards and post market surveillance certificate. Devices in Class II are held to a higher level of assurance than Class I devices, and are designed to perform as indicated without causing injury or harm to patient or user. Examples of Class II devices include powered wheelchairs, infusion pumps, and surgical drapes*" (MD report of FDA, 2010).

Class III: General Controls and Premarket Approval

Class III devices need premarket approval (PMA), a scientific review to ensure the device's safety and effectiveness, in addition to the general controls of Class I (MD report of FDA, 2010). "*Class III devices are usually those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury*" (USFDA, 2009). Medical devices specialists believe that there is a great deal of similarity between Class III devices and high-tech medical devices in terms of focusing on sensitive and vital issues in medical science.

4.1.2 MD Development Process and Need for a Sectional Framework

Due to new technology concepts, stricter regulatory requirements and the increasing importance of reimbursement decisions in healthcare systems, the development process of MDs has become increasingly complex (Pietzsch et al, 2009). Therefore, one of the most important determinants of successful DI diffusion is to understand the MD development process well enough to figure out the gaps in the commercialization process. Although DIs don't usually follow the same pattern of diffusion as Bass' model or the stage-gate system of innovation diffusion, in order to explain the regular process of MD development, we may consider the stage-gate model of Cooper (1990) as a framework to briefly explain the MD development process. As depicted in Figure 4.4, in order to develop a new MD, a variety of clinical studies is conducted in five different stages (Stark, 2001).

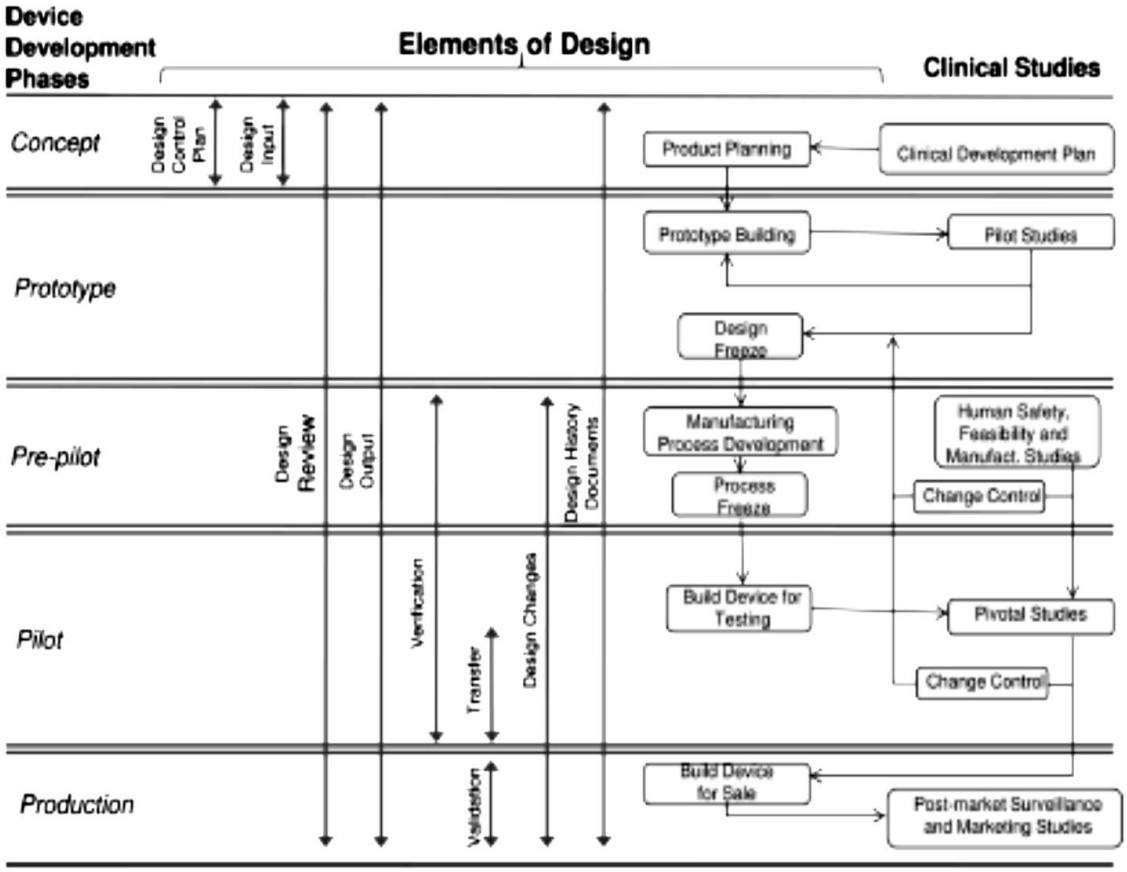


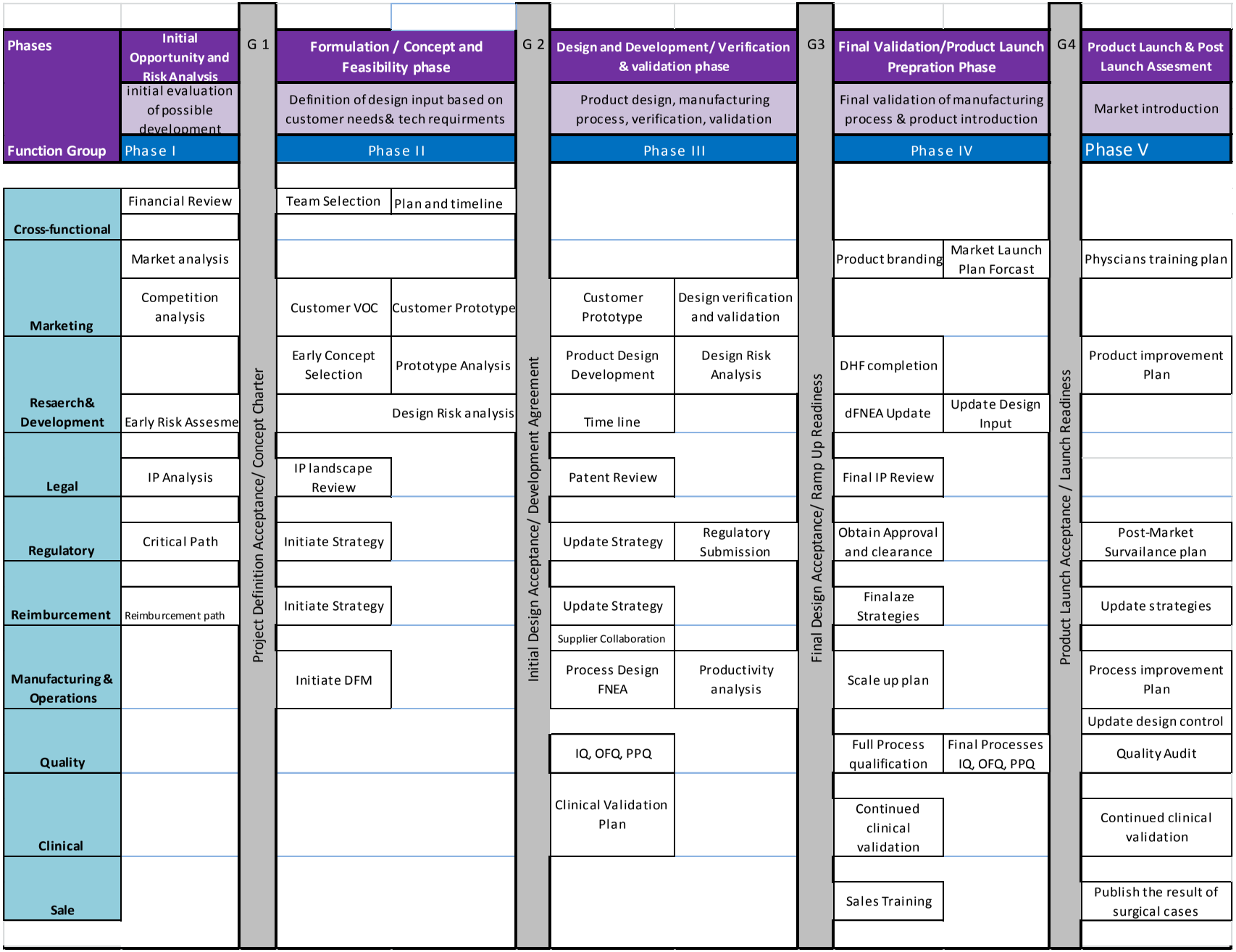
Figure 4.4 Schematic Overview of Clinical Research in the Product Development Cycle (Stark, 2001)

This life cycle contains a design phase, engineering activities, a mode of action assurance, an integration of clinical sciences, a setting up of robust and vigorous quality systems, and finally a post-market surveillance plan (Kaplan et al, 2004). The MD development process usually starts with a clinical development plan during the conceptual design phase. This clinical development plan would guide a product planning which is a prior requirement to prototype building plan. Next, pilot studies are conducted to modify and confirm the first freeze design,[1] which is subject to further studies in the pre-pilot phase of clinical research. In pilot studies the MD is built to progress through more pivotal studies, while in production studies the post-market surveillance and marketing studies are at the centre of attention. However, it should be noted that these studies are conducted in different MD development phases, and, therefore, they may not follow a linear idealized model. Rather, they involve fuzzy boundaries between the decisions gates mentioned in Figure 4.5. Based on Cooper's (1990) stage-gate framework of launching new products, Pietzsch et al (2009) suggest a linear model of MD development that includes five stages; initial opportunity analysis, a formulation and feasibility phase, a design-development-verification-validation (DDVV) phase, a product launch preparation phase, and post launch assessments. Pietzch argues that although understanding of the actual market size and potential clinical impact are at the centre of concern during the initiation phase, the importance of legal and IP analysis and regulatory and clinical paths in the market entry point should not be down played. Indeed, as we will discuss in chapter six, strategic adoption of regulatory and clinical paths by the incumbents could contribute to DI diffusion in further stages of the product launch.

During the formulation and feasibility phase, the main team of the project would be formed and general timelines and plans would be outlined. At this stage, budgets would be projected and finally allocated. The main decisions of this phase would be concerning the value proposition of new MD, and value chain concerns. Hence, considering the pivotal role of perceived performance values by customers in DI diffusion, according to Markides (2006) and Daneels (2004), the second phase of MD development possesses a critical impact on development of a potential DI. In terms of clinical

[1] A product life cycle management phase in which the product's design would be determined for the first time.

Figure 4.5 Medical Devices Development Phases (Pietzch et al , 2009)



research, the second phase contains some initial animal and cadaver studies of the MD to test the physical performance of the device (Fries, 2006). The DDVV phase plays a pivotal role in MD development from a technical perspective. Validation and verification tests are run before and after the design freeze, which means that installation qualification (IQ), operational qualification (OQ), performance qualification (PQ), and product performance qualification (PPQ) will be tested (FDA report, 2005). At the third phase clinical regulatory strategies would also be updated in order to be submitted under clinical regulation protocol to receive the required regulatory approvals before the limit market release (LMR) in the next phase (Chai, 2000). The DDVV phase actually includes a huge amount of clinical tests before and after the design freeze.

The interaction between the selected hospitals, physicians, regulatory agencies, and incumbents' R&Ds is the essence of the DDVV phase, in order to conduct the verification and validation tests. This is because from this phase onwards, clinical tests will be conducted and physicians will be involved in the process of IQ, OQ, PQ, and PPQ assessment. The involvement of physicians and healthcare professionals in the validation and verification process makes a reliable market base to diffuse the potential DI in further stages of launch. In other words, the involvement of physicians in MD development processes increases the effect of opinion leaders and peer pressure during DI diffusion, which could accelerate the rate at which it occurs.

This is the main difference between the diffusion of nesting DIs and DIs which have not been developed in collaboration with the market actors. Indeed, nesting DIs are developed in constant interaction between the market actors and the development team, while non-nesting DIs usually develop without the impact of market actors. Therefore, when DI development and diffusion happen in the same market (nesting DI) the diffusion dynamics and mechanisms are very different, as the development and diffusion of a given DI takes place without any previous interaction (non-nesting DI). Indeed, while most of the studies on DI diffusion have not distinguished between nesting and none-nesting DI diffusion dynamics and mechanisms, most of them consider DIs nested in their studies. In other words, in most of the studies, DI development and diffusion happen in the same

market, while in the real world examples, the number of non-nesting DIs is significantly higher. Therefore, this research focuses on non-nesting DI diffusion to establish the diffusion dynamics and mechanisms of this type of DI.

4.2 Cardiovascular (CV) Industry

4.2.1 Brief History

Sir James Mackenzie was a Scottish cardiologist who was a pioneer in cardiac arrhythmia studies. He once famously said, "*There are three stages in the history of every medical discovery. When it is first announced people says it is not true. Then, a little later when its truth has been borne in on them, so that it can no longer be denied, they say it is not important. After that if its importance become sufficiently obvious, they say any way it is not new!"* (Wilson, 1926). Indeed, this is the story of diffusion in medical fields which Mackenzie expressed so well. But today, through the advancement of technology, there are significant examination milestones which ensure the quality of innovation. There are also extensive media outlets which help to immediately diffuse news of the emergence of a given innovation.

We can classify the invention, development, and refinement of the invasive diagnostic and therapeutic modalities of cardiac catheterization, angiography, angioplasty, and stenting within the greatest achievements in cardiovascular medicine during the past century. These endeavours have facilitated the emergence of implicit and explicit knowledge of interventional cardiology. So eminent to humanity are these endeavours that the 1956 Nobel Prize in Medicine or Physiology was awarded to Cournand, Richards and Forssmann, three pioneers in cardiac catheterization (Richards et al, 1995).

Most medical textbooks, such as Harrison's (2004), consider cardiac catheterization as the intervention of a catheter into the heart's chambers or vessels. The evolution of catheterization can be divided into four different eras (Yoo et al, 2010). The history of catheterization began in Egypt in 3000 B.C.E with the use of gold, silver, or bronze pipes for bladder catheterization. Later, in 400

B.C.E, Hippocrates used hollow reeds in an attempt to understand the cardiac valves by putting the reeds into the cadaver's aorta and pumping in air or water (Richards et al, 1995).

Perhaps the most significant incident since ancient times was Harvey's catheterization of a cadaver's inferior vena cava in 1651. By doing this, he proved that the venous blood flowed toward the lungs rather than peripherally (Miller, 1984). However, the evidence shows that the "earliest known cardiac catheterization was performed by Hales in 1711, when he inserted brass pipes through the venous and arterial systems into the ventricles of [a] horse by rout of the jugular vein and carotid artery" (Richards et al, 1995). Dieffenbach performed the first left-heart catheterization in 1831 while trying to rescue a patient from dehydration. Dieffenbach was trying to get into the main central circulation, but unintentionally entered through the left heart (Cournand, 1975).

The next major leap of invasive cardiology occurred in the late nineteenth century with the notable innovation of Rotengen in 1895. Rotengen's X-rays had a great impact on Williams, who made fluoroscopic images of the beating heart in 1896. After this, and up until 1925, the concepts of arteriogram and angiogram were being developed by different scientists (Espinosa et al, 1983).

The second era of catheterization took place between 1929 and 1949, when Forssmann and Cournand succeeded to unlock the right-heart's mystery. During that period, Antonio Egas Moniz performed the first arteriogram in 1926. In 1932, along with his team Moniz made the first right-heart angiograms by contrast injection into the right atrium (Richards et al, 1995). In 1949, a major advancement occurred in X-ray technology, and the single-plate angiogram was replaced by automatic film cassette changers that made a rapid series of cut-films (Millers, 1984). In 1951 Charles Dotter, who is considered the father of angioplasty, invented the first balloon tipped angiographic catheter (Espinosa et al, 1983). It can be considered a disruptive innovation based on knowledge at that time.

The third era of cardiac catheterization (1950 to 1957) included the unlocking of the left heart by anterograde, retrograde, and direct access. However, the most important event occurred in the fourth era (1958 to 1995) with the unlocking of the coronary arteries by Sones and Judkines (Richards et al,

1995). Unlocking the right-heart made it possible to study the left-heart and demystify it, which allowed scientists to study the coronary arteries. The emergence of catheterization made it possible to study the heart's physiology and obtain knowledge about the relevant mechanisms. The invention of catheterization led to the development of angiography and angioplasty.

Nevertheless, as Mina (2009) argues, percutaneous transluminal coronary angioplasty (PTCA)[2] is one of the most prominent medical innovations of the last decade. Although the technique has some roots in previous advancements of the catheterization field, technically and practically, it cannot be considered as a path dependent innovation. In fact, as Mina (2009) states, the performance values of PTCA technique was tremendously successful to the extent that in the last decade it was used more than the coronary artery bypass graft (CABG). Based on the definition of Mina (2009), PTCA techniques should be considered as a DI firstly because PTCA offers new performance values which radically transformed the division of labour in medicine and established a new discipline of interventional cardiology.

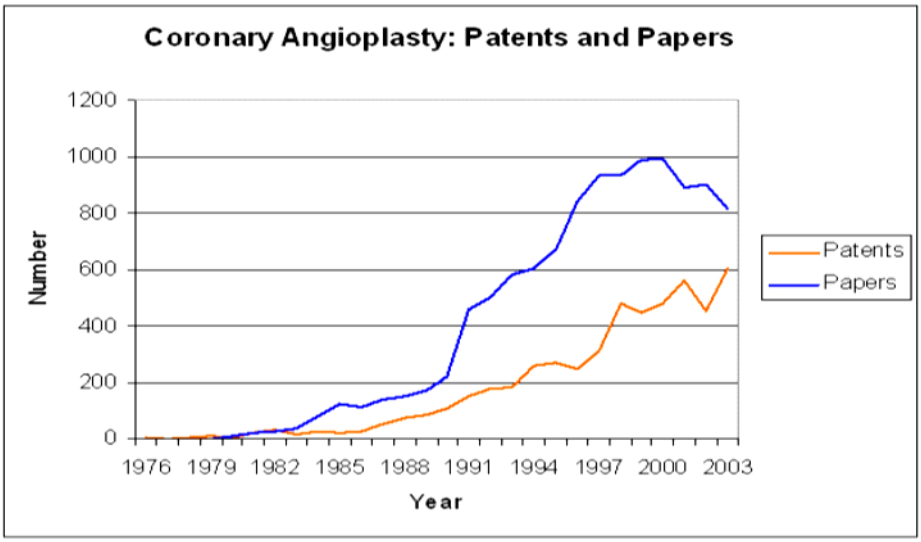


Figure 4.6 Number of Patents in CAD Devices between 1979-2003 from Mina's (2009) Research

In other words, as with many other DIs, the emergence of PTCA can be classified as competence destroying rather than competence enhancing, which necessitates attaining new skills to perform the

[2] Percutaneous transluminal coronary angioplasty (PTCA) is a minimally invasive procedure to open up blocked coronary arteries, allowing blood to circulate unobstructed to the heart muscle.

new practice. Indeed, the advancements during the fourth era of catheterization development led to the discovering of how the mechanisms of coronary vessels work, and opened the doors to new realms of interdisciplinary knowledge of cardiology: coronary artery disease (CAD) science. Therefore, science and technology (S&T) trajectories in the field of catheterization, led to CAD science, which introduced new opportunities to the emergence of new DIs. This claim is proven by Mina (2009) when he analyses the rate of FDA approvals in CAD devices between 1979 and 2003 (Figure 4.6). The PTCA technique in the late 1970s by Gruntzige, a Germen clinician, was a DI which began a new generation of cardiovascular devices and provided a reliable foundation for further innovations

4.2.2 Medical Overview of CV and CAD

The cardiovascular industry is the main focus of this research. On the one hand, as it is evident from the FDA list of launched medical devices during the last ten years, most of the MD innovations during this time span took place in the cardiovascular realm. In other words, of the 422 MDs launched during the past ten years (42.2 products launched each year), 111 innovations were in the realm of cardiovascular science (more details in Table 4.2). One of the main purposes of this research is to scan the MD trajectories to find the DI cases and conduct research about their diffusion dynamics and mechanisms.

Years	Total Medical Devices Innovations	Cardio vascular Innovations	Percent
2000	38	12	31%
2001	60	10	17%
2002	46	13	28%
2003	31	13	42%
2004	58	13	22%
2005	40	14	35%
2006	41	6	15%
2007	35	9	26%
2008	26	10	39%
2009	20	4	20%
2010	27	7	26%
Total	422	111	26.3

Table 4.2. Analysis of FDA List (Based on Table 2 of the Appendix)

It seems that the CV industry could be an appropriate option for the purpose of this research due to the remarkable variety of innovations in this field during the last ten years. Moreover, as Figure 4.7 shows, the CV industry is one of the most prolific and important markets, effecting a 55.80 billion dollar turnover in 2010, which places it at the top of the lucrative MD market. Consequently, since it is almost impossible to follow all of the MD evolutionary trends in different medical realms, and given the lack of knowledge in all fields which distinguish DIs, it seems rational to choose the CV industry as the main focus of this research's fieldwork.

The CV industry is one of the most prolific segments of the medical devices market, with the greatest amount of innovation per year (based on the FDA 2011 report). As Mina et al (2007) state, knowledge creation networks play the most prominent role in creating performance values in this realm. Similar to the other medical segments, the main aim of the CV industry is to decrease the performance risk and increase the effectiveness and efficiency of the circle of examination, diagnosis therapy, and surgery. Since Cutler and McClellan (2001) consider the focus on disease level as the main leverage to unveil the dynamic and mechanisms of S&T advancement of MDs, this research will consider CV disorders in this chapter and as well as focusing more specifically on CADs.

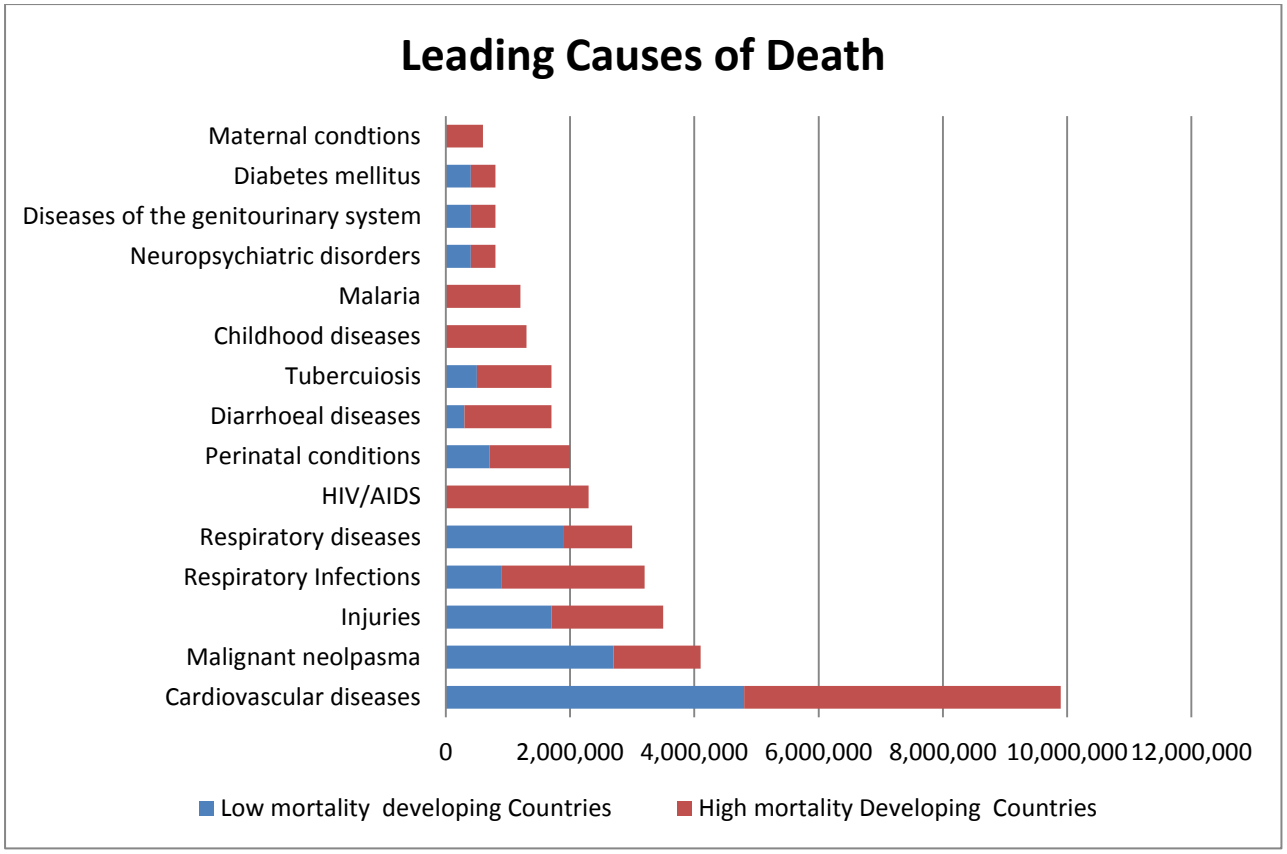


Figure 4.7. Leading Causes of Death in Developing Countries (WHO, 2003)

"*Cardiovascular disease is the term used for a variety of ailments including chronic heart failure, atrial fibrillation, angina and peripheral arterial disease, amongst others*" (Maton,1993). The highest rate of cardiovascular disease belongs to the USA, with Japan and Germany in second and third place respectively. Despite a decline in cardiovascular diseases in the world, it still remains the leading cause of death and is responsible for 53% of all deaths around the world.

In recent decades, huge amounts of heart disorders have been identified. Coronary Artery Disease (CAD), Angina Pectoris, Acute Myocardial Infarction (MI), Heart Valve Disorders, High Blood Pressure: Hypertension, Heart Rhythm Disorders (Heart Arrhythmia), Peripheral Vascular Disease, and Stroke or Cerebrovascular Accidents (CVA) are some of the most prevalent heart disorders.

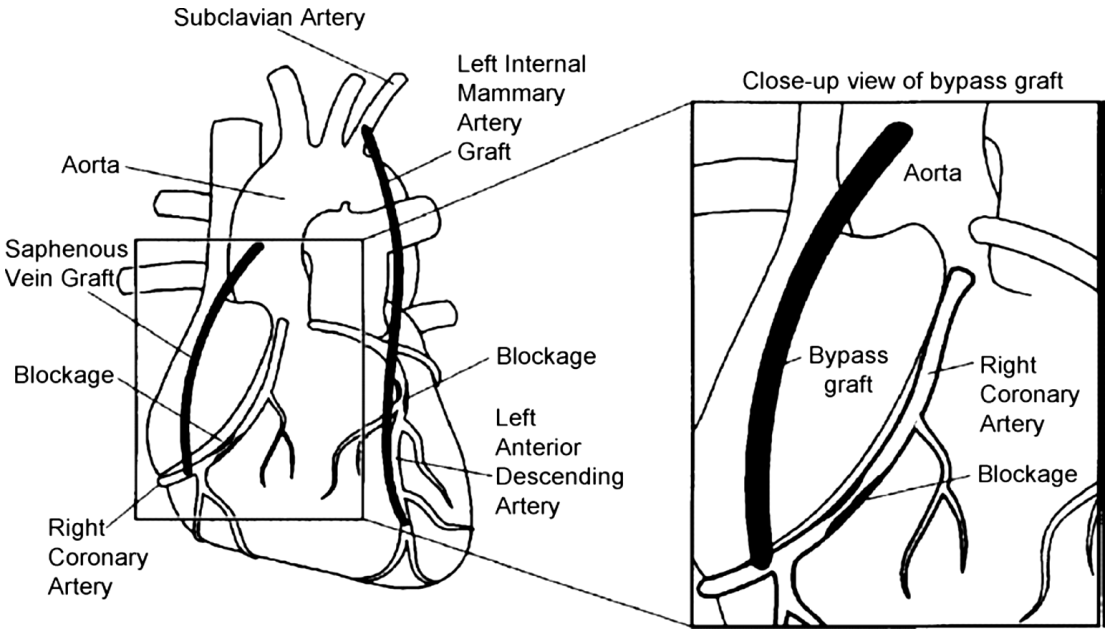


Figure 4.8. Human Heart anatomy

Most of the medical references, such as Harrison (2009), Cecil (2004), and Davidson (2006), have classified heart conditions into five main categories: heart valve disorder, vascular disorder, atrial fibrillation problems, heart rhythm disorder (arrhythmia), and pericarditis disorder. Heart valve disorder, or valvular heart disorder, is defined as any cardiac situation process which involves any problem with heart valves. These include the Aortic valve, the coronary valves, the tricuspid valve, and the pulmonary valve (Anthony et al, 2009).

Vascular disorders are certain cardiac situation which affects blood vessels (Allen et al, 2004). Peripheral vascular disease, cerebrovascular disease, and coronary artery disease (CAD) are some examples of this heart condition. The main and most prevalent example of atrial fibrillation could be "acute myocardial infarction" (Anthony et al, 2009).

Having discussed the main heart conditions and their classifications, we provide Table 4.3 for an overview of CV disorders and their main implications.

Main Area of Concern	Devices
Cardiac Rhythm Management (CRM) Devices	Implantable pacemakers, implantable cardioverter defibrillators (ICD)
	Implantable cardiac resynchronization therapy (CRT) devices
	Monitoring systems, Diagnostic catheter
Vascular Devices	Stents (BMS, DES, AMS, …)
	Guidewires, and other cardiac accessories, Balloon catheter
Cardiac Device	Ventricular assist devices (VAD)
	Devices for atrial fibrillation (AF) therapy
	Heart valves, grafts, electrophysiology catheters,
External Defibrillators	Automated external defibrillators and related accessories

Table 4.3 Initial Introduction to the CV Medical Devices

Fuch and Sox (2001), ranked coronary angioplasty as the third the most significant medical innovation of the last twenty-five years after MRI and CT scanning, and ACE inhibitors (Mina et al, 2007). Indeed, coronary angioplasty is the process through which deposits from the inner layer of the coronary arteries are removed in order to facilitate the blood flow to the heart. Otherwise, the probable outcome of this obstruction is a heart attack (Mina, 2009). Contributing to treat the occlusions in coronary arteries, PTCA was introduced by Gruentzig in the late 1970s as a minimally-invasive procedure that resolves plaques and restores blood flow (Ramlogan, 2007). As Mina et al (2007) claim, among CV disorders, CAD is the most prevalent cause of death in developed countries. CAD is initially symptomless, but will eventually cause shortness of breath and chest pain (angina) in further stages of the illness (Mina et al, 2007). Table 4.4 shows the S&T trajectories of CAD treatment based on Mina et al (2007).

Decade/Year	Advancement	Aftermath	Reactions
1960s	Prescription of some medication and rest for angina and acute myocardial infarction	Did not affect the causes and led to high rate of mortality	Conducting of much research on helpful medications
	Improvement of coronary artery bypass surgery	• Major and complicated invasive surgery • Took 3-6 hours • Required general anaesthesia. • Required heat-lung machine to substitute heart-lung function during surgery • A lengthy post-surgery recuperation period	• More helpful medication before and after surgeries • Enhancing the performance of surgeons • Led to more research on catheterization and the emergence of PTCA in 1977
1970s	Introduction of beta blockers and calcium channel blockers to CAD medication to deal with angina	A Relief of angina but not a solution to underlying CAD	More research
1977	First PTCA procedure by Greuntzig in Zurich	Spreadquickly and many cardiologists adopted the method	Improvement of device and practice
1980 (Figure 4.9)	Invention of the steerable balloon Catheter by Simpson	Restenosis: reformation of plaques after the procedure caused the reduction of the treatment's efficiency	The invention of the stent: an expandable metal device to support the blood vessel walls.
1997	Palmaz-Chute: the very first bare? metal stent (BMS) by Cordis came to the market	Cut residual restenosis by over 50% and became a major complimentary development in PTCA technology.	Recoiling of the vessels in some cases.
2002	Cypher, the first Drug eluting stent (DES) came to the market from Cordis	It solved the problem of vessel recoiling and somehow substituted BMSs.	• Late thrombosis, which is the formation of a blood clot inside a blood vessel obstructing the flow of blood through the circulatory system • Remaining piece of metal in the in coronary vessels caused some invasive pos?t-reactions
2005	Big debate between cardiologists and surgeons to compare the efficacy rate of BMS and DES	The BMS market was going to be obsolete but after this debate the rate of BMS consumption significantly increased	Decrease in the consumption rate of DES and a drop in their prices
2007	Xience was introduced to the market as the advanced version of DES by Abbott Laboratories	It solved the problem of restenosis and thrombosis in PTCA, and its Chrome-cobalt steel showed a great flexibility in the procedure time.	Xience took the leadership from Cypher and implemented new sets of standards.
2010	Abbott introduced the first Bio absorbable stent (AMS) to the market, named BVS	The metal in these types of stents absorbed into the vessel walls and did not cause any invasive reaction in the body	Cordis decided to shift its R&D activities into peripherals studies.

Table 4.4 S&T trajectories over the CAD treatment

This trend demonstrates the evolution of CAD treatment based on S&T trajectories in the field. We will use these trajectories to analyse the FDA list of CV devices to distinguish DIs within the realm of CV science. In fact, this table shows that new MD innovations created new opportunities for further creativity. For instance, the invention of catheterization leads to the emergence of the PTCA procedure later on, and more elaboration on PTCA techniques led to the creation of the Balloon catheter, and finally, stents. Indeed, the path-dependent nature of medical innovations is a unique part of their S&T trajectories. Although some scholars, such as Christensen (1997) and Adner (2002) point to the discontinuous nature of some medical innovation, as Ramlogan et al (2007) and Mina et al (2007) demonstrate in their medical network analysis, these discontinuities happen because of the path dependent nature of medical S&T trajectories.

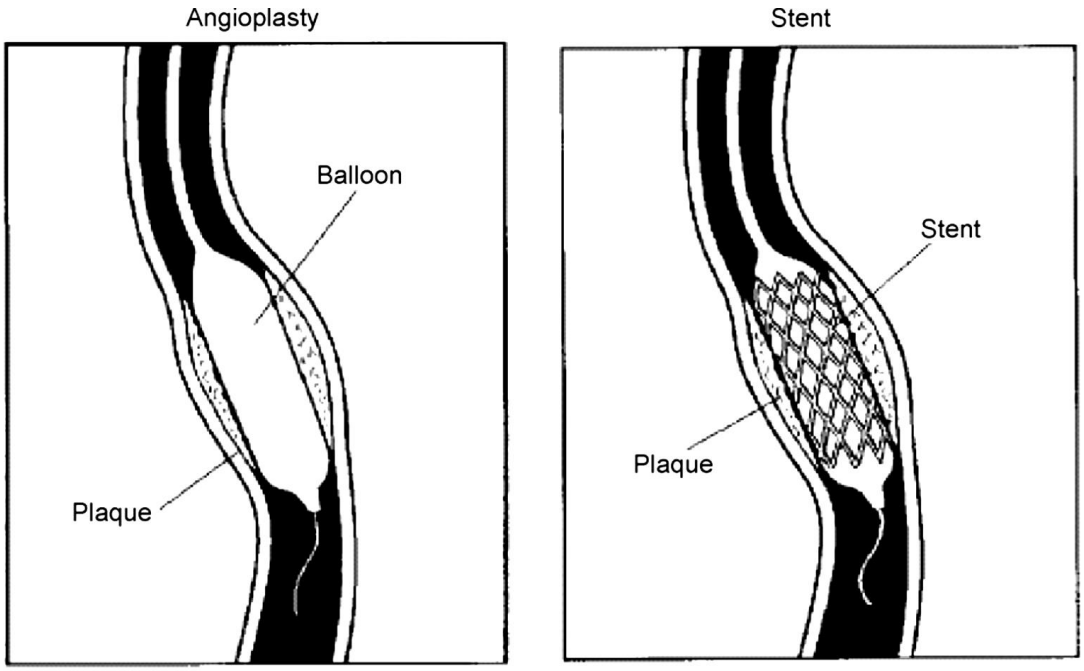


Figure 4.9 mechanisms of Balloon and stent catheterization over CAD treatment

4.2.3 The Structure of the CV Market

Table 4.5 demonstrates the top ten incumbents of the global CV market from an exhaustive list of active companies in this industry. As is evident, nearly 97 % of the market shares belong to the top ten incumbents of the market. In other words, most of the successful CV device innovations have been

commercialized by the top ten incumbents of the market during the abovementioned time span. The market shares' relativity has been volatile among the incumbents of the CV market during the last ten years. Table 4.6 shows the most critical volatilities of the CV market share structure among the top ten incumbents between 2007 and 2009. As Tables 4.5, 4.6, and 4.8 show, Medtronic seems to be the main player of the CV market with 29.5 %, since they provide a varied range of CV devices, from cardio rhythm management devices (CRM) to cardiovascular products, to different varieties of CV market segments. Boston Scientific and St. Jude also follow the same strategy and provide the whole range of CV products to the market. On the other hand, Thoratec, Trumo, and Abbott Laboratories have significantly increased their market shares during the last ten years. Among these fast growing incumbents, Thoratec which has concentred on ventricular assisted devices, has the highest growth rate of market shares at 39%. At the same time, focusing on PTCA technologies, Abbott Laboratories and Trumo increased their market shares by 27% and 15% respectively during the last ten years. Interestingly, Cordis, who introduced the first BMS and DES in the market, has lost 10% of their market shares.

Companies	**CV Device Revenue**	**Market share**
Medtronic	9070.42	29.5
Boston Scientific	6446.92	21
St.Jude	4612.06	15
Abbotte	2853.52	9.3
Cordis (J&J owned company)	2839.74	9.2
Terumo	1551.84	5.1
Edwards	921.14	3
Sorin	543.78	1.8
Zoll	408.1	1.3
Thoratec	296.8	1
Top Ten Total	29544.32	96.2
Others	1170.24	3.8
Total	30714.56	100

Table 4.5. Top Ten Companies and their Market Share in 2010. From the Business Insight Report

Companies	2007 ($m)	2008 ($m)	2009 ($m)	CAGR (06-09)%
Medtronic	7423	7794	8557	7.4
Boston Schientific	5979	6002	6082	0.9
St.Jude	3570	4109	4351	10.4
Abbotte	1663	2240	2692	27.2
Cordis	3314	2988	2679	-10.2
Terumo	1095	1270	1464	15.6
Edwards	666	786	869	14.2
Sorin	454	494	513	6.3
Zoll	310	398	385	11.4
Thoratec	144	215	280	39.4
Total	24618	26296	27872	6.4

Table 4.6. Revenue of Top Ten CV Companies ($m) 2007-2009

It deserves mentioning that in the Cardiac Rhythm Management (CRM) market, Medtronic holds the leadership position with 50% of the market shares in the USA (Business Insight, 2010). Also, Boston Corporation owns a vast portfolio over 12,000 products in forty-five different countries (Boston Co Annual Report, 2010). The main products of Boston Scientific are cardiovascular devices, which are classified among the major incumbents of the market (Frost and Sullivan, 2011). St. Jude Corporation's revenue comes largely from the Atrial Fibrillation market, where they are the market leaders. St. Jude Corporation also owns a steady compound annual growth rate of 10% in the market. In 2009, Abbott Laboratories' revenue in the vascular division increased by 20.2% and became one of leading players in the drug eluting stents (DES) business (Business Insight, 2010).

However, the CV market has witnessed one of the most drastic drops in the market by Johnson &Johnson (Cordis) Corporation between 2006 and 2009. For many years DES was the flagship of Cordis, but after their 2005-2006 product recall over safety concerns, their market share dropped dramatically (Frost and Sullivan, 2011).

Terumo is the only Japanese medical devices company within the top ten CV corporations. Terumo grew by approximately 15.6% between 2007 and 2009, and their products are sold in more than one hundred and fifty countries. They mainly operate in the catheter and cardio vascular division (Terumo Annual Report, 2010). Edwards Life Science is a leading manufacturer of heart valves, and their products are sold in over one hundred countries around the world. Sorin Corporation is an Italian

medical devices company which has been known as the follower of the leading CV incumbents in the market. Zoll Medical is the main manufacturer of external defibrillation, and Thoratec is the exclusive manufacturer of Ventricular assist devices (VAD).

This information shows that Medtronic and Boston Scientific have been the CV market leaders, while Abbott Laboratories is the most successful incumbent which works on PTCA technology. Nevertheless, as previously mentioned, Cordis, one of the main incumbents of PTCA technologies has faced failure between 2007 and 2009. Therefore, these four incumbents will be the subject of more investigations in this research.

Product	**Sales Volume**	**Percent**
ICD	7.21	23.4
Pacemaker	4.77	15.5
CRM total	11.98	39.0
	0.00	0.0
Drug Eluting Stent	5.19	16.9
Atrial Fibrilation	2.33	7.6
Dilatation Catheter	0.85	2.8
Cardiac Valves	0.85	2.8
Ventricular Assist Device	0.32	1.0
Others	7.74	25.2
Cardiovascular Total	17.17	55.9
External Defibrillators	1.48	4.8
Total	30.74	100.0

Table 4.7. Sales Volume of CV Devices Product in the Market, 2010. From Frost and Sullivan, 2010

Segments	CV Devices	Medtronic	Boston Scientific	St.Jude Medical	Abbotte Laboratories	Cordis	Terumo	Edwards Lifescience	Sorin	Zoll Medical	Thoratec
Cardiac Rhythm Management (CRM) Devices	Implantable pacemakers, implantable cardioverter defibrillators (ICD)	■	■	■					■		
	Implantable cardiac resynchronization therapy (CRT) devices	■	■	■					■		
	Monitoring systems: Diagnostic catheter		■		■	■				■	
Cardiovascular Devices	Stents (BMS, DES, AMS, …)	■	■		■	■	■				
	Heart valves, grafts	■		■				■	■		
	Ventricular assist devices (VAD)										■
	Devices for atrial fibrillation (AF) therapy			■							
	electrophysiology catheters, guidewires, and other cardiac accessories, Balloon catheter	■	■	■	■	■	■				
External defibrillators	Automated external defibrillators and related accessories	■								■	

Table 4.8. Analysing the Products of the Top Ten CV Companies

4.4 Analytical Framework to Distinguish DIs within the CV Market

The main objectives of this research are to understand the dynamic of DI diffusion in medical markets and unveil the mechanisms which shape these dynamics. While other scholars such as Mina et al (2007, 2009) and Ramlogan et al (2007) focus on the existing networks of S&T from an innovation system perspective to understand the manner in which MD innovations emerge, this research aims to understand the nature of the interactions in medical markets to understand the dynamic of DI diffusion Addressing this issue necessitates a retrospective glance into at the evolutionary trends of MDs in order to distinguish disruptive DI cases. However, there are two problems: first of all, this research aims to focus on high-tech MDs rather than the whole industry, and secondly, it is not possible to follow the evolutionary trends of all MDs in all the various and complex medical fields. Therefore, the CV industry is chosen as a representative of high-tech MDs. The main actors in the CV market

have been selected, and retrospective analysis of their innovation trends will be conducted in order to justify the main case study of this research.

In this section, we will to focus on CV market trends in order to identify DIs based on the literature's definitions. As previously mentioned, approximately 97% of CV market shares belong to the top ten incumbents, and, therefore, retrospective analysis of the innovation trends of these incumbents will highlight some appropriate cases on which to conduct the research.

Conducting this initial research, we have used all the ten companies' sales reports from the last ten years and attempted to match them with the FDA list of the launched MDs over the abovementioned time span (Appendix 1) in order to confirm the findings of the retrospective analysis. The result can be seen in Figure 4.9. In each column we compare different innovations of each company during the last ten years, while in each row we identify the competition of the major incumbents to commercialize CV innovations.

Table 4.9. The Evolutionary Trends of CV Medical Devices During the Last Ten Years

		Medtronic	**Boston Scientific**	**St.Jude Medical**	**Abbotte Laboratories**	**Cordis**	**Terumo**	**Edwards Lifescience**	**Sorin**	**Zoll Medical**	**Thoratec**
Cardiac Rhythm Management (CRM) Devices	**Implantable pacemakers, implantable cardioverter defibrillators (ICD)**	Secura, Maximo II, Virtuoso, EnTrust, Marquis, Maximo, CareLink, Secura, Virtuoso Pacemakers Adapta, EnRhythm, CareLink	Afocus, Constellation, Inquiry H-Curve, Luma-Cath, Ten-Ten ICD Confient, Teligen Pacemaker Altrua RF ablation system Maestro	ICD Atlas, Current, Epic, Fortify Pacemaker Accent, Affinity, Entity, Integrity, Identity, Microny, Regency, Verity, Victory, Zephyr					Pacemaker Reply, Esprit, Symphony, Rhapsody ICD Paradym, Ovatio		
	Implantable cardiac resynchronization therapy (CRT) devices	Consulta, Maximo II, Concerto, InSync Maximo	Cognis, Contak Renewal	Anthem, Atlas, Epic, Frontier, Promote, Unify					Paradym, Ovatio	PocketCPR	
	Monitoring systems; Diagnostic catheter		Blazer, Explorer 360, Explorer ST, Inquiry, Polaris, SteeroCath-Dx		Jocath, Jography, Joguide, NC Mercury, NC Merlin	Avanti sheath introducer, Emerald guidewire, Infiniti Catheter				CoolGard 3000, Thermogard XP RescueNet, CodeNet	

Cardiovascular Devices	**Stents (BMS, DES, AMS, …)**	Driver, Endeavor, Complete	Carotid, Monorail, Promus, Taxus, VeriFlex		Acculink, Xact, Flexmaster, Frontier, Minivision, Multilink, Pixel, Trimaxx, Ultra, Vision, Xience, Xeta, Graftmaster, Jostent	S.M.A.R.T. transhepatic stent, S.M.A.R.T. Control, Stent, Precise transhepatic stent Cypher coronary stent, Velocity NEVO Sirolimus-eluting coronary stent	Misago				
	Heart valves, grafts, Cardiac surgery	Reveal Heart valve repair Profile 3D, CG Future, Duran AnCore Heart valve replacement Freestyle, HallEasy-Fit, Hancock II, Mosaic, Contegra, Melody		Mechanical valves SJM, Masters, Medical Pericardial patch SJM EnCap Repair rings Attune, Tailor, Seguin, Rigid Saddle Tissue allografts Allograft Cardiovascular Tissue valves Epic, Biocor				Pericardial heart valve Magna, Theon, Perimount Heart valve repair Carpentier, Cosgrove, Geoform, Carpentier-Edwards Classic Other tissue valves SAV aortic, Edwards Prima, Aortic Porcine, Duraflex Mitral, Mitral Porcine, Valved Conduit, Bovine Pericardial patch Cardiac surgery Cardiac surgery systems EMBOL-X Glide, OptiSite & Fem-Flex II, Femtrak, Retrograde, Venous Return, EZ Glide aortic, Femoral, Pediatric, AviD, Blood Field Management Vascular Vascular surgery Clot management, Atraumatic Occlusion, EPTFE Graft, Biliary, Carotid Shunt, Cardiovascular Catheters	Mechanical valve Bicarbon, Carbomedics, Aortovalvular Prostheses Biological valve Stented, Stentless, Freedom Solo Repair products Annuloplasty rings		

	Ventricular assist devices (VAD)										Hemodynamic stabilization CentriMag PVAD Thoratec PVAD LVAD HeartMate XVE, HeartMate II IVAD Thoratec IVAD
	Devices for atrial fibrillation (AF) therapy			Fame II, Interventional Cardiology FFR assessment PressureWire, RadiAnalyzer							
	Electrophysiology catheters, guidewires, and other cardiac accessories, balloon catheter	LUCAS	Apex, Flextome, Maverick, Sterling, Therapeutic catheter Blazer II XP, Blazer Prime, Blazer Temperature Interventional cardiology Angiographic catheter Imager II, Coronary	Livewire, Safire, Therapy	Embolic protection system Accunet, Emboshield Interventional cardiology Guidewire Advance, Asahi, Balance, Confianza, Cross-it, Grandslam, High-torque, Pilot, Prowater, Whisper	Access products Vista Brite Tip catheter Steerable guidewires 15 specialty guidewires Fire Star PTCA dilation catheter, Dura Star PTCA dilation catheter Front Runner XP CTO catheter, Outback LTD re-entry catheter, Aquatrack hydrophilic guidewire, Tempo Aqua diagnostic catheter, Sleek RX PTA dilation catheter, Savvy long PTA, dilation catheter	Sheaths Pinnacle, GlideAccess, TR Band Guidewire Standard, Shapeable, Long Taper, Stiff Shaft, J-tip, Bolia, Glidewire, Runthrough Catheter Glidecath, Finecross, Optitorque, Progreat, Coaxial				
External Defibrillators	**automated external defibrillators and related accessories**	LIFEPAK								R, E, M series, AED Plus, AED Pro	

Figure 4.9 offers a retrospective overview of the innovations during the last ten years in the CV market. To distinguish DIs within the incumbents' innovation trends, some standard measures should be defined in order to identify CV DI cases. As we discussed in the literature review, MD innovations in CV industries can be classified with the criteria given in Table 2.3 in chapter two.

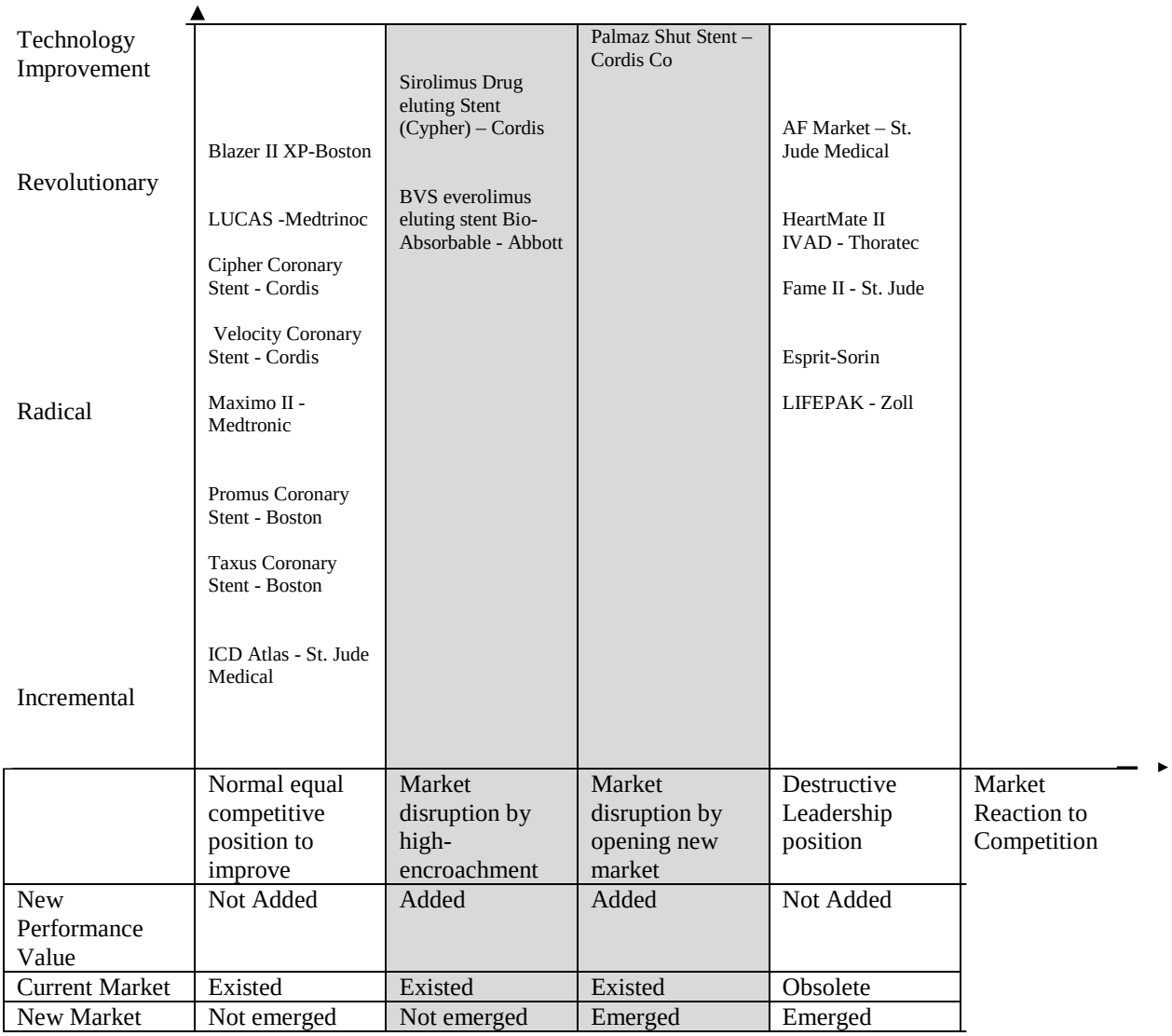
Attributes	Radical Innovation	Disruptive Innovation
Position of older technologies (Tushman and Anderson, 1990)	Not obsolete but in constant competition	Totally obsolete and all the competition will take place in and around new technologies
Consequence of innovation	Attaining the dominant position in the market (Utterback, 1994) (Secondary dominant design)	Lead to the next generation of technologies, which means the start of another competition (Christensen, 1997) (Primary dominant design)
Their position toward discontinuous innovation	The consequence of discontinuity (Tushman and Anderson, 1990)	The cause of discontinuity (Abernathy and Clark, 1984)
Lead to dominant design (Teece, 1986)	Directly	Indirectly
Their effect on current market competencies (Tushman and Anderson, 1990)	Competence enhancing	Competence destroying
Dominant origin (Utterback and Teece, 2005)	Mixture of needs and technologies	Technology driven and need attention
Competition's actors (Markids, 2006)	More incumbents than new entrants	More new entrants than incumbents
Types of knowledge to generate an innovation (Tushman and Anderson, 1990)	Existing knowledge in the market	New, interdisciplinary knowledge as the result of R&D research

Table 2.3. Differences between Radical and Disruptive Innovations (from Chapter .2)

Indeed, three different factors have a role in how medical innovations are categorised: the ability to introduce new performance value to the customers (Christensen, 1997), the current market situation (Schmidt and Druhel, 2008), and the possibility of new market emergence (Daneels, 2004). Regarding these three factors, there are some innovations which are the consequences of the routine competition in the market to improve the quality of the existing products. Technologically, most of them are incremental and radical innovations, which are developed during the same generation of products. In other words, they do not shift to the next generation of products. Rather, they take place in the same market and do not create the opportunity for new markets (Markides and Geroski, 2005). There are some examples of these types of market reactions toward new innovations in Figure 4.10.

However, the major attribute of DI is introducing new performance values to the market. This is mostly competence destroying and disrupts the current market in two ways. On the one hand, new performance values can be introduced by some modifications to the existing product. In this case, incumbents usually focus on the market demands and target the high or low end of the market, rather than the mainstream part, and try to modify their products for the marginal consumers. Focusing on the low ends of the market (low encroachment) (Schmidt and Druhel, 2008), incumbents follow strategies to offer lower prices for new innovations, and at the same time focus on other performance values of innovation rather than the existing one. As Christensen (2000) states, by the time incumbents attempt to improve the technical capabilities of the existing product by some radical or incremental innovations, finally the low-end encroachment innovation may disrupt the mainstream market. The important issue in this type of DI is the absence of new market emergence. In other words, this type of DI begins by targeting low or high ends of the existing market. Albeit, in this type of medical DI the main focus would be on high encroachment rather than the low end of the market. Since the medical market is less elastic in terms of price than other markets, and the major priority in this market is to provide fair treatment for the patients, the major mission of DIs is to increase the technical capabilities and efficiency of the current performance and decrease the accompanied risk of treatment. Therefore, incumbents of the MD market usually prefer to focus on the high ends of the market by delivering more performance values and technical capabilities to the market (Daneels, 2004).

On the other hand, introducing new performance values could take place by invention of a totally new innovation in the market, which solves the same problem as the existing product by means of a different practice, and, therefore, introduces the new performance value to the market through this new method (Markides and Geroski, 2005). These types of disruptive innovations usually try to attack the whole market, relying on their own technological advantages. The most example of disruptive innovation in this field by establishing a new market is the emergence of bare metal stent (DES) in the CV market (Figure 4.10).



	Normal equal competitive position to improve	Market disruption by high-encroachment	Market disruption by opening new market	Destructive Leadership position	Market Reaction to Competition
New Performance Value	Not Added	Added	Added	Not Added	
Current Market	Existed	Existed	Existed	Obsolete	
New Market	Not emerged	Not emerged	Emerged	Emerged	

Figure 4.10. Typology of Market Reaction in Competition of High-tech Innovations in the Cardiovascular Market between 2000-2010

The other possible scenario for potential DI is the obtaining of a destructive leadership position. In this case, a given innovation could exclusively takeover the market and emerge a new market by making the previous one obsolete. Although at first glance it might seem similar to the ordinary DI situation, destructive innovations would not introduce any new performance value to the market (Daneels, 2002).

Based on these classifications, the launched medical innovations in the market (based on FDA reports) can be categorized as in Figure 4.10.

Based on the retrospective analysis of the innovation trends of the major incumbents of the CV market, and by concentrating on S&T trajectories of PTCA as the third most remarkable revolutionary innovation during the last thirty years (Mina, 2009), this research focuses on the successive generations of stents (BMS, DES and AMS) as an example of DI in MD industries. As mentioned earlier in this chapter, BMS first became commercialized in the market by Cordis in 1998, which was a well-established example of market disruption considering the DI characteristics and behaviour in the market outlined in Table 2.3.

Stents	**BMS**	**DES**	**AMS**
Technology	Revolutionary (creation of metal)	Revolutionary (adding drug container)	Revolutionary (absorption of metal)
Market	Discontinuous	Continuous	Continuous
Innovation	Disruptive	Potentially Disruptive	Potentially Disruptive

Table 4.10. Typology of Stent Generations for CAD Treatment

Although from an S&T perspective BMS could be considered a path-dependent innovation, since it was a competence destroying innovation which introduced many remarkable performance values and substitutes coronary bypass surgery, it should be considered as a great example of DI. The BMS intervention was cheaper, with less accompanied risk of an operation, which made CAD treatment easier (Table 4.4). However, in 2002 Cordis introduced the first DES into the market, which was a revolutionary innovation from a technical point of view. Although DES did not introduce any new performance values and was not competence destroying, it was able to replace BMS and establish a new generation of products. DES was a more destructive innovation, therefore, as it delivered a better performance and modified the BMS's problems. The case of AMS introduced by Abbott Laboratories

is the subject of more investigation in this research. AMS is introducing a new set of performance values (absorption of the metal into the vessels walls) which are in some way competence destroying (the intervention procedure is completely different). So, from a technical point of view, AMS is quite revolutionary, yet form the market's perspective the dynamic is still in progress, making it impossible to analyse retrospectively (Table 4.6).

In the next chapter the case of PTCA treatment in the Iranian CV market will be discussed. The challenges faced by four main incumbents (Cordis, Abbott laboratories, Boston Scientific and Medtronic) to diffuse their own solution to the market, and how these market challenges shaped the dynamic of DIs during the last ten years will be discussed.

Chapter 5

[CASE STUDY]

Introduction

From a national point of view medical disruptive innovation (DI) diffusion is an issue affected by a mixture of factors, such as health and education indictors, level of income, and some medical factors, including a number of specialist and reimbursement systems. Therefore, the attempt of this study to understand the dynamic of DI diffusion in the medical market is to some extent culturally restricted. In other words, the direct effect of the markets' human development indicators (HDI) on the dynamic of medical DI diffusion and activation of certain diffusion mechanisms necessitate the understanding of the market context.

Therefore, in this chapter we will first describe the healthcare and medical devices markets in the Middle East, and specifically discuss the position of Iran. Then, we will focus on the technology trajectories of cardiovascular (CV) devices in the Iranian medical market and highlight the main challenges of DI diffusion in this market. Finally, we will concentrate on the event based narrative of the CV market evolution, based on interaction of the four major players in the market: Cordis, Abbott Laboratories, Boston Scientific, and Medtronic.

5.1 Iranian CV Market

5.1.1 Position of Iran in the Middle East MD Market

The Middle East medical market is an appealing market for medical companies, and its importance has been downplayed in the literature in comparison to developed countries. On the one hand, the Middle East is not in general the origin of nested innovations.[1] Rather, it is considered as one of the most important diffusion centres of high-tech medical devices. On the other hand, the high-level of income and the great amount of GDP and GDP per capita distinguish this market from other developing or emerging markets around the globe. Therefore, since Iran is an importer of technology

[1] As we will discuss later, nested innovation is a metaphor referring to innovation where the emergence and diffusion processes happen in different innovation ecosystems.

rather than a generator, the method of technology diffusion is critical and should be the subject of more investigation due to the different nature of this prolific market.

However, it is not practically possible to conduct this research across all Middle Eastern countries. For instance, some Middle Eastern countries have a low population, meaning that the concept of DI diffusion would not have a real meaning in these countries. There needs to be a significant population in order to trace the diffusion of DI and study the relevant dynamics and mechanism. From this point of view, there are few countries in the Middle East which have sufficiently large populations to conduct the study (Table 5.1).

Country	Population	**Per capita**	**HDI Index**	**HDI Classification**
Egypt	77,498,000	$5,898 (2008)	0.620	Medium
Turkey	73,914,000	$13,920 (2008)	0.679	High
Iran	71,208,000	$11,250 (2008)	0.702	High
Iraq	31,001,816	$6,500 (2008)	_____	_____
Saudi Arabia	23,513,330	$23,834 (2008)	0.752	High
Syria	22,505,000	$5,043 (2010)	0.589	Medium
Yemen	18,701,257	$2,412 (2008)	0.439	Low
Jordan	6,407,085	$5,314 (2008)	0.681	High
United Arab Emirates	5,432,746	$38,830 (2008)	0.815	Very High
Lebanon	4,224,000	$14,988 (2010)	_____	_____
Oman	3,200,000	$24,153 (2008)	_____	_____
Kuwait	3,100,000	$39,849 (2008)	0.771	High
Qatar	793,341	$85,867 (2008)	0.803	Very High
Bahrain	656,397	$34,605 (2008)	0.801	Very High

Table 5.1. Middle Eastern Countries HDI (UNDP Report 2010)

In order to address the research questions comprehensively, the target market for the case study should possess some specific characteristics to enrich the case study and address the research questions sufficiently. Otherwise, the research outcomes will not be sufficient to be generalized theoretically. When the focus of the fieldwork is on the DI diffusion, the target countries (in which to

conduct the fieldwork) should possess a high HDI index. In addition, some other healthcare indexes such as total amount of specialists, physicians, healthcare professionals, and hospitals, should be considered in targeting a market for the fieldwork.

As was mentioned earlier, most of the required characteristics of the market to conduct the research on medical DI diffusion could be summarized in HDI. "*The Human Development Index (HDI) is a comparative measure of life expectancy, literacy, education and standards of living for countries worldwide. It is a standard means of measuring well-being, especially child welfare. It is used to distinguish whether the country is a developed, a developing or an under-developed country, and also to measure the impact of economic policies on quality of life. There are also HDI for states, cities, villages, etc. by local organizations or companies*" (McGillivray and White, 2006).

As Wolff et al (2011) state, we can find a direct relationship between human development, the rate of technology diffusion, and new innovation acceptance in the market. As a result, it seems that choosing Middle Eastern markets with a higher level of HDI could contribute more to the research objectives. Therefore, it seems that Turkey, Iran and Saudi Arabia are appropriate cases both from a population point of view and appropriate HDI indexes.

In theory then, these three countries would be appropriate for this research. However, because of the focus of this research on CAD related DIs and the availability of data, we have chosen one of them in particular in which to conduct our fieldwork. Some scholars may suggest conducting a comparative case study utilising all three countries, but this is not feasible for various reasons. Firstly, this research will be based on longitudinal case studies concentrated on variation of products rather than countries. For this reason it seems rational to choose one country to appropriately limit the research.

While all three of these countries are classified as high HDI countries, they have some differences. For instance, while the leading causes of death in Iran and Turkey are cardiovascular diseases, Saudi Arabia's main problem is respiratory illness, which makes cardiovascular devices less relevant for that market zone. Additionally, within these three countries, Saudi Arabia has the lowest amount of GDP expenditure in the health sector (Table 5.2). The other important issue concerning Saudi Arabia

is that the health sector in this country is dependent on and managed by a foreign workforce, rather than indigenous healthcare professionals. Therefore, the concepts of diffusion and innovation acceptance are slightly different in Saudi Arabia from the other countries at this HDI level.

In Iran and Turkey cardiovascular diseases are the main cause of death. Therefore, in both of these countries the cardiovascular markets are potentially interesting. However, there are various reasons suggesting Iran is the ideal target for the fieldwork in this research.

		Turkey	**Iran**	**Saudi Arabia**
Health Expenditure (%GDP) (World Bank Development Indicators, 2010)	Public	5.1	2.2	3.3
	Private	1.7	3.4	1.6
	Total	6.8	5.6	4.9
Main Cause of Death (TurkStat's, 2007),		Cardiovascular disease 38% Malignant neoplasms 16% Symptoms and ill-defined conditions 10%	Cardiovascular disease 38% Accidents and Injuries 18% Cancer 14% Neonatal disease 6% Respiratory disease 6%	Malaria, TB and other respiratory disease Diabetic disease Cardiovascular disease 19%

Table 5.2. Comparison of Turkey, Iran and Saudi Arabia based on their Health Systems

Firstly, Turkey has a lower HDI than Iran, which makes Iran an excellent case to study DI diffusion. Moreover, from a political territorial division perspective, Turkey is also classified as an emerging rather than a developing country, which makes it difficult to generalise the results of the study to the other Middle Eastern countries. Therefore, it seems that Iran is an appropriate choice for the fieldwork in this study. The Iranian medical market and the Iranian medical system's structures will be discussed in the next section

5.1.2 Introduction to the Iranian Medical System

"The Islamic Republic of Iran has achieved significant improvements in health status over the past 20 years, driven largely by a focus on preventive health, primary healthcare and family planning services. The country's success in achieving a U-turn in rapid population growth presents a model for the Middle East region, and this focus on curbing population growth has helped to ease a widening gap between healthcare demand and provision" (Global Insight, 2010). The average life expectancy in Iran at birth was 72 years in 2009, compared to 55.3 years between 1970 and 1975, while the country's infant mortality rate has fallen from 31 deaths per 1,000 live births in 2005 to 26 deaths per 1,000 live births in 2009 (World Bank Report, 2010). Immunisation coverage of one-year-old children stood at 99% in 2009 against tuberculosis (TB), polio, measles, hepatitis B, and tetanus, as well as DPT3 (diphtheria, pertussis, tetanus) (data sourced from UNICEF, 2011).

"The Ministry of Health and Medical Education (MOHME) co-ordinates most healthcare facilities in the public sector and administer healthcare policy. Individual departments within the MOHME deal with the procurement of supplies for hospitals and the regulation of domestic production and distribution. Since the integration of healthcare provision and medical education, significant authority has been devolved to the country's university hospitals. The division of the MOHME into departments with responsibility for health, education, research, drugs, curative care, logistics and students is mirrored in the university teaching hospitals. In its third Five-Year Development Plan (2000–05), the government emphasised the importance of private-sector expansion in the health sector in order to help reduce the burden of healthcare provisions on state revenue, which tend to fluctuate together with prices in the international oil market. This policy was continued in the fourth Five-Year Development Plan (2005–10), and is set to continue under the fifth Five-Year Development Plan (2010–15)" (Global Insight, 2010, p. 7).

"For administrative purposes, the Republic is divided into 24 provinces (*ostans*), which are divided further into sub-provinces (*shahrestans*), counties (*bakhshes*), cities, and rural districts (*dehestans*). The public sector is the main provider of healthcare. In rural areas, at the community level, rural

health centers (RHCs) provide basic primary healthcare. In urban areas, urban health centers (UHCs) serve the same purpose. In rural areas, health houses (HHs), supported by RHCs, provide basic preventive and curative services and also offer guidance, supervision and referral services. District health centers (DHCs) deliver secondary healthcare. Tertiary care is provided by a range of public and private hospitals located in the country's main urban centers" (WHO Report, 2010, p. 13). Based on the Global Insight Report (2010), Iran has a well-developed primary healthcare system delivered via RHCs, UHCs, and HHs, which provide guidance, supervision, and referral services.

Position	Total	Public Sector	% of Total	Private Sector	% of Total
Physicians	60,791	20,653	34	40,137	66
Nurses	83,175	53,661	64.5	29,514	35.5
Midwives	13,087	8,443	64.5	4,644	35.5
Dentists	13,135	3,875	29.5	9,260	70.5
Pharmacists	14,140	4,019	28.4	10,121	71.6
Community Health Workers	25,242	25,242	100	0	0

Table 5.3. Iranian Health Personnel Indicators, 2010. Source: World Health Organization (WHO) Country Cooperation Strategy for Islamic Republic of Iran 2010-2014

The fourth Five-Year Development Plan (2005-2010) increased the target number of hospital beds from 13.6 to 17.2 per 10,000 persons. According to 2007 data from the WHO's "*Country Cooperation Strategy for the Islamic Republic of Iran 2010–14*," there were 814 operating hospitals in Iran, of which 532 fell under the remit of the MOHME and are operated by the provincial Medical Science Universities. A total of 154 hospitals were run by other national sectors, such as the Bank Melli Iran, the National Iranian Oil Company, national TV and radio networks, charitable trusts, and other ministries, including the Ministry of Education. It should be mentioned that approximately 80% of hospitals in Iran are managed by public sectors. However, medical universities play an important role in Iranian medical systems by constituting principal research centres.

On the other hand based on the experts' opinions according to the Iranian healthcare system, we can categorise the hospitals into four main groups: Public or educational hospitals (which belong to the government and serve the educational purposes), semi-public or foundations' hospitals (such as army hospitals), social security hospitals and private hospitals. The CEO of Abbott Laboratories' franchise in Iran claims: **"***Governmental hospitals are mainly governed by public sector, but university hospitals' main mission is to nurture fellows and medical students. There are semi-public hospitals that are related to different foundations, such as Boniad Mostazafan and Boniad Shahid. Sasan and Khatam, for instance, are semi-public hospitals related to Boniad Shahid. Also, there are some banks that have their own hospitals. I do believe that there is an effect of hospitals' ownership on the rate of DI diffusion and the process of reimbursement. There is another type of hospital called a social security hospital. Army based hospitals are another type also. Army based hospitals are divided into revolutionary guard and army sections. Funding, insurance, and payment methods are totally different in the different types of Iranian hospitals, and this is the main point. We have to pay attention to the different segments of the market in order to accelerate the process of DI diffusion based on the requirements of each segment. We have to approach each segment based on the information gathered through our market intelligence system. We have our comprehensive guidelines and relevant strategies, but we use different sets in dealing with different segments of the market. Our prices are the same for all segments, but our marketing strategies are different*."

The CEO of Cordis Co's franchise in Iran sates: "*University hospitals usually consist of medical lecturers and young fellowship students. We usually spend most of our educational budget over there. Since we are always in the market we monitor the young fellows and follow their results. In private hospitals, service, quality, and availability of the product are the most important values, apart from technical issues. Physicians of the private hospitals are mostly those young fellowship students that we invested in when they were young. The foundation hospitals should be the subject of sales promotions since they usually have problems with their payments*." Therefore, the research findings show that each market segment has its own structures and requirements, and in order to accelerate the

diffusion rate of a DI, a given incumbent should identify the structural differences and various interactions between the network's actors in different segments of the market, as shown in Table 5.4.

Type of Hospital	Main Focus of Enabling Mechanism
Public Hospitals	• **Nurturing medical students** • **Allocating more educational budget for them**
Semi-Public Hospitals (Organizations+ Army)	• **Offering more sales promotions to facilitate the DI diffusion** • **Choosing proper pricing strategies due to high elasticity of DI prices**
Social Security Hospital	• **Social responsibilities**
Private Hospitals	• **Concentrating on technical capabilities of DI** • **Proposing a well-designed bundle of sales services** • **Perfect market availability**

Table 5.4 Main Enabling Mechanism of DI Diffusion in each Segment

5.2 Case Study Selection

Focusing on CAD S&T trajectories in chapter four , three main generations of cardiovascular stents have been identified (including BMS, DES, and AMS, which are identified in Tables 5.4, 5.5 and 5.6) to focus on their diffusion trends in the Iranian cardiovascular market . Therefore, in this chapter we will explain the diffusion of these successive generations in the Iranian market from the market point of view, and in chapter six we will analyse the dynamic of these DI diffusions based on the attitudes of the innovation launch decision makers of the main incumbents of the market. Furthermore, we will discuss the enabling mechanisms of DI diffusion based on the cases' diffusion scenarios. In the following section we will explain the three generations of stents in the last ten years, before discussing the diffusion narratives gathered from the interviews, and supported by some archival research and DI diffusion facts and figures.

5.2.1 Palmaz Schatz Stent – Cordis Co:

The Emergence of the First CV Disruptive Innovation which Introduced Many New Performance Values to the Market

"The Palmaz-Schatz slotted-tube stent, developed by Johnson & Johnson Interventional Systems, was shown to produce a clinically significant reduction in abruption. Results from the ongoing STRESS trial demonstrated that patients receiving the Palmaz-Schatz stent experienced a restenosis rate of only 15% versus a rate of 30% for patients treated with balloon angioplasty alone. Based on the results of that study, the Palmaz-Schatz stent was rapidly adopted throughout Europe and the U.S. for reducing the rate of restenosis following balloon angioplasty" (Business Insight, 2010). This disruptive innovation case deserves to be studied, since it was the first CV stent which disrupted the coronary artery bypass surgery market, and changed the dynamic of competition in the CAD treatment market.

5.2.2 Sirolimus Drug Eluting Stent (Cypher) – Cordis Co :

The Failure of a Disruptive Innovation in Keeping the Dominant Position in the Market

"Considerable advances have been made since the late 1990s into resolving the problem of restenosis and research focused on the use of pharmaceuticals rather than purely mechanical devices as a means of reducing the incidence of restoisis. The concept is to combine the principle of mechanical scaffolding (stent) with that of local pharmacological action (drug). The ultimate goal is to provide a controlled, local release of an efficient drug that inhibits the development of neointimal hyperplasia from the stent surface. This research led to the creation of stents known as Drug-Eluting Stents (DES) which deliver prolonged and sufficient drug concentrations to overcome the problems associated with restenosis" (Business Insight, 2010). "The emergence of drug-eluting stents as a breakthrough technology has been heralded as the dawning of a new era of cardiovascular treatments, and since their introduction have had a dramatic impact on the growth and development of coronary stents worldwide" (Frost and Sullivan, 2010). This CV innovation is a special case to study. Cordis

introduced the first DES to the world with Cypher, and to some extent disrupted the BMS market. However, after roughly two years, Cordis lost the DES market leadership and was substituted by Xianc and Endeavour from Abbot, Boston, and Medtronic. Therefore, this case includes both success (introduction of Xience) and failure (demise of Cypher) in medical disruptive innovations.

5.2.3 BVS Everolimus Eluting Stent Bio-Absorbable - Abbott:

Introducing New Performance Value to the Market by Nanotechnology (Disruptive Innovation by Interdisciplinary Technology)

"Although cardiologists are recommending and prescribing anti-clotting (antiplatelet) medications such as Clopidogrel (Plavix) or Ticlopidine (Ticlid) for twelve months and aspirin for life there are growing concerns that late developing thrombosis of stent could be a major complication for DESs. In order to overcome these problems and in recognition of the advantages of non-metallic implants, which would otherwise interfere with magnetic resonance imaging and multi-slice computerized CT scanning, researchers are developing new types of "bio absorbable" stents that may reduce or eliminate these risks" (Business Insight, 2010). "The BVS everolimus-eluting bio absorbable stent is the first AMS stent to have clinical and imaging outcomes similar to those following metallic DES implantation. The BVS stent has a polymer coating that contains and controls the release of the drug everolimus, which stops cells from reproducing by decreasing blood supply to the cells" (Shabto, 2011) (Figure 5.1).

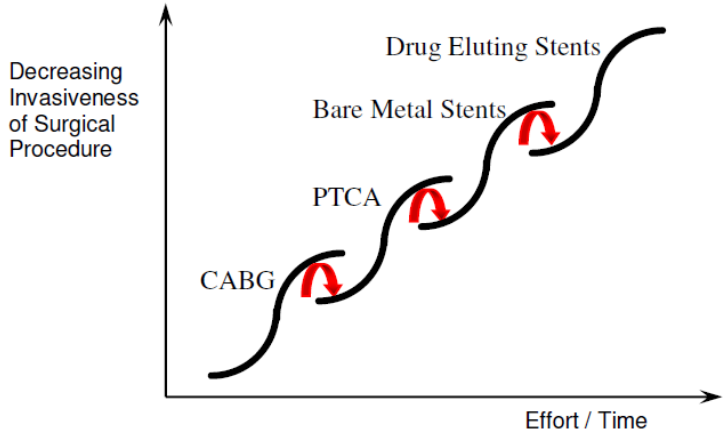


Figure 5.1. S&T Trajectories of CAD Treatment

BMS:

- Express Coronary Stent System
- Veriflex Bare Metal Coronary Stent System

DES:

- Promus Everolimus-eluting coronary Stent system
- Taxus Express Atom paclitaxel-eluting coronary stent system
- Taxus Express Coronary stent system
- Taxus Liberte Atom paxitaxel-eluting coronary stent system
- Taxus Liberte paxitaxel-eluting coronary stent system
- Taxus-Liberte Long paclitaxel-eluting coronary stent system

Table 5.5. Stent Innovation Trajectories of Boston Scientific

BMS:

- Absolute Pro LL Peripheral Self-Expanding Stent System
- Flexmaster F1 Coronary Stent System
- Multi-Link Frontier Coronary Bifurication Stent System
- Jostent Peripheral Bare stent System
- Multi-Link Mini Vision Coronary Stent System
- Ultra Multi-Link Coronary System
- Vision Multi LinkCoronary Stent System
- Multi-Link Zeta Coronary Stent System
- XPERT self-Expanding Stent System
- Zeta Multi-Link Coronary Stent System
-

DES:

- XIENCE V Everolimus-Eluting Coronary Stent System
- XIENCE PRIME Everolimus-eluting Coronary Stent System

Table 5.6. Stent Innovation Trajectories of Abbott Laboratories

BMS:

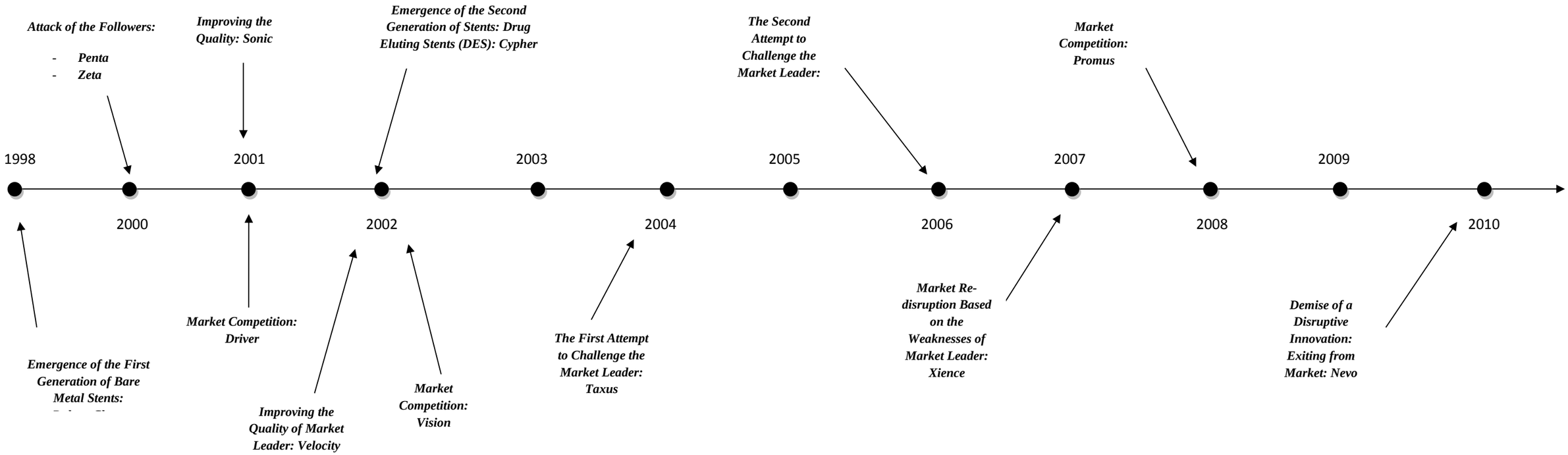
- Driver coronary stent system

DES:

- Endeavor Sprint Zotaralimus-eluting coronary stent system.

Table 5.7. Stent Innovation Trajectories of Medtronic

Case Study in Brief



Main Incumbents	*1998*	*2000*	*2001*	*2002*	*2003*	*2004*	*2005*	*2006*	*2007*	*2008*	*2009*	*2010*
Johnson and Johnson (Cordis)	• *Palmaz Chute*		• *Sonic*	• *Velocity* • *Cypher*								• *Nevo*
Abbott Laboratories		• *Penta* • *Zata*		• *Vision*					• *Xience*			
Boston Scientific						• *Taxus*				• *Promus*		
Medtronic			• *Driver*					• *Endeavour*				

5.3 Role of Public Sector in the Emergence of New Medical Techniques and the First Stenting Operation in Iran

According to the CEO of the Cordis franchise in Iran, the economic situation of the time (1980-1990) required that patients in need of bypass surgery had to pass procedural examinations to be eligible to be sent to England for their surgery. The required documents had to be submitted to the Committee of Medical Diagnosis for approval for a medical treatment trip, and the UK was the first destination of Iranian patients who needed to receive bypass surgery.

Moreover, no angiography operations were taking place in Iranian hospitals; however, diagnostic testing of heart problems was available. On this issue, one of Taxus' (one of Boston Scientific's main stents) launches manager states: "most heart conditions had been resolved through the use of drugs up until 1988. At that time heart conditions were diagnosed through exercise tests, and if the result was positive for a heart condition the patient would be sent abroad (mostly England) for angiography and further medication therapy. Because of the hard currency in the market, patients had to go to the medical committee for confirmation of the currency allocation. Therefore, it was a long process for those who sought a cure for their heart conditions."

Consequently, the government constituted an organization called The Currency Committee (TCC). The TCC's main mission was to provide treatment to patients by sending them abroad or importing the required medical devices for the healthcare professionals to accelerate the process of treatment. Regarding this issue, the technology manager of Cordis says that TCC used to obtain quotes from most of the cardiovascular market leaders to provide the required MDs for the healthcare centres, which at that time were mostly public. The committee was mainly dealing with Medtronic and Abbott Laboratories to provide the required cardiovascular solutions for the healthcare centres. Cordis did not collaborate with TCC, since they believed that TCC procurement procedure would merely satisfy the temporary demand of the market without making any base from which to diffuse S&T flows to build the market and intellectual capacity for further innovation diffusion activities. In other words, Cordis believed that it was better to invest in expanding the potential market rather than selling the products

to the current market. Therefore, Cordis worked independently, which was difficult initially because the committee had three major advantages over them. First of all, Cordis was working on a market which was being managed by the government. At that time, most of the healthcare centres were public and tended to buy their required products from public organizations such as TCC, rather than a private company like Cordis. Secondly, TCC were importing their products without paying any tariffs or custom duties. Moreover, they were not paying tax since they were a part of a public sector that was governed by the central government. These privileges helped TCC to reduce their costs, keep their prices reasonable, and enjoy a significant margin at the same time.

Initially, TCC was helpful and acted based on the their stated mission to facilitate the procurement of required MDs for the healthcare sector, but their patient driven attitude later shifted to a business oriented perspective, which was totally contrary to their initial values.

According to one of the Abbott Laboratories sales managers, TCC regulated the CV market before economic liberalization in 2000. Between 1985 and 1995, some of the healthcare professionals attained knowledge of stenting and PTCA intervention by attending seminars and conferences outside the country. They returned to Iran to practice what they had learned and diffuse the knowledge among the medical community. At the same time, coronary artery bypass graft (CABG) surgery was also becoming prevalent, a trend that continued until stenting and angioplasty clinically emerged among physicians in the 1990s. At that time there were not sufficient amounts of interventionists to perform this operation, however, by launching Palmaz-Schatz (the first BMS) in the Iranian CV market in 1996 many physicians were attracted to this new disruptive innovation.

Dr. Iraj Nazeri, who is considered the father of PTCA, stenting, and angioplasty in Iran, performed the first stenting operation in an Iranian hospital. He remembers those days, stating that "*in 1978 the first angioplasty was carried out by balloon. This technology took some time to be diffused around the world. In Iran, when medical students began graduating from medical universities, we were just able to perform angiography, which is a diagnostic operation rather than a treatment, and PTCA procedures used to be performed by balloons*."

During the Iran-Iraq War (1980-1990), Dr. Nazeri was hired by the Houston, Texas heart centre where he was educated about new PTCA procedures. Because of the war, there were no advanced medical devices in the country and Dr. Nazeri started to gather second-hand catheters, guide wires and balloons to take back to Iran. He was also the first doctor to implant the first stent in Iran. In 1986 Nazeri performed the first angioplasty operation by balloon at Tehran University, first opening a coronary vein then an aortic valve. He then taught many fellowships (medical students) to perform angioplasty. At the same time in the United States, the first bare metal stent (BMS) had been invented, though it was not available in Iran until the 1990s. Two years after the launching of the first stent in the US market, it was launched in the Iranian market.

According to the Cordis marketing manager, the period between 1998 and 2000 was the beginning of economic liberalisation and privatization in Iran. During that time the MD market competition surged when private companies joined the market. When the economic liberalization began to affect Iranian MDs, considerable amount of private companies joined the Iranian CV markets' competition. TCC, however, was not prepared at all for any such competition. For almost eight years TCC was exclusively in charge of providing MDs for the market without any competition, and, therefore, they did not have any strategy for competition in a competitive CV market. At the same time, according to Cypher's launch manager, private hospitals were growing during the economic liberalisation. Some private hospitals started to procure their required MDs themselves.

5.4. Emergence of the First Generation of Stents: Bare Metal Stents (BMS)

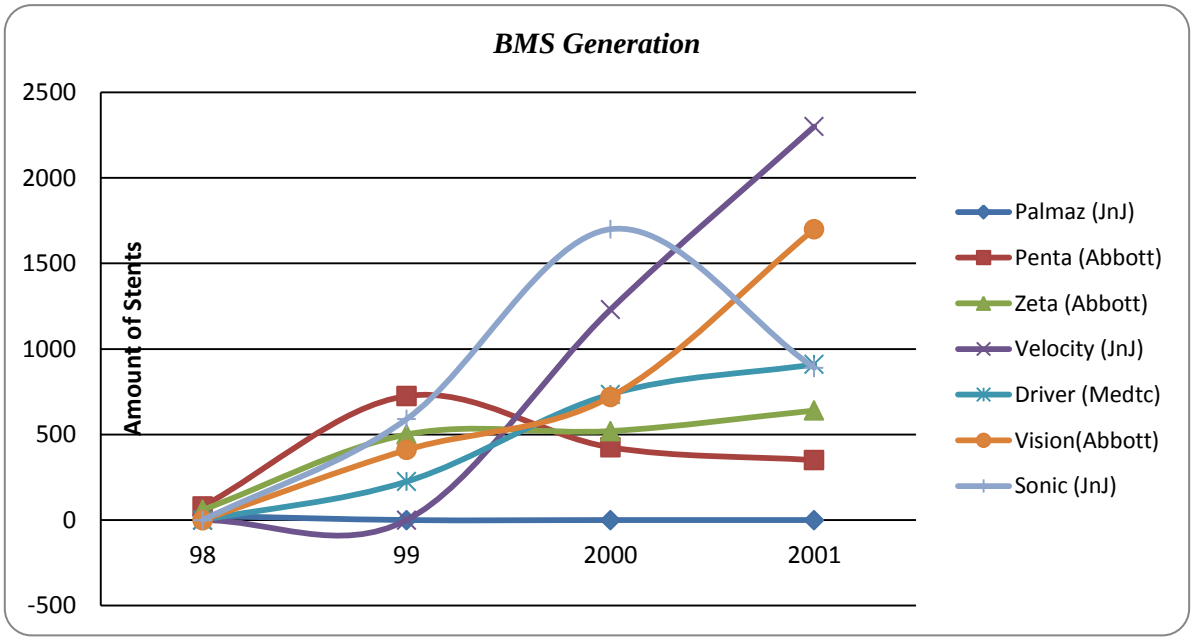
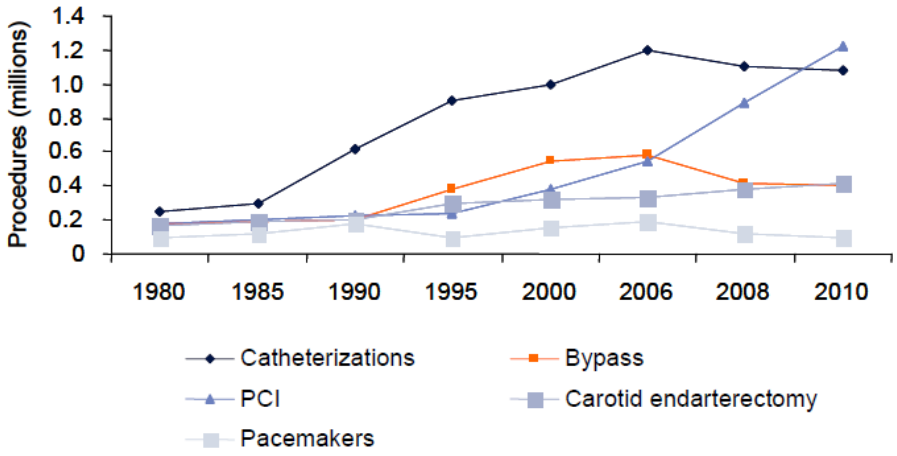


Figure 5.2. Diffusion of BMS in the Market (Iranian Health Ministry Report, 2005)

According to the Cordis franchise manager, Palmaz-Schatz was the first BMS stent, made by Cordis. It was the first stent launched in the CV market in 1998. Dr. Nazeri was the first practitioner in Iran to conduct the intervention operation in Iran. The first generation of BMS, specifically Palmaz-Schatz, were extremely expensive since they introduced a new technology to the CV market. Before stenting methods, angioplasty had been performed by the intervention of bare balloons. However, the rate of the vein recoiling was extremely high in balloon interventions. Therefore, the emergence of the stent as a disruptive innovation introduced a new performance value to the medical community. Keeping the blood vessels open after angioplasty was the new performance value of this innovation, and stenting was a new practice which destroyed the CABG's competencies in the CV market. The Palmaz-Schatz stent was followed by new versions of BMSs from Cordis (Sonic and Velocity) and by the other competitors such as Guidant (Penta and Zeta). Guidant was a company that later merged into Abbott and Boston Scientific (Figure 5.2). The CEO of Abbott from the Iranian branch states that owing to the M&A contract between Abbott and Guidant, Abbott launched their new BMS to the

market. Abbott laboratories launched many different generations of BMS in the CV market, such as Tetra, Tree star (which were both from the multilink family), Penta, Zeta, Vision, and Emulate, which was the eighth generation of Abbott's BMSs (more detailed information on Abbott's BMSs can be found in Table 5.5).

Figure 5.3 **Trends in cardiovascular operations and procedures in the US, 1980–2010**



Source: American Heart Association; Business Insights

BUSINESS INSIGHTS

As demonstrated in Figure 5.3, there is a regression between the rate of PCI and catheterization procedure in Iran and the US. While the rate of catheterization and PCI has been increasing during the last ten years, the rate of CABG surgery declined from 2002 in both countries.

Cordis' sales manager explains that not long after the first generation of BMS, Cordis was able to maintain the lead in the market by releasing Sonic as the second generation of BMS. It was more flexible than the other stents, and because of the successful trial results, Sonic was able to keep Cordis' leading position in the market. The competitive advantage of Sonic was its unique design that made it more flexible. Moreover the sales manager says: "*According to many criteria such as the number of published papers in international conferences and the S&T trajectories of CAD treatment, knowledge of physicians and their absorptive capacity of new technologies should be considered as at the same level as Europe. The market benefits from a scientific structure and the physicians' decisions are made scientifically. Since stenting is classified within the recently emerged knowledge, all the*

cardiologists and interventionists are equipped with up to date knowledge. This stenting and CAD treatment has over twenty-two years of history."

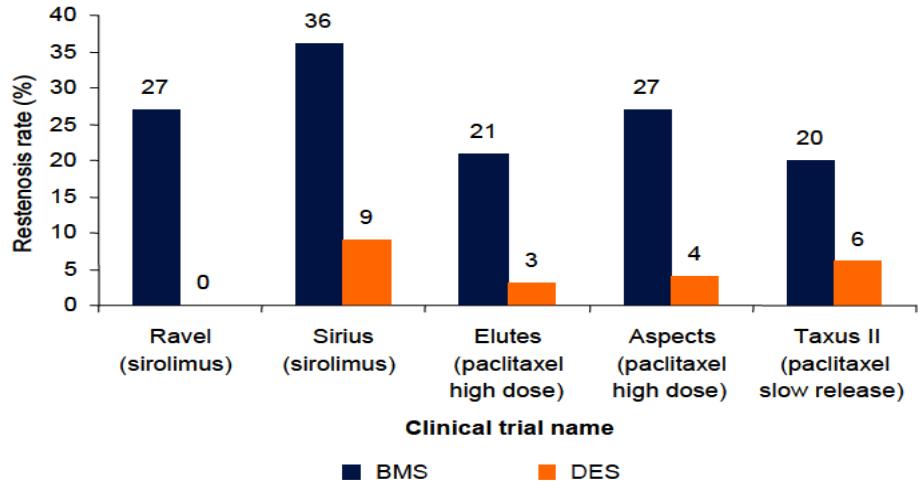
Dr. Nazeri (the father of stenting in Iran) states: "*After BMS became more prevalent in the Iranian market, many other followers attacked this newly founded market. However, some tried to demonstrate different sets of performance values to be delivered to the market. For instance, Medtronic focused on the small narrow vein stents, while Cordis was working on CAD's special cases treatment. Therefore, the quantity and types of BMSs increased and different generations of BMS emerged in the market. The only problem was the high rate of restenosis,*[2] *which was 30-40%. I attended various conferences in order to increase my knowledge and bring it back to the country. Each year at these conferences, new BMSs along with their trial results were introduced to the medical society. However, the problem of restenosis continued. Within three to four months after an operation, some patients returned with chest pain and angiography determined that angioplasty was required again."*

Therefore, as is evident from these quotes, after the emergence of the BMS in the cardiovascular market by Cordis, other followers entered the market to challenge the fragile dominant position of Cordis. Nevertheless, the BMSs' deficiencies, such as the significant rate of restenosis, opened new opportunities for the emergence of new DIs, which changed the dynamic of the market later on.

Dr. Kazemi-Saleh, a well-known Iranian cardiologist, believes that the rate of restenosis offered an opportunity to introduce a new performance value to the market by a potential disruptive innovation. According to Dr. Kazemi-Saleh, R&D sections were studying new innovations to reduce the rate of restenosis. Finally, Cordis invented a disruptive innovation, and after two years became the market leader in the Iranian cardiovascular market. Cypher was the first drug eluting stent (DES) in the world which reduced the rate of restenosis by 10-15% (Figure 5.4). Dr. Nazeri was the first doctor to intervene with DES in Iran in Day Hospital in Tehran in 2002.

[2] This literally means the reoccurrence of *stenosis*, a narrowing of a blood vessel, leading to restricted blood flow. Restenosis usually pertains to an artery or other large blood vessel that has become narrowed, received treatment to clear the blockage, and subsequently become re-narrowed (Hamid, 2007).

Figure 5.4 **Randomized clinical trials showing reduced rates of restenosis with DES**



Source: Lemos et al., 2003

BUSINESS INSIGHTS

A Cordis technology manager explain the dynamic of the BMS market after the emergence of Cypher as the first DES in the Iranian market: "*The other incumbents obtained some significant shares of the BMS market, since Cordis was focused on the newly founded DES market, and the BMS market was the only market that they could work since they did not have DES technology. The dynamic of competition for the other competitors was mainly focused on the BMS market, while Cordis basically concentrated on DES and catheterization device markets. When Cypher was launched in the Iranian market in 2002, only five interventionists adopted it, which should be considered as a few diffusion nodes to start the process of market diffusion. Initially, there was some resistance to the use of DES by younger physicians with less experience. On the one hand, they wanted to intervene stents in cardiac cases. On the other hand, since DES was more expensive than BMS, they decided to use BMS in order to avoid further cost in case of failure in the stenting operation.*"

Cordis' marketing team manager in Iran mentions that Velocity, the last BMS of Cordis, was a great progression in stent design, however, the emergence of Cypher as the first DES downplayed the importance of Velocity's technical capabilities. The manager continues: "*In 2003 and 2004 Cordis experienced an unexpected volatility in selling Velocity to the market. Velocity's technical capabilities,*

such as a flexible platform and well performing balloon which kept the heart veins open efficiently, were superior. But since Cordis was more focused on the DES market, the other incumbents grabbed more market shares by constant improvement of their BMSs."

There were two important issues which changed the dynamic of the CV stenting market significantly during the DES generation: the battle of trial results and supportive documents, and the eminent M&As accelerating the process of market diffusion. In fact, the importance of pre-market trial results was not elucidated during the BMS generation in the same way that it was later on in the DES era. The battle of trial results during the DES era totally changed the dynamic of the stenting market, as we will discuss in the next section. In addition, the significant number of M&As (shown in Table 5.8) changed the dynamic of actors' interaction in this market.

Major Mergers and Acquisitions (M&A) of DES Market
• Acquisition of Guidant by Boston scientific (2006) • Acquisition of Conor Co stars by Cordis (2007) • Acquisition of Setagon by Medtronic (2007) • Acquisition of Lab coat by Boston Scientific (2009)

Table 5.8. Major M&As in DES Market

The Boston Scientific sales manager indicates that during the BMS generation trial results were not important factors since knowledge of stenting was still in its infancy. Nowadays, the developments of stenting technologies necessitate the emergence of many different trial results to check the devices' technical capabilities from different aspects. The most authenticated trials were run after 2003. The complexity and capabilities of these trials has been evolving over the years, as the measuring tools of these medical devices' technical capabilities. A Medtronic marketing officer confirms this idea and states that when the DES came to the market, the trial results were highly developed. In fact, the emergence of the BMS led to the evolution of running trials, and during the next generation of stents (DESs) these highlighted the significant differences between these two generations, as shown in Figure 5.5. Between 2003 and 2005 the usage of DESs vastly outnumbered the diffusion of BMSs.

When Cypher came to the market, it led to the radical decrease in the usage of BMSs. In other words, enjoying the advantage of being the first mover, Cypher established a new market besides the BMS market.

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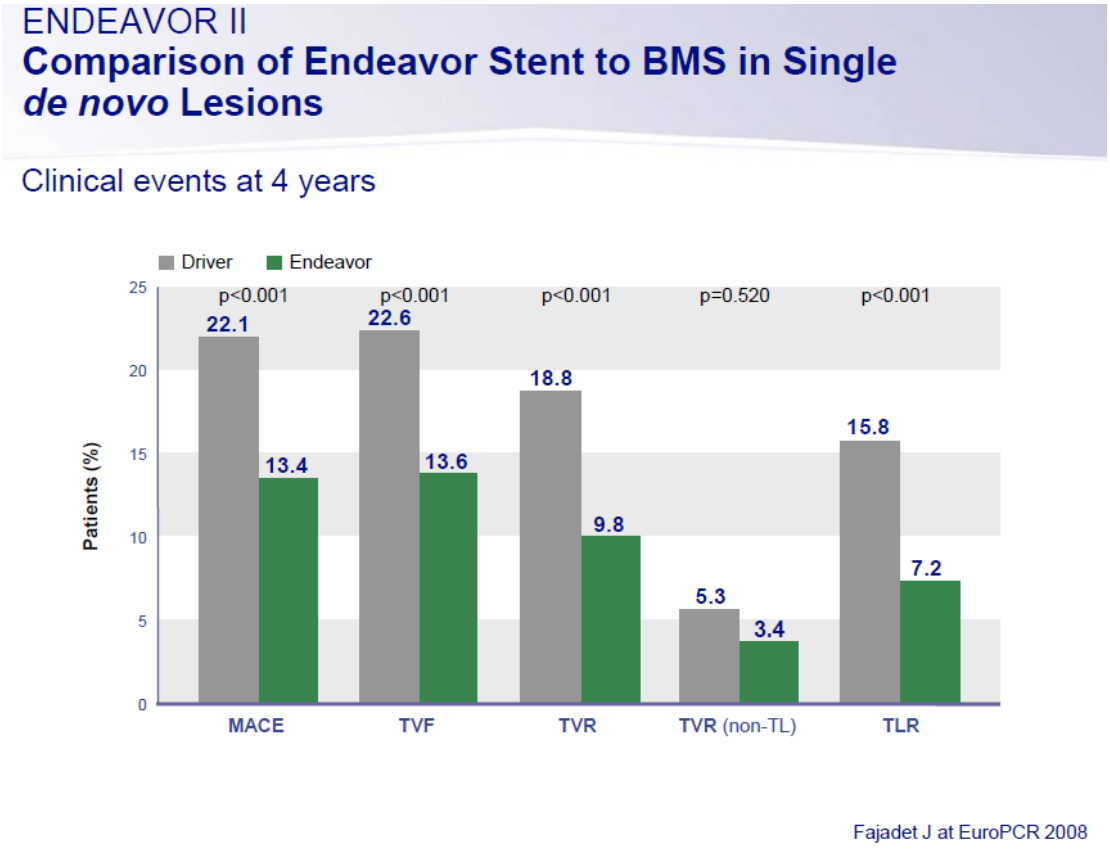


Figure 5.5. Results of Premarket Trials to Compare BMSs and Endeavor

5.5 The Emergence of Drug Eluting Stents (DES) in the Market

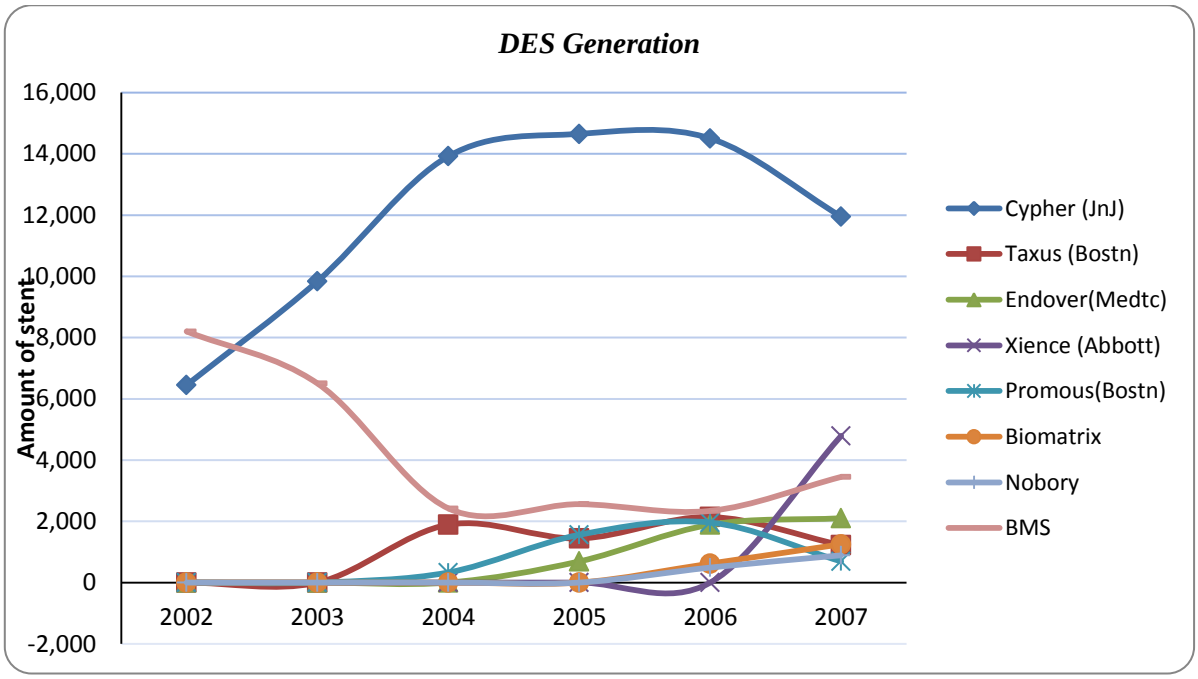


Figure 5.6. Diffusion of DES in the Market (Iranian Health Ministry Report, 2009)

From 2000, Abbott laboratories had been working intensively on the DES generation and planned to produce the first DES in the world. However, in spite of creating a successful prototype they could not achieve this goal. On this subject, the CEO of the Iranian branch of Abbott states: "*Guidant was supposed to make a DES called Champion. However, after the acquisition of Guidant by Abbott, many clinical trials were conducted and since the results didn't meet the standards to get the required market launch approvals, Abbott failed to launch it to the market. At the same time Cordis was experiencing successful clinical trial results which let them launch the first DES into the market in 2002*." A Cordis technology officer confirms the abovementioned claim. Although Cordis launched the first DES in the market, and to some extent disrupted the BMS market, Abbott laboratories also had the chance to do so. Indeed, Cordis' pre-emption to disrupt the market postponed the launch of Champions by Abbott for almost four years.

The emergence of the DES in the stenting market was revolutionary for the consumption patterns of the BMS market. The DES had introduced new performance values to the market which enabled it to disrupt the BMS market by shrinking the BMS market shares after two years. The DES reduced the risk of restenosis by 23%, and due to its significant flexibility, the average number of stents needing to be replaced after intervention dropped tremendously.

Reduced occurrence of restenosis	The use of DESs has brought down the risk of restenosis from 28.8% to 5.8% (Lomos et al., 2003) thus making minimally invasive PCI procedures an attractive alternative to CABG.
Reduction in the average number of stents needing to be replaced	The average number of stents placed per procedure has reduced from 4.5 in the case of BMSs to 1.7 for DESs (Hirshfeld et al., 2004).
Increase in the final lumen diameter	Owing to the reduction in restenosis rates of DES, a longer stent length can be used, thus allowing for a greater increase in luminal diameter and preventing post-operative complications such as the reduction of blood-pressure owing to the narrowing of the arterial wall.
Decrease in target vessel revascularization (TVR)	The use of DESs reduces the risk of TVR from 13.4% to about 5.6% (Laarman et al., 2006).
Diversification to treat multiple conditions	The DES can be combined with multiple drugs to treat a variety of conditions such as cardiac arrhythmias

Table 5.9. Newly Introduced Performance Values by DES

As Table 5.9 shows, an increase in the final lumen[3] diameter, a decreased rate of TVR, and the treatment of multiple conditions are the newly introduced performance values of the DES. These performance values encouraged the physicians to follow the trial results of the DES and study further the associated risk of DES intervention. However, it took more than a year for the market and physicians to rely on this new innovation and adopt it. As is shown in Figure 5.6, the high cost of the DES compared to the MBS, as well as the unknown performance values of the DES for the market were the major reasons preventing the diffusion of the DES during the initial stages of the launch.

[3] In biology, a lumen is the inside space of a tubular structure, such as an artery or intestine

However, the battles of premarket trials, the evidence of late thrombosis and the associated problems with DES reimbursement in healthcare systems (Table 5.10) later on in 2005 and 2006 decreased the rate of DES adoption, as shown in Figure 5.7.

Drivers of DES Adoption	***Resistors of DES Adoption***
• Prevention of late in-stent restenosis • Decreased need to repeat the procedure • Demographics - rise in mean age of the population • Lifestyle changes – increased prevalence of obesity	• High cost of DES compared to BMS • Release of the adverse clinical data pertaining to late stent thrombosis • Release of COURAGE data indicating no significant advantage of DES over BMS • Problems associated with Medicare reimbursement of DES

Table 5.10 New Drivers and Resistors of DES Adoption

According to the Cordis franchise manager in Iran, Cordis was the market leader in the BMS market when they were developing Cypher to disrupt the market. Not only did Cordis not cannibalize its own market share, they shifted their current customers to a new market which emerged from the disruption of the BMS market. Focusing on the DES market caused Cordis to lose its dominancy in the BMS market, which brought more opportunities for other followers. The DES received a warm welcome from Iranian physicians, and some hospitals wanted to use it regardless of its unforeseen associated risks. At the same time, the BMS technologies were being improved in order to keep in competition with DESs. For instance, while the core material of Sonic was made of stainless steel, the new generation of BMS was made of chrome-cobalt, giving it a competitive edge over the older generation. Chrome-cobalt stents were more flexible than the stainless steel stents, and their trial results were excellent. The first Chrome-cobalt stent which took the leading position in the market from Sonic was "Driver" by Medtronic. "Vision" was another chrome-cobalt stent made by Guidant (which later merged into Abbott). Meanwhile, Cordis was working on new technology to disrupt the mainstream market, which was the BMS market at that time.

When Cypher launched into the Iranian market, the rate of diffusion in private hospitals was significantly higher than in other types of hospital due to the DES's high prices and the healthcare system's reimbursement problems. Nevertheless, the rate of restenosis decreased radically, making the stenting procedure more effective. The new performance values of the DES in technical capabilities decreased the perceived risks of stenting by patients and had a direct effect on the physicians' reputation. Consequently, well-known physicians began to adopt the DES in their stenting operations. Therefore, the diffusion of the DES increased radically by the pioneering of the private hospitals in 2003.

In 2004, Boston Scientific launched the second DES in history (Taxus) to the market, while Cypher was in the latest stages of receiving FDA approval. Although Taxus was supposed to challenge Cypher's leading position in the market, Cypher was still the undeniable leader owing to its first mover advantage. This time Cypher did not face the same challenges as with Palmaz-Chute, since the required technical competencies were already there, and the emergence of DES was not competence destroying.

Although the DES can be considered a DI, it did not lead to destruction of the BMS market for several reasons. A Medtronic sales manager states: "*From 2002 to 2005 the use of the BMS didn't decline much due to the complex reimbursement procedure of DESs. In developed countries, because of the significant trial results, the consumption of the DES increased dramatically while the rate of BMS adoption dropped drastically during the mentioned time span. The higher price of the DES was not an issue for the consumers in developed countries as it was for the Iranian clients due to the private healthcare reimbursement system in Iran. But in Iran and the other developing countries, since most of the healthcare expenditures are a burden on the patients, the market is more price elastic. Therefore, the higher price of DESs acted as a hindrance to diffusion of the DES.*"

After a year and a half in the leading position in the DES market, Cypher saw a new competitor in the market. Boston Scientific released new comparison trials with Cypher, attempting to compare Taxus with Cypher. Taxus attacked the DES market by challenging Cypher, but the results of the

comparative trials were disappointing for Boston Scientific. As it can be seen from Figures 5.7, 5.8, and 5.9, the results of the comparative clinical trials between Cypher and Taxus proved the higher position of Cypher in terms of technical capabilities. It was some well-structured marketing strategies and some costly promotion plans which helped Taxus stay in competition. Boston Scientific spent a huge amount of money to send the healthcare professionals to several conferences and seminars as part of their promotion plans. However, Cordis responded to Boston Scientific's heavy marketing campaign by investing more to improve sales services.

	Study Type	n	F/U	Primary outcome	Magnitude of Benefit
ISAR-DIABETES Dibra A. et al. NEJM. 2008;353;663-70	RCTs Enrolling only Diabetic Patienets	250	6-8m	Sig.Red.in in-Segment LL	36%
Korean RCT Kim MH, et al, J Interven Cardiol. 2008;21:225-231		169	6-m	Trend for less in- Segment LL	33%
DES- DIBETES Lee S-W.et al. JACC 2008:51;1181-87		400	2-y	Sig.Red.in 9-month in –stent LL	75%
DiabeDES Jensen L, et al. Eur Heart .J.2008; e-Publication Oct 2, 2008		130	8-m	Sig.Red.in 9-month in –stent LL	100%
Italian W/in Pt RCT Tomai F.et al, Diabetes case. 2008 :31 15-19		60	8-m	Sig.Red.in in-stent LL	48%

Figure 5.7. Comparative Trial Results of Cypher and Taxus

Indeed, Cordis' strategy was to invest in sales services capabilities and increase perceived performance values by physicians. For instance, before the emergence of Xience in the DES market in 2006, the expiry date of the DES was extremely short (approximately one month), and, therefore, most of the incumbents were reluctant to keep large inventories. Therefore, they could not satisfy the demand of the market all the time. However, Cordis considered this market deficiency an opportunity

to deliver a new service to the market. They introduced a new sales service based on their inventory management; they kept sufficient amount of stents in stock and built a fast delivery system to avoid any stent expiry. Sometimes, a product was transferred between different hospitals eight times

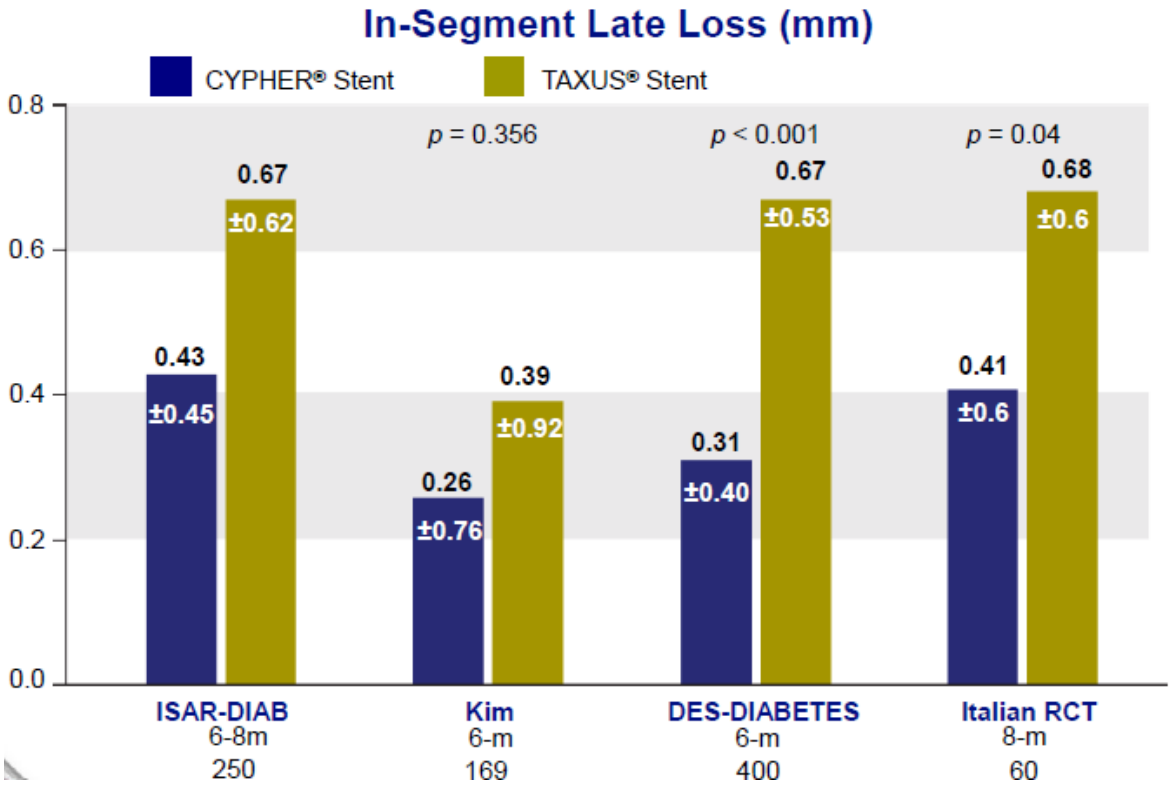


Figure 5.8. Comparative Trial Results of Cypher and Taxus

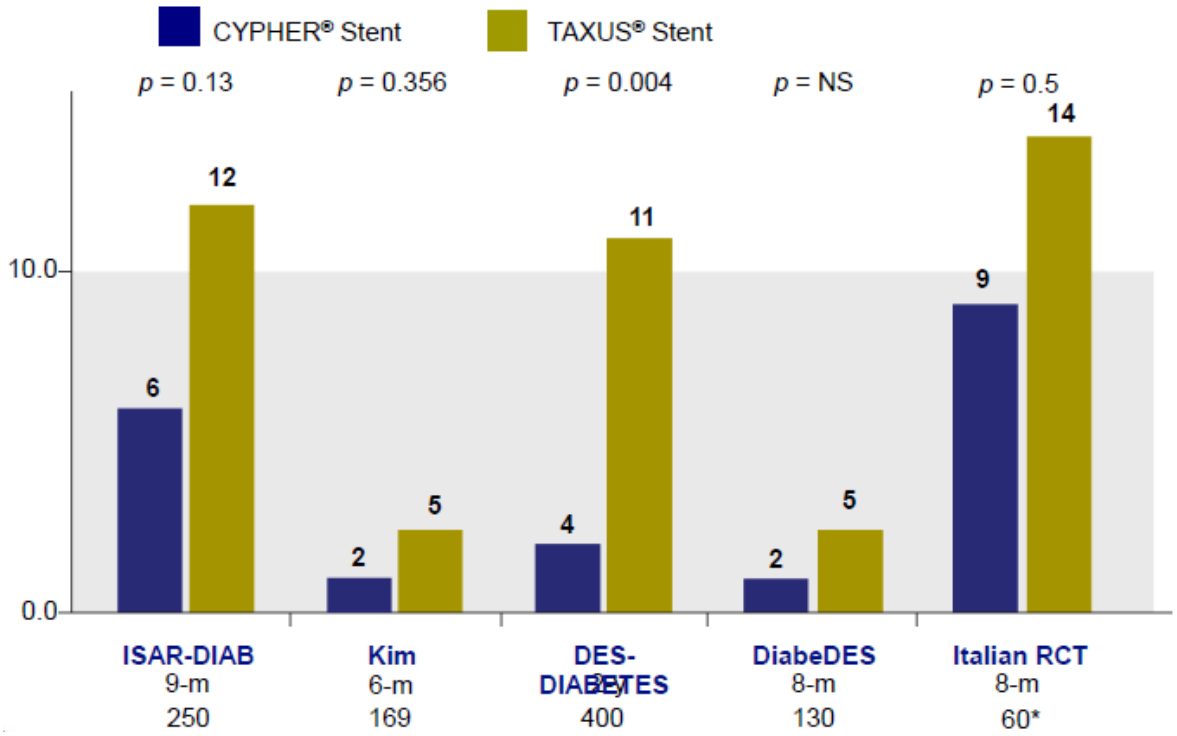


Figure 5.9. Comparative Trial Results of Cypher and Taxus

before being used in an operation. Consequently, these kinds of sales services increased the effect of perceived performance values, which had until this point been based solely on Cyphers technical capabilities. Hence, the synergy between Cypher's technical capabilities and the associated sales services gave Cypher an invincible position for almost four years.

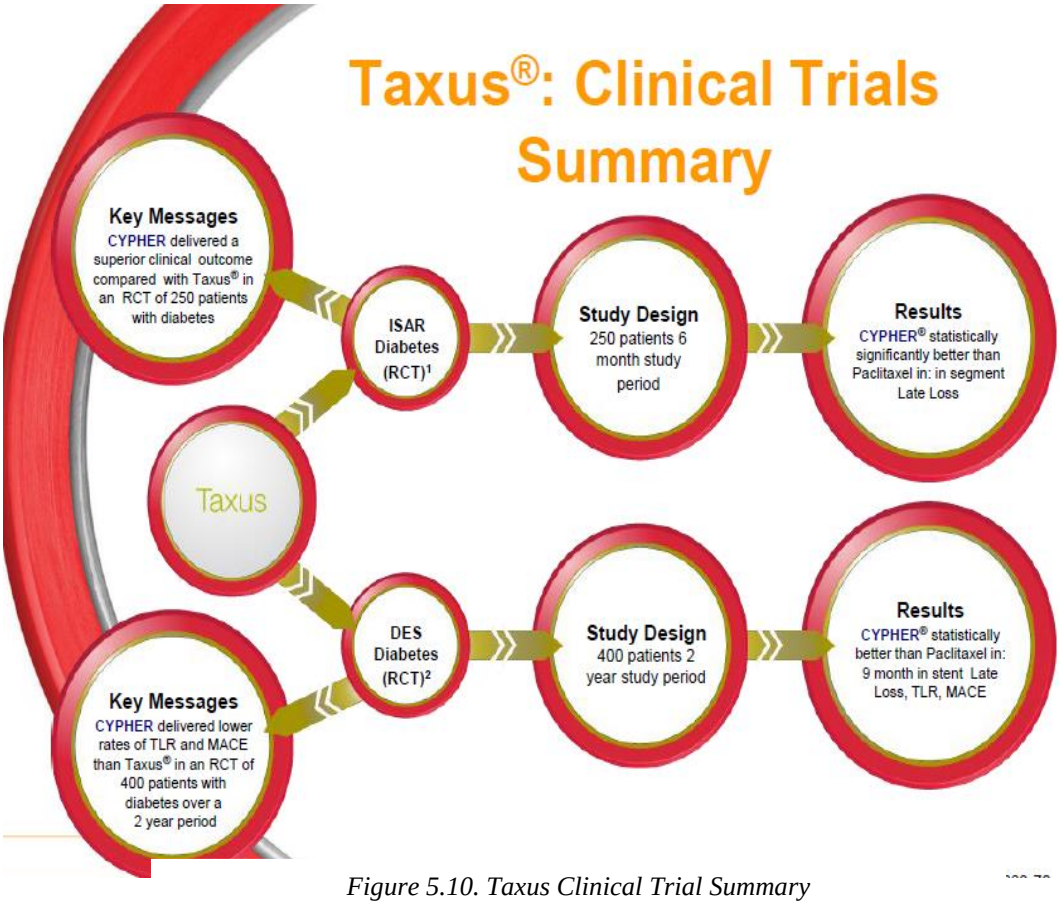


Figure 5.10. Taxus Clinical Trial Summary

Concerning the first trial results battle of the DES market, Dr. Kazemi-Saleh, a famous Iranian interventionist, states: "*Cypher was introduced into the market by Cordis and disrupted the market relying on its technical capabilities. From its initial launch time, Cypher seized the market and saw exponential sales growth. Cypher's low rate of restenosis prevented Taxus from getting into the leading position (Figure 5.10). Cypher's quality was significant. When the rate of restenosis is low perhaps the rate of thrombosis and late thrombosis will increase in future. Although Cypher was one of the best DESs, it had some deficiencies as well. For instance, it was not flexible enough for the complex cases*." Dr. Nazeri also stated that after two years, Boston Scientific introduced Taxus on the market claiming that Taxus was better for diabetic patients because the rate of drug absorption was lower than that of Cypher (Figure 5.11).

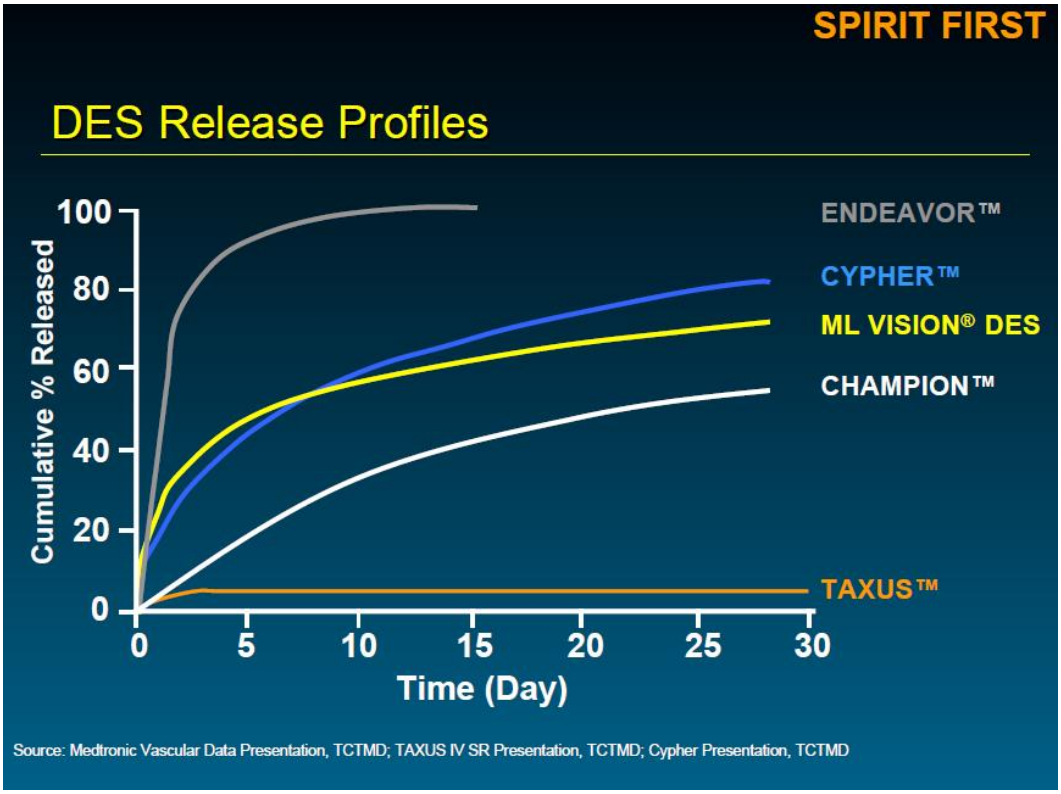


Figure 5.11. Comparison Rate of Drug Release in DESs

However, Boston Scientific managed to keep their small market shares in the DES market due to their marketing strategies; they manipulated the perceived performance values of the market and made some modifications to enhance their technical capabilities. A sales manager of Abbott laboratories states: "*Boston Scientific had other survival strategies. They put more effort into their marketing strategies. At the same time, Boston Scientific decided to manipulate the perceived performance values of the market by comparing their trial results to BMS performance. However, since Taxus lost the trial competition to Cypher, Boston scientific decided to find another competitive advantage to keep the competition. Since Taxus' restenosis rate was higher than Cypher, Boston Scientific produced accessory tools associated with Taxus to improve the rate of restenosis: a balloon called NC. This architectural innovation opened up the market for NC balloons and also improved the results of Taxus' clinical trials.*"

For almost four years Taxus had been competing with Cypher in several comparative clinical trials, but could not show any superior performance value over Cypher. One of Cypher's promising

competitive advantages was its eluted drug Sirolimus. In fact Sirolimus' efficiency was one of the core competencies of Cypher in competing with the other incumbents and newcomers (Table 5.11).

Product name	Company name	Approval	Drug eluted	Innovative feature
Endeavor Resolute	Medtronic	CE mark 2007, PMA 2012 (E)	Zotaralimus	Improved Polymer
XIENCE Prime	Abbott	CE mark 2009, US trials ongoing	Everolimus	Improved deliverability
Promus Element	Boston Scientific	CE mark 2009, PMA 2012 (E)	Everolimus	Improved deliverability and lesion coverage
Taxus Element	Boston Scientific	CE mark 2010, PMA 2011 (E)	Paclitaxel	Improved flexibility and deliverability
Resolute Integrity	Medtronic	CE mark 2010, PMA 2013 (E)	Zotaralimus	Improved polymer and deliverability
Nevo	Cordis	CE mark, Submitted in 2010	Sirolimus	Reservoirs with polymer- matrix
BVS	Abbott	CE mark 2011	Everolimus	Bio absorbable stent
Synergy (Evolution	Boston Scientific	EU Trials ongoing	Everolimus	Bio absorbable polymer

Table 5.11. Eluted Drugs of DES between 2002 and 2010

It is worthwhile mentioning that only Cordis had patent protection over Sirolimus, while Boston Scientific had no patent protection for Paclitaxel. This unprotected patent of Taxus' eluted drugs enabled the other competitors to generate their own drug based on paclitaxel and invade the DES market. At the same time the followers of Cordis, such as Abbott, attempted to use similar drugs to Sirolimus such as Everolimus and Zotarolimus. As a result, the new generation of DESs were launched into the market, such as Endeavor by Medtronic and Xcience by Abbott in 2007. Medtronic eluted the structure of Driver (their famous BMS) with Zotarolimus and launched it into the market with the name Endeavor Resolute. These imitations and the intellectual property right (IPR) issue mentioned earlier increased the number of incumbents in the market in early 2007. These newcomers

mostly followed Taxus' strategy to gain their position in the market by conducting comparative clinical trials with the market leader. In the first comparison trials of Endeavor vs. Cypher, Medtronic tried to show greater performance values and technical capabilities over Cypher, which was a failure (Figures 5.12 and 5.13).

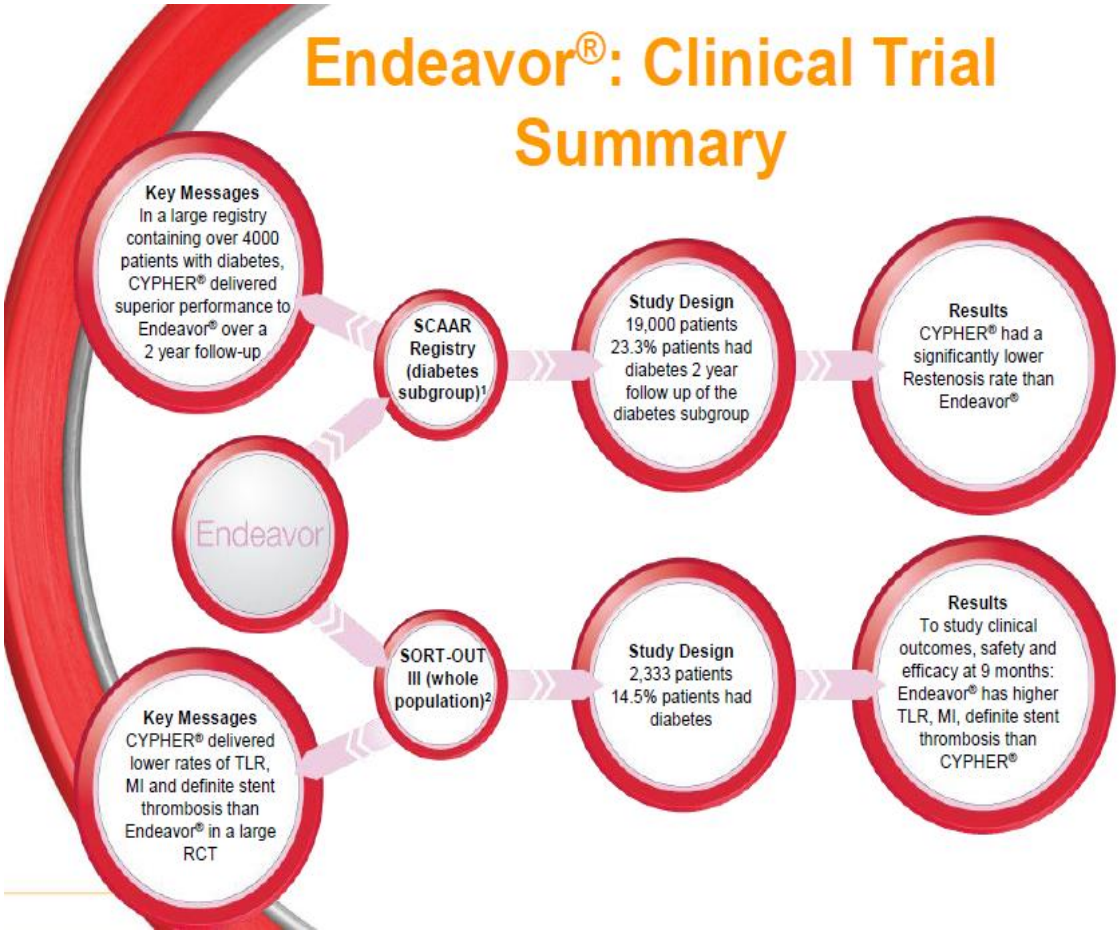


Figure 5.12. Comparative Trial Results of Cypher vs. Endeavor

A Medtronic sales manager notes that Medtronic decided to enter the DES market after losing a significant share in BMS market. He states: "*Losing the BMS market share had ruined Medtronic's reputation in the market. Therefore, we decided to move to the DES market seeking new opportunities. Therefore, we conducted a comparative clinical trial between Cypher and Endeavor. We were confident on the assumable results since we were seeing benefits from or chrome-cobalt metal stent frames. However, the trial results were absolutely disappointing*." Medtronic's prime goal was to win

nearly 30% of the market, but they did not win more than 10%. The restenosis rate of Endeavor was more than 12%, which was its main drawback (Figure 5.13).

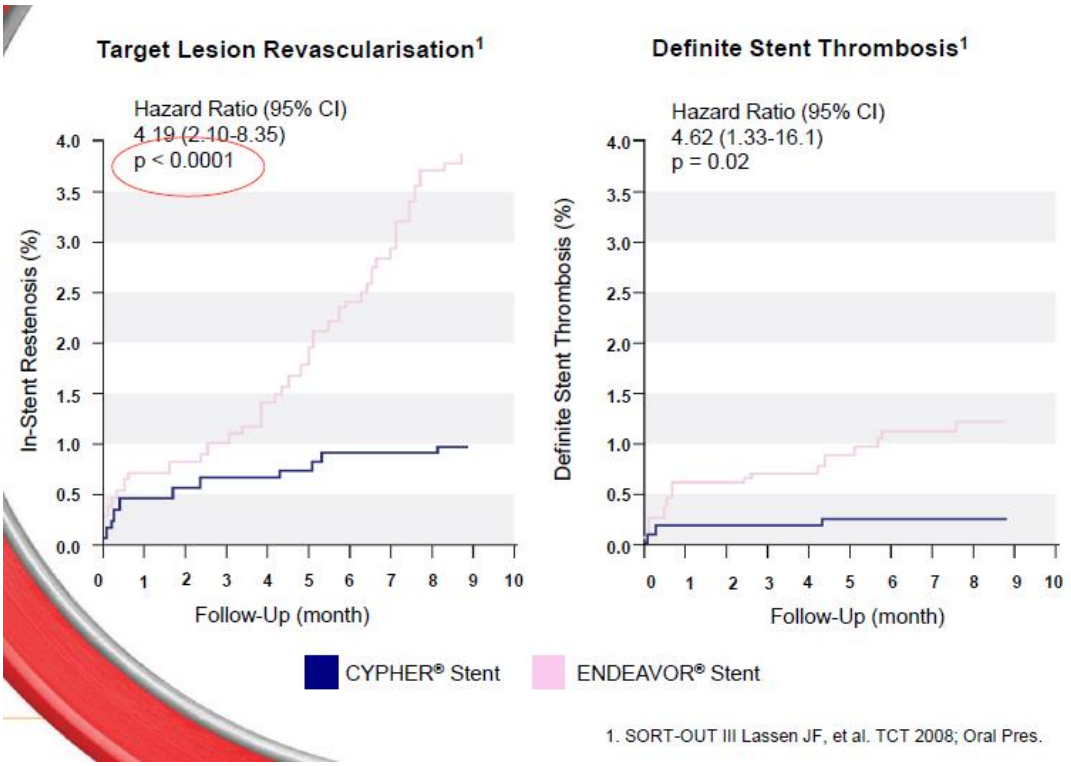
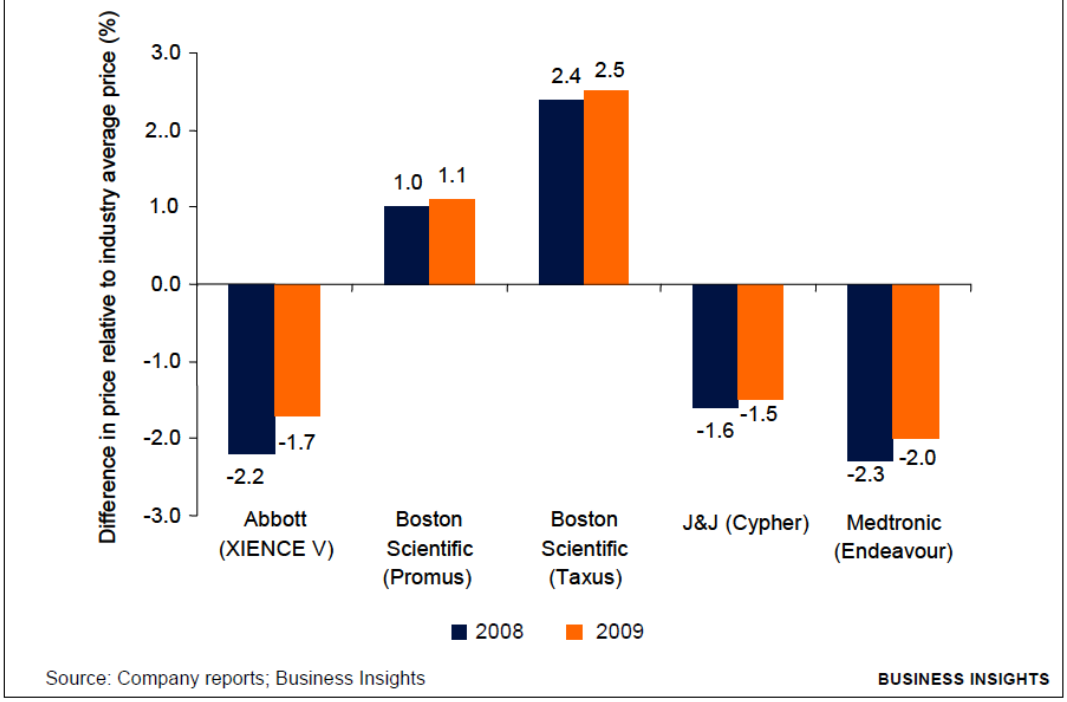


Figure 5.13. Comparisons of TLR and Thrombosis in Cypher and Endeavor

Endeavor was the third DES in the market which had a great impact on the dynamic of the DES market. By joining the DES market, Endeavor reduced the average prices of available DESs in the market (Figure 5.14), and the conduction of several clinical trials with Endeavor by Medtronic led to the exploration of another criterion for checking a DES's technical capabilities: Thrombosis. Therefore, although Endeavor caused a high rate of restenosis it held considerable records on thrombosis reduction.

Therefore, Medtronic decided to conduct several comparative clinical trials to compare Endeavor's thrombosis rate with the other available DESs in the market to demonstrate Endeavor's performance values (the reduced rate of thrombosis). At the same time, Medtronic improved the drug release period of Endeavor (Figure 5.11), which enabled them to keep their 10% market share.

Figure 5.14 **DES price differences relative to the industry average price (%), 2008–**



Source: Company reports; Business Insights BUSINESS INSIGHTS

Therefore, Medtronic introduced new performance values to the market in order to shape the dynamic of the market to their own benefit. In fact, results of the clinical trials by Medtronic on thrombosis changed the dynamic of the market and convinced the market to return to the consumption of BMSs which had not caused thrombosis before. An Abbott sales manager states: "*From 2005 to 2006, when the clinical trials showed some late thrombosis problems in DESs, the rate of BMS consumption slightly increased in the world. But as a result, scientists found that DESs shouldn't be considered as a substitute for BMSs. In fact, they are two different stents that should be used in situations based on a patient's problem.*"

Thus the new clinical trials got BMSs back into the competition. Allegedly, many cardio surgeons were behind these clinical trials, since the BMS market was shrinking and thus many relevant surgical competencies were about to be useless. Since 2006 the medical protocol of cardiologists was changed slightly, and DESs were employed only for specific cases. Better collaboration between surgeons and cardiologists facilitated the diffusion of both BMSs and DESs. Cardio surgeons are usually vascular surgeons who may gain cardio related expertise as well. However, interventionists are cardiologists

who have expertise in intervention surgery. By attending different cad labs, all cardiologists could carry out angiography operations, but to perform stenting operations complementary courses on intervention were required.

In 2006 two major incidents affected Cypher's dominant position in the DES market. First of all, Guidant, which was a strong incumbent in the BMS and DES market merged into Abbott Laboratories and Boson Scientific, two main competitors of Cordis. In fact, Guidant had planned to merge with Cordis, and, therefore, Cordis did not prepare any strategic plan to compete with Guidant. Thus, this unforeseen M&A ruined the strategic plan of Cordis to keep Cypher's dominancy in the DES market. This M&A not only destroyed Cordis' strategic plan, but also increased the potential technical capabilities of Abbott and Boston Scientific. Another incident that harmed Cypher's reputation in the market was the product recall of Cordis in 2006 due to some technical deficiencies. These two incidents created an opportunity for a strong incumbent to attack the dominant position of Cypher in the DES market.

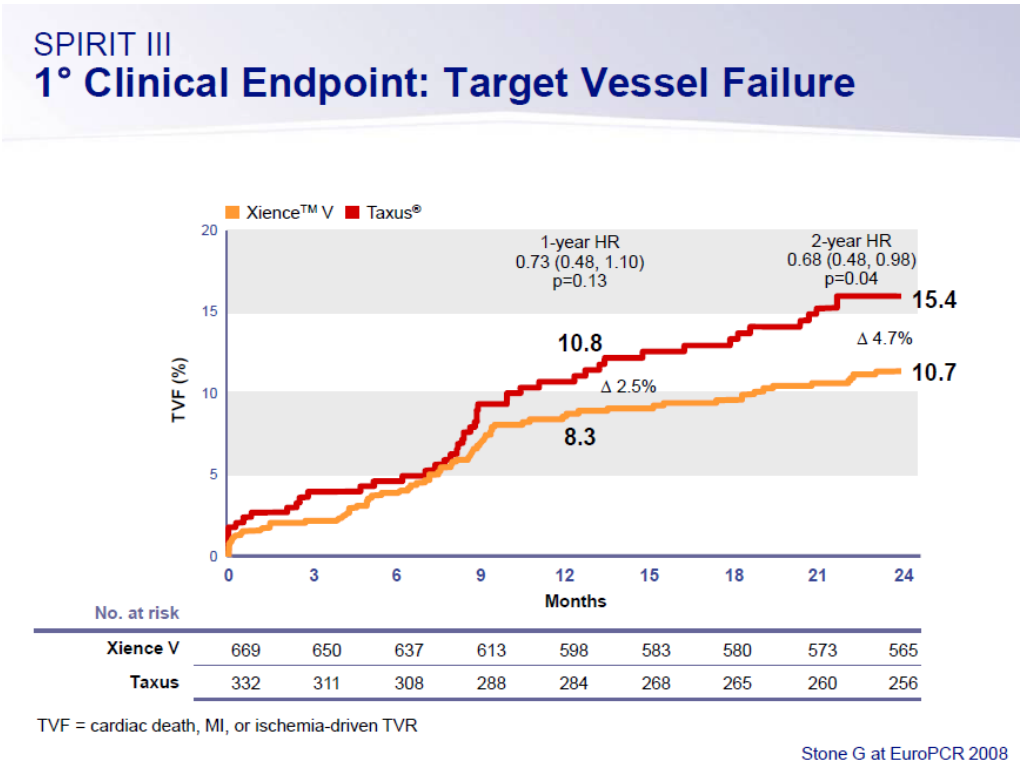
In 2007 Abbott Laboratories launched an advanced version of a DES called Xience. Abbott laboratories benefited from a late mover advantage, and waited four to five years, identifying the market gaps to introduce new performance values. Abbott had been investing in a breakthrough performance and had increased Xience's technical capabilities. As a result, Xience demonstrated significant performance values, such as significant decrease in restenosis and thrombosis rates, its flexibility in practice, and its extended life time. These performance values changed the dynamic of the market again, and different incumbents reacted immediately. Cordis targeted special niches in the market and produced a DES for specific cases, including diabetic patients and multi-vessel diseases.

After 2008 the number of DESs increased radically, as most of the newcomers had obtained the technology since 2002. For instance, Terumo came to the market with its new product Nobory. Obviously, when the amount of competitors increased in the market each company's shares declined.

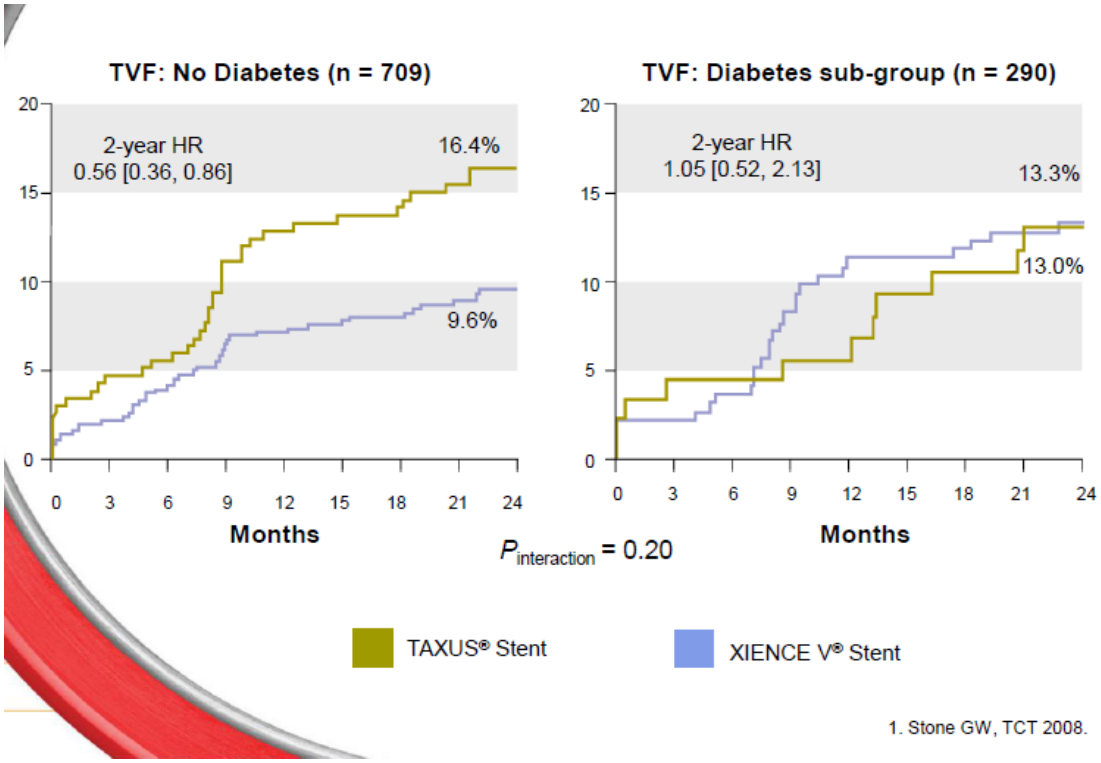
According to Abbott's technology officer, Xience made its platform from cobalt-chrome, making it softer and more flexible than Cypher. This alloy also helped the stent to release the drug more

efficiently. Abbot believes that the drug-releasing capability was the most significant competitive advantage of Xience over Cypher. The findings show that Xience had a significant adoption take-off. In addition, Xience had a one-year shelf life, while Cypher expired after one month. Although the results of the clinical trials for Xience was not tangibly better than Cypher's, the introduced performance values of Xience soon enabled Abbott to take the market leading position from Cordis.

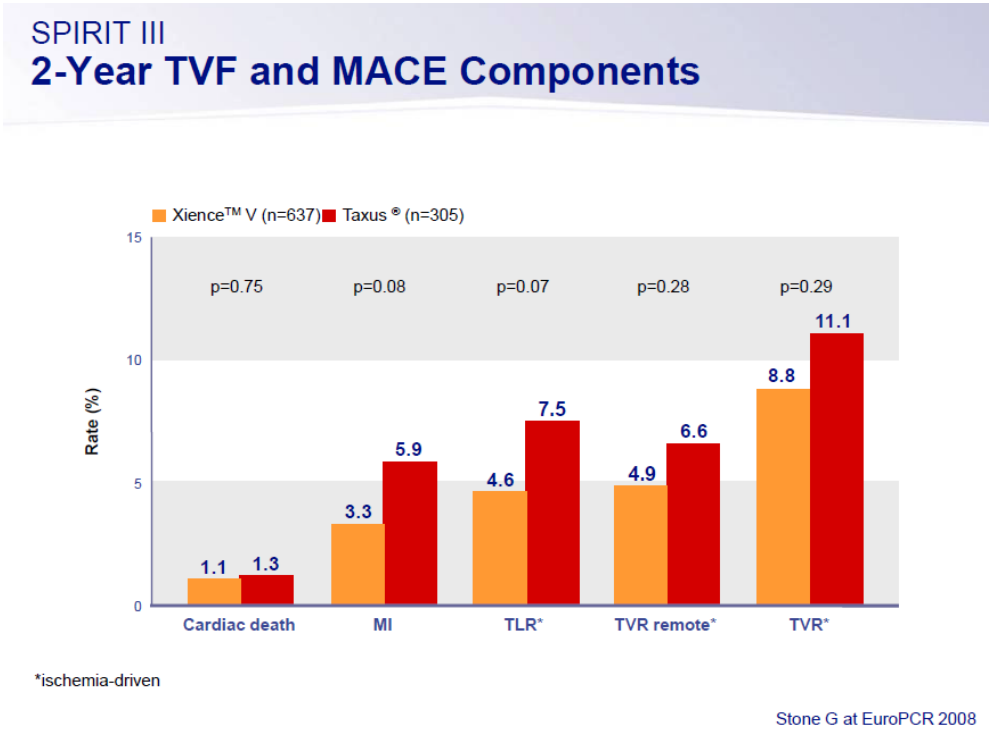
Abbott's strategy to obtain the dominant position in the market was the conduction of clinical trials with follower incumbents instead of the market leader. This strategy had two benefits for Abbott: first of all, it gave them the flexibility to modify the probable deficiencies during the initial trials, in order to be ready to conduct a comparative trial with Cypher, and secondly, this strategy enabled Abbott to form some market bases and grow gradually before the final round of trial competition with Cypher. Figures 5.15, 5.16, 5.17, and 5.18 show the results of the comparative clinical trials between Xience and Taxus.



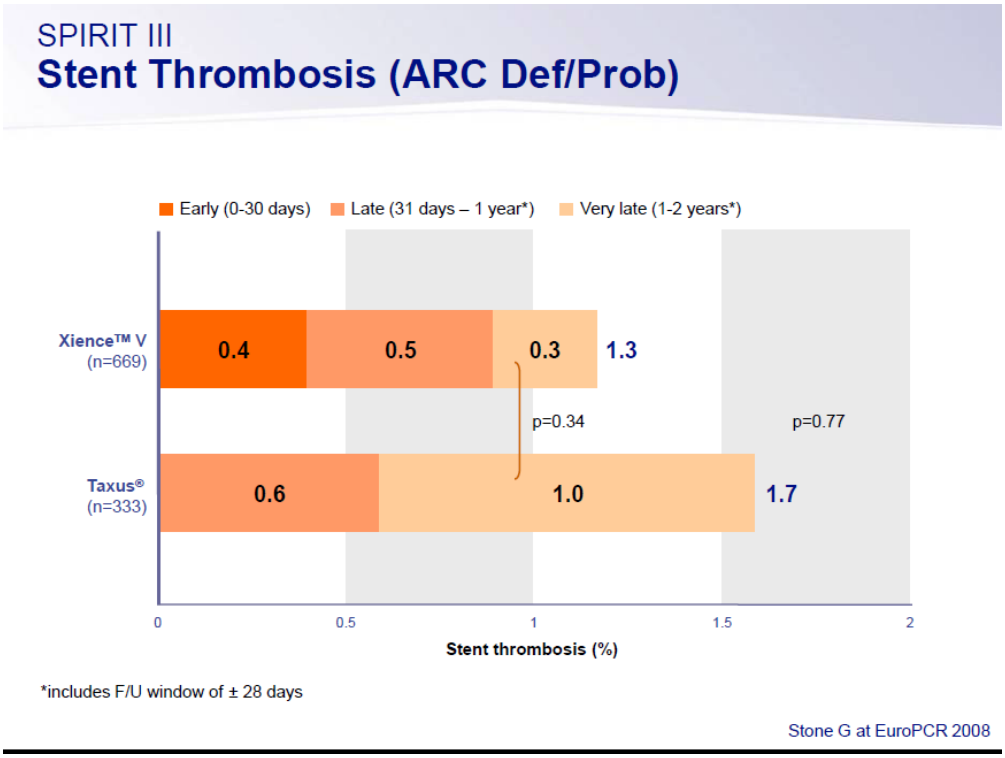
5.15. Comparative Trial Results of Xience and Taxus



5.16. Comparative Trial Results of Xience and Taxus



5.17. Comparative Trial Results of Xience and Taxus



5.18. Comparative Trial Results of Xience and Taxus

In 2007 Medtronic released Endeavor Resolute, the new version of Endeavor, and conducted several clinical trials. The trial results proved the high performance of Resolute, and most of the practitioners believed that Resolute had the potential to gain almost 50% of the DES market shares. However, since Endeavor did not have a reliable reputation in the market, the perceived performance values of the market were completely based on the technical capabilities of Resolute. In other words, the previous failure of Medtronic in the DES market affected the diffusion of the new innovation (Resolute). After 2008 most of the market incumbents improved the eluted drugs and bare stents incrementally in order to survive in the market. Medtronic made Resolute–Integrity by changing the metal part of Resolute, and are waiting for the new trial results. Abbott made a new version of Xience called Xience Prime by making small changes for better drug efficiency, and Taxus and Promus Liberate from Boston are still struggling with their market shares. Cypher has been discontinued for various reasons, and recently, the new bio absorbable stents, such as Nobory and Bio Matrix, have launched in the market. The future of this industry will be in polymer-free stents, which reduce thrombosis and restenosis rates. The evolution of DES innovations can be found in Table 5.12.

Major Innovations of DES Generations
• Innovations of the polymer component Bio-absorbable polymer Polymer free DES Bio absorbable stent platform Biodegradable metallic stents • Drug coated balloon • Bifurcation stents

Table 5.12. Major Innovations of DES Generations

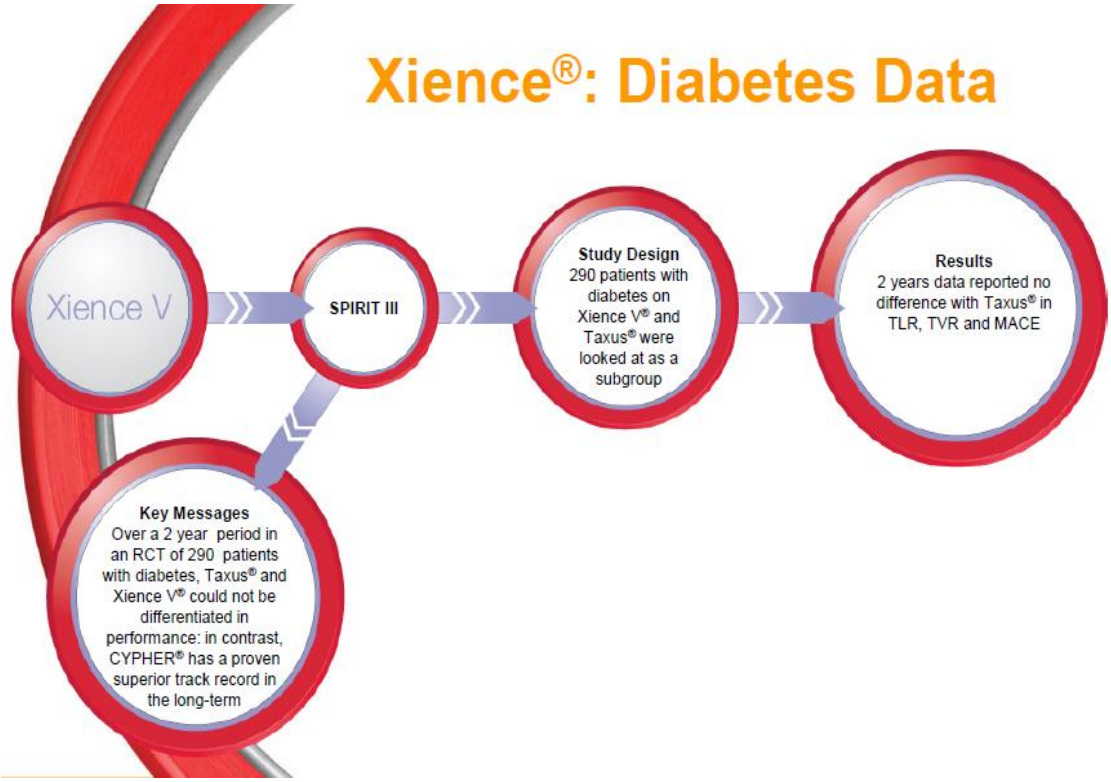


Figure 5.19. Clinical Trial Results of Xience

5.6. Post-DES Generation

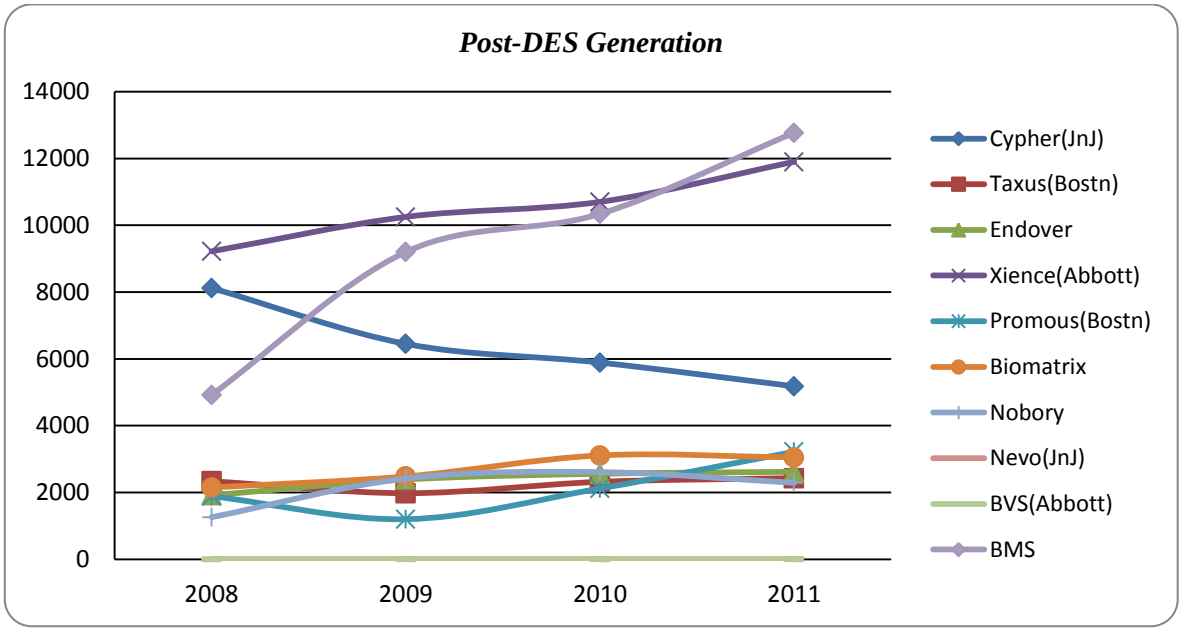


Figure 5.20. Diffusion of DESs and BMSs in the Market (Iranian Health Ministry Report, 2012)

After the first (BMS) and second (DES) generation of stents, the third generation of stents (AMS) has been launched. For a long time during the BMS and DES generations, after the treatment of CAD, the metal part of the stent would remain in the vein and could cause several side effects for patients. The emergence of AMS has solved this problem by introducing new performance values. The polymer absorbs into the vessel walls after treatment and patients do not suffer the effects of this piece of metal remaining in their body.

Conor. Co invented the AMS, and Cordis. Co acquired Conor and managed it for two years. In 2007 Cordis acquired Conor and conducted several clinical trials to elaborate on the new innovation of polymer-free DESs. The initial results of the conducted clinical trials were successful, and, thus, Nevo (the first polymer-free DES) was awarded the CE certificate.

In the meantime, the problem of the insurance reimbursement system made Cordis more cautious in launching this new innovation into the market. Cordis was also concerned about the patent of

Sirolimus, which was patented in 2002 for ten years, and was due to expire in 2012. Therefore, a great deal of challenges was expected for them if they continued with Sirolimus as the main eluted drug. On the other hand, by 2010 a significant amount of newcomers and small incumbents attacked the DES market and the competition was not genuine anymore. Considering all these facts, Cordis decided to leave the DES market in order to apply the stacked stenting knowledge and technology in another field of MDs. Therefore, although Cordis could have launched Nevo in the market they decided to discontinue the diffusion of Nevo in 2011.

Dr. Kazemi-Saleh believes that the S&T trajectories of CAD treatment soon will be monopolised by Nano and bio technologies. However, the next generation of stents will be bio-absorbable. There are two aims of a cardio vascular section: unblocking a vain, and preventing it becoming blocked again. Abbott laboratory is now the pioneer of the AMS market after Cordis left the competition. Most of the expert interventionists believe that the future of CAD treatment and stenting is with the AMS, indicating that the market has been disrupted a third time by the introduction of new and unexpected values to the market.

However, many practitioners criticized Cordis' decision to leave the AMS market. They believe that Cordis had more competitive advantages in the AMS market than Abbott Laboratories due to its technical capacities. Indeed, Ethicon, a subdivision of Johnson&Johnson, is the market leader of bio-absorbable surgical sutures. Thus, it would be easier for Cordis to benefit from this technical advantage and introduce the new AMS based on the cross sectional R&D collaboration between Ethicon and Cordis. Since the stent would be absorbed into the vessel wall, there would be no further material remaining inside the vascular system and it would reduce the drug consumption after the stenting operation; this would be the performance value. However, Cordis could not solve the problem of vessel recoiling after the absorption of polymer to vessel walls.

As mentioned earlier, in order to solve this issue, Cordis merged with Conor Co in the R&D system in order to synergize the technical capabilities of their R&D teams. Conor Co stents had several competitive advantages in their designs. The porous surface of Conor Co stents facilitated the process

of drug releasing, which increased the efficiency of stent. This new style of stent reduced the average rate of thrombosis (the main concern about DESs) and introduced new performance values to the market. Indeed, Nevo was the outcome of the M&A contract between Conor Co and Cordis, which possessed the capabilities of Cypher and the advantages of Conor Co's structure. According to the Medtronic sales manager, Nevo was a masterpiece of medical design. Its surface was porous with the drug inside the holes, which accelerated the drug releasing process. Also, the polymer was decreased by 70% in this new DES. The flexibility problem of Cypher was also resolved in Nevo.

Although Cordis had planned to conduct several comparative trials between Xience and Nevo in 2011, Nevo was discontinued. Bio matrix and Nobori are two new DESs that could get a significant market share in the DES and AMS markets. Nobori is a DES from Truma, and Bio matrix is a German DES produced in China. Since the price of Bio matrix is much lower than Nobori and has a higher availability, it can be diffused into the market faster and more easily. Bio matrix is now the strongest competitor of Xience in the market.

To sum up, then, thus far we have described the main dynamics of the Iranian CV market between 1998 and 2010, and depicted the main events which have affected the dynamics of DI diffusion in this market. In the next chapter we will discuss the generative mechanisms of the dynamic discussed earlier from the point of views of the key decision makers of the four major incumbents in the market, and analyse their main concerns and strategies regarding the efficient diffusion of medical DIs in the Iranian medical market.

Chapter 6

[FINDINGS AND DISCUSSION]

Introduction

As we discussed within the literature review chapter, DI diffusion has been considered as a socio-economic phenomenon by most scholars. In other words, economic factors are not the only incentives to accelerate the diffusion of DIs; social factors also play an eminent role in this process. Therefore, this research has attempted to unveil the dynamic of DI diffusion and relevant mechanisms to shape this dynamic in medical markets. The results we will discuss in this chapter are based on a longitudinal historical analysis of a competition between incumbents of medical devices in the Iranian cardiovascular market that has lasted for ten years. This research was conducted via in-depth elite interviews with the key decision makers of the launched cardiovascular DIs during the decade in question.

The results demonstrate that those incumbents who downplayed the importance of social factors on DI diffusion have not been successful in progressing to the phase of market encroachment which would lead to disruption of the mainstream market. For instance, when Cordis. Co entered the Iranian cardiovascular market; they were not in a position to challenge the other incumbents in the market due to its public and rigid structure. However, they focused on the social drivers of DI diffusion which enabled them to overcome the market challenges and disrupt the mainstream market. Abbott Laboratories re-disrupted the market during the DES generation by benefitting from the other mechanisms of the market and changing the dynamic of DI diffusion to their own benefit. Therefore, we can see the importance of social drivers and their indirect, but eminent contribution to disrupting the mainstream medical market.

Within the first section of this chapter, we are going to explore the dynamic of DI diffusion in medical markets based on the findings of our longitudinal case study analysis of the Iranian cardiovascular devices market between 2000 and 2010. The results of the in-depth elite interviews with the key decision makers in launching new innovations into the leading medical devices companies in Iran will form a central part of this. In this section, the proposed research model of micro-level dynamic of DI

diffusion will be challenged based on the findings of the research, which has undergone template and discourse analysis, and some partial modifications will be advised based on the requirements of this model. It appears that the role of competitive forces and business-level structural factors have been missing in this model, and, therefore, this research has sought to consider these factors in order to offer a more realistic view of DI diffusion dynamics from a micro-level perspective.

In the second part of this chapter, the mechanisms of DI diffusion in the medical devices industry will be discussed, and the main mechanisms for shaping the dynamics of DI diffusion in medical devices industries will be investigated through the findings of this research. These mechanisms necessitate the adoption of diffusion strategies to form the dynamic of DI diffusion. The findings of this research pinpoint some strategic mechanisms which enable the diffusion of DIs in medical markets. The most important of these is the institutionalizing of the required organizational values to build up the necessary DI diffusion competencies inside medical firms. While most of the other models of innovation diffusion and new product launching such as Easingwood and Harrington (2002), Beard and Easingwood (1996), and Guiltinant (1999) begin the market disruption from the market preparation phase, this research offers a model which positions the starting point of market disruption inside the incumbents' firms. Therefore, while the other models focus on the market, the findings of this research give priority to organizational values which build up the necessary organizational competencies to disrupt the market. The findings state that during the market encroachment phase these organizational competencies may aid the incumbents to gain reputation, prestige, and brand power in the market, which could facilitate the process of market disruption.

The second DI diffusion mechanism introduced by this research is based on less-structured communication channels among physicians, which makes informal groups of colleagues and word of mouth the main leverages of DI diffusion in medical fields. Based on the findings, there is a gap among the healthcare professionals for more effective and well-structured communication channels. The third mechanism of DI diffusion highlighted by this research is market intelligence systems,

which enable the medical firms to modify their DI diffusion strategies based on the market needs in different market segments. Finally, the role of modified launching tactics of new DIs is discussed based on the priorities of four main disruption triggers, such as a DI's technical capabilities, the proposed bundle of performance values by new DIs, designed sales services around DIs, and perfect market availability, along with elastic pricing. The findings state that technical capabilities and a proposed bundle of performance values determine the structure of offered sales services, and also modify the launching, marketing, and sales tactics of the medical incumbents.

Finally, planting the bundle of newly proposed performance values in customers' evaluation systems is the most important task of a market disruptor in crossing the bridge between the encroachment phase and the market disruption period. Many different sub-mechanisms will be explained (Figure 6.1) based on the findings of this research to outline the strategic view of this critical mechanism for market disruption.

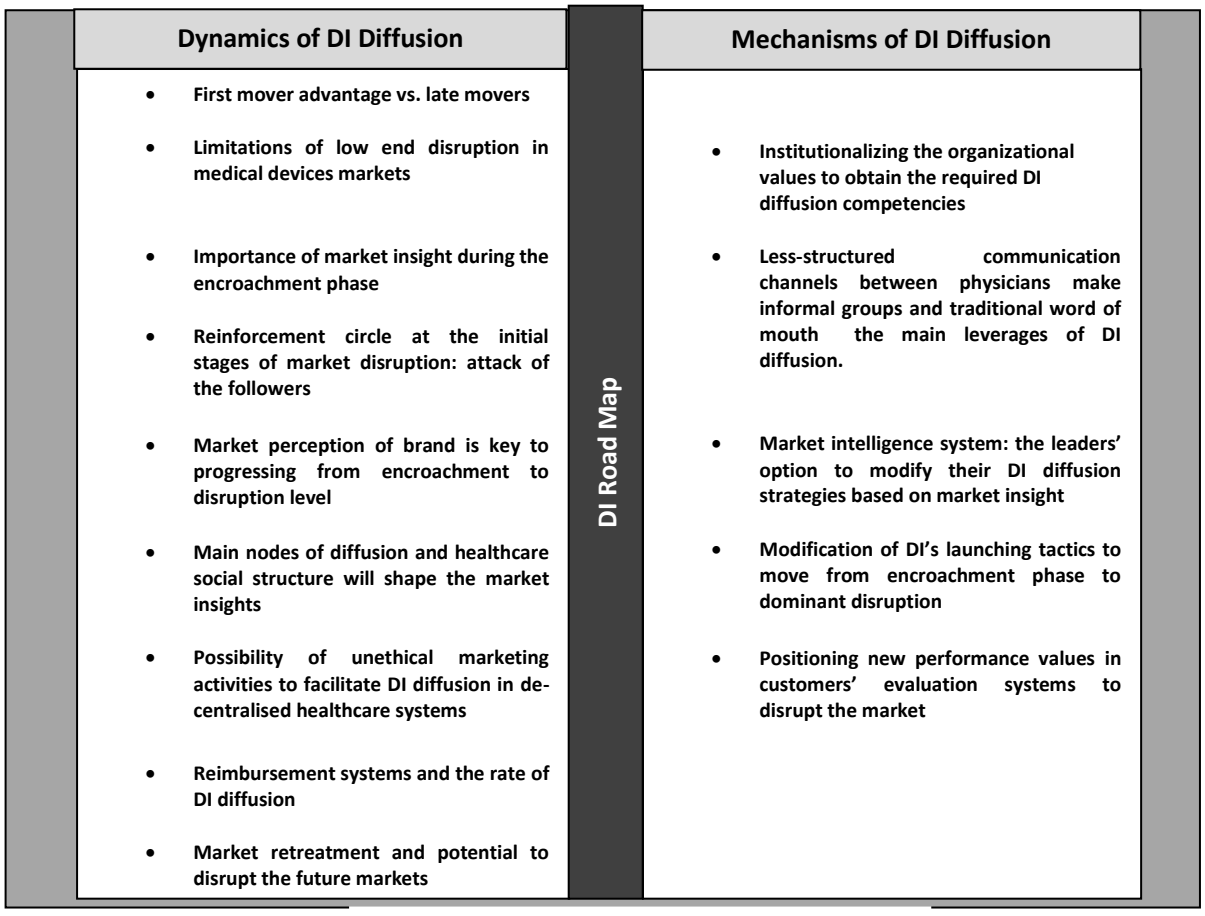


Figure 6.1. Findings Outline

6.1 Dynamics of DI Diffusion in Medical Markets

Based on the findings of this research, market disruption usually happens when other competitors are trying to improve the performance of their products incrementally or radically. In other words, while most of the incumbents are engaged in improving the performance of their products in the mainstream market to extend their product life cycle (PLC), there are some other newcomers or incumbents that try to bring a new generation of products to the mainstream market by revolutionary innovations from their R&D labs. Indeed, as was mentioned in chapter two, Daneels (2004) challenged Christensen's (2000) understanding of DI by posing a fundamental question about DI diffusion dynamic: do incumbents lose their leadership when they face a potential DI in the market?

This question challenged the whole concept of DI first defined by Christensen in 1997. Hence, in our analysis we will try to demystify the dynamic of DI diffusion based on observed reactions of market incumbents when they faced a potential DI in the Iranian medical market. Some scholars have partially addressed this question in different ways. For instance, King and Tucci (1999) and Chesbrough (2003) believe that the firms with experience of serving in the prior market have a better chance of disrupting the mainstream market due to their accumulated knowledge of it. The findings of this research also demonstrate this. The findings of our ten-year longitudinal case study of the Iranian medical market reveal that most of the market disruptions were by the leading incumbents of the market. For instance, although Conor Co invented the first DES, it was Cordis Co who disrupted the BMS market by acquisition of Conor Co. Abbott Laboratories responded to this challenge with the acquisition of Guident Co and utilized its strategic capabilities. However, Christensen and Raynore (2003) state that incumbents usually lose their leadership in the market when they face a potential DI. They argue that since incumbents are busy improving their existing products' performance, they are ignorant of potential Dis, and when they face them they probably do not know how to react. The findings of this research cannot agree with Christensen and Raynor (2003) on this issue. Based on our findings, the rate of market disruption by leading incumbents is significantly higher than new firms'

successful market penetration for two main reasons: 1) incumbents' accumulated knowledge of market structure and market insight, and 2) the significant rate of M&A in medical industries. The findings show that the rate of in-house R&D activities have dropped dramatically due to the recent financial crises, and leading incumbents prefer to benefit from M&A activities to aid disruption of the mainstream market. Charitu and Markides (2003) and Tushman and Anderson (1986) believe that most competence enhancing innovations come from existing incumbents, while competence destroying innovations usually emerge from new firms, as the latter need to offer a new bundle of performance values to gain entry into the market.

Therefore, Daneels (2004) criticizes Christensen's (2000) definition of DI and argues that DIs are not necessarily inexpensive and simple, nor do they necessarily disrupt the market from low end. Instead, Daneels believes that DIs could open a new market by introducing new performance values to the market and changing the basis of competition. Following from this notion, the findings of this research elucidate three different phases of market disruption: DI emergence, encroachment, and market disruption. The findings state that while the amount of in-house DI emergence has decreased significantly due to financial difficulties, leading incumbents mostly focus on the encroachment phase to disrupt the mainstream market based on their accumulated market knowledge, market insights, and established channels of commercialization. As a matter of fact, they allocate a budget to scan the market activities and catch new potential DI opportunities, as well as benefiting from M&A activities, such as can be seen in the acquisition of Conor co by Cordis in 2006, or the M&A contract between Guidant, Boston Scientific, and Abbott in 2007. The findings also demonstrate that a successful market disruptor can keep its dominant position while it is still new in the market. However, according to many cases of DI diffusion in medical markets, successful market disruptors will be the subject of attack by the other incumbents when they recognize the potential of newly proposed technology by the market disruptor. As we will discuss later in this chapter, if the market leader is prepared with strategic follow up plans to maintain their share, or even expand it in the market, the invasion of followers in the market can help them to reinforce their dominant position as the leader in

the market. Basically, when the other incumbents enter this new market, customers rely on new, unknown innovations and proposed technology by the main market disruptor (Salter and Mohr, 2010). During this period there are usually some stronger followers who are monitoring the market's activities and observing the incumbents' performance to identify potential for penetration (Figure 6.2). According to Christensen and Raynor (2003), followers either change the entire value and process of the current organization or react by gaining benefit from spin-offs and M&A to respond to the challenges of market disruption.

Hence, after in-depth scanning of the market, latecomers should propose superior performance values to the recently introduced values of the market disruptor. This allows the dynamic of competition to continue and some smaller newcomers may even enter the market to respond to any price elastic gaps in the newly formed market. These small companies usually target niches that are not of interest to market leaders and other followers. While most of the market incumbents concentrate on improving the quality of their products radically or incrementally, there are other companies contemplating disrupting the new mainstream market; this circle will continue.

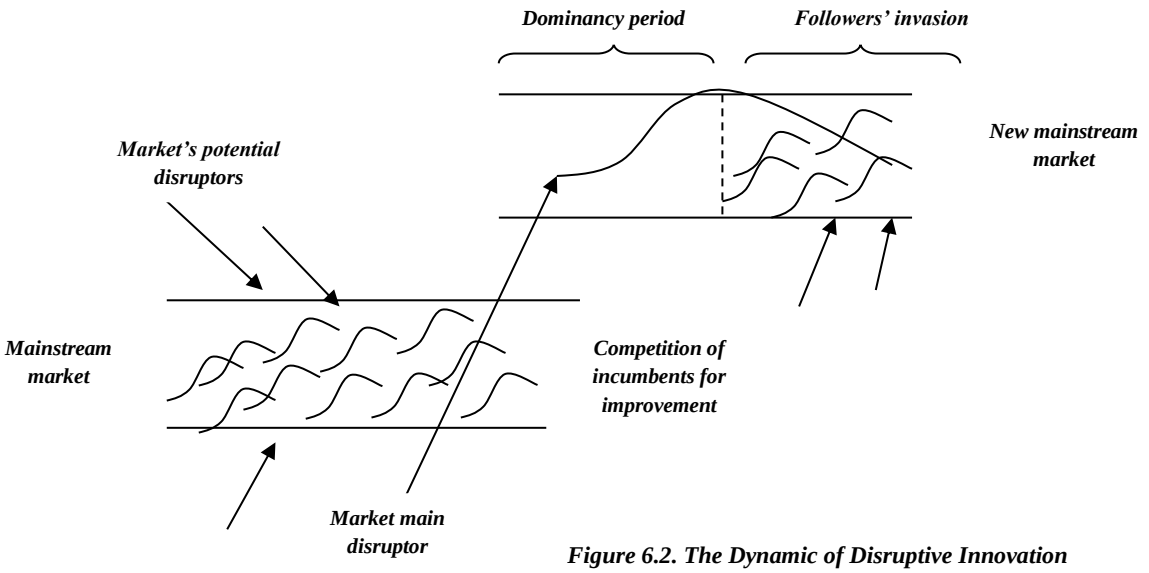


Figure 6.2. The Dynamic of Disruptive Innovation

The franchise manager of Cordis. Co states: "*Cypher was a unique product when it was launched. It was a breakthrough innovation moving at least two years ahead of the other DESs. The time span is*

really important regarding this issue. Cypher's technology with a specific coated drug in it was a unique innovation with remarkable trial results. Fascinating technology, remarkable services and superb trial results helped Cypher to become a first class DES. But as with other technological challenges, competitors never stay and follow the market trends. Based on their position (leader, follower, nichers) they are working every day to survive in this cruel market. Leaders usually try to either use the late mover advantages, focus on the weaknesses of DIs and make a new superb version of it, or disrupt the market themselves and create a new market by making the previous generations obsolete. Followers, however, try to seek benefit by imitating the market leaders and get the lower positions in the market. It deserves mentioning that the followers should have an agile R&D in order to respond to the market challenges, since otherwise they will be removed from the market. Finally, the nichers who include the small companies usually try to fill the price sensitive gaps of the market with their lower performance values compared to the main incumbents."

Moreover, regarding the market mechanism of disruptive innovation, Abbott's CEO claims: "*In the Iranian market we can see a phenomenon. While the major incumbents in the market have a reasonable margin, newcomers usually sell less qualified products in the market make a huge margin. Usually, the real price for them is extremely low but their pricing strategies apply different rules. They usually set their price a bit lower than the market leaders, therefore, they will make a huge surplus that could be spent on advertising or unethical marketing promotions. Actually, we have a competitor who is selling Indian stents in the market. His selling volume is one-tenth of ours, but his surplus is significantly more. These newcomers are temporary in the market, but they are too many; therefore, you can always see them in the market. They are always rising, falling and disappearing, but always these sorts of companies allocate a certain amount of the market share to themselves*."

6.1.1 *First Mover Advantage vs. Late Movers: Solving the Trade-off between Time and Cost of getting Stronger Trial Results in the Lab and becoming a Pioneer in the Market.*

According to Lieberman and Montgomery (1987) there are three main mechanisms leading to advantages for the first mover in the market: (1) technological leadership, (2) pre-emption of assets, and (3) buyer switching costs. Huff and Robinson (1994) believe that technological leadership mostly arises from a learning curve where costs will fall with the cumulative outputs and successful patenting in R&D races. It deserves mentioning that most of the first mover activities in medical devices industries could be categorised as technological leaderships. However, merger and acquisition (M&A) is a more prevalent tool of market disruption than in-house technological leadership. As Xiaobo et al (2010) state, there are many cases of M&As in the medical devices industry, which usually try to pre-empt R&D activities to attain more opportunities (based on new performances introduced by advanced technologies) to disrupt the mainstream market. The case of Conor Co Stars' stents confirms this, demonstrating the same dynamic of market disruption. Indeed, based on the findings of the longitudinal case study, Cordis disrupted the Iranian cardiovascular market by the acquisition of Conor Co Star, to bring the first DES into the market. Nevertheless, Abbott laboratories challenged Cordis' dominant position by owning Guidant Company, one of the most famous cardiovascular stent producers at the time. It can be seen, therefore, that technological leadership and M&A activities are two main pillars of the first mover advantage in disrupting the mainstream markets in medical industries.

However, based on the findings of the research there are also many examples of first mover failures and late mover advantages in launching new medical innovations. For instance, the Boston Scientific sales manager states: "*The game was going on until Abbott came to the market in late 2007 with a new generation of DES, Xience. Indeed, Xience was benefitting from the late mover advantage. Abbott Laboratories had been waiting four years to see the weaknesses and strengths of the market leader and other competitors. The R&D section of Abbott had been working day and night in order to make Xience the most perfect DES in the market in order to defeat the market leader, Cypher. The main*

advantage of Xience was decreasing thrombosis and restenosis rates tremendously at the same time. Simultaneously, it was significantly flexible in practice and the shelf-life was longer than the other DESs. Therefore, it could be stocked for longer." As the findings demonstrate, latecomers can benefit from the time span of the encroachment phase in order to produce a more desirable value proposition to disrupt the newly shaped market. Therefore, while first movers can benefit from setting a dominant design in order to disrupt the mainstream market, the threat of the latecomers should not be underestimated.

In this regard, Abbott's CEO claims: "*When Xience got in to the market, relying on its superiorities over Cypher and benefitting from late mover advantage, it changed the game. Indeed, after four years studying the market and knowing about the strengths and weaknesses of the competitors, they tried to present the new generation of DES wisely. We tried to convince all the main nodes of diffusion in the market to accelerate the diffusion of this product*."

Christensen and Rosenbloom (1995) state that while early movers benefit from their technological leaderships and setting of dominant designs in the market, they should be aware of some threats to their position, such as changes in consumer tastes, change in technologies, consumers' learning curves, and above all, free-ride effects. The findings of this research show that taking the first mover advantage to disrupt the market can be remarkably resource consuming. Therefore, if a given incumbent wants to disrupt the market they should prepare themselves for further reactions of followers. The findings illustrate that a market disruptor without a follow up plan for keeping their dominant position usually fails.

Regarding this issue the Medtronic sales manager states: **"***You shouldn't think that the new innovations that are coming to the market have been recently invented. For instance, Abbott is releasing a new generation of bio-absorbable stents. The company bought this technology twenty years ago from Duke University. But when Cypher came to the market, Abbott didn't use this technology against Cordis. Co. It actually teaches us a valuable lesson about the importance of late*

mover advantage. Abbott Laboratories have been working on this technology until they could get defendable results that could lead to superior trial results. The main reason that a given product can disrupt the market is its pioneering technological position. The production is just the beginning of the story. After that you have to show the best trial results in order to get accepted in market competition. For instance, there are more than thirty Indian stent brands in the market that have less than 3% of the market shares. There are a huge amount of pre-market trials (PMA) before launching a new innovation to the market. Laboratory tests, pre-clinical test, clinical tests, and post-market studies should be done in order to get CE and FDA approvals that guarantee the safety of medical devices. Different companies have different strategies towards PMAs. Some of them limit themselves to the first and initial steps of trials, and launch their products without stronger and more valid trial results. But the bigger corporations wait longer and longer until they can get unbeatable results. Then, they launch their products into the market and disrupt the market by getting the majority of the market shares. The launch time actually has a direct relationship to the brand management and reputation."

Indeed, based on the findings, both first and last mover advantages can be considered as useful for disrupting the mainstream market. Being the first mover and pioneer in the market has its own advantages and disadvantages. The findings show that if a given company has a strong follow-up plan for the further stages of product launch (in order to compete with the invasion of followers), they can benefit from being the first mover and keep the leading position for a long time. However, if the company does not have any specific plans to continue their dominancy in the market they may lose their leading position and enable a free-rider opportunity for other incumbents. In this case, the market pioneer opens a new gate into the field that all the other competitors can benefit from, and if they cannot manage to establish their dominant position in the market at a specific time, the other competitors will establish a new market themselves.

Nevertheless, being a late mover has its advantages and disadvantages as well. Indeed, taking the late mover position could give the company the option of conducting in-depth studies about the dominant

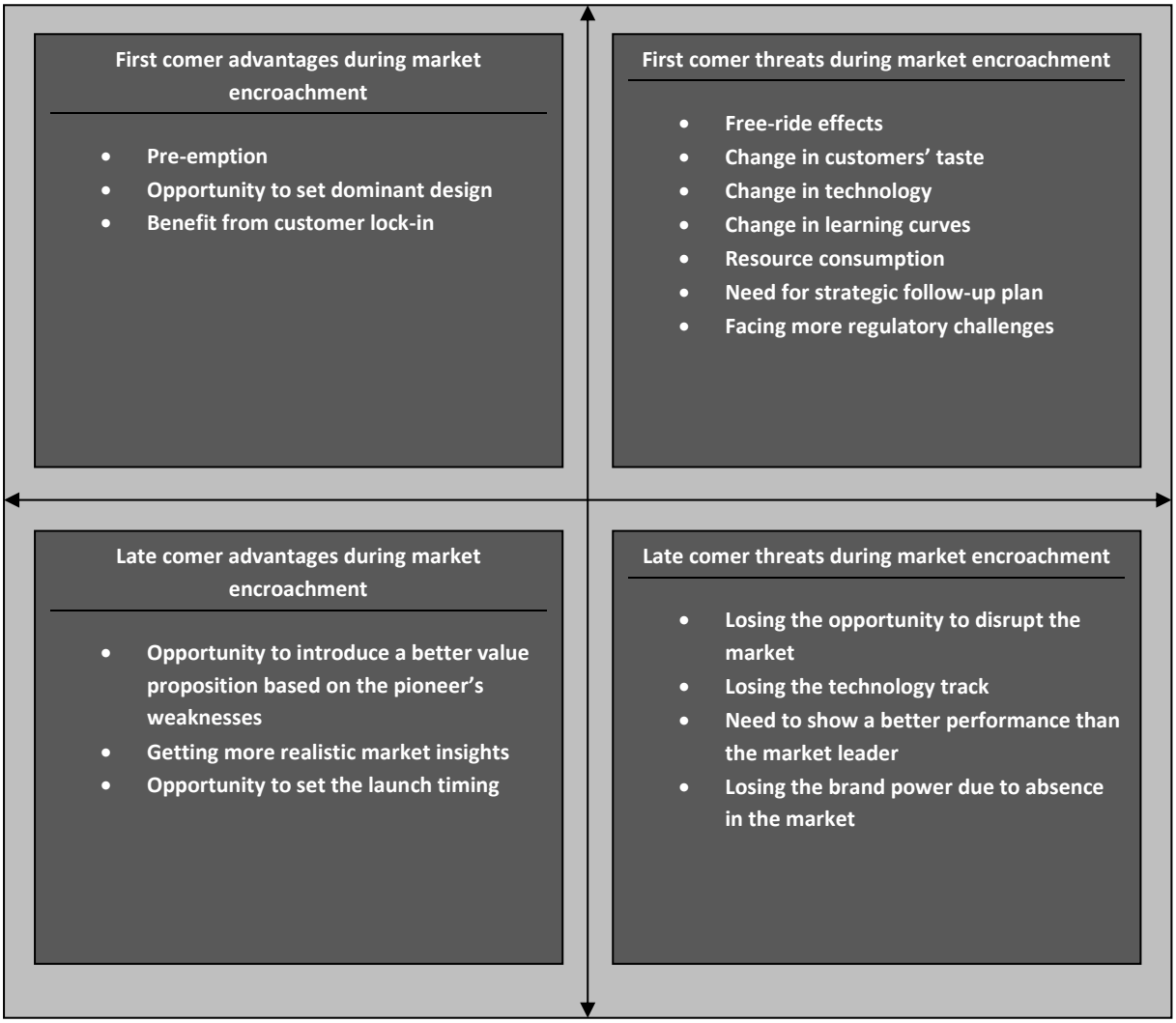
incumbents' strengths and weaknesses. In this case, the late mover targets the main performance value of the market leader and tries to produce a superior value proposition. Additionally, by focusing on the market leader's weakness, they try to bring a flawless version of the current innovation to solve the customers' difficulties. Therefore, they can secure the leading position in the market and benefit from the free-ride effect. On the other hand, there is the possibility that by being a late mover in the market a given company loses the chance to disrupt the market again if the first mover performs well in the market.

The research findings show us that when a revolutionary innovation succeeds in disrupting the market it will change the evaluation's criteria during its life cycle. For instance, when the first BMS was launched in the market there were no comprehensive frameworks to evaluate its performance, but when the followers joined the market, the framework had been introduced by the market pioneer. Indeed, during the diffusion of a new revolutionary disruptive innovation, the emergence of new criteria to evaluate the new sets of proposed values is inevitable. Therefore, in order to evaluate a new innovation in the market and compare it with previous inventions, evaluation milestones must evolve. In other words, by launching each new innovation in the market, the evaluation criteria of products in that field will be more comprehensive and accurate.

On this issue, Medtronic Co's franchise manager states: "*Before the Endeavour stent nobody had heard about this product, but actually, Endeavor showed significant performance in solving the thrombosis issue. So, it was a trade-off between the rates of restenosis and thrombosis. The producers, then, had to balance these two criteria, since the new trials by Medtronic showed that the other DESs caused a huge rate of thrombosis, while Endeavor did not have this problem. Since Endeavour was benefitting from chrome-cobalt polymer, the rate of thrombosis was low. Therefore, Medtronic found out that although they could not work on their efficiency, they could work on their safety, and by some sort of innovation release the drug quicker. They even improved the rate of restenosis.*"

As we can see here, although the Endeavour stent could not disrupt the market it had a great effect on the market's evaluation criteria by highlighting the effect of thrombosis in DES users. Indeed, the main contribution of Endeavour by Medtronic was to introduce new, important performance values to the value framework of physicians. Indeed, after 2007 the Cypher stent lost the leading position in the market because of the newly introduced criteria by Medtronic. Dr. Kazemi-Saleleh states: "*After the entrance of the other competitors, Cypher lost its leading position. The main reason was the high rate of thrombosis and late thrombosis compared to the other competitors. It made us really annoyed, since we were losing our patients after one or two years from sudden death, which was the result of late thrombosis.*"

Figure 6.3. The Advantages and Threats of First and Late Movers during the Market Encroachment Phase



However, regarding the evolving status of evaluation criteria during the diffusion of new products, the sales manager of Cordis. Co states: "*At that time trial results were not that important, since stenting knowledge was so young. Today, the variation of patients, the number of them, and also the number of special cases that the product could handle are considered the most important issues of trial authentication. The main authenticated trials were run after 2003. Indeed, the complexity of these trials had been evolving during these years. Therefore, the measurement tools of these medical devices were evolving as well*." Therefore, the first mover should always be aware of the regulatory challenges caused by the force of the other incumbents in the market. Also, late movers should notice that they may change the dynamic of the market by affecting regulatory issues to re-disrupt the market.

6.1.2 Limitations of Low-End Disruption in Medical Devices Markets

Druhel and Schmidt (2008) claim that disruptive innovation is not necessarily 'disruptive' innovation as Christensen (1997) argues. Although there have been many scholars who have criticized Christensen's notion of disruptive innovation, Druhel and Schmidt (2008) made a significant difference by introducing their "Encroachment Theory." As we mentioned in the second chapter, Christensen (1997) believed that while most of the incumbents in the mainstream market compete to improve the performance of their products by benefitting from technological modification to serve the high end of the market, there will be opportunities for other small competitors to serve the low end of the market by focusing on their unfulfilled needs. Christensen and Raynor (2003) consider this gap an opportunity for small competitors who want to avoid the competition from market leaders in the mainstream market. Christensen (1997) based his theory on a twofold market classification: mainstream, and less demanding customers. Droege and Johnson (2010) state that disruptive innovation theory adopts a rough–grained approach to segment the market based on two main pillars: price sensitivity, and customer participation in existing markets. Christensen et al (2004) argue that while mainstream market customers are busy with sustaining innovations, less demanding customers

are subjected to low-end disruptive innovations' endeavours by being targeted for their unsatisfied needs. Christensen (2000) attempts to explain why some products become more prominently featured, sometimes leaving behind the customers who prefer less expensive products. This is the main reason that Christensen and Raynor (2003) and Christensen et al (2004) believe that incumbent firms usually fail to recognize the threat of market disruptors. Therefore, Christensen (2006) considers low-end disruptive innovation to focus on the less demanding low-end of the market, which is extremely price sensitive, and improve the performance of products in order to move upwards and disrupt the mainstream market. Price sensitivity, then, is the main concern of low-end market disruption.

However, the findings of this research show a different pattern of market disruption in medical devices markets. Indeed, during the past ten years in the Iranian cardiovascular market, most of the market disruption happened due to technological advancement, and later on companies attempted to modify their prices to attract the mainstream market customers. For instance, when bare metal stents (BMSs) were introduced to the market, they did not target the lower end or less demanding part of the market. Although their proposed price was cheaper than bypass surgeries, they were not specifically aimed at the low end of the market. Christensen (2000) claims that when angioplasty was first introduced to the market, it was only performed in simpler cases, and was much less effective than surgery. Therefore, specialists viewed the procedure with scepticism. Christensen mentions that subsequently other sustaining innovations enabled the first stent come to the market, and later on angioplasty succeeded in supplanting bypass surgeries in many cases. Considering the findings of this research and the proposed framework by Christensen (2000), it seems there is a dilemma here: should we call the BMS a sustaining or disruptive innovation? Moreover, should we consider the BMS a low-end disruptive innovation?

It seems that as Deneels (2002; 2004) states, it is one of the limits of Christensen's (1997) theory about disruptive innovations. There is a time span between the first introduction of potential

disruptive innovations to the market, and the main market disruption, which Tushman and Anderson (1989) call the ferment era. Moor (1991) names this period a chasm, and Utterbak and Abernathy (1978) consider it dominant design competition. It appears that Christensen (1997) totally ignored this time span, and considers a disruptive innovation as one that sustains after the ferment era. This is the main reason that Druhel and Schmidt (2008) introduce their "Encroachment Theory." The main idea behind this theory is that a disruptive innovation begins its life by encroachment either from the low or high end of the market, and if it succeeds in disrupting the mainstream market, it will become a disruptive innovation.

In the case study of this research, the BMS was a low–end market encroachment at first, and later became a disruptive innovation by opening a new market in addition to the existing one. Moreover, the findings show that low-end disruption, as Christensen (2000) argues has never been the main purpose of any incumbent on the Iranian cardiovascular market in the last ten years. Indeed, based on the interviews we conducted, most of the incumbents targeted the most important experts to introduce the BMS as a new development of cardiovascular science. Cordis, for instance, did not base its launch strategies on the needs of the low-end market.

Consequently, as Droege and Johnson (2010) state, despite the growing popularity of low-end disruptive innovation theory among academics and practitioners, most of the generated predictions by this theory are limited by industry structure. In the case of medical markets, as Neir et al (2008) and Niranjan et al (2012) mention, since their nature is relatively inelastic regarding price, it seems that low-end disruptive innovation is not the best theory to explain the dynamic of disruptive innovation diffusion. In other words, since price sensitivity is the main leverage of market disruption from the lower end, and the main concern in medical industries is quality of treatment rather than price, low-end disruptive innovation theory may not fully explain the dynamic of diffusion.

The findings of this research state that most disruptive innovations happen as a result of high-end encroachment, as with the case of the DES and post-DES generations over the last ten years in Iranian

cardiovascular industries. However, there are other small competitors that as Christensen et al (2004) claim, may wish to concentrate on the unfulfilled needs of less demanding patients. This does not necessarily mean that they will target the low end of the market, as in this case price sensitivity is not the main trigger of market disruption. The main pillar of market encroachment, as Druhel and Schmidt (2008) identify, is applying advanced technologies to serve the needs of less demanding costumers. Therefore, since the medical market is not extremely price sensitive, and quality treatment at a reasonable price is the main priority, the final price of potential disruptive innovation can be relatively higher or lower than the current treatments in the mainstream market. The findings of this research suggest that if the price of potential disruptive innovations is relatively higher, then high-end encroachment theory could provide a better explanation of disruptive innovation diffusion. Alternatively, low-end encroachment could be an appropriate choice for explaining the diffusion of disruptive innovations when the price of the final product is relativity lower.

6.1.3 Importance of Market Insight during the Encroachment Phase

As was mentioned earlier in this chapter, to modify Christensen's (1997) notion of DI in order to address the great deal of criticisms from many scholars, such as Daneels (2002; 2004) , Markides (2006) and Druhel and Schmidt (2008), we should first concentrate on the encroachment phase. The findings of this research have revealed the importance of information management during the encroachment phase. Usually, potential market disruptors focus on vital information from the markets and modify their launch strategies based on them. In addition, they need to disclose a certain amount of information (Figure 6.4) about their new innovation to remove all informational barriers to market consumption. Cordis. Co's marketing manager states: "*In order to launch a new revolutionary innovation to disrupt the mainstream market, we have two different groups: a sales team and a marketing team. The marketing group has to increase the market knowledge of the product, and the sales team is responsible for making the product available in the market at a fair price. The marketing team has to increase the market knowledge by asking different questions of market actors. Increasing*

the market's knowledge of a new innovation means that you need to attract practitioners' attention to the main performance values of the new innovation, and this is a tremendously culturally embedded job to do. Indeed, the ways in which to increase the market's knowledge is totally based on the market's cultural context. Understanding this culture and performing based on it would help a given innovation to disrupt the market as fast as it possible. For instance, asking questions is the best way of introducing any new innovation into the Iranian medical market. In other words, we have to ask about the main values of the new innovation and stimulate their needs by asking, for example, 'wouldn't it be better if the product does have these performance values?' By asking these sorts of questions, the market's intelligence will get prepared to accept new innovation. If a given revolutionary innovation shows significant results in pre-market trials, more than 90% of the market will react positively and adopt this new innovation. Doctors who show affirmative signals towards adopting the new innovation will be selected and given more information, including pre-market trial results, studies, and so on. After that, we give them free samples to test this new innovation. Intentionally or not, doctors try to get the same results as the published studies that they have been given. Indeed, we perform positive marketing, and by giving them the trial results prior to their sample studies, we tell them what their results should be."

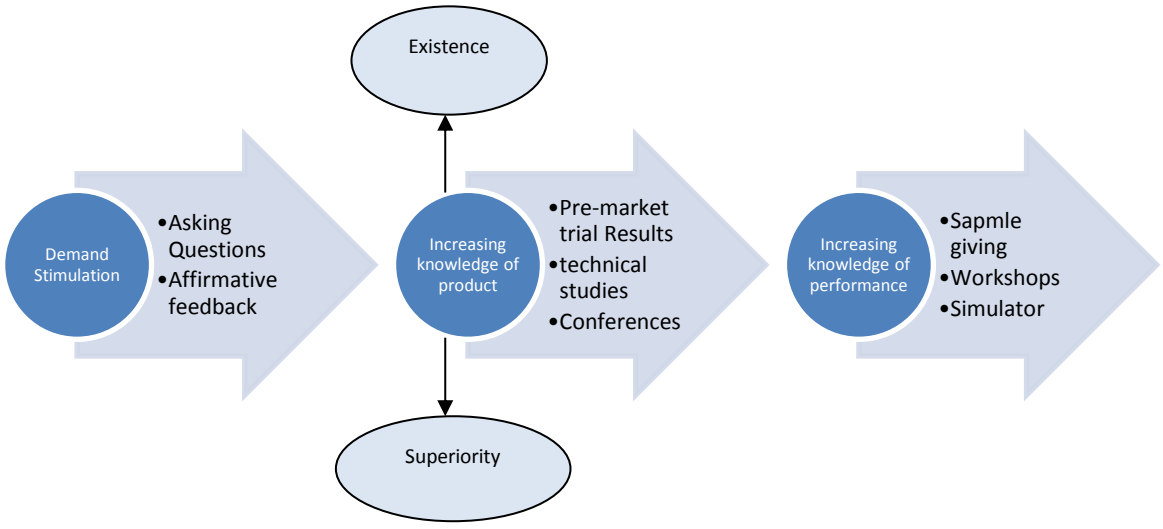


Figure 6.4. Pre-launch Dynamics of DI in Medical Markets

Relevant studies by Van den Bulte and Lilien (2001) describe the main pillars of DI's information diffusion as mass media exposure, marketing efforts, and social contagion. Zappa (2011) defines social contagion as a result of social communication, which could be in the form of information transfer, normative pressure, competitive concerns, or performance network effect. In other words, as Katz and Lazarsfelf (1955) argue, actors may gain knowledge of an innovation's existence through word of mouth from a previous adopter (information transfer), or adopt a new innovation in order to avoid the risk of losing competition to colleagues (competitive concern). Nevertheless, considering the studies of Coleman et al (1966) on the diffusion of Tetracycline, and Roger's (1995) diffusion of innovation theories, information management during the encroachment phase of diffusion should be based on decreasing complexity, increasing the compatibility of the DI with the current requirements of the market, trialability, observability of results, and demonstrating the relative advantage of the new DI over other proposed solutions.

Indeed, the research findings suggest that the most crucial challenge facing a new DI looking to be accepted in the market during the encroachment phase is the lack of market knowledge about the new innovation. Since the revolutionary innovation is unknown to the market, it is usually looked upon with a significant amount of skepticism during its initial introduction to the market. Therefore, the main task of companies who wish to disrupt the market is to remove any information barriers around a new revolutionary innovation. On this subject, Cordis Co's CEO states: "*The main leverage of high-tech medical innovation diffusion through the market is increasing the knowledge of users. In medical markets we encounter some doctors who do not want anyone to know about their knowledge of recently developed practices in the world. Therefore, they must be dealt with delicately. Because of this, we put our simulator machine in our central lab and let doctors come and practice their cases there. Each doctor has their own private time with the machine in order to understand more about new stents and stenting operations without any hesitation. The only issue is that this machine works only with Cordis stents. Therefore, this educational tool helps the cardiology society to nurture more interventionists and also make the stenting operation more prevalent. At the same time, they learn the*

stenting and intervention procedure with Cordis stents. So, the first stenting experience of many young doctors will be with Cordis. This makes the young medical students loyal to the Cordis brand. Indeed, we spend a huge amount of money on this simulator, but at the same time we guarantee our future market. As you can see, our credo, values, educational goals, market creation strategies, and identification of our potential and actual market, are in a synergic interaction and collaboration to disrupt the mainstream market. We believe that if we allocate just 5% of our sales to educational programs (such as the simulator) we can make it back by selling more during the next year. Actually, we are the first company in Iran that sent nurses to educational conferences. We believe that their knowledge of medicine hasn't developed in the same way as doctors', and we need to increase the knowledge of nurses in order to keep a balance. The first nurse that we sent to a conference now has one of the best rates of publications in different seminars, such as PCR and the European Heart Conference."

Therefore, information management and especially educational programs to increase the market's knowledge of the existence, superiority, and performance of new DIs are tremendously vital during the encroachment phase. Many scholars, such as Zappa (2011), Keating et al (2007), Nair et al (2008), Trzeciak et al (2006) and Valente (1996), have described how information is diffused amongst physicians, and how individual and contextual factors facilitate its spontaneous diffusion. Their findings concentrate on the importance of informal flows of information via mutual information-seeking relationships, previous studies, and peers. Specifically, the findings of Zappa (2011) focus on the propensity of information sharing between physicians as one of the most important leverages of information diffusion during the encroachment phase. Trzeciak et al (2006) state that social networking is the most important part of DI diffusion to accelerate the overall comprehension of a DI during the encroachment phase, and to reduce the barriers to change. The Abbott sales manager states: "*Market development strategies are really important for us. We usually launch a new innovation in our core business market, since we are well known throughout the entire social network of physicians there and so may have a better image. Also, we launch our core product in new markets as we have*

experience of launching that product and we can make a good impression with this new innovation through social networks."

While many scholars such as Van den Bulte and Lilien (2001), Burte (1987), and Valente (1996) concentrate on the impact of peer pressure, others such as Nair et al (2008), and Valente and Pumpuang (2007) focus on the role of advice seeking behavior of physicians, and the role of opinion leaders in medical societies in the adoption a new DI in the medical market. Zappa (2011) mentions that the inclination to engage in knowledge sharing is increased by a negative attitude towards a DI. However, this is still the most important leverage of information diffusion through the medical society. Knowledge sharing among physicians is also affected by individual characteristics of doctors, such as age (Barlow and Burn, 2008), their hierarchical position (Van den Bulte and Joshi, 2006), their commercial connections (Mukherjee, 2002), and whether or not they are research oriented (Hirschman, 1980).

On this issue, Cordis Co's franchise manager comments: "*Cordis decided to build the capacity in the market by forming an attraction to new innovations. The main problem of TCC was that they didn't give any choice to interventionists between different stents based on their needs. They just presented some specific stent brands in the market and hospitals and made their interventionists use them. Therefore, Cordis tried to fill this gap and provide more options for interventionists. In making this important difference, Cordis understood that it is necessary to increase the knowledge of practitioners about new innovations, which necessitates the learning of new practices. Because of this, Cordis established a scientific team inside the organization to work on these affairs. In Iranian culture, if the scientific team discussed the price, the market would be reluctant to get in touch with them. Therefore, Cordis separated the sales, marketing, and scientific teams from each other in order to increase their productivity. Then, Cordis adopted the strategy of better selling, rather than focusing on sales volumes. This means that they focused on the quality of sales rather than quantity. They tried to*

increase the customers' satisfaction rather than the sales volumes. They believed that better selling could lead finally to a high volume of sales."

Nevertheless, regarding Cordis' success in removing information barriers around new innovations, their sales manager states: "*However, we believed that it was necessary to increase doctors' knowledge of products and procedures, since our products were totally new in the market and doctors needed to know more about them. Therefore, we started to educate the doctors and allocate some of our budget to educational activities. We divided the education into three different levels: elementary, intermediate, and advanced. Based on doctors' demands, we defined their education and their level of studies. But defining these levels was really difficult, since doctors didn't like being evaluated and ranked by companies. Therefore, it was better to classify them invisibly. In other words, we classified them when we were inviting them to different conferences. We invited different groups of specialists to different conferences, and, therefore, were able to manage their educational program. We are also the only cardiovascular company in the region that has got a simulator machine. This machine is a sort of educational tool that can simulate the patient's situation, and doctors can rehearse the intervention practices here and receive feedback, rather than practicing on live patients. Doctors can use this simulator for free to simulate their cases and see the results, which could decrease the rate of resistance towards using the new devices. Therefore, it can accelerate the rate of diffusion. This simulator cost something around 300,000 dollars. But this amount should be invested in order to accelerate the diffusion rate of innovation, and, therefore, facilitate market disruption. Since our priority is patients' treatment rather than financial incentives, increasing the doctors' knowledge by using the simulator machine is the best strategy*."

Greenberg et al (2005) view increased cost-effectiveness, increased efficiency, and decreased rate of complications as the main incentives of innovation adoption by medical markets. Geer (1988) categorizes adoption approaches of medical actors as either profit maximization or technology competition. However, the findings of this research demonstrate that while the profit maximization

approach could enhance the adoption of incremental and radical innovations in medical markets, the technology competition model is the main approach of medical actors during the encroachment phase of diffusion. Considering information management during the encroachment phase, Greenberg et al (2005) believe that the most important sources of information for physicians are the opinions of local experts, medical conferences, leading general medical journals, specialized medical journals, and the opinions of international experts. Nevertheless, Zappa (2011) points to the pivotal role of medical centers and hospitals in providing new DIs to physicians. He prioritizes the following incentives as the most important motives on hospitals when adopting DI innovations: the ability to expand or enhance services, return of investment, the ability to reduce operation costs, and finally, medical staff pressure. Therefore, as the findings of this research declare, hospitals need different information from physicians to adopt new DIs. Therefore, during the encroachment phase both physicians and medical centers should be targeted for information transaction.

Abbott's marketing manager also shares the same ideas as Cordis' managers: "*On the other hand, running different training sessions is highly important in order to disrupt the market. By holding these training sessions we will remove the last barriers of consumption for doctors and specialists. All of these educational strategies are costly, but this is the price that you have to pay for market disruption. For instance, one of the strategies to increase the future market shares is to choose the young fellows that have graduated from medical schools recently, and send them to internal and external workshops to learn how to work with the new innovations. Indeed, whatever they have learnt in medical school will make not more than forty percent of their future knowledge. The rest will be provided by workshops and practical education that they will get from medical companies. Indeed, they are providing a great deal of valuable support for young fellows*."

Based on the research findings, path dependency is another challenge facing DI diffusion during the encroachment phase. Most of the interviewees have pointed to the importance of path dependent reputation in medical markets. Indeed, they mention that accessory products can form a respectable

reputation in the market and prepare the market for the launching of a new innovation by the same brand. Regarding this issue, Medtronic's marketing manager states: "*One of the competitive advantages of Cordis is that they are a pioneer in the accessory market, with products such as catheters and guide wires. All new medical students use Cordis accessory products from their first day, and this makes them loyal to the brand name. It's really difficult to visit all the doctors in Iran, but you should know that there are just three different universities that all of those doctors have graduated from. Therefore, by investing in educational universities and targeting them you can ensure the future market share for yourself. At the same time, considering the key doctors as the main nodes of diffusion is tremendously important. Tehran, Mashhad, Shiraz, and Isfahan are the main universities that have intervention fellowship courses*."

In addition, the technology manager of Cordis Co states: "*The way that Cordis is working will ensure a steady foundation for the future. While our competitors don't care about brand management and just think about their daily sales volumes, we are thinking about our credo, reputation, and brand power*." There is also another issue: if a given innovation suffers a failure in the market, incumbents usually attempt to remove it from the market's mind by introducing the new version of it with a different name. For instance, Boston Scientific's sales manager states: "*All the great incumbents in the market were trying to launch the new version of their stents in order to compete for dominancy in the market. For instance, Cordis launched "Cypher Select" and "Cypher Select Plus" in the market. Cypher and Xience launched the new versions of their product by the same name, but Taxus introduced the new product by a new name. Adopting this strategy, Taxus could convince the market that the new version of products was something different from the previous ones, which had failed*." Therefore, as we can see, path dependency plays a great role in the initial stages of DI diffusion.

Finally, based on the research findings, it is usually the task of headquarters to ask the representative branches to provide a launch plan, in order to provide some market preparation strategies based on real information. Medtronic's sales manager states: "*The point that I would like to discuss is the way*

we start any new product launch project in Iran. First, we are asked to make a strategic plan. We need to know about the actual and potential markets. But unfortunately there is a problem in Iran. When you want to get the consumption ratio and the other information, it is really difficult, and sometimes there is no database. Therefore, we should set a benchmark in these situations. We know that the Iranian medical demographic is in some ways similar to the American one. For instance, we know that the outbreak rate of a given disease in the US is 2%. Therefore, we look over the other factors that may cause this problem in Iran. The factors and their weights in modification rate are calculated. Then, we find a modification ratio that we can multiply by the US rate of disease, and estimate the Iranian rate of disease outbreak."

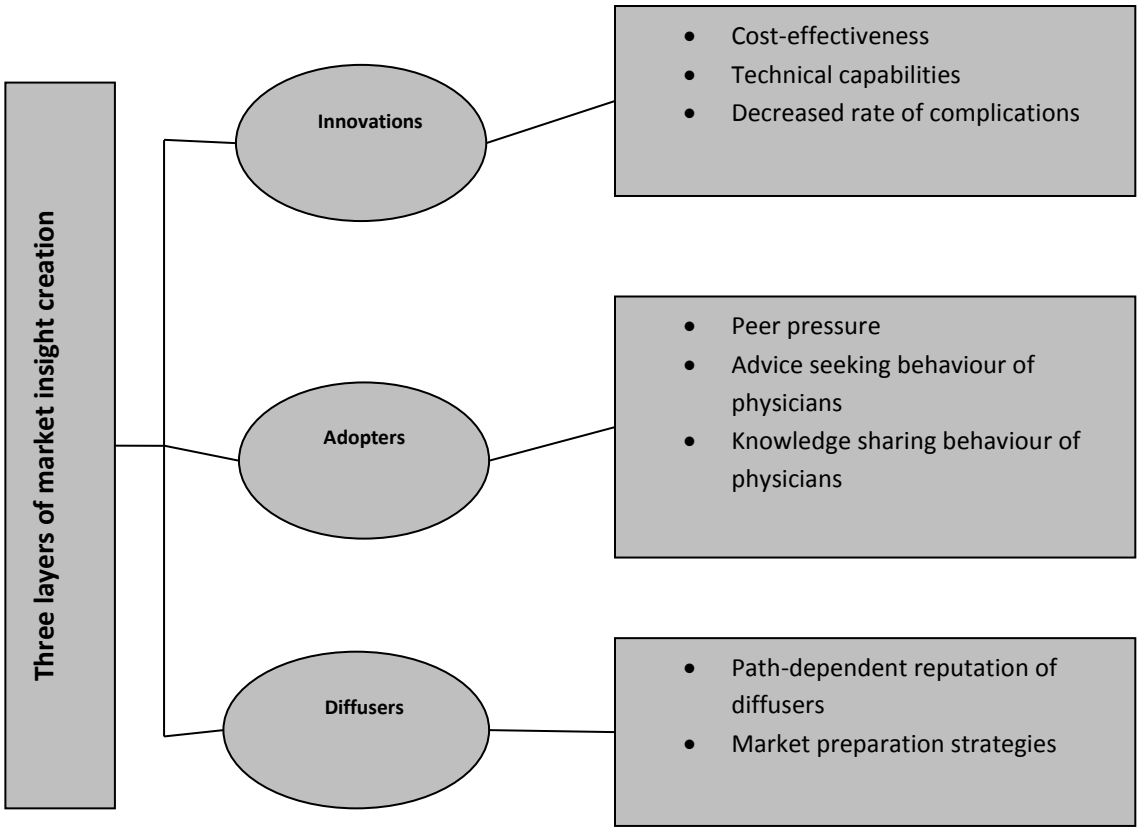


Figure 6.5. Three Layers of Market Insight Creation to Diffuse DIs

6.1.4 Reinforcement Circle at the Initial Stages of Market Disruption: Attack of the Followers

As has been discussed by many scholars such as Tushman and Anderson (1990), Crawford (1994), Utterback and Abernathy, and Telis (2010), the dynamic of competition is totally different before and after the settlement of a dominant design. Tushman and Anderson (1990) believe that dominant design settlement usually happens between two technological discontinuities, which divide the time span into two main eras: the era of ferment, which is basically focused on design competition and substitution, and the era of incremental changes after dominant design settlement, involving further elaboration of the dominant design.

This ferment era, which is referred to as the 'crossing of the chasm' by Moor (1991), plays a pivotal role in market disruption. Utterback and Abernathy (1975) and Abernathy and Clark's (1985) dynamic models of innovation attempt to describe the dynamic of innovation during the ferment era. Reconciliation of the dynamic models of innovation in the ferment era (Tushman and Anderson, 1990), crossing the chasm (Moor, 19901), and the encroachment theory of DI (Druhel and Schmidt, 2008) may enable us to describe the competition of potential DIs to disrupt the market.

As Abernathy and Clark (1985) argue, the number of competitors will increase during the initial stages of the encroachment phase. However, as Druhel and Schmidt (2008) declare, most potential disruptors have left the competition by this time. Golder and Tellis (1997) believe that the ferment era will end with market disruption when a successful DI crosses the chasm between early adopters and the early majority. They call this take-off time, and define it as a dramatic increase in sales. Following this take-off, scholars such as Goldenberg et al (2002), Golder and Tellis (2004), and Van den bulte and Joshi (2007), have reported a phenomenon called "saddle". Saddle is defined as a small drop in the sales ratio after the initial peak, which will be followed by the second peak during the maturity phase of the product life cycle. This saddle usually occurs with the attack of followers in the market, which leaves few market shares for the market pioneer. It could also be attributed to causes such as technology changes, micro-economic reasons, or industrial patterns (Peres et al, 2010).

However, regarding the impact of followers' attacks during the initial stages of encroachment, the findings do not show any symptom of saddle in the medical DI life cycle. Instead, the findings show that at the initial stages of the diffusion of any new revolutionary innovation, the attack of the followers in the market could be helpful for the market pioneer. This will make the market more confident about the new innovation, and help the market pioneer to accelerate the process of market disruption in case others show superiority. Based on the findings of this research, there are different examples of market leaders' positions being reinforced by the followers' invasion of the market. For instance, Medtronic's sales manager states: "*The Emergence of the Taxus stent in the market had another implicit impact on the market as well. With the release of the second DES in the market, the first DES (the market leader) gained more acceptances in the market. Indeed, by the attack of the followers in the market, the diffusion of the first mover's innovation was accelerated. Taxus was not successful in the market, but it helped Cypher to reinforce its leading position. On the other hand, these two DESs in the market were downsizing the BMS market significantly. They made a new market in which 85% of the shares were Cypher's and the rest were Taxus'*."

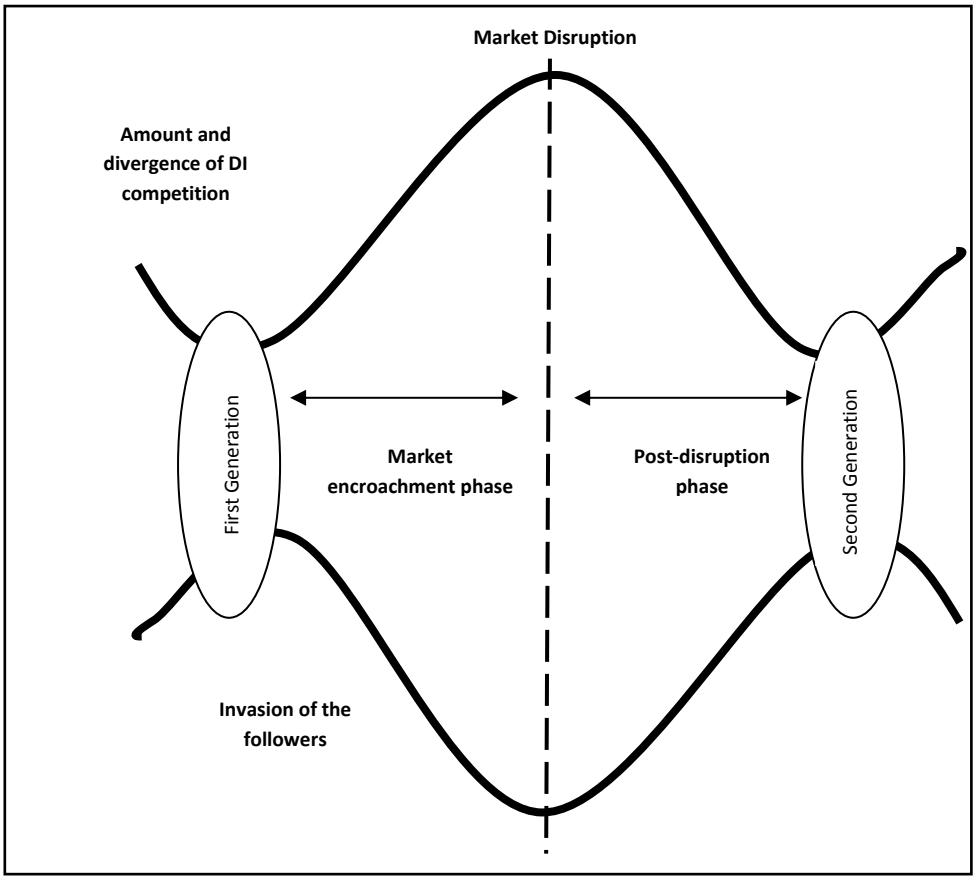


Figure 6.6. The Dynamic of DI Diffusion from the Market Point of View

Consequently, as Figure 6.6 shows, the findings indicate that the invasion of the followers at the initial stages of a given revolutionary innovation's launch time, might assure the market that this could be a new generation of products which offer new performance values, and may establish a dominant position in the market. Therefore, the attack of the followers during the encroachment phase of diffusion could enhance the leader's ability to pass through the ferment era successfully. As we can see in figure 6.6 there are some divergent efforts by incumbents to bring up a new innovation to disrupt the market and establish a certain dominant design. However in post-disruption phase most of the remaining incumbents would follow the market leader and attempt to enhance the newly introduced performance values of DI by their new innovations.

6.1.5 *Market Perception of Brand is Key to Progressing from Encroachment to Disruption Level*

Many scholars have discussed the undeniable role of innovators' attributes to facilitate the diffusion of innovations into the market (Rogers, 1995; Robertson and Gating, 1986; Wejnerd, 2002; Peansupap and Walker, 2005). Nevertheless, the findings of this research suggest that from a cultural point of view, a company's brand power is one of the most important factors in accelerating the process of diffusion. Indeed, in developing countries such as Iran, the process of trust building is culturally embedded. In different cultural contexts trust has different meanings, and is considered a result of different sets of actions. On the other hand, since the architecture of the market is less structured in developing countries and trust building procedures are less developed and structured, cultural issues play significant roles in the process of trust building in the market. The only factor that can accelerate the market penetration for a revolutionary innovation is the company's prestige and brand power. To Abbott Laboratory's CEO states: "*If we didn't have such a respectable prestige in the market, nobody would listen to us in the first place, and, thus, we couldn't diffuse our innovation into the market.*" Most of the interviewees mention that since revolutionary innovations are new and require different sets of knowledge to be worked with, most of the doctors resist accepting them during the initial steps of diffusion; in fact, the doctors do not know much about these revolutionary innovations. The only thing that they know is the company, its reputation and prestige, and its position in the market. Therefore, the main stimulus encouraging physicians to attend an initial presentation meeting is the company's prestige, rather than the DI's attributes.

The research findings elucidate that a company's prestige is the result of many factors, including the company's current position in the market, and the launching team's prestige. Cordis' Sales manager states: "*One of our special services is the delivering of our products by our own personnel, rather than sending it with other people. This gives nurses and doctors a good impression of the company, which could be helpful in the brand management process. We teach these personnel to know the product which they are delivering.*" There is another issue that effects a company's prestige in a

market filled with emotional incentives and reactions, as is the case in the Iranian medical market. Being patient oriented and showing commitment to social responsibilities is considered a strong competitive advantage in the Iranian medical market. Since not all the incumbents are committed to their social responsibilities, the Iranian medical market tremendously respects an incumbent who serves society and commits to social responsibilities. Therefore, being patient oriented will enhance the creditability of any given incumbent in the Iranian medical market. This is an issue that the marketing manager of Boston Scientific insists upon, and believes that western headquarters should know more about: "*The western headquarters usually have little information about Iran, and view the Iranian market as a sort of black box. Sometimes, they wonder why some international procedures do not work in Iran. They may think it has something to do with management problems. But, they may not know that each market has its own rules and structure. I think we need a balance between global strategies and procedures of high-tech launching, and the local implications. All the standard procedures should be implemented, but we need to modify them based on local environmental requirements. Sometimes, the low sales ratio of medical innovations is related to many macro-economic factors, such as tax, sanctions, inflation, or maybe a public healthcare program.*"

As we can see, there are many different ways of forming a reputation according to the findings of this research. Being visible locally, participating in charitable activities, fair pricing, and honesty in services are the main leverages in creating a reputation for market incumbents. However, sometimes the market's main actors decide to take a short cut by seeking benefits from M&A (Christensen and Raynor, 2003). Adner (2002) and Govanjan and Kopalla (2006), however, believe that M&A could bring a respectable reputation to incumbents, whereas Daneels (2004) understands M&A activities to enhance the reputation of the innovation rather than the diffuser. In other words, Daneels believes that spin-off is the best way of innovation commercialization to disrupt mainstream markets. Following this notion, Markides (2006) states that spin- off activities and local oriented services can help the incumbent to build a respectable reputation. Therefore, while M&A activities help incumbents to effectively borrow a technical reputation, spin-offs and locally oriented services can

help diffusers acquire a social reputation, which would facilitate the diffusion of a potential DI during the encroachment phase and give some leverage to the disrupted mainstream market.

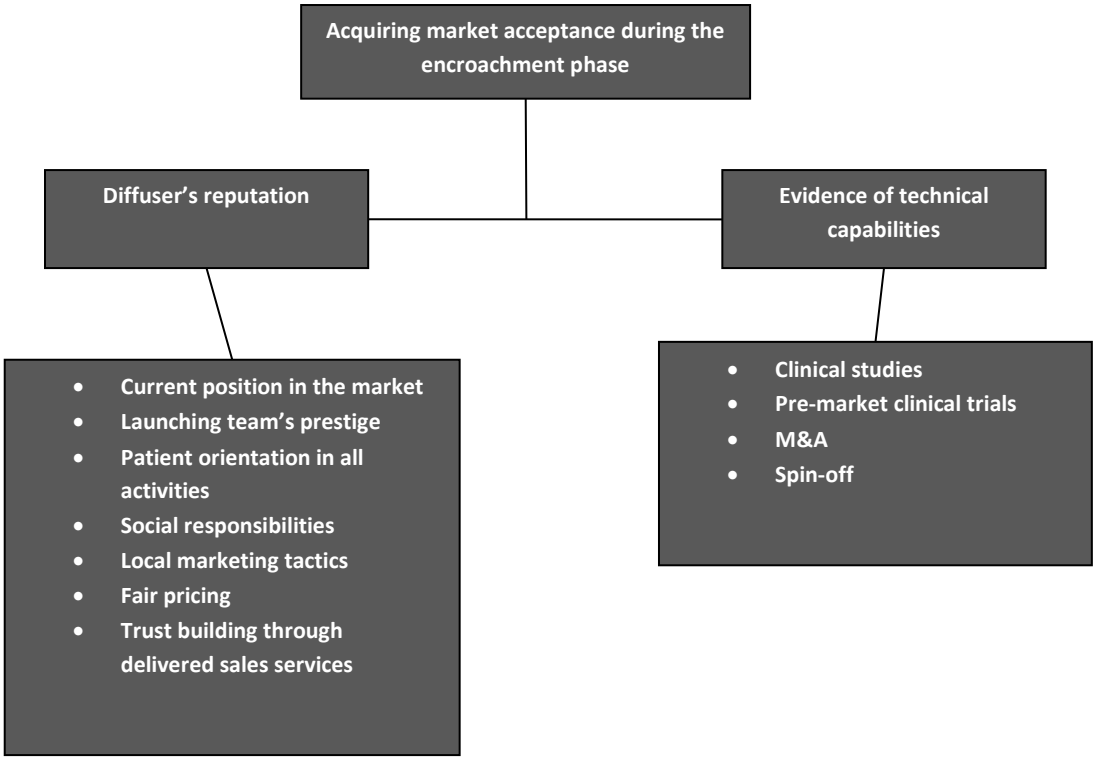


Figure 6.7. Acquiring Market Acceptance during the Encroachment Phase

However, there are many examples that show the importance of possessing reputable brand power in the Iranian medical market. For instance, the Medtronic sales manager mentions: "*Actually the "Resolute" DES could have got more of the market share, up to 50%, but the problem was something unpredictable. The market didn't have a good image of either the Driver or Endeavor bare polymer stents. Therefore, they couldn't trust Resolute (which was made by the same incumbent) anymore."* In addition, Cordis' franchise manager states: "*There is a famous business case many years ago in which some children in Ohio suspected of being given the famous pills of Johnson and Johnson (J&J) died, but nobody could prove it. Voluntarily, J&J recalled all of those drugs from the market all over the*

world, and tolerated a loss of more than 36 million pill boxes. Later on, it was revealed that it was a plot by a local pharmacy, and the product hadn't caused any problems. But, the good reputation of J&J remained for years and years. J&J was suspected of product defects two more times and recalled the products voluntarily. This honesty and care for patients has made a great name for J&J, and this helps to disrupt medical markets." Abbott laboratory's CEO states: "*Although we couldn't release our DES at that time we could diffuse our last generation of BMS (Vision) in the market and make a reputation for it as "The poor man's DES." In other words, if someone couldn't afford a DES, doctors would automatically use Vision. That was our reputation*." Therefore, the role of respectable prestige is undeniable in disrupting the market. Prestige or brand image in the market can facilitate the process of market disruption by affecting the process of trust building.

6.1.6 Main Nodes of Diffusion and Healthcare Social Structure will Shape Market Insights

The research findings also highlight the importance of the main nodes of diffusion in medical markets. The social structure of the healthcare system which determines the position of the main nodes of diffusion could affect the diffusion rates of DIs. As Williams et al (2008) state, healthcare is different from other markets because a remarkable amount of professionals are working in this market, contributing to a complex network of expertise. Moreover, our findings show that since customers (physicians) and consumers (patients) are different in this market, the role of key decision makers is slightly complicated. Christensen et al (2000) believe that safety and ethical issues also change the dynamic of the healthcare market. Although the healthcare network consists of many stakeholders, such as users, healthcare professionals, suppliers, regulatory agencies, reimbursement systems, and so on, most scholars believe that physicians are the main nodes of diffusion in this market. In other words, healthcare professionals play an incomparably pivotal role in adoption of new innovations in medical markets (Williams et al, 2008). As we have mentioned before, specific drivers,

such as the interest in knowledge sharing with colleagues, constituting informal groups and seeking opinion leaders may shape the structures of healthcare networks (Van den Bulte and Joshi, 2006).

On this issue, Cordis' technology manager states: "*Medical society is a hierarchical social system. There are many diffusion nodes that accelerate the diffusion of innovation, and consequently, through more interaction and communication between the main nodes, diffusion can lead to market disruption. Therefore, I believe that we have to target pioneer doctors and key physicians to disrupt the market. Every new innovation gets diffused downward through this hierarchy in Iranian medical society. For example, in provinces other than Tehran, physicians always follow the same consumption pattern as the hospitals in Tehran, the capital of Iran. Therefore, in this hierarchical system, finding the main nodes of diffusion is really important. I do believe that in order to disrupt the market we need to have a reliable knowledge of the market (market insight) and also we need to know core powers, market makers, and the main nodes of diffusion*."

However, some other interviewees such as Medtronic's marketing manager define this aristocracy in a different way: "*Social development level is tremendously important as well. We still have a sort of 'job aristocracy' in Iranian society. We have two occupations that give the occupant a superior position in society: doctors and clergy members. As a matter of fact, if you see someone with a tie, unintentionally, you will think that he is a doctor. Therefore, we can shape the market insight using the power of those key physicians*."

The franchise manager of Boston Scientific adds the following: "*There is an interesting issue surrounding medical innovations. Totally contrary to other mainstream markets, physicians in medical markets are inclined to use new innovations instead of showing resistance. Therefore, if innovations show good trial results during pre-market trials, doctors will show enthusiasm towards using them during the diffusion phase*." Indeed, our findings suggest that while advice seeking and formation of informal groups of physicians may reinforce horizontal integration of the healthcare network, seeking opinion leaders will lead to vertical integration of the healthcare systems. Vertical

integration implies different hierarchical levels and intra-connection of actors, which can be either top-down or bottom-up oriented. Horizontal integration necessitates the peer to peer connection of actors at the same level. Moreover, culturally embedded factors, such as the aristocratic behavior of actors at higher levels of the healthcare hierarchy have made the top-down diffusion strategies more successful.

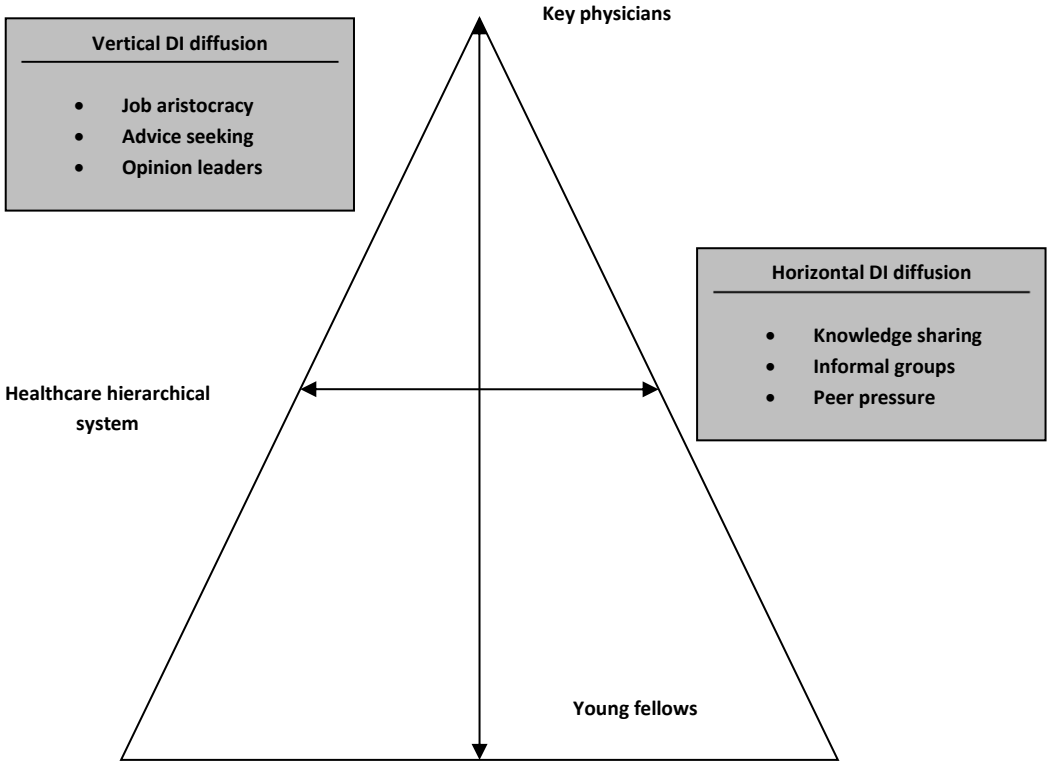


Figure 6.8. Horizontal and Vertical DI Diffusion in Healthcare Systems

Dr. Nazeri, as the first node of diffusion of both BMSs and DESs tells the story of stenting knowledge diffusion as follows: "*After the Iranian revolution in 1979 most of physicians left the country. But I stayed here and didn't let cardiovascular knowledge disappear. I've been nurturing and teaching medical students at hospitals and medical universities. I was trying to diffuse the knowledge of stenting through young physicians. I was the first person to introduce international seminars, workshops and conferences to cardiologists and interventionists. I was brave enough to increase the*

knowledge of intervention in medical society. I was in love with my job. My passion for intervention has always pushed me forward and compelled me to diffuse this knowledge through education."

Although most of the interviewees in this research believed in the presence of job aristocracy in Iran, and, therefore, top-down diffusion strategies, the sales manager of Medtronic has a different idea. He states: "*If I want to launch a new revolutionary innovation in order to disrupt the market, I never go first to the key physicians, since they are never as enthusiastic as young medical students. The best way to diffuse new medical innovation is to target younger doctors or fellows, since they will cost you less to become convinced, and they will give more attention to new innovations at the same time. Another strategy is to target the cardiologists rather than surgeons or interventionists. Cardiologists are doctors who refer patients either to interventionists or surgeons after having undergone some general examination. Usually, cardiologists expect less from medical companies, but they can make a great impact on the mainstream market and shape the market insight during the encroachment phase of diffusion. Also, we have to be aware of the effect of the key decision makers. For instance, operating theatre technicians play pivotal roles in decision making, as they are like interventionists' assistants.. They can change a doctor's decisions during the intervention by manipulating the patients' situational information. I do believe that in Iran the most important thing is your relationship with doctors, since the market is culturally sensitive."*

Therefore, considering the social structure of the healthcare network in which diffuse DIs, it seems controversial to suggest a specific diffusion strategy. For instance, while Lave and Wenger (1991) argue that physicians with more experience will adopt new DIs faster due to their ability to understand and evaluate new proposed values, Barlow and Burn (2008), believe that younger physicians are keener to adopt new Dis, since they are more inclined to take risks than their older colleagues. Gollop et al (2004) consider hierarchical position the main barrier to the acceptance new innovations. They believe that the fear of losing one's position in the healthcare hierarchy makes the main nodes of diffusion resistant towards new DIs.

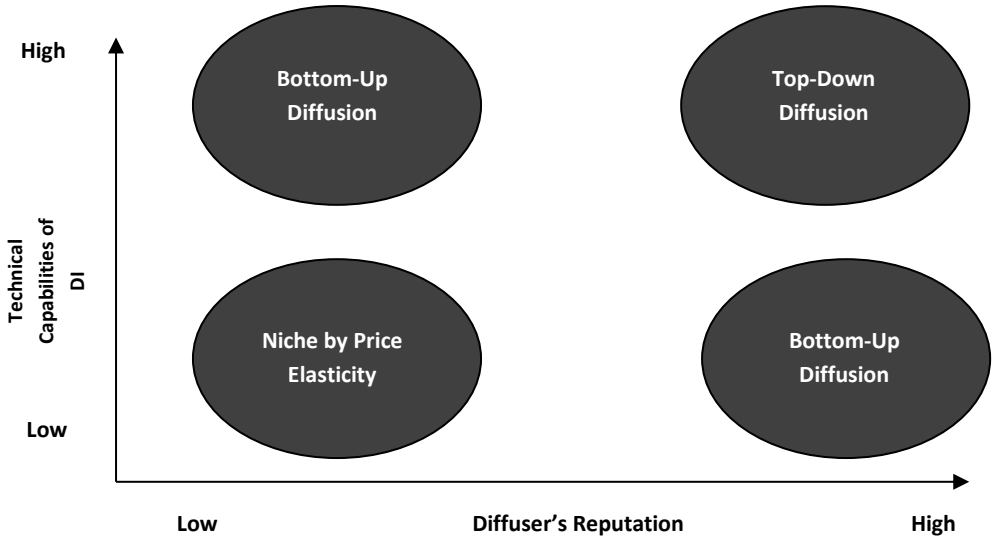


Figure 6.9. Vertical DI Diffusion Strategies

However, the findings of this research state that diffusion strategies and the role of the main nodes of diffusion in healthcare markets depend on the attributes of both the diffuser and the new innovation. In other words, if a DI's value proposition is significant and the DI diffuser's reputation is respectable enough, incumbents should target the top of the medical hierarchy and key physicians as the main nodes of diffusion. Otherwise, they may consider the middle or bottom of the healthcare hierarchy (this depends on the power of their brand and their DI's performance values), depending on their encroachment plan.

Consequently, the healthcare social structure should be considered during the diffusion of medical DIs. In order to facilitate the diffusion of a given DI, incumbents should recognize the market potentials, healthcare social structure, DI value proposition, and the main target of those newly introduced values to choose the main nodes of diffusion. Indeed, when the prestige and brand power of incumbents are respectfully high, they may choose top-down diffusion strategies and consider bottom-up strategies as a back-up plan. Targeting key physicians should be the priority of well-known

medical brands, as they have sufficient credibility in the market. Therefore, market leaders may also consider young physicians as their main targets to guarantee the future markets. On the other hand, companies with less prestige, or new brand incumbents should consider bottom-up diffusion strategies, and after gaining a reputation in the market may be able to adopt a top-down diffusion strategy in order to disrupt the market later on.

Regarding this issue Cordis' marketing manager states: "*Physicians' process of medical device adoption is quite rational. A specialist usually pays attention to the quality of the innovation to preserve his or her reputation. In other words, if he fails in an operation because of a device's failure, nobody blames the medical device companies; rather, they put all the blame on the physician. Therefore, since physicians will be in charge of further issues relevant to the patients they will choose the best device with the greatest value proposition. However, even with the best devices there are other attributes that may affect the decision making process, such as a patient's financial situation, availability of the device, and the availability of accessories for that specific product. If I want to prioritize the effective factors in facilitating the diffusion of a DI, it is first and foremost the quality of the device. After that, other factors, such as availability, services, and price can be considered*."

The technology manager of Abbott argues the same: *"In the medical market the most important issue for physicians is their own reputation. They always try to protect their reputation, since their reputation means everything to them."* This seems to be true, as Dr. Kazemi-Saleh states: "*Doctors cannot be loyal to any particular brand. The most important thing for doctors is their reputation in their job. Therefore, they prefer to choose a device with less operational risk. We have to choose the best at the time for our patients*."

6.1.7 Possibility of Unethical Marketing Activities to Facilitate DI Diffusion in De-centralised Healthcare Systems

It seems that the effect of healthcare system architecture on the diffusion of potential DIs has been downplayed in the relevant literature. Based on the definition of the WHO (2009), healthcare systems can be classified anywhere between totally centralised to reasonably decentralised. In centralised healthcare systems the main authority is possessed by public parties related to the government. However, in decentralised systems most of the authority and responsibility is delegated to healthcare actors within the system (WHO, 2009). The Iranian healthcare system was centralised before Iran's economic liberalization, and TCC held all the authority in the Iranian health care system (see chapter five). But after Iran's economic liberalization in 1995, the Iranian healthcare system became more decentralized. As we discussed in chapter four, Iran is the only country in the Middle East where private healthcare expenditure is more than that of the public system (Tables 4-12). Our findings show that with the growth of private healthcare and the decentralization of the Iranian healthcare system[1] during recent decades, the role of healthcare professionals has become more prominent in the adoption of new medical innovations. Before Iran's economic liberalization only TCC made the final decision to adopt a new medical innovation, but today, healthcare professionals play a pivotal role in medical innovation adoption. Therefore, companies usually target physicians and other healthcare professionals to diffuse their new innovations. Since healthcare professionals are the main subjects of innovation diffusion, companies ought to convince these individuals in order to tackle the most prominent barriers to innovation adoption. As can be seen from the following results, due to an unstable economic situation, some incumbents might benefit from unethical marketing incentives to convince key decision makers to adopt their innovations. Indeed, as is mentioned by many interviewees in this research, the market's instability has led incumbents to focus on short-term gain rather than long-term programs during the encroachment phase.

[1] Refer to chapters four and five.

For instance, the Cordis sales manager states: "*When a new revolutionary innovation is in question, generally price cannot play the main role. Indeed, when you don't have any competitors and your innovation is totally superior, price cannot play the main role. We don't believe in price competition at the beginning stages of market encroachment. We believe in fair pricing of new innovations and will stick to this price for a long time. Since we price our products fairly, we are considered as the main reference point of Iranian medical society against which to check the market prices. Nevertheless, competitors' pricing strategies are usually based on our reference prices in the market. During the competition time of the DES generation, Cordis' DES prices were relatively higher than the others. In fact, since the other competitors were collaborating with TCC, most of the time they were exempted from paying tax or other customs costs. They were spending remarkable parts of this huge margin on some unethical marketing promotions. This issue made the competition mainly unfair, which made us vulnerable in terms of marketing competitions. This type of promotion was tempting to some physicians at the same time. Cypher's trial results were superb, but Cordis had rarely sent physicians to any conferences (as a promotional gift), whereas the other companies were sending healthcare professionals to different holiday conferences at least three times a year. We considered these activities quite unethical, but we couldn't respond in the same way. Instead, we decided to focus on our services, and, thus, offered the whole range of service to healthcare professionals. We established a scientific section which was responsible for increasing physicians' knowledge about new innovations and showing them the latest papers, studies, and trials.*"

Moreover, the franchise manager of Cordis claims: "*The Iranian medical market has its own specific situation. One of the most irritating issues in the Iranian market dynamic is unethical marketing promotions, which are getting worse day by day. Indeed, if a new innovation disrupts the mainstream market and establishes a new dominant position in the market, we cannot surely consider it as a result of its technological superiority. Sometimes, these hidden unethical activities affect the diffusion of DIs tremendously. Unfortunately, this kind of corruption has been institutionalized in medical markets. The main reason behind the prevalence of unethical marketing promotions in the Iranian medical*

market is the lack of specific regulation of medical industries. For instance, one of our closest competitors used to make extremely friendly relationships with healthcare professionals to persuade them to adopt the companies' new innovations. Since the economic situation is in some ways unstable in Iran, practitioners in the market tend to look for short-term gain instead of long-term benefits. Hence, they have chosen short term plans, such as unethical marketing promotions, to gain short-term benefits. One of the main reasons that we don't act the same is out shared beliefs with our company's leader. Dr. Moradi, the leader of Cordis in Iran, has never believed in unethical marketing promotions, and actually disseminates this value to the whole working organization. Therefore, based on our credo and organizational values, we don't believe in this sort of unethical marketing promotion."

The marketing manager of Medtronic also states: "*I do believe that we should be reasonably tough in pricing. This means that if some small newcomers come to the market with their radically low prices and unqualified products, we shouldn't respond to their threats by decreasing our prices. We should compare ourselves based on our market position and the level of competition. For instance, one of our main competitors decreased their prices by more than 30%. They could do this since they were importing their products without paying any taxes or tariffs. Here you can see the effect of unfair competition leverages on the market dynamic. Some of the other competitors even smuggled their products into the country. Customs and duty affairs take so much time, and medical companies cannot make their customers wait. This is the origin of corruption. Basically, we do believe that we have to follow the principals of our business, and we are ready to pay all the costs of this. But sometimes it seems that in this unstable economy, working based on principals won't pay off, and like the other companies, perhaps it's better to think about some short-term gains and seek exceptional opportunities.*"

Cordis' franchise manager states: "*Regarding unethical marketing promotions, the issue is the nature of competition in the healthcare market. Indeed, if an incumbent provides healthcare professionals*

with some unethical marketing incentives to facilitate innovation diffusion, the second incumbent should supply them with more to buy their attention back. Therefore, instead of focusing on patients and real business they focus on trivial competition, which could be endless. Indeed, unethical marketing incentives will not produce any competitive advantage in long-term competition. They are not sustainable, and just provide a temporary sales increase, which is quite rootless. Therefore, rather than engaging in unethical marketing strategies, investing in increasing capabilities and knowledge of human resources in order to deliver a better service to the customers, or focusing on educational programs for healthcare professionals could be more sustainable, and result in a constant, long-term effect. I want to talk about Johnson and Johnson's HCC certificate. According to this standard, if someone in any franchise in each part of the world gives the clients a gift of more than six pounds, headquarters will dismiss all of the branch's staff. This is one of the glorious values that J&J can always be proud of."

The CEO of Abbott franchise in Iran adds: "*I do believe that although we are suffering from unethical activates in the Iranian healthcare market at the end of the day we will be the real winner. Instead of allocating money to unethical marketing activities we invest in our own employees to increase their knowledge and capabilities in order to provide a better service and show better performance to the customers. We have a social responsibility and we have to uphold it*."

Based on the research findings, it seems that since Corids Co has strongly insisted upon implementing their credo statement. Indeed, there are more transcripts from their mangers regarding this issue: "*Another issue about the Iranian market is emotional reactions towards incumbents' marketing actions. In our experience, in the worst case there are only 2% of patients who cannot afford their medical operations. Therefore, we have allocated 2% of our sales to this category of customers in order to avoid their rejection from hospitals. This 2% is actually nothing in our calculations, but it made a great impact on the market, since the market is so sensitive, and this special treatment has made a respectable reputation for us."* In addition, the franchise manager of Cordis Co mentions:

"*One of the key factors in market disruption is the following: based on our credo, if there is a patient who cannot afford his treatment costs, we won't reject him. It is interesting that all the donations that we have given so far have not been more than 2% of our sales, but the effect of this action has been unbelievable. By making such donations, we made a good reputation in the market and have disseminated the massage that Cordis Co always thinks about patients. It doesn't make any difference if the stent is from another company; if a patient cannot afford it, we will take responsibility of reimbursing him. Therefore, we have a respectable reputation in the market due to our commitment to our social responsibilities*."

Therefore, because of this positive image, when the Xience DES came to the market, despite its superiority, it could not take over the market totally, since Cordis Co had gained a respectable image in the market. Commitment to social responsibility, then, can have a vigorous effect on the diffusion rate of DIs in a sensitive medical market such as the Iranian market.

6.1.8 ***Reimbursement Systems and the Rate of DI Diffusion***

Based on the findings of this research, another considerable issue shaping diffusion dynamics is the nature of the healthcare reimbursement system. Indeed, scholars such as Williams et al (2008) and Van den Bulte and Lilien (2001) consider the reimbursement system as the foundation of innovation diffusion. Our findings demonstrate that successful market disruptors of the Iranian medical market are those that react better to the challenges of the reimbursement system in different market segments. They usually adopt and modify their sales, marketing, and penetration strategies based on the requirements and restrictions of reimbursement systems.[2] Based on most of the interviewees' opinions from this research, the reimbursement system can be considered both as a hindrance or an accelerator during the diffusion of a potential DI. The findings show that successful market disruptors usually

[2] Three characteristics describe the various methods of healthcare reimbursement. These characteristics are the unit of payment, the time span, and the degree of financial risk for the parties (Wouters, Bennett, and Leighton 1998, p. 3).

create opportunities from the inefficiencies of reimbursement systems. The findings suggest that in their attempts to release themselves from the boundaries of reimbursement systems, successful market disruptors usually adopt some innovative marketing and sales strategies to cross the chasm between early adopters and early majorities of consumers.

Regarding this, Cordis Co's sales manager states: "*At the initial stages of launching a BMS in the Iranian medical market, insurance companies used to reimburse a higher percentage of incurred medical costs. The Iranian healthcare reimbursement system is to some extent different from those in developing countries, which strongly affects the diffusion of DIs in this market. Depending on the type of hospital (public, educational, private, foundation based, military, or social security) the main actors in the process of reimbursement systems will be different. For instance, while insurance plays a pivotal role in public, educational, and social security hospitals, other organizations, such as banks, financial institutes, and the military are responsible for their own clients. Therefore, price elasticity becomes a major issue in shaping the dynamic of DI diffusion in different segments of the market. One of the main reasons that in the time between 2002 and 2005 the BMS market didn't fall like other markets was the structure of the Iranian healthcare reimbursement system. In fact, due to technical superiorities, consumption of DESs increased radically in developed countries, and the rate of BMS consumption fell dramatically, since the higher price of DESs was not an issue for consumers while the public and centralized healthcare reimbursement system was in charge. However, because patients were playing the main role in the reimbursement systems in the Iranian medical market the consumption of BMSs didn't reduce as it did in developed countries, since price elasticity was determinant yet. The higher price of DESs was considered a hindrance to diffusing this product into the market."* Moreover, Dr. Nazeri, the father of the intervention operation in Iran, states: "*The cost of DESs was obviously higher than BMSs, which was one of the hindrances to its consumption in the Iranian market, as patients have the main role in reimbursing incurred medical costs*."

Abbott Laboratories' sales manager states: "*Private hospitals are classified among the interesting markets for us, since patients can afford whatever doctors recommend to them. In public hospitals you have to keep the prices sufficiently low so that treatment will be covered by insurance reimbursement, otherwise it will be a problem for hospitals' procurement processes. Although the quality of products is important in public hospitals, price elasticity is the most important concern of incumbents. To launch a new product we should target public hospitals which deal with a large amount of cardiovascular cases every day, as we have to expand our market during the initial stages of market encroachment to disrupt the mainstream market later on. Therefore, these huge public centers, such as Tehran Heart Center with ninety cardiovascular cases per day, could be the center of attention for initial launching activities. This center acts as an opinion leader and influences other hospitals. The reimbursement systems of private hospitals are remarkably efficient, since the actors' network of the reimbursement process does not consist of many dependent actors as in the other segments of the market. Therefore, private hospitals are so much more attractive to the market incumbents. As I said before, some of the public hospitals are opinion leaders in this network, and they should be considered as important nodes of diffusion in this process. But foundation based hospitals are not at the center of launching activities, since they represent a small portion of the market. Therefore, providing a good service, selling more to private hospitals, education, and medical presentations in opinion leading public hospitals should be considered as the main leverages of initial launch activities in the medical market.*"

Although many scholars have discussed the nature of innovation adoption within healthcare networks, such as Greenberg et al (2005) and Geer (1988), it seems that the role of reimbursement systems in different healthcare structures in shaping the dynamic of DI diffusion has been downplayed. There are many scholars who have focused on the role of medical actors' networks in bringing new medical innovations to the market, such as Ramlogan and Consoli (2008), Gejins and Rosenborg (2005), and Mokyr (1998). However, few of them pay attention to the important role of the healthcare reimbursement systems in shaping the DI diffusion dynamic. Moreover, a lack of efficient insurance

systems highlights the importance of social security hospitals. Educational hospitals with reliable insurance support could be the most important targets of incumbents in accelerating the diffusion of their potential DI. In the absence of a reliable insurance system in a healthcare structure, the findings suggest that social security hospitals may help to diffuse potential DIs. Educational, public, and social security hospitals are all appropriate diffusion bases in terms of facilitated reimbursement systems, but the resistance of these reimbursement systems to include new DIs in their insurance policies is considerably higher compared to private hospitals.

6.1.9 Market Retreatment and Potential to Disrupt the Future Markets

The research findings show that market retreatment is as important as market disruption in terms of impact on the dynamic of DI diffusion. In fact, since market retreatment might be understood as a symptom of weakness in the market, incumbents should act conservatively when leaving the mainstream market, since it could cause irreversible damage to their reputation. It is vital for the mainstream market to know the main reason for market retreatment. Indeed, leaving the market due to long-term strategic plans would be responded to differently by the mainstream market to market retreatment due to incompetency. In other words, the specific circumstances of market retreatment will reflect the strength or weakness of incumbents, thereby directly affecting the company's reputation, which is the key to further market disruption.

The findings of this research reveal an example of unsuccessful market retreatment strategy, which lead the incumbent to lose the competition. Cordis Co's franchise manager states: "*When we decided to discontinue Cyphers sales, the market's reaction was dramatic and unexpected for us. I do believe that we should be honest with our clients, but we shouldn't diffuse such news quickly, since the Iranian market was equipped to cope with such news. Therefore, this news ruined our reputation faster than we thought could be possible, and at the same time the other competitors used this opportunity to exaggerate the main reasons for Cordis' market retreatment. At that stage I agreed*

with being honest with our clients and telling them about the issues surrounding Cypher's discontinuation, but at the same time I did believe that we should disclose this news slowly, and prepare the market to react rationally. Actually, disclosing this news ruined Cordis Co's reputation in the market and created an opportunity for the other competitors to gain more market shares."

In addition, the CEO of Cordis Co declares: "*I do believe that moving out of the market was the best solution for Cypher. Indeed, if Cypher had stayed in the market it would definitely have destroyed its reputation and reduced the chance for further disruptions. In a normal situation, small newcomers with their unknown brands and poorly performing products cannot compete with the main incumbents of the market. But in such a situation that there are many sanction against Iran, and the market's financial position is deteriorating drastically, an opportunity is unveiled for small newcomers to get into the Iranian medical market, since they are significantly cheaper*." Therefore, it is evident that exiting market incorrectly will reduce the opportunity of further market disruption by the same incumbent.

6.2 Mechanisms of DI Diffusion in Medical Markets

So far we have discussed the dynamic of market disruption in medical markets. We have broken down the market disruption period into three periods: the market encroachment phase, market disruption, and maintaining the dominancy in the market. This classification has focused on the importance of the dynamic of DI during the market encroachment phase. Subsequently, the concept of low-end disruption in medical markets was challenged, and the relevant dynamic of DI during the encroachment phase was analysed based on low and high-end market disruption frameworks. Next, the battle between incumbents and newcomers in medical markets within regulatory regimes have been analysed, and the dynamics of challenges to pre-market medical trial results were investigated.

In addition, the reinforcing effect of the followers' attack on the market for creating a new market, and the probable positions of the market leader were investigated.

In the following section we will discuss the practical mechanisms through which a potential DI would be able to disrupt the mainstream market and create a new one. Regarding this research objective, firstly we are going to discuss the mechanism through which competitors could develop the required organizational competencies to disrupt the mainstream market. Furthermore, we will reveal our findings concerning the relevant mechanisms for accelerating DI diffusion through less-structured communication channels and informal groups in decentralized healthcare systems such as Iran. Finally, the mechanisms of insight building into the character of the new market and the practical mechanisms for positioning the newly introduced performance values of DIs will be discussed in more detail.

6.2.1 Institutionalizing the Organizational Values to Obtain the Required DI Diffusion Competencies

Organizational competencies are the most important part of disrupting a mainstream market according to Adner (2002). The findings of this research demonstrate that since most of the incumbents in the medical market benefit from spin-off and M&A to create a new DI candidate to disrupt the market, institutionalization of organizational values should be considered the main task of market disruptors in creating their new team to implement DI diffusion. In fact, the findings show the important role of "credo" in this institutionalization of organizational values. A credo is a statement of the code of ethics that each company, firm, or corporation issue to unify the orientation of their human resources in a constructive manner and boost their organizational performance in the market. During the fieldwork it has become evident that most of the incumbents in the market have an official credo which states their code of ethics and organizational values. However, based on the different points of view of the interviewees, possession of a credo itself cannot guarantee organizational productivity.

Indeed, institutionalizing these values and codes of ethics is the key to high organizational performance, which itself affects the rate of diffusion.

A Cordis marketing manager makes an interesting point related to this issue: "*I do believe that if Cypher succeeded to cement its dominant position in the market, this happened solely because of its technological performance values.*" However, the sales manager of Cordis states: "*I believe that the main leverage helping Cypher to become dominant in the market was our principals. Our principals and our method of presenting our product in the market were the most helpful factors in market disruption*."

Our findings show that institutionalization of organizational values and belief in a credo are a matter of top-down enforcement from superior management. The CEO of Cordis states: "*We do believe that we have to use our knowledge and capabilities to the patients' benefit. We have a social responsibility in society that we have to consider all the time. We shouldn't work just in order to make profit. Even if we don't believe in God, we assume that we have been given many things from Mother Nature; therefore, we have to be thankful by using our profits for society rather than ourselves. You might understand these theories better than me, but these are my experiences that have helped me in my mission*." The interviews show that Cordis Co has a stronger emphasis on institutionalization of organizational values than the other incumbents in the Iranian market.

Discourse analysis of the interview transcripts demonstrates that most of the Cordis employees have mentioned the word "credo" in their interviews, and most of them explain the role of credo and organizational values in their activities. For instance, a member of Cypher's launching team states: "*The main concern of Cordis' credo was helping patients by providing fair treatment for them. Therefore, based on this credo, Cordis tried to present a solution which seemed more appropriate for patients. We believe that there isn't anyone that could sell Cordis' cardiovascular products as fairly as us. We never collaborate with any intermediaries and sell our products directly to the end users.*

We believe that if we give our products to intermediaries, we cannot manage and control our product and our reputation, and this is not fair to the patients."

In addition, the franchise manager of Abbott laboratories states: "*We define our stakeholders and priorities them in groups such as patients, society, staff, and shareholders. When you think about the patient you have to do it correctly. Therefore, here in the Iranian medical market we are well known for doing fair business and have gained a significant reputation for this. We never engage in any unethical or unprofessional relationships with physicians because we believe that by focusing on doctors rather than patients we are opening the gates to unethical business. We never educate the doctors unreasonably; it should be justified first, and then we send them to educational seminars or conferences. The main incentive for sending healthcare professionals to conferences or workshops shouldn't be commercial. It should be done simply in order to increase the knowledge of practitioners to increase their performance with patients. If we look at the patient commercially (look at them as a customer rather than a patient) it is the beginning of corruption that will ruin our reputation. There is a huge difference between patient, consumer, and customer in the medical field. Physicians are consumers, since they are the ones who do the intervention procedures. Nevertheless, hospitals are the customers that procure medical devices to be used during procedures, and patients should be viewed as the main stakeholder in the medical business.*"

Therefore, creating a learning atmosphere in order to institutionalize the organizational values and belief in a credo may directly affect a launching team's attitude, and, therefore, their productivity in diffusion of the new DI.

Indeed holding regular meetings to review the credo statement and the organizational values, and having the support of the organization's leader could help a given company to institutionalize their organizational values. By relying on a credo and organizational values, Cordis Co entered the cardiovascular market, and after launching Cypher, it remained the market leader for five years. Most

of the interviewees believe that this happened not only because of Cordis' technological superiority, but also because of their organizational culture.

6.2.2 Less-structured Communication Channels between Physicians Lead Informal Groups and Traditional Word of Mouth as the Main Leverage of DI diffusion.

Boston Scientific's franchise manager states: "*Another issue with the diffusion of a DI in the Iranian medical market is the impact of word of mouth. Word of mouth is one of the most important leverages in DI diffusion in the Iranian medical market. Considering the job aristocracy in Iran the role of word of mouth is undeniable in the diffusion of a new DI in a market with powerful nodes of diffusion. The hierarchical structure of Iranian physicians is not just about experience or expertise. Geographical locations also give physicians some advantages in this hierarchy. For instance, physicians in other provinces prefer to follow the choices of their colleagues in Tehran."*

A Corids Co franchise manager adds: "*The other means of diffusing a DI in medical markets is through informal groups of doctors. In other words, different doctors belong to various informal groups that we have to consider during the process of DI diffusion. This affects the targeting strategies of incumbents. These informal groups accelerate the process of diffusion by benefiting from a domino effect. For instance, when we decided to discontinue the diffusion of Cypher, the market's reaction was enormously disappointing. I do believe that we should have been honest with doctors, but we shouldn't have spread the news so quickly, as the market was not ready to hear our news at that time. Therefore, the market's response affected us, and the other competitors abused the opportunity to ruin our reputation in the market*."

The CEO of Abbott discusses the importance of word of mouth compared to other diffusion methods. He states: "*Healthcare professionals paid attention to our promotions mainly because of our reputation and brand power in the market; otherwise, they wouldn't have wasted their time attending*

our promotional sessions. Abbott's reputation was the main factor attracting the physicians' attention. New medical innovation knowledge was usually diffused through many studies and published scientific papers, then confirmed with a remarkable amount of pre-market trials and sample testing. Trial results are the most convincing index for healthcare professionals to judge a new innovation, and if a given innovation qualifies,, it may have a great chance of getting into the mainstream market through unofficial groups and word of mouth in healthcare society. Word of mouth is undeniably important in the Iranian medical market where other provinces look to Tehran and follow Tehran's example."

Therefore, it seems that word of mouth as a diffusion accelerator could help a given company to disrupt the market earlier than other competitors. Indeed, in Iran and other developing countries, since communication between healthcare professionals is still relatively traditional, word of mouth should be considered the most important factor in accelerating the diffusion of a given DI.

6.2.3 Market Intelligence System: The Leader's Option to Modify their DI Diffusion Strategies based on Market Insight

According to the research findings, a clear market insight is key to disrupting the mainstream market, since it will reveal the major opportunities in the market. In fact, since most market incumbents fail to adopt a realistic insight into the future market, they cannot allocate the recourses properly to their R&D sections in order to create revolutionary strategies to disrupt the market. To disrupt the mainstream market successfully, the market should be studied accurately in order to identify the main nodes of diffusion.

For instance, a Cordis Co sales manager attributes Cordis' success at disrupting the BMS market to their clear market insights. He states: "*Our competitors had a mistaken image of the market. The market that they had assumed was the whole market was only 15% of the actual market. In other*

words, they were mistaken about the actual and potential size of the market. Since they hadn't identified the actual size of the market, they assumed that we could not compete with them in their pre-established market. However, we identified the actual size of the market, which was at least seven times bigger than our competitors had assumed, and established our launching process there."

The research findings indicate that incumbents of medical markets define their markets based on a great deal of criteria. In fact, in medical markets they face a market structure with a complex adoption network. There are many decision makers involved in the process of medical procurement, and various actors which engage in market interactions. This complexity makes it difficult for the market incumbents to define their markets and build up their market insight. Therefore, it is vitally important for market incumbents to identify the actual market and the relevant actors in market interactions. A Boston Scientific sales manager states: "*We define our market by the number of working hospitals in different regions, since we believe that hospitals are basically in charge of medical procurement, although physicians have a great impact on this process at the same time. In fact, healthcare professionals make the main decisions, and hospitals follow their decisions. Patients' financial situations also affect the rate of diffusion. Therefore, the decision process will be as follows: doctors, hospitals, and patients*." However, Medtronic's marketing manager has a different opinion: "*We define our market by the number of physicians in private hospitals, while we define our market by the number of hospitals in public sector. Indeed, we define the market based on the main decision makers in the process of procurement*."

Indeed, the main purpose of having reliable market insight is to find a disruption opportunity within the mainstream market. The research findings state that a clear market insight is usually considered by the leading incumbents as the main requirement of pre-disruption preparation. However, some of the interviewees mention that a clear market definition will not help to find any disruption opportunities. Indeed, they believe that in order to find any disruption opportunity, they need to focus on illnesses and their main causes. Hence, by following the trend of causes of disease incumbents will be able to

find an opportunity to disrupt the market. Therefore, according to the findings of this research, a reliable market insight in terms of market structure and interaction, and potential disruption opportunities will enable the incumbent to disrupt the mainstream market (see Figure 6.10). In other words, incumbents' market intelligence systems should be focused on two major areas: the market's current structure and the interaction between the actors in the medical network, and potential chances to open new opportunities for further market disruption.

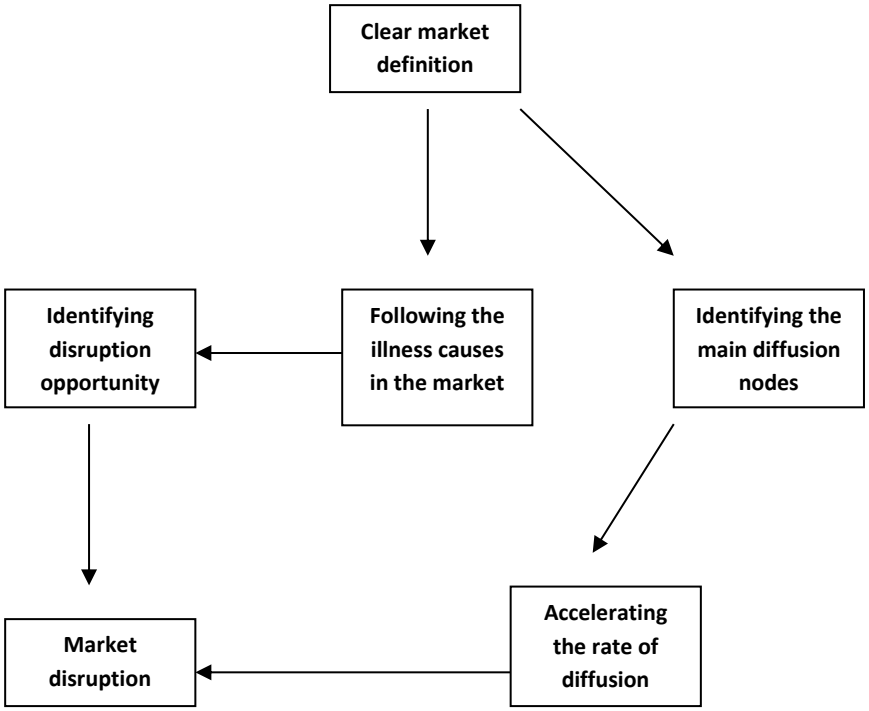


Figure 6.10. The Impact of Clear Market Definition

The research findings also demonstrate that market segmentation based on the mainstream market requirements may contribute to the incumbents' need to focus more on the market's requirements. In this way, the market diffusion of a given revolutionary innovation will be facilitated. Therefore, in order to diffuse the technology in a specific part of the market incumbents need to understand the specific attributes of that segment. As a result, incumbents will have a clear idea of segmentation, and this will help them to disrupt the market more easily (see Figure 6.12). Regarding this, the technology

manager of Cordis Co states: *"If I wanted to describe the market segments, I would divide the market into two different segments: public and private hospitals. We actually define the market according to hospitals rather than doctors or patients. Although physicians and patients are equally important in the process of decision making, in general, the medical market is defined by hospitals*."

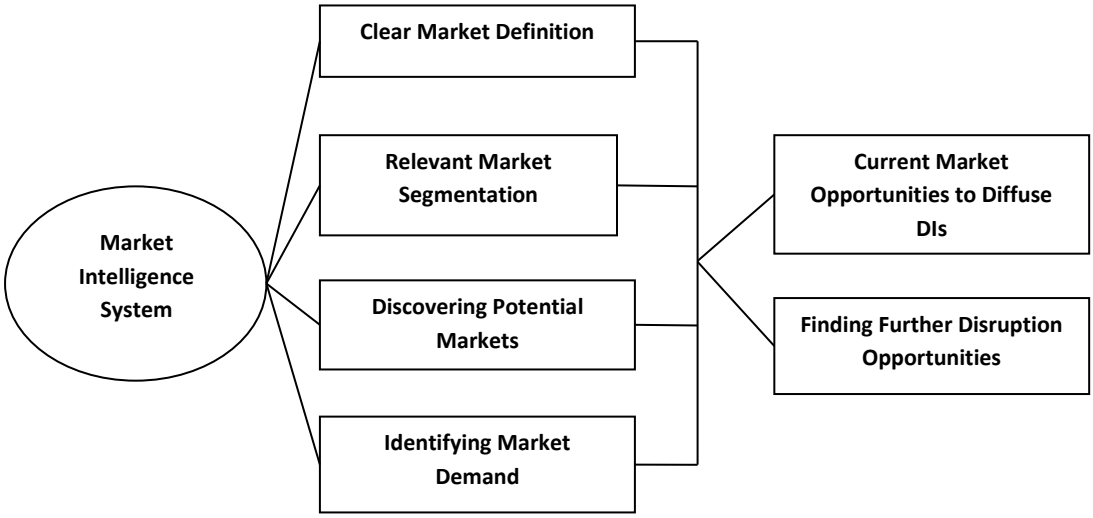


Figure 6.11 Main Enabling Mechanism of DI Diffusion in each Segment

Finally, a firm's intelligence systems can help them to seize opportunities to create DI candidates. The CEO of Cordis Co's Iranian franchise states: "*We always study the causes of illness rather than their effect, to predict further opportunities for DIs. These trend studies will help us to predict the unforeseen future needs in the medical market. Therefore, we predict the opportunities of the future in the present, and plan to disrupt the market at the right time*." Indeed, the findings of this research show that incumbents should focus on the causes of illnesses in order to predict future trends and find an opportunity to disrupt the mainstream market.

6.2.4 Modification of a DI's Launching Tactics to Move from Encroachment Phase to Dominant Disruption

The findings suggest that in order attract the early majority of the market during the encroachment phase, launching tactics should be modified in order to meet the requirements of market disruption. The findings demonstrate that technical capabilities of the proposed DI, availability of the DI in the market, proposed services attached to the DI in order to offer a bundle of performance values to the customers, and fair pricing are the main strategies that successful market disruptors apply. R&D sections of medical devices firms are responsible for the technical capabilities of their proposed DI, while strategic business units (SBUs), or spin-off marketing teams, are mainly in charge of other modifying strategies. Regarding DI availability, the research findings state that two major types of firm have been successful at making DIs available to disrupt the mainstream markets: firms with direct distribution channels, or pre-encroachment market bases. Pre-encroachment market bases refer to the relevant market segments that firms have built up their reputation with through their marketing activities.

The research findings also emphasise the role of educational programs for healthcare professionals. This is a major service, which may add more value to the newly introduced bundle of performance values by the disrupting firms. The final modification of launching tactics should take place based on the price elasticity of medical markets; the findings suggest the adoption of a fair pricing strategy.

Regarding the value of proposed services to enhance a DIs' performance values, the CEO of Cordis Co states: "*In 2002 Cypher was launched in the market as the first DES, and challenged the technical capabilities of successful BMSs in the market, such as Sonic, Velocity, and Victor. When Sonic was released to the market, most of the hospitals wished to return their Velocity BMSs back to Cordis Co due to the higher technical capabilities of Sonic, and its lower risk of collateral application. We responded affirmatively to the markets desires, and their stock was changed to Velocity stents. Despite the challenging nature of this occurrence, it enhanced our reputation in the market in terms*

of post-sales services. This challenge actually unveiled the value of sales services offering a more desirable bundle of performance values to the customers. It also made clear to us that if there was a company in the market which could offer the ultimate sales services and provide a wide range of choices to the hospitals, it could challenge TCC and perhaps be able to open a new market stream. In fact, after this occurrence the lack of sales services in the market was identified by Cordis Co."

The findings demonstrate that successful market disruptors usually emphasise the role of sales services in disrupting the market. An Abbott sales manager points out the importance of service oriented organization of sales teams in order to disrupt the market. He claims: "*In order to serve the market properly we have organized two groups, scientific and sales teams. The scientific team targets the healthcare professionals and presents the latest technical advancements of the company based on facts and figures, to position the new performance values in the market, and the sales team are in charge of further interactions with the key decision makers in the device's procurement. Indeed, the scientific team increases the market's knowledge of the DI, and sales team make it available in the market*."

The findings state that DI availability in the market usually necessitates the activation of at least one of the following sub-mechanisms: mass marketing relying on the current market bases, and hospital stock management by providing the whole range of products. Considering the first of these, a Cordis Co sales manager states: "*In 2003 we launched many consuming cardio devices base on our reputation in the market. We decided to substitute the old cardio facilities and consuming products with newer devices, and then facilitate the procurement process for the hospitals. In adopting these strategies we were not thinking of our sales volume, but creating market bases for further market activities."* In other words, Cordis Co tied hospitals to its own consuming products by providing the market with massive amounts of them. This lock-in strategy was a pre-encroachment tactic to build up market bases for further market disruption.

The findings pinpoint hospital stock management as another sales service which indirectly enables firms to provide DI availability in the market. A Boston Scientific sales manager states: "*The most important issue that affected the availability of the DES was the short use by date (UBD) of these products, which made the stock management of the hospitals a valuable service. In managing their stock of DES, we required hospitals' stock information, which could be vitally useful for making our marketing decisions at the same time*." Additionally, Cordis Co's sales manager states: "*In order to avoid wasting the hospitals' budget on medical procurements, Cordis Co usually offered hospitals the option to order only a few DESs, but make their orders more frequently. This strategy helped hospitals to avoid any DES expiration and retain some of their budget, rather than spending it all on medical devices. This 'just in time' (JIT) order system actually benefited hospitals due to less warehouse occupation, and also had other benefits. For instance, by buying less but more frequently, hospitals never became indebted to the firm*." Therefore, hospital stock management service indirectly facilitated the hospitals' procurements of devices, and had other benefits for them at the same time. In fact, these kinds of sales services enable DIs to present their proposed bundle of performance values more effectively to the target market. At the same time, these services would build up a trust relationship between the firm and the customers, which forms customer bases for further market disruption activities. Finally, these services provide the market incumbents with precious information about the consumption pattern of the mainstream market, which in turn may enable the firms to make the relevant marketing decisions to respond the market challenges and disrupt the mainstream market.

However, Cordis' marketing manager believes that Cordis basically offered a bundle of significant services to disrupt the mainstream market. He states that: "*In the critical economic situation, based on our stock management we were able to provide enough DES stock to all our target hospitals. Also, our hospital stock management was really helpful in diffusing the product into the market efficiently*." The CEO of Cordis Co also states: "*We didn't let any intermediaries disturb our direct relationship with the market, and, therefore, decrease the possibility of any black market occurrence. We actually needed to have a comprehensive market insight based on the collected data from the market. Since*

our DESs possessed remarkable technical capabilities compared to the other available options in the market, we suggested hospitals purchase based on their actual needs, rather than the potential requirements of the hospital, to avoid any product expiration. By offering remarkable sales services and relying on Cypher's technical performances, we gained Boston and Medtronic's market share immediately. In 2005 we gained more than 67% of the Iranian cardiovascular market with our consuming and commercial products. At the same time, launching Cypher (the first DES in the world) reinforced our leading position in the market and gave us a better reputation. Actually, we were one of the top seven companies to launch."

In terms of product availability, the findings point to the importance of mass distribution. In other words, the findings show that the most successful market disruptors are the firms who provide the whole range of products to the market and have a conspicuous presence there. As shown in Figure 6.12, the findings indicate that the process of trust building between early adopters and DI diffusers is highly dependent on the availability of the DI during the initial stages of market encroachment. The findings also show that Cordis Co has been a pioneer in adopting this strategy to disrupt the mainstream market during the DES launch time. A Cordis Co franchise manager states: "*We have been superior in terms of providing various ranges of products to the market. For example, we have been the only firm to provide cardiovascular devices for infants to the market. Despite the fact that mass distribution and total presence in the market are extremely costly, our mission is to serve every category of patient. We increase our efforts to deliver better services to our prior stakeholders. Although DES distribution was our core business, delivering sales services was the main part of our business. We believe that selling medical innovations without the relevant services never leads successfully to disruption of the mainstream markets. By providing this amount of sales service we could take over the market completely and disrupt it intelligently*." In another part of his interview, the Cordis Co franchise manger states that the technical capabilities of a DI defines the types of plausible sales services offered by incumbents: "*During the DES generation, most of the incumbents were reluctant to import massive amount of stents due to its short UBD. Therefore, there was a*

significant gap between the market needs and stent supply in the market. However, we were brave enough to import a massive amount of DESs of different types, and managed to sell all of them before their expiry date. Sometimes it happened that a stent was transferred between cardio centres forty times before being used by a doctor. These sorts of services were really valuable for the healthcare professionals at that time, and helped us to build a significant level of trust with our healthcare professionals."

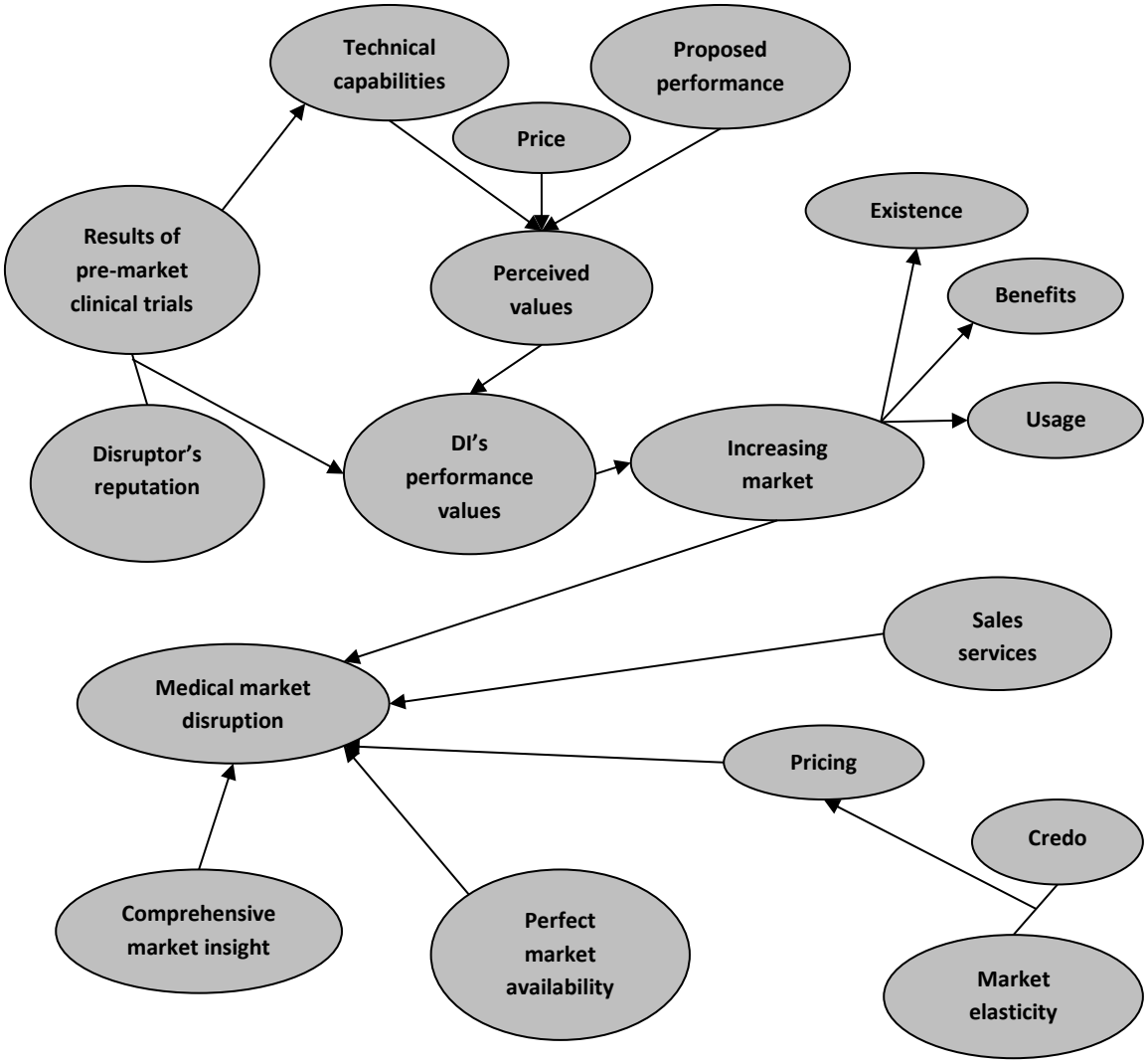


Figure 6.12 DI Diffusion Mechanisms in Medical Markets

A Cordis Co sales manager states: "*Although stents form the main part of our business, the packages provided by companies (including accessories and sales services) are essential for healthcare professionals to make a decision about purchasing. It is important for the companies to provide the complete range of products and offer a complete package of accessories in order to gain the trust of the healthcare society. Availability is also important for the customers. Actually, physicians need to have the entire range, including all sizes of stents, in their stock in order to give them more flexibility in their medical operations. This is one of the most important issues in the process of trust building between healthcare professionals and medical firms. Companies should make sure that all types of their products and accessories are available to healthcare professionals in order to enable them to deal with different groups of patients. Therefore, offering stock management to hospitals plays a vital role in the trust building process between healthcare professionals and medical companies.*"

Based on our research findings, another type of service that medical companies should provide for doctors in order to facilitate the diffusion of new innovations in the market, is education. Because a revolutionary innovation is unknown in the market, it should be introduced properly during the encroachment phase in order to disrupt the mainstream market. Nevertheless, this new revolutionary innovation necessitates the learning of some new practices. Therefore, one of the most necessary services in the medical business is an educational program for healthcare professionals. On this issue, the technology manager of Cordis Co's franchise in Iran states: "*We believe that we should teach doctors how to work with new medical devices and help them to learn about new medical procedures. Therefore, we bought a simulator for the new generation and put it in the central lab to train the young physicians how to perform the stenting intervention. By doing this we facilitated teaching for key doctors and attracted them to our central lab*." Moreover, the CEO of Cordis Co states: "*We never make the doctors use our products. We simply tell them about the benefits of the new innovation and give them more options from which to choose. It is a doctor's job to diagnose which device is better for the patients.*"

Finally, after bringing a DI with high technological capabilities into the market and building a trust relationship with healthcare professionals, sales conditions should be facilitated. Here, based on the research findings, pricing strategies play a pivotal role. Regarding the importance of pricing strategies a Cordis Co sales manager says: "*Our competitors had their own pricing strategies which were useful for them, but we have had a different pricing strategy from the rest of the market. For instance, we wouldn't consider any discount for the doctors who use our products. Our stent prices were the same all around Iran, since we believe in fair pricing: the total cost with the minimum margin.*"

An Abbott marketing manager also says: "*Maybe one of the differences between Xience and Cypher was their different pricing strategies in the market. Public hospitals had privileges in Abbott pricing strategies and would get Xinece at a cheaper price than private hospitals. In fact, contrary to Cordis, with their fair pricing strategies, Abbott adopted a multi-pricing strategy to compete with Cordis. They issued different prices in Tehran and the other provinces. Abbott's products were technically qualified and available in the market, and, therefore. they managed to get a huge market share. It is interesting to know that this multi-pricing strategy hasn't led to any corruption in the market yet*."

Cordis Co's marketing manager points to other issues related to pricing strategies. He states: "*Another issue is our low sales margin. We believe that we shouldn't get financial benefit from patients. We should create the market value with our own pricing and marketing strategies. We managed to get our surplus from the volume of sales, rather than high margins. Therefore, since this objective was compatible with our credo, we succeeded with it, and I can say confidently that there isn't any one in the Middle East who can sell Cordis stents more professionally than us. We also attracted other competitors to come to the Iranian cardiovascular market, but since our margin is so small they can rarely compete with us in this market. For instance, TCC, which possessed both financial and political power before the economic liberalization in Iran, couldn't compete with us in terms of relevant price based upon the technical performance of the products. Since our services to the*

hospitals delivered significant performance values and our innovations' availabilities were considered, TCC couldn't keep competing with us."

According to the key decision makers of all the major incumbents in the Iranian medical market, pricing strategies should be determined in conjunction with three other key factors: the technical capabilities of the DI, market availability, and sales services. The findings demonstrate that while Cordis disrupted the BMS market ,relying on fair pricing and focusing on sales services targeting healthcare professionals. Abbott laboratories, on the other hand, concentrated on multi-pricing strategies and focused on the satisfaction of marketing channels. Therefore, it seems that there should be a meaningful correlation between the levels of sales services and the adopted pricing strategies in order to disrupt the mainstream market successfully. While the firms with fair pricing strategy chose to design their sales services around their customers, those adopting a multi-pricing strategy target the marketing channels to deliver the values of sales services. The technical capabilities of DIs and perfect market availabilities, then, are necessary conditions for a market disruption mechanism, while value driven sales services and facilitating pricing strategies are sufficient terms.

6.2.5 Positioning New Performance Values in Customers' Evaluation Systems to Disrupt the Market

A Boston Scientific's sales manager states: "*Perhaps too much flexibility in the pricing strategies will ruin the image of firms and potential DIs in the market. Indeed, market disruption takes place when there is balance between a potential DI's prestige and the flexibility of related sales strategies. There are always some people who know the price of everything and the value of nothing. The value of a given DI is determined by its technical capabilities (proved by studies and clinical trials), perceived performance values by customers (delivered by sales services), and the price of delivering these values to the customers (by pricing strategies). Therefore, in order to disrupt the market we should talk about the performance values perceived by customers, rather than the values themselves. In fact,*

market disruption faces failure if the intended performance values are not perceived by the target market. Therefore, positioning the designed performance values of DIs in market evaluation systems plays an eminent role in forming the mechanisms of market disruption."

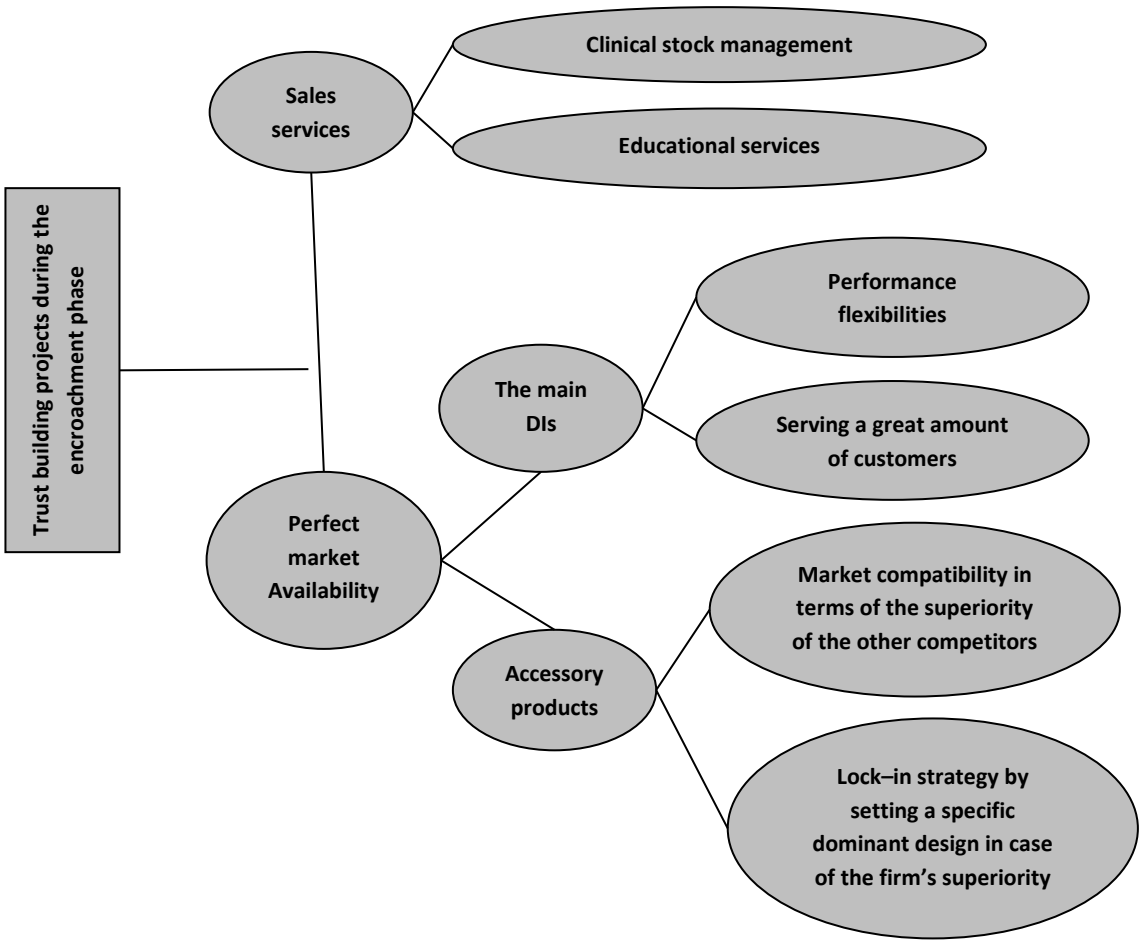


Figure 6.13. Process of Trust Building during the Encroachment Phase

However, the process of enabling the perceived values of a DI has its own mechanism for integrating the new values with the current beliefs of the market. The findings demonstrate that this process is more industry oriented. In other words, it is the nature of the industry which determines the actors and mechanisms that enable the DI's perceived values. Dr. Kazemi-Saleh states: "*If I want to adopt a new*

innovation in the medical devices field, I will first need to know about the clinical studies that have been published about this new device. After this, I will ask the company to provide me with CE and FDA certificates, which make me more confident about that product. After having look on all these documents, it would make sense for me to spend time talking with them about the new innovation to learn more about the new value proposition of this new innovation. Next, I need a sample to see the quality and productivity of the product in practice. I use these samples in the most complex cases in order to see the result and performance of the new innovation. At the last stage I ask them to give me their follow up studies on their drugs and the further possible side-effect of the device. However, companies can rarely present a follow up study." Therefore, as is evident from the research findings, stressing the value propositions of a new innovation through constant interaction between the healthcare professionals and the medical firms is one of the most significant parts of the market disruption mechanism.

Based on the findings, technical capabilities and the proposed performance values of DIs could produce new opportunities for generating and adopting new launching strategies. A Medtronic technology manager states: "*Today, through the development of knowledge, shelf life has been increased up to one year, and has changed the form of services in the cardiovascular business*."

From the comments of a Cordis Co sales manager, we can see that the emergence of Xience in the market highlighted Cypher's deficiencies in terms of technical capability, such as a lack of flexibility and a short shelf life. Indeed, Xience showed great performance and delivered a useful bundle of new values to customers. While Cypher had to be sold in less than four month due to its use by date (UBD), Xience could be preserved for almost a year, which provided new opportunities for Abbott laboratories in their launching strategies and sales services designs. Therefore, by targeting Cyphers deficiencies and bringing a new innovation offering a better bundle of values, Xience replaced Cypher as the market leader and re-disrupted the newly created market. The newly offered values by Xience actually helped Abbott laboratories to produce more flexible marketing and sales strategies, which

played eminent roles in market re-disruption. Therefore, new technical capabilities and newly offered values by Xience not only met the demands of the market and rectified Cypher's' deficiencies, but also created many opportunities for Abbott Laboratories to re-disrupt the market by adopting new launching and marketing strategies, and designing new sales services. Therefore, it appears that there is a direct correlation between technical capabilities and newly offered values by DIs, and the potential to adopt new marketing and launching strategies and design new sales services on to enable the mechanism of DI diffusion in the mainstream market. In addition, based on the findings of this research, a firm's reputation and clinical studies of DIs both increase the probability of new values impacting the mainstream market. Commenting on this issue, a technology manager of Boston Scientific states that pre-market and clinical trials as proof of technical capabilities, and a firm's reputation built on previous actions in the market, form a synergic interaction in which new performance values of DIs can be communicated through the diffusion channels to position the new performance values in the mainstream market. Hence, at this stage KM would enable this mechanism to diffuse the knowledge of the DI in the market during the encroachment phase, while market disruption will be guaranteed by perfect market availability of DIs at a competitive price.

The franchise manager of Cordis Co in Iran explains the pivotal role of clinical and pre-market trials as the proof of a DI's technical capabilities. He believes that trials with larger numbers of studies, random selections of cases, and multi-centered[3] conduction of trials have more validity. In addition, Dr. Kazemi-Saleh points to the convincing role of pre-market trials in the process of DI diffusion in the medical market. He states: "*Cardiovascular knowledge is significantly developed in Iran, as most of our colleagues attend different American and European seminars and workshops. Therefore, most of the time, before the launch announcement of any new innovation in the cardiovascular market, we know about it and have consulted the recent studies and pre-market trial results. Sometimes we even push companies to bring new products into the market*."

[3] Running clinical studies in more than 2 hospitals or health centres

Conclusion

Inn this chapter we have presented the research findings on the dynamics and enabling mechanisms of DI diffusion in medical markets. Concerning the dynamics of DI diffusion in medical markets we first introduced the concept of market encroachment during the initial stages of the market disruption process. Based on our definition we indicated the priority of organizational competency development in disrupting the market, via various leverages, such as institutionalization of the organizational values (credo), encouraging the sprit de corp, and SBU and spin-off management, which build up reputation, prestige, and brand power for an incumbent. Nevertheless, the process of trust building during the encroachment phase requires comprehensive knowledge of market information to build up market insight, in order to choose the correct penetration point for disrupting the mainstream market (it does not matter whether this is the high or low end of the market), and adopt the most appropriate launching strategies to deliver the most required performance values to the customers. The process of pre-market clinical trial results and the reinforcing effect of the followers who attack the position of the market pioneers are other components of DI diffusion dynamics that should be considered by market incumbents.

However, according to the findings of this research there are some prominent mechanisms which enable the process of market disruption. These mechanisms are as follows: increasing the market's knowledge of new DIs, positioning new performance values in customers' value frameworks, building up market insight based on information management during the encroachment phase, and building an agile R&D division to respond to clinical trial challenges.

Therefore, in the next chapter, we will focus on the managerial lessons that emerge from the findings of this research, and in the final chapter of this thesis we will summarize the findings of this research and discuss the main contribution it makes to the academic world: the introduction of a DI diffusion regime. A DI diffusion regime is the combination of DI diffusion enabling mechanisms and their direct effect on the components of DI diffusion dynamics. In the eighth chapter, after summarizing the

findings from a theoretical point of view, we will put the dynamic and mechanisms competent of DI diffusion aligned in a newly introduced framework, by which the dynamic and origin of market disruption by a potential DI will be analysed and demystified.

Chapter 7

[MANAGERIAL IMPLICATIONS]

Introduction

The longitudinal case study of this research into the stenting market and in-depth interviews with the key decision makers of the innovation launching teams of four of the main incumbents of the Iranian CV market, have enriched the findings of the research with a significant amount of managerial lessons for the practitioners of the CV market. The presented findings and analysis in Chapter six elaborated on the dynamic of DI diffusion in medical markets and investigated the major mechanisms which form the pictured dynamic. In fact, the mentioned mechanisms and depicted dynamic of DI diffusion elucidate the emergence of a new diffusion regime, which is called the disruptive diffusion regime. This regime consists of DI diffusion mechanisms and eventual dynamic based on the constant interaction of actors in medical systems. In this chapter the most important managerial lessons from the analysis and findings will be discussed (Table 7.1). Focusing on the managerial toolkit during the encroachment phase to disrupt the mainstream market, the importance of esprit de corps when launching to tolerate diffusion ambiguities during the encroachment phase will be discussed. Next, the main difference between customers and consumers in medical markets and the relevance of this for delivering new performance values to the market will be analysed. Manipulation of the clinical trial results for marketing purposes and the importance of risk tolerance during the encroachment phase will be noted afterwards. Finally, the role of scenario making and follow-up plans to face the challenges of the market, caused by the invasion of followers to the newly opened market, is discussed. Consequently, the importance of technical capabilities of medical DIs and the role of new performance values in disruptive diffusion regime will be discussed. The managerial implications mentioned in this chapter could be a subject of further attention by all practitioners in the medical markets, including healthcare professionals, medical device companies' senior managers, and key stakeholders of medical device companies.

	Managerial Implications
1	Give priority to developing the required organizational competencies by organizing mechanisms to disrupt the mainstream market.
2	Enabling mechanism of value creation and delivering those values to disrupt the mainstream medical markets
3	Scenario making and follow-up plans to respond to the unpredictable challenges of the market and agile R&D responses to continue the market leadership based on market intelligence system mechanism.
4	Keep the balance between technical capabilities, DI pricing, and required sales services to efficiently deliver desirable and convincing sets of new performance values.

Table 7.1 Managerial Implications

7.1 Give Priority to Developing the Required Organizational Competencies by Organizing Mechanisms to Disrupt the Mainstream Market.

One of the most important findings for managers is understanding the importance of sprit de corps at the initial stages of launching new revolutionary innovation in the market. During the interviews most of the interviewees pointed to the pivotal role of their launching team's esprit de corps during the encroachment phase. Based on the findings, medical incumbents usually make a separate strategic business unit (SBU) to take charge of launching new innovations. Indeed, this team is responsible for seeing this revolutionary innovation through infancy, the encroachment phase, and disrupting the market. In other words, this team will be responsible for building an identity for potential disruptive innovation and diffusing it through the market for sustainable market disruption. From a corporate strategy perspective this may be to do with accelerating innovations to market in a smaller, faster business environment (to behave like small companies with more flexibility and away from regular

constraints and bureaucracy of the firm). This of course has management implications for senior strategists when deciding whether to allocate resources for a new SBU.

Most of the interviewees mentioned that there would be a considerable amount of internal and external pressure on the launching team during the encroachment phase of innovation diffusion. Internal pressures are usually from senior management, which forces the launching team to achieve the organizational goals regardless of their realistic or unrealistic natures. Additionally, there are some external pressures mostly imposed by regulatory bodies of the industry, and competitive forces from the current competitors. Hence, in order to tolerate the initial pressures successfully and pass through the encroachment phase, a high level of esprit de corps is needed among the launching team members. In order to provide such esprit de corps among the launching team members it is necessary to understand the cultural context of organization in order to know how to motivate the launching team and keep them motivated. In response to this a sales manager of Cordis states: "*The human resources have had undeniable impact on our job. Indeed, the working atmosphere is tremendously intimate, flexible and at the same time professional, which makes the team members well-coordinated. Relying upon the strong leadership and flexible, creative working environment, Cordis could disrupt the market by offering innovative sales services, which delivered new performance values to the market. These innovative services would never be delivered if Cordis didn't have a rigorous coordination. It deserves mentioning that the role of Dr.Moradi as the leader of Cordis was really important, since he designed a well-structured report system to control the diffusion procedures, but at the same time the team work was incredibly flexible.*"

One of the most important competencies to disrupt the mainstream market is the capability of the incumbents to tolerate the risk during the encroachment phase. In fact, risk taking is one of the most required characteristics of the incumbents who tend to disrupt the mainstream market. Cordis provides a suitable example of risk tolerance, since they disrupted the CAD treatment market during the BMS and DES generations. In this regard the Cordis CEO of the Iranian franchise states: "*The first DES in the Iranian medical market was launched in 2002. Although it was a risky decision to launch this*

unknown innovation into the market we did it, since Cypher had shown significant results during the clinical trials. During the initial launch times, the expiry date of Cypher was tremendously short, which gave us no choice but to accelerate the process of sales and diffusion. We wanted to invest in market creation for Cypher as the first DES of the world, and it required a time consuming and risky process. Tolerating the initial pressure caused by market uncertainty, Cordis managed to create a new market and partly disrupt the BMS market."

The Cordis franchise manager unveils the other side of Cordis' risk tolerance. He states: "*in 1995 TCC was so strong because they had some privileges, including tax exemption, tariffs, and barrier exemption, and all the other public cost exemptions, while the other competitors didn't benefit from these advantages, which was not fair at all. Therefore, we decided to work independently in the market, since first of all we aimed to invest in market creation rather than a normal marketing procedure, and secondly working with TCC wouldn't make the market any more absorbent for healthcare forces. Cordis was told that they might go bankrupt if they don't collaborate with TCC. This fear was rooted in incumbents' ignorance. In fact, none of the incumbents had studied the market before, and thus, they didn't have any idea about the actual and potential market size. However, Cordis studied the market and found that this fear is rootless, and the actual size of the stenting market is at least 8 times bigger than TCC assumed.*" Therefore, more knowledge of the market would help incumbents to tolerate the associated risk with the diffusion of potential DI.

However, the organization of the launching team in coordination with the other parts of organization is equally important. In this regard, the Cordis franchise manager says: "*Indeed, all of the administrative personnel know about the innovation and associate values with it. It gives them a good feeling of knowing what they are doing and also makes them more responsible. Although we have fixed pricing strategies, on the other hand, we have provided different types of sales services and training for all the stakeholders, including healthcare professionals, physicians and also our own personnel. We distributed the sales responsibilities based on geographical locations of hospitals and allocated each region to a person to manage all the sales affairs in the region's hospitals. This*

organization strategy based on the market enabled us to collect the required information about the current market for the market intelligence system to analyse the market insight to disrupt the current market. In other words, this organization strategy enables the company to focus on the market, therefore, all the attempts will lead to a better DI presentation in the market, which facilitates the process of market diffusion."

Therefore, creating a separate strategic business unit for new revolutionary innovation could be a useful strategy in accelerating the diffusion rate of potential DI. In addition, based on the research findings it seems that geographical organization of sales teams could be helpful as well in order to focus on the market needs and collect the required information to build market insight.

Therefore, managers should give priority to developing the required organizational skills and competencies to disrupt the mainstream market, since according to the findings of this research, market disruption is not just based on technical capabilities of potential DIs. Rather, it is rather about the quality of newly introduced performance values and the way these values will be delivered to the customers. According to the findings of this research, institutionalizing the organizational values which have been stated in the organization's credo, developing a high level of esprit de corp through leadership, and organizing strategies of SBUs and Spin-offs would build a certain level of reputation, prestige, and brand power based on the previous performance of the incumbent in the market within a path dependent context.

In other words, since the amounts of in-house DI developments have been decreased in medical industries recently, many great incumbents have partly outsourced their R&D activities. Therefore, today leading incumbents of medical markets are mainly focused on DI diffusion, which makes diffusion team organization tremendously important for them.

According to the findings of this research, successful market disruptors in medical markets, such as Cordis and Abbott Laboratories, usually define two main teams in their DI launching organizations: marketing and sales. While the sales team should take care of DI availability in the market and

performing sales services, the marketing team is responsible for delivering the new performance values to the customers. As it can be seen in Table 7.2, their main task is to increase the market knowledge of DI's existence, superiority, and performance. In other words, the marketing team should highlight the introduced performance values of potential DI and challenge the structure marker's current demand to fit the new introduced performance values with the stimulated needs of market. According to the findings of this research, the marketing team should mainly focus on the social contagion of DI's knowledge, benefitting from mass media exposure, normative peer pressure, and competition resources. The marketing team is also in charge of product, market development strategies, which are meant to diffuse new DI in the current market, and sustaining innovations in new markets. Finally, the marketing team should be in constant communication with healthcare professionals to understand their needs and also define self-learning mechanisms in order to increase their own knowledge, since healthcare professionals' education should be delivered delicately.

Marketing Team Tasks	Sales Team Tasks
• Increasing the market's knowledge of new DI • Highlight the new introduced performance values by DI and challenge the current nature of demands in the market to increase its compatibility with the market needs • Defining self-learning mechanisms for healthcare professionals to increase the Trialability and observability of the new DIs	• Availability of DI in the market • Performance of sales services • Decreasing complexity of DI diffusion • Focus on customers' satisfaction rather than solely selling

Table 7.2 Main Values and Tasks of DI Diffusion SBUs

Consequently, since DIs are quite unknown in the market, during the encroachment phase there would be significant internal and external (market) pressure on the launching team to take the potential DI from its dark corner and introduce it to the market from different aspects. Thus, designing a

mechanism to increase the sprit de corps is the key task of senior managers in diffusing an unknown DI to the market in a disruptive manner. Setting a market intelligence system by establishing an efficient report system could give the senior managers the ability to control the system during the encroachment phase. However, the report system should be designed in such a way as to keep the creativity of the launching team in order to face the unpredictable challenges of the market.

7.2 Enabling Mechanism of Value Creation and Delivering those Values to Disrupt the Mainstream Medical Markets

Based on the findings of this research the role of clinical trial results are pivotal to convince physicians to adopt new unknown DI. However, the scientific authentication of the trial results should be considered during the process of trust building. Sometimes clinical trials have wider applications than scientific evidence of technical capabilities on new MDs. In fact, the findings show that sometimes incumbents manipulate the clinical trials and the relevant results based on their marketing strategies to affect the market's perception of new introduced performance values by themselves or the other incumbents.

For instance, Boston scientific conducted some clinical trials focusing on restenosis rate, but the clinical results would not show the high rate of late thrombosis of Taxus. Therefore, healthcare professionals should evaluate the validity of the clinical trials by their relevancy, consistency, number of samples, amount of random samples, and amount of complex cases within a clinical trial. Nevertheless, it is of paramount importance to consider the duration of clinical trials, as the longer the trial period the more reliable their indications. Senior managers of medical devices companies should be aware of the various ways they can present the results of their clinical trials based on the preferred performance values they want to be perceived by the market. At the same time they should be concerned about the authentication of the clinical trials, since the more authenticated the clinical trials, the easier the potential DI diffusion. Victor BMS by Medtronic was one of the DIs which failed

to benefit from the leverage of clinical trials in showing its technical capabilities. It seems that Medtronic could not present Victor very well, while the incumbents were successful in diffusing their products relying on their successful clinical trial results. There is a difference, therefore, between scientific evidence and scientific illusions.

Consequently, MD companies usually try to present their trial results in a convincing pattern to facilitate the process of innovation adoption, but at the same time they should be concerned about the validity and authentication of the conducted trials in order to convince the market.

However, the value creation mechanism (as we will discuss more in detail in 7.4) delivering these values to the right customers through certain diffusion channels should be noticed by senior managers. The findings of this research show that in order to target the main modes of diffusion in the market we have to distinguish between customers and consumers, since they have different roles during the procurement process.[1] On this subject a Cordis sales manager states: "*The most important question is 'who are the real costumers.' In each segment of the medical market there are specific target customers. For instance, in private hospitals physicians are the target customers. In social security hospitals, procurement managers are the most prominent actors since they have access to the public financial resources. In university hospitals the procurement decisions are made by a group of healthcare professionals. Therefore, the senior managers of medical devices companies should distinguish between customers and consumers in medical fields.*"

In addition, an Abbott marketing manager states: *"If we fail to distinguish the real customers, we may not be able to diffuse a given innovation during the encroachment time. If we follow the market trend, we will find out that the adoption pattern of the market has changed. In fact, during the encroachment time of the BMS market, private hospitals were our main customers. But now we are selling more to the public and social security hospitals. Therefore, knowing the target customers and distinguishing*

[1] The findings highlight the difference between customers and consumers in medical markets. As was mentioned in chapter six, physicians are considered customers in the medical devices market, while consumers are the patients. Then, while the customers in other medical facilities are hospitals, in some specific medical devices markets physicians should be the target of adoption incentives.

between consumers and customers has great value for the managers of medical devices companies. Different customers have different sets of values, priorities, payment methods and reimbursement procedures. Then, if we identify our main customers correctly, we can deliver more required performance values by them which is the main leverage of market disruption."

The findings elucidate that distinguishing the role of customers and consumers could contribute to accelerating the diffusion rate of potential DIs and disrupting the market based on the innovation's technical capabilities and delivered performance values. Distinguishing between customers and consumers in the healthcare market enables the senior managers to design different sets of performance values to disrupt the market. In fact, while the performance values offered to the customers (i.e. healthcare professionals in the medical market) are mostly based on technical capabilities and services, the suggested performance values to consumers (i.e. patients) should be based on other factors, such as perfect availability, fair pricing, and ability to deliver reliable treatments.

7.3 Scenario Making and Follow-up Plans to Respond to the Unpredictable Challenges of the Market and Agile R&D responses to Continue the Market Leadership based on Market Intelligence System Mechanism.

The global mechanism of successful market disruption does not necessarily work in the same way in the Iranian medical market. There are other factors affecting the ability of a medical DI in the Iranian medical market to pass the encroachment phase successfully and become the dominant design in the market. Since the market dynamic of DIs are tremendously complex and competence destroying, the reaction of other incumbents to this market revolution is partly unpredictable. Therefore, a given incumbent should imagine different scenarios to face the unpredictable challenges of the market. In fact, senior managers should consider follow up plans in different scenarios if they intend not to lose market leadership after they disrupt the market.

Indeed, several examples of scenario-specific follow up plans and agile R&D responses to the challenges of the market are observable in the history of BMS, DES and AMS diffusion in the Iranian market. For instance, as was mentioned in the fifth chapter, when Taxus failed in comparative trial results with Cypher, their agile R&D unit responded to this challenge. Based on their pre-planned scenario, and relying on architectural innovation, Boston Scientific launched NC balloons to modify the rate of restenosis and thrombosis. On the other hand, however, Cordis could not imagine a scenario to predict the late mover advantage of Xinece in the market, and, therefore, failed face the challenge of the new rival.

According to the findings of this research, based on the diffusers' reputation and technical capabilities of DIs, and also upon the market structure, diffusers may choose a combination of vertical diffusion leverages, such as job aristocracy, advice seeking habits of healthcare professionals, and opinion leaders or horizontal triggers, including knowledge sharing habits of physicians, informal groups, and peer pressure, to accelerate the diffusion of a potential DI.

In fact, based on the role of other actors in healthcare reimbursement systems, such as insurance companies, governments, and social security parties, incumbents should choose different scenarios to disrupt the market. In addition, the nature of newly introduced performance values of DIs should be considered by managers during the making of scenarios (see Figure 7.1).

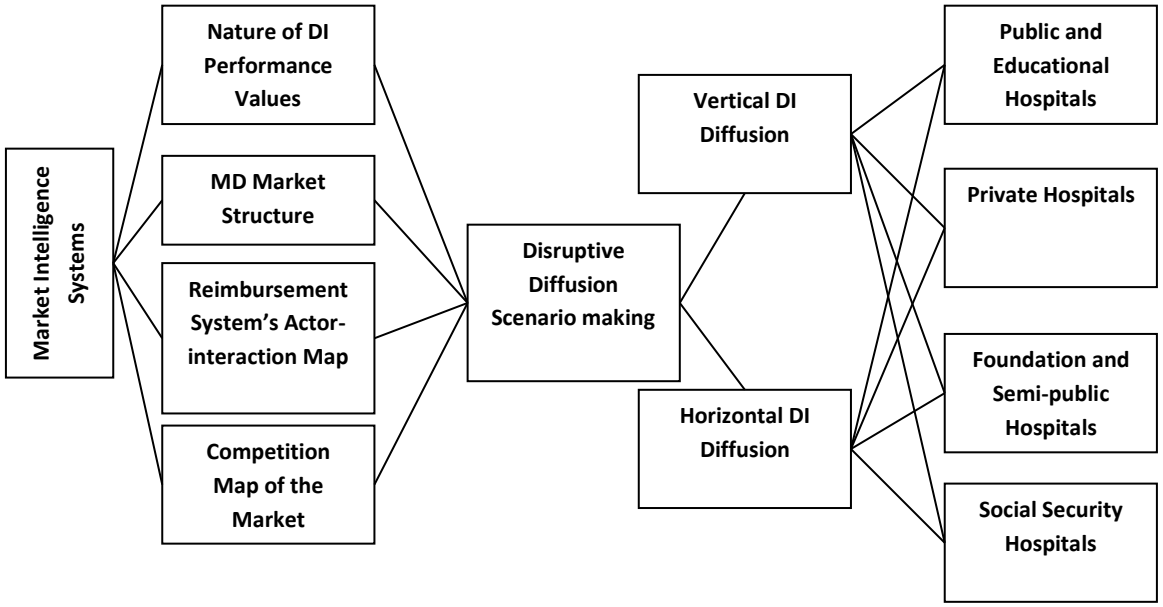


Figure 7.1 Components of Disruptive Diffusion Scenario Making

Therefore, market intelligence systems would help the incumbents to recognize the real size of the market and correct segmentation of it based on the centralized or de-centralized nature of the healthcare industry. In addition, it would give managers more information about the structure of needs, influential actors, and interaction between actors in each market segment, which enable incumbents to make their disruptive diffusion scenarios and deliver the right sets of performance values to each group of customers in each segment.

Consequently, the first mover advantage strategy to disrupt the mainstream market should be associated with different scenarios to predict the reaction of other incumbents. Besides this, some follow-up plans should be made to respond to the market challenges. In fact, when market disruptors create a new market there are significant potentials for other followers to attack and benefit from this new opportunity. While market disruptors benefit from pre-emption, technical advancements, and opportunity to set the dominant design, they should be concerned about their five year strategic follow-up plans based on different plausible scenarios, to keep their leading position in the market.

7.4 Keep the Balance between Technical Capabilities, DI Pricing and Required Sales Services to Efficiently Deliver Desirable and Convincing Sets of New Performance Values

Based on the findings of this research, there are different opinions about the position of technical capabilities of DI in the disruptive diffusion regime. Indeed, as we mentioned in the second chapter, although disruptive innovations emerge relying on new performance values they introduce to the market based on their technical capabilities but there are two considerable issues regarding these technical based performance values. First of all, since we are talking about values, it depends on the market perception about the performance of new innovations. Most of the time the results of the clinical trials and the conducted studies about the performance of the new innovation affect the market's perception of newly introduced performance values by DIs. However, as was mentioned in the second chapter, there are many other factors, such as the position of physicians in the healthcare system hierarchy, their ages, and their experiences, which affect the market perception of the performance values. Nevertheless, due to different types of constant interaction, such as peer pressure, opinion leaders and informal groups, and advice seeking behaviour of physicians, the disruptive diffusion regime should be considered as the subject of senior managers' attention in order to disrupt the mainstream market. Therefore, technical capabilities of DIs are essential for market disruption and should be considered as part of bigger frame, which is the disruptive innovation diffusion regime. The disruptive diffusion regime (DDR) of innovation (which will be discussed in the final chapter) is a framework which explains the enabling mechanisms of DI diffusion, which accelerates the diffusion of DI and at the same time facilitates the process of market disruption.

Based on DDR framework, the technical capabilities, the amount of sales services, and the offered price should be reasonably balanced to deliver a set of new performance values (introduced by potential DI). Based on the findings of this research, most of the market disruptions usually happen from the high end of the market. In other words, market disruption in MD industries is mostly about technical capabilities than price elasticity. However, although the competition is about the technical capabilities in the MD market, the findings state that the closer the price to the mainstream sustaining

innovation, the more chance a potential DI has to disrupt the mainstream market and open a new market.

In other words, the findings show that the market pioneers usually price their potential DIs close to the current market prices in order to attract the mainstream market customers to the newly opened market. Therefore, a successful DI should show a great technical performance in pre-market trial results, and at the same time support this with a great amount of pre and post sales services at a reasonably fair price close to the sustaining innovations in the mainstream market, in order to benefit from price elasticity as an auxiliary leverage to disrupt the mainstream market.

For instance, comparing the effect of Xience's technological capabilities and Abbott's innovation diffusion regime, it is conceivable that Xience's technological capabilities could introduce a more accepted set of performance values to the market. Therefore, market incumbents should be aware of different sets of performance values they want to introduce to various segments of the market. In other words, the adopted innovation diffusion regime should be balanced between the introduction of technical values and other sets of values introduced by other leverages, such as sales service, fair pricing, or perfect availability.

Dr. Kazemi-Saleh states: "*Cypher used to hold a respectable position in the market due to the strong technical capabilities of this innovation at that time. It doesn't necessarily mean that they didn't want to deliver any other kinds of values however; Cordis established an innovation diffusion regime based on the technical capabilities of Cypher. In fact, healthcare professionals usually get the information on the new innovations from conferences, seminars, and conducted studies around the new innovations. In other words, if there was not any other company to present the Cypher in the market, healthcare professionals' demand would force other responsible organizations to launch this product in the market.*"

Another example is the failure of Conor Co. stents in market diffusion. Conor was a DES from Biotronic, a private medical company in Germany. It was one of the best stents on the market, but

while Conor showed great technical performance in clinical trials, they could not gain more than 5% of the market shares. Although Taxus did not possess better trial results than Conor, their sales volume was at least five times bigger than Biotronic. This does not seem to be due to any other reason apart from the efficient innovation diffusion regime of Boston Scientific.

As we have discussed, there are several managerial implications conceivable from the study of DI diffusion dynamics to understand the associated mechanisms of DI diffusions in medical markets. There have been many other practical lessons for managers during this research, since the longitudinal case study in this research has been enriched by several practical findings during the fieldwork, presented in the fifth and sixth chapters. In this chapter we have attempted to highlight some meticulous managerial implications which had not been discussed in the previous chapters. In general, the structure and findings of this research are appropriate for practitioners, and there are plenty of managerial lessons in each chapter.

During the next chapter we will summarize the study's findings in their entirety, and will demonstrate the DDR framework as the main contribution of this research to both academics and medical practitioners'.

Chapter 8

[CONCLUSION]

Introduction

As stated within the introduction chapter, this research has aimed to provide further understanding of the dynamic of DI diffusion, since most of the discussion over the last decade has been concerned with the concept of DI diffusion, rather than its market level dynamic. Thus, this research has considered the dynamic of DI diffusion in its disruption of the mainstream market. Since the diffusion of DI has been the main concern of this research, the main body of innovation diffusion literature was discussed to understand the differences between economics and social-structure models of innovation diffusion. Probing further into the history of innovation diffusion and focusing more on the gaps in social structure studies, the research introduced the social structure based dynamic model of DI diffusion.

In order to complete this model, this research has focused on two objectives: understanding the dynamic of market disruption via potential DIs, and enabling mechanisms of market disruption through which DIs can disrupt the mainstream markets.

Market level dynamics of innovation diffusion were discussed within the second chapter. In addition, to enrich the innovation diffusion literature, we discussed the dynamic of technology trajectories in order to investigate the market level dynamic of innovation diffusion during the evolution of relevant technologies. Next, the disputable concept of disruptive innovation was discussed to distinguish between revolutionary innovations and disruptive ones; while the former is revolutionary in terms of technology, the latter is mainly concerned with opening a new market by disrupting the mainstream one. Therefore, based on evolutionary theories of technology trajectories and by focusing on the dynamic of discontinuous innovation, this research discussed the theories of new market openings via disruption of the mainstream market. The main focus of the literature review was re-defining the enabling mechanisms of the dominant design's settlement to disrupt the mainstream market, considering the dilemma of the relevant technology's path-dependency.

After the introduction of the social structure dynamic model of DI diffusion at market level, the relevant literature was discussed to provide more understanding about the enabling mechanisms of DI

diffusion based on the model introduced in the last section. In order to answer the second question that this research sought to answer, regarding the enabling mechanisms of DI diffusion to disrupt the mainstream market, the second chapter focused on theories of new product development (NPD) strategies and attempted to modify them based on the requirements of DIs developed by the DI attribute framework.

In order to enrich the abovementioned literature, the research considered the theories of innovation adoption to re-design the NPD strategies by focusing on customer analysis methods (CAMs). At the same time, the combination of marketing STP theories (including segmentation, targeting, and positioning) with the mentioned literature aided the designing of the proposed mechanisms of DI diffusion.

In the final section of the second chapter, all of the abovementioned discussions concerning mechanisms and dynamics of DI diffusion were reflected upon in the context of the medical devices market. In other words, the nature, structure, and the main actors of the medical devices market were discussed along with the dynamic and enabling mechanisms of DI diffusion in this complex network.

The third chapter explained the methodological position of this research and presented the research design to collect and analyse the required information to answer the research questions. The main objective of this research is to make new DI diffusion theories regarding the social structure dynamics of DIs in market, and enabling mechanisms to shape the mentioned dynamic which have been achieved by testing the introduced frameworks in the second chapter. Based on the critical realist school of thought, which insists on finding the generative mechanisms behind the reality, we conducted a longitudinal case study of the Iranian CAD treatment market in order to understand the evolution of technology and diffusion of successive generations of DIs between 1998 and 2010. This descriptive-explorative case study benefited from archival research of the targeted actors in the market and conducted thirty semi-structured interviews with the key decision makers of the leading companies in regard to their DI diffusion strategies.

These semi-structured interviews were conducted in two phases. The first round of interviews focused on the market's dynamic over the last ten years, and after enrichment of these findings with the findings of archival research and secondary published data, the fieldwork moved onto to the second phase. In the second phase of interviews the main concern was to understand the main strategies of market incumbents to shape the market dynamic and the main mechanisms behind market disruption.

The fourth chapter discussed the background of the medical devices market and briefly considered the co-evolution of CAD treatment and the relevant technology trajectory to bring new innovation to the CAD treatment market. The fifth chapter discussed the case of the Iranian CAD treatment market in more details and provided more information through sales and pre-market trial reports gathered during the archival research.

The findings of this research were presented in the sixth chapter. The foremost advantages of the market's first movers and late movers in disrupting the mainstream market were discussed. Afterwards, the limitations of the market's low-end disruption in the medical devices markets were investigated based on the facts and figures presented during the fieldwork period. The main areas of research related to the social structure dynamic of DI infusion in medical markets were:

1. The reinforcement effect of the followers' attack on the pioneer's market share during the encroachment phase.
2. The impact of the market insight of the actors on the dynamic of DI diffusion.
3. The importance of the social network's structure of the main nodes of diffusion to disrupt the mainstream market.
4. The, impact of unethical marketing activities of the incumbents to accelerate the rate of DI diffusion.
5. The effect of the healthcare reimbursement system on the dynamic of DI diffusion.
6. The outcomes of inappropriate market retreatment for further disruption activities.

In terms of the enabling mechanisms of DI diffusion in medical markets, different sets of mechanisms were investigated in the sixth chapter, such as: the relevant mechanisms to institutionalize the organizational values to obtain the required DI diffusion competencies, the enabling mechanisms of DI diffusion through the less structured communication channels and informal groups, the mechanisms of insight building to disrupt the mainstream market, and finally, the relevant mechanisms for positioning new performance values of the potential DI in the customer evaluation framework.

Some important managerial lessons highlighted in the findings were discussed in the seventh chapter. These lessons were mostly practical ways to organize an appropriate launching team to enable market disruption through the diffusion process of innovation. In addition, enabling mechanisms of value creation to introduce new performance values to the market were identified. Finally, the main strategies of maintaining the new market's leading position after the mainstream market disruption were discussed.

In this final chapter of this thesis, we are going to summarise the presented findings of the sixth chapter which address the research questions defined in the second chapter, and based on these findings we will reveal the major contribution of this research as a "DI Diffusion Regime" (DDRI). Based on the observed social structure dynamic of DI diffusion at market level and the abovementioned enabling mechanisms of DI diffusion to shape such a dynamic, this research has identified a diffusion regime which may lead to market disruption. Finally, the other theoretical, methodological, and managerial contributions of this research will be demonstrated and some suggestions made for further research in this field.

8.1 Major Findings of the Research

This research contains many theoretical and managerial findings which will contribute to academics' and practitioners' understanding of the dynamic and mechanisms of DI diffusion in more details. In

this section these findings will be presented to address the research questions of this project. Firstly we will consider the social structure dynamic of DI diffusion in the medical market, and afterward we will reflect upon the findings surrounding the enabling mechanisms of DI diffusion.

8.1.1 Social Structure Dynamic of DI Diffusion in Medical Markets

Although many scholars such as Abernathy and Utterback (1975), Abernathy (1978), Utterback (1996), Tushman and Anderson (1990) have attempted to shed light on the dynamic of technology trajectories, and others such as Rogers (1985), Norton and Bass (1987), Mahajan and Muller (1979, 1985, 1986, 1994), Mahajan et al (1978, 1984, 1986, 1988, 1990), Bass and Bayus (1987) and Bass (1988) have investigated the concept of innovation diffusion, the social structure dynamic of DI diffusion required more investigation.

According to the findings of this research, the social structure dynamic of DI diffusion is subject to four main determinants: the diffuser company's characteristics, the structure of the industry, the situations of the adoption market, and the DI's performance values. As Figure 8.1 shows, a Diffuser Company's characteristics determine its organizational competences, social entity, intellectual capabilities, persistency, reputation, and its ability to become an achiever and risk taker in a new market. The structure of the industry also affects the diffusion of DIs in the market, which are represented by a mixture of factors, such as industry competitiveness, technology standardization, vertical coordination of industry, and the industry's heterogeneity. The factors inside the adoption market are equally important in shaping the dynamic of DI diffusion, and these include the market's reimbursement system, opinion leader networks in the market, level of social contagion, and the prevalence of unethical marketing activities in the market. Finally, the most important determinants of the dynamic of DI diffusion are the DI's performance values, such as its technical capabilities, sales services, and the perfect availability of the DI in the market.

These determinants affect the social structure dynamic of DI diffusion, which begins with the market encroachment of the DI. As it mentioned in the second chapter, DI is a powerful means of broadening and developing new markets and providing new functionality, which, in turn, may disrupt existing market linkages. However, based on the debates about this concept by a great deal of scholars during the last decade, we offered a conceptual framework to extend the definition of DI. Based on the requirements of medical markets we focused on the DIs which benefit from disrupting technologies to open a new market, aimed at current customers in the mainstream market. Although the concept of DI introduced by Christensen (1997) focuses on low-end encroachment of the market during the initial stages of innovation diffusion, the findings of this research indicate the prevalence of high–end disruption. In other words, while most of the scholars focus on high or low end encroachment of the market to explain the dynamic of DIs, the findings of this research state that due to the inelastic prices of medical markets, the cardinal emphasis of medical DIs should be on delivering new performance values to the customers rather than targeting the high or low end of the market. Therefore, the notion of low-end market disruption is criticised by the findings of this research in the sixth chapter.

To figure out the social structure dynamic of DI diffusion, the findings suggest breaking down the dynamic of DI diffusion into three separate phases: market encroachment, market disruption, and post disruption. According to the findings, the main strategic concerns of potential market disruptors are threefold during the encroachment phase: the improvement of introduced performance values for low-end disruption and decreasing the price for high-end disruption, taking advantage of first movers or enjoying the benefits of late movers, and constructing a reliable market insight to work out the actual size of the market and increase the market's knowledge of the DI.

Thus, reflecting on the innovation diffusion determinants mentioned in the last paragraph, competitors try to meet the strategic demands and work out the actual size of the market to execute market disruption. The findings indicate that it is usually the first movers, who have managed to come up with the most appealing performance values to the market, that increase the knowledge of the market properly in terms of how the new DI could disrupt the market. Therefore, DI can transfer to the

second phase of the diffusion dynamic and open a window into a new market. This involves setting a dominant design and challenging the current actors, networks, and regulations of the market.

Based on the findings of this research, the main significance of social structure dynamic of DI diffusion during the second phase is the attack of the other followers, which gravely affects the dynamic of DI diffusion. The findings indicate that in this phase, invasion of the market by other followers reinforces the position of the market disruptor in a bid to protect against superior performance. In other words, the attack of followers forces the potential adopters to be sure about the arrival of new generations of innovation to the market. Hence, if the leading DI demonstrates a superior bundle of performance values, its leading position is reinforced in the market. Otherwise, the market leader may lose the leading position in the market and the new market might be re-disrupted by other incumbents.

Finally, according to the findings of this research, the third phase of social structure dynamics of DI diffusion indicates regulatory battles of different innovations to set the dominant regulations, standards, and designs in the market. In the context of the medical devices industry, many clinical trials attempt to make clear the technical capabilities of potential DIs, and highlight the weakness of the other competing innovations. The combination of these clinical trial challenges might affect the regulatory standards in the market and consequently affect the whole network of actors in the market.

The final point to be made relating to the social structure dynamic of DI diffusion is the way in which market retreatment should be executed to avoid damaging the disruptor's reputation and decreasing the potential for further market disruption activities of the company.

8.1.2 Enabling Mechanisms of DI Diffusion in Medical Markets

Having discussed the social structure dynamic of DI diffusion, we can now investigate the enabling mechanisms of DI diffusion which shape such dynamics in medical markets. Referring back to the second chapter, the major mechanisms of mainstream market disruption (Table 2.10) have been

modified based on the specific necessities of DIs. In fact, the major mechanisms of market disruption are classified into three phases: market preparation, targeting, and positioning and execution (Markides, 2006). Market preparation mechanisms usually entail forming a strategic alliance with the other actors in the network, increasing the market information in terms of the product's existence, performance, and selling points, and creating unique distribution channels. However, based on the specific requirements of DIs, these strategies should be enriched by some particular strategies underlying the market preparation mechanisms. The findings of this research indicate that the first step of market preparation mechanisms should focus on institutionalization of organizational values to obtain the required competencies for market disruption. In this regard, many incumbents establish a separate division to launch a new potential DI and benefit from spin-offs or strategic business units (SBUs). The most cardinal strategies of market preparation mechanisms refer to the construction of a market intelligence system to increase the market's knowledge about the potential DI, and at the same time obtaining detailed information of the actual market to map further strategies for activating, targeting, and positioning mechanisms. Thus, information management is the most prominent concern of incumbents underlying the market preparation mechanism.

Targeting and positioning mechanisms include some basic strategies, such as targeting the high-value users and emphasizing the technology's superiority. To enrich these mechanisms and make them sufficiently effective for market disruption, the findings of this research suggest some further strategies, such as focusing on market creation rather than marketing activities, keeping the balance between vertical and horizontal diffusion of DI through the hierarchy of experts, entering the critical mass of the adopters during the initial stages of market encroachment, and considering a bottom-up rather than a top-down attitude toward the diffusion activities based on the nature of experts' networks in the mainstream market. Therefore, the most central concern of incumbents regarding the targeting and positioning mechanisms of DI diffusion is the positioning of newly introduced values of DIs into the customer's value framework. In other words, the main task of potential market disruptors is to highlight the necessity of newly introduced values of the DI to the market, to disrupt the market based on the competencies of the potential DI. According to the findings of this research, clinical trials are

the most efficient and reliable leverages to introduce the new performance values of the DI and position them in customers' value frameworks. Based on the findings, clinical trials are primarily focused on the advantages of a DI's performance values in the medical markets, while their next mission is to highlight the performance deficiency of the other potential DIs in the market.

Finally, incumbents concentrate on the execution mechanisms in which the relevant strategies would be executed by sales team, rather than the marketing group. According to the findings of this research, facilitation of sales and concentration on the requirements of the market in different segments of the healthcare market, such as education, public, private, military, foundations, and social security hospitals, are the most prominent strategies of DI diffusion execution based on the dynamic in Figure 2.20. However, the importance of post-sales services, availability of the potential DIs in the market, and fair pricing are undeniably the vital strategies of market disruption according to the findings of this research. According to the findings of this research, potential market disruptors should prepare various scenarios and follow up plans to respond to the unpredicted challenges of the market to maintain their dominancy after the initial market disruption.

8.2 Addressing the Literature's gaps

As it was discussed in the 2nd chapter, the role of new entrants and incumbents to disrupt the mainstream market, possibility of the low-end vs high-end market disruption within the social structure of the healthcare systems and introduction of the required criteria to distinguish DIs from the other types of innovation are the main gaps of DI diffusion literature which are going to be addressed as below.

8.2.1 Who usually disrupt the mainstream market in medical devices industries?

One of the main disputable gaps of DI literature is about the position of market disruptors within the social structure of DI diffusion systems. King and Tucci (2002) argue that incumbents stand a good chance of winning over the competition and attaining the dominant design based on their accumulated

experience in the market. But Christensen (1997) believes that the mainstream markets get disrupted by the new comers as they own the new patents and technologies. The findings of this research mostly confirm the former notion which highlights the pivotal role of incumbents to disrupt the mainstream markets. According to the findings of this research since the process of new product development (NPD) in medical and pharmaceutical industries is massively costly, considering the table 4.3 in the chapter 4, significant amount of merger and acquisitions (M&A)s happen in these field. In other world the R&D sections usually come up with new prototypes which require the main incumbents of the market to support their commercialization and diffusion processes. Therefore the mainstream markets usually get disrupted by the main well-known incumbents in medical devices industries.

8.2.2 Possibility of Low-end vs High-end market disruption in medical devices industries

As Droege and Johnson (2010) state, despite the growing popularity of low-end disruptive innovation theory among academics and practitioners, most of the generated predictions by this theory are limited by industry structure. In the case of medical markets, as Neir et al (2008) and Niranjan et al (2012) mention, since their nature is relatively inelastic regarding price, it seems that low-end disruptive innovation is not the best theory to explain the dynamic of disruptive innovation diffusion. In other words, since price sensitivity is the main leverage of market disruption from the lower end, and the main concern in medical industries is quality of treatment rather than price, low-end disruptive innovation theory may not fully explain the dynamic of diffusion.

Therefore, since the medical market is not extremely price sensitive (due to the complex nature of reimbursement systems), and quality treatment at a reasonable price is the main priority, the final price of potential disruptive innovation can be relatively higher or lower than the current treatments in the mainstream market. The findings of this research suggest that if the price of potential disruptive innovations is relatively higher, then high-end encroachment theory could provide a better explanation of disruptive innovation diffusion. Alternatively, low-end encroachment could be an appropriate

choice for explaining the diffusion of disruptive innovations when the price of the final product is relativity lower.

8.2.3 Introduction of criteria to distinguish DIs

Since the concept of DI was coined by Christensen (1997), there have been so many disputes over the definition of this concept and the main criteria to distinguish it from the other types of innovation. This has been one of the main gaps which this research has addressed relying on the relevant part of literature confirmed by the findings of this research. For instance while Tushman and Anderson (1990) believe that the older technologies would be obsolete after the market disruption the findings of this research mention that the older technology wouldn't be necessarily be obsolete as in the case of BMS it didn't eliminate CABG techniques from the market. However, the findings of this research indicate that DIs usually lead to the next generation of technologies in medical markets which shift the competition paradigm to another level by introducing new performance values at the beginning and new ways of measuring them to legitimize the position of DI in the market. In other world, the findings of this research elucidate that from the social perspective, market disruption happen when a given innovation introduce new performance values to the market and manage to legitimize and institutionalize them within the social structure of the market.

Therefore while innovation diffusion is necessary to disrupt the mainstream market, legitimization and institutionalization of innovation's new performance values are the sufficient conditions of market disruption. Then based on the findings of this research, DIs are competence destroying innovations which have outdated the previous performance values in the market by introducing new functionalities and diffusing, legitimizing and institutionalizing the new performance values within the market's social structure. As a result, it will shift the competition paradigm which lead to the creation of new actors in the market including new incumbents and new regulatory bodies and also would change current social structure of the market to better deliver the new performance values to the market.

8.3 From the DI Roadmap to the Disruptive Diffusion Regime of Innovation

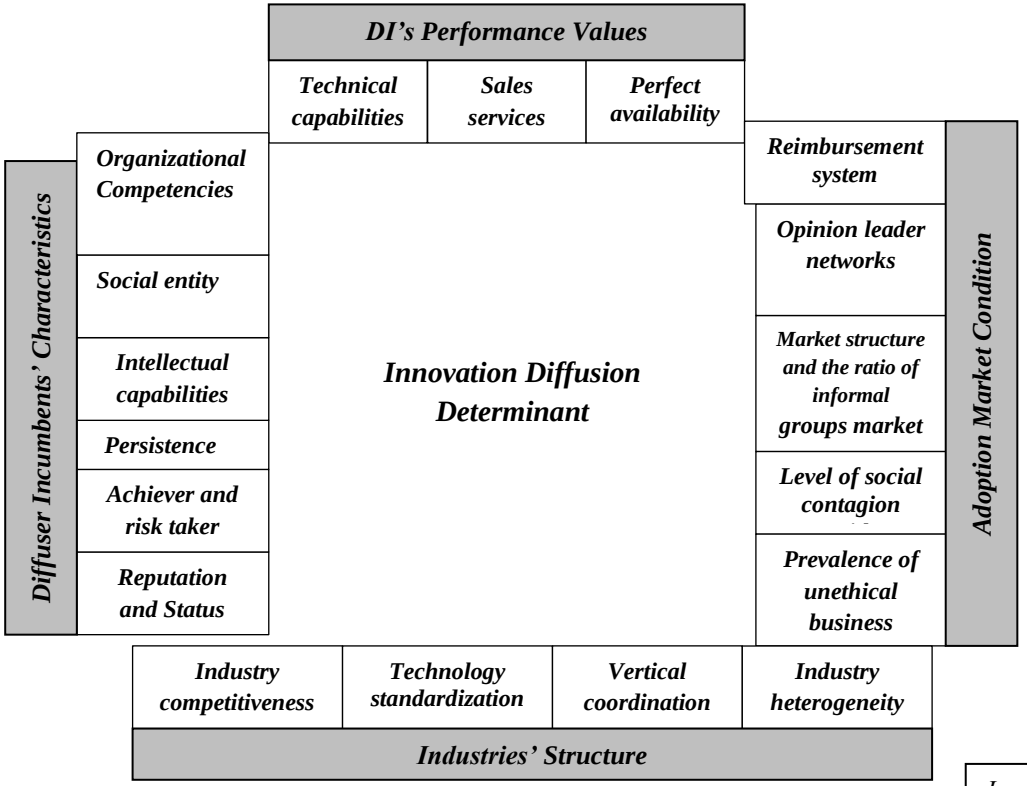
The main contribution of this research is the combination of the social structure dynamic of DI diffusion in medical markets and the relevant enabling mechanisms to disrupt the mainstream market. Therefore, we have termed this new process a "*Disruptive Diffusion Regime of Innovation*" (DDRI). Although possessing promising technical capabilities is a necessary attribute of DIs in medical markets, according to the findings of this research, this is not sufficient. This is because DIs are the consequences of their diffusion paradigm rather than their revolutionary technology. In fact, the present research suggests attributing the term "Disruptive" to diffusion rather than innovation itself. Therefore, if any potential innovation fits into the suggested DDRI framework in Figure 8.1, then potentially we may call it a 'disruptive innovation', and it will be able to disrupt the mainstream market. In fact, this framework, which indicates the social structure dynamic of DI diffusion is a result of constant interaction between enabling mechanisms of DI diffusion, consists of four main components, including innovation diffusion determinants, DI diffusion dynamics, strategic concerns of DI diffusion, and enabling mechanisms of DI diffusion.

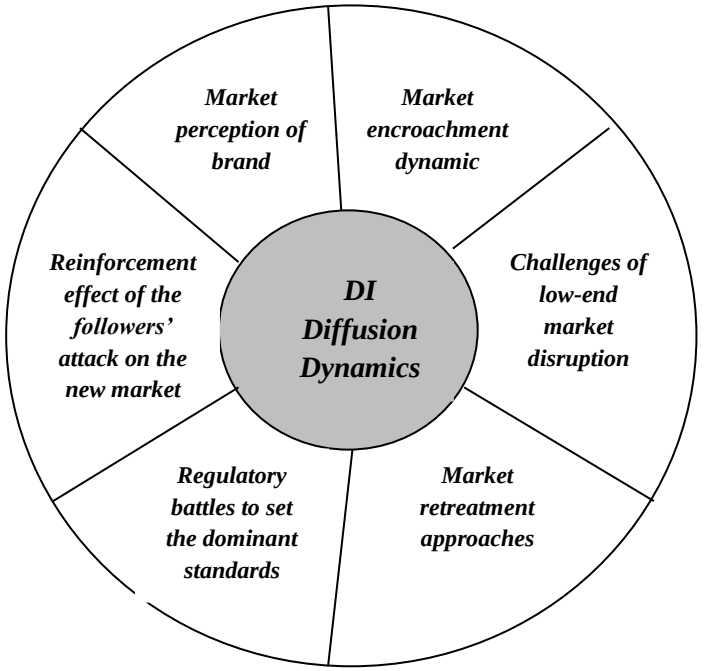
As Figure 8.1 shows, innovation diffusion determinants consist of the potential market disruptor's characteristics, the DI's performance values, the industry structure, and the adoption market condition. Considering these determinants, incumbents should choose their strategic settings, such as priority of market creation, first mover versus late mover strategic settings, ratio of vertical and horizontal diffusion of innovation within the market network, up-down or bottom-up innovation diffusion strategies through the hierarchy of experts, and the ratio of resource allocation to diffuse the potential DI during the encroachment phase. At the social structure of the market, strategic concerns of incumbents shape the market dynamic in terms of DI diffusion, including the market encroachment phase, challenges of the low-end market disruption, reinforcement effect of the followers' attack on the new market, regulatory battles of incumbents to set the dominant design, and market retreatment.

The abovementioned dynamic of DI diffusion is the consequence of certain enabling mechanisms, such as increasing the market's knowledge of the innovation's existence, technical performance and application, positioning the newly introduced performance values in customers' frameworks of values, understanding the actual size of the market to build the relevant market insight and potential scenarios, follow up plans to respond to the unpredicted challenges of the market, and agile R&D responses to continue the market leadership.

Besides the main contribution of this research, there are other theoretical and managerial contributions with will be pointed out in the next section.

Figure 8.1. Disruptive Diffusion Regime of Innovation (DDRI)





Strategic Concerns of DI Diffusion
Priority of market creation instead of marketing
First mover vs. late mover advantages to disrupt the market
Ratio of vertical vs. horizontal innovation diffusion within the hierarchy of experts to enter the critical mass
Top-down vs. bottom-up diffusion strategies
The ratio of resource allocation to innovation diffusion during the encroachment phase

DI Diffusion Mechanism
Increasing the market knowledge of innovations' existence, technical performances, and performance procedure
Positioning the newly introduced performance values into customers' values frameworks
Understanding of the actual size of the market to build a correct market insight based on a well-structured market intelligence system
Institutionalizing the new organizational values compatible with the newly introduced performance values
Scenario making and follow-up plans to respond to the unpredictable challenges of the market, and agile R&D responses to maintain the market leadership

8.4 Major Contribution of the Thesis

During the research process, data collection, and analysis of the data, there have been many theoretical and managerial implications which may add to the previous findings of other scholars in terms of DI diffusions in medical market. Here, we may present some major contributions of this research to emphasis the originality and validity of the findings.

8.4.1 Suggestion of the Social structure and Dynamic Model of DI Diffusion

Throughout the last decade, many scholars have discussed the dynamic of innovation diffusion. However, each one focused on a specific part of innovation diffusion. For instance, while some scholars pinpoint the macro-level mathematical models of innovation diffusion based on the overall statistical behaviour of potential adopters, others discussed the social structure simulation models based on individual decision-making behaviours. Therefore, through the in-depth literature review in the second chapter, the lack of an interdisciplinary model to explain the real dynamic of innovation diffusion from a social structure view of the market was highlighted. To address this gap in the literature, this research suggested the social structure dynamic model of DI diffusion as shown in Figure 2.13.

Based on Roger's (1985) and Robertson and Gating's (1986) model of innovation diffusion (Figure 2.11), Howell and Higgins' (1990) model of champion personality characteristics (Figure 2.9), Wejnert's (2002) diffusion framework (Table 2.4), and Peansupap and Walker's (2005) ICT diffusion framework (Figure 2.12), the social structure dynamic model of DI diffusion was offered.

It was suggested that structural factors at corporation and industry level, and resource commitment in marketing and R&D activities affect the adoption process of DI innovations, in regards with innovation attributes, communication channels, and diffusion strategies. Finally, the role of social structure at market and national level was discussed in this model.

8.4.2 Suggestion of the Five Indexes Framework to Classify Different Types of DI

For many years after the concept of DI was first coined by Christensen (1997), scholars have discussed the notion of DI from different perspectives and suggested various definitions. However, the existence of a concrete framework to categorize different types of DI was missing. To address this gap in literature, this research suggested the five index framework to classify different types of DIs (Table 2.7). Based on the cases of DI in the literature, the research introduced a framework to classify different types of DI based on five criteria, including the introduced performance values of DIs (new or existing), types of market encroachment approach (high or low-end approach), types of customers (new or current), types of market (new or existing), and types of correlated technology with DI (sustaining or disruptive).

8.4.3 Modification of the Existing Model of Innovation Dynamic in the Healthcare Industry

Another contribution of this research is the introduction of the interactive model of medical innovations based on the modified model of gateways and pathways in the health system by Ramlogan and Consoli (2007). This was a comprehensive model classifying healthcare actors of medical innovation networks into four categories: individual sphere, service provision, scientific community, and market. This model provided more understanding about the dynamic of medical innovations before the diffusion phase. Although this model seems fairly appropriate as a framework for analysing the interactions of the actors involved in creating new medical innovations, based on the findings of this research, another model of innovation dynamic in the healthcare industry is suggested, and is shown in Figure 2.18.

In this model introduced by this research, the scientific community is located between medical markets which generate practices and services, and actors involved in medical technology evolution, such as R&D sections of medical technology businesses and relevant industries (Figure 2.18).

Therefore, a restructuring of the existing model of innovation dynamic in the healthcare industry has contributed to the current knowledge of medical innovation dynamic and helped scholars to gain a more realistic view about the dynamic of DI diffusion in medical markets.

8.4.4 Suggestion of the Social structure Model of Enabling Mechanisms of DI Adoption in Healthcare Markets

As mentioned earlier, most of the scholars have discussed the concept of DI rather than the actual dynamic or enabling mechanisms of market disruption. One of the most critical contributions of this research is to introduce the social structure model of enabling mechanisms of DI diffusion in healthcare markets. Based on the main leverages of innovation adoption, and considering the new applied product launch strategies in the medical market, this research attempted to introduce the model of enabling mechanisms of market disruption in the medical market. This model will help scholars and practitioners understand out the main mechanisms of market disruption in the medical market based on the market situation.

According to this model, promotional marketing, and clinical trial result publication and observation will increase the healthcare professionals' volume of information about potential DIs. At the same time, accumulated experiences of healthcare professionals, primary growth in purchase, and the relevant sophistication of healthcare societies will increase the absorptive capacity of the market, which will affect the perceived average performance of potential DIs by healthcare professionals. Thus, the increased volume of information in the market and the perceived average performance by the market will determine the level of acceptance of potential DIs by the mainstream market. This level of acceptance should be supported by perfect availability of the potential DI in the market. This model will guide scholars and practitioners to design new innovative strategies to disrupt mainstream medical markets.

8.4.5 Introduction of the Concept of Non-nested DIs and the Relevant DI Diffusion Dynamics

As discussed in the fifth chapter, development of a potential DI from concept to prototype, and through the pre-pilot, pilot, and production phases require intensive interactions between the selected hospitals, physicians, regulatory agencies, and incumbents' R&Ds in order to conduct the verification and validation tests. Physicians are involved in the process of IQ, OQ, PQ and PPQ assessment. The involvement of physicians and healthcare professionals in the validation and verification process makes a reliable market basis from which to diffuse the potential DI into further launch stages. In other words, the involvement of physicians in the MD development process increases the effect of opinion leaders and peer pressure during DI diffusion, which remarkably increases the rate of DI diffusion. This is the particular niche of this research, which contributes towards the generation of the concepts of nested and non-nested DI diffusion.

According to the findings of this research, some potential DIs are diffused in the market having progressed through the interactions of the actors mentioned above. We suggest this type of DI should be referred to as "nested," since they are diffused in the same market they have evolved in. Nested DIs have more opportunities to disrupt the mainstream market, since the involvement of physicians and healthcare professionals in the validation and verification process makes a reliable market base from which to diffuse the potential DI. However, this research has focused on the other type of DI, which this research terms as "non-nested."

In the case of non-nested DIs, development and diffusion market places are very different. The main actors in the market, such as hospitals, physicians, regulatory, agencies and incumbents' R&Ds don't have any presuppositions about the DI. Therefore, diffusion of a non-nested DI is much more difficult than that of a nested one, and necessitates a specific approach to understanding the enabling mechanism to disrupt the mainstream market.

Generating the concept of non-nested DI is one of the major contributions of this research, which adds to the previous categories of DIs of the last decade. Differentiation between nested and non-nested DI diffusion will open the new field to further research for other scholars.

8.4.6 Introduction of the Disruptive Diffusion Regime of Innovation (DDRI) Model

Finally, the most prominent contribution of this research is the introduction of the DDRI model, which describes the dynamic of DI diffusion in medical markets from a social structure point of view, in conjunction with enabling mechanisms of DI diffusion during the respected dynamic. This model depicts the effect of various enabling mechanisms of DI diffusion to shape the relevant dynamic of DI diffusion (Figure 8.1). This prominent contribution will enable other scholars and relevant practitioners to understand the suitable strategies of market disruption based on the innovation diffusion determinants, DI diffusion dynamic, strategic concerns around DI diffusion, and enabling mechanisms of DI diffusion.

This model has solved the dilemma faced by innovators in modifying relevant new product launch strategies based on the requirements of disruptive innovations. Additionally, this model will equip scholars with strong and reliable analytical tools to analyze DI diffusion in the market and improve the process of market disruption based on the relevant dynamic and affecting mechanisms on the stated phase of DI diffusion dynamic.

8.5 Expert Validation and Statement of the Research's Uniqueness

The results of this research have been validated and confirmed by the incumbents involved in the longitudinal case study, including the Iranian branches of Cordis, Medtronic, Boston Scientific, and Abbot Laboratories. This research has won a research prize by the Iranian branch of Cordis due to its great contribution to the Iranian healthcare industry. The findings and contributions of this research are unique and genuine, since the researcher has made a considerable effort to gain access to the required information from the abovementioned companies, and the restricted nature of the collected data makes the findings increasingly valuable.

8.6 Suggestion for further Research

This research has provided a clear and comprehensive understanding of the dynamic and enabling mechanisms of DI diffusion in medical markets. At this point the researcher will take the opportunity to make some suggestions for further research in this field based on the observed gaps in the relevant literature and the medical industry itself.

Foremost, the concept of DI needs more classification to be understood properly. In a quest to clarify the concept of DI during the fieldwork, the research clarified two types of DI which had not been mentioned in the relevant literature: nested and non-nested DIs. Although this research has introduced these concepts, it seems necessary to conduct further research to understand the main differences between nested and non-nested DIs and their particular dynamics and diffusion mechanisms in the market. Therefore, while this research has focused on the concept of DI diffusion dynamic and its enabling mechanisms, it is strongly suggested that other scholars conduct further research into the relevant dynamic and enabling mechanisms of nested DI diffusions in the medical market.

Secondly, while this research is mainly focused on the context of medical devices and healthcare, it seems that conducting the same research with in the other fields, such as ITC and

telecommunications, would increase the breadth of the findings about the dynamic and enabling mechanisms of DI diffusions. The findings of the same research in the other fields could then be compared with the findings of this research to provide more clarity and validity to the results.

While this research has proposed a framework to classify different types of DI and focused on one of these, other scholars could focus on the other types of DI and attempt to understand the dynamic and enabling mechanisms of the other types of DI diffusions. This research has introduced seven different types of DI and focused on one of them. Other scholars are encouraged to conduct further research into the diffusion dynamic and relevant enabling mechanisms of the other types of DI, and to compare the results with the findings of the present research to provide more in-depth understanding of the concept.

Another opportunity for further research arises from the nature of the market. The healthcare market is a network classified between B2B and B2C markets. However, the dynamic and enabling mechanisms of DI diffusion are tremendously different in B2B markets, where market disruption is mostly assigned to Disruptive Technology (DT) rather than DI. Therefore, it is suggested that other scholars conduct further research on the dynamic and enabling mechanisms of DT diffusion in B2B markets.

Finally, based on the recognized gaps in the relevant literature, the findings of this research could be variant towards the healthcare market structure as defined by the level of public authority in the market. In other words, diffusion dynamic and enabling mechanisms of DIs are dependent on the centralized or decentralized nature of the healthcare market. Therefore, building on this research, other researchers may conduct the same research in different markets to understand the differences of diffusion dynamic and enabling mechanisms of DI diffusion in centralized and decentralized markets.

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Appendix 1

FDA List Of Launched Medical Devices During The Last 10 Years

Medical Devices Approved by FDA in 2000		
Device Name	**Category**	**Date**
Microny SR+ Cardiac Pacemaker (Model 245T) - P970013[1]	Pacemaker	12/21/00
Q-103 Needle Management System - P980020[2]	Needle Destruction Device	12/21/00
Roche Elecsys free Prostate-Specific Antigen (fPSA) Assay on the Elecsys 1010 and 2010 immunoassay analyzers (P000027) (Revised 2/28/01)[3]	PSA Test	12/12/00
Psychemedics Corporation Opiate Assay - K000851[4]	Drugs of Abuse Test	12/11/00
Stinger™ Ablation Catheter and TempLink™ Extension Cable - P000020[5]	Ablation Catheter	11/29/00
PATHWAY™ Her 2 (Clone CB11) - P990081[6]	Breast Cancer Test	11/28/00
Roche Elecsys Total Prostate-Specific Antigen (PSA) Assay on the 1010 and 2010 - p990056 (Revised 2/28/2001)[7]	PSA Test	11/22/00
Optical Biopsy™ System[8]	Colonoscopy Device	11/14/00
Cordis Checkmate™ System - P990036[9]	Angioplasty Device	11/03/00
Novoste™ Beta-Cath™ System - P000018[10]	Angioplasty Device	11/03/00
Photon™ DR Implantable Cardioverter Defibrillator[11]	Defibrillator	10/27/00
Nucleus 24 Auditory Brainstem Implant System - P000015[12]	Hearing Implant	10/20/00
BeStent™ 2 with Discrete Technology™ Over-the-Wire and Rapid Exchange Coronary Stent Delivery Systems - P000022[13]	Stent	10/16/00
ATS Open Pivot® Bileaflet Heart Valve[14]	Heart Valve	10/13/00
OssaTron - P990086[15]	Shock Wave Therapy	10/12/00
BiodivYsio™AS PC (phosphorylcholine) Coated Stent Delivery System - P000011[16]	Stent	09/29/00
Phylax AV Implantable Cardioverter Defibrillator System with Programmer Software - P000009[17]	Defibrillator	09/29/00
Vitros Immunodiagnostic Products Anti-HBs Reagent Pack and Calibrators - P000014[18]	Hepatitis Test	09/29/00
TRUFILL® n-Butyl Cyanoacrylate (n-BCA) Liquid Embolic System[19]	Embolizing Device	09/25/00
DTU-One Ultrasound Scanner - P980010[20]	Bone Ultrasound	09/19/00
Bayer Immuno 1™ Complexed Prostate-Specific Antigen (PSA) Assay- P990055[21]	PSA Test	09/08/00
Medstone STS™ Lithotripter - P970042[22]	Shock Wave Therapy	09/05/00
Vibrant Soundbridge - P990052[23]	Hearing Implant	08/31/00
Horizon 55 EW and Horizon 55 EW Westint Contact Lenses - P990072[24]	Contact Lens	08/22/00
QUS-2 Calcaneal Ultrasonometer - P990039[25]	Bone Ultrasound	08/08/00
Medtronic® IsoMed® Constant Flow Infusion System[26]	Infusion Pump	07/21/00
Mentor Alpha I Inflatable Penile Prosthesis - P000006[27]	Penile Implant	07/14/00
Mosaic Porcine Bioprosthesis, Model 305 (Aortic) and Model 310 (Mitral) - P990064[28]	Heart Valve	07/14/00
Menicon Z™ (tisilfocon A) Rigid Gas Permeable Contact Lens - P990018[29]	Contact Lens	07/11/00
Diomed 630 PDT Laser Model T2USA - P990021[30]	Laser	06/30/00
Hyperion™ LTK System - P990078[31]	Laser	06/30/00
Vascular Solutions Duett™ Sealing Device[32]	Vascular Sealant	06/22/00
NAVI-STAR® Diagnostic/Ablation Deflectable Tip Catheter - P990025[33]	Ablation Catheter	06/15/00
Medtronic Model 7250 Jewel® AF Implantable Cardioverter Defibrillator System - P980050[34]	Defibrillator	06/14/00
CoStasis/DynaStat Surgical Hemostat - P990030[35]	Vascular Sealant	06/13/00
Stockert 70 RF Generator - P990071[36]	Ablation Device	05/31/00
FocalSeal-Synthetic Absorbable Sealant[37]	Lung Sealants	05/26/00
OxiFirst Fetal Oxygen Saturation Monitoring System[38]	Fetal Oxygen Monitor	05/12/00

Medical Devices Approved by FDA in 2002		
Device Name	**Category**	**Date**
VISX Excimer Laser System and Custom Contoured Ablation Pattern (C-CAP) Method™ - H000002[1]	Laser	12/19/01
Acticon™ Neosphincter - P010020[2]	Sphincter	12/18/01
LIFECOR Wearable Cardioverter Defibrillator (WCD®) 2000 System - P010030[3]	Defibrillator	12/18/01
CoSeal® Surgical Sealant - P010022[4]	Vascular Sealant	12/14/01
AMPLATZER® Septal Occluder - P000039[5]	Septal Occluder	12/05/01
NNMT Medical, Inc. CardioSEAL® Septal Occlusion System with QwikLoad™ -	Septal Occluders	12/05/01

P000049[6]		
CryoLife BioGlue Surgical Adhesive - P010003[7]	Skin Adhesive	12/03/01
QuantiFERON® -TB - P010033[8]	TB Test	11/28/01
Genesis Neurostimulation (IPG) System - P010032[9]	Stimulator	11/21/01
Ascension® MCP - P000057[10]	Finger Joint Prosthesis	11/19/01
GYNECARE INTERGEL® Adhesion Prevention Solution - P990015[11]	Adhesion Prevention	11/16/01
WALLSTENT® Venous Endoprosthesis with Unistep™ Plus Delivery System - P980033[12]	Stent	11/16/01
IMMULITE® AFP and IMMULITE® 2000 AFP - P010007[13]	Alpha-Fetoprotein Test	11/09/01
OP-1™ - H010002[14]	Bone Implant	10/17/01
Focus® Night and Day Soft Contact Lens - P010019[15]	Contact Lens	10/11/01
Home Monitoring System with the BA03 DDDR Pulse Generator - P950037/S19[16]	Pacemaker	10/11/01
DERMAGRAFT® - P000036[17]	Skin Repair	09/28/01
NovaSure™ Impedance Controlled Endometrial Ablation System - P010013[18]	Ablation Devices	09/28/01
SenoScan® Full Field Digital Mammography System - P010017[19]	Mammography	09/25/01
IDeflux® Injectable Gel - P000029[20]	Urinary Bulking Agent	09/24/01
Model 3100B High-Frequency Oscillatory Ventilator - P890057/S014[21]	Ventilator	09/24/01
SOUNDTEC® Direct Drive Hearing System - P010023[22]	Hearing Aid	09/07/01
OrCel™ Bilayered Cellular Matrix - P010016[23]	Skin Repair	08/31/01
Vitros Immunodiagnostic Products Anti-HCV Reagent Pack and Calibrator - P010021[24]	Hepatitis Test	08/30/01
Avanta Metacarpophalangeal (MCP) Joint Implant Finger Prosthesis - H010001[25]	Finger Joint Prosthesis	08/28/01
Medtronic® InSync® Biventricular Pacing System including the InSync ®Model 8040 Pulse Generator, Attain™ LV Model 2187 and Attain ™CS Model 2188 Leads - P010015[26]	Pacemaker	08/28/01
MED-EL COMBI 40+ Cochlear Implant System - P000025[27]	Cochlear Implant	08/20/01
Given® Diagnostic Imaging System - K010312[28]	Camera	08/01/01
UBIS 5000 Ultrasound Bone Sonometer - P000055[29]	Bone Ultrasound	07/17/01
AquaFlow™ Collagen Glaucoma Drainage Device - Model CGDD-20 - P000026[30]	Glaucoma Device	07/12/01
RapidScreen™ RS-2000 - P000041[31]	Computer Aided Diagnosis	07/12/01
INTEGRITY™ AFx DR MODEL 5346 / P880086/S083 (Generator) & P830045/S076 (Programmer)[32]	Pacemaker	07/11/01
AMPLICOR™ Hepatitis C Virus (HCV) Test, version 2.0 (v2.0) P000010[33]	Hepatitis Test	07/05/01
Dimension RxL PSA Flex Reagent Cartridge - P000021[34]	PSA Test	07/05/01
COBAS AMPLICOR™ Hepatitis C Virus (HCV) Test, version 2.0 (v2.0) P000012[35]	Hepatitis Test	07/03/01
TMx-2000™ BPH Thermotherapy System - P000043[36]	Microwave Therapy	06/29/01
Carisolv Non-Invasive Caries Removal System - P000005[37]	Dental Treatment	06/27/01
Diagnostic Products Corporation's Total Prostate Specific Antgen (PSA) Assays on the Immulite and Immulite 2000 Analyzers - P930027/S4[38]	PSA Test	06/19/01
AMS Sphincter 800™ Urinary Prosthesis - P000053[39]	Sphincter	06/14/01
LAP-BAND® Adjustable Gastric Banding (LAGB®) System - P000008[40]	Obesity Treatment	06/05/01
Elecsys® HBsAg Immunoassay, Elecsys® HBsAg Confirmatory, and PreciControl HBsAg- P990012[41]	Hepatitis Test	06/01/01
On-X® Prosthetic Heart Valve - P000037[42]	Heart Valve	05/30/01
Heartstream FR2 AED with Attenuated Defibrillation Pads K003819[43]	Automated External Defibrillator (AED)	05/02/01
Vitros Immunodiagnostic Products HBsAg Reagent Pack and Calibrator, and HBsAg Confirmatory Kit - P000044[44]	Hepatitis Test	04/27/01
BAK/Cervical (BAK/C®) Interbody Fusion System - P980048[45]	Spinal Implant	04/20/01
HerOption™ Uterine Cryoblation Therapy™ System - P000032[46]	Ablation Device	04/20/01
STAARVISC™ Sodium Hyaluronate - P000046[47]	Eye Implant	04/18/01
Medtronic Model 7250 Jewel®AF Implantable Cardioverter Defibrillator System - P980050/S1[48]	Defibrillator	04/06/06
CeeOn™ Edge Foldable Intraocular Lens - Model 911A - P990080[49]	Intraocular Lens (IOL)	04/05/01
Devices For Testing The Hepatitis B Virus (HBV)[50]	Hepatitis Test	03/30/01
Prostalac Hip Temporary Prosthesis - H000004[51]	Hip Prosthesis	03/23/01
GlucoWatch® Automatic Glucose Biographer - P990026[52]	Glucose Monitors	03/22/01
N Latex Cystatin C Test Kit - K003503[53]	Kidney Test	03/13/01
Edwards Prima™ Plus Stentless Bioprosthesis Model 2500P - P000007[54]	Heart Valve	02/27/01
TMJ Fossa Eminence Prosthesis™ - P000035[55]	Jaw Prosthesis	02/27/01
Composite Cultured Skin - H990013[56]	Skin Repair	02/21/01
VISTAKON (lenefilcon A) Soft Contact Lenses - P990085[57]	Contact Lens	02/16/01
Corometrics 120 F-Series Maternal/Fetal Monitor with Integrated Fetal Oxygen	Fetal Monitor	02/09/01

Saturation Monitoring - P000016[58]		
SUPARTZ™ DISPO- P980044[59]	Arthritis Treatment	01/24/01
TMJ (Temporomandibular Joint) Metal-on-Metal Total Joint Replacement Prostheses System - P000023[60]	Jaw Prosthesis	01/05/01
Medical Devices Approved by FDA in 2002		
Device Name	**Category**	**Date**
ProstaLund® Core Therm™[1]	BPH Treatment	12/23/02
Bridge™ Extra Support Over-The-Wire Renal Stent System - P020007[2]	Stent	12/18/02
Metrika A1cNow® for Home Use - K022661[3]	Diabetes Test	12/13/02
Karl Storz Autofluorescence System - P020008[4]	Bronchoscope	12/12/02
ALERT® System - P990069[5]	Defibrillator	11/27/02
Elecsys® proBNP Immunoassay - K022516[6]	Heart Failure Test	11/19/02
IDI-Strep B Assay - K022504[7]	Strep Test	11/18/02
EXCLUDER™ Bifurcated Endoprosthesis - P020004[8]	Vascular Graft	11/16/02
HeartMate® SNAP-VE LVAS - P920014/S016[9]	LVAD	11/06/02
VERSANT™ HCV RNA Qualitative Assay - P020011[10]	Hepatitis Test	11/07/02
Essure™ System - P020014[11]	Contraceptive	11/04/02
NaviStar DS and Celsius DS Diagnostic/Ablation Catheters, Stockert 70 RF Generator and accessories – P010068[12]	Ablation Catheter	09/27/02
Neuroform™ Microdelivery Stent System - H020002[13]	Stent	09/11/02
GlucoWatch G2 Biographer - P990026/S0008[14]	Glucose Monitor	08/26/02
RetroX Transcutaneous Air Conduction Hearing Aid System - K013298[15]	Hearing Aid	08/20/02
NEUROLINK® System - H010004[16]	Stent	08/09/02
IMMULITE® HBsAg and IMMULITE® 2000 HBsAg and Confirmatory Kit - P010050[17]	Hepatitis Test	07/26/02
IMMULITE® Anti-HBc IgM and IMMULITE® 2000 Anti-HBc IgM - P010053[18]	Hepatitis Test	07/26/02
IMMULITE® Anti-HBc and IMMULITE® 2000 Anti-HBc - P010051[19]	Hepatitis Test	07/24/02
IMMULITE® Anti-HBs and IMMULITE® 2000 Anti-HBs - P010052[20]	Hepatitis Test	07/22/02
Mentor Saline-Filled Testicular Prosthesis - P020003[21]	Testicular Prostheses	07/19/02
SONOCUR® - P010039[22]	Shock Wave Therapy	07/19/02
Expanded Use of Guidant Ventak Implantable Cardioverter Defibrillators - P910077 S037[23]	Defibrillator	07/18/02
PALMAZ® Balloon-Expandable Stent for Renal Arteries - P890017/S10[24]	Stent	07/10/02
InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device - P000058[25]	Spinal Implant	07/02/02
Medtronic® InSync® ICD Model 7272 Dual Chamber Implantable Cardioverter Defibrillator System with Cardiac Resynchronization Therapy - P010031[26]	Defibrillator	06/26/02
AFFINITY™ Cage System - P000028[27]	Spinal Implant	06/13/02
Paragon CRT™ (paflufocon B), Paragon CRT ™100 (paflufocon D), Paragon Quadra RG ™(paflufocon B), and Paragon Quadra RG ™100 (paflufocon D) Rigid Gas Permeable Contact Lenses for Overnight Wear- P870024S043[28]	Contact Lens	06/13/02
Roche Diagnostics Accu-Check® Advantage® Module - K021513[29]	Glucose Monitor	06/11/02
TheraSense, Inc. FreeStyle Tracker™ Diabetes Management System - K020866[30]	Glucose Monitor	06/11/02
Indermil™ Tissue Adhesive - P010002[31]	Skin Adhesive	05/22/02
Guidant Cardiac Resynchronization Therapy Defibrillator System including the CONTAK CD® pulse generator and the EASYTRAK® left ventricular coronary venous lead - P010012[32]	Defibrillator	05/02/02
Ancure® Aortoiliac System - P990017/S030[33]	Endovascular Graft	04/24/02
INTEGRA® Dermal Regeneration Template - P900033/S008[34]	Skin Repair	04/19/02
ViewPoint™ CK System - P010018[35]	Keratoplasty Device	04/11/02
IntraCoil® Self-Expanding Peripheral Stent - P000033[36]	Stent	04/03/02
QuickSeal Arterial Closure System - P010049[37]	Vascular Sealant	03/25/02
Disintegrator™Insulin Needle Destruction Unit - P010040[38]	Needles Destruction Device	03/15/02
Lorad Digital Breast Imager - P010025[39]	Mammography	03/15/02
Lea's Shield® - P010043[40]	Contraceptive	03/14/02
SIR-Spheres®- P990065[41]	Cancer Injection	03/05/02
Roche Elecsys® Anti-HBs Immunoassay & Elecsys® PreciControl Anti-HBs - P010054[42]	Hepatitis Test	02/27/02
Wartner Wart Removal System K011708[43]	Wart Remover	02/20/02
Second Look™ - P010034[44]	Mammography	01/31/02
MammoReader - P010038[45]	Mammography	01/15/02
Activa® Parkinson's Control System P960009/S7[46]	Brain Stimulator	01/14/02
Medical Devices Approved by FDA in 2003		

Device Name	Category	Date
CoSeal™ Surgical Sealant - P030039[1]	Vascular Sealant	12/12/03
Restylane™ Injectable Gel - P020023[2]	Wrinkle Filler	12/12/03
Keramos™ Ceramic/Ceramic Total Hip System - D980003[3]	Hip Prosthesis	11/26/03
Contegra® Pulmonary Valved Conduit, Models 200 (unsupported) and 200S (supported) - H020003[4]	Heart Valve	11/21/03
CrystaLens™ Model AT-45 Accommodating IOL - P030002[5]	Itraocular Lens (IOL)	11/14/03
NIRflex™ Premounted Coronary Stent System - P020040[6]	Stent	10/24/03
Morcher Endocapsular Tension Ring - P010059[7]	Intraocular Lens (IOL)	10/23/03
WaveLight ALLEGRETTO WAVE™ Excimer Laser System - P030008[8]	LASIK	10/13/03
WaveLight ALLEGRETTO WAVE™ Excimer Laser System - P020050[9]	LASIK	10/07/03
Microwave Endometrial Ablation (MEA) System – P020031[10]	Ablation Device	09/23/03
Blazer II XP Cardiac Ablation Catheter, EPT-1000 XP Cardiac Ablation Controller and Accessories - P020025[11]	Ablation Catheter	08/25/03
INDEPENDENCE™ iBOT™ 3000 Mobility System – P020033[12]	Wheelchair	08/13/03
S.M.A.R.T.™ Nitinol Stent System / S.M.A.R.T.™ Control™ Nitinol Stent System - P020036[13]	Stent	08/12/03
MULTI-LINK VISION™ RX & OTW Coronary Stent System - P020047[14]	Stent	07/16/03
FX miniRAIL™ RX Percutaneous Transluminal Coronary Angioplasty PTCA Catheter - P020037[15]	Angioplasty Catheter	06/11/03
ThinPrep™ Imaging System - P020002[16]	Imaging System	06/06/03
Zenith® AAA Endovascular Graft - P020018[17]	Vascular Graft	05/23/03
Respect™ CV Catheter System - P020052[18]	Cardiac Catheter	05/07/03
CYPHER™ Sirolimus-eluting Coronary Stent - P020026[19]	Stent	04/24/03
7F Freezor® Cardiac Cryoablation Catheter and CCT.2 CryoConsole System - P020045[20]	Ablation Devices	04/17/03
Medtronic Activa® Dystonia Therapy - H020007[21]	Brain Stimulator	04/15/03
Digene Hybrid Capture 2 High-Risk HPV DNA Test - P890064 S009 A004[22]	Cervical Cancer Test	03/31/03
Bayer Versant™ HCV RNA 3.0 Assay (bDNA) – P020022[23]	Hepatitis Test	03/28/03
FemCap™ - P020041[24]	Contraceptive	03/28/03
Medtronic AT500TM DDDRP Pacing System - P980035/S13[25]	Pacemaker	03/26/03
NeedleZap™ - P010065[26]	Needle-Destruction Device	03/14/03
CosmoDerm™ 1 Human-Based Collagen, CosmoDerm™ 2 Human-Based Collagen and CosmoPlast™ Human-Based Collagen - P800022/S050[27]	Wrinkle Filler	03/11/03
Ceramic TRANSCEND® Hip Articulation System - P010001[28]	Hip Prosthesis	02/03/03
Osteonics® ABC System and Trident™ System – P000013[29]	Hip Prosthesis	02/03/03
Dimension® Free Specific Antigen (FPSA) Flex® Reagent Cartridge - P020027[30]	PSA Test	01/24/03
Philips Series 50 XMO Fetal/Maternal Monitor (Model M1350C) with Integrated Fetal Oxygen Saturation Monitoring - P020028[31]	Fetal Monitor	01/03/03
Medical Devices Approved by FDA in 2004		
Device Name	**Category**	**Date**
ADVIA Centaur® HBc Total ReadyPack Reagents, ADVIA Centaur® HBc Total Quality Control Materials - P040004[1]	Hepatitis Test	12/27/04
Roche AmpliChip Cytochrome P450 Genotyping test and Affymetrix GeneChip Microarray Instrumentation System - K042259[2]	Genetic Test	12/23/04
ADVIA Centaur® HAV IgM - P040018[3]	Hepatitis Test	12/22/04
Bayer ADVIA® Centaur™ HCV Assay - P030056[4]	Hepatitis Test	12/22/04
InSite™ Her-2/neu kit - P040030[5]	Breast Cancer Test	12/22/04
Reflection® Ceramic Acetabular System[6]	Hip Prostheses	12/17/04
GORE VIATORR® TIPS Endoprosthesis - P040027[7]	Stent	12/06/04
URYX® Urethral Bulking Agent - P030030[8]	Urinary Bulking Agent	12/16/04
Vysis® AutoVysion™ System - K041875[9]	Genetic Test	12/13/04
Nuflexxa™ (1 percent Sodium Hyaluronate) - P010029[10]	Arthritis Injection	12/03/04
Kodak Mammography CAD ENGINE - P030007[11]	Mammography	11/23/04
NAVISTAR™ and CELSIUS™ THERMOCOOL® Irrigated Deflectable Diagnostic/Ablation Catheter - P030031[12]	Ablation Catheter	11/05/04
Hamilton Thorne Zona Infrared Laser Optical System (ZILOS-tk®) - K040045[13]	Laser	11/04/04
EVS™ Vascular Closure System - P040022[14]	Vascular Closure Device	11/03/04
Endologix PowerLink® System - P040002[15]	Vascular Graft	10/29/04
CHARITÉ™ Artificial Disc - P040006[16]	Spinal Disc	10/26/04
ExAblate® 2000 System - P040003[17]	Fibroid Treatment	10/22/04
Syncardia Temporary CardioWest Total Artificial Heart (TAH-t) - P030011[18]	Artificial Heart	10/15/04

JSZ Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear - P040029[19]	Contact Lens	09/29/04
Philips HeartStart Home OTC Defibrillator - K040904[20]	Defibrillator	09/16/04
Guidant Cardiac Resynchronization Therapy Defibrillators (COMPANION trial) - P010012/S026[21]	Defibrillator	09/14/04
ADVIA Centaur® Anti-HBs ReadyPack Reagents and Calibrators - P030029[22]	Hepatitis Test	09/10/04
Verisyse™ Phakic IOL - P030028[23]	Intraocular Lens (IOL)	09/10/04
ACCULINK™ Carotid Stent System / RX ACCULINK™ Carotid Stent System - P040012[24]	Stent	08/30/04
NeoGram Amino Acids and Acylcarnitines Tandem Mass Spectrometry Kit, Model MS-8970 - K031878[25]	Amino Acid Test	08/24/04
Vertical Expandable Prosthetic Titanium Rib (VEPTR) - H030009[26]	Prostheses	08/23/04
Siemens Mammomat Novation DR Full Field Digital Mammography System - PMA P030010[27]	Mammography	08/20/04
Ventana® Medical Systems' PATHWAY Anti-c-KIT (9.7) Primary Antibody[28]	Rib Prosthesis	08/11/04
ADVIA Centaur® HBc IgM ReadyPack Reagents / ADVIA Centaur® HBc IgM Quality Control (Calibrator and Control) Materials - P030040[29]	Hepatitis Test	08/06/04
Sculptra - P030050[30]	Wrinkle Filler	08/03/04
CEDIA® Sirolimus Assay - K034069[31]	Lab Test	07/28/04
INTACS® Prescription Inserts for Keratoconus - H040002[32]	Corneal Insert	07/26/04
Stelid II, Stelix, and Stelix II steroid eluting endocardial pacing leads - P020030[33]	Pacemaker	07/17/04
bioMerieux VIDAS total PSA assay - P040008[34]	PSA Test	07/08/04
St. Jude Medical® Epic™ HF and Atlas® + HF Dual Chamber Implantable Cardioverter Defibrillator Systems with Cardiac Resynchronization Therapy - P030054[35]	Defibrillators	06/30/04
IntraStent® DoubleStrut™ Stent- P030045[36]	Stent	06/08/04
Euclid Systems Orthokeratology (oprifocon A) Contact Lenses for Overnight Wear - P010062[37]	Contact Lens	06/07/04
Glucatell™ - K032373[38]	Lab Test	05/21/04
St. Jude Medical Frontier™ Biventricular Cardiac Pacing System[39]	Pacemaker	05/13/04
INFUSE® Bone Graft - P000054[40]	Bone Graft	04/30/04
Oculaid™ Capsular Tension Ring, or Stableyes™ Capsular Tension Ring - P030023[41]	Intraocular Lens (IOL)	04/27/04
PRECISION™ Spinal Cord Stimulator (SCS) System - P030017[42]	Spinal Stimulator	04/27/04
Hylaform - P030032[43]	Wrinkle Filler	04/22/04
Oxford™ Meniscal Unicompartmental Knee System - P010014[44]	Knee Prosthesis	04/21/04
OP-1 Putty - H020008[45]	Spinal Implant	04/07/04
TAXUS™ Express2™ Paclitaxel-Eluting Coronary Stent System - P030025[46]	Stent	03/04/04
Vitros Immunodiagnostic Products Anti-HBc IgM Reagent Pack and Vitros Immunodiagnostic Products Anti-HBc IgM Calibrator - P030026[47]	Hepatitis Test	04/03/04
Vitros Immunodiagnostic Products Anti-HBc Reagent Pack and Vitros Immunodiagnostic Products Anti-HBc Calibrator - P030024[48]	Hepatitis Test	03/04/04
DeBakey VAD® Child - H030003[49]	Ventricular Assist Device	02/25/04
Heartsbreath - H030004[50]	Lab Test	02/24/04
Prolieve™ - P030006[51]	Prostate Treatment	02/19/04
DakoCytomation EGFR pharmDx™ - P030044[52]	Lab Test	02/12/04
Abbott AxSYM® Antibody to Hepatitis C Virus - P970027[53]	Hepatitis Test	02/05/04
AxSYM Free PSA - P980007[54]	PSA Test	02/05/04
Orthovisc® High Molecular Weight Hyaluronan - P030019[55]	Arthritis Injection	02/04/04
CONTAK® RENEWAL™ TR Models H120 and H125 - P030005[56]	Pacemaker	01/26/04
CellSearch™ Epithelial Cell Kit / CellSpotter™ Analyzer - K031588[57]	Breast Cancer Test	01/21/04

Medical Devices Approved by FDA in 2005

Device Name	Category	Date
Visian ICL™ - P030016[1]	Intraocular Lens (IOL)	12/22/05
StarClose™ Vascular Closure System - P050007[2]	Vascular Sealant	12/21/05
Ceralas I Laser and Ceralink Slit Lamp Adapter - P050021[3]	Laser	12/20/05
VISTAKON® (senofilcon A) Contact Lens - P040045[4]	Contact Lens	12/20/05
C2a – Taper™ Acetabular System - P050009[5]	Hip Prostheses	12/16/05
X STOP® Interspinous Process Decompression System (XSTOP) - P040001[6]	Spinal Implant	11/21/05
GEM 21S (Growth-factor Enhanced Matrix) - P040013[7]	Dental Bone Filler	11/18/05
IBI Therapy™ Dual 8™ Ablation Catheter and IBI 1500T6 (USA) Cardiac Ablation Generator - P040042[8]	Ablation Catheter	11/18/05
Coaptite® - P040047[9]	Urinary Bulking Agent	11/10/05
STAN® S31 Fetal Heart Monitor - P020001[10]	Heart Monitor	11/01/05

Total Temporomandibular Joint Replacement System - P020016[11]	Jaw Prostheses	09/21/05
ACRYSOF® Single-Piece Posterior Chamber Intraocular Lenses With Toric Optic, Models SA60T3, SA60T4 and SA60T5 - P930014/S015[12]	Intraocular Lens (IOL)	09/14/05
Xact® Carotid Stent System - P040038[13]	Stent	09/06/05
Matrix VSG™ System - P040044[14]	Vascular Sealant	08/17/05
Orbasone Pain Relief System - P040039[15]	Shock Wave Therapy	08/10/05
SJM Biocor™ and Biocor™ Supra Valves - P040021[16]	Heart Valve	08/05/05
SelectSecure™ Lead Model 3830 - P030036[17]	Pacemaker Lead	08/03/05
Wingspan™ Stent System with Gateway™ PTA Balloon Catheter - H50001[18]	Stent	08/03/05
Onyx® Liquid Embolic System (LES) - P030004[19]	Embolizing Device	07/21/05
VNS Therapy System - P970003s050[20]	Vagus Nerve Stimulator	07/15/05
DakoCytomation c-Kit pharmDx™ - P040011[21]	Gastrointestinal Tumor Test	06/27/05
GORE VIABAHN™ Endoprosthesis - P040037[22]	Stent	06/14/05
ADVIA Centaur® HBsAg ReadyPack Reagents, ADVIA Centaur® HBsAg Confirmatory ReadyPack Reagents, and ADVIA Centaur® HBsAg Quality Control Material - P030049[23]	Hepatitis Test	05/31/05
Wako LBA AFP-L3 - K041847[24]	Liver Cancer Test	05/19/05
Tag-It™ Cystic Fibrosis Kit - K043011[25]	Cystic Fibrosis Test	05/09/05
Duraloc® Option Ceramic Hip System - P040023[26]	Hip Prostheses	05/03/05
DakoCytomation Her2 FISH pharmDx™ Kit - p040005[27]	Breast Cancer Test	05/03/06
Rithron-XR Coronary Stent System - P030037[28]	Stent	04/29/05
Decapinol Oral Rinse - K041482[29]	Gingivitis Rinse	04/18/05
PAXgene™ Blood RNA System - K042613[30]	Genetic Test	04/18/05
Boston Scientific Liberte™ Monorail™ and Over-the-Wire Coronary Stent Systems - P040016[31]	Stent	04/12/05
DuraSeal Dural Sealant System - P040034[32]	Dural Sealant	04/07/05
OrthospecTM Extracorporeal Shock Wave Therapy - P040026[33]	Shock Wave Therapy	04/01/05
CoAxia NeuroFlo™ Catheter - H030005[34]	Catheter	03/30/05
Restylane™ Injectable Gel - P040024[35]	Wrinkle Filler	03/25/06
GORE TAG Thoracic Endoprosthesis - P040043[36]	Vascular Graft	03/23/05
AcrySof® ReSTOR Apodized Diffractive Posterior Chamber Intraocular Lens (IOL) - P040020[37]	Intraocular Lens (IOL)	03/21/05
ADVIA Centaur® HAV Total Assay - P040017[38]	Hepatitis Test	03/07/05
UroVysion™ Bladder Cancer - P030052[39]	Bladder Cancer Test	01/24/05
IBI Therapy™ Cardiac Ablation System - P040014[40]	Ablation Catheter	01/14/05
Medical Devices Approved by FDA in 2006		
Device Name	**Category**	**Date**
Radiesse - P050037[1]	Wrinkle Filler	12/22/06
Radiesse - P050052[2]	Wrinkle Filler	12/22/06
Cosmetic Tissue Augmentation Product - P050033[3]	Wrinkle Filler	12/20/06
Olympic Cool-Cap ®- P040025[4]	Cooling Unit	12/20/06
The Spanner™ Temporary Prostatic Stent - P060010[5]	Stent	12/14/06
Allergan Inamed® Silicone-Filled Breast Implants - P020056[6]	Breast Implant	11/17/06
Mentor MemoryGel™ Silicone Gel-Filled Breast Implants - P030053[7]	Breast Implant	11/17/06
Paragon Z CRT® (tisilfocon A) Rigid Gas Permeable Contact Lenses for Corneal Refractive Therapy - P050031[8]	Contact Lens	11/16/06
Macroplastique ® Implants - P040050[9]	Urinary Bulking Agent	10/30/06
ArteFill® - P020012[10]	Wrinkle Filler	10/27/06
NexStent® - P050025[11]	Stent	10/27/06
Arista™ AH Absorbable Hemostat - P050038[12]	Blood Clotting Aid	09/26/06
Cordis PRECISE™ OTW Nitinol Stent System - P030047[13]	Stent	09/22/06
INTROL™ CF Panel I Control - K060070[14]	Cystic Fibrosis Test	09/18/06
AxSYM CORE™ 2.0 - P060012[15]	Hepatitis Test	09/08/06
ARCHITECT® HBsAg Assay - P060007[16]	Hepatitis Test	09/07/06
AbioCor® Implantable Replacement Heart - H040006[17]	Artificial Heart	09/05/06
AxSYM CORE-M ™ 2.0 Controls - P060009[18]	Hepatitis Test	08/25/06
MONOLISA™ Anti-HBs and MONOLISA™ Anti-HBs Calibrator Kit - P050048[19]	Hepatitis Test	08/25/06
PRODISC®-L Total Disc Replacement - P050010[20]	Spinal Disc	08/14/06
Carl Zeiss Meditec MEL 80 Excimer Laser System - P060004[21]	LASIK	08/11/06
Gore HELEX® Septal Occluder - P050006[22]	Septal Occluder	08/11/06

BIOTRONIK's Kronos LV-T and Tupos LV/ATx Implantable Cardioverter Defibrillator Systems with Cardiac Resynchronization Therapy - P050023[23]	Defibrillator	08/10/06
AxSYM® AUSAB® Reagent Kit, Calibrator and Controls - P060003[24]	Hepatitis Test	08/07/06
Adept® Adhesion Reduction Solution (4 percent Icodextrin) - P050011[25]	Adhesion Prevention	07/28/06
Fuji Computed Radiography Mammography Suite (FCRMS) - P050014[26]	Mammography	07/10/06
Trilogy AB Acetabular System - P040048[27]	Hip Prosthesis	06/28/06
Zilver Vascular Stent - P050017[28]	Stent	06/26/06
Vitagel™ Surgical Hemostat - P050044[29]	Hemostat	06/16/06
ARCHTECT® Anti-HCV - P050042[30]	Hepatitis Test	06/07/06
Juvéderm Gel Implants - P050047[31]	Wrinkle Filler	06/02/06
ARCHITECT® AUSAB® Reagent Kit - P050051[32]	Hepatitis Test	06/01/06
AxSYM® HBsAg Assay - P050049[33]	Hepatitis Test	06/01/06
Stelkast Supass™ Acetabular System - P040051[34]	Hip Prosthesis	05/12/06
Birmingham Hip Resurfacing (BHR) System - P040033[35]	Hip Prosthesis	05/09/06
PhiCal™ Fecal Calprotectin Immunoassay - K050007[36]	Fecal Test	04/26/06
Karl Storz Rigid TTTS Fetoscopy Instrument Set - H040005[37]	Fetoscope Instrument	03/31/06
DexCom™ STS™ Continuous Glucose Monitoring System - P050012[38]	Glucose Monitor	03/24/06
LUMA™ Cervical Imaging System - P040028[39]	Cervical Imaging System	03/16/06
MonoPrep Pap Test - P040052[40]	Cervical Cancer	03/03/06

Medical Devices Approved by FDA in 2007		
Device Name	**Category**	**Date**
ProDisc™-C Total Disc Replacement - P070001[1]	Spinal Disc	12/17/07
Zimmer NexGen® LPS-Flex Mobile and LPS-Mobile Bearing Knees - P060037[2]	Knee Prostheses	12/10/07
ARCHITECT® CORE-M - P060035[3]	Hepatitis Test	11/06/07
Epicel® cultured epidermal autograft (CEA) - H990002[4]	Skin Graft	10/25/07
Exponent® Self-Expanding Carotid Stent with Over-the-Wire (OTW) or Rapid-Exchange (RX) Delivery Systems - P070012[5]	Stent	10/23/07
Mitroflow Aortic Pericardial Heart Valve - P060038[6]	Heart Valve	10/23/07
REALIZE™ Band - P070009[7]	Gastric Band	09/28/07
AMPLATZER® Muscular VSD Occluder - P040040[8]	Heart Occlusion Device	09/07/07
Femoral Introducer Sheath and Hemostasis Device (FISH™) - P050043[9]	Cardiac Catheter	08/20/07
CryoCor Cryoablation - P050024[10]	Ablation Catheter	08/01/07
FLAIR Endovascular Stent Graft - P060002[11]	Stent	07/23/07
GeneSearch™ BLN Test Kit - P060017[12]	Breast Cancer Test	07/16/07
PRESTIGE® Cervical Disc System - P060018[13]	Spinal Disc	07/16/07
VISX STAR S4 IR™ Excimer Laser System with Variable Spot Scanning (VSS™) and WaveScan WaveFront® System - P930016/S25[14]	LASIK	07/11/07
NOVATION™ Ceramic Articulation Hip System - P050039[15]	Hip Prostheses	07/05/07
Cormet Hip Resurfacing System - P050016[16]	Hip Prostheses	07/03/07
Binax Now® Malaria Test - K061542[17]	Malaria Test	06/13/07
INRange Remote Medication Management System - K051338[18]	Medication Management	06/13/07
MONOLISA™ Anti-HBc IgM EIA - P060034[19]	Hepatitis Test	05/31/07
STS-7 Continuous Glucose Monitoring System - P050012/S001[20]	Glucose Monitor	05/31/07
Mynx™ Vascular Closure System - P040044/S001[21]	Vascular Sealant	05/16/07
IMMULITE®/IMMULITE® 1000 and IMMULITE® 2000 Free PSA - P060005[22]	PSA Test	05/11/07
CORDIS ENTERPRISE™ Vascular Reconstruction Device and Delivery System - H060001[23]	Stent	05/08/07
EMS Swiss Dolorclast® - P050004[24]	Shock Wave Therapy	05/08/07
C-flex™ intraocular lens - P060011[25]	Intraocular Lens (IOL)	05/03/07
Perlane® Injectable Gel - P040024/S006[26]	Wrinkle Filler	05/02/07
MONOLISA™ Anti-HBc EIA - P060031[27]	Hepatitis Test	04/27/07
ACUITY™ Steerable Lead Models 4554, 4555, and 4556 - P050046[28]	Pacemaker	04/13/07
Onyx® Liquid Embolic System (Onyx® HD-500)[29]	Aneurism Block	04/11/07
IBI Therapy™ Cool Path™ Ablation Catheter and IBI 1500T9 RF Generator - P060019[30]	Ablation Device	03/16/07
INFUSE® Bone Graft - P050053[31]	Dental Graft	03/09/07
Paradigm REAL-Time and Guardian REAL-Time Systems P980022/S015[32]	Glucose Monitor	03/08/07
Histoacryl and Histoacryl Blue - P050013[33]	Skin Adhesive	02/16/07

MESOMARK™ - H060004[34]	Cancer Test	01/24/07
Protégé® GPS™ and Protégé® RX Carotid Stent Systems - P060001[35]	Stent	01/24/07
Medical Devices Approved by FDA in 2008		
Device Name	**Category**	**Date**
Express® SD Renal Monorail® Premounted Stent System - P060006[1]	Stent	12/11/08
BD FocalPoint™ GS Imaging System - P950009/S008[2]	Imaging System	12/03/08
E-LUMINEXX Vascular Stent - P080007[3]	Stent	12/04/08
BIOFINITY® (comfilcon A) Soft Contact Lens for Extended Wear - P080011[4]	Contact Lenses	11/19/08
COBAS TaqMan HCV Test For Use With the COBAS AmpliPrep Instrument and the COBAS TaqMan Analyzer or the COBAS TaqMan 48 Analyzer - P060030[5]	Hepatitis Test	10/30/08
Carotid WALLSTENT® Monorail® Endoprosthesis – P050019[6]	Stent	10/23/08
Helios II Ablation Catheter– P050029[7]	Ablation Catheters	10/08/08
Hoya iSpheric™ Model YA-60BB Intraocular Lens - P080004[8]	Intraocular Lens (IOL)	09/26/08
Akreos® Posterior Chamber Intraocular Lens - P060022[9]	Intraocular Lens (IOL)	09/05/08
COBAS TaqMan HBV Test For Use With The High Pure System - P050028[10]	Hepatitis Test	09/04/08
T-SPOT®.TB - P070006[11]	Tuberculosis Test	07/25/08
XIENCE™ V Everolimus Eluting Coronary Stent on the Over-the-Wire (OTW) or Rapid Exchange (RX) Stent Delivery Systems - P070015[12]	Stent	07/02/08
Invitrogen SPOT-Light® HER2 CISH™ Kit - P050040[13]	Breast Cancer Test	07/01/08
EVOLENCE® Collagen Filler - P070013[14]	Wrinkle Filler	06/27/08
Medtronic® Attain StarFix™ Model 4195 Lead - P060039[15]	Pacemaker	06/13/08
Talent™ Thoracic Stent Graft System - P070007[16]	Stent	06/05/08
Zenith® TX2® Thoracic TAA Endovascular Graft with the H&LB One-Shot™ Introduction System - P070016[17]	Endovascular Graft	05/21/08
ELA Ovatio CRT-D System - P060027[18]	Ventricular Assist Device	05/15/08
BIOTRONIK's Stratos LV and Stratos LV T Cardiac Resynchronization Therapy Pacemakers and Corox OTW BP and Corox OTW S BP Left Ventricular Pacing Leads - P070008[19]	Pacemaker	05/12/08
Thoratec HeartMate II LVAS - P060040[20]	Ventricular Assist Device	04/21/08
Talent™ Abdominal Stent Graft System – P070027[21]	Endovascular Graft	04/15/08
CONTAK RENEWAL® 3 AVT® Models M150, M155, M157 and M159 - P010012/S037[22]	Implantable Cardioverter Defibrillator	03/13/08
FreeStyle Navigator® Continuous Glucose Monitoring System - P050020[23]	Glucose Monitor	03/12/08
Endeavor® Zotarolimus-Eluting Coronary Stent on the Over-the-Wire (OTW), Rapid Exchange (RX), or Multi Exchange II (MX2) Stent Delivery Systems - P060033[24]	Stents	02/01/08
Dako TOP2A FISH pharmDx™ Kit - P050045[25]	Breast Cancer Test	01/11/08
xTAG™ Respiratory Viral Panel (RVP) - K063765[26]	Respiratory Virus Test	01/03/08
Medical Devices Approved by FDA in 2009		
Device Name	**Category**	**Date**
CONSERVE® Plus Total Resurfacing Hip System - P030042[1]	Artificial Hip	11/03/09
VIDAS fPSA rt Assay - P080008[2]	PSA Test	10/08/09
DuraSeal Spine Sealant System - P080013[3]	Spine	09/04/09
Sculptra Aesthetic - P030050/S002[4]	Wrinkles	07/28/09
TAXUS® Liberte™ Long (2.75–4.00 mm x 38 mm) Paclitaxel-Eluting Coronary Stent System (Monorail and Over-the Wire Delivery Systems) - P060008/S011[5]	Stent	07/13/09
Scandinavian Total Ankle Replacement System (STAR Ankle) - P050050[6]	Ankle Replacement	05/27/09
TAXUS® Liberté® Atom™ (2.25 mm) Paclitaxel-Eluting Coronary Stent System (Monorail and Over-the Wire Delivery Systems) - P060008/S008[7]	Stent	05/21/09
BRYAN® Cervical Disc - P060023[8]	Cervical Disc	05/12/09
REPEL-CV Bioresorbable Adhesion Barrier - P070005[9]	Adhesion Barrier	03/06/09
ARCHITECT® CORE Reagent Kit, Calibrator and Controls - P080023[10]	HBV Test	04/10/09
Medtronic® Attain Ability™ Model 4196 Lead - P080006[11]	Pacemaker Leads	04/07/09
Cervista™ HPV 16/18 - P080015[12]	HPV Test Kit	03/12/09
CervistaTM HPV HR and GenfindTM DNA Extraction Kit - P080014[13]	HPV Test Kit	03/12/09
FC2 Female Condom - P080002[14]	Condom	03/10/09
Synvisc-One (hylan GF-20) - P940015/S012[15]	Osteoarthritis treatment	02/26/09
Reclaim™ DBS™ Therapy for OCD - H050003[16]	Brain Stimulator	02/19/09

LifeStent FlexStar and FlexStar XL Vascular Stent - P070014[17]	Stent	02/13/09
NAVISTAR® THERMOCOOL® and EZ Steer THERMOCOOL® Nav Irrigated Deflectable Diagnostic/Ablation Catheter for Treatment of Paroxysmal Atrial Fibrillation - P030031S011[18]	Catheter	02/06/09
XACT® Soft Acrylic UV Light-Absorbing Posterior Chamber Intraocular Lens - P080021[19]	Intraocular Lens	02/02/09
TECNIS® Multifocal Foldable Silicone and Acrylic Intraocular Lenses - P080010[20]	Intraocular Lens (IOL)	01/16/09
Medical Devices Cleared or Approved by FDA in 2010		
Device Name	**Category**	**Date**
Bard LifeStent and LifeStent XL Vascular Stent - P070014/S010[1]	Stent	12/23/10
DePuy Orthopaedics Ceramax Ceramic Total Hip System - P070026[2]	Hip Replacement	12/23/10
Arctic Front® Cardiac CryoAblation Catheter - P100010[3]	Catheter	12/17/10
Endurant Stent Graft System - P100021[4]	Stent	12/16/10
KODAK DirectView CR Mammography System - P080018[5]	Mammography	11/03/10
Dako HER2 FISH pharmDx™ - P040005/S005[6]	Cancer Test	10/20/10
Dako HercepTest™ - P980018/S010[7]	Cancer Test	10/20/10
EC-3 Posterior Chamber Intraocular Lenses (IOLs), Models EC-3 and EC-3 Precision Aspheric Lens (PAL) - P100016[8]	Intraocular Lens	10/19/10
Boston Scientific Cardiac Resynchronization Therapy Defibrillators - P010012/S230[9]	Defibrillator	09/16/10
Abbott RealTime HBV Assay - P080026[10]	HBV test	08/13/10
Implantable Miniature Telescope™ - P050034[11]	Ophthalmic	07/01/10
OraQuick HCV Rapid Antibody Test - P080027[12]	Antibody Test	06/25/10
Photodynamic Diagnostic D-Light C (PDD) System - P050027[13]	Cystoscopy	05/28/10
Elecsys® Anti-HCV Immunoassay and Elecsys® PreciControl Anti-HCV on the MODULAR ANALYTICS E170 Immunoassay Analyzer - P090009[14]	Immunoassay Analyzer	04/29/10
Elecsys® Anti-HCV Immunoassay and Elecsys® PreciControl Anti-HCV on the cobas e 601 Immunoassay Analyzer - P090008[15]	Immunoassay Analyzer	04/29/10
Elecsys® Anti-HCV Immunoassay and Elecsys® PreciControl Anti-HCV on the cobas e 411 Immunoassay Analyzer - P090007[16]	Immunoassay Analyzer	04/29/10
Asthmatx, Inc. Alair Bronchial Thermoplasty System - P080032[17]	Thermoplasty System	04/27/10
Softec HD Aspheric Posterior Chamber Intraocular Lens - P090022[18]	Intraocular Lens	04/12/10
Quick-Close® Vascular Suturing System - P080029[19]	Sutures	04/08/10
STERIS System 1E (SS1E) Liquid Chemical Sterilant - K090036[20]	Sterilant	04/05/10
Esteem® Implantable Hearing System - P090018[21]	Hearing Implant	03/17/10
Medtronic Vascular Complete® SE Vascular Stent System - P090006[22]	Stent	03/17/10
Express® LD Iliac Premounted Stent System - P090003[23]	Stent	03/05/10
Ethicon™ OMNEX™ Surgical Sealant - P060029[24]	Surgical Sealant	03/03/10
Medtronic Melody® Transcatheter Pulmonary Valve - H080002[25]	Heart Valve	01/25/10
Thoratec HeartMate II LVAS - P060040/S005[26]	LVAS	01/20/10
ProGEL™ Pleural Air Leak Sealant - P010047[27]	Surgical Sealant	01/14/10
Medical Devices Cleared or Approved by FDA in 2011		
Device Name	**Category**	**Date**
Vysis ALK Break Apart FISH Probe Kit, with the Vysis Paraffin Pretreatment IV and Post Hybridization Wash Buffer Kit, ProbeChek ALK Negative Control Slides, and ProbeChek ALK Positive Control Slides - P110012[1]	Genetic Test	08/26/11
cobas® 4800 BRAF V600 Mutation Test - P110020[2]	Molecular Assay	08/17/11
Propel - P100044[3]	Sinus Implant	08/11/11
RX Herculink Elite Renal Stent System - P110001[4]	Renal Stent	07/20/11
VITROS® Immunodiagnostic Products Anti-HBe Reagent Pack, Calibrator and Controls - P100001[5]	HBV test	07/20/11
Elecsys® Anti-HBc Immunoassay and Elecsys® PreciControl Anti-HBc on the Elecsys® 2010 Immunoassay Analyzer – P100032[6]	HBV test	06/27/11
Elecsys® Anti-HBc Immunoassay and Elecsys® PreciControl Anti-HBc for use on the E170 MODULAR ANALYTICS - P100031[7]	HBV test	06/22/11
INFORM HER2 Dual ISH DNA Probe Cocktail – P100027[8]	DNA Probe Cocktail	06/14/11
Pinnacle® CoMplete® Acetabular Hip System - P090002[9]	Hip Replacement	06/13/11
Solesta® - P100014[10]	Fecal Incontinence	05/27/11
XIENCE nano™ Everolimus Eluting Coronary Stent System - P070015/S054[11]	Stents	05/24/11
EXOSEAL Vascular Closure Device - P100013[12]	Vascular Plug	05/19/11
Abbott RealTime HCV – P100017[13]	Hepatitis C	05/17/11
VITROS® Immunodiagnostic Products HBeAg Reagent Pack, Calibrator and Controls - P090028[14]	HBV test	05/11/11
RX Acculink Carotid Stent System - P040012/S034[15]	Stents	05/06/11

AcrySof® Toric Intraocular Lens - (IOL) - P930014/S045[16]	Intraocular Lens	05/03/11
ION™ Paclitaxel-Eluting Coronary Stent System - P100023[17]	Stents	04/22/11
St. Jude Medical® Trifecta™ Valve – P100029[18]	Heart Valve	04/20/11
cobas HPV Test – P100020[19]	HPV test	04/19/11
NovoTTF-100A System - P100034[20]	Tumor Treatment	04/08/11
Pipeline™ Embolization Device - P100018[21]	Aneurysms	04/06/11
cPAX Aneurysm Treatment System - H100002[22]	Aneurysms	04/01/11
Valiant® Thoracic Stent Graft with the Captiva Delivery System - P100040[23]	Aneurysms	04/01/11
MEL 80™ Excimer Laser System - P060004/S001[24]	LASIK	03/28/11
Gel-One® - P080020[25]	Osteoarthritis	03/22/11
Medtronic® InterStim® Therapy System - P080025[26]	Incontinence	03/14/11
Elana Surgical KitHUD - H080005[27]	Neurosurgery	03/10/11
OraQuick HCV Rapid Antibody Test - P080027/S001[28]	Hepatitis C	02/18/11
LAP-BAND® Adjustable Gastric Banding System - P000008/S017[29]	Gastric Band	02/16/11
Selenia Dimensions 3D System - P080003[30]	Mammography	02/11/11
Revo MRI SureScan Pacing System - P090013[31]	Pacing	02/08/11
Formula Balloon-Expandable Renal Stent System - P100028[32]	Stents	01/14/11

Appendix 2

List of Interviewees and their Positions

	Interviewees' Positions	Company- Specialty
1	CEO	Johnson&Johnson (Cordis)
2	Franchise manager	Johnson&Johnson (Cordis)
3	Technology manager	Johnson&Johnson (Cordis)
4	Sales manager	Johnson&Johnson (Cordis)
5	Marketing manager	Johnson&Johnson (Cordis)
6	Sales manager	Johnson&Johnson (Cordis)
7	Business Strategist	Johnson&Johnson (Cordis)
8	CEO	Abbott Laboratories
9	Sales manager	Abbott Laboratories
10	Franchise manager	Abbott Laboratories
11	Technology Officer	Abbott Laboratories
12	Marketing manager	Abbott Laboratories
13	Marketing manager	Abbott Laboratories
14	CEO	Boston Scientific
15	Marketing manager	Boston Scientific
16	Marketing Strategist	Boston Scientific
17	Sales manager	Boston Scientific
18	Sales manager	Boston Scientific
19	Franchise manager	Boston Scientific
20	Technology officer	Boston Scientific
21	CEO	Medtronic.Co
22	Sales manager	Medtronic.Co
23	Franchise manger	Medtronic.Co
24	Technology manager	Medtronic.Co
25	Marketing manager	Medtronic.Co
26	Marketing manger	Medtronic.Co
27	Dr.Iraj Nazeri	Chief Interventionist- Cardio surgeon
28	Dr. Hushang Kazemi-Saleh	Chief Interventionist- Cardio surgeon
29	Dr.RezaAbdi	Chief Interventionist- Cardio surgeon
30	Dr.Farrokh Moradi	Chief Interventionist- Cardio surgeon

List of Selected Cad-Labs and Cardio-Centres	
1	Army(502)
2	Afshar Yazd
3	Azar Nabz
4	Aliyebneh-abitleb
5	Atieh
6	Bahman
7	Beasat-niro havaei
8	BoAli
9	Dalta-ariya
10	Day
11	Esfehan-sepahan
12	Erfan
13	Fajr
14	chamran-esfhan
15	Ghamran-the
16	Golsar Rasht
17	Hshmat
18	Imam Hossein
19	Imam Khomeini
20	Imam Khomeini Ahwaz
21	Imam Ali Kermanshah
22	Imam Reza Bandar
23	IranMehr
24	Iranshahr
25	Jamaran
26	Jam
27	Kasra
28	Khatam anbiya
29	Khatam Kosar
30	Kowsar Gorgan
31	Kowsar Shiraz
32	Laleh
33	Madaen
34	mashad
35	Madani Tabriz
36	Mehr
37	Mehr Ahwaz
38	Milad
39	Modarres
40	Moheb
41	Naft the
42	Nimeh shaban
43	Naft Ahwaz

44	Payambaran
45	Pars
46	Sasan
47	Shiraz-kala
48	Sari-fateh
49	Shafa Sari
50	Shahid Modars
51	Shahid Madani
52	Shahid-hashemi
53	Shahid-mohammadi-bandar
54	Shahid-behashti-gom
55	Shahid-Rajae
56	Sepahan-esfehan
57	Sina Esfahan
58	T.H.C
59	Tajikestan
60	T.H.C Karaj
61	Tehranpars
62	Valiasr Ghom
63	rasol akram
64	darokhaneh-shahid rajae
65	delta
66	Valiasr Naja