Ultrasonic Mapping Needle

Final Design Review

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Abstract

When gaining access to a vein or organ for the purpose of ablation or other reasons, the common procedural method of entry is to use the Seldinger technique. This has been the standard entry procedure since its introduction in 1953, and the technique has not been modified during this time. While effective, it is prone to complication as it relies solely on the operator's precision and experience. It is our task and goal to develop a modifying kit for this procedure that would aid the operator in this process. It would make use of mapping technology and standard products used in hospitals and Arrhythmia Centers, including ultrasound and magnetic cardiovascular mapping systems, as well as hypodermic needles and catheters. Ultimately this product will focus on minimizing the time, complexity, and overall complications currently associated with this procedure. This report outlines the ideation process and explains how we came to our concept design. Our concept design comprises of two main components— a handle and tunneller. The handle guides and orients the ultrasound catheter. The tunneller will secure the mapping catheter and guide the needle to the desired spot of insertion. Following approval of the concept design and direction, we moved towards 3-D modeling, prototyping, and testing. This led to the final design of the handle, which comprises of a ultrasound head, handle, and Tuohy-Borst mechanism. The tunneller final design consists of a needle insert, needle shaft, and a Touhy-Borst/Luer Lock mechanism. We outline any changes made from concept design to our final design and describe the final assembly of this project along with manufacturing cost and the next steps to get this project into production.

Chapter 1: Introduction

1.1 - Sponsor Background and Needs

Kusmo, a company of the Arrhythmia Center of Northern California, wants to reimagine vascular and pericardial access so that physicians can have real time visualization of the puncture site of patients undergoing this procedure. The client, Dr. Walter Kusumoto, has asked for a kit that contains a needle system with an ultrasound adaptor that will work concurrently with a cardiac electrophysiology (EP) mapping system.

In medicine, the process for pericardial and vascular access has been left virtually unchanged for the past 70 years. The Seldinger technique has been the most widely used process for vascular access. Nevertheless, inadvertent punctures are still a risk when using this technique. Ultrasound has been introduced to help reduce risks but has been an incomplete solution. A group of two Cal Poly mechanical engineering students, an FDA team, and Dr. Kusumoto are to design a kit to reduce these risks. Risks that could include failed access, puncture, or misidentification.

This project's goal is to design a kit that will cut down the complications that arise in using the Seldinger technique. The kit will combine ultrasound and EP mapping into a handheld device that will help guide the physician to the correct puncture site. The device will be needed for three different lengths of needles: short, up to four inch, six inch, and eight inch. Lastly, the device’s goal is to be used in conjunction with an 8 french catheter, which is diameter measurement of both the ultrasound and electrophysiology mapping catheter.

Chapter 2: Background

2.1 - Technical Background

Pericardial and vascular access has been difficult in the past from lack of visualization. To access pericardial space, cardiologists have implemented the use of ultrasound, x-ray, and applying their own knowledge of pericardial space anatomy. Cardiologists can use a small injection of contrast to provide a better visualization of the heart wall to guide the location of the needle into the pericardial space. Some complications can arise such as ventricular puncture/tear, injury to blood vessels, or a buildup of fluid in the heart. When using a guide wire another complication has included a broken wire in pericardial space.

Current instrument guiding technologies are the physician's anatomical analysis, ultrasound, and X-ray. Anatomical methods work often for access close to the surface of the skin, but as there is no visual for the needle tip or point of vascular access, if the patient is larger or if the point of access is complicated, complications are more likely to occur. Ultrasound can be effective, nevertheless the visual can still be very unclear even to experienced operators, and there is no visual on the needle tip. The final method, X-ray, can be effective in visualizing the needle tip, but there is no visual of the organs or vessels, and exposes those in the room to harmful radiation. Our proposed method allows the operator to have a full visual of the patient’s vascular system, as well as other soft tissue obstructions, such as nerves. This would also allow the operator to view the tip of the mapping needle in relation to the patient’s anatomy, allowing for a much more complete and clear visualization process throughout the procedure.

Ablation is a procedure where energy is used to scar inside the heart with the purpose of disrupting signals in the heart that cause an irregular heartbeat, called an arrhythmia. This is usually done by inserting a catheter into the patient’s vessel or organ and feeding a specialized catheter into the heart. Access to these points within the patient can result in complications due to limitations in current procedures described above, causing misplaced needle insertion.

Electrophysiology (EP) mapping is a series of tests that examine the heart’s electrical activity and provide a detailed look at how electrical signals move through the heart. In cardiac ablation, EP mapping can help pinpoint the area of irregular heart rhythm.

2.2 - Review of Existing Products

In this stage of research, we came to realize that there is no such product on the market that exists. The following is a table of existing products that are similar, but do not reach all the intended goals of this project.

Table 1: Existing Products

Type	Manufacturer	Product Name
Ultrasound	Phillips	Lumify
Ultrasound	General Electric	Vscan
Ultrasound Catheter	Biosense Webster	Soundstar Ultrasound Catheter
Catheter		Tunneled Dialysis Catheter
Catheter	Biosense Webster	Navistar Catheter
Catheter	Biosense Webster	Thermocool Smarttouch SF Catheter
EP Mapping Catheter	Biosense Webster	OPTRELL Mapping Catheter with TRUEref Technology
EP Mapping Catheter	Biosense Webster	PENTARY NAV eco High-density Mapping Catheter
Mapping System	Accutus Medical, Inc.	AcQMap System
Method		Seldinger Technique

In Table 1, we observe that not one product encompasses the needs of the sponsor. For example, the ultrasounds, Lumify and Vscan, are good products in that they are handheld, but they would only work in conjunction with the Seldinger technique for vascular and pericardial access. Conversely, the Seldinger technique does not have the needed visualization to gain access in the vascular or pericardial network. The catheters can be implemented with the Seldinger technique, but better visualization is still needed. Looking at the AcQMap System, the system would utilize ultrasound and mapping, but lacks the specific device that physicians need to use the system. The EP mapping catheters accomplish the goal of utilizing EP mapping, but again, lack an ultrasound component needed for better visualization.

The last existing product currently available is a Tuohy Borst adapter. This mechanism comprised of a silicone ring and cap that will torque around a tube to hold it in place. This mechanism is widely used in the medical field to facilitate catheter introduction. It may also be used to prevent backflow of fluid. This mechanism is to simply secure tubing and instruments without causing damage or completely cutting off flow through a tube. This mechanism has no use in ultrasound or electrophysiology, but has potential to be the mechanical solution in implementing both ultrasound and electrophysiology mapping.

2.3 - Patent Discussion

Prior to our meetings with Dr. Kusumoto, we explored the technologies proposed by other inventor's patents related to our design field. Whether the patent discussed mapping systems, the Seldinger technique, or proposed alterations to current ablation procedures, we found these existing patents to be helpful in framing the challenges the medical community find worthy of effort, as well as allowing us to see how physicians might approach these problems. In doing so, we gained a more engineering solution-based understanding of the challenges that surround this field.

US20170296792A1

Single hand Insertion apparatus, US20170296792A1. This is a patent that proposes a new method of deploying a lumen catheter in a similar manner to the Seldinger technique and incorporates the use of ultrasound to visualize the needle. Nevertheless, it does not make use of a mapping system for added accuracy. This patent was explored to gain information and knowledge about the need and use of a tunneling needle prior to more complete information being sent to us by Dr. Kusumoto.

DE4319033C1

Catheter extension/elongation probe, DE4319033C1. This patent discusses the control and orientation of mapping catheters and designs for catheter extension to aid in the control of catheters that is a design problem we need to solve. This patent helped us further educate us about the current problem with catheter orientation and exposed us to potential solutions to this problem.

US9521961B2

Systems and Methods For guiding a Medical Instrument, US9521961B2. This patent discusses the tracking and imaging of a needle or other medical instruments. While not specific, the patent exposed us to desirable outcomes for needle tracking during a procedure and was used to research ultrasound/magnetic tracking before the extent of Dr. Kusumoto's research was known to us.

US20180200497A1

Catheters, Catheter Systems, and Methods for puncturing through a tissue structure and ablating a tissue region, US20180200497A1. This patent discusses the ablation procedure and possible mechanisms to aid in this procedure, including catheter and energy storage. This is not the issue we are to design a solution for, but again, this patent exposed us to issues and potential solutions physicians may encounter, furthering our knowledge of the field.

US20120059270

Apparatus and method for catheter navigation using endovascular energy mapping, US20120059270. This patent discusses the use of endovascular energy mapping to aid in the placement of a medical device used for the procedures previously discussed. While this project utilizes a magnetic mapping system, we explored this patent to better understand how the inventor and physician approach instrument placement with the aid of a mapping system.

US10251579B2

Magnetic Resonance guidance of a shaft to a target zone, US10251579B2. This patent discusses an apparatus comprising a magnetic resonance imaging system to position medical device. The device would pass through a port, broadcasting a magnetic resonance image. The way this patent discusses the use of fiducial markers and their use with medical devices helped us begin to form an idea about the problem at hand.

2.4 - Sponsor Review

Following our initial research into the field and proposed solutions to similar problems, we began meeting with our sponsor Dr. Kusumoto and his development team. This led to our understanding of the procedure in question, knowledge of the current technologies available, and we were able to begin to develop designs that would satisfy the sponsors solution needs while maintaining the sponsors' vision. While we were not approaching specific designs, the design requirements were now understood. After communications with the sponsors design team began, we gained an understanding of how to navigate the FDA requirements for designing a medical product, as well as information on development processes currently used in the creation of other medical processes and devices.

Chapter 3: Objectives

3.1 - Problem Statement

Use of the Seldinger technique has remained unchanged since 1953 despite the common complications that can arise from this procedure. Today's physicians are in need of a procedure to modify this technique using the technology available to us today. Using modern ultrasound and magnetic mapping technologies, this modification would allow the physician to see where the instruments are within the patient during the procedure, cutting down on the complications that accompany doing this procedure blind.

3.2 - Team Objective

We will create a single use kit using technology available in today's hospitals and heart clinics that would supplement the current procedure. In total it should cost about $800 and allow the operator to be able to view the instruments in use, in real time on the ultrasound monitor, to stop the operator from making any harmful punctures or other harmful mistakes that can be common with the current procedure. It will need to be FDA compliant, simple, quick to set up, and produce reliable and consistent results. Our customer, Dr. Kusumoto, intends to market a single use non-reprocessable kit to accompany technology currently available in current heart clinics and arrhythmia centers including ultrasound equipped catheters, electronic and magnetic imaging systems, and hypodermic needles. This kit would be marketed to physicians, cardiovascular clinicians, hospitals, and health systems. The kit must be easy and quick for the operating physician or medical assistant to set up, and the use of this kit should fit seamlessly into the already existing procedure, resulting in faster, safer, and more reliable operations.

3.3 - House of Quality

This project's House of Quality in Appendix 1 summarizes the design specifications, engineering specifications, the importance of these specifications, how these specifications relate to current products, and finally how these specifications relate to each other. The House of Quality in Appendix 2 has been updated with each new insight into the project's specifications, function, and scope, and so space has been left with the intention to be filled.

3.4 - Team Boundary

While using the Seldinger technique in cardiac ablation and other procedures that require access into the patient's vascular system, our boundary relates to how the cardiologist holds the handle/tunneller, and how these devices interact with the patient so that the ultrasound is unimpeded, and the operation is completed safely, smoothly, and quickly.

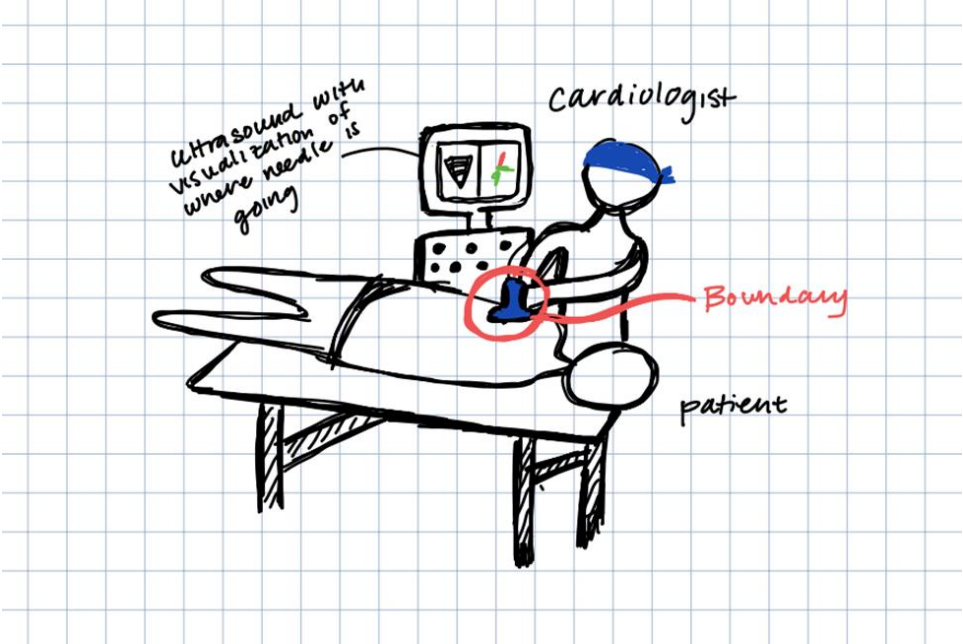

Figure 1: Team Boundary Drawing

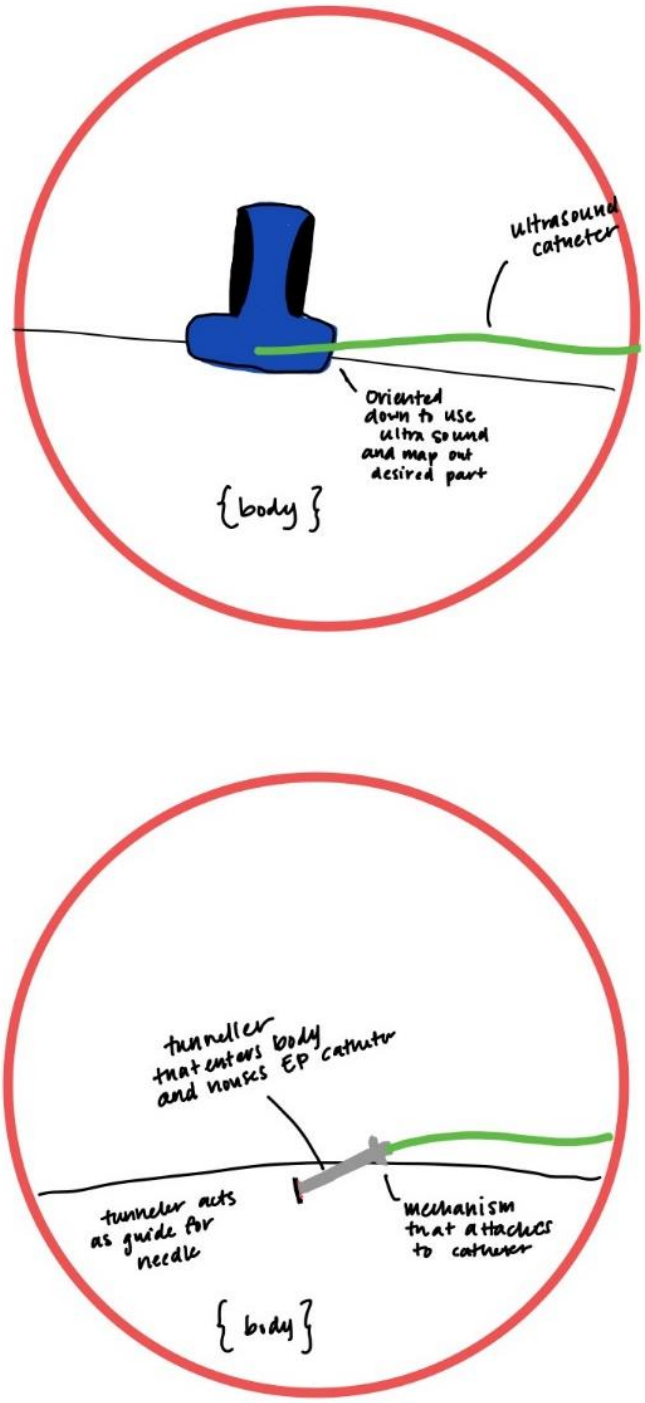

Figure 2: Team Boundary Blow-Up View

3.5 - Design Requirement Table

Table 2, the Design Requirement Table, takes the engineering specifications from our House of Quality, describes our engineering specifications, and how we intend to complete them. After listing our Specification Description and Target Requirements, the fourth column lists the tolerances allowed when designing for the satisfaction of each goal. If no tolerance is allowed, the tolerance will specify that the requirement is either a maximum or minimum. The fifth column contains our prediction of the level of difficulty in achieving each target, ranging from high (H) to medium (M) to low (L). Last, our sixth column predicts how we intend to confirm the achievement of each target. As an analysis of the House of Quality, this table will be updated throughout the project to include added engineering specifications.

Table 2: Design Requirement Table

Spec. #	Spec. Description	Requirement or Target	Tolerance ±	Difficulty of Requirement	Compliance
1	**Time to Set Up [s]**	**15**	**5**	**H**	**Test**
2	**Cost [$]**	**700**	**200**	**M**	**Analysis, Test**
3	**Complication [# mistakes]**	**0**	**MAX**	**H**	**Test**
4	**Parts [#]**	**5**	**3**	**M**	**Inspection**
5	**Weight [g]**	**150**	**50**	**L**	**Analysis, Test**
6	**Colors [#]**	**5**	**3**	**L**	**Inspection**

The engineering specifications we identified were time to set up, cost, complication rate, number of parts in kit, the weight of the kit, and available colors. Time to set up and complication rate are the most important engineering specifications for the kit, as the product must be easy to use and fit seamlessly into the existing procedure. The modification kit must reduce the complication rate from ~5% to less than 1%, meaning that this product should negate any possible user error that is brought on from operator error using an anatomical, X-ray, or ultrasound needle placement approach. These specifications have the most rigid specified targets, and this target leaves little room for error. This specification applies to each unique length of tunneller necessary for each needle length. There shall be three unique lengths of tunnellers needed for a short, sighting method, a vascular length, and pericardial length. The needle lengths for each method will be up to a 4 inch needle, a 6 inch needle, and an 8 inch needle, respectively. Specifications of cost, weight, and number of parts are more fluid, as these change with the evolving inclusions in the product. Finally, color options are present to provide some choice to the operators, and this target is completely fluid and depends on the manufacturing and branding choices of the supplier.

Chapter 4: Concept Design

After defining the problem definition for this project and gaining a full understanding of the scope of this project, we began the design process. Our first step was the ideation phase. We divided the ideation phase into two different subjects— the handle and the tunneller. To begin ideation, we had a brainstorming session together where we came up with as many ideas for the handle as we could. These ideas can be found in Appendix 3. The first ones to be eliminated were the impractical and hard to manufacture ideas. This left us with a couple of concepts for us to use. Separately, we took the concepts we had come up with and created Pugh matrices for them. This is how we obtained our top five concepts to go into our weighted decision matrix, found in Appendix 4. Shown in Figures 3 through 7 are our top five concepts.

Figure 3: Defibrillator

This model, Figure 3, was inspired by the defibrillator shown to us by our sponsor. This model is much smaller than a traditional wand, saving resources on production. It is small and easy to package, as well as providing more control in orientating the catheter than more bulky, traditional handles. What kept this model from being our final design choice was that it would feel unfamiliar in the operator's hands, which may result in an unnecessary barrier to widespread use.

Figure 4: Infrared Thermometer

This model, Figure 4, was inspired by the infrared thermometers that became commonplace during and after the pandemic. The device functions like a standard ultrasound handle, with a more ergonomic grip that would fit into the operator's hand. The drawback for this design was

that its utility was limited to specific patient orientations, providing a potential barrier to entry into the market.

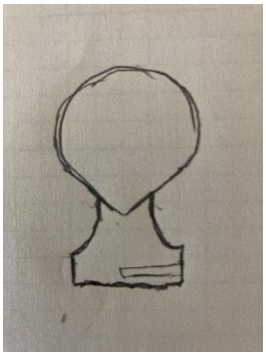

Figure 5: Air Hocky

The inspiration from this design, Figure 5, came from the game of air hockey, where the mechanism would sit comfortably in the operator's palm. The ultrasound device would be moved to create the image in a similar fashion to a computer mouse. This design is ergonomic and easy to package but supplies the same barrier to entry as other less traditional options.

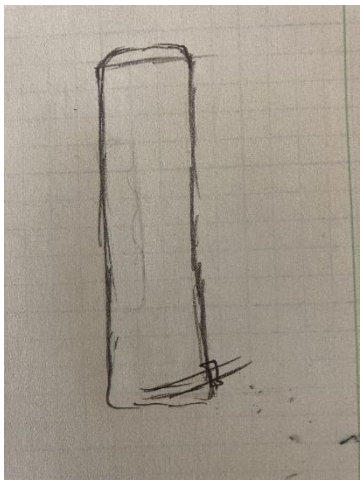

Figure 6: Straight Edged Wand

This design, Figure 6, is the most manufacturable and easy to package design. During our iterations and tests, we found that due to the lack of a flare at the base of the wand, we were not comfortable with the usability of the wand with attached catheter. Furthermore, we felt that the flare allowed for safer catheter insertion and protection.

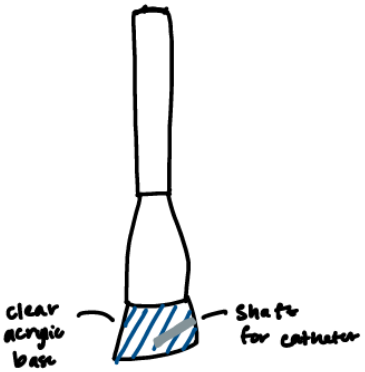

Figure 7: Foundation Brush

This model, Figure 7, is based on a foundation brush. While similar to a traditional wand, it has a thinner handle, and a more ergonomic design as it is designed to be used quickly, easily, and precisely. The thinner handle works for this design, as the upper portion of the handle does not need to house any equipment. The lower section in blue would be packaged separate from the upper, created using a clear material. Using the qualities from our defibrillator model, this small piece would provide more control for easier catheter orientation. Once the catheter is orientated and fastened, the lower piece would then be fastened to the upper handle, satisfying our familiarity criteria. This model proved to be the best choice, as it satisfies all necessary criteria, while maximizing the other specifications we deemed important.

Engineering Specification	Design Weight	Wand (Cyl)	Air Hockey	Belt Sander	Defibrilator	Foundation Brush
Time to Set Up	10	7	2	3	9	7
Simplicity	8	10	5	4	8	10
Weights	2	8	2	2	10	8
Cost	9	10	3	1	8	9
Accompanies Current Tech	10	10	6	6	8	10
Ease of Orientation	9	8	1	1	10	9
Ergonomic	7	8	7	7	8	10
Protects Catheter	10	8	10	10	8	9
Familiarity	9	10	1	1	1	10
Total	65	69	36	34	69	72

Figure 8: Weighted Decision Matrix

Figure 8 displays the weighted decision matrix that helped us choose our concept design. The left column displays the engineering specifications we set for our project. We then assigned a number to each concept on how well they satisfy each specification— ten being the specification is met and one being the specification is not adequately met. A sum of the rankings of each

concept gave us an overall score for each concept. The foundation brush design achieved the highest ranking, which is highlighted in yellow. This is the concept design we are moving forward with.

Through ideation, we came up with many possible handle shapes, some of which are shown in Figure 9. While the handle should be elegant, ergonomic, and marketable, the image and feel should align with common medical instruments. This criterion led us to begin designs based on the simpler concepts shown.

Figure 9: Concept Prototypes

The ideation process for the tunneller was slightly different than the ideation process for the handle since we were constrained in what we could design for it. Dr. Kusumoto also provided us with a concept for the tunneller that we closely followed and optimized. For example, the tunneller is required to accommodate a six-inch needle, an eight-inch needle, and one used in the sighting method, where the tunneller does not necessarily need to enter the skin. Additionally, the tunneller would also need to accommodate an 8 French catheter, which constrained the inner diameter size of the tunneller. We also knew that the tunneller would have to utilize a Tuohy Borst mechanism to secure the catheter in place. This left us with three options on the shape of the tunneller as shown in Figures 10, 11, and 12, and what length the tunneller would be.

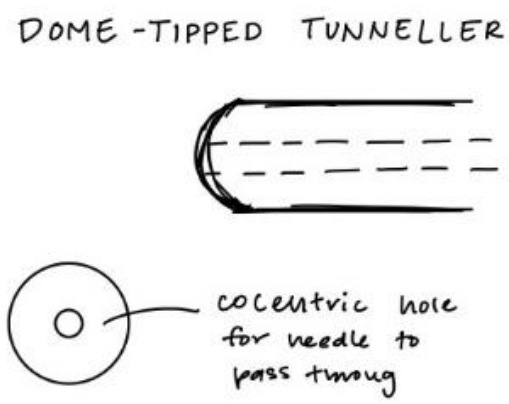

Figure 10: Dome-tipped tunneller idea sketch

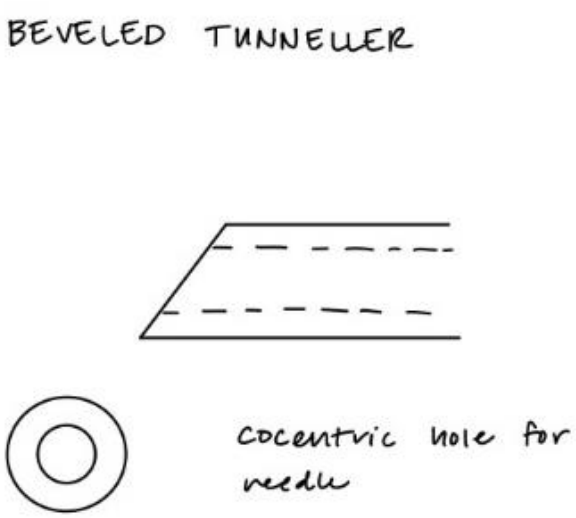

Figure 11: Beveled tunneller sketch idea

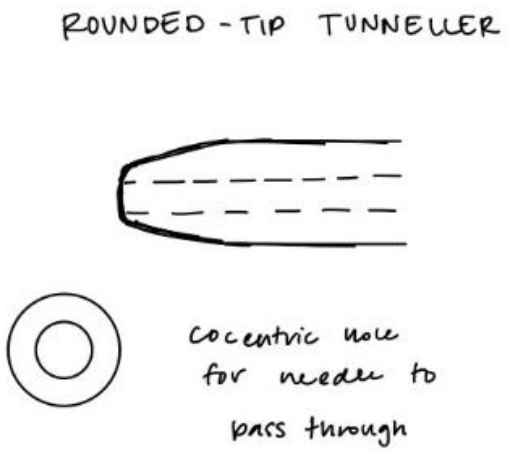

Figure 12: Rounded tip tunneller sketch idea

From a teaching demonstration provided by Dr. Kusumoto, we learned that the rounded or domed tipped tunneller was easier to insert into the skin. We found that the beveled tunneller tore into the skin, while the other two separated and pushed the tissue and skin out of the way. From this, we were able to eliminate the beveled tunneller from our concept design.

One part of the design we had difficulty coming up with a solution for was the length. Figure 13 displays a concept drawing of the tunneller.

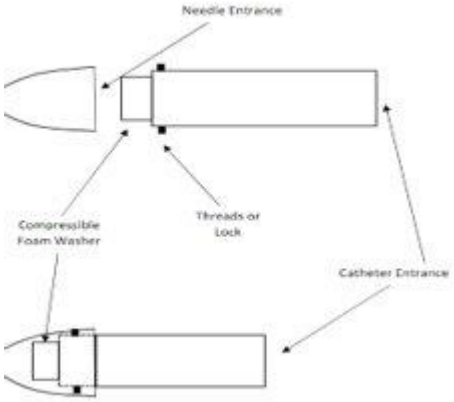

Figure 13: Tunneller Tuohy Borst Mechanism

The Tuohy Borst mechanism was taking a lot of the length on the tunneller on our original design. This created a problem with the amount of needle length that would be able to exit the tunneller. To address this, we decided that since the Tuohy Borst mechanism is only needed when the mapping catheter is in place, then the Tuohy Borst mechanism can leave when the mapping catheter leaves. The solution we came up with is having a removable Tuohy Borst

mechanism, so we gain back the length it was taking and instead adding it back to the length the needle can stick out of the tunneller.

The next part of the tunneller we needed to consider is how the user would be notified when the needle is exiting the tunneller and into the body. For this, we originally thought having a notch and groove would be the best mechanism to provide this. The groove would be located on the inside of the tunneller and the notch would be located on the needle. Once the notch enters the groove, this would signify to the user that the needle is about to exit the tunneller once more force is applied to the needle. After speaking with Dr. Kusumoto, we came up with the idea of having an insert that would be pre-attached to the needle. Once the tunneller is in position and ready for the needle to be inserted, the operator would insert the needle/insert combination, the insert would lock into place, and then the needle would be ready for use. We envision two possibilities for needle notification, the best of which can be decided after testing. First, the insert could be positioned onto the needle so that, when locked into the place, the needle would be just about to exit the tunneller and into the body. Once the insert is locked, this would be the notification to the operator that the needle is about to exit the tunneller. Second, the insert could be shorter and near the middle of the needle. The needle would have a marking on it to visually indicate to the operator when the needle tip is about to exit the tunneller. For our concept, this is the design we decided to move forward with. This concept provides us with three distinct advantages. First, an insert would decrease the diameter of the tunneller allowing for a more accurate guide, maximizing the benefits of a tunneller. Second, this makes the tunneller single use, as the insert would not be removable, and the tunneller would no longer fit a catheter. Finally, this concept allows us to proceed with minimally altered hypodermic needles, as opposed to designing and manufacturing custom needles.

Our chosen concept design has no design hazards, which is shown by the design hazard checklist in Appendix 5. Our main safety concerns surround what materials the concept would be made of. For example, we need medical grade material since our design will be used during procedures and placed within the body. This is one of the few challenges we are facing in our design process.

We also foresee a couple of other challenges in our design. The first challenge is what material the tunneller is going to be made of. It is important that the material of the tunneller does not interfere with the magnets that are part of the EP Mapping system; if the material affects these magnets, then the EP Mapping system is rendered useless. We know that plastics and titanium do not interfere with the magnets, so we are deciding among these. Plastics are cheaper to manufacture, but there's a possibility a tunneller made of plastic will have too much deflection when force is applied to it. Titanium is the more expensive material, but we know that there is less risk of deflection or failure during a procedure. Second, there needs to be a way that helps orient the ultrasound correctly. Our current idea to overcome this challenge is a vinyl sticker that is attached to the portion of the handle that interacts with the body. The sticker would display some sort of image on the ultrasound monitor when the catheter is oriented properly. When the image is in clear view, then the operator would be able to remove the sticker and the handle is ready for use. The final challenge is making sure the components are not re-processable. To

overcome this challenge, we were thinking of having an insert loaded onto the needle that would insert into the tunneller. This insert would have a smaller diameter that would help guide the needle through the tunneller and into the body. The insert would lock into the tunneller and would not be removable, thus rendering the tunneller as single-use and unable to be reprocessed.

Chapter 5: Final Design

The procedure kit will contain three main components: ultrasound head, ultrasound handle, and tunneller. To use the kit, the user will need an ultrasound catheter, an ultrasound imaging system, electrophysiology mapping catheter, and electrophysiology mapping machine, the Carto 3 in our case. All of these are standard equipment and machines found in hospital catheterization labs. To start the procedure, the user will insert the ultrasound catheter into the ultrasound head. They will then orient the catheter using an indicator on the ultrasound imaging system. Once oriented properly, the user will fasten the Tuohy-Borst and snap on the ultrasound handle. The two components together can be used as a typical ultrasound wand. Following this, the user will use the ultrasound wand and ultrasound imaging system to capture images of the patient. After capturing the necessary ultrasound images of the patient, to the discretion of the user, the ultrasound wand and catheter can then be set aside for the rest of the procedure. Next, the user will take the tunneller, insert the electrophysiology mapping catheter into the tunneller, and fasten the Tuohy-Borst. The ultrasound machine will then give the user real-time feedback on the location of the tunneller relative to the ultrasound images previously taken. The user will then choose the location on the patient where they will insert the needle. The user will then unfasten and remove the luer lock containing the catheter from the tunneller while keeping the tunneller in the position where they want needle insertion. The needle can then be inserted into the tunneller and into the patient at their desired location. In the following discussion we will analyze our designs with respect to safety, convenience, usability, and reusability. These considerations will lead to a discussion of design and material decisions in optimizing our chosen design.

5.1 Tunneller

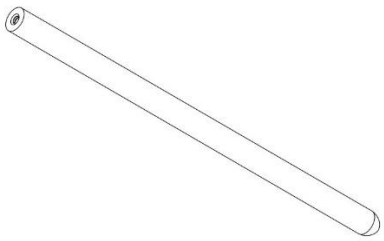

Figure 14: Final Design of Tunneller

The first part of the kit is the tunneller, displayed in Figure 14. This piece secures the electrophysiology mapping catheter and will then be inserted into the patient. Tracking the location of the catheter in real time, the tunneller will then be inserted as a needle, until the end of the tunneller is placed at the exact location of vascular entry. As this piece of the kit will be used internally, it is associated with the most risk, and so requires the most selective design and rigorous testing. The tunneller will have external threads on the base, forming the bottom half of

the Touhy Borst mechanism attached to the tunneller. The tunneller will then have a Touhy Borst disk place on the base, and a threaded cap attached. In this way, the catheter fastening system will be part of the tunneller, allowing us to preserve length of the tunneller, and cutting down on set up time, as well as steps in the procedure. The Tuohy Borst mechanism will be made by Qosina who will supply the 3-D model of the mechanism, and we are in communication with Qosina on acquiring the 3-D model. A rough model with the tunneller and Touhy Borst mechanism is shown in Figure 15.

Figure 15: Tunneller Assembled with Tuohy Borst Mechanism

Due to our constraint of the device being unable to be reused, we decided to manufacture the piece using a low temperature thermoplastic, which will warp and become unusable with heat sterilization (134 °C). This material poses unique challenges that are not present in titanium. The most important requirement is that the thermoplastic be rated for medical and internal use. Second, the piece must not deflect upon insertion, so that the placement of the tunneller tip is accurate. As thermoplastics can warp under high temperatures, we must ensure that the tunneller will not be warped upon arrival at the medical facilities and must not warp while in use. Finally, the piece must never break inside the patient. FEA and other calculations for strength and stiffness must be extensive to ensure the pieces function and safety.

The tunneller will be supplied in three unique lengths, requiring individual testing and design criteria for each length ensuring that each tunneller remains within our deflection, ergonomic, and convenience criteria. The tunneller and Touhy Borst mechanism must be separable. The current design specifies that the tunneller will have internal threads on the base, while the Touhy Borst mechanism will have external threads. They will arrive assembled, allowing for quick catheter insertion. Once the physician is satisfied with the placement, the mechanism and catheter will be removed in one piece. The needle and insert will then be inserted into the tunneller. The mechanism must accommodate an 8 French catheter and must be threaded so that it can be removed from the tunneller once it is no longer needed.

5.2 Needle/Insert

Once the tunneller is accurately placed, the catheter will be removed, and the needle will be inserted. The issue that arises from this step of the process is that the catheter is thicker than our needle, which may result in inaccurate needle placement. To solve this problem, the supplied

needles will be packaged with a thin sleeve, allowing for a tighter tolerance and a more accurate needle placement. The insert would be positioned such that once the top of the insert is aligned with the edge of the tunneller, the insert would halt. At this point, the tip of the needle will be positioned at the tip of the tunneller. The user would then apply force, and the needle would break free from the insert, and penetrate the vessel.

This piece should not come into contact with the patient yet will still need to be manufactured from a medical grade material. Since we are already working with a thermoplastic supplier and manufacturer, and since this piece should not be re-processable, we will use the same material as the tunneller. The only constraint for this piece is that the needle should be able to easily slide free of the insert, and the insert cannot break.

5.3 Ultrasound Handle and Head

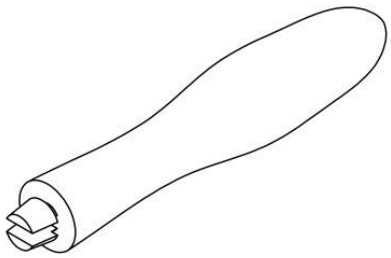

Figure 16: Final Design of Ultrasound Handle

The handle of the ultrasound assembly will continue to be refined, as the user will interact with this piece more than any other. The user's reaction to the handle will shape the response to the product, so it will need to be ergonomic to a wide variety of hands. It will be separate from the head and will have a cantilever snap joint for attachment to the head, as shown in Figure 16. It must fit comfortably in a wide range of hand sizes, must be familiar yet unique, and must have a rubberized grip pattern. The handle will be made of the same thermoplastic as the tunneller as the thermoplastic is available in both opaque and clear.

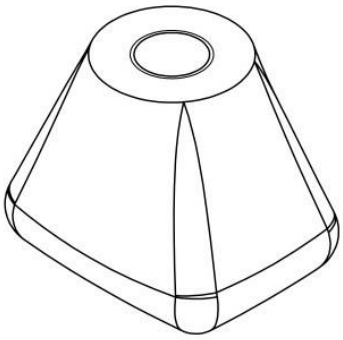

Figure 17: Final Design of Ultrasound Head

The ultrasound head will house the ultrasound catheter. Figure 17 displays the isometric view of the solid model of the ultrasound head. Once the catheter is secured and oriented within the head, the ultrasound head will be attached to the handle, forming the complete ultrasound wand, displayed in Figure 18.

Figure 18: Full Assembly of Ultrasound Wand

The ultrasound head must succeed in three objectives. First, the catheter in question is extremely fragile, so our method of securing the catheter must be gentle. Second, the catheter is difficult to orient. Because one of our most important design goals is speed and ease of use, we must allow for the orientation to be easy and quick. Finally, the material of the head must not impede the ultrasound images formed using the ultrasound catheter.

To accomplish our first goal in protecting and securing the ultrasound catheter, the head will be fitted with a Touhy Borst mechanism similar to the tunneller. The head will have a port with external threads manufactured in the piece. We have communicated with Qosina on acquiring the 3-D model of the Tuohy Borst mechanism. The disk and cap will arrive assembled. The head

will arrive prefilled with ultrasonic gel in the catheter port to ensure no air bubbles can impede the ultrasound imaging. The catheter will then be inserted into the gel, and once oriented correctly, will be secured.

To orient the catheter, there will be a thin attachment to the face of the head. This will look like a thin plate or vinyl sticker. Using carbon or metal, two materials that block ultrasound, we will print a logo or image on the face of the head, so that once the catheter is oriented correctly, a clear image will be visible on the ultrasound imaging system, telling the user to secure the catheter. Since we do not have access to an ultrasound machine, we will be relying heavily on the testing of materials after prototyping of the ultrasound wand to guide this design.

To help with the catheter placement, the head will be clear allowing for the user to more quickly orient the imaging catheter. The head will be manufactured from polycarbonate, a clear thermoplastic commonly used in medical devices, which also provides another barrier in being able to re-process the piece.

5.4 Tunneller Revisions

Figure 19: Titanium 6-inch Tunneller

The initial design of the tunneller was deemed to be too large a diameter. Thinning the tunneller became problematic as the chosen thermoplastic would deform under pressure at body heat and left a factor of safety that was too low. In order to solve this problem, the tunneller is made from Ti 6AL4V ELI, a common titanium alloy in medical equipment. This material change allowed the tunneller to become much thinner, with a new diameter of 0.275 inches, with a safety factor equal to four in the most extreme loading conditions. In order to determine our tunneller sizes, the pieces were analyzed using two separate experiments. Our first experiment placed 7.5 pounds force at the tip. While this situation should never occur, we used this as an absolute safety barometer, with our only constraint being that at no point should the member break. This test was

influenced by our conversations with our sponsors FDA team as well as from the advice and experiences of multiple surgeons and surgical tool representatives. An incredibly common theme from these conversations was the mistreatment of tools by shipping and by tool representatives. A common theme from operators was a lack of confidence in many tools brought before them, and it was important to us that there be as little barrier to entry in the market as we could allow. Our second experiment involved a series of loading conditions that we believed to be possible in the correct use of the device. These loading conditions were determined through our testing, with the most common and correct of these conditions forming the basis of our judgment. It was under this experiment that we judged our deflection constraint, which we took seriously after learning from surgeons, which influenced their confidence in various products. Under a small load, we have a deflection less than 1mm, which also greatly improved our tunneller accuracy. The tunneller will be bonded to internal Luer Lock threads that will be injection molded out of Makrolon. Finite element analysis is presented in the appendices, showing complete security under extreme loads. When the tunneller is analyzed using typical loads, we see tip displacement on the eight-inch tunneller of 0.89 mm. Typical displacement will be less than this and will be negligible on the six-inch and four-inch tunnellers. A Touhy-Borst mechanism will be packaged pre-assembled using a Qosina brand Touhy-Borst gasket. This mechanism will be fitted with external Luer Lock threads. The assembly will be easily attached and removed with the catheter. Once the base is threaded onto the cap, the disk will be bonded to the base of the cap, ensuring that the assembly cannot be easily taken apart for re-use, shown in Figures 20, 21, and 22. Figure 23 shows the completed tunneller assembly.

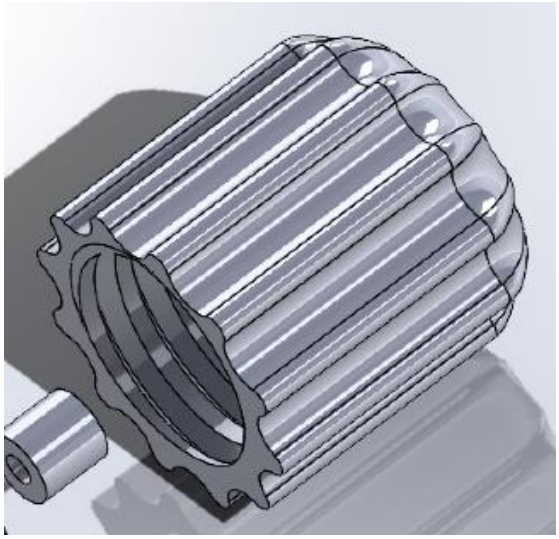

Figure 20: Borst Touhy Cap

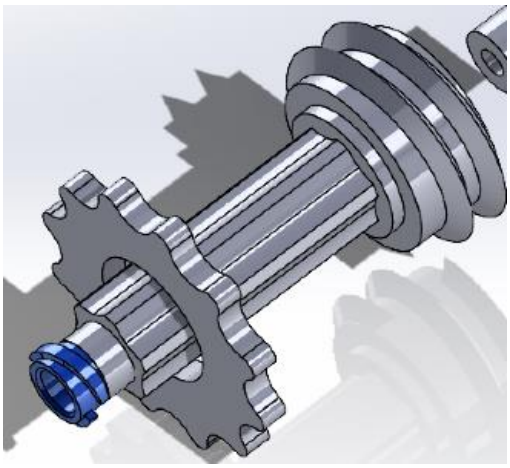

Figure 21: Borst Touhy Base and Disk

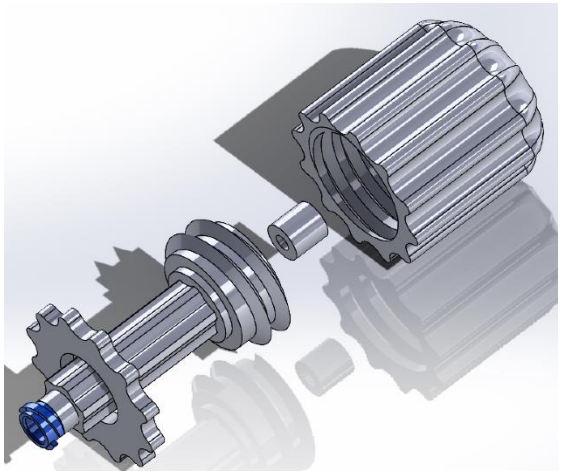

Figure 22: Touhy-Borst Assembly for Tunneller

Figure 23: Complete Tunneller Assembly with 6-inch Tunneller

5.5 Needle/Insert Revisions

Sponsor feedback indicated that the needle insert should at no point break free of the needle, as this would introduce a foreign element to the process. To remedy this, the inserts are shorter to allow the needle tip to freely exit the tunneller. The needle insert will still function as intended, where the inserts will be pre-fixed on the needle in such a way that when the top of the insert is flush with the top of the tunneller, the tip of the needle is about to exit the tunneller. An example is presented in Figure 24.

Figure 24: 8-inch Needle Insert

5.6 Ultrasound Handle and Head Revisions

The final design and assembly of the Ultrasound handle and head are displayed in Figure 25 below.

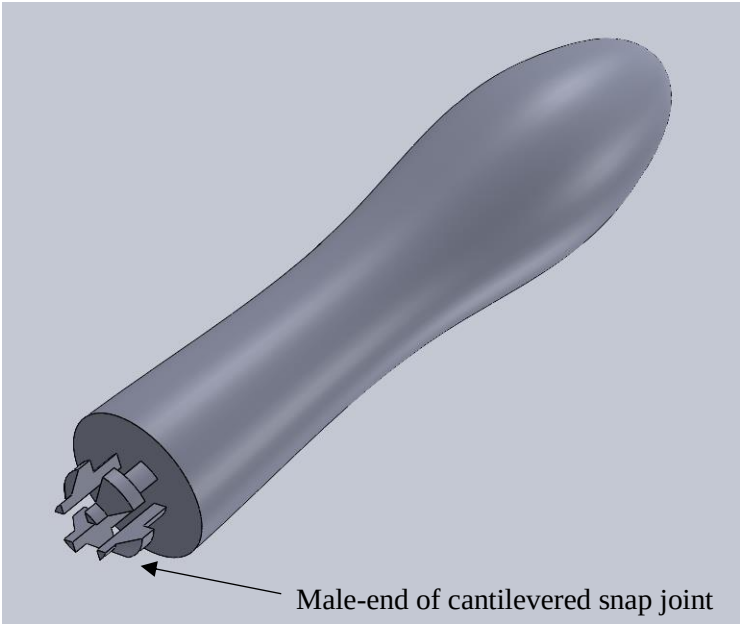

Figure 25: Ultrasound Handle

In the early stages of prototyping the concept design, we noticed the annular snap joint to be virtually unusable. This was because the outer diameter of the cantilevered member on the handle that was supposed to snap into the hole within the ultrasound head was too large. Additionally, the cantilevered part of the joint contained too much material to be able to bend into place with a reasonable amount of force. So, in the final design of the joint, material was removed from the cantilevered member and the outer radius was reduced. The final revision was shortening the length. The final design of the handle can be found in Appendix 7.

The ultrasound head was also revised to better accommodate the Tuohy-Borst mechanism. The general shape of the head remains unchanged, but the internal features were further refined. A cross section view shows the internal features in Figure 26 below.

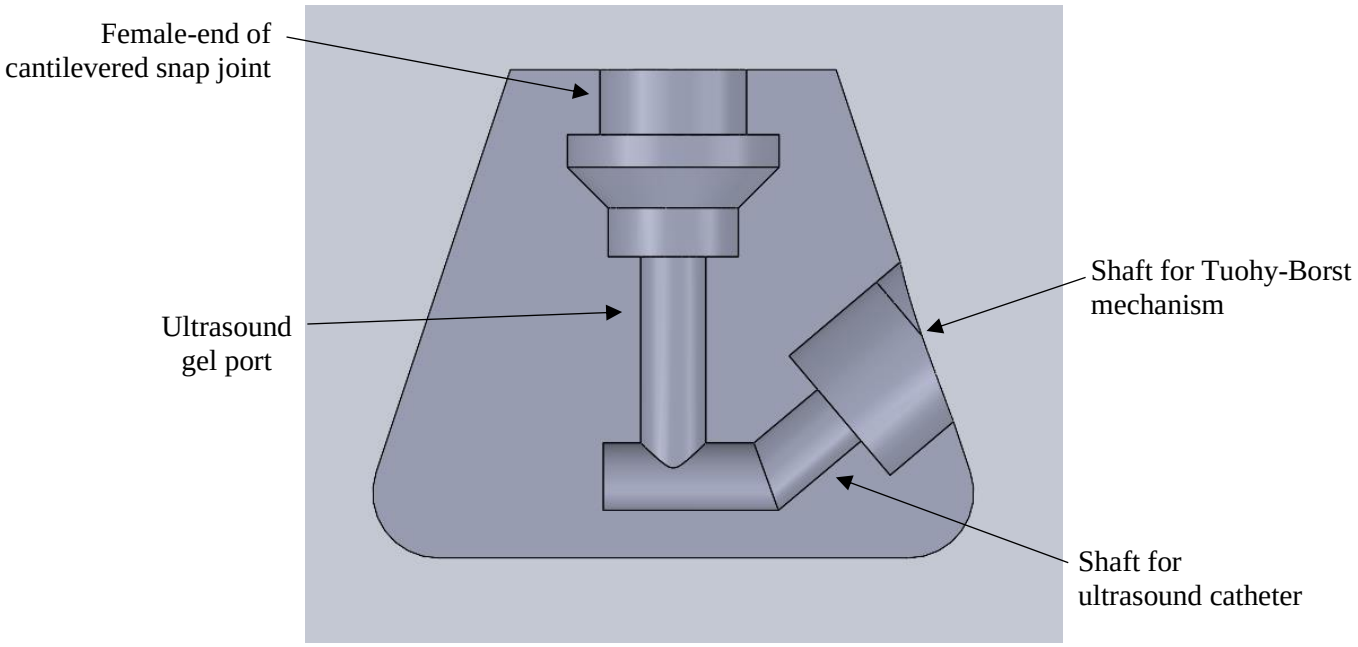

Figure 26: Cross Sectional View of Ultrasound Head

The right side of the ultrasound head contains a hole sized to fit the Tuohy-Borst mechanism we have designed. A smaller shaft runs further into the head that will guide the ultrasound catheter into the inner cavity of the head. Another shaft runs vertically from the catheter shaft that will serve as the port for ultrasound gel to be loaded into so no pockets of air can impede the ultrasound before the handle is inserted into the head.

In the initial concept design, we wanted to procure the Tuohy-Borst mechanism from a medical supplier, Qosina. This was to ensure that the design would have a mechanism that most surgeons would be familiar with using, and we found the Qosina Tuohy-Borst mechanism to be quite seamless in design and already widely used. We also proceeded to design our own Tuohy-Borst mechanism shown in Figure 27.

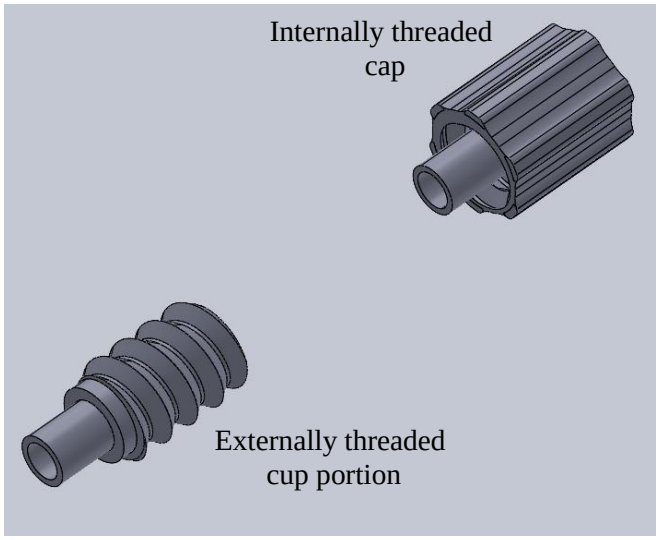

Figure 27: Tuohy-Borst Mechanism

The Tuohy-Borst mechanism is comprised of two parts— the externally threaded cup and the internally threaded cap. In the full assembly the cup is adhered to the shaft on the right side of the ultrasound head. A silicone disk is placed inside the cup portion. The cap contains an extruded cylinder that acts as a plunger, so as the cap is screwed on the silicone disk is compressed. The silicone disk will be compressed around the ultrasound catheter and the catheter will be held into place. The full assembly of the ultrasound handle is pictured in Figure 28.

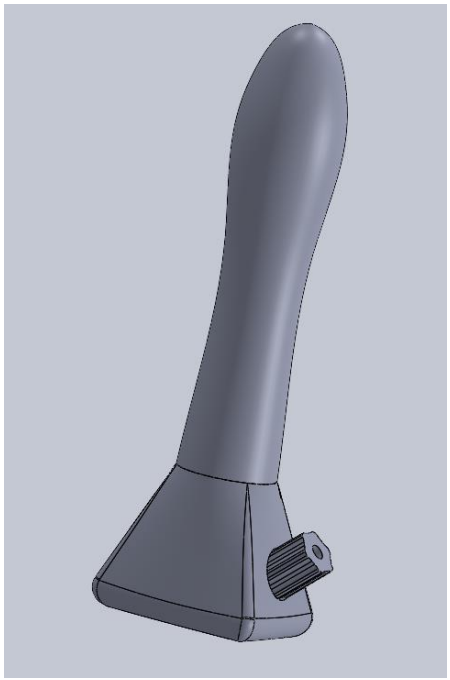

Figure 28: Ultrasound Handle Full Assembly

As a supplementary design of the ultrasound handle, we also designed a head that fits the Tuohy-Borst mechanism from Qosina. So, the sponsor may use either design to his discretion. The full assembly of the ultrasound handle with the Qosina Tuohy Borst mechanism is pictured in Figure 29 below.

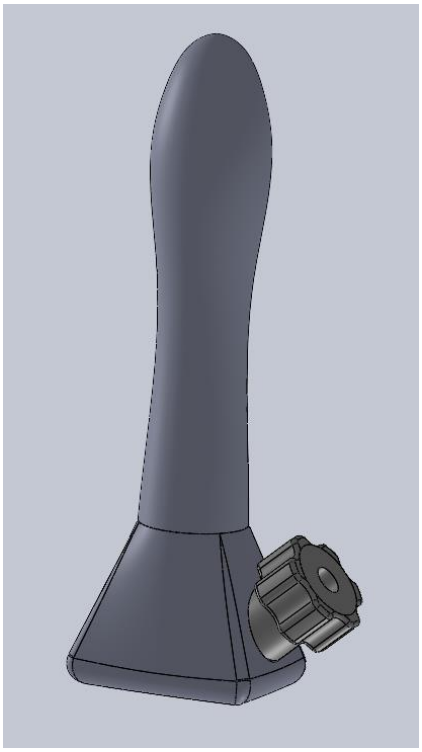

Figure 29: Qosina Ultrasound Handle Full Assembly

All drawings of the final design can be found in Appendix 7.

Chapter 6: Manufacturing

For our prototypes, we 3-D printed each component. The materials for the prototypes required a roll of 1.75 mm PLA filament, a 3-D printer, and a silicone mixing kit. The roll of PLA filament was procured from Amazon at a price of approximately $17. To 3-D print the components, we utilized the 3-D printers at Cal Poly's Mustang 60 Machine Shop. The STL files for 3-D printing were acquired using our 3-D models of each component. The drawing package of each component can be found in Appendix 7. For prototyping, we also required a silicone molding kit procured from Amazon at $23. This brought the prototyping budget to approximately $40.

Following 3-D printing of the ultrasound head, ultrasound handle, and the Touhy-Borst mechanism, the ultrasound handle assembly is as follows.

1. The small diameter cylinder on the externally threaded Tuohy-Borst cup portion shall be inserted into the shaft on the right side of the ultrasound head with an adhesive.
2. A silicone disk shall be inserted into the cup of the externally threaded Tuohy-Borst portion.
3. The Tuohy-Borst cap shall be threaded onto the externally threaded Tuohy-Borst cup.

After these steps, the ultrasound handle is ready to be packaged as part of the modifying kit. Once in possession of the user, the user will perform the following to finish the assembly.

1. The user will insert ultrasound gel into the vertical shaft atop the ultrasound until the internal cavity is full.
2. The user will then insert the ultrasound catheter into the Touhy-Borst mechanism and rotate the head around the catheter until the ultrasound image is clear and present on the ultrasound monitor.
3. Once satisfied with the ultrasound image, the user can then screw the Tuohy-Borst to secure the catheter in place.
4. To finish the assembly, the user can then insert the male end of the cantilevered snap joint on the ultrasound handle into the female end atop the ultrasound head. The user may place the flat, rectangular portion of the ultrasound head on a flat surface for easier insertion of the ultrasound handle.

For the tunneller, the Touhy-Borst mechanism, comprising of a compressible ring and threaded compressor, will screw onto the external threads of the Luer Lock on the tunneller. The Tuohy-Borst mechanism will be screwed into place on the opposite end of the domed tip and will be on the end that will not be entering the body. A full assembly of the project and exploded view can be found in Appendix 7.

While most of the products will be manufactured from Makrolon, the three tunnellers will be made from half inch round stock titanium 6AL4V ELI. Prices will vary with suppliers, but this stock is usually sold for $15/lbm. A full cost estimate is provided below.

With sponsor approval of the final design, we were able to move forward in looking for places to injection mold our designs. For injection molding, a mold of each individual component will be

needed. Plastic injection molds can vary in complexity and sizes. High volume injection molds with high complexity can cost up to $100,000, while low volume, low complexity molds can cost as low as $100. For our design, each component is relatively low volume, with somewhat complex features, so we anticipate the molds to cost a few hundred dollars each. However, for low volume production on components, the production and labor cost we estimate to be about $3 per part. We recommend Xometry to begin the injection mold process. Xometry is a manufacturing company that offers services in plastic injection molding and 3D printing. They have experience in producing medical devices and offer molds for prototyping to production. We recommend starting off with the Class 105 Mold for any redesigned prototypes and Class 104 Mold for low production that's under 100,000 cycles. The Class 104 Mold also provides a low to moderate price range.

For our design, once in production, we have decided that the tunneller and the ultrasound wand shall be made of a polycarbonate, called Makrolon 2458, procured from Service Polymers Inc for $6.33 per pound. This polycarbonate is a medical grade thermoplastic that can be radiation sterilized and used for injection molding. This polycarbonate can come in both opaque and clear, which is ideal for our design. Its rated yield stress is 65 MPa. The material properties of this polycarbonate can be found in Appendix 10. The ultrasound head shall be clear polycarbonate to give visual indication to the user that the ultrasound catheter has been inserted fully. The transparency of the tunneller shall be up to the sponsor. The rest of the ultrasound handle shall be made of an opaque version of Makrolon 2458 polycarbonate procured from Service Polymers Inc. For the Tuohy Borst mechanisms, the sponsor can choose to use the Tuohy-Borst we have designed or procure the mechanism from Qosina. Our designed Tuohy-Borst will require a *Tuohy Borst Adapter Gasket, Extruded Style* (Part no. 80430) from Qosina for $0.98 each. Our supplementary design is sized to fit a Qosina *Tuohy Borst Adapter, Small Body* (Part no. 11219) for $10.63. An abbreviated production cost estimate for the ultrasound handle can be found below.

As mentioned above the tunnellers will be machined out of titanium. The tunnellers will be machined out of 0.5" round Ti-6AL4V ELI stock which when bought in bulk can cost as low as $9.00 per pound. However, as this project will begin with a lower production volume, we have modeled our material cost to be $20.00 per pound, as this is more in line with small-scale production orders.

By having the internal threads be molded out of Makrolon 2458 rather than be machined out of titanium, we have been able to lower the manufacturing cost of the tunnellers considerably, as machining titanium can become expensive as the designs get more complicated. By having the tunneller housing alone made from titanium, we estimate that the production will cost anywhere from five to eight dollars depending on negotiation. This price will depend on order scale.

Table 3: Ultrasound Cost Estimate

	Qty.	Part No.	Mass	Weight	Material	Material Cost	Unit Cost	Production Cost	Cost per part
	[-]		[lbm]	[lb]	[-]	[$/lb]	[$]	[$]	[$]
Ultrasound Assembly									
Handle	1	-	0.108	3.4776	Makrolon	$6.33	$22.01	$3.00	$25.01
Head	1	-	0.085	2.737	Makrolon	$6.33	$17.33	$3.00	$20.33
Tuohy Borst Mechanism									
Touhy Borst (f)	1	-	0.001	0.0322	Makrolon	$6.33	$0.20	$3.00	$3.20
Tuohy Borst (m)	1	-	0.002	0.0644	Makrolon	$6.33	$0.41	$3.00	$3.41
Qosina Silicone Disk	1	80430	-	-	Silicone	$0.99	$0.99	-	$0.99
								Total Cost =	**$52.94**

The abbreviated production cost estimate for the design utilizing Qosina's Tuohy-Borst mechanism can be found below.

Table 4: Qosina Ultrasound Cost Estimate

	Qty.	Part No.	Mass	Weight	Material	Material Cost	Unit Cost	Production Cost	Cost per part
	[-]		[lbm]	[lb]	[-]	[$/lb]	[$]	[$]	[$]
Ultrasound Assembly									
Handle	1	-	0.108	3.4776	Makrolon	$6.33	$22.01	$3.00	$25.01
Head	1	-	0.085	2.737	Makrolon	$6.33	$17.33	$3.00	$20.33
Qosina Touhy Borst	1	11219	-	-	-	$10.83	$10.83	-	$10.83
Qosina Silicone Disk	1	80430	-	-	Silicone	$0.99	$0.99	-	$0.99
								Total Cost =	**$57.16**

Table 5: Four-inch Tunneller Cost Estimate

Tuneller Assembly - 4inch	Qty.	Part No.	Mass	Weight	Material	Material Cost	Unit Cost	Production Cost	Cost per part
Tunneller	1		0.032	0.032	Ti 6AL4V ELI	$20.00	$0.64	$6.00	$3.84
Needle insert	1		0.000868	0.0279496	Makrolon	$6.33	$0.18	$3.00	$3.18
Internal Threads	1		0.000868	0.0279496	Makrolon	$6.33	$0.18	$3.00	$3.18
								Total Cost =	**$10.19**

Table 6: Six-inch Tunneller Cost Estimate

Tuneller Assembly - 6 inch	Qty.	Part No.	Mass	Weight	Material	Material Cost	Unit Cost	Production Cost	Cost per part
Tunneller	1	-	0.052	0.052	Ti 6AL4V ELI	$20.00	$1.04	$6.00	$6.24
Needle insert	1		0.001736	0.0558992	Makrolon	$6.33	$0.35	$3.00	$3.35
Internal Threads	1		0.000868	0.0279496	Makrolon	$6.33	$0.18	$3.00	$3.18
								Total Cost =	**$12.77**

Table 7: Eight-inch Tunneller Cost Estimate

Tuneller Assembly - 8 inch	Qty.	Part No.	Mass	Weight	Material	Material Cost	Unit Cost	Production Cost	Cost per part
Tunneller	1	-	0.072	0.072	Ti 6AL4V ELI	$20.00	$1.44	$6.00	$8.64
Needle insert	1	-	0.00217	0.069874	Makrolon	$6.33	$0.44	$3.00	$3.44
Internal Threads	1		0.000868	0.0279496	Makrolon	$6.33	$0.18	$3.00	$3.18
							3.18	**Total Cost =**	**$15.26**

Table 8: Tunneller Borst Touhy Cost Estimate

Tuneller -Touhy Borst Assembly	Qty.	Part No.	Mass	Weight	Material	Material Cost	Unit Cost	Production Cost	Cost per part
Cap	1	-	0.020832	0.6707904	Makrolon	$6.33	$4.25	$3.00	$7.25
Base	1	-	0.009548	0.3074456	Makrolon	$6.33	$1.95	$3.00	$4.95
Qosina Silicone Disk	1		-	-	Silicone	$0.99	$0.99	-	$0.99
Disk	1		0.001302	0.0419244	Makrolon	$6.33	$0.27	$3.00	$3.27
								Total Cost =	$16.45

With a final estimated total cost of $104.41 for the whole kit, we satisfy our cost design requirement of being less than $700. We outline the full cost estimate in the Bill of Materials found in Appendix 7.

There were several challenges we faced in the construction of our prototype. The first major challenge involved the 3D printers available to us lacking the resolution we were hoping for in producing our prototype. We felt if we were to outsource the construction of the prototype, then we wouldn't have the convenience of being able to redesign as fast as could with the 3D printers available to us. There would have been a give and take of quality of the prototype and less time to iterate if we outsourced, and vice versa if we utilized the 3D printers. Ultimately, because we were struggling with the construction of the Tuohy-Borst, we decided that we needed more iterations in order for this project to be successful, so we used the 3D printers.

The second major challenge we faced was failure in printing. The 3D printers would occasionally fail in printing, which set us back multiple times when iterating over the design. In addition to this, the machine shop was only open three days out of the week. These challenges helped us learn to be meaningful with our designs and iterations. We learned that it was easier to print only part of the overall design to verify that a particular portion of the design worked and was usable. This reduced printing hours and helped us test components of the design without the full assembly needed.

The last challenge we faced was the construction of the silicone disk. We created a mold with the correct dimensions for the silicone disk for its construction, however the silicone disks came out usable, but somewhat low quality.

Chapter 7: Design Verification

To ensure our final design meets the needs of our sponsor and end users, we have set forth a series of verification tests to ensure we meet our design specifications. This section outlines what our specifications are and how they will be tested. Our test plan can be found in Appendix 9.

1. **Ultrasound is Unimpeded**

   The first requirement of our design is the ultrasound should remain unimpeded while using any component of our design. This ensures that ultrasound imaging is viable, and clarity remains. This will need to be tested using an ultrasound catheter and ultrasound machine found within a hospital catheterization lab.

2. **Tunneller deflection shall be less than 1 mm at the tip**

   This design specification ensures that the tunneller will not break while inserted into a body. This shall be tested using finite element analysis and testing in a catheterization lab. In the catheterization lab, a human replica will be used to perform the procedure of the test kit. When the tunneller is inserted into the human replica, if the tunneller experiences any cracking or breaking, this test will end in failure and the design criteria will not have been met.

3. **Speed of procedure shall be less than 15 seconds**

   This specification will require timed trials in using the final design. The timed trials will give us an average time and uncertainty of the time to set up. This ensures that our design will not be a hindrance to the user while in medical procedures. If the average time to set up the kit exceeds more than 15 seconds, then this will result in failure and the design specification will not have been met.

4. **Tunneller and Handle shall secure catheters**

   To test this specification, we will need to test the functionality of the Tuohy Borst mechanism. If either of the catheters are secured but loose or become unfastened to the components, then this will result in failure and the design specification will not have been met.

5. **Tunneller places needle in correct location**

   We will require several trials and locations on the body to ensure this specification is met. To test this specification, we will use lab testing and different users to evaluate the success rate of the design. The tests will be conducted on a human replica supplied by the sponsor in a hospital catheterization lab. If the success rate is less than 99%, then this will result in failure and the design specification will not have been met.

In order to test our design verification parameters, as our prototypes began to become more sophisticated, we began measuring our prototypes against our goals. Out of our five core necessities, we were unfortunately unable to test one in person, as we did not have regular access to an ultrasound. It was explained to us that in order to use an ultrasound catheter, we would need to use the EP mapping system. This became problematic as the EP mapping system can only be used with a representative from Johnson & Johnson who needs to be called and scheduled in advance for a procedure. However, our research shows that no hindrance of the ultrasound should be present as no materials used in this project are made from a ferrous metal. Secondly, most ultrasound wands are made from plastic, so we can base off precedence that the ultrasound will be left unimpeded. We were very strict about what materials we incorporated into our design, using only materials that had a long standing and widespread use with ultrasound technologies. The materials we incorporated in our final designs have been shown through the history of their use to be compatible with ultrasonic frequencies.

After this, surprisingly to us, the most challenging goal was tip deflection. Our initial plan to mold the tunnellers out of thermoplastic proved impossible. The plastics we were working with would deflect at warmer temperatures, and ultimately, we were unable to make a plastic tunneller that was both thin enough and stiff enough at the desired temperatures, though we tried many plastic solutions. Finally, we pivoted back to titanium, with which we were able to make thin, sturdy tunnellers. By keeping the threads plastic, we were able to ensure a solid satisfying connection between the tunneller and the Touhy-Borst mechanism. Simulations of these experiments are shown in the appendices. We performed Finite Element Analysis on the tunnellers to determine the deflection experienced by the tunnellers under load. The results can be found in Appendix 8. Appendix 8-1 is the stress and deflection analysis for the 8-inch tunneller. After analyzing the tunneller and its potential failures at different loading conditions, it was determined point loads represented the most dangerous loading conditions that could theoretically occur. The loads are placed on the tip of the tunneller. The base of the tunneller was fixed, as this face will be bonded to Luer threads. We analyzed our final design under two experiments. The first used a force of 7.5 lbf. When using Ti 6AL4V, we see a deflection on 2.24 mm of deflection, and a stress safety factor of over 4. These results gave us confidence in the designs ultimate safety. Our second experiment, Appendix 8-2, more accurately represented a worst-case scenario for correct usage, which gives us a force of 2.0 lbf located at the tip of the tunneller. The same face is fixed. This gives us a stress safety factor of 10, and a needle tip deflection of 0.89 mm, which is well within our initial design constraint.

Our third test, speed, was the test we were most worried about but ended up being the first achieved. As we iterated through our designs, using the equipment provided by our sponsor, we very quickly narrowed our designs to the fastest solutions. We tested this ourselves and a range of volunteers, finding that most trials were easily completed in under fifteen seconds. We were hesitant to use ourselves for continuous data as we viewed this as practice, but we ourselves recorded times under ten seconds regularly. The average speed to set up the assembly came out to be 14.12 seconds, which satisfies our specification of set up being under 15 seconds. To test this we set up the ultrasound assembly in front of the user. They were tasked with having to insert the catheter into the head, rotate the ultrasound head about the catheter once, fasten the

Tuohy-Borst mechanism, and finally insert the ultrasound head into the head. The time it took to complete these steps was recorded.

Catheter security was judged using our prototypes, the medical equipment provided and, in some cases, similar stand ins. We found this test rather tricky to judge, because we did not want to treat the catheter in a violent or inappropriate manner, or intentionally damage a piece of equipment. However, we are confident in our designs' ability to protect the catheters, and at no point did we feel like our design did not completely succeed in achieving this goal. To perform this test we inserted a catheter into the Tuohy Borst mechanism on the ultrasound head and fastened it. We then guided the ultrasound head side-to-side and up and down along a pillow in order to mimic moving the ultrasound over a patient. After this we gave the catheter a couple of tugs with moderate force to try and dislodge the catheter. We found that the catheter stayed fastened during the entire test, thus passing the test.

Finally was tunneller accuracy, which again, was tested using our continuously iterated prototypes. We performed these experiments in a similar way as we were shown in a hospital setting, using a variety of materials to simulate the environments. While we did not have continuous access to an ultrasound, we were able to use these tests to iterate our prototype design, and are confident in calling our results a success in this area

Table 9: Verification Results

Test	Goal	Result
1. Ultrasound is unimpeded		Unable to test
2. Deflection	Less than 1mm	Success $\delta = 0.89$ mm
3. Speed	15 Seconds	Success $t = 14.12 \pm 1.45$ s
4. Catheter Security	Catheters are protected	Success
5. Tunneller accuracy		Success

Chapter 8: Project Management

To ensure we stay on track for completing this project, the first quarter of this project we met every Tuesday and Thursday during our designated lab time to work on the project. For the first quarter of this project, we set aside an alternative meeting time— Wednesdays at 4 PM— to further discuss the project and conduct weekly meetings with the project sponsor, Dr. Kusumoto. In our second quarter of this project, we reduced our meetings to twice a week— Tuesdays and Thursdays at 8 AM. Following the CDR, our group didn't set aside time to meet with each other during the week. Instead, we assigned a subassembly to each team member. Each member would prototype, test, and iterate each subassembly individually. This method worked well because each member was able to focus more time and effort on the few parts that made up each subassembly, rather than having to split time and effort amongst the several components that make up the whole project. This also ensured that all changes to the designs could be accounted for and prevented any mix-up in dimensioning or file management. However, throughout the design process, the other team member was consulted on design decisions and informed of project development to ensure that the project remained united in its vision.

We started the first stage of this project by identifying the problem definition and conducting technical research, reviewing FDA testing, and investigating existing products. This helped us understand what is needed from us in our future design process and helped us gain better knowledge and understanding of the goal and purpose of the project. In addition, we are continuously working in conjunction with Dr. Kusumoto to ensure we have a thorough understanding of the customer's wants and needs. Using the information gathered, we moved forward to setting design requirements for the Scope of Work.

Following the Scope of Work, we moved on to concept design. We first began with brainstorming and ideation. From ideation, we were able to come up with a couple of concepts that we liked. Using Pugh matrices and a weighted decision matrix, a concept design was selected. Our design process and concept selection is outlined in the Preliminary Design Review (PDR). After the PDR, our concept design was then further refined using feedback from Dr. Kusumoto. This feedback and reiteration of our design lead us to the final design concept, outlined in the Critical Design Review (CDR).

Following the CDR, our next steps were continuing to iterate and test the components to our sponsor's specifications. We performed Finite Element Analysis (FEA) and calculations for strength and stiffness to ensure that the switch to the thermoplastic and the resulting manufacturing methods do not impact the product's function. With FEA we were able to determine the stress and deflection on the tunneller. We focused on stress analysis only on the tunneller as this is the only part that will enter a body. The prototypes of the handles and tunnellers were 3-D printed using PLA. Using these prototypes, and once we were satisfied with our prototype, the models were sent to our sponsor, Dr. Kusumoto, so he can test the pieces in a clinical setting, ensuring that the products are satisfactory to physicians. We were then able to redesign the components based on Dr. Kusumoto's feedback. Dr. Kusumoto was satisfied with

the overall design and informed us that the 3D files would satisfy as the final deliverable for this project, which we outline in this Final Design Review (FDR).

The only hindrance we experienced to our project management were outside factors, such as the machine shop being open only three days out of the week or having obligations to other classes. A lot of the delays in the project were due to having to wait several hours for a print to finish, having a print fail, or waiting for the printers to free up from other student projects. In the future it would be more beneficial to acquire a 3D printer dedicated to the project.

The following table is a summary of key milestones and deadlines for this project. For a more detailed timeline for this quarter, refer to the Gantt chart in Appendix 2.

Table 10: Timetable of Key Deliverables

Key Milestone	**Due Date**
Scope of Work	Week of 04/24/2022
Preliminary Design Review	Week of 05/22/2022
Critical Design Review	Week of 10/24/2022
Final Design Review	Week of 03/12/2023

Chapter 9: Conclusions & Recommendations

To conclude, the task and goal is to develop a single-use, easy-to-use, precise modification kit to the already used Seldinger technique, to minimize the possibility for error, time, and complexity associated with this procedure and the resulting complications that would come from these imperfections. This would involve ultrasound, mapping systems, and physical tools to help the operator use these technologies during the procedure. In the Scope of Work our work had comprised of fully understanding the problem we were tasked with solving, as well as the resources we had to solve it. This research began with existing products and patents relating to the field in question, communication with our sponsor to understand the problem to solve, and the ideal result of our potential solution. Due to the medical nature of this device, it must be safe and comply with standards set by regulatory agencies, such as the Food and Drug Administration (FDA). This led to communication with our sponsor's development team. This development team helped us navigate the procedures needed when designing a medical product. This information helped us in choosing correct materials, as well as giving us insight into the procedures followed by other products in order to comply with the FDA. In the Critical Design Review, we describe the process we underwent to design an FDA compliant, easy-to-use, kit that should streamline the Seldinger process currently used for cardiovascular entry in the concept design portion that we had begun in the Preliminary Design Review. Following this, we refined our design in the final design portion of the Critical Design Review. Following the Critical Design Review, we began the construction of the final design in the final quarter of this project. We chose to 3D print our design because of our access to the 3D printers located in the machine shop and for the flexibility of getting instant feedback after a print was finished. However, we faced challenges in construction as the machine shop was only open three days out of the week, prints failed, and low resolution of the printers. Eventually, we were able to send over prototypes of the design for our sponsor to approve and begin testing. Following his feedback and no adverse complications from his testing, we were able to converge on the final design outlined in the final design revision sections. Because of the resolution of the 3D printers and this project being a client driven project, our sponsor requested that the final deliverable be the CAD files used to make our designs. This slightly affected our ability to perform the design verification tests we had initially done in the Critical Design Review, as we were testing more rudimentary models than would be designed. However, we still moved forward with creating the final prototype, and we were able to use these limitations to simplify our pieces and assemblies which we believe led to a more ergonomic and natural final design. Lastly, in this Final Design Review we describe the manufacturing process for injection molding and machining of this project and provide a cost estimate for the production of each assembly. Upon completion of this report, we conclude this project and submit our final prototype to our sponsor, Dr. Kusumoto.

Overall, in this project we were able to create functional prototypes and provide our sponsor with the CAD files needed to begin production of this design. We were able to refresh our skills in 3D modeling to generate the needed files to construct our prototype. We also became very familiar with using 3D printing software, which is something that both members had no experience in using before. We think that our prototype and design achieved the desired goal of this project.

The prototypes were able to work enough to be tested and verify they work, but they were not as high a quality that we had hoped to achieve when first venturing on this project. We also were not able to physically test the ultrasound and electrophysiology mapping ourselves, as we could not make the trip up to Chico during this final quarter. The weather made a particularly strange hindrance on our ability to complete this project. For instance, school was canceled due to flooding and rain, and many of the road conditions throughout these months made travel unsafe and increased the risk of becoming stranded and missing school. If we were to do this project again, we think it would be beneficial to procure our own 3D printer. Especially, in retrospect, with how low the budget was for making our working prototype. It seems beneficial now to have spent more money to have been able to quicken the time spent reiterating. This would have helped us iterate at a faster pace and given us time to continually improve in a way that we were otherwise not able to enjoy.

Next Steps

Following this project, we recommend using Xometry to begin the injection mold process. This will give a high-quality product that can be further tested and used to submit to the Food and Drug Administration. At the time of writing this FDR we are still waiting for a quote from Xometry for the price to injection mold the pieces. We were limited by the resolution of the printers used for prototyping, but in the next versions of this project we recommend exploring an integrated Tuohy-Borst and ultrasound head. This would reduce the steps to assemble and produce a more seamless design. Additionally, during this project, we did some testing of ways to indicate the ultrasound catheter was in the correct orientation. We are providing to the sponsor some silicone forms that utilize the testing that was performed with the ultrasound. They have a metal piece suspended within the silicone at a depth of 3 centimeters. Since they're made of silicone, this eliminates any pockets of air from hindering the ultrasound capabilities.

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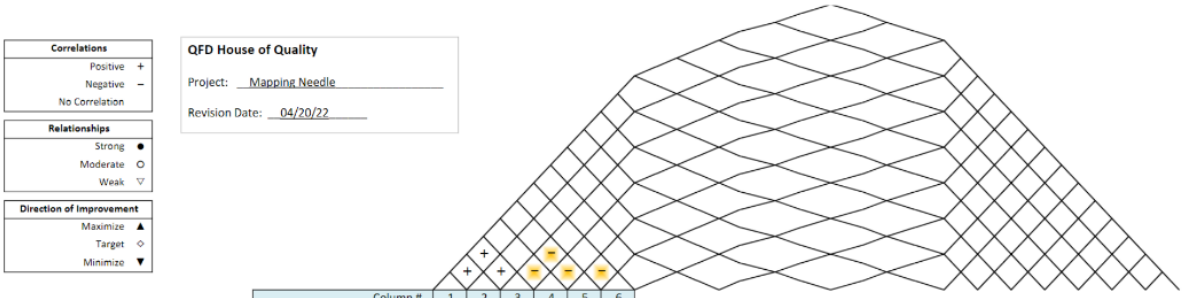
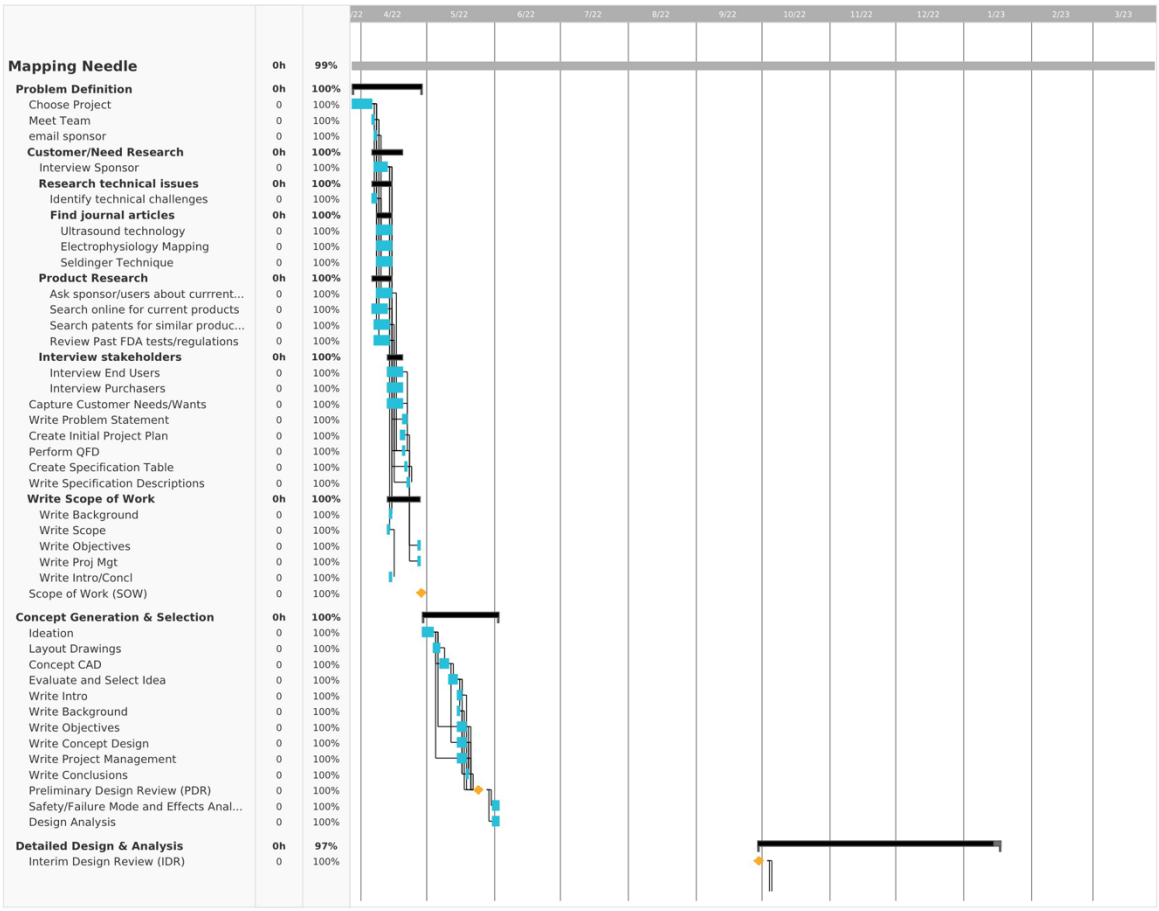
Appendix

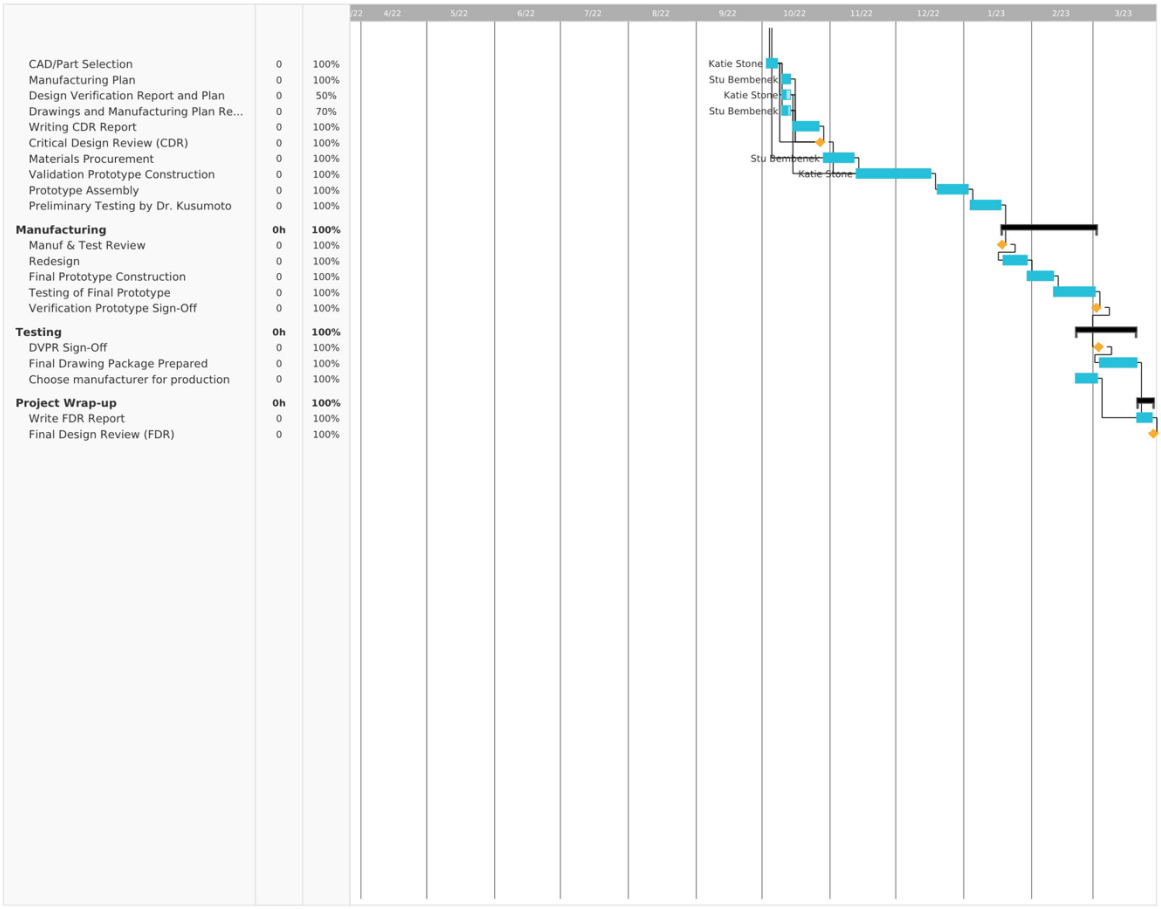
A-1: House of Quality



Row #	Weight Chart	Relative Weight	Physicians	Hospitals/Health Systems	Marketing		Maximum Relationship	WHAT: Customer Requirements (Needs/Wants) / HOW: Engineering Specifications (Tests)	Time to Set Up (s)	Ease Of Procedure (Complicati	Number Of Parts (#)	Weight (g)	Cost ($)	Colors (#)	Our Current Product	Lumify - Phillips	Vscan	Traditional Ultrasound	Seldinger	Row #
		WHO: Customers						Column #	1	2	3	4	5	6	NOW: Curr. Products					
								Direction of Improvement	▼	▲	▼	▼	◇	◇						
1		13%	9	9	9		9	Simplicity	●	●	●		○		3	4	4	3	2	1
2		3%	2	2	2		9	Price			●	○	●	▽	4	1	1	1	5	2
3		6%	4	4	4		9	Light Weight			○	●			3	4	4	1	4	3
4		9%	9	7	4		9	Quick	●	●	○				5	3	3	3	4	4
5		11%	9	7	7		9	Reliability		●	▽				5	4	4	4	3	5
6		6%	1	1	9		3	One time use					○		5	1	1	1	2	6
7		13%	9	9	9		9	Fits machines already in use		●					5	3	3	3	3	7
8		9%	9	9	3		9	Accommodates French size 8 or 10		○	●				5	2	2	2	5	8
9		10%	9	9	4		9	Ultrasound unimpeded		●					5	5	5	5	1	9
10		11%	9	9	5		9	Orients needle	▽	●					5	1	1	1	3	10
11		11%	9	9	5		9	Orients ultrasound	▽	●					5	5	5	5	1	11
12								HOW MUCH: Target Values	10 s	99%	2	200 g (not to	$800	5						
13								Max Relationship	5	5	5	5	5	5						
14								Technical Importance Rating	217.3	715	279.8	59.34	80.93	2.826						
15								Relative Weight	16%	53%	21%	4%	6%	0%						
16								Weight Chart												
								Curr. Products: Our Current Product	3	3	2	5	5	5						
								Curr. Products: Lumify - Phillips	5	3	4	1	1	1						
								Curr. Products: Vscan	5	3	4	1	1	1						
								Curr. Products: Traditional Ultrasound	5	3	4	1	1	1						
								Curr. Products: Seldinger	2	2	2	3	5	1						

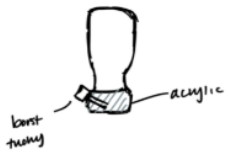
A-2: Gantt Chart




22
4/22
5/22
6/22
7/22
8/22
9/22
10/22
11/22
12/22
1/23
2/23
3/23
CAD/Part Selection 0 100%
Manufacturing Plan 0 100%
Design Verification Report and Plan 0 50%
Drawings and Manufacturing Plan Re... 0 70%
Writing CDR Report 0 100%
Critical Design Review (CDR) 0 100%
Materials Procurement 0 100%
Validation Prototype Construction 0 100%
Prototype Assembly 0 100%
Preliminary Testing by Dr. Kusumoto 0 100%
Manufacturing 0h 100%
Manuf & Test Review 0 100%
Redesign 0 100%
Final Prototype Construction 0 100%
Testing of Final Prototype 0 100%
Verification Prototype Sign-Off 0 100%
Testing 0h 100%
DVPR Sign-Off 0 100%
Final Drawing Package Prepared 0 100%
Choose manufacturer for production 0 100%
Project Wrap-up 0h 100%
Write FDR Report 0 100%
Final Design Review (FDR) 0 100%
Katie Stone
Stu Bembenek
Katie Stone
Stu Bembenek
Stu Bembenek
Katie Stone

A-3: Assorted Ideation Handle Models

This one is most similar to the concept Dr. Kusumoto provided. The handle is similar to a pipe bending handle. One thing I realized from this design is that the access to the port that would house the ultrasound would be hard to use, so I needed a design that would improve that.



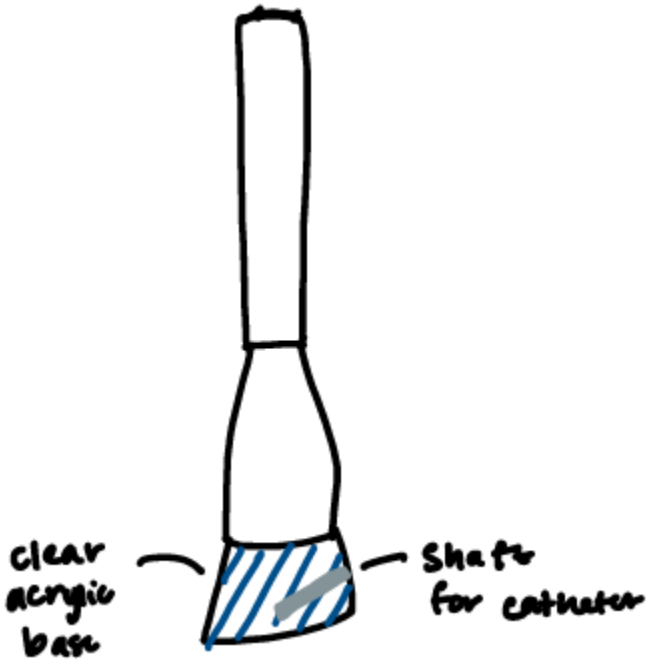
This handle is most similar to an ultrasound handle already in use. Again, the access to the port that guides the ultrasound catheter would be hard to get to, but doctors would be most comfortable with this type of handle.

This design took inspiration from a thermometer guide. Access to the port would be easy, but may be uncomfortable for doctors to use.

This design took inspiration from a defibrillator and a computer mouse. Access to the port would be easy and, assuming most people know how to use a computer mouse, the design would be comfortable for doctors to use.

This design took inspiration from a foundation brush. The handle is similar to the ultrasound handles doctors already use, but tapers so that access to the port would be made easier.


Belt sander
air wakey
thermo-gun

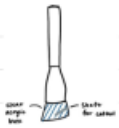

clear acrylic base
Shafts for catheter

A-4: Pugh Matrices

Pugh Matrix

	①	②	③	④	⑤
Simplicity	-	+	-	+	+
Price	S	S	-	-	-
Light weight	S	S	S	+	S
Quick	+	+	-	+	+
Reliability	+	+	+	+	+
Fits machine already in use	+	+	+	+	+
Ultrasound unimpeded	-	+	+	+	+
Orients ultrasound	-	-	-	+	-
Total	0	5	-1	7	3

A-5: Handle Decision Matrix

Engineering Specification	Design Weight	Wand (Cyl)	Air Hockey	Belt Sander	Defibrilator	Foundation Brush
						
Time to Set Up	10	7	2	3	9	7
Simplicity	8	10	5	4	8	10
Weights	2	8	2	2	10	8
Cost	9	10	3	1	8	9
Accompanies Current Tech	10	10	6	6	8	10
Ease of Orientation	9	8	1	1	10	9
Ergonomic	7	8	7	7	8	10
Protects Catheter	10	8	10	10	8	9
Familiarity	9	10	1	1	1	10
Total	65	69	36	34	69	72

A-6: Design Hazard Checklist

DESIGN HAZARD CHECKLIST

Team: Mapping Needle Faculty Coach: Fabijanic

Y	N	
☐	☒	1. Will any part of the design create hazardous revolving, reciprocating, running, shearing, punching, pressing, squeezing, drawing, cutting, rolling, mixing or similar action, including pinch points and sheer points?
☐	☒	2. Can any part of the design undergo high accelerations/decelerations?
☐	☒	3. Will the system have any large moving masses or large forces?
☐	☒	4. Will the system produce a projectile?
☐	☒	5. Would it be possible for the system to fall under gravity creating injury?
☐	☒	6. Will a user be exposed to overhanging weights as part of the design?
☐	☒	7. Will the system have any sharp edges?
☐	☒	8. Will you have any non-grounded electrical systems?
☐	☒	9. Will there be any large batteries or electrical voltage (above 40 V) in the system?
☐	☒	10. Will there be any stored energy in the system such as batteries, flywheels, hanging weights or pressurized fluids?
☐	☒	11. Will there be any explosive or flammable liquids, gases, or dust fuel as part of the system?
☐	☒	12. Will the user of the design be required to exert any abnormal effort or physical posture during the use of the design?
☐	☒	13. Will there be any materials known to be hazardous to humans involved in either the design or the manufacturing of the design?
☐	☒	14. Could the system generate high levels of noise?
☐	☒	15. Will the device/system be exposed to extreme environmental conditions such as fog, humidity, cold, high temperatures, etc.?
☐	☒	16. Is it possible for the system to be used in an unsafe manner?
☐	☒	17. Will there be any other potential hazards not listed above? If yes, please explain on reverse.

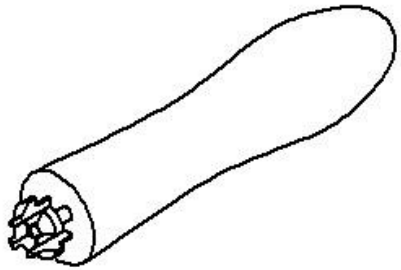
A-7: Drawing Package

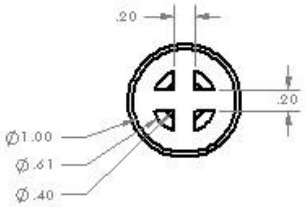
Ultrasound Mapping Handle

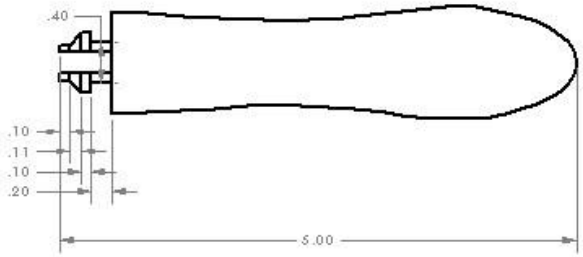
Indented Bill of Material (iBOM)

Assy Level	Part Number	Descriptive Part Name	Column1	Column2	Column3	Column4	Column5	Qty	Mat'l Cost	Production Cost	Total Cost	Column6	Part Source	More Info
	Lvl0	Final	Lvl1	Lvl2	Lvl3	Lvl4								
0	10000													
1	11000		Ultrasound Assy											
2	11100			Handle				1	22.01	3	25.01			
2	11200			Head				1	17.33	3	20.33			
3	11210				Touhy Borst Mech									
4	11211					Silicone Gasket		1	0.998		0.998		qosina or approved equivalent	Part 80430
4	11212					Male Threaded		1	0.41	3	3.41		----	
4	11213					Female Threaded		1	0.2	3	3.2		-----	
2	11300			Adhesive				1					qosina or approved equivalent	UV Curable preferred
1	12000		Tunneller Assy											
2	12100			4" Tunneller shaft				1	0.64	3.84	4.48		Made-in-China or equivalent	0.5" Round Stock
2	12200			6" Tunneller shaft				1	1.04	6.24	7.28		Made-in-China	0.5" Round Stock
2	12300			8" Tunneller shaft				1	1.44	8.64	10.08		Made-in-China	0.5" Round Stock
2	12400			Female Luer Threads				3	0.18	3	3.18			
2	12500			Touhy Borst Mech				1						
3	12210				Silicone Gasket			1	0.998		0.998		qosina or approved equivalent	Part 80430
3	122200				Borst Touhy Base			1	1.95	3	4.95		----	
3	122300				Borst Touhy Cap			1	4.25	3	7.25		----	
3	122400				Borst Touhy Disk			1	0.27	3	3.27			
1	13000		Needle Assy											
2	13100			PreLoaded Insert 4"					0.18	3	3.18			
2	13200			PreLoaded Insert 6"					0.35	3	3.35			
2	13300			PreLoaded Insert 8"					0.44	3	3.44			
2	13400			Adhesive				1					qosina or approved equivalent	UV Curable preferred
	Total Parts							18	52.686	51.72	104.406			

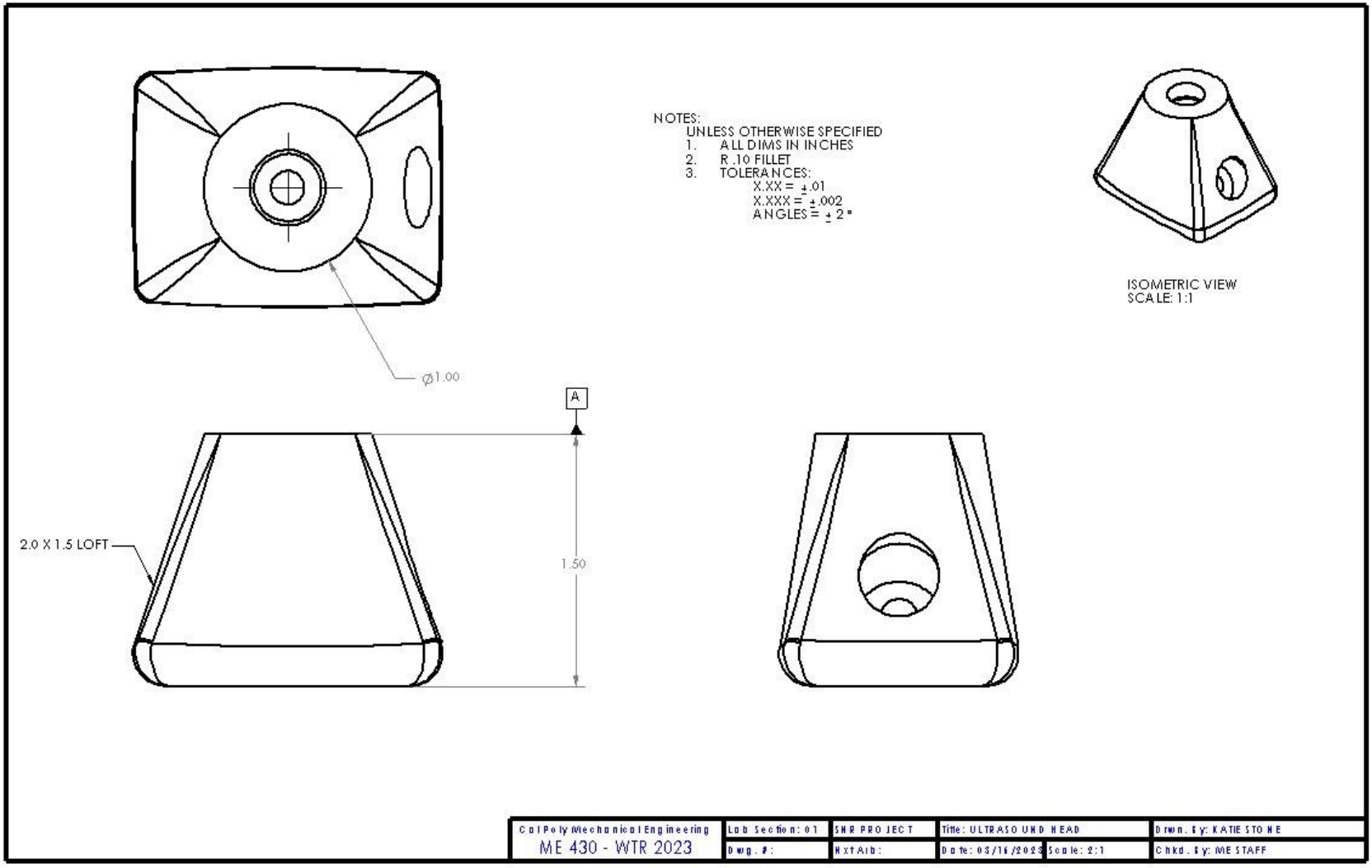
NOTES:
UNLESS OTHERWISE SPECIFIED
1. ALL DIMS IN INCHES
2. TOLERANCES:
X.XX = ±.01
X.XXX = ±.002
ANGLES = ±2°



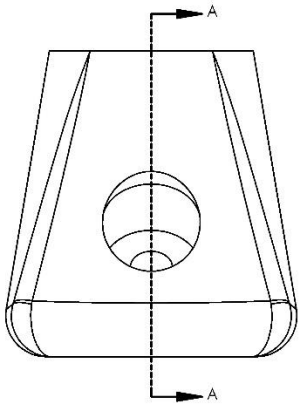


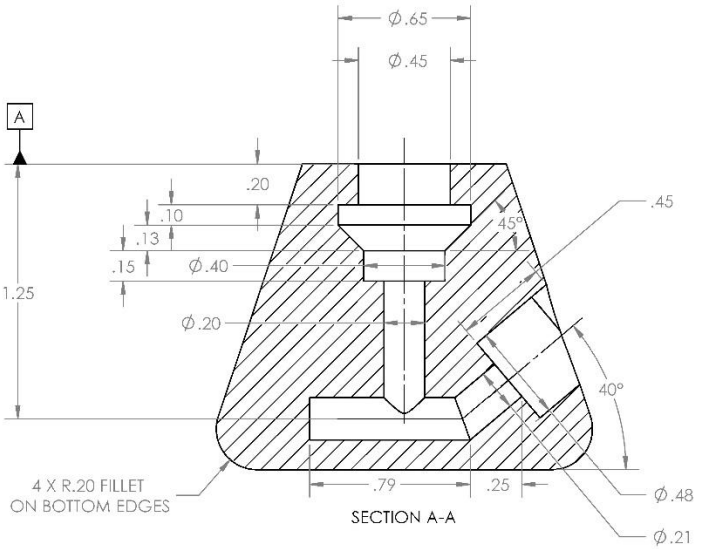


Cal Poly Mechanical Engineering ME 430 - WTR 2023	Lab Section: 01 Dwg. #:	SHR PROJECT Mat'l:	Title: ULTRASOUND HANDLE Date: 03/14/2023	Drwn. By: KATIE STONE Scale: 1:1	Chkd. By: ME STAFF


NOTES:
UNLESS OTHERWISE SPECIFIED
1. ALL DIMS IN INCHES
2. R .10 FILLET
3. TOLERANCES:
X.XX = ±.01
X.XXX = ±.002
ANGLES = ± 2°
ISOMETRIC VIEW
SCALE: 1:1
Ø1.00
A
2.0 X 1.5 LOFT
1.50
Cal Poly Mechanical Engineering
ME 430 - WTR 2023
Lab Section: 01
Dwg. #:
SHP PROJECT
Nxt Alb:
Title: ULTRASOUND HEAD
Date: 03/16/2023
Scale: 2:1
Drwn. By: KATIE STONE
Chkd. By: ME STAFF

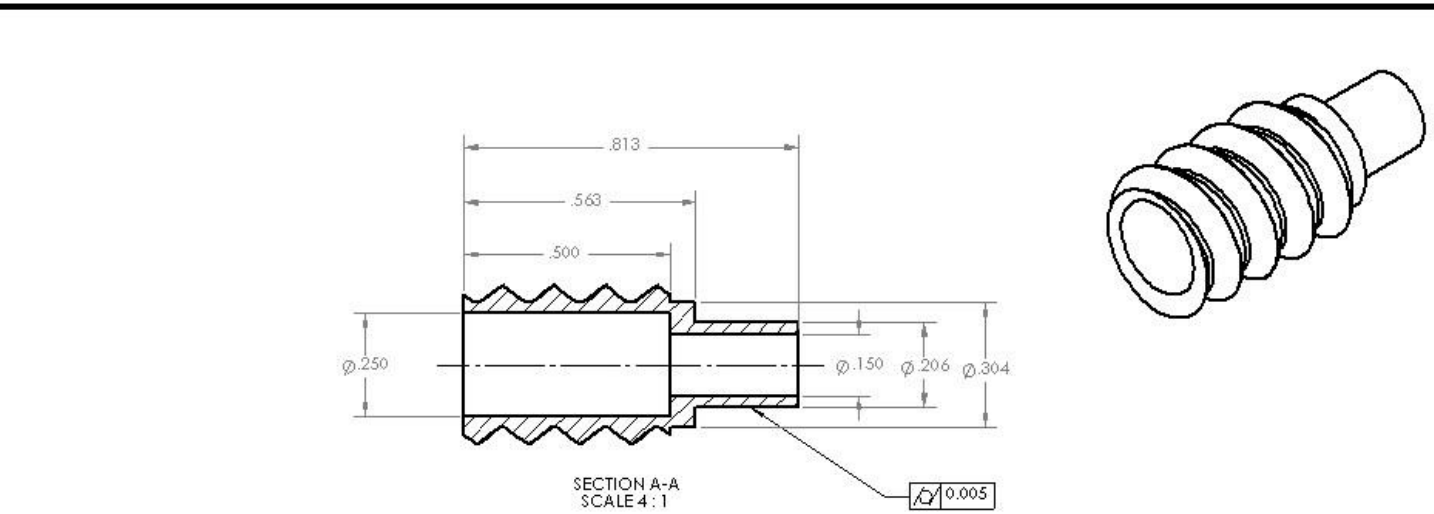
NOTES:
UNLESS OTHERWISE SPECIFIED
1. ALL DIMS IN INCHES
2. TOLERANCES:
X.XX = ±.01
X.XXX = ±.002
ANGLES = ± 2°

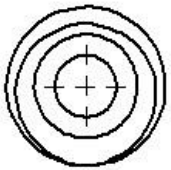


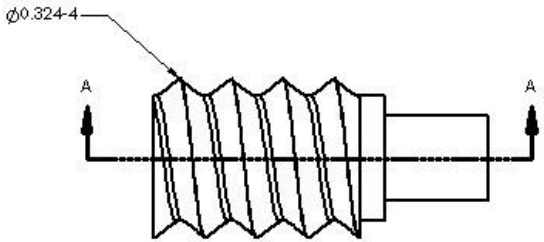


SECTION A-A

Cal Poly Mechanical Engineering	Lab Section: 01	SNR PROJECT	Title: ULTRASOUND HEAD	Drwn. By: KATIE STONE
ME 430 - WTR 2023	Dwg. #:	Nxt Asb:	Date: 03/16/2023 Scale: 2:1	Chkd. By: ME STAFF



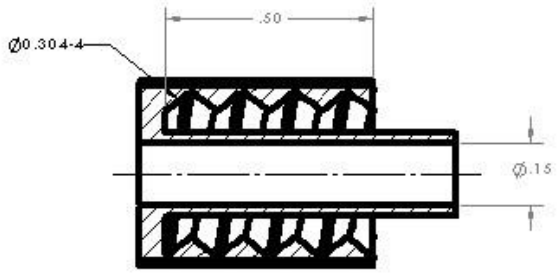




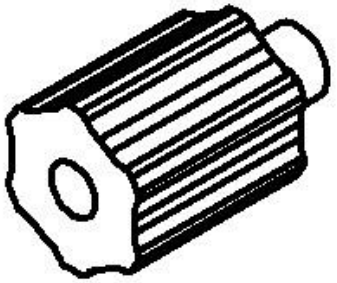
NOTES:
UNLESS OTHERWISE SPECIFIED
1. ALL DIMS IN INCHES
2. TOLERANCES:
   X.XX = ±.01
   X.XXX = ±.002
   ANGLES = ± 2°
3. CUSTOM THREADS USED:
   PITCH Ø0.324 IN
   MAJOR Ø0.385 IN
   MINOR Ø0.304 IN
   SINGLE LEAD

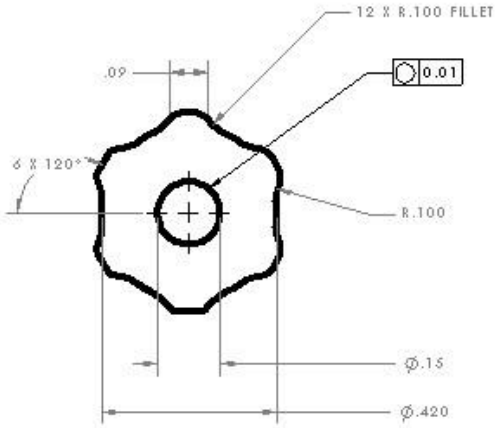
Cal Poly Mechanical Engineering ME 430 - WTR 2023	Lab Section: 01 Dwg. #:	SHR PROJECT Nxt Asb:	Title: TUOHY BORST FEMALE Date: 03/16/2023	Scale: 4:1	Drwn. by: KATIE STONE Chkd. by: ME STAFF

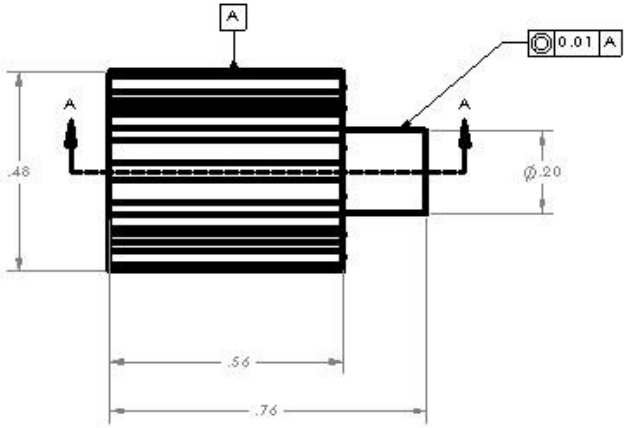
NOTES:
UNLESS OTHERWISE SPECIFIED
1. ALL DIMS IN INCHES
2. TOLERANCES:
X.XX = ±.01
X.XXX = ±.002
ANGLES = ± 2°
3. CUSTOM THREADS USED:
PITCH Ø0.324 IN
MAJOR Ø0.385 IN
MINOR Ø0.304 IN
SINGLE LEAD



SECTION A-A
SCALE 4 : 1

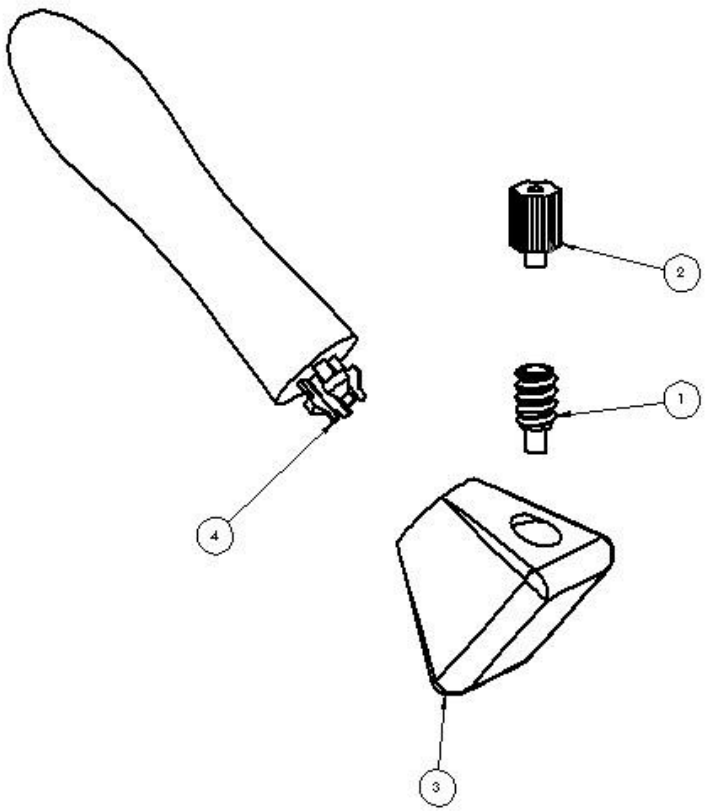


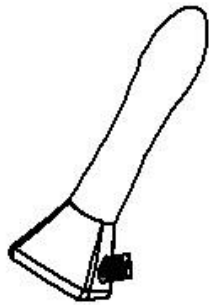




Cal Poly Mechanical Engineering ME 430 - WTR 2023	Lab Section: 01 Dwg. #:	SNR PROJECT Nxt Asb:	Title: Tushy Bent Male Date: 03/14/2023	Scale: 4:1	Drwn. By: KATIE STONE Chkd. By: ME STAFF

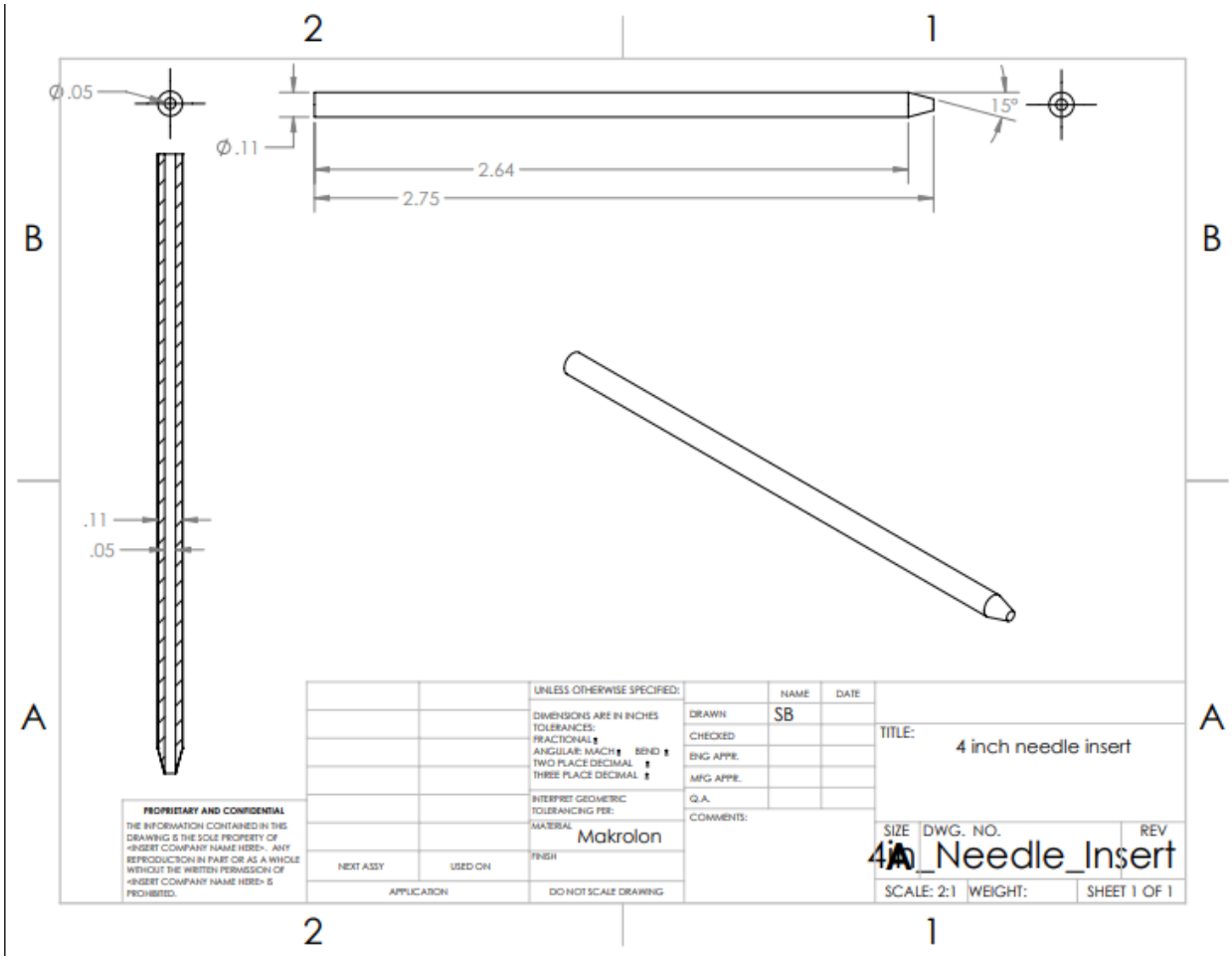
ITEM NO.	DESCRIPTION	QTY.
1	Tuohy Borst Female	1
2	Tuohy Borst Male	1
3	Head Version 4	1
4	Handle Version 2	1

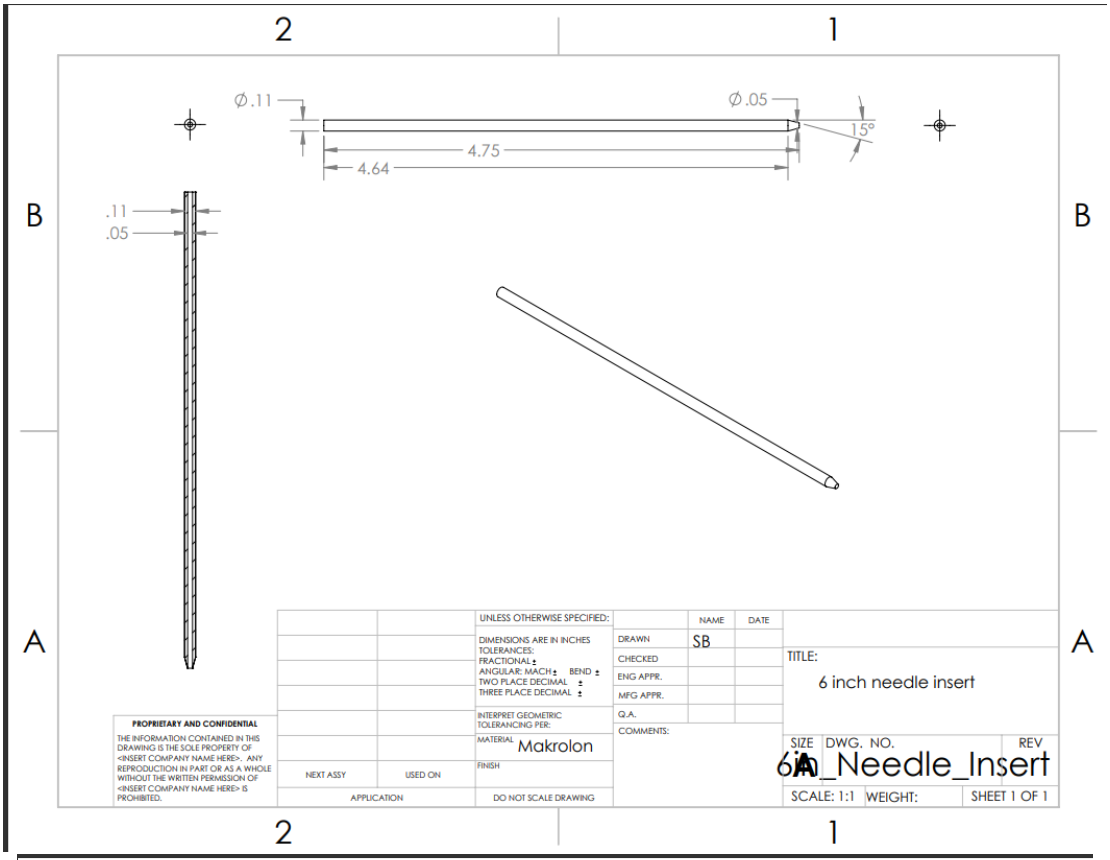




FULL ASSEMBLY
SCALE: 1:2

Cal Poly Mechanical Engineering ME 430 - WTR 2023	Lab Section: 01	SHR PROJECT	Title: ULTRASOUND ASSEMBLY		Drwn. By: KATIE STONE
	Dwg. #:	Next Asb:	Date: 03/14/2023	Scale: 1:1	Chkd. By: ME STAFF


Ø.05
Ø.11
2.64
2.75
15°
.11
.05
PROPRIETARY AND CONFIDENTIAL
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF <INSERT COMPANY NAME HERE>. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF <INSERT COMPANY NAME HERE> IS PROHIBITED.
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL
ANGULAR: MACH BEND
TWO PLACE DECIMAL
THREE PLACE DECIMAL
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
Makrolon
FINISH
NEXT ASSY
USED ON
APPLICATION
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
SB
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
TITLE:
4 inch needle insert
SIZE
DWG. NO.
REV
4in_Needle_Insert
SCALE: 2:1
WEIGHT:
SHEET 1 OF 1


2
1
B
A
Ø.11
Ø.05
15°
4.75
4.64
.11
.05
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL Makrolon
FINISH
NEXT ASSY
USED ON
APPLICATION
DO NOT SCALE DRAWING
NAME
DATE
DRAWN SB
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
PROPRIETARY AND CONFIDENTIAL
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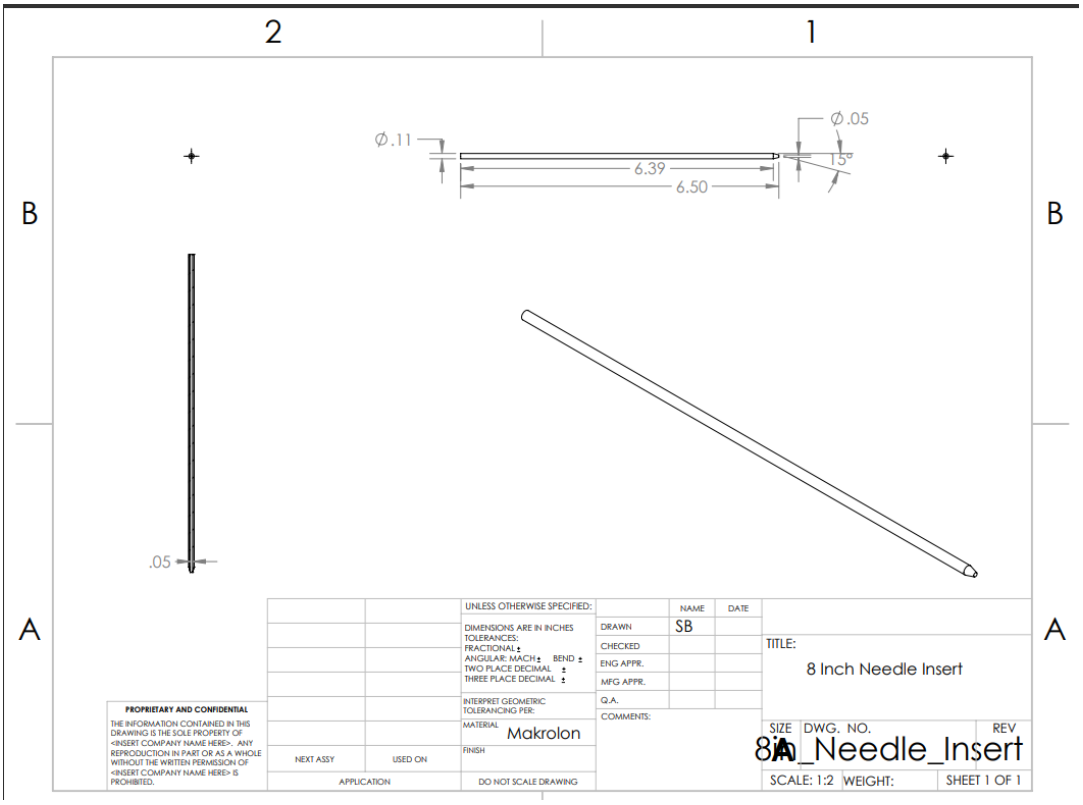
TITLE:
6 inch needle insert
SIZE A
DWG. NO.
6in_Needle_Insert
REV
SCALE: 1:1
WEIGHT:
SHEET 1 OF 1


2
1
B
A
Ø.11
Ø.05
15°
6.39
6.50
.05
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL Makrolon
FINISH
NEXT ASSY
USED ON
APPLICATION
DO NOT SCALE DRAWING
NAME
DATE
DRAWN SB
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
PROPRIETARY AND CONFIDENTIAL
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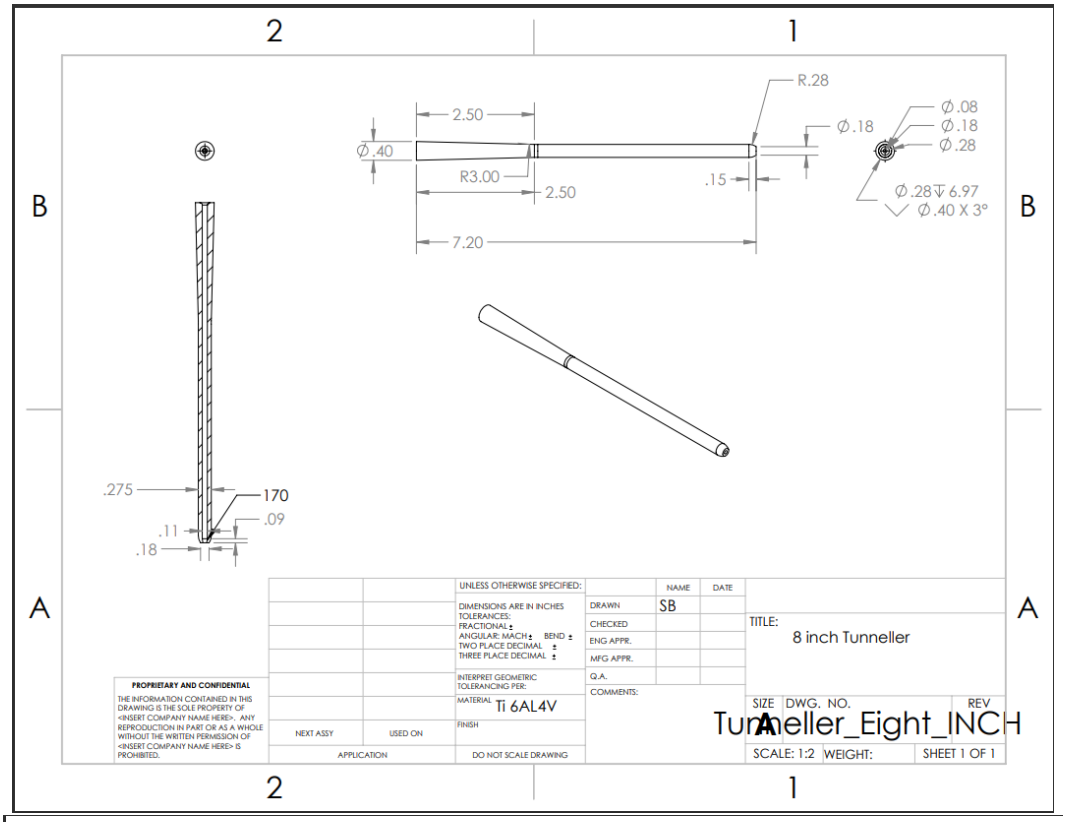
TITLE:
8 Inch Needle Insert
SIZE A
DWG. NO.
8in_Needle_Insert
REV
SCALE: 1:2
WEIGHT:
SHEET 1 OF 1


2
1
B
A
2.50
R.28
Ø.40
Ø.18
Ø.08
Ø.18
Ø.28
R3.00
2.50
.15
Ø.28↧6.97
Ø.40 X 3°
7.20
.275
170
.09
.11
.18
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL Ti 6AL4V
FINISH
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
SB
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
TITLE:
8 inch Tunneller
SIZE
DWG. NO.
REV
A
Tunneller_Eight_INCH
SCALE: 1:2
WEIGHT:
SHEET 1 OF 1
NEXT ASSY
USED ON
APPLICATION
PROPRIETARY AND CONFIDENTIAL
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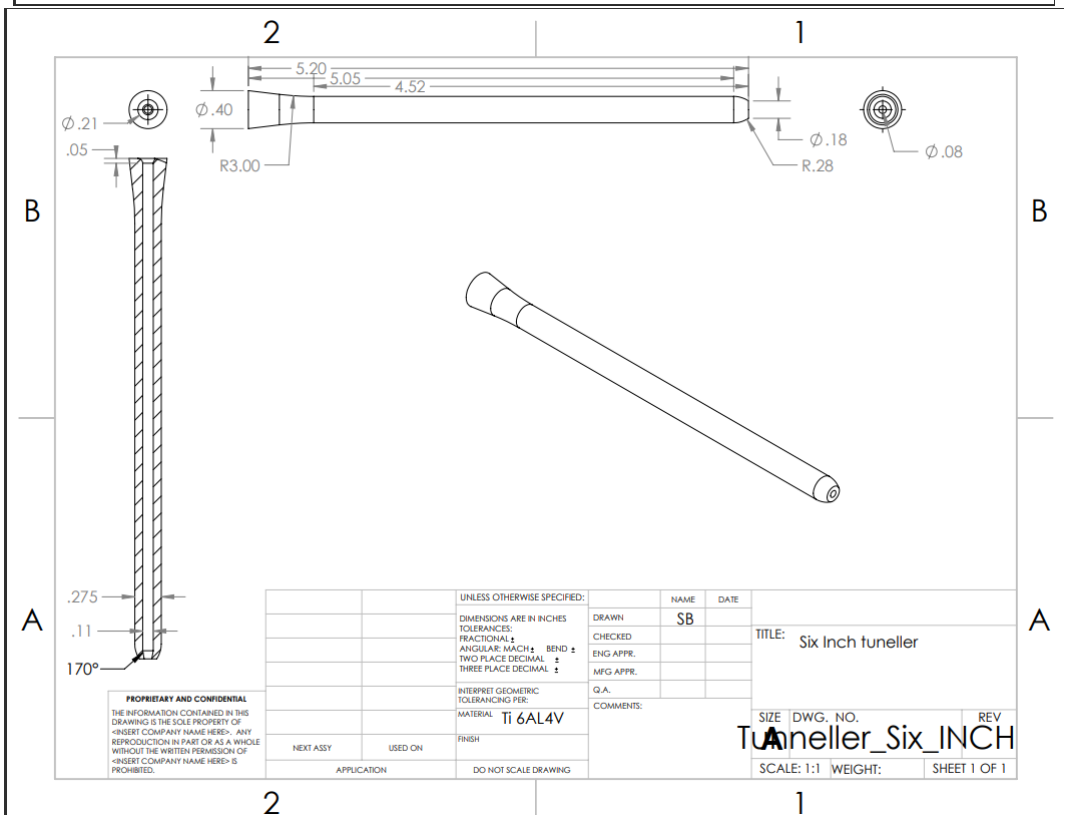
2
1
B
A
5.20
5.05
4.52
Ø.21
.05
Ø.40
R3.00
Ø.18
R.28
Ø.08
.275
.11
170°
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL Ti 6AL4V
FINISH
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
SB
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
TITLE:
Six Inch tunneller
SIZE
DWG. NO.
REV
A
Tunneller_Six_INCH
SCALE: 1:1
WEIGHT:
SHEET 1 OF 1
NEXT ASSY
USED ON
APPLICATION
PROPRIETARY AND CONFIDENTIAL
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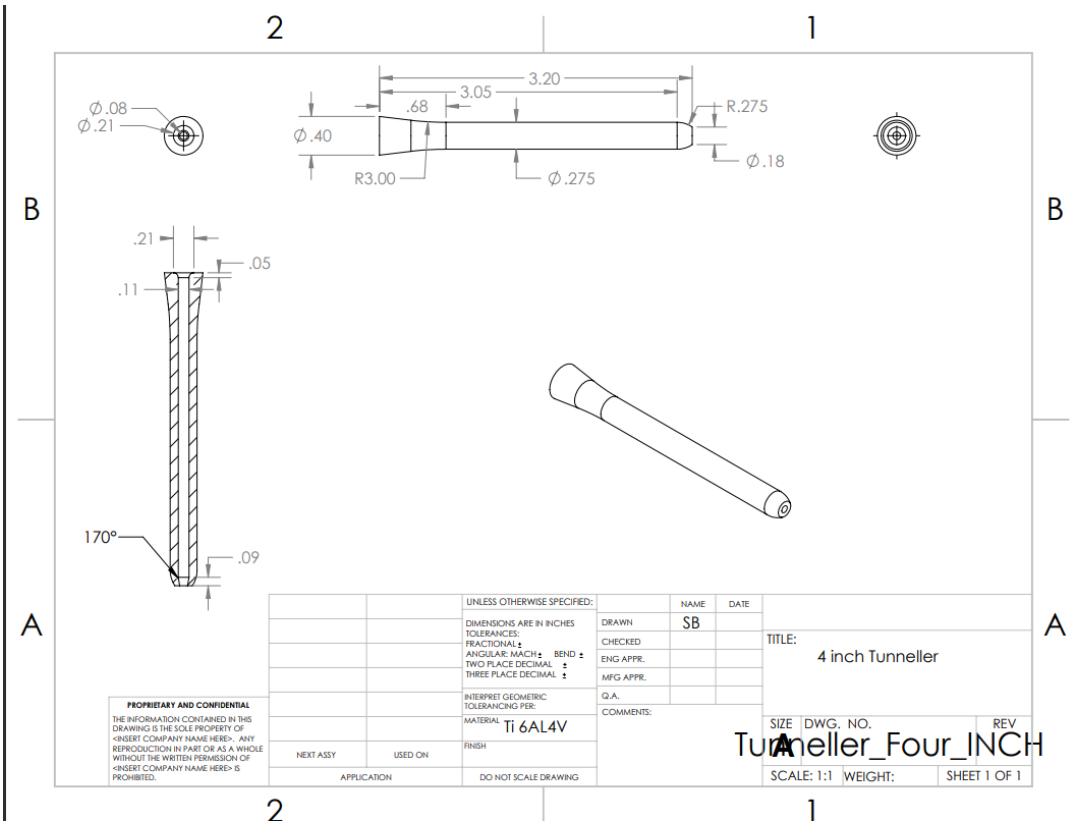
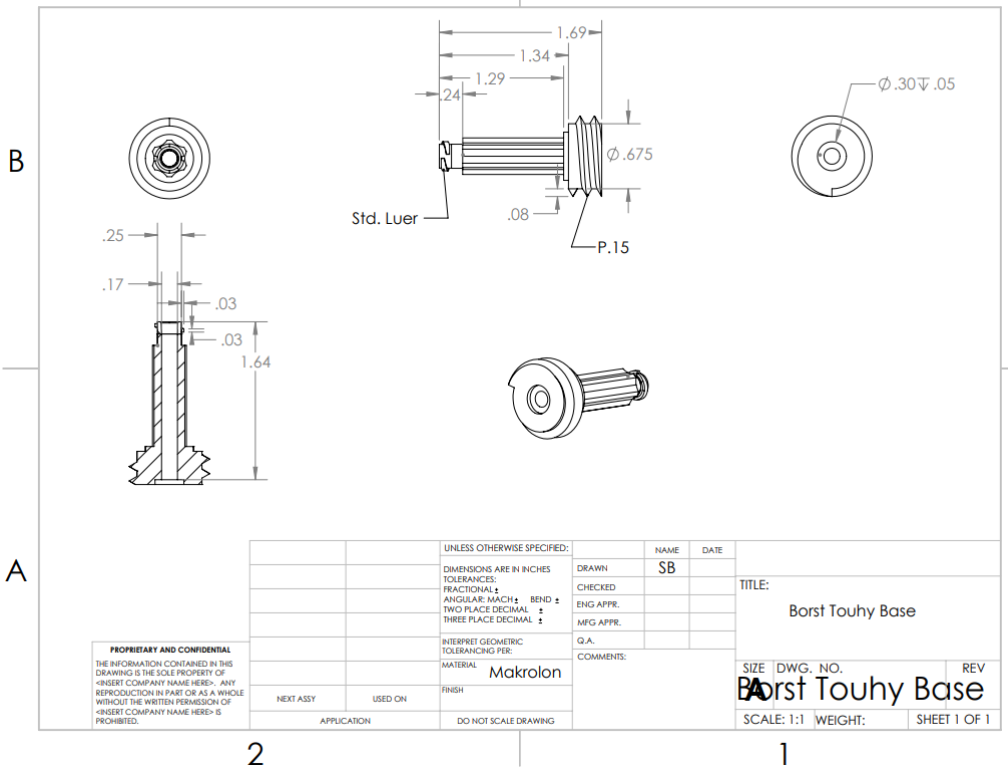
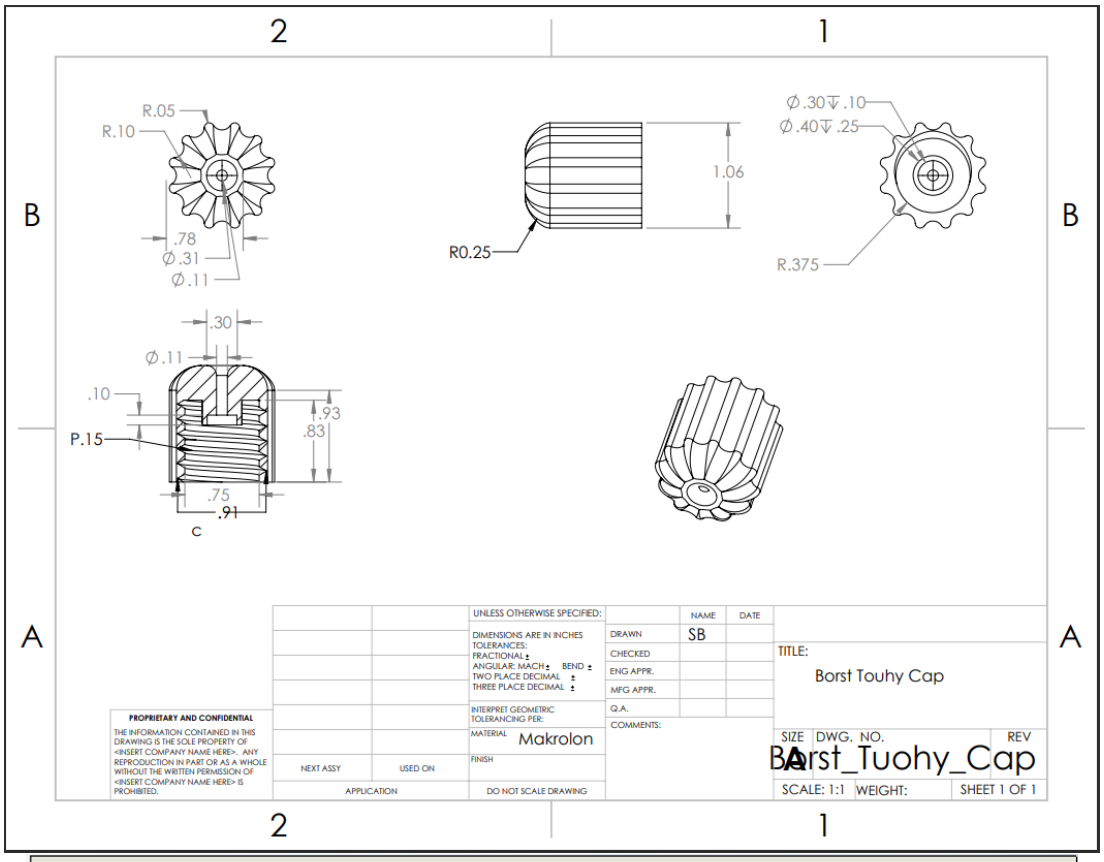

3.20
3.05
.68
R.275
Ø.08
Ø.21
Ø.40
Ø.18
R3.00
Ø.275
.21
.05
.11
170°
.09
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL Ti 6AL4V
FINISH
NAME
DATE
DRAWN SB
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
TITLE:
4 inch Tunneller
SIZE
DWG. NO.
REV
Tunneller_Four_INCH
SCALE: 1:1
WEIGHT:
SHEET 1 OF 1
NEXT ASSY
USED ON
APPLICATION
DO NOT SCALE DRAWING
PROPRIETARY AND CONFIDENTIAL
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF <INSERT COMPANY NAME HERE>. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF <INSERT COMPANY NAME HERE> IS PROHIBITED.


1.69
1.34
1.29
.24
Ø.675
.08
P.15
Std. Luer
Ø.30↧.05
.25
.17
.03
.03
1.64
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL Makrolon
FINISH
NAME
DATE
DRAWN SB
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
TITLE:
Borst Touhy Base
SIZE
DWG. NO.
REV
Borst Touhy Base
SCALE: 1:1
WEIGHT:
SHEET 1 OF 1
NEXT ASSY
USED ON
APPLICATION
DO NOT SCALE DRAWING
PROPRIETARY AND CONFIDENTIAL
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF <INSERT COMPANY NAME HERE>. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF <INSERT COMPANY NAME HERE> IS PROHIBITED.


R.05
R.10
.78
Ø.31
Ø.11
1.06
R0.25
Ø.30↧.10
Ø.40↧.25
R.375
.30
Ø.11
.10
P.15
.93
.83
.75
.91
C
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL Makrolon
FINISH
NEXT ASSY
USED ON
APPLICATION
DO NOT SCALE DRAWING
NAME
DATE
DRAWN SB
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
TITLE: Borst Touhy Cap
SIZE
DWG. NO. Borst_Tuohy_Cap
REV
SCALE: 1:1
WEIGHT:
SHEET 1 OF 1
PROPRIETARY AND CONFIDENTIAL
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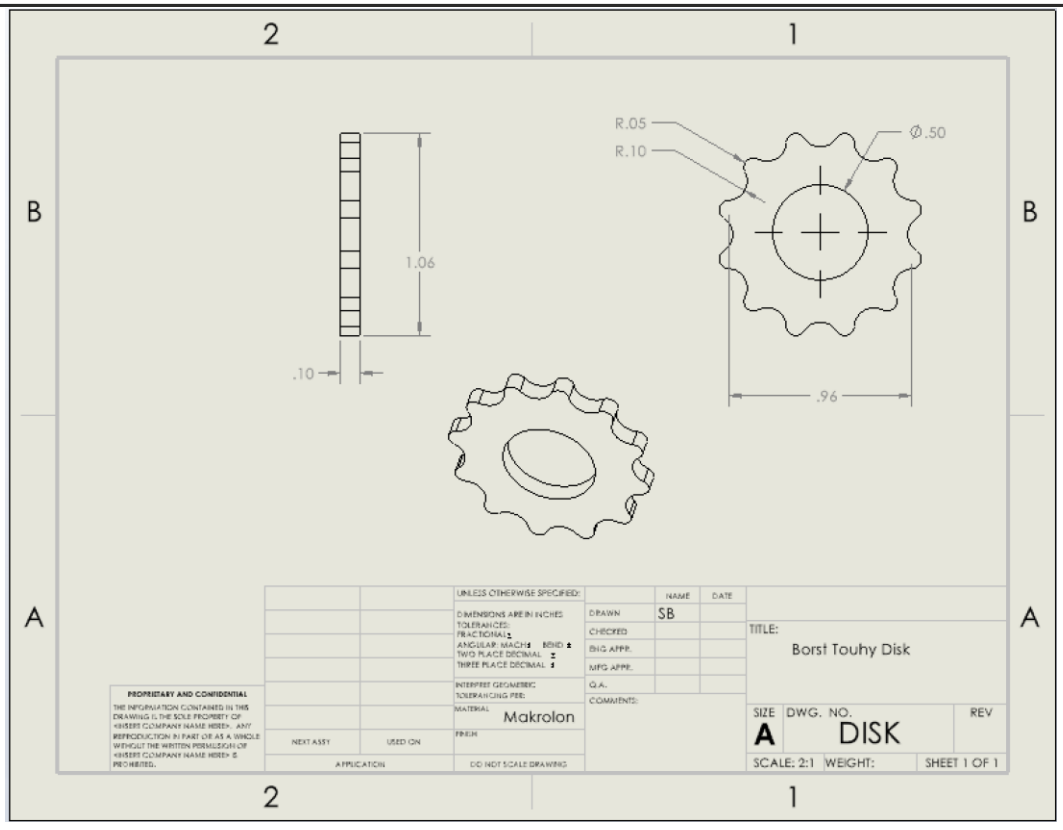
1.06
.10
R.05
R.10
Ø.50
.96
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL Makrolon
FINISH
NEXT ASSY
USED ON
APPLICATION
DO NOT SCALE DRAWING
NAME
DATE
DRAWN SB
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
TITLE: Borst Touhy Disk
SIZE A
DWG. NO. DISK
REV
SCALE: 2:1
WEIGHT:
SHEET 1 OF 1
PROPRIETARY AND CONFIDENTIAL
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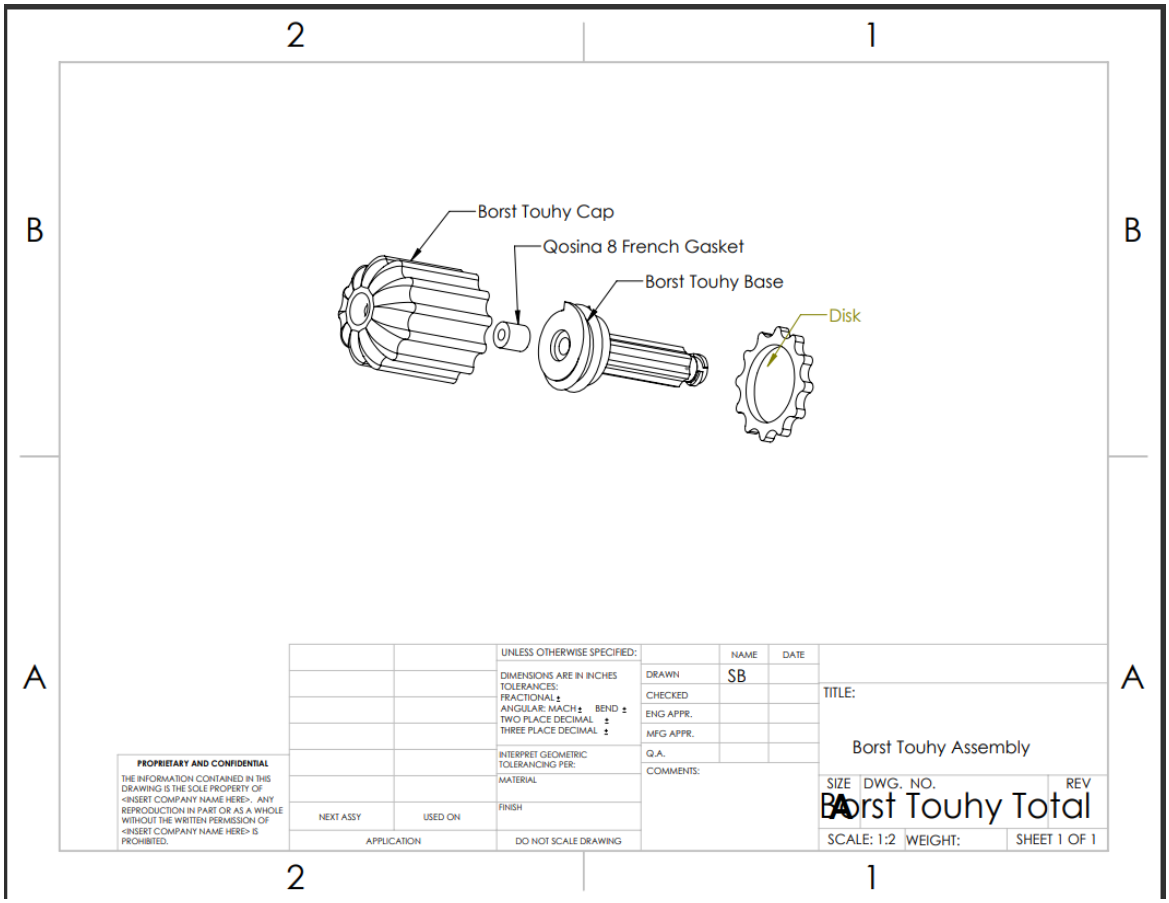
2
1
B
B
A
A
Borst Touhy Cap
Qosina 8 French Gasket
Borst Touhy Base
Disk
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
FINISH
NEXT ASSY
USED ON
APPLICATION
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
SB
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
TITLE:
Borst Touhy Assembly
SIZE
DWG. NO.
REV
A
Borst Touhy Total
SCALE: 1:2
WEIGHT:
SHEET 1 OF 1
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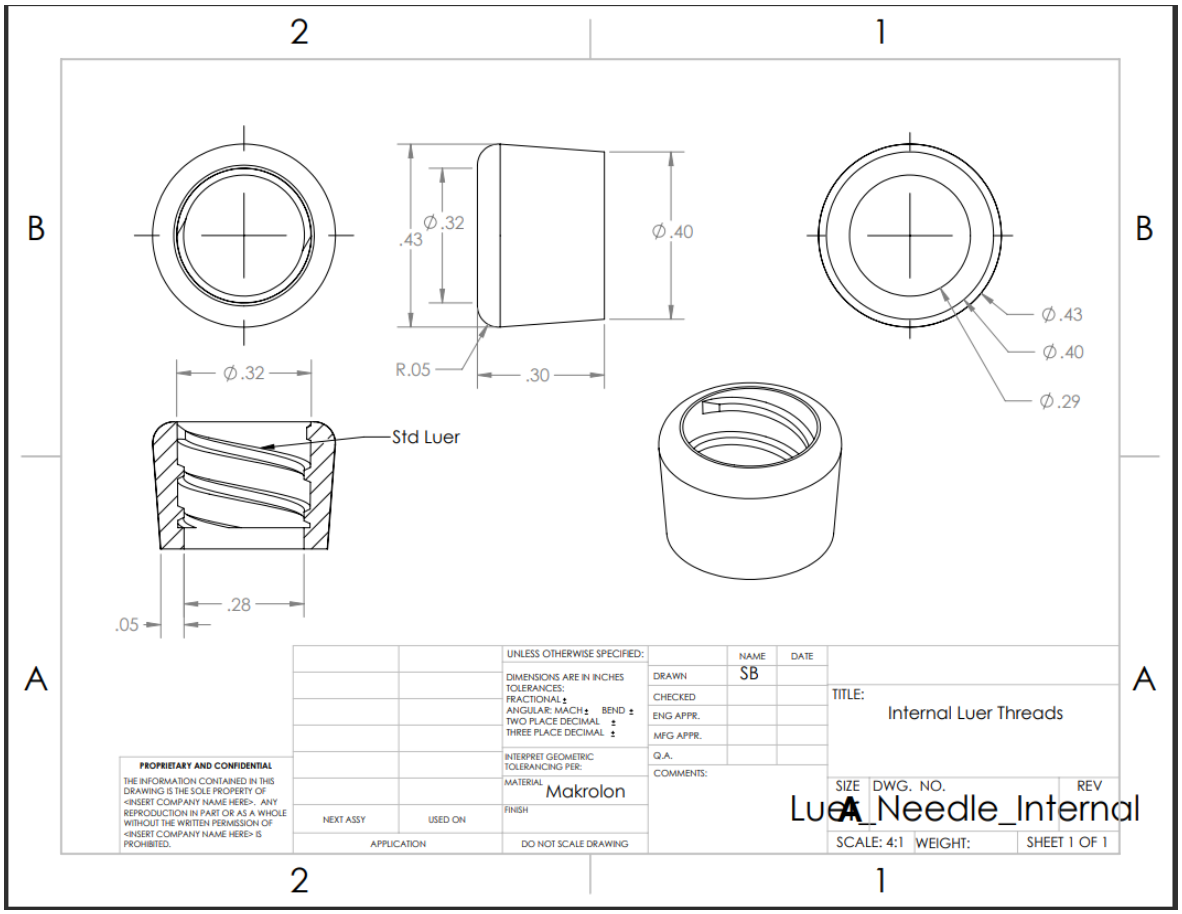
2
1
B
A
Ø .32
.43
Ø .40
R.05
.30
Ø .43
Ø .40
Ø .29
Ø .32
Std Luer
.05
.28
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
Makrolon
FINISH
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
SB
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
TITLE:
Internal Luer Threads
SIZE
A
DWG. NO.
Luer_Needle_Internal
REV
SCALE: 4:1
WEIGHT:
SHEET 1 OF 1
NEXT ASSY
USED ON
APPLICATION
PROPRIETARY AND CONFIDENTIAL
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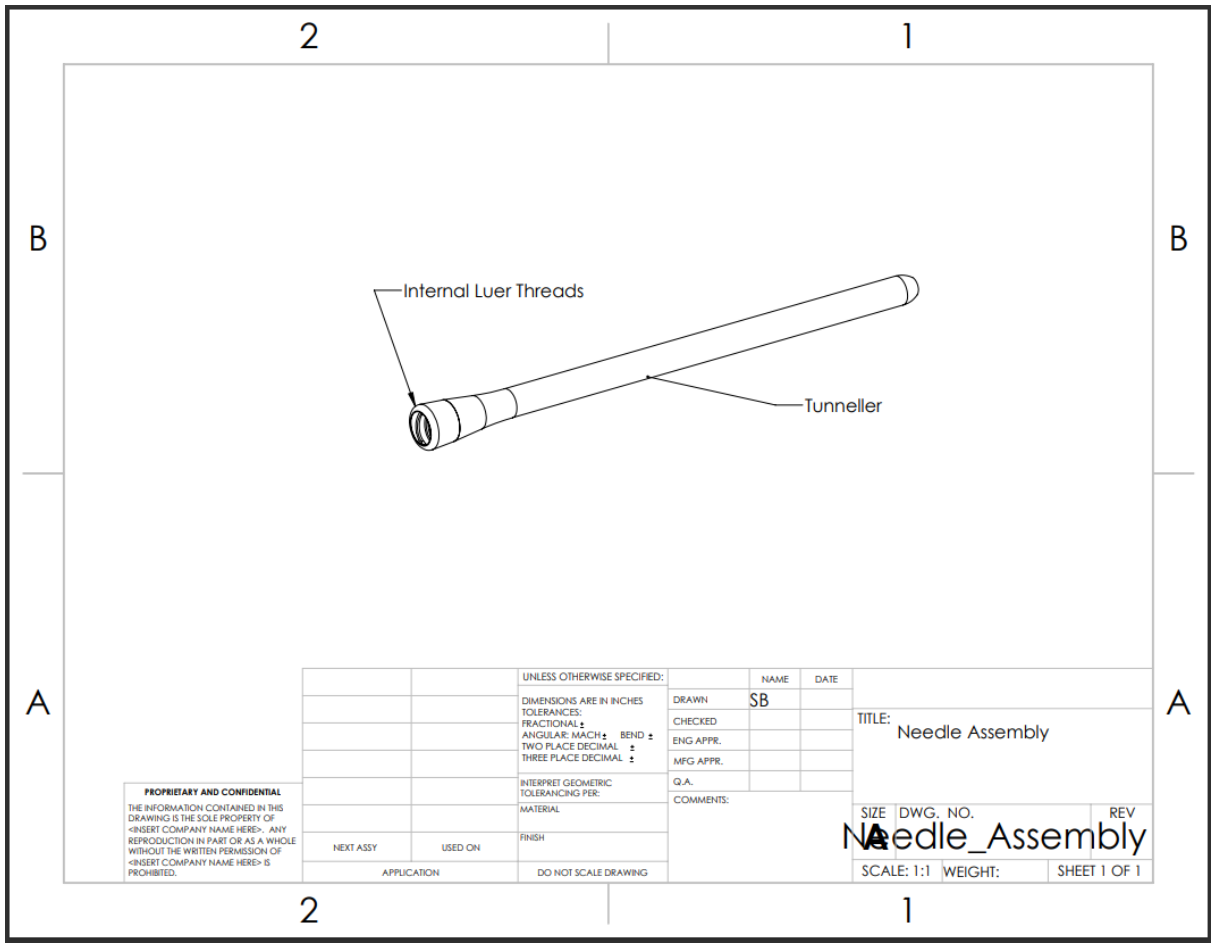
2
1
B
B
Internal Luer Threads
Tunneller
A
A
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
FINISH
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
SB
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
TITLE:
Needle Assembly
SIZE
A
DWG. NO.
Needle_Assembly
REV
SCALE: 1:1
WEIGHT:
SHEET 1 OF 1
NEXT ASSY
USED ON
APPLICATION
PROPRIETARY AND CONFIDENTIAL
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2
1

A-8: Failure Modes & Effects Analysis

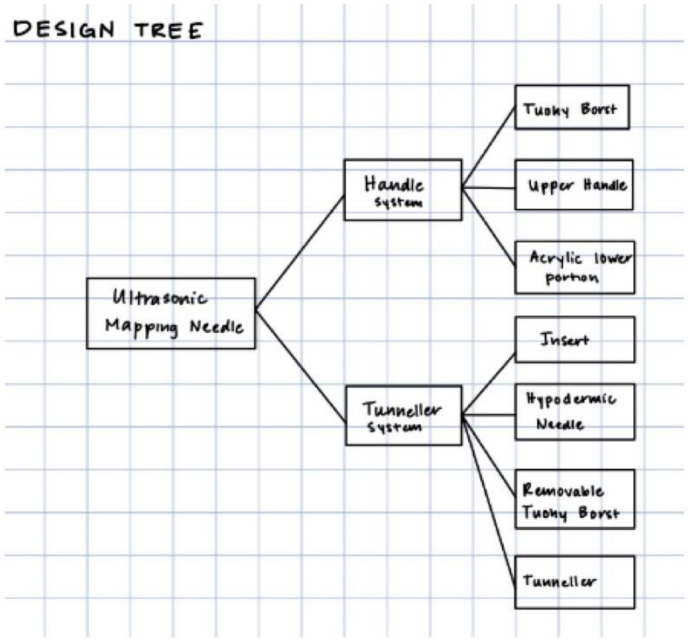
FMEA UltraSonic Needle

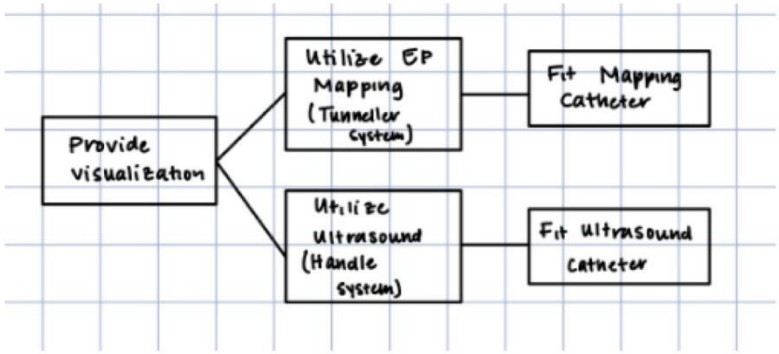
Stuart Bembenek

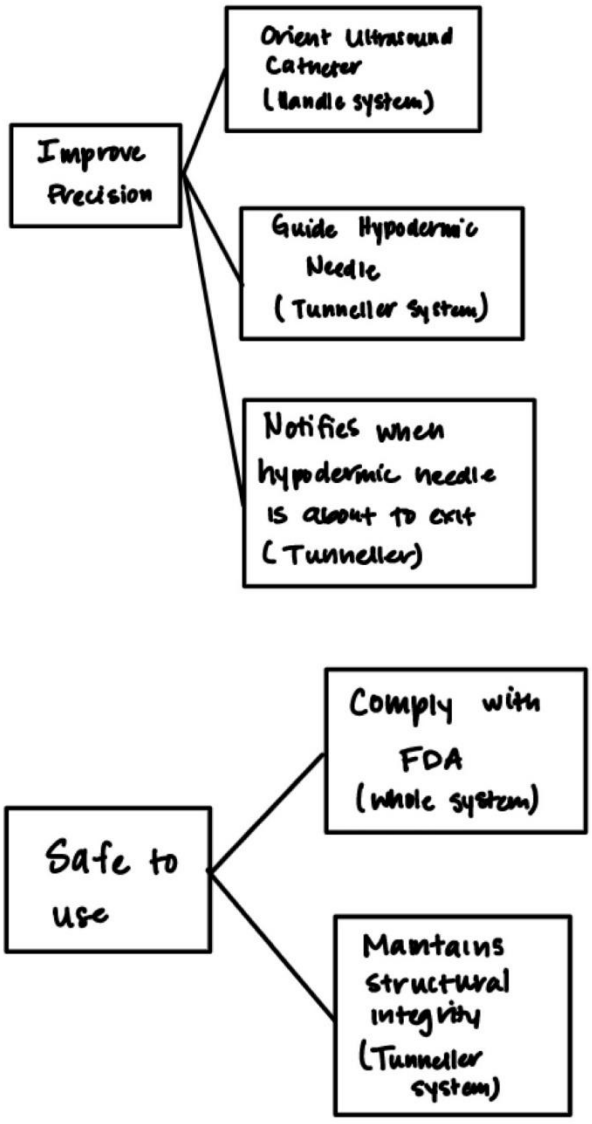
Katie Stone

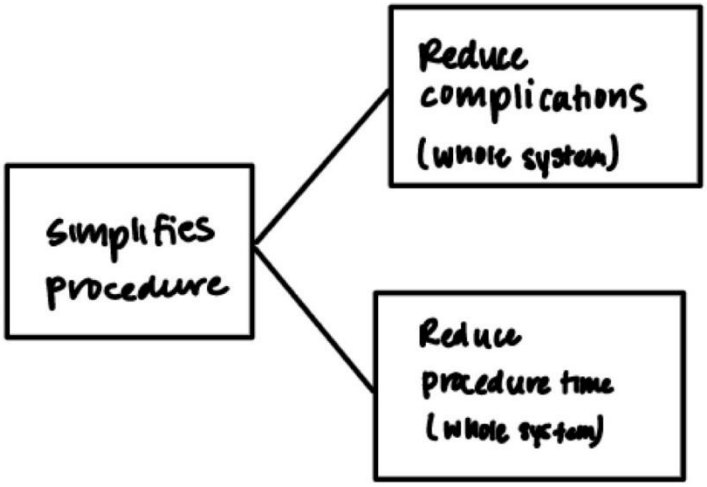
6/02/2022

Function Trees





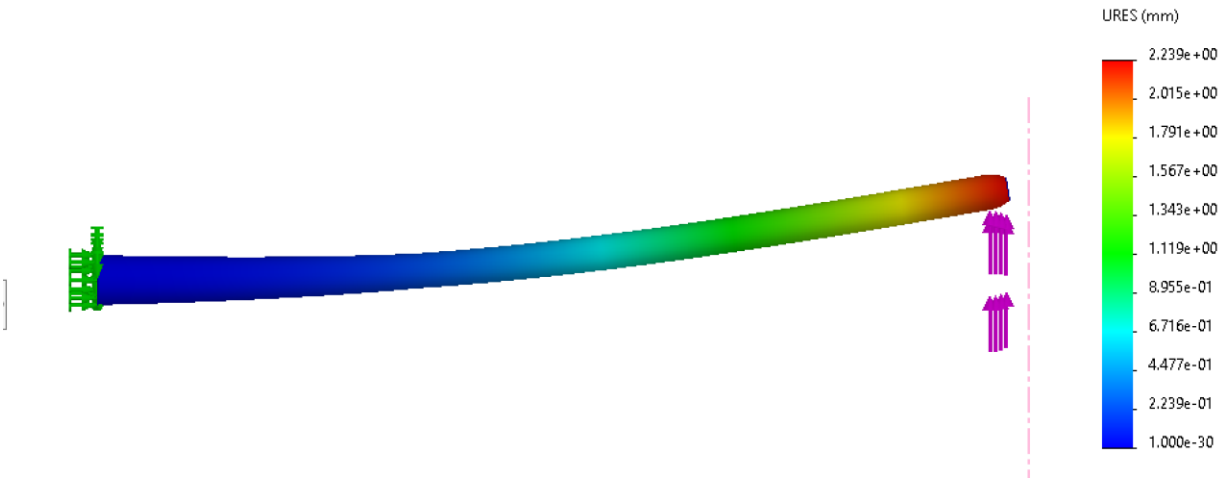

Improve Precision
Orient Ultrasound Catheter (Handle system)
Guide Hypodermic Needle (Tunneller System)
Notifies when hypodermic needle is about to exit (Tunneller)
Safe to use
Comply with FDA (whole system)
Maintains structural integrity (Tunneller system)



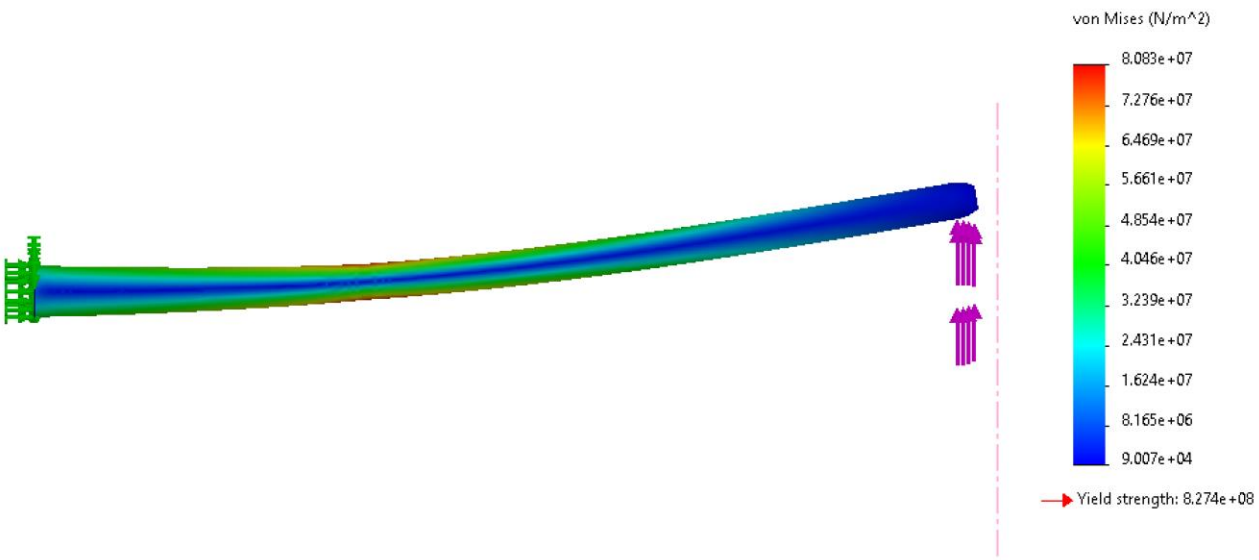
FMEA

System / Function	Potential Failure Mode	Potential Effects of the Failure Mode	Severity	Potential Causes of the Failure Mode	Current Preventative Activities	Occurence	Current Detection Activities	Detection	Priority	Recommended Action(s)	Responsibility & Target Completion Date	Actions Taken	Severity	Occurence	Criticality
Handle/ Utilize Ultrasound	Doesn't Fit/Guide Catheter Correctly	a) Damages Catheter b) Doesn't produce clear picture	8	1) Guide too short 2) too sharp an angle 3) wrong material	1) Measure length of crystal 2) Do not bend crystal 3) Use compatible material	4	Force Analysis and Testing	2	64	Test prototype	Stu/Katie 10/22		8	2	1
Tunneller/ Utilize EP Mapping	Blocks Position location, doesn't fit catheter	Stops device from locating needle tip	7	1) Incompatible material 2) Small Diameter	1) Measure diameter of catheter 2) Use compatible material	2	Measurement and testing	2	28	Test prototype	Stu/Katie 10/22		7	1	1
Handle/ Orient Ultrasound	Doesn't allow easy orientation	increased time to set up	3	Inadequate apparatus	Continued material research	6	Research and testing	1	18	Test prototype	Stu/Katie 10/22		3	3	1
Tunneller/ Guide Hypodermic Needle	Needle is not guided accurately	decreased needle accuracy	8	diameter is too large	Needle measurement	2	Measurement and testing	1	16	Test prototype	Stu/Katie 10/22		8	1	1
Tunneller/ Maintains Structural Integrity	Tunneller Flexes	Misplaced Puncture	9	wrong material/thickness	Force analysis, FEA, Measurement	4	Force Analysis, Testing, FEA	1	36	Test prototype under load	Stu/Katie 10/22		9	1	1
Tunneller/ Maintains Structural Integrity	Tunneller Breaks	Piece must be surgically removed	10	wrong material/thickness	Force analysis, FEA, measurement	4	Force Analysis, Testing, FEA	2	80	Test prototype under load	Stu/Katie 10/22		10	1	1
Whole System/ Comply with FDA	Materials/Use not compliant	Product is not allowed to go to market	10	Wrong Material Selection	Continued material research, documented testing	4	Material selection/compliance	4	160	Submit material plans for review	Stu/Katie 10/1		10	2	2
Whole System/ Reduce complications	Product does not limit complications	Product is not accepted by users	9	Needle is less accurate than expected	Testing and tolerance design	1	Testing and Tolerance Design	5	45	Consumer Testing	Professional Trials10/22		9	3	2
Whole System/ Reduce procedure time	Product is not convenient to use	Slower to be accepted by new users	6	Product is complicated, or difficult to set up	Procedure planning, focus on simple parts	5	Customer Testing	2	60	Consumer Testing	Professional Trials10/22		6	3	1
Tunneller/ Notifies operator when needle exits tunneller	Operator is unaware when needle leaves tunneller	Difficulty gaining access/ frustration with procedure Product not accepted by users	7	Visual marker is ineffective to operators	Make marker obvious	1	Customer Testing	1	7	Testing Prototype	Stu/Katie/ Professional 10/22		7	1	1

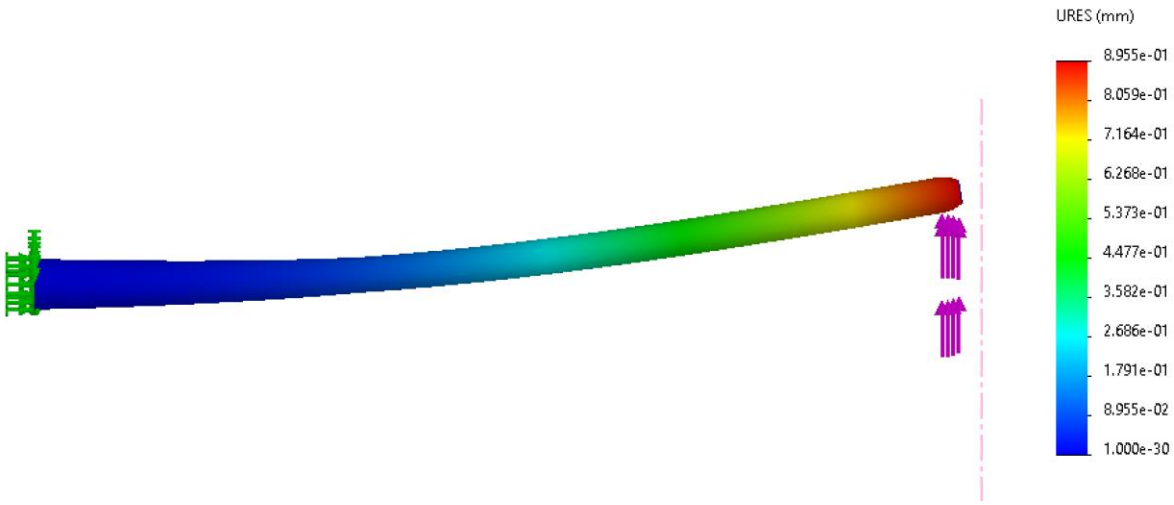
A-8-1


URES (mm)
2.239e+00
2.015e+00
1.791e+00
1.567e+00
1.343e+00
1.119e+00
8.955e-01
6.716e-01
4.477e-01
2.239e-01
1.000e-30

A-8-2


von Mises (N/m^2)
8.083e+07
7.276e+07
6.469e+07
5.661e+07
4.854e+07
4.046e+07
3.239e+07
2.431e+07
1.624e+07
8.165e+06
9.007e+04
Yield strength: 8.274e+08

A-8-3


URES (mm)
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8.059e-01
7.164e-01
6.268e-01
5.373e-01
4.477e-01
3.582e-01
2.686e-01
1.791e-01
8.955e-02
1.000e-30

DVP&R - Design Verification Plan (& Report)

Project:	Mapping Needle	Sponsor:	Professor Fabijanic				Edit Date:	

TEST PLAN

TEST RESULTS

Test #	Specification	Test Description	Measurements	Acceptance Criteria	Required Facilities/Equipment	Parts Needed	Responsibility	TIMING		Numerical Results	Notes on Testing
								Start date	Finish date		
1	4,6	Ergonomics, user is happy with prototypes	user is satisfied	user is satisfied	Lab testing	N/A	Stu/Katie	2/10/2023	2/18/2023	N/A	Sponsor approved. Test passed.
2	3	Test Ultrasound capabilities, material does not interfere with ultrasound	use of ultrasound, in lab testing	user is satisfied	Lab testing	Ultra sound and EP mapping system	Stu/Katie	2/10/2023	2/18/2023	N/A	Non-ferrous materials specified. Sponsor approved. Test Passed.
3	2	stiffness, tunneller does not deflect under load	deflection measurements	under 1 mm deflection at tip	Lab testing	ultrasound & EP mapping system	Stu/Katie	1/28/2023	2/7/2023	Deflection < 1	Refer to FEA
4	1	speed of procedure, user is satisfied	Time	total time with kit < 15s	user testing	stopwatch	Stu/Katie	3/13/2023	3/17/2023	Average time 14.12 ±1.45 seconds	Timed trials.
5	3	length, tunnellerplaces needle tip in correct spot	measurement	%success rate, at least 99%	ultrasound & EP mapping system	ultrasound & EP mapping system	Stu/Katie	3/13/2023	3/17/2023	N/A	Previously experimented with sponsor. Test passed.
6	1	Handle and Tunneller secure catheters	user testing	user is satisfied	Lab Testing	N/A	Stu/Katie	3/13/2023	3/17/2023	N/A	Final Tuohy Borst Mechanism created in the shop. Due to geometry of shaft on the ultrasound the catheter was able to stay in place. Tuohy Borst mechanism only further secured catheter in place. Test passed.

Design Verification Test Trials

Trial	Time [s]
1	15.61
2	12.18
3	15.63
4	12.61
5	13.08
6	14.80
7	15.38
8	13.6
9	12.55
10	15.71

A-10: Material Properties

Makrolon

Makrolon 2458

Grades / Medical devices	MVR (300 °C/1.2 kg) 19 cm³/10 min; medical devices; suitable for ETO and steam sterilization at 121 °C; biocompatible according to many ISO 10993-1 test requirements; low viscosity; easy release; injection molding - melt temperature 280 - 320 °C; available in transparent and opaque colors
ISO Shortname	ISO 7391-PC,MR,(,,)-18-9

	Property	Test Condition	Unit	Standard	typical Value
Rheological properties					
C	Melt volume-flow rate	300 °C; 1.2 kg	cm³/10 min	ISO 1133	19
C	Molding shrinkage, parallel	60x60x2 mm; 500 bar	%	ISO 294-4	0.65
C	Molding shrinkage, normal	60x60x2 mm; 500 bar	%	ISO 294-4	0,70
	Molding shrinkage, parallel/normal	Value range based on general practical experience	%	b.o. ISO 2577	0.5 - 0.7
	Melt mass-flow rate	300 °C; 1.2 kg	g/10 min	ISO 1133	20
Mechanical properties (23 °C/50 % r. h.)					
C	Tensile modulus	1 mm/min	MPa	ISO 527-1,-2	2400
C	Yield stress	50 mm/min	MPa	ISO 527-1,-2	65
C	Yield strain	50 mm/min	%	ISO 527-1,-2	6.1
C	Nominal strain at break	50 mm/min	%	ISO 527-1,-2	> 50
	Stress at break	50 mm/min	MPa	ISO 527-1,-2	70
	Strain at break	50 mm/min	%	b.o. ISO 527-1,-2	130
C	Tensile creep modulus	1 h	MPa	ISO 899-1	2200
C	Tensile creep modulus	1000 h	MPa	ISO 899-1	1900
	Flexural modulus	2 mm/min	MPa	ISO 178	2350
	Flexural strength	2 mm/min	MPa	ISO 178	97
	Flexural strain at flexural strength	2 mm/min	%	ISO 178	7.1
	Flexural stress at 3.5 % strain	2 mm/min	MPa	ISO 178	73
C	Charpy impact strength	23 °C	kJ/m²	ISO 179-1eU	N
C	Charpy impact strength	-30 °C	kJ/m²	ISO 179-1eU	N
	Charpy impact strength	-60 °C	kJ/m²	ISO 179-1eU	N
	Charpy notched impact strength	23 °C; 3 mm	kJ/m²	ISO 7391/b.o. ISO 179-1eA	65P
	Charpy notched impact strength	-30 °C; 3 mm	kJ/m²	ISO 7391/b.o. ISO 179-1eA	14C
	Izod notched impact strength	23 °C; 3.2 mm	kJ/m²	b.o. ISO 180-A	75P(C)
	Izod notched impact strength	-30 °C; 3.2 mm	kJ/m²	b.o. ISO 180-A	12C
C	Puncture maximum force	23 °C	N	ISO 6603-2	5100
C	Puncture maximum force	-30 °C	N	ISO 6603-2	6000
C	Puncture energy	23 °C	J	ISO 6603-2	55
C	Puncture energy	-30 °C	J	ISO 6603-2	65
	Ball indentation hardness		N/mm²	ISO 2039-1	115
Thermal properties					
C	Glass transition temperature	10 °C/min	°C	ISO 11357-1,-2	146
C	Temperature of deflection under load	1.80 MPa	°C	ISO 75-1,-2	125
C	Temperature of deflection under load	0.45 MPa	°C	ISO 75-1,-2	139
C	Vicat softening temperature	50 N; 50 °C/h	°C	ISO 306	145
	Vicat softening temperature	50 N; 120 °C/h	°C	ISO 306	146
C	Coefficient of linear thermal expansion, parallel	23 to 55 °C	10^{-4}/K	ISO 11359-1,-2	0.65
C	Coefficient of linear thermal expansion, transverse	23 to 55 °C	10^{-4}/K	ISO 11359-1,-2	0.65
C	Oxygen index	Method A	%	ISO 4589-2	28
	Thermal conductivity, cross-flow	23 °C; 50 % r. h.	W/(m·K)	ISO 8302	0.20
	Resistance to heat (ball pressure test)		°C	IEC 60695-10-2	138
	Flash ignition temperature		°C	ASTM D1929	480
	Self ignition temperature		°C	ASTM D1929	550

Makrolon 2458

	Property	Test Condition	Unit	Standard	typical Value
Electrical properties (23 °C/50 % r. h.)					
C	Relative permittivity	100 Hz	-	IEC 60250	3.1
C	Relative permittivity	1 MHz	-	IEC 60250	3.0
C	Dissipation factor	100 Hz	10^{-4}	IEC 60250	5.0
C	Dissipation factor	1 MHz	10^{-4}	IEC 60250	90
C	Volume resistivity		Ohm·m	IEC 60093	1E14
C	Surface resistivity		Ohm	IEC 60093	1E16
C	Electrical strength	1 mm	kV/mm	IEC 60243-1	34
C	Comparative tracking index CTI	Solution A	Rating	IEC 60112	250
Other properties (23 °C)					
C	Water absorption (saturation value)	Water at 23 °C	%	ISO 62	0.30
C	Water absorption (equilibrium value)	23 °C; 50 % r. h.	%	ISO 62	0.12
C	Density		kg/m³	ISO 1183-1	1200
	Bulk density	Pellets	kg/m³	ISO 60	660
Material specific properties					
	Refractive index	Procedure A	-	ISO 489	1.586
	Haze for transparent materials	3 mm	%	ISO 14782	< 0.8
	Luminous transmittance (clear transparent materials)	1 mm	%	ISO 13468-2	89
C	Luminous transmittance (clear transparent materials)	2 mm	%	ISO 13468-2	89
	Luminous transmittance (clear transparent materials)	3 mm	%	ISO 13468-2	88
	Luminous transmittance (clear transparent materials)	4 mm	%	ISO 13468-2	87
Processing conditions for test specimens					
C	Injection molding-Melt temperature		°C	ISO 294	280
C	Injection molding-Mold temperature		°C	ISO 294	80
C	Injection molding-Injection velocity		mm/s	ISO 294	200

C These property characteristics are taken from the CAMPUS plastics data bank and are based on the international catalogue of basic data for plastics according to ISO 10350.

Impact properties: N = non-break, P = partial break, C = complete break

Ti-6AL4V ELI

Titanium Ti-6Al-4V ELI (Grade 23), Annealed

Categories: Metal; Nonferrous Metal; Titanium Alloy; Alpha/Beta Titanium Alloy

Material Notes: Information provided by Allvac and the references. Annealing Temperature 700-785ºC. ELI (Extra Low Interstitial) grade has lower impurity limits, especially oxygen and iron. Alpha-Beta Alloy

Applications: Applications requiring excellent fracture toughness and fatigue strength; aircraft, structural components, and biomedical implants.

Biocompatibility: Excellent, especially when direct contact with tissue or bone is required. Ti-6Al-4V's poor shear strength makes it undesirable for bone screws or plates. It also has poor surface wear properties and tends to seize when in sliding contact with itself and other metals. Surface treatments such as nitriding and oxidizing can improve the surface wear properties.

4 other heat treatments of this alloy are listed in MatWeb.

Key Words: Ti-6-4; ASTM Grade 23 titanium; UNS R56401 (ELI); Ti6Al4V, Ti64, biomaterials, biomedical implants, biocompatibility

Vendors: No vendors are listed for this material. Please click here if you are a supplier and would like information on how to add your listing to this material.

Physical Properties	Metric	English	Comments
Density	4.43 g/cc	0.160 lb/in³	

Mechanical Properties	Metric	English	Comments
Hardness, Brinell	326	326	Estimated from Rockwell C.
Hardness, Knoop	354	354	Estimated from Rockwell C.
Hardness, Rockwell C	35	35	
Hardness, Vickers	341	341	Estimated from Rockwell C.
Tensile Strength, Ultimate	860 MPa	125000 psi	
Tensile Strength, Yield	790 MPa	115000 psi	
Elongation at Break	15 %	15 %	
Modulus of Elasticity	113.8 GPa	16510 ksi	
Compressive Yield Strength	860 MPa	125000 psi	
Notched Tensile Strength	1170 MPa	170000 psi	K_t (stress concentration factor) = 3.5
Ultimate Bearing Strength	1740 MPa	252000 psi	e/D = 2
Bearing Yield Strength	1430 MPa	207000 psi	e/D = 2
Poissons Ratio	0.342	0.342	
Fatigue Strength	140 MPa @# of Cycles 1.00e+7	20300 psi @# of Cycles 1.00e+7	K_t (stress concentration factor) = 3.1
	300 MPa @# of Cycles 1.00e+7	43500 psi @# of Cycles 1.00e+7	unnotched
Fracture Toughness	100 MPa-m½	91.0 ksi-in½	K_{IC}
Shear Modulus	44.0 GPa	6380 ksi	
Shear Strength	550 MPa	79800 psi	Ultimate shear strength

Charpy Impact	24.0 J	17.7 ft-lb	V-notch

Electrical Properties	Metric	English	Comments
Electrical Resistivity	0.000178 ohm-cm	0.000178 ohm-cm	
Magnetic Permeability	1.00005	1.00005	at 1.6 kA/m
Magnetic Susceptibility	0.0000033	0.0000033	cgs/g

Thermal Properties	Metric	English	Comments
CTE, linear	8.60 µm/m-°C @Temperature 20.0 - 100 °C	4.78 µin/in-°F @Temperature 68.0 - 212 °F	
	9.20 µm/m-°C @Temperature 20.0 - 315 °C	5.11 µin/in-°F @Temperature 68.0 - 599 °F	average
	9.70 µm/m-°C @Temperature 20.0 - 650 °C	5.39 µin/in-°F @Temperature 68.0 - 1200 °F	average
Specific Heat Capacity	0.5263 J/g-°C	0.1258 BTU/lb-°F	
Thermal Conductivity	6.70 W/m-K	46.5 BTU-in/hr-ft²-°F	
Melting Point	1604 - 1660 °C	2919 - 3020 °F	
Solidus	1604 °C	2919 °F	
Liquidus	1660 °C	3020 °F	

Component Elements Properties	Metric	English	Comments
Aluminum, Al	5.5 - 6.5 %	5.5 - 6.5 %	
Carbon, C	<= 0.080 %	<= 0.080 %	
Hydrogen, H	<= 0.0125 %	<= 0.0125 %	
Iron, Fe	<= 0.25 %	<= 0.25 %	
Nitrogen, N	<= 0.030 %	<= 0.030 %	
Other, each	<= 0.10 %	<= 0.10 %	
Other, total	<= 0.40 %	<= 0.40 %	
Oxygen, O	<= 0.13 %	<= 0.13 %	
Titanium, Ti	88.1 - 91 %	88.1 - 91 %	As Balance; Elemental Composition per ASTM B265
Vanadium, V	3.5 - 4.5 %	3.5 - 4.5 %	

Descriptive Properties			
Velocity of Sound		4.987 km/s	Heat treatment not specified

References for this datasheet.