WPI

# Surgical Product Investigation for Maxima's Advanced Bipolar Energy Device


**Written by**
Alexander Kirkman
Shaylie Lagasse
Isha Medasani
Samuel Rooney

**Advisors**
Wen-Hua Du
Robert Kinicki

**Sponsor**
Dr. Tang Hsiao-Wei
*Maxima Biotech Inc.*


MAXIMA

# Surgical Product Investigation for Maxima's Advanced Bipolar Energy Device

An Interactive Qualifying Project
submitted to the Faculty of
WORCESTER POLYTECHNIC INSTITUTE
in partial fulfilment of the requirements for the
degree of Bachelor of Science

by
Alexander Kirkman
Shaylie Lagasse
Isha Medasani
Samuel Rooney

Date:
May 1st, 2024

Report Submitted to:

Dr. Tang Hsiao-Wei
Maxima Biotech Inc.

Professors Robert Kinicki and Wen-Hua Du
Worcester Polytechnic Institute

# Abstract

The project goal was to collaborate with Maxima Biotech Inc., a Taiwanese medical device company, to aid the development of their upcoming advanced bipolar surgical device. Maxima recognized the potential profit involved with developing a cost-effective advanced bipolar surgical device for improved postoperative outcomes. From interviews with surgical experts, a social survey to understand consumer priorities and environmental sustainability, and competitor analysis on rival companies, the team gathered insights into safety, simplicity, and environmental impact for Maxima's development. The team generated recommendations to improve the marketability of Maxima's advanced bipolar surgical device, addressing the need to reduce preventable surgical accidents through an innovative product.

## Acknowledgements

We would like to thank our sponsor, Maxima Biotech Inc., and specifically Dr. Tang Hsiao-Wei, for being such a gracious and helpful host. We would also like to thank our advisors, Professor Robert Kinicki and Professor Wen-Hua Du, for helping us make our presentation and final report the best possible. Next, we thank Professor Amanda Wittman, who helped us assemble our proposal for this project. Additionally, we would like to thank our expert interviewees, including Dr. Ranson Liao, Dr. Edward Rooney, Dr. Liu Yuyin, and Dr. David Caparrelli, for giving us their valuable time and insights, which comprise our project's core. We also thank our friends, family, and colleagues who took our survey and gave us their opinions. Finally, we thank you, the reader, for reading through our work.

# Executive Summary

## Introduction & Background

Every year, surgeons around the world perform 310 million major surgeries, and approximately 1 in 25, or 8 million, of these patients die soon afterward (Dobson, 2020). A network of researchers, surgeons, and engineers worldwide are always working to improve the survival rate of patients, to improve the rate of successful outcomes, and to minimize the rate of surgical complications. Minimally invasive surgery is one of the most successful tools ever developed to enhance patient outcomes.

Surgeons define minimally invasive surgery, or MIS, by using roughly half-inch wide incisions to access the interior of their patients, instead of the more than six-inch incisions typical open surgery. There are many benefits to this kind of operation, including reduced blood loss and pain, reduced risk of postoperative complications, and lower infection risk. During MIS, surgeons typically use cameras to visualize structures, such as bones, tissues, or organs within the patient's body, as the small incisions prohibit direct visual inspection. This characteristic increases the complexity of learning and performing MIS procedures.

Originally brought to market in the late 1990s, advanced bipolar energy devices use electrical current or energy to create heat between two jaws. Three specific tasks performed during surgery use heat. The surgeon can cut, desiccate (dry out) body tissue, like parts of organs or fat, or coagulate (solidify) blood to stop a patient from bleeding. Advanced bipolar energy devices, unlike basic bipolar devices, use modern sensor technology to specialize in performing coagulation on things like cutting blood vessels while applying the minimum amount of current needed. This modern technology helps surgeons reduce blood loss and damage to the patient's body compared to other methods.

There are a small number of advanced bipolar energy devices currently available. The primary manufacturers of these devices are Covidien, a subsidiary of Medtronic, and Ethicon, from Johnson & Johnson. Covidien's device (as shown in Figure 0.1) is LigaSure and Ethicon's is ENSEAL. Sales of the LigaSure device alone account for 84% of the advanced bipolar energy market. All the devices on the market now, including LigaSure, ENSEAL, and their few smaller competitors, are single-use disposable devices that cost roughly $450 USD per device. This is a steep cost, and their continued use has a few impacts. First, it impacts the amount of money patients spend on health insurance. If manufacturers reduced the price of the devices while maintaining quality and effectiveness, it could affect the average person's cost of care. Second, the disposable nature of these devices (and the use of "new" plastic materials to manufacture them) means there is a material environmental cost to consider when developing new devices.

**Figure 0.1:** *Medtronic's LigaSure Surgical Device*

Any time a business is trying to develop and sell a new product, like an advanced bipolar energy device, the business must navigate patent law. In countries like Taiwan, patent law is much less restrictive relative to United States patent laws. Patent laws make the market more competitive, implying that businesses cannot set high product prices. Inside the United States, patent law is very restrictive, which allows businesses to charge more for their products until the patent expires. There are benefits and drawbacks to both solutions. For example, medical care is broadly less expensive in Taiwan, but healthcare quality is slightly lower (Wu et al., 2010). Medical care is expensive in the United States, but the quality is very good.

Maxima Biotech (久方生技) is a medical device manufacturer based out of Taipei, Taiwan that focuses on MIS devices. Maxima is currently starting the development of a new advanced bipolar energy device. The company's founders are Mr. Hong Yi-Ping and Dr. Tang Hsiao-Wei, who have decades of entrepreneurial experience in the medical device industry. They believe that creating less expensive tools that are just as good as the most expensive ones on the market is a way to increase both the quality-of-care patients receive and the number of patients they can help. To better understand the requirements for

advanced bipolar energy devices, Maxima sponsored a team from Worcester Polytechnic Institute to recommend development priorities for this new device.

The team created an outline of their critical objectives for this project. First, they decided to assess the market for advanced bipolar energy devices locally and globally to understand competitive positioning and demand. Second, they would identify key product features that influence the adoption rate among surgeons in Taiwan and the United States. Third, they chose to assess surgical devices' sustainability, environmental impact, and reusability and gauge public concern and interest regarding these topics.

## Methods

The team's goal for this project was to collaborate with Maxima Biotech Inc. to aid the development of their upcoming advanced bipolar surgical device. Our methodology included three distinct yet interconnected approaches to implement the project's goal. The team's methodology utilized surgeon interviews, competitor analysis involving two major advanced bipolar market shareholders and a potential collaboration with Maxima, and a consumer survey to assess preferences and opinions on certain surgical priorities and sustainability. The results of these three methods allowed the team to create strategic recommendations for Maxima to consider for their upcoming advanced bipolar surgical device.

The first method, conducting surgeon interviews, helped the team gather perspectives on certain aspects of Taiwan's healthcare landscape. The team interviewed four surgeons, two from the United States and two from Taiwan, using a semi-structured method that allowed the surgeons to express their knowledge openly. The interviews opened with demographic questions to gather job titles, ages, amount of experience in the medical/surgical field, and familiarity with bipolar devices. The team then asked the surgeons about qualities they believe are essential in surgical devices and the factors guiding their device selection. Other questions targeted the surgeons' level of involvement in device selection, the time it took to train to use advanced bipolar devices, and opinions on sustainability. Since the team conducted a limited number of interviews, they manually studied the transcripts to extract key features Maxima can implement in their upcoming advanced bipolar device.

Secondly, the team conducted competitor analysis using the SWOT and PESTLE analysis techniques. SWOT analysis determines the company's internal strengths, weaknesses, opportunities, and threats, whereas PESTEL analysis investigates the company's external political, economic, social, technological, environmental, and legal factors. The team studied three companies: Medtronic, Ethicon (a subsidiary of Johnson & Johnson), and CONMED. The team used the information gathered from the PESTEL analysis to help identify opportunities and threats in their SWOT analysis. The team gathered this information in tables and performed analysis, helping them understand the current bipolar energy device market.

Lastly, the team conducted an anonymous online social survey. This survey used snowball sampling, where the team distributed the link to fellow US and Taiwan university students and Maxima. Subsequently, these recipients shared the survey with their families and team members. The team split this survey into two sections. The first included four demographic questions addressing age, country of residence, income bracket, and occupation, as well as two general questions that looked at the respondents' medical insurance and surgical device experience. Additionally, the survey asked respondents to rank the following priorities: cost of surgery, safety, environmental impact, usage of the latest technology, and ethically sourced materials based on their perceived importance regarding surgery. The final question focused on respondents' inclination towards environmentally friendly materials or options during surgery, should such alternatives be available.

## Results and Analysis

The word cloud in Figure 0.2 highlights the topics which surgeons discussed most during the interviews by size. Firstly, there was a consensus among the interviewees that safety is the priority in surgical device design. Each surgeon emphasized the requirement for devices to prioritize patient safety and aim to reduce postoperative complications.


**Figure 0.2:** *Surgeon Interview Topic Word Cloud*

Simplicity emerged as another high priority among the interviewees. Surgeons stressed the utility of intuitive designs that allow them to focus more on the patient than on the tool. For instance, Dr. Rooney highlighted the pitfalls of overly complicated devices, recalling his experience with older units with too many power settings, causing inefficiencies. He stated, "...the older units had a lot more choices as far as going up and down in power. And that was usually a bad thing because you can never find the right setting." Similarly, Dr. Liao recounted a failed demonstration of a device due to its complexity, emphasizing the importance of user-friendly design. He mentioned, "10 years ago, [company name redacted] had come to our hospital for trial, but it failed. As I said, it's not so simple to use, and the surgeon did not like that."

Furthermore, the surgeons were concerned about ensuring good visibility during surgical procedures through better smoke ventilation. Dr. Caparrelli expressed dissatisfaction with current smoke ventilation methods, mentioning their bulky nature and impact on surgical precision. He explained, "…one thing that's not handled very well with cautery devices is smoke evacuation. I have not found a monopolar or cautery type device that handles smoke evacuation very well because they get very cumbersome." Dr. Rooney also suggested that a means to remove smoke would be a valuable feature for future devices.

Finally, multiple interviewees mentioned the importance of one-handed use, indicating a need for devices with close-together, simple controls. Dr. Liu noted that surgeons often need their second hand for tasks like tissue manipulation and camera operation, and the added step to use that second hand to change the settings on a device is often not possible; instead, a nurse or other assistant might have to lend a hand, which increases the risk and the complexity of the surgical procedure. Dr. Liu cites this as his reason for preferring one-handed tools.

Overall, these interviews revealed that designers must address many considerations while developing advanced bipolar energy devices. By prioritizing safety, simplicity, proper smoke ventilation, and one-handed use, device manufacturers can enhance surgical outcomes and streamline procedures for surgeons.

The team analyzed three major competitors in the surgical device market to gain insights into the factors shaping the market landscape. With this analysis, the team aimed to identify key areas where Maxima can gain a competitive edge as it prepares to enter the global market.

Medtronic, a leading player in the medical device industry, boasts a diverse product portfolio and a strong global presence, with over 50% of its sales coming from international markets. Its innovative technologies, including advanced bipolar devices, contribute to its large market share. However, Medtronic faces challenges such as soft growth in critical segments and cybersecurity concerns, highlighting the importance of continued innovation and strategic adjustments.

Johnson & Johnson's Ethicon subsidiary excels in minimally invasive surgery and digital health solutions, taking advantage of its extensive global network and aggressive expansion in medical technologies. Yet, it confronts challenges such as political instability and high R&D costs, emphasizing the need for risk management.

CONMED, though smaller in revenue than Medtronic and Johnson & Johnson, focuses specifically on surgical products and has a history of strategic acquisitions to expand its product line. However, it lacks an advanced bipolar energy device, presenting both a weakness and an opportunity for a partnership for Maxima.

In summary, while Medtronic and Ethicon face challenges in the competitive environment, their diverse portfolios and continuous innovation sustain their market power. CONMED's focus on surgical products and strategic partnerships offers growth opportunities. By learning from these competitors' experiences and leveraging its own strengths, Maxima can strategically position itself for success in the global surgical equipment market.

Figure 0.3 from the survey reveals a common preference for disposable surgical devices across all respondents. While there was no strong correlation between device preference and age or income, the data suggests that US consumers may have a slightly higher awareness or concern regarding environmental impact compared to respondents from Taiwan.

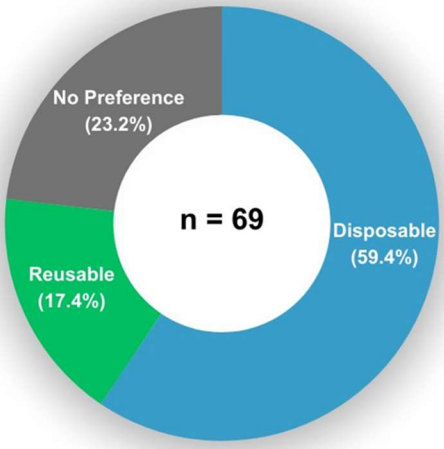


**Figure 0.3:** *Reusable vs Disposable Device Preference*

However, despite this tendency, both groups still have a substantial preference for disposable devices. Figure 0.4 shows that safety emerged as the top priority when considering surgical devices, while environmental impact ranked the lowest.

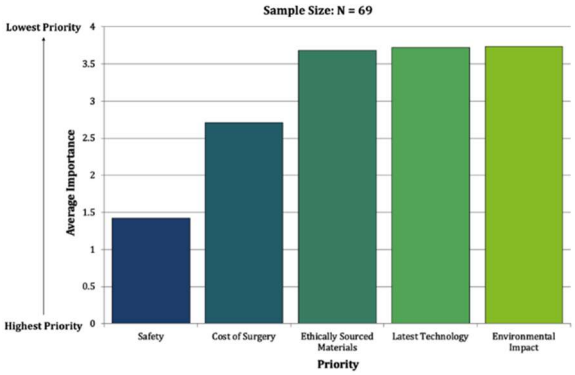


**Figure 0.4***: Respondent Surgical Device Priorities*

Additionally, older age groups expressed greater concern for ethically sourced materials and technological advancements, whereas younger age groups expressed greater concern for cost. Although environmental impact was not a top priority, the majority of respondents expressed an interest in environmentally friendly materials or options used in surgical devices if feasible, underscoring the importance of considering sustainability in healthcare practices.

**Recommendations**

The team's recommendations cover several concepts, including design improvements, market strategies, and competitive positioning. Each recommendation leverages Maxima's strengths and addresses the needs of the industry and surgical professionals.

*Surgeon Interface*

The team recommends that Maxima design a simplified interface to improve the surgeon's experience and enhance the competitiveness of their advanced bipolar device. This should include one-handed controls, ensuring intuitive operation during surgical procedures. Feedback from surgeons highlights the importance of a design that minimizes cognitive load, which is critical for adoption and trust in the device. The integration of controls directly on the handheld unit, as suggested by Dr. Caparrelli, will enable surgeons to operate the device single-handedly while managing other tools simultaneously, simplifying use and maintaining consistent performance.

*Smoke Ventilation*

To enhance safety and operation efficiency, the team recommends incorporating a smoke ventilation system within the device. This integration will streamline the device, improving ergonomics and allowing for greater precision by clearing the visual field during surgery. This design will reduce the reliance on bulky external evacuation methods and promote a safer, clearer surgical environment, ultimately simplifying the surgeon's workflow.

*Disposable Tips*

The team suggests Maxima explore the development of disposable tips for their device to address sterilization challenges and component longevity. This modification would allow surgeons to discard only the tip after use, maximizing safety from infection while minimizing environmental impact. By replacing only the device's jaw after each surgery, Maxima can offer a cost-effective, reliable solution that conserves materials used in the handle and reusable electronics.

*Environmentally Friendly Materials*

Based on surgeon feedback regarding sustainable practices, the team recommends integrating environmentally friendly materials in the device. This approach minimizes environmental impact and aligns with the growing market trend towards sustainability. By using sustainable materials, particularly for the handles in tandem with disposable tips, Maxima can strengthen its market position and appeal to environmentally conscious stakeholders.

*Strategic Partnership*

Lastly, the team recommends that Maxima form a strategic partnership with CONMED. Given Maxima's resource limitations compared to larger competitors like J&J and Medtronic, partnering with CONMED would allow Maxima to leverage their distribution network and industry experience while maintaining its operational independence. This strategy will enable Maxima to expand its market reach and enhance its product offerings through collaborative innovation. Additionally, Maxima's product portfolio addresses various gaps within CONMED's product line. This encompasses not only the upcoming advanced bipolar device but also extends to their existing ultrasonic dissector, which has already been manufactured and marketed.

**Conclusion**

Despite the complexity of the surgical device industry, the team is confident in their recommendations, derived from a thorough analysis of interviews, surveys, and competitor data. The team advises Maxima Biotech to seek strategic partnerships with established companies like CONMED to boost its R&D capabilities and broaden its market reach. With these proposed recommendations and enhancements serving as a guideline, Maxima Biotech can establish a strong foundation for innovating and marketing its new surgical device, applying insights gathered from the interviewed surgeons. The team believes that this project's findings and recommendations will guide Maxima Biotech as it continues to innovate and compete in the global surgical device market.

# Executive Summary References

Dobson, Geoffrey P. "Trauma of Major Surgery: A Global Problem That Is Not Going Away." *International Journal of Surgery*, vol. 81, Sept. 2020, pp. 47–54, https://doi.org/10.1016/j.ijsu.2020.07.017.

Wu, Tai-Yin, et al. "An Overview of the Healthcare System in Taiwan." *London Journal of Primary Care*, vol. 3, no. 2, Dec. 2010, pp. 115–19, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3960712/.

# Table of Contents

Abstract ..... iii
Acknowledgements ..... iv
Executive Summary ..... v
Executive Summary References ..... x
Table of Contents ..... xi
List of Figures ..... xiv
List of Tables ..... xvi
Authorship Table ..... xvii
1.0 Introduction ..... 1
1.1 Sponsor ..... 1
1.2 Goal, Objectives, and Implementation Methods ..... 3
2.0 Background ..... 5
2.1 Introduction to Minimally Invasive Surgery ..... 5
2.2 History of MIS Instruments ..... 6
2.3 Types of Electrical Energies ..... 7
2.3.1 Basic Bipolar to Advanced Bipolar Energy ..... 7
2.4 Advanced Bipolar Device Market ..... 8
2.4.1 Device Competitors ..... 9
2.4.1.1 Medtronic's LigaSure ..... 9
2.4.1.2 Johnson and Johnson's ENSEAL ..... 10
2.4.2 Pricing, Health Insurance, and Impact on Consumer ..... 11
2.5 Sustainability ..... 12
2.5.1 Advanced Bipolar Device Reusability ..... 13
2.5.2 Environmental Impacts of Advanced Bipolar Devices ..... 13
2.6 Patent Information ..... 14
2.6.1 International Patent Laws ..... 15
2.6.1.1 Taiwan Patent Laws ..... 15
2.6.1.2 United States Patent Laws ..... 16
2.7 Summary ..... 16
3.0 Methodology ..... 18

3.1 Surgeon Interviews ..... 19
3.1.1 Ethics Considerations ..... 20
3.2 Market Sector and Competitor Analysis ..... 21
3.2.1 PESTEL Analysis ..... 21
3.2.2 SWOT Analysis ..... 22
3.2.3 Sources and Application ..... 23
3.3 Social Surveys ..... 24
4.0 Results & Analysis ..... 26
4.1 Surgeon Interviews ..... 26
4.1.1 Dr. Liao Interview ..... 26
4.1.2 Dr. Liu Interview ..... 27
4.1.3 Dr. Rooney Interview ..... 28
4.1.4 Dr. Caparrelli Interview ..... 28
4.1.5 Interviews Conclusion ..... 29
4.2 Competitor Analysis ..... 30
4.2.1 Medtronic ..... 30
4.2.2 Johnson & Johnson ..... 32
4.2.3 CONMED ..... 34
4.2.4 Shared PESTEL Analysis ..... 36
4.2.5 Shared SWOT Analysis ..... 37
4.2.5.1 Strengths ..... 37
4.2.5.2 Weaknesses ..... 38
4.2.5.3 Opportunities ..... 38
4.2.5.4 Threats ..... 38
4.3 Social Survey ..... 39
4.3.1 Survey Results & Analysis ..... 39
4.3.2 Overall Survey Results & Analysis ..... 46
5.0 Recommendations to Maxima ..... 47
5.1 Recommendation 1: Surgeon Interface ..... 47
5.2 Recommendation 2: Smoke Ventilation ..... 47
5.3 Recommendation 3: Disposable Tips ..... 47

5.4 Recommendation 4: Environmentally Friendly Material ..... 48
5.5 Recommendation 5: Strategic Partnership ..... 48
5.6 Ideal Design Scenario ..... 48
6.0 Conclusion ..... 50
References ..... 51
Appendix A: Glossary ..... 58
Appendix B: Interview Process ..... 59
Interview Setup ..... 59
Surgeon Interview Questions ..... 60
Appendix C: Survey Questionnaire ..... 61
Preferences on Surgical Devices: Disposable vs. Reusable ..... 61
WPI 團隊 BPES 手術設備認知調查 ..... 66
Appendix D: Dr. Liao Interview Transcript ..... 71
Appendix E: Dr. Rooney Interview Transcript ..... 82
Appendix F: Dr. Liu Interview Transcript ..... 90
Appendix G: Dr. Caparrelli Interview Transcript ..... 117
Appendix H: Social Survey Results – Extra Graphs ..... 136

# List of Figures

Figure 0.1: Medtronic's LigaSure Surgical Device…… x
Figure 0.2: Surgeon Interview Topic Word Cloud…….vii
Figure 0.3: Reusable vs Disposable Device Preference…….....viii
Figure 0.4: Respondent Surgical Device Priorities…….....viii
Figure 1: Profile Images of the co-founders of Maxima. (a) Mr. Hong Yi-Ping, Chairman (b) Dr. Tang Hsiao-Wei, General Manager (Maxima Biotech Inc, n.d.) ..... 2
Figure 2: Maxima's Cordless Ultrasonic Dissector (Healthcare Expo Taiwan, 2022)..... 2
Figure 3**:** Medtronic's LigaSure device ("Vessel Sealing," 2024)..... 10
Figure 4**:** Johnson & Johnson's ENSEAL Device ("ENSEAL$^{TM}$ G2 Straight Tissue Sealer," 2023) .....11
Figure 5**:** Visual of Goal, Objectives, and Methods..... 18
Figure 6**:** A visual representation of PESTEL analysis. ("PESTEL Analysis," 2024)..... 21
Figure **7**: A visual representation of the four segments of SWOT analysis. (Young, n.d.)..... 22
Figure 8: Pestel Analysis Chart for Medtronic ..... 32
Figure 9**:** PESTEL Analysis Chart for Ethicon..... 34
Figure 10**:** CONMED PESTEL Analysis..... 36
Figure 11**:** Shared PESTEL Analysis Among Analyzed Companies..... 37
Figure 12: Age Distribution of Respondents ..... 39
Figure 13**:** Country of Residence Distribution of Respondents..... 40
Figure 14: Income Distribution Among Respondents Reporting in USD ..... 41
Figure 15: Income Distribution Among Respondents Reporting in NT$..... 41
Figure 16: If you were undergoing surgery and had the choice, would you tell your surgeon to operate with a disposable or reusable device (considering cost, safety, and environmental impact)?..... 42
Figure 17: Effect of Respondent Country of Residence on Device Preference..... 43
Figure 18: Effect of Respondent US Income on Device Preference ..... 44
Figure 19: Drag each choice to rank the following priorities by how important you think they are from top to bottom (1 most important, 6 = least important ["other" (6) option omitted due to low number of responses]):..... 45

Figure 20: Would you be willing to pay more for surgeries that use environmentally friendly practices or materials? ..... 46
Figure 21: Combined Recommendations for Maxima ..... 49
Figure 22: Effect of Age on Device Preference ..... 136
Figure 23: Effect of US Income on Device Preference ..... 136
Figure 24: Effect of Taiwan Income on Device Preference ..... 137
Figure 25: If you have ever undergone surgery, were you provided with information about your surgical procedure and the devices used to perform it? ..... 138
Figure 26: Effect of respondent's age on information about surgical procedure and devices. ... 139
Figure 27: Effect of Age on Average Ranking of Safety ..... 139
Figure 28: Effect of Age on Average Ranking of Cost of Surgery ..... 140
Figure 29: Effect of Age on Average Ranking of Ethically Sourced Materials ..... 140
Figure 30: Effect of Age on Average Ranking of the Usage of the Latest Technology ..... 141
Figure 31: Effect of Age on Average Ranking of Environmental Impact ..... 141
Figure 32: If you were a patient choosing which surgical device would be used for your operation, would you prefer one with environmentally friendly options? ..... 142

# List of Tables

Table 1: Surgeon Interview Schedule……20

# Authorship Table

| Section | Authors | Editors |
|---|---|---|
| Abstract | Alexander Kirkman | All |
| Acknowledgements | Samuel Rooney | All |
| Executive Summary | All | All |
| 1.0 Introduction | Shaylie Lagasse & Samuel Rooney | Alexander Kirkman |
| 1.1 Sponsor | Shaylie Lagasse & Isha Medasani | Alexander Kirkman |
| 1.2 Goal, Objectives, and Implementation Methods | Shaylie Lagasse & Isha Medasani | Alexander Kirkman & Shaylie Lagasse |
| 2.0 Background | Isha Medasani | Shaylie Lagasse |
| 2.1 Introduction to Minimally Invasive Surgery | Shaylie Lagasse | Alexander Kirkman |
| 2.2 History of MIS Instruments | Shaylie Lagasse | Samuel Rooney |
| 2.3 Types of Electrical Energies | Isha Medasani | Shaylie Lagasse |
| 2.3.1 Basic Bipolar to Advanced Bipolar | Isha Medasani | Alexander Kirkman |
| 2.4 Bipolar Device Market | Samuel Rooney | Isha Medasani |
| 2.4.1 Device Competitors | Samuel Rooney | Isha Medasani |
| 2.4.2 Pricing, Health Insurance and Impact on Consumer | Samuel Rooney | Isha Medasani |
| 2.5 Sustainability | Isha Medasani | Shaylie Lagasse |
| 2.5.1 Advanced Bipolar Device Reusability | Alexander Kirkman | Isha Medasani |
| 2.5.2 Environmental Impacts of Advanced Bipolar Devices | Shaylie Lagasse | Isha Medasani |
| 2.6 Patent Information | Alexander Kirkman | All |
| 2.6.1 International Patent Laws | Alexander Kirkman | Isha Medasani |
| 2.7 Summary | Isha Medasani | Shaylie Lagasse |
| 3.0 Methodology | Samuel Rooney | Shaylie Lagasse |
| 3.1 Surgeon Interviews | Samuel Rooney | Shaylie Lagasse & Alexander Kirkman |
| 3.1.1 Ethics Considerations | Shaylie Lagasse | Samuel Rooney & Alexander Kirkman |
| 3.2 Market Sector and Competitor Analysis | Samuel Rooney | Alexander Kirkman |

| | | |
|---|---|---|
| 3.2.1 PESTEL Analysis | Samuel Rooney | Alexander Kirkman |
| 3.2.2 SWOT Analysis | Samuel Rooney | Alexander Kirkman |
| 3.2.3 Sources and Application | Alexander Kirkman | Shaylie Lagasse |
| 3.3 Social Surveys | Isha Medasani | All |
| 4.0 Results & Analysis | Alexander Kirkman | Shaylie Lagasse |
| 4.1 Surgeon Interviews | Alexander Kirkman | Shaylie Lagasse |
| 4.1.1 Dr. Liao Interview | Alexander Kirkman | Alexander Kirkman |
| 4.1.2 Dr. Liu Interview | Alexander Kirkman | Shaylie Lagasse |
| 4.1.3 Dr. Rooney Interview | Shaylie Lagasse | Alexander Kirkman |
| 4.1.4 Dr. Caparrelli Interview | Samuel Rooney | Alexander Kirkman |
| 4.1.5 Interview Conclusion | Alexander Kirkman | Samuel Rooney |
| 4.2 Competitor Analysis | Alexander Kirkman | Isha Medasani |
| 4.2.1 Medtronic | Alexander Kirkman | Shaylie Lagasse |
| 4.2.2 Johnson & Johnson | Alexander Kirkman | Shaylie Lagasse |
| 4.2.3 CONMED | Samuel Rooney | Alexander Kirkman |
| 4.2.4 Shared PESTEL Analysis | Alexander Kirkman | Shaylie Lagasse |
| 4.2.5 Shared SWOT Analysis | Alexander Kirkman | Shaylie Lagasse & Sam Rooney |
| 4.3 Social Survey Analysis | Shaylie Lagasse & Isha Medasani | Samuel Rooney |
| 4.3.1 Survey Results & Analysis | Shaylie Lagasse & Isha Medasani | Alexander Kirkman |
| 4.3.2 Overall Survey Results & Analysis | Shaylie Lagasse & Isha Medasani | Alexander Kirkman |
| 5.0 Recommendations to Maxima | Alexander Kirkman | Shaylie Lagasse |
| 5.1 Recommendations 1: Surgeon Interface | Alexander Kirkman | Shaylie Lagasse |
| 5.2 Recommendations 2: Smoke Ventilation | Alexander Kirkman | Shaylie Lagasse |
| 5.3 Recommendations 3: Disposable Tips | Alexander Kirkman | Shaylie Lagasse |
| 5.4 Recommendations 4: Environmentally Friendly Device | Alexander Kirkman | Shaylie Lagasse |
| 5.5 Recommendations 5: Strategic Partnership | Alexander Kirkman | Shaylie Lagasse |

| | | |
|---|---|---|
| 5.6 Ideal Design Scenario | Alexander Kirkman | Shaylie Lagasse |
| 6.0 Conclusion | Alexander Kirkman | Shaylie Lagasse |
| References | All | All |
| Appendix A | All | All |
| Appendix B | All | All |
| Appendix C | Shaylie Lagasse | All |
| Appendix D | Shaylie Lagasse | All |
| Appendix E | Shaylie Lagasse | All |
| Appendix F | Shaylie Lagasse | All |
| Appendix G | Shaylie Lagasse | All |
| Appendix H | Isha Medasani | All |

# 1.0 Introduction

The healthcare field is continuously evolving, driven by constant innovation aimed at improving patient outcomes and expanding medical technologies' capabilities. Each year, medical professionals perform 310 million major surgeries worldwide, emphasizing the scale and importance of surgical procedures and medical devices in global health. However, the complexity and risks associated with these procedures are significant, with about 1 in 25 patients (roughly 8 million people) dying shortly after surgery (Dobson, 2020). This alarming statistic highlights the need for enhanced surgical techniques and devices to improve safety and reduce mortality rates. In pursuit of this goal, a global network of medical professionals, researchers, and engineers is dedicated to pushing the boundaries of innovation in surgical care, focusing on developments such as minimally invasive procedures to improve patient outcomes.

Against this backdrop of urgent medical needs and technological advancements, Maxima Biotech Inc., a contender in the medical device industry, has initiated a strategic collaboration with this team. This partnership utilizes the fresh perspectives of engineering students to explore the potential of a new advanced bipolar surgical device tailored to surgeon needs. The collaborative project between Maxima and WPI students involves a thorough investigation into past device development, technological preferences, and market dynamics of surgical devices. By combining interviews, market analysis techniques, and social surveys, the team seeks to deliver a multifaceted overview of the current device landscape and challenges in surgical innovations. This project aims to help Maxima Biotech's products succeed in the market and reduce deaths from surgeries and increase the chances of successful surgical outcomes.

## *1.1 Sponsor*

Hong Yi-Ping (see Figure 1) and Tang Hsiao-Wei (see Figure 1) co-founded Maxima Biotech Inc., also known as 久方生技股份有限公司 (Jiufang Biotechnology Co., Ltd.), in April of 2019 (Maxima Biotech Inc., 2021). Operating from many locations across Taiwan, including Taipei, Taichung, and Hualien, Maxima specializes in designing, developing, and marketing surgical equipment, focusing on laparoscopic and minimally invasive surgery (MIS) instruments (Maxima Biotech Inc., 2021). Maxima is committed to developing cost-effective products that match the quality of industry leaders. Additionally, Maxima recognizes the importance of

actively considering primary users' feedback, that is, surgeons' feedback, to pinpoint key areas for improvement and refinement.

Maxima Biotech Inc. recently developed a wireless version of a traditional wired ultrasonic dissector commonly used by surgeons (see Figure 2). This medical device employs high-frequency vibrations to cut tissues precisely during surgery. Creating a wireless version positioned the company uniquely in the market as one of the few producers of wireless ultrasonic tools. Leveraging its expertise from developing the ultrasonic device, Maxima aims to broaden its product line by designing and marketing a new device that harnesses basic bipolar energy, planning to introduce an advanced bipolar surgical device.

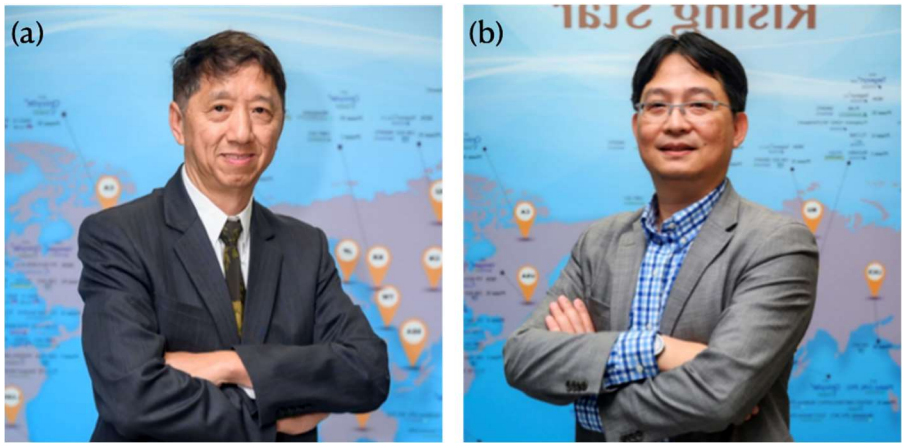


*Figure 1: Profile Images of the co-founders of Maxima. (a) Mr. Hong Yi-Ping, Chairman (b) Dr. Tang Hsiao-Wei, General Manager (Maxima Biotech Inc, n.d.)*


*Figure 2: Maxima's Cordless Ultrasonic Dissector (Healthcare Expo Taiwan, 2022)*

Maxima wants to understand what features surgeons would like in advanced bipolar devices as well as some market strategies. Maxima sought out a collaboration with one of the

Worcester Polytechnic Institute's Interactive Qualifying Project (IQP) teams, seeking to leverage the perspectives of engineering students for their exploration into advanced bipolar energy surgical devices.

## *1.2 Goal, Objectives, and Implementation Methods*

The goal of this IQP was to collaborate with Maxima Biotech Inc., to aid the development of their upcoming advanced bipolar surgical device. The team outlined four objectives necessary to achieve this goal:

1. Assess the market for advanced bipolar energy devices both locally and globally to understand competitive positioning and demand.
2. Identify key product features that influence adoption rates among surgeons in Taiwan and the US.
3. Assess the sustainability, environmental impact, and reusability of surgical devices, while also gauging public concern and interest in these topics.
4. Provide Maxima Biotech Inc. with tailored recommendations for their upcoming device, ensuring it meets market demands and considers public opinions.

The team delved into the background of advanced bipolar surgical devices, exploring their historical development, technological progress, market trends, and societal and environmental impacts to understand what factors needed to be considered for these devices. The project explored the advanced bipolar surgical device market using a combination of qualitative and quantitative data collection methods.

The team implemented three methods: conducting surgeon interviews, conducting a competitor analysis, and conducting a social survey. Surgeon interviews provided insights into preferences and requirements for surgical devices as well as key product features influencing adoption rates among surgeons in Taiwan and the US, directly addressing the second objective. The competitor analysis used PESTLE (Political, Economic, Sociological, Technological, Legal, and Environmental) and SWOT (Strengths, Weaknesses, Opportunities, and Threats) analyses, to assess the market and competitive landscape, complemented by reviews of patents and insurance policies. This analysis addresses the first objective. Lastly, the social survey looked at university students, their families, and Maxima's contacts' surgical priorities as well as assessing public concern and interest around sustainability, environmental impact, and reusability of surgical devices, hence addressing the third objective.

By combining interviews, data analysis techniques, and a social survey, the team delivered an overview of the surgical innovation landscape and provided recommendations for Maxima to consider when developing their new device. Therefore, the combination of the project's methods addresses the fourth and final objective. This integrated approach, drawing on insights from biomedical engineering, economics, and social sciences, aimed to equip Maxima with an understanding essential for navigating the advanced bipolar device market successfully.

# 2.0 Background

This chapter offers an overview of the shift from traditional open surgery to minimally invasive surgery (MIS), delving into the challenges, considerations, and historical background of MIS. Additionally, it provides an overview of various types of electrical energies, with a focus on advanced bipolar energy. Furthermore, this chapter examines the economic landscape of the bipolar device market, including key competitors like Medtronic's LigaSure and Johnson & Johnson's ENSEAL. Section 2.6 covers patent information, detailing United States and Taiwan patent laws, along with the social implications associated with reusable and disposable surgical devices. Understanding these aspects is crucial for implementing the project's methodologies and achieving the team's objectives. For definitions of unfamiliar terms within this section, please refer to the Glossary in Appendix A.

## *2.1 Introduction to Minimally Invasive Surgery*

Surgeons minimize patient tissue trauma in MIS by utilizing two to four small "keyhole" incisions on the patient. Surgeons typically make incisions of half an inch or less in size during MIS procedures, significantly smaller than the six to twelve-inch incisions made in open surgeries (Garceau & Gopal, 2023). This approach not only reduces patient blood loss, discomfort, and pain but also lowers the risk of postoperative complications (Agha & Muir, 2003). Minimized tissue handling and decreased exposure to outside contaminants such as bacteria greatly reduce the likelihood of infections and obstructions (Agha & Muir, 2003). These small incisions performed during MIS allow the entry of a surgical tool known as an endoscope. (Cleveland Clinic, 2023). Surgeons and engineers name endoscopes differently based on their individual applications within the body. For example, a laparoscope is an endoscope used in the abdominal cavity, a thoracoscope in the chest cavity, and an arthroscope for joints (Cleveland Clinic, 2023). Along with the endoscope for visibility, surgeons must also use an electrosurgical device to cut, coagulate, and seal the tissues involved in the operation. Many varieties of electrosurgical devices exist, such as ultrasonic, monopolar, bipolar, and advanced bipolar devices. Maxima Biotech’s current ultrasonic device and future advanced bipolar device are both examples of minimally invasive electrosurgical devices. However, this report specifically delves into advanced bipolar devices, detailing them later.

During initial research on MIS surgeries, the team identified several shared challenges with the devices, including a comparative lack of organ and tissue visuals, concerns about cost-effectiveness, environmental safety, and the debated need for reusability. Despite the increased safety risks, open surgery does provide benefits such as improved training opportunities, improved surgical site visibility, and increased maneuverability for surgeons (Zhao & Gu, 2022). In laparoscopic surgeries where visualization is crucial, inexperienced surgeons may face challenges due to endoscopes' limited field of view. This restriction makes it difficult for new surgeons to learn and assess patient anatomy and may increase the risk of accidental tissue damage. Additionally, the medical community debates the benefits and risks of disposable devices. While disposable devices typically involve higher costs and are more harmful to the environment, they are also regarded as safer and more time-efficient (Cunha & Pellino, 2023). Single-use devices allow for easy switching between different devices, mitigating the risks of infections or the loss of time associated with cleaning procedures. Developing a device that prioritizes safety, efficiency, environmental sustainability, and cost-effectiveness is crucial for increasing Maxima's proposed device's overall acceptance. While Maxima's dedication to determining surgeon preferences and addressing challenges in minimally invasive surgeries is promising, it is important to also consider the cost and market factors when assessing the potential success of their new device.

## *2.2 History of MIS Instruments*

Phillip Bozzini invented the first cystoscope in 1806 (Kelley, 2008). Veterinarians examined canine bladders using the minimally invasive device and made a large step toward advanced laparoscopic technology (Kelley, 2008). However, human surgeons never used this cystoscope (Kelley, 2008). Veterinarians continued to use this device 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 for 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, some called him the "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 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, a tool that surgeons use to this day to puncture the patient's skin and provide a pathway for the safe insertion of surgical instruments, 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 using these technologies (Kelley, 2008). This "revolution" of minimally invasive surgeries occurred in the 1980s and 90s, but this technology continues to improve today (Kelley, 2008).

## *2.3 Types of Electrical Energies*

This section defines the several types of electrical energies currently used in laparoscopic surgeries to provide a contextual understanding of surgical energy systems terminology. Electrical energy uses high-frequency alternating currents to coagulate, cut, fulgurate, and desiccate tissue. There are three types of electrical energy: monopolar, bipolar, or basic 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 and advanced electrosurgery involve passing current between the operated tissue and an electrode with two forceps-shaped arms (Smith et al., 2018).

### *2.3.1 Basic Bipolar to Advanced Bipolar Energy*

This section explains the definition of advanced bipolar energy and its respective advantages, disadvantages, and constraints. These insights are crucial to the development of

Maxima's upcoming advanced bipolar device. Basic bipolar energy systems consist of a generator that delivers a non-modulated, low-voltage current waveform to the surgical instrument. These systems enable surgeons to stop blood vessel bleeding and reduce collateral damage and thermal spread. These systems employ a simple circuit connecting active and return electrodes, effectively coagulating tissue and stopping bleeding. They are ideal for techniques like desiccation and coaptation (Smith et al., 2018). However, they lack advanced safety features like closed-loop control or real-time monitoring.

Although similar, advanced bipolar energy systems use a high-pulsatile, low-voltage current waveform and feedback control of the output energy during tissue coagulation (Ümit et al., 2021) that allows ample tissue compression, tissue cooling during use, and reduced thermal spread (Zorzato et al., 2024). This electrical energy flow to the tissue incrementally increases up to almost 100°C, at which point the energy flow ceases, and a blade executes the cutting through the tissue process (Ümit et al., 2021). These devices are ideal for desiccation, coaptation, and tissue transection (Smith et al., 2018).

Recent advancements in advanced bipolar surgical devices incorporate closed-loop control, tissue impedance measurement, vessel sealing technologies, and temperature control, enhancing surgical efficiency and safety by reducing thermal spread (Smith et al., 2018). Additionally, they enable precise control over tissue coagulation, facilitate blood vessel repair, and achieve uniform peak temperatures across different tissue types and thicknesses. They minimize operation time (Patrone et al., 2019), thermal damage, tissue sticking, smoke production, and lateral thermal spread, and restrict the current flow to the targeting tissues (Sankaranarayanan et al., 2013).

Advanced bipolar devices, akin to their basic counterparts, are available in various forms, such as forceps, grips, dissectors, and scissors (Sankaranarayanan et al., 2013). For instance, LigaSure™ (Medtronic, 2024) is one of the pioneering and widely utilized advanced bipolar surgical energy devices.

## *2.4 Advanced Bipolar Device Market*

Advanced bipolar energy surgical devices are an essential tool for surgeons performing laparoscopic surgery in today's hospitals, being able to perform a variety of roles in surgeries across disciplines like dermatology, orthopedics, and gynecology. Their widespread use has led the total annual market for these devices to balloon to the size of $2.24 billion ("Advanced

Bipolar Direct Energy Devices Market," 2023), a significant portion of the total $29.98 billion market for all surgical devices ("Surgical Equipment Global Market Report 2024," 2024). The market is growing rapidly at an estimated rate of 14.4% growth every year ("Advanced Bipolar Direct Energy Devices Market," 2023), much higher than the average growth rate of 8.4% for the global economy ("Surgical Equipment Global Market Report 2024," 2024). This strong growth means that there is space in the market for new competitors with interesting products, such as Maxima, to break in.

### *2.4.1 Device Competitors*

Maxima's goal in developing an advanced bipolar device is to seize market share, which means that they need to sell a product that is superior to the competition in terms of price, availability, or effectiveness. Maxima needs to pay attention to their most popular and highly developed competitors in the advanced bipolar surgical device market, specifically Medtronic's Ligasure and Johnson & Johnson's ENSEAL devices. LigaSure is currently the most popular device, with approximately 84% market share (Chivukula et al., 2020).

#### *2.4.1.1 Medtronic's LigaSure*

Medtronic, through their subsidiary Covidien, originally released the LigaSure line of devices in 1998 (see Figure 3). The company maintains 84% market share with this device, making it unarguably the most popular option available to surgeons today. LigaSure works by combining pressure generated by the clamping arms and heat generated by passing electrical current through the bipolar contacts on the clamping arms to 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 (Medtronic, 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 (Figure 4) in their operations. First, the surgeon repeatedly noted that the burst pressure on LigaSure device seals produced is three times normal systolic blood pressure, making these seals reliable. (Karande, 2015).


*Figure 3: Medtronic's LigaSure device ("Vessel Sealing," 2024)*

The surgeon additionally mentioned improvements in reduced blood loss and reduced time spent in surgery compared to other devices. Finally, LigaSure reduced overall recovery time, meaning the total time spent in the hospital for the patient, especially compared to sutures or other mechanical ligation devices. The LigaSure device also has subjective improvements the surgeon noted, specifically the design of the handle, which is comfortable and reduces fatigue (*Karande, 2015*).

### *2.4.1.2 Johnson and Johnson's ENSEAL*

Johnson & Johnson, through their subsidiary Ethicon, announced the release of the ENSEAL advanced bipolar device (see Figure 4) on June 15, 2011. Fundamentally, this device works the same way as Ligasure, using a combination of pressure generated by the clamping arms and electrical current passed between them to heat up, cut, or desiccate a section of tissue. The advantage the device that Ethicon initially offered was a large jaw useful for sealing or cutting larger sections of tissue at a time, facilitating shorter procedure times. It includes several proprietary features, including a mechanical design that allows the device to maintain equal force along the full lengths of the blades, and a positive temperature coefficient (PTC) system that allows the device to passively maintain a temperature of at most 100°C. The ENSEAL single-use device costs $435 ("ETHICON ENSEAL," 2023), and the G11 generator which powers ENSEAL costs $6440. These prices make this option noticeably less expensive than LigaSure, particularly in terms of setup costs ("Ethicon Gen11 Endo Surgery Generator," 2024).

*Figure 4: Johnson & Johnson's ENSEAL Device ("ENSEAL™ G2 Straight Tissue Sealer," 2023)*

A randomized controlled trial of the ENSEAL device versus Ligasure resulted in equivalent clinical and surgical outcomes for 140 total patients (that is 70 patients per device), although there were some disadvantages, including increased perceived surgeon workload and an increased number of device failures for the ENSEAL device. Operation times were slightly longer for the ENSEAL device as well (Shiber et al., 2018).

### *2.4.2 Pricing, Health Insurance, and Impact on Consumer*

In modern human medical practice, surgeons and hospitals consider advanced bipolar energy devices to be single-use consumables. This means that every surgery that uses one of these devices bears the direct marginal cost of one single-use device, which is typically around $450 (*"LF1623 - Ligasure Disposable," 2023*) ("ETHICON ENSEAL," 2023), as well as a portion of the initial cost of the generator that powers the single-use devices, which can be anything between $6000 and $12500 ("Ethicon Gen11 Endo Surgery Generator," 2024) (*"Covidien ForceTriad Platform," 2024*). Insurance generally pays the direct cost of surgery. Health insurance is an arrangement where a central pool of money which many people pay is responsible for paying surgical and other medical costs. In general, either governments or private organizations manage this pool of money by charging the people they cover either a tax or an insurance premium. These organizations set the price of an insurance premium based on a guess or a statistical analysis. The organizations base their analysis on the average cost of surgery/healthcare, the average percentage of people who need surgery a year, the costs of operating the insurer organization, and a margin for error and profit (Beers, 2023). Often, insurance providers reduce the premiums they charge by reducing the proportion of medical

costs they cover. They introduce terms such as deductibles, copays, and coinsurance, all of which are beyond the scope of this report (*How U.S. Health Insurance Works*, n.d.).

For a simplified model of an insurance company, if surgeons use a $500 advanced bipolar energy device in surgery for 1% of insured persons every year, that device contributes $5 to the total insurance premium for all insured persons for the year. Due to the complexity involved, however, it is not feasible for the team or the insurers to precisely understand the impact on premiums of any single surgical device. Additionally, a strictly financial analysis does not consider quality of care, which might reduce the chances of a patient returning to the hospital or might increase a patient's ability to pay for further procedures leading to a higher quality of life.

In Taiwan, a government body handles the insurance system by charging a premium of 5.2% of all citizens' salaries. This body structures the premium such that most Taiwanese citizens only directly pay about 1.5% of their salary for national health insurance, with employers or government taxes paying for the rest (*How Premiums Are Calculated*, 2023). The system receives praise globally for its low administrative costs of around 2%, coverage rate for citizens of about 99%, and high approval rate by patients of around 70%. However, citizens criticize the system for its varying quality of care (particularly for specialist services), financial problems, and for overworking doctors (Wu et al., 2010).

In the United States, the insurance system is less straightforward. A patchwork combination of employer-sponsored plans, government-handled plans, and individually purchased plans sums up the US system, which results in about 92% of Americans having proper health insurance coverage (Keisler-Starkey et al., 2023). The average US citizen can expect to pay roughly 11% of their income on health insurance, although this can vary widely depending on employer benefits, government coverage, or the decision to purchase health insurance on the open market without employer support. This variety of options can result in overall health insurance charges near 0% of patient income or as high as 20%. By design, copays and deductibles in insurance plans cause covered individuals to pay more when they experience health problems (Joyce, 2019).

## *2.5 Sustainability*

This section delves into the sustainability aspects surrounding advanced bipolar energy devices, specifically focusing on their reusability and environmental impacts. Utilizing these

devices not only transforms surgical methods but raises crucial concerns about their carbon footprint and safety within healthcare systems.

### *2.5.1 Advanced Bipolar Device Reusability*

Reusable advanced bipolar energy devices are a feature that sets them apart from other competitors in the market. Businesses sometimes promote designs that incorporate reusable advanced bipolar energy technology, such as Caiman 5, because surgeons can use them multiple times before disposal. Analysis considering the broader adoption of these devices within hospital settings suggests significant cost savings, with similar outcomes predicted for other devices upon full integration (Danolić et al., nd). This shift towards reusable advanced bipolar devices supports a sustainable healthcare model by reducing waste and operational costs. It highlights the essential role these devices play in modern surgical practices and advocates for their broader integration into healthcare institutions for their clinical and economic benefits.

However, the reuse of advanced bipolar energy devices brings significant safety, effectiveness, and legal risks within healthcare systems. The Medicines and Healthcare Products Regulatory Agency has outlined challenges in incorporating best practice quality control measures into the reprocessing workflow, leading to potential cross-infection, material degradation, and mechanical failures, and highlighting the need for stringent oversight and a proactive safety culture (The Medicines and Healthcare Products Regulatory Agency, 2021). Healthcare professionals play a crucial role in adhering to quality control protocols and mitigating the risks associated with device reuse. This approach requires a thorough understanding of regulatory requirements and a commitment to patient and staff safety, emphasizing the importance of maintaining high standards of quality control in the reprocessing of surgical devices to prevent unnecessary exposure to risks (Whelan, 2023). Ensuring adherence to regulatory guidance and maintaining strict quality control measures is vital when utilizing reusable advanced bipolar energy devices despite their substantial economic, environmental, and social advantages.

### *2.5.2 Environmental Impacts of Advanced Bipolar Devices*

The transition towards environmentally stable practices in MIS poses a multifaceted challenge. While medical professionals increase the adoption of single-use instruments from a health standpoint, environmentalists push toward adopting reusable devices from an environmental perspective (Chan et al., 2023).

Research suggests reusable devices offer environmental benefits over their disposable counterparts. For instance, Boberg et al. (2022) performed a life cycle assessment (LCA) on single-use and reusable devices. An LCA is a method used to estimate a product's environmental impact throughout its entire lifecycle, from material harvesting to device disposal. The researchers assessed many categories of impact, including climate change, ecosystem quality, resources, and human health. They found that single-use devices had a 379% higher overall environmental impact than reusable devices. Additionally, a separate study conducted by Rizan and Bhutta (2022) found that compared to their single-use counterparts, reusable surgical instruments exhibited a 60% mean reduction in carbon footprint.

Beyond the reduction in carbon footprint, reusable instruments offer several additional environmental benefits. For instance, they contribute to waste reduction by minimizing the volume of medical waste generated during surgical procedures. This reduction in waste lessens the burden on landfills and reduces the energy required for waste management and disposal (Chan et al., 2023). Furthermore, using reusable instruments promotes a circular economy model, by conserving resources and promoting their reuse instead of disposal after a single use. Hospitals can reduce their reliance on single-use plastics and similar disposable materials by investing in higher-quality, more durable instruments that can withstand multiple sterilization cycles (Harris et al., 2021). Many surgeons are increasingly recognizing the importance of environmental sustainability. A survey conducted in the UK found that 94% of respondents expressed concern about climate change and indicated willingness to change their hospital practices to improve environmental sustainability (Harris et al., 2021). The team hoped that developing their own social survey for users in the U.S. and Taiwan (detailed later in the methods chapter) would either support or refute this idea for these two countries.

## *2.6 Patent Information*

A common strategy for companies is to utilize patents to foster technological development in similar domains. Understanding how Maxima intends to use patents for advancing bipolar energy technology necessitates a clear grasp of patent law. The World Intellectual Property Organization (WIPO) defines patents as exclusive rights granted for an invention or idea, which might be a product or process that introduces a new technical solution to a problem (World Intellectual Property Organization, n.d.). Patents play various roles, such as documenting and protecting intellectual property (IP). They enable the public disclosure of

works without the threat of copying. Additionally, patents can offer financial benefits, as the owners may exclusively sell their IP for the duration of the patent, typically 20 years, providing a financial incentive for ongoing research investment (Van Norman and Eisenkot, 2017). This exclusivity benefits companies by enabling continuous research funding. Patents are also advantageous from a consumer perspective as they promote competition among inventors, leading to quick advancements in technologies and products. In the medical device industry, for instance, large companies like Johnson & Johnson frequently buy patents from smaller manufacturers. Maxima aims to leverage patents to swiftly progress in the biomedical field in Taiwan. By making use of expiring patents, known as patent cliffs, Maxima plans to expedite the development of bipolar energy applications in their surgical devices. However, assessing the cost-effectiveness of this approach requires an in-depth understanding of patent mechanisms, their international regulatory environments, and strategies for their application.

### *2.6.1 International Patent Laws*

As Maxima aims to expand its product reach both locally and internationally, understanding international patent regulations becomes important for assessing the cost-effectiveness of their products. After developing a product tailored for the Taiwanese market, Maxima is looking to increase its exports to other countries. The upcoming sections will provide an overview of the patent laws in the countries where Maxima intends to research for R&D, offering insights into the markets Maxima aims to penetrate.

Navigating the international market necessitates a thorough understanding of each target country's patent laws and regulations. This knowledge is vital for Maxima to avoid any infringement on existing patents, thereby minimizing legal risks and potential financial losses. In the United States, for example, Maxima plans to investigate competitor patents to support research and further develop bipolar energy into their products. As Maxima ventures into new territories, comprehending the legal landscape concerning patents in each country is essential. This understanding will not only facilitate regulatory compliance but also enhance Maxima's chances of success in the global market.

#### *2.6.1.1 Taiwan Patent Laws*

Applying for a patent in Taiwan requires submission to the Taiwan Intellectual Property Office (TIPO), operating on a "first come, first served" basis to grant filing priority (Patent Act-Article 31, 2022). Taiwan's patent system distinguishes between Invention, Utility Model, and

Design patents, with Invention patents being necessary for protecting new products and technologies, providing 20 years of protection (Patent Act- Chapter 2, 2022). The system's transparency supports innovation, offering public access to patent documents through TIPO's online database. However, Taiwan is not a member of the World Intellectual Property Organization (WIPO) and does not adhere to its agreements, creating a unique framework for foreign patents. For foreign entities to file patents, a reciprocal treaty between Taiwan and the applicant's home country (Patent Act-Article 4, 2022). The existence of such treaties, like those with the United States, simplifies the patent application process for nationals of treaty countries, enhancing the ease of securing patent protection in Taiwan and reducing the potential for legal hurdles.

#### *2.6.1.2 United States Patent Laws*

The United States patent system, underpinned by Title 35 of the United States Code and managed by the United States Patent and Trademark Office (USPTO), awards inventors the exclusive rights to their inventions while demanding novelty and utility for patent eligibility (USPTO Office of Public Affairs (OPA), n.d.). International treaties like Patent Cooperation Treaty (PCT) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) integrate this system, granting inventors the right to exclude others from replicating or selling their inventions for 20 years to support patent protection globally. However, securing worldwide patent protection requires filing applications in each country and adhering to distinct legal standards due to variations in international law. Mechanisms such as the PCT and the Hague System for the Registration of Industrial Designs aim to simplify the international patent process. Nevertheless, inventors must navigate specific publication and licensing rules to effectively protect their innovations.

### *2.7 Summary*

This chapter provides a comprehensive overview of the crucial factors that will aid Maxima Biotech Inc.'s goal within the surgical device market, particularly in Taiwan. By exploring the transition from traditional open surgery to MIS, MIS challenges, historical context, and economic considerations, the chapter underscores the significance of understanding the landscape for Maxima's strategic planning. Further emphasis focuses on the types of electrical energy used in laparoscopic surgeries, particularly the transition from basic bipolar to advanced bipolar, to provide beneficial insights into the development of Maxima’s upcoming advanced

bipolar device. Additionally, through an exploration into the competitive landscape, including key device competitors such as Medtronic's LigaSure™ and Johnson & Johnson's ENSEAL®, along with an examination of US and Taiwan patent laws, the team aimed to gain perspectives into the competitor advantage over Maxima and to provide recommendations for their upcoming advanced bipolar device. Furthermore, exploring the social implications of surgical devices allows Maxima and the team to understand the potential impact of certain device choices on patients. These observations aim to support the team's goal of providing Maxima with recommendations for producing a device that not only offers a competitive edge over its peers but also maintains high quality and disposability. The succeeding chapter delves into applying the knowledge from this chapter to the team's methods for this project, illustrating how the insights gained informed the strategies and approaches the utilized to address Maxima's objectives effectively.

# 3.0 Methodology

The goal of this Interactive Qualifying Project (IQP) was to collaborate with Maxima Biotech Inc., to aid the development of their upcoming advanced bipolar surgical device. The team outlined several critical objectives necessary to achieve this goal:

1. Assess the market for advanced bipolar energy devices both locally and globally to understand competitive positioning and demand.
2. Identify key product features that influence adoption rates among surgeons in Taiwan and the US.
3. Assess the sustainability, environmental impact, and reusability of surgical devices, while also gauging public concern and interest in these topics.
4. Provide Maxima Biotech Inc. with tailored recommendations for their upcoming device, ensuring it meets market demands and considers public opinions.

Figure 5 provides a visual representation of the goal, objectives, and methods implemented by the team to complete the above objectives.

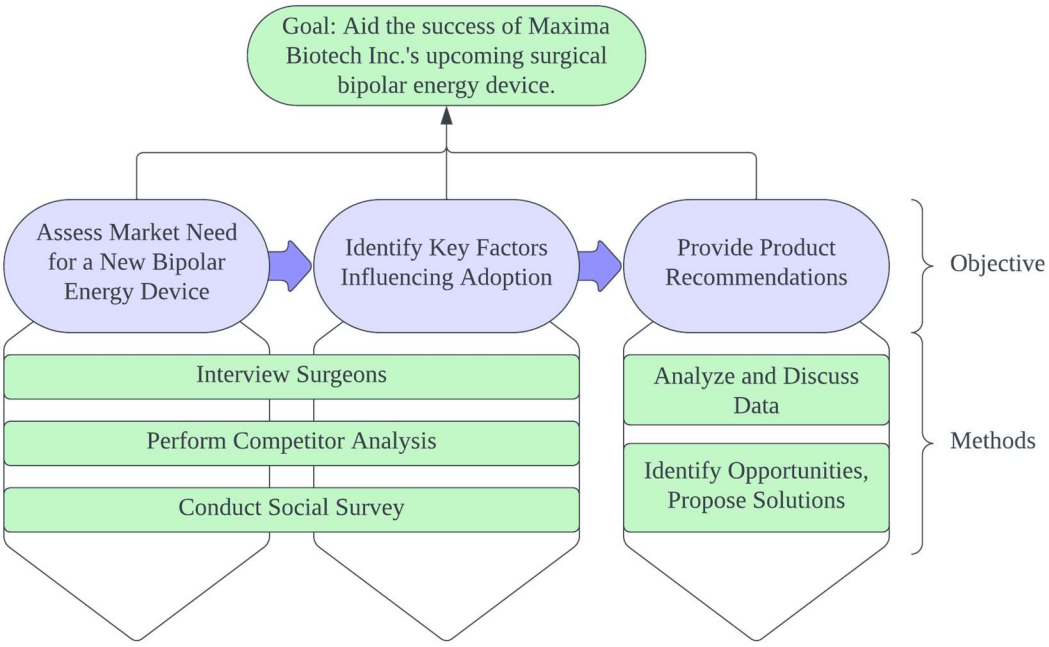


*Figure 5: Visual of Goal, Objectives, and Methods*

The research methods in this chapter include surgeon interviews, market sector and competitor analysis, and a social perspective survey, providing a comprehensive overview of the

device and market landscape. Through semi-structured interviews with surgeons from Taiwan and the United States (US), analytical techniques including SWOT and PESTLE, and a wider survey of people in Taiwan, the team gathered insights into professional preferences, market dynamics, and public preferences. This multifaceted approach helped the team inform Maxima's development priorities, identify technological gaps and competitive opportunities, and propose a road map for the future of Maxima's advanced bipolar energy device.

## *3.1 Surgeon Interviews*

The team conducted semi-structured interviews with two surgeons from Taiwan and two from the US to gather their opinions and perspectives on bipolar energy devices, including but not limited to features they would like to see, their level of choice over the devices they use, and the influence of environmental sustainability over their decisions. For a list of the interviewed surgeons, see Table 1. The team created and analyzed interview transcripts to determine characteristics brought up by multiple surgeons that they could recommend to Maxima for their advanced bipolar energy device.

The team utilized the conducted interviews and systematically cross-referenced them to identify the most desired features of the device. By analyzing how frequently certain topics appeared across the transcripts, they pinpointed key features that the interviewed surgeons valued. This method proved effective for most discussions. However, it had limitations; interviewees mentioned some features and phrases only once or twice but emphasized them as critical. This highlighted the importance of not solely relying on frequency but also considering the emphasized significance of specific features, even if mentioned infrequently.

The team primarily sourced surgeon contact information through direct networking. They initially contacted two Taiwanese surgeons through the sponsor, Dr. Tang, and they used the personal connections of team members to contact two American surgeons. The team conducted in-person interviews with Taiwanese surgeons. As the US surgeons were on the other side of the Pacific Ocean, the team conducted those interviews virtually instead. At least two team members attended each interview, which lasted about sixty minutes and took place in English. These interviews aimed to collect surgeons' views on the devices they currently use and the factors influencing their choice of device, including device features, surgeons' involvement in device selection, and the difficulty of training for new users.

The team first asked the surgeons what key qualities they believed were essential to a bipolar energy surgical device with the intent of starting the interview openly and allowing the surgeons to first give their opinions about the device characteristics that they feel are most important. This approach enabled the team to gain insights into the surgeons' immediate priorities and first impressions, which provided a foundation for further questions. The team also gauged the importance of device brand, training, and reusability by asking the surgeons questions about their own experiences with these brands, how long it took them to train (or to train others), and whether they used reusable or non-reusable devices. This semi-structured format allowed the surgeons to discuss their own experiences, while also allowing the team to interject with more specific questions when necessary.

The team prepared a set of questions that enabled this flexible questioning process during the interviews. The team intended these questions to be broad enough to get the conversation started about each of the target topics but expected the interviewers to expand on the answers the surgeons gave. A copy of these questions is in Appendix B.

*Table 2: Surgeon Interview Schedule*

| Surgeon | Date of Interview | Country of Residence |
|---|---|---|
| Dr. Liao | March 25, 2024 | Taiwan |
| Dr Liu | April 12, 2024 | Taiwan |
| Dr. Rooney | April 9, 2024 | United States |
| Dr. Caparrelli | April 17, 2024 | United States |

### *3.1.1 Ethics Considerations*

The team wanted to ensure that the interview process was ethically sound. To this end, they first recognized the importance of obtaining informed consent (Creswell and Creswell, 2018). Before conducting each interview, the team explained the purpose and voluntary nature of the interview (Santa Clara University, n.d.). The team encountered no problems obtaining consent from surgeons to conduct, record, or use quotations from interviews.

The team investigated plausible causes of bias and minimized them during interviews. They conducted a review of interview questions and removed leading language, ensuring they did not direct surgeons toward discussing features of the device positively or negatively based on

the interviewer's knowledge or opinion (Qualtrics, 2024). For example, the team chose to omit phrases such as 'do you agree that [concept] is problematic' or 'would you agree [feature] needs improving'. Additionally, the team collected demographic data such as age, gender, and job title. These details did not influence the set of questions the team asked the participants.

## *3.2 Market Sector and Competitor Analysis*

The team applied the PESTEL and SWOT analysis techniques to interpret the current bipolar energy device market and study the features of competitor devices.

### *3.2.1 PESTEL Analysis*

PESTEL analysis is a wide-sweeping analysis designed to understand the external factors that could impact a product's operations, strategy, and overall success. The acronym **PESTEL** stands for **P**olitical, **E**conomic, **S**ocial, **T**echnological, **E**nvironmental, and **L**egal factors. The following list provides more detail on the topics that fall under each of the six PESTEL factors:

1. Political - Conflicts, tariffs, fiscal policy, government activity (Specifically within Taiwan)
2. Economic - Market size, inflation, customer budget, exchange rates, taxes
3. Social - Demographics, cultural norms, education level
4. Technological - Infrastructure, research, technological trends, access
5. Environmental - Recycling, reuse, production processes, pollution
6. Legal - Regulations, certification, litigation, patents


*Figure 6: A visual representation of PESTEL analysis. ("PESTEL Analysis," 2024)*

The PESTEL analysis explores the external environment in which Maxima and its competitors operate. This approach not only enabled the team to evaluate opportunities and threats with greater precision than with SWOT analysis but also offered fresh insights into crucial elements that could impact the adoption of Maxima's forthcoming bipolar energy device. By examining these dimensions, the team hoped to provide Maxima with insights into the broader landscape of advanced bipolar energy, identifying potential opportunities and threats that are consistent in other products, and making informed decisions to navigate their future (CIPD, 2024).

### *3.2.2 SWOT Analysis*

In contrast, SWOT analysis (see Figure 7), also known as situational assessment, considers the following four properties of a business (Weihrich, 1982) (Schooley, 2024):

1. Strengths - Internal properties of a company or product that are advantageous.
2. Weaknesses - Internal properties of a company or product that make them worse.
3. Opportunities - External properties of a market that a business can take advantage of.
4. Threats - External properties of a market that could cause trouble.

After analyzing various competitors' advanced bipolar energy products using SWOT, the team processed the information collected into a table to visually represent the findings. The objective of this technique is to be able to compare each competitor's product side by side and to identify patterns that appear to aid Maxima with their product goals.

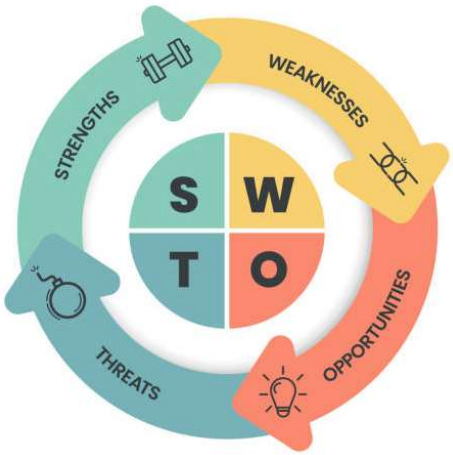


*Figure 7: A visual representation of the four segments of SWOT analysis. (Young, n.d.)*

### *3.2.3 Sources and Application*

The application of competitor analysis in this study involved the team using PESTEL and SWOT analyses to gain a comprehensive understanding of external and internal factors affecting our competitors in the advanced bipolar device market. Through this analysis, the team aimed to identify any aspects of the surgical device market that could allow Maxima to gain traction in this competitive field.

Initially, the team employed PESTEL analysis to systematically assess the external factors influencing the competitors, such as Medtronic (Ligasure) and Johnson & Johnson (ENSEAL), focusing on researching competitors based on information derived from their websites, medical journals, and company documents. This analysis focused on Political, Economic, Social, Technological, Environmental, and Legal factors. The team detailed each factor in a structured table, highlighting how these elements impacted the competitors' operational and strategic capabilities. By examining aspects like regulatory changes, economic trends, and technological advancements, we identified potential opportunities and threats that could impact the industry landscape.

After gathering data through PESTEL analyses, the team organized these findings into uniform tables for each method, which facilitated a clear and comparative visual representation of each competitor's strengths and weaknesses. This structured analysis yielded the ability to discern patterns of success and areas for improvement across the competitive landscape.

The team conducted a SWOT analysis utilizing the results of the PESTEL analysis. The team outlined shared strengths and weaknesses among the competitors, using the results to create strategic recommendations for Maxima, aiming to leverage industry opportunities and mitigate potential threats. The team based their final recommendations on an understanding of the external and internal factors shaping the competitive market dynamics, thus hopefully positioning Maxima to improve its strategic choices and competitive advantage in the development of their advanced bipolar device as well as how to approach the surgical market.

The team also acknowledged potential limitations due to incomplete data from competitors. The team's application of PESTEL and SWOT analyses minimized the risk of overlooking critical information and enhanced our understanding of the market. This approach ensured that our strategic recommendations for Maxima were well-informed and capable of potentially guiding the company through its next developmental steps effectively.

### *3.3 Social Surveys*

To collect survey responses, the team utilized Qualtrics (an online survey tool) to distribute virtual anonymous links to individuals in both the US and Taiwan. This method ensured that the selection of participants represented both cultural perspectives of interest to the sponsor. The team anonymized the survey links, respondents' IP addresses and other identifying information, to protect participant privacy. The survey mainly targeted university students (particularly WPI and Soochow) and their families, and Dr. Tang's local Taiwanese contacts. The team sent social media notifications and messages to classmates, friends, and family to encourage participation. The team initially wrote their survey in English, then with the help of their advisors and classmates from Soochow University, created a second survey translated into Mandarin. The team shared the Mandarin survey with their Taiwanese contacts and made small necessary changes due to cultural and societal differences (USD to NT$, insurance, etc.).

The team designed the survey questionnaire to gather insights into consumer preferences and attitudes towards surgical devices, with a focus on evaluating the market need for a new surgical device and identifying key factors influencing its adoption (see Appendix B). It included demographic questions (such as age, country of residence, household income, occupation) and general questions (such as whether the individual has private or government medical insurance, and if they have previous experience with surgical devices to identify potential biases). Participants received a brief description of minimally invasive surgery (MIS) and the differences between disposable and reusable devices before expressing their preferences regarding these options in terms of cost, safety, and environmental impact. Additionally, they ranked the importance of various device features using a 1-6 scale (including cost, safety, environmental impact, latest technology use, ethical sourcing, and an optional free response). Finally, they indicated their preference for environmentally friendly devices and their willingness to pay more for surgeries that use environmentally friendly practices, demonstrating a proactive approach to sustainability and ethical sourcing considerations.

By examining the connection between various factors, such as the importance of these device features ranked on a scale from 1 to 6, the team hoped to identify underlying preferences and priorities among consumers. Furthermore, by exploring participants' willingness to receive information about environmental impacts and their readiness to pay a premium for environmentally friendly surgical practices, the team aims to improve their knowledge of

evolving consumer expectations and concerns. The team hopes to provide Maxima with actionable recommendations for decision-making using this method, serving as a foundation for informed decision-making regarding the development and introduction of Maxima's new advanced bipolar energy device.

# 4.0 Results & Analysis

This chapter examines multiple sources to analyze the outcomes of the methods above to yield results for Maxima's upcoming bipolar energy surgical device. It begins by detailing the preferences and feedback from surgeons gathered through interviews, highlighting key features and usability factors influencing their choice of devices. The next section includes a PESTEL and SWOT analysis of competitors like Medtronic and Johnson & Johnson, which covers the broader market dynamics and identifies opportunities or threats in the current landscape. The final section reviews data from a survey of university students and their families to assess their perceptions and preferences between the use of reusable and disposable devices in surgeries.

## *4.1 Surgeon Interviews*

To ensure a thorough investigation and gain insights from key markets, the team conducted interviews with two Taiwanese surgeons and two US surgeons, reflecting the countries Maxima is targeting for its marketing efforts.

### *4.1.1 Dr. Liao Interview*

The team first interviewed Dr. Liao, a Taiwanese trauma and emergency surgeon with twenty years of experience. Dr. Liao's perspective in the interview offers an overview of the current state and future direction of bipolar energy devices in surgical practices. During his interview, his emphasis on safety and efficiency as primary qualities demonstrates a massive priority regarding the essential characteristics of surgical devices. Although safety was not a major topic throughout the interview, his early emphasis on its importance, as shown in Appendix D, clearly demonstrated to the team that it is a top priority in device design. Dr. Liao preferred devices that ensure clear, precise cuts and secure, efficient sealing, highlighting the delicate balance between operational effectiveness and patient safety. Moreover, he identified the simplicity of a device's use as an essential feature, mentioning it eleven times in the interview. Dr. Liao's preference for Medtronic devices is driven by their wider availability in Taiwan and their positive reputation. According to him, he uses the device provided by the hospital, which tends to be Medtronic due to its stronghold in the industry. Nonetheless, according to Dr. Liao's experiences with bipolar energy devices, the ease of adoption and training on these devices suggests a high level of user-friendliness. Overall Dr. Liao stated that the current devices on the market were "near perfect" in design (see Appendix D).

Moreover, his thoughts on the shift towards disposable devices were motivated by his stated concerns over the efficiency and safety of reusable options. Dr. Liao's preference for disposable devices led him to discuss the significant debate within the surgical equipment field regarding the environmental impact of such devices. Although he acknowledges the issue, he admits it falls outside his expertise and does not significantly influence his choice of bipolar energy device.

### *4.1.2 Dr. Liu Interview*

The team interviewed Dr. Liu, an experienced gastrointestinal surgeon with twenty years of practice, specializing in surgeries on patients' stomachs, livers, and pancreas in Taiwan. Dr. Liu said he frequently employs Medtronic LigaSure and B. Braun bipolar systems and he indicated that he appreciates LigaSure for its efficiency in large vessel ligation and B. Braun for its articulable design even though it requires manual adjustment during use which can “interrupt the surgical workflow”. Appendix F contains the transcript from this interview.

Dr. Liu identified several functional challenges with current bipolar energy devices, particularly their limitations in performing delicate dissections and surface coagulation. He stressed the importance of a smaller, more precise device jaw in enhancing surgical precision, he mentioned this jaw characteristic is useful for operations with cancerous tissues. The current design of bipolar energy devices facilitates easy training and simplifies the learning process for new users.

Moreover, Dr. Liu expressed a strong preference for devices that enable single-handed operation to improve surgical efficiency and user comfort. He suggested design improvements such a sleek simple design and less bulk that could make a new bipolar device competitive with ultrasonic devices in specific surgical applications, see Appendix F for more mentioned features. Additionally, Dr. Liu expressed his awareness of the environmental impacts of disposable surgical devices and while acknowledging the practical and economic challenges of sustainability in surgical practices, he sees a potential for innovation in developing devices that balance ecological concerns with clinical effectiveness. Dr. Liu's insights from the interview will be a valuable reference as Maxima continues to explore improvements and innovations in the design of bipolar energy devices.

### *4.1.3 Dr. Rooney Interview*

The team interviewed Dr. Rooney, a veterinarian with 40 years of experience with basic bipolar energy devices in veterinary medicine. He highlighted the evolution of bipolar energy devices, noting the transition from foot controls to handheld controls to increase ease of use. Additionally, he mentioned that older devices typically had more complicated settings for adjusting power, which users found awkward. He noted that surgeons encountered problems with the flexibility in power adjustment, as they encountered it difficult to set the power correctly, leading to unintentional charring. In contrast, Dr. Rooney mentioned that newer models perform this process with a single dial that greatly simplifies setting the power.

In addition to handheld controls, the interviewee pointed out replaceable tips as a crucial feature of the surgical device. In his experience, the ability to switch from a larger to a finer tip quickly and easily during surgery (or vice versa) proved extremely beneficial. He emphasized the importance of small size and portability for moving the device in and out of operating rooms, and sufficient power for effective cauterization during surgeries.

Dr. Rooney also spoke on factors influencing device selection, such as ease of use, size, price, and company reputation. While sustainability was not a primary factor in his decision-making, Doctor Rooney mentioned that his practice did tend to clean and reuse “disposable” devices for non-sterile veterinary operations. He continued by discussing potential improvements, such as built-in smoke extraction systems and specialized interchangeable tips for varying surgical needs. Dr. Rooney provided overall insights into the evolution and current state of bipolar energy devices, offering a practical perspective that can inform future improvements and innovations in the field.

### *4.1.4 Dr. Caparrelli Interview*

The team conducted a Zoom interview with Dr. Caparrelli, an American cardiovascular surgeon with over 30 years of experience. He conveyed that advanced bipolar devices are less relevant in cardiovascular surgery than in gastrointestinal or other types of surgeries. Nonetheless, he expressed several opinions on the priorities for developing surgical devices. Dr. Caparrelli emphasized that safety is the foremost consideration in creating a surgical device. He stated that “a tool that harms a patient is worse than useless”.  See Appendix G for the full transcript of his interview.

According to Dr. Caparrelli, the second priority in surgical device development should be control. He explained that a surgeon should be able to manage everything that occurs at the business end of the device single-handedly, without needing to communicate verbally with a nurse operating the device's generator. Dr. Caparrelli suggested utilizing presets on energy generators which surgeons can access on the device itself, rather than on the power source as is in a traditional bipolar energy device.

Regarding cardiovascular surgeries, Dr. Caparrelli informed the team that these procedures typically use non-energy tools such as knives and scissors to avoid unwanted damage to the heart, contrasting with surgeries like those on the stomach where thermal spread is less of a concern. In heart surgeries, even minor unintended damage can significantly increase the risk of death or severe disability for the patient.

### *4.1.5 Interviews Conclusion*

In conclusion, the insights gathered from Dr. Liao, Dr. Liu, Dr. Rooney, and Dr. Caparrelli collectively bring a wealth of experience from different surgical specialties to the discussion on bipolar energy devices. The interviewed surgeons emphasize the significance of simplicity, effectiveness, and user-friendliness in the design of bipolar energy devices.

Dr. Liao's interview highlights a significant emphasis on the efficiency and safety of bipolar energy devices, which are crucial for trauma and emergency surgeries. His preference for devices like Medtronic's, which are dominant in Taiwan due to their market presence and reliability, indicates the importance of brand reputation and device availability in surgical settings. Additionally, Dr. Liao's support for disposable devices despite acknowledging their environmental impact reflects a complex balance between practical surgical needs and broader ecological concerns.

Dr. Liu's feedback brings greater attention to the technical nuances that can enhance surgical precision, such as the need for smaller, more precise device jaws for delicate dissections, especially in gastrointestinal surgeries involving cancerous tissues. His call for single-handed operation capabilities and improvements that could make bipolar devices competitive with ultrasonic ones suggests a push towards more innovative, user-centric designs that also consider environmental sustainability.

Dr. Rooney's experiences in veterinary medicine underline the evolution from more cumbersome older devices with foot controls to newer models with handheld controls and a

simplified power adjustment dial. His emphasis on the practicality of replaceable tips and the portability of devices highlights the ongoing need to adapt device features to the realities of diverse surgical environments, from human to veterinary medicine. Additionally, he brought to attention the issue of smoke that builds from burning tissue during surgery which was an issue not discussed in the prior interviews.

Finally, Dr. Caparrelli's perspective from the field of cardiovascular surgery, where precision and safety are paramount, stresses the need for control and minimal thermal spread. His suggestion to integrate presets directly into the device to avoid external adjustments during surgeries reflects an acute awareness of the operational dynamics in high-stakes environments like cardiovascular operating rooms. He also gave more understanding on smoking during surgery and recommended a small vacuum integrated into the device.

Together, these interviews provided specific insights into the current state and potential directions for the development of bipolar energy devices. Furthermore, they reflect the diverse needs and challenges across different surgical disciplines. The team utilized these interview results to provide suggestions on design and key functions of their next generation of bipolar devices and ensure they meet the nuanced demands of various surgical specialists while pushing for certainty in safety, efficiency, and sustainability. This comprehensive understanding will be crucial for Maxima to develop a competitive edge in the highly dynamic field of surgical technology.

## *4.2 Competitor Analysis*

The team conducted PESTEL and SWOT analyses for three major competitors in the surgical equipment market. This strategic evaluation would provide the team with an understanding of the external and internal factors shaping the industry landscape. The team aimed to identify key areas where Maxima can gain a competitive edge. This thorough analysis aided in developing recommendations for Maxima's next steps as it prepares to enter the global market.

### *4.2.1 Medtronic*

Medtronic, a dominant player in the medical device industry, leverages its global reach and innovative prowess to maintain a competitive edge. Over 50% of its sales derive from international markets, demonstrating resilience across varied economic conditions (GuruFocus Research, 2023). The company’s innovative technologies encompass a diverse product portfolio

of medical devices including defibrillators, pacemakers, stents, spinal fixation devices, insulin pumps, neurovascular products, and heart valves (GuruFocus Research, 2023). Further evidence of Medtronic's leadership appears in the advanced bipolar device market, where it holds an impressive 78.5% market share in 2023 (Pedersen, 2023). This strength derives from a strong commitment to research and development which is essential for sustaining innovation and market leadership (Hivelr Business Review, 2024). Medtronic's financial health remains robust, with reported net sales rising 5.3% from the previous year and increasing to $7,984 million in 2023rise. Being well-positioned to capitalize on emerging trends such as the demand for sustainable medical devices, advancements in digital health solutions and artificial intelligence, the company is setting the stage for future growth.

Despite its strengths, Medtronic faces significant challenges and threats that could impact on its market position. The company experiences soft growth in critical segments like the US diabetes management sector, where it faces stiff competition from newer technologies. Operating in a heavily regulated industry, Medtronic must navigate complex government regulations and healthcare policies, which can significantly influence product demand. Economic factors such as inflation and exchange rate fluctuations also threaten its financial stability. Cybersecurity concerns have notably impacted Medtronic's reputation, exemplified by the recall of 31,000 insulin pump devices due to security vulnerabilities (Kovacs, 2021). Additionally, the FDA alleged that the company engaged in unauthorized product use, scamming government health programs, and participating in anti-competitive behavior. These issues have undermined consumer trust and pose ethical challenges. Intense competition from industry giants like Abbott Laboratories, Stryker Corporation, Boston Scientific Corporation, and Johnson & Johnson necessitates Medtronic to continually innovate and make strategic adjustments to maintain its market leadership. Addressing these weaknesses is crucial for Medtronic to sustain its competitive edge and secure long-term growth.

Nevertheless, Medtronic's experiences and strategies offer valuable insights from which Maxima can benefit. While Maxima focuses on cost-effective surgical devices, the corporation can learn from Medtronic's global presence and technological leadership to enhance its competitive position. Maxima's current output goal of producing disposable devices aligns with Medtronic's efforts to reduce manufacturing costs and achieve profit and puts them in a good position to move forward. Additionally, as Maxima aims to enter the advanced bipolar device

market, it can focus on developing innovative features or device modifications tailored to the surgical domain. Moreover, Maxima's local production capabilities provide a competitive advantage, enabling the company to respond swiftly to market demands, offer customized surgical devices tailored to the needs of specific regions, and further strengthen its market position. Figure 8 below has been designed to visually represent the aspects of Medtronic's PESTEL analysis discussed above, highlighting the diversity of each PESTEL element across the company. This visualization allows for deeper insights into Medtronic's weaknesses and potential opportunities.

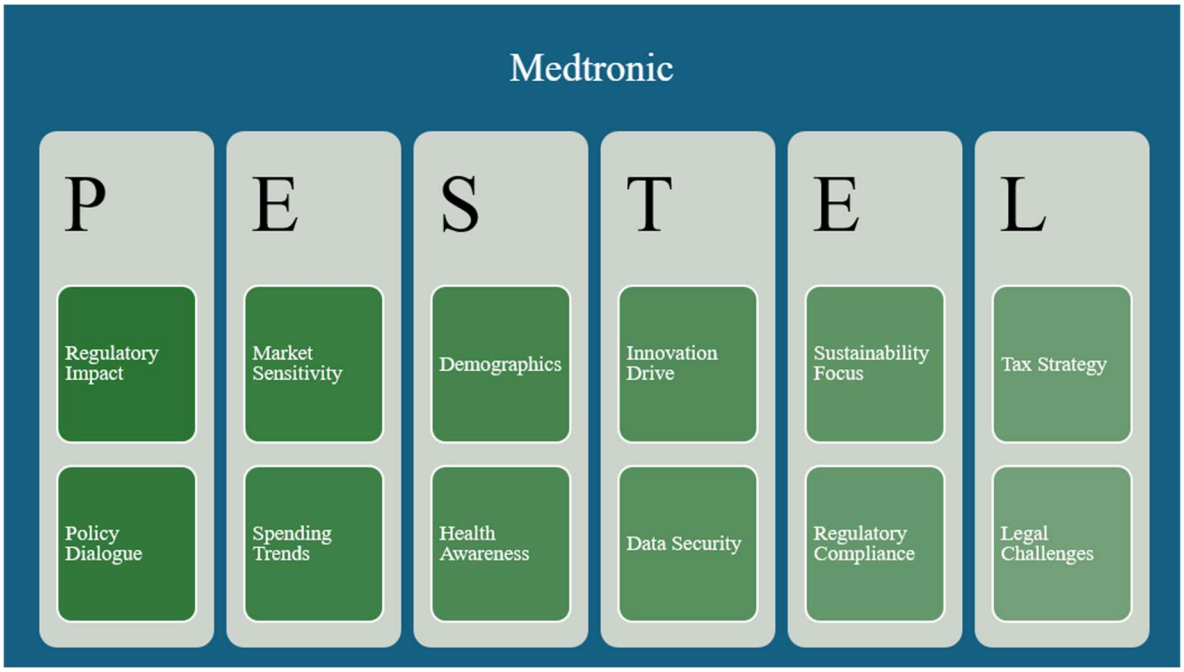


*Figure 8: Pestel Analysis Chart for Medtronic*

### *4.2.2 Johnson & Johnson*

Ethicon, a subsidiary of Johnson & Johnson, stands out in the global surgical devices market with its advanced bipolar energy devices and focus on minimally invasive surgery and digital health solutions. Ethicon effectively utilizes Johnson & Johnson's extensive global network to navigate the complexities of various political and economic landscapes and benefits significantly from trends such as an aging, longer-living global population. This strategic positioning enables Ethicon to maintain a leading role in technological advancements in minimally invasive healthcare. Ethicon made $8,550 million USD worth of acquisition deals in 2019, indicating its aggressive expansion into cutting-edge surgical technologies and companies to bolster its market presence and technological capabilities (Ethicon US LLC, 2019). Their

dynamic intellectual property strategy supports this focus on innovation and secures Ethicon's competitive edge. The vast resources and distribution capabilities that Johnson & Johnson provides further enable Ethicon to fund, resource, and distribute products globally more easily than smaller competitors like Maxima.

However, Ethicon faces several challenges that could impact its market position and operational efficiency. As a larger company with a massive global reach, it shares weaknesses with other medical industry superpowers. This included risks associated with political instability, trade policy sensitivities, and economic downturns in key markets, which can affect healthcare spending and the demand for its products (Ethicon US LLC. 2022). Being a part of Johnson & Johnson, which operates globally, requires that all Ethicon products and innovations adhere to the health codes of every country to maximize profit. Similarly, the global reach of Johnson & Johnson means that the need to adhere to varying patent laws from country to country slows down innovation (Ethicon US LLC. 2019). Ethicon's investment in innovation, such as the venture financing rounds for Auris Surgical Robotics, points to the high costs associated with staying at the forefront of technology. These investments underscore the necessity for continuous R&D to maintain a competitive edge, which could be financially taxing and risky if market conditions turn unfavorable (Ethicon US LLC. 2022). The rapid pace of technological innovation and the necessity for continuous R&D investment to prevent obsolescence in medical devices pose significant challenges.

With its operations in Taiwan, Maxima is well-placed to leverage Ethicon's challenges thanks to its advantages in local manufacturing, which allow it to produce cost-effective devices without facing the import costs that Ethicon encounters (Ethicon US LLC. 2022). The agility and faster innovation cycles of Maxima could surpass those of Ethicon, adapting swiftly to technological and market shifts. This local production strategy minimizes Maxima's exposure to political and trade instabilities, offering a stable alternative in the market. Additionally, by focusing on manufacturing in Taiwan, Maxima only needs to navigate the local government's patent laws and IP regulations and not deal with these issues on a global scale. Similar to Figure 8, Figure 9 below provides a visual representation of the PESTEL analysis for Johnson & Johnson, as discussed above. This chart shows how these factors are integrated throughout various aspects of the company, understanding its strategic responses and potential vulnerabilities.

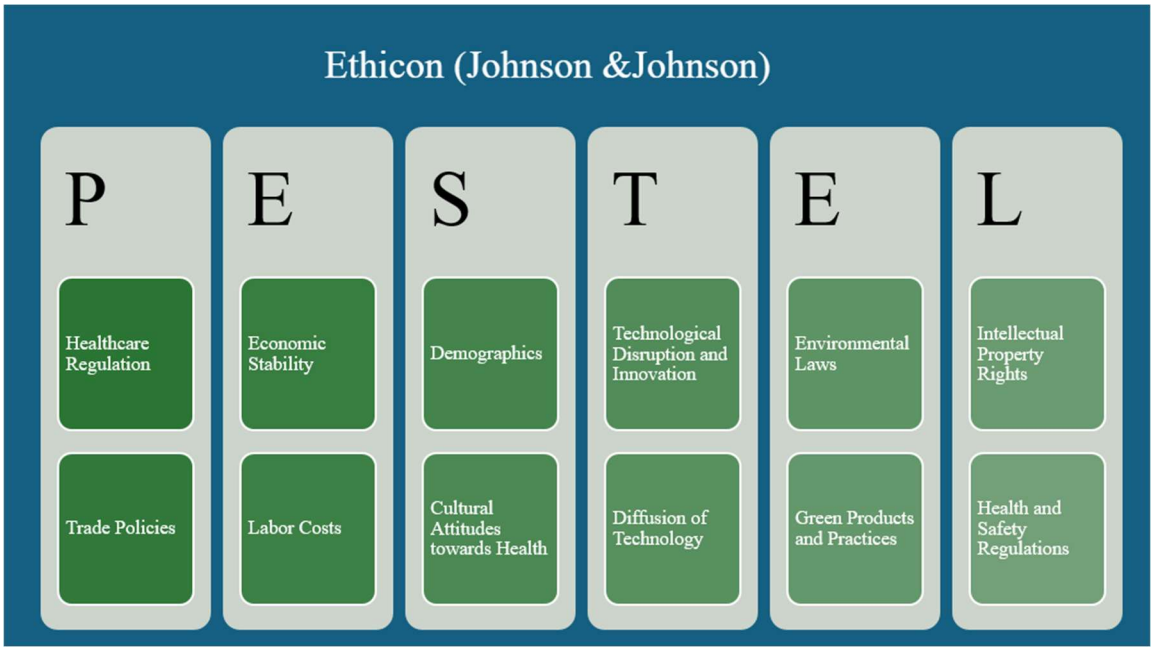


*Figure 9: PESTEL Analysis Chart for Ethicon*

### *4.2.3 CONMED*

CONMED, an independent company with annual revenue of roughly 1 billion USD, focuses specifically on surgical products (*CONMED 2022 Annual Report*, 2023). This company is similar to Medtronic and J&J in that it is a massive multinational business, which produces hundreds of products for use in hospitals. Their statement of purpose is to "[enable] healthcare providers worldwide to deliver exceptional outcomes for their patients through accessible CONMED solutions," which makes it clear that their goal is to expand their product line and decrease the amount of 'shopping around' that hospital staff must do (*Why CONMED?*, 2023).

In pursuit of this goal, the company produces a wide variety of hospital tools and consumables. Their product range includes almost everything surgeons use in an operating room, including sutures, razors for hair removal, laparoscopic cameras, and basic bipolar energy devices. However, CONMED's portfolio has serious weaknesses, notably the lack of an advanced bipolar energy device which can compete with the likes of Medtronic and J&J. This is a weakness because CONMED's goal is to create comprehensive and accessible solutions; however, this weakness is also an opportunity for other businesses to establish a partnership with CONMED and close this gap in their product line.

One of CONMED's greatest strengths is their capital base and they have a long history of using that capital to make acquisitions and strategic partnerships to further their goals. In 2004,

CONMED purchased C.R. Bard's line of endoscopic products, which included their System 5000 basic bipolar energy device that to this day remains a popular choice for surgeons that do not require advanced bipolar technology. Next, in 2016, the company acquired AirSeal, a product specifically designed to deliver carbon dioxide into the body to create space for laparoscopic surgical devices. Most recently, in 2019, CONMED acquired Buffalo Filter, a company which produces surgical smoke filters to improve visibility during surgery (*CONMED: A History of Innovation*, 2023). These acquisitions, which totaled approximately $710 million USD, indicate that laparoscopic surgery is one of CONMED's primary areas of expansion, and that there is real opportunity for partnership with CONMED in this space (*CONMED Bard Endoscopic Acquisition*, 2004) (*CONMED Announces SurgiQuest Acquisition*, 2015) (*CONMED Announces Buffalo Filter Acquisition*, 2018).

One weakness with any medical device company trying to introduce a competing product in a preexisting market is in patent law. In the United States, which generates 55% of CONMED's revenue (*CONMED 2022 Annual Report*, 2023), medical device manufacturers are infamous for their constant litigation related to patent law. This does raise the risk that if CONMED were to create or partner with a company that creates advanced bipolar energy devices, both parties might waste their time and money as litigation could erase profits made for both companies. However, many of the original patents for Ligasure, which Ethicon filed before the device's introduction in 1998, have since expired. Additionally, Johnson and Johnson released the successfully competing ENSEAL device as recently as 2011, demonstrating that it is possible to compete in the advanced bipolar market without facing patent litigation barriers. In many countries in Asia, for which CONMED credits 16% of their revenue (*CONMED 2022 Annual Report*, 2023), the risk associated with patent law is significantly less, making it easier for a partnership to succeed. Figure 10 below offers a PESTEL analysis for CONMED, highlighting its unique position compared to the other companies discussed. This chart differs from Figures 9 and 10 because CONMED's lack of an advanced bipolar device on the market influences its external factors compared to companies like Medtronic and Johnson & Johnson.

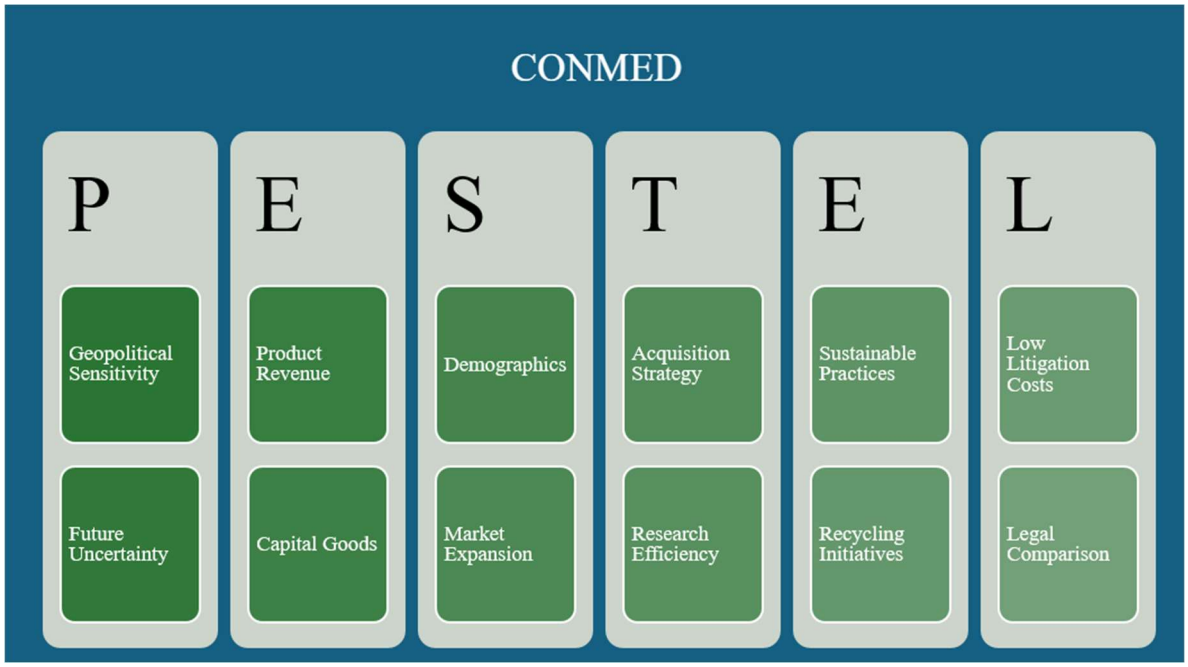


*Figure 10: CONMED PESTEL Analysis*

### *4.2.4 Shared PESTEL Analysis*

In the preceding sections, the team examined how Medtronic, Ethicon, and CONMED, while distinct in many ways, face similar strategic challenges and opportunities within the surgical device market. Building on this analysis, Figure 11, as seen below, organizes and highlights these similarities in a manner similar to Figures 9-11. Politically, these companies navigate complex global healthcare policies and regulatory environments that can affect market access and product approvals. Economically, they are impacted by global economic shifts, including exchange rates and inflation, which influence pricing and profitability. Socially, they cater to an aging global population and a growing awareness of health issues, driving demand for advanced medical technologies. Technologically, each invests significantly in innovation to maintain competitiveness, focusing on minimally invasive technologies and digital health solutions. Environmentally, there is an increased focus on sustainable medical device production. Legally, stringent international and local regulations, patent law management, and cybersecurity are crucial areas they must navigate to maintain market positions and ensure compliance. These shared PESTEL aspects underscore the interconnected nature of their business environments and offer Maxima valuable insights into distinguishing itself from its competitors.

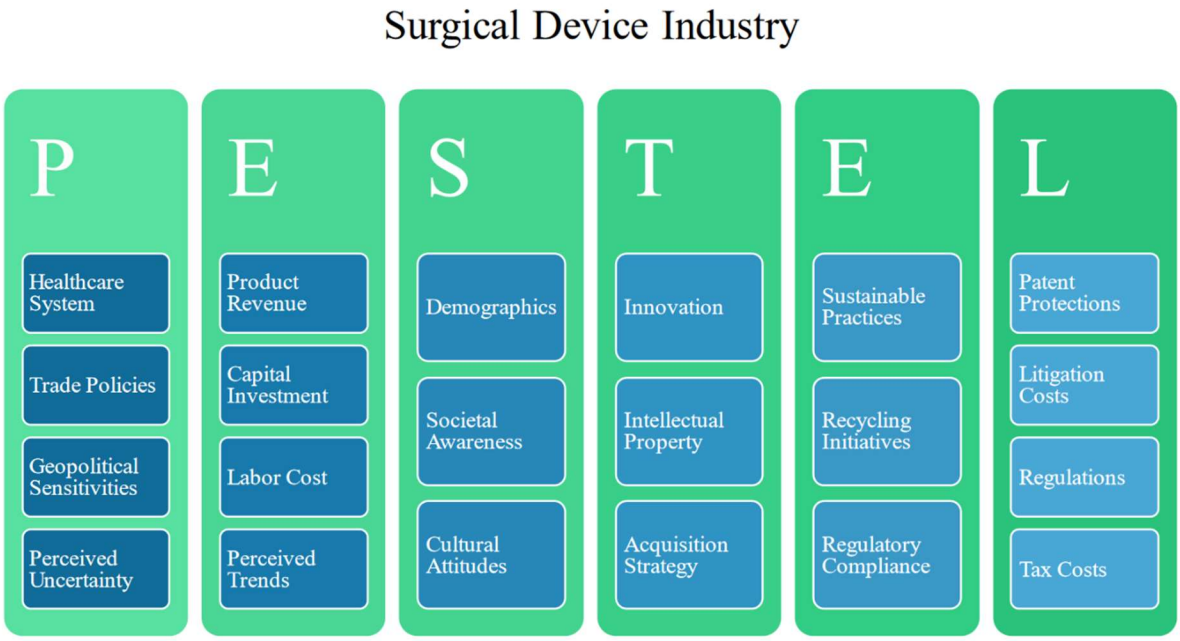


Figure 11: Shared PESTEL Analysis Among Analyzed Companies

### *4.2.5 Shared SWOT Analysis*

Below, the team provides a SWOT analysis of the surgical device market based on the three companies Medtronic, Johnson & Johnson, and CONMED.

#### *4.2.5.1 Strengths*

Medtronic, Johnson & Johnson, and CONMED each display considerable strengths because of not only their corporate structure and size, but also their diverse product portfolios and organizational skills. Each of these companies earns over $1 billion USD in revenue annually, which means they have considerable resources to use when bringing new products to market. Additionally, they each sell a wide array of medical and surgical devices which, when combined, make up almost all of the tools and devices that are used in modern hospitals. This fact makes these companies some of the most stable in the world, because if people need medical care, these companies will profit from selling the devices that allow surgeons and hospitals to provide that care. Finally, all three of these companies are the core of a highly innovative medical industry, and they specialize in taking technologies that aren't products yet and developing them into tools that can be trusted in a surgeon's operating room. This skill of these organizations makes them irreplaceable in the modern medical industry.

#### *4.2.5.2 Weaknesses*

While these companies all have notable strengths, they also have significant weaknesses stemming from operating within a highly competitive and tightly regulated industry. Navigating complex international regulations impacts everything from product development to market entry strategies, as seen with Medtronic's adherence to varied health codes and Ethicon's compliance with differing patent laws across markets. Their substantial size subjects them to intense competition from their highly successful peers and more agile innovators, necessitating continuous innovation and strategic adaptability. Additionally, stringent patent laws and intellectual property challenges can delay new product launches and stifle innovation. CONMED suffers from many of the same issues, but they also suffer in some parts of the surgical device market as they do not have as comprehensive a set of products as Medtronic and J&J.

#### *4.2.5.3 Opportunities*

When looking at these companies' positions in the global medical device market, it is easy to see where their opportunities lie. First, entrepreneurial product developers in the medical industry very often sell their products to these corporations as a way to quickly produce a return on investment, and also because the skills it takes to be an entrepreneur (fast moving, visionary) are very different from the skills it takes to produce a successful surgical product (very slow moving, test everything). Medtronic, Johnson & Johnson, and CONMED each have their own long history of acquiring these small businesses who attempt to develop medical technology. CONMED alone has spent over $700 million USD on acquiring small businesses specifically in minimally invasive surgery over the last 20 years, not counting any other acquisitions they have made (*CONMED Bard Endoscopic Acquisition*, 2004) (*CONMED Announces SurgiQuest Acquisition*, 2015) (*CONMED Announces Buffalo Filter Acquisition*, 2018). Medtronic and Johnson & Johnson have each spent more than that on acquisitions in the same industry (*Acquisitions by Johnson & Johnson*, 2024) (*Acquisitions by Medtronic*, 2024).

#### *4.2.5.4 Threats*

These companies still face threats to their continued success in this industry. Some of these threats are technological, like cybersecurity threats, which have led to devices which are used outside the surgical theater being recalled in the past (Kovacs, 2021). Some of these threats are legal, between changing FDA regulations and threats of antitrust litigation to corporations like Medtronic and Johnson & Johnson (Newmarker, 2023). Finally, these companies face fierce

competition from the other highly capable businesses in the industry, like Boston Scientific, Stryker Corporation, and Abbott Laboratories, each of which compete in different areas of medical and surgical device manufacturing. Because of these threats, businesses like Medtronic need to continue developing new and better medical products to ensure their long-term success.

## *4.3 Social Survey*

The team aimed to enhance Maxima's strategic approach to the surgical device market by conducting a survey which gauged consumer attitudes toward surgical devices and environmental sustainability. The team received 73 responses, but discounted four surveys due to incomplete or blank submissions. Therefore, the team analyzed 69 data sets, with 32 from the US, 36 from Taiwan, and one from India.

### *4.3.1 Survey Results & Analysis*

Figure 12 shows the age distribution among the survey respondents, encompassing multiple generations from 18 to 60+. This wide representation of ages presents an opportunity for Maxima to engage with a broad spectrum of potential customers, allowing for a more comprehensive understanding of their needs and preferences. Overall, the survey age distribution was well balanced, with 49.3% of respondents aged 18-45, and 50.7% of respondents aged 46-60+.

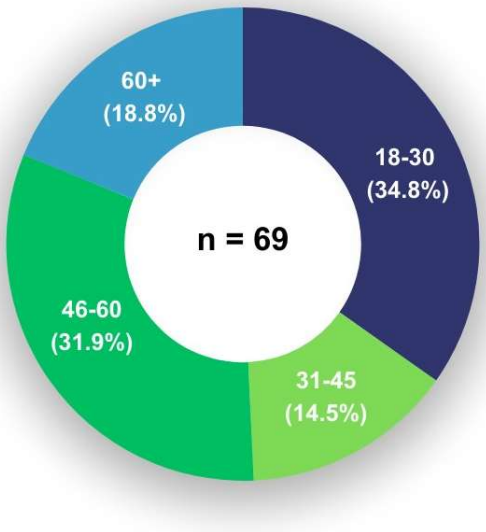


*Figure 12: Age Distribution of Respondents*

The data collected for this study reflects a targeted international sample. Figure 13 highlights the utilization of snowball sampling, leveraging both the team's and sponsor's contacts, to primarily capture perspectives from the US and Taiwan. By concentrating on these regions, this study gains valuable insights into the specific cultural and personal contexts relevant to Maxima's potential expansion in Taiwan and the US.

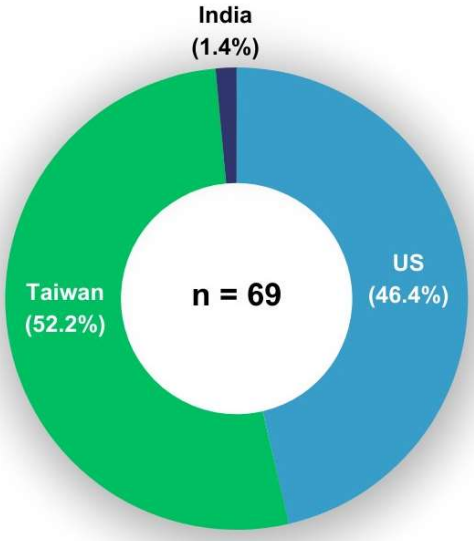


*Figure 13: Country of Residence Distribution of Respondents*

Figure 14 shows that among respondents reporting in USD, a significant proportion falls within the $120,000+ bracket, suggesting a substantial presence of higher-income individuals. Whereas Figure 15 shows that among respondents reporting in NT, the majority falls within a much larger NT$90,000 - NT$200,000 bracket, indicating a varied socioeconomic representation. Understanding these income distributions is crucial for the team's further analysis of the survey data, particularly regarding the preferences of respondents from the US, who are more likely to have higher incomes (63.6% of respondents have a greater than $80,000 income).

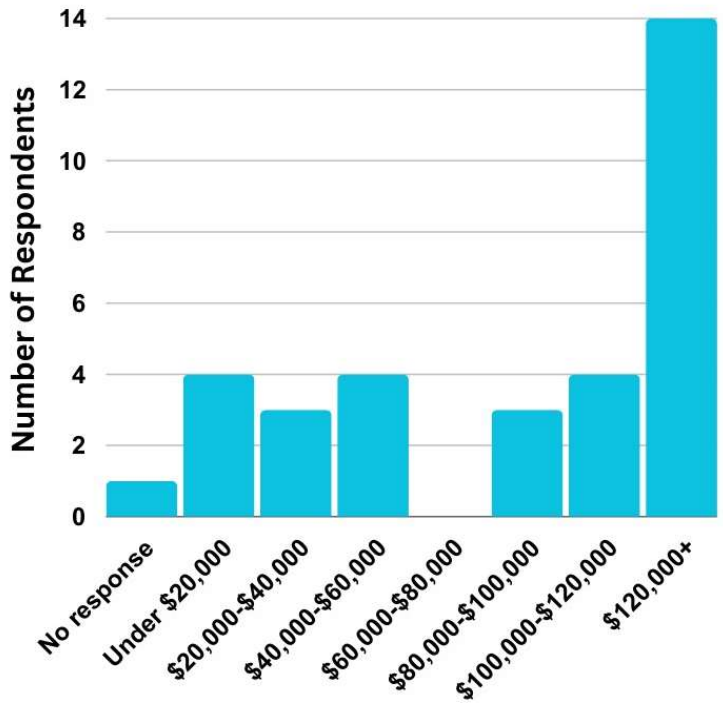


*Figure 14: Income Distribution Among Respondents Reporting in USD*

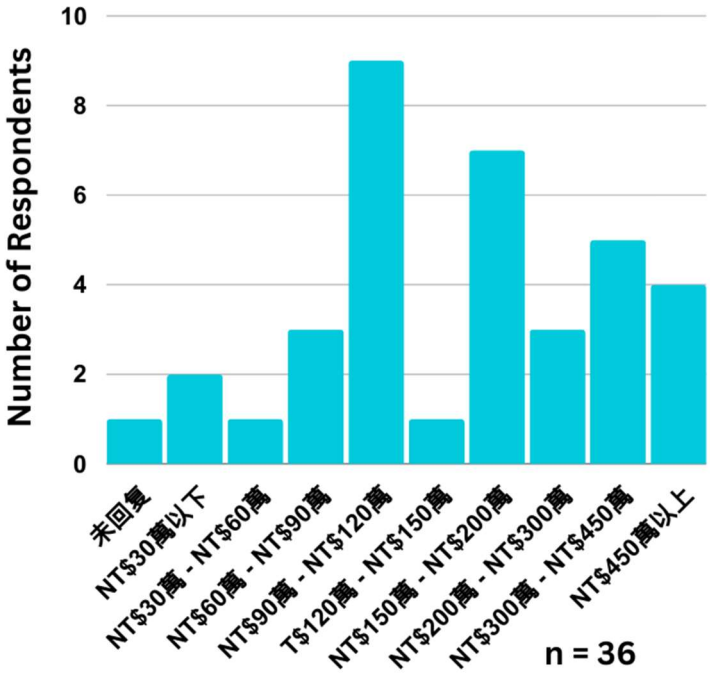


*Figure 15: Income Distribution Among Respondents Reporting in NT$*

The team presented respondents with a brief overview of the advantages and drawbacks of disposable and reusable minimally invasive surgical (MIS) devices. They then requested respondents indicate their preference for disposable or reusable devices based on key factors like safety, cost, and environmental impact. Figure 16 clearly indicates that the preferred choice among respondents is disposable devices. Disposable devices offer a lower risk of infection due to their single-use nature, lessening concerns associated with improper sterilization. However, they tend to be more expensive and contribute to environmental waste. In contrast, reusable devices, while more environmentally friendly and cost-effective, carry a higher risk for patients if not properly sterilized. The data suggests patients greatly prioritized the option that offers the safest outcome. These considerations highlight the trade-offs in biomedical product choices, where businesses must consider economic, environmental, and patient safety concerns. Understanding and accommodating these preferences are key for Maxima's product development, marketing strategies, and overall business success.

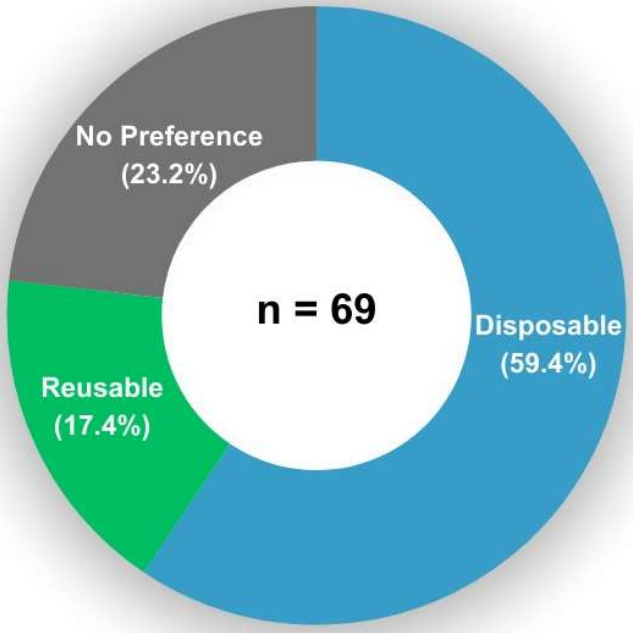


*Figure 16: If you were undergoing surgery and had the choice, would you tell your surgeon to operate with a disposable or reusable device (considering cost, safety, and environmental impact)?*

The observed trend in Figure 17 shows that US consumers may have a slightly higher awareness or concern regarding environmental impact compared to respondents from Taiwan. However, despite this tendency, both groups still strongly prefer disposable devices. The team wanted to analyze the difference between the US and Taiwan specifically, so the team removed the response from India. For Maxima, understanding these differences in consumer preferences across different regions is crucial for effectively tailoring their products and marketing strategies. Maxima must acknowledge the growing concern for environmental sustainability among certain demographics while also recognizing the predominant preference for disposable devices.

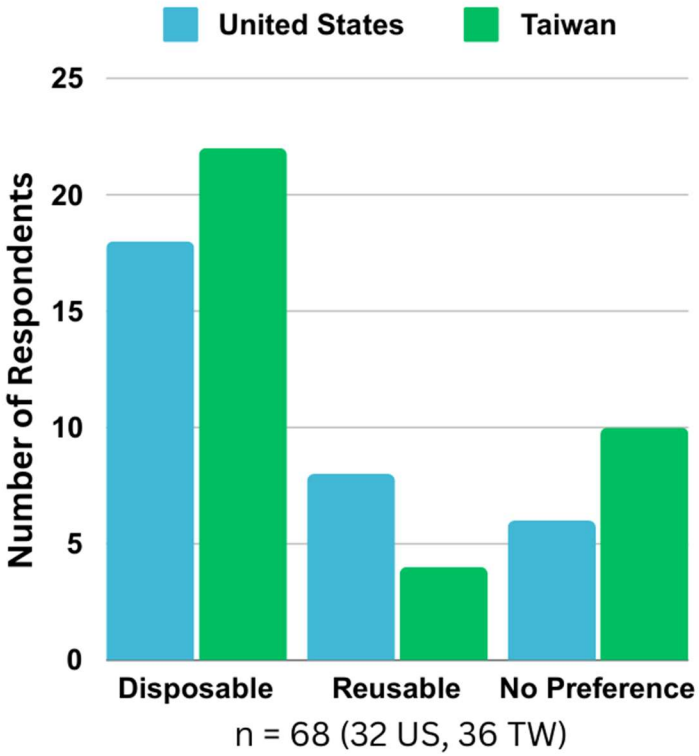


*Figure 17: Effect of Respondent Country of Residence on Device Preference*

In analyzing respondents' preferences on surgical devices across different income ranges, it is evident that the majority of respondents prefer disposable devices across all brackets. However, based on the data in Figure 18, there is an increased percentage of individuals who prefer reusable devices in the lowest income category. While the population samples vary in number, one notable comparison is the Under $20,000-$40,000 category and the $80,000-$120,000 category, which had the same number of respondents, and a clear preference for

reusable devices among the lower incomes. This preference suggests that while safety remains a significant factor, respondents are willing to consider reusable devices which involve more risk but are comparatively cheaper if their income is lower.

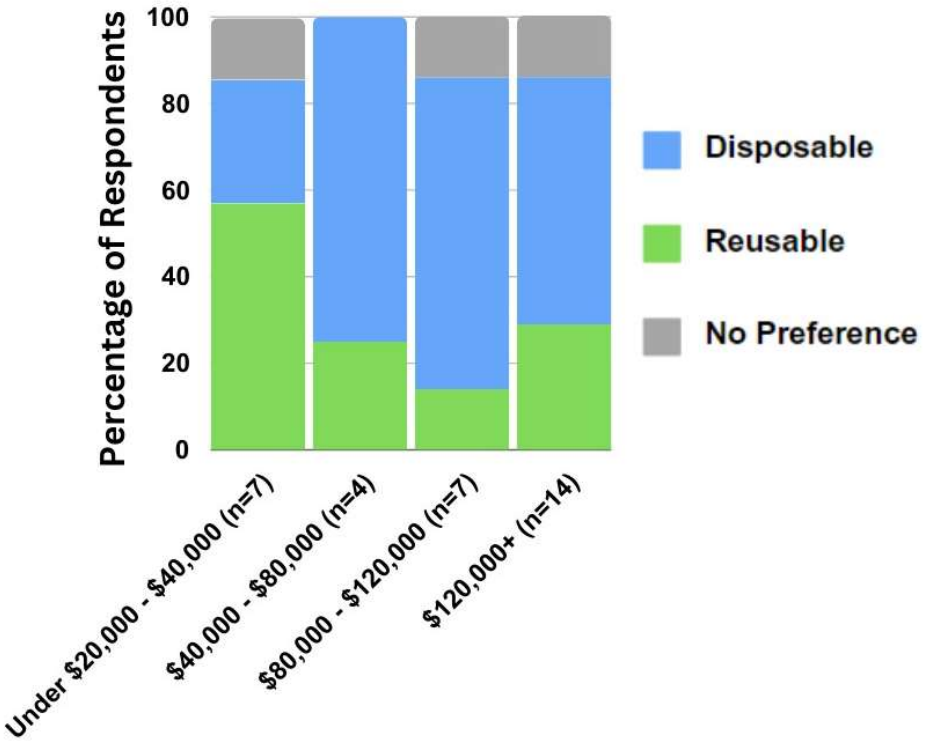


*Figure 18: Effect of Respondent US Income on Device Preference*

The team then asked respondents to rank the factors they felt were most important when it came to surgical devices. Figure 19 shows the high emphasis placed on safety, suggesting that ensuring the safety and reliability of their surgical devices should be the primary concern in product development and marketing efforts, backing up the team's survey results. The relatively high ranking of cost of surgery highlights the significance of cost-effectiveness in the decision-making process for both healthcare providers and patients. Maxima may benefit from developing innovative solutions that not only meet high safety standards but also offer competitive pricing to address cost concerns and enhance accessibility to their products.

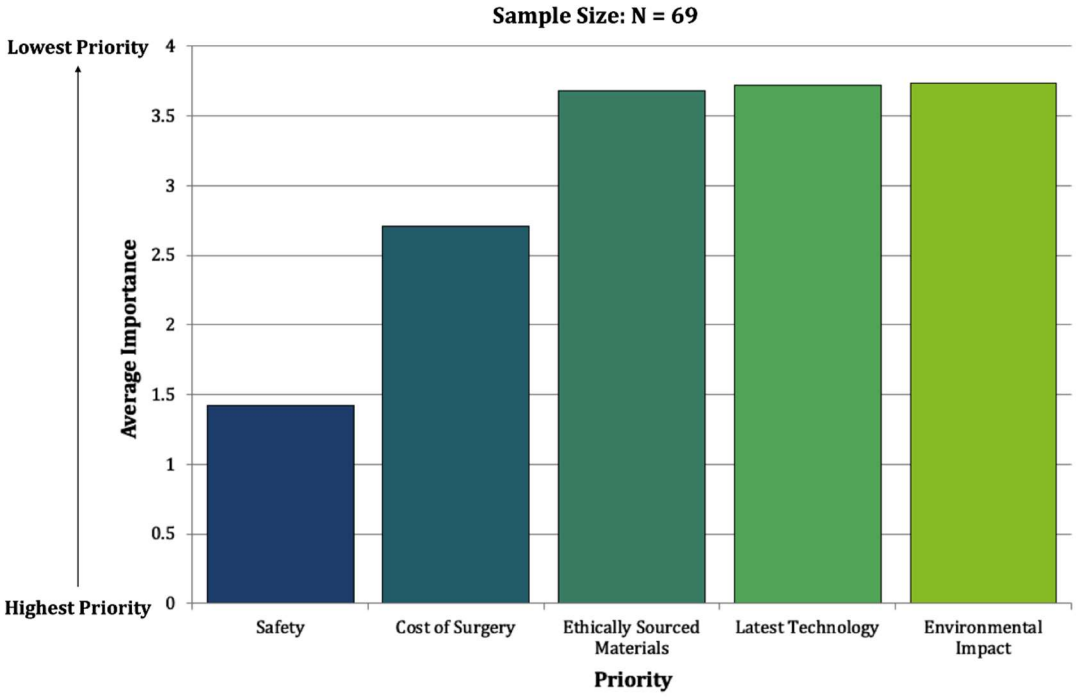


*Figure 19: Drag each choice to rank the following priorities by how important you think they are from top to bottom (1 most important, 6 = least important ["other" (6) option omitted due to low number of responses]):*

Figure 20 shows the responses to the question, "Would you be willing to pay more for surgeries that use environmentally friendly practices or materials?" One respondent explained their "no" response, attributing it to their current low-income situation, but expressing a willingness to pay more if financially able, stating, "If I had enough money to pay more to save the environment, I definitely would choose to pay more for surgeries that use environmentally friendly practices or materials." Backing this idea, another respondent who chose "maybe" highlighted the importance of affordability, stating, "If the payment difference is a lot, say more than 20%, then I will not choose disposable as affordability will become a priority." These factors are interesting insights into the minds of consumers when it comes to medical devices.

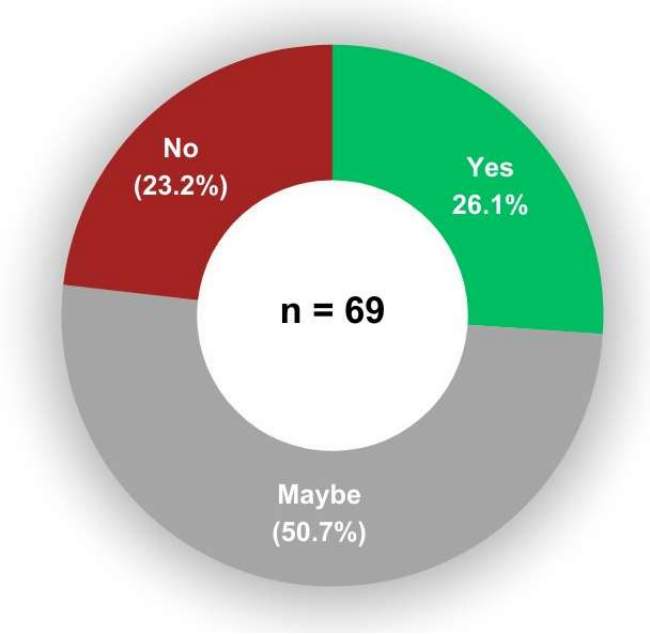


*Figure 20: Would you be willing to pay more for surgeries that use environmentally friendly practices or materials?*

### *4.3.2 Overall Survey Results & Analysis*

The age distribution among respondents is well-balanced, which provides the company with a comprehensive view of their customers' needs and preferences across different age groups. The survey results indicate an overarching preference for disposable surgical devices across all demographics. However, more US respondents preferred reusable devices than Taiwanese respondents, and a higher percentage of lower income respondents chose reusable devices compared to higher income respondents due to financial concerns. Safety remains a significant factor, but affordability influences decision-making, suggesting opportunities for Maxima to address cost-effectiveness in product offerings. When looking at the important factors of surgical devices from a patient perspective, it is evident that safety is the top priority, followed closely by the cost of surgery, with environmental impact as the lowest priority. Additionally, insights into consumer willingness to pay more for environmentally friendly practices or materials highlight the importance of financial situations and insurance coverage in decision-making. This knowledge may help inform Maxima's marketing strategy and product development efforts, emphasizing the need to prioritize safety, cost-effectiveness, and environmental considerations to effectively meet the needs of its audience (both surgeons and patients) and drive business success.

# 5.0 Recommendations to Maxima

In this section, the team provides five specific recommendations which Maxima can consider following to improve their future product success. Particularly, three focused on Maxima's future device itself, one on environmentally friendly materials, and one on potential future partnerships.

## *5.1 Recommendation 1: Surgeon Interface*

To enhance the surgeon experience and market competitiveness of Maxima's advanced bipolar device, the team recommends designing a device with a focus on simplifying the interface to ensure seamless operation during surgical procedures. This would come in the form of simplistic controls that can be adjusted using one hand. The feedback from surgeons highlighted in Appendix D-G underscores the importance of an intuitive design that minimizes cognitive load during an operation. Surgeons emphasized the need for simplicity in device operations to support ease of use and adoption. Implementing device controls directly on the handheld unit, as suggested by Dr. Caparrelli, would allow surgeons to operate the device with one hand while using their other hand for different tools such as a laparoscopic camera. This design would not only simplify the operation but also maintain consistency in performance, crucial for gaining surgeons' trust and preference.

## *5.2 Recommendation 2: Smoke Ventilation*

The team also recommends incorporating a smoke ventilation system directly within the shaft of surgical devices to enhance safety and maintain operational efficiency. This integration minimizes the bulkiness of external evacuation methods, improves the device's ergonomics, and allows surgeons to operate with greater precision. By efficiently dispersing smoke, this design clears the visual field, providing the surgeon with a clear line of sight, which reduces mistakes. This streamlined approach supports a safer, clearer surgical environment and simplifies the workflow by eliminating the need for cumbersome additional equipment.

## *5.3 Recommendation 3: Disposable Tips*

Considering the challenges associated with sterilization and the longevity of components, the team recommends Maxima to explore the development of disposable tips for their advanced bipolar device. A standard disposable device has the surgeon discard the device after use to prevent infection. However, by only disposing of the tip, it still allows for maximum safety from

infection by discarding the parts that enter the patient. This recommendation aligns with the insights from the surgeons who noted the advantages of minimizing the use of disposable components to reduce waste and cost. By allowing the replacement of just the jaw of the device — the part that typically lasts only one surgery — Maxima can offer a cost-effective solution that also addresses environmental concerns. This approach would not only conserve materials used in the handle and reusable electronics but also provide a safer, more reliable option for hospitals wary of the risks associated with reusable devices.

### *5.4 Recommendation 4: Environmentally Friendly Material*

In response to survey insights, specifically regarding environmentally friendly materials, the team recommends that Maxima should integrate sustainable materials and processes into the manufacturing of the handles of its devices. This approach will not only minimize environmental impact but also align with trends favoring sustainability which is becoming more prominent in the surgical device market. By implementing an eco-friendly handle, in tandem with disposable tips, Maxima can enhance its competitive edge and meet the evolving preferences of its customer base.

### *5.5 Recommendation 5: Strategic Partnership*

For Maxima, the team recommends forming a partnership with CONMED over being acquired. Maxima does not have the means of outcompeting larger companies like Johnson and Johnson (J&J) and Medtronic due to their ability to outpace Maxima in terms of finance and resources. However, when compared to the top contenders in the surgical device market, Maxima's strength lies in its hyperfocus on MIS, allowing for them to pool all resources into producing the best device possible. When compared with CONMED, a company that has resources and funding on a similar level to Medtronic and J&J, but lacks an advanced bipolar device on the market, an opportunity presents itself. By partnering, Maxima can leverage CONMED's extensive distribution network and industry experience while maintaining its own operational independence and corporate identity. This collaboration would enable Maxima to tap into new markets and innovate alongside an established player, enhancing its product offerings and reach.

### *5.6 Ideal Design Scenario*

To enhance the recommendations for Maxima's advanced bipolar surgical device further, the team brainstormed and developed an early-stage prototype digital model (see Figure 25).

This model serves as a graphic tool to effectively encapsulate the innovation and features based on the project recommendations.

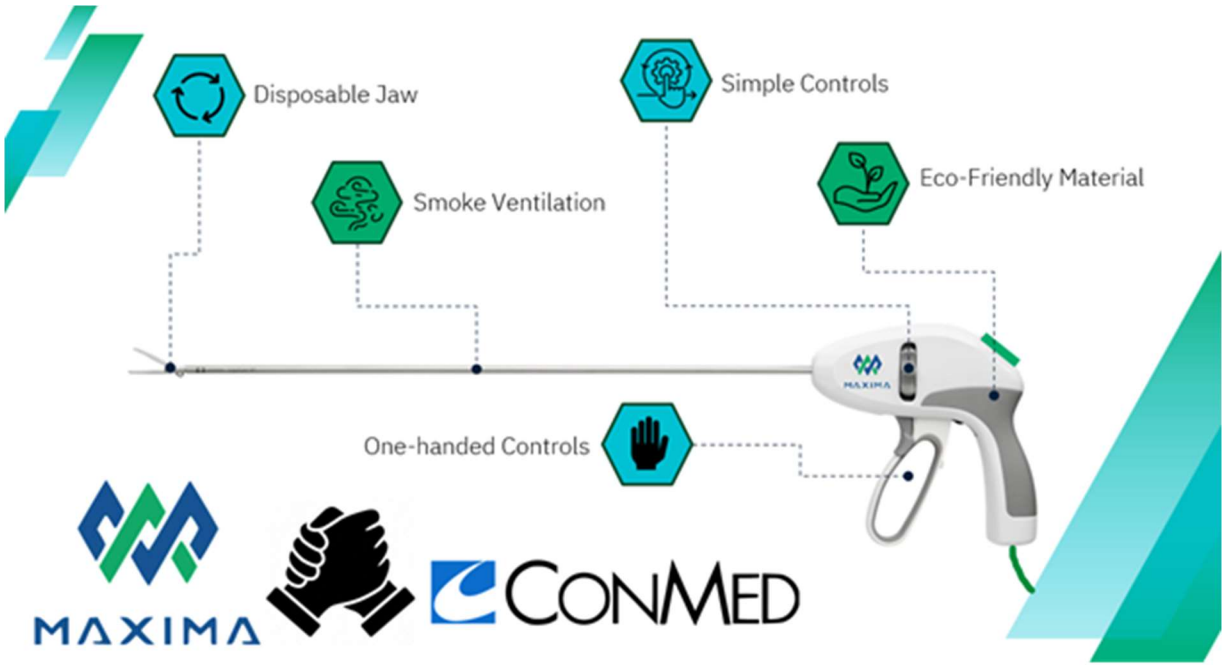


*Figure 21: Combined Recommendations for Maxima*

# 6.0 Conclusion

Although the surgical device industry is highly complex, the team reached through analysis of interviews, surveys, and competitors. Using the recommended strategies and enhancements as a guide, Maxima Biotech has solid guidelines for enhancing and marketing its new surgical device. The team hopes the strategic recommendations provided will position Maxima to not only meet current market demands but also to innovate and lead in the surgical device industry, ensuring long-term growth and success. The team believes that the recommendations presented could establish a foundation for future IQP groups to build upon. Future work on this project might include developing a fully digital model or a mock-up of the device for presentation, along with further development of strategic partnership plans with Maxima. The team recommends that any future groups working on this project should schedule meetings with surgeons well in advance of arriving in Taiwan, as securing interviewees was a challenge for the group.

# References


*Acquisitions by Johnson & Johnson*. (2024, April 8). [Research]. Tracxn. https://tracxn.com/d/acquisitions/acquisitions-by-johnson-johnson/__QQnOvfmDr7cMNF7rAf5SOqW8gO3RJj2wEk4fcibAPFs

*Acquisitions by Medtronic*. (2024, April 9). [Research]. Tracxn. https://tracxn.com/d/acquisitions/acquisitions-by-medtronic/__hOupGPL5sZOEOFwwaRhtAh_CkHx5JcO2XH2dAOxY-uk

*Advanced Bipolar Direct Energy Devices Market By End User, By Product and By Region: Industry Analysis, Market Share, Revenue Opportunity, Competitive Analysis and Forecast 2023-2031*. (2023). [Market Analysis]. FutureWiseResearch. https://www.futurewiseresearch.com/

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/

Beers, B. (2023, May 16). *A Brief Overview of the Insurance Sector* [Blog]. Investopedia. https://www.investopedia.com/ask/answers/051915/how-does-insurance-sector-work.asp

Boberg, L., Singh, J., Montgomery, A., & Bentzer, P. (2022). Environmental impact of single-use, reusable, and mixed trocar systems used for laparoscopic cholecystectomies. *PLOS ONE*, *17*(7), e0271601. https://doi.org/10.1371/journal.pone.0271601

Chan, K. S., Lo, H. Y., & Shelat, V. G. (2023). Carbon footprints in minimally invasive surgery: Good patient outcomes, but costly for the environment. *World Journal of Gastrointestinal Surgery*, *15*(7), 1277–1285. https://doi.org/10.4240/wjgs.v15.i7.1277

Chicago Institute of Minimally Invasive Surgery. (2016). *Laparoscopic History | Laparoscopic Surgery | History of Minimally Invasive Surgery*. http://www.laparoscopicexperts.com/introduction/

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

CIPD. (2024, March 13). *CIPD | PESTLE analysis*. CIPD. https://www.cipd.org/en/knowledge/factsheets/pestle-analysis-factsheet/

Cleveland Clinic. (2023, October 29). *What Is Minimally Invasive Surgery?* Cleveland Clinic. https://my.clevelandclinic.org/health/procedures/minimally-invasive-surgery

*CONMED 2022 Annual Report*. (2023). CONMED. https://conmed.gcs-web.com/static-files/a5bd1186-b5f8-4baf-a769-b54294e63af7

*CONMED: A History of Innovation*. (2023). CONMED. https://www.conmed.com/en/why-conmed/a-history-of-innovation

*CONMED Announces Definitive Agreement to Acquire Buffalo Filter LLC*. (2018, December 13). [Press Release]. CONMED. https://conmed.gcs-web.com/news-releases/news-release-details/conmed-announces-definitive-agreement-acquire-buffalo-filter-llc

*CONMED Announces Definitive Agreement to Acquire SurgiQuest, Inc.* (2015, November 16). [News]. BusinessWire. https://www.businesswire.com/news/home/20151116005639/en/CONMED-Announces-Definitive-Agreement-to-Acquire-SurgiQuest-Inc

*CONMED Corporation to Acquire C.R. Bard's Endoscopic Technologies Product Line*. (2004, August 18). [Press Release]. CONMED. https://conmed.gcs-web.com/news-releases/news-release-details/conmed-corporation-acquire-cr-bards-endoscopic-technologies

*Covidien Valleylab™ ForceTriad™ 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

Danolić, D., Marcelić, L., & Alvir, I. (n.d.). *EP1265 Advanced bipolar seal and cut technology - ProQuest*. Retrieved April 2, 2024, from https://www.proquest.com/docview/2552947759/fulltextPDF/9EA0C9293B4D49CAPQ/1

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

*ENSEAL™ G2 Straight Tissue Sealer*. (2023). Johnson&Johnson MedTech. https://www.jnjmedtech.com/en-US/product/enseal-g2-straight-tissue-sealer

*ETHICON ENSEAL*. (2023). [Store Page]. SPS. https://www.shopsps.com/shop/nslx137s-code-nslx137s-ethicon-enseal-x1-straight-jaw- advanced-bipolar-tissue-sealer-37cm-straight-tip-237716

*Ethicon Gen11 Endo Surgery Generator*. (2024). [Store Page]. ACTIVE Medical Store. http://activemedicalstore.com/products.php?product=Ethicon-Gen11-Endo-Surgery- Generator

Garceau, A., & Gopal, A. (2023, December 21). *What Is Laparoscopic Surgery?* WebMD. https://www.webmd.com/digestive-disorders/laparoscopic-surgery

GlobalData. (n.d.). *Ethicon US LLC - ProQuest (2022)*. Retrieved April 16, 2024, from https://www.proquest.com/docview/2470845463?parentSessionId=og%2FqIJUqduZi1SKzpsqglkXABDPT6GALcIxk3TXxD%2Fg%3D&parentSessionId=v7BTOoN4gMJQHWvlwH9JbAXMRY7cDSKT3NfnYQjMU7I%3D&pq-origsite=primo&sourcetype=Reports

GlobalData. (2022, December). *Ethicon US LLC - ProQuest (2019)*. https://www.proquest.com/docview/2470845463?parentSessionId=og%2FqIJUqduZi1SKzpsqglkXABDPT6GALcIxk3TXxD%2Fg%3D&parentSessionId=v7BTOoN4gMJQHWvlwH9JbAXMRY7cDSKT3NfnYQjMU7I%3D&pq-origsite=primo&sourcetype=Reports

GuruFocus Research. (2023, July 20). *Medtronic PLC (MDT): An Undervalued Gem in the Medical Device In*. https://www.gurufocus.com/news/2045271/medtronic-plc-mdt-an-undervalued-gem-in-the-medical-device-industry

Harris, H., Bhutta, M., & Rizan, C. (2021). A survey of UK and Irish surgeons' attitudes, behaviours and barriers to change for environmental sustainability. *The Annals of The Royal College of Surgeons of England*, *103*(10), 725–729. https://doi.org/10.1308/rcsann.2021.0271

Hivelr Business Review. (2024, January 19). Medtronic (MDT): Porter's Five Forces Industry and Competition Analysis. *Hivelr*. https://www.hivelr.com/2024/01/medtronic-mdt-porters-five-forces-industry-and-competition-analysis/

*How Premiums Are Calculated*. (2023, November 20). [Government]. National Health Insurance Administration of Taiwan. https://www.nhi.gov.tw/en/cp-1112-0dec1-201-2.html

*How U.S. Health Insurance Works*. (n.d.). [University]. Stanford University. Retrieved April 2, 2024, from https://vaden.stanford.edu/insurance-referral-office/health-insurance-overview/how-us-health-insurance-works

Karande, V. (2015). LigaSure™ 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

Keisler-Starkey, K., Bunch, L., & Lindstrom, R. (2023, September 12). *Health Insurance Coverage in the United States: 2022* [Government]. United States Census Bureau. https://www.census.gov/library/publications/2023/demo/p60-281.html

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/

Kovacs, E. (2021, October 7). *Medtronic Recalls Medical Devices Due to Security Risks That Can Lead to Injury, Death* [News]. https://www.securityweek.com/medtronic-recalls-medical-devices-due-security-risks-can-lead-injury-death/

Laws & Regulations Database of The Republic of China (Taiwan). (2022, May 4). *PATENT ACT - Article Content - Laws & Regulations Database of The Republic of China (Taiwan)*. https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=J0070007

*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/

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. (2021). *Home Page*. Maxima Biotech Inc. https://www.maximabio.com/?lang=en

McKellar, S. (2010). A history of surgery: From superstition to science. *CMAJ : Canadian Medical Association Journal*, *182*(8), 809. https://doi.org/10.1503/cmaj.100436

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

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

Newmarker, C. (2023, July 5). *FTC critiques Medtronic's legal reasoning in antitrust case* [News]. Mass Device. https://www.massdevice.com/ftc-critiques-medtronics-legal-reasoning-in-antitrust-case/

Özdemir, Ü., Karayiğit, A., Karakaya, İ., Özdemir, D., Dizen, H., Özer, İ., & Ünal, B. (2021). Is electrosurgery a revolution? Mechanism, benefits, complications and precautions. *Journal of Pharmaceutical Technology*, *1*(3), 60–64. https://dergipark.org.tr/en/download/article-file/1411251

Patrone, R., Gambardella, C., Romano, R. M., Gugliemo, C., Offi, C., Andretta, C., Vitiello, A., Tartaglia, E., Flagiello, L., Conzo, A., Mauriello, C., & Conzo, G. (2019). The impact of the ultrasonic, bipolar and integrated energy devices in the adrenal gland surgery: literature review and our experience. *BMC Surgery*, *18*(1), 123. https://doi.org/10.1186/s12893-018-0457-5

Pedersen, A. (2023, February 18). *Medtronic Accused of Trying to Illegally Block Competition*. https://www.mddionline.com/surgical/medtronic-accused-of-trying-to-illegally-block-competition

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

Rizan, C., & Bhutta, M. F. (2022). Environmental impact and life cycle financial cost of hybrid (reusable/single-use) instruments versus single-use equivalents in laparoscopic cholecystectomy. *Surgical Endoscopy*, *36*(6), 4067–4078. https://doi.org/10.1007/s00464-021-08728-z

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.

Schooley, S. (2024, January 6). *What is a SWOT Analysis? How To Use It for Business*. Business News Daily. https://www.businessnewsdaily.com/4245-swot-analysis.html

Shiber, L.-D., Ginn, D., Jan, A., Gaskins, J., Biscette, S., & Pasic, R. (2018). Comparison of Industry-Leading Energy Devices for Use in Gynecologic Laparoscopy: Articulating ENSEAL versus LigaSure Energy Devices. *Journal of Minimally Invasive Gynecology*, *25*(3), 467–473. https://doi.org/https://doi.org/10.1016/j.jmig.2017.10.006

*Single-use medical devices: implications and consequences of reuse*. (2021). The Medicines and Healthcare products Regulatory Agency.

https://assets.publishing.service.gov.uk/media/60117a378fa8f565559191cd/Single_use_medical_devices.pdf

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

*Surgical Equipment Global Market Report 2024 - By Type (Surgical Sutures and Staples, Handheld Surgical Devices and Equipment, Electrosurgical Devices and Equipment), By End User (Hospitals and Clinics, Diagnostic Laboratories, Other End Users), By Type Of Expenditure (Public, Private), By Product (Instruments/Equipment, Disposables) - Market Size, Trends, And Global Forecast 2024-2033*. (2024, January). [Market Research]. The Business Research Company. https://www.thebusinessresearchcompany.com/report/surgical-equipment-global-market-report

*The Real Cost of Health Care: Interactive Calculator Estimates Both Direct and Hidden Household Spending*. (2019, February 21). [News]. KFF. https://www.kff.org/health-costs/press-release/interactive-calculator-estimates-both-direct-and-hidden-household-spending/

USPTO Office of Public Affairs (OPA). (n.d.). *United States Patent and Trademark Office* [Text]. Retrieved March 26, 2024, from https://www.uspto.gov/

Van Norman, G. A., & Eisenkot, R. (2017). Technology Transfer: From the Research Bench to Commercialization. *JACC: Basic to Translational Science*, *2*(1), 85–97. https://doi.org/10.1016/j.jacbts.2017.01.003

Weihrich, H. (1982). The TOWS matrix—A tool for situational analysis. *Long Range Planning*, *15*(2), 54–66. https://doi.org/10.1016/0024-6301(82)90120-0

Whelan, J. (2023). Current issues in reprocessing of medical and surgical instruments. *American Journal of Infection Control*, *51*(10), 1185–1188. https://doi.org/10.1016/j.ajic.2023.04.004

*Why CONMED?* (2023). CONMED. https://www.conmed.com/en/why-conmed

World Journal of Laparoscopic Surgery. (n.d.). *All Issues ( World Journal Of Laparoscopic Surgery )* [Text]. World Journal of Laparoscopic Surgery. Retrieved March 21, 2024, from https://www.wjols.com/lov/WJOLS

Wu, T.-Y., Majeed, A., & Kuo, K. N. (2010). An overview of the healthcare system in Taiwan. *London Journal of Primary Care*, *3*(2), 115–119. https://doi.org/10.1080/17571472.2010.11493315

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

Zorzato, P. C., Ferrari, F. A., Garzon, S., Franchi, M., Cianci, S., Laganà, A. S., Chiantera, V., Casarin, J., Ghezzi, F., & Uccella, S. (2024). Advanced bipolar vessel sealing devices vs conventional bipolar energy in minimally invasive hysterectomy: a systematic review and meta-analysis. *Archives of Gynecology and Obstetrics*, *309*(4), 1165–1174. https://doi.org/10.1007/s00404-023-07270-8

# Appendix A: Glossary

| | |
|---|---|
| Advanced Bipolar Energy | Refers to bipolar energy surgical devices which use sensors to automatically control the amount of heat put into a patient's body. |
| Bipolar Energy Surgical Device | A tool used during surgery which uses electrical energy to cut or ablate tissue, to cauterize blood vessels, or to remove moisture from an area to coagulate blood. |
| Coagulation | Refers to the process by which a blood clot is formed. |
| Coaptation | Refers to the joining or readjustment of two surfaces. |
| Desiccation | Refers to the drying of tissue or loss of moisture. |
| Endoscope | Refers to a surgical tool that is a long, thin tube with a lit camera on the end that provides video feed to surgeons. |
| High-pulsatile | Refers to a state identified by a rapid, rhythmic pulsation or fluctuation, often used to describe conditions or systems exhibiting intense and frequent pulsations. |
| Laparoscopic Surgery | Refers to 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 | Refers to the surgical procedure of closing a blood vessel or other tube in the body using a clip, ligature (surgical thread), or other means. |
| Mechanical Ligation | Refers to using ligatures 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. |
| Sutures | Refers to a surgical tool that holds body tissue in the form of wounds or surgical incisions closed to heal properly. |
| Tissue Transection | Refers to the cross-section, or cutting, of a piece of tissue. |
| Tissue Impedance | Refers to the response of tissues to electrical energy when connected to an alternating electrical voltage source. |

# Appendix B: Interview Process

## *Interview Setup*

The team produced a standard email to send to surgeons to make contact. That email was phrased as follows:

*Dear <Recipient>,*

*I hope this message finds you well. My name is <Sender>. I received your info from Dr.Tang, and I am part of Team BPES at Worcester Polytechnic Institute in the United States. We are collaborating with Maxima Biotech Inc (久方生技股份有限公司), our local Taiwanese sponsor, on a project to improve bipolar surgical devices.*

*We seek to understand expert opinions on current devices, focusing on key qualities and areas for improvement. Your expertise in bipolar energy surgery would be invaluable to our research. This information will be assessed and reported to Maxima Biotech for future device development.*

*The interview, lasting 45 to 60 minutes, can be conducted in person or virtually, based on your preference. In-person interviews are preferred, in which case we are willing to travel to your location, if possible, but we can schedule a virtual meeting in cases where that is not feasible for the interviewee or the team. It will be a semi-structured dialogue, ensuring flexibility to discuss your insights thoroughly. Your participation is voluntary, and anonymity in our findings is optional.*

*If interested, please contact us and schedule directly here. We appreciate your consideration and are happy to address any questions or concerns.*

*Thank you for your time,*

*<Sender>*

*Team BPES gr-BPES-d24@wpi.edu*

The team set up a Calendly page to schedule appointments, providing surgeons with easy access to select times that suited them, while also enabling the team to block off unavailable times. The scheduling software provided surgeons the following information and questions to receive consent for interviewing practices:

Thank you for agreeing to be interviewed as a part of our project. This consent form is necessary for us to ensure that you understand the purpose of your involvement and that you agree to the conditions of your participation.

- A transcript of the interview will be produced.
- The transcript of the interview will be analyzed by the team (Team BPES).
- Access to the interview transcript will be limited to our team and our colleagues with whom we might collaborate as part of the research process.
- You may choose not to answer questions or stop the interview at any time.
- Do we have your permission to audio record this interview? (Y/N)
- Would you like to remain anonymous? (Y/N)
- Are you okay with quotes from this interview being used in our report? (If you have elected to remain anonymous, quotes will not be used.) (Y/N)

## *Surgeon Interview Questions*

For the interview itself, the team produced a set of questions as follows:

- **Demographics**:

D1. What is your job title?

D2. What is your age?

D3. How long have you worked in the medical/surgical field?

D4. How familiar are you with bipolar energy devices?

- **General:**

G1. What key qualities do you believe are essential in a surgical bipolar energy device?

G2. What brand of bipolar energy device do you use? What factors influenced that choice?

G3. How long did it take you to train to properly use a bipolar energy device? What did you find particularly difficult or easy about utilizing the device?

G4. What kinds of features would you like to see in bipolar energy devices that they do not already have?

G5. Of the bipolar energy systems you have encountered in your work, what features have you found particularly helpful or unhelpful?

- **Closing**:

C1. Is there anything else we should know that we have not covered?

C2. Do you have any other contacts willing to participate in this interview?

# Appendix C: Survey Questionnaire

## *Preferences on Surgical Devices: Disposable vs. Reusable*

**Our team:** We are a team of students from Worcester Polytechnic Institute in Worcester, Massachusetts, USA. As part of our study abroad project in Taiwan, we are developing a set of strategic goals and recommendations for a new surgical device. Our project aims to enhance the performance of existing devices as well as boost their acceptance by considering the social implications.

**Introduction:** This survey aims to gather insights into the public's preferences regarding disposable and reusable surgical devices. It should take no longer than 5-10 minutes. Your input will help the team understand the factors influencing preferences such as cost, safety, and environmental impact in choosing surgical devices. All responses will remain anonymous. You do not need any prior device knowledge. You may choose to skip any question you do not understand or are uncomfortable answering.

- Section 1: Demographics

  D1. Age:

  - ☐ 18-30
  - ☐ 31-45
  - ☐ 46-60
  - ☐ 61+

  D2. Country of Residence:

  - ☐ United States
  - ☐ Taiwan
  - ☐ Other: If so, then what country?

  D3A. Household Income (Approximate) [User selects US/Other Country of Residence]:

  - ☐ Under $20,000
  - ☐ $20,000-$40,000
  - ☐ $40,000-$60,000
  - ☐ $60,000-$80,000
  - ☐ $80,000-$100,000
  - ☐ $100,000-$120,000
  - ☐ Above $120,000

D3B. Household Income (Approximate) [User selects Taiwan Country of Residence]:

- ☐ Less than NT$300,000
- ☐ NT$300,000 - NT$600,000
- ☐ NT$600,000 - NT$900,000
- ☐ NT$900,000 - NT$1,200,000
- ☐ NT$1,200,000 - NT$1,500,000
- ☐ NT$1,500,000 - NT$2,000,000
- ☐ NT$2.000,000 - NT$3,000,000
- ☐ NT$3,000,000 - NT$4,500,000
- ☐ NT$4,500,000+

D4. Occupation:

- ☐ Undergraduate Student
- ☐ Graduate and Above Student
- ☐ Medical / Biomedical Engineer
- ☐ Other Engineering Discipline
- ☐ Doctor / Surgeon
- ☐ Lawyer
- ☐ Scientist
- ☐ Politics
- ☐ Education
- ☐ Humanities
- ☐ Social Work
- ☐ Unemployed
- ☐ Other. - If other, then what?

D5. Do you have private or government medical insurance?

- ☐ Private
- ☐ Government
- ☐ Both
- ☐ None

D6. Do you have any experience using minimally invasive surgery devices?

- ☐ Yes
- ☐ No

- **Section 2: Preferences and Perceptions**
  - Background Information:

    Minimally invasive surgery (MIS) involves performing surgical procedures through small incisions, utilizing tiny tubes, cameras, and instruments for the operation to avoid large open cuts (increasing safety). MIS devices are made from materials like plastic and metal. They can be disposable (single use, more environmental waste, more expensive, but lower chance of infection) or reusable (multi-use, less environmental waste, and less expensive, but higher chance of infection due to cleaning errors).

P1. If you were undergoing surgery and had the choice, would you tell your surgeon to operate with a disposable or reusable device (considering cost, safety, and environmental impact)?

- ☐ Disposable
- ☐ Reusable
- ☐ No Preference

P2. If you have ever undergone surgery, were you provided with information about your surgical procedure and the devices used to perform it?

- ☐ Yes, Procedure
- ☐ Yes, Devices
- ☐ Both
- ☐ Neither
- ☐ No Experience

P3. Drag each choice to rank the following priorities by how important you think they are from top to bottom (1 most important, 6 = least important):

- ☐ The cost of surgery
- ☐ Safety (Success rate, Postop complications, long term effects, etc.)
- ☐ The environmental impact of discarded surgical tools
- ☐ Using the latest technology (robotic surgery, 3D printing, etc.)
- ☐ Ethically sourcing the materials needed during surgery
- ☐ Other (Please Elaborate): [A free response box]

P4. If you were a patient choosing surgical devices, would you consider environmental factors?

- ☐ Yes, I would strongly prefer environmentally friendly options.
- ☐ Yes, I would prefer environmentally friendly options if possible.
- ☐ No, it makes little to no impact on my preference.

P5. In the future, would you like it if surgeons informed you about the environmental impacts of your medical treatment options?

- ☐ Yes
- ☐ No
- ☐ Maybe

P6. Would you be willing to pay more for surgeries that use environmentally friendly practices or materials?

- ☐ Yes
- ☐ No
- ☐ Maybe

C1: If you have any comments or questions about the nature of this survey, please include them here:

- [Open ended text box]

Thank you for participating in our survey!

Your feedback is valuable and will contribute significantly to our understanding of preferences and concerns related to surgical devices. Your responses have been recorded.

## *WPI 團隊 BPES 手術設備認知調查*

**我們的團隊：**我們是來自美國馬薩諸塞州伍斯特的伍斯特理工學院的學生團隊。作為我們在台灣的留學項目的一部分，我們正在為一款新的外科設備制定一套戰略目標和建議。我們的項目旨在通過考慮社會影響來提高現有設備的性能以及促進其接受度。

**介紹：**本調查旨在瞭解公眾對一次性和可重複使用外科設備的偏好。完成問卷大約需 5-10 分鐘。您的意見將有助於團隊了解影響偏好的因素，如成本、安全性和對環境的影響。所有回答將保持匿名。您無需具備任何先備的設備知識。您可以選擇跳過任何您不理解或不願回答的問題。

- 基本資訊:

D1. 年齡:

- ☐ 18-30 歲
- ☐ 31-45 歲
- ☐ 46-60 歲
- ☐ 61 歲以上

D2. 居住國家：

- ☐ 美國
- ☐ 臺灣
- ☐ 其他：如果是，請註明

D3A. 家庭收入（大約）[User Selects Taiwan]

- ☐ NT$30 萬以下
- ☐ NT$30 萬 - NT$60 萬
- ☐ NT$60 萬 - NT$90 萬
- ☐ NT$90 萬 - NT$120 萬

- ☐ NT$120 萬 - NT$150 萬
- ☐ NT$150 萬 - NT$200 萬
- ☐ NT$200 萬 - NT$300 萬
- ☐ NT$300 萬 - NT$450 萬
- ☐ NT$450 萬以上

D3B. 家庭收入（大約）[User selects US/Other Country of Residence]:

- ☐ $20,000 以下
- ☐ $20,000-$40,000
- ☐ $40,000-$60,000
- ☐ $60,000-$80,000
- ☐ $80,000-$100,000
- ☐ $100,000-$120,000
- ☐ $120,000 以上

D4:職業：

- ☐ 大學生
- ☐ 研究生及以上學歷
- ☐ 醫療/生物醫學工程師
- ☐ 其他工程類別
- ☐ 醫生/外科醫生
- ☐ 律師
- ☐ 科學家
- ☐ 政治
- ☐ 教育
- ☐ 人文學科
- ☐ 社會工作
- ☐ 失業

☐ 其他：如果是，請註明

D5. 您是否擁有私人或政府保險？

☐ 私人保險

☐ 政府保險

☐ 兩者皆有

☐ 都沒有

D6. 你是否有使用微創手術設備的經驗？

☐ 是

☐ 否

- 偏好和看法:

**背景資訊**：微創手術是透過小切口進行手術程序，利用微小的管道、攝影機和器械進行手術，以避免大型開刀（提高安全性）。微創手術設備通常由塑膠和金屬等材料製成。它們可以是一次性的（單次使用，產生較多環境廢物，成本較高，但感染機會較低）或可重複使用的（多次使用，產生較少環境廢物，成本較低，但由於清潔失誤而增加感染機會）。

| 一次性 | 可重複使用 |
|---|---|
| - 單次使用，感染風險較低 | - 多次使用，感染風險較高 |
| - 成本較高 | - 成本較低 |
| - 產生較多環境廢物 | - 產生較少環境廢物 |

P1. 如果您正在接受手術並且有選擇權，您會告訴您的外科醫生使用一次性還是可重複使用的設備（考慮成本、安全性和環境影響）？

☐ 一次性

☐ 可重複使用

☐ 無特別偏好

P2. 根據您的經驗，外科醫生是否有提供您相關手術程序及使用設備的資訊？

☐ 是，手術程序

☐ 是，設備

☐ 兩者皆有

☐ 兩者都沒有

☐ 沒有相關經驗

P3. 請將每個選擇拖曳，根據您認為的重要程度，將以下優先事項從頂部排到底部（1 最重要，6 最不重要）：

☐ 手術費用

☐ 安全性（成功率、手術後併發症、後遺症等）

☐ 廢棄醫療用品對環境的影響

☐ 是否使用最新技術（機器人手術、3D 列印等）

☐ 以合乎道德的方式購買手術所需的材料

☐ 其他（請詳述）：

P4. 如果您是一位選擇手術設備的患者，您是否會考慮環境影響因素？

☐ 是的，我會強烈偏好環保選擇。

☐ 是的，如果可能的話，我會偏好環保選擇。

☐ 不，這對我的偏好幾乎沒有影響。

P5. 在未來，您是否希望外科醫生告知您醫療治療方案的環境影響？

☐ 是

☐ 否

☐ 或許

P6. 您是否願意自掏腰包支付更多費用，以環境友善的方式或材料進行手術？

☐ 是

☐ 否

☐ 或許

C1: 如果您對本次調查的性質有任何意見或問題，請在此處提出：

感謝您參與我們的調查!

您的反饋對我們而言很寶貴, 將對我們了解對手術設備相關的偏好和顧慮做出重要貢獻。

# Appendix D: Dr. Liao Interview Transcript

[Xander]
So we just wanted to start with a few questions kind of covering your demographic. You said that you are a trauma and emergency surgeon. What is your age range?

[Dr. Liao]
My age range? I'm 46.

[Xander]
46, okay.

And what's your gender?

[Dr. Liao]
Male.

[Xander]
Male. And how long have you been working in the medical or the surgical field?

[Dr. Liao]
Around 20 years. Yeah, 20 years. Okay.

[Sam]
And just, yeah, just as a note, I don't think we ever did ask you for, like, permission to record or anything. But do you mind if we record this meeting?

[Dr. Liao]
Sure, of course.

[Sam]
...And take notes. Yeah, actually, I might set up an audio recording.

[Isha]
I just did.

[Sam]
Perfect.

[Xander]
So when looking at an advanced bipolar energy device, what are some qualities that you believe are essential in the device?

[Dr. Liao]
I think the safety is the most important. Yeah. And then [I'd] go with the efficiency. There needs to be very clear cutting and sealing of the vessel. In a very short time.

[Xander]
Yeah, the precision? So safety and precision. Could you elaborate a little more on the safety aspect?

[Dr. Liao]
Perhaps, like I said, once we finish every bite and every cutting, the machine should be safe on us while you're doing the work, right? [When] we release the bipolar [device]. I don't want to see any bloating or any mis-working happening.

So I think the well[ness] and the very safely seal of the vessels is very important.

[Xander]
Is there any specific issue that you run into?

[Dr. Liao]
Oh, yeah, sure. All the time. We- all the time. You want to use bipolar with cutting of vessels. In my routine, I will cut every vessel for twice. I will fire it for twice to prevent any unsealing. I've seen that process happen.- Brief pause as Dr. Liao takes a phone call -

[Xander]
And do you know what brand of device is used in your hospital?

[Dr. Liao]
Well, the most common one is a Medtronic. Medtronic.

[Xander]
And did you have, like, a say in it or was it just supplied by the hospital?

[Dr. Liao]
No. The very common in Taiwan is, Medtronic. Some hospitals use, Olympus, or, a similar one. I think it was a... very conventional bipolar device. Yes, it was a basic bipolar device.

[Xander]
Do you have, like, experience using different ones [devices] or do you only use them [Medtronic]?

[Dr. Liao]
Like I said, mostly, I use Medtronic. Because this is the only one chose in my hospital. When I work in a different hospital, I can approach different kinds of devices.

[Xander]
And how long did it take you to train properly to use the device?

[Dr. Liao]
15 minutes.

[Xander]
15 minutes? And did you find - well, I assume because [it took you] 15 minutes - you found it particularly easy to pick up and understand?

[Dr. Liao]
Yeah, very easy to understand.

[Sam]
Did you have previous experience using, like, basic bipolar...

[Dr. Liao]
Yes, sure.

[Sam]
...before you used that [device]?

[Dr. Liao]
Yeah, yeah.

[Xander]
What kind of features would you like to see in a bipolar energy device that you don't already see in the device?

[Dr. Liao]
Hmm, see in the device? I think it’s almost perfect, by current design. I think it's very simple, and- oh, there is another consideration. Once you use a device, I want to know all the necessities for the basic fiscal rule of the device. How do we give it the energy? How do we see the structure?

And I think bipolar devices are very, very straightforward. It's not like some fancy heating process. But I think bipolar devices are very straightforward and very simple.

I think it's another consideration for these new devices.

[Xander]
That it's simplistic?

[Dr. Liao]
Yes.

[Xander]
Are there any aspects of it that you would have removed? Or like you said, is it just a relatively perfect device?

[Dr. Liao]
I think harmonic scalpel is better than bipolar, right now.

[Sam]
Sorry, for ultrasonic?

[Dr. Liao]
Ultrasonic is better.

The new ones [harmonic scalpel] we use for some dissections, are for a very difficult process. But for the very common procedures I think bipolar is very... quicker, is better.

[Shaylie]
So is ultrasonic better for more complicated procedures? Whereas the bipolar is sort of quicker, and easier, for smaller...

[Dr. Liao]
Yeah. I use - once we have to do the dissection which is called - or something like liver surgery, appendix surgery. I use harmonic scalpel to do the complicated dissection. But in a very common world, where we don't need as much power, I think bipolar is better.

[Xander]
How do you think, if Maxima were to produce a new device and it were to be successful, how do you think it would affect the general social aspect of the hospital? Like having a new competitor added to the field?

[Dr. Liao]
Yeah. You mean from the hospital administrative side or from the procedure side?

[Xander]
Both.

[Dr. Liao]
Yeah, I think for them the confidence is very important. Once they improve the safety, the confidence improves. For the operators, I think they're happy to use some tools. So if you want to develop the device, it needs to not do too innovative or so different from current products. A little bit similar like that. And I think we can change from one variant to another variant. And for me, once they've improved safety and I can update to the new device, as long as the device stays as simply [simplistic] as possible.

[Sam]
So with the bipolar devices that you use, are they all wired? So they're all connected to a generator? So if I understand correctly, Maxima already developed a wireless ultrasound device. So do you think doing something similar, developing a wireless bipolar device, do you think that would be a useful innovation?

[Dr. Liao]
Yeah... I think wireless is an innovation. Not only in the procedure, but also in the inventory. But the weight of the battery or the power supply system is also another kind of innovation.

I have some follow-up on my research in this particular area. I hope that the weight of the bipolar can work with this. So we can start with that.

Currently, bipolar devices are very, very light. Although very simple, they're very light. I think it's a very important point.

If you want to innovate some kind of device. We should consider its weight.

[Xander]
From what we've researched so far, we've heard of bipolar energy devices that are disposable, and also some that are reusable. Do you have an opinion on which aspect is better to delve into?

[Dr. Liao]
I like disposable, right now. I can share my experience. Since maybe 15 years ago, bipolar was very expensive in Taiwan.

And we would reuse. So for each device, we would use maybe four to five times separately for different patients, to cut. But once we used it for certain times, a lot of devices become not so efficient. And there's simply a question of whether [it can be efficient enough]. But right now, I prefer to use disposable.

[Xander]
But if there was a means to reuse it more often while still keeping it effective, would that be something you'd be interested in?

[Dr. Liao]
Yeah, yeah. It's still has a market around it.

[Isha]
Adding on to the reusable aspect, do you explain to patients the difference between whether... Do you give them the option to use the... [disposable vs reusable]?

[Dr. Liao]
Yeah, yeah. In the past, we could not. We could not decide which was the first one, or three [third time use]. But right now, maybe 10 years ago, we had the option to tell this patient. But right now, we always use the new device, because of current safety regulations.

[Sam]
So, my understanding of bipolar devices is that they have a cut and a coagulate mode. Is that correct for advanced bipolar devices as well?

[Dr. Liao]
Yes.

[Sam]
Okay, so, how simple is it for a surgeon to get used to those two modes? Do you think that different metrics, like maybe a wattage metric, would be more useful?

[Dr. Liao]
Yeah, yeah. It's kind of a changing mode option. It's more close to an ultrasonic cutter. Like a harmonic [scalpel]. Because, in previous, the advantage of harmonic scalpel was that you could do the dissection at the same time.And I think... But, in my opinion, I think it's a way of selling. And it takes a very short time to get used to.

So, I don't think there's much more to say.

[Sam]
Right. But do you think that having a wattage mode might be also equally useful?

[Dr. Liao]
Yeah.

[Sam]
Do advanced bipolar devices have that now?

[Dr. Liao]
Hmm, I don't think so. It's very similar. The new device is very similar. It has a similar function like that. But I am not completely sure.

[Xander]
We actually had the opportunity to kind of hold and look at different bipolar devices. Something that I noticed was that the head, from where the cutter is to where the handle is, is a fixed mount. Do you think there's any marketability in being able to adjust that?

[Dr. Liao]
Yes, I think it has a market. If you can choose the shape of the handle.

[Xander]
I also saw that it's rotated via a cog closer to the hilt. Do you find that to be an effective way of maneuvering it? Or would you like a simpler or some other way of doing it?

[Dr. Liao]
It may take some time to maneuver it but I think it works.

[Sam]
Another thing that I noticed is that all of the surface for the electricity is flat. Do you think having a curved surface might be better to seal blood vessels shut, but not necessarily to enclose them off? To allow blood flow within the vessel?

[Dr. Liao]
Mhm, mhm. Yeah, I think it's worth. Might be worth.

[Sam]
What's the role of a surgeon in selecting bipolar devices in the hospital? So you mentioned that the hospital only gives you the option of using the Medtronic LigaSure device. Would you have... How relevant do you think your voice would be in the hospital selecting a new device if one was to come out?

[Dr. Liao]
In my hospital, every surgeon can announce this kind of process. So if I want to buy a new device and the company will survey if this kind of device works or not, if it's acceptable, how it's functioned, or if it's got people who want that, and how much it costs. But for a surgeon, we can decide which one we want to have. At least, we can in our hospital.

[Sam]
To sort of follow on that, have you ever had experience with the Johnson & Johnson ENSEAL device or the ConMed Edge device?

[Dr. Liao]
Yeah, I remember that. Maybe 10 years ago, ENSEAL had come to our hospital for trial, but it failed.

[Sam]
It failed?

[Dr. Liao]
Yeah, it's not so... As I said, it's not so simple to use, and the surgeon did not like that. He [the surgeon] knows when he's cutting, it goes from sealing, to sealing and cutting the tissue at the same time. Yeah, it's not... For me, it's not... I would now make sure it's sealed enough. And this is my habit. I like to fire twice. ENSEAL would not do that.

[Sam]
Really? So you fire it twice?

[Dr. Liao]
Yeah, and most of my colleagues fire it twice.

[Sam]
Have you ever had experience with the ConMed Edge device as well or no?

[Dr. Liao]
Hmm, ConMed, the conventional bipolar I have, but this is advanced bipolar, I do not have much experience.

[Xander]
It might be redundant to ask, but do you have a preferred favorite device? Like, not something the hospital provides, but something that you personally prefer?

[Dr. Liao]
Prefer what?

[Xander]
Do you have a specific advanced bipolar device that you prefer to use? Or is it...

[Dr. Liao]
Oh, yeah, I prefer... Yeah, the Medtronic one. It's very simple. In my procedure right now, I teach a lot of med students. And I have the collaboration. So simple is very important ... Okay. But the Medtronic one... It should be very easy. Yeah.

So it is... They say it's simpler.

[Sam]
So when you're teaching these students, the most important thing to you is simplicity. And I didn't quite catch the last thing that you said there. So you said that it wouldn't be able to complete all dissections? Did I mishear that?

[Dr. Liao]
Yeah. Very simple procedure that actually can be very clear.

Very clear. Right. Grab, fire, and cut.

Okay.

[Sam]
So the Medtronic device... I think I misheard what you said. Because what I thought you said was it would not be able to finish the operation. But it works perfectly, just, no matter what?

[Dr. Liao]
Yeah.

[Sam]
Okay.

[Dr. Liao]
There's a... Sometimes it's a reason to use my other instrument.

And... depends on the situation.

[Sam]
So when you're choosing whether to use the ultrasonic device or the bipolar device, what's sort of your number one reason to choose one over the other?

[Dr. Liao]
Okay. I think procedure is my... The quickest procedure is my procedure.

Now, there's a lot of Medtronic. And I just started using it. Or I want to teach our students how to use bipolar device.

Because it's very easy to use. And it's a very complicated operation. I always teach this one because the others are more complicated.

[Sam]
Right. So why exactly is that? So I hear it's complicated. Or more complicated to teach people. But is that because... What features of the harmonic scalpel make it so much more useful for complicated operations?

[Dr. Liao]
Oh, yeah. It's easier to do the execution. It's easier to do the execution.

And you know the scalpel always has something on it. There's a feature on that. And it's very powerful to do the execution.

I just used a 3D scaffold function called Mesentery. You know. Lysate is the peritoneum.

And lysate is the thread. And it's very easy to look at. It's very solid.

Yeah. This is my habit. To do the execution like that.

[Xander]
Okay.

[Sam]
Interesting. So in that case... So you said appendectomies as well. What other surgeries would you more reliably use a bipolar device for?

[Dr. Liao]
I think cholecystectomy and appendectomy is good.

[Sam]
So, appendectomy, cholecystectomy? Is that it? Or are there a lot of other common ones? Or just anything quick?

[Dr. Liao]
Yes quick. Yeah. Very quick.

And sometimes we use bipolar in bowel resection. In case of bowel resection, the anatomic structure of the bowel is very simple. We just cut the mesentery and resection the bowel.

So the basal group can be cut and sealed by the bowel quickly. And we don't need to do the dissection.

[Isha]
I had a question about coming back to the device itself. We were told that the device is made out of plastic and metal. If you were to go the disposable route, how would that affect the environment? Is that something you know?

[Dr. Liao]
Maybe it's not my duty to know that. It's a very good question. And I have no answer about it.

And everything is made as disposable as possible. And it's a very important instrument.

[Sam]
I suppose an interesting way to start that would be, how many bipolar devices do you use in, say, a month?

[Dr. Liao]
Maybe 12. Or, 15. Yeah.

[Brief omitted unrelated chatter]

[Sam]
I think that's actually a perfect opportunity to get into perhaps talking about expanding our set of interviews. Expanding your network. Exactly.

So, yeah, Dr. Tang has talked a lot about how many different surgeons he knows. I mean, we already spoke briefly about how you very often use bipolar devices in intestinal surgeries. So, appendectomies or cholecystectomies.

Other things in that sort of area at the bottom. So, would it be safe to assume that surgeons that specialize in those areas. If they exist.

If they do specialize in those areas. Would they be the most useful people to interview? So, let me think about it.

[Xander]
So, you would just like to get into contact with other surgeons that might have more experience. Yeah. With advanced bipolar devices.

So, we were wondering if you could. Sure.

[Dr. Liao]
So, I want to make sure. Do you want to find a surgeon like me or some guys from different fields or different departments. Do you want to find a general surgeon or an ENT or a general surgeon or something like that.

[Isha]
I'm just going to say, I think we're pretty flexible. As long as people have experience with the bipolar energy devices. We're willing to be flexible with exactly who we interview.

As long as they have experience with the devices. We ask them similar questions.

[Dr. Liao]
Okay.

[Sam]
Because I think that at the end of the day, we just want to understand what they think the device should have. And if they have any changes, what would they be?
Because our number one preference is the surgeon's choice. What do they prefer in the device?
Okay.

# Appendix E: Dr. Rooney Interview Transcript

[Xander]
So, we just want to open up with some quick demographic questions just so we can categorize. So what specifically is your job title.

[Dr. Rooney]
Well, currently, I'm retired, but I recently retired as medical director of the Daniel Webster Animal Hospital. I'm a veterinarian.

[Xander]
Right. Okay. And how old are you?

[Dr. Rooney]
63 as of a week ago.

[Xander]
Oh, happy belated birthday.

[Dr. Rooney]
Thank you.

[Xander]
And how long have you worked in the medical or surgical field?

[Dr. Rooney]
33 years? Actually longer than that was almost 40 years.

[Xander]
And how familiar would you say you are with bipolar energy devices?

[Dr. Rooney]
So, pretty, pretty familiar we have three of them. You know they've morphed over the years gotten smaller and more powerful. So we've used them for... ever since I started practice actually.

[Xander]
So with that in mind, what qualities do you believe are essential in a surgical bipolar device?

[Dr. Rooney]
Well, I think the small size and portability. I think a hand control - [in the past it] used to be that they were foot controls with just the, the scalpel blade type thing in your hand, but you'd have to do everything with your foot. And that was a pain so the new ones have the handheld controls on the same unit.

And those are key, you know, much easier to use. And I guess just enough power to cauterize, you know, a good size blood vessel is the other key to the, you know, so far as the power of the unit. Sometimes the controls can be a little touchy and too much power and you end up cooking the tissue you're trying to perform surgery on. So you do have to- There's some finesse with the controls. But it is important to have access to more power if you if you have a bloody surgery you need to be able to cauterize some of those vessels.

[Xander]
Right. So would you say like any... You mentioned how the, the devices in that have been developed have switched from foot control to hand control. Are there any other like ease of use, stuff like that or for surgeons that you would find essential for a device now?

[Dr. Rooney]
Well, yeah, sometimes the probe or the actual cutting, what do you call it, it's like a, they come with different kind of probes that you can put on so there's big ones wide ones, and very fine wire probes. And so the, you know, the finesse of the surgery has to do with how small a cutting wire you can use you know like if you're, if you're trying to do a very delicate surgery you don't want a big huge, you know, paddle that you're trying to cut through tissue with you want a very fine like a wire. So types of, you know, changes where you can change it in and out, you know, use a big, a big cutting surface if you're doing a huge surgery, or a very fine wire if you're doing something delicate.

That's important. And then having the, you know, the on off switch in your hand is, is much easier than doing it with your foot, I guess if that's what you're asking.

[Xander]
Do you know what brand of device that you use?

[Dr. Rooney]
So the oldest one was a Bard. We also had an Elman. And then they got a new one since then.

Sam took a picture of it. I can't remember the name of it actually. It's there so.

[Xander]
Oh, hey Sam.

[Sam]
Yeah, I'll take a quick look. Hello dad. Sorry I wasn't - I'm not, I'm not one of the interviewers, but I meant to introduce you, my bad. Yeah, keep going, I'll find this picture.

[Xander]
We'll cover that with Sam later. So, were there any, like, did you have any influence over the choice of device or was it more or less provided by the administrators?

[Dr. Rooney]

Well, since I own the practice yes, we bought our own equipment.

[Xander]
So, this might line up a little more with question one and two, that I asked, but what factors did you consider when picking a device to use for your practice?

[Dr. Rooney]
Well, the first the first factor is, does it do the job and is it easy to use. Second would be probably size, you know, because some of the units, the old ones are huge. And then third would be price.

Fourth would probably be, you know, the company and is it someplace you can get repairs done, you know, things like that if something goes wrong, warranties, things like that.

[Xander]
Did sustainability ever play a factor in your decision?

[Dr. Rooney]
Not really. What kind of sustainability are we talking?

[Xander]
Reusability of devices and like environmental impact. That's just an aspect we're overviewing in this so we just wanted to understand.

[Dr. Rooney]
So our units, the newest unit did come with its -each, you know, individually packed like a plug with the handheld surgery device. But in veterinary medicine, what we would do sometimes is reuse that unit on non sterile surgeries, like if we're doing dental work or something. We'd obviously clean the cutting surface, but We didn't necessarily throw every one of those away.

We did throw you know some away because they get damaged or after a couple uses, they get pretty gummed up. But, we would frequently reuse each of those quote "disposable" handheld surgery units. More than once, you know, so I feel like we did get our use out of them, but no, we didn't specifically make a decision on whether to buy the unit based on that.

[Xander]
Right. And how long would you say it took you to train properly with every new device that you kind of- had to become familiar with?

[Dr. Rooney]
About a half hour.

[Xander]
What did you find particularly difficult and easy about utilizing the device?

[Dr. Rooney]

Well, they're- They're great because they cut and cauterize at the same time. So a lot of times you have a more blood free surgical field. They... especially in use the real fine wires, you can get into a really tight spot like between a tooth. Like if you have a tumor or a gum problem between teeth. You can actually get in between the tooth and and address that without like with a scalpel blade. You can't really do that.

And then, like I said, the the cautery is great because when you use the scalpel blade everything bleeds like crazy. And with this unit or these units when you cut a lot of times there's not much blood at all, or if any. So I feel like it was faster.

I will say that the disadvantage would be that -especially if your power is a little high - when you if you were trying to bring surgical edges together, and your power was too high when you cut ,those edges would be charred and wouldn't heal as well. So they tend to, you know, heal slower than if you use the scalpel blade.

[Xander]
So what kind of features, would you like to, would you like to see in a bipolar energy device that you don't already see very often in them?

[Dr. Rooney]
Hmm, that's a good question. Maybe a fan? Because when you're doing surgery with electricity you, you produce smoke. So that can be a problem, you know, so if they had some sort of a vent or a fan to suck off the smoke. That would be nice. Beyond that interchangeable tips, you know, so you can like if you find you're in the middle of a surgery and you need a finer tip, you can just, you know, pull out another sterile tip, put it on and use that. So interchangeable tips are great.

Other than that, small size is important because You know, you're, you're wheeling the thing in and out of different rooms and stuff. So, you know, I feel like the smaller the unit is the easier it is to handle. Other than that, I can't think of too many things that are missing.

[Xander]
Well, from our experience with looking at them so far, we've noticed that all the the neck lengths are fixed. Would you say like, a changeable [length] extension would be something you'd be interested in?

[Dr. Rooney]
Like what, what do you mean by the neck? Like from the...?

[Xander]
From the handle to the tip. The- I'm not entirely sure how to describe it other than neck. Shaft of the device. Would you be...?

[Dr. Rooney]

I guess I'd never found that to be a problem. You know, it's always like, you know, sort of like a pencil. And it's- no, it's usually they're about the same size. And that's about the same size as a scalpel blades. You're kind of used to that size. So no, I haven't found that to be a big issue.

[Xander]
Of the bipolar energy systems that you've encountered in your work. What features have you found particularly helpful or unhelpful?

[Dr. Rooney]
So in the older ones, they had- they had settings where you just ablate, a mass like just burn it off. And we never really use those. So that's probably unhelpful.

The newer units. I found that the handheld control is is much better. The replaceable tips much better.

Yeah, I mean just the things we talked about. I think the size of the unit, the ability to vary the power as you need it. I will say the older units had a lot more, you know, choices as far as going up and down and power. And that was usually a bad thing because you can never find the right setting. The newer ones tend to be more simple. It's kind of like one dial and you just turn it and if it's cutting well and not burning tissue, you're good. And if you know otherwise you can turn it up or down a little bit. So it's much more simple. But I think that's about all I got for that.

[Xander]
Just for brevity sake, if you could rank kind of features in a device based off, I guess, your own priority. How would you rank them?

[Dr. Rooney]
Handheld controls. Number one. Multiple tips at number two. Small portable device number three. And, you know, obviously the cost of the unit, the warranty, all that stuff is important, but not - It doesn't have anything to do with the actual use of the unit.

[Xander]
Is there anything like older devices that you kind of wish would come back? If that makes sense?

[Dr. Rooney]
Yeah. No, I think the new ones are better. I think the old one... I don't even know why we never threw it out, but we still had it sitting there, but it was really difficult to use. I had it just to scare the new doctors coming in, you know, say, look at this thing.

[Xander]
You have to train them with the old one and they'd be like, okay, you're good enough.

[Dr. Rooney]
Exactly. And then you're coming in and use the new one. They're like, what, what are you doing?

[Xander]
How are we doing this the whole time?

Have you had to train a lot of new people with bipolar energy devices?

[Dr. Rooney]
Yep. Because usually they have not used them coming out of school.

[Xander]
I guess I mentioned how easy is it to pick up a new device, how easy it to kind of teach a new person how to use the device.

[Dr. Rooney]
They're pretty easy. Yeah, it just, I mean, basically, if you schedule surgery, by the time you're done the surgery, you've trained yourself on how to use it, you know, because it's, it's pretty intuitive.

[Xander]
All right. Well, that covers most of actually all of the general questions I had. I mean, Sam, while we're here, do you have any questions regarding the device?

[Sam]
Yeah, actually, there's one that stuck out to me while we were talking, and I don't know why I didn't think of this when, you know, I went to Daniel Webster with you, Dad, but actually let me turn my camera on real fast. But the question is, like, for the bipolar energy devices that you've used, so you Kevin, how useful do you think a device would be that automatically, like stopped inputting power, so that you still get the coagulation that you want to get the sealing that you want, but you don't get the charring.

[Dr. Rooney]
Yeah, that would be great. The only problem is that blood vessels are different sizes. So you, you know, if you're, if you're cutting through skin and you're just using, you know, the setting for capillary bleed.

That's great. But if you happen to hit a vein or an artery that's big that settings not going to cauterize that you need to turn it up so that you can set up. So I don't know how that automatically would happen.

You know, because it's a, that's where you turn it up, you zap the vessel. And if it still doesn't work, you ligate it by hand and then you go back to the cutting setting, you know, so you're not burning the tissue, but I guess it'd be awesome to have. I'm just not sure how it would work because there is a lot of variation in the vessel sizes.

[Sam]
Yeah.

[Dr. Rooney]
And some tumors are very, very well vascularized. So, you know, you get in there and they got these huge vessels and you're like, Oh my God, you know, so you really need to crank the power.

[Sam]
What would you say the biggest blood vessel that you have to deal with on a regular basis is like seven millimeters? Is it bigger? Is it smaller?

[Dr. Rooney]
Probably smaller. Seven's pretty big.

[Sam]
It's a, it's a little funny that I'm talking about this just because so our project is specifically about advanced bipolar and the entire purpose of advanced bipolar is to do exactly what I was saying, which is you automatically sort of modulate the amount of power you're putting in. So it's, it's interesting to sort of see the justification come out of the interview.

[Dr. Rooney]
Yeah. I mean, it would be, if it could, like, if you, if you could have that adjustment on your handheld device, that would be great. If it did it automatically, I guess it would be great.

I'm just, I'm sort of skeptical that it would actually work because, you know, there's so much variation in the amount of blood that one cut will produce. So for that, that thing to be able to sense that and then, you know, fix it would be probably more than I would expect. But if you could adjust the power, because that does, those, those units don't have that currently, they just have a on off switch, you know, so, you know, on your cutting, and then you just lift up your thumb and it's off.

It doesn't go like hotter or colder, you know?

[Sam]
Yeah, I think that's all for me. All right.

[Xander]
All right, just to cover a few [closing questions]. Is there, is there anything you think that we should know that we didn't? Like bipolar energy, kind of the surgical process with it?

[Dr. Rooney]
Well, the newest, my understanding, the newest technology is the like a radio wave technology. So, there was a time when they were saying bipolar might be sort of obsolete. And they're using more, you know, radio waves of vibrating surgical tips instead of hot surgical tips.

But then they didn't go away. So, I think I gather that the radio wave technology didn't really pan out as well as they thought. I think, at least in our business, price was always important.

Has to be a reasonable competitive price. Because we had to justify its use, you know, maybe less so in a human medical, you know, scenario where they can, they use more expensive equipment anyway. But, you know, the packet with the plug and the handheld surgical device, times when we couldn't get them forever or whatever, and we just couldn't get the, couldn't get the units delivered. So, supply, of course, is very important. Can't think of too much else. Okay.

[Xander]
And do you have any other contacts you could put us, I was going to say into contact. Do you have any other doctors you could put us into contact with that would be willing to participate in this interview?

[Dr. Rooney]
Probably, yeah. If you, you know, I know mainly veterinarians. I don't know physicians so much.

[Xander]
Just what we're looking for is experience with bipolar energy devices. Yeah.

[Dr. Rooney]
I mean, all the people in my practice use them. So, they'd be happy probably to talk to you about, you know, the same units, we're all using the same stuff.

[Xander]
Great. Well, we can probably have Sam grab that info from you later.

[Dr. Rooney]
Yeah. I would think any dermatology practice, human dermatology, they probably use those too. Okay.

I just don't know them personally, you know, to ask them.

[Xander]
Might be something we consider when looking for more people to interview. Yeah. That's all the questions I have for you.

Thank you so much for meeting with us.

[Dr. Rooney]
Yeah. Good luck with the project.

# Appendix F: Dr. Liu Interview Transcript

[Sam]
So I don't know how much of our project you are aware of just yet, but we came up with a presentation. Just a brief one, like three slides, just to tell you about our school and our project. So Isha and I, we both go to the Worcester Polytechnic Institute. That is a engineering college in Massachusetts, right by Boston. So this is a picture of our campus.

[Dr. Tang]
Do you need to connect to the television?

[Dr. Liu]
I don't think so.

[Sam]
This is just a brief introduction to our school and our project.

[Dr. Tang]
Because it is Android, you can project it.

[Sam]
It's iPad. I wish. So we are here in Taiwan working with Maxima on what is called an interactive qualifying project. This is a project that our school puts us on. We come to different countries around the world. This is actually a map of all the different places that WPI sends students. And it's groups of four, and we work with different organizations. So there's actually 24 of us here in Taiwan. There's four of us that are working with Dr. Tang and Maxima. There's a group of us that are working with 东吴大学 [Soochow University]. There's a few other groups of us working with different organizations around, especially Taipei, but also Taichung. So us specifically, we are here working with Dr. Tang, and we are here helping him develop the new bipolar energy device that his company is interested in creating. So we're here to speak with you and understand more about your perspective on bipolar energy devices, in the hopes of helping Dr. Tang and also understanding more about how we can help people in the medical device industry. That's that presentation.

[Dr. Liu]
So what is the WPI program?

[Sam]
So it's called an Interactive Qualified Project. So it's the nearest thing we have to a study abroad program.

So we are in our third year of college, of university. And so we come here, and we work with local businesses. And we look at both engineering problems and social problems.

So in our case, we're looking at how does Maxima's development of a new bipolar device, how does that help people exactly?

[Dr. Liu]
So you only develop the bipolar system?

[Sam]
So we're not doing the engineering.

What we're doing with Maxima is we're coming up with recommendations by interacting with surgeons such as yourself, as well as surveying regular people.

[Isha]
I think our goal is to understand what different features or new features advanced bipolar devices should have. As we already know that there are certain devices already in the market, and we would like to understand the surgeon's aspect into that, basically.

[Dr. Liu]
Well, as I know, now have a lot of energy device, like a harmonic and the Ligasure. Ligasure is one kind of bipolar with the cutting, scissor, the function. So I want to know which kind of bipolar. Just the bipolar forceps or the...?

[Sam]
So we are interested in advanced bipolar in general, which is usually the bipolar forceps. But we've also seen a couple of other designs. But I believe we're most interested in bipolar forceps.

Is that correct? Yes.

[Dr. Tang]
Let me explain from Maxima's point of view. Actually, we're focusing in energy device sector. So energy device, you have monopolar, bipolar, ultrasonic, plasma, and other lasers.

So our first product is ultrasonic. But we think we need to have another product line. And this is our second line.

We think bipolar has the biggest market share in the energy sector. And then, because also we need to find a strategy to enter the market, because we are newcomers in the market. So we ask the IQP team to help us to identify, to explore the opportunities, the competitiveness, the social needs, and also the needs from the users.

What are the requirements, must-haves? And what are the features that we can add on top of it? So eventually, for Maxima, we want to have a roadmap of the development.

It's not only one product, but a series of products that is adding on top of each other to extend the capability of surgeons, and also to capture the market by adding the innovations. So that is the basic requirement for this project. But now we are in the very beginning turn, is to know the basics of this energy, the usage, the market situations, and how you face, how you use it, how you learn it, and how you compare the other different devices.

What is your direct feedback? Because normally, for surgeons, we don't have time to know the history, the theory of the device. We take it, and we use it, and finish it.

We throw it away. But for companies like us, we have to build a research team. We have to build these.

We have to hire engineers. And we have to know all the fundamentals to make our capacities to be able to supply a good product. That is the background of this project.

[Sam]
Yes. So to that end, we have a couple of questions to ask you. Dr. Tang put our goals very succinctly. Really appreciate that. But yeah, so our first question is, in your hospital, in your practice, what brand of bipolar energy devices do you use? And do you know why you use them?

[Dr. Liu]
For the bipolar, I want to ask, in the Medtronic LigaSure, does it belong to the bipolar energy or not?

[Sam]
Yes, it absolutely does.

[Dr. Liu]
It belongs to the bipolar, right? So now we have two bipolar systems, Medtronic LigaSure. Another is the B. Braun.

[Sam]
Braun?

[Dr. Liu]
B. Braun, yes, B. Braun. I forgot the name. But also the bipolar system, very similar to the Medtronic one, but it can, it has an angle. It can turn. In the Medtronic, it's only the straight form. But in the B. Braun system, you can have an angle. You can turn a little like this. So now only these two, these two products.

[Sam]
And do you know why you use them? So was it a choice by the surgeons? Was it a choice that was between the surgeons and the administration?

[Dr. Liu]
Mostly if like a very simple procedure, like we just want to ligation the, because we have the two systems. One is a harmonic. One is the bipolar system, like a LigaSure. Why we choose these two? If we favor the more, like get the vessel, we will try use the LigaSure. If you want to do more detail, more precise dissection, we will use the harmonic. Because I think it's a little

different, because the bipolar, it needs two joints together. Then it can also correct the vessel. At this time, the tip is more big, because you must have two joints.

So this time when you do the dissection, they will have more, not so delicate. If you only use the harmonic, because the tip is like a vibration. So you also can use like a monopolar system.

You can coagulation. You can vibration a little to make a tunnel to go through the tissue. Then after you turn, make a tunnel to go through the tissue, then you close.

Then you can ligation. So it's different. Like a bipolar system, they don't have this function.

You must be, like if this is a tissue, you must be close to the tissue. Then you can make the coagulation. But sometimes, like a very big tissue, then the harmonic can vibration, make a tunnel, then coagulation, ligation. So for the harmonic you can do more precise dissection. But for the licorice shoot, if we just very, very powerful ligation in the vessel, then we will try to use the LigaSure.

[Sam]
That's interesting.

[Isha]
Just before we continue, what exactly is your job title?

[Dr. Liu]
I belong to a surgeon. Belong to the up GI surgeon.

[Sam]
So GI surgeon?

[Dr. Liu]
Yeah, GI surgeon. So in general, we do the stomach, periatric, liver, pancreas, just belong to the upper.

[Sam]
Absolutely.

[Isha]
And if you don't mind me asking, your age?

[Dr. Liu]
49.

[Isha]
You don't look that old. And how long have you been working in the medical or the surgical field?

[Dr. Liu]
Maybe 20 years.

[Sam]
Actually, this is just me being curious. How long did it take you to get through medical school?

[Dr. Liu]
Seven.

[Sam]
Seven years?

[Dr. Liu]
Seven years, including to the hospital. We have two years in hospital for observe, then one year like an internship. You can do some assistant work.

[Isha]
How long was it in the US?

[Sam]
It's a very long time. It's like four years of pre-medical, and then at least six years of regular medical school after that. It's a very long time to get educated as a surgeon in the States.

[Isha]
In India, it's only four.

[Dr. Liu]
Four?

[Isha]
Only four.

[Dr. Liu]
Including the hospital?

[Isha]
In those four years itself, yeah. Because you don't do undergrad. That is your undergrad, everything. It's very easy to do medical school in India.

[Sam]
Back to the interview, though. Have you encountered any difficulties using particularly the Medtronic and Braun devices? Like, have you encountered any pain points? Not to do with malfunctioning, but just difficulties that you experience with the design of the device.

[Dr. Liu]
You mean the design, or I use the instrument?

[Sam]
So when you use it, is there anything that you wish it could do that it doesn't?

[Dr. Liu]
If you do the liver, right? If I do the liver resection, they have some. It's not something you can cut. It's like you're cutting the edge, right? So in the surface, maybe they were oozing or something. At this time, use the bipolar. You cannot make the vessel coagulation, because you don't close. Like this. So the function is not so well. So at this time, we will change to another bipolar forceps. Bipolar forceps, the major work is make a coagulation. So this is the liver surface. This is the breathing. So we use a bipolar forceps. Then we close like this, and touch, and make a coagulation like this. So in the B. Braun and Medtronic system, you cannot have this function.

[Sam]
So it's difficult to coagulate on the surface of an organ.

[Dr. Liu]
On the surface, yeah. You only can cut. When you cover the tissue, you can coagulate. But if you cannot cover, close the tissue, you cannot coagulate. Maybe it's the disadvantage around this part.

[Sam]
So you mentioned that you switched to a different bipolar device in order to coagulate at the surface of an organ. What devices would you use for that?

[Dr. Liu]
Mostly, it's just the normal bipolar forceps.

[Sam]
So like basic bipolar?

[Dr. Liu]
Yeah, yeah, basic bipolar forceps.

[Sam]
OK. Interesting. The next question, I believe, is how long did it take you to train to use the bipolar energy device, Medtronic, or the Braun device, or any others?

[Dr. Liu]
Normally, not so much time.

[Sam]
Not very long?

[Dr. Liu]
Not. Maybe just we try one time, two time, we can use. Because we have the best technology. We can use the whole- we can use the forceps. So the design is very similar to this kind of instrument. So it's not so difficult to use. We just know how to use. Then we know how to use.

[Sam]
Right.

[Dr. Liu]
Yeah.

[Sam]
And would you say that it takes longer to like, so besides just using it, would you say that it takes longer to gain expertise with it? As time goes on, have you experienced that you make fewer, like, let me try to phrase this in a way that won't get WPI angry with me. Have you experienced that it's easier to do exactly what you want to do as you continue to practice with the devices?

[Dr. Liu]
You mean, if I feel it's very easy to do it, then I will continue this device. You mean this thing?

[Isha]
I think what he means is that, like, as time progresses and you use the same instrument, do you get any, like, better? Or are there still some things that can possibly go wrong or something like that?

[Sam]
Does it get easier with time?

[Isha]
In the usage of the device.

[Dr. Liu]
Yeah. If you mean the time, the coagulation vessel, because in the Medtronic system and the B. Braun system, a little different is the coagulation. In the B. Braun system, you need more time to coagulate. But in the Medtronic, it's a short time. So you can save the time. Every time we want to close the vessel, we should wait maybe three seconds, four seconds. If you can shorten the time, the surgeon likes to use.

[Sam]
And did you say that it takes longer to get used to the Braun system than it takes to get used to the LigaSure?

[Dr. Liu]
Yeah, B. Braun, yeah.

[Sam]
That's very interesting. And so what effect does, like, the administration of your hospital have on the choice of devices that you use?

[Dr. Liu]
Just B. Braun? You mean why I choose?

[Sam]
Yeah, why did you choose them originally?

[Dr. Liu]
Originally?

[Isha]
Basically, I think his question is to ask, is that in the hospital, when deciding which devices to look at, who's involved in that process? Are you involved in it?

[Dr. Liu]
No.

Mostly, it's the company. We have the new product. Then the hospital, we introduce the hospital to want to make the surgeon use this instrument.

Then the hospital will ask the surgeon try to use the instrument maybe one time, two times, then give some feedback. If a surgeon like this product, then the company can sell to the hospital. Then if a surgeon want to use, then we use one.

Then they charge one. You pay one like this. This is the normal procedure.

So normally, there are two ways. Like the company want to introduce. Or another, like a surgeon, we go to the foreign country to see the surgeon, and to find some instrument is very good.

So we ask the company to introduce to my hospital. So this is the second. But the hospital, we are not spontaneous to introduce.

It's just like not a primary request.

[Sam]
So the companies have to go to the hospital.

[Dr. Liu]
Companies should introduce to hospital.

[Sam]
That's interesting. So I'm curious.

Dr. Tang, of course, has already developed his ultrasonic device. Has that been introduced to you at your hospital?

[Dr. Liu]
I tried one in the conference. They tried to sell to my hospital. But now, the contract is still ongoing. It's still negotiating the price. So we still not use in my hospital. But we heard about his device.

This is the wireless, and it's very similar to the Medtronic one. Metronic also have the wireless, the harmonic.

[Sam]
Yeah, the ultrasonic.

[Dr. Liu]
Yeah, ultrasonic.

[Sam]
That's very interesting. I know there's one more question I'm forgetting. Do you happen to have the list with you Isha?

[Isha]
Yeah, so it's like, what kind of features would you like to see in bipolar energy devices that aren't already there in the market?

[Dr. Liu]
Say that one again.

[Isha]
So it's like, what features are not there in the current devices, the bipolar devices in the market itself?

[Dr. Liu]
You mean from my perspective?

[Isha]
From your perspective.

[Dr. Liu]
Maybe you can create the bipolar is very delicate. I think it has the market. Because we got the gastric cancer, you need a very delicate dissection. But for the bariatric, it's not so much delicate. You can use the LigaSure. But if you want to replace the ultrasonic device, you must do a very delicate jaw. If your jaw is more delicate, more small, then you can also have the ligation power. Then you can replace the ultrasonic one.

[Isha]

So in terms of delicate, I'm assuming you meant small and easy, small jaw.

[Dr. Liu]
Small jaw. And the tip is a small one. Because previous, the round shape is very like this. Then second, I mean in the LigaSure. Previous is like a very round tip to correct it. Now they have the more flat or more curved one. But it's still very not so delicate.

So if you can create a more delicate one, then you have a market. But for my knowledge, maybe more delicate, the ligation power will decrease. So maybe the engineer view, if you can make a more ligation power, then also have a delicate jaw. I think you can replace the ultrasonic.

[Sam]
And just going back to what you said earlier, I know you also mentioned that you had some difficulties doing bipolar coagulation on the surface of an organ. So would you also like to see that?

[Dr. Liu]
Yeah. So you have also had this problem. Because now, for the basic bipolar, it's like this kind that you close. You close, then you can coagulate.

Maybe if you have a bipolar in the posterior, have some like a metal, like if you have jaw, mostly you close the ligation. If we here have some metal part, you can like this, then you can coagulate.

[Sam]
Oh, coagulate right on the edge.

[Dr. Liu]
Right on the edge, yeah.

[Isha]
And so rather than just having them in between, you have them on the edge as well.

[Dr. Liu]
Yeah, in the edge.

You can have the two functions. One is in the center, then you can do the ligation. Second, you have a little metal here, then you can do a service ligation.

Then we don't need to change the instrument. Then they will have a benefit.

[Sam]
And you also mentioned the Braun device. I apologize, I didn't see that device before, so I don't know exactly what it looks like. But you said that it curves to the side.

Do you mean that it has a hinge, or that it's built with like a curve?

[Dr. Liu]
No, it's the straight one, but it can turn. In the original, it's a straight one. But in the hand of the instrument, if you switch some button, then they can switch that.

[Sam]
Yeah, it has like a wrist.

[Isha]
It has the ability to turn.

[Dr. Liu]
Yeah, you can have a jaw. You have a jaw, so you can turn around. So sometimes, it's a benefit. But in B. Braun system, it's not so good to use, because you have to switch. Like if I do, I have something I want to make a curve, right?

One hand, I will close. I will hold in this material. But one hand, I will do like this.

At this time, if I want to turn, you must have another hand to push. At this time, I always have some people to just say, please turn a little, like this. So it's not so convenient.

[Sam]
Oh, like multiple hands on the one device.

[Dr. Liu]
Yeah.

[Isha]
Indicating that, while you're working with one hand, and you are using the device with the other hand, there are multiple functions to be able to move it around. You need other people to be involved in the process.

[Dr. Liu]
Yeah, so if you have something, like a second finger, when you close, then I can turn by myself. One hand is closed, then one hand is turned.

Then one finger is like action. One hand is turned, then maybe I can do by myself. No need for other people to help.

[Sam]
Yeah, I like that. So would it be most convenient for you to only need to use one hand to do all these functions? Or would two hands still be an option?

Or do you need your second hand to do something else?

[Dr. Liu]

I always need a second hand. Because when we do something, we must have two hands. So we're holding, we close.

So I must use another hand to lift the tissue, then coagulation.

[Sam]
And going back again to, what was it that I had something in my mind? I'm going to think of it in just a second. Isha are there any more questions on there?

[Isha]
We covered most of them. So you've already addressed the features that you found helpful and useful. Are there any that are unhelpful in the devices you currently are working? Like you explained that the bipolar devices, the jaw is too big. And it's not very useful. Are there any other particular features other than that that you think could be changed?

[Dr. Liu]
Hmm... No, no special. No, yes.

[Isha]
OK, no problem.

[Dr. Liu]
Also, did you have a call?

[Sam]
Oh, he's got a call. - Brief pause for Dr. Liu's phone call -

[Dr. Liu]
OK, go ahead.

[Sam]
So this isn't the question that I had in my head a second ago. But this is still a really useful question.

Do you ever consider the environmental sustainability of the devices that you use in hospitals? So a lot of these devices that are used for especially human surgery are single use. Are you ever concerned about the waste that's generated from surgery?

[Dr. Liu]
You mean single use and what?

[Sam]
So when things are disposable and you throw them out after a surgery, are you ever concerned about the amount of waste that's generated?

[Dr. Liu]

Yeah. Mostly it's that waste. Now, most instruments are single use.

But it's wasting the natural resource. So if you can create something, just change the tip. Like the handle.

Because if you don't touch the human, then there's no disease, contamination.

[Sam]
Right.

[Dr. Liu]
So mostly the contamination is the tip, the tip and the jaw.

So if you can use a handle with a switch, you can something connect to. This one is disposable. Another one can be useful.

Then you can save the source, then decrease the charge.

[Sam]
That's interesting. Yeah, so you're mentioning that if you replace the tip, that's another interesting option. But would you be particularly against a totally reusable device?

[Dr. Liu]
Totally reusable?

[Sam]
Yeah. Perhaps thrown in an autoclave between surgeries with maybe some other factors.

[Dr. Liu]
If totally reusable, the company cannot earn the money.

[Sam]
True enough, true enough.

[Dr. Liu]
So but if for like a scissor, for my knowledge, if you want to use the disposable, because there's something you cannot very dedicate to make a set tip.

Some jaw inside, you cannot clean. So it must be disposable, single use. But if you always have reuse, you cannot make a very complicated design.

You only can have the one metal, then energy generation, like our basic one. Basic one is just the very simple one. You have just the metal, then metal and process, and energy generation, then you can reuse.

But if you're so too much dedicated, like a chip inside, you can control the temperature or something. I think it's very difficult to make a very effective. So that is the problem.

You must be single use.

[Isha]
Yeah, so just going on to the environmental aspect of the platform, we know that for cost manufacturing, that disposable devices are better for the company. But from online research that we did, we found that disposable devices are more expensive for patients. Do you give your patients the choice to choose from them? I know that here in Taiwan, it is assumed that everyone already has an insurance plan that covers it. And after, I'm assuming that there's an option for people who have private insurance to get more options. Is there the option for them to choose whether they would prefer a reusable or disposable device?
[Dr. Liu]
Yeah, yeah, I think the problem is some people are not so rich. So in my hospital, we also have no insurance people. And so he cannot get the benefit for the minimally invasive, because everything needs the money. So we always want to use the reused one. So if we cannot use the LigaSure, like appendicitis, now it's always minimally invasive. But sometimes you must be ligation the vessel.

So at this time, we will use the basic one, the monopolar system to ligation the vessel and cut, use the scissor to cut. But if it's rich or you have a lot of insurance, we can use the LigaSure. It's very simple.
You can save the time. So always need another choice. I think the reused one still need to develop.

If it's a very complicated device, you can think about maybe decrease the cost, just change some part, like maybe the tip part. I think you still have the market.

[Isha]
Just from what I've read online, do most people prefer disposable devices over reusable ones?

[Dr. Liu]
Yeah, because it's more clean.

[Isha]
More clean, more sterile.

[Dr. Liu]
If you have to get it, I want to use the first one. No people want to use the reused one. This is the problem, but it must be considered about the economic, people's economic.

[Isha]
I wanted to know more about that.

[Sam]

So you've also mentioned a few times that you use primarily forceps-based bipolar devices, so even, I mean, Medtronic LigaSure, as well as the B. Braun device, and even the basic bipolar devices that you use have forceps. Have you ever used non-forceps bipolar devices in your practice?

[Dr. Liu]
Non-forceps bipolar?

[Sam]
Yeah, so.

[Dr. Liu]
What do you mean by non-forceps bipolar?

[Sam]
There's an example that I might connect to the Wi-Fi just to bring up a picture or something.

So basically, there's a stick with multiple different electrodes across, like, around the tip of the stick. And so this is, it's a bipolar device that's, it just looks like a finger. And the tip of it will generate a field around the full circumference of the tip.

[Dr. Liu]
No, I don't, I don't know this instrument. This also can call a bipolar?

[Sam]
Interestingly enough, yeah.
[Dr. Liu]
For my, for my knowledge, the bipolar must be have the two joints.

[Sam]
This is a fairly unique device that I found from a company called ConMed, but there's also other bipolar devices that have, like, there's, my father's a veterinarian. He does surgery on animals. And he's used a device, a fairly old device, actually, I think, manufactured in the early 2000s.

And it only has two electrodes, but one of the electrodes is a ball on the end, and then the other electrode is just behind it, like, on the stick of it. And so he uses that a lot. It almost acts like a monopolar device, but it's a bipolar device, so you don't have to attach, like, an adhesive electrode to the outside of the patient.

So he uses that for a lot of similar things in his practice. He also has to do a lot of just getting rid of masses and just trying to essentially burn them away, so.

[Dr. Liu]
But I don't have this experience for this one.

[Sam]

It's an interesting, different design of a device, but yeah, I was just trying to figure out if you used it.

[Isha]
I think most technological advancements read in interviews, you found that most bipolar devices are through two electrodes in the forceps arms, and then advanced bipolar just has the closed-loop function, mainly that.

[Sam]
But there are a couple different ones, which are interesting, but yeah. They seem a lot less common.

[Isha]
Adding on to that, do you potentially see Taiwan having a market for that?

[Dr. Liu]
You mean this one?

[Isha]
The one that he was talking about.

[Sam]
The alternative.

[Isha]
But sometime in the future, maybe.

[Dr. Liu]
But I mean, I never see this kind, so I cannot say.

[Sam]
The one that I am familiar with is manufactured by a company called ConMed, which is C-O-N-M-E-D. It's an interesting one, but yeah, definitely not very common. Do you have any more questions? Because I'm trying to think of the one that I was thinking of earlier. I lost it.

[Isha]
I think we mainly were asking for features that the device should have. We have a bunch of options, like already a lot of information from there, particularly. And then we also asked about what the devices don't have in the market, and what could be added to it.

And that also we've received. Sustainability-wise, we've asked a bunch of questions.

[Sam]
I have thought of something different. So how long usually do your surgeries with bipolar energy devices last? I'm trying to get an idea of how long it takes for you to be holding it to complete the operation that you're trying to do.

[Dr. Liu]
You mean how many times I'm holding the bipolar to do the surgery? How much time?

[Isha]
How much time during the operation time do you have to have it in your hand?

[Dr. Liu]
In one surgery? Maybe, for example, we do the bariatric surgery, do the sleeve gastrectomy. We remove the stomach, one part of the stomach.

They have the vessel like this. This is a very simple procedure. So the procedure is that we cut the vessel, then coagulation, cut, coagulation, cut, coagulation.

So at this part, maybe 15 minutes, 15 minutes. Then we switch to another procedure. But depends on the different surgery.

So it's very difficult to say how much time, how many times we go in, go out.

[Sam]
I'm trying to understand how important the ergonomics of the device are, how comfortable it is in your hand. So would you say that that's a primary concern, is how comfortable it is in your hands?

[Dr. Liu]
Yes. But for some things, because also when we do a surgery, we must be holding the tissue. Sometimes we need to adjust the position. But if we have two hands, one hand is the clasper, but another hand is the LigaSure or B. Braun one, it's very difficult to hold the tissue. So we must switch another one to holding well. Then we take another to cut it. So maybe for my experience, for the LigaSure or for the B. Braun, the clasp power is not so strong. So every time, like the stomach, the vessel, we want to lift. But when we catch this one, easy to lose the tissue. So their catch power is not so strong.

Maybe you can improve this part. If the catch power is strong, then maybe we don't need to change the instrument. We can save the time.

[Sam]
And we also were talking earlier about the size of the device and how that impacts things. So typically, when you have smaller forceps, they can be more difficult to hold onto things, because there's a lot higher pressures involved.

And oftentimes, they're smaller, so they have less torque. So would you prefer to have a lot of different options in the one device for like styles of forceps tips, like smaller options for what you were talking about earlier to do similar things to what a ultrasonic device does, like the harmonic scalpel? Or even larger ones that might be able to ligate or coagulate larger blood vessels or larger pieces of tissue at once?

[Dr. Liu]
Because if you have a lot of function, the instrument is very heavy. So I think it's very difficult to do multiple functions in one hand, and still very light. So for a surgeon, the weight of the instrument is very important, because we do a lot of the work.

If it's very heavy, like a wireless ultrasonic, it's very heavy. So we like to use. This is the problem why they are not popular.

We still use the wire one, because it's more light and more delicate. But if you have everything in one hand, you need the material, you need a lot of function, you want to have the LigaSure function, harmonic function, then it must be very heavy. So the weight is very important.

That's interesting. So if you can, like an instrument, then your generator is outside?

[Sam]
Yeah, the generator is on some rolling rack.

[Dr. Liu]
Some area, you have a lot of function, then generator is outside. Then it's convenient.

[Sam]
Have you ever run into problems with the wire between the generator and the tool getting in the way?

[Dr. Liu]
You mean the?

[Sam]
Is it ever inconvenient to have that wire there?

[Dr. Liu]
In fact, it's not so inconvenient. I think it's OK. Wireless is better, but you cannot produce wireless as a very light one. Yeah, because it's very heavy. So there's a reason why the wireless cannot replace the normal one.

[Sam]
Interesting. So if there was a wireless device that managed to solve this weight constraint, I'm imagining perhaps one that has a smaller battery, so maybe it doesn't last as long. But maybe it's also meant for the shorter surgeries, like the gastrointestinal one, or the stomach.

I forget exactly what the term was that you used. So perhaps one that had a very lightweight battery that would only last, say, 20, 30 minutes of use, would that be more useful for you?

[Dr. Liu]

Maybe you can do this. I depend on the surgery to choose the material. If this is very, maybe like appendicitis, only five minutes, then I can choose the very light material.

If the gastric cancer is the wrong time, then I use the more longer material, or I can switch in the table. Because now the material maybe cannot switch in the table. So we can use the light material, but we can switch.

If they have no material, immediately we can change. So the very important is the weight. If you can decrease the weight, then surgeon like to use. They will become popular.

[Sam]
And do you have any concerns about the increasing complexity of the device? So one thing that we've encountered when we're talking to other surgeons is that they're very concerned about how complex the device is.

We've heard a lot about LigaSure's advantage being that it's extremely simple to use. You just take the device, you put it in the patient, you trigger the thing, maybe do it twice, and that's all you have to think about. Would you be more worried about having to think about it?

[Dr. Liu]
So if it's more simple, I think it will become more popular. Like I was talking about the LigaSure and the B. Braun system. So in LigaSure, in Medtronic now, they can grab the forceps, then at the same time they can coagulate the vessel, like this one. This is the older generation.

[Dr. Tang]
Do you use ENSEAL? [Translated]

[Dr. Liu]
No, I don't use that one. [Translated] So this is the old system. They have another button here. So now this is also like a B. Braun system. I close, then I have to push, push, then I have to cut. So you have the three steps. Now the new one is for the Covidien one. You just close and at the same time, you have the coagulation button is here. So you coagulation, then you cut. So you have two steps.

[Sam]
So that reduces the amount of just thinking that you have to do.

[Dr. Liu]
Yeah.

These are... are these J&J ENSEAL? Yes.

[Sam]
Yeah.

[Dr. Liu]
But this cannot populate. This jaw is not so delicate. This is also the LigaSure bipolar system. You only can the ligation, but when you do the delicate dissection, it's very difficult. Because the jaw is still, it cannot do very precise jaw.

[Sam]
This jaw is about, what, is that 15, 20 millimeters long? So what would you say would be the length that you would be looking for in a delicate jaw?

[Dr. Liu]
This jaw, you can do the curved one.

[Sam]
Oh, but it's because the end is very narrow.

[Dr. Liu]
Very thin. Yeah. Very small. Now the harmonic, Johnson & Johnson harmonic, is very similar to this one. It's small and curved. So you can do a dissection, then you close. Then one hand is energy, so you can correct.

You take a monopolar to dissection, then close. You can coagulate. So if we want to do a very delicate one, you need a more small jaw.

[Isha]
If you look at it, the diameter of the tube itself is very, for the covenient versus this material right here.

[Sam]
This one is very small diameter, but this one is much larger.

[Dr. Liu]
For the energy, you must be, you cannot, it's very difficult to do so thin, right?

[Sam]
It can be. Although, with something this long, I don't think it would be too difficult.

[Dr. Liu]
If the bipolar can do so small, I think it's very useful.

[Sam]
I'm more worried about the ability of this to stay together when there's a lot of weight of person behind it. I don't want it to break inside of a person. That would be my primary concern.

[Dr. Liu]
This is the older one, so I just say it's a blunt tip. So only you can, like, actually in the brittle, then you cannot do a dissection. You cannot do a very delicate digestion.

[Sam]
That's interesting. So from this conversation, I'm understanding that you're really only primarily concerned that you have a very narrow tip of it. Would it be more useful to have a broad, sort of, this style towards the proximal end, and then only get super narrow at the distal end?

[Dr. Liu]
Yes.

[Isha]
So wider at the tip, at the base.

[Sam]
Yeah, wider at the base then narrow at the tip. Just out of curiosity, because so we were mentioning, so we want this to be narrower so that it's easier, because then you can have a narrower tip. How... these are, like, very stiff. Is there any room for flexibility? This feels like a, I don't know, a less useful question, because I feel like if it's flexible, then it's more difficult to get things into position. But would there be any room for flexibility, like, along this shaft?

[Dr. Liu]
In fact, no need this shaft for the flexibility. Only this part. Because everything you do, you must be, like, have a target.

Then you go through this one. Then only turn is need to the tip one.

[Sam]
Only need to turn around the last inch or two?

[Dr. Liu]
No need to turn this one. Because for a surgeon, you must be have a, you must be see, then do something. So for a see is always the stress one.

So you only can see the direct vision. So your instrument's always like this. But mainly around here, it's very difficult to cut.

Like this, you cannot cut around here. At this time, if you can turn a little, then you can cut posterior side. So no need to turn this part.

Only just this part.

[Sam]
Just try to get around things.

[Dr. Liu]
Cut a little, a little.

[Dr. Tang]
So you mean actuation like da Vinci?

[Dr. Liu]
Yeah. You can see the da Vinci system, it's only just turn around the tip part.

Because we always, because it is the, the surgeon always, you can see, it's the straight line. You cannot see, turn this one. So you no need to turn like this.

But for, for me, we also have some dream like, you know, some Spider-Man, the movie also have, there's a hand, like this, you can close. So in the future, maybe.

[Sam]
Oh yes, from Doc Ock.

[Dr. Liu]
Yeah, Doc Ock. You can have the, now have some similar one. You can have the flexible, the flexible, the scope. You can see around here, then your instrument can turn around here.

Then maybe you can do this part.

[Sam]
So if both your scope and the instrument can do that?

[Dr. Liu]
Yeah, if all the scope can also turn the flexible one, then maybe it's more useful.

Then if your curve can turn, it's use. But if your scope still can only see the right side, then at this time, the curve is not useful.

[Dr. Tang]
Let me ask additional question. So you mean that if our bipolar has one degrees of freedom articulation, that will help you?

[Dr. Liu]
Yeah, because now the B. Braun system have articulation.

[Dr. Tang]
The B. Braun?

[Dr. Liu]
Mhm. But the disadvantage is like this. They can curve, they have to, they like this system. You close, you actually push a button, you cut this one.

And you want to turn, you have another device around here.
[Dr. Tang]

It's not intuitive.

[Dr. Liu]
So I cannot, I don't have hand to push the articulation.

So I must ask some people to help me. So if you can...

[Dr. Tang]
Use the interface.

[Dr. Liu]
Correct [Translated]. So if like this, if your turn is around here, this one is the jaw, right? If you have another one, you can turn. Then I can...

[Isha]
Automatic turning.

[Dr. Liu]
Another turn. Yeah, Turn the wrist.

Then I can finish by myself. Then they can improve this advantage.

[Dr. Tang]
Nice to know.

[Isha]
Yeah.

[Sam]
And just for Dr. Tang's benefit, we were also talking about, what is it? Coagulation on the surface of organs. Like on the surface of the liver that you were talking about.

And having, so if we had, or if a device had that articulation, it would be very useful to also have electrodes on the very edge of the jaw, correct? And so then you could coagulate the, like an incision on the surface of an organ. That was something else we were thinking about.

[Dr. Tang]
We think of a lot of combinations of design. But the truth is we can only make one thing at one time. And this one thing for one time may be two, three years.

[Dr. Liu]
Yeah.

[Dr. Tang]
So that is why we ask them, because they are still young. So if we don't finish it, they can continue. So the road map, maybe it will extend up to 20, 30 years. And if we can build the

basics, then step on step to incrementally. So we are not able to satisfy everything you want, but we want you to help us to make better device at each step. Yeah, that's what we want to cooperate with surgeons in this perspective.
[Sam]
We want all the good ideas, even if we might not be able to do them right now.

[Dr. Tang]
Yeah, we want all the ideas, but later, later.

[Isha]
It's definitely better to know all the ideas now than have to figure them out later. Is there anything that we should know regarding bipolar devices that we haven't already covered?

[Dr. Liu]
Hmm...I don't know?

[Sam]
So we've investigated coagulation and cutting with the bipolar devices. Is there anything else that is really useful to you that you would want to be able to do? For example, by removing like a mass.

[Dr. Liu]
Removing? I mean the grasp power.

[Sam]
The grasp power, right?

[Dr. Liu]
Like this, this have a grasp power. Like this. You always have one time.

You cannot grasp something like this. This is a problem.

[Isha]
I just noticed that the thickness of the handle itself also varies. Does that affect the ability to constantly click and move things for the device?

[Dr. Liu]
You mean this design?

[Isha]
The handle.

[Dr. Liu]
The handle. I think it's very similar. This handle and this handle.

[Isha]

Is there a preference in the type of thickness of the handle?

[Dr. Liu]
You mean the handle? If like this is better, this kind is more convenient.

[Sam]
So you prefer if it's a thumb active, or like a thumb switch rather than like a.

[Isha]
Index.

[Sam]
Yeah, I'm trying to phrase this in a way that we can understand it in the recording.

[Dr. Liu]
So this handle, you cannot do very delicate for grasping something like this. But use this one, it's easy. You can grasp something to lifting.

But this is not so. You must use the wrist. This one is use the finger.

This one use the finger. So use the wrist is not- The movement is large.

You cannot do very small, small.

[Sam]
More difficult to do delicate. Yeah, yeah, that's interesting.

[Isha]
So from what I understand is when you're saying that if they're wrist-based devices, then it's difficult to move around. Versus if it's a thumb-based actionable device, then it becomes easier to be more delicate.

[Dr. Liu]
Yeah.

[Isha]
Okay.

[Sam]
I like that. So I'm noticing that some of these devices have significantly different like tools on the actual hand. So this one has, what is it?

Yeah, it's a switch. So it's this as well as the thumb thing. And then it also has this trigger.

So I'm actually not totally familiar.

[Dr. Liu]
It's not so familiar.

[Sam]
Yeah, I'm especially not familiar with it.

[Dr. Liu]
Too much function.

[Sam]
There's a lot going on here.

[Dr. Liu]
Yeah, so it's mostly is no need too much function.

[Sam]
So perhaps you're more interested in something that's similar, like simple like this, but maybe more similar to the thumb grip with this one. So it's keeping it simple, but maybe trying to follow the design of the LAGIS system. Interesting.

So are there any other advantages of these designs relative to each other that you're interested in? So we're looking at, what is it? That's a Ethicon, and what is that?

That's Enseal, no, Ethicon, LigaSure, Covidien.

[Isha]
LAGIS.

[Sam]
No.

Ethicon is ENSEAL; Covidien, LigaSure; LAGIS.

[Dr. Tang]
Forceps. These are only forceps.

[Sam]
Just forceps. And then the other LAGIS, forceps. So are there any other like pros and cons between these designs, or any other devices that you've used?

[Dr. Liu]
Most of the time we use the Storz one, forceps.

[Sam]
Mostly use the forceps ones.

[Dr. Liu]
Storz is reusable. Reusable. They use it, they clean it every time, because it's more economical.

Right. In Taiwan, I think we still have to consider the cost, but in United States, actually, so far as I know, it's a kit. Every surgery, they provide a kit with everything, and then after that, clean it up, because the cost for these operating theater is much more than the cost of these devices.

So they want to increase this turntable rate for these operating theater. So there's still different considerations in the logistics, but in Taiwan, most of these standard devices, the forceps are Storz, because it's actually more light, light and the stiffness, the quality, because this is a disposable one. So it's cheap.

But the Storz- It's a German, yeah, Storz is German. So it's built for, lasts forever.

[Isha]
I know that Medtronic usually provides a biohazard safety kit, so when they are done with the device, the reusable device, they put it in that, give it back to Medtronic, they sterilize it, and they bring it back to you. That's what I read up online for some of the devices.

[Dr. Tang]
Because in the States, there is another business, is the reprocess of the single-use device, and that is the business of Stryker. Stryker has the business for these single-use devices.

[Sam]
Especially the LigaSure devices.

[Dr. Tang]
LigaSure harmonics, and all these cardiovascular, as long as it's expensive, then you can reprocess it for maybe additional use. But then it's the surgeon's choice, because Dr. Liu mentioned, depends on different application, if it only takes five minutes, I can reduce the cost. But if it's a very heavy surgery, then I need the best weapon to conquer these challenges. So I think we still have to consider all the situations, and then, because we have three different lengths in ultrasonic dissector, and I don't think it will fit into all the surgeries for surgeons to apply, because still, we can customize it, but the customization must fit to his needs. And also, for business, we have to build a sustainable business model to sustain the operation. So there are more considerations in, in the technical parts. Because the technology, is actually, one part of this market intelligence. And they [surgeons] have all kinds of needs. They have every kinds of needs. And then for us, we have to consider our own cost, our operation overhead, our channel deliveries, and all the certifications and reliabilities. And most importantly, is that we don't want them, we don't want the device to break. While they are using it. This is the most important thing to make your system, to help the surgeons finish their job. If you have finished, I can ask my colleagues to introduce our ultrasonic dissector.

# Appendix G: Dr. Caparrelli Interview Transcript

[Dr. Caparrelli]
[Asked for permission to record] Not at all. That's just fine.

[Sam]
Fantastic.

[Shaylie]
All right. And so for sort of just basic demographic questions, real quick before I hand it over to Sam. So what is your job title in terms of working with surgical devices?

[Dr. Caparrelli]
Yeah. So my name is David Capperelli. I'm the chief of cardiac surgery currently at Catholic medical Center in Manchester, New Hampshire. I'll soon [Zoom audio briefly cuts] in Annapolis, Maryland. We're moving in a couple of weeks, in fact.

[Sam]
Oh, really?

[Dr. Caparrelli]
I'm a cardiac and vascular surgeon.

[Sam]
Fantastic.

[Shaylie]
And do you mind me asking how old you are?

[Dr. Caparrelli]
I am 53 years old.

[Shaylie]
And about how long have you worked in the surgical field?

[Dr. Caparrelli]
So I started my surgical training in 19[audio cuts (probably 92 given the 16 years)] to 2008. So I was working in the surgical field during that period of time, attending surgeon, cardiac vasc, as I said, cardiac, vascular, and thoracic surgery, 16 years.

[Sam]
Great.

[Shaylie]
Thank you very much.

[Sam]
Shaylie. Do you have any more questions there? I'm freezing up a little bit.

[Shaylie]
Yeah, I am too. I was going to say, I think that's all I had for demographic questions. If you want to start with general questions.

[Sam]
Absolutely. First question really is, let's see, how long have you been working with bipolar devices in particular, how often do you use those in surgery?

[Dr. Caparrelli]
Sure. So, you know, I look at realms in which I use frequency or bipolar devices. One is in, you know, tissue. Well, tissue ablation from a cautery standpoint, which I don't use it very often. I usually use monopolar. Bipolar energy is often used around nerves. I don't do a lot of that kind of surgery, so I don't typically use bipolar energy in that realm, but I do use a lot of bipolar. Is it an arrhythmia of the heart? So typically ablation in that manner is done with a variety of energy sources. Cryoablation, bipolar radio frequency. They've tried high frequency ultrasound, laser, a variety of other techniques. But really, the bipolar devices are the most popular and the most effective, and I've been using those for the last probably eight to ten years.

[Sam]
Fantastic. Yeah, sorry, I'm just moving because I was getting a lot of freezing issues somewhere I know has better connection. That's fantastic. So you mentioned that you've used a lot of radio frequency bipolar, and I'm assuming you meant basic bipolar when you were talking earlier. So have you used the advanced bipolar devices like LigaSure or ENSEAL?

[Dr. Caparrelli]
So I, on occasion, will use those in the operations that I do, but I don't need the type of operation I, the temper operations I do don't usually require ligash or the harmonic scalp or those sorts of things. I do have a little bit of familiarity with LigaSure. I use that as part of one of the operations when I'm opening the pericardium, which is the sac around the heart for thoracic, for procedures I do through the left chest. But it's really bipolar RF from a company called AtriCure that I do the most. And that's with, that causes, again, the ablation, the scars, the tissue destruction on the heart that prevents electrical activity and the arrhythmias. I'm sorry, I'm not resecting bowel or going through a lot of vessels where the LigaSure and those type of devices are very useful.

[Sam]
Yeah, yeah. What they're designed for. That's fantastic. So when you're using so primarily basic bipolar devices, have you encountered any primary or major challenges with just the technology itself or the ergonomics and using it or anything like that?

[Dr. Caparrelli]
So not really. Like I said a couple of times I've used basic bipolar devices. I don't perceive that there's a lot of thermal spread. You know, you're getting ablation between the tips of the, you know, the instrument. Similarly with a device like the LigaSure, you know, they, you know, you have to be careful with the devices in terms of pat, what you're clamping across. But if you're mindful of where the tips are, that's not much of an issue because all of the energy is directed between, you know, between the clamps.

[Sam]
Right, right. So when you're, when you're in surgery, is there. So, yeah, there's no issue with thermal spread or anything like that. But is there any issue that you've ever had with. How do I want to phrase this? Have you had any issues with, you know, the ergonomics of the device or with the. Just that side of things where it's like it's inconvenient to use, has that ever been an issue?

[Dr. Caparrelli]
No, I haven't really found that to be too much of an issue. You know, I think that the devices that I've encountered haven't been terribly difficult to use. But again, I think the devices you're referring to are not ones that I use a great deal and they're more appropriate for procedures that I don't do. So I think somebody who is, is using those devices more frequently might have more issues with it. When it comes to ergonomics, I've never had an issue, however.

[Sam]
Yeah. Okay, so another topic that we're interested in investigating for our project is sort of the environmental impacts. So many bipolar devices, particularly advanced bipolar devices, they tend to be like disposable single use devices. They get thrown out after they're used or at least sent to a recycling company. Is there any appetite in either the hospitals that you work in or perhaps for yourself in reusable devices that might be less expensive, that might also be a little bit more environmentally friendly?

[Dr. Caparrelli]
Sometimes in the hospital setting, it's the disposable devices that are less expensive per unit cost, I think. Or maybe I'm thinking about the other way around. Yeah, the reusable devices are more expensive, but you're getting more uses out of them. So you look at the cost benefit. I think there's always, you know, and I'm not so sure that hospitals, per se, have an appetite, necessarily have an appetite for the environmentally friendly device per se. Hospitals, you know, whether they're for profit, not for profit, you know, they want to keep costs down. So if the cost is down by using a disposable device, you know, they can buy ten devices cheaper than they can buy one device that works ten times, they're going to do that and they're going to throw it in the garbage. I think from, from a practical standpoint, I would like to see more environmentally friendly, you know, more environmentally friendly devices. Reusable devices. We, there are some devices, I believe the ligatures want them, that they can reprocess them. So even though they're built as one use devices, you can send them back to the company and they can resterilize them and test them for quality control, reprocess them. And so it's recycled in a sense, but not so much. Not the raw materials, but the actual device. I think that's very useful as long as the devices are fully functional. I have had a few repurposed or recycled devices that haven't worked properly when

we've taken them out of the package, and that sort of defeats the purpose. Yeah, then there's, then there's not, you know, it's not, it's not worth it. So I'd rather just open a new device once and not have to go through that situation. I mean, usually we test the, you know, we test the devices in non vital, you know, tissues before we, you know, do something that's, you know, irreversible or could be at risk to the patient. But I have had devices that, that were brought, sent back from the company, supposedly fully functional, but weren't. So that, that's a bit of an issue when it comes to recycled or repurposed devices, I think that anytime that you can see, you can get the same quality for less overhead, whether that's a reusable device that's more expensive, or, you know, a large volume of disposable devices, I think that's where hospitals are tend to look at, because the profit margins on these procedures, you know, although you're taking care of patients, which is the number one priority, you got to keep the doors open. And whether you're working for a for profit or not for profit, you know, the surgeon that can do the best operation for less money is. Is where the hospital wants to go. I don't particularly care how much the operation costs, as long as the patient gets the right, gets the best care. But if you can do it, if you have two devices and they do them exactly the same, and one's $100 cheaper, then you go with the cheaper one. If there's any compromise and care, though, or compromise and function, then it's not worth it to me. I'd rather pay the higher price and be more comfortable with the instrument.

[Sam]
Right. So you mentioned that you work at the hospital in Manchester. Do you have any experience working at larger hospitals and dealing with their, how do you say, like device acquisition?

[Dr. Caparrelli]
So, you know, I've worked in a number of. A number of environments. Obviously, I trained at a very large institution, but at that point in my career, I had no, you know, no contact with purchasing or anything like that. Most of the hospitals I've worked, I've worked with have been smaller institutions, you know, you know, 200, 9300 bed hospitals, some of them multi, multi hospital systems where there is some benefits to buying in bulk, or a big hospital system like HCA, who's got thousands of hospitals, can get cost advantages from buying a lot of a particular product. But mostly I've dealt with purchasing people at smaller institutions looking to try and minimize the, or maximize the bottom line through cost containment.

[Sam]
Right. Yeah. So when you're in these hospitals, especially the smaller hospitals, when they're looking to maximize value for the surgeon, and also they're concerned about cost, how much input do you specifically have on which device they're using in surgery? Or is that down to the purchasing department and they're looking at, are these things functionally the same and are they making that decision, or do you have a lot of input?

[Dr. Caparrelli]
So it's different in every institution, but I think in general, the surgeons have, at least in smaller institutions. Again, I don't know. My hospital is being purchased by HCA, which is one of the larger hospital systems in the country, maybe even in the world. And I think they're going to tell us. That's part of why I'm leaving, but I think they're going to tell us what they have on contract and what they don't have on contract. And you have to make a really compelling argument to buy

something outside of the contract that's more expensive. In my current situation, where I am not, I mean, not even just as the chief, but as a surgeon, most times the value assessment team, within reason, in my experience, will bow to the will of the surgeon because, I mean, all you have to say is this is what I think is best for the patient. Now, if you're somebody who asks for the five of the $5 million robots and you need to have every bell and whistle, then people are going to call you on that. But I think if you're really asking for something that you truly believe is better, I think that the doctor still has a lot of sway with those value assessment teams. They give you a lot of pushback and they make you do trials and they make you fill out a lot of paperwork. But if you want it, at least in my experience, if I've wanted it, I get it.

[Sam]
Sort of that same sense of which devices to use in particular. Do you know which brand of bipolar devices, basic as well as perhaps monopoly devices as well? Just for sake of argument, do you know which brands of those you use?

[Dr. Caparrelli]
So the, so honestly, you know, the only device that I really know in that realm is the LigaSure, and that's what we care, you know, what we use for monopolar, what we have for bipolar devices, that doesn't really, that really doesn't touch my, I'm not that attuned to those now, like I said, other people who use those devices, you know, a lot of those devices more frequently, what we use for standard electric cautery, you know, I don't know what pens we have, that sort of thing. You know, what, what kind of, you know, what else we have in terms of whether it's harmonic scalpels or ligatures? Like I said, we have a LigaSure, but other than that, the devices, I'm not familiar with those companies. Sometimes I'll take calls from Salesforce people, but most of the time because they're devices that I'm not using widely. Again, for me, I'm not, you know, I might not be the best interview for you for these kind of issues because I don't use the devices that much. Like I said, I do use a lot of bipolar when it comes to cardiac tissue ablation, but that's a whole separate issue from what you're talking about.

[Sam]
I mean, you say it's a separate issue, but we're also trying to get a general understanding of how purchasing works in hospitals in the states. This is a pretty important process, especially as this company is trying to expand. It might take a little while, but sure.

[Dr. Caparrelli]
Well, what I can tell you is that if you want a new device, whatever it is, or a new drug, but just stay on the device side, there's a form you have to fill out data from the, typically you have to provide some data from the company. If there's peer reviewed journal articles discussing the particular device or use of the particular device, that's helpful. And typically, typically, if you with that, you then can enter into a trial and that'll be five cases, ten cases. Typically, the company gives the equipment for free at that point and provides on-site service. So, the sales rep, their clinical rep, will come to all the cases, they'll educate the OR team, and then typically there are forms to fill out with each case. Was it, did it do what it was supposed to? Did it not do plus, minus, I think both for the company and for the hospital. And then if you get to the end and it's something that you want to add to the formulary or add to the, you know, to the stock, then that's when the value team really looks at it and says, what is the cost per unit? How many units? Is it

replacing something, or is this just a secondary, is this an instrument for one guy and the other five surgeons use the other thing, or is this something that all the surgeons adopt? What are the benefits? What are the risks? Sometimes it even comes down to just how much space they have on the shelves. They'll say, well, it's a good product, but we have no place to put it, which I think is a stupid reason not to have something, but they have to have storage space. So at a certain point, when you put one thing on the shelf, something's got to come off. And it's not always a one for one swap. It's not like, well, I like this valve. So we're going to get rid of these valves. Well, I might use this valve, this other valve for a particular patient or in a particular situation. So I want to have both. I think packaging, I mean, this gets a little granular, but even packaging, if things come in ginormous boxes, they're harder to store. If they're, if they're prepackaged small, that's beneficial. If they are reusable, you know, then you have to get, you get into sterile processing and where, you know, where are they? Where are those instruments stored when they're not being used? How often are they used? How many uses do you get out of them? How do you keep track of how many uses, you know, what happens if, what is the shelf life? Both of you know them usable and disposable. You know, reusable and disposable products. Because if you buy, are they on consignment? Are they not on consignment? You know, you have to pay for them upfront, you know, so there's a lot that goes into it, but that sort of all is discussed after the five or so or ten cases, whatever it is, when you decide that there's actually clinical benefit or clinical utility. So that's how it goes through in our institution. And most of the time, even when they push back and say, well, it's this much more expensive, I say, well, yeah, but that's what I want. Now, if they come back and say it's three times as expensive, I'm like, well, that's ridiculous. I can do it with the other thing. You know what I mean? But if it's a matter of a couple bucks here or there or a couple hundred bucks here or there, and it provides a clinical benefit or a level of comfort for me, I'm going to push for it. If it's ridiculously expensive, it better be ridiculously better than everything else on the market.

[Sam]
Yeah. So in this case, we're a little bit more focused on, like an incremental improvement and a cost reduction. That's what our sponsor is primarily trying to do. For a little bit of background, they're essentially trying to improve upon LigaSure's device and make it expensive. So LigaSure costs something like $500 for every reusable device and $12,000 for the generator itself. And I don't remember what price point they were going for, but significantly less. Okay, so I guess the question is, like, how often do you use, well, you already mentioned that you don't use advanced bipolar, but like, how much of an impact do you think that would make? And how interested would perhaps your hospital's purchasing department be in that?

[Dr. Caparrelli]
I mean, I think a couple hundred dollars savings on a device that works virtually the same is impactful. Even 100, even 50 or $100 on a $500 device, that's a ten or 15% savings plus, again, if you use it for me, I use the ligature probably 20 or 30 times a year. $100, that's a couple thousand bucks. Now, that's better on the bottom line. But if you're using three devices a day because you're doing three cases a day or you're using it ten times a week, then the savings really add up. Even at 50 or $100, you're talking about 1015, 5100 thousand dollars worth of savings over the course of a year. Again, it's scalable to the size of a hospital. We have a ten or hospital with 290 beds. If you're in a bigger hospital, we have, I don't know how many surgeons, we have about 50 surgeons that use those ten ors. But if you're in an institution that's got 500, 600, 700

beds, has a couple hundred surgeons, got outpatient center, you've got, and it's being used by gyn, it's being used by general surgery, it's being used by urology. Now, you're talking about substantial savings from incrementally, fairly small changes in cost as long as it works the same. And if it's a little bit better, the handle's a little bit better, or it's a little bit more reliable, or the cutting length is a little, the tips are a little bit longer, so you get a little bit more, or it's articulating in some way that it's not that kind of thing. Incremental clinical or tactile improvement with a cost reduction would be substantial.

[Sam]
Yeah, that's fantastic. Shaylie, I'm sure I'm missing something out of our interview question.

[Shaylie]
I was going to ask something actually sort of going off of what you just said there. So on top of like the cost and the hospital logistics, so our team is very focused on understanding surgeon preferences for the devices. So I know even though your experience is maybe a little bit different than specifically what maxima is focusing on, anything like that would be useful to us. So I know you mentioned some of the different lengths of the tools and stuff like that just now. Could you go into a little bit more detail onto what for you are the most important features for the devices?

[Dr. Caparrelli]
Sure. So, I mean, for the, again, you know, for something like the LigaSure, you know, I think that, you know, you know, the ease of, I mean, typically, I mean, when I use it, I'm doing it through thoracoscopic incisions. So I'm doing small, small incision surgery as opposed to having a wide open abdomen or chest in a big open and a lot of surgery is going that way these days. You know, you don't get a big incision for a cholecystectomy anymore for getting your gallbladder out. You know, bowel surgery is done robotically or laparoscopically. So, you know, longer devices in those situations are sometimes necessary. They're sometimes too. They're sometimes cumbersome. So if you're a company trying to break into the market, at least what I've seen is that for open cases, they have shorter handles. For thoracoscopic or laparoscopic cases, they have longer handles. They've all articulate. But the manner in which they articulate, the ease in which they turn so that you can get the angle you need from the angle you are. Again, when you're working through ports, it's like operating with chopsticks. It's not exactly necessarily the, the most, the most. Well, it's not the most tactile. You know, I mean, again, you're working at the end of the end of sticks, so, you know, different, you know, different lengths. The ability to articulate the bulk of the handle, I think, sometimes plays a role, particularly because as you move, as you're moving your hand up to move the tips down or moving the tent your hands down to move up, you're meeting against retractors, you're meeting against the patient's chest wall. There are anatomic criteria or anatomic things that if you have a really bulky handle that's hard to manipulate, it's going to be harder to make fine adjustments within the body from outside the body. So a refined, a refined ergonomic, a handpiece, I think is important.

[Sam]
So you're mentioning about, like, turning the blade to get to where you need to go. There are certain. So there's a lot of differences between, you know, all the devices on the market. Ligature,

in particular, I don't believe, has a hinge. Do the basic bipolar devices you use have a hinge that you can use to.

[Dr. Caparrelli]
They don't. I was really thinking more about, and again, my only, my only familiarity with the LigaSure is with the curve, the curved blade or, you know, the curve tips. And I think they have other ones, to be honest. Yeah, straighter ones. But particularly when you're using the curve, you know, obviously, if you need to, you know, direct your cut upward, you're going to turn the blades. You might not be able to drop your hand as much because of the chest wall or what have you. So we turn the blades this way and are able to get in versus turning down. Sometimes we're going to. We're cauterizing very close to nerves for me, the phrenic nerve, which runs along the pericardium to the diaphragm, if you disrupt that or cause any thermal injury to that, the diaphragm is not going to work very well, and the patient's not going to breathe very well. So that's one of the big concerns when we're using the LigaSure near the phrenic nerve. But how much you can put in the jaws, how much you're able to, how much force you're able to apply on the tip if you have to grab tissue, sometimes it's a bit of a challenge, but there's nothing that I know that articulates in the way that a robotic arm does. When you look at save the hands of an intuitive robot. I don't know if you are familiar at all with the da Vinci robot that does surgery inside that provides a lot of articulation, and they have cautery that's on the end of that. They have graspers on the end of that. They have staplers on the end of that. And that's a huge benefit over standard thoracoscopic or laparoscopic, not only because of the 3d vision you have sitting at the console, but because of the articulation of the hands. Now, there's not a lot of devices out there that have a lot of articulation like that. And in a. In a handpiece, the. In a hand piece, it becomes somewhat cost prohibitive to engineer, you know, say, a disposable handpiece that articulates in five different directions. And it's also easy to get lost. You know, you start turning the thing the wrong way, and then you spin it. You don't realize that there's such a hook on it that now you're poking into the heart or you're poking into the bowel or something. So I think there's a certain amount of manipulation and adjustment that is helpful and then a certain amount that's probably too much or dangerous. But, yeah, I don't know of anything really that articulates in the way I'm describing. But there are those issues. I mean, if you had a way to do that effectively, it would make some of these small port surgeries a little bit easier and safer.

[Sam]
Absolutely. Specifically, what I was referring to is, yes, all these devices have this kind of motion where they, like, rotate the grasp, where you can grasp in different directions, but there are, like, one or two devices in the market that also have a wrist.

[Dr. Caparrelli]
Yeah, I haven't used any of those, but I mean, like I said, I think that that can be useful. I think for the novice, you know, probably more dangerous than not, but in somebody that really knows how to use it and knows, you know, knows the device, I think that's a huge benefit because, again, not so much when you're doing a big open surgery, but when you're doing a thoracoscopic or laparoscopic surgery, sometimes you just don't get, you can't get the angle, you know, and it's a whole different skill set to be operating looking at a camera and working through ports than it is through a big open incision. So, I think that kind of articulation, you know, if done ergonomically, can be very beneficial and worth, and worth extra, you know, if it's extra cost,

because time is money. Again, you know, I don't like to talk about finances when you're talking about an operation, but the reality is every minute in the operating room costs a certain amount of money. I mean, it's, it's not a direct charge, but if you can do three cases in a day rather than two cases, because you're able to ligate the tissues effectively and you don't have bleeding and you can do it quickly and the device is not bulky, three cases in a day over a year is substantially more than two cases in a day over a year. It's incremental. There are little things here and there. If you're efficient and you have a good device, then it can make a significant, it can impact both quality of patient care as well as the bottom line. Plus, the fewer complications you have, the faster the patients go home and shorter length of stay is better for the patient and better for the hospital. So those are sort of some. I think if I were advising a company, I would talk about price, ease of use, effectiveness, maybe not. Obviously not in that order, but effectiveness, ease of use and cost, and potentially benefit in terms of time and safety. That's a lot of stuff. But I mean, those, those are all the things that I, you know, I think about, is it, is it effective? Is it safe? Does it make me faster? Is it what's best for the patient? You know, and then I think about cost, you know, and, you know, if you can, if you can hit most of those and it's cheaper, then great. If you hit all of those and it's a little more expensive, I think you're going to, you're going to win with surgeons. You're just going to get a little pushback from the CFO.

[Sam]
Absolutely.

[Dr. Caparrelli]
Yeah.

[Sam]
I mean, I personally think that this company, like, they're, they're putting a lot of effort towards, you know, making sure the effectiveness, making sure the safety, like those are definitely paramount. Like, they absolutely agree. But the difference is their competitive advantage over the US. They don't have the same R and D budgets. So their advantage really primarily is in terms of cost. Yeah, so that I think, yeah, because all the people that we're actually working with around here in this company, they are also surgeons, primarily like GI surgeons. So, you know, working around the stomach and they're, you know, they have a lot of experience with, you know, similar devices. They in particular work a lot with LigaSure and those sort of sorts of devices.

[Dr. Caparrelli]
Yeah. When you're taking down the short gastrics and things, when you're resecting stomachs and, but I mean, as opposed to hand tying everything and I mean, just, you know, the safety and the, and the efficiency, you know, are substantial. I think the, you know, the other thing, you know, that, you know, for a small company, you know, or a company trying to break into the market, I think it's really important that you have the right combination of salesforce and clinical support. You know, you know, if you have people, I mean, and I might be different than others, but like hardcore salesmen that come in the or I can't stand, you know, push, push, push. You know, I feel like they're, if they're trying to sell me a device, then maybe then I'm not interested. I think really the people that I value, the reps that I value the most are ones that I feel like are part of the team. I feel like the patient gets a better operation because they're there now. They rely on

my expertise. These are guys that have never touched a bowel or never touched a heart. But they see the case that I'm doing every day and I'm doing different things every day, but they're seeing this same operation every day. They're seeing the use of that device every day, whether it be an implantable or disposable device, like a ligature or something like that. So when they say, oh, I think that you might want to try this or my experience to this and that, I find that very helpful. Some surgeons are arrogant and don't want to hear from the reps. So, I mean, you've got to strike a balance. Some guys will just say you're, you're the rep, I'm the doctor. Just give me the device and get the hell out of my OR. But I do think that, you know, I value. I, the people that I value the most, and the companies that I value the most are the ones that provide excellent clinical support. And I don't feel like they're selling me anything, you know, now they might, they might just happen to have the best product on the market, and therefore they don't have to sell me anything, you know, they're just there to support. But I found myself switched from one device to another. In general, based on the support that I get, if the devices are equivalent, the prices are close, then the guy that shows up to my or and is helpful and not a pain in my ass is the one that I'm going to use and the one that I really believe cares more about the patient than how much he sells. That's, that's a hands down winner. So, you know, I think that you have to be very careful when trying to break into a market with the, with the people you hire. From a sales and clinical perspective, I think it's extremely important. Obviously, you have to have a good device. If you have the best device on the market, it makes it a little bit easier for the salesman. Yeah, but I seen small companies, you know, with very small market share move up very quickly. If they have a good device and they have the right, they have the right team. I've seen devices that are very, very good that fail because their team's just a bunch of used car salesmen. That's just my aside. I mean, that's, that's just how I deal with reps and, and my, my thought, it's a little off. Maybe not off topic, but off your, you know, the, the stream of questioning, but I would advise any company trying to break into a market like this that's pretty saturated with devices already to be very, very laser focused on hiring experienced people that really speak to what's best for the patient first.

[Sam]
Right. You know, that's, that's a very good point. Definitely, you know, like focus on sort of reliability and that attitude that they sort of show towards the product is definitely important, too.

[Dr. Caparrelli]
Yeah. Like I said, reliability, safety, some iterative change that makes it easier to use and then price. If you just come in and say, I've got a cheaper device than this one, and it's the same, someone's going to be able to try and find fault with it, or it might be better or it might be more convenient, but people like what they like, you know, there's a little bit of that. You know, there's some resistance. I mean, I even see it amongst my partners, you know, operations and procedures that are pretty straightforward and certainly, and are proven to benefit the patients, but it's hard to get them to change their ways because old dogs knew tricks, you know? So developing the appropriate sales and clinical team is important when you're. When you're introducing something new or something slightly different.

[Sam]
Right? Yeah. And speaking of things that are slightly new and slightly different, I think we have a couple more questions that we want to focus on with feature focus. So when you've used

bipolar energy devices in the past, again, primarily the basic ones, but just in general, have you found any features to be particularly helpful or unhelpful that you found? Because there's the core ones, like coagulation and cutting and fulguration and all those, but is there anything that you found particularly helpful that you've seen one device do that others haven't or unhelpful that a lot of devices do?

[Dr. Caparrelli]
Well, in general, I think that anytime that you can put more control into the surgeon's hands, the better. So, you know, for standard electric cautery, I have. I have a cautery that has a little slide clicker on the side so I can change the level of energy that I'm delivering. I used to have one where if you double click the button, then you could control it that way up and down. Otherwise, you've got to ask the nurse, can I have it on 40? 40. Can I have this? You know, can I have it on spread? Can I have it on, you know, pure cut, set it at the beginning of the case. So any. Any opportunity to. Just to make the surgeon more efficient, you know, because I use a different amount of energy when I'm opening the chest and when I'm taking down the mammary artery or when I'm operating near the heart or, I mean, you know, those sorts of things, I'm operating when I am operating near nerves or, you know, that sort of thing. So I think that's somewhat important. You know, one thing that's not handled very well with, with cautery devices is, you know, smoke evacuation. I mean, they make a big. People make a big deal about, you know, when you're, when you're causing, when you're coagulating tissue or cutting tissue, you know that there are carcinogens that are spread into the air, and there's a big deal on smoke evacuation. I have not found a monopolar, you know, uh, cautery type device that handles smoke evacuation very well because they get very cumbersome. You know, you want to have a nice small pen so that you can do fine work. And then they put this big vacuum cleaner on it. You know, it's, it's a pain in the ass. So, you know, when it comes to things like that, I think that, you know, whether it be handling fluids or not causing char of tissue and certain, you know, certain there are certain devices that can minimize the amount of char so your impedance doesn't go up, so you get greater depth of penetration, things like that. Again, I'm starting to now just throw out words, but in general, you put more utility in the surgeon's hands. It makes them more efficient. They like that. I like to be able to just go, beep. I'm at three, I'm at two, I'm at one, I'm at four, and off I go. If I had to stop every time and say, can someone come over here and push the button 30 times to get it from 30 to 60? That's, that's a challenge.

[Sam]
So in that sense, you're saying, so you're saying more control in the hands of the surgeon. But in some sense, you're also saying, like, improve, make the device simpler to use in, like, so the surgeon, yes.

[Dr. Caparrelli]
Simpler from a team standpoint. Right. You know, I mean, you know, if you're circulating nurse, you know, the nurse that's not scrubbed in at the table has to come and manipulate the generator as a million times a case. That's not simple. I mean, it might be, it might be the simplest construction of the pen or the clamp or the device, but it's not the simplest operation. So, again, but if you build a device that's got so many bells and whistles on it, so many buttons, that no one can figure out how to use it, then it just becomes a waste. So, you know, there's that sort of the feng shui of a device, so to speak, you know, how much utility do you put in the hand versus

how much engineering goes into that? How much cost goes into that? Because every wire and cable and everything that has to be insulated, et cetera, et cetera, is a higher cost and more opportunity to fail. You know, so, you know, that's where, that's where the. The engineering challenge comes in, is making a simple device with the most functionality. So, yes, simple, but more control. But there's, there. There's certainly things that are over engineered. I've seen plenty of devices, particularly and not necessarily or not at all with regard to, you know, energy delivery. But, you know, whether it be stents or, you know, other things where you're like, what the hell were these engineers thinking? These engineers have never stepped in an operating room. They have no idea what it is because, you know, on the back table, it seems great. They can turn the nose this way. They can do this, they can do that, they can do the other thing. You can partially deploy it, you can pull it back, you can do it, whatever. But the delivery system is a football this size. It's packaged in a box this big. And you look at it, and you're like, this is ridiculous. And it might give you all the utility in the world, but do you really need that 90% of the time? So you want something that's easy to use 90% of the time and has functionality to make the 10% of difficult cases a little bit easier. But if you overengineer for that 10% and make the 90% a pain in the ass, then you're shooting yourself in the foot. You're really over engineering the device.

[Sam]
Yeah, I mean, where I was really trying to go with that was like, so you mentioned that the generator has all these 0 to 100 percentage power levels, basically. And then you mentioned that on the actual clicker itself, you have power levels like one, two, three, and four. And it's simplified like that. But maybe you get a little bit less information on that about exactly how much power is in there. Maybe you set the settings beforehand and do configuration, but when you're actually in surgery, you don't have to think about like, hey, give me 75% power, and I need to think about how different that is in terms of 65% power.

[Dr. Caparrelli]
Right. Yeah. No, I mean, again, you know, I think, you know, what I'm talking about is, you know, is presets, you know, setting one. And so as an example for just standard electric cautery, my system has settings one, two, three, and four. And if you're on, click one. On setting one, it's like 15 cut and 15 coag[ulate]. And if you click up, it goes to 15 and 30, and then it goes to 20 and 40 or something like that. If you set the machine at two, then click one starts at like 40, and then you go to 60 and 80. If you go to. If you set the. So it's a combination of the setting on the, on the generator and then what the handle actually controls. So I'm not setting cut and coag independently on the dial. I'm clicking through a series of presets that are predetermined by the generator. Now, theoretically, you could have a generator that had custom settings, a doctor a setting and Doctor B setting and Doctor C setting. And all you had to do was press Doctor C and then Doctor C would know that clicks one, two and three. Did these three different things. And if you put it on Doctor B, those might be widely different. But then you have to be careful, because if the doctor thinks they're on Doctor C and you're on Doctor B, then you're delivering a ton more energy, you could cause difficulty. So that amount of customization is primarily over engineering, but knowing that you can ramp up or ramp down the amount of energy based on the handpiece, I think has some utility without making it fully customizable.

[Sam]
Right. And sort of in general, while we're thinking about what might be useful as features, what other features do you want to see in bipolar energy devices or monopolar energy devices? Really all of the above that would make them easier to use and more effective in the operator room?

[Dr. Caparrelli]
Well, I think that I said, for devices that generate a lot of smoke, smoke, an effective system of smoke evacuation is needed because it's being mandated in operating rooms. It's not been done well yet. I think that adjustability in length, as an example, you know, we, the cautery that I use, you know, you get a standard tip. If I want the medium tip, I got to open a second tip. If I need the really long one, I get a third tip. There is a device that has a little screw and you can extend and retract the plasma blade by Medtronic has an extendable, extendable tip. I think that's useful because one device functions, functions from six inches to twelve inches. I think, you know, that's not a new invention, but it would be something that, if you're looking at a device, is helpful and probably not terribly difficult to engineer. So some sense of customizability or being able to change on the fly, make incremental changes. Because again, if there's a tip that's this long and a tip that's this long and a tip that's this long, you might need something in between. And if you have a telescopic rod, then you can make it seven inches. When you need it seven inches, you can make it five inches when you need it five inches. Do you need all of those increments? Probably not, but I would bet that if I had one of those, I would probably, if I measured it every time, I would probably do it slightly different each time depending on how, you know, how deep the chest wall was and that a little bit beneficial there. Some tips are insulated to prevent tissue from being, being injured that you're not intending. I don't find those particularly useful, but I mean, that's something else that, again, when you're talking about, you know, you're talking about clamps like the LigaSure, you're really delivering the energy between the two clamps. So, you know, you really shouldn't be having too much, a ton of thermal spread with that and injuring tissues around. But, you know, different length devices, you know, you can get the tissues done, you know, get more tissue in the clamp, you know, ligate it faster, but then sometimes too long is cumbersome and then you're getting into trouble. So, you know, then you lose some of the ability to articulate. If you've got a long hook versus a small hook. Sometimes it's faster to a lot of small bites than one huge bite, depending on, you know, the anatomy. So.

[Sam]
I have about the size of the tip of the device. You said that if it's a bigger jaw, you're going to be able to grab more tissue, and that is useful in many cases. But one of the other surgeons that we spoke to also was talking about how it might be also useful to have a smaller jaw so you can get more accurate surgeries, you can do more fine work. Would that be useful in your practice as well?

[Dr. Caparrelli]
You know, I think that for what I use it for, the tips are pretty appropriate. You know, I'm just, I'm sort of thinking, you know, in general, you know, I mean, I think that when you're, when you're doing delicate work, when you're working around, you know, structures that you're really, you know, you need, you need good tissue, you know, coagulation or good cutting, but, but you're near vital structures, I think smaller tips could be a benefit. I probably wouldn't need them

because the work that I do with the device isn't that fine. But certainly I feel like I know that I've dealt with instruments being too long, and you're like, oh, if this were just a little bit shorter, I'd be able to get in there and do this or this or that or the other thing. For what I use the devices for, the ligature with the Maryland angled clamp is perfect. If I were ligating a lot of mesenteric vessels, a larger jaw that could really get the tissue more tissue effectively faster would be of benefit. I don't know to what surgery that surgeon was referring to, but certainly that's another opinion. I'm not saying vigor is always better. I'm just saying that, you know, and then, you know, the question becomes, you know, how much for a company that's innovating or doing product, you know, there, every time you have a. You know, if you have a different angle on the exact same length device, it probably has to be FDA cleared, you know, I mean, so it's a lot of work to have multiple tips to accommodate, you know, the preferences of a few, you know, so I think that's where you have to do. You have to do your due diligence and talk to, you know, hundreds of surgeons and see what works best for the majority, and you just can't worry necessarily about the one or two that have this great idea that works only for them.

[Sam]
Right? Yeah. And then so on top of that, one question that's just on our list that I forgot to ask earlier is how long did it take you to train to properly use bipolar energy systems, whether that's the advanced ligature, which you've used in the past, or the bipolar devices that you use now. A more interesting question, maybe, is how different is the training process? How much more difficult is it to use one than the other?

[Dr. Caparrelli]
I don't, you know, I don't think that they're particularly. I mean, they're not particularly difficult to use. And I think that, you know, I think you just have to understand. You have to understand the, you know, like with the LigaSure, or you grab the tissue, you squeeze the handle, you wait for it to beep, then you can pull the knife, you know? You know, the harmonic scalpel might be a little bit different. I mean, but you just have, you know, and I don't. I don't know what the harmonic does compared to the LigaSure and these other devices. Again, I'm not super well versed, but they're not devices that require a lot of training. You know, I mean, it's, you know, you're. You're grabbing tissue, you're staying away from stuff that you shouldn't put holes in, you're, you know, and as long as, as long as you're well instructed on the steps are, you know, grab the tissue, check the back, you know, check, make sure there's nothing, you know, inadvertently in the clamp, squeeze the clamp, and step on the pedal, whatever it is, push the button, then pull the, you know, pull the trigger. You know, it's. It's not a rocket. That part of it's not rocket science. So I don't think there's a whole lot of training that goes into using these devices. You just have to be familiar with them. When you get in the operating room and you might like one better than the other, you might find that one does the job a little bit faster or more confidently, you know, you might use one device and you get some bleeding, or you get, you know, you have to do the, you do the thing twice, or you pull the blade and it doesn't really cut it, you've got to do it again, or the tissue consistently comes out of the grasper because of tension or this, that, and the other thing. So that is experience, but it's not training, so to speak. It's just sort of getting a sense for the device. You don't have to take a test on this, on how to use these things. You just have to read the manual once or have somebody that's used before say, do it this way. But then how it feels in your hand and how it handles the tissue, that's an experiential thing, but not a training thing. So much in my mind.

[Sam]
Yeah. So one question that, I mean, really, this one just comes from me. So the primary difference between basic bipolar and advanced bipolar is really that there's a lot of sensing involved. So you have a lot of closed loop control in terms of level of heat, how much energy has been put through this wire, put through these two things like that. Is there anywhere in your practice where that sort of closed loop control of how much energy you're putting into the patient would be useful?

[Dr. Caparrelli]
I think it is. I do think that as opposed to looking, you know, to just a, you know, a bipolar, like a bipolar electrocautery, where you're just coagulating between the tips of basically forceps and a LigaSure, or you're getting that feedback, whatever it is, impedance, you know, conductance, you know, whatever algorithm it is, the generator is telling you that the tissue is safe to transect. I think that's really important. I mean, that's something that you know, again, in the. Is of paramount importance in what I do on the heart, because transmurality of the tissue destruction is of utmost importance. If you don't have transmurality, then you don't have blocking of the electrical signals. So I think those feedback loops or that that feedback that you get, whatever it is from the generator, I think is important in those advanced devices. I do think that's significant.

[Sam]
Yeah. Forgive me, I might need a definition here. Can you elaborate a little bit more on what transmurality is?

[Dr. Caparrelli]
So transmurality is getting the energy and the destruction of the tissue all the way through.

[Sam]
Okay.

[Dr. Caparrelli]
So in the heart, you know, the hearts of muscle, again, this is a little bit different than the ligature. I'm not cutting holes in the heart with. And they've got a slight hook on them. So you basically clamp around the veins of the heart, the big veins of the heart in the back graft. And when the impedance drops or the conductance, where the conductance shocks, the impedance goes up to a certain point, it shuts off, and it basically tells you that you've delivered enough energy through that tissue to ablate all the way through that tissue. And when you do that, electrical signals, it forms a scar, and the electrical signals cannot pass through. So this is a device that is used to block electrical signals on the heart to treat irregular heartbeats, but it is a bipolar, by definition, is a bipolar radio frequency device, but it doesn't end up cutting the tissue, but it ends up delivering energy from clamp to clamp through the tissue, and it makes sure that everything between that clamp is dead.

[Sam]
Right. So that's the device that you currently use.

[Dr. Caparrelli]
Right. That's what I use on the heart. Like I said, it's very different than the LigaSure or those kind of devices, but it is a transmural RF delivery system, and the feedback is very important because you have to make sure that the energy has been delivered and that all the tissue between the clamps is non viable.

[Sam]
Right. So you mentioned a few times during this interview about, like, heart valves, basically, and that you, I mean, as a cardiovascular surgeon, I'm sure you do a lot of work with replacing heart valves. Is there anywhere in those sorts of surgery outside of the, we've just spoken about with the transmural RF device, where close loop control might be useful, whether that's cutting through, maybe removing the old valve, maybe there would be some use for that? Or is it primarily visual control that you want to have?

[Dr. Caparrelli]
So when you're talking about? It's an interesting question. Most of what I do, with the exception of the surgery for arrhythmia, most of you know, most of what I do is done sharply with a knife or a scissor on the inside of the heart. So that kind of closed loop control ablation, cautery inside the heart, I don't see as being useful in too many situations. There are a couple of, couple of situations where you're resecting some muscle from the inside of the heart where that kind of, that kind of energy delivery and enclosed loop control could be important. But those are very, very rare, unusual types of surgeries and the standard cardiac operations that are going on every day, that would be profitable for a company to be involved in. I don't see bipolar rf as being particularly useful, with the exception of, like I said, the arrhythmia surgery, which, you know, AtriCure is pretty much cornered the market at the moment on that.

[Sam]
Right.

[Dr. Caparrelli]
I think Medtronic has some devices, but they're not widely used.

[Sam]
Yeah.

[Dr. Caparrelli]
And there are ones that are cooled with saline and things like that so that you don't get char and you're able to deliver more energy. But that was an old school way of sort of preventing the device from shutting down too fast, because if you deliver too much energy too fast, the tissue gets too hot, you char the tissue and then the energy delivery stops or you excessively damage the tissue. So there's been saline, cooled, rf and those sorts of things, but they have not panned out, as well as the clamping device, the bipolar clamping devices that are currently used.

[Sam]
Yeah. So out of curiosity as well. So when you're trying to reach the heart. So when you're doing your cutting from the outside going in, is there any need to, like, make it more simple? Make that

process more simple? So you mentioned that it's, I mean, you use the bipolar device to cut through skin and then use it to cut through, like, tissue and then use it to, like, cauterize blood vessels along the way. Is there any need to have a device that's easier to use for that specific process.

[Dr. Caparrelli]
You know, in general, that is not a particularly long part of the operation with current tools. So I don't see a lot of, a lot of utility in engineering something for that purpose. You know, I, I did use, there was a thing called. What is it? Medtronic made. It was a saline cool thing. I can't remember what it was called, but I used it to sort of, sort of pre-cauterize blood vessels before I cut through them, and it was saline cooled. It was a dual pronged. I can't remember what it was called, but anyway, I used that, and I. And it took me longer to get in, but I thought I was getting in, you know? It was better because there was sort of less bleeding and less spot cautery that I had to do, but I ended up with a lot of. A lot of tissue damage ultimately, and seromas and wound problems. So I think in general, you know, you use a knife to get through the skin, you use standard cautery to get down to the bone, and you cut the bone with a saw, and then you're in the heart. So, I mean, I'm not sure there's much more there to.

[Sam]
You, Doctor Caparelli. Or maybe I should call you David.

[Dr. Caparrelli]
Yeah, please.

[Sam]
Fine. Yeah, yeah. Thank you so much for your time.

[Dr. Caparrelli]
I hope it was helpful. Like I said, you know, my experience is not as robust because I don't do some of the surgeries that a lot of these devices are used for. But in general, you know, I understand the technology, I think, and at least I understand some aspects of bringing product to market and what excites surgeons and what doesn't. So I hope it was, you know, I hope it was helpful. If there's that survey you'd like me to fill out, I'll be happy to do that as well. And if there's ever anything you ever need, please let me know.

[Sam]
Thank you very much. Yeah. Thank you very much. Yes. Because like, all the surgeons we've spoken to in Taiwan, I mean, maybe this is just like what they're doing differently, but so many of them seem to use the advanced bipolar devices. Maybe that's just selection bias because we're talking to the people who are making it their friends, but. And then in the US, there's so relatively few that do. Again, I think it's just like the difference in what operations are being performed.

[Dr. Caparrelli]
Well, yeah, it might be that. It also might. It might be cost, you know, because stuff tends to be a hell of a lot more expensive in the. In the US because of everything you have to do with the FDA, et cetera, et cetera. And there's a certain amount of hashtag old school thinking in, in

training surgeons, you know. So just to give you one example, you know, when you sew in a new heart valve, you put it in like 15 stitches, you know, into the heart, and then you put the stitches through the new valve and then you lower the valve into place.

[Sam]
Right?

[Dr. Caparrelli]
Now, the way I was taught, each one of those stitches received seven knots and they had to be done a certain way. And the doctors would watch you do seven knots this way, that way, this way, that way, this way, that way. And seven knots times 15 stitches is a lot of knots to sew. You know, there's now a device called the core knot, which basically fires a titanium clip down on this, on the suture, and crimps it. It takes a second and a half to do, you know, one stitch. So it takes me 15 seconds to do 15 stitches, as opposed to 90 something knots, which probably takes me five minutes. But doctors at academic centers are like, well, surgeons need to know how to sew. So they know how to sew. They need to know how to tie. Well, yes and no. When you used to sew intestines together, that used to be two layers of, like, silks and then vicral sutures and then another row of silks and everything hand tied 100 different times. Now surgeons go, staple, staple, staple, and these staple lines never leak. And you can do an anastomosis in 15 seconds instead of 30 minutes, and they're more reliable. But if you only teach doctors how to staple, then they never know how to sew. So I think in the US, I think people are. This is how I did it, so this is how you. You should do it. And then people are just sort of adherent to the old school way of doing things, even when it's not necessarily the best or what is cutting edge. Whereas in Taiwan, Japan, or some of these other countries that are more innovative, this device works and boom, they do it. And they have large populations and they're at big centers sometimes doing thousands and thousands of cases, and they do them very efficiently. But to then break into the US market with that kind of device, you know, you have to break a lot of tradition.

[Sam]
Yeah. Also there's a lot of cultural. Yeah, it's a little bit cultural, but also, like, where, as we're finding in our project, there's a lot of legal as well. Like patent law can make it very difficult to break in, and the FDA in the first place as well, like, yeah, between. Between those two, it's very, very difficult to break into the US market, even though it is like a very, very potentially lucrative. Excuse me, very potentially lucrative market. It's very expensive.

[Dr. Caparrelli]
Yeah. What you find, particularly, I think, with device in particular, is that the US might have the best medical care in the world or the best health system. I mean, I won't say our insurance system is the best, but people think of the Mayo Clinic, they think of Cleveland clinic, they think of these massive places and some of the best surgeons in the world. There's some of the best doctors in the world. But when it comes to device, I think we're easily ten or 15 years behind Japan, Europe, even South America, where a lot of it's a third world. But you can get devices down there that you can't get in the United States because the FDA, it's just such a huge burden. So, I mean, that's why a lot of device companies, you know, Medtronic and Abbott and all these companies have moved to Ireland, you know, because the taxes are better. They can get product to market with whatever, 510K approvals and CE marks and those sorts, you know, these are

different. I'm not fully versed, but this is kind of stuff that I've heard, you know, so, you know, you know, valve surgery, you know, from the groin, you know that people from the US were going to Germany to learn how to do it. They've been doing it for ten years, more than we've been doing it, which is hard to believe, given all of the resources, and that so many of the companies that develop these products have to take them to Europe or to South America to trial them, and then they have to come back and do the trials again because the FDA won't accept European trials as data. You know, they'll allow you to do the trial in the US because of trials in Europe, but they won't approve a product because, like, Europeans are not humans, you know, I know getting into Japan is very difficult. Difficult, too, I think, for cost reasons. For a lot of these companies, they have a hard time breaking into the Japanese market, but they're also very innovative there, too. I mean, I've lectured in Japan and, I mean, they were doing stuff that, you know, I could only dream about doing. But their patient population is also very different. So sometimes there are cultural differences, their body habitus differences, their diet differences.

[Sam]
Their.

[Dr. Caparrelli]
Health system differences that affect, you know, bringing products to market. But the US is difficult. It really is.

[Sam]
Yeah, very much so.

[Dr. Caparrelli]
That's what you're finding out, I guess, right? An exciting project, though.

[Sam]
Yeah, it's a lot of fun.
[Dr. Caparrelli]
Yeah.

[Sam]
Because, I mean, for one thing, we're in beautiful city here in Taipei. We're talking to so many, like, really smart people in, you know, the Taiwanese medical field.

[Dr. Caparrelli]
Yeah, it's really. It's really cool. It's really exciting to see.

# Appendix H: Social Survey Results – Extra Graphs

Figure 22 looks at the effect of age on device preference. It shows that 20% of the 18-30, 10% of the 31-45, 24% of the 46-60, and 15% of the 61+ age group chose reusable devices. The graph indicates a relatively greater number of reusable selections in the 18-30 and 46-60 age groups. However, this difference wasn't quite significant, as every age group still demonstrated a notable preference for disposable devices.

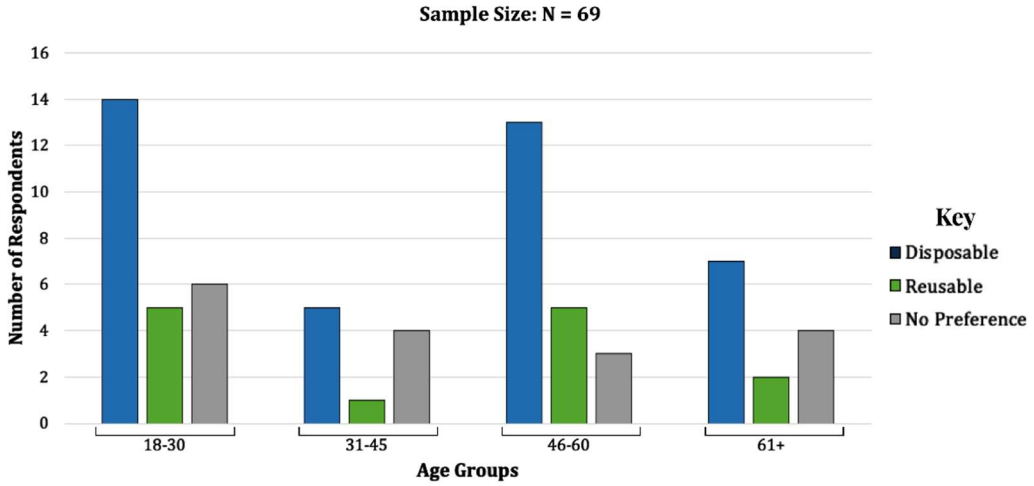


*Figure 22: Effect of Age on Device Preference*

Figure 23 shows the effect of Income (USD) on Device Preference. As observed in the figure, there is no direct correlation between the income and the device preference.

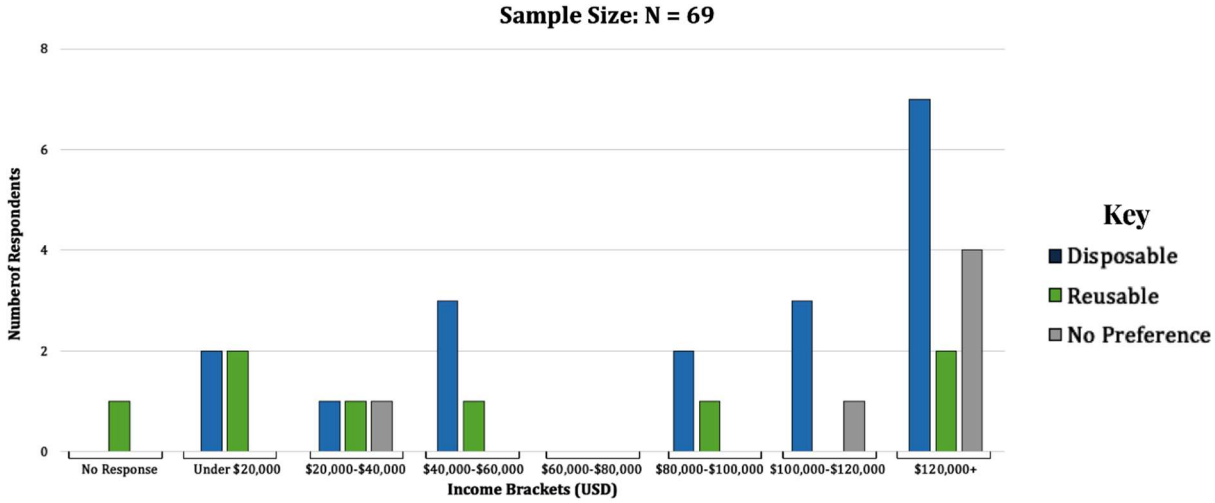


*Figure 23: Effect of US Income on Device Preference*

Figure 24 shows the effect of Income (NTD) on Device Preference. As observed in the figure, there is no direct correlation between the income and the device preference.

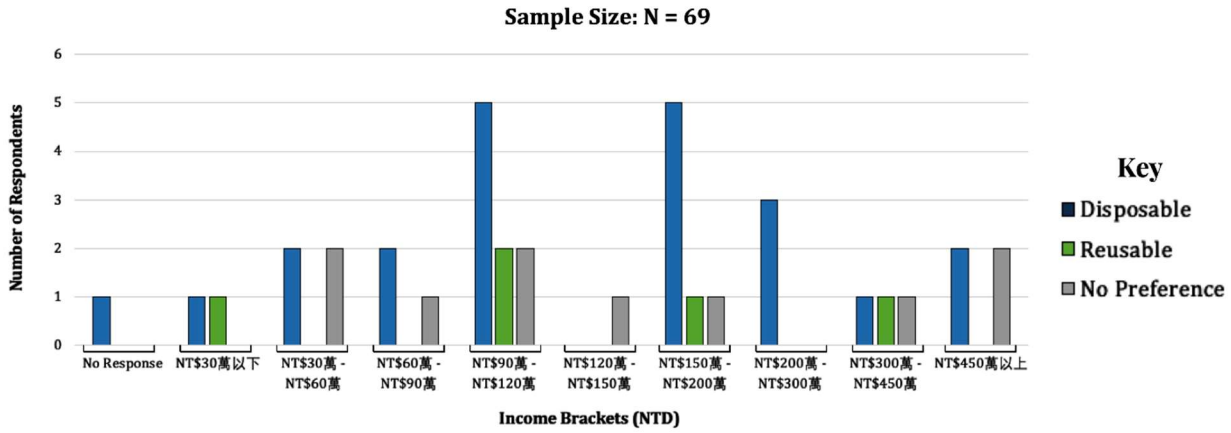


*Figure 24: Effect of Taiwan Income on Device Preference*

Figure 25 shows the overall distribution of survey responses on the device and procedure. From the data, only 56% of the survey respondents had undergone surgery before, indicating that a significant portion of the population surveyed had not experienced surgery. Among those who had undergone surgery, 41% knew about the procedure, while 26% knew about the device used. This difference suggests a potential gap in information provision regarding the devices used in surgical procedures, as fewer respondents received information about the devices than the procedure.

According to the requirements of Informed Consent for a medical or surgical procedure necessitates that the operator (i) ensures that the patient possesses the ability to comprehend and make decisions, (ii) provides the patient with complete information, (iii) confirms that the patient understands the information, (iv) allows the patient to act of their own free will, and (v) prove that the patient agrees to the proposed course of action (Varkey, 2020). The complete information includes the patient's procedures and the devices used in that surgery. However, the extent of information given may differ based on the patient's preferences and the complexity of the treatment. Certain patients may desire comprehensive information on the surgical instruments utilized, while others may choose a simpler explanation. Healthcare providers may need to improve communication to ensure that patients are well-informed about both the procedures and the devices used in their surgeries.

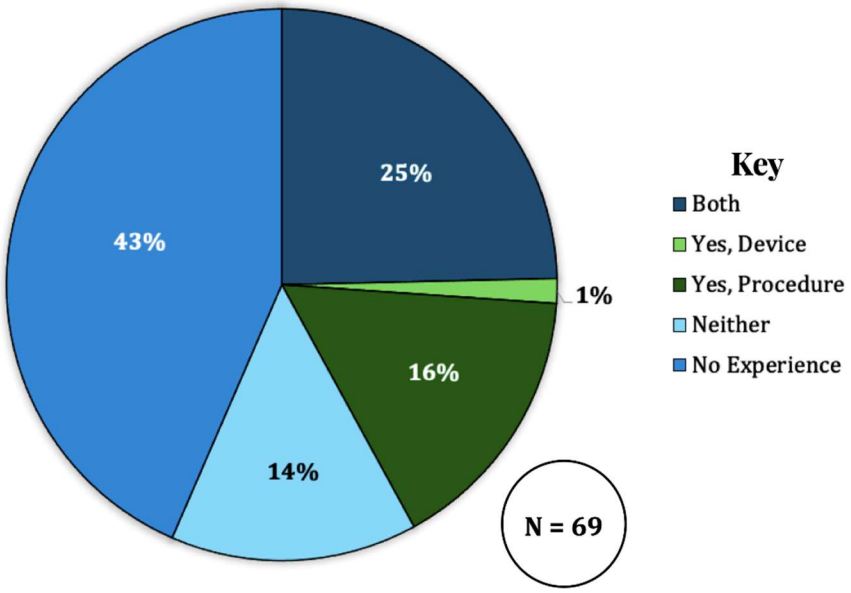


*Figure 25: If you have ever undergone surgery, were you provided with information about your surgical procedure and the devices used to perform it?*

From Figure 26, we can see that approximately 60% of the 18-30 age group had no experience in undergoing surgery. Notably, the youngest age group, 18-30, was the least informed, with 20% having neither knowledge of the procedures or devices, and this accounted for 50% of neither knowledge data of the total sample population. Overall, the data suggests that information provision regarding surgical procedure and the devices used varies across age groups, with older age groups generally having more experience, particularly with both the procedure and device, compared to younger age groups.

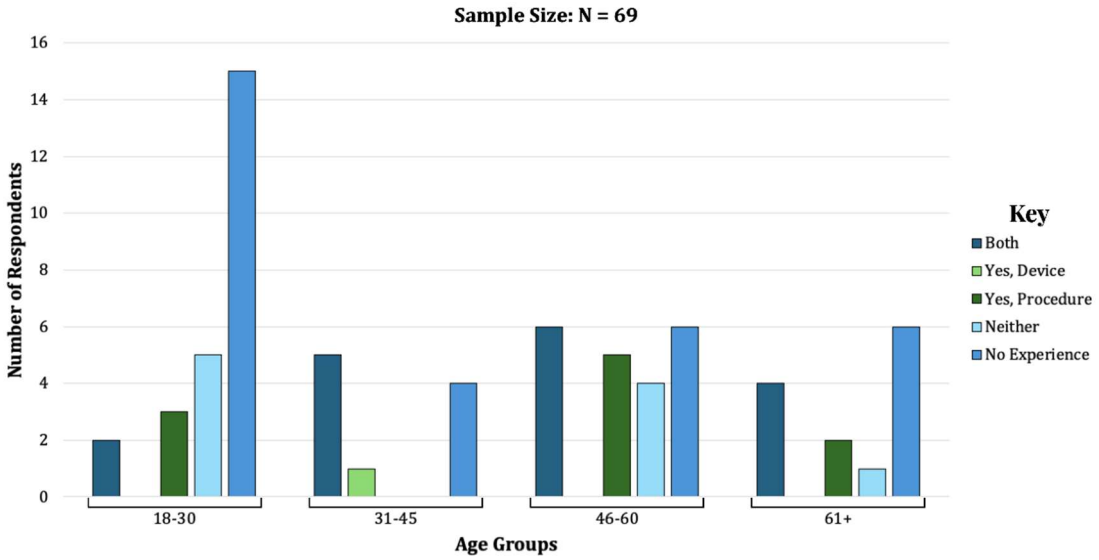


*Figure 26: Effect of respondent's age on information about surgical procedure and devices.*

As seen in Figure 27 Safety was consistently ranked as the most important priority (closer to 1) among all age groups. This suggests a universal concern for the success rate of surgeries, the minimization of postoperative complications, and the long-term effects of surgical procedures. Overall, Figure 28 indicates that regardless of age demographics differences, safety is a crucial factor that the survey respondents prioritize highly when considering surgical options.

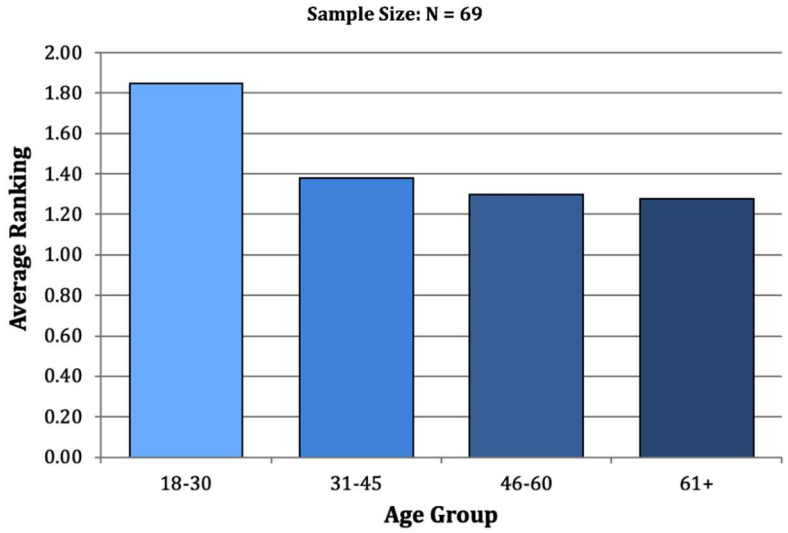


*Figure 27: Effect of Age on Average Ranking of Safety*

Figure 28 shows that the importance of cost decreases with age. Younger age groups (18-30 and 31-45) find the cost of surgery more important as seen by the lower rankings, while older age groups (46-60 and 61+) find it less critical.

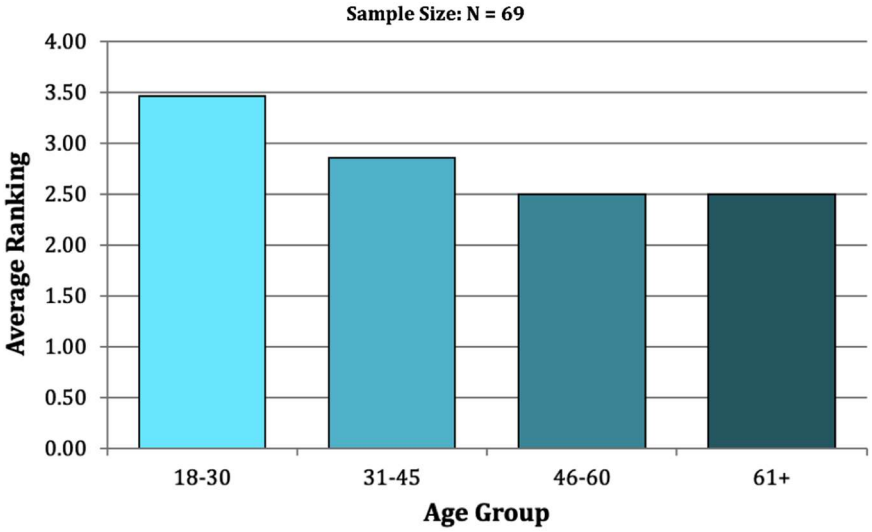


*Figure 28: Effect of Age on Average Ranking of Cost of Surgery*

Figure 29 looks at the effect of age on average ranking of ethically sourced materials. It shows that the lower older age group, 46-60, ranks ethically sourced materials as the highest priority, indicating a greater concern than other age groups.

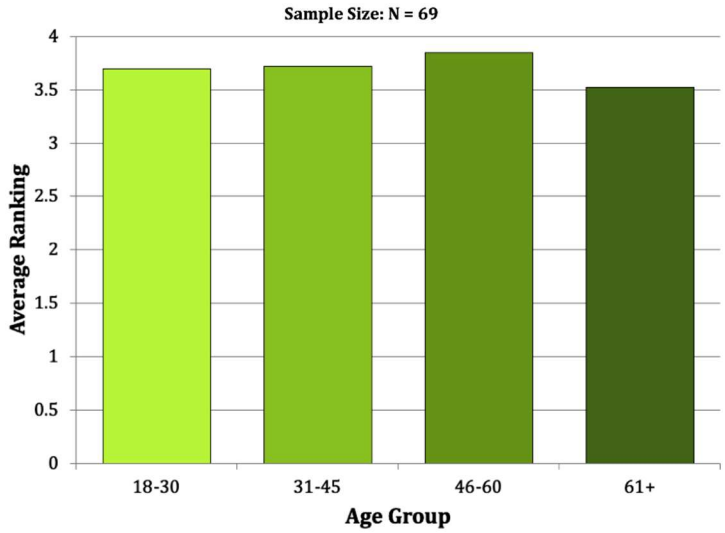


*Figure 29: Effect of Age on Average Ranking of Ethically Sourced Materials*

Figure 30 looks at the effect of age on average ranking of the usage of the latest technology. Interestingly, it shows that the 61+ age group shows more interest in the usage of the latest technology in surgery, as indicated by the lowest average ranking (higher importance). This data suggests that older adults place a significant value on technological advancements in their

medical treatments, potentially due to a higher appreciation for how they could improve treatment outcomes and the quality of life.

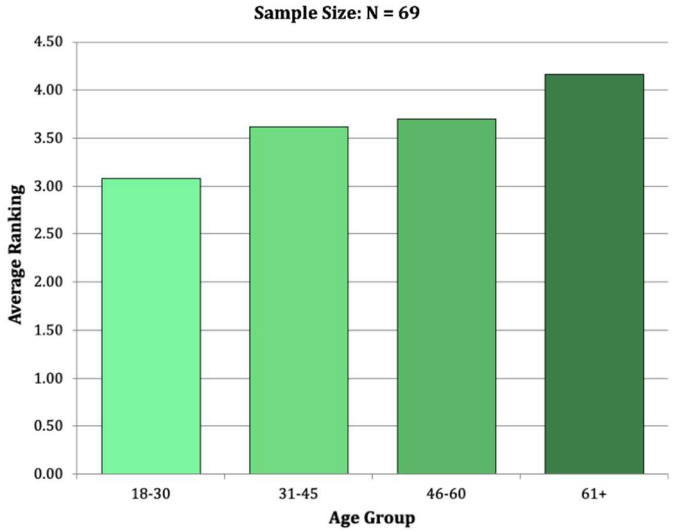


*Figure 30: Effect of Age on Average Ranking of the Usage of the Latest Technology*

Figure 31 shows that while there is a slight decrease in the importance of environmental impact as age decreases, the differences across age groups are not significant. All age groups express similar levels of environmental concerns towards the impact of discarded surgical tools.

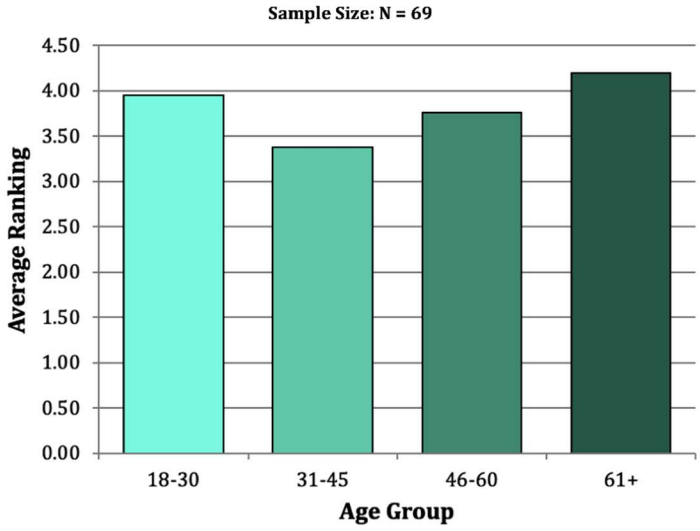


*Figure 31: Effect of Age on Average Ranking of Environmental Impact*

From Figure 32, 72% of the survey respondents would consider and prefer environmentally friendly materials for the surgical device, if possible, when asked what they would like to use for their operation.

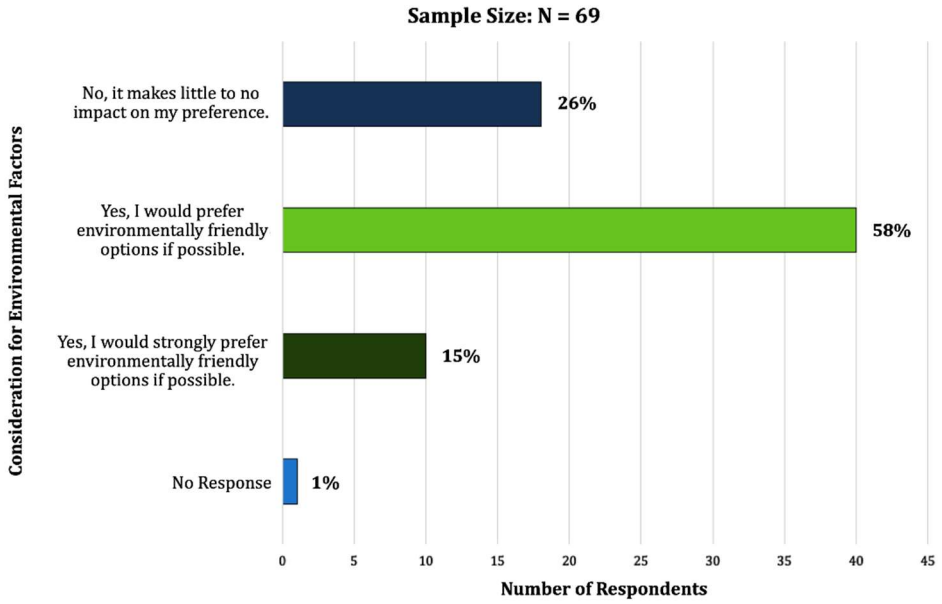


*Figure 32: If you were a patient choosing which surgical device would be used for your operation, would you prefer one with environmentally friendly options?*