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DEVELOPMENT OF A SINGLE USE DEVICE INTENDED TO WASH BLOOD CLOT DEBRIS FROM A STENT RETRIEVER IN THE OPERATING ROOM

A thesis submitted to fulfill the requirements for the degree of Master of Science in Mechanical and Nuclear Engineering at Virginia Commonwealth University

by

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Abstract

DEVELOPMENT OF A SINGLE USE DEVICE INTENDED TO WASH BLOOD CLOT DEBRIS FROM A STENT RETRIEVER IN THE OPERATING ROOM

By Shane Diller, B.S. in Biomedical Engineering

A thesis submitted to fulfill the requirements for the degree of Master of Science in Mechanical and Nuclear Engineering at Virginia Commonwealth University

Virginia Commonwealth University, 2020

Advisor: Franklin Bost

Professor, Co-Director, VCU Institute for Engineering and Medicine

Ischemic stroke is a life-threatening condition that requires immediate surgical intervention to remove the blood clot that is lodged in the blood vessels of the brain. Mechanical thrombectomy, performed by an endovascular surgeon, involves inserting a stent retriever, which deploys distally and attempts to capture the clot when dragged backwards. A complication prevalent in 50% - 67% of cases is that the blood clot is only partially removed and clings to the mesh framework of the stent. The operating surgeon must either clean the debris from the stent retriever, to be reinserted or throw the stent retriever away and open a new one. At \$7,000 - \$10,000 per stent, most prefer to clean the stent retriever. For this paper, the terms “stent clot retriever”, “stent retriever” and “stent” will be interchanged for brevity.

The current method is to use a syringe of sterile saline to squirt the clot off of the stent retriever, but this is ineffective and time-consuming. Stent retrievers are often only 3-6mm in diameter and 40-60mm long, and so they are incredibly fragile. This project's objective was to create a method and medical device to:

1. Wash thrombus debris off of an arterial stent retriever
2. Reduce OR time in cleaning the stent retriever
3. Result in a cleaner stent retriever
4. Reduce the chances for stent retriever damage
5. Per manufacturer's IFU, allow the stent retriever to be used additional times for removing additional clot debris
6. Allow the thrombus to be collected for composition analysis

A device was successfully designed that satisfies the above criteria, and this paper will discuss the process of designing a physical product, exploration of manufacturing methods, evaluation of the prototypes, and the requirements in certifying a medical device.

1. Introduction

1.1 Background

Every year there are more than 795,000 people in the United States who have a stroke, and over 87%, approximately 691,000 of these are ischemic strokes (*Stroke Facts | Cdc.Gov*, 2020). Ischemic stroke is a condition that results from decreased blood flow to the brain, and while this can result from low blood pressure (hypotension), this is more traditionally due to a blood clot becoming lodged in the blood vessels of the brain, and blocking blood flow. Since 1995, the standard has been administering tissue plasminogen activator (tPA) but over 60% of patients treated this way do not regain functional independence (Saver et al., 2015). A newer form of treatment uses emergency surgical intervention by an endovascular surgeon to remove the blockage, known as a mechanical thrombectomy (Damani, 2018). This method requires first passing a guidewire through an incision in the wrist or abdomen to gain access to an artery, and navigating the guidewire to the blocked blood vessel via fluoroscopy. Then the surgeon uses the guidewire to pierce the blood clot, and passes a catheter over this wire, removing the guidewire, and inserting a stent retriever. The stent retriever is deployed distally to the insertion point and when dragged backwards, will capture the blood clot in the mesh of the stent, and pull it backwards through the catheter and out of the body (*Mechanical Thrombectomy | UPMC | Pittsburgh, PA*, n.d.). This procedure has become more common since the University of Pittsburgh Medicine (UPMC) published a journal in 2015 detailing the success rates of this procedure (Jovin & Chamorro et al., 2015). Since the publishing of the UPMC journal, the number of

mechanical thrombectomies increased, from 2% to 3% in 2016 and it is estimated that over 10% of patients presenting with ischemic stroke are eligible for this treatment (Hughes, 2017). Of the 691,000 ischemic stroke cases per year, that means 20,000 cases are being treated with mechanical thrombectomy but up to 69,000 could be performed each year.

1.2 Unmet Need

The first approved stent retrieval device was the Solitaire Flow Restoration Device, manufactured by Medtronic (Raychev & Saver, 2012). Since then, many other companies have created or repurposed stents into stent retrieval devices, but the 4 main manufacturers in the United States are Medtronic, Cerenovus/J&J, Penumbra and Stryker. Each of these medical device companies have a proprietary stent retrieval device and they can range from spiral stents, to intraluminal chamber stents, to hexagonal mesh, self deploying stents. These different morphologies are chosen by the endovascular surgeon based on physician preference. Due to the small diameter blood vessels in the brain, these stents are often only 4-5mm in diameter, and range from 24-40mm in length, and are often composed of a Nitinol or Stainless Steel mesh. Each may cost the hospital somewhere between \$7,000 and \$10,000, and this cost is passed to the patient, often at significant markup. Each stent comes in a sterile package and is approved for up to 3 passes, which means the stent can be removed, cleaned of debris, and then reinserted up to 2 times (*Solitaire X - AIS Revascularization Products* | Medtronic, 2019). In most surgeries, the retrieval of the blood clot is not immediately successful, known as First Pass Success.

There are many reasons that there is a low First Pass Success rate of only 25% and many problems that can arise when performing this procedure. For instance, the diameter of the blood vessel changes significantly along this 40mm path, from 2.2mm in diameter to around 1.2mm in diameter and the stent expands to accommodate this change (Nikoubashman Omid et al., 2019). As the stent is retrieved, it expands, and the blood clot may loosen and be lost. In addition, there is no tactile or mechanical feedback for the surgeon to know that the clot has been captured or lost by the stent. There has been increased First Pass Success by using a wider diameter stent, such as 6mm, but these must be peer reviewed to determine if there are other unintended consequences of using a larger stent, such as damage to the arterial wall due to increased radial force (Zaidat Osama O. et al., 2019). The blood clot itself is composed of fibrinogen and coagulated blood, which may tear or fragment while being retrieved. Since the surgeon has no method of knowing if the clot is tearing or has torn, the only indication is visual once the stent has been removed from the catheter. The surgeon then has to decide whether to clean the stent off and perform another pass or open a new stent package.

The current method for cleaning the stent off is by using a syringe to squirt sterile saline, which is time consuming and largely ineffective. The surgeon may have to try to physically touch the stent to remove the blood clot, but due to the small size and mesh structure, stents can be damaged and will not redeploy correctly. If the stent is damaged, a new stent must be opened. While there are multiple manufacturers of stents approved for use in mechanical thrombectomy in the United States, however there is no commercial device to clean the stent for reuse during the procedure.

A better way to clean these stents, and therefore reduce waste, is to create a device that can remove the thrombus from the stent, without requiring mechanical manipulation by the surgeon. Further, this device should aid in the rinsing syringe being able to collect the removed blood clot debris, as these samples are often sent off to a testing facility for composition testing.

1.3 Design Criteria

The following major design criteria was developed from interviews with Dr. Dennis Rivet, Associate professor, Department of Neurosurgery at VCU.

1. Accommodates stents from 4-6mm in diameter, 24-40mm in length
2. Uses sterile saline solution to remove the thrombus from the stent
3. Minimal leakage of the wash from the device
4. Minimize chances of damage to stent during cleaning procedure
5. Reduce time to clean the stent
6. Result in a cleaner stent
7. Allow thrombus debris to be collected for composition analysis
8. Sterile packaging of device for use in sterile OR field.

1.4 Project Aims and Goals

The aim of this project was to develop a medical device to remove blood clot debris from a stent retriever during a mechanical thrombectomy procedure. This will allow the stent to be reinserted multiple times, saving the expense of another \$7,000 to \$10,000 stent package. The following goals were established:

- A. Create a method, design and validate a prototype for functionality.

- B. Satisfy critical design criteria:
 - a. Ability to effectively clean all three stent clot retriever morphologies
 - b. Ease of use in sterile operating field
 - c. Economy in production of a single-use sterile packaged device
 - d. Operating of device takes 15 seconds or less
- C. Develop an alpha prototype that meets Technology Readiness Level 5
 - a. Evaluate in a simulated environment
- D. Prepare and submit engineering design document package and final report by November 30th, 2020.

1.5 Market Landscape

Stent retrievers were first approved by the Food and Drug Administration (FDA) in 2012, in the treatment of acute ischemic stroke, and it was predicted that over 60,000 mechanical thrombectomies would be performed per year by the end of the decade (*Cleveland Clinic Innovations - Top 10 Medical Inventions | Cleveland Clinic Innovations, 2016*). In 2016, 13,010 mechanical thrombectomies were performed in the United States, up 1.3% from the previous year (MacKenzie et al., 2020). The financial firm Jeffires estimated that the current mechanical thrombectomy market is valued at \$300 million and could reach as much as \$700 million by 2025 (*Mechanical Thrombectomy Market Poised to Double: Analysts | MedTech Dive, 2019*). Since the four main stent retriever manufacturers, Stryker, Cerenovous, Medtronic and Penumbra carry different morphologies of stents, it is important to create a single device that can be used on all.

1.6 Thesis Outline

The following chapters describe the approach to ideation, concept development, prototyping, testing and refinement of a solution to the problems stated above. Section 2 covers the early research of similar devices, and ideation of concepts that would satisfy the design criteria. Section 3 focuses heavily on initial prototypes generated and learning how to create prototypes for testing. Section 4 introduces refined prototypes and evaluation of these in testing, as well as exploration of manufacturing techniques. Section 5 describes the final design and costs associated with it. Section 6 details the process of receiving approval from the FDA and Section 7 is a discussion of the project in retrospect.

2. Ideation and Early Concepts:

2.1 Establishing Current Method used in the Surgery Suite

Due to COVID-19, clinical observations have not been permitted at MCV Hospital since early March 2020. This eliminated the opportunity to observe surgeries, using the current cleaning procedure. Instead, information in discussions with Dr. Dennis Rivet was used to guide established design criteria, human factors decisions, evaluation of alternative concepts, and direction of the final design solution. All of this information, as well as the progress of this project, has been maintained in a design notebook.

2.1.1 Current cleaning method with a 20mL syringe

The first round of testing was focused on establishing the method currently used in the operating field, of holding the stent retriever over a basin and spraying with a syringe containing sterile saline. For this test, a simple spring, from a ballpoint pen,

attached to a wire, was used to simulate the stent retriever, and ketchup used as a blood clot substitute as can be seen in Figure 1.

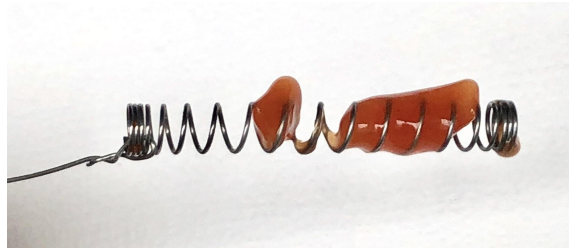


Fig. 1 - Rudimentary stent with ketchup clot

The results were promising but not conclusive. It was relatively easy to remove the ketchup from the spring using a stream of water, but ketchup is a poor substitute for a blood clot due to the lubricious qualities of ketchup. In addition, the spring directed the water sprayed from a syringe, down the body of the spring, which aided in removing ketchup.

2.1.2 Stationary syringe at different angles

The next phase of testing focused on how the ketchup responded to a syringe at a fixed position and angle. Three different positions were tested, as can be seen in Figures 2, 3 and 4.



Fig. 2 - Base test with a 20mL syringe perpendicular to the spring, squirting a jet of tap water at a ketchup clot.



Fig. 3 - Base test with a 20mL syringe angled at 45° to the spring, squirting a jet of tap water at a ketchup clot.



Fig. 4 - Base test with a 20mL syringe parallel to the spring, squirting a jet of tap water at a ketchup clot.

Position one was directly perpendicular to the long axis of the spring, as can be seen in Figure 2, and the stream of water was directed towards the midpoint of the ketchup “clot.” This position would remove a large amount of the ketchup, but a narrow stream was not effective at removing all of it. A wider stream, achieved by using a larger tip, 4 French (1.33mm) instead of 2 French (0.67mm), resulted in more ketchup being removed. The second position, seen in Figure 3 was still aimed at the midpoint of the ketchup “clot” but was angled at 45 degrees. This position was much more effective at removing the ketchup clot with a narrow stream as it directed the water stream closer to parallel to the long axis. The last position, seen in Figure 4, was directly parallel to the spring and pointed at the center of the clot, along the long axis. This position was the most effective, although it required a larger pressure at the beginning to get the clot moving. The limits of base testing had been reached.

2.2 Method Exploration

There are multiple methods for cleaning the stent retriever, and early work aimed to gather and compare these methods. Some were tested and some were only compared in theory.

2.2.1 Ultrasonic cleaner

Ultrasound cleaning devices used in a hospital setting are often large, expensive, and use chemical cleaning agents. A cheaper, smaller unit was purchased for trial testing and it was unable to remove a fake clot, consisting of jack fruit, from the tines of the stent retriever. A Medtronic Solitaire™ X stent retriever, donated by Dr. Rivet for testing purposes, can be seen in Figure 5.



Fig. 5 - Medtronic Solitaire™ X stent retriever received from Dr. Rivet for testing purposes.

For this experiment, jack fruit was purchased from a local grocery store and processed with a kitchen knife to try and create small fibers no longer than 1cm in length. Jackfruit is a very fibrous fruit that is used to simulate pork in vegan cooking. The fibrous qualities help simulate the fibrin and clotting effect of biological blood. The

loaded jackfruit stent retriever can be seen in Figure 6 and a still image of the stent retriever being washed by the ultrasonic cleaner can be seen in Figure 7. This concept was abandoned due to the failure to effectively clean the stent retriever using a low footprint ultrasonic machine.



Fig. 6 - Jackfruit loaded stent retriever for testing in the small Ultrasonic cleaner.



Fig. 7 - Ultrasonic cleaner dissolving some of the oils off of the jackfruit loaded stent retriever. This device was unable to detach the fibrous jackfruit from the tines.

2.2.2 Chemical debridement

Any amount of clot debris left can be a risk for reintroducing clotting factors that can cause complications. Chemical debridement was considered, as this would greatly increase the chances of removing not just visible clot debris, but even microscopic clot debris. However, any chemical debrider would require much more extensive clinical

evaluation, to prove the chemicals used do not adversely interact with biological tissues, and it was decided to not pursue this path.

2.2.3 Nozzle attachment for syringe

In the current method of cleaning, the saline is kept in a bowl, and the stent retriever is cleaned over top of this bowl, and sometimes submerged and shaken. An early concept was to create a nozzle attachment for a syringe that would have micromachined holes, and a series of one way valves and tubing could be used to draw saline from the bowl by continuously cycling the syringe. The micromachined holes would act similar to a shower head, turning one stream into multiple smaller streams, with a higher pressure. This method is still a viable method, but it does not aid in collecting the thrombus to be sent for analysis, and the saline in the bowl will have to be changed out after cleaning - adding to the time required.

2.2.4 Powered wash cycle

A method of using electrically powered motors to agitate a chamber of fluid was considered, but the requirements for certifying electronic devices require meeting multiple other standards such as IEC 60601-1+A1:2012 - Electrical Safety, and IEC 60601-1-2:2014 - Electromagnetic Capability (*Elvie Breast Pump 510k Summary*, 2018). These certifications come with significant price tags, and adds to the complexity of the device. For these reasons, a powered unit was not pursued.

2.2.5 Manual wash cycle

It was determined that creating the maximum turbulence inside a small chamber, via manpower, would be the method pursued. By limiting the internal volume of the

chamber, a standard 20mL syringe can be used. An agitated fluid can be created by rapidly cycling the plunger of the syringe in and out, which results in a pressure differential and moves the fluid over the stent retriever very rapidly. It is important to use less fluid than the chamber can hold, otherwise the fluid will not move rapidly.

2.3 Narrowing Concepts

A total of seven (7) concepts were generated that utilized a manual washing method. These concepts varied in use and design complexity. Four (4) would likely be more effective, but complex in overall cleaning, and potentially outside of the cost-constrained criteria. Three (3) simpler methods were explored to address cost restraint, and single-use criteria for this sterile product. Concepts that used small channels or small laser machined details fell into this category and were abandoned in favor of concepts that generated more flow via human interaction.

2.3.1 Environment considerations

Because the operation of this device is performed in a sterile field, great attention was taken to address the position and control of the 100cm tailwire coming off of the stent retriever. This tailwire is so long due to the incision site often being in the wrist or abdomen. The optimal orientation of this tailwire is lateral from the operator as this can be laid in the sterile field or held by an assistant. This would decrease the chance of the tailwire being stepped on or falling out of the sterile field.

2.3.2 Sterilization considerations

The device will be provided as a sterile, single use device. The sterilization method and material considerations were considered in tandem. The device would likely

be made out of a molded thermoplastic, as this is a cheaper product to produce for single use, and therefore the sterilization method must be appropriate for thermoplastics. The most common methods for sterilizing medical devices are Ethylene Oxide (EtO), Gamma Irradiation, and wet or dry steam autoclaving (*Plastics Compatability with Sterilization Methods* | ISM, n.d.). Steam can have adverse effects on dimensional accuracy of parts, and gamma irradiation can cause discoloration without additional stabilizers (Lagneaux, 2018). It was decided that Ethylene Oxide would be the most appropriate choice. The sterilization protocols will follow ISO 10993-7:2008 - Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals (*ISO 10993-7*, 2016).

2.3.3 Material considerations

The plastics used in this device need to be optically transparent in order to allow the operator to visually inspect the results of the washing cycle without opening the device. The plastics identified that are appropriate for this application in medical devices are polycarbonate and polypropylene. These thermoplastics have different material characteristics which will be discussed in Section 5 for final device considerations. For early ideation and research, it was important to identify what materials are appropriate to look up appropriate design guidelines.

2.3.4 Human Factors

In parallel with designing the engineering characteristics of a medical device, human factors, and ergonomics for the user cannot be overlooked (*Human Factors Considerations*, 2019). Because this device will be operated in a sterile field,

precautions must be taken to optimize the shape of the device and how it is used. When assessing human factors, it was determined:

- Curved shapes are secure and comfortable for the surgeon to hold
- Any rounded shapes need to have a flat side to prevent them from rolling off of the table and out of the sterile field
- The device should be able to be operated with two syringes and a single user
- The user's hands will be covered by surgical gloves, and often wet, which makes small parts difficult to grasp
- The syringe attachment angles should be positioned such that the user's arms are not fatigued or in an abnormal position when operating the device

These decisions were made with the help of sources describing the optimal sizes for handles in hand tools (Wang & Cai, 2017).

2.3.5 Top three concepts

The three concepts selected were:

1. Simple, single opening with a female Luer attachment for a male syringe
2. Double female Luer attachments around the perimeter for creation of an agitated saline chamber via dual male syringes and
3. Cone with drilled holes around the perimeter that could spray saline in multiple directions

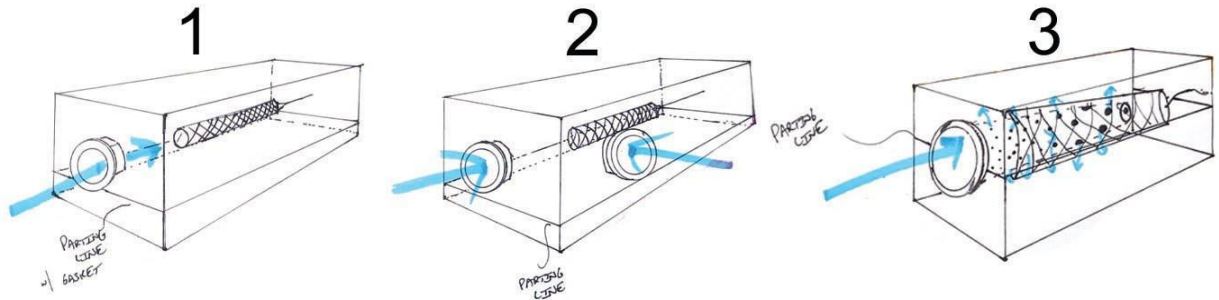


Fig. 8 - Sketches of three initial concepts for washing the blood clot off of the stent

As can be seen in Figure 9 the parting line for the top and bottom part is not on center, but rather above the Luer fittings, for ease of manufacturing. This created a potential problem in that the stent retriever would sit above the main jet of saline from the syringes, which was not accounted for in Figure 8. To account for this, and the different morphologies of the three stent retriever brands, more stress was put on creating maximum turbulence within the chamber. This method was determined to be the most likely to physically debride all three stent retriever morphologies.

3. Initial Prototypes

The purpose of this phase was to prototype the concepts selected, using store-bought materials, before moving to CAD models for proof-of-concept prototypes. The prototypes created using store-bought materials were critical in identifying potential design roadblocks and failures on the more expensive prototypes.

3.1 “Frankenstein” low fidelity prototypes

In order to test early concepts and assumptions, multiple “frankenstein” prototypes were created. These are called frankenstein prototypes due to the nature of buying off-the-shelf materials and components to assemble a low fidelity prototype.

Plastic, hinge top bead boxes were purchased from Amazon, and holes were drilled in the sides to accept the barrel of a female Luer, as can be seen in Figure 9.



Fig. 9 - Plastic, hinge top box drilled to accept female Luers.

Two different sizes of plastic boxes were purchased, one being 3.75cm x 3.75cm x 2.50cm deep, and the other being 5.50cm x 5.50cm x 2.50cm deep. The small box was discarded in favor of the larger bead box. In addition, a TicTac® box was purchased to test the effect of a longer, narrower box with a smaller lid.

Unfortunately, the snap-fit lid of the plastic boxes prevented a watertight seal, and these often leaked where the lid met the body. This is because these parts are only making face contact and there is not a high compressive force to create a seal. The small box was too small to fit a stent in, without damaging the stent itself. The TicTac® container was the most successful when taped closed. However, this method did not work when the stent retriever was placed inside, as a small gap was created by the lid not closing around the guidewire, creating a leak point. Without the stent, a rudimentary agitated water chamber was created and could be controlled via two syringes, as can be seen in Figure 10.



Fig. 10 - Agitated bubble chamber created from a Tic Tac® box. Note the water droplets still escaping around the top of the box where the tape is.

The lid being semi watertight but not airtight, allowed air to be pulled into the syringes, and then reintroduced into the chamber, which created bubbles, and agitated the water. However, the seal was not watertight enough to allow the water to agitate to the point of creating the turbulence desired.

3.1.1 Snap fit

Multiple products were purchased that incorporated various fastening methods. One method explored was that of a snap fit, which uses small teeth on one part, and recessed grooves on the other. The snap fit teeth are put under stress, perpendicular to their long axis, and deform as the two halves are brought together. Then, the snap fit tooth will mate into the recessed groove, bringing it back into an unstressed state, and keeping the two halves together as they are manipulated. To uncouple, the parts must be pried apart. Often these types of devices include a “thumbcatch” which is a physical groove or tab that can be used to create enough force to pull the tooth upward out of the groove. An example of a cross section of a snap fit case can be seen in Figure 11.

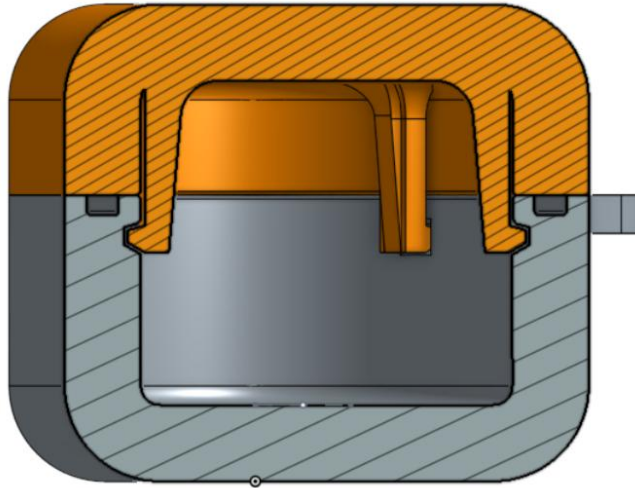


Fig. 11 - Cross section of a snap fit case in the closed position

This, and other snap fit cases served as inspiration for initial prototypes. While not part of this phase of the design, a solution to a two-part device would be to create a tether that attaches the lid to the body so it cannot be lost.

3.1.2 Bayonet mount

Another method of securing two parts together is to use a bayonet mount. Named after the method of securing a bayonet to a rifle in close quarters combat, this method consists of a pin and an L shaped slot, as can be seen in Figure 12.

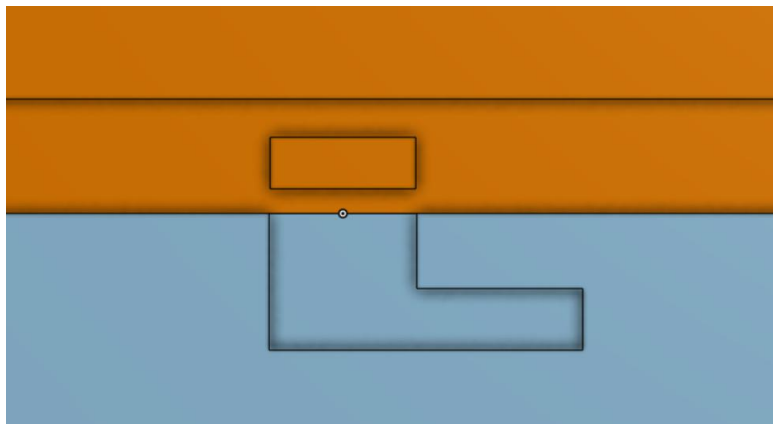


Fig. 12 - Example of bayonet mount pin and L slot

The two halves can only come together when the pin and the vertical part of the L slot are aligned. Then the two halves are twisted, the pin moving transversely along the short part of the L slot. Once twisted, the pin is trapped and cannot move upward, sealing the two halves together. While effective, the bayonet mount forced a round profile that was not rated well in human factors evaluation.

3.1.3 Fastener closure

There are multiple forms of waterproofing, known as Ingress Protection (IP) and electrical enclosures are most commonly covered by the ratings 65, 66, 67, and 68 (*IP Rated Enclosures Explained*, n.d.). For our purposes, an IP65 enclosure, known as “dust tight” and protected against moderate jets of water, from any angle, was purchased for study. The product photo for this enclosure can be seen in Figure 13 (*Junction Box, Zulkit Project Box IP65 Waterproof Dustproof ABS Plastic Electrical Boxes Enclosure Black 3.27 x 3.19 x 2.20 Inch (83 x 81 x 56mm)(Pack of 2) - - Amazon.Com*, n.d.).



Fig. 13 - IP65 Enclosure purchased off of Amazon.com

This enclosure used a channel groove, that a rubber cord or O-ring lays in, and screws that could be tightened to engage the rubber cord/O-ring with a plastic tooth. While this would be effective, the time required to close the device and seal it to IP65 using screws was well outside the range of desired operating time and would negate the value-added goal of the device in the Operating Room.

3.2 Sealing methods

It was decided to move in a direction that could allow a tight seal, using the channel groove and O-ring, without the need for fasteners. A small amount of leaking was deemed acceptable, and a snap fit method that had a high compressive force to engage a seated O-ring was pursued. This is also known as a flange or face seal o-ring design.

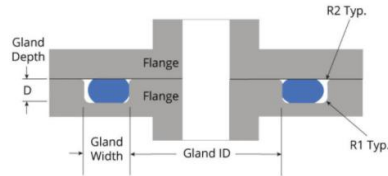
3.2.1 O-ring design guidelines

The AS568 standard, published by the Society of Automotive Engineers, was followed in selecting a nominal thickness of o-ring. To minimize wall thickness in plastic injection molding, and due to the relatively low pressure in the chamber, a 50A durometer, 0.070in. o-ring was selected.

3.2.2 Design specifications

When designing the channel that this rubber cord would sit in, the width of the channel was set at 0.084" and the height of the channel at 0.052in. according to the table published by Global O-ring and Seal (*O-Ring Groove Design*, n.d.). The table can be seen in Figure 14. The corners of the channel were given a slight radius, 0.005" at the top of the channel and 0.010" at the bottom, to create a better seal with the O-ring

as the lid compresses the cord. A cross-section view of the designed channel can be seen in Figure 15.



AS568 Series	O-Ring Cross-Section		Gland Depth (D)	Squeeze		Gland Width (W) Liquids		Gland Width (W) Vacuum & Gases		Gland Corner Radii	
	Nominal	TOL (+/-)		Actual	Percent	Nominal	TOL (+/-)	Nominal	TOL (+/-)	R1	R2
-0XX	0.070	0.003	.055-.057	.010-.018	15%-25%	0.103	0.002	0.084	0.003	0.010	0.005
-1XX	0.103	0.004	.088-.090	.010-.018	10%-17%	0.140	0.003	0.121	0.003	0.010	0.005
-2XX	0.139	0.004	.121-.123	.012-.022	9%-16%	0.180	0.003	0.160	0.003	0.018	0.005
-3XX	0.210	0.005	.185-.188	.017-.030	8%-14%	0.280	0.003	0.240	0.003	0.028	0.005
-4XX	0.275	0.006	.237-.240	.029-.044	11%-16%	0.352	0.003	0.310	0.003	0.028	0.005

Fig. 14 - Table used to design flange O-ring seal

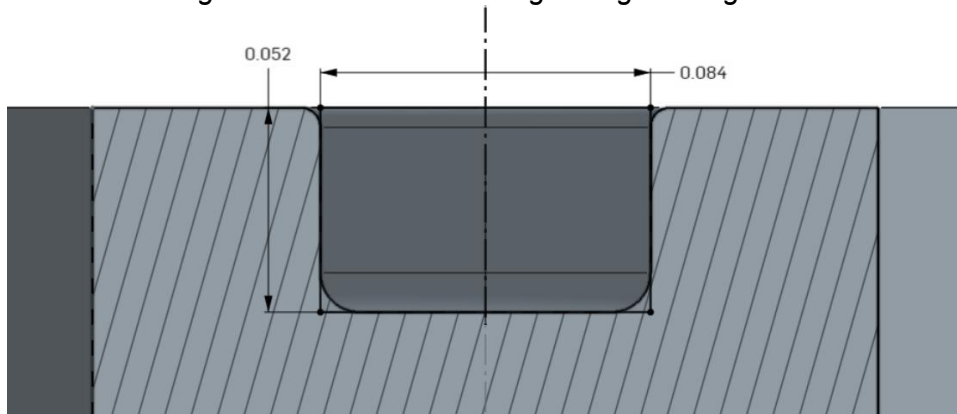


Fig. 15 - O ring channel design

3.2.3 Effect of geometry on seal capability

As discovered in testing the square plastic bead boxes, a square profile has problems in creating a watertight seal. Because a tight seal is required for this device, the force required to separate the top from the bottom should be high, making it difficult

to separate without a physical catch. For this reason, a large thumbcatch was added to the top and bottom to aid in opening the device.

3.3 FDM (Fused Deposition Modeling) Prototypes

3.3.1 CAD generated prototype designs

All prototypes were designed in the Onshape® CAD software. After the solid top and bottom parts were generated and the parting line added, the two parts were shelled with a 0.200in. thickness for ease in 3D printing.

To evaluate human factors in using the device, CAD prototypes were generated with holes surrounding the perimeter. Multiple access holes were created to evaluate washing angles from different locations. These holes were created to accept a ¼in.-28 threaded panel mount female Luer fitting purchased from McMaster Carr (*McMaster-Carr SKU 51525K317*, 2020). A hex nut can be used to tighten down to the wall of the device, and each has a female Luer and male Luer cap. Each device used in testing had Luer parts installed in all holes, and then the user could uncap the Luers they wished to use for testing. This configuration was chosen because it allows testing the attachment of syringes in multiple configurations. This can be used to collect data from users on which configurations feel the most comfortable, ergonomically.

The inside edge of the top was used as the reference point to create snap-fit teeth. When designing a snap-fit enclosure, there are specific guidelines that must be followed. The number of snaps, the depth of the snap, the leading, and receding angles will all affect the force required to close and open the device. There are many sources for design guidelines, but the one chosen was “Snap-Fit Joints for Plastic - A Design Guide” published by MIT in partnership with Bayer Sciences (*Snap-Fit Joints for Plastics*

- *A Design Guide*, n.d.). Because the snap-fit teeth are meant to interfere and deflect with the bottom of the device, these were made into a cantilevered beam to reduce the likelihood of shearing of the snap-fit teeth. In total, two models were created, one with six snap-fit teeth and one with four. The dimensions used to generate the snap fit teeth can be seen in Figure 16. The guidelines recommended a 2mm (0.079in.) depth for a secure fit but as that is more than half of the chosen wall thickness, a shallower depth of 1.14mm (0.045in.) was used on the prototypes. These were given a draft of 3 degrees to form a cantilevered beam, allowing it to better flex under load.

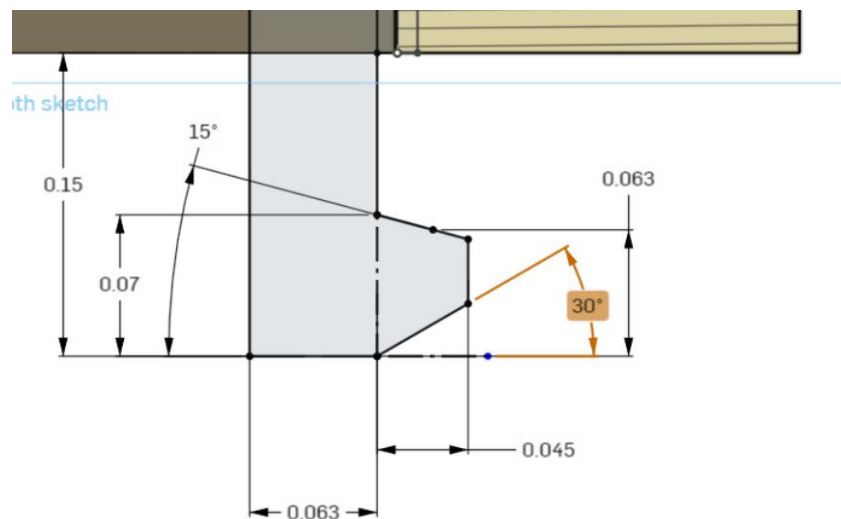


Fig. 16 - Dimensions of the snap fit tooth

To further reduce the stress in the snap-fit teeth, and prevent failure, it is recommended that small fillets are added to the point at which the snap-fit tooth body meets the part it is protruding out of. Due to the low tolerance of 3D printing and reduced part strength, a 0.100in. fillet was added to these parts, as can be seen in Figure 17.

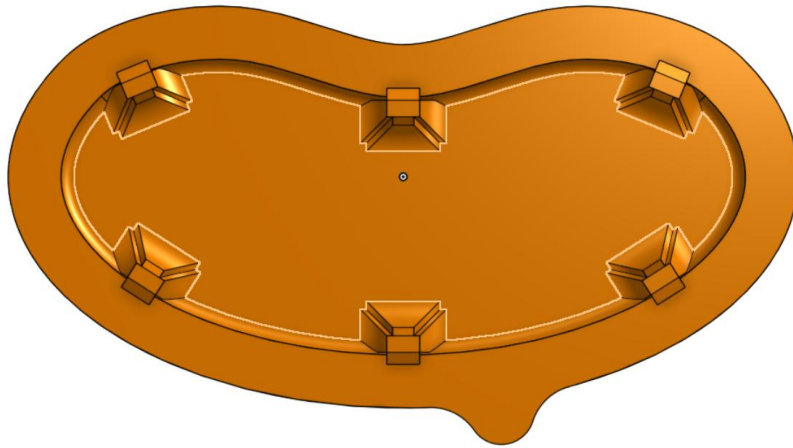


Fig. 17 - 0.100in. fillets applied to snap fit teeth to reduce stress

Additionally, the leading edge of the device bottom that interacts with the snap-fit tooth was given a chamfer of 0.010in. to help ease the transition when closing the device.

The hole was 0.010in. taller than the snap-fit tooth and 0.030in. wider, as can be seen in Figure 18.

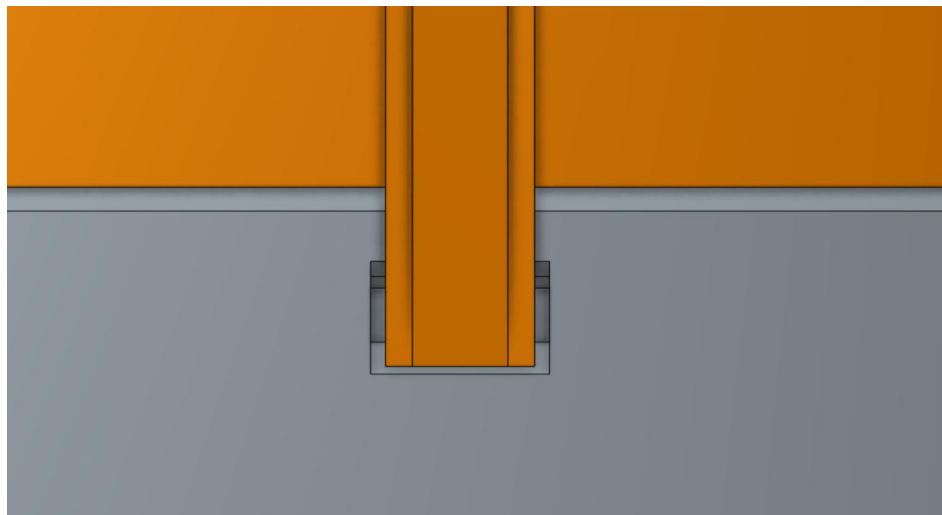


Fig. 18 - Snap fit tooth in hole. Hole was made larger to account for tolerances in 3D printing.

3.3.2 Initial results

CAD files were 3D printed on an Up! Plus 2 machine, using the following settings in Table 1:

Layer height	Infill	Support	Raft	Material	Speed
0.15mm	80%	yes	yes	Tiertime ABS	Slow

Table 1 - Settings used to print the initial CAD prototypes.

The print orientation directly affected the strength of the snap fit teeth. This is due to the technology behind 3D printing, known as Fused Deposition Modeling, which “prints” the physical model by heating up and extruding a 1.75mm ABS filament through a 0.4mm nozzle to create small layers. The print is built layer by layer, with each layer of molten plastic adhering to the lower layer as it cools (*How FDM/FFF 3D Printing Technology Works?* - MANUFACTUR3D, 2018).

The snap fit teeth broke off when the two parts were pressed together in initial prototypes. Upon further inspection, it was determined that the 3D printing orientation partially played a role in this weakening of the snap fit teeth. The parts were oriented in the 3D printing software to minimize the support material needed, and thus the snap fit teeth were composed of multiple layers that were oriented in the wrong direction to withstand shear forces as can be seen in Figure 19.

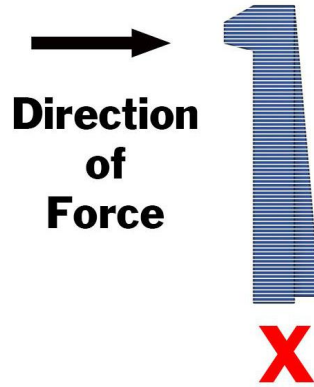


Fig. 19 - Snap fit tooth oriented the wrong way. Print lines dramatized to show how part will shear under load

The adhesion between layers is the weakest point of the print and when oriented parallel to the direction of force, these 3D printed parts would shear off as opposed to flexing. These can be thought of macroscopic slip planes and plastic deformation occurs when the bond is broken between slip planes, resulting in shear.

3.3.3 Print orientation optimization

The strongest part was generated when the part was rotated 90 degrees on the build platform, as can be seen in Figure 20.

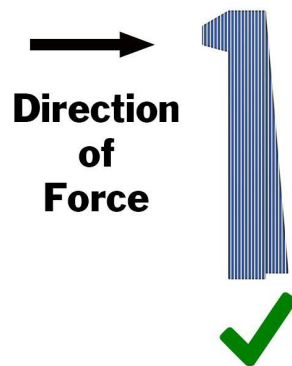


Fig. 20 - Snap fit tooth oriented to make it stronger. Print lines dramatized to show how this print orientation results in a much stronger part.

This is because the direction of force was perpendicular to the slip plane, allowing the snap fit tooth to flex (*3D Printed Joinery: Simplifying Assembly*, n.d.).

3.3.4 Second round testing results

The correctly oriented 3D prints performed well in testing the ability to continuously open and close the device. The snap fit teeth did not shear off, and the lid was not trivial to remove without the physical thumb catches. These dimensions for the snap fit teeth were copied into the three shape concepts discussed below.

3.3.5 Top three concepts

With the information obtained from these initial tests, the decision was made to move into proof-of-concept prototyping. The 3D models were designed to be reasonably watertight, ergonomic, and capable of being closed and opened without tools.

The first problem addressed was that of the watertight seal, as it would affect the rest of the physical shape. To create a tight seal, that is semi watertight, equal pressure must be exerted around all sides of the device. Curved shapes and cylindrical shapes are much better at this and so each concept was given a curved shape. The egg-shaped design is the most promising in theory but may fail in testing due to other human factor issues.

Three shapes were selected based on human factors in handling, one representing a kidney bean, the second a peanut, and the third an egg shape. Sketches of these designs can be seen in Figures 21, 22 and 23. Ultimately it was decided to increase the size of the device to 3.5in. wide for a better fit in hand.

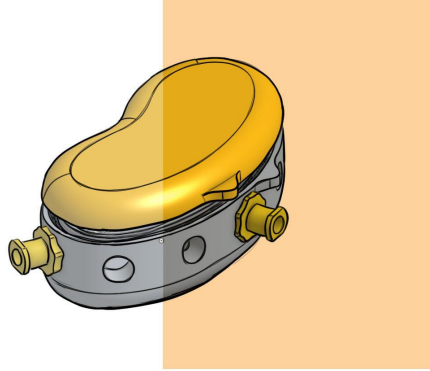


Fig. 21 - Kidney bean shaped concept for the stent washing chamber

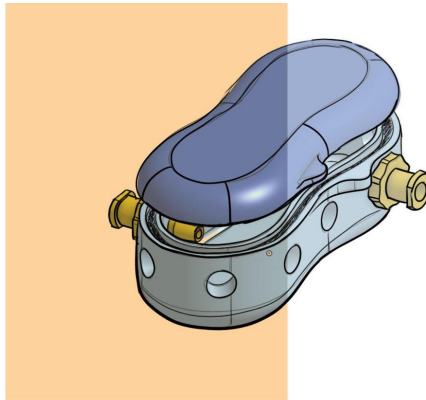


Fig. 22 - Peanut shaped concept for the stent washing chamber

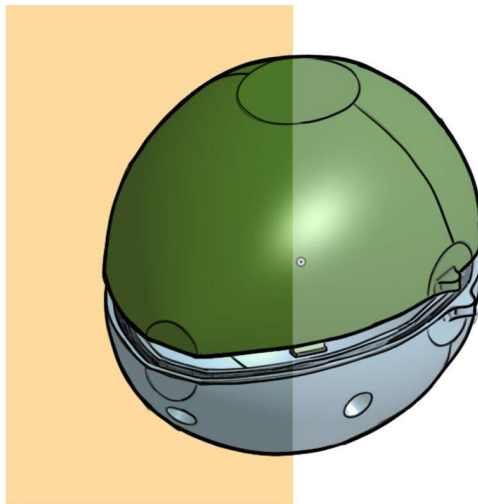


Fig. 23 - Egg-shaped concept for the stent washing chamber

3.4 Clear Resin Prototype Models

To simulate Polycarbonate, the prototypes were printed on a Formlabs Form2 3D printer using the CLEAR FLGPCL04 resin. The material properties of this resin, post cured, compared to those of Polycarbonate can be found in Table 2.

Material property	Form2 Clear FLGPCL04 resin	Polycarbonate
Ultimate Tensile Strength	65MPa	61 - 69MPa
Tensile Modulus	2.8GPa	2.2 - 2.5GPa
Elongation at Break	6%	50% - 120%
Flexural Modulus	2.2GPa	2.2 - 2.5GPa
Density	1.15 - 1.20g/cm ³	1.20–1.22 g/cm ³

Table 2 - Comparison of Polycarbonate and Formlabs clear resin mechanical properties. (Materials Data Sheet Photopolymer Resin for Form 1+ and Form 2, 2019) (Polycarbonate (PC) Plastic, 2018)

These parts were post processed to try and improve the optical qualities for testing, using 1000 grit sandpaper and a clear coat of Krylon Lacquer Specialty Gloss Clear Spray. As can be seen in Figure 24, this did improve the optical qualities.



Fig 24 - Transparent clear resin prototype of Kidney bean top

The Luer components and the port openings were coated in an E6000 rubber-based adhesive, left to dry for 2 minutes each, and then mated together. A small straw was used to clear the Luer port of any adhesive. These were allowed to cure for 24 hours before testing.

3.4.1 Fruit model testing protocol

The protocol that was used to determine the effectiveness of the position, angle, and container shape on physically debriding the clot, was to weigh the simulated clot, plus stent retriever, before and after debridement. The stent retriever was deployed to a length of 40mm and then covered in water, to pre-wet the tines. The stent retriever was weighed wet because post washing, any remaining fake clot and the stent will be saturated with water. The fake clot was then applied along the tines of the stent and inside the stent retriever, and then the stent retriever was reweighed, and weights were recorded. The kidney bean and peanut shape each received a total of 15mL of tap water via syringes. The syringes were then cycled, alternating pushing and pulling to agitate the liquid in the chamber, for 10s. The egg received 20mL due to the larger internal volume. After physical debridement, using room temperature tap water, the position of the ports were noted and then the stent retriever was reweighed. This

difference in weight before and afterwards was used to assess what percentage of the fake clot was washed away.

3.4.2 Fruit model testing

Jackfruit was prepared according to the protocol and inserted into the lumen of the stent retriever. The stent on average weighed 0.10g when wet. Every combination of ports was tested, across all three forms and assigned a rating between 1 and 10 (1 being the worst, 10 being the best) based on visual inspection of jackfruit clot removal. In addition to testing dual syringes, each port was tested individually as well. A visual image of the port numbering can be seen in Figure 25.

Any port location with a 9 or better rating was moved into a second round of testing to compare the three forms against one another. It should be noted that none of the Egg port locations received above a 4 but those with a 4 moved onward.

The second round of testing consisted of repeatedly testing each port location using the fruit testing protocol above. Each was weighed before and after washing for 10s. During washing, the device was angled so that gravity would aid in bringing water back to the entry port of the syringes. This allowed the water to be better agitated, as more water was drawn back into the syringe when reversing the plunger. Each port location was tested a total of three times and the results were averaged.

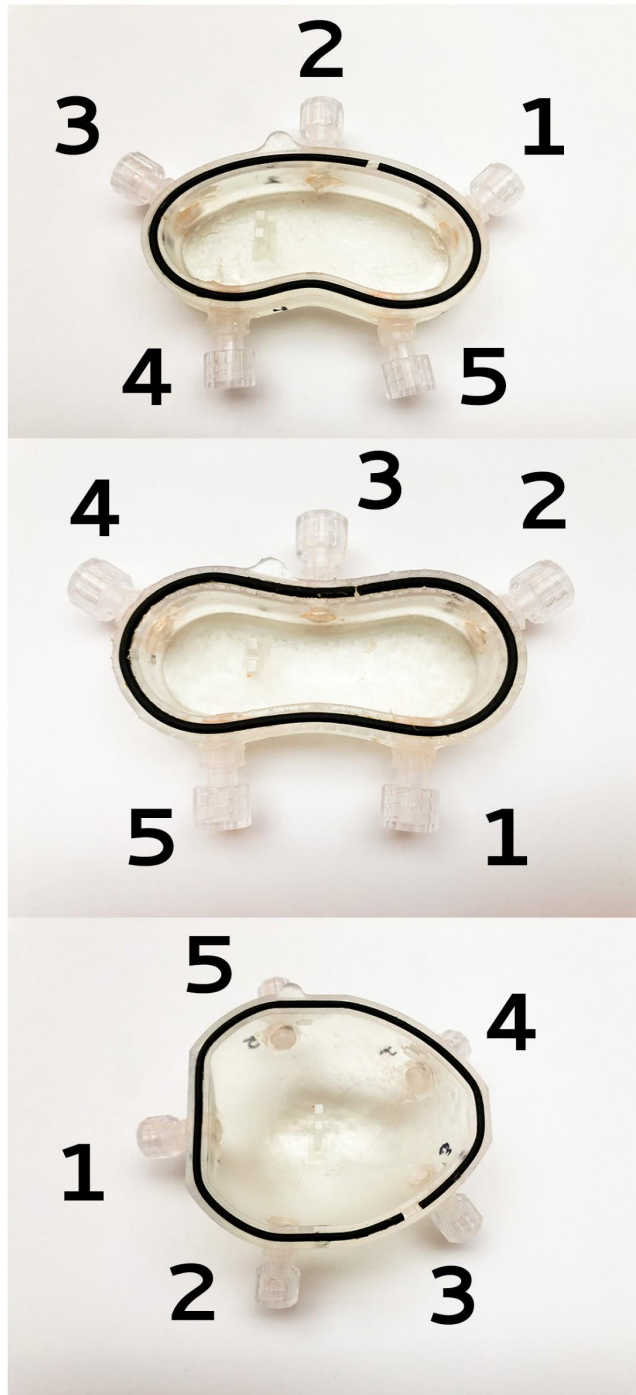


Fig. 25 - Port locations and numbering of clear resin prototypes

3.4.3 Evaluation results

The results of the first round of testing can be seen in Table 3, 4 and 5. The second testing results can be seen in Table 6, 7 and 8.

Kidney Bean shape initial tests					
Port used (1-5)	Port used (1-5)	Volume used	Time washed	Cleaning Rating (1-10)	Comments
1		15mL	10s	1	Barely hit the stent at all
3	5	15mL	10s	1	Awkward to hold
1	2	15mL	10s	2	
3	4	15mL	10s	2	Water lost velocity quickly
4	5	15mL	10s	2	Stent pushed into wall
1	4	15mL	10s	3	
2	3	15mL	10s	3	
1	3	15mL	10s	4	
4		15mL	10s	4	Not effective
2		15mL	10s	6	
5		15mL	10s	6	
2	4	15mL	10s	7	Required a shake to dislodge
3		15mL	10s	7	
1	5	15mL	10s	9	Very strong removal
2	5	15mL	10s	9	Very quickly removed clot

Table 3 - Initial observations of the Kidney bean shaped prototype in testing

As can be seen, the Kidney Bean shape had two port combinations that were incredibly effective at removing the simulated clot.

Peanut shape initial tests					
Port used (1-5)	Port used (1-5)	Volume used	Time washed	Cleaning Rating (1-10)	Comments
1	4	15mL	10s	1	Awkward
1	5	15mL	10s	2	Pushed stent into wall
2	4	15mL	10s	2	Very awkward
3	5	15mL	10s	4	Very awkward hand position
2	5	15mL	10s	5	Not aimed at the stent
2	3	15mL	10s	5	Awkward
3	4	15mL	10s	5	Too far away from clot
4		15mL	10s	5	
4	5	15mL	10s	6	Awkward to hold
1	3	15mL	10s	7	
2		15mL	10s	7	Pushed blood clot down stent
5		15mL	10s	7	
1		15mL	10s	9	Very effective
1	2	15mL	10s	9	
3		15mL	10s	9	Pulverised it very well

Table 4 - Initial observations of the Peanut shaped prototype in testing

The peanut shape had three winning combinations that moved onto the final round. The single syringe testing was effective using these ports due to the narrow midsection of the peanut which helped channel the fluid into the stent retriever. However, the peanut shape was difficult to shut due to the torturous path of the curved shape. The symmetric nature of the shape also makes it easy to reverse the alignment of the lid, snapping off some of the snap fit teeth. If this shape were to move on, alignment features would have to be built into the model.

Egg shape initial tests					
Port used (1-5)	Port used (1-5)	Volume used	Time washed	Cleaning Rating (1-10)	Comment
1	2	20mL	10s	1	Missed the stent
1	4	20mL	10s	1	
1	3	20mL	10s	1	Very awkward to hold
1	5	20mL	10s	1	Very little debridement
2		20mL	10s	1	Missed the stent
2	5	20mL	10s	1	Awkward hand position
3	5	20mL	10s	1	
5		20mL	10s	1	
1		20mL	10s	2	Port right below tailwire
2	4	20mL	10s	2	No turbulence
3	4	20mL	10s	2	
4	5	20mL	10s	2	
4		20mL	10s	3	
3		20mL	10s	4	Not enough turbulence
2	3	20mL	10s	4	Very little debridement

Table 5 - Initial observations of the Egg shaped prototype in testing

The egg shape performed the worst out of all three shapes. The internal volume was too great, making it difficult to create turbulent flow that would wash over the stent. In addition, the curved shape of the egg, and setting luer fittings tangent to this curve, made the human factors awkward. The hands were positioned in a way that made it difficult to cycle the syringes.

Kidney Bean shape final tests						
Port used (1-5)	Port used (1-5)	Volume used	Time washed	Before wt (g)	After wt (g)	% Removed
1	5	15mL	10s	0.2	0.09	55.00%
1	5	15mL	10s	0.14	0.02	85.71%
1	5	15mL	10s	0.23	0.03	86.96%
1	5	15mL	10s	0.16	0.02	87.50%
					Avg	78.79%
2	5	15mL	10s	0.19	0.04	78.95%
2	5	15mL	10s	0.25	0.02	92.00%
2	5	15mL	10s	0.19	0.02	89.47%
2	5	15mL	10s	0.23	0.05	78.26%
					Avg	84.67%

Table 6 - Averaged values in removing simulated clot material in the Kidney Bean shape

Peanut shape final tests						
Port used (1-5)	Port used (1-5)	Volume used	Time washed	Before wt (g)	After wt (g)	% Removed
1		15mL	10s	0.18	0.06	66.67%
1		15mL	10s	0.2	0.12	40.00%
1		15mL	10s	0.18	0.08	55.56%
1		15mL	10s	0.21	0.14	33.33%
					Avg	48.89%
1	2	15mL	10s	0.16	0.05	68.75%
1	2	15mL	10s	0.16	0.03	81.25%
1	2	15mL	10s	0.26	0.15	42.31%
1	2	15mL	10s	0.25	0.11	56.00%
					Avg	62.08%
3		15mL	10s	0.25	0.03	88.00%
3		15mL	10s	0.23	0.04	82.61%
3		15mL	10s	0.23	0.07	69.57%
3		15mL	10s	0.24	0.08	66.67%
					Avg	76.71%

Table 7 - Averaged values in removing simulated clot material in the Peanut shape

Egg shape final tests						
Port used (1-5)	Port used (1-5)	Volume used	Time washed	Before wt (g)	After wt (g)	% Cleaned
3		20mL	10s	0.15	0.09	40.00%
3		20mL	10s	0.18	0.09	50.00%
3		20mL	10s	0.25	0.17	32.00%
3		20mL	10s	0.21	0.17	19.05%
3		20mL	10s	0.18	0.14	22.22%
					Avg	30.82%
2	3	20mL	10s	0.2	0.15	25.00%
2	3	20mL	10s	0.16	0.1	37.50%
2	3	20mL	10s	0.16	0.08	50.00%
2	3	20mL	10s	0.14	0.09	35.71%
2	3	20mL	10s	0.22	0.16	27.27%
					Avg	37.62%

Table 8 - Averaged values in removing simulated clot material in the Egg shape

Port location combinations 2 and 5, and 1 and 5 of the kidney bean were experimentally determined to produce the greatest effect in washing the fake clot from the stent retriever. Port locations that were behind the stent retriever often failed to create enough turbulence and velocity to remove clot material. Dual syringe port locations that were on the same side of the device were awkward to hold and cycle, especially when trying to angle the device to let gravity assist in backwash. Using a single port location was effective, but only when the water stream entered transverse to the long axis of the stent retriever. When the water stream was aligned with the long axis, it often pushed the jackfruit down the lumen of the stent. Due to the higher effectiveness, and acceptable human factors, the Kidney Bean shape was selected as the geometry to be used in the final design.

4. Final Design considerations

4.1 Snap fit to living hinge

There were multiple reasons for moving from a snap fit enclosure, consisting of two separate parts, to an integrated living hinge. Number one among these though was the need to quickly assemble the device. In testing the clear resin prototypes, assembly of the unit took over ten seconds. It was decided that the living hinge would provide better alignment and one handed closing.

4.1.1 Living hinge standards

Examples of living hinges can be found on plastic products inside almost every American household. Shampoo bottles, condiment bottles, toothpaste tubes - and many more devices where the cap is meant to stay attached to the body. The living hinge is a well established design, and there are multiple sources for industry standard guidelines to designing one for plastic injection molding. Some examples of living hinges can be seen in Figure 26.



Fig. 26 - Living hinge on a vinegar bottle that keeps the lid attached

A helpful graphic, with approximate dimensions for the living hinge, was published by ProtoLabs in a recent blog article (*Living Hinge Basics for Injection Molding*, 2017). A

cross section of the living hinge designed, to be prototyped via Material Jet Fusion, can be seen in Figure 27.

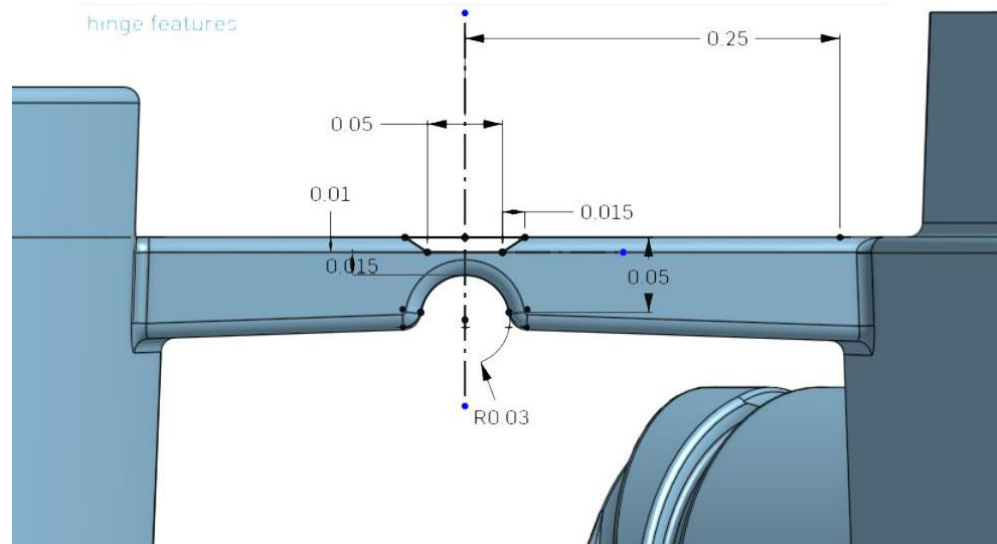


Fig. 27 - Cross section of living hinge

4.1.2 Shortcomings of the snap fit device

The snap fit enclosure was unable to provide a strong enough compressive force on the o-ring to create a watertight seal during testing. Referencing published tables, the 50A durometer requires approximately 6.6lbs per linear inch of force to compress the 0.070in. O-ring enough to create a face seal (*How Much Force Is Needed to Compress Static Axial Seals and Gaskets? | Hot Topics, 2013*). The snap fit enclosure used 7.2in. of rubber cord, so the approximate force needed to seal the chamber was 47.52lbs. The snap fit teeth, as designed, were not able to provide such a compressive force.

4.1.3 Living hinge material considerations

Living hinge parts are recommended to be made of polypropylene as they are more capable of withstanding flexure and not warping when coming out of the mold

after plastic injection. While not as optically transparent as polycarbonate, this is still an acceptable material for this device.

4.2 Annular snap fit

Although a softer o-ring could be tested, it was decided to change from individual snap fit teeth to an annular snap fit ring that could provide a physical barrier to water escaping the chamber. This ultimately could result in removing the need for an o-ring, reducing part cost, and assembly cost. For these reasons, the snap fit teeth were abandoned. Instead, an annular snap fit ring was modeled and prototyped via Material Jet Fusion. A cross section can be seen in Figure 28.

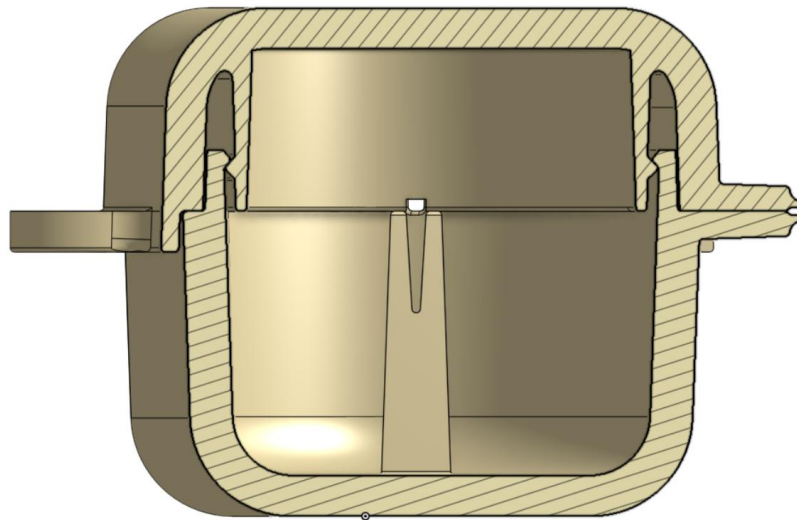


Fig. 28 - Cross section of annular snap fit ring

This snap fit ring encounters interference as the top ring slides across the bottom ring as the device is being closed. The first prototype was easy to close but did not perform well in keeping water in when the device was filled and tilted. This is likely due to the resting position of the two rings having a small gap of 0.002" to reduce stress on the part. It was decided to change the design so in the resting position, a small amount

of interference would be maintained between the two annular rings in order to create a better seal.

4.3 Reduced stress on tailwire

One concern raised by Dr. Rivet when examining the clear resin prototypes was that the stress put on the tailwire may create a kink, or at the very least the perception of one. If the tailwire is deformed, this can cause problems when redeploying the cleaned stent retriever in the narrow blood vessels. For this reason, a small window was designed into the part as can be seen in Figure 28. While this will be a definite source of leak, this can be controlled by the operator, and is opposite to the side of fluid entry.

4.4 Adding Luer Fittings

The final device is intended to have luer fittings molded into the part, as opposed to sonic welding luer fittings into holes. For this reason, it was important to find the standards by which luer fittings are designed. For over two decades, ISO 594-2 served as this standard, and was replaced recently by ISO 80369 (*ISO-80369 / Small Bore Connectors* | Qosina, 2019). The new ISO designates changes to the ISO 594-2 based on surgical procedure category. For instance, ISO 80369-7 applies specifically to intravascular and hypodermic applications.

4.4.1 ISO 594-2 standards

Final luer changes to come into compliance with ISO 80369-7 will be made in the future, once the appropriate ISO is procured. For this stage, following ISO 594-2 for general luer standardization was deemed appropriate. Table 7 shows the dimensions for the luer fitting (*30505-92/ISO 594-2 LUER TAPER STANDARDS.Pdf*, 1998).

Outer diameter of luer	0.300"	Inner diameter of luer	0.165"
Pitch of thread	0.197"	Num. revolutions	0.8
Thread height	0.02"	Thread width	0.039"
Angle of thread	65 degrees	Thread mirror	360 degrees
Min length of luer	0.200"	Lead in chamfer	0.010"

Table 9 - Dimensions necessary to create luer

This table was used to design the luer fittings on the device, and all edges were given a 0.005" radius.

4.5 Injection Molding

4.5.1 Overall process

Plastic Injection Molding has existed as a technology since 1872, when Isaiah and John Hyatt sought to patent a new device that was used to mass produce combs and buttons (*History of Plastic Molding | Plastic Injection Molding Manufacturers, n.d.*). The process starts with creating a cavity in a metal plate, in the form of the plastic part. This can be done by multiple methods but the two most common are Computer Numerical Control (CNC) machines and Electrical Discharge Machining (EDM). Both are subtractive processes where a block of material, often hardened or pre-hardened steel, is altered to make the mold cavity. CNC machining uses drill bits of various shapes and sizes to machine away the material to create the cavity. EDM uses an electrode, often graphite or copper, positioned a few thousandths away from the workpiece, in a dielectric fluid, to electrically destroy the material and create the cavity (*Plastic Injection Mold Making | CS Tool Engineering, n.d.*). Small channels, called sprues are placed around the mold cavity, and these are the sites where melted plastic

is injected into the cavity. There are often at least two halves of a plate that are pressed together, before the plastic is injected (*What Is Injection Moulding | How Does Injection Moulding Work*, n.d.). This leads to a parting line in the part where the two molds come together. After the appropriate amount of plastic is injected, called the shot size, the machine waits for the plastic to cool and harden, which often only takes about 1 - 2 seconds (*Molding Cycle - an Overview | ScienceDirect Topics*, 2015). Then the cycle begins again. This method allows thousands of parts to be produced per day. But there are guidelines to follow when designing a part that is meant to be injection molded.

4.5.2 Wall thickness considerations

One of the biggest challenges in injection molding is preventing warping. Warping can occur for many reasons, but often is a result of plastic cooling unevenly. Different thicknesses of plastic will cool at different rates according to Figure 29 (*Example of Calculating the Cooling Time (1) | Technical Tutorial - MISUMI*, 2009).

$$t_{cool} = \frac{s^2}{2\pi * \alpha} * \ln\left[\frac{8}{2\pi} \left(\frac{T_p - T_s}{T_e - T_s}\right)\right]$$

Fig. 29 - Equation for calculating time to cool part

t_{cool} is the time it takes the part to cool down to 90° Celsius where it can then be ejected from the mold, known as T_e ; s is the wall thickness; α is the rate of heat diffusion of the plastic; T_p is the temperature of the molten plastic injected into the mold, T_s is the surface temperature of the mold.

As can be seen, part thickness affects the cooling time and when parts cool unevenly, they create a residual stress in the part which leads to the visual effect of warping (*Residual Stress in Plastics Parts EN(1612 R1)*, 2016). Knowing this, parts are

designed with a nominal wall thickness, limited by the material. Polypropylene has a range between 0.025" - 0.150" and Polycarbonate has a range between 0.040" and 0.150" (*Design Tip: Improving Part Design with Uniform Wall Thickness*, n.d.).

For the purposes of this device, a nominal wall thickness of 0.100" was chosen to give rigidity to the parts and eliminate the need for structural ribs in the top.

4.5.3 Rib thickness

A rib is defined as a thinner section designed to add strength to the part, much like support structure in a truss. Rib features are recommended to be designed with 40% wall thickness and so for this application, a rib thickness of 0.040" was chosen. The parts designed to snap fit and flex were treated as ribs and given this same thickness as can be seen in Figure 30.

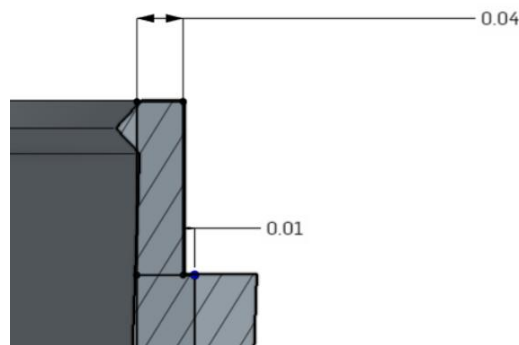


Fig. 30 - Using a 0.040" thickness for the snap rings body

4.5.4 Draft

When plastic parts are ejected from the mold, they can sometimes stick if they are not designed to easily push free. An easy way to aid in this process is to give surfaces a draft. Draft is defined as tapering vertical surfaces and the direction of taper is dependent on the direction of pull, or draw, in the mold (*Design Tip: 5 Ways to Improve Part Mouldability with Draft*, n.d.). In determining the angle to set, a general

rule of thumb is 1 degree of draft per 1 inch of cavity depth. Since this device is 1.5" tall, a draft of 2 degrees was deemed sufficient for the outside draft and small internal features were given a minimum of 1 degree. As can be seen in Figure 31, if the draft angle is negative, it can create a bind when trying to pull apart the mold and damage or warp the part, and possibly the mold too (*How to Design for Injection Moulding*, 2019).

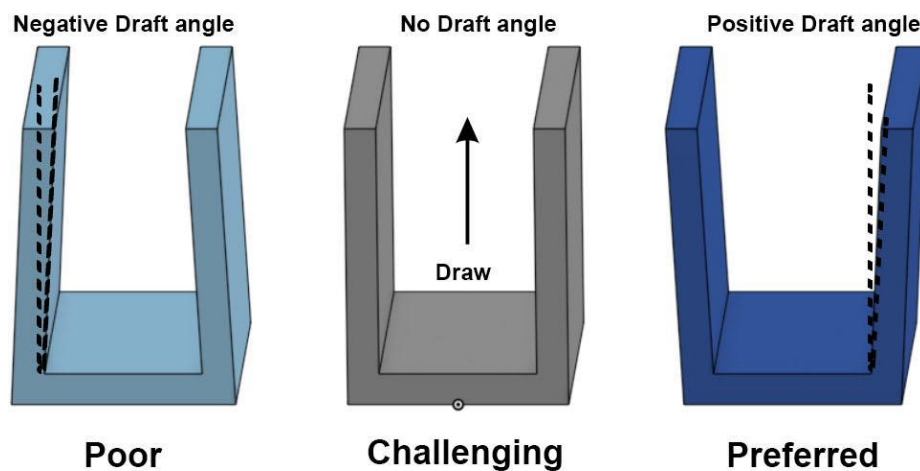


Fig. 31 - How draft can affect the ability of a mold to pull apart

4.5.5 Creating good flow with radii

In order to improve the ability of plastic to flow around corners when injected into the mold, all sharp corners are given a bevel, or radius (*Design Essentials for Injection Molding*, 2018). The amount of bevel is determined by the nominal wall thickness. In order to keep the thickness consistent as possible, internal surfaces are given a radius of one half the nominal wall thickness, and external surfaces are given a radius of one and a half times the nominal wall thickness. For a nominal wall thickness of 0.100", internal corners were radiused at 0.050" and external corners were given 0.150" radii. Small features such as ribs and the annular snap fit corners were given 0.010" radii and

the luer fittings were given 0.005” radii according to ISO 594-2. When the part is put into full production, the tooling engineer may change some of the smaller feature fillets, and this is known as “breaking the corners” as the exact radius does not matter in the end result, as long as the part is not affected. This allows the tooling engineer to make decisions that will save the client money, and these decisions will be reflected in the engineering drawings.

4.5.6 Feedback from GoProto, Inc.

STEP files were submitted to GoProto, a custom plastic injection molding service located in San Diego California, for feedback on the manufacturability of the design. These are known as Design for Manufacturability (DFM) services. Initial feedback centered around eliminating undercuts in the part to increase the moldability. The annular snap ring in particular was identified as being the most likely to warp when the mold comes apart, as the tool below the snap ring will rub against the ring and possibly warp the part.

5. Final Design

5.1 Product Description

The final design, named RE-STENT, is a single plastic injection molded part with a living hinge, and an annular snap fit ring. It has two female luer ports that attach to any standard male syringe part. It will ship with one male luer cap in case the user wishes to block one of the ports, and use the device with a single syringe. The device is recommended to be used with 15mL to 20mL of sterile saline. Overall dimensions are

3.82in by 2.9in long and the internal volume is just under 21.32mL. When closed, the device is 1.25in tall.

5.2 Engineering Drawings

The engineering drawings were produced using Onshape® software and the scale was 1:1 for most parts and detailed views were scaled up to increase visibility. These are likely to change according to manufacturer request and final DFM feedback. All units are given in inches unless otherwise noted. Tolerances will be adjusted based on feedback and fit after an aluminum mold is produced for test runs of parts. Figures 32, 33 and 34 show the final part design and dimensions. Full size drawings will be included in Appendix B.

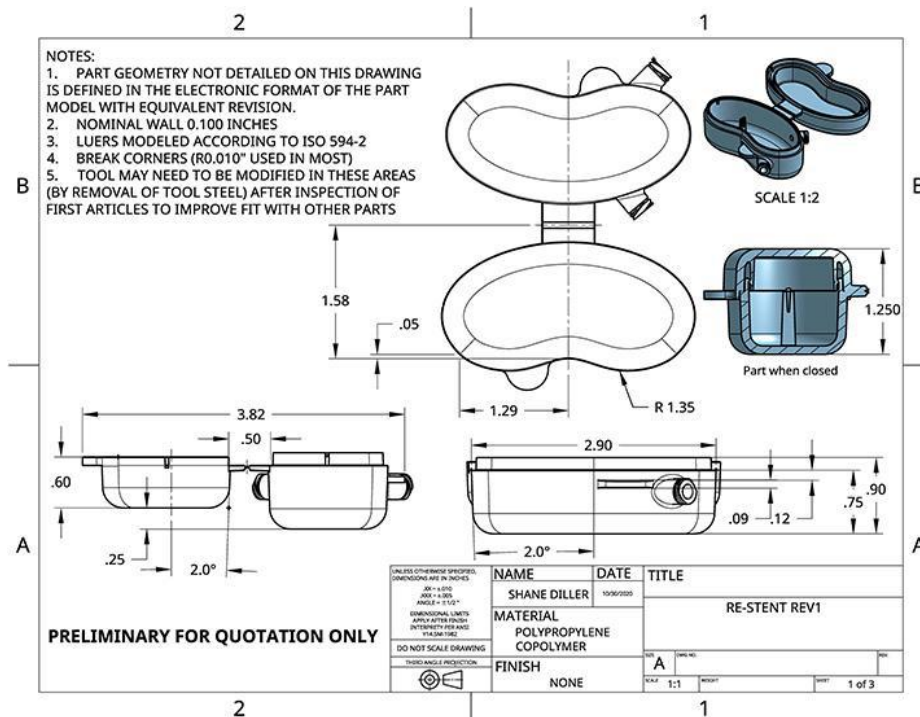


Fig. 32 - Overall dimensions of the final RE-STENT Cleaner device

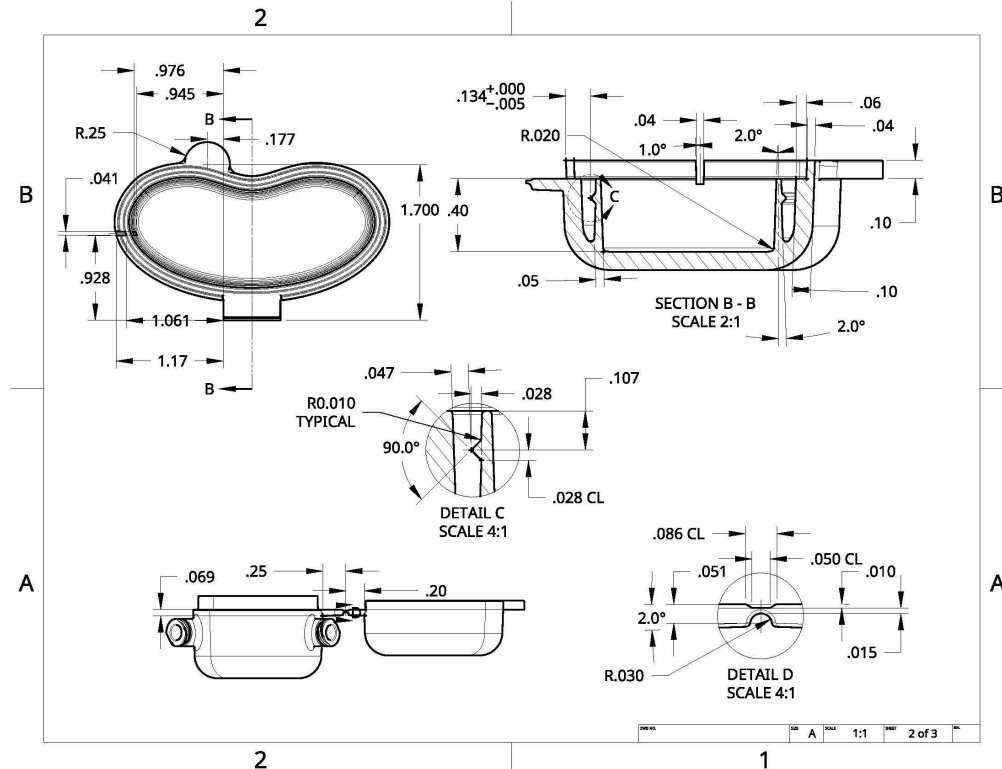


Fig. 33 - Dimensions for the top of the device and living hinge

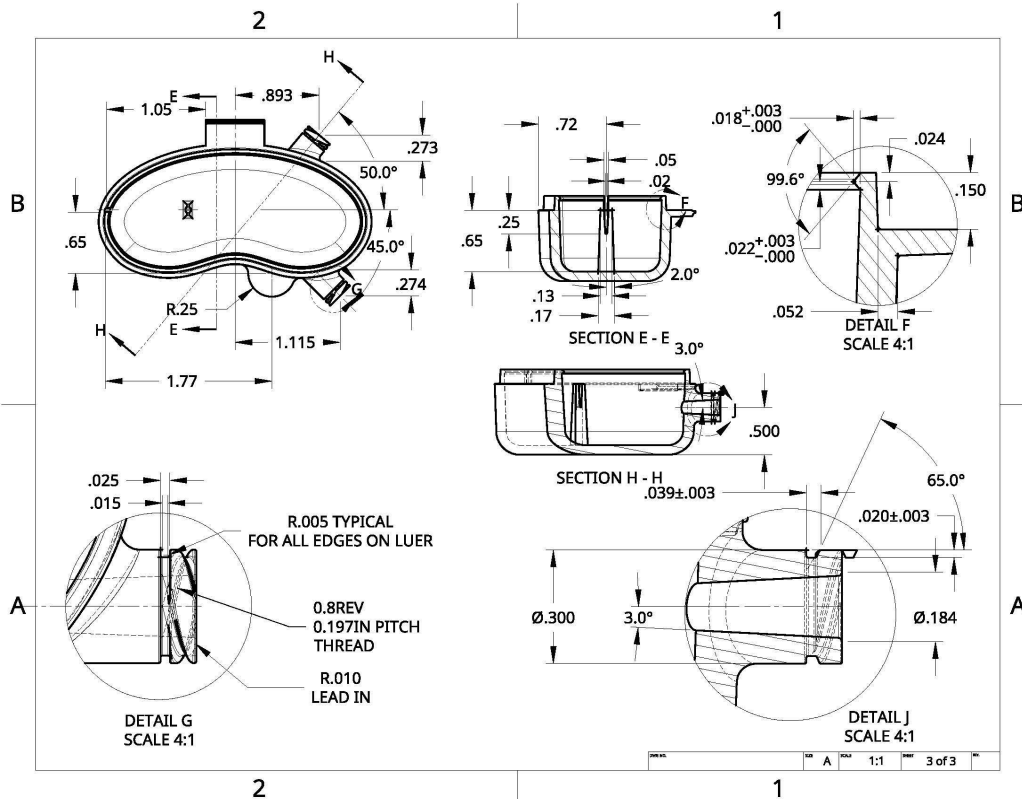


Fig. 34 - Dimensions for the bottom of the device and luer parts

5.3 Material Specifications

The final device will be made from a plastic injection molded, medical grade polypropylene and batch testing will be required to prove biocompatibility compliance periodically. This material satisfies the requirements and design recommendations for a living hinge. The packaging will be made from a thermoformed plastic and a teflon tear away cover.

5.4 Estimated Unit Production Cost

While conversations with GoProto, Inc. are ongoing in regards to the final design and tooling needed, it is estimated that the final steel hardened tooling will be in the range of \$35,000 to \$50,000. Individual cost per unit is likely \$5.00 if no overmolding or further refinements are needed. This estimate does not include the amortization required due to upfront expenses on seeking FDA approval and any clinical evaluation.

5.5 Packaging Description

5.5.1 Sterile pack

The package will be made from a vacuum formed rigid plastic bottom and a heat bonded, tear away Tyvek® top, that has labeling printed on it. The package will then be sterilized using EtO to the ISO standard of 10^{-6} .

5.5.2 Shelf box package

The products will likely ship in boxes of 20 devices per shelf box package. A shelf box is kept in the supply closet of surgery floors and serves as the backup stock.

5.5.3 Shipping Box package

Due to the small footprint of the device, four (4) to six (6) shelf boxes will likely be packaged in a single shipping box, to save on shipping costs.

6. FDA Documentation

6.1 FDA Process Overview

The Food and Drug Administration (FDA) is the entity that oversees the approval of medical devices after the Safe Medical Devices Act was passed in 1990 (“A History of Medical Device Regulation & Oversight in the United States,” 2019). This established the program by which most medical devices are authorized to be marketed and sold, the 510k program. This program is intended to provide a pathway for medical devices to prove that they are safe and effective and a channel to streamline the process by claiming substantial equivalence to a previously approved device.

6.1.1 Device classification

All medical devices are classified according to the level of control needed to ensure safety and efficacy in use (*Classify Your Medical Device*, 2020). These fall into one of three categories:

- Class I - the lowest risk devices. Metal trays, most syringes, and gauze fall into this category as they do not have a high degree of contact with the body.
- Class II - mid risk devices. Surgical tools, breast pumps, and other instruments are often included in this category.
- Class III - highest risk devices. Implantable devices fall into this category.

All devices are controlled by the Code of Federal Regulations (CFR) and use a 7 digit code to further classify the device and provide information on additional regulations that may apply to it. An example of this 7 digit code would be 21CFR880.6150 where the 880 implies the category “General Hospital and Personal Use Devices” and 6150 is specific to “Ultrasonic cleaner for medical instruments” (*CFR - Code of Federal Regulations Title 21 Part 880, 2019*).

For this device, there is no exact predicate that can be used to classify the device. In drawing comparisons, the device exhibits a function similar to an Irrigating syringe, a Class I device regulated under 21CFR880.6960 (*CFR - Code of Federal Regulations Title 21 Part 880.6960, 2019*). However, an Irrigating syringe is not intended to retain bodily fluids and so this device also exhibits function similar to a general medical washer, a Class II device regulated under 21CFR880.6991 (*CFR - Code of Federal Regulations Title 21 Part 880.6991, 2019*).

6.1.2 Predicate devices

In researching predicate devices, emphasis was placed on finding devices that performed some kind of washing or cleaning function and those that contacted blood, without using an electronic power source. A device previously approved by the FDA is the Zerowet Splashshield, which is a Class I medical device that is intended to shield the user from bodily fluids splashing on them when irrigating a wound or incision. It is an attachment for a standard irrigating syringe (*Zerowet Splash Shield 510k Summary, 1998*). This is closest in function and used as evidence for classifying the RE-STENT washer as a Class I medical device.

There were two medical washer devices found that are intended to be used for a much deeper level of cleaning. The Steri-Vers (*Steri-Vers 510(k) Premarket Notification*, 1981) and the Decomat 4656, both Class II medical devices are intended to sterilize medical equipment using hot water, and pasteurization methods (*Decomat 4656 510(k) Premarket Notification*, 1995). This is far above what this device is intended to do, and thus the RE-STENT is maintained as a Class I medical device.

6.1.3 Materials biocompatibility

According to ISO 10093-1 and ISO14971 this device would likely be categorized as an External Communication Device - Blood Path Indirect - Limited contact duration (*ISO 10993-1*, 2018). According to ISO 10993-1 this would likely require the following Biocompatibility tests:

- Cytotoxicity
- Sensitization
- Irritation or intracutaneous reactivity
- Acute systemic toxicity

These biocompatibility tests will likely cost somewhere around \$15,000 according to industry estimates (*New Standard for Biocompatibility Testing*, 2019).

6.1.4 Product labeling

Labeling was created based on the FDA guidelines (*Device Labeling*, 2020). A draft of the label that will be on the package can be seen in Figure 35.

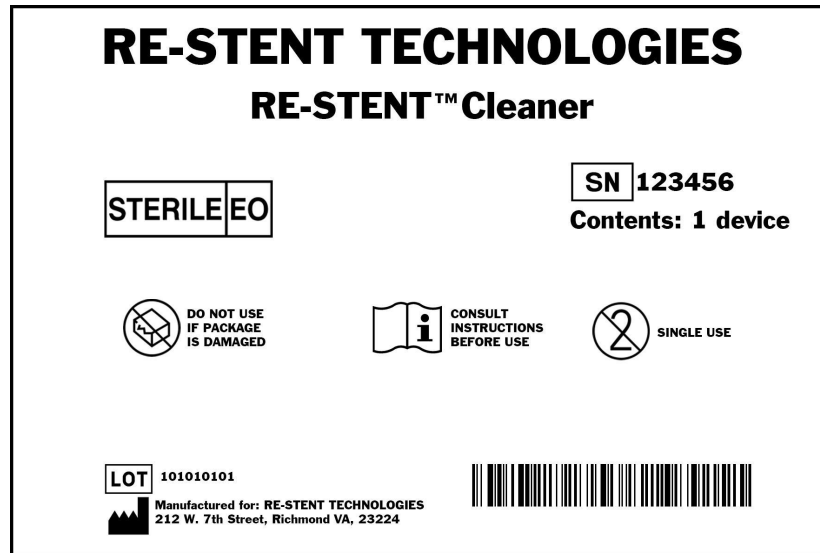


Fig. 35 - Proposed package labeling, using medical symbols

Indications for Use:

The RE-STENT is indicated for use in physically debriding thrombus fragments from a stent retriever system, using hospital-grade saline, or heparinized saline. This device is intended to be used in the sterile field, during a mechanical thrombectomy procedure.

Contraindications:

None known.

Warnings:

- This device is provided STERILE for single use only. Do not reprocess or re-sterilize the device. Reprocessing and re-sterilization may increase risk of infection to the patient and compromise device integrity.
- For device safety, do not open and close the device more than three times.
- Do not over-tighten syringes on luer locks
- When cycling the syringes in use, do not bend the syringe or part may break.

Precautions:

- The RE-STENT Device should only be used by physicians and medical staff trained in the treatment of Ischemic stroke and Interventional Neuroradiology.
- Carefully inspect the sterile package and the RE-STENT device prior to use to verify that neither has been damaged during shipment. Do not use damaged components.
- The RE-STENT Device is not to be used after the expiration date imprinted on the product label.

Special Patient populations:

None known.

Potential Complications:

None known.

6.2 Traditional 510k Draft Application - Class I Device

Neither a premarket approval notification (PMA), nor a traditional 510k is required for this device. (“Premarket Notification Truthful And Accurate Statement,” 2020).

However, it was beneficial to understand the process and in case the device is classified as a Class II device, which does require a 510k submission, a draft 510k application can be found in Appendix C. Sections that are missing require bench top testing using animal blood clots. This does not require approval from the Institutional Review Board at VCU (*Activities Requiring IRB Review - Virginia Commonwealth University*, n.d.). An animal model established in literature will be used to evaluate the ability of removing clot material.

7. Discussion

7.1 Design Input = Design Output

When designing a new product, it is important to establish not only what features the product will have, but what features will be intentionally left out. The absence of this thought, results in what is known as “Feature creep” which is a tendency for products to add in unnecessary services, functions, or components (*Feature Creep, What Is It and How It Affects Your Customers | UX Collective, 2017*). The three most critical criteria for this product were:

1. Ability to effectively clean all three stent clot retriever morphologies
2. Ease of use in sterile operating field
3. Economy in production of a single-use sterile packaged device

While a battery or wall powered device with motors and incredibly complex fluid mechanics will likely perform better in bench testing, it would likely not come at a production price tag of under \$40.00. The internal cone concept, from Figure 9, would be highly effective at cleaning the Medtronic Solitaire™ stent but would likely fail at cleaning the Cerenovous Pulserider™ due to the double internal lumen. The need for the device to be operated by one user, in a sterile field, required consideration in how the part can be closed by one hand.

A full list of the design input can be found in a matrix in Appendix A. Without following this design criteria closely, it would be entirely possible to design a device that while functionally superior, is of no value to Dr. Rivet or a purchasing company.

7.2 Unexpected Findings

While testing early prototypes, there were many unexpected lessons. Simulating a blood clot and the way which a partially retrieved blood clot adheres to a stent retriever proved challenging. Ultimately, the need for a biological animal blood clot that is created using established protocols is required to perform bench testing.

While there are published design guidelines for snap fit parts, there is a lot of experimentation required. Without the aid of 3D printing, much of this experimentation and failing of designs, would not have been possible. For instance, the leading and receding angle of the snap fit teeth played a large role in ease of closing the device, and took 3 iterations in order to establish the proper fit.

3D printing also comes with downsides. 3D printers do not have a high degree of consistency and precision - resulting in subtle differences among prototypes that made evaluation more challenging. It was ultimately decided to not perfect a design via 3D printing. They also have poor thermodynamic properties and as the printed parts cool, this can create warping in long flat parts. The lid of early prototypes constantly warped and did not create a watertight seal, as can be seen in Figure 36.



Fig. 36 - Early resin prototypes with visible gap between the top and bottom

Another unexpected challenge came in creating a watertight seal, while also not introducing stress on the stent retriever tail wire, as it exits the chamber. The original concept of using an o-ring was promising, but the hardness should have been lowered to 30A instead of using 50A in testing. Ultimately this part was removed for cost saving measures, but overmolding may still be a possibility if sealing is an issue.

When discussing the manufacturability of the final part with GoProto, concerns were raised about the continuous annular snap fit ring. The concern was in the part warping as the part was ejected. Experimentation in mold design and designing a part so that it can be altered by a mold maker is an important, and often overlooked step of product design.

7.3 Practical Implications

This device aims to reduce the time required to clean a stent retriever, and reduce the risk of damaging the stent retriever during the cleaning process. This allows the stent retriever to be reused, saving cost to the patient. At \$7,000 to \$10,000 per stent retriever, this is a massive cost saving step. Additionally, by reducing time and complications in cleaning the stent retriever, it reduces the overall time spent in the operating room, which has an average cost of \$35.00/min. This project was founded as a trial of a new partnership between VCU Engineering and the surgery department of MCV Hospital. Connecting users that are directly experiencing problems with engineers that can design, test and refine solutions results in a higher quality of service provided by MCV Hospital and better patient outcomes.

7.4 Future Work

In order to get this device into the market, there are expenses in getting the device certified. Aside from biocompatibility, clinical evaluations must be performed. In order to perform these clinical evaluations, an aluminum mold must be tooled to then produce the device for testing, in its final form. An aluminum mold will likely cost somewhere between \$2,500 and \$5,000. This mold will likely be able to produce close to 1000 units of the device and allow final design changes to optimize the performance of the molding.

The funding for this may be provided by VCU Innovation Gateway, and an application for funding is currently in process. An alternative funding source may be found in an established company, preferably one that manufactures stent retrievers, such as Medtronic, Cerenovous or Stryker. This company may purchase the intellectual property from VCU and then finish testing independently.

Refinements will likely be made in the final hardened steel mold. Changes made to increase the ability of the snap fit ring to keep out water, improving the living hinge, and optimizing the mold for luer attachments are all parts of the final steps.

The purpose of this work was to create an Alpha prototype. Once this moves into a Beta prototype, a Quality Management System will be required to track changes. This alone has a high cost due to the man hours needed to properly maintain the Design History File.

8. Conclusion

This device is functionally equivalent to predicate devices, satisfies design criteria established at the outset of the work, and comes in under projected costs. The

most challenging part, creating a relatively watertight seal, was accomplished while reducing parts required. Multiple iterations and forms of the device were explored and evaluated against one another, and the annular snap ring emerged as the most effective method. A living hinge was utilized to reduce assembly time in the Operating Room, and enhance human factors in handling of the device with one hand. The two female luer ports locations were established after thorough testing and exploration was deemed sufficiently thorough and clinical trials and evaluations will establish effectiveness in the future. But most importantly, this device may save lives and help reduce cost to patients.

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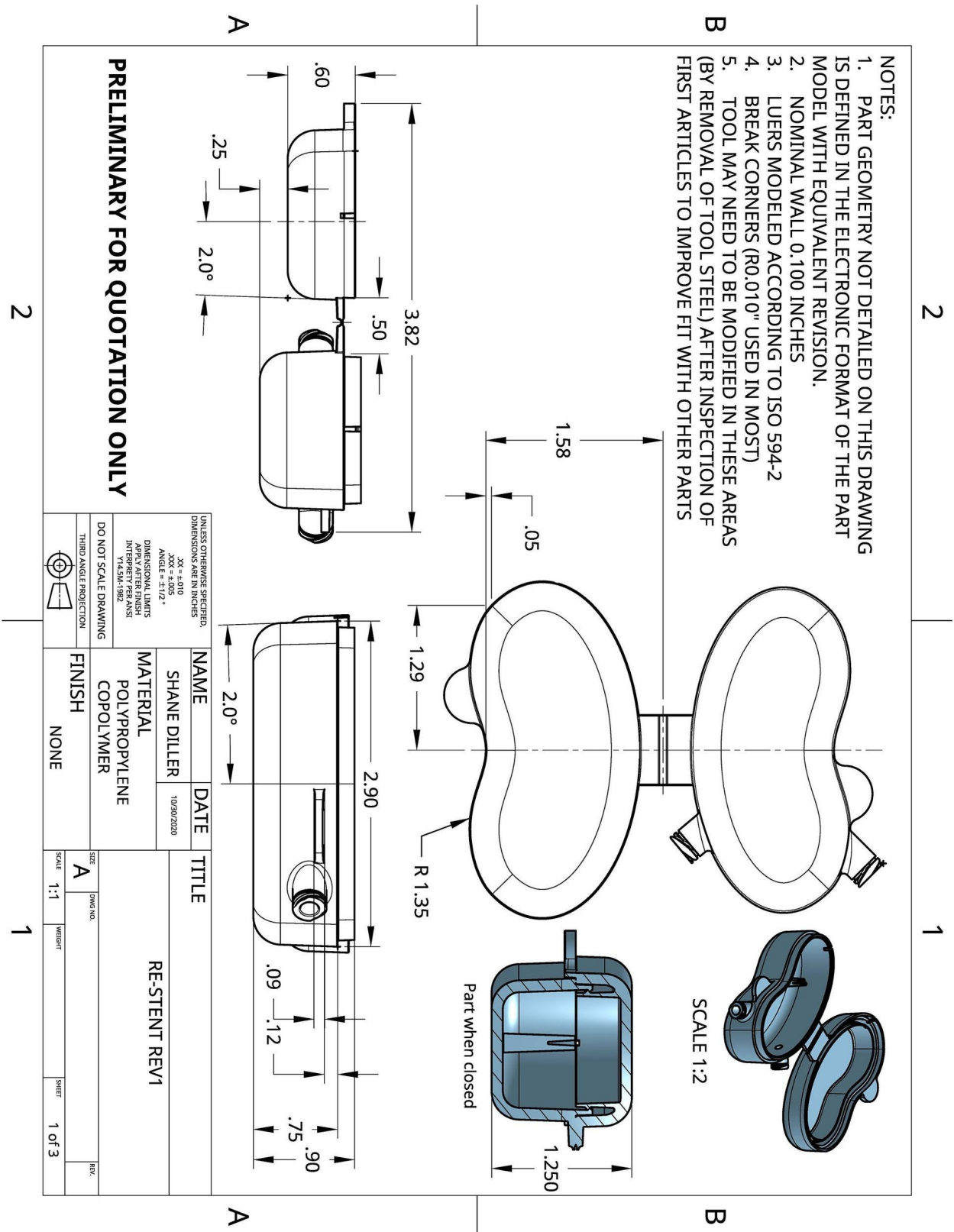
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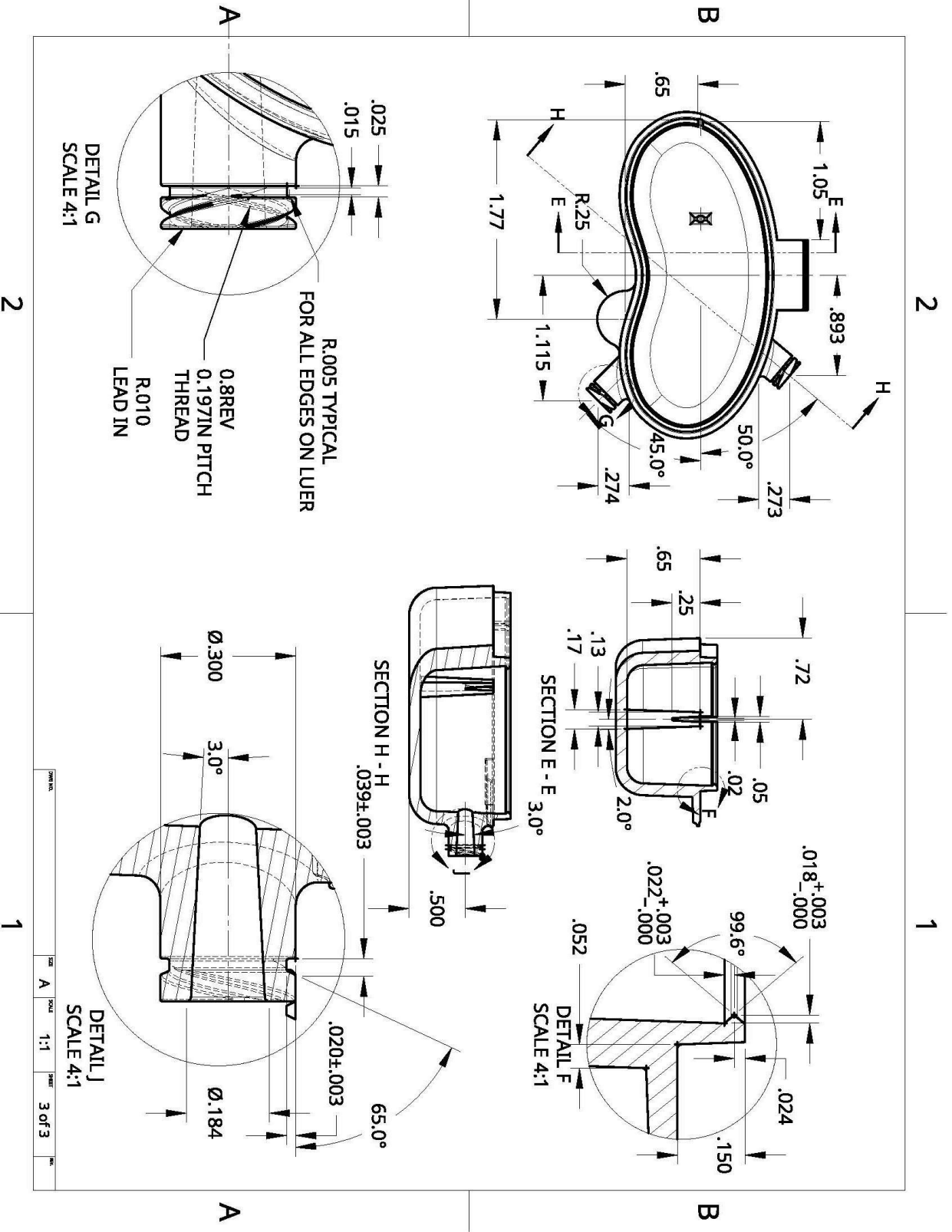
Appendix A: Design Input

000000FPCCO Matrix Function, Performance, Constraint, Other

Parameter	Comment	Voice of Customer (VoC)										Rating		Reference		
		Functional	Performance	Constraint	Other	Physician	Assisting Tech	Scrub Nurse	Circulating Nurse	Purchasing Agent	Manufacturer	Metric	Critical		Essential	Want
Cleans the stent in under 15 seconds	2 - 3 passes/cycles max		X			X								X		Transient Contact cert?
Can be used with standard Luer syringes	For ease in setup	X					X	X						X		
Only requires two hands / one operator	Can be braced on table					X	X	X	X					X		AAMI HE75
Requires little assembly	Patient safety					X	X	X		X				X		
Stent doesn't make contact with the chamber	Stent can't be pushed by liquid pressure into chamber wall					X	X							X		
No fluid escapes chamber during use of device	Silicone protection					X	X							X		
For use in sterile OR field	Material can be sterilized, put into peel pouch					X	X	X	X					X		Gamma Irradiation or EO
Under target production price	<\$40.00					X	X							X		
Hits target market price	<\$500.00					X			X					X		
Can be used on stents of multiple designs	Spiral, double lumen, 4-6mm diameter 24-40mm length	X					X		X					X		
Only need 20mL of saline to flush	More saline means more likely to clean		X				X							X		
Can retrieve the blood clot for composition analysis	Some way of sucking all fluid back up	X					X							X		
One way valve to prevent airflow into chamber	Air can't be in chamber when trying to push saline in	X					X							X		
Surgeon able to see the stent being cleaned	Polycarbonate, polypropylene					X	X		X					X		
Can be prepared operated with little training	Need to find insert for stent retriever		X				X							X		
Operates within 20 - 37 Celsius range	Some saline is cooled and some is warmed to body temp		X				X							X		
75% success rate in cleaning the stent	Arbitrary number, need to confirm		X				X							X		
Delivery wire does not fall out of sterile field	100cm tailwire	X					X	X						X		ISO 10993
Can be evaluated outside of OR		X					X							X		ISO 10993
Biocompatible for short term blood contact						X								X		ISO 10993

Appendix B: Full scale engineering drawings





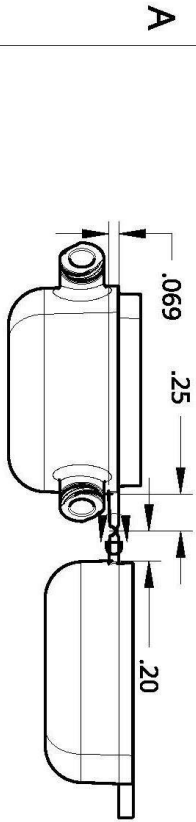
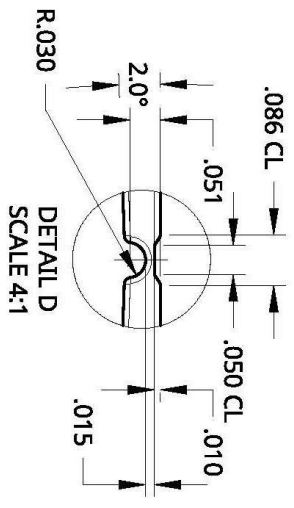
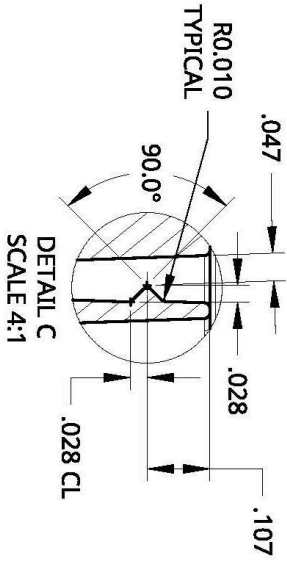
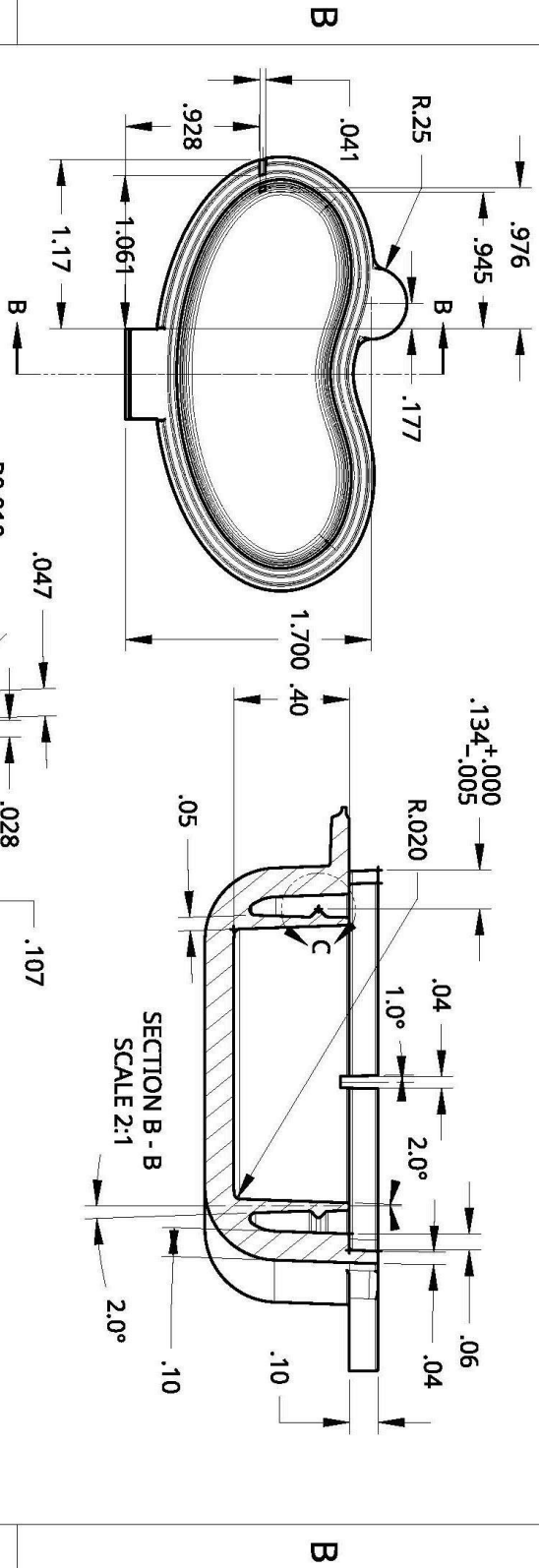
2

2

1

1

2



2

1

DATE	SIZE	A	FOOT	1:1	SHEET	2 OF 3	PK
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Appendix C: Draft 510k Application

DRAFT 510K APPLICATION FOR RE-STENT™ Cleaner

by

SHANE DILLER

December 4th, 2020

Advisor: FRANKLIN BOST

PROFESSOR, CO-DIRECTOR, VCU INSTITUTE FOR ENGINEERING AND
MEDICINE

Advisor: DENNIS RIVET, MD

ASSOCIATE PROFESSOR, DEPARTMENT OF NEUROSURGERY

Department of Mechanical and Nuclear Engineering

Virginia Commonwealth University

Richmond, Virginia

2019-2020

Traditional 510k Notification

Submitter:

RE-STENT Technologies
212 W. 7th Street Unit 113
Richmond VA, 23224

Official Contact Person:

Shane Diller - 804.878.7838

Device Type:

Sterile single use device to clean stent retrievers

Device Name:

RE-STENT™ Cleaner

Device Class and Panel:

Class I, General Hospital Devices, 21CFR880.6960 - KYZ

Premarket Approval (PMA) Exempt?:

Yes

Predicate Device:

The RE-STENT is equivalent in function to the following devices:

Device Name:	510k number:	Product Code:
ZEROWET SPLASHIELD	K974288	KYZ
E.M. ADAMS SPLASH GUARD	K905173	KYZ
IRRIGATION CAP	K780794	KYZ

Statement of Indications for Use:

The RE-STENT is indicated for use in physically debriding thrombus fragments from a stent retriever, using hospital-grade saline, or heparinized saline. This device is intended to be used in the sterile field, during a mechanical thrombectomy procedure.

510k statement:

I certify that, in my capacity as co-founder of RE-STENT Technologies, I believe to the best of my knowledge, that all data and information submitted in this traditional 510k is accurate, and that no material fact has been omitted.

Proposed Labeling:

Packaging Labels:



Indications for Use:

The RE-STENT is indicated for use in physically debriding thrombus fragments from a stent retriever system, using hospital-grade saline, or heparinized saline. This device is intended to be used in the sterile field, during a mechanical thrombectomy procedure.

Contraindications:

None known.

Warnings:

- This device is provided STERILE for single use only. Do not reprocess or re-sterilize the device. Reprocessing and re-sterilization may increase risk of infection to the patient and compromise device integrity.
- For device safety, do not open and close the device more than three times.
- Do not over-tighten syringes on luer locks
- When cycling the syringes in use, do not bend syringe or part may break.

Precautions:

- The RE-STENT Device should only be used by physicians and medical staff trained in the treatment of Ischemic stroke and Interventional Neuroradiology.
- Carefully inspect the sterile package and the RE-STENT device prior to use to verify that neither has been damaged during shipment. Do not use damaged components.
- The RE-STENT Device is not to be used after the expiration date imprinted on the product label.

Special Patient populations:

None known.

Potential Complications:

None known.

Specifications:

Executive Summary:

The RE-STENT is a novel device that is to be used in the treatment of Ischemic Stroke by Mechanical Thrombectomy. Many complications can occur, but one that is prevalent in 50% - 67% of cases is that the blood clot is only partially removed and clings to the mesh framework of the stent retriever. The operating surgeon must either clean the debris from the stent retriever, to be reinserted or throw the stent retriever away and open a new one. At \$7,000 - \$10,000 per stent retriever, most prefer to clean the stent retriever.

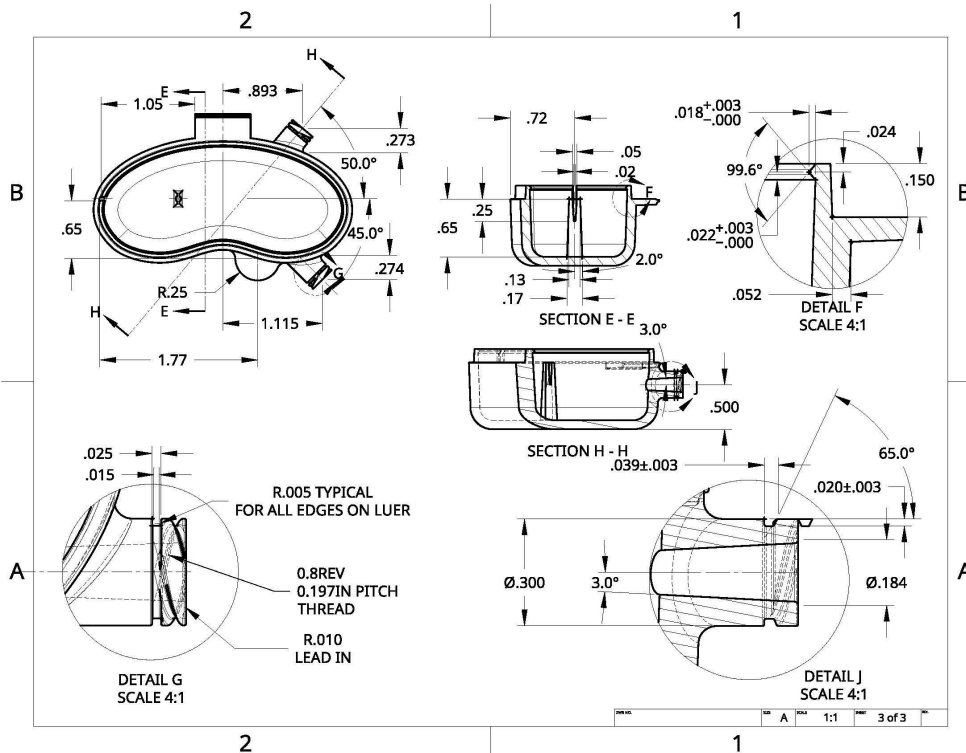
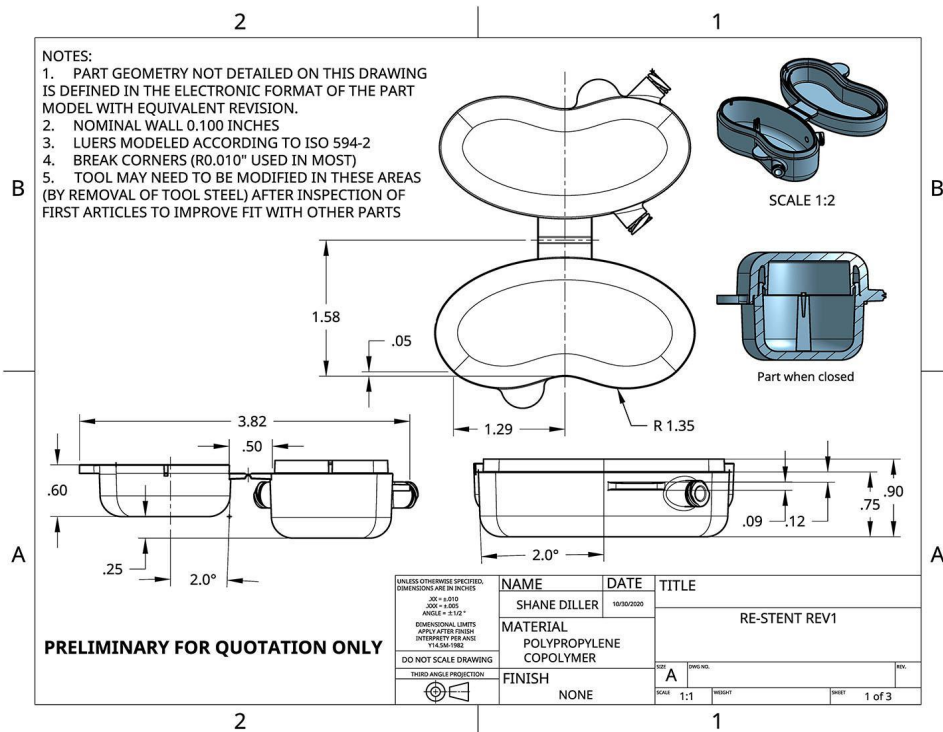
The current method is to use a syringe of sterile saline to squirt the clot off of the stent retriever, but this is ineffective and time-consuming. Sometimes the surgeon will use physical means to attempt to remove debris, which can damage the mesh tines of the stent retriever. This novel device aims to wash the blood clot debris from the stent retriever, without damaging the stent retriever, and allow it to be collected to be sent off for analysis.

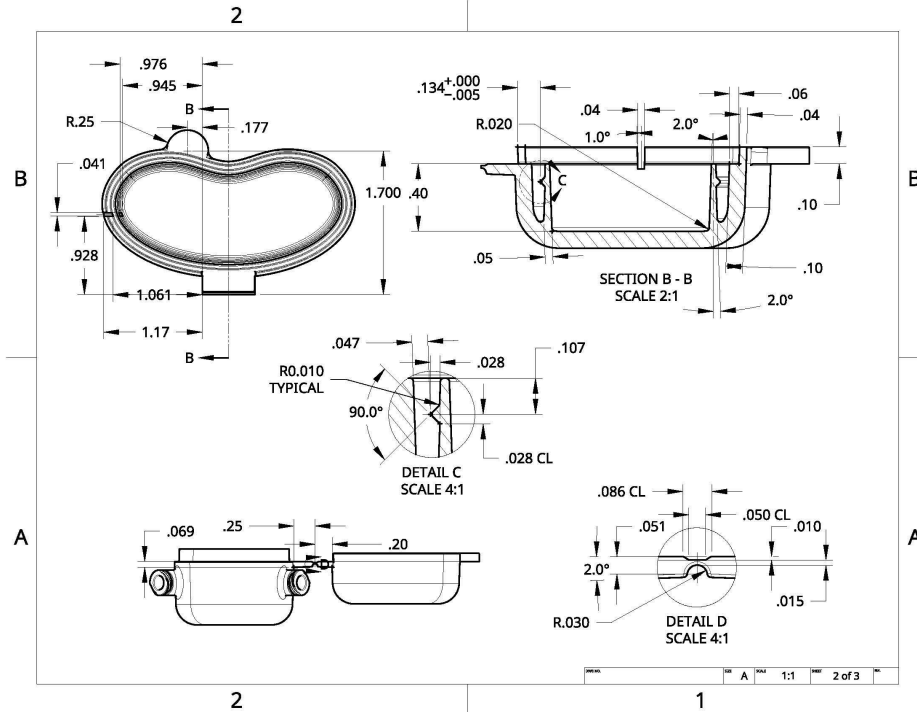
The device is a hinged chamber that has two luer port attachments for syringes. The stent retriever is placed in the device, the lid is closed, and the operator uses two syringes of saline to create turbulence in the chamber, physically debriding the stent retriever. This device is intended to reduce the time required to clean the stent retriever before re-insertion to under fifteen seconds. In addition, the device is intended to be used by one operator.

Device Description:

The final design, named RE-STENT, is a single plastic injection molded part with a living hinge, and an annular snap fit ring. It has two female luer ports that attach to any standard male syringe part. The device is recommended to be used with 15mL to 20mL of sterile saline. Overall dimensions are 3.82in by 2.9in long and the internal volume is just under 21.32mL. When closed, the device is 1.25in tall.

Engineering Drawings:





Power Source:

This device requires no power source.

Component Materials:

The entire device is made from polypropylene, manufactured by injection molding.

The device is provided sterile in a Tyvek® peel pouch.

Included Directions for Use:

1. Peel open the package and place in the in the sterile field.
2. Open the Re-Stent device by using the thumb catches on the RE-STENT to open the lid.
3. To place the stent retriever product in the main compartment by guiding the tail-wire across the notched post and into the notch in the lid. The stent retriever should be facing the luer connectors.

4. Close the lid of the RE-STENT, ensuring that the tail-wire stays in the notch, and that the lid closes firmly.
5. Fill two syringes with 10mL of saline each. Attach each syringe to a luer connector site.
6. Grasp one syringe in each hand, and begin alternately depressing the plungers, similar to creating an agitated bubble chamber, for 10 - 15 seconds.
 - a. You may need to angle the RE-STENT device so that the saline flows back into the syringes in order to create max turbulence.
7. Visually inspect the stent retriever through the clear lid; see if the blood clot has been removed from the stent retriever.
8. If the clot has not been adequately removed for the stent retriever, repeat steps 4 for another 10-15 seconds. The user may wish to let go of one syringe and grasp the RE-STENT device and shaking gently for 3 - 4 seconds.
9. Once the stent retriever is appropriately cleaned, use the thumb catches on the RE-STENT to open the lid.
10. Remove the stent retriever. The surgeon must determine if the stent retriever is adequately cleaned of clot debris.
11. If required, tilt the chamber and use the attached syringe to collect the thrombus and saline for composition analysis.

Substantial Equivalence Comparison:

The device and design are similar to that of the Zerowet Splashield, K974288, and most other products in the KYZ category. Most products in category LDS such as the STERI-VERS go above and beyond in using steam and are electrically powered.

The RE-STENT device is not intended to sterilize or chemically clean, and is hand powered.

Substantial Equivalence Criteria Table:

To be filled in by the purchasing company after they decide what predicate devices to purchase for testing.

Criteria	RE-STENT	ZEROWET	IRR. CAP	SPLASHGUARD
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Biocompatibility:

According to ISO 10093-1 and ISO14971 this device would likely be categorized as an Externally Communication Device - Blood Path Indirect - Limited contact duration.

According to ISO 100931-1 this would likely require the following Biocompatibility tests:

1. Cytotoxicity
2. Sensitization
3. Irritation or intracutaneous reactivity
4. Acute systemic toxicity

Sterilization method:

Sterilization of the device will follow ISO 11135:2014 for Ethylene Oxide Sterilization. The sterilization assurance level (SAL) reached will be 10^{-6} or a 1 in 1,000,000 chance of a non-sterile unit.

Performance Testing - Bench:

No bench testing on an alpha prototype has performed to this date.

Performance Testing - Animal:

No animal testing has been performed to this date.

Performance Testing - Clinical:

No clinical testing has been performed to this date.