Proteus Medical

Providing veterinarians with renewed confidence in endoscopic retrieval

Final Report

May 8, 2017

Connor J. McBride, Edward F. Ruppel, Chandler W. Woo
www.proteus-medical.com

Prepared For: Dr. Amy Lerner, Dr. Scott Seidman
Supervisor: Dr. Diane Dalecki
Customer: Dr. Erika de Papp, DVM, DACVIM

Table of Contents

Executive Summary

Problem

Every canine deserves to receive the safest treatment when they ingest a foreign body. Doctors of Veterinary Medicine (DVMs) rely on either endoscopic retrieval or surgery as their two methods of retrieving these foreign bodies from the gastrointestinal (GI) tracts of these canines. However, current endoscopic devices are flimsy and often deform after a single-use, making the procedure both challenging and costly. Though endoscopic retrieval is minimally-invasive and often the preferred method to remove foreign objects, the retrieval devices used in these procedures dissuade veterinarians from using them effectively or regularly.

Solution

Our company restores the advantages of utilizing endoscopic retrieval methods for veterinarians over the more invasive and expensive surgical alternative. We utilized direct input from top DVMs around the country to develop a product that they are comfortable using, and that is optimized for a higher rate of foreign body retrieval success. This is implemented using novel technology through a two-part system that allows for easy replacement of parts while simultaneously driving down yearly expenditures for the veterinarian. A rendering of the final prototype design can be seen in the figure to the right.

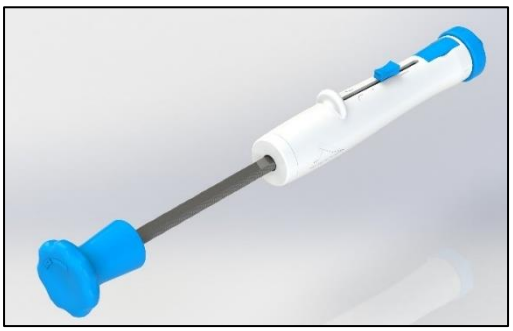


***Figure 1**: Render of final ProCaptive device design*

Market

Our target end-users are DVMs who use endoscopic retrieval devices to remove foreign bodies from canines. Per the American Veterinary Medical Association (AVMA), there are currently 107,995 registered veterinarians in the United States, growing at an annual rate of 2.5% per year. Approximately 20% of this population performs endoscopy, as it is generally limited to referral institutions due to the costs of the endoscopes. Though DVMs are the direct end-users of this product, pet owners and pet insurance companies are responsible for the payments to the veterinarian. This creates a priority of effective endoscopic retrieval over surgical options, which are typically 50% more expensive than endoscopy.

Evaluation & Future Direction

Testing results from time of retrieval, peak tensile force, and degradation tests of our most recent design demonstrate that our device performs at the same or at a better standard than competitive devices on the market today. Our retrieval heads are designed with a factor of safety of 5 to ensure that it does not break while tensioning against foreign bodies. Future directions of our product and company will focus on DFMA through injection molding to apply snap features and more robust material selections for our device.

Why Us?

We are a team of socially-minded and highly-driven engineers who believe that veterinary endoscopy should not be limited by the devices which veterinarians currently have available for use. By improving the mechanisms whereby DVMs can retrieve foreign bodies more confidently, canines are not subject to extended and painful post-operative recovery common with invasive surgery. Pet owners can feel relieved that their pets are healthy and pain-free without paying a possibly insurmountable veterinary bill for the procedure.

Introduction

For canines and other household pets, foreign body consumption is identified as a top 10 reason for a veterinary visit (Veterinary Practice News, 2014). One of the biggest misconceptions of household pets is that they can pass foreign objects that they have consumed; however, a study demonstrated that out of 200 cases, only 2 dogs were able to successfully pass their foreign body without veterinary intervention, stressing the importance of developing methods to retrieve the object quickly and effectively to prevent further harm to the animal (Park, 2015). Endoscopy is a minimally-invasive method that veterinarians use to retrieve these foreign bodies, but due to several limitations in the design of current retrieval devices, endoscopy is both a costly and often frustrating method for the veterinarian to perform.

In this report, we at Proteus Medical will provide extensive background into the market of veterinary endoscopy, as well as the limitations behind current designs. This documentation will then further elaborate upon our novel design that aims to reduce the financial burden on the veterinarian while optimizing the retrieval process, elaborating upon our testing results and considerations for future prototypes. Ultimately, Proteus Medical seeks to redefine veterinary endoscopy by restoring confidence to the veterinarians that endoscopic retrieval can be an effective and preferable option for removing foreign objects from everyday household pets.

Problem Statement

Household canines, specifically those between 40 and 60 lbs., are at a high risk of ingesting foreign bodies (de Papp, 2016). This simple pathology threatens their health due to gastrointestinal tract obstruction. The majority of Doctors of Veterinary Medicine (DVMs) currently remove these larger objects endoscopically with a set of minimally-invasive retrieval tools that are neither robust enough to be reusable, nor do they have effective guidance control. This results in increased frustration for the veterinarian as it prolongs the procedural time to retrieve the object. Additionally, once these devices deform, veterinarians must dispose of them and purchase new devices, resulting in wasted material and unnecessary sunk costs.

Background

Stakeholders

Veterinarians with proper training and resources to perform endoscopic retrieval are the primary stakeholders for this device. Our customer, Dr. Erika de Papp and her clinic at the Angell Animal Medical Center in Boston, presented the problem regarding the retrieval device space to our team, and we have worked with her to develop a device that addresses her essential customer needs and wants. Additionally, just as equally important customers that must be considered are the pets undergoing the retrieval procedure, specifically canines ranging from 40-60 lbs., who are identified as the most common offenders of consuming foreign bodies (de Papp, 2016). Currently there are roughly 70 million dogs that could be a risk of ingesting a foreign body (FiveThirtyEight, 2014).

The pet owners who care for their pets are also considerable stakeholders to address as they fund the minimally-invasive procedures which use these devices. Ultimately, the animals and the veterinarians will be the primary customers since the design of this device will be heavily tailored towards them. Besides the two primary customers and pet owners, secondary stakeholders would be hospitals and doctors if our product were to become commercially available for human use. Finally, pet insurance companies are also stakeholders since the endoscopic retrieval procedure is covered under pet insurance for the 10-15% of pet owners that purchase it (de Papp, 2017).

Clinical Scenario

Our endoscopic foreign body retrieval device will be catered to canines to retrieve various sized objects from the esophagus or the stomach. While our device can be tailored for use with felines or humans, the device's size and structure is best suited for dogs between a 40-60 lbs. range.

A typical customer scenario is when a canine is brought into the veterinarian's office after ingesting a foreign object, such as a coin or fruit pit. The veterinarian will take an x-ray to locate the object and then decide whether surgery or endoscopic retrieval is the best course of action. If the object has already passed into the lower intestine, or the object is deemed too difficult to grasp endoscopically, then the veterinarian must perform surgery; otherwise, endoscopic retrieval is the preferred route due its minimally-invasive method. After the dog is placed under general anesthetic, the endoscope is then guided through the dog's esophagus to the location of the object. Once the veterinarian has located the object through the camera on the endoscope, the veterinarian will choose the type of device head that will most effectively retrieve the foreign body. They will then insert our endoscopic retrieval device into the biopsy port in the endoscope. Our proposed replaceable tubing sets will be multifaceted and have the ability to retrieve objects of various sizes. However, if the incorrect device head was chosen, our device design includes the ability to switch out device heads from the user interface (UI). Once the correct device head is chosen, the veterinarian will use our advanced UI to navigate the head into an orientation that will allow for effective removal of the foreign object. Once the object has been grasped, the object, endoscope, and the retrieval device are pulled out simultaneously.

During the procedure, our device limited by certain physical constraints: the 2.7mm ID size of the port on the endoscope, the veterinarians who must be able to perform complex retrieval procedures (fatigue time, ~1 hour), and so on. Other devices currently on the market are very hard to control the retrieval head, and they strain the hand of the user. Therefore, with our prototype, we have

implemented variable tension locking to reduce strain on the hand when operating with the device. Working with our prototype has helped identify which type of heads would be most practical and provide the largest improvement to the current standards.

Competition

Our strongest competitors in this field are Karl Storz Endoscopy and Endoscopic Surgical Solutions, endoscope manufacturers that develop retrieval devices that are used by DVMs. Both sell a variety of products that address the different geometries of foreign bodies. Karl Storz is based in Germany, making quick delivery of devices a concern for veterinarians. Endoscopic Surgical Solutions provides an effective online service that markets devices from other vendors but often at an increased price, which may dissuade veterinarians from their products (ESS, 2017). Even so, these marketed devices additionally suffer from the same problem: both are packaged as a single device that must be entirely disposed after deformation of the retrieval head, often referred to as "single-use" devices. In this manner, our product has the distinct advantage.

A second form of competition is a surgical option for removal of foreign bodies. This often is prioritized over endoscopic retrieval when the foreign body cannot be physically removed endoscopically (e.g. object in small intestine), or when the veterinarian has failed to retrieve it endoscopically, whether through access difficulty or where the canine has spent extended periods of time under anesthesia (e.g. procedures over 1.5 hours). Though approximately 50% more expensive than endoscopic retrieval, surgery is an assured method of retrieval that may persuade DVMs to choose this option, especially when they do not have confidence in the endoscopic tools (AVMA, 2014).

Customer Needs & Wants

Presented in Table 1 below is a table of customer needs & wants as defined during our conversations with Dr. de Papp over the course of the year. These have been updated and redefined during our prototyping phase, recognizing our limitations and adapting our device accordingly.

***Table 1**: Determined customer needs and wants for endoscopic foreign body retrieval devices (ranked in terms of importance)*

Needs		***Wants***	
Name	***Description***	***Name***	***Description***
Reusability	Resistant to degradation from stomach acid and must be reusable over several uses	Affordable	Cost efficient for number of uses
Flexibility & Maneuverability	Easily adjustable while moving through GI tract to avoid injuring the surrounding lumen	Ergonomic User Interface	A simple, yet effective design to allow user to easily control device with one hand without strain
Effective Tension Control	Device should be able to maintain tensioning of object independent of the user	Head Translation	Ability for user to control retrieval head to properly orient object for optimal retrieval
Retrieve Various Sized Objects	Device needs to be able to retrieve larger foreign objects ranging from rocks to tennis balls	Clear Visibility	Allows for clear view with endoscope during retrieval to see if device captured object
Retrieve Various Surface properties	Foreign objects have different surface properties which makes them difficult to grab or scoop (i.e. grass clump vs. coins vs. chew toy)	Dimensionally Stable Shape	Shape of retrieval device will not deform when ejected for prolonged lifetime and usability
Fits in Insufflation Port	Device needs to fit in standard endoscope setup	Sterilizable	Easily cleanable after retrieval for multiple uses
Device Head Rotation	Ability for device to rotate before retrieval to orient the device alongside the foreign body for easier extraction		

Prototype Development

Design Overview

Device Subsystems

The Proteus device contains two subassemblies that are separable for interchangeability: the tubing set and the control handle, as seen in Figure 1. Each subassembly consists of multiple parts that require various levels of integration. The device was designed and modified through an iterative process with manufacturing in mind. This allowed the team to "fail-fast" while ensuring that the device was easy to assemble and produce once designed. To further explain each assembly, they have been split into broad sections for initial explanation.

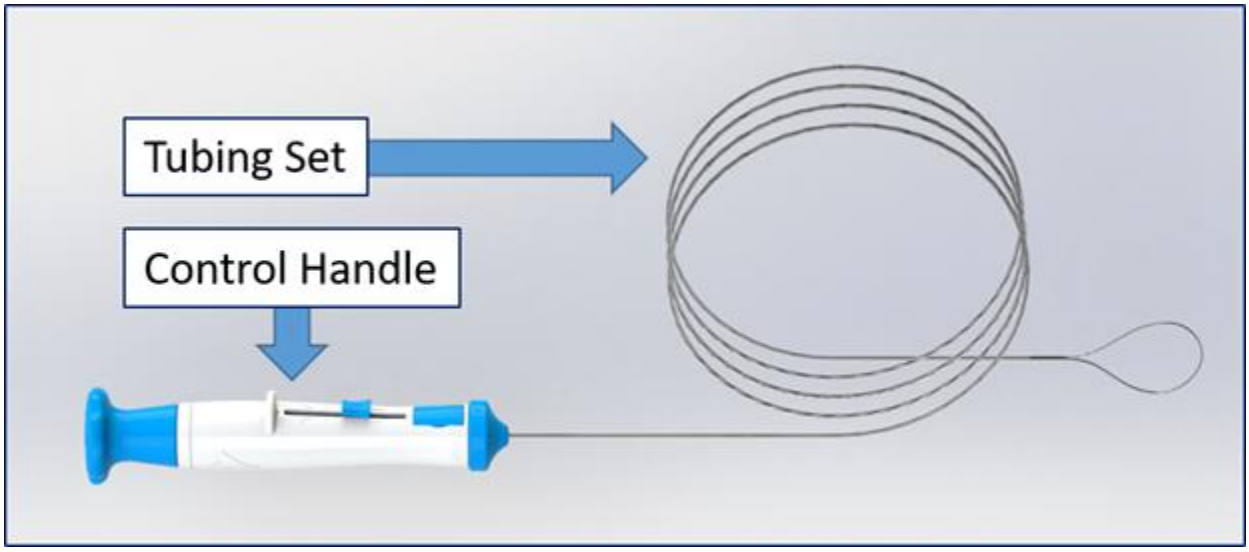


Figure 2: *Subassemblies of Proteus retrieval device*

Control Handle Assembly

The control handle assembly consists of seven unique parts, with five manufactured in-house, one purchased through major distributors, and one that require secondary operations. The simplified bill of materials below specifies the parts and their specifics.

Part Name	Part #	Purchase/Manufacture/Modify	Mfg Part #	Vendor	Material	Colorant	Surface Finish
Left Body	PC-R3-01	Manufacture	PC-R3-01 (Custom)	PMI Industries	Sustanat PC MG	Nat-White	Media Blast
Right Body	PC-R3-02	Manufacture	PC-R3-02 (Custom)	PMI Industries	Sustanat PC MG	Nat-White	Media Blast
Screw Cap	PC-R3-03	Manufacture	PC-R3-03 (Custom)	PMI Industries	Sustanat PC MG	Blue 3	Polish
Rear Knob	PC-R3-04	Manufacture	PC-R3-04 (Custom)	PMI Industries	Sustanat PC MG	Blue 4	Media Blast
Slider	PC-R3-05	Manufacture	PC-R3-05 (Custom)	PMI Industries	Sustanat PC MG	Blue 5	Polish
Allthread Rod	PC-R3-06	Modify	FTS3/8-16X600	Marsh Fasteners	304 SS	NA	Electropolish
Coupling Nut	PC-R3-07	Purchase	NHCOUP3/8-16	Marsh Fasteners	18-8 SS	NA	Electropolish

Tubing Set Assembly

The tubing set assembly consists of four unique parts, with all parts assembled in house, and three required secondary operations. The simplified bill of materials below specifies the parts and their specifics.

Part Name	Part #	Purchase/Manufacture/Modify	Mfg Part #	Vendor	Material	Colorant	Surface Finish
Catheter Tubing	PC-R3-08	Purchase	AME-507-705	Apollo Medex	PEBAX	Nat-Clear	NA
Steering Cable	PC-R3-09	Purchase	PC-R3-09 (Custom)	Fort Wayne Meta	304 SS/PTFE	NA	Electropolish
In/Out Cable	PC-R3-10	Purchase	PC-R3-10 (Custom)	Fort Wayne Meta	Nitinol	NA	Electropolish
Hypodermic Tubing	PC-R3-11	Purchase	18G-XXTW	M+M Internation	304 SS	NA	Electropolish

System Level Design

The systems diagram, as shown in Figure 2, is an exhaustive outline of all the components of the endoscopic retrieval procedure that affect the retrieval device and its ability to retrieve the foreign body successfully.

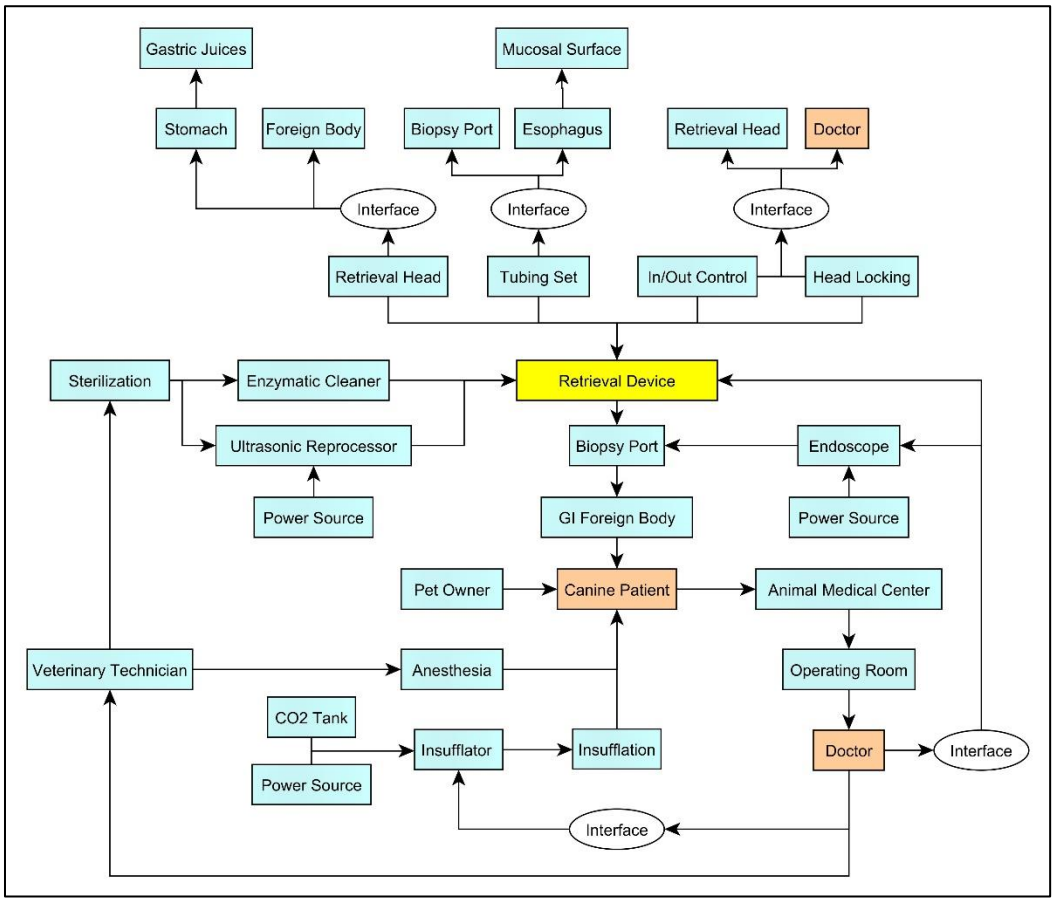


***Figure 3**: Systems-level diagram of the endoscopic retrieval device interface and process*

To achieve these goals, Connor was lead for the retrieval head design and testing, as well as the interaction between the retrieval head and tubing set. Eddie designed and modeled an improved user interface that includes both the in/out control mechanism as well as translational head steering. Together, they form the foundation of the retrieval device that will be inserted into the biopsy port during the procedure. Chandler focused the interactions between the device and the patient, making sure that all material testing and physical interactions are considered and tested. In order to validate this, Chandler focused on constructing a physiologically relevant canine model that will allow for testing of the retrieval device under realistic conditions.

Design Specifications

Given our list of customer needs and wants, we developed a set of relevant metrics and a House of Quality table (Appendix 1) that has allowed us to define design specifications for our device and its subassemblies, which can be seen in Table 2 below.

***Table 2**: Specifications of device design for user interface and tubing sets*

User Interface	
Specific Need or Want	**Specification**
Reusability	~150 procedures
Flexibility & Maneuverability	R < 0.75" (tennis ball)
Effective Tension Control	+/- 0.01" locking tolerance
Retrieve Various Sized Objects	0.5" – 2.7" OD
Tubing Sets	
Specific Need or Want	**Specification**
Robust	0% degradation *in vivo*
Fits in Biopsy Port	<0.1" OD
Retrieve Various Surface Properties	>2 points of contact for some device heads

Detailed Design

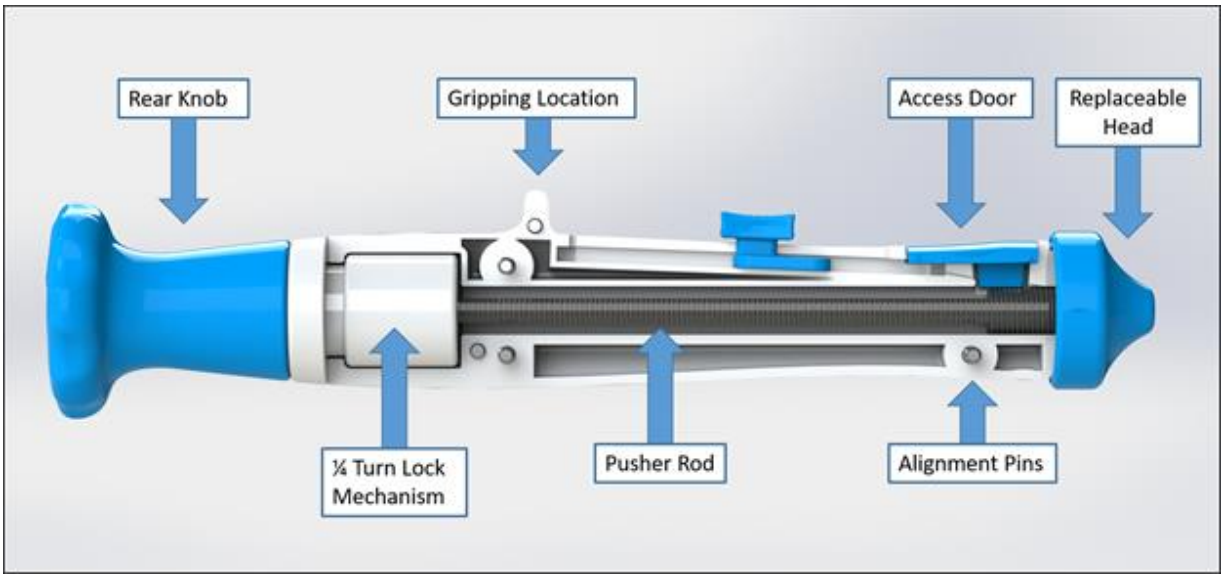


***Figure 2**: Cutaway schematic of ProCaptive design*

To provide a more thorough explanation of the ProCaptive design, the components and design inputs have been split up for subsequent explanation. They are as follows: human factors, tubing set replacement, variable tension locking, device strength, retrieval head design, injection molded plastics, secondary operations, and assembly.

Human Factors

When developing the design for the ProCaptive device, the human factors were taken into account to ensure comfortability. The external diameter and sweeping curve of the main handle surface were modeled to keep the hand at a neutral closed position that would be easy to leverage for pulling force once extracting the foreign body. The rear handle was additionally designed to feel comfortable and controllable in the palm of a user's hand. It was modeled to be similar to a hose knob to subliminally train the user on the usage.

Tubing Set Replacement

A key design factor of the device to eliminate cost while improving efficacy was the replaceability of the tubing sets. To this end, a simple common thread (SP-400) was modeled into mating parts with sufficient tolerance and bottoming features. A snap-close access door has also been added to aid in tubing set crimp alignment when attaching/removing tubing sets. This provides the user with a simple, hassle-free, tubing set replacement process. The user is thus supplied with one control handle and various tubing sets.

Variable Tension Locking

A key issue that stems from the endoscopic retrieval process is how the veterinary tech has to keep tension on the devices currently on the market while they are trying to pull the object out of the canine. This provides a point of failure and fatigue for the user. Therefore, a quarter-turn lock has been implemented on the pusher rod. The user simply rotates the rear handle 90 degrees and the tensile grip on the object is kept where it was left. This provides the user with the ability to put their hand anywhere on the device to pull it out while freeing up the other hand to aid the veterinarian in any other aspect.

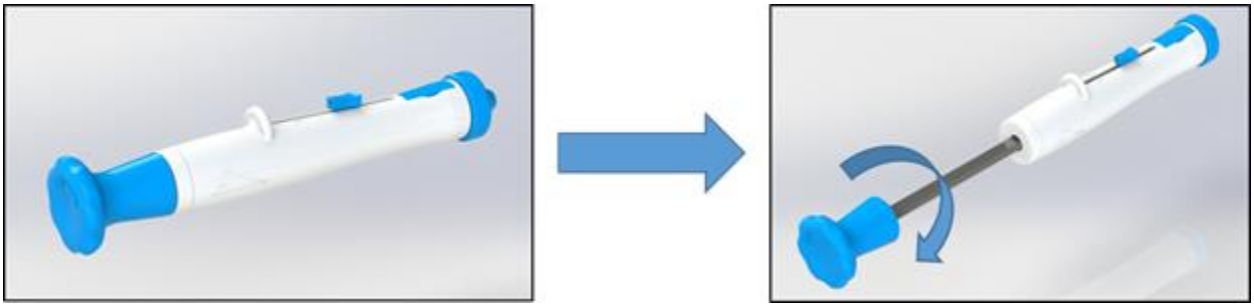


Figure 4: *Device actuation and 1/4 turn locking mechanism*

Device Strength

A key issue with current devices is that they are flimsy and easy to break. To prevent that from happening further, the ProCaptive device is designed to be much stronger. This is implemented through a couple features. First, the pusher rod is a solid 3/8" rod of stainless steel all-thread. This provides a solid backbone for the device as well as a smooth linear slide for the in/out mechanism of the retrieval head. Second, the plastic parts were designed with numerous ribs and alignment features to ensure strength and dimensional rigidity. Third, the PTFE tubing and the stainless braided cable chosen for the tubing sets were sourced for their increased strength and deformation resistance than the current market standard.

Retrieval Head Design

An important part of Proteus' initial efforts were focused on the retrieval head designs. A preliminary proposed design image is shown in figure 5.

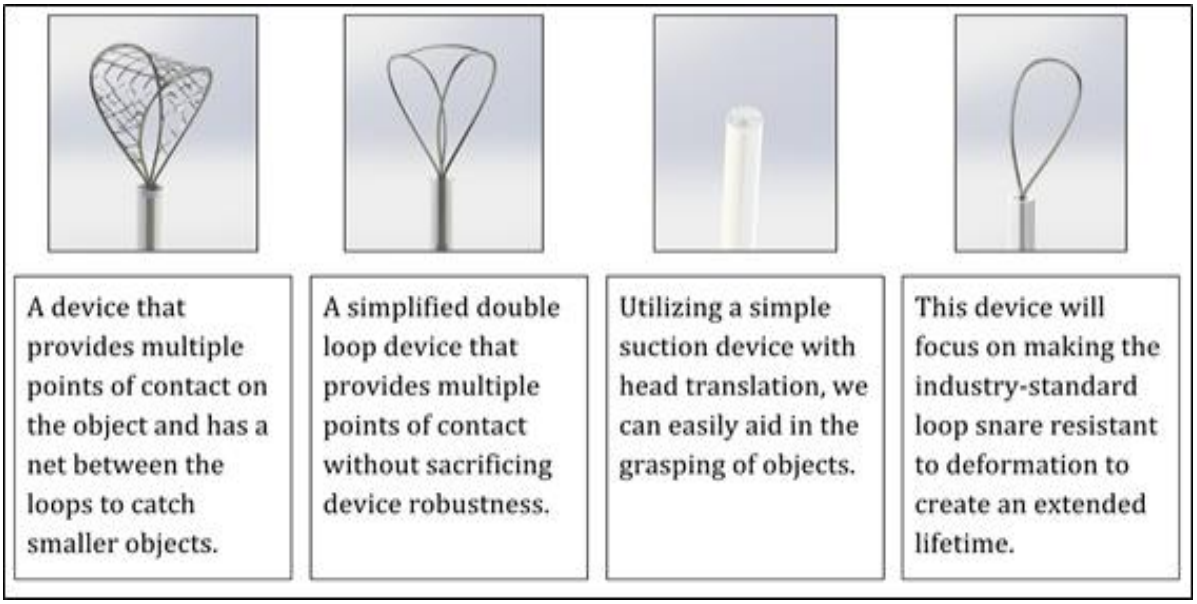


Figure 5: *Preliminary designs showing initial thoughts about head design*

The designs after being tested extensively, showed the efficacy of a three-member basket, a double-loop, and a single snare. To that end, multiples of those heads were built for our client. These were designed to be manufactured from off-the-shelf components to minimize cost and maximize throughput with ease-of-assembly. The industry standard method for making pushable cables was adopted, where the cable is radially crimped by hypodermic tubing.

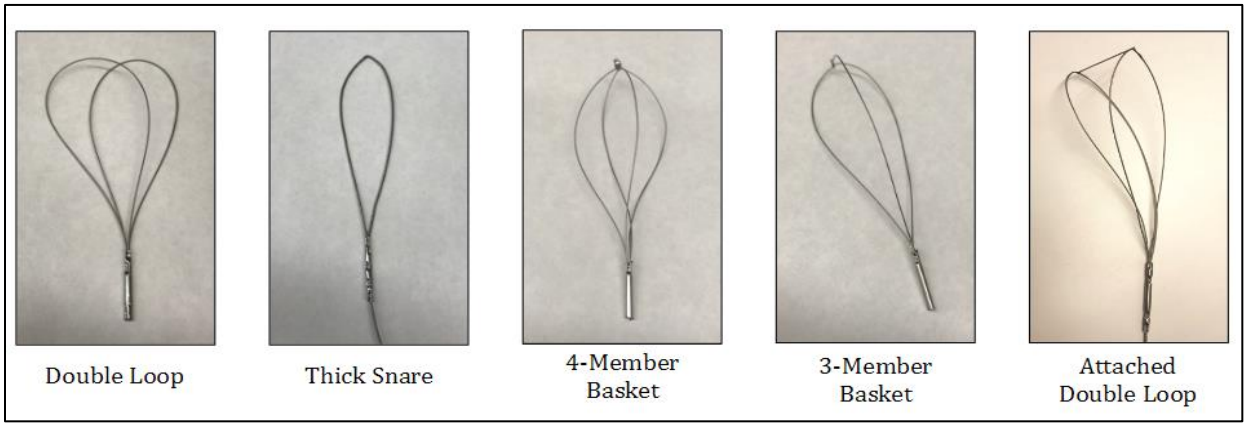


Figure 6: *Designs of final retrieval heads*

Injection Molded Plastics

All plastic parts were designed for manufacture by injection molding due the low end-use production costs involved. Although the initial fixed costs are expensive to buy the tools (soft or hard), the initial costs easily amortize at high production volumes.

To design the parts for injection molding, many classical plastics features were used to enable ease of manufacturability and assembly. These include mating alignment bosses, inseparable snap features (annular and cantilever), standard molded threads, and constant nominal wall thickness to aid in mold flow (0.07”). Mating alignment bosses and annular snap features ensure proper registration of the parts when assembling, Cantilever snap features provide a strong positive mechanical hold (these snap features require the mating force to be greater than the expected stress conditions and require the male and female features to be designed for non-stress conditions when placed together.) Utilizing extensive previous knowledge of injection molding, a medical grade polycarbonate has been chosen from Ruchler Engineered Plastics (Sustanat) due to its strength characteristics, ease of molding, and its low coefficient of friction. Soft tools will be cut initially to provide a low volume platform to make changes if necessary with hard tools being cut after extensive design validation.

Secondary Operations

In certain cases, purchased, stock components must be modified to work within an assembly. This option is usually chosen when it would be prohibitively expensive to have the parts custom manufactured or in extreme cases purchase the required tooling to manufacture in house. As is shown in the bill of materials, multiple parts require secondary operations. The parts that require these are sourced from dynamic manufacturers that have the built infrastructure to support the part changes and drop ship the completed parts at a nominal cost. For example, Fort Wayne Metals has been chosen to supply the hypodermic tubing and braided cable because they have the capability to crimp and cut-to-length the assembly alongside the standalone part manufacturing.

Assembly

Designing for assembly is as important as the manufacturability of the device as assembly can be a significant factor in the end-product price point. Assembly was designed into the Proteus device in multiple ways. All parts were designed with registration points for each part to easily “fall” into their fixtures with a positive mechanical hold. Each step is designed to be simple so that a complex assembly can be easily broken down for rapid manufacture. The fixtures themselves are designed to OSHA standards to ensure that the human factors are correctly accounted for (work in circles with natural movements). The goal of this methodology is to lower manufacturing cost, eliminate the possibility of fatigue in the worker, and maximize throughput.

Evaluation of Design

We evaluated our device in several stages through our four prototypes, as can be seen in Appendix 2. For our first prototype, we set out to design a device that looks and has similar function to a typical endoscopic retrieval device currently on the market. In addition, we also began designing with retrieval heads that might improve the capturing process. During initial testing, we noticed how flimsy the device felt, along with a lack of steering and a retrieval head that was not detachable from the user interface. We wanted to address and implement these design features based off the recommendations and concerns from our customer. Upon talking further with Dr. de Papp, we identified that her main needs focused on the reusability and efficacy of the retrieval device. We then took this feedback that we had received and used it to create our second-generation user interface.

While the second prototype improved upon the previous user interface by making it much more robust and ergonomic, there were several issues with this device: the steering was not as responsive as hoped and the tubing set was not replaceable. When discussing these developments with our customer, we then identified another need for tensioning the foreign body independent of the veterinarian hold. This developed our third design, which integrated the mechanisms from the first two prototypes. However, testing then demonstrated a glaring issue where the threaded rod required 160 turns along a 5 ½ inch path to fully extrude and retract. Our customer responded that she needed to be able to quickly tension against a foreign body, and being too slow with the rotations would result in an unsuccessful grasp.

Concurrently discussing the issues with the third prototype, we received a second opinion of our device and its mechanisms with Dr. Kothari at URMC. He provided keen insight into our technologies and insisted that steering could be achieved with the endoscope, making the need for translation of the retrieval device not the priority for an improved device. He additionally added an emphasis on stiffer cables for a more robust retrieval head. Together, the insight allowed us to modify our device to generate our fourth and most current prototype, which focuses on different retrieval head type replaceability on our device along with variable tension locking.

Outside of general feedback, we conducted testing on our device to choose the best retrieval head designs. We ran three types of tests for our device to compare the effectiveness of each. The first test focused on time of retrieval, with variability in the device heads of the fourth-generation prototype occurring due to different materials and head types. Below in Figure 7 is a graph with the times reported to capture a ball with different head designs, as a ball would give her the most effective data since she often struggles with retrieving ball fragments or entire balls during the procedures.

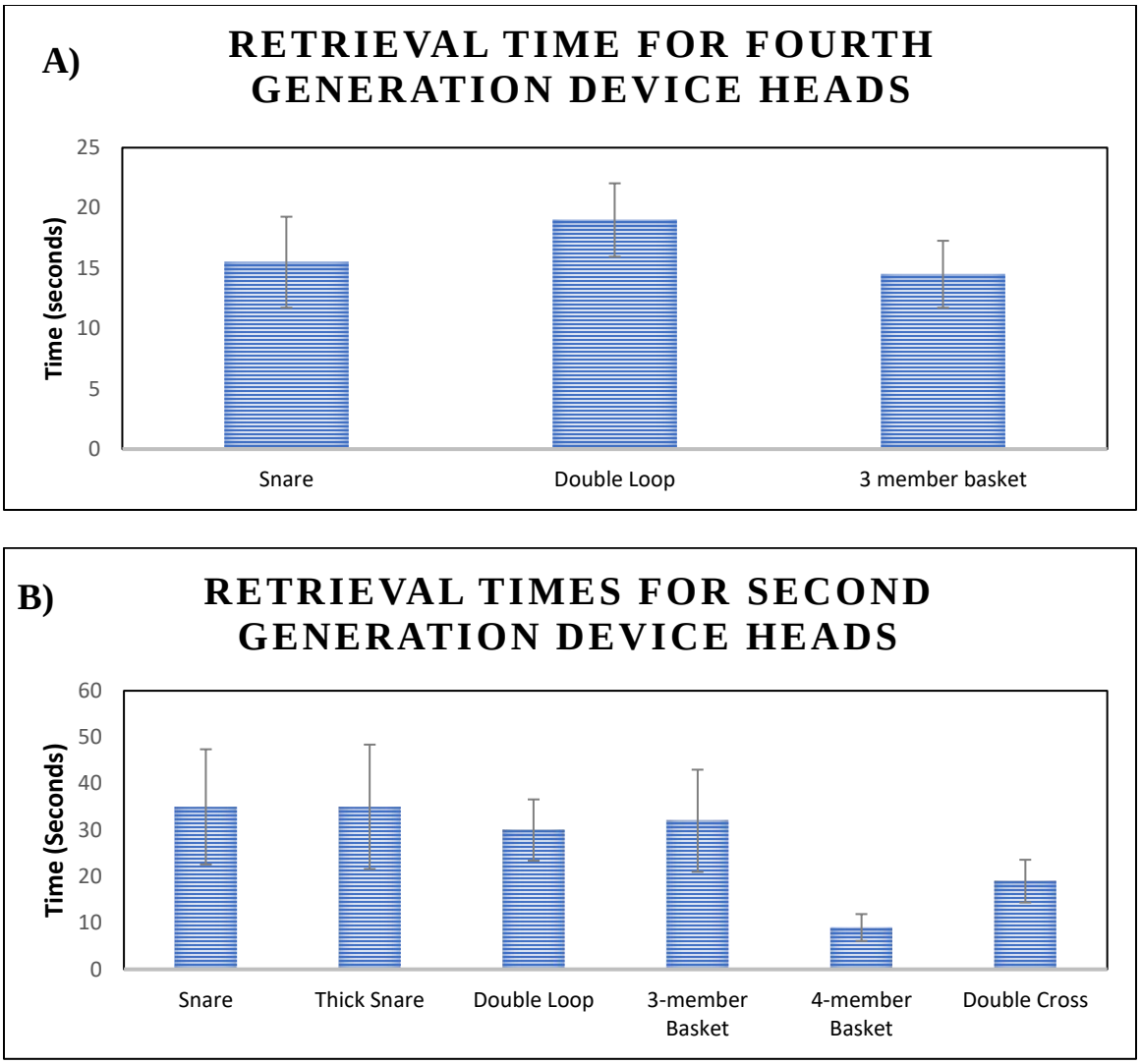


Figure 7: *A) Retrieval times for the 4th generation heads; B) Retrieval times for 2nd generation heads*

It was found that retrieval times were much lower when using stiffer cable as suggested by Dr. Kothari from our meeting. In addition, the standard deviations of the retrieval times were reduced since the head deploys in a much more consistent manner. While there was no statistical significance between retrieval head types, the development of new retrieval heads provides our customer with more options to grasp foreign bodies of varying sizes and geometries.

The second form of testing was a peak pulling force test to determine how much tension our retrieval heads could withstand before failure. The test was conducted by pulling two different objects of varying size and geometry through a silicon hole punch, which closely simulates the canine's lower esophageal sphincter. The resulting data can be seen in Figure 8.

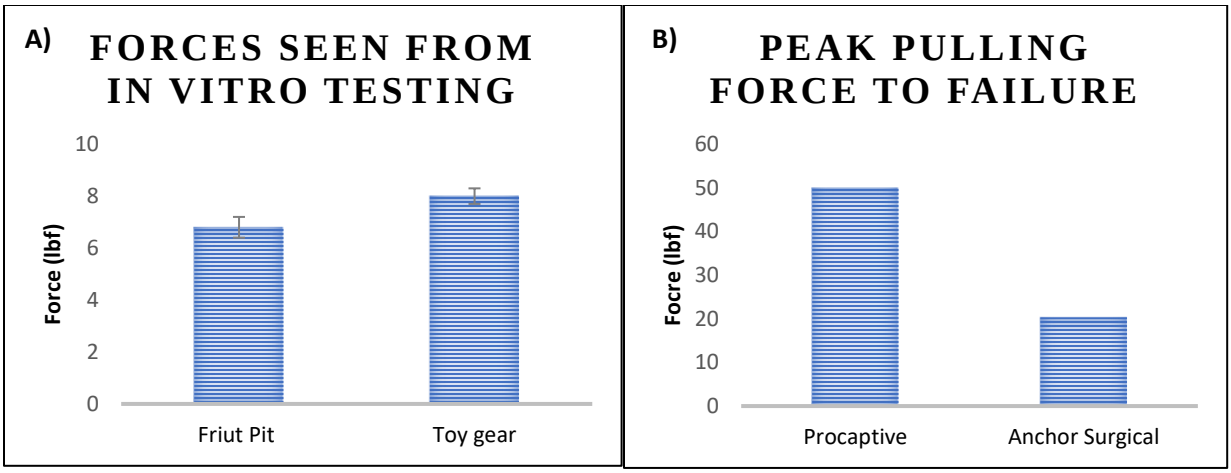


Figure 8: *Forces observed in vitro when A) testing our device against two different objects and B) against a market competitor*

From our testing, our retrieval heads, which consisted of hypodermic tubing to crimp the wire together, maxed out the scale at 50 lbf. When passing the objects through the silicon punch, the highest pulling force seen was approximately 10 lbf, demonstrating that our retrieval heads have a safety factor of 5. This is a major improvement over initial testing on earlier retrieval heads with flexible wiring as they could only last for 22 lbf.

Our third and final test was a degradation test to determine whether our material choices would be able to withstand the acidic environment of the stomach gastric juices. Initial measurements of the wire thickness were recorded prior to placing the wire in a 1M HCl bath for 48 hours. After the given length of time, the thickness of the wire was recorded once again. It was concluded that 0% degradation occurred using braided stainless steel wire and PTFE tubing. Additionally, an added test to determine the strength of the variable tension locking mechanism was conducted (n=5) and determined to hold up to 15.2 ± 2.4 lbf.

Considerations for Further Development

Realistic Constraints

When designing for manufacture and assembly (DFMA), it is crucial to understand the capabilities and limitations to the technologies available for production of a design. Initial prototyping tends to create non-manufacturable devices to create a proof-of-concept. This process then takes extensive amounts of time to develop a design for manufacturing due to the inherent shortcuts available in rapid prototyping. From previous experience, it is most effective to adopt a mixture of full DFMA and the fail fast methodology. The devices are designed to be easy to modify by governing equation and surface manipulation so that tolerances can be directly changed while the overall design requires very little to change for end-use manufacturing.

The goal of correct DFMA is to not only provide a design for manufacturability and assembly, but to provide the simplest, and most robust solution to eliminate manufacturing cost and complex operation stages. However, it is necessary to ensure that the end-use parts can be correctly mocked up by rapid prototyping processes. For example, the control handle was designed to be screwed together for prototyping due to the brittle UV sintered plastics being used, while with end-use molded parts, snap features are the correct path. Any constraint from a design standpoint should be corrected in the 3D model, as good design has no limitations in terms of manufacturability; especially due to the extensive capabilities of manufacturing processes today. As was the goal with the Proteus device, all parts were designed for ease of manufacture, secondary operation, and assembly.

Future Design Considerations

During the design process, Proteus focused on practical DFMA principles to eliminate the need for major redesigns between the prototyping and commercialization stages. Therefore, to develop the product with the end goal of being hard tool commercialization, the current designs will have to be minorly changed to have snap features for ease of assembly. This is due to the rapid prototyping polycarbonate printing materials used. Although the Stratysys VeroClear PC material used is strong in compressive strength, excellent in dimensional stability, and similar to the resolution of injection molding, it lacks the ability to handle the one-time stress conditions of snap features. Therefore, the current prototypes were screwed together to ensure a strong mechanical hold between parts rather than risk brittle fracture with snap features. Once the snap features are unsuppressed in the models, venting locations are chosen, final drafting, etc. the parts will be ready for manufacture. All of the peripheral parts (i.e. metal parts, and tubing) are off-the-shelf parts that require simple secondary operations that are outsourced to strategic partners. Therefore, there is no need to change their design for commercialization.

Proteus aims to create a pilot run with the current design to gain customer feedback to isolate the final customer-driven design for commercialization.

Market Size & Pricing

According to the American Veterinary Medical Association (AVMA), our research reveals that of the 107,995 registered veterinarians in the United States in 2016, only 20% of them perform endoscopy, mainly due to the costs of the endoscopes. This equates to approximately 21,600 DVMs in the United States with access to endoscopes that are qualified to perform these procedures. With the number of veterinarians increasing at an annual rate of 2.5% per year, there is a growing need for more effective retrieval devices, especially if they perform an average of 150 retrieval procedures per year (de Papp, 2017). In addition, with over 78 million canines in the United States, veterinarians need to be prepared for an increased foreign body ingestion risk. These numbers are for the U.S. only, and vary between cities.

The base unit cost of current veterinary retrieval devices on the market range between $30-$40 per single-use device, making it expensive for veterinarians as there is no reimbursement process to subsidize these purchases (ESS, 2017). Effectively, they must purchase 5-7 devices at a time with the intent of using one per procedure prior to disposal. In contrast, Proteus Medical has calculated a 5-year projection and followed a "Razor-Razorblades Model" approach to selling our product. The initial buy-in, which includes the advanced user interface and a tubing set, will be priced at $300 for a gross profit of 50%, with follow up purchases of replaceable tubing sets for $17 at a 42% gross margin. As seen in Appendix 3, a price comparison was conducted to demonstrate the savings a veterinarian would have for the year by using our product versus other products on the market. Ultimately, Proteus' product provides the veterinarian with more than 40% in annual savings from the next competitive device on the market.

Project Management

Overview

To ensure the completion of Proteus' desired product development cycle, the team used a multitude of organizational and task-based controls. Progress reports were submitted to our advisor and our TA weekly, along with an in-person meeting to maintain open channels of communication. The teams' project status was maintained using a Gantt chart that was updated weekly for each progress report, as can be seen in Appendix 4. To maintain communication and concurrent file-editing capability a Google Drive folder was created to organize the team's efforts in the cloud as well as setting up a direct messaging platform.

Team

Management Team

- Connor McBride –VP of Clinical & Regulatory
- Edward Ruppel III – President, CEO
- Chandler Woo – Director of Research & Development

Advisors

Our primary advisors are Dr. Diane Dalecki, Dr. Amy Lerner, and Dr. Scott Seidman of the Department of Biomedical Engineering at the University of Rochester. We additionally have a veterinary professional, Dr. Erika de Papp, who also is our customer.

Yearly Review

Lessons Learned

Connor

Over the course of this project I have learned a lot. I came in with almost zero knowledge on how the design process works and it has been a great learn about it with some of the best teammates I could hope for and who ended up sharing the same passion that I do. While I have learned a lot I think some critical things I learned were how to prioritize needs and wants. You want to give your customer everything she asks for but at the end of the day everything is not usually feasible so having a method to weight the cost and benefits of each helped me out. In addition, another thing I learned is these type of projects require consistent work you can't just cram at the end and hope it works you have to consistently put work in over the semester and I am thankful for having teammates that were proactive. In regards to the project I think we as a whole team have learned a lot. This device turned out to be a bit more complicated than we thought and with our budget ultimately had to scale back on some design features. The next lesson learned was be careful on shipping we spent a decent amount of money on shipping since we did not order in advance far enough and while this is a simple fix it was definitely a lesson learned. Overall though how to brainstorm then take the idea from brainstorming and make a product.

Eddie

Throughout the course of this product development cycle I have further isolated my preferred design methodology. The fail-fast methodology we implemented allowed us to try many things over the course of the semester while maintaining effective progress and technological development. This experience has also showed to me that no matter the size of the team, it is the passion and camaraderie that drives an effective “startup style” venture to be successful. The key takeaway being that continuous effort and investment from every team member drives the best final product. Another key takeaway from this experience is to maintain focus on the required needs without dilution from unnecessary wants.

Chandler

It goes without saying that I have just scratched the surface about the complexities of bringing a successful device from conception to prototype to market. As a hands-on experience type of person, Senior Design was a great introduction into the medical device space, and I feel that our project truly captured the opportunities for future growth. Besides simply learning the engineering jargon and terminologies used in developing a product, I learned the value of the “fail fast, fail often” methodology through our rapid prototyping. It was especially helpful that our project focused on actual medical device design for a veterinary space, where I could learn about designing a device that can be injection molded along with other design considerations that I had not realized going into Senior Design.

One of the most valuable experiences that I had this year, however, was applying for the business competitions. It not only forced me to learn about the marketing and sales side of our product, but it gave me a more comprehensive understanding of our market and forced me to ask the right questions to our customer regarding the endoscopic space. Developing 5-year projections and understanding how our product could compete against the current market was invaluable in developing my economic realistic constraints as well as bringing our project to a strong conclusion.

Future Recommendations

One of our major recommendations is that senior design capstone projects should truly be an entire year experience. While we see the value in the first project of the year (e.g. Thermometers, wheelchairs, etc.), it takes away time from our capstone project. After talking to other teams, we would all have seen the value of having an extra month to continue prototyping and developing our designs. Much of the aspects that the first project tries to instill can, and should, be taught in our first three years of the Biomedical Engineering curriculum, ultimately bringing all of the knowledge and experience to our final projects.

While we understand that the business plan competition is a forethought relative to developing a fully functional device design for Design Day, some of the aspects of developing a business plan has helped elucidate and ask some of the more important questions regarding the importance of our device in the market. This would be especially beneficial for all teams earlier in the year to understand the market that they are working in, how they can advertise and develop their solution to make it competitive, and how they can price point their product to bring it to market. More importantly, it helps drive realistic constraints for their design, as it addresses economic, manufacturing, and environmental constraints that their device must consider. In short, building a business plan forces us as engineers to think in an alternative way other than just an engineering mindset about our project. This is especially beneficial when it comes time for Design Day and pitching our projects to other people where the technical detail is not the focus, but rather describing how our solution can improve or even revolutionize the market.

Conclusion

Proteus Medical has developed a veterinary endoscopic retrieval solution that provides intuitive controls, variable tension locking, and replaceable tubing sets with increased performance at a reduced cost. Along with the development of four unique retrieval head designs and two provisional patents covering the key IP of our control methodology, we have created a product that will restore confidence within veterinarians to use endoscopy as a primary method of foreign body retrieval. With our ability to save the veterinarian more than 40% in direct costs from the next competitive endoscopic solution in the market, Proteus Medical has placed itself in a favorable position for future growth and development. This growth not only allows us to succeed within the market, but it also brings us closer to our ultimate goal of improving the veterinary endoscopic space and reducing harm for the canine.

Acknowledgements

We would like to acknowledge our client, Dr. Erika de Papp along with her clinic at the Angell Animal Medical Center in Boston, for the extensive knowledge that she has imparted on us. Our advisor, Dr. Diane Dalecki, for the excellent strategy sessions that we have had. Our TA, Caeli Quiter, for her insightful feedback throughout the product development process.

We would also like to acknowledge the following individuals and groups who have graciously provided us with materials and insight that have allowed us to develop a successful product: Dr. Mike Richards, Paul Osborne, Marty Gira, Dr. Mark Buckley, James Alkins, and University of Rochester Solar Splash.

Lastly, we would like to thank Dr. Amy Lerner and Dr. Scott Seidman for their contributions to a successful Senior Design curriculum that has allowed us to learn and develop our biomedical engineering skills.

References

[1] de Papp, Erika. *Customer Meeting Minutes*, 2016.

[2]"Pet Statistics." ASPCA. N.p., n.d. Web. 21 Mar. 2017.

[3]" U.S. Pet Ownership Statistics." AVMA. Web. 21 Dec. 2016.

[4]Lee, Si Hyung, and Kyung Sik Park. "Removal of Gastrointestinal Foreign Body." Therapeutic Gastrointestinal Endoscopy (2015): 91-109.

[5] "PK Cutting Forceps." Olympus -PK Cutting Forceps| Medical Systems.

[6] Birk, Michael, Peter Bauerfeind, Pierre Deprez, Michael Häfner, Dirk Hartmann, Cesare Hassan, Tomas Hucl, Gilles Lesur, Lars Aabakken, and Alexander Meining. "Removal of foreign bodies in the upper gastrointestinal tract in adults: European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline." *Endoscopy* 48.05 (2016): 489-96. Web.

[7] Bounds, Brenna C. "Endoscopic Retrieval Devices." *Techniques in Gastrointestinal Endoscopy* 8.1 (2006): 16-21. Web.

[8] "Small Animal Topics." *Gastrointestinal Foreign Bodies*. AVCS, n.d. Web. 20 Jan. 2017.

[9] Chalabi, Mona. "What Cats And Dogs Are Swallowing." *FiveThirtyEight*. New York Magazine, 04 Sept. 2014. Web. 20 Feb. 2017.

[10] Roth Net Retrieval Devices [Devices Document], n.d, Roth Net Retrievers. URL http://www.usendoscopy.com/endoscopy/roth-net-retrieval-devices.aspx (accessed 1.5.2017).

[11] Endoscopic Foreign body Retrieval, n.d.URL http://todaysveterinarypractice.navc.com/wp-content/uploads/2016/05/t1511c07.pdf (accessed 2.15.2017).

[12] Removal of foreign bodies in the upper gastrointestinal … , n.d. URL https://www.esge.com/assets/downloads/pdfs/guidelines/2016_s_0042_100456.pdf.

[13] Management of ingested foreign bodies and food impactions, n.d. URL http://www.asge.org/uploadedfiles/publications_and_products/practice_guidelines/management of ingested foreign bodies and food impactions.pdf.

[14] Proceeding of the NAVC North American Veterinary Conference , 2005 URL http://www.ivis.org/proceedings/navc/2005/sae/130.pdf.

[15] Olympus Retrieval Devices for Endoscopy, n.d. olympus. URL http://et-catalogue.olympus.eu/en/index.php?category=764.

[16] FDA warns of Endoscope Contamination, n.d. Medscape. URL http://www.medscape.com/viewarticle/840057.

[17] 510(k) Premarket Notification, n.d. 510(k) Premarket Notification. URL http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm.

[18] Intentional Swallowing of Foreign Bodies and its Impact on the Cost of Health Care n.d.. URL http://www.rhodeislandhospital.org/templates/onecolumnpb.aspx?pageid=43061.

[19] Sugawa, Choichi. "Endoscopic management of foreign bodies in the upper gastrointestinal tract: A review." *World Journal of Gastrointestinal Endoscopy* 6.10 (2014): 475-81. *WJGE*. Web.

[20] "Endoscopic baskets." *Endoscopic baskets - All medical device manufacturers - Videos*. Medical Expo, n.d. Web. 20 Dec. 2016.

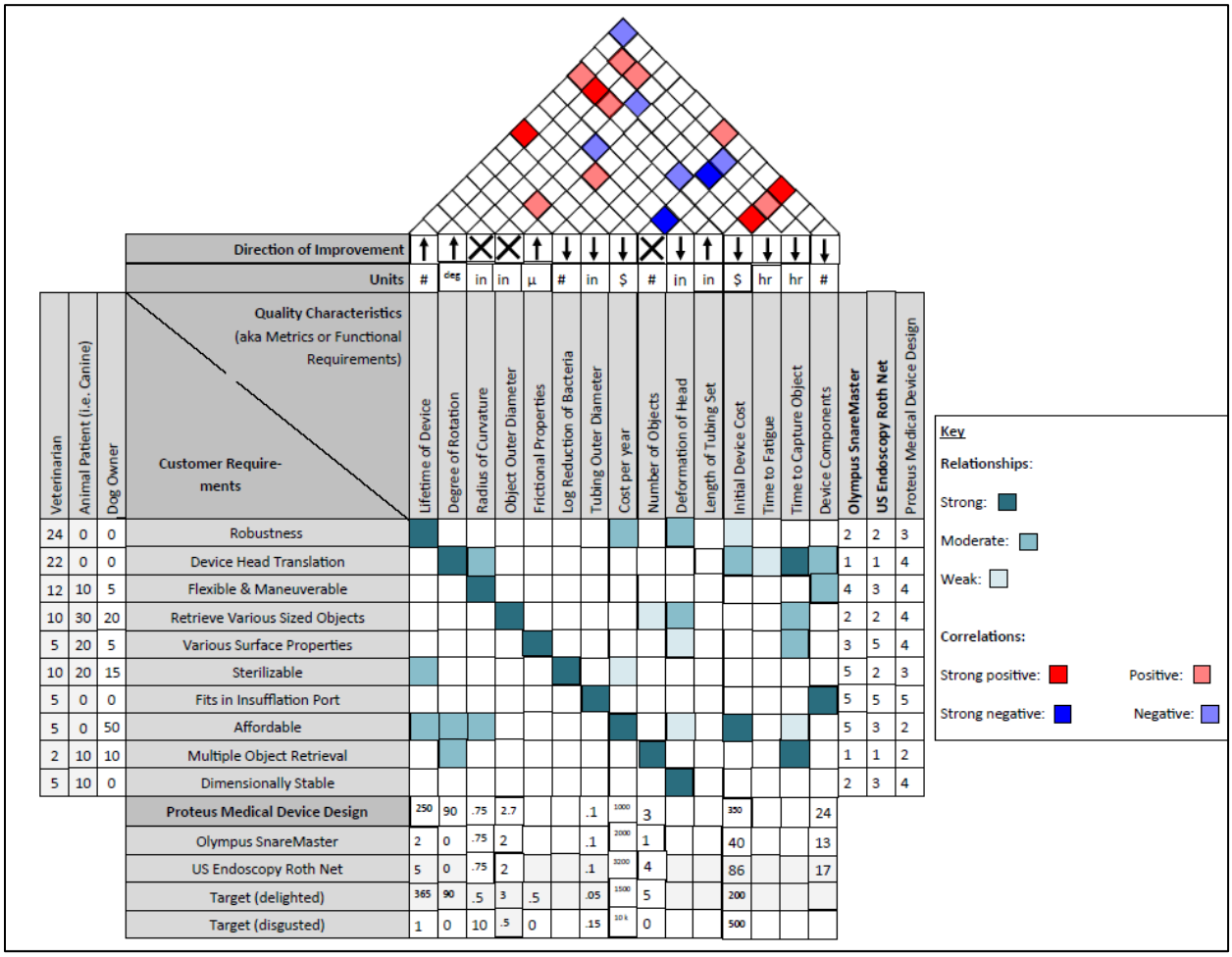
[21] Gregorski, Maciek. "Practice Guidelines." ASGE: Practice Guidelines. N.p., n.d. Web. 21 Dec. 2016.

[22] "Top 10 Vet Visit Reasons For Dogs And Cats." *Veterinary Practice News*. Web. 07 May 2017.

[23] "Endoscope options." *Endoscopy Support Services, Inc.* Web. 05 April 2017.

List of Appendices

Appendix 1: House of Quality



Veterinarian	Animal Patient (i.e. Canine)	Dog Owner	Customer Requirements \ Quality Characteristics (aka Metrics or Functional Requirements)	Lifetime of Device	Degree of Rotation	Radius of Curvature	Object Outer Diameter	Frictional Properties	Log Reduction of Bacteria	Tubing Outer Diameter	Cost per year	Number of Objects	Deformation of Head	Length of Tubing Set	Initial Device Cost	Time to Fatigue	Time to Capture Object	Device Components	**Olympus SnareMaster**	**US Endoscopy Roth Net**	Proteus Medical Device Design
			Direction of Improvement	↑	↑	X	X	↑	↓	↓	↓	X	↓	↑	↓	↓	↓	↓			
			Units	#	deg	in	in	μ	#	in	$	#	in	in	$	hr	hr	#			
24	0	0	Robustness	■							■		■		□				2	2	3
22	0	0	Device Head Translation		■	■									■	□	■	■	1	1	4
12	10	5	Flexible & Maneuverable			■												■	4	3	4
10	30	20	Retrieve Various Sized Objects				■					□	■				■		2	2	4
5	20	5	Various Surface Properties					■					□				■		3	5	4
10	20	15	Sterilizable	■					■		□								5	2	3
5	0	0	Fits in Insufflation Port							■								■	5	5	5
5	0	50	Affordable	■	■	■					■		□		■		□		5	3	2
2	10	10	Multiple Object Retrieval		■							■					■		1	1	2
5	10	0	Dimensionally Stable										■						2	3	4
			Proteus Medical Device Design	250	90	.75	2.7			.1	1000	3			350			24			
			Olympus SnareMaster	2	0	.75	2			.1	2000	1			40			13			
			US Endoscopy Roth Net	5	0	.75	2			.1	3200	4			86			17			
			Target (delighted)	365	90	.5	3	.5		.05	1500	5			200						
			Target (disgusted)	1	0	10	.5	0		.15	10 k	0			500						

Key

Relationships:

Strong: ■

Moderate: □

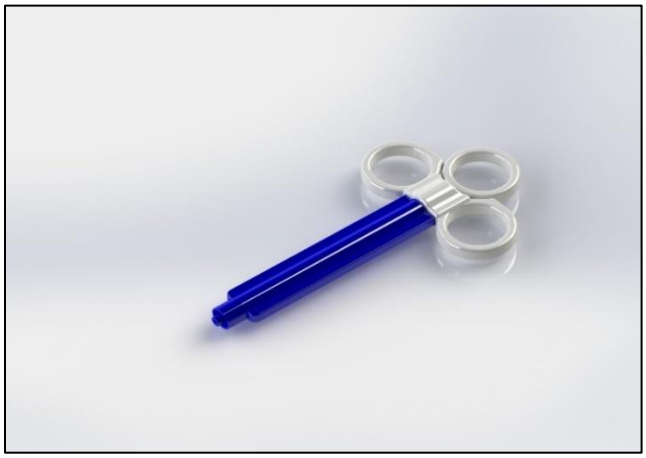
Weak: □

Correlations:

Strong positive: ■ Positive: ■

Strong negative: ■ Negative: ■

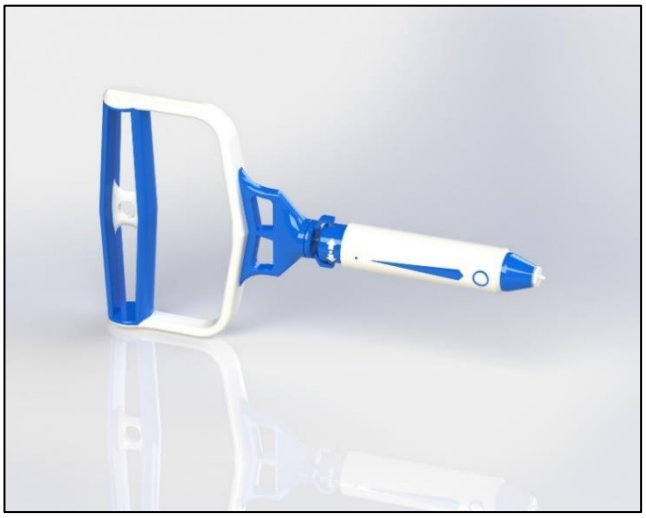
Appendix 2: Prototype Development



Initial Prototype:

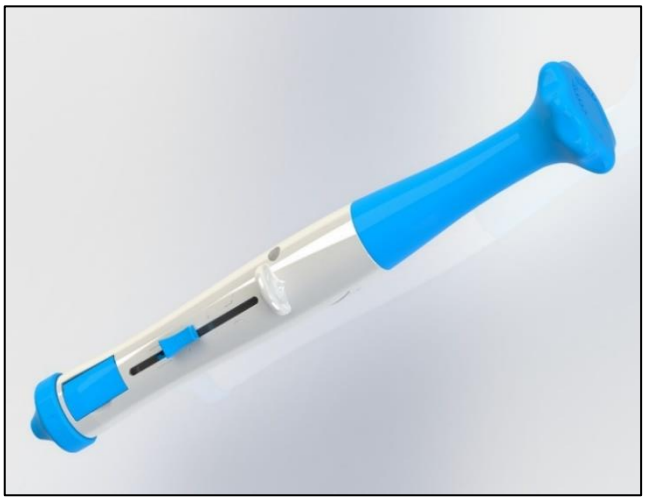
A simple proof-of-concept device that allows for a detachable tubing set without the affordances of steering. This device allows for a quick and cheap option to replace tubing sets with different retrieval heads that is deemed most effective to retrieve a specific foreign body.

This prototype most closely models the current standard of retrieval devices on the market currently.



Second Prototype:

An ergonomic control handle developed to test the ability to rotate and translate the retrieval head at the end of the tubing set. The large handle allows veterinarians to tension a foreign body with the full force of the body, along with the ability to bend side-to-side to allow the retrieval head to curve for easier grasping of oddly shaped foreign bodies.

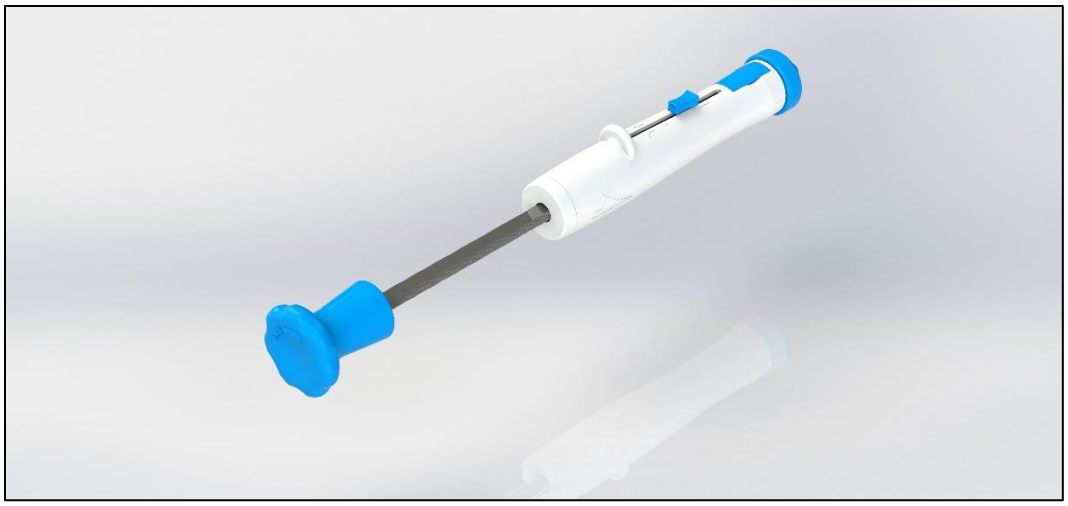


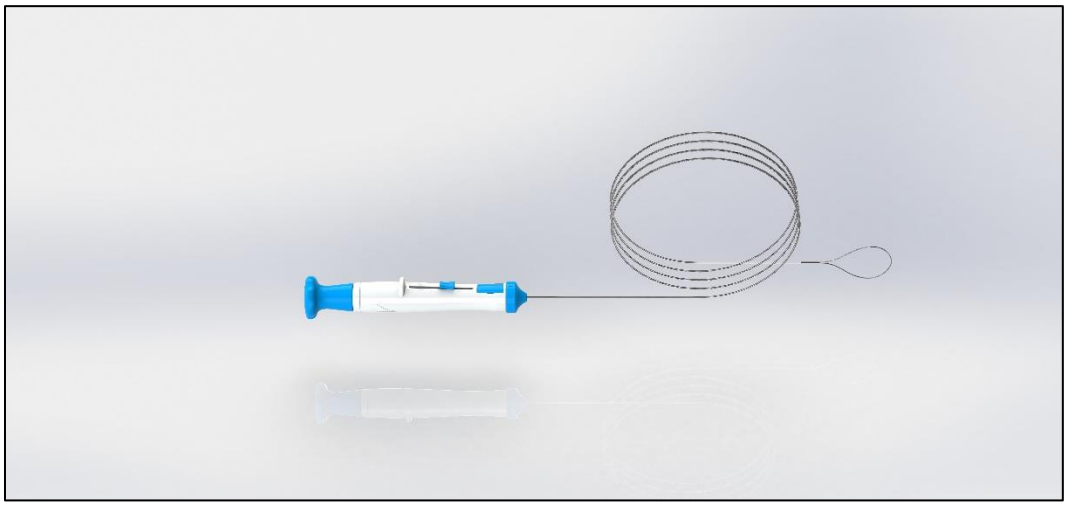
Third Prototype:

Taking the advancements from the previous prototypes, this prototype was developed to encapsulate the strengths of the previous two. The device has both steering capability as well as a door panel to easily replace tubing sets for the next procedure. Additionally, a twisting handle allows for an instantaneous locking mechanism to allow the person to pull the device as a whole rather than focusing on maintaining tension against the foreign body.

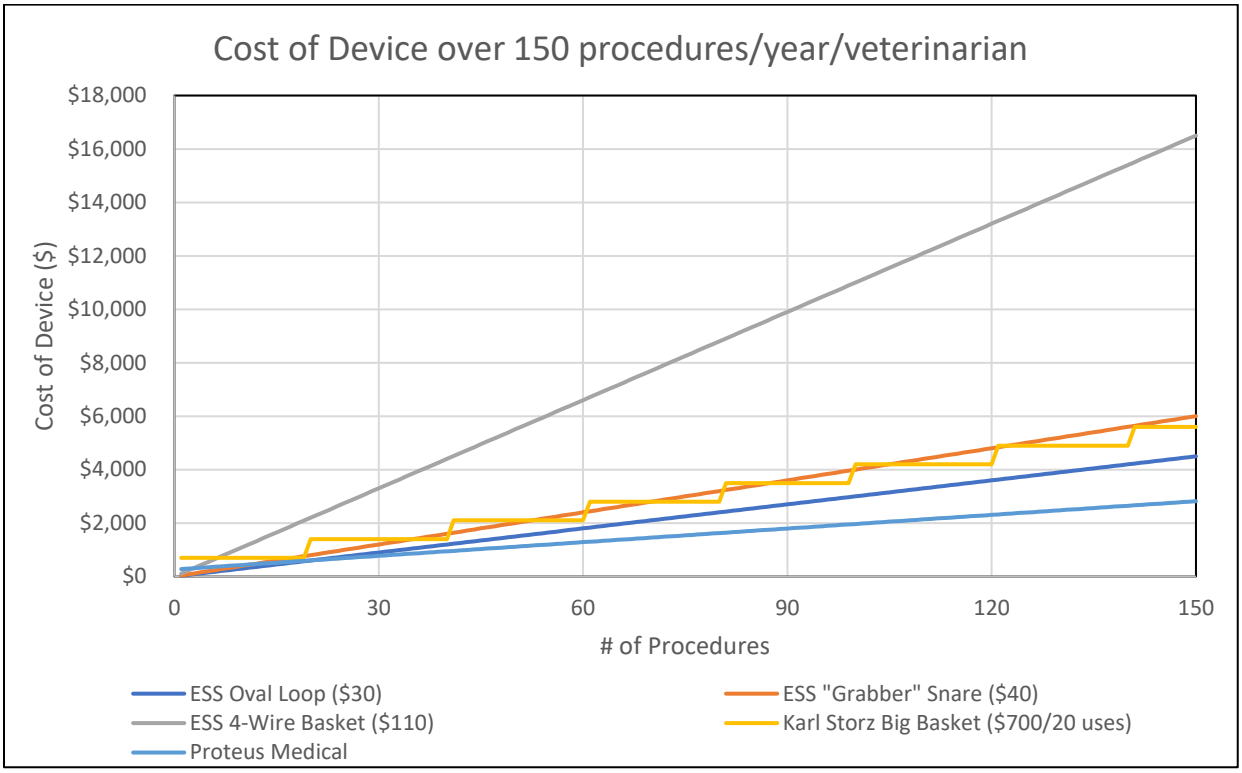
Current Prototype

Adapting our device to model the third prototype along with more ergonomic measures for faster retrieval, this latest prototype allows the veterinarian to quickly actuate the in/out mechanism of the device to grasp the foreign body. A quarter-turn locking mechanism to keep the tension of the retrieval head in place addresses several grasping issues for the veterinarian, while still maintaining an ergonomic user interface and replaceable tubing set that veterinarians want to use.





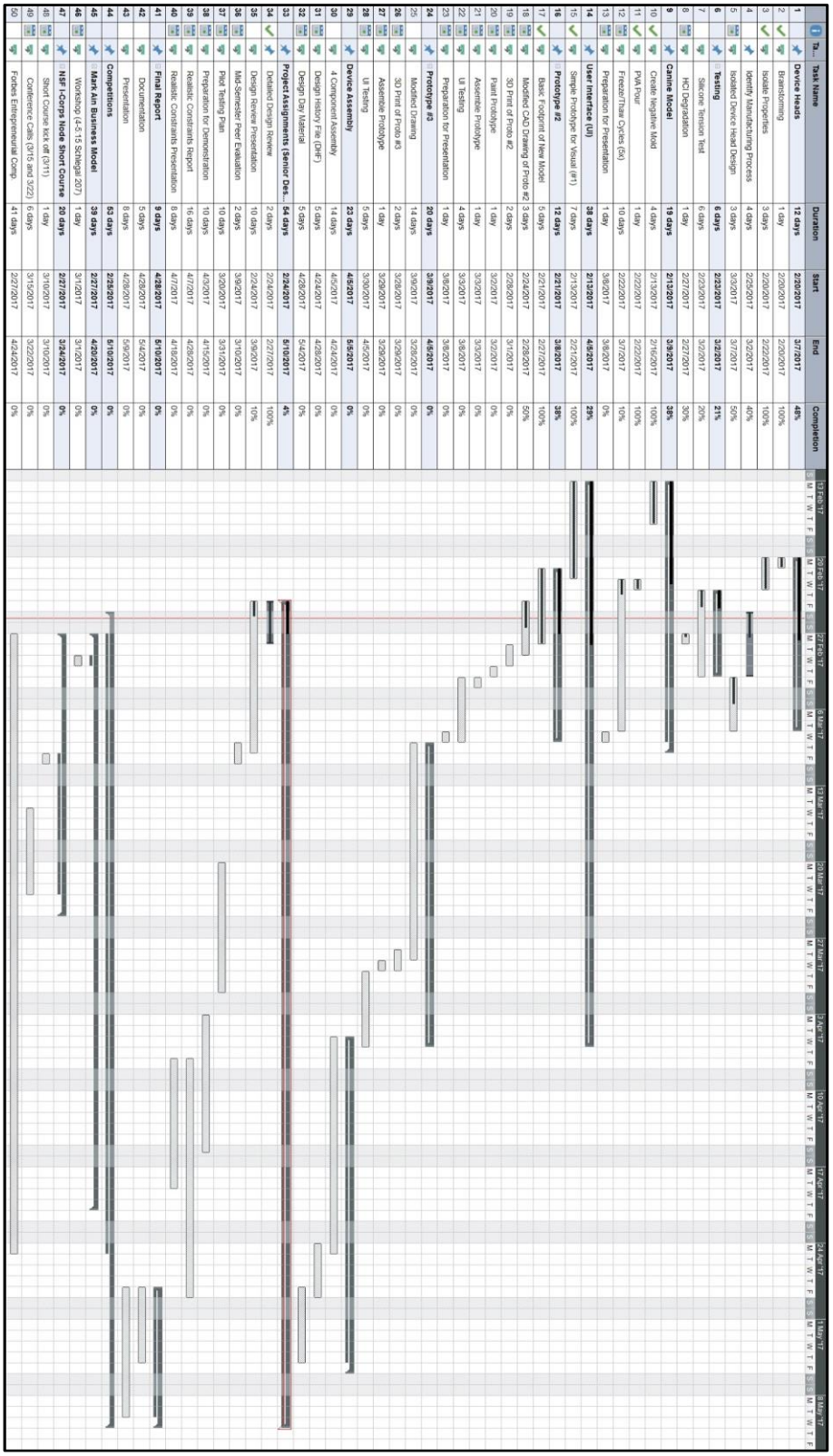
Appendix 3: Price Comparison over 150 Procedures Annually



The graph above displays the costs of "single-use" veterinary retrieval devices of current competitors and Proteus Medical for 150 procedures per year, the average number of veterinary foreign body retrievals performed by individual veterinarians in the United States. Indicated in the legend presents the cost of the single-use device, with Karl Storz Big Basket costing $700 since it can be used approximately 20 times before permanent deformation. The table below displays the expenditures per year that the veterinarian would need to spend to obtain each of those devices to perform the procedures.

Device	***~Annual Cost***
ESS Oval Loop	$4,500
ESS "Grabber" Snare	$6,000
ESS 4-Wire Basket	$16,500
Karl Storz Big Basket	$5,600
Proteus Medical	$2,820

Appendix 4: Gantt Chart



	Ta...	Task Name	Duration	Start	End	Completion
1		**Device Heads**	**12 days**	**2/20/2017**	**3/7/2017**	**48%**
2		Brainstorming	1 day	2/20/2017	2/20/2017	100%
3		Isolate Properties	3 days	2/20/2017	2/22/2017	100%
4		Identify Manufacturing Process	4 days	2/25/2017	3/2/2017	40%
5		Isolated Device Head Design	3 days	3/3/2017	3/7/2017	50%
6		**Testing**	**6 days**	**2/23/2017**	**3/2/2017**	**21%**
7		Silicone Tension Test	6 days	2/23/2017	3/2/2017	20%
8		HCl Degradation	1 day	2/27/2017	2/27/2017	30%
9		**Canine Model**	**19 days**	**2/13/2017**	**3/8/2017**	**38%**
10		Create Negative Mold	4 days	2/13/2017	2/16/2017	100%
11		PVA Pour	1 day	2/22/2017	2/22/2017	100%
12		Freeze/Thaw Cycles (5x)	10 days	2/22/2017	3/7/2017	10%
13		Preparation for Presentation	1 day	3/8/2017	3/8/2017	0%
14		**User Interface (UI)**	**38 days**	**2/13/2017**	**4/5/2017**	**29%**
15		Simple Prototype for Visual (#1)	7 days	2/13/2017	2/21/2017	100%
16		**Prototype #2**	**12 days**	**2/21/2017**	**3/8/2017**	**38%**
17		Basic Footprint of New Model	5 days	2/21/2017	2/27/2017	100%
18		Modified CAD Drawing of Proto #2	3 days	2/24/2017	2/28/2017	50%
19		3D Print of Proto #2	2 days	2/28/2017	3/1/2017	0%
20		Paint Prototype	1 day	3/2/2017	3/2/2017	0%
21		Assemble Prototype	1 day	3/3/2017	3/3/2017	0%
22		UI testing	4 days	3/3/2017	3/6/2017	0%
23		Preparation for Presentation	1 day	3/6/2017	3/6/2017	0%
24		**Prototype #3**	**20 days**	**3/8/2017**	**4/5/2017**	**0%**
25		Modified Drawing	14 days	3/8/2017	3/28/2017	0%
26		3D Print of Proto #3	2 days	3/28/2017	3/29/2017	0%
27		Assemble Prototype	1 day	3/29/2017	3/29/2017	0%
28		UI Testing	5 days	3/30/2017	4/5/2017	0%
29		**Device Assembly**	**22 days**	**4/5/2017**	**5/5/2017**	**0%**
30		4 Component Assembly	14 days	4/5/2017	4/24/2017	0%
31		Design History File (DHF)	5 days	4/24/2017	4/28/2017	0%
32		Design Day Material	5 days	4/28/2017	5/4/2017	0%
33		**Project Assignments (Senior Des...**	**54 days**	**2/24/2017**	**5/10/2017**	**4%**
34		Detailed Design Review	2 days	2/24/2017	2/27/2017	100%
35		Design Review Presentation	10 days	2/24/2017	3/6/2017	10%
36		Mid-Semester Peer Evaluation	2 days	3/9/2017	3/10/2017	0%
37		Pilot Testing Plan	10 days	3/20/2017	3/31/2017	0%
38		Preparation for Demonstration	10 days	4/3/2017	4/15/2017	0%
39		Realistic Constraints Report	16 days	4/7/2017	4/28/2017	0%
40		Realistic Constraints Presentation	8 days	4/7/2017	4/18/2017	0%
41		**Final Report**	**9 days**	**4/28/2017**	**5/10/2017**	**0%**
42		Documentation	5 days	4/28/2017	5/4/2017	0%
43		Presentation	8 days	4/28/2017	5/9/2017	0%
44		**Competitions**	**52 days**	**2/28/2017**	**5/10/2017**	**0%**
45		**Mark Am Business Model**	**39 days**	**2/27/2017**	**4/20/2017**	**0%**
46		Workshop (4-5 15 Scthegal 207)	1 day	3/1/2017	3/1/2017	0%
47		**NSF I-Corps Node Short Course**	**20 days**	**2/27/2017**	**3/24/2017**	**0%**
48		Short Course kick off (3/11)	1 day	3/10/2017	3/10/2017	0%
49		Conference Calls (3/15 and 3/22)	6 days	3/15/2017	3/22/2017	0%
50		Forbes Estrepreneurial Comp	41 days	2/27/2017	4/24/2017	0%

Appendix 5: Money Spent

Date Ordered	***Manufacturer***	***Product***	***Cost***
1/20/2017	McMaster-Carr	Coated Stainless Steel Wire - Braided, 0.014" OD, 25' length	$11.50
1/20/2017	McMaster-Carr	Stainless Steel Wire - Lubricated, 0.03" OD, 25' length	$15.50
1/20/2017	McMaster-Carr	Stainless Steel Tubing - 0.042" OD, 0.004" Wall Thickness, 1' length	$7.93
		SHIPPING	$6.32
1/20/2017	MSC	PTFE Tubing - 3/64" ID, 0.071" OD	$8.50
		SHIPPING	$11.60
1/26/2017	Components Supply Co.	Stainless Steel Tubing -.071" ID, .082" OD	$10.44
1/26/2017	Components Supply Co.	Stainless Steel Tubing - .066" ID, .082" OD	$9.56
1/26/2017	Components Supply Co.	PTFE Tubing - 2.3mm ID, 2.5mm OD	$29.42
		SHIPPING	$52.10
1/30/2017	A.C. Moore Arts & Crafts	Plaster of Paris (8lb); Air dry clay (10lb)	$16.18
3/26/2017	Apollo Medical	Double lumen tubing	$166.00
3/30/2017	McMaster-Carr	Wire for double lumen	$36.99
4/5/2017	McMaster- Carr	Parts for 3rd Gen UI	$39.00
Expenses to date			**~$480**

Appendix 6: Business Plan

CONFIDENTIAL

Proteus Medical

Providing veterinarians with renewed confidence in endoscopic retrieval

Business Plan

Prepared May 2017

Contact Information
Chandler Woo
chandler.w.woo@gmail.com

Table of Contents

Executive Summary

Opportunity

Problem

Every canine deserves to receive the safest treatment when they ingest a foreign body. Doctors of Veterinary Medicine (DVMs) rely on either endoscopic retrieval or surgery as their two methods of retrieving these foreign bodies from the gastrointestinal tracts of these canines. However, current devices on the market to retrieve larger foreign bodies through endoscopic means (e.g. rocks, fruit pits) are flimsy and often deform after a single-use, making the procedure both challenging and costly. Though endoscopic retrieval is a minimally-invasive and often the preferred method to remove foreign objects, the retrieval devices used in these procedures dissuade veterinarians from using them effectively or regularly.

Solution

Our company restores the advantages of utilizing endoscopic retrieval methods for veterinarians over the more invasive and expensive surgical alternative. We utilized direct input from top DVMs around the country to develop a product that they are comfortable to use, optimized for a higher rate of foreign body retrieval success, and minimizes procedure time. This is implemented using novel technology through a two-part system that allows for easy replacement of parts while simultaneously driving down yearly expenditures for the veterinarian.

Market

Our target end-users are DVMs who use endoscopic retrieval devices to remove foreign bodies from canines. Per the American Veterinary Medical Association (AVMA), there are currently 107,995 registered veterinarians in the United States, growing at an annual rate of 2.5% per year. Approximately 20% of this population performs endoscopy, as it is generally limited to referral institutions due to the costs of the endoscopes. Though DVMs are the direct end-users of this product, pet owners and pet insurance companies are responsible for the payments to the veterinarian. This creates a priority of effective endoscopic retrieval over surgical options, which are typically 50% more expensive than endoscopy.

Competition

Compared to larger endoscopic companies that invest their resources toward improving the endoscopes specifically for human use, our company uses direct DVM input to develop retrieval devices that are optimized for a veterinary space. Our solutions, implemented by experienced engineers and technicians, are cheaper and more functional than current devices on the market, making them the convenient and budget-friendly devices that our customers will search for when performing endoscopic retrieval procedures.

Why Us?

We are a team of socially-minded and highly-driven engineers who believe that veterinary endoscopy should not be limited by the devices which veterinarians currently have available for use. By improving the mechanisms whereby DVMs can retrieve foreign bodies more confidently, canines are not subject to extended and painful post-operative recovery common with invasive surgery. Pet owners can feel relieved that their pets are healthy and pain-free without paying a possibly insurmountable veterinary bill for the procedure. We are confident that our members' creative problem-solving skills, design and machining expertise, business know-how, and passion for animal safety make our company the solution that vets have been looking for.

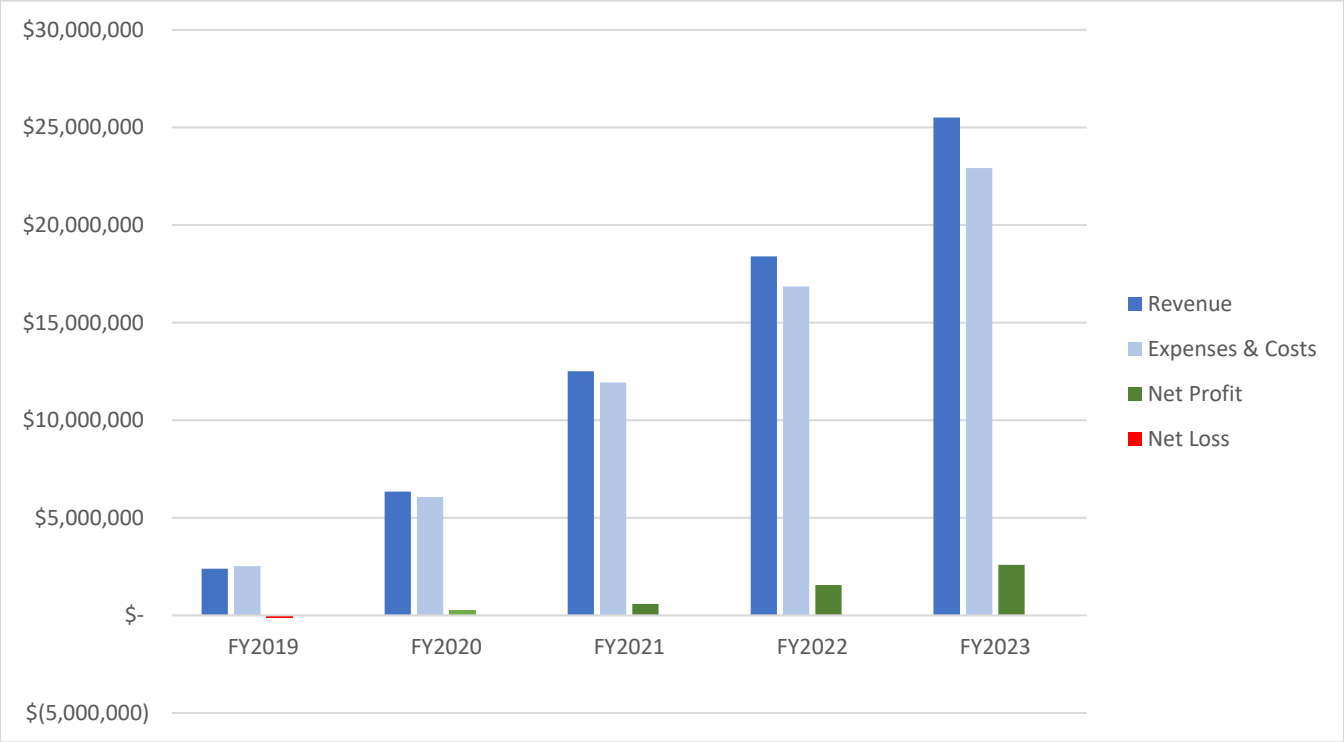
Expectations

Forecast

All Proteus founders will be taking one year starting June 2017 to pursue various device design Masters programs with an emphasis on product development. Two provisional patents have been submitted to protect our key IP for control methodology of the device for that year, where we will then implement a six-month research and development phase prior to manufacturing of our product in FY19. We will be working on our product development and customer base on the side during our graduate studies.

We expect to make ~$2,400,000 in revenue within FY19. We expect an increase in revenue over the following four years, expecting to make ~$6,300,000 and ~$12,500,000 for FY20 and FY21, respectively. The revenue projections include the three top areas in the US for pet spending (Atlanta, Seattle, and Miami[1]) in year one, then expanding beyond these cities in years two and three. We anticipate making a profit within the second year.

Financial Highlights



Financing Needed

To begin production, we require an initial investment of $100,000. Initially, we plan to self-fund our startup venture through a $25,000 contribution from each of the founders, as well as the remaining $25,000 through strategic partnerships. After our six-month final development phase is complete, we will seek additional seed funding from Angels and Family & Friends.

[1] These 20 cities spend the most on pets http://time.com/80980/these-20-cities-spend-the-most-on-pets/

Opportunity

Problem & Solution

A Problem Worth Solving

Household canines, specifically those between 40 and 60 lbs., are at a high risk of ingesting foreign bodies. This simple pathology threatens their health due to gastrointestinal tract obstruction. The majority of DVMs currently remove these larger objects endoscopically with a set of minimally-invasive retrieval tools that are neither robust enough to be reusable, nor do they have effective guidance control. This results in increased frustration for the veterinarian as it prolongs the procedural time to retrieve the object. Additionally, once these devices deform, veterinarians must dispose of them and purchase new devices, resulting in wasted material and unnecessary sunk costs.

Our Solution

Our device imparts novel technology to endoscopic retrieval through the addition of hand-controlled translation and rotation of the device retrieval head. Our overall goal to reduce the foreign body retrieval time for veterinarians is supplemented by a competitive price point that saves over 50% in yearly expenditures and minimizes wasted material. We achieve this through a robust two-part system, which includes an advanced control system (device handle) and a replaceable retrieval tubing set.

Target Market

Our primary customers are veterinarians who utilize endoscopy to retrieve foreign bodies from their patients. We anticipate our largest market segment to be DVMs in their referral institutions (e.g. veterinary hospitals) in major cities around the country, especially those cities that are statistically deemed pet-friendly cities. This is determined by data sets ranging from “minimum pet-care provider rate per visit” to “number of pet businesses per capita” where we expect to see a high population of pets and DVMs. Our target DVMs are expected to use our services regularly throughout the year. For the sustainability of our company, we envision developing our product line to include several retrieval head options as well as other devices required in the veterinary space that can be sold online or through retailers.

According to the American Veterinary Medical Association (AVMA), our research reveals that of the 107,995 registered veterinarians in the United States, only 20% of them perform endoscopy, mainly due to the costs of the endoscopes. This equates to approximately 21,600 DVMs with endoscopic training. With the number of veterinarians increasing at an annual rate of 2.5% per year, there is a growing need for more effective retrieval devices. In addition, with over 78 million canines in the United States, veterinarians need to be prepared for a continued foreign body ingestion risk. These numbers are for the U.S. only, and vary between cities.

Competition

Current Alternatives

Our strongest competitors in this field are Karl Storz Endoscopy and Endoscopic Surgical Solutions (ESS), endoscope manufacturers that develop retrieval devices that are used by DVMs. Both sell a variety of products that address the different geometries of foreign bodies. Karl Storz is based in Germany, making quick delivery of devices a concern for veterinarians. ESS provides an effective online service that markets devices from other vendors but often at an increased price, which may dissuade veterinarians from their products. Even so, these marketed devices additionally suffer from the same problem: both are packaged as a single device that must be entirely disposed after deformation of the retrieval head, often referred to as "single-use" devices. In this manner, our product has the distinct advantage.

A second form of competition is a surgical option for removal of foreign bodies. This often is prioritized over endoscopic retrieval when the foreign body cannot be physically removed endoscopically (e.g. object in small intestine), or when the veterinarian has failed to retrieve it endoscopically, whether through access difficulty or where the canine has spent extended periods of time under anesthesia (e.g. procedures over 1.5 hours). Though approximately 50% more expensive than endoscopic retrieval, surgery is an assured method of retrieval that may persuade DVMs to choose this option, especially when they do not have confidence in the endoscopic tools.

Competitive Advantage

Proteus Medical adds unique technology in the form of an advance control system that allows precise control of the retrieval head through independent rotation and translation. In addition, while many competitive devices come as a single piece, our device incorporates a user-separable tubing set, allowing for efficient replacement of the retrieval head when it inevitably deforms under high tensile environments. An advantage to our device is that it does not alter the current standard cleaning process for endoscopic devices, as our device can undergo enzymatic detergent and ultrasonic reprocessing to sterilize it completely. Due to a limited number of suppliers and no formal regulations for veterinary endoscopic retrieval devices, our product will not have regulatory barriers to entry in the veterinary field. This allows for immediate testing and production of our product.

Execution

Manufacturing

Proteus Medical adopts Lean Manufacturing and Theory of Constraints methodologies to eliminate the "bottlenecks" or constraints in standard manufacturing processes. Lean Manufacturing focuses on reducing waste from the manufacturing process to maximize throughput by adopting a Just-in-Time manufacturing method, which eliminates inventory cost such that production of products never exceeds sales at any given time. Theory of Constraints focuses on identifying and removing constraints that limit throughput with the use of strategic partners to eliminate costly manufacturing steps. This in effect allows us to increase manufacturing capacity by sourcing specific manufacturing needs to partners that can address our need at a nominal cost due to their pre-built infrastructure. Proteus Medical has established connections with Fort Wayne Metals and K-S-Plastics to source professional manufacturing processes at comparatively reduced costs in this manner.

Marketing & Sales

Marketing Plan

Sales channels:

1. Services sold directly to customers (e.g. DVMs)
2. Sales through endoscopic retrieval device suppliers

Advertising:

1. Direct contact with loyal customer base
2. American Veterinary Medical Association (AVMA) Conventions and Leadership Conferences
3. Veterinary website and magazine ads

Pricing:

We split our pricing on our device based on a first time buy-in and successive purchases thereafter. Based on a 'Razor and Blades' model approach, our cost of goods and average sales price is detailed below:

1. First time buy-in: We estimate that for the initial buy-in for our product, which includes both our advanced user interface and a replaceable tubing set, would cost Proteus $186.54 in materials, labor, and overhead. This is totaled from the fixed costs of the molds amortized over 5 years ($1.99), materials and distribution ($33.65), work space ($46.02), and burdened labor ($104.89). For a 50% gross margin, we would charge a base cost $279.82 for the product. This one-time buy-in cost would provide a user interface and a single tubing set as well as dedicated customer service from our end.
2. Follow up: We estimate that for any replacement tubing set following the initial buy-in, the cost of materials would be $12 per set. This is totaled from materials ($8.25 for injection molded screw cap, catheter tubing, nitinol cable, hypodermic tubing) and manufacturing ($1.50 for assembly line worker paid $15/hour), and overhead ($2.25). For a 42% gross margin, we would charge $17 per replacement tubing set.

Sales Plan

We will initially sell directly to the customer, who pays up front. We will accept cash, credit, debit, and electronic payments. We eventually plan to sell through distributors once we have a larger penetration rate in the veterinary endoscopic retrieval device field.

Sales activities:

1. Networking with local DVMs
2. Establishing network effects with endoscopy distributors
3. Soliciting via phone calls, door-to-door visits, and emails
4. Discount rewards (on future endeavors) for people who make referrals

Operations

Locations & Facilities

We will be working alongside with FedEx as Proteus' order taking and distribution means to save money and to ensure quick delivery of devices upon order placement.

Year 1: Atlanta Area, Customer Development Site
Year 2: Atlanta Downtown, Distribution Location for Proteus Medical
Year 3: Miami Area, Distribution Location for Proteus Medical
Year 4: Seattle Area, Distribution Location for Proteus Medical
Year 5: Scottsdale AZ, Distribution Location for Proteus Medical

Equipment & Tools

Research & Development:

To develop the devices and their hierarchical assemblies, all 3D models were built in Dassault Systemes' Solidworks. A Stratysys' Objet30 UV sintering printer and a Stratasys' UPrint FDM printer were used to rapidly prototype the plastics designs for end-use product testing. The metal components requiring secondary operations were modified with a 3-axis Bridgeport Mill.

Manufacturing:

All plastics parts are manufactured using soft, single cavity, injection molds for rapid modification as needed. The soft tools are a one-time purchase from the injection molder with maintenance and plastic cost built-in to each end-use part cost. Parts requiring secondary operations are outsourced to strategic partners that will dropship completed subassemblies for final assembly at the Proteus site.

Assembly:

A custom assembly fixture is required to minimize assembler fatigue and maximize throughput. This device is built utilizing off-the-shelf fixturing components and machined parts utilizing a 3-axis Mill. A uniaxial testing device is also required for material and assembly characterization and design validation.

Milestones & Metrics

Milestones Table

Milestone	Due Date
Secure facility space for offices and prototyping stations	July 31, 2018
Finalize device design using DVM input (6-month R&D)	December 31, 2018
Generate molds of design and begin initial manufacturing	January 15, 2019
Complete testing and begin shipping devices to local veterinary hospitals	February 28, 2019
Begin major manufacturing and distribution	March 20, 2019

Key Metrics

Our immediate focus is to establish ourselves in an area with a high number of veterinary hospitals and DVMs. We want to secure dialog with these veterinarians to promote a loyal sales base and gather user input to develop a device that they will be excited to use. It is imperative that our company expand to additional cities each year to reach more customers and increase our penetration rate in the market.

Exit Strategy

The additional six months of product development will be crucial to identify the optimal retrieval process that will allow us to develop IP based off further customer input. The current Proteus designs implement common technologies in a novel manner to retrieve foreign bodies. After further iterations, we plan to license our IP to larger endoscopic companies that have the streamlined infrastructure required for maximum market penetration. This will provide us with the capital to pursue the human market and expand into other product lines.

Company

Overview

Founded as a capstone Senior Design project through the Department of Biomedical Engineering at the University of Rochester, Proteus Medical is assembled of three highly-motivated engineers committed to improving veterinary endoscopic foreign body retrieval procedures. All founders will work at Proteus on the side while attending device design Masters programs around the country starting June 2017, developing the necessary skills to advance our company upon graduation in summer 2018.

Team

Management Team

- Connor McBride – VP of Manufacturing, VP of Clin & Reg
- Edward Ruppel III – President, CEO
- Chandler Woo – Director of R&D, VP of Sales and Financing

Advisors

Our advisors consist of engineering and veterinary professionals, as well as prominent members of the University of Rochester Department of Biomedical Engineering community.

Financial Plan

Forecast

Key Assumptions

We base our financial forecast on a sample projection of a hypothetical customer: a local DVM at a veterinary hospital in Atlanta who performs approximately 150 foreign body retrievals per year. We also anticipate that based on our geographic expansion, our penetration rate will aggressively increase over 5 years, attaining 3%, 8%, 15%, 22%, and 30%, respectively. Here is the anticipated breakdown:

1. Total manufacturing cost: $1974.54 per year per customer*
2. Sales cost of device (50% gross margin for buy-in and 42% for replaceable tubing sets): $2,818.78 per year per customer

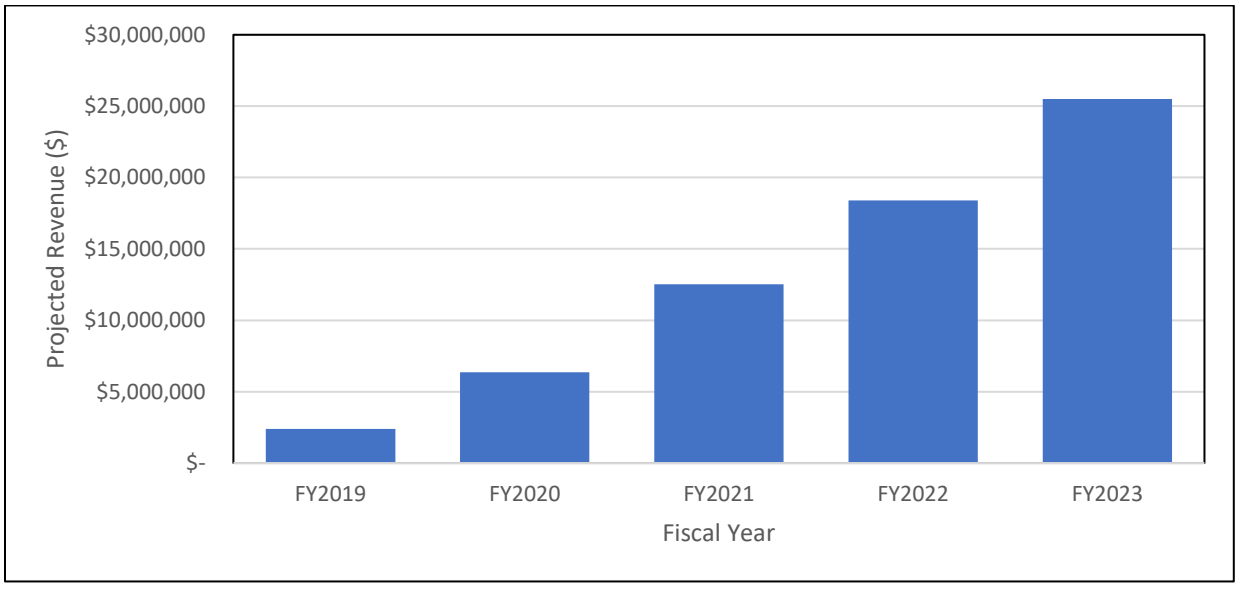
*Cost of Goods per unit (including material and labor):

1. $186.54 for user interface and one tubing set
2. $1,788.00 for tubing sets (149 additional tubing sets per year)

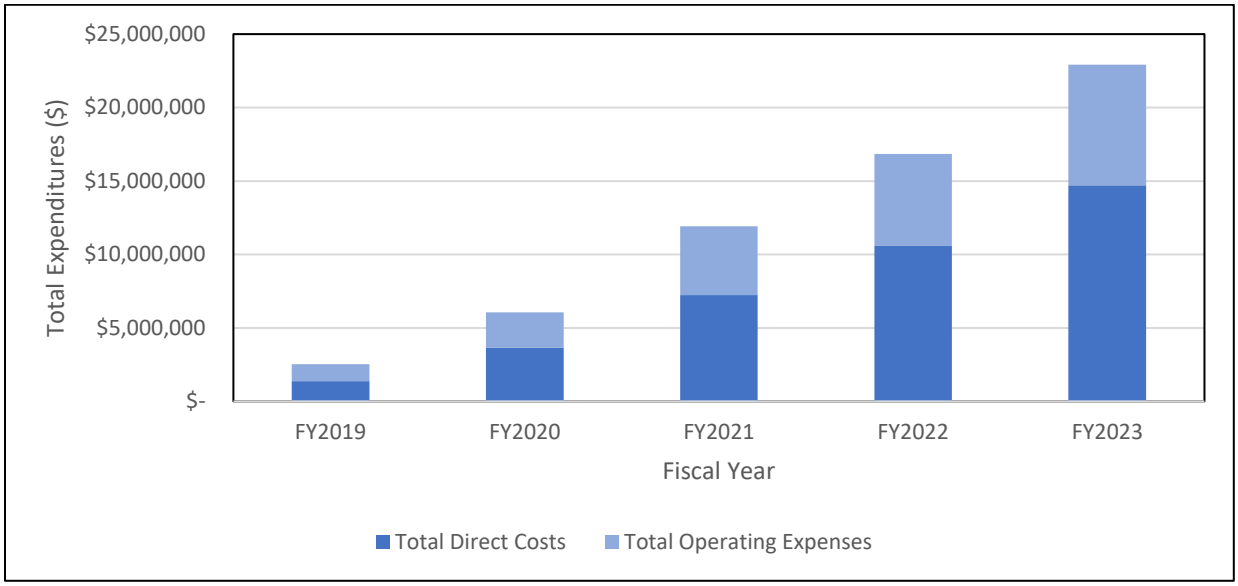
We understand that we will need to adjust our costs based on location and demand for our product. Once we understand the actual market we are working with, we can develop an average cost per device and a gross profit. From there we can refine our projections for revenue and expenses.

Revenue by Year

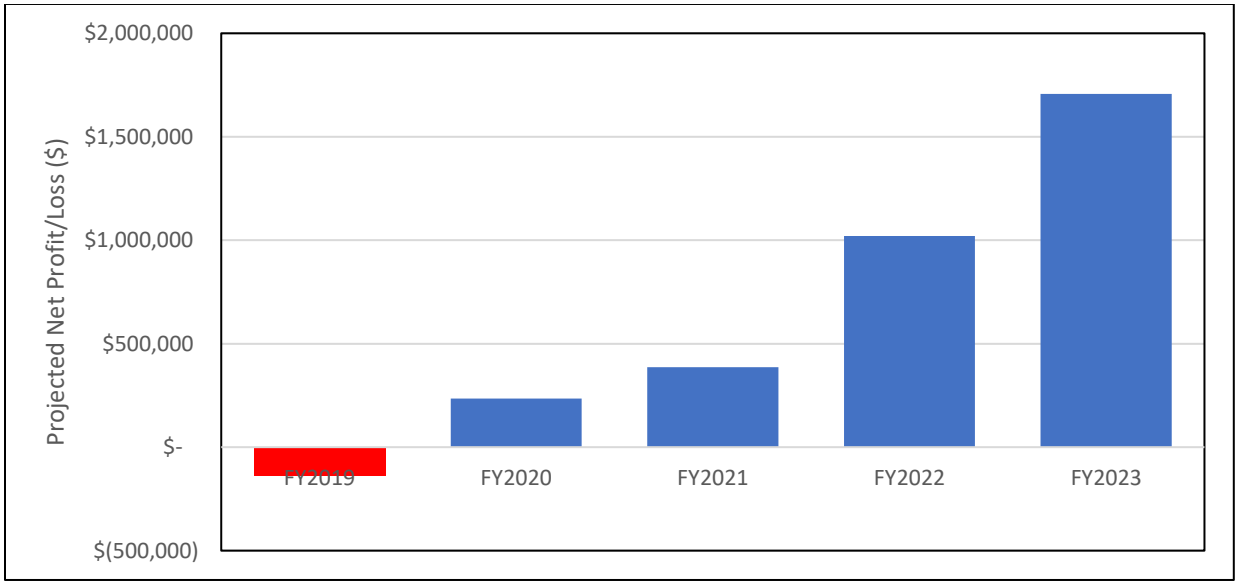
Revenue is projected on the basis that each veterinarian will purchase one (or two as a backup) user interfaces and approximately 149 tubing sets per year for all procedures at single-use. At each fiscal year, new veterinarians will buy into the user interface, but the tubing sets will be manufactured for all veterinarians who utilize our product on a yearly basis.



Expenses by Year



Net Profit (or Loss) by Year



Financing

Use of Funds

Invest in fixed costs:

1. Molds used for injection molding of parts for device (soft tools)
2. Facility/office space
3. Onsite Research & Development Tools
4. Individual seat license of Solidworks 3D CAD software

Source of Funds

1. Founders' investment
2. Angel investors
3. Friends & Family

Financial Projections

Projected Profit & Loss

	FY2019	FY2020	FY2021	FY2022	FY2023
Veterinarians involved in endoscopy	21,599	22,139	22,692	23,260	23,841
Market Penetration	3%	8%	15%	22%	30%
# of Veterinarians Acquired	**648**	**1,771**	**3,404**	**5,117**	**7,152**
New Veterinarians per Year	648	1,123	1,633	1,713	2,035
# of Interface Devices per Veterinarian	1	1	2	2	2
Projected # of Interface Devices Sold per Year	**648**	**1,123**	**3,266**	**3,426**	**4,070**
# of Foreign Body Retrievals per Year per Veterinarian	150	150	150	150	150
Projected # of Tubing Sets Sold per Year	**129,600**	**354,200**	**680,800**	**1,023,400**	**1,430,400**
Sales - Interface devices:					
Number of units	648	1,123	3,266	3,426	4,070
Sales price (B2B)	$ 279.82	$ 279.82	$ 279.82	$ 279.82	$ 279.82
Total Sales - Interface devices	**$ 181,321**	**$ 314,234**	**$ 913,880**	**$ 958,651**	**$ 1,138,853**
Sales - Tubing sets:					
Number of units	129,600	354,200	680,800	1,023,400	1,430,400
Sales price (B2B)	$ 17.04	$ 17.04	$ 17.04	$ 17.04	$ 17.04
Total Sales - Tubing sets	**$ 2,208,384**	**$ 6,035,568**	**$ 11,600,832**	**$ 17,438,736**	**$ 24,374,016**
Total Sales Revenue	**$ 2,389,705**	**$ 6,349,802**	**$ 12,514,712**	**$ 18,397,387**	**$ 25,512,869**
Cost - Interface devices:					
Number of units	648	1,123	3,266	3,426	4,070
Fixed/variable costs per unit	$ 186.54	$ 186.54	$ 186.54	$ 186.54	$ 186.54
Total Costs - Interface devices	**$ 120,881**	**$ 209,489**	**$ 609,254**	**$ 639,101**	**$ 759,235**
Costs - Tubing sets:					
Number of units	129,600	354,200	680,800	1,023,400	1,430,400
Fixed/variable costs per unit	$ 9.75	$ 9.75	$ 9.75	$ 9.75	$ 9.75
Total Costs - Tubing sets	**$ 1,263,600**	**$ 3,453,450**	**$ 6,637,800**	**$ 9,978,150**	**$ 13,946,400**
Total Direct Costs	**$ 1,384,481**	**$ 3,662,939**	**$ 7,247,054**	**$ 10,617,251**	**$ 14,705,635**
Gross Margin	**$ 1,005,224**	**$ 2,686,863**	**$ 5,267,659**	**$ 7,780,136**	**$ 10,807,234**
Gross Margin %	**42%**	**42%**	**42%**	**42%**	**42%**
Operating Expenses					
Salary	$ 135,936	$ 543,744	$ 1,359,360	$ 1,699,200	$ 2,039,040
Employee Related Expenses	$ 33,984	$ 135,936	$ 339,840	$ 424,800	$ 509,760
Product Liability Insurance (increase with growth rate)	$ 125,000	$ 333,333	$ 625,000	$ 916,667	$ 1,250,000
Office Supplies	$ 20,000	$ 54,660	$ 105,062	$ 157,932	$ 220,741
Postage	$ 66,420	$ 179,908	$ 348,565	$ 520,265	$ 725,375
Workstations	$ 15,000	$ 22,500	$ 33,750	$ 50,625	$ 75,938
Software	$ 25,000	$ 37,500	$ 56,250	$ 84,375	$ 126,563
Incidental Costs	$ 100,000	$ 120,000	$ 144,000	$ 172,800	$ 207,360
Legal	$ 250,000	$ 300,000	$ 360,000	$ 432,000	$ 518,400
Security	$ 13,200	$ 15,840	$ 22,968	$ 27,562	$ 33,074
Rent	$ 72,000	$ 79,200	$ 158,400	$ 237,600	$ 475,200
Utilities	$ 21,600	$ 23,760	$ 47,520	$ 71,280	$ 142,560
Total Operating Expenses before Interests	**$ 878,140**	**$ 1,846,381**	**$ 3,600,715**	**$ 4,795,105**	**$ 6,324,010**
Interest Incurred	263,442	553,914	1,080,214	1,438,532	1,897,203
Total Operating Expenses with Interests	**$ 1,141,582**	**$ 2,400,296**	**$ 4,680,929**	**$ 6,233,637**	**$ 8,221,213**
Net Profit	**$ (136,358)**	**$ 286,567**	**$ 586,730**	**$ 1,546,499**	**$ 2,586,021**
Net Profit / Sales	**-6%**	**5%**	**5%**	**8%**	**10%**
Income Taxes (blended rate of 34%)	$ -	$ 51,071	$ 199,488	$ 525,810	$ 879,247
Net Income (After Tax)	**$ (136,358)**	**$ 235,496**	**$ 387,242**	**$ 1,020,690**	**$ 1,706,774**
	$ 2,526,063	$ 6,063,235	$ 11,927,983	$ 16,850,888	$ 22,926,848