

CONFIDENTIAL



Providing veterinarians with renewed confidence in endoscopic retrieval

Business Plan

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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.

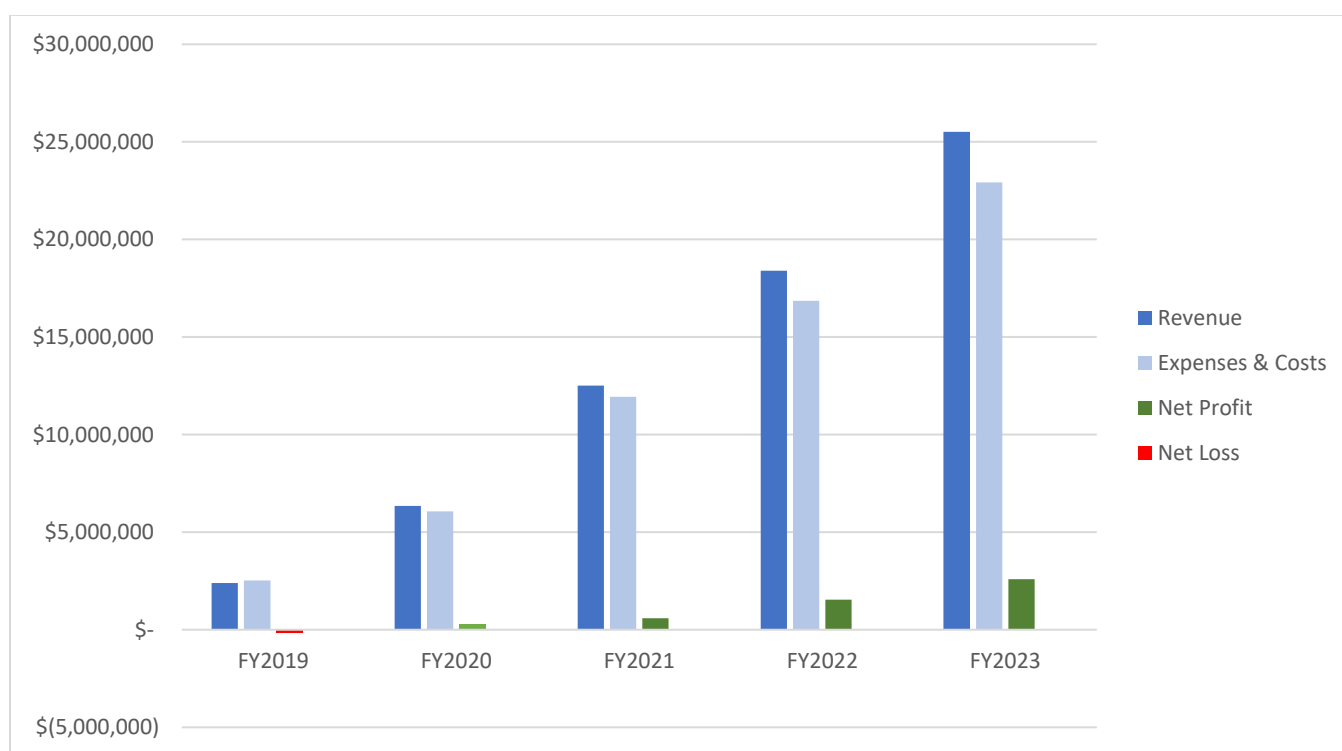
Expectations

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 Miami¹) 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 Stratasys' 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

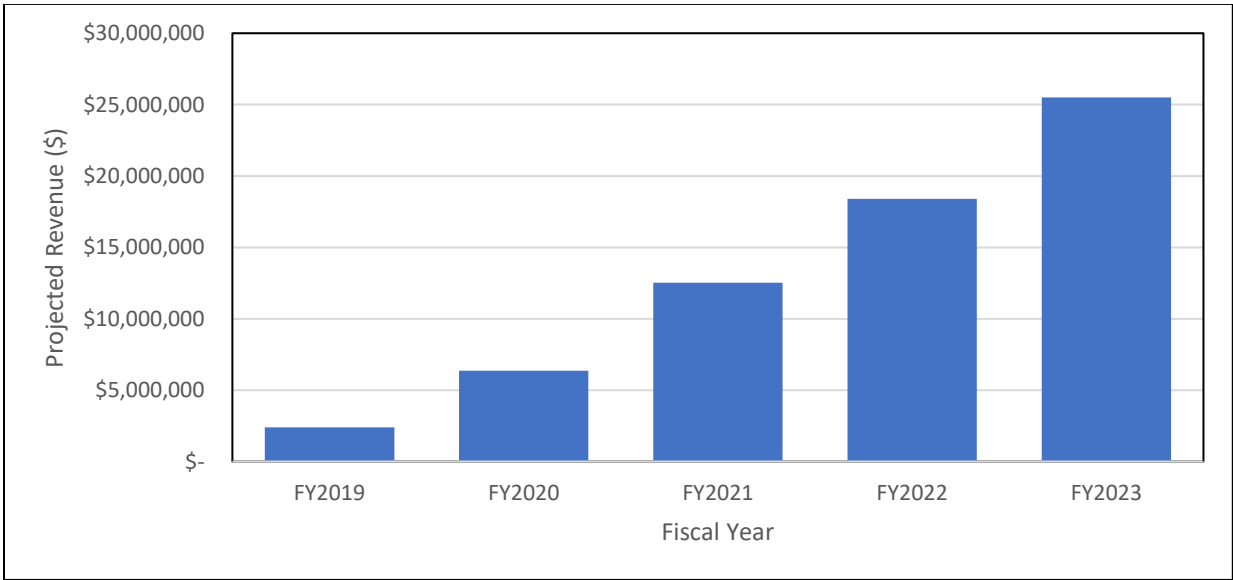
*Cost of Goods per unit (including material and labor):

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

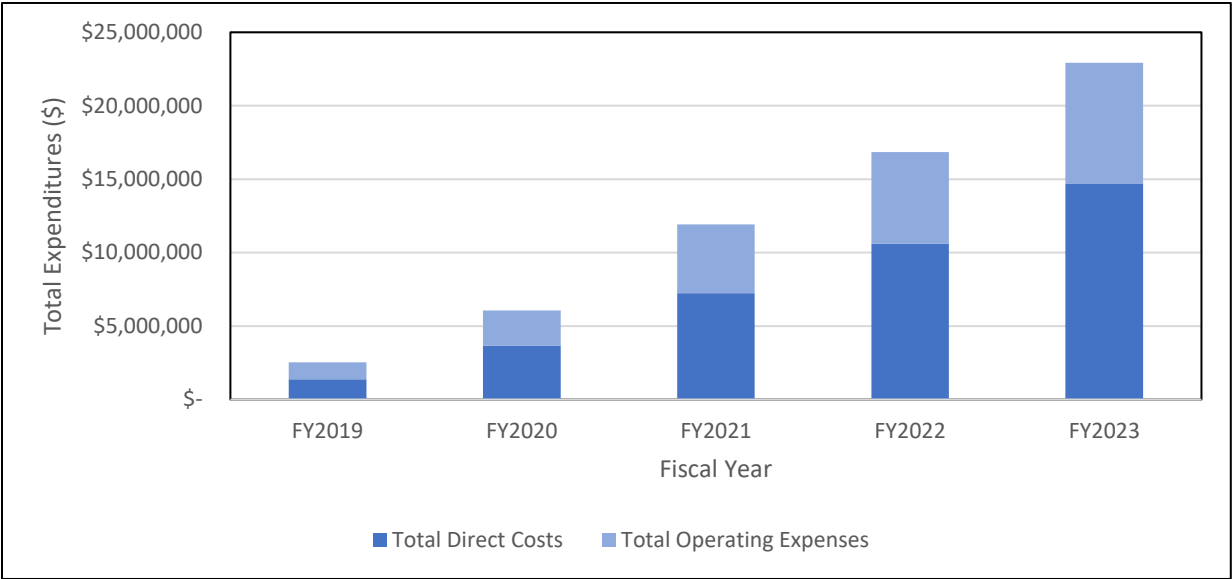
We understand that we will need to adjust our costs based on location and demand for our product. Once we understand the actual market we are working with, we can develop an average cost per device and a gross profit. From there we can refine our projections for revenue and expenses.

Revenue by Year

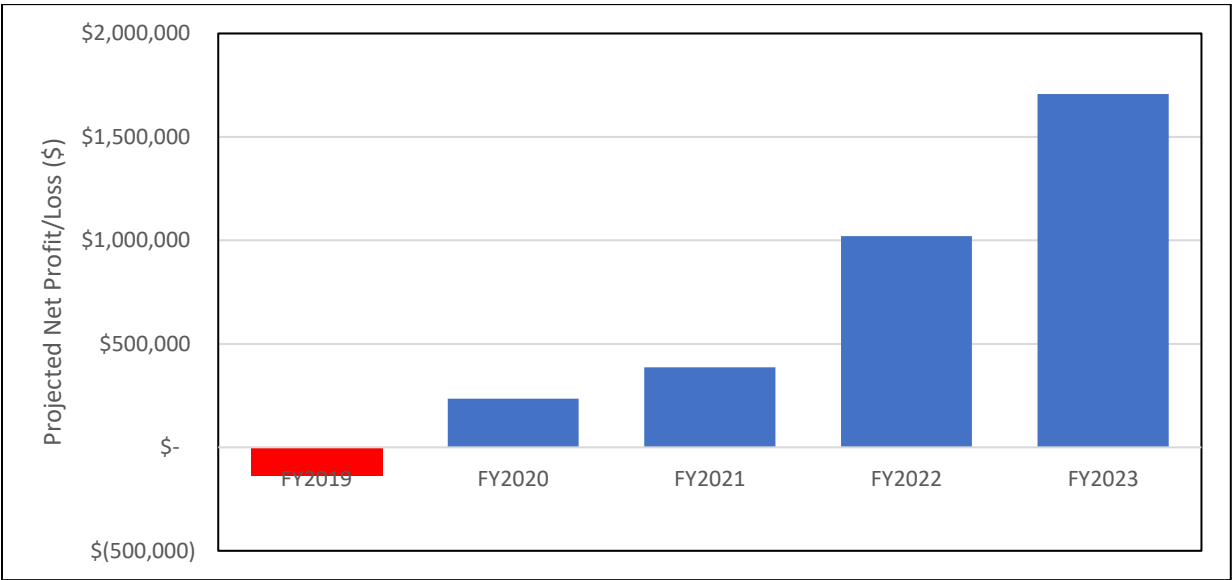
Revenue is projected on the basis that each veterinarian will purchase one (or two as a backup) user interfaces and approximately 149 tubing sets per year for all procedures at single-use. At each fiscal year, new veterinarians will buy into the user interface, but the tubing sets will be manufactured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

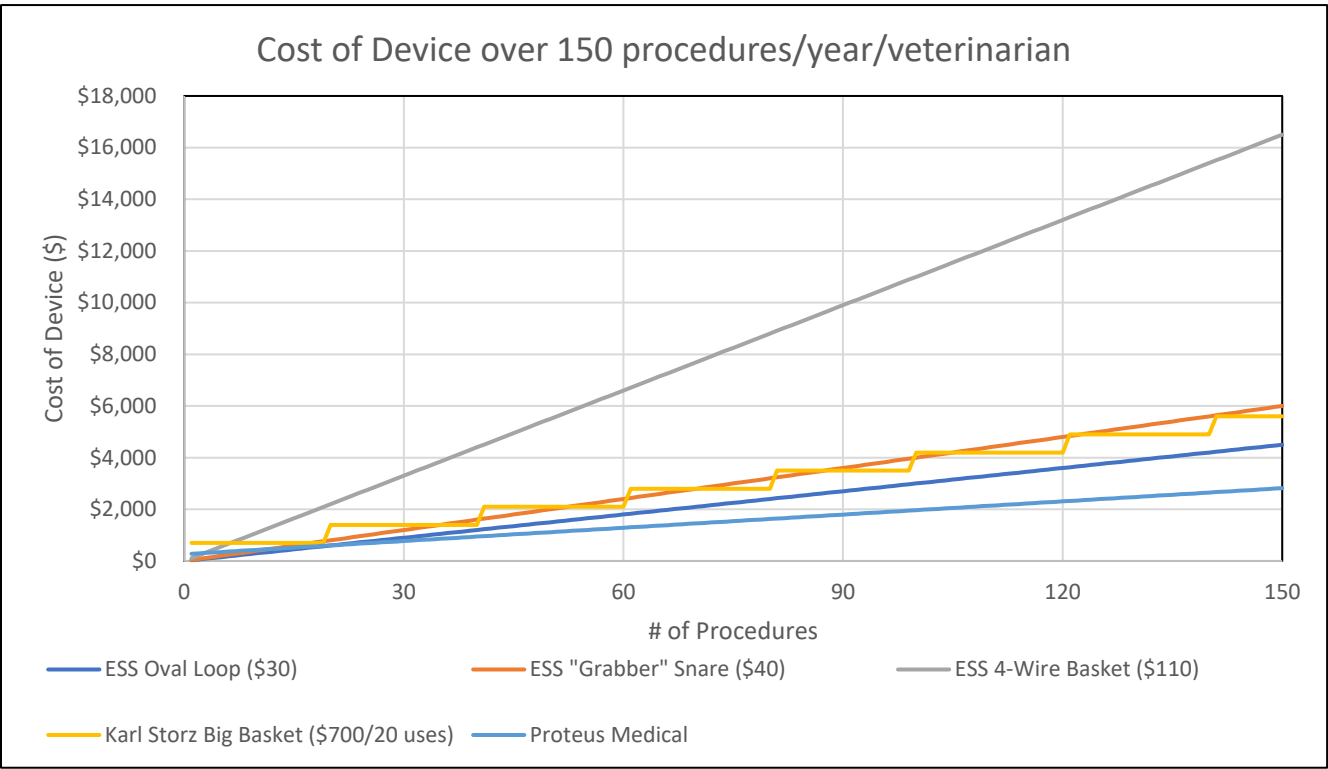
Financial Projections

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

Appendix

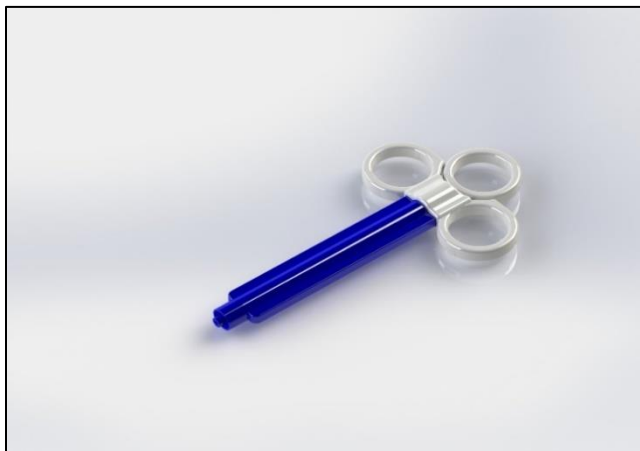
Price Comparison over 150 Procedures Annually



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

Prototype Development (over 5-month period)



Initial Prototype - PreCaptive:

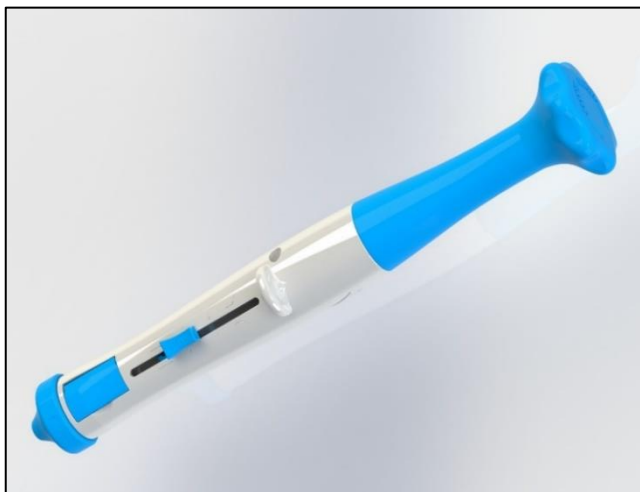
A simple proof-of-concept device that allows for a detachable tubing set without the affordances of steering. This device allows for a quick and cheap option to replace tubing sets with different retrieval heads that is deemed most effective to retrieve a specific foreign body.

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



Second Prototype - ProCaptive:

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 - OmniCaptive:

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.

