Proposal for an Innovative Disposable Endoscope in Partnership with Summed Taiwan in 2021

An Interactive Qualifying Project Proposal
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Abstract

Summed Taiwan is a venture capital company aiming to fulfill new unmet needs in the Taiwan medical industry. Disposable endoscopes are a new product with significant market potential, as they solve the cross-contamination issue for traditional reusable endoscopes. The goal of this project is to help Summed Taiwan design a new disposable endoscope product. To realize this goal, the research team carried out a content analysis on endoscope patents, conducted interviews with surgeons, and summarized findings through technical drawings and a patent map. The research team proposed recommendations to assist Summed Taiwan with designing a disposable endoscope.

Acknowledgment

The team would not be able to make it this far without the support from varied individuals in every bit of the past few months. We would like to take this chance to express our gratitude to everyone for their time and effort.

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Executive Summary

Introduction

Tens of millions of Americans undergo endoscopy every year, a surgical procedure that lets medical professionals see inside the human body using a device called an endoscope. An endoscope is a long, flexible tube with a light and camera attached at the end. Provided endoscopes are such a widely used medical instrument in our daily lives; their safety is of utmost importance. Multiple researches suggest that the use of conventional reusable endoscopes might result in bacterial cross-infection. In order to cope with the infection problem, Summed Taiwan, a medical supply venture capital company in Taiwan, proposed to develop a single-used disposable endoscope. The goal of the student research team is to assist Summed Taiwan in designing and inventing their new disposable endoscope.

Methodology

To complete the goal of this project, the research team set the following research objectives:

1. Identify gaps in the market of disposable endoscopes using patent visualization.
2. Verify the validity of modification to disposable endoscopes through interviews with surgeons.
3. Create a technical drawing to present the patent information.

Objective 1: Identify Gaps in the Market of Disposable Endoscopes

This objective is to identify gaps in the market of disposable endoscopes using patent visualization methods, including patent briefs and a patent map. Patent briefs are summaries of essential information for individual patients. And the patent map is a form where we lay out and organize all the patents. The team went through a total of 500 patents and converted them into patent briefs. All the patent briefs are categorized in a patent map.

Objective 2: Verify the validity of modification to disposable endoscopes through interviews with surgeons.

The second objective is to find a way to design a new disposable endoscope so that it is better than its competitors in terms of its camera and structure design. To achieve this objective,

the student researchers collected insights via one-on-one semi-structured interviews with surgeons, who have experience with reusable and disposable endoscopes. The team conducted interviews with two surgeons from Taiwan via the introduction from Summed Taiwan.

Objective 3: Create a technical drawing to present the patent information.

The third objective is to combine the data from objective 1, and summarize them in the form of a technical drawing. The technical drawing presents an endoscope structure with different parts highlighted in different colors. The sponsors could click on the color-coded parts and patents related to that endoscope part will appear. This is a more intuitive and interactive way for the team to present the patent information.

Key Findings

The key findings come from the patent research and the interviews with surgeons. For the patent research, the research team analyzed statistics of patents based on the patent briefs and the patent map. For the interviews, the research team identified features that make a good disposable endoscope and areas of an endoscopes for potential improvements.

Patent Research

The research team identified and analyzed the trend of patents for endoscopes based on their functionalities and technologies from the patent research.

Among 13 functionalities, the most popular ones are ease of operations and preventing infection/protection, with 102 and 88 patents representing each. For ease of operation, around 40% of patents have expired; for patents regarding preventing infection/protection, 46.6% are expired. From this statistic, it is apparent that many patents have already addressed the issue with infection and aimed to ease the process of operation from long ago, which serve as abundant references for Summed Taiwan. On the other hand, the least frequently used functionalities are high definition and stability, with only 12 and 7 patents representing them. However, only 1 and 0 patents have expired for each of these two functionalities. This can be explained through the small sample size, yet it also indicates a growing market for functionalities regarding these two fields. There is a growing need for vision quality and stability of disposable endoscopes, which provides an area of development for Summed Taiwan.

From 18 technologies, the most popular types are removable disposable parts and endoscopy supplement/accessories, with 96 and 45 patents representing each. Around 19.4% of patents for removable disposable parts have expired within these patients, and only 9.1% of patents have expired for endoscopy supplements/accessories. Although none of these technologies are for complete disposable endoscopic devices, they provide a direction for Summed Taiwan's designs. Both of these technologies have a large market, especially the removable disposable parts. Additionally, with many patents for these technologies, it becomes much easier for Summed Taiwan to learn about them. Meanwhile, handle/stand/hold, and data display are the least frequently technologies, with only 9 and 4 patents representing them. This suggests a gap in the market.

Interviews

The research team identified essential features for designing a good disposable endoscope and surgeons' concerns with disposable endoscopes from the two interviews conducted with surgeons from different fields.

The essential features include greater flexibility, improved vision, and ease of operating treatments. Endoscopes are inserted into human bodies for inspection and other medical treatment when necessary. Hence, it is vital for an endoscope to be flexible when inserted into human orifices. However, when an endoscope is too flexible, it does not have the rigidity to support the body of an endoscope. Hence, finding a balance between softness and rigidity for endoscopes is an important part of a design. Disposable endoscopes are usually made of cheap materials, which sacrifices the vision quality. Therefore, an improved vision becomes an inevitable feature for designing a successful disposable endoscope. Last but not least, surgeons expressed that they were more prone to use disposable endoscopes during medical treatment as opposed to regular body examinations, where the infection is less of a concern. Thus, Summed Taiwan must consider the ease of operation for a variety of endoscopic procedures.

Apart from these features, the surgeons expressed their concerns with disposable endoscopes, which concludes with the usability and costs of a disposable endoscope. Both surgeons have disappointing experiences with disposable endoscopes in terms of their flexibility. It is mainly because there is hardly a balance between softness and rigidity for endoscopes that they have used. They can be too thick and stiff, which causes unnecessary injuries to patients.

Alternatively, they are too thin and soft that they do not allow for the insertion of medical supplies. Additionally, they were not looking forward to replacing reusable endoscopes with disposable ones in regular body examinations, as they did not consider it necessary due to common concerns with infection. Another concern comes with the cost. Some endoscopes, such as a ureteroscope, have a short lifespan with a maximum 10 times of usage. This causes a higher price for disposable endoscopes compared to reusable ones for each use. Additionally, the health insurance in Taiwan does not cover the usage of a disposable endoscope, which makes it even harder to adopt the product within Taiwan widely.

Recommendation

Based on the findings of our research, we propose the following recommendations:

1. Improve flexibility of endoscopes by using a multi-lumen probe made of silicone rubber or polyurethane materials. The patents for references are US8333691B2 and US10307042B2.
2. Improve vision quality of disposable endoscopes through three approaches:
    a. Use a fiber optical system to improve the brightness, refraction, and transmission of lights. US9901256B2 is an example patent for this technology.
    b. Design a disposable endoscope sheath made of transparent, innovative polyurethane materials to help reduce infection while maintaining the same view quality. Patent CN211933972U discloses details for this technology.
    c. Create a controlling pressure system that can monitor and control the pressure inside human bodies during endoscopic procedures to reduce the interference of patients' secretions on visual qualities. US9301796B2 details a system for cryosurgeries.
3. Ease operations for a variety of treatments. The patents vary for the type of endoscopic treatment, so it is hard to summarize standard technologies among different types of treatment. To assist Summed Taiwan with designing one specific disposable endoscope, the research team identified three types of treatments with patents representing them. Summed Taiwan can make their choice of treatment based on the following list:
    a. Simple surgeries: US10932771B2 (suturing device), US10820905B2 (ligation surgeries);

b. Extraction: CN204618305U (suction lumens), US10307042B2 (distal end with biopsy forceps);
c. Substance delivery/irrigation: US5176629A (special needling design), US9301796B2 (pressure control system).

4. Fill the gaps inside the patent map. Following are suggestions for potential designs based on blank cells from the patent map:
    a. Functionality:
        i. Portability:
            1. Smaller proximal end;
            2. Smaller working joint.
        ii. Increasing Patient Quality of Life:
            1. Low-friction tubing;
            2. Use of antimicrobial parts.
    b. Technology:
        i. Sensors:
            1. Pressure sensor;
            2. Gyroscopic sensor.
        ii. Handle:
            1. Handle that conforms to the hand of the doctor;
            2. Built-in battery.

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1. Introduction

Tens of millions of Americans undergo an endoscopy every year, a surgical procedure that lets medical professionals see inside the human body using a device called an endoscope. An endoscope is a long, flexible tube with a light and camera attached at the end. It is used as an investigative tool and for taking biopsies during surgery or endoscopy. Although the terminology may sound alien, it is not uncommon in daily lives. As reported by Joseph et al., 15 million patients underwent colonoscopies in 2012, in addition to other endoscopic procedures (2016). Because endoscopes are so widely used, their safety is of utmost importance. It has become apparent that endoscopies can sometimes cause infection, which should cause concern for patients, medical professionals, and endoscope manufacturers alike.

Conventional endoscopes are reusable and must be cleaned meticulously after each use. However, research suggests that bacterial infection still occurs even with correct procedures for cleaning and reprocessing. Therefore, scientists are exploring disposable endoscopes as an alternative to traditional endoscopes. The implementation of single-use endoscopes entirely avoids the issue of infection caused by reusing endoscopes. Though disposable endoscopes have not been widely adopted worldwide, the market size is expected to grow (*Disposable Endoscopes Market Size Report, 2020*). Companies like Ambu and Boston Scientific are pioneers in this area. As a venture capital company that focuses on investing in medical supplies in Taiwan, Summed Taiwan is taking initiatives to design and bring a new disposable endoscope to the global market that improves the design of its competitors. This proposal aims to assist Summed Taiwan in its venture to design a new disposable endoscope.

One of the first steps in creating any new product is to understand what has been made before. Patent research is an important way of doing this, and it is crucial for two key reasons. Firstly, by taking stock of all patents similar to an idea, the inventor can avoid making the exact same product as someone else, thereby avoid falling into legal trouble. Secondly, patent research can expose possibilities that have not been thought of before. By carefully organizing a large sample of patients, a researcher can find gaps that no patent has ever filled. Summed Taiwan intends to market a new disposable endoscope in the future, and through this project, the team has helped them by doing patent research to explore what has come before.

Learning from experts in the field is another way to gain insider knowledge when designing a new product. The research team has interviewed people who use endoscopes daily, such as gastroenterologists, urologists, and surgeons. They have gained important insights from these interviews from a user's perspective and incorporated them into their recommendations for Summed Taiwan. They have also made a technical drawing to present the research data in a more interactive way.

In summary, this project aims to assist Summed Taiwan in designing and inventing a new disposable endoscope to reduce infections. To do this, the project team will search for a large sample of patents related to disposable endoscopes and conveniently visualize them to provide insights to Summed Taiwan. They will also conduct interviews with surgeons and medical device company representatives to gain critical insights and develop ways to modify existing endoscope designs.

2. Literature review

2.1 Summed Taiwan

The project's sponsor, Summed Taiwan, is a venture capital company that focuses on investing in medical supply companies in Taiwan. It aims to support projects that fulfill new unmet needs in the Taiwan medical scene. To identify unmet needs, Summed Taiwan hosts a seminar called the Unmet Need Club, which hosts medical professionals worldwide to let them share their thoughts.

The motif that supports Summed Taiwan's vision is to bring the Taiwanese medical scene out of their comfort zones. Taiwan is a global hub of medical supply manufacturing and trade, but Summed Taiwan believes that the Taiwanese medical industry has a much greater potential. To bring the region to new heights, there is a need for more indigenous ideas coming from local businesses. Until now, Summed Taiwan has successfully invested in five medical supply firms and is actively looking for new opportunities.

Through previous research, Summed Taiwan has determined an unmet need for disposable endoscopes both in the Taiwanese medical scene and all around the world. Summed Taiwan concluded that Taiwan has adequate technology to develop a disposable endoscope product, and there is a growing demand for disposable endoscopes in the global medical supply business. However, Summed Taiwan is not the only company aiming for this market. There are competitor companies such as Ambu and Boston Scientific that have disposable endoscopes under development. Now, Summed Taiwan is in the early stages of developing their own disposable endoscope, mainly focusing on research and design.

To understand why Summed Taiwan wants to make a disposable endoscope, and how the project will support them, we first describe what endoscopes are and the problem with reusable endoscopes.

2.2 Introduction to Endoscopes

An endoscope is a medical device that is used to take images of internals during surgeries and procedures called endoscopies. They consist of a long, flexible tube with a light and a small

camera at the end that feeds live video to the surgeon. The tube is fed into an orifice, such as the mouth, and directionally controlled by a remote mechanism. Endoscopes are used in many types of procedures, including colonoscopies, ureteroscopies, bronchoscopies, and laparoscopic surgeries. Most endoscopes used today are reusable, meaning no part of it is discarded, and it must undergo an extremely thorough cleaning after each use.

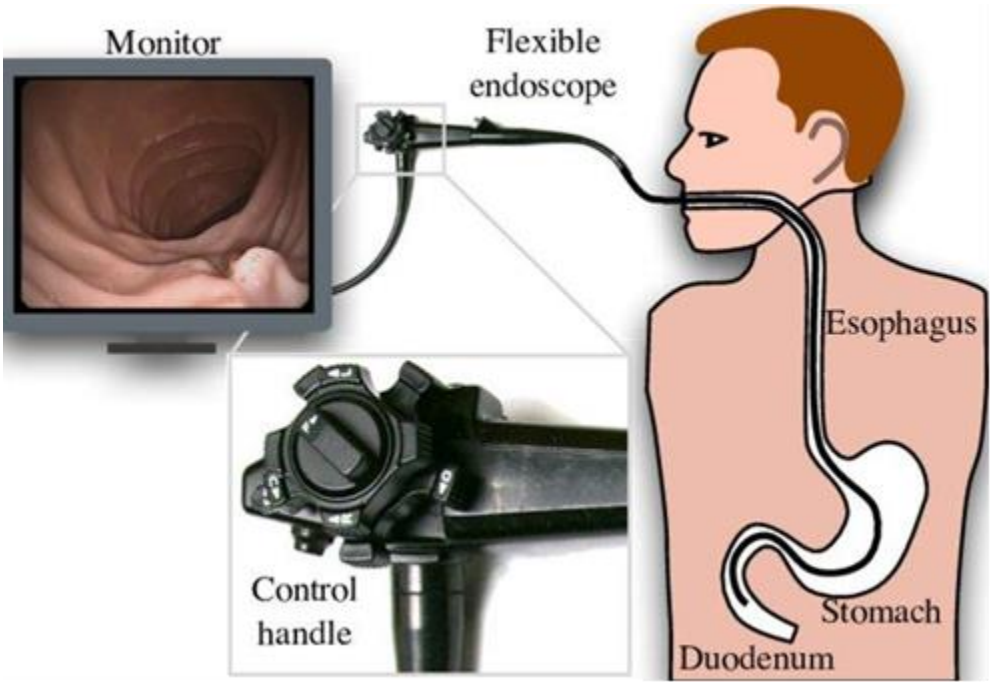

Figure 1. A demonstration of Traditional Endoscopy (Stramigioli, 2010).

2.2.1 Infections Related to Reusable Endoscopes

Bacterial infections linked to endoscopes have been increasingly documented in the last ten years. In 2013, the CDC (Centers for Disease Control and Prevention) alerted the FDA (US Food and Drug Administration) that a link had been found between multi-drug resistant bacterial infections and duodenoscopes ("Infections Associated with Reprocessed Duodenoscopes", FDA, 2021). Duodenoscopes are a specific type of endoscope that is inserted down the throat and past the stomach into the top of the small intestine (the duodenum). According to the FDA, these infections occurred despite proper adherence to cleaning protocols. They have been active in enacting policy intended to protect the public from further infections, and engaging manufacturers to improve device design.

Numerous examples of outbreaks connected to a variety of types of endoscopic procedures have been documented. A study from the Netherlands provides one such example. After rising cases of multi-drug resistant infections across Europe and the US, researchers sampled hundreds of duodenoscopes across the Netherlands to test for contaminants. 22% of duodenoscopes from 39% of locations were contaminated, indicating that the disinfection procedures at those locations were not sufficient to remove all bacteria (Rauwers et al., 2018). Also, 15% of the endoscopes tested had gastrointestinal bacteria on them, which could only have come from previous patients. These bacteria are especially dangerous (Rauwers et al., 2018). Another study conducted in the US found that 71% of endoscopes tested had microbes on them, even after proper cleaning, drying, and storage (Ofstead et al., 2018). The increasing prevalence of infections spread patient-to-patient by endoscopes represents a danger to patients and medical professionals alike. By ignoring this issue, hospitals may be opening themselves up to malpractice lawsuits. This should concern doctors as well, as it could be argued that the neglect of the problem would violate the Hippocratic Oath of "Do no harm."

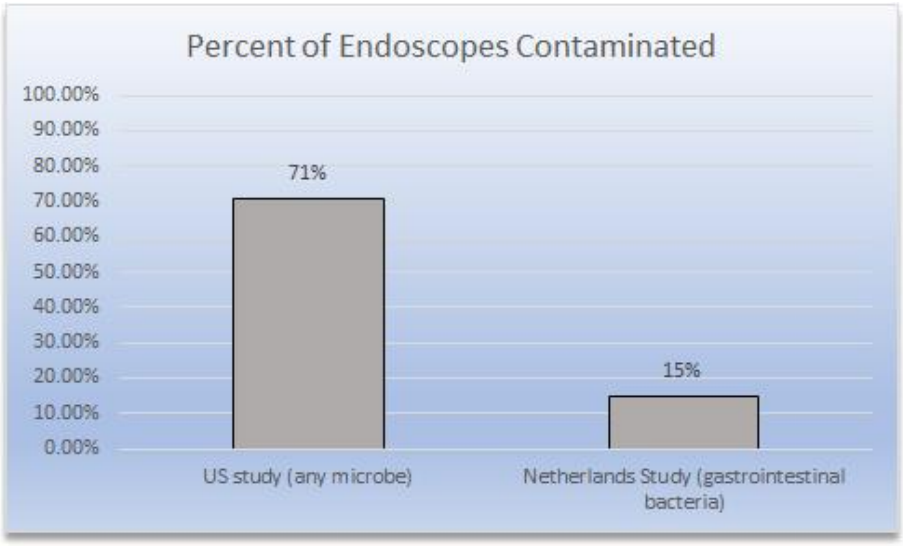

Figure 2. Percentage of cleaned endoscopes that were contaminated according to two studies (Rauwers et al., 2018), (Ofstead et al., 2018).

No cases of viral infection have been linked to endoscopes, including infections of Sars-Cov2 (Chua et al., 2020). However, multi-drug resistant bacteria pose an equally serious threat, as there have been deaths associated with endoscope-transmitted bacterial infections (Rauwers et

al., 2018). Bacteria have a high mutation rate that allows them to develop resistance to specific antibiotics by chance. When a drug is administered to a patient with an infection, only the microbes with mutations that confer resistance survive. These cells then multiply, essentially accelerating evolution by selection. This means that multi-drug resistant infections are very difficult to treat and can be extremely serious, even fatal because few or no antibiotics available can effectively treat the infection.

Bacterial infections have been linked to a diverse set of endoscopic procedures and types of endoscopes, including duodenoscopes and ureteroscopes. Some evidence suggests that insufficient drying of endoscopes could be a factor, but it is likely that there are many more complicated factors at play (Ofstead et al., 2018). It is also possible that instrument age, which brings normal wear and tears, could be an issue. As endoscopes are kept in a hospital's rotation for a long time, they can develop small scratches, where bacteria may be kept hidden from cleaning procedures. They can also stretch or tear in hard-to-reach places, making reprocessing less effective (Kumarage et al., 2019). In the fight against infections caused by endoscopes, it is clear that the procedures medical professionals use to clean their tools between patients must be done with vigilance and care. Additionally, procedures and cleaning equipment need innovative improvements whenever possible.

2.2.2 The Parts of an Endoscope

There are many different types of endoscopes, though they all include a set of key components. These components generally consist of a camera and LED light, a catheter or tube to enter the body, a lens nozzle, and some wires and other hardware to hold the endoscope together and transmit video and other signals. A typical disposable endoscope, according to one developed in partnership with Vanderbilt University, costs totals around $35 (Garbin et al., 2019). However, this price based on a large-scale production is not representative of all endoscopes, especially the ones with more capabilities.

The conventional duodenoscope costs around $35,000, in addition to maintenance and repair, which totals around an additional $1,500 per endoscope (Travis & Ehlers, 2020). These higher costs are attributed to a higher quality of materials, testing, overall ease of use, and much-increased performance. However, for the disposable counterpart of this duodenoscope, it would cost around $800 for large medical centers (Bang et al., 2019). This is why it is important to be

mindful of what type of endoscope is being produced, as they are not all created equal. There are many different types that can dramatically increase the cost and subsequently change the parts going into it. In most cases, disposable endoscopes are preferred because of their slow costs and ability to reduce infection rate while obtaining the same effect as reusable ones (England et al., 2020; Ciocîrlan, 2019; Garbin et al., 2019).

2.3 Disposable Endoscopes

Disposable endoscopes are a type of endoscope that cannot be reused. They have the same elements and functionality as conventional endoscopes, yet they have a better capability of controlling hospital-acquired infections compared to traditional ones. Just like all reusable endoscopes, disposable ones can inspect and manipulate internal organs through natural or man-made orifices for medical purposes. Meanwhile, due to their disposable nature, they can avoid cross-contamination that might occur using conventional endoscopes. In fact, disposable endoscopes have become more and more popular in the past decade, especially in European and North American hospitals.

Figure 3: A Disposable endoscope model by Boston Scientific (2021).

2.3.1 Attributes of Disposable Endoscopes

In 2017, the Food and Drug Administration (FDA) announced the clearance of the first disposable sinoscope, a type of endoscope, for use; in 2019, the FDA approved the use of disposable duodenoscope for the first time; and in 2021, the FDA announced the clearance of most disposable endoscopes in the market. In fact, in August 2019, the FDA recommended hospitals and other facilities replace reusable endoscopes with their single-use counterparts (*Disposable Endoscopes Market Size Report, 2020*). Ever since traditional endoscopes have gradually shifted to disposable endoscopes. Obviously, countries with higher technology advancement are more conveniently able to adapt to these new products, such as the US, European countries, and China.

Some large companies that produce disposable endoscopes include Ambu from Denmark; Lumenis-Polyscope from Germany; and Boston Scientific, Maxiflex, and Verathon from the United States. These companies primarily design and produce disposable ureteroscopes, bronchoscopes, and duodenoscopes. Each of these endoscopes has their own purpose and are especially easy to make disposable, as they are less fragile than other types of endoscopes.

According to Disposable Endoscopes Market Size Report, disposable endoscopes prospects are bright. The global disposable endoscopes market size was valued at $1.03 billion in 2019 and is expected to exceed 3 billion dollars by 2027. With the increasing infection rate during endoscopic surgeries caused by poor endoscope reprocessing, this figure is not surprising. Though North America has dominated the disposable endoscopes market, there is evidence that the Asia Pacific will take the lead in the next ten years (Disposable Endoscopes Market Size Report, 2020). As reported by the Open Journal of Obstetrics and Gynecology, health-related infections are twenty times higher in developing countries compared to developed countries (Sahiledengle et al., 2020). This will urge developing countries to adopt disposable endoscopes to improve patient experiences and decrease infection rates. Thus, Summed Taiwan is willing to take initiatives regarding this issue.

2.3.2 Usability of Disposable Endoscopes

Surgeons may be concerned about whether or not a disposable endoscope is as effective as a reusable one. However, through ample testing by research and its corresponding feedback,

studies have shown that there is no difference in performance between the two types of endoscopes (England et al., 2020; Ciocîrlan, 2019; Garbin et al., 2019).

Various tests have been done to examine the usability and effectiveness of reusable versus disposable endoscopes. In a test conducted by Vanderbilt University, participants were tasked to use each type of endoscope to find gastric landmarks within a specific time frame and correctly identify them (Garbin et al., 2019). All participants successfully completed the task without any struggle. Another study examined the performance of disposable endoscopes compared to conventional ones in terms of ease of use, performance, and irrigation flow (England et al., 2020). The result of this testing was that disposable endoscopes performed better than their reusable counterparts, though, for both, the video output was comparable.

In addition to their effectiveness, disposable endoscopes are much more affordable than reusable endoscopes. A conventional endoscope can cost from $20,000 to $200,000, not counting the costs for reprocessing and training (Ciocîrlan, 2019). In fact, each training for reprocessing a reusable endoscope can cost around $140 to $280. Conversely, disposable endoscopes cost as low as $35 and do not exceed $350 per device. They do not require reprocessing or continuous training after use, which further lowers cost. Some special types of endoscopes, such as disposable duodenoscopes, can have a higher price, but most common disposable endoscopes appear to be economical.

2.3.3 Environmental Concerns Regarding Disposable Endoscopes

Although disposable endoscopes have proven to be an effective and economical alternative to reusable ones, their potential environmental impact must be taken into account before their implementation. As a medical supply, disposable endoscopes are considered to be biohazards; as a single-use product, disposable endoscopes contribute to plastic waste. When designing a new disposable endoscope, these problems must be considered in order to make a safe and environmentally friendly product.

Endoscopes usually make direct contact with the patients' organs. As a result, disposed of endoscopes are identified as a type of medical waste (Luken, 1998). Such medical wastes cause pollution and health risks if hospitals do not treat them correctly. Untreated endoscopes can contain contagious bacteria from patients who can transfer diseases. They can also contaminate the landfill and further pollute nearby soil and water sources. In fact, there is 3.26kg of medical

waste generated per bed per day in Taiwan. The medical wastes need to be processed and transported to a certain location where they can be disposed of safely (Windfeld et al., 2015). Making an important piece of medical equipment disposable simply adds to the cost and waste generated by a hospital. This cost to dispose of medical waste would be a more severe problem in the less developed part of the world.

Additionally, widely adopting disposable endoscopes can exert great pressure upon the already stressful environmental status. Disposable endoscopes are mostly composed of durable metals and plastic connectors. Durable metals can be recycled after proper cleaning, whereas plastic connectors become part of the plastic waste. In most cases, the plastic connectors may not be replaced by durable metals, sometimes due to material incompatibility and sometimes because of the high cost of durable metals (Rutala et al., 1991). Since disposable endoscopes have not been widely adopted, there is little information available regarding the plastic waste resulting from disposable endoscopes. Nevertheless, the environmental impact of 169,000 to 389,000 disposable duodenoscopes serves as a reference (Elta & Law, 2020). Hence, as disposable endoscopes become more and more popular, the plastic waste resulting from them will be an especially concerning aspect regarding environmental impact.

2.4 Patents

The idea of a product itself is considered intellectual property, and patent laws exist to protect intellectual property from theft. Although details regarding patent laws vary between countries, patents always work as certifications that give the owners of the patents the right to exclude others from making a profit. It is vital for any investor to be aware of patents, not only to protect their own ideas but also to prevent themselves from violating others' intellectual property rights.

2.4.1 Patent Infringement

Patent Infringement, defined by the United States Code 35, occurs when whoever without authority makes, uses, offers to sell, or sells any patented invention. Government institutions are responsible for overseeing the market and enforcing regulations to prevent entities from committing patent infringement. In the US, the institution is named the United States Patent and Trademark Office. If a company infringes a patent, they are required to provide remedies to the

damage caused by their misdeed. In other words, the company would pay a large fine to settle the lawsuit. For example, Samsung was ordered, after a 7-year legal fight, to pay Apple $539 million for infringing Apple's patents (Nicas, 2018). A company's failure to provide a remedy would be evidence of a lack of good faith in the court, which could lead to even more severe legal consequences. As a result, businesses cannot afford to steal intellectual property by plagiarism, and they also hire patent attorney groups to help them avoid any possibilities for infringement.

2.4.2 Applying for Patents

The following steps for applying for patents are based on the United States patent law, and all information as such was sourced from the *Patent Process Overview*.

The first part of the process of applying for a patent is determining the intellectual property that one possesses. This would entail assessing whether one needs a patent for their product or idea in the first place. Following this step, one would need to determine if their intellectual property is patentable. This depends on whether the idea is an improvement on something that currently exists and whether it is claimed by the inventor in very clear and definite terms. One cannot patent abstract ideas, laws, or events that occur naturally in real life, past works of art, and inventions that serve no purpose. Following this, one must check if there already is a patent for the product or idea that they have. It is highly advisable that one has an attorney or agent when performing patent searches to prevent any lawsuits in the future.

Once one has determined that they can file a patent for their product or idea, they must then determine what type of patent they need. The three types of patents are utility, design, and plant. Utility patents are for people that invent or discover a new and useful process or the machine or improvement of such. Design patents are for people that invent an original design for manufacturing. Plant patents are for new breeds or new types of genetically modified plants. For this research, Summed Taiwan is seeking to apply for a design patent. After determining what type of patent one needs, it is now time to apply for the patent.

Applying for a patent costs money and takes time to process, and both depend on what type of patent is being applied for. Again, it is advisable that one has an attorney or agent for this process. Once the application is submitted, it will undergo examination, following which it will be deemed completed. It is at this point that an application can be either approved or rejected. If

the patent is rejected, the applicant can make changes to it to comply with patent law. If the patent is approved, the applicant then pays a publication fee and an issue fee, and then the patent gets published.

2.4.3 Prior Arts of Disposable Endoscopes

To respond to the increasing endoscope-related infection rate in Taiwan, Summed Taiwan decided to invent new disposable endoscopes. However, before applying for patents, it is important for Summed Taiwan to be aware of the prior arts of disposable endoscopes. Prior arts of an invention are any previous inventions similar or related to it. In this case, the prior arts of disposable endoscopes will be all disposable endoscopes accessible at present. Without careful research on prior arts, the patent application for the disposable endoscope invented by Summed Taiwan will be rejected. In worse scenarios, this invention may cause serious lawsuits for them regarding patent infringements.

2.5 Gaps in the literature

Throughout the literature review, the student researchers built up an understanding of the background knowledge related to traditional and disposable endoscopes along with their respective patents. It is apparent that the transition from reusable to disposable endoscopes is feasible and would increase safety in surgical sites. However, the team also found several problems that the articles failed to address.

First and foremost, there is an enormous amount of literature in online databases regarding disposable endoscopes. The student researchers, given a limited scope, could only conclude the literature they reviewed.

From the reviewed literature, the team concluded that there is minimal information that acts as a road map when designing a disposable endoscope product. Those road maps could be design details for disposable endoscope products in the market or patents related to disposable endoscopes. The literature regarding disposable endoscopes usually provides more high-level explanations. So the literature review could hardly give the team any practical guidance in design. Another gap from the literature is the limited amount of qualitative data regarding disposable endoscopes. Since it is a relatively new product, there is little in-depth information about its feasibility in endoscopies, including personal experiences from both surgeons and

patients. Without these qualitative data, it is difficult to improve the design of endoscopes and discover potential modifications. This project aims to address these gaps.

2.6 Summary: Research Goals and Objectives

The mission of this IQP project was to help Summed Taiwan design a new disposable endoscope product. To achieve this, the student researchers planned to carry out research to address the literature gaps.

The first research objective was to carry out patent research to analyze existing patents of disposable endoscopes. The student researchers collected a large amount of patent data to help them understand the mechanics behind disposable endoscopes. In addition, the team composed a database, or patent map, which categorizes the patent information. Summed Taiwan could use this list to identify the scope of their product without the risk of patent infringement. The second objective was to identify potential improvements or modifications to implement in the disposable endoscope. The researchers conducted a semi-structured interview with surgeons experienced in endoscopy. Through the interview, the team collected qualitative data and learned about the details of an endoscope to propose potential modifications. Optimal user experience is the key to a successful product. So, the interview data can improve the user experience of Summed Taiwan's disposable endoscope and further distinguish it from its competitors in the market.

After data collection, the team analyzed their data and concluded their findings. At the end of the project term, the team presented their findings and recommendations to Summed Taiwan to help them make informed decisions when designing their disposable endoscope. These recommendations included improvements in tubing material, optical lens with a liquid light guide, and cutting down costs.

3. Methodology

3.1 Introduction

The mission of this project is to help Summed Taiwan with designing a new disposable endoscope. To accomplish this, the student investigators, together with Summed Taiwan, identified three objectives for this research:

1. Identify gaps in the market of disposable endoscopes through patent research.
2. Verify the validity of modification to disposable endoscopes through interviews with surgeons.
3. Create a technical drawing to present our data.

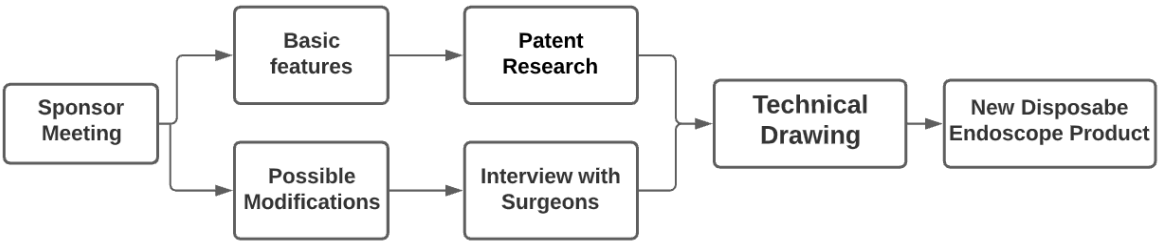

Figure 4. An overview of the data collection strategy.

The sections following this discuss each objective in detail and present the method that the project team planned to achieve them.

3.2 Objective 1: Identify Gaps in the Market of Disposable Endoscopes

The first objective would allow Summed Taiwan to get inspiration for their commercial implementation of a disposable endoscope based on existing patents. This objective is to identify gaps in the market of disposable endoscopes using patent visualization methods, including patent briefs and a patent map. Patent briefs are summaries of key information for individual patients. The patent briefs are useful when any stakeholders want to go through a patent they are interested in quickly. Furthermore, the patent map is a form where the researchers lay out all the

patents. This serves the purpose of both classifying and visualizing the patent information. The team stored the data in a shared google drive folder.

The researchers conducted content analysis by searching for all kinds of patents regarding disposable or even reusable endoscopes. Moreover, the team would highlight every not expired patent to prevent potential patent infringement. This data collection process would provide the team with fundamentals on endoscopes knowledge, which would be helpful when analyzing future data.

3.2.1 Data Collection Design: Patent Research

Patent research will consist of the collection of patents regarding disposable endoscopes, especially patents that are expired or are soon going to expire. The project team mainly used Google Patents and Patent Cloud to perform content analysis of at least 500 eligible patents. After discussing with our sponsor, the team settled down with the number of 500 patents, as it allows the researchers to have a thorough understanding of disposable endoscopes. Among these, Google Patents was the primary database throughout the research. It stores information on registered patents around the world. Summed Taiwan also recommends Patent Cloud as a secondary database for particular research on patents from Taiwan. Apart from these two, other platforms, such as WPI Library, European patent office, Indian patent office, and Japan patent office, also provide much information on patents, and may be used throughout the research. These smaller platforms are useful when the team want to research patents in a specific country. The team planned to turn to the platform above if we feel Google Patent cannot provide enough information. The team ended up only using Google Patent as a database as it contains sufficient patent information for the research.

All these databases support search with filters. Therefore, the research team applied appropriate filters to find the information that is desired. These filters included expiration dates, patent type, as well as the location for the publication of each patent. The strategy of how to apply these filters is called Boolean strategy. To aid the search of databases, Summed Taiwan has shared a list of patents related to disposable endoscopes that the project team utilized. Based on the list of patents, the team compose a Boolean strategy to search for more patents.

3.2.2 Content Analysis Design

All the patent information collected would be stored in a format of patent brief. A patent brief is a shortened version of a patent document which contains key information. Along with the patent title and its serial number, a patent brief must also include a patent claim. A patent claim contains key words that define the scope of that patent. Figure 5 demonstrates an example of extracting key information from a patent. Reading a patent brief would be one of the quickest ways to study on a patent. The student researchers made a patent brief for every single patent they feel useful. The patent briefs, together, form a database the researchers can refer to in the future.

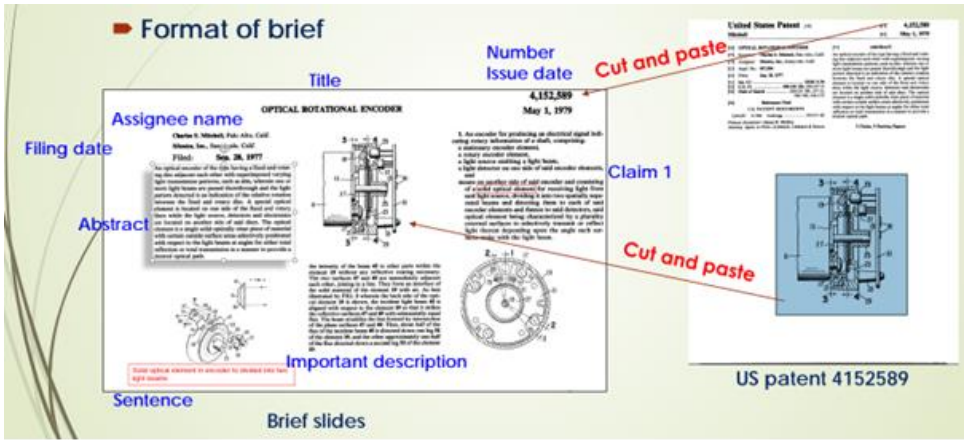

Figure 5. An example of a patent brief provided by Summed Taiwan.

After finishing every patent brief, the next step is to build a platform that acts as a quick catalog for them. That platform is the patent map. A patent map is a collection of patent numbers, sorted by their functions and technologies. Each patent number corresponds to a patent brief. For example, figure 6 shows a patent map for different patents of chairs. The columns stand for the key function of each chair, such as mobility and support; the rows stand for special technologies used by each chair, such as mobile parts or flexible material. The patent numbers in the patent map are in the form of hyperlinks, which lead to its corresponding patent brief. In this way, the researchers could quickly access the patent brief to gain details of each patent number. The patent map helps researchers navigate through patent information easily and efficiently.

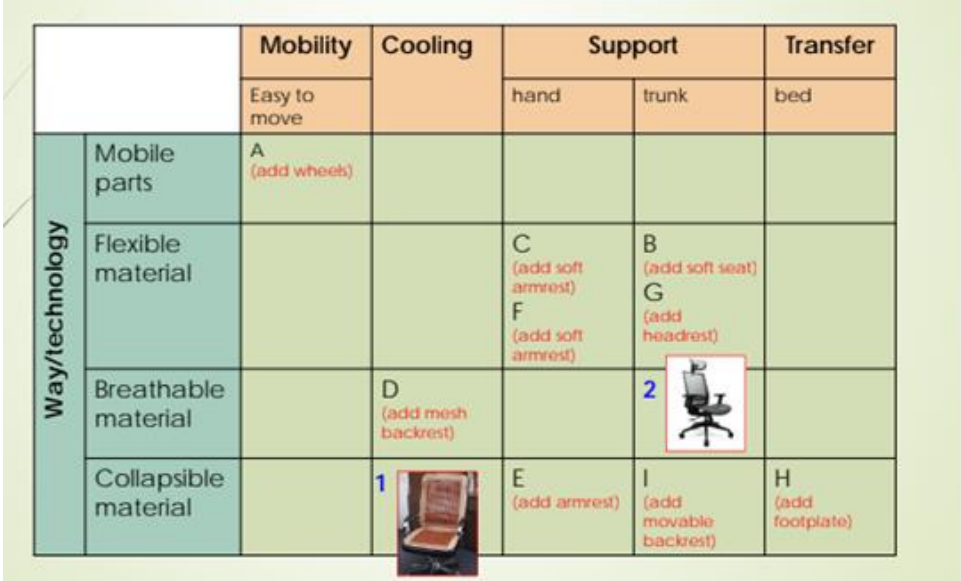

Figure 6. An example of a patent map provided by Summed Taiwan.

3.2.3 Challenges

One of the main challenges that the researchers have regarding this objective is the sheer number of patents available on search engines that may be difficult to sift through. To tackle this challenge, the research team evenly divided 500 patents (the targeted number of patents in patent research) among four team members. That said, each team member were responsible for researching 167 patents within the time frame. During their research, they were responsible for completing patent briefs and filling out the patent map for each patent researched. In addition, the process of composing patent briefs was also much more time-consuming than the team estimated. At the early stages for the patent research, student researchers struggled a lot at creating patent briefs. The time for completing each patent brief and filling it into the patent map was around 10 minutes, which made the target of 500 patent briefs seem impossible. Luckily, the team became more experienced and improved their workflow as they proceed the patent research, and finished their objectives on time.

Another challenge in the research was to correctly identify the technologies and functions of each patent. To successfully design a feasible disposable endoscope from prior arts, it is vital to articulate the basic features and functions of each patent. Hence, the research team asked for confirmation from Summed Taiwan for each function and technology identified. This successfully avoided mistakes while analyzing data. Still, the research team moved

a lot of the technologies and functions back and forth to make the categories more detailed and reasonable.

3.3 Objective 2: Verify Validity of Possible Modifications

Proper execution of the first objective directly tied into the completion of the second objective. The second objective was to find a way to design a new disposable endoscope so that it is better than its competitors in terms of its camera and structure design. To achieve this objective, the student researchers collected insights via one-on-one semi-structured interviews with surgeons, who have experience with endoscopes and even disposable endoscopes. Through these interviews, the researchers gained an inside perspective from people who use endoscopes daily, and this perspective informed possible improvements to existing designs. It would also be advantageous to research current patents to see what current innovations people are developing to identify common areas of innovation for disposable endoscopes.

3.3.1 Interview Design

The surgeons that the project team reached out to were from St. Vincent Hospital and other hospitals based in Worcester, Massachusetts. The team also used connections from their sponsors to conduct interviews with surgeons from Taiwan. Two members in the project team are fluent in Mandarin and were able to conduct the interviews in Mandarin for convenience. To reach surgeons from St. Vincent Hospital and the surrounding area, cold calling was used to reach out with no avail unfortunately. Additionally, contact was also made with Worcester Polytechnic Institute alumni at Boston Scientific, however, due to their non-compete agreement and the nature of the team's project, an interview could not take place.

The student researchers used Zoom as a data collection tool for the interviews. During each interview, one project team member served as an interviewer, and another as a note taker. It is anticipated that about two to three surgeons will be reached for interviews lasting for thirty minutes.

The purpose for the interviews was to gain an insider's opinions and insights on disposable endoscopes. Knowledge gained from the first objective enabled the team to craft strategic questions used during the one-on-one interviews. Some examples of the types of questions that may be used during the interviews can be found in Appendix 1.

Preceding this interview, the project team became knowledgeable of all the basic parts of endoscopes and how they work in daily practice in order to fulfill the requirements of this proposal for Summed Taiwan.

3.3.2 Data Analysis

As mentioned previously, Zoom will be used for conducting the one-on-one interviews, and they will be recorded using the same software. After each interview, the project team will use the transcription feature via Zoom to transcribe to English. Additionally, one team member will take notes during all the interviews. Even after using Zoom transcription, the project team will watch the recordings to ensure no verbal contents are missing from the audio to the transcripts.

In addition to processing the transcripts from the interviews, the project team will locate possible themes that may arise from the conversations about patents to see where innovations are being made in new endoscopic technology.

3.3.3 Challenges

The first limitation of the interview design stems from the limited availability of the surgeons. Indeed, the research team aimed to target surgeons with endoscope experience, such as urologists or gastrologists, but it was difficult to find enough surgeons who are willing to take time out of their schedule to participate in an unpaid interview. In fact, the team only managed to interview two surgeons from Taiwan through Summed Taiwan's connections. The surgeons from St. Vincent Hospital in Worcester did not respond upon the request for interviews. To tackle this, the project team turned to the Biomedical Engineering (BME) department at WPI, who had connections with alumni that have experiences with endoscopes. After the research team reached out to the BME department, its head provided the team with contact information from two colleagues working at Boston Scientific. One of them responded with his inability to conduct the interview due to the non-compete agreement, whereas the other did not respond.

Another limitation that concerned the project team was the incapability of determining trends in endoscope innovation. It became more apparent as the project proceeded, yet the research team had limited knowledge to propose potential trends during the interviews. To tackle this, the team enumerated related patents to the surgeons during the interview. Additionally, the

team carefully listened to and took notes of surgeons' concerns for endoscopes and their suggestions on designing a more successful disposable endoscope. As a result, though the team was unable to provide potential modifications to disposable endoscopes during the interview, they gained insights by actively providing relevant information throughout the interview and thoroughly analyzing the contents after the interview. Finally, the team was able to determine potential trends for disposable endoscopes as one of the deliverables.

3.4: Objective 3: Create a Technical Drawing for a Disposable Endoscope

Initially, the research team aimed to create a computer-aided design (CAD) model for a disposable endoscope. However, it appeared that none of the team members was skilled enough to create a professional CAD model. Hence, the team came up with the idea of a technical drawing, which would color-code each component of a conventional endoscope, and link relevant patents to them.

3.4.1 Initial Drawing Outline

The deliverable for this part of the objective was a PDF with color-coded components of a conventional endoscope. The team identified these components through their analysis on the patent research. These components included proximal end, handle, working channel, sheath, bending joint, distal end, and camera. All of these components had relevant patents describing specific technologies and functions, which were linked to each component with different colors. Chapter 4.4 detailed this deliverable.

3.4.2 Challenges

One obstacle for creating a technical drawing was the choice of the endoscopic model. There are different types of endoscopes that have different functionalities and technologies based on their purposes for endoscopic procedures. Summed Taiwan did not specify a type of endoscope to design, which made it harder for the research team to find a model. In order to generalize the results in the technical drawing, the research team first identified the components common to all endoscopes, then utilized a basic model for an endoscope with all these components. The team only highlighted the components that were common to all endoscopes and

left the other parts blank. By looking at this drawing, Summed Taiwan will be able to decide on potential modifications specific to one type of endoscope, with the foundation of innovative designs for common components of a disposable endoscope.

3.5 Ethics

This research proposal is of minimal risk, and a crucial part of the ethical practice of a research is the protection of participants. Firstly, this study has been approved by the Worcester Polytechnic Institute Institutional Review Board (IRB) for the Rights of Human Participants in Research and Training Programs. The project team or student investigators have received IRB training and are fully aware of any human rights issue that may occur. Before each interview session, participants were notified for their consent to participate in a virtual interview and were told how the data would be used for research purposes alone. Participants were notified about the questions about endoscopy and infection that could make them feel uncomfortable. Respondents have the right to end the interview if they feel uncomfortable answering any question. The interview questions do not include any identifying information. The data were kept fully anonymous and cannot be traced back to any individual. The information gathered was kept confidential, only available to the members of Summed Taiwan IQP Team. After the research period, all research data would be deleted.

4. Findings

4.1 Overview

Over four weeks, the research team conducted patent research and interviewed surgeons to gather information on disposable endoscopes. The team bases its findings on research of 500 patents of endoscopes and interviews with two surgeons from Taiwan. While conducting the patent research, the research team initially applied filters for different countries for its first 120 patent searches. After thorough discussion with Summed Taiwan, the research team adjusted its Boolean strategy to use the same filter for the rest of its patent research. During the process, the research team gained basic understanding of disposable endoscope design and interviewed two surgeons from Taiwan through Summed Taiwan's connections. The following chapters detail the processes for both patent research and the interviews, the findings from these research, and initial analysis of the information collected.

4.2 Patent research

The patent research was divided into two phases. In the first phase, from week 1 to week 2, the research team collected information on endoscopes and disposable endoscopes to gain basic understanding of the functionality and technologies of disposable endoscopes. In the second phase, from week 3 to week 6, the research team was able to analyze researched patents to create a patent map. The following section details the process of patent research and major findings from this research. Some major findings include the frequency of past patents on certain technologies and functions, the reasons for these frequencies, and their relations with Summed Taiwan's needs.

4.2.1 Patent Review Process

The process of patent research first started with the manner in which patents were being looked up. Initially, since the research team had limited knowledge on the design of endoscopes, they conducted their research based on different patent offices. At this stage, the research team did not create patent maps and were only able to create patent briefs for each patent. To facilitate future analysis, these patents were stored in a Google Spreadsheet for records. After researching

around 120 patents, the team created a patent map based on the functions and technologies of endoscopes. At the same time, Summed Taiwan provided feedback on the patent research and suggested special keywords for the rest of patent research. These keywords were combined to form the Boolean strategy ((AB=(disposable)) OR (TI=(disposable)) OR (CL=(disposable))) ((AB=(endoscop$)) OR (TI=(endoscop$)) OR (CL=(endoscop$))) country:US status:GRANT, where AB stands for abstract, TI stands for title, and CL stands for claims. This Boolean strategy filters patents with the word “disposable” or with phrases containing “endoscop” in the abstract, the title, or the claims. This Boolean strategy also limits the patent office to the US only and only shows patents with granted status. By utilizing these key words, the number of results yielded on Google Patents went down to 550 for preciseness. Each group member was then assigned a section of patents coming from the specific search.

The research team then created patent briefs for each patent researched. As illustrated in Figure 7, each patent brief consists of the patent number, name of the invention, inventor(s), assignee, filing date, publication date, abstract, description, claims, and relevant pictures.

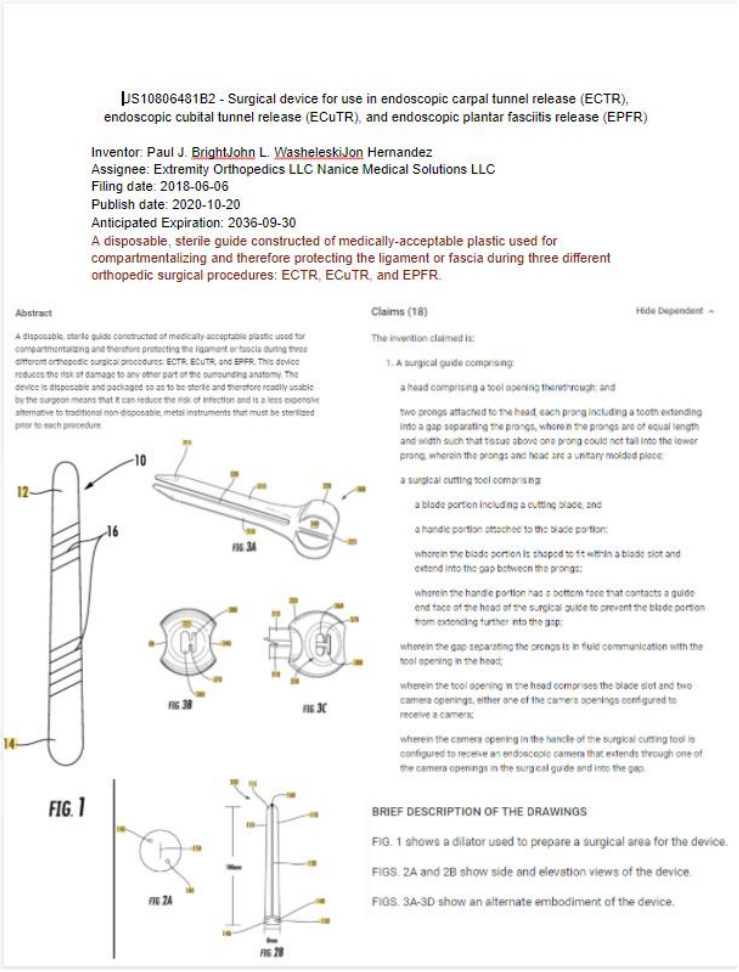

Figure 7. An example of a patent brief from the research team.

The team stored all patent briefs in a Google Drive folder. Additionally, patent maps visually represented the patent research by categorizing functionality and technology implemented. Some examples of functionality include flexibility, portability, substance delivery, and lower cost, while examples of technology include disposable sheath, removable disposable parts, sensors, and integrated displays. The patent map represents the culmination of researching 500 patents and therefore serves as the main deliverable of this project.

4.2.2 Various Endoscope Technologies and Functionalities

Doctors use endoscopes primarily to go within a patient's body to view the internal organs of the patient and conveniently apply treatments when necessary. To achieve these goals, inventors implemented various technologies to design endoscopes and/or disposable endoscopes.

Based on the research conducted on past patents, the research team identified 13 functionalities and 18 technologies to represent in the patent map. In the patent map, each column represents one functionality of endoscope; each row presents one technology applied to achieve the functionalities; and each cell corresponds to the primary outcome through the application of certain technology. For instance, as shown in Figure 8, “prevention/protection”, “flexibility”, and “aided perception” represent functionalities of an endoscope in the columns; “endoscope sheath” and “disposable endoscope sheath” represent two distinct technologies from patents; whereas the intersection between “endoscope sheath” and “prevent infection/ protection” denotes all the patents that use endoscope sheath as a technology to achieve the goal of preventing infection for an endoscope.

Red: Expired Orange: Soon Expiring Blue: Active **Text in empty cells: Potential Modification**		Prevent Infection/ Protection	Flexibility	Aided Perception		
				High Definition	Improved View	Full Camera Angle
	Endoscope Sheath	US5201908A US4522196A US4907395A US6537207B1 US4809678A US4920961A US10736655B1 US6997867B2 US4254762A US8551058B2 US5413092A	KR100971812B1 US10722103B2 US9055864B2 US6461294B1		US7311660B2 US20110257477A1	US6899672B2
	Disposable Endoscope Sheath	US7481764B2 US5704892A US5402768A US4741326A US4869238A USRE34110E	KR102226947B1 CN202801687U US6383209B1 US9498108B1 US5483951A		US6126592A JP2011104383A	US6899672B2

Figure 8: A part of the patent map

The research team identified the functions and technologies after the first phase of research. Figure 9 enumerates all functionalities and technologies in the patent map. Each functionality represents one expected outcome while using endoscopes. With background knowledge of endoscopes from literature review, the team easily identified functions such as

“prevent infection/protection”, “aided perception”, and “reduced cost”. Other functions became more clear to the researchers after the first phase of patent research. These functions include “aided treatment”, “flexibility”, “reduce risk of operation / improve patient experience”, and many others. Similar to the functionalities, each technology represents one major technology of an endoscope. Surprisingly, patents on endoscopes are not limited to inventions of an endoscope as a whole. In fact, there are more patents on parts of endoscopes than on whole endoscopic devices. This helped the team to identify technologies based on different parts of an endoscope. For example, some technologies used to achieve functionalities include “endoscope sheath”, a cover for distal end of an endoscope; “removable parts”, components of an endoscope that can be dissembled; and “working channel”, the tube where doctors can apply special treatment.

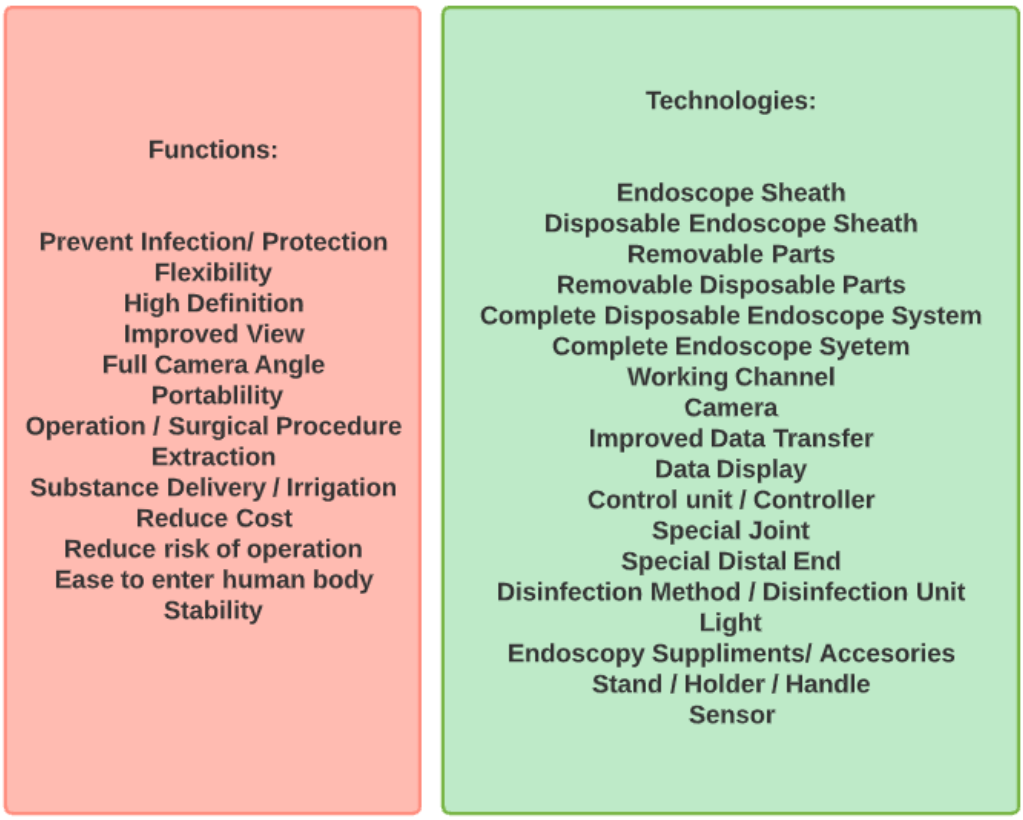

Figure 9: A list of all functions and technologies in the patent map

4.2.3 Trends of Functionalities and Technologies

Trends very quickly emerged when grouping patents together on the patent map. For instance, looking at the number of patents in a particular row, column, or even cell reveals category frequency. Furthermore, color coding illustrates which patents are still in effect, have expired, or are close to expiring. This additionally allows the research team to see trends in designs in terms of a simple timeframe to see what used to be popular compared to what is now popular.

When looking specifically at the popularity of categories, it is important to note what type of category is being observed: functionality of an endoscopic device or implemented technology used by the endoscopic device. Figure 10 is a distribution for functionalities of patents. The most popular functionalities include preventing infection, operation/surgical procedures, and improved view, with 88, 102, and 68 patents representing each. Among these categories of functionalities, 20.6% of patents for ease of operation have expired, 17.8% of patents for preventing infection are expired, and 13.7% of patents for improved view have expired. While there are categories that receive a lot of attention in the form of patents, some other categories do not. The least popular categories of functionality are stability and high definition, with only 7 and 9 patents representing them. It is worth mentioning, however, that all patents for these unpopular functions are still active except for US5916146A, a patent for stability.

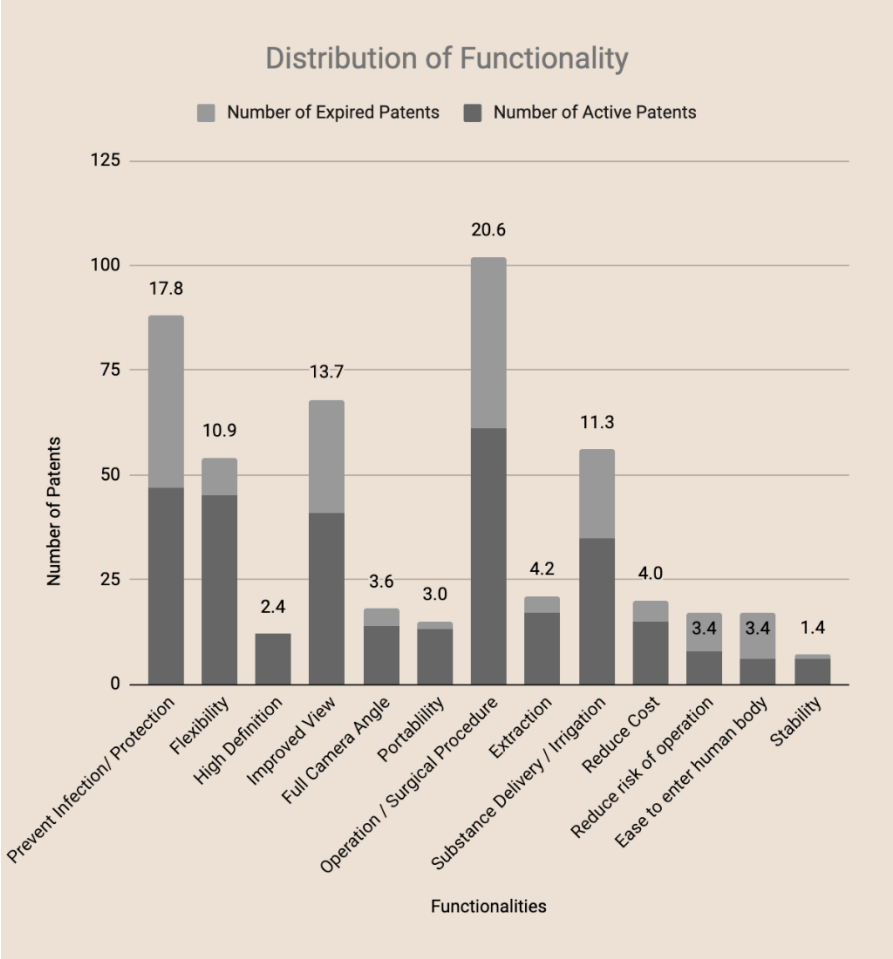

Figure 10: A distribution for functionalities of patents

Figure 11 depicts a distribution for technologies of patents. The most popular implementations of technology are the use of removable disposable parts, special distal ends, and endoscopy supplements/accessories, which has 96, 42, and 45 patents accordingly. Around 19.4% of patents for removable disposable parts have expired within these patients, and only 9.1% of patents have expired for endoscopy supplements/accessories. For special distal ends, 8.5% of patents have expired. On the other hand, the least popular categories of technologies are improved data transfer, data display, and stand/hold/handle, with only 3, 4, and 9 patents to represent each accordingly. Just like those least popular patents on functionalities, almost all patents for these unpopular technologies are active with several exceptions.

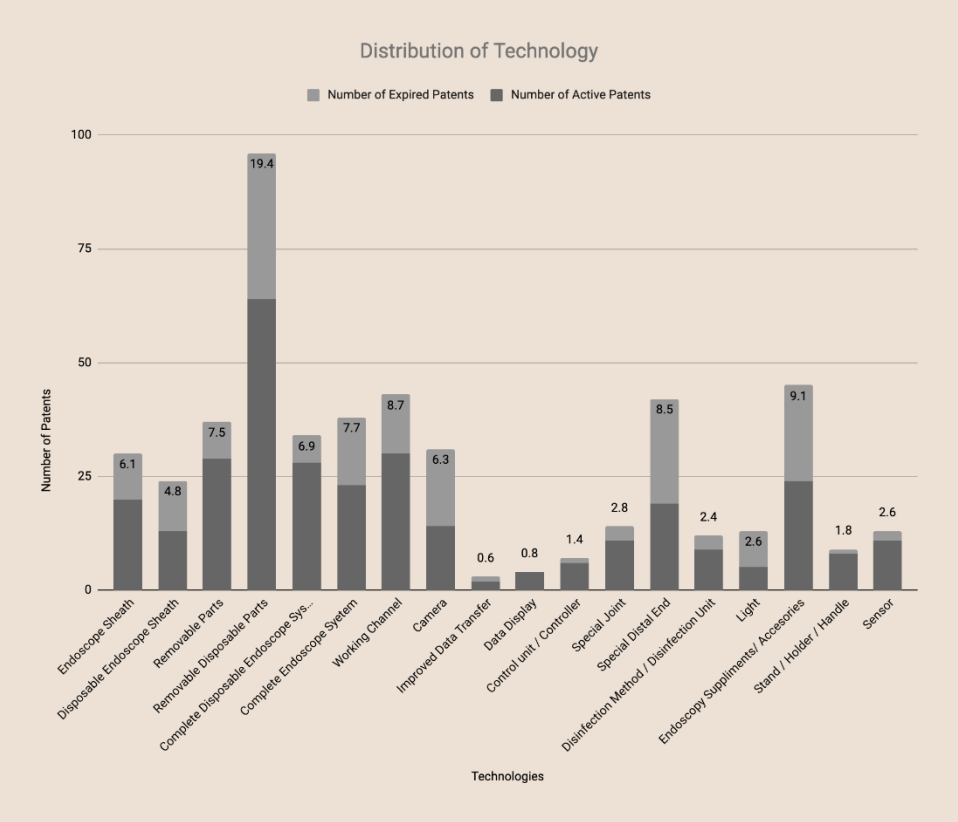

Figure 11: A distribution for technologies of patents

Lastly, when combining technologies and functionalities to look at the cells, the most popular designs are removable disposable parts to prevent infection, cameras for improved views, and special distal end for operations. Unsurprisingly, most patents for removable disposable parts for preventing infections are still active, while the other two popular designs are mostly expired. Meanwhile, some designs with certain technologies aiming for specific functions have very little to no patents. Some combinations of technology with function do not make sense, such as (disposable) endoscope sheath for high definition, portable working channel, or optical systems for substance delivery. Other blank cells represent gaps in the endoscopy market, which is, in fact, highly relevant to Summed Taiwan's needs. The research team proposed possible suggestions for these designs within the patent map as part of the deliverable of the project.

4.2.4 Research Analysis

To assist Summed Taiwan with designing a new disposable endoscope, the research team analyzed the trends found from their patent research. Although the main goal of the patent map is to identify gaps in the endoscope market, it is equally important to summarize findings from popular patents and learn from them. Therefore, the following section provides explanatory descriptions for both popular and unpopular patents, from which the research team can propose reasonable recommendations to Summed Taiwan.

When looking at the columns of the patent map that represent the functionalities of endoscopes, improved view, ease of operation, and preventing infections are most frequently addressed. One of the reasons for the development of disposable endoscopes is due to high infection rate resulting from reusable endoscopes, so it is reasonable that preventing infection became a popular goal for designing endoscopes. Additionally, since increasing infection is a newly emerging issue, most patents that address this issue are relatively new and hence still active. On the other hand, with earlier versions of endoscopes, their main purpose was to observe internal organs and allow for medical treatment, which explains the reason for the popularity of improved views and ease of operation as functionalities of endoscopes. As time went on, much effort went into advances for this purpose. As a result, it makes sense that many expired patents exist for it now. Examples of this include US5359453A and US7273452B2, with advances made regarding the viewing quality of the endoscope. Patent US5535754A and US7094245B2 illustrate this effort to make the process of endoscopy easier, including the process of opening and closing any incisions made to the patient's body.

Meanwhile, it is also important to examine functionalities that are not as popular. As previously presented, stability and high definition are two functionalities that have not been widely addressed among the 500 covered patents. It makes sense that stability may not be the primary concern for surgeons or doctors when using an endoscope, because they are usually presumably experienced enough that stability should not be a problem. However, disposable endoscopes are usually made of lighter and cheaper materials than reusable ones to reduce costs, which may cause stability of endoscopes to become a concerning issue as widely adoption of disposable endoscopes. Similarly, maintaining a high definition for an endoscope has not been a pursuit for designing endoscopes but may potentially be a contributing factor for high-quality endoscopes in the near future. As technology advances, doctors' and patients' standards for

medical equipment will also increase. As a result, endoscopes with high definition may be preferred over their counterparts. These also explain why patents with these functionalities are rarely invented yet are mostly active.

Above all, preventing infection may be the most popular functionality when designing an endoscope, but the market of it is relatively full; though the markets for improved view and ease of operation are also at high capacity, they are mostly full of expired patents, which makes it possible for Summed Taiwan to enter the market; stability and high definition may not be as popular in the endoscope market right now, they may become important functionalities to consider in the near future.

The most popular implementations of technology are the use of removable disposable parts, special distal ends, and endoscopy supplements/accessories. The trend in using removable disposable parts greatly supports the trend in preventing infection. After a procedure, doctors or technicians can easily remove and dispose of parts that make contact with the patient while still retaining the more expensive parts of the core endoscope, as in, for example, a removable sheath and tubing running from the camera to the proximal end of the endoscope. The sheathing and tubing can be disposed of, while the camera and wiring can be preserved for reusage. Removable disposable parts are simpler and cheaper alternatives of complete disposable endoscope devices, which explains their fast-pacing emergence within the market. The trend in using special distal end also highly corresponds to the trend in ease of operation. Most special distal ends are designed to allow for easier treatment during endoscopic procedures, including operation, extraction, and substance delivery. Since these have been one of the main purposes of using an endoscope, the patents for these technologies outdate really fast. For the same reason, endoscopy supplement/accessories are also dominant technologies in the market.

The least popular categories of technologies are improved data transfer, data display, and stand/hold/handle. Data display is highly related to high definition of endoscopes, whereas the technology of stand/hold/handle largely contributes to stability of an endoscope. That said, the trend in these technologies can explain the unpopularity of their corresponding functionalities, and vice versa. Implementing more designs and inventions on data display and stand/hold/handle can allow for higher quality of the image and better stability of an endoscope, which can expand the market for these functionalities accordingly. Data transfer relates to this as the higher quality

the image is, the more data there is to transfer, though this is something that is not hard to implement given today's technological capabilities.

In conclusion, the development of technologies are highly related to their corresponding functionalities. Removable disposable parts of an endoscope may be the most popular technology for the invention of an endoscope, but the competition regarding this technology is relatively high; though many technologies of special distal ends and endoscopy supplementary/accessories have been developed, the need for updating these technologies will never decline; though the technologies for data display and stand/hold/handle may not have been frequently seen, the fast-pacing technical development in medical equipment will inspire these technologies to blossom.

4.3 Interviews

The research team conducted interviews with two surgeons from Taiwan after they gained basic knowledge on the design of a disposable endoscope. Introduced by Summed Taiwan, one was an ENT (ear-nose-throat) surgeon, whereas the other one was a urologist. Both surgeons spoke Mandarin, so the two members of the research team who spoke Mandarin conducted the interviews, with liaisons from Summed Taiwan attending. In addition, since both surgeons have experiences with disposable endoscopes and regular endoscopes, they could provide professional feedback on the usage and improvements of disposable endoscopes. Each interview lasted for approximately thirty minutes, allowing for the collection of ample information.

To get opinions from a different angle, the team also reached out to surgeons in US. The team collected contact information of endoscopy surgeons from different hospitals and clinics in Worcester. Unfortunately, the team failed to get replies from any of the surgeons. In addition, the team reached out to the head of Biomedical Engineering department in WPI and acquired the contact information for two alumni working as endoscope engineers in Boston Scientifics. The team hoped to hear about more details on endoscope technologies from the endoscope engineers. The interview with Boston Scientific engineers did not take place because the team was working on the behalf of Summed Taiwan, a potential rival company for Boston Scientific. Attending the interview would be a violation to the non-compete agreement for the engineers. As a result, the

team only got the chance to talk with the Taiwanese surgeons. The following sections summarize the findings from those two interviews.

4.3.1 What makes a good endoscope

Hearing from professionals who use disposable and traditional endoscopes helps identify what defines a successful one. Throughout the interviews, the surgeons expressed their ideas of what makes a good endoscope product. In conclusion, there are three determinant factors: greater flexibility, improved vision, and the ability to conduct operation.

Endoscopes can only function after entering the human body. Hence, flexibility is essential for endoscopes to navigate through the human body without causing injuries. A flexible endoscope has to find a balance between softness and rigidity. It needs to be soft enough to make large degree turns inside cavities. For example, an ureteroscope needs to turn up to 270 degrees in order to make its way to the kidneys. At the same time, the endoscopes also need to be rigid enough to have the strength to make all the turns when it needs to.

Traditional endoscopes used by Taiwan surgeons in the past utilized fiber optics as their way to transfer images. Sights from the endoscope lens were directly transferred to a fixed eyepiece on the other end of the endoscope, which means that the surgeons had to keep looking into the eyepiece while doing operations. The fiber optics method was cumbersome and the image quality was not ideal. So, improved vision for an endoscope means it needs to use a new image transfer method that not only produces images with high resolution, but also displays images on a separate screen, allowing surgeons to move more freely during operations.

Last but not least, the ability to conduct operations usually depends on the design of the working channel and distal end of an endoscope. These two parts could be modified to give special functions required during endoscopic operations. For example, when doing ureteroscope operations, the ureteroscope must include the function of irrigation. The irrigation function can transfer fluid into the patients' kidneys and open up paths for the ureteroscope to sneak through. Other examples of operation could be laser treatment or suture, and there are endoscopes specified for those operations. A specific modification is needed for a specific type of endoscope.

These three factors mentioned above are adaptable to both endoscopes and disposable endoscopes. Researchers would use them as guidelines when proposing possible modifications on new disposable endoscope products.

4.3.2 Discussions on disposable endoscopes

Apart from surgeons' opinions on conventional endoscopes, the researchers also collected information on their perspectives on disposable endoscopes, which could contain hints on how to improve Summed Taiwan's disposable endoscope product. Both interviewed surgeons have previous experience using disposable endoscopes, and they shared their views on the future of disposable endoscope.

Significantly, both surgeons agreed that disposable endoscopes are superior to reusable endoscopes in terms of sterilization, yet they also came to the conclusion that it is not realistic for disposable endoscopes to entirely replace reusable endoscopes for now. This is because the benefit of using disposable endoscopes is outweighed by its drawbacks.

First, in terms of sterilization, using disposable endoscopes is indeed safer than using reusable ones. Contaminated reusable endoscopes could contribute to the spread of diseases such as AIDS. However, a majority of endoscopic procedures, such as colonoscopy and gastroscopy for examination purposes, does not require a very high level of sterilization, since there is already a lot of bacteria in the human body, especially inside the stomach and intestinal tract, where many endoscope procedures are located. Proper sterilization for reusable endoscopes would be enough to prevent the diseases from spreading during examinations.

When it comes to drawbacks of using disposable endoscopes, there are two major concerns. Flexibility is one aspect that concerns the surgeons. The implementation of disposable material could make the endoscopes more rigid and harder to bend. This issue can be addressed by using a combination of different disposable materials that are softer, such as rubber and fiber.

Conversely, the other concern is more challenging. The cost of using disposable endoscopes is much higher than that of using reusable endoscopes. In order to compare the cost between reusable and single-used disposable endoscopes, we need to calculate the cost for using a reusable endoscope once, the unit price. That unit price of reusable endoscope equals to the cost for purchasing the whole endoscope over its lifespan. In other words, it is the cost for using a reusable endoscope for one time. The unit price for reusable endoscope is higher when the lifespan is shorter. With this relationship established, the price difference between reusable and disposable endoscope can be clearly illustrated by comparing the reusable endoscope with the highest unit price with its disposable counterpart.

Reusable ureteroscope is among the endoscopes with the shortest lifespans. Based on the interview with the urologist, each reusable ureteroscope in Taiwan costs around 600,000 to 700,000 New Taiwan Dollar (NTD), or around 21,438 to 25,000 US Dollars (USD). Ureteroscope is very likely to wear and tear during operations. Reusable ureteroscope, in the hands of the most skilled surgeons, would only last around 10 examinations. According to the formula , the cost of using a reusable ureteroscope once would be 700,000 divided by 10, that is 70,000 NTD, or 2,500 USD. On the other hand, the cost of using each single-used disposable ureteroscope would be around 100,000 NTD, or 3,572 USD. Even in the case of ureteroscope, using a disposable ureteroscope is still more expensive than using a reusable one. Not to mention there are other kinds of endoscopes that have much longer lifespans and a much lower unit price. For example, from our interview with the ENT surgeon, a reusable laryngoscope could last from five to ten years. In those cases, there would be a more significant difference between the price of using reusable and disposable endoscopes.

As a result, another focus on our recommendations is to highlight advantages for using disposable endoscopes, as well as the ways to deal with these concerns. One focus point would be how to shrink down the price.

4.4 Technical Drawing

The purpose of the technical drawing is a reorganization of the patent data that was collected during patent research. While the patent map organized patents based on functionality and technology, the technical drawing organizes the patents based on where the implemented technology is located on the endoscope itself. For example, if the team's sponsor wanted to look at specific patents for the proximal end of an endoscope, it would be easier to look at this technical drawing than the patent map. The seven parts of the endoscope that this drawing would be sorted by is proximal end, handle, working channel, sheath, bending joint, distal end, and camera.

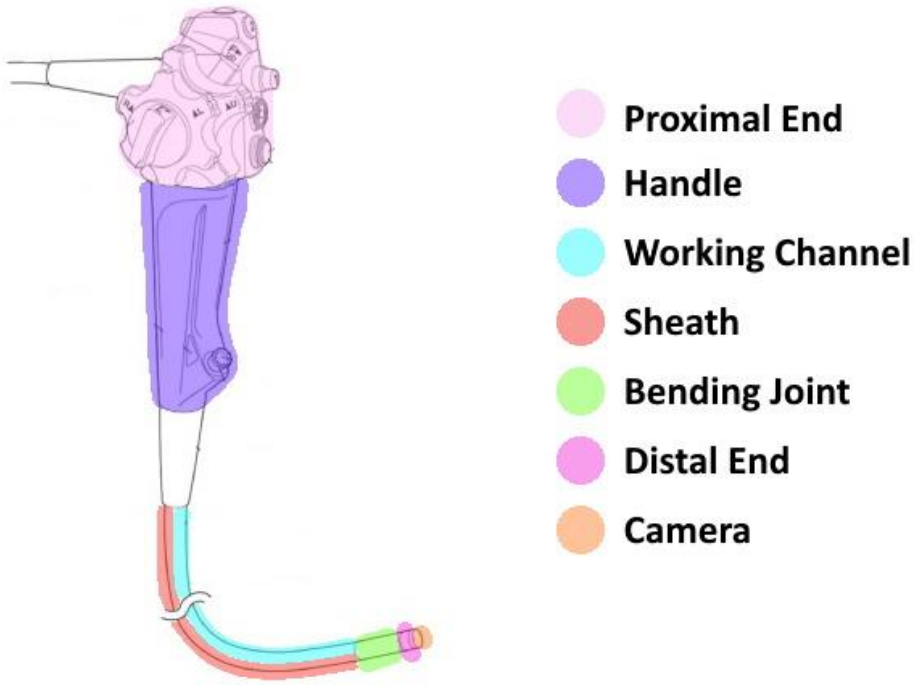

Figure 12: The technical drawing

4.5 Summary

From patent research, the team focused on technology and functionality of endoscopes separately through the analysis of their popularity and trends in the endoscope market. The research team came to the conclusion that technologies and functionalities are highly relevant to each other in terms of their popularity and trends. It is evident that a new design of endoscope can either aim for developments on commonly used technologies or gamble on future market of certain functionality of endoscopes. In either case, the technologies serve for improvements in functionalities, and the functionalities inspire developments in technologies. Nevertheless, it is worth mentioning that the findings from the team's research and its corresponding analysis only account for the relatively small number of patents researched compared to the vast majority of medical patents that exist for this topic.

From interviews with surgeons, the team identified advantages of disposable endoscopes and the concerns for using them. Some of these results coincided with findings from the patent research. For instance, preventing infection, improved view, and ease of operation are the most

popular functionalities of endoscopes, which happen to be the advantages of disposable endoscopes according to the surgeons. Additionally, disposable endoscopes' drawbacks as identified by the surgeons are functionalities on the patent map that have large number of patents addressing these issues. Hence, the research team utilized their findings from the patent research to address these concerns for Summed Taiwan so as to assist them with their new invention.

5. Recommendations

5.1 Overview

As mentioned in the previous chapter, the team has collected various information on disposable endoscopes. After analyzing the results, the team is able to draw some directional recommendations for Summed Taiwan for their future development of the disposable endoscope product. The directions for recommendations include:

1. Key improvements for disposable endoscope Summed Taiwan should implement on their product.
2. New modifications to disposable endoscopes that might have great market potential.

5.2 Key improvements

According to the research data, the research team is positive that better sterilization is a very competitive advantage for disposable endoscopes. However, current disposable endoscope products are still far from reaching market success. This is because those products have some major flaws that need to be addressed. The team has concluded four key improvements Summed Taiwan could implement on their disposable endoscope product. They are: greater flexibility, improved vision, more operation functions, and lower costs.

5.2.1 Greater Flexibility

From the interviews, it is evident that surgeons consider flexibility an important feature of an endoscope. A flexible endoscope has a flexible tube that can be used both for clear inspections and easy treatments. For an endoscope to be categorized as flexible, its tube must be soft enough so that it can bend easily inside human bodies while maintaining rigidity for general support of the endoscope. Additionally, the tube of the endoscope must be thin enough to avoid injuries during endoscopic procedures and be wide enough to allow for medical supplies to enter. Hence, the research team will propose suggestions to find a balance between softness and rigidity for greater flexibility.

Material is the first component to discuss. From the patent research, most patents with the feature of flexibility use silicone rubber and polyurethane film as the material. These materials are expandable, which allows for easy bending when required so as to achieve a higher flexibility. Meanwhile, when flexibility is not desired, both materials are hard enough so that they can provide support for general inspection functions as well. Hence, Summed Taiwan could consider using these materials for the design of the tube of their endoscopes. Secondly, to avoid injuries while allowing for medical treatments, one must look at the technologies for designing the tube. One most common technology is the use of a multi-lumen probe. A lumen is a working channel within the tube that allows for insertion of medical supplies. A multi-lumen probe, as suggested by its name, is a probe with multiple lumen in it. These lumens are usually of different diameters, which allows for medical supplies with different sizes to enter and in turn increases the ability to apply different treatments in specific procedures.

Patent US8333691B2 is an example of a patent that utilizes the technology of multi-lumen probe. This technology has lumens of different diameters and materials for different purposes. Some of them are for optical lenses on the distal end of the tube, whereas the others are for connections with associated terminal devices on the proximal end. The ones on the distal end are more likely to be composed of softer materials and cannot be dissembled from the endoscope, since the distal end is always going to travel inside human bodies for inspections. On the proximal end, however, the lumens can be dissembled and are much harder and thicker for the insertion of medical devices. Depending on surgeons' needs for specific endoscopic procedures, they can choose lumens of different sizes to connect with the tube for insertion of medical supplies. This technology can also be seen in patent US10307042B2, where only two lumens are used with a disposable sheath device.

5.2.2 Improved Vision

Improved vision has always been a pursuit for endoscopes. Particularly, since disposable endoscopes or disposable endoscopic devices usually come with lower costs, they must sacrifice their vision quality, both in terms of its resolution and of its display. In addition, during endoscopic procedures, it is almost unavoidable for cameras to blur as it contacts with patients' secretions. This happens regardless of the type of endoscopic procedures and the type of

endoscopic devices. Hence, an improved vision must address both the vision quality and the interference from patients' secretions.

The patents researched suggest two types of technologies to improve the visual quality of an endoscope. The first technology is to utilize fiber optics in a specific way to ensure suitable brightness, refraction, and reflection of the lights. Fiber optics are optical elements primarily made of fibers that can refract lights for light transmission, which in turn transfer images to eyes. The patent US9901256B2 depicts a multicore fiber endoscope that implements this technology. The fibers are distributed in different optical configurations, including the distal end and the proximal end of the endoscope. With the fiber optics on both ends, there is no need to attach a lens on the distal tip unless the observer needs an image presentation. The other technology for improving visual quality of a disposable endoscope is to design a disposable sheath cover such that observers can use uncontaminated devices while maintaining the same visual quality. The patent CN211933972U details a disposable hard tube ear-nose-throat endoscope sleeve made of transparent innovative polyurethane material.

Addressing the interference from patients' secretions can also improve the vision quality of using an endoscope. Most patents address this issue with the design of an endoscopic system that can control the pressure and heat as an anti-fog solution. This system is usually a medical device connected to an endoscope. Though this particular system is far from creating a disposable endoscope, it indeed can help improve success rates of endoscopic procedures. The patent US9301796B2 is an example for a cryosurgery system with an anti-fog solution. The system has a pump for self-check of pressure and heat, which locks itself when reaching a targeted level and reduces the fog inside patient bodies as a result.

5.2.3 Variety of Treatments / Ease for Operations

One of the most popular functions for using an endoscope is to apply treatments, which can include operations, extraction, substance delivery, and irrigation. In fact, from the interviews, both surgeons expressed that they were more likely to use disposable endoscopes for simple treatments as opposed to mere body examinations. During body examinations, surgeons are less concerned about cross-contamination and hence are less prone to use disposable endoscope devices. On the other hand, treatments require more sanitized environments, which is where

disposable endoscopes become preferred. If disposable endoscopes are easier to use for simple treatments, patients will also have a better experience without having to become hospitalized.

Many patents have detailed technologies for different treatments. These technologies vary from each other based on their types of treatment. The research team divided treatment into three types in the patent map: operation, extraction, and substance delivery/irrigation. For simple operations, there are many patents on suturing and ligation, since both are simple operations that do not require patients to become hospitalized. Patent US10932771B2 features a suturing device that allows for constant movements of needling within the working channel, and patent US10820905B2 presents removable disposable parts of an endoscopes for ligation. For extraction, patent CN204618305U uses a portable disposable endoscope with biopsy forceps on its distal end, whereas patent US10307042B2 is a disposable sheath device that allows for extraction with a multi-lumen probe. For substance delivery and irrigation, patent US5176629A and patent US9301796B2 are both examples of an endoscopic system with an anti-fog solution for easier irrigation.

5.2.4 Lower costs

Cost-effectiveness is a direct competitive advantage of a product. The reality for a lot of disposable endoscope products turns out to be they are too expensive for hospitals and patients to choose. No matter how superb the quality of a disposable endoscope product is, no hospital would purchase it if the patients cannot afford using them. In some developed countries, the cost of using disposable endoscope could be paid by health insurance. But this does not apply to the developing countries, or countries with poor health insurance. The costs of disposable endoscopes is one of the biggest obstacles preventing them from entering the market. So, lowering the cost should be a focus when Summed Taiwan develops their own disposable endoscope. However, this conclusion could lead to a dilemma. First and foremost, lower costs comes with compromises. Without significant advance in manufacture technology, it is impossible to make a cheaper disposable endoscope product without sacrificing its quality. As a result, the research team focused on solutions that reduces the cost of disposable endoscopes with minimum sacrifice in performance.

The research team recommends replacing the digital cameras in the distal end to optical lens with liquid light guide. Disposable endoscope usually use digital cameras as their data

collection tool. Miniature digital cameras inserted in the distal end would be an expensive component. The digital cameras could be replaced by an optical lens. The image in the human cavity would travel from the lens, all the way through the liquid light guide, to the eyepiece. Patent US5717807A and US4919112A are examples of low-cost disposable endoscope instruments utilizing liquid light guides in their working channel as media for data transfer. Replacing the digital camera to optical lens and eyepiece could cut down the cost of a disposable endoscope product immensely, because manufacturing of miniature digital cameras is costly. Indeed, a digital camera provides the surgeons with the best quality of views. But, another advantage of using liquid light guide is that it maintains impressive image quality. The image quality transferred by liquid light guide would still be better than that transferred by traditional fiber optics. Yet, this method has a significant drawback. The use of an eyepiece means the surgeon cannot take their eye away from it. This would directly limit the freedom and performance of the surgeon, which further impairs effectiveness of the endoscopy procedure. Whether adapting this method or not depends on the priority of the final disposable endoscope product. If the final disposable endoscope product require less of the surgeon's precision, this method of replacing the digital camera could be very applicable.

5.3 Potential Modifications

The nature of a patent map means that there are some combinations of functionality and technology that there are no patents for. This was the case for the team's patent map as there were a number of blank cells following its completion. In the eyes of both the sponsor and the team, these blank cells are an opportunity to explore new potential modifications to endoscopes. Given this, the team went through the blank cells on the patent map and gave some examples of potential modifications that could be applied to new endoscopes. However, it is worth mentioning that there are some combinations that are simply better than others. A camera with optical image stabilization is going to be a lot more practical than an HD display on the proximal end of an endoscope.

Potential modifications that can be made in terms of functionality can include portability and increasing the patient quality of life during an endoscopic procedure. Portability may be an emerging market as doctors and surgeons travel to other areas of the world that may not have as advanced medical tools. In this case, having a more portable endoscope would be imperative as

to lighten the load of the medical team traveling abroad. Within the realm of portability, a smaller proximal end may be advantageous in cutting down in unnecessary weight. Additionally, a smaller working joint on the distal end of the endoscope that can be easily folded up may also make the process of carrying an endoscope easier. Taking steps for increasing quality of patient experience could be advantageous in retaining patients' business. A way that this could be achieved is by using lower friction tubing that slides into the patient easier. This would make for less discomfort for the patient. Another way that the patient experience can be improved is by using antimicrobial parts. These would prevent the growth of microorganisms on endoscopes even after cleaning to prevent infection.

Modifications can be made to existing endoscopes in terms of technology in sensors and a better handle. Different sensors can be used for anything from measuring irrigation pressure to measuring the orientation of the distal end of the endoscope. Additionally, with the advent of medical robotics, implementing sensors into endoscopes now may pave the way for more elaborate robotic schemes in endoscopy for the future. Making a better handle for an endoscope is important as well; if the handle were uncomfortable for the doctor using it, then they would not want to use that specific endoscope anymore. Thus, creating a handle that better fits one's hand, or even conforms to one's hand, may be advantageous. Additional functionality can also be built into the handle such as that of a battery, which can also make the endoscope more portable.

6. Summary

This project aimed to assist Summed Taiwan to design a disposable endoscope. To achieve it, the research team conducted patent research and two interviews with surgeons. In the patent research, the team created patent briefs for each of the 500 patents researched and a patent map that kept track of the functionality and technology of each patent. By analyzing data from these deliverables, the research team found a trend in the market for disposable endoscopes. At the same time, during the interviews, the team understood the features that makes a good disposable endoscope and the areas for improvements for the design of a disposable endoscope. Combining the findings from both the patent research and interviews with surgeons, the team identified gaps in the market by spotting blank cells inside the patent map and proposed potential modifications for improved designs of a disposable endoscope. Lastly, to present a visual representation of the result, the research team created a technical drawing with color-coded components for endoscopes, where each component was linked to relevant patents representing specific technologies and functionalities. All these findings along with the deliverables will assist Summed Taiwan to successfully design a disposable endoscope that improves on past endoscopes and has innovative prospects.

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Taherpour, N., Mehrabi, Y., Seifi, A., Eshrati, B., & Hashemi Nazari, S. S. (2021). Epidemiologic characteristics of orthopedic surgical site infections and under-reporting estimation of registries using capture-recapture analysis. BMC *Infectious Diseases*, *21*(1). Scopus. https://doi.org/10.1186/s12879-020-05687-z

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"USC. Title 35 - PATENTS." Accessed April 22, 2021. https://www.govinfo.gov/content/pkg/USCODE-2011-title35/html/USCODE-2011-title35.htm.

Wiktorczyk, N., Kwiecińska-Piróg, J., Skowron, K., Michalska, A., Zalas-Więcek, P., Białucha, A., Budzyńska, A., Grudlewska-Buda, K., Prażyńska, M., & Gospodarek-Komkowska, E. (2020). Assessment of endoscope cleaning and disinfection efficacy, and the impact of endoscope storage on the microbiological safety level. *Journal of Applied Microbiology*, *128*(5), 1503–1513. https://doi.org/10.1111/jam.14558

Windfeld, E. S., & Brooks, M. S.-L. (2015). Medical waste management – A review. *Journal of Environmental Management*, *163*, 98–108. https://doi.org/10.1016/j.jenvman.2015.08.013

Appendix 1: Interview Questions

- What does your day-to-day job typically consist of?
- Do you use endoscopes regularly?
- Have you ever seen or heard of an infection caused by an endoscope?
- Have you ever used a disposable endoscope or anything of that nature?
- Do you think it would be worth it for hospitals to switch to disposable endoscopes?
- Are there any parts of current endoscopes that you wish were different?

Appendix 2: Consent Letter

Informed Consent Agreement for Participation in a Research Study

Investigator: Summed Taiwan IQP Team
Contact Information: Summed Taiwan IQP Team gr-summedtaiwaniqp@wpi.edu.
Title of Research Study: Proposal for an Innovative Disposable Endoscope in Partnership with Summed Taiwan
Sponsor: Summed Taiwan Inc.

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

Purpose of the study: This study is carried out in order to collect insights from surgeons and the professionals upon endoscopes. The research team would take inspiration from the experts' opinions to help design a new disposable endoscope product.

Procedures to be followed: The interview would be semi-structured. The student researchers will use Zoom as a data collection tool. During each interview, one project team member will serve in each of the following roles: interviewer, note taker, and observer. All the subjects will receive the drafted questions before the interview, and the student researchers will use those questions to structure and conduct the interview. The project team will also ask the interviewee for additional surgeons or other hospital staff that may be important to interview.

Risks to study participants: This study is of minimal risk. It does, however, ask questions about endoscopy and infection that could make the respondent feel uncomfortable. Please respond to as many questions as possible, but if you do not feel comfortable answering any of these questions, you may skip the question(s) or leave the interview.

Benefits to research participants and others: N/A

Record keeping and confidentiality:
Notes will be taken during the interview, and the interview itself will be recorded.
Our interview does not involve any identifying information; your responses will be kept fully anonymous and cannot be traced back to you. However, if you do not wish to anonymize your data, we will, with your approval, include you in the credit section. The information gathered will be kept confidential. The interview notes and record data will be kept in a private folder, which is only available to the members of Summed Taiwan IQP Team.

The interview responses would be used as reference for the conclusions in the final report. After the research period, all research data will be deleted.
Records of your participation in this study will be held confidential so far as permitted by law. However, the study investigators, the sponsor or it's designee and, under certain circumstances, the Worcester Polytechnic Institute Institutional Review Board (WPI IRB) will be able to inspect and have access to confidential data that identify you by name. Any publication or presentation of the data will not identify you."

Compensation or treatment in the event of injury: As this research is of minimal risk, there would be no chances for injuries to take place during the interviews. You do not give up any of your legal rights by signing this statement.

For more information about this research or about the rights of research participants, or in case of research-related injury, contact: gr-summedtaiwaniqp@wpi.edu. The supervisors for this research are Professor Jennifer Rudolph and Professor Wen-Hua Du. They can be reached by email at jrudolph@wpi.edu, and wenhuadu@wpi.edu. The IRB Manager: Ruth McKeogh, Tel. 508 831-6699, Email: irb@wpi.edu. The Human Protection Administrator: Gabriel Johnson, Tel. 508-831-4989, Email: gjohnson@wpi.edu

Your participation in this research is voluntary. Your refusal to participate will not result in any penalty to you or any loss of benefits to which you may otherwise be entitled. You may decide to stop participating in the research at any time without penalty or loss of other benefits. The project investigators retain the right to cancel or postpone the experimental procedures at any time they see fit.
By signing below, you acknowledge that you have been informed about and consent to be a participant in the study described above. Make sure that your questions are answered to your satisfaction before signing. You are entitled to retain a copy of this consent agreement.

_____ Date: _____
Study Participant Signature

_____
Study Participant Name (Please print)

_____ Date: _____
Signature of Person who explained this study.

Appendix 3: Patent Briefs

A portion of the patent briefs referenced in the report. The complete collection of patent briefs can be found in:
https://drive.google.com/drive/folders/1dFq7ez5e-TvtyNYP822qiKO6V-XteFPo?usp=sharing

US10307042B2 - Disposable sheath device

Inventor: Edward J. Lombardi
Current Assignee: Opportunity/discovery LLC
Filing date: 2016-10-22
Publish date: 2019-06-04
Anticipated expiration date: 2035-10-31

A disposable sheath with a working channel that can be easily connected to operation tools through its second lumen.

Abstract

A disposable sheath device for use with an endoscope is disclosed. The endoscope has a body with an insertion tube having optics at its distal end. The disposable sheath device has a primary lumen and at least one secondary lumen attached to the primary lumen along a length of the lumen. The primary lumen is for covering and protecting the insertion tube from bodily contamination. The secondary lumen is for accommodating a desired tool. The secondary lumen has an insert substantially commensurate in length to the secondary lumen and the insert has a slit longitudinally along its length. The slit permits radial expansion to accommodate tools having a radius larger than that of the secondary lumen, which preferably is made of a flexible material that expands. A connector is attached to the proximal end of the primary lumen and connects to he body of the endoscope. The connector extends longitudinally to accommodate different length insertion tubes. Optionally, an adapter can be used to attach the connector to the body of the endoscope. Varying the adapter permits the sheath device to be attached to various endoscope bodies.

1. A disposable sheath device to be used in conjunction with an endoscope comprised of a body having an insertion tube with optics at a distal end, the disposable sheath device comprising:

a primary lumen for covering and protecting the insertion tube from bodily contamination;

a connector attached to a proximal end of the primary lumen, the connector being structured and arranged for connecting the disposable sheath device to the body of the endoscope, the connector being adapted to extend longitudinally to accommodate different length insertion tubes; and

a second lumen having a radius to accommodate a desired tool and being attached exteriorly to a length of the primary lumen, the second lumen having an insert comprising a tubular body with a longitudinal slit formed therein extending the length of the insert, wherein the slit extends parallel to a longitudinal axis of the secondary lumen to permit radial expansion to accommodate devices having a radius larger than the second lumen radius.

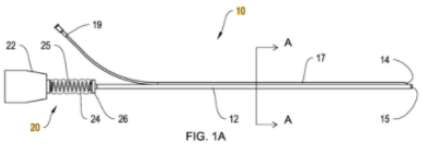


FIG. 1A

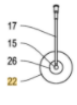


FIG. 1B

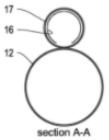


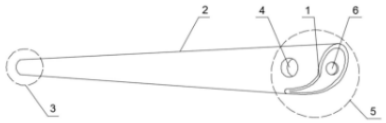
FIG. 1C

Important description: As illustrated in FIGS. 3A-3D, a ureteroscope 50 having a body 51 and a viewing tube 52 is inserted into the disposable sheath system 10. The viewing tube 52 is inserted into the disposable heath system 10 by first inserting the viewing tube into the connector 20 at the proximal end of the disposable sheath system (FIG. 3A). Insertion continues until the distal end of the viewing tube abuts the viewing window 15 of the primary lumen 12 (FIGS. 3B-3C). When the distal end of the viewing tube abuts the viewing window 15 of the primary lumen 12, the body 51 of the ureteroscope is partially within the connector body section 22 of the sheath system (see FIG. 3C). Two pins 55 extending radially 180 degrees apart on the body of the ureteroscope engage openings in the body section 22 of the sheath system. A 90 degree rotation of the ureteroscope body 51 with respect to the connector body section 22 (FIG. 3D) locks the ureteroscope and sheath system together through the pins 55.

CN211933972U - Disposable hard tube ear-nose-throat endoscope sleeve

Inventor: 雷佳微, 权雅霜
Filing date: 2020-03-12
Publish date: 2020-11-17
Anticipated expiration date: 2030-03-12

A disposable sleeve for ear-nose-throat endoscopes that does not reduce the quality of the pictures captured from the camera.



Abstract

The utility model discloses a disposable hard tube otolaryngology endoscope cover, including body cover, body cover one end is lens body cover end, and another is grab handle cover end, grab handle cover end is opened there is the U type mouth of department complex with endoscope handle, opens the through-hole that has to be connected with the endoscope handle in U type mouth both sides, grab handle cover end is opened there is the entrance to a cave of placing the endoscope. The utility model provides a disposable hard tube otolaryngology endoscope cover, this endoscope cover direct suit are fixed on otolaryngology endoscope, and the definition is high, and the operation of being convenient for protects the endoscope lens, and cross infection is avoided in disposable.

1. Disposable hard tube otolaryngology endoscope cover, including endoscope body cover (2), its characterized in that, endoscope body cover (2) one end is lens body cover end (3), and another head is grab handle cover end (5), grab handle cover end (5) are opened have with endoscope handle department complex U type mouth (1), open in U type mouth (1) both sides have with the through-hole (4) that the endoscope handle is connected, grab handle cover end (5) are opened there is entrance to a cave (6) of placing the endoscope.

Important description: In this embodiment, the small end of the endoscope body sleeve 2 of the disposable endoscope sleeve is a lens body sleeve end 3, which is in contact with the lens end of the endoscope, the large end of the endoscope body sleeve 2 is a handle sleeve end 5, the handle sleeve end 5 is in contact with the scope interface of the endoscope, the U-shaped opening 1 of the endoscope body sleeve 2 is completely attached to the handle of the endoscope, the through holes 4 formed on the two sides of the U-shaped opening 1 are clamped with the scope interface of the endoscope, the endoscope sleeve is completely sleeved on the endoscope, the handle sleeve end 5 is provided with a hole 6 for allowing the lens of the endoscope to pass through the hole 6, and the whole endoscope sleeve is completely sleeved on the endoscope. Wherein, the endoscope cover adopts the material that the ductility is good, the length of endoscope cover is roughly the same with endoscope length when using, the ductility of utilizing the endoscope cover with the endoscope cover suit on the endoscope, the use of endoscope cover has avoided endoscope and patient's body fluid contact, prevention cross infection, the hard tube otolaryngology endoscope cover of disposable in this scheme is because the ductility is better, can be used to the hard tube otolaryngology endoscope of different models, the protection hard tube endoscope mirror body.

US9301796B2 - Cryosurgery system

Inventor: Ron Burr, Janel Petrilli
Current Assignee: CSA Medical Inc
Filing date: 2012-03-02
Publish date: 2016-04-05
Anticipated expiration date: 2033-11-26

A endoscopy system for cryosurgery that can effectively increase success rate of surgeries while improving patient experiences with a suitable diameter for the catheter and by absorbing affective gasses and liquid.

Abstract

An improved cryosurgical system for application of medical-grade liquid nitrogen to a treatment area via a small, low pressure, open tipped catheter. The system includes a console, including a touch panel computer, a cryogen module, a suction module and an electronics module, all packaged in a mobile cart, and a disposable spray kit. Improved features include optional low cryogen flow setting to reduce the cryogen flow rate by 50%, improved cryogen flow consistency reducing pressure pulses and peaks (improved sensors, control systems, and control algorithms), an integrated suction pump for improved consistency and self-checks, specified vent tube areas and corresponding maximum expected pressures during cryospray procedure; optional pressure sensing capability to monitor pressure during a treatment, and improved catheter design.

Important description:
As the liquid nitrogen travels from tank 126 to the proximal end of cryogen delivery catheter 128, the liquid is warmed and starts to boil, resulting in cool gas emerging from the distal end or tip of catheter 128. The amount of boiling in catheter 128 depends on the mass and thermal capacity of catheter 128. Since catheter 128 is of small diameter and mass, the amount of boiling is not great. (The catheter would preferably be "French Seven".) When the liquid nitrogen undergoes phase change from liquid to gaseous nitrogen, additional pressure is created throughout the length of catheter 128. This is especially true at the solenoid/catheter junction, where the diameter of the supply tube relative to the lumen of catheter 128 decreases

1. A mobile cryosurgical apparatus for cryogenic spray ablation comprising:

a cryogen tank for storing cryogen under pressure;

a cryogen pressure measuring device configured to measure a pressure of the cryogen tank;

a cryogen pressure maintenance system configured to monitor a pressure of the cryogen tank via the cryogen pressure measuring device and control the pressure of the cryogen in the cryogen tank during use of the mobile cryosurgical apparatus;

a cryogen level measuring device configured to measure a cryogen level in the cryogen tank;

a cryogen tank fill system for filling the cryogen tank with cryogen;

a catheter attachment apparatus for attaching a catheter to the mobile cryosurgical apparatus;

a catheter pre-cool system for precooling the catheter;

a catheter defrost system for defrosting the catheter;

an on-board suction system configured to evacuate gas from a treatment area;

a user-control system for user-control of cryogen flow and application of suction via the on-board suction system;

an on-board computer screen for interacting with the mobile cryosurgical apparatus; and

an on-board control system comprising a non-transitory computer readable medium containing computer readable instructions for: monitoring and adjusting cryogen pressure via the cryogen pressure maintenance system, controlling a cryogen tank fill operation via the cryogen tank fill system, running pre-procedure system checks, controlling catheter pre-cool and defrost using the catheter pre-cool system and the catheter defrost system, respectively, and controlling thermal, timing and suction functions at least in part using the user-control system during user treatment of patient;

wherein said cryogen level measuring device comprises:

a three-point cryogen tank support system;

an electronic load cell located at one point of the three point cryogen tank support system and configured to determine the load borne by the support at one point;

and electronics for communication the load recorded to the on-board control system.

US10932771B2 - Suture based closure device

Inventor: Shaun D. Comee, Dennis B. HUBBARD, JR., Jason R. Lebeau, Norman C. May, Paul Smith, Robert B. DeVries, Christopher R. Deuel, Stan Robert GILBERT
Current Assignee: Boston Scientific Scimed Inc
Filing date: 2018-02-21
Publish date: 2021-03-02
Anticipated expiration date: 2038-11-18

A suture based device that can be connected with an endoscope as a working channel to allow for movements of surgical tools during endoscopic procedures.

Abstract

A suture device may include a suture translation assembly configured to be axially translatable within a lumen of a delivery system and a distal assembly configured to be securable to the distal end of the delivery system. The suture translation assembly and the distal assembly may cooperate to enable a user to pass a needle back and forth between the two in order to endoscopically suture a defect.

1. A suture device for use in combination with a delivery system including a lumen extending through the delivery system, the suture device comprising:

a needle usable to carry a suture;

a distal shuttle configured to releasably secure the needle; and

a user interface extending proximally from the distal shuttle, the user interface configured to enable a user to releasably engage the needle; and

an endcap securable to the delivery system and configured to releasably engage and disengage the needle, the endcap configured to engage the needle when the needle is advanced distally into the endcap, and to release the needle when the needle is locked to the distal shuttle and the distal shuttle is withdrawn proximally;

wherein the needle comprises a distal region and a proximal region, the distal region including a distal detent for releasably engaging the endcap, the proximal region including a proximal detent for releasably engaging the distal shuttle; and

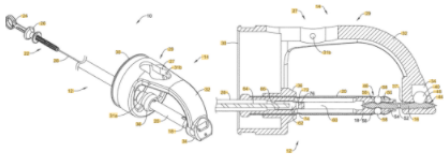
wherein the distal shuttle includes:

a distal needle opening configured to accommodate the needle when the distal shuttle is advanced distally over the needle, the distal needle opening aligned with a longitudinal axis of the needle;

one or more bearing ball openings arranged orthogonal to the distal needle opening such that the one or more bearing ball openings align with the proximal detent when the needle is secured to the distal shuttle; and

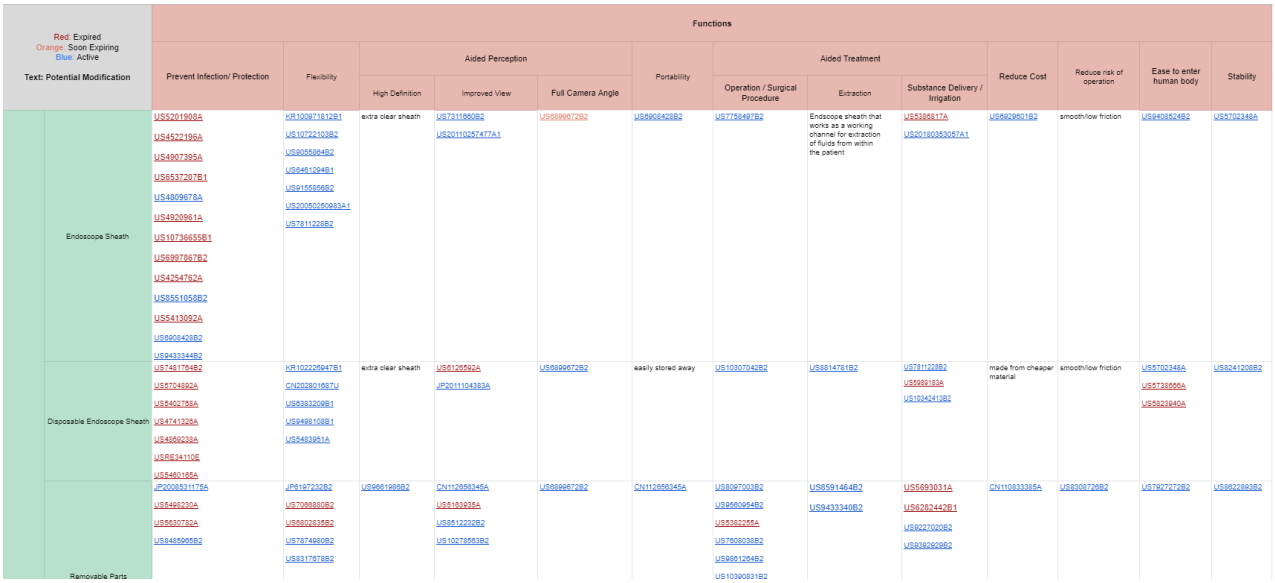
one or more bearing balls disposed within the one or more bearing ball openings and disposable within the proximal detent when the needle is secured to the distal shuttle.

Important description:
A member 20 may be disposed over the distal shuttle 18 and, as will be shown in subsequent Figures, is movable between a locked position in which the needle 16 is secured to the distal shuttle 18 and an unlocked position in which the needle 16 is releasable from the distal shuttle 18. In some cases, for example, the member 20 may be a sleeve 20. A user interface 22 extends proximally from the distal shuttle 18 and the sleeve 20, and may be configured to move the sleeve 20 between the locked position and the unlocked position. In some cases, as shown, the user interface 22 may include a proximal handle 24 and a translating handle 26 that is disposed relative to the proximal handle 24. In some cases, as will be described, the proximal handle 24 may be used to move the suture device 10 proximally or distally, while the translating handle 26 may be used to move the needle 16 between the distal shuttle 18 and the distal assembly 14. A shaft 28 may extend distally from the proximal handle 24 to the suture translation assembly 12, and may in particular be coupled to the sleeve 20.



In some cases, the distal assembly 14 includes a body 29 having a proximal connector 30 that may be configured to be coupled to the distal end of an endoscope or other delivery system. The body 29 includes an arm 32 that extends to an endcap 34. As will be discussed, the endcap 34 may be configured to releasably engage and disengage the needle 16. In some cases, for example, the endcap 34 may be configured to engage the needle 16 when the needle 16 is advanced distally into the endcap 34, and to release the needle 16 when the needle 16 is locked into the distal shuttle 18 (as will be discussed) and the distal shuttle 18 is withdrawn proximally. The distal assembly 14 may be considered as including a guide

Appendix 4: Patent Map



Red: Expired Orange: Soon Expiring Blue: Active Text: Potential Modification		Functions											
		Prevent Infection/ Protection	Flexibility	Aided Perception			Portability	Aided Treatment			Reduce Cost	Reduce risk of operation	Ease to enter human body	Stability
				High Definition	Improved View	Full Camera Angle		Operation / Surgical Procedure	Extraction	Substance Delivery / Irrigation				
	Endoscope Sheath	US5201908A US4522196A US4907395A US6537207B1 US4809678A US4920961A US10736655B1 US6997867B2 US4254762A US8551058B2 US5413092A US6908428B2 US9433344B2	KR100971812B1 US10722103B2 US9055864B2 US8461284B1 US9156956B2 US20050250983A1 US7811228B2	extra clear sheath	US7311660B2 US20110257477A1	US6899672B2	US6908428B2	US7758497B2	Endoscope sheath that works as a working channel for extraction of fluids from within the patient	US5386817A US20180353057A1	US6929501B2	smooth/low friction	US9408524B2	US5702348A
	Disposable Endoscope Sheath	US7481764B2 US5704892A US5402768A US4741326A US4869238A USRE34110E US5460165A	KR102226947B1 CN202801667U US6383209B1 US9498108B1 US5483951A	extra clear sheath	US6126592A JP2011104383A	US6899672B2	easily stored away	US10307042B2	US8814781B2	US7811228B2 US5989183A US10342413B2	made from cheaper material	smooth/low friction	US5702348A US5738666A US5823940A	US8241208B2
	Removable Parts	JP2008531175A US5498230A US5930782A US8485965B2	JP6197232B2 US7066880B2 US6802835B2 US7874980B2 US8317678B2	US9861988B2	CN112656345A US5163935A US8512232B2 US10278563B2	US6899672B2	CN112656345A	US8097003B2 US9560954B2 US5382255A US7608038B2 US9861264B2 US10390631B2	US8591464B2 US9433340B2	US5693031A US6282442B1 US9227020B2 US9392929B2	CN110833385A	US8308726B2	US7927272B2	US9622893B2

A screenshot of a portion of the patent map. The complete patent map: https://docs.google.com/spreadsheets/d/10xOYKLw2PRuWDb70c47gLOmbYY1P0Fc5z-asVhR_dIY/edit?usp=sharing