Spring 2019

ErgoscopeTM – Ergonomic Endoscope

Drew Drum
dsd34@zips.uakron.edu

John D'Egidio
jad186@zips.uakron.edu

Bethany Scarpitti
bjp63@zips.uakron.edu

Ceara Stack
Cds106@zips.uakron.edu

Sara Kerestman
sak95@zips.uakron.edu

Ergoscope™ – Ergonomic Endoscope

Honors Project Final Report

John D'Egidio
Drew Drum
Bethany Scarpitti
Ceara Stack
With contributions by Sara Kerestman

26 April 2019
The University of Akron
BME Senior Design
4800:492-001
26 April 2019

ABSTRACT

Medical endoscopy is a growing industry, with a trend of chronic hand pain for gastroenterologists and flexible endoscope users. In order to address the lack of ergonomics in traditional gastrointestinal (GI) flexible endoscopes, the design team collaborated with a GI professional to design a more ergonomic endoscope interface, focusing on the more problematic controls. Two prototypes, as well as a mock-up were fabricated, which underwent verification and a user evaluation to assess the design's benefits. As the number of endoscopies each year increase, the Ergoscope, offers an alternative to the traditional angulation controls and much-needed relief for the issues that plague physicians—especially those with smaller hands—today.

Contents

1. Background

1.1. Endoscope Use

Endoscopy is widely used as a minimally invasive option for performing exploratory, diagnostic, or therapeutic procedures within biological systems with an external orifice, such as the gastrointestinal (GI), respiratory, and excretory systems. Modern endoscopes include a camera or lens at the distal tip, which allows clinicians to view internal features of the patient without the need for surgery. In addition to a camera and light guides, flexible endoscopes include air/water suction and a biopsy channel for use with a plethora of accessories (1).

Common endoscopic GI procedures include examining the digestive tract for ulcers, gastritis, internal bleeding, polyps and growths. When an abnormal polyp or tissue is identified, an endoscope can be used to biopsy the tissue for pathological analysis, or even remove gallstones which have exited the gallbladder and entered the bile duct. In the event a dangerous item is swallowed (or otherwise placed in the GI tract), endoscopes can be used for foreign body retrieval. Procedures vary from fifteen minutes to one or more hours, but are often scheduled so that a clinician is required to handle the device for hours at a time (2).

Flexible endoscopes have a bending section at the distal end that allows the clinician to maneuver through the body using mechanical hand controls. Due to the shape of the colon, stomach, and duodenum, flexible scopes allow the clinician to treat areas that would otherwise require surgery. The flexible tip angulation is controlled using two knobs on the right side of the scope grip, which are rotated to control up and down, or left and right angulation. Figure 1.1 shows a diagram of a video gastroscope, a style of flexible GI endoscope commonly used. While endoscopes may differ in length, image quality, or working orientation, the dual knob design is standard across all modern flexible GI scopes, the only exception being preliminary marketing information about a disposable endoscope with motor driven angulation that has not been introduced to market (3).

1.2. Ergonomic Issues

The controls of an endoscope are designed to be used with one hand while the other hand guides the insertion tube or advances devices, as shown in Figure 1.2. The angulation knobs in most endoscopes are positioned on the right side of the control housing, with their locking mechanisms too far away for a practical reach. Many gastroenterologists use two hands to reach the angulation and locking controls that they need (3), which requires them to release either the working length of the scope or the device being used. Additionally, the force required to turn the knobs induces painful strain on hand joints (3).

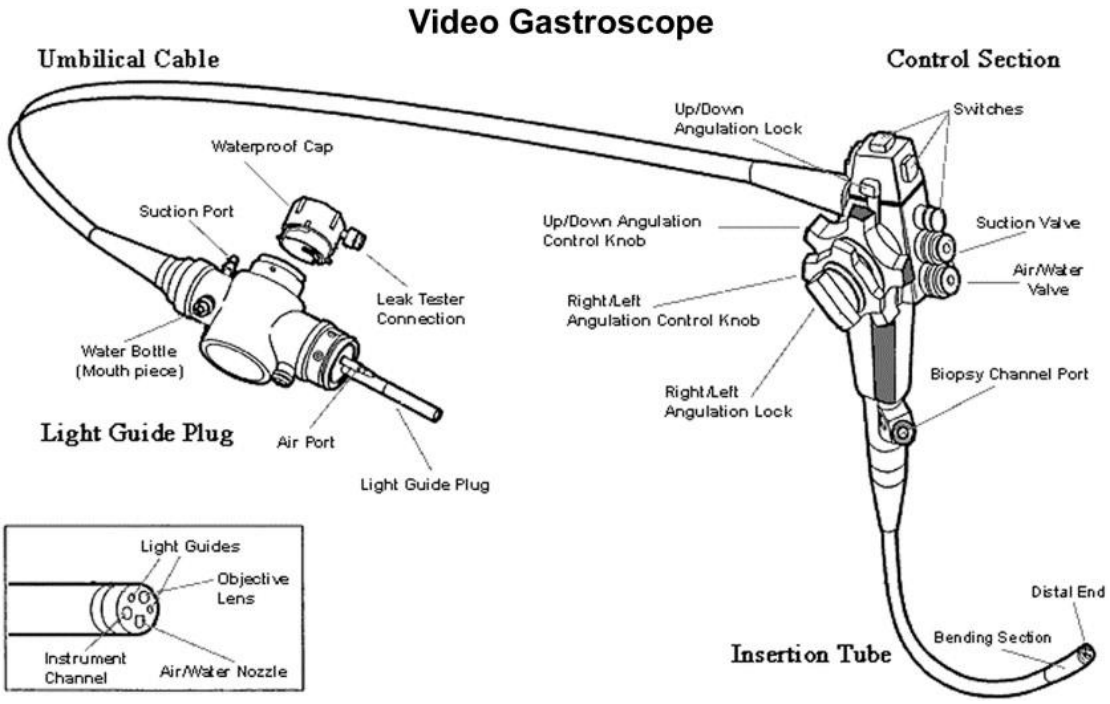

Figure 1.1. Diagram of a flexible endoscope.
Retrieved from https://www.sciencedirect.com/science/article/pii/S1096286703000732

Due to the layout of deflection, air/water, and suction controls, one gastroenterologist confirmed that using a traditional endoscope results in chronic discomfort and soreness (3). The physician interviewed, who is among a growing number of female gastroenterologists (4), also commented that her experience is not unique. Shergill et al. confirms that those with smaller hands, typically women, are more likely to experience chronic pain or injury from endoscope use (4). The duration and intensity of endoscope use magnifies the ergonomic issues introduced by the traditional design, especially for female clinicians who experience symptoms an average of three years before their male colleagues (5).

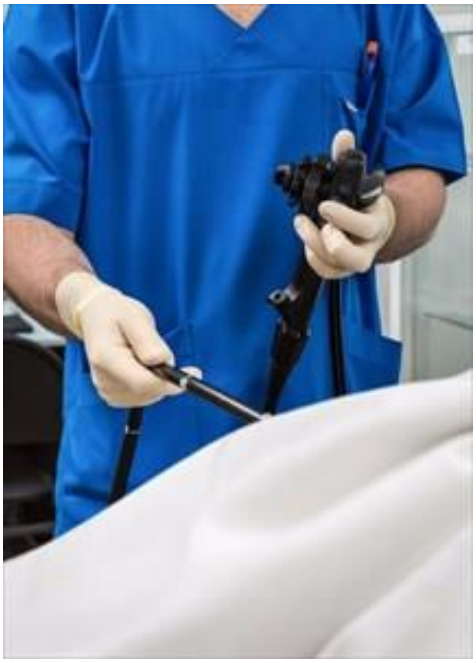

Figure 1.2. Photograph of proper endoscope handling.
Retrieved from https://www.mymed.com/tests-procedures/endoscopy/what-happens-during-an-endoscopy-procedure

Despite ample improvements in other systems, the design of the angulation knobs has remained virtually unchanged since the introduction of the fiberscope in 1964 (6). While

physicians have adapted to the current endoscope design, the discomfort not only affects the users, but it may increase procedure time and reduce physician responsiveness, increasing the risk to patients. While these concerns have been raised with manufacturers such as Olympus and Pentax, an alternative has not been introduced to market (2).

2. Project Description

Since the first fiberscope was introduced in 1964, the angulation controls of flexible endoscopes have remained virtually unchanged (1). While major improvements have been seen in the camera, processor, and accessories, the interface between human and machine has been largely neglected (6). Due to the lack of ergonomic concern, physicians often experience chronic hand pain, which often requires surgical intervention (2).

In an effort to remediate the harmful side effects of using traditional endoscopes, the design team sought to design a new, more ergonomic interface. The angulation controls were identified as the most problematic, thus the objective was to design an angulation control system that would lessen the strain on physician joints, while maintaining functionality and tactile feedback.

Replicating the complexity of a fully functional endoscope was far beyond the time, expertise, and budget of this project, thus the objective was to produce a proof of concept for a new angulation interface, with a mockup to simulate the user interface. A retired endoscope was donated by the client to be dismantled and retrofitted, which served as the foundation of the prototypes. The auxiliary systems, such as video, fiberoptic, ultrasound, suction, irrigation, insufflation, lighting, and the processor connections were removed to isolate the angulation drive system.

3. Design Process Overview

As shown in Appendix B, Figure 1, a traditional engineering process was applied in order to arrive at the final implementation. In order to approach the problem in a systematic and logical manner, initial information was obtained to shape the overall project scope. This included information on device usage, consumer concerns, and competitive devices already on the market, all included in the design requirements stage. This information fed into the product concept, and was broadened through market research, ideation, and different functional diagrams. More specifically, these functional diagrams were used to isolate the relevant areas of the device that were within scope of the project. It was important to ensure that scope creep, when a project seeks to solve problems outside of the initial scope, did not occur. Additionally, information on interacting components, such as the order in which they influence each other, and their related sub functions helped to shape the brainstorming process. After the initial brainstorming and information gathering stages were completed, the best solution concept was selected generated using a down select analysis, visual representations of the idea, and initial design concepts.

Solution concept generation and selection then led into prototyping, during which physical models were produced, more specifically a proof of concept. Prototyping encompassed

manufacturing and assembly concerns, including 3D printing components, which was handled within the team, parts sourcing from suppliers, and the actual build. Two design revisions were completed, producing a proof of concept prototype for each. A proof of concept prototype only seeks to represent a pilot design, and may not consist of a fully functional design. Verification testing, to ensure the design met specifications set at the beginning of the project, included basic parameters such as force and angulation testing, as laid out in the design verification matrix.

Finally, the scope of the project ended with preliminary validation testing. As validation seeks to ensure specifications meet customer needs, the design team met with the client for feedback on various aspects of the Ergoscope device. An itemized list of deliverables can be viewed in Appendix B, Tables 1 and 2.

4. Design Requirements

The design requirements and project specifications were derived from the initial client interview and the client's expectations for the final project, as well as several additional meetings and discussions with the client. As a first step for determining design requirements, the design team met with the client to capture customer needs. The comments made by the client were translated into a set of design objectives, which are organize as an objective tree in Appendix B, Figure 2. As seen in the objective tree, the main concerns were improving the safety, economics, ergonomics, quality, and effectiveness of the endoscope design. The objective tree allowed for a visual representation of those categories broken down into detailed subsections and tasks that guided the design process.

The objectives were then used to develop a set of functions, organized as a function tree in Appendix B, Figure 3. As discussed in the Section 2, Project Description, the time and budget constraints limited the scope for the project. The design team assessed a broader range of customer requirements and objectives, with the understanding that many would not be applicable for the delivered prototype. The function tree was then used, with preliminary design ideas, to develop a set of specifications for a completed device. Again, the list of specifications encompassed a fully functional endoscope, and thus, many were not applicable within the scope of this project. After deliberation regarding which specifications could be feasibly fulfilled, the design team identified the key specifications that would be tested. These specifications can be seen in Table 4.1. In addition to the quantitative specification, the device also needed to be comfortable to hold, and the interface needed to be easily reached by a person with below-average hand size. These specifications were assessed by conducting a user evaluation with the client.

Table 4.1 Overview of Applicable Specifications

Specification	Metric	Test Method
Tip Angulation - Up	60°	Protractor
Tip Angulation - Down	35°	Protractor
Tip Angulation - Right	53°	Protractor
Tip Angulation - Left	48°	Protractor
Max Force to Move Levers	10 N	Load Cell

5. Final Implementation

The team constructed two separate prototypes as well as a design mockup in order to embody the design concept. Both prototypes offered information about mechanical viability, while the mock-up acted as a means for simulating user experience with the improved interface.

[Additional information omitted due to confidentiality and possible intellectual property]

6. Performance Testing

A test plan was used to organize testing, as well as ensure the design verification matrix (Appendix C) was reflected in the testing conducted. The two aspects the testing focused on were the force required to use the new angulation mechanism, as well as the angulation range.

The design team measured the force required to engage the new angulation mechanism, completing five trials on the beta prototype. A summary of the beta force testing data can be seen in Table 6.1. A comparison of the angulation range of the original scope to the modified scope can be viewed in Table 6.2. Due to the age of the modified endoscope, the prototype's performance was compared against the endoscope's performance prior to modification.

The forces fell within specification for each trial and the direction averages; however, the design modifications reduced the range of angulation considerably. The design team theorizes that deconstructing the scope may have loosened some of the angulation drive system or allowed crucial lubricants to rub off. The results provided evidence that the redesigned mechanism had the potential to be a replacement to the current angulation control, although further refinement is required to ensure the proper range of motion.

Table 6.1 Summary of Force Test Data

Angulation Direction	Average Force (N)	Spec (N)	Pass/Fail
Up/Down	2.88	10	Pass
Left/Right	2.85	10	Pass

Table 6.2 Comparison of Angulation Data

Angulation Direction	Unmodified Device (degrees)	Beta Prototype (degrees)	Difference (degrees)
Up	59.3	33.2	-26.1
Down	34.7	19.4	-15.3
Right	53.0	26.4	-26.6
Left	48.3	30.2	-18.1

In addition to the mechanical tests, one prototype and the design mock-up were taken to the client for user evaluation, which was used to assess the ergonomics of the design. Multiple sources agreed that the design changes felt beneficial, but a proper usability study would be needed to confirm the ergonomic impact.

[Additional information omitted due to confidentiality and possible intellectual property]

7. Feasibility Discussion

The Beta Prototype is considered a proof-of-concept prototype. The team was able to design a product that met the customer's primary need, an angulation mechanism that is more ergonomic for the gastroenterologists with small hands; however, due to the narrowness of the project scope, many important aspects of an endoscope were ignored or removed. While the design team believes that the initial need was met, there are significant areas of improvement that need to be addressed before the design would be ready for clinical use.

By developing a proof of concept prototype, the design team determined the validity of the dual lever angulation mechanism. With additional time and resources, the current model could be redesigned to include endoscope features such as air/suction/water, optics, and utility channel, as well as have a sleeker design. This would provide a product that would meet all needs of practicing gastroenterologists, making it a viable alternative to endoscopes in use today.

8. Business Aspects

While the client may want to pursue further research and commercialization, the limited resources inhibited the design team from any such ventures thus far. Partnering with a hospital is a significant advantage over other endoscope manufacturers and developers since the specific insight of professionals is easily accessible during the design process. As seen in Figure 8.1, on a global scale, hospitals account for 48% of the end users of endoscopes (7), making a hospital

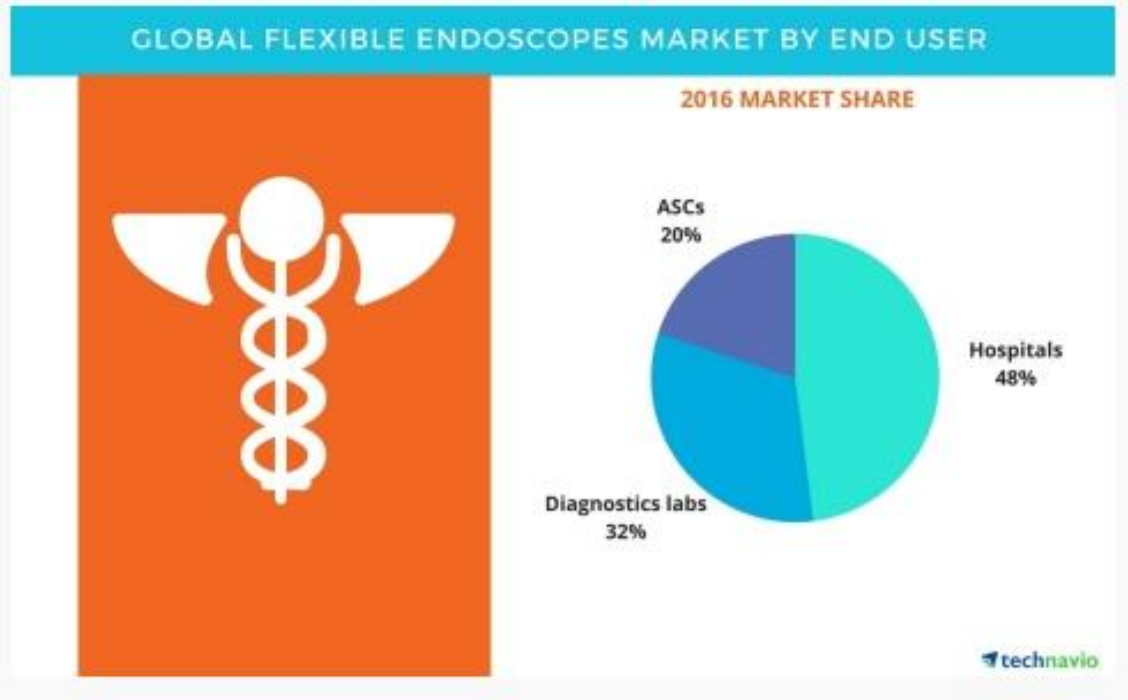

Figure 8.1. Graph of global flexible endoscope market
Retrieved from https://www.businesswire.com/news/home/20170725005755/en/Global-Flexible-Endoscopes-Market---Forecasts-Segmentation

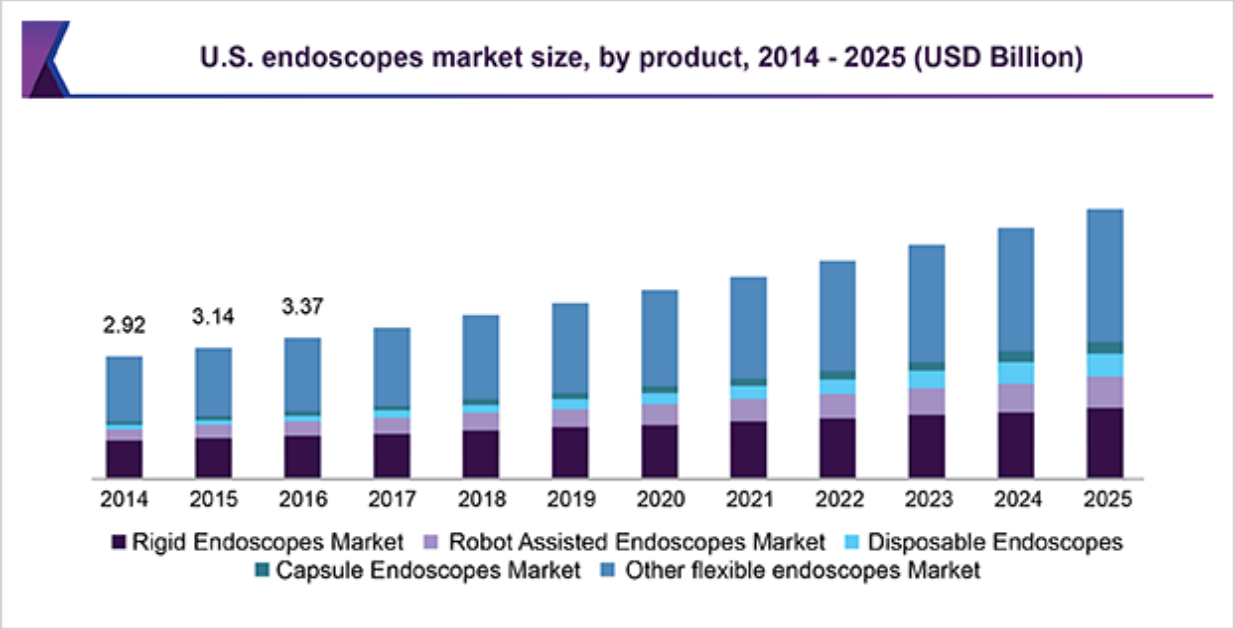

Figure 8.2. U.S. Endoscopes Market Size by product.
Retrieved from https://www.grandviewresearch.com/industry-analysis/endoscopes-market

the ideal source for voice of customer insight. If taken to market, the objective would be to capture fifteen percent of the U.S. flexible endoscope market. As shown in Figure 8.2, the U.S. endoscope market is dominated by the flexible endoscope market (8). Customers include the hospitals and independent facilities that complete the endoscopy procedures as well as accessory manufacturers and research institutes. Such customers would need to buy multiples of the devices as well as different lengths and versions for different applications. Furthermore, the North American endoscope market accounts for more than 33% of the global market with the U.S. owning over 94% of the market share (8). Assuming partnership with an established endoscope manufacturer, such a device could expect to garner that possible 15% of the market by 2025, which is projected at over $5 billion (9). This shows the potential for an Ergoscope Endoscope to make a hearty return on investment.

9. Financial Considerations

The major financial considerations for commercializing an Ergoscope endoscope include mass production, regulatory registrations, and product integration with existing processors and product portfolios.

The design team only delivered a proof of concept, thus design a proof-of-product and proof-of-production would require substantially more investment. Not only would the design have to be finalized to include the other endoscope systems initially discarded, but the entire system would have to be tested for reprocessibility (sterilizing an endoscope between procedures), biocompatibility, and reliability. From usability studies and other service-learning studies, valuable input should be collected to improve the device's ergonomics, function, and overall design as to

be most useful for the end user. These studies are critical to learn how the device may compare to competitors and personal preferences as well as gathering statistical market data. Important data, such as the usefulness of the product and preferences, helps to narrow the scope of the stakeholders and market. This enables management to focus their efforts on aspects that might be lacking and to improve them. These studies may reveal the lack of thought behind manufacturing for the environment and available technology to advance the device's capabilities or functionality. Lastly, the design should be evaluated for any manufacturing concerns, and designed for manufacturability, if applicable.

Once the design is finalized, it would also have to be mass-produced with quality controls. Based on different tool requirements and manufacturing technologies, production alone could require significant start-up costs.

Despite hefty start-up costs, due to the isolated nature of the design, the design team predicts that variable manufacturing costs would mirror the costs to produce current endoscope models. The design does not add large amounts of materials, and the cost for the additional components would be compensated for by the increased market share.

Regulatory registrations would also be a major consideration moving forward, since medical devices require registration for market entry. First, intellectual property would have to be protected through patenting, and then the design would have to be evaluated to determine the appropriate regulatory pathways, and the required testing. While it is likely the device improvement may fall under a 510K or special 510K filing, special care would still need to be given to ensure the proper regulatory pathway is pursued. Documenting the design process is essential in creating a comprehensive design history file, which includes documentation of customer specifications, communications, brainstorming articles, business brief, and related forms to show the pathway from concept to construction. These forms will help the FDA analyze the device and clear quickly, but require time and expertise to compile.

These costs make commercialization cost prohibitive but partnering with an existing endoscope manufacturer would be a significant advantage, especially if the rights could be maintained by the design team. With the weight of an established company and brand, the Ergoscope would have a much better opportunity to enter the market and capture market share.

Once introduced, the improved interface could be universally adapted for different types of scopes. While a standard gastroscope or colonoscope may offer the surest option to enter the market initially, the design could be used for virtually any type of GI flexible endoscope produced. The design team predicts that selling the Ergoscope at a price comparable to traditional scopes will provide a faster entry into the market, with the possibility for gathering a larger margin as the device takes hold in the market.

10. Conclusion

The team partnered with a practicing gastroenterologist to gather information and design a more ergonomic endoscope for physicians with smaller hands as well as to reduce the resulting pain from multiple daily endoscopic procedures. The design team documented the design process and major milestones as they developed the Ergoscope, which consists of an improved angulation control design. The team members worked diligently to complete a myriad of tasks and produce a design that should be more user-friendly than any available on the market currently. Scope of work completed indicates a successful initial design and proof of concept, with further revisions needed in order to implement the design within a hospital setting.

Regulatory registration, full design validation, and manufacturing require a huge investment, making those activities far beyond the scope of a student-led project. Beyond general commercialization activities, the future work that could be completed by a second student team includes refining the proof-of-concept and incorporating more of the endoscope functionality. Additional testing regarding biocompatibility, sterilization and clinical trials would also need to be done. Furthermore, miniaturizing the design components would be necessary to produce a streamlined and efficient product that could enter the medical device market. Considerations for miniaturized components would require additional force, angulation and ergonomic testing, including but not limited to, testing done within this project. Overall the project is deemed a success, with the understanding that the goal of producing a proof of concept was achieved, and the design will need future revisions and testing before entering the medical device market.

REFERENCES

1. **ASGE.** Endoscopic Procedures. *American Society for Gastrointestinal Endoscopy.* [Online] August 2014. [Cited: November 30, 2018.] https://www.asge.org/home/about-asge/newsroom/media-backgrounders-detail/endoscopic-procedures.

2. **Name Omitted due to Confidentiality.** *MD.* [interv.] Drew Drum, et al. September 28, 2018.

3. *Flexible Gastro-intestinal Endoscopy--Clinical Challenges and Technical Achievements.* **Kurniawan, Niehls and Keuchel, Martin.** Hamburg, Germany : Computational and Structural Biotechnology Journal, 2017, Vol. 15.

4. *Ergonomics and GI Endoscopy.* **Shergill, Amandeep K., McQuaid, Kenneth R. and Rempel, David.** 1, s.l. : Gastrointestinal Endoscopy, 2009, Vol. 70.

5. **DDW News.** AGE Survey Shows Endoscopists at High Risk for Musculoskeletal Injuries. *Digestive Disease Week Blog.* [Online] May 7, 2017. [Cited: November 30, 2018.] http://blog.ddw.org/aga-survey-shows-endoscopists-at-high-risk-for-musculoskeletal-injuries/.

6. **Olympus.** The Olympus Museum: Endoscopes. *Olympus Global Homepage.* [Online] [Cited: November 30, 2018.] https://www.olympus-global.com/technology/museum/endo/.

7. **Maida, Jesse.** Global Flexible Endoscopes Market - Forecasts, Segmentation, Drivers, and Opportunity Assessment by Technavio. *Business Wire.* [Online] July 28, 2017. [Cited: March 24, 2019.] https://www.businesswire.com/news/home/20170725005755/en/Global-Flexible-Endoscopes-Market---Forecasts-Segmentation.

8. **Grand View Research.** Endoscopes Market Size, Chare, and Trends Analysis Report by Produc, By End Use, and Segment Forecasts, 2018-2025. *Grand View Research.* [Online] August 20, 2018. [Cited: March 24, 2019.] https://www.grandviewresearch.com/industry-analysis/endoscopes-market.

9. **Wills, Stewart.** Report: A US$40.9 Billion Endoscopy Market by 2022. *Optics & Photonics News.* [Online] January 9, 2017. [Cited: March 24, 2019.] https://www.osa-opn.org/news/endoscopy-market/.

APPENDIX A: REPORT CONTRIBUTIONS

Report Section	Contributors
Abstract	Bethany Scarpitti
1. Background	John D'Egidio & Bethany Scarpitti
2. Project Description	Bethany Scarpitti
3. Design Process Overview	Ceara Stack
4. Design Requirements	Sara Kerestman
5. Final Implementation	N/A
6. Performance Testing	Drew Drum
7. Feasibility Discussion	Drew Drum
8. Business Aspects	John D'Egidio
9. Financial Considerations	John D'Egidio & Bethany Scarpitti
10. Conclusion	John D'Egidio & Ceara Stack
Formatting & Appendices	Bethany Scarpitti

APPENDIX B: ADDITIONAL TABLES & FIGURES

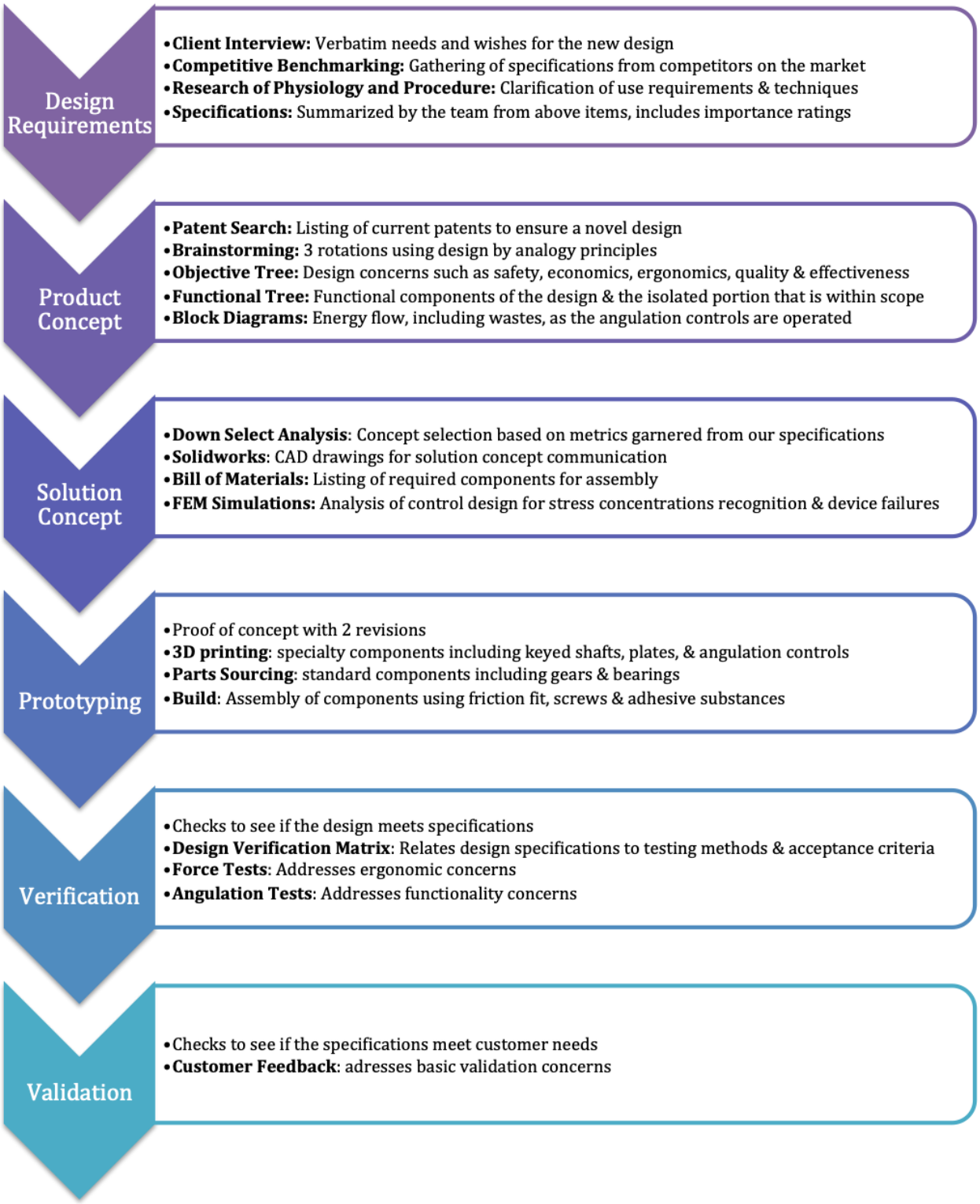

Figure 1. Diagram of the design process

Table 1. Fall Deliverables

Fall Deliverables				
No.	Item	Lead	Start	Due
1	**Need**		9/11/18	10/9/18
1.1	Endoscope Functionality	John	9/11/18	9/19/18
1.2	USE Meeting	Bethany	9/14/18	9/25/18
1.3	Customer Contact Info	Sara	9/11/18	9/14/18
1.4	Customer Interview Notes (200.00)	Drew	9/14/18	9/23/18
1.5	Customer Requirements (200.10)	Sara	9/14/18	10/1/18
1.6	Project Description: MOU (207.00)	Ceara	10/1/18	10/9/18
2	**Research Problem**		10/9/18	10/24/18
2.1	Competitive Products	Bethany	10/9/18	10/18/18
2.2	Patent Search	John	10/9/18	10/18/18
2.3	Research of Physiology/Science	Ceara	10/15/18	10/24/18
3	**Development Plan**		10/9/18	11/15/18
3.1	Gantt Chart With Scope	Ceara	10/9/18	10/14/18
3.2	Preliminary Specifications	Sara	10/9/18	11/6/18
3.3	Preliminary NABC Project Sheet (405.20)	Drew	11/6/18	11/15/18
4	**Design Development**		10/20/18	11/30/18
4.1	Brainstorming	Bethany	10/20/18	10/25/18
4.2	Down Select Analysis (502.00)	Drew	10/25/18	11/7/18
4.3	Initial Drawings (Solidworks)	Ceara	11/6/18	11/20/18
4.4	**Modeling**	Team	11/20/18	11/29/18
4.4.1	Objective Tree	John	11/17/18	11/23/18
4.4.2	Functional Diagrams	Sara & Drew	11/17/18	11/29/18
4.4.3	Block Diagrams	Bethany	11/17/18	11/21/18
4.4.4	Predictive Modelling	John & Ceara	11/21/18	11/28/18
4.5	Revised Specifications (402.00)	Sara	11/20/18	11/30/18
5	**Etc.**		9/11/18	11/30/18
5.1	Team Correspondence Documentation	Team	9/11/18	11/30/18
5.2	Meeting Minutes	Team	9/11/18	11/30/18
5.3	Status Presentation (602.20)	Bethany	10/9/18	10/16/18
5.4	Project Proposal (603.20)	Bethany	11/12/18	12/2/18
5.5	Project Presentation (603.20)	Drew	11/20/18	11/29/18
5.6	DHF jump drive	Bethany	11/20/18	11/30/18

Table 2. Spring Deliverables

Spring Deliverables				
No.	Task	Owner	Start	End
1	**Alpha Prototyping**		**1/7**	**2/19**
1.01	Deconstruction of Scope	Team	1/7	1/11
1.02	Design Interface (Alpha)	Bethany	1/11	1/23
1.03	CAD Drawings (Alpha)	Bethany	1/23	1/28
1.04	Analysis of Design	Ceara	1/23	1/28
1.05	BOM Drawings (Alpha)	Bethany	1/28	1/30
1.06	Parts Sourcing	Bethany	1/30	2/3
1.07	Initial Purchase Order	Sara	2/3	2/7
1.08	Initial 3D Prints	Ceara	1/30	2/8
1.09	Initial Build (record)	Team	2/14	2/19
2	**Bench Testing**		**2/3**	**2/25**
2.01	Test Plan/Criteria **[202 a,b,c]**	John, Drew	2/3	2/11
2.02	Angulation/Force Test	Team	2/19	2/25
2.03	Customer Feedback	Team	2/19	2/25
3	**Beta Prototyping**		**2/25**	**3/18**
3.01	Revisions	Bethany	2/25	3/1
3.02	Additional Parts Sourcing	Bethany	3/1	3/5
3.03	Add.Purchase Orders	Sara	3/5	3/11
3.04	Additional 3D Prints	Ceara	3/1	3/11
3.05	Build (record)	Team	3/15	3/18
4	**Verification & Validation**		**3/5**	**4/25**
4.01	Test Plan/Criteria **[202 a,b,c] Revisions**	John, Drew, Sara	3/5	3/18
4.02	Angulation/Force Test	Sara, Drew	3/18	3/23
4.03	Customer Feedback	Team	3/18	3/23
4.04	Video Demo	Ceara, John	3/18	4/25
4.05	Analysis of Results	Drew	3/23	3/25
5	**Etc.**		**1/14**	**5/1**
5.01	Gantt Chart Construction	Ceara	1/14	1/18
5.02	Analytical Methods - FEM?	Team	3/25	4/10

Spring Deliverables				
No.	Task	Owner	Start	End
5.03	Design Verification Matrix	Sara	3/11	3/18
5.04	Meeting Minutes	Bethany	1/14	4/26
5.05	Status Report 1	Drew	1/15	1/22
5.06	Status Report 2	Drew	3/4	3/11
5.07	Class Presentation	Drew	2/17	2/24
5.08	Market Summary	John	1/14	3/12
5.09	Executive Summary	Ceara	3/1	3/15
5.10	Project Budget	Sara	1/14	3/11
5.11	DHF	Sara, John	4/18	4/25
5.12	Report -Rough Draft	Team	3/18	4/1
5.13	Poster for Capstone	John	4/1	4/10
5.14	Final Report	Bethany	4/1	4/15
5.15	Team Evaluations	Team	4/25	5/1

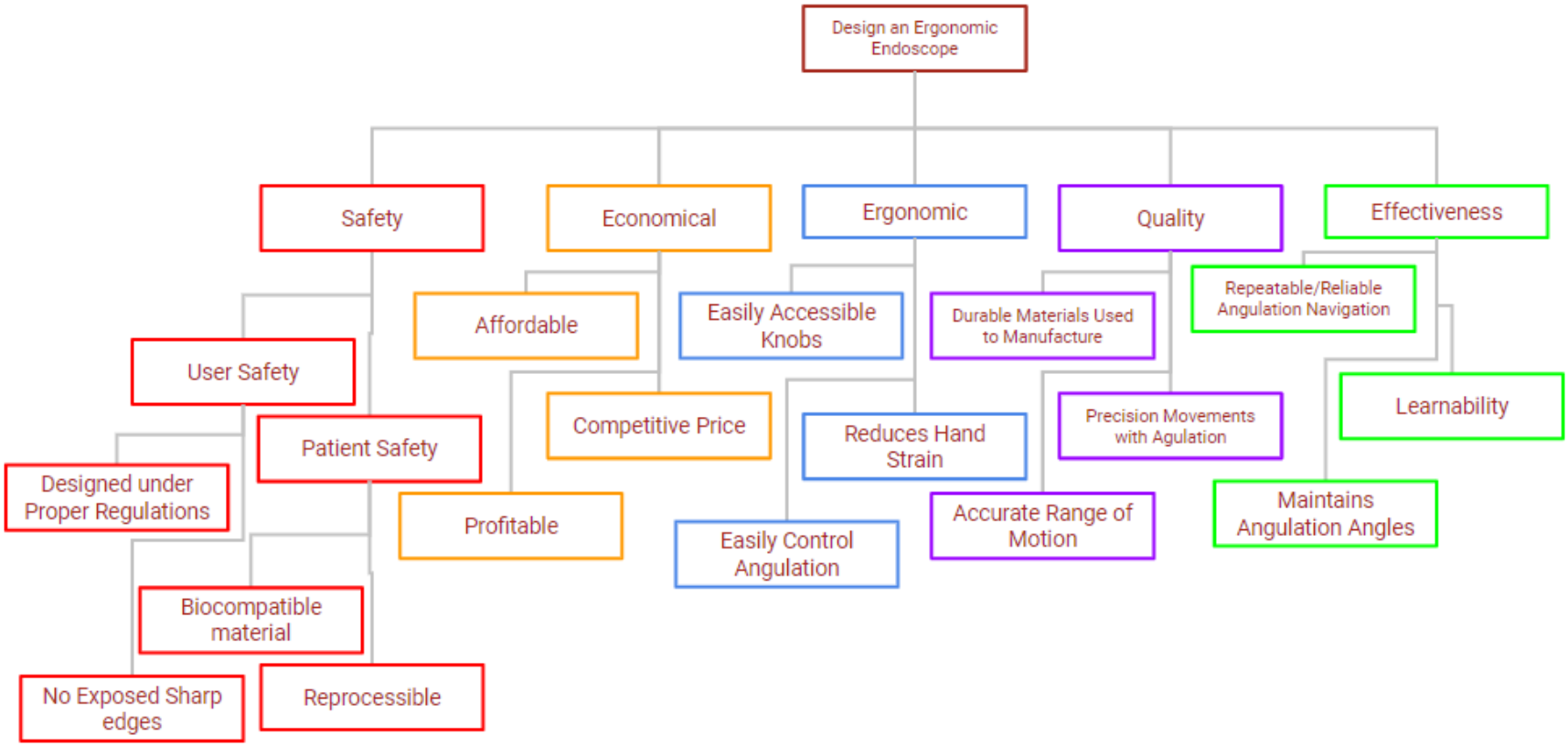

Figure 2. Object tree diagram

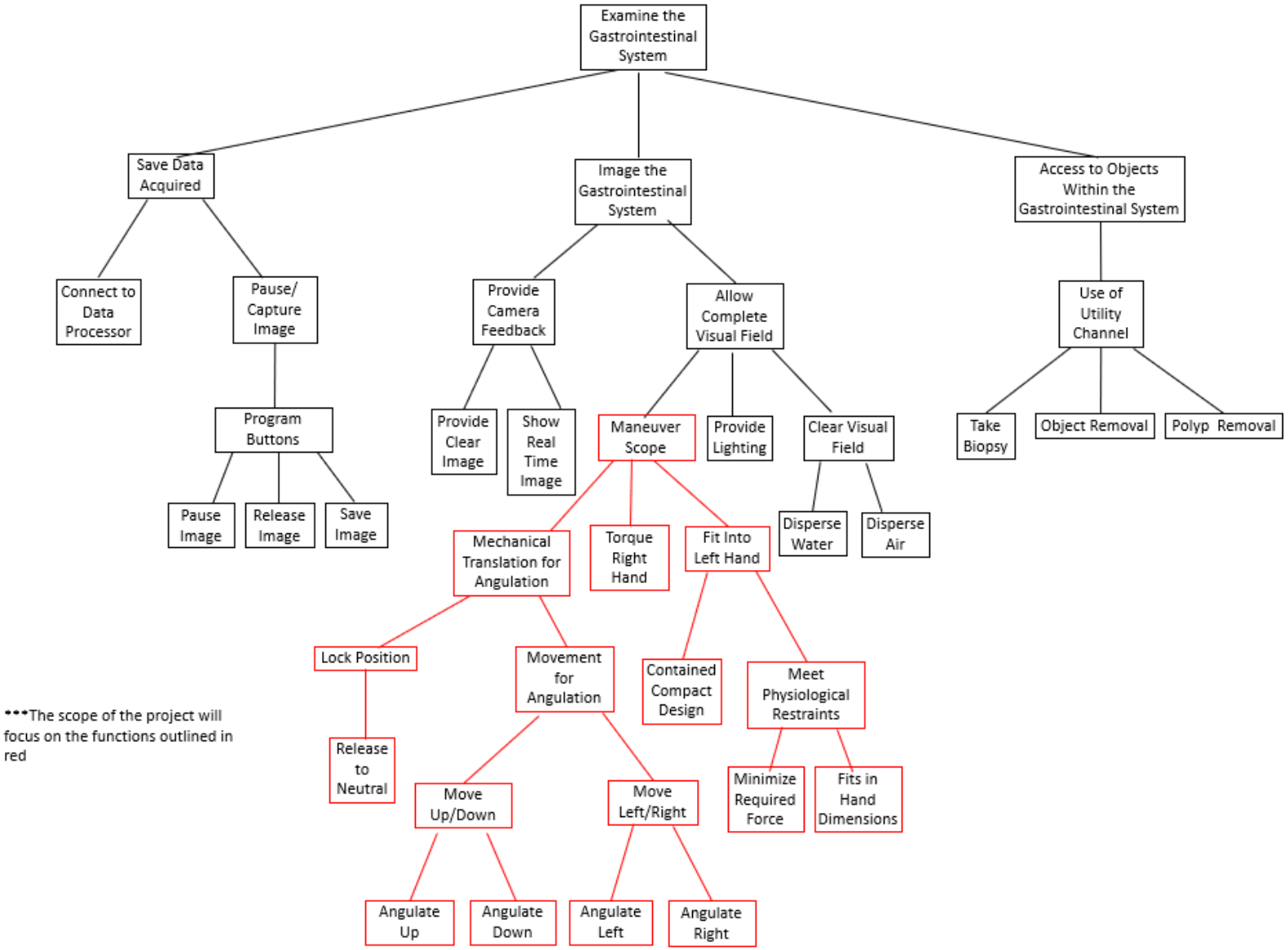

Figure 3. Function Tree Diagram

APPENDIX C: DESIGN VERIFICATION MATRIX

Item Number	Design Input	Design Output	Test Methodology	Acceptance Criteria
1.0 User/patient/clinical performance characteristics				
1.1	The device will allow for an easier reach for one hand to any of the buttons or knobs on it.	Client's comfort level improves	User Evaluation	Acceptable patient satisfaction rating
1.2	Limit the strain on the muscles of the hand that are used when operating	Client's comfort level improves	Force Test	Less than 10N is required to move each knob
1.3	Will accomodate a large range of hand sizes	No difficulty in reach for physicians with small hands, large hands, or those in between. Equally comfortable for all hand sizes.	User Evaluation	Acceptable patient satisfaction rating
1.4	Maintains the range of motion of a traditional endoscope	Measure angulation of current model scope and measure angulation of new design angulation.	Angulation Test	Pass if the angulation range of the new design is equal to or greater than that of the unmodified scope
2.0 Requirements for intended markets (domestic or international)				
2.1	*Internationally understood and recognized*	*N/A*	*N/A*	*N/A*
2.2	*Approved and integrated into common practice in the U.S.*	*N/A*	*N/A*	*N/A*
2.3	*Regulatory Clearance*	*N/A*	*N/A*	*N/A*
3.0 Safety				
3.1 Mechanical				
3.1.1	All internal mechanics safely contained within the device	Housing is design to encase all of the internal mechanics, leaving nothing exposed	Virtual Inspection	Pass if device does not visibly show any exposed mechanics and contains a proper housing unit

3.1.2	*Mechanical parts are able to withstand many procedures*	*Material must not break or fail after multiple procedures and prolonged forces applied*	*Reliability Study*	*Design and materials endure repeated use within the expected life of the device without noticeable wear*
3.1.3	No sharp edges or scratch hazards	No sharp corners or edges	Visual Inspection	Pass if device does not visibly show any sharp edges
3.2 Electrical				
3.2.1	Minimize or protect electrical components for reprocessing purposes	No exposed wires or pathways to internals of scope	Virtual Inspection	Pass is device does not visibly show any exposed electrical components and housing that covers all of the internal mechanics
3.3 Biological				
3.31	*Hypoallergenic material*	*Material chosen has no chance of creating an allergic reaction when in contact with patient*	*Material Testing*	*Pass if material has no reported allergic reactions*
3.4 Chemical				
3.4.1	*Device is non flammable*	*Material chosen is noncombustible*	*Material Testing*	*Pass if material testing provides results of noncombustible material*
3.4.2	*Inert material*	*Material chosen is inert*	*Material Testing*	*Pass if material testing provides results of inert material*
4.0 Regulatory				
4.1 FDA Medical Device Registration				
4.1.1	*N/A*	*N/A*	*N/A*	*N/A*
4.2 Standards to ensure safety and effectiveness of the medical device				
4.2.1	*N/A*	*N/A*	*N/A*	*N/A*
5.0 Quality				
5.1	*N/A*	*N/A*	*N/A*	*N/A*
6.0 Reliability				
6.1	*Will endure multiple uses without any noticeable wear*	*Material must not break or fail after multiple procedures and prolonged forces applied*	*Reliability Study*	*Design and materials endure repeated use within the expected life of the device without noticeable wear*

6.2	*Lifetime of device is compatible with the cost of the product*	*Device should be comparable to both the manufacturing cost and lifetime of a current endoscope on the market*	*Mechanical Testing/Cost Analysis*	*Pass if lifetime of device is the same as that of a current endoscope on the market*
7.0 Compatibility with accessories/auxiliary devices or products				
7.1	*Air/Water Valves*	*Design does not interfere with the accessory already in place on the scope*	*Usability Study & mechanical tolerancing study*	*Tolerances for device interfaces are within the appropriate range. Accessories can be attached and removed easily. Accessories do not malfunction during use.*
7.2	*Suction Valve*	*Design does not interfere with the accessory already in place on the scope*	*Usability Study & mechanical tolerancing study*	*Tolerances for device interfaces are within the appropriate range. Accessories can be attached and removed easily. Accessories do not malfunction during use.*
7.3	*Biopsy Valve*	*Design does not interfere with the accessory already in place on the scope*	*Usability Study & mechanical tolerancing study*	*Tolerances for device interfaces are within the appropriate range. Accessories can be attached and removed easily. Accessories do not malfunction during use.*
7.4	*Biopsy Channel Accessories*	*Design does not interfere with the accessory already in place on the scope*	*Usability Study & mechanical tolerancing study*	*Tolerances for device interfaces are within the appropriate range. Accessories can be attached and removed easily. Accessories do not malfunction during use.*
7.5	*Compatible with the flexible shaft and camera of a traditional endoscope*	*Design does not interfere with the accessory already in place on the scope*	*Usability Study & mechanical tolerancing study*	*Tolerances for device interfaces are within the appropriate range. Accessories can be attached and removed easily. Accessories do not malfunction during use.*
7.6	*Can be operated while wearing gloves*	*Gloves do not interfere with an design elements*	*Usability Study*	*Acceptable patient satisfaction rating & gloves do not contribute to any use failures*
8.0 Compatibility with the intended environment				
8.1	*Able to function with temperatures of 70 to 75*	*Material chosen is not affected by temperature differences*	*Material Testing*	*Pass if form, structure, and safety are not comprimised at temperatures and*

	degrees Fahrenheit and 50 to 60% relative humidity			*relative humidity of intended environment of human body*
8.2	*Able to withstand multiple procedures in one day/short amounts of time*	*Material must not break or fail after multiple procedures and prolonged forces applied*	*Reliability Study*	*Design and materials endure repeated use within the expected life of the device without noticeable wear*
9.0 Human factors				
9.1	*Compatible with hands from the 5th percentile female to 95th percentile male.*	*No difficulty in reach for physicians with small hands, large hands, or those in between. Equally comfortable for all hand sizes.*	*Usability Study*	*Participants with varying hand sizes do not show a significant difference in ability to use the device.*
9.2	Keep knobs and buttons intuitive to use or similar to the way that physicians are trained to use the device	No large learning curve for converting from original model to new ergonomic model	User Evaluation	Acceptable patient satisfaction rating
9.3	Will provide a tactile feedback when the scope is looping on the mesentery	Physician will feel force or tension in angulation levers when the scope is looped in the mesentery	User Evaluation	Acceptable patient satisfaction rating
10.0 Physical characteristics				
10.1	Will resemble a traditional endoscope	Only the angulation knobs will change, and they will remain two separate angulation mechanisms for up/down and left/right angulation.	Virtual Inspection	Pass if visually comparable to design of original scope
10.2	Fits comfortably in any physicians hand	Client's comfort level improves	User Evaluation	Acceptable patient satisfaction rating
10.3	No sharp edges or scratch hazards	No sharp corners or edges	Visual Inspection	Pass if device does not visibly show any sharp edges
10.4	Easy to grip texture	Client's comfort level improves	Use Evaluation	Acceptable patient satisfaction rating
11.0 Sterility				
11.1	*N/A*	*N/A*	*N/A*	*N/A*
***12.0 Manufacturability**				
12.1	*Cost of manufacturing close to or less than that of an original*	*Either equal in cost to manufacture or anywhere in range of up to 10% more than that of an original model scope*	*Cost Analysis*	*Pass if +10% more or less than the cost to manufacture original model*

13.0 Serviceability				
13.1	*Compatible with common interchangeable parts*	*Standard sizes used for gears and other hardware*	*Measure*	*Pass if hardware sizes are standard and not custom*
14.0 Labeling, packaging, storage				
14.1	*Able to be stored in any temperature other than extremes*	*Material chosen is not affected by temperature differences*	*Ship Test*	*No decrease in visual or functional integrity*

*Note: Line items in blue italics were considered for design purposes, but not verified due to resource constraints.