CHALMERS

Cardiovascular innovation

A qualitative study exploring the current REBOA-market and how an innovation can penetrate it

Bachelor's thesis in Industrial Engineering and Management

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Kardiovaskulär innovation

En kvalitativ studie som utforskar dagens REBOA-marknad samt hur en innovation kan penetrera den

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SUMMARY

REBOA, resuscitative endovascular balloon occlusion of the aorta, is a method used for gaining control of traumatic bleeding by occluding the aorta with an endovascular balloon. However, this procedure increases blood pressure above the occlusion point and decreases blood pressure below it; increasing the risk of cerebral hemorrhage and ischemia. This bachelor's thesis analyzes the potential market of a new cardiovascular product, in the study referred to as λ (lambda), which is currently being developed by a project group at Sahlgrenska University Hospital in Gothenburg, Sweden. The goal of λ is to minimize the risk of cerebral hemorrhage and ischemia during a REBOA intervention, hopefully eliminating the controversy REBOA is exposed to.

Keywords: REBOA, pREBOA, medical innovation, cardiovascular innovation, market analysis

Note: The report is written in English.

SAMMANFATTNING

REBOA, resuscitative endovascular balloon occlusion of the aorta, är en metod som används för att få kontroll över akut blödning genom att ockludera stora kroppspulsådern med en endovaskulär ballong. Men, proceduren ökar blodtrycket ovanför ocklusionspunkten och sänker det nedanför vilket ökar risken för hjärnblödning och ischemi. Denna kandidat-uppsats analyserar den potentiella marknaden för en ny kardiovaskulär produkt, i studien kallad λ (lambda), vilken utvecklas av en projektgrupp på Sahlgrenska Universitetssjukhuset i Göteborg. Målet med λ är att minimera risken för hjärnblödning och ischemi under REBOA-ingrepp, vilket förhoppningsvis eliminerar den kontrovers REBOA är exponerad för.

Nyckelord: REBOA, pREBOA, medicinteknisk innovation, kardiovaskulär innovation, marknadsanalys

Notera: Rapporten är skriven på engelska.

Contents

1 Introduction 1
1.1 Background 1
1.2 Problem Discussion 2
1.3 Sustainability and ethics 4
1.4 Purpose 4
1.5 Research questions 4
1.6 Scope and assumptions 5
1.7 Report structure 5

2 Origin of the cardiovascular innovation λ 7

3 Theoretical framework 7
3.1 Definition of a market 9
3.1.1 Defining characteristics 9
3.1.2 Public actors as customers 10
3.2 The basis of market research 10
3.3 Market research for medical innovations 12
3.3.1 PEST analysis 12
3.3.2 Porter's Five Forces model 12
3.3.3 SWOT analysis 13
3.4 Reaching the analytical framework 14
3.4.1 Macro level 15
3.4.2 Meso level 15
3.4.3 Micro level 16

4 Method 17
4.1 Qualitative study 17
4.2 Literature sources 18
4.2.1 Theory literature sources 18
4.2.2 REBOA empirical literature sources 18
4.3 Interview sources 18
4.3.1 Interview design 19
4.3.2 Interview respondents 19
4.3.3 Interview analysis 19
4.4 Method reflections 20

5 Empirical study: REBOA today and tomorrow 22
5.1 REBOA today 23
5.1.1 Competing products 23
5.1.2 Problems with existing products 25

5.1.3 Existing efforts to solve the issue 27
5.1.4 Market 28
5.1.5 COVID-19 pandemic and healthcare budgets 29
5.2 REBOA tomorrow 30
5.2.1 Research's thoughts of REBOA's future 30
5.2.2 Physicians' thoughts of REBOA's future 31
5.2.3 The new product, λ 33
5.2.4 Entrance barriers for new products 34
5.2.5 Potential market 34
5.2.6 United Nations' sustainable development goals 36
5.3 Chapter summary 36

6 Analysis 37
6.1 Macro level analysis 37
6.1.1 Political factors 37
6.1.2 Economical factors 37
6.1.3 Social factors 38
6.1.4 Technological factors 38
6.1.5 Sustainable factors 38
6.1.6 Legal factors 40
6.2 Meso level analysis 40
6.2.1 Threat of new entrants 40
6.2.2 Threat of substitutes 42
6.2.3 Bargaining power of customers 42
6.2.4 Bargaining power of suppliers 43
6.2.5 Competitive rivalry 44
6.3 Micro level analysis 44
6.4 Result of analysis 46

7 Discussion 49

8 Conclusion and further research 51
8.1 Conclusion 51
8.2 Further research 52

References 53

Appendices 61
Appendix 1 - Interview questions in Swedish 61

Preface

This bachelor's thesis was written during the spring of 2022 at the Department of Technology Management and Economics at Chalmers University of Technology, Gothenburg. The thesis was written by six students of Industrial Engineering and Management under supervision from Frida Lind of the Division of Supply and Operations Management.

First and foremost, we would like to thank Frida who has been a very competent and understanding supervisor who we have been able to work dynamically with through the entire study. We are very thankful that you have been our supervisor.

Secondly, we would like to thank all the interview respondents who all have had very tight schedules but still have managed to answer our questions brilliantly. Without you this study would have had a lot less substance, we are very thankful for your time and knowledge.

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Chalmers University of Technology
Gothenburg, May 10th, 2022

Terminology

λ (lambda)	The cardiovascular innovation being developed at Sahlgrenska
Aerobic	Relating to, involving, or requiring free oxygen
Cardiovascular	Relating to the inside of heart or blood vessels
Catheter	A hollow flexible tube for insertion into a body cavity, duct, or vessel to allow the passage of fluids or distend a passageway
Cerebral hemorrhage	An artery in the brain bursting and causing localized bleeding in the surrounding tissues
Circulatory collapse	Defined as a general or specific failure of the circulation
Endovascular	Relating to the inside of blood vessels
Endovascular surgery	A surgical procedure in which a catheter containing medications or miniature instruments is inserted through the skin into a blood vessel for the treatment of vascular disease.
Fluoroscopy	Examination of the tissues and deep structures of the body by x-ray, using the fluoroscope
French (Fr)	Diameter unit for catheters, 1 Fr = ⅓ mm
Introducer sheath	An instrument, such as a catheter, needle, or endotracheal tube, for introduction of a flexible device
Ischemia	An insufficient supply of blood to an organ, usually due to a blocked artery
Occlusion	The blockage or closing of a blood vessel or hollow organ
Perfusion	The flow of blood or other perfusate per unit volume of tissue, as in ventilation
REBOA	*Resuscitative Endovascular Balloon Occlusion of the Aorta,* blocking the blood flow in the aorta using a balloon
Renal	Refers to the kidney
Seldinger technique	A method of percutaneous insertion of a catheter into a blood vessel or space. A needle is used to puncture the structure and a guide wire is threaded through the needle; when the needle is withdrawn, a catheter is threaded over the wire; the wire is then withdrawn, leaving the catheter in place
Thoracoabdominal	Relating to the thorax and the abdomen
Thoracotomy	Surgical incision of the chest wall
Transfemoral	Endovascular access through the femoral artery
Traumatic	Acute

1 Introduction

When a patient suffers a severe injury to the upper body or abdominal area, internal bleeding can occur which could be fatal. Since the bleeding is internal and often affects the larger blood vessels, it is vital to quickly stop the loss of blood whilst maintaining a sufficient blood pressure for perfusion (P Skoog, personal communication, January 17, 2022); in these cases, one of two methods are mainly used today. One of them is a method in which a large incision is made on the patient's torso; the incision is then used to clamp off the affected arteries and/or veins (P Skoog, personal communication, January 17, 2022). The other procedure is less invasive; it involves making an incision on the patient's upper leg where an instrument is guided through an artery to the thoracoabdominal area, to internally occlude the aortic blood flow to achieve sufficient perfusion (P Skoog, personal communication, January 17, 2022). The latter method, named REBOA, Skoog explains, brings controversy because of the risk of cerebral hemorrhage and ischemia during the intervention.

This Bachelor's thesis analyzes the potential market of a new cardiovascular (affecting the heart or blood vessels) product, in the report referred to as λ (lambda), which is currently being developed by a project group at Sahlgrenska University Hospital in Gothenburg, Sweden. The goal of λ is to minimize the risk of cerebral hemorrhage and ischemia during a REBOA intervention, hopefully eliminating the controversy the procedure is exposed to.

1.1 Background

P. Skoog (personal communication, January 17, 2022) says that traumatic bleeding, caused by blunt or penetrating injuries will cause the blood pressure to fall to insufficient levels for oxygenation of essential organs. To prevent this from happening, Skoog explains that a balloon catheter placed in the aorta is inflated; when the balloon is placed and inflated, as seen in figure 1.1, the blood above it will create a pressure, allowing perfusion of essential organs. However, too high blood pressure above the balloon can create hemorrhages, while too low blood pressure below the balloon can lead to ischemia.

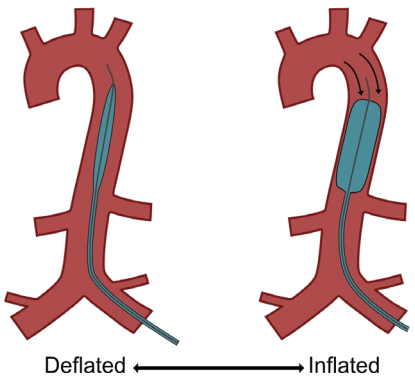

Figure 1.1
Schematic overview of a REBOA balloon

λ aims to solve problems, which today's products face. Thereby λ can create a minor product development, as it is expanding an existing market (Granstrand, 2010). The report intends to further examine the existing problems the current product faces in comparison to the innovation. By comparing the current market with the potential market for λ, one will get a better understanding of the potential of a product that solves today's issues. At the same time, by understanding the value the market places on the individual solutions, an insight to the evaluation of the innovation in the potential market could be made.

Three of the authors of this report are involved with the development of the new product and the market analysis has been requested by the research team they operate in. However, technical information regarding λ will not be disclosed since it is not protected by a patent at the time of writing.

1.2 Problem Discussion

The procedure of REBOA begins by using the Seldinger technique to gain transfemoral arterial access. When the introducer sheath (a wider hollow pipe) has entered the femoral artery, the catheter can be inserted and endovascular access is gained (Sadeghi & Hörer, 2017). By locating anatomical landmarks using fluoroscopy, the catheter can be guided to the right zone of the aorta and inflated for occlusion (Okada et al., 2017). P. Skoog (personal communication, January 17, 2022) explains that diameters of introducer sheaths and catheters are measured in French (Fr) where one French is equivalent to one third of a millimeter.

Olsen et al. (2020) explains how REBOA stabilizes the state of patients with circulatory collapse by occluding the blood flow in the aorta in either zone I or III. In zone II occlusion is discouraged since it has connections to vital organs and occluding here could stop blood flow to the gastrointestinal (GI) tract, liver, and kidneys (Heindl et al., 2020). The zones are visualized in figure 1.2 below.

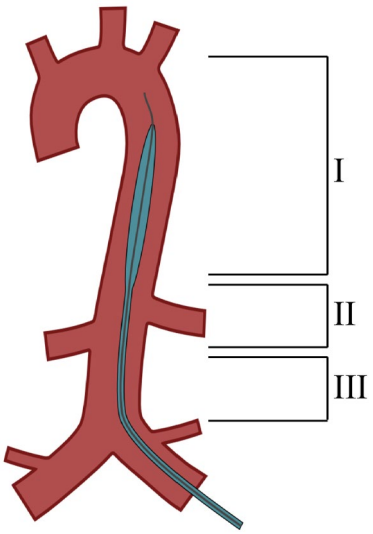

Figure 1.2
Balloon placement zones in the aorta

Traumatic bleeding is a leading cause of death in both civilian and military trauma (Alarhayem et al., 2016). Therefore, a procedure for temporary stabilization of the circulatory collapse is essential for the resuscitative process (measures taken to sustain life of a dying patient). Today, two alternatives of occlusive procedures predominate the field of resuscitation of thoracoabdominal penetrating or blunt injuries: Resuscitative Thoracotomy (RT), and Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) (Stern, 2021). Resuscitative Thoracotomy (RT) is an invasive procedure intended to control major hemorrhage with aortic occlusion (Pust & Namias, 2016), whilst REBOA is the endovascular counterpart (Sadeghi & Hörer, 2017).

Occlusion of the aorta prevents circulatory collapse due to thoracoabdominal hemorrhage and thereby allows regular perfusion and aerobic cell respiration (Hooper and Armstrong, 2021) above the occlusion where blood pressure can be restored. At the same time, occlusion of the aorta can lead to complications due to either too high of a blood pressure above the occlusion, or too low blood pressure and flow beneath. Too high, or too low, blood pressure can lead to complications like intracranial hemorrhage or ischemia (renal failure or ischemia of limbs, possibly leading to amputation of extremities), respectively (Ribeiro Junior et al., 2018). Complications due to other factors are prevalent as well. For example thromboembolism, vascular rupture and perforation (due to access to the vessel by introducers), balloon rupture, balloon migration and infection (Ribeiro Junior et al., 2018; Sadeghi & Hörer, 2017).

Furthermore, controversy arises due to the disputed benefit the procedure and technology induce (Stern, 2021). The Hippocratic Oath: *"primum non nocere"*, or *"first, do no harm"*, is well associated with the medical profession (Shmerling, 2015), and the same argument is reasoned in the debate about the feasibility of aortic occlusion as a resuscitative method due to the high mortality rate (Brenner et al., 2018). At the same time, the high mortality rate may be traceable to the severe injuries which makes the procedure necessary in the first place.

However, the procedure and technology of REBOA have increased in use and are characterized by a decreasing complication rate (Bukur et al., 2021; Manzano Nunez et al., 2017; DuBose et al., 2016). Nevertheless, the medical market's controversy focuses on the mortality rate in comparison to alternative resuscitative methods (Renna et al., 2017).

In addition to the ongoing discussion of the benefits of the procedure, further questions arise due to the unwieldy characteristics of the current products (P. Skoog, personal communication, January 17, 2022). The technical use of the REBOA procedure is characterized by the products' shapes and designs. Therefore, today's balloon-design faces some difficulties in both the outcome and the ergonomics of use.

λ intends to solve most of the problems today's products fail to solve. As previously stated, today's product faces complications such as intracranial hemorrhage due to high blood pressure, ischemia due to low blood pressure, balloon migration due to the cross-sectional occlusion of the balloon and due to a weak catheter, thromboembolisms as well as infection and vascular rupture due to the insertion of the introducer, and balloon rupture.

λ intends to avoid many of the issues by a complete redesign of the product. However, the insertion of the catheter will be the same, thus thromboembolisms, infections and vascular rupture will still be possible complications. Potentially avoidable complications include the structure of the product, the area of occlusion as well as the regulation of pressure. Therefore, complications such as intracranial hemorrhage, ischemia, balloon migration and balloon rupture must be minimized if not completely eradicated.

1.3 Sustainability and ethics

Regarding sustainability, the focus will be discussing the social impact on society. The aim of λ is to save lives, but to which extent will it be able to fulfill these expectations? This can also lead to a discussion about expectations on healthcare in general. Questions such as the effects of saving more lives have been relevant to take up. Furthermore, it is not only the patients who will be impacted by λ, it will also impact the surgeons' daily workflow. Is λ favorable over the old product? Or what requirements does it need to achieve to be that?

The topics related to sustainability and ethics are naturally integrated in the report due to the sensitivity within the industry and the fact that the innovation can be the difference between life and death of emergency patients. The questions formulated in the report can easily generate closely related questions such as *how much is a human life worth?* The thesis does, for self-explanatory reasons, not aim to answer questions like this, but their utter presence is proof of how central ethics are in the study.

The study aims to answer whether λ will be received as controversial, like its precursor, which is a question of ethics due to the harm the product could inflict. Since the current solution is attributed with complications such as renal failure, what if λ could eliminate renal failure with the tradeoff of being more expensive (Sadeghi & Hörer, 2017)? Conversely, if λ contributes with new complications, or a higher risk of complications than current solutions entail, but at a greatly reduced price. Consider the fact that λ could eliminate certain complications but induce new ones. Consequently, the ethics of λ will be one factor determining how it will be received by the market, hence it will be of importance to discuss it.

1.4 Purpose

The purpose of the study is to explore and characterize the current and the potential market of the cardiovascular innovation λ.

1.5 Research questions

With quite a wide purpose and scope, the study's research question is divided into two sub questions with the aim of helping fulfill the purpose.

RQ1: What does the current REBOA market look like?

The goal of answering research question one is to investigate the size, competition, profitability and risks of the current market. The research question intends to explore if the problems the new product aims to resolve have been attempted to be solved by earlier developers.

RQ2: What are enablers and barriers for the cardiovascular innovation λ?

With RQ1 as its starting point RQ2 should analyze the potential market for λ. What factors enable market penetration? What factors are instead barriers for market penetration?

1.6 Scope and assumptions

The study delimits itself to studying the Swedish market only, in other words only Swedish buyers and users will be included in the scope of the study due to the vast amount of information available worldwide. The interview respondents interviewed in the study are all active in Gothenburg, however, their experiences and opinions are assumed to match the experiences and opinions of people working in corresponding roles in other parts of Sweden. On the competitive side, global competitors are examined due to the numerous, and international, actors within the medical technology industry which have products competing with λ.

The study sees λ as a finished product even though it actually is in its R&D-phase today. λ is, during the study, assumed to fulfill all the current technical specifications and objectives set by the developing team, when analyzing its potential competitiveness on the market. Given this, a patent is also assumed during the study to be present. However, the discussion will analyze the differences of a potential market regarding whether all technical specifications were fulfilled. When λ is compared to the current solution, it is the REBOA solution that is referred to. There will be no comparison between λ and resuscitative thoracotomy (RT) since the latter has a wider area of use and is not intended to be replaced by the new product.

Furthermore, the sustainability aspect in terms of environmental impact of λ will not be thoroughly explored in the report. The explanation for this relates to the nature of the product and what it aims to achieve. Materials for the innovation will be selected based on biocompatibility and function, with little concern regarding environmental sustainability and/or recyclability. P. Skoog (personal communication, January 17, 2022) explains that because of the product being surgical equipment which enters the body of the patient, the product must also be of one time use for clinical reasons. Sustainability efforts in this study will instead mostly focus on social and economic sustainability, with small inputs of environmental aspects.

1.7 Report structure

The report is structured in the following way: after this introduction, chapter 2 follows, which is a short description of the origin of this innovation project and the project group at Sahlgrenska University Hospital. Chapter 3 starts off with theories on market analysis which later forms the analytical framework used in the analysis. Chapter 4 presents the method which

the study has followed during its execution. Chapter 5 studies the REBOA market and provides the empirical information from literature and interviews analyzed in the analysis. Chapter 6 presents the analysis of the empirical information presented in chapter 5 through the lens of the analytical framework presented in chapter 3, answering the research questions. At last chapter 7 discusses the analysis and then chapter 8 provides the conclusion of the report where the purpose is reconnected to.

2 Origin of the cardiovascular innovation λ

As a necessity of an innovation arose, a project group was created for the forthcoming development. The problem, formulated by a cardiovascular surgeon at Sahlgrenska University Hospital, was defined as improving the outcome and ergonomics of use for surgeons around the globe. Apart from the surgeon, a medical technology engineer and three engineering students joined the project group to reach both the necessary technical and medical expertise.

Thus far, the project group has collected initial funding for the first months of development with the intent to gather more funding, governmental or private, in forthcoming months. With regards to the market analysis, required to portray the potential market for investors, this study came to life. The connections between the project group and the group writing this report are the three engineering students working with both the project group and the report. These students are Emil Leijon, Albin Thelander and Otto Stuhlhofer.

The forthcoming work of the project group takes place at Sahlgrenska University Hospital in an office located in the same hallway as the cardiovascular surgeons for a proximity to bridge the knowledge gap between medical and technical.

3 Theoretical framework

The aim of this chapter is to give the reader a basic understanding of what a market is and how it is defined, different methods for market research and how market research is applied in the medical-technology field in previous research. Furthermore, a suitable analysis model for the conducted research in this paper will be presented. Readers with extensive knowledge about the field of market research may find some information presented to be obvious.

3.1 Definition of a market

A market is in its most basic sense a platform where something is bought and sold. The market can be separated into two fractions, business-to-business (B2B) market and business-to-consumer (B2C) market. The main difference between these two markets is that the customer is an organization in B2B compared to an individual consumer in B2C according to Brennan et al. (2020). Therefore, it is not the characteristics that decides which market the product belongs in, instead it is the predetermined customer.

However, it is a bit more complicated in this case. λ's intended customers are public actors, and thereby the market is not ultimately B2C or B2B, even though it is closer to the latter. In the study the customers are treated as B2B-customers, with the buying "business" being a public actor. This might impact the buyer behavior of the customer, which will be elaborated further.

3.1.1 Defining characteristics

To interpret a market, certain characteristics are important to understand. Thereby, derived demand, the accelerator effect and the concentration ratio will be treated below.

Demand can be either direct or derived. In marketing, the demand is direct if it originates from consumers and derived if it arises from business (Brennan et al., 2020). In the most simplified case, consumers are only expected to purchase products and services to satisfy their needs, while businesses exclusively purchase equipment to enable the production of goods and services. In this context, derived implies that there is a certain demand for the product or service that only remains while there still is a demand for the services that are being fulfilled by the product. To clarify, organizations want to buy trucks for their capability to move certain objects. If the business did not need to move the object, they would not have to buy the truck. Hence, the demand for purchasing a truck is derived.

The accelerator effect is linked with derived demand. Marketers need to be mindful of developments that might affect their market. These changes can appear both up- and downstream, but primarily it is the downstream shift that causes different levels of derived demand, argue Brennan et al. (2020). This appears to be obvious since more components of a certain product will be needed if the product's demand increases. Nonetheless, what might not be so clear, is that the percentage change can be differentiated in the derived demand compared

to the initial. This phenomenon is called the accelerator effect. Hence, it is important to be aware of changes outside the business so that proper adjustments can be implemented.

The concentration ratio of a market can be helpful to properly interpret the economic behavior of a market. The concentration ratio is defined as the sum of the few largest companies' market shares of the market, where these firms are acknowledged as the oligopoly group. This group often consists of the top three to five biggest firms (Brennan et al., 2020). B2B markets do normally have a higher concentration ratio than B2C markets. As previously stated, the concentration ratio is important to understand for analyzing the economical market. Brennan et al. (2020) argue that a higher concentration ratio leads to a bigger risk that the firms collude and thereby raise the price over the level that would have been the case in a genuinely competitive market. Furthermore, higher concentration ratios might even imply a less stable production volume as well as a less innovative industry.

3.1.2 Public actors as customers

The conditions for customers in the private and public sector differ. When it comes to the acquisition of services or products in the public sector, it is often defined as procurement rather than purchasing. In public procurement, the target groups are classified by rights rather than segmentation (Stentoft Arlbjørn & Vagn Freytag, 2012). Changes in procurement are more politically driven instead of demand-driven. Furthermore, public procurement has higher demands on transparency and integrity. It is also driven by multiple goals; both political and economic. Finally, public procurement is distinguished by operating under strict rules and procedures, especially during major transactions (*Upphandlingsmyndigheten*, 2022), and suppliers often find themselves in more long-term relationships with the public sector (Stentoft Arlbjørn & Vagn Freytag, 2012).

The public procurement legislation in Sweden also follows these basic principles. It is partly based on EU directives and state that all public procurement must be transparent, suppliers must be equally treated, no discrimination should occur and social considerations is to be taken into account, to name a few (Richardson et al., 2022). Furthermore, the Swedish National Agency for Public Procurement declares that public procurements take longer than private purchases and that different rules and legislations apply based on the monetary size of the transaction (*Upphandlingsmyndigheten*, 2022).

3.2 The basis of market research

Market research is an extremely broad subject and exploring every detail is far beyond the scope of this report. Instead this section should be seen as a highlighter of important elements of market research which will be the foundation of this reports analytical framework. Therefore the reader is encouraged to perfectly understand this segment or read up on the subject before proceeding.

There is no established definition of the comprehensiveness of market research. A definition could be, study of the requirements of various markets, the acceptability of products, and methods of developing or exploiting new markets (Britannica, 2013). Another more extensive definition from ICC/ESOMAR International Code On Market And Social Research:

"Market research, which includes social and opinion research, is the systematic gathering and interpretation of information about individuals or organizations using the statistical and analytical methods and techniques of the applied sciences to gain insight or support decision making. The identity of respondents will not be revealed to the user of the information without explicit consent and no sales approach will be made to them as a direct result of their having provided information." (ICC/ESOMAR, 2016)

These examples help us pin down and understand the many aspects of market research. However, they are hard to fully grasp, hence a final definition will be presented to simplify this complex subject. Market research could be said to be the process where insight is gained on how markets work (Sarstedt & Mooi, 2019).

Building on this last definition of market research, the insight gained on markets can be differentiated between quantitative and qualitative research. Quantitative research concerns the raw data measurement of the market (Hague et al., 2013). This can include information such as market size, market segments and the size of the segments, purchase frequencies, brand shares, etc. Qualitative research is considerably harder to define by nature since it in most cases cannot be measured with a number. The emphasis of the information is instead focused on understanding complex views such as why market campaign A is effective and B is not (Hague et al., 2013). Another way of viewing quantitative research is not simply by a measurement, but by the detailed description, understanding and insight of data collected (Mcgivern, 2009). This view clearly differentiates itself from Hague et al. (2013). However, a consensus is that quantitative research should be conducted in a way that creates statistical significance.

Quantitative and qualitative research are interesting concepts which have slightly different meanings depending on who you ask. The foundation of both methods however, stems from quantitative data, and qualitative data which both are clearly defined. Sarstedt & Mooi (2019) recognize both these data types but present a different approach to quantitative and qualitative research. The research method consists of exploratory, descriptive and causal research. Exploratory research is explained to cover ambiguous problems and the main use cases include understanding structure, formulating problems precisely, generating hypotheses and developing measurement scales. Descriptive research covers somewhat defined problems and includes descriptions of customers or competitors, market size, market segments and performance measurements (e.g., brand awareness). Finally, causal research is defined as research covering clearly defined problems and understanding relationships between variables (Sarstedt & Mooi, 2019).

According to ESOMARs definition of market research presented above, market research also includes social and opinion research. Opinion research includes information gathering

concerning political matters and conclusions are made based on knowledge from political science and psephology (Mcgivern, 2009). Social research is broader and Mcgivern refers to it as "*research conducted to explore, discover, test, verify, measure, explain and/or understand the nature of social phenomena, of groups, of organizations and of people, of the social world."* (pp. 7-8).

3.3 Market research for medical innovations

Building on the knowledge obtained from previous segments on market research, the goal of this chapter is to explore how market research within medical technology can differ from traditional market research. One potential challenge stems from the dilemma of technology foresight versus market research (Postma et al., 2007). The dilemma is based on how market research often focuses too much on the users, in this case medical specialists or the market perspective. This can lead to a short-sighted view on innovations which can result in poor market research outcome. Instead Postma et al.(2007) suggest that a combined method should be used where traditional market research is complemented with the Delphi-technique. The Delphi-panel's expectations of long-term technology advancements of the innovation should be taken into consideration to create a better forecasting perspective.

Building upon the well-known framework of micro and macro, which refers to the local respectively the global level, the micro-meso-macro partition brings another level into the analysis. Van Notten (2006) explains that within business', the micro level consists of the organization, whilst the macro level consists of the contextual environment such as socio-cultural, technological, ecological, political and economic developments. Furthermore, van Notten (2006) describes the meso-level as the transactional environment between micro and macro consisting of regulatory organizations, clients, interest groups, suppliers, competitors and media. Earlier studies, such as Garcia et al. (2019), have used this three-level analysis framework successfully.

3.3.1 PEST analysis

The PEST analysis framework is another strategic tool designed to analyze and identify external macro-factors that can affect the environment a company operates in (Sammut-Bonnici & Galea, 2014). It is best used in combination with other frameworks to identify strengths and weaknesses (Carruthers, 2009). In this way, it is similar to the SWOT-analysis, although PEST only focuses on the external aspects. The factors included in the most common form are political, economic, sociological and technical. Some variants include PESTEL, STEEPLE and STEER which all add macro-factors to consider.

3.3.2 Porter's Five Forces model

Michael E. Porter's (1979) article *How Competitive Forces Shape Strategy* states that competition in an industry depends on five basic variables, or forces. The sum of these forces is what will determine how well a business performs in an industry. Porter states that "The essence of strategy formulation is coping with competition" and further explains how analyzing

the five forces can be used to formulate a strategy for a business. Although the ambition of this paper is not to formulate a business strategy, Porter's model can still be applied and used as a framework to analyze a market. Industries where the forces are strong are named *intense*. In these markets, there is no room for major returns. Correspondingly, in markets where the sum of the forces is weak, called *mild*, has potential for more returns (Porter, 1979). This paper will simply translate these definitions into strong or weak markets.

The five forces that Porter describes are as follows; 1) Threat of new entrants, 2) Bargaining power of suppliers, 3) Bargaining power of customers, 4) Threat of substitute products or services and 5) Jockeying for position among current competitors (Porter, 1979), or simply put; rivalry among competitors (Grundy, 2006).

Furthermore, different markets will have different dominant forces or perhaps a single dominant force. The strongest one, or ones, of these five forces is what will be the determining factor(s) for the strength of the market. Subsequently, in a market where four forces are insignificant but the fifth is prominent, that force will be the determining factor (Porter, 1979).

Some of the limits of the five-force model from Porter are that it tends to disregard or overlook the importance of micro analysis, i.e. how specific product segments can affect the business (Grundy, 2006). Another limiting factor is that the model views the environment of the business as a separate entity, in contrast to the PEST model for example, which examines the dynamic or "bigger" environment in which the business operates (Grundy, 2006).

Although the above-mentioned limiting aspects strip some of the validity of the model, this report aims to use it in an aggregate form together with other models which focus on areas that the five-force model does not.

3.3.3 SWOT analysis

A SWOT analysis is a powerful method to deal with the increasing competition worldwide in a proper way, and thereby achieve future growth. SWOT is short for Strengths, Weaknesses, Opportunities and Threats, which are the four covered factors in the analysis. The method identifies the organization's internal strengths and weaknesses accompanied with the market's opportunities and threats. Hence, both an internal and external survey are required, suggests Pant (2019).

More exhaustively, strengths speak for the specific competencies that make a firm more successful than its competitors, explains Pant (2019). Likewise, weaknesses represent those attributes that cause a competitive disadvantage. As mentioned above, these are the two internal factors, and are identified by examining the organization's core competencies, functional regions and value chain activities among other aspects. The external elements, opportunities and threats, can be addressed in a similar way. Opportunities include those elements that are truly beneficial for the firm. In the same way threats are external factors that can be harmful for the organization. To determine these two, a PESTEL analysis can be performed.

Furthermore, Porter's Five Forces model might be used to enrich the identification of the organization's competitive position.

3.4 Reaching the analytical framework

To analyze the empirical information, these theories will be used by first subdividing them into three categories of scope. The three categories are; macro, meso and micro. On a macro-level, the analysis methods are the PESTEL-forces where the environmental *E* is swapped for sustainability, *S,* to provide a wider discussion of sustainability rather than only the environmental subdivision. On a meso-level, the subdivisions consist of Porter's Five Forces, which allows an analysis of the network surrounding the firm responsible for the medical innovation. Finally, on a micro-level, a variant of SWOT is used to analyze the strengths and weaknesses of the cardiovascular innovation, λ. The opportunities and threats, which are the two external factors in a SWOT analysis, are omitted since they are not included in the micro-level. These two factors are instead treated in the macro- and meso-level since they are advantageously analyzed through a PESTEL analysis and Porter's Five Forces model. The framework is presented in figure 3.1 below.

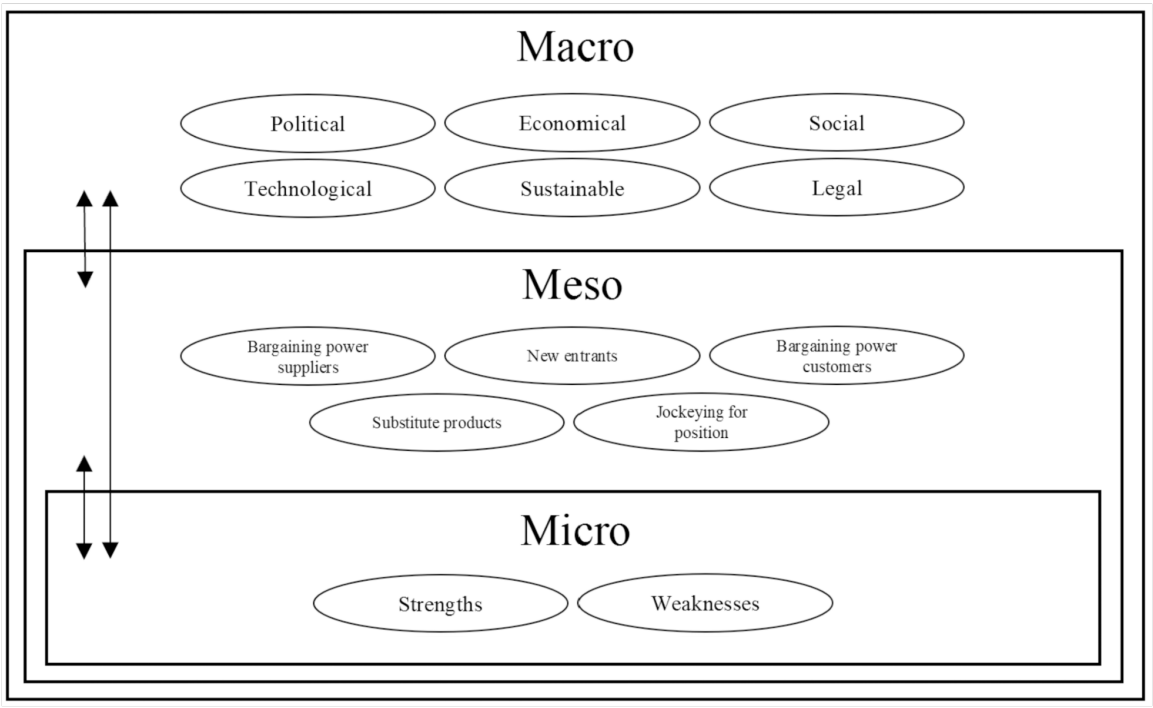

Figure 3.1
Analytical framework for market analysis.

To form the framework even further for medical technology innovations, multiple factors have been identified on each level respectively. The factors identified are characteristics of the market being studied chosen by the authors after internal discussion. In the following sections these factors are presented level per level.

3.4.1 Macro level

On the macro level some important factors are procurement, budgets, market state, product need, product disregard, innovative technical solutions, ethics, the environment, CE-marking and patents. To make it clearer the macro level PESTSL factors for medical technology are presented in table 3.1 below. The factors are discussed and identified by the authors.

Table 3.1
Macro level PESTSL factors.

Factor	Identified influencers
Political	Procurement and budgets.
Economic	State of the market.
Social	Need and product disregard.
Technological	Innovative technical solutions.
Sustainable	Ethics and environment.
Legal	CE-marking and patents.

3.4.2 Meso level

On a meso level some important forces are incumbency advantages, competing products, price sensitivity, switching costs and low degree of differentiation. In table 3.2 below Porter's Five Forces applied on medical technology are presented. The forces are discussed and identified by the authors.

Table 3.2
Meso level, Porter's Five Forces.

Force	Influencing factors
Threat of new entrants	Entry barriers in the form of big capital requirements, knowledge about regulatory processes and incumbency advantages.
Threat of substitutes	Use of other REBOA products instead.
Bargaining power of customers	Price sensitivity, switching costs for customers and learning effects.
Bargaining power of suppliers	Low degree of differentiation in the product components and easy to get hold of.
Competitive rivalry	Healthcare budgets and paused investments during COVID-19.

3.4.3 Micro level

On a micro level some important factors are technological superiority and branding. In table 3.3 below the micro level SW factors for medical technology are presented. The factors are discussed and identified by the authors.

Table 3.3
Micro level SW factors.

Factor	Identified influencers
Strengths	Technological superiority.
Weaknesses	Brand weaker than competitors'.

4 Method

In this section the method of the study is explained and discussed with regard to potential risks. The method is the foundation of the entire study and the framework followed during its execution.

4.1 Qualitative study

The study has a qualitative research approach; since the study gathers information about the process rather than collecting statistical data, the qualitative approach becomes a natural choice (Brandenburg, 2013). Qualitative research allows interviews and other open-ended sources (Bryman, 2018). However, allowing these kinds of sources requires extra caution and analysis of the quality of the resulting information (Blomkvist & Hallin, 2015). The interpretation of the information is also deeply biased by the researchers themselves since the researcher is the main data collection instrument in qualitative research (Teherani et al., 2015) which implies that an in depth analysis of the information is necessary.

The method is split into several different parts. Firstly, a theory section which presents the theory of market analysis through literature sources; the theory section ends in the presentation of an analytical framework. The theory section is followed by an empirical section which presents the views on the current, and future, REBOA market. The empirical section uses both literature and interview sources to access as much information about the REBOA market as possible. To summarize, the theoretical section outputs an analytical framework and the empirical section outputs empirical information to be analyzed. Next, the empirical information is analyzed through the analytical framework in the analysis section. Lastly, the study's research questions are answered in the result and summarized in the conclusion.

The entire method's validity is something which must be discussed to make sure that the used method is the correct way to gather information and answer the research questions. Therefore, the method validity is discussed in 4.4. Below, the methodology of the study is presented graphically in figure 4.1.

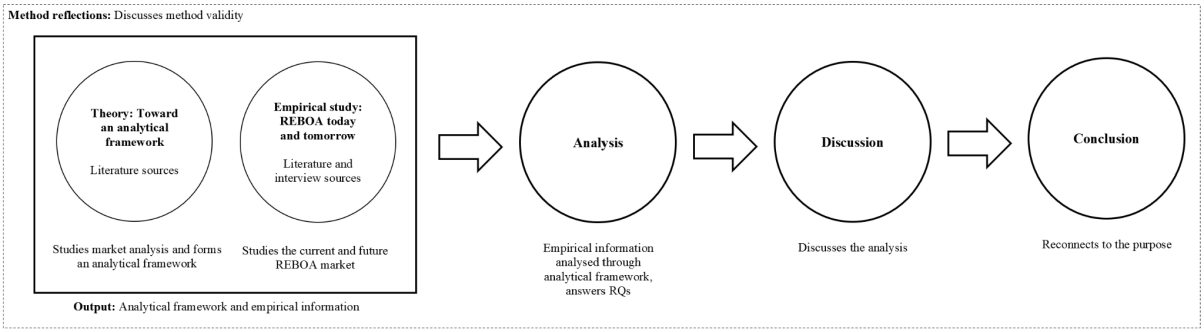

Figure 4.1
Overview of the study

On one hand, an inductive methodological perspective is used in the study which implies that there is no initial hypothesis to be tested - instead a topic is studied with the aim to generate new theories (Bryman, 2018). On the other hand, there is a hypothesis, the hypothesis being that the new product will successfully penetrate the market and therefore the researchers are studying the result of this market penetration; in this case the methodological perspective is deductive (Bryman, 2018). A combination of the two can be defined as an abductive perspective, which may be the case in this study, as in an abductive study the researchers collect information from the persons or contexts they study and create a theory based off of this new social truth (Bryman, 2018).

4.2 Literature sources

The study uses many literature sources, for two different chapters in the report, to provide a broad spectrum of information. The chapters referring to these sources are chapter 3 and chapter 5. Research was accessed through Scopus, Google Scholar and Chalmers Library. The aim during the study was always to find as recent literature as possible to be able to see the latest trends.

4.2.1 Theory literature sources

The theory section aims to bring knowledge of market research in general, as well as market analysis of medical innovations particularly by looking at earlier research within the field. The theory lays ground for the analytical framework used in the analysis. In the theory section, the main keywords used in search were “Market research”, “SWOT”, ”Porter's Five Forces”, “PESTEL” and “Market Analysis Medical Technology”. Beyond the research found through these keywords the supervisor contributed with relevant literature as well.

4.2.2 REBOA empirical literature sources

To present information regarding the current REBOA market and opinions on the future REBOA market many sources are referred to in chapter 5. The literature sources referred to are partly existing research on REBOA as well as websites of competitors and governments. The empirical literature sources work together with the interview sources forming a wide conception of the current market of REBOA and the potential market of λ. For the empirical chapter the main keywords searched for when browsing research were “REBOA”, “pREBOA”, “REBOA future”, “pREBOA future” and “REBOA trends".

4.3 Interview sources

According to Virginia Tech (2018) interviews are a good method for obtaining rich information from a small number of people. It is also a fitting information collection method for qualitative research since it aids understanding of the respondents’ opinions, behavior and experiences (Virginia Tech, 2018). Based on this information, interviews were an obvious component to implement in the study to collect information for the study regarding the current REBOA-market and the potential market of λ.

4.3.1 Interview design

The interviews were of the semi structured kind, containing open questions (see appendix 1) planned in a script, with allowance for the respondent to elaborate and lead the conversation deeper into the subject than the question script originally intended (Alsaawi, 2015).

The purpose of the interviews was to gather information and combine said information with the information obtained from literature. The interviews were intended to provide new aspects of the current market and the potential market of λ. The researchers acquired all respondents' permission to record the interviews and call them by their real names in the report.

4.3.2 Interview respondents

The interview respondents are people with good insight in the medical industry in general as well as vascular surgery and the use of REBOA in particular. Below, the interview respondents are presented in table 4.1.

Table 4.1

List of interview respondents.

Respondent	Organization	Title	Date	Length
Per Skoog, Part I	Sahlgrenska University Hospital	Vascular surgeon	22-01-17	92 minutes
Per Skoog, Part II	Sahlgrenska University Hospital	Vascular Surgeon	22-04-17	25 minutes
Sofia Strömberg	Sahlgrenska University Hospital	Vascular surgeon	22-04-26	20 minutes
Sofia Axelsson	Västra Götalandsregionen	Material consultant within purchase	22-04-26	37 minutes
Joakim Nordanstig	Sahlgrenska University Hospital	Vascular surgeon	22-04-17	30 minutes
Mahia Aivaz Ihari	Sahlgrenska University Hospital	Vascular surgeon	22-04-25	22 minutes

4.3.3 Interview analysis

All interviews were recorded and then transcribed at a later point in time. The interview analysis was performed according to the "Systematic Text Condensation"- framework developed by Malterud (2012). The framework provides four steps for going from chaos to descriptions and concepts. The four steps are total impression (from chaos to themes), identifying and sorting meaning units (from themes to codes), condensation (from codes to meaning) and synthesizing (from condensation to descriptions and concepts) (Malterud, 2012).

In other words, it is a methodology going from a raw interview transcript to useful concepts, which can be provided as a resource helping the researchers in answering the research questions. In short, the process applied to one interview in this specific study was the following. The researchers began by reading the full transcript to get a good overall picture of the interview, after that another read is needed to review the transcript for information relevant for

the research questions. After this is done, meaning units, in other words pieces of relevant information, are grouped logically. At this point, the interview has gone from a long transcript to small groups of information which is useful for the study. Lastly, the pieces are put together again forming a cleaner whole with higher information density. These descriptions and concepts should now be part of the information which can help the researchers answer the research questions (Malterud, 2012).

All interviews were performed in Swedish, and the results were translated to English with the translation being controlled by the interview respondent, which eliminated the risk of a deceptive translation providing false information to the study.

4.4 Method reflections

To ensure high scientific quality of the method, multiple potential risks have been brought to the surface and discussed. Bryman (2018) states that the qualitative study has four primary issues. It is subjective, difficult to replicate, hard to generalize and holds transparency issues regarding how the study was performed in detail.

The risk of the study being too subjective is highly affected by the fact that the information gathered from interviews is the interview respondent's personal truth and perhaps not the fully objective truth. This risk was reduced during the study by informing the respondents of the purpose of the study. In an attempt to reach the utter objective truth all interview respondents had the possibility of anonymity in the study, opening up for answers which may not have been reached without anonymity. However, none of the interview respondents wanted to be anonymous. Reducing subjectivity originally was planned to be achieved by interviewing a larger number of respondents than five, which is the final number of interview respondents in the study. However, finding surgeons and purchasers with enough time and interest in the study to participate in an interview was found to be more challenging than the authors originally believed. Worth noting is that the interview respondents featured in the study have a lot of knowledge and are very well respected in the field. Also, even though the number of interviews landed at a smaller number than originally intended, saturation could be experienced to some extent. Hennink et al. (2016) describes saturation as the point in an interview study where no additional issues or insight emerge.

The replication issue is natural and something which is hard to prevent; according to Bryman (2018) the researcher is the main tool when collecting information, this means that the outcome of the study would be very different if the researchers were replaced. The replication issue is not something the researchers of this study have chosen to actively prevent; however, it is worth noting its presence. The generalization issue is normal within qualitative research; the importance here is, according to Bryman (2018), to generalize towards theory and not towards a population. The goal during the study was to make the report as useful as possible in general, even though it was performed with one case in focus. The belief is that at least the analytical framework can be used by others in similar situations where a medical innovation's market potential is to be analyzed. The transparency issue is minimized by explaining to the reader as

best as possible how the study was performed. The fact that three of the authors are part of the project group at Sahlgrenska University Hospital, while three are not, creates a good balance between internal and external review of the study and its method.

5 Empirical study: REBOA today and tomorrow

The number of trauma deaths per year, globally, is estimated to be 4,4 million (World Health Organization, 2021), of which hemorrhage accounts for 30-40% or 1,32-1,76 million (Kauvar et al., 2006). The proportion that is estimated to be non-compressible hemorrhage amounts to 60-70%, or 0,8-1,23 million people (Vella et al., 2019). As presented in earlier sections, REBOA aims to reduce these numbers.

In chapter 5 the study explores REBOA through secondary data gathered from already existing literature and webpages as well as primary data gathered from interviews conducted by the researchers. The information provided in this section is the empirical information which is later analyzed in section 6 through the theoretical framework presented in section 4.

5.1 REBOA today

In section 5.1 the study explores the state of REBOA today, starting off by comparing the existing REBOA products and their differences. Following this, the existing efforts to solve the issues with REBOA are presented as well as how the market looks like today and what impact the covid-19 pandemic has had.

5.1.1 Competing products

There are already many REBOA products on the market, the most well known ones are presented in table 5.1 below. In sub-section 5.1.1 these products are all presented with their respective advantages and disadvantages.

Table 5.1

Competing REBOA products

Product (Company)	Shaft size (Fr)	Minimal sheath (Fr)	Guidewire (inch)	Max diameter (mm)	Length (cm)
Reliant (Medtronic)	12/8	14/12	0,035/0,038	46/46	100/100
Coda Balloon (Cook Medical)	10/9	14/12	0,035/0,035	40/32	120/100-120
ResQ (QXMédical)	8	11	0,035	38	67
ER-REBOA (Prytime Medical)	6	7	Free	32	120
pREBOA PRO (Prytime Medical)	Unknown	Unknown	Unknown	Unknown	Unknown
Rescue Balloon (Tokai Medical)	7	7	0,025	40	80

Medtronic is an American company and is one of the biggest, if not the biggest, medical device company. Their REBOA product, Reliant should, according to Medtronic themselves, be able to “temporarily occlude large vessels or expand vascular prostheses” (Medtronic, 2021). Vascular prostheses, or stent grafts, are used in order to treat aneurysms in a through EVAR; endovascular aortic repair (Cleveland Clinic, 2019). As seen in table 5.1, the Reliant balloon has the biggest available balloon profile with a 12 Fr or 8 Fr catheter diameter.

The Coda balloon catheter also has the intention to be used for both temporary occlusion of large vessels as well as expansion of vascular prostheses. It is very similar to the Reliant balloon

in the measurements aspect, one of the two models has a 10 Fr catheter and the other a 9 Fr catheter (Cook Medical, 2016). In an interview conducted with J. Nordanstig (personal communication, April 17, 2022), Nordanstig states that even though he is a loyal Reliant user, he experiences that the Coda balloon is a little better at guiding thanks to the slightly smaller catheter.

QX Medical offers separate balloons for occlusion and expansion of vascular prostheses; the occlusion balloon, *ResQ*, is of smaller model with an 8 Fr catheter, and unlike previous products this balloon has an oblong shape instead of a spherical one. According to QX Medical themselves, the product is a "*catheter shaft uniquely designed in order to offer maximum stability during inflation thus minimizing possible migration*" (QX Medical, 2018).

Prytime Medical Devices is an US based medical device company that develops minimally invasive solutions for hemorrhage control. Since the start of the company in 2015, they have raised more than 25 million USD. They launched their ER-REBOA in 2016, followed by an updated version of the product in 2021 (Prytime Medical, 2022a). The ER-REBOA and the ER-REBOA plus, which is the second version, are both compatible with a 7 Fr introducer sheath. According to a Ruborg (2021), this could have had an impact on the degree of utilization since the expectation on vascular complications decreased with a lower sheath size. The study continues to elaborate on whether smaller sheath size has had an impact on the survival rate of the patients. It concludes that sheath size may have an positive impact regarding the survival rate from 0 hours to 24 hours after the injury, but the survival rate thereafter seems to be unchanged.

The differences between the ER-REBOA and the ER-REBOA plus are small and it is mainly a matter of design, such as the ER-REBOA plus has dual-side length markers to increase visibility for the surgeon. Length markers help the user to see how far the REBOA is introduced. There is a third version on its way from Prytime Medical, which will be called pREBOA PRO. The available information shows that it will have a semi-compliant balloon with flow channels which will allow partial blood occlusion (Prytime Medical, 2022b); pREBOA PRO is further presented in sub-section 5.1.3.

Tokai Medical Products is a Japanese company that launched the Rescue Balloon which was approved in Europe in 2020. This balloon is similar to the ER-REBOA, except that it requires a guidewire to place the balloon. Normally, the guidewire is slowly introduced through the sheath and real-time fluoroscopic guidance is used in order to confirm the positioning of the guidewire (Dong Hung et al., 2018). The same study indicates that the ER-REBOA catheter, which is a wireless system, may be more useful for field REBOA, such as in military medicine. Regarding size, the Rescue Balloon is also a low-profile occlusion balloon catheter and compatible with a 7 Fr sheath, however, a 8 Fr sheath is more appropriate for removal since it could get stuck otherwise (Onishi et al., 2019). Onishi also describes an overall issue with the smaller and less rigid catheters, the so-called loop formation.

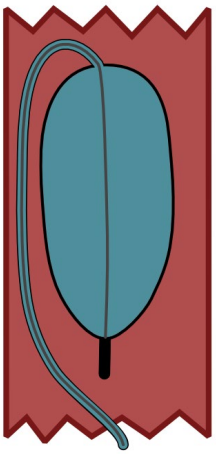

Figure 5.2
Schematic overview of loop formation during REBOA due to catheter kink.

The loop formation means that the catheter forms a circle above the balloon as seen in figure 5.2. The loop formation occurs due to high blood pressure that causes the balloon to migrate and flip downwards. As mentioned earlier, the rescue balloon requires a guidewire before the catheter is introduced. After the catheter is placed in the correct position, the guidewire is pulled out and replaced with a stiff stylet. This is done in order to prevent balloon migration (Chang et al., 2021). However, even with the stylet placed in a correct manner, Onishi et al (2019) experienced balloon migration. The study concludes that loop formation of this kind could lead to catastrophic bleeding and the weaker rigidity of the low-profile occlusion balloon catheters that causes the migration. Furthermore, it suggests that balloon position should always be monitored during REBOA.

5.1.2 Problems with existing products

In an interview conducted with the chief physician and vascular surgeon J. Nordanstig (personal communication, April 17, 2022), Nordanstig describes that the procedure for modeling stent grafts with a balloon is the same as when using it for occlusion in the aorta. Furthermore, Nordanstig explains this is the reason that the surgeons know the procedure at all since they conduct an EVAR approximately five times per month, which is more frequent than the number of times they use the balloon for circulatory collapse; however, the number of EVAR procedures have decreased since Nordanstig first started working as a surgeon. Nordanstig further says that he is a diligent user of the Reliant balloon and a reason behind this is the compliant properties the balloon has. This means that when the diameter of the balloon reaches the aortic diameter it grows in height instead of putting extra pressure on the vascular wall. Beyond the compliant properties the main reason behind Nordanstig's choice is his experience with the Reliant balloon; he knows exactly in which order the instruments enter the body and how the balloon behaves inside the vessels. Nordanstig explains that one sub-optimal aspect of the Reliant balloon is the necessity to perpetually fill the balloon with multiple syringes, since available syringes are insufficient for the balloon's total volume. Nordanstig

states that a larger syringe would solve this issue but syringes larger than 20 ml are uncommon in healthcare, and 20 ml is not even always enough.

When questioning J. Nordanstig (personal communication, April 17, 2022) and P. Skoog (personal communication, January 17, 2022) about general technical requirements, they say that a thicker catheter probably will lead to increased stability of the balloon and the risk for a loop formation will decrease since it is supposedly caused by a weak catheter. Both Skoog and Nordanstig claim that from a safety point of view there is not a problem working with catheter diameter such as 12 Fr since they are accustomed to the issue, as vascular surgeons. However, according to Nordanstig there might be an issue with larger catheters when placing the balloon transaxillary, due to the smaller vessels in the clavicle region. Another positive aspect of smaller catheters is that they would not require the need for a closure device, which is used to stop the bleeding from where the sheath introducer was inserted (S. Strömberg, personal communication, April 26, 2022). Regarding the profile height of the balloon, Nordanstig explains that when he uses the balloon in vascular surgery, he expects that it will occlude all the important visceral arteries. A balloon with a larger height would thus not be negative, but rather create a better vascular contact. Skoog has a different view and claims that the balloon should not exceed five centimeters in height, since the joint part of branched vascular prostheses are this long, and by putting pressure outside of the prosthesis might cause damage to the vascular walls.

When P. Skoog (personal communication, January 17, 2022) is asked if he has experienced balloon migration, he replies that it is a common occurrence. According to Skoog balloon migration has mainly occurred when a supportive introducer has been disregarded and inflation of the balloon did not happen fast enough; these factors, in combination with pressure from the blood, causes the balloon to migrate downwards. Skoog elaborates further on other unlikely events he has encountered; balloons have been inflated and when they have been taken down, the balloon material was stuck on the vascular prosthesis, which made an invasive surgery necessary. On another occasion, Skoog experienced that a catheter flexed and kinked, which made the team unable to deflate the balloon.

The main hindrance of REBOA today is the necessity of the multiple steps needed to place an occlusive balloon, according to J. Nordanstig (personal communication, April 17, 2022). For Nordanstig personally, this may not be a concerning issue, since he, as a vascular surgeon, practices the procedure every time he conducts an EVAR. However, Nordanstig believes that healthcare staff who work in an emergency room do not have this expertise. P. Skoog, on the other hand, recognizes the need for a supportive introducer as the main disadvantage with REBOA, since this adds an additional step and requires an enlarged transfemoral incision (personal communication, January 17, 2022).

5.1.3 Existing efforts to solve the issue

The project group at Sahlgrenska University, currently trying to develop λ, are not the first in their effort. In this subsection some existing efforts, with the intent to revolutionize REBOA, are presented.

The procedure, referred to in the study as REBOA, can also be referred to as c-REBOA, complete REBOA, since it completely occludes the aorta when the balloon is inflated (Heindl et al., 2020). This appellation is to be preferred when also discussing p-REBOA, partial REBOA, which according to Heindl et. al. is a very similar method, except for the fact that the balloon is inflated to titrate the proximal blood pressure to approximately 80-90 mmHg whilst observing the distal blood pressure to allow for distal perfusion.

Products that aim to simplify the p-REBOA procedure are entering the market at the time of the study; one such is Prytime Medical's pREBOA-PRO making use of a semi-compliant balloon and patented flow channels to let a small amount of blood pass the occlusive point (Prytime Medical, 2022b). Heindl et al. (2020) show through their study that partial REBOA has more favorable physiological effects than complete REBOA, as partial REBOA results in lower metabolic alterations, mortality, and long-term complications. The technical specifications of λ would classify the product as a p-REBOA solution as it partially occludes the aorta.

One existing product on the market is the Tri-Lobe Balloon Catheter from manufacturer GORE Medical, which is a balloon catheter designed for multiple endovascular procedures (GORE Medical, 2022). S. Strömberg (personal communication, April 26, 2022) explains that the Tri-Lobe consists of three separate balloons mounted on a catheter, allowing some blood to pass and only occludes at the very last moment of inflation. A sketch of GORE's Tri-Lobe is presented in figure 5.3.

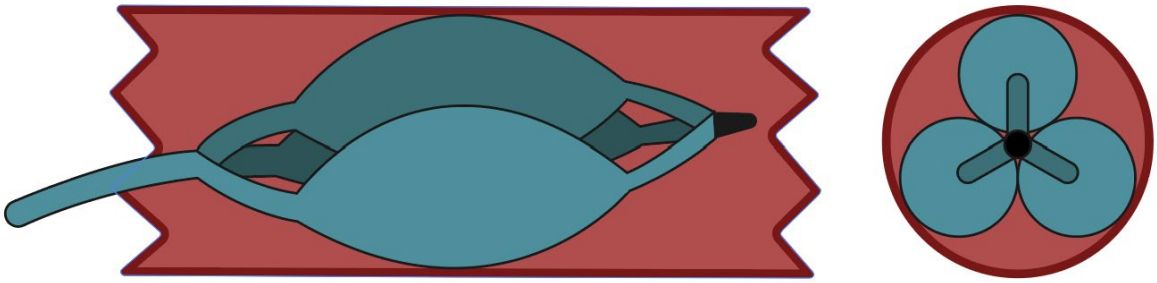

Figure 5.3
Sketch of GORE Medical's Tri-Lobe Balloon Catheter

Even though Tri-Lobe's main purpose is placing and modeling stent grafts (GORE Medical, 2022), Daniel et al. (2021) have studied the possibilities of using the Tri-Lobe catheter for p-REBOA. Daniel et al. performed their study on fifteen swine to investigate the complications of different REBOA procedures. The aorta was occluded using complete REBOA, a prototype

designed specifically for partial REBOA and GORE Medical's Tri-Lobe which main intended use is not REBOA. The rate of survival after two hours of occlusion was studied. After this time, 40% of the swine survived complete REBOA, 60% survived partial REBOA and 50% survived partial REBOA performed by the Tri-Lobe (Daniel et al., 2021). Furthermore, Daniel et al. (2021) sees the outcome of the study as an indication that GORE Medical's Tri-Lobe Balloon Catheter, even though it is not its main intended use, could be a commercially possible device for p-REBOA. S. Strömberg states that the Tri-Lobe is her favorite product for modeling stent grafts considering it does not occlude until the very last moment; Strömberg however explains that *Tri-Lobe* is inferior to Medtronic's *Reliant* when it comes to profile size as it needs a larger introducer sheath for insertion (personal communication, April 26, 2022).

5.1.4 Market

According to Swedvasc (2021), a registry of all vascular surgeries done in Sweden, the market has over some time been constant. However, this is speculated not to be due to increasing health, but rather due to better preventative screening methods (*Swedvasc*, 2021). With better screening methods, surgeons can schedule surgeries to prevent acute events in need of extensive surgery. In figure 5.1 below, a slight decrease in surgeries is shown. The slight decrease is partly due to COVID-19 since some non-acute scheduled surgeries were postponed due to the increased work-load (*Swedvasc,* 2021).

P. Skoog informs that at Sahlgrenska University Hospital, they perform, approximately, 80 endovascular procedures each year which require a balloon and an additional 12-15 circulatory collapses (REBOA). Skoog is one out of eight surgeons in the hospital who perform these procedures, which means that he does about 12 interventions with balloons each year. S. Axelsson (personal communication, April 26, 2022) informs that pricing between the different occlusion balloons differ a little but not much. Sahlgrenska University Hospital pays 2495 SEK for the Reliant balloon and 2214 SEK for the CODA balloon. For the remaining balloons there is no pricing data available.

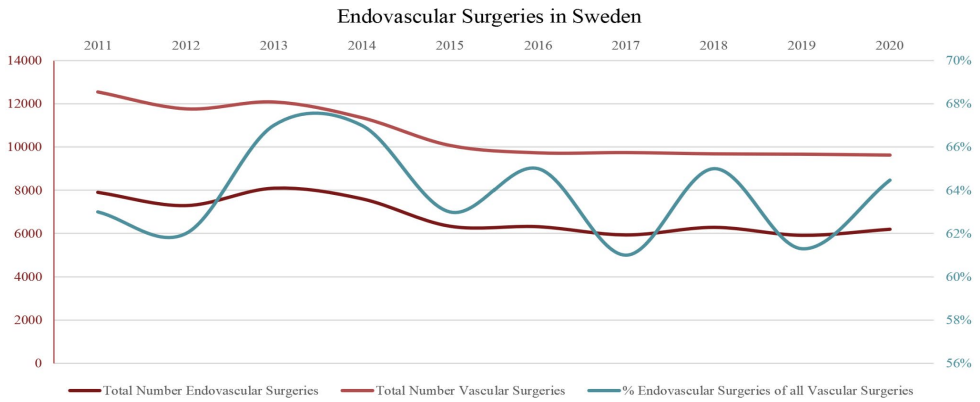

Figure 5.4

Registered vascular surgeries in Sweden 2011 - 2020 as well as how many of these were endovascular surgeries. Excluding varicose veins due to loss of data in first years (Swedvasc, 2021).

On the question whether environmental impact is taken into account before purchasing a product, Axelsson says yes. Environmental strategists are included in procurements that are environmentally prioritized. However, Axelsson clarifies that it is not possible to make demands that the market cannot maintain and one of the most important things with endovascular products is that the surgeon feels safe practicing with them.

5.1.5 COVID-19 pandemic and healthcare budgets

The COVID-19 pandemic has had an enormous impact on investments in innovation, some were paused and others were completely stopped (Am et al., 2020). Furthermore, the pandemic halted the acquisitions of new projects and events such as conferences, where ideas can be exchanged, were canceled (Schütt & Pabst, 2020). On the other hand, the crisis proved to be useful in that it gave new insights and new perspectives which stimulated solution finding and new innovations (Schütt & Pabst, 2020).

Aside from the global pandemic, the healthcare sector has recently experienced a worldwide rise of costs (Töteberg-Harms et al., 2017), and growth, particularly among medical devices (Lee et al., 2019). The authors also explain that a new market is being created for medical devices that integrate multidisciplinary technologies. Moreover, aging populations create a greater need for medical products which in turn increase the consumption of named products (van Baal et al., 2014). This results in the products increasing life expectancy which drives the spiral of medical product consumption forward (van Baal et al., 2014).

Roper and Turner (2020) have a different opinion on what we can expect in the coming years now after the COVID-19 pandemic. The authors compare the pandemic to the global financial crisis in 2008, and point to the fact that innovation was sharply reduced in the following years of recession, due to - but not limited to, firms being financially constrained (Roper & Turner, 2020).

S. Axelsson (personal communication, April 26, 2022) points out that economic cycles are not a factor which affects procurements. Axelsson further explains that medical products needed for healthcare will be procured even in times of recession-induced shortages and price surges to supply necessary products for a sufficient healthcare.

5.2 REBOA tomorrow

In section 5.2 sentiments on multiple possible futures for REBOA are studied through literature and interviews. The potential market for λ is studied by presenting the interview results regarding λ and its features.

5.2.1 Research's thoughts of REBOA's future

REBOA is a heavily studied and discussed subject as of today (March of 2022). Using the keyword *REBOA* when searching Google Scholar results in 148 results published during the first two and a half months of 2022 alone, the total being 4700 when no limit is set to the release date. With this much research on the subject naturally, there are also many opinions on where the procedure is headed and what research and development should focus on when evolving the procedure further in the future. Sub-section 5.2.1 aims to bring many of these opinions to the surface.

Thrailkill et al. (2021) believe that the number one priority of future REBOA research should be developing more efficient vascular access devices. Considering the difficulty in diagnosing the presence of circulatory collapse, especially from blunt trauma, a more time efficient vessel cannulation would allow the REBOA procedure to begin faster once the hemorrhagic shock has been diagnosed. A more efficient vascular access device would also simplify the process overall when it is performed by a inexperienced physician, in a stressful situation with substandard visualization equipment (Thrailkill et al, 2021). According to J. Nordanstig (personal communication, April 17, 2022) the biggest issue concerning the current design of the available occlusion balloons is the fact that the occlusion procedure consists of too many steps and the fact that when treating an unstable patient, the procedure feels very time consuming even though the time consumed is only a couple of minutes.

Ribeiro Junior et al. (2018) state that ischemia caused by total aortic occlusion is the main limitation of REBOA and that occlusion exceeding 40 minutes even can lead to lethal outcomes. Therefore, technology which minimizes risk of ischemia injuries below the balloon is necessary for safer REBOA use in the future (Thrailkill et al., 2021). According to P. Skoog (personal communication, January 17, 2022) the optimal scenario would be allowing a small amount of blood to flow through while maintaining vessel wall contact and still achieving the expected effects from the occlusion.

Williams et al. (2019) have previously developed and tested a computer-controlled extracorporeal flow circuit which was meant to be capable of precision aortic flow regulation. However, according to the authors, this approach was not clinically applicable. Instead, they developed a technology they call the first endovascular variable aortic control (EVAC) which during tests in swine was able to effectively maintain precise aortic flow, better than what is possible through manual control. According to Williams et al. (2019), future development of REBOA should focus on evolving this technology into a state where it is fully clinically

applicable allowing precise aortic control, mainly through further development of the balloon control algorithms.

Thrailkill et al. (2021) believe that directed practice for physicians who may perform REBOA is necessary. However, Hilbert-Carius (2020) claims that who is performing the REBOA does not necessarily affect the outcome in a substantial way and that the future focus should be which patients benefit the most from REBOA rather than who is performing REBOA. According to Brenner et al. (2020) there are currently no high-quality, multicenter, randomized controlled trials of REBOA which implies that there have not existed any possibilities to identify the optimal REBOA patient. Therefore, Brenner et al (2020) claim that future research should aim to pinpoint this patient.

Thrailkill et al. (2021) believe that improved visualization technology during REBOA is vital for evolution of the procedure. Wessels et al. (2018) show that using RFID-tags to achieve correct balloon placement in the aorta works well in zone I of the aorta. Ogura et al. (2018) show that it is possible to perform REBOA using ultrasound which is positive since it eliminates the transportation of the patient to the radiology department for fluoroscopy. According to Smith et al. (2017) ultrasound is the most attractive technique to use when performing REBOA in combat, one reason being the fact that ultrasound is a technology which military physicians are already familiar with.

Thrailkill et al. (2021) claim that another way forward is animal studies on REBOA technology which must be performed in a way which imitates a blunt or penetrating human injury in the closest way possible. Upon this criteria extra focus should also be long term follow-up after the animal operation making sure no complications have occurred after the intervention.

To sum up the sub-section there are multiple views and no clear answer to where development focus should be located to evolve the REBOA technology in the best way possible. In the following sub-section λ and its features are studied through interviews which may provide a clearer vision of the possible future for REBOA.

5.2.2 Physicians' thoughts of REBOA's future

When asked about if he believes REBOA has a future within trauma treatment J. Nordanstig (personal communication, April 17, 2022) states that he is doubtful, considering the fact that getting control of the blood flow is important. But what happens after the occlusion is just as important - making REBOA is a double-edged sword as it successfully provides blood flow control but risks blocking important vessels causing future complications.

P. Skoog (personal communication, April 17, 2022) believes that REBOA has a future considering the fact the procedure is minimally invasive and has the potential to save lives; what is causing the controversy of REBOA today is lack of solid research which supports the procedure. Skoog further explains that solid research is missing since generally written consent

is needed from the research objects and in many REBOA usage cases the research subjects are bleeding to death.

The belief of J. Nordanstig (personal communication, April 17, 2022) is that REBOA equipment would benefit from being sold as a kit, with the kit containing all equipment necessary for performing the REBOA procedure. Nordanstig explains that this would facilitate physicians not performing REBOA often by letting them know that this, and only this, is what you are expected to perform the occlusion with. P. Skoog (personal communication, April 17, 2022) confirms that there is a difference in experience between different physicians when it comes to collecting the equipment necessary for REBOA. Skoog also emphasizes that an illustration or drawing of the product printed on the package is beneficial.

M. Aivaz Ihari (personal communication, April 25, 2022) further emphasizes the importance of evident usage of the REBOA product; she believes a kit-based product would make the process easier primarily for the nurses. Aivaz Ihari imagines a REBOA kit where the components are named A, B, C and so forth; where, if a nurse follows the alphabetical order, he or she will without mistake provide the correct component to the physician. S. Strömberg (personal communication, April 26, 2022) further emphasizes the benefits of a kit-based REBOA product which makes it possible for nurses without major competence within the field to collect the necessary gear as this gives the surgeon more time to evaluate the patient. Strömberg also claims that classic box packages are preferable over hanging packages, if this is possible without compromising the balloon's strength, as this enables more efficient and clear storage possibilities.

J. Nordanstig (personal communication, April 17, 2022) speculates that many probably have thought about developing a product dedicated for REBOA as its single purpose, making it as easy and intuitive as possible when needed. However, Nordanstig continues by explaining that a product like this probably would not be a bestseller but instead something physicians would appreciate having on the shelf; but if physicians at every hospital in the world would think like this there would exist a market even though the product in itself is not a bestseller by definition.

When asked if she has ever used a balloon catheter without guide wire need, such as Prytime Medical's ER-REBOA, S. Strömberg (personal communication, April 26, 2022) answers that she has once but does not see the need for eliminating the guidewire. According to Strömberg placing the guidewire is not an issue during the procedure and not something worth removing when developing a new product.

In contrast, M. Aivaz Ihari (personal communication, April 25, 2022) believes that when developing a REBOA catheter the utmost important aspect is that the procedure is simplified; possibly by eliminating one of the many steps necessary today, still making sure that every step works just as intended. Aivaz Ihari explains that this aspect is general, but even more important if the product's target users are not only vascular surgeons. However, when informed that if λ succeeds, it is not simply the usual balloon catheter, Aivaz Ihari says that believes in this kind of innovative thinking saying that one must aim high.

According to J. Nordanstig (personal communication, April 17, 2022) when placing the REBOA balloon blindly without fluoroscopy, as is possible with the Medtronic's Reliant, it would be beneficial to have sensors detecting that you are actually proceeding up the aorta and not down through the other leg which can happen. Nordanstig explains that eliminating the transillumination procedure would be useful, however, it is not preferable without substituting techniques for identifying the balloon's current position in the aorta.

S. Strömberg (personal communication, April 26, 2022) believes that the controversy REBOA causes is rooted in the fact that many believe that the procedure is a flawless lifesaver. However, according to Strömberg, even though REBOA saves lives it often brings complications such as ischemia which can lead to mortality further down the road. Strömberg emphasizes the importance of a general understanding of REBOA, the fact that rather than REBOA being a lifesaver it is a crucial aid to help anesthesia catch up while at the same time working on the source of bleeding; making it more of a helper than a revolutionizing lifesaver in itself. The belief of Strömberg is that if a general understanding of REBOA's true role within trauma treatment is achieved, making the risk of ischemia more well known, REBOA has potential of growing in the future. According to Strömberg this would require research from countries with more trauma cases than Sweden, education and ease of use in the product itself.

5.2.3 The new product, λ

As mentioned earlier, λ aims to revolutionize the REBOA procedure by reducing the risk of complications such as brain hemorrhage and ischemia injuries by letting a relevant amount of blood pass the occlusion point in the aorta. It also aims to eliminate the risk of catheter kink due to the force applied by blood on top of the balloon before it has established vascular contact for stabilization. The respondents in the interview study were asked multiple questions regarding whether a product like λ could be the solution to the current issues of REBOA. The results of the study are presented in this section.

When presented with the possible features of λ, Nordanstig explains that such features in a new product are very appealing since every minute of the REBOA procedure matters; the possibility of letting some amount of blood pass the occlusive point, reaching vital visceral arteries and organs during occlusion, regardless of access point, would be optimal. M. Aivaz Ihari (personal communication, April 25, 2022) also responds positively when presented with the possible features of λ, specifically the fact that the visceral vessels are not occluded by the balloon.

To S. Strömberg (personal communication, April 26, 2022) a REBOA product preferably also can be used when placing stent grafts, which makes the elimination of balloon migration even more important when developing a new REBOA product. Strömberg explains that one of the worst kinds of failure she has experienced is when molding a stent graft using a balloon, the balloon gets swept away by the bloodstream causing the stent graft to migrate as well hurting the vessel wall. Strömberg means that, given this information, if λ can mold stent grafts while letting blood pass through that would be an optimal design. P. Skoog (personal communication,

April 17, 2022) says that a dedicated REBOA must also be able to perform other cardiovascular procedures to make the physicians used to the product considering REBOA is not a procedure performed often.

S. Strömberg (personal communication, April 26, 2022) believes that if one is to develop a product and compete with the enormous already existing range of endovascular products, one must be a visionary and think outside the box; maybe using new technologies such as 3D-technology or combining already existing technologies. However, Strömberg emphasizes that one of the most important aspects of launching a new product is that it is properly tested and has research published around it; the presence of studies is very important for clinicians.

5.2.4 Entrance barriers for new products

J. Nordanstig (personal communication, April 17, 2022) explains that after experiencing a balloon rapture when testing the Tokai balloon, he has become more conservative and resistant to trying new REBOA balloons and instead continues using Medtronic's Reliant since it feels thick, stable and generally more unbreakable. Nordanstig explains that what makes him feel safe using a balloon is how certain he is of the multiple steps, in other words how much experience he has of using the product.

P. Skoog (personal communication, April 17, 2022) lists what is important when introducing a new product to physicians; intuitive usage, performance as expected and the possibility to practice using the product. Skoog explains that the latter is not as common as one would believe, in many cases physicians do not get to try new products in safe environments and instead must debut during operation. Therefore, according to Skoog, when marketing a new product to a hospital one should require from the hospital that the physicians get proper training in using the product to eliminate the risk of disliking it due to unfamiliarity.

To be able to launch a new product within the medical field, the product has to be CE-marked. It is the manufacturer who places the CE-mark on the product but to do so it has to undergo a conformity assessment (EMA, 2022). In 2021, the new Medical Device Regulation (MDR) entered into application, replacing the old directive which was introduced in 1993. In general, the new directive requires tightening requirements on manufacturers in terms of quality control and traceability. Products which were placed during the old directive will have a 5-year transition period during which they will have to fulfill the requirements from the new directive (EMA, 2022).

5.2.5 Potential market

S. Axelsson (personal communication, April 26, 2022), who works as a material consultant within purchase at Västra Götalandsregionen, explains that in her role it is necessary to understand different technologies and what the doctors value, as well as evaluating different options economically. Axelsson says that when launching a new medical product, it is important that one knows that there is a need and a market for it; it is also positive if material consultants at the purchase departments of hospitals, such as herself, are aware of the product.

Axelsson says that often knowledge of useful products is spread internally in the buying organizations.

S. Axelsson (personal communication, April 26, 2022) explains that before purchasing a new product several different should- and shall requirements are determined by the users. Axelsson explains that should requirements are properties that the product must meet and shall requirements are properties that the product preferably should meet; below the should- and shall requirements for occlusion balloons are presented in table 5.2.

Table 5.2

Should- and shall requirements for occlusion balloons (S. Axelsson, personal communication, April 26, 2022).

Should	Shall
Be able to expand stents	Good passability
Be able to occlude the aorta	Low profile and compatible with several introducer brands
Be compatible with a 0,35-inch wire	Quick inflation and deflation
The balloon must be of compliant material	Good rewrap
Well visible x-ray markings	Easy to open packaging
At least 40mm in diameter	Good description

S. Axelsson (personal communication, April 26, 2022) explains that a product which solves problems that are not included in the should- and shall requirements can end up in their own category; in this way the product might not compete in price with existing products. What the value would be if one manages to solve the problems associated with REBOA, Axelsson does not want to speculate. Axelsson draws a parallel to when the first stent for coronary vessels was launched on the market, the price at that time was approximately 20 times higher than what the procured price is today. According to Axelsson, the high initial price is explained by the fact that it was in its own category and did not compete with other products; later, the competition increased which led to a decrease in price.

S. Axelsson (personal communication, April 26, 2022) informs that the duration for an agreement, once a procurement has been won, is four years. During this period, competing products cannot win a procurement in the same category, which means that competitors must wait until they have a chance to win the next rounds of procurements. P. Skoog (personal communication, April 17, 2022) and S. Strömberg (personal communication, April 26, 2022) explain that they, as vascular surgeons, have a large impact on which products are procured as they take part in the purchasing process; however, too high of a price can override the surgeons' opinions as it is not economically feasible.

5.2.6 United Nations' sustainable development goals

The United Nations have 17 sustainability goals (2018e), in this subsection five of these goals, which may be relevant for REBOA development, are presented. How they can be handled in the case of λ is analyzed in the analysis.

Goal 3 consists of ensuring healthy lives and promoting well-being for all, at all ages, partly by promoting efficient healthcare for everyone (United Nations, 2018b). Goal 5 consists of ensuring gender equality, with one of the targets being ending all discrimination against women and girls everywhere (United Nations, 2021). Goal 8 consists of providing decent work and economic growth, with targets such as promoting policies supporting job creation and growing enterprises (United Nations, 2018a). Goal 9 consists of building resilient infrastructure, promoting sustainable industrialization and fostering innovation with targets such as enhancing research and promoting inclusive and sustainable industrialization. (United Nations, 2018d). Lastly, goal 12 consists of ensuring responsible consumption and production, with goals such as having sustainable management and use of natural resources (United Nations, 2018c).

5.3 Chapter summary

Sections 5.1 and 5.2 have presented empirical information regarding the present and future of REBOA; through manufacturer websites, existing research and interviews with respondents within the field. This information is essentially the core of the study.

There are already many REBOA products on the market, each with their own advantages and disadvantages. There are also products dedicated to partial REBOA on the rise, allowing for some blood to pass the occlusion point without doing this work manually by controlling the inflation of the balloon. Regarding the future of REBOA there are many opinions, both among users but research as well. At the same time, vascular surgeons claim that there is not enough research available in Sweden since the procedure is often performed under traumatic situations where the research subjects are bleeding to death; making it difficult to receive a signature of approval.

To make sense of all the empirical information presented in chapter 5, and later allowing the research questions to be answered and fulfilling the study's purpose, the information is analyzed through the analytical framework presented in chapter 3. This means that the information is analyzed through macro, meso and micro perspectives respectively. The analysis is performed in chapter 6, following on the next page.

6 Analysis

In this section the empirical information from section 5 is analyzed according to the analytical framework developed in section 4 to answer the research questions presented in section 1. This means that the empirical information is analyzed through macro, meso and micro level perspective respectively.

6.1 Macro level analysis

In this section macro-level factors presented in section 5 are analyzed through a PSTSL-framework as described in chapter 3.

6.1.1 Political factors

Varied healthcare budgets are something that directly can affect the potential market and usage of λ. As stated by P. Skoog and S. Strömberg, that they, as vascular surgeons, have a large impact on which products are purchased as they are part of the purchasing process. However, if the price of the product is not economically defensible the procurement of the product will not be attainable. This creates the need for λ to be able to compete in terms of price to even be considered. This need could however potentially be disregarded if λ manages to create a new market. S. Axelsson mentions the first stent for coronary vessels which launched at the time of a price approximately 20 times higher than today. Consequently, managing to create an entirely new or sub-market could potentially lead to more price flexibility for λ.

Acquisition in the public sector in Sweden is done through procurement instead of purchasing which adds the need for it to be transparent. Suppliers must be equally treated, no discrimination should occur, and social considerations is to be taken into account to name a few (Richardson et al., 2022). This does not necessarily create a problem, but a hindrance since the process of selling the product is not as straightforward as it would be if the customer would not purchase directly. Customers using direct purchasing could potentially be a possibility. However, since this report limits itself to the Swedish market, these cases will not be analyzed. The Swedish National Agency for Public Procurement states that public procurements take longer than private purchases. Different rules and legislations are also applied based on the monetary size of transactions (*Upphandlingsmyndigheten*, 2022). Considering these factors, it becomes clear that entering the market with current regulations is a difficult and long process.

6.1.2 Economical factors

Relative to numerous other products and types of medical equipment, endovascular balloons are a small market. Figure 5.4 shows that the total number of registered endovascular surgeries in Sweden from 2011-2020 varies between approx. 8.000 and approx. 6.000. At Sahlgrenska University Hospital, they perform, approximately, 80 endovascular procedures each year which require a balloon, P. Skoog. This relatively small market size potentially creates the need for λ

to be procured or purchased by other companies or countries other than Sweden to make it financially sustainable.

6.1.3 Social factors

Since the vascular surgeons will be the main user of λ, it will be important to gain acceptance in this group. This said, it is incredibly hard to gain an overall view of every surgeon's opinion on the matter which makes these requirements extremely difficult to bring to light. However, J. Nordanstig (personal communication, April 17, 2022) says that the many steps required to place the balloon is the biggest problem with REBOA today. Nordanstig explains that he got experience in the procedure which makes it less of an issue for him personally, but he believes healthcare staff in emergency rooms does not possess this expertise. Moreover, M. Aivaz Ihari (personal communication, April 25, 2022) believes that when developing a REBOA catheter the utmost important aspect is that the procedure is simplified. Considering the use case of REBOA in traumatic bleeding in the thorax region it could be a very valid point. Cases where REBOA could be of use to stabilize a patient can of course occur without experienced surgeons or advanced medical equipment nearby. Therefore, there could be a potential market for a product which simplifies the process, making it easier to use without proper experience or equipment.

6.1.4 Technological factors

The ease of use of the product is of vital importance for the innovation's performance. If users cannot handle the product's peculiarity, the market will be non-existent. Hence, technological advancements to improve and simplify the product is essential. As stated by Thrailkill et al. (2021), improvements in medical visualization technology is vital for the evolution of REBOA as a procedure. New advancements could potentially create markets for innovative products which make use of the new technological advancements. Ogura et al. (2018) show that it is possible to perform REBOA using ultrasound, which is positive, since it eliminates the transportation of the patient to the radiology department for fluoroscopy. If λ could take advantage of different locating techniques other than fluoroscopy, then there is a possibility for λ to be more appealing as a product. Smith et al. (2017) mentions that ultrasound is an attractive technique when performing REBOA in combat since military physicians are already familiar with this technique. Taking this into consideration, together with other techniques such as using RFID-tags to achieve correct balloon placements in zone I of the aorta as shown by Wessels et al. (2018), an expanded market could be achievable for λ if it can make use of these techniques. Similarly, if λ could make use of technical advancements not mentioned, innovative performances would make the product appealing to the market.

6.1.5 Sustainable factors

The sustainability aspects of this section cover both ethical- and environmental sustainability. Ethical sustainability is a difficult subject to approach since it is both hard to define and research. However, it is central to understand that λ is a product that could potentially cause harm if used incorrectly. J. Nordanstig (personal communication, April 17, 2022) explains that

after experiencing a balloon rapture when testing the Tokai balloon, he has become more conservative and hesitant to try new REBOA products. This could be seen as an ethical approach, since comfort in using the product can generate better results. Nordanstig further explains that experience is key in feeling safe using the product. Assuming other surgeons and physicians also feel this way, then comfort and ergonomics of use is a high priority to enable λ to be accepted by the market.

This could possibly be done through supplying practice equipment together with λ. P. Skoog (personal communication, April 17, 2022) explains that in many cases physicians do not get to try new products in safe environments and instead must debut during operation. This can understandably create uncertainties for users, which results in them gravitating towards equipment they are more comfortable with. Creating functional practice equipment to make the learning curve of λ less steep and the adoption process as smooth as possible can be seen as a critical factor. Without sufficient efforts in making λ attractive to new users creates an increased risk of not being accepted by new users.

The environmental aspect of λ has been clarified to not be the main scope of this report. However, it cannot be totally disregarded. S. Axelsson (personal communication, April 26, 2022) explains that environmental strategists are included in procurement processes, but the most important thing is surgeons feeling safe operating with the equipment procured. Hence, the focus on the environmental aspects should probably not be of highest priority, instead the overall image of how safe and easy to use the product is.

A measure to fulfill the United Nations' third goal is extensive funding to healthcare. With more money it is possible to treat more patients as well as fund new medical technology. Therefore, it is an interesting aspect to discuss how an innovator can benefit from the UN's intentions to improve healthcare when introducing a new product to the market. The United Nation's fifth goal can be considered by developing the innovation for both genders to ensure safe treatment, regardless of gender. P. Skoog (personal communication, April 17, 2022) explains that the aorta in women is smaller than the aorta in men, which is an important aspect to have in mind when developing a new REBOA product.

The eighth goal of the United Nations' can be contributed to by the development of REBOA product as it can bring work and economic growth over time. However, decent working conditions are important, not least for production workers. Ensuring these conditions is important for the wellbeing of workers but also a more qualitative product in the future. The ninth goal of the United Nations is central both during the development and the production of REBOA-products as it is important choosing as sustainable materials as possible, for patients as well as manufacturers. Another important aspect of the ninth goal is trying to use sustainability as a performance index during development. In the case of REBOA products which are of one time use, United Nations' twelfth goal can be fulfilled mainly by reducing waste during production since many units are produced.

6.1.6 Legal factors

To be able to launch a new product within the medical field, the product must be CE-marked. It is the manufacturer who places the CE-mark on the product but to do so it has to undergo a conformity assessment (EMA, 2022). This process has the potential to drag out over an extensive period of time and become costly. Certification also brings an uncertain aspect since the outcome could be that the medical device does not fulfill the requirements. Moreover, there is always the risk of a similar product undergoing the certification process, or a patent process, whilst λ still being developed. This could create a temporary monopoly making it difficult for λ to be adopted upon certification since there is already a similar product which every surgeon and physician are familiar with.

6.2 Meso level analysis

In this section, meso-level factors, presented in chapter 5, are analyzed through Porters' Five Forces. The meso-level will present a perspective which aims to describe both the local and broad environment in terms of customers, suppliers and competitors to name a few, for a hypothetical producer of λ. The meso-level factors overlap between the macro and micro levels and therefore intends to describe the interplay between macro- and micro-levels and how this affects the meso-level.

Porter describes the forces in the context of a firm already on the market. Since λ is in the process of being launched, this paper will aim to use Porter's model from the perspective of a firm which prepares to enter the market. Therefore, the forces will have different consequences than for an established firm. An example of this is the first force, the threat of new entrants. A high threat of entrants would be in favor of λ, when preparing to enter, since it signifies undemanding entry-conditions. However, a high threat of entrants would be a drawback when λ is established on the market, seeing that the risk of new competitors is high.

6.2.1 Threat of new entrants

Often when entering a market, an actor must overcome certain obstacles to have a profitable business. Michael E. Porter brings up several hurdles, among these are big capital requirements, regulatory requirements and incumbency advantages (Porter, 1979) which are identified as the most impactful underlying factors for the first force, in the potential market for λ.

As detailed by Porter, developing any new product requires capital to fund facilities, research, development, build up inventories and to fund startup losses (Porter, 2008). Furthermore, medical devices often use interdisciplinary technologies which require even more expertise and research as a consequence of the various fields. Other factors, which increase the need of capital to launch a medical product successfully, are the regulations for both manufacturing and clinical tests of devices, along with the hesitance among hospitals to use new products (Lee et al., 2019).

The effect of these elements on the capital needed can be seen in how Prytime Medical Devices (PMD) needed to raise $25 million since the start of their business in 2015. Despite the lack of information regarding funding for the other producers in table 5.1, previous studies (Mas & Hsueh, 2017) and data from PMD suggests that capital requirements can be a difficult hurdle for small ventures to overcome. This will probably be an obstacle for λ before entering the market, but if the launch is successful, this obstacle will most likely be in its favor by hindering other newcomers in the market.

Figure 5.4 suggests that industry growth is slow, therefore newcomers can only gain volume by removing from the incumbents, as Porter (2008) describes it. This implies a good opportunity for λ but subsequently a threat, when λ can secure a position on the market.

To enter a market where the main customers are in the public sector, one must be familiar with the strict demands on transparency and integrity on the product supplier (Stentoft Arlbjørn & Vagn Freytag, 2012). In addition to this, an entrant in the Swedish medical market must comply with a conformity assessment in order to be able to CE-mark the product which is required by all customers of healthcare equipment. Furthermore, the requirements on quality and traceability have recently been elevated (EMA, 2022) which puts even more demand on a potential entrant.

Moreover, a new entrant in the medical market must also consider which requirements are demanded by the individual customer, i.e. material consultants working for hospitals and healthcare regions, and the actual users i.e. medical doctors and healthcare staff who influence the above mentioned customer. S. Axelsson presents (personal communication, April 26, 2022) a variety of properties which must be met by a new product along with properties, which are preferred if met. These types of requirements and preferences should therefore be considered and measures undertaken by the producer to meet them in order to maximize chances of being selected as a supplier.

In summary, to successfully launch λ, familiarity with public procurement processes in the healthcare sector is central. In other words, knowledge about how procurement contracts work, what conformities must be met, what the requirements are on quality and the different properties which are valued by the final user, must all be attained.

Another aspect which can prove a barrier for new entrants in the market is incumbency advantages for existing actors and their products (Porter, 2008). Among others, Porter highlights the advantages of being recognized as a brand. J. Nordanstig explains in his interview that he prefers the *Reliant* REBOA product from Medtronic over others because of the familiarity of the product. New producers of REBOA products may have the same components and the same order in which they should be used, but users will probably still prefer products with which they are familiar. This illustrates the difficulty for newcomers to gain market shares.

6.2.2 Threat of substitutes

P. Skoog (personal communication, April 17, 2022) states that physicians rarely have time to practice with new products and sometimes find themselves in situations where they use products for the first time when conducting surgery. He further explains that a product should be both simple and intuitive to use. J. Nordanstig elaborates on this topic and states that cumulative experience with REBOA products is crucial and explains that his reason for choosing one product over another is his level of familiarity. In the same vein, M. Aivaz Ihari points out that she prefers products with which she is most accustomed to. As stated by S. Strömberg (personal communication, April 26, 2022) physicians have a substantial impact on what REBOA products are purchased. Having this in mind, along with the statements from physicians mentioned above, one can argue that the greatest threat for REBOA products is the risk of being replaced with another which the physicians are more acquainted with. Simultaneously, this points out how essential it is for REBOA products to strive for simplicity in order to ease the use for unacquainted physicians, which in turn increases the chances of them taking a liking to the product and continuing to use it.

Thrailkill et al. (2021) describes that current REBOA products could be more time efficient. Solving this would both allow the procedure to begin faster and streamline the overall process, leading to more ease of use for physicians unaccustomed with the process. Therefore, the optimal strategy for an innovator of λ, would be to construct a product which is substantially more time efficient than the competitors' products. Furthermore, the innovator should strive to continuously improve the product to constantly be the market leader when it comes to time efficiency to minimize the risk of being substituted.

6.2.3 Bargaining power of customers

As previously stated, physicians prefer REBOA products that they are most familiar with. Although there is a preference when it comes to familiarity, S. Strömberg states that it is hard to notice any difference between the respective components of different products. One may therefore conclude that current REBOA products are fairly similar, but preferences among physicians are still existent. Furthermore, the procurement of similar products, which all satisfy the should-demands, will be competing by price complementary to the physicians demands (S. Axelsson, personal communication, April 26, 2022). Nevertheless, it seems that the physician's preferences is what mostly governs the purchaser's decisions if the products meet the should-requirements.

Although price sometimes becomes the determining factor, Axelsson further explains that products which fall in their own category, i.e., products which do not compete with other producers for contracts, will sometimes be purchased above the price of similar product categories which do not meet the new should-requirements. Albeit everything in dialogue with the hospitals.

Furthermore, Axelsson explains that the pricing for the Reliant and CODA balloons are at a similar level. No information is given about the price for the other balloons in table 5.1,

nonetheless, considering that their components are fairly similar, one could argue that there is not a significant difference in prices among the other products as well.

To summarize, there is some price sensitivity for REBOA products, but it is hard to pinpoint to what degree. Their prices are similar as well as their function, to an extent. As mentioned in previous sections, physicians have a substantial impact on what products are purchased but a too big price can deter customers from choosing the product. For λ, this suggests that a somewhat higher price point than the competitors could be viable, as long as the product is simplistic in its nature and intuitive to use, which would lead to a preference for λ among physicians over the other products.

Another factor to consider when it comes to the bargaining power of customers is how the switching costs affect the customer's choice of products. In this area, there is a certain dilemma. On one hand, P. Skoog brings up that there are multiple occasions where physicians come in contact with medical tools with which they have no prior experience. With no prior experience, there should not be any preferences of REBOA products. This in turn could lead to lower switching costs. On the other hand, S. Strömberg declares that physicians have a significant impact on what products are purchased. Therefore, with physicians having prior experience with a product, the customer will have learned how to use the product and consequently prefer it over others, as pointed out by J. Nordanstig.

The nature of public contracts also affects the switching costs for a product. S. Axelsson details that contracts are written for 4-year periods. During a contract period, one producer and their product have in essence a monopoly in a hospital or healthcare region. This leads to 4 years where physicians in a hospital will get accustomed to a specific product and therefore leading to higher switching costs.

The switching costs are therefore on the higher side which could impede the launch of λ. On the other hand, if the launch is successful and the product can penetrate the market, the higher switching costs would be in favor of λ. This is of course only as long as the contracts are won by getting the physicians to prefer the product and by winning the procurement contracts.

6.2.4 Bargaining power of suppliers

Looking at table 5.1, there seems to be minor differences between the function of the various REBOA products. Physicians also seem to agree with this as stated by S. Strömberg (personal communication, April 26, 2022). Adding to this is the fact that all REBOA products essentially solve the existing problem in the same way, by blocking off the aorta by inflating some sort of a balloon. These types of non- or minimally differentiated products among suppliers are what Porter defines as a factor which weaken the bargaining power of suppliers (Porter, 2008).

However, there isn't any other alternative that can solve the same problem as REBOA products do, apart from resuscitative thoracotomy which falls outside the paper's scope. Therefore, it is concluded that the bargaining power of suppliers is ambiguous, meaning that it neither

strengthens or weakens the position of current REBOA producers. The nonalignment of the suppliers' bargaining power so to speak, could be positive for λ. By introducing a unique and differentiated product, the bargaining power of λ would be high.

6.2.5 Competitive rivalry

In recent years, the healthcare sector has experienced a steady rise of costs (Töteberg-Harms et al., 2017), which also indicates bigger healthcare budgets, and the continuous rise of life expectancies suggests that this trend will continue. van Baal et al. points out that there is a sort of self-driving force in the consumption of medical products (van Baal et al., 2014). This is due to the fact that the increased consumption of medical products leads to increased longevity which then in turn further increases longevity. This signals for higher competitive rivalry among producers of REBOA products since higher budgets could lead to higher returns. The higher rivalry could in turn make it harder for λ to gain market shares. But at the same time, higher healthcare budgets could be a golden opportunity to develop a REBOA product in the coming years, considering that healthcare providers will most likely spend more on medical products.

Synchronously with more spending comes the fact that more than one million incompressible bleedings occur globally every year. With higher healthcare budgets worldwide, this offers a good chance for higher volumes internationally for λ.

The fact remains that during the pandemic, many investments in all areas of innovation have either paused or stopped completely (Am et al., 2020). Along with this comes the fact that many opportunities for the exchange of ideas, i.e., conferences and events, were canceled. Inversely, the crisis came with positive changes in the form of giving people new insights by forcing them to find new solutions to problems (Schütt & Pabst, 2020). With the recent rise of costs in the healthcare sector (Töteberg-Harms et al., 2017) one can safely assume that budgets will follow and also grow larger. Larger budgets, along with the other factors mentioned above, could prove to be an optimal climate for new medical innovations to enter the market. Stopped and paused investments will probably be continued, occasions for exchange of ideas will be resumed and together with new insights gained, indicates good chances for λ to enter the market.

At the same time, competitors already present on the market will probably also experience good economic opportunities going forward. To summarize, it is hard to pinpoint if the competitors or the producer of λ will gain the most from this economic climate, but considering that the consumption of healthcare products is consistently rising, it is fair to assume that both sides will benefit from it.

6.3 Micro level analysis

In this section micro-level factors presented in chapter 5 are analyzed through an extensive SWOT analysis. However, as described in section 3.4, the external forces, opportunities and

threats, are not micro-level and have therefore been treated in previous sections. Hence, this part focuses on the internal factors, strengths and weaknesses.

The main strength of λ is its technological superiority over the already existing products. As presented in section 5, none of the products present on the market satisfy all different needs which entails possibilities. If λ solves the current issues regarding REBOA it will include features outside of the current should and shall requirements of occlusion balloons, therefore placing it in its own category. This means that λ competes with technical performance rather than price if all features specified are achieved. As mentioned in sub-section 5.2.3, λ will be able to regulate the blood flow in a controlled manner by letting a sufficient amount of blood flow past the occlusion point in the aorta. When the surgeons were asked if such a property would be interesting, the answer was positive. The partial-flow property seems to be very attractive which suggests that λ would be well received and that the doctors might change their should and shall requirements. If λ is the only product which can fulfill such requirements it can lead to a monopoly position for the product. λ aims to have a higher stability than the existing products and while stability is not a stated requirement, a 0.035 inch wire is. The wire is in turn used for both guiding as well as stability which suggests that stability is one of the should requirements. By meeting the should requirements to a higher degree, the selling company can gain an advantage over the competitors and demand a higher price for its product.

On the other hand, one of λ's weaknesses is the brand strength compared to the already existing firms such as Medtronic, Tokai and other larger medical technology firms mentioned earlier in the report. The weaker brand name results in more skepticism, less broad sales channels and an inferior customer network; which of course is a disadvantage. To overcome this, the marketing of λ is crucial where the technological supremacy of the product needs to be prominent. Bigger, more renowned companies do have bigger budgets and thus a better position for market penetration through marketing.

However, the small size of the company does bring some advantages as well. One indirect aspect is that the economical profit that λ's market can generate might not be big enough to arouse interest from the biggest companies. Accordingly, the market becomes less interesting for them and thereby results in less competition. Hence, λ chances for penetrating the market increases. Moreover, since the company was recently founded there is not a heritage to cherish which makes it more agile. The opportunities are foremost in the structure of the organization, which is of a non-complex character. Compared to a more complex and slow-moving firm, the ability to be alert and follow trends and fluctuations in the market is possible which is of great importance. Into a bigger organization which is highly centralized, the time for the information from the source to the decision maker is much shorter. Thus, the company can have a rapid response to the market's fluctuations and be proactive. The product developers do also have a close connection to the users, which makes it possible to tailor λ to the exact needs. All together this creates a great environment for the possibility to develop a well-functioning and innovative product.

Furthermore, the fact that λ is a new product entails obstacles in itself and old products are still favorable. The reason for this is because physicians prefer products they are used to, since there often is a lack of possibilities to use the products outside of actual surgery. Consequently, this might lead to a bad first impression of implementing a new product. To address this matter, it is recommended to ensure that the hospital provides training of the physicians in the usage of λ. To handle the risk that physicians might prefer old products over λ it is important that there are studies conducted involving λ. It is also important that knowledge of the dangers of ischemia is spread so that the vitality of λ's ischemia reducing features are truly appreciated by the users. Therefore, λ should be developed into a product which is easy to use for all intended users at the same time as it is innovative and interesting enough to the surgeons; allowing it to become a disruptive technology replacing the old.

6.4 Result of analysis

By reading chapter 5 and the parts of chapter 6 leading up to this point, *RQ1: What does the current REBOA market look like?* has been answered in as concise a manner as possible. This section aims to answer *RQ2: What are enablers and barriers for the cardiovascular innovation?* based on the complete analysis presented above. A brief explanation of the enablers and barriers are presented followed by a summary of them in table 6.1 on page 48.

On the macro scale there are three enablers identified. The first one is a result of political factors making the creation of a submarket or market separation for λ a substantial enabler since the price flexibility could increase. The second enabler is of social character and stems from the current process of placing an aorta balloon. Creation of a product which requires less steps is therefore an enabler. The last identified enabler within the macro point of view makes use of innovations within medical visualization. If λ can be used together with different visualization techniques, then it will be differentiated from the current market which is a considerable enabler.

Four barriers on the macro scale have also been identified. First one being the procurement process which could make it difficult to enter the market hence making it a barrier. The second barrier is the relatively small market size making the product difficult to profit from.
The third, and probably most difficult barrier to overcome, is the fact that surgeons and physicians will need to learn how to use λ. Finally, the last identified barrier is the legal requirement of CE-marking which can complicate the production process.

The threat of new entrants is deemed to be low, in other words it is difficult for innovators to enter the market. High capital requirements due to medical products relying on interdisciplinary technologies, clinical test and research costs, among others, causes a barrier for new entrants. Furthermore, high knowledge-requirements about procurement and regulations also contribute to the difficulty for start-ups to enter the market which is also categorized as a barrier for lambda. Finally, incumbency advantages for existing products on the market in the form of

brand recognition, familiarity, and previous experience among physicians with existing products likewise act as barriers.

Physicians have a big impact on what REBOA products are purchased. Along with this comes the fact that current REBOA products have a potential to be extensively more time efficient, and physicians prefer simple, efficient and intuitive products. This leads to a high threat of products being substituted. For lambda, this results in a good opportunity to break ground in the market if the product is developed in line with the professionals' preferences, thereby being classified as an enabler.

The bargaining power of customers is categorized as being on the lower side. There is some price sensitivity among customers which can be seen by how price sometimes dictates what products are purchased, over what is actually preferred by the users. This can however probably be countered by developing a product which is simple and efficient to a degree that the users' preferences overshadow an imaginable price increase over competitors' products. Still, price sensitivity is categorized as a barrier along with switching costs, which are on the higher side partly due to learning effects being present.

The suppliers' bargaining power is on the lower side. The current products on the market are all fairly similar in composition. However, there is not an alternative for the REBOA products which should increase the power of suppliers, but the homogeneity of the products outweighs this. A low bargaining power among suppliers is in λ's favor, which could be utilized by creating a differentiated and unique product, but it is hard to pinpoint if it is low enough to achieve this. The similarity of current products and the non-existing alternatives for them are consequently classified as enablers.

The level of competitive rivalry is inconclusive at the time of writing. Higher healthcare budgets along with a rise of investments after the COVID-19 pandemic could mean more competition in the future but as of now, it is hard to determine what current rivalry means for λ. The factors which contribute to competitive rivalry are therefore neither categorized as enablers or barriers.

One of the most important factors for a successful implementation of λ to the market based on the micro level is that the technological superiority of λ appears. This needs to be dealt with delicately, especially since the resources are exhaustive and the brand name weaker in comparison to the biggest firms. Since physicians don't get much of an opportunity to try new products outside of real-life situations, they are restrained with unfamiliar products and tend to choose the known and safe option. Hence, it is crucial that the physicians and the people in charge of the purchase process of intended customers understand the potential and need for λ as a product. When that's achieved, it needs to be assured that the users of λ get proper training with the product, so they are aware of how to use it. Otherwise, that might affect the impression of λ in a bad way and damage the chance for future market penetration.

However, as mentioned in section 6.3, the smaller size of the firm doesn't only bring challenges but also opportunities. The flexible structure and small size of the company makes it possible to respond directly to the market's fluctuations. Furthermore, the product developers work very closely with concerned and knowledgeable physicians. All together creating a suitable environment for a successful market penetration of λ.

Table 6.1
Enablers and barriers on macro, meso and micro level

Level	Enablers	Barriers
Macro	Creation of a submarket or market separation	Procurement process
	Product which requires less steps	Relatively small market size
	New medical visualization techniques	Learning curve for physicians
		CE-marking
Meso	Use of other REBOA products	Capital requirements
	Physicians prefer simple & intuitive products	Knowledge about regulations
	Current products are similar	Incumbency advantages
	No alternative exists for REBOA products	Price sensitivity among customers
		Switching costs
		Learning effects among users
Micro	Technological superiority	Weaker brand than competitors
	Flexible structure of the organization	Smaller budget than competitors
		Physicians prefer products they are familiar with

7 Discussion

Since the research delimits itself to the assumptions in section 1.6, the research covers the Swedish market, exclusively. However, the procedure is currently used worldwide and thus further research is necessary to describe the international market. At the same time, collecting empirical information from the Swedish market resulted in qualitative questions being answered rather than the quantitative. This was due to the lack of quantitative data accessible to the public, creating a barrier for a further quantitative characterization and understanding of the national market.

Assumptions of λ's attributes construct the substratum of the report's analysis. The actualization of the innovation might have slightly, or entirely, different characteristics. Thus, the analysis of λ is strictly deduced to the assumed attributes. However, the empirical literature collected would apply to any innovation in this specific field, no matter the attributes. Hence, λ could be subject to change due to further alignment to the market demands.

Environmental sustainability did not procure an extensive part of the report. This is due to the incredibly small room of change the innovation could have to be functional, compatible with blood, tissue or lipids, certifiable due to the heavy regulations in the field. The report could have faced the issue of recycling after the one time use. However, recycling of the specific alloys used, does not exist today. An idea would be to further explore the option of recycling, however, this was not part of the purpose of the report and would have lessened the quality of research.

8 Conclusion and further research

REBOA and λ have now been studied, analyzed and discussed thoroughly which leads the report into its eighth and final chapter; firstly containing the conclusion, where the purpose of the study is reconnected to. Secondly containing recommendations for further research to be conducted on the subject.

8.1 Conclusion

The present market for REBOA consists of products similar to each other, with the main difference being the size of the catheter and the balloon diameter. To determine which of these products is the best, one has to consider the user's habit of similar procedures. For a vascular surgeon, the best available balloon will probably be the one he uses for expanding vascular prostheses, since this procedure occurs much more often than REBOA itself. For other, less trained staff, the most important property is probably simplicity. According to studies there seems to be a general view that smaller shaft sizes are easier to work with - this suggests that balloons such as ResQ and Rescue Balloon are preferred by less experienced staff. Overall, this indicates that the market has different user segments with different requirements on the product.

At present, the main actors in the market are large medical technology companies or smaller, more niche companies with a lot of venture capital. Understanding the size of the market is, however, very difficult since there are no public figures on the sales of the products. Despite uncertainty in size, it can be stated that the market is large enough for competition and companies to see a benefit developing new and improved products.

To be able to evaluate different products within Swedish healthcare, there is, for every product category, a set of should- and shall requirements. Today's occlusion balloons meet these requirements to varying degrees but none of them stand out; which reflects the minimal price difference. It will be important for λ to end up in its own category; to not compete in price with existing products. We believe that the following properties are the most important to achieve this separate market position, thus increasing the probability for a successful market launch:

- Disruptive features which reduce the risks of brain hemorrhage and ischemia.
- Possible to use for cardiovascular procedures other than REBOA.
- A simplifying kit-based product which clearly shows which component to use at what time.

Given that one succeeds in developing a product with these properties, there will still be high demands on the innovator in terms of knowledge about the current regulations and access to venture capital. As mentioned in an earlier paragraph, the competition at product level does not seem to be that big at the moment. However, it should be taken into account that partial REBOA is on the rise with designated products under development, which can lead to an increased competition for λ in the future.

8.2 Further research

This study has explored enablers and barriers for the cardiovascular innovation λ, but does not claim to be absolute. Further research should be conducted on REBOA in general and λ as a REBOA product, when the product is patented further research on the product's functions should be researched. Partly with the aim to achieve more certain indications of its competitiveness on the market but most importantly to gain the interest and respect from its potential users, vascular surgeons and others who perform REBOA. Further research can also be conducted on how one can benefit from cooperation during the different stages of the developing the product.

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Appendices

Appendix 1 - Interview questions in Swedish

Teknikalitet

Är storleken på katetern avgörande för en säker användning?

Kan få mer stabilitet med större storlek men kräver samtidigt en större introducer, hur ser du på användandet av en större introducer?

Har ni/och isåfall när har ni upplevt migration av ballongen?

Vad är den största nackdelen med dagens ocklusionsballonger?

Vad skulle du vilja ha med framtida ocklusionsballonger?

Hur ofta använder du ocklusionsballonger? Hur ofta används dem till cirkulationskollaps?

Reliant-ballongen från Medtronic sägs kunna expandera vaskulära proteser, har du använt den till det och hur fungerade det isåfall?

Vilken ballong föredrar du idag? Och varför?

PESTSL & Porter-relaterat

Är det jobbigt att använda olika ballonger? (Ifall personen gör/har gjort det)

Vad hade krävts för att känna dig bekväm med en ballong? Antal ingrepp? Annat?

Upplever du att det är en kontroversiell teknik? Varför och vad krävs för att få bort den stämpeln?

Vilken påverkan har ni som användare av produkten på inköp till sjukhuset?

Om framtiden

Tror ni att REBOA-tekniken kommer vara mer utbredd än vad den är idag? Varför

Något annat ni vill skicka med oss?

Inköp

Kan du gå igenom steg för steg hur det går till när ett sjukhus väljer att köpa in en ny produkt?

Kan du gå igenom steg för steg hur det går till när ett sjukhus väljer att köpa in en ersättningsprodukt för en produkt man redan använder sig av?

När det kommer till endovaskulära ingrepp rör det sig mycket om engångsanvändning och förbrukningsvaror, ser man annorlunda på såna typer av inköp gentemot exempelvis maskiner? miljömässigt?

Vad är man beredd att betala för en ballong som är bättre än de existerande och som efterfrågas av läkare?

Påverkas inköpen mycket av konjunktursvängningar/politiska faktorer? Hur ser det ut just nu?

Påverkar valutakurser?

Kan helt nya produkter köpas in direkt? Anses dessa som säkra?

Tar man hänsyn till miljöpåverkan vid inköp?

Vad bör en innovatör tänka på att för att vinna en upphandling?

Vilken påverkan har läkarna som användare av produkten på inköp till sjukhuset?

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