UKRAINIAN CATHOLIC UNIVERSITY

BACHELOR THESIS

Developing recommendations to increase adoption rate of eronomic scalpels on the US market of surgical instruments

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Declaration of Authorship

I, Sofiia PETSIUKH, declare that this thesis titled, "Developing recommendations to increase adoption rate of eronomic scalpels on the US market of surgical instruments " and the work presented in it are my own. I confirm that:

- This work was done wholly or mainly while in candidature for a research degree at this University.
- Where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated.
- Where I have consulted the published work of others, this is always clearly attributed.
- Where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work.
- I have acknowledged all main sources of help.
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Signed:

Date:

"We fear the future because we are wasting today."

Mother Theresa

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Developing recommendations to increase adoption rate of eronomic scalpels on the US market of surgical instruments

by Sofiia PETSIUKH

Abstract

The history of scalpel usage in medicine goes back to the ancient times. And throughout all that time the scalpel design has not gone through a major improvement process compared to other medical devices. If we look at the pictures of knives that early Egyptians used, they will not differ significantly from what the doctors use today during surgery. Dr. Raymond Dunn, a practicing plastic surgeon at UMass Medical Hospital, saw the room for improvement and created a design of an ergonomic scalpel handle to improve doctors' experience. However, the market of surgical scalpels already has a number of approved and tested by time products, so entering it will be a challenge. In this bachelor thesis, I will look at important aspects of the scalpels market in the US and develop recommendations to increase the adoption rate of ergonomic scalpels designed by Dr. Dunn. To achieve this I use Business Analysis techniques and apply the Axiomatic Design methodology to design the steps for a successful market entry. The results of my work state that in order to increase adoption rate of scalpels it is necessary to conduct further testing with the current prototype, collect enough data to understand the interest of the market. If needed, the design should be augmented to better fit customer needs. It is also important to find product champions, who would advocate for the advantages of the product in front of VACs.

Keywords: *business analysis, axiomatic design, ergonomic scalpel.*

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List of Abbreviations

AD	**A**xiomatic **D**esign
CA	**C**ustomer **A**ttribute
DP	**D**esign **P**arameter
FDA	**F**ood and **D**rug **A**dministration
FR	**F**unctional **R**equirement
MQP	**M**ajor **Q**ualifying **P**roject
PV	**P**rocess**V**ariable
VAC	**V**alue **A**nalsis **C**ommittee
WPI	**W**orcester**P**olytechnic **I**nstitute

For all those who fight for our lives…

Chapter 1

Introduction

The topic of this bachelor thesis is - Developing recommendations to increase the adoption rate of ergonomic scalpels on the US market of surgical instruments. The ergonomic scalpel project was introduced to me by my supervisor, PhD Walter TOWNER, who has worked on the project with other students at Worcester Polytechnic Institute. The students' projects are mostly concentrated on the manufacturing aspect of the problem and also touch on the commercialization area. In my bachelor thesis, I decided to concentrate on the problem of entering the market of surgical instruments and develop recommendations to increase adoption rate of the scalpel by analyzing the market using business analysis techniques and axiomatic design methodology.

The work in this bachelor thesis is organized in the following way: Chapter 1 is about the motivation behind the paper and its goal. Chapter 2 aims to give background information about the scalpels market and Dr. Dunn's design of the ergonomic scalpel handle. Chapter 3 describes methods used for analysis in this bachelor thesis. Chapter 4 provides a review of works related to the topic of ergonomic scalpel design and axiomatic design. Chapter 5 contains the analysis part of the paper, including stakeholder analysis and axiomaic design decomposition. Chapter 6 in the final chapter, which aims to provide summary of the completed work and contains developed recommendations.

1.1 Motivation

As mentioned in the Abstract, currently used scalpels' designs are outdated and haven't been significantly updated for a long time. The overall medical instruments market is constantly developing and moving more onto the side of new technology. We hear more and more about robotic surgery. However, common surgical instruments, scalpels included, will not be fully eliminated from the market any time soon. Dr. Raymond Dunn, a practicing plastic surgeon at UMass Memorial Medical Center, created and patented the design of a new ergonomic scalpel handle to help surgeons with their performance, increase comfort during operations and improve the outcome of the operations. The US Food and Drug Administration has stated in the past that out of all people, who die from medical errors in hospitals, there is a part of fatalities, which happened because of human errors involving medical equipment or systems (R. Stone, 2004). This means that more attention should be given to design of equipment used in the operating room. The details of Dr. Dunn's scalpel design will be discussed in further chapters of this bachelor thesis. The motivation of the initiator of the project is understandable, my personal motivation for doing this project is to provide an analysis of how the surgical instrument market in the US works, and develop recommendations on how the new product can successfully enter the market. An additional motivation behind this work is to learn how to correctly apply axiomatic design methodology.

1.2 Goal

The goal of my analysis is to give recommendations that will help increase the adoption rate of the new ergonomic scalpel handle on the market. I will analyze what the current circumstances of the market and develop steps that can be done to increase the adoption rate.

Chapter 2

Background

2.1 Scalpels' design history overview

A surgical scalpel is a sharp-bladed instrument used every day by thousands of surgeons all around the world. For the purposes of this bachelor thesis, I have interviewed Dr. Raymond Dunn, who told me more about currently used scalpels and I have reviewed a number of publications online to learn about this instrument.

From the words of Dr. Dunn, a scalpel is the most common surgical instrument, but it has not undergone any major design updates for a long time. One of the reasons for this is that the operating room is a very physically demanding space. Instruments that are not discarded or disposable, have to be sterilized repeatedly, which is standardly done by hot steam. The sterilization process has put a strict requirement on the materials that can be used to manufacture instruments, which are used in the operating room because not all materials can tolerate the heat that is used for sterilization. So the vast majority of the instruments used today are made of solid stainless steel. The use of this material in manufacturing has led to a standard of making the design of these instruments relatively simple in order to balance the weight of the instrument and lower the cost. By making the scalpel design simple, in result it has become not necessarily convenient to use in terms of hand movements, which can lead to surgeon's fatigue and negative outcomes of surgeries. In the last 20 years there has been a significant shift from traditional surgery, where medium to large incisions had to be made to operate patients, to minimally invasive surgery, the most common example of which is Laparoscopy. These types of surgery are a lot faster, since the small incisions do not require to spend a lot of time on sutures. Moreover, the patients' recovery process after the procedure is also much quicker. The evolution of laparoscopic surgery required the development of a completely different set of tools, which included the use of new materials. As a result, new OR compatible plastic materials started to be more and more used in manufacturing of surgical tools. This opened a new opportunity to improve the existing designs of surgical tools by taking into account ability to use new materials.

Today on the market there are different types of scalpels: single-use, disposable and re-usable scalpels. Each scalpel itself consists from two parts: the blade and

the handle. Handles of disposable scalpels are usually made from plastic, while reusable handles are usually made from stainless steel or titanium materials ("Scalpel Handles" 2020).

There are standard types of scalpels used in surgery today. The most commonly used handle is 3 (see Figure 1), which is compatible with different types of blades, for example the most commonly used blade 10 or 15.

FIGURE 2.1: Scalpel 3

2.2 Scalpel market in the US

Since no data regarding the market of surgical blades was available for free, the statistics stated in this chapter are taken out of a sample report (industryresearch.biz, 2022), where not all data was open for view.

A lot of scalpels on the market consist of two parts: handle and blade. The proportion of blades on the market in 2021 was about 37%, while the proportion of scalpel handles was 23%. The rest of the market, meaning 40%, is related to other types of products on the scalpels market, which was not disclosed in the report.

Scalpels are used in hospitals, clinics, and other places/medical institutions. The proportion of scalpels used in hospitals was 51% in 2021, and in clinics - 12% (industryresearch.biz, 2022).

Based on the report, there are such top players in the manufacturing and distribution of scalpels industry in 2021: Hill-Rom, Swann-Morton, Huaiyin Medical, KAI Group, Feather, SteriLance, Mani, Surgical Specialties.

The surgical blades and scalpel market is considered to be a growing market, which is expected to grow at a CAGR of roughly 7.2% over the next five years, will reach 530 million USD in 2024, from 350 million USD in 2019 (industryresearch.biz, 2022).

The available market data shows promising results about the future of the market. As a result, it can be said that entering this market with a new product that is in demand would be a good idea. Moreover, this data gives us an idea about who are our customers and competitors.

2.3 Dr. Dunn's ergonomic scalpel handle design

Dr. Raymond Dunn is a practicing plastic surgeon in UMass Memorial Medical Center, who has been a chairman of pastic surgery since 1998 up until recently. Dr. Dunn is board certified in plastic and reconstructive surgery, as well as hand surgery and plastic surgery within head and neck.

Apart from practicing surgery, after recognizing the drawbacks of currently used surgical scalpels, Dr. Dunn has decided to go into the innovation field and started a startup company called 5G Medical, which now holds several patents for surgical tools. One of which is the topic of this bachelor thesis - ergonomic scalpel handle. This handle is supposed to provide adequate grip so that the scalpel is not too slippery when bodily fluids come into contact with it. The round shape of of the handle is aimed to provide ease and comfort of holding, while also minimising fatigue. I allows to make circular incisions more easily, which is specifically helpful in plastic surgery. Currently the status of the product can be specified as "In testing". Dr. Dunn is working with a German company KLS Martin to produce enough prototypes for testing. The prototypes are manufactured from stainless steel and are reusable. This results in a high price for such tool. That is why in parallel Dr. Dunn's team is trying to find ways to manufacture a disposable version of the scalpel, which would be much cheaper. The design of the stainless steel scalpel prototype can be seen on the figure below:

FIGURE 2.2: Dr. Dunn's Ergonomic Scalpel

Chapter 3

Overview of used methods

3.1 Axiomatic design

In order to provide good recommendations on increasing adoption rate of Dr. Dunn's ergonomic scalpels, it is important to understand what steps will be taken in the process of introducing the product to the market and how they are related to each other. Axiomatic design can serve as a great method for decomposing a problem into smaller tasks in the form of requirements by applying predefined axioms to them.That is why it was decided to use this methodology for the purposes of the bachelor thesis.

The methodology of axiomatic design was developed by Dr. Nam Pyo Suh in 1990. It is mostly applied to designing complex manufacturing or software systems, but Suh states in his work that this methodology can also be applied to various business problems (Suh, 2001).

The AD approach gets its name from the usage of two design axioms. However, prior to explaining the usage of axioms, it is necessary to understand the concept of four domains that lie in the basis of AD.

Suh states that the design world consists of four domains (Suh, 2001):
1. Customer domain
2. Functional domain
3. Physical domain
4. Process domain

In the customer domain, elements are customer needs (or attributes - CAs). They capture what the customer wants and what adds value to the final result. CAs usually relate to the highest level functional requirements. The customer needs desired in a product are sometimes difficult to define. Nevertheless, they are irreplaceable, so to obtain them we need to ask the right questions to the right customers at the right time.

In the functional domain customer needs are specified in terms of functional requirements (FRs) and constraints (Cs). The functional domain contains answers to "What needs to be achieved?". This domain satisfies customer needs, establishes design intent and initializes the design solution. The formulation of each functional

requirement begins with a verb, stated in the imperative (e.g., provide adequate friction (FR) could satisfy the CA the product can't be slippery). Good formulation of the FRs is critical for a good design: FRs communicate the objective and intent, FRs define the problem to be solved, FRs are the foundation for solution, and correct formulation of FRs is one of the most important steps in design.

The physical domain answers the question "How can it be achieved?", with the design parameters (DPs). This domain fulfills the FRs: each DP is selected to fulfill one FR. Ideally, that would be the only FR it influences, for the best compliance with Axiom one (maintaining independence).

Finally, the process domain contains process variables (PVs), answering the question "How to produce the elements in the physical domain?".

As you can see in Figure below, each domain is mapped onto another. However, both during the mapping process and the formulation of entries it is important to make the right decisions using the two axioms used in AD.

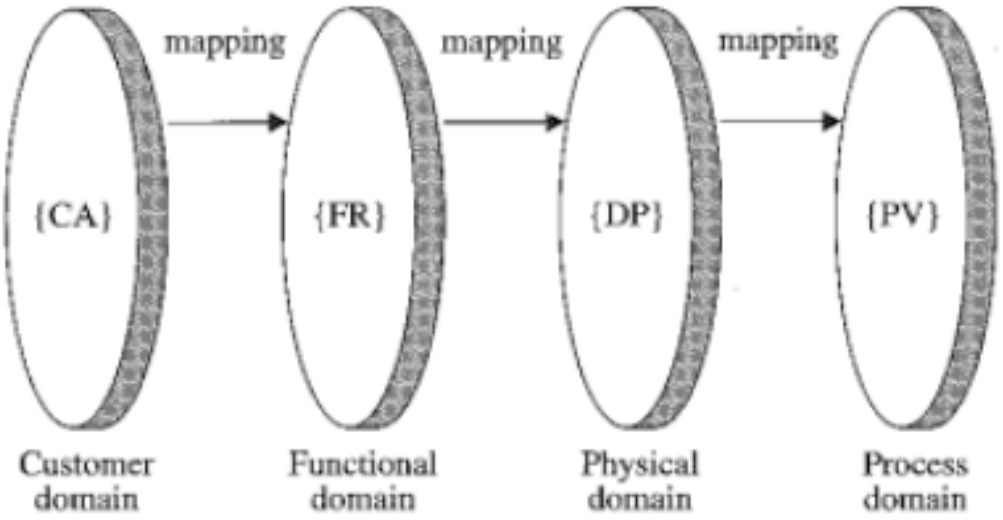


FIGURE 3.1: Relationships between 4 domains

AD theory states that the best design solutions can be selected using such two axioms (Suh 2001):
1. The Independence Axiom: "Maintain the independence of the functional requirements (FRs)";
2. The Information Axiom: "Minimize the information content of the design."

The mapping process between the domains can be expressed mathematically in terms of the characteristics vectors that define the design goals and design solutions. Let's look at the relationship between the functional and physical domains. The set of FRs constitutes the FR vector and the set of DPs constitutes the DP vector. As a result, the relationship between two domains can be written as: FR = [A]DP Where [A] is called a design matrix that characterizes the product design.

In general, each FR can be expressed as:

$$FR_i = \sum_{i=l}^{n} A_{ij} DP_j$$

In order to make sure that the 1st Axiom is satisfied, the design matrix should be diagonal, lower-triangular, or upper-triangular. If the matrix is diagonal, the design is called uncoupled where each of the FRs can be satisfied independently by means of one DP. If the matrix is triangular, the design is called decoupled and the independence between the FRs can be guaranteed only if they were stated in the correct order. Any other version of the design matrix results in coupled design.

For the purposes of this bachelor thesis, I will focus on the construction of FRs and DPs and the resulting design matrix. This will be enough to understand the steps for entering the market with a new product.

3.2 Business analysis techniques overview

Several business analysis techniques were used for this bachelor thesis, including stakeholder analysis, document analysis and interviews. This part aims to describe the overview of the techniques based on the information obtained from Business Analysis Book of Knowledge (IIBA, 2015).

Stakeholder analysis includes identifying the parties involved in and affected by a proposed initiative. It also includes recognizing stakeholders, who can affect the outcome of a proposed change, for example, regulators. While analyzing each stakeholder it is important to define their level of power or influence in the domain, interest in the initiative, decision-making authority, their needs and how the change affects them. This technique was chosen because, in order to identify aspects that can increase the adoption rate of the ergonomic scalpels on the market, it is crucial to understand whose and what needs should be fulfilled by Dr. Dunn's product.

In order to collect the necessary data both for the stakeholder analysis and for the axiomatic design decomposition, document analysis was used and several interviews were conducted. The purpose of document analysis is to elicit business analysis information by examining available materials about the business environment. This technique was used to gather background information in order to understand the business need behind the new ergonomic scalpel (see Chapter 2. Background). It also helped to research existing solutions in the field of ergonomic scalpels and the application of axiomatic design methodology (see Chapter 4. Related works).

Interviews with industry professionals were conducted in order to obtain relevant information about the needs of the market. According to BABoK (IIBA, 2015), there are two types of interviews: structured (with a list of predefined questions) and unstructured (without a predetermined format or order of questions). For the interviews conducted in the scope of working on this bachelor thesis, a combination

of two types was applied. A predefined list of questions was sent to the interviewees prior to the meeting, which allowed interviewees to prepare well-structured answers. However, as the conversation was going additional questions were also asked. A list of predefined questions can be reviewed in the appendices of this bachelor thesis.

Chapter 4

Related works

The topic of putting out Dr. Dunn's scalpel handle design onto the market of surgical tools has been reviewed from different angles by students from Worcester Polytechnic Institute (WPI). The goal of this chapter is to give an analysis of what has already been done and how my work complements and differs from their analysis. The topic of applying axiomatic design methodology is also reviewed in this chapter to show how others used it.

4.1 Review of Major Qualifying Projects from WPI

Throughout the previous years, there have been several groups of students from WPI, who presented their major qualifying projects on the topic of ergonomic scalpel handle design.

In 2014, a group of students from WPI worked on MQP "The Commercialization of an Ergonomic Scalpel" (Mukhanov E., 2014). In order to provide recommendations, the team evaluated four areas: the medical device market, manufacturing, consumer research and intellectual property. An important part of this work was analyzing the strength and uniqueness of Dr. Dunn's patent for the ergonomic scalpel handle design. The first attempt to patent the design was rejected due to lack of uniqueness, which means that there are similar ideas already patented. This allows us to make an assumption that it will be hard to stand out on the market, which must be taken into account when choosing a marketing strategy for this product. The next filing of the patent was approved by the same examiner, who initially rejected it, which was pointed out as a good sign. As a result, with the help of a professional analysis by two patent attorneys, the patent was found to be of "medium" to "mediocre" strength. This result means the the patent does not provide too much room for movement in the industry. The team also facilitated focus groups in order to understand the moods of practicing surgeons regarding currently used scalpels and the new scalpel design. The participants did not find any major drawbacks in the standard scalpels and shared that it could be hard to switch to a newer design because of habit and muscle memory. They also pointed out that the only major plus of the ergonomic scalpel was ability to perform curved incisions more easily. In result, the participants stated that there would be no use in switching to a new instrument,

unless it "had all the benefits of the traditional scalpel as well as all the benefits of the prototype". After their analysis,the team concluded that the scalpel "would not be viable for commercialization as a stand-alone product", which is understandable as all the signs show that it would be hard to survive on the surgical instruments market. However, since the analysis was done 8 years ago, this bachelor thesis aims to review some of the claims that have been made in "The Commercialization of an Ergonomic Scalpel" project.

In 2020, two projects related to the ergonomic scalpel handle were submitted: "Designing of Ergonomic Scalpel Handles with Optimized Weight and Balance" (Paul W., 2020) and "Design of Improved Surgical Scalpel Handles with Optimized Grips" (Rueda R., 2020). The first project focused on developing a set of prototypes with an optimized balance and weight to test how surgeons would respond to the proposed changes in the scalpel design. Balance and weight of the instrument are major factors for surgeons. A scalpel, which is too light can result in a deeper than needed incision because there may be an imbalance between the surgeon's force and the weight of the tool. A heavy scalpel can result in doctor's fatigue. Same with balance - depending on where the centre of gravity is, the surgeon will have a different experience in using the instrument. While it is good to know that these nuances were included in the design of Dr. Dunn's ergonomic scalpel, it brings out a question of whether or not surgeon's will be willing to switch and take time to adjust to a new product if their muscle memory has already encoded the experience of current scalpels and their physical capabilities. After conducting a series of usability tests, the team proposed their final design in a form of a stainless steel scalpel handle that weighs 50 grams. According to their research, the initial stainless steel version with weight 109 grams was too heavy for testers, while the plastic version with weight 20 was too light.

"Design of Improved Surgical Scalpel Handles with Optimized Grips" (Rueda R., 2020) focused on designing the right grip for the scalpel to improve surgeon's experience with rotational motions and reduce slipping of the instrument to the minimum. This factor is in no way less important than weight and balance. For the sake of doctors' and patients' safety, it is crucial for the surgical instrument to have enough grip when it comes in contact with bodily fluids. The team solely focused on describing different manufacturing processes in detail and comparing the materials which can be used for the scalpel handle. They proposed to use stainless steel material for the reusable version of the scalpel and TPE (Thermoplastic Elastomer) for the disposable version. As for the grip part, it was decided to use a replaceable "pencil grip" design.

The latest work on this topic has been presented last year in April under a name "Product Launch Analysis for an Ergonomic Scalpel Handle" (Audrey Berner, 2021). The objective of this project was to develop production and marketing recommendations to bring the ergonomic scalpel to market. In the scope of this MQP, the students

identified three potential manufacturing methods, such as machining, additive manufacturing and injection molding. For each method they developed cost structures, based on which the injection molding technique was the recommended option. As of now, Dr. Dunn's team is working on the idea to manufacture a disposable version of the ergonomic scalpel handle using the proposed injection molding technique. Another part of deliverables was introduction of the idea to enter the market of medical devices' accessories. The team worked on the prototype of a scalpel sleeve, which can be attached to standard scalpels in order to create a feel of an ergonomic scalpel handle. However, this option would need a separate conduction of analysis with more focus on the current options on the accessory market, as well as the sterilization process of the tool. The team also focused on overall market analysis and what would be needed to launch the product successfully, including review of FDA approval process. All MQPs have been a valuable source of information for this bachelor thesis. Most importantly, they show the timeline of scalpel handle design improvement, review details of manufacturing process. While the projects touch on the topic of how to market the ergonomic scalpel handle and have been a good basis of information for this bachelor thesis, the teams were more focused on the production part and the design of the handle itself. In this bachelor thesis, I aim to complement and update their market research, focus more on the needs of end users and look into the steps of entering the market.

4.2 Application of axiomatic design

The standard application of axiomatic design is perfectly represented in the 2021 MQP (Audrey Berner, 2021), where the team used this methodology to illustrate the scalpel production process and evaluate potential process options. Axiomatic Design is a good way to evaluate whether the created production plan is viable or something should be changed. The team defined a set of functional requirements needed to achieve successful scalpel production with the main requirement being: "FR0: Prepare ergonomic scalpel handle for production". After that a set of design parameters was composed to satisfy each requirement. For example, to satisfy "FR1.2: Select appropriate materials", a design parameter "DP1.2: Stainless steel" was specified by the team, which means that they decided to use stainless steel for manufacturing. The next important part was creating a design matrix to see how the FRs relate to DPs. Based on the matrix outcome, the design proved to be mostly uncoupled, which means that most of the design could be manipulated without impacting multiple FRs. However, one section of FRs was coupled. This meant that "manufacturing method to be designed was impacted by the CAD model and material design choices made to validate the scalpel design".

Application of AD methodology helped the team to assess relationships between FRs and DPs, make sure that the project's outcome fulfilled requirements, prioritize specific project decisions and finalize the project's scope.

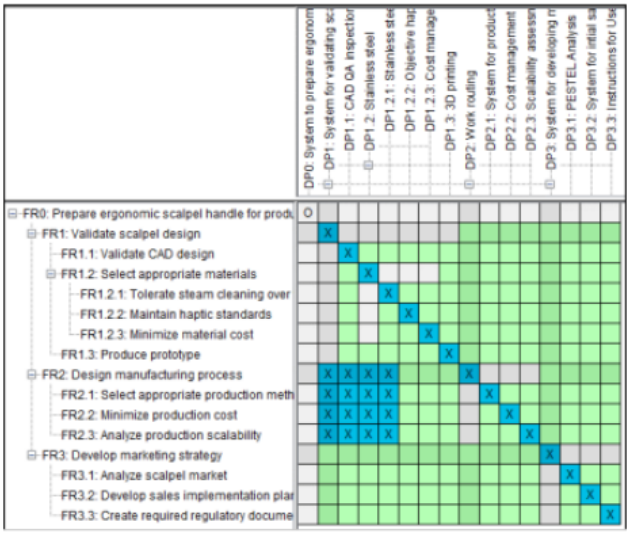


FIGURE 4.1: Design Matrix

The team used Acclaro software to work with and visualize the results of decomposing their problem. For the purposes of this bachelor thesis, I have used regular Excel spreadsheets to work with my FRs and DPs, since the Acclaro software requires purchase. I have tried to download and use free software, which was developed for the same purposes, but it did not work properly, so it was decided to work in Excel.

Each year an International Conference on Axiomatic Design (ICAD) is held, where participants can submit their works related to AD. Their website provides a list of papers presented on the conference in the previous years. Most of the publications also describe the application of AD in the manufacturing field. However, in the list of submissions from ICAD 2016 I have found a paper that in my opinion coincides the most with the application of AD in this bachelor thesis. "Application of Axiomatic Design for Project-Based Learning Methodology" (Gabriele Arcidiacono, 2016) shows how axiomatic design can be used not only to design a manufacturing or software system, but also to design and improve a process. As stated in the paper: "Axiomatic Design can contribute to improve the outcomes opportunities and the process efficiency by identifying where complexity exists within the requirements and design activities that underpin the model". The authors define the Project-Based Learning process requirements and analyze their relationships with the design parameters from the "current state" point of view. After that, the design parameters are optimized in order to make the design matrix diagonal and at least partially uncoupled. In result, the number of independent FRs is higher and the authors state that even further optimization can be performed to make the design fully uncoupled. In this bachelor thesis, I want to present the process of putting out the ergonomic scalpel on the market, which relates more to this example of AD application than to other applications in the manufacturing field.

Chapter 5

Main part

5.1 Stakeholder Analysis

Prior to putting out a new surgical tool on the market, it is necessary to define the main stakeholders - parties, who are related to, will have an influence on, and will be affected by the new product. After identifying the stakeholders, it is important to define their needs and describe any information that can influence the successful adoption of the new ergonomic scalpel. I have identified such major players that can influence the adoption rate of ergonomic scalpel: surgeons, value analysis committees, purchasing departments in hospitals and clinics, Food and Drug Administration, patients, manufacturers and competitors.

5.1.1 Surgeons

Surgeons are at the top of the list if we look at the importance of stakeholders. They are going to be the ones who use the scalpel and whose work experience should improve after the adoption of this scalpel. They have some level of authority in the adoption process since they can be the ones, who ask to specifically use the ergonomic scalpels. This means that a large focus of marketing resources should be pointed in the direction of surgeons.

If we talk about the surgeons' needs related to the scalpel, the most important aspects, mentioned by Dr. Dunn during our interview, are grip, weight, and balance of the scalpel. These three points sum up to making a good quality scalpel. The scalpel handle has to be comfortable for holding and rotating to easily make both straight, curved, and circular incisions. And most importantly, it has to outstand the performance of currently used scalpels. Without this factor, most surgeons can say that there is no use in spending the time to adjust to a new design if the standard scalpel performs the same.

To better understand how surgeons feel about currently used scalpels and what do they think about Dr. Dunn's design, I wanted to reach out to doctors who have already tried and tested the latest stainless steel prototype and ask about their experience. Unfortunately, it was not possible to receive contacts of testers, so instead, I asked for a professional opinion from a Ukrainian surgeon, who agreed to fill out a short questionnaire. He has worked as a surgeon for almost 5 years and is currently

practicing trauma surgery in St. Lucas Hospital, Lviv. The questionnaire focused on his experience with currently used scalpels and his opinion about ergonomic scalpel design. The photo of the latest stainless steel scalpel handle prototype was provided in the questionnaire.

The surgeon is most commonly using disposable scalpels. For planned operations a reusable scalpel is used. Photos of the scalpels used by recipient can be reviewed in Appendix D. The surgeon outlined that the advantage of the currently used scalpel is its accessibility (easy to buy in bigger quantities) and ability to fit different types of blades to the handle. The drawbacks were about the part were the blade is attached, in currently used scalpels the blade can sometimes move because it is not properly attached, which causes complications during surgeries. Another drawback is that the handles are usually too small for a person with big hands, such as his.

When asked about what he would improve in currently used scalpels, he mentioned that ergonomics would be the most important part: he would add curves to the handle for a more comfortable holding position. And he mentioned that gripping material is also important.

Even though the surgeon is interested in changing the current scalpel and knows that the design can be improved with ergonomic features, he did not like the proposed prototype as much. The surgeon outlined only one positive thing about the ergonomic scalpel - the round shape would make it easier to maneuver the scalpel. As for the drawbacks of the scalpel, he said that the handle was too thick, which would make it inconvenient to use the scalpel in deep wounds, and it looked to him like the scalpel length was too short for people with large hands and long fingers. Another drawback was that the grip material was covering only a small part of the scalpel. When asked about what he would change, the surgeon proposed to cover the whole scalpel handle with the gripping material.

I also asked whether he was interested in overall innovations in the surgical tools field, to which the answer was yes and three most used channels to get information about innovations were outlined by him:
- Colleagues at work
- Medical publications
- Product presentations on medical conferences

The options of social media platforms were not chosen as a used channel. This can be a valuable piece of information when choosing how and where to present the scalpel to end-users.

5.1.2 Value Analysis Committee (VAC)

The Value Analysis Committee is a group of professionals, who are responsible for deciding whether the new product brings enough value to the table and whether it is worth it to switch to a new design and manufacturer of the surgical tool. To better understand the process I had pleasure to interview Edward Browne, who was the

chairman of the Value Analysis Steering Committee at Cambridge Health Alliance (CHA). The aim of this interview was to learn how this structure works and understand what would it take for the committee to approve a purchase of ergonomic scalpels.

The Value Analysis Committee can be structured in different ways, Mr. Browne shared what the committee looked like in CHA. The initial version of the committee was very narrow. Only people from purchasing and materials management departments were involved in the process, which made it not effective, more cost-oriented, thus the committee structure in CHA was updated several years ago.

At the top of the hierarchy they set up a steering committee, which can consist of a senior administrator, nursing and physicians representatives, quality representatives and representatives from epidemiology or infection control. This ensured higher quality of the evaluation process and showed that the decision making group covered different points of view. Beneath the steering committee various more specialized multidisciplinary sub-groups were set up. For instance, the facilities representatives group, the nursery and IT groups, etc. The surgery representatives also had their own value analysis sub-group to review surgical equipment and everything that is used in the OR.

Anyone from the hospital can suggest or ask for a product to be reviewed. When the suggestion is submitted, the steering committee first analyzes whether it is worth pursuing the proposal. The steering committee usually has a financial range. For instance, if a requested product is below a certain financial value, it is not worth to spend the the committee's time on it, so the product is usually transferred right to the purchasing department. If the product is proved to be viable for analysis, they assign a specific sub-group, which specializes in the suggested product, to conduct a thorough investigation of the product.

The points, which the VAC focuses on the most are:
- Patients outcome
- Hospital benefits
- Costs
- Transition process

It is important to understand that this is the improved process, which was used in CHA. Other hospitals or hospital groups can have more cost-oriented or stanadrtization-oriented VACs. To see all possible levels at which VAC can operate, please review Appendix C. However, Mr. Browne mentioned that more and more hospitals are trying to be more flexible and focus on the patients more, so it is possible that improved versions of VACs are becoming more popular.

5.1.3 Purchasing department of hospital or clinic

Hospitals and clinics, in the face of their purchasing departments, who are responsible for buying supplies, are a part of the stakeholders list. They are the ones, who

will interact with the supplier of 5G Medical scalpel directly or indirectly. It is also important to mention that many hospitals tend to become members of large purchasing organizations, who can order hospital supplies in bulk for cheaper prices and cell them to hospitals. An example of such organization is Premier. If a hospital is a member of such an organization, it means that the hospital can purchase their supplies for cheaper prices. If the ergonomic scalpel would be sold to such organization, the purchasing department would not interact directly with the supplier.

5.1.4 Food and Drug Administration (FDA)

FDA plays the role of a regulator of the US market of medical devices. The administration makes sure that all devices on the market are safe both for the patients and the end-users, who in our case are surgeons. Prior to entering the market with a new surgical tool, the product should undergo the process of FDA approval. All devices have to obey the primary criteria of "do no harm". But it is also important to understand that sometimes to achieve a clinical goal, some harm is inevitable. That is why FDA classifies all medical devices in terms of risk. They try to answer the question "Is the risk from this medical device acceptable compared to the harm its usage can create?" For example, let us look at the surgical scalpel. What is bigger harm: making an incision on a patient's skin or not doing the operation. To balance between risk and doing no harm, FDA has identified three classes of medical devices. The higher the class, the bigger the chance that the device could do some harm (Peter, 2020). A surgical scalpel is classified as a Class I product and is exempt from premarket application 510(k). However, it still has to comply with general regulatory controls specified by FDA, such as labeling requirements, for instance.

5.1.5 Manufacturer

Manufacturer influences the adoption rate of ergonomic scalpels through the quality they provide to end-users. It is important to choose a good and reliable manufacturer who in the end provides a product of good quality. For manufacturing the stainless steel prototypes Dr. Dunn chose to work with a German manufacturing company called KLS Martin, which specializes in the manufacturing of surgical supplies and overall innovation in the surgical industry. During our interview, Dr. Dunn pointed out that the company is interested in taking on the manufacturing of the stainless steel ergonomic scalpel, which is a good sign.

5.1.6 Competitors

Competitors are those who indirectly influence the success of the ergonomic scalpel on the market. During the interview with Edward Browne, he mentioned that the VAC will look at how the proposed scalpel differs from other players on the market, so it is important to understand if Dr. Dunn's scalpel handle stands out.

One of the MQPs, mentioned in Chapter 4. Related Works, reviewed other patents for ergonomic scalpels, which means that there are similar products in the progress of entering the market. However, it is also interesting to look at the current already existing products, which are marketed to be ergonomic and compare their designs to Dr. Dunn's.

The major players on the market that are mentioned in Chapter 2.2 are automatically our competitors. And I found that one of them has a proposed ergonomic scalpel handle position. It is the most common search result - Swann-Mortons's ergonomic sleeved scalpel handle, which is "designed to maximise performance and dexterity and feature a textured surface finish for ease and comfort of grip whilst minimising fatigue" (Scalpels and Blades, n.d.). While the goal of the product is very similar to Dr. Dunn's, it was interesting to see that this scalpel is marketed toward Histology, Pathology, Autopsy, and Laboratory settings. This can be a good guideline for finding demand in the broad surgical field. The price of the scalpel handle is $12.13.

FIGURE 5.1: Swann-Morton Ergonomic Scalpel

The next option is ergonomic plastic scalpel handle by Cancer Dianostics, Inc. Not much information was provided for this option, but from the photo we can see that the shape of the handle is pretty similar to Swann-Morton's product. The design of Dr. Dunn's scalpel handle differs from the options I have reviewed.

FIGURE 5.2: Ergonomic plastic scalpel handle by Cancer Dianostics, Inc.

5.2 Decomposing the goal using axiomatic design

To illustrate the process of entering a market of surgical instruments and see the relationships between the initial requirements of the process and the design outcome, it was decided to use axiomatic design, which is described in detail in Chapter 3. By the rules of AD, an initial FR_0 should be chosen and all other requirements will be set as children to this FR. For this bachelor thesis it was decided to go with the next statement of FR_0: Facilitate widespread adoption of a new disposable ergonomic

scalpel for surgical applications. The next requirements are elicited from the stakeholder and document analysis performed in earlier chapters. It was decided to take the current state of the project and describe the next steps, which should be done.

FR_0	Facilitate widespread adoption of a new disposable ergonomic scalpel for surgical applications.	DP_0	System to facilitate widespread adoption of a new disposable ergonomic scalpel for surgical applications.
FR_1	Manufacture enough of the pilot ergonomic scalpels for testing	DP_1	KLS Martin manufacturing system
FR_2	Conduct testing of the pilot eronomic scalpel usability	DP_2	Testing plan
FR_2.1	Find surgeons for testing (testers)	DP_2.1	List of testers
FR_2.2	Provide the pilot ergonomic scalpel to testers	DP_2.2	Ditribution plan #1
FR_2.3	Collect feedback from testers	DP_2.3	Survey
FR_2.4	Analyze feedback from testers	DP_2.4	Data Analysis
FR_3	Work to improve the design of the scalpel to ensure it satisfies all user's needs	DP_3	Design review
FR_4	Apply for FDA approval	DP_4	Application letter to FDA
FR_5	Work out a manufacturing process for producing large quantities of disposable scalpels	DP_5	MFG Scale-up plan
FR_6	Design a distibution plan	DP_6	Distribution plan #2
FR_7	Market the product to the customers	DP_7	Marketing plan
FR_8	Ensure hospitals' interest in the product	FR_8	Adoption plan
FR_8.1	Find surgeons-champions for the product	FR_8.1	List of champios for the product
FR_8.2	Apply for VAC approval	FR_8.2	Application form

FIGURE 5.3: FRs and DPs.

	DP_0	DP_1	DP_2	DP_2.1	DP_2.2	DP_2.3	DP_2.4	DP_3	DP_4	DP_5	DP_6	DP_7	DP_8	DP_8.1	DP_8.2
FR_0	X														
FR_1		X													
FR_2		X	X												
FR_2.1				X											
FR_2.2		X		X	X										
FR_2.3				X	X	X									
FR_2.4						X	X								
FR_3							X	X							
FR_4									X						
FR_5										X					
FR_6											X				
FR_7									X			X			
FR_8													X		
FR_8.1														X	
FR_8.2									X						X

FIGURE 5.4: Design Matrix

The resulting design matrix is lower triangular and most of the design is uncoupled, which is good. This means that some of the requirements can be fulfilled independently of others, which is the ideal approach.

However, we can see that there are some nondiagonal relationships between FRs and DPs. The scalpels for testing cannot be provided to testers without manufacturing, hence the relationship between FR2.2 and DP1. And we won't have the people

to whom provide the scalpels, so firstly a list of potential testers should be created, that's why there is a relationship between FR2.2 and DP2.1. The next relationships are also understandable, since we cannot collect feedback without firstly providing the scalpels to testers, and we cannot analyze the feedback without having the feedback. Looks like all the relationships are not critical and only show that the FRs should be satisfied in the correct order, one by one. So, the first and most important thing to do is manufacture the scalpels for testing, and then move onto the next step and the next and so on. The design matrix also shows the importance of filing the scalpel handle for FDA approval since we cannot move into the marketing phase of the product without having it approved by the FDA, same with going through checks of VAC.

Chapter 6

Results and recommendations

After thorough research of the surgical instruments market, analysis of stakeholders, their needs and axiomatic design decomposition of the market entering process, this chapter aims to summarize the results of my research and analysis and provide recommendations on how the adoption rate can be increased.

As a result of interviewing Edward Browne, it occurred that the most important parts of successful adoption are end-user satisfaction and the ability of the scalpel to go through the value analysis committee approval, because without their approval no hospitals will switch to another product.

When we talked about VACs, Mr. Browne mentioned the importance of a product champion in the hospital. He said that when someone from the surgeons is pushing and advocating for the product, the probability of that product being approved for purchase is much higher. So getting someone to submit the product for VAC approval is not enough. It is recommended to find reliable product champions, who will advocate for the ergonomic scalpel throughout the process of its approval.

Reviewing other students' works in Chapter 4. Related works and interviewing Dr. Dunn helped me define that the initial focus of marketing should be pointed toward plastic surgeons, which would most benefit from the ergonomic scalpel handle. Their work needs the most precision during incisions since it will affect scarring. However, after seeing that ergonomic scalpels on the market are currently marketed in Histology, Pathology, Autopsy, and Laboratory settings, I would recommend finding professionals from these fields to test the ergonomic scalpel. If they are satisfied with the product, this may lead to having another field of doctors ready to advocate for the scalpel, thus will increase the adoption rate.

The Ukrainian respondent was a professional in trauma surgery and gave a recommendation to analyze PubMed researches, especially the ones about First Aid cases, when there no time to think about the visual design, the only thing that matters is whether the scalpel is useful or not. This would help in later future, when thinking about new designs, since for initial scalpel introduction I would not recommend the trauma surgeons. They would not care about improvements in rotating the scalpel if someone needs help immediately. This does not mean that they should not be considered for end-users list at all, just that in the beginning of entering the market they would not be viable advocates.

Previous MQPs stated that further testing of the scalpel should be conducted and this has not changed. In the interview, Dr. Dunn mentioned that some surgeons have already tried and tested the ergonomic scalpel handle, their responses were positive, but not documented. For successful adoption, it is necessary to understand what the end-users need and what are the advantages/disadvantages of the product on the market. So the next step would be to conduct proper scientific testing of the scalpel to collect data and statistics on its properties. As proposed in the axiomatic design decomposition, an easy method for collecting data would be a survey.

From the analysis in this bachelor thesis, I would say that for better adoption it would be good to reiterate through the design of the scalpel again. Both previous MQPs and my Ukrainian respondent outlined what drawbacks the current scalpel has. Further testing would give even more information on what to improve in order to stand out on the market.

The ideas for improveent that I have outlined after analysis are the following:
- Add gripping material to the whole handle
- Make different sizes of handles to suite different hands
- Think about adding color coding o the scalpel
- Try making the end of the handle thinner to widen surgeons' vision scope and to make it easier to use for deep wounds

Finally, I defined a set of major factors that impact the adoption rate of the ergonomic scalpel and constructed a table of recommendations for Dr. Dunn, so that the direction in which the product should be moving in the future is clear.

Adoption rate factor	Details	Recommendation
End-user satisfaction	Provide better experience than currently used scalpels	Conduct testing to collect data on whether the scalpel satisfies end-users needs
Patients satisfaction	Affects VAC decision, who checks whether the new product improves the outcome of the procedure for the patient	Conduct testing to collect data on whether the scalpel can improve healing of scars, make the procedure faster, circular incisions more precise, etc.
Hospital, and clinic satisfaction	Focused on low price, convenient options to order products, and patient satisfaction.	- Ensure patient satisfaction factor is fulfilled - Look into supplying for purchasing organizations - Set reasonable price
Product champion	Pushes the product to be reviewed by VAC, recommends to other surgeons, acts as an advocate for the product	- Find surgeons who are willing to be product champions in different hospitals. - Channels: can be suggested to satisfied testers, medical conferences, publications - Start from plastic surgeons

FIGURE 6.1: Recommendations

Appendix A

Questions to Dr. Dunn

1. How did you come to an idea to do this in the first place? Was this only your dissatisfaction with how the current scalpels on the market worked or is this a conversation that goes on in the surgical field commonly? Did you hear other surgeons complain?

2. What are the benefits of the ergonomic scalpel?

3. Does the scalpel consist only of the handle or both the blade and the handle? If separate, are you going to manufacture the blade also?

4. Why is it important for the scalpel handle to be disposable? Is the only drawback of a stainless scalpel in price?

5. How do you think, does new technology influence the market and how do you think it may influence the adoption of this new scalpel?

6. What is the progress on the scalpel project right now? Are there any results already or is it still being tested? What is the progress on manufacturing of disposable scalpels?

7. Are there any doctors who have already tried the test product and can share their feedback?

8. Are there any patients who noticed a difference when this kind of scalpel was used? Are there any feedbacks from patients?

9. Do you know if there are any sources for statistical data regarding how many scalpels are used/bought, do hospitals keep track of such things?

10. Have you thought about how are you going to sell this scalpel, will you do this through a distributor?

11. Is the scalpel FDA approved or is it in the progress of being approved?

Appendix B

Questions to Edward Browne:
1. VAC Overview:
- What is a Value Analysis Committee?
- Is it tied to one hospital or operates in several hospitals at once?
- Who are usually the members?
- Is there any hierarchy in the committee? Who makes the final decision after a product has been reviewed?

2. VAC work process:
- How does a product for reviewal come in?
- Who can ask/suggest for a product to be reviewed?
- How the product's value is evaluated? What are the key aspects that the team focuses on during the analysis?
- What happens after the product has been analyzed and approved/rejected?

3. Past cases:
- Have you ever had a case of analyzing a new scalpel during your work as a member of VAC? Or maybe some other surgical instruments?

4. Ordering hospitals supplies:
- What is the process of ordering the supplies, is there a separate hospital department responsible for this or one person?
- Is there a regular list of needed supplies? How often is it reviewed/updated?
- Where do hospitals usually order their supplies - directly from manufacturers/through distributors?
- How often do hospitals order supplies?
- Is the VAC involved in the process of ordering?

5. Recommendations:
- How would you recommend proceeding with the ergonomic scalpel? What would make it stand out in the eyes of VAC?
- Is there anything else related to the hospital's adoption of new products that was missed in the questions above, but is important to understand?

Appendix C

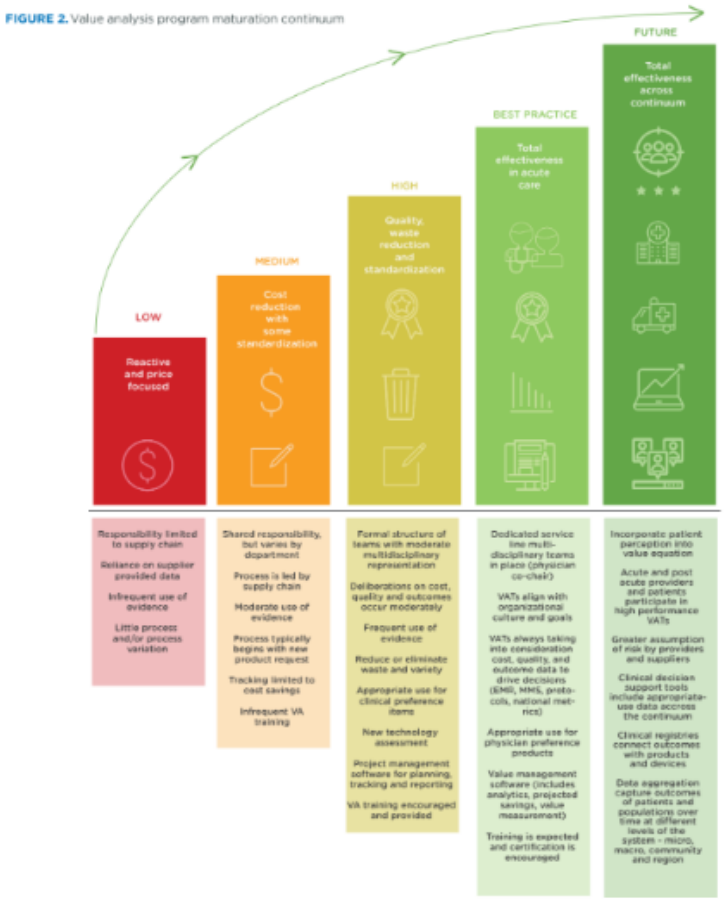
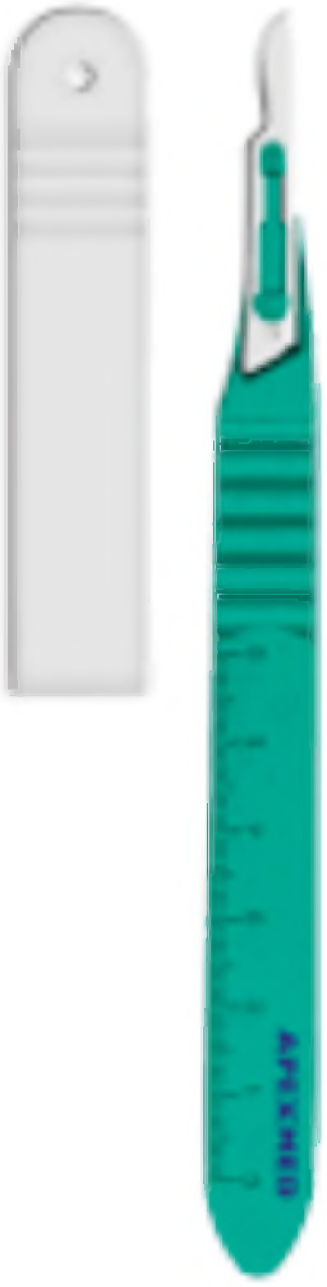


FIGURE 2. Value analysis program maturation continuum
LOW
Reactive and price focused
Responsibility limited to supply chain
Reliance on supplier provided data
Infrequent use of evidence
Little process and/or process variation
MEDIUM
Cost reduction with some standardization
Shared responsibility, but varies by department
Process is led by supply chain
Moderate use of evidence
Process typically begins with new product request
Tracking limited to cost savings
Infrequent VA training
HIGH
Quality, waste reduction and standardization
Formal structure of teams with moderate multidisciplinary representation
Deliberations on cost, quality and outcomes occur moderately
Frequent use of evidence
Reduce or eliminate waste and variety
Appropriate use for clinical preference items
New technology assessment
Project management software for planning, tracking and reporting
VA training encouraged and provided
BEST PRACTICE
Total effectiveness in acute care
Dedicated service line multi-disciplinary teams in place (physician co-chair)
VATs align with organizational culture and goals
VATs always taking into consideration cost, quality, and outcome data to drive decisions (EMR, MMS, protocols, national metrics)
Appropriate use for physician preference products
Value management software (includes analytics, projected savings, value measurement)
Training is expected and certification is encouraged
FUTURE
Total effectiveness across continuum
Incorporate patient perception into value equation
Acute and post acute providers and patients participate in high performance VATs
Greater assumption of risk by providers and suppliers
Clinical decision support tools include appropriate-use data across the continuum
Clinical registries connect outcomes with products and devices
Data aggregation capture outcomes of patients and populations over time at different levels of the system - micro, macro, community and region

Appendix D

Reusable scalpel used by the respondent.

Disposable scalpel used by the respondent.



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