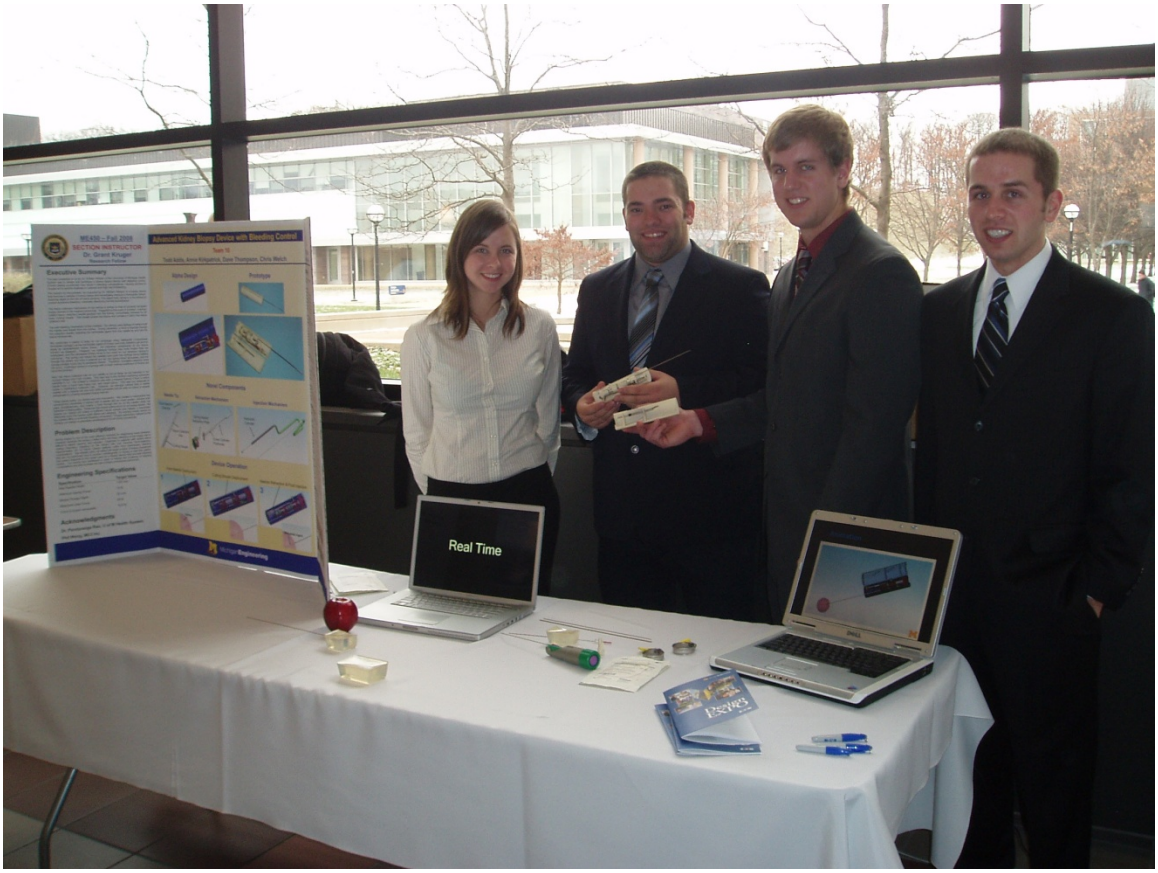
Advanced Kidney Biopsy Device with Bleeding Control



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EXECUTIVE SUMMARY

Biopsies are one of the most effective and least invasive methods of diagnosing renal diseases. Without a sample of kidney tissue, Nephrologists are not able to properly diagnose a patient, leading to incorrect or delayed treatment. However, if a patient is at high risk for excessive bleeding, a physician may be hesitant to perform a biopsy. The kidneys are deep solid organs, and if bleeding occurs through a biopsy site, doctors have no way of stopping the bleeding. Therefore, in patients with high blood pressure or conditions causing a low platelet count, this bleeding could become life threatening.

The solution to this problem, as proposed by Dr. William Weitzel in the Nephrology department at the University of Michigan health system, is a biopsy device that will remove a sample of kidney tissue and immediately deploy a hemostatic (blood-stopping) agent in the cavity. This agent is left in order to stop excessive bleeding from occurring. No existing biopsy device on the market offers this novel component, and it would be very beneficial for medical professionals. This design would be advantageous for all biopsy procedures, but particularly in the kidneys, where blood flow is higher than in most regions of the body.

In talking to Dr. Weitzel and focusing on the crucial engineering specifications, we combined our preliminary concept sketches for each biopsy device subfunction to make three full product assemblies of possible biopsy devices. From these designs, we selected our alpha biopsy device design: a needle that deploys a Gelfoam® plug by creating fluid pressure behind the plug after the kidney sample is captured. We feel that this design best fits the customer needs supplied by Dr. Weitzel, and is also the most manufacturable of our biopsy device concepts.

To determine the best material choices, we ran a series of tests and mechanical analyses on the potential weak points of the design. From the tests on the BARD® Monopty® device, we determined the appropriate spring forces needed to puncture a kidney, and also determined the necessary spring force to drive a Gelfoam® plug out of the tip of the needle using a hydraulic system. These force measurements, when inserted into the CES Edupack filter led us to pick Delrin plastic for our parts and type 304 Stainless Steel for our needles and springs. The Delrin plastic was injection molded, and the steel needles were hot metal extruded. The springs were bought through a third party supplier.

We created a working prototype and verified it functionality through a series of tests. We were able to fire our inner needle and outer sheath consecutively, and immediately retract both simultaneously. Also, we were able to expel a fluid out of the tip of our needle after firing the device. Thirdly, we were able to insert a small piece of Gelfoam® into a kidney-like material. Each of these successful tests proved that our device will work the way that we designed it to. We were not able to use the device to take a sample of kidney tissue and deploy a hemostatic plug due to issues with our needle tip leaking from the collection site and our fluid plunger locking up, but we are confident that our device will function as designed after further work is put into developing some aspects of the design. Our device will be effective in preventing significant bleeding after biopsy.

1.0 PROBLEM DESCRIPTION

Kidney biopsies are a very important procedure for the diagnosis of renal diseases. However, due to the high blood flow to the area, Nephrologists are hesitant to perform biopsies on patients who are at high risk for bleeding problems. Without a kidney biopsy, making an accurate diagnosis is difficult and proper treatment can be hindered. The current preferred biopsy method is a percutaneous biopsy, as it minimally invasive with low morbidity. However, if a patient has a bleeding condition, the small hole left by this procedure can be enough to create a serious bleeding problem [1]. While this is not common, it can become life-threatening in such patients.

Our solution to this problem, as proposed by Dr. William Weitzel in the Nephrology department at the University of Michigan, is to create a biopsy device that takes a sample of kidney tissue and then immediately fills the biopsy "hole" with a hemostatic agent to stop any bleeding problems from occurring. This design would be beneficial to any deep solid organ biopsy procedure, as it would greatly reduce the risk of any serious bleeding problem occurring.

The needle will stop bleeding by deploying a core of a hemostatic agent in the cavity left by the biopsy needle immediately after the kidney sample is retracted into the sheath of the needle. The typical biopsy device design is a two-step mechanism to cut and then collect the biopsy. Our design will add a third step of leaving a plug to stop bleeding in the biopsy site. This needle design will have all of the advantages of a minimally invasive percutaneous design while preventing its major flaw: excessive bleeding. This will increase patient safety and the rate of biopsies performed, therefore increasing the successful diagnosis and treatment of kidney disease.

2.0 BENCHMARKING

In order to better understand the task at hand, benchmarking of biopsy procedures, devices, and hemostatic methods was performed.

2.1 Percutaneous Procedure

The current biopsy method is percutaneous biopsy, or a biopsy through the skin directly into the kidney. For this method, Nephrologists at the University of Michigan health system use a Monopty® device (BARD® Pat.). This device has a needle that is inserted 8-10 centimeters into the skin until the physician can feel the hard, outer cortex of the kidney. Once the needle is in this position, its mechanism is triggered to remove a small tissue sample from the cortex.

In talking with Dr. Weitzel, we found out that this is the highly preferred method for kidney biopsy by Nephrologists because it is minimally invasive to the patient. It is the most direct method to take a kidney biopsy, and its success rate for taking a usable sample from the cortex is high. However, this procedure involves the puncture of a deep solid organ, meaning that there is no direct access to the wound if heavy bleeding occurs.

This is a risk that doctors sometimes are not willing to take if a patient's life could be in danger from excessive bleeding.

2.2 Current Preferred Biopsy Device

Nephrologists at The University of Michigan Hospitals currently prefer to use BARD® Monopty® brand biopsy devices as shown in Figure 1 below.

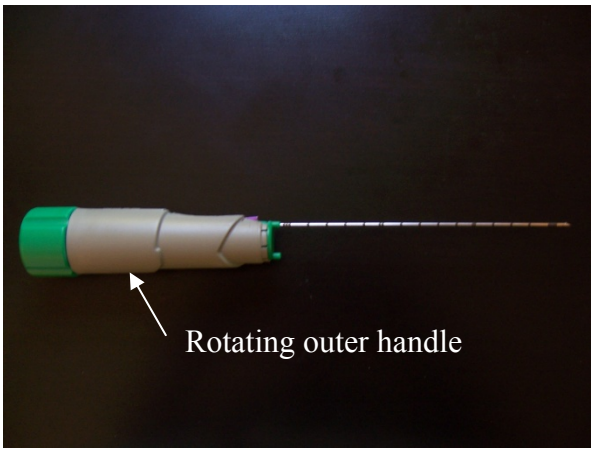


Figure 1: BARD® Monopty® biopsy device

These devices require three steps to complete the tissue collection procedure, and can be deployed with a simple, one-handed operation. In order to prepare for tissue collection, the doctor first rotates the outer handle to cock the outer cutting sheath. The doctor then continues to rotate the handle to cock the inner collection needle. The doctor then inserts the needle into the patient's lower back and positions the tip of the needle just outside of the outer cortex of the kidney. Next, the doctor presses the release trigger which first deploys the inner collection needle, immediately followed by the outer cutting sheath. The doctor then manually removes the needle from the kidney and body of the patient. The Figures 2.a, 2.b, and 2.c show the how the device operates to collect a sample. (Note that these models do not show the springs that provide the forces for needle deployment, or the outer rotating handle used to retract the needles and initiate the device).

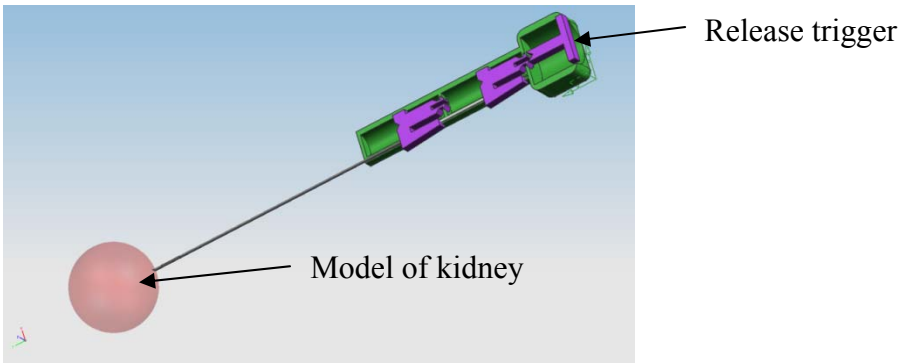


Figure 2.a: BARD® Monopty® biopsy device placed outside of kidney cortex

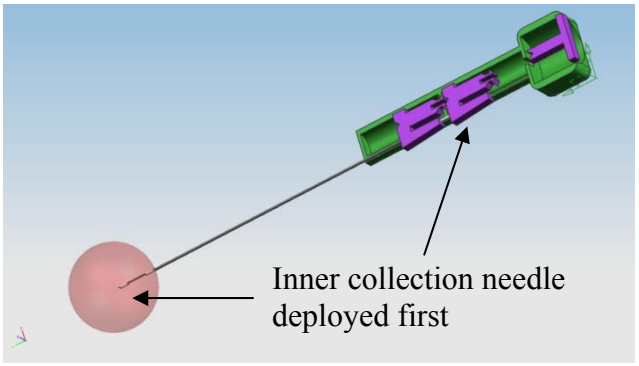


Figure 2.b: Inner collection needle deployed into kidney tissue

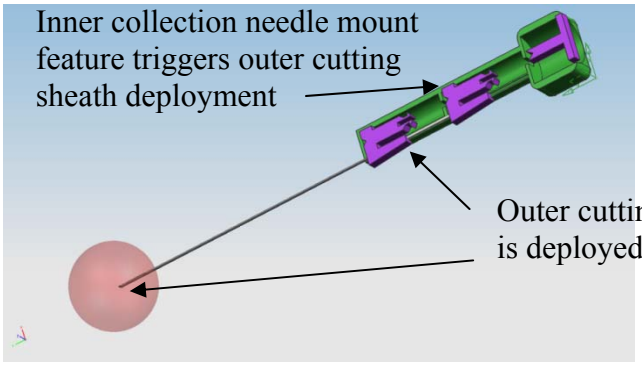


Figure 2.c: Outer cutting sheath deployed into kidney tissue

2.3 Kidney Characteristics

We need to have an understanding of the kidney anatomy, the kidney tissue desired for biopsy, and also its functional processes in order to create a safe and effective biopsy device. Dr. Weitzel shared all of this information with us (unless otherwise noted), as he has an extensive knowledge of the kidneys.

- Location: The two kidneys lie just above the waist and below the diaphragm. They are located 8-10 cm deep, depending on patient size, within the abdominal cavity when measured from the back.
- Material properties: Density = 1050 kg/m^3, Bulk modulus = 2500 MPa, Young's modulus = 1.2 MPa [2].
- Size: The typical adult kidney size is 10-12 cm in length, 5-7 cm wide, and 3 cm thick, with a mass of 135-50 g [2]. The tissue required for biopsy must be obtained from the kidney cortex, or outer layer. We found a value for the mean kidney cortex thickness to be 0.72+/-0.14 cm [3].
- Purpose: The kidney's main purpose is to filter the blood and excrete waste, along with water, as urine. The kidney also serves to regulate blood pressure, acid-base balance, and plasma volume [4].

2.4 Hemostatic Methods

Determining current hemostatic methods, and gaining a better understanding of these methods, would benefit us in our development of the hemostatic component to our biopsy device. We obtained the information on these methods from Dr. Weitzel.

- Gelfoam® (compressed sponge): Gelfoam® is a hemostatic substance that is used in medical procedures to assist in the coagulation of blood. Gelfoam® itself can hold up to 45 times the volume of its original shape. Gelfoam® is unique in that it can be used with or without thrombin, which is described below.
- Suturing Devices: Closing the wound with a suture (stitch) or multiple sutures is one method to help stop bleeding. The sutures may be dissolvable or manually removed. On the kidney, sutures are currently used in the open biopsy procedure.
- Cauterizing: Electrocautery and Chemical Cauterization are two methods by which tissue is burned and are frequently used to stop the bleeding of small blood vessels. Electrocautery is generally preferred to Chemical Cauterization because the dispersion of Chemicals within the body is difficult to predict and control, which could lead to unwanted cauterization.
- Fibrin (clotting stimulant): A protein that, when in the presence of blood platelets, forms a mesh for a blood clot. Fibrin is naturally found in blood.
- Fabric coil: A metal or fabric coil may be introduced in order to act as a structure for and facilitate clotting. The metal may remain permanently in the body or a biodegradable alternative material may be suggested.
- Thrombin: Thrombin is a protein found in blood. This protein converts fibrinogen from the blood into strands of fibrin. Methods currently used include prothrombin complex concentrate and fresh frozen plasma [5].

2.5 Transjugular Procedure

One alternative to a percutaneous kidney biopsy is a transjugular kidney biopsy [6]. This procedure is a method of taking a biopsy by running a long, thin catheter from the jugular vein in the neck all the way down to the kidney. Once the catheter has reached the kidney, a small needle at the tip is used to cut and remove a sample from the area. This sample is then pulled back out through the neck.

However, this method cannot be considered a serious alternative to the percutaneous approach [7]. This is because of issues of personnel, time, cost, and morbidity. An experienced angiographer is required for the procedure, which is much longer and costlier than the percutaneous biopsy procedure. Also, the desired region for sampling in the kidney is the outer layer, called the cortex. A transjugular biopsy needle must go through the interior of the kidney to reach the cortex. This leads to greater chance of unusable tissue samples and more damage done to the interior of the kidney.

2.6 Open Biopsy Procedure

Another alternative to the percutaneous biopsy method is open biopsy. Open biopsy is surgery to get a sample of kidney tissue. The reason that it may be used is that the site of bleeding is exposed, and doctors can stop bleeding directly, if it is deemed necessary. This is a last resort for doctors, as it is much more costly and invasive than any other biopsy method. The time required in preparation for surgery and observation of the patient after surgery is long and expensive.

2.7 Angiogram Procedure

An angiogram is simply an x-ray of the blood vessels in a body focusing on arteries, veins, or the heart. A catheter is threaded through the arteries and an x-ray contrast is administered. The blood flow can then be monitored by the images obtained by the x-ray. In the case of the kidney biopsy, an angiogram is done to see how much bleeding has occurred in the kidney as a result of the biopsy. If necessary, a hemostatic agent (most frequently Gelfoam®) can be threaded through the catheter and deployed in the blood stream to stop excessive bleeding.

2.8 Other Patents

US Patent #5,487,392 held by John R. Haaga describes a device that is similar to the currently used BARD® Monopty®, but is designed to deposit a semi-circular hemostatic insert into the biopsy site upon removal of the needle. This design does not protect the hemostatic insert during the procedure, and functions with the insert being in direct contact with kidney tissue throughout the needle insertion process. We believe this could cause damage to the insert. Our design will differ in this aspect, as we plan to provide protection for our bleeding control agent. We believe that this will allow our design to be a more reliable device that does not have the risk of causing damage to the bleeding control agent and ensures bleeding stoppage every time.

US Patent #5,080,655 – Medical Biopsy Needle – John R. Haaga
This device is designed to have a bioabsorbable gelatin needle tip which is deposited and left behind during a biopsy procedure. This tip acts to help control bleeding following the procedure.

US Patent #4,838,280 – Hemostatic Sheath for a Biopsy Needle and Method of Use – John R. Haaga
This design is similar to Haaga's design described in US Patent #5,487,392.

US Patent #7,220,266 – Tissue Capturing and Suturing Device and Method – Richard A. Gambale
This device is used for endoscopic procedures, typically in the gastro-esophageal tract. The design incorporates a tissue sewing feature on the end of the needle.

US Patent #7,232,421 – Agent Delivery Systems – Richard A. Gambale, et. al.

This invention is designed to deliver a therapeutic substance in the form of a pellet into tissue. The design allows blood to pool around the pellet to mix with the substance.

US Patent #5,858,781 – Method of Tissue Transfer and Retrieval – John R. Matyas, et. al.
This patent describes a method of transferring intact cells from the surface of organ tissue to a damaged or non-intact tissue area.

US Patent #5,993,399 – Automated Tissue Sampling Device – Pruitt, et. al.
This device is similar to the currently used BARD® Monopty® design. It requires three steps to operate, and collects a sample with a simple, one-handed operation.

US Patent #5,876,354 – Biopsy Needle Hub Assembly – Brad Quinn, et. al.
This design is similar to the currently used BARD® Monopty® design, but uses disposable needles and a permanent housing.

US Patent #7,097,637 – Safety Needle with Positive Flush – Daniel J. Triplett, et. al.
This device is designed to deposit a fluid through a needle as it is withdrawn from a vascular access port.

US Patent #6,546,276 – Ultrasonic Based Detection of Interventional Medical Device Contact and Alignment – Claudio I. Zanelli
This is a device and method that can be used to monitor the location of medical device within the body through ultrasonic signals. Accurate position and alignment monitoring of medical devices with tissue is possible with this device.

3.0 CUSTOMER REQUIREMENTS AND ENGINEERING SPECIFICATIONS

3.1 Customer Requirements

Our meetings with Dr. Weitzel and Dr. Rao gave us a very clear set of customer needs upon which to base our design. We determined that some of the key requirements include that the device stops bleeding, is easy to operate, is reliable, and collects a sufficient tissue sample every time. The complete list of requirements can be seen in Table 1. All requirements are rated on a scale of 1-10 with 10 corresponding to the highest level of importance

Customer Requirements	Weight
Minimally invasive	7
Stops bleeding	10
Low noise	4
Easy to maneuver - lightweight/balance	9
One handed ambidextrous operation	9
Fast operation	8
Re-usable	2
Easy to operate	8
Obtains sufficient sample every time	9
Robust/Durable	5
Reliable	9
Has long shelf life	4
Low cost	2

Table 1: Customer requirements

3.2 Engineering Specifications

After examination of the current biopsy device, we determined that the engineering specifications that we need to design to are as follows:

1. Needle length
2. Needle width
3. Handle length
4. Handle width
5. Number of parts
6. Sample collection capacity
7. Number of steps to operate
8. Force of collection mechanism
9. Mass
10. Minimum force required to operate
11. Lifetime (cycles)
12. Operation time
13. Flexibility of needle

We developed this list by determining the design features that would need to be controlled to satisfy the customer requirements. For example, in order for our design to be minimally invasive, we need to control the size of the needle and the operation time. For our design to be easy to maneuver and operate, we need to control features such as the number of steps to operate, the mass, and the minimum force to operate the device.

3.3 Results of Quality Function Deployment (QFD)

Our QFD diagram allowed us to determine the most important aspects of our design and gave us an idea of where our priorities should lie. By determining the level of relationship between each of our customer requirements and engineering specifications, we were able to assign importance rankings to each of our engineering specifications.

We discovered that the number of parts, the number of steps to operate, and the needle width were the most important design features that we should focus on. Our complete QFD can be seen in Appendix A.

4.0 CONCEPT GENERATION

Our first goal was to generate many ideas for our advanced biopsy needle to form a strong conceptual base from which we could develop our alpha design. During the process of generating concepts, we divided our designs into two major subfunctions: first, the actual needle that punctures the kidney and extracts tissue; second, the external mechanism which deploys the needle.

Within the needle subfunction, our concepts were further broken into two categories. The first category consists of designs that feature a tissue collection mechanism based upon the existing BARD® Monopty® needle, where the inner collection needle features a depression into which the kidney tissue can fold and be quickly cut from surrounding tissue by the outer cutting sheath. We adapted this design to include the insertion of a hemostatic core. One concept within this category includes the addition of a hemostatic agent insertion channel to the existing inner collection needle. Another utilizes the existing tip geometry and widens to a dual-channel, revolver-like mechanism for deploying both the inner collection needle and the hemostatic agent. Additional BARD® Monopty®-derived concepts and variations on these designs exist in this category as well.

The second category of needle-subfunction designs features a complete redesign of the tip of the needle. These designs include such ideas as a rotating needle that displaces a hemostatic agent into the kidney and then rotates to collect a sample, a suctioning hole to grab kidney tissue, as well as a needle tip which teeth to pull tissue inwards upon removal from the kidney, while pushing Gelfoam® out.

Within the handle subfunction, concepts were also broken into two categories. The first category utilizes mechanical deployment of the needle. Concepts within this category include springs and pushing rods to deploy the cutting mechanism and insert a hemostatic agent. The second category of concepts accomplishes the same tasks through use of a fluid or fluid and mechanical mechanism. All of these designs are shown in further detail in our preliminary ideas section.

5.0 PRELIMINARY IDEAS

5.1 Rotating, Gelfoam®-ejecting Mechanism 1

This design is an attempt to maximize the volume of the tissue collection site while still providing space to hold the Gelfoam® prior to deployment. The needle would deploy into the kidney and quickly rotate 360 degrees as indicated in the sketch. The edge of the tissue collection site would be sharp and angled so as to draw the tissue into the cavity of the needle. When the needle has rotated 360 degrees, the needle would retract while the

Gelfoam® ‘plug’ is deployed at the same rate in the opposite direction. This could be accomplished by a spring connecting the two mechanisms within the handle. This would result in the Gelfoam® being ejected to the exact position of the hole.

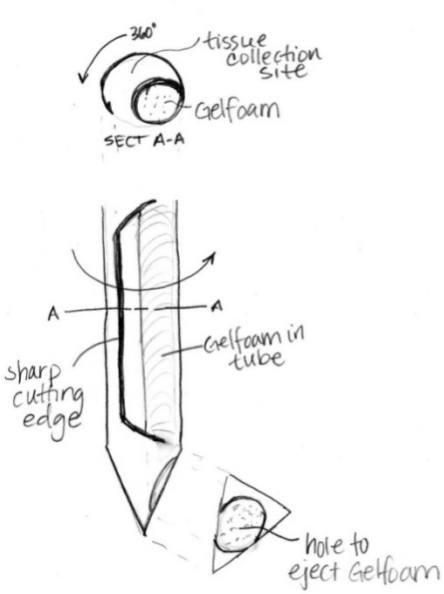


Figure 3: Rotating, Gelfoam®-ejecting Mechanism 1

5.2 Rotating, Gelfoam®-ejecting Mechanism 2

This design is similar to the previous design except it places the Gelfoam® below (or further into the kidney than) the tissue collection site. This would allow the design of a narrower needle. The tissue collection site would have a small cutting hole that is very sharp and angled in order to draw the tissue up and into the device. After a 360-degree rotation the Gelfoam® would be deployed in a manner similar to that described in the previous design. This design could also utilize a vacuum to assist in drawing the kidney tissue into the needle.

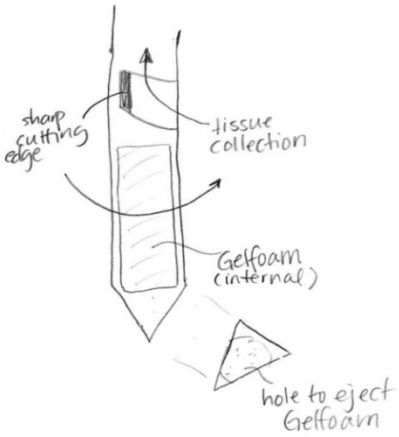


Figure 4: Rotating, Gelfoam®-ejecting Mechanism 2

5.3 Dual-Channel Needle Design

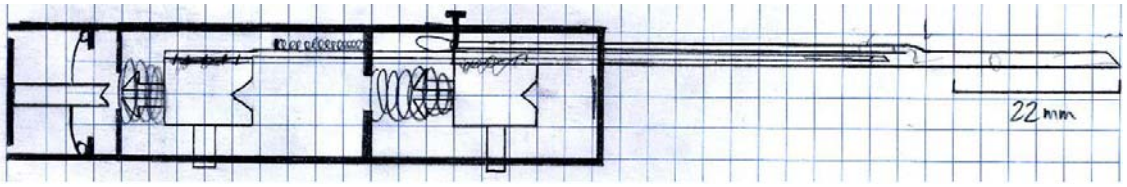


Figure 5: Dual-Channel Design

This concept uses two channels within the outer cutting sheath that allows for the collection needle to travel as in the current BARD® Monopty® device, and for a plunger to travel down a second channel to push out the hemostatic agent. The needle would be thicker near the device, and be the standard 16-gauge size where there is the 22mm penetration of the kidney tissue. The second channel allows for a larger amount of hemostatic agent to be applied, since the inner collection needle could be retracted back and the entire outer cutting sheath diameter would be open for use. Potential concerns with this design are how the larger area of the needle would affect muscle tissue, and if there would be a chance that this larger area could ever travel into the kidney tissue.

5.4 Manual Inner Plunger Design

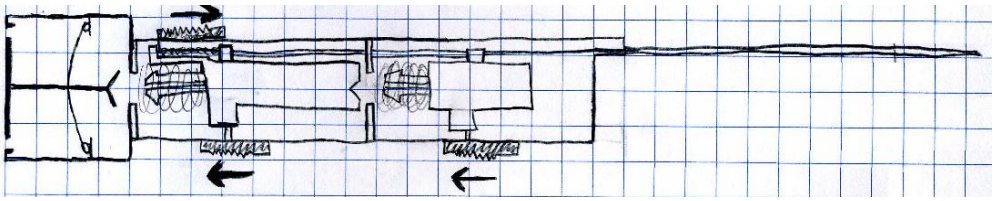


Figure 6: Manual Inner Plunger Design

This device would require that the doctor manually push a slider upon removal of the needle from the kidney that would deposit the hemostatic agent. A major concern with this design is that the doctor would need to correspond the pushing of the slider with removal of the needle from the kidney tissue. There could be uncertainty of whether or not the agent was deposited correctly.

5.5 Reverse Cut Needle Tip

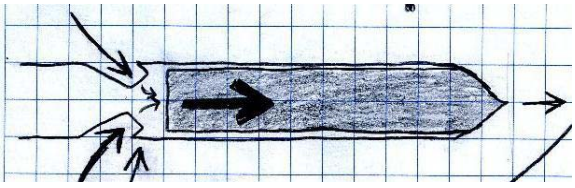


Figure 7: Reverse Cut Needle Tip

This needle would sample tissue by cutting it on removal of the needle from the kidney. As the sample is deposited in the needle tip, it would push out a hemostatic agent that would fill the sample hole.

5.6 Hydraulic Injection of Gelfoam®

This design uses a spring loaded retracting mechanism to eject a set amount of hydraulic solution to push out a core of Gelfoam®. Instead of using a piston-plunger type mechanism to push the Gelfoam® plug into the cavity left by the biopsy, the retracting of the needle and sheath from the kidney would compress a small container of fluid in the handle of the device. This compression would then send fluid down the needle behind the pre-loaded Gelfoam® core.

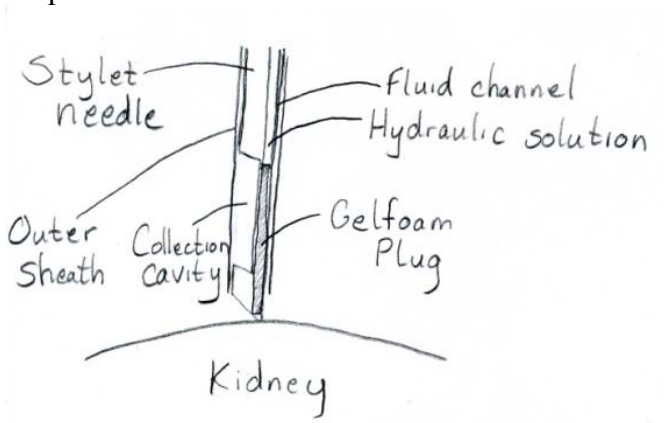


Figure 8: Hydraulic Injection Design

5.7 Needle Twist Design

The needle twist design of the biopsy device makes a small adjustment to the existing BARD® design to allow for deployment of a hemostatic agent. The Monopty® needle is pre-loaded with a core of Gelfoam® in the cavity used to collect kidney samples in the stylet needle. When the needle plunges into the kidney, it carries the Gelfoam® with it. At the very bottom of the motion, the needle twists, cutting the kidney sample, and wiping the Gelfoam® out of the needle. The outer sheath then fires into the kidney, cutting and collecting the kidney sample, while the hemostatic remains outside of the assembly. The needle is removed manually, and the Gelfoam® is left in the biopsy hole.

Figure 9: Needle Twist Design

5.8 Cauterization

This idea involves the concept of electro cauterization. This uses a design similar to the BARD® biopsy device with an electric probe added to the tip and wired within non-conductive material to an electrical source within, or attached to, the handle. The needle would be deployed in a similar matter to the current design. At the instant the cutting sheath is deployed, an impulse of electrical current would be sent through the conductive wiring to the probe. This would serve to cauterize the local tissue and prevent bleeding. The needle would be removed in the same manner as the BARD® device.

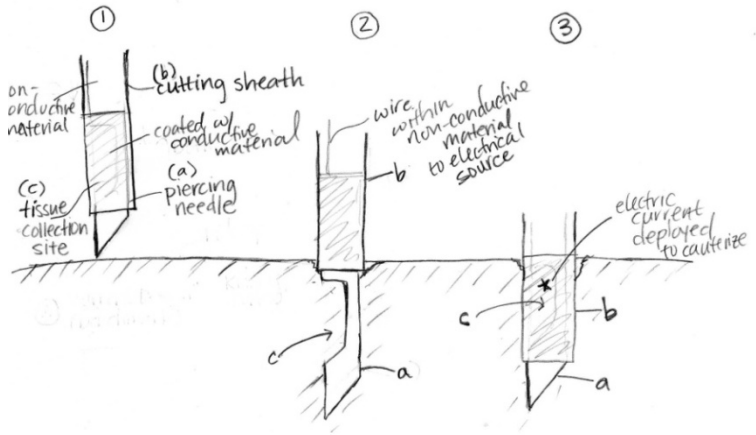


Figure 10: Cauterization Design

5.9 Fluid Injection Design

In order to maximize the tissue collection site volume, the hemostatic agent could be introduced through a tiny needle (or tube) embedded in the biopsy device. Dissolved Gelfoam®, fibrin, thrombin, or another liquid hemostatic agent could be injected through this tube as the needle enters the kidney.

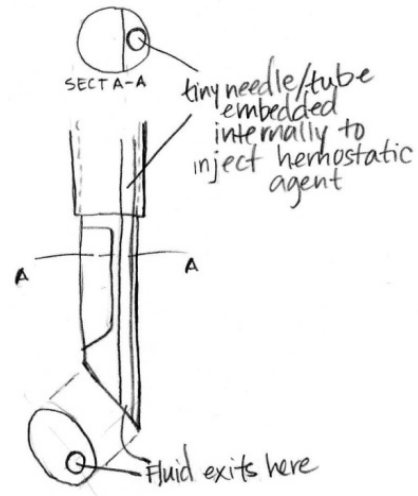


Figure 11: Fluid Injection Design

5.10 Revolving Needle Design

This design includes a four part process in accomplishing the goal of performing the extraction of tissue and deploying Gelfoam® into the kidney. The first step is very similar to the BARD® Monopty® design. An inner collection needle and cutting sheath are deployed into the kidney.

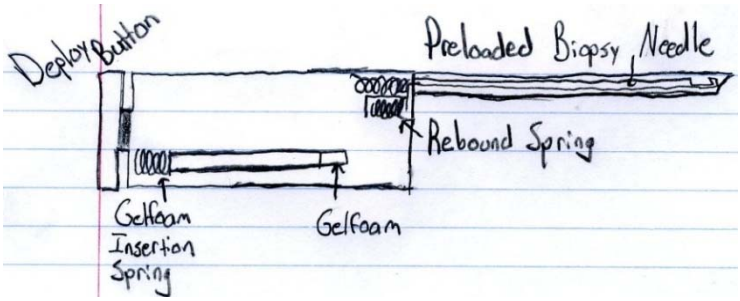


Figure 12.a: Preloaded Revolving Needle Design

The next step in the process is that the inner collection needle retracts completely into the handle of the Revolving Needle Design.

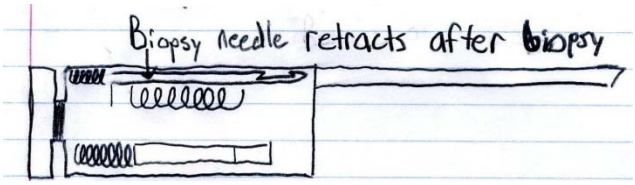


Figure 12.b: Needle Retraction

The Gelfoam® insert now rotates into place where it can be deployed.

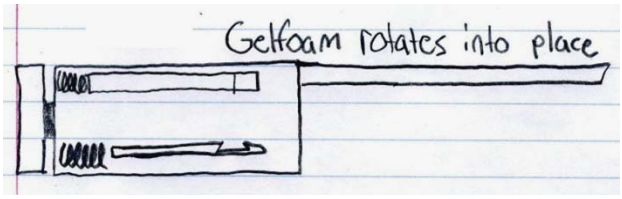


Figure 12.c: Rotation

Finally, the Gelfoam® core is injected into to the kidney.

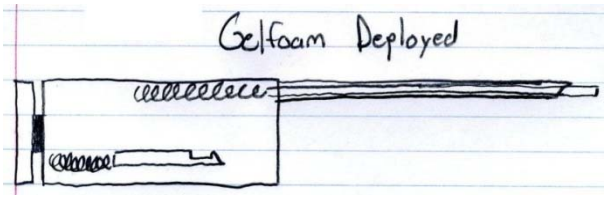


Figure 12.d: Injection

6.0 CONCEPT REFINEMENT

After going through the concept generation process, we determined the most important factors that needed to be incorporated into our design. From our customer requirements and engineering specifications as documented in our QFD we developed three refined ideas.

6.1 Fluid Injection Design

The first design is one that uses fluid pressure to inject a plug of Gelfoam® out of the tip of the needle. The mechanism has a rear-facing spring to retract the needles and also compress a container of fluid to send fluid down the needle, pushing a pre-loaded Gelfoam® plug out of the needle tip. To retract the needles from the kidney, they must be first detached from the springs used to plunge them into the kidneys, and then fired back with the rear-facing spring. To detach the needles, a novel rotating design is used. The forward-firing springs push on a cylinder inside of another shell to which the needles are attached. A helical contour on the inside of the handle then unlocks the outer cylindrical shells from the inner cylinder as they fire down the handle, releasing the needles from the first set of springs. Once this release has taken place, the needles can be retracted out of the kidney. This design is diagrammed in Figure 13, below.

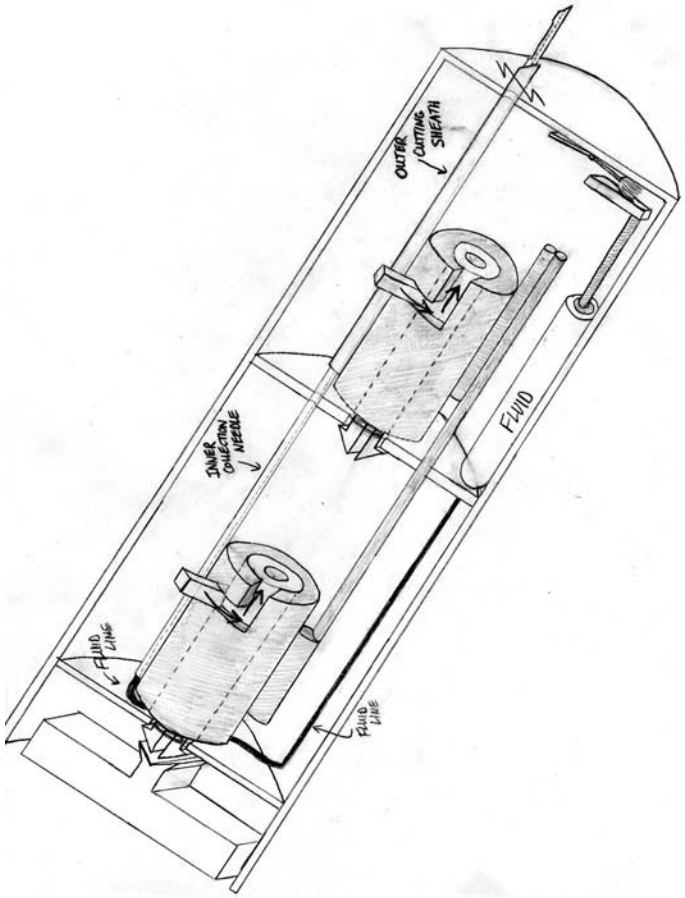


Figure 13: Fluid Injection Design

6.2 Torsional Spring Design

The second design looks to achieve our main goals in a much different way than that of our first Fluid Injection Design. The first major design change is to use a torsional spring instead of a more traditional spring. This torsional spring would turn a spool of wire that would push down the inside of the inner collection needle and insert the Gelfoam®. After the tissue collection takes place, a shaft would rotate and pull two stoppers out of the way that would retract the needles and release the torsional spring. A major problem with this design however is that the Gelfoam® is deployed by a solid rod, which could result in a less robust device due to the small rod diameter required. This design is shown in Figure 14, below.

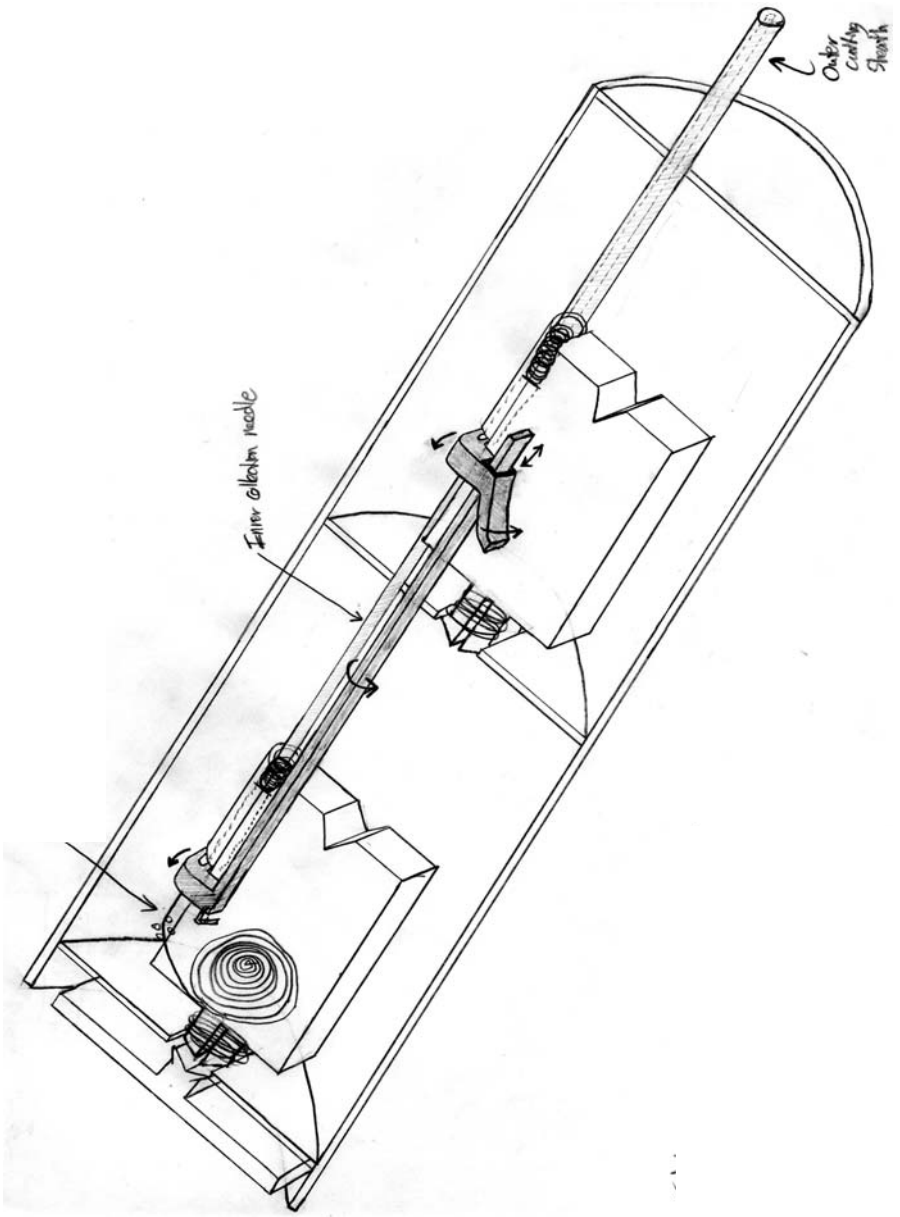


Figure 14: Torsional Spring Design

6.3 Dual Release Design

The dual release design features the use of the spring-loaded mechanism found currently in the BARD® Monopty® biopsy device. Our design expands upon the current device with the addition of two mechanisms. One of these is a spring-loaded plunger for the ejection of Gelfoam® into the kidney. The other is a spring-loaded mechanism to retract both the tissue collection needle and cutting sheath after their deployment into the kidney. The push of a single button would trigger the release of both the tissue collection needle and the Gelfoam®-ejecting plunger, hence the name 'Dual Release Design'. The deployment of the tissue collection needle triggers the cutting sheath deployment, which then triggers a retraction mechanism. The simultaneous but separate deployment of the two initial mechanisms allows the collection needle and cutting sheath to be retracted while the plunger remains extended, therefore ejecting the Gelfoam® into the wound site. For a diagram of this model, see Figure 15, below.

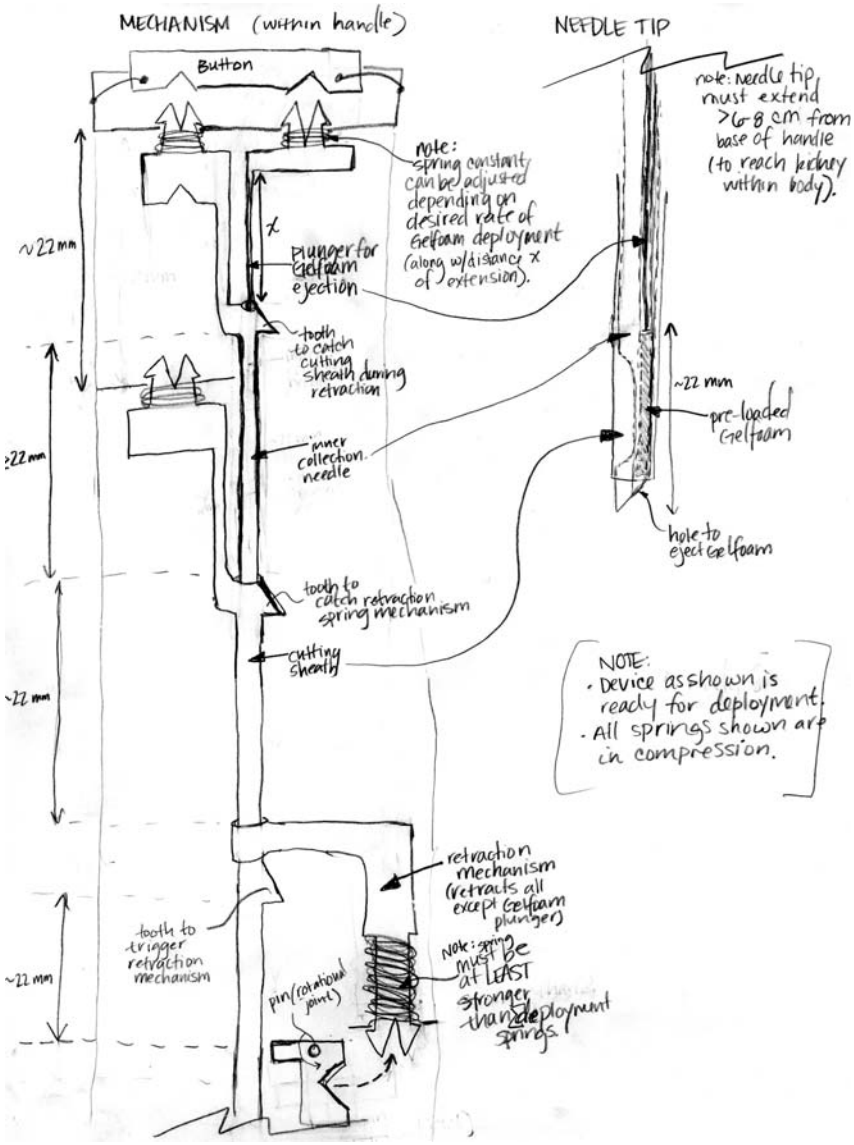


Figure 15: Dual Release Design

7.0 SELECTION OF ALPHA DESIGN

We drew upon our customer requirements and engineering specifications (as documented in our QFD in Appendix A) to perform both qualitative and quantitative analysis in order to select the best design as our alpha design.

7.1 Qualitative Assessment: Pro-Con Analysis

We extensively examined each of these designs and compared the pros and cons of each. Our results are documented in Table 2, below.

Design	Advantages	Disadvantages
Design 1: Fluid Injection	• Amount of gel-foam deposited is adjustable • Small number of moving parts needed • Eliminates need for very small gel-foam depositing plunger shaft	• May be difficult to re-load for multiple collections • May require safety precautions to ensure no air is in fluid lines • May leak or pre-expand gel-foam before depositing
Design 2: Torsional Spring	• Amount of gel-foam deposited is adjustable • Fully mechanical gel-foam depositing mechanism • Gel-foam depositing mechanism minimizes space required to fit within housing	• May be difficult to re-load for multiple collections • Rotating spool may result in kinking or breakage of gel-foam plunger • Moderate number of moving parts needed
Design 3: Dual-release	• Simple, fully mechanical operation • Small number of parts needed • Common parts used – reduced tooling required	• Large housing required to fit parts • High force required in retraction mechanism • Manufacturing/assembly may be difficult

Table 2: Pros and cons of final designs

From this analysis we concluded that the Fluid Injection Design contained the most positive design aspects and would be the easiest to manufacture. All of the designs are effective designs; however, the Fluid Injection Design does everything we need in a simple and innovative manner.

7.2 Quantitative Assessment: Pugh Analysis

We also used a Pugh analysis to determine which of our designs best fits the customer and engineering demands of a biopsy device with bleeding control. The Pugh analysis compares how well each concept satisfies customer and engineering needs in a Boolean

fashion. If a concept does a better job satisfying a particular design specification than the benchmark, it receives a plus (+) and a minus (-) if it is worse. The total number of pluses and minuses from each weighted row are totaled, giving a total satisfaction value. The Pugh chart can be seen in Table 3, below. In this chart, design 1 is our dual-releasing mechanism, design 2 is our design with a sliding rod release mechanism, and design 3 is the fluid injection mechanism. The initial goals (datum) category represents the current technology of the BARD® Monopty® biopsy device. As a team, we decided how each of the three concepts compared to our original goals for the project, and how they compared to the BARD® Monopty® needle when applicable, as the BARD® design does not include bleeding control.

Design Criteria	Weight*	Design 1	Design 2	Design 3	Initial goals (datum)
Stops bleeding	10	+	+	+	0
Manufacturability	8	0	-	-	0
Easy to maneuver and operate	9	0	0	0	0
Simple mechanism operation	8	-	-	0	0
Re-usable	2	0	-	0	0
Few parts	7	+	-	0	0
Obtains sufficient sample	10	0	0	0	0
Robust/Durable mechanism	6	+	-	0	0
	+	23	10	10	
	0	29	19	42	
	-	8	31	8	
	Total	15	-21	2	
	Ranking	**1**	**3**	**2**	

Table 3: Pugh analysis for alpha design selection

The Pugh analysis allowed us to subjectively but quantitatively determine which of our three design possibilities was the best choice for our alpha design. This analysis resulted in the Fluid Injection Design to be the best choice for our advanced biopsy device. While the Pugh analysis was not the sole reason for choosing this option for our alpha design, it was heavily included in our concept selection process.

8.0 THE ALPHA DESIGN

As a result of both the Quantitative and Qualitative Assessments, we selected the Fluid Injection Design as our alpha design. The following section describes, in detail, the alpha design of a biopsy needle device with bleeding control that we chose. The design is fully diagrammed in Figure 13 on page 18.

8.1 Device Summary

The alpha design is a biopsy device that deploys a hemostatic plug using a fluid injection mechanism after collecting the kidney sample. The cutting needle and outer cutting sheath are plunged into the kidney sequentially, and then retracted out of the cortex. The mechanism used to retract the needle from the kidney also compresses a fluid reservoir inside of the handle, expelling fluid down the cutting needle. At the tip of the cutting needle, a pre-loaded Gelfoam® plug is pushed out of the retracting needle and into the cavity left in the kidney.

This entire process is triggered by one button on the end of the biopsy device. The collection of tissue and deployment of a hemostatic occur sequentially without extra input from the physician using the device. This was an important aspect of the design, as our target for time that the needle was physically inside of the kidney was less than 1 second. The BARD® Monopty® design required that the physician remove the needle from the patient's kidney after it had been triggered. Our design will automatically retract and deploy bleeding control, which is safer for the patient and is a simpler procedure for the doctor.

8.2 Needle Tip Design

Our alpha design for the needle tip is very similar to the BARD® Monopty® needle, except a small tube runs down the length of the inner cutting needle, behind the tissue collection groove, and out the front of the tip as seen in Figure 16 on the following page. This channel will be plugged at the tip of the needle by the hemostatic agent. When the needle is plunged into the kidney and then retracted with a kidney sample, fluid pressure will drive the hemostatic agent out of the tip of the needle and into the biopsy cavity in the kidney. We used the BARD® design as a benchmark because Dr. Weitzel recommended it based upon its reliability and frequency of use across the field of Nephrology. Dimensions of this needle will be very small: Dr. Weitzel recommended that we constrain the diameter no larger than a 16-gauge needle in order to be widely accepted by medical professionals.

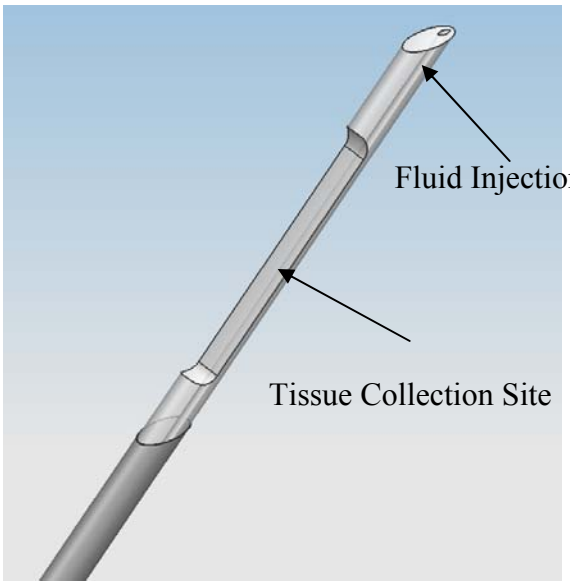


Figure 16: Needle tip showing channel for hemostatic agent deployment

8.3 Needle-Spring Detachment Mechanism

One novel component of this design is the twisting needle release used on both the cutting needle and outer cutting sheath within the handle of the biopsy device as seen in Figure 17, below. A crucial part of this design was having a spring-loaded retracting mechanism for the biopsy needles. Without having an automated retraction of the needles, there would be no room in the biopsy cavity for a hemostatic agent to be deployed. The needle and sheath must pull out of the cavity before the hemostatic agent is used. Therefore our design needs to fire a cutting needle and cutting sheath forward, detach them from the forward firing mechanism, and then have a mechanism to fire the needles backwards and retract them out of the kidney to make room for the hemostatic agent. This critical detaching mechanism is diagrammed and described below.

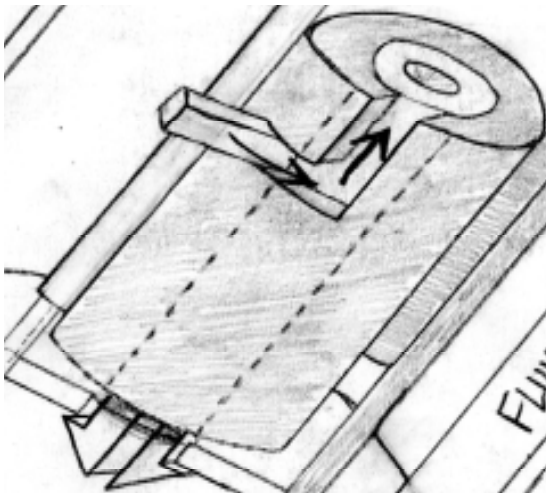


Figure 17: Twisting needle release

This design uses an inner cylinder surrounded by a cylindrical shell to which the needle is attached. The inner cylinder has a small peg extruding perpendicularly outward and through a slot in the cylindrical shell. The inner cylinder is also attached to the spring used to deploy the needle.

When the spring is released from a compressed position, it pushes both the cylinder and cylindrical shell down the handle of the biopsy device. Because the cutting needle is attached to the top cylinder assembly, and the cutting sheath is attached to the lower cylinder assembly, the two are automatically fired sequentially into the kidney. When the cylinder assemblies reach the end of their travel, a helical contour (not shown in Figure) along the inside of the biopsy device handle guides the small peg attached to the inner cylinder in an angular fashion, twisting within the outer shell. The peg spins until it is even with the axial slot in the outer shell. Once this occurs, the outer shell, to which the needle is attached, is free to move upwards, as the shell can fit around the entire spring. This is the key mechanism to have springs fire the needles forwards and then backwards.

8.4 Fluid Injection System

We decided that a fluid injection system should be used to deploy the hemostatic agent. We decided on this mechanism because it would be easy to control the amount of material injected into the biopsy cavity. Also, because of the small nature of the device, it would be much simpler than a mechanical pushing mechanism. A solid plunger would be much smaller and more fragile than a fluid system. A fluid system would be relatively simple to assemble during manufacturing. Lastly, the fluid could be used as an accelerant to the rate of expansion of the Gelfoam® in the kidney, rendering it less likely to be washed out by excess blood.

The fluid system can be seen in Figure 13 on page 18. The same spring used to retract the cutting needle and sheath is used to compress a small container of fluid. A tube from this container is connected to the end of the hollow channel which runs down the length of the cutting needle to the hemostatic plug at the tip. When the container is compressed during retraction of the needles, the fluid pressure causes fluid to be pushed down the needle, expelling the hemostatic and a volume of fluid out of the needle tip and into the kidney wound caused by tissue removal.

9.0 ENGINEERING PARAMETER ANALYSIS

9.1 Fluid Pressure Requirements

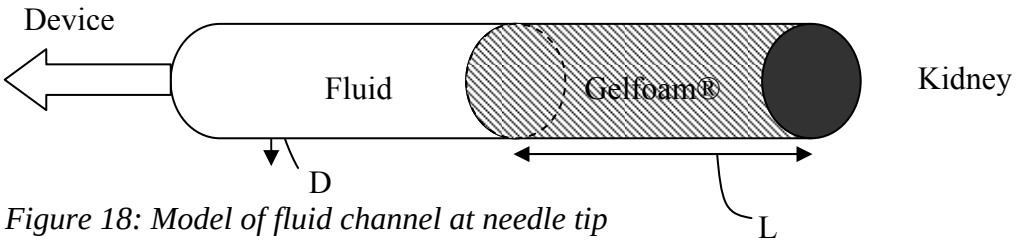


Figure 18: Model of fluid channel at needle tip

For this fluid model, it is safe to assume quasi-static equilibrium (acceleration not considered). This is because our only concern is expelling the Gelfoam® from the tip of the device. For these calculations, the velocity of the fluid is not important to us, so the fluid mechanics of small diameter pipe flow are not needed.

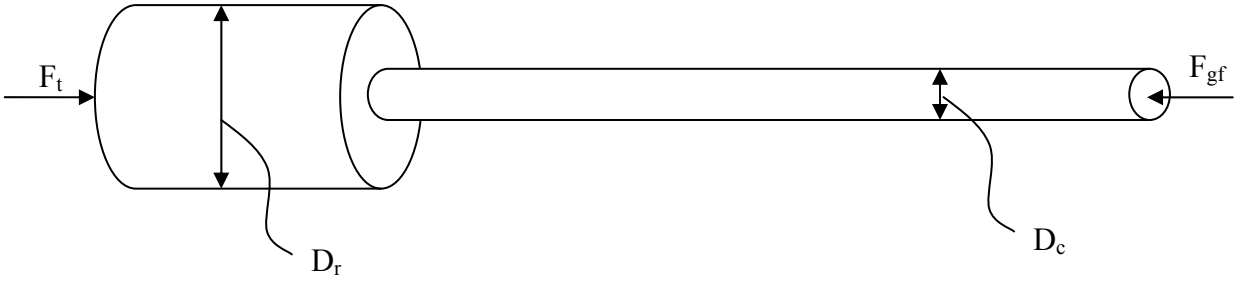


Figure 19: Model of fluid reservoir and fluid channel

Because we are assuming steady state conditions, the pressure at all points must be equal

$$\frac{F_t}{A_r} = \frac{F_{gf}}{A_c} \tag{1}$$

Where F_t is the total force from the plunger compressing the reservoir, and F_{gf} is the frictional force of the Gelfoam® in the tip of the fluid channel. Using the relationship for area, we get

$$F_t = \left(\frac{D_r}{D_c}\right)^2 F_{gf} \tag{2}$$

To determine F_{gf}, we can use the coefficient of static friction, μ, and the average pressure of the Gelfoam® plug against the channel wall, P_{avg}, to get

$$F_{gf} = \frac{P_{avg} L \pi D_c^2 \mu}{4} \tag{3}$$

However, because it was too difficult to calculate the average Gelfoam® pressure, and we were unable to determine the coefficient of friction of the Gelfoam® against the inside of a needle tube, we determined the force needed to expel Gelfoam® from a small needle by testing on medical supplies that we had. For the scope of this project, we felt that this was the most efficient way to determine this force.

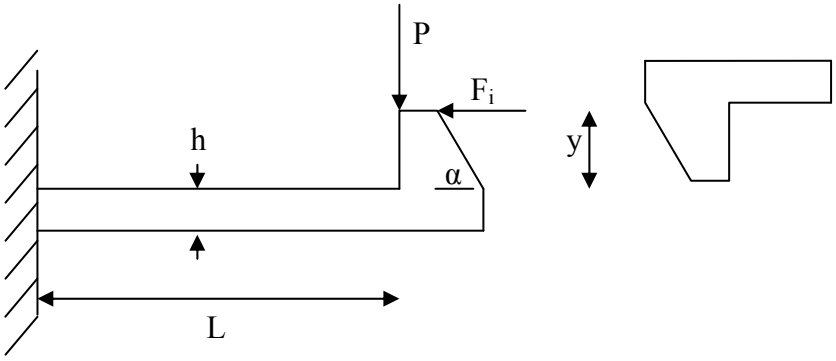
9.2 Gelfoam® Testing

The pressure needed at the needle tip to push out a Gelfoam® core is the spring force in the retraction spring times the area of the fluid reservoir, as given in Equation 1, above. In our test, we measured F_t using a 15 mm diameter syringe was 22.5 N. We plan on using a 1 mL syringe in our prototype with a diameter of 7 mm. Therefore, using Equation (1), we determined that the necessary spring force for a syringe this size was 10.5 N. This value was below the spring force of the BARD® biopsy device springs, and therefore was not a limiting value in our spring selection.

9.3 Snap Fit Analysis

We decided to use snap fit parts in three components of our design. The BARD® Monopty® device that we used as our primary benchmark used snap fits for the same functions as our device, and through studying the effectiveness of this design and further research, we have decided that snap fit components are good design choices for our biopsy device. Snap fits decrease the number of parts and greatly decrease the assembly time for the device, making it cheaper to manufacture. Below are the equations governing the mechanics of snap fits that we used in the design of our parts.

For a snap fit connection,



h = height
b = base width
L = length of deflected region
α = insertion angle
ε = permissible strain value (42% of yield strain for repeated-use snap fit parts)
E = young's modulus
μ = coefficient of friction between two snap fit parts

Figure 20a: Snap-fit tooth diagram

Maximum deflection of straight cantilever beam, y

$$y = \frac{2}{3}\frac{\varepsilon L^2}{h} \tag{4}$$

Deflection force, P

$$P = \frac{bh^2}{6}\frac{E\varepsilon}{l} \tag{5}$$

Engagement (insertion) force from friction

$$F_i = P\left[\frac{\mu+\tan\alpha}{1-\mu\tan\alpha}\right] \tag{6}$$

Because several assumptions need to be made before this analysis can be done, the best method for designing a snap fit part is to use excel to keep track of all of the variables. This way, quick iterations to optimize geometry and material can be performed.

Our device has snap fit parts to retain each loaded spring. An image of this is in Figure 20b, below.

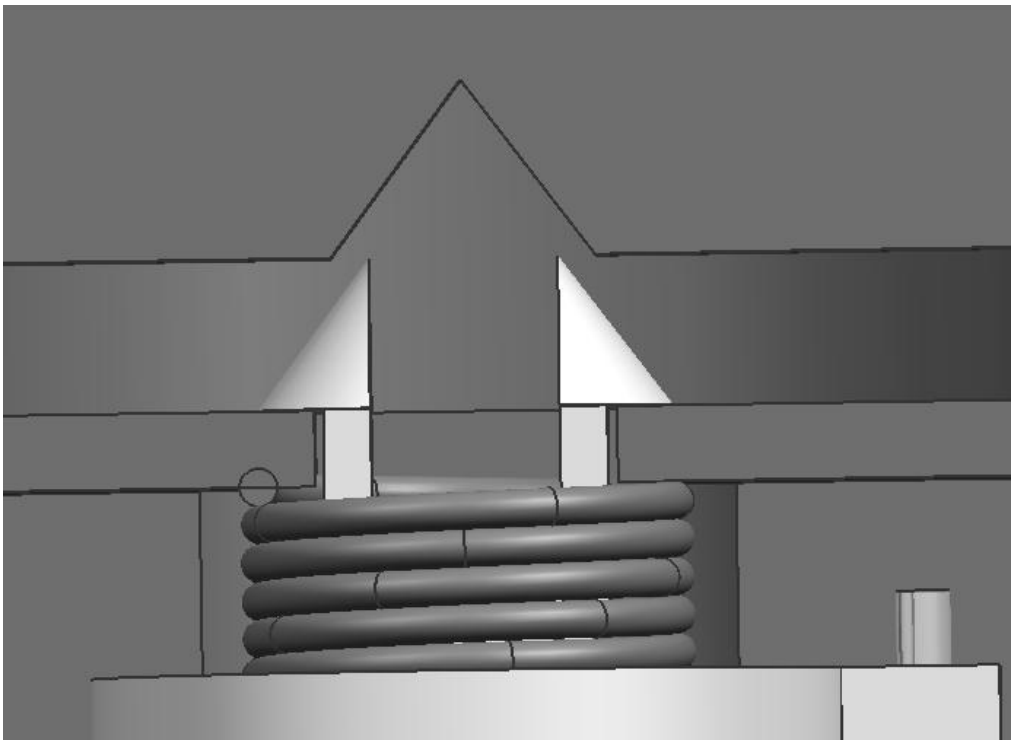


Figure 20b: Loaded spring being held in place by snap fit teeth

This is the upper spring, which is used to fire the inner collection needle into the kidney. To cock this spring to prepare for deployment, it is first compressed by having an assembler raise the cylinder (in white at the bottom of Figure 20b) that it is resting on. When the snap fit mechanism reaches the opening at the top of the chamber, the teeth are forced inwards because of their outer slope. The displacement is purely elastic, as the teeth and cylinder are all one piece. Once they have been pushed through this opening, the elastic energy of the material forces the teeth to snap outwards, and they rest on the top side edges. Once they are resting in this position, the spring is fully compressed and ready to deploy, as the teeth provide an equal and opposite force to keep the spring compressed. To fire the spring, the button (directly above the teeth) is depressed. The triangular cut in the bottom the button forces the teeth to deflect inwards and off of the edge of the opening. Once they have been forced inwards, the spring is free to fire, and the entire assembly is forced downwards by the elastic energy in the compressed spring.

The second spring and the spring of the retraction mechanism both use a compliant mechanism in the same way. Using compliant teeth to hold a compressed spring is very effective because it requires few parts and a relatively low activation force to operate. However, it was critical to calculate this activation force, because it would be applied by other springs. Therefore, the force was prescribed, and the design needed to have an insertion (non-inward) force requirement that was less than the spring force. To ensure this, we used a spreadsheet to perform iterations of geometry and material properties to find the optimal combination to give a minimum required insertion force. The critical

rows are shown below in Table 4. For the entire table of geometrical values of the compliant teeth, see Appendix C.

	Snap Fit Part		
Variables	Upper cylinder	Lower cylinder	Retract mechanism
deflect force, P (N)	4.586	4.586	5.732
insert force, F_i (N)	6.213	6.213	6.526
Force to release mechanism (N)	12.43	12.43	13.05

Table 4: Force to release compliant teeth in biopsy device

The crucial row of this table is "Force to release mechanism." This is the total force needed to cause the teeth to be deflected the necessary distance to release the compliant mechanism. The typical thumb force a human is able to apply is 133-191 N [8], well above the release force values we calculated. Therefore, the only concern was to make the force below the spring force of our chosen springs.

9.4 Spring Force Measurements

To simplify the design process, we decided to use spring forces similar to the BARD® Monopty® biopsy device. This was a good benchmark to use because, as Dr. Weitzel informed us, it was widely accepted as a good device for kidney biopsies (if patient bleeding is not a concern). Therefore, we could safely assume that the springs in the device were strong enough to penetrate the cortex of the kidney. With the help of Jason Moore and the prostate biopsy project team in the Wu Manufacturing center, we used a Kistler© load cell to measure the force of the springs when fully loaded and at the end of the 22mm stroke into the kidney. At the fully compressed length, the spring force is 14.67 N, and at the extended length, the force is 9.32 N. The averaged values from each trial are seen below, in Table 5.

Compression to 19 mm total spring length						
	Spring 1			**Spring 2**		
Run	1	2	3	1	2	3
avg value (N)	15.48	16.11	14.79	13.57	12.78	15.32
Total average (N)	**14.67**					

Table 5: The average spring force from all trials is 14.67 N

From Table 4, the force to release the mechanism is only 12.42 N, which is below the measured spring force in Table 5. This was a critical requirement for our design, as it cannot function if the springs are not strong enough to deploy the next stages in the

biopsy device mechanism. Therefore, we will be using 13 mm diameter springs that have a 50 mm rest length, and 9 coils. These are the same dimensions as the BARD® design, but we have proven that they will work for our design. We will use 3 of these springs.

9.5 Kidney Insertion Force Measurements/Needle Analysis

In order to understand the forces needed to insert a needle into the cortex of the kidney, we met with Dr. Rao in the Nephrology department at the U of M health system to discuss kidney models. Before the meeting, we made several blocks of biogel, the material used by the kidney biopsy team at the Wu Manufacturing center to model human organs. We made blocks of several stiffnesses to present to Dr. Rao for comparison. We did this because although through research, we determined that typical kidney has a density of 1050 kg/m^3 and a Young's modulus of 1.2 MPa [9], we had no reliable way to measure either of those quantities within the scope of our project.

After biopsying all of our biogel blocks, Dr. Rao selected which was the most similar to a human kidney. He also recommended biopsying a normal red apple as it is very similar to a kidney. We used both an apple and our biogel in our biopsy force tests. To perform these tests, we placed the tip of the BARD® Monopty® needle to the surface of the kidney material and biopsied it while it was resting in a force transducer. This measured the compressive force applied through the needle during operation.

The biogel data resulted in a maximum insertion force of 3.175 N. Because Dr. Weitzel strongly recommended that we use a 16-gauge needle for our design, we will assume a solid cylindrical needle with a diameter of 1.65 mm. Using the following equation

$$\sigma = \frac{F}{A} \tag{7}$$

Where σ is the normal stress of the needle, σ = 1.48 MPa. Therefore, the material chosen for our needle must have a yield strength of at least 1.48 MPa. Applying a factor of safety of 1.5, the yield strength should be, at minimum, 2.23 MPa.

9.6 Fluid Volume Calculation

Because the device needs to expel enough fluid to push the Gelfoam® core out of the tip of the needle, we calculated exactly how much fluid the system should expel to be effective. It was important to inject enough to get the Gelfoam® out of the device, but also not too much, as this would be wasteful and cause fluid to spill after the tissue sample was removed.

We decided that the volume of the hole created by the needle within the kidney should be equal to the amount of fluid that is driven forward by the fluid plunger mechanism. This way it is guaranteed that the cavity in the kidney will be completely filled by Gelfoam® and fluid. Assuming a 22 mm needle plunge depth and a needle diameter of 1.65 mm, the fluid volume equal to the volume of the needle that is fired into the kidney is 0.047 mL.

Also important to the fluid system of the device is the total fluid volume throughout the system. To determine this value, we calculated the volume of the three major components of the device: the fluid reservoir, the tube from the reservoir to the needle, and the needle. To see the table of values for each of these components, see Appendix D. The total volume of the system that we calculated is 0.528 mL.

Because this value is very different than the volume of fluid that needs to be injected into the cavity left by the biopsy, two hydraulic devices will need to be used in the loading of our device. One will be used to fill the system with fluid, and the other will be used during the operation of the device to push fluid through the system and out the tip of the channel at the distal end of the needle. For the prototype, we will be using syringes, as it will be easy to order them and assemble them into our device. To fill the needle and tubing with fluid, a large syringe will be attached to the tubing attached to the needle. When the needle tip is submerged into the fluid solution and the plunger is drawn back, the system will fill with fluid. Once this has been done, the large syringe will be removed, and a smaller diameter, prefilled syringe will be attached to the tube and loaded into the retracting mechanism. The smaller diameter syringe will inject the correct amount of fluid when used with a 22mm stroke. However, it does not have the volume to fill the entire fluid system in preparation for the biopsy. The larger diameter syringe will be used for this function.

10.0 FINAL DESIGN DESCRIPTION

10.1 Device Overview and Component List

Our final design was based on the engineering design parameter analysis as discussed above, and can be seen in its entirety in Figures 21 and 22.

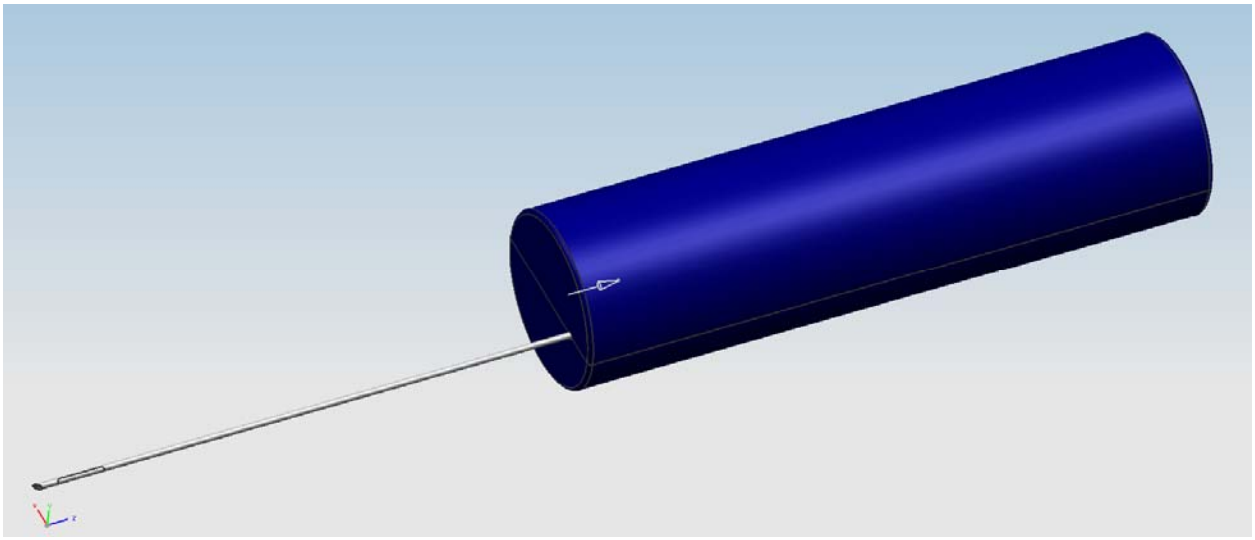


Figure 21: Fully assembled final design

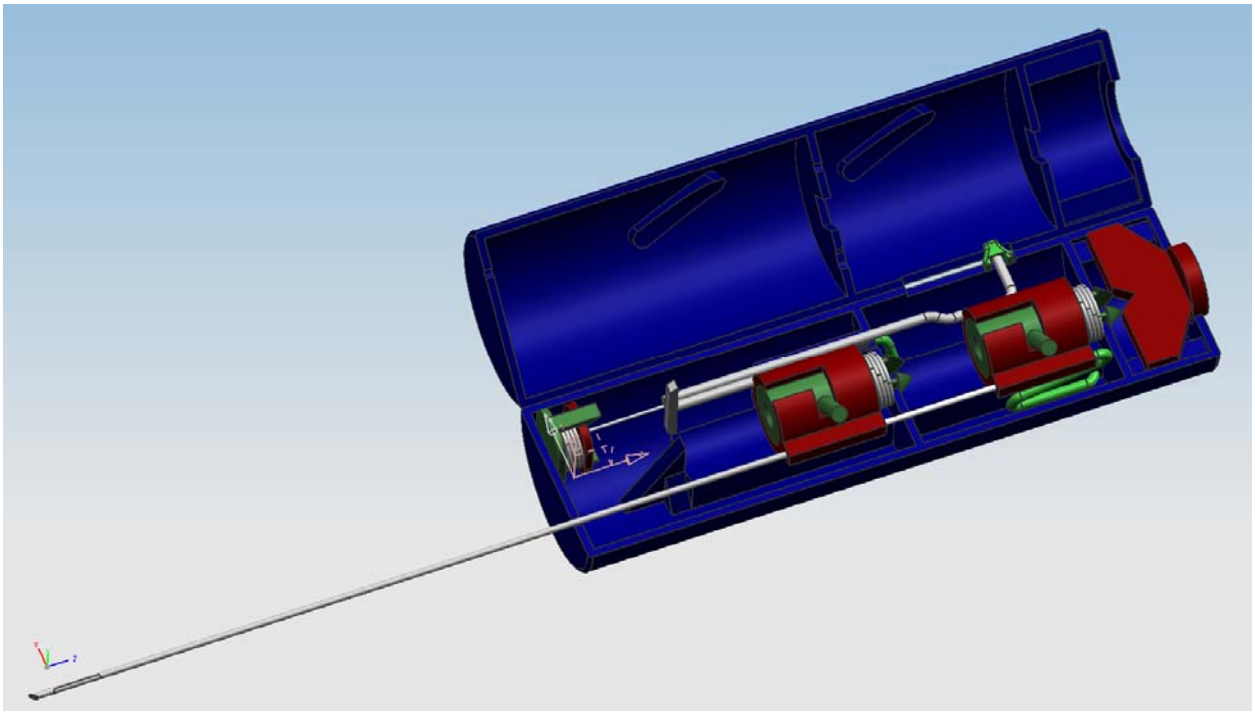


Figure 22: Final design shown with internal detail

The parts and components used in this device can be seen in Figure 23, with descriptions in Table 6. Detailed engineering drawings with part dimensions can be found in Appendix E.

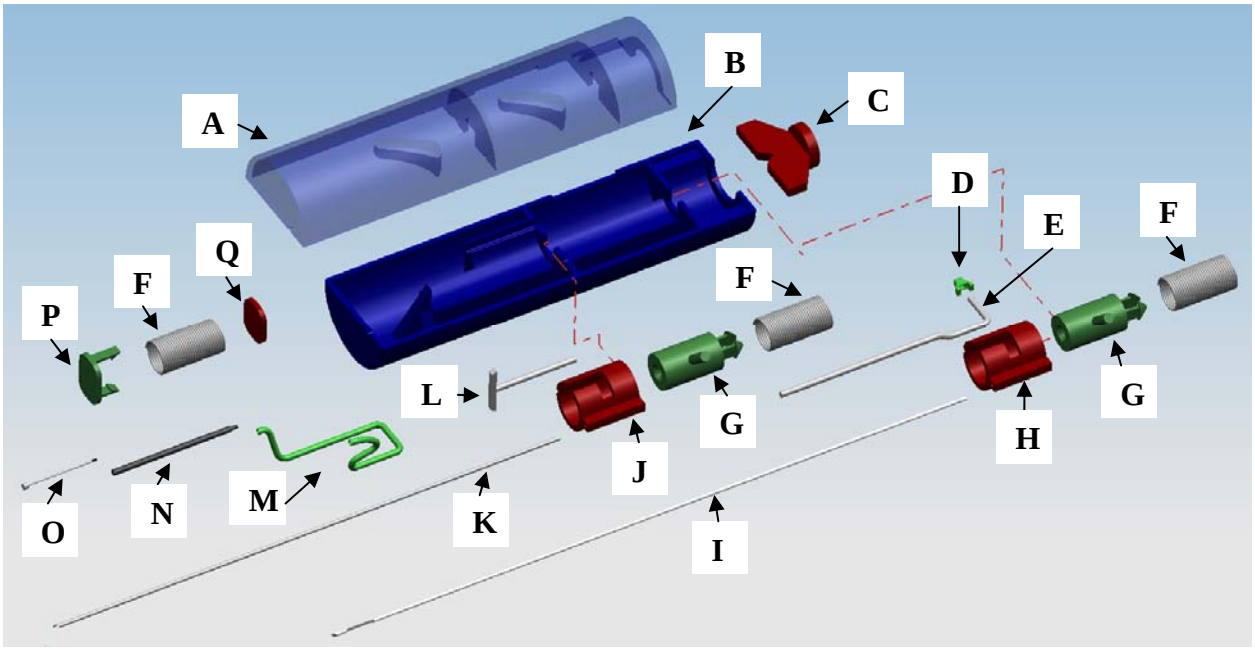


Figure 23: Exploded view of device

Part Label	Description
A	Upper half of housing
B	Lower half of housing
C	Deployment button
D	Inner collection needle outer cylinder push rod slider button
E	Inner collection needle outer cylinder push rod
F	Deployment spring
G	Inner cylinder/Spring disengagement cylinder
H	Inner collection needle outer cylinder
I	Inner collection needle
J	Outer cutting sheath outer cylinder
K	Outer cutting sheath
L	Outer cutting sheath outer cylinder push rod
M	Fluid tubing
N	Hydraulic cylinder
O	Hydraulic plunger
P	Needle retract/hyrdraulic plunger compress mechanism
Q	Push plate

Table 6: Part descriptions

10.2 Device Description

Tissue collection with this device is initiated by pressing the deployment button on the top of the cylindrical handle. This deployment button triggers a sequence of actions within the device that function to collect tissue and deposit Gelfoam® to control bleeding at the collection site. The deployment button consists of a triangular notch in the bottom which triggers the first action in the sequence by releasing a spring loaded compliant mechanism. This release causes a spring to propel an inner cylinder surrounded by an outer cylinder with an attached needle, resulting in the attached needle plunging into the kidney tissue to a depth of 22 millimeters. This attached needle is called the inner collection needle, and consists of a sharpened tip, a tissue collection site, and a Gelfoam® injection channel which will be discussed later. The inner and outer cylinders are locked together by a peg that is attached to the inner cylinder and sits in a slot in the outer cylinder. While the cylinders travel down the device, a helical track on the inside of the top half of the housing guides the peg around the slot to disengage the two cylinders. The purpose of this disengagement will be discussed later. In addition, a push rod that is attached to the outer cylinder and works in conjunction with the disengagement mechanism is propelled down the device by the motion of the outer cylinder. Figures 24, 25, and 26 show these described motions in detail.

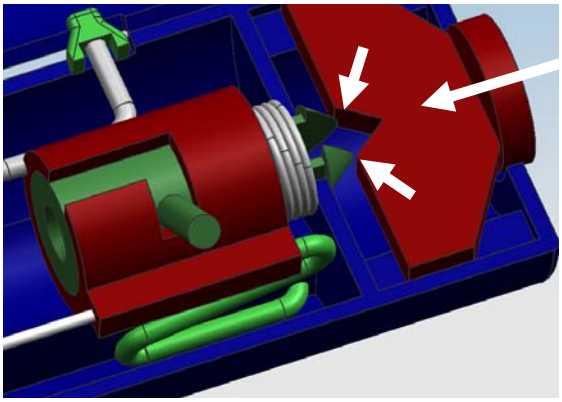


Figure 24: When button is pressed, compliant teeth of inner cylinder are compressed together

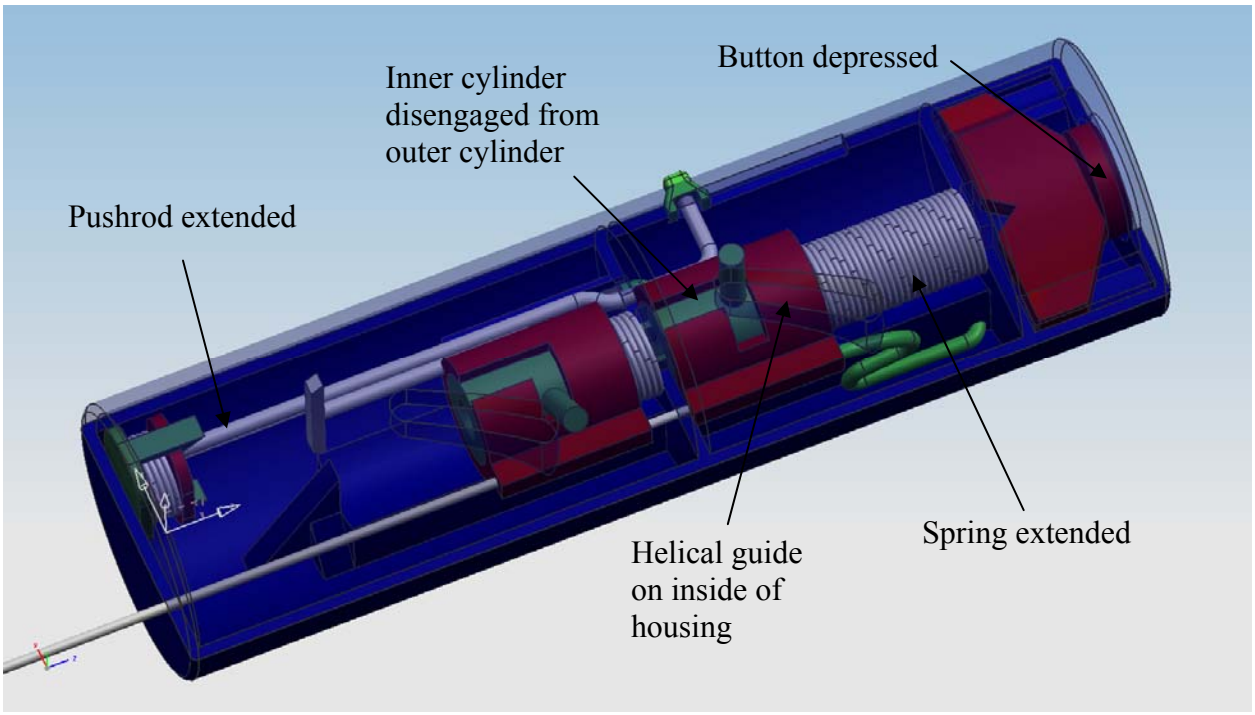


Figure 25: Position of internal components in first action of sequence

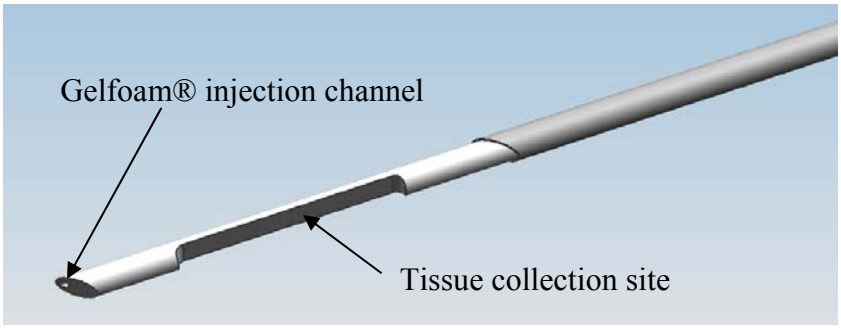


Figure 26: Inner collection needle in first position of sequence

The second action in the sequence is triggered by the inner cylinder that moved in the first action of the sequence. This cylinder has a conical notch on the end opposite the composite teeth that acts like the triangular notch on the deployment button. When this inner cylinder reaches its full travel stroke, the conical feature compresses a set of compliant teeth on the second cylinder and triggers an action very similar to the first. The second cylinder and corresponding cylindrical shell with attached needle and push rod travel 22 millimeters, as in the first action. The needle attached to this second outer cylinder is hollow, and is called the outer cutting sheath. This needle cuts tissue during its travel, and holds the tissue sample in the sample collection site on the inner collection needle. Figures 27, 28, and 29 show the motions of the second action in the sequence in detail.

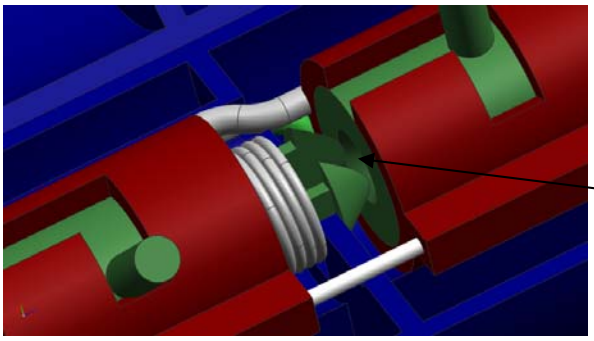


Figure 27: First cylinders positioned just before reaching full length of travel

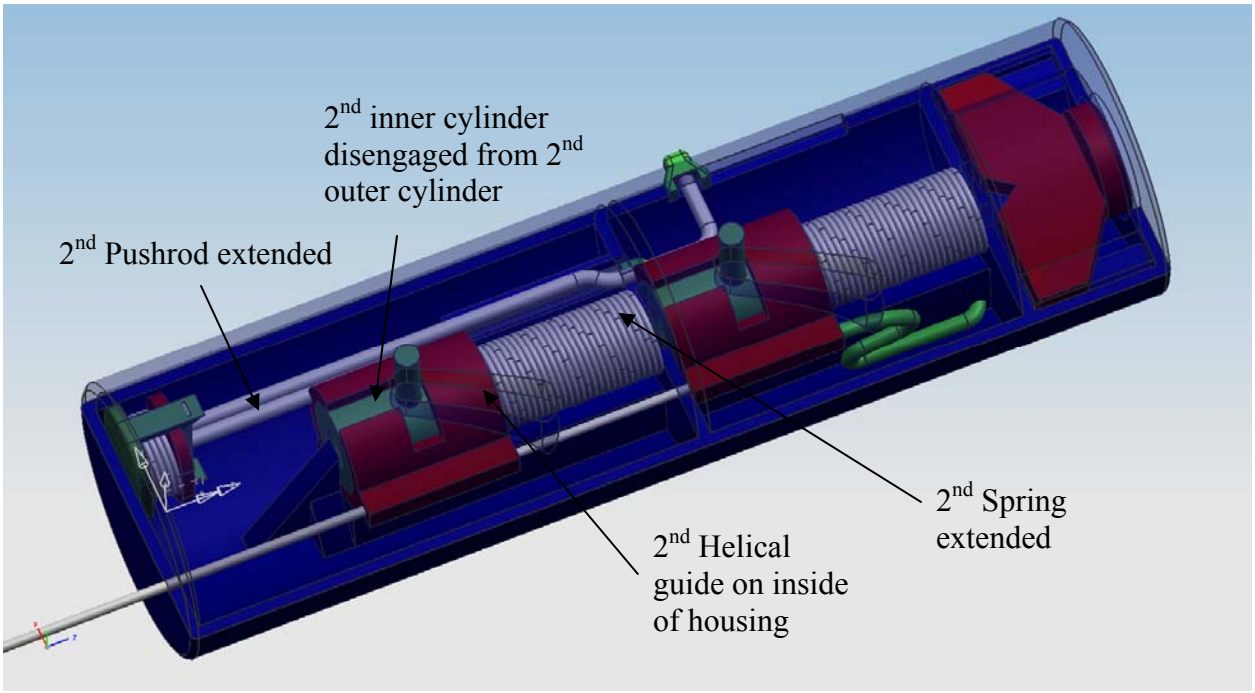


Figure 28: Position of internal components in second action of sequence

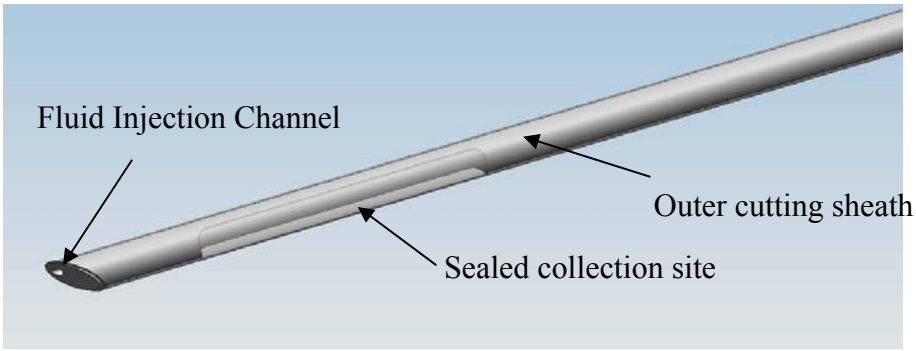


Figure 29: Outer cutting sheath extended over inner collection needle

The final action in the sequence results in the retraction of the needles from kidney tissue, while simultaneously depositing Gelfoam® into the tissue cavity left behind. When the second inner cylinder reaches its full length of travel, its attached push rod triggers a set of compliant teeth, releasing a spring-loaded push plate (see Figure 30). When this plate

is released, the spring propels the plate and pushes on the push rods attached to both outer cylinders. Since both inner cylinders have been disengaged from the outer cylinders by the helical guides, the outer cylinders are free to slide back up the device and pull the needles out of out of the kidney tissue. In addition, this push plate serves to compress a fluid plunger into a syringe-like fluid chamber. The syringe-like device is connected by tubing to the end of the inner collection needle, which features a hollow channel for fluid injection purposes (see Figure 29). A pre-loaded amount of Gelfoam® is located in the tip of the Gelfoam® injection channel of the inner collection needle, and the remainder of the channel, connective tubing, and the fluid chamber is filled with saline solution. When the needles are retracted, the plunger of the syringe-like device is compressed, injecting the Gelfoam® out of the end of the inner collection needle and into the tissue sample cavity. Figures 30-33 show the motions of this third action and final positions in detail.

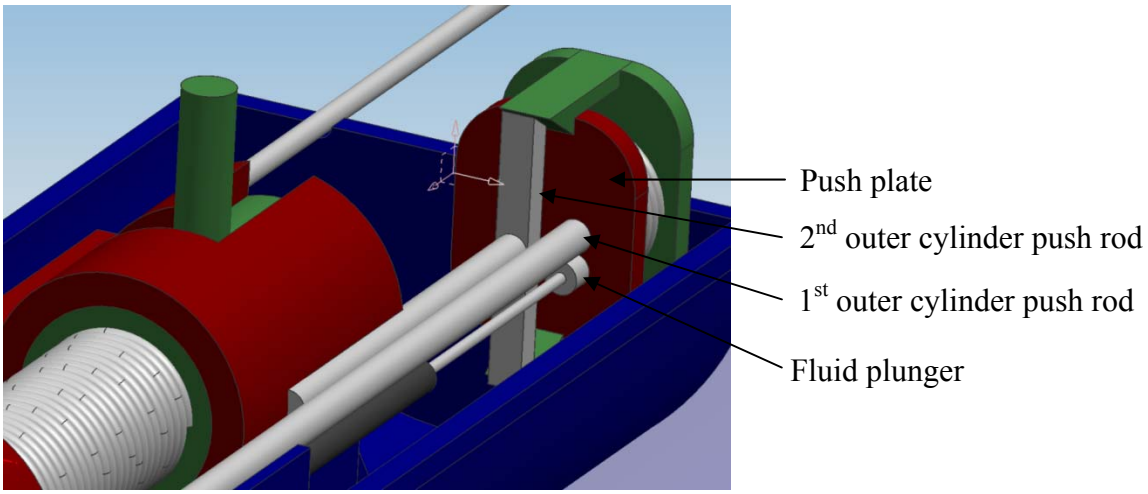


Figure 30: Second cylinder positioned just before reaching full length of travel

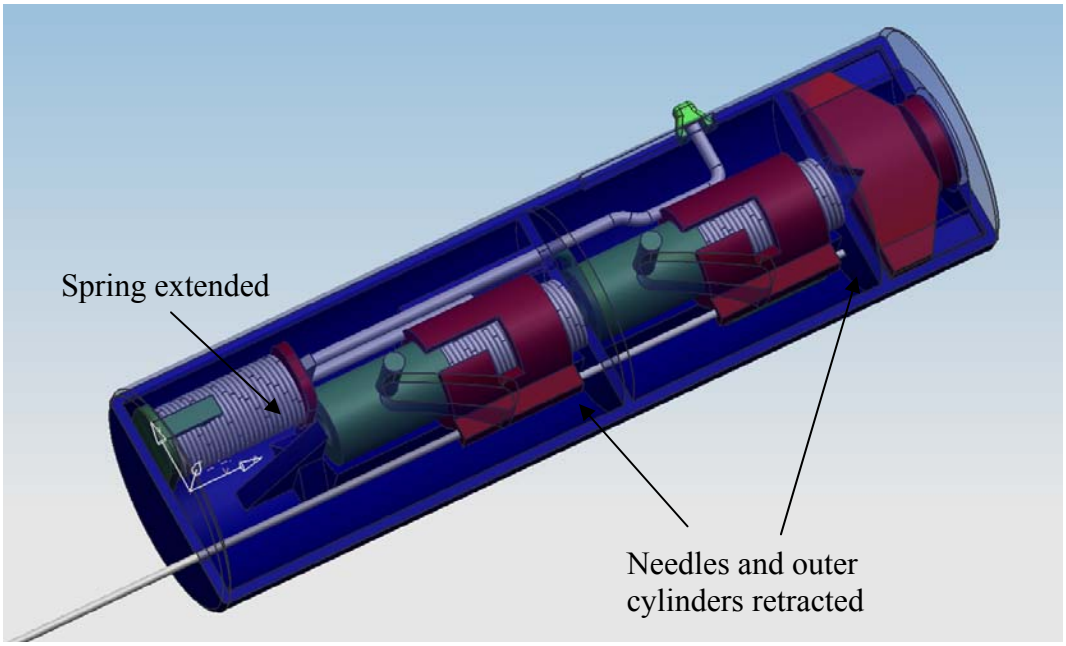


Figure 31: Position of internal components at end of sequence

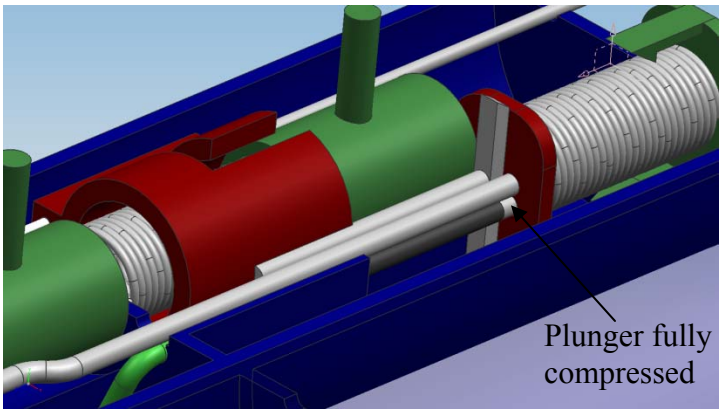


Figure 32: Position of internal components at end of sequence

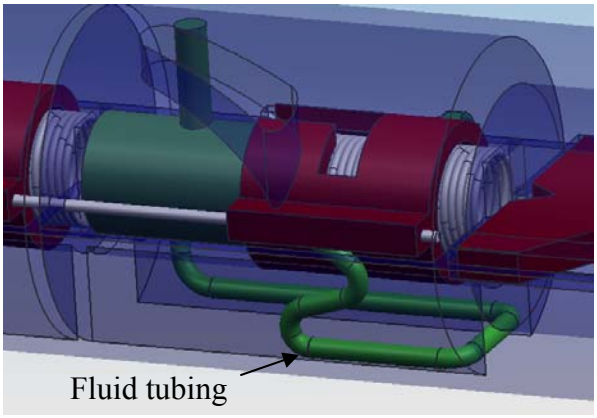


Figure 33: Flexible fluid tubing connecting syringe-like device to inner collection needle

Once the sequence of events has completed, the doctor can remove the tissue sample from the device by using an external slider. This external slider is attached to the push rod of the first outer cylinder. By moving the external slider, the push rod compresses the retraction spring and allows the inner collection needle to slide out from inside of the outer cutting sheath and expose the tissue collection site. This can be seen in Figure 34.

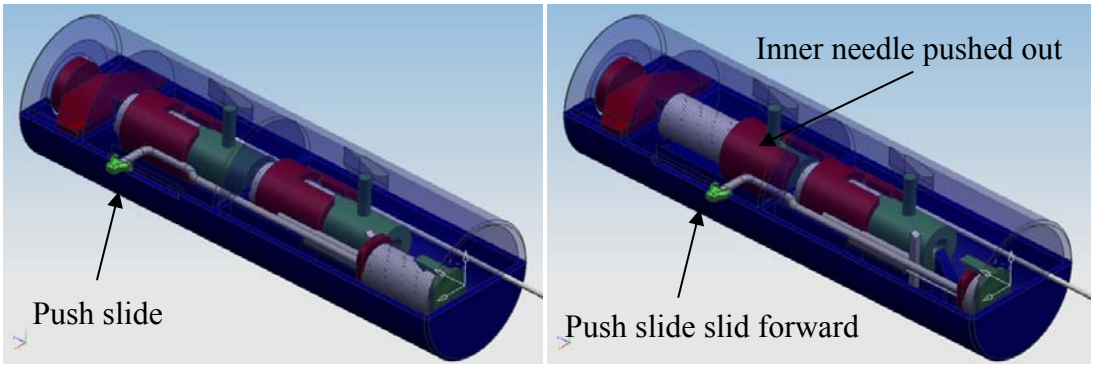


Figure 34: Push slide slides inner collection needle outside for tissue removal

10.3 How Gelfoam® Works

Gelfoam® (a Pfizer™ product) is a hemostatic agent fabricated from absorbable pig skin gelatin and can come in two forms, an absorbable gelatin compressed sponge and an absorbable gelatin powder. Gelfoam® is placed within the wound and prevents excessive bleeding by acting as both a physical obstruction to blood flow and acting as a lattice for blood clot formation. It is able to hold up to 45 times its weight in blood. When placed in soft tissue, Gelfoam® liquefies within a week and completely dissolves in 4-6 weeks [11].

The absorbable gelatin powder is created by milling and sterilizing the compressed sponge into a fine powder. The powder is then combined with saline solution to form a thick paste. Compressed sponge Gelfoam® is to also be pre-saturated with saline solution. Details on Gelfoam® preparation can be found in Appendix G.

Our device will eject a saline-saturated compressed sponge of Gelfoam® into the tissue removal site. After the ejection channel and fluid tubing of our device have been pre-loaded with sterile saline solution as described in the Engineering Design Parameter Analysis, Gelfoam® will be prepared as described in Appendix G and manually loaded into the tip of the ejection needle. The saline solution will be compressed by the fluid ejection mechanism within our device, generating enough pressure (as determined in the Fluid Pressure Requirements section of the Engineering Design Parameter Analysis) to drive the Gelfoam® out of the needle and into the kidney.

11.0 INITIAL MANUFACTURING PLAN AND MATERIAL SELECTION

To start our manufacturing plan, we looked at the function of each component and generated material property requirements (see Engineering Parameter Analysis section), and developed a feasible manufacturing approach for each.
To categorize our parts, we formed groups of components with similar manufacturing processes. We will further discuss the reasoning behind each grouping in the individual component breakdowns. We also noted the mechanical properties of many materials to help us in the proper selection. Our components are broken into the following categories: plastic parts, the needle, fluid deployment assembly, pushrods, and springs. Tables 7 and 8 summarize our chosen manufacturing processes, materials, and estimated costs for manufacturing our prototype and for mass production.

PART	MANUFACTURING TYPE	MATERIAL	UNIT COST
Housing	Injection Molding	Delrin	$1.03-$1.13 per lb.
Outer Cylinder (2)	Injection Molding	Delrin	$1.03-$1.13 per lb.
Inner Cylinder (2)	Injection Molding	Delrin	$1.03-$1.13 per lb.
Retraction Plate	Injection Molding	Delrin	$1.03-$1.13 per lb.
RetractionMechanism	Injection Molding	Delrin	$1.03-$1.13 per lb.

Pushrods (2)	Injection Molding	Delrin	$1.03-$1.13 per lb.
Buttons (2)	Injection Molding	Delrin	$1.03-$1.13 per lb.
Cutting Sheath	Extrusion	Type 304 Stainless Steel	$2.50-$3.50 per lb.
Inner Needle	Extrusion and Milling	Type 304 Stainless Steel	$2.50-$3.50 per lb.
Syringe	Injection Mold	Delrin	$1.03-$1.13 per lb.
Fluid Mechanism Tubing	Purchase	Clear PVC Tubing	$0.13 per foot
Springs	Purchase	Type 302 Stainless Steel	$2.93-$3.23 per lb.

Table 6: Bill of materials for mass production

PART	**MANUFACTURING TYPE**	**MATERIAL**	**COST AND PROVIDER**
Housing (2 halves)	FDM	ABS Plastic	$88 from UM 3D Printing Lab
Outer Cylinders (2)	FDM	ABS Plastic	$64 from UM 3D Printing Lab
Inner Cylinders (2)	FDM	ABS Plastic	$64 from UM 3D Printing Lab (Same Print as Outer Cylinder)
Compliant Release Mechanisms (2)	Mill	PVC	Received from Bob Coury
Retraction Platform	FDM	ABS Plastic	$64 from UM 3D Printing Lab (Same Print as Outer Cylinder)
Retraction Release Mechanism	FDM	ABS Plastic	$64 from UM 3D Printing Lab (Same Print as Outer Cylinder)
Buttons (2)	FDM	ABS Plastic	$64 from UM 3D Printing Lab (Same Print as Outer Cylinder)
Pushrods	Hand Forming (Pliers)	Type 304 Stainless Steel	$2.20 from McMaster Carr
Cutting Sheath	Band Saw, Dremel	Type 304 Stainless Steel	$19.41 from McMaster Carr
Inner Needle	Band Saw, Dremel, and Epoxy	Type 304 Stainless Steel	$19.28 from McMaster Carr
Syringe	Purchase	Plastic	Received from Dr. Weitzel
Fluid Mechanism Tubing	Purchase	Clear PVC Tubing	$4.25 from McMaster Carr
Springs	Purchase	Type 302 Stainless Steel	$3.99 from Home Depot

Table 7: Bill of materials for prototype

In the following sections we will describe each component, broken down by material. Further specifications on their precise dimensions can be found in Appendix E.

11.1 Plastics

The majority of components in our handle mechanism will be manufactured out of plastic; specifically, medical grade Delrin. The parts included in this category are the outer housing, the outer cylinders, the inner cylinders with compliant release mechanisms, the pushrods, button, retraction plate and retraction compliant release mechanism, syringe, and tubing used to connect the syringe to the needle.

11.1.1 Material Selection

To begin we gathered as much information as we could from other sources as to what would work the best for these plastic components. We began by benchmarking current devices and investigated commonly used materials used in the medical field today. The most obvious benchmark was the BARD® MONOPTY® kidney biopsy. The plastic components of the BARD® device are constructed out of a Vinyl PVC (Polyvinylchloride) that easily withstands forces, including the spring forces and the bending of the compliant release mechanisms. We also spoke with Phil Wong about potential materials, with his recommendation being a material similar to Vinyl PVC called Delrin (Polyoxymethylene).

The physical properties of both Vinyl PVC and Delrin are diagrammed in Figure 35, below. We used CES Edupack software [11] to generate this plot and organize material property data. In generating this plot we considered important physical properties that would affect the performance of our design, such as density, young's modulus, and percent elongation. Cross referencing these two materials with all other materials only provided one other viable material option, PET (Polyethylene terephthalate).

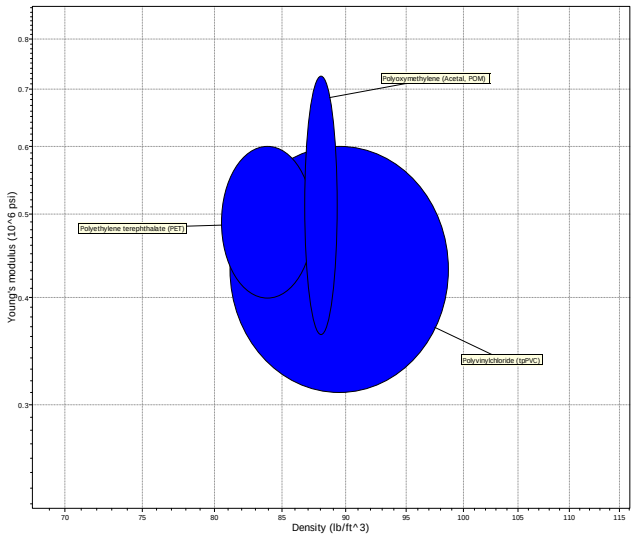


Figure 35: Density versus Young's Modulus for Materials Similar to PVC and Delrin

Each of these materials could satisfy most of the requirements of our design. To determine a frontrunner, however, we considered our engineering design parameter analysis. To make this manufacturing process simpler, we decided to use the same type of plastic for all components. Therefore we found the components that were (a) subjected to the highest stresses and (b) required the most elasticity in order to determine the limiting material properties of the plastics within our device. Based on our analyses, one part satisfies both (a) and (b): the compliant snap fit mechanism. This part is both subjected to a high force and requires bending. Therefore it must be made from a material which is strong enough to prevent breaking, but also has a Young's modulus low enough to permit deflection. This is further examined in Appendix C.

The Yield Strength and Tensile Stress of the Delrin plastic are higher than that of the other two plastics, and Delrin is also strong enough to withstand the calculated forces that will be encountered during release. In Table 8, the Young's Modulus and Yield Stress to Ultimate Strength values of Delrin Plastic are compared with values determined by the equations in Appendix C. The values of Delrin satisfy values determined through analysis of the snap fit mechanism; therefore, we chose to manufacture all plastic components out of Delrin.

	Young's Modulus	Strength
Delrin Plastic	5 GPa	72 MPa – Yield Strength 90 MPa – Ultimate Strength
SNAP FIT equation numbers	3 GPa	80 MPa – Yield Strength

Table 8: Selected material and required properties [11]

Details on the manufacturing of each plastic component can be found in the following sections.

11.1.2 Housing

The housing is the largest component of our device and requires the greatest amount of material (see Figures 36 and 37). We looked at its many complexities to determine the best manufacturing process.

Mass Production

The housing is two-piece item that could be injection molded. Because it is a plastic component and has a complex geometry, injection molding is the manufacturing process of choice for mass production.

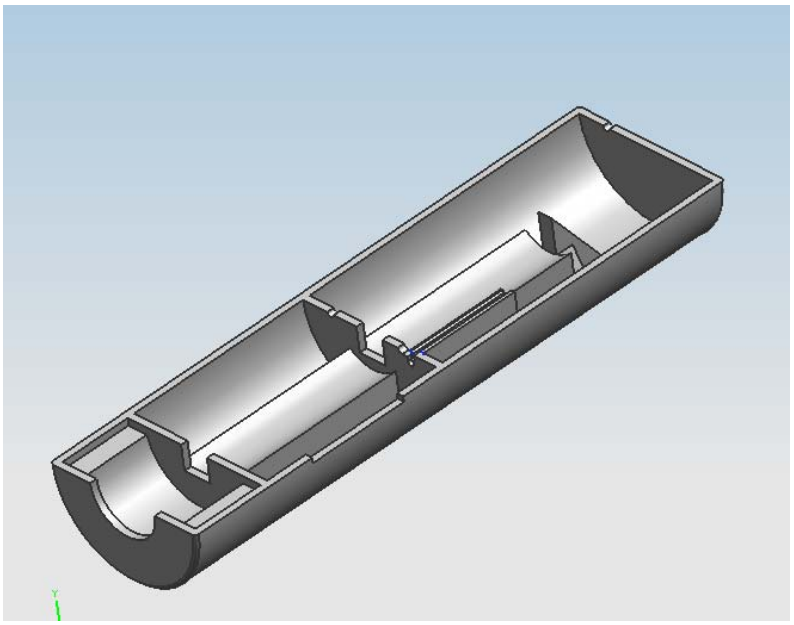


Figure 36: Handle Mechanism Housing – Side 1

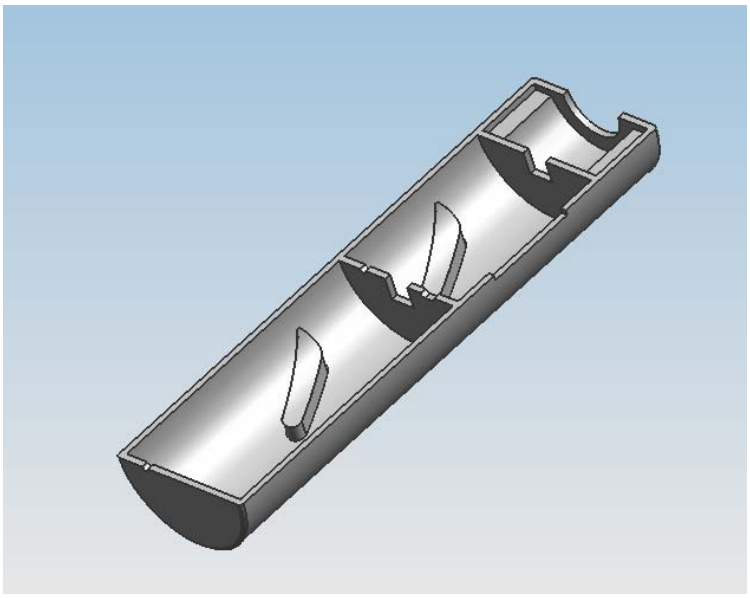


Figure 37: Handle Mechanism Housing – Side 2

Prototype Manufacturing

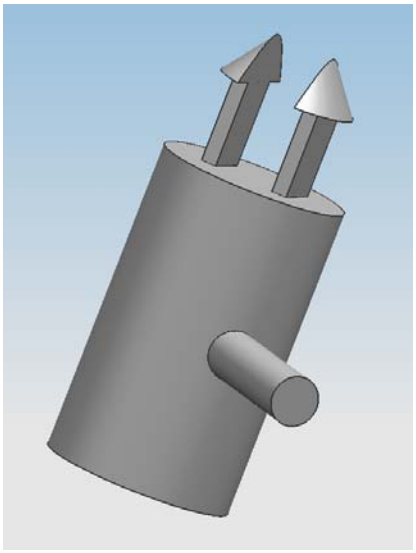
Injection molding is not a viable option for our prototype due to budget and time constraints. Therefore we considered two main options for manufacturing our prototype housing: milling or 3-D printing by a Fused Deposition Modeler (FDM). The FDM process reads the part file of a CAD drawing and dispenses molten polymer through a nozzle to build the part layer by layer. We researched both options and also sought advice from Phil Wong of MC3 Manufacturing. We very quickly found disadvantages for the milling process and advantages for the FDM process. One disadvantage of the

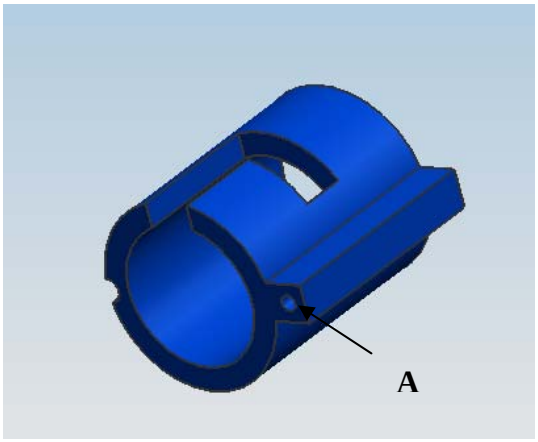
milling process is that we would be working with round stock, which can be hard to secure within a mill. Another disadvantage of milling is due to the level of complexity and detail within the housing, which would require a complex tool path. The FDM process, on the other hand, allows for a great amount of detail and requires much less labor time than the milling process. We concluded that the best way to manufacture this part is by 3-D FDM printing. This decision was also approved by Phil Wong of MC3.

11.1.3 Inner and Outer Cylinders

Mass Production

In mass production, the inner and outer cylinders (see Figures 38 and 39) would also be manufactured through injection molding, allowing for precise and consistent dimensions and rapid production.





Figures 38 and 39: Inner Cylinder and Outer Cylinder

Prototype Manufacturing

The method of prototype manufacturing for both the two inner and the two outer cylinders was also by 3-D FDM Printing, with slight modifications:

- The hole for the needle (see "A" in Figure 39, above) was manually drilled. The needle (either cutting sheath or inner needle) will be glued within this hole, and the retraction mechanism pushrods will be glued to the opposite side of the outer cylinder.
- The compliant release 'teeth' of the inner cylinders were manufactured separately due to the high forces and bending stresses they must be able to withstand (recall reasoning from the Materials Selection section). These teeth were hand milled from PVC stock and glued into a socket-like inner cylinder, which featured two slots just for this purpose.

11.1.4 Retraction Mechanism

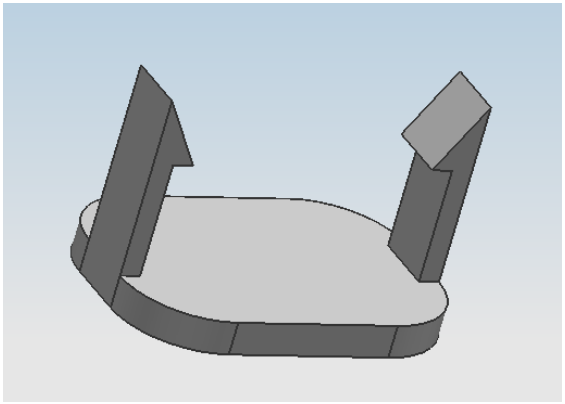
The plastic components of the retraction mechanism consist of the Retraction Release Mechanism and the Retraction Plate, which can be seen in Figures 40 and 41, below.

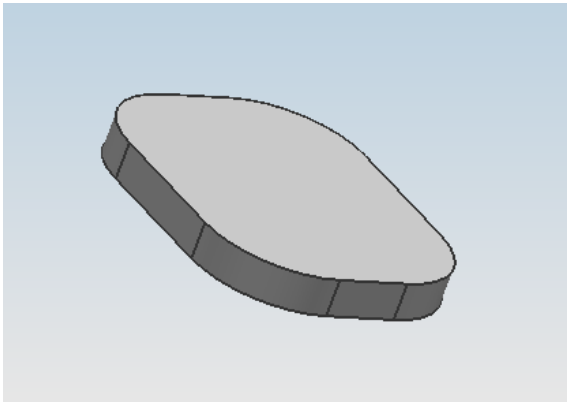
Mass Production

These plastic parts are to be injection molded from Delrin plastic.

Prototype Manufacturing

For our prototype, both of these components were generated by the 3-D FDM printing.





Figures 40 and 41: Retraction Release Mechanism and Retraction Plate

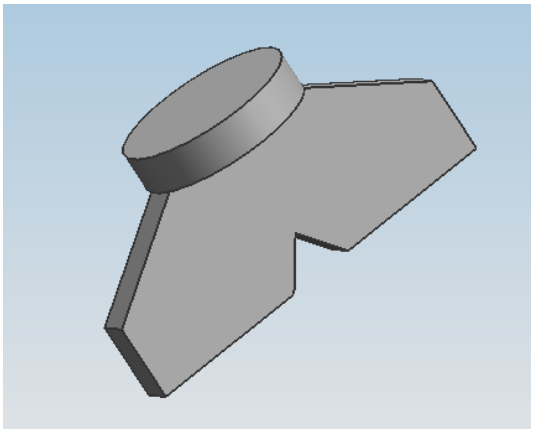
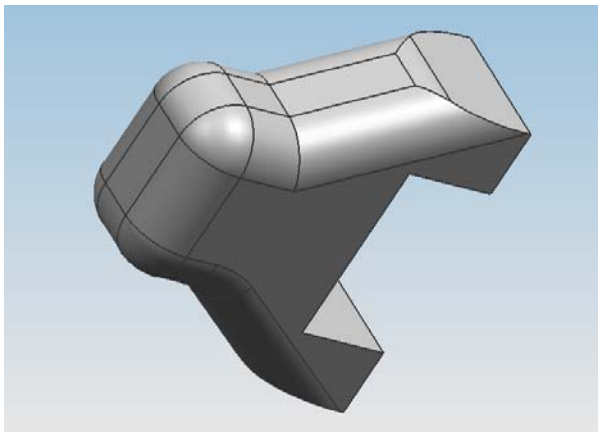
11.1.5 Buttons

Mass Production

The deployment button and collection sample retrieval button (see Figures 42 and 43, below) will both be produced by injection molding as well.

Prototype Manufacturing

For our prototype, both of these buttons were manufactured by 3-D FDM printing.

Figures 42 and 43: Deployment Button And Collection Sample Retrieval Button

11.1.6 Pushrods

Mass Production

Both retraction pushrods (for upper and lower outer cylinders) are to be injection molded from Delrin plastic. See Figures 44 and 45 for diagrams of these pushrods.

Prototype Manufacturing

In the manufacturing of our prototype pushrods acquired some round metal stock and form it into the shape we needed for our uses. The first pushrod, which is longer and connected to the inner collection needle cylinder, required one bend. The second pushrod, which is connected to the cylinder of the outer cutting sheath, required two pieces of metal which were then soldered together.

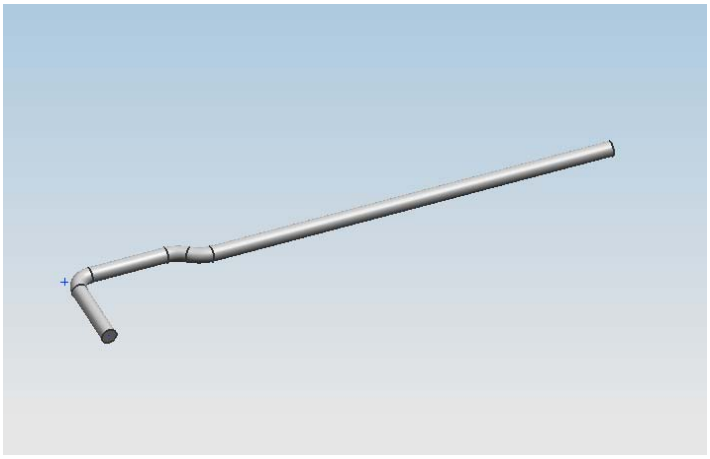


Figure 44: Inner collection needle pushrod

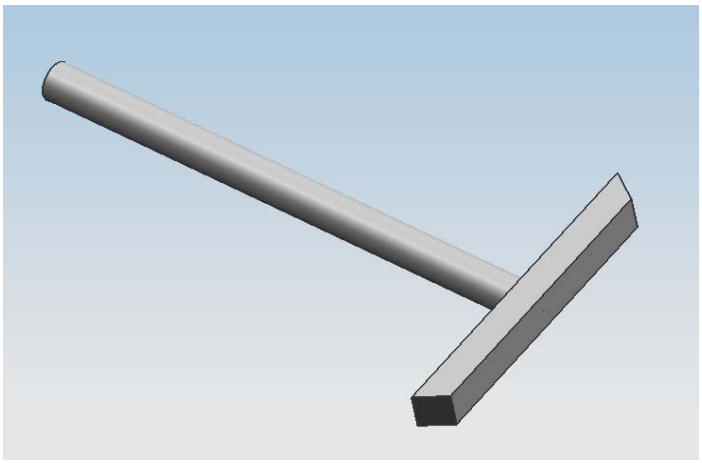


Figure 45: Outer cutting pushrod

11.2 Stainless Steel Components

The major stainless steel components of our design are the cutting sheath and the inner collection needle.

11.2.1 Material Selection

From consultation with Dr. Weitzel and analysis of current medical devices, we knew the needle components would need to be made from medical grade stainless steel or a similar material. From this conclusion and results of our engineering parameter analysis of the stress in the biopsy needle, we found that one acceptable material was type 304 Stainless Steel. Once we again we took this information and used CES Edupack [11] to compare other materials. We used values of the type 304 Stainless Steel and obtained the results shown in Figure 46. We further researched more specific Stainless Steels and found other materials with similar physical properties. All options are presented in Figure 47.

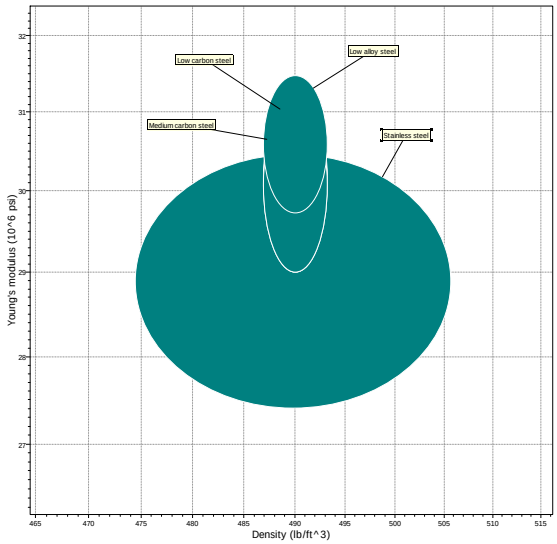


Figure 46: CES Edupack [11] Material Comparison

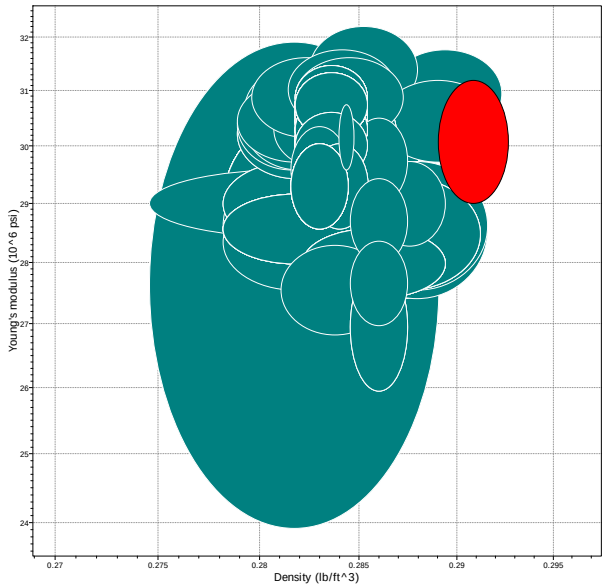


Figure 47: CES Edupack [11] Material Comparison

From these possibilities, we selected a medical grade type 304 Stainless Steel due to its current acceptance in the medical industry. This material has been proven in biomedical applications.

11.2.2 Inner Needle

Our needle design was based off the current biopsy device, but features and internal channel for Gelfoam® deployment into the kidney. The size, shape, and dimensions are virtually the same except for this new channel. This new channel will affect our design, however, due to the fact that structural integrity is compromised. See Figure 48 for a diagram of our inner needle.

Mass Production

To mass produce the inner collection needle, we propose using hot metal extrusion. In the hot metal extrusion, liquid metal will be pushed through a die in order to make a piece with the same cross section as the die. Because of the long prismatic nature of the needle, this process is ideal for mass production. A die would be need to made into the same shape as the cross section of the needle, and type 304 Stainless Steel would be pushed through it to form a very long section of needle. It would be cut into needle-sized lengths using wire EDM, and the tissue collection site would be cut using the same method.

Prototype Manufacturing

The manufacturing of the inner needle is the most difficult piece to complete for our prototype. We spoke many times with Dr. Weitzel and Phil Wong to see what their best

ideas were for manufacturing. The channel which will be delegated to deploy the Gelfoam® was too small to manufacture from a solid rod. There was also the difficulty of creating this feature underneath the tissue collection site. Therefore we had to look for another method of manufacturing.

What we came up with for our inner needle was to first obtain a hollow needle that will fit inside of our cutting sheath. Once we had this hollow needle, we would cut an indentation the size of the tissue collection site using a wire EDM. Once this hole was created, we would use a small piece of wire to make a separation between the tissue collection site and the Gelfoam® deployment channel. We would then pour epoxy into the tissue collection site and hand form it into the correct shape. Once this is done we would be able to remove the wire or shim and we will have effectively created both the tissue collection site and the Gelfoam® deployment channel.

This plan was not effective, however, because we were unable to create a thin enough barrier between the tissue collection site and ejection channel. We therefore used a second method of prototype fabrication: we heated the steel, then pressing a collection site into the distal end of the needle. In this way we were able to depress the material into a collection site, although it was much shallower than designed. Research into a more effective inner needle manufacturing process is recommended.

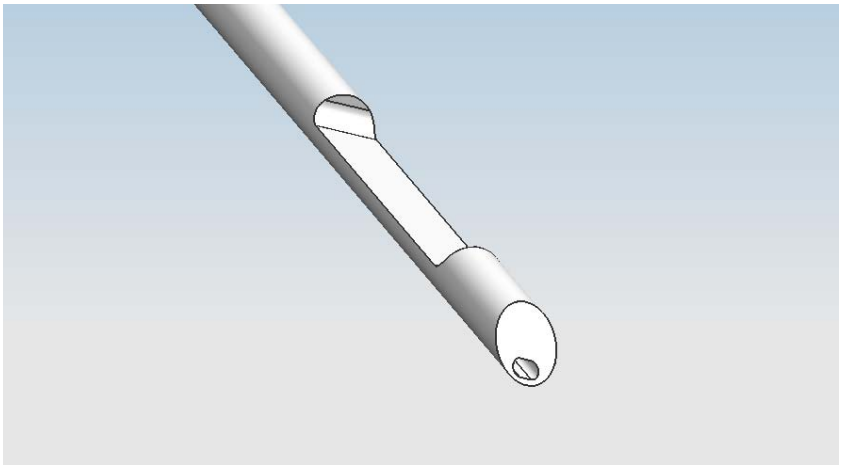


Figure 48: Inner Collection Needle With Gelfoam® Deployment Channel

11.2.3 Cutting Sheath

Mass Production

For manufacturing the cutting sheath, we recommend a hot extrusion method. This metal would then have to be treated to make sure it was compatible in a biomedical setting. Also, a wire EDM cutting operation is recommended in order to create the sharp tip of the needle so that it will penetrate the kidney cortex and tissue.

Prototype Manufacturing

For our prototype, we purchased a 16-gauge hollow needle. We then used a mill to cut this needle to the appropriate length, and to create the sharp tip.

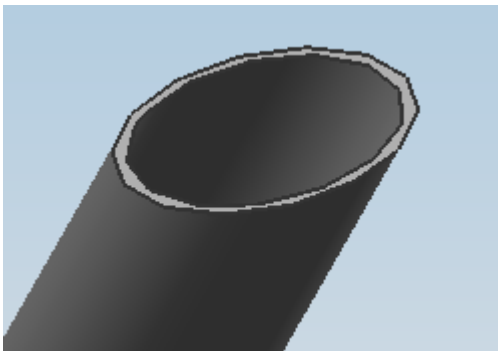


Figure 49: Outer Cutting Sheath

11.3 Other Materials: Hydraulic Mechanism

The components of the hydraulic mechanism consist of the fluid chamber, plunger, and connective tubing, which are manufactured from various materials. See Figures 50, 51, and 52 for diagrams of these components.

Materials Selection

The material for the hydraulic mechanism consists of Delrin plastic for the hydraulic chamber and syringe and flexible PVC tubing for the connective tubing. See section 11.1, Plastic Components, for further information on Delrin plastic and the reasoning behind its selection as a material within our device. Flexible PVC tubing was selected for its current industry acceptance in fluid systems.

Mass Production

In a mass production situation, the fluid chamber part would be integrated into the housing design. Therefore when the two sides of the housing are closed together, the fluid reservoir is created. The plunger would be placed in the fluid reservoir as it was closed together, creating a sealed system. The plunger itself could be injection molded from Delrin plastic. The plastic tubing would be purchased from an external party.

Prototype Manufacturing

These components vary greatly from the rest of the design because this entire piece was purchased for our prototyping purposes. We used a modified 10 mL medical syringe and flexible PVC tubing for our hydraulic system. We secured the system by gluing the syringe to the housing, which has a spot delegated for this in its design.

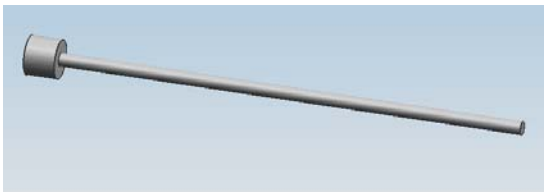


Figure 50: Plunger

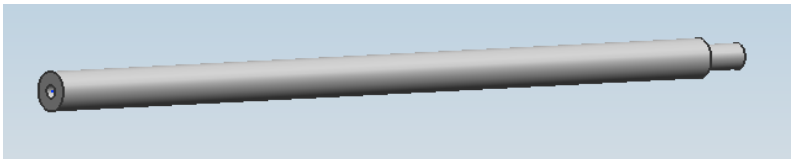


Figure 51: Syringe Tube

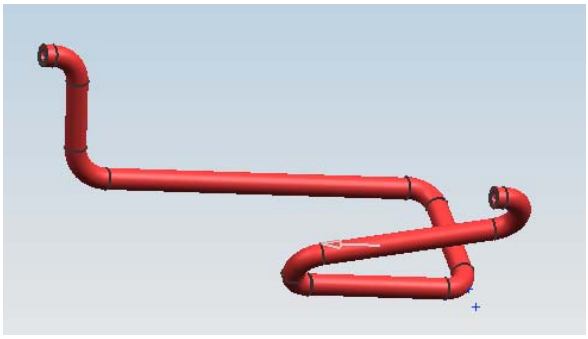


Figure 52: Tubing

11.4 Other Materials: Springs

Our device consists of three springs: two for deployment and one within the retraction mechanism.

Material Selection

We decided to use type 302 Stainless Steel for our springs. After researching multiple suppliers online such as McMaster-Carr and Home Depot, we found this spring material to be common and inexpensive. The wide variety of spring sizes and rates with this material makes it an ideal choice for our device.

Mass Production

For our prototype, we will be purchasing springs from McMaster-Carr. For mass production, we would also recommend using a third party supplier. Buying a large number of springs from a third party will be more cost efficient than investing in machines to make springs to our specifications.

Prototype Manufacturing

The springs that we will be using for our prototype will be purchased, and their size, shape, and spring force will be based off the previously determined values from the BARD® Monopty® device. These have proven that they can be strong enough to penetrate the kidney, which is most important in picking the springs.

12.0 DESIGN FOR THE ENVIRONMENT

12.1 Environmental Impact

The environmental impact of our design was analyzed through SimaPro, a software package designed to determine the amount of raw materials, air, water, and waste associated with the design. The analysis was based off of the type 304 stainless steel used for our device needles, and the Delrin plastic used for our housing and internal components. A similar material, injection-molded PVC, was substituted for Delrin in this analysis as Delrin is not available in SimaPro. By these calculations, each one of our devices (not including packaging or shipping materials) would use approximately 15 kg of raw material, affect 351 g of air, affect 18 g of water, and produce 47 g of waste. Graphs showing the values associated with each material can be seen below.

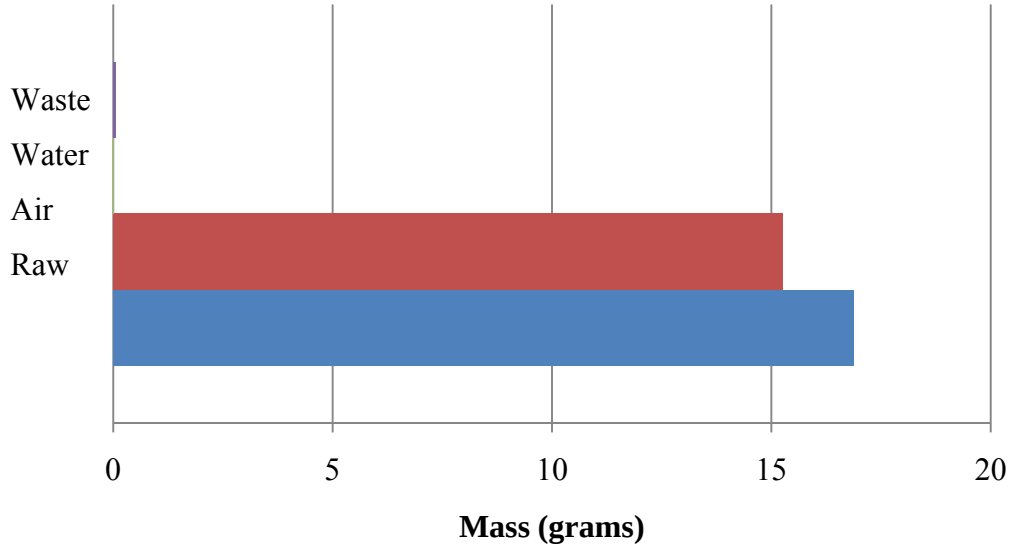


Figure 53: Amount affected by stainless steel used in one of our devices

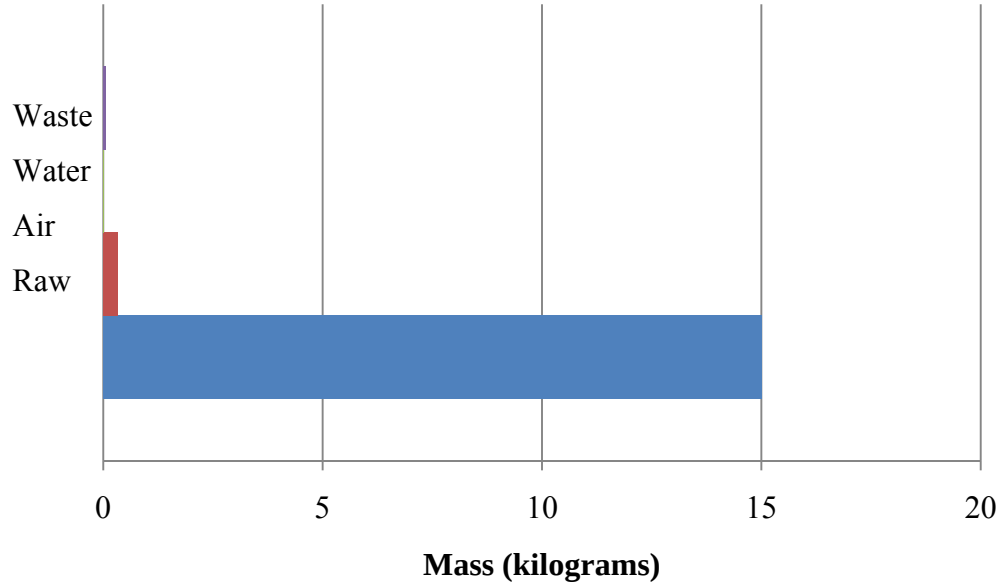


Figure 54: Amount affected by plastic used in one of our devices

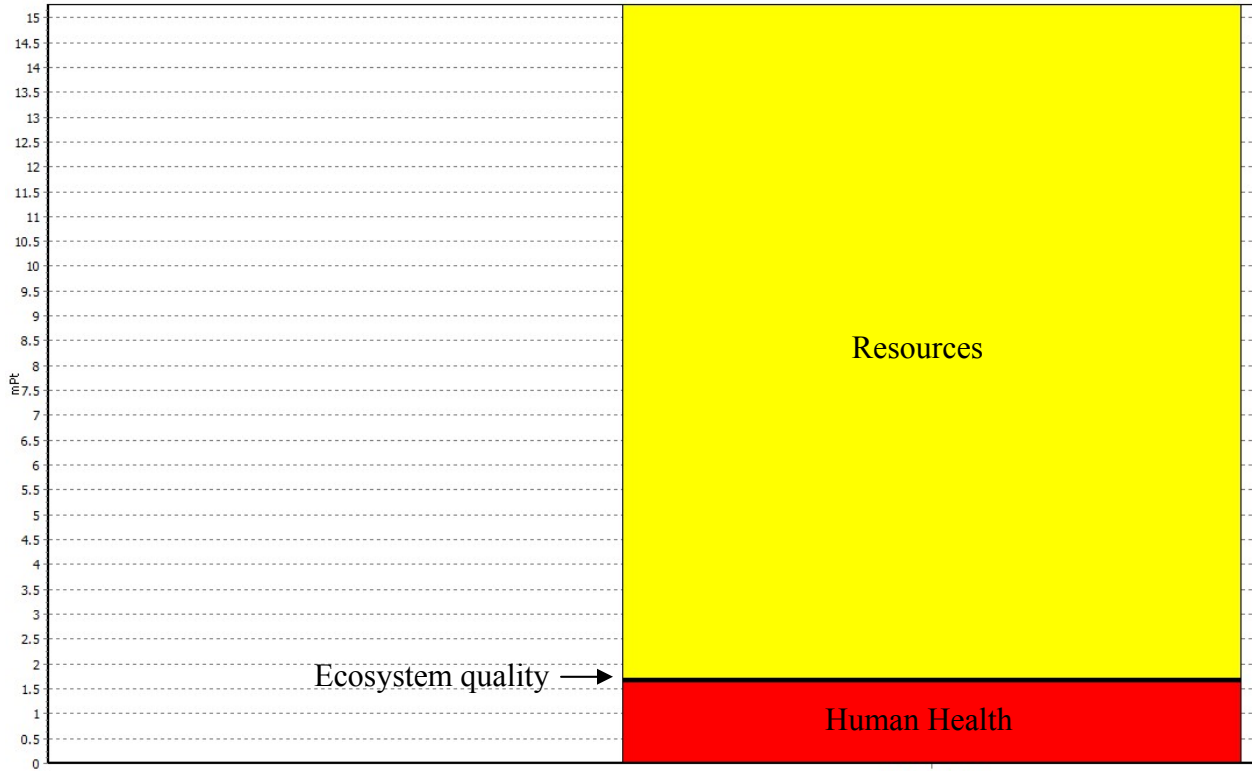


Figure 55: Relative point levels for effects by stainless steel in one device

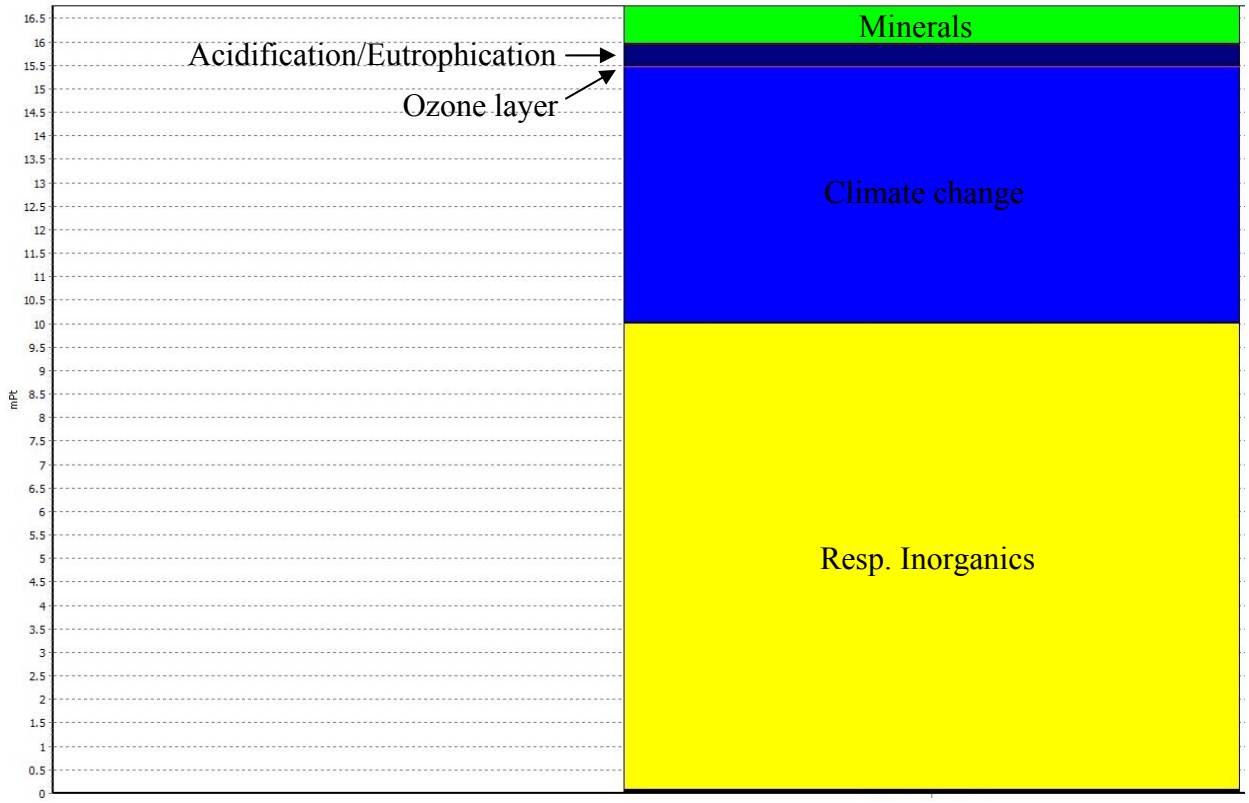


Figure 56: Relative point levels for effects by plastic used in one device

13.0 FAILURE/SAFETY ANALYSIS

Because our device will be used in medical applications, safety is of critical importance. To ensure the risks of our device to the user population have been addressed, we have generated a Failure Mode and Effect Analysis (FMEA) using DesignSafe software. The complete report, which includes potential failure modes and proposed solutions, can be found in Appendix H. We have identified three major classes of potential safety hazards and failure modes: Contamination, hydraulic system failure, and mechanical system failure, which are described in further detail below.

1. Contamination: Contamination of the device (especially the needle), the hemostatic agent, or the hydraulic fluid (e.g. saline solution) may lead to infection in the biopsy patient. Careful consideration must be given in the following areas to prevent contamination:
    a. Manufacturing/Assembly: Manufacturing and assembly of the needle and hemostat system must be performed in a sterile environment.
    b. Shipping/Storage: Reliable medical grade sterile packaging must be used to prevent contamination during shipment and storage. Additionally, a shelf life rating for the device (especially for the hemostat and fluid system, which may be prone to bacteria or mold) must be determined and enforced. Unused devices must be discarded when this shelf life has been reached.

    c. Operation: The biopsy, as is standard procedure today, must be performed under sterile conditions.
    d. Post-use: Post-biopsy device is a biohazard and must be properly disposed by the operator.
2. Hydraulic system failure: Hydraulic system failure is of concern because it would likely mean the hemostat has not been effectively deployed into the kidney, therefore rendering our device useless at preventing excessive bleeding.
    a. Leakage: Leakage within the hydraulic system would cause a loss of pressure and failure to deploy the hemostat into the kidney. Emphasis must be placed on precision of hydraulic system assembly to ensure no leakage and component interfaces.
    b. Rupture: Rupture of the system may occur due to a 'clog' or excessive kidney backpressure due to variation of operator technique (i.e. moving the device deeper into the kidney during hemostat deployment). Emphasis on a debris-free interior, standardization of hemostat insert, and doctor operation standardization would all reduce the risk of hydraulic system rupture.
3. Mechanical system failure: Mechanical system failure would mean the functionality of the device has been compromised. This is of critical concern because mechanical failure may result in some, or all of the following problems: injury to patient or doctor; insufficient tissue sample size; ineffective anti-bleeding control. All of these problems are unacceptable.
    a. Fatigue failure: Our device features many small, moving parts. The current industry standard is a repetition of three uses per device. Therefore, a fatigue failure test must be performed to ensure the device will not fatigue prior to intended lifetime. If the device is made reusable, the fatigue failure lifetime must be substantially greater, with strict controls in place to discard devices once they have reached their fatigue lifetime (reduced, of course, by a sufficient factor of safety). Critical components which may fatigue are all three compliant release mechanisms ('snap locks') and the rotating cylinders, "teeth" and corresponding guide, though the entire system must be tested to determine the weakest component.
    b. Misalignment failure: Misalignment of the moving parts of our system would prevent proper functionality of our device. A precise, standardized assembly system and device inspection strategy must be developed to ensure correct alignment.

14.0 FINAL PROTOTYPE

Our complete assembled prototype is shown below.

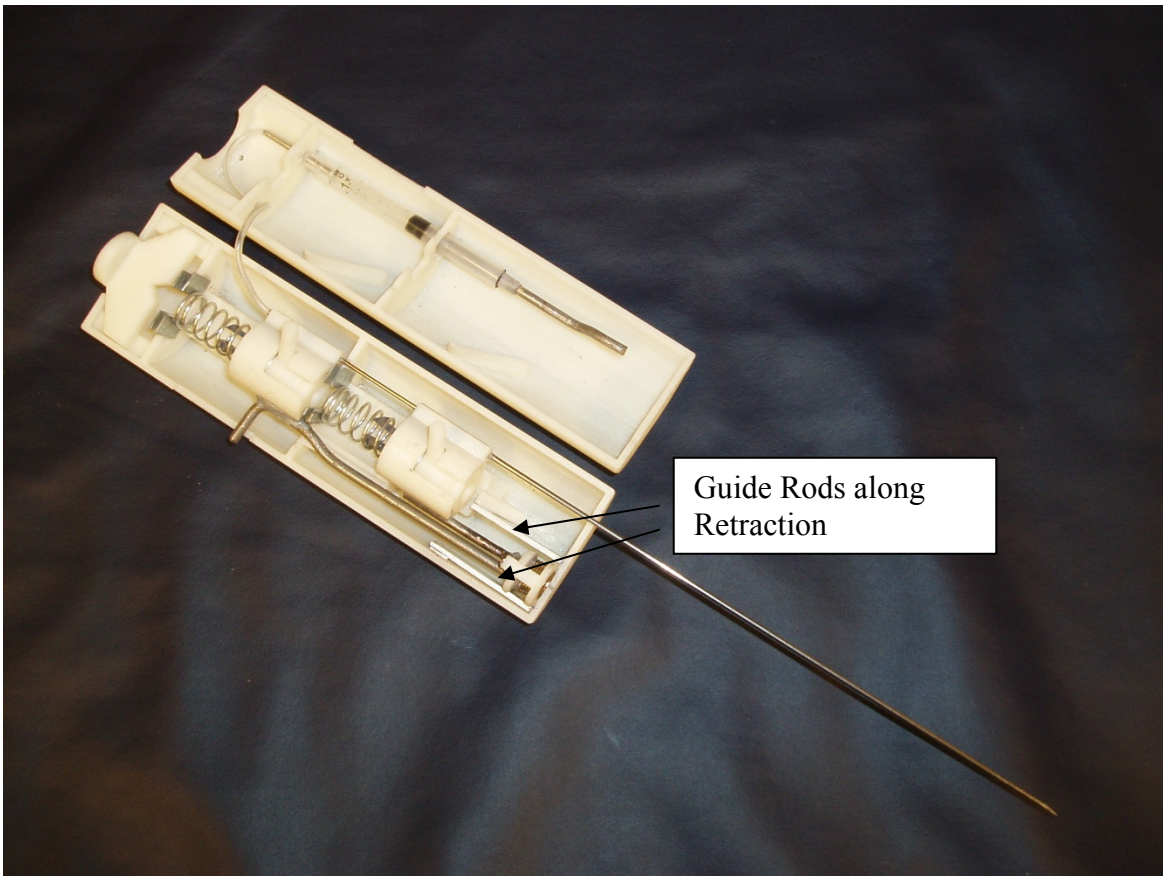


Figure 57: The final prototype

14.1 Changes from Final Design

Our prototype held very true to our final design. Our CAD drawings represented almost exactly what we produced.
The main differences of our prototype were two steel guides on the retraction mechanism and the inner cylinder. The two guides were added to assist in maintaining the straight path of the retraction spring and prevent excessive deflection, a problem noted during preliminary trials. These served the purpose of maintaining the spring's alignment and intended path of travel, and were added when we realized the reaction force of all three items to be retracted (lower cylinder push rod, upper cylinder push rod, and fluid chamber) was causing the retraction spring and push plate to bend out of alignment. Consequently, without the addition of the guide rods, the retraction mechanism failed. See Figure 57 for the additional guide rods.

The other main difference was the inner cylinder. The compliant mechanism was not working correctly with the original inner cylinder as the ABS plastic teeth (the material used in 3-D FDM printing) were breaking. Therefore we changed the design of the inner

cylinder to have sockets for new teeth we created with the stronger Delrin plastic. These teeth were glued into the sockets, solving the problem. The inner cylinder was no different than the CAD drawing of the inner cylinder, but was produced in a different fashion than we had previously determined. This adjustment was necessary as components printed on the FDM machine were not as strong as the Delrin plastic, the material of intended use.

Our final design only changed with the addition of the guides and the change in the prototype material of the inner cylinder. With these minor adjustments our prototype was not affected and we were very successful in designing almost exactly what we had designed.

14.2 Test Results

We performed several tests with our protoytype device in order to validate that it functioned as designed. We began testing by performing a mock biopsy on an apple, a general test of our fluid injection system, and a test for proper Gelfoam deployment. We determined that all features of the design were demonstrated by our device, but that some of the features did not work together due to deviations from the final design that were made in the prototype.

14.2.1 Apple Biopsy

We performed our first apple biopsy using the same method as described to us by Dr. Weitzel and Dr. Rao. We held the needle tip just outside the skin of the apple and pressed the release button to deploy the device. In this test, the device was assembled with the fluid injection system disengaged so that we could validate the retraction system only. In repeated tests, we determined that our device was capable of sequentially deploying the inner and outer needles, and retracting them out of the tissue simultaneoulsy. Figure 58 displays one of our successful test runs.

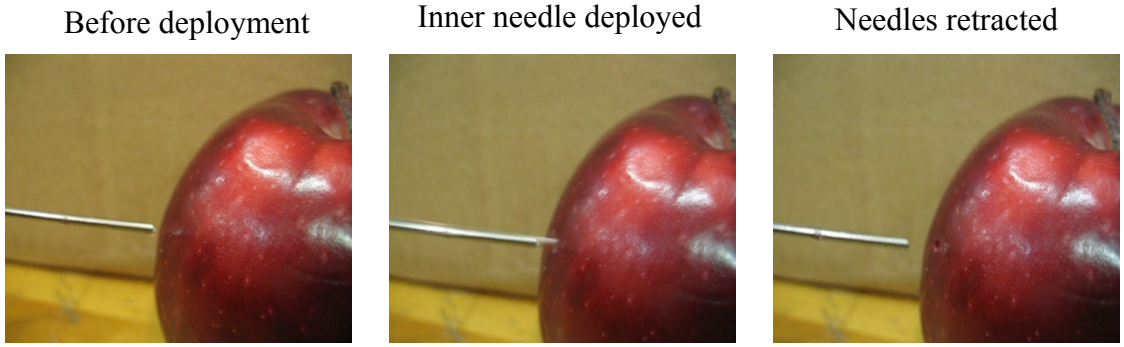


Figure 58: Mock biopsy performed on an apple with prototype device

14.2.2 Fluid Injection System Test

In order to test our fluid injection system, we deployed the device without allowing the needles to travel into tissue. By not using tissue, we were able to better tell whether or not fluid was actually being ejected from the needle tip. Through this test, we determined

that our device is capable of ejecting fluid as can be seen in Figure 59. We also determined that due to deviations that were made in our prototype from our final design, the hydraulic chamber could not be fully compressed. This was a result of using an oversized cylinder and mounting it to the upper half of the housing rather than the lower half as specified in the design. This resulted in the plunger being offset on our retraction mechanism plate, which created a torque and caused the retraction spring to bend during its travel. This problem was partially corrected by the addition of guides (see section 14.1), but the hydraulic chamber was still not completely compressed.

Figure 59: Test of fluid injection system on prototype device

14.2.3 Gelfoam Deployment Test

In order to prove that Gelfoam could be ejected from our needle via fluid injection, we loaded our device with fluid and the inner needle tip with Gelfoam. We manually depressed the hydraulic cylinder plunger for this test, but immediately found that our tissue collection site of our inner needle was not properly sealed, which resulted in a fluid leak and loss of pressure. This improper seal was a result of the manufacturing method that we had to use to create the collection site, and was unable to be fixed due to our limited manufacturing capabilities. From here, we decided to use a similarly sized needle to eject Gelfoam from our device, which would validate our design with the assumption that a proper manufacturing method would be used in actual production of our device. Though this test, we were able to eject Gelfoam via fluid injection into a mass of biogel. This can be seen in Figure 60.

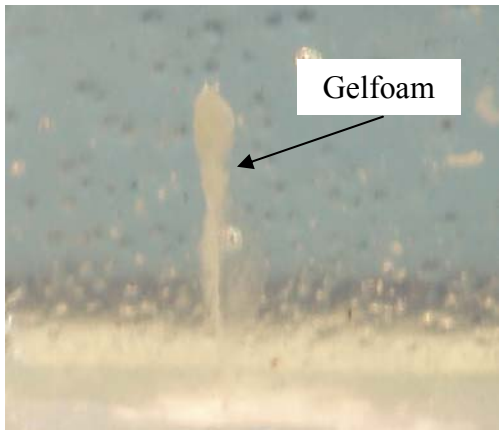


Figure 60: Gelfoam deposited in biogel sample

14.2.4 Overall Device Performance

Our prototype demonstrated that our design for needle retraction, fluid injection, and Gelfoam placement all would work in a mass produced device. Although we had some difficulty with interaction between the retraction mechanism and the hydraulic cylinder plunger, we are confident that the problems would be solved if the device was built to design specifications with a properly sized and placed hydraulic cylinder. With proper manufacturing techniques for the inner collection needle that allow for a liquid-tight seal through the entire fluid ejection channel, there would be no issue with pressure loss, and Gelfoam could easily be deployed.

15.0 DISCUSSION

Looking back on the design process, we had many great successes and a few weaknesses in our final design. However, having been given the broad task of designing a whole kidney biopsy device, I believe that our creativity and technical knowledge led us to create a truly innovative, successful design. With some future work, this device will be useful in the medical field for biopsies. This section describes the weaknesses of our device, and what we would have done differently to improve the design.

15.1 Weaknesses

The first change we would have made would have been to the inner needle collection site. We were charged with the task of designing and prototyping a needle that contained both a collection site, and a channel running down its length to carry a hydraulic fluid. This needle also needed to be no bigger than 1.65 mm in diameter. Our solution to this problem, for the prototype, was to form a collection site into a 1.65 mm diameter hollow stainless steel tube. We did this by heating the steel, and pressing a collection site into the distal end of the needle. This was not an adequate method, as the tolerances were very large, and the steel was cracked and weakened in the site. Because of this, we were never able to collect a decent sample. Also, because of the leaks in the collection site, we were never able to expel Gelfoam through the tip of the needle.

Our solution to this problem is to custom order a 1.65 mm diameter piece of stainless steel stock with a channel running down its length. This allows for the channel size to be minimized. A precise collection site can then be machined using a wire EDM. We were not able to wire EDM our needles because they were completely hollow; cutting into them at any depth meant also cutting into the fluid channel. If a solid needle with a small channel on one side can be produced, an inner biopsy needle would be easy to prototype.

Secondly, we did not allow enough room for springs with sufficient spring forces. In our preliminary calculations, we calculated the necessary forces that all of our springs needed to output, but we didn't know how large those springs were going to be. We had to cut the spring used in the retraction mechanism to fit it under the compliant teeth and in the process, losing spring force. This force was needed to complete the operation of the device, and the device could never fully finish the retraction stroke when fully loaded

with fluid. To change this, we would have ordered our springs online as soon as we had calculated our spring forces. This would have allowed us to design our device around the springs, as they were a crucial element, and one of the few parts that we made no modifications; we had to use what we bought.

Thirdly, we would have liked more time to experiment with the compliant mechanisms in our device. We ran calculations given the material that we were planning to use for snap fit teeth, but the theoretical values are always going to differ from the experimental by some amount. We determined that there were many more factors in the operation of a snap fit than were accounted for in the calculations. Early on, we frequently broke teeth and had teeth wear away very rapidly. We ended up custom making the teeth on our cylinders out of PVC plastic. However, having known how difficult making compliant mechanisms were, we would have delegated more time to strictly experimenting with teeth sizes, or redesigned the device to not incorporate compliant mechanisms.

16.0 RECOMMENDATIONS

We recommend that our device be worked on by future teams. We are excited by the results that we got, and believe that with some work, this biopsy device could be finalized and put into use after only a few iterations. These are the recommendations for future work that needs to take place.

Firstly, research into a fluid reservoir needs to take place. In our prototype, we used a pre-manufactured syringe. This was not sufficient, as the coefficient of friction ended up being much higher than we had expected. This caused our device to struggle with injecting a fluid. Also, the syringe we used was too large. A cylindrical fluid reservoir needs to only be as large as the diameter of the needle to inject the correct amount of fluid into the cavity left by the biopsy. Research into possible deployment devices and lubrication methods needs to be performed to determine the optimal method for pushing fluid through the needle.

Also, iterations of our compliant mechanisms should be performed. Having the compliant teeth hold evenly and firmly is critical to having the device perform the best that it can. Iterations can be performed to optimize the size and material of the teeth. In experimenting with the teeth we had made using 3-D printing, they frequently failed due to a bending load, shearing, or from the tips wearing away, leaving them unable to hold the edges of our housing. When we machined the teeth from PVC, these issues were not as common, but still occurred.

Gelfoam behavior was another area that could use further research. We had samples of Gelfoam, but we did not have extensive literature or background knowledge of it. The questions that need to be resolved regarding the Gelfoam are as follows:

1) How can a Gelfoam plug be loaded into the tip of the needle?
2) Can a needle be manufactured with a Gelfoam plug preloaded so that it doesn't need to be manually inserted?

3) What is the shelf life of Gelfoam? Will a preloaded Gelfoam plug expire if a biopsy device is not used for a long period of time?

Lastly, we plan on this device being re-usable. After discussions with Dr. Weitzel and after having witnessed a live biopsy, we believe the design of a device with disposable needles and a reusable housing would be a great improvement in cost and environmental impact. Therefore the interface between the needles and the housing needs to be redesigned for easy loading and reloading, and the housing itself must be designed with sterilization in mind.

17.0 CONCLUSIONS

This biopsy device design has the potential to make improvements in the field of Nephrology. A biopsy device with bleeding control would give Nephrologists confidence when performing kidney biopsy procedures, allowing patients at high risk of bleeding to receive accurate and quick treatment. Dr. Weitzel's biopsy device design proposal is a biopsy device with a hemostatic agent deployment mechanism, which would stop bleeding at the biopsy site. However, no specific deployment mechanism currently exists.

To make a successful design of Dr. Weitzel's concept, the team first researched related biopsy methods, biopsy devices, and hemostatic methods. Dr. Weitzel provided an extensive library of patents and articles that were relevant to the objectives of the design. These were used as benchmarks to determine the bounds that the design could possibly span. Fully researching these concepts was necessary to find the current related technologies used in the medical field today, which was helpful in creating innovative concept ideas.

In meeting with Dr. Weitzel, the team determined exactly what customer needs are crucial for a biopsy device. The needs were listed in a QFD diagram in order to determine the importance of the engineering specifications of the design. In performing this analysis, the customer needs remained the main focus during concept brainstorming.

From the benchmarking and QFD analysis, the team came up with over 10 concepts for needle tips and deployment mechanisms. After our first design review, we received feedback from Dr. Weitzel and were able to draw upon our concept sketches to create three refined concept ideas. We applied qualitative and quantitative analysis on these three ideas to select our alpha design, which is a biopsy device that deploys a hemostatic plug using a fluid injection mechanism after collecting the kidney sample.

Once we selected our alpha design, we created CAD models with specific dimensions to prepare for the prototyping phase. We were able to model the entire device in order to present it for our design review, and also to begin sending requests for material purchases.

In order to ensure the right dimensions and materials were chosen for our final design, a majority of our design review 3 efforts consisted of physical testing of the forces involved in a biopsy procedure. We used our measured forces to determine the internal stresses and forces within a biopsy device during operation. We were able to take these values to analyze which materials would be the most appropriate for our particular device and manufacturing applications. We decided that Delrin plastic and type 304 Stainless Steel would be the two materials used.

We have fabricated and assembled our prototype and verified its functionality through validation testing. Tests were conducted to verify the device's deployment mechanism, retraction mechanism, and fluid deployment system, along with the feasibility of Gelfoam injection via a needle. All tests were separately satisfied and we believe a more robust manufacturing process (as would be used in mass production) would allow the complete functionality of our device.

From the results of our tests, we are confident that our device will perform as we designed. With further research as suggested, our device will make kidney biopsies a much safer procedure, and doctors will not be hesitant to biopsy a patient at high risk of excessive bleeding after the procedure. This will result in more accurate diagnosis of renal disease, and more effective treatment of people affected by these diseases.

18.0 ACKNOWLEDGEMENTS

Our team would like to acknowledge the contributions of many people during our involvement with this project.

- Dr. William (Rick) Weitzel of the University of Michigan Health System, our project sponsor, for developing and spearheading this project and his support has been invaluable.
- Dr. Panduranga Rao of the University of Michigan Health System, for his input during the design process, and for help determining the correct biogel for use in our mock biopsy procedures.
- Phil Wong of MC3 Manufacturing Corporation, for his helpful insight into mass manufacturing processes, material selection, and prototype fabrication.
- Dr. Grant Kruger, section instructor, for his tireless technical assistance and valuable contributions to the design process.
- Dr. Albert Shih, course coordinator
- Shawn O'Grady, UM 3D Printing Lab
- Bob Coury, ME Shop
- Jason Moore and Carl McGill – Prostate Biopsy Team
- Dan Johnson – Section Leader
- Robin Rasor
- Fernando Alberdi
- Missy Rippee

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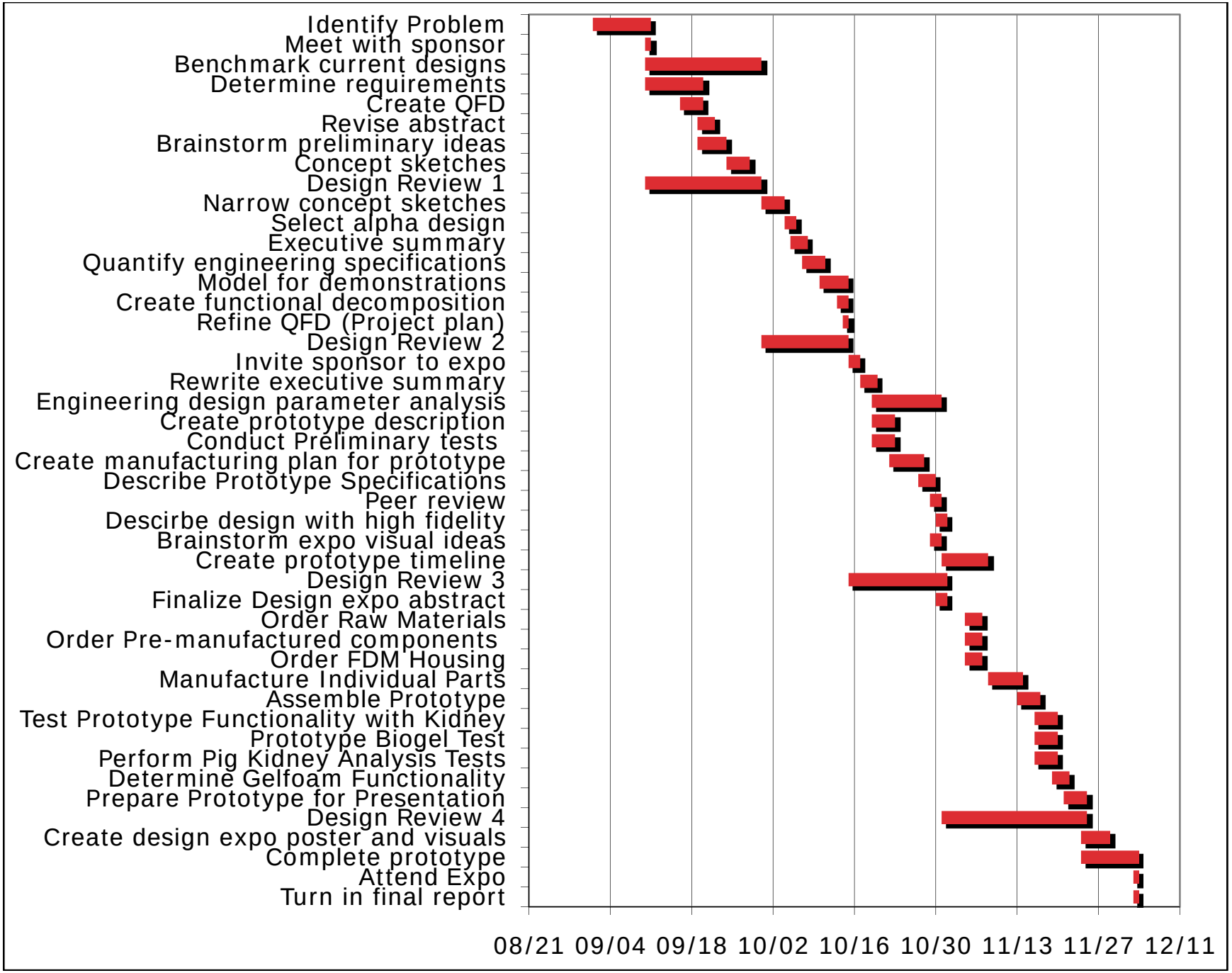
APPENDIX A: QFD (QUALITY FUNCTIONAL DEPLOYMENT)

Relationship Key:
9 Strong
3 Moderate
1 Weak
++ Strong Positive Correlation
+ Positive Correlation
- Negative Correlation
-- Strong Negative Correlation

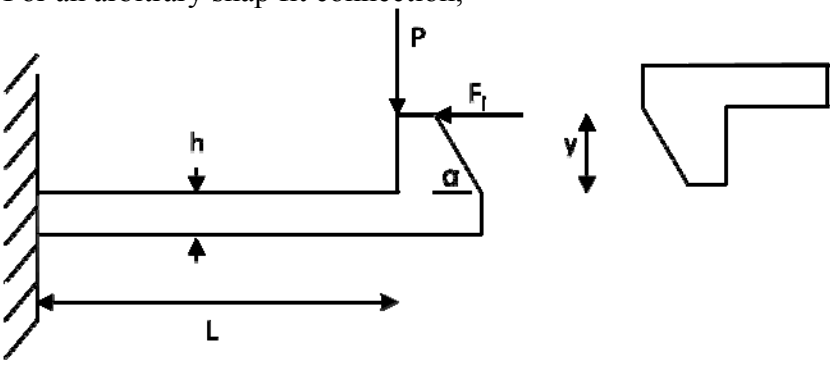
				Patient Needs												Functionality										Mechanism/Components				Budget
Customer Requirements / Engineering Specifications		Weight		Needle length	Needle width	Handle length	Handle width	Number of parts	Sample collection capacity	Number of steps to operate	Force of collection mechanism	Mass	Minimum force to operate	Lifetime	Operation time	Flexibility of needle														
Minimally invasive		7	1	1	9			3	9		9				9															
Stops bleeding		10			9			9	9	1	3				9															
Low noise		4						3		9	3		1																	
Easy to manuver - lightweight/balance		9	1	1	3	9	9	3		3		9				3														
One handed ambidextrous operation		9			3	3	3	3		9		9	9			1														
Fast operation		8	1	1	1	3	3	3	1	9					1	9														
Re-usable		2						3	1																					
Easy to operate		8	3	3	3	9	9	9	1	9		3	9			3														
Obtains sufficient sample every time		9	9	9	9			1	9	1	9				1	1														
Robust/Durable		5						9		1	3																			
Reliable		9						9	1	3	3		1			3														
Has long shelf life		4												9																
Low cost		2	1	1	1	3	3	9	1			1																		
Unit			mm	mm	mm	mm	#	mm^3	#	N	g	N	Cycles	sec	Gpa															
BARD Monopty			160	1.6	140	35	10	20	3				3	<1																
Target			140-180	0.9-2	120-180	20-50	<20	>15	5				3	<1																
Total			131	295	210	210	432	263	339	228	188	174	36	258	161															
Rank			12	3	7	7	1	4	2	6	9	10	13	5	11															

APPENDIX B: GANTT CHART



APPENDIX C: SNAP FIT ANALYSIS

For an arbitrary snap fit connection,



The table below incorporates the mechanical governing equations for each of the values. This is the table we used to determine our geometrical values and materials.

ME 450 Snap Fit Design Analysis

	Snap Fit Part		
Variables	Upper cylinder	Lower cylinder	Retract mechanism
height, h (mm)	1.25	1.25	1.25
length, L (mm)	11	11	11
base width, b (mm)	5	5	5
deflection, y (mm)	1	1	1.25
insertion angle, α (rad)	0.643501109	0.643501109	0.558599315
insertion angle, α (°)	36.86989765	36.86989765	32.00538321
Young's modulus, E (GPa)	2.5	2.5	2.5
coefficient of friction, μ	0.3	0.3	0.3
permissible strain, ε (mm/mm)	0.015495868	0.015495868	0.019369835
yield strain (mm/mm)	0.036894923	0.036894923	0.046118654
deflect force, P (N)	4.585661627	4.585661627	5.732077033
insert force, F_i (N)	6.212831881	6.212831881	6.525749238
Force to release mechanism (N)	12.42566376	12.42566376	13.05149848

APPENDIX D: FLUID VOLUME ANALYSIS

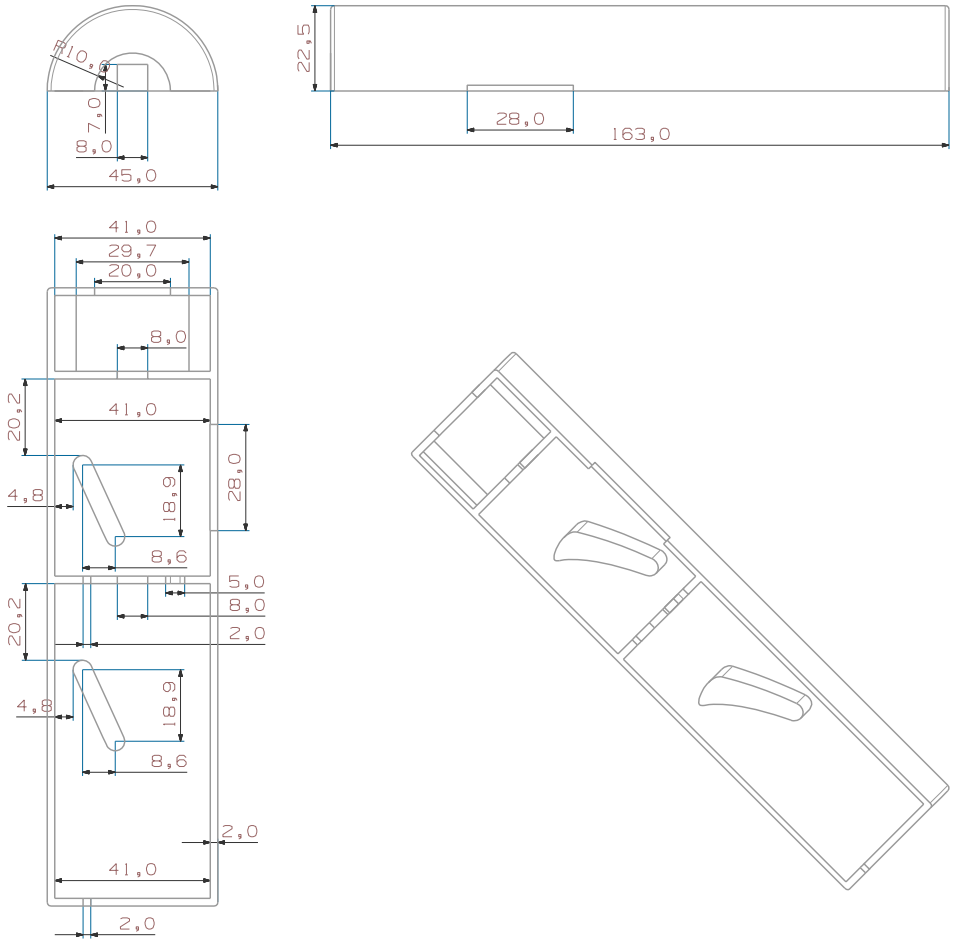
Below is the table of fluid volumes for each component of the biopsy device.

VOLUME OF FLUID CHAMBER (V_chamber)

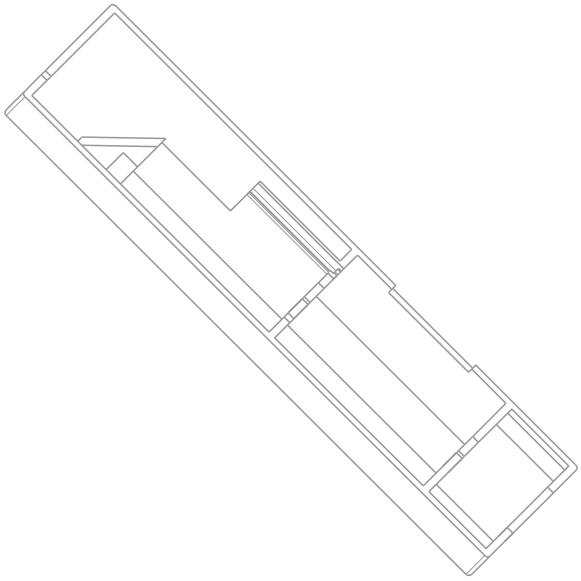
V_chamber = SafetyFactor*(V_wound)

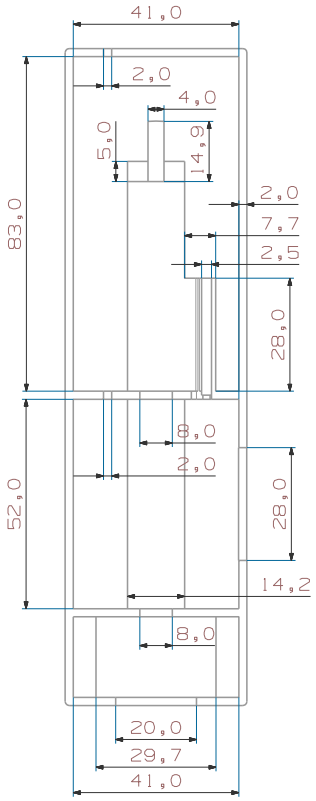
SafetyFactor	1
d_needle (mm)	1.65
incision_depth (mm)	22
V_wound (mm^3)	47.041423
V_chamber (mm^3)	47.041423
V_needle (mm^3)	412.8249096
V_tube (mm^3)	115.5909747
V_system (mm^3)	528.4158843
V_chamber (mL)	**0.047041423**
V_system (mL)	0.528415884

APPENDIX E: DETAILED ENGINEERING DRAWINGS WITH DIMENSIONS



A – Upper half of housing

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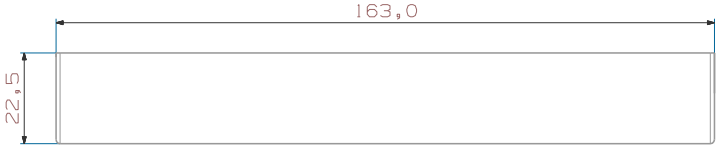
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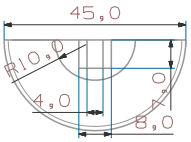
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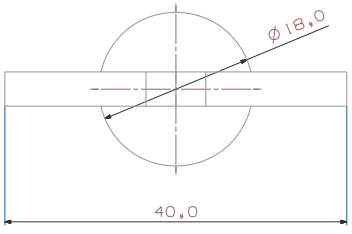
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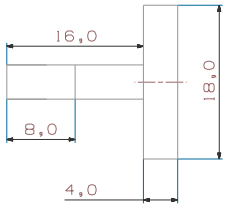
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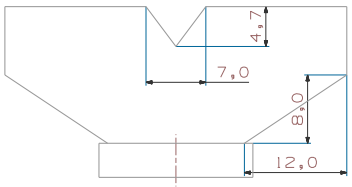
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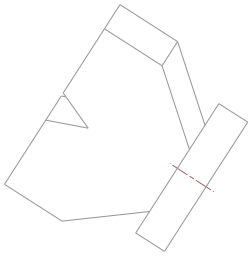

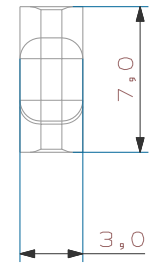
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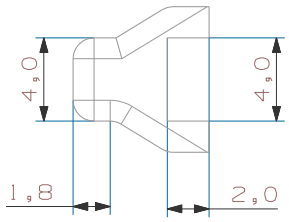
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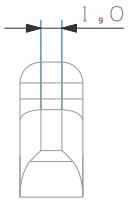
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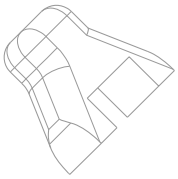

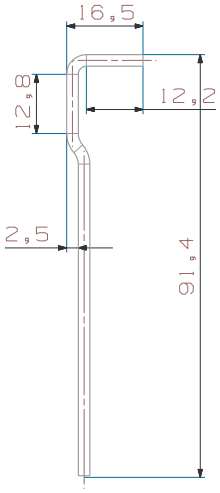
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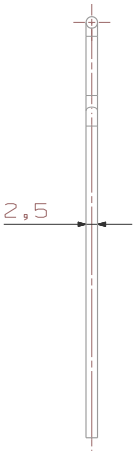
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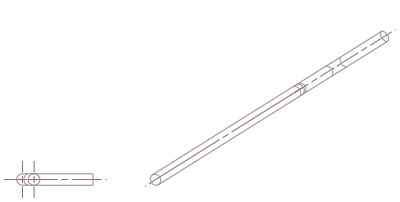

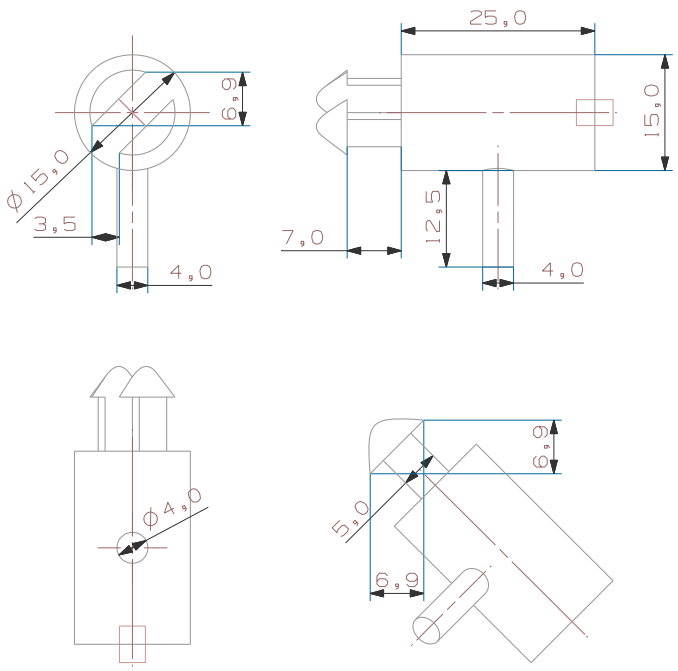
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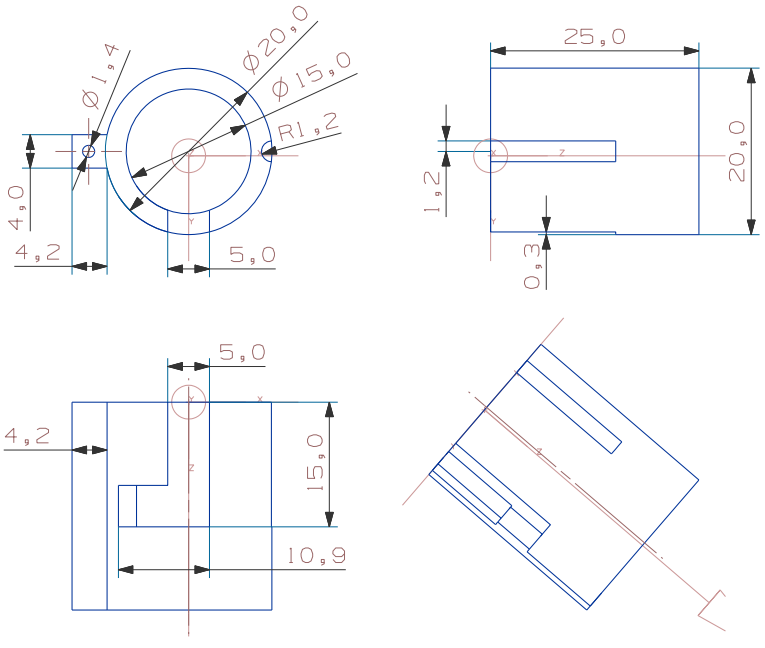
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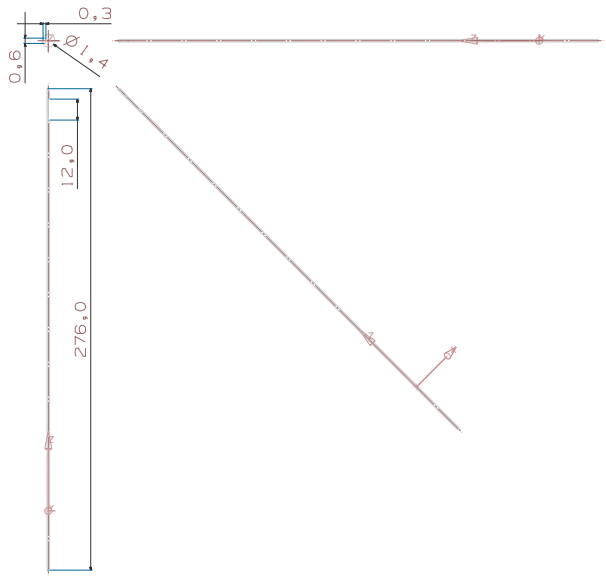
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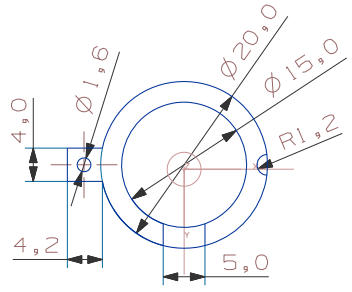
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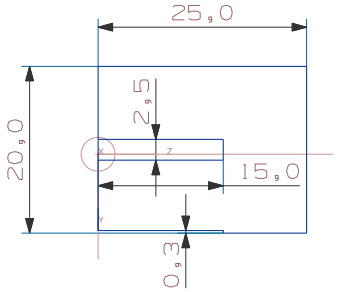
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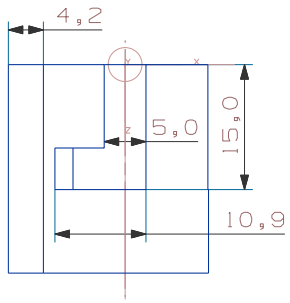
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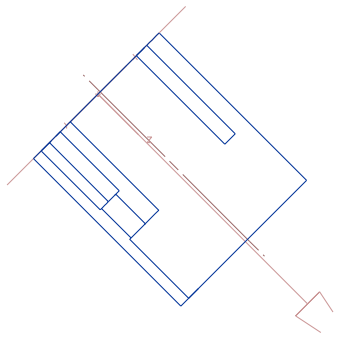

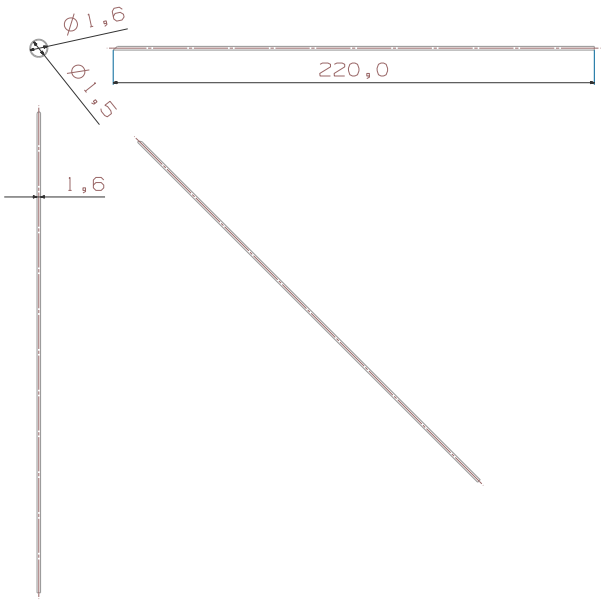
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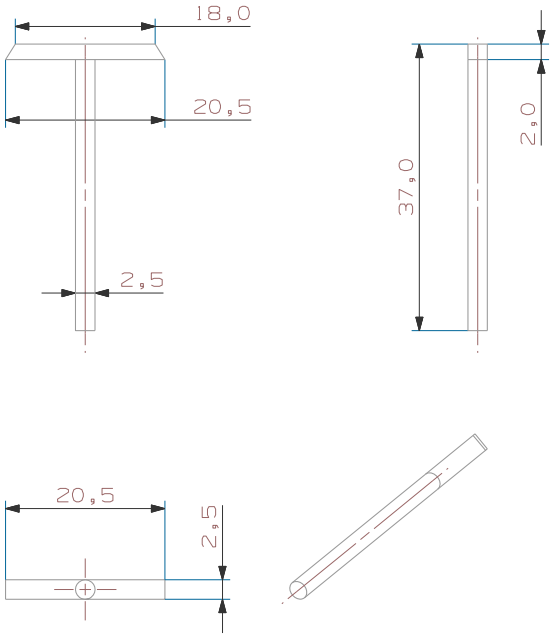
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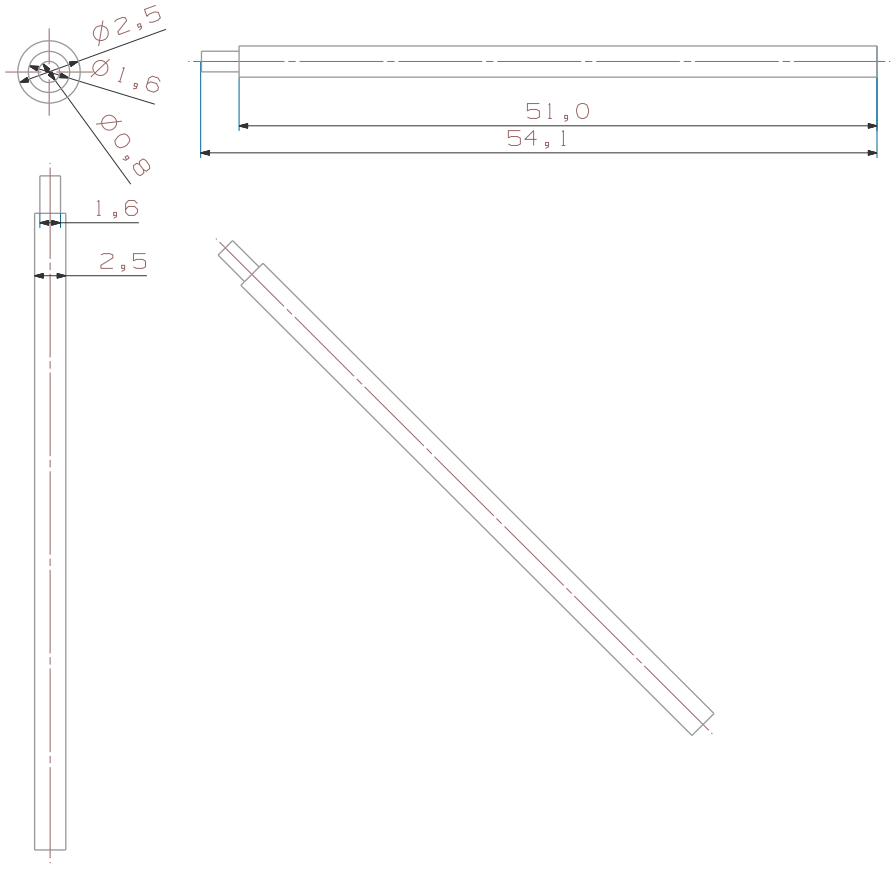
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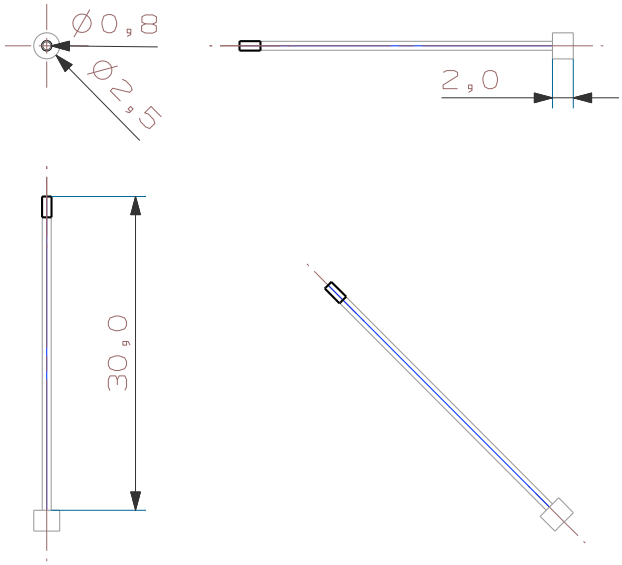
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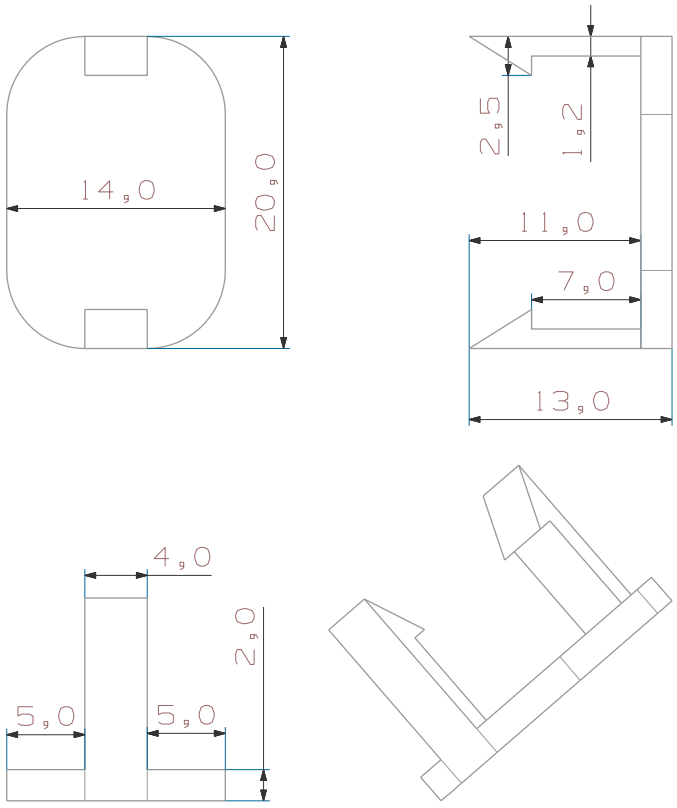

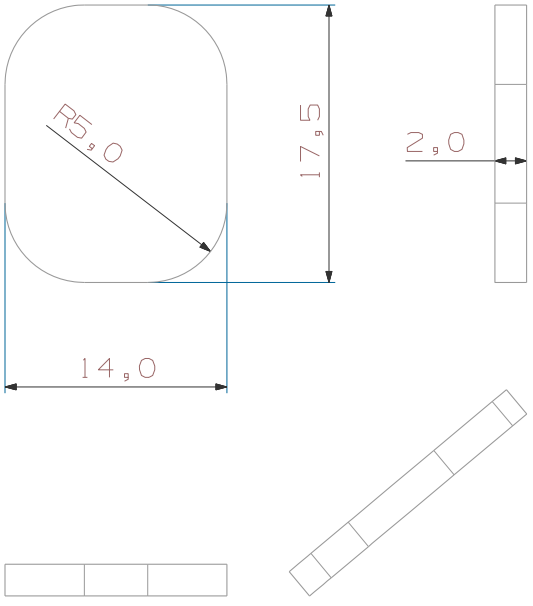

Q – Push plate

APPENDIX F: MATERIAL PROPERTIES

General properties

Density	86.8	-	89.3	lb/ft^3
Price	1.03	-	1.13	USD/lb

Mechanical properties

Young's modulus	0.363	-	0.725	10^6 psi
Yield strength (elastic limit)	7.05	-	10.5	ksi
Tensile strength	8.7	-	13	ksi
Elongation	10	-	75	%
Hardness - Vickers	14.6	-	24.8	HV
Fatigue strength at 10^7 cycles	* 3.18	-	4.97	ksi
Fracture toughness	1.55	-	3.82	ksi.in^1/2

Delrin Properties

General properties

Density	81.2	-	98.6	lb/ft^3
Price	0.689	-	0.758	USD/lb

Mechanical properties

Young's modulus	0.31	-	0.6	10^6 psi
Yield strength (elastic limit)	5.13	-	7.56	ksi
Tensile strength	5.9	-	9.45	ksi
Elongation	11.9	-	80	%
Hardness - Vickers	10.6	-	15.6	HV
Fatigue strength at 10^7 cycles	2.35	-	3.78	ksi
Fracture toughness	1.33	-	4.66	ksi.in^1/2

Vinyl PVC Properties

General properties

Density	80.5	-	87.4	lb/ft^3
Price	* 0.739	-	0.813	USD/lb

Mechanical properties

Young's modulus	0.4	-	0.6	10^6 psi
Yield strength (elastic limit)	8.19	-	9.04	ksi
Tensile strength	7.01	-	10.5	ksi
Elongation	30	-	300	%
Hardness - Vickers	17	-	18.7	HV
Fatigue strength at 10^7 cycles	* 2.8	-	4.2	ksi
Fracture toughness	4.1	-	5.01	ksi.in^1/2

PET Properties

General properties

Designation

S-Steel: AISI 304, annealed

Density	0.284	-	0.291	lb/in^3
Price	2.85	-	3.14	USD/lb

Mechanical properties

Young's modulus	27.6	-	29.4	10^6 psi
Shear modulus	10.7	-	11.7	10^6 psi
Bulk modulus	19.4	-	21.9	10^6 psi
Poisson's ratio	0.265	-	0.275	
Shape factor	62			
Yield strength (elastic limit)	29.7	-	45	ksi
Tensile strength	74	-	89.9	ksi
Compressive strength	29.7	-	45	ksi
Flexural strength (modulus of rupture)	29.7	-	45	ksi
Elongation	45	-	60	%
Hardness - Vickers	170	-	210	HV
Fatigue strength at 10^7 cycles	33.2	-	36.7	ksi
Fracture toughness	50.1	-	64.6	ksi.in^1/2
Mechanical loss coefficient (tan delta)	* 9.5e-4	-	0.0013	

Type 304 Stainless Steel Properties

APPENDIX G: GELFOAM® PREPARATION PROCEDURE

A. Preparation of Gelfoam® absorbable gelatin compressed sponge
   - When used in a fluid ejection system, sterile saline solution is to act as the fluid.
   - Desired quantity of Gelfoam® should be first immersed in solution.
   - Remove Gelfoam® from solution and squeeze to manually expel air bubbles
   - Place it back in saline until needed; Gelfoam® should return to original size with slight increase in thickness and shape when in saline.

B. Preparation for Gelfoam® absorbable gelatin powder
   - Gelfoam® powder can be purchased in 1-gram envelopes, or created by milling and sterilizing an absorbable gelatin compressed sponge.
   - Carefully pour one envelope (1 gram) of powder into sterile beaker
   - Add 3-4 mL of sterile saline to form thick paste
     - Note: to prevent dispersion of the powder when saline is added, compressing the powder into the bottom of the bottom of the beaker. After saline is added, knead to desired consistency.

APPENDIX H: FMEA ANALYSIS

designsafe Report

Application: Advanced Kidney Biopsy Device with Bleeding Control
Description: ME 450
Product Identifier:
Assessment Type: Detailed
Limits:
Sources:
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Company: The University of Michigan
Facility Location: Ann Arbor, MI

Guide sentence: When doing [task], the [user] could be injured by the [hazard] due to the [failure mode].

User / Task	Hazard / Failure Mode	Initial Assessment Severity Exposure Probability	Risk Level	Risk Reduction Methods /Comments	Final Assessment Severity Exposure Probability	Risk Level	Status / Responsible /Reference
All Users All Tasks	mechanical : cutting / severing unshielded collection needle/cutting sheath may be hazardous to handlers	Slight Frequent Unlikely	Moderate	design protective sheath to keep needle covered unti needed; employ safe handling techniques	Slight Remote Unlikely	Low	
All Users All Tasks	mechanical : drawing-in / trapping / entanglement many small internal moving/rotating parts	Serious None Unlikely	Low	no action needed - encasement encloses moving parts	Serious None Unlikely	Low	
All Users All Tasks	mechanical : pinch point sliding button protrudes through encasement and moves with deployment	Slight Frequent Possible	High	desing encasement to enclose sliding button during deployment	Minimal None Negligible	Low	
All Users All Tasks	mechanical : stabbing / puncture unshielded collection needle/cutting sheath may be hazardous to handlers	Slight Frequent Unlikely	Moderate	design protective sheath to keep needle covered unti needed; employ safe handling techniques	Slight Remote Unlikely	Low	
All Users All Tasks	mechanical : unexpected start Mechanism may trigger if button is somehow inadvertently depressed	Serious Frequent Unlikely	High	design encasement so that button is difficult to inadvertantly depress	Slight Remote Unlikely	Low	
All Users All Tasks	mechanical : fatigue many moving/sliding/force bearing components prone to fatigue	Serious Frequent Negligible	Moderate	create life cycle rating through fatigue testing and use new device when lifetime(reduced by safety factor) has been reached; determine weakest components and redesign to increase lifetime.	Slight Remote Unlikely	Low	

Advanced Kidney Biopsy Device with Bleeding Control

User / Task	Hazard / Failure Mode	Initial Assessment Severity Exposure Probability	Risk Level	Risk Reduction Methods /Comments	Final Assessment Severity Exposure Probability	Risk Level	Status / Responsible /Reference
All Users All Tasks	mechanical : break up during operation internal misalignment could lead to break up of mechanism	Serious Frequent Unlikely	High	ensure proper assembly procedures are followed; include robust internal 'guides' in design to align components	Slight Remote Unlikely	Low	
All Users All Tasks	ergonomics / human factors : posture doctors may fatigue due to posture required to use device	Minimal Occasional Unlikely	Low	employ proper posture during operation; esure patient is at proper elevation	Minimal Remote Unlikely	Low	
All Users All Tasks	ergonomics / human factors : repetition doctors may fatigue due to repetition of device usage (currenty industry standard ~ 3 operations)	Minimal Occasional Unlikely	Low	employ proper posture during operation; design ergonomic handle	Minimal Remote Unlikely	Low	
All Users All Tasks	ergonomics / human factors : human errors / behaviors operator error may result in misfire of device into kidney; misfire of hemostatic into wound	Serious Remote Unlikely	Moderate	employ proper technique (medical training)	Slight Remote Unlikely	Low	
All Users All Tasks	ergonomics / human factors : deviations from safe work practices patient may suffer by contact with sharp needle due to operator incapability	Serious Remote Negligible	Low	employ safe handling techniques	Slight Remote Negligible	Low	
All Users All Tasks	material handling : storing contamination in storage environment unacceptable for medical device; components with limited shelf life (hemostatic) may requre short storage time	Serious Frequent Possible	High	store device in incontaminable packaging; create shelf life rating of hemostat and discard devices that exceed shelf life	Slight Remote Unlikely	Low	
All Users All Tasks	material handling : movement to / from storage misalignment may occur during shipment; contamination; inadvertant firing of device	Serious Frequent Possible	High	ship devices in "uncocked" position; create proper packaging to protect device and prevent misalignment	Minimal Remote Negligible	Low	

Advanced Kidney Biopsy Device with Bleeding Control

User / Task	Hazard / Failure Mode	Initial Assessment Severity Exposure Probability	Risk Level	Risk Reduction Methods /Comments	Final Assessment Severity Exposure Probability	Risk Level	Status / Responsible /Reference
All Users All Tasks	biological / health : blood borne diseases doctor must be wary of contracting blood borne diseases from patient blood	Serious Remote Negligible	Low	employ safe handling techniques	Slight Remote Unlikely	Low	
All Users All Tasks	biological / health : unsanitary conditions patient could contract disease from contaminated needle	Serious Remote Unlikely	Moderate	use device in sterile environment	Slight None Unlikely	Low	
All Users All Tasks	biological / health : hazardous biological waste after use, needles will be contaminated	Slight Frequent Probable	High	discard of needles properly ('sharps' disposal)	Minimal Remote Negligible	Low	
All Users All Tasks	biological / health : bacterial bacterial contamination of device may lead to patient or operator infection	Serious Remote Negligible	Low	store and use device in sterile environment	Minimal Remote Negligible	Low	
All Users All Tasks	biological / health : viral viral contamination of device may lead to patient or operator infection	Serious Remote Unlikely	Moderate	store and use device in sterile environment	Minimal Remote Negligible	Low	
All Users All Tasks	biological / health : mold hemostat suspended in fluid may be prone to mold; other components with static fluid may be prone to mold	Serious Occasional Possible	High	store and use device in sterile environment; discard device when shelf life rating has been reached	Slight Remote Unlikely	Low	
All Users All Tasks	fluid / pressure : hydraulics rupture backpressure within kidney may lead to hydraulic system rupture; thin wall thicknesses of tubing and needle channel may be prone to rupture	Serious Remote Negligible	Low	design robust hydraulic system (increase wall thicknesses if possible); create control to stop/slow injection if pressure level is too high	Slight Remote Unlikely	Low	
All Users All Tasks	fluid / pressure : fluid leakage / ejection poor assembly of connections between components; potential leakage of fluid through hemostat at tip of needle	Slight Occasional Unlikely	Moderate	create assembly plan to reduce instances of poor assembly; optimize fit of hemostat at tip of needle to prevent leakage	Slight Remote Unlikely	Low	

TEAM BIOGRAPHIES

Todd Addis

Todd was born in Traverse City, MI, and has lived in the small town of Lake Ann (about 20 minutes west of T.C.) ever since. Lake Ann has two general stores, a restaurant, a pizza place, and a population of about 300. He grew up spending time waterskiing and tubing on the lake, downhill skiing, snowmobiling, hunting, fishing, and other up-north activities. In his free time, Todd also enjoys working on cars and trucks, watching football, and spending time with friends and family. Todd is currently in his final year studying mechanical engineering at the University of Michigan, and plans to pursue a career in the energy, HVAC, or automotive industries. He became interested mechanical engineering mainly through his Dad's work in HVAC and hobby of automotive work, and his Grandfather's manufacturing and body shop business. Eventually, Todd would like to pursue an MBA and maybe further down the road start his own company.

Annie Kirkpatrick

Annie Kirkpatrick is a senior in Mechanical Engineering. She is from Northville, Michigan. She is interested in our project because of its potential to make life better for people suffering from kidney disease. Should we find a successful solution, more biopsies could be performed and allow proper diagnosis and treatment of their specific kidney disease. It would be great to have such a tangible positive effect. She is interested in the medical applications of mechanical engineering for these same reasons, and is planning to earn her Masters through the Biomed SGUS program here at Michigan (biomechanics concentration). She hopes to eventually work for a medical device company. Outside of school she enjoys figure skating and synchronized skating for the U of M team. She also plays IM sports when she can, including soccer, flag football, and broomball. She enjoys skiing, the outdoors, and Michigan football.

David Thompson

David Thompson is a senior in Mechanical Engineering who resides from the quiet and serene waterfront town of Port Huron, Michigan. David was raised as a child under a family structure that strongly supported the Michigan Wolverines and any sporting events they may have participated in during Saturday afternoons in the fall. David became a Wolverine himself and now enjoys many activities; including snowboarding, wakeboarding, IM sports, football Saturdays, and a number of other sports. David is scheduled to graduate in May, when he then has no idea what he will do with his time or how he will procure necessary funds to live, but hopes to solve this dilemma in the upcoming months. David also enjoys travelling, hiking, and astronomically overpriced sports cars.

Chris Welch

Chris is a 4th year Mechanical Engineering student from Livonia, MI. After graduation in April of 2009, he plans on getting his M.S.E. in Mechanical Engineering through the University of Michigan. Beyond this, he doesn't know what he is going to do with his life. Chris enjoys running, weightlifting, downhill skiing, and indoor rock climbing. Although he has climbed indoors for years, he has never set foot on a real rock face, which he hopes to be able to do someday. He is also a member of Phi Sigma Pi, a National Honor fraternity, and was in charge of putting on a 5k race to raise money for the Make-A-Wish Foundation last winter.