



WPI

Lean Service for the Legacy Gastroscope

A Major Qualifying Project

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Abstract

KARL STORZ offers repair services for the Legacy Gastroscope at their Charlton, MA facility. This particular endoscope was first manufactured in this facility in 2007 but is no longer available to be newly manufactured. For this project we investigated alternatives to save parts and components for the Legacy Gastroscope to help delay its product obsolescence. We observed and interviewed evaluators, repair technicians, and floor managers. Analysis of evaluation reports and other procedural documentation was completed to assess how repair levels were assigned. Recommendations were generated on how to delay product obsolescence for the Legacy Gastroscope.

Executive Summary

Introduction

KARL STORZ Endoscopy- America Inc., a subsidiary of KARL STORZ GmbH & Co., is a leading manufacturer of endoscopic equipment in the United States. KARL STORZ manufactures a wide range of endoscopic devices which have many applications in human and veterinary medicines. The KARL STORZ facility in Charlton, MA is a manufacturing and repairing center for their endoscope devices.

KARL STORZ places a high importance on customer service for their repair services. If customers experience any abnormal problems with the endoscopes, then the customers can return the endoscope to the Charlton, MA facility to be evaluated. The evaluation process is designed to reveal defects in the endoscope that may cause it to malfunction at the customer's end. Common causes for malfunctioning include normal wear and tear, improper handling, and more. KARL STORZ offers a repair service that fixes endoscope defects with a fee to the customer. In this optional repair service, the returned endoscope is thoroughly cleaned, disassembled, rebuilt using new components as needed, inspected, then shipped back to the customer. This repair service allows the customers to fix and reuse their existing endoscopes, which results in a lower cost for the customer compared to buying a brand-new endoscope.

The Legacy Gastroscope has not been manufactured new at the Charlton, MA facility since 2012. Therefore, the Legacy Gastroscope is only being serviced for repairs until the customer decides to replace it with a newer model. While the Legacy Gastroscope is nearing the end of its product life cycle, its components are becoming more difficult to acquire due to component obsolescence. While these out-of-house sourced components were easy to acquire in 2012, these components have become more expensive and more difficult to acquire as manufacturers develop new components. This project aims at delaying component obsolescence for the Legacy Gastroscope by identifying opportunities for repairing and reusing damaged components that are returned for repair at the Charlton, MA facility. In addition, this project identifies strategies for influencing KARL STORZ customers who own Legacy Gastroscopes into upgrading to the Silver Gastroscopes, the in-house manufactured successor to the Legacy Gastroscope.

Background

In the United States, the medical device industry is a highly competitive and highly profit-oriented industry. The United States is the 3rd largest medical device market in the world and, in 2012, accounted for 38% of the global medical market. Key drivers of this industry include: an increasing number of hospital visits, technological advances, an improving economy, and the expansion of healthcare funding programs. By 2020, it is expected that the medical device industry will generate \$55 billion of annual revenue in the United States. Customers of medical device manufacturers like KARL STORZ include hospitals, clinics, alternative care providers, and medical device distributors. Purchasing trends in the medical device market are changing as hospitals join Group Purchasing Organizations (GPOs), which have led to manufacturers adapting new marketing strategies to differentiate their products from competitors.

Endoscope production is a component of the medical device industry and is considered to be an electro medical device. Gastrointestinal (GI) endoscopes are a specific type of endoscope used to examine the gastrointestinal tract. KARL STORZ's Legacy Gastroscope is a product in the GI endoscope market. The main components of a GI endoscope are: the insertion tube, the control section, and the connector section. Each GI endoscope can be paired with an external lighting source and a monitor, which allows medical professionals to view the inner parts of the human body. Recent endoscopic innovations have improved the lighting component and productivity of endoscopes. Recent endoscopic innovations have improved the lighting component and productivity of endoscopes, for example, the Colon Sight endoscope used for colonoscopies.

Methodology

The following objectives were set for this project:

1. Understand the repair process for Legacy Gastroscopes,
2. Collect and analyze data for Legacy Gastroscope repair,
3. Identify opportunities for waste reduction in Legacy Gastroscope repair,
4. Understand the product life cycle and its influence on customer purchasing habits.

To understand the repair process for Legacy Gastroscopes, our team used process mapping and technical research to study the flow of materials and information throughout the repair process.

We conducted two rounds of observations, high-level and low-level, while following a Legacy Gastroscope through each station in the repair process. Our team interviewed floor managers, evaluators, and repair technicians to better understand the repair process at different perspectives. We synthesized information obtained from our observations and interviews to develop an “as is” process map. This process map helped our team to better understand the cross-functional relationship between the different stages in the repair process. Our project sponsors also provided us with detailed instructions for each station in the repair process to help understand the more technical aspects of the Legacy Gastroscope.

To collect and analyze data for the repair process of the Legacy Gastroscope, we reviewed reports and documents referring to the repair of Legacy Gastroscopes. First we reviewed evaluation reports, standard forms for recording product evaluation results, to identify the most common defects found during the repair process of a Legacy Gastroscope. Second, the Bill of Material (BOM) Orders were reviewed to identify a list of components consistently ordered and required for Legacy Gastroscope repairs. Eighty BOM orders from 2015 were examined using a Microsoft Access database we created to understand the relationship between the evaluation reports and the materials being ordered for repairs. Based on the evaluation reports and BOM orders, we estimated the amount that customers were spending on Legacy Gastroscope repairs and identified the components responsible for the largest share of repair cost. Finally the team reviewed the Start and Stop records of Legacy Gastroscope repairs to identify opportunities for waste reduction. This document contains information about each endoscope repair including key dates, processing times, device history, and more.

Using probabilistic cost analysis we identified the components which should be examined for reclaim. The probabilistic cost analysis accounted for the replacement frequency of each component within our sample size¹ in order to model the population of Legacy Gastroscope repairs. We combined these population frequencies with their respective purchasing costs, to reveal the components responsible for the largest share of repair costs. From our probabilistic

¹ We used a sample of 80 BOM orders that had an evaluation date in the year 2015 and were recorded in KARL STORZ’s data management system in the year 2015. This sample was used to estimate the replacement frequency for each component in the repair data population.

cost analysis we identified three components to investigate opportunities for reclaim: the Printed Circuit Board (PCB) Assembly, the Housing with Control Unit, and the Connector Housing Assembly.

Using online research and interviews with industry professionals we gained a better understanding of the Legacy Gastroscope's product life cycle and its influence on customer purchasing habits. We reviewed news reports and articles for current market and technological trends. In addition, we utilized personal contacts in hospitals and medical device manufacturers to better understand the customer purchasing habits from industry professionals. From this research, we developed a product strategy for the Legacy Gastroscope at KARL STORZ.

Results and Recommendations

The PCB Assembly, the Housing with Control Unit, and the Connector Assembly were identified as the components with the greatest opportunity for reclaim. From our review of in-house reports and documents related to the repair of Legacy Gastrosopes, as well as multiple rounds of process observations and interviews with industry professionals, we determined that these components were best suited for preventive measures and not corrective measures. We deemed that a repair service for these out-of-house sourced components was too costly for implementation.

The most common damage to the PCB Assembly was corrosion due to internal fluid invasion. Once the PCB Assembly was compromised, the costs to repair outweighed the benefits of buying a new PCB Assembly. Therefore, our team focused on methods for preventing corrosion as opposed to repairing the damages. We recommended that conformal coating be applied to the PCB Assembly for each returned Legacy Gastroscope moving forward. Conformal coating is applied to electrical components to prevent short-circuiting from fluid contact. Conformal coating is a low cost material, has a minimal application time, and has an existing application in other KARL STORZ endoscope products. From an economical, technical, and organizational aspect, the application of conformal coating to the Legacy Gastroscope is feasible. In addition, this recommendation would increase the chance of preventing corrosion caused damages in the PCB Assembly, which will result in lower repair costs for the customer.

The most common damage to the Housing with Control Unit and Connector Assembly is cosmetic damages to their exterior. Since these components are sourced out-of-house, the proper repair methods are proprietary to the original manufacturer, and any temporary fixes by KARL STORZ could result in negative safety implications, then the costs and consequences of repair could outweigh the cost of buying new components. We recommended that KARL STORZ survey existing Legacy Gastroscope customers to reevaluate customer expectations for cosmetic defects and redefine KARL STORZ's cosmetic defect specifications. Through our discussions with industry professionals and a customer liaison at KARL STORZ, we concluded that customers are more concerned about safety implications and not physical appearance for their Legacy Gastroscopes. Therefore, the current cosmetic defect specifications can be expanded to allow more cosmetic damages per customer expectations. Redefining specifications may reduce the cost for future repairs since the need to buy a new component will not be required.

In addition to the reclaim recommendations for the above components, our team outlined further recommendations for Gastroscopes products at KARL STORZ in the form of a product strategy for Legacy Gastroscopes. From interviews with industry professionals and a KARL STORZ customer liaison, we provided insight into the customer purchasing habits for medical devices, customer expectations for legacy products, and how both of these influences should be accounted for with Legacy Gastroscopes at KARL STORZ. We concluded that most new gastroscopes in the market are considered novelty improvements and the marginal costs to the customer highly influences whether or not they purchase the newer model. Therefore, using a cost assessment of Gastroscope repair at KARL STORZ, we provided insight into Legacy Gastroscope repair compared to Silver Gastroscope repair and how this comparison can be used to benefit the customer and KARL STORZ from an economic standpoint.

Lastly, we identified opportunities for improved communication between the evaluation station and the disassembly station. The disassembly station is where the endoscopes are disassembled before they are rebuilt. Occasionally, repair levels are revised as the endoscope is processed through the repair service. Revised repair levels occur when the rebuilding stations identify damaged components that went previously undetected, which may escalate the assigned repair

level for that particular endoscope. If the customer is billed prior to detecting additional damaged components, then the cost difference is assumed by KARL STORZ. While the frequency of revised repair levels are low (footnote), the costs that KARL STORZ consumes is unnecessary waste. Our team decided that this improvement opportunity was not as imperative to our project as other opportunities, however, we recommended that these revised repair level occurrence be reviewed in detail in future projects for possible improvements to the evaluation procedure.

Conclusions

As the manufacturing of Legacy Gastrosopes ends, and newer models are introduced into the market, components for the Legacy Gastroscope become increasingly costly and difficult to source. This project investigated methods for delaying component obsolescence in the Legacy Gastroscope at KARL STORZ. From our findings, we created short-term recommendations for the Legacy Gastroscope and long-term recommendations for Gastrosopes at KARL STORZ. In addition, we identified opportunities for improved communication between the evaluation station and the disassembly station. In this project, the lessons learned about Legacy Gastrosopes provided insight into the production of legacy medical devices overall.

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Results and Recommendations	Adam	All
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Glossary of Terms

Bill of Material (BOM) Orders-A generated statement of components that were consumed in the endoscope repair process. This statement is sent to the customer for billing purposes, excluding warranty situations.

Evaluation Reports- A standard form that evaluators complete while assessing the condition of endoscopes that have been received from customers.

Legacy Gastroscope- refers to the older model of gastroscopes, more specifically model 13801NKS.

PFMEA- Process Failure Mode Effect Analysis is an analytical tool used to evaluate potential failures in a process.

Product Obsolescence- The time and state in which a product ceases to be useful, productive, or compatible.

RA- Repair Angle, a low level cost of endoscope repair mainly involving the angle cover.

RE- Repair Evaluation. This this the repair cost and the customer is only charged for the evaluation of the scope.

RH- Repair High, a high level cost of endoscope repair usually involving the housing assembly.

RHC- Repair High Camera, a level of endoscope repair that is the highest cost. This involves replacing aspects of the camera of the scope.

RL- Repair Low, a low level cost of endoscope repair usually involving the strain relief.

RM- Repair Medium, a medium level cost of endoscope repairs and involves the shaft repair.

RS- Repair Small, a low level cost of endoscope repair usually involving the lens.

Silver Gastroscope- refers to the Flexible Silver Scope Gastroscope which is the newer model of video gastroscopes, more specifically the 13821NKS.

Start and Stop Records for Endoscope Repair- A standard record of all endoscope repairs. This record includes details about the endoscopes, shipping and receiving dates, repair processing times, repair completion dates, and repair levels.

Chapter 1: Introduction

Repair services in the medical device industry are essential for customers to consider when purchasing medical devices. Customers can decide to seek repair services from the original manufacturer, or customers can seek repair services from third party vendors. Original manufacturers can initially be more expensive but as the life cycle of the product goes on it can become less expensive. It is important to stick with the original manufacturer because the repair service quality is higher due to the proprietary manufacturing processes, known only by the original manufacturer. During the repair process it is important for manufacturers to keep the process fast, efficient, and most importantly inexpensive. Expensive repair services can motivate customers to seek lower quality, less expensive third party vendors as an alternative. In addition, companies should also be cognizant of a product's life cycle, and where each product is located in that cycle at all times. If a product is nearing obsolescence, an effective strategy should be established to either extend its product lifespan, or phase into the newer model.

KARL STORZ Endoscopy-America Inc. is a subsidiary of KARL STORZ GmbH & Co., a global leader in the production of medical devices. KARL STORZ Endoscopy-America Inc. designs, develops, and distributes a wide range of medical imaging devices and equipment in the United States. KARL STORZ offers more than 15,000 different products that have applications in human and veterinary medicine. In addition to manufacturing, KARL STORZ provides repair services for their portfolio of products. For example, the Charlton, MA facility offers repair services for the Legacy Gastroscope. This particular endoscope is used by medical professionals to observe the lining of a patient's gastrointestinal (GI) tract. Like many other medical devices, the GI endoscope is reusable for multiple surgical procedures. If a problem or defect is found with a GI endoscope, the device can be sent for repair to the original manufacturer or a third party vendor.

KARL STORZ is committed to providing their customers with timely and quality repair services. Customers can send in their medical devices to be evaluated and repaired at the Charlton, MA facility. The standard turnaround time is 7 days once received by KARL STORZ. In addition, KARL STORZ strives to maintain low repair costs for the customer, while ensuring "like-new" conditions for the medical device. Keeping repair costs low allows KARL STORZ to compete

with third party vendors. The Legacy Gastroscope, the predecessor to the new Silver Gastroscope, has not been manufactured new since 2007. As the Legacy Gastroscope nears the end of its product life cycle, its out-of-house sourced components become more costly and more difficult to acquire, which raises the total cost per repair. This project aims at delaying component obsolescence and reducing repair costs for the Legacy Gastroscope by identifying opportunities for repairing and reusing damaged components in Legacy Gastroscopes that are returned at the Charlton, MA facility. In addition, this project develops a product strategy for the Legacy Gastroscope backed by market research, interviews with industry professionals, and technical and economical comparisons to the newer Silver Gastroscope.

1.1 Problem Statement

While the Legacy Gastroscope is nearing the end of its product lifespan at KARL STORZ, its components are becoming more difficult to acquire due to component obsolescence. As these out-of-house sourced components become more difficult and more costly to acquire, the repair cost per endoscope becomes more expensive for the customer². A high repair cost could influence customers to use third party vendors for product repair, or to purchase future products from a KARL STORZ competitor. This project aims at delaying component obsolescence and reducing repair costs for the Legacy Gastroscope by identifying opportunities for repairing and reusing damaged components in Legacy Gastroscopes that are returned at the Charlton, MA facility.

1.2 Project Goals and Objectives

The overall goals of this project was to reduce process waste within the endoscope repair process, to develop a plan of action for repairing and reusing components of the Legacy Gastroscope, and to develop a product strategy for the Legacy Gastroscope. To accomplish our goals we developed the following four objectives:

² Bill of Material (BOM) orders, the list of new components that were used in repaired endoscopes and their related costs, was reviewed. Based on a sample size of 93 BOM orders in 2015.(including 5 samples from each repair level), we calculated the average cost to repair an endoscope by repair level. Next, we reviewed an in-house record of evaluated Legacy Gastroscope and found that identified the repair level (RHC, RH, RM, etc.) for each evaluation. The in-house repair records were combined with their average repair level costs to identify that approximately \$520,000 in new components were used in repaired Legacy Gastroscope annually.

1. Understand the repair process for Legacy Gastrosopes,
2. Collect and analyze data for repairing Legacy Gastrosopes,
3. Identify opportunities for waste reduction in the Legacy Gastroscope repair process,
4. Understand the product life cycle and its influence on customer purchasing habits.

1.3 Project Deliverables

The deliverables for this project are:

1. A list of components with a plan of action for reclaim in the Legacy Gastroscope
2. A list of opportunities for waste reduction in the Legacy Gastroscope repair process
3. Product strategy for the Legacy Gastroscope
 - Market analysis containing competitor research, customer expectations on surgical devices, and technology trends on endoscopes.
 - Financial analysis of servicing Legacy Gastroscope compared to upgrading and servicing the newer Silver Gastroscope.

1.4 Project Scope

The scope of this project contains the in-house steps of the Legacy Gastroscope repair process at the KARL STORZ Endoscopy-America Inc. facility in Charlton, MA. The design of the Legacy Gastroscope and the physical layout of the repair process are outside the scope of this project; however, we can provide suggestions or recommendations for the individual stations. In addition, all out of house steps are outside the scope of this project including delivery and handling conducted by the customer, as well as any outside production of assemblies and sub-assemblies. This project collects and analyzes data for the Silver Gastroscope; however, the motivation was to draw comparisons to the Legacy Gastroscope, and not to provide recommendations for the Silver Gastroscope specifically. Although this project can help aid other endoscopic product lines, this project primarily focuses on the Legacy Gastroscope.

Chapter 2: Background

KARL STORZ GmbH & Co. is one of the world's leading endoscope manufacturers. Founded in 1945 the company originally produced eyes, nose, and throat instruments, headlamps, and binocular lenses (KARL STORZ Inc. e, n.d.). Over time the company sought to develop a device that could aid medical professionals in examining the inside of a human body; however, during the 1940s the only medical technology available to accomplish this was to illuminate a body using miniature lamps. KARL STORZ sought to find an alternative solution by creating a new medical device that focused on utilizing external lighting sources that could be introduced to the body through a flexible cable. This idea laid the foundation for modern endoscopy and by the early 1950s KARL STORZ was developing and producing its first endoscopes. Since then, KARL STORZ has designed, manufactured, and distributed over 15,000 different endoscopic products covering both human and veterinary needs. Their endoscopes aid many different practices in the medical field and include functions in neurology, cardiovascular, and plastic surgery, as well as procedures in gynecology, urology, and laparoscopy (KARL STORZ Inc. (d), n.d.). Globally, KARL STORZ has locations in over 40 different countries in 50 subsidiaries, including their headquarters, which is located in Tuttlingen, Germany. KARL STORZ Endoscopy- America Inc. is a subsidiary of KARL STORZ GmbH & Co. and has six locations in the United States, including their Charlton, MA facility (KARL STORZ Inc. h, n.d.).

2.1 Endoscopes

Endoscopes utilize fiber optic imaging, which was first utilized in the 1960s; however, scientists have observed and researched the 'guiding of light' in certain materials, such as water and quartz rods as early as the 1840s (Baillie, 2007). In 1954 Professor Harold Hopkins observed that light could travel through thin glass fibers due to the property of internal reflection and subsequently Doctor Basil Hirschowitz utilized this scientific phenomenon to develop the first gastroscope prototype. By coating the glass fibers, the internal reflection increased the power of the natural light shining (Baillie, 2007). In addition, a buffer coating was added to protect endoscopes from moisture damage and impact damage. In addition, an external light source was attached to the tip of the endoscope to further illuminate the image. By the 1990s, fiber optic imaging had competition with video-chip endoscopes, which utilized a charge coupled device (CCD), also

used in digital cameras. This would allow for multiple medical professionals to view the images on an external video screen instead of viewing the images through an eye/head piece (Baillie, 2007).

2.1.1 Gastro Intestinal Endoscopes

Gastrointestinal (GI) endoscopes, a subset of all endoscopes, are used to examine and treat the GI tract. They can differ from other endoscopes in function, purpose, and size. While endoscopes are able to look at a wide range of bodily compartments, GI endoscopes specifically look at the gastrointestinal tract. A basic GI endoscope is made of three parts: the insertion tube, the control section, and the connector section, which can be seen in Figure 1 (Varadarajulu, et al., 2011).

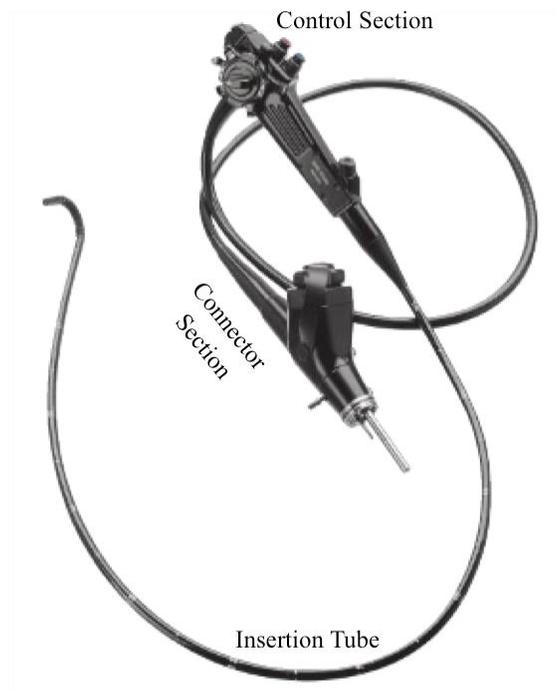


Figure 1: Parts of an Endoscope (Gentek, n.d.)

The insertion tube is a flexible channel that travels through the patient's mouth, down the patient's GI tract, and can be oriented in many angles (Varadarajulu, et al., 2011). Attached to the tip of the insertion tube is a charged-coupled device (CCD) which allows for colored images, a light source, water and air flow, and an objective lens. The control section is the part of the endoscope that the medical professional holds and maneuvers to control the movement of the

insertion tube. The control section has two control dials that can move the tip of the insertion tube up, down, left, and right. The connector section allows the endoscope to be attached to external devices such as a light or electrical source and a video screen (KARL STORZ Inc. b, n.d.).

2.1.2 Endoscopic Innovations

The medical device industry is highly competitive, as companies work to continuously redesign and improve their products. In the early years of endoscopic development, innovations such as the use of fiber optic cables, charged-coupled-devices, and external light sources allowed endoscopic access to more areas in the human body (Reavis & Melvin, 2008.) Recently endoscopic innovations include new techniques for lighting, productivity, and sterilization. Over the past few decades, endoscopic technologies have evolved steadily; however, in recent years, advances in this field have formed the foundations for the next generation of endoscopes.

One problem GI endoscopes face is visible white light in images. Studies have shown that endoscopists can miss 30% of abnormalities due to white light (Valdastri, et al., 2012.).

Innovations that can help eliminate white light issues are chromoendoscopy, autofluorescence, and charged-coupled-device cameras. Chromoendoscopy is a technique that uses dye solutions in the GI tract which enhances the visibility of changes in the GI tract. Autofluorescence is an imaging technique used to detect subtle changes in the tissues of the GI tract when specific chemicals are activated by specific wavelengths. Advances in charged-coupled-devices have also made it possible for new high-resolution and high-magnification cameras for endoscopes (Waxman, 2002.) Innovations with charged-coupled-devices have made it possible to increase image zoom from 30x to 100x.

The productivity of endoscopes has recently changed as single-use devices and accessories have been developed (Croffie, & et al, 2005.) The advantages of single use products are: increased convenience and variety, lower cost per unit, and lower risk of infection. The disadvantages of single use products are: the potential for higher cumulative costs, the need for proper disposal

methods, and the negative impacts on the environment due to material waste. These advantages and disadvantages are in direct contrast to multi-use devices, such as the Legacy Gastroscope and Silver Gastroscope manufactured at KARL STORZ.

The Fraunhofer Institute for Reliability and Microintegration in Berlin, Germany has developed inexpensive micro-cameras that will help aid the production and use of disposable endoscopes (“Cameras Out of the Salt Shaker,” 2011.) Through the institute’s research and development they have streamlined the electronical components of the camera so that the size of the entire system is roughly the size of a grain of salt. This allows the camera to be mounted on the tip of the endoscope as oppose to the base of the endoscope (“Microcamera for Disposable Endoscopes,” 2011.)

2.1.3 The ColonSight

Another example of an endoscopic innovation, described by the American Society for Gastrointestinal Endoscopy, is the ColonSight, which is used in colonoscopies. The ColonSight was developed by researchers from the Memorial Sloan-Kettering Cancer Centers in Italy and Israel (“New Era of Colon Screening Emerging,” 2004). This scope is particularly innovative because it utilizes a contaminant resistant sheath, or cover, a self- propulsion system, and an LED light source (Reavis & Melvin, 2008.) The disposable sheath covers the endoscope and creates a barrier between the patient, the scope, and the physician. This sheath eliminates the need for a disinfection or sterilization process and reduces the risk of infections, because the endoscope doesn't make contact with neither the patient nor the physician. The propulsion system improves the speed at which the scope can travel through the human body and it also reduces the amount of force the medical professional needs to use. The light at the end of the scope utilizes an LED which eliminates the need for fiber optic cables and reduces repair costs. The ColonSight has been tested on 84 patients in Italy, Israel, and the United States. Of those tests, 88% were able to reach the cecum, which is the furthestmost part of the colon, and examination times were reduced to an average of 12 minutes (“New Era of Colon Screening Emerging,” 2004).

2.2 Medical Device Industry in the US

The medical device industry is prominent to the healthcare sector and focuses on the development and production of electromedical and electrotherapeutic devices such as endoscopes, hearing aids, and ultrasound equipment (“Electromedical, Electrotherapeutic,” 2015). Key drivers of the development and growth of the medical device manufacturing industry include: the increasing number of hospital visits, adults over the age of 65 years, and healthcare funding programs (Hartford, 2015). Hospitals and clinics are the main customers of medical devices because they need to continuously purchase new equipment to keep up with the increasing number of patient visits. Recently, the boost in economy has encouraged more people to seek medical care and schedule routine doctor visits. In 2015, the number of physician visits was expected to increase by 3.3% (Phillips, 2015). In addition, the increasing number of adults over the age of 65 in the United States has also contributed to the growth in the medical device industry as well as the demand for medical devices. The risk of disease and disorders increase with age, which subsequently increases the demand for medical procedures, and consequently medical devices (Phillips, 2015). Increased health care programs will also allow for more people to have access to medical procedures that may utilize medical devices (Phillips, 2015).

The medical device industry in the United States is a highly-competitive and high-profit industry. In 2011, industry performance, in terms of profit margins, fell when hospitals experienced financial constraints and were unable to raise the necessary funds to purchase new medical devices (Phillips, 2015). But despite 2011’s low performance, the medical device industry remained successful from 2012-2015. In 2012 the medical device market in the United States accounted for 38% of the global medical market (“The Medical Device Industry in the United States,” n.d.). The medical device manufacturing industry will continue to grow due to technological advances, to the expansion of healthcare access through legislative initiatives, and the improving economy (“Electromedical, Electrotherapeutic,” 2015). By 2020 the medical device manufacturing industry is expected to earn revenues of \$55 billion per year (Phillips, 2015).

Despite the growth in the medical device industry, the number of medical device companies is expected to decrease due to globalization, mergers, and company acquisitions (Hartford, 2015). Increasing costs of medical devices are causing companies to rely on outsourcing their manufacturing and research efforts to foreign companies. In addition, large companies are looking to offset costs through mergers and acquisitions, where they can utilize smaller companies to gain insight into their technological and research developments (Phillips, 2015). Similarly, large companies are seeking to invest in smaller companies so they may benefit from the technologies they develop without having to go through the process of buying a company (“Electromedical, Electrotherapeutic,” 2015).

2.2.1 Products and Markets

Medical devices encompass a wide range of products such as x-rays, CT/CAT scanners, pacemakers, defibrillators, CPAP machines and ventilators, cochlear implants, and endoscopes. Demand for these products is driven by demographics, capital expenditure, technological advances, and the needs of the healthcare industry (“Electromedical, Electrotherapeutic,” 2015). Demographics, age and health of patients keep demand for products relatively constant even during economically weak times (Hartford, 2015). Demand for products is also driven by capital expenditures. Companies will purchase new equipment when previous equipment exceeds its designated lifespan. When new equipment is needed, companies will seek equipment with the newest technological advances, while remaining in their set budget.

The customers for medical device manufacturers are hospitals, clinics, alternative care providers, and distributors. Over the past few years, customers of the medical device industry, specifically hospitals, have joined Group Purchasing Organizations (GPOs) to increase their purchasing power (Hughes and Valyko, 2012). GPOs will often enter into long term contracts with medical device providers which places pressure to lower medical equipment prices and to increase the use of preferred vendors (“Electromedical, Electrotherapeutic,” 2015).

Almost 40% of medical devices manufactured in the United States are exported to countries including Japan, the Netherlands, Germany, and China (“Electromedical, Electrotherapeutic,” 2015). Approximately 35% of medical devices are sold to hospitals. A hospital’s size affects its

purchasing power for medical devices. For example, large general medical, surgical, and teaching hospitals will purchase a wider variety of medical devices while smaller and more specialized hospitals will be limited to the type and number of medical devices they can purchase. Specialists and alternative care providers consume approximately 15% of the medical device market. This figure will continue to grow as access to specialists and alternative care providers increases (Phillips, 2015).

Distributors, who are involved in 12% of the market segmentation, purchase large quantities of medical devices and then resell them to different customers; however, most customers would prefer to go through the manufacturer than a distributor, which is why they make up the smallest percentage of the market segmentation. The medical devices manufactured at KARL STORZ are predominantly purchased directly by the end user.

2.2.2 Competitive Landscape

Competition between medical device manufacturers is high and customers base their purchasing decisions on price, quality, and performance of new endoscopes (Phillips, 2015). Price is an important factor for customers looking to purchase large quantities of medical devices. Quality and performance is important because customers want to ensure they are receiving reliable products that can produce dependable results during medical procedures. Large companies, with over 10,000 employees, stay competitive through economies of scale and use this to their advantage during their research, manufacturing, marketing, and distribution efforts. KARL STORZ, a medium sized company, stays competitive by developing new and innovative technologies (“Electromedical, Electrotherapeutic,” 2015).

Medical device manufacturers are continuously developing new and innovative products for customers at a relatively low and competitive price. Since medical devices are created with new technology and are specialized to accommodate a wide range of medical procedures, many companies have high security standards to protect their intellectual property to safeguard themselves against manufacturing competitors (Hartford, 2015). In addition, many companies will require customers to sign non-disclosure agreements to protect their technological advances

from competitors. Major companies in the medical device manufacturing industry include Medtronic Inc., General Electric Company, and St. Jude Medical Inc. (Zhong, 2012). Although KARL STORZ is considered a medium sized company, they are still a leader in quality and versatility.

2.2.3 Product Life Cycle

The Legacy Gastroscope is nearing the end of its product life cycle and its components are becoming more difficult and more costly to acquire. The Legacy Gastroscope was first introduced in the Charlton, MA facility in 2007 and was manufactured until 2012. This product is no longer manufactured or repaired in Europe and is only available for repair in the United States at the Charlton, MA facility. To plan for product obsolescence of the Legacy Gastroscope, it is important to understand the product cycle. The product life cycle describes the four stages a product will undergo throughout its lifespan. The stages of a product's life cycle are determined by the amount of revenue it can generate from the time the product is introduced to the market to the time the product becomes obsolete ("Product Life Cycle," 2010). The four stages of the product life cycle are: research and development, growth, maturity, and decline, which can be seen in Figure 2 ("Product Life Cycle," 2009). Each product life cycle stage has its own flow of materials, information, and distribution characteristics ("Product Life Cycle," n.d.). In Figure 2, the activity of the innovating firm and competitor firms are also charted based on the amount of their sales of each firm versus the time since the product was introduced.

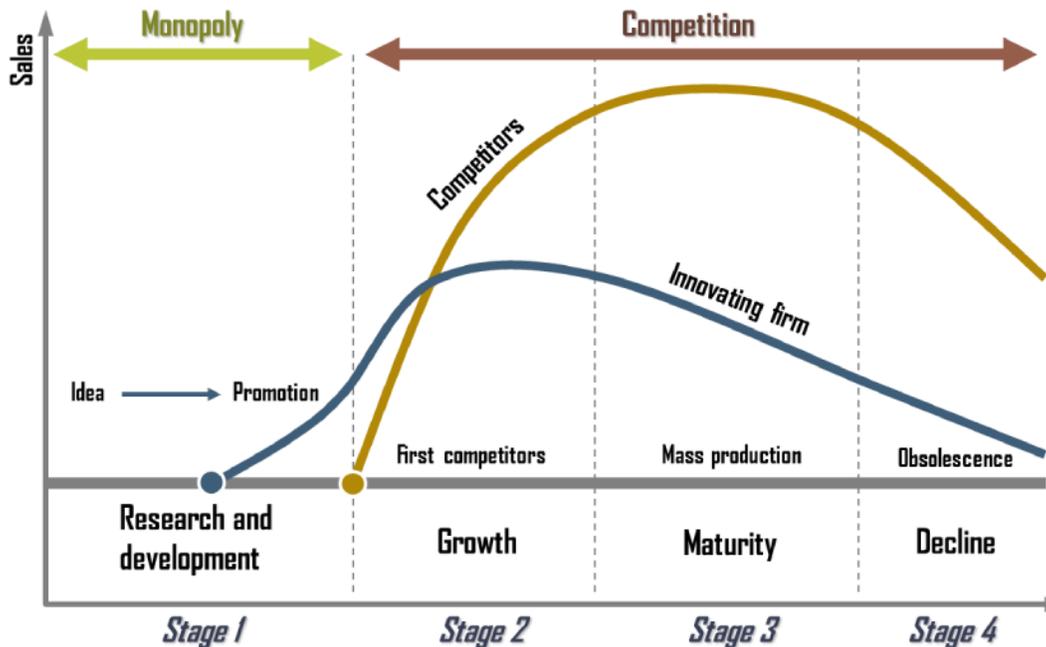


Figure 2: Product Life Cycle (Product Life Cycle, 2010)

In the research and development phase, the product is introduced to the market. The main goal is to increase awareness of the new product and to create customer demand. During stage 1, the newly introduced product is the first of its kind, the price is high, and the distribution is selective and strategic for promoting the product to potential customers (“Product Life Cycle,” 2010).

In stage 2, the product experiences rapid growth in revenue and demand, which increases the distribution and marketing efforts for the product (Product Life Cycle, 2010). During this stage, the price of the product will remain the same and new versions or iterations of the product may be released. At this time more competitors may appear in the market as competitors try to replicate the product and develop their own variations (“Product Life Cycle,” (n.d.).

In stage 3, the maturity phase, the product is widely available to customers and competitors compete with the original manufacturer by offering competitive prices. To stay competitive, companies will increase their marketing efforts to highlight what differentiates their version of the product and decrease the product’s price by reducing production expenses (“Product Life Cycle,” 2009).

The final stage in the product life cycle is the decline phase. During this time, the original company is unable to differentiate themselves from its competitors and they have to decide whether or not they should maintain or discontinue the product (Product Life Cycle, 2009). It is at this time that a product can become obsolete.

Obsolescence occurs when there is a loss in value of a product. In KARL STORZ, new product development is continuously occurring to keep up with new medical technologies and needs, which increases the rate of product obsolescence (Brouillat, 2014). KARL STORZ is currently facing product obsolescence with their Legacy Gastroscope due to new technologies that can replace this specific model. The Legacy Gastroscope has been repaired at the Charlton, MA facility since 2004 and components for this product are becoming harder to acquire. To continue repairing Legacy Gastrosopes, KARL STORZ needs to extend the product's life cycle by delaying obsolescence. To delay product obsolescence, companies develop a plan to monitor the product's life cycle to be aware of market fluctuations or implications with material and resource suppliers (Trenchard, 2005). In his article "Exploit the Product Life Cycle," Theodore Levitt suggests that a company can extend the life cycle of a product by attempting to predict the "slope and duration of a product's life (Levitt, 1965)." This initiative before the product is released can help create an "active" culture within the organization to produce long term marketing and product development goals and strategies. It helps the company determine how different profit-increasing strategies can best work together to optimize results and, most importantly, it helps broaden the company's perspective on the scope and capabilities of their products (Levitt, 1965).

Medical device companies must also focus on process consistency when manufacturing medical devices to expand the lifespan of their products (Duckett & Green, 2008). It is important for companies to design a product with its lifespan and purpose of use in mind in order to utilize materials and resources that will not react to fluctuations in the market. Designs also need to account for suppliers and their ability to produce critical manufacturing components. There is also the possibility of delaying obsolescence by partially redesigning the product when suppliers of materials begin to run low (Trenchard, 2005).

2.2.4 Porter’s Five Forces

Porter’s five forces tool helps to identify KARL STORZ’s competitive power in the GI endoscope market. The strength of each of the forces is helpful to understand KARL STORZ’s advantages and disadvantages. (“Porter’s Five Forces”, n.d.)

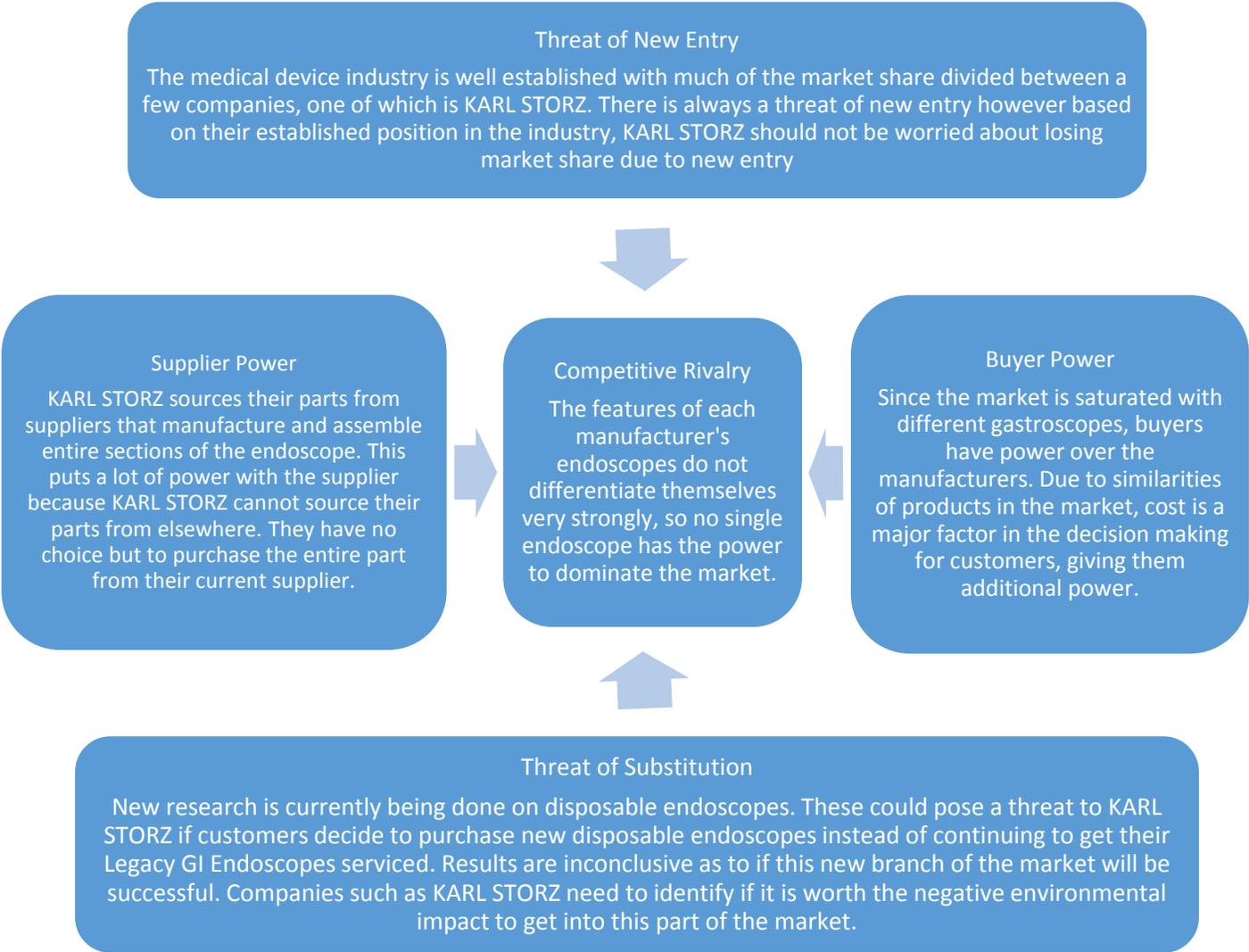


Figure 3: Porter's Five Forces in the Endoscopic Market

2.2.5 Competitor Reclaim Processes'

The production and repair processes of GI endoscopes, like most medical devices, are proprietary to the manufacturing company. Process designs for KARL STORZ competitors are not publicly accessible for this reason. GI endoscopes may appear similar and serve similar functions, but differ in their technologies and designs. Since these processes and designs are proprietary to the original manufacturer, it is difficult for third party vendors to service products as effectively as the original manufacturer. Many product malfunctions that are reported are consistent with third party repairs. Therefore, the original manufacturer has an advantage over the third party vendor, in terms of quality of repair. The original manufacturer can charge high prices for repair services due to their consistency in high-quality repairs.

2.3 Lean Tools for Process Analysis

Lean practices were first formed by the Toyota Motor Corporation in Japan, during the 1930s and 1940s to reduce waste and costs in their processes (Cudney, et al., 2013). Toyota executives looked to the Henry Ford's original method of mass production with the Ford Model T and sought to utilize their method of mass production as a basis for a new, and at the time radical, way of thinking. Henry Ford's model of manufacturing was called flow production which enabled Model T cars to be built on an assembly line; however, this approach did not take into account variability in the products. Toyota was able to take his approach and develop the Toyota Production System, which addressed both mass production and product variability ("A Brief History," n.d.). This new way of "lean thinking" focused on the production flow throughout the whole process as opposed to analyzing segments of the process at a time. Today, Toyota remains as the leading lean experts and their continued success has helped bring about a greater push for lean thinking ("Principles of Lean," n.d.). Lean thinking and tools are no longer being applied to just manufacturing but also logistics, distribution, services, retail, and healthcare. In a medical device company, lean practices can be used to make the process of introducing new technologies and devices into the market faster and more efficient. By utilizing lean tools, medical device companies can make their development and manufacturing processes more efficient. In this project, lean tools will be utilized to remove waste from the endoscope repair process at the Charlton, MA facility.

2.3.1 Process Mapping

A process map is a visual diagram of a process to show the cross-functional relationship between organizational units (Kalman, 2002). Businesses use process mapping to define and document their core processes in order to standardize their resource consumption and reduce variability in their output. While each organizational unit may have a specific procedure for operating, a process map is the connector between the many organizational units. For KARL STORZ, an organizational unit is represented as sub-processes including evaluation, disassembly, assembly, and more. Businesses can more easily identify unnecessary steps in their processes when each step is shown in a visual format. Process mapping can help reduce cycle time, or the total time spent in one iteration of a process, by eliminating unnecessary steps. Also, mapping the material and information flow between organization units can reduce delay times and streamline this transfer between sub-processes (Kalman, 2002).

KARL STORZ has detailed procedures for each station in the repair process of endoscopes; however, a standard work process map that links these separate procedures together has not been developed in many years. A process map can improve the efficiency and effectiveness of the repair process by understanding and analyzing the cross-functional relationships between organizational units.

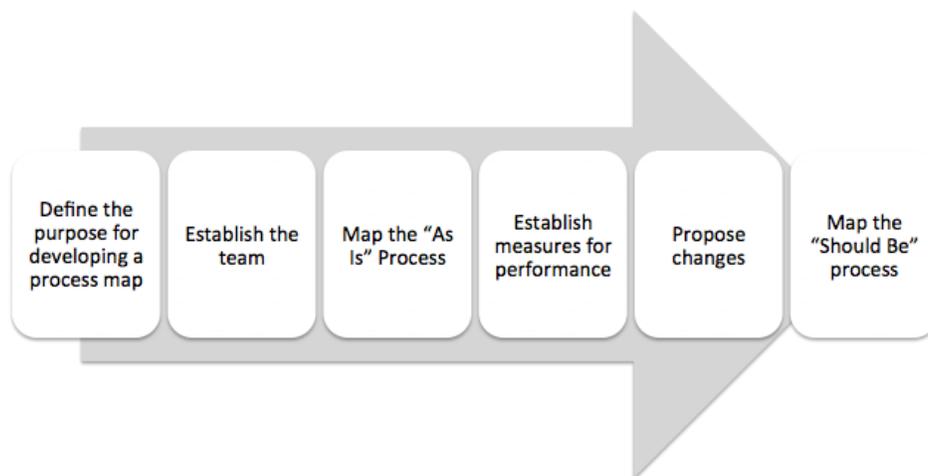


Figure 4: Steps in Process Mapping

The procedure for developing a process map is defined in Figure 3. The first step is to define the purpose for developing a process map. This helps narrow the project scope so efforts can be

focused on the most critical sections of the repair process. The next step is to establish the team who has the most interest, knowledge, and involvement in the process that is going to be mapped. The team should then use techniques such as shadowing and videotaping to map the “as is” process. This “as is” process map will serve as a base for any future process improvements. The team will also have to establish measures for performance which will help the team determine the successfulness of any process improvement initiatives. The process mapping team should then identify opportunities for improvement and propose changes to the process. Finally the team will map the “should be” process which is a visual representation of the process initiatives that should be taken. The “as is” process map and the “should be” process map will serve as snapshots of the before and after process.

2.4 Risk Management

Before a repaired endoscope is returned to the customer, it goes through a quality assurance examination to identify any defective components or functionalities. For this project, any new designs to the current repair process will undergo a risk assessment at KARL STORZ before implementation. Risk assessments will consider how these changes will affect the routine tasks of each employee and the potential risk implications that can arise from both a quality and a legal standpoint. Due to these factors, risk management is a high priority at KARL STORZ. Risk assessment is conducted by a committee of department supervisors at the KARL STORZ facility.

2.4.1 Regulations and Policy

The Food and Drug Administration (FDA) is the leading regulatory organization in the United States. The FDA cautions patients who encounter endoscopes. In a safety communication issued in November of 2009, the FDA reminded endoscope users of the infection risks associated with not cleaning and sterilizing endoscopes properly after each use. The safety communication notice also included reminders for manufacturers of their responsibilities regarding user processing. Endoscope manufacturers are required to provide detailed and updated materials to instruct users on how to properly process (clean and disinfect) endoscopes. The FDA also has a Manufacturer and User Facility Device Experience (MAUDE) database that contains Medical Device Reports (MDRs) submitted to the FDA (“Effective Reprocessing...,” 2015). The FDA uses these reports to monitor all devices including GI endoscopes. They can run queries on the

database to find incidents relating to GI endoscopes, and more specifically whether the issue stemmed from insufficient reprocessing (cleaning and sterilizing after use) or if the issue could have been prevented by the manufacturer.

When an endoscope needs to be repaired, a customer can either send their product to the original manufacturer or to an independent service organization (ISO) (Calderwood, et al., 2014). Endoscopes are considered to be Class 2 Devices, because they are used on human patients, which require the device to follow strict quality regulations as set by the FDA. If the endoscope is returned to the original manufacturer for repair, then the FDA mandates that the endoscope is repaired back to the original manufacturing specifications. Additionally, the repair process must comply with FDA audits and Medical Device Reporting (MDR) requirements. ISOs are classified by the FDA as refurbishing and reconditioning organizations; therefore they do not fall under FDA jurisdiction. ISOs can voluntarily follow the repair regulations set by the FDA; however, they cannot register with the FDA. Customers may choose ISOs as opposed to the original manufacturer because of its low costs and easy convenience; however it is important for customers to consider the quality of the repair. Many repairs performed at ISOs come from reverse engineering, or unauthorized acquisition of manufacturers' manuals, which leads to a lower quality repair. If there are legal grounds for ISO audits, the FDA may do so; however, these are the only formal interactions between the FDA and ISOs.

2.4.2 FDA Warning Letter

FDA warning letters are sent to manufacturers when they are not complying with FDA rules and regulations. An FDA warning letter will identify the rule or regulation the manufacturer is violating, request specific correct actions, and suggest a timeline for which the company should fix the problem. After a warning letter is sent, it is the organization's responsibility to perform the necessary changes to their internal processes and stand work. The FDA will follow up with the company to ensure the proper changes are made by the preset deadline.

2.4.3 Superbug

The FDA seeks to reduce the risk of infections and patient to patient cross-contaminations by setting strict rules and regulations on the manufacturers. Ultimately it is the responsibility of endoscope manufacturers to create instructions on how to properly clean and sterilize their endoscopes before each use. Hospitals can follow the cleaning process designed by the manufacturers; however, there is still a risk that the endoscope is not fully cleaned and/or sterilized due to user error. In the case of the “LA superbug”, the Los Angeles Ronald Reagan Medical Center followed the manufacturer's guidelines when cleaning an endoscope; however, they soon discovered that this process was not properly sterilizing their endoscopes. The small crevices of the endoscope were not easily accessible by the cleaning brushes and subsequently the remaining debris was unable to be removed. This caused cross-contamination of the Carbapenem-Resistant Enterobacteriaceae (CRE) superbug between patients. A superbug is a drug resistant strain of bacteria, and is therefore extremely difficult to treat. Unfortunately for the Los Angeles Ronald Reagan Medical Center, the superbug infected nine patients, two of which died from the virus.

When the CRE outbreak was found, the FDA ordered endoscope manufacturers to conduct market research and determine the effectiveness of their cleaning procedures on their endoscopes (U.S. FDA, a, 2015). The FDA’s most recent announcement states that manufacturers need to keep the challenges of reprocessing, or cleaning the endoscope before each procedure, in mind during the initial design phases of new endoscopes (U.S. FDA, b, 2015). Additionally, manufacturers must test their endoscopes to validate if they can be properly cleaned and sterilized using the instructions provided to the customer. Once data on the cleaning process is gathered, companies must submit their findings to the FDA to gain approval and end investigations.

2.4.4 Post Market Complications

Original manufacturers and third party repair vendors are always looking to manage risk from repaired GI endoscopes, as like all other repaired medical devices. A defective endoscope can

cause many problems such as the cross-contamination as described in the spread of the Superbug virus. These adverse events compromise the safety of the patients and leave the hospital and manufacturer liable. As described earlier, FDA regulations require original manufacturers to report any adverse events that are a result of their products, but third party vendors do not fall under those same regulations. Also, the process for reporting MDRs is a voluntary system, and it is up to the manufacturer to ensure that an MDR is submitted for all cases. Since only original manufacturers are required to submit an MDR and the original manufacturer must voluntarily submit the MDR, this can result in the underreporting of many adverse events for all medical device products. The impact of underreporting is difficult to quantify and can lead to the unrecognition of common defects in a particular product. Although there is no evidence for a defective product to repair, this could be due to failure to report an adverse event. Thus, this project must examine all reported adverse events related to endoscopes and ensure that any changes to the repair process at KARL STORZ would not result in the similar malfunctioning of their Legacy Gastroscope.

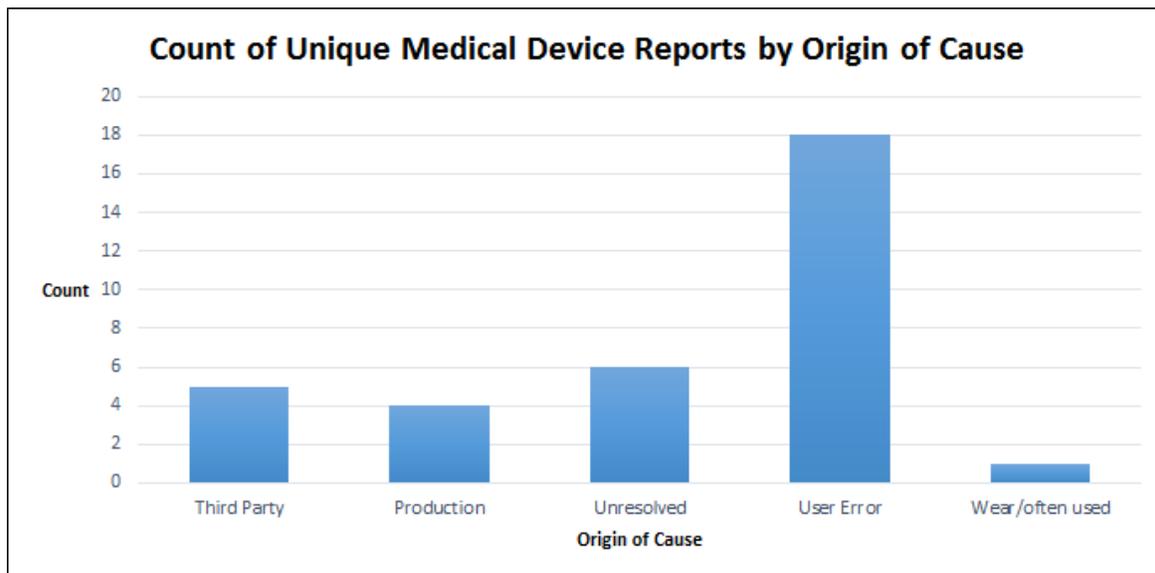


Figure 5: Origin of Causes based on 34 unique Medical Device Reports (MDRs) for KARL STORZ

2.4.5 Patents

KARL STORZ has over 400 patents on different medical imaging devices (USPTO). KARL STORZ has succeeded in their previous efforts to enforce patent designs for their endoscopes products such as their past lawsuit with FemSuite (Pierson, 2008). KARL STORZ sued FemSuite for patent infringement on their patent titled “Endoscope having provision for

repositioning a video sensor to a location which does not provide the same cross-sectional viewed relationship with the distal end.” KARL STORZ won the case, however lawsuits are no longer an option for their Legacy Gastroscope. Every patent that KARL STORZ owns for the Legacy Gastroscope date back to the early 1990’s and have expired by the fourteen to twenty year threshold allowed for patents. Therefore, the production of Legacy Gastroscope can be replicated by competitors with little to no repercussions. This is a risk with the attempts to increase the lifespan of this Legacy Gastroscope as it allows third party vendors to claim the rights for production, and reduce the customer base for KARL STORZ.

2.4.6 Process Failure Mode Effect Analysis

Process failure mode effects analysis (PFMEA) are used to identify potential failures in a process and how they will affect the final outcome (Johnson & Kahn, 2003). PFMEA also helps identify the specific actions that can be taken to commandeer the failures. KARL STORZ currently uses this type of analysis for their processes. It is a preventative measure used before finalizing new designs and processes (Shridhar, 2010). This method of assessing risk has been around since 1940, but it did not become commonly used until the automotive industry adapted it to manufacturing in 1970. As a manufacturer of medical devices KARL STORZ is held responsible for safety problems that arise with their endoscopes. PFMEA helps to address and solve any issues that can affect the customer before the endoscope is manufactured. A common way of creating a PFMEA is to develop a risk matrix. Risk levels are assigned to each step in the process. These matrixes are sometimes color coded with each color associated to a certain level of risk. Determinants of risk vary based on the company, the product, and what is valued.

2.5 Case Studies

To better understand lean processes in medical device companies, we researched two companies: Tefen Management Consulting and Phase 2 Medical Devices for lessons learned on how to make processes more efficient and streamlined. Many medical device companies viewed the lean philosophy as a way to ‘cut corners’ and have been reluctant to adapt them because of the high regulations that accompany the medical device manufacturing industry (Brown, et al., 2008.) As

this industry continues to become more and more competitive, medical device industries have been more willing to accept lean as a tool to stay competitive.

2.5.1 Tefen Management Consulting

In 2013 Tefen, a management consulting firm conducted a diagnostic survey across a world leading medical device company to assess their entire supply chain (Aharonson, 2014). The initial assessment revealed the following:

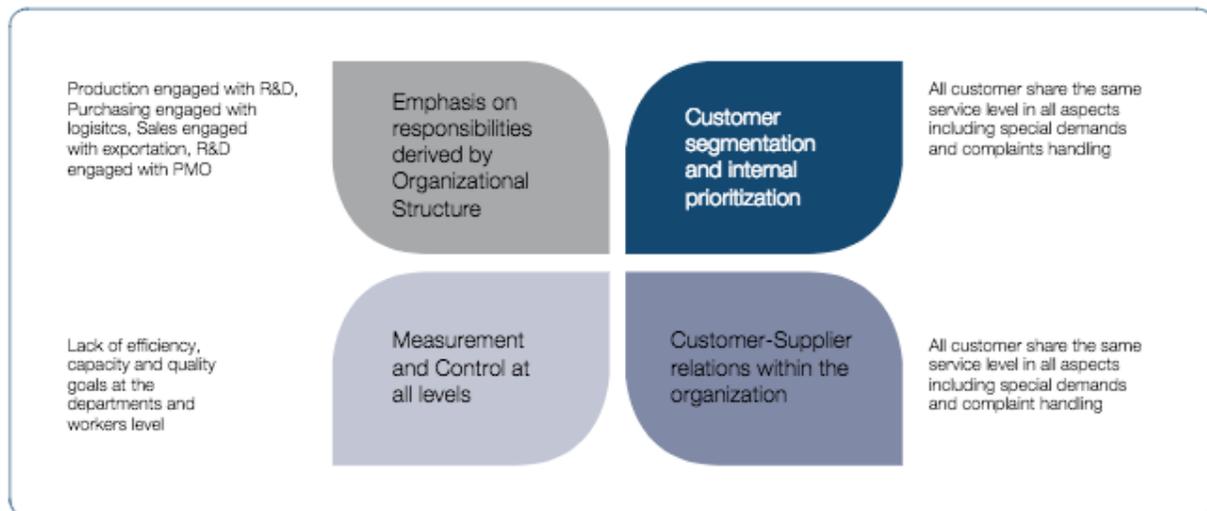


Figure 6: Common Issues Found by Tefen (Aharonson, 2014)

In Figure 5 the main problems Tefen identified are: lack of efficiency and customer specialization in processes. In addition to the initial assessment, Tefen also performed a company audit based off of lean principles, such as leadership, standard work, problem solving, quick change overtime, and visual management (Aharonson, 2014). An analysis on their strategic sourcing and management efforts indicated that most of their resources came from only a few suppliers which greatly increase their dependency on that supplier. In addition, Tefen found that all the products were being produced the same way; however, 10% of the products make up 90% of the company's profits. The 10% of the products, who are ordered more frequently and with a higher demand, were given the same amount of space and resources as products with low frequency and demand, causing an imbalance of processes.

Based off their initial findings, Tefen developed an implementation plan to “lean out” the company (Aharonson, 2014). The implementation plan consisted of six objectives: modify schedule of processes to drive operations, eliminate waste in supply chain to maximize income and profits, create effective work processes to meet business goals, modify organizational structure to allow for flexibility, make continuous improvement goals, and create a lean culture in the workplace. To meet these objectives Tefen was able to change the layout of the production lines and utilize distributors and diffusers to manage and transport products in all stages of the production process which decreased cycle times. They were also able to reduce the amount of inventory on stock as well as the labor costs. Finally, Tefen was able to create a better management structure by utilizing visual management tools to help monitor the everyday production routines. The main lessons learned from Tefen that can be applied to our project are:

- Obtain management involvement in creation of a new process
- Develop employee support during the early implementation phases
- Implement pilot program to identify areas of improvement
- Create specific implementation guidelines for future use

2.5.2 Phase 2 Medical Manufacturing

Phase 2 Medical Manufacturing is a medical device company that has been using lean tools to increase their profit margins after offshore competitors threatened the company’s success (Marchwinski, 2014). Phase 2 problems began when their main customer, Medtronic Advanced Energy (MAE), sought overseas medical device manufacturing companies to produce disposable medical devices. This switch in supplier would have had a severely negative impact on Phase 2. MAE already utilized lean within its operations and wanted a supplier to follow the same principles. In order to maintain business relations and contracts with MAE, Phase 2 decided to adapt the lean way of thinking. Phase 2 eventually met the global price of single use medical devices and maintained MAE as a customer. The decrease in price encouraged Phase 2 to focus on changing the organizational structure and adapt a lean way of thinking to reduce waste in their processes and to maintain operations with the newly reduced price of products.

The process of making Phase 2 leaner was a joint task between MAE operation directors and the Phase 2 continuous improvement team (Marchwinski, 2014). This team developed a two part

improvement strategy that focused on decreasing the cost of materials and developing a lean cell operating system. To decrease the costs of materials, the team worked with the suppliers to reduce the cost of parts, then, the team worked on the production floor to find ways to save and minimize part replacements.

Phase 2's most valued improvement was the development of a lean cell operating system that was a u-shaped single piece flow production process which could balance three different takt times and employee levels based on the demand of products (Marchwinski, 2014.) This change in layout helped Phase 2 improve productivity by 33% and reduce the cycle time by two days. The elimination of kitting was another critical change for Phase 2 which reduced non-value added labor and resources. To achieve this, Phase 2 combined a new on-site warehouse for supplies with a Kanban inventory system to alleviate the costs of restocking inventory. Phase 2 also adopted the kamishibai tool, which is a Japanese tool for visual storytelling. Phase 2 applied the kamishibai tool to standard work which made managers more accountable for maintaining visual control over their processes. Employees would utilize kamishibai cue cards to observe and evaluate different operations each hour. A kamishibai board was utilized to check main operation activities hourly to observe whether the activity was normal, abnormal, or abnormal with correction action occurring. The main lessons learned from Phase 2 Medical Manufacturing that can be applied to this project are:

- Customers are attracted to suppliers with lean operations.
- GI endoscopes may be in danger of being replaced by disposable endoscope devices. Reducing repair costs will alleviate a financial burden that could accommodate price change for GI endoscopes.
- The use of visual management tools can reduce waste and will give employees visual control over their processes.
- Utilizing a kanban system for inventory management can reduce the cost of inventory.

Chapter 3: Methodology

The overall goals of this project was to reduce waste within the endoscope repair process, to develop a plan of action for repairing and reusing components of the Legacy Gastroscope, and to develop a product strategy for the Legacy Gastroscope. To achieve these goals, we mapped out our goals, objectives, and methods in Figure 6. The overall project goal is shown at the top while the objectives are shown below in the left column. Each project objective is then broken down into steps taken for achieving that objective.

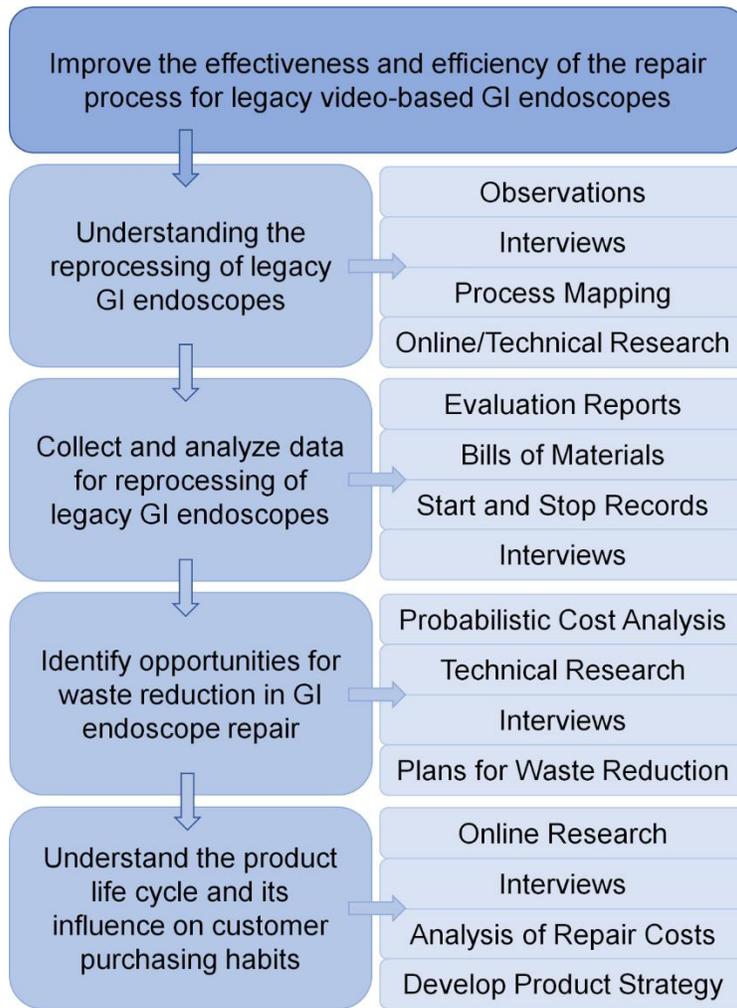


Figure 7: Project Goal, Objective, and Methods Overview

3.1 Objective 1: Understanding the Reprocessing of Legacy Gastroscope

Understanding the current repair process was essential before analyzing data related to the Legacy Gastroscope repair. To understand the repair process, we conducted process mapping to conceptualize the flow of material and information using the steps outlined in Section 2.3.1. To effectively map the repair process, we followed a Legacy Gastroscope through each step in the repair process to observe the procedure at each station and the material and information flow between stations. The process starts when the Legacy Gastroscope arrives at the warehouse's receiving station and ends when the Legacy Gastroscope departs at the warehouse's shipping station.

We conducted two rounds of observations: high-level observations and low-level observations. During the high-level observations, we followed a Legacy Gastroscope through each step in the repair process, accompanied by a KARL STORZ floor manager who described the standard procedure at each station and the transfer procedure between stations. The goal of the high-level observations was to familiarize ourselves with the repair process at KARL STORZ and to quickly identify critical sub processes related to our project. For the low-level observations, we observed the critical sub process, which included observations of employees performing specific procedures. From observations and discussions, we developed an "as is" map of the repair process. At the time, KARL STORZ did not have a standard process map to show this cross-functional relationships between stations; therefore, the goal for developing a process map was to understand the cross-functional relationships between each station in the repair process as well as provide a supporting resource to floor managers. To avoid seizing excessive working time from repair technicians to develop this process map, we developed a preliminary process map, and then performed multiple revisions as needed after reviewing each iteration with a floor manager. The process map also helped us better conceptualize the material flow and information flow and identify any areas of waste.

In addition, we performed technical research that helped us understand how the internal mechanism of the Legacy Gastroscope functions which helped us conceptualize the performance specifications for each of its components. This technical research took the form of online research through KARL STORZ's online product brochures, review of standard work

documentation at KARL STORZ, and direct examination of the Legacy Gastroscope at KARL STORZ. The standard work documentation outlined the procedures an employee follows at each station in the Legacy Gastroscope repair process. Stations included evaluation, data entry, disassembly, and more. While we developed a process map to understand the cross-functional relationships between stations, the goal of reviewing standard work procedural documents was to understand the specific steps performed within each station. Lastly, the Legacy Gastroscope samples for direct examination were damaged endoscope components that were intended to be discarded at the disassembly station. These discarded components are typically disposed of and are not reused in any of the KARL STORZ products. We examined the internal mechanism of the discarded endoscope components as well as their defects.

3.2 Objective 2: Collect and Analyze Data for Repairing Legacy Gastroscopes

We performed and reviewed the following steps and documents, respectively, to collect and analyze data for Legacy Gastroscope repair:

1. Evaluation Reports
2. Bill of Material (BOM) Orders
3. Start and Stop Records for Endoscope Repair
4. Interviews with KARL STORZ personnel

3.2.1 Evaluation Reports

The goal for reviewing evaluation reports was to identify the most common defects, determine how repair levels are decided and how components are discarded during the repair process. We reviewed a sample of 94 evaluation reports for the Legacy Gastroscope. The evaluation dates, when an Evaluator first assessed the condition of the endoscope, span from December 16th, 2014 to December 16th, 2015. These evaluations were contained electronically, which made it efficient to perform simple data analytics, as opposed to sorting through paper copies of evaluation reports. We first gained an understanding of the trends related to the number of cycles completed before the endoscope was returned for evaluation, the assigned repair levels, and the primary defects and their locations. A cycle is considered as one round of procedural use followed by sterilization of the endoscope in the hospitals. Since each repair level is directly linked to the cost

of repair, we calculated how much customers' were spending on Legacy Gastroscope repair and made projects for future years. Reviewing the primary defects and locations acted as a primitive root cause analysis to understand why these endoscopes were being returned for evaluation and most times repair. This summary report can be found in the Findings/Results section of this report.

3.2.2 Bill of Materials (BOM) Orders

The goal of reviewing BOM orders was to identify a standard list of components that were consistently being repaired or replaced based on the endoscope evaluation. The factors that affected which components were consumed were mostly the specific defect and its location. We reviewed BOM orders for Legacy Gastroscope repairs that were evaluated in the year 2015. These BOM orders were downloaded from the in-house data storage system in an excel format. For ease of analyzing, we used Microsoft Access to generate different reports and queries to sort through the data to better understand the relationship between the components that were being consumed, or BOM orders, and their original evaluation reports. Using this sample data we were able to approximate an average repair cost per repair level. Our assumptions are that this BOM sample sizes an appropriate representation of the BOM population size. In future research, a larger sample of BOM orders must be used to derive more accurate average repair levels.

3.2.2 Start and Stop Records for Endoscope Repair

The goal for reviewing the Start and Stop Records was to identify opportunities for waste reduction in the endoscope repair process. We reviewed the Start and Stop Records because they contain information about multiple endoscopes repair processes, not just the Legacy Gastroscope. This document is a living document that is updated after each endoscope repair by an employee. We obtained this document from a floor manager who first explained the data fields and other particulars of the document before sending us the file. To review this document, we searched for data fields that reflect waste in the repair process. The information contained in the document was mostly related to wait times and defects. The wait times represented the total time to complete each step and the time that an endoscope will stay in an employee's queue before being processed. The defects represented inaccurate labeling of repair levels during the

evaluation. Instances occurred where the repair level was modified as more damages were found at the repair station.

3.2.4 Interviews with KARL STORZ Personnel

The goal for conducting interviews was to gain a deeper understanding of the nuances with each task performed throughout these critical sub processes. From interviewing key employees, we also gathered information about common problems or delays in their day-to-day responsibilities that may not be reflected in any report or documentation that we've reviewed. The guidelines and questions for KARL STORZ interviews can be found in Appendix A - Appendix C.

3.3 Objective 3: Identify Opportunities for Waste Reduction in Legacy Gastroscope Repair

We combined the data collected in Objective 2 with our understanding of the current repair process to highlight opportunities for waste reduction for Legacy Gastroscope repairs. We reviewed the summary report of components consumed in Legacy Gastroscope repair from Objective 2 and investigated opportunities for either repairing the components for reuse, or redefining component specifications. The goal of both methods was to salvage a component, and thereby reducing and/or eliminating the repair cost of having to discard that component and replace it with a new component. It is important to note, however, that the components that would be most valuable to salvage are those with the highest financial impact, and are not necessarily the components that are consumed most often. Therefore, we identified the critical components based on their financial impact, or the number of consumed components multiplied by the standard component cost.

In order to find this financial impact, we conducted a probabilistic cost analysis. The purpose of this cost analysis was to find a cost per part, per repair based on how often that part was being replaced and how much it costs to replace that part each time. We felt that a probabilistic cost analysis was the best way to initially determine which parts to further look into reclaiming, accounting for both how often parts were getting replaced as well as how expensive each part is. We used initial data given to us as examples of what each repair level typically looked like

and what costs to expect from each type of repair and assumed it would be an accurate representation of the entire data set.

Once we developed a list of components to narrow our scope on, we reviewed this list of components with floor managers to confirm the scope of our project. We presumed that the floor managers had an exceptional understanding of the particulars of each component and the potential requirements for salvaging them. The goal was to eliminate any component from the scope of our project that would be impractical to salvage due to extenuating circumstances. For example, a particular component could be responsible for the highest cost impact for Legacy Gastroscope repairs, but due to federal laws or severe risk to the patient, the component can be eliminated from our project scope. Interviewing floor managers was a time-efficient method for accessing this knowledge.

Then, we investigated the opportunities for salvaging each critical component and/or redefining component specifications. Initially we researched the standard work procedural documents and all other products to find each critical component and any other process or product. If the critical component was found, then this would have given us insight into how this issue was managed elsewhere in KARL STORZ. Any results were then tailored to the context of Legacy Gastroscope repair.

In addition to these critical components, we investigated other opportunities for waste reduction in the repair process. From our process mapping in Objective 1 and informal interviews with floor managers, repair technicians, and evaluators, we identified other forms of waste production in the repair process. The goal was to promote a lean environment at KARL STORZ by not only focusing the material waste, or the critical components, but process waste as well. For our project, we will define process waste that which results in unnecessary time and/or money being consumed in any given process.

Next, we investigated any internal projects that were being conducted that could give us valuable insight into each critical component process waste. We identified these internal projects through discussions with floor managers as we assumed they are exceptionally knowledgeable about the day-to-day operations. Once these projects were identified, the floors managers gave us a contact

representative in each project that would be most relevant to our project scope. Through discussions with these contact representatives, we gained valuable insight and developed a plan of action for each critical component and process waste.

Since KARL STORZ has already adopted 5S and visual management techniques to organize and structure their processes, any standard work or documentation recommended by us must adhere to the visual management policy that is already established. In addition, it is important to highlight improvement opportunities that are not Legacy Gastroscope. Although this project's focus is on the Legacy Gastrosopes, the lessons obtained can be used as a baseline for other types of endoscopes. General improvements that are not specific to the Legacy Gastroscope will be communicated in the guideline for best practices.

3.4 Objective 4: Understand the Product Life Cycle and its Influence on Customer Purchasing Habits

We used external sources to better understand how the product life cycle of endoscopes can have an effect on Legacy Gastroscope at KARL STORZ. For our research, we used primarily two sources: online research and interviews with industry professionals. Our online research consisted of news reports and online articles that contained information on the technology trends and market behaviors of for endoscopes. One alternative we found to typical multi-use endoscopes, that are up and coming in the medical device industry are single use endoscopes. We researched online, as well as interviewed industry professionals, to understand the advantages and disadvantages of other technologies like the disposable endoscope, as well as its impact on multiple-use technologies like the Legacy Gastroscope at KARL STORZ.

In addition, we interviewed industry professionals to better understand the hospital's decision making process for purchasing medical devices, and more specifically endoscopes. The industry professionals, in this context, refers to the personnel (surgeons, nurses, supervisors, accountants) who influence the decisions on which medical devices to purchase and use within the hospital. To obtain this information, we first utilized existing personal contacts that we had in many hospitals and medical device manufacturers. Our existing contacts connected us with coworkers and/or colleagues who were involved in either the sales or marketing for medical device

manufacturers or the hospital's personnel that was defined above. The list of questions asked can be found in Appendix C.

Combined with internal data regarding endoscope repair and the external data related to product sales and technology trends, we developed a product strategy for the Legacy Gastroscope at KARL STORZ. The goal of the product strategy document was to provide KARL STORZ a concise action plan for the Legacy Gastroscope, as well as provide insight into the hospital's perspective. Knowing hospitals perspective allowed us to draw connections that could be useful for other KARL STORZ products when they reach this stage in the product life cycle. The full product strategy can be found in Appendix H.

Chapter 4: Procedures

4.1 Interviews for Process Mapping

In order to develop the process map of the repair process, we gathered data and information by interviewing floor managers and repair technicians, as well as observing the various stations in the process. Our MQP team met with various KARL STORZ employees to visit each section in the repair process to gain a better understanding of the repair process. During these meetings, notes were recorded. Most conversations included product/process knowledge and information specific to KARL STORZ and will remain confidential.

4.1.1 Interviews with Floor Managers

During our project site visits our sponsors brought us onto the manufacturing floor to observe the evaluation and disassembly stations of the repair process. During this time they were also able to put us in contact with the floor managers. The floor managers took us around the manufacturing floor and described what was occurring at each station. The questions and protocol for the floor manager interviews and observations can be found in Appendix A.

4.1.2 Interviews with Repair Technicians

During our interactions with our project sponsor and floor managers were put in contact with different repair technicians. Repair technicians have direct contact with the Legacy Gastroscope and use their own product knowledge for evaluation, teardown, and repair. The questions and protocol for the repair technicians can be found in Appendix B.

4.2 Interviews with Industry Professionals

To set up interview times with industry professionals we first individually reached out to personal connections within hospitals and medical device companies. From our personal connections we were able to be put in contact with the correct people to answer questions regarding the product life cycle of an endoscope and the purchasing habits of endoscope customers. We also were able to find contacts by reaching out to medical device manufacturers similar to KARL STORZ. The questions and protocol for the interviews with industry professionals can be found in Appendix C.

4.3 Probabilistic Cost Analysis

We initially conducted a probabilistic cost analysis to determine which parts and components of the Legacy Gastroscope were worth examining. The probabilistic cost analysis took into account how expensive a part or component cost each time a repair occurred and how often a part or component needed to be repaired. Due to time constraints, we first looked at a sample size of twenty repair bills of materials at varying repair levels and found how often each part or component was repaired for each repair level. From there we took the actual data of how often each repair level was occurring. Assuming the data shown in our sample of twenty bills of materials was an accurate representation of the total data, we calculated how often each part would get replaced based on the occurrence at each repair level. We took the frequency of occurrence and the cost per repair to find our probabilistic cost per repair for each part. For example, issues with the 'Housing with Control Unit' occurred twice in RM repairs, three times in RH repairs and four times in RHC repairs. We then calculated how often this part would occur overall by taking how often these repair levels occurred in our sample size and how often they actually occurred in a year. From this we found that this part would be involved in repair roughly 9 times in RM repairs, 11 times in RH repairs and 59 times in RHC repairs. We then took these 'actual occurrences' and the total number of repairs to find the probability this part would get repaired. The 'Housing with Control Unit', for example, has a 61% probability of occurring during a repair. Our final probabilistic cost values represented how much each specific part costs each repair whether it is being replaced or not that specific time based on its cost and probability of occurring. We did this to narrow our scope of parts to look into while factoring in multiple criteria (cost and frequency) in the process.

Chapter 5: Results and Analysis

The following section consists of the results and analysis of the data collection during this MQP.

5.1 Repair Process Mapping

The Legacy Gastroscope repair process is shown in the following process map, Figure 7. This process map resembles the in-house process steps for video-based endoscopes.

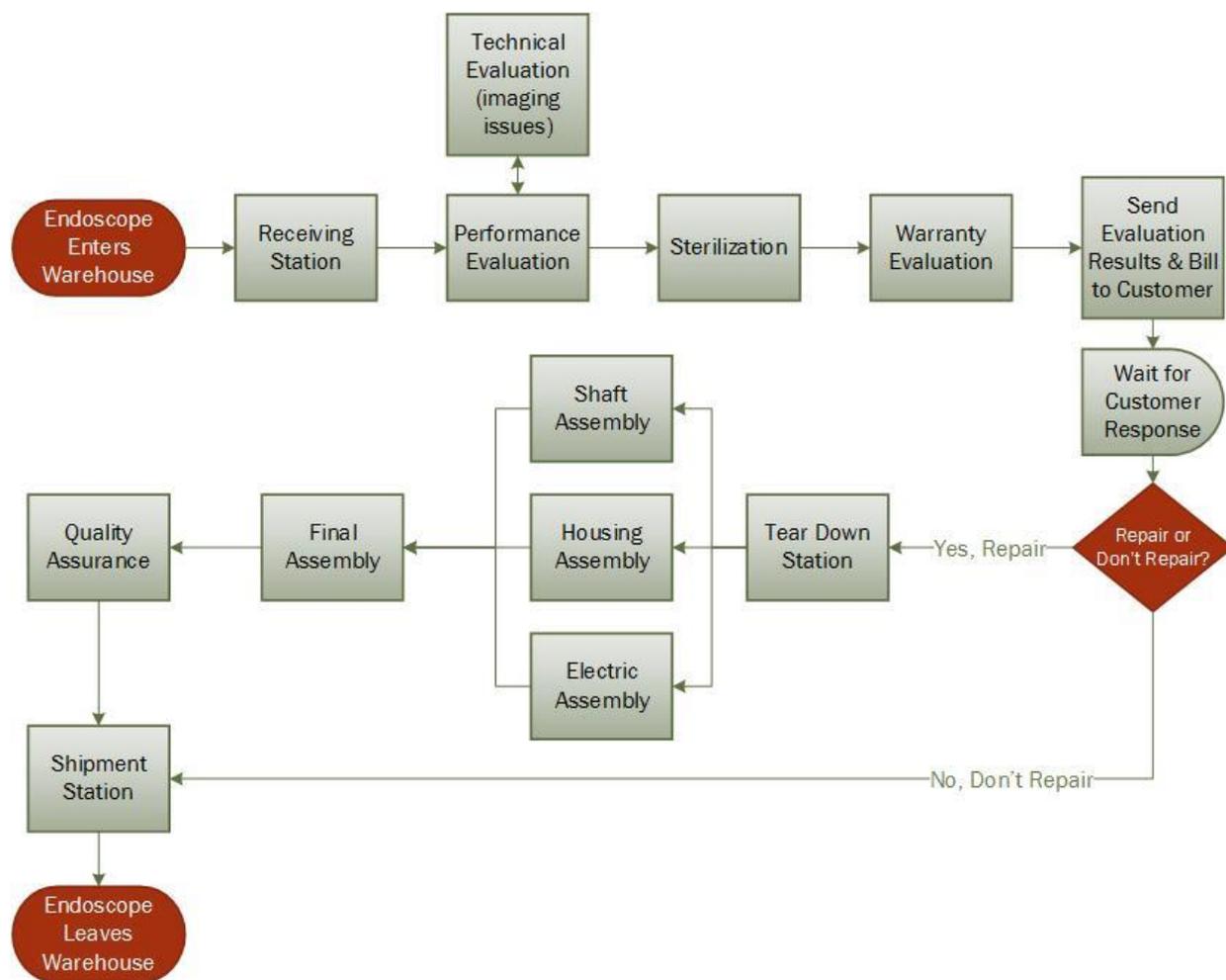


Figure 8: Current repair process map for returned Legacy Gastroscope at KARL STORZ's Charlton, MA facility.

When endoscopes are sent back to KARL STORZ for repair, they are first processed by the receiving station. During the receiving phase the endoscopes are unpackaged and stored on a hanger while an employee confirms that the serial number on each endoscope matches their

respective shipping forms. Once the endoscopes are checked, they are put into a queuing system until each endoscope is ready to be examined by a KARL STORZ evaluator.

At the evaluation station, a series of performance tests are conducted on the endoscope. For example, the evaluator will check for leaks in the tubing and housing units that would affect the overall pressure inside the endoscope. The evaluator will also check the control mechanism and the video system to identify any discrepancies in their performances. With the addition of more performance tests, the evaluation process can take up to 3 hours depending on the severity of its condition. Two forms are then completed:

1. Form for customer use - a summary of the evaluation results along with pictures of critical areas
2. Form for in-house use - a detailed evaluation report that feeds the Start and Stop Records

These forms describe the condition of the endoscope and the components or functions that failed, along with pictures of critical areas.

Next, for all endoscopes that require a repair, an internal committee assesses each endoscope's evaluation results to determine if it is covered under warranty. Once a warranty decision is made, the evaluation results and the warranty decision are communicated to the customer. The total repair cost, based on the repair level assigned at evaluation, is sent to the customer as well. It is the customer's decision to continue with the repair process or not. If the customer decides not to have their endoscope repaired through KARL STORZ, they may have their endoscope sterilized and sent back to them. However, the customer can elect to continue with the in-house repair process.

The next step for the in-house repair process is the disassembly station. Here an employee will disassemble the endoscope to remove the damaged components based on the evaluation report. The evaluation report describes the tests that failed, but not the components that must be discarded. If a component is revealed to be damaged and went unnoticed during the evaluation phase, the component must be discarded and the repair level may be modified.

Once the damaged components are removed, the endoscope is transferred to the necessary assembly stations (shaft, housing, electric), where the endoscope is reassembled with new components to replace the damaged components. Once the endoscope is fully assembled, the endoscope is checked for quality assurance purposes then shipped back to the customer from the shipping station.

5.2 Modified Repair Levels after Customer Billing

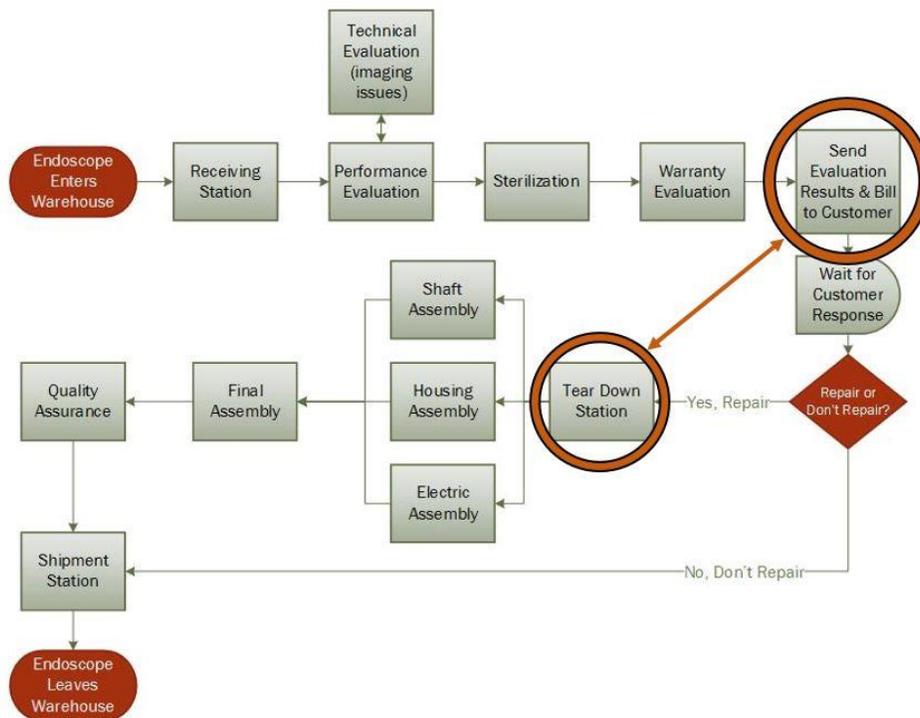


Figure 9: Current repair process map for returned Legacy Gastroscope, highlighting the location where customers are billed and where repair levels are occasionally modified.

From our review of the Start and Stop Records and interviews with floor managers at KARL STORZ, we identified that repair levels were occasionally modified during the repair of an endoscope. In other words, evaluators would assess the endoscope and determine its repair level, the customer would then be billed for that repair level, and then additional damages on the endoscope would be revealed at the disassembly station that went previously unnoticed due to

existing evaluation limitations. Figure 8 shows on the process map where the disconnect in the stations is occurring. These additional damages resulted in more components that were discarded than anticipated and the customer was under-billed for their endoscope repair, while KARL STORZ assumed the additional costs. Based on time constraints for this project, we did not investigate the exact, additional costs that KARL STORZ acquired for Legacy Gastroscope; however, a summary of all product types and the number of cases in which the repair level has changed can be found in Appendix D. The number of modified repair levels for the Legacy Gastroscope is shown in Table 1.

Table 1: Number of modified repair levels by Legacy Gastroscope product description

Product Description	# of Modified Repair Levels
VIDEO GASTROSCOPE COLOR SYSTEM NTSC	7
9.7 VIDEO GASTROSCOPE COLOR SYSTEM NTSC	3

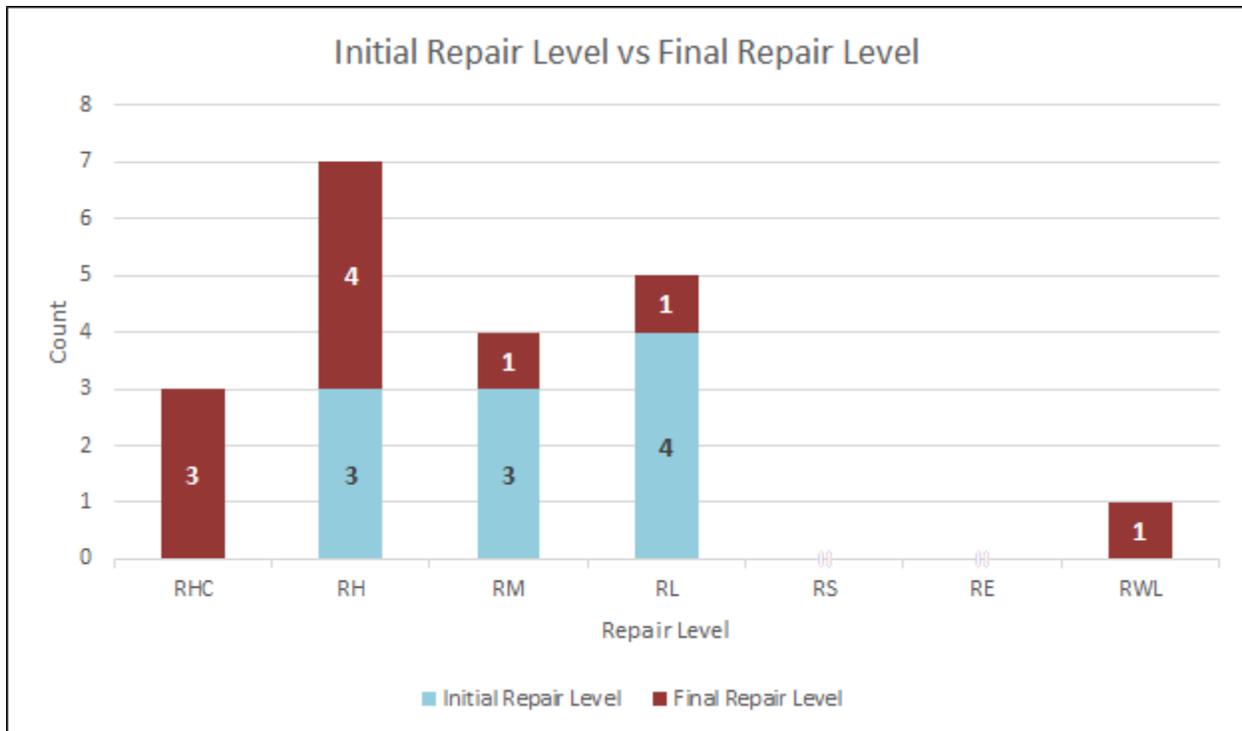


Figure 10: Chart of initial repair levels compared to their final repair levels³

Figure 9 shows the initial repair levels compared to their final repair levels for the Legacy Gastroscope. The light blue bars represent the initial repair levels for these 15 cases while the dark red bars represent the final repair levels for these 15 cases. Using the average repair level for the Legacy Gastroscope, the initial repair costs was approximated at and the final repair cost was found for the 15 cases. From these numbers we were able to approximate that the modified repair levels would have accounted for 10.4% of the total sum billed to customers in the year 2015.

We surmise that the 10.4% per year is not a substantial financial impact to KARL STORZ. This is because of the low volume of Legacy Gastroscopes that are sent in for repair. The Legacy Gastroscope is a product that is phasing out. In the year 2015, the Legacy Gastroscope accounted for only 0.3% of all KARL STORZ products to be received for evaluation. If 10.4% of repair costs were unbilled to the customer for a major product line, then our findings could represent a greater financial impact to KARL STORZ.

³ Figure 9 only includes Legacy Gastroscope repairs that included a modified repair level in the Start and Stop Records.

Through discussions with repair technicians and evaluators, a probable cause may be with the repair level associated with each repair item. For example, there may exist a misalignment of the actual requirements to replace particular assemblies. An evaluator could perceive a particular assembly to be an RM repair level while a repair technician could perceive that same assembly to be an RH repair level. Since this discussion was initially outside the scope of our project, and due to time constraints, our team did not pursue an investigation into the repair level assignments for each assembly. However, this was a valuable topic to pursue and could lead to improvement opportunities with future projects.

5.3 Evaluation Report

As mentioned in the previous section, there exist cases of KARL STORZ products having their repair level modified once they finally arrive at the disassembly station. One reason for these occurrences was that damages went unnoticed through evaluation and were revealed at the disassembly station, resulting in a modified repair level. However, through discussions with repair technicians and evaluators, another cause is from a miscommunication of which components result in which repair levels between the tear station and the evaluation station. For example, an evaluator may notice a damaged assembly and assign that scope as an RM. However, a repair technician may perceive that same assembly as a much higher cost, because the removal of other components in order to access that particular assembly may be required.

Currently evaluators use a matrix to determine the repair level for an evaluated endoscope. The matrix is shown in Table 2.

Table 2: Initial repair levels compared to their final repair level

Repairs	Scope Type		
	GI Scopes	Small Dia. CCD Scopes	CMOS Scopes
No problem found	RE	RE	RE
Reset deflection, replace angle cover (see 25.1)	RAPL	RS	RS
Replace Spread Lens	RS	RS	N/A
Replace PCB	RL	RS	RL
Replace Only Angle Cover (Customer Damage see 25.1)	RA	RA	RA
Replace Umbilical Strain Relief	RL	RM	N/A
Replace Connector Housing	RM	RM	N/A
Replace Control Housing	RM	RM	RM
Replace Channel	RH	RH	RH
Replace Monocoil	RH	RH	RH
Replace Vertebrae	RH	RH	RH
Replace Control Wires	RL	RL	RH
Replace Light Guide	RH	RH	RH
Replace Camera	RHC	RHC	RH
Replace Umbilical Shaft	RM	RM	RM
Replace Cap & Strap	CAP	CAP	N/A

Each repair field corresponds with a performance test that an endoscope goes through at the evaluation station. The endoscope will then assume the repair level of the failed performance with the highest associated repair level. For example, if a Legacy Gastroscope needs a replacement Connector Housing (RM), a replacement Monocoil (RH), and replacement Control Wires (RL), then the endoscope will assume an RH repair level as that is the highest involved repair level. The evaluator would then enter the appropriate repair level onto the evaluation report, which will then be used to bill the customer.

From discussions with repair technicians and evaluators, a problem that occasionally arises is from an incorrect assignment of a repair level to an evaluated endoscope. For example, an evaluated, Legacy Gastroscope could only need a replacement Channel; however, a repair level other than RH could be assigned due to human error while using the matrix shown in Table 2. Since the customers are billed a standard cost based on the repair level, a defect like the one in the above scenario could result in thousands of dollars of unbilled cost that KARL STORZ would assume. While we did not fully pursue this area due to time constraints, we identified this as an opportunity for automation in the evaluation process and brief recommendations can be found in Chapter 6.1.

5.4 Discarded Components in Legacy Gastroscope

From our review of BOM orders for Legacy Gastroscope, we developed Table 3, which is a list of all discarded components that were related to evaluations between December 16, 2014 and December 16, 2015. The list shows only the top 15 components listed in the order from highest repair cost to lowest repair cost.

Table 3: Table of Total Costs for Discarded Components in Legacy Gastroscope Repair by Component Description based on data from December 16, 2014 to December 16, 2015

Total Costs for Discarded Components in Legacy Gastroscope
Component Description
Loaded Shaft Assembly
Housing with Control Unit
Labor
Cover with Pin Connector
Connector Housing Assembly
Camera Assembly
Monocoil Assembly
PCB Assembly
Vertebrae with Net
Umbilical Assembly

Using this list, we discussed with floor managers the most opportunistic components to focus on. From those discussions, we decided to focus on the following components:

1. Housing with Control Unit
2. Connector Housing Assembly
3. PCB Assembly

The other components on this list were excluded for various reasons discussed with floor managers⁴. For each of the three components above, we investigated further any preventative or corrective measures to alleviate the costs for endoscope repair.

5.4.1 Housing with Control Unit & Connector Housing Assembly

The most common damages to the Housing with Control Unit, as well as the Connector Housing Assembly, was internal corrosion and cosmetic damages. First, we interviewed repair technicians to determine the root causes for the internal corrosion within both components. Through our discussions, the primary cause we uncovered was with the manufacturing quality of the components. Both components are sourced out-of-house, and the quality of the components can cause leaks in both components over time. A hole that causes a leak could develop years later or could exist upon receipt from the out-of-house manufacturer. Either way, corrosion in both components are associated with design and quality issues, and not with the customers' irregular use of the product. Since manufacturing and the product design of the Legacy Gastroscope is outside the scope of our project, we decided to no longer investigate internal corrosion issues.

Next, we investigated the cosmetic damages for the Housing with Control Unit and the Connector Housing Assembly. These components are discarded if they contain cosmetic damages longer than acceptable length based on their product specifications. Figures 10 and Figure 11 show cosmetic damages on the Housing with Control Unit and the Connector Housing Assembly, respectively.

⁴ Due to many components being made by sister divisions, it was not feasible to look into reusing any parts of the Legacy Scopes. However, we focused on the selected components to apply preventative measures for reducing the probability of a future repair and/or reassessing the acceptable specifications of the selected components. From our discussions with floor managers, this approach was not appropriate to the other components for the Legacy Gastroscope.



Figure 11 : Image of Discarded Housing with Control Unit 1



Figure 12: Image of Discarded Housing with Control Unit 2

Through brainstorming sessions within our team, we developed the following two options to pursue: repair the cosmetic damages and/or reevaluate the product specifications.

Repair the Cosmetic Damages

To identify associated requirements for repairing either the Housing with Control Unit or the Connector Housing Assembly, we discussed with floor managers to determine a proper

approach. From our discussions, we determined that cosmetic damages are difficult to properly repair on-site, due to the material and process that are required. Any temporary fixes would be dissatisfying to the customer and could pose additional risk to the patient, therefore, we concluded that these components would need to be repaired at the original manufacturer, and the cost to do so would exceed the cost to purchase brand new. Because of this we no longer decided to pursue a repair option for these cosmetic defects.

Re-evaluate the Product Specifications

Another option was to reevaluate the product specifications to accept more cosmetic damages, and avoid having to purchase a brand new component. The deciding factor was what the customers were willing to accept or not accept. To obtain a better understanding of customer expectations, we connected with a Clinical Product Performance Liaison, whose role is to interact with customers who use KARL STORZ products and to gather customer feedback and expectations. He has also performed similar customer surveys regarding cosmetic damages for other product lines.

We determined through his former work as well as some research of our own with customers that most if not all of the concern with cosmetic damages are due to concern of safety rather than appearance. Large scratches and areas with multiple scratches raise concern that in the future that area of the product could have flaking or peeling and will become an area of leaking or contamination during a procedure, which in the medical industry could cost lives.

To prepare for our meeting with this customer liaison, we examined and documented 23 bins that contained Housing with Control Units and Connector Housing Assemblies that were discarded at the disassembly station. We took pictures of the cosmetic damages that were found on both components, and sent the pictures to the customer liaison to assess the cosmetic damages based on his prior knowledge of customer expectations.

Based on our discussion with the customer liaison, and his assessment of the discarded Housing with Control Units and Connector Housing Assemblies, we concluded that the customers might be willing to accept more cosmetic damages than is defined the product specifications.

5.4.2 PCB Assembly

The most common damages with the PCB Assembly are malfunctioning due to internal leaks. The PCB Assembly is responsible for regulating the electronics of the endoscopes, which is required in order to capture a visual at the distal lens and display it on the external monitor. When internal leaks cause fluid invasion inside the PCB Assembly, the entire Camera Assembly may be replaced, which results in a repair level of RHC (Repair High Camera).

Once a circuit board is short-circuited, the effects are frequently irreversible. To determine options for protecting the PCB Assembly, we quickly understood, and confirmed with floor managers, that repairing a PCB Assembly after fluid damage would require a large amount of time and money that would exceed the cost of purchasing the component brand new. Therefore, we pursued options that were preventative rather than corrective.

Through our research of standard work procedure documents, we found that conformal coating, a special coating that creates a seal around electrical components and protects them against fluids, is already in use for other product lines. The advantage for using conformal coating is that it protects electrical components against fluid invasions, which extends their lifespan. However, the disadvantage for using conformal coating is related to hardware defects not caused by fluid invasion. For example, a non-short-circuited PCB Assembly could be repairable through a simple soldering treatment in some cases. However, the conformal coating would make it difficult to access the surface of the PCB Assembly, and it would be less easy to purchase a brand new PCB Assembly instead.

To assess the application of conformal coating to the PCB Assemblies of the Legacy Gastroscope, we conducted brief interviews with repair technicians to better understand the cause of PCB Assembly replacements. Based on those discussions, the repair technicians concluded that almost all PCB Assembly replacements were due to fluid invasions with little to no cases of solely hardware defects; therefore, conformal coating would be an appropriate preventative measure that would save PCB Assemblies from fluid invasion induced problems.

5.5 Interviews with Hospital Personnel

In speaking to multiple representatives for various different hospitals and medical services, we found some information on the customer end of purchasing, repairing and using medical devices, specifically endoscopes. Many customers do not have brand loyalty for the brand name itself, but rather for the services the brand offers. This is especially true with customer services and product servicing such as repair and transparency between the company and the customer. Customers do not particularly like to upgrade to new models until it is necessary because of the upfront costs with little major improvement improvements for the most part. Cost is something that is looked into and strongly considered, however based on our conversations, money is usually not a limiting factor and a hospital or client will find or allocate money in the budget if needed. The major factor is how companies treat their customers and if there is a good relationship or opportunity for a good relationship when buying products or discussing new contracts.

5.6 Interviews with Sales and Marketing Personnel

To better understand the current sales model and business strategy, we spoke to representatives from the sales and services team for KARL STORZ. We wanted to determine if there was a standard sales model in place and if it varies from model to model or is universally accepted across product generations. We found that there is no sales plan fully in place for the Legacy Gastroscope for either sales or potential obsolescence. KARL STORZ as a company does not address product obsolescence until it is determined that a product is about a year away from being fully obsolete.

Many of KARL STORZ's products can have similar sales models and obsolescence planning based on their product line, however there is no type of universal business plan currently in place to address phasing out a product. There are many processes in place across all of the product lines within the company, some of which could potentially be implemented into other products which they are currently not being used for.

5.7 Interviews with Medical Device Companies

Our market research took us too many conversations with medical device companies where we learned some of the decision making behind big companies dealing with the end of product life cycle. Many industry professionals were the first to admit that companies do a horrible job at letting go of products even when they know that the product is at the end of its life cycle. There are costs with phasing out a product, but also costs for continuing to make or service a product. In the later stages of a device's life cycle the profit to the manufacturer decreases. The price point can get so low that the cost to sustain the product is not worth it, and the money should be spent developing new products. Another topic discussed with companies is their thoughts on the new disposable endoscopes being researched. The professionals agreed that although it would be a promising revenue stream for their companies, it is not an area their company is interested in pursuing because of the negative environmental and social aspects.

Chapter 6: Recommendations

This section contains our recommendations moving forward based on our finding in Chapter 5.

6.1 Short-Term Recommendations

This section contains our recommendations that can be initiated immediately and has a 1-3 month focus. We recommend that KARL STORZ:

1. Assess each replacement component's repair level on the repair level matrix,
2. Change the evaluation report layout and content,
3. Assess customer expectations for the housing with control unit & connector housing assembly in Legacy Gastroscope,
4. Apply conformal coating to the PCB assemblies in Legacy Gastroscope.

6.1.1 Assess Each Replacement Component's Repair Level on the Repair Level Matrix

In the year 2015, the repair level for 10.4% of all evaluated, Legacy Gastroscope was modified at the disassembly station. Through discussions with repair technicians, we identified that many of these cases involved the misunderstanding between evaluators and repair technicians regarding the requirements to replace certain components. For example, an evaluator may assign a low repair level to replace a particular assembly, but the repair technicians may modify the repair level because other components need to be discarded in order to access that particular assembly.

We recommend a reassessment of each replacement components' repair level on the repair level matrix. A reassessment would require a group discussion that includes both the knowledgeable perspective of the evaluation process, product design, and the standard purchasing cost for each component. This way, we can reduce the under billing of customers due to unclear repair requirements at both the evaluation station and the disassembly station.

6.1.2 Changes to the Evaluation Report

As of now, the evaluator assigns a repair level to an evaluated endoscope using a reference matrix. However, a problem can occur if an inaccurate repair level is assigned to an evaluated endoscope. For the Legacy Gastroscope, 10.4% of all repairs contained a modified repair level after being processed at the disassembly station. Although future work can clarify the root cause of these modifications, we believe that this presents an opportunity for automation in the evaluation process.

We recommend that the reference matrix be embedded into the Microsoft Excel file that the evaluation report is contained in. Since each performance test is directly linked to a specific component on the reference matrix, and each component is directly linked to a repair level, then this logic can be programmed in the file so that the repair level field is auto generated based on the evaluation test results. By doing so, the potential for human error in assessing the repair level is minimized, as it will be auto-generated. In addition, this can be used to apply logic that couldn't be derived from a matrix format. A replacement component could have a variable repair level associated with it. The variable could depend on the results of other evaluation test results, or details about the endoscope that may not be captured in evaluation testing. For example, a Legacy Gastroscope that has an approximately two year old camera assembly typically has it replaced due to the probability of the camera failing sooner than later at that age. An endoscope that has a two year old camera will always result in a repair level of RHC. Although, this factor is not reflected on the current repair level matrix, it can be programmed into the excel file itself.

6.1.3 Assess Customer Expectations for the Housing with Control Unit & Connector Housing Assembly in Legacy Gastrosopes

The Housing with Control Unit and the Connector Housing Assembly were found to have the same main defects: cosmetic defects and internal corrosion. To address the cosmetic defects we recommend that KARL STORZ continue to collect the assemblies and document what the extent of the cosmetic defects. We also suggest that KARL STORZ reach out to their clients to see what they are willing to accept on their endoscopes. Because the Legacy Gastroscope is nearing the end of its product life cycle customers may be more lenient on what they deem is acceptable.

6.1.4 Apply Conformal Coating to the PCB Assemblies in Legacy Gastroscope

The PCB Assembly is made up of a circuit board that is surrounded by a metal enclosure to protect itself from fluids, rust, or dust. The metal enclosure helps to decrease the chance of a defect; however, this does not prevent the board from corrosion, the main defect found in the PCB Assembly. Once a board corrodes it is no longer useable and unsalvageable. We recommend that all future Legacy Gastroscope that are sent back to KARL STORZ should be examined and a layer of conformal coating should be applied. The conformal coated will serve as a preventative measure to stop corrosion from occurring.

6.2 Long-Term Recommendations

This section contains our recommendations that can be initiated immediately and has a 4 month or longer focus. We recommend that KARL STORZ:

1. Investigate a reclaim process for the newer model GI endoscopes,
2. Take into account older model product components when designing newer model products,
3. Convert all banked products into customer-owned products.

6.2.1 Reclaim Process for Newer Model GI Endoscopes

The reclaim of many components in the Legacy Gastroscope was a difficult task. This was because many components were contained with sub-assemblies that were sourced out-of-house. Therefore, if there was a defect with a particular component in most cases, a larger assembly had to be replaced. In the repair of Legacy Gastroscope, the housing with control unit was a commonly replace component. In many cases, the only exterior shell was damaged. However, since the housing with control unit was sourced out-sourced, the entire housing had to be replaced due to the lack of material resources.

We recommend that a reclaim process for the newer GI endoscopes be investigated. The biggest difference is that the newer model GI endoscopes are manufactured in-house at KARL STORZ. Since the Silver Scope is made in house at the Charlton facility, there is more opportunities to

develop a reclaim process. If a particular component needs to be replaced, there is greater chance that only that particular component can be replaced without the need to replace a larger assembly, which would reduce the repair costs.

6.2.2 Take into Account Older Model Product Components when Designing Newer Model Products

Through discussions with product design employees at KARL STORZ, we brainstormed the plausible actions to take for managing material waste from obsolete products. Once the Legacy Gastroscope becomes obsolete, the product will typically be disposed of while a newer model takes its place. From these discussions, we determined that an opportunity for waste reduction would be to reuse components in the obsolete product by using them in newer model products.

Our recommendation is to take into account older model GI endoscopes when designing newer model GI endoscopes. When an endoscope is approaching obsolescence because a newer model is out in the market, there many factors that the customer considers when deciding to upgrade to the newer model endoscope. One of those factors is cost to upgrade. If the newer model is sufficiently inexpensive enough for a customer to invest into a higher quality product, then the customer will make that investment. In addition, if we alleviated the future cost of repairs with the newer model endoscopes by using the components in obsolete products, than that cost savings could have the potential to subsidize a program in which we sell the newer model endoscopes to the customer at a discounted rate. This discounted price for the customer could be a substantial enough incentive to upgrade to the newer model endoscope. This will also help KARL STORZ to force obsolescence in the older model endoscopes, and focus on servicing the newer model endoscopes, while still profiting on the customer when they make their investment in the newer model endoscope.

6.2.3 Convert All Banked Products into Customer-Owned Products

In our research, we found that the biggest deciding factor for purchasing new products on the customer end is customer service, and not necessarily brand loyalty. The repair service being a big consideration in the customer service discussions. When one of their devices is damaged and

needs to be repaired, customers highly consider companies that can perform a quick turnaround on their devices, and at an affordable cost.

We recommend that KARL STORZ convert all of their banked products into customer-owned products by highly emphasizing the rapid repair program. Many of KARL STORZ customers' use this banked purchasing option. This means that the customer can send in their endoscope and receive a different endoscope of the same model in "like new" condition at a quick turnaround. Based on our discussions with industry professionals, the attractive aspect of the banked program is the quick turnaround with a "like new" condition product. However, this results in KARL STORZ to assume high repair costs to repair the returned endoscope to "like new" condition, as opposed to repairing the endoscope to performance specifications only. Customer owned products with a rapid repair service will highly attract customers as well as reduce repair costs on KARL STORZ's end.

6.3 Product Strategy for Legacy Gastroscope

To structure our findings and recommendations for the Legacy Gastroscope, we developed a product strategy plan which can be found in Appendix H. This product strategy includes findings from market and financial research as well as our recommendations for proceeding with the Legacy Gastroscope as it nears the end of its product life cycle.

Chapter 7: Conclusion

Video-based endoscopy has become an integral part of modern medicine. KARL STORZ is a leading manufacturer and distributor in the endoscopic market due in part to their customer service and repair services. Currently the Legacy Gastroscope is only available for repair services at the Charlton, MA facility. Our goal was to assess different strategies to address the nearing obsolescence of the Legacy Gastroscope. We identified components with the highest financial impact to the repair process and developed strategies to salvage these components to increase their product lifespan. We also provided recommendations on changes to the evaluation sheet for better communicating the repair levels between the evaluation station and disassembly station. Finally, a product strategy plan was created to outline our recommendations for managing the Legacy Gastroscope with considerations of the newer GI endoscope.

Our recommendations for the Legacy Gastroscope components require employee and material resources that were already available in existing processes, and are therefore feasible from a technical standpoint. Through our cost-benefit analysis, the costs associated the surface evaluation reassessment would be customer dissatisfaction if the reassessment did not accurately resemble the customers' needs, which would be mitigated through constant customer feedback. The conformal coating recommendation would be a low cost impact due to the low cost of the conformal coating and the low volume of Legacy Gastroscope repair. Therefore, the benefit of increasing the lifespan of these major components and decreasing the repair cost for customers both outweigh the cost for implementation. Our recommendations were developed with key managers who oversaw the processes that our recommendations would affect, including production and manufacturing; however, recent organizational changes were made to separate small and large diameter endoscope production. Therefore, the support of product managers in the large diameter endoscope division will be required in order to implement our recommendations.

Our project did present some limitations. The scope of our project only allowed us to focus on the Charlton, MA facility; therefore, all of our observations and data collection and analysis on the repair process was based off of the current practices at the Charlton facility. Because of this we do not know how other KARL STORZ facilities function and manage their repair processes.

Based off of our findings from the Charlton facility we were able to develop recommendations on how to reclaim certain parts of the Legacy Gastroscope as well as how to improve the overall flow of materials and information within the repair process. For future process improvement project we recommend that other KARL STORZ facilities be looked into to observe other reclaim practices in repair processes. The Charlton location could find helpful tools and techniques on reclaim processes based off of other facilities practices.

Another limitation of this project was the physical design of the Legacy Gastroscope. During this project we were unable to make changes to the design of the Legacy Gastroscope. This would have required much more time and resources, as well as more employee and executive involvement. For future research, we recommend that the design of the endoscopes be taken into consideration during the design phase so parts and components could be made more universal. If parts and components could be easily broken down then not a whole aspect of the endoscope would have to be repaired just the specific part. This would allow parts and components to be salvaged and reused more easily. Part of this limitation which affected our analyses greatly was the Legacy Gastroscope comprising of assemblies made out of house. We used this information along with our repair and part analyses to conduct a cost analysis in a way that had prior not been done within the company, relating the potential for reclaim with the new Silver Gastroscope to that of the Legacy Gastroscope and comparing repair levels and costs, which are heavily affected by many assemblies being pre made out of house, finding the Silver Gastroscope to potentially be a beneficial upgrade financially for both KARL STORZ as well as any previous customer.

This project allowed our team to look at a real world problem and utilize the knowledge and skills we have learned over our four years at WPI. It gave us the opportunity for practical real world experience. Over the past three terms we were able to learn more about the manufacturing process of medical devices and explore various aspects of the KARL STORZ operations. One of the main takeaways we received from this project was the interactions with the various employees from different backgrounds and positions. Much of our time at KARL STORZ was spent on the production floor and we were able to have exposure to many stations of the repair process. Overall this project experience allowed us to bring together all our previous classroom work and experiences and apply that to a hands on major specific project. We are thankful for

our project sponsors who have given us this opportunity and for our advisors who helped guide us through this process.

Chapter 8: ABET Reflections

The engineering design process is a series of steps to follow in order to identify a problem and develop a solution. These series of steps includes:

1. Researching the problem,
2. Developing possible solutions,
3. Evaluating the options,
4. Choosing the best option,
5. Testing the best option,
6. Analyzing the results.

Due to constraints in our project, we were unable to test our recommendations and analyze the results. However, our recommendations include a detailed evaluation of our options and the steps for implementation. This section summarizes our team's experience using the engineering design process to find a way to reduce repair costs for Legacy Gastroscope and increase the lifespan of its increasingly obsolete components.

One major constraint that our MQP team faced when developing a reclaim process was with the manufacturing capability of KARL STORZ. The Legacy Gastroscope is an older model that is manufactured with outsourced assemblies. If a component that we sought to reclaim was included in one of these outsourced assemblies, then KARL STORZ was incapable of properly repairing and replacing the one component only. For example, the process and equipment for properly repairing the component would be owned by the original manufacturer, the KARL STORZ supplier. In addition, the component itself could not be discarded and replaced, because component spares are not kept onsite at KARL STORZ since the component was sourced with the larger assembly. Therefore, our recommendations for reclaiming components involved preventative measures and the adjustment of product specifications, which did not require repairing or replacing components.

To research the problem, our team closely observed the repair process for Legacy Gastroscope. This consisted of GEMBA walks and employee interviews at each station of the repair process. The result of this first phase was a process map that resembles the process flow from when the

endoscope is received by KARL STORZ to when the endoscopes is shipped back to the customer. In addition, we reviewed records related to Legacy Gastroscope repair including evaluation reports, start and stop records, and BOM orders. We reviewed these records to better understand the data history of Legacy Gastroscope repair. After observing the entire repair process and reviewing data related to Legacy Gastroscope repair, our team narrowed our focus on opportunities for waste reduction in the form of damaged components in evaluated Legacy Gastroscope.

We investigated several approaches to reduce waste from damaged components such as repairing or reusing the damaged components. We brainstormed these approaches after discussing with floor managers and using our existing understanding of the repair process. To evaluate the appropriateness of each option, we performed an informal cost benefit analysis of each option. We summarized the BOM order history to determine the financial impact of components that could be salvaged with each option and the required costs to perform each option. To identify the most appropriate solution, we chose the option with the more desirable cost-benefit ratio.

In the end, we recommended reassessing the product specifications based on customer expectations for Legacy Gastroscope. More specifically, we recommended the conformal coating of PCB assemblies to reduce the probability of future repairs and to allow cosmetic defects with no performance risk to pass quality inspection.

The team spent 21 weeks examining the repair process for Legacy Gastrosopes and investigating customer, manufacturer, and market nuances. This would not have been possible without the ongoing guidance of our sponsor, KARL STORZ. During this time, we observed the repair process at KARL STORZ, studied documents and reports related to the repair process, examined components that were discarded, interviewed repair techniques and floor managers, and questioned each step in the process. Overall, we had a great experience and were thankful for the opportunity to put our theoretical knowledge into practice.

One main takeaway from the project was that identifying your audience is important for effective communication. It is necessary to adjust your communication strategies depending on who you are talking to at KARL STORZ, as well as most companies. For example, repair technicians are specialists for a particular station of the repair process. They are highly familiar with the technical and procedural aspects of that particular station, but not necessarily the higher level repair process that floor managers oversee. Therefore, we found greater success when asking questions like “Where does this endoscope go when you are finished?” to repair technicians as opposed to “What is the next step in the repair process?” On the other hand, the repair technicians had an extensive technical knowledge of the endoscopes. Therefore, we found greater success by asking questions regarding the specific model number 13801NKS, as opposed to the more general “Legacy Gastroscope label”, or “black-handle” model. In addition, floor managers were well-knowledgeable about the repair process in terms of time, money, and regulations. We contact floor managers for insight into the larger cycle times of the repair process, the expectations of the customer, the purchasing cost of specific components, the effects of federal regulations on repair processes, and more. Understanding the audience’s scope of expertise as well as their interests allowed us to obtain the data we needed in an effective, efficient, and appropriate manner.

Another main takeaway was that new information will continue to surface throughout the project, and implementing a solution too early can put a halt on our progress. We experienced this temporarily at the early stages of our project. From interviews with floor managers and observations of the repair process, the popular belief was that the tear station was discarding more components than was specified on the evaluation report. Therefore, we accepted this conclusion and consumed a few weeks investigating opportunities for improved communication using the evaluation reports, so that the disassembly station discarded only what was necessary and nothing more. However, following a closer review of the Start and Stop Records and following interviews with more repair technicians, we determined that the disassembly station was in fact discarding only damaged components. Since the larger assemblies were manufactured out-of-house, the larger assembly was required to be replaced if a component within that assembly was damaged. These requirements provided a misleading condition in which the disassembly station was discarding more than was necessary. This holdup in the

project conveyed the importance of data collection and extensive research before making conclusions. It is important to understand the problem and question popular belief in any process improvement project.

As a team, we learned many lessons beyond the main takeaways above. We had the opportunity to assume the consulting role for a well-established company, as well as interview and learn from industry professionals outside of the company. In the WPI curriculum, students learn about the theoretical concepts in many areas including supply chain, facility planning, project management, and more. However, it's difficult to understand the obstacles and implications of these concepts until they are put into practice. Fortunately, we had the opportunity to put these concepts into practice. Along the way, we received insight and practical tools from professionals in project management and process improvement. Moving forward, is it important that we continue to study the theoretical concepts in any industry we pursue, but it is just as important to seek the insight of professionals who have put these concepts into practice.

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Appendix A: Interview Protocol for Floor Managers

- Initial Contact by Email
 - Request KARL STORZ primary contacts to identify floor managers
 - KARL STORZ primary contacts include Jason Johnson, Steven Konicki, and Dudley Greene
 - Primary contacts introduces us to the floor managers
- Assign roles (note-taker, interviewer)
- Introductions
 - We are students from WPI working on a senior capstone project
 - We are assessing the repair process for older model GI endoscopes
 - Applying concepts learned in the classroom to existing business processes
- Interview Question
 - What steps are being completed in your section of the repair process?
 - How are the repair stations connected with one another in terms of process flow?
 - Where are these repair stations located?
 - Who performs the service at each repair station?
 - How long should these steps take?
 - How many working shifts are there for each station?
 - What is KARL STORZ's standard for total repair cycle time?
- Conclusion
 - We'd like to interview the repair technicians to understand the procedural steps at each station
 - Could you introduce us to these repair technicians?
 - Could we email you if we have any more questions later in our project?
 - Thank the floor manager for than time

Summary: The questions related to process flow (where and how are stations connected) resulted in similar responses to those from the repair technicians. Both perspectives were represented in our process map in Section 5.1. The staffing schedule is separated into three working shifts which are, however, not represented in our process map. Overall, the cycle time of each station is not monitored as closely as the total repair cycle time is monitored. The total repair cycle time represents the time between when the endoscope is received and when the endoscope is shipped back to the customer. The company's standard is to have the endoscope received and shipped back to the customer within 5 business days.

Appendix B: Interview and Observation Protocol for Repair Technicians

- Assign roles (note-taker, interviewers)
- Initial Contact:
 - Request floor managers to identify the repair technicians
 - What is the next step in the repair process?
 - Which individuals perform this step?
 - Floor managers introduce us to the repair technician
- Introduction
 - We are students from WPI working on a senior capstone project
 - We are assessing the repair process for older model GI endoscopes
- Interview Questions
 - Where does the endoscope come from prior to your station?
 - Where is the endoscope stored before you work on it?
 - What actions are done to the endoscope at this station?
 - How long does this station's procedure take?
 - How many total endoscopes do you process per day?
 - How many older model GI endoscopes do you process per day?
 - Do you add any new forms or materials to the traveling endoscope tray?
 - Do you modify or change any existing forms or materials?
 - Where do you store the processed endoscope?
 - Where does the endoscope go next?
- Conclusion
 - Thank the repair technician for their time

Observations

- Assign observer(s)
- Initial Contact
 - Schedule an appropriate time to visit with the KARL STORZ primary contacts
 - Email primary contacts the list of repair process steps that we'd like to observe in the upcoming visit
 - Request KARL STORZ primary contacts to introduce us to floor managers or repair technicians in each section of the repair process
- Introduction
 - Primary contact or floor manager introduces us to repair technician
 - Primary contact or floor manager describes our project and visit purpose
- Observations
 - Repair technician continues work while we quietly observe
 - Primary contact or floor manager describes the steps being completed as the repair technician is working
 - We record observations in personal note taking book

- Clarification questions are asked
 - What is the current procedural step?
 - What is the purpose of this step?
- Conclusion
 - Is there a written procedure for this step that we can have access to?
 - Thank you for your time

Appendix C: Interview Protocol for Industry Professionals

- Initial Contact:
 - Email medical device company contacts to set up phone call
- Call Introduction
 - We are students from WPI working on a senior capstone project.
 - We are investigating how medical device companies decide when and how to take a product off the market once it has reached obsolescence.
- Interview Questions
 - What do your warranties cover and how do they affect repairs?
 - Do you have a repair program for your devices?
 - Do salesmen promote repairing older models or buying new models? What factors go into the salesman's' decision?
 - What factors go into the decision making with procedural devices when it comes to repairing an old product vs selling a newer model?
 - How it is decided when and how to go about discontinuing an older model in the sales business plan and manufacturing, etc.?
- Conclusion
 - Thank them for their time.
 - Ask if we can contact them with any follow-up questions.

Appendix D: Table of Number of Modified Repair Level Cases by Product Type

A modified repair level represents a scenario in which a repair level was changed, either raised or lowered, at the disassembly station as a result of more or less components needed to be replaced than previously discovered. The following table displays the total number of documented modified repair level occurrences by KARL STORZ product.

Table 4: Number of Modified Repair Level Cases by Product Type

Product Description	# of Modified Repair Levels
CMOS Video Ureteroscope,, 8.5 FR. X 700MM	36
Flex. Intubation Video Scope, 4.0 X 65CM	14
Video-Rhino-Laryngoscope, NTSC	13
16 FR. Flexible Video Cystoscope	12
Veterinary Video Endoscope 7.8MM X 140CM	9
Video Gastroscope Color System NTSC	7
Video Colonoscope 12.9MMX1600MM NTSC	5
Video Gastroscope, 9.3MM x 1100MM NTSC	5
Video Bronchoscope	4
CMOS Video-Cysto-Urethroscope	4
16 FR. Flexible Video Cystoscope	3
9.7 Video Gastroscope Color System NTSC	3
Video Colonoscope, 13MM X 160CM	2
Flex. Intubation Video Scope 5.5 X 65 CM	2
Spies CMOS Video Ureteroscope	1
CMOS Video Choledochoscope 8.5 FR X 675MM	1
CMOS Video-Cysto-Urethroscope US	1
SA Videoscope 9.7 MM X 1400 MM	1
CMOS Video-Rhino-Laryngoscope	1
CMOS Video Ureteroscope, 8.5 FR. X 675MM	1
SA Videoscope 8.9 MM X 1400 MM	1

Appendix E: Organizational Feasibility Analysis

Table 5: Organizational Feasibility

Organizational Feasibility Analysis		
Recommendation	Topic	Result
Apply conformal coating to all PCB Assemblies in legacy GI endoscope repairs	Project Champion	Jason Johnson, Manager of Endoscope Production
	Already Worked With	Jason Johnson, Manager of Endoscope Production Steve Konicki Dudley Greene
	Required Employee Resources	Jason Johnson, manager of Endoscope Production
	Addressing User Needs	Conformal coating is an internal, preventative measure that does not affect the customers' experience with the endoscope. Therefore, there is no need for a continuing plan to address the customers' needs with this recommendation.
	Alignment with Business Direction	One of KARL STORZ's aims is to provide quick, low cost repairs to their customers. The application of conformal coating can prevent the replacement of the PCB Assemblies due to internal corrosion in future repairs, resulting in a reduced repair cost for the customer.
Create surface evaluation specifications for legacy repairs using customer expectations	Project Champion	Jason Johnson, Manager of Endoscope Production
	Already Worked With	Jason Johnson, Manager of Endoscope Production Steve Konicki Dudley Greene Kurt Audette, Clinical Product Performance Liaison
	Required Employee Resources	Jason Johnson, Manager of Endoscope Production Kurt Audette, Clinical Product Performance Liaison
	Addressing User Needs	To reassess the product specifications for cosmetic defects, Kurt Audette and other liaisons will need to communicate with key customers who continue to use the legacy GI endoscopes. These expectations can then be reflected by updating the TAPPI Chart for endoscope repair.
	Alignment with Business Direction	One of KARL STORZ's aims is to provide quick, low cost repairs to their customers. The ability to deem more cosmetic defects as acceptable, especially for the House with Control Unit, will reduce the repair costs for customers as long as it meets the customers' needs.

Appendix F: Technical Feasibility Analysis

Table 6: Technical Feasibility

Technical Feasibility Analysis		
Recommendation	Criteria Type	Result
Apply conformal coating to all PCB assemblies in legacy GI endoscope repairs	Employee Resources	The application of conformal coating includes a <1 minute application period followed by a 20 minute waiting period. Since legacy GI endoscopes are a low volume repair, this will have a low time impact overall and existing employees can incorporate this into their existing repair process without the need of additional employee resources.
	Employee Capabilities	A process for applying conformal coating to PCB assemblies already exists for similar fiberscope repairs, and can be transferable to endoscope repairs. Employees in endoscope repair will need to be trained using existing standard work.
	Material Resources	A sufficient amount of conformal coating is already available for other endoscope repairs. Since conformal coating is a minimal expense to KARL STORZ, and legacy GI endoscopes are a low volume repair, then a sufficient amount of conformal coating can be available for legacy GI endoscope repairs as well.
Create surface evaluation specifications for legacy repairs using customer expectations	Employee Resources	These new specifications will require the collaboration between floor managers and customer liaisons. This can be achieved with a series of meetings between both parties. Once established, the results a change in the decision making process and will not consume additional working time from the existing employee resources.
	Employee Capabilities	Kurt is a Clinical Product Performance Liaison who has experience discussing with clients about their expectations and concerns with KARL STORZ products.
	Material Resources	Specifications affect the intangible decision making process and does not consume any material resources, excluding the initial printing of reference materials for employees. Therefore, it can be assumed that no material resources are required.

Appendix H: Product Strategy Plan



KARL STORZ COMPANY

A project strategy addressing the obsolescence of the Legacy Gastroscope

91 Carpenter Hill Rd
Charlton, MA 01507

Company Description

The KARL STORZ GmbH & Co is a global leader in the production of medical devices and was founded in 1945. This family owned company is based in Tuttingen, Germany and serves customers with a wide range of medical devices spanning from human medicine to veterinary medicine. KARL STORZ Endoscopy-America Inc. is a subsidiary of KARL STORZ GmbH & Co and was founded in 1971, based in El Segundo, California. KARL STORZ Endoscopy-America Inc. designs, develops, and distributes medical devices in the United States.

KARL STORZ focuses on visionary design, precision craftsmanship, and clinical effectiveness. Their mission is to “benefit humanity by advancing medical technology through innovation and education.” The company is a leader in creativity, flexibility, and expertise; and strives to provide customers with reliable, world-class medical devices. The company values: legal compliance, honesty, loyalty, transparency, sustainability, and fairness; govern the company culture and has driven KARL STORZ’s success. Most recently, KARL STORZ has placed emphasis on gaining a global reputation for quality and innovation and has instilled the responsibility to maintain these values in their employees.

The medical device manufacturing industry includes a wide range of highly innovated products used to aid healthcare systems and patients globally. This industry can range from simple medical devices, such as bandages to more complex and sophisticated medical devices, such as surgical instruments and electro-medical instruments. The three largest subgroups in the medical device industry are: surgical appliances and supplies, surgical and medical instruments, and electro-medical equipment. KARL STORZ, as a supplier of endoscopes, falls within the electro-medical subgroup, which makes up about 20% of the medical device industry. In recent decades the medical device industry has experienced growth as the industry has become more innovative and competitive. In 2012 the medical device market in the US accounted for 38% of the global medical market. The medical device manufacturing industry will continue to grow due to technological advances, the expansion of access to healthcare through legislative initiatives, and the improving economy. By 2020 the medical device manufacturing industry is expected to earn revenues of \$55 billion per year.

In this United States the medical device industry services the healthcare sector. Recently, the buyer power in this industry has changed due to consolidation efforts and physicians preferring employment from larger hospitals and healthcare organizations. Over the past few years, buyers of the medical device industry, specifically hospitals, have joined Group Purchasing Organizations (GPOs) to increase their purchasing power. GPOs will often enter into long term contracts with medical device providers which places pressure to lower medical equipment prices and to increase the use of preferred vendors. To differentiate themselves against other medical device manufacturers, companies need to adopt new and innovative marketing strategies.

Purchasing Market

Through discussion with customers in the market we found two categories of indicators to when a customer will purchase a new model of a product they currently own. The first indicator is if the new product has clinical evidence proving increased safety to their patients. The purchasing groups at hospitals will find funds for these new products so that it does not become an ethical dilemma of knowing a safer product is available while they continue to use the legacy product. The second purchasing indicator is outlined in the following two scenarios. The first scenario is that physicians will upgrade to a newer model if they attend a conference and other strongly regarded members of their field endorse the product. The second relates to private practices. Private practices get paid a set rate for the type of procedure, independent of the operating costs of their equipment. Often new models of medical devices have what they consider “novelty” improvements. The improvement may make the procedure slightly easier or faster, but the physician who owns the clinic needs to weigh the cost versus benefits, and may prefer to spend an extra thirty minutes performing the procedure to keep the larger profit margin. There are clearly improvements from the Legacy Gastroscope to the Silver Scope, but since there have been no randomized controlled clinical trials with the Silver Scope, KARL STORZ customer purchasing habits fall under the second category.

Financial Analysis

We conducted a financial analysis on the current repair processes within KARL STORZ for both the Legacy Gastroscope and the newer Silver Gastroscope. One major manufacturing difference between the two models is that the Silver Gastroscopes are manufactured in-house while the Legacy Gastroscopes are mainly outsourced and consist of pre-made assemblies. Our financial analysis is based on data for evaluations from the 2015 calendar year. Because of how often each of the repair levels is occurring, the Silver Gastroscope is cheaper on average per repair by a significant amount. We took how often each level of repair was occurring in a year and what the standard cost at each level was for that same year. Using this total repair cost for each year we found an average cost of repair overall, which proved to be significantly less for the Silver Gastroscopes than the Legacy Gastroscope. In 2015, the Legacy Gastroscope cost on average almost double the new model per repair.

It is our understanding that on the producer end, KARL STORZ is not affected by these cost differences because the customer is being billed for them, however it could be used as a sales model of sorts. Currently customers who are looking to have their Legacy Gastroscope repaired are informed about the newer model. We feel that it would be beneficial to show them how through repairs, customers could save a lot of money by upgrading to the newer model endoscope. We took some data from Beth Israel Deaconess Hospital in Needham, MA for our calculations. We found that on average they perform between 2600 and 3000 endoscopy procedures a year. We are also aware that they have about 25 endoscopes at all times in the hospital. Based on these numbers, we can assume that each endoscope is being used roughly 120 times in a year. Based on evaluation records from 2015, an endoscope tends to be sent in for repair roughly every 34 uses. This would mean that 4 times a year each endoscope is sent in for repair.

We recommend that KARL STORZ promotes the sale of their Silver Gastroscopes to existing Legacy Gastroscopes customers as the repair costs are lower on both ends since the repair and manufacturing are performed in-house. In addition to the repair costs alone, the Silver Gastroscopes being made in-house allows for a much more controlled and high impact reclaim process to be designed and implemented for the future.

Sales Strategy

While KARL STORZ begins to deplete inventory of the repair parts for the Legacy Gastroscope, we advise the sales team to begin discussions with current Legacy Gastroscope users about converting to the Silver Scope. The biggest push the sales team can use is the information previously discussed in the financial analysis. While the sales team can highlight the improvements made from the Legacy Gastroscope to the Silver Gastroscope, the biggest impact for customers will be the lower service cost. With all of the parts in house, KARL STORZ will be able to efficiently and more cost effectively repair the Silver Scope for their customers. The data suggests that due to this lower service cost per repair, upgrading from Legacy Gastrosopes to the new Silver Gastrosopes would allow customers to break even on their investment in approximately one and a half years.

Conclusion

As a company, KARL STORZ is in business to generate revenue and profit, so deciding when to force obsolescence with any product needs to be an economic decision. For GI endoscopes, the cost to service the product for customers increases as parts become more difficult and more expensive to acquire. We advise that KARL STORZ continue to service the Legacy Gastroscope while implementing our sales strategy until inventory of parts for repair depleted to levels unsustainable for endoscope service.