Surgical Sheath Valve

Date: December 13th 2006

By: Team 11 - *BVE Medical*

Bryan Ladd
Senior, Mechanical Engineering
University of Michigan

Caitlin McCarthy
Senior, Mechanical Engineering
University of Michigan

Seth McCubbin
Senior, Mechanical Engineering
University of Michigan

Jeff Moss
Senior, Aerospace and Mechanical Engineering
University of Michigan

Sponsor

Hitinder Gurm, M.D.
Assistant Professor of Internal Medicine – Cardiology
University of Michigan Health Systems

Section Instructor

Professor Albert Shih
Professor of Mechanical Engineering
College of Engineering
University of Michigan

Abstract:

Sponsor: Dr. Hitinder Gurm, UM Cardiovascular Center, hgurm@med.umich.edu
The goal of this project is to develop a ductile valve for a surgical sheath, which will be used primarily for non-invasive surgical procedures utilizing the femoral artery as an entry point. The procedures, which enter though the major arteries, such as the femoral artery, are becoming more common and larger sheaths, to be used for these procedures, are also needed. Sheath sizes of 6 French (2 mm) in diameter are not uncommon, however, a demand for sheath sizes of 12 – 20 French (4 mm - 6.7 mm in diameter) also exists. For smaller sheath sizes, a star valve is used to stop patient blood loss through the sheath as well as allow the surgeon to insert and remove tools from the sheath. For larger sheath sizes, a bifurcated valve is used, which is designed to perform the same operation on a larger scale. The combination of this style of valve and the stiffer guide wire needed for larger sheath sizes produces an inadequate seal between the guide wire and the valve, which can cause patients to loose roughly one unit of blood (approximately 500 mL) during procedures such as stent grafting to repair aortic aneurysms and installation of percutaneous aortic valves. These procedures can last between 20 and 30 minutes. It is of interest to develop a new valve or a combination of valves that will provide a suitable seal between the sheath, guide wire, and surgical tools so that blood loss will not occur through the sheath during the procedure. As a group, we will be working with an interventional cardiology doctor, Dr. Gurm, at UM Medical Center.

Executive Summary:

Design Problem

Some interventional cardiology procedures, such as stent grafting for aortic aneurysms and installation of percutaneous aortic valves, require surgeons to enter the vascular system through the femoral artery in the groin. A specialized sheath is used to act as an entry point, through which surgical tools may be inserted while a valve in the sheath prevents patient blood loss. These procedures require large diameter valves and sheaths, on the order of 4 to 6.7 mm. Cardiologists have documented that these large sheaths do not provide an adequate seal around the guide wires during procedures and patients can lose up to a unit of blood or 500 mL during a 20 to 30 minute operation. The task of BVE Medical is to redesign the large diameter sheath valve to eliminate patient blood loss.

Specifications

The specifications that our valve design must satisfy have been outlined by Dr. Gurm and common FDA surgical regulations. The requirements of the valve design are that the valve must limit patient blood loss to less than 40 mL during a procedure, it must not leak when subjected to a static back pressure of 21.3 kPa without tools or wires passed through the valve, and it must also allow entry of tools as large as 6.7 mm in diameter. The valve must also require a similar amount of force to operate and no more than 15 N should be needed to insert or remove a tool. In addition to these primary requirements the valve must also be biocompatible, sterile, and disposable. To compete with other products on the market the new valve must operate in a similar manner as other valves on the market. This means a pressure port for taking blood pressure must be available behind the valve, the overall size of the valve must not interfere with the procedure, and the valve must cost less than $50.

Final Design and Manufacturing Process

After several iterations of our alpha designs we produced a working prototype of the reinforced star valve. This valve was made out of the GLS Dynaflex G2711-1000-00 elastomer material. Our final manufacturing process began with printing a mold at the UM3D lab's stereolithography printer. The Dynaflex polymer was melted in an oven and then poured into a mold. The mold was then closed and allowed to cool and solidify.

Conclusions

Our final valve design is the reinforced star valve, made out of GLS Dynaflex elastomer. This design met all design specifications and customer requirements. Our manufacturing process was limited due to the quality of the powder and epoxy molds made at the UM3D lab and high cooling rate of the polymer; however, several working prototypes were made. The quality of these prototypes could have been increased by forcing the polymer in under pressure to eliminate air bubbles. The valve could be easily produced on a large scale using injection molding processes. We tested the prototype using the same force insertion and removal test as well as the same leak test from our benchmarking trials and concluded it met all specifications.

Table of Contents:

I. Introduction:

I.1 Problem Description

In the growing interest of invasive surgical methods, many cardiovascular surgical procedures are now being performed using an endovascular approach. These minimally invasive procedures, such as stent grafting of aortic aneurysms and placement of percutaneous aortic valve replacements, commonly use the femoral artery as an entry site to gain access to a patient's cardiovascular system.

Commonly, a large needle containing a flexible guide wire is inserted through the skin in the groin area and into the femoral artery (**A** of Figure 1, below). After the needle has successfully entered the patient's femoral artery, the guide wire is pushed through the tip of the needle and into the artery (**B** of Figure 1). The needle is then removed from the patient, by sliding the needle over the guide wire, leaving the guide wire within the femoral artery. At this time, the opening in the skin where the guide wire enters must be opened further to allow room for sheath insertion. This is done by cutting back and opening the entry site with a scalpel (**C** of Figure 1). The external end of the guide wire is then fed into a dilator (pre-inserted into the sheath) and slid down the guide wire, into the artery (**D** of Figure 1). At this point, the guide wire used for guiding the sheath to the femoral artery and the dilator are removed from the sheath and the patient (**E** of Figure 1). The entry procedure is now complete, leaving the sheath with one end protruding from the entry site and the other seated in the femoral artery (**F** of Figure 1). The sheath acts somewhat like a gateway, in the way that it acts as a passageway for the surgeon to feed additional tools in and out of the artery during the procedure.

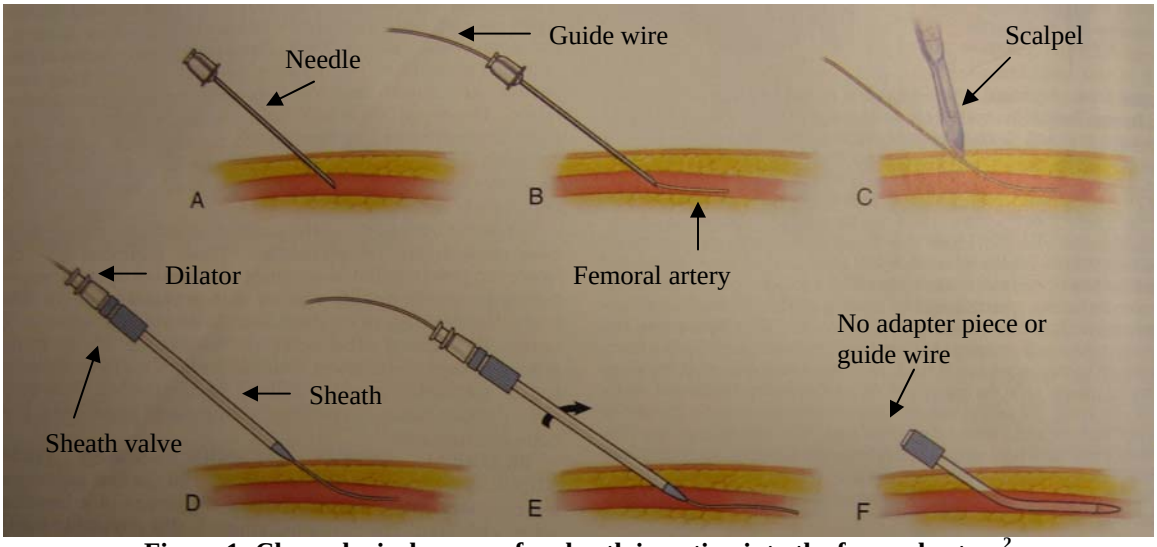


Figure 1: Chronological process for sheath insertion into the femoral artery[2]

To guide tools to the point of interest during the surgery, the surgeon will insert a longer guide wire, with the same style ductile end. By feeding more guide wire through the sheath and into the patient's artery, the surgeon can follow the progress of the wire using an X-ray machine. The ductile hooked end of the guide wire allows the surgeon to steer

the wire past off-shooting arteries along the artery and to the patient's heart or another desired location within the body.

The surgeon will now use the sheath as an entry point to insert tools into the artery by threading the tool over the external end of the guide wire and passing the tool through the inside of the sheath. The tool is then slid along the guide wire to the area of interest and the particular procedure details follow.

Upon completion of the procedure, all the tools are removed from the patient, using the guide wire to return to the entry point. The guide wire is then simply pulled out. The sheath is then removed, and the entry point is quickly closed up with sutures to prevent the patient from loosing large amounts of blood from the femoral artery entry point.

The key issue our team has been asked to address occurs at several instances during this procedure. First, as the surgeon is guiding the guide wire to the heart, secondly as the surgeon is removing one tool from the sheath and preparing to insert another, finally after the procedure is complete and the surgeon is preparing to remove the guide wire from the patient.

The sheath is not only a gateway to pass tools into the artery, it is also where the valve is located that prevents the blood in the artery from passing up the sheath and out of the patient. Two styles of valves are used to prevent the backflow of blood. For procedures requiring a smaller diameter sheath (3mm in diameter), a star valve is used which can be seen in Figure 6 and will be discussed in more detail below. For procedures requiring a larger diameter sheath (4mm - 6.7mm in diameter) deflection of the star valve flaps becomes a problem so a bifurcated valve is used. The star valve reportedly works excellently for small diameter sheaths, with a reported zero blood loss during the procedure. The bifurcated valve design is used in larger diameter sheaths. Unfortunately, this design has been proven to leak during procedures.

While the guide wire is inserted through the sheath it deflects the valve. Since the wire is much smaller in diameter than that maximum opening of the valve it does not completely fill the valve opening. The valve leaks during these times because the geometry of the guide wire and bifurcated valve do not create a full seal. The patient will continue to lose blood until a tool with a large enough diameter is inserted to fully occlude the valve opening and create a seal. Dr. Hitinder Gurm of the University of Michigan Cardiovascular Center has estimated that on average 500 mL of blood loss is common over a 20 to 30 minute procedure.

Dr. Gurm would like our team to design a new valve to reduce and eliminate, if possible, the blood loss. The blood loss is not life threatening to the patient because a blood transfusion can be given to compensate for the loss. The issue is that blood transfusions are costly and can result in serious complications if the patient's body rejects the blood being transfused. Dr. Gurm would like our valve to accommodate larger sheaths of 12-20 French, withstand the 21.3 kPa femoral artery blood pressure, and eliminate patient blood loss while the surgeon passes tools and equipment though the valve to the heart. Also our

new valve should be biocompatible, sterile, and disposable. Dr. Gurm noted that current sheath valve systems on the market are sold for roughly $125, thus we believe the design of our new valve should cost less than $50 to maintain the cost of the entire sheath at $125. Even though Dr. Gurm remarked that the valve could be as big as need be, the team understands that the size of the valve must be within reason and must certainly not interfere with anything the surgeon is doing. As a group, we believe not only are the vital functions of the valve (i.e. being able to pass tools though it and eliminating blood loss) important to the valve's design but also the ability to gauge the blood pressure behind the valve, a common feature in today's models seen below in Figure 2.

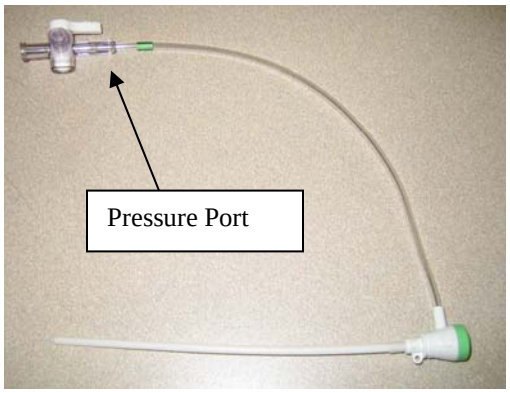


Figure 2: Pressure port attached to sheath

The reason a new valve has not been developed in recent years to address the concerns stated above is strictly financial. There are roughly 20,000 of these surgeries performed nation wide per year, which does not fully justify the cost of research and development for a company. Another reason companies do not justify developing such a valve is because sheaths are usually given to hospitals for free. Health care companies will often give the sheaths to the hospitals for free when the hospitals purchase stents, which regularly cost about $2,000 each. The cost of the stents highly outweighs the cost of the sheaths and thus can be included as a bundle package when being sold.

I.2 Background of Relevant Anatomy and Related Procedures

Noninvasive heart surgery has been made possible by the placement of a sheath within the femoral artery located in the groan. With the hip being a ball and socket joint, sheath insertion is executed near the edge of the femoral head, the "ball" of the ball and socket joint[1], circled in Figure 3. The femoral artery leads directly back to the aorta and heart through major, large diameter, arteries in the body, yet it lies outside the thorax and abdomen where vital organs exist. Remaining superficial to the skin, the femoral artery provides the best noninvasive access to the heart in the body.

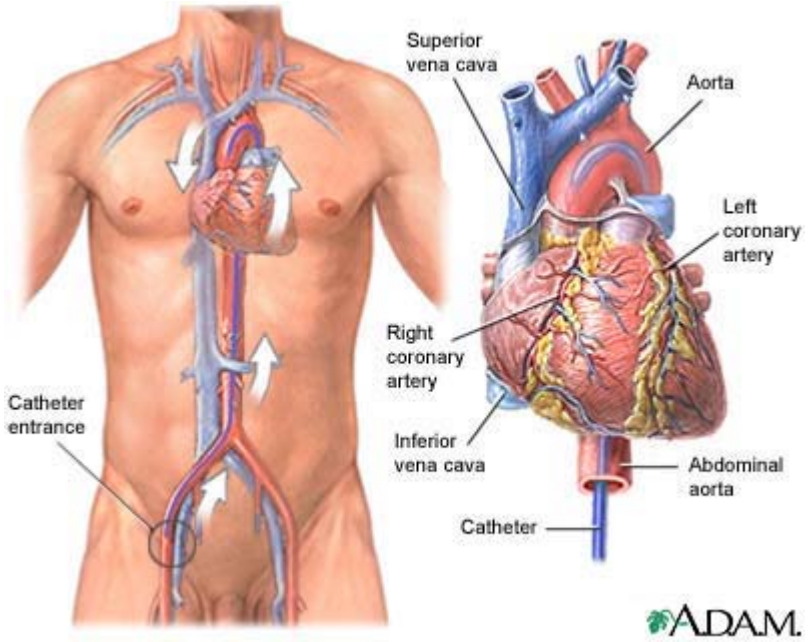


Figure 3: Femoral Artery Access to Heart[9]

Aortic Aneurysm Repair Procedure

An aortic aneurysm, seen in Figure 4, is an abnormal bulge in the aorta that, if left untreated, will eventually rupture, causing internal bleeding and eventually death. Previous treatment involved invasive open chest or abdominal surgery where the abnormal portion of the aorta would be replaced using an artificial graft usually made of Dacron then sewn in place with permanent suture material.[11] It has now become common place for aortic aneurysms to be repaired endovascularly, or inside blood vessels, where access to the aneurysm is obtained through the femoral artery. With this noninvasive procedure, a large stent graft is now installed within the artery. The stent graft has the same stainless steel mesh frame as for a blockage but is now covered in a polymer which, being stronger than the weakened artery, will allow blood to pass through it without pushing on the bulge. The stent graft is fed up to the aneurysm, as seen in Figure 5, left, then expanded, sealing tightly inside the aorta above and below the aneurysm. These stents are much larger than other stents for procedures such as coronary stent grafts and thus require large diameter sheaths.

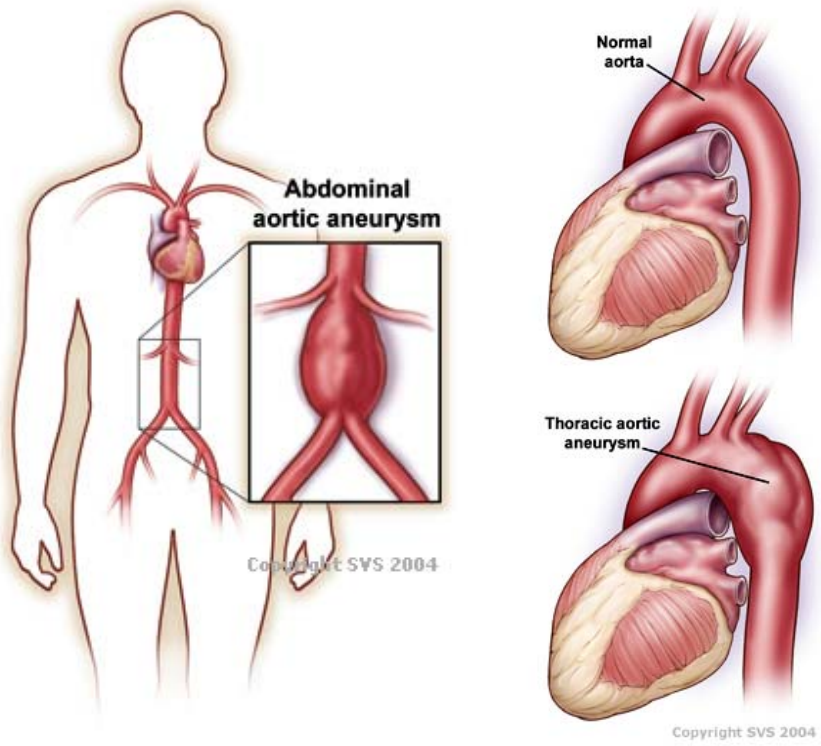


Figure 4: abdominal, left, and thoracic, right, aortic aneurysms[10]

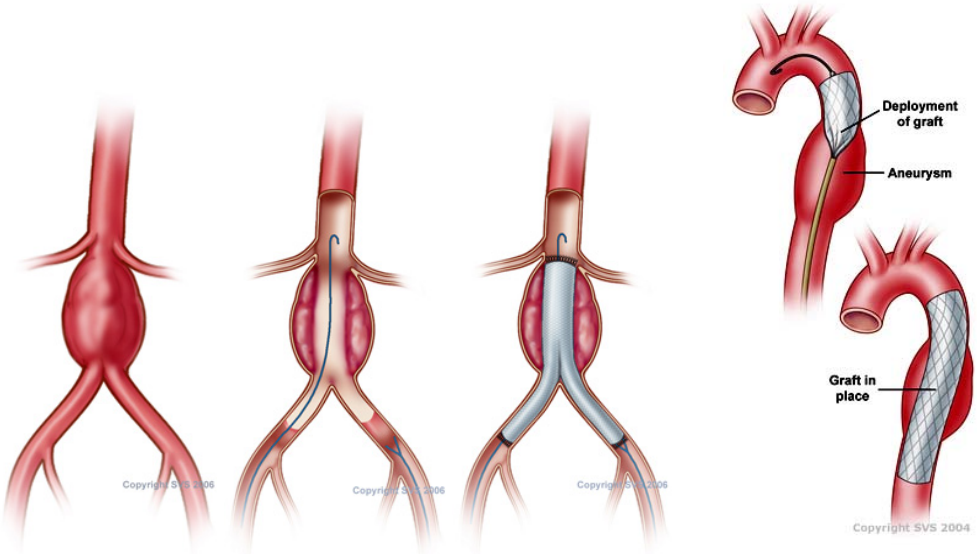


Figure 5: Stent graft implantation in abdominal, left, and thoracic, right, aorta[10]

Percutaneous Aortic Valve Replacement Procedure

Currently, treatment for aortic stenosis, a disorder that narrows or obstructs the aortic valve hindering blood flow to the body, necessitates cardiopulmonary bypass, carrying with it a significant risk of death. Clinical experiments are being conducted to evaluate the use of percutaneous, or through the skin, aortic valve replacement to eliminate the risk from this highly invasive procedure.[8] The procedure involves the insertion of a femoral artery sheath. The valve prosthesis consists of a harvested valve attached within a stainless steel mesh stent and is mounted onto a valvuloplasty balloon as seen in Figure 6. The balloon passes through the sheath up to the heart where it is inflated causing the stent to expand permanently in the aorta.

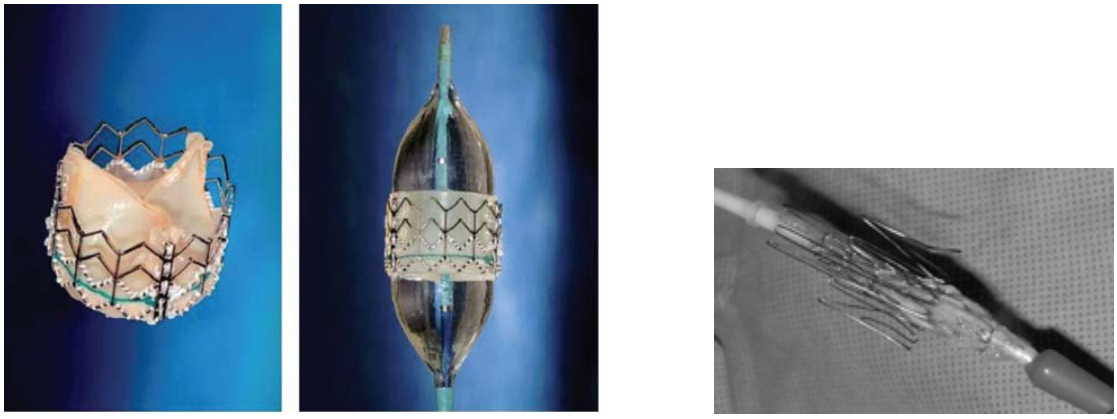


Figure 6: From left to right, aortic valve replacement, valve replacement with valvuloplasty balloon inflated, valve replacement with balloon deflated[9]

Arteries, blood vessels that carry blood away from the heart, consist of three layers. The outer layer is composed of connective tissue containing elastic fibers that permit stretching and recoiling of the vessel. Smooth muscle makes up the middle layer where peristalsis, or wavelike contraction along the path of the artery, can aid the heart in pumping blood to all parts of the body. The endothelium makes up the inner surface of the artery providing a smooth layer of flattened cells, decreasing resistance to blood flow. Arteries have thicker outer and middle layers than veins to increase blood pressure and flow to capillaries while veins take a more passive role, relying on preexisting force and momentum from arteries and containing valves to prevent backflow. The added elasticity of arteries aids in maintaining blood pressure even during relaxation of the heart between contractions.

Systemic arterial blood pressure, the pressure in large arteries of the body including the femoral artery, generally ranges from 10 to 33 kPa, where the maximum pressure occurs during contraction of the heart and the minimum pressure corresponds to its relaxation. Pressures above 22 kPa during heart contractions are rare in most humans. During surgery involving incisions of the femoral artery, the blood will have to be contained under these pressures. The femoral artery has an approximate inner diameter of 6 to 7 mm and an outer diameter of 10 to 11, meaning equipment is confined to these measurements. This artery can be easily accessed close to the surface of the leg for a

noninvasive and short path to the heart by way of only a few major arteries in the abdomen.[1]

I.3 Current Designs

Dr. Gurm specified two different valve designs which he uses during surgical procedures. The first design is used for small diameter tools, generally up to 4 mm. This design resembles a star pattern as can be seen in Figure 7, which was patented by United States Surgical Corp. The star pattern is ideal for small diameter tools and provides an excellent seal during the procedures.

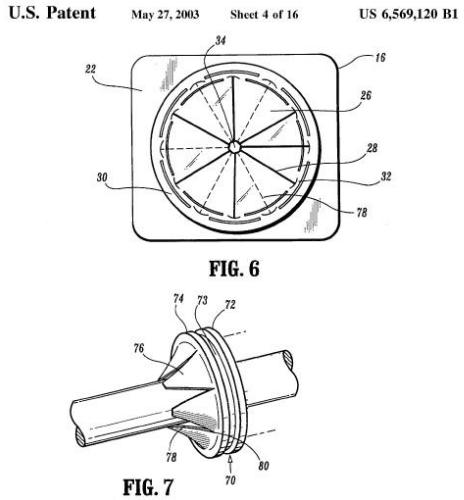


Figure 7: Star Valve Drawing[6]

For larger diameter valves the star pattern is unable to provide adequate seal integrity due to the stiffness of the valve material. In these cases where a larger diameter valve is needed a bifurcated seal is used, as seen in Figure 8. This valve design was patented and produced by St. Jude Medical, Daig Division. Unfortunately, this seal does not provide very good seal integrity either. In use, generally, one of the lips of the valve will fully deflect while the other lip is left undeformed. This allows significant blood loss through the valve.

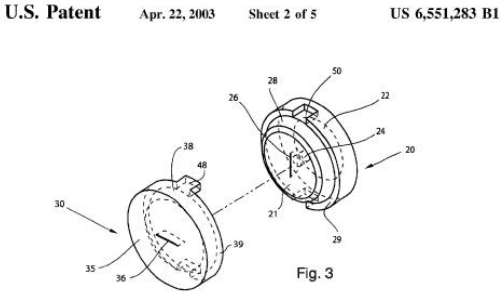
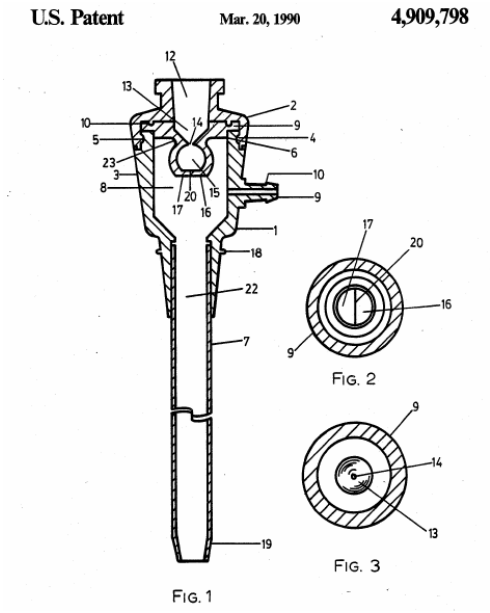


Figure 8: Bifurcated Valve Drawing[7]

Dr. Gurm provided our team with several examples of current sheaths. Figure 9 shows a cross sectional view of a 12F sheath he gave us. This design has a small hole which the tool must pass through initially and then it passes through a single bifurcated seal. The second type of sheath Dr. Gurm gave us was a 16F one with multiple bifurcated valves places in series as seen in Figure 10. Both sheaths were produced by St. Jude Medical Daig Division.



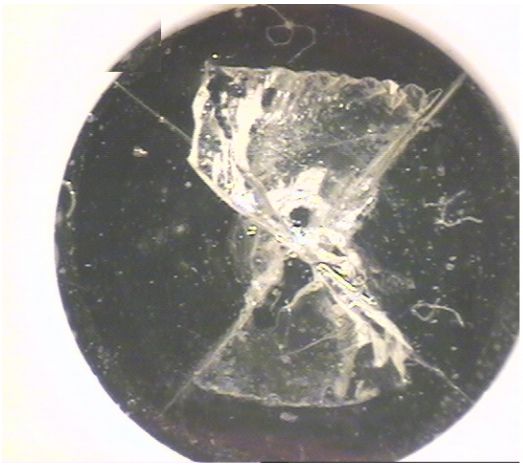


Figure 9: 12F Bifurcated Sheath Cross Section[4] **Figure 10: 16F Multiple Bifurcated Valve**

The 16F valve's bifurcated layers were not cut directly through the polymer valve material. Instead, the cuts are made in a spiraling pattern. Figure 11 shows the dilator for the 16F sheath passing partially through the valve to illustrate the valve's opening characteristics. It is very noticeable that the bifurcated cuts do not allow the valve material to create a symmetric seal around the circular dilator. This is the basis of the leakage problem for the large diameter valves.

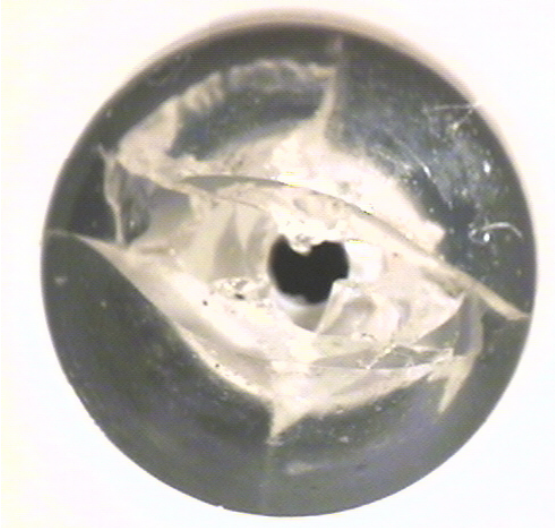


Figure 11: Dilator passing through 16F valve

After conducting a patent search we surveyed a range of other designs proposed for sheath valves. The designs range from sequences of star and bifurcated valves to exotic valve shapes such as toroidal and spherical valves. Drawings of the toroidal and spherical valve designs can be seen in Figures 12 and 13, respectively. Both designs were patented by the Cordis Corporation.

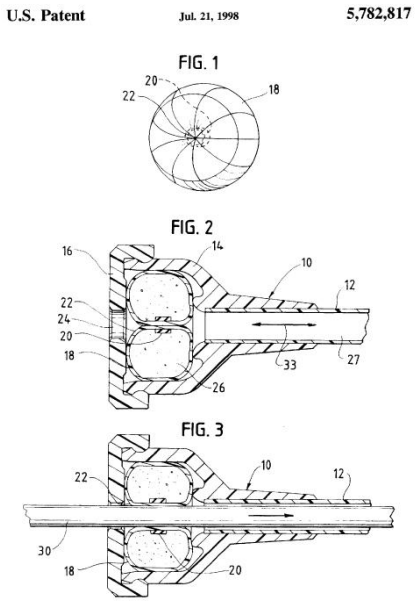


Figure 12: Toroidal Valve Drawing[5]

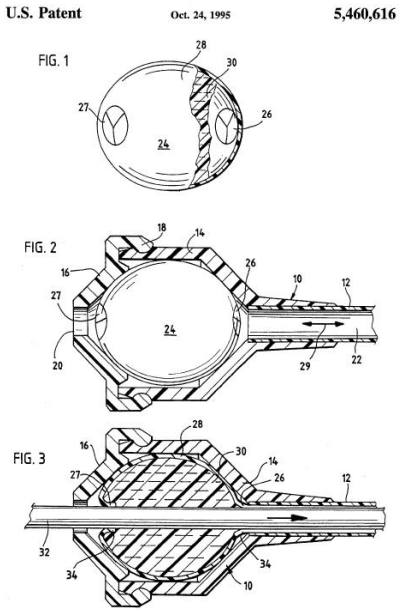


Figure 13: Spherical Valve Drawing[12]

Throughout our research we were unable to find evidence that these designs were ever manufactured. From our conversation with Dr. Gurm, the only designs he uses are the star and bifurcated valve patterns. We believe that these other designs found in our patent search are merely ideas which have not been brought to market as actual devices.

I.4 Benchmarking of Current Valve Designs

Our team conducted two different tests to benchmark the current valve designs. Our first test was meant to characterize the force required to insert objects through the valves. This test will be used to gauge the ease of use of our design once completed. The test consisted of a load cell which had a vice to clamp onto the valve housing. The dilators for the 12F and the 16F sheaths were then inserted and removed from their respective sheaths. On each insertion and removal the force profile was recorded using data acquisition software. An average force was then calculated from the force profile. Each test was conducted three times and the results were averaged. Table A1 in Appendix A shows the results of the force characterization testing. Table 1 below displays the averaged results of the testing.

Sheath Sizes and Tool Inserted	**Normalized Force (N)**		
16F Sheath Force with Dilator force insertion	3.04	±	0.88
16F Sheath Force with Dilator force removal	9.78	±	3.76
12F Sheath with 12F dilator force insertion	6.10	±	2.81
12F Sheath with 12F dilator force removal	9.19	±	1.12
12F Sheath with 11F stopper force insertion	2.39	±	1.30
12F Sheath with 11F stopper force removal	5.76	±	0.26

Table 1: Averaged Results from Force Characterization Testing

The second test was performed on our venous pressure testing apparatus, which can be seen in Figure 14. This apparatus allowed us to pressurize water to approximately 21.3 kPa to simulate the body's blood pressure acting on the valves. We performed several tests to determine the rate at which each valve leaked when only the guide wire was inserted through the valve. We also used a large diameter wire to simulate the larger stiffer wires used to guide the tools to the heart. Table 2 below shows the results of timing how long each valve took to fill a measuring cup with 10 mL of water.

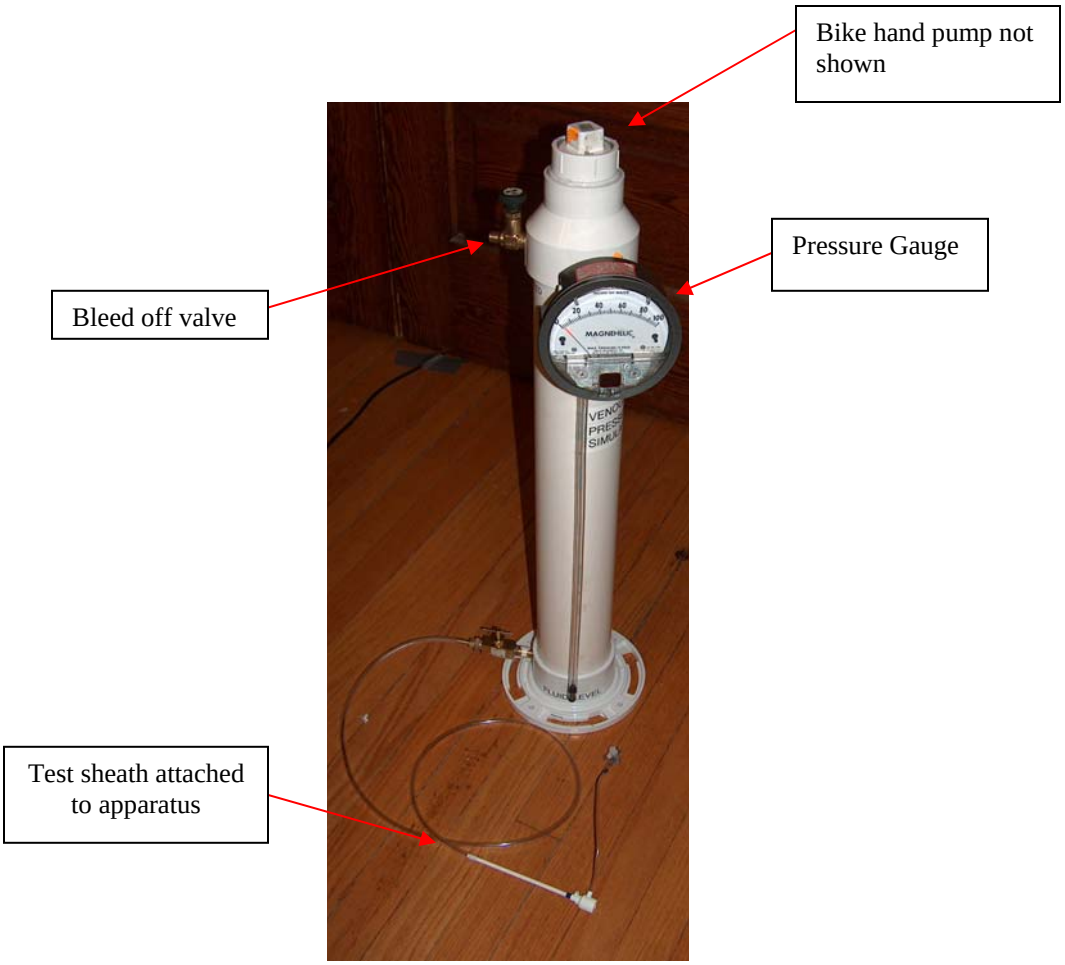


Figure 14: Venous Pressure Testing Apparatus

	Tools Inserted (Diameters)	Volume Filled (mL)	Elapsed Time (s)	Leak Rate (mL/min)
16F Sheath Made by Daig	.9398 mm wire	10	330	1.82
	1.1938 mm wire	10	22.4	26.79
	16F dilator over .9398 mm wire	no leakage	n/a	n/a
12F Sheath Made by Daig	.9398 mm wire	10	1630	0.37
	1.1938 mm wire	10	15.1	39.74
	12F dilator over .9398 mm wire	no leakage	n/a	n/a

Table 2: Results of Leakage Testing

The 12F sheath performed very well when only the guide wire was inserted through the valve. However, when the same valve had a larger diameter wire passed through, the leakage was the worst we observed. Both valves had zero leakage when their respective dilators and guide wires were inserted together. This corroborates Dr. Gurm's claim that when a tool of almost the maximum diameter of the valve is inserted, the valve does not leak. While experimenting with the valves and the guide wires we noticed that the valves would leak excessively whenever the wire was handled and moved. The tests were conducted with the wire inserted but left undisturbed. We believe the leak rates for both valves would be substantially greater during an actual procedure in which the valve and

wire are constantly being adjusted and moved. It is apparent from the leak rates observed that both valves would lose well over 500 mL of blood during a 30 minute procedure.

II. Customer Requirements

The customer requirements have not changed from Design Review 1. What has been added to the customer requirements is a ranking of importance, which was provided by the sponsor. For customer requirements that were not specifically stated ("aesthetic features"), the team ranked them against those provided by the sponsor. The "aesthetic features" added were considered by the team to be necessary features such as, sterile, biocompatible, and disposable. These were not specifically stated by our sponsor as requirements, but for our valve to be used in the medical market, it must conform to FDA regulations for patient safety. A full list of the sponsor requirements and the added features with their respective ranking is listed below in Table 3. The normalized importance to customer ratings were assigned by our group. The importance ranking was generated from our QFD chart.

Customer Requirements	Normalized Importance to Customer	Importance Ranking
Blood loss will not be significant to require a blood transfusion	0.9	1
Pressure port available to measure body blood pressure	0.6	9
Overall device size must not interfere with surgeon's procedure	0.4	5
Sterile	1.0	6
Biocompatible	1.0	4
Ease of use	0.6	7
Will not allow for blood to sit stagnate	0.4	2
Maximum cost less than current benchmarks ($125)	0.4	8
Disposable	0.2	10
Can be used for the same procedures that today's 12-20 French sheaths are used for	0.9	3

Table 3: Customer Requirements Importance Table

II.1 Description of Customer Requirements

Blood loss will not be significant to require a blood transfusion: This is the main focus of our project. Patients who require procedures involving large diameter tools need a large sheath to accommodate those tools. These larger sheaths currently have valves that do not seal well. These bad seals allow for a blood loss, which normally is significant enough to require a blood transfusion. The main focus of our project is to limit the amount of blood loss, such that a blood transfusion is not required.

Pressure port available to measure body blood pressure: This is a current feature, which our sponsor said he would like to see from our design as well. This port allows for the

patient's blood pressure behind the valve to be monitored and if need be, saline can be administered through this line to the patient.

Overall device size must not interfere with surgeon's procedure: Even though our sponsor said this was highly unlikely to happen, we believe it is a customer requirement worth documenting. This requirement is a guideline to overall size of the valve and sheath system we are designing. We could have a massive feedback pump system, but this would interfere with the surgeon's procedure and thus not be acceptable.

Sterile, Biocompatible: These two customer requirements were not specifically stated by our sponsor but our team believed them to be important requirements nonetheless. These are not only crucial to the safety of the patient but are also required according to FDA regulations.

Ease of Use: The new valve design must be as easy to use as the current designs. This means that the new design should require about the same force to operate and not require additional hands to actuate the valve. A valve that would require a second hand would be, for example, the adaptor Y piece that requires a second hand to depress the seal to allow for tools to be passed through it. This Y piece can be seen in Figure 15.

Maximum cost is less than current benchmarks ($125) and disposable: The sheaths that house the valve we are redesigning are not very important. The stints and other tools that are passed through the sheaths are of much higher importance than the sheaths themselves. The costs of the sheaths are relatively low compared to the tools passed through them as well. Dr. Gurm informed us that the sheaths are generally given to hospitals in conjunction with the more expensive tools that require them. The sheaths are a small fraction of the price when a stent can cost as much as $3000. The average cost of a sheath, however, is approximately $125. Our sheath must be competitive with this price so that the same marketing and distribution can occur. Also, since the sheaths are relatively inexpensive and contaminated with a patient's blood after a procedure, they must be disposable.

Can be used for the same procedure that current 20 French sheaths are used for: This is the second major goal of our project. Not only must the valve hold a better seal than the valves today, but it must be able to pass all the tools through it that the problematic sheaths can. This is what creates the largest challenge to us as a team because valves traditionally are harder to design the larger they are.

II.2 Description of Engineering Specifications

These customer requirements were translated into engineering targets. The targets were generated by input from a combination of our sponsor, section instructor, and the team. These targets were chosen as logical values that would have to be met in order to satisfy the existing customer requirements. For example "Disposable" from the Customer Requirements Table, Table 3, is not an engineering specification. However, the question we asked ourselves to determine the engineering specification for this category was: What engineering parameters dictate a disposable product? The major contributor to this

specification is the materials used of the product. In this instance, the materials should not be harmful to the environment and not require a special disposal system. This cannot be quantified however, and there are a number of materials that would satisfy these requirements. This requirement must be further refined then, leading towards the cost of the material. This requirement can be quantified and does narrow the field of possible materials. Taking into account current valve costs and an estimated cost of manufacturing, we can then provide an engineering target. This thought process was performed for all of the customer requirements and an engineering specifications table was then generated as can be seen in Table 4.

Engineering Specifications	Values
Inner diameter of valve	6.7mm
Material glass transition temperature	> 37° C
The force required to insert a tool	< 15 N
Overall valve casing diameter	< 38 mm
Material costs	< $50
Blood loss	≤ 40 mL
The back pressure the valve can withstand without a tool inserted	≥ 21.3 kPa
Diameter tool that must fit through valve	4 – 6.67 mm

Table 4: Engineering Specifications

II.3 Comparison of Competitive Products

The following analysis of competitive valves was done on a series of valves which demonstrated the same functionality and/or concepts that we saw as being important to our valve design.

Bifurcated valve: According to our sponsor, this is the standard valve used at UMHS for sheaths of 12F and larger, produced by St Jude Medical, Daig Division. This was confirmed by examining a large sheath from the storage room. This valve works well as large tools (10-12F) are being passed through it and holds well against a static pressure. The valve fails, however, when only a guide wire is present in it. The pressure of the blood and the poor seal allow for blood to sometimes squirt past the valve, as can be seen in Figure 15.

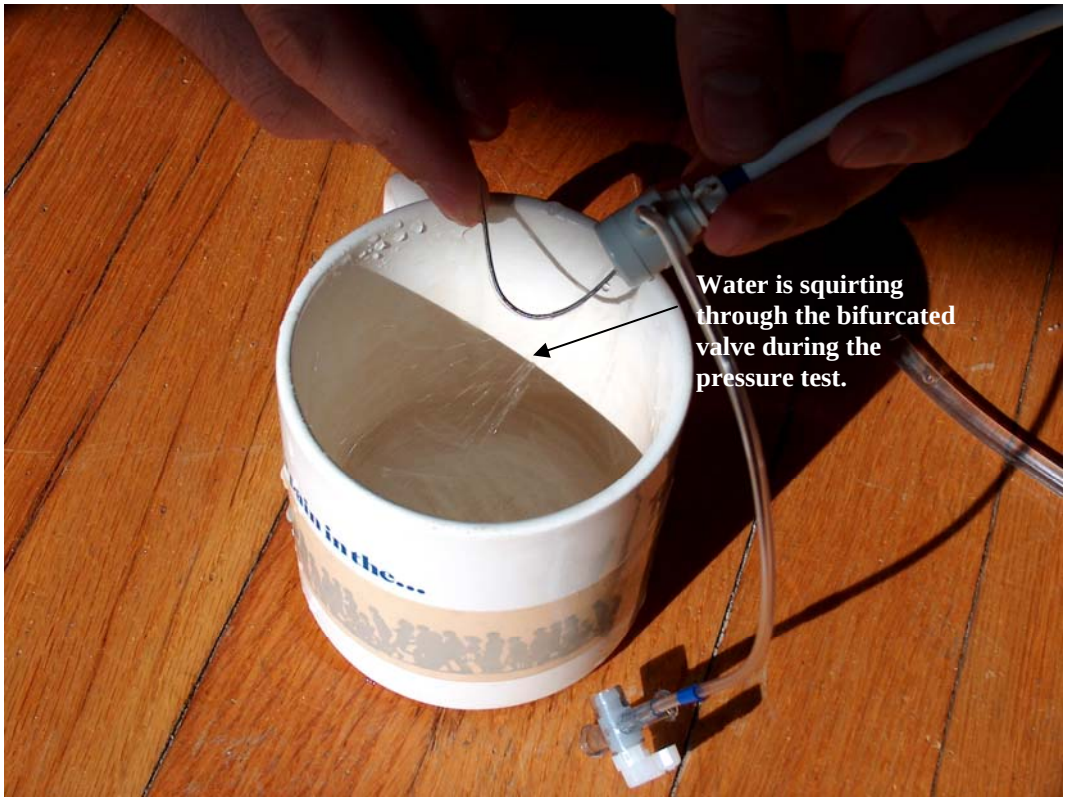


Figure 15: 12F valve leaking under 21.3 kPa backpressure

Star Valve: According to our sponsor, the star valve is the standard valve used at UMHS for sheaths of 11F and smaller, also produced by St Jude Medical, Daig Division. This was confirmed by examining a small sheath from the storage room. This style valve works very well for preventing blood flow through it and for allowing tools up to 11F through it. This valve is not produced in a size larger than 11F that we know of, however. This is possibly due to structural limitations, but without further testing, this is only speculation. One of our many design ideals included a larger version of the star valve with some possible reinforcements if needed.

Y Adaptor Piece: This valve style was obtained from a cardiologist at Wayne State Hospital, and it is shown in Figure 16. This adaptor sits where the valve would be in the sheaths we have previously depicted. The difference is that the adaptor can be removed from the tube section of the sheath. This has the advantage that if the adaptor has a faulty or worn out valve, a new adaptor can replace the existing one, simply by unscrewing it from the tube section of the sheath. This allows the surgeons to leave the tube section in the patient's femoral artery and continue the procedure more quickly. The disadvantage is that this system requires assembly, which the surgeons do not necessarily like. The Y adaptor also has another disadvantage, in that the valve must be depressed by another hand to open the seal to allow tools to pass through it. This is not desirable since the surgeons are trying to feed the guide wire or other tools past the valve at this time. Now the surgeon must try to do three things with his two hands which can prove to be tricky.

Figure 16: Y-adapter for catheter

Bifurcated Valve coupled with a star valve: This design was provided to us by our sponsor as well. It tries to use the idea that alone neither valve functions as well as one would like, but together they could. Even though this is a sound idea, the concept does not perform as well as one would think. When tested in the pressurized water test, this valve performed worse than the lone star valve. This was mainly due to the fact that the coupled design was of a larger size than the lone star valve. This illustrates that the star valve does struggle under the larger sheath sizes.

Butterfly Valve: This valve is not used for this medical procedure and perhaps not for medical procedures all together, but is more prevalent in piping and engines. This valve style is very good for stopping fluid from moving through pipes on a larger scale. This style was considered because we are working on a larger than normal scale and wanted to benchmark against an industry standard. This style would not be good for our project, however, due to the fact that is would require another hand to open and close the valve similar to the Y adaptor piece.

Tire Valve: This is another valve style that is not to prevalent in the medical field but is very effective. This valve is normally used for stopping the pressurized air from escaping from a tire. These valves can be a challenge to use at times, but offer a degree of use of use. The major drawback to this design towards our project is that it will not allow for tools to be passed through it as needed. This design does offer some guidance towards a design that would work though. This guidance being, use the pressure of what we are trying to seal, to seal itself. The tire valve is held shut mainly by the air pressure behind it trying to push past the valve, effectively holding the valve shut. If this concept of using the pressure, in our case blood pressure, to hold a valve shut could be utilized, it could prove to be a powerful and innovative design.

II.4 QFD

All of the information provided in this section can be seen numerically in the QFD, which is located in Appendix C. The QFD also numerically depicts the relationships between individual engineering specifications and how that could impact our design and manufacturing process.

III. Conceptual Design

III.1 Concept Generation

We began our concept generation by individually brainstorming ten concepts. We then convened and shared our concepts. The designs ranged from modifications of the existing valve designs to new shapes and mechanisms. Appendix B contains sketches of all concepts, excluding repeated designs

At one end of the spectrum we came up with a modification of the star valve, in which each of the flaps of the star would be reinforced with a sort of buttress. The entire valve could be made of in one molding and then the star pattern cut through the material. The buttresses could in theory provide enough added stiffness so that the star valve design could maintain a seal at larger diameters. A sketch of the design can bee seen in Figure 17. Figure 18 is a preliminary 3D CAD model to illustrate the design.

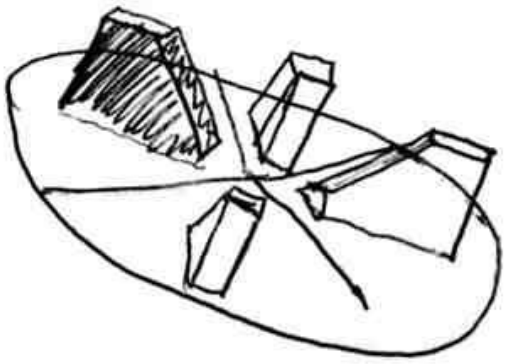


Figure 17: Sketch of reinforced star valve

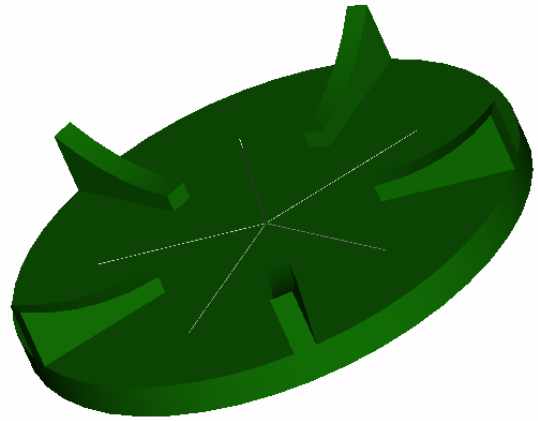


Figure 18: CAD model of reinforced star valve

Another variation on this idea was to have a star valve backed with a type of o-ring. The o-ring would be contained in a channel behind the valve and could expand into the channel when displaced by large diameter tools. The o-ring would provide additional support to the star valve flaps to maintain a seal at large diameters. A sketch of the design can be seen in Figure 19.

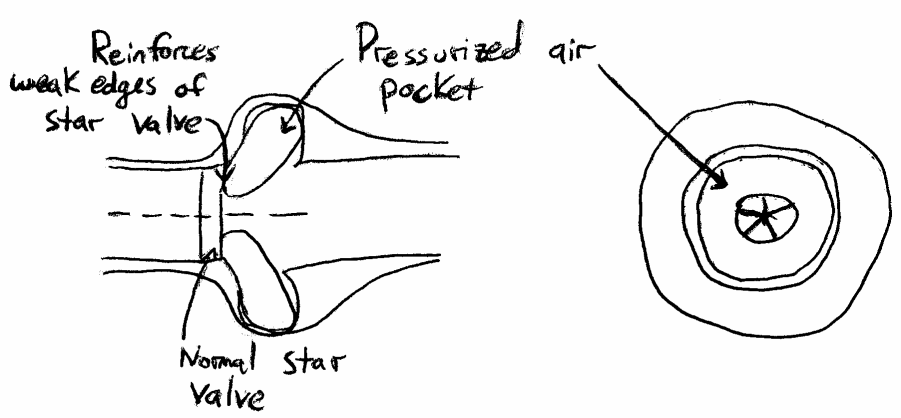


Figure 19: Sketch of star valve and o-ring

A different approach to the bifurcated valve involved making the elastomer much longer and encircling it with a pressurized sack. The sack would minimize the deflection of the bifurcated sides of the elastomer and the addition length could help support the weight of tools and wires passed through the valve, ultimately providing a better seal. A sketch of this design can be seen below in Figure 20. Figure 21 shows a CAD model of the design.

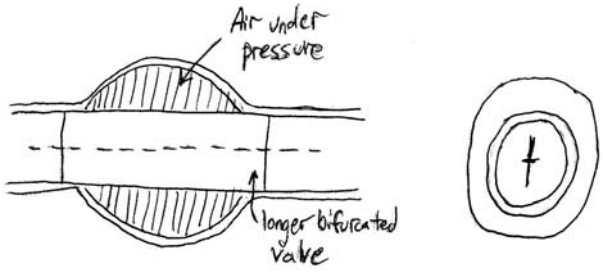


Figure 20: Sketch of pressurized long bifurcated design

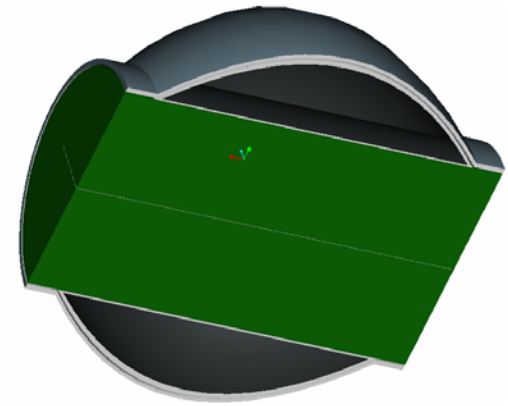


Figure 21: CAD model of pressurized long bifurcated design

Along different lines, another design concept involved a non-axial symmetric valve housing. Inside of the housing would be a bed of springs supporting a slab of elastomer material. The slab would be large enough to fully occlude the valve openings at either end to prevent blood loss. When a tool or wire would be inserted into the valve the spring bed would maintain pressure on the object and force the elastomer to conform to its shape to minimize leakage. A sketch of this design can be seen in Figure 22.

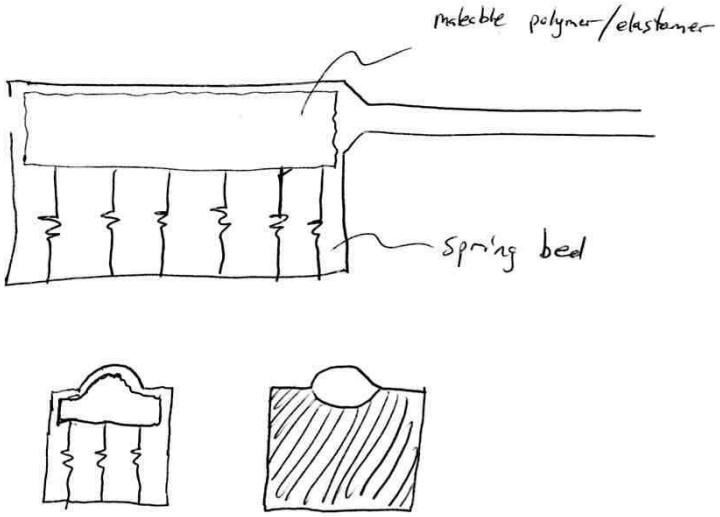


Figure 22: Sketch of spring loaded valve

Another idea was to create a wholly new shape for the valve. The toroidal valve design would be fixed at the outer end and the inner surfaces would be able to slide along the valve housing. As an object is passed through the valve it could deform and slide into the housing and opening wider to accommodate larger tools. This design would be able to provide an excellent seal on all circular tools passed through the valve. A cross sectional sketch of the design can be seen in Figure 23. Figure 24 shows a CAD model of the design.

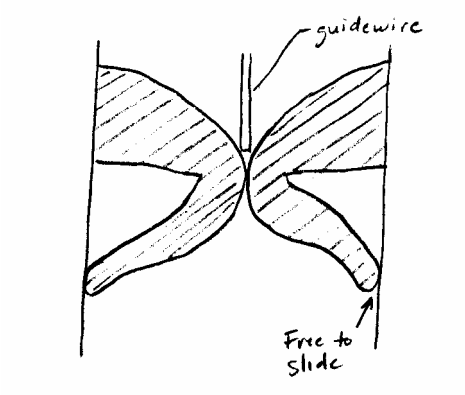


Figure 23: Cross sectional sketch of deformable toroid

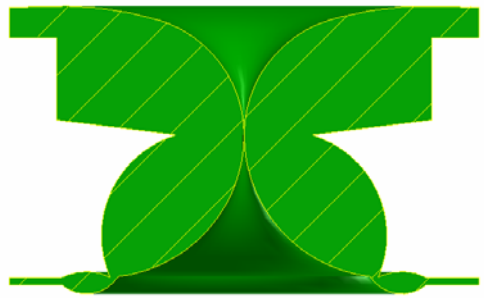


Figure 24: CAD model of deformable toroid

We also came up with a concept which improved upon the original bifurcated valve. We envisioned adding reinforcements to the standard bifurcated valve. A concept CAD model of the design can be seen in Figure 25.

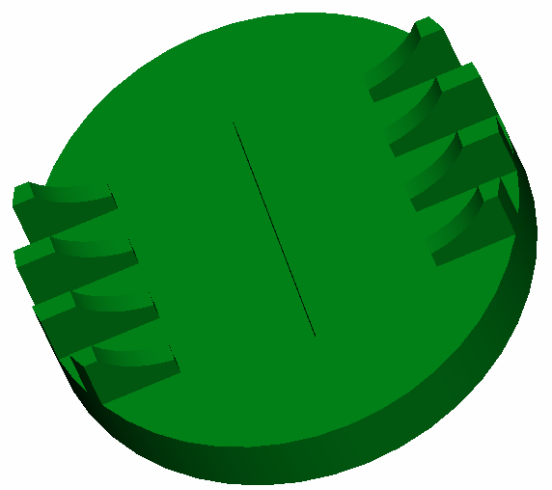


Figure 25: Reinforced bifurcated valve concept

III.2 Design Selection Process

We used the QFD to rank our designs. We rated each of the preselected design concepts in the same manner that we rated the existing designs. These ratings were based on our best estimation of the design's capabilities in each design specification category. Our process determined that the reinforced star and bifurcated valves and the toroidal design were our top three ranking designs. The reinforced designs rank higher than the toroidal design, however we feel that this design is fairly original and will work just as well. The results from the QFD have led us to these three designs which we will pursue in more detail. We will use Finite Element Analysis (FEA) in conjunction with experimental testing to determine which of the three designs best meets the design specifications.

III.3 FEA Process

Due to the large deformations our valve was going to be subject to, it was very difficult to analytically predict our valve's response. This difficulty was due to the nonlinear deformations that occurred as our valve stretched to allow a tool to pass through it. We used FEA to overcome the large computational requirements. To do the FEA, we used Abaqus CAE for the toroid valve and CosmosWorks for the star valve.

Using Abaqus CAE for the toroidal valve was more difficult than first anticipated. The mesh was having difficulty handling the small features and large deformations. In order to get a model to come close to running, we had to create a super fine mesh. This might have worked, but to find out we would have had to wait weeks, even months for results. To reduce the computational effort needed to do the FEA, we moved to an axisymmetric version of the 3-dimensional valve. The axisymmetric version was a 2-dimensional representation of the revolved 3-dimensional part, which alleviated much of the computational effort. These models still took a large amount of time to run, therefore, by the time we had the model working completely, we did not have the time required to run many simulations to determine the final geometry. The results of a simulation that took 60 hours to run are shown below in Figure 26.

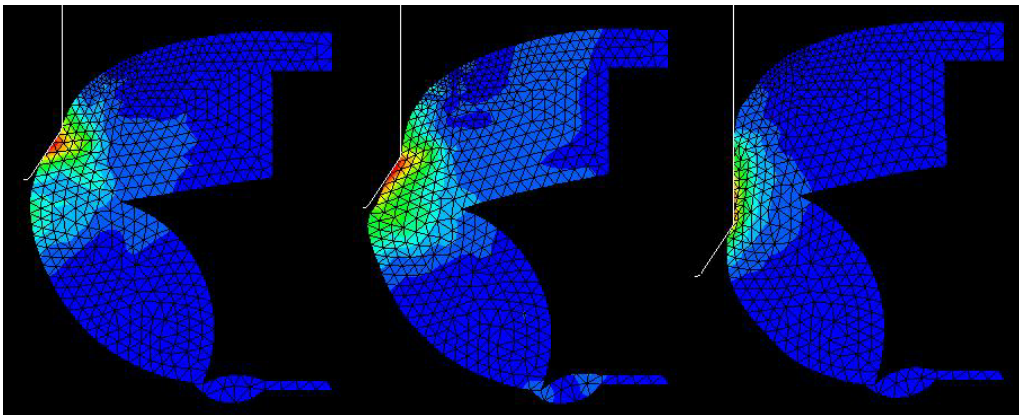


Figure 26: Abaqus simulation of a tool being passed through an axisymmetric valve

We did not have the time to run many valve design iterations in FEA, but from what was done, there was a lot to learn from the results. As can be seen in Figure 26, above, the tool is able to push its way through the valve, as was desired. Not only does the material open for the tool, but one can also see that the material is conforming around the material in a self sealing manner. This tells us that the material we chose has properties that will perform very well under our conditions. More importantly, this FEA model showed us that our original alpha design would not function as originally anticipated. As can be seen in Figure 26, the material does not flex and squeeze together at the bottom as desired. This is due to the large amount of material in the hinging areas and joints. It can also be seen, by looking at the progression of the tool, that the joint location does not support the desired movement required as well.

The question as to how to fix these issues was thoroughly discussed among the group and a new design was produced. This design, as seen below in Figure 27, has much of the material in the flexing regions removed. The locations of the joints are also moved slightly toward the center of the valve to encourage the valve to flex inward while a tool is pressing down from above.

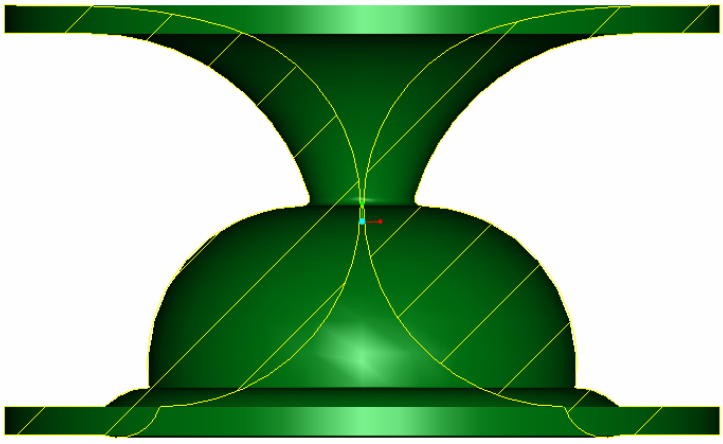


Figure 27: CAD model of the next iteration of our toroidal alpha design

As was stated above, time was becoming a factor, for that reason, a working FEA model for this iteration was not created. This decision was made due to concerns of our ability to manufacture the valve. These concerns will be addressed later in our manufacturing section.

FEA was also done on the reinforced star valve in CosmosWorks, as stated above. This FEA model was slightly easier to create due to the nature of the valve. The reinforced star valve did not have to stretch and expand to allow a tool to pass through it; it merely had to allow for slight deformations. The FEA model produced to demonstrate the concept is seen below in Figure 28.

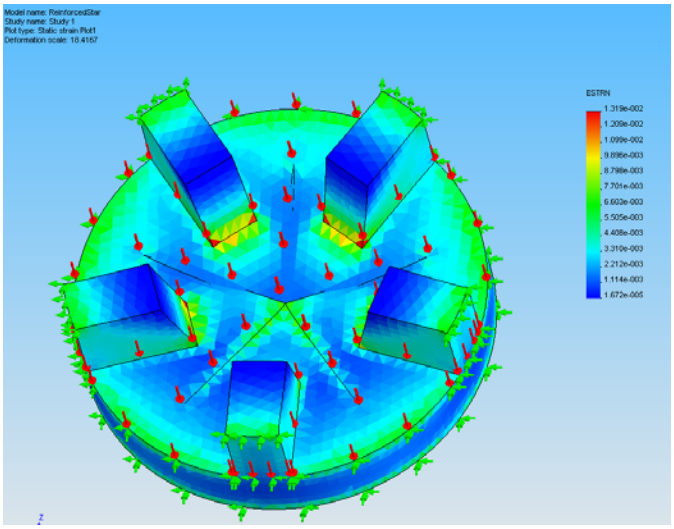


Figure 28: FEA model to simulate the response of the reinforced star valve

As can be seen in Figure 28, above, the star cut sections of the valve could move too far and separate to allow blood to flow past them. The result of this model was again, not a proof of a final concept, but a guide to a final design. Since the flaps of the star cut move too far under pressure, it was thought that a thicker, more self-sealing style valve would work better. Again, due to time constraints a new FEA simulation was not created to prove this. This decision was made largely due to the ease of manufacturability of this style of valve, which will be discussed in detail later in the report.

An FEA simulation of our final design was not created for the reasons stated above. Many proofs of concept FEA simulations were created, though. The successful simulations are shown here, although, no failed simulation data is presented, because output data for the failed simulations was not created by Abaqus and CosmosWorks.

III.4 "Alpha" Design Selection

We decided on the deformable toroid as one of our "Alpha" design. We believe that a single piece valve design will be one of the easiest for our manufacturing capabilities. This design will allow us to make a single mold, most likely using rapid prototyping and stereolithography, from which we can cast an elastomeric valve. This design will also

form the best seal around most tools since most tools have a circular cross section. The design has a very simple method of operation and with only one part there is less cost in manufacturing and fewer pieces to assemble for the entire sheath. The valve can be bonded to the valve housing with an adhesive on the flat upper sides as seen in Figure 24. The lower lips of the toroid will be free to slide within the valve housing. Ample space will be left inside the housing to allow the valve to fully deform when a maximum diameter tool is inserted. Figure 29 below shows an isometric view of the valve, which shows the small opening which tools will pass through. If this opening is determined to be too large and will not allow adequate static sealing it is very simple to add a thin bifurcated valve before the toroid to provide additional sealing.

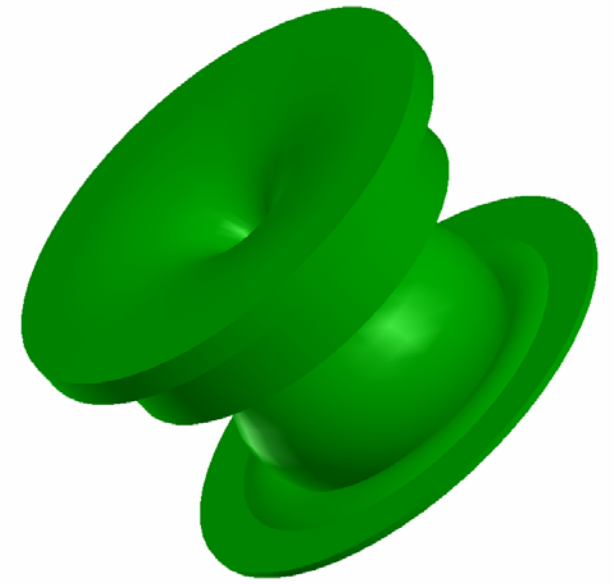


Figure 29: Isometric view of deformable toroid valve

Our other two designs will be modifications to the current bifurcation and star valve designs currently in production. We believe that the addition of material to the surface of the valve will add enough stiffness to prevent the valves from failing. These designs should be easily manufactured using the rapid prototyping and molding process considered for the toroidal design. The slits can be cut into the valve after the molding process is complete.

All three designs will be mounted in to a model valve housing in similar fashion. The valves will have slight excess material on the outer surfaces that will be glued and pressed between sections of plastic tubing. Then the plastic tubing will be glued inside of another continuous piece concentric tubing which will act as the sheath. A preliminary drawing of this sheath system is shown in Figure 30. The open slots will accept the tabs at the outer edges of the toroidal design shown above. The other designs will be secured similarly.

All of the alpha designs' engineering drawings can be seen in Appendix E. The preliminary dimensions of the valve components have been determined from measurements of the current designs we have been able to inspect. The first prototypes

will give us more insight into the necessary thicknesses of material in different locations. It is difficult to predict the behavior of the specific polymers due to their large displacements and elongation properties. However, after initial testing is completed we are confident we will be able to make significant improvements on the designs.

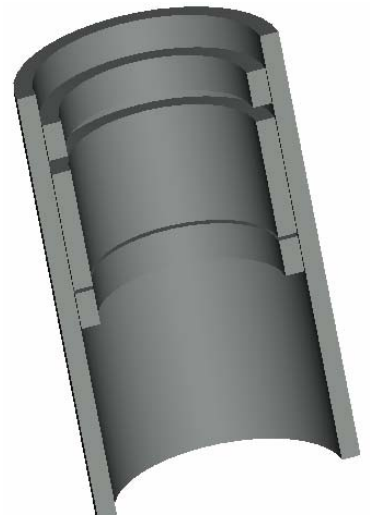


Figure 30: Sample drawing of valve housing

IV. Project Plan and Schedule

A detailed Gantt chart with our project schedule can be seen in Chart 1 below. This chart illustrates the path our group took to complete our prototype, testing and validation. Further work could be done on this project in cooperation with Dr. Gurm. Dr. Gurm has expressed interest in filing an Invention Discloser to the University of Michigan and possibly working with Cook Medical Devices to design an injection molded version of our final valve design as well as the toroid design. Further analytical analysis should also be conducted using FEA to better understand the dynamics of the valve's motion.

Task Name	Duration	Start	Finish
Project Problem Description	5 days	Tue 9/19/06	Mon 9/25/06
Definition of Customer Requirements	4 days	Tue 9/19/06	Fri 9/22/06
Research Necessary Medical Information	5 days	Tue 9/19/06	Mon 9/25/06
Brainstorm Design Ideas	14 days	Tue 9/19/06	Fri 10/6/06
Benchmark competing products	3 days	Tue 9/19/06	Thu 9/21/06
Write DR1 Report	3 days	Thu 9/21/06	Mon 9/25/06
Make DR1 Presentation	3 days	Thu 9/21/06	Mon 9/25/06
Weekly Group Meeting	**56 days**	**Thu 9/21/06**	**Thu 12/7/06**
Design Review #1	0 days	Tue 9/26/06	Tue 9/26/06
Build/CAD Preliminary Design Model	8 days	Mon 10/2/06	Wed 10/11/06
Design Selection	6 days	Mon 10/2/06	Mon 10/9/06
Write DR2 Report	5 days	Thu 10/5/06	Wed 10/11/06
Make DR2 Presentation	5 days	Thu 10/5/06	Wed 10/11/06
Design Prototype	15 days?	Mon 10/9/06	Fri 10/27/06
Revise Project Schedule	2 days	Tue 10/10/06	Wed 10/11/06
Design Review #2	0 days	Thu 10/19/06	Thu 10/19/06
Research available elastomers	5 days	Thu 10/19/06	Wed 10/25/06
FEA modelling of prototype	10 days	Thu 10/19/06	Wed 11/1/06
Write DR3 Report	5 days	Tue 10/24/06	Mon 10/30/06
Make DR3 Presentation	5 days	Tue 10/24/06	Mon 10/30/06
Order Necessary Parts and Supplies	5 days	Mon 10/30/06	Fri 11/3/06
Manufacture and Assembly of Prototype	28 days?	Mon 10/30/06	Wed 12/6/06
Secure materials and devices for testing	15 days?	Mon 10/30/06	Fri 11/17/06
Design Review #3	0 days	Tue 10/31/06	Tue 10/31/06
Write DR4 Report	5 days	Tue 11/14/06	Mon 11/20/06
Make DR4 Presentation	5 days	Tue 11/14/06	Mon 11/20/06
Perform prototype testing and comparison	3 days	Tue 11/14/06	Thu 11/16/06
Design Review #4	0 days	Tue 11/21/06	Tue 11/21/06
Prepare For Design Expo Display	5 days	Thu 11/30/06	Wed 12/6/06
Write DR4 Report	5 days	Tue 11/14/06	Mon 11/20/06
Make DR4 Presentation	5 days	Tue 11/14/06	Mon 11/20/06
Perform prototype testing and comparison	3 days	Tue 11/14/06	Thu 11/16/06
Design Review #4	0 days	Tue 11/21/06	Tue 11/21/06
Prepare For Design Expo Display	5 days	Thu 11/30/06	Wed 12/6/06
Write Final Report	5 days	Tue 12/5/06	Mon 12/11/06
Design Expo	0 days	Thu 12/7/06	Thu 12/7/06
Final Report Due	0 days	Tue 12/12/06	Tue 12/12/06

Chart 1a: Task list for Project Scheduling

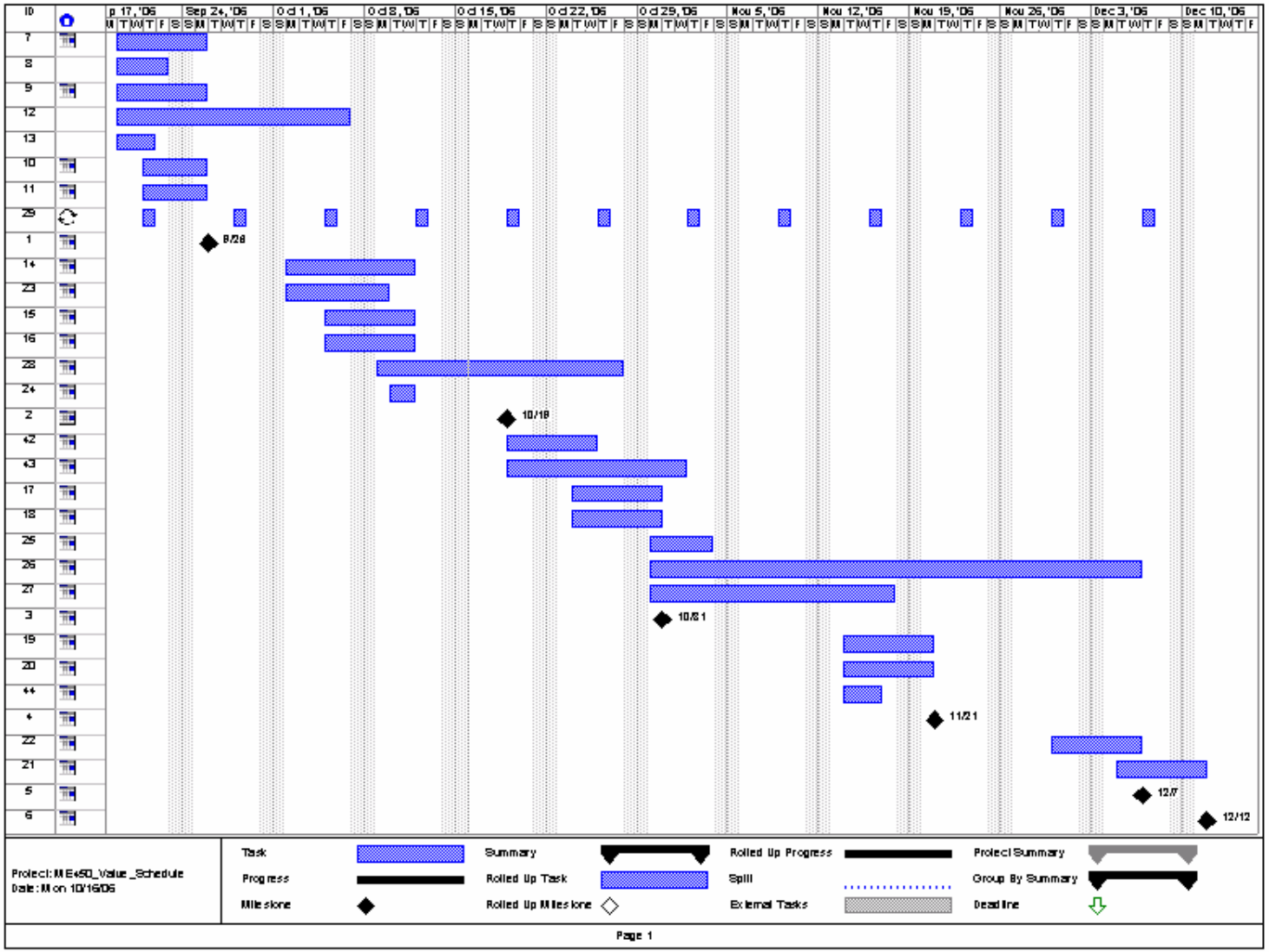


Chart 1b: Gantt Chart

V. Final Design Description

V.1 Final Design Selection

Our final design was determined to be the reinforced star valve. The final dimensions of this valve were determined experimentally through an iterative manufacturing process and can be seen in the engineering drawings in Appendix F. After three iterations of the molds for all three alpha designs the reinforced star valve molds produced a working valve. This valve was able to maintain a static seal and a dynamic seal with tools inserted through it. Figure 31 below shows a 3D CAD model of how our prototype would be integrated into a functional sheath and Figure 32 shows what a full sheath would look like.

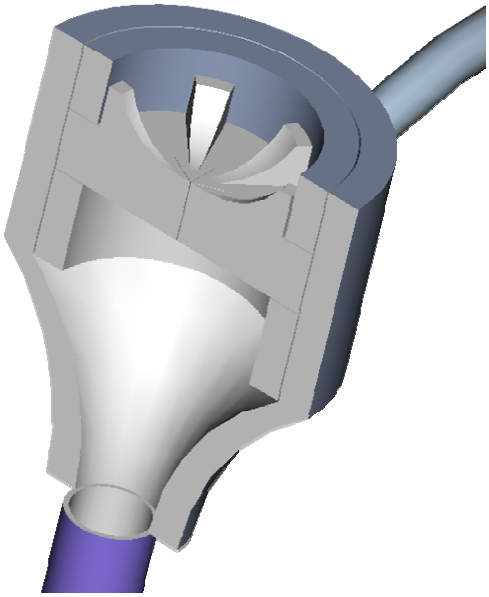


Figure 31: Prototype reinforced star valve integrated into a sheath housing

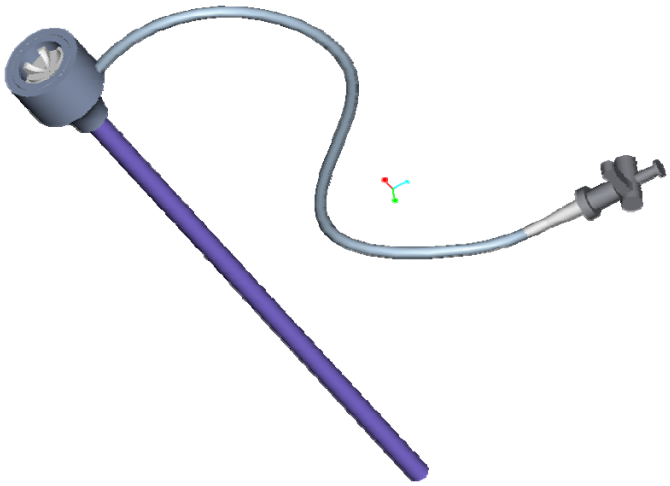


Figure 32: Full size model of prototype sheath

V.2 Material Selection

The final material selection for the valve was the GLS Dynaflex G2711-1000-00 elastomer. This elastomer came in a pelletized form, which we melted in a metal container in an oven at approximately 200 °C. This material's properties can be seen in Table 5.

Property	Units	Value
Shore Hardness	A	43
Tensile Strength	kPa	5723
% Elongation	-	650%
Tear Strength	kN/m	23
Specific Gravity	-	.89

Table 5: GLS Dynaflex G2711-1000-00 Material Properties

V.3 Manufacturing

Our molds were printed on the 3D printer in the UM3D lab. These molds were made out of a powder and epoxy binder then coated in West Systems epoxy for additional strength. Figure 33 shows the molds in the stereolithography printer used.

Figure 33: Molds still inside stereolithography printer bed

The iterations of the molds can be seen in Figure 34. The first iteration of molds were determined to be too small after our first attempts at molding valves. It was very difficult to completely fill the molds with the elastomer. We made the second iteration of molds twice the size of the first iteration to accommodate both the dimensional tolerances of the UM3D lab's printer and the flow properties of the liquid melt elastomer. The second iteration still had problems with the elastomer not flowing into small spaces in the mold. We were able to produce several valves from the second generation of molds, however when we tested them they were not able to hold a good seal. The third and final iteration

enlarged those portions of the mold which had difficulties flowing liquid elastomer. Some portions of the third iteration of molds were also enlarged to compensate for the failures of the second iteration. The differences between the second iteration (shown below) and the final iteration are nearly indistinguishable in photographs as they are merely small dimensional changes, thus they are not shown.

Figure 34: Iterations of prototype molds, Top 1st Generation, Bottom 2nd Generation

The Dynaflex elastomer pellets were put into aluminum cups and placed in an oven at approximately 205 °C until melted. Once the elastomer was melted it was removed from the oven and immediately poured into the mold halves. Figures 35 and 36 illustrate the molding process. The mold halves were then forced together and left to cool. Once cooled the halves of the mold were separated and the valves were pulled out.

Figure 35: Dynaflex polymer melting in an oven

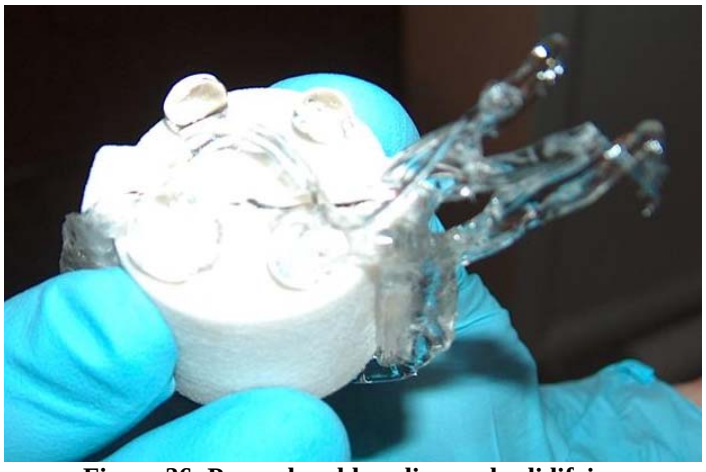


Figure 36: Pressed mold cooling and solidifying

V.4 Validation Process

Force Testing

We tested a 20F tool and 16F and 12F dilators with our final valve prototype to determine the force required to insert and remove each one. We used the force transducer in the Wu Manufacturing Lab, the same one that was used to benchmark the current valve designs. Each insertion and removal was performed twice, and we averaged the data and calculated the error. Table 6 summarized our prototype force test results and compares them with the current design benchmarks.

	Sheath Sizes and Tool Inserted	Normalized Force (N)
Current Design Made by Daig		
16F valve	16F dilator insertion	3.04 ± 0.88
16F valve	16F dilator removal	9.78 ± 3.76
12F valve	12F dilator insertion	6.10 ± 2.81
12F valve	12F dilator removal	9.19 ± 1.12
12F valve	11F stopper insertion	2.39 ± 1.30
12F valve	11F stopper removal	5.76 ± 0.26
Prototype		
20F valve	20F tool insertion	3.50 ± 1.50
20F valve	20F tool removal	2.10 ± 1.25
20F valve	16F dilator insertion	1.80 ± 1.00
20F valve	16F dilator removal	5.10 ± 0.62
20F valve	12F dilator insertion	2.50 ± 0.94
20F valve	12F dilator removal	4.80 ± 2.05

Table 6: Force testing for the current design vs. our final prototype

As shown in the table above, the maximum force required for our valve is less than 6 N. Therefore, our valve meets our engineering specifications, which require a maximum force of 15 N. Figure 37 below shows our force testing setup.

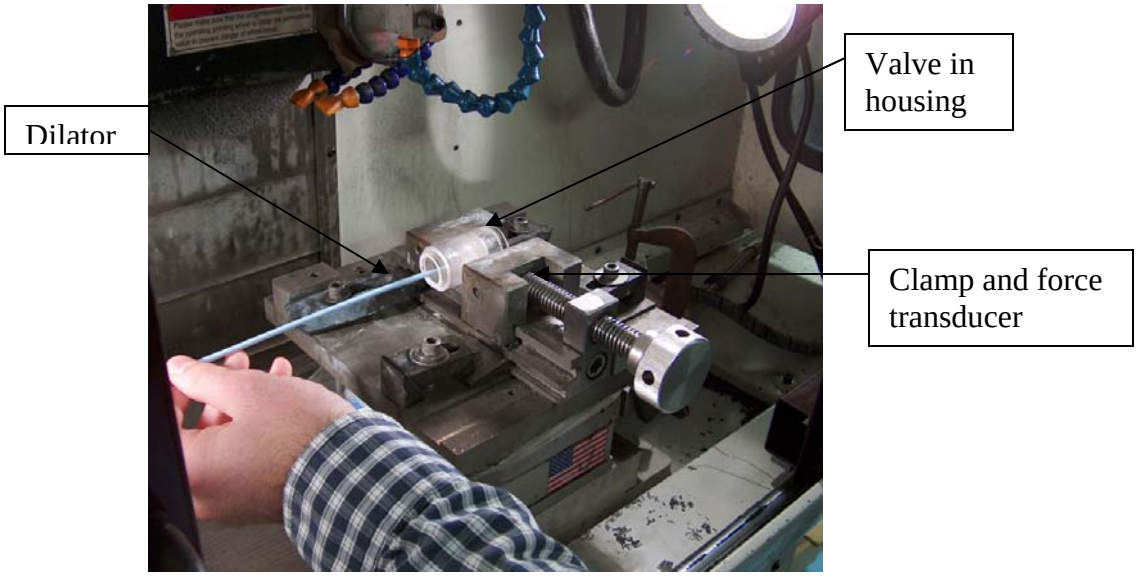


Figure 37: Force testing setup

Leak Testing

Leak testing was performed using our pressure test apparatus (see Figure 14, page 15). The valve housing for our final prototype design has an outer diameter of 31.75 mm, so

we had to use a test hose with an inner diameter of 31.75 mm. As with the benchmark leak tests, we pumped the pressure to approximately 21 kPa. Our leak test results are summarized in Table 7 below.

	Tools Inserted (Diameters)	Volume Filled (mL)	Elapsed Time (s)	Leak Rate ($^{mL}/_{min}$)
Current Design				
16F Sheath	0.9398 mm wire	10	330	1.82
(made by Daig)	1.1938 mm wire	10	22	26.79
	16F dilator over .9398 mm wire	no leakage	N/A	N/A
12F Sheath	0.9398 mm wire	10	1630	0.37
(made by Daig)	1.1938 mm wire	10	15	39.74
	12F dilator over .9398 mm wire	no leakage	N/A	N/A
Prototype				
20F Sheath	0.9398 mm wire	no leakage	N/A	N/A
(reinforced star)	1.1938 mm wire	1	60	1.00
	12F dilator over .9398 mm wire	1	60	1.00
20F Sheath	0.9398 mm wire	5	60	5.00
(regular star)	1.1938 mm wire	7	60	7.00
	12F dilator over .9398 mm wire	1	60	1.00
20F Sheath	0.9398 mm wire	10	58	10.34
(toroid and reinf. star)	1.1938 mm wire	10	47	12.77
	12F dilator over .9398 mm wire	-	-	-

Table 7: Leak testing for the current design vs. our prototypes

As shown in the table above, our final prototype (reinforced star valve) leaks 1 mL/min. This equates to 30 mL during a 30 minute operation, which is lower than our maximum engineering specification of 40 mL. Figure 38 below shows our leak testing setup.

Figure 38: Leak testing setup

VI. Conclusions

Modern minimally invasive heart surgeries use the femoral artery as an entry point, from which the surgeon can follow the arteries to the heart. The sheaths, used as gateways, to pass tools to and from the artery must not allow for blood to flow up the sheath and out of the patient. For this reason, a lot of attention is given to the valve in the sheath. Of recent interest are sheaths with a diameter of 6.7 mm that utilize a bifurcated valve. These bifurcated valves do not seal under certain conditions, however, which is the focus of our investigation. During certain instances, the guide wire is the only tool present in the sheath and due to the geometry of these valves, creases are formed along the valve's seam and blood flow results across the valve.

To design a satisfactory new valve means that our valve must not only abide by all present FDA regulations, but it must also fully seal with a blood pressure of 21.3 kPa behind the valve for sheaths up to 6.7 mm in diameter. To insure that these requirements are accomplished, our team has given a lot of attention to fully understanding the problem at hand.

We have researched and benchmarked current designs and patents, from which we brainstormed new concepts. We gathered data on the leakage rates of the current valve designs. We also were able to measure the average force required to insert and remove tools from the current valves. This data helped us determine engineering specifications for our valve design.

We determined our final valve design was the reinforced star valve by using a combination of analytical tools and experimental iterations. It met all of the design specifications and customer requirements. The valve achieved a maximum leak rate of just 1 mL/min with the large diameter guide wire inserted through it, which met the specification of less than 40 mL of blood loss during a 30 minute procedure. It was also able to maintain a static seal with a 21.3 kPa backpressure. The valve housing was 31.75 mm in diameter, which is less than the required 38 mm maximum diameter. It could pass a 20F diameter tool through as well as smaller tools. The valve required less than 15 N of force to insert or remove a tool. Also since the valve was made out of GLS Dynaflex G2711-1000-00, it is biocompatible and is able to be sterilized after manufacturing.

Our sponsor, Dr. Gurm, tried our final valve design on the venous pressure testing apparatus and was very impressed with its functionality. He has suggested moving forward with the design and possibly working with Cook Medical Devices to produce a production version of the valve.

We would like to give special thanks to Bin Shen, Rui Li, Mr. McCubbin, Mr. McCarthy, Brent Lyons, and Michael Pritchett for their assistance throughout this project.

References

1) Bonow RO, Braunwald EB, Libby P, Zipes DP [eds]: Braunwald's Heart Disease – A Textbook of Cardiovascular Medicine. 7th ed, volume 1. Philadelphia, Pennsylvania. Elsevier Saunders, 2005, p 404.

2) Boudjemline, Y. (2002). Steps toward percutaneous aortic valve replacement. *American Heart Association Journal*, 105, 775.

3) Food and Drug Administration (2005). Medical Device Classification Procedures Title 21 Part 860 Subpart C. Retrieved September 24, 2006, from FDA website: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=860.132&SearchTerm=performance%20standards

4) Fleishhacker, John J, et al. (1987). U.S. Patent No. 4,909,798. Washington, D.C.:U.S. Patent and Trademark Office.

5) Franzel, R.C., et al. (1998). U.S. Patent No. 5,782,817. Washington, D.C.: U.S. Patent and Trademark Office.

6) Guo, X., et al. (2003). U.S. Patent No. 6,551,283. Washington, D.C.: U.S. Patent and Trademark Office.

7) Green, D., et al. (2003). U.S. Patent No. 6,569,120. Washington, D.C.: U.S. Patent and Trademark Office.

8) Lichtenstein, S. V. (2006). Transapical transcatheter aortic valve implantation in humans. *American Heart Association Journal*, 114, 529.

9) National Institute of Medicine (2006). Medline Plus Medical Encyclopedia. Retrieved October 12, 2006, from FDA website: http://www.nlm.nih.gov/medlineplus/encyclopedia.html

10) Society for Vascular Surgery (2006). Vascular Web. Retrieved October 30, 2006, from website: http://www.vascularweb.org/_CONTRIBUTION_PAGES/Patient_Information/NorthPoint/Endovascular_Stent_Graft.html

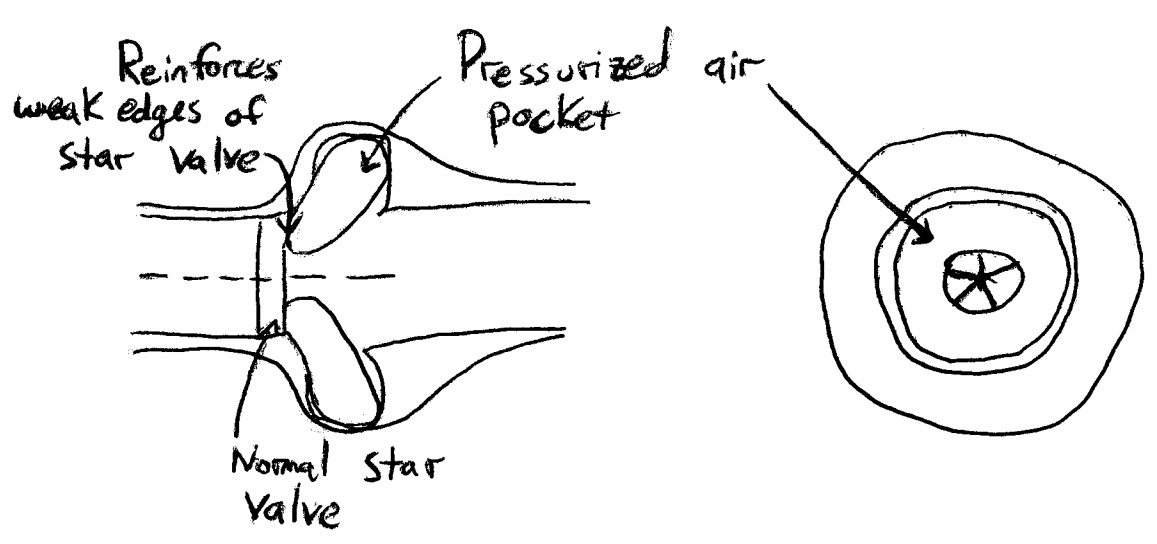
11) Society of Thoracic Surgeons (2006). The Society of Thoracic Surgeons. Retrieved October 30, 2006, from website: http://www.sts.org/sections/patientinformation/aneurysmsurgery/aorticaneurysms/

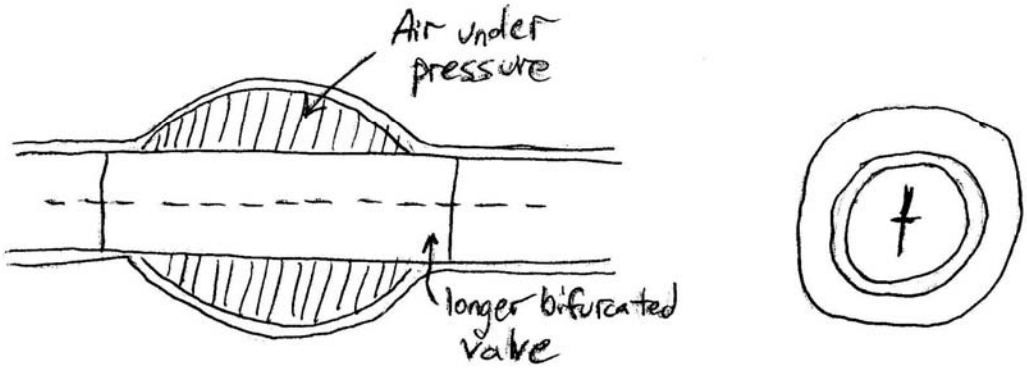
12) Weinstein, L.A., et al. (1995). U.S. Patent No. 5,460,616. Washington, D.C.: U.S. Patent and Trademark Office.

Appendix A: Table A1

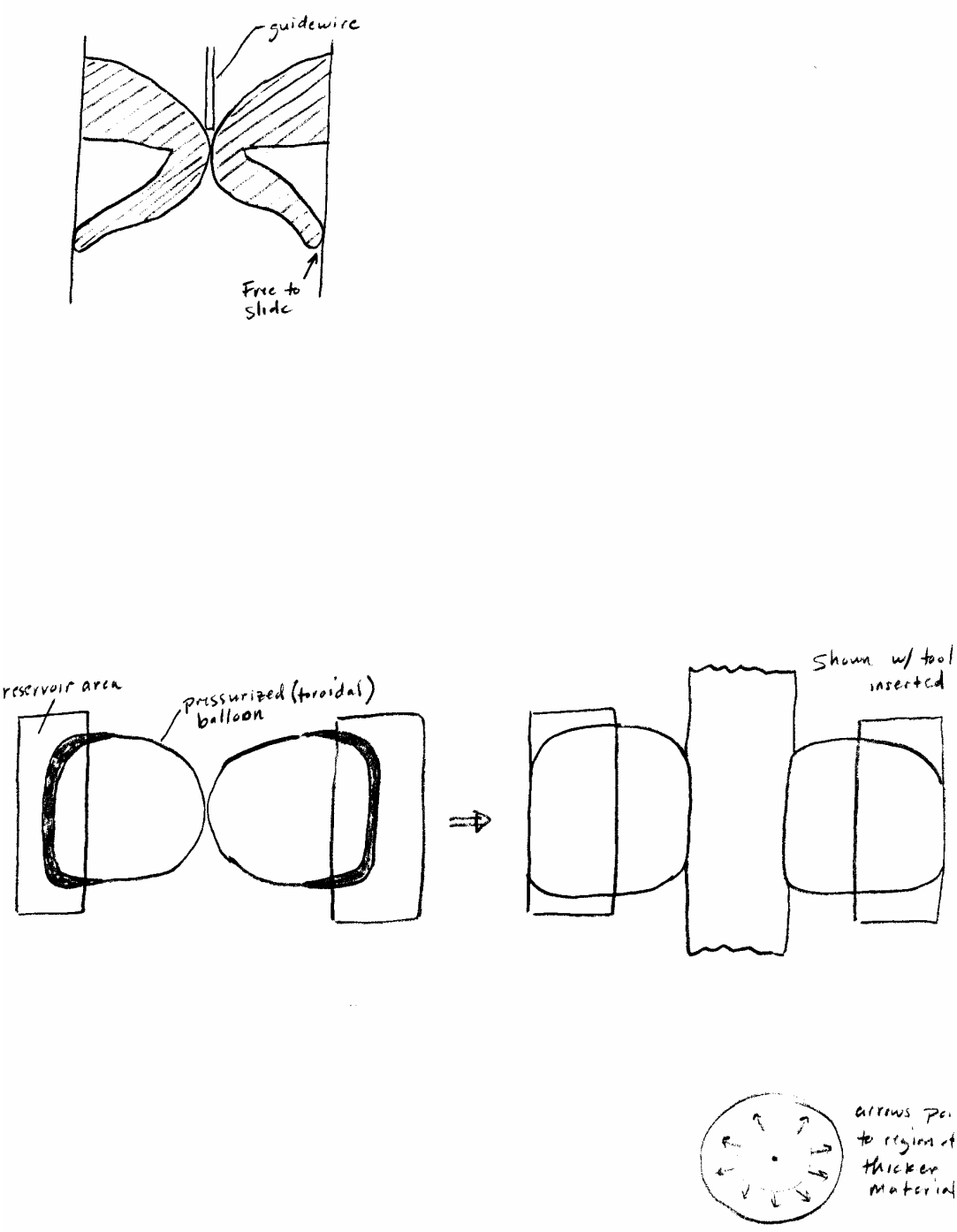
Test Name	Average Force (N)	Test Time (s)	Normalized Force (N)	Precision Error	Resolution Error
16 French Sheath Force with Dilator force insertion1	3.50	6.0	2.86	0.878582	0.005
16F Sheath Force with Dilator force insertion2	2.51	7.9	2.72		
16F Sheath Force with Dilator force insertion3	3.21	8.0	3.54		
	Average time:	7.3			
16F Sheath Force with Dilator force removal1	10.02	5.3	7.85	3.756198	0.005
16F Sheath Force with Dilator force removal2	9.23	7.2	9.87		
16F Sheath Force with Dilator force removal3	10.10	7.7	11.61		
	Average time:	6.7			
12F Sheath with 12F dilator force insertion1	6.58	4.7	4.56	2.81174	0.005
12F Sheath with 12F dilator force insertion2	5.88	7.4	6.42		
12F Sheath with 12F dilator force insertion3	6.01	8.2	7.31		
	Average time:	6.7			
12F Sheath with 12F dilator force removal1	8.97	6.6	9.58	1.119907	0.005
12F Sheath with 12F dilator force removal2	9.43	5.7	8.79		
12F Sheath with 12F dilator force removal3	Failure	N/A	N/A		
	Average time:	6.1			
12F Sheath with 11F stopper force insertion1	2.49	8.7	2.98	1.300565	0.005
12F Sheath with 11F stopper force insertion2	2.05	6.0	1.69		
12F Sheath with 11F stopper force insertion3	2.54	7.2	2.50		
	Average time:	7.3			
12F Sheath with 11F stopper force removal1	6.63	6.4	5.84	0.260658	0.005
12F Sheath with 11F stopper force removal2	5.42	7.5	5.61		
12F Sheath with 11F stopper force removal3	5.37	7.8	5.84		
	Average time:	7.2			

Appendix B

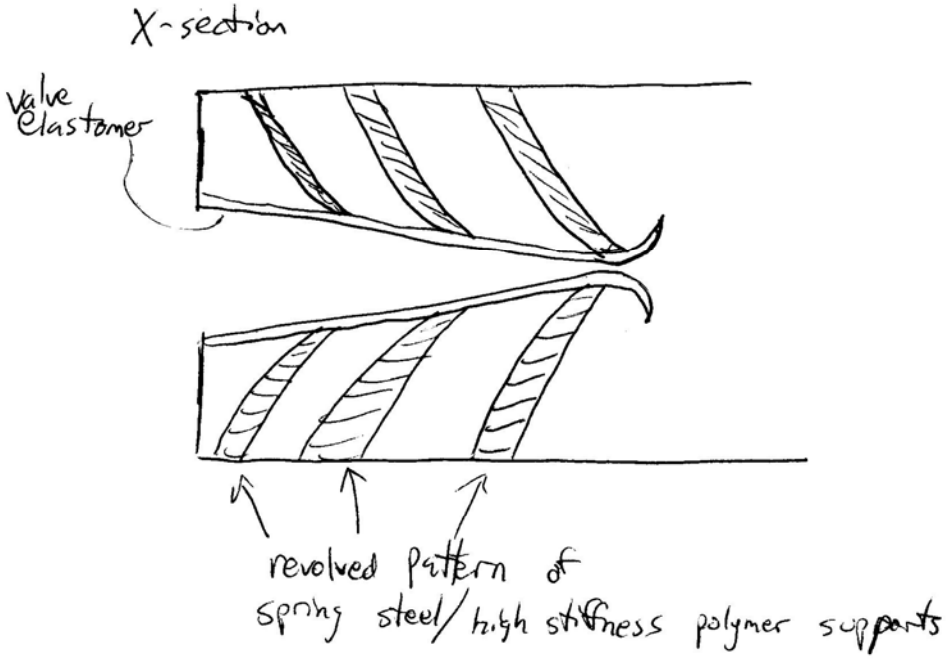

Reinforces weak edges of star valve
Pressurized air pocket
Normal Star Valve

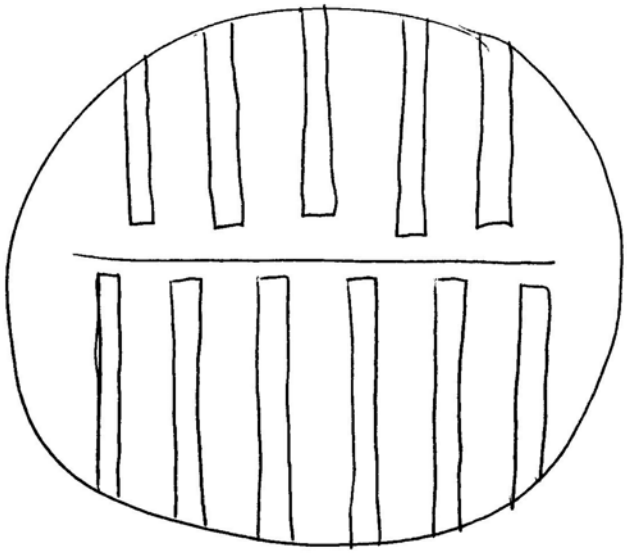

Air under pressure
longer bifurcated valve

Appendix B


guidewire
Free to slide
reservoir area
pressurized (toroidal) balloon
Shown w/ tool inserted
arrows po
to region of
thicker
material

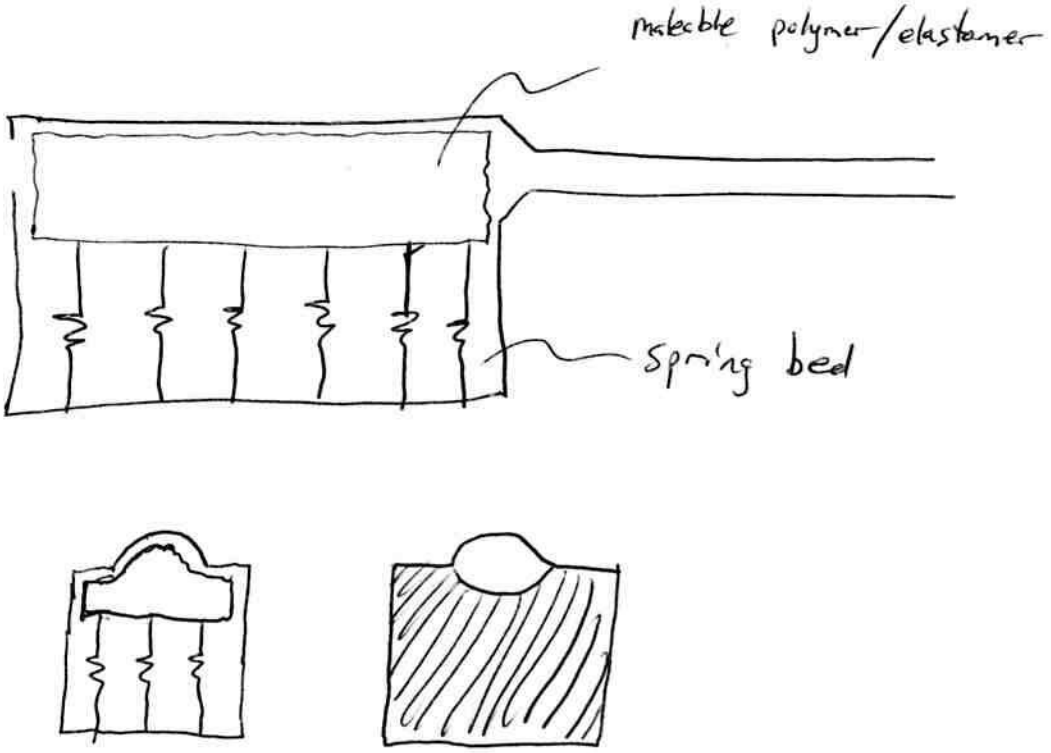
Appendix B

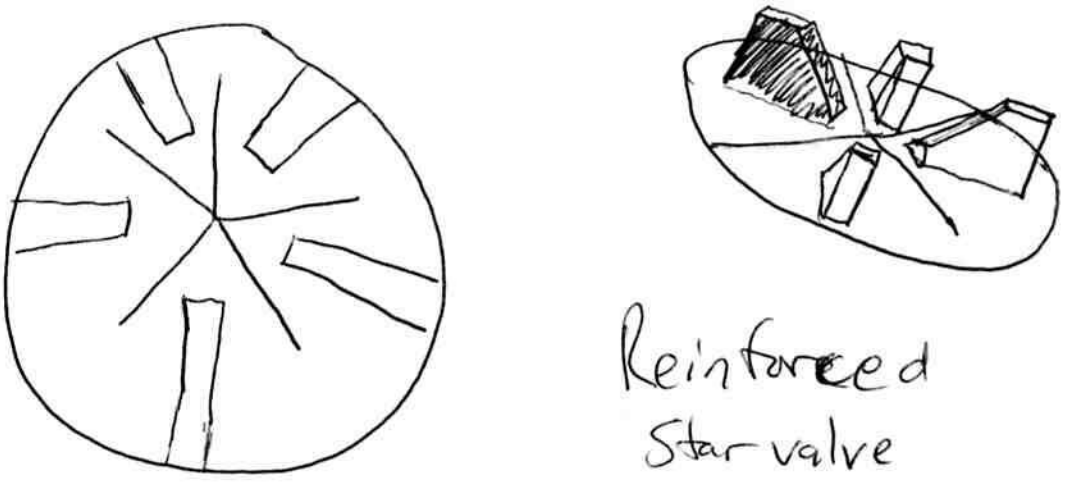




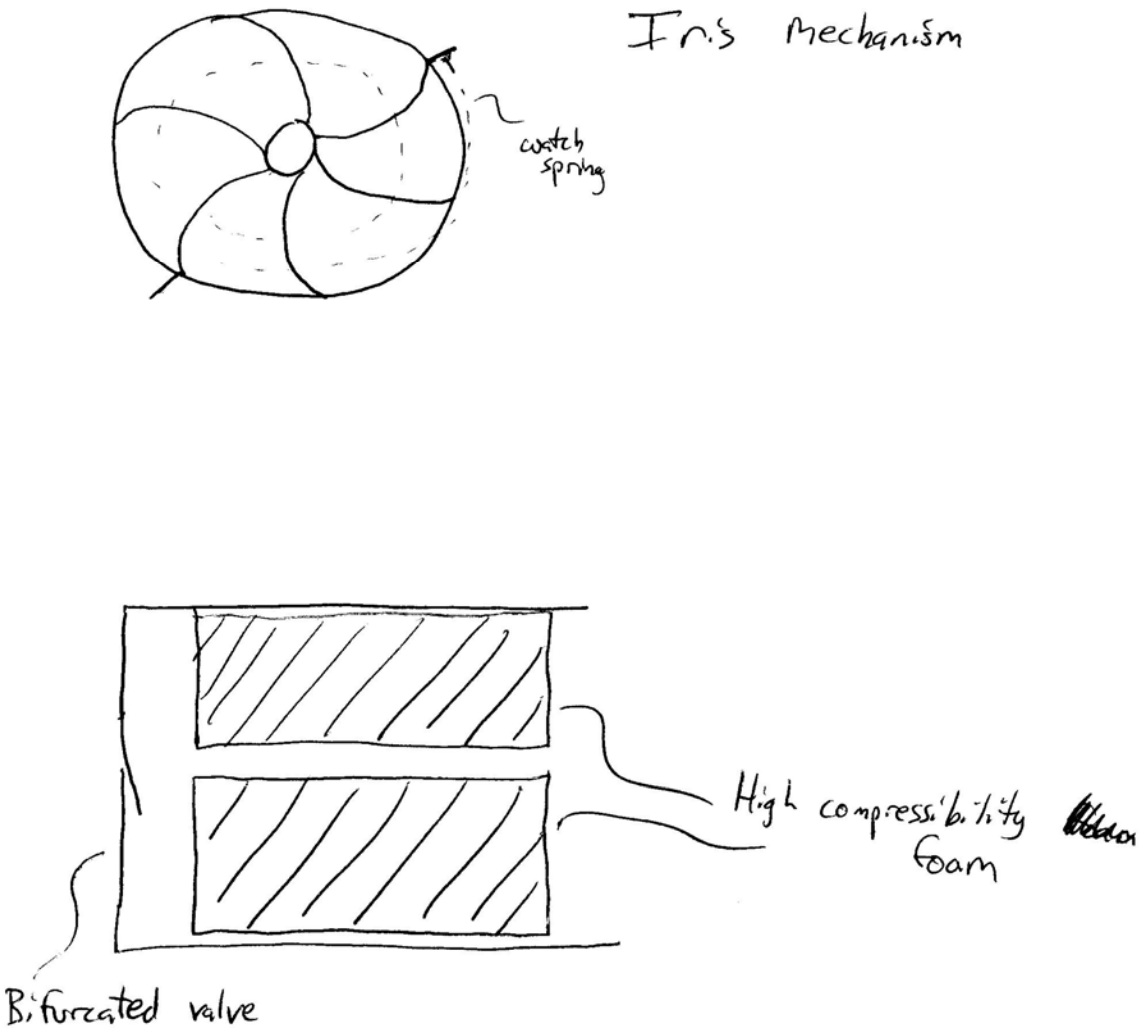
Reinforced Bifurcated

Appendix B

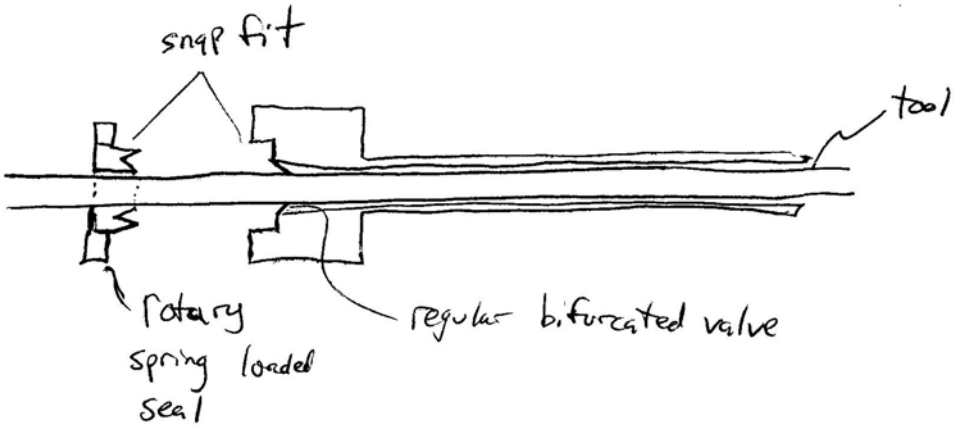

malecble polymer/elastomer
spring bed

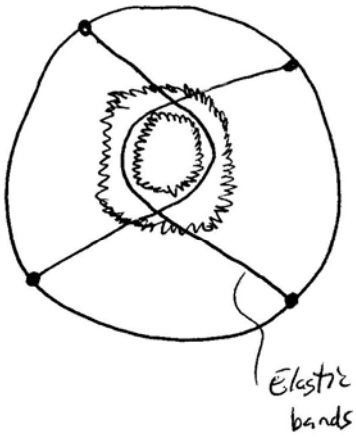

Reinforced
Star valve

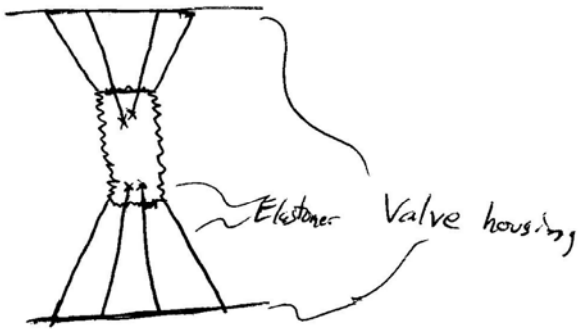
Appendix B


Iris Mechanism
watch spring
High compressibility Foam
Bifurcated valve

Appendix B

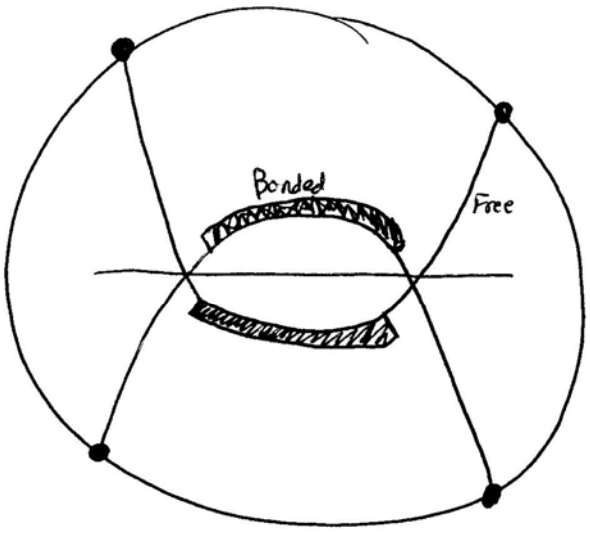




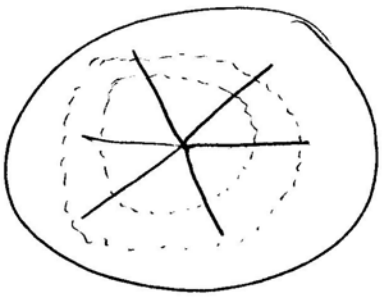


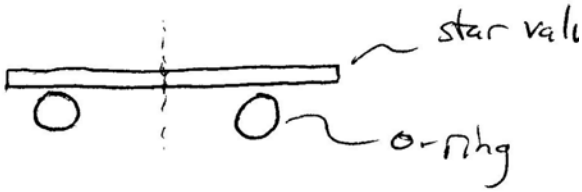
trash bag draw string design

Appendix B



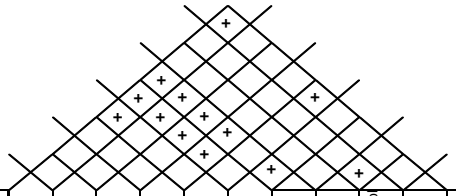
Elastic bands
Bonded at valve housing
and on opposing
lip of bifurcation





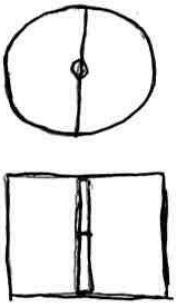
Appendix C

1	Not related
3	Weakly related
5	Neutral
7	Moderately related
9	Strongly Related

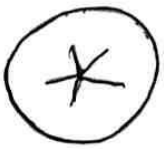


	Customer Requirements \ Part Characteristics	Normalized Importance to Customer (Relative Weight)	Inner Diameter of valve must be 6.7mm	Material Glass transition temperature must be higher than 37° C	Valve material should provide a static friction of 25 N	The force required to insert a tool should not exceed 15 N	Overall valve casing diameter must be less than 38mm	Manufacturing costs should not exceed $70	Materials should cost less than $50	Blood loss is limited to 40mL	The valve can withstand a back pressure of 160 mmHg without tool inserted	12-14 (max of 20) French Diameter Tool must fit through valve	TOTAL - CUSTOMER REQUIREMENTS	RANK	Importance	Current Competitive designs	Bifurcated Valve (Large valve, used in industry)	Star Valve (Small valve, used in industry)	Y Adapter piece (Adaptive housing, used in experiment)	Bifucated valve coupled with four valve star valve	Butterfly valve (Used in sinks and engins to restrict fluid flow)	Tire valve (Used to restrict air flow out of a tire)	Design Alternatives	Flowing O-ring reinforced star valve design	Toroidal, pressureized valve design	Trash bag style, close drawn frizzled design	Material reinforced bifurcated valve	Material reinforced star valve	Bifurcated backed by a self sealing, springy material	Flowing gel material valve design	Longer valve with pressurized air bubble design	Revolved, multi-level blade design	Spring bed design / Springy material design
USER-PERCEIVED QUALITY	Blood loss will not be significant to require a blood transfusion	0.9	5	1	1	1	3	1	1	9	9	3	30.6	1	0.15		1	7	7	1	1	3										
	Pressure port available to measure body blood pressure	0.6	1	1	1	1	5	5	5	1	1	1	13.2	9	0.06		9	9	7	9	1	1		7	9	9	9	9	5	9	5	7	7
	Overall device size must not interfere with surgeon's procedure	0.4	7	3	3	7	9	1	1	3	3	9	18.4	5	0.09		9	9	3	9	3	9		9	7	5	9	9	7	9	7	5	7
	Can be used for the same procedures that today's 12-20 French sheaths are used for	0.9	9	1	1	1	5	3	3	1	1	9	30.6	3	0.15		7	1	1	7	7	1		7	7	9	9	9	7	7	7	5	9
	Sterile	1	1	1	1	1	1	7	3	1	1	1	18	6	0.09		9	9	9	9	1	1		9	9	9	9	9	9	9	9	9	9
	Biocompatible	1	1	9	1	1	1	5	9	1	1	1	30	4	0.14		9	9	9	9	1	1		9	7	9	9	9	7	7	7	7	7
	Ease of Use	0.6	5	1	3	7	1	1	1	5	3	3	18	7	0.09		5	9	1	5	1	1		7	9	7	9	9	7	9	7	5	7
	Will not allow for blood to sit stagnate	0.9	7	1	3	3	9	5	3	1	1	1	30.6	2	0.15		9	9	5	3	7	5		7	9	7	9	9	5	7	9	7	7
	Maximum cost less than current benchmarks ($125)	0.4	3	3	3	3	3	9	9	1	1	1	14.4	8	0.07		7	7	5	7	7	9		5	3	5	9	9	5	9	7	5	5
	Disposable	0.2	1	5	1	1	1	5	7	1	1	1	4.8	10	0.02		7	7	7	7	5	5		9	9	9	9	9	7	9	9	9	7
	Units		mm	°C	N	N	mm	$	$	ml	mmHg	F																					
	Now (Redesigned Valve)		?	?	?	?	?	?	?	?	?	?																					
	Competitor (Bifurcated Valve)																																
	Target (Plan)																																
	Total		22.4	16.4	8.8	12.8	17.8	24.2	24.6	16.4	15.2	19.4																					
	Rating (%)		13%	9%	5%	7%	10%	14%	14%	9%	9%	11%																					
	Ranked Importance		3	7	10	9	8	2	1	5	6	4																					
	Importance																							69	69	69	81	81	59	75	67	59	65
	Ranking																							4	6	5	3	2	9	1	7	10	8

Appendix B



- one large bifurcated valve with several small bifurcations to accomodate guide wire



- 'web' pieces between slits.

Appendix D

Team Biographies

Bryan Ladd:

My hometown is Milford, Michigan. I am currently a senior in the college of Mechanical Engineering at the University of Michigan. I chose the field of Mechanical Engineering for several reasons, which date back to my freshman and sophomore years in college. I began my college career as undecided engineering, which in some respect is still true today. Mechanical Engineering is a very broad field, with many opportunities to work in very different job settings, ranging from working in a laboratory to a manufacturing plant. It is this diversity and flexibility in a discipline that attracted me to Mechanical Engineering in the first place. What has kept me in this major is the prospect of making major real world applications, which could potentially better the lives of millions of people. I am a firm believer in the philosophy; find a career that makes you happy and for which you have passion for, the money will follow suit. Perhaps this outlook is a bit naive, but experience from my own life has taught me that I produce my best work when I feel strongly for something and have a personal urge to change or better it. This holds true for all dimensions of my life; personal relationships, family, school, and to my point, my career. This being said, parting from loved ones and seeing the ones that went to their rest too early is one of the hardest facts of life that we all have to cope with. If I can use my knowledge to help make surgeries more successful, lives more healthy and fruitful, and add a little more gold to those precious golden years, then I will try. My passions lie in the realm of helping people and that is my reason for focusing my Mechanical Engineering degree towards the biomedical field. It is also a personal fight for me. Alzheimer's, Cancer, and Diabetes are common illnesses, which run in my family, that have claimed the lives of people close to me. Probability also says, one day I will develop one these diseases. This leads me to the thought that I should try to do something about this while I can, which is why I have been trying to gain experience and knowledge in the field of soft tissues and soft tissue mechanics. In this way, I can help millions of others and at the same time help my future self, which is how I got to where I am today.

Caitlin McCarthy:

I attended Troy High School in Troy, Michigan. There, sophomore year, I took a basic anatomy and physiology class and quickly gained a love of biology. I assisted the athletic trainer in my extracurricular time where I learned common injuries to high school sports and their treatment while playing basketball and softball myself. I have retained a good deal of the knowledge and nomenclature despite many courses in biology and chemistry at the University of Michigan. I have sought out a career in biomedical engineering ever since I watched a program on the field, covering prosthetics to regeneration of skin cells in the laboratory. Being that the study of biomedical engineering is so new and not fully developed, I decided to study mechanical engineering to provide a strong foundation for BME. I think mechanical engineering is the core of the science of engineering, the oldest application of thought in action predating even language. Advances in the medical field directly benefit people, people most likely going through one of the hardest things in their life, and to have some miniscule part in helping them through must provide a great satisfaction in what one does. After graduation, I would like to attain a job with a biomedical firm combining my knowledge of mechanical engineering with the science of biology.

Seth McCubbin:

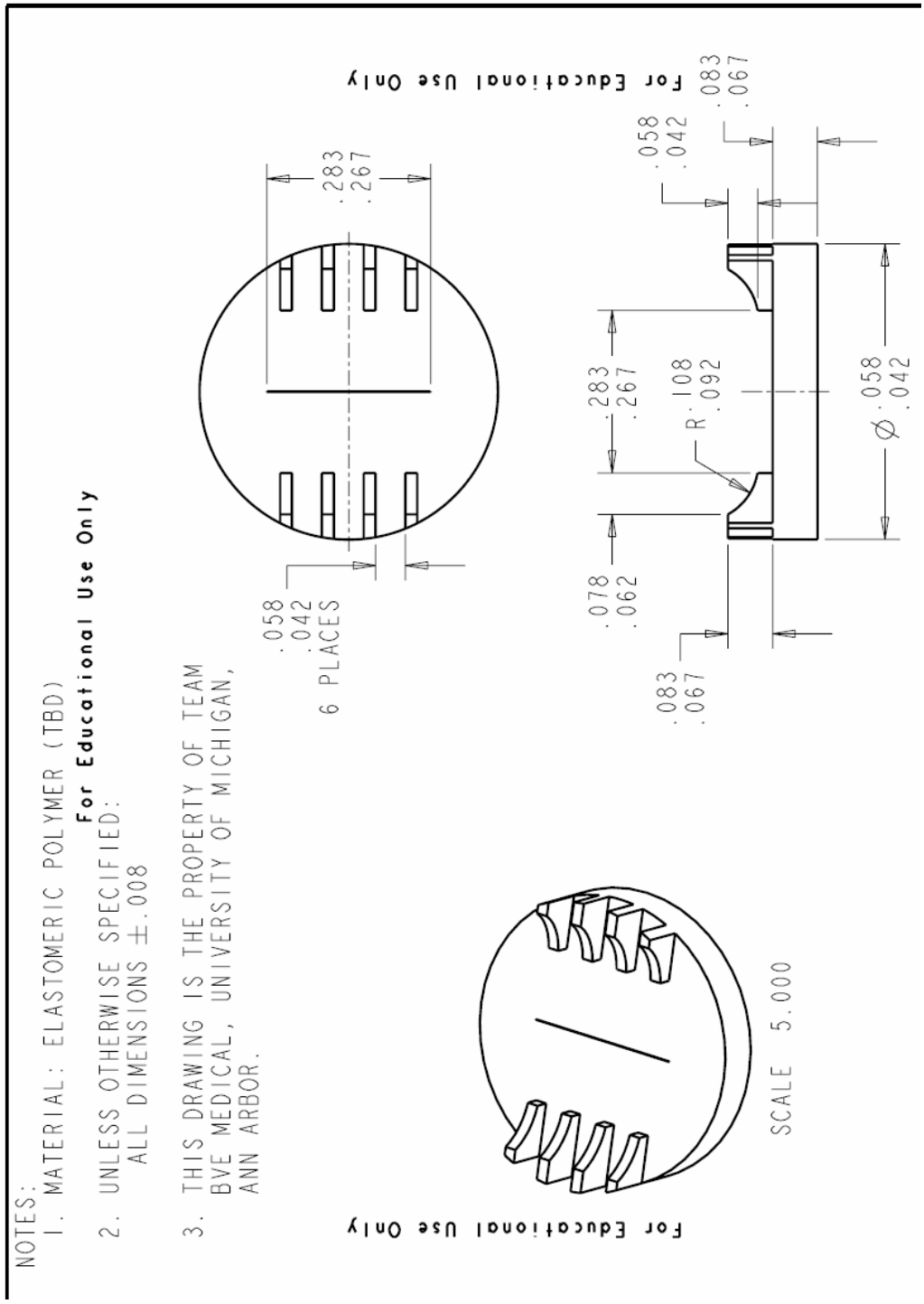
[Removed at the request of the author.]

Jeff Moss:

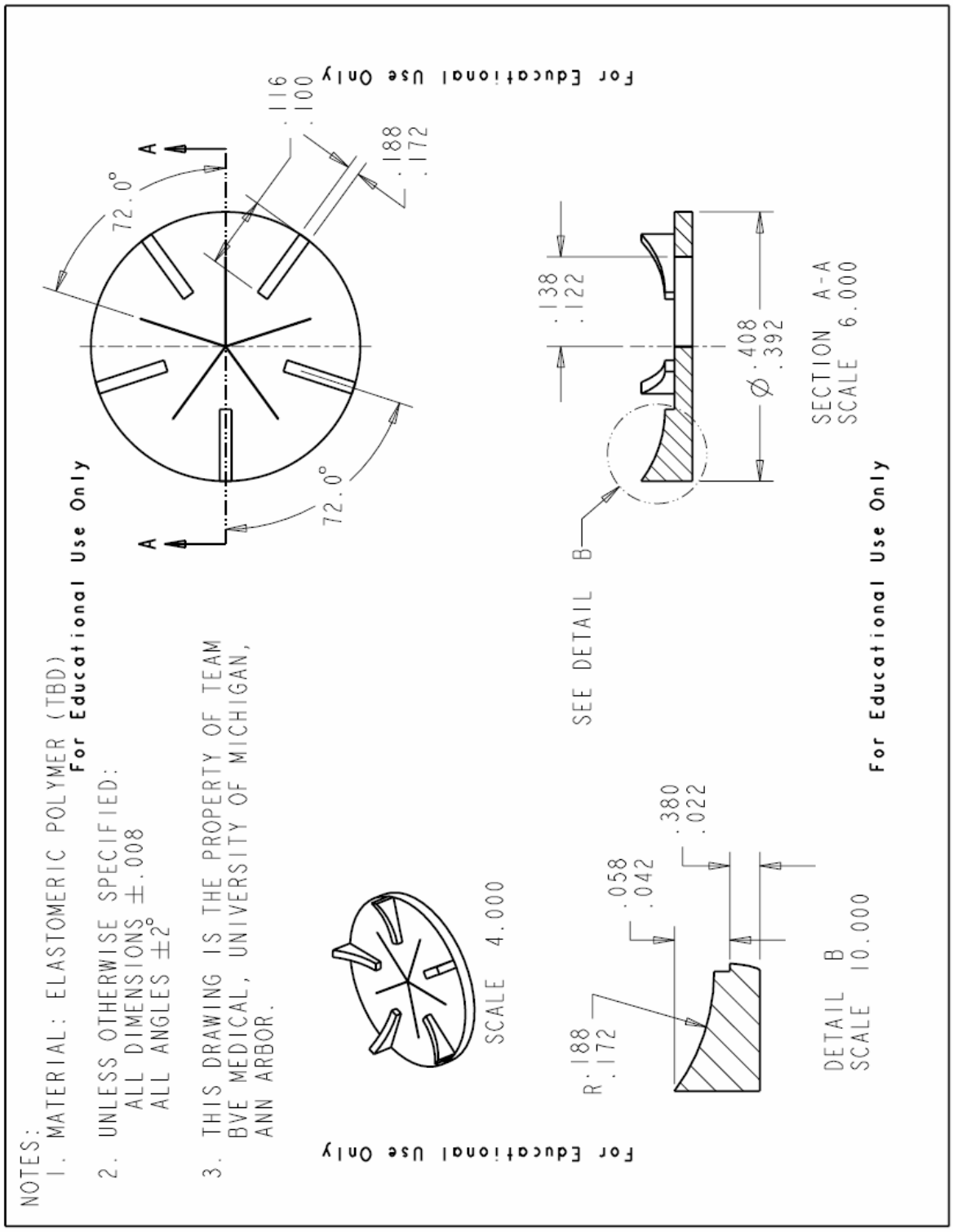
I am from Collegeville, Pennsylvania. My hometown is just outside of Philadelphia, PA. I am a senior in aerospace and mechanical engineering. I have always been very interested in aviation and space exploration. When I came to college I wanted to learn both the science of flight and how to design and manufacture things. I chose mechanical engineering to supplement my aerospace degree so that I would have more experience in selection of materials, the design process and a more general engineering understanding beyond aerospace. I came into college with the ultimate goal of learning the necessary skills to design and build launch vehicles and spacecraft. I would like to eventually start my own company doing these things.

Along with learning how to design things that fly I also enjoy flying them. I have been a pilot for the past few years. I am currently working on getting signed off to fly a Piper Cherokee, which is a small single engine low-wing plane. I also enjoy playing a variety of sports, including ice hockey, soccer and lacrosse. I've recently taken up hiking and climbing, which I hope to become more knowledgeable about so that I can eventually do full fledged mountaineering.

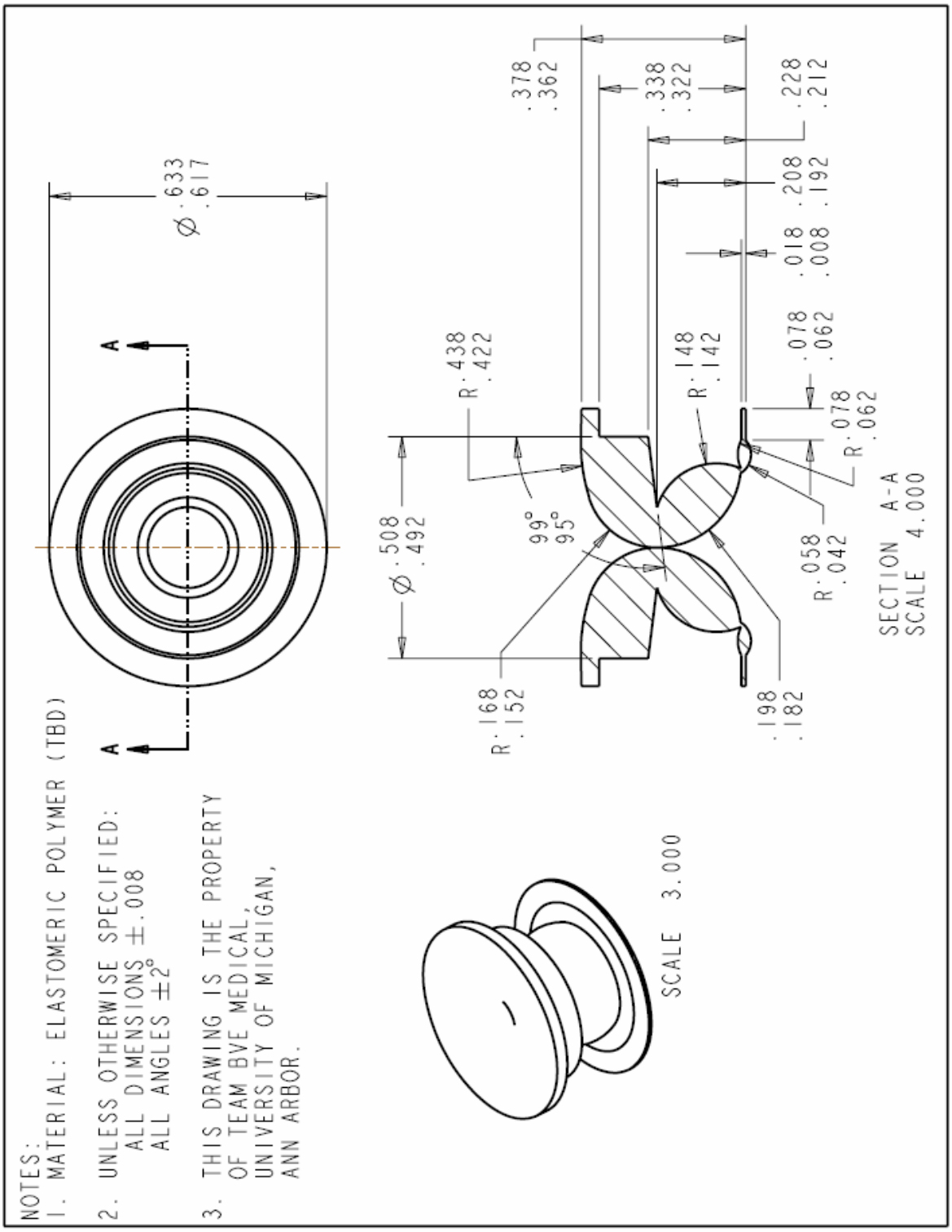
Appendix E


NOTES:
1. MATERIAL: ELASTOMERIC POLYMER (TBD)
For Educational Use Only
2. UNLESS OTHERWISE SPECIFIED:
ALL DIMENSIONS ±.008
3. THIS DRAWING IS THE PROPERTY OF TEAM
BVE MEDICAL, UNIVERSITY OF MICHIGAN,
ANN ARBOR.
.283
.267
.058
.042
6 PLACES
.058
.042
.083
.067
.283
.267
R .108
.092
.078
.062
.083
.067
Ø .058
.042
SCALE 5.000
For Educational Use Only
For Educational Use Only

Appendix E


NOTES:
1. MATERIAL: ELASTOMERIC POLYMER (TBD)
2. UNLESS OTHERWISE SPECIFIED:
ALL DIMENSIONS ±.008
ALL ANGLES ±2°
3. THIS DRAWING IS THE PROPERTY OF TEAM BVE MEDICAL, UNIVERSITY OF MICHIGAN, ANN ARBOR.
For Educational Use Only
72.0°
72.0°
A
A
.116
.100
.188
.172
SCALE 4.000
SEE DETAIL B
.138
.122
Ø.408
.392
SECTION A-A
SCALE 6.000
R.188
.172
.058
.042
.380
.022
DETAIL B
SCALE 10.000
For Educational Use Only
For Educational Use Only

Appendix E

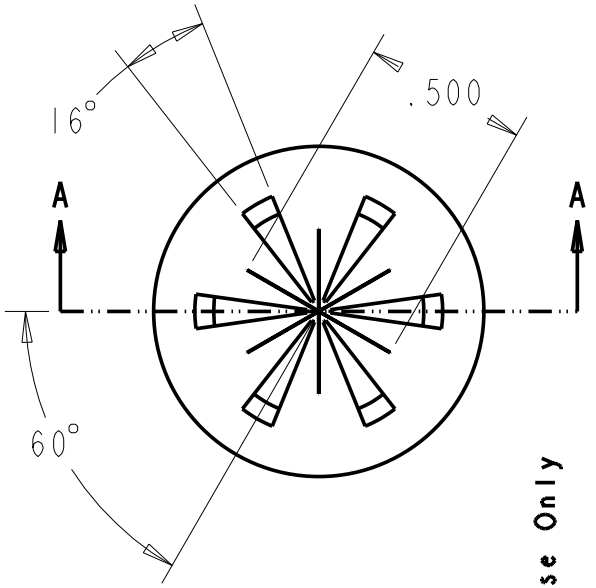

NOTES:
1. MATERIAL: ELASTOMERIC POLYMER (TBD)
2. UNLESS OTHERWISE SPECIFIED:
ALL DIMENSIONS ±.008
ALL ANGLES ±2°
3. THIS DRAWING IS THE PROPERTY OF TEAM BVE MEDICAL, UNIVERSITY OF MICHIGAN, ANN ARBOR.
A
A
Ø .633
.617
SCALE 3.000
Ø .508
.492
R .438
.422
R .168
.152
99°
95°
.378
.362
.338
.322
.228
.212
.208
.192
.018
.008
R .148
.142
.078
.062
R .078
.062
R .058
.042
.198
.182
SECTION A-A
SCALE 4.000

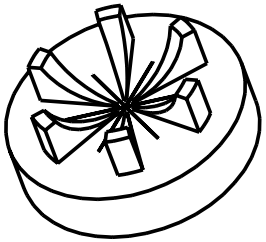
NOTES:

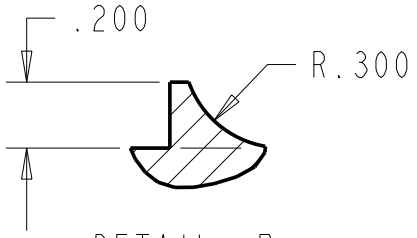
1. MATERIAL: GLS DYNAFLEX

2. UNLESS OTHERWISE SPECIFIED:
   ALL DIMENSIONS ±.008
   ALL ANGLES ±1°
   UNITS ARE IN INCHES

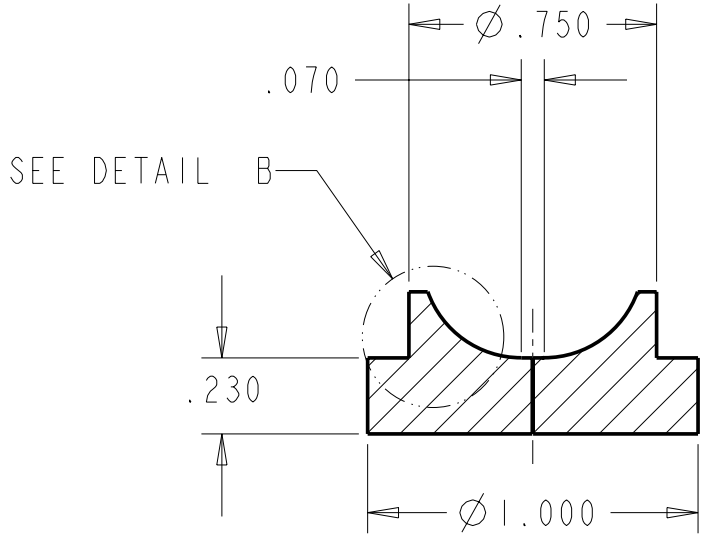
3. THIS DRAWING IS THE PROPERTY
   OF TEAM BVE MEDICAL,
   UNIVERSITY OF MICHIGAN,}
   ANN ARBOR.







DETAIL B
SCALE 2.000



SECTION A-A
SCALE 2.000