WORCESTER POLYTECHNIC INSTITUTE

WPI

Product Launch Analysis for an Ergonomic Scalpel Handle

A Major Qualifying Project

Submitted to the Faculty

Of

WORCESTER POLYTECHNIC INSTITUTE

In partial fulfillment of the

Requirements for the degree of

BACHELOR of SCIENCE

By

Audrey Berner, Sara Beauchesne, Mustafa Eracar, Thomas King,

Isabella Speer, and Johanna Whitwell

Submitted on April 6, 2021

Sponsor: Raymond Dunn M.D.

Advisors: Professor Walter Towner Ph.D.

Professor Edward Gonsalves

Mark Robichaud

Torbjorn Bergstrom Ph.D.

Abstract

The objective of this project was to develop production and marketing recommendations to bring the ergonomic scalpel handle to market. The rationale was two-fold: the ergonomic scalpel handle has significant technical advantages, and the design is ready for production assessment and testing. The methods used include evaluating recommendations from previous MQPs to select materials and finalize grip design. Using research, interviews, and pilot testing, we developed cost structures for three separate manufacturing possibilities: machining, additive manufacturing, and injection molding. The results showed that the ergonomic scalpel handle should utilize injection molding. The conclusion is that additional customer testing is required to finalize the design prior to production.

Acknowledgements

Our team would like to thank the following individuals:

- Our advisors, Walter Towner, Edward Gonsalves, Mark Robichaud, and Torbjorn Bergstrom for their support and dedication throughout our project.
- Dr. Raymond Dunn for his sponsorship, excellent guidance, and contacts at KLS Martin and UMass Medical.
- All our interviewees, whose insight was invaluable to our work.
- Previous MQP teams that laid the groundwork for our project.
- And special thanks to Carl Mills for support and guidance throughout the prototyping process as well as material donation.

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Executive Summary

The need for high-quality ergonomic tools is growing exponentially alongside developing technologies in modern medical fields. This includes the commonplace but versatile scalpel, which has seen no significant innovation since it was first designed in 1914.

Dr. Raymond Dunn ‘78, our sponsor and a practicing plastic surgeon at UMass Memorial Medical Center, recognized a personal and general need for more ergonomic surgical tools. His design for an ergonomic scalpel handle takes into consideration the shape, grip, weight, and balance of the handle. For our project, we considered the market environment, cost, and manufacturability of this scalpel design. This project evaluated both a one-use disposable plastic handle and a multi-use reusable metal handle.

To better understand the scalpel market and help Dr. Dunn in his mission of launching his own scalpel design, our team conducted a PESTEL Analysis. With the support of Professor Bergstrom, we conducted a segmented trial run for manufacturing the ergonomic scalpel handle. From this, a stainless steel scalpel “blank” that imitated a rough likeness to the ergonomic scalpel handle manufactured by KLS Martin was produced without a silicon overlay. We gathered cost information accounting for the labor, material, and machining associated with the small pilot run. A significant deliverable of this MQP was to complete an analysis of potential manufacturing methods for the ergonomic scalpel handle at initial and scaled volumes. The costs of additive manufacturing and injection molding methods are detailed in our cost comparison.

Building upon conclusions made from previous MQPs, we aided Dr. Dunn in designing a plan to launch production and meet potential future demands. This production plan included relevant cost and scaling information. We also developed documentation and recommendations to guide future decisions concerning marketing, scalability, and integration into the market. Finally, we created but did not deploy survey metrics to gather data from practicing surgeons who will be given product samples. This data should be used in the future to convey the qualitative and quantitative benefits of the ergonomic scalpel handle.

Chapter 1: Introduction

1.1 Introduction

The need for high-quality ergonomic tools is growing exponentially alongside developing technologies in modern medical fields. This includes the commonplace but versatile scalpel, which is used across the world every day in surgery. Considering the scalpel's widespread use, it is surprising that there have been no significant changes made to the traditional flat handle since it was first designed in 1914 (Brill & Harrison, 2018).

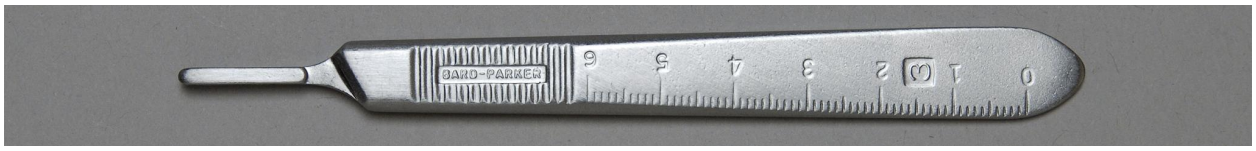


Figure 1. Bard-Parker Surgical Blade Handle Size 3 371030 (Aspen Surgical, 2021)

A flat handle design limits the surgeon's range of motion and grip, making it difficult to complete circular or curved cuts. These cuts require twisting and manipulation of the handle. Additionally, the flat metal handle may become uncomfortable for the surgeon, compromising the safety and precision of the procedure.

Dr. Raymond Dunn '78, our sponsor and a practicing plastic surgeon at UMass Memorial Medical Center recognized a personal and general need for more ergonomic surgical tools. Formed in 2011, his company 5G Medical holds multiple medical device patents, including the ergonomic scalpel handle. His design takes into consideration the shape, grip, weight, and balance of the handle. For our project, we considered the material options, cost, and manufacturability of this design. It is our hope that this new design will lead the switch from uncomfortable handled instruments to more ergonomic tools for general surgical use.

1.2 Problem Statement

The goal of any ergonomic design is to minimize user discomfort and error while increasing productivity. This design philosophy is increasingly being used in new areas of the market where it previously had not been considered. Tremendous business opportunities can be found when ergonomic designs are applied to long-standing products that are considered industry standard. One product that has not changed design in over 100 years is the surgical scalpel. Dr. Dunn created and patented a design for an

ergonomic scalpel handle. The ergonomic scalpel handle is still in developmental stages and requires a solid business plan that focuses on trial testing, manufacturing, and marketing prior to market launch.

1.3 Project Goals and Objectives

The goal of this Major Qualifying Project (MQP) was to assist Dr. Dunn's preparations to bring his ergonomic scalpel handle to market. To achieve this goal, our team provided final recommendations on the material, design, and overall manufacturing process for the ergonomic scalpel handle. Guided by the work of previous MQP projects and our own research, we designed a plan to manufacture the scalpels to meet potential future demand. This manufacturing plan included relevant cost and scaling information. We also developed documentation and recommendations to guide future decisions concerning marketing, scalability, and integration into the market. Finally, we created but did not deploy survey metrics to gather data from practicing surgeons. This data should be used in the future to convey the qualitative and quantitative benefits of the ergonomic scalpel handle.

1.4 Scope and Deliverables

This project built on several previous MQPs related to Dr. Dunn's ergonomic scalpel handle. These projects were completed by interdisciplinary teams, including Biomedical Engineers, Mechanical Engineers, Industrial Engineers, and others. In chronological order, the previous MQPs focused on handle design (2010), product commercialization (2014), weight and balance adjustments (2020), and grip design (2020). Our project was intended to solidify production recommendations and finalize 2020 MQP recommendations. The project deliverables were as follows:

- Finalized scalpel computer aided design (CAD) modeling, grip pattern, and material
- Prototype(s) for marketing purposes
- Cost comparison of manufacturing processes
- Production run manufacturing process recommendation with scaling predictions
- Marketing strategy and useful marketing, regulatory, and sales documentation for the ergonomic scalpel handle (including a prepared survey for future deployment)
- Final project report, poster, and presentation

1.5 Project Timeline

This project was completed over the course of the 2020-2021 academic year from August 2020 to March 2021. Work was completed over three Worcester Polytechnic Institute (WPI) terms (A-term,

B-term, and C-term) and during Winter Break. Regular weekly meetings were held with project advisors. We also conducted biweekly meetings with the project sponsor. Project work was separated into terms as follows:

- A-Term: Project definition, review of previous MQPs, KLS Martin project evaluation and contacts
- B-Term: Prototyping with machining, axiomatic design decomposition, grip design reviews, expert interviews (medical device sales, purchasing, design, production, and sterilization)
- Winter Break: Paper drafting, additional interviews, prototyping with additive manufacturing
- C-Term: Manufacturing process cost comparison, finalized recommendations, final paper, poster, and presentation

1.6 Traditional Scalpel Background

A thorough understanding of the traditional scalpel handle is necessary before recommending future innovative designs. Our group investigated the impact, production, sterilization, and historical timeline of traditional scalpels and ergonomic medical tools.

1.6.1 Scalpel History

The surgical scalpel is one of the world's oldest medical instruments. Sharp-edged knives intended for surgical use have been uncovered by archaeologists and date back to as early as the Paleolithic and Neolithic periods (10,000 BCE – 8,000 BCE). Common materials used in these ancient scalpels include flint, jade, and obsidian. Archaeologists unearthed an obsidian blade in ancient Anatolia (modern-day Turkey) that dates to 4,000 BCE. It was likely used for craniotomies, surgeries involving the opening of the skull (Brill & Harrison, 2018). Fracture and flake techniques were used to sharpen these surgical tools. Some obsidian blades have even been found to exceed the sharpness of today's scalpels (Figure 2).

Figure 2. Ancient Obsidian Blade Used for Craniotomies (Shadbolt, 2017).

As human technology developed, so did scalpel design. Copper scalpels replaced sharpened stones around 3500 BCE; bronze and iron scalpels replaced those around 1400 BCE. The ancient Greek physician Hippocrates was the first to describe the scalpel. He compared it to the machaira, "a broad cutting blade with a single edge and a sharpened point" (Brill & Harrison, 2018). This description is similar to the modern-day definition of the scalpel, "a pointed knife with a convex edge" (Brill & Harrison, 2018). The name "scalpel" comes from the ancient Roman word *scallpellus*. This is derived from the Roman word *scalper* meaning "incisor" or "cutter" (Brill & Harrison, 2018).

In the 14th and 15th centuries, the Renaissance brought about more specialized scalpels with innovative design features, including fixed and folding blades and specialized tips. The evolution of the scalpel and its design culminated in 1914 with Morgan Parker, a 22-year-old engineer who invented the two-piece handle and blade design that is used to this day. Parker partnered with the business-minded C.R. Bard to found the Bard-Parker company. The scalpel they developed is the industry standard in surgical scalpels today. Few changes have been made to this design since its inception (Brill & Harrison, 2018). Stainless steel replaced carbon steel due to its corrosion resistant qualities, and retractable blades became a more common safety feature. Except for these minor alterations, the Bard-Parker design has been largely unchanged for over 100 years. Ergonomics have had little influence on the scalpel's modern design.

1.6.2 Ergonomic Medical Tools

While ergonomics has had a large influence on the design of tools and equipment in many industries, it has yet to be seriously introduced into the medical field. In the limited areas of the medical field where ergonomic designs have been introduced, they were created with patients in mind. The use of ergonomic design for practitioners has not been a significant focus. A 1999 study conducted over the course of a year found that at least 44,000 people died in the United States due to medical errors in hospitals (Stone & McCloy, 2014). Some of these errors may have been attributed to the stress and fatigue associated with long term use of surgical equipment (Stone & McCloy, 2014). This shows both a need and an opportunity to develop ergonomic surgical tools.

1.6.3 Applicable Incisions

Multiple characteristics differentiate surgical incisions. They vary by size, shape, depth, location, and other features. For example, some procedures involve a curved surface-level incision, which is commonly used in skin lesion removal. Skin lesions are areas of the skin that are different from the surrounding skin. They can be anything from lumps or sores to skin cancer. Each type of lesion calls for a

unique removal technique. Lesions that reside in the deeper levels of the skin, like skin cancer, require skin excisions that remove not only the entirety of the lesion, but also a 3 to 4 millimeter margin of tissue surrounding it. In this procedure, surgeons typically remove an elliptical area that encompasses the lesion (Lehrer, 2020). With the traditional flat handle scalpel, surgeons rotate the scalpel between the thumb and fingers to create a curved elliptical shape. This, along with all incisions, requires complete control over the surgical tool. Surgeons must keep the blade cutting at a 90-degree angle to the skin to avoid slicing and devascularization of the thinner side of the incision (Lehrer, 2020).

The standard Bard-Parker scalpel has a flat handle that does not lend itself well to rotation. The design of Dr. Dunn's curved ergonomic scalpel handle would fare better in these types of situations because it can be rotated more easily and naturally. Consumer research performed during a 2014 WPI MQP provides anecdotal evidence of this benefit. While being interviewed about the ergonomic scalpel handle, a resident of UMass Memorial hospital suggested that a "real use for this new scalpel is to make curved incisions…" (Comeau et al., 2014). However, one concern that emerged from the consumer research was that the scalpel handle was large and might obstruct a surgeon's view during deeper tissue incisions. The residents of the hospital and the 2010 MQP group concluded that the ergonomic scalpel handle would be best suited for plastic surgeons (Brown et al., 2010). Plastic surgeons commonly make surface-level curved incisions, and they require a great deal of control over their instrument to avoid as much scarring as possible.

1.6.4 Handle and Blade Production

Traditional scalpels are often made from stainless steel and are meant for reuse, unlike their single use plastic counterparts. These scalpels use various steel alloys made up of two parts, a handle and a disposable blade. Blades are typically made from stainless or high carbon steels. This steel is tempered, or heat treated, to reduce the brittleness of the blade and achieve the flexibility required for surgical operations (Dossett & Boyer, 2006). Blades are made with slots that fit into scalpel handles (Figure 3).

Figure 3. Various Bard-Parker Scalpel Blades (Aspen Surgical, 2021)

With this feature, scalpel blades can be replaced to uphold a one-time use policy. This is done to ensure the sharpness of the blade for each unique surgical procedure. Both scalpel handles and blades come in a variety of shapes and sizes. For surface level incisions, numbers 15, 10, and 11 blades are used most frequently. The Bard-Parker number 3 and 7 handles are most often used with the number 15 blade for dermatosurgery and plastic surgery, respectively. These generic scalpel handles are flattened and not rounded. They are made of stainless steel and are reusable with each procedure (Chandra et. al, 2018). To be used in a procedure, a scalpel handle and blade must first be sterilized.

1.6.5 Sterilization

Some medical device components come pre-sterilized, like scalpel blades. Others must be sterilized on-site, like reusable scalpel handles. There are several ways to sterilize a piece of equipment, including heat, cold, and radiation methods. The most used sterilization process in hospitals is steam sterilization. This is because steam sterilization is comparatively safe, inexpensive, and reliable (Rutala & Weber, 2019). Autoclaves introduce steam at either the top or sides of the chamber and force air out of the bottom. To sterilize a piece of equipment, like a stainless-steel scalpel handle, the autoclave must reach a required temperature and sustain it for a designated period. Typically, a temperature of 121 degrees Celsius or 132 degrees Celsius is used in the autoclave for 10 minutes and 4 minutes, respectively (Rutala & Weber, 2019).

These metrics are used to ensure the medical device's safety. Safety in this situation is measured in SAL, or sterility assurance level. SAL is the probability of a single microorganism being on the device after sterilization. The standard SAL for surgical scalpels is 10^{-6}, or a one in a million chance that a microorganism is present on the device (Rutala & Weber, 2019). Throughout the autoclave process, surgical scalpels must remain mainly unchanged by the process. Scalpels made of stainless steel can withstand the steam sterilization process; however, some plastic medical devices cannot. Cold or radiation sterilization are used in these situations.

1.7 FDA Regulations for Surgical Tools

Due to the high level of risk associated with design and introducing new surgical equipment, Food and Drug Administration (FDA) regulations play a key role in innovation and design. The ergonomic scalpel handle will be used in surgeries; therefore, it must meet the high standards set by the medical industry and specifically the FDA. This section explores the standards and processes that must be followed to introduce a new medical device or tool.

When the FDA considers new Medical Devices, it breaks them down into three classes. Each class is subject to different requirements and levels of scrutiny. If the product is a new version of a pre-existing device, the device class can be found in the FDA classification database. According to the Code of Federal Regulations Title 21 Section 878 Subpart E, a scalpel is considered a Class I device (CFR - Code of Federal Regulations Title 21, 2020). This section also specifies that scalpels are "exempt from the premarket notification procedures," which means that the ergonomic scalpel handle will not be required to complete the 510(k) premarket application for approval (CFR - Code of Federal Regulations Title 21, 2020). Without this exemption, the device would need to be submitted for a 90 day review. The scalpel will instead be considered in regulations in Parts 868 through 892 and Limitations in 878.9 (CFR - Code of Federal Regulations Title 21, 2020).

The limitations dictate that manufacturers of a commercial Class I device exempt from premarket notification must still submit a premarket notification when:

a. "The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only;
b. "The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade." (FDA, 2021).

Because the ergonomic scalpel handle is a new version of a pre-existing device that is intended for use in the same way, it is still exempt based on the requirements stated above.

Class I devices are required to comply with labeling requirements. The FDA will regulate the ergonomic scalpel handle's labeling procedure, approved labeling, sterilization validation procedure, sterilization protocol and report, design transfer procedure, approved Device Master Record (DMR), and design change procedure.

The steps for clearing a Class I medical device for manufacturing are as follows:

1. Confirm the product is a medical device.
2. Confirm the product is a Class I medical device through the MDCG guidance document.
3. Ensure general safety and performance requirements are met, check Annex, and the machinery directive. Also, the product must be compliant with harmonized standards and common specifications.
4. Perform a clinical evaluation.

5. Prepare technical documentation in accordance with Annexes 1 and 2. Here, you must justify the classification, reference similar devices, and explain how it complies with the common specifications.
6. Request notified body involvement. Here, the applicable codes are “devices in sterile conditions” Code MDS 1005, and “reusable surgical instruments” Code MDS 1006. Use the NANDO database for codes.
7. Prepare instructions and labeling. This is required for clinical testing and evaluation. No instructions for use are required if safe use is guaranteed. The product needs to be labeled a Medical Device.
8. Check for compliance with general obligations for manufactures. This is where the manufacturer sets up a QM system for insurance.
9. Establish EU Declaration of Conformity. This is where the manufacturer declares conformity with MDR and EU regulations.
10. Affix the CE marketing. The CE marking must be accompanied by an identification number.
11. Registration of devices and manufacturers in the EUAMED. Manufacturers must register where they are assigned an SRN and a basic UDI-ID.
12. Collect post market data, create a post market surveillance report, and create periodic safety reports (PSUR).

Considering this process, we concluded that a section of the requirements would rely on data from the device manufacturer. The device owner is responsible for completing all regulatory requirements. Steps 1-5, 7, and 12 are relevant to our project.

Based on this evaluation, Dr. Dunn will be required to produce product specifications, prove the product is a Class I device that qualifies for the exemption, prove the product is compliant and similar to the device cited, provide a use and sterilization procedure, collect pre-market and post-market data, and collect data for periodic safety reports. We believe that the chosen manufacturer will supply data for the other tasks and may also be able to participate in the steps listed above.

1.8 5G Medical

5G Medical is a start-up biotechnology company founded by Dr. Dunn with the intention of commercializing Dr. Dunn’s ten surgical device patents (WPI, 2013). This includes the ergonomic scalpel, which achieved provisional patent status in 2010, Patent Number: US 2010/0324577 (Massachusetts Medical Device Development Center, 2020). Dr. Dunn’s patents have been supported by the Massachusetts Medical Device Development Center, or M2D2 (Gray, 2011). M2D2 is intended to make

the process from invention to commercialization easier for inventors. Dr. Dunn's patents have been partially sponsored by UMass and M2D2 to facilitate ease of achievement of the patent and manage legal considerations.

The ergonomic scalpel project has been in development since 2010. This includes support from five WPI student MQP teams, beginning with an initial product development project in 2010, commercialization assessment in 2014, two additional refining projects in 2020, and finally this production focused MQP. These MQPs will be discussed in the following section. Currently, Dr. Dunn is working closely with KLS Martin, a global supplier of medical technology. This cooperation includes work on the production, design, and evaluation of the ergonomic scalpel. We also collaborated with KLS Martin to successfully participate in the development of the scalpel, its production, and marketing.

1.9 Previous Research at WPI

Several WPI student teams have completed Major Qualifying Projects (MQPs) developing and evaluating the ergonomic scalpel handle. Beginning in 2010, students developed an initial handle design based on ergonomic requirements and surgeon feedback. In 2014, a team evaluated the potential for commercialization of the ergonomic scalpel. In 2020, two teams looked at weight and balance and haptics of the scalpel. The current team evaluated these MQPs and utilized their groundwork and outcomes to build on previous work.

1.9.1 2010 Design MQP

The first collaboration between Dr. Dunn and WPI MQP students occurred in 2010 with the "Ergonomic Scalpel Handle for Accurate Incision" MQP. The team analyzed the difficulties with a traditional, flat-handled scalpel and concluded that a round-handled, ergonomic design would increase the accuracy and ease of circular and elliptical incisions. One specific surgical procedure, the removal of skin lesions, was identified as a case study for the value of a circular ergonomic scalpel. This procedure involves mirrored v-shaped incisions that are then sutured together to avoid scarring. The flat handle of the traditional scalpel makes creating these mirrored incisions difficult.

The team's objective was to "design, prototype, and test a novel scalpel handle and sleeve which would allow more controlled and precise use by the surgeon" (Brown et al., 2010). First, the team conducted a design review of existing scalpels and found that the handle designs frequently caused surgeons to manipulate the handle outside of the designed methods (i.e. gripping the scalpel handle at a different location than the design grips). This, combined with the poor grip design, led surgeons to complain of difficulty gripping the scalpel. Using this design review, the team determined the most

critical design elements were grip, width, length, balance, and shape. The defined design goal was to increase the stability, control, and comfort of the scalpel for the surgeon.

The team explored three design methods: a sleeve fitting for the traditional scalpel, a completely redesigned stand-alone handle, and an attachment grip (non-sleeve format). The team created five separate design alternatives and redesigned each twice. Incision accuracy and force testing were completed to select the final design. Force testing specifically was used to determine ergonomic comfort and revealed that changes in force and moment indicated personal compensation for poor scalpel design and control. Lag time at the start of the incision indicated poor grip. Variation with a negative trend over several trial tests indicated poor handle design creating fatigue. Variation generally indicated attempts by the surgeon to find a more successful method of cutting, which was likely caused by difficulty using the scalpel handle consistently.

The testing and analysis ultimately supported the initial hypothesis that a circular, ergonomic handle would increase ease and consistency in creating circular and elliptical incisions. Recommendations of the team included developing differently sized ergonomic handles to account for different hand sizes more easily. Manufacturing recommendations included selecting a metal for a reusable handle and plastic for a disposable handle. The team recommended selecting a polymer blend to avoid scalpel slippage due to contact with fluids during surgery. This was recommended over machining grooves or knurling into a metal handle. Finally, the team recommended color coding scalpel handles to limit confusion in the operating room (OR).

1.9.2 2014 Commercialization MQP

In 2014, an MQP group analyzed the feasibility of the commercialization of Dr. Dunn's ergonomic scalpel. They identified four key aspects that were believed to impact the commercialization of the product the most: intellectual property, manufacturing, consumer research, and current market state. Using these areas of focus to base their assessment, the 2014 MQP group concluded that the ergonomic scalpel design was not suitable for commercialization as a stand-alone product (Comeau et al., 2014).

By bringing in two third-party experts, the 2014 MQP group assessed the ergonomic scalpel patent to be of "medium to weak" strength. One aspect of the patent that was negatively viewed by experts was the fact that the patent was reviewed and rejected on the first attempt for a lack of uniqueness. However, the same patent reviewer accepted the filing on the second attempt. The initial lack of uniqueness in the patent, despite being ultimately resolved, suggested that competition from similar products could hinder the overall success of the ergonomic scalpel. For this reason, the two third-party experts concluded that this would give the ergonomic scalpel less room to operate. With the patent's

overall grading of “medium to weak,” the 2014 MQP group found that the ergonomic scalpel would be best marketed toward niche markets.

For the manufacturing assessment of the scalpel design, the previous MQP group considered pricing, raw material, and possible risks as focus points. The group first assumed that the scalpels would be manufactured by injection molding. The total cost of the molds was estimated to be $35,000. Including overhead costs, the cost per unit was found to be $4 to $5. The materials used to manufacture the scalpel handle and grip in the analysis were polycarbonate and elastomers, respectively.

Six residents at UMASS Memorial Hospital were involved in the consumer research portion of the project. One key takeaway from the research was the current standard scalpel design. They did mention that the ergonomic scalpel design lends itself to making curved surface incisions. Along with the six residents who participated in the consumer research, two nurses were also included. The biggest takeaway from the nurses was that the blade replaceability was their main concern. Overall, the group concluded that to be successful, the scalpel had to have “all the benefits of the traditional scalpel as well as the benefits of the prototype” (Comeau et al., 2014).

The 2014 MQP group came up with three strategies for the pricing of the ergonomic scalpel: reduction, generalization, and differentiation. The estimated variable cost of the three strategies were $3.70, $5.70, and $7.70, respectively. It was concluded that the target market of specialist surgeons would not provide a high volume of demand. With a small population of potential customers, high profit margins were found to be critical in the success of the commercialization of the ergonomic scalpel. For this reason, the group's differentiation strategy was seen to be the only viable strategy, with an estimated pricing of $25.

The conclusion of the 2014 MQP group was that the ergonomic scalpel design was not suitable for commercialization as a stand-alone product. This was based on the analysis of the four key areas of focus: intellectual property, manufacturing, consumer research, and current market. The findings of this project will help guide our own project to avoid the plans that they deemed non-viable.

1.9.3 2020 Weight & Balance Design MQP

In 2020, a student team completed an MQP titled “Designing of Ergonomic Scalpel Handles with Optimized Weight and Balance,” which laid the foundation for future students’ work towards machining the ideal scalpel handle. Their design process started with a Needs Analysis for all stakeholders invested in the product. Each person involved in the creation of this project was evaluated so that their needs could be addressed in each design. Conversations about the needs for each stakeholder lead to a discussion on material selection.

Several different materials were used for their work. PLS plastic and 6061 Aluminum were used for building the body of their handle designs, while tungsten and wooden rods were used to act as weights. Numerous slots were carved into the handle grips to allow for weighted tungsten inserts that could allow for more front heavy weight. Stainless steel was selected for the final design. It was chosen for its ability to be easily cleaned via steaming disinfection. Results would later show a heavier front weight preferred by most surgeons interviewed by the team. As the project developed, their work focused on the potential for user experience (UX) testing with the machined prototypes.

After the first round of scalpels were produced, it was important that surgeons were able to see the designs and provide feedback. The team then focused on the best aspects of each design and created a final "screw mechanism in the middle of the model to allow for interchangeable grips" (Martin et al., 2020). This would give their final design a hollowed out back and a balance point at the front of their prototype. The team's final design had a weight of 50 grams and stainless steel was selected as the material.

1.9.4 2020 Grip Design MQP

In 2020, an MQP group analyzed the ergonomic scalpel handle's haptic features and developed a grip design and material. Haptics is "the use of electronically or mechanically generated movement that a user experiences through the sense of touch as part of an interface," (Merriam-Webster, 2020). The group focused on haptic design to improve the ergonomic scalpel handle's effectiveness.

When considering materials for the scalpel prototypes, the group selected stainless steel for the reusable handle material and TPE for the disposable material. The group discussed additive silicon grips, but ultimately favored neoprene, which is a synthetic rubber. This rubber has a high slip resistance and can withstand the intense sanitization process. Neoprene comes in varying levels of softness, allowing potential design alternatives. The group also considered PP, or polypropylene, for the disposable material. This plastic is also very resistant to sanitation and chemicals. The suggested selection was ISO 10993, because it is preapproved for this use and is also low cost (Shaidani et al., 2020).

The group also investigated rubber and overmolding using injection molding. They evaluated two methods of adding rubber grips to the prototype: latex dripping and compression molding. Latex dripping is advantageous when thin layers of rubber are needed, while compression molding is required for thicker rubber grips. To compression mold a grip, a rubber blank must be inserted in a mold cavity, where it is heated and compressed onto the prototype. The group ultimately recommended a replaceable "pencil grip" design for further testing (Shaidani et al., 2020).

Chapter 2: Rationale

In this chapter, we focus on the unique value provided by our team of industrial engineers to the ergonomic scalpel project, where previous support was provided primarily by biomedical and mechanical engineers. Additionally, we evaluate the market rationale for the production of the ergonomic scalpel handle by reviewing its significant surgical benefits compared to traditional scalpels currently used by medical professionals.

2.1 Project Rationale

Dr. Dunn has collaborated with WPI students on fifteen MQPs, including this project. Four previous projects focused on his ergonomic scalpel handle design. Each successive project progressed the potential production and sale of the ergonomic scalpel handle. This project's rationale is to establish a realistic production plan and compile a cost comparison report for different manufacturing scenarios. Based on this rationale and the development trends of previous MQPs, we determined that this MQP could provide value to the ongoing efforts to produce and sell the ergonomic scalpel handle and subsequently to the surgical community at large.

2.2 Surgical Scalpel

The surgical scalpel is the primary tool for cutting and slicing precise incisions. There are reusable and disposable scalpels; both consist of two parts, a handle and a blade. The most common handle design for reusable scalpels is a thin rectangular slab of stainless steel. Disposable scalpels are made from pre-sterilized plastic designed for single use. A specialized attachment end connects the blade to the handle without risk of detachment or slippage (see Figure 4). This allows blades to be disposed of without having to dispose of the handle. This is important because blades can only be used once in medical operations. There is a wide range of sizes for both scalpel handles and blades that vary in length, thickness, and curvature. The scalpel selection is dependent on the operator's preference. Each reusable scalpel tends to cost between $10 and $17 USD, while disposable versions generally cost between $1.50 and $3.20 USD each (Ted Pella, 2021).

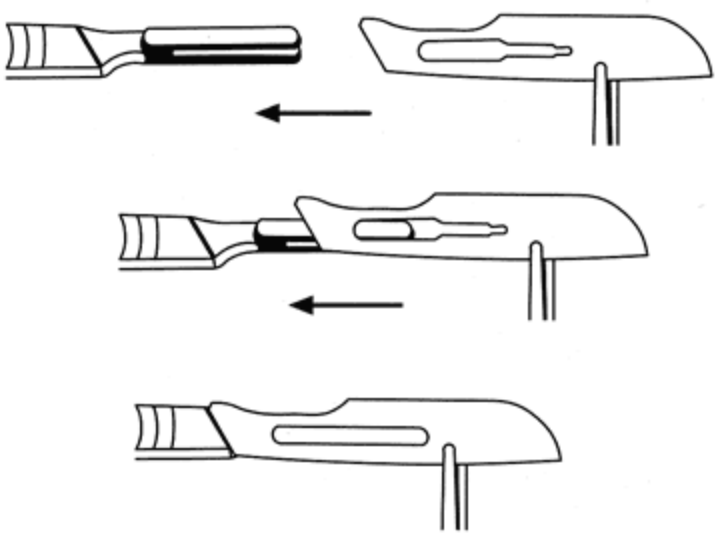


Figure 4. Handle and Blade Attachment (Swann-Morton, 2017)

2.3 Ergonomic Scalpel Handle Benefits

The ergonomic scalpel handle design aims to address the lack of ergonomic scalpels in the current scalpel market. This scalpel has the potential to be a revolutionary product in the standard OR tray. The round handle allows better hand placement, while the grip pattern and material selection decrease slippage. Surgeons that use an ergonomic scalpel handle will experience increased haptic feedback and more mobility in surgery. A scalpel that enhances a surgeon's ability to perform in the OR benefits both the surgeon's comfort as well as the patient's care.

2.4 Surgical Scalpel Market Projections

The global market opportunity for surgical scalpels looks promising for Dr. Dunn's emerging design. Launching within the next few years would introduce the ergonomic scalpel handle during a period of significant growth. Despite setbacks created by the COVID-19 pandemic, the demand for medical procedures has grown consistently in recent years. The number of cosmetic surgical medical procedures performed in the U.S. in 1997 was approximately 900,000 and has grown to nearly 1.5 million procedures in 2019 (ASAPS, 2020). The market demand for surgical scalpels is projected to continue to rise. In 2016, the market was valued at $554.8 million USD with a projected value of $759.4 million USD by 2025 (Insight Partners, 2018).

2.5 Design Concept Overview

Our team approached this manufacturing project with a lean manufacturing perspective and applied Axiomatic Design to generate structure. This methodology was used to systematically address complex problems that could arise for Dr. Dunn in the manufacturing stages of his product launch. Our team evaluated each functional requirement and the corresponding design parameters for each requirement. The lean manufacturing approach was included to keep waste within the system to a minimum.

2.5.1 Axiomatic Design

Axiomatic Design is a key method we used to illustrate the scalpel production process and evaluate potential process options. The goal of this method is to rank designs from most to least efficient by controlling complexity and adhering to specific axiomatic rules. By identifying all key requirements of the design and then matching prospective solutions, the designer develops a high understanding of the design and its solution interactions. Axiomatic Design is based around Customer Needs (CNs), Functional Requirements (FRs), Design Parameters (DPs), and Process Variables (PVs) (Suh, 1998). These factors exist within four design domains: Customer, Functional, Physical and Process. This framework allows the designer to systematically categorize and evaluate their design requirements and solutions. Designs should be collectively exhaustive and mutually exclusive; that is, they should include all relevant considerations and avoid redundancy to remain simple.

Axiomatic Design is based around two main Axioms, the Independence Axiom and the Information Axiom. Axiom 1 (the Independence Axiom) states that designs must "maintain the independence of the functional requirements" (Suh, 1990). This axiom requires the designer to consider and reduce design complexity, making adjustment and problem isolation easier. Axiom 2 (the Information Axiom) states that designers should "minimize the information content of the design" (Suh, 1990). Following satisfaction of the Independence Axiom, the designer can then focus on eliminating excessive information content. This is useful because designs with reduced information content tend to be more successful as they are easier to manage, understand, and execute.

Designing CNs, FRs, DPs, and PVs to meet these Axioms increases design success. Customer Needs should be identified first based on stakeholder analysis. Functional Requirements should then be developed to translate CNs into more technical engineering language. FR_0 represents the primary functional requirement for the design. Design Parameters fulfill FRs: they describe how to achieve the design requirements. Finally, Process Variables describe the process characteristics required to produce a specific DP (Suh, 1998). This hierarchy can be analyzed based on its adherence to the Axioms and then

reviewed and reformulated to develop a robust design. Ultimately, Axiomatic Design was identified as a useful tool because of the possibility of objective design evaluation.

2.5.2 Lean Manufacturing for Design

Lean is a set of manufacturing practices that reduce and eliminate waste in manufacturing production (American Society for Quality, 2021). By cutting out non-value added activities, designers can reduce waste in a business. For the ergonomic scalpel handle, lean manufacturing can be applied both in production and enterprise. Essentially, the entire supply chain for scalpels must implement lean through suppliers and other third parties.

Achieving lean manufacturing through lean design is an important goal of this MQP. There are several options we considered when beginning to plan the manufacturing process for this project. The first option included the use of a simulation. Lean design and simulation analysis could be a very successful pairing in this situation because both methods aim to better design and improve processes so companies can be more competitive (Uriarte, et. al, 2015). This type of modeling is often a faster way to analyze the relationship between materials, process flow, and other factors that have a significant impact on the system. (Bolbach & Guiliani, 2013). Despite this process seeing high standard industry use, we did not select it for use on this project. Finding the ideal software program and developing a new process would not be possible under time and information constraints.

Another lean design tool considered was a Design Structure Matrix (DSM), or Dependency and Structure Modeling. DSM allows the user to perform analysis on complex systems while also modeling the dependencies among different subcategories of the system (Laboratory for Product Development and Lightweight Design, 2019). A DSM is a square matrix with a diagonal row of squares cutting through from the top left corner to the bottom right. Dots or symbols that lie adjacent to the diagonal line will indicate whether there is a direct relationship present amongst two elements in the system. Additional extensions to the model can be added for further sorting according to a specified organization or process. The DSM tool was selected for its high compatibility with the Axiomatic Design technique.

Chapter 3: Methods

This chapter discusses the methods used during this MQP. Method selection reasoning and method process are included. Each method was selected and designed to achieve the key deliverables of our project. Results of each method are discussed in Chapter 4: Results and Discussion.

3.1 Design of Methods

The following methods were used to achieve the overall project goal of finalizing the ergonomic scalpel design and developing manufacturing and marketing recommendations. We gathered information and used strategies to achieve three key deliverables. Each deliverable required the use of several methods, including evaluating mechanical designs, gathering information, analyzing financial metrics and developing marketing strategies. See Figure 5 below for an illustration of the method hierarchy.

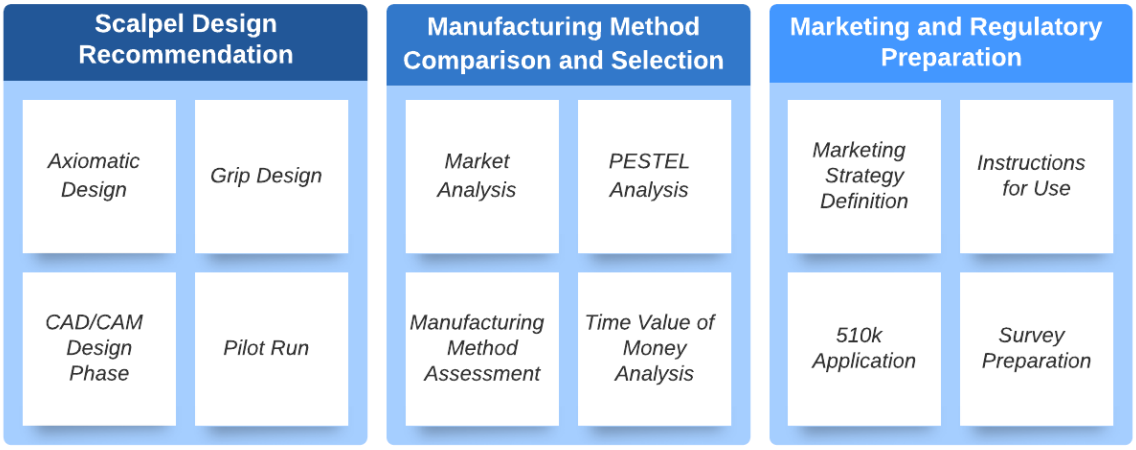


Figure 5. Key Deliverables and Associated Methods

3.2 Axiomatic Design Decomposition

To illustrate the scalpel production process and evaluate potential process options, we used Axiomatic Design. We established our MQP's top-level functional requirement, FR_0, as the need to "prepare the ergonomic scalpel handle for production." FR_0 served as the basis from which all other tasks were derived, including the translation of all sublevel Customer Needs (CNs) to Functional Requirements (FRs). These sub FRs described the building block actions required to achieve FR_0. The Functional Requirements of the MQP were defined as follows:

FR_0	Prepare ergonomic scalpel handle for production
FR_1	Validate scalpel design
$FR_{1.1}$	Validate CAD design
$FR_{1.2}$	Select appropriate materials
$FR_{1.2.1}$	Tolerate steam cleaning over time
$FR_{1.2.2}$	Maintain haptic standards
$FR_{1.2.3}$	Minimize material cost
$FR_{1.3}$	Produce prototype
FR_2	Design manufacturing process
$FR_{2.1}$	Select appropriate production method
$FR_{2.2}$	Minimize production cost
$FR_{2.3}$	Analyze production scalability
FR_3	Develop marketing strategy
$FR_{3.1}$	Analyze scalpel market
$FR_{3.2}$	Develop sales implementation plan
$FR_{3.3}$	Create required regulatory documentation

Table 1. Axiomatic Design Functional Requirements

3.2.1 Acclaro®

We captured the Axiomatic Design Decomposition using Acclaro® software. This decomposition included a list of Functional Requirements and their corresponding Design Parameters. Acclaro® also generated the design matrix which was used to understand the quality and ease of manipulation for the design. Figure 6 below shows the list of FRs and DPs, while Figure 7 displays the Design Matrix.

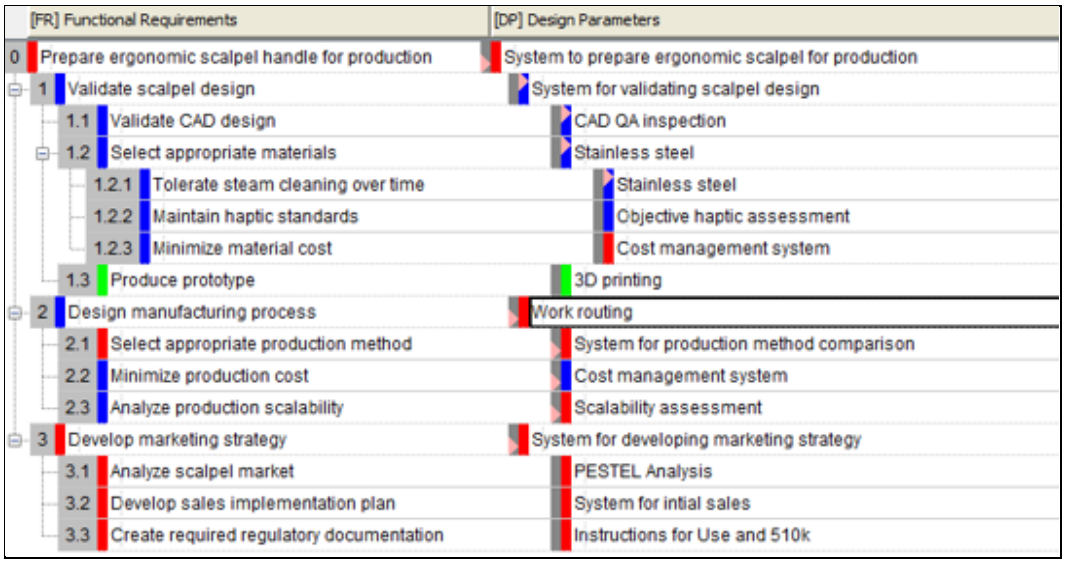


Figure 6. Axiomatic Design Functional Requirements and Design Parameters

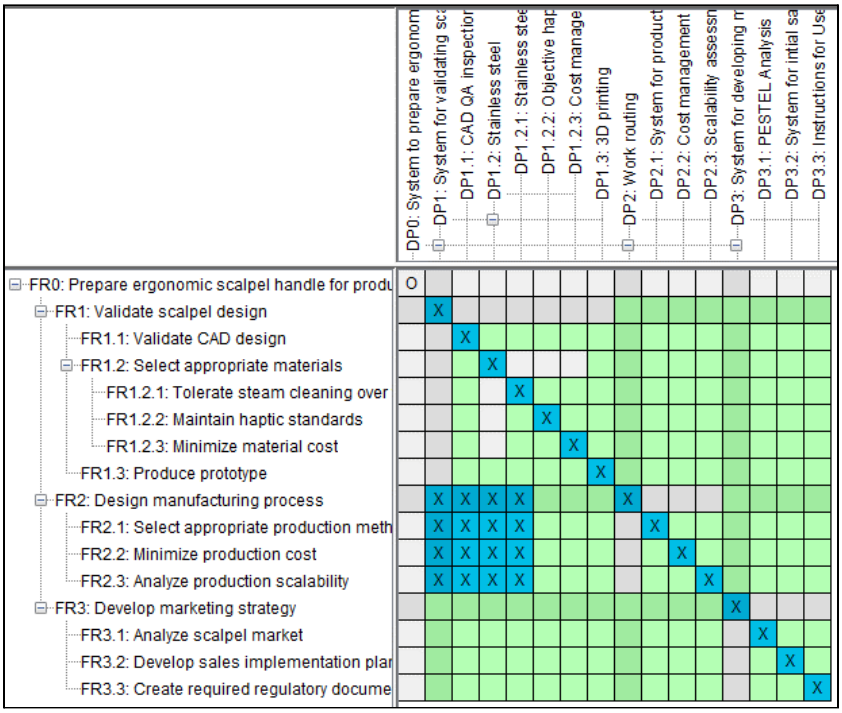


Figure 7. Design Matrix

The design matrix produced two key conclusions. The first being that most of the design was uncoupled. This meant that much of the design could be manipulated without impacting multiple FRs. There was one large coupled section, with "Design manufacturing process" (FR_2) coupled to the Design Parameters selected to achieve $FR_{1.1}$, $FR_{1.2}$, $FR_{1.2.1}$, $FR_{1.2.2}$, and $FR_{1.2.3}$. This coupled section meant that the

manufacturing method to be designed was impacted by the CAD model and material design choices made to validate the scalpel design. Though this was not ideal for the decomposition structure and ease of adjustment, it was unavoidable based on the circumstances of our project. After reviewing previous MQP efforts in conjunction with our schedule, we developed an order of adjustment to finalize the scalpel structural design and grip prior to assessing manufacturing methods. Thus, we were able to effectively manage the coupled section without restricting solution ideas.

Additionally, to avoid restriction on design manipulation, we chose to evaluate the material selection DPs for $FR_{1.1}$ and $FR_{1.2}$ separately. The manufacturing process was evaluated without restriction from material selection for prototyping and design validation.

Evaluating the MQPs core objectives and requirements using axiomatic design helped us assess interactions between different design requirements and prioritize specific project decisions and outcomes. The axiomatic design decomposition also clearly defined the project's scope and created space to ensure outcomes directly fulfilled requirements.

3.3 Data Collection through Interviews

To further understand the intricacies of this project, we interviewed several professionals throughout a variety of fields, including medical device invention, purchasing, sales, and manufacturing. These interviews were conducted over Zoom due to the travel restrictions in place during the COVID-19 pandemic. All interviewees were provided a list of questions and project background information prior to the meeting. The following sections describe subject backgrounds and interview results. Names of those not directly associated with the project have been removed from the paper for the privacy of the interviewees.

3.3.1 Dr. Raymond Dunn, Plastic Surgeon, UMass Memorial Healthcare

Our first interviewee was Dr. Raymond Dunn. He practices plastic surgery at UMass Memorial Medical Center and is our project sponsor. He is a graduate of WPI and Albany Medical, and he has worked and taught at UMass for 30 years.

During the initial interview, Dr. Dunn explained that while surgeons use scalpels daily, these tools have not seen the same technological advancements compared to other surgical instruments. Dr. Dunn highlighted the faults behind the current most popular scalpel design, citing its lack of an ergonomic grip. Dr. Dunn likened using his ergonomic scalpel to "driving a Ferrari," while comparing it to the rudimentary alternative.

Dr. Dunn believed the market for his design was viable and eager to respond to his scalpel designs. His biggest challenge was to introduce his design successfully. He requested that we study previous projects submitted by earlier completed MQP teams to assist in the development of a final plan for introducing his product to the market. He also requested financial comparisons and material suggestions be made together with a step by step process for manufacturing reusable and disposable scalpels.

3.3.2 Director of Business Operations, Hospital Management

We also interviewed a Director for Business Operations in Hospital Management. This connection was established to increase our understanding of how medical devices are bought and selected for hospital use. As a purchasing specialist, the director's insight into business operations from a hospital perspective was invaluable to our team. The director had control over 42 OR rooms across three sites.

We generated two key findings from this interview. First, hospitals purchase specific surgical tools through programs like Vizient and Lumere. Second, budget cuts affect various groups, including the Surgical Processing Department (SPD). For UMass specifically, comparing potential suppliers and products within a field comes down to cost. If products are significantly more expensive, doctors will have to strongly advocate for a product or demonstrate that it will provide extensive long term benefits. At least one or two surgeons will request specific products each month.

The director's main concern for the ergonomic scalpel handle design within the niche surgical tool market was cost. The traditional scalpel cost was significantly lower than that of the ergonomic scalpel. For example, an estimated price for a retractable safety scalpel from Aspen Surgical is around $1.50, while the ergonomic scalpel was projected to cost approximately $600 by KLS Martin. He recommended looking to create a relationship or sign a contract with a distributor to directly sell the ergonomic scalpel handle. This way the delivery of the product to market and stocking is easier.

3.3.3 Senior Product Manager, KLS Martin

Our team interviewed a Senior Product Manager for KLS Martin Group North America to gather background on the interaction between KLS Martin and Dr. Dunn. Additionally, we collected KLS Martin's opinions and predictions associated with the ergonomic scalpel project. The manager had experience working with periodontology and surgical instrumentation for all relevant departments. He had been involved with the ergonomic scalpel project since May 2010 and participated in recent efforts beginning August 2018. He also collaborated on four other surgical tool projects with Dr. Dunn.

Based on the manager's project and industry experience, we asked him questions specific to finances, materials, and production. He agreed that the ergonomic scalpel handle would be marketed as the "Mercedes" of scalpel handles. The handle would benefit from early career purchases by residents and word-of-mouth advertising. For early stage marketing, he mentioned selling the scalpel to Dr. Dunn's contacts at a discount. KLS estimated the retail price for an ergonomic scalpel handle would be $742 USD. However, if sold at a discount based on quantity, it would be 40% off for 15-20 scalpels and 20% for one scalpel. His predictions for early sales were approximately 20 to 30 a year with the possibility of including the ergonomic scalpel handle in KLS Martin's cardiothoracic kit. This would ideally increase interest in purchase by surgeons exposed to the kit.

Furthermore, KLS Martin's current ergonomic scalpel handle prototype is made from 1.403 stainless steel. This selection is partly based on German standards. The grip is high grade silicon, which can withstand sterilization in an autoclave. Material selection was partly driven by the goal of achieving true luxury status. The manager commented that he saw significant trends in material selection, specifically that plastics were emphasized for lightness and tactile feel.

From KLS Martin's perspective, the ergonomic scalpel prototype only required adjustment in the silicon grip. They planned to keep the material the same but adjust the pattern height and placement in the grip. Adjusting the pattern creates difficulty because it requires a new molding tool, which costs approximately $12,000 USD. KLS Martin production typically has a 16 week turnaround for orders placed by sales representatives. The manager recommends initially ordering five ergonomic scalpels for sale and responding to demand, then adjusting orders based on the first round of collected data or reviews from surgeons.

3.3.4 Product Development Engineer, KLS Martin

Our team also interviewed a Product Development Engineer from the KLS Martin Group, to learn more about product development, regulatory requirements, and specifically the development of Dr. Dunn's ergonomic surgical tools. We asked the engineer general questions about product development at KLS Martin, prototyping and production, silicon grips, and FDA and regulatory requirements. He explained that he had limited experience with silicone grips. Different tooling for machines is required depending on the contouring or features of the design. Additionally, silicone grips are unique to specific products.

The group also discussed FDA submission. KLS Martin has significant experience with this because much of their product is first designed and produced in Germany, then sold in the United States. This process often involves 510(k) and PMA submissions (FDA, 2020). KLS must prove the safety and

efficacy of all products through testing. Development engineers are not involved with the approval process for legal reasons. However, they may be involved in the design of the testing process.

3.3.5 Key Account Manager, Medela Inc.

Our team interviewed a Key Account Sales representative for Medela Inc. to better understand the process of marketing medical devices to hospitals and surgeons. The representative had experience working with distributors in addition to roles as both an independent and direct sales representative.

His extensive insight into this side of medical business operations revealed that when starting to introduce a new product to hospitals and surgeons alike, cost is always a factor in the conversation. The number of hospitals implementing budget cuts due to COVID-19 pandemic have skyrocketed in the last year. The process for getting a product into a hospital now depends on the immediate benefits realized from the use of the product.

The first step to getting a product successfully into a hospital is to have a surgeon or doctor specifically request your merchandise. The next step is to run a cost estimate which will help illustrate any fiscal impact. The third step is to have the Value Analysis Committee (VAC) evaluate the products and either approve or deny the application's trial. After the VAC confirms the products' place in the hospital inventory, it enters a trial phase where 3-4 surgeons will trial it for a few cases and then give their final approval. With a final approval in hand, VAC meets again to approve and establish a budget to determine the quantity they can afford. If the price of the product is more than 15-20% of what is already established in the market, VAC will have a difficult time supporting that purchase. Additionally, if a product is more expensive than the current product in use, there would have to be extensive beta testing and clinical trials to prove it would be attractive as a long term investment.

3.3.6 Torbjorn Bergstrom, Professor, Operations Manager, WPI Washburn Shops

To achieve a better understanding of the potential process and costs of machining the ergonomic scalpel, our group interviewed Torbjorn Bergstrom, a manufacturing engineer and operations manager at WPI. Professor Bergstrom reverse engineered a scalpel based on previous CAD designs and prototypes. Over the course of this project's duration, Professor Bergstrom provided our team with sequential steps for building his version of the ergonomic scalpel handle design. The goal was to determine the feasibility of cost effective manufacturing practices.

Professor Bergstrom first identified that he would make the design in two parts: an elongated handle and blade attachment. The handle was made in a lathe while the blade attachment part was made in

a CNC milling machine. Professor Bergstrom recommended that the two parts be laser welded together. For a large production size, the lathe should have an automatic bar feeder to not waste time and energy while making large batches. Professor Bergstrom also recommended that the task of transferring the parts into the welding portion of the process should be carried out by a person and not a robot. This would change if production volumes warranted scaling up due to increased demand.

Professor Bergstrom identified four main areas of cost: machine, labor, insurance, and facility cost. The HAAS brand milling and lathe machines that were used in Professor Bergstrom's test run cost $50,000 and $60,000, respectively. He also estimated that the first scalpel would cost between $2,500 and $5,000 and every scalpel thereafter would be roughly $50 to $100. With his process, Professor Bergstrom estimated that it would take between 20 minutes to an hour to completely machine a scalpel. With the knowledge and recommendations provided to us by Professor Bergstrom, our group developed estimated numbers regarding the process cost and manufacturing time involved in machining the ergonomic scalpel.

3.4 Market Analysis

When conducting a marketing analysis prior to implementing our team's methods, research into the global scalpel market was conducted to better understand what is currently happening around the world. The global scalpel market has incredible potential to grow in the next several years. In fact, the global surgical scalpel market was projected to have a market value of over $1 billion in 2017 but will grow to a new market valuation greater than $1.4 billion by 2027 (Future Market Insights Global and Consulting Pvt. Ltd., 2017). That translates into $400 million in ten years of development with a compound annual growth rate (CAGR) of 3.8%.

3.4.1 PESTEL Analysis

To better understand the scalpel market, our team conducted a PESTEL Analysis. This tool is used to understand the political, economic, social, technological, environmental, and legal factors that impact the open market (Oxford College of Marketing, 2020). With a clear understanding of the situational obstacles within the scalpel market, our team will be better prepared to support Dr. Dunn in his mission of launching his own scalpel design into the market.

3.4.2 Product Direction

Our team initially focused on manufacturing the ergonomic scalpel handles in large scale production. Upon analysis of the scalpel market and the results of the 2010 MQP focus groups (Brown et. al, 2010), we decided to adjust the direction of the project. Other factors that contributed to this decision

include the complexity of small scale manufacturing, the cost of the ergonomic scalpel handle, and the need and adoption rate for new products in the market.

With those factors in mind, instead of creating a replacement product for the classic, inexpensive, and often disposable hospital scalpels, we saw opportunity in the accessory market. This led us to design a similarly shaped grip sleeve that slides over the classic hospital scalpels. This would offer a lower cost option that would be easier to adopt. Over time, this would create an opportunity to migrate to the ergonomic scalpel handle. Gradual adoption would allow for larger scale production of the ergonomic scalpel handle since the demand would be much higher at that point, therefore lowering the cost per item.

3.5 3D Prototyping

The following section lays out the 3D prototyping phase of grip patterns, blade tip modeling, and a product alternative (the “sleeve” concept). The sleeve concept stages are discussed here.

3.5.1 CAD Design Phase

Figure 8. Ergonomic Scalpel Handle Sans Blade Attachment (left) and Sleeve Prototype Versions 1 through 6

Ergonomic Scalpel Handle: The first model on the left is the ergonomic scalpel handle without the blade attachment tip. We printed this model to get an idea of sizing, grip pattern, curve ratios, and general hand comfort.

Version 1: The second model from the left is the first model we 3D printed. For our first model, our goal was to increase the scale until it was possible to slide the plastic hospital scalpel into the handle. The radii ratios were kept the same, resulting in a wider handle than typical. This model hindered the surgeon's view of the incision. To keep prototyping simple, grip patterns were omitted on version 1, 2, and 4.

Version 2: Due to the view hindrance issues of the second model, the third model was designed into an ellipse. This made it so we could slide the plastic hospital blade into the sleeve while still allowing the surgeon a good line of vision and maintaining Dr. Dunn's curve ratios. This sleeve had better ergonomics and comfort compared to version 1 but was not the easiest to rotate between the fingers. This led us back to a round model.

Version 3: Version 3 was the first to deviate from Dr. Dunn's established curve ratios. We created a model that was just large enough to fit the plastic hospital scalpel, resulting in a diameter just slightly wider than the finger grip section of Dr. Dunn's model. We also chose to design a grip pattern onto version 3 to start to get a better understanding of how plowing friction relates to geometric patterns on a surface. We found that with this model, similar to version 1, hindered the surgeon's incision view.

Version 4: To avoid view hindrance while still achieving an ergonomic design, we designed version 4. This version has the same dimensions and curve ratios as Dr. Dunn's model, while still allowing a plastic hospital scalpel to be inserted. We found that eliminating the second curved section did not eliminate the general comfort. We selected this model as the best representation of the ergonomic scalpel handle if it were to allow for a plastic hospital scalpel to be inserted inside. The following versions are small-scale modifications of version 4.

Version 5: Between versions 4 and 5, we did not change general dimensioning to test various grip patterns (see section 4.2.1). The first grip trials were variations of horizontal ring patterns. This version was preferred. After we tested the patterns, we realized that a strictly horizontal pattern does not allow for vertical finger rotation, therefore eliminating this as a final recommendation.

Figure 9. Cross Section of Version 6 with Inserted Traditional Scalpel

Version 6: Our last version was created after initial introduction with an injection molding contact. He recommended we make the sleeve slot a thru hole for ease of molding as well as to include a threaded hole for inserting a clamping screw. The purpose of the clamping screw will be to hold the

plastic hospital scalpel in place instead of assuming a snug fit as we had been doing. These features were essential in obtaining an accurate quote for injection molding. In the image above (Figure 9), you can see how the classic disposable hospital scalpels may be inserted into the sleeve concept. Any grip pattern may be added onto version 6. In the rest of this section, we lay out the grip pattern modeling process.

Figure 10. Printed Grip Pattern Set 1

A portion of our prototyping phase was dedicated to running different tests for grip patterns. For version 1 (Figure 10) seen above, we tested how different horizontal ring pattern ratios affect ploughing friction. From left to right, we have the following dimension ratios: 7:2:7, 7:3:7, 10:3:7 (spacing:height:width). We found that the middle version with ratio 7:3:7 offered the best grip and friction. Once we realized that this horizontal ring pattern would not easily allow for vertical finger rotation, we eliminated this option as a future final recommendation.

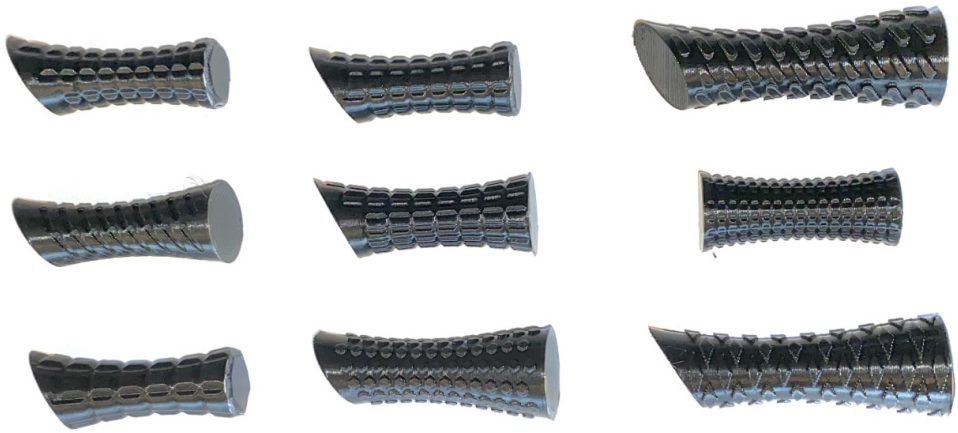


Figure 11. Printed Grip Pattern Set 2

After initially printing the ring pattern grip seen in Figure 11, the following nine patterns were printed in the highest printer resolution to get a better idea of the relationship of pattern to ploughing and rotational friction. These models were obtained from the 2020 MQP “Design of Improved Surgical

Scalpel Handles with Optimized Grips" (Shaidani et al., 2020). The grips are ordered from the least amount of friction on the left to the most on the right. Overall, the grips on the right had the best comfort along with the proper ploughing and rotational friction ratios. In Section 3.5.2, we further discuss our recommended patterns and their rationale.

3.5.2 Grip Decision

To make final recommendations on the grip pattern for the ergonomic scalpel, our group used secondary sources as references and based our decision on their findings. In 2020, an MQP group worked to optimize the grip of Dr. Dunn's ergonomic scalpel (Shaidani et al., 2020). Part of their findings included analysis of grip patterns to maximize comfort and control of the scalpel. To understand their work, we familiarized ourselves with the sources they referenced to gain a better understanding of the choices they made. This led us to two main sources, one that analyzed the effects of "Human finger friction in contact with ridged surfaces," and another that focused on friction involved with different "sliding orientations" (Tomlinson et al., 2013; Zhang et al., 2017). From the former, we learned of the importance of optimal ridge height, width, and distance in grip patterns to increase "ploughing friction," surface friction," and in turn, maximum coefficient of friction (Tomlinson et al., 2013). From the latter, we became more familiar with how grip patterns vary in friction coefficient based on their orientation (Zhang et al., 2017).

Our group then moved on to considering the previous MQP group's final grip pattern recommendations. They conducted two tests for each grip pattern candidate that measured comfort and performance (Shaidani et al., 2020). From the pool of potential candidates they recommended, we narrowed the recommendations down to reflect the findings of our shared research more closely. We chose grip patterns that were symmetric with the purpose of keeping consistent friction in all directions relative to the length of the scalpel. We also chose grip patterns that closely resembled the numbers of ridge height, width, and distance to optimize coefficient of friction.

3.6 Cost Comparison of Manufacturing Methods

A significant deliverable of this MQP was to complete an analysis of potential manufacturing methods for the ergonomic scalpel handle at initial and scaled volumes. This section details background on the machining and injection molding methods as well as a description of the cost comparison methods employed. Final recommendations for this comparison can be found in Section 4.3.

3.6.1 Machining

To determine the estimated costs involved with machining the ergonomic scalpel out of steel, our group relied on the figures given to us in our interview with Torbjorn Bergstrom. We evaluated machine, facility, material, labor, and insurance costs for machining. This will also be affected by the production scale. Our group used the information we gathered about machining costs and cycle times to complete cost comparisons with additive manufacturing and injection molding methods of manufacturing. Each of these production processes comes with a different cost estimation. Our group aimed to find a standardized method that most machine shops would use if tasked with manufacturing the ergonomic scalpel design.

3.6.2 Injection Molding

Our team researched the use of elastomers and injection molding. Injection molding is a process in manufacturing where material is melted and then forced into a mold using high pressures. The material is then cooled and removed from the mold having taken the shape of the mold. Injection molding is often used for the large scale production of plastic and polymer parts because it is repeatable and fast. To mold a product, one must have these molds custom made, which can be expensive.

3.6.3 Cost Comparison

The team evaluated the established options for manufacturing method selection. Based on the different requirements and processes for each method, several different metrics were assessed, as shown in Table 2 below.

Type	Metrics	Machining	Additive Manufacturing	Injection Molding
Cost	Material cost	X	X	X
	Tooling cost	X		
	Mold cost			X
	Production cost	X	X	X
Other	Cycle time	X	X	X
	Material	X	X	X

Table 2. Manufacturing Options Assessment Metrics

Information about the machining metrics was gathered through research and communication with Torbjorn Bergstrom, Operations Manager in WPI Washburn Shops. Professor Bergstrom consulted on the machining process required to produce stainless steel ergonomic scalpels on the lathe. Information about the additive manufacturing metrics was gathered through research and team experience printing prototypes. Much of this effort focused on determining appropriate filament selection to produce sterilizable and reusable 3D printed scalpel parts. Finally, information about the injection molding metrics was gathered through interaction with Mark Robichaud ‘83, Business Development at Comar and former long-term employee of Jabil Healthcare (formerly Nypro).

3.7 Marketing Strategy

When commercializing a product, one of the first considerations is how to introduce the product to the market. For most markets, there are two options for advertising channels: outbound marketing and inbound marketing. Most frequently a combination of the two is used. These methods can be conceptualized with the following quote: “Outbound marketing brings your offering to your prospects. Inbound marketing brings your prospects to you” (Bond, 2020).

3.7.1 Outbound Marketing

Outbound marketing, also called interruption marketing, is a strategy where companies bring customers in by promoting their offerings. Outbound marketing involves directly approaching a population of potential customers in the form of targeted outreach through a variety of tools which include trade shows or seminars. Other strategies include targeted digital and print advertising in addition to public relations activities to promote awareness. Cold calling, television commercials, or magazine ads are often considered the more aggressive approach compared to outbound marketing. Depending on the industry and product, outbound marketing has varying potential. It can be compared to a marketer pushing his or her message out far and wide hoping that it resonates with that needle in the haystack (Burnes, 2019).

Knowing and understanding the needs of the target audience is essential for successful marketing. The negative aspects of outbound marketing almost negate themselves in situations where the customers have already been identified. For example, we can compare two outbound methods; one where the audience is defined and one where it is not. At a trade show, chances are that those attending are exactly the target audience for the companies present. Attendees are direct potential buyers. YouTube ads are less precise and cast a wide net. These ads are still effective due to their various algorithms to narrow a viewer

down to their demographic, location, and potential interests (Scott, 2018). Though YouTube advertising is effective, it does not target customers as precisely as trade shows and product sampling.

3.7.2 Inbound Marketing

Inbound marketing involves reaching out to a population of potential customers; examples include social media posts or podcasts. Inbound marketing strategies revolve around "create[ing] content or social media tactics that spread brand awareness so people learn about you, might go to your website for information, and then purchase or show interest in your product" (Halligan, 2019). Products that require the customer to take their time weighing the pros and cons might employ a greater ratio of inbound to outbound marketing.

The goal is to choose a ratio of inbound to outbound based on the product and the target audience. This requires an "understanding [of] the proper mix between the two [which] can be vital to the success of your business" (Leone, 2015). Oftentimes, companies might use 80% outbound, 20% inbound, 60:40, or even 50:50. These ratios commonly emphasize outbound marketing. A large contributor to a company's ratio is their size. "The smaller the company, the more pervasive inbound marketing, while larger companies are likely to deploy a mixture of both. For businesses with less than 25 employees, inbound is used by a whopping 84% of firms, versus just 13% for outbound" (Leone, 2015). The most important concept to understand when designing a ratio is to know the customer and predict their response to various marketing strategies.

3.7.3 Sampling

To understand the ergonomic scalpel's customer, our team prepared a survey and sampling method for Dr. Dunn. There are a variety of different sampling strategies, including non-random, (systematic and convenience), and random (stratified and cluster). In the case of the ergonomic scalpel handle, we selected convenience sampling, which would involve utilizing Dr. Dunn's colleagues first. If the convenience sampling garnered positive results, the next step would be snowball sampling, during which the original samplers would recruit others to try the product. This is a slower method of growth, but it is effective for a targeted product like the ergonomic scalpel handle. Based on these sampling methods, we developed a potential survey to be used for future evaluation.

3.7.4 Survey Design and Structure

To test our changes to the prototype, we created a comprehensive survey to identify positives and negatives associated with using the prototype. Dr. Dunn worked closely with us in identifying the most

important factors in ergonomics and precision when using a scalpel in surgery. Given these factors, we created a comprehensive survey using questions based around the Likert scale and open response to quantify how well our prototype met these factors. This survey was created in Qualtrics which has a very user friendly platform and allows for the group to actively analyze data as it is received. This software is compatible with QR codes and available online, allowing for the survey to be administered remotely at the convenience of the subject. See Figure 12 below for an illustration of the survey's presentation on a computer and mobile device and Appendix A for a list of survey questions.

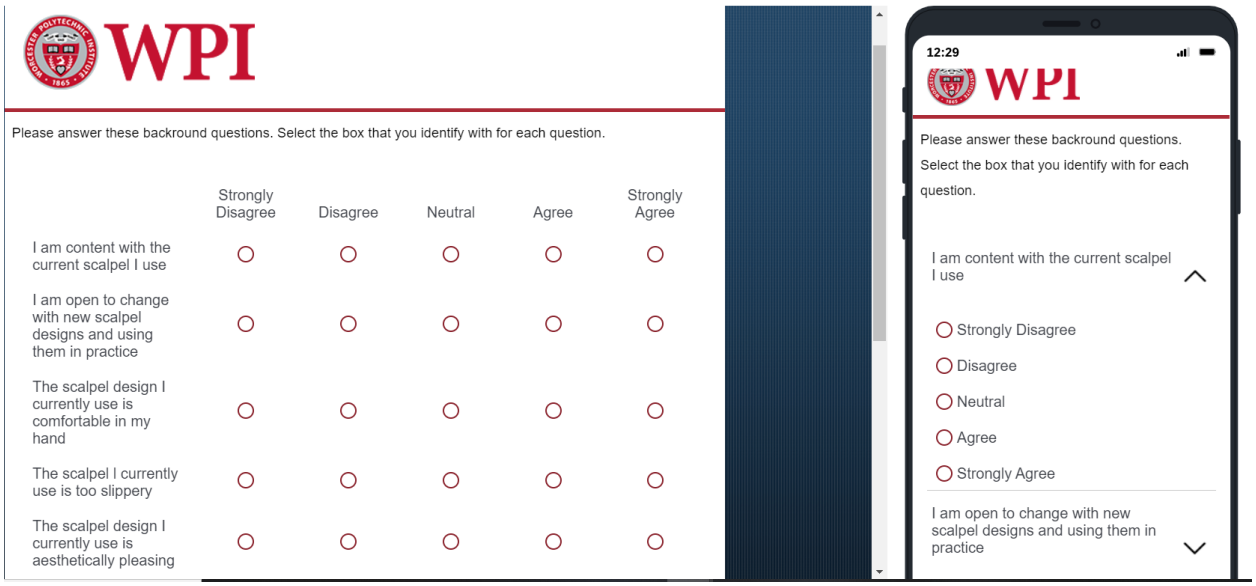


Figure 12. Qualtrics Survey Design

Chapter 4: Results and Discussion

This chapter presents the results of the applied methods. This includes results of the market analysis, prototype production, material and grip selection process, manufacturing cost comparison, and marketing strategy. Overall project conclusions are discussed in Chapter 5: Conclusion.

4.1 PESTEL Analysis

This section details the results of the PESTEL Analysis. This information is useful to understand the market factors that will impact the ergonomic scalpel handle before, during, and after product launch.

4.1.1 Political

Political factors to consider for the ergonomic scalpel handle include the product classification and definition. The FDA classifies both the blade and scalpel handle as a manual surgical instrument for general use as a "non powered, hand-held, or hand-manipulated device, either reusable or disposable, intended to be used in various general surgical procedures" (FDA, 2021). This classification determines the regulations to which the product must adhere. For example, this submission type means that a general scalpel (the ergonomic scalpel handle included) is 510(k) exempt. A 510(k) is a premarket notification that companies or inventors must submit to the FDA "to demonstrate that the device to be marketed is safe and effective" and "substantially equivalent to a legally marketed device" (Center for Devices and Radiological Health, 2020).

4.1.2 Economic

Economic factors indicate that there is an opportunity for the ergonomic scalpel handle to enter the medical device industry in the near future. There is a projected 5% growth in total global medical technology for 2022 according to a survey conducted by Evaluate (Evaluate, 2017). This projection can be seen in Figure 13 below. Furthermore, TechNavio estimates a strong positive impact on the growth of the scalpel market due to COVID-19 pandemic (Technavio, 2020).

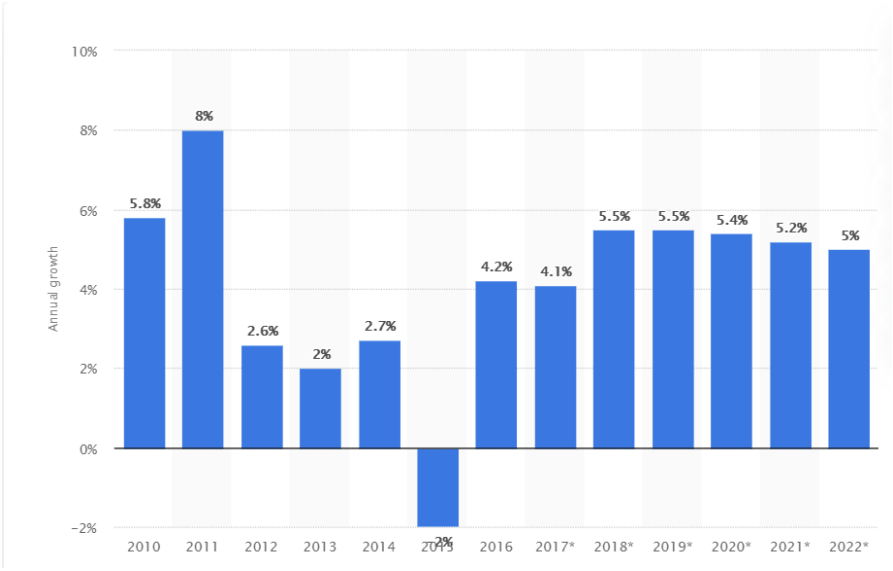


Figure 13. Total Global Medical Technology Growth per Year from 2010 to 2022 (Stewart, 2019).

4.1.3 Social

The ergonomic scalpel handle has significant potential to create positive social impacts. Across the board, injuries and complications in the OR are something hospitals and doctors alike want to avoid at all costs. Improved scalpel safety features are valued by researchers and safety review boards. Such research can be found in the Canadian Journal of Surgery with Dr. Kristin DeGiorlamo of the University of Alberta. Her research into scalpel safety practices demonstrates an active interest in scalpel safety and user-friendly haptics in the medical field (DeGiorlamo, 2012).

4.1.4 Technological

Stainless steel is a common material to manufacture and utilize in the medical tool industry. Its strong characteristics have allowed it to replace carbon steel in most surgical settings. Technological advancements in materials science research have also proved stainless steel has superior corrosion resistance. According to an article written by Dr. Brill, Chief Resident of General Surgery at the Naval Medical Center, “reusable handles [have] benefited most from the high chromium content of stainless steel” (Brill et. al, 2018). These trends support the material selection for the ergonomic scalpel handle.

4.1.5 Environmental

Environmental factors will impact the scalpel market significantly due to an increase in the focus on sustainability. For this initial product launch, our team is targeting the American surgical community

primarily. This led us to believe that if the American public demanded the medical industry have a positive impact on the environment, businesses would be incentivized to reflect those sentiments in their manufacturing choices. Fortunately, the stainless steel used for the ergonomic scalpel handle is environmentally conscious. Stainless steel is 100% recyclable and does not produce any toxic run-off (Sassda, 2021). This will encourage a sustainable engineering outlook on the project.

4.1.6 Legal

When examining legal ramifications for the project it is important to consider consumer laws, product labeling, and product safety. A common feature that comes with product safety is Instructions for Use (IFU). IFUs are required instructions written in colloquial language for patients to understand the product better. IFUs will cover everything from preparation instructions, precautions, storage instructions, disposal instructions to material information. An example IFU of the Bard-Parker Conventional Blade System is available for reference in Appendix B.

4.2 Pilot Run Results

Conducting a pilot run for the ergonomic scalpel handle was one of the deliverables that our team aimed to provide at the conclusion of this project. As time progressed and the impacts of the COVID-19 pandemic developed, it was not possible to conduct a full pilot run for the ergonomic scalpel handle. However, a segmented trial run was conducted to produce a stainless steel scalpel "blank" without a silicon overlay. This scalpel imitated a rough likeness to the ergonomic scalpel handle manufactured by KLS Martin. An image of the pilot run scalpel is shown in Figure 14 below.

Figure 14. Pilot Run Scalpel Blanks

4.2.1 Grip Patterns

After familiarizing ourselves with sources that studied grip patterns, including the work of the previous 2020 Grip MQP, our group had enough information to make an informed recommendation on

the grip pattern of the ergonomic scalpel. There are two main areas of focus when considering the final texture design for the ergonomic scalpel: friction coefficient and overall comfort. Comfort is relatively subjective and requires survey data from intended users. The data should be collected by testing realistic scenarios and movements that are encountered in surgical scalpel use.

The 2020 Grip MQP group conducted testing regarding different scalpel textures and analyzed both their friction coefficients and their comfortability. Unfortunately, they were not able to conduct the testing with trained surgical residents and instead collected data from their own group members (Shaidani et al., 2020). While this data cannot be completely reflective of testing done with trained residents, their research into the comfort of different texture designs gives our group valuable insight. Friction coefficients of different texture designs have been tested by the previous 2020 MQP group and other peer-reviewed studies. This combination of work from outside sources and previous MQP groups will provide sufficient information and allow our group to make recommendations for the texture of the ergonomic scalpel.

The coefficient of friction on a textured surface is made up of two different types of friction: ploughing and surface. Ploughing friction is the friction involved when a finger is in contact with the edge of a ridge and must be deformed to slide past the ridge. This type of friction is affected most by varying the height, width, and distances of the ridges in a texture. Surface friction is simply the friction between the finger and a flat surface. This depends on the type of material that is used and the surface area of contact (Tomlinson et al., 2013).

An increased percentage of ploughing friction is known to increase the maximum friction coefficient. Increased surface friction provides more consistency of friction of slippage (Tomlinson et al., 2013). A study done on human finger friction when in contact with ridged surfaces provided optimal ranges for the height, width, and distance of ridges in a texture to achieve maximum friction coefficient. When increased, height increased friction (up to 2.5mm), width decreased friction (up to 4mm), and distance increased friction (up to 10mm) (Tomlinson et al., 2013). This study only evaluated friction in one direction. Another study done on sliding orientation found that symmetrical patterns performed best when tested in multiple directions: perpendicular, parallel, and 45° to the texture (Zhang et al., 2017).

4.2.1.1 Initial Recommendations

When our group was tasked with making recommendations for the ergonomic scalpel grip pattern, we were aware of two ways that they could be applied to the scalpel: directly into the handle or on a cylindrical overlay that would be placed around the handle. Based on the capabilities in the Washburn Shops machine shop, our group determined that the grip overlay would not be possible for the machined pilot run. With this in mind, we decided to recommend grip patterns that could be produced

easily through machining, mainly on a lathe, without requiring knurling. The patterns that we found to be best, in this case, were a square pattern and an annular ring pattern. Illustrations of both patterns are shown below in Figure 15.

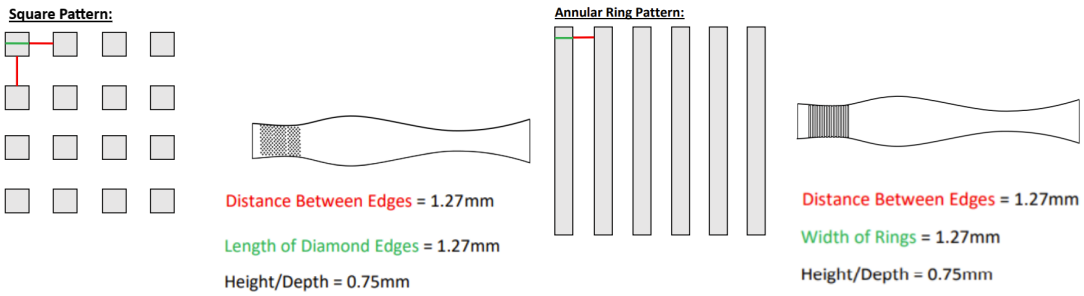


Figure 15. Square Pattern (left) and Annular Ring Pattern (right)

The first pattern is a checkered square design. It is intended to provide symmetric friction forces so slipping does not occur in directions parallel or perpendicular to the length of the scalpel handle. This pattern cannot be made on a lathe; instead, CNC milling would need to be used to apply this grip to the handle. This would increase lead times in the scalpel-making process but would ensure optimal frictional forces for the user when rotating the scalpel. Alternatively, the second grip displayed can be made entirely on a lathe. The annular ring pattern provides a sufficient friction coefficient in the direction parallel to the length of the scalpel.

The 2020 Grip MQP included a similar design in their testing called “Straight Knurl 3mm” (Shaidani et al., 2020). They found that it outperformed all other grip patterns when conducting their practical user testing (Shaidani et al., 2020). Despite their testing being done by a group member and not a practicing surgeon, we believe that their results still prove this grip pattern to be viable for the purposes of the scalpel prototypes. The dimensions of the grip patterns were chosen based on the research we gathered regarding optimal ridge height, width, and distance, while also considering comfort.

4.2.1.2 Revised Recommendations

After our group made initial recommendations for the ergonomic scalpel handle’s grip pattern, the manufacturing options for the ergonomic scalpel and its grip expanded. Through conversations with Dr. Dunn, our group determined that the grip overlay manufacturing method was preferred for the final handle design. This opened possibilities for the grip patterns because the overlays could be injection molded, making it easier to produce more complex patterns. Further testing on the initially recommended grip patterns was also performed. By 3D printing the grips onto prototypes, we found that the annular ring pattern that we initially recommended did not provide sufficient rotational friction. This testing led us to

not only reevaluate our recommendations, but also the recommendations made by the previous grip MQP. The 2020 Grip MQP concluded with four recommendations of grip patterns: checkered knurl 6mm, straight knurl 3mm, knurl bump #4 3mm, and knurl bump 6mm with increased depth. Designs of the different patterns are shown in Figure 16 and Figure 17 below.

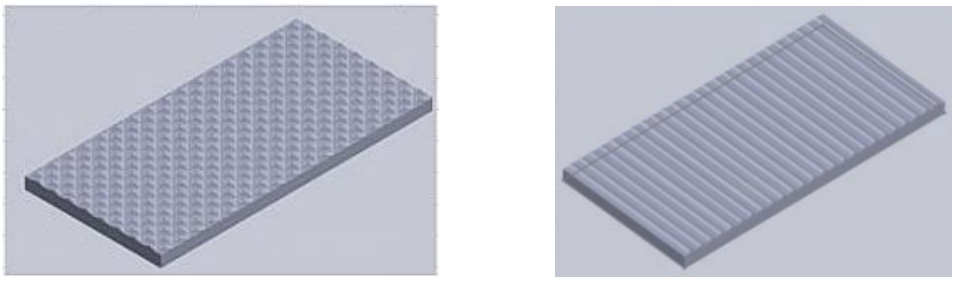


Figure 16. Checkered Knurl (Left) and Straight Knurl (Right) (Shaidani et al., 2020).

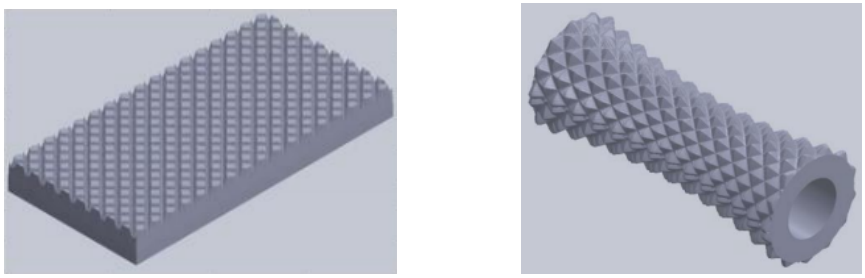


Figure 17. Knurl Bump 4 (left) and Knurl Bump (Right) (Shaidani et al., 2020).

These patterns were chosen because they combined optimal performances in comfort and friction coefficient (Shaidani et al., 2020). By injection molding the grip overlays, the complex patterns can be efficiently manufactured. Our group confirmed these recommendations using additive manufacturing as discussed in Section 3.5.1. We place an emphasis on the knurl bump grip pattern because it is supported by an outside source. A study done on the friction of grip patterns when in contact with a wet gloved finger found that a medium knurl bump, or "diamond knurl," pattern (~20 TPI, or teeth per inch) performed best when in contact with gloves made of Nitrile and Latex (Charles et al., 2007). Additionally, we recommend the diamond pattern we tested through 3D printing prototypes (shown in Figure 18).

Figure 18. Model with Final Grip Pattern and Click-in Blade Tip

We found this pattern to combine sufficient comfort and coefficient of friction in directions both perpendicular and parallel to the length of the scalpel. This grip, along with the recommendations made by the previous MQP group, would provide the ergonomic scalpel and its users optimal friction coefficient and comfort.

4.3 Cost Comparison of Manufacturing Methods

This section details the results of our analysis of manufacturing methods based on a cost comparison for early stage and scaled production of the ergonomic scalpel handle. We compared three production methods: machining, additive manufacturing, and injection molding. Based on the different requirements and processes for each method, several different metrics were assessed. Table 3 includes cost information for each manufacturing type.

Type	Metrics	Machining	Additive Manufacturing	Injection Molding
Cost	Material cost	$3-10	$0.18 per handle*	$3.93 per handle
	Tooling cost	Fluctuates by shop		
	Mold cost			$12,000
	Production cost	$35 per handle	$67.27	$3.93 per handle**
Other	Volume (handles per year)	16,000	1	100,000
	Cycle time (per handle)	8 minutes	3.5 hours	30 seconds
	Material	304 Stainless Steel	PLA plastic handle and grip	ABS plastic handle and TPU grip

Table 3. Manufacturing Options Assessment Metrics, Complete

*With a 10% infill

**at 100,000 per year

4.3.1 Machining Cost Estimate

This section of results was completed by consulting with a local machine shop. The quote included information related to the production of the reusable metal handle. This estimate was based around evaluating an hourly shop rate, including shop overhead, fixed expenses, machine and tooling cost, insurance cost, and labor cost. The following information was based on the handle material of 304

stainless steel. Accounting for fluctuation, material cost per handle was determined to be between $3 and $10. A reasonable cost estimate was described to be three times the material cost.

The following estimate is based on a breakpoint threshold of 16,000 handles per year. Above this threshold, the cost estimate from the local machine shop per handle is $35. This is most likely the lowest cost achievable without personal ownership of the required machines and tooling. With ownership, if production were to hit a volume of 50,000 handles per year, the approximate cost per handle is estimated to be $15. See Figure 19 below for a linear representation of cost per handle from the machine shop for volumes below 16,000 per year.

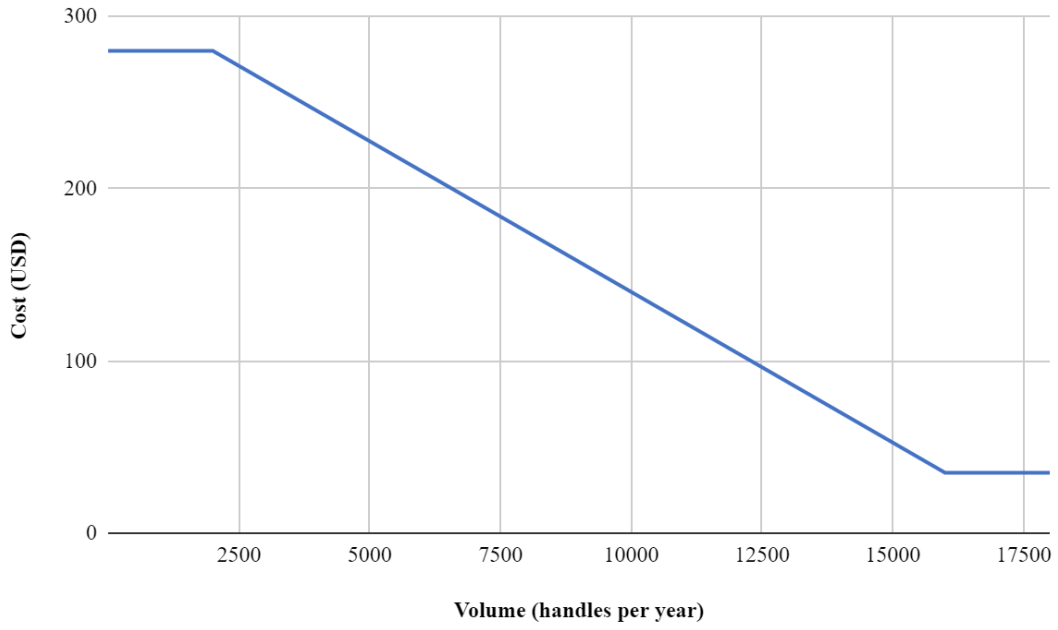


Figure 19. Cost per Handle vs. Volume per Year

The production process described in this cost estimate does not include the cost of manufacturing and attaching the grip overlay. This process must be considered separately. The components of the machining process for the metal handle production are as follows. Production utilizes three main processes. The handle itself is machined using a lathe to transform the raw stainless steel rod into the shape of the ergonomic scalpel handle. Additionally, during this phase material is removed from the core of the handle to manage weight and balance.

The blade attachment is produced using a milling machine. This requires 2 orientations to produce the shape and attachment features. Finally, the handle and blade attachment are welded together using a laser welder. The milling process is by far the longest process with the most significant set-up involved. The takt time for a single handle was evaluated to be 8 minutes. This is estimated including

overlap in the milling and lathing process. It also includes time for packaging and batch sterilization in an autoclave.

4.3.2 Additive Manufacturing Cost Estimate

Our group used an Ender 3 Version 2 3D printer throughout the prototyping process of blade tips, grip patterns, and concept models, extruding a common black PLA plastic filament. Though the models produced cannot be sterilized and put into surgical use, they were useful in adjusting dimensions, brainstorming innovative changes, and physically testing grip patterns. The stand-alone grip costs approximately $0.06-$0.08 per model, while the final sleeve version (version 6) costs approximately $0.32 (depending on the grip pattern chosen), both with a 10% internal support material infill.

During the introduction stages of product launch, future work should include several additive manufacturing display models to represent the ergonomic scalpel handle. These models could be used for trade show applications and as non-usable samples to get pre-launch surgeon feedback. They can be printed from the common black PLA, which costs just $0.18 with a 10% internal support material infill.

The team also used an online quote generator from Protolabs to estimate quotes for 3D printing disposable and reusable models as well as CNC machined, injection molded, and overlay injection molded versions. Protolabs quotes can be found in Appendix C. For a single plastic handle produced from a sterilizable filament capable of being autoclaved, the estimated cost per handle is $67.27. Additionally, Protolabs is capable of 3D printing metals. For a single metal handle, the estimated cost per handle is $608.48. These quotes are both significantly higher than our prototyping cost because they account for partial machine cost and labor cost of an external contractor.

4.3.3 Injection Molding Cost Estimate

To produce accurate cost estimates for manufacturing the ergonomic scalpel handle at scale using injection molding, our group presented the design to Mark Robichaud for his insight. Mr. Robichaud indicated that the lower threshold required to justify the costs of injection molding was 100,000 scalpels per year. He then provided us with quote information for various volume thresholds for a disposable version of the ergonomic scalpel handle with a grip overlay.

This quote included information related to the production of the handle and grip, purchased blades and blade protectors, packaging, and manual assembly. The time for a single production cycle was evaluated to be 30 seconds. The following information was based on the handle material of Acrylonitrile Butadiene Styrene (ABS), costing $3.50 per pound, and the grip material of Thermoplastic Polyurethane (TPU), costing $7.50 per pound.

Information describing the cost structure of the disposable handle produced using a two cavity mold is included in Table 4 below. A two cavity mold would produce two ergonomic scalpel handles and attached grip overlays in one cycle.

	Cost per handle at volume		
Price segment	50k handles per year	100k handles per year	500k handles per year
Handle and grip	$0.64	$0.55	$0.53
Blade	$0.60	$0.60	$0.60
Blade protector	$0.10	$0.08	$0.05
Packaging	$1.94	$1.38	$0.87
Manual assembly	$1.46	$1.32	$1.19
Total cost	$4.74	$3.93	$3.24
Annual cost	$237,000	$393,000	$1,965,000

Table 4. Two Cavity Mold Estimate

The cost structure of the disposable handle produced using a four cavity mold is listed in Table 5 below. A four cavity mold would produce four ergonomic scalpel handles and attached grip overlays in one cycle. At scale, the four cavity mold has a cost savings of $365,000 per year compared to the two cavity mold. For this reason, it is more cost effective to begin injection molding production using a four cavity mold.

	Cost per handle at volume		
Price segment	50k handles per year	100k handles per year	500k handles per year
Handle and grip	$0.54	$0.53	$0.49
Blade	$0.60	$0.60	$0.60
Blade protector	$0.10	$0.08	$0.05
Packaging	$1.94	$1.38	$0.87
Manual assembly	$1.46	$1.32	$1.19
Total	$4.64	$3.91	$3.20
Annual cost	$232,000	$391,000	$1,600,000

Table 5. Four Cavity Mold Estimate

This quote assessment included several assumptions associated with the packaging and assembly rates. Packaging includes a Tyvek® pouch for transportation and sterilization following production. Additionally, the packaging includes an IFU paper insert, printed inner shipping carton, shipping carton, shipping label, and pallet. The assembly process is as follows:

1. Attaching the scalpel blade to the ergonomic scalpel handle,
2. Staking the blade in place permanently,
3. Covering the blade with the blade protector,
4. Placing the scalpel and IFU paper insert in the Tyvek® pouch,
5. Sealing the Tyvek® pouch,
6. Placing the Tyvek® pouch in the printed inner shipping carton,
7. Placing 36 printed inner shipping cartons into one shipping carton,
8. Labeling the shipping carton (Robichaud, 2020).

Assembly is estimated to be completed by two US-based operators completing one handle and blade assembly every 30 seconds.

4.4 Marketing Results

Market analysis is a critical stage in production planning. This analysis includes an assessment of the target audience size, its willingness to adopt a new product, and the product's potential impact. These metrics should be treated as equally important and assessed simultaneously.

Using methods discussed in the prior chapter, our group produced the following results. First, when launching any product, thorough preparation and market research must validate an assumption of the need for the product in the market. This is supported by the Harvard Business Review, which published that "the biggest problem we've encountered is lack of preparation: Companies are so focused on designing and manufacturing new products that they postpone the hard work of getting ready to market them until too late in the game" (Hall & Schneider, 2014). The ergonomic scalpel handle not only has significant opportunity in the surgical tool market but also will fill a significant need for medical professionals. If the launch of the ergonomic scalpel handle is not strategic, it may negatively affect the product's future.

Another key point to emphasize is to assess whether "the product is revolutionary, but there's no market for it… 'Who will buy this and at what price?'" (Hall & Schneider, 2014). The ergonomic scalpel handle has a narrow target audience, which brings this concern to the forefront. As of the end of 2020, there are around 8,000 certified and practicing plastic surgeons in the United States. Then, if we are then

assessing the number of disposable scalpel handles they might need, a plastic surgeon will perform anywhere from one to eight surgeries per day (Placik, 2015).

While the number of scalpels used during each surgery will drastically vary depending on the surgical procedure, it is estimated to be anywhere from two to ten. This results in a total maximum demand of between 15 million and 77 million disposable handles (8,000-16,000 non disposable) per year assuming complete adoption of the plastic surgeons in the United States. This led to our focus on understanding the market for the ergonomic scalpel handle while also developing a marketing and business plan. We found that "the increasing use of surgical scalpel, owing to the rising incidences of neurological and cardiovascular diseases is projected to encourage the growth of the global surgical scalpel market in the coming years" as well as beneficial news pertaining to the world of plastic surgery; "The increasing demand for reconstructive and plastic surgery and the rising healthcare expenditure are likely to drive the [scalpel] market" (TMR Research, 2020).

With an accepting and growing market, it is still important to call forth the original question of "who will buy this and at what price" (Hall & Schneider, 2014). To enter the market, you must first determine if the market will positively adopt your product, no matter how ready the market is. As discussed in Section 3.7.2.1, our chosen strategy is to offer samples paired with a follow-up survey to get a sense of potential customer interest and develop word-of-mouth marketing. We suggest future MQP groups further develop and pursue this approach to understand and access the target audience and their opinions.

After reviewing other product launch histories, we concluded that an incremental innovation may be more likely to succeed in a market than a breakthrough innovation. Incremental innovation is defined as "making small, incremental improvements to add or sustain value to existing products...It relies on existing technology and an existing business model and as such, is low risk" (Yonder, 2020). A breakthrough innovation "requires introduction of a new technology. [It] is high risk as it requires greater investment than incremental innovation. However, the rewards can be greater too: it often results in a product or service which provides significantly better value to customers" (Yonder, 2020). The ergonomic scalpel handle can be considered a breakthrough innovation.

Though scalpel handles already exist, the curved-incision-enabling ergonomic scalpel handle has yet to be integrated into common medical practice. General feedback gathered by previous MQP teams indicated concerns over adoption as well as suggestions that the ergonomic scalpel handle in its current design may be too heavy for surgeon muscle memory (Comeau et al., 2014). To address the concerns about adoption, we suggest implementing incremental innovation. Rather than beginning with a breakthrough product, it may be easier to introduce an accessory product rather than a replacement

product. This accessory product would introduce the general idea to the audience in a more gradual way to allow for smooth adoption of the final ergonomic scalpel handle over time.

4.4.1 Sleeve Research

The accessory product we prototyped is referred to as the "sleeve" throughout this paper. This conceptual product would be slid over the current disposable or reusable hospital scalpel used in procedures. It would be secured with a simple clamping screw or a press fit and could be designed to be disposable or reusable. Prototyping methods are discussed in Section 3.7.2.1. In the prototyping stage, we used additive manufacturing to produce the sleeve out of PLA plastic, although this material cannot be sterilized in the autoclave. If this product were brought into production, it would need to either be produced using additive manufacturing out of a sterilizable material or injection molded out of ABS.

The sleeve product could address the issues associated with easier adoption and market potential, as well as other factors including cost and customizability. There is a significant variation specifically related to the cost of grip production when using additive manufacturing or injection molding compared to 5-axis machining. Production of the blade attachment requires precise tooling, increasing manufacturing costs. The sleeve does not include a blade attachment as it relies on the attachment on the inserted handle. Another benefit is that the sleeve is customizable. Surgeons can have their name etched into the handle as well as choose a desired grip and custom dimensions. For example, the ergonomic scalpel handle is currently targeted toward plastic surgeons and other specialties that require curved incisions. An additive manufactured sleeve model could allow for other specialties to choose a shape that would be just as beneficial to them.

4.5 Innovations and Recommendations for Future Research

Our main marketing recommendation is to offer the ergonomic scalpel handle to plastic surgeons as a free sample. Following this stage of product introduction, we then recommend pursuing trade shows and offering products to medical schools. A reasonable threshold for this transition could be positive feedback from 30+ plastic surgeons across several hospitals. According to the senior product manager at KLS Martin, trade shows are the main access point to advertise directly to surgeons. We recommend pairing this strategy with additional sampling and free product samples. We also suggest that integrating the ergonomic scalpel handle into medical schools, beginning locally. This would allow for gradual adoption that would negate the potential threat that "if consumers can't quickly grasp how to use your product, it's toast" (Hall & Schneider, 2014). If a medical student is finishing their schooling and building

their residency product wish list, the goal is for them to include the ergonomic scalpel handle after they have used it for some time in medical school.

In competition with other products currently being launched in today's technological environment, it is critical to develop a product innovation strategy. We must answer the question: what will be next for the ergonomic scalpel handle? Innovation can come from a variety of sources. It does not necessarily require changing the grip to be even better in the hand or that creating the next best tool based on the ergonomic scalpel handle. It could mean creating a website, marketing on social media, generating ads, adjusting materials, or changing from one manufacturing technique to another. After the initial pilot run produced using small-scale machining, the disposable handle could be introduced via additive manufacturing and eventually manufactured at scale using injection molding. A competitive product keeps pace with market trends. The ergonomic scalpel handle will be successful by the continual pursuit of various innovations, such as how to decrease production costs, increase production, extend marketing, and increase market share.

As we conclude our project knowing that constant improvement is required, we have a few recommendations for future working groups. We recommend continuing to develop customer review metrics by producing ergonomic scalpel handle prototypes to share with around thirty surgeons. Data was then gathered by pairing samples with the survey provided in Appendix A. Those sample scalpels could either be machined in WPI's Washburn Shops manufacturing lab or produced by additive manufacturing using sterilizable materials, which may need to be outsourced to an outside company. 3D Printable sterilizable material recommendation specification sheets can be found in Appendix D. After gathering feedback, several actions could be taken to address various features of the ergonomic scalpel handle market plan. This could include making a website, applying for trade shows, running surgeon focus groups, and continuing material selection and analysis.

Chapter 5: Conclusion

5.1 Recommendations and Conclusion

The primary focus of this project was to establish a feasible plan to launch the ergonomic scalpel handle in the surgical tool market. The conclusions of the MQP were as follows:

1) A holistic PESTEL analysis led our team to believe that the surgical tool market is ready to support the ergonomic scalpel handle.
2) A pilot run study was conducted to test run a machining manufacturing process. The cost structure of the pilot run was projected to be $35 per scalpel at a production volume of 16,000 per year.
3) Three manufacturing options were compared: machining, additive manufacturing, and injection molding. We recommend producing volumes greater than 100,000 handles per year using injection molding, which will have a per unit cost of $3.93. For initial production, we recommend using additive manufacturing (selective laser sintering) to print the handle. Specifically, this would allow easy adjustment of handle dimensions for user testing and potential for differently dimensioned models for users of various hand sizes, grip patterns, and shape preferences.

We recommend producing the disposable scalpel version using ABS plastic for the handle and TPU for the grip. Additionally, the reusable handle should be produced from 304 surgical stainless steel with a similar TPU grip. The final grip pattern recommendation is the diamond knurl pattern which offered the best friction in varying test procedures. We recommend further work to investigate customer response to the ergonomic scalpel handle. This work could use our developed survey tools and recommendations to support that effort. Due to predicted increasing demand for plastic surgery and the healthcare market generally, we predict that the ergonomic scalpel handle will be profitable given a successful product launch.

Chapter 6: Reflections

6.1 Assessing Customer Needs

When reflecting on the progress this team has experienced throughout the course of this project, addressing customer needs has been at the top of our priority list. Using effective communication skills to thoroughly understand our sponsor's needs was essential for every team interaction. Addressing and adjusting our FR_0, checking in with Dr. Dunn on a bi-weekly basis, repeatedly following through with research, and presenting new materials section documentation were all tasks our team made with Dr. Dunn's needs in mind. Learning to keep the customer's needs at the heart of our work was critical to staying focused throughout each task. It centered our team and kept us aligned on a common focal point. Having an anchor like that made working through a pandemic much easier.

6.2 Applying Decision Theory

Applying decision theory through the implementation of an axiomatic design into our problem statement was another skill critical to our success as a team. It taught us how to systematically identify our problem with the foresight to list potential functional requirements and design parameters. Addressing problems in this fashion creates an efficient team because every team member remains on the same page. By defining each step of the problem, and the subset problems that need to be addressed before an entire task is complete, there leaves little room for miscommunication. To set a team up for success in this way is an incredible project management skill for future leaders.

6.3 Disregarding Biases

Putting aside biases we might have with the investors, the ergonomic scalpel is viable for a product launch. However, given these unprecedented times, the cost of medical equipment is more important than ever. It is going to be an uphill battle to commercialize the ergonomic scalpel handle since it has a niche market and large overhead and fixed costs. Regardless, based on our PESTEL analysis, pilot run, cost comparison, and time value of money analysis (see Appendix E), we concluded that the market is ready for this innovative technology. The ergonomic scalpel handle does have the potential to be a great product, but it will be expensive to enter the market and slow to gain recognition.

6.4 Controlling Scope Creep

During the span of a large project, it is important to establish the scope of the project by defining the project goals, identifying what the project needs to produce, and what work is needed to complete it. Scope creep occurs when the group or its members start to spend time on work that does not build to the group's final goal or is outside the boundaries of the project. At the beginning of our group's project, we worked hard to establish the scope of our project with our sponsor. We had to work closely with Dr. Dunn to identify what he wanted to get out of our project, and with our advisor to make sure our work satisfied our MQP requirements. The establishment of the scope alone took weeks to establish and changed slightly as the project progressed. This evolution of our project scope challenged our group to stay organized using Gantt charts and other methods to make sure we avoided scope creep. However, with the evolution of the project goals, there was scope creep. We were lucky enough to have a very involved sponsor and advisor who were able to help us identify creep and help clarify any misconceptions that led to time being wasted. Although we faced many challenges during our project our group was able to follow the scope, reach all our deadlines, and gave our sponsor what he needed.

6.5 Determining Production Costs

Determining the cost of production for each of the three methods of manufacturing was an integral part of our project. The cost estimates required in depth analysis from industry professionals. Many variables affect these estimates including material, batch size, and production scale. The cost of production of the different manufacturing methods was useful to develop the final cost of production. This information will help to guide Dr. Dunn in making key decisions regarding the method in which to produce the ergonomic scalpel handle.

One takeaway from our work in acquiring the production costs was that detailed dimensions of the product will result in detailed cost estimates. Without CAD files for reference, it is difficult for industry professionals to create an accurate representation of the potential production costs. These interactions with industry professionals were extremely helpful in determining the production costs for the ergonomic scalpel handle.

6.6 Communicating with Industry Professionals

A large portion of the work associated with this MQP involved communicating with industry professionals. We conducted several interviews with various subjects as discussed in Chapter 3: Methods. These individuals were extremely helpful for building a background understanding of the various

processes and stakeholders associated with the ergonomic scalpel. Additionally, several individuals provided essential insight into manufacturing methods and cost estimates.

One major takeaway from this effort was the understanding that developing a competent set of contacts can provide essential specific information. To generate key information about the ergonomic scalpel handle features, pricing, and manufacturing, these direct contacts provided extremely valuable and direct information. This was much more helpful for the specific project than other research methods might have been. Drawing on contact expertise elevated the level of information our team could communicate with confidence to our sponsor.

6.7 Managing a Chaotic Work Environment

The standard work for an MQP tests students' abilities to work under pressure and in chaotic environments. This project has been no different. The effects of the COVID-19 pandemic have been significant, and its challenges were felt deeply by this team. With some members in remote locations and in-person meetings in a lab or on-campus prohibited, our ability to collaborate was challenged daily. We all had to adjust to supply the best deliverables we could under the circumstances given to us. Adaptability was by far one of the most important qualities for our team members to exemplify. Learning how to work in difficult environments, virtual or otherwise, will be a very valuable skill we take with us into the workforce post-graduation. This year is the first of many transformative years to come for us as entry-level engineers.

6.8 Working in an Interdisciplinary Group

Working in a large multidisciplinary team of Management Engineers and Industrial Engineers we were able to utilize our respective majors to complete this project. As our project shifted to be heavily manufacturing-based, we were fortunate enough to have one of our group members, Sara Beauchesne, who had experience with SolidWorks. She was able to provide our team with CAD/CAM files of the ergonomic scalpel handle along with 3D printed grip models that can be used for demonstration purposes. Another hurdle our team overcame was working remotely due to the COVID-19 pandemic. All interviews and the majority of team meetings were conducted via Zoom. It took great communication to distribute scalpels to interviewees and those responsible for prototyping. As the project neared completion with the help of Professor Bergstrom, operations manager at Washburn Shops, were able to utilize Washburn Shops to create a pilot run of the manufacturing of an ergonomic scalpel handle. We hope that with the continuation of this project in the future, more teams will develop further recommendations and prototypes to commercialize the ergonomic scalpel handle.

References

American Society for Quality. (2021). What is Lean? Retrieved February 20, 2021, from https://asq.org/quality-resources/lean

ASAPS. (May 19, 2020). Number of surgical and nonsurgical cosmetic procedures in the United States in 1997 and 2019 [Graph]. In Statista. Retrieved February 20, 2021, from https://www-statista-com.ezpxy-web-p-u01.wpi.edu/statistics/281211/us-surgical-and-nonsurgical-cosmetic-procedures/

Aspen Surgical. (2019). Instructions For Use: Bard-Parker Conventional Blade System. Retrieved February 9, 2021, from https://www.aspensurgical.com/ifu/

Aspen Surgical (n.d.). Bard-Parker® Conventional Blades & SCALPELS. Retrieved April 06, 2021, from https://www.aspensurgical.com/catalog/blades-scalpels/bard-parker-conventional-blades-scalpels/

Aspen Surgical. (2021). Bard-Parker® Surgical Blade Handle Size 3 371030. Retrieved February 12, 2021, from https://www.aspensurgical.com/catalog/blades-scalpels/bard-parker-conventional-blades-scalpels/bard-parker-conventional-handles/371030

Bond, C. (2020, May 4). 9 Examples of Inbound Marketing that Gets Customers. Retrieved October 25, 2020, from https://www.wordstream.com/blog/ws/2018/11/05/inbound-marketing-examples

Brill, J. B., & Harrison, E. K. (2018, January 31). The history of the scalpel: From flint to zirconium-coated steel. Retrieved November 20, 2020, from https://bulletin.facs.org/2018/02/the-history-of-the-scalpel-from-flint-to-zirconium-coated-steel/

Brill, J. B., Harrison, E. K., Sise, M. J., & Ignacio, R. C., Jr. (2018, January 1). The history of the scalpel: From flint to zirconium-coated steel. Retrieved February 9, 2021, from https://bulletin.facs.org/2018/02/the-history-of-the-scalpel-from-flint-to-zirconium-coated-steel/

Brown, P., Dahlmann, J., Palumbo, N. (2010). Improving the Ergonomic Design of Scalpel Handles (Undergraduate Major Qualifying Project No. E-Project-042910-163310). Retrieved from Worcester Polytechnic Institute Electronic Projects Collection:. https://web.wpi.edu/Pubs/E-project/Available/E-project-042910-163310

Burnes, R. (2019, October 30). Inbound Marketing vs. Outbound Marketing. Retrieved October 25, 2020, from https://brayve.net/blog/2019/10/30/inbound-marketing-vs-outbound-marketing/

BusinessWire. (2020, August 31). COVID-19 Pandemic Impact on Global Surgical Scalpel Market 2020-2024: Technavio. Retrieved February 9, 2021, from https://www.businesswire.com/news/home/20200831005616/en/

Center for Devices and Radiological Health. (2020, March 13). Premarket Notification 510(k). Retrieved February 9, 2021, from https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k

Chandra, S., Podder, I., Chatterjee, M., & Field, L. (2018). Anatomy and Applications of the #15 Scalpel Blade and Its Variations. Journal of cutaneous and aesthetic surgery, 11(2), 79–82. https://doi.org/10.4103/JCAS.JCAS_70_16

Comeau, N., Dunn, S., Salazar, E., Travison, C., & Mukhanov, E. (2014). The Commercialization of an Ergonomic Scalpel. : Worcester Polytechnic Institute.

DeGiorlamo, K. M., Courtemanche, D. J., Hill, W. D., Kennedy, A., & Skarsgard, E. D. (2012, August 15). Use of safety scalpels and other safety practices to reduce sharps injury in the operating room: What is the evidence? Retrieved February 9, 2021, from http://canjsurg.ca/vol56-issue4/56-4-263/

Dossett, J. L., & Boyer, H. E. (2006). Practical heat treating. Asm International.

Evaluate. (September 26, 2017). Total global medical technology growth per year from 2010 to 2022 [Graph]. In Statista. Retrieved February 09, 2021, from https://www-statista-com.ezpxy-web-p-u01.wpi.edu/statistics/329048/worldwide-medical-technology-growth-per-year/

Future Market Insights Global and Consulting Pvt. Ltd. (2017, November 21). Global Surgical Scalpels Market to reach US$ 1400 Mn by 2027 End – Future Market Insights. Retrieved March 9, 2021, from https://www.globenewswire.com/news-release/2017/11/21/1197900/0/en/Global-Surgical-Scalpels-Market-to-reach-US-1400-Mn-by-2027-End-Future-Market-Insights.html

Gray S. M2D2 helps great ideas become commercial products. UMass Med News Website. https://www.umassmed.edu/es/news/news-archives/2011/07/m2d2/. Updated 2011. Accessed November 20, 2020.

Guiliani, R., & Bolbach, T. (2013, July 3). Achieving Lean Manufacturing through Lean Design. Retrieved March 1, 2021, from https://www.industryweek.com/operations/continuous-improvement/article/21960645/achieving-lean-manufacturing-through-lean-design

Hall, J., & Schneider, J. (2014, August 1). Why most product launches fail. Retrieved March 03, 2021, from https://hbr.org/2011/04/why-most-product-launches-fail

Halligan, B. (2019, October 31). Inbound Marketing vs. Outbound Marketing. Retrieved October 25, 2020, from

https://blog.hubspot.com/blog/tabid/6307/bid/2989/inbound-marketing-vs-outbound-marketing.aspx

"Haptics." Merriam-Webster.com Dictionary, Merriam-Webster, https://www.merriam-webster.com/dictionary/haptics. Accessed 25 Feb. 2021.

Laboratory for Product Development and Lightweight Design. (2019, October 14). The Design Structure Matrix. Retrieved March 1, 2021, from https://dsmweb.org/home-2/

Lehrer, M., MD. (2020, January 21). Skin Lesion Removal. In Medline Plus. Retrieved November 24, 2020, from https://medlineplus.gov/ency/article/007673.htm

Leone, C. (2015, October). What Is The Right Inbound and Outbound Marketing Mix? Retrieved November 25, 2020, from https://www.webstrategiesinc.com/blog/what-is-the-right-inbound-outbound-marketing-mix

MarketWatch. (2021, April). Surgical Scalpel Sales Market Size with Top Countries Industry Chain Structure, Competitive Landscape, New projects and Investment Analysis By 360 Research Report. Retrieved April 6, 2021, from https://www.marketwatch.com/press-release/surgical-scalpel-sales-market-size-with-top-countries-industry-chain-structure-competitive-landscape-new-projects-and-investment-analysis-by-360-research-report-2021-04-06#:~:text=The%20global%20Surgical%20Scalpel%20market,4.2%25%20during%202022%2D2027.&text=The%20global%20Surgical%20Scalpel%20market%20is%20segmented%20by%20company%2C%20region,by%20Type%2C%20and%20by%20Application.

Martin, O., Schiebel, R., Truc Pham, P., & Paul, W. (2020). Designing of Ergonomic Scalpel Handles with Optimized Weight and Balance. : Worcester Polytechnic Institute.

Placik, O. (2015, December 6). How many patients does a plastic Surgeon operate per day? Retrieved March 11, 2021, from https://www.realself.com/question/Plastic-surgeon-number-patients-average

Rutala, W. A., & Weber, D. J. (2019, May 24). Guideline for Disinfection and Sterilization in Healthcare Facilities. Retrieved from https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html

Scott, W. (2018, February). Top 5 Reasons to Advertise on YouTube. Retrieved November 25, 2020, from https://marketingbitz.com/top-5-reasons-to-advertise-on- youtube/

Shadbolt P. (2015, April 2). How Stone Age blades are still cutting it in modern surgery. CNN. Available at: www.cnn.com/2015/04/02/health/surgery-scalpels-obsidian/index.html. Accessed November 10, 2017.

Southern Africa Stainless Steel Development Association (Sassda). (2021, February 04). Stainless Steel and the Environment. Retrieved February 9, 2021, from https://sassda.co.za/about-stainless/stainless-steel-and-the-environment/

Stewart, C. (2019, September 13). Total Global Medical Technology Growth Per Year 2010-2022. Retrieved April 06, 2021, from https://www.statista.com/statistics/329048/worldwide-medical-technology-growth-per-year/

Stone, R., & McCloy, R. (2004). Ergonomics in medicine and surgery. BMJ: British Medical Journal, 328(7448), 1115-1118. Retrieved November 20, 2020, from http://www.jstor.org.ezpxy-web-p-u01.wpi.edu/stable/41709733

Nam P. Suh. Axiomatic design theory for systems. Res Eng Des. 1998;10(4):189-209. https://link.springer.com/article/10.1007/s001639870001. doi: 10.1007/s001639870001.

Nam P. Suh. The principles of design. Oxford University Press; 1990.

Ted Pella. (2021). Retrieved April 06, 2021, from https://www.tedpella.com/

The Insight Partners. (2018, June). Surgical Scalpel Market to 2025 - Global Analysis and Forecasts by Product (Disposable Surgical Scalpel, Reusable Surgical Scalpels and Accessories); Type (Standard Surgical Scalpels and Safety Surgical Scalpels); Material (Stainless Steel, High Grade Carbon Steel and Others); End User (Hospitals, Ambulatory Surgical Centers, Nursing Centers and Reference Laboratories) and Geography. Retrieved February 20, 2021, from https://www.theinsightpartners.com/reports/surgical-scalpel-market

TMR Research. (2020, July 03). Surgical scalpel market competitive analysis and Forecast report by 2025. Retrieved March 11, 2021, from https://www.biospace.com/article/surgical-scalpel-market-competitive-analysis-and-forecast-report-by-2025/

U.S. Food & Drug Administration. (2021, February 8). Product Classification. Retrieved February 9, 2021, from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=GES

Uriarte, A. G., Moris, M. U., Ng, A. H., & Oscarsson, J. (2015, Winter). LEAN, SIMULATION AND OPTIMIZATION: A WIN-WIN COMBINATION. Retrieved February 20, 2021, from https://www.informs-sim.org/wsc15papers/226.pdf

Worcester Polytechnic Institute (WPI). Robert H. Goddard award for outstanding professional achievement: Raymond Dunn '78. 2013.

Yonder. (2020, September 24). Incremental, breakthrough and radical innovation: Deciphering the differences. Retrieved March 03, 2021, from https://yonderconsulting.com/incremental-breakthrough-radical-innovation/

Appendix

Appendix A: Survey for Future Testing

Intro Questions: (Short Response)

1. What is your surgical specialty?
2. How many years have you been practicing?
3. Do you use a standard scalpel design when practicing surgery?

Background Questions: (Multiple Choice)

The scale for these questions will be from 0-5, zero being strongly disagree and five being strongly agree

1. I am content with the current scalpel I use
2. I am open to change with new scalpel designs and using them in practice
3. The scalpel design I currently use is comfortable in my hand
4. The scalpel l currently use is too slippery
5. The scalpel design I currently use is aesthetically pleasing
6. With the scalpel I currently use I have difficulty making curved or precise incisions
7. I would consider a scalpel that has a more precise grip and facilitates more precise incision placement.

Questions Regarding the Ergonomic Scalpel Handle:

The scale for these questions will be from 0-5, zero being strongly disagree and five being strongly agree

1. The ergonomic scalpel grip is too heavy/ too light
2. The ergonomic scalpel grip is more secure than a regular scalpel
3. The ergonomic scalpel is well balanced, (it is tip heavy 0 / well balanced 3 / back heavy 5)
4. The ergonomic scalpel is too heavy/light
5. The ergonomic scalpel is aesthetically preferable
6. I would prefer to use an an ergonomic handle over a traditional scalpel
7. I would recommend an ergonomic scalpel to my colleagues

Open Response Questions:

How did you hear about the Dr. Dunn Scalpel?

Appendix B: Instructions for Use - Aspen Surgical: Blade

Aspen Surgical

Instructions for Use

Bard-Parker® Conventional Blade System

Intended Use

- Intended for tissue separation and other procedures that require a sharp blade to puncture or cut.

Precautions

- The way in which a surgical blade is handled prior to use can affect the way in which the blade performs during use. Take care to ensure the cutting edge of a blade does not become damaged once removed from its packaging. This includes dropping the blade into a metal bowl or other container that could potentially dull the blade. It also includes not gripping the blade with a forceps or needle clamp across the cutting edge of the blade.
- During use, avoid putting excessive force or strain on the blade in order to help prevent breakage.
- Keep in mind that surgical blades are sharp instruments. Take proper precautions in handling the blade so as not to injure yourself or others before, during, or after use. Seek proper training and instruction on use before handling.
- This device is single use only. Reuse of this device may lead to patient cross contamination and/or device failure.
- During use avoid twisting, bending or putting excessive force or strain on the blade in order to help prevent breakage.
- A singular blade is intended to cut tissue up to 24 inches.
- If blade becomes dull or breaks, dispose and replace product.

Instructions for Use

Attaching the Surgical Blade

1. Peel pouch open. Grip blade with forceps or needle clamp and remove from pouch, taking special care not to grip across the cutting edge of the blade itself.
2. Holding on to the thickest part of blade with forceps or needle clamp, insert the handle into blade track.
3. Slide blade back onto handle until it clicks into position.

Removing the Surgical Blade

1. Grip bottom of blade with forceps or needle clamp and pull up to loosen blade from handle.
2. Push blade forward from handle to remove blade, being careful not to jerk the blade off the track.
3. Dispose in an approved puncture-resistant sharps container according to facility protocol.

Do not use if package is damaged

Does not contain natural rubber latex

℞ONLY Caution: Federal law restricts this device to sale by or on the order of a physician

Aspen Surgical Products, Inc.
6945 Southbelt Dr. SE
Caledonia, MI 49316 USA
Phone 616-698-7100
Toll-Free 888-364-7004
www.aspensurgical.com

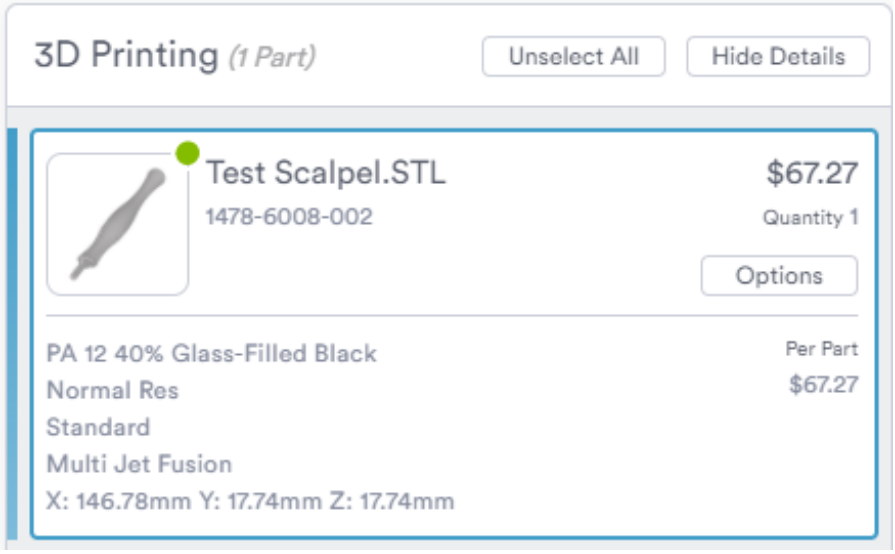
EC REP
Hill-Rom Limited
Clinitron House, Ashby Park
Ashby De La Zouch
Leicestershire, LE65 1JG
England

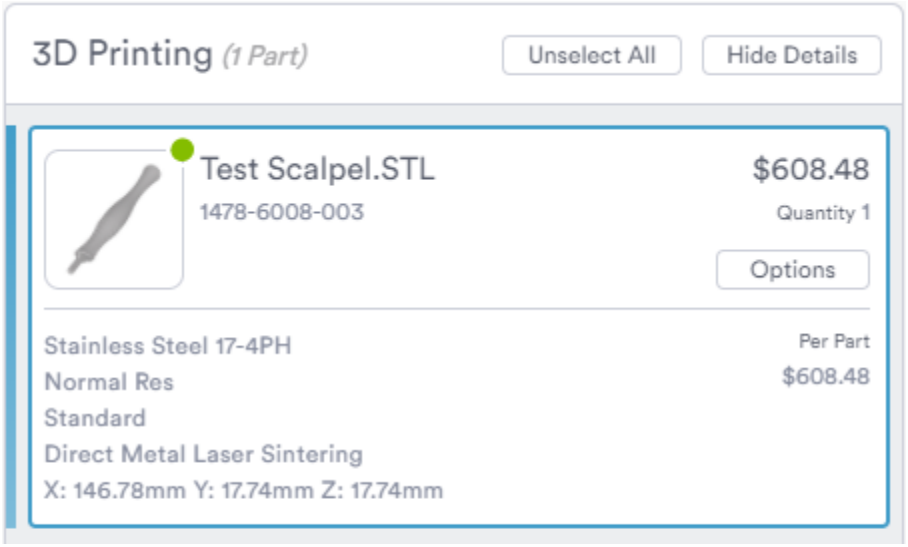
CE 0086 ℞ONLY STERILE R

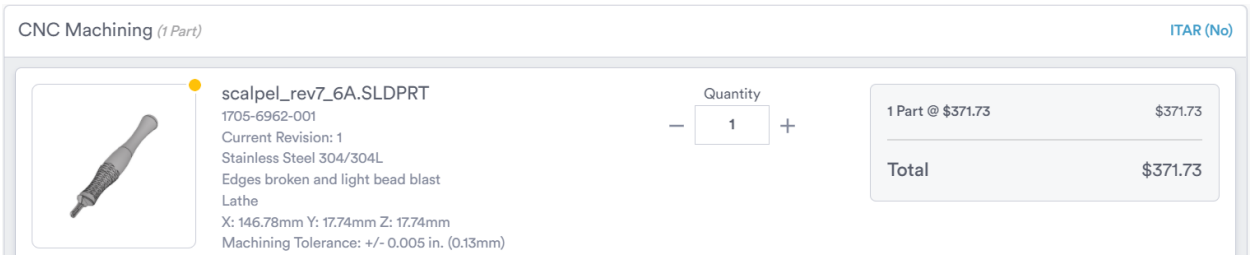
1007576 rev 6 ENG – US

Enhancing outcomes for patients and their caregivers: Hill-Rom

Appendix C: Protolab Quotes: Additive Manufacturing, CNC Machining, and Injection Molding







Injection Molding *(1 Part)*

ITAR (No)

View Analysis
Configure Part
Upload Revision
Part Options

scalpel_rev7_6A.SLDPRT
1752-9007-002
Current Revision: 1
Mold Life: Unlimited
1 Cavity
PC : Lexan 940 (Black) [LOW STOCK]
Black (Original Material Color)
Cosmetic: PM-F1
Non-Cosmetic: PM-F0
X: 146.78mm Y: 17.74mm Z: 17.74mm
Machining Tolerance: +/- 0.003 in. (0.076 mm)

⚠ This part needs your attention: ⓘ

Sample Quantity
– 25 +

See volume pricing as low as $0.78

25 Parts @ $2.77	$69.25
Mold	$12,095.00
Total	**$12,164.25**

Overmolding *(1 Part)*

ITAR (No)

View Analysis
Configure Part
Upload Revision
Part Options

Assem1.SLDASM
1463-6220-002
X: 5.778in Y: 0.702in Z: 0.702in

Substrate
Mold Life: Unlimited
1 Cavity
Nylon 12 : Grilamid TR 55
Clear (Original Material Color)
Cosmetic: PM-F0
Non-Cosmetic: PM-F0
X: 146.78mm Y: 17.24mm Z: 17.24mm
Machining Tolerance: +/- 0.003 in. (0.076 mm)

Overmold
Mold Life: Unlimited
1 Cavity
Silicone : Elastosil 3003/40 A/B (Clear) [LOW STOCK]
Blue Tint 2% (Blue 292)
Cosmetic: PM-F0
Non-Cosmetic: PM-F0
X: 43.50mm Y: 17.84mm Z: 17.84mm
Machining Tolerance: +/- 0.003 in. (0.076 mm)

Sample Quantity
– 25 +

See volume pricing as low as $4.59

25 Parts @ $8.48	$212.00
Mold	$11,485.00
Total	**$11,697.00**

Appendix D: 3D Printable Sterilizable Material

HP 3D High Reusability PA 12 Glass Beads

Stiff, low-cost, quality parts

3D data courtesy of NACAR

Produce stiff, functional parts

- 40% glass bead filled thermoplastic material with both optimal mechanical properties and high reusability.[1]
- Provides dimensional stability along with repeatability.[2]
- Ideal for applications requiring high stiffness like enclosures and housings, fixtures and tooling.

Quality at a low cost per part

- Produce at a low cost per part and reduce your total cost of ownership.[3]
- Less waste—reuse surplus powder batch after batch and get functional parts, no throwing away anymore.[1]
- Get consistent performance while achieving up to 70% surplus powder reusability.[4]
- Optimize cost and part quality—cost-efficient material with high surplus powder reusability.[1]

Engineered for HP Multi Jet Fusion technology

- Designed for production of functional parts across a variety of industries.
- Provides the best balance between performance and reusability.[5]
- Engineered to produce common glass bead applications with detail and dimensional accuracy.

For more information, please visit
hp.com/go/3DMaterials

Technical specifications[6]

Category	Measurement	Value	Method
General properties	Powder melting point (DSC)	186° C/367° F	ASTM D3418
	Particle size	58 µm	ASTM D3451
	Bulk density of powder	0.48 g/cm³/0.017 lb/in³	ASTM D1895
	Density of parts	1.3 g/cm³/0.047 lb/in³	ASTM D792
Mechanical properties	Tensile strength, max load[7], XY, XZ, YX, YZ	30 MPa/4351 psi	ASTM D638
	Tensile strength, max load[7], ZX, XY	30 MPa/4351 psi	ASTM D638
	Tensile modulus[7], XY, XZ, YX, YZ	2500 MPa/363 ksi	ASTM D638
	Tensile modulus[7], ZX, XY	2700 MPa/392 ksi	ASTM D638
	Elongation at break[7], XY, XZ, YX, YZ	10%	ASTM D638
	Elongation at break[7], ZX, XY	10%	ASTM D638
	Flexural strength (@ 5%),[8] XY, XZ, YX, YZ	57.5 MPa/8340 psi	ASTM D790
	Flexural strength (@ 5%),[8] ZX, XY	65 MPa/9427 psi	ASTM D790
	Flexural modulus,[8] XY, XZ, YX, YZ	2400 MPa/348 ksi	ASTM D790
	Flexural modulus,[8] ZX, XY	2700 MPa/392 ksi	ASTM D790
	Izod impact notched (@ 3.2 mm, 23ºC), XY, XZ, YX, YZ, ZX, ZY	3 KJ/m²	ASTM D256 Test Method A
	Shore Hardness D, XY, XZ, YX, YZ, ZX, ZY	82	ASTM D2240
Thermal properties	Heat deflection temperature (@ 0.45 MPa, 66 psi), XY, XZ, YX, YZ	174° C/345° F	ASTM D648 Test Method A
	Heat deflection temperature (@ 0.45 MPa, 66 psi), ZX, XY	175° C/347° F	ASTM D648 Test Method A
	Heat deflection temperature (@ 1.82 MPa, 264 psi), XY, XZ, YX, YZ	114° C/237° F	ASTM D648 Test Method A
	Heat deflection temperature (@ 1.82 MPa, 264 psi), ZX, XY	120° C/248° F	ASTM D648 Test Method A
Reusability	Minimum refresh ratio for stable performance	30%	
Recommended environmental conditions	Recommended relative humidity	50–70% RH	
Certifications	UL 94, UL 746A, RoHS,[5] REACH, PAHs		

Ordering information

	HP 3D High Reusability PA 12 Glass Beads	HP 3D High Reusability PA 12 Glass Beads	HP 3D High Reusability PA 12 Glass Beads Production Material	HP 3D High Reusability PA 12 Glass Beads[10, 11, 12, 13]
Product Number	V1R11A	V1R22A	V1R35A	V1R23A
Weight	15 kg/33.1 lb	150 kg/330.7 lb	150 kg/330.7 lb	700 kg/1543.2 lb
Capacity	30L[14]	300L[14]	300L[14]	1400L[14]
Dimensions (xyz)	600 x 333 x 302 mm (23.6 x 13.1 x 11.9 in)	800 x 600 x 1205 mm (31.5 x 23.6 x 47.4 in)	800 x 600 x 1205 mm (31.5 x 23.6 x 47.4 in)	1143 x 1143 x 1500 mm (45 x 45 x 59 in)
Printer compatibility	HP Jet Fusion 3D 4210/4200 Printing Solutions	HP Jet Fusion 3D 4210/4200 Printing Solutions	HP Jet Fusion 3D 4210 Printing Solution	HP Jet Fusion 3D 4210 Printing Solution
Fast cooling compatibility	Compatible	Compatible	Compatible	Compatible

Eco Highlights

- Powders and agents are not classified as hazardous[15]
- Cleaner, more comfortable workplace—enclosed printing system, and automatic powder management[16]
- Minimizes waste due to high reusability of powder[17]

Find out more about HP sustainable solutions at hp.com/ecosolutions

Dynamic security enabled printer. Only intended to be used with cartridges using an HP original chip. Cartridges using a non-HP chip may not work, and those that work today may not work in the future. More at: hp.com/go/learnaboutsupplies

Learn more at
hp.com/go/3DMaterials

1. Based on using recommended packing densities, offers high reusability of surplus powder. Liters refers to the materials container size and not the actual materials volume. Materials are measured in kilograms.
2. Testing according to ASTM D638, ASTM D256, and ASTM D648 using HDT at different loads with a 3D scanner for dimensional stability. Testing monitored using statistical process controls.
3. Compared to selective laser sintering (SLS) and fused deposition modeling (FDM) technologies, HP Multi Jet Fusion technology can reduce the overall energy requirements needed to attain full fusing and reduce the system requirements for large, vacuum-sealed ovens. In addition, HP Multi Jet Fusion technology uses less heating power than SLS systems for better material properties and material reuse rates, minimizing waste.
4. HP Jet Fusion 3D Printing Solutions using HP 3D High Reusability PA 12 Glass Beads provide up to 70% post-production surplus powder reusability, producing functional parts batch after batch. For testing, material is aged in real printing conditions and powder is tracked by generations (worst case for reusability). Parts are then made from each generation and tested for mechanical properties and accuracy.
5. Compared to selective laser sintering (SLS) technology. Based on running a scan on the 3D printing part to measure and compare with the original STL file (using GOM software). For testing, material is aged in real printing conditions and powder is tracked by generations (worst case for reusability). Parts are then made from each generation and tested for mechanical properties and accuracy.
6. The following technical information should be considered representative of averages or typical values and should not be used for specification purposes. These values refer to a balanced print mode with FW TATDAG_15_18_11.69. Orientations defined according to ASTM F2971.
7. Test results realized under the ASTM D638 with a test rate of 1 mm/min for Z type test and a test rate of 10 mm/min for XY type test, specimens type V.
8. Test results realized under ASTM D790 Procedure B at a test rate of 13.55 mm/min.
9. RoHS certification for EU, Bosnia-Herzegovina, China, India, Japan, Jordan, Korea, Serbia, Singapore, Turkey, Ukraine, Vietnam.
10. Additional material management equipment is required.
11. This SKU is only available for the HP Jet Fusion 3D 4210B Printing Solution.
12. This product number is sold directly by HP.
13. Available during the second half of 2019.
14. Liters refers to the materials container size and not the actual materials volume. Materials are measured in kilograms.
15. The HP powder and agents do not meet the criteria for classification as hazardous according to Regulation (EC) 1272/2008 as amended.
16. Compared to manual print retrieval process used by other powder-based technologies. The term "cleaner" does not refer to any indoor air quality requirements and/or consider related air quality regulations or testing that may be applicable.
17. HP Jet Fusion 3D Printing Solutions using HP 3D High Reusability PA 12 Glass Beads material provide up to 70% post-production surplus powder reusability, producing functional parts batch after batch.

4AA7-0716ENE, January 2019

This is an HP Indigo digital print.

DIRECT METAL LASER SINTERING

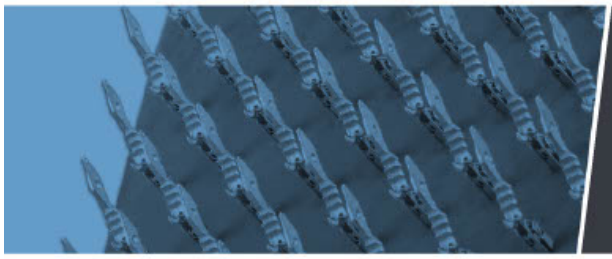
STAINLESS STEEL 17-4PH
PRODUCT SPECIFICATIONS

PRODUCT DESCRIPTION:

Protolabs' Stainless Steel 17-4PH material is used in our Direct Metal Laser Sintering process. It is available in micro-resolution.

APPLICATIONS:

Used in our micro-resolution DMLS process, Protolabs' Stainless Steel 17-4PH allows for production quality metal parts with the finest features and tightest tolerances in the industry. 17-4PH is a martensitic precipitation hardening stainless steel that is known for its hardness and corrosion resistance. Applications include medical, aerospace, and mechanical components. To increase mechanical properties, 17-4PH can be hardened with heat treatment. H900 heat treatment will be standard, but parts can be left in the annealed condition upon request.



KEY PRODUCT BENEFITS

- Heat treated for full hardness and strength
- High hardness
- Corrosion resistant

PROPERTIES:

Standard	Ultimate Tensile Strength (ksi)	0.2% Yield (ksi)	Elongation (%)	Hardness (HRC)
AMS5604G	190	170	8	40–47 HRC

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Protolabs HQ, 5540 Pioneer Creek Dr., Maple Plain, MN 55359 USA

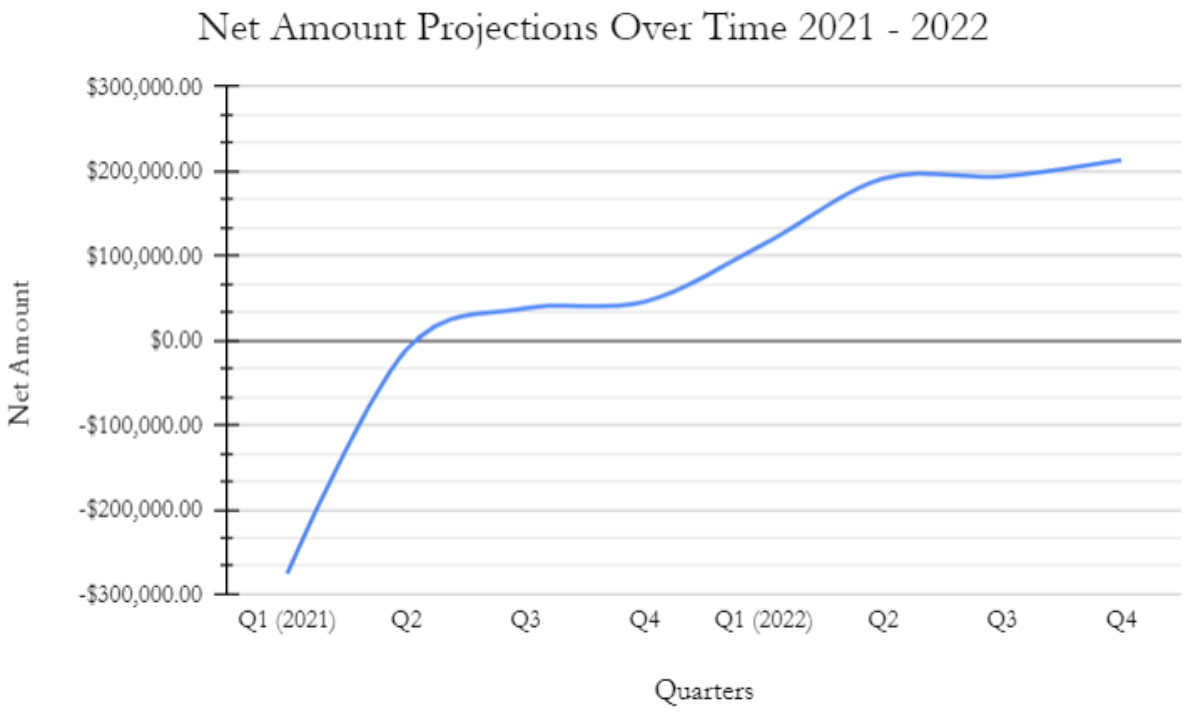
Appendix E: Time Value of Money Analysis

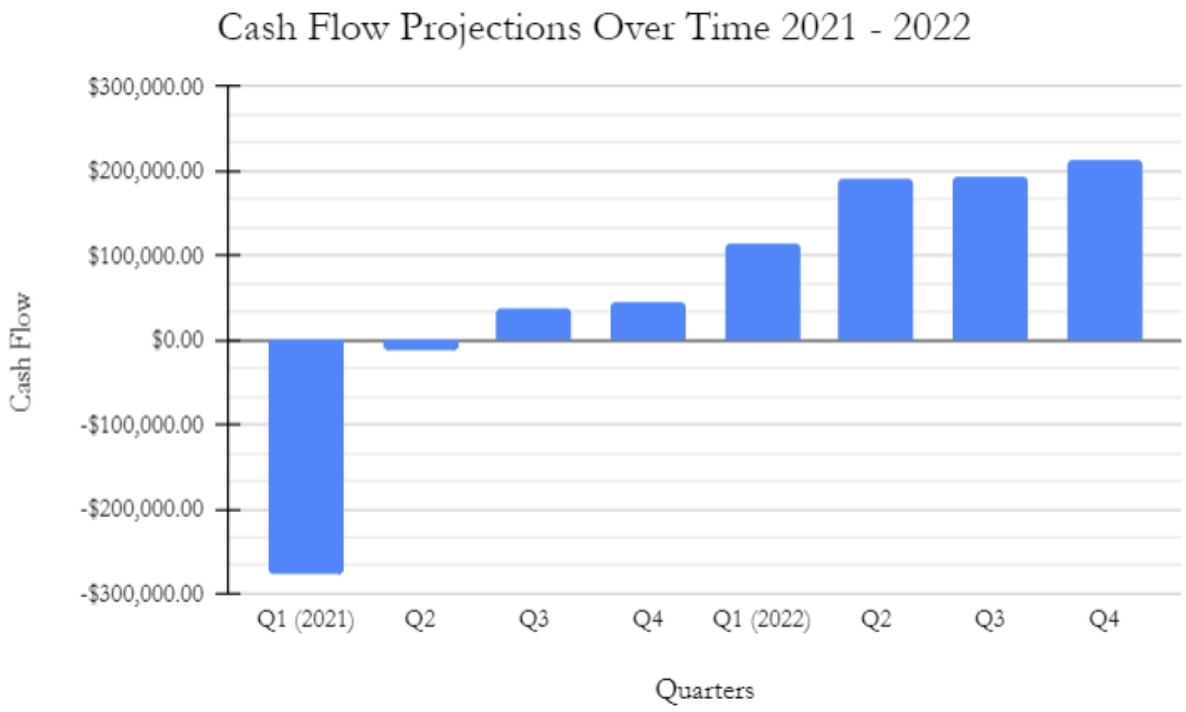
Adoption Rates Impacting Time Value Money Analysis				
Adoption rates	Quarter Per Year	Market Share	Units	Demand Per Year
2021	Q1	0.0001%	387.6	
	Q2	0.00040%	1550.4	
	Q3	0.00200%	7752	
	Q4	0.0022%	8527.2	18217.2
2022	Q1	0.0040%	15504	
	Q2	0.0060%	23256	
	Q3	0.0066%	25581.6	
	Q4	0.0071%	27519.6	91861.2
Global Surgical Scalpel Market Value (MarketWatch, 2021)	387,600,000	110078.4		
Price Per Unit	$10.00			

Table 6. Adoption Rates Impacting Time Value Money Analysis

Break-Even Point = Fixed Costs ÷ (Revenue per Unit – Variable Cost per Unit)	
Break-Even Point (Units)	34,375
Fixed costs	$253,000.00
Revenue per unit	$10.00
Variable cost per unit	$2.64

Table 7. Break Even point


Net Amount Projections Over Time 2021 - 2022
$300,000.00
$200,000.00
$100,000.00
$0.00
-$100,000.00
-$200,000.00
-$300,000.00
Net Amount
Q1 (2021)
Q2
Q3
Q4
Q1 (2022)
Q2
Q3
Q4
Quarters


Cash Flow Projections Over Time 2021 - 2022
$300,000.00
$200,000.00
$100,000.00
$0.00
-$100,000.00
-$200,000.00
-$300,000.00
Cash Flow
Q1 (2021)
Q2
Q3
Q4
Q1 (2022)
Q2
Q3
Q4
Quarters

Cash Flows (Accounting for Inflation)							
		Cash Out	Cash In	Net Amount	Year Net	Adjusted for Inflation	Inflation
2021	Q1	$279,400.00	$3,876.00	-$275,524.00			1.80%
	Q2	$26,400.00	$15,504.00	-$10,896.00			1.80%
	Q3	$39,600.00	$77,520.00	$37,920.00			1.80%
	Q4	$39,600.00	$85,272.00	$45,672.00	-$202,828.00	-$202,829.02	1.80%
2022	Q1	$41,200.00	$155,040.00	$113,840.00			1.90%
	Q2	$41,200.00	$232,560.00	$191,360.00			1.90%
	Q3	$61,800.00	$255,816.00	$194,016.00			1.90%
	Q4	$61,800.00	$275,196.00	$213,396.00	$712,612.00	$712,613.04	1.90%

Table 8. Cash Flows (Accounting for Inflation)