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SimpliScope: A novel device for in-office laryngeal biopsies

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Project Report

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Background:

Current laryngeal biopsies are performed in the operating room as opposed to in-office due to the procedural complexity and associated patient risk. Technological and medical advancements in screening for head and neck cancers have aided in diagnosing 184,625 new cases of laryngeal cancer in 2020 alone. As a result of these diagnoses, 99,840, or approximately 54%, of these patients lost their lives [1,2]. This substantial death rate is partially due to the scheduling delays associated with biopsies performed in the operating room. Currently, waiting times for an operating room biopsy is 48.8±49.4 days which is equivalent to 14 weeks in the future [3].

Data concerning laryngeal cancer and its prevalence based on gender and age is depicted by different studies performed around the world. Laryngeal cancers are more common in males than females, showing a significant spike in new cases starting at the age of 40. The total number of laryngeal cancers diagnosed in men are approximately 7 times more common by the age of 65 compared to women at the same age [4].

When evaluating procedures performed on lesions found in the larynx, the procedures are more likely to be performed in the operating room (OR) as opposed to in-office due to the patient being placed under general anesthesia to further reduce any associated risks. However, when these OR biopsies are performed the associated hospital costs, hospital charges, and physician fees increase significantly. Biopsies performed in the laryngeal region proved to have a relative cost reduction of 22% to 46%, OB (office based) to OR, when excluding physicians fees, while relative cost ranged from 27% to 95% , OB to OR, when physician fees were included [5]. This indicates the economic importance of transitioning these biopsies from the operating room to the office, leading to more affordable procedures, creating more timely diagnoses for patients around the world.

Current biopsy procedures fall into two categories: direct and indirect. A direct laryngoscopy is often performed under general anesthesia in the OR where a rigid laryngoscope is anchored in place to further expose the laryngeal inlet and vocal chords [6]. This procedural method can be extremely painful and prohibits all movement of the patient making it almost impossible to be a viable in-office procedure. Recently, more indirect methods have been introduced, including the use of a malleable optical stylet which is inserted into the oral or nasal cavity. This helps to focus the live video feed on the affected region in the larynx [6]. Indirect scopes allow for higher rates of maneuverability, increasing the patient's comfort and the range of motion to the scope and tools.

A common way of entry for endoscopes during current in-office procedures are through the nasal cavity ultimately leading a probe into the throat. Prior to improvements in sanitization, endoscopes used for these procedures were covered in a thin, disposable sheath meant to protect the equipment from blood, mucus, and other bodily secretions. These sheaths created a frictionless surface that also prevented high-level contamination of equipment [7]. Due to advancements in sterilization technology, sheaths used for sterilization purposes have been moved on from reducing the cost of extra, unneeded surgical equipment.

Alongside these laryngoscopes are a wide array of tools used to make incisions and obtain effective biopsy samples within the region of interest. Different combinations of forceps, blades, and lasers are currently used to obtain biopsy samples within the larynx. Both Maryland Graspers and Cupped Laryngeal Forceps are currently used during biopsy procedures. Maryland Graspers have a unique curvature that allows a surgeon to more easily access hard to reach places, while Cupped Laryngeal Forceps have cupped tips allowing the device to obtain, and protect, a larger cellular sampling from the area of interest. In more severe cases, a curved blade

will be used to cut a lesion or polyp out of the desired area. Blades are used more often during direct procedures due to their increased risk of drawing blood and administering pain to the patient. Lasers used for biopsies are safer and more accurate than a blade alternative during indirect procedures. These lasers allow physicians to easily cut through tissue layers, exposing underlying tissue that is needed for further sampling purposes.

Data regarding economic draw and patient safety opens the door for alternative devices within the field. The implementation of devices used for current direct laryngoscopy procedures into indirect procedures gives promise to the transition of procedure location and reduction of procedure cost through development.

Looking at alternative devices and patents of devices within the field can emphasize certain elements of the design that need to be focused on. In one patent the authors are working on an apparatus to apply a sheath to an endoscope [8]. The main takeaway from the first patent was in regard to the importance of the sanitation aspect of the sheath. Non-disposable endoscopes are notoriously difficult to clean and lead to problems concerning patient cross-contamination. By incorporating a sheath, the time between uses can be reduced and the risk of patient cross-contamination will be eliminated.

Problem statement

Head and neck cancer is the 5th most common cancer in the world and in 2020 there were 184,625 new cases of larynx cancer that resulted in 99,840 deaths [1,2]. Current devices that are used to take biopsies in-office return a ~30% cellular yield, while devices used in the operating room return a ~90% cellular yield. However, there can be long delays in the time it takes to diagnose laryngeal cancer as operating rooms can be booked for weeks in advance. By

developing a device for physicians to increase cellular yield during in-office laryngeal biopsies, patient safety will be improved as a result of a faster diagnosis.

Device Customer Requirements

To determine the customer requirements that fulfill our problem statement, we found it necessary to develop two different devices that are able to be used simultaneously. Our requirements were determined using two Quality Function Deployment (QFD) charts, shown in **Appendix A**. We identified the customer of our device to be an ENT surgeon who will perform laryngeal biopsies, and identified ten key customer requirements for each device. These were determined by evaluating two aspects: comparing the functional operation of laryngeal biopsies when performed in an operating room, with the concerns related to moving such procedures into an office space and comparing the functional qualities of competitor devices. The requirements were then ranked based on importance on a scale of 1 to 10, 10 being the highest priority. The most important customer requirements for each device are summarized in Table 1.

Table 1. The four highest priority customer requirements identified for ENT doctors/surgeons to be able to perform laryngeal biopsies in-office, while maintaining high yielding rates of the biopsies.

|__| = Blind Scope |__| = Channeled Sheath

Customer Importance	**Customer Requirement**	**Customer Importance**	**Customer Requirements**
10	Ability to fix in larynx w/ a separate scope	10	Material transparency
9	Channel maneuverability	10	Smooth insertion
9	Tool maneuverability	9	Ability to fit over scope
8	Wide enough for multiple tools	9	Tool maneuverability
		9	Secure fit

Device Functions

To meet the previously stated customer requirements, we designed two different devices both with tool dedicated channels that are capable of functioning simultaneously, with one inserted into each nostril and then into the nasal cavity. One device would fit over existing endoscopes, which we termed the Channeled Sheath, and the other device would be separate from the endoscope, which we termed the Blind Scope. There are three main functions for each device that encompass all other functions.

Channeled Sheath

For the Channeled Sheath, the main functions are sliding the sheath over the endoscope, holding a tool in place, and removal of the sheath from the endoscope. For sliding the sheath over the endoscope, the physician manually fits the sheath to the endoscope, the sheath remains secure around the endoscope throughout surgery, and a tool is inserted down the sheath's external tool channels. Regarding the security of tools, we focused on the device's ability to keep the tool secured in place throughout the duration of the procedure, followed by the removal of the tool. For removal of the sheath off the endoscope, the physician first removes the endoscope from the patient's nasal cavity and then manually removes the sheath from the endoscope. The functional decomposition of the Channeled Sheath is shown in Figure 1.

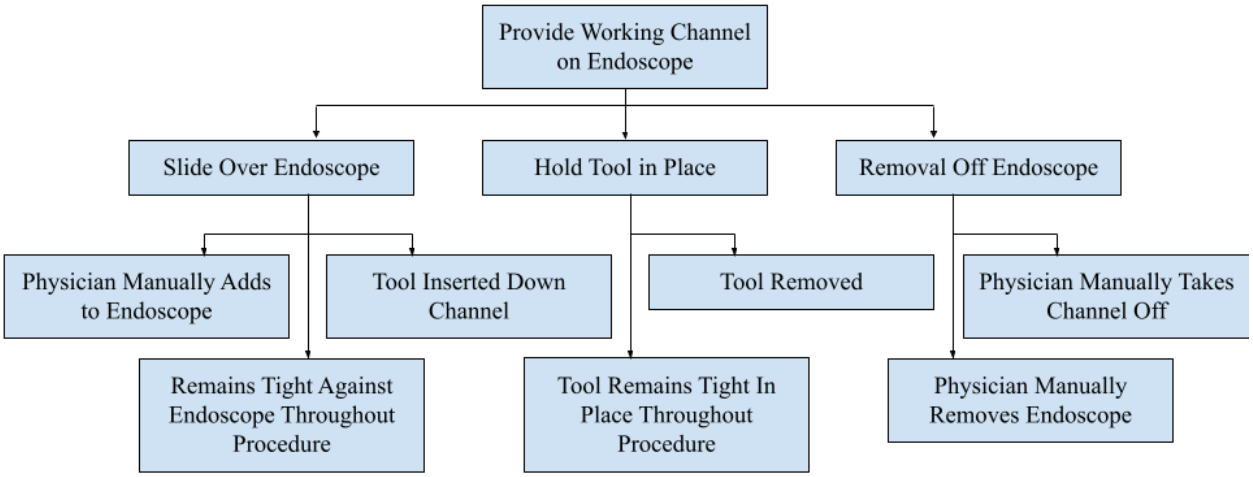

Figure 1. The functional decomposition of the Channeled Sheath, broken down into three main functions and additional subfunctions.

Blind Scope

For the Blind Scope device, the three main functions are the physician's ability to manually insert the channel through the nose, the channel remaining in place during the procedure, and the physician manually removing the channel through the nose. During the procedure, tools are inserted into the channel, the end of the channel is maneuvered in different directions, and the tools are removed at the end of the procedure. The functional decomposition of the Blind Scope device is shown in Figure 2.

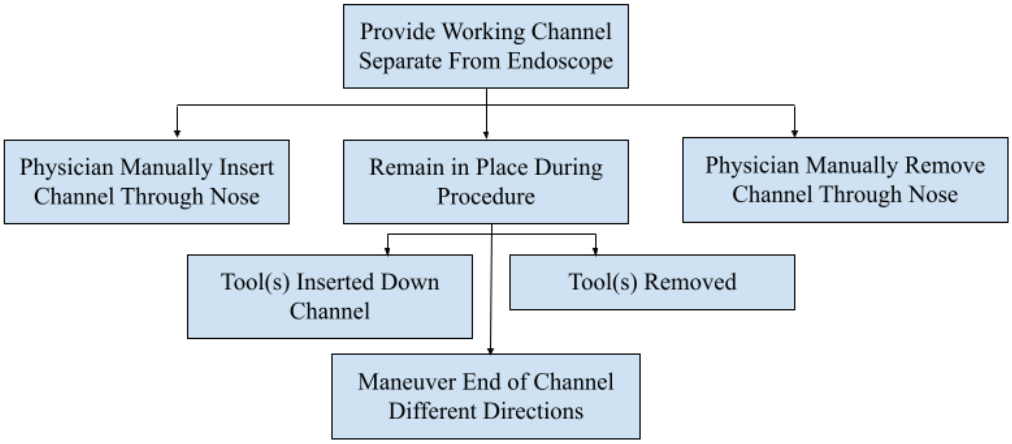

Figure 2. The functional decomposition of the Blind Scope, broken down into three main functions and additional subfunctions.

Engineering Standards

When further designing the Channeled Sheath and the Blind Scope for manufacturing and use, we need to consider the standards in place for the design of current endoscopes and endoscopic devices. ISO 8600, Parts 1-7, is pertinent to medical endoscopes and endotherapy devices. ISO 8600-1 states the general requirements of medical endoscopes and endotherapy devices. According to Part 1, both the Channeled Sheath and the Blind Scope would be considered endotherapy devices, which are "instrument(s) to create the body opening and through which an endoscope or endotherapy device is inserted, such as a guide tube [9]." For the Channeled Sheath, ISO 8600-6, updated most recently in 2020, has specifications for the overall length of the device, defined as the distance between the proximal and distal ends of the device [4]. ISO 8600-6 provides several design specifications that define the dimensioning of the overall length of the Blind Scope and the Channeled Sheath. Additionally for the Blind Scope, the document provides standards for angulation range and tip length. Angulation range is defined as the degree angle "between the normal axis of the flexible endoscope (endotherapy device) and the central axis of the deflected distal end [10]." The tip length is considered the length of the mechanically working portion of the distal end of the device, which would be the bending portion of the distal end of the Blind Scope [10]. When it comes to the use of the devices, the Channeled Sheath is designed to be disposable but the Blind Scope will need to be reprocessed, the medical term for sanitization, in a clinical setting after use. There is a standard for "Practice of Reprocessing of Reusable, Heat-Stable Endoscopic Accessory Instruments (EAI) Used with Flexible Endoscopes," ASTM F1992-99 [11]. This standard has since been withdrawn in 2016,

and a study in 2018 found that there is no current worldwide standard for flexible endoscope and endoscopic device reprocessing practices [12].

Design Specifications

To fulfill our customer requirements, we determined functional requirements for each device that act as design specifications, shown in the QFDs in **Appendix A**. The functional requirements were ranked based on their correlation to the customer requirements specified in Table 1.

Channeled Sheath

The three most important design specifications for the Channeled Sheath device are the diameter of the sheath (measured in millimeters), the diameter of the tool channel (measured in millimeters), and the number of tools in the channel. By decreasing the diameter of the sheath to between 5 to 7 mm, the sheath can still fit over the scope while remaining secure to the scope. By creating a tool channel ranging 2 to 4 mm in diameter, the tools will be secured in the channel while still allowing for tool maneuverability. This will also be accomplished by allowing 1 to 2 tools in the channel(s).

Blind Scope

The three most important design specifications for the Blind Scope are the diameter of the channel (measured in millimeters), the angle of movement of the distal tip (measured in degrees), and the number of tools in the channel. By decreasing the diameter of the channel to between 3 and 4 mm, multiple customer requirements can be accomplished: the channel will be wide enough to fit multiple tools, it will allow for tool maneuverability, it will allow for smooth

insertion of the channel, and will fit within the larynx at the same time as a separate scope. Maneuverability of both the channel and tools will increase as the degree of angulation will range from 100° to 120°. By allowing at least 1 tool in the channel simultaneously during the procedure, it will enable the surgeon to be able to use multiple tools at a time and allow for tool maneuverability.

Documentation of the final design

Channeled Sheath

Currently, endoscopes placed into the nasal cavity have little to no space for the surgeon to easily insert and control the necessary instruments needed to conduct surgery. Taking this into consideration, we decided to design a disposable sheath with two identical tool channels. The endoscope sheath is a tube the length of the standard current nasal endoscope without the handle. It is sealed on one end with a clear material to maintain visualization of the surgical site through the camera of the endoscope at the distal tip. This sheath will fit securely around the endoscope to minimize any movement and maximize stability. Additionally, there are two working tool channels above the scope that will allow for the necessary tools to be inserted into the patient's larynx. We decided to change the outer channel from crescent shaped to two 2 mm channels after discussing with our doctor. This way the amount of tools that can be inserted is still increased while also providing security and limiting the movement of the tools while they are being inserted. When designing the overall shape of the Channeled Sheath, we had to consider the limited space within the patient's larynx and ensure our design was comfortable while still being able to fit all of the desired tools. To ensure patient comfort, we determined the ideal height and width of the channel should be less than 7 mm while still being cognisant of the tools required by the surgeon. The height of the final prototype was 7.74 mm and the width was 6.67 mm. The

height measurement is slightly higher than we aimed for, but with more precise manufacturing techniques the height could be decreased. The CAD drawings of the Channeled Sheath can be seen in Figure 3.

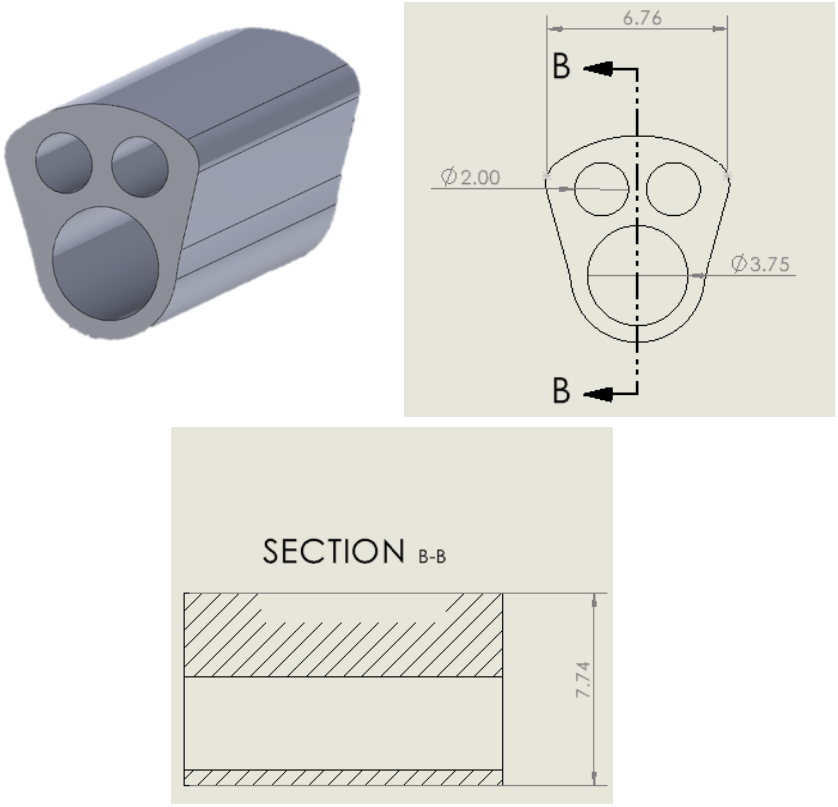

Figure 3. The complete model for the Channeled Sheath is shown in the top left. Shown on the top right and bottom are the CAD drawings of the Channeled Sheath. The endoscope channel has a diameter of 3.75 mm and the tool channels have diameters of 2 mm.

This design has three major components: the tools channels, the endoscope channel, and the material properties of the sheath. We decided to go with tool channels that have a 2 mm diameter as this was the maximum size of the tools that Dr. Gildener-Leapman uses. These additional channels also have the potential to serve as a channel for a CO_2 or KTP laser utilized by physicians in-office to make incisions in the larynx instead of a blade to minimize bleeding. These channels have to be large enough that the tools can be inserted with very little force, but small enough that there is very little side to side movement of the tools. The reason that we want

to limit the side to side movement of the tools is because once the sheath is inserted into the patient, any excessive movement of the tools could lead to injury of the patient. It is also necessary for the sheath to have a secure fit on the endoscope in order to prevent it from falling off during a procedure. In order to combat this we decided to decrease the diameter of the endoscope channel to be less than the 4 mm diameter of the endoscopes that Dr. Gildener-Leapman uses. Having this difference in diameter allows the sheath to stretch around the endoscope when it is inserted, this stretch can be seen in Figure 4. Once the endoscope is fully inserted into the sheath, the separate systems should act like one device. The sheath will be able to bend with the endoscope and should have very little resistance when bending.

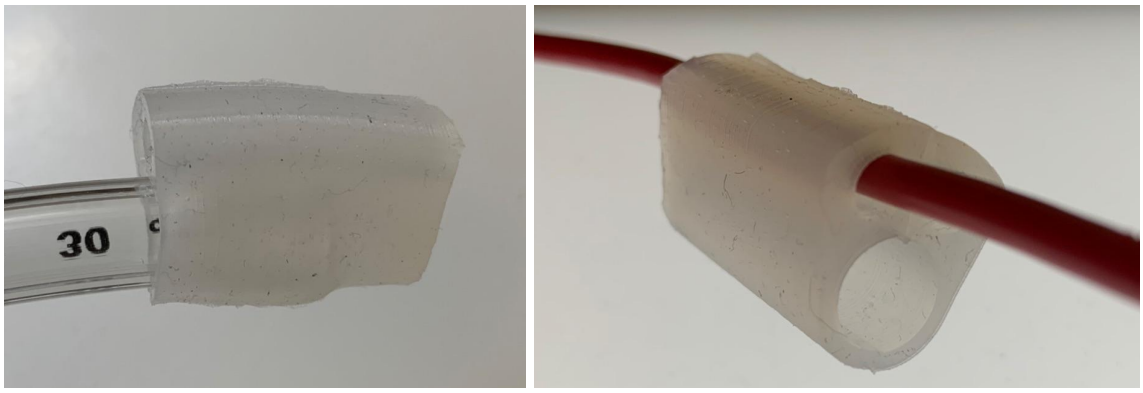

Figure 4. Fit testing of the scale Channeled Sheath model. The left image shows the stretching of the endoscope channel when a mock endoscope is inserted. The right image shows the fit of mock tools inside the tool channels.

Blind Scope

One of our main goals is to increase cellular yield in tissue samples taken during in-office procedures. To accomplish this goal, we decided to design a second Blind Scope, in addition to our Channeled Sheath, that will be inserted into the patient's other nasal cavity while the endoscope is inserted simultaneously into the other nostril. The purpose of this scope is not to gain additional visualization, but instead to allow for more instruments to be inserted into the patient's larynx while not obstructing the visualization of the actual endoscope. This additional

scope will also provide a larger channel for larger cupped forceps to be inserted into the larynx, providing a better angle while increasing the sample size taken when taking the biopsy.

The body of the Blind scope, shown in Figure 5, is composed of soft, flexible rubber tubing that has an outer diameter (OD) of 10 mm, an inner diameter (ID) of 7 mm, and is 300 mm long, the working length of current market endoscopes. The distal tip is controlled by 3 ft of a strong but flexible wire that runs down the inside of the tubing and comes out of the distal end and runs up the outside of the tubing on opposite sides. These control wires are held inside control wire channels made of very small clear tubing attached to opposite sides of flexible tubing to ensure that the wires stay parallel to the scope while still being able to move freely. We also designed and printed a distal tip cap for better attachment of the wires to the distal tip, which can be seen in Figure 6. This cap was designed in SolidWorks with an OD of 12 mm, an ID of 10 mm for the body of the cap, and the end of the cap has an id of 7 mm. With the addition of this new, zero tolerance cap, we were able to attach the control wires more securely to the distal end to create a more rigid end to the Blind Scope. The distal tip of the Blind Scope has the capability to move left and right to assist the surgeon in controlling the tools effectively when trying to reach the target site. With the final addition of this cap, the Blind Scope was able to reach degrees of angulation that placed us within our target range.

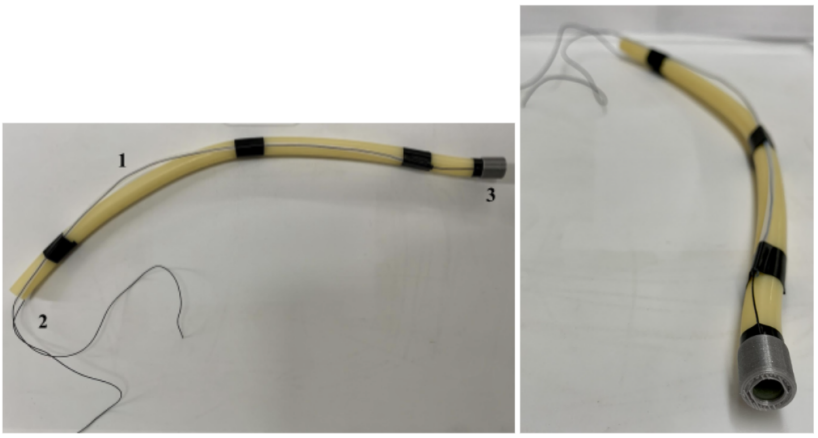

Figure 5. Top down view and distal end view of the Blind Scope Prototype II. Marker (1) shows the small plastic tubing that are used as control wire channels that run parallel down the rubber tube, (2) shows the proximal end of the Blind Scope where the wires come out and movement is manipulated from, and (3) shows the distal end of the Blind Scope where the cap had been added over the end of the rubber tube to hold the wire attachment and create a rigid tip to the tubing.

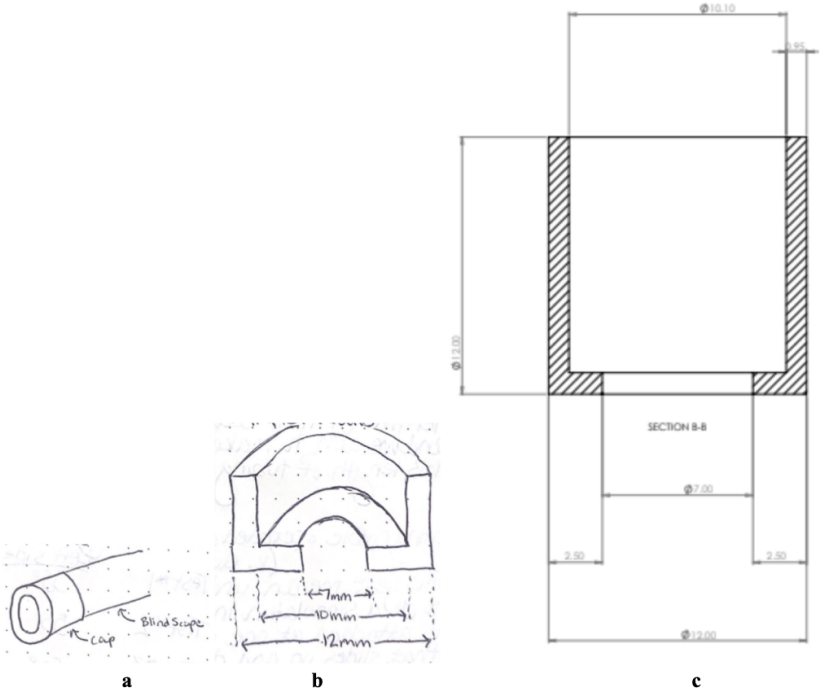

Figure 6. Sketches of the distal end cap for the Blind Scope with dimensions; (a) is a side view of the cap on the distal end of the Blind Scope, (b) is a cross-sectional view of the cap to get a view of the cut-out interior, (c) is a SolidWorks drawing with dimensions in mm of the cap.

Final Prototype

Channeled Sheath

For the final prototype of the Channeled Sheath there were a few steps that we took before reaching the final model. At first we tried to use a range of flexible 3D printing filaments.

We tried using PLA+ and TPU but neither of these plastics had the material properties that we were looking for. With this method we were also not able to print with enough precision to replicate the small dimensions of our CAD model. To get around the limitations of 3D printing we decided instead to create a two times scaled up mold that we could pour material into. The mold was created using the cavity tool in SolidWorks to cut the already existing sheath model out of a cube. This new model, the resultant space of where the sheath used to be, was then split in half. The mold can be seen in Figure 7.

With the mold ready, silicone was poured inside to cure. We wanted the Channeled Sheath to be extremely flexible so as to not impede the bending of the endoscope so we used Smooth-On Ecoflex silicone with a shore rating of 00-30. This silicone comes in two parts, part A and part B, that are mixed in a 1:1 ratio and cure completely in four hours. With this material, the halves of the mold were taped together to prevent any leakage and the silicone was poured inside. After curing, the sheath could be separated from the mold. As shown in Figure 8, the resulting sheath maintains all wanted features and is almost identical to the CAD model. This sheath is also extremely flexible and requires very little force to bend. All of these factors combine to create a final prototype that meets all the goals that we had set. It is able to contain and limit the movement of tools in the tool channel, while being flexible enough to both stretch over the endoscope without adding more bending resistance.

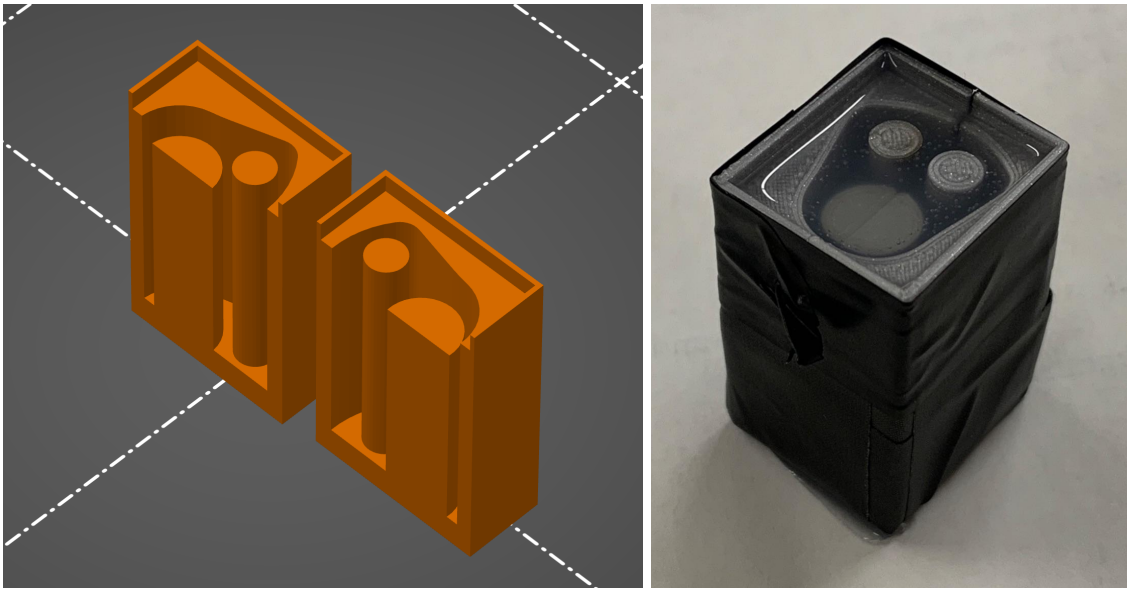

Figure 7: On the left are the CAD models of the two halves of the mold that were scaled up by a factor of 2. The cylinders that are extruded up are where the channels in the sheath are located. On the right is the mold after it has been secured together and the silicone was poured inside.

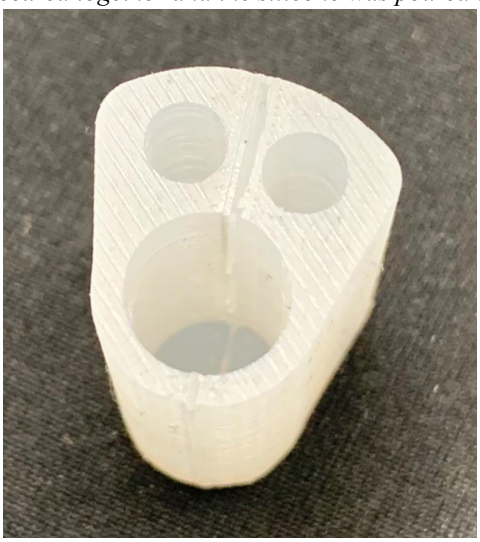

Figure 8: The silicone model of the Channeled Sheath after it was removed from the mold. The size of the tool and endoscope channel were maintained throughout the creation of this model.

Blind Scope

For the final prototype of our Blind Scope, there were less steps required than for our Channeled Sheath before we reached our final design. We needed to make a model that would allow us to test the angulation of movement able to be obtained by the distal tip of the Blind Scope. To do this, we used a soft rubber tubing and strong but flexible wire to create our

prototype I. The wires were run down the inside of the tubing from the proximal end to the distal tip. The control wires were then pulled through the distal tip and ran up the side of the tubing 180 degrees from one another. Thin plastic tubing was secured on each side of the tubing and acted as channels for the control wires. These control wire channels were secured with electrical at three points down the body of prototype I to create the desired bending point and to secure them to the tubing and to ensure that they ran parallel to one another. This was also to make sure that they were encased in a frictionless channel that allowed them to be controlled and moved easily.

For prototype II we maintained the same design, but we increased the length of the overall body to 300 mm which is the working length of current market endoscopes. We also decreased the size of the control wires channels and designed a distal tip cap to better secure the control wires to the end of the cap, which can be seen above in Figures 5 and 6. This cap was designed in SolidWorks and was dimensioned with zero tolerance to the tubing which created a very tight junction between the cap and the tubing and printed using a PLA plastic. Prior to the addition of the cap, our prototype I had very good initial movement placing us about 10 degrees, on both sides, away from our desired angulation range. By adding this cap, we were able to obtain a degree of angulation which placed us within our desired angulation range of 100 to 120 degrees when tested both inside of the body and outside of the body. These results proved to us that this design was capable of meeting the goals and requirements we had initially set.

Design Validation

A series of tests were performed for each device to further explore their proof of concept and effectiveness in hypothetical practices. For our Blind Scope we ran three individual tests: an out-of-body angulation test, an in-body angulation test, and a fit test to ensure the channel size

allowed for the appropriate tools to be used. For our Channeled Sheath we focused on two tests: a fit test and a 3-point bend test, in addition to a set of subtests to find proper materials for our device's prototypes.

The out-of-body angulation test of our Blind Scope was used to provide the necessary data to prove the scope could achieve the desired angulation to meet the needs and requirements. This test was performed by placing the distal end of the scope in the middle of a protractor at 90° and pulling the control wires on both sides, recording the angles reached and summing the left and right recorded angles to obtain an overall angulation value for each test. The results of this test can be observed below in Table 2. Following the conclusion of three successive out-of-body angulation tests, all three tests fell within the desired range of angulation which was between 100° to 120°. The maximum angulation had an average measurement of 103.3° with a standard deviation of ±2.67°, which satisfies the range overall.

Table 2: Recorded data for the leftward, rightward and overall angulation of the Blind Scope overserved over a series of three separate tests.

	Angle Obtained from Left Wire Pulled	Angle Obtained from Right Wire Pulled	Maximum Angulation
Test #1	55°	50°	105°
Test #2	55°	50°	105°
Test #3	50°	50°	100°

The in-body angulation test was performed by creating a 2 times scaled up PVC model to vaguely mimic the complex anatomy on the nasal cavity and its transition into the larynx. Once the Blind Scope was inserted into the model, the large, cupped forceps were inserted into the

Blind Scope. The control wires on both the left and right side were pulled to assess if the forceps could take simulated biopsies of Jell-O at increasing angles. The purpose of the Jell-O was to simulate the soft, loose properties of laryngeal tissue that would be present. A Jell-O sample was fixed at an angle of 10°, 40°, and 50° directly below the PVC model, as shown in Figure 9. This was used to validate the Blind Scope's ability to obtain an effective biopsy sample when having to work at different angles within the "affected area."

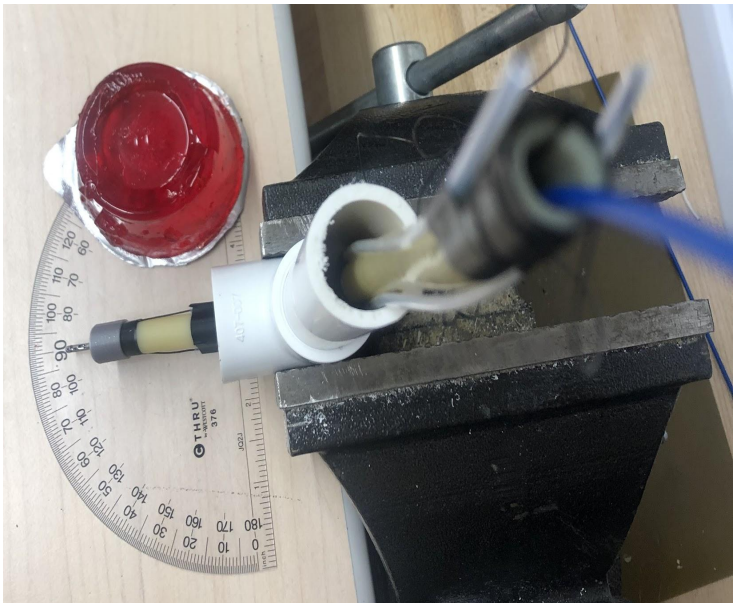

Figure 9. Top down view of in-body angulation test simulated using PVC piping to replicate the real anatomy.

The results of this test can be seen below in Table 3. The in-body angulation test consisted of three sample locations at the 10°, 40°, and 50° location on a protractor in relation to the Blind Scope. When manipulated, the device was capable of moving within the restrictions posed by the anatomy while still obtaining an effective "tissue" sample at all three locations.

Table 3: Tests performed at three different angles to observe the biopsy effectiveness of the Blind Scope when woven through a restrictive cavity.

	Location of "Sample"	Biopsy Obtained

Test #1	10°	Yes
Test #2	40°	Yes
Test #3	50°	Yes

The third and final primary test we ran for our Blind Scope was a simple fit test. Our prototype was scaled up by a factor of 2, meaning that the inner diameter of our device was approximately 8 mm opposed to the desired 4 mm of our actual product. Due to this, upscaled objects to mimic the desired forceps were woven through our devices and tests to ensure there were no restrictive properties when a device was present within the Blind Scope. This was properly executed, and upscaled devices were capable of being placed down the Blind Scope while the target range of angulation was still achieved as shown by our in-body angulation test.

Overall, our Blind Scope was capable of meeting a series of design validation testing to prove its functionality. Through the process of performing the out-of-body and in-body angulation tests, we were able to prove the device's ability of angulating within the range of 100° to 120°. Additionally, this angulation could be mimicked when placed in a restrictive location, such as the nasal cavity and larynx, simulated by a PVC model, while still being capable of obtaining a biopsy. Another function we made a priority was the Blind Scope's ability to fit a sizable forcep within its channel allowing a physician to obtain a more effective biopsy sample. This was proven to be possible through our fitment test, proving the device's ability to fit a cylindrical object, simulating the shape of a set of forceps, which had dimensions of approximately 3.5 mm in diameter. This provided us with adequate data regarding the ability of our Blind Scope to perform on a level that is beneficial in achieving overall proof of concept.

In regards to our Channeled Sheath, the first set of testing we ran was a fit test to assess the mechanism's ability to fit the required tools that would be used during a procedure. After experimenting with a series of different materials which had different mechanical properties, the device ended up being made of silicone. The material properties of this silicone allowed for the expansive properties of both the tools channels and endoscope channel. Similarly to our blind scope, the Channeled Sheath was scaled up by a factor of two meaning the tools channels had a diameter of approximately 4 mm and the endoscope channel had a diameter of approximately 7 mm. As represented in Figure 4 previously, a wire of approximately 4 mm in diameter was placed within the tool channels, mimicking the upscaled size of a normal 2 mm forcep diameter, while an 8 mm diameter tube was placed in the 7 mm endoscope channel to prove the device's ability to securely hold a simulated, upscaled device while also expressing its elastic material properties.

The second set of testing performed on the Channeled Sheath was a series of 3-point bending simulations within SolidWorks. Using the custom material feature in SolidWorks, the material properties of the silicone we used were entered allowing us the most realistic simulation possible. Fixing both the distal and proximal ends of the sheath, a force of 0.44 N, which is equivalent to 1 lbf, was applied on the top edge of the device. This was then replicated with the applied force on the bottom edge of the device for comparative reasoning. These distributed stress measurements can be seen below in Figure 10.

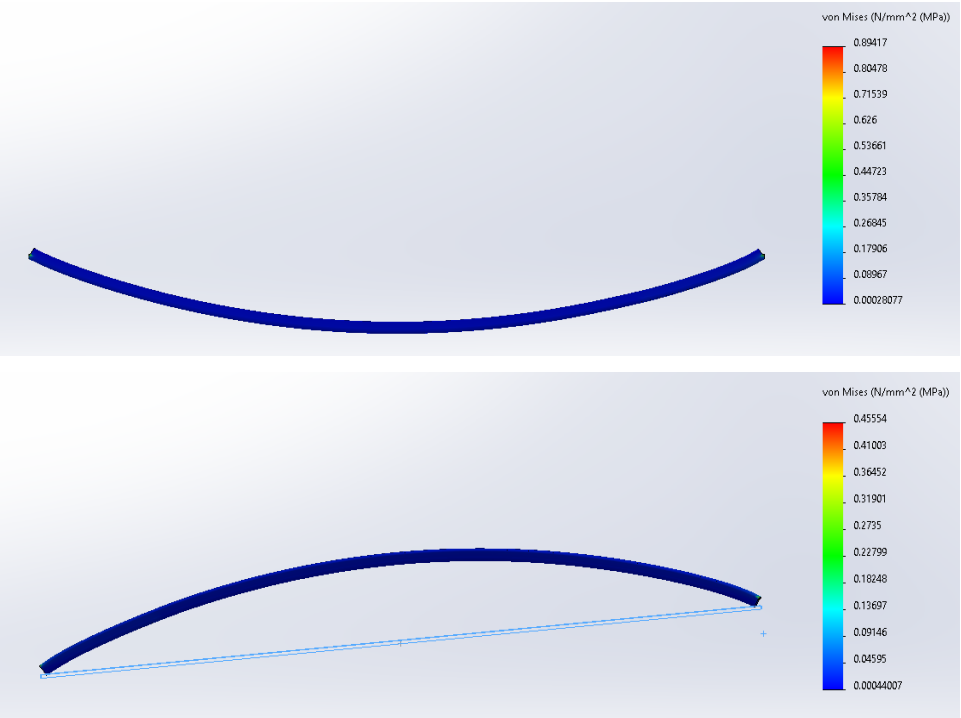

Figure 10: Simulation result of SolidWorks, 3-point bend test displaying distributed stress when force is applied to the top edge of the Channeled Sheath (Top); Simulation result of SolidWorks, 3-point bend test displaying distributed stress when force is applied to the bottom edge of the Channeled Sheath (Bottom).

The overall stress value when the force was applied to the top edge of the Channeled Sheath has an almost uniform stress distribution of approximately 0.08967 MPa. Similarly to when the force was applied on the device's top edge, the stress distribution when applied on the bottom edge was also almost entirely uniform at approximately 0.04595 MPa. These two sets of results differ from one another due to the difference in symmetry and amount of material on the top and bottom edge of the device.

When analyzing the two primary tests run on our Channeled Sheath, the results were satisfying when reviewing what qualities we were looking for. Regarding our fit testing, the device showed adequate elastic properties, which provide the device versatility when different size and shape tools may be needed during a procedure. For the SolidWorks simulations we were shown that our device showed sizable deflection when a small load was applied proving that

minimal resistance would be present when placed on an endoscope allowing the scope to maintain its mechanical properties. Through the combination of these testing procedures we were also given an idea of what material type we need to look for as progression takes place. Through our testing, it was determined that a material with a shore hardness of 30A or less provides adequate material properties when tested upon allowing for future progression.

Ethical Considerations

When designing anything, it is important to ensure that a device is made with ethical considerations in mind, especially if that device is to be built for and tested on human subjects. As future engineers, it is expected of us to uphold the highest standards of honesty and integrity when designing a product that will have a direct impact on the quality of life for a large majority of people. Throughout this process, we made a conscious effort to keep ethics in mind when designing our two devices. It was vital to consider if we were being honest, safe, impartial, fair, and equal when progressing through the design process, as well as that we adhered to the highest level of ethical principles and maintained them throughout every step of our project.

In order to ensure that we were correctly implementing ethical considerations throughout this process, we needed to familiarize ourselves with the fundamental canons and rules of practice. The first canon and rule of practice we kept in mind was to only perform services only in areas of our competence. To ensure this, extensive research needed to be done on the current devices, procedures, and anatomy of the nasal cavity and larynx, while also consulting a specialized doctor, to establish a solid background and knowledge of this area. This knowledge was necessary so we could prioritize the overall safety, health, and welfare of the public. Next, we focused on making sure we issued public statements only in an objective and truthful manner. While we were not giving publicized statements, we were presenting weekly to the class and

professors so it was important that all information stated in these presentations was 100% truthful and objective. This ties into the next canon of avoiding deceptive acts. We had to ensure that all of the results from our testing were truthful and we were not manipulating tests to get the results we wanted. The last canon focused on conducting ourselves honorably, responsibly, ethically, and lawfully to ensure that we are preserving the honor, reputation, and usefulness of the engineering profession [13].

In addition to these fundamental canons and rules of practice, we also had to keep professional obligations in mind. It was important that we acknowledged all of the errors we made so that nothing in our project could be discredited. All updates and conversations we had with our guiding doctor needed to be honest and upfront as to not mislead him in any way of our progress or intent. Much like the canons, we needed to consider that we were avoiding all practices that could possibly deceive the public. It was very important that we did not take credit for facts we found when conducting research and avoid misrepresenting any part of our project as this could lead to all of our hard work being discredited. It was also important for us to make sure we gave credit to the group member who was responsible and who earned said credit [13].

If we were to continue this project in the future, we would need to ensure that we maintained these ethical considerations and incorporated them into every step taken as we did throughout our capstone project. We would have to ensure that all information concerning business affairs or technical processes of any current or former client or employer were kept confidential throughout the proceedings. From start to finish of any project like this, it is vital to keep ethical considerations in mind as to ensure public safety and success of one's device.

Anticipated Regulatory Pathway

After reviewing the FDA's Center for Devices and Radiological Health (CDRH) classification criteria, it was determined that both the Blind Scope and Channeled Sheath would be classified as Class II devices. A Class II device is defined as a medical device that has a moderate to high risk for the patient and/or user of the product. Due to both of our devices falling into this category, we must be familiar with the importance of general controls along with special controls as we continue our design and development. General controls are essential for all devices, requiring companies to properly report all project progression, whether it is positive or negative, while also properly branding and manufacturing the product to ensure safety of patients from both an engineering and manufacturing standpoint. In terms of special controls, specific standards must be met to further progress a product as it moves toward the market. These device-specific controls ensure the safety and effectiveness of a device by providing adequate surveillance and review of a product during its time leading up to its market release and postmarket reviews. This allows the FDA and company to not ensure safety of all operators of the device and the patient being operated on. This means if problems begin to arise, recalls can still be called in an appropriate time frame. To determine the classification of our devices, in accordance with the FDA's CDRH classification standards, we referred to current, on the market devices that serve similar purposes and have gone through the same processes our devices might encounter in the future.

Regarding our Blind Scope, we found a device manufactured by Endo Tools Therapeutics S.A. in Belgium that was passed through the 510(k) process. Their device, labeled as the Endomina System (K211309), is an endoscope accessory used by gastroenterologists to provide a flexible therapeutic channel that can move independently from an endoscope during a

procedure [14,15]. This was defined as a Class II device because of its importance and use within the body during a procedure. Similarly to the Endomina System, our Blind Scope is a simplified piece of equipment that is able to move independently of the endoscope. However, our device is an independent device that will not be connected to a scope during a procedure. Additionally, the Blind Scope is aimed for laryngeal procedures opposed to intestinal procedures while both devices are able to introduce additional, alternative tools into the affected area of the body.

For our Channeled Sheath, the Endoscope Sheath (K940028) devised by XOMED-TREACE, INC. in Jacksonville, Florida was submitted to FDA premarket as a Class II device for similar reasons to that of the Blind Scope and Endomina System as previously mentioned [16]. This Endoscope Sheath by XOMED-TREACE is a device that covers an endoscope to aid the endoscope and its ability during a procedure. Specifically, this device is a sleeve that is designed to primarily improve the visual by improving fogging and glare in the endoscopes field of view (FOV). In contrast, our Channeled Sheath is designed to improve the working space of a physician by introducing tools in and around the device's distal tip, providing a more functional product as a whole.

Similarly to both the Endomina System and Endoscope Sheath, both the Blind Scope and Channeled Sheath would be submitted to the FDA as Class II devices meaning they will require a 510(k) submission to get passed and then introduced to the market. In the lead up to this submission process, devices will go through rigorous design alterations and testing procedures to ensure each device is able to meet standards met by different organizations as mentioned previously in the *Engineering Standards* section. After meeting those requirements, a 510(k) submission will be devised and passed through rigorous review by the FDA to ensure each device is capable of meeting all general and special controls, according to their strict criteria. If

cleared, the devices will begin their review and introduction to manufacturing and the post market review. However, if a device is deemed not adequate, an intricate review of the device will take place to further critique and satisfy market standards.

Conclusions & Future Work

Based on the evolution of our devices throughout BME 495 and BME 496, we believe our device is in a very respectable place. This is due to many trials and errors that have helped us get to the point we are at today. We encountered many pivots and obstacles when it came to materials, methods of production, and how to best satisfy the design requirements we set for ourselves and those of our doctor. From prototype to prototype, we were able to work through these obstacles and pivot effectively to produce the devices we have today. For our Crescent-Channeled Sheath, our prototype I was just a simulation in SolidWorks of a silicone tube with no tool channels. As we progressed to prototype II, our doctor expressed the desire for two separate channels as opposed to one big channel, thus causing the pivot to renaming and redesigning the Crescent-Channeled Sheath into the Channeled Sheath. Prototype II of our sheath was a six times scaled up model of our desired design, one was 3D printed out of a rigid filament and the other printed out of a flexible PLA+ filament. While we finally developed the ideal shape, the size and material were way off. We decided to explore other modes of production and decided on printing a mold and pouring a flexible silicone material into the mold and allowing it to cure. Through this method, we were able to make a two times scaled up model as well as one that was our desired dimensions.

Luckily, the evolution of our Blind Scope design from prototype to prototype was not as drastic. Instead, it was more making the necessary improvements on prototype I and then working to make a to-scale model. In prototype I, we were happy with the overall function of our

prototype but it fell short of our target range of motion. After deliberation, we concluded that it was due to the control wires not being tightly secured to the distal tip. The connection was not strong enough to exert the force needed to pull the distal tip the amount we needed it to. To solve this for prototype II, a cap for the distal tip was designed. This cap fit snugly onto the tip of the Blind Scope and tightened the control wires to the point that the ideal angulation range was achieved. We were also able to produce a nonfunctional to-scale model of our Blind Scope which was very encouraging.

In the future, we would like to have these devices work cohesively through one handle to allow for laryngeal biopsies to be moved from the operating room to in-office. More specifically, we need to look into better materials to construct the to-scale Channeled Sheath out of. The silicone currently being used was very effective for our current needs, but a slicker and rigid material will be better for final production. Ideally, the material used would have a high elastic modulus vertically, but a lower one horizontally thus allowing for the necessary stretch over tools while maintaining a more substantial shape over the body of the endoscope. As for our Blind Scope, we would find a new material, as well, that allows for the bending of the distal tip and movement through the curvature of the anatomy, while also being durable and able to be used for multiple procedures. Furthermore, we would like to move the control wires from external channels to channels within the inner wall. As previously mentioned, these two devices will become a cohesive device through the use of a handle, however, we, along with our doctor, would like to see the Blind Scope also function as its own device and be utilized in other types of procedures.

References

[1] D.J. Wellenstein, J.K. de Witt, H.W. Schutte, et al, “Safety of flexible endoscopic biopsy of the pharynx and larynx under topical anesthesia”, Eur Arch Otorhinolaryngology, vol. 274, no. 9, pp. 3471-3476, 2017. https://doi.org/10.1007/s00405-017-4647-z

[2] International Agency for Research on Cancer, World Health Organization, “Estimated number of new cases in 2020, worldwide, both sexes, all ages”, Global Cancer Observatory. Available: https://gco.iarc.fr/today/online-analysis-table?v=2020&mode=cancer&mode_population=continents&population=900&populations=900&key=asr&sex=0&cancer=39&type=0&statistic=5&prevalence=0&population_group=0&ages_group%5B%5D=17&group_cancer=1&include_nmsc=1&include_nmsc_other=1

[3] David J. Wellenstein, Henrieke W. Schutte, Robert P. Takes, Jimmie Honings, Henri A.M. Marres, James A. Burns, Guido B. van den Broek, Office-Based Procedures for the Diagnosis and Treatment of Laryngeal Pathology, Journal of Voice, Volume 32, Issue 4, 2018, Pages 502-513, ISSN 0892-1997, https://doi.org/10.1016/j.jvoice.2017.07.018.

[4] Nocini, Riccardo et al. “Updates on larynx cancer epidemiology.” Chinese journal of cancer research = Chung-kuo yen cheng yen chiu vol. 32,1 (2020): 18-25. doi:10.21147/j.issn.1000-9604.2020.01.03

[5] Schimberg, Anouk S et al. “Office-based vs. operating room-performed laryngopharyngeal surgery: a review of cost differences.” European archives of oto-rhino-laryngology : official journal of the European Federation of Oto-Rhino-Laryngological Societies (EUFOS) : affiliated with the German Society for Oto-Rhino-Laryngology - Head and Neck Surgery vol. 276,11 (2019): 2963-2973. doi:10.1007/s00405-019-05617-z

[6] Collins, S. R. (2014). “Direct and indirect laryngoscopy: Equipment and techniques”. Respiratory Care, 59(6), 850–864. https://doi.org/10.4187/respcare.03033

[7] A. Aizenfeld, Y. Baror, G. Salman, and O. Sheziffi, “Sleeve for endoscopic tools,” 26-Oct-2006.

[8] Ofstead, Cori L et al. “A Systematic Review of Disposable Sheath Use During Flexible Endoscopy.” AORN journal vol. 109,6 (2019): 757-771. doi:10.1002/aorn.12699

[9] *Endoscopes — Medical endoscopes and endotherapy devices — Part 1: General requirements*, ISO 8600-1:2015(en), 2015.

[10] *Endoscopes — Medical endoscopes and endotherapy devices — Part 6: Vocabulary*, ISO 8600-6:2020(en), 2020.

[11] *Standard Practice for Reprocessing of Reusable, Heat-Stable Endoscopic Accessory Instruments (EAI) Used with Flexible Endoscopes (Withdrawn 2016)*, ASTM F1992-99, 2007.

[12] N. Kenters, E. Tartari, J. Hopman, et al, “Worldwide practices on flexible endoscope reprocessing”, Antimicrobial Resistance & Infection Control, vol. 7, no. 153, 2018. https://doi.org/10.1186/s13756-018-0446-6

[13] “Code of ethics,” *Code of Ethics | National Society of Professional Engineers*. [Online]. Available: https://www.nspe.org/resources/ethics/code-ethics.
[14] S. A. Endo Tools Therapeutics, “endomina system,” 2021.
[15] E. Therapeutics, “Our technology,” 2020. https://www.endotools.be/our-technology/ (accessed 2022).
[16] I. XOMED-TREACE, “ENDOSCOPE SHEATH,” Mar. 24, 1995.

Appendix A

Project:	AMC Blank Channel																						
Date:																							
	Customer: ENT doctor/surgeon																						
		Direction of Improvement	▲	▼	▲	▼	▼	▲	▲	▼													
Relative Weight	Customer Importance	Customer Requirements (Physician)	Length of channel (mm)	Diameter of channel (mm)	Distance traveled by tools in the channel (mm)	Tool control (# of steps)	Procedure time (min)	Number of tools in channel (#)	Angle of movement in channel (deg)	Channel insertion force into nose (Newtons)	Our Product	Transoral Long Curved Forceps	Olympus ENF-VH Video Rhinolaryngoscope	CORFLO Nasogastric/Nasointestinal 8FR Feeding...									
16%	10	Ability to fit in larynx w/ a separate scope		●				○	○	▽	-	5	3	1									
11%	7	Security of speciman sample within channel		▽	▽	○		○			-	4	1	1									
14%	9	Channel maneuverbaillity							●		-	1	1	1									
14%	9	Tool maneuverability		●		○	○	●	●		-	1	2	1									
9%	6	Ability for blind insertion	▽	▽					○	○	-	3	5	5									
13%	8	Wide enough for mulitple tools		●				●	○		-	1	1	3									
8%	5	Usable under local anesthesia				○	○			▽	-	4	3	4									
5%	3	Durability				▽	▽			▽	-	4	4	5									
11%	7	Smooth insertion		●			▽			●	-	3	5	5									
		Importance Rating Sum (Importance x Relationship)	9,375	498,4	10,9375	103,1	81,25	318,7	365,625	154,6													
		Relative Weight	1%	32%	1%	7%	5%	21%	24%	10%													
		Our Product	-	-	-	-	-	-	-	-													
		Delighted -> Disgusted	350-300	3-4	350-300	3		2-1	100-120														
		Transoral Long Curved Forceps	N/A	N/A	220	3	N/A	1	70	N/A													
		Olympus ENF-VH Video Rhinolaryngoscope	325	3.9	N/A	3	N/A	N/A	110	N/A													
		CORFLO Nasogastric/Nasointestinal 8FR Fee	600	2.64	N/A	3	N/A	N/A	N/A	N/A													
		Technical Competitive Assessment																					

Channel insertion force into nose (N)	
Angle of movement in channel (deg)	
Number of tools in channel (#)	- +
Procedure time (min)	
Tool control (# of steps)	- -
Distance traveled by tools in the channel (mm)	-
Diameter of channel (mm)	- + + +
Length of channel (mm)	+ - -

Functional Requirements

Customer Competitive Assessment

Correlations	
Positive	+
Negative	-
No Correlation	

Relationships		Weight
Strong	●	9
Medium	○	3
Weak	▽	1

Maximize	▲
Target	□
Minimize	▼

Figure 11. The Quality Function Decomposition chart developed for the AMC Blind Scope device for Laryngeal Surgical.

Project:	AMC Sheath												Scope insertion force (Newtons)
Date:													Diameter of tool channel (fr)
												-	Tool insertion force (N)
											-		Stretch distance (mm)
										+	+	+	Number of tools in channel (#)
													Procedure time (min)
								-			+		Tool control (# of steps)
							-						Distance traveled by tools in the channel (mm)
						-						+	Diameter of sheath (mm)
					+	-		+					Length of sheath (mm)
	Customer: ENT doctor/surgeon		Functional Requirements										
		Direction of Improvement	▲	▼	▲	▼	▼	▲	▲	▼	▲	▼	Customer Competitive Assessment

Relative Weight	Customer Importance	Customer Requirements (Physician)	Length of sheath (mm)	Diameter of sheath (mm)	Distance traveled by tools in the channel (mm)	Tool control (# of steps)	Procedure time (min)	Number of tools in channel (#)	Stretch distance length (mm)	Tool insertion force (N)	Diameter of tool channel (mm)	Scope insertion force into nose (Newtons)	Our Product	Cogenix EndoSheath protective barrier	Medtronic ENT slide-on EndoSheath	BR Surgical Flexible Endoscope Disposable Sheaths
12%	9	Ability to fit over scope		●					○				N/A	5	5	5
12%	9	Tool security in channel	○	●	●	○		●		●	●		N/A	4	1	1
12%	9	Tool maneuverbaillity			▽	●	○	●		▽	●		N/A	4	1	1
9%	7	Secure fit		●					▽				N/A	4	5	4
8%	6	Elasticity	▽	▽	○				○	○			N/A	4	5	4
13%	10	Material transparency					○						N/A	5	5	1
6%	5	Usable under local anesthesia					○						N/A	2	2	2
8%	6	Durability							○				N/A	5	4	5
13%	10	Smooth insertion					▽					●	N/A	5	5	4
8%	6	Thin sheath wall		○					▽			○	N/A	5	4	5
		Importance Rating Sum (Importance x Relationship)	42,857	323,376	140,2	140,2	106,4	210,3	98,70	140,2	210,3	140,2				
		Relative Weight	3%	21%	9%	9%	7%	14%	6%	9%	14%	9%				
		Our Product	-	-	-	-	-	-	-	-	-	-				
		Delighted -> Disgusted	370-300	5-7	0	2		1		2-0	4-2					
		Cogenix EndoSheath protective barrier	370	2.1	360	2	N/A	N/A	N/A	N/A	N/A	N/A				
		Medtronic ENT slide-on EndoSheath	75	2.1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A				
		BR Surgical Flexible Endoscope Dispos	300	3.4	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A				
		Technical Competitive Assessment														

Correlations	
Positive	+
Negative	-
No Correlation	

Relationships		Weight
Strong	●	9
Medium	○	3
Weak	▽	1

Direction of Improvem	
Maximize	▲
Target	□
Minimize	▼

Figure 12. The Quality Function Decomposition chart developed for the AMC Channeled Sheath device for Laryngeal Surgical.

Appendix B

Figure 13. Project progression including all prototypes from BME 495 and 496. Channeled Sheath progression from left to right (top). Blind Scope progression from left to right (bottom).