New Production Development (NPD):

Bipolar Energy System

An Interactive Qualifying Project Proposal submitted to the faculty of

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By:

Alexander Kirkman

Shaylie Lagasse

Isha Medasani

Samuel Rooney

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Project Sponsor:

Dr. Siao-Wei Tang

Maxima Biotech Inc.

Professors Amanda Wittman, Robert Kinicki, and Wen-Hua Du

Worcester Polytechnic Institute

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1.0 Introduction

Every year, medical professionals perform 310 million major surgeries on patients around the world. Roughly one in twenty-five of these surgical patients die soon after their operation. This places major surgery as a leading cause of death, with a loss of about 8 million patients per year (Dobson, 2020). In response to this, researchers, doctors, and engineers worldwide work to improve surgical products and processes. They aim to reduce the number of preventable deaths each year by developing safer and more effective devices, thereby increasing the likelihood of positive surgical outcomes. Maxima Biotech Inc. recognized this imperative and initiated a collaboration with Worcester Polytechnic Institute (WPI) to utilize engineering students' perspectives on their work. Specifically, Maxima is interested in comprehensively analyzing the feasibility of including a cost-effective bipolar energy system device in their product line.

1.1 Sponsor

Hong Yi-Ping (**Figure 1.1.1**) and Tang Xiao-Wei (**Figure 1.1.2**) established Maxima Biotech Inc., also known as 久方生技股份有限公司 (Jiufang Biotechnology Co., Ltd.) in April 2019 (Maxima Biotech Inc., 2021). The corporation specializes in designing, developing, and marketing surgical equipment, focusing on laparoscopic instruments and minimally invasive surgery (MIS) (Maxima Biotech Inc., 2021). Summed Taiwan, a Taiwanese company that invests in crucial medical devices with the goal of establishing Taiwan as a hub for biomedical advancements, backs Maxima. They support Maxima Biotech through investments in key technologies, managerial assistance for faster product development, and collaboration with funds and partners, helping them to leverage Taiwan's strengths in the medical device industry (Summed, 2020).

Figure 1.1.1: HONG YI-PING
(Maxima Biotech Inc.'s Chairman)

Figure 1.1.2: TANG XIAO-WEI
(Maxima Biotech Inc.'s General Manager)

Maxima Biotech Inc

According to our team's liaison, Dr. Tang, Maxima Biotech Inc. recently developed a wireless version of the traditional ultrasonic dissector currently in use (see **Figure 1.1.3**).

Figure 1.1.3: An image of Maxima Cordless Ultrasonic Dissector.

Healthcare+ Expo Taiwan, 2022

This medical device precisely cuts tissues during surgery using high-frequency vibrations. By creating a wireless version of this technology, the company positioned itself in a unique market niche as one of the few producers of wireless ultrasonic tools. Maxima aims to leverage the experience gained from developing this device and the expertise of their team to design and market a new device that uses bipolar energy instead of ultrasonic energy. Moreover, Maxima actively participates in the biotech community by attending events like the Taiwan Innotech Expo and BioAsia-Taiwan Expo, demonstrating their innovations. Dr. Tang prioritizes open communication with the biomedical community and commits to creating cost-effective products that rival the quality of those from industry leaders. Furthermore, Maxima underscores the critical importance of patient safety and risk management in device development. They also

recognize the value of consulting with surgeons, the primary device users, to pinpoint the most significant enhancements.

1.2 Goals & Objectives

This Interactive Qualifying Project (IQP) will collaborate with Maxima Biotech Inc. in order to aid the development of the corporation's upcoming surgical bipolar energy system product. The team will do this by producing a report at the end of the project term which provides recommendations for product requirements, assesses the market need for cost-effective products, and identifies key factors influencing adoption of a new bipolar device by surgeons. The team determined that the following methods were required to complete these tasks:

1. Conduct interviews with relevant professionals, particularly surgeons, to gather insights on surgical bipolar device requirements and preferences. These insights will include at minimum value-adding features that may impact the adoption of a bipolar energy device by the surgeons and the impact of price on the adoption of a bipolar energy device.
2. Create a case study that analyzes primary and secondary data related to medical device failure and testing, to identify variables that can cause device malfunction and provide device requirements to prevent these issues.
3. Perform SWOT and PESTLE analysis on competing devices in the bipolar energy device sector, which will include, but is not limited to, patent database research for the US, Taiwan, South Korea, and Thailand to identify potential areas for innovation and collaboration.

2.0 Background

The chapter discusses the history of minimally invasive surgery (MIS), and the integration of bipolar energy devices with other types of energies in such procedures. It also delves into the economic and legal details of the market environments that Maxima Biotech’s new bipolar energy device product will enter. For definitions of unfamiliar terms within this section, please refer to Appendix A located at the end of the document.

2.1 Minimally Invasive Surgery

During open surgery, surgeons cut the patient's skin and tissues to fully visualize the organs and structures involved in the operation (Stanford Medicine, 2024). While it provides benefits such as improved training opportunities, increased surgical site visibility, and expanded maneuverability for surgeons, open surgery comes with significant risks for patients compared to minimally invasive surgery (MIS) (Zhao & Gu, 2022). Comparatively, open surgeries result in longer recovery times, increased blood loss, and more intense postoperative pain (Agha & Muir, 2003).

In contrast, laparoscopic surgery, a specific type of minimally invasive surgical (MIS) technique typically employed in abdominal procedures, has revolutionized the field of surgery. Laparoscopic surgery utilizes a thin, cascading rod with a camera at the end, known as a laparoscope. This allows surgeons visualization of a patient’s body without incising it fully (Laparoscopic Surgery, 2022). Laparoscopic surgery typically requires two to four small incisions, each a half inch or less in size, instead of the six to twelve-inch cut required for open surgery (Laparoscopic Surgery, 2022). The less invasive nature of laparoscopic surgery greatly increases the quality of surgical and patient outcomes. These benefits include decreased bleeding, shorter surgical times, lower postoperative pain scores, fewer surgical complications, and reduced mortality rates (Smith et al., 2018).

2.2.1 Brief History of MIS Instruments

Phillip Bozzini invented the first cystoscope in 1806 (Kelley, 2008). Veterinarians examined canine bladders using the minimally invasive device, marking a large step toward advanced laparoscopic technology (Kelley, 2008). However, human surgery never utilized this cystoscope (Kelley, 2008). This device remained popular for the next 100 years as MIS technologies developed (Chicago Institute of Minimally Invasive Surgery, 2016). The first surge of interest and success in laparoscopic surgery happened in 1929, when a German gastroenterologist named Heinz Kalk improved the cystoscope, enhancing it for use in human procedures, adding a better viewing scope, and upgrading the lenses. He adopted the terms “laparoscopy” and “laparothoracoscope” for his process and device, respectively (Litynski, 1997). Due to these improvements, he earned the title "Father of Modern Laparoscopy" (Kelley, 2008). In the 1930s, an intern from the United States named John Ruddock improved upon

Kalk's design, popularizing laparoscopy, to create safer, less-invasive alternatives to current laparoscopy methods (Kelley, 2008). Following Ruddock's invention, in 1936, a Swiss gynecologist named Boesch performed the first successful laparoscopic surgery on the fallopian tubes (Kelley, 2008). This marked the beginning of the success of laparoscopic surgeries. However, progress was very slow due to technological limits and resistance to change in the medical community at that time, and thirty-five years after this successful breakthrough, laparoscopy accounted for only 1% of performed sterilization surgeries (Kelley, 2008). In the 1970s, gynecologists Kurt Semm and Harrith Hasson played pivotal roles in advancing laparoscopic technology (Kelley, 2008). Semm introduced technical refinements, including a device to maintain controlled carbon dioxide pressure during surgery to create a clear workspace, and an irrigator to remove fluids and debris from the surgical site (Kelley, 2008). Concurrently, Hasson enhanced safety with the development of the Hasson trocar which surgeons use to puncture patient skin and provide a pathway for surgical instruments to be inserted safely, reducing the risk of injury to internal organs (Kelley, 2008). In 1983, Kurt Semm performed the first successful laparoscopic appendectomy, but skepticism persisted in the medical community until video laparoscopy advanced with the improvement of video technology, enabling high-enough resolution visuals for effective surgical procedures (Kelley, 2008). Finally, in the mid-1980s, several surgeons successfully performed video laparoscopic cholecystectomies due to these advancements (Kelley, 2008). John Wicker, who established a department of minimally invasive surgery at the Institute for Urological Surgery, henceforth coined the term "minimally invasive surgery," and the primary evolutionary stage of laparoscopic surgery ended (Kelley, 2008). This "revolution" of minimally invasive surgeries occurred in the 1980s and 90s, but the technology continues to improve today (Kelley, 2008).

2.2.2 Challenges and Considerations in MIS Device Development

Today, the minimally invasive surgery landscape presents challenges critically important for Maxima's consideration when developing their new device. An essential aspect of these devices is minimizing postoperative patient pain and morbidity compared to traditional open surgery practices (Ochsner, 2000). Maxima's new device aims to be affordable, making it accessible to a wide range of people. This cost-effectiveness not only addresses economic factors but also helps promote its adoption for broader use in healthcare (Jaiswal & Huang, 2017).

Another factor that may help Maxima's products grow in the market is the development of training programs for these types of devices. Due to the reduced visibility involved in minimally invasive surgeries compared to open surgeries, training new surgeons becomes more difficult. Additionally, environmental concerns constitute another important challenge. Though minimally invasive surgeries have brought about many benefits for patients, these instruments are typically single-use and lead to environmental waste and hidden costs related to their disposal (Cunha & Pellino, 2023). Developing a device that minimizes environmental waste will increase the device's acceptance. The possibility of reusable devices or reduced disposal costs should be a factor in Maxima's design. Maxima's dedication to overcoming the challenges of minimally invasive surgery with their new device hints at promising new advancements such as improved safety, accessibility, and environmental sustainability for future surgical practices.

2.3 Types of Energy in Laparoscopic Surgeries

As the field of laparoscopic surgery develops, technology also improves. This section defines the various types of energies currently utilized in laparoscopic surgeries to provide a contextual understanding of surgical energy system terminology. These types of energy include electrical, mechanical, plasma, ferromagnetic heat, and laser.

Electrical energy uses high-frequency alternating currents to coagulate, cut, fulgurate, and desiccate tissue. There are three types of electrical energy: monopolar, bipolar, and advanced bipolar. Electrosurgery uses electrodes in two different ways. In monopolar electrosurgery, a probe electrode passes through a patient and back to a pad to complete a current circuit. On the other hand, bipolar electrosurgery involves passing current between the operated tissue and an electrode with two forceps-shaped arms (Smith et al., 2018).

Mechanical energy uses the piezoelectric effect to create high-velocity vibrations, inducing heat and cavitation within tissues (Smith et al., 2018). Notably, ultrasonic energy, a subtype of mechanical energy, operates on this principle and plays a significant role in modern surgical procedures. Ultrasonic surgical instrument technology works when a high-frequency ultrasonic device converts electrical energy into mechanical energy, and the vibrations create mechanical friction, generating thermal energy. The generation of thermal energy leads to extracellular heating, followed by intracellular heating, which helps seal vessels (Zurawin et al.).

Plasma energy involves energizing gas that allows for coagulation, cutting, and fulguration with ionized gas in a single instrument (Monopolar Electrosurgery vs. Bipolar Electrosurgery, 2016). Ferromagnetic heat energy utilizes radio frequency in a metal loop coated with ferromagnetic materials, producing precise thermal heat via magnetic hysteresis, heat loss, and ohmic heating. Laser energy converts light to heat, heat transfer, and tissue reaction (Pantelić et al., 2015).

2.3.1 Ultrasonic Energy & Bipolar Energy

While various kinds of energy exist, Maxima is interested in the development of devices that build on ultrasonic energy principles but utilize bipolar energy. This section explains further the definitions of ultrasonic and bipolar energy, as well as their respective advantages, disadvantages, and constraints in the context of Maxima Biotech Inc.'s current ultrasonic dissector. These insights are crucial to the development of their upcoming bipolar device.

Maxima Biotech Inc.'s current product is an ultrasonic cordless dissector (an ultrasonic surgical instrument) that uses mechanical energy in the form of low-frequency mechanical vibrations, high-speed mobilization, and cavitation principles based on high velocity, low amplitude manipulation techniques (LaPelusa & Bordoni, 2024) to transect tissues and seal vessels without the need for an electric current to flow through the patient like electrosurgery (Zurawin et al.).

There are many advantages of ultrasonic surgical devices, such as allowing for simultaneous coagulation and cutting, enhancing efficiency in surgical interventions, and thereby lowering the temperature at which tissue plane dissection occurs. Ultrasonic devices reduce surgeons' visual impairment caused by smoke or mist, improving overall surgical visibility and accuracy. Ultrasonic devices also come in the form of generators, which can adjust the mechanical energy delivery to tissues, providing precision and control tailored to the desired effect. Unlike bipolar devices, where passing current through tissues generates heat, ultrasonic devices contain heat within the blade, minimizing damage to surrounding tissues. In addition, this containment reduces lateral thermal spread, lowering the risk of nerve damage during surgical procedures. However, it may present challenges, including increased heating of the device tip and blade, which can cause damage to surrounding tissues or organs upon contact. Furthermore, it can result in slower coagulation compared to electrosurgery, altering the frequency or impedance

of the surgical system itself due to factors such as blade fatigue, temperature elevation, excessive pressure, or improper use.

Maxima is developing a bipolar energy device in addition to the ultrasonic device they have already produced. Bipolar energy is a type of electrical energy that uses a non-modulated, low-voltage current waveform to allow surgeons to stop blood vessel bleeding, which leads to reduced collateral damage and thermal spread. It is ideal for techniques like desiccation and coaptation, the joining or readjusting of two surfaces (Smith et al., 2018). Recent advancements in surgical bipolar devices incorporate tissue impedance measurement, vessel sealing technologies, and temperature control, enhancing surgical efficiency and safety by reducing thermal spread (Smith et al., 2018). Additionally, they minimize operation time (Mbah et al., 2012), enable precise control over tissue coagulation, minimize thermal damage, restrict the current flow to the targeting tissue, facilitate blood vessel repair, and achieve uniform peak temperatures across different tissue types and thicknesses. These devices are available in various forms, such as forceps, grips, dissectors, and scissors (Sankaranarayanan et al., 2013). However, tissue characteristics and thicknesses may limit bipolar energy devices. Bipolar energy devices are ineffective on smaller blood vessels, and they produce smoke. In addition, the user's skill and power settings of the bipolar energy device usually determine the degree of thermal dispersion, thus warranting careful consideration during device development (Sankaranarayanan et al., 2013).

Ultimately, surgeons decide when to use ultrasonic or bipolar energy devices, tailoring their choice to the unique demands of each surgical scenario. However, it is important to note that other factors, such as cost-effectiveness and hospital administrators and policies, may influence these decisions. The methodology chapter (see section 3.1) explores the connection between surgical need and hospital considerations, as interviews with medical professionals will shed light on the multifaceted nature of device selection in surgical practice.

2.4 Bipolar Device Market

Government regulations are central to defining the market behavior for surgical devices in a given country. For example, the United States maintains intellectual property protections for businesses that develop new cutting-edge surgical technologies, which ideally has the benefit of incentivizing innovation at the cost of increasing prices. On the other hand, Eastern Asian

countries like Taiwan typically maintain fewer protections with the benefit of driving costs down, but at the risk of potentially disincentivizing innovation.

2.4.1 Demand for Bipolar Energy

Bipolar energy devices are in high demand across various surgical specialties, including general surgery, gynecology, urology, cardiovascular surgery, gynecology, dermatology, and orthopedics. The demand for bipolar energy devices arises from the increasing number of surgical procedures worldwide due to the rise of chronic ailments and conditions like cardiovascular diseases and cancer, ongoing technological advancements, and the desire for cost-effectiveness and reusability. Bipolar energy's capabilities, including its capacity to fulfill many roles during a surgical procedure, make it extremely valuable in treating diseases and life-threatening problems (OmniMark, 2023).

According to three worldwide competitors and major bipolar electrosurgery market stakeholders, Covidien (Medtronic, US), Ethicon (Johnson & Johnson, US), and B. Braun Melsungen (Melsungen, Germany), their estimated sales revenue for their electrosurgery products falls within the range of $1-4 billion. These figures represent estimates of their sales revenue within the competitive bipolar electrosurgery market and do not necessarily indicate total annual revenue for 2023. This market data suggests significant growth in the global bipolar electrosurgery market, with projections indicating sustained expansion driven by evolving healthcare demographics and increasing adoption rates of advanced surgical techniques, particularly in regions like North America, Europe, Asia-Pacific, Latin America, the Middle East, and Africa (OmniMark, 2023).

2.4.2 Competitors

Maxima Biotech's goal in developing a bipolar device is to increase its market share, which means that Maxima needs to produce a product that is superior to their competitors in terms of price, availability, or effectiveness in some way. Maxima needs to pay attention to the two most popular competitors, developed by large medical corporations, LigaSure, which the American corporation Medtronic Plc developed in 1998, and the Thunderbeat device, developed by the Japanese Olympus Corporation and released in 2012. LigaSure is currently the most popular bipolar energy device, with an 84% market share (Chivukula et al., 2020). Meanwhile,

the Thunderbeat device stands out due to its hybrid ultrasonic/bipolar design, offering a unique advantage compared to a purely bipolar energy system.

2.4.2.1 LigaSure

As aforementioned, Medtronic originally released the LigaSure line of devices in 1998, and these devices are by far the most popular bipolar energy devices on the market, holding 84% market share. LigaSure's basic technology combines pressure (generated by clamping arms) and heat (generated by bipolar contacts on the clamping arms). The company and most of the market understand that this combination can reliably seal blood vessels. Further technological advancements include a feedback control system that automatically stops the heating cycle when the blood vessels seal properly, rather than relying on a surgeon's intuition (*LigaSure Technology*, 2024). The ForceTriad platform that provides electrical power to LigaSure devices costs an estimated $12500 (*Covidien ForceTriad Platform*, 2024), and the hand tools cost approximately $450 per single-use disposable tool (*LF1623 - LigaSure Disposable*, 2023).

One surgeon documented why they use the LigaSure bipolar energy system (see Figure 2.4.1) in their operations. First, the surgeon repeatedly noted that the burst pressure on LigaSure device seals produced is three times normal systolic blood pressure. The surgeon mentioned improvements in reduced blood loss and reduced time spent actively in surgery. Finally, LigaSure reduced overall recovery time, specifically time spent in the hospital for the patient, especially compared to sutures or other mechanical ligation devices. The LigaSure device also has improvements the surgeon noted in terms of subjective opinion, specifically the design of the handle, which is comfortable and reduces fatigue *(Karande, 2015)*.

Figure 2.4.1: An image of Medtronic's (Covidien) LigaSure™, a Bipolar Dissector. Charles Kuntz, 2016

According to the FDA's MAUDE database, between 2010 and 2020, the LigaSure device caused 134 adverse events during thyroidectomy surgeries (Lee et al., 2022). One hundred nine of these events were device malfunctions, and the remaining twenty-five were adverse events to patients. For LigaSure, the twenty-five adverse events to patients mostly resulted in incomplete hemostasis (i.e., unsuccessful blood vessel sealing) and burns. However, the device also caused two vocal cord injuries.

2.4.2.2 Thunderbeat

The Olympus Corporation of America developed and released the Thunderbeat line of hybrid bipolar/ultrasonic devices (see Figure 2.4.2) in 2012 (*Olympus to Launch THUNDERBEAT*, 2012). The defining feature of this line of devices is the ability to cut and seal tissue/blood vessels. This ability to perform multiple operations makes the Thunderbeat devices very convenient for surgeons who would otherwise have to exchange tools between cutting a blood vessel open and sealing it. The ability to coagulate blood immediately as the surgeon cuts blood vessels directly leads to reduced patient blood loss. Additionally, the Thunderbeat system offers Intelligent Tissue Monitoring [ITM] for ultrasonic cutting, reducing the risk of over-activation of the cutter, which can result in negative effects. This capability limits the bipolar energy system, which automatically seals tissues as soon as it cuts them. The ability of ITM to manage the temperature inside the patient is beneficial to reducing burns, which is one of the primary concerns for surgeons regarding using bipolar devices (*Thunderbeat*, 2024). The EPF-1 Surgical Tissue Management System (energy platform) pricing, which provides electrical power

to Thunderbeat, is not publicly available. Still, the handheld device has similar pricing to the LigaSure system at $475 per disposable handheld device (*TB-0535FCS - Thunderbeat Disposable*, 2023).

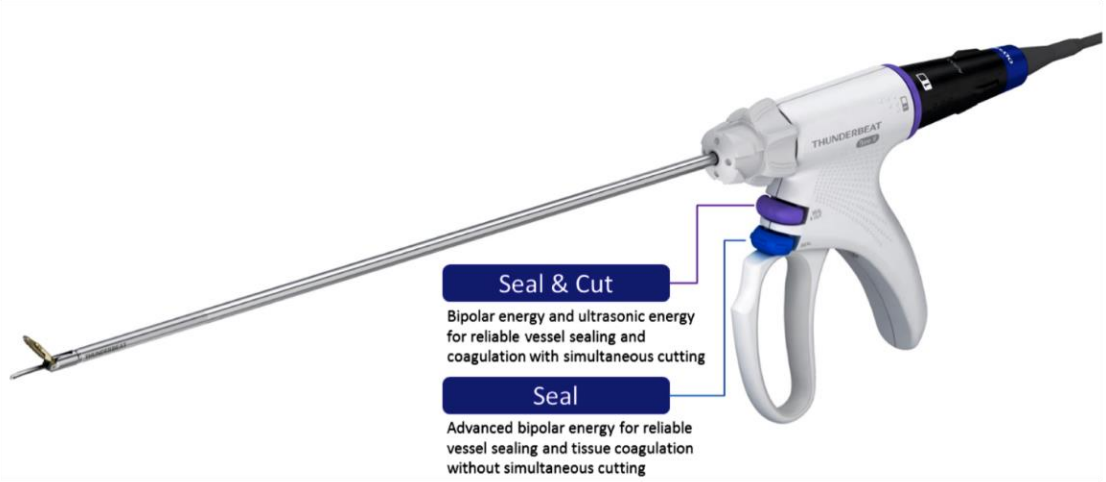

Figure 2.4.2: An image of OLYMPUS's Thunderbeat, an Ultrasonic & Bipolar Energy Hybrid Dissector. OLYMPUS, 2018

Between 2010 and 2020, the MAUDE database associated the Thunderbeat device with ninety-two adverse events (Lee et al., 2022). Eighty-eight of these events were device malfunctions, two were adverse events to patients, and two were operator injuries. Note that while these numbers are lower than those for LigaSure, which came from the same study, the Thunderbeat device only came out in 2012. Despite this, Thunderbeat still has a remarkably low rate of adverse events in patients compared to LigaSure. For Thunderbeat, the two reported adverse events to patients were a burn and a vocal cord injury.

2.5 Patent Information

It is a common technique for companies to leverage patents to promote technology development within similar applications. To better understand how Maxima plans to utilize patents in the development of bipolar energy, it is crucial to understand what a patent is and the laws surrounding them. The World Intellectual Property Organization (WIPO) describes patents as an exclusive right granted for an invention or idea. This could be a product or a process that provides a new technical solution to a problem (World Intellectual Property Organization, n.d.). Patents can be used in various ways to document and protect intellectual property (IP). For instance, they ensure the release of works to the public without the risk of replication. Patents can also be used for monetary gain, as the owners can sell their IP exclusively for the duration of

the patent's lifespan (Van Norman 2017). The exclusivity provides an incentive to companies that allows them to continue financing research.

Furthermore, patents are beneficial from a customer's perspective because they breed competition between inventors. Competition leads to rapid innovation in technologies and products. In the case of the medical device industry, large manufacturers, such as Johnson & Johnson, will often purchase patents from smaller manufacturers. Maxima aims to use patents to rapidly advance in the biomedical industry in Taiwan. By utilizing expiring patents, better known as patent cliffs, Maxima intends to speed up the development of the application of bipolar energy in their surgical devices. However, to effectively gauge the cost-effectiveness of this endeavor, it is essential to understand the workings of patents, their regulation across various countries, and strategies for their utilization.

2.6 International Patent Laws

As Maxima tries to grow their products in a local and global market, it is important to consider patent regulation internationally to understand their product's cost-effectiveness. Maxima developed a product for the local market in Taiwan but plans to push its exports further. Maxima tried to export biomedical goods to other countries in the region, like South Korea and Thailand. The following subsections provide an overview of the patent laws in countries where Maxima intends to start exportation while offering insights into the market in which Maxima aims to succeed. As Maxima expands in the international market, they must identify and understand each target country's patent laws and regulations to minimize the risk of patent law violations. Specifically, in terms of the US, Maxima intends to utilize patents obtained from successful products to support their research and further develop bipolar energy into their products. As Maxima grows, understanding patent laws in each country is necessary to ensure market success and regulation compliance.

2.6.1 Taiwan

The patent application process in Taiwan involves an application to the Taiwan Intellectual Property Office (TIPO). The patent system operates on a "first come, first served" basis. This means that the individual who submits a patent for an IP typically receives priority over subsequent applicants. Each application is reviewed by the TIPO to ensure a product is not

in violation (Patent Act-Article 31 2022). Taiwan has three types of patents: Invention, Utility Model, and Design. However, regarding Maxima's goals, only the invention patent is relevant. Invention patents preserve new products and technologies by providing 20 years of protection from the filing date before becoming public domain (Patent Act-Chapter 2, 2022). Taiwan's patent system is transparent, and documents are freely available to the public through TIPO's online patent database, making market research and innovation much easier.

However, Taiwan is not a member of the WIPO and has not signed on to most WIPO-administered agreements. The Taiwanese government has its own rules and regulations about foreign patents. If a foreign applicant wants to file a patent in Taiwan, their home country must have a treaty with Taiwan for patent protection (Patent Act-Article 4 2022). Additionally, if there is no agreement between organizations in Taiwan and the foreign country, or if the laws of the foreign country do not accept patent applications from Taiwanese nationals, the respective patent office will reject the application. Fortunately, the US belongs to the group of countries with which Taiwan has established treaties, and vice versa; Taiwan also holds treaties with the US, Thailand, and South Korea. As the team and Maxima navigate IPs and technological development patents from the US, the treaty allows the process to become more manageable and carry fewer risks to violate patent laws.

2.6.2 US

The United States patent system grants exclusive rights to inventors for their inventions and provides a legal framework to protect and incentivize innovation (United States Patent and Trademark Office n.d.). Governed by Title 35 of the United States Code and regulations administered by the United States Patent and Trademark Office (USPTO), the system requires inventions to meet criteria and utility to qualify for patent protection. Patents give inventors the exclusive right to prevent others from duplicating and importing their patented inventions, lasting 20 years from the filing date. The US patent system supports international patent protection through treaties such as the Patent Cooperation Treaty (PCT) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which fosters patent laws across borders (United States Patent and Trademark Office n.d.). US international patent law varies from US patent law as each country has its own rules. Companies will seek patent applications in each country separately to ensure global protection for IPs beyond the United States, aligning

with their specific regulatory criteria. Treaties like the PCT and the Hague System for Industrial Designs (HSID) streamline this process. However, publication rules and the availability of compulsory licenses make it essential for inventors to navigate these complexities.

2.6.3 South Korea

The Korean patent system is a legal framework designed to protect inventions and foster innovation within South Korea. Overseen by the Korean Intellectual Property Office (KIPO), this system grants rights to inventors for their creations, ensuring they can benefit from their innovations (Korean Intellectual Property Office n.d.). Similar to processes in the US and Taiwan, applicants submit a patent application to KIPO, which conducts studies to assess the invention's patentability. Once KIPO grants a patent, that patent gives inventors exclusive rights to prevent others from using, making, selling, or importing their patented inventions within South Korea. Like the US and Taiwan, South Korea uses international patent regulations through membership in key treaties like the PCT and the TRIPS. These agreements simplify the process for Korean inventors to seek patents abroad and vice versa.

2.6.4 Thailand

Thailand's patent system, overseen by the Department of Intellectual Property (DIP), provides legal protection for inventions within the country. Applicants submit a patent application to the DIP, which conducts examinations to assess the invention's patentability. Once granted, patents give designers exclusive rights to stop others from using, making, selling, or importing their patented inventions within Thailand. Regarding international patents, Thailand participates in various international agreements, such as the PCT and the TRIPS. These agreements streamline the process for Thai developers to seek patent protection internationally (International Trade Administration, 2024).

2.7 Patent Cliffing

Patent cliffing refers to a practice in the pharmaceutical and biotechnology market where the expiration of patents on key products leads to significant market changes (Hariharan, 2023). When patents expire, other companies can use the intellectual property, which costs substantially less than developing IPs independently or attempting to purchase them before they expire. This

results in a sharp decline in sales and revenue for the original manufacturers as they lose market exclusivity (Landsman, 2023). It also offers opportunities for other companies to innovate, diversify, and re-strategize, ultimately leading to business growth and sustainability in a competitive market. The impact of patent cliffing forces companies to adopt various strategies to mitigate financial losses, such as accelerating new drug development, reformulating existing products, or diversifying their drug portfolios. Patent cliffing highlights the critical need for continuous innovation and adaptation in these industries to sustain competitiveness in a rapidly evolving market landscape. Given its significance in the pharmaceutical and biotechnology sectors, Maxima employed patent cliffing previously and intends to leverage the practice to advance their research and development efforts in bipolar energy systems.

2.8 Summary

This section highlights the important role of minimally invasive surgical devices in the overall surgical market by analyzing different aspects of the literature pertaining to Maxima and their overall goal. Focusing on Maxima Biotech Inc., a contributor in the field in the Taiwan area, this research aims to illustrate the usage, market, and challenges regarding laparoscopic surgery devices. Further emphasis is placed on the types of energy used in laparoscopic surgeries, particularly bipolar and ultrasound, to provide beneficial insights into the development of Maxima's future products. Using information on the global market, specifically international patent regulations and patent cliffing, as well as analyzing similar products on the market, the team plans to help inform how Maxima's product can be more cost-effective. Finally, by focusing on the U.S., Taiwan, South Korea, and Thailand markets, where Maxima hopes to expand to, the team will show the proper means of integrating the product into the global market.

Building on the understanding of the importance and challenges of laparoscopic surgery devices, focusing on Maxima Biotech Inc., the subsequent methodology chapter outlines the steps the team plans to take to analyze the viability of introducing a bipolar device into Maxima's future market.

3.0 Methodology

Maxima Biotech Inc. wants our project team to help them analyze the viability of developing a bipolar energy device for minimally invasive surgeries. This project aims to provide recommendations for product requirements and marketing strategies for Maxima's upcoming bipolar device. This chapter includes the following methods to achieve the goal of this project, shown below in **Figure 3.0**:

- Conduct various research analyses:
    - Interviewing Professionals
    - Case Studies
    - Market Research
    - Competitor Analysis
- Process findings to determine feasibility of the Maxima's bipolar energy device.
- Provide market and feature suggestions to Maxima's R&D team.

This chapter discusses how the team will utilize these three approaches to assess the need for improved cost-efficiency in the bipolar device market. When the project concludes, the result of these methods will be a full analysis of the economic feasibility of integrating a bipolar energy system device into their product line and recommendations for specific product requirements.

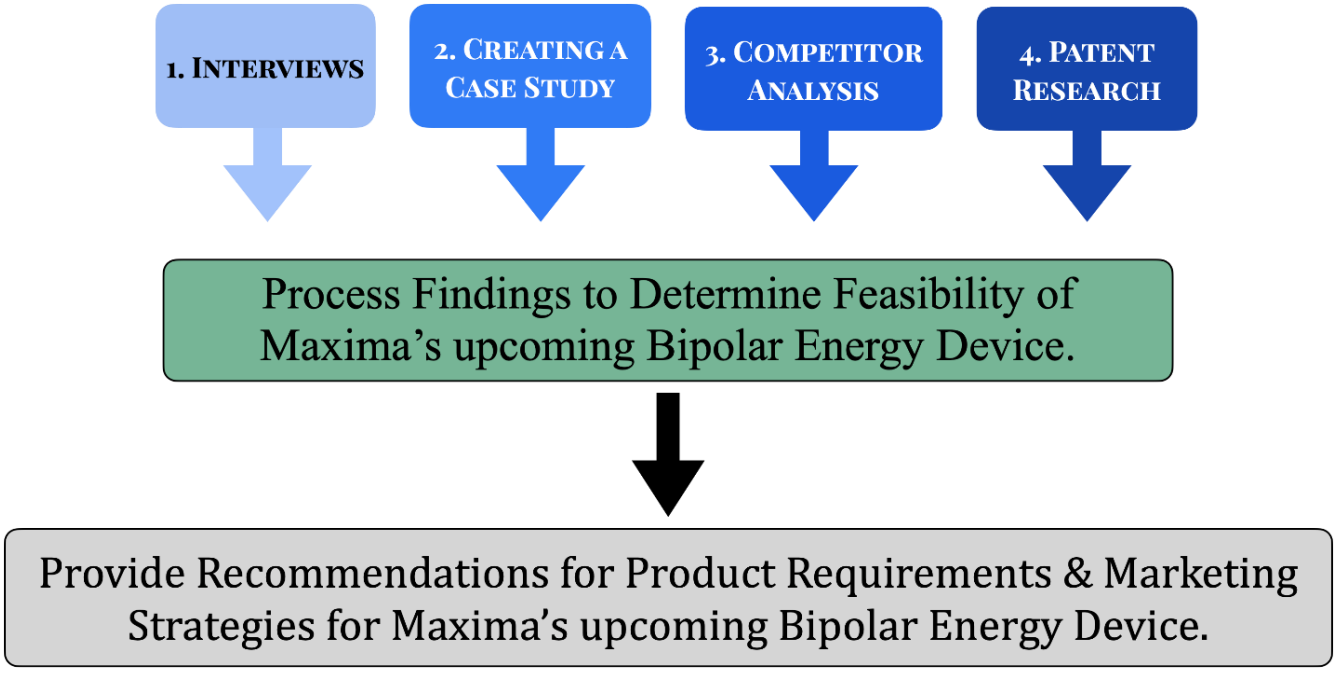

Figure 3.0: A project methods flowchart to achieve the project goal for Maxima Biotech Inc.

3.1 Interviews

During the IQP term, the team will conduct semi-structured interviews with at least four surgeons from Taiwan and at least one from the United States to obtain firsthand insights into the thoughts of the device's primary users. The team intends to hold in-person interviews when possible and provide a virtual option for those unable to attend in person. In Taiwan, the team will conduct in-person interviews at a sponsor-recommended medical center, and the United States interviews will take place at Boston medical facilities. The team plans to have two members present at each session, and they expect each interview to last between thirty to sixty minutes.

The team is conducting interviews to thoroughly understand laparoscopic surgical devices from Maxima Biotech Inc. and their competitors from the perspective of those directly involved in their usage. For a detailed list of interview questions, please reference Appendix B at the end of the paper. Firstly, the team's goal is to determine the preferences of surgeons and patients, clearing up the key factors that influence a bipolar device's use and acclaim within the community, with a particular focus on quality, cost-effectiveness, and safety. Additionally, the interviews aim to analyze surgeries in which the devices are already applied, examining their effectiveness, and identifying areas of improvement. Interviews are a beneficial technique for collecting information about these topics because they offer insights into the perspectives and experiences of surgeons, who are the main users of Maxima Biotech Inc.'s laparoscopic surgery devices. Through discussions with the surgeons, the team can analyze surgeon preferences and determine the factors that impact the use and acceptance of bipolar devices in the medical field. This enables the team to analyze the collected data to provide recommendations to Maxima Biotech, including information to aid optimal decision-making in Maxima's future device development.

The interview addresses ethical considerations as seen in the interview process in Appendix B. Ensuring participants' privacy and obtaining informed consent are the foundational principles of proper interviews (Creswell & Creswell, 2018). Before performing interviews, the team will provide a clear and comprehensive explanation about the purpose of the interview, the voluntary nature of the interview, and the confidentiality of the responses to the interviewees (Santa Clara University, n.d.). Communication should be open and honest, and the participant's time and energy should be respected (Santa Clara University, n.d.). The interviewers should

prioritize establishing a rapport with the interviewees and ensure a respectful and non-judgmental atmosphere is provided (Santa Clara University, n.d.). Another crucial challenge that must be addressed is the potential for sampling bias, interviewer bias, and response bias (Qualtrics, 2024). The questions must not be asked in a leading manner or to draw the participant's answers in a particular direction (Qualtrics, 2024). In addition, the interviewers must ensure no assumptions are made based on a participant's age, gender, nationality, etc., and do not change the questions per individual (Qualtrics, 2024). Additionally, surgeons might be hesitant to discuss device failures, leading to answers that align with assumed expectations (Qualtrics, 2024). Another issue that is specifically relevant to interviews in Taiwan is the potential for communication, language, and cultural barriers between the team and the interviewees. Lastly, it is also important to consider that some interviewees may be constrained by non-disclosure agreements and unable to discuss certain details about devices, prototypes, or surgeries. These considerations require the team to demonstrate flexibility and adaptability, ensuring successful interviews. By adhering to ethical and interview principles, the team aims to perform interviews to aid Maxima in developing their upcoming device.

3.2 Creating a Case Study

Case studies are important data tools that explore multiple dimensions and perspectives, such as social, cultural, and economic factors that could influence a given situation (Seth Batiste, 2024). There are two main ways of conducting research, each leading to various usable research tools. The first method involves the person involved in conducting the research. In contrast, the second focuses on the type of data collected (Schicker, 2022). Primary data collection involves researchers directly collecting data. In contrast, secondary data refers to information previously gathered by others (Public Health Research Guide: Primary & Secondary Data Definitions). After establishing who is conducting the research, the focus shifts to differentiating the types of data to be collected. Quantitative data is numerical-based data, whereas qualitative data is interpretation-based data (The FullStory Education Team, 2021).

This method explores bipolar medical device malfunction by incorporating both primary and secondary data while utilizing qualitative data collection methods. Insights into the root causes of medical device malfunction are derived from primary data from surgeons and secondary data from the Manufacturer and User Facility Device Experience (MAUDE) Database

and extended archival research. The team plans to collect the data from the medical device malfunction-related interview questions and eight to ten MAUDE database cases for bipolar energy devices to identify the causes of medical device failures and establish criteria to prevent future incidents. This approach will ensure a comprehensive understanding of the various factors influencing the development and utilization of bipolar energy system devices in surgical settings.

The team developed criteria to standardize medical device malfunction cases analysis from the MAUDE database. This criterion includes the following:

1. **Case Study Identification:** Describe the details of the date, location, and device type or specification (for example, bipolar or both ultrasonic and bipolar).
2. **Incident Details:** Summarize the incident, highlighting the malfunction and describing the impact on patients and healthcare providers.
3. **Malfunction Description:** Describe the device's malfunction, severity, and immediate consequences.
4. **Impact Assessment:** Assess the impact of device malfunction on patients or surgeons and mention any additional medical interventions, if any.
5. **Root Cause Analysis:** Analysis of contributing factors and underlying issues leading to the malfunction, including design flaws, manufacturing defects, and user error.
6. **Recommendations:** Summarize key factors influencing the malfunction and provide recommendations to prevent those issues.

Cultural and ethical considerations play a significant role in research, particularly in creating case studies involving medical device failures resulting in patient or surgeon injury or harm. While the primary focus is on understanding the root causes of these incidents, it is equally important to prioritize ethical responsibility by learning from these instances to prevent future harm and avoid any harm to those involved. Ultimately, the outcome of this method is to create a case study suggesting medical device requirements to prevent future occurrences of these issues and for Maxima’s upcoming bipolar device.

3.3 Patent Database Research

To determine the cost-effectiveness of Maxima's bipolar energy product inside the biotech markets of the US, Taiwan, Korea, and Thailand, the team will conduct secondary market research through patent analysis and research. For this method, the team will utilize patent databases such as the Taiwanese Patent Search Database (TWPAT) offered by TIPO, the United States Patent and Trademark Office (USPTO), and Google Patents to find patents relating to bipolar energy devices in MIS. These databases provide access to numerous patents, including patents related to Maxima's developments, such as ultrasonic dissectors and bipolar energy devices. The team plans to use each database to identify patents related to Maxima's new bipolar technology and evaluate other devices to see what aspects contribute to its success in the market. This search will cover IPs with similar designs or components and patents utilizing a bipolar energy system.

Each database, while having a unique design and interface, supports direct searches using specific patent identification numbers, ensuring precise retrieval of relevant technologies. Every published patent receives a number that can be used to search for an IP directly if the identification number is known. They also feature translator functions, enhancing accessibility for researchers with different linguistic backgrounds. Moreover, the option for general searches accommodates instances where exact patent numbers are unknown, which broadens the scope of research. This approach aids in identifying potential competitive advantages and areas for innovation within Maxima's product offerings.

Navigating challenges and limitations is imperative when searching databases for information to ensure data relevance and reliability. Only official documentation will be considered to mitigate the risk of using unreliable or false sources. It is important to avoid cherry-picking data supporting a desired outcome, highlighting the requirement of drawing from various sources. To reduce potential inherent biases, the information-gathering process extends beyond a single database, such as only using patents from Taiwan. This approach ensures a more balanced and complete understanding by incorporating varied perspectives and reducing the likelihood of biased conclusions.

3.4 Technology Function Table

After gathering data from various databases, organizing information is necessary to evaluate Maxima's product's cost-effectiveness. A Technology Function Table will enable clear data organization and communication. When analyzing past IQP project groups with similar projects in Taiwan that partnered with Summed Taiwan, the use of a technology function table achieved promising results. A Technology Function Table would both visualize the relationship between other technology patents and Maxima's bipolar energy device and show cost-effective features in related products and how they can be applied in evaluating Maxima's design. The table organizes information to highlight how various technological solutions address the functional requirements of a product. It is a tool for analyzing the biotechnology landscape, determining innovation opportunities, and understanding how existing solutions can be improved, or new solutions can be developed to meet needs (Carson et al, 2023). This approach will allow for a detailed examination of how other patents relate to Maxima's product and the identification of cost-effective features that can be applied to Maxima's bipolar energy system, ensuring a thorough analysis of the product's market viability.

3.5 SWOT & PESTLE Analysis

The team will conduct a SWOT analysis to assess various product's viability involves examining its strengths, weaknesses, opportunities, and threats, particularly in the context of the biotech market. This method can uncover the competitive edge of both product and company, and their competitive weaknesses which should be recognized. Much of the information for a SWOT analysis comes from a direct investigation of the products of a company, and of the partnerships that company has made. Alternatively, a PESTLE examination delves into political, economic, sociological, technological, legal, and environmental factors affecting the product. The information for a PESTLE analysis primarily comes from a review of the market a company is involved in, rather than specifically of the company itself or its products. One exception to this rule includes patents: researchers performing PESTLE analysis often scrutinize patents and patent law, categorized under legal factors, to identify regulatory hurdles or protections that influence the product's market entry and long-term viability. The SWOT and PESTLE analytical tools provide a comprehensive overview of the product's potential success, incorporating both internal capabilities and external market conditions (see Figure 3.5).

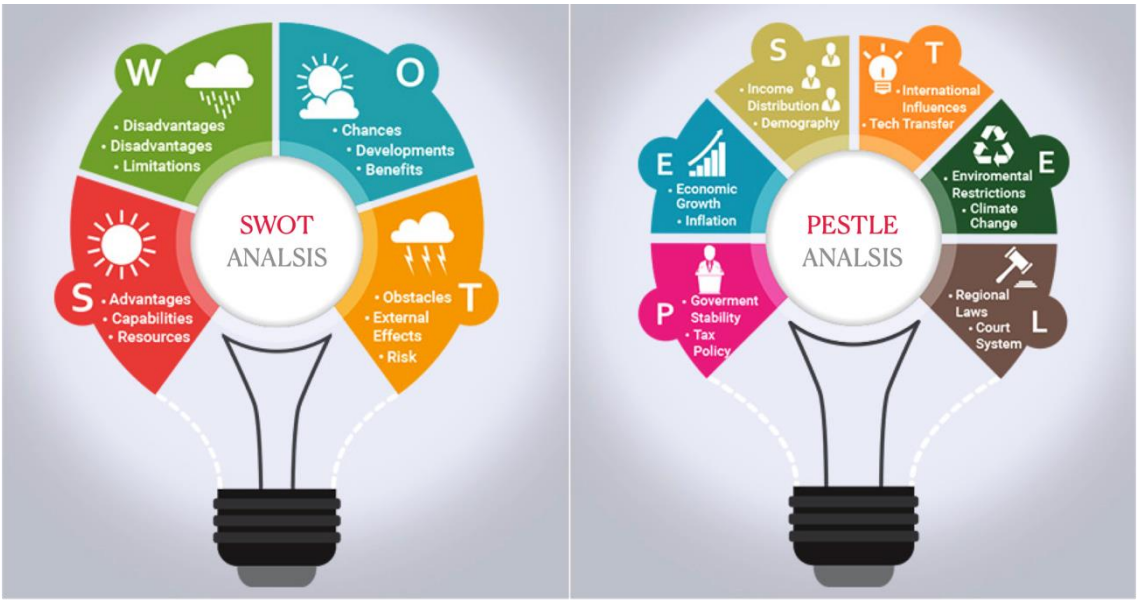

Figure 3.5: A visual representation of the components/variables considered in the SWOT & PESTLE analysis.
Research Optimus, 2021

3.6 Analysis of the Bipolar Energy Device Sector

To fully understand the bipolar energy device field's challenges and opportunities, we must sift through all the related research to improve the technology's effectiveness, reliability, and safety. Several avenues for research can help answer these questions. Research journals like the World Journal of Laparoscopic Surgery, in particular, hold knowledge gained from surgeons working with bipolar devices over decades. As the surgeons write many of the articles in these journals, they can hold institutional wisdom about how bipolar energy devices are thought of and used. This kind of information is vital to understand the development priorities for bipolar devices. Research journals are not an authoritative solution to our problem, however. Out of the PESTLE research segments mentioned in the above section, research journals primarily focus on social, technological, and often environmental issues rather than political, economic, or legal ones. The above methods will adequately cover all PESTLE components.

Ethically, the primary concern about our team taking data from academic journals is the skill of our team in accurately understanding, citing, and using the information found in them. Due to our team's education in conducting research, primarily through our education at the Worcester Polytechnic Institute, we believe we are capable of doing this. Additionally, we must be mindful of bias and outdated information. To minimize these risks, the team will look for data from published academic journals over the last five years.

It would be negligent of a study about any product class to ignore what is already available on the market. As a result of its characteristic slow motion, caused equally by law and the generally high development costs incurred, any innovations made in the medical industry are likely to only become popular over the span of years. The team understands that Medtronic and Olympus are not the only businesses to develop bipolar energy devices. However, due to their market size, they were the first priority for investigation. When the team goes to Taiwan properly, we intend to investigate other bipolar energy products, for example, Johnson and Johnson's ENSEAL product and CONMED's Edge.

One must always overcome challenges when performing analysis based on published information. For example, businesses may consider certain information sensitive, particularly costs, parts, and manufacturing processes, and will not publish them. These challenges can make it difficult to find information to perform a complete economic analysis based on publicized data, which may require the team to make estimations.

4.0 Conclusion

In conclusion, the above research will provide insights into the development and market introduction of surgical devices incorporating bipolar energy systems. Through an extensive process of interviews with medical professionals, analysis of case studies, and examination of competitor products and patents, this project will highlight the potential for significant advancements in surgical technology. As Maxima Biotech Inc. moves forward, the team's suggestions will help guide the development and marketing strategies for their innovative bipolar energy device, enabling Maxima to meet the ever-evolving needs of the medical industry and ultimately improves patient care.

Bibliography

Agha, R., & Muir, G. (2003). Does laparoscopic surgery spell the end of the open surgeon? Journal of the Royal Society of Medicine, 96(11), 544–546. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC539626/

Cason, Duncan, Moralas, & Valery. (n.d.). Patent Clustering Program and Business Strategies for an Ultrasonic Dissector in Taiwan. Retrieved March 1, 2024, from https://wpi.primo.exlibrisgroup.com/discovery/fulldisplay?docid=alma9937226230004746&context=L&vid=01WPI_INST:Default&lang=en&search_scope=WPI_Students_Project&adaptor=Local%20Search%20Engine&tab=WPI_Student_Projects&query=any,contains,Taiwan%20AND%20IQP&offset=0

Charles, K. (2016, March 31). Tools of the Trade - LigaSure [Blog]. Vet Practice. https://www.vetpracticemag.com.au/tools-trade-ligasure/

Charles Kuntz. (2016, March 31). Tools of the trade: LigaSure. Vet Practice Magazine. https://www.vetpracticemag.com.au/tools-trade-ligasure/

Chicago Institute of Minimally Invasive Surgery. (n.d.). History of Minimally Invasive Surgery. Retrieved February 9, 2024, from http://www.laparoscopicexperts.com/introduction/

Chivukula, S., Lammers, S., & Wagner, J. (2020). Assessing organic material on single-use vessel sealing devices: a comparative study of reprocessed and new LigaSureTM devices. Surgical Endoscopy, 35, 4539–4549. https://doi.org/10.1007/s00464-020-07969-8

Cleveland Clinic. (n.d.). Laparoscopic Surgery: Purpose, Procedure & What it Is. Cleveland Clinic. Retrieved February 9, 2024, from https://my.clevelandclinic.org/health/treatments/22552-laparoscopic-surgery

Covidien ValleylabTM ForceTriadTM Energy Platform (ESU), Recertified. (2024). [Online Store]. Envi Health Solutions. https://www.envihs.com/products/covidien-valleylab-forcetriad-esu-recertified

Creswell, J. W., & Creswell, J. D. (2018). Research design: qualitative, quantitative, and mixed methods approaches (Fifth edition). SAGE.

Cunha, M. F., & Pellino, G. (2023). Environmental effects of surgical procedures and strategies for sustainable surgery. Nature Reviews. Gastroenterology & Hepatology, 20(6), 399–410. https://doi.org/10.1038/s41575-022-00716-5

Dobson, G. P. (2020). Trauma of major surgery: A global problem that is not going away. International Journal of Surgery, 81, 47–54. https://doi.org/10.1016/j.ijsu.2020.07.017

Hariharan, V. G., Landsman, V., & Stremersch, S. (2023). Branded response to generic entry: Detailing beyond the patent cliff. International Journal of Research in Marketing. https://doi.org/10.1016/j.ijresmar.2023.12.004

Healthcare Expo Taiwan. (2022, November 17). “Maxima” Cordless Ultrasonic Dissector | Healthcare+ Expo, Taiwan | Getting Ahead in Healthcare Business booming in the APAC region. Healthcare+ Expo, Taiwan. https://expo.taiwan-healthcare.org/en/news_detail.php?REFDOCID=0rlgzu75bt4r0t4o

Hysteresis. (2024). [Explainer Website]. BYJU’s. https://byjus.com/jee/hysteresis/

International Trade Administration. (2024a, January 9). Thailand - Protecting Intellectual Property. https://www.trade.gov/country-commercial-guides/thailand-protecting-intellectual-property

International Trade Administration. (2024b, January 10). Taiwan - Protecting Intellectual Property. https://www.trade.gov/country-commercial-guides/taiwan-protecting-intellectual-property

Jaiswal, A., & Huang, K.-G. (2017). Energy devices in gynecological laparoscopy – Archaic to modern era. Gynecology and Minimally Invasive Therapy, 6(4), 147–151. https://doi.org/10.1016/j.gmit.2017.08.002

Karande, V. (2015). LigaSureTM 5-mm Blunt Tip Laparoscopic Instrument. The Journal of Obstetrics and Gynecology of India, 65, 350–352. https://doi.org/10.1007/s13224-015-0745-2

Kelley, W. E. (2008). The Evolution of Laparoscopy and the Revolution in Surgery in the Decade of the 1990s. JSLS : Journal of the Society of Laparoendoscopic Surgeons, 12(4), 351–357. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3016007/

Korean Intellectual Property Office. (2023). Patents. https://www.kipo.go.kr/en/HtmlApp?c=92000&catmenu=ek03_01_01

LaPelusa, A., & Bordoni, B. (2024). High-Velocity Low-Amplitude Manipulation Techniques. StatPearls Publishing. https://www.ncbi.nlm.nih.gov/books/NBK574527/

Lee, E., Tong, J., Pasick, L., Benito, D., Joshi, A., Thakkar, P., & Goodman, J. (2022). Complications associated with energy-based devices during thyroidectomy from 2010–2020. World Journal of Otorhinolaryngology - Head and Neck Surgery, 9(1), 35–44. https://doi.org/10.1016/j.wjorl.2021.04.008

LF1623 – Covidien Ligasure Laparoscopic Sealer/Divider Blunt Tip 23.0Mm. (2023). [Online Store]. SurgiShop. https://surgishop.com/product/lf1623-covidien-ligasure-laparoscopic-sealer-divider-blunt-tip-23-0mm/

Ligasure Technology. (2024). [Sales Page]. Medtronic. https://www.medtronic.com/covidien/en-us/products/vessel-sealing/ligasure-technology.html

LigaSure Vessel Sealing System - 6/Case. (2024). [Online Store]. Tiger Medical. https://tigermedical.com/products/ligasure-vessel-sealing-system-covlf1823-oo

Litynski, G. S. (1997). Laparoscopy Between the World Wars: The Barriers to Trans-Atlantic Exchange. JSLS : Journal of the Society of Laparoendoscopic Surgeons, 1(2), 185–188. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3021276/

Maxima Biotech Inc. (n.d.). Home Page. Maxima Biotech Inc. Retrieved February 9, 2024, from https://www.maximabio.com/?lang=en

Mbah, N. A., Brown, R. E., Bower, M. R., Scoggins, C. R., McMasters, K. M., & Martin, R. C. G. (2012). Differences between bipolar compression and ultrasonic devices for parenchymal transection during laparoscopic liver resection. HPB : The Official Journal of the International Hepato Pancreato Biliary Association, 14(2), 126–131. https://doi.org/10.1111/j.1477-2574.2011.00414.x

Medtronic. (n.d.). LigasureTM XP Maryland Jaw Sealer/Divider With Nano-coating | Medtronic. Retrieved February 27, 2024, from https://www.medtronic.com/covidien/en-us/products/vessel-sealing/ligasure-xp-maryland-jaw-sealer-divider-nano-coating.html

Monopolar Electrosurgery vs. Bipolar Electrosurgery. (2016, October 3). [Blog]. Symmetry Surgical. https://symmetrysurgical.com/bipolar-electrosurgery-vs-monopolar-electrosurgery/

Ochsner, J. L. (2000). Minimally Invasive Surgical Procedures. The Ochsner Journal, 2(3), 135–136. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3117518/

OLRC Home. (n.d.). Retrieved February 9, 2024, from https://uscode.house.gov/browse/prelim@title35&edition=prelim

OLYMPUS. (2018). THUNDERBEAT Technology [Explainer]. OLYMPUS. https://www.olympusprofed.com/gyn/lapgyn/22072/

Olympus. (2024). THUNDERBEAT | Hybrid Energy | General Surgery | Olympus Medical Systems. https://www.olympus-europa.com/medical/en/Products-and-Solutions/Products/Product/THUNDERBEAT-General-Surgery.html

Olympus to Launch THUNDERBEAT. (2012, March 21). [Press Release]. Olympus America. https://www.olympus-global.com/en/news/2012a/nr120321thunderbeate.html

OmniMark. (2023, December 6). Bipolar Electrosurgery Market Size 2023 - 2030 Global Industrial Analysis, Key Geographical Regions, Market Share, Top Key Players, Product Types and. LinkedIn. https://www.linkedin.com/pulse/bipolar-electrosurgery-market-size-2023-2030-global-industrial-b6iee

Pantelić, M., Ljikar, J., Devecerski, G., & Karadzić, J. (2015). Energy Systems in Surgery. Medicinski Pregled, 68(11–12), 394–399. https://doi.org/10.2298/mpns1512394p

PATENT ACT - Article Content - Laws & Regulations Database of The Republic of China (Taiwan). (n.d.). Retrieved February 9, 2024, from https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=J0070007

Patents. (n.d.). Retrieved February 9, 2024, from https://www.wipo.int/patents/en/index.html

Piemontese, A., Cohen, L., Wright, G., Robledinos-Antón, N., Jamous, N., & Tommaselli, G. (2023). Adopting a portfolio of ultrasonic and advanced bipolar electrosurgery devices from a single manufacturer compared to currently used ultrasonic and advanced bipolar devices: a probabilistic budget impact analysis from a Spanish hospital perspective. Journal of Medical Economics, 26(1), 179–188. https://doi.org/10.1080/13696998.2023.2169496

Prosecution History Estoppel: Differences in Regulations between U.S., China, and Taiwan and Suggested Strategies. (n.d.). Default. Retrieved February 9, 2024, from https://www.aipla.org/list/innovate-articles/prosecution-history-estoppel-differences-in-regulations-between-u.s.-china-and-taiwan-and-suggested-strategies

Qualtrics. (2024). Survey bias types that researchers need to know about. Qualtrics. https://www.qualtrics.com/experience-management/research/survey-bias/

Research Optimus. (2021, July 23). Using SWOT and PESTLE Analysis Together for Crafting Strategy. Research Optimus. https://www.researchoptimus.com/blog/using-swot-and-pestle-analysis-together-for-crafting-strategy/

Robert K. Zurawin, T. Bartley Pickron, & Robin P. Blackstone. (n.d.). Intelligent Ultrasonic Energy. ETHICON. Retrieved February 15, 2024, from https://www.jnjmedtech.com/sites/default/files/user_uploaded_assets/pdf_assets/2019-10/Intelligent-Ultrasonic-Energy-Delivered-by-HARMONIC-Devices-Springer-Paper-018618-140721.pdf

Sankaranarayanan, G., Resapu, R. R., Jones, D. B., Schwaitzberg, S., & De, S. (2013). Common Uses and Cited Complications of Energy in Surgery. Surgical Endoscopy, 27(9), 3056–3072. https://doi.org/10.1007/s00464-013-2823-9

Santa Clara University. (n.d.). Conducting Effective and Ethical Interviews. The HUB Think. Write. Speak, 1–5.

Schicker, E. (2022, August 25). Understanding primary & secondary, quantitative & qualitative research methods in UX. Medium. https://evaschicker.medium.com/understanding-primary-secondary-quantitative-qualitative-research-methods-in-ux-df3d1e327e7f

ScienceDirect.com | Science, health and medical journals, full text articles and books. (n.d.). Retrieved February 9, 2024, from https://www.sciencedirect.com/?ref=pdf_download&fr=RR-11&rr=852f7a3d0f070597

Seth Batiste. (2024). What are the advantages and disadvantages of using case studies? https://www.linkedin.com/advice/0/what-advantages-disadvantages-using-case-studies

Smith, A., Kondo, M., Kondo, W., & Cabrera, R. (2018). Laparoscopic Surgical Devices: A Review of the Newest Energies and Instruments. International Journal of Medical Science and Health Research, 2(6), 40–60. https://ijmshr.com/uploads/pdf/archivepdf/2020/IJMSHR_02_100.pdf

Stanford Medicine. (2024). General Surgery Types. https://stanfordhealthcare.org/medical-treatments/g/general-surgery/types.html

Summed. (2020). About Summed. 苡樂創新平台. https://www.summedtw.com/關於苡樂?lang=en

TB-0535FCS – Olympus Thunderbeat 5Mm 35Cm Front Actuated Grip Type S. (2023). [Online Store]. SurgiShop. https://surgishop.com/product/tb-0535fcs-olympus-thunderbeat-5mm-35cm-front-actuated-grip-type-s/

The FullStory Education Team. (2021, October 6). Qualitative vs. Quantitative Data: The Difference | FullStory. https://www.fullstory.com/blog/qualitative-vs-quantitative-data/

Thunderbeat. (2024). [Sales Page]. Olympus America. https://medical.olympusamerica.com/products/thunderbeat

VALLEYLAB LigaSure. (2024). [Online Store]. Bimedis. https://bimedis.com/valleylab-ligasure-m25480

Velanovich, V. (2000). Laparoscopic vs open surgery: A preliminary comparison of quality-of-life outcomes. Surgical Endoscopy, 14(1), 16–21. https://doi.org/10.1007/s004649900003

Vettoretto, N., Foglia, E., Gerardi, C., Lettieri, E., Nocco, U., Botteri, E., Bracale, U., Caracino, V., Carrano, F. M., Cassinotti, E., Giovenzana, M., Giuliani, B., Iossa, A., Milone, M., Montori, G., Peltrini, R., Piatto, G., Podda, M., Sartori, A., … on behalf of the HTA-HED Collaborative Group. (2023). High-energy devices in different surgical settings: lessons learnt from a full health technology assessment report developed by SICE (Società Italiana di Chirurgia Endoscopica). Surgical Endoscopy, 37(4), 2548–2565. https://doi.org/10.1007/s00464-022-09734-5

Zhao, Z., & Gu, J. (2022). Open surgery in the era of minimally invasive surgery. Chinese Journal of Cancer Research, 34(1), 63–65. https://doi.org/10.21147/j.issn.1000-9604.2022.01.06

Appendix A: Glossary

Cavitation is a process that uses mechanical force to form a gas bubble in joint spaces between bones.

Cholecystectomy is the process of surgically removing the gallbladder.

Coagulation is the process by which a blood clot is formed.

Coaptation is the joining or readjustment of two surfaces.

Desiccation is the drying of tissue or loss of moisture

Dissection is the process of cutting or separating tissues.

Extracellular Heating is the process of raising the environment's temperature surrounding cells or tissues, often employed in medical treatments and research applications.

Fulguration is the destruction of tissue (i.e. small growths) by electrical means.

Hysteresis is a phenomenon that occurs when the magnetization of ferromagnetic materials lags behind the magnetic field.

Intracellular Heating involves increasing the temperature within the interior of cells, typically achieved through methods like targeted nanoparticles or electromagnetic radiation and is utilized in various biomedical and research contexts.

Laparoscopic Surgery is a type of minimally invasive surgery performed on the pelvic and abdominal areas.

Lateral Thermal Spread refers to how heat generated during a surgical procedure spreads laterally (horizontally) from the intended target area.

Ligation is the surgical procedure of closing a blood vessel or other tube in the body by the use of a clip, ligature (surgical thread), or other means

Mechanical Ligation is the use of specific clips or ligatures (surgical threads) in order to close blood vessels, as opposed to electrical or heat-based means

Non-Modulated Frequency refers to a steady, continuous energy output at a specific frequency without any variation.

Ohmic heating, or resistive heating, is the process of a material heating up due to electrical current flowing through it.

Sutures are stitches that hold a wound or surgical incision closed in order for it to heal properly.

The Piezoelectric Effect is the ability of certain materials to generate an electric charge in response to applied mechanical stress.

Tissue Impedance or **electrical impedance of tissues** is the response of tissues to electrical energy when connected to an alternating electrical voltage source.

Appendix B: Surgeon Interview Questions

Introduction: You are being asked to participate in a research study. Before you agree, however, you must be fully informed about the purpose of the study, the procedures to be followed, and any benefits, risks, or discomfort that you may experience as a result of your participation. This form presents information about the study so that you may make a fully informed decision regarding your participation.

Purpose of the study: This study aims to understand laparoscopic surgical devices from Maxima Biotech Inc. and their competitors. The team aims to determine surgeons' and patients' preferences, including key factors such as quality, cost-effectiveness, and safety. Additionally, the interviews seek to analyze surgeries where these devices are applied, evaluating their effectiveness, and identifying areas for improvement. The insights gathered will be analyzed to provide recommendations to Maxima Biotech, aiding optimal decision-making in future device development.

Procedures to be followed: The interviewer will ask questions about laparoscopic surgical devices and their uses in a flexible, semi-structured manner. In-person interviews are preferred, but a virtual option is available for those unable to attend in person. We expect each interview to last thirty to sixty minutes, and two team members will be present. Interviewees may decline to answer questions at any time in the case of reluctance or discomfort.

Record keeping and confidentiality: A team member will transcribe your responses during the interview. Records of your participation in this study will be confidential as permitted by law. However, the study investigators, the sponsor, or its designee, and, under certain circumstances, the Worcester Polytechnic Institute Institutional Review Board (WPI IRB) will be able to inspect and have access to confidential data that identify you by name. Any publication or presentation of the data will not identify you.

Your participation in this interview is voluntary. Your refusal to participate will not result in any penalty to you or any loss of benefits to which you may otherwise be entitled. You may decide to stop participating at any time without penalty or loss of other benefits.

- **Gatekeeper Questions:**
  1. Do you have experience using bipolar energy devices in surgery?
  2. Would you prefer to meet in person or virtually?
  3. Do we have your consent to record this interview?
     → If not, would it be possible to take notes while documenting an anonymous name, age, and gender?
- **Interview Questions: (During Official Interview)**
  - **Demographics:**
    4. What is your job title?
    5. What is your age? (20–30? 30–40?)
    6. What is your gender?
    7. How long have you been working in the medical/surgical field?
  - **About the Devices:**
    - ❖ **Background:**
    8. What types of surgeries are bipolar devices used in?
    9. How are the devices used during these surgeries?
    10. What are some qualities that you saw or would like to see in a surgical bipolar energy device?
    11. What model/brand of device do you use?
    12. Who was involved in the device decision-making process? - If you were involved, what factors informed your decision to use one bipolar energy device over another?
    13. How difficult is it to learn to use bipolar devices?
    14. Is it difficult to learn to use a new bipolar device after using a different model previously?
    15. We have found conflicting online research on the reusability of bipolar energy devices. Have you come across any reusable bipolar energy devices? - If not, do you think that bipolar energy device reusability is possible?

❖ **Economics:**

16. What are the estimated costs of using that device for the patients and the hospital? Do you think it should be higher or lower?
17. What would the cost of switching to a different model/brand of bipolar energy device be?

❖ **Reliability and Ethics:**

18. Are there ethical considerations you consider when choosing to use a bipolar energy device, especially in terms of patient safety and outcomes?
19. Are you aware of any cases of surgeon or patient harm from bipolar or hybrid device malfunction?

→ If so, what was the malfunction?

- Could you provide us with some details about the type and brand of the device?

→ Do you know what the cause of the malfunction was?

- If so, what variables or factors caused the malfunction?

→ Do you perhaps know about the regulatory compliance or hospital protocol that was in place during the event of the malfunction?

❖ **Closing:**

20. Is there anything else we should know we have not covered?