

SeaSpine Force Limiting Handle With Replaceable Components

A Senior Project
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I. Executive Summary

This document outlines details of the Cal Poly-SeaSpine senior project collaboration for the force limiting handle with replaceable components. This document will cover a brief introduction of the project itself, background information about the problem, customer requirements and engineering specifications, ideation and concept selection, detailed design, description of testing and manufacturing plans, design verification and validation results, conclusions, and future work.

The design process included background research and scope identification, ideation, concept selection based on quality functions and customer requirements, detailed design, manufacturing, testing and iteration, and design verification and validation. Key specifications for the device included a force to break the device greater than the force to insert the spinal cage during spinal fusion surgery, 378.3 N, and less than the lower limit of the force to break the spinal cage, 923 N. The force to break the device was found to be 776 N, with upper and lower tolerance limits of 793 N and 759 N, which were well within the specified allowable range. Further details of data analysis and testing are included in Section XIII.

II. Introduction

The SeaSpine force limiting surgical handle is a project creating a replaceable handle component that yields before the spinal cage yields during implantation. This will prevent damage to the spinal cage during hammering in spinal fusion surgeries. This project is intended for use with SeaSpine's surgical tools for spinal surgery, specifically their handles and spinal cages indicated for Posterior Lumbar Interbody Fusion (PLIF) and Transforaminal Lumbar Interbody Fusion (TLIF) surgeries. The device is intended to limit the force applied to the SeaSpine spinal cages during insertion to address spinal cage damage and failures reported during spinal fusion procedures. Key stakeholders for this project include SeaSpine sponsor, Zac Dooley, and senior project advisor, Britta Berg-Johansen. We have met our goal to deliver a working prototype with a detailed report, including relevant data, process documentation, design details, and instructions for use.

The first conceptual report included background information, objectives, project management, and conclusions for the project. The *background* section includes existing information that will have a bearing on the proposed work, including current products, a patent search, a summary of relevant technical literature and industry standards. The *objectives* section sets the scope of our project including problem definition, quality definition, engineering specifications, testing, etc. The *project management* section touches on our plan and timeline, key deliverables, unique techniques, next steps, and includes a Gantt chart. The *morphology* section outlines the method

we used to ideate concepts, the *concept selection* section walks through our selection process, and the *conceptual design* section describes our selected design in further detail. The *FMEA*, or *Failure Mode and Effects Analysis*, walks through all the risks associated with our device and their severities.

Adding on to the previous conceptual report for the critical design review, the report was updated to include detailed design, prototype manufacturing plans, and a summary of test plans for each specification. The *detailed design* section includes a description of the final design, material selection, cost estimation, and dimensioning. This section also includes detailed drawings and solid models with a full assembly of the device. The *prototype manufacturing plans* section includes detailed manufacturing process instructions, list of facilities, equipment, and a bill of materials. The *test plans* section includes a description of all experiments, an overview of protocols, sample sizes, and expected results, along with identification of testing facilities, equipment, a bill of materials, and training and certification required to carry out the desired testing plans.

Since the test plan report was completed, Section XIII Testing Data and Analyses and Section XIV Instructions for Use were added. The *testing data and analyses* section includes all of the results from testing our engineering specifications, summarized in a table, and a breakdown of the results from each completed test. Finally, the *instructions for use* section includes instructions for how to use the device during surgery, and how to replace the components of the device.

III. Background

Summary of Customer Observations

Our project manager, Zac Dooley, is a research and testing lab manager at SeaSpine. Our group has met with him several times to help guide our force limiting surgical handle project. Through zoom calls and meetings we have gotten a better understanding of the project, as well as more knowledge about the resources that they are able to provide to support our project. Table I shows a summary of our customer meetings and takeaways from all major correspondence.

Table I. Summary of sponsor/customer meetings and observations.

Meeting/Correspondence Date and Type	Summary of Customer Observations and Meetings
09/27/2022 Zoom Call	<ul style="list-style-type: none"> ● In-house machine shop <ul style="list-style-type: none"> ○ 2-3 day turnaround time ○ Plastic 3D printer ● Can have parts made on SeaSpine’s site ● Can order parts from McMaster <ul style="list-style-type: none"> ○ Send to Zac to order them and ship to us

	<ul style="list-style-type: none"> ● Handle needs to break before cage during hammering ● Final print with proper tolerances ● Cages with highest fail rate are for Tlif and Plif surgeries <ul style="list-style-type: none"> ○ Tlif: transforaminal lumbar interbody fusion ○ Plif: posterior lumbar interbody fusion ● Threaded with anti-rotation mechanism ● Handle should be universally compatible with current SeaSpine fittings <ul style="list-style-type: none"> ○ Should be compatible with multiple cages ● Cages are PEEK coated with titanium ● Previous researched solutions: <ul style="list-style-type: none"> ○ Implant to instrument interface ● Material must be biocompatible <ul style="list-style-type: none"> ○ Should be same material as verified biocompatible predicate device to avoid additional testing
<p>09/27/2022 Email</p>	<ul style="list-style-type: none"> ● Surgical techniques for Hollywood VI (Variable Insertion) and Ventura <ul style="list-style-type: none"> ○ TLIF devices ○ Surgical techniques documentation ● Spine surgery: https://www.youtube.com/watch?v=okNJPMbh_W0
<p>09/29/2022 Email</p>	<ul style="list-style-type: none"> ● In-house sterilization at the hospital for instruments <ul style="list-style-type: none"> ○ Primarily steam sterilization ○ Want 10+ cycles of sterilization for surgical handle ● For testing, have on-site sterilization at SeaSpine <ul style="list-style-type: none"> ○ Takes up to an hour to run a cycle
<p>10/04/2022 Zoom Meeting</p>	<ul style="list-style-type: none"> ● Want to re-use handle if it doesn't break during procedure ● Should be able to "wack" handle 20 times for 5 surgeries or have an estimate of how many times it can be hit/for how many surgeries <ul style="list-style-type: none"> ○ Watch surgery videos on YouTube to count approximate number of times it takes to insert a surgical cage into spine ● Load cells needed for testing <ul style="list-style-type: none"> ○ Transducertechniques.com ● Can be a new handle completely or an add-on to current ● Budget: should be kept under 5k <ul style="list-style-type: none"> ○ Mass production units normally cost \$80-\$120 per unit ○ \$600 per unit for a single piece ○ \$3k per unit for more intricate designs

<p>10/04/2022 Email</p>	<ul style="list-style-type: none"> ● Items SeaSpine could send us for testing: <ol style="list-style-type: none"> 1). NI DAQ Board USB-6003 2). NI DAQ Board USB-6001 3). Interface Force load cell WMC-100 (100 lbf) 4). Transducer Techniques load cell LBO-250 (250 lbf). I have 2 of these 5). Transducer Techniques load cell LBO-1K (1,000 lbf) 6). Transducer Techniques load cell amplifier LCA-RTC. I have 3 of these 7). Transducer Techniques power adapter APD-12VDC. I have 3 of these. <p>I also have the following that have to be used with a portable display (Transducer Techniques Model SSI) due to the TEDs chip inside of them.</p> <ol style="list-style-type: none"> 1). Transducer Techniques load cell SWP-1K (1,000 lbf) 2). Transducer Techniques load cell SWP-3K (3,000 lbf)
<p>10/11/2022 Zoom Meeting</p>	<ul style="list-style-type: none"> ● Zac sent us an ASTM cage <ul style="list-style-type: none"> ○ They use the ASTM cage for worst case scenario testing ● We should remove the threads for FEA (finite element analysis) ● Use generic PEEK from in vivo <ul style="list-style-type: none"> ○ Medical grade not industrial grade ○ Follows F2026 standard (can send to us) ● Specialized coating is unique to SeaSpine ● Cage sizes selected based on bell curve of human sizes <ul style="list-style-type: none"> ○ 1 mm to 2 mm height steps in varying sizes ● Surgeon specifies the size ● Off-set handles are used less often ● Loaning out not renting system <ul style="list-style-type: none"> ○ Note to change language in documentation
<p>10/21/2022 Zoom Meeting</p>	<ul style="list-style-type: none"> ● Went over initial design proposals <ul style="list-style-type: none"> ○ Zac approved first idea or second ● Suggestions from Zac: <ul style="list-style-type: none"> ○ Add holes to control the fracture strength ○ Make sure that shards are contained <ul style="list-style-type: none"> ■ Add silicone casing or sleeve ○ Use design to minimize the likelihood of surgeon hitting the device incorrectly ● Notes from Zac: <ul style="list-style-type: none"> ○ Things aren't likely to be hit squarely ○ Likely won't only hit the strike pad

<p>10/25/2022 Zoom Meeting</p>	<ul style="list-style-type: none"> ● Make the hitting pad taller to make sure you're not hitting the casing ● Fine to put a thread in the back of the handle that was given to us ● Would send multiple handles or add ons <ul style="list-style-type: none"> ○ Would send 2 add ons with loan out packages ● Going to 3D print first prototypes this week <ul style="list-style-type: none"> ○ Okay to pay retroactively ● Impact force measurements <ul style="list-style-type: none"> ○ Use current handle and spinal cage and then switch to using entire set up ● Zac has given us most of all the cages that he has, probably can send us less than 10 ● Small chance that they go through and reject more cages ● Costs around \$300-\$800 to manufacture each cage ● \$2000-2500 for the hospital or purchaser to buy a cage
<p>11/8/2022 Zoom Meeting</p>	<ul style="list-style-type: none"> ● CAD Notes <ul style="list-style-type: none"> ○ Show him the new model with encased puck and newly positioned screws ○ 3D printing prototype ● Get the puck and metal components machined <ul style="list-style-type: none"> ○ Starting with aluminum ● Puck is now fully contained ● Solid disk <ul style="list-style-type: none"> ○ Potentially add geometry to disc ○ Add cutouts to discs to make sure it breaks where we want it to ○ Could add geometry to the bottom of the hitting pad ● Don't want too much over interference of the disc, do a one-sided tolerance to make sure it fitsAesthetics are not much of a concern <ul style="list-style-type: none"> ○ Cheaper to have through holes ○ Easier to clean ● Ball end on mill to cut the internal radius <ul style="list-style-type: none"> ○ Bigger radius means machining will go faster ● Sharp corners where the discs fit are hard to machine ● Delrin for the disc ● No laser cutting in SeaSpine office <ul style="list-style-type: none"> ○ Can traditionally machine it ● Extend the thread more and then run a circle cut <ul style="list-style-type: none"> ○ As is will not fully fit into the threads on the back of the handle ● Testing notes: <ul style="list-style-type: none"> ○ Breaks around 5000 N ○ 25 kN on site max instron testing- MTS bionix 2 ○ Can control the machine to do a quick pulse ○ Test final version on site ○ Zac will send us a load cell with display

<p>11/14/2022 Email</p>	<p>Comments on initial CAD drawings:</p> <ul style="list-style-type: none"> ● Thread calls need to have a thread class. Look this up online. ● THRU All is implied, you don't need to write it out. If it is a through hole, no extra notation is necessary. ● Glenn (our manufacturing engineer) was thinking that the part would be lathed. Hence, for the 2 large holes on the bottom housing and the sliding punch, there will be a drill point in the remaining material. It doesn't look like it will affect anything, but if it does, you need to let us know. Mainly, he wants to point it out just so you are aware of the cosmetic difference. ● The one fillet you have in the drawing, Glenn labeled with a max call out. He might be able to make it smaller, but if there is a maximum size it cannot be any larger than, you should let him know. Max call out in this case gives the machinist a lot more flexibility in making that feature. ● No need to call out the hole size if you are tapping the part. Just say 3 X 2-56 UNC -2B. The machinist will use what drill is best for the thread. ● The line to line call out is the main issue in the drawings. Basically, If something is 1 ± 0.005 and it fits into something that is $1\pm .005$. There is a large chance it won't fit. So you will need to call out things differently. Also, if both items are exactly 1" is that a problem? Meaning do you want a little gap to insure things will actually move? However, you don't want such a large gap that it would cause the part to kink, when moving. Hence, please examine your tolerance surrounding the sliding punch and housing. Then, you need to examine your edges between the top housing and the punch to make sure that there is enough coverage over the punch to keep it in.
<p>11/15/2022 Zoom Meeting</p>	<ul style="list-style-type: none"> ● Timeline for manufacturing <ul style="list-style-type: none"> ○ Will have an update later today <ul style="list-style-type: none"> ■ Meeting with civil department about potential testing option ● Cancel 11/22 meeting <ul style="list-style-type: none"> ○ Next meeting 11/29 at 9:30 AM ● Testing fixture possibilities <ul style="list-style-type: none"> ○ jagged edges ○ Will send us sawbones <ul style="list-style-type: none"> ■ Simulates bone ■ Grade 15-generic bone (600-700N) ■ Can potentially send super dense material ● Radius of curvature on the back of the handle <ul style="list-style-type: none"> ○ Grind it flat

<p>11/16/2022 Email</p>	<ul style="list-style-type: none"> ● That test frame (2000 lbs) should work fine. (Referring to civil department's compression testing discussed previously) ● The website for the sawbones block is this: https://www.sawbones.com/block-15-40-x-130-x-180mm-152-02.html. I shipped those to your address earlier in the week. They should arrive on or before Friday. Cut them into any shape/size that you need to. Any saw will work to cut them. ● Cost will mainly be wrapped up in machining time. The material costs are pretty cheap, about \$65.00. The machining time is pretty pricey. I suspect it would take about 5 hours of work. Typical hourly rate for machining time is about \$90/hour. Machining time includes the cost of running the machine, the cost of the tools to use on the machine, and the labor costs. Hence, you'll be at about \$515 total cost.
<p>12/4/2022 Email</p>	<ul style="list-style-type: none"> ● Questions for Zac and Glenn (machinist) about our second prototype: <ul style="list-style-type: none"> ○ Is the 0.03" shelf too small to machine? What would be the minimum shelf size? ○ How big does the groove proximal to the 3/8" screw need to be to make sure we can still put threads all the way down the base? ● Sent ordering list for McMaster: <ul style="list-style-type: none"> ○ Thread converters- 95316A825 ○ Vise- 52855A24 ○ Spring- 9657K358 ○ Dowel- 97195A110 ○ Delrin sheets- 5ft for all <ul style="list-style-type: none"> ■ 2638T15 - .02" ■ 2638T75 - .025" ■ 2638T85 - .04" ■ 2638T35 - .062" ■ 2638T45 - .093"
<p>12/23/2022 Email</p>	<ul style="list-style-type: none"> ● Testing fixtures sent to Zac for machining ● Drawings for second prototype send to Zac for machining
<p>1/12/2023 Email</p>	<ul style="list-style-type: none"> ● Updated fixture dimension drawings sent to Zac ● Weekly sponsor meeting agreed upon for Fridays at 3:30 pm ● LBO-1k load cell with TEDs chip and display ordered and shipped to Anna for testing
<p>1/20/2023 Zoom Meeting</p>	<ul style="list-style-type: none"> ● Need to exchange current 6 inch vise for the 4 inch version <ul style="list-style-type: none"> ○ Decided that the larger vise will be a donation to senior project room ● New ordering list from McMaster: <ul style="list-style-type: none"> ○ 4 in Vise ○ New thread converter ○ Bottoming tap for surgical handle ● Talked about updates from first prototype testing session

	<ul style="list-style-type: none"> ○ Forces to break Delrin were much higher than expected (1400-1800 N) ○ Civil testing constraints surrounding sampling rate ● Next steps include: <ul style="list-style-type: none"> ○ Testing the spinal cages to get breakage data ○ Etching a circle into the Delrin pucks ○ How will be keep the sawbone parallel during testing ○ Potentially switching to higher density sawbone
<p>1/27/2023 Zoom Meeting</p>	<ul style="list-style-type: none"> ● We had questions about where we should be clamping the spinal cages in the sawbone <ul style="list-style-type: none"> ○ Not too concerned as long as we are consistent ● Apply to SeaSpine internships <ul style="list-style-type: none"> ○ Zac only takes mechanical or biomedical engineering students ○ Looks for technical skills, CAD work, lab work, leadership positions ○ Design engineer roles more focused on CAD work ○ Quality engineer roles more focused on labs and experiences with statistics ○ Zac's intern is the "test engineer intern" ○ Feel free to use Zac as an internal reference ● Visiting Carlsbad office <ul style="list-style-type: none"> ○ Send Zac a few dates ○ Mondays are usually the best days for him ● Turn around time for new parts is around 2-3 weeks currently
<p>1/27/2023 Email</p>	<ul style="list-style-type: none"> ● Planning potential date for SeaSpine visit ● First general visit February 6th ● Second visit later in the quarter for cadaver testing ● Need to send Zac list of goals for first visit (what we want to accomplish during our visit)
<p>2/3/2023 Zoom Meeting</p>	<ul style="list-style-type: none"> ● Asked about quantifying the length or percentage of the dashed lines on the pucks? <ul style="list-style-type: none"> ○ OGP white light measuring tool on site at SeaSpine ● What should we bring to the SeaSpine visit? <ul style="list-style-type: none"> ○ Device ○ Pucks that we want to test ○ Screws ● What SeaSpine has for us to test on site: <ul style="list-style-type: none"> ○ Vise and converter for compression testing ○ Inputs for their compression testing: <ul style="list-style-type: none"> ■ N, mm ■ Sampling rate: 5 Hz ■ Speed range: 5 mm/min - 5 mm/sec ● Enter the building on Armatta drive ● Monday: <ul style="list-style-type: none"> ○ Meeting with vendors is at 1pm ○ 10-1 open for testing and tour of facility

	<ul style="list-style-type: none"> ○ Business casual ○ Closed toed shoes ● Asked about the possibility of using a scale to quantify impact forces: <ul style="list-style-type: none"> ○ Response is usually not quick enough to collect data ○ Dial scale may be an option ● How does SeaSpine do impact testing? <ul style="list-style-type: none"> ○ Bought an impact hammer <ul style="list-style-type: none"> ■ Accelerometer (g force) measurements ■ Still need energy conversion
2/9/2023 Email	<ul style="list-style-type: none"> ● Cancel 2/10 meeting ● Sent Zac our test plan report for feedback ● Feedback on test plan report: <ul style="list-style-type: none"> ○ On page 40, assembly instructions Step 4. Need to provide a tolerance for tightening to 3 in-lbs. Would use a torque cell or breakaway handle, which are usually +/- 10%. ○ On page 43, recommends that we may want to have 3 people test 3 times so that we can get an average. Good for reproducibility and repeatability.
2/24/2023 Zoom Meeting	<ul style="list-style-type: none"> ● Zac received the pucks and screws for testing ● Final prototype has been machined ● Confirm visit for 3/6 for cadaver testing <ul style="list-style-type: none"> ○ Could start as early as 9 AM ○ Validate final design ○ Bring device and pucks ○ Likelihood of cage breaking is very low ● Zac will complete mechanical testing by the end of the week and send us the data ● To do: <ul style="list-style-type: none"> ○ Send Zac final zoom link for presentation ○ Send Zac expo poster for feedback ○ Send Zac outstanding shipping costs to Venmo
2/27/2023 Email	<ul style="list-style-type: none"> ● Zac sent us data from mechanical testing ● Inconsistent data ● Included the data sheet and photos of the final device from testing
3/2/2023 Email	<ul style="list-style-type: none"> ● Sent Zac expo poster draft for feedback in lieu of a meeting ● Zac provided feedback on the poster: <ul style="list-style-type: none"> ○ Need more explanation of spinal fusion surgery, or add additional pictures. Majority of people looking at the current image will not know the backstory of how the spine became injured or why this surgery is required. ○ Need to add more to the goal statement, protects the spinal cage from failure during implantation. ○ Explain why the fully enclosed puck is important in

	<p>detailed design.</p> <ul style="list-style-type: none"> ○ Final part was 17-4 stainless, not 304. ○ Should increase the size of the bar chart of the force to break the device, only include one of the test setups to create more room.
3/7/2023 Email	<ul style="list-style-type: none"> ● Zac sent us the maximum break forces from onsite testing 3/6 ● Used the second prototype for testing <ul style="list-style-type: none"> ○ Got much more consistent with result ○ Allowed us to determine ideal dash pattern
3/10/2023 Zoom Meeting	<ul style="list-style-type: none"> ● Went over expo poster updates <ul style="list-style-type: none"> ○ Approved by Zac ○ He liked the new changes and didn't have any more feedback ● Zac said we could use him as a reference in the future ● We will use our usual zoom code for final presentation <ul style="list-style-type: none"> ○ Tuesday at 12:15 pm

Existing Designs

Below are five designs used by other manufacturers for installing interbody devices. These products serve a similar purpose to our device.

First is the Rudischhauser Customizable PLIF/TLIF Cage Instrument Sets [1]. Rudishhhauser makes a similar product to SeaSpine’s current surgical instruments for PLIF and TLIF procedures. Their cage instrument sets include a trial spacer, slotted mallet, osteotomes, box curettes, rotary scrapers, grooved scrapers, cage holders, cage pushers, bone pushers, and more. The specific products that are similar to our product are the cage pusher, cage holder, and handles. The cage pusher is the most similar as it is the connection between the cage and the mallet. This would be the same positioning as our surgical handle, however ours would have an additional replaceable component. The cage holder also has similar properties as our potential product, but again missing the replaceable component. This component is removable and has a customizable fitting that can be changed out depending on the specific cage being placed.

All of their cage instruments have customizable handles dependent on the customer's wants. It seems as though the handles can be interchanged, however it is not fully clear from their advertisements and descriptions.

The second device Globulus Implant Holders [2]. Globulus makes several implant handles for TLIF procedures very similar to our product. The most similar ones are the implant holders assembled with a quick coupling handle, and a L-handle.

The short implant holder with the quick coupling handle comes equipped with a universal connector to their other products, and a platform to hammer the holder with.

The short implant holder with L-handle is also very similar to SeaSpine’s current handle that we will be adapting. The handle has a similar anti-rotation mechanism, with handle perpendicular to the holder shaft, with an additional pad to hit when inserting the cage.

The third related existing design Stryker AccuLIF TL Insertion Handle [3]. AccuLIF utilizes the same handle for both their expandable TLIF and PLIF procedures. This handle utilizes the blue rotator knob to thread the inserter into the interbody device. The insertion handle can be locked and unlocked in respect to rotating the interbody device.

The next existing design we looked at was the Medtronic Mazor X Stealth Edition [4]. Medtronic takes a different approach to installing interbody devices using robotic guidance. Their Mazor X Stealth Edition uses a robot to install interbody devices for their TLIF procedures to increase accuracy.

In addition to assisting with manual precision, the Mazor X also delivers live visuals on where the implant is in the patient’s spine to dramatically increase accuracy.

The fifth existing design we looked at was the AnyPlus TLIF Interbody System Articulating Inserter [5]. AnyPlus utilizes an Articulating Inserter that allows the implant to be rotated between 0 and 60 degrees. The inserter grips serrated slots on the interbody device with the jaws of the inserter. A nut on the handle is used to tighten the jaws. The back of the device provides a surface to utilize the AnyPlus surgical mallet.

Patent Search Results

Related to existing designs, there are several published patents that have some potential overlap with our project. These patents are summarized in Table III. This table includes the name and description of the patent, as well as how to avoid infringing on the patent. While many surgical handles exist for transforaminal lumbar interbody fusion and posterior lumbar interbody fusion surgeries, none include replaceable parts designed to fail before the spinal cage breaks during placement.

Table III. Summary of patent search results relating to SeaSpine force limiting surgical handle.

Patent	Description of Potential Infringement Claims	How to Avoid Infringement
Interbody Implants and Instrumentation: US 11298244 B2 Published 2022	This patent describes instruments used to assist in the placement of implants into the intervertebral space. Claim 1 explains the device that	We can avoid infringing on the Interbody Implants and Instrumentation patent with the replaceable component of our

	<p>includes a combination of an insertion tool, extended body, and drill guide. Claim 11 also has potential for an overlap with our device, this claim describes a locking mechanism between the components of the body of the instrument.</p>	<p>handle. This will make it so that we are modifying current patents to develop a new device independent of existing patents. As for claim 11, we will take care to closely follow SeaSpine’s current locking mechanisms to ensure we are in-scope of their patents.</p>
<p>Spinal Fusion Cage System With Inserter: US 10179054 B2 Published 2022</p>	<p>The Spinal Fusion Cage System patent describes a device interacting with a spinal cage implant. This device focuses on the introduction of bone tissue into the intervertebral space, but involves instrumentation similar to our surgical handle instructions. Specifically the 1st claim states a connection between the elongated shaft and cage implant between the two vertebrae.</p>	<p>Our device will have a similar connection point between the handle shaft and spinal cage, so we will have to take care to avoid specific aspects of their design. Since we are planning on using SeaSpine’s current connections we should be able to stay within the scope of their patented designs.</p>
<p>Force Limiting Device And Method : US 8,601,897 B2 Published 2013</p>	<p>This patent outlines a way to limit the force exerted on a robot by using torque limiters on each joint, so the robot functions as mechanically “stiff” below a certain threshold of force, but becomes compliant above that threshold. While this patent was intended for use in robotics, it includes any application of this method of limiting force.</p>	<p>To avoid infringing on this patent, we will avoid using torque limiters as joints for mechanical components.</p>
<p>Anti-rotation Fixation Element for Spinal Prostheses: US 8187303 B2 Published 2012</p>	<p>This patent describes an anti-lock mechanism that prevents prosthesis fastener rotation when attached to a patient’s vertebra. Claim 1 describes several fixation locations in the prosthesis in addition to anti-rotation elements described in claim 2 that are coupled to the vertebra.</p>	<p>The surgical handle that will be undergoing excessive force to place the spinal cage during surgery requires an additional anti-rotation mechanism to ensure the spinal cage stays in place during placement. One way we could still have anti-rotating features in our design while still avoiding the patent is to design the</p>

		anti-rotation mechanisms into the standard connections instead of to the vertebra.
Instruments for Use During Spine Surgery: US 11406430 B2 Published 2022	This patent uses a rack and pinion system coupled with a trigger to push a device into position. Claim 1 describes a cam with a circular body, which Claim 3 further describes an attachment that when depressed releases an inner shaft.	Infringement can be avoided by changing the geometry of the cam body to make it not be “generally circular”, or changing the orientation of rack and pinion teeth should we decide to use a geared mechanism to apply force.

Relevant Background Research

The high level function of the spine is to transmit loads from the upper body, through the pelvis, and into the lower extremities [6]. This highly complicated mechanism can have abnormalities, as there are nuanced mechanisms for both structure and stability in the spine. As such, there is a high incidence of back pain in the population -- approximately 80% [7]. One of the most common causes of chronic back pain is degenerative disc disease, which is characterized by wear of the intervertebral disc [7]. Degenerative disc disease can be caused by a major injury, or a series of smaller injuries resulting in a loss of shock absorption between the vertebrae. Segmental instability is when disc degeneration allows more than normal movement between vertebrae [7], resulting in an abnormal response to applied loads [6] and irritation to nerve roots [7]. This leads to back pain in patients and in some cases, leg pain [7].

To address segmental instability, physicians will prescribe spinal fusion surgery after more than 6 months of unsuccessful alternative treatments [8]. The high level goal of spinal fusion is so the implant takes on the everyday loads of the spine until it integrates with native bones, where the load will then be shared [6]. There are 3 surgical strategies for spinal fusion: *in situ*, *onlay*, and *interbody*. *In situ* fusion allows native bone to contact other native bone, which was previously prevented due to soft tissue. *Onlay* fusion uses a decorticated graft bed and subsequent application of cortical and cancellous autografts to redistribute loads. *Interbody* fusion uses an implant composed of bone, nonbone materials such as acrylic, or a combination of both such as in interbody cages [9]. *Interbody* fusion is preferable due to lower rates of postoperative complications and pseudoarthrosis [10], and is the focus of this project.

Interbody spinal fusion procedures can be open or minimally invasive (MI) and are traditionally approached from the posterior [10]. However, there are also anterior approaches that have hit the market since the initial introduction of spinal fusion. There are 5 main types of interbody fusion techniques briefly described below [10] - 2 posterior and 3 anterior.

1. *Posterior Lumbar Interbody Fusion (PLIF)* is the traditional approach to interbody fusion where the surgeon approaches the interbody space from the posterior. PLIF is indicated for degenerative pathologies.
2. *Transforaminal Lumbar Interbody Fusion (TLIF)* is a posterior approach to the spine that can be open or minimally invasive (MI-TLIF). TLIF is indicated for all degenerative pathologies.
3. *Anterior Lumbar Interbody Fusion (ALIF)* is an anterior approach to the spine which is predominant for discogenic low back pain. ALIF is also indicated for degenerative disc disease, discogenic disease, and the revision of a failed posterior fusion.
4. *Lateral Lumbar Interbody Fusion (LLIF)* is a minimally invasive surgical technique which approaches the spine from the anterior. LLIF is indicated for all degenerative indications, especially for conditions that require access to the interbody disc space from T12/L1 to L4/5 and lumbar degenerative scoliosis with anterolisthesis.
5. *Oblique Lateral Interbody Fusion (OLIF)/ Anterior to Psoas (ATP) fusion* of the lumbar spine is a minimally invasive, anterior approach to the spine via the corridor between the peritoneum and psoas muscle. This approach is indicated for all degenerative indications and is excellent for sagittal and coronal deformity correction.

SeaSpine offers several cages for PLIF and TLIF procedures, including the Reef TA, Reef TO, Hollywood, Hollywood VI, Ventura, and Ventura NM. The Hollywood VI is the most applicable to this project, and is made of PEEK with a NanoMetalene coating [11]. NanoMetalene is a sub micron layer of bonded titanium on the surface of the PEEK core, intended to add microscopic surface roughness, improve the osteogenic response, and provide hydrophilicity [12].

In the MAUDE database, some complications that are somewhat highly reported in spinal fusion procedures are spinal cage migration and spinal cage failure during insertion [13]. Spinal cage migration is the movement of the spinal cage following surgery, and is more likely to occur with pear-shaped spinal cages and in patients with lower BMIs [14]. Spinal cage failure is the damage or fracture of the spinal cage during insertion. In one reported instance, the spinal cage broke into many pieces and was explanted during the procedure [13]. In a study of break forces in Marquardt, Stryker, and Ray spinal cages, the median break forces of the spinal cages were 5486N, 8359N, and 8413N under cyclic, clinically relevant loading after implantation [15]. This project focuses on spinal cage failure during insertion and will take these numbers into consideration when validating our device.

Applicable industry codes, standards, and regulations

Our device should be in accordance with the following standards and regulations:

- ISO/TC 170 Surgical Instruments
- ISO 10993 Biological Evaluation of Medical Device Package
- ISO 7151:1988 Surgical Instruments- Non-cutting, articulated instruments - General requirements and test methods

- ISO 7153-1:2016 Surgical Instruments- Materials- Part 1: Metals
- ASTM F1744-96(2016) Standard Guide for Care and Handling of Stainless Steel Surgical Instruments

IV. Objectives

Problem Statement

One common mechanism of failure for interbody devices, particularly during TLIF and PLIF procedures, is spinal cage fracture during installation. This typically occurs when the surgeon impacts the device with excessive force with a surgical mallet on the impacting surface of the installation handle.

Boundary Definition

We will be developing a force limiting surgical handle to minimize the risk of spinal cage fractures during TLIF and PLIF procedures. The force limiting aspect of the handle must be replaceable. This can either be in the form of a new handle, or an attachment. The handle must interface with a variety of SeaSpine interbody devices. This project will not involve the modification of any interbody implants or other surgical instruments used in TLIF and PLIF procedures.

Indications for Use

SeaSpine's Force Limiting Surgical Handle with Replaceable Parts is intended for use during PLIF and TLIF surgery to aid insertion of the spinal cage into the intervertebral space. This device is intended to limit the force applied to the spinal cage during the hammering process, and is specified as a supplemental surgical instrument to be used for all patients undergoing the TLIF and PLIF procedures. There are no additional contraindications specific to this device, and all the indications previously specified for TLIF AND PLIF insertion device by SeaSpine are applicable to this device. The Force Limiting Handle with Replaceable Parts is intended for skeletally mature individuals and has no contraindications for elderly individuals [16].

Customer Requirements

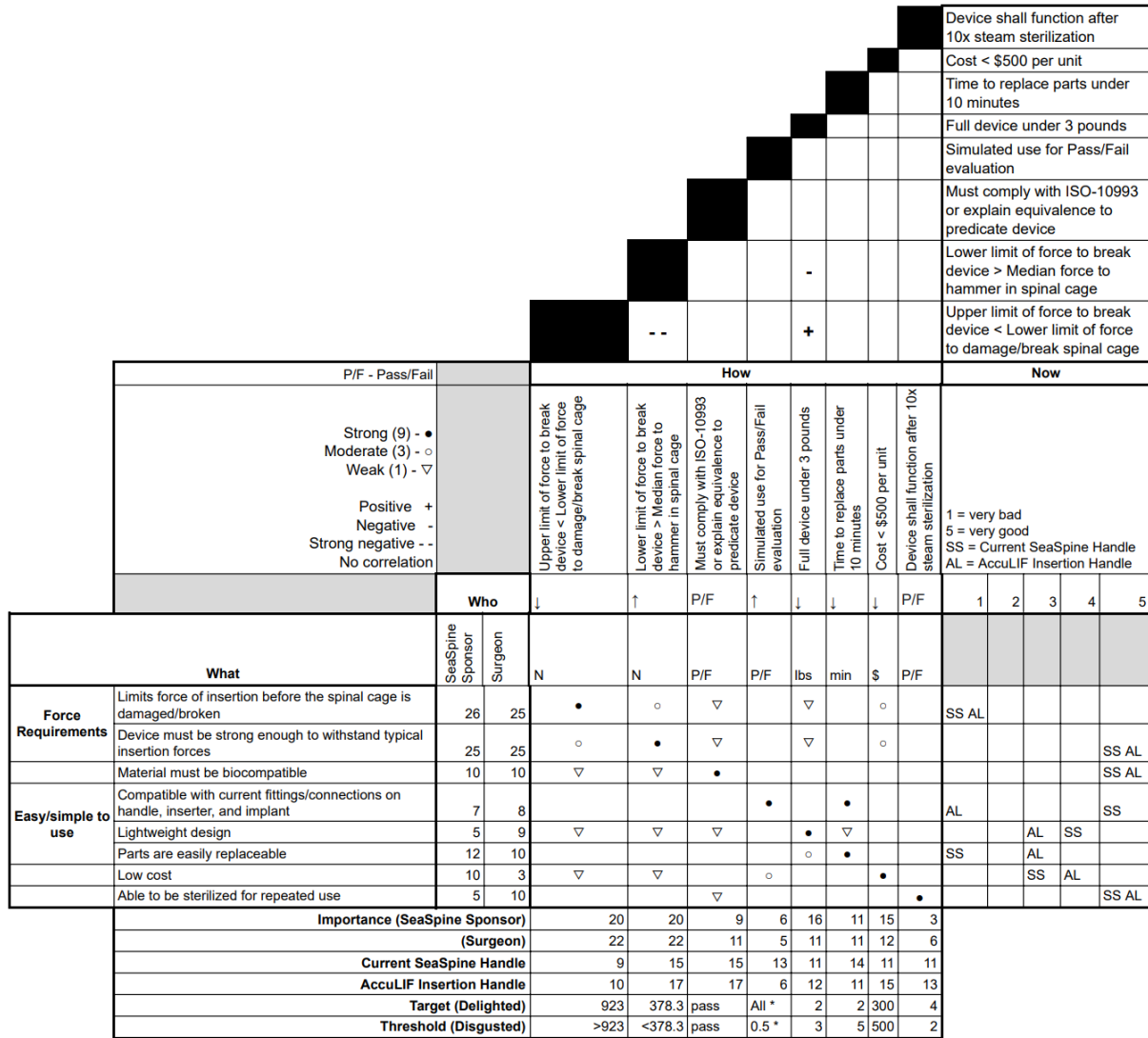
Most of our customer needs revolve around force and durability. Our customer has expressed that the surgical handle must be able to withstand multiple surgeries, as well as sanitation cycles. SeaSpine's current business model is to rent out instrument cages for surgeries, and then evaluate and repair them as needed between surgeries. This means that the surgical handle needs to be durable enough to withstand surgery as well as a fair amount of transportation. And while SeaSpine may choose to replace parts of the handle that are fairly damaged after surgery, if the device breaks during surgery, the surgeon should be able to easily and quickly replace the part that broke.

Our customer has also expressed that they wish the material of the handle to be biocompatible. Current surgical handles are made of Delrin, Radel, stainless steel, or some combination of the three. The handle must be compact and lightweight, roughly the size of current SeaSpine spinal instrumentation. Our main customer is SeaSpine, but we should make sure to keep the user in mind, which means making the device easy and convenient for surgeons to use.

We have generated a comprehensive list of customer wants and needs based on our meetings and correspondence with our customer. A full list can be found in Appendix A-1.

Quality Function Deployment- House of Quality

Quality function development helps create measurable design targets for specific customer requirements. First we identified our customers as SeaSpine, our project sponsor, and the surgeons who will be using our product. Next we determined our customer requirements, which we then ranked the percent importance out of 100%. We evaluated a similar surgical handle product on the market, the AccuLIF, against our customer requirements to see where there is room for improvement in our design. Then we generated a set of measurable engineering specifications to use for testing, these were then compared to the customer's requirements to ensure that each spec matches and accomplishes at least one customer requirement. We then set numerical targets for each of the engineering specifications and showed their importance. Lastly, we identified relationships between engineering specifications to show which ones depended on each other and to see if we had any redundant specs. The full house of quality is shown below in Figure 15.



* compatible with all SeaSpine components
 * compatible with 1/2 of SeaSpine's products

Figure 15. House of quality.

Engineering Specifications

Table IV below provides further information regarding the engineering specifications for this project, as related to customer requirements in the house of quality.

Table IV. Engineering specifications.

Spec. #	Description	Target Value	Tolerance on the target	Risk	Compliance method
1	Upper limit of force to break device < Lower limit of force to	923 N	Max	M	Test

	damage/break spinal cage				
2	Lower limit of force to break device is greater than the median force to hammer in spinal cage	378.3 N [17]	Min	H	Test
3	Must comply with ISO-10993 to explain equivalence to predicate device	Equivalence to predicate device	Pass/Fail	L	Equivalence to predicate device
4	Simulated use for evaluation of form, fit, function of interface with current device(s)	Pass	Pass/Fail	M	Test
5	Full device under 3 pounds	3 lbs	4lb max	L	Inspection
6	Time to replace parts under 10 minutes	10 mins	Max	L	Test
7	Cost per unit	\$500	Max	M	Analysis
8	Device shall function after 10x steam sterilization	Pass	Pass/Fail	M	Test

The following details how our team plans to measure each engineering specification:

1. *Upper limit of force to break device < Lower limit of force to damage/break spinal cage*

This specification was measured using a comparative compression test. The target value listed is based on a literature review, and is subject to change following further testing. To conduct this testing, the force it takes to yield our device will be tested on a compression testing machine for its yield strength in psi. The same test will be conducted using a clinically relevant interface between the spinal cage and the test fixture to get the yield strength of the SeaSpine spinal cage. We will conduct this test on n=3 units for each test and compare the upper limit of the force required to yield our force limiting device to the lower limit of the force required to yield the spinal cage. Upper limits will be calculated as the average plus 1 standard error, and lower limits will be calculated as the average minus 1 standard error. Passing this test will require the upper limit of the force to yield the device to be less than the lower limit of the force to yield the spinal cage.

2. *Lower limit of force to break device is greater than the median force to hammer in spinal cage*

This specification will be measured using a clinically representative force, indicated in the target value applied to the finished device. The device will undergo compression testing under clinically representative shear constraints. The lower limit of the yield force experienced by the device during compression testing will be compared to the peak force experienced by spinal cages during surgery. Spinal cages experience a peak force of approximately 378.3 N during PLIF or TLIF procedures [17]. If the lower limit of the force required to yield the device is greater than 378.3 N, the device will pass for this

specification.

3. *Must comply with ISO-10993 to explain equivalence to predicate device*

This standard will be evaluated using pass/fail criteria, based on proven equivalence to a predicate device approved by the FDA. This is standard for devices undergoing both PMA and 510(k) pathways in the medical device field, and is used as an alternative to biocompatibility testing outlined in ISO-10993.

4. *Simulated use for evaluation of form, fit, function of interface with current device(s)*

This pass/fail specification is an evaluation of how the device performs interprocedurally in PLIF and TLIF procedures. To evaluate if this specification passes, the device must interface with the current intraoperative surgical tools while the operator follows the instructions for use for the device.

5. *Full device under 3 pounds*

This specification will be measured using a calibrated scale capable of outputting lbs. If the device is under the targeted 3lbs, it will pass.

6. *Time to replace parts under 10 minutes*

This specification will be measured through simulated replacement of the device, outlined in the instructions for use. This test assumes the user will have adequate training, and will not need to reference the instructions for use during the test. The device operator will start to replace the device as the time operator starts a stopwatch. When the component is fully replaced, the time operator will record the time. Passing requires the total time for replacement to be under 10 minutes, as specified in Table IV above.

7. *Cost per unit*

This specification will be measured using quotes from SeaSpine's in-house machine shop. The device will pass this specification if the quote shows a price per part less than the target value when adjusted for mass production.

8. *Device shall function after 10x steam sterilization*

This specification is based on SeaSpine's current method of sterilization. This specification will be evaluated through equivalence to predicate devices.

Discussion of High Risk Specifications

The only high-risk specification is number 2 shown in Table IV above. This specification is high risk due to the ambiguity of interprocedure forces, and the high variation the device could see in intraoperative forces due to physician variability and spinal cage sizing in the intervertebral space.

V. Project Management

Throughout our project, we followed a six phase design process. We started with product discovery, then moved through project planning, product definition, conceptual design, product development, and product support.

Our design process started from studying surgical techniques that utilize interbody devices and seeing how SeaSpine and other industry leaders currently install them or attempt to address the problem of them fracturing during installation. We then moved to our brainstorming phase, where we each sketched three design ideas and presented them to the group. From there, we discussed options and combined ideas. Once we had a list of ideas, we decided on a design to move forward with utilizing a decision matrix. We then moved on to modeling and began prototyping our device. Following our first prototype, we iterated based on learnings from feasibility testing and made a final prototype, which went through design verification and validation testing.

The Gantt Chart used to pace this project is found in Appendix B-1. Of note is our critical path shown below. To stay on our critical path, as we were constructing our detailed design, we began design verification testing early, so that we had values for both the puck forces and the spinal cage forces, and had plenty of time to adapt our design.

1. Ideation
2. Concept Selection
3. Conceptual Model Build
4. Detailed design
5. Iteration
6. Final Prototyping
7. Manufacturing and Sterilizing DV units
8. DV Testing
9. DV Analysis
10. Final Reports and Presentations

The finalized budget for the project is shown in Table V below.

Table V. Final budget for force limiting handle project.

Item Description	Product Number	Purpose	Associated Task (on Gantt Chart)	Planned				
				Unit	Quantity	Cost/Unit	Total Cost	Notes
3D printing filament	FibreX™ PEEK+GF20 EDXTech	Prototyping	Ideation, iteration, final prototypes	g	1	\$0.00	\$0.00	Using free 3D printing provided by the BMED department using specified material.
Machining time for 1st prototype	N/A	Prototyping & DV components	Ideation, iteration, final prototypes	Time (hours)	5	\$90	\$450.00	Labor costs for in-house manufacturing of initial prototypes.
Delrin sheets for all prototypes	(McMaster) 2638T15 - .02" 2638T75 - .025" 2638T85 - .04" 2638T35 - .062" 2638T45 - .093"	Prototyping & DV components	Ideation, iteration, final prototypes	Total	5	\$75	\$75.00	Material costs for components for initial testing, includes several pucks for iteration of thickness and geometry.
1st Prototype	Aluminum	Top housing	Detail design, iteration, final prototypes	g	1	\$20	\$20.00	Material costs for components for initial testing.
		Bottom housing		g	1	\$20	\$20.00	
		Sliding punch		g	1	\$15	\$15.00	
Machining time for 1st prototype	N/A	Prototyping & DV components	Ideation, iteration, final prototypes	Time (hours)	5	\$90	\$450.00	Labor costs for in-house manufacturing of initial prototypes.
2nd Prototype	Aluminum	Top housing	Detail design, iteration, final prototypes	g	1	\$20	\$20.00	Material costs for components for initial testing.
		Bottom housing		g	1	\$20	\$20.00	
		Sliding punch		g	1	\$15	\$15.00	
Load cell	Transducer Techniques load cell SWP-3K (3,000 lbf)	Testing	Ideation, iteration, SeaSpine comparative spec testing & analysis, DV testing	EA	1	On hand	\$0.00	Choice from options: at SeaSpine to minimize lead time and cost of fixturing
Mallet	Generic surgical mallet https://www.g-source.com/	Testing	Iteration, testing	EA	1	On hand	\$0.00	Surgical mallet given to us by SeaSpine for testing on initial and final prototypes.
Testing fixtures	2X Vices: (McMaster) 52855A22 52855A24	Feasibility testing	Ideation, iteration, SeaSpine comparative spec testing & analysis, DV testing	EA	2	\$150.00	\$300.00	Estimate of cost of fixture optimized for low cost machining and stock materials
	Bottoming 5/16-24 tap: (McMaster) 26955A92			EA	1	\$9.98	\$9.98	
	SS Male-to-Male adapter, Handle to GeoJack tester: (McMaster) 95316A783			EA	2	\$13.69	\$27.38	
	Springs: (McMaster) 9657K358			EA	1	\$5.97	\$5.97	
	SS Male-to-Female adapter, handle to device: (McMaster) 92499A174			EA	1	\$6.42	\$6.42	
	Sawbone https://www.sawbones.com/block-15-40-x-130-x-180mm-1522-02.html			EA	14	On hand	\$0.00	
Machining time for final prototype	N/A	DV components	Final prototype	Time (hours)	5	\$90	\$450.00	Upper range estimate for each component, not including potential machinist time
Final Prototype	304 Stainless steel	Top housing	Final prototype	g	1	\$30	\$30.00	Material costs for final prototype made with stainless steel and Delrin.
		Bottom housing		g	1	\$30	\$30.00	
		Sliding punch		g	1	\$25	\$25.00	
Total							\$1,969.75	

Unique Techniques

In the design of this device, we used a GeoJac fixture for feasibility testing of early prototypes. This allows us to quickly assess prototypes for functionality without being limited by lab time or time-consuming operation of Instrons, impact testers, etc. Another fixture we used for early stage testing was to determine more clinically-relevant intraoperative forces seen by the spinal cage. This fixture utilized bone blocks and a load cell to simulate the mechanical properties of intervertebral discs and vertebrae to approximate the force needed to implant the spinal cage in the intervertebral space during PLIF or TLIF procedures. Additionally, we used a dash pattern to dial in the force to break our device.

VI. Morphology

To start generating concepts we separated our force limited surgical handle's main functions. The device must limit the force applied to a surgical cage during placement, include replaceable components that can be changed out when they're broken, contain the parts after failure occurs

so that no pieces fall into the patient or operating room, and an indication when excessive force has been reached. Next we developed a few concepts for each function, at least four for each function. Lastly, we combined concepts from each function to produce some final concepts.















Morphology						
Product: <i>Force Limiting Handle</i>		Organization Name: <i>SeaSpine</i>				
Function	Concept 1	Concept 2	Concept 3	Concept 4	Concept 5	Concept 6
Limits Force	<i>Springs</i> 	<i>Breakable Material</i> 	<i>Breaking Support</i> 	<i>3x legs</i> <i>Breakable geometry</i> 	<i>Air Chamber w/ valve</i> 	
Replaceable Components	<i>Screw in back</i> 	<i>Screw in center</i> 	<i>screw into case</i> 	<i>replace air</i> 		
All parts contained after impact	<i>Physical barrier</i> 	<i>Springs don't break</i> 	<i>Air doesn't break</i> 	<i>shield</i> 	<i>Valves don't break</i> 	
Indication of excessive force	<i>Audible sound "Click"</i> <i>snap fit</i>	<i>Audible sound valve release air</i>	<i>visible indicator obolous yielding</i>	<i>visible indicator line to indicate shrinkage</i>		
Team member: <i>Natalie Adams</i>		Team member: <i>Anna Burke</i>		Prepared by:		
Team member: <i>Megan Phillip</i>		Team member:		Checked by:		Approved by:
The Mechanical Design Process Copyright 2008, McGraw Hill				Designed by Professor David G. Ullman Form # 15.0		

Figure 16. Morphology Chart.

The concepts produced from the morphology table shown in Figure 16 are shown below in Figure 17, 18, and 19. Figure 17 shows the snap spring concept. This concept uses the constant force associated with spring displacement to limit the force applied to the handle. For assembly, there is a nominal snap which positions one piece over the spring (no compression of the spring in this state). The spring will be specified with a high spring constant to minimize the length of the device, and the “bounce back” effect on the physician. During use, the piece will be free to compress the spring until it reaches a second snap when it reaches the limiting force. The snap will be audible to alert the physician they have reached the maximum force. At this point, the physician will either replace the whole assembly, or release the snaps for reuse. This idea was developed using a morphology, which outputs the spring as a method to limit force and potentially be reused, a screw for attachment and easy replacement, and an audible “snap” to indicate the limiting force was reached.

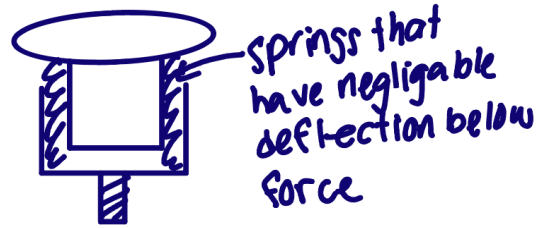


Figure 17. Snap springs concept.

Our second concept sketch is shown below in Figure 18. Some of our most important functions are having force limiting parts that are replaceable or reusable. Focusing on these guidelines we developed the concept of having a screw in part to the end of SeaSpine's current surgical handles. This screw-in consists of a cage that prevents any parts of the breakable component from falling into the patient, and a breakable component that screws into the cage. The breakable component would be replaceable, and would be designed to break just before the surgical cage would break. The components used in this design include elements from each of our four functions, limiting force, replaceable components, contained parts after impact, and an indication of excessive force.

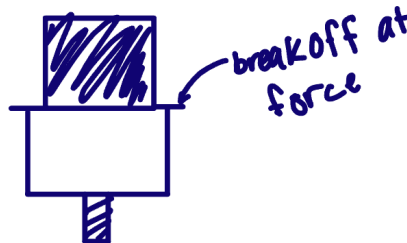


Figure 18. Breakable parts concept.

The final concept we are interested in is an air chamber with a pressure valve, shown in Figure 19. When excessive force is applied, the valve would release air at that pressure, and the surgeon would hear the air release, and know to reset the device. While this device does not utilize replacement parts, the air would need to be replaced if excessive force was used. Since air does not produce fragments, we would not have to worry about keeping the surgical sight clean. This device would screw into the back of SeaSpine's current surgical handles. This idea was developed because it could utilize pre existing air release valves that release at a given pressure, and it would be easy to keep the surgical site sterile. It utilizes the air chamber with valve idea for force limiting from our morphology table, the screw in the back and replacing air from the replaceable parts section, the containing fragments did not apply to this idea, and the noise of the valve would indicate the use of excessive force.

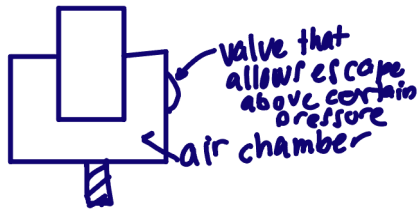


Figure 19. Air chamber with valve concept.

VII. Concept Selection

To evaluate the 3 concepts we ideated from the morphology, we used a series of Pugh Matrices shown in Figure 20 below. The matrix uses weighted values for each of the design requirements based on the SeaSpine importance rating from the House of Quality in Figure 15. We then chose each of our three concepts as a baseline to rate the other two concepts against - resulting in three matrices below. All team members individually completed all matrices, not included, and then discussed and averaged to produce the matrices shown in Figure 20. The concept with the highest score in each matrix, highlighted in green, is the concept we chose to move forward with.

Issue: Choose a Force Limiting Surgical Handle Configuration		Snap Springs Handle Add-On	Enclosed Breaking Component Add-On	Air Chamber with Valve Add-On	Issue: Choose a Force Limiting Surgical Handle Configuration		Enclosed Breaking Component Add-On	Snap Springs Handle Add-On	Air Chamber with Valve Add-On	Issue: Choose a Force Limiting Surgical Handle Configuration		Air Chamber with Valve Add-On	Snap Springs Handle Add-On	Enclosed Breaking Component Add-On
Limits force of insertion before the spinal cage is damaged/broken	26		1	1	Limits force of insertion before the spinal cage is damaged/broken	26		-1	0	Limits force of insertion before the spinal cage is damaged/broken	26		-1	0
Device must be strong enough to withstand typical insertion forces	25	D	0	0	Device must be strong enough to withstand typical insertion forces	25	D	0	0	Device must be strong enough to withstand typical insertion forces	25	D	0	0
Material must be biocompatible	10	A	-1	0	Material must be biocompatible	10	A	1	1	Material must be biocompatible	10	A	0	-1
Compatible with current fittings/connections on handle, inserter, and implant	7	U	0	0	Compatible with current fittings/connections on handle, inserter, and implant	7	U	0	0	Compatible with current fittings/connections on handle, inserter, and implant	7	U	0	0
Lightweight design	5	M	0	-1	Lightweight design	5	M	0	-1	Lightweight design	5	M	1	1
Parts are easily replaceable	12		0	0	Parts are easily replaceable	12		0	0	Parts are easily replaceable	12		0	0
Low cost	10		1	-1	Low cost	10		-1	-1	Low cost	10		1	1
Able to be sterilized for repeated use	5		0	-1	Able to be sterilized for repeated use	5		0	-1	Able to be sterilized for repeated use	5		1	1
Total			1	-2	Total			-1	-2	Total			2	2
Weighted Total			26	6	Weighted Total			-26	-10	Weighted Total			-6	10

Figure 20. Pugh matrices used to evaluate three concepts, resulting in a superior concept, highlighted in green.

This process narrowed the scope of our concepts to an enclosed breaking component added on to the current SeaSpine handle. There are a variety of geometries which could satisfy all the

customer requirements with this concept, so we ideated possible solutions given our force-limiting concept. We further narrowed those concepts to the two concepts shown in Figures 21 and 22 below because they provided the most promise in providing a consistent force limit before breaking.

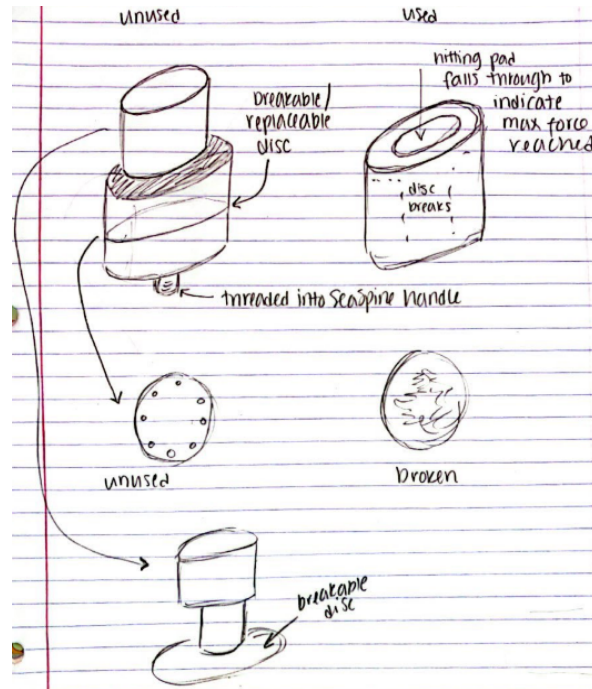


Figure 21. Idea 1: Replaceable puck designed to yield under shear stress in cylindrical housing.

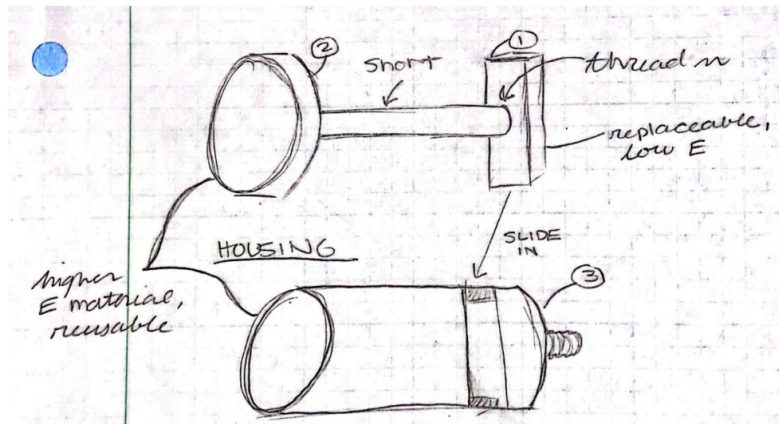


Figure 22. Idea 2: Replaceable bar enclosed in cylindrical housing designed to yield under bending stress.

These two ideas both use the geometry and material properties of a component to limit the force applied before breaking. The component breaking under shear is intended to absorb the impact of hammering during insertion, rather than pass it along to the spinal cage. While they use similar concepts in each design, Idea 2 shown in Figure 22 poses the risk of stress concentrations occurring in the threaded region in the breakable bar, which could result in break force

inconsistencies. For this reason, our team chose to move forward with Idea 1 in Figure 21, as it provides a more robust design capable of consistent shear breaking force.

VIII. Conceptual Model

We developed a conceptual model of our device to find functional geometries and run initial finite element analysis (FEAs) to test if our concept looks like it can limit the forces we need.

Description and Images of Model

This model consists of four custom components and 8 screws. Two cylindrical components, shown in orange and purple in Figure 23 below, act as a housing for a sliding cylindrical component, shown in green, and a replaceable puck, shown in red, designed to break at a force threshold below the fracture force of the spinal cage. During use, the physician will hammer on the surface of the sliding cylinder, applying a shear force to the puck. The puck will break under a consistent shear force as the sliding cylinder punches a hole through the puck. The physician will notice the hammering surface drop into the housing cylinder at this point, indicating they must replace the component before continuing with insertion. The $\frac{3}{8}$ -16 thread on the distal end of the device threads into the proximal end of one current SeaSpine handle, and will thread into the end of the Hollywood Inserter given a simple addition of a $\frac{3}{8}$ - 16 hole on the proximal end. This allows for quick, easy replacement of the device, as specified in our customer requirements. The puck can later be replaced by SeaSpine by removing screws from the counterbores in the proximal end of the housing, replacing the puck, and reinserting screws.

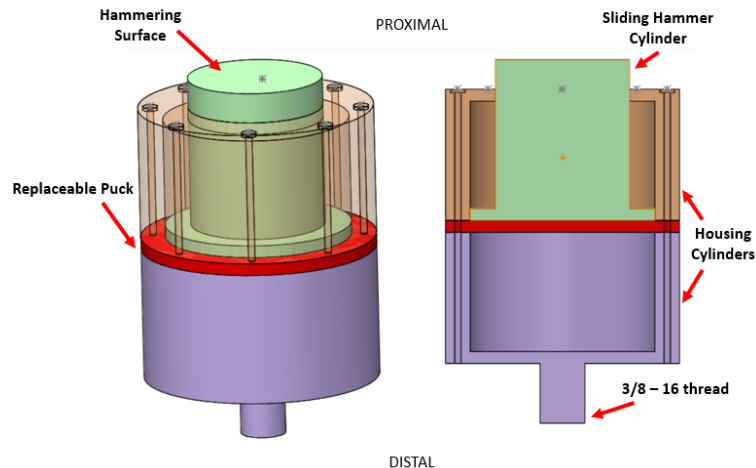


Figure 23. Isometric and cross-section views of concept with component names and key features of design.

Analysis Performed

Our first FEA was performed on SeaSpine’s ASTM cage, which is the cage they do the majority of their testing on, and one of the most fragile cases. A force of 5,480 N was found to break the PEEK cage (Figure 24).

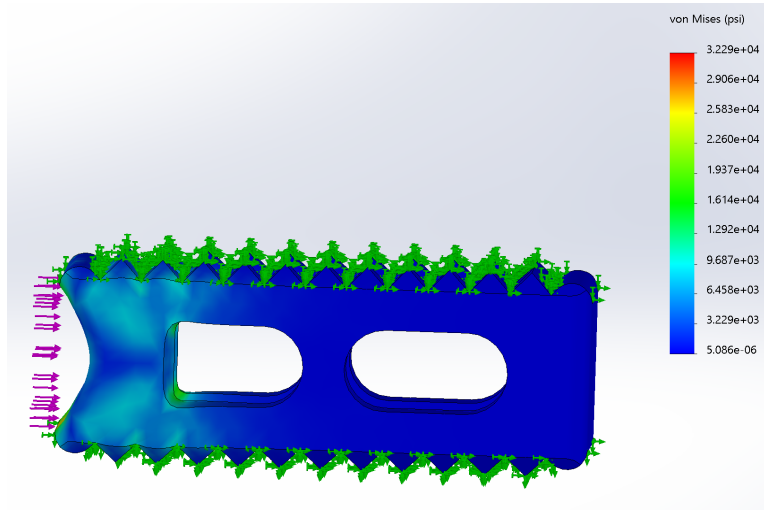


Figure 24. FEA of SeaSpine’s ASTM cage with 5480 N of force applied to the cage which is fixed on the top and bottom.

Using these FEA results, we began testing materials for the replaceable component of our device through FEA modeling. We found that acrylic would break under a load of 5,480 N with the geometries of our current model (Figure 25). However, Delrin would not fracture under a load of 5,480 N (Figure 26).

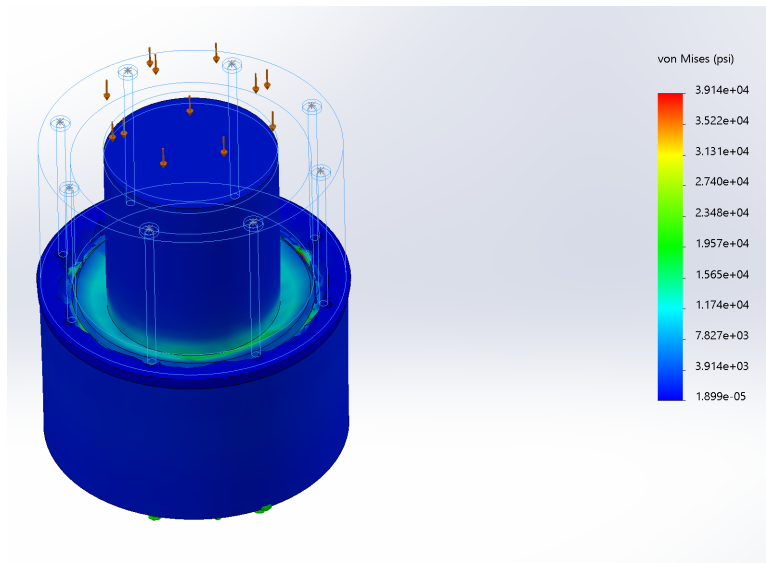


Figure 25. FEA of 5,480 N applied to the device with acrylic as the replaceable puck.

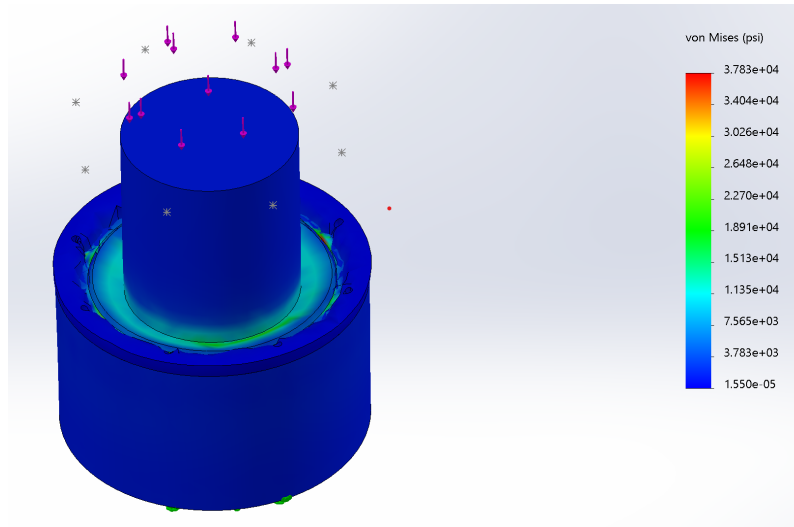


Figure 26. FEA of 5,480 N applied to the device with Delrin as the replaceable puck.

The results from the FEA on the device show that acrylic or Delrin would be reasonable material choices for the device, as acrylic could be made thicker, or Delrin could be made thinner to achieve the desired breaking characteristics including a factor of safety.

Learnings from Model Development and Analysis

From model development of our two front running concepts, we realized that one of our concepts would provide a more consistent break force. One of our most important customer requirements was making a force limiting surgical handle that has replaceable parts that are easy to change out. The design shown in Figure 27 would require a silicone sleeve around the outside of the cylindrical casing that would prevent any broken pieces from falling into the patient or loose into the operating room. While this sleeve would be easy and cheap to manufacture, it adds a layer of complication to exchanging the parts upon breakage. By making the models and comparing their characteristics to our customer requirements it was clear to see which one matched better with our requirements. This illustrates the importance of considering our customer requirements in every step of the design process, as well as the importance of using a pugh matrix to evaluate different potential designs.

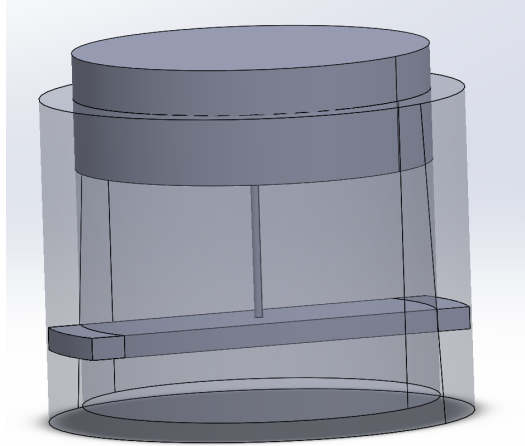


Figure 27. Obsolete conceptual model.

Further Development of Design

Moving forward the created 3D computer aided design (CAD) models educated material selection, particularly for the breakable component of the device. The design needed a force to break the puck below the force to break the spinal cage, but greater than the force required to insert the cage into the spine. Doing FEA and different simulations on the initial CAD model drove material selection to match these force standards and which material was selected for prototyping.

IX. FMEA

In order to identify and evaluate the potential failure modes of our initial conceptual design we completed an FMEA. The results of our FMEA are summarized in Table VI. This process involved identifying failure modes and what function they correlate to, the potential effects of each failure, ranking the risk of each failure using OCC (occurrence), DET (detection), SEV (severity), and RPN (risk priority number). These are ranked on a scale of one to ten, where ten is the worst case scenario. The failure modes with the highest RPN are the ones we will focus on working our design around to reduce risk. Based on the results the most likely and high impact failure modes are that the device doesn't break at expected yield which could damage the spinal cage, the device yields before the cage does, and a surgeon applied forces at an off-axis angle.

Table VI. FMEA for conceptual model.

Function Affected	Potential Failure Mode	Potential Effect(s) of Failure	OCC	DET	SEV	RPN	Cause of Failure	Recommended Actions	Responsible Person
Biocompatibility	Shards are able to escape device	Shards get into patient	3	4	8	96	Improper seal on device, improper assembly	Ensure that all components are enclosed regardless of failure.	Natalie
		Patient under anesthesia for longer	3	4	3	36			
		More blood loss for patient	3	4	6	72			
Force Limiting	Device doesn't break at expected yield	Spinal cage gets damaged	6	6	8	288	Improper material, material defect, improper assembly, off-axis hitting	Complete thorough testing to ensure a well established failure force for spinal cage and failure force for device.	Megan
		Shards from spinal cage get into patient	4	6	10	240			
Spinal Cage Placement	Device yields at a force lower than insertion force	Spinal cage can't be implanted	5	7	7	245	Manufacturing defect, inaccurate test results	Test fully assembled add-on with handle and spinal cage to ensure that the add-on breaks just below cage failing rather than extremely below.	Megan
		Patient under anesthesia for longer	3	7	3	63			
		Patient experiences extreme blood loss	2	7	9	126			
Force Limiting	Surgeon introduces off-axis forces to the device	Spinal cage gets damaged	7	4	7	196	Surgeon does not follow instructions for use	Training includes specific instructions to hit this device on-axis	Anna
		Device gets damaged	7	4	7	196			
		Particles get into patient	2	4	8	64			
Spinal Cage Placement	Device cannot be threaded onto handle	Cannot assemble device onto preexisting handle. Need to get new device.	1	1	2	2	Not manufactured to specifications	Supplier to provide certificate of conformance, including material.	Natalie
Spinal Cage Placement	Device components don't fit together as intended	Cannot assemble device on the manufacturing line. Need to scrap component.	1	1	2	2	Not manufactured to specifications	Supplier to provide certificate of conformance, including material.	Anna
Biocompatibility	Device is made of wrong material	Non-biocompatible material gets introduced into system	1	6	8	48	Poor material selection	Supplier to provide certificate of conformance, including material.	Megan

X. Detailed Design

As discussed in Section VIII, we moved forward with the concept shown in Figure 23, which uses a sliding hammer component to punch a hole in a Delrin puck designed to yield before the spinal cage during insertion. This section outlines the detailed design of this component, including how we addressed the risks outlined in the FMEA in Section IX. The detailed design CAD model is shown in Figure 28 below and will be discussed in depth in this section.

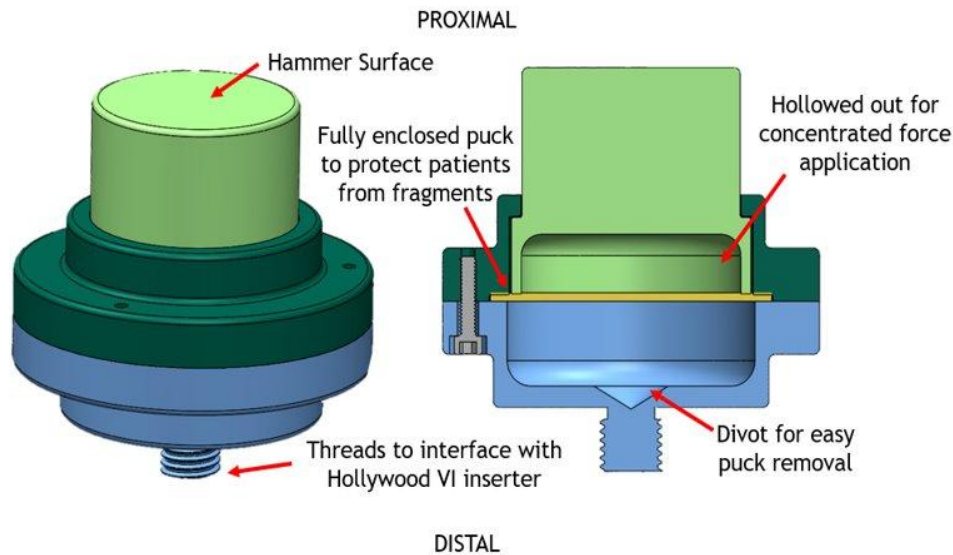

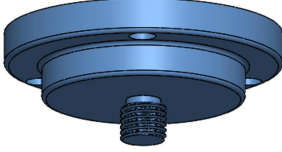
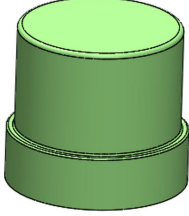



Figure 28. Detail design CAD model with key feature callouts.

The final design includes 3X size 2 stainless steel screws and 4 custom components, summarized in Table VII below. The custom components will be the focus of this section.

Table VII. Components, selected materials, and cost estimations for final design.

Item Number	Component	CAD	Material	Cost Estimation
1	Top Housing		17-4 Stainless Steel	Material:\$20 1.5 hours machine time at \$90/hour: \$135 Total: \$155
2	Bottom Housing		17-4 Stainless Steel	Material:\$20 2 hours machine time at \$90/hour: \$180 Total: \$200
3	Sliding Punch		17-4 Stainless Steel	Material:\$15 1 hour machine time at \$90/hour: \$90 Total: \$105
4	Puck		Delrin	Material:\$10 ½ hour machine time at \$90/hour: \$45 Total: \$55
Total Cost				\$515

The cost estimates for these components were provided from SeaSpine’s machine shop based on their machinist’s hourly rate and the estimated cost for materials. These estimated costs reflect a quantity of 1 for each component and is expected to decrease in the future with higher quantities.

The detailed drawing for the full assembly is included in Figure 29 below. This page of the detailed drawing includes a bill of materials and balloon callouts for each component. The preceding pages include dimensional details for each component, seen in Appendix C-1. Please note that the drawings for the *Top Housing*, *Bottom Housing*, and *Sliding Punch* call out 6061 aluminum as the material. This is only for initial prototypes since the mechanical properties are acceptable and cheap for initial testing; the final prototypes will be 17-4 stainless steel to meet

our biocompatibility design requirement. Another thing to note is that the final drawings will ask for a certificate of conformance to ensure the material and dimensions for each component are as specified in the drawing. See Appendix C-1 for the detailed drawings of each component.

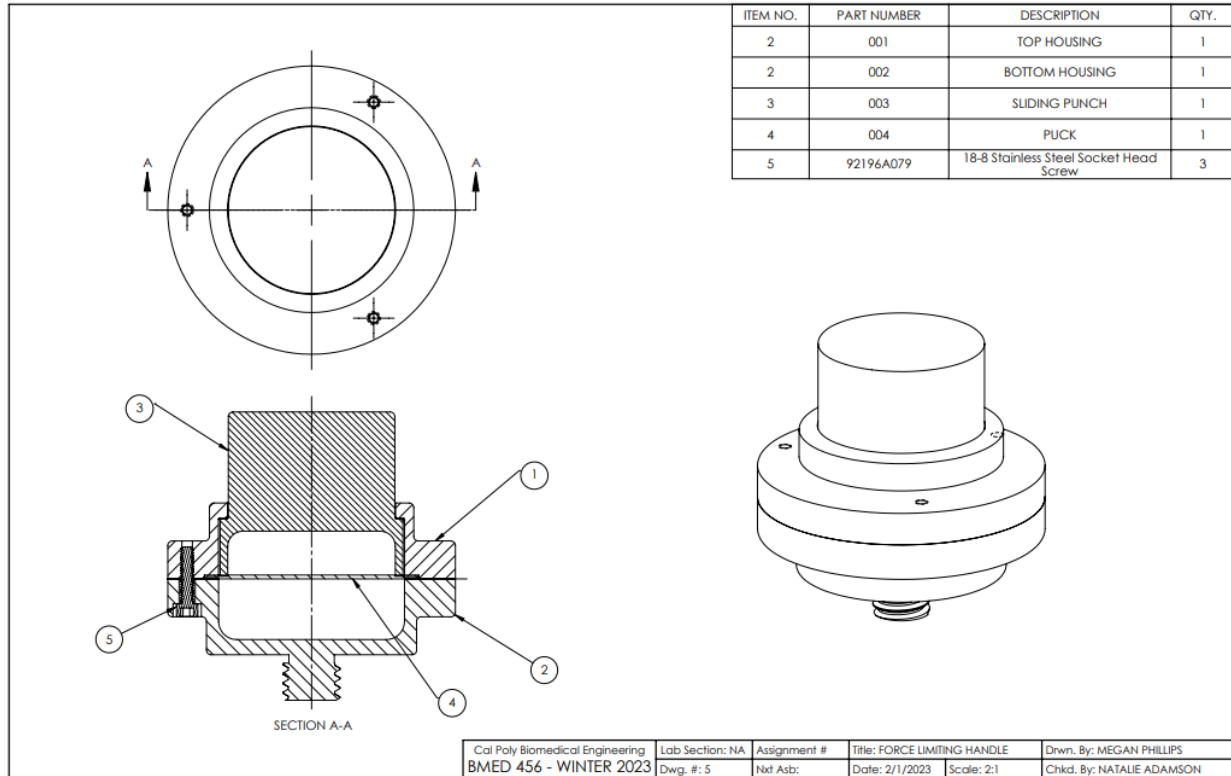


Figure 29. Detailed design assembly drawing.

The first component, *Top Housing*, acts as the joining piece with the *Bottom Housing* and holds the *Sliding Punch* in place until it breaks the *Puck* and drops into the bottom housing. A detailed drawing of the *Top Housing* can be seen in Appendix C-1. The max outer diameter (OD) of the component is 1.750", designed to be between the maximum OD, about 1.9", and the minimum OD, about 1.3", of the current Hollywood VI Inserter. This will allow for an aesthetically pleasing interface as well as plenty of space for the screws' lip and a maximized hitting surface area. The lip holding the *Sliding Punch* in place is approximately .030" on each side to ensure retention of the *Sliding Punch* while maximizing the hitting surface area. The fillets on this component are for aesthetic and machining purposes since this component will not be taking any loads during use.

The *Bottom Housing* detail drawing is shown next in Appendix C-1. The *Bottom Housing* has the same OD as the *Top Housing* for the same reasons. This component has threaded size 2-56 holes to mate with the screws that fit through the counterbores in the *Top Housing* seen in Figure 29. The large fillets on this component are intended for stress concentration relief since this component will experience the reaction force from the physician hitting the *Sliding Punch*. This

component also has a $\frac{3}{8}$ - 16 external thread on the proximal end of the housing (“proximal” as defined in Figure 28) to connect the force limiting handle components to the inserter during use. A threaded connection allows for quick and easy replacement of the full device during the surgery if it yields due to excessive force. The cutout on the distal end of the thread is for machining purposes and provides no functional purpose. This component also has a groove for the *Puck* to hold it centered during use and allow for easy assembly of the device.

The detailed drawing for the *Sliding Punch* is shown next in Appendix C-1. This component has a hollowed-out center to concentrate the stresses on the *Puck* to a smaller surface, allowing for a more consistent yielding force of the *Puck*. The component also has a large fillet on the inner diameter (ID) for stress relief since this component will be taking the majority of the hitting load during use.

The final figure in Appendix C-1 shows the detailed drawing for the *Puck*. This component is designed to fail under excess shear forces from the *Sliding Punch*. The yield force of this component is highly influenced by the thickness of the component and will be dialed in based on feasibility testing in the testing and iteration phase during Winter Quarter. The puck is designed to have .005” of interference in the space between the groove on the *Bottom Housing* and the *Top Housing* to ensure we get solid contact for frictional retention between the housings. To reduce the cost of this component, our team decided to perform initial prototype testing with a simple disc shape but is considering adding a centering/retaining groove feature to lock it into the groove in the bottom housing. We will evaluate if this change is necessary during feasibility testing.

The Bill of Materials for the device is shown below in Table VIII, including the item numbers, part numbers, names, materials, and sources for each component.

Table VIII. Bill of Materials.

Item No.	Part Number	Name	Material	Source
1	001	Top Housing	17-4 Stainless Steel	SeaSpine
2	002	Bottom Housing	17-4 Stainless Steel	SeaSpine
3	003	Sliding Punch	17-4 Stainless Steel	SeaSpine
4	004	Puck	Delrin	SeaSpine
5	92196A079	#2 Screws	Stainless Steel	McMaster-Carr

XI. Prototype Manufacturing Plans

Manufacturing Process Instructions (MPI)

All parts will be manufactured by our sponsor, SeaSpine per the detailed drawings provided. These drawings can be found in Appendix C-1. Prototypes will be manufactured from aluminum for the housing and punch. These components will be machined from 304 stainless steel for the final product. The puck will be manufactured from Delrin.

Housing and Punch:

Due to the circular nature of our parts, they will be machined by the SeaSpine manufacturing team using a lathe. Please note that safety goggles are to be worn at all times during the manufacturing process.

Step 1: Secure raw material in lathe

1. Mount cylindrical stainless steel stock in 3 jaw chuck using the lathe's chuck key
2. Stainless steel stock must be greater than or equal to 2" diameter

Step 2: Create parts per engineering drawings

1. Zero the lathe per stock diameter
2. Apply constant cutting fluid stream to work piece
3. Remove material until the piece is the desired shape in accordance with engineering drawings seen in Appendix C-1

Puck:

Step 1: Cut Delrin to size for the laser

1. In order to fit into the laser, the Delrin pieces must be 18"x32" or smaller
2. Use bandsaw to cut Delrin sheets to appropriate size

Step 2: Load Adobe illustrator file into laser software

1. Open the file in illustrator and "print" it to the laser software
2. Adjust for kerf as determined through prototyping

Step 3: Set up material settings

1. Open settings and open materials database
2. Plastics->Delrin
3. Enter material thickness

Step 4: Move laser

1. Put the laser in the bottom left corner of design
2. All of the design should be above and to the right of the laser

Step 5: Insert Delrin into laser

1. Load Delrin concave down, sliding beneath laser

2. Place water jet weights on Delrin to flatten as much as possible while not placing them anywhere between the current position of the laser and the top right corner of the laser cutter
3. Set Z height of laser using level on left hand side and control screen on laser

Step 6: Cut

1. Turn on fan and air assist
2. Hit play, and be careful to watch the entire cut
3. If the laser goes close to the water jet weights, immediately pause the cut and move them further away before resuming

Assembly:

These steps can be seen below in the exploded view (Figure 33), and a list of required parts can be found in the bill of materials (Table VIII).

Step 1: Insert puck into lower housing

Step 2: Place sliding punch on top of puck

Step 3: Slide on upper housing

Step 4: Insert three screws and tighten to 3 in-lb +/- 10% using a torque-cell

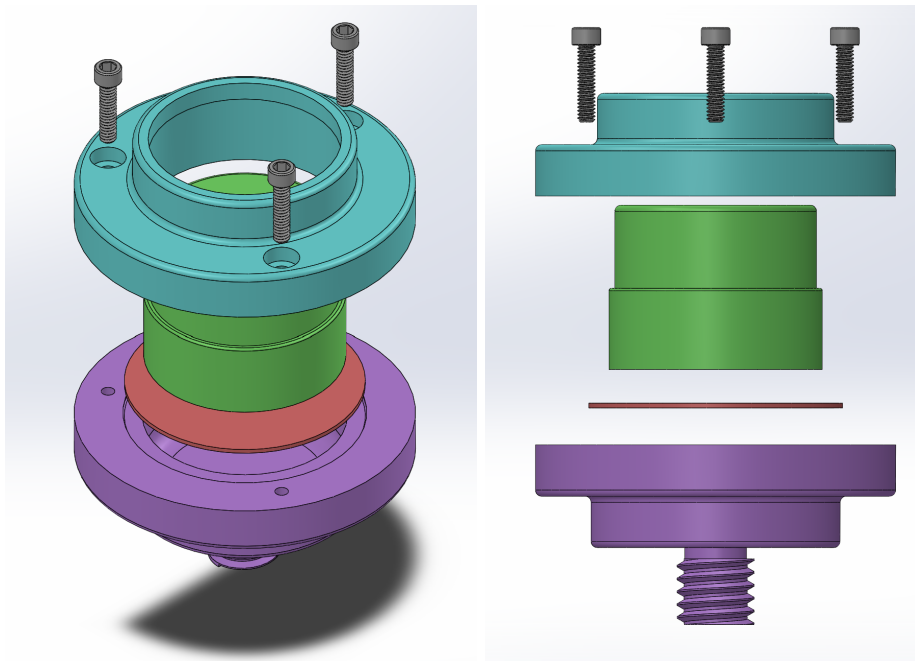


Figure 33. Exploded views of device assembly.

Step 5: Once assembled, the device should be screwed hand tight onto the threaded hole on the proximal end of the SeaSpine surgical handle shown in Figure 34.



Figure 34. Thread on proximal end of Seaspine handle.

XII. Detailed Test Plans

Tests Specified for Specifications

Tests performed to verify each engineering specification are found in Table IX, below.

Table IX. Tests for each engineering specification.

Spec. #	Description	Target Value	Test
1	Upper limit of force to break device < Lower limit of force to damage/break spinal cage	923 N	Compression testing
2	Lower limit of force to break device is greater than the median force to hammer in spinal cage	378.3 N [17]	Compression testing
3	Must comply with ISO-10993 to explain equivalence to predicate device for biocompatibility	Equivalence to predicate device	Research material for biocompatibility
4	Simulated use for evaluation of form, fit, function of interface with current device(s)	Pass	Attaches to all handles provided by SeaSpine
5	Full device under 3 pounds	3 lbs	Weigh device on scale
6	Time to replace parts under 10	10 mins	Timed assembly by persons unfamiliar

	minutes		with product
7	Cost per unit	\$500	Estimate cost of materials when purchased at volume
8	Device shall function after 10x steam sterilization	Pass	Research material for sterilizability

Design of Experiments (DOE)

Before continuing to final force testing to verify our design and prototype, we are in progress of completing some initial pilot testing to iterate the device. Table X includes a list and description of our preliminary experiments, with sample size, experimental groups, and expected outcome for each experiment.

Table X. Preliminary testing DOE.

Experiment/Purpose	Sample Size	Experimental Groups	Expected Outcome
Determine desired puck thickness based on the force to break a cage.	Starting by testing 2-3 pucks of each thickness, 0.02", 0.025", and 0.063".	Testing three different thicknesses of pucks, 0.02", 0.025", and 0.063". Each puck is 1.42" in diameter.	Want to determine the force to break each puck thickness to decide which thickness to use in final testing.
Determine dashed etching intervals on Delrin pucks to get desired break force and consistent breaking.	We will test 3 pucks of each dashed interval that will be etched into the pucks.	Testing three intervals of percent filled of circumference of etched circle. Dashes will go through the puck completely. Will test 50%, 60%, and 76% of dashed portions over total etched circle circumference.	Want to determine the final etching pattern to be used in future force testing.

Upon the completion of preliminary pilot testing, we will be moving on to verification testing of our final device. The final testing is detailed in Table XI, which includes a list of all final experiments, sample size, experimental groups, and expected outcome for each experiment.

Table XI. Final Testing DOE.

Experiment/Purpose	Sample Size	Experimental Groups	Expected Outcome
Find the force to break the smallest spinal cage (Hollywood VI).	3 small Hollywood VI spinal cages.	Testing one experimental group, the Hollywood VI spinal cages, because they are the smallest and worst case spinal cages	A lower limit of the force to break the spinal cage, average minus 1 standard error. This specification will be compared to the upper limit of the force to break the puck

		that we were given. We want to ensure that our device can prevent the worst case cage from breaking.	component of our device.
Determine the force to break our device, specifically the puck component.	3 different dashed Delrin pucks of same thickness. Will take the desired puck thickness from preliminary testing.	This experiment will consist of one experimental group, which will include our final prototype and final patterned Delrin puck.	The upper and lower limits of the force to break the puck component in the device. This specification will be compared to the force to break the surgical cage to ensure it is lower, and to the average force to place a spinal cage during surgery taken from literature.
Ensure that the time to replace components of the device is under 10 minutes.	Will disassemble and reassemble the full device with changing out a puck 3 times with 3 different operators.	There is one experimental group for this, which includes our final prototype with the final Delrin puck.	Record the upper limit (average plus 1 standard error) of the time from 3 assemblies from 3 different users to ensure that the time to replace components is under 10 minutes.
Verify that our device interfaces with SeaSpine's current surgical handle.	Will verify that our final prototype screws into the back of the SeaSpine surgical handle.	This experimental group will consist of our final prototype, specifically the bottom housing, and SeaSpine's surgical handle.	Will confirm that our device functions and fits properly with SeaSpine's surgical handle.
Verify that the final weight of the device is under 3 pounds.	Will verify that our final device (sample size of 1) weighs under desired specification.	This single experimental group will consist of our final device fully assembled with puck and screws.	Will verify that the weight measurement is under 3 pounds to meet our desired engineering specification.

Detailed Protocol

The following details experimental set up, data acquisition, and analysis for each test based on engineering specifications outlined in Tables IX, X, and XI. Detailed protocol will not be included for engineering specification 7, as no testing or data analysis is required for this spec. If the cost is less than our target value, the device passes for this specification.

Test 1: Force to Break the Spinal Cage

- 1.1 Locate the tall GeoJac testing frame and place it near the GeoJac computer in the CE Lab. Rotate the bottom set of hex nuts until the desired height for the GeoJac head is reached, as approved by Professor Derbridge. Place the GeoJac testing head onto the bottom nuts and rotate the pair of top nuts until they are hand tightened over the GeoJac head.
- 1.2 Select a spinal cage for testing and attach it to the SeaSpine spinal cage inserter using the rotating knob on the proximal end of the metal shaft. Orient the cage onto the handle per the orientation shown in Figure 35 below. *Play close attention to the orientation of the grooves on the proximal end of the cage.*



Figure 35. Orientation of spinal cage on inserter for spinal cage testing.

- 1.3 Place the 4” opening vice between the threaded rods in the GeoJac tester. Then screw the male-male 5/16-24 to 1/2-20 adapter into the SeaSpine handle and screw the subassembly into the head of the GeoJac tester.

- 1.4 Assemble the bone blocks, aluminum fixture parts, load cell, and spinal cage into the orientation shown in Figure 36 below.

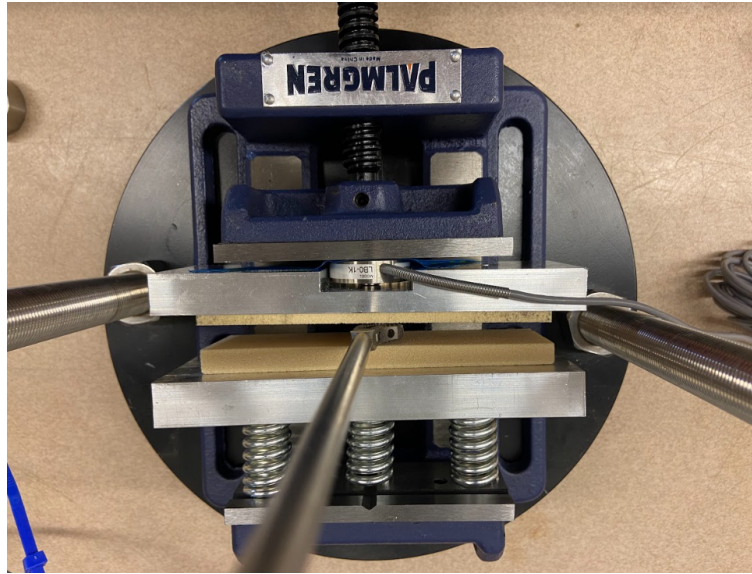


Figure 36. Clamping fixture component orientations in GeoJac tester.

Plug the load cell into the data acquisition system (Daq) and turn the Daq on.

- 1.5 Lower the actuator using the GeoJac computer software until the distance between the top of the bone blocks and the most distal part of the handle measures approximately .372", as shown in Figure 37 below. *Please note this photo shows the spinal cage already clamped into the fixture.* Use calipers to confirm proper spacing of the spinal cage.



Figure 37. Spinal cage clamped between bone blocks in clamping fixture.

- 1.6 Rotate the handle on the vice to clamp all the fixture components until the Daq reads 150+/-5N. *Make sure the SeaSpine handle is as vertical as possible following clamping, as it may shift during the process. Aim to have a preload on*

the system as low as possible. <10lb required.

The final orientation for spinal cage testing is shown in Figure 38 below.

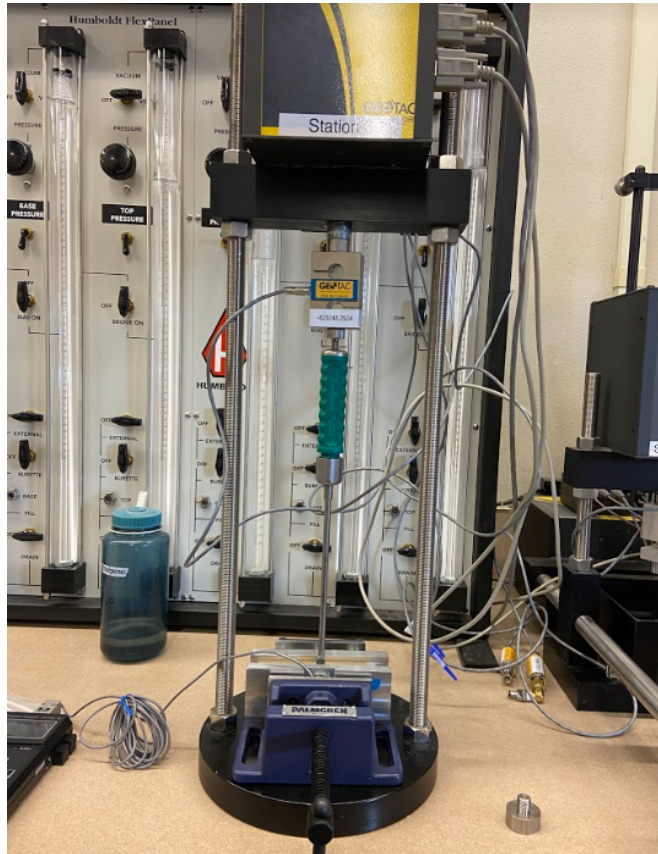


Figure 38. Complete orientation of testing setup for spinal cage testing.

- 1.7 Set the GeoJac software to the following presets:
Length of sample: 1”
Strain rate: 80%/min
Maximum strain: 80%
- 1.8 Set up a video camera to capture the full screen of the GeoJac software. Use miscellaneous parts from CE Lab to stabilize the camera. Press record.
- 1.9 Label the specimen in GeoJac Software and create appropriate save path in computer. Press “Start” on GeoJac software to begin testing. Verbally note when the spinal cage breaks for future video processing.
- 1.10 When the test finishes, stop the video recording and remove the spinal cage from the clamping fixture by rotating the vice clamping arm counterclockwise. Label the broken spinal cage and set aside.
- 1.11 Repeat steps 1.4 through 1.10 for remaining samples.

1.12 Export data from GeoJac software using a flash drive. Import into a secondary computer for data processing.

1.13 *Data Processing*

Open the data template provided by Professor Derbridge. In the data processing tab in the Excel file, click on Import, and select the appropriate data file to process. Once imported, click on Calculate.

1.14 *Data Processing*

In the data tab, use the following equation to convert the GeoJac data to pounds.

$$Force (lb) = \frac{(External\ Load\ Cell - Zero) \times (Cal. Factor)}{(Excitation)}$$

Plot the data using Insert->ScatterPlot.

1.15 *Data Processing*

To find the peak force during testing, watch the recorded video and note the maximum force when yielding occurs. Record this number in an Excel document.

1.16 *Data Processing*

Import the data into Minitab or Excel and find the average minus 1 standard error. This is the value that will be compared against data found in Part 2.

Test 2: Force to Break the Device & Time to Replace Components

2.1 Locate the shorter GeoJac testing frame and place it near the GeoJac computer in the CE Lab. Rotate the bottom set of hex nuts until the desired head height for the GeoJac head is reached, as approved by Professor Derbridge. Place the GeoJac testing head onto the bottom nuts and rotate the pair of top nuts until they are hand tightened over the GeoJac head.

Place the 4" opening vice between the threaded rods in the GeoJac tester.

2.2 Assemble the full device with desired puck thickness by placing the puck into the groove on the top housing and using an allen key to secure 3 size 2 screws through the counterbores on the bottom housing and into the threaded holes in the top housing. Tighten screws securely to ensure proper puck contact with the housing groove.

2.3 Screw the male-male 3/8-16 to 1/2-20 adapter into the proximal end of the assembled device and screw the subassembly into the head of the GeoJac tester.

2.4 Use the rotating knob on the vice to position the clamping plates just outside the 3/8-16 threads on the distal end of the device. *The plates should not be touching*

the threads.

- 2.5 Use the linear actuator on the GeoJac software to position the device so the distal threads are positioned between the plates of the vice and barely hovering over the top of the vice plates. Please see approximate positioning shown in Figure 39 below. *Please note that fixture plates are shown in this photo in place of a vice - photo for reference only.*

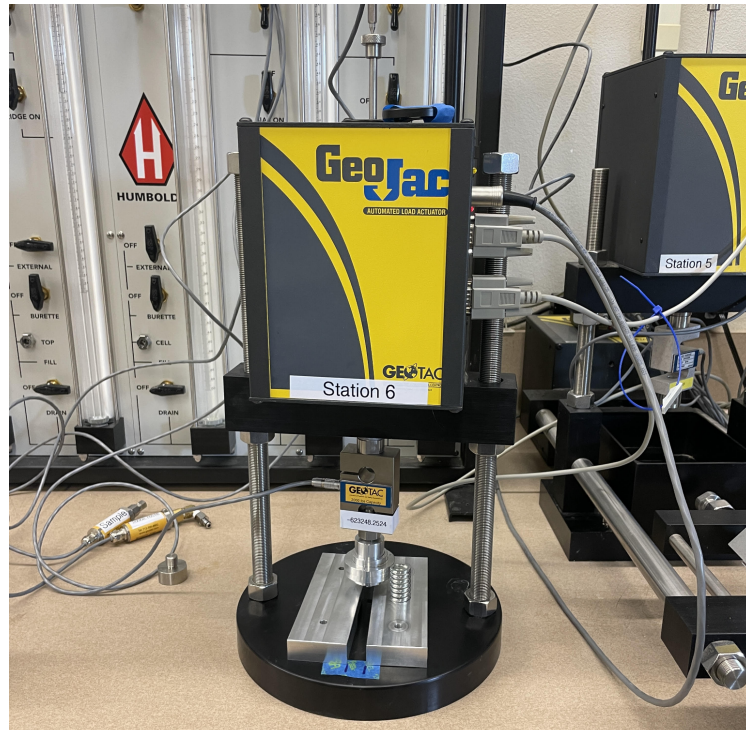


Figure 39. Complete orientation of testing setup for device testing.

- 2.6 Set the GeoJac software to the following presets:
Length of sample: 1”
Strain rate: 80%/min
Maximum strain: 80%
- 2.7 Set up a video camera to capture the full screen of the GeoJac software. Use miscellaneous parts from CE Lab to stabilize the camera. Press record.
- 2.8 Label the specimen in GeoJac Software and create appropriate save path in computer. Press “Start” on GeoJac software to begin testing. Verbally note when the puck appears to break for future video processing.
- 2.9 When the test finishes, stop the video recording and remove the device from the GeoJac tester. Unscrew the 3 size 2 screws from the device using an allen key and label the broken puck to set aside.
- 2.10 Repeat steps 2.3 through 2.10 for remaining samples.

2.11 Export data from GeoJac software using a flash drive. Import into a secondary computer for data processing.

2.12 *Data Processing*

Open the data template provided by Professor Derbridge. In the data processing tab in the Excel file, click on Import, and select the appropriate data file to process.

2.13 *Data Processing*

In the data tab, use the following equation to convert the GeoJac data to pounds.

$$Force (lb) = \frac{(External\ Load\ Cell - Zero) \times (Cal.\ Factor)}{(Excitation)}$$

Plot the data using Insert->ScatterPlot.

2.14 *Data Processing*

To find the peak force during testing, watch the recorded video and note the maximum force when yielding occurs. Record this number in an Excel document.

2.16 *Data Processing (Upper limit, force to break device)*

Import the data into Minitab or Excel and find the average plus 1 standard error. This is the value that will be compared against data found in Test 1.

2.17 *Data Processing (Upper limit, force to break device)*

Compare the values from Test 1 and 2 to determine if the device passes the specification. If the value from Test 1 is greater than the value from Test 2, the device passes for this specification.

2.18 *Data Processing (Lower limit, force to break device)*

Import the data into Minitab or Excel and find the average minus 1 standard error of the break forces. This is the value that will be compared against the value for specification 2 in Table IV.

2.19 *Data Processing (Lower limit, force to break device)*

Compare the lower value from Test 2 to the value in engineering specification 2 in Table IV to determine if the device passes the specification. If the value from Test 2 is greater than the value in the engineering spec, the device passes for this specification.

Test 3: Simulated Use, Interface with Current Handle

3.1 Screw the male threads on the distal end of the device into the female threads on the end of the current SeaSpine handle.

3.2 *Data Processing*

If the device successfully assembles with the current SeaSpine handle, record “Pass” in the data sheet. If not, record “Fail”. Note any observations.

Test 4: Weight of Device

- 4.1 Assemble the full device with desired puck thickness by pacing the puck into the groove on the top housing and using an allen key to secure 3 size 2 screws through the counterbores on the bottom housing and into the threaded holes in the top housing. Tighten screws securely to ensure proper puck contact with the housing groove.
- 4.2 Place the assembled device on a scale. Record the weight of the device onto the data sheet.
- 4.3 *Data Processing*
If testing multiple devices, import data into Minitab and find the UTL of the weights. If the sample size was not high enough, find the upper confidence limit at 90% confidence. If only one sample was measured, skip this step.
- 4.4 *Data Processing*
If the weight from step 4.3 is less than 3 lbs, the device passes for this specification. If not, it fails.

Test 5: Equivalence to Predicate Devices

- 5.1 *Biocompatibility*
Research use of Delrin and 304 Stainless Steel in predicate devices and illustrate equivalence to establish biocompatibility.
- 5.2 *Steam Sterilizability*
Research use of Delrin and 304 Stainless Steel in predicate devices and illustrate equivalence to establish ability to be sterilized through steam sterilization.

Test 6: Time to Replace Components

- 6.1 *Prep before each trial*
Have a broken puck inside the housing after hammering the device to failure.
- 6.2 Start a timer and immediately unscrew the 3 size 2 screws from the device using an allen key.
- 6.3 Use a pick to remove the broken puck from the device by sticking it through the inside hole of the puck and using a scooping motion to lift it from the housing.
- 6.4 Insert a new puck and repeat step 2.2. Stop the timer and record the time to replace components.

- 6.5 Repeat steps 6.1-6.4 three times with three separate operators.
- 6.6 *Data Processing (Time to replace components)*
Import the data into Minitab or Excel, and find the average of the time to replace components.
- 6.6 *Data Processing (Time to replace components)*
If the value found in step 6.6 is less than 10 minutes, the device passes for this specification. If not, it fails.

Equipment, Supplies, and Personnel

Table XII below outlines the required supplies, equipment, and personnel for each test outlined in Tables X and XI.

Table XII. Supplies, equipment, and personnel for each engineering specification/test.

Spec. #	Description	Test	Equipment Required	Supplies Required	Personnel Required
1	Upper limit of force to break device < Lower limit of force to damage/break spinal cage	Compression testing	Compression tester	Device, aluminum blocks, pucks, thread converters, allen key	Professor Derbidge, Natalie, Megan
2	Lower limit of force to break device is greater than the median force to hammer in spinal cage	Compression testing	Compression Tester	Device, aluminum blocks, pucks, thread converters, allen key, test fixture, spinal cages, surgical handles	Professor Derbidge, Anna, Megan
3	Must comply with ISO-10993 to explain equivalence to predicate device for biocompatibility	Research material for biocompatibility	Computer	Computer	Natalie
4	Simulated use for evaluation of form, fit, function of interface with current device(s)	Attaches to all handles provided by SeaSpine	None	Device, surgical handles	Anna
5	Full device under 3 pounds	Weigh device on scale	Scale	Device	Natalie
6	Time to replace parts under 10 minutes	Timed assembly by 3 separate	Stopwatch	Device, allen key, puck, surgical handle, assembly	Natalie + 2 other people

		individuals		instructions	
7	Cost per unit	Estimate cost when purchased at volume	Computer	Computer	Megan
8	Device shall function after 10x steam sterilization	Research material for sterilizability	Computer	Computer	Anna

XIII. Testing Data and Analyses

Summary of Test Results

Table XIII below summarizes the results of design verification and validation testing in order of engineering specifications.

Table XIII. Summary of tests relating to engineering specifications with results.

Test Number	Engineering Specifications	Target and Tolerance	Result	Pass/Fail
1/2	Upper limit of force to break device < Lower limit of force to damage/break spinal cage	<923 N	776 N	Pass
1/2	Lower limit of force to break device is greater than the median force to hammer in spinal cage	>378.3 N	776 N	Pass
N/A	Must comply with ISO-10993 to explain equivalence to predicate device for biocompatibility	Pass/Fail	Comparison to predicate materials	Pass
4	Simulated use for evaluation of form, fit, function of interface with current device(s)	Pass/Fail	Fits with current devices	Pass
5	Full device under 3 pounds	< 3 lbs	0.19 lbs	Pass
3	Time to replace parts under 10 minutes	< 10 mins	2 mins 32 sec	Pass
N/A	Cost per unit	< \$500/unit	\$515	Will pass with high volume production
N/A	Device shall function after 10x steam sterilization	Pass/Fail	Comparison to predicate materials	Pass

Data and Analysis

Below is a description of each test that we performed; each test includes results and a comparison to our original engineering specification. All of the following tests were performed on our second prototype made of aluminum following the protocol detailed in section XII.

Test 1: Force to Break the Spinal Cage

In order to determine the average force to break the small Hollywood VI cage, we tested 3 cages. Table XIV summarizes the results of the maximum force applied to each cage before breaking. It was determined that the lower limit of the force to break the cage was 923 N, which became our ceiling for the force to break the puck component.

Table XIV. Results from spinal cage testing.

Spinal Cage Sample	Maximum Force (lb)	Initial clamp force (lb)	Maximum Force (N)
1	233.71	149	1038.71
2	281.78	149	1252.36
3	275.14	147	1222.84
Average	263.54		1171.30
Standard Deviation	26.049		115.77
Lower Limit	207.66		922.94

Test 2: Force to Break the Device

Once the force to break the spinal cage was determined to be 923 N, we altered the puck so that our device broke below the force to break the cage. We initially tested three dash patterns on the puck, labeled in Table XV as small, medium, and long. Small correlates to the dashed pattern making up 50% of the total puck circumference, medium correlates to making up 60%, and long correlates to 76%. We tested these three dash patterns on three different puck thicknesses. The resulting data from our first round of patterned puck testing is shown below in Table XV. From the first round of testing we were able to conclude that the 0.025 in thick Delrin gave us the most consistent and close to specification break forces. Moving forward all tests were done using the 0.025 in thick Delrin.

Table XV. Results from 2/6 puck testing.

Puck Thickness (in)	Dash Size	Force (N)	Force (lb)
0.025	long	623.41	140.27
0.02	long	701.23	157.78
0.02	long	727.59	163.71
0.025	long	802.34	180.53

0.04	long	1226.78	276.03
0.025	medium	1251.90	281.68
0.02	medium	1258.44	283.15
0.04	long	1273.77	286.60
0.02	small	1866.56	419.98
0.04	medium	2210.38	497.34
0.025	small	2387.29	537.14
0.04	small	3470.03	780.76

From the first round of testing patterned pucks, shown in Table XV, we found that the average force to break the pucks was not close enough to our specification. We were targeting a break force less than 923 N, but greater than 378.3 N. In order to get closer to the desired break force we ran the regression shown in Figure 40 to determine the patterns for the next round of testing.

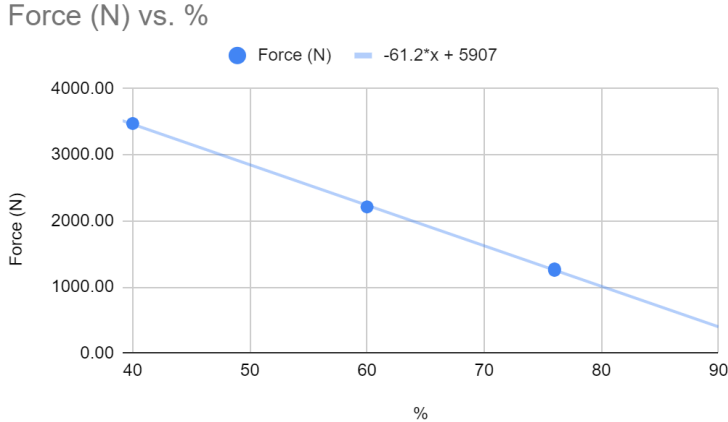


Figure 40. Regression on 2/6 Puck Force Data.

Next, we created three new dashed patterns based on the results from Figure 40. We created a 80%, 82%, and 85% dash pattern for the pucks and tested four samples of each pattern. The resulting data from our second round of puck testing is included below in Table XVI. The data from this round of testing was very inconsistent, we hypothesized that this was due to the Delrin being served due to shipping in rolls and with manufacturing concerns with our final stainless steel prototype. Moving forward we only used our second aluminum prototype, which passed all of our engineering specifications with more consistent force data results.

Table XVI. Results from 2/27 puck testing.

Dash Pattern (%)	Maximum Force (N)
80	1400.7
80	2063.3
80	1411.3
80	1516.0
82	1762.0
82	1006.1
82	1035.1
82	1090.4
85	1080.6
85	1230.8
85	1056.0
85	1248.3

Since the 2/27 data, shown in Table XVI, was very inconsistent, we tried to flatten the Delrin as much as possible before completing a final round of puck testing. This round of puck testing was completed using the 82% and 85% pucks. The third round of puck testing is shown below in Table XVII. From this data we concluded that the 85% dash pattern on the 0.025 in puck would be implemented into our final design. The 85% pattern yielded an average maximum force of 776 N, which met our specification of being below 923 N and above 378.3 N.

Table XVII. Results from 3/6 puck testing.

Dash Pattern (%)	Maximum Force (N)
85	775.4
85	792.9
85	759.0
82	1764.6
82	1053.5

Test 3: Time to Replace Components

In order to verify that the time to replace the components of our device was under 10 minutes, we had three participants fully replace the puck component of the device three times. The results of the trials are shown in Table XVIII. From these trials we found that the average time to replace parts was 2 minutes and 32 seconds which was well under our specification of 10 minutes.

Table XVIII. Results from time to replace puck trials.

Person	Trial Number	Time to Replace Pucks
Megan	1	2:57
Megan	2	1:47
Megan	3	3:55
Natalie	1	1:37
Natalie	2	1:14
Natalie	3	1:41
Anna	1	2:29
Anna	2	3:46
Anna	3	3:23
	Average Time	2:32

Test 4: Simulated Use, Interface with Current Handle

In order to verify that our device interfaced with SeaSpine's current handle we completed a visual inspection. Both our aluminum version two prototype and our third stainless steel prototype correctly interfaced with the handle by screwing into the back of the handle. As both prototypes correctly interfaced with the SeaSpine surgical handle, we concluded that the simulated use and interface with current handle specification was passed.

Test 5: Weight of the Device

Both our second and final prototype passed our engineering specification for weight. We specified that we wanted the device to weigh under 3 pounds, including the puck component. Once manufacturing was completed, we weighed both devices at SeaSpine's facility. The weights of the device can be found below in Table XIX.

Table XIX. Weights of the second and third prototypes.

Prototype	Weight (lbs)
Aluminum version 2 prototype	0.19
Stainless version 3 prototype	0.53

Test 6: Equivalence to Predicate Devices for Biocompatibility and Sterilization

In order to verify that our device was biocompatible and able to withstand ten rounds of steam sterilization we compared similar predicate devices made of the same material. As the aluminum prototype yielded the best force data, we used this prototype to compare for biocompatibility and sterilization. Aluminum is a well-known biocompatible material that has been supported by many ISO 10993-1 in vitro and in vivo tests [18]. For sterilization we concluded that our aluminum device would be able to withstand 10 cycles of steam sterilization. A study looking at aluminum dental pliers after 12 steam sterilization cycles found that there was no significant change to the pliers after the 12 cycles [19].

XIV. Instructions for Use (IFU)

Using the Device During Surgery

1. During spinal fusion surgery, when it is time to hammer the spinal cage between the vertebrae, follow instructions in the IFU for the SeaSpine spinal cage to attach the spinal cage to the end of the inserter.
2. Screw the pre-assembled device onto the proximal end of the inserter by rotating the device clockwise while holding the inserter stationary.
3. Rotate the device until snug against the bottom of the threads. No need for excessive force; the threads will hold the device in place with a moderately tight fit.
4. Follow SeaSpine’s instructions for spinal cage insertion while hammering on the “hammer surface,” as demonstrated during training. Ensure forces are along the axis of the inserter and normal to the hammer surface.
5. During the hammering process, have the surgeon or an operating assistant watch the device for the visual drop of the hammer surface. This indicates to the surgeon that they need to replace the device in full before proceeding with the procedure - see “Replacing the Device” below.
6. If the hammer surface remains in its raised position, continue with insertion until complete per SeaSpine’s IFU for spinal cages.
7. Upon completion of the surgery, label the used device as “used.” Include the used device with SeaSpine surgical tool set to be returned to SeaSpine for maintenance.

Replacing the Device

1. Unscrew the device from the inserter by rotating the device counterclockwise, while holding the inserter stationary, until it disengages from the inserter.
2. Label the broken device and set aside to be sent back to SeaSpine for replacement.
3. Retrieve a new device from the SeaSpine surgical tool set and screw onto the proximal end of the inserter using Steps 2 and 3 from “Using the Device During Surgery” above.

XV. Discussion and Conclusion

We have successfully finished a force limiting surgical handle prototype that meets all of our engineering specifications. The device included a force to break the device greater than the force to insert the spinal cage during spinal fusion surgery, 378.3 N, and less than the lower limit of the force to break the spinal cage, 923 N. The force to break the device was found to be 776 N, with upper and lower tolerance limits of 793 N and 759 N, which were well within the specified allowable range. The device is biocompatible and sterilizable, and well within our weight specification at less than 0.5 pounds. The parts were easy to replace, and an experienced user can replace all pucks in under 2 minutes. The cost of the final prototype was \$515, but at volume the specification that it needs to cost under \$500 would be met. This device interfaces with current SeaSpine interbody devices, and the force limiting handle will help reduce risk of spinal cage fracture during TLIF and PLIF procedures that use the small Hollywood VI cage.

Limitations for the device include, if the surgeon were to apply excessive force on many occasions, they may run out of devices to use, and have to use the traditional surgical handle, as they do currently. Additionally, the Delrin for the puck should be better sourced, so eliminate inconsistencies in force data due to the pucks being bent.

For future work our final design can be applied to other sized cages by doing research on the force to break different cage models and sizes. The design can be modified by changing the dash pattern and thickness of the Delrin puck to accommodate different force specifications.

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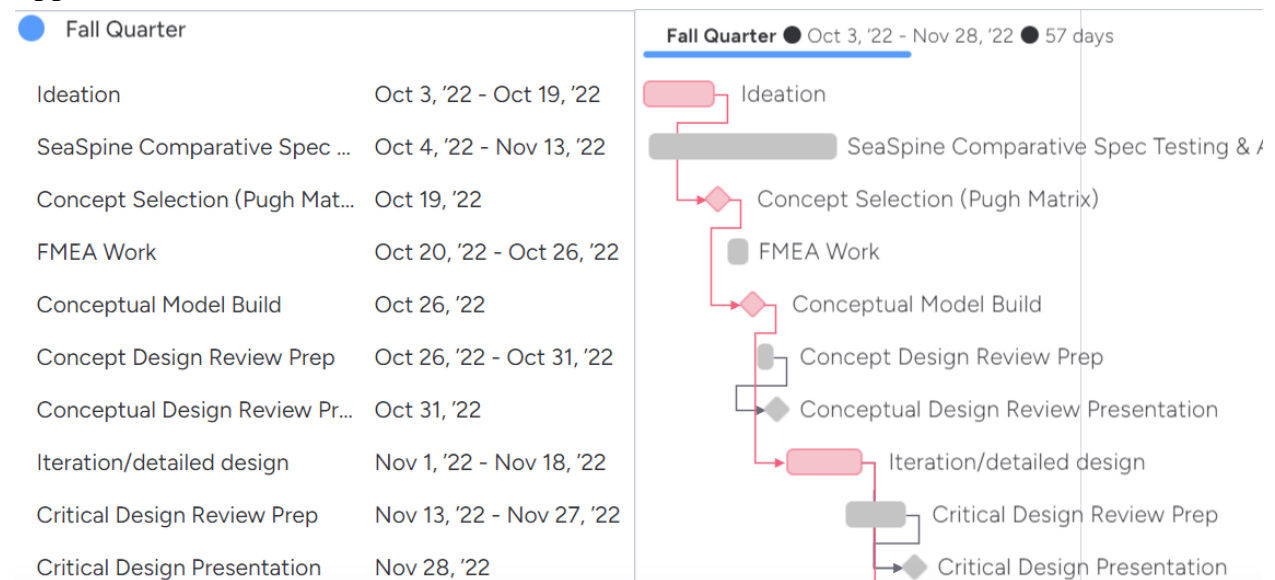
XV. Appendices

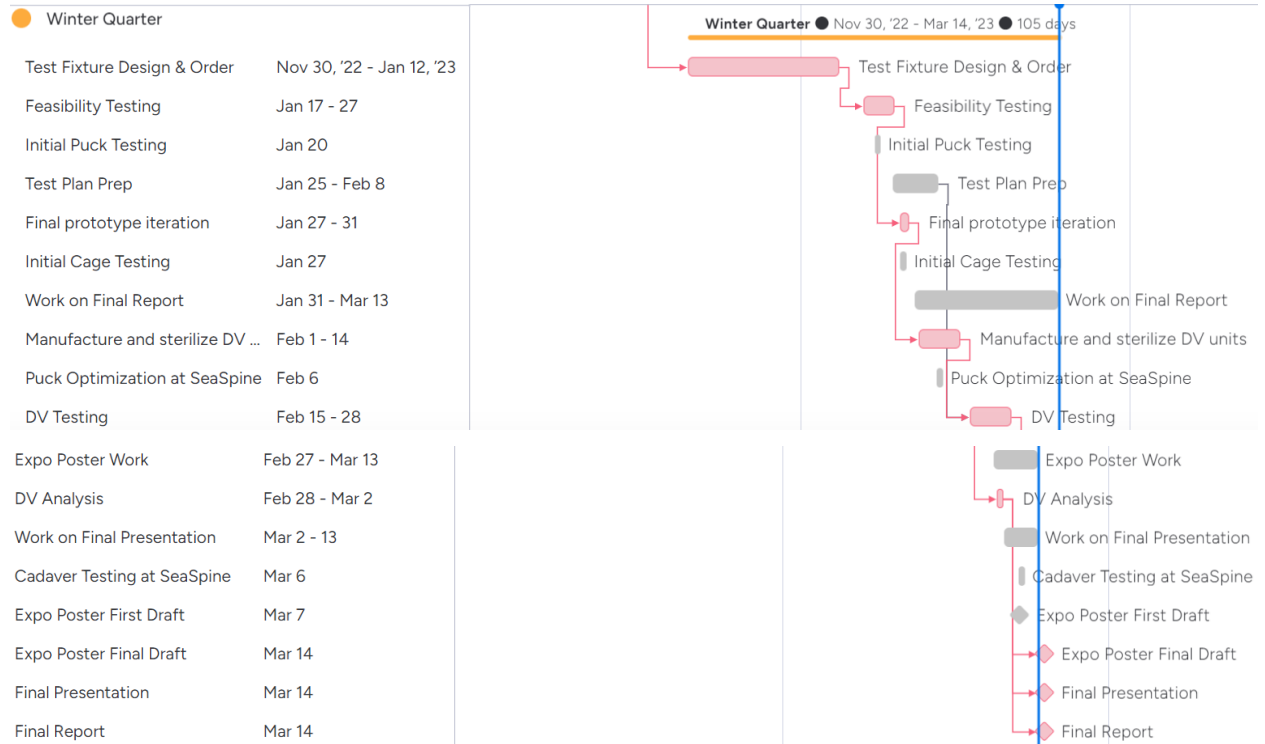
Appendix A-1: Full Customer Requirements List

Customer Requirements Full List:

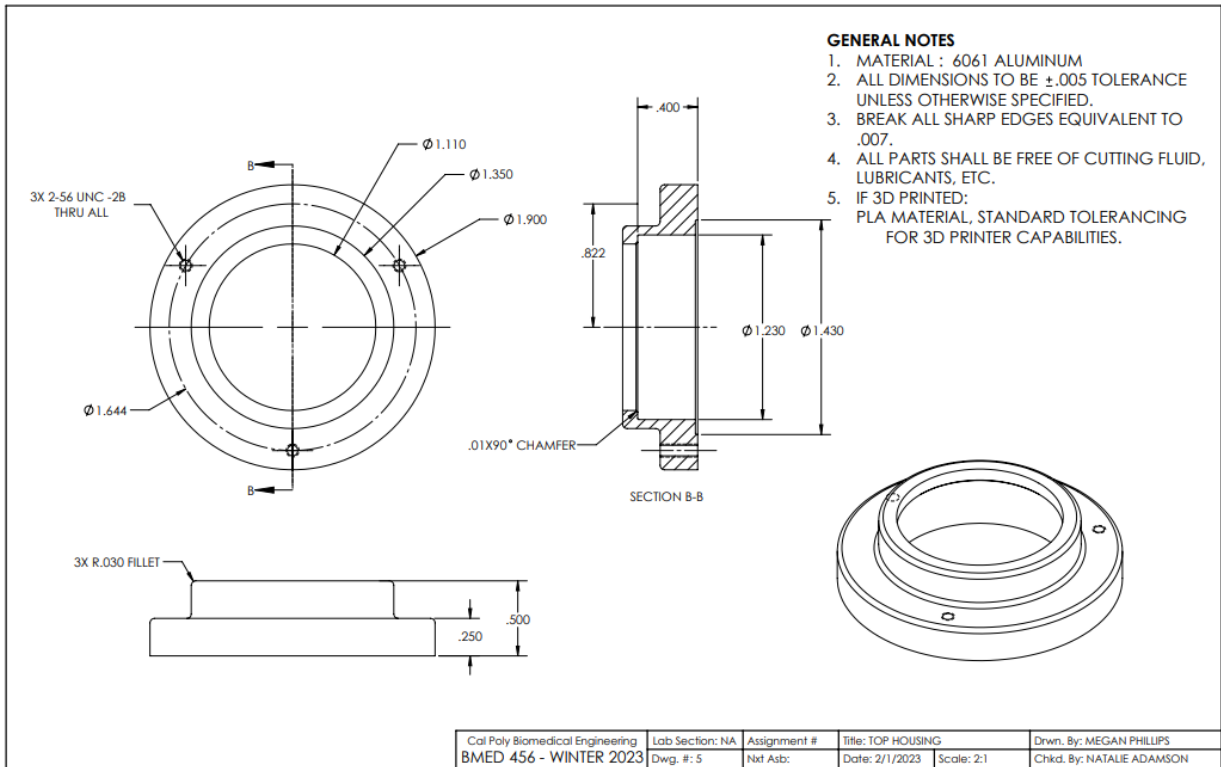
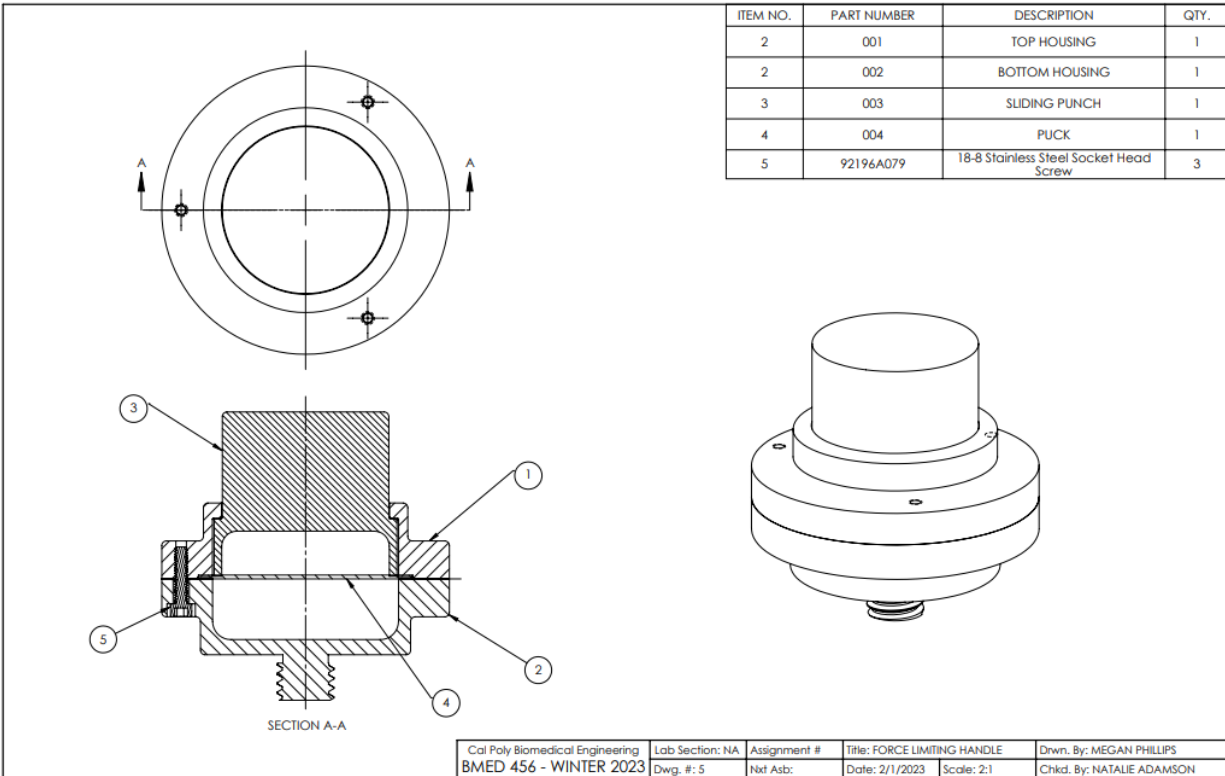
- A force limiting surgical handle with replaceable parts that break before the spinal cage during placement.
- The surgical handle should fit all current SeaSpine connections (i.e. spinal cage interface, connection to current surgical handles, SeaSpine universal connector).
- The final product should be made out of a biocompatible material.
- Surgical handle should last multiple successful procedures. The handle should be durable and relatively difficult to break.
- The process of changing out the replaceable part(s) should be easy and quick.
- The surgical handle should be able to be sanitized multiple times.
- The final product should be lightweight and compact, easy for a surgeon to use.
- When using the surgical handle to implant a spinal cage, the spinal cage should not break.
- Final device should be similar in price point to other SeaSpine surgical handles.
- Final device should be compatible and fit within current SeaSpine instrument transportation packaging.

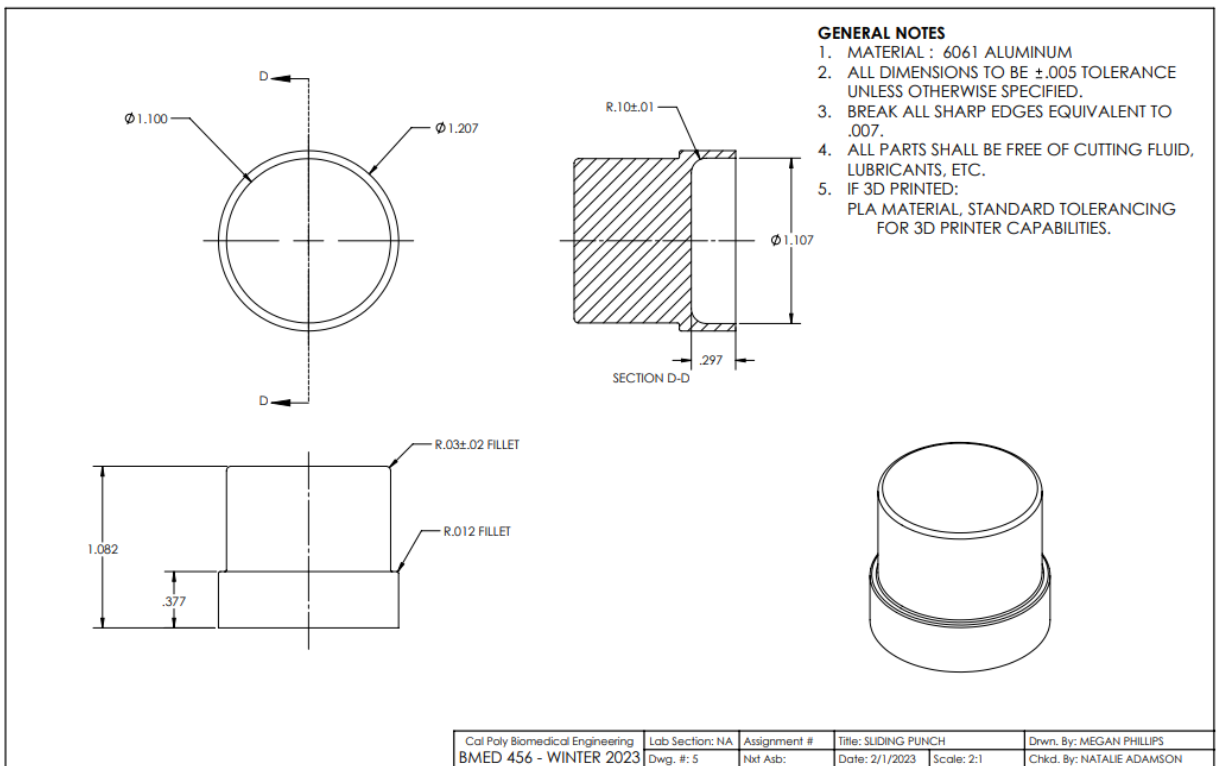
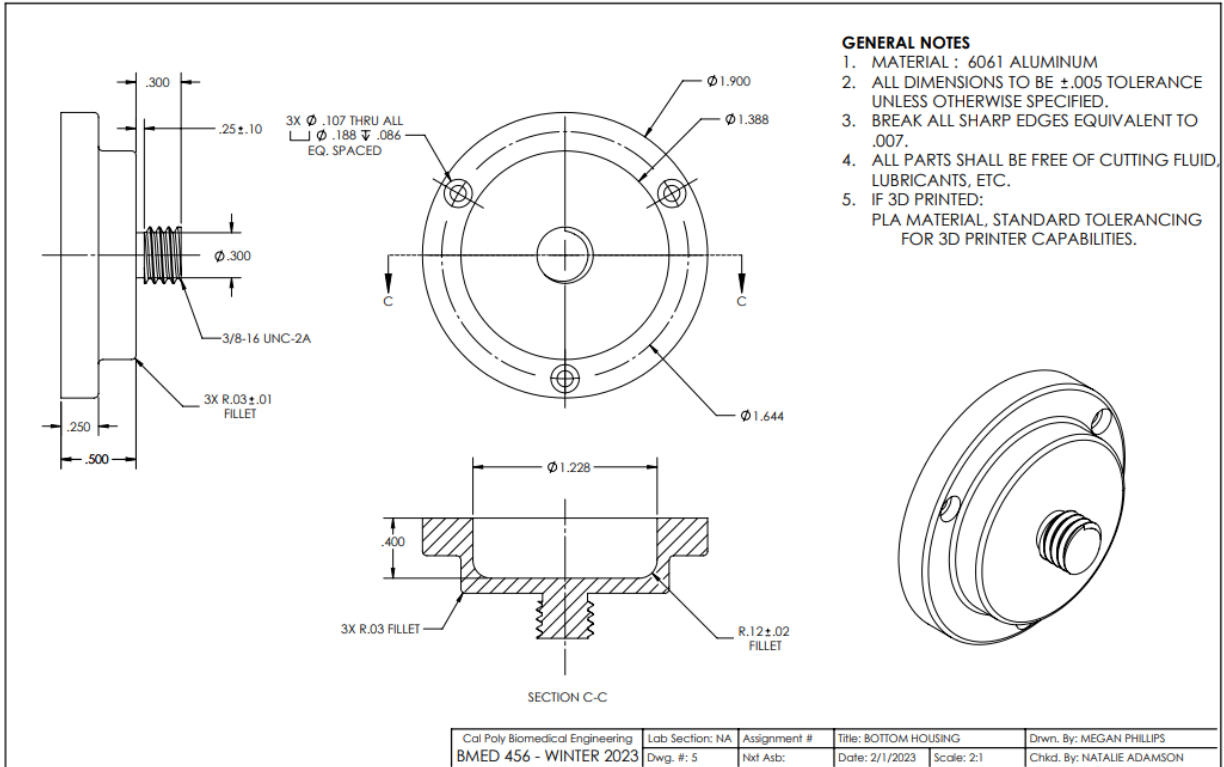
Appendix B-1: Winter Quarter - Gantt Chart

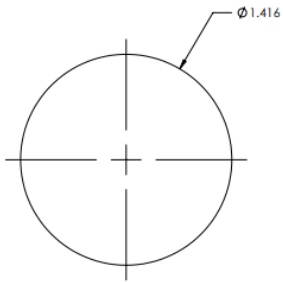




Appendix C-1: Detailed Drawing

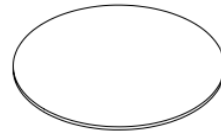






GENERAL NOTES

1. MATERIAL : DELRIN
2. ALL DIMENSIONS TO BE $\pm .005$ TOLERANCE UNLESS OTHERWISE SPECIFIED.
3. BREAK ALL SHARP EDGES EQUIVALENT TO .007.
4. ALL PARTS SHALL BE FREE OF CUTTING FLUID, LUBRICANTS, ETC.
5. IF 3D PRINTED:
PLA MATERIAL, STANDARD TOLERANCING FOR 3D PRINTER CAPABILITIES.



Cal Poly Biomedical Engineering BMED 456 - WINTER 2023	Lab Section: NA Dwg. #: 5	Assignment # Nxt Asb:	Title: PUCK Date: 2/1/2023	Scale: 2:1	Drwn. By: MEGAN PHILLIPS Chkd. By: NATALIE ADAMSON
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