

# Veterinary Endoscopy



Connor McBride, Edward Ruppel, Chandler Woo

*Supervisor:* Dr. Diane Dalecki, University of Rochester

*Customer:* Dr. Erika de Papp, Angell Animal Medical Center in Boston

December 21, 2016



## Executive Summary

Canines and other household pets are at an increased risk of ingesting foreign objects that threaten their health due to obstruction of the gastrointestinal tract [de Papp, 2016]. If the object is retrievable without conducting invasive methods such as surgery, Doctors of Veterinary Medicine (DVM) will remove these objects endoscopically with a range of surgical tools that are neither robust, reusable, nor do they have effective guidance control. This consequently affects the efficacy of the retrieval process, as veterinarians will become fatigued and frustrated due to prolonged procedures and will ultimately resort to surgical options if they are unable to retrieve the foreign body. Additionally, current devices are designed to cater to specific properties of a singular foreign body, but with pets being able to consume a variety of objects, the amount of devices on the market today has become superfluous. To that end, we aim to develop a universal device that provides the practitioner with full control of the retrieval head to expedite the removal process and to provide a platform for effective gripping of various sizes of materials.

There are currently 70 million domestic canines in the United States, and with an average veterinary visit rate of 1.6 times per year, the endoscopic foreign body retrieval process is ever present as the fourth most common veterinary emergency [ASPCA, 2016; AVMA, 2016]. A study has shown that out of 200 cases, only 2 dogs were able to successfully pass their foreign body without intervention, demonstrating the need for foreign body retrieval [Park, 2015]. This leaves the vast majority of canines in danger of a gastrointestinal perforation that can create a plethora of issues due to the contaminated contents entering the abdominal cavity.

In order to address this problem, Proteus Medical has developed a team of talented individuals, together forming more than 60 years of experience. Connor McBride brings extensive laboratory animal model experience that directly translates to the clinical canine space. Edward Ruppel brings extensive R&D and manufacturing experience to develop the product design efficiently and effectively. Lastly, Chandler Woo brings laboratory and anatomy experience to provide physiological grounding for the device design.

In terms of researching the issues inherent in the device space, we focused on isolating the competitors in the marketplace and their respective specifications and capabilities. In order to properly modify upon existing devices, we aim to fully understand the endoscopic process from pre- to postoperative care. Through this, the Proteus team broke down the research into several components to provide a comprehensive background of the problem. This research provided the key considerations for designing the next-generation retrieval device and the isolation of the four necessary device sub-systems: the retrieval head, the tubing set, the in/out mechanism, and the head steering mechanism. The Proteus team utilized these key considerations to brainstorm multiple solutions for the retrieval device. To iteratively prototype towards the creation of a finalized device design, a physiologically relevant canine gastrointestinal model will be built. This will serve as both a R&D prototyping tool and as an endoscopic training device for veterinarians in training.

Proteus Medical thus aims to implement a three phase deliverable schedule; the first phase involves the creation of the initial prototype platform and the physiologically relevant animal model, the second phase consists of the iterative prototyping process, the third phase consisting of the final design for manufacture prototype formulation. Proteus looks forward to improving the endoscopic retrieval device space with the creation of a device suite for our client, Dr. de Papp.

## Table of Contents

<b>INTRODUCTION AND BACKGROUND</b>	<b>4</b>
<b>PROBLEM STATEMENT</b>	<b>5</b>
<b>DESCRIPTION OF CUSTOMERS, STAKEHOLDERS</b>	<b>5</b>
<b>LIST OF CUSTOMER NEEDS / WANTS AND METRICS</b>	<b>6</b>
<b>CLINICAL (OR OTHER) USE SCENARIO</b>	<b>8</b>
<b>SYSTEMS OVERVIEW</b>	<b>10</b>
<b>DESIGN ALTERNATIVES</b>	<b>11</b>
<b>STRATEGY FOR DESIGN SELECTION</b>	<b>15</b>
<b>PROJECT MANAGEMENT</b>	<b>16</b>
Deliverables	17
Schedule	19
Weekly Schedule / Team Organization	20
Design Team	21
Budget	22
<b>CONCLUSION</b>	<b>24</b>
<b>ACKNOWLEDGEMENTS</b>	<b>24</b>
<b>REFERENCES</b>	<b>25</b>
<b>LIST OF APPENDICES</b>	<b>26</b>
<i>Appendix 1:</i> Resumes	27
<i>Appendix 2:</i> House of Quality	30
<i>Appendix 3:</i> Brainstorming Images	31
<i>Appendix 4:</i> Abridged Annotated Research	33
<i>Appendix 5:</i> Systems Diagram	35
<i>Appendix 6:</i> Quantitative Assessment of Device Brainstorming	36

## Introduction and Background.

A substantial concern often encountered as a pet owner is when the pet ingests foreign objects that should not be consumed. In many cases, immediate veterinary care must be taken to retrieve the foreign object before it causes gastrointestinal distress, which could harm or potentially even kill the animal. The most common offenders that require veterinary care to remove foreign bodies are dogs that range between 20-60 lbs., though other domesticated animals such as cats must also be considered [AVCS, 2016]. More often than not, these canines eat objects ranging from coins, fruit pits, to balls of various sizes. Several methods for retrieving these objects are readily available today, but endoscopic foreign body retrieval devices present a minimally-invasive surgical option with the potential for vast improvement in the veterinary clinical setting [ASGE, 2016]. The tools that are currently on the market are neither robust enough to be reusable nor are they suitable for a wide range of objects. To that end, this proposal will present a solution to retrieving various sized foreign bodies whilst maintaining an extended service lifetime to minimize costs.

Currently there are numerous retrieval devices on the market such as the net, the single loop snare, a multi-wire cage and forceps (Bounds, 2006). While there are various iterations based on these designs, most of retrieval devices stem from one of these main four categories. Each device is particularly effective in grasping a single foreign body type, ranging from blunt objects, sharp objects, to food boluses. This is problematic since the devices are designed to cater to a single foreign body rather than generating a universal device to encapsulate as many foreign bodies as possible. The snare can only capture a single object at a time, and its structure typically deforms after a single use. One of the key concerns with many current endoscopic devices is its robustness, and designing a product that will have a lifespan of a year will significantly reduce costs and streamline the retrieval process. The multi-wire enclosure is able to capture many objects at a time, but its individual wires that compose the basket are extremely flimsy and subject to significant deformation. Forceps present a very durable device head option, but due to the size and orientation, they are limited in their retrieval of foreign body types and cannot grasp objects greater than the size of a fruit pit (Bounds, 2006). Finally, the net creates a good environment for retrieval of small foreign objects, as it fully surrounds the object before passing it back through the esophageal sphincter. While the mechanism is good, they are limited by their size, and often are difficult to clean after a single use. At Proteus Medical, we have seen how each of these devices presents some issue for the veterinarian during the retrieval process, and we aim to focus on designing a universal device that will make it easier for the veterinarian to use. Not only will we focus on extending the lifetime of the device, we will also generate concepts to expedite the entire retrieval process, as we will describe in more detail below. By creating a universal device, veterinarians will only have to rely on a single device for foreign body extraction, ultimately saving time and money in the long run.

## Problem Statement

Household canines between 40 and 60 lbs. are at an increased risk of ingesting foreign objects that threaten their health due to obstruction of the gastrointestinal tract (de Papp, 2016). Doctors of Veterinary Medicine (DVM) currently remove these objects endoscopically with a range of surgical tools that are neither robust enough to be reusable, nor do they have effective guidance control. We aim to develop a universal device that provides the practitioner with full control of the retrieval head to expedite the removal process and to provide a platform for effective gripping of various sized objects.

## Description of Customers, Stakeholders

The intended customer for this device will be the veterinarians who will be using the endoscopic device to retrieve foreign bodies. More specifically, the customer who presented this problem for our team is Dr. Erika de Papp and her clinic at Angell Animal Medical Center in Boston. Equally important customers that must be considered, for ethical purposes, are the pets, more specifically canines ranging from 20-60 lbs. in size, those that will undergo the procedure to remove the various objects lodged in the esophagus or the stomach. Though several other animals such as cats are capable of ingesting foreign bodies, we will be focusing our research towards canines to address a specific population. Currently there are roughly 70 million dogs that could be a risk of ingesting a foreign body (FiveThirtyEight, 2014). The pet owners who are responsible for the well-being of their pet are also considerable stakeholders to consider since they fund the minimally-invasive surgery which uses these device. Ultimately, the animal and the veterinarians will be the primary customers since the needs and wants of this device will be heavily tailored towards them. Besides the two primary customers, secondary stakeholders could be hospitals and doctors if our product becomes commercially available for human use. Finally, insurance companies are stakeholders since this endoscopic retrieval procedure is covered under animal health insurance for those that have it.

## List of Customer Needs / Wants and Metrics

Our customer needs and wants were tailored from our conversations with Dr. Erika de Papp. During these meetings, Dr. de Papp identified the issues with the current devices she uses during endoscopic retrieval and what she believes would be beneficial in a future design. Below in Table 1 and 2, we have devised a customized list of customer needs and wants, ranked in order of importance, in terms of those that we believe need to be achieved for an improved retrieval device design. Along with the needs and wants, we also posted a set of relevant metrics that we aim to work with in order to give us a quantitative measure of how to achieve each need or want.

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

<b>Needs</b>		<b>Metrics</b>	
<b>Name</b>	<b>Description</b>	<b>Name</b>	<b>Units</b>
Robustness	Resistant to degradation from stomach acid and be reusable	Lifetime of Device (de Papp, 2016)	~ 1 year
Device Head Translation	Ability for device to rotate before retrieval to orient the device alongside the foreign body for easier extraction	Control head of device to position that increases likelihood of success (de Papp, 2016)	(0-90 deg.) from central axis in 360 deg.
Flexibility & Maneuverability	Easily adjustable while moving through GI tract to avoid injuring the surrounding lumen	Ability to move around a radius of curvature for the minimum size stomach operated on in study (Roth net, n.d.)	$R < 0.75''$
Retrieve Various Sized Objects	Foreign objects range from wedding rings to tennis balls, and the device needs to be universal to retrieve all objects	Foreign body size ranges (minimum based off what is easily passable through system) (Today's Veterinary Practice, n.d.)	0.1" - 2.7" OD
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)	Retrieve objects with variant friction properties (most objects covered in stomach fluids and food particulates) (ESGE, n.d.)	$0 < \mu < 1$

Sterilizable	Easily cleanable after retrieval for multiple uses	Device must sterilizable under current FDA standards, bacterial log reduction (ASGE, n.d.)	>6 log reduction
Fits in Insufflation Port	Device needs to fit in standard endoscope setup	The device must be able to fit into the current surgical port (IVIS, 2005)	<0.1" OD

**Table 2:** Determined customer wants and respective metrics for endoscopic foreign body retrieval devices

<b>Wants</b>		<b>Metrics</b>	
<b>Name</b>	<b>Description</b>	<b>Name</b>	<b>Units</b>
Ergonomic User Interface	A simple, yet effective design to allow user to easily control device with one hand without strain	User fatigue time (de Papp, 2016)	>30 min
Clear Visibility	Allows for clear view with endoscope during retrieval to see if device actually retrieved object	Endoscopic view field range covered by device, range acquired from customer (Olympus, n.d.)	<30%
Multiple Object Retrieval	Shortened procedure time for veterinarian if all objects can be retrieved at once	Ability to remove multiple objects at once (Medscape, n.d.)	n > 1
Dimensionally Stable Shape	Shape of retrieval device will not deform when ejected for prolonged lifetime and usability	Dimensional stability of the retrieval mechanism members (FDA, n.d.)	+/- 0.05"
Affordable	Cost efficient for number of uses	Cost Comparison/lifetime (Rhode Island Hospital, n.d.)	\$/year
Sizable Length for all Animals	Long enough to reach stomach of various-sized animal while remaining cost efficient	Length must be comparable to what's on the market (Medical Expo, n.d.)	~80"

In order to further elucidate whether our metrics can be fully achieved under the given conditions, a House of Quality was devised, as seen in Appendix B. It compares a Proteus proposed device to two industry leaders, Olympus and US Endoscopy.



## Clinical Use Scenario

When an animal is suspected of consuming a foreign body, they are first brought into the veterinary clinic for examination. An x-ray is performed on the animal to locate the foreign body, which allows the veterinarian to determine whether surgery or endoscopic retrieval is the best course of action [Sugawa, 2014]. Generally, if the foreign body has not yet passed into the small intestine, endoscopic retrieval is the preferred, less-invasive method of retrieval. During the procedure, the patient species is anesthetized, and their stomach is insufflated with carbon dioxide to expand the region. The endoscope is then inserted to locate the foreign body, and then the retrieval device is fitted through the biopsy port of the endoscope to retrieve the object.

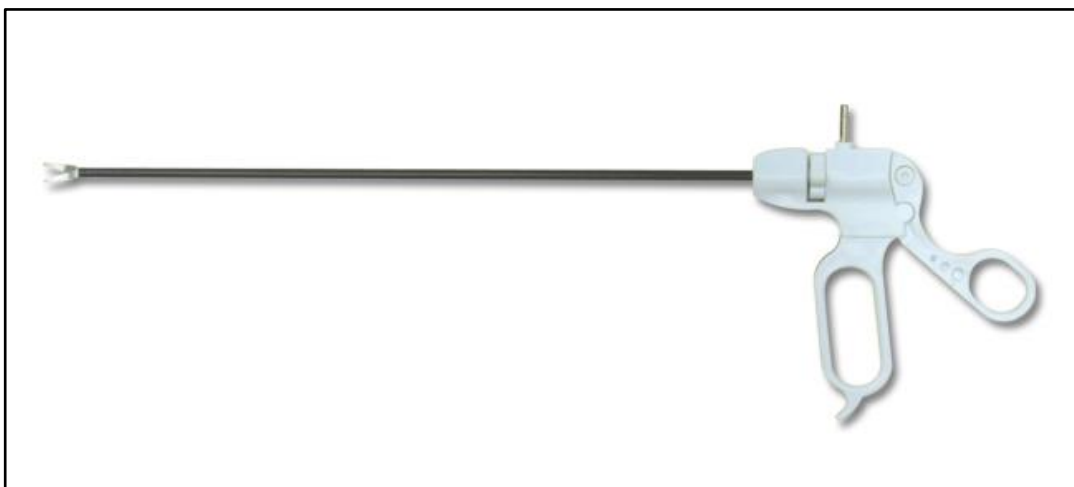
Typically this procedure can last between 3 minutes and 1.5 hours, or as long as the veterinarian is able to [de Papp, 2016]. With procedures lasting on the longer end of the spectrum, it is expected that fatigue and frustration would begin to set in for the veterinarian, especially if the object is not successfully passing through the esophageal sphincter. A common complaint with the interface of the device is the inability to maneuver the object to an orientation that makes it easy to extract. For example, a bone shard needs to be oriented vertically to avoid damaging the lining of the esophagus. Nearly all interfaces on current endoscopic retrieval devices only have an in/out mechanism for the device head, but they do not have any head steering mechanism. Controlling the head orientation will vastly improve the speed of foreign body retrieval, but due to its cost, it is not a viable option for current devices that are meant to be disposable.

The main concern with retrieving foreign bodies is the size of the foreign body itself [de Papp, 2016]. Ranging from coins to fruit pits to tennis balls, current endoscopic devices utilize a variety of different models to retrieve these types of objects, such as nets, clamps, or loops. Though there is nothing particularly wrong with using different device head types, it is challenging to pick the correct device to appropriately extract the foreign body. In that regard, by simplifying the device to create a universal option to retrieve many types of objects ranging in size and geometry, the procedure will be much easier to conduct and much easier to replace once the device lifespan has been reached.

Reusability and deformation of the device head have been identified as a few of the major flaws with current endoscopic foreign body retrieval within veterinary use [de Papp, 2016]. In several cases, the device must be discarded after a single use since it either degrades from the acidic environment of the stomach or the original device head shape is altered by the shape of the foreign body. While there are measures taken to reuse the retrieval device, such as enzymatic cleaners and ultrasonic reprocessors, these devices become less effective over time and will only be viable for a few more uses. Ultimately this is problematic since the average price of a new foreign body retrieval device costs around \$40, making endoscopic retrieval an unnecessarily expensive procedure [Medical Expo, n.d.]. One of the reasons for this price point is that purchasing a new device includes the entire device setup: the retrieval head, tubing set, and user interface, as seen in

Figure 1. As far as we have identified, the retrieval head is usually the only component of the device that needs to be replaced after repeated use, making the user interface a sunk cost when disposed.

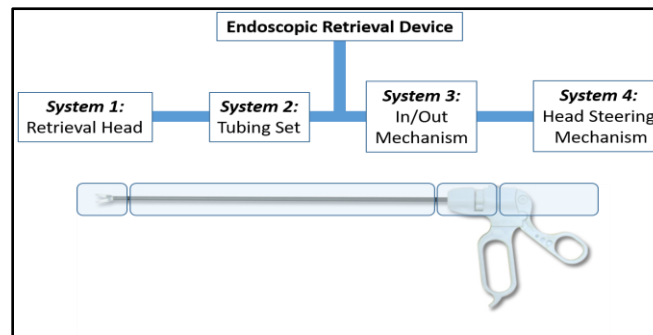
To that end, Proteus Medical believes that a modified design solution is necessary to improve the interface steering and device head as well as reduce the costs of the device over a long-term period. We believe that by first improving the interface steering, it will allow the veterinarian performing the operation to effectively retrieve foreign bodies without fatiguing as quickly. By creating a more universal device head, production costs can be cut down and retrieval will become more efficient since the veterinarian will only need to operate a singular model rather than catering device heads to the type of foreign body. Additionally, training new doctors to conduct the foreign body retrieval operation will become more streamlined due to less components to work with. Lastly, by dividing the user interface from the tubing and device head, a more robust and mechanized interface device can be created for long-term use. More importantly, by only having to replace the tubing and device head, costs of the device will be substantially reduced, especially if the device degrades or deforms due to the nature of the gastrointestinal environment. In essence, we strongly believe that by focusing on a long-term solution, endoscopic foreign body retrieval will become more effective while driving the price of operations down.



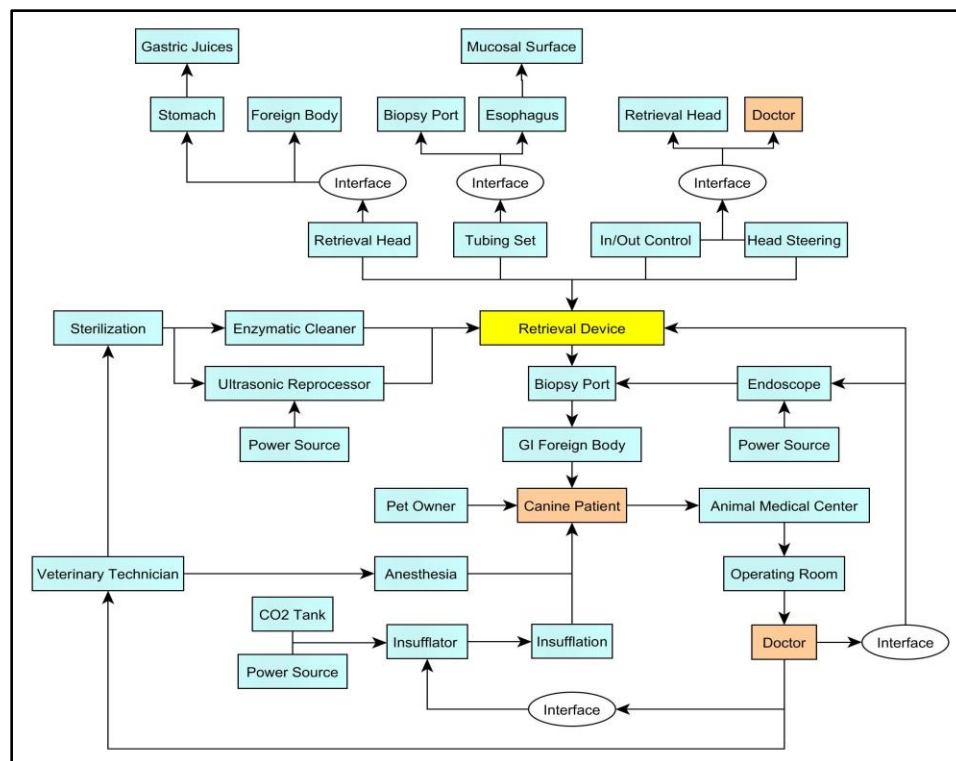
**Figure 1:** An example of an endoscopic foreign body retrieval device used in clinical settings [Olympus, 2016]

## Systems Overview

As we can see in Figure 2, the endoscopic retrieval system has been split up into four subsystems; the retrieval head, the tubing set, the in/out mechanism, and the head steering mechanism. The first system, the retrieval head, is the primary focus as per the needs requirements of the customer. The fourth system being the novel technology implementation being solely developed by the Proteus team.



**Figure 2:** Block diagram consisting of four major components associated with the retrieval device, a current Olympus device on the market is utilized to visualize subsystems locations [Olympus, 2016]



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

The systems diagram shown in Figure 3, is an exhaustive outline of all of the components of the endoscopic retrieval procedure that affect the retrieval device and its ability to retrieve the foreign body successfully.

## Design Alternatives

In terms of research, we focused on isolating the competitors in the marketplace to see what is out there and their respective specifications/capabilities. In order to properly design the device we need to fully understand the endoscopic process from pre to postoperative care. To research the issues, endoscopic process, and competing devices, our group is utilizing a plethora of sources. To obtain current guidance, sterilization processes, and lists of endoscopic retrieval devices, we used the expansive FDA website. In order to understand the capabilities and specifications of current devices we cross-referenced the companies approved by the FDA with Google Scholar, WIPO database, and multiple other relevant patent search databases to find each company's product details. In order to gauge the veterinary space, we have met multiple times with our customer to ask questions and gain necessary design details. Our customer has graciously put our team into contact with two local Veterinarians who have allowed us access to both emergency retrieval procedures as well as access to the endoscopic devices that they use in their practice. To provide us sources on other surgical practice, we have used Voyager to find endoscopy texts and scientific literature databases to find statistically significant data.

We have broken down our research into several components to provide a comprehensive background of the problem. More specifically, each member has been responsible for compiling and relaying information to the team about the following categories: R&D, clinical, and regulatory. R&D is responsible for understanding the current technology of the device space and formulating an optimal design direction. Clinical will focus on the processes of device implementation and isolating the data driving the device design. Lastly, regulatory will document all processes involved with bringing this product successfully into the market, using FDA databases and relevant patent searches.

From our research, our team found a plethora of devices that cover all aspects of the device space. However, in order to categorize the devices into the veterinary space, we have divided them based on the common foreign bodies; the resulting categories are shown in Table 3. Examples of the research can be found in the annotated bibliography shown in Appendix 4.

**Table 3:** Categories of device types isolated from research

<b><i>Object Type</i></b>	<b><i>Appropriate Retrieval Devices</i></b>
<i>Blunt Objects</i>	Grasping forceps, basket, snare, retrieval net
<i>Sharp-pointed Objects</i>	Grasping forceps, basket, retrieval net, snare, latex rubber hood
<i>Long Objects</i>	Basket, snare
<i>Food Bolus</i>	Grasping forceps, snare, basket, retrieval net

In order to provide various designs for the team to work around and to further isolate what the physical device needs to be, a multi-stage brainstorming session was held. The issues that we hope to address with our device design have been isolated from talks with our client and from exhaustive literature meta-reviews; as shown in the R&D section of Appendix 4.

The initial brainstorming session consisted of multiple 5-minute ideation sessions that were built around the HMW (How Might We?) framework. During each of the ideation sessions, each team member was given a stack of post-its to both write and draw the idea that they had. Once each idea was generated the team member would place it on the HMW wall matrix while explaining the idea and how it works. There are only questions allowed for clarification of the idea; as is the case with all brainstorming, there is no judgement until the HMW exercise is completed. The visual results of the brainstorming is shown in Appendix 2.

**Table 4:** Brainstormed device types and their corresponding strengths and shortcomings

<b>Types of Devices</b>	<b>Types of objects devices works with</b>	<b>Positives / How to make device</b>	<b>Negatives</b>
<i>Dry wall anchor, loop with puncture, puncture objects</i>	Only soft object not for bone, grass clumps, etc.	Ballistics, Spring mechanism, fish hook good grip once punctured, screw in,	Puncture stomach, Has to hold in place can't move
<i>Suction with loop, loop with forceps, snare with teeth, multi wire snare, double loop snare, loop</i>	Larger objects, Flat objects, Bone	Easy, DFM, Cheap, replaceable, size varies	Deforms after each use, hard to guide into place with just loop, low number of contact points
<i>Forceps, Claw, Free string with magnets on the end, claw plus a net</i>	Smaller objects	Very adaptable	Easy deformable and only fits small range of objects
<i>Suction with net, net, EM Net</i>	All object sizes though smaller usually	Any shape, Metal frame with kevlar string	Net could get tangled up, complicated manufacturing
<i>Shovel on catheter end, water jet, suction, glue at tip</i>	Any, but needs smooth surface at interface	Help orient device, good hold on object	Toxicity of glue, suction could get clogged, might not fit
<i>Mold around objects, rubber gripper, cocoon, cocoon with teeth, magnet compression</i>	Groups of smaller objects like grass, coins or acorns	Good at capture, possible springs needed for cocoons	Might not fit in the catheter

The secondary brainstorming session consisted of qualitative design screening that focused on the manufacturing and cost feasibility of each design. Each of the designs was talked over by the team with both pros and cons being applied to think through the best application for each and their inherent shortcomings in terms of materials required and manufacturing processes. Quantitative screening of each design was done by means of a matrix that is explained in the design selection section; the results of this screening is shown in Table 6.

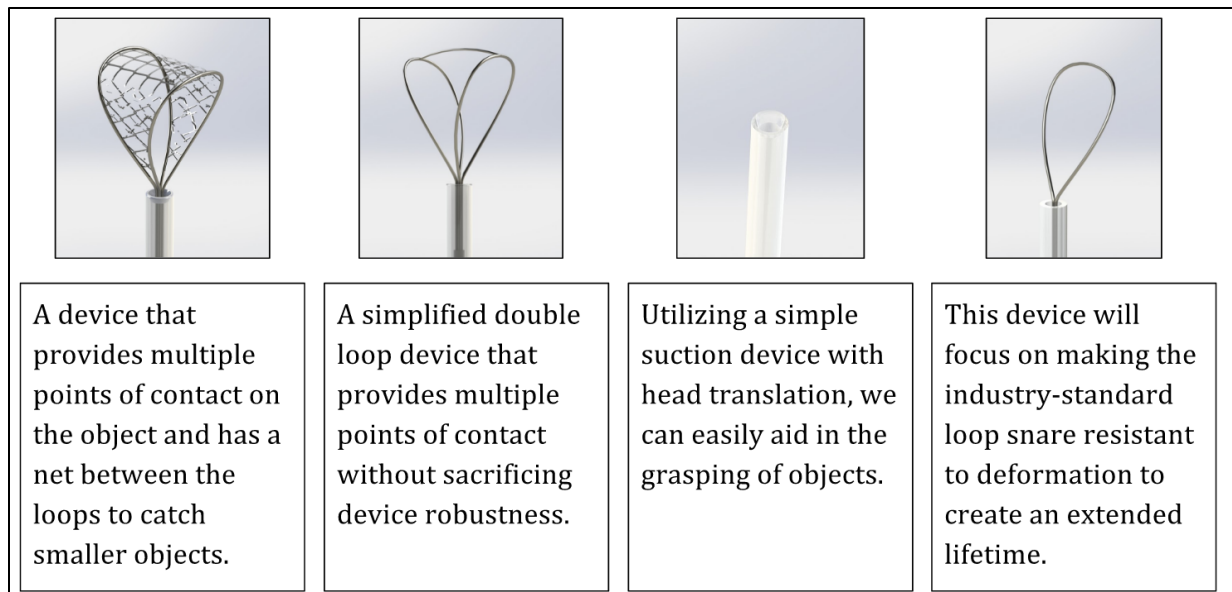
After the main ideation, we grouped each of the designs into similar types of devices to correlate the specificities of each respective category. This brainstorm was successful since it provided our team with numerous device designs that encompass the entire range of the needs and wants spectrum. This session also allowed for unconventional ideas to be thrown around which inspires in depth thought about the problem statement. This ultimately pushed us to come up with ideas that fit the majority of our needs while being practical to manufacture. From this brainstorming we isolated the key ideas of the proposed device; this is shown in Table 5.

**Table 5:** Key takeaways from the brainstorming exercise

<b><i>Key Ideas</i></b>	<b><i>Effect on Design Space</i></b>
Multiple points of contact	Must have multi-wire or enveloping design
Repeatable	A robust material
Variable Force head control	Individual loops/side tension control
Adjustable size	Covers a wide range of objects

These key takeaways provided the team with the necessary design cues to create four initial design renders with the quantitative device comparison “winner” being applied to a House of Quality. The renders and their respective descriptions are shown in Figure 4.

The House of Quality is shown in Appendix 2, it outlines the quantitative comparison of the Double-loop with the net prototype with the a competing snare device from Olympus medical and a competing net device from US Endoscopy. With the intended device key ideas instituted into the Proteus device, the double-loop with the net scored higher than both of the industry-leading competitors. Therefore we believe that we have isolated a key rift in the market that is an excellent opportunity for our device to fill.



**Figure 4:** Renders of Proteus proposed device designs

By no means are these device prototypes defining the final path that we are taking for the creation of the next generation retrieval device. They are initial “prototypes” that elucidate the key ideas that institute a successful next-generation retrieval device. They will be exhaustively tested with a canine testing device that is outlined in phase 1 of the deliverables. The model will help in the iterative prototyping process by providing the team with a viable solution for testing the efficacy of the devices without having to use them on canine patients. As the canine model is not the focus of Proteus Medicals’ device space, and is just a physiologically relevant R&D testing platform, its design requirements are not fully detailed in the device specific proposal.

## Strategy for Design Selection

When selecting the final design, we will consider the key takeaways of we envision in an ideal device and use that knowledge to isolate the best design. An initial brainstorming process yielded several design considerations and device options, and a concept screening matrix was generated to relate whether the device achieved the intended customer needs and wants, as seen in Table 6. This table presents a list of our initial prototype ideas and ranked each design against the list of customer needs and wants. The needs were scaled from 1-10 with a correction factor of 0.5-1 to identify the relative importance of each need to one another. Additionally, wants were scaled from 1-10 but with a correction factor from 0.1-0.5 to demonstrate that a customer want should not be ranked as heavily as a customer need.

**Table 6:** Concept screening matrix of the all brainstorming device ideas, with each need and want weighted to demonstrate their relative importance in the final design (full page table can be seen in Appendix 5).

		Customer Needs							Customer Wants					Total		
		Robustness	Head Translation	Maneuverability	Flexibility & Object Sizes	Various Surface Properties	Sterilizable	Fits in Insufflation Port	Ergonomic UI	Clear Visibility	Multiple Object Retrieval	Dimensionally Stable	Affordable		Sizeable Length	
	Correction Factor	1	1	0.9	0.8	0.7	0.5	0.5	0.5	0	0.1	0	0.2	0		
Loop	Multiwire Enclosure	7	-	6	8	7	10	10	-	N/A at this stage of device development	5	N/A at this stage of device development	7	Dependent on tubing and connection length (works for all)		35.6
	Loop	9	-	8	10	5	10	10	-		2		10			39.9
	Loop w/ suction	9	-	8	10	6	10	10	-		2		8			40.2
	Snare w/ teeth	5	-	6	8	7	10	10	-		5		4			33
	Double Loop	9	-	9	10	7	10	10	-		3		9			42.1
Trap	Net	5	-	10	6	10	10	10	-		10		6			38
	Double loop w/ net	7	-	9	10	8	10	10	-		5		7			40.6
	Dredge	6	-	8	5	10	10	10	-		10		6			36.4
	1 loop/1 net	6	-	9	7	8	10	10	-		10		6			37.5
	Cocoon (serrated)	2	-	5	3	5	5	1	-		2		5			16.6
	Net w/ suction	5	-	10	6	10	10	10	-		10		6			38
	Electromagnetic Net	2	-	4	10	7	10	10	-		5		3			29.6
	Mold around object	0	-	3	10	4	1	1	-		4		3			15.5
	Rubber Gripper	4	-	6	6	6	5	2	-		6		3			23.1
Open End	Claw (3-prong)	3	-	5	7	4	10	10	-		1		8			27.6
	Free EM Strands	2	-	3	7	2	10	10	-		1		5			22.8
	Magnetic Compression	0	-	2	6	1	10	4	-		0		3			14.9
	Slingshot w/ Magnetic Hold	4	-	0	2	1	10	0	-		0		3			11.9
	Suction	10	-	8	10	6	10	10	-		2		10			41.6
	Glue at tip	1	-	5	10	4	10	10	-		1		7			27.8
	Forceps	9	-	9	3	6	10	10	-		1		8			35.4
Dis-lodge	Shovel	10	-	-	-	-	-	-	-		-		10			12
	Waterjet	10	-	-	-	-	-	-	-		-		10			12
Puncture	Drywall anchor	6	-	6	10	4	10	10	-		1		7			33.7
	Loop w/ puncture	6	-	8	10	5	10	10	-		1		8			36.4
	Object puncture	3	-	4	10	4	10	10	-		1		8			29.1
Interface/Steering	4-finger string	5	10	-	-	-	-	-	5	-	-	-	7	-	-	18.9
	Lever	8	5	-	-	-	-	-	6	-	-	-	8	-	-	17.6
	Wrist Movement	7	10	-	-	-	-	-	8	-	-	-	7	-	-	22.4
	Steering Wheel	3	3	-	-	-	-	-	3	-	-	-	3	-	-	7
	Knobs	10	10	-	-	-	-	-	3	-	-	-	5	-	-	22.5
	Joystick	8	10	-	-	-	-	-	10	-	-	-	7	-	-	24.4
	Handle Steering	8	10	-	-	-	-	-	9	-	-	-	9	-	-	24.3

After following up with our customer and discussing the results of our brainstorming session, as seen in Appendix 3, we are now ready to begin isolating the qualities for our device design. Specifically, we are looking to modify the device head to see how they fair in a physiological model of a canine. As we continue to obtain results from testing, as well as receiving feedback from our client, we will tweak and adjust our designs as needed. We will conduct a second brainstorming session after the break and further concept screening in order to finalize the design properties that



we intend to pursue. The needs that seem the most critical in driving the design of our device are the robustness, device head translation, and the ability to pick up various sized objects. Taking these needs into consideration, we have given ourselves a set of deliverables to achieve these goals that are described in the section below. We propose that the head will be made out of a braided stainless steel along with the tubing which will be made out of a nylon-based tubing, similar to the current standards in the market. We have not yet decided on the material or materials that will be used for the user interface.

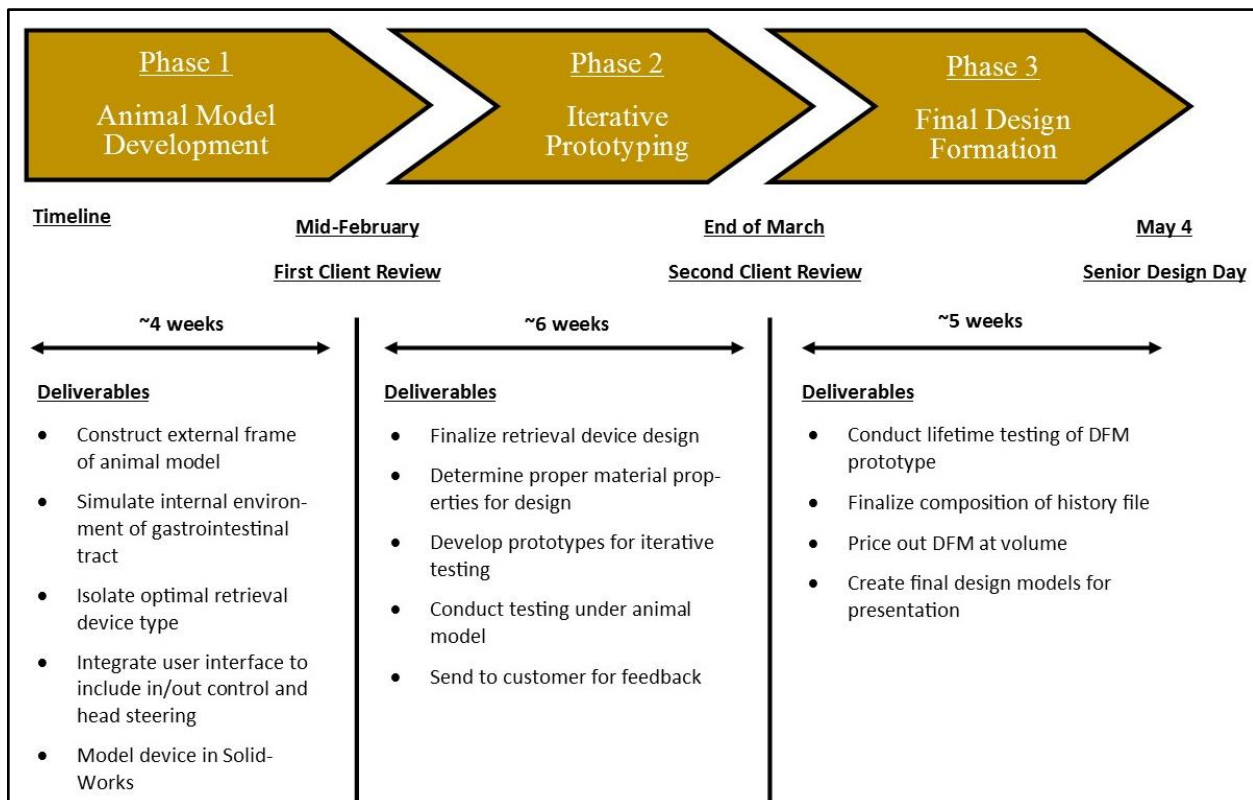
At the moment, we believe we have a solid fundamental understanding of the task required. Although it may seem like Proteus Medical is trying to complete a lot of sub-projects, such as building a model of a dog, creating a new device head and overhauling the user interface to provide head rotation, we believe that our dedication as a team and our ability to complete tasks in an efficient manner makes these deliverables feasible. As a team, we do understand that issues are bound to arise throughout this prototyping phase, and we are prepared to simplify our goals in order to meet a final product at the end of the year. More specifically, we are prepared to divert time from the device head to focus on the user interface, effectively creating a two-part system that will allow the user interface to be reusable over several uses while using standard retrieval heads in the market. Though we strive to create a more robust device head, it may not be feasible due to the conditions of the stomach, a factor that we have no control over. If we identify that this is the case during our prototyping stages, we will focus on simplifying the cost through other means and readjust our deliverables.

## **Project Management**

In order to properly maintain both file organization and sufficient documentation, Proteus has implemented the usage of multiple cloud-based tools. For file organization, and unilateral editing capabilities, all files are stored on Google Drive. This allows all team members access to files whenever they need them for both computer and mobile platforms. For calendar based controls, we utilize Google Calendar to sync all of our schedules and set meeting times with reminders. To ensure that every team member is on schedule with their assigned tasks, we utilize the Asana task-control software. It is both a resident on google chrome, and on mobile to provide notification daily for tasks that need to be worked on. Finally, to control real-time messaging amongst the team, we utilize Slack. Slack is a messaging tool that provides channel control for specific project sub-systems and it can be ported with Asana to seamlessly integrate communications and industrial organization. These tools allow the team to keep track of all files, allow for revision control, full timeline adherence as per both Google Calendar and Asana, as well real-time messaging capabilities to ensure that all team members are up to date, no matter their location geographically. The capabilities provided to us by these software suites are paramount in keeping the team on schedule and up to date on the processes necessary for document completion. As a team, we input our timeline and goals into our network and thus consistently are able to adhere to the set dates by conforming our schedules to ensure success.

## Deliverables

We have devised a list of deliverables for the following semester that we intend to follow to ultimately reach our goal of designing a next generation endoscopic retrieval device. As seen in Figure 5 below, we have divided our deliverables into 3 main phases: animal model development, iterative prototyping, and final design formation.



**Figure 5:** A set of deliverables and its associated timeline to reach a final prototype

During the first four weeks into the Spring Semester, we will construct a physiologically relevant canine model to conduct prototype testing later on. Designing a model to test our products in is extremely important to understand the potential issues that may arise during testing, without actually testing our products on actual canines. The current standard of training veterinarians to remove foreign bodies is by trial and error in actual canines, which poses potential ethical issues. Therefore, the model will serve two purposes in our project: firstly to test our devices under a realistic environment, and secondly to serve as a training tool for future veterinarians. We will be working in conjunction with Dr. Mike Richards of the University of Rochester Medical Center to design and mold a system that models a 40-60 lb. canine. The model will include a surfactant impregnated elastomeric gastrointestinal tract to provide accurate conditions within the stomach. Additionally during this phase, we will be isolating the optimal retrieval device head type through computational simulations as well as integrating the user interface to include both the in/out control and head steering mechanisms. These designs will be developed in CAD software to provide a structural visual of our design before manufacturing. All of these tasks will be completed by mid-

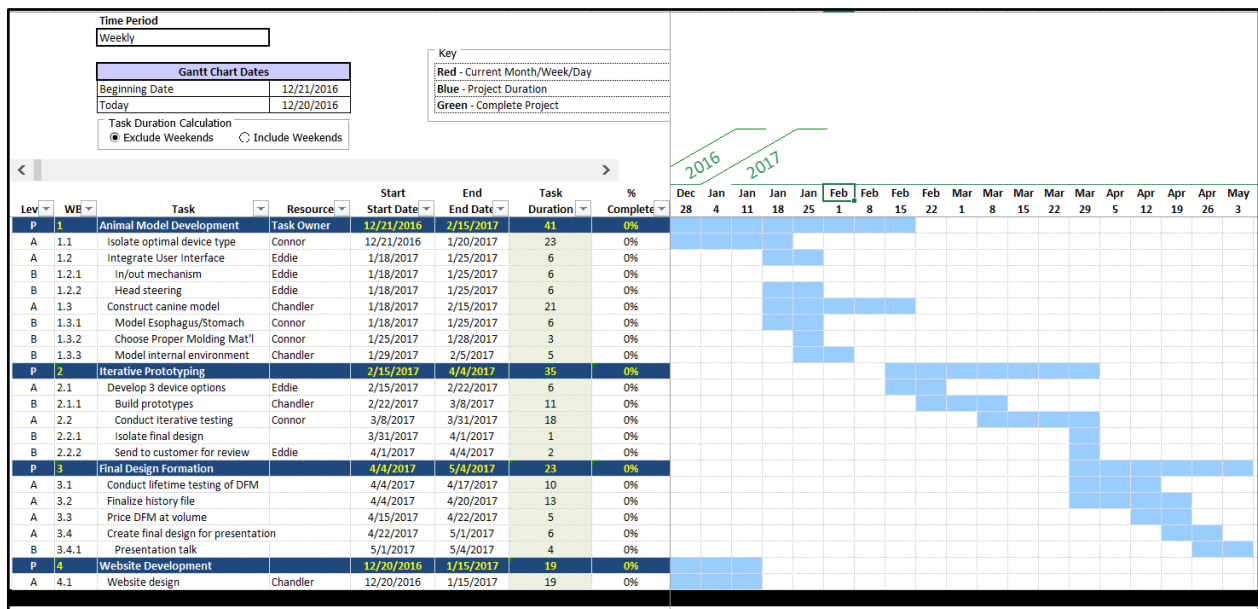
February, by when we will conduct our first client review to update Dr. Erika de Papp of the progress we have made in our design.

The next phase concerns iterative prototyping where the main deliverable is manufacturing our device designs for physiological testing. We plan to focus on three unique device head designs that we will test for stability and usability. Additionally, we will manufacture the user interface and combine both systems for iterative testing within the canine model. This six-week period is crucial for prototype testing and development to ultimately construct a market ready prototype that encapsulates all primary needs of the customer. A full DFM analysis will be conducted, and a full engineering design log will be kept to record all data from tests. Once a final prototype is determined, we will send our device concept to Dr. Erika de Papp for direct feedback and implementation in an actual retrieval procedure.

The last phase is the formation of our final device. Most importantly, material property analysis will be conducted to make our device as robust as possible. All materials that will be considered will have pre-approval by the FDA in order to expedite the 510k process. A history file of the device project process will be created as well as pricing of our device at volume for marketability. We will deliver a final product design and testing demonstration for our customer at the end of the year. If time permits, a website will be developed to market our product.

## Schedule

A Gantt Chart as provided in Figure 6 presents our time estimates on how we plan on achieving our deliverables. Individual goals are identified and given a deadline, presenting the appropriate dates we need to reach in order to stay on track with our device design. Individual assignments will be given at the commencement of the spring semester. This Gantt chart has been uploaded and coupled with our cloud-based organization software suite to ensure that all team members are up to date continuously on the status of the projects and its subsystems.



**Figure 6:** Initial scheduling with deadlines to meet our deliverables in a timely fashion

## Weekly Schedule / Team Organization

During the spring 2017 semester, the times stated below in Table 7 present the available work hours that our team is available to meet:

**Table 7:** Available work hours for the Proteus Medical team

Available Times During the Day				
Monday	Tuesday	Wednesday	Thursday	Friday
12 - 6 PM	Busy	12 - 6 PM	3:30 - 6 PM	12 - 6 PM

Additionally, we will be holding weekly supervisor meetings with Dr. Diane Dalecki and TA Caeli Quiter to present any updates or problems that we have during the design phases. We will be in constant contact with Caeli to provide progress reports, and as seen in Table 8, we have identified the times that Caeli is available to meet in the event that we need extra assistance.

**Table 8:** Available meeting times for Caeli Quiter

Available Times During the Day				
Monday	Tuesday	Wednesday	Thursday	Friday
12 - 3, 5 - 6 PM	Busy	12 - 6 PM	Busy	12 - 6 PM

Our advisor meetings, which include Dr. Diane Dalecki and TA Caeli Quiter, will be held on **Mondays from 12-1 PM** during the spring 2017 semester. Our personal meetings will be held twice a week for three hours, Wednesday and Friday, 12-3 PM. These times are blocked for all team members in order to ensure that the team has sufficient time in the work week to be a success with the multiple deliverables that we have outlined.

## Design Team

Individual resumes and accomplishments are highlighted for each of our three team members on this Veterinary Endoscopy team, as listed under Appendix A. Working together as Proteus Medical's development team, Connor McBride, Eddie Ruppel, and Chandler Woo all have unique personalities and backgrounds that will contribute a wide variety of perspectives to address the problems surrounding current endoscopic retrieval devices.

Connor has extensive laboratory experience working with animals, and his knowledge is fully translatable towards understanding the clinical and ethical considerations when working with animals. Additionally, he has grown up with a dog and has had personal experience when his own dog consumes foreign bodies, giving our team a prime stakeholder perspective on how treatment and the procedures go for veterinary foreign body retrieval. Connor's keen eye for detail will be important for the validation and quality control of our product, as we aim to improve the functionality of the endoscopic retrieval device for veterinarian use.

Eddie has had extensive R&D and device design experience during his consulting time at Ideaboxx and Prescient Surgical, and his knowledge of manufacturing and product design is an invaluable tool that will help devise a marketable product for our team. His experience with prototyping under CAD software such as SolidWorks will expedite the design process and allow us to model our device design in a timely manner. Most importantly, his professionalism meshes well as a customer liaison for our project team, as his quick responses and time management have allowed us to stay on schedule with our deliverables.

Lastly, Chandler has considerable background in designing protocols and has worked in several laboratory settings, learning how to refine and optimize methods for the most effective result. His knowledge of anatomy during his time as a Teaching Assistant for Human Anatomy has given him keen insight into physiological systems, of which is translatable towards a canine model. Additionally, the interpersonal skills that he has developed in his time as a TA and at conferences when presenting his research gives him the tools to convey the needs and design considerations of our project in a succinct and clear manner. To that end, Chandler will work on making our product marketable as well as manage finances for the team, while providing input on how to reduce the cost of our project while maintaining its efficacy.

Proteus Medical's team brings different strengths to the table, but our ability to mesh well with one another has already given us a substantial edge over other competition. Though we all have different mindsets, our greatest strength is our ability to listen to one another, an invaluable tool that serves as the foundation of our team's dynamic. We have made decisions as a team and are truly looking forward to working with Dr. de Papp to generate an improved foreign body retrieval device.

## Budget

To provide a basic list of the components Proteus Medical requires, each assembly has been outlined to provide a projected budget, as well as a comparison to current device costs. Table 9 provides the current cost for a few of the retrieval device heads on the market to act as a comparison for what we are planning to make and a rough estimate of its cost. Below in Table 10 and Table 11 are projected costs for our canine model and device design, respectively. Currently, the biggest issue with cost, is the size of the device that we are trying to make. The cost of making a smaller and accurate model is substantially higher than generating a larger-scale model. We are aiming to make a device with a max thickness of 2.5 mm to simulate the true scale of the device.

**Table 9:** Current cost for competitive devices on the market [Gregorski, 2016].

<b>Vendor</b>	<b>Type of Device</b>	<b>Cost</b>
Boston Scientific	Snare, single use	\$36.00
Medi-Globe	Snare, single use	\$65.00
Medi-Globe	Snare, Reusable	\$259.00
Olympus America	Alligator tooth retrieval forceps, reusable	\$601.00
US Endoscopy	Net, single use	\$85.00

**Table 10:** Projected costs for creation of canine training model

<b>Description</b>	<b>Vendor</b>	<b>Cost</b>
Silicone molding material (Shore 40a)	Smooth-on	\$30.00
LDPE sheet (0.375" x 24" x 24")	Mcmaster-Carr	\$30.00
SS Hardware	Mcmaster-Carr	\$25.00
Mold Making material (wooden buck)	Home depot	\$10.00
Mold release (Carnauba wax)	Home Depot	\$8.00
Mouth geometry 3D Printing	On campus	Free
Model imagery printing	On campus	\$5.00
	<b>Total Projected</b>	<b>~\$108.00</b>

**Table 11:** Projected costs for creation of endoscopic retrieval device

Device Components	Vendor	Quantity	Price
Med. Grade Tubing 0.1" OD	Mcmaster-Carr	25 ft.	\$25.00
Stainless Braided Cable	Mcmaster-Carr	25 ft.	\$35.00
Stainless Crimps	Amazon	1 (bag of 10)	\$5.00
3D Printing	Rettner Multimedia Center	500 grams	\$50.00
Motion Component Hardware	SDP/SI	2 gears	\$50.00
Kevlar Mesh	AFC	1 sq. yard	\$25.00
		<b>Total Projected</b>	<b>~\$190</b>



## Conclusion

This document aims to exhibit why the Proteus Medical team is the correct group to create a successful retrieval device for veterinary endoscopy, as specified by the client, Dr. Erika De Papp. Our team is passionate and ready to put in the hard work and effort required to accomplish our goals. We have done extensive research on this topic to help formulate our current design alternatives to counter the solutions currently on the market. The research that we have gained from our customer meetings, brainstorming, and extensive background research pertaining to clinical use and competitive devices on the market will provide us the capabilities to iteratively formulate a final manufacturable design solution. Although this project is deeply important to our customer Dr. De Papp, this project has implications beyond her excellent work at the Angell Animal Medical Center in Boston. If the device created meets the requirements that we have specified, it will vastly improve the ease, efficacy, and speed of retrieval. This benefits all parties involved in the procedure; especially the dog due to the procedure being minimally invasive and requiring no post-operative recovery time. This all culminates in a faster recovery time for the dog and peace of mind for the owner. If this device is successful there is the possibility of it being used in other veterinary clinics and possibly being implemented for human use due to its universal retrieval qualities. Thus, Proteus has three main goals for this project. The first is to create a robust retrieval head that has the ability to capture objects of various shapes and size while giving the device head a one year life span. Next we aim to add head translation to the device without sacrificing an ergonomic user interface. Finally, we aim to create a canine model that can be used to test our prototypes as well be applied to train future veterinarians in the endoscopic retrieval process. While this is an ambitious set of goals, Proteus is ready for the task and we look forward to accomplishing it.

## Acknowledgements

We would like to acknowledge our client, Dr. Erika De Papp, 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. Finally, we would like to thank Dr. Mike Richards for his advising on the creation of our model testing device.

## References

- [1] de Papp, Erika. *Customer Meeting Minutes*, 2016.
- [2]"Pet Statistics." ASPCA. N.p., n.d. Web. 21 Nov. 2016.
- [3]" U.S. Pet Ownership Statistics." AVMA. N.p., n.d. 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. N.p., n.d.
- [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 Dec. 2016.
- [9] Chalabi, Mona. "What Cats And Dogs Are Swallowing." *FiveThirtyEight*. New York Magazine, 04 Sept. 2014. Web. 20 Dec. 2016.
- [10] Roth Net Retrieval Devices [Devices Document], n.d, Roth Net Retrievers. URL <http://www.usendoscopy.com/endoscopy/roth-net-retrieval-devices.aspx> (accessed 11.10.16).
- [11] Endoscopic Foreign body Retrieval, n.d.URL <http://todaysveterinarypractice.navc.com/wp-content/uploads/2016/05/t1511c07.pdf> (accessed 11.10.16).
- [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](https://www.esge.com/assets/downloads/pdfs/guidelines/2016_s_0042_100456.pdf) (accessed 11.10.16).
- [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](http://www.asge.org/uploadedfiles/publications_and_products/practice_guidelines/management_of_ingested_foreign_bodies_and_food_impactions.pdf) (accessed 11.10.16).
- [14] Proceeding of the NAVC North American Veterinary Conference , 2005 URL <http://www.ivis.org/proceedings/navc/2005/sae/130.pdf> (accessed 11.10.16).
- [15] Olympus Retrieval Devices for Endoscopy, n.d. olympus. URL <http://et-catalogue.olympus.eu/en/index.php?category=764> (accessed 11.10.16).
- [16] FDA warns of Endoscope Contamination, n.d. Medscape. URL <http://www.medscape.com/viewarticle/840057> (accessed 11.10.16).
- [17] 510(k) Premarket Notification, n.d. 510(k) Premarket Notification. URL <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> (accessed 11.10.16).
- [18] Intentional Swallowing of Foreign Bodies and its Impact on the Cost of Health Care n.d.. URL <http://www.rhodeislandhospital.org/templates/onecolumnnpb.aspx?pageid=43061> (accessed 11.10.16).
- [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.

## List of Appendices

- Appendix 1:*** Resumes
- Appendix 2:*** House of Quality
- Appendix 3:*** Brainstorming Images
- Appendix 4:*** Abridged Annotated Research
- Appendix 5:*** Systems Diagram
- Appendix 6:*** Quantitative Assessment of Device Brainstorming

## Appendix 1: Resumes

<b>Connor McBride</b>		719.360.8959 • cmcbrid4@u.rochester.edu
<b>SUMMARY BIOMEDICAL ENGINEERING INTERNSHIP QUALIFICATIONS</b>		
<ul style="list-style-type: none"><li>• Capacity to use MATLAB and Excel to analyze data, produce graphs, create functions, scripts of code and GUIs.</li><li>• Ability to work with Arduino hardware and software</li><li>• Ability to build and design circuits gained through coursework and projects in Biosystems and Circuits</li><li>• Fundamental understanding of laboratory techniques and procedures</li><li>• Communication and teamwork abilities exhibited in classroom and projects.</li><li>• Ability to use Adobe Suite</li></ul>		
<b>BIOMEDICAL ENGINEERING EDUCATION, AWARDS AND ACTIVITIES</b>		
UNIVERSITY OF ROCHESTER	ROCHESTER, NY	
<b>Bachelor of Science in Biomedical Engineering</b>	<b>Expected May 2017</b>	
Concentration in Cell and Tissue Engineering		
<ul style="list-style-type: none"><li>• Overall GPA: 3.45/4.0</li><li>• Dean's List 4 of 6 Semesters</li><li>• Biomedical Engineering Society, Member; and Engineers Without Borders, Member</li></ul>		
<b>BIOMEDICAL ENGINEERING COURSES AND PROJECTS</b>		
Biomedical Computation and Statistics; Biomaterials; Signals, Systems and Imaging; Heat and Mass Transfer; Biosystems and Circuits; Fluid Dynamics; Biomechanics; Biomedical Engineering; Principles of Biology; Chemical Concepts, Systems, and Practices I & II; Organic Chemistry I & II; Physics-Electricity and Magnetism; Physics-Mechanics; Multidimensional Calculus; Linear Algebra with Differential Equations; Calculus and Applied Statistics		
<ul style="list-style-type: none"><li>• <b>Sensor for a Prosthetic Hand, Spring 2015:</b> team of two developed a sensor that could be used on a prosthetic hand to feel and differentiate between different materials; using a vibration to determine the intensity of strength used to touch the object with a prosthetic hand. Using op amp various filters built out of resistors and capacitors this sensor was able to be completed.</li><li>• <b>Biomechanics/MATLAB Analysis Project, Fall 2014:</b> team of four, developed a MATLAB program for children to test their hearing level in the form of a game. Developed GUI to present game. Produced a test sound whose volume was based on a two-down-one-up (2D1U) system. Created a graph of results after twelve reversals of the slope.</li></ul>		
<b>RESEARCH EXPERIENCE</b>		
Cancer Center, University of Rochester	Rochester, NY	
<b>Research Assistant</b>	<b>Summer 2015</b>	
<ul style="list-style-type: none"><li>• Assisted in the genomics center helping with daily tasks while learning about preparing DNA and RNA for analysis along with doing PCR and working with a Bioanalyzer for DNA and RNA.</li></ul>		
Department of Physiology, University of Colorado	Denver, CO	
<b>Research Assistant</b>	<b>Summer 2016</b>	
<ul style="list-style-type: none"><li>• Worked with chinchillas doing behavioral testing pertaining to their hearing. In addition, helped design and build the device that housed the chinchillas during the testing and help code the program used for the behavioral testing with both MATLAB and Arduino.</li></ul>		
<b>EXTRACURRICULAR ACTIVITIES AND INTERESTS</b>		
Ski Team, President	Cycling Team, Member	Eagle Scout, Boy Scouts of America
Prepared: October 7, 2016		

**Figure 7: Connor McBrides' Resume**

**Edward F. Ruppel, III**  
20860 Kittridge Road -- Saratoga, CA 95070  
(408) 355-4866 (Cell) • Email: eruppel2@u.rochester.edu

*Innovative and driven young professional looking to have a significant impact on the medical device industry.*

**Education:**

- University of Rochester class of 2017 Biomedical Engineering, Biomechanics Concentration

**Experience:**

*Prescient Surgical - - Fully dedicated to reducing the risk of surgical site infection (SSI).*

**Research & Development/ Manufacturing**

**Summer 2016**

- Designed and built multiple cleanroom based manufacturing fixtures to hold tolerance specifications
- Radially variable retraction mechanism links design for manufacture (DFM)
- Applied advanced statistical and computation methods to provide precise models of GI incisions
- Developed and implemented numerous test methods for material-device characterizations
- Extensive experience with all levels of prototyping; represented company at the 2016 ASCRS Clinical Congress

*Buckley Lab, URM - - The Buckley lab focuses on evaluating pathology-associated mechanical changes in cartilage, tendon, cornea, sclera and other connective tissues, and using the findings to develop novel diagnostic tools and therapeutic strategies.*

**Design/Research Associate**

**April 2015-Current**

- Designed, built, and verified multiple mechanical testing devices for various connective tissues; modular biaxial bioreactor, US elastography bioreactor, confined/cyclical/hydrostatic compression device, Embryonic CETV inducer, cytomolecular loader
- FEA modeling of viscoelastic connective tissue in Abaqus and FeBio; attended BMES 2016, and will be presenting at ARVO 2017

*The IdeaBoxx LLC - - An innovative start-up company focused on applying cutting edge technology to revolutionize the Medical and Commercial Food Processing Industries. I worked at the IdeaBoxx for two summers and during the school year part time.*

**Research, Development, and Deployment Engineer/Regulatory Compliance**

**May 2014-May 2016**

- Lead documenter for compliance with NSF/ANSI 6 certification policies; *Cert. granted Jan. 2015*
- Researched, developed, and deployed several products to the marketplace; multiple filing for patents
  - Named as co-inventor on the HydraRinse® Universal Dairy Equipment CIP System Patent Filing

*United Sources Sought LLC [IdeaBoxx LLC; Spinout] - - A start-up company focused on creating next generation wearable technologies for Military applications. Worked part-time during the school year.*

**Product Manager/RD&D Engineer/Regulatory Compliance**

**Oct. 2015-Current**

- Project lead on multiple military specification and IP67 certified products; various projects in process of being filed for patent approval

*ProNatural Brands LLC [IdeaBoxx LLC; Spinout] - - Developing products with the goal of using naturally derived, minimal toxicity, and environmentally responsible ingredients with comparative cleaning ability of synthetic products. Worked part-time during the school year.*

**Research and Development Engineer/Marketing Intern**

**Sept. 2014-May 2016**

- Design and execute experiments to validate antimicrobial efficacy of product line
- Maintain third party laboratory efficacy reports backlog for EPA approval

*John Allen Marine Restoration - - A privately held company that specializes in the restoration of antique and classic wooden boats*

**Engine Technician**

**May 2011- Aug. 2016**

- Restored, rebuilt, and painted engines to concourse boat show engine quality specifications

**Activities/Interests:**

*Solar Splash - - Intercollegiate competition group that designs, engineers, and builds a solar powered racing boat to compete against schools from all over the world.*

**President & Chief Systems Engineer**

**Apr. 2014-Current**

- Chief Engineer, builder, and designer of fiberglass hull, steering and mechanical drive systems
- Facilitate meetings, contact professors for club guidance, and contact sponsors continuously
- Organized logistics for a successful trips to competition over the summer 2014, 2015, 2016
- Delegate tasks and implement club organization/Process Documentation

**Awards:**

- AEMB Biomedical Engineering Honor Society MINDS Scholar
- Solar Splash International Championship of Solar Boating- 1<sup>st</sup> Place Visual Display (2x) , 2<sup>nd</sup> Place Technical Report , Perseverance Award, Teamwork Award, Outstanding Hull Design Award (2x) , Outstanding System Design Award
- Saratoga High School class of 2013, Community Service Award
- 2014, 2015 UR ASME Pumpkin Launch – First Place (2x)

2016-11-30

**Figure 8: Edward Ruppels' Resume**

## Chandler W. Woo

626-848-6226 | chandler.w.woo@gmail.com | 20 Winbourne Rd. Rochester, NY 14611

### SUMMARY OF MEDICAL DEVICE QUALIFICATIONS

- Desire to seek hands-on application of skill sets, guided by a strong attention to detail and a willingness for new challenges
- Quick ability to adapt in professional and social exchanges with a passion to learn as demonstrated by participation in conferences
- Developed techniques using confocal and stereo microscopy as well as image analysis tools such as ImageJ and Fluoview
- Skilled using MATLAB for mathematical and statistical analysis, Microsoft Excel, Abaqus, HTML 5 and JavaScript
- Proficient comprehension in Spanish

### BIOMEDICAL ENGINEERING EDUCATION

UNIVERSITY OF ROCHESTER

**Bachelor of Science in Biomedical Engineering, Concentration in Biomechanics**

ROCHESTER, NY

**Expected May 2017**

Current GPA: 3.48/4.0; Dean's List

- Executive Board Member, Upperclassmen Hall Council, Sigma Chi Fraternity, Newman Catholic Community
- Member of Solar Splash, Engineers without Borders, Biomedical Engineering Society

### SELECTED BIOMEDICAL ENGINEERING COURSES AND PROJECTS

Biomaterials; Thermodynamics; Biomedical Computation & Statistics; Signals, Systems, and Imaging; MATLAB; Biosolid Mechanics; Mammalian Physiology; Biosystems & Circuits; Solid Mechanics; Human Anatomy; Biomechanics

- **Biomedical Computation Final Project:** Analyzed confocal microscopic images to quantify depth dependent properties of cartilage under sinusoidal shear. Generated MATLAB code to extract and track the position of photobleached lines under shear and used statistical analysis to confirm significance. Assembled and presented results and discussion in the form of a journal article.
- **Biosolid Mechanics Final Project:** Analyzed the injury to cervical spine associated with high acceleration flight in fighter jet pilots. Researched and designed potential helmet designs to prevent spinal injury under intense loading using OpenSim software and SolidWorks. Compiled into a formal research proposal under the assumption of unlimited resources.
- **Biosystems & Circuits Final Project:** Designed an artificial touch sensor, suitable for a Raptor 3-D printed hand, to sense pressure at the "fingertip" and deliver a signal to the hand. Analyzed circuit design using OrCAD to calculate appropriate frequency response for a Pacinian Corpuscle; crafted final design onto a circuit board using general design considerations.
- **MATLAB Final Project:** Directed a 3-person team to design a hearing test for young children in MATLAB. Identified considerations for project such as maintaining the child's interest with a reward system as well as determining the subject's average threshold through both 2-down-1-up and reversal algorithms.

### BIOMEDICAL AND MECHANICAL ENGINEERING EXPERIENCE

BUCKLEY LAB at DEPARTMENT OF BIOMEDICAL ENGINEERING, UNIVERSITY OF ROCHESTER ROCHESTER, NY

**Undergraduate Research Assistant**

**September 2015 – Present**

- Utilize confocal microscopy to analyze force distributions of murine femoral condyles under mechanical loading.
- Develop MATLAB code to directly measure cartilage strain under different loading conditions and use inverse finite element analysis to obtain material properties and boundary conditions of murine cartilage.
- SB3C Conference, Presentation Attendee, Summer 2016 - "A Quasi-Static Method to Quantify Murine Mechanical Properties"
- BMES Conference, Poster Presenter, Fall 2016 - "Effects of Mechanical Preconditioning on Material Properties of Murine Cartilage"

IDEALAB

PASADENA, CA

**Summer Engineering Intern**

**Summer 2011, 2012, 2014, 2015**

- Operated machine shop tools and SolidWorks to devise novel product prototypes.
- Self-directed projects include, but not limited to, optimizing angles of 100 mirror array to centralize light on single point for solar tower design consideration; designing heat retentive system for effective water desalination.
- Researched efficiency of solar desalination comparatively to reverse osmosis desalination and conducted test experiments under a given budget.

CRANE LAB at UNIVERSITY OF ROCHESTER MEDICAL CENTER

ROCHESTER, NY

**Undergraduate Research Assistant**

**September 2014 – May 2015**

- Directed evening human trial sessions for data to better understand human motion perception and spatial orientation.
- Managed personal MATLAB projects to update the aesthetic and functional display while running tests.

### TEACHING EXPERIENCE

DEPARTMENT OF BIOMEDICAL ENGINEERING, UNIVERSITY OF ROCHESTER

ROCHESTER, NY

**Teaching Assistant, Introduction to Biomedical Engineering**

**Fall 2014, Fall 2015, Fall 2016**

**Teaching Assistant, Human Anatomy**

**Spring 2016**

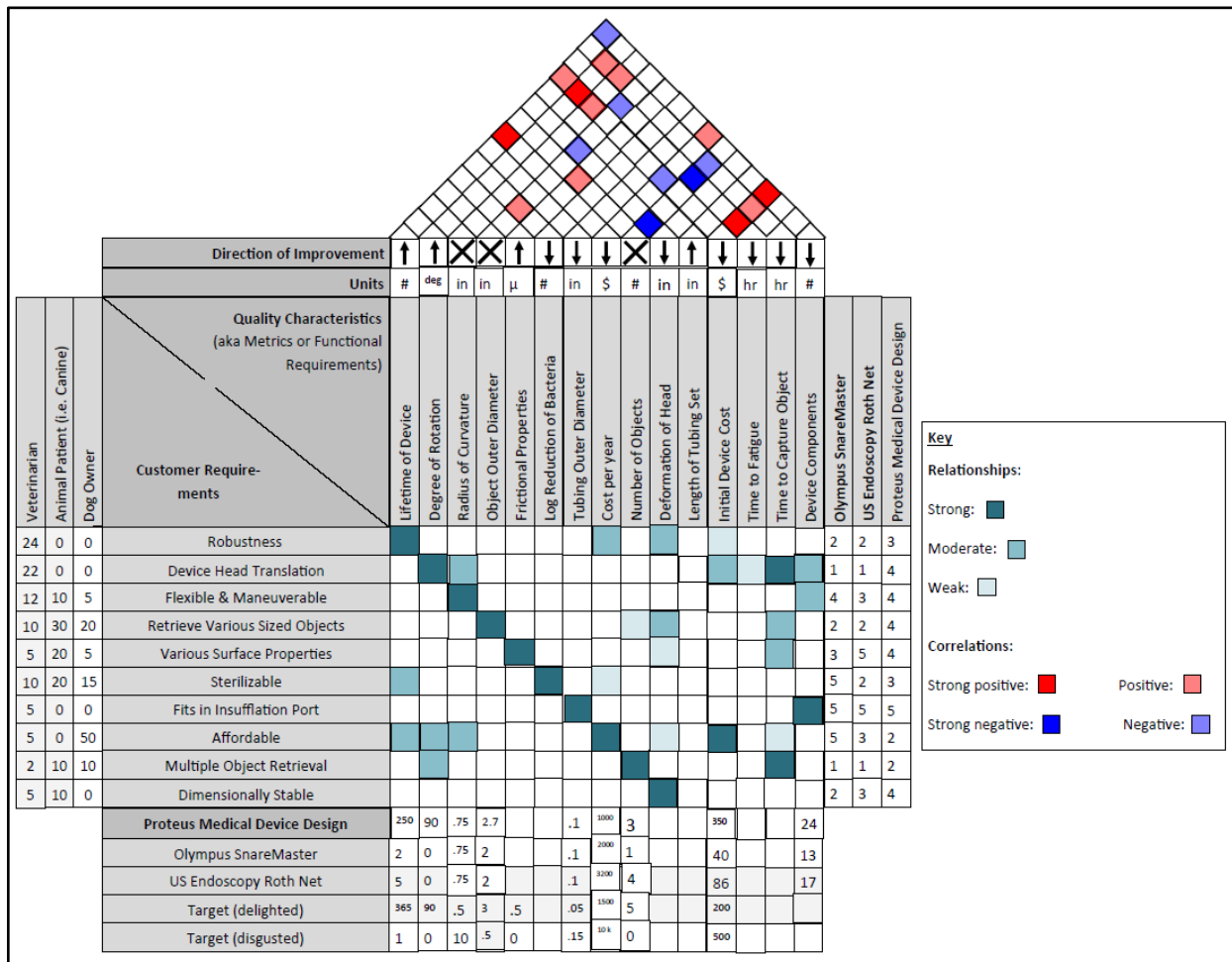
**Teaching Assistant, BME Signals, Systems and Imaging**

**Fall 2016**

Last Updated: October 4, 2016

**Figure 9: Chandler Woos' Resume**

## Appendix 2: House of Quality



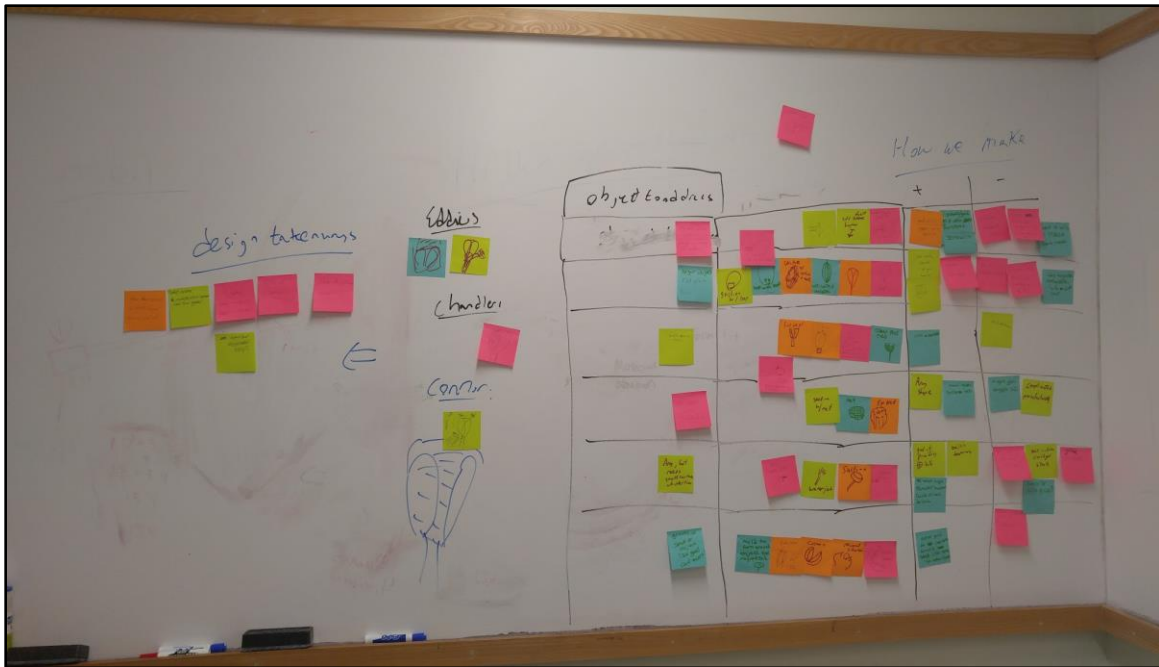
**Figure 10:** House of Quality comparing Proteus Medical device design with the Olympus snaremaster and the US Endoscopy Roth Net



### Appendix 3: Brainstorming Sketches



**Figure 11:** Detail view of brainstorming qualitative matrix



**Figure 12:** Qualitative brainstorming matrix



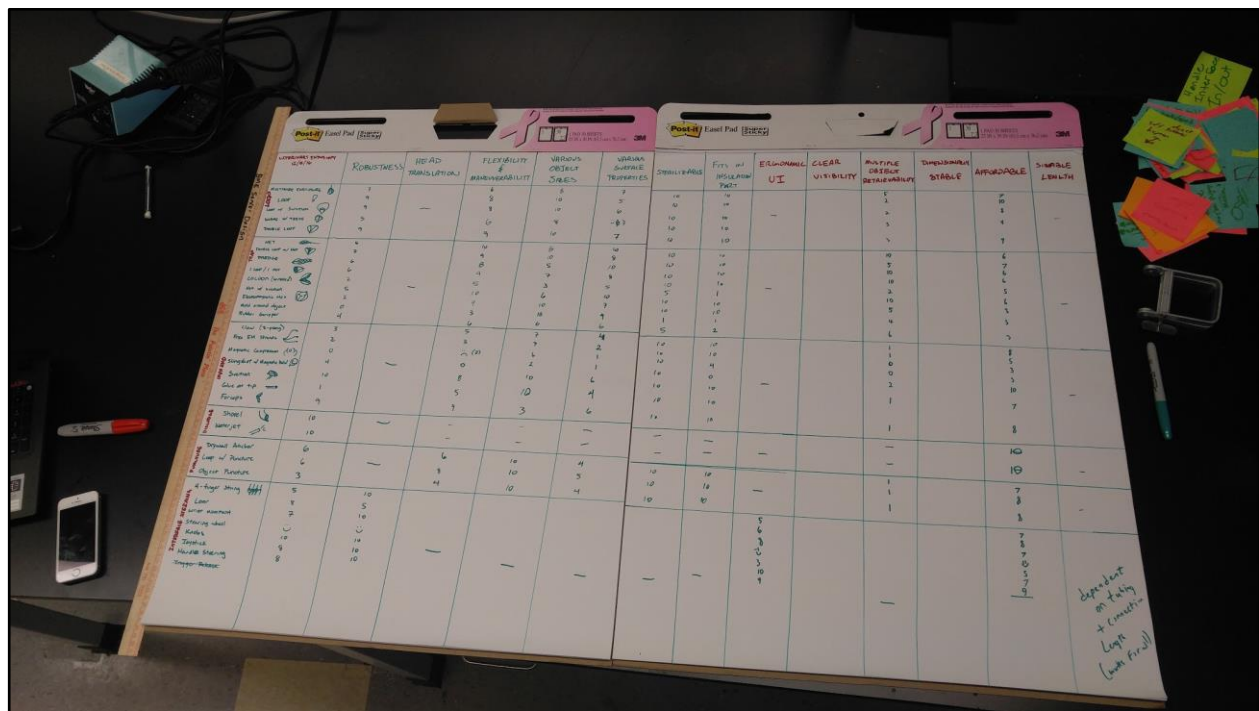


Figure 13: Quantitative brainstorming matrix, Stage 2 of process

## Appendix 4: Abridged Annotated Research

### Clinical - procedures and materials for conducting endoscopic foreign body retrieval

- This chapter presents an evidence-based review of which tools are used in endoscopic foreign body retrieval in humans as well as procedure. Additionally, it provides a brief historical context of tracheobronchial foreign body (TFB) extraction. Understanding how foreign body retrieval works in humans will be helpful in shedding light on the veterinary practices on animals.  
*Dilaz-Jimeñez, J. P., and Alicia N. Rodriguez. Interventions in Pulmonary Medicine. New York: Springer, 2013. Print. Chapter 32: Endoscopic Foreign Body Removal Karen L. Swanson*  
[http://link.springer.com/chapter/10.1007%2F978-1-4614-6009-1\\_32](http://link.springer.com/chapter/10.1007%2F978-1-4614-6009-1_32)
- American College of Veterinary Surgeons (ACVS) provides general symptoms and diagnoses when a pet consumes a foreign body. Many times vomiting is the most common sign that an animal ingested an object that it should not have. *"Small Animal Topics." Gastrointestinal Foreign Bodies. AVCS, n.d. Web. 20 Dec. 2016.*
- This article provides a broad overview of the procedures conducted to extract the foreign body from an animal. It goes into detail about the endoscopic gastronomy tubes that are used to open the airway to pass the endoscope into the stomach.  
*Leib, Michael S., DVM. "Foreign Procedures: Foreign Body Retrieval and Peg Tube Placement." IVIS (2005): n. pag. Web. 18 Nov. 2016.*  
<http://www.ivis.org/proceedings/navc/2005/SAE/130.pdf?LA=1>
- Process associated with insufflating the stomach with CO2 in order to make retrieval of object easier. This will be helpful with identifying the other procedures required to conduct a proper foreign body retrieval.  
*Lawes, E. G., I. Campbell, and D. Mercer. "Inflation Pressure, Gastric Insufflation and Rapid Sequence Induction." Survey of Anesthesiology 31.5 (1987): 271. Web.*

### R&D - Current devices on the market and technology used to accomplish retrieval task as well as isolating design space specifications

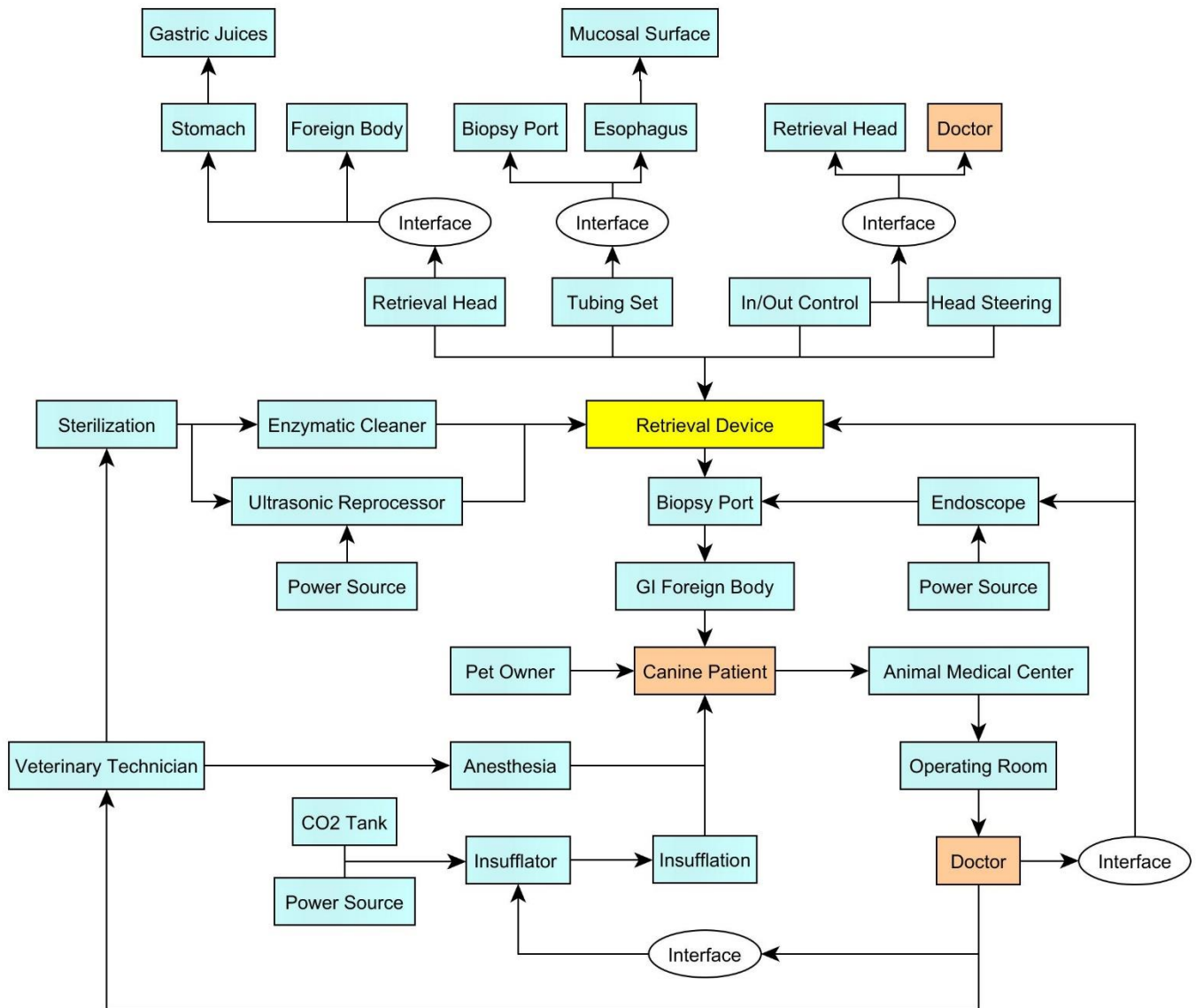
- This patent exhibits the simplest design of a two-wire basket retrieval device. This is the foremost used device by our customers practice for the removal of large objects from the gastrointestinal tract. *Medical Retrieval Device. Annex Medical, Inc., assignee. Patent US151397925. 08 Nov. 2015. Print.*
- This patent exhibits various designs for basket retrieval mechanisms. These designs are foremost used by the customer to remove small objects, like coins and leaves. *Foreign Body Retrieval Device and Method. Ams Research Company, assignee. Patent US 6802846 B2. 12 Oct. 2004. Print.*
- This is the source of retrieval devices that our customer's practice uses. Therefore these are the devices they are most familiar with *"Snares/Retrievers (Vet)." ESS Veterinary Graspers, Retrievers and Snares. N.p., n.d. Web. 21 Dec. 2016.*

- Olympus is the leading source of endoscopic instruments in the United States in terms of market share; hence the reason while we are gauging current market technology on Olympus's offerings. *Olympus Retrieval Devices for Endoscopy*, n.d. olympus. URL <http://et-catalogue.olympus.eu/en/index.php?category=764> (accessed 11.10.16).
- This clinical guideline outlines the various foreign body categories and isolates the device and method to use in each specific circumstance. 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.
- This clinical guideline provides metadata on the removal of the various foreign bodies with respect to the device and method. *Endoscopic Foreign Body Retrieval*. Research Institute At Nationwide Children's Hospital, assignee. Patent US 20140213847 A1. N.d. Print. Bordas, Josep M., Josep Llach, and Miguel Muñoz-Navas. "Removal of Gastrointestinal Foreign Bodies." *Frontiers of Gastrointestinal Research Interventional and Therapeutic Gastrointestinal Endoscopy* (2009): 79-90. Web.
- This is a clinical review of all the devices that are currently on the market for the retrieval of gastrointestinal foreign bodies endoscopically. This will aid as a reference point in isolating what offerings are on the market now and what we aim to bring to the table. Gregorski, Maciek. "Practice Guidelines." *ASGE: Practice Guidelines*. N.p., n.d. Web. 21 Dec. 2016.

#### Regulatory - Understand regulatory status and controls for endoscopic retrieval tools

- Two FDA 510K's of endoscopic retrieval devices describing the regulations for the class 2 endoscopic device. It also looks at tests the devices had to pass in order to be approved. [http://www.accessdata.fda.gov/cdrh\\_docs/pdf12/k122462.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf12/k122462.pdf) and [http://www.accessdata.fda.gov/cdrh\\_docs/pdf15/k152580.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf15/k152580.pdf)
- Provides a background of all the current devices on the market and the talks about the benefits of each type of retrieval device along with safety issues that can arise from the devices. *Technology Status Evaluation Report: Endoscopic Retrieval Devices, 2009*. *Gastrointestinal Endoscopy* 69, 997–1003. Web.
- A summary of the process in which an endoscopic retrieval device would have to go through when being approved by the FDA for biocompatibility and sterilization on the device. *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, 2009*. AAMI. Web.
- An overview of what specifically the FDA regulates for veterinarians. The process has similarities to human devices but is not nearly as strict. "What We Regulate: Veterinary." *FDA*. N.p., n.d. URL: <http://www.fda.gov/AnimalVeterinary/ResourcesforYou/ucm268125.htm> Web. 21 Dec. 2016.

## Appendix 5: Systems Diagram



**Figure 14:** Systems level diagram of retrieval device

## Appendix 6: Quantitative Assessment of Device Brainstorming

		Customer Needs								Customer Wants						Total
		Robustness	Head Translation	Flexibility & Maneuverability	Various Object Sizes	Various Surface Properties	Sterilizable	Fits in Insufflation Port	Ergonomic UI	Clear Visibility	Multiple Object Retrievability	Dimensionally Stable	Affordable	Sizeable Length		
	Correction Factor	1	1	0.9	0.8	0.7	0.5	0.5	0.5	0	0.1	0	0.2	0		
Loop	Multiwire Enclosure	7	-	6	8	7	10	10	-	N/A at this stage of device development	5	N/A at this stage of device development	7	Dependent on tubing and connection length (works for all)	35.6	
	Loop	9	-	8	10	5	10	10	-		2		10		39.9	
	Loop w/ suction	9	-	8	10	6	10	10	-		2		8		40.2	
	Snare w/ teeth	5	-	6	8	7	10	10	-		5		4		33	
Double Loop	9	-	9	10	7	10	10	-	3		9		42.1			
Trap	Net	5	-	10	6	10	10	10	-		10		6		38	
	Double loop w/ net	7	-	9	10	8	10	10	-		5		7		40.6	
	Dredge	6	-	8	5	10	10	10	-		10		6		36.4	
	1 loop/1 net	6	-	9	7	8	10	10	-		10		6		37.5	
	Cocoon (serrated)	2	-	5	3	5	5	1	-		2		5		16.6	
	Net w/ suction	5	-	10	6	10	10	10	-		10		6		38	
	Electromagnetic Net	2	-	4	10	7	10	10	-		5		3		29.6	
	Mold around object	0	-	3	10	4	1	1	-		4		3		15.5	
Rubber Gripper	4	-	6	6	6	5	2	-	6		3		23.1			
Open End	Claw (3-prong)	3	-	5	7	4	10	10	-		1		8		27.6	
	Free EM Strands	2	-	3	7	2	10	10	-		1		5		22.8	
	Magnetic Compression	0	-	2	6	1	10	4	-		0		3		14.9	
	ingshot w/ Magnetic Ho	4	-	0	2	1	10	0	-		0		3		11.9	
	Suction	10	-	8	10	6	10	10	-		2		10		41.6	
	Glue at tip	1	-	5	10	4	10	10	-		1		7		27.8	
	Forceps	9	-	9	3	6	10	10	-		1		8		35.4	
Dis-lodge	Shovel	10	-	-	-	-	-	-	-		-		10		12	
	Waterjet	10	-	-	-	-	-	-	-		-		10		12	
Puncture	Drywall anchor	6	-	6	10	4	10	10	-		1		7		33.7	
	Loop w/ puncture	6	-	8	10	5	10	10	-		1		8		36.4	
	Object puncture	3	-	4	10	4	10	10	-		1		8		29.1	
Interface Steering	4-finger string	5	10	-	-	-			5				7		18.9	
	Lever	8	5	-	-	-			6				8		17.6	
	Wrist Movement	7	10	-	-	-			8				7		22.4	
	Steering Wheel	:)	:)	-	-	-			:)				:)		22.5	
	Knobs	10	10	-	-	-			3				5		22.5	
	Joystick	8	10	-	-	-			10				7		24.4	
	Handle Steering	8	10	-	-	-			9				9		24.3	

**Figure 15:** Documented version of quantitative assessment performed in the second stage of brainstorming, shown in Appendix 3, Figure 13