SeaSpine ContraTech

ME189 Final Design Packet

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1 Documents

1.1 Executive Summary

The aim of this project is to create an intervertebral disc preparation tool designed to articulate and completely remove disc material for the discectomy, or disc removal step, of Minimally-Invasive Transforaminal Lumbar Interbody Fusion (MIS-TLIF) surgical procedures. Current tools are unable to reach and clear the contralateral space – the far side of the disc [17][28], leading to longer surgical procedure and recovery times due to the increased surgeon time and effort, as well as inadequate preparation for the following spinal cage insertion and bone graft steps of the procedure. To directly address this challenge, the University of California, Santa Barbara's ContraTech team has partnered with spine surgical device company SeaSpine to design and develop an articulating surgical instrument for a thorough discectomy.

The final tool design is shown below in Figure 1, and features a thin, robust linkage mechanism with a ringed curette tool tip attached to the distal end. A dial at the proximal end of the device rotates a lead screw within the handle, articulating the tool.

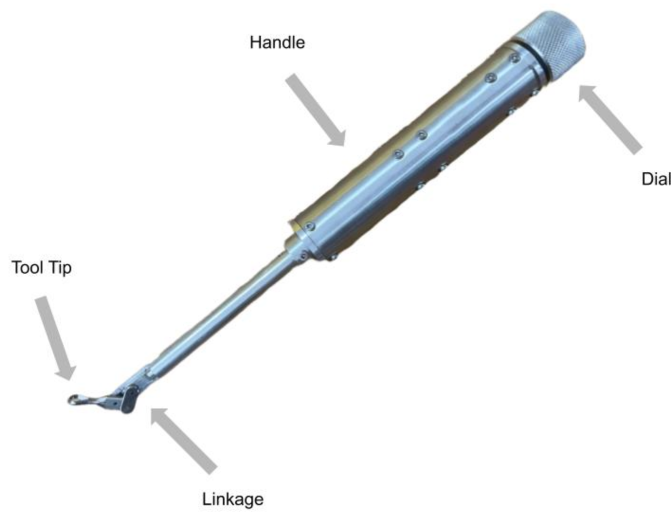


Figure 1: Final Design

The instrument has an angle of mobility adequate to reach the contralateral disc space, a shaft diameter of 9.5 mm, a neck width of less than 10 mm, a cytotoxicity level of one [19], a microbe reduction of 10^6 [30], an ability to withstand 132°C temperatures for autoclaving [27], and can withstand 40 N for scooping. This project is constrained to operate within the tight anatomical boundaries imposed by the spine and is subject to various forces as well as various surgical methods, as different surgeons may use the tool differently. To address all of these needs, designs were iterated upon through testing, engineering analysis, and feedback from a spine surgeon to produce the final design, which has been manufactured out of aluminum and steel.

To test our design, the team will complete a series of verification and validation tests on the manufactured assembly, including: geometric fit test, bone rasp and repetitive use fatigue test, and volumetric disc material removal test. Various forms of modeling and engineering analysis have been performed, including: FEA and failure analysis, geometric fit simulation, and analysis on fatigue, thermal expansion, linkage force transmission, impact force, buckling force, and lead screw force. The complete design, analysis, and safety operating procedures (SOP) related to the full development of the ContraTech instrument are documented in this design packet.

1.2 Introduction and Background

1.2.1 Technical Research

The spine provides the body with structure, support, and flexibility. The spine is made up of 24 vertebrae, which are small bones that stack up to create the spinal column. Between each vertebra is an intervertebral disc – a soft, gel-like cushion that acts as a shock absorber. Each disc has a strong outer ring called the annulus and a soft, jelly-like center called the nucleus pulposus. Facet joints link the vertebrae together and allow for vertebrae to move against each other [7].

MIS-TLIF procedures are performed on the lumbar spine, which describes the lower 5-6 vertebrae of the spine with vertebrae labeled L1 to L5 [6]. The purpose of this procedure is to fuse two or more vertebrae together, which limits mobility but increases spine strength and stability to treat a number of traumatic spine injuries and degenerative disc conditions [23]. The MIS-TLIF procedure involves approaching the spine from an angle posteriorly, using a tubular retractor to gain access to the spinal disc, removing the spinal disc, inserting a spinal cage and bone graft to promote bone growth, and using screws to connect the vertebrae as the bone heals and grows [7].

The minimally invasive approach employs Kambin's triangle to access the disc space. Kambin's triangle is defined as a right triangle over the dorsolateral disc. The hypotenuse is the exiting nerve root, the base is the superior border of the caudal vertebra, and the height is the traversing nerve root. This approach is the safest access to the disc space as it protects the epidural and nervous system [21]. From L1 to L5, the area of Kambin's triangle, and therefore the maximum tube diameter permissible, increases [29][11]. Inserting the tubular retractor at a 35° converging angle is optimal because the Kambin's triangle boundaries are visualizable without a facetectomy, so a large converging angle is optimal for our device [31].

The tool will be subjected to an impact force when positioning and a non-impact force when scooping material and rasping bone. For minimally invasive spine surgeries, an impact force of 100 N is imparted during bone graft insertion and 573 N during spinal cage insertion [9]. For non-impulse tool insertion, the force ranges from 19.56 N to 29.75 N. Breaking through the outer annulus requires 20.55 N to 55 N [22].

Performing a discectomy on the contralateral side requires the tool's end effector to be at an angle with its entry vector. Patent US8394101B2 claims a discectomy tool which uses an outer sleeve with an angled end. The sleeve constrains the movement of the tool to the angle of the outer sleeve when the tool is pressed against an unconstrained end effector [12]. This tool's maximum angle of articulation is limited by the outer sleeve angle, which reduces the disc-clearing ability. To actuate the end effector, several handle designs are possible. Simple methods involve revolving the tool itself, as seen in patent US8915936B2 [12]. This design provides user benefits since the surgeon has an understanding of relative position. More complicated handle types, like kerrisons, are beneficial for control and stability [15]. A flexible torque transmission shaft can be used to transmit motion to the tip.

The materials used must be biocompatible. SeaSpine's current disc prep instruments are constructed primarily from stainless steel and silicone [27]. ISO 10993-1 includes standards for determining biocompatibility of medical devices [30]. Sterilization is determined successful when the microbial load is reduced by a factor of 10^6. SeaSpine's suggested method of sterilization is autoclaving, where AAMI ST79 guidelines dictate a temperature of 270°F, exposure time of 8 minutes, and minimum drying time of 30 minutes [27]. The biological materials interfacing with our device include fibrous cartilage in the annulus, elastin fibers and proteoglycans in the nucleus pulposus, and bone and cartilage in the vertebral endplates [16][24][18].

1.2.2 Physician Interview and Surgical Experience

On November 8, 2023, the team had the opportunity to go to SeaSpine's headquarters in Carlsbad, CA to take part in a Level-1 TLIF procedure on a cadaver to understand the procedure and problem better. During this experience, a qualitative understanding of the procedure steps and forces required was gained to guide the problem definition and key specifications.

On February 29, 2024, after undergoing several device design iterations, the team had the opportunity to speak with Dr. Nolan Wessell, an orthopedic spine surgeon in Colorado, about his experience performing MIS-TLIF procedures and his feedback on the design. Dr. Wessell explained his TLIF approach, noting that disc space distraction can be done to widen the disc space allowing for slightly larger tools and that he navigates within the disc space purely off of feel, while other surgeons may employ fluoroscopy, lights, or cameras.

Dr. Wessell enjoys using current devices that are five to six millimeters wide as he can easily maneuver to thoroughly clean the vertebral endplates. He prefers ringed curette tips as they are smaller and more versatile than traditional curettes or rasps, and allow for him to cut and remove material without changing tools. He does not anticipate impacting this tool, but notes that some physicians may use light impaction. He prefers visual indicators to know he has reached full tool tip articulation and a dial at the proximal end to apply more torque when binding inside the disc space. Meeting with Dr. Wessell provided valuable information that was incorporated into the final design.

1.3 Introduction and Final Specifications

The product being developed is a discectomy tool that can reach the posterior contralateral aspect of the disc space during a MIS-TLIF surgery. In order to limit tissue disruption, the tool is introduced into the disc space through Kambin's triangle using a tube retractor of limited size. The angle at which the tool enters the disc space constrains the tool tip to the near half of the space. The tool must be able to enter through the straight channel of the retractor; once through, the surgeon must have the ability to articulate the tip and orient it to remove the nucleus pulposus and rasp the vertebral body. The tool must be able to handle the aggressive nature of spine surgeries, such as sudden jerks and impacts from hammers. Additionally, the tool is operated within the human body, so it must be biocompatible, non-corrosive, and sterilizable with an autoclave.

Requirements:

1. The instrument must reach the posterior contralateral disc space to maximize the volumetric disc removal.
2. The instrument must fit through a 10 mm diameter cannula.
3. The instrument must be modular and/or expandable with a distal connection to allow attachment of common discectomy tools such as rotary scrapers, rasps, and box cutters of varying sizes.
4. The instrument must be biocompatible, easily cleanable, and able to withstand repeated sterilization.

Needs	Engineering Characteristics	Target Spec (Min)	Target Spec (Final)
Reach the contralateral disk space	Angle of mobility (P/F)	Pass	Pass
Fit inside retractor	Diameter (mm)	18 mm	9.5 mm
Articulate within the disc space	Width (mm)	10 mm	< 10 mm
Biocompatible	Cytotoxicity level (0-4)	Level 2	Level 1
Sterilizable	Microbe reduction	10^6	10^6
Handle high temperatures	Temperature	121°C	132°C
Impact Strength (straight)	Impact load (N)	500 N	1000 N
Scooping Force	Load (N)	30 N	40 N
Within budget	Dollar	$5000	$5000

Table 1: Target Specifications

These minimum requirement and target specifications were chosen after conducting a general research of the project's many facets, meeting with the SeaSpine team, and even witnessing/performing a TLIF surgery onsite. The minimum and target requirement is for our device to be able to reach the contralateral side, which is graded on a pass or fail basis. The smallest tube retractor diameter SeaSpine produces is 18 mm, so the tool should fit inside an 18 mm diameter tube at a minimum; however, a smaller ideal target of 10 mm would be preferable for surgeons since they will have more space to work within the retractor as well as be less invasive. Given the nature of the MIS-TLIF procedure, the tool will not have to endure some of the greater stresses found in spinal surgeries as the breaking of bones and connective tissues will be done beforehand with other tools. There is the possibility of light impaction to gain a better position within the disc space in the range of 500 N or 1000 N with a safety factor 2, which will be our target spec.

Since the tool is reusable, it must be able to withstand the standard reprocessing procedure at hospitals, the most rigorous step being sterilization via an autoclave. The autoclave will reach standard temperatures of 121°C and 132°C, and potentially more, so they are our minimum and maximum [27]. The main concern is with stresses induced by thermal expansion of the tool components. The tool must also be made in such a way that the sterilization cycle will reduce microbes by a factor of 10^6 [4]. As a medical device that operates within the body, the discectomy tool must be biocompatible with a cytoxicity level of 2 at a minimum with a target level of 1. Cytotoxicity grades are assigned based on an estimated percent of cell death and morphology. Such levels correspond to the toxicity of the tool's material to human cells, where lower levels indicate less toxicity [20]. A score of 2 corresponds to 50% lysis and a general cytotoxicity test pass [19].

For these purposes, a final concept was selected similar to that shown in Figure 1 where the actuation of the linkage will be provided by a linearly-moving element from the handle: a lead screw-based design. The linkage's width is also 9.5 mm, which fits within the disc space and allows the surgeon to have some room to work within. Overall, this final concept should meet all the requirements laid out in Table 1.

1.3.1 Tested Specifications

We were able to test the device's ability to reach the contralateral disk space both in CAD and physically in a mold of a disc space we printed. Also, as mentioned above, the tool measures only 9.5 mm in diameter and can thus fit inside a 10 mm retractor. An added and tested need is the device's ability to handle a nominal scooping load, which was validated during our fatigue testing. Finally, the device fits within the budget since we did not have to spend more than the budget we were allocated.

1.3.2 Untested Specifications

However, we were unable to test a few specifications. The device's biocompatability, sterilizability, and autoclavability were left untested due to a lack of means of doing so; even so, the materials selected for the device are intended to meet these specifications. Impact strength was also not tested due to fear of not being able to demonstrate the device or test other specifications. The aluminum prototype is more prone to mechanical failure, and the stainless steel parts did not arrive quickly enough for testing.

1.4 Description of Design

The device is composed of several components and the device is divided into subsections that remain relevant to the assembly.

1.4.1 Tool Tip

The tool tip refers to the distal end of the device. SeaSpine uses several different types of curette heads as well as distractors and tools. A selection of heads used by SeaSpine are listed below:

1. Rasp: used to file bone and hard material
2. Distractors (various): used in prying
3. Scrapers (various): used to cut material to provide room for curette operation
4. Curettes (angled, straight, teardrop): used to cut and remove disc material

1.4.2 Linkage

The main mechanism by which our device will reach the contralateral side. This subsection enters the disc during surgery. Our design will provide higher mobility by reaching larger angles than the previous devices. The linkage will have to be strong enough to withstand forces applied when operating. The construction is a linkage design using a combination of two shoulder bolts and a dowel used as pins and our custom geometry links. Notably, a shoulder bolt is hidden within P5 and moves along a sliding joint.

1.4.3 Dial

Dial is placed at the proximal end of the device. It runs through the handle and is rotated by the surgeon to articulate the curette tip. By rotating counterclockwise, it will articulate the curette tip and by rotating clockwise it will straighten the curette tip.

1.4.4 Handle

The handle is an aluminum tube that houses the connection between the dial at the end and the nut that articulates the lead screw. The shaft that connects these two (the nut connector) runs along two bearings to ensure a longer lifespan and smooth rotation. The front of the handle holds the connection between the nut and lead screw and P1. The pinned connection between P1 and the lead screw limits the max articulation of the curette head. The nut connector limits the movement of retraction of the curette head by bottoming out the lead screw in a bore hole.

The only constraint is that the head diameter will match with the neck of our device for smooth incorporation into SeaSpine's toolbox.

1.4.5 Assembly

The tool will be assembled in three main parts.

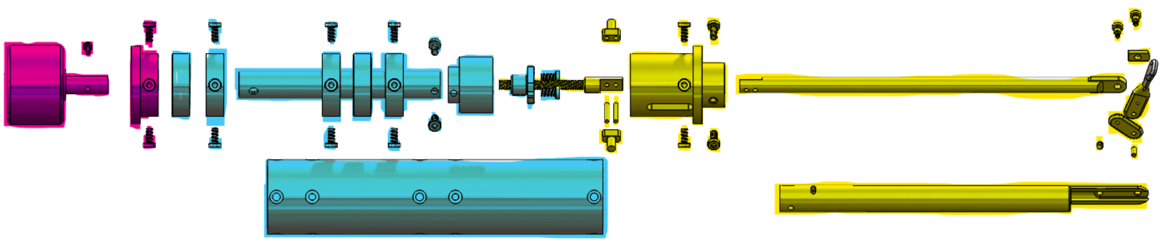


Figure 2: exploded assembly view

1. (Blue) Start assembling the handle with the nut and nut connector, then place the bearings into the shroud. Then the nut and nut connector sub-assembly will slide into the bearings and shroud.

2. (Pink) The rear section composed of the end cap and and dial are attached to the nut connector with a single bolt accessed through the access port in the shroud. Then the end cap can be screwed into the shroud.

3. (Yellow) Next the entire linkage can be made by first placing a shoulder bolt into P1, then sliding both into P5. The linkage portion with the currette can then be screwed in with the other shoulder bolt. At the other end, P5 is screwed into the front cap of the handle with two M3 screws. Then the lead screw can be pinned into P1 through the slots in the front shroud. The front assembly can now be placed into the handle and screwed into place.

1.5 Assembly Drawings

There is a single assembly of the device included. These drawings are an iteration of the current design. The assembly drawing is found in Appendix A.1.

1.6 Sub-assembly Drawings

The two sub-assemblies are the controls and the linkage, with drawings found in Appendix A.2.

1. Linkage Sub-Assembly
   The linkage sub-assembly (Figure 10) provides the actuation required to reach the contralateral side. As the inner rod slides through the outer tube toward the head of the sub-assembly the linkage actuates to a greater angle. When brought all the way back the linkage will be almost straight with the curette tip almost parallel to the tube. It will not be fully straight because it is constrained to prevent the linkage from slipping and actuating in the wrong direction. The load at the tip is designed to be translated into the tube through a base that is pinned. In figure 10 the base is on the back side.

2. Handle Sub-Assembly
   The control assembly consists of the handle and dial used to turn a lead screw nut to actuate a lead screw up and down. The lead screw will be pined to the linkage and will be constrained from rotating by the same pins. The lead screw nut is supported by two bearings to ensure stability when translating.

1.7 Detailed Working Drawings

A list of the drawing numbers and the associated parts of critical fabricated components with dimensions and GD&T specifications are included below, with the drawings found in Appendix A.3.

1. SSP-300: Slot Rod
2. SSP-400: A104 316 SS Socket Head Screw
3. SSP-500: Plastic Handle
4. SSP-600: A744 316 SS Socket Head Screw
5. SSP-700: A012 316 SS Socket Head Screw
6. SSP-800: Back Plate
7. SSP-900: Slider
8. SSP-101: Capstone Design P1
9. SSP-102: Capstone Design P2
10. SSP-103: Capstone Design P4
11. SSP-104: Capstone Design P3
12. SSP-105: Linkage P5
13. SSP-107: Steel Dowel 1
14. SSP-108: Steel Dowel 2
15. SSP-109: Short-Thread Alloy Steel Shoulder Screw
16. SSP-201: Shroud
17. SSP-202: Front Handle Face

18. SSP-203: Knob
19. SSP-204: Lead Screw
20. 4537N188: Flange Nut
21. SSP-206: Back Plug
22. SSP-207: Handle Rod
23. 6680K12: Angular-Contact Ball Bearing
24. SSP-210: Low-Profile Socket Head Screw
25. 90666A104: Super-Corrosion-Resistant 316 Stainless Steel Socket Head Screw

1.8 Operational Flowchart

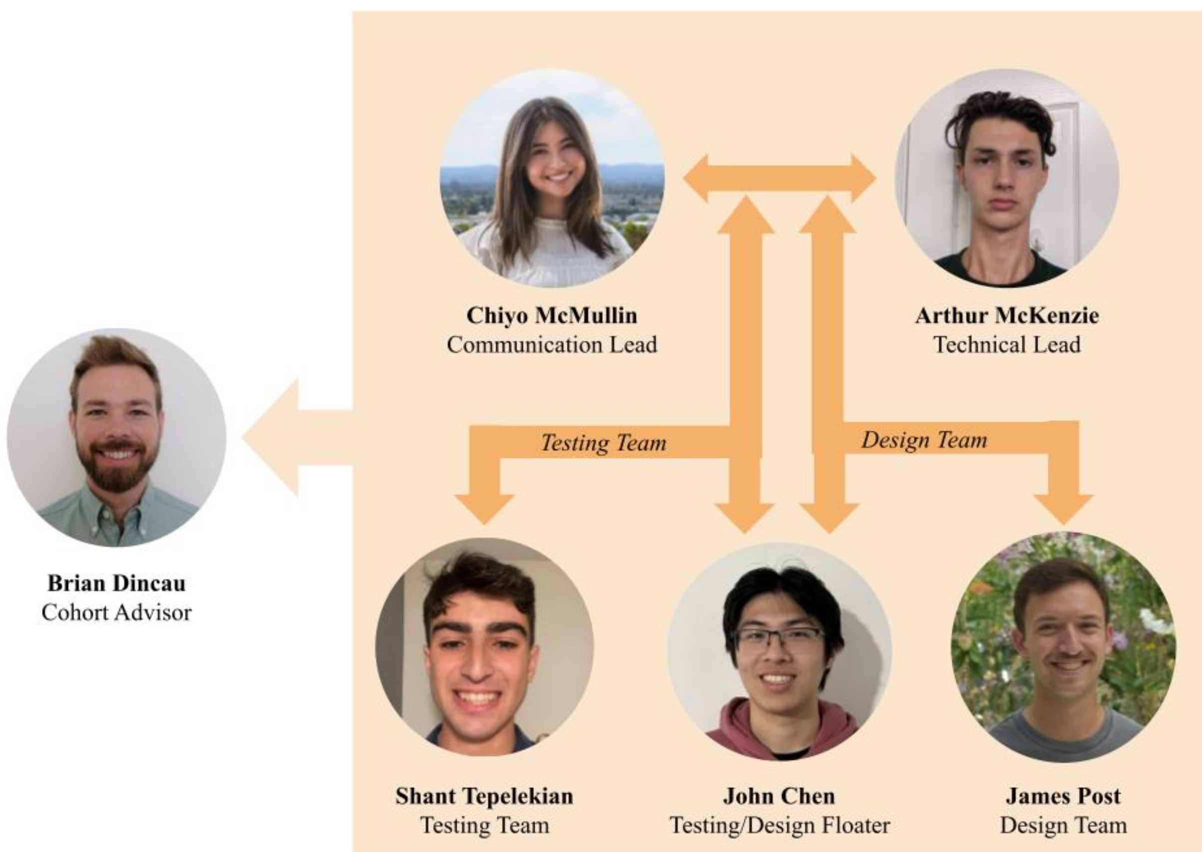


Figure 3: Team Organization

2 Prototypes and Testing

2.1 Testing Report

This section introduces and explores design questions that have been answered or will be answered by testing using prototypes.

2.1.1 Geometric Test

- Design Question: Can the tool articulate and reach the contralateral space?
- Fall Quarter: During fall quarter, the physical prototype was a 1:1 scale laser-cut acrylic version of the linkage prototype. A 1:1 scale of the L4-5 vertebral disc space was 3D printed and the linkage was tested by placing it between the vertebrae and ensuring that the width would fit inside the disc space, and also that the linkage could articulate and reach the contralateral space, which it succeeded in doing.
- Winter Quarter: During winter quarter, the physical prototype will consist of a 1:1 scale full device, with the linkage portion 3D printed and the controls machined out of aluminum. This prototype will be used to see if the pieces all fit together properly and that they can articulate and reach the contralateral space, using the test rig designed. The test rig, shown below in Figure 4, is a clear 3D resin print mold of a L4-5 disc, with a hole for a tubular retractor, so that the device can be inserted into the tubular retractor hole and can be articulated inside the disc space.

Figure 4: Disc Test Rig

- Spring Quarter: During spring quarter, a final steel prototype will be manufactured and that prototype will be tested with the test rig and in a cadaver (see Section 2.1.7) to ensure it can fully articulate.

2.1.2 Bone Rasp Test

- Design Question: Will the force experienced by the tool due to the surgeon rasping a bone during a MIS-TLIF procedure be significant enough to design against?

- Winter Quarter: In order to determine whether the forces the tool experiences during bone rasping would be significant enough to design against, we conducted a bone rasp test. To simulate the spinal bone rasped during a surgery, we used a wet cow bone for the test. This bone was place on a load cell and the total weight applied to the bone was measured while a SeaSpine rasping tool was used to rasp the bone. A picture of the bone after the rasping was conducted can be seen in Figure 6. After processing the data retrieved from the load cell, we saw that the force experienced while rasping the bone is relatively constant, as seen in Figure 7. Additionally, we found that the average force was 14.76 N and the maximum force was 22.77 N. Based on this data, we concluded that the forces our tool would experience during rasping is not significant enough to design against, as our tool will experience higher loads throughout the surgery in different ways, such as through impact with a hammer.

Figure 5: Rasped Bone

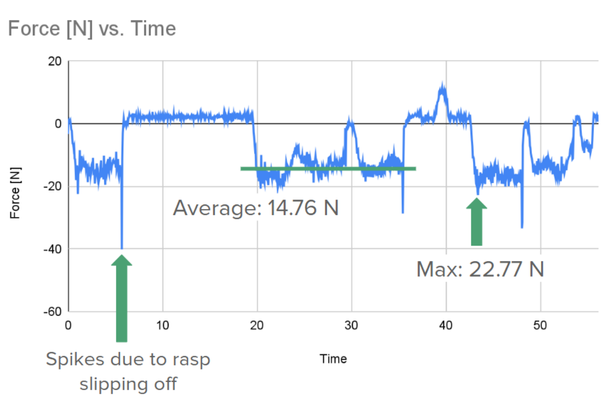


Figure 6: Rasping Test data

2.1.3 Impact Load Test

- Design Question: Can the tool survive impact loads expected during a MIS-TLIF procedure?
- Spring Quarter: The full aluminum prototype will be used to test forces sustained during the surgical procedure. This tool is expected to experience a maximum of 1000N of impact

hammering force, so it must be able to sustain that load under operation. To test, the device will be fixtured to the disc test rig (shown in Figure 4) and impacted with a three pound surgical mallet to see if failure will occur. This test was ultimately never executed due to fear of breakage of components and having to redo the arduous manufacturing process with no prototype to demonstrate during presentations. The stainless steel components did not come in time, so there was no backup plan if either the aluminum or stainless prototypes were broken beyond repair.

2.1.4 Disc Material Removal Test

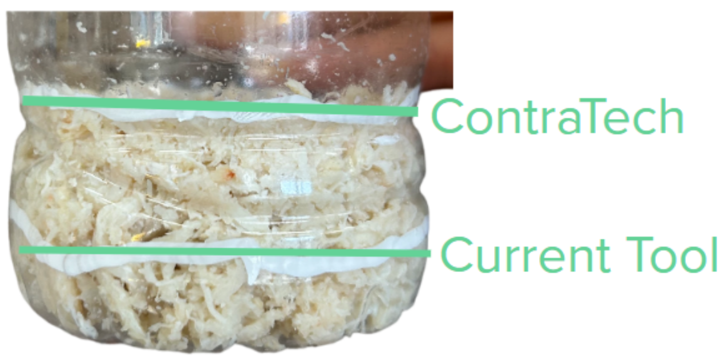
- Design Question: Can the tool be used to dislodge material on the contralateral side of the disc?
- Spring Quarter: The full aluminum prototype will be used inside the test rig (shown in Figure 4) and filled with crab meat to simulate the disc material. The tool will be operated as it would be in an actual procedure, so this test will demonstrate the effectiveness of reaching the contralateral side and the motion/technique that can be used to dislodge the flesh. This test is an addition to the geometric test as it not only tests articulation but also tests the expected surgical forces, ensuring the device can survive the procedure in preparation for the cadaver test. This test will also assess if the tool gets jammed in any particular position. If the disc material gets stuck between pieces, preventing articulation, then the device would have to be redesigned to negate that. This test was also ultimately not completed, as we did not have a surgeon to provide critical feedback on the experience of using our tool in the disc space.

2.1.5 Scooping Test

- Design Question: Can the tool disturb more material in the disc space than current instruments?
- Spring Quarter: This test is meant mainly as a simple performance metric to highlight the benefits of an articulating tool tip and the extra space it can reach. Although not representative of the actual geometry of the disc space, this test will demonstrate the limited angle of probing by a rigid tool within a tubular retractor compared to the articulating version. As illustrated in Figure 7, our articulating tool can disturb more than twice the amount of material as the current rigid device.

(a) Area disturbed by current SeaSpine rigid tool

(b) Area disturbed by our ContraTech tool



(c) Volumetric comparison of the material disturbed by current tool and our tool

Figure 7: We can see a comparison between the amount of material disturbed by SeaSpine's current rigid tool and our articulating tool, further visualized by a volumetric comparison in Figure 7c.

2.1.6 Fatigue Test

- Design Question: Can the tool handle repetitive cycling?
- Spring Quarter: The front linkage will be separated from the handle such that the inner sliding linkage is accessible. A spring will be attached to the end of the inner linkage to provide a resistive force to the tool tip as well as return it to the extended position. There will be a force gauge attached to an actuator that will press into the tool tip on the other side to facilitate the articulation of the linkage. This test was completed at a frequency of 1 Hz, which is much faster than what the device may experience in real life, but it operated

without an issues for 400 cycles before there was a seizure between the sliding inner linkage and the outer shaft, stemming from the aluminum cold welding. There was some loosening of the hole inner diameter around the shoulder bolt, which led to more slop. Overall, once the device was cleaned off, it functioned fine. A maximum force of 40 N was achieved during testing, although a nominal force of 30 N was reached every cycle as seen in the sample data in Figure 8.

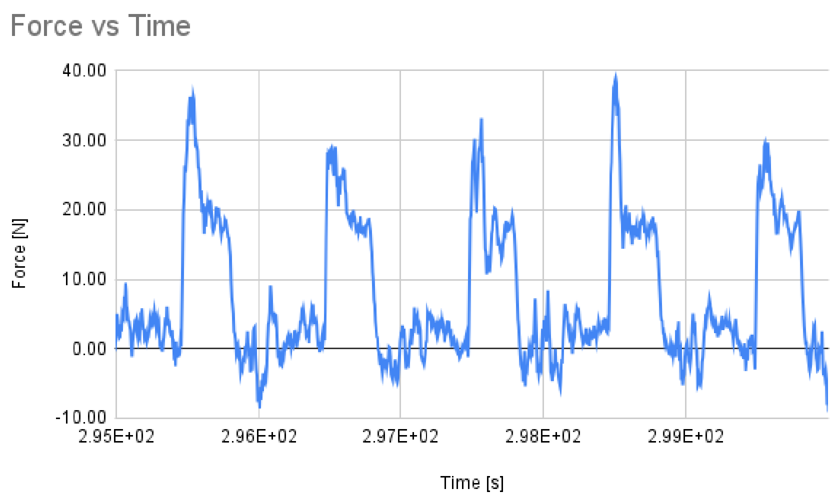


Figure 8: Cyclic loading of tool tip over time

2.1.7 Cadaver Test

- Design Question: Upon completion of a final prototype, the ultimate goal of this project is to use our device on a real cadaver to prove its efficacy. Ideally, the final device would be made of 303 stainless steel so that it may withstand the impact forces inherent to this surgery and provide a biocompatible interaction. Performing an MIS-TLIF surgery would reveal the pain points of our device, which would ideally be minimal, as well as how the surgeon may have to adapt to the tool's method of use. The device would ideally have already passed all of our engineering specifications, both quantitative and qualitative, such that the surgeon will have little trouble using it. The cadaver test would be the most representative testing ground for how usable our device is. The spacial dimensions as well as material texture/qualities are mostly equal to a real person. This test would illustrate the small changes needed to optimize the device, such as possibly needing an even smaller linkage width, greater articulation, or other visual/tactile aids for controls. Can the tool be easily and effectively used by a surgeon on a cadaver? While it would have been nice to test our device on a real cadaver to prove its efficacy, we were unable to find a time to perform such a test within the constraints of our school schedule.

2.2 Engineering Prototypes

This section describes the past and planned prototypes and the purpose and findings from each one. The prototype iteration process is continuous with the latest design in Figure 10. This design does not match the current drawings, however the drawings provide a basis for all subsequent prototypes and can reliably be used for future iterations as no major changes have occurred. Due to this rapid iteration, several versions of the tool may be present in the design packet. They all act identically and perform the same.

2.2.1 Laser-Cut Linkage Prototype

The first prototype was created using the initial linkage design from fall quarter. The individual links were laser cut from Delrin and pinned together with wooden rods. The tool tip was 3D printed to achieve a more complex shape. This inexpensive prototype was only used to demonstrate the intended motion, and was not used for any testing. The final design of fall quarter was eventually 3D printed, again only to demonstrate intended motion.

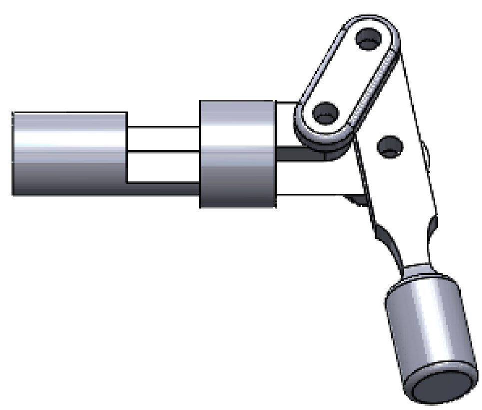


Figure 9: Initial CAD prototype model

The difference between this prototype and following iterations is that the actuation is driven by the outer tube rather than the inner tube. This was modified to produce a machinable part.

2.2.2 3D Printed Linkage + Aluminum Controls Prototype

The next prototype will consist of a 3D printed linkage paired with an aluminum prototype of the handle and controls. This allows for quick manufacturing, as the more simple handle components can be machined first, while the complicated linkage can be created with an SLA 3D printer. This prototype will be used for geometric testing within the disc space test rig.

2.2.3 Full Aluminum Prototype

The full aluminum prototype will consist of the same handle as before with an aluminum machined linkage. This prototype will be used to verify tolerances and for geometric and force testing to verify the FEA model before ordering stainless steel components.

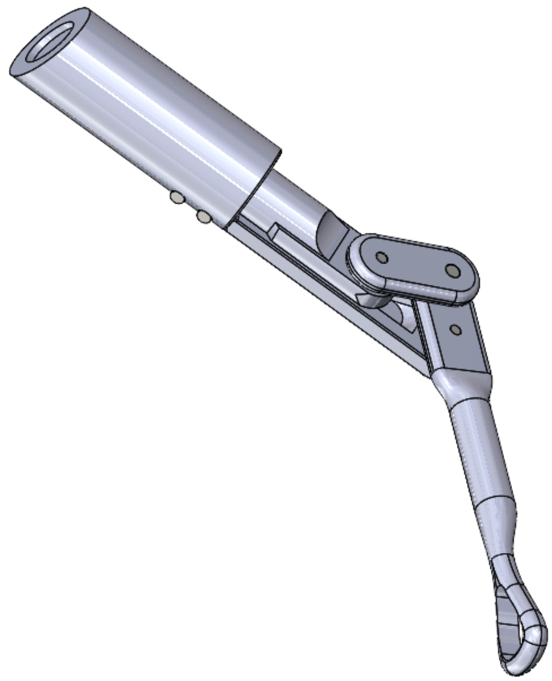


Figure 10: Current CAD Model of Linkage Sub-Assembly

2.2.4 Aluminum + Steel Final Prototype

The final prototype will feature a stainless steel linkage ordered from ProtoLabs, along with any necessary changes to the handle design machined out of aluminum.

3 Analysis and Modeling

This section describes the design questions that will be answered with modeling and analysis and the type of analysis done for each.

3.1 FEA and Failure Analysis

General analysis of the model was performed using the SolidWorks FEA simulation program. Although physical testing would be the ideal setup for measuring the success of our design, performing an FEA simulation offers the next best option for obtaining a preliminary understanding of the stresses and points of failure in our design.

To begin, the most failure-prone components of the design should be addressed: the tool-tip linkage mechanism. This subsystem is composed of various small and thin components under high loads from both the general operation as well as their relative orientation. Applying loads at the end of a lever arm generates large moments and forces that are awkwardly transmitted through the rest of the linkage. This force transmission is studied in Section 3.4.

To do so, the linkage is constrained as follows:

1. Fixed geometry along the top face of the outer sleeve as well as the two pin holes at the top end of the inner shaft
2. Pinned connections for the two pin holes aligning the outer sleeve to the cantilever support
3. Pinned connections where the linkages articulate (substituting the screws from the model)
4. Local contact interaction among all faces of the linkage (only sliding)
5. Force applied at the end of the tool tip, either along the axis of articulation (scooping/impacting) or perpendicular to that face (bone rasping)

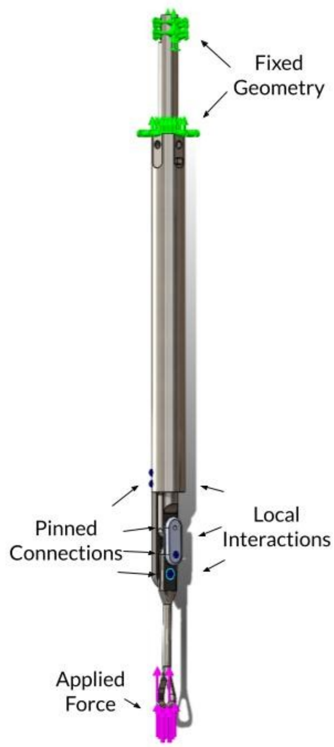


Figure 11: Example of constraints from FEA

Figure 11 illustrates the constraints listed above. However, given the material properties of 303 stainless steel, high forces cannot be applied directly on the thin walls of the curette without there being some yielding of the material. This can be observed in Figure 12.

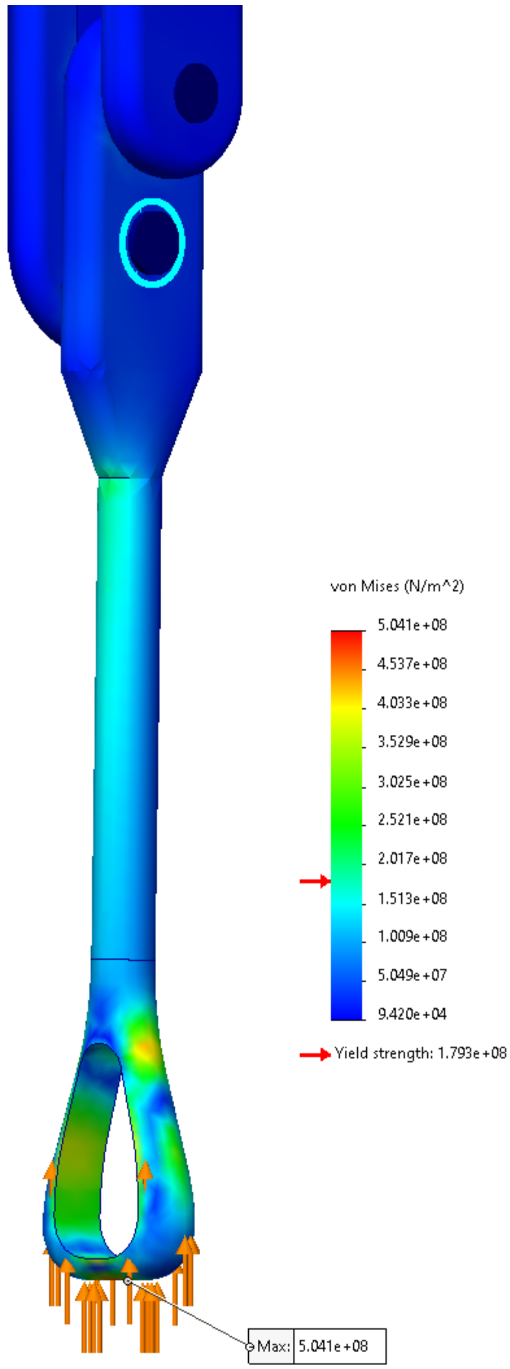
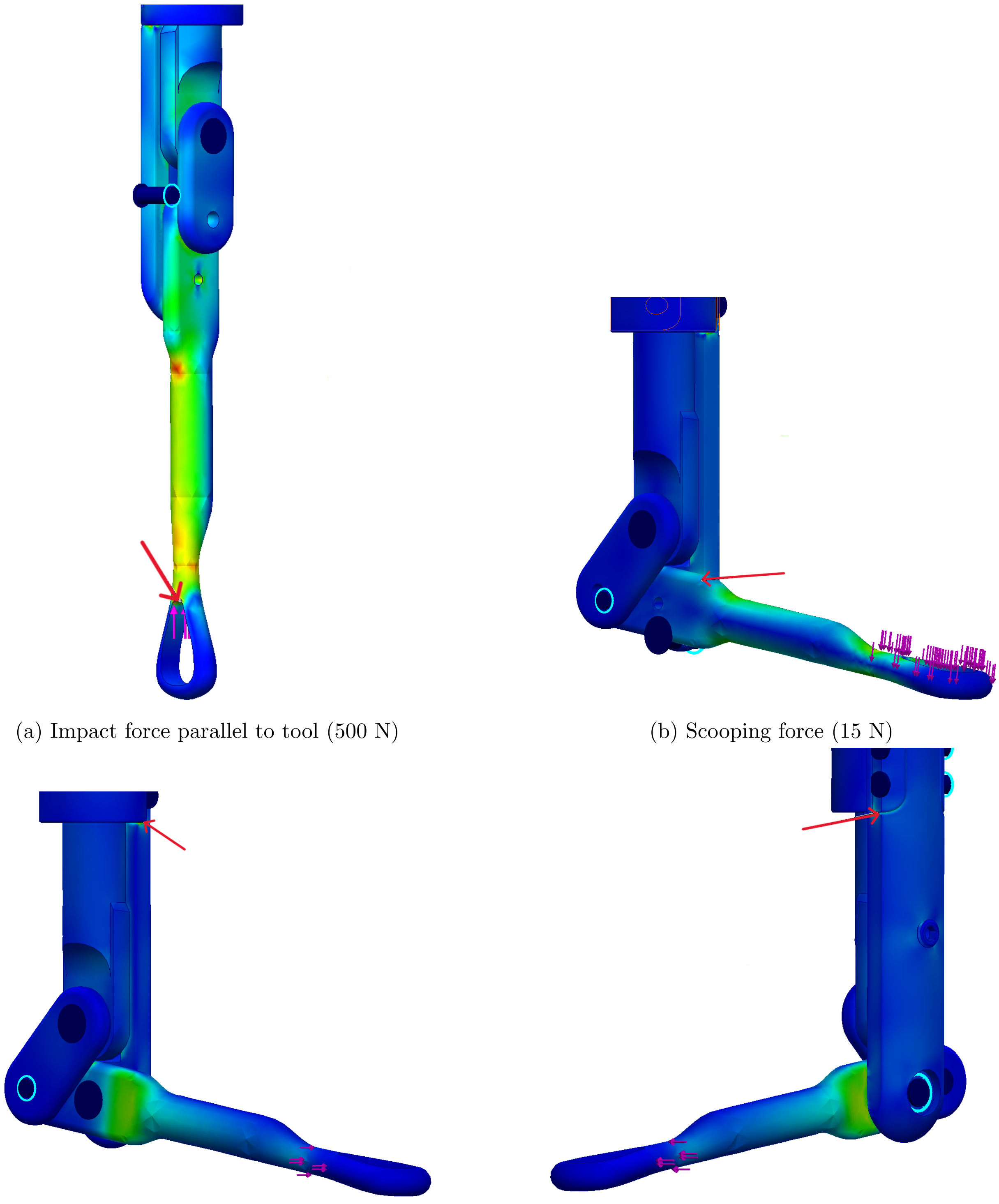


Figure 12: Yielding of curette under 500 N

The 500 N is the result of light impact forces but can be alleviated by choosing a stronger material for the curette that is not the same as that of the linkage. For the purposes of this study, attention will be focused on the strength of the linkage as opposed to the end effector. The applied force will instead be applied at the base of the curette's hole to skirt around the thin structure. Various methods of use from a surgery were simulated under these new constraints to ascertain areas of weakness and ensure the safety of the device. Below are the results of our FEAs on the linkage mechanism.



(a) Impact force parallel to tool (500 N)

(b) Scooping force (15 N)

(c) Rasping force from the left side (15 N)

(d) Rasping force from the right side (15 N)

Figure 13: FEAs of forces being applied from four different orientations to the tool tip, where all materials are 303 stainless steel. The red arrows point to the areas of highest stress.

From Figure 13, it can be observed that, in all cases, the linkage mechanism is able to handle the corresponding forces without yielding. The stress plot legend is not shown since it is illegible at this size, but the stresses on the tool are below the yield strength of 303 stainless steel. The forces used are what is expected to be experienced. The red arrows point to the areas of highest stress, and thus the areas of concern regarding yielding during operation. These areas are generally sharp/abrupt corners, also known as stress concentrators, which can be optimized to reduce potential yielding or fatigue.

It should be noted that this FEA simulation does not at all perfectly reflect the interactions between the tool's components and the external forces. This simple model simplifies the connections normally held by threaded bolts into pinned connections with a retaining ring boundary condition (no translation). Normal operation may result in some strains that make the overall linkage system more ductile and pliable for a given force orientation. Real bolts and realistically-toleranced parts may provide different outcomes, but this FEA affirms that under the modeled conditions, the device will function properly without failure.

3.2 Fatigue Analysis

Another key aspect of analysis is the fatigue on the linkage components from so many cycles of use as a reusable medical device. Life expectancy can be estimated to be around 300 operations [14] throughout its lifetime and thus producing 6000 cycles if force is applied 20 times in an operation.

To solve for fatigue of 303 stainless steel, an S-N curve and constant life fatigue diagram will be derived to understand the tool's life expectancy to the amount of force applied. Bending during scooping or rasping will be the greatest contributors to fatigue of the tool arm.

$$S_{f,3} = 0.9S_uC_T \tag{1}$$

$$S_{f,6} = S'_nC_LC_GC_SC_TC_R \tag{2}$$

where $C_T = 1.0, S'_n = 0.5S_u, C_L = 1.0, C_G = 0.9, C_S = 0.78, C_R = 0.814$ for Equations 1 and 2. The ultimate tensile strength of 303 stainless steel is 620 MPa and its yield strength is 240 MPa [1]. Thus, $S_{f,3}$ and $S_{f,6}$ are calculated below as:

$$S_{f,3} = 0.9(620MPa)(1.0) = 558 \text{ MPa}$$
$$S_{f,6} = (0.5)(620MPa)(1.0)(0.9)(0.78)(1.0)(0.814) = 177.14 \text{ MPa}$$

Basquin's power law relates $S_{f,3}$ and $S_{f,6}$ such that $S_f = 414.36$ MPa at 6×10^3 cycles. The load line will have a slope of 1 since the loading is zero-based where ($\sigma_a = \sigma_m$).The important aspect of this diagram is that the yield strength is lower than both the S_f of the calculated cycles and the ultimate strength. Therefore, the load line will be loaded by the yield line before it encounters the S_f line of 6×10^3 cycles. The resulting σ_{max} is equal to two times that intersection (120 MPa) which brings it back to 240 MPa.

The bending of the arm can be described conservatively as below:

$$\sigma_{bending} = \frac{Mc}{I} \tag{3}$$

where $M = Fl$ and F=30N, l=27.5mm, c=r=2.5mm, and I is the area moment of inertia for a circle. The length is calculated from the edge of the fillet to a central location in the curette close to the base of the loop. The resulting bending moment is:

$$\sigma_{bending} = \frac{(30N)(27.5mm)(2.5mm)}{\frac{\pi}{4}(2.5mm)^4} = 67.2 \text{ MPa}$$

which is much less than the yield strength of 303 stainless steel (240 MPa). Fatigue will not be an issue for this tool based on this analysis. Generally, this tool will not go through many cycles of high loading.

3.3 Thermal Expansion Analysis

One concern about fabricating a prototype using both aluminum and stainless steel parts is the variance in thermal stresses both parts will experience, which will cause different rates of thermal expansion in the parts. Thermal stresses are an important consideration in the case of our tool because, before each use, the tool is placed in an autoclave, where high temperatures are experienced, specifically 132 °C. Because of this, the tool will experience high temperature gradients from room temperature to the autoclave temperature each time it is used for a surgery. Although all linkage fabricated parts and its associated fasteners will be made of stainless steel, some parts in the controls sub-assembly are planned to be fabricated with aluminum, while some of the fasteners used are made of stainless steel. These interfaces could be a place where thermal cycling can be a failure mode. Most notably, the highest risk interface where different rates of thermal expansion may cause failure is the interface between the machinable end of the lead screw and its associated hole in the "Front Handle Face" part. While the lead screw is made of 17-4 PH stainless steel, the part it interfaces with will be made out of 6061 T6 aluminum alloy. To investigate this, we first calculated the difference in thermal stresses experienced based on the material of a part, using the part's material properties (coefficient of thermal expansion α and Young's modulus E) and the temperature gradient experienced from the tool moving from a room temperature environment into an autoclave (132 °C - 22 °C).

Thermal stress for 17-4 PH Stainless Steel:

$$\sigma_T = \alpha E \Delta T = (10.8 * 10^{-6} m/m^{\circ}C)(197 * 10^9 N/m^2)(110^{\circ}C) = 234.04MPa \tag{4}$$

Thermal stress for 6061 T6 Aluminum Alloy:

$$\sigma_T = \alpha E \Delta T = (25.2 * 10^{-6} m/m^{\circ}C)(68.9 * 10^9 N/m^2)(110^{\circ}C) = 190.99MPa \tag{5}$$

Although the results display thermal stresses that are on the same order of magnitude for both materials, further calculations were done to ensure that the faster expansion of the aluminum "Front Handle Face" compared to the stainless steel lead screw will not cause any issues. This was done by calculating the change in area of the lead screw after autoclaving and comparing that to the change in area of the hole:

$$\Delta A = 2\alpha A \Delta T \tag{6}$$

Change in area for the stainless steel lead screw's machinable end, with a 7 mm diameter:

$$\Delta A = 2(10.8 * 10^{-6} m/m^{\circ}C) * (0.0000385m^2)(110^{\circ}C) = 9.15 * 10^{-8} m^2 \tag{7}$$

Change in area for the corresponding hole in the aluminum "Front Handle Face":

$$\Delta A = 2(25.2 * 10^{-6} m/m^{\circ}C) * (0.0000385m^2)(110^{\circ}C) = 2.16 * 10^{-7} m^2 \tag{8}$$

The analysis above shows that the change in area of the lead screw and hole is negligible during one session of autoclave. However, the whole lifetime of the tool must be considered when determining if thermal cycling will be a failure mode. In the previous section, it was estimated that this tool has a life expectancy of 300 operations. Based on this, the change in area after 300 autoclave sessions is the following for each part:

Change in area for the stainless steel lead screw's machinable end, with a 7 mm diameter:

$$\Delta A_{lifetime} = 300\,cycles * \Delta A = 300(9.15 * 10^{-8} m^2) = 2.75 * 10^{-5} m^2 \tag{9}$$

Change in area for the corresponding hole in the aluminum "Front Handle Face":

$$\Delta A_{lifetime} = 300\,cycles * \Delta A = 300(2.16 * 10^{-7} m^2) = 6.48 * 10^{-5} m^2 \tag{10}$$

Based on these calculations, it was concluded that the change in area of the lead screw's machinable end and its associated hole in the "Front Handle Face" due to thermal expansion is negligible during the lifespan of the tool. Hence, it is safe to have these two parts be made out of two different materials.

3.4 Linkage Force Transmission

To study the transmission of force from the tool tip to the inside shaft, key lengths and angles between components can be related with the equations below. They describe the relationship between the displacement of the inner shaft and the transmission ratio observed from the tool tip end to the inner shaft.

$$\begin{aligned}
a^2 &= b^2 + c^2 - 2bc\cos\alpha \\
b^2 &= a^2 + c^2 - 2ac\cos\beta \\
c^2 &= a^2 + b^2 - 2ab\cos\gamma \\
\phi &= 90^\circ - \gamma \\
F_1 &= F_2 cos\beta \\
F_3 &= F_2 cos\phi \\
T_1 &= F_3 b \\
T_2 &= F_4 d \\
T_1 &= T_2 \\
F_5 &= F_4\cos\alpha
\end{aligned} \tag{11}$$

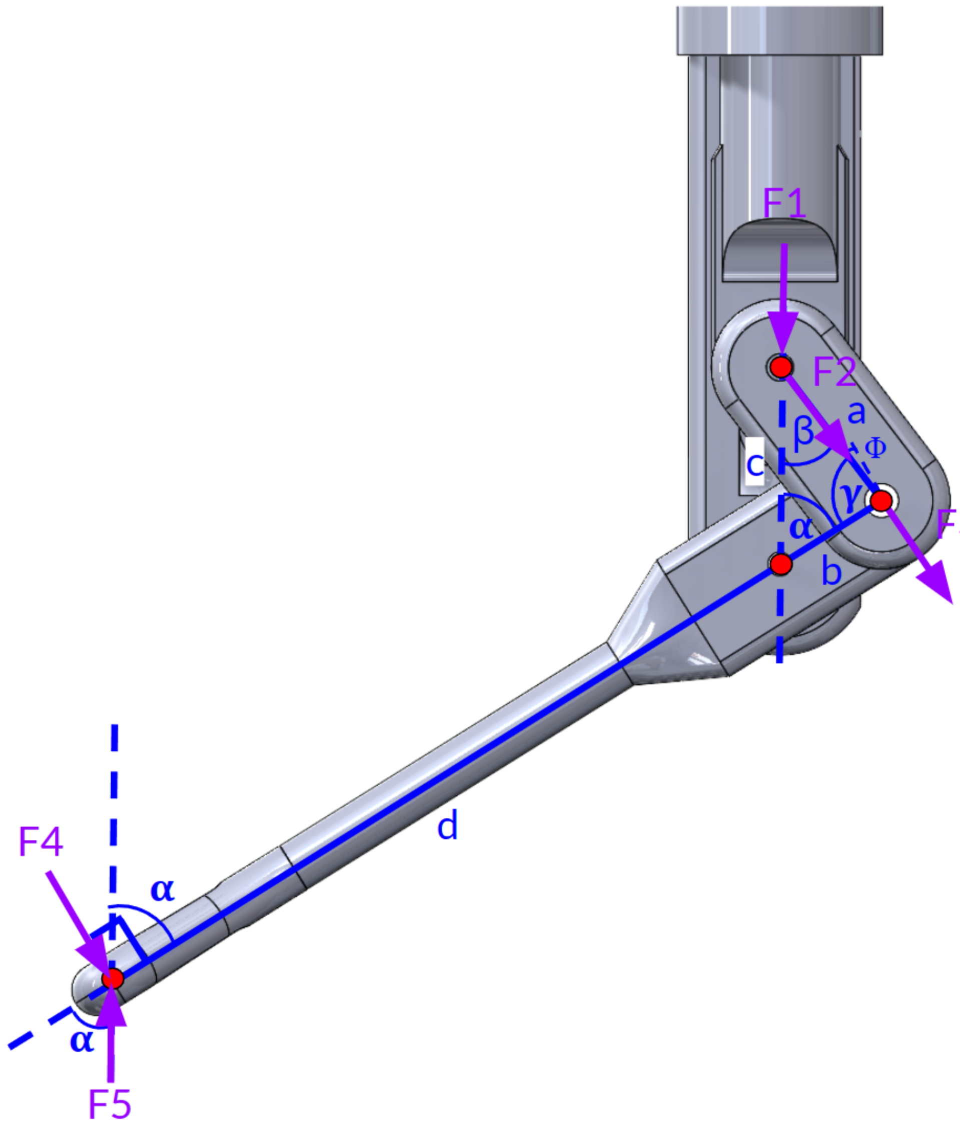


Figure 14: Force Transmission Diagram

For this analysis, static loading can be assumed such that none of the components are moving. The tool is driven via a high-pitch lead screw, so an insignificant amount of backlash can also be assumed. Thus, there is no articulation of the linkage, provided the transmitted force is less than force required to fail any component within the tool. The transmission ratio of force in and out is, therefore, influenced solely by the vertical distance between the two co-linear pins. Force can be calculated via the code in Appendix A.5.1.

3.5 Impact Force Analysis

The tool may be subject to light impaction by a small surgical mallet in order to get the tool in the right position within the disc space. Dr. Wessell has stated that he would not anticipate impacting the tool, as if it is stuck inside the disc space then the tool cannot serve its purpose anyway. However, as different surgeons have different techniques, a misuse case of impaction is to be expected and designed to withstand.

To calculate the expected impact load, a simplified impact model was used of the surgical mallet hitting the tool. The surgical mallet has impact weight W and the steel tool has length L, diameter d, stiffness k, Young's modulus E, and static deflection δ_{st}, and is being impacted at a height h with velocity v, as depicted in the diagram in Figure 15 below.

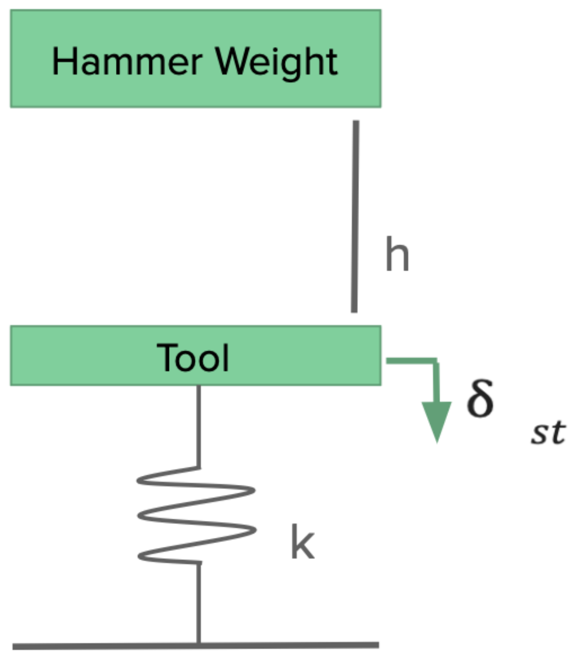


Figure 15: Impact Calculation Figure

The force was calculated as follows:

$$W_{hammer} = 3pounds = 13.3447N$$
$$\delta_{st} = \frac{W}{k} = \frac{WL}{EA} = \frac{(13.3447N)(361.22mm)}{(190GPa)\pi(5mm)^2} = 3.230 * 10^{-7}m$$
$$F_e = W\left(1 + \sqrt{(1 + \frac{v^2}{g\delta_{st}}}\right) = (13.3447N)\left(1 + \sqrt{1 + \frac{(0.8m/s)^2}{(9.81m/s^2)(3.230 * 10^{-7}m)}}\right) = 613.21N \tag{12}$$

The assumptions made in this model are as follows:

- Small surgical mallet is used (weight of mallet = 3 pounds)
- The impact velocity is slow (the velocity value was determined by recording a hammer swing at 30 fps)
- The tool can be modeled as a cylindrical rod for determining the stiffness and static deflection

Because of the assumptions made and the generally large uncertainty with this calculated value, the calculation was compared with a literature review of surgical impact forces and impact force values that SeaSpine currently uses for their device designs. From literature, surgical impact forces vary from 100 N for bone grafts to 573 N for spinal cage insertion. It is stipulated that performing a discectomy would require more force than a bone graft but less force than inserting a spinal cage, so the impact force is expected to be between 100 to 573 N. SeaSpine sponsors currently use impact force inputs between 1000 N to 1500 N for their typical applications, but they recommended a 500 N impact force for this project, as the discectomy step requires lighter impaction than other steps of the TLIF procedure. Therefore, the force that the tool should be able to withstand is 500 N. Incorporating a safety factor of 2, the tool will be designed to withstand 1000 N.

3.6 Buckling Force Analysis

Because the tool is essentially a long slender rod subject to compressive forces, buckling is a possible failure mode that must be considered. To calculate the critical load for buckling, two key assumptions were made:

- The tool can be modeled as a cylinder for finding the radius of gyration
- The tool has pinned/pinned connections at its ends

First, the slenderness ratio was calculated to determine whether to use the Euler or Johnson buckling equation. For a pinned/pinned connection, the equivalent length is the full length and the radius of gyration is $r/2$:

$$\begin{aligned} &L_e = L = 361.22mm \\ &r = 5mm \\ &\text{Slenderness Ratio} = \frac{L_e}{\rho} = \frac{L_e}{\frac{r}{2}} = \frac{361.22mm}{5mm} = 0.144 \\ &\text{Tangency Point} = \sqrt{\frac{2\pi^2 E}{S_y}} = \sqrt{\frac{2\pi^2(190GPa)}{240MPa}} = 125.01 \end{aligned} \tag{13}$$

Because the slenderness ratio is less than the tangency point, the scenario falls in the Euler buckling regime. Applying the Euler buckling equation,

$$P_{cr} = \frac{\pi^2 E}{(\frac{L_e}{\rho})^2} = \frac{\pi^2(190GPa}{0.144^2} = 7054.72N \tag{14}$$

The critical load for buckling is 7054.72 N, which is much greater than the impact force anticipated during the procedure, and therefore buckling is not a mode of failure of high concern.

3.7 Lead Screw Analysis

The tool must remain rigid when not actively articulating the tool tip. This means it must not be back driven at any point during the procedure including during impaction. Fortunately, backdriving is not a critical device failure as it does not damage any parts. However, it does result in a non-optimal use case. In the event that the tool is backdriven during impact, it will not act as a rigid body, meaning the surgeon may not be able to perform certain procedures, such as jamming the device deeper into the nucleus pulposus. As such, it is important to avoid backdriving if possible. The selected lead screw provides a 1mm thread pitch, M4 thread size, and one thread start. Because of only one thread start, the lead is the same value as the pitch and the lead angle can be determined with Equation 15. Different options for lead screws have greater starting threads, resulting in much higher lead angles λ, given by:

$$\lambda = \arctan\left(\frac{L}{\pi D}\right) \tag{15}$$

All Acme screws have thread angle $\alpha = 29^o$, which can be used to determine the normal thread angle α_n:

$$\alpha_n = \arctan(\cos\lambda * \tan\alpha) \tag{16}$$

The tool can be back driven if the torque applied by a force driving a nut vertically is greater than the friction force holding the screw in place. The backdrive torque is:

$$T_b = \frac{LPe_b}{2\pi} \tag{17}$$

The torque required to lower a load with the force in the direction of application is:

$$T = \left(\frac{Wd_m}{2}\right)\left(\frac{f\pi d_m - L\cos\alpha_n}{\pi d_m \cos\alpha_n}\right) + \frac{Wf_c d_c}{2} \tag{18}$$

If $T_b > T$, then the device will be backdriven. However, most acme screws are inherently self-locking, so they cannot ever be backdriven. This is because the backdriving efficiency e_b is negative [25].

$$e_b = \left(\frac{1}{\tan\lambda}\right)\left(\frac{\cos\alpha_n \tan\lambda - \mu}{\cos\phi_n + \mu\tan\lambda}\right) \tag{19}$$

Selecting for this condition is easier and ultimately was the only option due to the small size and to ensure no slipping will occur regardless of applied force.

Using the values determined by the lead screw, we can determine the backdriving efficiency of this power screw with lead angle $\lambda = 4.55^o$ and thread angle $\alpha = 29^o$. The coefficient of friction is assumed to be $\mu = 0.2$ which is typical for all screws. From Equation 19, efficiency is determined to be $e_b = -1.84$. This is a self-locking screw so calculating backdriving torque is unnecessary. If the efficiency was not negative, the torque would have to be considered and therefore the force applied would have a large bearing on the functionality of the device.

3.8 Geometric Fit Simulation

To verify that the design fits in the disc space as needed, the assembly was positioned in SolidWorks with a model lumbar spine provided to us by SeaSpine. Figures 16, 17, and 18 show how the tool can enter at a 30° to 35° converging angle and articulate throughout the disc space. Dr. Wessell confirmed that when the tool is in the articulated position, the elbow is in an anatomically safe position for protrusions, and therefore the design satisfies the geometric fit.

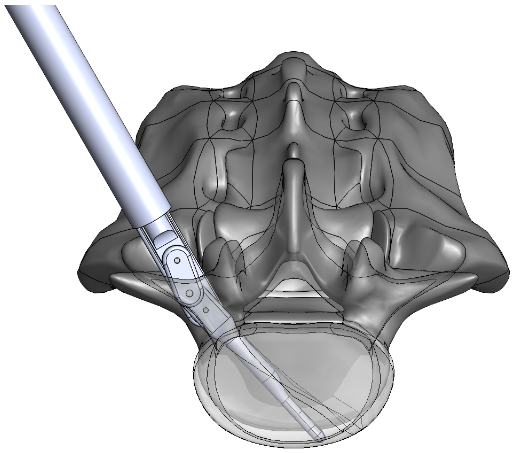


Figure 16: Top view of tool in straight position

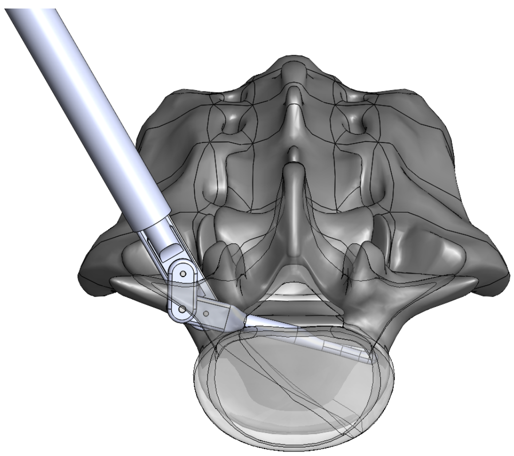


Figure 17: Top view of tool in articulated position

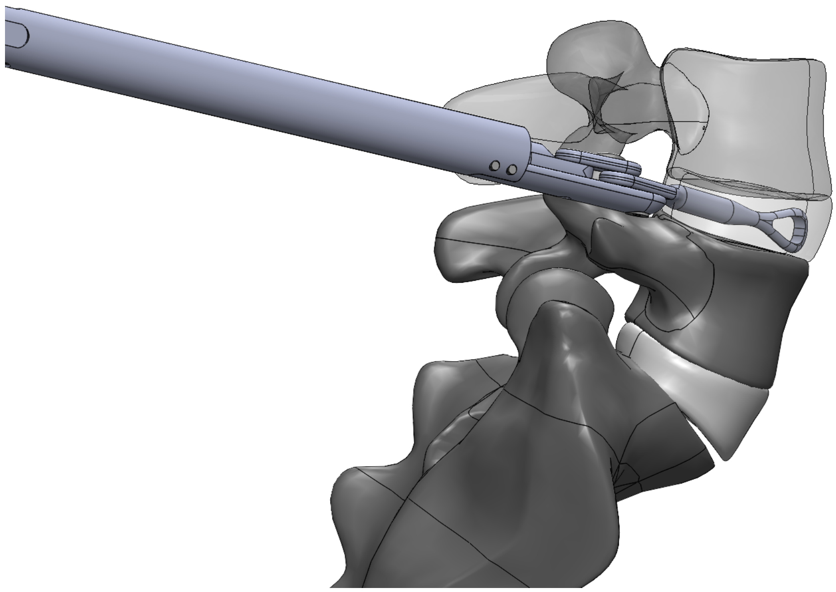


Figure 18: Side view of the tool in position

3.9 Estimated Failure Point Shear Analysis

The device's linkage portion will most likely experience the most force during surgery, so we analyze the smallest part experiencing force which are the two shoulder bolts – more specifically the front shoulder bolt.

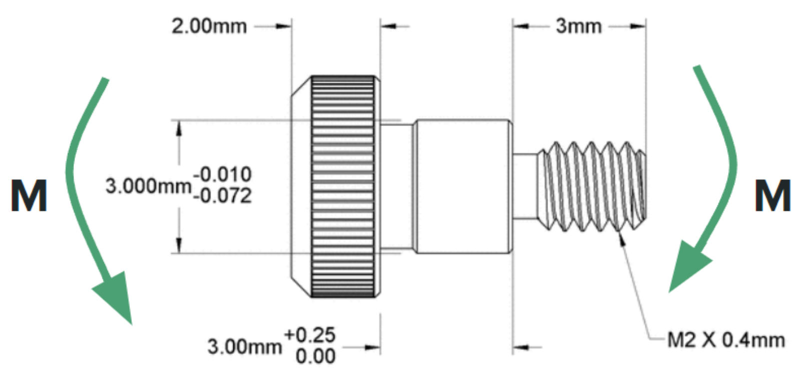


Figure 19: Shoulder Bolt Assumption of Failure Point M = Bending Moment

We assume this bolt will be the failure point; the failure will be due to the bending stress about the narrowest point, which also is affected by stress concentration factors. The Rated Ultimate bending strength is $\sigma_{max} = 140 * 10^3 (psi)$ and its diameter is $d = 0.0787402$". Shear stress with concentration factor is calculated from:

$$\sigma_{max} = K_t \sigma nom \tag{20}$$

And ultimate moment is from:

$$\sigma_{nom} = \frac{32 M_B}{\pi d} \tag{21}$$

Where K_t is determined from the graph:

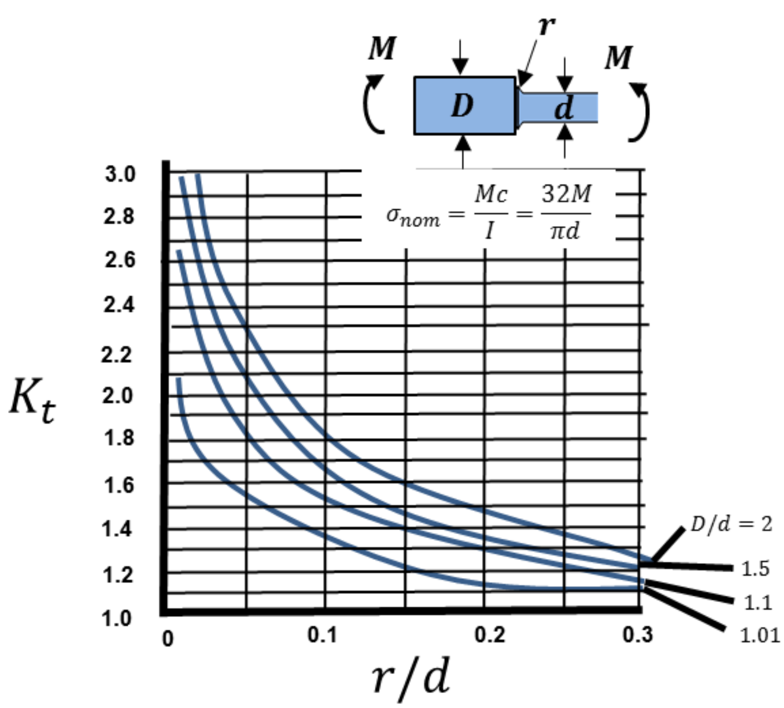


Figure 20: graph kt vs D,d

Using this graph and D=3mm and d=2mm $K_t = 1.5$, now M which is our max moment can be found from using these equations:

$$\frac{140000}{1.5} \cdot \pi \cdot \frac{0.0787402}{32} = M$$

M is determined to be 721 lb-in.

4 Final Test Results

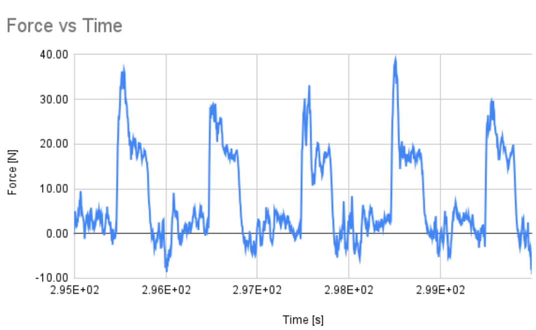
After completing the final prototype, we conducted two comprehensive tests to gather numerical data and evidence that the tool worked.

4.1 Fatigue Test

The front linkage was separated from the handle such that the inner sliding linkage was accessible. A spring was attached to the end of the inner linkage to provide a resistive force to the tool tip, and return it to the straight position after each actuation. A linear actuator pressed into the tool tip on the other side to facilitate the articulation of the linkage, and a force gauge recorded data. This test was completed at a frequency of 1 Hz, much higher than the tool is capable of moving during normal operation. It operated without issues for 400 cycles before there was a seizure between the sliding inner linkage and the outer shaft, stemming from the aluminum cold welding. There was some loosening of the hole inner diameter around the shoulder bolt, which resulted in a loosening of the linkage. After performing some basic maintenance, the device again worked properly. We anticipate that there would be less issues if operated at a slower speed. A maximum force of 40 N was achieved during testing, although a nominal force of 30 N was reached every cycle as seen in the sample data in Figure 21a.

4.2 Scooping Test

Here we took a plastic container and cut a hole in the side. We fit an 18 mm tubular retractor into the hole, and then filled the container with a layer of canned crab meat. The crab meat was to simulate the nucleus pulposus. First with the angled curette from SeaSpine, and then with ContraTech, we reached through the retractor and disturbed as much material as we were able to. After removing the disturbed material and measuring it, the results were clear. ContraTech was able to reach more than twice the volume of material compared to the existing curette tool, as shown in Figure 21b.



(a) Cyclic loading results

(b) Current SeaSpine curette vs. ContraTech

Figure 21: Final test results

5 Broader Impacts

As future engineers, it is crucial to understand how our work can impact the world, in terms of public health and global, cultural, social, environmental, and economic factors. Because the ContraTech is a medical device, it will undergo extreme scrutiny to ensure potential public harm is very minimal. We are responsible for ensuring that our device will not fail in a harmful way, which we have done by identifying risks through a Design Failure Modes and Effects Analysis document and mitigating those by taking proper actions. We have also conducted preliminary verification and validation tests, but those would need to be continued to ensure that no major risks remain at all. If this project continued from the groundwork our team has laid, the next step would be manufacturing a prototype completely out of 17-4 Stainless Steel and using that to perform a 1-Level MIS-TLIF discectomy on a cadaver. If this is successful, SeaSpine could get an Investigational Device Exemption approved from the U.S. Food and Drug Administration (FDA) to perform clinical trials, which are research studies in human volunteers to address the safety and effectiveness of a device or system.

After the clinical trials, if the device proves to be safe and effective, the next step is for SeaSpine to submit a Premarket Approval to the FDA, which is required to market a Class III medical device with scientific and clinical data that does not have a substantially equivalent predicate device. Through these thorough FDA processes, the device will demonstrate that it is medically safe and effective for public use.

The ContraTech is intended to fit within the pre-existing posterior disc preparation tool kit. SeaSpine does not sell these tool kits, but rather lends them out to hospitals that purchase their spinal implants. As a result, the ContraTech will be subject to low-volume production and the cost to produce this tool is not of large concern, so the economic impacts of our device are minimal.

In terms of global impacts, the ContraTech device strives to align with the United Nation's Sustainable Development Goals, specifically Goal 3 – Good Health and Well-Being. By serving a purpose to save time on your spine, the ContraTech will help to reduce potential risks associated with current MIS-TLIF procedures and will ensure that patients have quick recoveries.

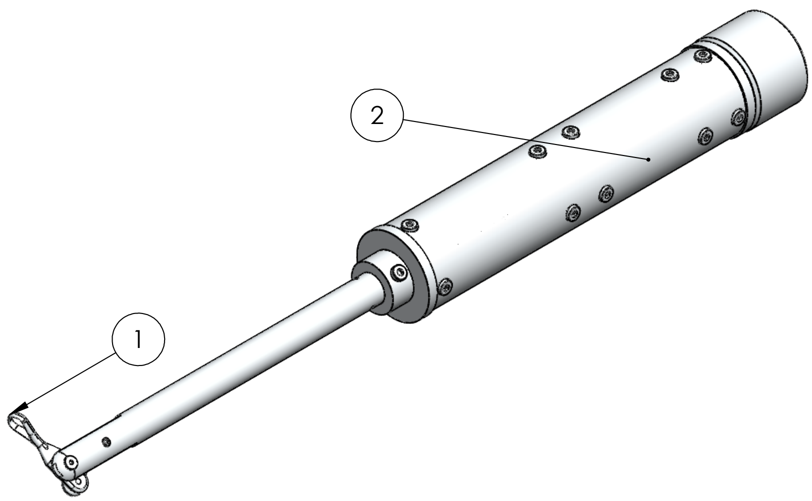
The ContraTech will fit well into the intended cultural setting, which is orthopedic surgical spaces. After speaking with Dr. Nolan Wessell, it was evident that spine surgeons like him would easily incorporate the ContraTech into their rotation of tools. Because the ContraTech is similar in style and feel to the current SeaSpine tools, our team does not anticipate a large culture shock or steep learning curve, so the integration of our tool into a surgical setting should be very seamless.

The implications of our work lie ultimately in the safety of our device. As medical device designers, the most important aspect of our work is safety and keeping the patients needs first. In its current state, the ContraTech is not ready to be used on humans, but with further refinement and testing, we believe our device can be FDA approved and used on patients in the future!

A Appendices

A.1 Assembly Drawings

ITEM NO.	PART NUMBER	DESCRIPTION
1	capfinal	Linkage Subassembly
2	Handle Assem	Handle Controls



Fabrication Steps
1. Fabricate each component/subassembly
2. Assemble with screws & pins in machine shop

PROPRIETARY AND CONFIDENTIAL

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NEXT ASSY | USED ON

APPLICATION

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN mm.
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±0.25
THREE PLACE DECIMAL ±0.130

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL

FINISH

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	SAT	6/11/2024
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS:

SeaSpine

TITLE:
Top Level Assembly

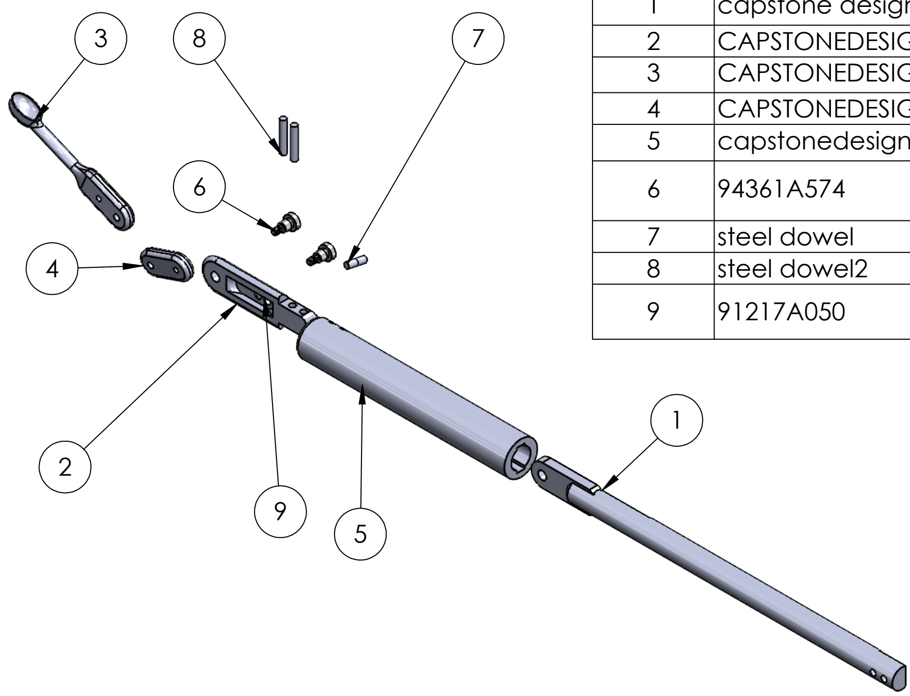
SIZE A | DWG. NO. SSP-001 | REV

SCALE: 1:2 | WEIGHT: | SHEET 1 OF 1

A.2 Subassembly Drawings

2 1

B B



ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	capstone design P1	Inner shaft	1
2	CAPSTONEDESIGN P2	Rounded side	1
3	CAPSTONEDESIGN P4	Tool tip link	1
4	CAPSTONEDESIGN P3	Connector link	1
5	capstonedesign p5	Outer shaft	1
6	94361A574	Short-Thread Alloy Steel Shoulder Screw	2
7	steel dowel	Steel dowel	1
8	steel dowel2	Steel dowel	2
9	91217A050	18-8 Stainless Steel Cone-Point Set Screw	1

A A

Fabrication Steps
1. Fabricate each part
2. Assemble with screws and dowels

PROPRIETARY AND CONFIDENTIAL

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NEXT ASSY | USED ON

APPLICATION

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN mm.
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±0.25
THREE PLACE DECIMAL ±0.130

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL

FINISH

DO NOT SCALE DRAWING

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DRAWN	C.M.M.	2/29/2024
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS:

SeaSpine

TITLE:

Linkage Subassembly

SIZE A | DWG. NO. SSP-002 | REV

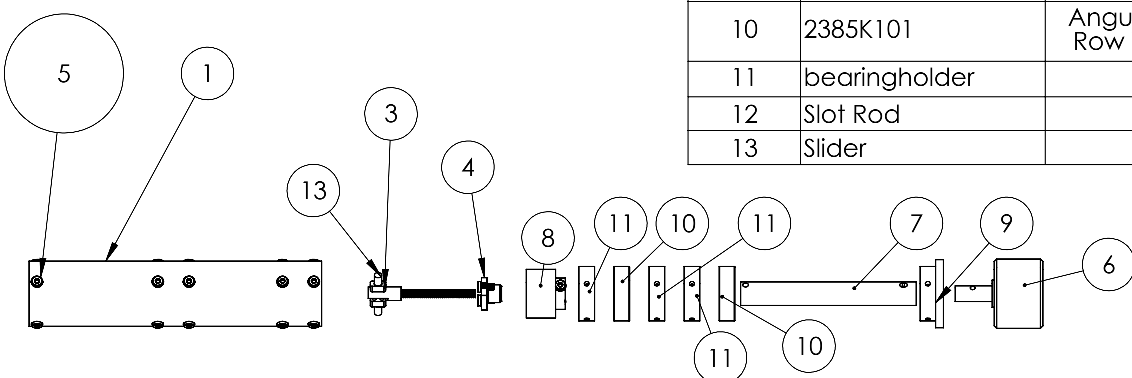
SCALE: 1:1.5 | WEIGHT: | SHEET 1 OF 1

2 1

2 1

B B

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	Shroud		1
2	Front Handle Face	Handle plug with slot for lead screw	1
3	4537N128	Fast-Travel Ultra-Precision Lead Screw	1
4	4537N188	Flange Nut	1
5	90666A104	Super-Corrosion-Resistant 316 Stainless Steel Socket Head Screw	24
6	KnobV2		1
7	Nut connector		1
8	Nutconnectorwide		1
9	Back Plug V2		1
10	2385K101	Angular-Contact Single Row Thrust Ball Bearing	2
11	bearingholder		3
12	Slot Rod		2
13	Slider		2

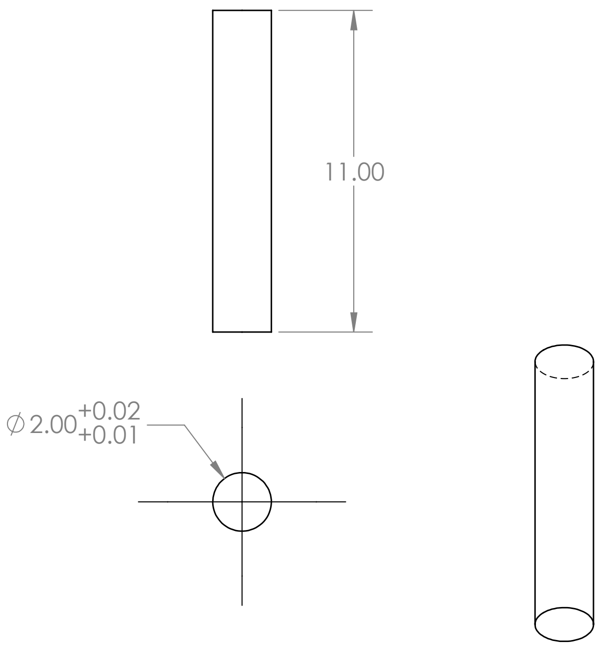


A A

Fabrication Steps	UNLESS OTHERWISE SPECIFIED:		NAME	DATE	SeaSpine
	DIMENSIONS ARE IN mm. TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ±0.25 THREE PLACE DECIMAL ±0.130	DRAWN	JC	2/29/2024	TITLE: Handle Assembly Exploded View
		CHECKED			
		ENG APPR.			
		MFG APPR.			
	INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.			
	MATERIAL	COMMENTS:			SIZE A DWG. NO. Handle Assem Exploded View Final REV
NEXT ASSY / USED ON	FINISH Machined				
APPLICATION	DO NOT SCALE DRAWING				SCALE: 1:2 WEIGHT: SHEET 1 OF 1

2 1

A.3 Part Drawings



Fabrication Steps
1. 2mm diameter aluminum rod stock
3. Use bandsaw to cut desired length

UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN mm.
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±0.25
THREE PLACE DECIMAL ±0.130

INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL
FINISH
DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	C.M.M.	2/29/2024
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS:

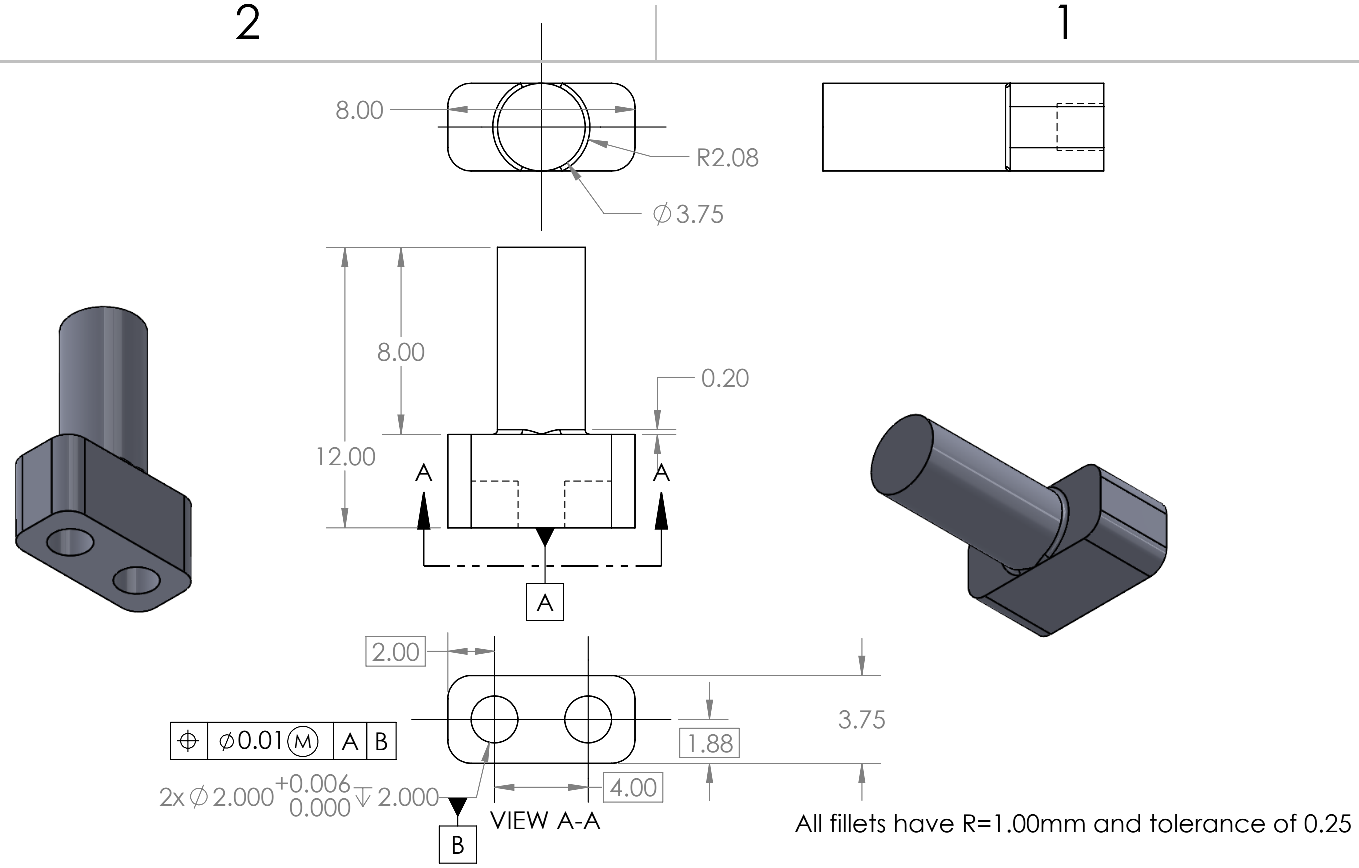
SeaSpine

TITLE:
Steel Dowel 2

SIZE	DWG. NO.	REV
A	SSP-108	

SCALE: 5:1 WEIGHT: SHEET 1 OF 1

NEXT ASSY	USED ON
APPLICATION	



Fabrication Steps
1. 8x12mm aluminum stock
2. Generate G-code in HSM
3. CNC with 3/16" EM

NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN mm.
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±0.25
THREE PLACE DECIMAL ±0.130

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL

FINISH

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	C.M.M.	2/29/2024
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS:

SeaSpine

TITLE:

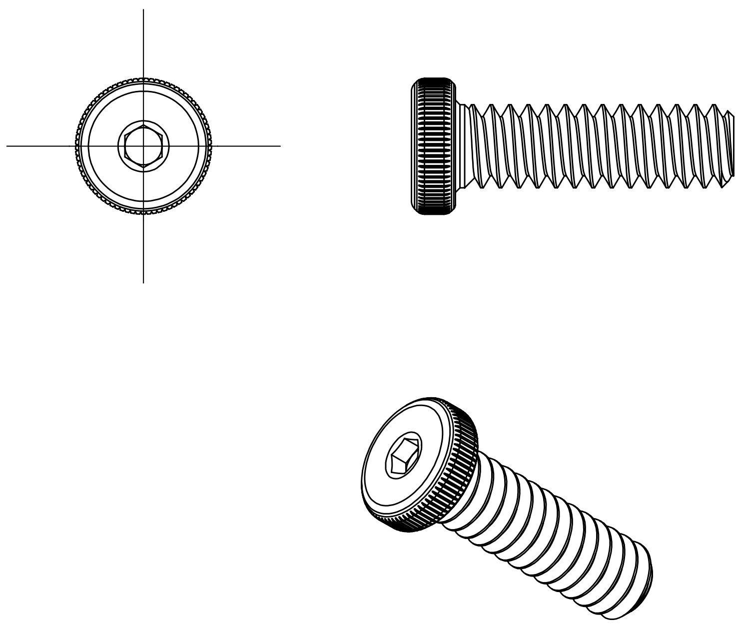
Slider

SIZE	DWG. NO.	REV
A	SSP-900	

SCALE: 4:1	WEIGHT:	SHEET 1 OF 1

2 1

B B



A A

Fabrication Steps
1. Buy from McMaster (93615A111_18-8 Stainless Steel Low-Profile Socket Head Screw)

UNLESS OTHERWISE SPECIFIED:		NAME	DATE
DIMENSIONS ARE IN mm. TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ±0.25 THREE PLACE DECIMAL ±0.130	DRAWN	C.M.M.	2/29/2024
	CHECKED		
	ENG APPR.		
	MFG APPR.		
INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
MATERIAL 18-8 Stainless Steel	COMMENTS:		
FINISH			
DO NOT SCALE DRAWING			

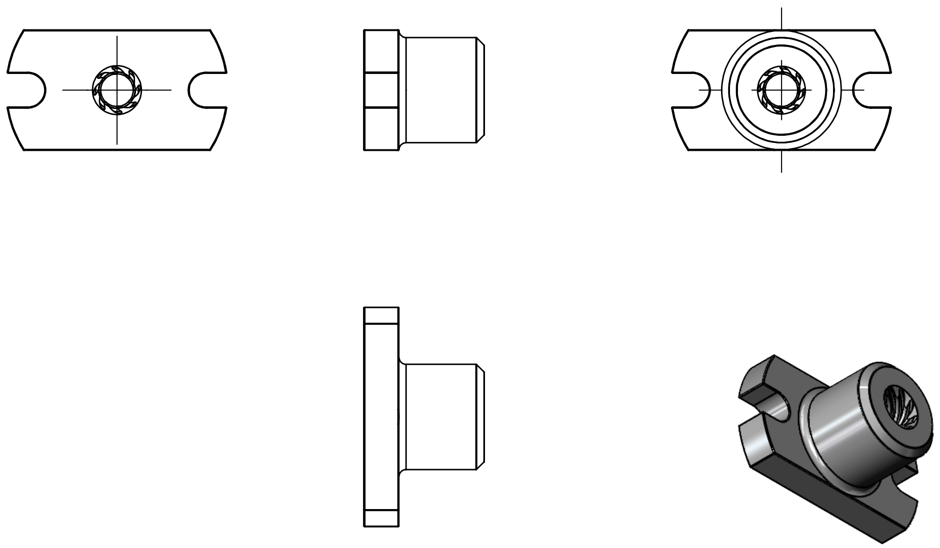
NEXT ASSY	USED ON
APPLICATION	

SeaSpine

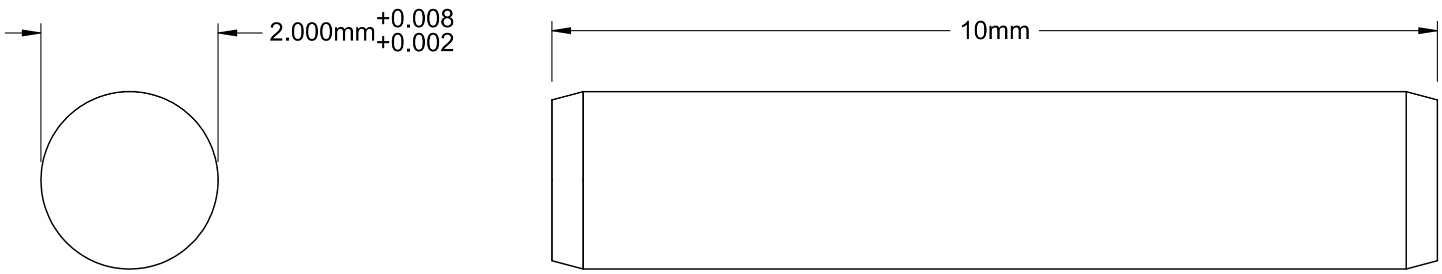
TITLE:
Low-Profile Socket Head Screw

SIZE	DWG. NO.	REV
A	SSP-210	
SCALE: 5:1	WEIGHT:	SHEET 1 OF 1

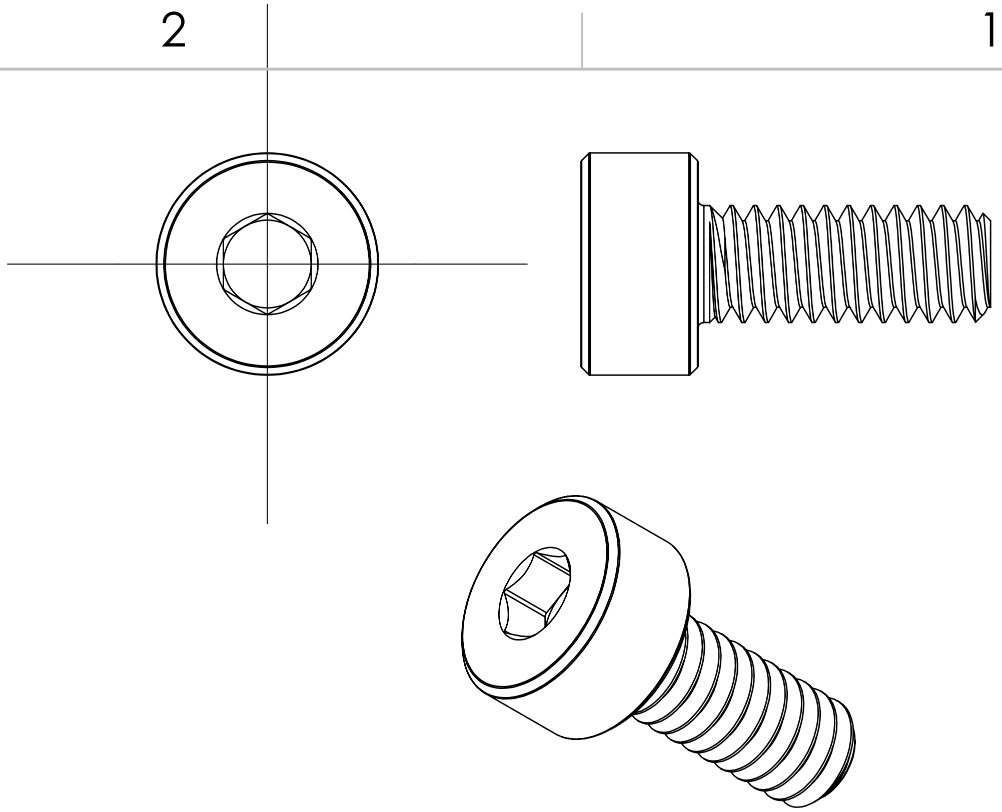
2 1



Fabrication Steps	UNLESS OTHERWISE SPECIFIED:		NAME	DATE	SeaSpine
1. Purchase from McMaster (4537N188 Flange Nut)	DIMENSIONS ARE IN mm. TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ±0.25 THREE PLACE DECIMAL ±0.130	DRAWN	C.M.M.	2/29/2024	TITLE: Flange Nut
		CHECKED			
		ENG APPR.			
		MFG APPR.			
	INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.			
	MATERIAL PEEK Plastic	COMMENTS:			SIZE A · DWG. NO. SSP-205 · REV
NEXT ASSY · USED ON	FINISH				
APPLICATION	DO NOT SCALE DRAWING				SCALE: 2:1 · WEIGHT: · SHEET 1 OF 1



McMASTER-CARR® CAD	PART NUMBER	91585A221
http://www.mcmaster.com	18-8 Stainless Steel Dowel Pin	



Fabrication Steps
1. Buy from McMaster (92290A012_Super-Corrosion-Resistant 316 Stainless Steel Socket Head Screw)

PROPRIETARY AND CONFIDENTIAL

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NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN mm.
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±0.25
THREE PLACE DECIMAL ±0.130

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL
316 Stainless Steel

FINISH

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	Name	2/29/2024
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS:

SeaSpine

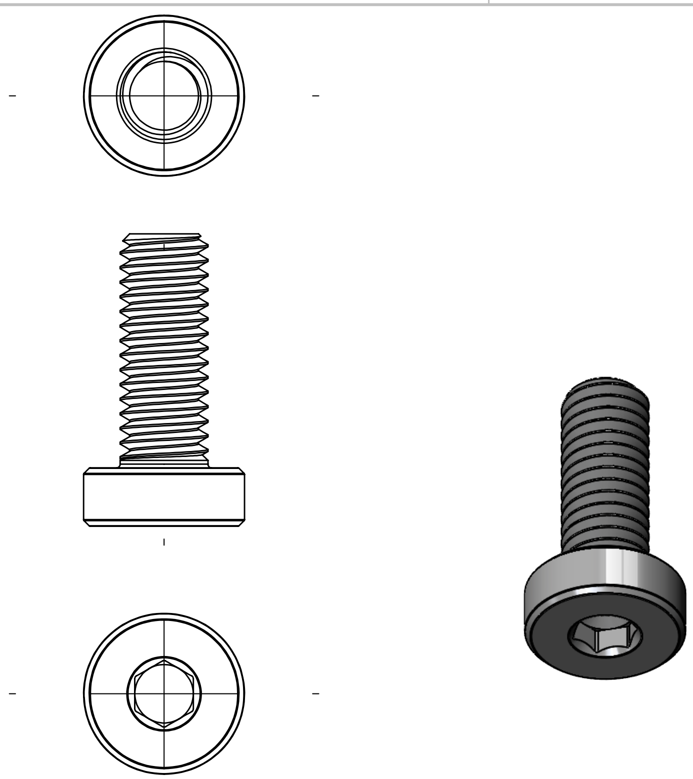
TITLE:
A012 316 SS Socket Head Screw

SIZE	DWG. NO.	REV
A	SSP-700	

SCALE: 10:1 WEIGHT: SHEET 1 OF 1

2 1

B B



A A

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Fabrication Steps
1. Buy from McMaster (90666A104_Super-Corrosion-Resistant 316 Stainless Steel Socket Head Screw)

NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN mm.
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±0.25
THREE PLACE DECIMAL ±0.130
INTERPRET GEOMETRIC TOLERANCING PER:
MATERIAL 316 Stainless Steel
FINISH
DO NOT SCALE DRAWING

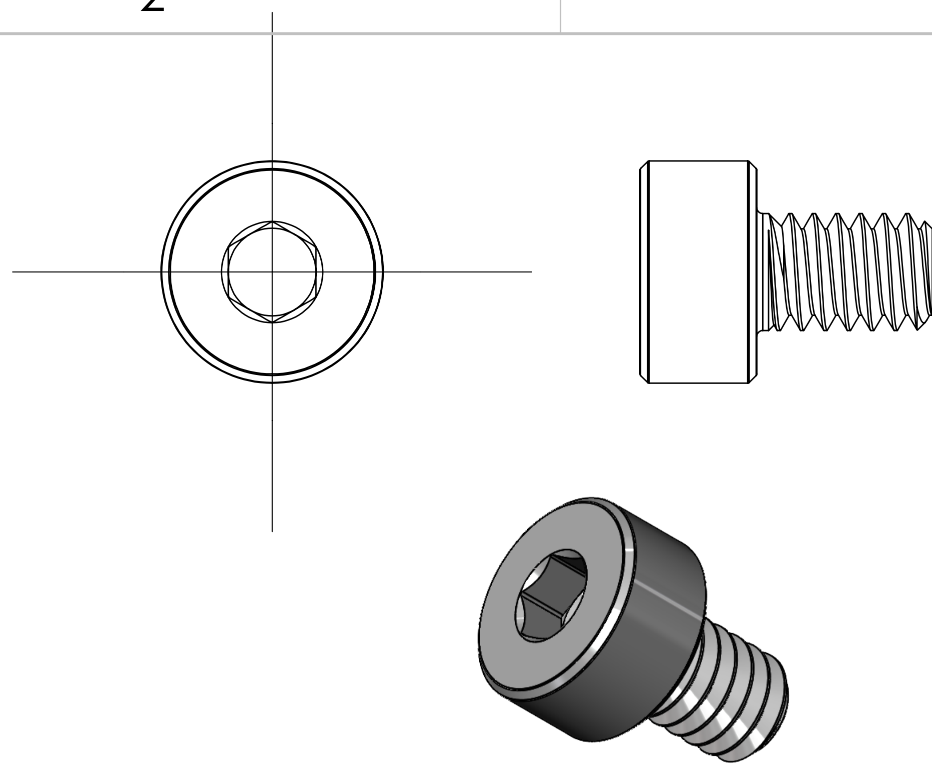
	NAME	DATE
DRAWN	C.M.M.	2/29/2024
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		
COMMENTS:		

SeaSpine

TITLE:
A104 316 SS Socket Head Screw

SIZE	DWG. NO.	REV
A	SSP-400	
SCALE: 5:1	WEIGHT:	SHEET 1 OF 1

2 1



Fabrication Steps
1. Buy from McMaster (92290A744_Super-Corrosion-Resistant ~~316 Stainless Steel~~ Socket Head Screw)

PROPRIETARY AND CONFIDENTIAL

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NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN mm.
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±0.25
THREE PLACE DECIMAL ±0.130

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL
316 Stainless Steel

FINISH

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	Name	2/29/2024
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		

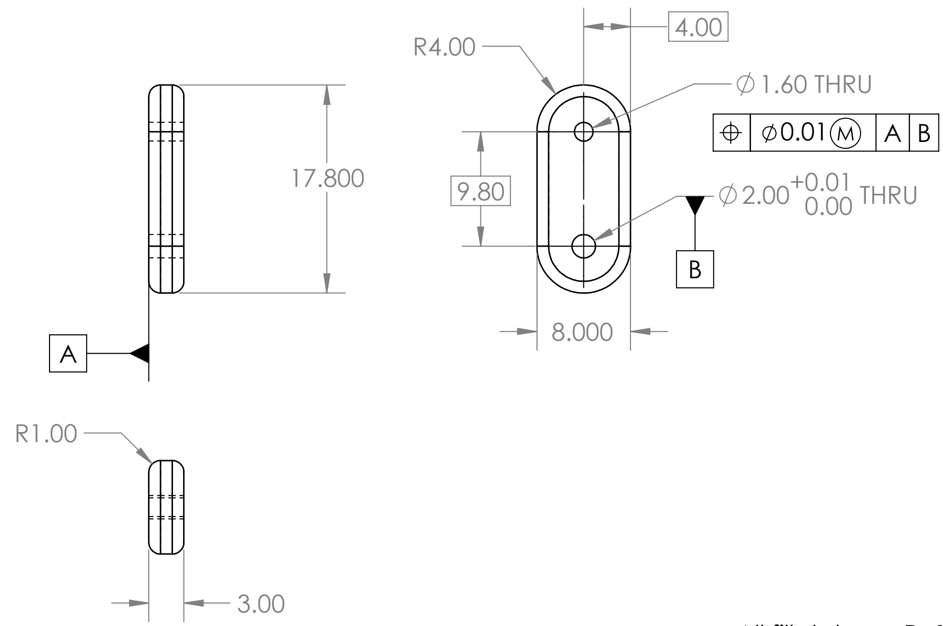
COMMENTS:

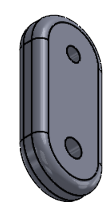
SeaSpine

TITLE:
A744 316 SS Socket Head Screw

SIZE	DWG. NO.	REV
A	SSP-600	

SCALE: 10:1 WEIGHT: SHEET 1 OF 1





All fillets have R=1.00 mm and tolerance of 0.25

Fabrication Steps
1. 18x8x3mm aluminum stock
2. Generate G-code in HSM
3. CNC with 3/16" EM

	NAME	DATE
DRAWN	C.M.M.	2/29/2024
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		
COMMENTS:		

UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN mm.
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±0.25
THREE PLACE DECIMAL ±0.130

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL

FINISH

DO NOT SCALE DRAWING

NEXT ASSY | USED ON

APPLICATION

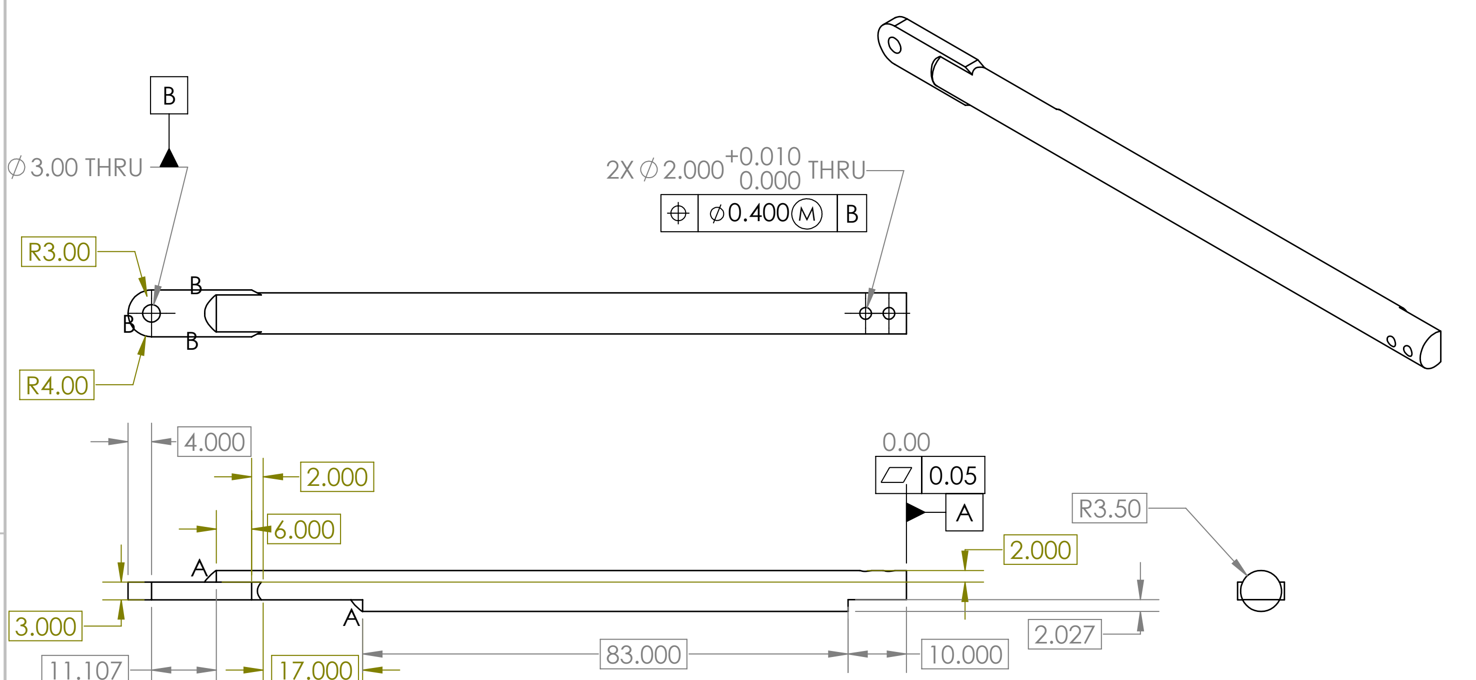
SeaSpine

TITLE:

Linkage Part 3

SIZE	DWG. NO.	REV
A	SSP-104	

SCALE: 2:1 | WEIGHT: | SHEET 1 OF 1



DRAWING NOTES

1. FILLETS THAT ARE LABELED "A" HAVE A FILLET RADIUS OF 2 mm.
2. FILLETS THAT ARE LABELED "B" HAVE A FILLET RADIUS OF 1 mm.

PROPRIETARY AND CONFIDENTIAL

NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±.25
THREE PLACE DECIMAL ±.130

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL
17-4 PH STAINLESS STEEL

FINISH

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	JC	
CHECKED	ST	
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS:
FABRICATION STEPS:
SEND TO PROTOLABS FOR FABRICATION

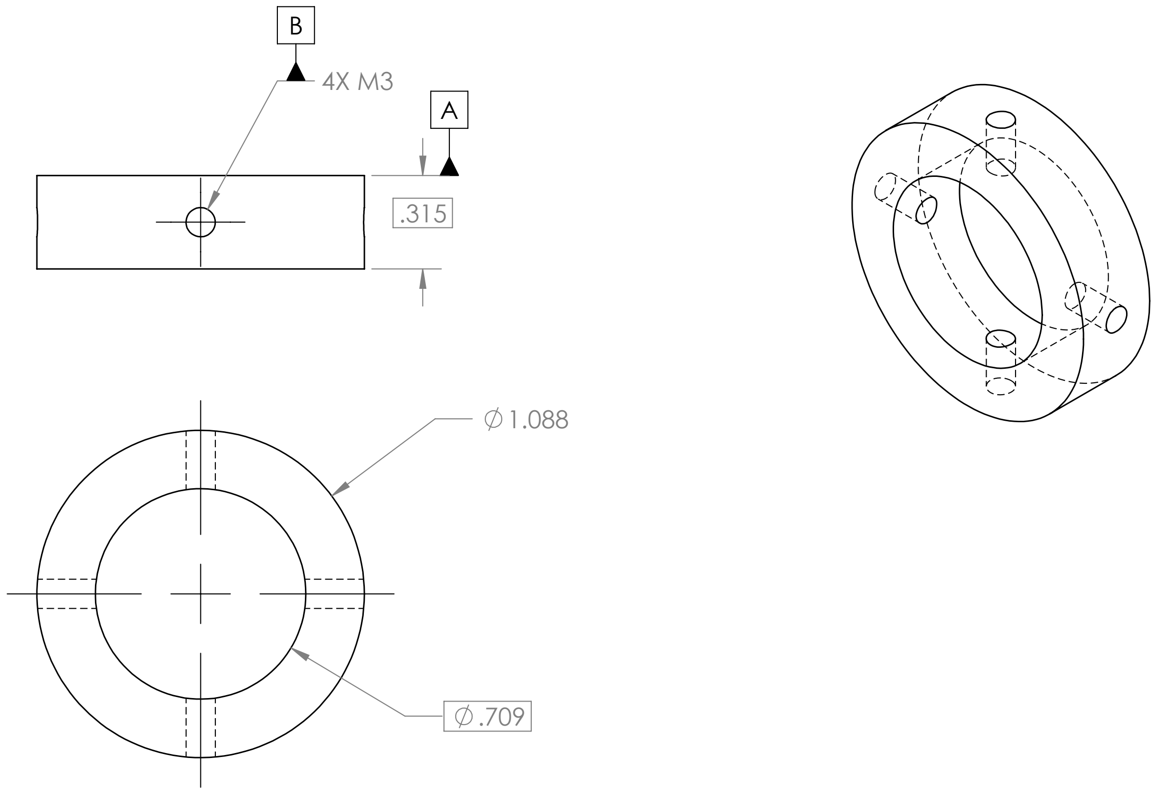
TITLE:
CAPSTONE DESIGN P1

SIZE	DWG. NO.	REV
A	SSP-101	A

SCALE: 1:1 WEIGHT: SHEET 1 OF 1

2 1

B



B

A

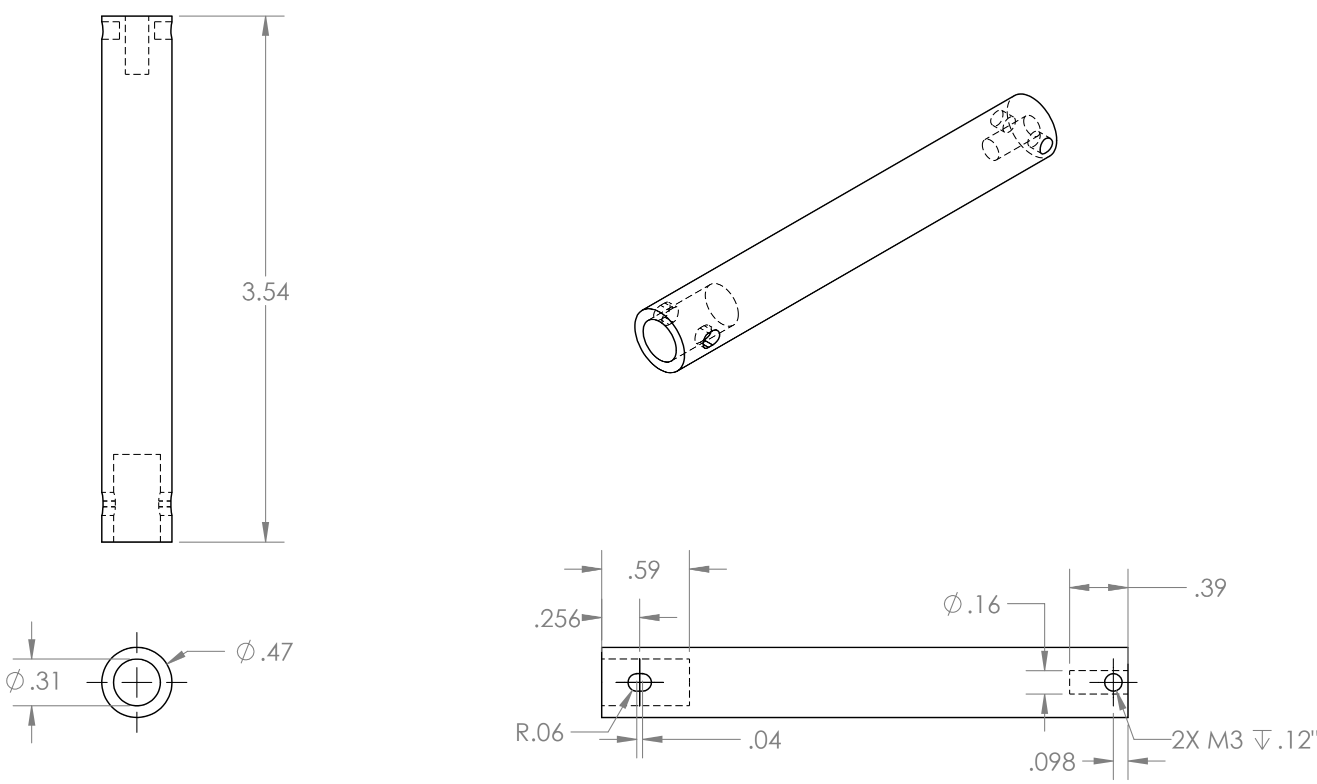
		UNLESS OTHERWISE SPECIFIED:		NAME	DATE	
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ±.01 THREE PLACE DECIMAL ±.005	DRAWN			TITLE: Bearing Holder
			CHECKED			
			ENG APPR.			
			MFG APPR.			
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.			
		MATERIAL 6061-T6 AL ALY	COMMENTS:			SIZE A DWG. NO. REV
NEXT ASSY	USED ON	FINISH				
APPLICATION		DO NOT SCALE DRAWING				SCALE: 2:1 WEIGHT: SHEET 1 OF 1

A

2 1

2 | 1

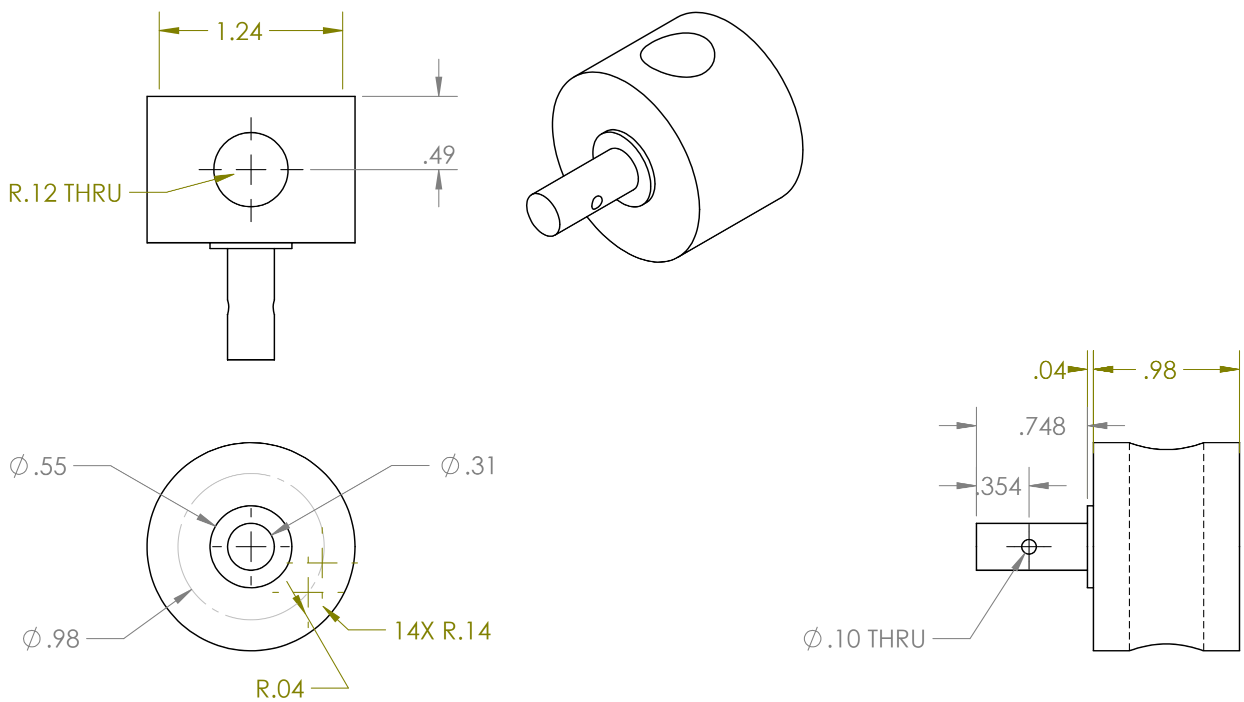
B | B



A | A

		UNLESS OTHERWISE SPECIFIED:		NAME	DATE	
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±	DRAWN			TITLE:
			CHECKED			
			ENG APPR.			
			MFG APPR.			
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.			
		MATERIAL	COMMENTS:			SIZE: A · DWG. NO.: Nut connector · REV
NEXT ASSY	USED ON	FINISH				
APPLICATION		DO NOT SCALE DRAWING				SCALE: 1:1 · WEIGHT: · SHEET 1 OF 1

2 | 1



		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±	DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
		MATERIAL	COMMENTS:		
NEXT ASSY	USED ON	FINISH			
APPLICATION		DO NOT SCALE DRAWING			

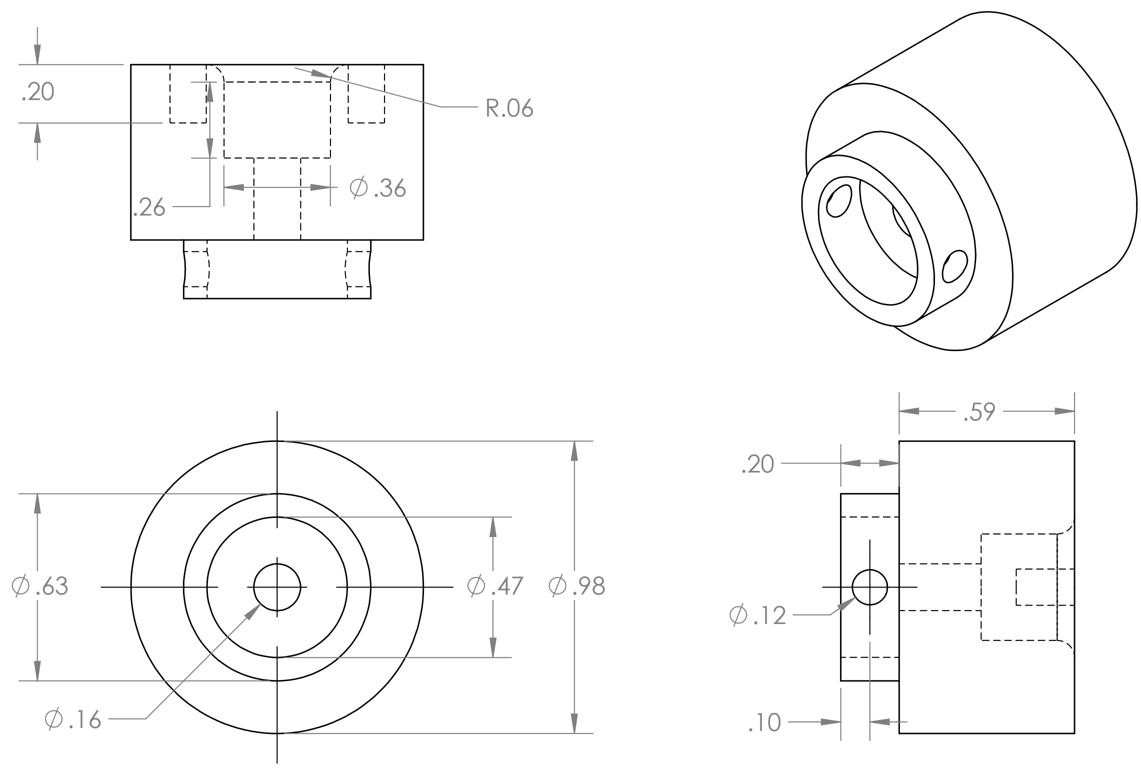
PROPRIETARY AND CONFIDENTIAL

TITLE: Knob

SIZE	DWG. NO.	REV
A		

SCALE: 1:1 WEIGHT: SHEET 1 OF 1

2 1



B B

A A

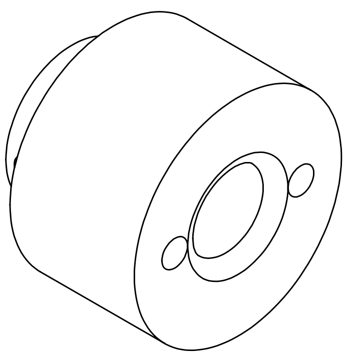
		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±	DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
		MATERIAL	COMMENTS:		
NEXT ASSY	USED ON	FINISH			
APPLICATION		DO NOT SCALE DRAWING			

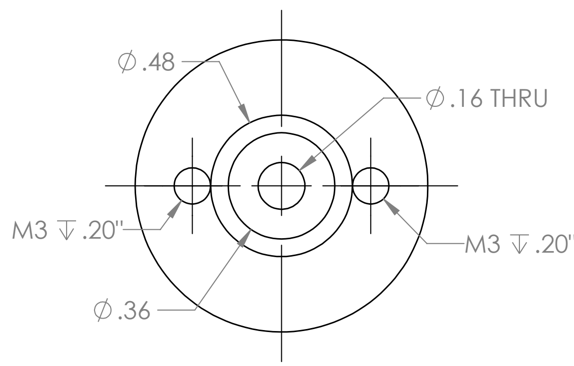
TITLE:

SIZE A DWG. NO. Nutconnectorwide REV

SCALE: 2:1 WEIGHT: SHEET 1 OF 2

2 1

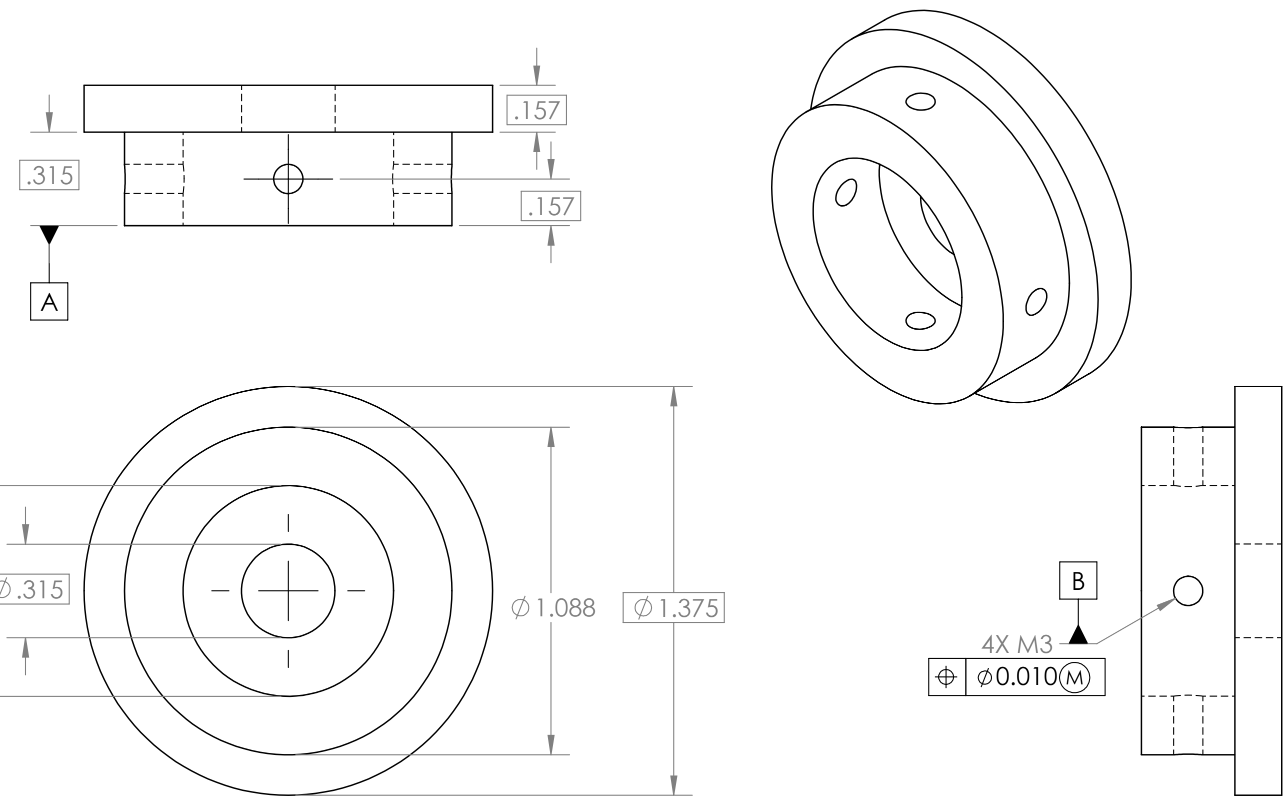




		UNLESS OTHERWISE SPECIFIED:		NAME	DATE	
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±	DRAWN			
			CHECKED			TITLE:
			ENG APPR.			
			MFG APPR.			
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.			
		MATERIAL	COMMENTS:			SIZE A DWG. NO. Nutconnectorwide REV
NEXT ASSY	USED ON	FINISH				
APPLICATION		DO NOT SCALE DRAWING				SCALE: 2:1 WEIGHT: SHEET 2 OF 2

2 1

B B



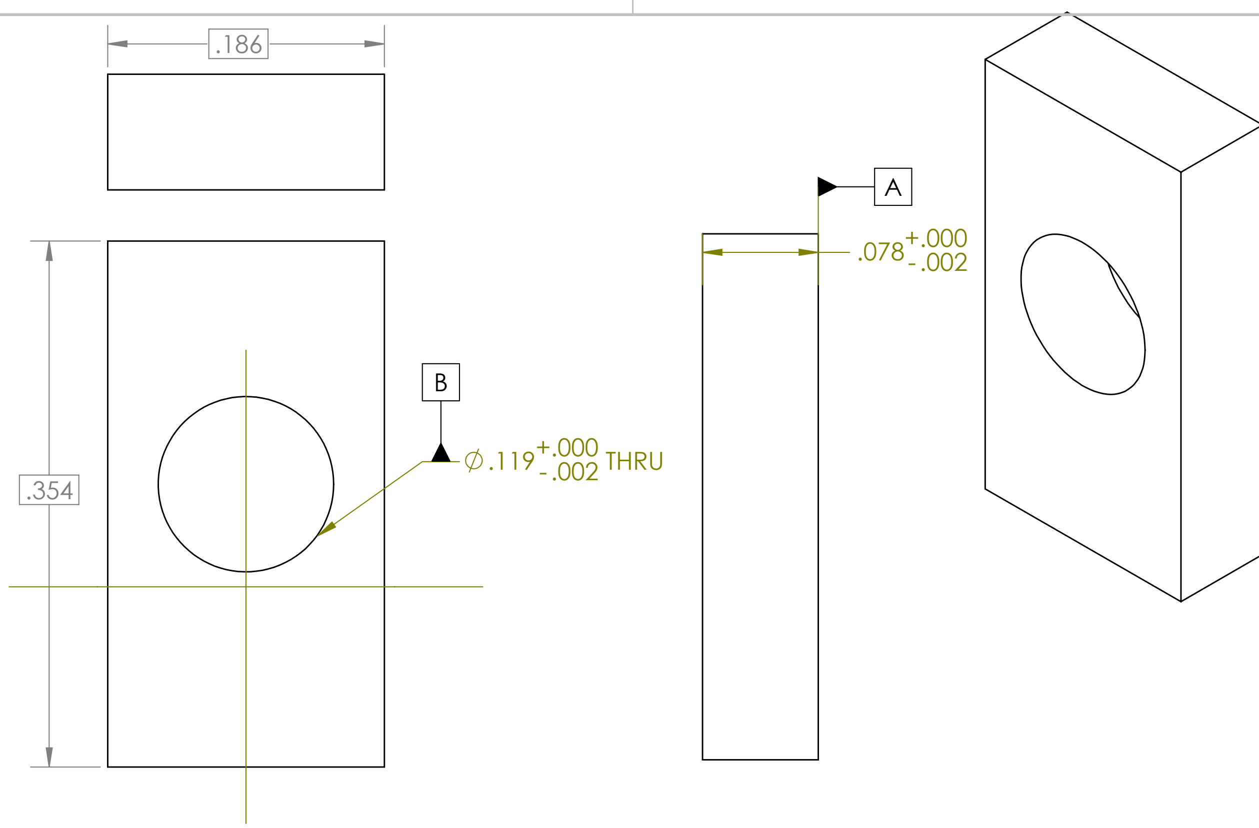
A A

		UNLESS OTHERWISE SPECIFIED:		NAME	DATE	
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ±.01 THREE PLACE DECIMAL ±.005	DRAWN			TITLE:
			CHECKED			
			ENG APPR.			
			MFG APPR.			
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.			
		MATERIAL 6061-T6 AL ALY	COMMENTS:			SIZE A DWG. NO. Back Plug V2 REV
NEXT ASSY	USED ON	FINISH				
APPLICATION		DO NOT SCALE DRAWING				SCALE: 2:1 WEIGHT: SHEET 1 OF 1

2 1

2 1

B B



A A

		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ±.01 THREE PLACE DECIMAL ±.005	DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
		MATERIAL 6061 T6 AL ALY	COMMENTS:		
NEXT ASSY	USED ON	FINISH			
APPLICATION		DO NOT SCALE DRAWING			

TITLE:

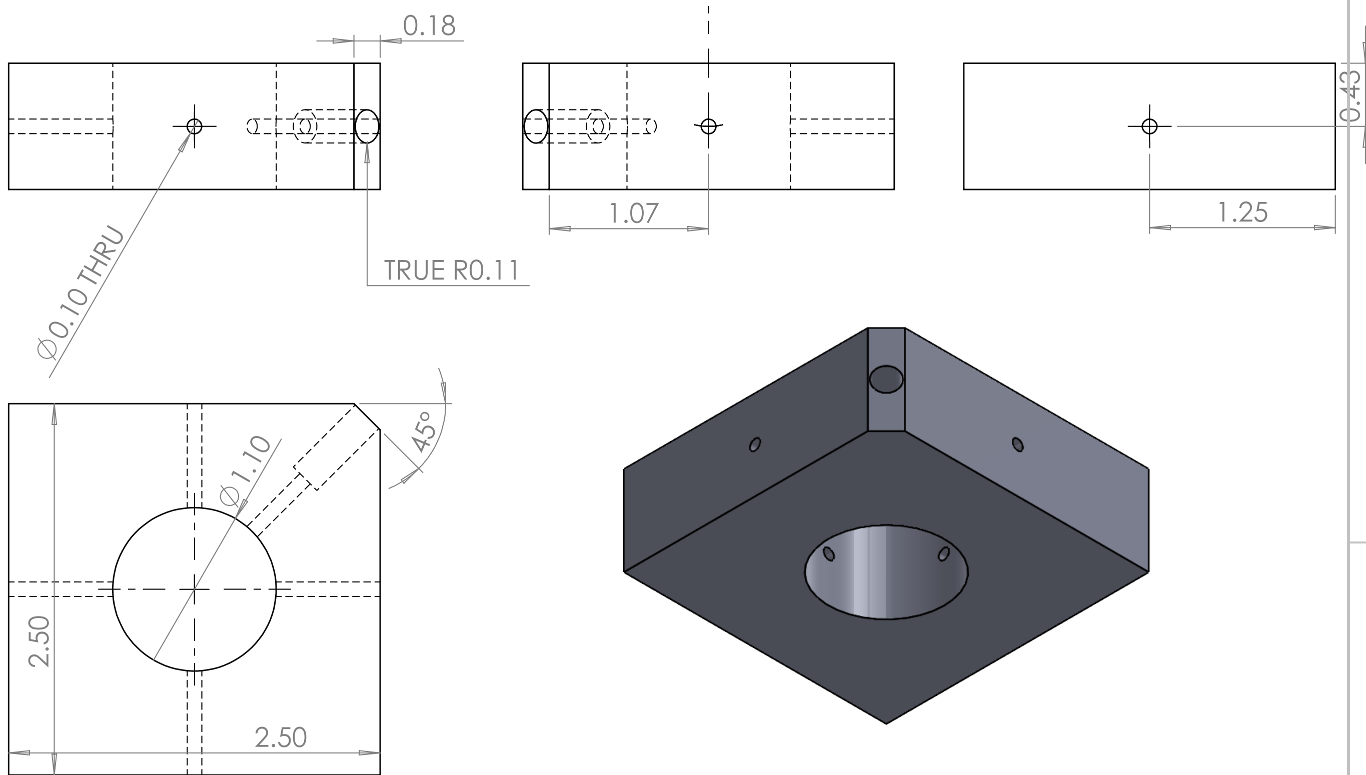
SIZE **A** DWG. NO. washer p2 REV

SCALE: 10:1 WEIGHT: SHEET 1 OF 1

2 1

2 1

B B



A A

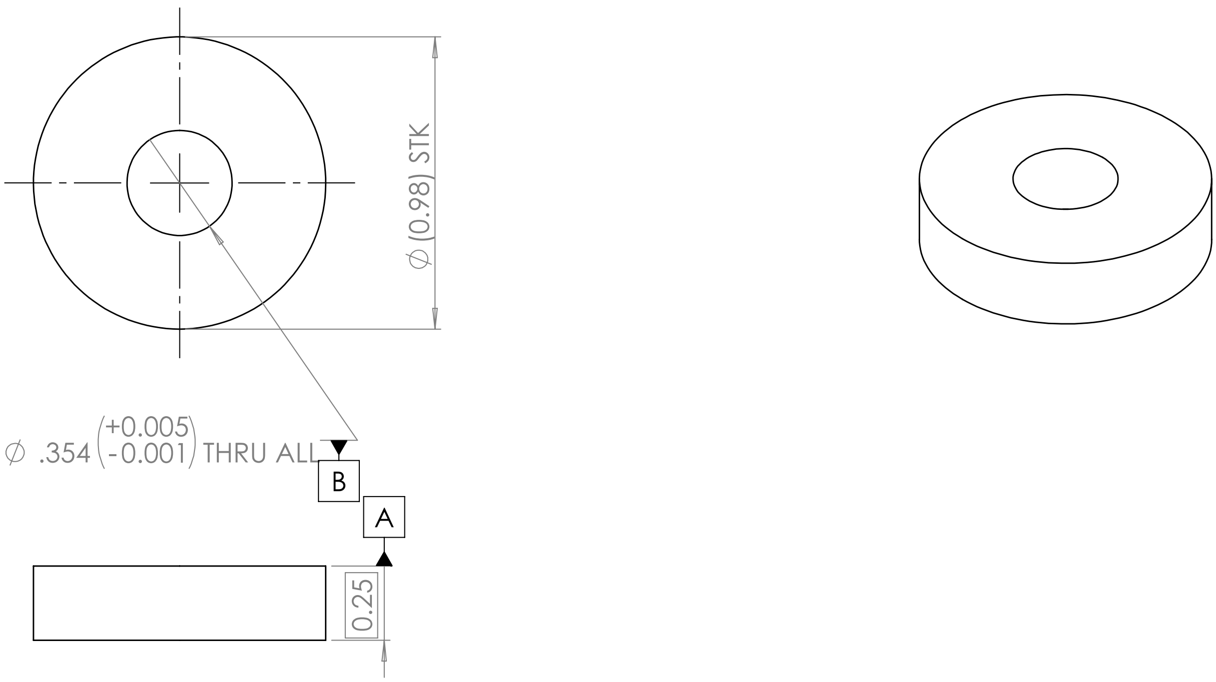
		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±	DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
		MATERIAL	COMMENTS:		
NEXT ASSY	USED ON	FINISH			
APPLICATION		DO NOT SCALE DRAWING			

TITLE:

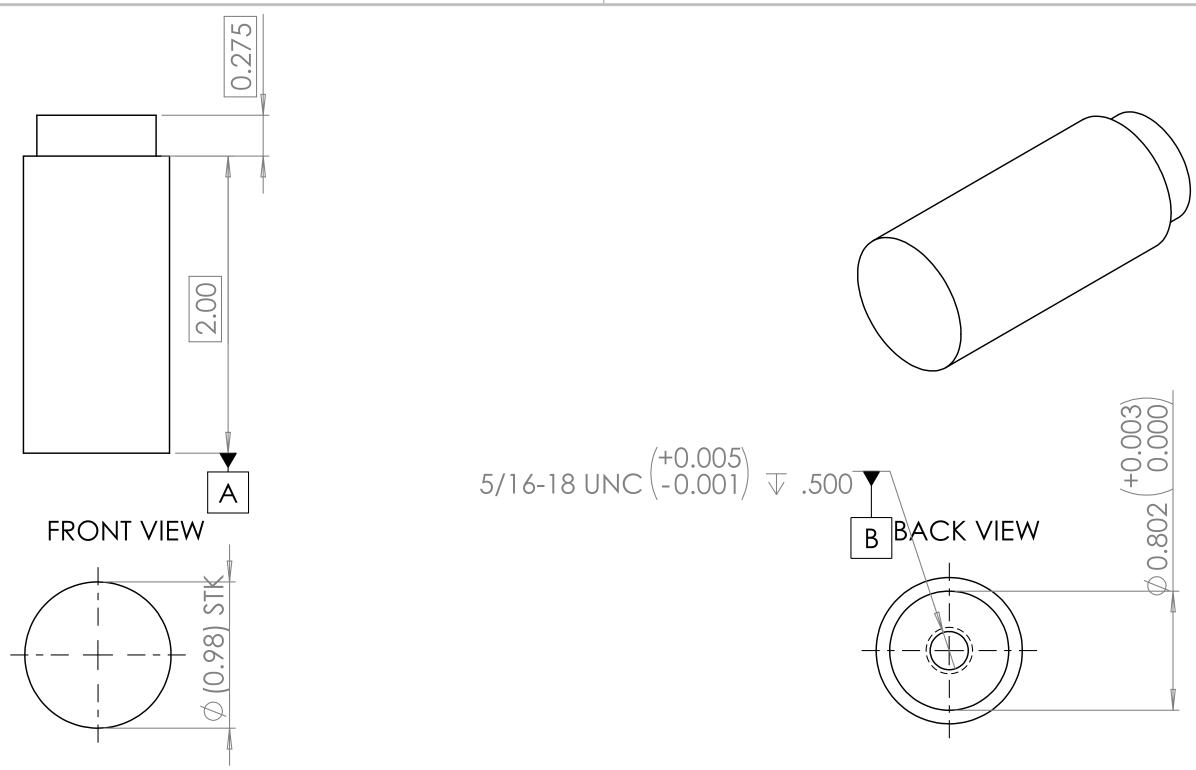
SIZE	DWG. NO.	REV
A	supArt for machining	

SCALE: 1:1 WEIGHT: SHEET 1 OF 1

2 1



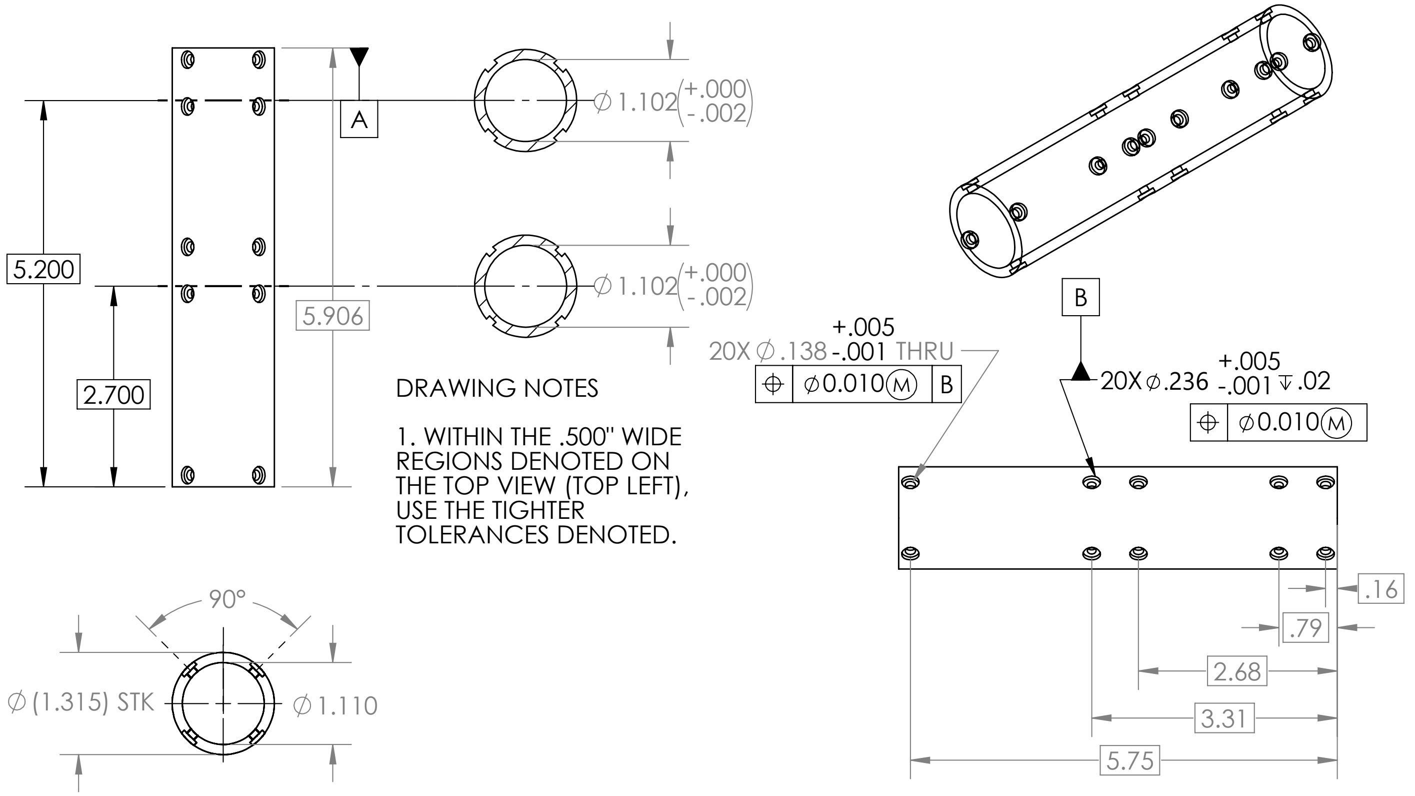
		UNLESS OTHERWISE SPECIFIED:		NAME	DATE	
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ±.01 THREE PLACE DECIMAL ±.005	DRAWN			
			CHECKED			TITLE:
			ENG APPR.			
			MFG APPR.			
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.			
		MATERIAL 6061-T6 AL ALY	COMMENTS:			SIZE A · DWG. NO. Fixture2_Cap · REV
NEXT ASSY	USED ON	FINISH				
APPLICATION		DO NOT SCALE DRAWING				SCALE: 2:1 · WEIGHT: · SHEET 1 OF 1



		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ±.01 THREE PLACE DECIMAL ±.005	DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
		MATERIAL 6061-T6 AL ALY	COMMENTS:		
NEXT ASSY	USED ON	FINISH			
APPLICATION		DO NOT SCALE DRAWING			

TITLE:

SIZE	DWG. NO.	REV
A	fixture1	
SCALE: 1:1	WEIGHT:	SHEET 1 OF 1



DRAWING NOTES

1. WITHIN THE .500" WIDE REGIONS DENOTED ON THE TOP VIEW (TOP LEFT), USE THE TIGHTER TOLERANCES DENOTED.

NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±.01
THREE PLACE DECIMAL ±.005

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL
6061-T6 AL ALY

FINISH

DO NOT SCALE DRAWING

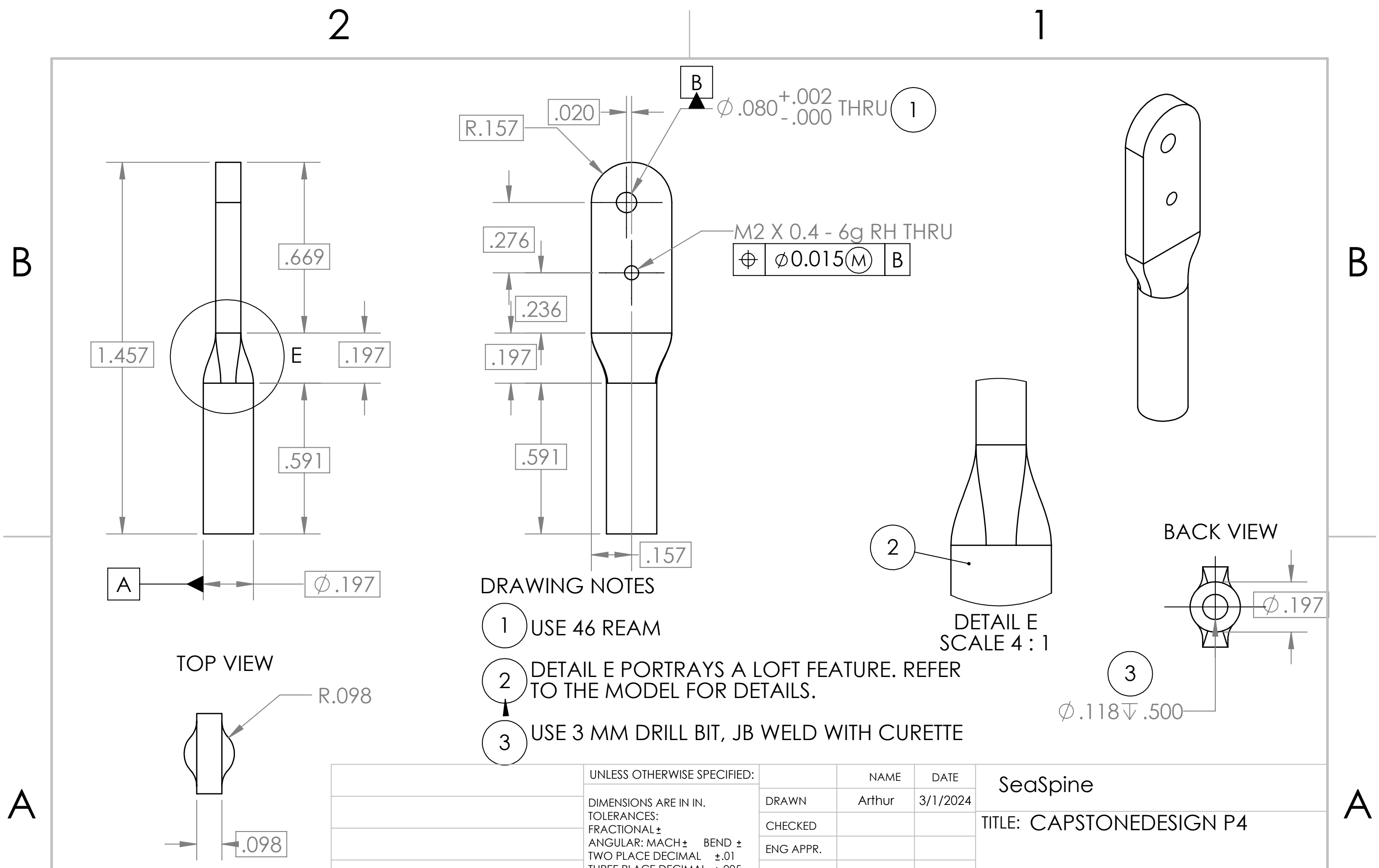
	NAME	DATE
DRAWN		
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS:

TITLE:

SIZE	DWG. NO.	REV
A	Shroud	A

SCALE: 1:2 WEIGHT: SHEET 1 OF 1



DRAWING NOTES

1. USE 46 REAM
2. DETAIL E PORTRAYS A LOFT FEATURE. REFER TO THE MODEL FOR DETAILS.
3. USE 3 MM DRILL BIT, JB WELD WITH CURETTE

UNLESS OTHERWISE SPECIFIED:		NAME	DATE
DIMENSIONS ARE IN IN. TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ±.01 THREE PLACE DECIMAL ±.005	DRAWN	Arthur	3/1/2024
	CHECKED		
	ENG APPR.		
	MFG APPR.		
INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
MATERIAL 6061-T6 AL ALY	COMMENTS:		
FINISH			
DO NOT SCALE DRAWING			

NEXT ASSY	USED ON
APPLICATION	

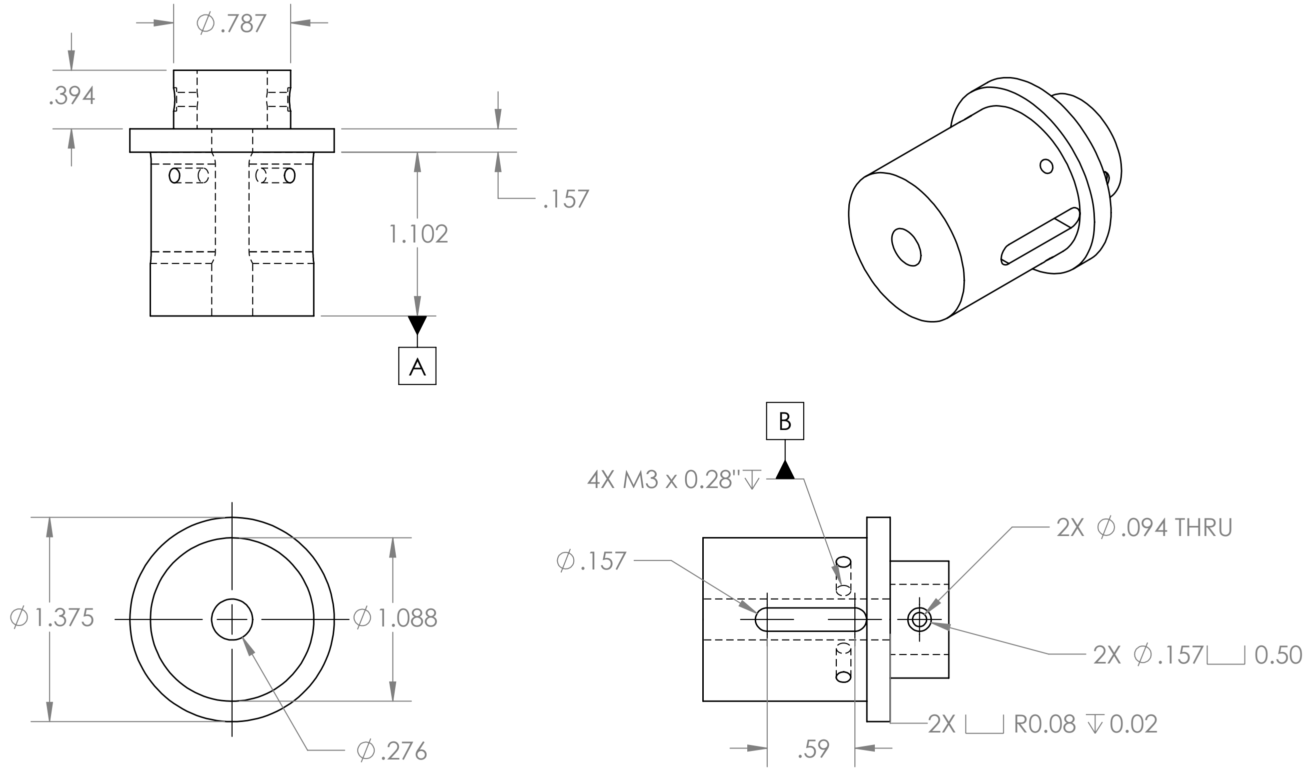
SeaSpine

TITLE: CAPSTONEDESIGN P4

SIZE	DWG. NO.	REV
A	SSP-103	A
SCALE: 2:1	WEIGHT:	SHEET 1 OF 1

2 1

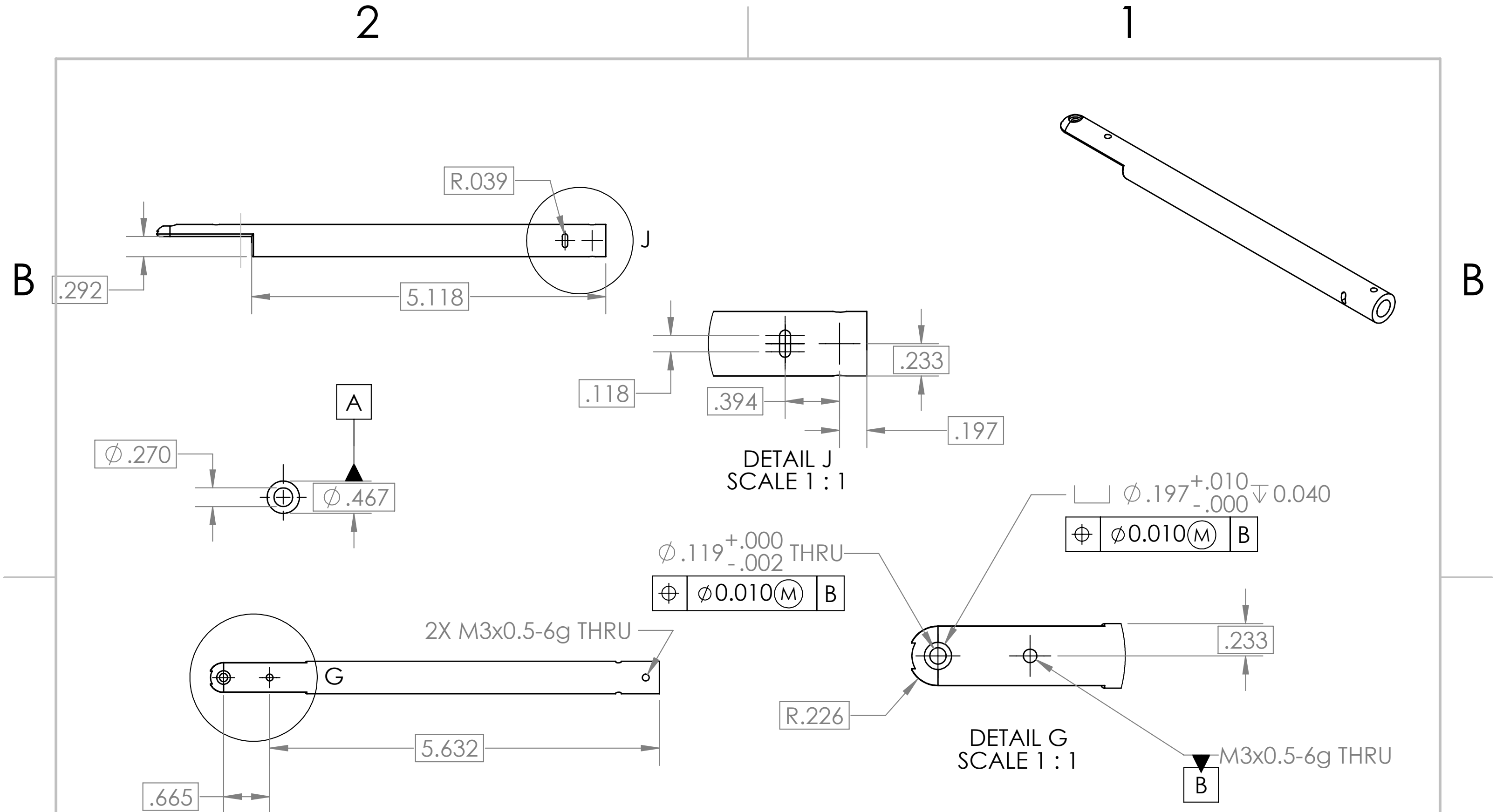
B B



A A

Fabrication Steps	UNLESS OTHERWISE SPECIFIED:		NAME	DATE	SeaSpine
	DIMENSIONS ARE IN mm. TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ±0.01 THREE PLACE DECIMAL ±0.005	DRAWN	Name	2/29/2024	TITLE: Handle plug with slot for lead screw
		CHECKED			
		ENG APPR.			
		MFG APPR.			
	INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.			
	MATERIAL	COMMENTS:			SIZE A — DWG. NO. Front Handle Face — REV
NEXT ASSY / USED ON	FINISH				
APPLICATION	DO NOT SCALE DRAWING				SCALE: 1:1 — WEIGHT: — SHEET 1 OF 1

2 1



		UNLESS OTHERWISE SPECIFIED:		NAME	DATE
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ±.01 THREE PLACE DECIMAL ±.005	DRAWN		
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
		MATERIAL 6061 T6 AL ALY	COMMENTS:		
NEXT ASSY	USED ON	FINISH			
APPLICATION		DO NOT SCALE DRAWING			

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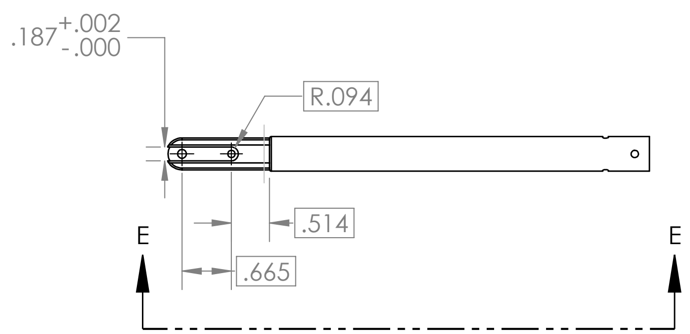
TITLE:

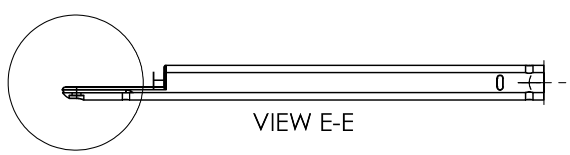
Long Linkage

SIZE	DWG. NO.	REV
A	aluminum long p5	

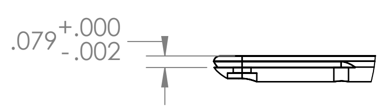
SCALE: 1:2 WEIGHT: SHEET 1 OF 2

2
1





VIEW E-E



DETAIL H
SCALE 1 : 1

		UNLESS OTHERWISE SPECIFIED:		NAME	DATE	
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ±.01 THREE PLACE DECIMAL ±.005	DRAWN			TITLE:
			CHECKED			
			ENG APPR.			
			MFG APPR.			
		INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.			
		MATERIAL 6061 T6 AL ALY	COMMENTS:			SIZE A DWG. NO. aluminum long p5 REV
NEXT ASSY	USED ON	FINISH				
APPLICATION		DO NOT SCALE DRAWING				SCALE: 1:2 WEIGHT: SHEET 2 OF 2

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.

A.4 Standard Operating Procedure (SOP)

An SOP is attached for each planned test.

Standard Operating Procedure: Disc Material Removal Test

Author:	Shant Tepelekian, Chiyo McMullin, John Chen
Course:	ME 189 – Capstone
Building/Room:	2171 (Engineering II)
Date:	TBD

1. Description

This SOP describes a test to determine if our prototype with the ringed curette is capable of articulating and reaching the contralateral space. This will be conducted by inserting the tool inside the empty disc test rig and using the controls to articulate and visually observing if the tool tip can reach the contralateral side with a pass/fail characteristic.

2. Hazards Overview

- *Bodily harm – Mishandling of prototype*
  - *Use eye protection when performing the test*
  - *Be mindful of protrusions and sharp edges*

3. Required Personal Protective Equipment (PPE)

- Safety glasses – eye protection

4. Waste Disposal

No waste is expected.

5. Accident and Spill Procedure

- *Minor cuts can be addressed using the Band-Aid station located above the sink.*
- *Seek medical help in the event of significant cuts/injury: Call 911. Notify lab manager.*

The lab manager must be notified in the event of any significant injury. A significant injury is any injury that cannot be addressed by the contents of the room's Band-Aid station.

6. Approvals Required

Permission of the lab manager is required before first run of the procedure.

7. Procedure

I. **Assembly**

Materials needed for 3 trials:

- 1x aluminum prototype
- 1x 3D printed test rig

Setup:

- Screw together test rig pieces

II. Pre-run

- Place the aluminum prototype through the hole of the test rig.

III. Run

- Use dial to articulate tool tip to full articulation while counting number of full turns
- Once full articulation is reached, see if tool tip has reached contralateral space
- Repeat 3 times and see if tool passes or fails for each trial, noting number of turns to full articulation.

IV. Post-Run

- Record pass/fail statistics and number of turns to full articulation
- Cleanup:
    - Take apart the test rig
    - Clean up the working area

Standard Operating Procedure: Bone Rasping Test

Author:	Chiyo McMullin, Shant Tepelekian, John Chen
Course:	ME 189 – Capstone
Building/Room:	2171 (Engineering II)
Date:	2/5/2024

1. Description

This SOP describes a test to characterize the force required to rasp bone and remove a certain amount of volumetric material. Wet cow bone will be used to emulate human bone and a rasp provided by SeaSpine will be used as the tool. Data acquisition is accomplished with an NI DAQ device, USB-6211 and load cell software.

2. Hazards Overview

- *Bodily Harm - Mishandling of rasp.*
  - *Keep hands clear of the part of the bone being rasped.*
- *Exposed moving parts with the potential to cause harm through entanglement and projectiles.*
  - *Work with care. Keep hands clear of work pieces.*
- *Flying debris – bone material flying off due to rasping*
  - *Stand clear of the area after impact is imparted.*
  - *Use eye protection when performing the test.*
- *Contamination – Handling raw meat/bone could pose a biohazard*
  - *Use gloves when handling the bone*
  - *Don't eat or drink while in lab*

3. Required Personal Protective Equipment (PPE)

- Safety glasses – eye protection
- Gloves – biohazard protection

4. Waste Disposal

Since all waste generated is non-hazardous, it may be disposed of in the general-rubbish bin. Care should be taken so as to reduce the amount of waste generated.

5. Accident and Spill Procedure

In case of skin contact with bone

- *Immediately flush affected area with water for 15 mintues. Call 911 to get emergency medical attention.*

For other accidents

- *Minor cuts can be addressed using the Band-Aid station located above the sink.*
- *Seek medical help in the event of significant cuts/injury: Call 911. Notify lab manager.*

The lab manager must be notified in the event of any significant injury. A significant injury is any injury that cannot be addressed by the contents of the room's Band-Aid station.

The lab manager must be notified in the event of a large spill, i.e., greater than 5 gallons, or a spill of any hazardous waste.

6. Approvals Required

Permission of the lab manager is required before the initial run of the procedure.

7. Procedure

I. **Assembly**

Materials needed:

- Wet cow bone soaked in saline solution
- 1x SeaSpine rasp
- Clamps
- Load cell
- Scale and weigh boats
- DAQ
- Plate to collect bone

Setup:

- Place plastic sheet on fixture and place bone on top to protect the fixture
- Screw bone in place
- Place fixture on load cell platen

II. **Pre-run**

- Turn on DAQ and load cell software

III. **Run**

- Start data collection
- Rasp bone in one direction applying an even normal force and ensuring passes are relatively similar
- End data collection
- Weigh the material removed on the scale
- Put material aside

IV. **Post-Run**

- Use the data acquired from the load cell to measure the amplitude of the maximum peak and retrieve the maximum force from that.
- Cleanup:
    - Turn off data acquisition software
    - Clean up and dispose any projectiles in normal trash can
    - Take apart test setup
    - Wipe down all surfaces with a disinfecting wipe

Standard Operating Procedure: Impact Force Test

Author:	Shant Tepelekian, Chiyo McMullin, John Chen
Course:	ME 189 – Capstone
Building/Room:	2171 (Engineering II)
Date:	TBD

1. Description

This SOP describes a test to determine if our aluminum prototype can withstand the impact force from a surgical mallet, which may be experienced during a surgery. This will be done by placing the aluminum prototype in the test rig to best simulate the surgery. The test will also denote a quantity of the force experienced by the tool with the surgical mallet, using a load cell will. Data acquisition is accomplished with an NI DAQ device, USB-6211 and load cell software.

2. Hazards Overview

- *Bodily Harm - Mishandling of hammer.*
    - *Keep hands clear of the part of the aluminum rod being hammered.*
- *Exposed moving parts with the potential to cause harm through entanglement and projectiles.*
    - *Work with care. Keep hands clear of work pieces.*
- *Flying debris – after impact, the aluminum material may fly off the work station as they are not secured to the stage.*
    - *Stand clear of the area after impact is imparted.*
    - *Use eye protection when performing the test.*

3. Required Personal Protective Equipment (PPE)

- Safety glasses – eye protection

4. Waste Disposal

Since all waste generated is non-hazardous, it may be disposed of in the general-rubbish bin. Care should be taken so as to reduce the amount of waste generated.

5. Accident and Spill Procedure

- *Minor cuts can be addressed using the Band-Aid station located above the sink.*
- *Seek medical help in the event of significant cuts/injury: Call 911. Notify lab manager.*

<u>The lab manager must be notified</u> in the event of any significant injury. A significant injury is any injury that cannot be addressed by the contents of the room's Band-Aid station.

6. Approvals Required

Permission of the lab manager is required before each run of the procedure.

7. Procedure

I. **<u>Assembly</u>**
    - 1x 3D printed test rig
    - 1x aluminum prototype
    - 1x load cell
    - 1x DAQ
    - Mechanical tester setup (will be helped by Kirk Fields)

- Clamps
- 1x 3-lb mallet

Setup:

- Place the aluminum prototype within the 3D printed test rig so that the handle is facing towards the person hitting the tool with the surgical mallet.

II. Pre-run

- Turn on DAQ and load cell software
- Make sure the person performing the test holds the hammer, is ready to use it, and is 5 feet away from any other humans or fragile equipment.

III. Run

- Initialize data collection
- Use the mallet to hit the aluminum prototype inside the 3D printed test rig.
- Stop data collection for the trial. Repeat for all 3 trials with the following considerations:
    - Stop the test if the prototype is broken.

IV. Post-Run

- Use the data acquired from the load cell to measure the amplitude of the first peak and retrieve the maximum force from that, for each trial.
- Cleanup:
    - Turn off data acquisition software
    - Clean up and dispose any projectiles in normal trash can
    - Take apart test setup.

Standard Operating Procedure:
Disc Material Removal Test

Author:	Shant Tepelekian, Chiyo McMullin, John Chen
Course:	ME 189 – Capstone
Building/Room:	2171 (Engineering II)
Date:	TBD

1. Description

This SOP describes a test to determine if our prototype with the ringed curette is capable of removing the nucleus pulposus from the disc space in both the non-articulated and articulated positions. This will be conducted by filling the 3D printed test rig with crab meat, which best simulates the nucleus pulposus, and removing the crab meat with our prototype. A percentage of the volume removed will be recorded to quantify the success of the prototype.

2. Hazards Overview

- *Flying debris – Crab meat may fly off the prototype after being scraped off.*
  - *Use eye protection when performing the test.*

3. Required Personal Protective Equipment (PPE)

- Safety glasses – eye protection

4. Waste Disposal

Since all waste generated is non-hazardous, it may be disposed of in the general-rubbish bin. Care should be taken so as to reduce the amount of waste generated.

5. Accident and Spill Procedure

- *Minor cuts can be addressed using the Band-Aid station located above the sink.*
- *Seek medical help in the event of significant cuts/injury: Call 911. Notify lab manager.*

The lab manager must be notified in the event of any significant injury. A significant injury is any injury that cannot be addressed by the contents of the room's Band-Aid station.

6. Approvals Required

Permission of the lab manager is required before each run of the procedure.

7. Procedure

I. **Assembly**

Materials needed for 3 trials:

- 1x aluminum prototype
- 1x 3D printed test rig
- 1x can of crab meat
- 1x weight measurement scale
- 1x plastic cup

Setup:

- Fill in as much of the test rig as possible with the crab meat, making sure to get enough crab meat spread onto both the contralateral and ipsilateral side of the test rig.

II. Pre-run

- Measure the total mass of the total amount of crab meat available
- Fill the test rig with the crab meat
- Measure the mass of the remaining amount of crab meat to accurately obtain the mass of the crab meat placed within the test rig.
- Place the aluminum prototype through the hole of the test rig.

III. Run

- Scrape as much of the crab meat from the test rig as possible, in both the non-articulated and articulated positions.
- With the tool, go inside and outside the test rig with multiple passes to ensure that the crab meat gathered from each pass is removed from the test rig and placed into a plastic cup for future measurement.
- Stop the test when all the crab meat that could be possible removed using the tool is removed.

IV. Post-Run

- Measure the mass of the crab meat in the cup (the mass removed from the test rig), to obtain a percentage of the crab meat removed from the test rig.
- Cleanup:
  - Take apart the test rig, remove all remaining crab meat, and rinse the test rig with water.
  - Disposes all crab meat in the normal trash can
  - Clean up the working area

Standard Operating Procedure: Cadaver Test

Author:	Shant Tepelekian, Chiyo McMullin, John Chen
Course:	ME 189 – Capstone
Building/Room:	Seaspine HQ, Carlsbad, CA
Date:	TBD

1. Description

This SOP describes a test to determine if the final prototype (consisting of completely steel or steel + aluminum) can perform a full discectomy in a cadaver, which is the closest simulation to a live human surgery as we can achieve without a clinical trial. Thus, this test will be the ultimate demonstration of our tool's capabilities in a surgical setting. The procedure will be performed by our team and SeaSpine employees with an experienced cadaver lab technician leading the operation. The functionality will be tested on a pass/fail basis, where the device either successfully completes the operation without device or cadaver damage, or fails.

2. Hazards Overview

- *Bodily Harm - Mishandling of hammer.*
  - *Keep hands clear of the part of the device being hammered.*
- *Exposed moving parts with the potential to cause harm through entanglement and projectiles.*
  - *Work with care. Keep hands clear of work pieces.*
- *Biohazardous material – Human tissue*
  - *Wear scrubs to cover clothes and gloves for hands*
  - *Avoid exposing personal belongings to cadaver lab area*
  - *Ensure that removed material is properly placed/disposed of*
- *Radiation hazard – Fluoroscopy for imaging*
  - *Wear x-ray protection*
  - *Take infrequent images to lower radiation levels*

3. Required Personal Protective Equipment (PPE)

- Safety glasses – eye protection
- Scrubs – clothing/body protection against human flesh/hazardous material
- Leads – clothing/body protection against x-rays

4. Waste Disposal

Waste is a biohazard and must be disposed of in proper biohazardous waste bins. Follow SeaSpine protocol to ensure proper disposal.

5. Accident and Spill Procedure

- *Minor cuts must be fully cleaned and cared for to ensure no infection occurs. Notify SeaSpine employees and follow their protocol.*
- *Seek medical help in the event of significant cuts/injury: Call 911. Notify SeaSpine employees and follow their protocol.*

<u>SeaSpine will be notified</u> in the event of any significant injury.

6. Approvals Required

Permission of the cadaver lab technician is required before each run of the procedure and the team will be under constant supervision by the cadaver lab technician, SeaSpine advisors, and other SeaSpine employees who are familiar with the procedure.

7. Procedure

I. **Assembly**

Materials needed for 1 trials:

- 1x completed final prototype
- 1x cadaver
- 1x SeaSpine posterior disc prep kit
- 1x 3 lb surgical mallet
- 1x x-ray imaging device
- Cadaver lab tools/available fixtures and tables

Setup:

- *SeaSpine will handle the setup*
  - Prep cadaver
  - Gather tools
  - Set up x-ray imaging

II. Pre-run

- Use dilators and tubular retractors to gain access to disc space
- Distract disc space as necessary
- Ensure tubular retractor is fixtured properly so it doesn't move when discectomy is happening
- Break through outer annulus

III. Run

- Perform discectomy by using ContraTech prototype to dislodge material in the straight and articulated position and remove with the ringed curette tip. If it is difficult to perform both actions, take note, and use a different tool.
  - Take note of what motions/techniques are easier or harder to perform
  - Take note on how much material is being removed
  - Compare ease of use of current tools to ContraTech

IV. Post-Run

- Continue with the rest of the MIS-TLIF procedure (insert spinal cage and bone graft)
- Cleanup:
  - Dispose of all waste properly
  - Clean lab room supplies and tables
  - Remove PPE outside of lab in proper order determined by SeaSpine

A.5 Additional Materials

MATLAB Code for Linkage Force Transmission

A.5.1 MATLAB Code for Linkage Force Transmission

```
F5 = 106.8; \% N FORCE THAT IS BEING PRESSED INTO TOOLTIP PARALLEL WITH INSTRUMENT

F5=500;

F5=30;

d = 38.5; \% BOTTOM LINKAGE LENGTH OF TOOL TIP MOMENT ARM

a=9.79; \% SMALL LINKAGE LENGTH

b=7; \% BOTTOM LINKAGE SMALL PIVOT LENGTH

c=8.23; \% VARIABLE VERTICAL DISTANCE

\%c=15.79;

gamma = acos((a\^2+b\^2-c\^2)/(2*a*b));

alpha = acos((b\^2+c\^2-a\^2)/(2*b*c));

phi = pi/2 - gamma;

beta = acos((a\^2+c\^2-b\^2)/(2*a*c));

F4=F5/cos(alpha);

T2=F4*d;

T1=T2;

F3=T1/b;

F2=F3/cos(phi);

F1=F2*cos(beta);

disp(F1);

SF = 1;

disp(F1*SF);
```

```
disp(F1*SF/4.44822);
```

B Works Cited

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