



# The Commercialization of an Ergonomic Scalpel

A Major Qualifying Project

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By

A handwritten signature in black ink, appearing to read "Nicholas Comeau", written over a horizontal line.

Nicholas Comeau

A handwritten signature in black ink, appearing to read "E. Salazar", written over a horizontal line.

Enrique Salazar

A handwritten signature in black ink, appearing to read "Sarah Dunn", written over a horizontal line.

Sarah Dunn

A handwritten signature in black ink, appearing to read "Cheryl Trivison", written over a horizontal line.

Cheryl Trivison

A handwritten signature in black ink, appearing to read "Elizabeth Mukhanov", written over a horizontal line.

Elizabeth Mukhanov

Submitted to:  
Dr. Raymond M. Dunn, MD  
UMass Memorial Medical Center

Prof Adrienne Hall-Phillips  
Prof Jerry Schaufeld

## **Abstract**

The goal of this project was to analyze the feasibility of commercializing a newly patented ergonomic surgical scalpel. In order to achieve this, we collected data, performed a feasibility analysis, and provided recommendations. We evaluated four areas: the medical device market, manufacturing, consumer research, and intellectual property. We concluded that this product would not be viable for commercialization as a stand-alone product. Alternative methods to commercialization may be required in order to generate future success if this product reaches market.

## **Acknowledgements**

The team would like to thank our sponsor, Dr. Dunn, and our advisors, Professor Hall-Phillips and Professor Schaufeld, for their continuous help and support on our project. We would also like to thank all those who participated in our research.

## Authorship

Each member within our group contributed a substantial amount to this paper, and the project as a whole. View the chart below for a more thorough breakdown of who contributed to each specific section of the paper. Additionally, all members involved edited this paper in equal parts.

<b>Chapter/Section</b>	<b>Primary Author</b>
<b>1</b>	Elizabeth Mukhanov/Sarah Dunn
<b>2.1</b>	Enrique Salazar/Nick Comeau
<b>2.2</b>	Enrique Salazar
<b>2.3</b>	Team
<b>2.4, 2.4.1</b>	Elizabeth Mukhanov
<b>2.5, 2.6</b>	Team
<b>2.7</b>	Sarah Dunn
<b>2.8</b>	Cheryl Trivison
<b>2.9</b>	Cheryl Trivison
<b>2.10</b>	Team
<b>3</b>	Elizabeth Mukhanov
<b>3.1</b>	Team
<b>3.1.1, 3.1.2</b>	Elizabeth Mukhanov
<b>3.1.3, 3.1.4, 3.1.5</b>	Team
<b>3.1.6</b>	Elizabeth Mukhanov
<b>3.2, 3.3</b>	Nick Comeau
<b>4</b>	Team
<b>4.1</b>	Nick Comeau
<b>4.2.1</b>	Sarah Dunn/Cheryl Trivison/ Elizabeth Mukhanov
<b>4.2.2</b>	Cheryl Trivison
<b>4.2.3</b>	Elizabeth Mukhanov
<b>4.3.1</b>	Team
<b>4.3.2</b>	Sarah Dunn
<b>4.4.1, 5, 5.1</b>	Nick Comeau
<b>5.2</b>	Elizabeth Mukhanov/Nick Comeau
<b>5.3, 5.3.1</b>	Nick Comeau
<b>5.3.2</b>	Cheryl Trivison
<b>5.3.3</b>	Sarah Dunn
<b>References</b>	Team
<b>Appendix A</b>	Nick Comeau
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## **Executive Summary**

Professionals in surgical fields often require high-quality surgical tools for increased precision and comfort. With the constant improvement of surgical devices, the use of ergonomically-efficient tools is becoming more common. The sponsor for our project was Dr. Raymond Dunn, Professor and Chief of Plastic Surgery at UMass Memorial Medical Center. His company, 5G Medical, was formed in 2011 and currently holds multiple patents in the medical device industry. Dr. Dunn aims to identify the ideal method for commercializing each of the patents. One of these patents is for recently designed surgical scalpel that features an ergonomic handle. He developed this scalpel because the scalpel that is currently used has some perceived design limitations.

## **Goal and Methodology**

Our project goal was to analyze if it was feasible to commercialize the 5G ergonomic scalpel. In order to achieve this goal, three objectives needed to be accomplished. The first objective was data collection. Background research was the first step in the data collection process. Afterwards, our team interviewed industry experts, manufacturers, users of the existing scalpel, and hospital staff. This allowed us to gain a better understanding of the aspects that needed to be considered in order to make an informed decision. After the data collection portion of the project had been completed, we performed a feasibility analysis to determine whether commercializing the scalpel was possible. This involved constructing a cost-benefit analysis based on all the information we had previously gathered. We identified four main aspects that impacted the commercialization of the 5G ergonomic scalpel: intellectual property, manufacturing, consumer research, and current state of the market. After having reached a



conclusion, our final task was to provide 5G Medical with recommendations on how to move forward in the market.

## **Results**

After having researched each of the four main aspects, we could then proceed to interpret the results. For intellectual property, we assessed whether the protection and freedom to operate offered by 5G's patent would significantly help this product succeed in the market. Our team determined that 5G's ergonomic scalpel patent is of marginal strength. Due to the limited protection and freedom to operate provided by the patent, a more conservative marketing scheme must be implemented in to order to reduce the heightened risk of substitute or imitation products. Thus, this conservative marketing scheme entails directing the marketing focus away from a more generalized market, and towards specialty or niche markets.

For the manufacturing aspect of our research, we needed to determine whether it was possible to create the ergonomic scalpel to 5G's specifications; and, if this was financially viable. From our visit to Nypro, a plastics manufacturing company, we decided that the feasibility of manufacturing this product was marginal. This was mainly due to the cost of the raw materials involved in the manufacturing process, and the design complexity of the scalpel's handle. We also had to take into account the possible distribution methods for 5G's scalpel, and the complications caused by the need to sterilize this product.

During the consumer research portion of our project, we aimed to determine how the surgeons perceived the benefits of the prototype; this would help us establish whether there was a need for the product. Overall, we learned that surgeons found almost no issues with the current scalpel. For the 5G prototype, surgeons saw the ease in making circular incisions as its only benefit; however, they did mention several disadvantages. In summary, they did not see a reason

to switch to a new scalpel unless that scalpel had all the benefits of the traditional scalpel as well as all the benefits of the prototype.

In respect to the current state of the market, our team determined that there is no present need for this new product. The industry has exhibited recent and continued success as a whole. Success was generated despite employing the same basic scalpel design for the past several decades. Because of this, we determined the need for a new product to be marginal.

### **Assessment and Recommendations**

Based on our determination that each of the previous four aspects were of marginal impact, we concluded that, as of now, the 5G ergonomic scalpel is not a viable option for commercialization as a stand-alone product. However, we do not believe that the product concept should be entirely abandoned. We identified alternative methods of commercialization that may be employed in order to generate future success if this product reaches market. These recommendations are to consider: targeting the hobbyist market, licensing the product to an existing company, developing and launching a family of ergonomic surgical tools, and analyzing any further possibilities.

## 1 Introduction

In the medical industry, quality patient care is the ultimate goal. Surgeries, known for their precision and intricate detail, require highly-skilled medical professionals and high-quality surgical tools. The more assured a surgeon feels when using his/her surgical tools in the operating room, the more confidence they will have in the procedure, and the smoother it will run. With the constant improvement of surgical devices, ergonomically efficient tools are on the rise, providing the best possible comfort and outcome from surgery. A surgical scalpel is a common medical tool utilized in all invasive surgical procedures, and will be the focus of this project.

Dr. Raymond Dunn, Professor and Chief of Plastic Surgery at UMass Memorial Medical Center, is a practicing plastic surgeon, with the vast majority of his work consisting of reconstructive surgery. In early 2011, Dr. Dunn formed the company 5G Medical, with the goal to improve lives using advanced technology in surgery and wound care. He currently holds over ten patents, primarily in the medical device field. 5G Medical focuses on managing these patents, and would like to determine the optimal method of commercialization for each individual patent. One of the devices specified by these patents is a new surgical scalpel that features an ergonomic handle.

The purpose of this project is to analyze the feasibility of commercialization for the newly patented 5G ergonomic scalpel. In order to perform a feasibility analysis, our team will make multiple assessments in order to reach a conclusion as to whether this tool will generate success when put on the market. A portion of this assessment will include providing a cost-benefit analysis in order to determine if the benefits of this device outweigh its costs. In addition, we will need to assess the risks associated with launching this new tool. An exhaustive market

assessment will also be conducted in order to identify potential competitors, as well as ascertain the ergonomic scalpel's room to operate within the surgical tool market. Lastly, we will need to determine the strength of the intellectual property (IP), and identify similar IP, which could pose a potential threat to the success of the ergonomic scalpel.

Launching a new product is difficult without gathering the information necessary to help it expand and create value in the market. Ultimately, 5G Medical currently lacks this commercialization information, which inhibits their ability to advance into the medical device market. By providing analysis and assessing the feasibility of commercializing the ergonomic scalpel, our team aims to provide 5G Medical with recommendations for the optimal method of bringing this design to market.

## 2 Background

### 2.1 History of the Scalpel

The word *surgery* comes from the Greek *kheir*, meaning hand, and *ourgos*, meaning work. In Latin, it is called *chir-urgia*, meaning “handwork” (Kirkup, 2006). It references the most important elements of all surgical procedures, the surgeon’s hands and the surgeon’s skill. The relevance of this point is such that a distinction has been made between natural and artificial surgical instruments. The natural instruments definition refers to the parts of the human body directly used in a surgical procedure, while the artificial instruments are the man-made tools that assist the former (Kirkup, 2006).

The most essential artificial tool for any surgeon is the surgical scalpel; it is ubiquitous to any surgical tray, since it is used in virtually all invasive procedures. A scalpel is a small, sharp-bladed instrument used for surgery and dissection. Scalpels are an essential component in all surgeons’ toolboxes, and are the most commonly utilized device by surgeons today. Surgical scalpels consist of a blade and a handle.

The handle is also known as a "B.P. handle", named after Charles Russell Bard and Morgan Parker, founders of the Bard-Parker Company. Parker patented the 2-piece scalpel design in 1915 and the Bard-Parker Company developed a method of cold sterilization that would not dull the blades, contrary to the heat-based method that was previously used (Ochsner, 2009). Medical scalpel blades are manufactured with a corresponding fitment size so that they fit on only one size handle.

Scalpels may be either disposable or re-usable. Re-usable scalpels can have attached blades or non-attached, replaceable blades. Disposable scalpels typically have a plastic handle and are used only once. Scalpel blades are individually packed in either sterile or non-sterile

pouches, with sterile pouches being the more common of the two. The most commonly utilized blades are those made of hardened and tempered steel, stainless steel, or high carbon steel. However, titanium, ceramic, diamond, and even obsidian blades are in the market.

The surgical field has substantially improved due to our enhanced anatomical knowledge, the establishment of the germ theory of disease, and the discovery of anesthesia, blood transfusion, and antibiotics. Due to these, and many more, advancements, surgeons today have many tools at their disposal that were not previously available.

The earliest medical tools were made of wood, bone, antlers, shells, or stone, dating back as long as 1 million years ago. The knife was the first tool to be developed, and it still maintains its status as the most commonly used tool to date. The discovery of copper smelting in the year 3500 B.C.E. accelerated the innovations in the surgical field. Bronze weapons and tools, such as those shown in Figure 1 below, overwhelmingly dominated any other materials for at least two thousand years (Ochsner, 2009).

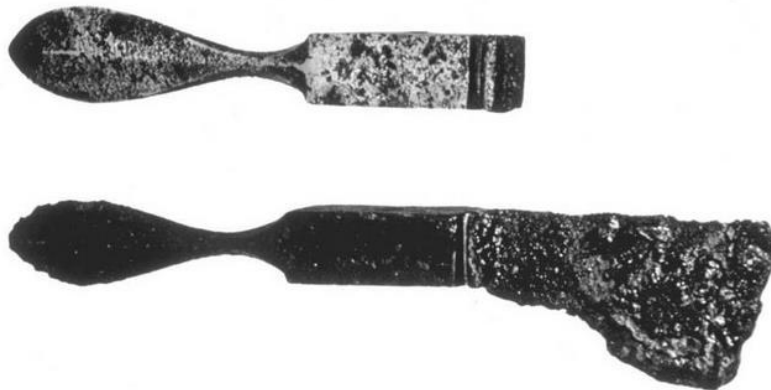


Figure 1: Bronze knives found in the destruction of Pompeii (Ochsner, 2009)

Knives dating to 3000 B.C.E. are believed to have been used for surgery. Around the year 1200 B.C.E., iron had replaced bronze tools entirely. A mix of bronze and iron scalpels have been found in Peruvian, Greek, and Roman settlements that flourished nearly 2,000 years ago

(Ochsner, 2009). However, surgical procedures remained virtually the same throughout the dark ages. Possibly the largest advancement in this field came in the 1800's; Louis Pasteur's revolutionary advancements in sterilization of medical devices greatly enhanced the safety and success of medical procedures. By those times, steel had become commonplace due to the introduction of the blast furnace.

The medical device market as a whole has experienced positive growth regardless of the absence of innovation on the scalpel industry. This rate of growth seen over the past several years is anticipated to be sustainable for years to come. This projected sustained growth is due to a plethora of factors, including average age of population and public spending on healthcare, that positively impact the medical supply manufacturing segment of the market. This market has experienced over two percent growth each of the past two years, and three out of the past four, with an industry total of over \$89 billion in revenues last year (Sonn, 2013).

One of the primary key external drivers of this market is the number of adults over 65 years of age. This is a vital demographic to the overall performance of the medical and surgical device industry because there is a strong positive correlation between the number of adults over the age of 65 and the demand for surgeries, meaning that the larger this demographic is the

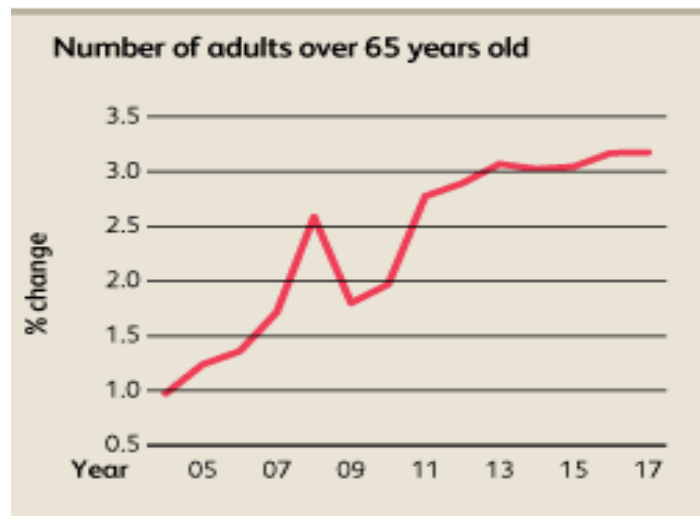


Figure 2: Number of Adults Over 65 Years Old (Sonn, 2013)

greater the demand for surgeries. The number of adults over the age of 65 has increased over the past decade; however, since the “baby-boomers” are nearing this 65 year-old threshold, this growth is only anticipated to continue in the near future (see Figure 2) (Sonn, 2013). Another

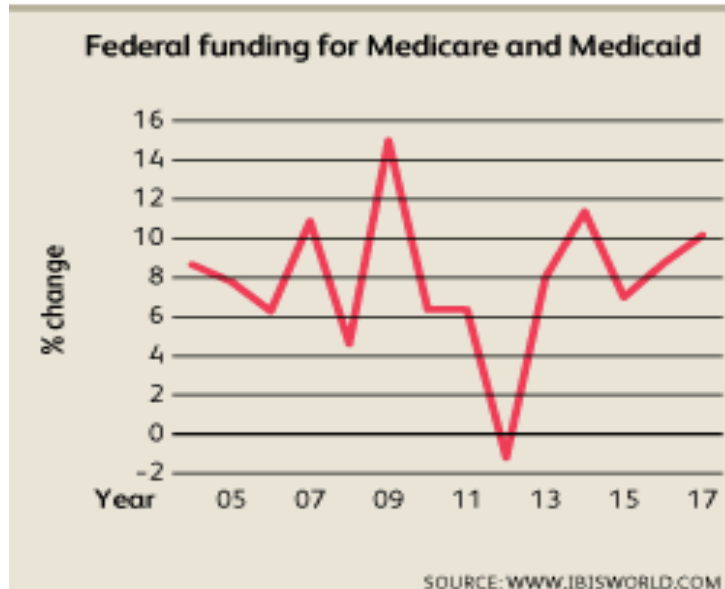


Figure 3: Federal Funding for Medicare and Medicaid (Sonn, 2013)

demographic driving demand for the medical and surgical devices, by requiring a heightened number of physicians visits and surgeries, is the obese and overweight demographic. Currently, over half of the U.S. population is overweight, with over a third of the population being considered obese, a number that has increased consistently over the past decade (Centers for Disease Control and Prevention, 2013). A 2009 government study shows that the average obese individual’s medical costs are \$1,429 more than a normal weight individual, and an estimated \$147 billion in total medical cost of obesity in the US in 2008 (Centers for Disease Control and Prevention, 2013).

An additional key external driver of the medical device manufacturing market is total healthcare expenditures. Government funding for Medicare and Medicaid, as well as the amount of consumers with private healthcare coverage, comprise this statistic. Federal funding for



healthcare coverage is a vital statistic because it directly affects how much patients must pay for industry products, and how much operators will receive in payments from Medicare. Since this funding has increased under the Obama administration, and anticipated to continue growing, more people can afford surgeries, thus positively benefiting the surgical device market through increased demand of surgeries. Similarly, private healthcare coverage provides insured patients with a more diverse choice of doctors, due to increased ability to pay for healthcare services. However, private healthcare coverage accounts for over half the revenue generated by specialist doctors, a demographic which is largely made up of surgeons. Therefore, as the number of people with private health insurance escalates, the amount of surgeries performed increases, fueling increased demand for medical supplies and equipment. Thus, it is a positive indication for the medical and surgical device market because the amount of people with private healthcare



Figure 4: Total Health Expenditure

has increased over the past several years, and is anticipated to increase gradually over the course of 2013 (Sonn, A. 2013) (MarketLine, 2011).



Figure 5: Industry Revenue (Sonn, 2013)



Figure 6: Number of Physician Visits (Sonn, 2013)

These key external drivers have a direct impact on the amount of physician visits per year. As one might expect, the number of physician visits per year correlates very closely to amount of surgeries performed, and thus the demand for surgical devices. Each of these external

drivers increases the amount of physician visits per year, a 2.6% increase last year, consequently benefitting the surgical device market. Therefore, since the number of physician visits is anticipated to increase by an estimated 4.8% in 2014, the revenue for the medical device market is projected to grow by a substantial 5.1% margin (Sonn, 2013). Furthermore, this growth is likely sustainable in the years to come because the demand for medical and surgical devices is extraordinarily inelastic. Meaning that, unlike many other products, the demand for medical and surgical devices is relatively immune to the current state of the economy; this is because people need healthcare regardless of economical state. This claim is verified by a 9.7% and 10.3% growth in revenues for the surgical device market over the course of 2007 and 2008. The external drivers previously discussed, coupled the inherent inelastic demand for the medical device market, suggest promising sustainable growth for this industry beyond just the estimated 5.1% revenue growth in 2014. These positive driving factors for this industry result in projected growth of over 3% each of the next five years.

## Annual Change

	Revenue (%)	IVA (%)	Establishments (%)	Enterprises (%)	Employment (%)	Exports (%)	Imports (%)	Wages (%)	Domestic Demand (%)	Number of physician visits (%)
2004	-0.8	0.6	1.9	1.9	0.5	5.9	0.9	3.7	-1.4	0.5
2005	7.5	7.6	0.2	0.0	0.5	5.5	0.5	1.1	7.0	5.8
2006	2.7	10.7	5.0	5.1	1.7	6.1	1.5	3.1	2.1	-6.4
2007	-2.4	-4.9	4.4	4.4	1.1	3.1	-0.3	2.0	-2.9	2.7
2008	4.6	-7.6	-1.4	-1.3	-2.2	15.2	3.8	-2.1	3.1	1.2
2009	0.2	-6.0	-0.2	-0.3	-1.9	-0.6	-2.6	-4.8	-0.1	1.3
2010	2.1	5.3	-0.4	-0.5	-6.1	10.0	6.1	-1.8	1.3	2.0
2011	0.3	-5.7	-1.1	-3.0	-2.1	7.6	2.5	-1.7	-0.6	2.1
2012	2.6	1.4	0.3	-1.5	-0.3	7.0	1.9	0.8	1.7	2.6
2013	2.4	3.0	0.6	-1.8	-1.0	7.8	2.3	0.5	1.4	2.5
2014	5.1	4.1	2.2	-0.5	2.0	6.4	2.0	4.0	4.5	4.8
2015	3.8	3.0	0.7	-1.6	0.5	7.8	3.0	3.0	2.9	2.0
2016	3.5	1.8	1.2	-1.7	-0.6	7.3	2.3	1.0	2.5	3.7
2017	3.6	2.1	0.5	-2.1	-0.1	7.3	2.3	1.5	2.6	3.9
2018	3.4	1.8	-1.7	-2.9	-0.5	2.5	2.8	1.2	3.5	4.0

Figure 4: Annual Change (Sonn, 2013)

Although, as a whole, the medical device industry is prospering, with anticipated growth in the foreseeable future, there are several factors hindering it from achieving heightened growth

## Products and Services

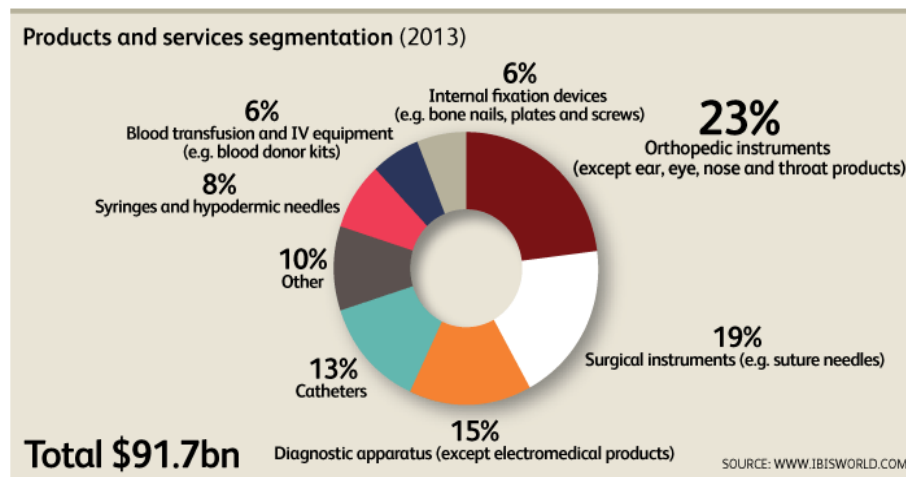
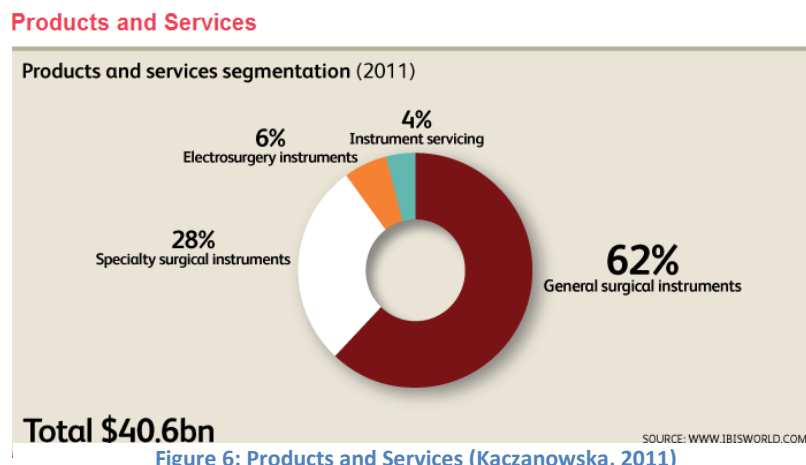


Figure 5: Products and Services (Sonn, 2013)

and success. Quite possibly the largest threat to this industry is the 2.3% excise tax levied on all medical devices by a manufacturer, producer, or exporter. The medical device excise tax was one of the key provisions put in place by the 2010 healthcare reform legislation, and was put into effect on January 1, 2013. This tax applies to all manufacturers of medical device, regardless of size or revenue, and is anticipated to have a substantial negative impact on some of the smaller players in the medical device industry. This excise tax is projected to cost the medical device industry over \$20 billion in the next ten years, hurting the bottom line of many companies' profits. The negative impact of this tax could extend further beyond just the small companies in the industry, as this tax could influence companies of all sizes to reduce funding for research and development operations, as well as workforce reductions through either lay-offs or outsourcing of manufacturing operations to lower-cost locations. Additionally, this tax could inhibit innovation for medical technology because the costs of the excise tax might impede investors' willingness to fund start-up companies and commercialization of new technology. However, stakeholders in the medical device industry could rest easier knowing that on March 21, 2013 the U.S. Senate voted to repeal the medical device excise tax. Although a final verdict has not been

made, the voting results evinced the industry's lobbying clout, who had been lobbying to repeal this tax ever since its onset (Sonn, 2013).

Now that the macroeconomic characteristics and factors of the medical device industry have been thoroughly elucidated, the next aspect to consider is the various segments within this industry. The total industry revenue for 2013 is \$91.7 billion, this annual revenue is dispersed among eight sub-sets that comprise the medical device industry (in order of largest to smallest revenues); orthopedic instruments, surgical instruments, diagnostic apparatus, catheters, "other", syringes and hypodermic needles, blood transfusion and IV equipment, and internal fixation devices. Revenue generated from orthopedic instruments comprises about 23% of the total revenue in the medical device industry, with surgical devices being the second largest segment with about 19% of total industry revenue. Orthopedic instruments are utilized in surgeries concerning conditions involving the musculoskeletal system. These are the most vital sub-sets in the medical device industry to this project because both require the production on surgical devices (Sonn, 2013) (MarketLine, 2011).



In 2011, these combined subsets, hereby referred to as the surgical device market, generated roughly \$40.6 billion in total annual revenues. This surgical device subset can be

broken down further into four additional market segments (in order of largest to smallest revenues); general surgical instruments, specialized surgical instruments, electrosurgery instruments, and instrument servicing. The vast majority of the total revenue is generated by the general surgical instruments subset, producing about 62% of the total industry revenue. The segment of general surgical instruments is comprised of basic instruments necessary to perform all types of surgeries, such as; scissors, scalpels, retractors, needles, clamps, and forceps. These products can be either reusable or disposable, although the current industry trend is towards more reusable equipment in order to reduce cost and minimize waste (Kaczanowska, 2011).

The following section focuses on how technology in the surgical field has changed at a rapid pace, and why this rate of change is possible. There is a noticeable difference before and after the year 1980; this is due to the introduction of the Bayh-Dole Act.

## **2.2 Bayh-Dole Act of 1980**

Technology transfer is the relocation of research conclusions from universities to the public market. The overwhelming success of the Manhattan Project served as a catalyst for increasing university research in the United States. Due to the growing acceptance of such a change, the Office of Naval Research and the National Science Foundation were created in the years 1946 and 1950, respectively. The movement also helped increase federal funding for the National Institutes of Health.

By the 1960's and 1970's, concerns arose regarding the introduction of new technologies into the public market. The rate at which technologies were being commercialized was woefully low, due largely to the lack of a standardized policy regarding authorship of federally-funded inventions. In 1980, for example, fewer than five percent of the 28,000 government-owned

patents were licensed or commercialized (Stevens, 2004). The patents that were commercialized had to go through an arduous waiver process prior to commercialization. Even then, the licensee would not have exclusive manufacturing rights, dissuading companies from investing in the new technologies in the first place - after witnessing a firm's success, competitors could just copy its marketing and business plan strategy.

In his introductory statement on September 13, 1978, Senator Birch Bayh said, "Unless private industry has the protection of some exclusive use under patent or license agreements, they cannot afford the risk of commercialization expenditures. As a result, many new developments resulting from government research are left idle" (Stevens, 2004, page 95). Evidently, industry leaders were not being attracted to government-owned patents. Taxpayers were obviously not benefitting from the almost non-existent commercialization of new innovations.

In order to counteract this persisting problem, the Bayh-Dole Act was passed on December 12 of 1980. It affects the ownership of inventions that were achieved through federal funding. The act allows universities, small businesses, and nonprofits to own the rights to an invention even if its development was federally funded. Whereas before, authorship of inventions arising from federally funded contracts or grants had to be assigned to the federal government. The possibility of having exclusivity rights served as an incentive for universities to participate in the commercialization process, leading to more innovations entering the market. Since the law was enacted in December of 1980, over 5,000 companies have been built around university research (Goldfarb & Henrekson, 2003). Figure 10 below illustrates the percentage of patents that were granted to U.S. research universities during the last half of the 20th century.

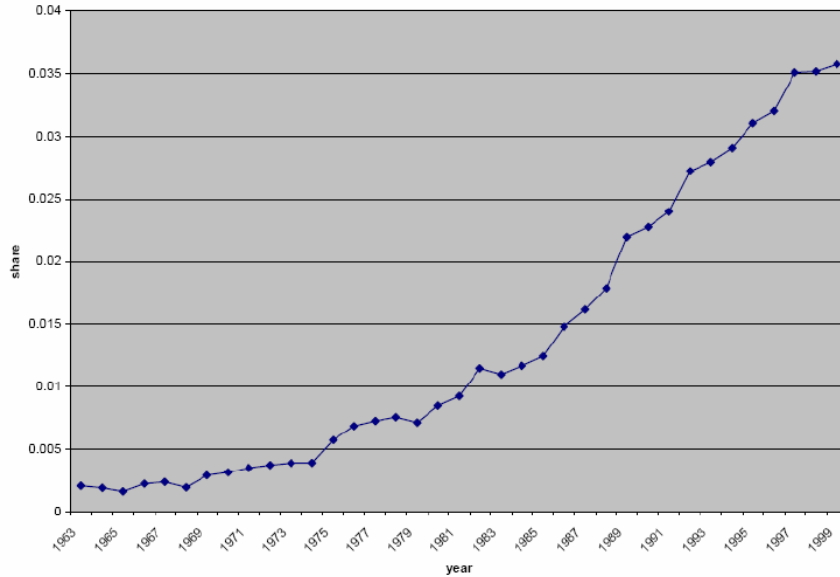


Figure 7: Percentage of US Patents Granted to Research Universities (Goldfarb & Henrekson)

It is important to note that the graph's y axis is in terms of percentages, indicating a significant change in the number of patents that were commercialized after the Bayh-Dole Act was introduced. As foreseen, the licensing of new technologies from universities to private industries greatly stimulated the U.S. economy. One example of this is the biotechnology industry: an industry that was created, and is being shaped, by university research.

Not all of the opinions surrounding the Bayh-Dole enactment debate were supportive. The opposition suggested that exclusivity would lead to monopolization and the raising of prices - they were doubtful about whether or not taxpayers would benefit equitably. Additionally, there was some concern about foreign industries unjustly profiting from the newly published knowledge and innovations.

In the United States, the university environment's competitive nature has encouraged educational institutions to facilitate the continued involvement of academic researchers. This active involvement is necessary because potentially innovative ideas typically reach technology licensing officers while still in a very primitive stage. Understandably, the majority of the



essential knowledge is implicit only to the researcher. Surprisingly, assigning authorship to universities or other research institutions has proven to be a better incentive for individual researchers than awarding the ownership rights to the researchers themselves. The activities required for academic research and the ones required when developing a commercialization plan are not similar - researchers are dissuaded from pursuing the latter. This is because prestige, and higher income, in the academic field can be associated with the number of reputable research publications. However, if the university can provide incentives for inventors to commercialize their innovations, the inventors will reap both academic and monetary benefits.

The Bayh-Dole Act has therefore had more beneficial consequences than initially anticipated. It has stimulated the creation of numerous technology transfer departments at many universities. Additionally, it has allowed individual researchers to strive for the commercialization of their inventions, without undertaking the entire costs and risks themselves. These departments usually cover a portion of the cost and also provide valuable resources and activities that the inventor could not pursue individually.

### **2.3 Use and Disposal Research**

In the late 1970s, a formerly single-use medical device started to become reused by their operators. Reusable medical devices became a more common practice in order to save money for hospitals and other institutions. “Approximately 20 to 30% of U.S. hospitals reported that they reuse at least one type of single-use device” (CDC, 2009). Over the past two decades, there has been general controversy due to regulatory, medical, ethical, legal, and economic issues surrounding this practice.

In most hospitals, surgeons use both reusable and disposable tools. Reusable tools are used over and over again until they show signs of weathering or are no longer able to fulfill surgical needs. They are sterilized after every use. For example, in a reusable scalpel, the blade is disposed of after usage, meanwhile the handle gets sterilized and reused for years. On the other hand, disposable tools are used once and disposed of after every surgery. When a disposable scalpel is being used, both the blade and handle get disposed of after surgery. Reusable scalpels are used during most surgeries; however, disposable scalpels can also be used for convenience purposes.

Because reusable tools are preferred to disposable ones, there have been additional precautions taken to ensure the safety of their use. People have become concerned by the risk of infections and injuries that could occur when these medical devices are reused. “In August 2000, FDA released a guidance document on single-use devices reprocessed by third parties or hospitals” (CDC, 2009). It states; “Hospitals or third-party reprocessors will be considered manufacturers and regulated” in the same way. A single-use device, with intentions for reuse, must adhere to these same regulatory requirements. In August of 2000, the FDA intended to enforce premarket submission requirements in the case of class I devices within 18 months.

## **2.4 Sterilization within Healthcare**

The sterilization of medical equipment is a crucial aspect in all healthcare facilities. Sterilization processes are required to ensure disinfection and the prevention of diseases. The surgical ergonomic scalpel that we will be working with will be evaluated for both reusable and one-time use material. This analysis will enable us to determine which option would prove more cost effective and plausible. As is the case with all reusable medical tools, this scalpel will need

to abide by strict sterilization guidelines in order to gain a positive reputation in making sure the patients' safety comes first. By identifying how much it will cost to sterilize the proposed prototype, we will be able to see how cost effective the reusability of the scalpel is.

In general, a tool is sterilized in order to kill potential bacteria, microorganisms, and fluids that may reside on its surface. Transmitting harmful microorganisms is a major concern, especially during surgeries lacking a proper sterilization process. This concern makes the need for sterilization of any medical tool essential, particularly surgical scalpels.

The materials that comprise the tools are a vital aspect of the sterilization process. Picking the right material to use, when manufacturing the scalpel handle, is difficult because it can have a substantial impact on the commercialization process. The material selected to manufacture the scalpel will likely undergo high heat treatment and therefore will need to be resistant to high temperatures.

Most surgical devices, such as scalpels, are considered critical items that require sterilization in order to prevent disease transmission and microbial contamination. The most common form of sterilization for these instruments is steam sterilization (CDC, 2009).

#### **2.4.1 Steam Sterilization**

As mentioned above, surgical tools predominantly undergo steam sterilization because of its wide use and dependability. Steam sterilization is described as “moist heat in the form of saturated steam under pressure... [And] is nontoxic, inexpensive, rapidly microbicidal, sporicidal, and rapidly heats and penetrates fabrics” (CDC, 2009). Moist heat is a vital component in the sterilization process because it eliminates all microorganisms by making enzymes and structural proteins unsuitable to thrive.

All sterilization takes place in an autoclave; an enclosed container used for chemical reactions (CDC, 2009). The tool that is in the process of being sterilized needs to be directly exposed to the steam for a specified period of time, at the ideal temperature and the correct pressure. The most effective parameters for sterilization within an autoclave are; thirty minutes at 250 degrees Fahrenheit, and then four minutes at 270 degrees Fahrenheit. In addition to exposing the device to the correct temperatures, the steam in the autoclave should have a dryness fraction of greater than or equal to 97 percent (CDC, 2009).

Instruments that are going to be put into an autoclave must be placed either individually or in sets, as well as covered in some sort of pouch. Additionally, a sterilization indicator is required to help identify which instruments have been sterilized, and which have not. This is determined by either putting an autoclave indicator strip on the device, or tape on to the pouch containing the instrument (Penn State, 2013).

Each day a Bowie-Dick test is performed before the first load of sterilization, in order to ensure that the autoclaves are running properly. This test is important to inform the sterilizer of any mishaps with the machine, such as air leaks or inadequate air removal (CDC, 2009). Any issues detected must be fixed right away, prior to continuing the sterilization process.

Understanding how the sterilization process influences the performance of 5G's ergonomic scalpel will allow the team to accurately compare the product to those of the competition. The following section discusses the existing competition in the surgical device manufacturing industry.

## 2.5 Industry Competition

Currently, there is a lot of internal competition within the surgical tool manufacturing industry, and this trend is expected to remain the same for the foreseeable future. Technological advances have made the manufacture of high-end medical devices easier, effectively reducing barriers to entry, such as specialization. Hence, the industry is riddled with a vast amount of players. This is a recent change, as competition used to be minimal within this industry. Technological competence, design excellence, high product performance, service quality, and pricing, are some of the factors affecting the level of competition in this industry. Price competition, in particular, is expected to become more of a factor in the few next years (Marketline, 2011). On the other hand, there is not much competition from external sources because surgeons need to use instruments that have been approved by certain entities after passing through regulations.

Covidien PLC is the only major player in the surgical device manufacturing industry, with 5.9% of the market share. Some of the company's best-known brand names are *ForceTriad*, *LigaSure*, and *V-Loc*. The remaining portion of the market share is divided amongst numerous smaller firms. Covidien's headquarters are located in Ireland. The company supplies hospitals worldwide, but the majority of its sales is to hospitals located in the United States – approximately 55%. After Tyco International separated into three distinct companies, Covidien became the head of the former Tyco healthcare branch. Covidien employs over 40,000 people, and has made purchased several smaller companies within the last five years, the largest being *ev3 Inc.* for \$2.5 billion. Covidien's revenue within the United States was \$2.4 billion in 2011, indicating a growth rate of 8.9% from 2006, when they gained \$1.6 billion in U.S. revenues (Kaczanowska, 2011).

Another industry that significantly overlaps with the surgical device manufacturing industry is that of medical instrument and supply manufacturing. Johnson & Johnson is the biggest player within it, with 14.3% of the market share and operating in over 60 countries. The company develops, manufactures, and markets pharmaceutical products and medical devices. These include surgical tools, orthopedic and cardiovascular care products, as well as monitoring devices. This product segment contributes to approximately 40% of the company's revenue. Out of its 146 manufacturing facilities, 51 are located within the United States (Sonn, 2013).

Baxter International is another significant player in the medical instrument and supply manufacturing industry. Its estimated market share is 4.1%. Incorporated in 1931, the company has recently created a medical products department. Overall, it employs approximately 50,000 people, manufacturing its products in over 27 countries. However, over 60% of its sales are outside of the United States (Sonn, 2013). The company ran into some major problems when one of its products, the *COLLEAGUE Infusion Pumps*, was forced to be recalled as ordered by the U.S. Food and Drug Administration (Baxter U.S.).

Boston Scientific Corporation owns about 4.0% of the market share. Like Johnson & Johnson, Boston Scientific develops, manufactures, and markets medical devices. The company has 12 manufacturing plants, employs approximately 24,000 people, and sells to over 40 countries. Around half of the company's revenue stems from its United States operations (Sonn, 2013). Some of the issues they faced were due to the company's inability to match other companies' product development and release speed.

Becton Dickinson and Company completes the list of the industry's major players. Becton Dickinson controls approximately 3.7% of the market share. Over 50 countries purchase the medical devices and instrument systems developed and manufactured by the company's

30,000 employees. Its main customers are healthcare institutions, research institutions, laboratories, and patients (Sonn, 2013).

## 2.6 Pricing

A major barrier to entry in the market for the ergonomic scalpel handle is physician adoption, even though reaching organizations and policies always play a vital role in buying decisions for hospitals and clinics. If the pricing is competitive or below current offerings, this will eliminate one barrier to entry, but overcoming physician adoption is still a problem facing 5G and its success going forward with the marketing of the scalpel handle. Depending on global location, the scalpel handles will be purchased by institutions directly from manufacturers or through distribution channels.

One competitor to the prototype ergonomic scalpel is the *Canica Standard Scalpel* by Canica Design Inc., which is reusable, stainless, and priced at \$100. This scalpel is supplied in a non-sterile condition. Additionally, the *Siegel knife handle* by INTEGRA Milex is reusable and stainless and priced at \$50. The *BD Surgical Blade handle* (371050,371060 and 371080) by Aspen Surgical Products, Inc., is of disposable, plastic, and priced at \$15- \$25 (5G Medical, 2011). Although looking at the competition is important for deciding the pricing of the proposed prototype, it is also important to look at the rules and regulations that control the scalpel manufacturing industry. The FDA sets the standards that surgical instruments must meet, and changes in these standards could affect the production and pricing of the proposed prototype.

## 2.7 FDA

A surgical scalpel is classified as a “manual surgical instrument for general use and is a non-powered, hand-held, or hand-manipulated device, either reusable or disposable, intended to be used in various general surgical procedures” (FDA, 2013).

Initially, there were regulations published for medical devices in 1976. They called for “establishment registration and device listing information to be submitted to the Center for Devices and Radiological Health (CDRH) on several paper forms: FDA 2891, Registration of Device Establishment; FDA 2891a, Annual Registration of Device Establishment; and FDA 2892, Device Listing” (FDA, 2013). Some amendments recently in the past years are worth noting in the case of a company involved with medical devices. “In October 2002, section 207 of MDUFMA further amended section 510 of the FD&C Act by extending the requirement for electronic submission of registration information to include domestic firms as well as foreign firms” (FDA, 2013).

Before a product goes to market, the FDA uses two types of requirements for nonexempt class I and II devices; a 510(k) submission and a premarket approval application. The 510(k) submission may have to show that the device is as safe and effective as the same device when new (CDC, 2009). It has to show scientific evidence that the device is safe and effective for whatever its intended use may be. The FDA’s has a 1-year leeway with allowing hospitals to comply with the non-premarket requirements (registration and listing, reporting adverse events associated with medical devices, quality system regulations, and proper labeling) (CDC, 2009). Hospitals have the option to stop reprocessing single-use devices, comply with the rule, or outsource to a third-party re-processor.



## 2.8 Ergonomics

“Ergonomics [is] the study of the engineering aspects of the relationship between workers and their working environment” (Daintith, pg 197, 2010). By using ergonomics, engineers are able to create better interactions between humans and their tools.

Ergonomics takes into account both the physical and psychological needs of the user.

These needs are taken into account in order to generate the optimal physical fit comfort, while also knowing how to use the device to its maximum capabilities. Some examples of how various studies overlap and are affected by human factors, which must be addressed by ergonomics in order to develop a safe and effective system, are listed below.

- Psychology and engineering overlap to create operations research
- Physiology and engineering overlap to affect industrial hygiene
- Industrial design and psychology overlap to affect product semantics (Kutz, 1998).

There are a plethora of issues that may arise in this process that can make user interface increasingly difficult. The list below illustrates the several common issues as well as how any particular issue can affect the user interface.

- The user’s ability to use a product is affected by the tool, the work station, the environment, and the task.
- The task (job content) is affected by application, new technology, training, support systems, and many other things.
- The work station and environment are affected by biomechanics, anthropometrics, lighting, climate, work surfaces, and many other things.

- The user is affected by anthropometrics, physical and psychological needs, training/experience, and capability (Kutz, 1998).

Ergonomics helps eliminate the stress and strain of the human body by making it easier for people to use, and even understand, the devices involved.

## 2.9 Uniqueness of Proposed Prototype

The proposed scalpel prototype is different from other surgical scalpels because of claims made in the patent of the 5G scalpel. The filing had been rejected several times before finally being accepted by the examiner. Many of the claims were rejected because they were too similar to other patents. The examiner worked with Dr. Dunn to fix the claims. All of the edits to the filing are contained in the file wrapper in the appendix. An example of the rejections is shown in Figure 11.

3. **Claims 1 – 2, 9 - 11** are rejected under 35 U.S.C. 102(b) as being anticipated by *Schutte et al.* (U.S. Patent No. 5,100,391).

As to **claim 1**, *Schutte et al.* disclose a scalpel handle comprising:

a scalpel handle (e.g., at 10) having a contoured handle surface to be held in a hand of a user having a distal trough and a larger diameter central portion (Figs. 11 and 14); and

a blade mounting element (e.g., at 33) extending from the handle (Fig. 14).

As to **claim 2**, dependent on claim 1, *Schutte et al.* disclose that the blade mounting element extends laterally from a post (e.g., at 15) (Fig. 14).

As to **claim 9**, dependent on claim 1, *Schutte et al.* disclose that the blade mounting element is adapted to be inserted into a blade slot (e.g., at 33) (Fig. 14). It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

As to **claim 10**, dependent on claim 1, *Schutte et al.* disclose that the handle comprises a molded plastic material (Col. 2, lines 34 - 35).

As to **claim 11**, dependent on claim 1, *Schutte et al.* disclose that the handle comprises a flared distal portion (Figs. 12 - 13).

### **Claim Rejections - 35 USC § 103**

**Figure 8: Patient Claims (Claim Rejection – 35 USC 103)**

Eventually, the filing was accepted with the claims listed in the appendix - setting it apart from all other prior art. A large portion of the claims are based on the first claim, which was originally rejected but has since been revised and accepted by the same patent reviewer, a good sign regarding the strength of the patent. According to the claims, the prototype will be used differently from traditional scalpels since it is made so surgeons only have to turn their wrists instead of their whole arm when cutting during surgery, theoretically enhancing the ease and safety of performing invasive surgery. The prototype is comprised of different material than most traditional scalpels; the proposed prototype has a plastic homopolymer (specific type not specified) handle, while traditional scalpels are made of steel.

## **2.10 Summary**

In the background, we have discussed the history of the scalpel, as well as the current state of the medical and surgical device industry as a whole. We proceed to discuss the specific competitors in the surgical device market, pertinent laws and regulations, and other vital information pertaining to scalpels in particular. Additionally, we elucidate how the proposed prototype, that 5G Medical is developing, is different from traditional scalpels currently in use today. This new ergonomic scalpel will allow surgeons and manufacturers to purchase a different type of tool that will provide additional comfort and operational flexibility when performing surgeries. The design allows the user to hold the handle at any angle with a greater degree of precision. Consequently, the ergonomic scalpel can be easily rotated with minimal body position adjustment. Based on our background research it is not clear yet whether there is a strong need for a new ergonomic scalpel; however, Dr. Dunn provides many insightful reasons as to how it will benefit the industry. Although the surgical device industry is growing independently of the

ergonomic scalpel, this leaves room for a new device that could fill a need that surgeons have not yet recognized. In the next section, Methodology, we will discuss how we plan to gather information and insight in order to determine the feasibility of bringing the proposed prototype to market.

### **3 Methodology**

The goal of this project is to provide an analysis of the potential commercialization of the 5G medical ergonomic scalpel prototype. It is crucial to accurately analyze and interpret the feasibility in order to determine the potential for success presented by this new product.

There are certain objectives that we will need to meet in order to accomplish our goals:

- Data collection
- Feasibility analysis
- Provide recommendations

Data collection was necessary to gain first-hand opinions from industry experts, users of the existing device, manufacturers, and other hospital staff. The data gathered was analyzed in order to aid us in providing a feasibility analysis. In order to help us gather the information we need, we met with personnel from the consumer and manufacturing end of the supply chain, as well as conducted extensive background research. After gathering the necessary information, we were able to perform a feasibility analysis to determine the viability of commercializing 5G's ergonomic scalpel. Our final objective is to provide 5G Medical with recommendations of, what we believe to be, the best method for bringing the scalpel to market, if at all. An analysis of the current market and industry's performance is required, as well as an analysis of the product's potential.

#### **3.1 Data Collection**

The following sections outline the specific details pertinent to the data collection process. This involved: conducting background research, interviews, and focus groups.

### **3.1.1 Background Research**

Performing the feasibility analysis required accumulating extensive background research.

This research contributed to our assessment of the current state of the surgical tool industry. In addition, this research helped us decide which materials will compose the scalpel handle. Further research will help prepare us for existing competitors in the market.

### **3.1.2 Patent Attorney**

In order to perform the analysis necessary to determine the market and product potential for 5G's ergonomic scalpel, we first needed to gather relevant data pertinent to intellectual property. Assessing the strength of the current patent of the scalpel required meeting with various patent attorneys to evaluate the perceived protection provided by 5G's scalpel patent. Since there are several patents issued regarding scalpels that differentiate from the existing scalpel, we needed to distinguish the similarities and differences between the existing scalpels and 5G's prototype.

### **3.1.3 Manufacturing**

To ascertain the projected costs associated with production of the 5G ergonomic scalpel, it was necessary to visit a manufacturing company. In addition to obtaining information on costs, we were able to gather valuable insight into the process and materials required to produce the product.

### **3.1.4 Sterilization**

Meeting with a sterilization specialist at UMass enabled us to identify the cost associated with manufacturing the scalpel. Information provided by the specialist allowed us to identify sterilization options, as well as potential costs associated with the sterilization process.

### **3.1.5 Supply Chain Distribution**

To comprehend how hospitals order medical supplies, we interviewed a purchasing specialist at UMass. In doing this research we strived to gather information on how medical supplies are procured. This included understanding the manner, frequency, and logistics involved in the purchasing process. Discussions with a purchasing agent enabled us to approximate the costs necessary to manufacture the scalpel, as well as an acceptable price for the product. Not only was this information needed for our cost-benefit analysis, but it is also useful when identifying the optimal locations to manufacture the handle for 5G Medical.

### **3.1.6 Consumer Research**

One of the most important methods we employed to collect data was conducting focus groups at hospitals. Through direct communication with practicing residents, as well as operating room nurses, we were able to obtain valuable feedback regarding their opinions on the traditional scalpel handle. Feedback from UMass residents helped us determine how likely they are to adopt this ergonomic scalpel. Additionally, we evaluated whether the 5G ergonomic scalpel provides enough benefits to surgeons in order to bypass the product inertia of the scalpel currently utilized.

WPI requires Institutional Review Board (IRB) approval for data collection from human subjects. We needed to go through the IRB approval procedure in order to conduct the focus groups. This process involved filling out required paperwork and discussing potential risks before any data collection could be started. The Principal Investigator then reviewed the risks and benefits of the study, and approved the paperwork. We worked with Dr. Dunn to secure residents from UMass Medical to conduct our focus group with. Prior to our focus group discussion, we prepared a series of questions targeted at finding out further information on the

extent of daily scalpel use. The last portion of the focus group was a discussion on the potential benefits of the use of an ergonomic scalpel by surgeons.

### **3.2 Feasibility Assessment**

After gathering a substantial amount of information pertaining to surgical device manufacturing, scalpels, and the 5G scalpel in particular, we began to assess of the feasibility of commercializing the ergonomic scalpel. We utilized this wealth of information and insight in order to systematically determine the feasibility of our project based on a multitude of aspects.

The first aspect analyzed was the benefits the 5G scalpel provides over the similar products currently being utilized. We then weighed these benefits against the costs presented by the product in order to obtain a perceived net outcome. Once we determined whether the 5G scalpel's benefits outweigh its costs, we then proceeded to evaluate the risks associated with the product. After all of the potential risks of the commercialization of the product had been thoroughly elucidated, we compared them to the benefits defined by our cost-benefit analysis to conclude whether commercializing the product still appears feasible. If so, we will proceed to assess and establish the resources crucial to making the commercialization of the product a viable possibility, such as people and capital. If it appears that these resources are plausible for our cause to attain, then we must assess the current state of the market. In this assessment, the current state of the industry will be evaluated, as well as the key competitors, external drivers, and demand conditions. Figure 12 illustrates the commercialization cycle. The feasibility analysis section, in particular, is of extreme importance to our project. Potential new products can arise from a variety of sources, such as the ones listed on the left side of the figure. After having recognized this potential and evaluated all relevant factors, it is possible to determine



what the best course of action is in respects to commercialization. Several options are available, and it is important to note that abandoning the venture is always one of them.

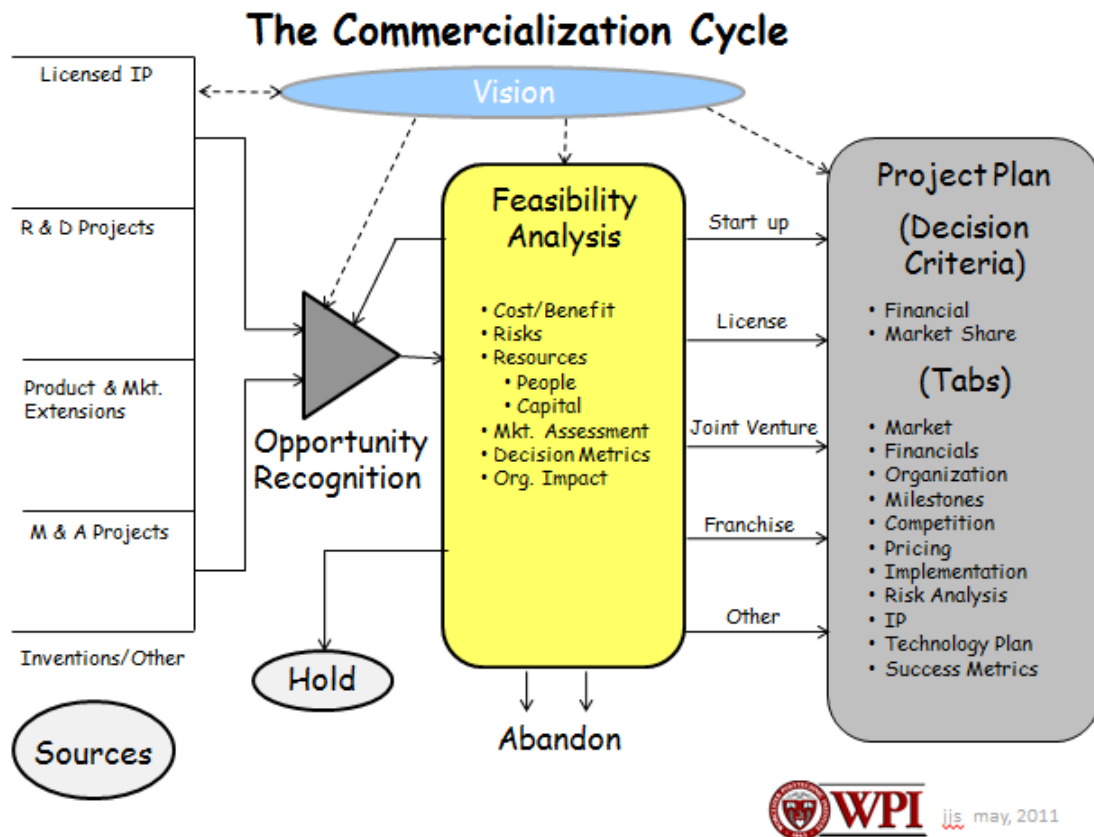


Figure 9: The Commercialization Cycle (Professor Schaufeld)

### 3.3 Providing Recommendations

Once we have gathered and thoroughly analyzed all of the criteria necessary in order to determine the feasibility of the 5G scalpel, the next step in the process is decision metrics. This step will require us to utilize our feasibility analysis in order to identify which approach to pursue for the commercialization of the product, if any. If it appears that this venture is a viable business opportunity, then we can begin to develop a project plan for the commercialization of the product. This plan would entail outlining the strengths and weaknesses of the 5G scalpel,

cost-benefit analysis, break-even analysis, production plan, as well as how to most effectively capitalize on these strengths to allow for the maximum potential of success. For instance, we may find that the scalpel is only feasible if we can attain the cost-reduction benefits of large-scale production, or resources of another company. If this is the case, we would likely suggest 5G form a joint venture or license the ergonomic scalpel to a competitor, rather than take on offering the product on their own. However, from our analysis we may conclude that this product is in fact not a viable business opportunity. If that is the case, we will provide 5G with a thorough, in-depth analysis of why we believe this product is not feasible. Additionally, we will provide 5G with numerous suggestions on how to improve on the feasibility aspects of the product in order to generate future success. By the end of this project we will be providing 5G a final report. In addition to the report, we will be meeting with our sponsor, Dr. Dunn, to present him with our findings and recommendations we have determined throughout the course of this project.

## 4 Results

This chapter presents the results obtained after conducting our research. There are four main aspects that our project aims to assess: intellectual property, manufacturing, consumer research, and market.

### 4.1 Intellectual Property

Once the surgical device market has been thoroughly elucidated by conducting extensive research about the current state of the industry, the next step taken was to evaluate the perceived strength of 5G's ergonomic scalpel patent. An accurate assessment of the patent's strength will enable us to determine the protection offered by this patent, and establish the room to operate within the industry. A patent that is evaluated and determined to be a "strong" patent will provide much room to operate within the industry, and allow for a more aggressive marketing campaign. However, if the patent is deemed as "moderate" or "weak" strength, the freedom of operation within the industry is severely reduced, due to lack of protection leading to possible substitute or knock-off products. Thus, a patent perceived as "moderate" to "weak" strength would likely entail a more specialized or niche market approach to advertising.

In order to ensure a lack of bias in the evaluation process of the patent, a third-party expert was brought in to examine and provide insight into the potential strength of the 5G ergonomic scalpel handle patent. The third-party patent expert that we were fortunate enough to meet with is Steve Carlson. Dr. Carlson is the president and CEO of OptoDot, a technology house corporation specializing in the development of high-technology equipment. He is a professional patent reviewer and writer, holding an excess of thirty patents in his name. Furthermore, Dr. Carlson is a registered legal patent witness, and has played a critical role in numerous high profile patent disputes.

Upon meeting with Dr. Carlson, he was able to provide us with a plethora of insight, which proved vitally helpful in assessing the strength of the patent. Dr. Carlson insisted that in order to attain a solid grasp on the strength of a patent you must first look at Public PAIR on the U.S. Patent and Trademark Office (USPTO or PTO for short) for said patent, and then view the patent's history under the Image File Wrapper. The USPTO defines a patent's File Wrapper as:

*"The folder into which papers for a particular application are collected and maintained. It contains a complete record of proceedings in the PTO from the filing of the initial patent application to the issued patent."* (USPTO, 2014)

The value of this File Wrapper cannot be understated. Dr. Carlson and the USPTO iterate this point heavily, as can be seen in the following excerpt from the USPTO website:

*"...the official record detailing the prosecution of a patent application in the United States Patent and Trademark Office (PTO) is more than just a historical record. During the life of a patent, the prosecution record defines the scope of the claimed invention and the patent owner's rights."* (USPTO, 2014)

Upon review of the 5G scalpel patent's File Wrapper, Dr. Carlson ascertained several key elements vital to assessing the strength of 5G's patent. First and foremost, he found that the patent had been reviewed and rejected once before for lack of uniqueness, due to broad claims conflicting with prior art. Although it is a common occurrence for a patent claim to be rejected following a first submission, it does have an impact on the perceived strength of the patent. Since Dr. Dunn's original U.S. filing on this product was rejected for possessing claims conflicting with prior art, it signifies that there are other similar products already patented, or even in the market. This fact hurts the perceived strength of the patent in question, allowing it less freedom to operate in the market due to the risk of potential substitute products from competitors.

However, Dr. Carlson did point out that the patent was accepted on the second filing, and was reviewed by the same individual who had rejected Dr. Dunn's initial filing. Dr. Carlson shared that the fact the reviewer of the patent was the same in both instances, and accepted the claim the second time, is positive with regards to the strength of the patent. Additionally, Dr. Carlson commended the second filing of this patents for possessing well-structured claims, stating that two strong independent claims, with a solid set of dependent claims branching off the two independent claims, speaks volumes to the strength of the patent.

Despite these several positive signs for the strength of the patent, Dr. Carlson ultimately concluded that 5G's ergonomic scalpel handle patent is of "medium" to "mediocre" strength. Dr. Carlson elaborated on the factors that eventually led to this final assessment of the patent's strength; concluding that, although there are several positive aspects associated with the second filing of the patent, "the patent reviewer gave him (Dr. Dunn) all he was going to get in the second filing". Therefore, this patent is of mediocre strength because it will not allow for too much room to operate within the industry, due to the presence of comparable prior art.

Although Dr. Carlson's credentials certainly make him a reputable third-party source for the evaluation of this patent, we sought a second opinion in order to verify Dr. Carlson's assessment of the patents strength. Therefore, we sought out the aid of an additional third-party source, which we were able to find in Steve Finch. Mr. Finch is a partner in a patent law firm called Finch and Mahoney, based out of Manchester, New Hampshire, making him an ideal consultant candidate for attaining a second opinion on the patent in question. After a brief phone conversation with Mr. Finch, it was abundantly evident that Mr. Finch's opinion on the strength of 5G's scalpel patent concurred, and validated, Dr. Carlson's assessment. Both parties accommodated the patent on the structure of the claims; however, both parties ultimately

concluded that the patent provided only minor protection and room to operate within the industry.

## **4.2 Manufacturing**

### **4.2.1 Nypro**

In order to perform a thorough cost-benefit analysis, we needed to obtain information on medical device manufacturing costs. The team visited the Nypro manufacturing facility in Clinton, MA. We spoke with Mark Robichaud, Business Development Manager, who helped us understand the details of an injection molding process. There were three main themes that we were able to extract from our conversation with Mr. Robichaud: pricing, raw materials, and possible risks for the scalpel handle.

#### Pricing

Mr. Robichaud talked a lot about the pricing of the individual materials as well as the price of the completed device. Polycarbonate, the plastic used for the handle, runs about three dollars per pound. Elastomers, which would be used for the handle grip, run between six and seven dollars per pound. The molds used to produce the devices will cost about \$20,000 for the front part and \$15,000 for the back part. A completed device will cost between four and five dollars, and that is including overhead costs. We are looking at a minimum initial cost of \$35,000 dollars just for the molds, meaning we will have to produce over 7,000 scalpels to make the investment worthwhile.

#### Raw material

As far as surgical devices go, the mold needed to complete the design of the scalpel, would be one consisting of one or two cavities because the volume does not indicate higher cavitation molds. ABS (Acrylonitrile Butadiene Styrene) is a good choice of material to craft the scalpel with; many medical products are made with ABS. ABS Plastic usually is medium in

strength. It is characterized as a resin with qualities similar to those of a standard resin and an engineering resin ([www.absmaterial.com](http://www.absmaterial.com)). This material is very tough and rigid, possessing a stable chemical resistance and high impact strength. Some of the limitations of material, however, are that it may have less than adequate weatherability and solvent resistance. Blends of Polycarbonate are about three dollars a pound. This blend is the cheapest resin that the company, Nypro, uses for medical parts. In order to make the weight of the scalpel greater, calcium carbonate could be added as filler.

In order to mass-produce the scalpel with the tactile rubberized handle grip, a two-shot mold would be the way to do this. ABS is very compatible with TPE, and you can get it so that the parts will be able to physically bond. One could mold the sub straight part, then rotate the mold and inject over that in the elastomer portion.

With two-shot molding, there are a couple of different ways in which the mold can be produced. If it were a four plus four model, where you mold four on the bottom sub straights on the bottom, you would inject one material, which forms the bottom, and subsequently rotate the mold up to another position. Then, another material will come in from the sides and over mold the second material. Therefore, every time the mold opens up, four parts come up, four sub straight parts rotate up, and as a result, there are four parts per shot. If it were a standard mold, there would be eight parts every time the mold opens up so only half the number of parts would be produced with the two shot mold.

As far as temperature resistance in terms of sterilization, ABS and polycarbonates would be compatible; they're both high temperature resins. The melting temperature of ABS and polycarbonate is around 300 degrees Fahrenheit and steam is 212 degrees. These materials would also be able to be compatible with Ethylene Oxide sterilization, a common method used to

sterilize medical and pharmaceutical products this day in age. Polyether Imide (PEI) is a material that has high thermo-resistance and would be a material to consider using. It has high tensile strength, is resistant to flame, and is hydrolytically stable.

### Risk

There were a few aspects about the scalpel handle that Mr. Robichaud mentioned which may be a concern for the future. Firstly, the weight of the handle will be the most important selling point for the surgeons. The surgeons will need to evaluate how the handle feels, meaning that the material of the mold and whether the mold is hollow or not will have a big effect on the feel of it. It will be a challenge to create something that the surgeons will feel total comfort in its application. In addition, this scalpel handle has no chance in competing in the regular scalpel market. This will be a custom high end device in order to have a chance or doing well in the market.

Another big concern that Mr. Robichaud mentioned was figuring out how the blade will fit into the non-disposable handle. Loading a blade in the handle will have to be simple so that the surgeons will be able to do it themselves and feel comfortable knowing that it will stay in there. The blade needs to be firmly fixed in the handle, or else the surgeons will not want to use an ergonomic handle if the blade itself cannot be guaranteed to stay in place.

#### **4.2.2 Sterilization**

We contacted the sterilization staff at the hospital to ask them a few questions about their sterilization process. Marlene Nintzel was able to answer a few of our questions about the hospital's sterilization process and give some ideas for improvements that could be made. Currently, the hospital sterilizes multiple units hourly, each containing a varying number of tools. The number of tools sterilized at one time depends on two factors:



- The size of the sterilization chamber
- The method of packaging of the tool

Depending on what type of sterilization technique the hospital is using and how many times they run a sterilization unit, the price can range from as low as \$200 to well over \$1000. The cost break down is shown in Table 1 below.

**Sterilization Costs**

	Steam Sterilization	Hydrogen Plasma Sterilization	ETO Sterilization
Utilities per Cycle	\$3	\$8	\$18
Packaging for Disposable/Reusable	\$0.50-\$3 Disposable \$250 Reusable	\$0.50-\$3 Disposable \$250 Reusable	\$0.50-\$3 Disposable \$250 Reusable
Cleaning per Mechanical Cycle	\$4	\$4	\$4
Pre Cleaning	\$1.50	\$1.50	\$1.50
Average Hourly Wage of SPD Tech	\$18.00	\$18.00	\$18.00

**Table 1: Sterilization Costs**

The hospital is currently purchasing about 75% reusable and 25% disposable. Because 75% of the surgical tools in the hospital are reusable, sterilization is a huge issue. Currently, the sterilization time for individual manufacturers differs from one to another; therefore, there is a high chance for mix-ups and incorrect sterilization to occur. Although most items require only four minutes of specific sterilization, some require times upward of twenty-five minutes. Recently, the FDA and AAMI (Association for the Advancement of Medical Instruments) are setting minimum requirements for manufacturers when it comes to sterilization. However, until

then hospitals must deal with different sterilization processes and time requirements. Some examples of different sterilization techniques and times are listed below.

- Prevac Steam requires 270-273 degrees Fahrenheit exposure for not less than 4 minutes
- Pulse Vac Steam requires 270-275 degrees Fahrenheit exposure for not less than 4 minutes
- Gravity Steam requires 270+ degrees Fahrenheit exposure for not less than 4 minutes
- Hydrogen Plasma (STERRAD) has a set cycle of 50 minutes with no cannulated or lumen items or implants
- Hydrogen Plasma (Sterrad NX) has a cycle of 28 minutes with no cannulated items or implants
- There is also Ethylene Oxide still used in some hospitals

After one of these sterilization processes is used, each surgical tool is validated for cleaning, and then inspection and packaging occur. Although each tool is sterilized and placed in a sterilized package, there is a shelf life called terminal sterilization.

#### **4.2.3 Supply Chain Distribution**

To gain additional background information on the surgical tool supply chain, we interviewed Dr. Zinkus, who is currently the Director of Perioperative Business Operations. All orders and purchases placed go through Dr. Zinkus. All orders come in on an as needed basis and the supplies are managed by the nurses. Even though the supplies are mostly managed by the nurses, the surgeons have the most impact on what gets purchased. Nothing comes in on a standing order because supply is hard to predict especially in trauma cases. The supplies that are managed in the Operating Room have pars on them so that for example, if the nurses know that they need to have 50 of a certain tool and stock gets half empty, they know to reorder. Bulk orders are not ordered because of holding costs and the desire to use up most of the supply within a month time frame or less. Hospitals rarely order in bulk unless they get a really enticing deal or

discount and if they have room to store it. Most scalpels come sterilized and prepackaged, without an expiration date.

Many hospitals order through distributors. UMass Medical specifically goes through Owens & Minor, a big distributor of medical supplies. The Materials Department at UMass orders supplies online from the distributors - this is the easiest way to place an order. Most distributors, like Owens & Minor will buy smaller disposable items in bulk and then hospitals like UMass will buy in smaller quantities from them. Dr. Zinkus recommended that 5G goes through direct suppliers instead of the distributors at first, in order to have the opportunity to gain some business.

## **4.3 Consumer Research**

### **4.3.1 Focus Group**

For our consumer research we intended to interview eight to ten residents from UMass Memorial who had not been exposed to the scalpel prototype yet. However, when we arrived at the focus group it was composed of conference attendants, many of whom had seen or heard of the prototype previously. Only six of the invited residents came to the focus group. One of the residents had previously used the prototype to dissect a pig, while another had watched the prototype being test sterilized previously. During our interview, there were four main themes that the residents kept coming back to. These themes were:

- The original scalpel
- The limited use for the prototype
- The existence of a tool that already fills the need
- Problems with the existing prototype

The residents did not see a problem with the scalpel they are currently using. Doctors have been using the current scalpel for centuries and it hasn't been a problem yet. There is muscle

memory built into using the current scalpel, which has been accumulating over the years. This allows the residents to barely think about what they are doing when using the scalpel. One of the residents actually addressed the issue of bringing a new scalpel into the market saying,

“...the only real use for this new scalpel is to make curved incisions...” (male subject 1).

Another resident said that it may be hard to get people to switch over and use the prototype.

[...because of] “tradition....we’ve been using the traditional scalpel since the 1900s”

(male subject 2).

The residents also brought up the fact that there is already a scalpel that is used to make curved incisions, the beaver blade.

After the first half of our discussion, we showed the residents the prototype and asked what they thought about it. During the interview, the residents described how the prototype would make it a lot easier to make curved incisions, but that this would be the only thing they would use it for. They asked many questions about the weight of the prototype because this is a huge factor for them. They need the prototype to weigh the same as the current scalpel so that their muscle memory is not affected. Another concern was that the prototype was a lot bigger than the current scalpel and it would block their view during some surgeries.

Overall, the residents thought the current scalpel was working fine and that the proposed prototype would have to be marketed toward a very select group of surgeons, plastic surgeons. They did not see a reason to switch to a new scalpel unless that scalpel

“had all the benefits of the traditional scalpel as well as all the benefits of the prototype”

(male subject 2).

#### **4.3.2 Operating Room Nurses**

*The following data was collected from two separate interviews. This provides a summary of the information:*

We talked to nurses at UMass Memorial Hospital in Worcester, Massachusetts so we could gain some insight into how they go about arranging for surgery, particularly focusing on instrumentation set-up. We spoke with a female nurse from UMass, as well as a male traveling nurse working at UMass for several months, after having been to a multitude of hospitals across the United States as well as outside of the country.

The amount of surgeries that a nurse will set up during their daily shift depends on the extent of the surgery. Sometimes, if it is an extensive procedure, they will set up for only one case. Their role when working the Operating Room is not only to prepare the room for surgery, but to prepare the patient, as well as to perform a count of the instruments. According to the male traveling nurse, certain instruments are typical for a standard set-up; however, every surgeon has preferences, which will tailor the final setup.

The tools are already sterilized prior to surgery. The packaging has to be intact in order to ensure this. At UMass, in particular, light-tan colored tags indicate that sterilization has happened. Blades come in packages and are designed to slide on without the use of hands. In order to remove the blade, a needle driver is most commonly utilized to perform this action.

Surgeons use one scalpel which they call a “number 3”. It is a metal scalpel and is the standard one that is used. It is reusable, made by Bard-Parker. It has been made by Bard-Parker for so long that, when asking the nurse for the instrument they need, some surgeons will refer to it as a “Bard-Parker”. Hospitals are trying to reduce the use of disposable scalpels. Currently, they are used for quick slices. Disposable scalpels already have the blade attached, and those

blades are retractable for safety. Sometimes, nurses are asked to take out sutures; and, to quickly do this, they use a disposable scalpel.

Depending on the surgery being performed and the preference of the surgeon, blades are chosen separately and then clicked into the metal handle. Once finished with the scalpel, it is thrown away into the sharps bucket. There are many different blades besides the standard blade. For example, different blades may be used for deep-tissue surgeries because surgeons do not want to risk transferring microbes from the skin into the wound. Some blades are even called hot blades because they are heated.

In the opinion of the male traveling nurse, it would be a good idea if the scalpels were able to adjust sizes. He told us,

“If ergonomics is your base, you have to look at the weight of the device, the angles. 70% of surgery is exposure, the ability to access that specific site.”

Therefore, it is necessary that the shape and size of the ergonomic scalpel cater to this need. He told us that in his past experiences, he has had some hassles with trying to slide the blades into the scalpel handle. There tends to always be wear and tear around the part of the scalpel handle where the blade slides in. Therefore, it is necessary, when designing a new model, to pay close attention to this area so that there is a tight fit between the blade and handle and the blade does not break off. In designing a reusable blade versus a disposable blade, durability will be a primary concern.

## **4.4 Market**

### **4.4.1 Cost-Benefit Analysis**

The first aspect to consider when generating a projected cost-benefit and break-even analysis is the fixed cost incurred when starting the new venture. From our discussions with

Nypro, we were able to determine that a 4-shot plastic injection molding machine would be required in order to create 5G's ergonomic scalpel handle in large-scale production. We can safely assume that the minimum cost for 4-shot injection mold needed to make this product to be about \$25,000 for the front of the mold and \$10,000 for the back portion, totaling an estimated \$35,000 of initial investment for the equipment. However, these are the minimum projected cost numbers for the mold, as this product may require a specialty mold, which will only increase costs further. The fixed cost of the mold is certainly the most costly portion of the overhead for this product. For more detail, see Appendix A.

Once the fixed costs of production have been thoroughly elucidated, the variable costs of the operation must be defined. The raw materials variable cost for this product appears to be relatively cheap. It is anticipated that a polycarbonate plastic will be utilized as the plastic homopolymer comprising the majority of the handle. The cost of the polycarbonate raw material is roughly \$5 a pound. Therefore, assuming that a pound of this material would constitute an estimated 20 scalpels, the projected variable cost of the polycarbonate material, per unit, is about \$0.25. The second material utilized in the creation of this product is a thermoplastic elastomer (TPE) that will comprise the grip portion of the scalpel handle. The purpose of utilizing this material is the better quality it provides when compared to the polycarbonate used for the majority of the handle. Therefore, the costs of this material are slightly higher than that of the polycarbonate material used, at roughly \$7 a pound. Thus, still assuming about 20 units produced per pound of material, the variable cost per unit for this material would total an estimated \$0.35. An additional cost that must be factored into the variable cost to produce each unit is the cost of the blade. Although this may not be a direct cost for 5G, because they would likely not produce or purchase the blades themselves, it still is a relevant cost the consumer will incur on the final

product; and, therefore, must be factored into the projected costs. From our research and discussions with Mr. Zinkus, we were able to ascertain that the average cost of a common scalpel blade, when bought in bulk, is roughly \$0.10 per unit. Consequently, the total variable cost of the raw materials totals a projected \$0.70 per unit produced.

Utilizing the numbers that we have attained through thorough research, we are able to generate a projected cost-benefit analysis for three potential marketing strategies: cost-reduction strategy, general strategy, and differentiation strategy. The overhead and R&D costs varied for each strategy depending on the perceived quality level of the product. For instance, the projected total variable cost, including raw materials and projected overhead and R&D cost for the general strategy, was an estimated \$5.70 per unit, while the cost of the differentiation strategy increased to \$7.70 per unit, with the cost reduction strategy reducing variable costs to a mere \$3.70 per unit. The reason for the variation on these numbers is based on the assumption that the higher-quality the product, the more it will cost to produce.

These variable cost figures have a direct impact on the projected selling price of the scalpel for each strategy. Therefore, in order to determine an ideal price range, three different prices were tested for each strategy. Furthermore, the projected demand for the product was aggregated depending on the selling price for that particular scenario (e.g. the higher the price, the lower the demand, and vice versa).

First, we will look at the cost reduction strategy. For this strategy the estimated variable cost per unit of production is \$3.70, and the three selling prices tested were \$4, \$5, and \$6. The projected demand for the lowest-cost product, \$4, was an estimated 3,000 units per quarter. This estimated demand dropped by 750 units each dollar increase in selling price. At the \$6 price level, the time, in months, until break-even was the lowest of any price or strategy tested at a



projected 30.43 months. However, from the research conducted, we do not believe this strategy to be a viable commercialization option moving forward. This is due to several distinct factors, the first of which being the amount of available customers in the area. According to US News, there are currently 1,022 surgeons practicing in Massachusetts. Additionally, from discussions with surgeons themselves, we were able to ascertain that this device would likely only be applicable to specialty surgeons, such as plastic surgeons. Thus, the target consumer population is reduced significantly. In order to achieve the projected demand for the scalpel priced at \$6, or 1500 units per quarter, 5G would need to secure virtually every potential customer in the New England area, or expand their operations to reach a larger market segment. Furthermore, since 5G's ergonomic scalpel handle is reusable, the ability to generate a steady demand for the product is exceedingly difficult and would require immediate expansion in order to find new customers and sustain demand. In conclusion, the cost reduction strategy is not ideal for a specialty product such as this (US News Health, 2014).

Next, we will thoroughly elucidate the general strategy projections. For this strategy the three prices tested were \$8, \$10, and \$12 per unit, generating a projected profit margin of 40%, 75%, and 115% respectively. Much like the previous strategy, the demand for the product is a function of the selling price of said product. Thus, the demand for the \$8 product is a projected 1,000 units per quarter, with the quarterly demand decreasing by a factor of 300 units each additional \$2 added to the selling price of the product. From these projections, the most efficient selling price, based off duration until break-even, would be \$10 per unit. With consistent demand at \$10 a unit, the projected time until break-even would be 34.88 months. However, much like the issue causing the cost-reduction strategy to not be a viable option, the demand required in order to make profit is likely unattainable in a small to moderately sized operation, due to the

fact that the scalpel is a one-time purchase because of its reusable capabilities. Therefore, generating sustainable demand, in order to make selling the product at this price level practical, would be extraordinarily difficult and likely not feasible.

Based on the research gathered, interviews conducted, and results attained from the previous strategies, it appears as though the differentiation strategy is the only potential viable option for 5G at this point in time. For such a specialty product, which is likely only a one-time purchase due to its reusability, the profit margin per product becomes vital. From our discussions with Mr. Zinkus, Purchasing Director at UMass Memorial Medical Center, we were able to determine that the average selling price of most high-quality reusable scalpels, when bought in quantities of 5 or more, to be around \$20. Therefore, the three selling prices tested for this strategy were \$20, \$25, and \$30. The projected quarterly demand for the scalpel priced at \$20 is 200 units, with the demand decreasing at an estimated 50 units for every \$5 increase in selling price. We perceive this to be a more realistic demand than the previous two strategies. However, since the demand is relatively low, due to it being such a highly specialized product, the profit margin generated per unit sold is a crucial statistic. For the \$20 scalpel, the profit margin per unit is a projected 160%, increasing to 225% and 290% for the \$25 and \$30 selling prices, respectively. From these projections, we were able to conclude that the optimal selling price for the scalpel, utilizing a differentiation strategy, would be about \$25. Selling the scalpel at \$25 per unit, when purchased in quantities of at least five units, would take 40.46 months to recoup the initial investment, assuming demand remains consistent. If demand does not remain consistent however, due to the reusable nature of the product, then the time required to break-even could increase significantly. This price remains consistent with the information provided to us by Mr. Zinkus, stating that the largest increase in price a hospital will be able to sustain over the current

cost of specialty scalpel purchases, roughly \$20 per unit on average, would be a \$5 increase. Although, Mr. Zinkus did specify that the cost expansion would only occur if the product were heavily demanded by the surgeons themselves. In conclusion, based on our projections, the ideal selling price for 5G's ergonomic scalpel handle, if commercialized, would be roughly \$25 per unit.

## **5 Discussion and Recommendations**

Chapter 5 encapsulates our final decision on the perceived feasibility of 5G's ergonomic scalpel, as well as a thorough explanation of the analysis that this decision derived from. Additionally, based off our assessment of the product's feasibility, we will provide 5G with possible strategies and alternative methods for commercialization of their ergonomic scalpel handle.

### **5.1 Discussion**

Based on the rigorous research conducted, and the resulting data and insights collected, as discussed in chapter 4, we were able to reach a final verdict on the perceived feasibility of 5G's ergonomic scalpel handle. Ultimately, we concluded that this product would not be a viable option for commercialization as a stand-alone product. However, this is not to say that the product concept should be abandoned entirely; rather, alternative methods to commercialization may be required in order to generate future success if this product reaches market. Several key aspects, found in our research, contributed the process of determining that this product would not thrive in the market as a stand-alone product. We isolated these key aspects, which ultimately led to our final assessment, into several distinct segments: the current marketplace, intellectual property, end-users, and financials.

Determining the need felt by the market for change and innovation is a crucial step when assessing a product's feasibility. In order to achieve this assessment, the current state of the marketplace must first be evaluated. The research gathered pertaining to the medical and surgical device industries in the early portions of our project, as can be seen in-depth in chapter 2, enabled our group to determine that the current state of the market does not present a need for this new product. This conclusion was ascertained due to the recent, and continued, success of the industry as a whole. The success seen was generated despite employing the same basic scalpel design for the past several decades. Therefore, although the market itself is prospering, which may have positive implications, it does not appear that the need for a new product is present.

Although the current state of the market does not call for change, this fact alone is simply not enough to deem 5G's scalpel not a viable option for commercialization. Next, we must determine the protection and freedom of operation provided by the intellectual property possessed by the product. From our discussions with several patent experts, we were able to determine that the patent is of "moderate" to "weak" strength. Therefore, the patent does not provide the luxury of exemplary protection when the product reaches market. Consequently, this entails a more conservative marketing scheme for the product, due to the fear of imitation products and competing on costs with much larger competitors if targeted at the general market. Thus, the moderate to weak characteristics of the patent require changing 5G's marketing focus from a generalized market, to more specialty and niche marketplaces. Although this assessment has negative implications on the feasibility of the product, because the potential market size has been vastly reduced, it does not constitute this product being a non-viable option for commercialization.

Due to the negative implications provided by the two previous segments analyzed above, there must be a distinct need felt from the end-user, surgeons, in order to help justify the validity of bringing 5G's ergonomic scalpel handle to market. Prior to assessing the end-user's opinions on the product in question, we must first determine if there is a need for change from the products currently utilized. From our discussions with hospital personnel we discovered that they found only minor, if any, shortcomings with the current scalpel. Thus, the need for change and introduction of a new product is not clear. Furthermore, not only is the need for change not evident, rather the fear of change supersedes the desire for change. The fear of change is derived from the comfort level felt with their current scalpel, and the concern that the learning curve associated with a new product will negatively impact their surgical performance. As one of the male surgeons we interviewed put it:

“...for surgeons it's all about muscle memory...I've grown so accustomed to my current scalpel that I can make an incision, with the appropriate amount of force applied, with my eyes closed.”

Although this is almost surely a hyperbole, the message behind the statement is critical. The reason that there has been virtually no innovation in this product category over the past several decades is due to the fact that there is simply no need for change. Furthermore, that the risks associated with change in this industry far outweigh the potential benefits any form of change may provide. Once again, this aspect has a negative effect on the perceived feasibility of 5G's scalpel handle, as it reduces the estimated demand for the product substantially.

Once this conclusion about the need for change from the currently utilized products had been drawn, we were able to discuss their opinions on 5G's prototype scalpel. Despite our subjects having been exposed to the prototype previously and their close working relationship

with the project's sponsor, we were able to extract several important insights from our focus group. First and foremost, it was iterated that this product's primary usage would be for circular, surface incisions. This is due to the bulkiness of the prototype inhibiting the surgeons' ability to use it inside a patient after the initial incision. Therefore, the subjects believe that this product would only be utilized by specialized surgeons, such as plastic surgeons, for only a handful of procedures. However, we were informed that there is already a specialty scalpel and blade for incisions of this type in use. This fact alone drastically reduces the perceived market size and estimated demand for 5G's ergonomic scalpel handle. A final bit of useful information that can be extracted from the focus group, that furthers the negative impact on the estimated demand, is the lifecycle of their current scalpel. We were astonished to discover that the reusable metal scalpels the surgeons presently use date back as far as forty or more years. This fact implies that the hospital does not currently expend much capital on the purchase of reusable scalpels, and that it is virtually a one-time purchase. Thus, the initial demand for 5G's product will have difficulty remaining sustainable over-time without continued expansion of market reach.

Each of the various aspects of feasibility, elucidated above, has a significant impact on the financial projections for 5G's ergonomic scalpel handle. Therefore, the negative implications drawn from each aspect, in the process of assessing the product's feasibility, will have an adverse effect on the profit potential for 5G's new scalpel. In order to determine the remaining profit potential for this product, a cost-benefit and break-even analysis were performed, for more detail refer to chapter 4 or the appendix for charts and tables of the projected financials. From our assessment, we concluded that the only potentially plausible pricing strategy would be the differentiation plan, due to the need for focusing on niche and specialty markets. From our discussions with Mr. Zinkus, the purchasing agent for UMass Memorial Hospital, we were able

to ascertain that the current specialty scalpels purchased cost roughly \$20, on average. Furthermore, Mr. Zinkus notified us that the threshold for additional cost they would be willing to spend on a scalpel, if the surgeons demanded it, would be about \$5 maximum per unit. Therefore, the price-level for the differentiation plan of \$30 per unit would likely not be a feasible selling price for this product. Thus, the only potentially viable selling prices for 5G's product would be between \$20 and \$25, from which we were able to determine that optimal price-level would be roughly \$25. At this price, assuming accurate assumptions and consistent demand, it would take over 2,000 units, or just over 40 months, to recoup the initial investment costs of the mold required. However, due to small-scale size of 5G's operation, it is irrational to believe that a demand that great could possibly be met because the target population, specialty surgeons, is far less than half the required demand to recoup the fixed costs if the entire target population utilizes this product. Furthermore, in order to generate any form of sustainable revenue over time, 5G's market reach and operation size would need to expand continuously to simply keep demand consistent. In conclusion, from a financial perspective this venture appears to offer little upside. The negative implications drawn from the financial aspects of the product, coupled with those from the other vital aspects discussed, appear to signify that 5G's ergonomic scalpel handle is simply not a viable option for commercialization as a stand-alone product at the moment.

## **5.2 Recommendations**

Despite arriving at the conclusion that 5G's ergonomic scalpel handle would not be feasible for commercialization as a stand-alone product currently, that is not to say that there is not profit potential in this product. However, as it stands currently, alternative methods may need

to be employed in order to quell some of the primary issues resulting in the products unfeasibility. In this section, we will explore and offer suggestions 5G might incorporate in order to salvage this product in the most effective manner possible. We will discuss a variety of alternative strategies 5G might consider for this product, such as: attacking niche markets unrelated to the surgical field, licensing the product to a large-scale and established company, and utilizing this concept as a platform product to generate a family of ergonomic surgical devices.

It appears that one of the most prevalent issues limiting the ergonomic scalpel's commercialization potential is the limited size of the target market segment: specialty surgeons. A possible alternative method 5G could employ is to expand their target segment to various other niche market segments, such as the hobbyist market. Although capturing demand from the hobbyist market alone would almost surely not be enough for this product to thrive, coupled with the initial target segment of specialty surgeons, it could help 5G expand their target market size and resolve some of the issues of sustainable demand. Additionally, the hobbyist market is merely one example of potential alternative markets 5G could explore with this scalpel product. Other possibilities could range from veterinarians to lab technicians.

It has become apparent, from the conclusions derived in the previous section, that one of the persistent issues hindering 5G's ergonomic scalpel from being considered feasible are the massive overhead and fixed costs incurred. One potential remedy for this obstacle would be licensing this product to a much larger, and more established, company, such as X-Acto. This would enable 5G to virtually negate any costs not associated with R&D, while generating a steady stream of revenue if the product proves successful. Furthermore, licensing may also help quell some of the sustainable demand issues caused by limited market size and reach. A



prominent company in a similar field, such as X-Acto, would have established demand in a wide array of locations that 5G might otherwise not have access to.

Our final suggestion for an alternative method to commercialization of 5G's ergonomic scalpel handle, is to utilize this product as a platform product and create a family of ergonomic surgical tools. Theoretically, this would enable 5G to expand their market potential by delving into various other target segments, aside from strictly specialty surgeons. Furthermore, introducing a line of ergonomic surgical tools may help suppress some of the surgeons' fear of change by incorporating a similar product concept in various other aspects of their work. Additionally, the hospital purchasing staff, as well as potential investors, may be more inclined to invest in a bundle of new products, as oppose to an individual new product. The suggestions elucidated above are merely a few potential avenues for alternative methods to commercialization, derived from several brainstorming sessions, that 5G may wish to incorporate to heighten the commercial feasibility of their ergonomic scalpel handle if brought to market.

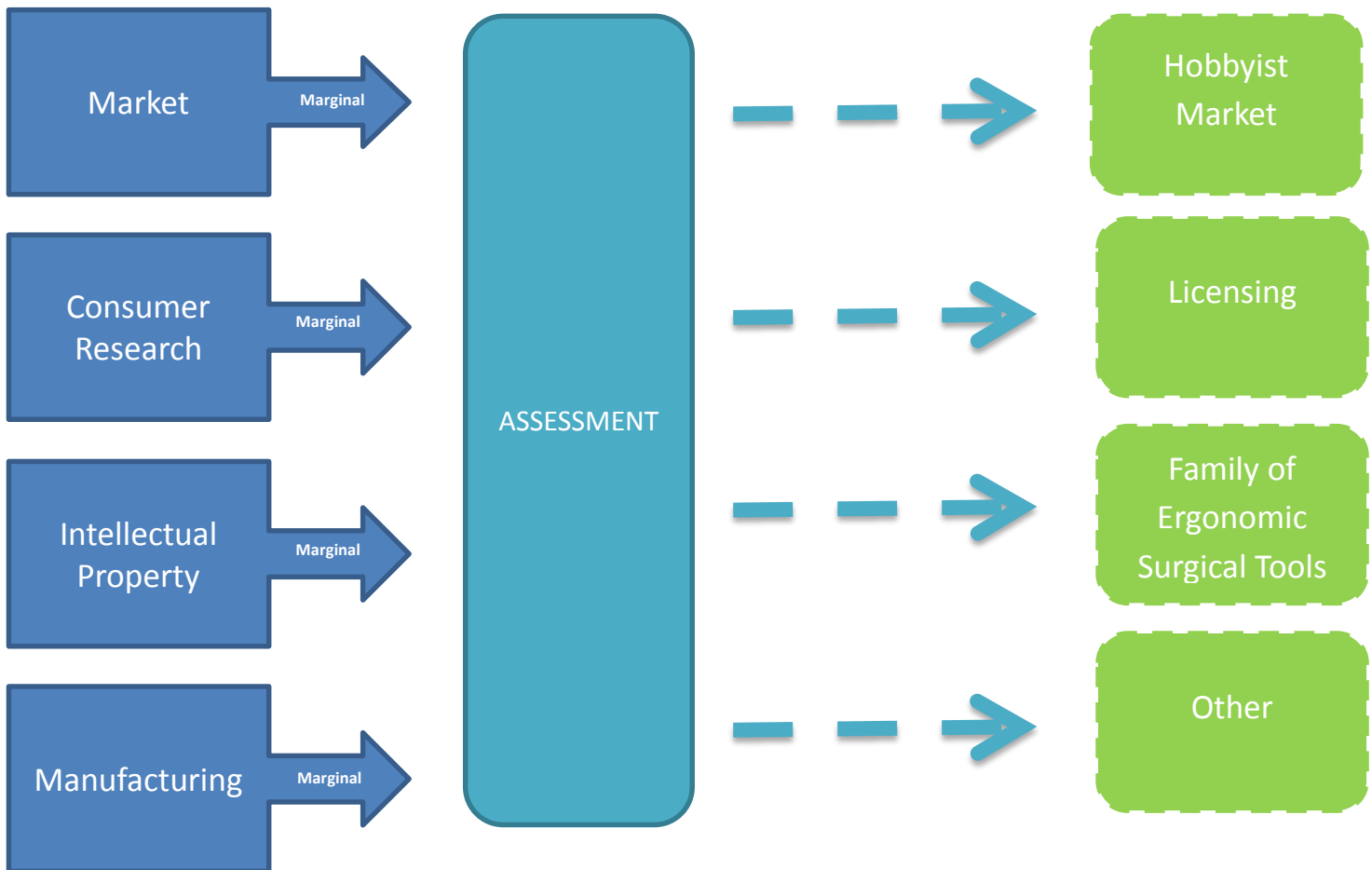


Figure 10: Potential Markets

In conclusion, we assessed four areas of the potential prototype: intellectual property, manufacturing, consumer research, and the market. After analyzing each area, we found that all four had marginal potential. This led us to recognize three potential possibilities for the proposed prototype. These three possibilities are hobbyist, licensing, and a family of ergonomic surgical tools.

## 5.3 Post-Presentation Considerations

### 5.3.1 Product Champion

After presenting the results of our findings to our sponsor, Dr. Dunn, he noticed that we quantified four distinct factors contributing to our ultimate determination of the perceived feasibility of 5G's ergonomic scalpel handle; the market, consumer research, intellectual property, and manufacturing. Although Dr. Dunn agreed with the conclusions drawn from each of these four various feasibility aspects, from an objective perspective, he offered an intriguing inquiry for our group to consider moving forward; "How can you quantify the impact, both positive and negative, of a product champion on the potential success of a given product?"

Product champions can be a vital component when introducing a new product innovation to the market. A product champion is typically a senior level individual, or executive, who acts as an advocate for the product and encourages further internal development and external promotion of a product. Often times this is the inventor. Virtually, all successful innovations, particularly radical innovations, require the constant support and knowledge provided by a product champion. However, where difficulty arises is in distinguishing whether the strong support and promotion provided by a product champion is warranted, and therefore beneficial, or if the product champion's emotional investment in their product hinders pragmatic decision making.

Although it is virtually impossible to accurately predict the role a product champion will play in the ultimate success, or failure, of a product from the onset, the benefits of a strong product champion can be seen more so in certain industries over others. For instance; the presence of a strong product champion for a radical innovation will present augmented value in a traditional, or conservative, industry hesitant to adopt change, such as the surgical device industry. Although the role, and impact, of a product champion can vary greatly from product to

product and is difficult to quantify, the fact remains that a product champion can play a significant role in the commercialization feasibility, and potential for success, of any new product.

### **5.3.2 Funding Options**

After presenting our findings to our sponsor, he requested we inquire about potential funding for 5G. Some forms of funding we suggest 5G look into if moving forward with the prototype are: grants from the small business technology transfer (STTR), the National Institutes of Health (NIH), or the National Science Foundation (NSF), angel investors, or venture capitalists. These various sources of funding may allow 5G to obtain enough capital to cover the initial investments needed to purchase the four shot injection molding as well as all other costs associated with starting production.

Grants are one option that 5G could potentially use for funding. In order to receive a grant you must submit an application, which will be reviewed by a minimum of three experts in the fields represented by your proposal. During the review process, each proposal is scrutinized for its potential technological and commercialization capabilities. Small business grants are a smart option because the government does not charge interest, nor does it demand control of your business in return. Although these are viable options for funding, grants are in high demand and are very competitive. Consequently, other forms of funding should be considered.

STTR, is another funding opportunity. This program is dedicated to “supporting scientific excellence and technological innovation through the investment of Federal research funds in critical American priorities to build a strong national economy” (“Small business innovation,” 2014). The program is split into three phases each of which would provide stability for 5G as it progresses through the research and development stages. The three phases are listed below:

- **Phase I:** \$100,000 maximum for 1 year - establish the technical merit, feasibility, and commercial potential of the proposed R/R&D efforts and to determine the quality of performance of the small businesses
- **Phase II:** \$750,000 maximum for 2 years - continue the R/R&D efforts
- **Phase III:** Not funded – business pursues commercialization objectives resulting from the Phase I/II R/R&D activities

The NIH is another possible funding option. The process to become approved takes almost a year. The first three months are the receipt and referral time period. During this time, reviewers are assigned to look at the applications for validity. The next four months are dedicated to peer review and scoring of each application. The last two months involve grant awarding and negotiations. Since a new scalpel is a medical improvement, 5G would qualify to enter an application to NIH to be evaluated.

Additionally, the NSF is an agency that provides funding for early stage research and development at small businesses. As stated on the website, the R&D funded by NSF should “be based on transformational technology with high technical risk and potential for significant societal or commercial impact” (NSF, 2014). The grants provided by the NSF are split into phases:

- **Phase I:** \$150k over 6 months - Feasibility Study
- **Phase II:** \$750k over 2 years - Development Project

When it comes to venture capital funding, it is suggested you exhaust all other options of funding before looking into this avenue. This is because venture capitalists take a large portion of your company, in equity and control, when they give you funding. Therefore, you should not use venture capital funding unless you require amounts greater than one million dollars.

Angel investors are another form of funding that 5G could potentially use. Angel networks usually provide between \$25,000 and \$250,000, which is in the range of 5G's needs. In order to obtain angel investment, you must network extensively to find an investor that understands and is interested in your industry. This is important because the angel investor will be involved in your business and needs to understand where you are trying to take your company and share your views.

### **5.3.3 Interview with Independent Medical Device Sales Representatives**

As requested as a follow-up analysis, after presenting to our sponsor, we interviewed two independent medical sales representatives in order to gain insight into medical equipment sales. The two representatives have dealt with representing innovative products similar to the ergonomic scalpel handle, throughout the duration of their careers. Both have had nearly 20 years of sales experience, including working for large companies in various sales roles, and as an independent sales representative. As one representative told us, he represents products that are just coming into market. He shows the product to physicians, hospitals, or whoever the target is; supporting the product along the way. He watches surgeries with the surgeons and gets involved with the hospital administration in purchasing the product.

In choosing a product to potentially represent, both representatives said they attend trade shows, and make rounds, looking at the various booths to see if there are particular products that best fit with what they feel comfortable selling. Both sales representatives also secure clients via referrals from people they've developed strong relationships with over the years. Both emphasized the importance of developing and maintaining relationships with physicians such as our sponsor Dr. Ray Dunn, when working in the medical sales industry, because they possess valuable first-hand knowledge about how the people and tools function in the medical field. Some of their sales relationships have been maintained for as long as fourteen years.

If a particular product interests them, they will also be more inclined to take on selling it. Also, if they can obtain a product with some existing business, they'll be more inclined to take it on because they know that if someone else can sell it, then they can sell it. Typically these medical device representatives carry with them, a range of four to six products on average in their daily bags at one time. They do this so that not "all their eggs are in one basket." These representatives are currently working as independents and entirely depend on actual sales for income. Finally, in discussing whether these sales representatives had ever worked with doctors who have invented a device themselves, they expressed to us that physicians in fact developed the majority of devices they have sold. They train with the physicians to learn about the product, and to see it and the process behind it.

## References

"Adult Obesity Facts." Centers for Disease Control and Prevention. Centers for Disease Control and Prevention, 16 Aug. 2013. Web. 10 Oct. 2013.

The Center for Disease Control and Prevention is a valid source because the statistics offered are from an official government database. There is no bias in the information presented because it is strictly facts and analysis of those facts. This database provides information about obesity in the US, which is an important topic to consider for our project because overweight and obese individuals require surgery more often. Brown, P., Dahlmann, J., Gielo-Perczak, K., Palumbo, N., Sotak, C. (2010). Ergonomic scalpel handle for accurate incision. Worcester Polytechnic Institute. Major Qualifying project. Accession number: 679143.

Baxter U.S. (2010). Baxter to Recall COLLEAGUE Infusion Pumps in U.S. Retrieved from:

[http://www.baxter.com/press\\_room/press\\_releases/2010/05\\_03\\_10\\_colleague.html](http://www.baxter.com/press_room/press_releases/2010/05_03_10_colleague.html)

Baxter Healthcare Corporation is the principal domestic operating subsidiary of Baxter International Inc. (NYSE: BAX). Baxter International Inc., through its subsidiaries, develops, manufactures and markets products that save and sustain the lives of people with hemophilia, immune disorders, infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions. As a global, diversified healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to create products that advance patient care worldwide.

Covidien Public Limited Company, SWOT Analysis. (2013). *Covidien Ltd. SWOT Analysis*, 1-8.



A business analysis of Covidien PLC, which is a global healthcare products company, is provided, focusing on its strengths, weaknesses, opportunities for improvement and threats to the company. Strengths include its focus on research and development. Weaknesses include decrease in sales of airway and ventilation products. Opportunities for improvement include growth in medical equipment industry. Threats to the company include changes in the healthcare laws in the U.S.

Daintith, John Martin, Elizabeth (2010). Dictionary of Science (6th Edition). Oxford University Press. Online version available at:

<http://app.knovel.com/hotlink/toc/id:kpDSE00001/dictionary-science-6th>

This dictionary is used as a source in many credible research documents. It is a well-known dictionary that has valuable definitions and other information on many topics related to science.

Elmuti, D., Khoury, G., Omran, O., & Abou-Zaid, A. S. (2013). Challenges and Opportunities of Health Care Supply Chain Management in the United States. *Health Marketing Quarterly*, 30(2), 128-143. doi: 10.1080/07359683.2013.787885

This article explores current supply chain management challenges and initiatives and identifies problems that affect supply chain management success in the U.S. health-care industry. In addition, it investigates the impact of health care supply chain management (SCM) initiatives on the overall organizational effectiveness. The attitudinal results, as well as the performance results presented in this study support the claim of health care

proponents that the SCM allows organizations to reduce cost, improve quality, and reduce cycle time, and leads to high performance.

Goldfarb, B. & Henrekson, M. (2003). Bottom-up versus top-down policies towards the commercialization of university intellectual property, *Research Policy*, Volume 32, Issue 4, April 2003, Pages 639–658. doi:10.1016/S0048-7333(02)00034-3

*Research Policy* (RP) is a multi-disciplinary journal devoted to analyzing, understanding, and responding to challenges posed by innovation, technology, R&D, and science.

Written by Brent Goldfarb (Department of Economics, Rensselaer Polytechnic Institute) and Magnus Henrekson (Department of Economics, Stockholm School of Economics), this particular journal article analyzes which national policies are most efficient in promoting the commercialization of university-generated knowledge. It also discusses methods of technology transfer.

Health Care Equipment & Supplies Industry Profile: Global. (2011) (pp. 1): MarketLine(2011), a Datamonitor business.

Presents a profile of the Health Care Equipment & Supplies industry in the World.

Executive summary of the industry; Market overview; Market value; Market segmentation; Competitive landscape; Leading companies in the industry; Market forecasts; Demographics; Further reading.

Kaczanowska, Agata. (Dec, 2011) Surgical Instrument Manufacturing. No Cutbacks: Strong revenue growth through the recession will continue as baby boomers enter retirement.

*IBISWorld Industry Report OD4103.*

IBISWorld is the largest provider of industry-based research, and employs a team of dedicated expert analysts that have been thoroughly researching economic, demographic, and government data in order to provide accurate and current business information, and have done so since 1971. IBISWorld supplies this information to over 1,500 clients and businesses worldwide, in order to aid them in market research. There is no bias involved because only factual information and analysis are presented. This article depicts the state of the surgical manufacturing industry at the end of 2011, showing that the market has grown recently. Additionally, future growth is anticipated due to increased demand for surgeries because the increased amount of people over the age of 65.

Kirkup, J. (2006). *The Evolution of Surgical Instruments: An Illustrated History from Ancient Times to the Twentieth Century*. Norman Publishing. ISBN: 0930405862, 978093040586. Pages 1-18.

*The Evolution of Surgical Instruments* is the first comprehensive work on the subject published in over sixty years and arguably the most important general history of surgical instruments ever published. The only prior work on the subject, C. J. S. Thompson's *The History and Evolution of Surgical Instruments* (1942) attempted to cover the entire history in only 113 pages. Elisabeth Bennion's *Antique Medical Instruments* (1979) concentrated chiefly upon the aesthetic aspects of medical and surgical instruments to

1870. James Edmonson's comprehensive history, *American Surgical Instruments* (1997), focused on instruments manufactured in the United States up to 1900.

Kutz, Myer (1998). *Mechanical Engineers' Handbook* (2nd Edition). John Wiley & Sons. Online version available at: <http://app.knovel.com/hotlink/toc/id:kpMEHE0004/mechanical-engineers>

This article offers information on all aspects of ergonomics. It gives detailed diagrams of different factors that affect ergonomics and how manufacturers should address them when trying to improve tools. The author is well known and has cited other credible sources to back up the information that he is providing.

Most Medical Devices to Carry Unique Device Identifier. (2012a). *National Intelligence Report*, 12(20), 6-7.

The article offers information on the unique device identifier (UDI) rulemaking launched by the U.S. Food and Drug Administration (FDA). It notes that rulemaking requires most medical devices to carry a UDI system. It adds that a UDI system enables tracking and identification of medical devices from production through use in clinical practice. It adds that the rulemaking is in response to a mandate in the FDA Amendment Act of 2007.

Most Medical Devices to Carry Unique Device Identifier. (2012b). *National Intelligence Report*, 12(20), 6-7.

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medical devices to carry a UDI system. It adds that a UDI system enables tracking and identification of medical devices from production through use in clinical practice. It adds that the rulemaking is in response to a mandate in the FDA Amendment Act of 2007.

Mowery, D. & Sampat, B. (2004). The Bayh-Dole Act of 1980 and University-Industry Technology Transfer: A Model for Other OECD Governments? *The Journal of Technology Transfer*. Volume 30, Issue 1-2, Page 120. doi: 10.1007/s10961-004-4361-z

David C. Mower is affiliated with the Haas School of Business, UC Berkeley. Bhaven N. Sampat is affiliated with the School of Public Policy, Georgia Institute of Technology, and the School of Public Health, Health Management and Policy, University of Michigan. This particular entry was published in *The Journal of Technology Transfer*, the Official Journal of the Technology Transfer Society. This society provides an international forum for the exchange of ideas that enhance and build an understanding of the practice of technology transfer.

*National institutes of health: Office of extramural research*. (2013). Retrieved from [http://grants.nih.gov/grants/grants\\_process.htm](http://grants.nih.gov/grants/grants_process.htm)

*National science foundation: Directorate of engineering (eng)*. (2014). Retrieved from <http://www.nsf.gov/eng/iip/sbir/index.jsp>

Ochsner, J. (2009). The surgical knife. *US National Library of Medicine National Institutes of Health; Texas Heart Institute Journal*; Volume 36, Number 5. Page 442. PMID: PMC2763477

John Ochsner, MD founded the Department of Surgery, Ochsner Clinic Foundation, New Orleans, Louisiana 70121. The article, published by the Texas Heart Institute (NIH), talks about the history of medicine, particularly the progress of surgical tools. Presented at the 16th International Symposium of the Denton A. Cooley Cardiovascular Surgical Society,

Galveston, Texas, 4–7 June 2009. This article is derived from a longer article: Ochsner, J. The surgical knife. *Bull Am Coll Surg* 1999;84(2):27–37, which in turn is an edited version of Dr. Ochsner's John H. Gibbon, Jr. Lecture, delivered at the 84th American College of Surgeons Clinical Congress in Orlando, Florida, 26 October 1998.

Palumbo, N. V., Dahlmann, J. C., Brown, P. A., Gielo-Perczak, K., & Sotak, C. H. (2010).

*Ergonomic scalpel handle for accurate incision* (pp. leaves col. ill. 28 cm.). Retrieved from <http://www.wpi.edu/Pubs/E-project/Available/E-project-042910-163310/>

Abstract: The goal of this project was to design, prototype, and test scalpel handles for small lesion removal. Scalpels are one of the most extensively used surgical tools in medicine today. However, the current flat-sided design limits the surgeons' ability to create precise, small incisions because the scalpel handle tends to rotate in their hands, especially for nonlinear incisions. To overcome this problem, we designed an ergonomic scalpel handle which features a cylindrical cross-section and smooth tapering that naturally fits hand positions which are used for creating an incision. Specifically, the scalpel handle was designed to increase the comfort, control, and precision a surgeon has during surgery.

The Pennsylvania State University (2013). *Instrument Preparation and Sterilization*. Retrieved from <http://www.research.psu.edu/arp/surgery/instrument-preparation-and-sterilization>

This article goes into an overview of steps to take in order to prepare and sterilize instruments before surgery. Tools that are used during surgery will initially be packed in a sealed bag or inside a folded cloth. Surgical packs will include everything that is needed for surgery- gauze, needles, and any instrument that may be needed. Any instrument that

will be in the surgical room will need to be previously sterilized. Methods for sterilization include steam sterilization, ethylene oxide and glass bead sterilization. The same set of instruments may be used during the same procedure.

Raymond, T. Product (2011) Briefs: Improving Lives with Advances Technology for Surgery. 5G Medical.

This is a product brief handout created by the President of 5G Medical, Tony Raymond, in 2011 to provide a brief synopsis of the scalpel's potential to progress in future years.

*SBIR/STTR: Small business innovation research small business technology transfer.* (2014). Retrieved from <https://www.sbir.gov/about/about-sttr>

Sonn, Anna. (2013) Medical Instrument & Supply Manufacturing in the US. Healthy Demand: Steady healthcare spending and innovation will continue driving revenue. *IBISWorld Industry Report 33911a*.

IBISWorld is the largest provider of industry-based research, and employs a team of dedicated expert analysts that have been thoroughly researching economic, demographic, and government data in order to provide accurate and current business information, and have done so since 1971. IBISWorld supplies this information to over 1,500 clients and businesses worldwide, in order to aid them in market research. There is no bias involved because only factual information and analysis are presented. This article discusses the healthy demand currently being felt in the medical instrument & supply manufacturing industry in the US, as a result of increased and steady healthcare spending. Additionally, innovation is continuing to drive revenue growth through increasing product turnover and replacement rates in order to keep up with the growing demand.

Sonn, Anna. (2013) Medical Supplies Wholesaling in the US. Steady Pulse: The aging population and new technologies will spur revenue growth. *IBISWorld Industry Report 42345*.

IBISWorld is the largest provider of industry-based research, and employs a team of dedicated expert analysts that have been thoroughly researching economic, demographic, and government data in order to provide accurate and current business information, and have done so since 1971. IBISWorld supplies this information to over 1,500 clients and businesses worldwide, in order to aid them in market research. There is no bias involved because only factual information and analysis are presented, not view points. Anna Sonn has shown she is competent and knowledgeable in this field because she also wrote the previous article I cited pertaining to the same industry (*IBISWorld Industry Report 33911a*). This article discusses the current state of the industry for medical supplies wholesaling, and discusses how revenue growth is continuing as the population ages and new advancements in technologies become more prevalent. This information is vital to our project because we may consider taking the wholesaling route for the 5G scalpel if we decide to compete on price and attach the general market.

Stevens, A. (2004). The Enactment of Bayh-Dole. *The Journal of Technology Transfer*. Volume 29, Issue 1, pp 93-99. Doi: 10.1023/B:JOTT.0000011183.40867.52

Dr. Stevens has been Director of the Office of Technology Transfer at Boston University since 1995 and was appointed a Lecturer in the School of Management in 2005, where he teaches a graduate level, inter-disciplinary course on Technology Commercialization. Dr. Stevens publishes and lectures frequently on many aspects of technology transfer. He is



very active with the Association of University Technology Managers, most recently as Vice President, Annual Meeting and Surveys. He was a Co-Founder of the Massachusetts Association of Technology Transfer Offices and was the first Chair of its Executive Committee, leading the effort to create the Massachusetts Technology Portal. This specific essay talks about the history of the Bayh-Dole Act, and the situation before and after it became legislature.

CDC, C. f. (2008). Guideline for Disinfection and Sterilization in Healthcare Facilities.

This article outlines the guidelines for sterilization within healthcare. Based on the specific medical instrument, there are multiple ways healthcare professionals can go about sterilizing the medical device. Specifically for a scalpel, the best way to sterilize is through steam sterilization. This process does not take too much time and is done in an autoclave. This article will help our project because the sterilization process will be something that 5G will need to be familiar with before it goes into the market.

US News Health. Doctors. (2014) *Surgeons in Massachusetts*.

US News Health is a trusted data base, reviewing hospitals and doctors alike. They have evaluated nearly 5,000 hospitals in 16 adult and 20 pediatric specialties. This is a useful resource to our project because it enables us to assess the size of the local market in order to aggregate a projected demand for the product.

USPTO (2014). US Patents and Trademarks Office.

The USPTO is the most prominent database for attaining and reviewing patents valid in the United States. Thousands of new patents are filed yearly through the USPTO. This is

an important resource to our project because it allows us to assess the strength of the patent in question, as well as find and prior art that appears to be similar to 5G's patent.

Zwilling , M. (2010, 2 12). *Top 10 sources of funding for start-ups*. Retrieved from <http://www.forbes.com/2010/02/12/funding-for-startups-entrepreneurs-finance-zwilling.htm>

