



FINAL DESIGN REVIEW

LMBN Surgical Neurotomy Device

Back in Action

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Executive Summary

Lumbar Medial Branch Nerve (LMBN) Surgical Neurotomy Device

Lower back pain (LBP) is a global phenomenon, affecting 2.4 billion people globally and contributing to the number one cause of disability worldwide. Chances are, someone you know has dealt with lower back pain. The leading cause of LBP is the irritation of the lumbar medial branch nerve in the facet joint, contributing to 25% of all LBP cases.

This report presents an innovative solution to facet-induced LBP. The proposed solution aims to permanently relieve said pain, unlike existing solutions which merely offer temporary relief. Similarly, the proposed solution is minimally invasive, giving it a competitive advantage over the rather invasive solutions that exist today. Finally, the proposed solution entails advanced and meticulous engineering principles to meet medical standards in the development of four medical tools: the Stylet, Portal, Back Stabilizer, and Denervator.

At this point in the design process, the team has manufactured and tested a medical-quality prototype for each tool (see **Figure 1**). The Stylet features a handle for axial leverage, a sharp tip for bodily penetration, and a Nub to interlock with the Portal. The Portal was designed as a hollow pathway into the body for other tools, and it features an interlocking mechanism for the Stylet. The Back Stabilizer features long petals for leverage, a concave-shaped base to counteract the convex-shaped patient's back, and a clamp to constrain the Portal. Finally, the Denervator features a handle for torsional leverage, a 7mm-long burred section for lesioning the nerve, and a blunt end to prevent collateral damage.



Figure 1 Final prototype of the medical tools (left to right: Stylet, Portal, Denervator, Back Stabilizer)

The team leveraged a variety of manufacturing and sourcing methods to turn the key CAD features into reality (see **Figure 2**). Namely, the team sourced high-quality, tight-tolerance, pre-manufactured stock for the Stylet, Denervator, and Portal shafts. They also used an array of machinery, including lathes, laser cutters, band saws, and much more to create the specific geometric features. The final prototype featured a surface finish of 0.1-0.5 microns, and a tolerance no greater than 0.5mm. Medical-grade materials such as SAE 316L and polypropylene make up the prototype, as reflected in the updated BOM and budget.

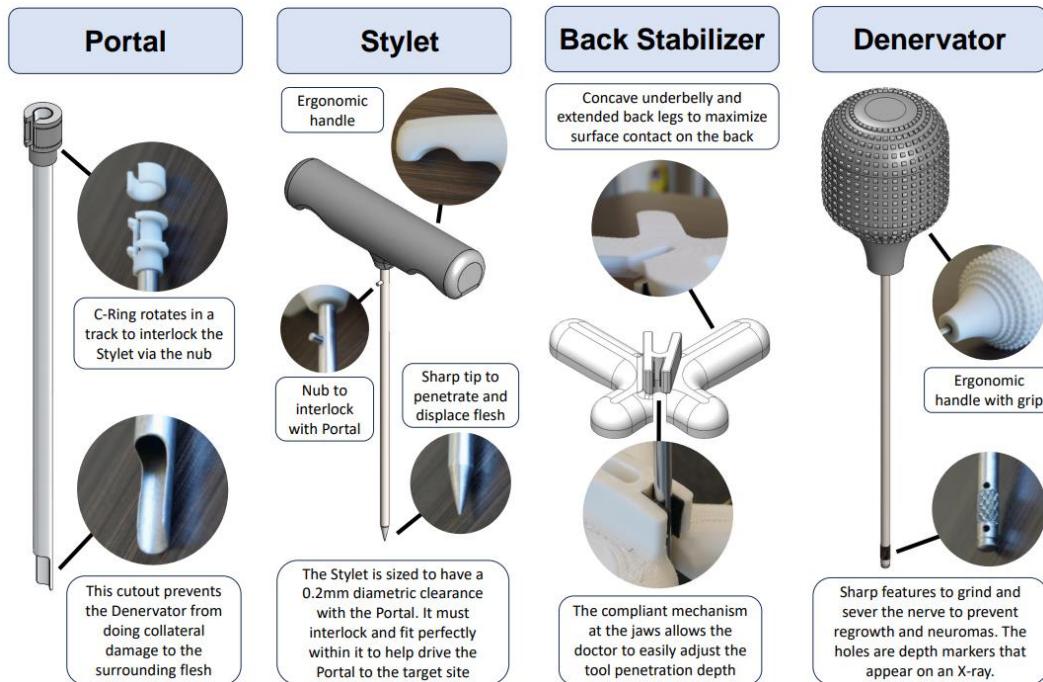


Figure 2 Final CAD of the medical tools, with key features noted

Along with previous engineering analyses, the team has validated the design through a variety of validation tests. This included modularity tests, force identification tests, and customer need tests. The results of these tests proved the prototype successful in meeting all specifications, allowing the project to reach a successful culmination.

Looking forward to the future, the team intends to perform animal and clinical testing to further validate the design. The team also plans on attending conferences with doctors to teach them about the medical tools and facilitate widespread adoption. Finally, the team intends to establish IP regarding their solution. Through the final design process, the team has showcased and analyzed a final prototype and requests to move on to future endeavors.

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Main Body

Chronic lower back pain (LBP), affecting 30% of all people, is the leading cause of disability worldwide and the second most common reason to visit a doctor after the common cold. Most LBP cases are incurable as arthritis has no solution. However, facet-induced LBP, accounting for 6% of the worldwide population, is commonly treated via a brute force method of denervating the medial branch nerve (MBN) – the nerve responsible for creating the pain signals. Most solutions to this problem are incredibly expensive, require surgical intervention, are ineffective, or do not yield long-term results.

Research into pain relief regarding the MBN showed that despite the number of people with back pain, there are no patents, products, or procedures available to permanently relieve facet-induced LBP through a minimally invasive procedure. Current alternative solutions for relieving back pain include physical therapy, cortisone shots, radiofrequency ablation, and spinal fusion. All these solutions are either temporary or ineffective and the stress of repeatability, and thus expenses, is apparent (**Section E.3**).

Given the gravity of this problem, the Back in Action team has decided to bridge this market gap and develop a solution that includes a disposable toolkit as part of a minimally invasive procedure to permanently relieve facet-induced LBP for patients. This solution will focus on the lumbar region but can also be implemented on a smaller scale in other areas of the spine in the future. The toolkit is comprised of a flesh-penetrating Stylet, a Portal to guide all invasive tools, a Back Stabilizer to stabilize the Portal, and a Denervator to lacerate the nerve such that it cannot regrow. The team is currently focused on a final design phase involving validating the model through analyses, manufacturing the devices, testing to ensure requirements are met, iterating on the design, developing a path forward, and finalizing the business model.

Extensive research was conducted to iterate on the design from CDR and to meet the updated engineering specifications chart (ESC). The medical-grade materials were selected primarily on the basis of biocompatibility, X-ray appearance, and temperature resistance (**Section G**). The material selections include SAE 316L, polypropylene, silicone rubber, and structural epoxy. Furthermore, the CAD models were updated to improve manufacturability and better meet customer requirements. These updated models were reanalyzed through FEA and

hand calculations to ensure yielding does not occur (**Sections H and I**). This included thermal analysis, stress analysis, and tolerancing.

Manufacturing Drawings, appended to the end of this report, and Operation Sheets (**Section K**) were also created to commence and guide the fabrication process. Several iterations of the tools were created to ensure a medical-grade prototype that met all tolerances as specified by the manufacturing drawings created. Through rigorous testing of customer needs, modularity, and forces, an iterative design process was pursued while mitigating risks based on timeline, information, budget, and functionality as detailed in the Risk Register and FMEA (**Sections D and J**). Some key tests conducted include X-ray imaging, sterilization, modularity, basic functionality, ability to meet target requirements, ease of use, and responsiveness to procedural forces as documented in **Section L**. The results of the testing drove dimension-related design as part of an iterative process.

Given that medical professionals and insurance companies are the team's direct customers, it was identified that patients are the indirect customers and those who drive the market. The target demographic was identified to be as large as 400,000 patients a year with the general demographic being in the order of millions. The market size and demand, in addition to the BOM and budget, were leveraged to update the initial price estimation for the product, taking inspiration from how similar competitors have done so (**Appendix II**). To remain competitive with the competitor procedure, RF Ablation, the team priced its kit at \$1,500 which yields an annual gross profit of \$6,059,650.

As per the current timeline, identified risks, vision, and budget (**Appendix I**), the team is very well on track to ensure project success and feasibility. The team is thus ready to begin documenting this data in a quality system to apply for FDA clearance and continue into the next phase of this project, beyond the scope of this class. A thorough analysis of applicable standards was conducted (**Section M**) and will aid the team in its next steps. Moving forward, the team plans to apply for patents, pursue more advanced preclinical testing, apply for clearance, and seek seed funding. Many victims of LBP have had to make severe lifestyle changes, sacrifice activities that they cannot do because of their condition, and partake in expensive and ineffective procedures. The team believes its proposed solution has great potential to become a well-crafted and medically certified product to yield monumental societal benefits, saving the lives of millions.

Appendix I – Project Management

A. Problem Charter

The notable changes to the Charter that took place during the FDR phase included a rewriting of the following sections to align with project progress: Key Resources Required and Project Scope. With regards to the Key Resources Required section, additional resources were added including all labs that were worked in (e.g. the Bambu lab in Bechtel Innovation Design Center and the X-ray lab in the Veterinary School), all the vendors that were sourced from for materials (e.g. Walmart and Amazon), and all people who provided guidance on this project (e.g. Justin Renfrow and Doug Applegate, who provided valuable workshops and feedback as a part of the Ventures pitch challenge). Additionally, the outsourcing section of Key Resources Required was removed, as the team pivoted to completing the design in-house. With regards to the Project Scope, the team adjusted this to reflect the progress of the team. For example, soft body modeling was moved to out of scope, while project introduction to industry sponsors was moved into scope. These updates are reflected in the updated Charter document, as is attached to this report and can be seen in **Figure A.1**.

To be comprehensive, the team feels it necessary to also discuss the changes that took place during the CDR phase. Namely, the following sections were shortened: Business/Society Benefit (Future State), Key Assumptions & Risks, and Key Milestones. The content was kept the same, but the length and depth was updated to reflect the length of the charter document. This made it more digestible, as reflected in the attached Charter document and in **Figure A.1**.

The following information was reviewed and slightly modified from the PDR phase to the CDR phase. The charter, as detailed in **Figure A.1**, is a live document. In the current state, lower back pain stemming from facet joint issues affects 6% of the global population, and the existing solutions present notable challenges. Patients seeking relief are subjected to frequent and inefficient medical visits, which often yield suboptimal results. This issue involves various key stakeholders, including patients experiencing facet-induced lower back pain, healthcare professionals specializing in its treatment (such as PM&R specialists and physiatrists), and insurance companies responsible for covering these procedures.

The envisioned future state entails the development of a company centered around a comprehensive medical tool kit, featuring a unique instrument designed for lumbar medial

branch nerve (LMBN) surgery. The innovative approach involves making these kits disposable, reducing sterilization needs, enabling in-office procedures, and ultimately cutting costs while increasing profit margins. This strategy fosters a symbiotic relationship within the supply chain, benefiting both the company, doctors, and patients. On a societal level, the product aims to provide a permanent and safer solution for facet-induced lower back pain, with the potential to alleviate 25% of lower back pain cases.

Within the project scope, the team is focused on developing a to-scale prototype while excluding elements such as the regulatory pathway, soft body modeling, and clinical testing. Key milestones in the project plan include conducting a thorough need assessment and conceptualization, followed by iterative design research and development, and culminating in preclinical testing.

While the team operates under the assumptions that the procedure is non-invasive, efficient, and falls under the open surgical code, the team recognize several risks, including potential patents, approval/certification challenges, and the possibility of side effects or unintended damage. The risk of potential patent infringement can be easily mitigated through patent research, as described in **Appendix E**.

Our team is composed of individuals (depicted in **Figure A.2**) with distinct roles and responsibilities as follows:

- Cameron Mostoufi: Project Manager, Chief Engineer, and Business Lead
- Agathiya Tharun: Project Manager, Chief Engineer, and Project POC
- Jacob Whitehouse: Buyer, Electronics Lead, Analysis Lead, and Validation Lead
- Joseph Misenar: Manufacturing Manager, Mechanical Design Lead, and CAD Lead

To support the project, the team will leverage both internal and external resources, including Purdue resources like the ME Machine Shop, the Rapid Prototyping Lab, ME PEARL Labs, and the Purdue Bechtel Innovation Design Center (BIDC). Additionally, the team plans to collaborate with experts such as Dr. S. Ali Mostoufi, Professor Cappelleri, Professor Hirleman, FDA POC's, Kyle Baer, Mark Baldwin, Martin Jun, Edward Null, Beth Hess, Justin Renfrow, Matt Dressler, and Doug Applegate.



ME 463 Senior Design

Project Title: LMBN Surgical Neurotomy Device	Vision Statement: We strive to develop a simple and effective functional medical tool kit and related procedure, to be used by operating specialists, thereby permanently relieving pain caused by the facet joint in every patient's lumbar region.	
Team Name: Back in Action		
Team Members: Cameron Mostoufi, Joseph Misener, Jacob Whitehouse, Agathiya Tharun		
Problem Statement (Current State)		
Lower back pain caused by the facet joint is experienced by 6% of all people. Current solutions to relieve this pain require repeated medical visits which yield suboptimal results. Current procedures are also procedurally inefficient and not user-friendly.		
Business / Society Benefit (Future State)		
Create disposable medical tool kit for LMBN surgical neurotomy, targeting FILBP treatment streamlining procedures by enabling in-office use and reducing costs, with materials designed for one-time sterilization to lower manufacturing and retail prices. Foster a symbiotic supply chain, linking company success to doctors' treatment capabilities and patients' needs. Aim to offer significant societal impact by providing a permanent solution to 25% of lower back pain cases and a safer alternative treatments, minimizing invasiveness and repeat procedures.		
Key Milestones		
1. Assess clinical need for a new lower back pain device, analyze current treatments, and design a superior solution. 2. Develop design plans, build prototypes, conduct software and bench tests for functionality and safety, and perform soft body modeling. 3. Conduct preclinical tests and mannequin trials to verify efficacy and safety.		
Team Members & Roles		
Cameron Mostoufi: Project Manager, Chief Engineer, Business Lead Jacob Whitehouse: Buyer, Electronics Lead, Analysis Lead, Validation Lead Joseph Misener: Manufacturing Manger, Mechanical Design Lead, CAD lead Agathiya Tharun: Project Manager, Chief Engineer		
Version:	3.0.0	
2.0.0		
1.0.4		
1.0.3		
1.0.2		
1.0.1		
1.0.0		
Last Updated:	Rewrote Key Resources Required and changed Project Scope to align with our progress. Rewrote Key Milestones, Business/Society Benefit, and Key Assumptions and Risks for conciseness. Added "Beth Hess" to the Key Resources box. Added "Edward Null" to the Key Resources box. Filled out every other box in the document besides the "Team Members & Roles". Inserted the vision statement. Started document by filling out the team members & roles and team/project information box.	
4/21/2024		
3/3/2024		
27/2024		
1/23/2024		
1/16/2024		
1/15/2024		
1/12/2024		

Figure A.1 Project Charter



Figure A.2 Team photo

B. Schedule

A project schedule was defined following a thorough overview of the scope and feasibility of the project. Along with extensive research, medical professionals were consulted to identify all steps along the process with regard to ensuring the project meets medical standards and has the potential to get approval from regulatory bodies. This process thus required the team to complete several tasks and assignments beyond the requirements of this course, including performing a Regulatory Environment Review. Work Breakdown Structures (WBS) for each phase were developed to highlight major milestones and overarching tasks. They can be seen chronologically below in **Figures B.1 through B.3**. A majority of the scheduling details have not changed since the CDR report. FDR fidelity, however, has significantly improved since then.

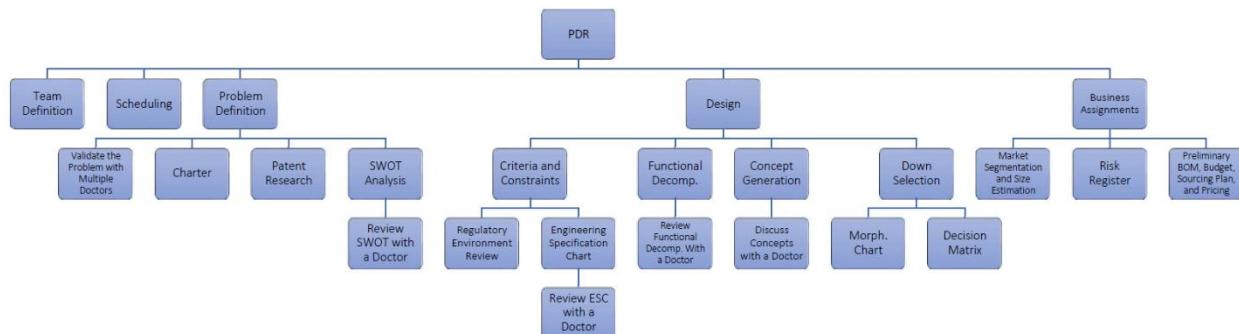


Figure B.1 WBS chart used for the PDR phase

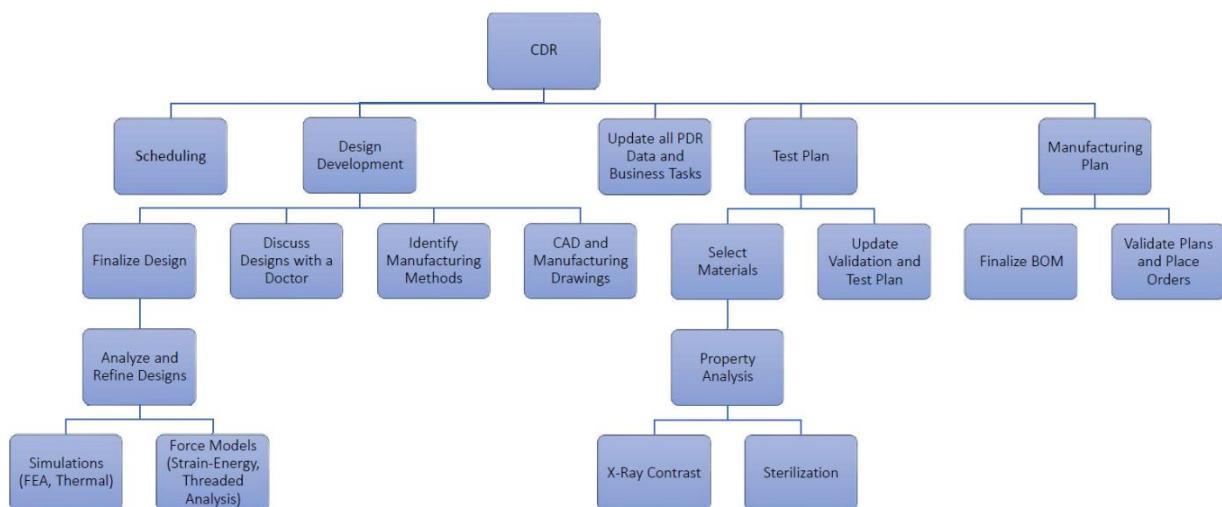
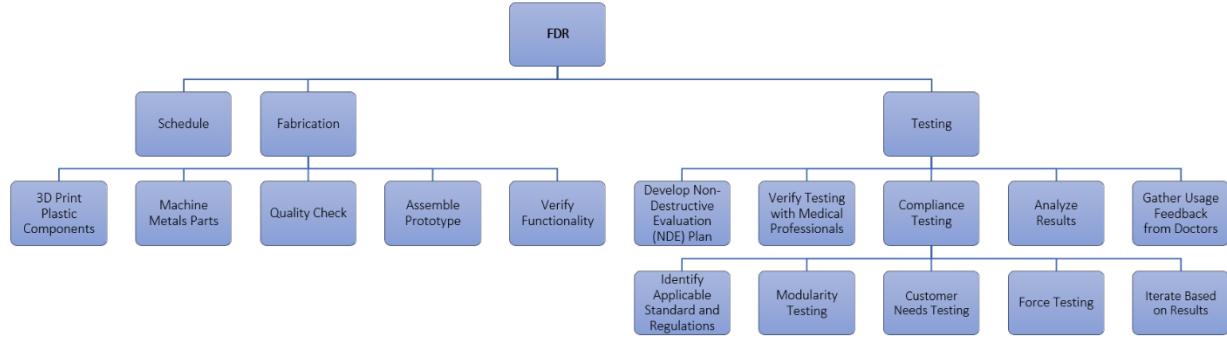


Figure B.2 WBS chart for the CDR phase

**Figure B.3** WBS chart for the FDR phase

Network Diagrams were also developed for each phase based on the WBS charts. These can be seen below in **Figures B.4 through B.6**.

**Figure B.4** Network Diagram used for the PDR phase

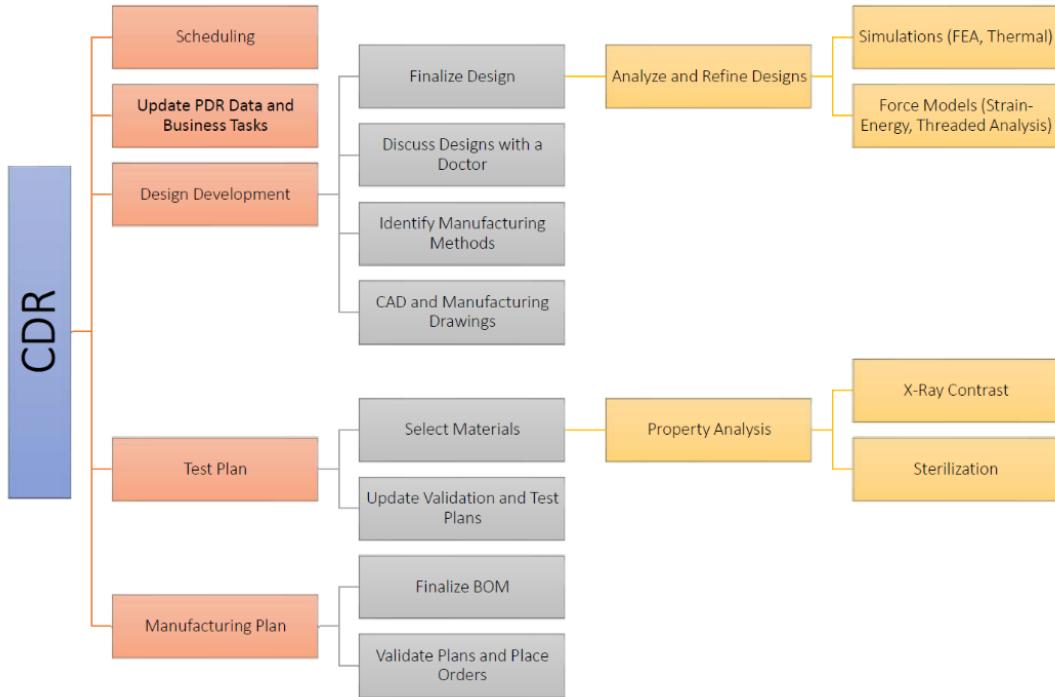


Figure B.5 Network Diagram for the CDR phase

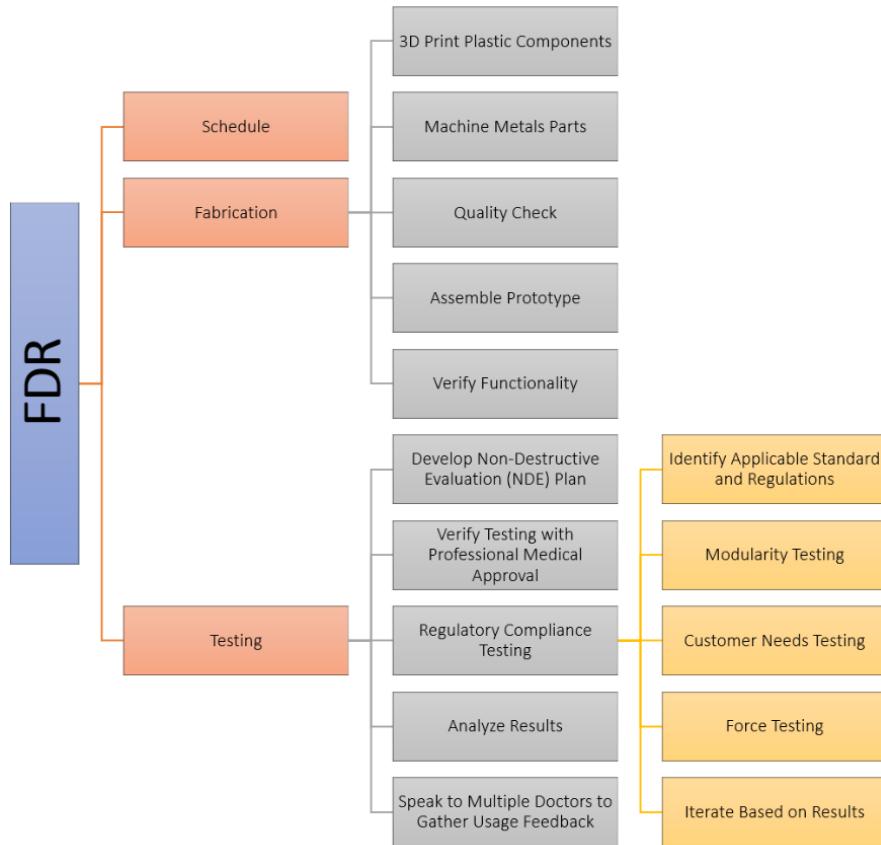


Figure B.6 Network Diagram for the FDR phase

In addition, a master checklist, off which the team's Gantt Chart is driven, was leveraged to have a complete project schedule. It is a live document where tasks will be edited with time, as can be seen in **Figure B.7**. Some tasks in this checklist, in addition to the “Independent Work” section, are tasks beyond the scope of the course rubric that the team plans to complete in order to guarantee project success.

PDR:	CDR:	FDR:
<p>Team Definition</p> <ul style="list-style-type: none"> Vision & Mission Team Roles Project/Team Name Company Name <p>Schedule</p> <ul style="list-style-type: none"> WBS Network Diagram Timelines <p>Problem Definition</p> <ul style="list-style-type: none"> Charter Problem Statement Patent Research (Google Patents) SWOT Analysis <ul style="list-style-type: none"> Talk with a Doctor About SWOT Customer Analysis Problem Verification <p>Design</p> <ul style="list-style-type: none"> Customer Requirements Constraint Identification Regulatory Environment Review Engineering Specifications Chart Validate ESC with a doctor Perform Functional Decomposition (FD) Validate FD with a Doctor Concept Generation Morphological Chart <ul style="list-style-type: none"> Develop Preliminary Designs and Sketches Discuss Brainstorming with Doctor(s) Perform Down Selection/Decision Matrix Refine Leading Design's Analysis Plan for CDR <ul style="list-style-type: none"> Identify Feasibility of Test Plans Preliminary BOM and Sourcing Plan <p>Business Assignments</p> <ul style="list-style-type: none"> Risk Register Preliminary Budget Value Proposition <ul style="list-style-type: none"> Product Cost/Value Preliminary Pricing Analysis Societal Benefit Gross Profit Market Segmentation Market Size Estimation Sales Quantity <p>Report Deliverables</p> <ul style="list-style-type: none"> Written Report Presentation Safety Review #1 	<p>Schedule</p> <ul style="list-style-type: none"> Update Roadmap Update Gantt Chart Update Charter <p>Prototype Development</p> <ul style="list-style-type: none"> Update Engineering Requirements and Constraints Finalize Design <ul style="list-style-type: none"> Validate Final Design with a Doctor Identify Suitable Manufacturers Create CAD Models <ul style="list-style-type: none"> Preliminary Prototype (Back Stabilizer) CAD Portal CAD Stylet CAD Denervator Create Assemblies <p>Model Analysis</p> <ul style="list-style-type: none"> Select Industry-Grade Materials X-ray Diffraction Biocompatibility Sterilization Perform Analyses <ul style="list-style-type: none"> Thermal and Finite Element Analysis (FEA) Stylet Tip and Nub Denervator Tip Handles/Bump Stop Back Stabilizer Hinge Point Portal and C-Ring Hand Calculations <ul style="list-style-type: none"> Clamping Friction on Portal Surface Fastener Analysis Interpret Results and Refine Models as Necessary Update Validation Plan <p>Manufacturing Plan</p> <ul style="list-style-type: none"> Update and Finalize BOM Discuss Mfg. Process with a Manufacturer <ul style="list-style-type: none"> Finalize Process Flowcharts as Needed Place Orders <p>Business Assignments</p> <ul style="list-style-type: none"> Update Risk Register FMEA Update Budget Update Value Proposition <ul style="list-style-type: none"> Product Cost/Value Sales Quantity Preliminary Pricing Analysis Societal Benefit Gross Profit Update Market Segmentation Update Market Size Estimation <p>Report Deliverables</p> <ul style="list-style-type: none"> Written Report Presentation Safety Review #2 	<p>Schedule</p> <ul style="list-style-type: none"> Update Roadmap Update Gantt Chart <p>Modeling</p> <ul style="list-style-type: none"> Update CAD <ul style="list-style-type: none"> Changes to Denervator Changes to Portal Back Stabilizer Ergonomic Improvements Changes to Stylet Create OP Sheets and Engineering DWGs <p>Fabrication</p> <ul style="list-style-type: none"> Fabricate Stylet at ME Machine Shop Fabricate Portal at BIDC Print All PP Components at BIDC Fabricate Denervator at ME Machine Shop Assemble Prototype Verify Basic Functionality and Iterate as Needed <p>Testing</p> <ul style="list-style-type: none"> Rerun FEA and Iterate Design Customer Needs Testing Force Testing Modularity Testing Customer Feedback <ul style="list-style-type: none"> Get Usage Feedback Verify Thoroughness of Testing Verify Feasibility of Procedure Analyze Test Results and Iterate as Needed <p>Business Assignments</p> <ul style="list-style-type: none"> Identify Standards Update BOM Update Budget Update all Other Business Sections as Needed <p>Report Deliverables</p> <ul style="list-style-type: none"> Written Report Presentation Safety Review #3 Mallott Poster Final Prototype Demo <p>Independent Work:</p> <ul style="list-style-type: none"> Regulatory Compliance Testing <ul style="list-style-type: none"> Perform Compliance Testing Biocompatibility Tests Sterilization and Cleanliness Tests Submit Documentation for Approval Market Analysis <ul style="list-style-type: none"> Industry Analysis PESTLE Positioning Strategy Detailed Pricing Analysis Sales Channels and Distribution Review Marketing Strategy Development Financial Projections

Figure B.7 Master project checklist/timeline

A detailed Gantt Chart for FDR with dates and deadlines can be seen below in **Figure B.8**. The team will continuously update all scheduling documents as more information becomes available. Scheduling details of the previous phases have not changed since the CDR report.

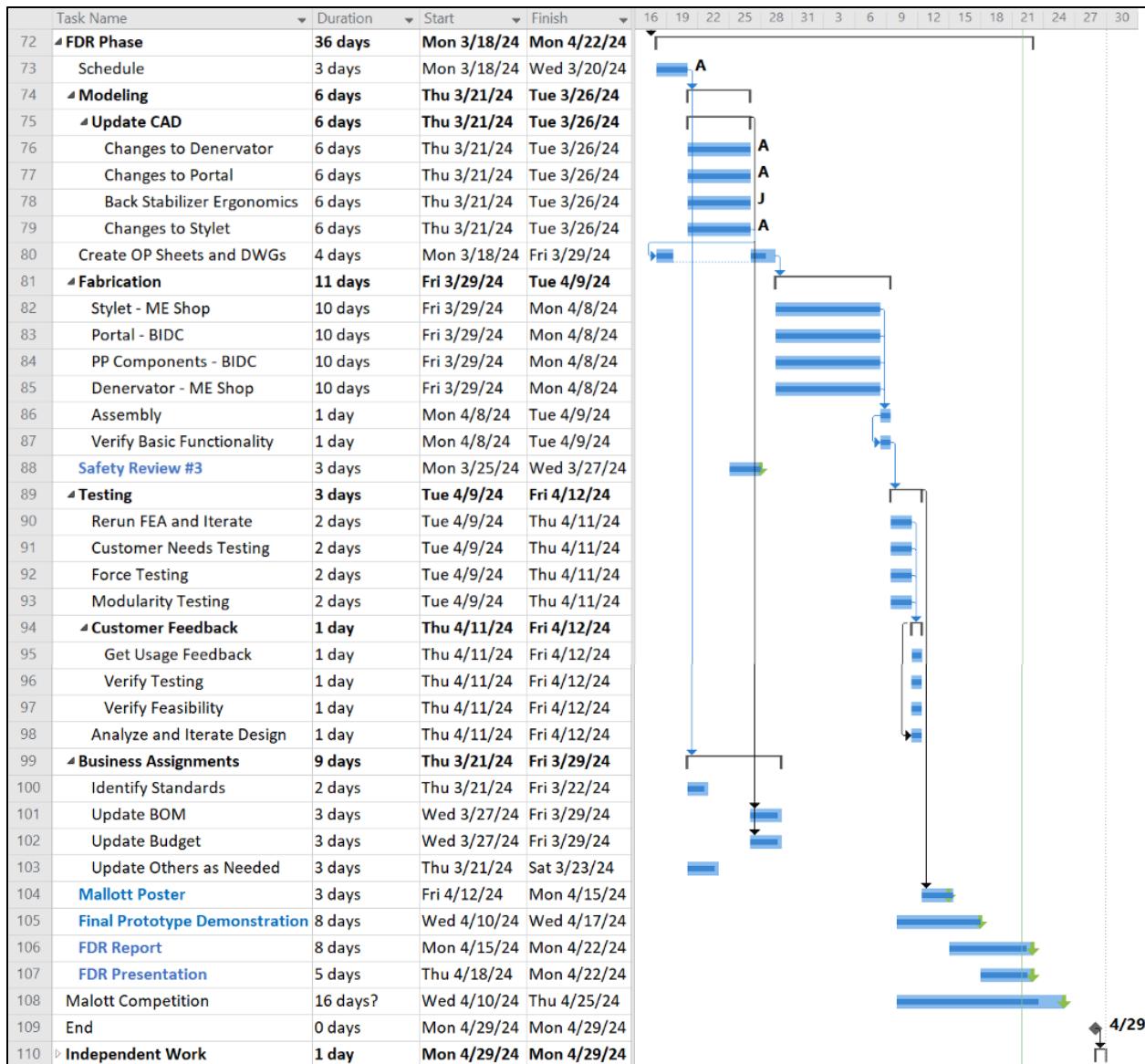


Figure B.8 FDR Gantt Chart

C. Preliminary Budget

The BOM and Sourcing Plan, as described in detail in **Appendix K**, describes an extensive list of all parts needed for a final prototype. It's important to note that all items in the BOM were sourced externally, considering the ME Machine Shop and other ME resources did not provide any materials required to manufacture the prototype. However, all parts needing to be 3D printed were done using free services through the Bechtel Innovation Design Center's Bambu Lab. The only incurred cost for 3D printing was from the purchase of polypropylene filament, which was implemented into the prototype due to its high mechanical strength. Like the 3D printing services, all parts needing to be manufactured via machinery were done using free services through the ME Machine Shop. The incurred costs for machining were from the purchase of grade 316L stainless steel stock, which was implemented into the prototype due to its high material strength and biocompatibility. These materials were all sourced via well-known suppliers to ensure high quality materials and quick lead times.

The materials purchased as a part of the Preliminary Budget (**Figure C.1**) ranged across five different purchase orders. Each purchase order required the creation of a Purchase Request Form (PRF), which had to be unique to one vendor. The PRF's were then sent to our professor to gain approval, before being sent to Purdue's engineering procurement center for placing. Each individual purchase order is grouped together in the completed orders section of the Preliminary Budget, with a blank row separating them.

PENDING ORDERS		COMPLETED ORDERS			
Item Description	How will the item be used for the project?	Vendor	Item Cost	Shipping Cost	Estimated Purchase date
Silicone Rubber Sheet	Rubber grips on the inside of the Back Stabilizer clamp	Amazon	\$ 8.99	\$ -	19-Mar-2024
3D Printer Adhesive Glue	Rub on the bed of 3D printers while printing polypropylene	Amazon	\$ 24.99	\$ -	19-Mar-2024
Polypropylene Filament	To print the 3D printed parts	Amazon	\$ 45.99	\$ -	19-Mar-2024
Dissolvable Filament	To print dissolvable supports for the 3D printed parts	Amazon	\$ 100.00	\$ -	19-Mar-2024
Packing Tape	Put on the printer bed for 3D printing PP filament adhesion (adhesive glue can be applied on top of tape)	Amazon	\$ 11.09	\$ -	19-Mar-2024
0.75" OD x 2' Cylindrical Shaft 316L Stainless Steel	Threaded adapter of the Stylet and threaded adapter of the Denervator	McMaster-Carr	\$ 62.47	\$ -	21-Mar-2024
Structural Epoxy	For securing threaded connections and other mates	McMaster-Carr	\$ 89.09	\$ -	21-Mar-2024
4mm OD x 3' Cylindrical Rod 316 Stainless Steel	Shaft of the Denervator	McMaster-Carr	\$ 30.77	\$ -	21-Mar-2024
McMaster-Carr Shipping	One time shipping cost for all items	McMaster-Carr	\$ -	\$ 18.71	21-Mar-2024
4.5mm OD x 24" Cylindrical Rod 316 Stainless Steel	Shaft of the Stylet	Alcobra Metals	\$ 21.54	\$ 31.90	21-Mar-2024
0.203" OD, 0.001" Wall Thickness, 3' Length 316 Stainless Steel Tube	Portal shaft for in-house manufacturing	McMaster-Carr	\$ 39.23	\$ -	25-Mar-2024
2mm OD 1' Length 316 Stainless Steel Shaft	Nub for the Stylet	McMaster-Carr	\$ 12.08	\$ -	25-Mar-2024
McMaster-Carr Shipping	One time shipping cost for all items	McMaster-Carr	\$ -	\$ 17.96	25-Mar-2024
Rubber Bands	Used to mimic the lumbar medial branch nerve for testing purposes	Walmart	\$ 1.18	\$ -	12-Apr-2024
Craft Knife	Used as a scalpel to make cuts in the pork shoulder	Walmart	\$ 3.76	\$ -	12-Apr-2024
Disposable Gloves	Used to protect skin from handling raw meat	Walmart	\$ 14.87	\$ -	12-Apr-2024
Pork Shoulder Ribs	Used to mimic the human body for testing purposes	Walmart	\$ 18.53	\$ -	12-Apr-2024
Chicken Drumsticks	The bone will be rasped with the Denervator to validate knurl sharpness	Walmart	\$ 3.88	\$ -	12-Apr-2024
TOTAL			\$ 478.54	\$ 68.57	\$ 547.11
GRAND TOTAL			\$ 478.54	\$ 68.57	\$ 547.11

Figure C.1 Preliminary Budget

As expected, the team made significant changes to the Preliminary Budget between the CDR and FDR phases. The most obvious update was that all purchase orders were placed and delivered, which allowed the team to move them from pending orders to completed orders. Another overarching update was that the overall budget was reduced from \$556.55 to \$547.11 between the CDR and FDR phases. Though this wasn't a significant reduction in cost, it demonstrates that the items within budget were changed between the two phases. A final overarching note is that the purchase orders were all placed a lot later than expected. This happened due to issues in the manufacturing process. The team did pre-manufacturing on aluminum stock prior to buying materials, which helped them uncover many design flaws. The team therefore underwent critical CAD updates, pushing back the purchasing of materials and manufacturing of the prototype.

Along with high level updates, it's important to discuss specific updates. Directly a consequence of the discussed pre-manufacturing, the team discovered that large stock wobbled too much when lathing down to considerably small diameters. The team had to pivot their manufacturing efforts by sourcing pre-sized stock online. By purchasing pre-sized stock, they only had to manufacture the features onto the tools. For example, the 4.5mm stock from Alcobia Metals was purchased as the Stylet body, such that the team only had to sharpen the tip and drill a blind hole for the Stylet Nub.

Another update with regards to manufacturing the tools is the pivot away from using any third-part manufacturing services. The team initially planned on using a third-party manufacturing service, called Xometry, to produce the unique geometries and near-micro-scale sizes of the Portal. However, after the purchase order was submitted to Xometry, they informed the team that they were unable to manufacture the Portal. This led to an updated design for the Portal, which is further discussed in **Appendix H**. This also forced the team to source new stock for the Portal, which is reflected by the 0.203in outer diameter by 0.01in wall thickness stock purchased from McMaster-Carr.

A third update to the Preliminary Budget is with regards to the 3D printing methods. The team discovered that the P1S printers in the Bambu Lab of the Bechtel Innovation Design Center (BIDC) are the only 3D printers capable of printing polypropylene. However, the resources required to print polypropylene on these printers were not directly available at the BIDC. For this fact, the team had to source proper dissolvable filament and bed adhesion to facilitate the 3D printing process. This is reflected in the entire Amazon purchase order, as seen in **Figure C.1**.

The next minor update that was made to the Preliminary Budget during the FDR phase was the removal of threaded inserts and assorted fasteners. After completing the design of the prototype, the team came to the realization that these parts were all unnecessary. By getting rid of these parts, the team was able to save some money.

The final update that was made to the Preliminary Budget was the addition of testing materials. When developing the original budget, the team only accounted for the materials needed to manufacture the prototype. As the team entered the validation testing phase, they realized that they didn't have the proper testing materials and equipment, nor had they previously looked into it. Therefore, the team made a purchase at Walmart to satisfy their validating testing, as seen in the Preliminary Budget.

Along with these updates and all the part costs, it's important to note that the Preliminary Budget also reflects service costs from manufacturers. These service costs are incurred through shipping, which made up about 13% of the spent budget. Overall, only about 50% of the team's budget was expended, which verified the feasibility of the prototype. The rest of the budget offered the team protection for handling unexpected issues, mitigating risks, and optimizing the design to a higher and medical-grade quality. An example of this protection is when the team had to dip into the excess budget when they realized they needed testing materials. The team also included medical-grade materials for manufacturing, consisting of grade 316L stainless steel, polypropylene filament, and structural epoxy. Furthermore, the team took into consideration comfort and ease of use with regards to their design budget. Finally, the team continuously made updates to this file as new information was acquired, as the project develops, and as purchase orders were placed and delivered.

D. Risk Register

It's important to explain what the Risk Register is, how the team approached it, and its role in the scope of the project. The Risk Register is a project management tool used to document any potential risk across all phases (PDR, CDR, and FDR) and in the entire scope of the project. These risks were identified at different levels, such as failing to meet engineering specifications versus grade 316L stainless steel failing sterilization testing. These risks were also identified across different focuses, ranging from dangerous manufacturing processes to misaligned team roles to insurance of no nerve regrowth. Because of its comprehensiveness, it is important to note that the Risk Register is considered a live document. It is not static; the Risk Register evolves with the project, incorporating new risks and updating mitigation strategies as necessary. This is especially important for high probability and high impact risks, which require more frequent attention than auxiliary risks. Being a live document allows the Risk Register to be both a guide for proactive risk management and a communication tool to inform all stakeholders of potential risks and mitigation plans. The Risk Register document has been attached to this report for further reference.

To understand the Risk Register, it's important to know how the team evaluated each risk and created the subsequent entry. The layout for the columns is detailed in **Figures D.1 and D.2**. The team began for each risk filling in who raises the risk and on what date it is raised. They then identified the risk and effect using an if-then method: the clause following "if" is what the risk is, and the clause following "then" is the effect that the risk will have on the project. Each risk is then assigned to a team member, where the person assigned to the risk is who will develop a mitigation strategy and will monitor the risk throughout the project. Each risk was then assessed by the team (according to their best judgment) via its probability and impact on a scale from L (low) to H (high). A low probability is defined as something happening less than 10% of the time, a high probability is defined as something happening more than 25% of the time, and a medium probability is anything in between. Low, medium, and high impacts are defined relative to each risk, considering the impact is defined different depending on the risk. These probability and impact rankings will calculate a current risk score (CRS), which communicates the magnitude of the risk. With each risk defined, the risk owner then developed a strategy to handle each of their assigned risks. They could choose to either accept the risk or mitigate it, where the

team put an emphasis on mitigating all risks as best as possible. Based on the strategy, the risk owner either described the reason for accepting the strategy or described the mitigation strategy in the next column. The risk owner then reevaluated the probability and impact of the risk after treatment, using the same scale and judgment as before. An important thing to note regarding the reevaluated rankings is that the team felt it nearly impossible to reduce the impact ranking. This is because, in almost all cases, the risk doesn't change, rather the way to manage it changes. Because of this, the Risk Register attached to this report rarely depicts a risk having a reduced impact. These updated rankings are referred to as the residual effects, and therefore a residual risk score (RRS) is calculated from the residual probability and impact in the same manner that the CRS was calculated. Finally for each risk, any comments are listed as well as the last time that anything in the row was updated.

1. IDENTIFICATION							2. CURRENT ASSESSMENT		
	DATE RAISEL	CAUSE (IF...)	EFFECT (THEN...)	RISK OWNER	P	I	Current Risk-Score		
' of	When the risk was first identified	If uncertain event occurs due to (or because of) specified root cause(s). Tip: ask "why, why, why..." to drill down to root cause	then the ultimate impact to our objectives are. Tip: ask "so what, so what, ..."	Single named owner	Probability of the event occurring	Worst' impact	Calculated risk score		

Figure D.1 Left half of the Risk Register spreadsheet

3. TREATMENT			4. RESIDUAL ASSESSMENT			5. REVIEW, CONTROL, COMMUNICATE		
STRATEG	TREATMENT DESCRIPTION	F	I	Residual Risk-Score	Commentary	Last Update		
Select overall approach to treatment (Mitigate or Accept)	Summary of the treatment responses (actions, controls, fallbacks) that treat the risk.	Probability of the event occurring	Worst' impact	Calculated risk score	Any additional notes, comments or actions	Enter the last review or update date for the risk		

Figure D.2 Right half of the Risk Register spreadsheet

During the PDR and CDR phases, the team put a strong effort towards following the defined treatment plans for the identified risks. For the sake of the FDR phase, the Risk Register was reviewed and updated accordingly before any new risks were identified. After going through each existing risk, the team did not feel that it was necessary to add new treatment methods or update any risk scores, as they believed the Risk Register to have been comprehensive through the CDR phase. Therefore, the team focused on updating the commentary for all existing risks with updated status, while also changing the last updated date as necessary. After finishing this,

the team then identified and appended six new risks to the Risk Register. These risks, as well as all specific risks for the FDR phase, can be seen in **Figures D.3 through D.5**. The new risks will be explicitly discussed to provide further context on how they impact the project.

The first new risk identified was specific to the manufacturing process of the Stylet and Denervator. Due to the size of the medical tools being developed, the team needed specifically small drill bit sizes. Considering how small these drill bits would be, the team was not sure whether any Purdue machine shop would have drill bits available in these sizes. If these drill bits were to not be available to the team, then the holes in the Denervator and Stylet could not be manufactured (or, if they could be manufactured, it would have to be at a different size). The team decided to mitigate this by going to the machine shop to scope out the available drill bit sizes and updating their CAD accordingly. This reduced the probability of the risk occurring almost completely, as the team would have designed their tools to the available manufacturing equipment.

The next new risk that was identified was if the Stylet or Denervator stock wobbles too much during manufacturing. This is a concern because the tools are designed to be much thinner than they will be long, and lateral lathing does not favor thin-yet-long stock. If the stock were to wobble too much during lathing, the manufacturing would produce very inaccurate and low-quality results. Therefore, to mitigate this risk, the team will have one member practice manufacturing the tools using excess stock. If there is wobbling during this process, the team will pivot their manufacturing methods to source a pre-manufactured, high quality, and tight tolerance stock online. This would remove the need for any lateral lathing, and significantly reduce the probability of the risk. The reduced probability would significantly lower the CRS by 8 points to the RRS.

The third new risk that was identified was regarding the identification of risks during validation testing. Specifically, if risks due to validation testing (e.g. puncturing, cutting, X-ray radiation, and foodborne illness) are not identified, and mitigation plans are not set forth before testing, then serious health hazards could occur during testing. This risk is naturally mitigated through the deliverables of ME 463: the team will write up Safety Review 3, which entails identifying all risks associated with each test. Within Safety Review 3, the team will also establish safety plans for each test. Finally, the team will sit down and discuss the testing plans, Safety Review 3, and the prototype with Mike Sherwood prior to carrying out the tests. This

again reduced the probability of any risk occurring, dropping the CRS down to a lower RRS by 4 points.

Another one of the new risks identified specifically regarded the 3D printing process that the team planned on going through to manufacture their polypropylene parts. The team was concerned that the dissolvable or polypropylene filaments may not be compatible with the P1S printers in the Bechtel Innovation Design Center, and similarly, that the Magigoo or tape would not work effectively as bed adhesion. If these concerns were to come to fruition, this would stand as a roadblock in the manufacturing process of the Back Stabilizer, Stylet handle, Denervator handle, Portal sleeve, and Portal c-ring. Therefore, this risk poses a huge concern for the team. Despite the concern, it is very unlikely that this risk will occur, due to the extensive research and guidance given to the team with regards to printing these materials. To treat the risk and reduce its impact, the team decided to take an acceptance approach: if the team's printing efforts on the P1S printers were to fail, they would pivot their printing efforts to the 3D print lab in the Mechanical Engineering building. This would of course mean that the team would be using PLA instead of polypropylene, which is a notable change in materials. If this were to happen, the team planned on purchasing a sterilizable and medically graded coating for the PLA. This treatment method brought much peace of mind to the team, considering the abundant amount of 3D printing resources across Purdue's campus.

The fifth new risk identified was if the outsourcing manufacturing company could not manufacture the desired tools. The team planned on having the Portal completely manufactured through an outsourcing company named Xometry. However, if Xometry is not able to manufacture the Portal, then the team will not have a prototype of this tool. As with the previously discussed risk, the team approached this with an acceptance strategy. If Xometry is not able to manufacture the Portal, the team would then make necessary changes to the CAD such that the tool could be manufactured in-house. This would still serve as a challenge; however, it would significantly reduce the risk of not having a prototype of the Portal.

The last newly identified risk took a higher-level perspective than the other ones. The team realized that, if the medical tools are not designed for mass manufacturing, then their design cannot be brought directly to industry. Considering the team wants to take their design to industry after the span of ME 463, this is a very important issue for them. To handle this risk, the team developed a straightforward mitigation plan. They will perform intense research into mass

manufacturing processes, and the CAD will be designed according to the findings. This should help ensure that the medical tools are designed in a scalable manner, reducing the CRS 4 points to the RRS. The rest of the specific risks for the FDR phase can be found in the Risk Register document attached to this report.

1. IDENTIFICATION				2. CURRENT ASSESSMENT			3. TREATMENT		4. RESIDUAL ASSESSMENT		5. REVIEW, CONTROL, COMMUNICATE				
Raised	Date Rec'd.	Cause (If...)	Effect (Then...)	Risk Owner	Probability of the event occurring	Current Risk Score	Strategy	Treatment Description	Residual Risk Score	Commentary	Last Update				
The originator of the risk	When their risk was first identified	"Uncertain event occurs due to (or because of) specific root cause(s)." Tip: ask "why, why, why..." to drill down to root cause	then the ultimate impact to our objectives are. Tip: ask "so what; so what; ..."	Single named owner	Prediction of the event occurring	Worst Impact	Calculated risk score	Select overall approach to treatment (Mitigate or Accept)	Summary of the treatment responses (actions, controls, fallbacks) that treat the risk.	Probability of the event occurring	Worst Impact	Calculated risk score	Enter the last review or update date for this risk		
12	Jacob Whitehouse	23-Feb-24	Purdue University does not offer the necessary machines and/or equipment	The team will not be able to manufacture their prototype	Joe Misnar	L	H	11	Mitigate	The team will look into creating a macro-scale prototype with the available equipment as well as outsource the medical tools which are not manufacturable at Purdue	L	L	1	Purdue probably doesn't have the medical grade equipment. In fact, the team has consult with Darrin Wilcoxson and Mike Sheehan, they will recommend manufacturing methods that specifically work with all of the available equipment at Purdue. The team has also gone into the machine shop and found that the equipment there is not suitable. The CAD was updated accordingly so that it could be manufactured with the available equipment. Before final manufacturing, the team also practiced printing the most important features on excess stock to validate the manufacturability.	
14	Jacob Whitehouse	23-Feb-24	The team is not able to afford medical grade materials (e.g. S3510L, polypropylene, or silicone)	The team will not be able to test the temperature and pressure (sterilization testing) resistance of the medical tools	Jacob Whitehouse	M	M	10	Mitigate	Proper medical grade materials will be assigned to the CAD models and throughout analysis to get valid results. Also, the first prototypes will be manufactured out of similar yet affordable materials	L	M	8	The materials themselves (S3510L, polypropylene, and silicone) are not practically expensive. It's more a question of how expensive outsourcing would be. The team will need to consider the cost of shipping and the expedited price to choosing a final design material. The team has determined that outsourcing complete manufacturing is not feasible, although it is well worth it for the first few prototypes. The team will keep some materials in stock. The team also identified affordable yet high quality polypropylene 3D printing filament as well as silicone pads. These costs can be analyzed in the BOM, and the team will keep these in mind.	20-Mar-24
15	Jacob Whitehouse	23-Feb-24	Materials and orders take too long to be shipped to the team	The team will face a roadblock in the manufacturing process of their prototyped part	Jacob Whitehouse	M	M	10	Mitigate	The team will search and confirm lead times with the vendor to ensure that they get their orders in a timely manner. The team will also have a back up vendor for each order	M	L	5	This will be a huge issue as the team run into it. Lead times must be identified and accounted for by all members of the team, considering it impacts manufacturing and testing. The team source all but 1 material from one vendor, which has been causing significant issues with lead times. The orders were placed about two weeks before manufacturing was expected to begin, and the materials were received within a week. This gave the team a short time to test and iterate on the design.	20-Mar-24
19	Jacob Whitehouse	23-Feb-24	All of the 3D printers in the ME shop are being used when the team is trying to manufacture a part	The team will not be able to manufacture their part	Joe Misnar	M	H	15	Mitigate	The team will identify other possible places to 3D print, such as Joe's research lab, Joe's neighbor, and other Purdue University buildings	L	M	8	There it would be a huge issue if 3D printers are unavailable, there are many alternate 3D printing sources that the team has access too. Joe has access to many at work. Joe has a neighbor with a 3D printer, and there are many other options available. The team will have to find a solution to this. It has been decided that the team will be printing on the 3D printers in the lab in the General Innovation Design Center. Therefore, the team will have to wait for the printers to come online, which will significantly reduce this risk of occurring.	20-Mar-24
20	Cameron Mostouf	8-Feb-24	There are technical issues with the manufacturing process (3D printing and/or machining)	The medical tools will not be produced according to their design and desired quality	Joe Misnar	M	M	10	Mitigate	The team will identify different places to perform machining and 3D printing (e.g. the General Innovation Center and Joe's research lab).	L	M	5	Jacob updated the wording for this risk to make it more applicable to the team's specific project. Expect these issues to arise, the team will just have to be prepared to handle them. The team will also start manufacturing 2 units in advance of the deadline.	23-Mar-24
21	Jacob Whitehouse	23-Feb-24	Testing destroys the medical tools	It will be expensive and time consuming to manufacture multiple quantities of the medical tools	Jacob Whitehouse	M	H	15	Mitigate	All testing will be nondestructive, such that it can be considered nondestructive evaluation (NDE) and destructive testing (DT).	L	L	1	Rather than repeatedly destroying prototypes (which would cost a lot of money and time), the team is making it a priority to create an NDE plan.	23-Feb-24
22	Jacob Whitehouse	23-Feb-24	The materials fail sterilization testing (in other words, they melt during temperature testing)	The materials will not be considered medical grade	Jacob Whitehouse	L	H	11	Accept	Considering material property analysis will have already been performed, this should not happen. In the case that it does, then another material will be chosen from the material property analysis.	L	M	0	There is no reason that the materials fail sterilization testing since industry-used medical materials will be chosen for the prototypes after extensive research.	23-Feb-24

Figure D.3 First section of specific risks for the FDR phase

1. IDENTIFICATION				2. CURRENT ASSESSMENT			3. TREATMENT			4. RESIDUAL ASSESSMENT			5. REVIEW, CONTROL, COMMUNICATE			
Raised	Date Raised	Cause (If...)	Effect (Then...)	Risk Owner	Impact	Current Risk Score	Strategy	Treatment Description	Impact	Residual Risk Score	Commentary	Last Update				
The originator of the risk	When the risk was first identified	If the uncertain event occurs due to (or because of) specified root cause(s). Tip: ask "why? why? to drill down to root cause.	then the ultimate impact to our objectives are. Tip: ask "so what; so what; ..."	Single named owner	Probability of the event occurring	Worst Impact	Calculated risk score	Select overall approach to treatment (Mitigate or Accept)	Summary of the treatment responses (actions, controls, fallbacks) that treat the risk	Probability of the event occurring	Worst Impact	Calculated risk score	Any additional notes, comments or actions			
23	Jacob Whitehouse	23-Feb-24	There is no medical equipment available for testing (e.g. dummies)	Testing of the medical tools will not be possible	Cameron Mostoufi	H	M	14	Mitigate	Alternative approaches will be taken to simulate the skin, flesh, and muscle (e.g. chicken breasts)	L	M	5	It may be difficult to get medical equipment to perform testing on the medical devices. Typically, cadavers or clinical testing is done. However, for the scope of senior design, the team does not have access to these. Therefore, the team will have to use alternative approaches to test the medical devices. Medical dummies, however, it may be hard to get the medical dummies to Purdue. Therefore, if the team cannot get medical dummies, they will carry-a-ring-a pig's shoulder blade. This will be used to simulate the skin and muscle layers to simulate the human body with pork shoulder during testing, as it is the closest simulation of the skin/fat/muscle layers that exist within the human body according to doctors).		
24	Jacob Whitehouse	23-Feb-24	Purdue University does not offer the necessary testing sensors (e.g. force gauges)	Force testing of the medical tools will not be possible	Jacob Whitehouse	L	M	6	Mitigate	The team will account part of the budget to testing materials and sensors.	L	L	1	Purdue does have force gauges, the team just has to get access to them.		
25	Jacob Whitehouse	23-Feb-24	Manufacturing and testing are not performed at least a week before the FDR	It will not be possible to iterate on the final prototypes	Agathyra Tharun	M	M	10	Mitigate	Hard deadlines will be incorporated into the schedule regarding the manufacturing and testing	L	M	8	Time is a huge constraint. Manufacturing (and placing orders for outsourcing) can take up to a week long. Therefore, the team needs to have enough time to iterate on their prototypes after validation tests have been performed.		
26	Jacob Whitehouse	23-Feb-24	Dangerous manufacturing processes are performed and/or there are dangerous features to the prototypes	The team can get hurt	Cameron Mostoufi	M	M	10	Mitigate	Proper machine handling should be discussed with the ME faculty and proper tool handling should be discussed within the team and with doctors	M	L	5	There are many potential risks to the team members. One of the main risks is the team actually getting hurt. The team is very aware of all safety regulations and will try to stick to them. The team has also identified all potential risks and has created a risk matrix. The team has also created a risk mitigation plan. The team discussed these risks and mitigation plans with Mike Sherwood, as long as the team follows the set forth plans, there will be no major issues.		
27	Jacob Whitehouse	23-Feb-24	The team pursues manufacturing a to-scale prototype	The design features might be too small to manufacture (at least, in a cost effective way)	Joe Misner	L	H	11	Mitigate	The team will use the drawings and CAD models to discuss with ME faculty about the viability of manufacturing. They will also get quotes from external manufacturing sources	L	L	1	It is important for the team to develop a to-scale prototype. With the current design, the team thinks that it is difficult to manufacture the Danevero and Deltavent. Therefore, the team has decided to outsource the manufacturing to an order outsourced manufacturing services. However, it was discovered that the outsourcing company (Kometrix) cannot manufacture the tools. Therefore, the team has decided to outsource the parts to Mohlase-Cair and Albra Metals. The team also simplified the CAD so that in-house manufacturing of the to-scale prototype will be more viable.		
30	Jacob Whitehouse	23-Feb-24	The prototype does not meet the engineering specifications	The prototype will not meet the customers needs	Jacob Whitehouse	M	H	15	Mitigate	First off, the team will discuss with multiple doctors to understand their customer needs. Then, the team will conduct research to create engineering specifications for these needs. Finally, the team will perform appropriate testing to validate each engineering specification.	M	M	10	The analysis and testing plan currently in place address each customer need. However, it is unknown what each customer need is based on customer testing. A to-scale prototype will be more viable.		
31	Jacob Whitehouse	23-Feb-24	The team is not able to test engineering specifications (e.g. sterilization or ergonomics)	The prototype will not meet the customers needs	Jacob Whitehouse	M	M	10	Mitigate	The team will discuss with professors and ME faculty (e.g. Mike Sherwood) about how to best test and validate the engineering specifications.	M	L	9	The team has refined the ESC to make each customer need testable. This was done through input from Professor Capelli and Mike Sherwood.		
32	Cameron Mostoufi	6-Feb-24	The prototype fails during testing	The prototype will not meet the customers needs	Jacob Whitehouse	M	H	15	Mitigate	Setup for each test will be performed prior to the testing. If the prototype passes the analysis, then the team have to analyze the results and redesign, manufacture a new prototype, and test again.	L	H	11	Jacob updated the wording for this risk to make it more applicable to the team's specific project. If the analysis has been performed and failure still happens, the team just has to accept this. Mitigation will have happened as best as possible.		

Figure D.4 Second section of specific risks for the FDR phase

1. IDENTIFICATION					2. CURRENT ASSESSMENT			3. TREATMENT			4. RESIDUAL ASSESSMENT			5. REVIEW, CONTROL, COMMUNICATE		
Raised	Date Raised	Cause (If...)	Effect (Then...)		Risk Owner	I	V	Current R Score	Strategy	Treatment Description		V	Residual R Score	Commentary	Last Update	
The originator of the risk (When the risk was first identified)	If uncertain event occurs due to (or because of) specific root cause(s) Tip: ask "Why, why, ...?" drill down to root cause	then the ultimate impact to our objectives are: Tip: ask "to what, as what, ...?"	Single named owner	Probability of the event occurring	Worst Impact	Calculated risk score	Select overall approach to treatment (Mitigate or Accept)	Summary of the treatment responses (actions, controls, fallbacks) that treat the risk.		Provide mitigation plan for the worst impact	Calculated risk score	Any additional notes, comments or actions		Enter the last review or update date for the risk		
33	Jacob Whitehouse	29-Mar-24	There are not appropriate drill sizes	Desired holes cannot be cut into the Stylet and Denivator	Agathiya Tharun	M	M	10	Mitigate	Before final manufacturing, at least one member of the team (ideally, the person who will be doing the manufacturing) will go down to the ME Machine Shop and test the manufacturing the tool with excess stock. If the stock wobbles too much, then the team will find a better tool, reworking, high quality, tight tolerance stock online for simpler manufacturing.		L	M	8	This risk has been identified because the team has already faced these challenges and has been constantly updating their CAD to support the available equipment in the ME Machine Shop.	29-Mar-24
34	Jacob Whitehouse	29-Mar-24	The stock wobbles too much during manufacturing	The manufacturing will be very inaccurate and low quality	Agathiya Tharun	H	M	14	Mitigate	Before final manufacturing, at least one member of the team (ideally, the person who will be doing the manufacturing) will go down to the ME Machine Shop and test the manufacturing the tool with excess stock. If the stock wobbles too much, then the team will find a better tool, reworking, high quality, tight tolerance stock online for simpler manufacturing.		L	M	8	This risk has been identified because the team has already faced these challenges and has been ordering materials based on the results of preliminary manufacturing tests	29-Mar-24
35	Jacob Whitehouse	29-Mar-24	Risks due to validation testing (e.g. puncturing, cutting, X-ray radiation, and foodborne illness) are not identified and mitigation plans are not put in place before testing	Serious health hazards could occur during testing	Jacob Whitehouse	M	M	10	Mitigate	Perform the safety review 3, which entails identifying potential risks and mitigating them. This also involves developing a mitigation plan for each test. Finally, sit down and discuss the health and safety review plan with Mike Shenvi.		L	M	8	It is important for the team to keep their safety as the most important priority throughout this entire process. Nobody should put their health at risk.	29-Mar-24
36	Jacob Whitehouse	29-Mar-24	Either the dissolvable/polypropylene filaments are not compatible with the F115 printer or the filament does not work as bed adhesion	The handles and Portal sleeve will not be manufactured	Agathiya Tharun	L	M	8	Accept	Manufacture the plastic components with PLA in the ME 3D print lab, and find a sterilizable and medically-grade coating for the PLA.		L	L	1	The team has researched into the filaments and has talked to the BDC, so this is not an issue. However, if it does become an issue, the team can always use PLA-C as a fine placeholder, as long as medical-grade coating can be sourced.	29-Mar-24
37	Jacob Whitehouse	29-Mar-24	Oversourcing companies cannot manufacture our tools	Refined CAD cannot be produced on the prototype	Joe Miserac	M	M	10	Accept	Change the CAD to be manufacturable in-house. This will involve consulting with manufacturing staff regarding how to change the design.		M	L	8	This risk has been identified due to Xometry not being able to manufacture the Portal.	29-Mar-24
38	Jacob Whitehouse	29-Mar-24	The medical tools are not designed for mass manufacturing	The design cannot be brought directly to industry	Agathiya Tharun	H	L	9	Mitigate	Intense research will be done regarding mass manufacturing processes, and the CAD will be designed according to these manufacturing processes.		M	L	8	It is important for the team to develop the tools for mass production, considering they want to bring these tools to industry.	29-Mar-24

Figure D.5 Third section of specific risks for the FDR phase

Appendix II – Business/Marketing

E. Market Analysis

E.1 Market Segmentation

The following information regarding the market segmentation has not undergone significant changes since the critical design review.

Focusing on the United States due to its regulatory framework governed by the FDA, the market segmentation strategy in question targets specific groups of patients and doctors based on distinct characteristics. Patients who are 18 years or older and belong to the middle and upper socioeconomic strata are identified as the primary market, chosen for their legal ability to give medical consent and their financial capacity to afford healthcare services. These individuals, suffering from facet-induced lower back pain and having responded positively to medial branch blockers, demonstrate a receptivity to medical advice and a preference for enduring solutions as opposed to repetitive treatments. Their comfort with undergoing surgical interventions for a lasting resolution to their pain identifies them as ideal candidates. From the perspective of healthcare providers, the segmentation encompasses physiatrists, specialists in physical medicine and rehabilitation (PM&R), anesthesiologists, and interventional radiologists throughout the United States. These medical professionals are characterized by their progressive outlook, enthusiasm for adopting new practices, and leadership in introducing innovative treatments within their fields. They prioritize minimally invasive, low-risk procedures that yield definitive results, which resonates with the preferences of the patient segment for permanent solutions. Their behavioral inclinations towards brand loyalty and a propensity to repurchase effective medical tools render them crucial to the adoption and success of novel medical procedures. This strategic approach ensures a focused effort, considering the specific needs and behaviors of both patients and doctors within the regulatory boundaries of the U.S. healthcare system, with the objective of facilitating the efficient introduction and adoption of innovative medical solutions.

E.2 Market Size Estimation

The following information regarding the market size estimation has been reviewed since the CDR phase. The team felt that it was unnecessary to make any changes to the existing market size calculations, although they made updates to present their market size in a more digestible form. Namely, the team converted their market size from people to dollars, all while defining their total addressable market (TAM), their serviceable addressable market (SAM), and their serviceable obtainable market (SOM). These developments are detailed in **Subsection E.2.3**.

To better understand the market at hand, the team performed a high-level analysis of the target and general demographics the product would cater to. The target demographic would include everyone who currently seeks out the competitor procedure, RF Ablation, as it would share the most similarities in demographic characteristics and would prefer a permanent solution. The general demographic includes everyone who suffers from chronic facet-induced lower back pain (LBP). The results of these market size estimations would inform various decisions such as pricing, production quantity, and impact. Due to limited available research, studies, and census data, the market size values calculated represent ballpark estimates and are only used to gauge an understanding of the demographics at hand. To arrive at such values, various educated assumptions and data-backed extrapolations were made. Since this product is to face regulatory review, the team decided it was best to begin with domestic approvals and constrain the market to only being within the US.

E.2.1 General Demographic Market Size Calculation

- 1) The total US population as of February 4, 2024:
 - 336,019,747⁵⁴ people
- 2) Number of people covered by some medical insurance in the US as of 2022:
 - 92%¹⁶ of 336,019,747 = 309,474,187 people
 - Note that this statistic is a conservative estimate and assumes that the percentage growth trend did not decline after 2022.
- 3) Number of people who suffer from chronic LBP worldwide as of December 2023:
 - 23%⁶ of 309,474,187 = 71,179,063 people
 - Note that this statistic assumes that the worldwide statistic can, with negligible error, be applied to Americans covered under some health insurance.

4) Number of people who suffer from facet-induced chronic LBP as of 2021:

- $15\% - 45\%^{35}$ of 71,179,063 = 10,676,859 - 32,030,578 people
- Note that it was assumed that this percentage can be applied to health-insured Americans experiencing chronic facet-induced lower back pain in 2024.

Based on this calculation, the team can predict that approximately 10-30 million people in the US would fall within the market's general demographic. To specify this number further, a target demographic calculation was also performed, starting with the number of health-insured Americans.

E.2.2 Target Demographic Market Size Calculation

1) Number of people covered by some medical insurance in the US as of 2022:

- 309,474,187 people

2) Number of people who seek RF Ablation treatment:

- 0.118% of 309,474,187 = 365,179 people/year
- Assuming a constant 9.7%⁴⁸ growth trend, it was extrapolated that there are 237 sessions performed annually per 100,000 insured members. A very conservative estimate was also made that a patient would undergo two RF Ablation sessions a year: $237/2 = 118$ annual patients per 100,000 enrollees = 0.118%.
- Note that it was assumed that the RF Ablation market size most closely resembled the team's potential market size. The demographics of competitor procedures, such as endoscopic rhizotomy, were ignored under the assumption that a negligible number of people would have sought out such invasive procedures without starting with RF Ablation first.

3) Number of people who would prefer a permanent solution alternative:

- 120% of 365,179 = 438,214 people/year
- Note that there exists limited data to support this value, so a very conservative value (20% increase) was used. The benefits of a permanent solution, like the one the team proposes, that does not require annual payments for multiple procedures, seemed to far outweigh the cons, such as fear of long-term side effects and lack of established reputation in the eyes of the patient.

The target demographic is thus estimated to be around 400,000 annual patients who will seek out the team's proposed procedure. This number is low compared to those who suffer from facet-induced chronic LBP for several reasons. Patients may not be aware of the existing procedures, face financial difficulties, not have access to a local practice offering RF Ablation, be afraid of the procedure, or have pursued other solutions such as lifestyle changes.

It is also important to note that this calculation did not factor in the direct target customers, the doctors. This is because the market for this product is driven by the indirect customers, the patients. The demand created by the patients in turn drives the medical professionals to adopt this procedure. Furthermore, sales would be dependent upon the number of patients, not doctors, as the product is single-use and per patient.

E.2.3 TAM, SAM, and SOM

When seeking venture capital and presenting market size to industry sponsors, it's important to present it in a digestible way. The common terms that are used to define the market size are the total addressable market (TAM), the serviceable addressable market (SAM), and the serviceable obtainable market (SOM). The TAM is simply defined as the total market for the product. The team defined their total addressable market as anyone who experiences facet-induced lower back pain in the US. The market for this has already been defined as 71,179,063 people in **Subsection E.2.1**, though the team wanted to convert this to a dollar amount. To convert the market size to a dollar amount, the team multiplied the amount of people by the price of the product, \$1500. This yielded a TAM of approximately \$107 billion.

Moving onto the SAM, this is defined as the portion of the market which is obtainable based on the product and business model. The team defined this by narrowing the scope of the TAM to include only insured individuals who suffer from facet-induced chronic lower back pain in the US. Again, this value has already been defined in **Subsection E.2.1** as 10,676,859-32,030,578 people. Therefore, the team converted this to a dollar amount, yielding a SAM of \$16-48 billion.

Finally, the team addressed the SOM. The SOM is defined as the percentage of the SAM that the team can realistically capture. In other words, this is the team's target market. Since the target market has been defined as 438,214 people/year in **Subsection E.2.2** (representing all

insured individuals who suffer from facet-induced chronic lower back pain and undergo radiofrequency ablation in the US), the team converted this to a dollar amount. The resulting SOM is about \$657 million. **Figure E.2.3.1** demonstrates the TAM, SAM, and SOM in visual format.

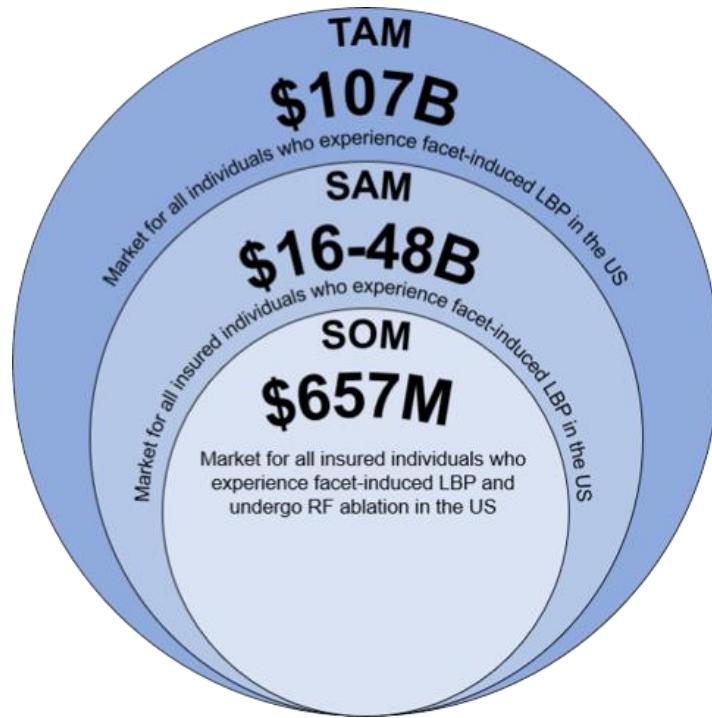


Figure E.2.3.1 The market size presented in dollars as a breakdown of the TAM, SAM, and SOM

E.3 Competitor Analysis

E.3.1 Patent Research

The following information regarding the patent research has been reviewed since the CDR phase, though the team didn't find updates necessary.

The patent research, conducted by the team, analyzed technologies with similarities to the proposed medical product in terms of functionality and design. This investigation yielded valuable insights into the competitive landscape and highlighted how the proposed innovation differs from existing solutions.

The depth-controlled Jamshidi needle, detailed in application number 20120226301¹⁹, was examined. This device employs a conically shaped tip and a bone-anchoring system regulated by a threaded sleeve and nut to achieve precise bone tissue penetration. While offering similar precision goals, the technology operates in a distinct context compared to the proposed device.

Further exploration included patents held by Khosrow Jamshidi, including numbers 5429138²⁰, 4356828²¹, 4266555²⁹, and 4262676³. These patents covered various biopsy needle technologies, encompassing needle tip design and operational features. While these innovations contribute to the field, they remain distinct from the proposed device's focus.

Patents 10201267²² and application 20170340194²⁴, related to endoscopic and surgical methods for nerve coagulation or severance, were also analyzed. These technologies incorporated an endoscope camera and specialized mechanisms for surgical procedures, aligning with some functional aspects of the proposed device. However, their applications and approaches diverged significantly.

The patent research revealed that while existing patents possessed functionalities and designs resembling aspects of the proposed device, they addressed different medical procedures and needs. The proposed device, by offering unique solutions not directly challenged by existing technologies, stands out as a distinct and innovative addition to the medical device landscape. This differentiation underscores the invention's potential impact and significance.

E.3.2 SWOT

The following information regarding SWOT analysis has been reviewed since the CDR phase, though the team didn't find updates necessary.

SWOT stands for Strengths, Weaknesses, Opportunities, and Threats. It represents a succinct framework for evaluating any situation, whether in a business context, personal sphere, or other scenarios, by examining internal aspects such as strengths and weaknesses, alongside external factors like opportunities and threats. The team conducted SWOT analysis leveraging the template shown in **Figure E.3.2.1**.



Figure E.3.2.1 SWOT template

In the domain of lumbar pain management, the product in question distinguishes itself through its user-centric design, providing a one-time, minimally invasive remedy for facet-related discomfort. The single-use nature of the tools involved simplifies the procedure, enabling its execution beyond the confines of conventional surgical environments, further facilitated by

the straightforward manufacturing process attributed to the mechanical essence of these tools. Nonetheless, obstacles such as limited brand visibility, substantial costs associated with development and regulatory approval, and a lack of experience within the team pose significant challenges. The specialized positioning of this product could potentially pave the way for market leadership and the ability to influence pricing, with opportunities to broaden the application of the solution throughout the spinal area. The team's network and commitment to ethical marketing practices stand as notable strengths. However, they encounter competition from well-established treatment modalities, potential legal challenges concerning patents, and barriers to market entry, in addition to consumer reservations about adopting new medical procedures. Strategically navigating these components is essential for securing a competitive edge. The aspects are further detailed in the project-specific SWOT analysis as seen in **Figure E.3.2.2**.

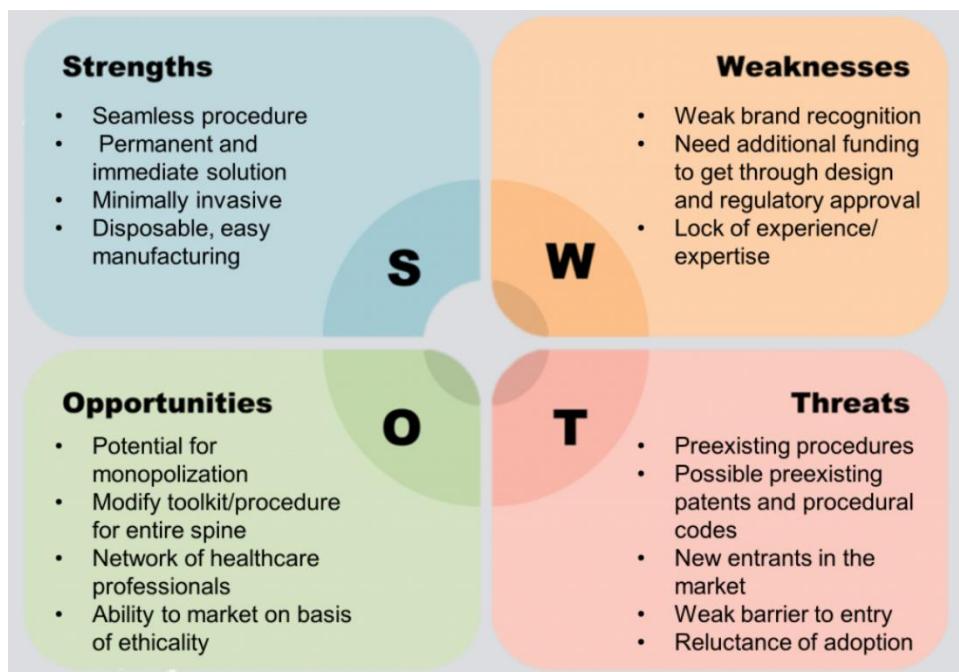


Figure E.3.2.2 Project-specific SWOT analysis

E.3.3 Regulatory Environment Review (RER)

The following information regarding the Regulatory Environment Review analysis has been reviewed since the CDR phase, though the team didn't find updates necessary. However, more in-depth information regarding standards is discussed in **Appendix M**. Some of the standards discussed in **Appendix M** coincide with the RER, so it's just as important to understand those as it is to understand the RER itself.

The regulatory environment for the LMBN Surgical Neurotomy Device involves stringent oversight by key bodies. In the United States, the Food and Drug Administration (FDA) is responsible for the approval of medical tools and procedures, while the Centers for Medicare & Medicaid Services (CMS) set healthcare coverage standards crucial for Medicare and Medicaid reimbursement. In Europe, the European Medicines Agency (EMA) holds regulatory authority.

As a Class II product, the team's solution is subject to moderate-risk regulations, necessitating compliance with special controls and a 510(k) premarket notification. This process demands a demonstration of substantial equivalence to a legally marketed product, involving a detailed comparison and technical specification analysis, typically reviewed within a 90-day timeframe, although this can vary based on the product's complexity.

Quality System Regulation compliance is critical, requiring the establishment of a comprehensive quality management system that encompasses design, document, and purchasing controls, along with stringent standards for labeling, packaging, records maintenance, internal audits, corrective and preventive actions (CAPA), and production and process controls as outlined in 21 CFR Part 820.

Moreover, the product must meet general standards and technical specifications including material specifications, electrical safety, electromagnetic compatibility, mechanical testing, sterilization, packaging, risk management (ISO 14971), usability engineering (IEC 62366-1), and adhere to the quality management principles of ISO 13485. These regulations and standards are essential for ensuring the product's safety, effectiveness, and market readiness, positioning it within the competitive landscape of medical products.

F. Value Proposition

F.1 Product Cost/Value

Throughout the manufacturing process of the FDR phase, the team made many changes to their design process and budget. This includes the transition of fabrication to be completely in-house, as well as associated changes to stock and materials. Therefore, the product cost has been updated to reflect current expenses, including finalized material costs, finalized labor and overhead costs, and finalized machining costs. Before any numerical or calculation change can be mentioned, it's important to mention that the components being costed changed between the CDR and FDR phases (as is touched on in **Appendices C and K**). During the CDR phase, the team calculated the product cost for the Stylet Shaft, Portal Hollow Tube, Denervator Shaft, C-clip, Back Stabilizer, epoxy coating, Denervator Handle, miscellaneous fasteners, threaded inserts, 3D printing filament, Stylet Handle, and structural epoxy. Items such as the miscellaneous fasteners, threaded inserts, and epoxy coating were not incorporated into the final design, so the team removed these from the product cost. The updated components that were analyzed to calculate the product cost can be seen in **Figures F.1.1 through F.1.7**.

The comprehensive approach to calculating the cost of each product component is a testament to the intricacy and precision required in manufacturing. It is important to note that the annual expected sales quantity is approximately 5000 units/year, which assumes that the team can capture 1% of the target market. Though this market share seems low, these medical tools are unique and must get over a large barrier to entry before even making it to market. Therefore, it is expected that the team only captures a fraction of the market to begin.

Moving on, the cost of toolkit can be described in more detail. Starting with the base retail cost of individual components, adjustments are made to reflect the expected volume of production. This involves a 95% volumized adjustment to account for the production of 5000 units/year, which has been updated from the 80% adjustment as calculated against during the CDR phase. Rather than an 80% adjustment be applied, considering this aligns with 5000 units/year, the team instead applied a 95% adjustment because each retail item is able to produce multiple toolkits per retail item. For example, items like the Rubber Pads can produce up to 288 toolkits. Therefore, the volumized adjustment was applied with respect to how many retail items

need to be bought to produce 5000 units, rather than applying it to 5000 units itself. This method ensures that the costs are scaled appropriately and provides benefits from the economies of scale.

Labor costs, particularly for machined parts, are calculated based on a standard rate of \$60/hr. The time required for machining varies by component, as seen with the machined Portal Shaft, which necessitates 0.25 hours of labor, resulting in a \$15 labor cost. This is then combined with the adjusted component cost and a specific overhead rate, which in the case of the machined Portal Shaft, amounts to 35% overhead. This eventually leads to a final component cost of \$35.29.

For materials used in smaller quantities, such as epoxy, the cost is determined per unit of consumption, offering a more accurate reflection of the material costs involved. This precision ensures that the pricing is directly correlated with the actual usage, avoiding the inaccuracies of bulk pricing. An update made during the FDR phase was to account for this when determining the product cost for all the metal stock. All stock was bought in excess, such that it could produce two to six toolkits. Therefore, the team adjusted the true cost according to the per unit consumption for these components.

The 3D printing process, including the cost of filament and associated labor, is also evaluated on a per-unit basis. This granular approach to cost calculation is evident in the pricing of the Denervator Handle. The cost of the 3D printing filament is set at \$3.68 according to the utilized volume, and there's an additional \$5.50 for 5.5 hours of printing labor, culminating at a total component cost of \$9.18. The labor cost of this component makes it evident that the 3D printing labor rate is \$1/hr, which was accounted for during the costing of each 3D printed component.

The final part of the product cost was the assembly costs. This wasn't accounted for during the CDR phase and can therefore be mentioned as another update made to the product cost during the FDR phase. The team recorded the cost per assembly at a labor rate of \$60/hr, as well as applied an overhead of 35%, aggregating to a total assembly cost of \$81.

The final cost per toolkit, \$288.07, is the result of aggregating these varied costs. This total encapsulates the adjusted component costs, labor expenses, and overhead across different parts, highlighting the detailed and comprehensive nature of the cost calculation process. This meticulous approach ensures that every aspect of production, from material costs to labor and overhead, is precisely accounted for, providing a clear and accurate picture of the production

costs involved. **Figures F.1.1 through F.1.7** provide continued detailed cost analyses for other components such as the Stylet Shaft, the Back Stabilizer, and various manufactured parts and retail items. This level of detail in the cost breakdown is essential for maintaining transparency and accuracy in financial planning and pricing strategies.

Component #1 - Machined Stylet Shaft			Component #2 - Machined Stylet Nub		
Raw Material	Dimensions	L: 194mm; D: 4.5mm	Raw Material	Dimensions	L: 5.17mm; D: 1.9mm
	Volume	0.181 cu. in.		Volume	0.001 cu. in.
	Material	Stainless Steel 316L		Material	Stainless Steel 316L
	Density	0.289 lbs. / cu. in.		Density	0.289 lbs. / cu. in.
	Weight	0.052 lbs.		Weight	2.58E-04 lbs.
Cost per lb.	\$ 125.98	\$ / lb.	Cost per lb.	\$ 715.33	\$ / lb.
Matl. Cost	\$ 6.61		Matl. Cost	\$ 0.18	
Labor	Machining Hrs.	0.5 hrs.	Labor	Machining Hrs.	0.083 hr.
	Labor Rate	\$ 60.00 \$ / hr.		Labor Rate	\$ 60.00 \$ / hr.
	Labor Cost	\$ 30.00		Labor Cost	\$ 4.98
	Matl. + Labor	\$ 36.61		Matl. + Labor	\$ 5.16
	Overhead	35%		Overhead	35%
Component Cost	\$ 49.42		Component Cost	\$ 6.97	

Figure F.1.1 Cost of the machined Stylet Shaft and the machined Stylet Nub

Component #3 - 3D Printed Stylet Handle			Component #4 - 3D Printed Denervator Handle		
Raw Material	Filament Diameter	0.069 in.	Raw Material	Filament Diameter	0.069 in.
	Filament Length	41.896 ft.		Filament Length	89.206 ft.
	Filament Density	0.031 lbs. / cu. in.		Filament Density	0.031 lbs. / cu. in.
	Filament Weight	0.083 lbs.		Filament Weight	0.176 lbs.
	Price	\$ 20.91 \$ / lb.		Price	\$ 20.91 \$ / lb.
Matl. Cost	\$ 1.74		Matl. Cost	\$ 3.68	
Labor	Printing Time	2.5 hrs.	Labor	Printing Time	5.5 hrs.
	Labor Rate	\$ 1.00 \$ / hr.		Labor Rate	\$ 1.00 \$ / hr.
	Labor Cost	\$ 2.50		Labor Cost	\$ 5.50
	Component Cost	\$ 4.24		Component Cost	\$ 9.18

Figure F.1.2 Cost of the 3D printed Stylet Handle and the 3D printed Denervator Handle

Component #5 - Machined Denervator Shaft			Component #6 - Machined Portal Shaft		
Raw Material	Dimensions	L: 222.5mm; D: 4mm		Dimensions	L: 157.5mm; D: 5.15mm
	Volume	0.171 cu. in.		Volume	0.032 cu. in.
	Material	Stainless Steel 316L		Material	Stainless Steel 316L
	Density	0.289 lbs. / cu. in.		Density	0.289 lbs. / cu. in.
	Weight	0.049 lbs.		Weight	0.009 lbs.
	Cost per lb.	\$ 151.84	\$/ lb.	Cost per lb.	\$ 1,212.36
Matl. Cost	\$ 7.51		Matl. Cost	\$ 11.14	
Labor	Machining Hrs.	1 hrs.		Machining Hrs.	0.25 hrs.
	Labor Rate	\$ 60.00	\$/ hr.	Labor Rate	\$ 60.00
	Labor Cost	\$ 60.00		Labor Cost	\$ 15.00
	Matl. + Labor	\$ 67.51		Matl. + Labor	\$ 26.14
Overhead	35%		Overhead	35%	
Component Cost	\$ 91.14		Component Cost	\$ 35.29	

Figure F.1.3 Cost of the machined Denervator Shaft and the machined Portal Shaft

Component #7 - 3D Printed Portal Sleeve			Component #8 - 3D Printed Portal C-ring		
Raw Material	Filament Diameter	0.069 in.	Filament Diameter	0.069 in.	
	Filament Length	1.772 ft.	Filament Length	0.492 ft.	
	Filament Density	0.031 lbs. / cu. in.	Filament Density	0.031 lbs. / cu. in.	
	Filament Weight	\$0.00 lbs.	Filament Weight	\$0.00 lbs.	
	Price	\$ 20.91	\$/ lb.	Price	\$ 20.91
	Matl. Cost	\$ 0.06		Matl. Cost	\$ 0.02
Labor	Printing Time	0.167 hrs.	Printing Time	0.083 hrs.	
	Labor Rate	\$ 1.00	\$/ hr.	Labor Rate	\$ 1.00
	Labor Cost	\$ 0.17		Labor Cost	\$ 0.08
	Component Cost	\$ 0.23		Component Cost	\$ 0.10

Figure F.1.4 Cost of the 3D printed Portal Sleeve and the 3D printed Portal C-ring

Component #9 - 3D Printed Back Stabilizer			Component #10 - Purchased Rubber Pads		
Raw Material	Filament Diameter	0.069 in.	Description	Rubber pads for grip	
	Filament Length	53.904 ft.	Vendor	Amazon	
	Filament Density	0.031 lbs. / cu. in.	Retail Cost	\$ 8.99	
	Filament Weight	\$0.11 lbs.	Units / yr.	17	
	Price	\$ 20.91	Volumized % of Retail	95%	
	Matl. Cost	\$ 2.22	Components Produced	288	
Labor	Printing Time	3.25 hrs.	Part Cost	\$ 0.03	
	Labor Rate	\$ 1.00	Overhead	8.5%	
	Labor Cost	\$ 3.25	Component Cost	\$ 0.03	
	Component Cost	\$ 5.47			

Figure F.1.5 Cost of the 3D printed Back Stabilizer and the purchased Rubber Pads

Component #11 - Structural Epoxy		Component #12 - Magigoo PP	
Material	Description	Material	Description
	Bonding adhesive		3D printing adhesive
Vendor	McMaster-Carr	Vendor	Amazon
Retail Cost	\$ 89.09	Retail Cost	\$ 24.99
Units / yr.	178	Units / yr.	334
Volumized % of Retail	95%	Volumized % of Retail	95%
Components Produced	28	Components Produced	15
Part Cost	\$ 3.02	Part Cost	\$ 1.58
Overhead	8.5%	Overhead	8.5%
Component Cost	\$ 3.28	Component Cost	\$ 1.72

Figure F.1.6 Cost of the structural epoxy and the Magigoo PP

Assembly			
Assembly	Portal Sub-Assembly	0.1	hrs.
	Back Stabilizer Sub-Assembly	0.2	hrs.
	Stylet Sub-Assembly	0.5	hrs.
	Denervator Sub-Assembly	0.1	hrs.
	Final Assembly/Packaging	0.1	hrs.
	Total Assy. Time	1	hrs.
Labor	Labor Rate	\$ 60.00	\$ / hr.
	Labor Cost	\$ 60.00	
	Overhead	35.0%	
	Component Cost	\$ 81.00	
	Total Cost per Kit	\$ 288.07	

Figure F.1.7 Assembly and total costs

F.2 Product Price

The product pricing for the proposed medical tools has been determined during the CDR phase. After careful review and consideration, the team did not find it necessary to update the product pricing during the FDR phase. It's important to note that, since the team is selling the medical tools, not the procedure, the pricing has previously been adjusted to specifically reflect the value of the medical tools.

To establish a competitive price, the team used competing medical procedures as benchmarks. They drew parallels with the radiofrequency (RF) ablation technique, considering this is by far the most prevalent and widely performed procedure targeting facet-induced lower back pain. According to industry experts, RF ablation is priced at approximately \$300, while online sources suggest a lower estimate of \$100⁴⁵. Prioritizing realism and industry standards, the final price was pegged closer to the expert's valuation of \$300.

Considering the product cost aggregates to \$288.07 per performed procedure (see **Section F.1**), a selling price of \$300 is not viable. The selling price must be adjusted to both make a profit and establish business value. Also, considering the intensity and lack of frequency of this procedure, the price can be heavily leveraged. RF ablation procedures are typically administered five times per patient, therefore, the cost per toolkit can be proportionately adjusted according to the number of eliminated procedural occurrences. The team implemented a quintupled pricing strategy, setting the total cost for the innovative procedure at \$1,500. This approach ensures that the pricing reflects both the procedural complexity and the market dynamics, offering a balanced and justifiable cost framework for the advanced medical service.

F.3 Societal Benefit

The following information regarding societal benefit has been reviewed since the CDR phase, though the team didn't find updates necessary.

Lower back pain is a significant health concern, ranking just below the common cold as a leading reason for doctor visits. It affects individuals across all age groups, with an estimated one-third of the population expected to experience it at some point. As the top cause of disability worldwide, back pain not only causes physical discomfort but also leads to major economic impacts, including direct medical costs and indirect losses such as reduced productivity and missed work or personal activities.

Current treatments, particularly for arthritis-related facet-induced pain, often provide only short-term relief. Given the lack of a cure for arthritis, blocking pain signals remains a critical treatment approach. The introduction of the team's LMBN neurotomy product is promising, aiming to offer sustained relief by interrupting these pain signals.

The potential benefits of effectively treating lower back pain with this product are significant. It could lead to substantial healthcare cost reductions by minimizing the need for ongoing treatments and long-term medication. Additionally, by addressing a leading disability cause, it could notably decrease work absenteeism, enhancing productivity and contributing to economic growth. The product also has the potential to improve individuals' quality of life by facilitating better pain management, enabling more active lifestyles, and possibly extending the working years of those affected by back pain, thereby supporting economic stability.

F.4 Gross Profit

The gross profit of the new medical toolkit is a crucial indicator of its financial health and the effectiveness of its pricing strategy, and it has been updated during the FDR phase to account for the change in product cost. The meticulous approach to calculating the production cost of each component and considering the intricacies of manufacturing, labor, and overhead now results in a comprehensive total cost of \$288.07 per unit, nearly a \$300 reduction since the CDR phase. This detailed cost calculation process, which includes adjustments for economies of scale and specific overhead rates, ensures a precise and accurate understanding of production expenses, thereby enabling a transparent and accurate financial planning and pricing strategy.

The product's pricing strategy, developed through a comparative analysis with existing radiofrequency (RF) ablation techniques and adjusted for the procedure's intensity and frequency, has been set at \$1,500. This price not only reflects the manufacturing complexity and market dynamics but also offers a balanced and justifiable framework for this advanced medical service. By setting the price at this level, the medical toolkit is positioned as a cost-effective alternative to traditional RF ablation treatments, which are typically priced between \$100 and \$300 but require multiple sessions.

The gross profit, derived by subtracting the total production cost from the selling price, highlights the financial viability of the procedure. With a selling price of \$1,500 and a production cost of \$288.07, the gross profit per unit stands at \$1,211.93, marking a \$300 increase since the CDR phase. This substantial margin underscores the strategic pricing model's effectiveness, balancing affordability for patients with the potential for reinvestment into further research, development, and market expansion. This profit margin is essential for sustaining the procedure's long-term success and ensuring that it remains an accessible and financially viable option for patients seeking relief from their ailments. The gross profit per year was then calculated by multiplying gross profit per unit by the expected yearly production quantity of 5000 units per year which yielded a total profit of \$6,059,650.

Appendix III – Design Process

G. Engineering Requirements & Constraints

G.1 Research-Based Approach

To identify the key functions of the product, extensive research was done. This research has been better integrated during the FDR phase to present as a cohesive story, however, the content was unchanged from the CDR phase. This content was driven by numerous NIH and NCBI articles, which were referenced to develop a biomedical understanding of the functionality of nerves. Specifically, the medial branch nerve (MBN) – a small sensory nerve part of the body's peripheral nervous system (PNS).

The portion of the MBN running over the pedicle, the area of interest on the facet joint, is primarily made of axons²⁷. These axons are contained within a protective myelin sheath³⁸ made of Schwann cells, as seen below in **Figure G.1.1**.

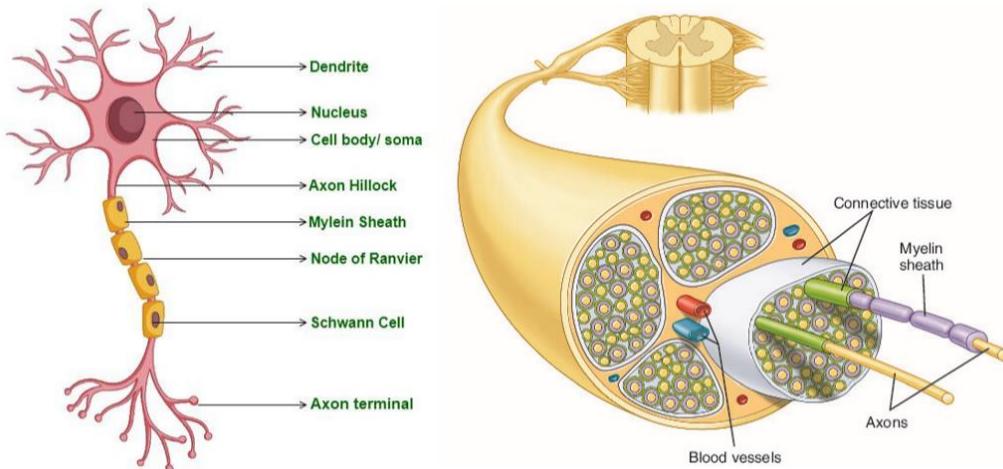


Figure G.1.1 Anatomy of a nerve

When a nerve is damaged and the axons are severed, the cell body (soma) encourages the Schwann cells to begin a process of axonal regeneration in which the severed ends (distal ends) try to reconnect (reapproximate). The effectiveness of this process depends on several factors contributing to nerve regrowth:

- **Type of Nerve:** Sensory nerves are more likely to regrow over motor nerves. Spinal and brain nerves are least likely to regrow.
- **Injury Type:** Clean cuts (smaller transected cross sections) can encourage nerve regrowth. Destroying a larger area of the nerve can inhibit regrowth.
- **Gap Between Severed Ends:** A larger gap⁴¹ between severed ends²⁵ of the nerve discourages the nerve from reconnecting.
- **General Health:** Younger age and better health help a severed nerve heal.
- **Scar Tissue:** Collagen⁵¹ based scar tissue may inhibit the development of neuromas and pain. Scar tissue may create dense physical barriers³⁴ to inhibit¹⁸ regrowth but may also serve as scaffolding²⁵ to promote regrowth.
- **Time:** A critical window (~18 months³³) exists within which axon regrowth from the distal stump is most receptive²⁵ to growth signals from the proximal (healthy) portion. With more time, regeneration potential decreases¹⁸. When intervention is delayed, Schwann cells undergo apoptosis³³ and repair potential drops.

This information guided the team with critical insight into how a nerve should be severed to permanently prevent regrowth. Furthermore, it was also discovered that axonal regeneration requires an intact endoneurium¹⁸ to reestablish a connection with the cell body and distal end. If this does not occur in 24 months, the tube is closed off by fibrosis. Thus, Grades 3-5 are suitable methods of unapproximating the nerve for the team, as seen below in **Figure G.1.2**.

Classification of Peripheral Nerve Injury						
Sunderland Grade	Seddon	Site of Pathology				
		Myelin	Axon	Endoneurium	Perineurium	Epineurium
1	Neurapraxia	+	-	-	-	-
2	Axonotmesis	+/-	+	-	-	-
3	Axonotmesis	+/-	+	+	-	-
4	Axonotmesis	+/-	+	+	+	-
5	Neurotmesis	+	+	+	+	+

Key: + means affected, - means unaffected

Figure G.1.2 Denervation injury severities

A key characteristic of the permanently damaged nerve is that it may contribute to the formation of neuromas⁴⁴, painful stumps that form in the process of the Schwann cells trying to

frantically reapproximate with the distal ends through a process known as Wallerian Degeneration. This frantic process leads to the haphazard growth of axonal sprouts and the development of neuromas. This is a key characteristic of neurotmesis, the most severe form of nerve damage in which all layers between the endoneurium and epineurium are severed.

Though limited studies exist on how to inhibit neuroma generation as opposed to retrospective treatment after their formation, the team found several methods of inhibiting neuroma growth including nerve implantation, pharmacological inhibition, TMR, cauterization, and laser photocoagulation⁵⁰. However, many of these methods were ineffective, inconsistent, or infeasible for the team's procedure.

Concerning the influence of a cutting method on neuroma formation, some studies have shown that there is no correlation¹². In contrast, other studies claim that oblique cutting, as opposed to perpendicular transections, created long and short nerve fibers that encouraged growth pathways amongst themselves at each distal end, thus discouraging neuroma development⁵³. The same study also highlighted how scar tissue and large displacements between distal ends contributed to preventing neuroma formation⁵³. Due to the contradicting research, the team made a judgment call to identify the best method of targeting the MBN. The pros and cons of each method considered can be seen below in **Table G.1.1**.

Table G.1.1 Pros and Cons of Unapproximation Methods

Method		Pros	Cons
Type of Cut	Clean Cut	Easier to achieve	Doesn't disfigure distal ends
	Grinding	<ul style="list-style-type: none"> • Simulates oblique cutting • Can pull out nerve debris • Can create scar tissue 	Risk of collateral damage
Type of Entry w.r.t MBN	Perpendicular	Targeted MBN destruction	Harder to locate the MBN
	Parallel	<ul style="list-style-type: none"> • Attacks a larger area • Similar to RF Ablation 	Harder to damage the MBN

Given these options and the new research, the team concluded that grinding the nerve as opposed to transecting it would be the best option. The team's functional decomposition chart was thus developed with this goal in mind. The results of this can be seen below in **Figure G.1.3**.

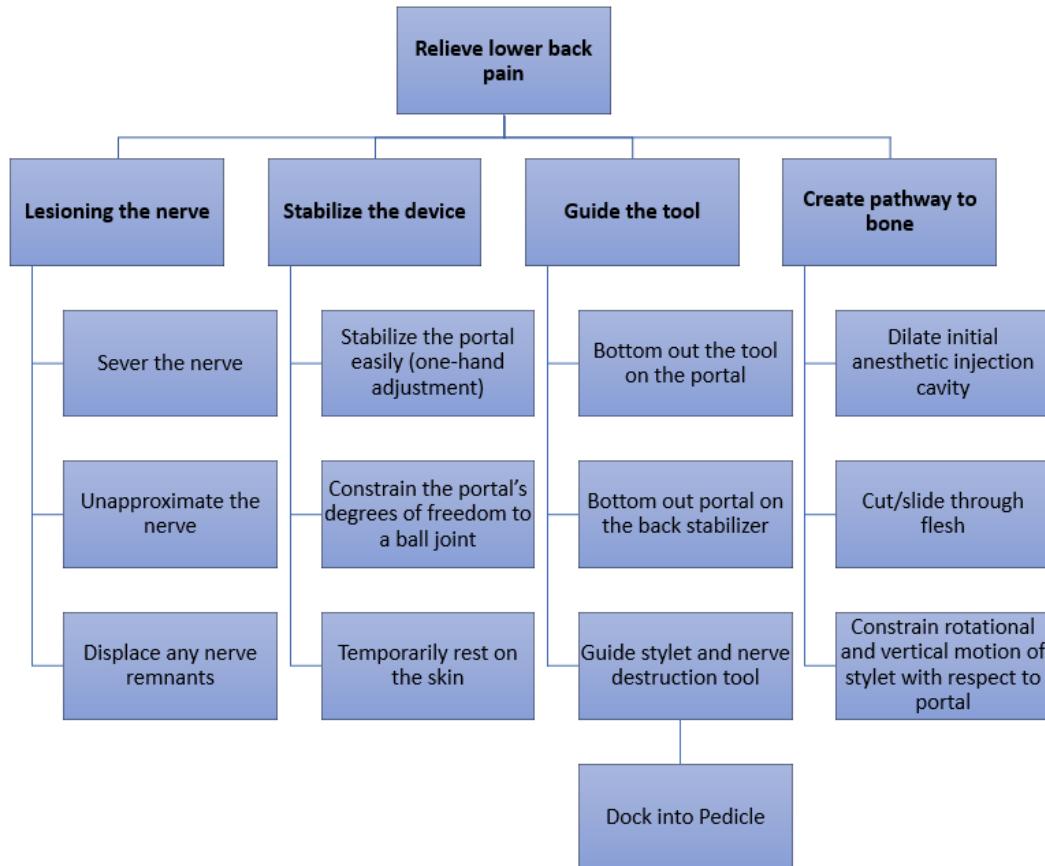


Figure G.1.3 Functional Decomposition chart

G.2 Material Selection

The team's research on industry-grade materials converged down to the final selections. Various materials used in industry were investigated for metals, plastics, rubbers, and adhesives – the four primary different types of materials the kit would be comprised of. This research did not change during the FDR phase, despite design changes.

The team investigated metals such as Grade 304, 316, and 316L stainless steel. As per ISO 10993⁵⁶ standards, stainless steel is 100% recyclable and biocompatible¹⁵, although certification is required to verify the biocompatibility. It also has a low thermal expansion coefficient¹⁵, making it a strong choice for high-temperature applications such as the sterilization procedure, which occurs at 273 degrees Fahrenheit. Moreover, all stainless steels should show up on X-rays due to their density³.

It was ultimately decided that SAE 316L would be the optimal option for a variety of reasons. SAE 316L has under 0.03% carbon content making it very resistant to corrosion⁵⁷. It is also a low-allergy material, non-magnetic, and biocompatible when produced to ASTM F138/F139 standards⁵⁷. The material is often used for implant devices and surgical instruments⁵⁷ and thus is well adopted by the industry. It is cheaper than its non-low-carbon alternative while retaining practically the same elasticity value. SAE 316L will also withstand the sterilization procedure as it has a melting temperature of 2500 degrees Fahrenheit⁴⁶. This material thus meets all the team's engineering requirements and is congruent with the Engineering Specifications Chart shown in **Section G.3**.

Nonessential and noncritical components that do not interact directly with the body do not need to follow stringent medical standards and thus often do not need to be made of metal. Often, plastics are used for the handles of tools as they are a more cost-effective option and can be easily shaped into complex geometries for ergonomic purposes – a benefit that metals do not have. More importantly, a large metal handle would appear on an X-ray and block the view of the area of interest for the operator. The plastics investigated by the team included PSU, PPSU, PEEK, polypropylene, polycarbonate, and polyacrylamide.

The team ultimately decided on polypropylene homopolymer for a variety of reasons. As a thermoplastic, it can be completely recycled⁵⁸. Though the melting point of polypropylene (PP) is 266-338 degrees Fahrenheit³⁶, it is meant for one sterilization cycle unless it is medical grade¹⁷. PP is commonly used in industry, especially in items like disposable syringes and

surgical trays⁵⁸. Moreover, PP is resistant to impact and corrosion²⁶. Finally, PP does not show up on X-ray imaging, which is desired by the team⁵⁹. While polycarbonate shares very similar benefits, it is transparent in nature while PP is opaque³⁷. From a customer perspective, an opaque handle is more visually appealing than a transparent one. Thus, PP was chosen over polycarbonate.

The decision to choose a rubber and adhesive was a lot less involved as there were not too many options to choose from. Due to their lack of interaction with the body, the team's selections did not need to meet many medical standards or requirements. Rubber silicone was selected as the optimal option for the rubber parts due to its biocompatibility, resistance to chemicals, antibacterial properties, and ability to withstand steam sterilization of up to 482 degrees Fahrenheit¹⁰. The adhesive selected by the team was a structural epoxy adhesive meant for a variety of purposes including metal to metal, metal to plastic, and plastic to rubber. It is also compatible with low surface energy plastics like PP. Its temperature resistance of up to 350 degrees Fahrenheit and its shear strength of 350 lb/sq.in makes it a suitable option for the team's purposes as it can easily withstand sterilization and procedural forces⁵.

Given these materials, the team concluded that all parts entering the body should be made of SAE 316. This includes the body of the Denervator, Stylet (including the Nub), and Portal. It was also concluded that all nonessential components that should not appear on the X-ray and won't enter the body should be made of PP. This includes the handles of the Stylet and Denervator, the Back Stabilizer, the Portal Sleeve, and the Portal's C-Ring. Furthermore, all permanent bonds between parts must leverage the structural epoxy. This includes the connections between the bodies and handles of the devices, the Nub to the Stylet body, and the rubber pads to the Back Stabilizer. Lastly, the team decided that the rubber pads in the Back Stabilizer should be made of silicone rubber.

G.3 Determining Engineering Specifications

In order to establish a strong understanding of the ESC, it's important to know how it was originally developed during the PDR phase. Before beginning the design and development of the proposed medical tools, it was important to determine what requirements and constraints exist. To get a deeper understanding of the problem at hand, extensive research was done. The research process involved both individual research and customer research.

The end goal of the team's design is to satisfy the customers' needs. In order to get insight as to what those needs are, the team performed customer research. This involved talking to experienced doctors. The doctors that were consulted include Physical Medication & Rehabilitation (PM&R) specialist Dr. Ali Mostoufi, PM&R specialist Dr. Tony George, and anesthesiologist Dr. Mohamed Hamouda. Each doctor brought a unique perspective to attention, which helped the team successfully identify customer needs in the PDR iteration of the Engineering Specifications Chart (ESC), as seen in **Figure G.3.1**.

Through conversation, Dr. Mostoufi expressed great interest in the medical tools and procedure being proposed by the team. Because of his interest, Dr. Mostoufi laid out the foundation of customer needs. He identified the most important customer need being that the medical tools and procedure should relieve patients' pain. And not only should pain be relieved, but it should be relieved for a longer period than existing solutions offer. After all, the purpose of the proposed tools and procedure is to create a more permanent solution to relieve facet-induced lower back pain in patients.

Dr. Mostoufi then elaborated on how he wanted the proposed procedure to take place, which invoked a few more customer needs. He first expressed that the tools need to be sterilized pre-operation, which is important to consider for the team when choosing the materials of the tools. Dr. Mostoufi then expressed that the tools need to appear on X-rays, as this is the method used to visualize the procedure. Similar to sterilization, X-ray imaging is important to consider when the team chooses materials. The last procedural-centric requirement that Dr. Mostoufi expressed was that the tools should be strong enough to withstand the procedural force. This is trivial, but important to note.

Apart from direct procedural needs, Dr. Mostoufi expressed a few more general customer needs. Though it's another trivial customer need, Dr. Mostoufi expressed that the tools need to be easy to use and have an inability to mishandle. He noted that this was particularly important

for less experienced doctors, unlike himself. Another need that Dr. Mostoufi mentioned was that the medical tools and procedure should be minimally invasive. The importance of a minimally invasive procedure is that it provides reduced pain, scarring, recovery periods, and risk of complications. Finally, Dr. Mostoufi said that the medical procedure should be able to be performed in an office setting. He elaborated on this by explaining that procedures can be performed in office settings when the tools are disposable. Therefore, the proposed medical tools must be disposable – a key customer need.

After discussing the proposed medical tools and procedure with Dr. Mostoufi, the team connected with Dr. Tony George. Dr. George came to a similar conclusion to Dr. Mostoufi with regards to a few of the customer needs. He emphasized that the medical tools must be easy to use, and the procedure must be easy to perform. Dr. George also said that a shorter relief period is desired, which can be accomplished by designing the medical tools and procedure to be minimally invasive. Dr. George gave more insight regarding this, as he noted that the medical field is moving towards minimally invasive and more aggressive approaches. The last customer need which Dr. George mentioned (he rather reaffirmed it, considering Dr. Mostoufi had already brought it to light) is that pain relief should last a significant amount of time. He expressed that patients would be happier and more satisfied if this was accomplished.

The last doctor who the team conversed with was Dr. Hamouda. Similar to the conversation with Dr. George, the conversation with Dr. Hamouda helped support previously defined customer needs. Dr. Hamouda expressed his desire for wider nerve separation, longer periods of pain relief, and a minimally invasive approach for the same aforementioned reasons. However, Dr. Hamouda brought a new perspective to the design which had not been considered yet. He discussed the possibilities of neuromas as complications from the procedure. Dr. Hamouda described that the medical tools and procedure should avoid neuromas at a high rate, which is very important to consider when designing the tools. This insight will play a key role in driving the design of the medical tools.

With a strong foundation of customer research and defined customer needs, the team then conducted medical research to define quantifiable measures and target values (to keep a sensible flow, the customer needs will be quantified in the same order as they are listed in **Figure G.3.1**). The first customer need listed in **Figure G.3.1** is that the medical tools must be easy to use. Due to the inherent subjectivity of such a requirement, the best way to sensibly quantify it is through

survey ratings. Therefore, the ease of use of the medical tools will be judged by their ease-of-use ratings. The required value set forth by the team was at least a 75% ease-of-use rating. This value was gathered through conversation with Dr. Mostoufi, who described 75% ease-of-use ratings as satisfactory.

The next customer need listed on the ESC in **Figure G.3.1** is that the medical tools and procedure need to be minimally invasive. Through research via Cleveland Clinic, the team was able to define minimally invasive procedures: a minimally invasive procedure is one which involves small incisions, which are often less than $\frac{1}{2}$ inches (12.7 millimeters) wide³⁸. Knowing this information, the team decided that the outer diameter of the Portal should not exceed 12.7mm in order to fit within a similarly sized incision, thus keeping the procedure within the realm of being minimally invasive. While this large value provides great leeway, the team aims to reduce the pain and recovery of this procedure as best as possible. Therefore, a target value of 4-5mm was chosen for the outer diameter of the Portal (with a similar sized incision). From medical research, it was found that stitches become optional when incisions get as small as 7mm⁵⁵. The team wants to produce a smaller incision to ensure stitches aren't necessary to close the incision, which is why the specific value of 4-5mm was chosen as a target.

The disposability of the medical tools is a trivial customer need. This just means that doctors should dispose of the medical tools after they are used for a procedure. This was quantified as a 0% reprocessing rate, where reprocessing is defined as cleaning, disinfecting, or sterilizing tools after use⁷. While the medical tools don't need to be re-sterilized, they do require single-time sterilization. This customer need can be directly quantified, as steam sterilization is performed at temperatures of 250-273°F and pressures of 15-30psi⁴⁷. The team determined that the target temperature and pressure at which the medical tools should be able to withstand are 273°F and 30psi, respectively. This ensures that the medical tools will withstand the entire range of steam sterilization.

Next customer need on the list is the X-ray appearance of the medical tools. According to research, an objects visibility under X-ray can be quantified as by contrast ratio⁴². This same source describes a ratio of 3:1 as being adequate to visualize things on X-rays. Therefore, this was the team's requirement. However, the team wants to provide a bit stronger contrast such that the medical tools stand out on X-ray images. For this reason, the team came to a consensus of setting a contrast ratio to a conservative target value of 5:1.

The next two customer needs are the most important with respect to the proposed design: the pain should be relieved, and the relief should last for long periods. To quantify the pain relief, the team did research into the effectiveness (how much of the pain relieved) and extent (how many cases was pain relief achieved) of pain relief from Radiofrequency Ablation (RFA). This research revealed that RFA relieved 50% of the pain for 80% of the patients^{51,40}. These numbers were therefore set as the requirements for the team's proposed medical procedure. Considering the goal of the proposed procedure is to be more effective than alternative procedures, the team decided on target values for effectiveness and extent as 70% of pain relief for 80% of the patients. The other focus of pain relief is its period. Through researching alternative procedures, the team discovered that endoscopic neurotomies provide the longest period of pain relief at an astounding 5 years⁵⁵. The team decided that this was an appropriate requirement and target value, considering it was already cumbersome for endoscopic neurotomies to achieve 5 years of pain relief. Nerve regrowth, which is affected by a multitude of variables, must be prevented to achieve this desired long-term pain relief. The most important variable in preventing nerve regrowth is the separation of the distal ends of the severed nerve, which happens to be the next customer's need. Research was conducted to better understand how nerve separation affects nerve regrowth, and it was discovered that gaps greater than 5mm significantly decrease regrowth capabilities³¹. The team decided this was an appropriate requirement, and a target separation distance of 7-8mm was defined in order to further hinder nerve regrowth.

The next customer need is another important one: neuromas must be avoided at a high rate. Neuromas can cause unwanted pain and complications, which is the opposite of what the proposed procedure offers. To quantify this customer need, the team researched the rate of neuroma occurrence in RFA sessions. It was discovered that, for transected nerves, neuromas occur across 7.8% of all RFA sessions⁴⁴. For this reason, the team decided that no more than 10% of cases yielding neuromas was an appropriate requirement. Dr. Mostoufi helped validate this requirement and guided the team in choosing a target value for neuroma generation of 5%.

The final two customer needs are a bit trivial, but it is nonetheless important to define quantitative requirements for them. With regards to the strength of the medical tools to withstand procedural force, research demonstrated that no more than 20 Newtons (approximately 5 pounds) is used within similar medical procedures³⁰. This value was also validated by Dr. Mostoufi. To set a target value, the team had to choose a Factor of Safety (FOS). The team settled on a FOS of

2, considering the medical tools are to be highly controlled and uncertainty will be minimized. Therefore, a target for the sustainable procedural force was set at 40N (approximately 10lbs). The last customer requirement shifts the focus to the sustainability of the medical tools. Through research, the team found that sustainability of medical tools is typically defined by the recycling rate (where the recycling rate is the amount of a tool which is recyclable or reusable)²⁴. The same source then described that half of medical tools should be recyclable. Therefore, the team set the sustainability requirement as 50% of the tools being recyclable. The team then decided on a target value for the recycling rate of 75%, which is greater than the 50% requirement to appeal to the market.

Priority (1 - most, 5 - least)	Customer Need	Technical Need	Technical Requirement	Target Value
3	Ease of use/inability for mishandling	Ease-of-use ratings	Doctors that are given the ability to test the medical tools give them an ease-of-use rating of at least 75% . This number is very subjective, hence it being a conservative percentage.	75%
1	Minimally invasive (no general anesthesia or stitches are needed)	Diameter	The outer diameter of the portal should be no larger than 12.7mm to fit within a small incision.	4-5mm
3	Disposable (one-time use)	Reprocessing rate	0% rate for reprocessing the device (cleaning, disinfecting, or sterilizing).	0%
1	Initial sterilization	Temperature and pressure	The medical tools should all be able to withstand steam sterilization at temperatures of 250-273°F and 15-30psi .	273°F and 30psi
1	Tool appearance on X-ray	Contrast Ratio (CR%)	The tool displayed on the X-ray should have a contrast ratio of at least 3:1 with bone	5:1
1	Relief of pain	Extent and effectiveness	The medical tools and procedure should successfully relieve 50% of pain, 80% of the time .	70% of pain relief, 80% of the time
1	Pain should be relieved for long periods	Duration of relief	The pain relief should last for at least 5 years .	5 years
2	Displacement between distal ends post-cut	Length	The destructive tool must create a lesion in the myelin sheath and displace the ends of the nerve by at least 5mm .	7-8mm
3	Avoidance of neuromas	Percentage of cases	Neuroma generation should not happen for any more than 10% of all patients.	5%
1	Strong enough to withstand procedural force	Force	The medical tools should withstand at least 20N .	40N
4	Sustainability	Recycling rate	At least 50% of the tools in the kit should be recyclable to be repurposed.	75%

Figure G.3.1 PDR-phase Engineering Specification Chart (ESC)

In efforts to create a comprehensive list detailing all relative engineering specifications, the team thoroughly revised the list generated during the PDR phase (as seen in **Figure G.3.1**). The team made modifications to the technical specifications to better align with the project's scope and capabilities. Specifically, the technical need associated with the "Avoidance of neuromas" customer need has been updated to "Length of displaced distal ends". This adjustment was necessitated by the impracticality of testing the former technical need, "Percentage of cases," within the project's confines. On top of this, it was found through research that neuroma

generation is much less frequent the further the distal ends of a nerve are displaced⁵³. For this reason, the updated technical need can be justified. This update also demonstrates a refined focus to a more measurable and testable parameter. The revised technical requirement stipulates a separation of at least 7mm between the nerve's distal ends, a decision informed by research indicating that limiting nerve regrowth factors (NGF) reduces the likelihood of neuroma formation⁵³. Given that the controllable NGF is the separation distance post-nerve transection, the team established a target separation of 10mm to underscore the importance of minimizing NGF, based on support from research articles on this quantification⁵³.

Furthermore, based on the research from **Section G.1**, the team decided that grinding the nerve would create scar tissue and simulate oblique cutting as it would create long and short fibers, thus preventing neuromas. It was decided that a parallel method of entry in conjunction with this cutting method would be the most advantageous to the procedure, as referenced in **Table G.1.1**. The engineering specification updates were thus derived based on this conclusion.

Another notable update is that the target value for the outer diameter of the Portal has been adjusted to 5mm. This was deemed a feasible value during the design phase. It subsequently played a large role in guiding the team's CAD design during the CDR phase.

In response to customer feedback, the team consolidated three needs, "Relief of pain," "Pain should be relieved for long periods," and "Displacement between distal ends post-cut", into a singular need: "Pain should be relieved effectively for long periods". This consolidation reflects the team's recognition that the distance between the distal ends is not an inherent customer requirement, but rather a metric for assessing the efficacy and duration of pain alleviation. The broader separation between distal ends correlates with more sustained pain relief. Thus, the technical need, requirement, and target value for these customer needs are all derived from the "Displacement between distal ends post-cut" specification (which was previously detailed in the PDR report). The initial technical needs associated with "Relief of pain" and "Pain should be relieved for long periods" were also beyond the project's scope, emphasizing the importance of establishing quantifiable and testable specifications. Apart from these updates, the ESC remained mostly unchanged from the PDR phase into the CDR phase. The CDR-updated ESC can be seen in **Figure G.3.2** for further understanding.

Priority (1 - most, 5 - least)	Customer Need	Technical Need	Technical Requirement	Target Value
3	Ease of use/inability for mishandling	Ease-of-use ratings	Doctors that are given the ability to test the medical tools give them an ease-of-use rating of at least 75% . This number is very subjective, hence it being a conservative percentage.	75%
1	Minimally invasive (no general anesthesia or stitches are needed)	Diameter	The outer diameter of the portal should be no larger than 12.7mm to fit within a small incision.	5mm
3	Disposable (one-time use)	Reprocessing rate	0% rate for reprocessing the device (cleaning, disinfecting, or sterilizing).	0%
1	Initial sterilization	Temperature and pressure	The medical tools should all be able to withstand steam sterilization at temperatures of 250-273°F and 15-30psi .	273°F and 30psi
1	Tool appearance on X-ray	Contrast Ratio (CR%)	The tool displayed on the X-ray should have a contrast ratio of at least 3:1 with bone	5:1
1	Pain should be relieved effectively for long periods	Length of displaced distal ends	The destructive tool must create a lesion in the myelin sheath and displace the ends of the nerve by at least 5mm .	7-8mm
3	Avoidance of neuromas	Length of displaced distal ends	The destructive tool must create a lesion in the myelin sheath and displace the ends of the nerve by at least 7mm .	10mm
1	Strong enough to withstand procedural force	Force	The medical tools should withstand at least 20N .	40N
4	Sustainability	Recycling rate	At least 50% of the material volume in the kit should be recyclable to be repurposed.	75%

Figure G.3.2 CDR-phase (partially updated) Engineering Specification Chart (ESC)

Over the span of the FDR phase, the team further revised the previously updated ESC (as seen in **Figure G.3.2**). The revisions made during this phase were a lot more minor, but also revolved around establishing feasible and testable customer requirements. One of the customer needs that was specifically updated during the FDR phase was the “Tool appearance on X-ray” need. The technical requirement for this had been previously established as an analysis of the contrast ratio. However, during the X-ray process and after further consideration, the team realized that it’s nearly impossible to find a quantitative way to convey whether the correct materials and geometry show up as desired on the X-ray images. For example, the contrast ratio could be satisfied by the X-ray images, however, the specific geometry of the tool may still be unrealized. Therefore, since both the engineering team and Dr. Mostoufi (who served as a consultant for the team) knew how the tools should appear in the X-ray images, they should have the capacity to determine if the tools meet the associated customer need. According to this logic, the team developed a binary pass-fail scale: each person will give the tools a score of 0 if they incorrectly show up on the X-ray images or a score of 1 if they correctly show up on the X-ray images. The total score will be aggregated between the five individuals and compared to the technical need. Considering the high level of priority for the tools to show up correctly on the X-ray images, the team assigned an aggregate score of 5 as the technical requirement. Similarly, the target value for this customer need was an aggregate score of 5. This is the maximum possible score, conveying the emphasis that the team has put on the tools’ X-ray appearances.

The other customer need that underwent updating during the FDR phase was the “Ease of use/inability for mishandling” need. Like the “Tool appearance on X-ray” need, the updates for this need happened with regards to its technical requirement to make the testing process more feasible. This update was a lot less minor though: the technical requirement was changed to be less dependent on doctors. Initially, the technical requirement entailed multiple doctors testing the developed medical tools and rating their ease of use. However, the team did not have immediate access to multiple doctors to provide them with the medical tools for any sort of testing. For this reason, the team decided to change the requirement such that the ease-of-use ratings could be assigned by any individual who uses or tests the medical tools, including the team themselves. The team felt confident in their own ability to rate the ease of use of the medical tools, especially after going through other testing methods that entail using the tools in a procedural manner. Outside of these two updates, the team felt confident in satisfying the customer needs through analysis or validation testing. Therefore, these were the only two changes made to the ESC between the CDR and FDR phases. The FDR-updated ESC can be seen in **Figure G.3.3** for further understanding.

Priority (1 - most, 5 - least)	Customer Need	Technical Need	Technical Requirement	Target Value
3	Ease of use/inability for mishandling	Ease-of-use ratings	The average ease-of-use rating from those who use or test the medical tools must be at least 75% . This number is very subjective, hence it being a conservative percentage.	75%
1	Minimally invasive (no general anesthesia or stitches are needed)	Diameter	The outer diameter of the portal should be no larger than 12.7mm to fit within a small incision.	5mm
3	Disposable (one-time use)	Reprocessing rate	0% rate for reprocessing the device (cleaning, disinfecting, or sterilizing).	0%
1	Initial sterilization	Temperature and pressure	The medical tools should all be able to withstand steam sterilization at temperatures of 250-273°F and 15-30psi .	273°F and 30psi
1	Tool appearance on X-ray	Validation score	The X-ray images must get a cumulative score of 5 when being evaluated by the four members of the engineering team and a doctor, where each person can give a rating of 1 (the tools show up as desired) or 0 (the tools do not show up as expected).	5
1	Pain should be relieved effectively for long periods	Length of displaced distal ends	The destructive tool must create a lesion in the myelin sheath and displace the ends of the nerve by at least 5mm .	7-8mm
3	Avoidance of neuromas	Length of displaced distal ends	The destructive tool must create a lesion in the myelin sheath and displace the ends of the nerve by at least 7mm .	10mm
1	Strong enough to withstand procedural force	Force	The medical tools should withstand at least 20N .	40N
4	Sustainability	Recycling rate	At least 50% of the material volume in the kit should be recyclable to be repurposed.	75%

Figure G.3.3 FDR-phase (fully updated) Engineering Specification Chart (ESC)

As important as it is to identify the customer needs and engineering specifications, it's just as important to understand the constraints associated with this project. The constraints are

what provide limitations or hold the team back from being able to achieve their goal. While the team will have to deal with them in their own ways, each constraint is just as important as the next. To give further context, these constraints are divided into five categories: design, information, anatomical, resource, and market constraints.

The scope of the design constraints heavily revolves around the materials. Specifically, biocompatibility, X-ray diffraction, and strength of materials are major constraints. These constraints are all material properties; therefore, the team has no control over them. Instead, these constraints guide the team in choosing the appropriate material for the medical tools. The fourth design constraint is the fact that the team is unable to visualize the MBN nerve via imaging. This is why endoscopes have been implemented in alternate procedures, and it will be a leading constraint throughout the design of the medical tools. The last two design constraints are that the medical tools must be medical grade and both the tools and procedure must get approved by FDA. The tools must meet industry standards to be considered medical grade, which will impact the design of the medical tools. Then, to get approved by FDA, the medical tools and procedure must fit within an open surgical code. An open surgical code means the incisions can only be so large, which limits the tool size and usage.

A briefer group of constraints is the information constraints. The most pressing information constraint is the lack of medical knowledge of the engineering team. With limited medical knowledge, the team must resort to medical professionals and research. However, the other information constraint is present in medical research: there is a lack of modern medical research from credible sources regarding the topic of this project. With limited medical knowledge and resources, the team faces the challenge of gathering information.

Despite the lack of medical research available, the team was able to gather some fundamental information about nerves and alternate procedures. However, the team then discovered that anatomical constraints exist in the scope of this project. The first identified anatomical constraint was the regeneration of the medial branch nerve. From research, it has been discovered that the body is able to regrow the medial branch nerve in a multitude of ways. As discussed earlier, there are a multitude of variables that affect nerve regrowth, some of which are out of the control of the team. These out-of-control variables include Schwann cell effectiveness and scar tissue development. This means that no matter how effectively the team can cut and separate the medial branch nerve, these variables will always affect the period of

pain relief. Along with nerve regrowth, the other anatomical constraint is neuroma development. Like nerve regrowth, neuroma generation happens within the body and cannot fully be controlled by the team. The team can do its best to limit neuroma generation, but there is no way to completely control it.

To follow through with this project, the team needs to be able to overcome all these constraints. However, the team also has resource constraints which limit them even further in overcoming the other constraints. The first resource constraint that exists is time: a limited amount of time (16 weeks) has been given to the team to complete this project. Considering each member of the team has individual commitments in their respective lives, time is a massive constraint in both the short- and long-term scope. Another resource constraint is the budget for the project. The team was allotted \$1000 for the design and development of the project, which will not be satisfactory to pay for all manufacturing, testing, and regulatory approval. Therefore, the scope of the project is limited by the budget provided to the team. The last resource constraint is the available manufacturing machines and equipment. Though the resources and facilities at Purdue University are fantastic, the project may necessitate external manufacturing methods. However, limitations may be in place which constrain the team with regards to manufacturing their medical tools.

The last set of constraints comes within the market. The most notable market constraint is the preexisting procedural and design patents. Any patents or existing solutions will guide and limit the design and development of the proposed medical tools and procedure. Another market constraint is the widespread adoption of the proposed procedure. The team has identified that doctors and medical professionals will only adopt this procedure based on their expertise and willingness to learn, therefore constraining the direct market size. A third market constraint is the willingness of patients to pay for a relatively expensive medical procedure. While the team can control the cost of the procedure, they cannot control how the indirect consumers will respond to the price. Similar to the patients' willingness to pay, the last market constraint is the patients' willingness to consent. For the proposed procedure to be practiced, patients must consent to it. The team can control the medical tools, procedure, and available information. However, the team isn't able to control whether patients consent to the procedure. The team will have to navigate both the direct market to doctors and the indirect market to consumers to maximize the potential of the proposed procedure and medical tool.

During the length of the CDR phase, the team revisited and reviewed the project constraints set forth during the PDR phase. However, the team felt that no changes needed to be made; the original list of constraints was comprehensive enough to cover the scope of both the PDR and CDR phases. Moving on to the FDR phase, the team again revisited and reviewed the established project constraints. This time, the team felt it was necessary to make some changes. While the team believed all existing constraints to still be applicable, they had failed to previously identify a few constraints which had been realized during the FDR phase. These new constraints fall within the anatomical and resource categories, which implies that the design, information, and market categories went unchanged between the PDR and FDR phases.

The first group of constraints which saw an addition was the anatomical constraints. Only one constraint was appended, although it's just as important as the rest. Throughout validation testing, the team realized that the strength of the human body served as a constraint for both the medical tools and the procedure. This involves the strength of the skin, flesh, and muscle during body penetration, as well as the strength of the lumbar medial branch nerve during lesioning. These anatomical strengths drove the original design of the medical tools, which can be seen in the Stylet tip and Denervator knurls. This constraint has continued to drive the iterative engineering process as the team progresses through their project, such that the medical tools must be able to overcome the body's natural strength to achieve success.

The other group of constraints that saw additions was the resource constraints. While the team had previously identified the available manufacturing machines and equipment being a constraint on the project, they had failed to think a step further to validation testing. One of the most important parts of the project is validating the final prototype, which requires proper testing machines and equipment. The availability of these machines and equipment are a constraint to the team, which can affect the ESC. An example of this having a negative impact on the project is if force gauges are not available to perform force identification testing. The other constraint which was appended to the group of resource constraints was the availability of mentors, consultants, and industry experts. As discussed with relation to the ESC, multiple doctors were involved in the development of the medical tools. Similarly, mentors and experts were consulted regarding the manufacturing and testing methods undergone in this project. The availability of these doctors, mentors, and experts all served as a roadblock for the team's ability to continue effective progress towards their project. This constraint had to be accounted for consistently

throughout the length of this project, and the team worked towards mitigating it by reducing their dependencies as much as possible.

H. CAD

The team spent significant time finalizing the produced prototype in the most optimal way to fulfill the customer's needs during the FDR phase. The final CAD was the culmination of many updates from the CDR phase, which are later discussed in detail. **Figures H.1 through H.4** resemble the toolkit's final produced prototype in four main components. In order, the Portal, Stylet, Back Stabilizer, and Denervator. All parts involved in the assembly of the Portal, Stylet, Back Stabilizer, and Denervator were manufactured in-house, which means they are all considered make-parts (though some individual parts were manufactured from buy parts). A more in-depth look at the mechanical capabilities and functions of each tool can be found in **Section I**. One way that the team analyzed their designs was by reviewing CAD models and assemblies for compatibility and functionality. The team also went through the process of 3D printing certain parts and reviewing them in-hand by testing each mechanism, brainstorming, and iterating on their designs. It is to be noted that the white components are made from polypropylene 3D filament and the rest of the components are made from grade 316L stainless steel. The functional requirements of the components are discussed below.

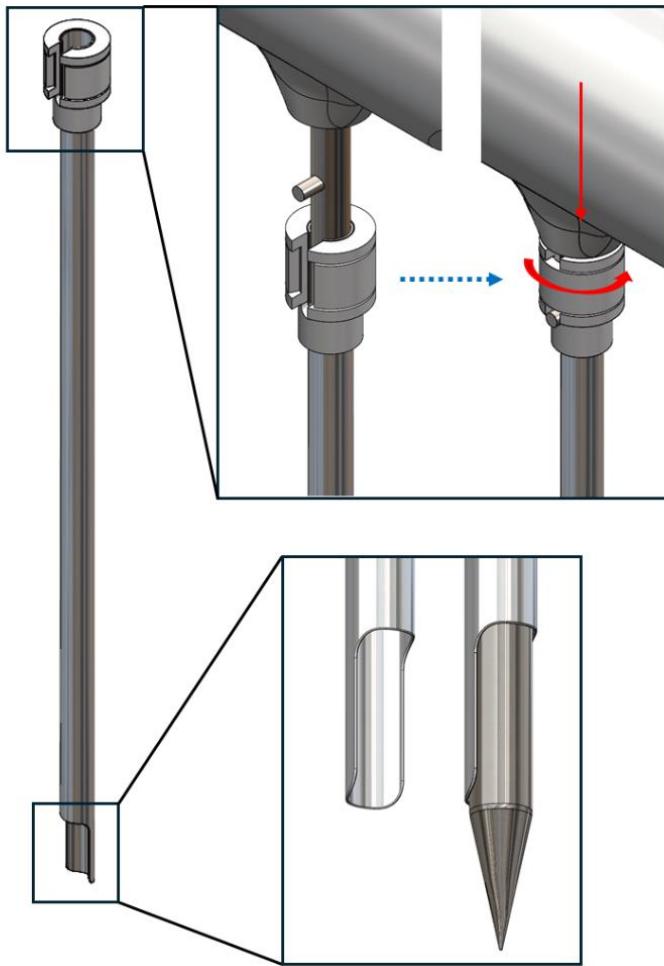


Figure H.1 Portal CAD model, which features the shield, the interlocking mechanism, as well as the three parts that make up the Portal assembly (Portal Shaft, sleeve, and C-ring)

The Portal, as seen in **Figure H.1**, shows a hollow cylinder with unique ends. The inner diameter of the Portal gives enough tolerance for both the Stylet and Denervator tools to slide in and out, considering they interact with the Portal during procedural use. Additionally, the Portal tolerances were designed to allow the Denervator tool to easily fit and drop down into the groove made by the cut-out section, which allows the active cutting site to come into direct contact with the nerve. The bottom 7mm of the Portal is only half-cut to avoid unwanted laceration to any structure or tissue other than the nerve by acting as a shield. During the FDR phase, the team filleted the edges of this feature to eliminate sharp edges, reducing potential damage to the inside of the body. The nerve sits in the groove of the facet joint, which means the only location that needs to be in contact with the active cutting site would be the open portion of the Portal. The

Denervator tool, which will be explained in greater detail, has a cutting section that perfectly aligns with the open portion of the Portal.

While the Portal must interact with the Denervator, it must also interact with the Stylet. The Portal must temporarily combine with the Stylet tool while initially inserting the tools into the patient's body. The two tools act as a single module when the interlocking mechanism is in use (seen at the top of the Portal). The interlocking mechanism features a cutout for the Stylet Nub, a track at the top of the Portal, and a C-ring, which is free to rotate around the track. When the Stylet Nub is inserted into the cutout, the C-ring is to be rotated around the track to lock the Stylet in place, thus creating the Stylet-Portal module.

During the CDR phase, the Portal CAD was designed such that the track was a part of the metal Portal Shaft. Despite this complicated geometry, the team planned on having the part outsourced to Xometry, a third-party manufacturer, to be made. However, during the FDR phase, Xometry expressed that they were not able to manufacture the Portal according to its design. For this reason, the team removed the track from the Portal CAD such that it is now just a hollow tube with a cutout at the top and a shield at the bottom. The track was designed in a separate, new CAD file, called the Portal sleeve. This part can be seen in **Figure H.1**, as it fits via transition fit and epoxy adherence to the Portal Shaft. The C-ring now attaches around the Portal sleeve, achieving the same performance as the original design. The other change made during the FDR phase was that the major dimensions of the hollow Portal Shaft (the inner and outer diameter) were changed to match the dimensions of sourced 316L stainless steel stock from McMaster-Carr. This was a minor change, though is necessary to mention. Overall, the final Portal featured three parts: the Portal Shaft, which was a “make” part (though it was made from a “buy” part), the Portal sleeve, which was a “make” part, and the Portal C-ring, which was also a “make” part.

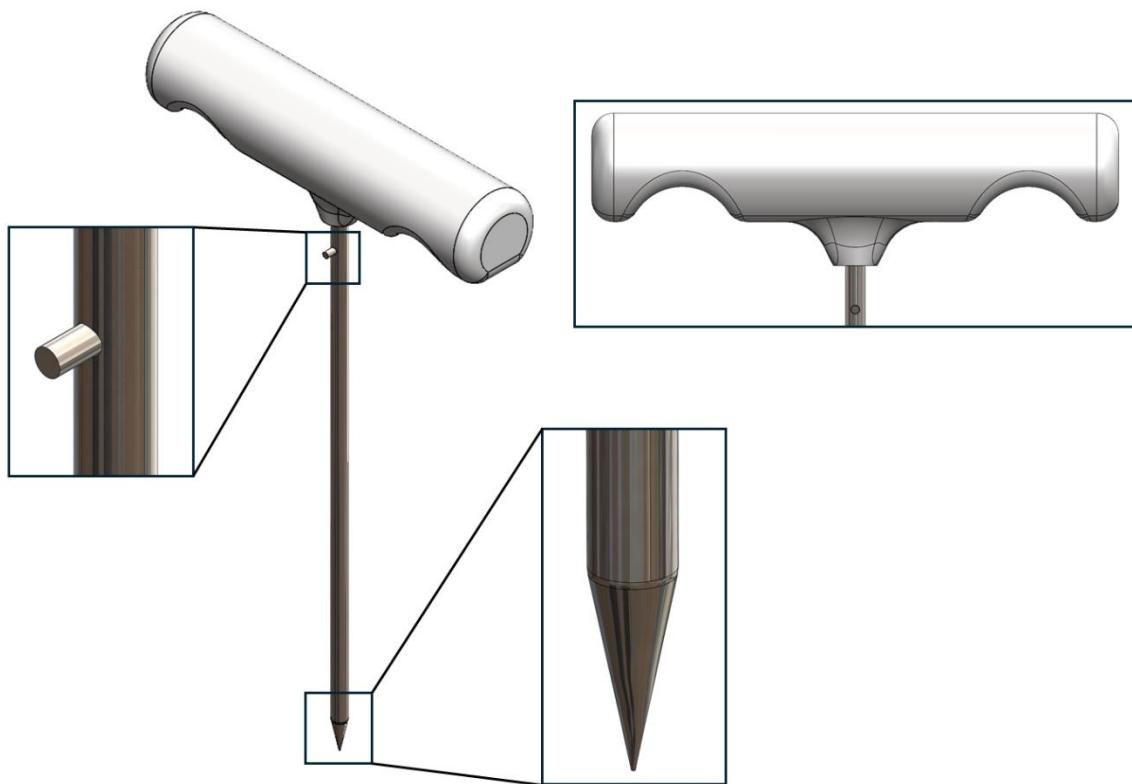


Figure H.2 Stylet CAD model, which features the sharp tip, the ergonomic handle, as well as the three parts that make up the Stylet assembly (Stylet Shaft, Nub, and handle)

The Stylet, as seen in **Figure H.2**, consists of a solid shaft with a conical tip and an ergonomic handle on the top. The Nub, highlighted above, is used as part of the interlocking mechanism between the Stylet and Portal. The functional requirement of the Stylet tip is to help guide the Portal into the body at the beginning of the procedure. The tip was made to have a sharp incline, but still have a blunt tip to limit excessive stresses and tip chipping, which could leave debris. The design choice of a conical tip for a cannula, with its gradual increase in diameter from the tip to the base, is strategic in gently separating rather than cutting through tissue. This is vital in reducing trauma and minimizing the risk of complications where tissue integrity is important like in the lumbar region. Despite data indicating that conical tips require more force for entry compared to diamond, otherwise known as pyramidal tips, they result in less tissue deformation⁴. After consulting with a medical professional who confirmed the suitability of both designs, the team opted for the conical tip, largely due to its manufacturing advantages. The simplicity of the conical shape allows for a majority of the fabrication process to be

efficiently executed on a lathe, streamlining production without compromising on effectiveness or safety. The conical shape with a seamless fillet helps minimize any unintended collateral damage to the patient.

One important change to note about the Stylet CAD that happened during the FDR phase was the removal of the tapered section with threads, which was supposed to mate the Stylet Shaft to the handle. The team practiced manufacturing aluminum stock on a lathe prior to placing purchase orders to figure out if their manufacturing plan was valid. During these practice sessions, the team realized that it was nearly impossible to effectively lathe down a large stock to small diameters of 4mm and 4.5mm. For this reason, the team chose to source pre-sized stocks from McMaster-Carr and Alcobra Metals for both the Stylet Shaft and the Stylet Nub. This relates to the connection between the Stylet Shaft and handle because, without a larger stock, the team had no effective way to manufacture the threaded portion of the design. The team removed this feature, making the Stylet Shaft constant in outer diameter at the top. Further analysis was performed to validate this design change, as discussed in detail in **Appendix I**. With the removal of the threads and tapered section of the Stylet Shaft, the team added a tapered section to the handle. This can be seen at the bottom of the handle in **Figure H.2**. The connection between the Stylet Shaft and the handle now features a tight tolerance transition fit, as well as high-strength structural epoxy for extra security. The handle was also iterated on during the FDR phase, as the team designed a more ergonomic fit for the average-sized person's hand to grasp and easily rotate to be pushed down into the body and dock onto the bone. Other changes that were made to the Stylet CAD during the FDR phase happened with regards to the dimensions. The outer diameter of the Stylet Shaft was changed to match the dimensions of the pre-sized Stylet stock, which was sourced from Alcobra Metals. Similarly, the outer diameter of the Stylet Nub (along with the inner diameter of the Stylet hole) was changed to match the dimensions of the pre-sized Nub stock that was sourced from McMaster-Carr. Overall, the final Stylet featured three parts: the Stylet Shaft, which was a make part (though it was made from a buy part), the Stylet Nub, which was a make part (though it was again made from a buy part), and the Stylet handle, which was also a make part.

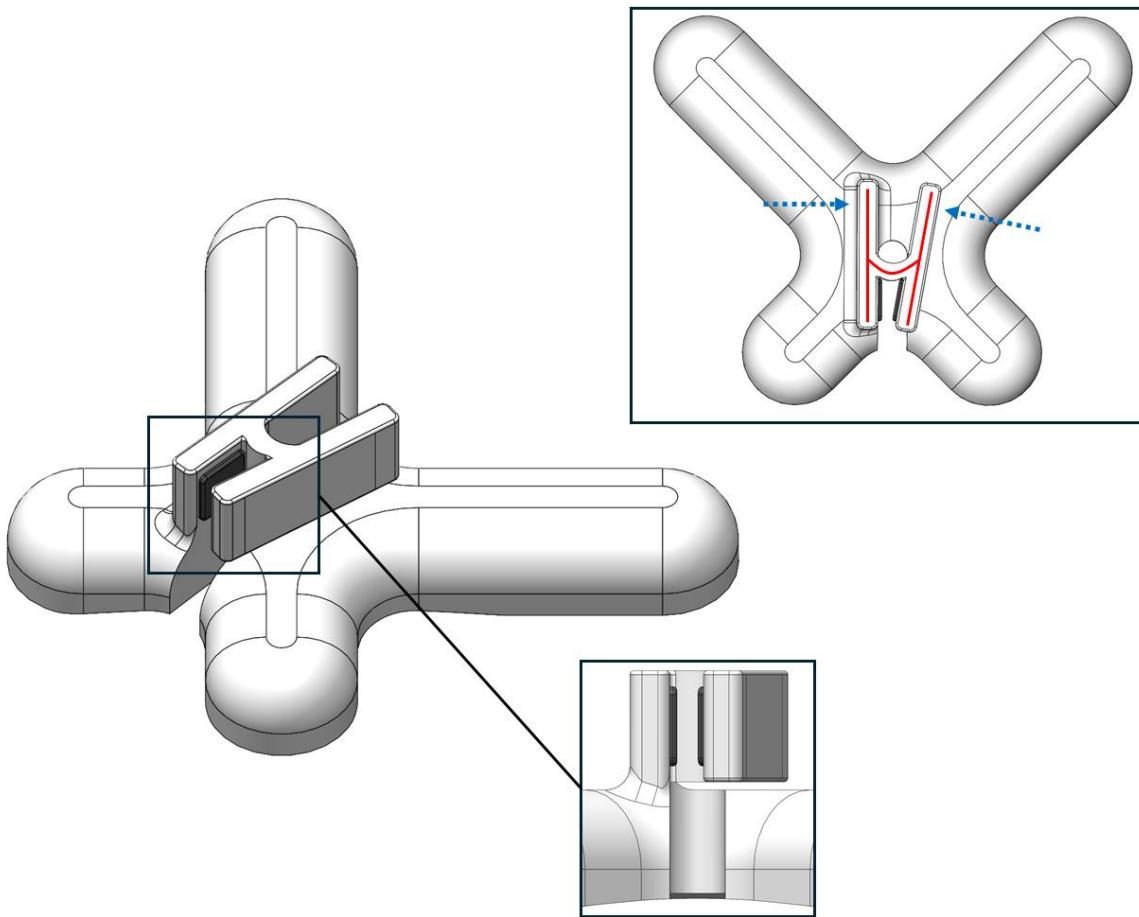


Figure H.3 Back Stabilizer CAD model, which features the compliant mechanism, the extended back legs, as well as the two parts that make up the Back Stabilizer assembly (Back Stabilizer base and rubber pads)

The Back Stabilizer is shown in **Figure H.3**, which has a large base that stabilizes the Portal after it is inserted and docked into the patient's body. One of the functional requirements of the Back Stabilizer is that it needs to lay and stabilize on the back of any patient. The team decided to add a concave-up feature to the bottom of the part, thus allowing the ends of the four legs to be the points in contact with the back at all times. Another feature of the Back Stabilizer is its clamp-like addition to the top. The functional requirement of this component is the need to clamp around the Portal to restrict Portal movement after the Back Stabilizer is inserted around the docked Portal. The team decided to utilize a compliant mechanism as the clamp. This choice reduces the price of the device by eliminating the need for separate components, like springs. By fixing only one side of the clip in a compliant mechanism, the design and manufacturing process is significantly streamlined. This eliminates the need for complex joints or additional

components associated with fully encased or two-sided fixation, thereby making the mechanism more cost-effective and simpler to produce, particularly with 3D printing. This cantilevered approach not only facilitates efficient stress distribution along the clip's length when force is applied – thereby minimizing the risk of failure – but also enhances design versatility. This approach allows for the customization of the clip's properties, such as thickness, material, and curvature, to meet specific force and deflection requirements, ensuring a tailored level of compliance and optimal force distribution. This design can also be easily modified to adjust features like clamp arm length, the thickness of the compliant “spring”, and the gap between the clamp's arms, in both the relaxed and tensioned states. The other important features to note in **Figure H.3**, seen in black, are the rubber pads that are epoxied to the inside face of the clamp arms to help restrict the Portal from moving. These are a much more minor part of the design, though their purpose is still crucial.

During the CDR phase, a preliminary prototype of the Back Stabilizer was manufactured to prove the viability of the design of this mechanism, and further adjustments were made based on the takeaways. Incorporating these adjustments, the arm lengths of the clip were increased to enhance compliance, facilitating a more adaptable and forgiving mechanism. Additionally, the orientation of the bend connecting the two arms, previously resembling a curve or a 'U' shape, was inverted. This strategic modification significantly improved the ease of operation, making the clip simpler to open and close. These refinements not only optimized the clip's functional performance but also underscored the iterative nature of design, where feedback and testing lead to modifications that refine the mechanism's overall efficacy and user experience.

During the FDR phase, the team 3D printed many iterations of the Back Stabilizer, keeping in mind that the customer needs to clamp the Portal with ease, but also be strong enough to restrict movement of the Portal. Through these iterations, the team updated the CAD many times. These updates happened specifically regarding the hinge thickness and arm lengths, as the team wanted to ensure proper forces were produced. The team was eventually able to find a good middle ground for these dimensions, as reflected in the final CAD. Another change that was made to the Back Stabilizer CAD during the FDR is that the back legs were extended in length. This was done because the team members realized that the ergonomics between the Back Stabilizer and the doctor's hand were poor due to the short legs. The lengthened legs are supposed to be able to better support the doctor's hand, as well as provide increased stabilization

leverage. Overall, the final Back Stabilizer featured two parts: the Back Stabilizer base, which was a make part, and the rubber pads, which were a buy part.

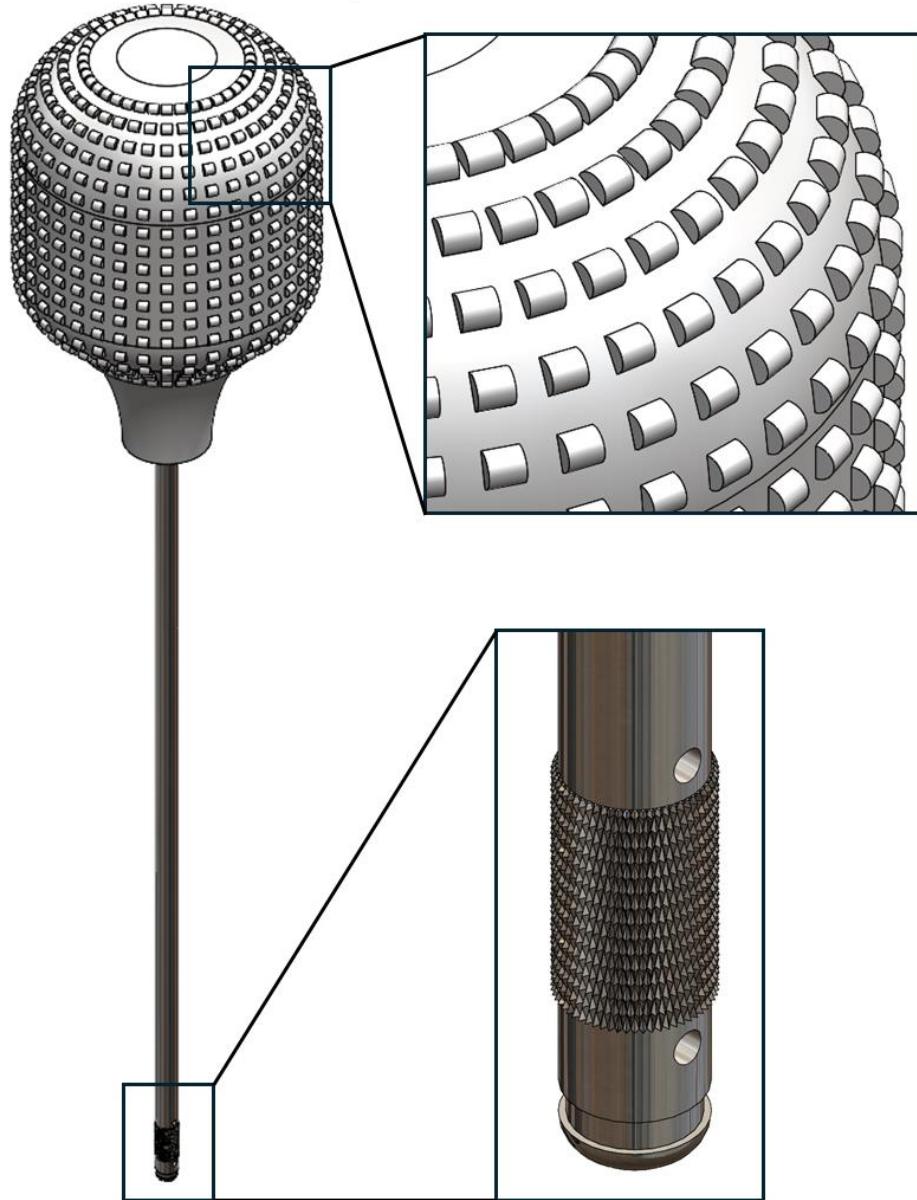


Figure H.4 Denervator CAD model, which features the knurled active cutting section, the handle grips, as well as the two parts that make up the Denervator assembly (Denervator Shaft and handle)

Lastly, the Denervator can be seen above in **Figure H.4** with a unique knurled bottom end effector and a handle on top. The functional requirement for the bottom of the tool is to lesion the nerve with the knurl-like end. The Denervator will be used on a very slight angle,

therefore the end of the tool needs to be smooth so that it does not harm the body around the nerve, while the knurled section does its job. The opposite end of the tool features another ergonomic handle for the doctor that can be twisted to leverage torsional force. This is accomplished using a bulbous-shaped handle that can be gripped by fingers and rest against the palm of a hand for axial exerted force or stability. The Denervator is further designed with patient safety in mind. The tip of the Denervator has a smooth section that spans 5mm from tip to knurl. The knurled section, also called the active cutting section, is 7mm and protrudes from the Denervator Shaft in order to lesion the nerve. This dimensioning also aligns with the Portal dimensions, as the active cutting section endpoint is flush with the end of the Portal, meaning doctors have elevated control over what is cut. As already mentioned, the tip is blunt in order to avoid severing additional structures deeper in the patient's lumbar region, which could lead to adverse side effects if sharp. These design features were specifically included in order to increase efficacy and ensure patient safety.

During the FDR phase, the Denervator CAD was notably changed. First off, the threaded and tapered section at the top of the Denervator Shaft (which served the purpose of connecting the Shaft to the handle) was removed from the design. The reasoning for this was the same as why the threaded and tapered section was removed from the Stylet, as the available manufacturing process did not permit it to be feasible. Therefore, the Denervator Shaft now connects to the handle via a tight tolerance transition fit and epoxy adhesion, just like the Stylet. Along these lines, the Denervator Shaft is now sourced from McMaster-Carr as pre-sized stock. Appropriate changes were made to the Denervator CAD to reflect the dimensions of this stock. Another notable change made to the Denervator design is the groove at the tip. This feature is 1mm in height and serves as a scale when the tool shows up on the X-ray imaging, helping the doctors establish intuition as to how deep the tools are within the patient's body. Another design change centered around the X-ray appearance of the Denervator was the addition of the two 1mm holes around the knurled section. These holes are designed to show up on X-ray imaging, and their purpose is to indicate to the doctors what the active cutting section is. The final change that was made during the FDR phase was the addition of grip bumps to the Denervator handle. After an iteration of the Denervator handle was 3D printed, the team realized that it was too smooth to provide good leverage. Therefore, the team designed grip bumps around the handle to provide the doctors with better torsional leverage when using the Denervator. Overall, the final

Denervator featured two parts: the Denervator Shaft, which was a make part (though it was made from a buy part), and the Stylet handle, which was also a make part.

I. Analysis

To ensure that the team's design is functional and meets all the engineering requirements, rigorous analysis was conducted in SolidWorks. This analysis not only helped verify the strength and effectiveness of the models but also gave valuable insight into how iterate on the designs. The team's designs were thus driven by the results of force modeling, finite element analysis (FEA) simulations, and thermal stress analysis.

Due to the nature of this product, no electronic components are present and thus electrical simulations and controls analysis were not performed. Mechanical and fluid dynamics analyses were also neglected as their results would provide no valuable information to the team. Analyses were only conducted in areas where potential failure points exist and required investigation, or a lack of critical information was present. Thus, all other regimes of analysis proved useless for the team to pursue.

I.1 Clamping Force Model

As later detailed in **Appendix J**, one of the biggest concerns in the design is whether the Portal will slip within the clamp on the Back Stabilizer. If the Portal does slip, it can cause serious collateral damage. To mitigate this risk, the team decided that the clamp on the Back Stabilizer should provide enough clamping force to prevent the Portal from slipping due to procedural force (with a built-in factor of safety of two). The first step for this design challenge is to identify what clamping force will be needed to prevent this from happening. Hand calculations were performed and can be detailed in **Section I.1.1**.

I.1.1 Required Clamping Force Analysis

FBD:

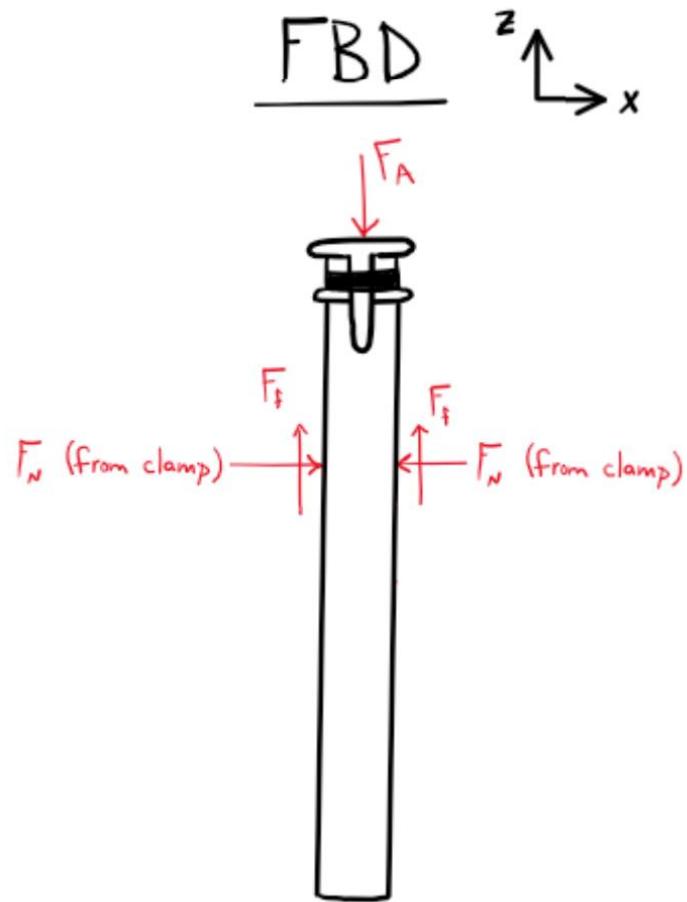


Figure I.1.1.1 FBD of the Portal when being clamped by the clamping mechanism and having an applied axial load

Assumptions:

- The Portal can be simplified to a cylindrical tube.
- The dry coefficient of static friction between the SAE 316L SS Portal and silicone rubber pads can be approximated as 0.64^9 .
 - Silicone rubber pads can be simplified as 60A rubber, which is commonly used in industrial applications⁴³.
 - SAE 316L SS can be simplified as SAE 316 SS considering all steels have nearly identical material properties.
- The maximum axial force to be applied onto the portal while the portal is clamped is 20N. This is according to the radial and axial vectors of force applied to the Portal during lesioning of the nerve. Since this will be performed at an angle, the 20N of procedural force magnitude is assumed to split into 10N radially and 17.5N axially. The axial force of 17.5N can then be conservatively rounded to 20N.
- A factor of safety of 2 is valid to use because the procedure and medical tools are highly controlled and their use is very certain (therefore, the model was designed to an axial force of 40N to account for this).

Variable Definitions:

- F_A : applied axial force on the Portal.
- F_f : frictional force between the Portal and rubber pads.
- F_N : normal force on the Portal from the clamp (in other words, this is the clamping force).
- μ_s : coefficient of static friction.

Known Values/Properties:

- $\mu_s = 0.64$
- $F_A = 40N$

Calculations:

Force balance:

$$\sum F_z = 2F_f - F_A = 0$$

Friction definition:

$$F_f = \mu_s F_N$$

Derivation:

$$2\mu_s F_N - F_A = 0$$

$$2\mu_s F_N = F_A$$

$$F_N = \frac{F_A}{2\mu_s}$$

Plug and solve:

$$F_N = \frac{40N}{2(0.64)}$$

$F_N = 31.25N$ (on either side; total clamping force is therefore 62.5N)

As noted in **Section I.1.1**, the clamping force required to prevent the Portal from slipping, according to a factor of safety of 2, is 62.5N. The team now knows that the clamp must be designed to provide a clamping force of 62.5N; this is a driving factor of the Back Stabilizer design.

The next step in this design challenge is to identify the critical dimensions of the clamping mechanism geometry according to this clamping force. The clamp is designed such that, in its relaxed state, the opening is narrower than the outer diameter of the Portal. Therefore, some sort of deflection must occur for the clamping mechanism to open and clamp around the Portal. When the Portal is then clamped by the clamping mechanism, it provides a normal force and subsequent deflection. Therefore, the team parametrized the clamping force according to the desired deflection and the clamping mechanism geometry. Bending-induced deflection hand calculations (following the strain-energy method taught in ME 323) were performed to achieve

this parametrization, considering the clamping mechanism is made of a relatively elastic material such as polypropylene. These calculations are detailed in **Section I.1.2**.

I.1.2 Generated Clamping Force Analysis

FBD:

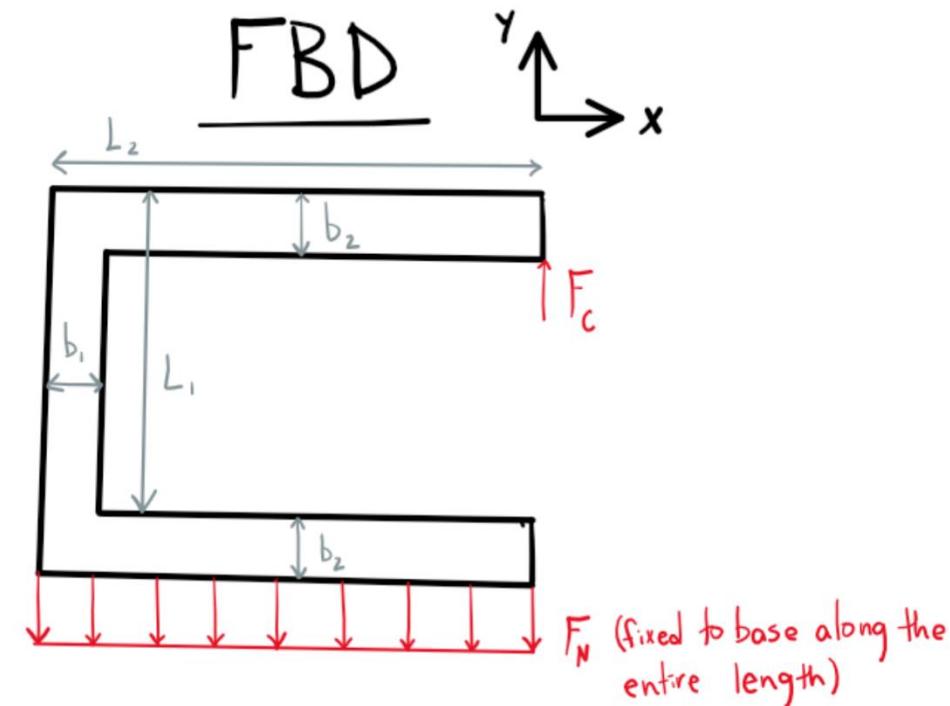


Figure I.1.2.1 FBD of the rectangularly simplified clamping mechanism with an applied force to deflect it open and a reactionary load due to the fixture to the base of the Back Stabilizer

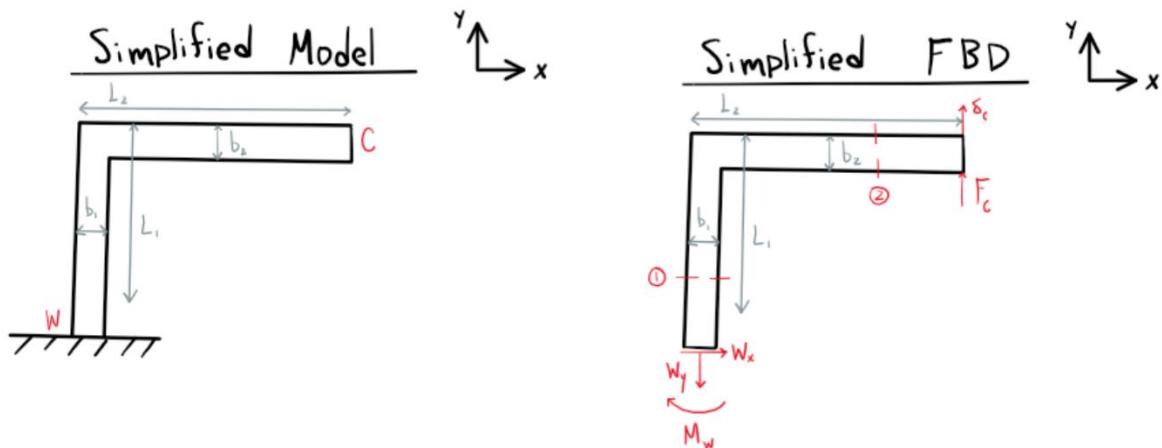


Figure I.1.2.2 Simplified model and FBD of the clamping mechanism (including locations for cuts)

Internal FBD's

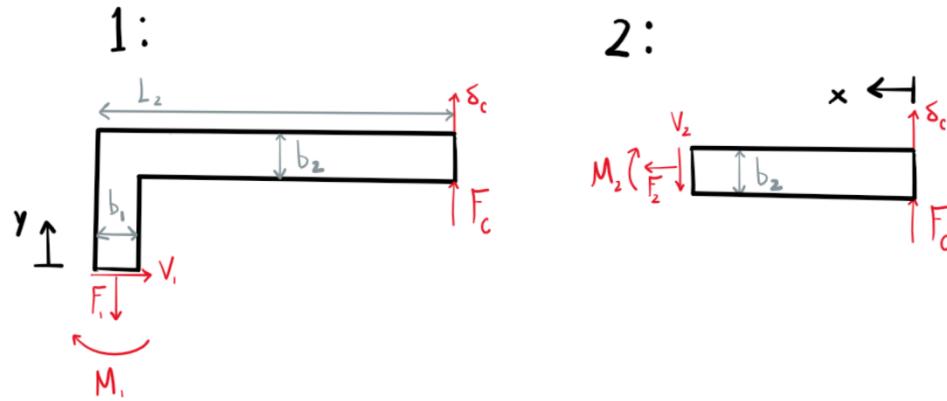


Figure I.1.2.3 Internal FBD's according to the two cuts

Assumptions:

- The clamp model can be simplified as rectangular beams in the shape of a “C” as opposed to a curved/filletted “C”.
- The bottom arm of the hinge can be modeled as a wall considering it is fixed to the Back Stabilizer base.
- Strain can be ignored.
- The actual measurements (e.g. height, h) of the CAD model can be used for calculations, though keeping the rectangular beam model.
- The clamp at point C needs to be displaced by, at maximum, 2.5mm (the displacement distance is the difference between the nominal distance between the clamp arms and the outer diameter of the Portal).
- The force to displace the clamp is equal to the clamping force of the clamp on the Portal.
- The modulus of elasticity of the polypropylene homopolymer material can be approximated as $1.3 \times 10^9 \text{ Pa}^{53}$.
 - The modulus of elasticity of Polycarbonate material can be approximated as $2.4 \times 10^9 \text{ Pa}^{51}$.

Variable Definitions:

- E : modulus of elasticity of polypropylene
- h : height of the clamping mechanism
- b_1 : thickness of the joint of the clamping mechanism
- b_2 : thickness of the arm of the clamping mechanism
- x : variable distance from point C according to cut 2
- A_1 : cross-sectional area of the joint according to cut 1
- I_1 : second moment of area of the cross-sectional area of the joint
- I_2 : second moment of area of the cross-sectional area of the arm
- F_C : clamping force
- F_1 and F_2 : axial force in the joint according to cut 1 and 2
- M_1 and M_2 : moment in the joint according to cut 1 and 2
- L_1 : length of the joint
- L_2 : length of the arm
- U_1 and U_2 : strain energy within the joint according to cut 1 and 2
- U : total strain energy
- δ_C : deflection of point C

Known Values/Properties:

- $E = 1.3 \times 10^9 Pa$
- $h = 13.500 mm = 0.0135 m$

Calculations:

Force balance:

$$\Sigma F_{y,1} = F_C - F_1 = 0$$

$$\Sigma M_1 = F_C L_2 - M_1 = 0$$

$$\Sigma F_{x,2} = -F_2 = 0$$

$$\Sigma M_2 = F_C x - M_2 = 0$$

Geometry:

$$A_1 = hb_1$$

$$I_1 = \frac{hb_1^3}{12}$$

$$I_2 = \frac{hb_2^3}{12}$$

Derivation:

$$F_1 = F_C$$

$$M_1 = F_C L_2$$

$$F_2 = 0$$

$$M_2 = F_C x$$

Strain-Energy Equation:

$$\begin{aligned} U_1 &= \frac{1}{2EA_1} \int_0^{L_1} F_1^2 dy + \frac{1}{2EI_1} \int_0^{L_1} M_1^2 dy \\ U_2 &= \frac{1}{2EI_2} \int_0^{L_2} M_2^2 dx \\ U &= U_1 + U_2 = \frac{1}{2EA_1} \int_0^{L_1} F_1^2 dy + \frac{1}{2EI_1} \int_0^{L_1} M_1^2 dy + \frac{1}{2EI_2} \int_0^{L_2} M_2^2 dx \end{aligned}$$

Solving Displacement:

$$\begin{aligned} \delta_C &= \frac{\partial U}{\partial F_C} = \frac{1}{EA_1} \int_0^{L_1} F_1 \frac{\partial F_1}{\partial F_C} dy + \frac{1}{EI_1} \int_0^{L_1} M_1 \frac{\partial M_1}{\partial F_C} dy + \frac{1}{EI_2} \int_0^{L_2} M_2 \frac{\partial M_2}{\partial F_C} dx \\ \delta_C &= \frac{F_1}{EA_1} \int_0^{L_1} dy + \frac{M_1}{EI_1} \int_0^{L_1} L_2 dy + \frac{1}{EI_2} \int_0^{L_2} M_2 x dx \\ \delta_C &= \frac{F_1 L_1}{EA_1} + \frac{M_1 L_2 L_1}{EI_1} + \frac{1}{EI_2} \int_0^{L_2} M_2 x dx \end{aligned}$$

$$\delta_c = \frac{F_c L_1}{EA_1} + \frac{F_c L_2^2 L_1}{EI_1} + \frac{1}{EI_2} \int_0^{L_2} F_c x^2 dx$$

$$\delta_c = \frac{F_c L_1}{EA_1} + \frac{F_c L_2^2 L_1}{EI_1} + \frac{F_c L_2^3}{3EI_2}$$

Solving for Force:

$$F_c = \left(\frac{L_1}{EA_1} + \frac{L_2^2 L_1}{EI_1} + \frac{L_2^3}{3EI_2} \right)^{-1} \delta_c$$

$$F_c = \left(\frac{L_1}{Ehb_1} + \frac{L_2^2 L_1}{E(hb_1^3/12)} + \frac{L_2^3}{3E(hb_1^3/12)} \right)^{-1} \delta_c$$

Plug and solve:

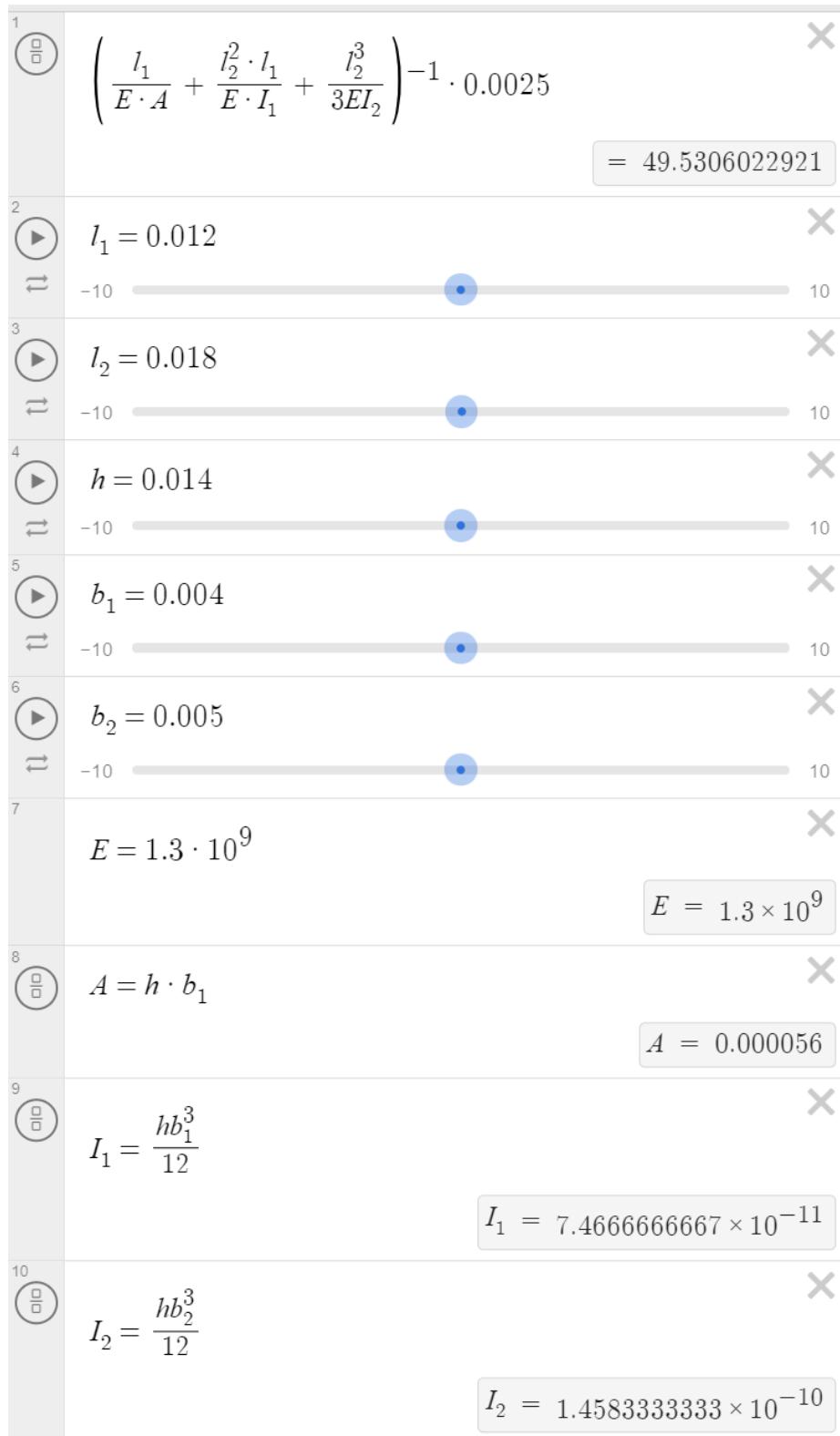
$$F_c = \left(\frac{L_1}{(0.0135m)(1.3 \times 10^9 Pa)b_1} + \frac{L_2^2 L_1}{(1.3 \times 10^9 Pa)((0.0135m)b_1^3/12)} \right.$$

$$\left. + \frac{L_2^3}{3(1.3 \times 10^9 Pa)((0.0135m)b_1^3/12)} \right)^{-1} \delta_c$$

$$F_c = \left(\frac{L_1}{(1.755 \times 10^7 N/m)b_1} + \frac{L_2^2 L_1}{(1.463 \times 10^6 N/m)b_1^3} \right.$$

$$\left. + \frac{L_2^3}{(4.388 \times 10^6 N/m)b_1^3} \right)^{-1} \delta_c$$

The result of **Section I.1.2** is a parametrized equation: the clamping force depends on the desired clamp deflection as well as the clamping mechanism geometry. This equation was scripted into the Desmos graphing calculator, as seen in **Figure I.1.2.4**, such that each variable has its own input. In this way, the geometrical effects on the clamping force could be easily studied. Through this calculator, it was found that the hinge thickness (b_1 in **Section I.1.2**) had the greatest impact on the clamping force. It was also found that the clamp arm thickness (b_2 in **Section I.1.2**), joint length (L_1 in **Section I.1.2**), and clamp height (h in **Section I.1.2**) had a noticeable effect on the clamping force. The team used these dimensions to iterate on the design of the Back Stabilizer to optimize the clamping force, as discussed in **Appendix H**.

**Figure I.1.2.4** Parametrized equation within the Desmos graphing calculator

It was great to establish a strong enough clamping force to mitigate any harmful risks. However, the team realized that there was a tradeoff between having a strong clamping force and requiring a small amount of force to open the clamp (which affects the ease of use of this design). Therefore, the team wanted to understand how best to limit this tradeoff. Hand calculations were done according to **Section I.1.3** to identify the controllable and significant dimensions of the clamping mechanism geometry.

I.1.3 Required Applied Force Analysis

FBD:

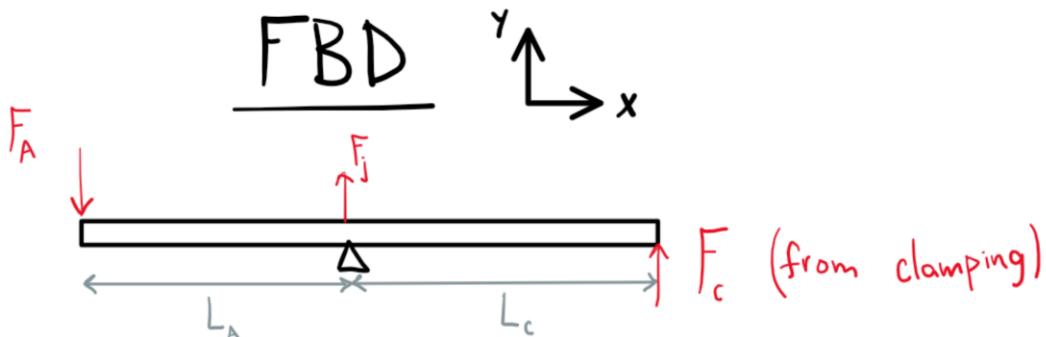


Figure I.1.3.1 FBD of the lever-simplified clamping arm

Assumptions:

- The clamp arm can be modeled as a level considering the joint in the middle is deformable.
- The clamping force acts at the tip of the clamping arm.
- The applied force to open the clamp acts at the tip of the pinch arm.
- The entire arm can be modeled as a uniform-geometry rectangle for simplification.

Variable Definitions:

- F_C : clamping force
- F_A : applied force
- L_C : distance between the joint and the front of the clamp
- L_A : distance between the joint and the back of the pinch arm

Known Values/Properties:

- N/A

Calculations:

Force balance:

$$\Sigma M_j = F_C L_C - F_A L_A = 0$$

Derivation:

$$F_A = \frac{L_C}{L_A} F_C$$

Section I.1.3 discovered that the clamp's arm and jaw lengths were the two critical dimensions as per the moment-arm model. Therefore, the findings from these hand calculations drove further design of the Back Stabilizer, as the team iterated on these dimensions to meet the desired opening force.

I.2 FEA Simulations

I.2.1 Stylet

The Stylet, as seen in **Figure I.2.1.1**, is primarily responsible for cutting and displacing flesh to allow for the Portal to enter the body. Thus, the team's primary concerns with this device were regarding the Stylet's tip and handle abilities in withstanding the procedural force. Since the tip of the Stylet converges to an extremely small point, the minuscule surface area would see large stresses. Furthermore, the T-Grip handle was very large in relation to the diameter of the Stylet and thus may induce large bending moments. Though fillets were added to minimize stress concentrations, FEA simulations were still run to ensure that all stresses experienced were under the yielding limits of every material used in the assembly. The loads applied were determined by the Engineering Specifications Chart (**Section G.3**) which already accounted for a factor of safety. Thus, the Stylet model would be deemed effective as long as the FEA-measured stresses of its critical features were anywhere under the yield point.



Figure I.2.1.1 CAD model of the Stylet assembly

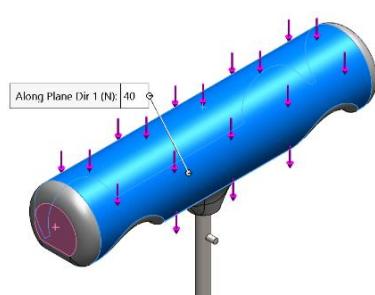
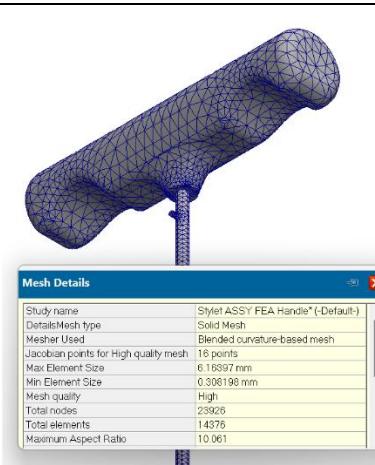
To configure the static structural simulations, materials were assigned, local interactions were created, a load was applied, and a resulting mesh was generated. The material assignments can be seen below in **Table I.2.1.1**.

Table I.2.1.1 Stylet Material Assignments

Stylet Body and Nub	Stylet Handle																																																															
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As seen above, the handle was assigned to PP homopolymer, and the body and Nub were assigned to SAE 316L. The remaining specifics regarding the configuration of the simulations can be found below in **Table I.2.1.2**.

Table I.2.1.2 Stylet Simulations Configuration

Bonded Local Interaction	Applied Load	Generated Mesh
		

As seen above, a 40N load was applied on the handle to account for a factor of safety of 2 on a very conservative procedural load estimation of 20N.

The first question the team needed to answer was if this applied load would deform the handle, Shaft, or tip when piercing the skin, the toughest part of the penetration. To test this, a fixture was applied at the tip to simulate resistance from the skin, as shown in the adjacent free body diagram (FBD) depicting this situation, as seen below in **Figure I.2.1.2**.

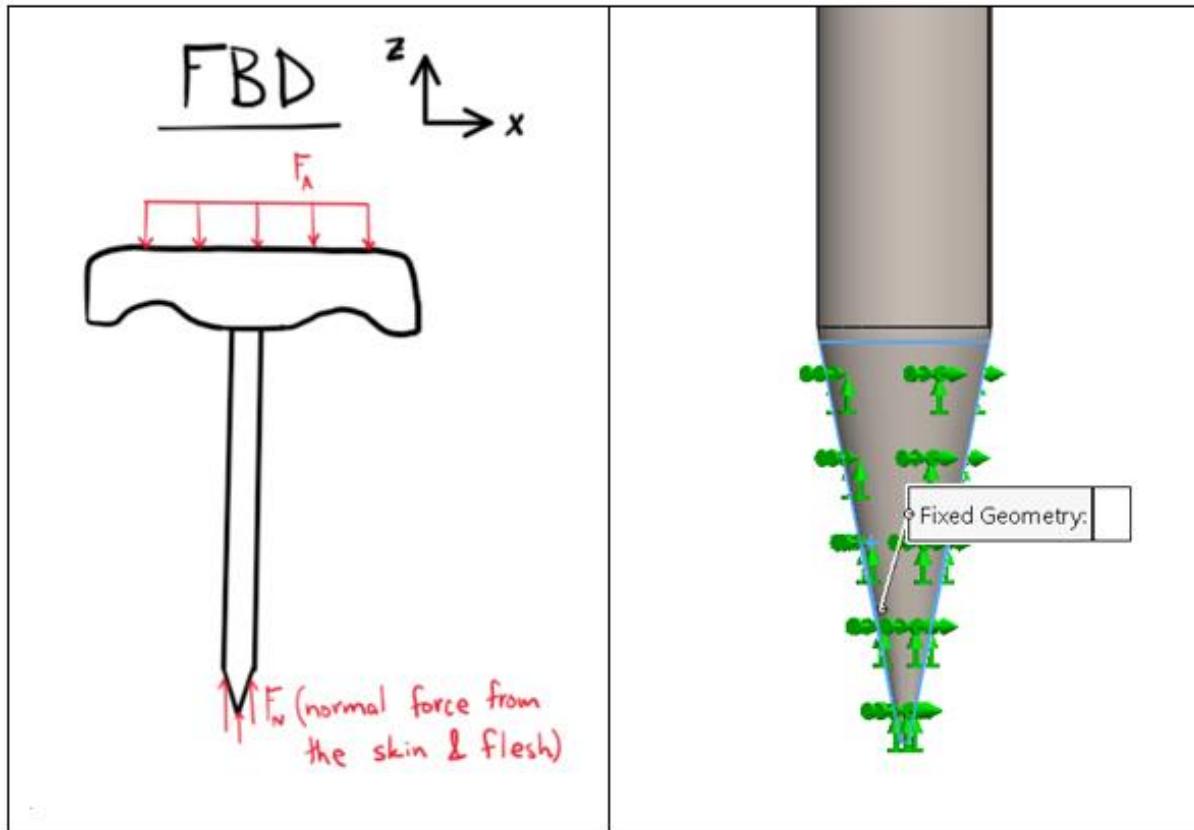
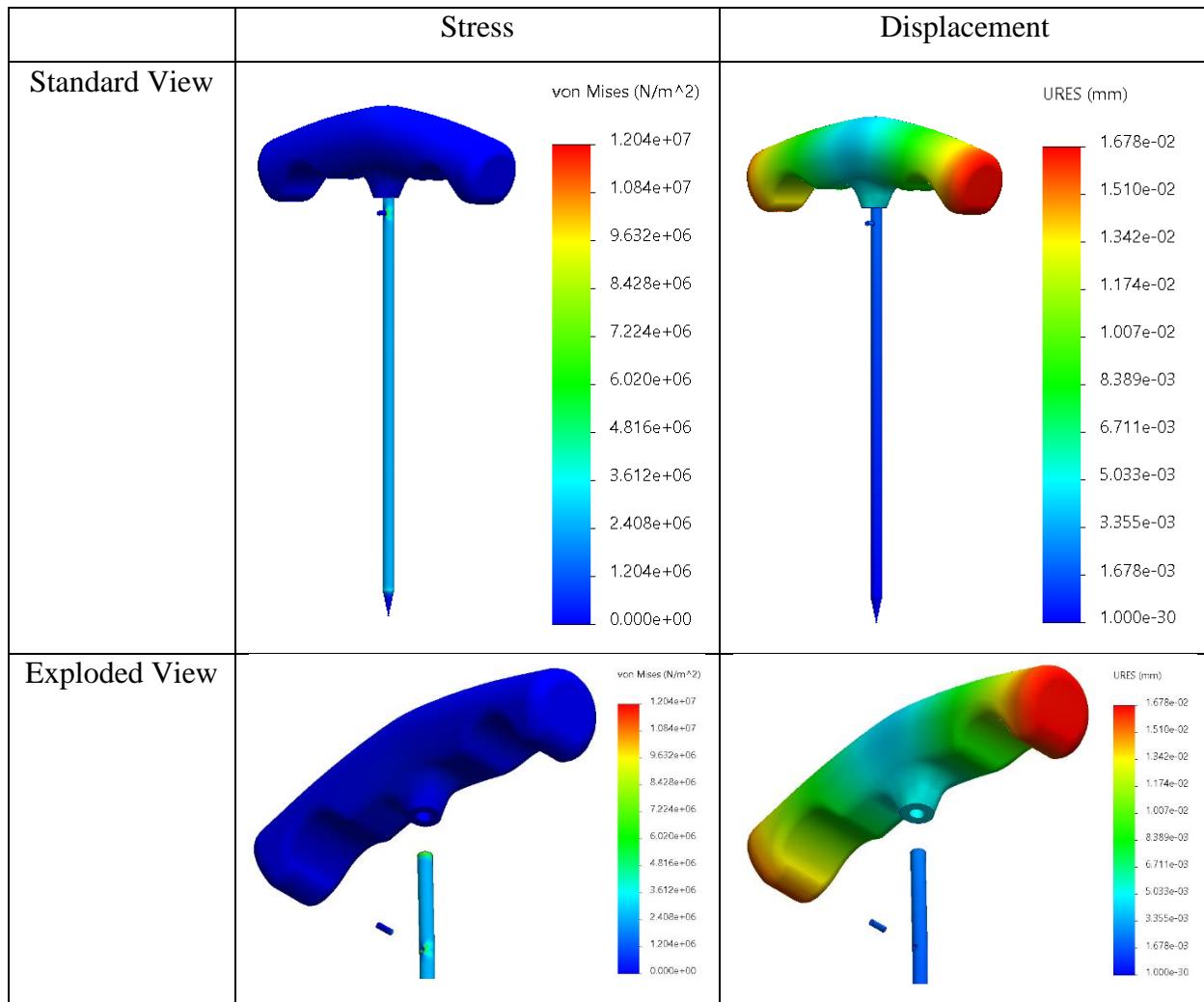


Figure I.2.1.2 A fixed geometry constraint being applied at the tip to simulate the Stylet's FBD

The stress and displacement results of this simulation, along with exploded views for viewing inside the assembly, can be seen below in **Table I.2.1.3**.

Table I.2.1.3 Stylet Deformation Results

These results prove that the displacement and deformation are negligible under this situation. It also highlights that all critical features of this device are within the yield limits of both materials. Thus, it can be safely concluded that the device can withstand procedural force in addition to a factor of safety.

The next question the team wanted to answer is if this applied load would deform the Nub of the Stylet when boring through the flesh and driving the Portal with it. It can be assumed that the circumferential resistance from the flesh along the shaft of the Portal would create a reactionary force primarily on the Nub of the Stylet. To test this, a fixture was applied at the Nub to simulate frictional resistance from the Portal, as shown in the adjacent free body diagram (FBD) depicting this situation, as seen below in **Figure I.2.1.3**.

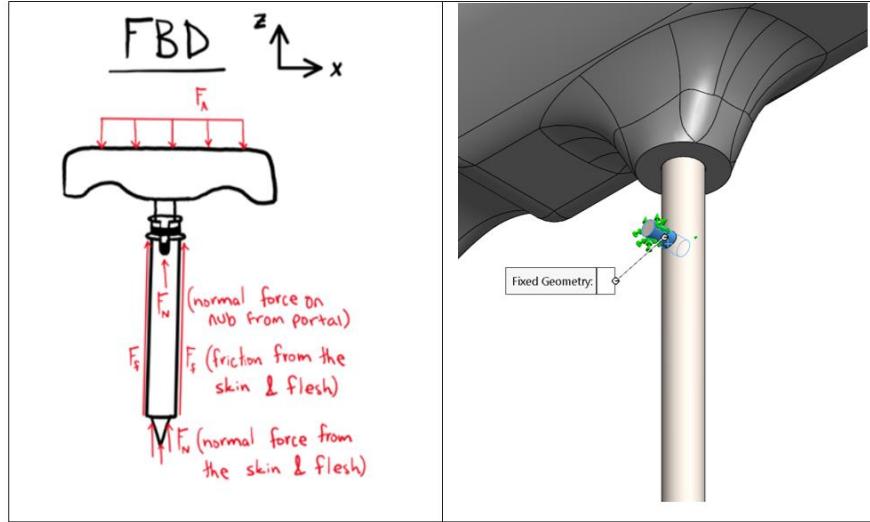
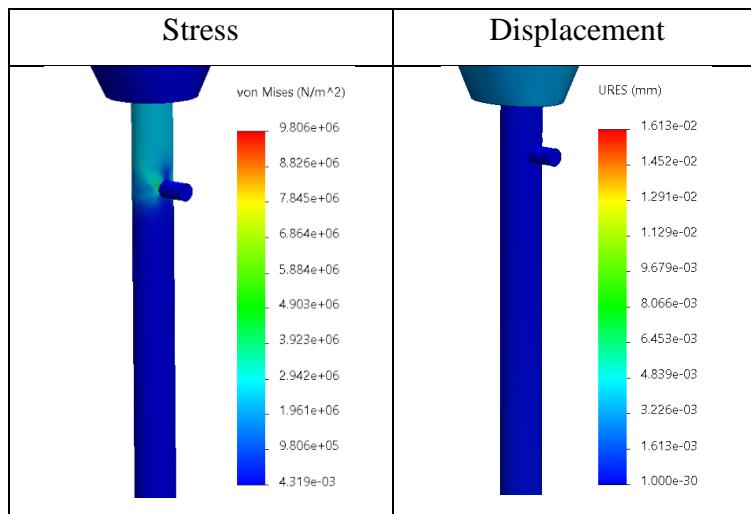


Figure I.2.1.3 A fixed geometry constraint being applied at the Nub to simulate the Stylet's FBD

The stress and displacement results of simulating a normal force on the Stylet's Nub can be seen below in **Table I.2.1.4**.

Table I.2.1.4 Stylet Nub Deformation Results



The conclusions of these results are the same as before: deformation is negligible, and all critical features remain under the yield points of both materials. Thus, when the Stylet is being pushed into the Portal, it is safe to conclude that the Nub can handle all of the procedural force in addition to a factor of safety.

I.2.2 Portal

The Portal, as seen in **Figure I.2.2.1**, is primarily responsible for guiding devices into the body and creating a direct pathway to the area of interest, the pedicle. To do this, the Portal must work in collaboration with the Stylet to bore through the flesh. The Portal must be rotationally and vertically interlocked with the Stylet as the Stylet drives the Portal into the body. This interlocking is achieved through a small C-Ring that rotates in a channel in the Portal Sleeve to lock the Nub in place. The C-Ring is slightly pried open at the expense of elastic deformation to assemble it onto the Sleeve – this is a one-time action. Thus, the team expressed concerns in ensuring the required deflection to expand the jaws of the C-Ring to fit around the Sleeve's diameter would not induce yielding. By subtracting the nominal gap between the idle C-Ring from the Sleeve diameter, a deflection requirement was found. Through an iterative process, the minimum force required to achieve such a deflection was found through FEA simulations.

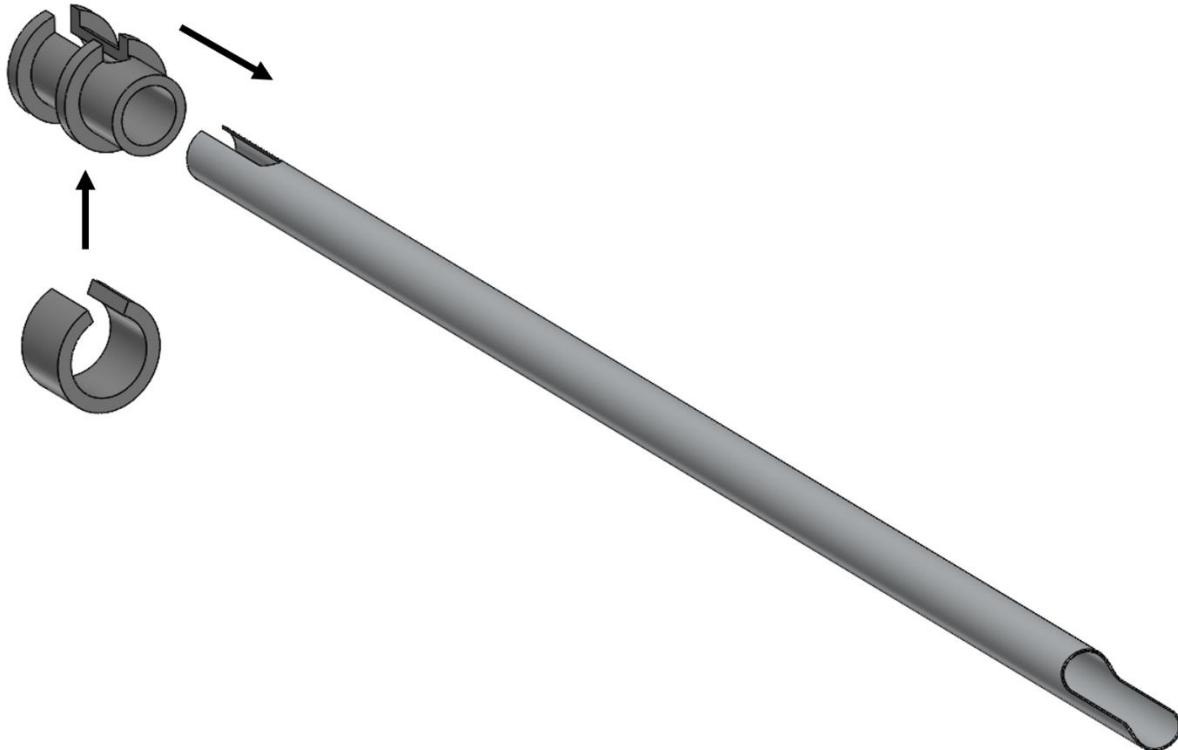
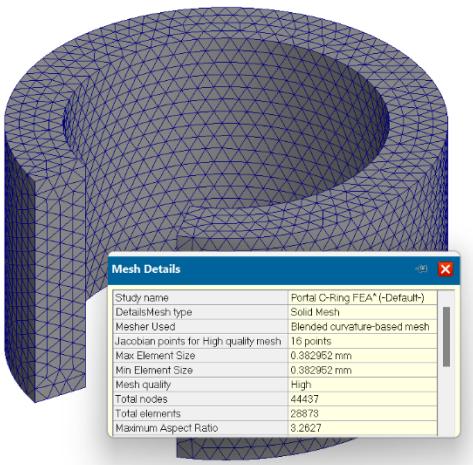
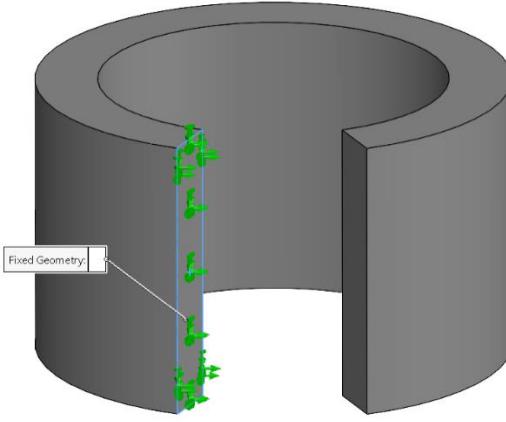
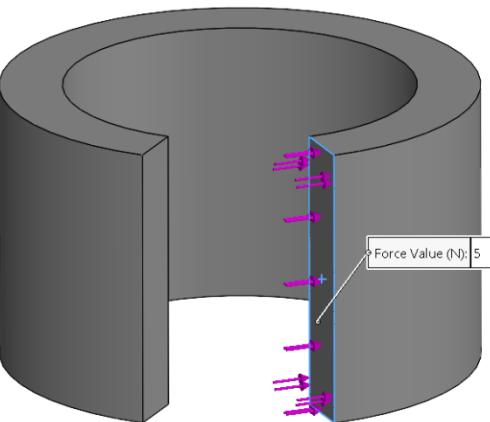


Figure I.2.2.1 CAD model of the Portal assembly with the C-Ring and Sleeve

To configure this static structural simulation, a material was assigned, a load and fixture were applied, and a resulting mesh was generated. The specifics of this simulation configuration can be found below in **Table I.2.2.1**.

Table I.2.2.1 C-Ring Simulation Configuration

Material	Generated Mesh																																																								
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As seen above, 5N of force was required to pry open the C-Ring to a deflection of the required deflection of approximately 2mm. The loads and fixtures were applied to be consistent with the FBD depicting this event as seen below in **Figure I.2.2.2**.

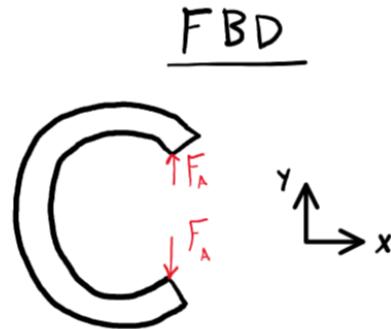
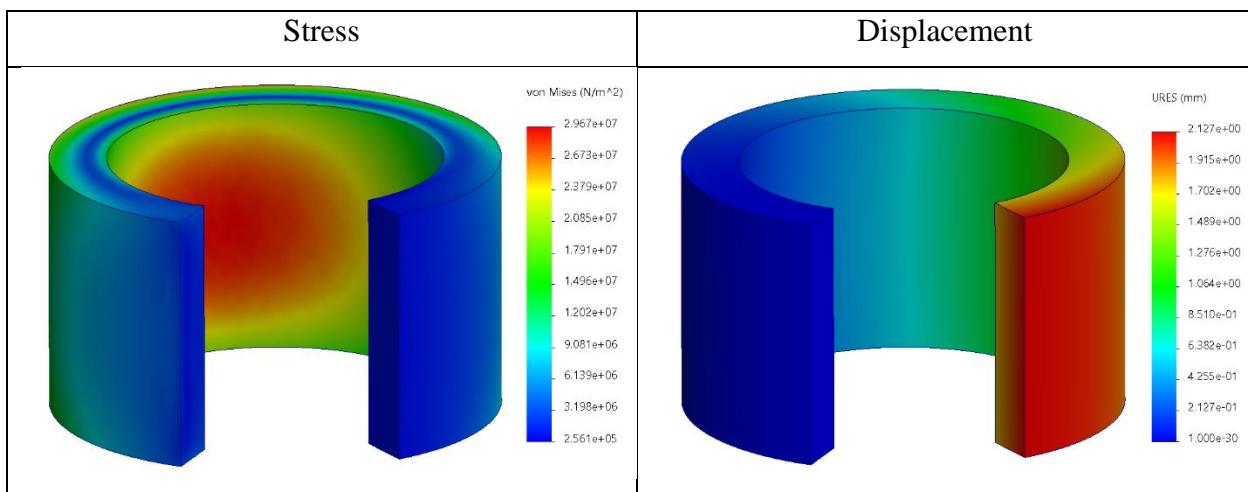


Figure I.2.2.2 An FBD of the C-Ring when being pried open

The team decided that a factor of safety of 1 was sufficient as there was little to no uncertainty to be involved with this situation. This deflection will only occur in a controlled environment by trained technicians during the initial assembly of the Portal. The end-user will never need to remove or re-insert the C-Ring and thus the thickness can be minimized at the expense of higher stresses to reduce mass, weight, and difficulty of assembly. The stress and displacement results of this simulation can be seen below in **Table I.2.2.2**.

Table I.2.2.2 Stylet Deformation Results



These results prove that to achieve the required 2mm deflection in the C-Ring to expand the gap, a 5N force is sufficient. It also proves that the C-Ring will not yield under this force. Thus, it can be safely concluded that the C-Ring will not permanently deform whilst being affixed onto the Portal Sleeve during initial assembly.

In addition to working with the Stylet, the Portal also has a key function of guiding all devices to the pedicle. Thus, it requires stabilization support from the Back Stabilizer which clamps onto the Portal with a clamping force of 62.5N as derived in **Section I.1.1**. The team had two primary concerns with this scenario. Not only should the clamping force not induce plastic deformation on the Portal, but it should also not induce significant elastic deformation and cause the Portal shell to collapse in on any of the tools within it, which would cause significant frictional resistance with the tools inside the Portal and hinder the procedure. Due to the extremely thin wall thickness (0.25mm), yielding and displacement of the stainless steel was a reasonable concern for the team.

These concerns were addressed by creating a static structural simulation to be congruent with the FBD, as seen below in **Figure I.2.2.3**, depicting this event.

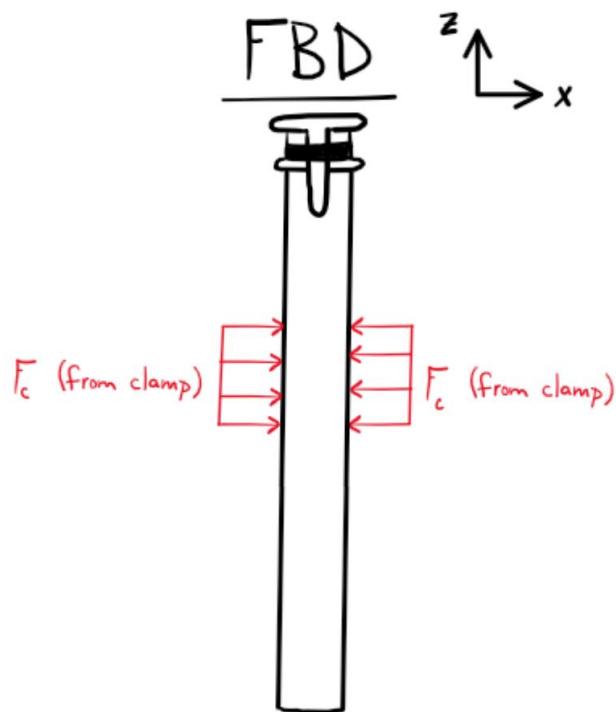
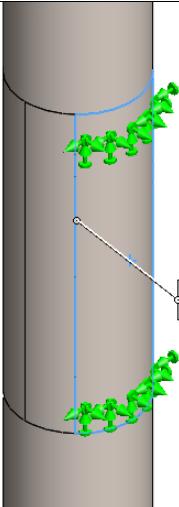
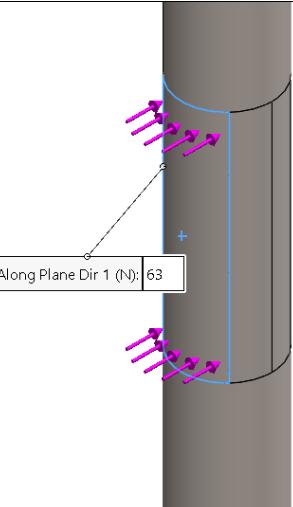


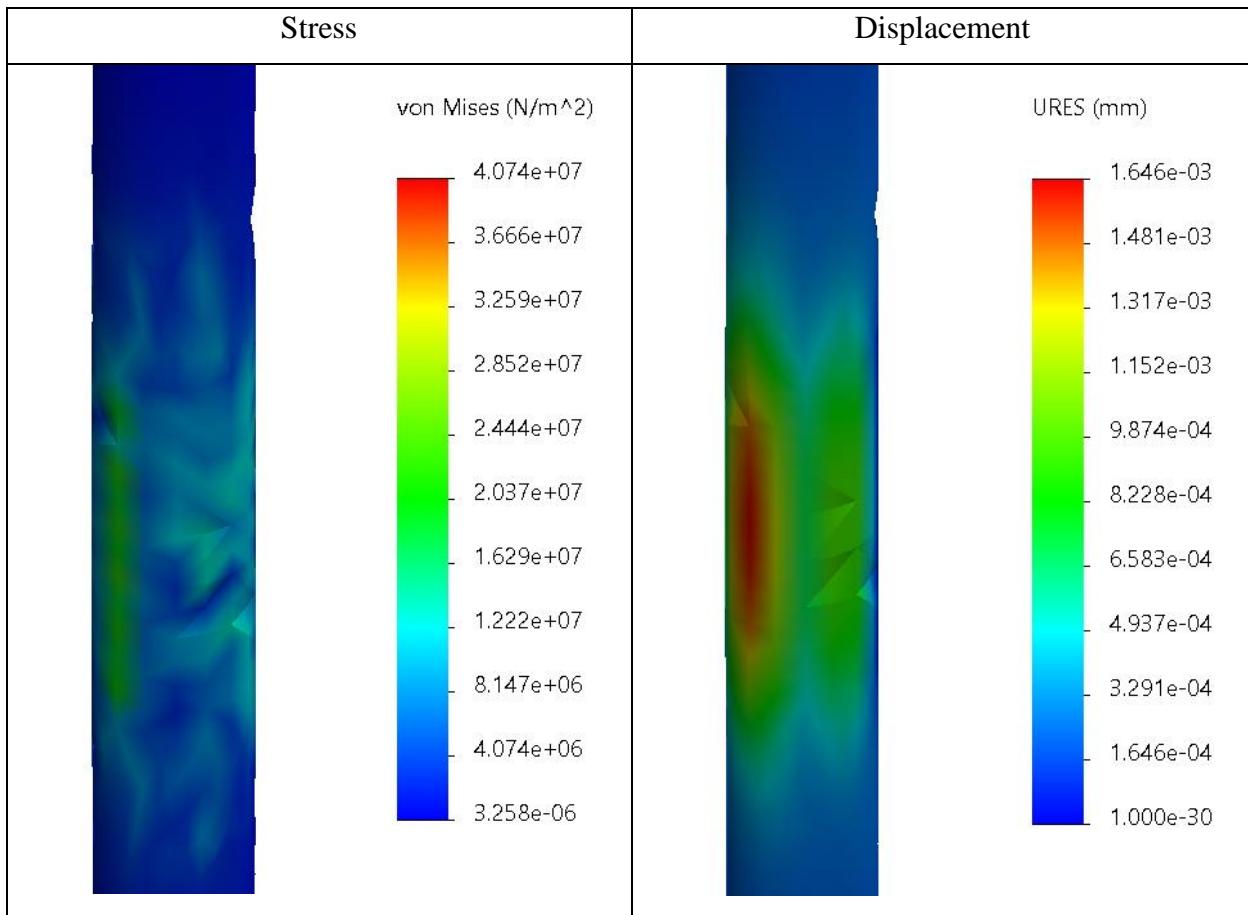
Figure I.2.2.3 An FBD of the Portal when being clamped on by the Back Stabilizer

To configure this simulation, a material was assigned, a load and fixture were applied, and a resulting mesh was generated, as seen below in **Table I.2.2.3**.

Table I.2.2.3 Portal Simulation Configuration

Material	Generated Mesh																																																	
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 <p>Fixed Geometry</p>	 <p>Along Plane Dir 1 (N): 63</p>																																																	

As seen above, opposite sides of the Portal saw a load and fixed constraints to simulate being clamped on. The size of the faces experiencing this load and fixture were equivalent to the height of the Back Stabilizer's jaws. The results of this study can be seen below in **Table I.2.2.4**.

Table I.2.2.4 Portal Deformation Results

The conclusions of these results are promising. The yielding is within the limits of the material and the elastic deformation is as low as 0.0016mm and is thus negligible. Therefore, it is safe to conclude that the Back Stabilizer will not inhibit the procedure or damage the Portal while clamping on it.

I.2.3 Back Stabilizer

The Back Stabilizer, as seen in **Figure I.2.3.1**, is a crucial device as it stabilizes all invasive tools, such as the Portal, Stylet, and Denervator when entering the patient's body. It achieves this through a clamping mechanism to vertically constrain the Portal while also leveraging Hertzian contacts to allow the Portal to rotate about the phantom axis created by such a contact. The team's primary concern was thus to ensure that the force required to open the jaws of the clamp is not extreme and that the "hinge" of the clamp does not yield. To test this, the difference between the Portal diameter and the relaxed distance between the inner rubber pads of the clamp's jaws were taken as the required minimum displacement necessary to insert the Portal within the jaws of the clamp. The measurements were taken at the tip to determine the maximum displacement to be produced from standard usage as the tip is the constraining factor for the Portal to enter the jaws. Although the silicone rubber pads should've been modeled as soft bodies since they are intended to deform, they were not for the purposes of simplicity and to offer a more conservative estimate of the force required to open the jaws.

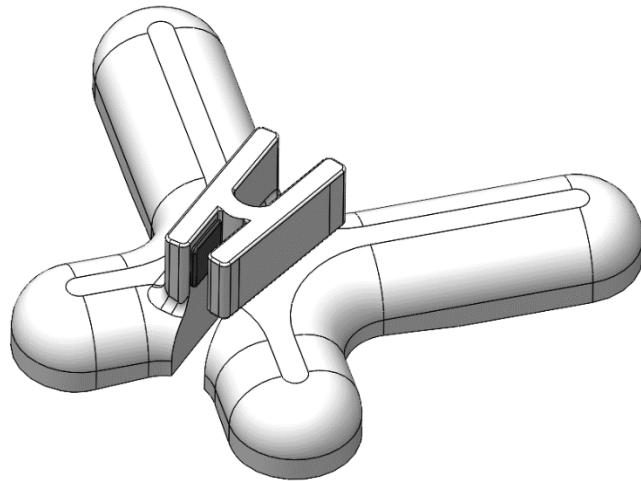


Figure I.2.3.1 CAD model of the Back Stabilizer assembly

Through an iterative process, the applied force necessary to produce the required displacement was found through FEA simulations. A factor of safety was not applied to this displacement requirement for many reasons. As addressed in **Section I.1.2**, the hinge thickness was the primary factor contributing to the clamping force. Increasing that thickness would not only increase the force required to open the jaws, thus reducing ease-of-use, but would also

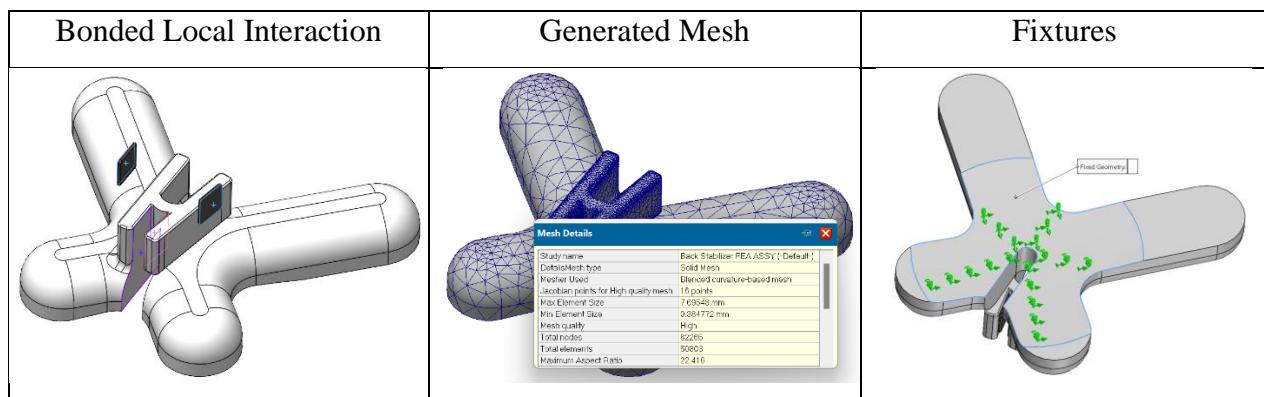
increase the clamping force to a point where it would be difficult to position and rotate the Portal while clamped. Since the end-users are to be professionals who will be trained on the procedure, it is safe to assume that the device will be used in a controlled environment with minimal uncertainty, thus warranting the lack of a factor of safety.

To configure this static structural simulation, materials were assigned, local interactions were created, a fixture was applied, and a resulting mesh was generated. The material assignments can be found in **Table I.2.3.1** and specifics of this configuration in **Table I.2.3.2**.

Table I.2.3.1 Back Stabilizer Material Assignments

Back Stabilizer Material	Rubber Pads Material																																																																								
<div style="border: 1px solid black; padding: 10px;"> <p>Material properties Materials in the default library can not be edited. You must first copy the material to a custom library to edit it.</p> <p>Model Type: Linear Elastic Isotropic <input type="checkbox"/> Save model type in library</p> <p>Units: SI - N/m² (Pa) <input type="checkbox"/></p> <p>Category: 463Materials</p> <p>Name: PP Homopolymer</p> <p>Default failure criterion: Unknown <input type="checkbox"/></p> <p>Description: PP-Homopolymer.unfilled</p> <p>Source:</p> <p>Sustainability: PP Homopolymer in SOLIDWORKS Materials <input type="checkbox"/> Select...</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Property</th> <th>Value</th> <th>Units</th> </tr> </thead> <tbody> <tr> <td>Elastic Modulus</td> <td>1300000000</td> <td>N/m²</td> </tr> <tr> <td>Poisson's Ratio</td> <td>0.42</td> <td>N/A</td> </tr> <tr> <td>Shear Modulus</td> <td></td> <td>N/m²</td> </tr> <tr> <td>Mass Density</td> <td>933</td> <td>kg/m³</td> </tr> <tr> <td>Tensile Strength</td> <td>32000000</td> <td>N/m²</td> </tr> <tr> <td>Compressive Strength</td> <td>39300000</td> <td>N/m²</td> </tr> <tr> <td>Yield Strength</td> <td>33000000</td> <td>N/m²</td> </tr> <tr> <td>Thermal Expansion Coefficient</td> <td>9e-05</td> <td>/K</td> </tr> <tr> <td>Thermal Conductivity</td> <td>0.117</td> <td>W/(mK)</td> </tr> <tr> <td>Specific Heat</td> <td></td> <td>J/kg/K</td> </tr> <tr> <td>Material Damping Ratio</td> <td></td> <td>N/A</td> </tr> </tbody> </table> </div>	Property	Value	Units	Elastic Modulus	1300000000	N/m ²	Poisson's Ratio	0.42	N/A	Shear Modulus		N/m ²	Mass Density	933	kg/m ³	Tensile Strength	32000000	N/m ²	Compressive Strength	39300000	N/m ²	Yield Strength	33000000	N/m ²	Thermal Expansion Coefficient	9e-05	/K	Thermal Conductivity	0.117	W/(mK)	Specific Heat		J/kg/K	Material Damping Ratio		N/A	<div style="border: 1px solid black; padding: 10px;"> <p>Material properties Materials in the default library can not be edited. You must first copy the material to a custom library to edit it.</p> <p>Model Type: Linear Elastic Isotropic <input type="checkbox"/> Save model type in library</p> <p>Units: SI - N/m² (Pa) <input type="checkbox"/></p> <p>Category: 463Materials</p> <p>Name: Silicon Rubber</p> <p>Default failure criterion: Unknown <input type="checkbox"/></p> <p>Description:</p> <p>Source:</p> <p>Sustainability: Silicon Rubber in SOLIDWORKS Materials <input type="checkbox"/> Select...</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Property</th> <th>Value</th> <th>Units</th> </tr> </thead> <tbody> <tr> <td>Elastic Modulus</td> <td>1670000</td> <td>N/m²</td> </tr> <tr> <td>Poisson's Ratio</td> <td>0.33</td> <td>N/A</td> </tr> <tr> <td>Shear Modulus</td> <td></td> <td>N/m²</td> </tr> <tr> <td>Mass Density</td> <td>1246.5</td> <td>kg/m³</td> </tr> <tr> <td>Tensile Strength</td> <td>6000000</td> <td>N/m²</td> </tr> <tr> <td>Compressive Strength</td> <td></td> <td>N/m²</td> </tr> <tr> <td>Yield Strength</td> <td>10400000</td> <td>N/m²</td> </tr> <tr> <td>Thermal Expansion Coefficient</td> <td>0.00025</td> <td>/K</td> </tr> <tr> <td>Thermal Conductivity</td> <td>0.2</td> <td>W/(mK)</td> </tr> <tr> <td>Specific Heat</td> <td>1300</td> <td>J/kg/K</td> </tr> <tr> <td>Material Damping Ratio</td> <td></td> <td>N/A</td> </tr> </tbody> </table> </div>	Property	Value	Units	Elastic Modulus	1670000	N/m ²	Poisson's Ratio	0.33	N/A	Shear Modulus		N/m ²	Mass Density	1246.5	kg/m ³	Tensile Strength	6000000	N/m ²	Compressive Strength		N/m ²	Yield Strength	10400000	N/m ²	Thermal Expansion Coefficient	0.00025	/K	Thermal Conductivity	0.2	W/(mK)	Specific Heat	1300	J/kg/K	Material Damping Ratio		N/A
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Table I.2.3.2 Back Stabilizer Jaw Displacement Simulation Configuration



To simulate pinching the arms to open the jaws, as depicted by the adjacent FBD, a load was applied, as seen in **Figure I.2.3.2**, to test if this would achieve the necessary displacement required to fit the Portal in the jaws of the clamp.

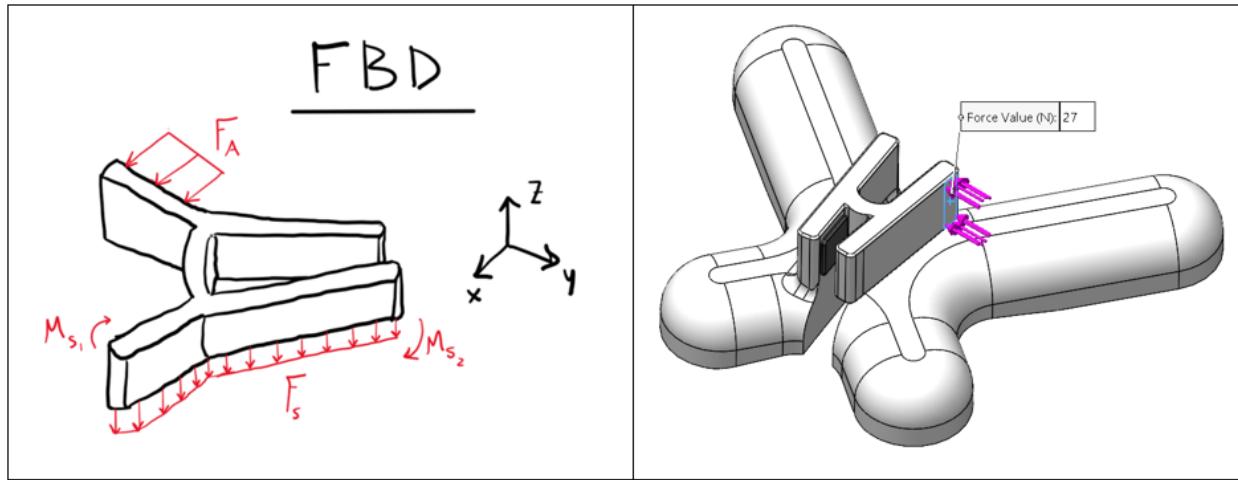
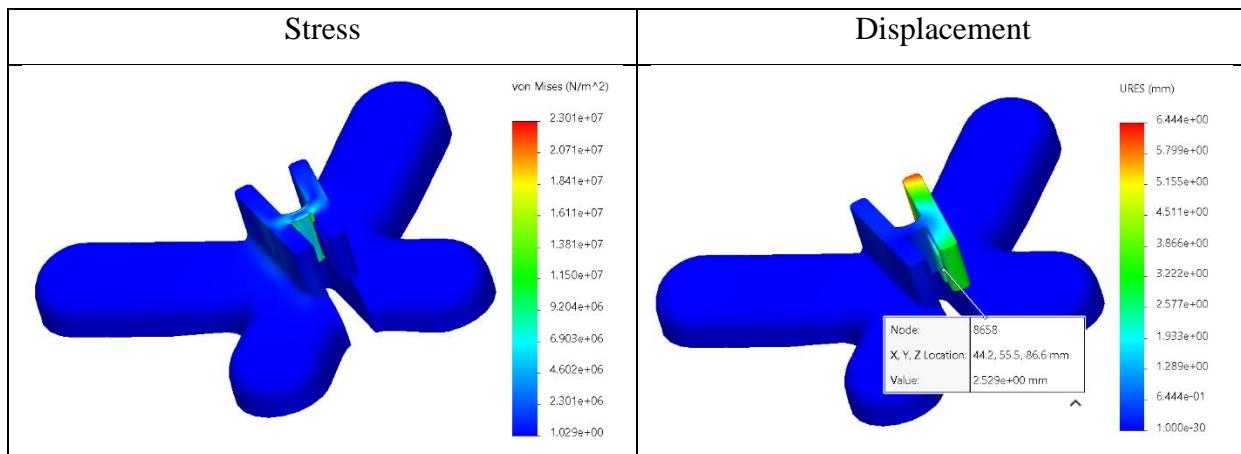


Figure I.2.3.2 Load applied to the clamp to simulate the FBD (left)

The stress and displacement results of simulating this applied force on the Back Stabilizer can be seen below in **Table I.2.3.3**.

Table I.2.3.3 Back Stabilizer Jaw Displacement Simulation Results



As seen above, the simulation proves that the 27N of applied force at the arms was enough to create a 2.5mm displacement at the tip. This is enough to increase the 2.65mm relaxed jaw gap to at least 5.15mm to allow the Portal to easily slip in between the jaws. Furthermore, the critical features of the Back Stabilizer were under the yielding point of the material. Therefore, it can safely be concluded that the device can withstand the applied force of opening the jaws to allow the Portal to enter the jaw gap.

Although a factor of safety wasn't applied to the required displacement to protect from yielding, one was incorporated into the intrinsic design and dimensions of the Back Stabilizer. As calculated in **Section I.1.1**, the required clamping force was already cushioned by a factor of safety of 2 based on the estimated procedural force to be applied via the Portal. This requirement then drove the design of the Back Stabilizer and thus the clamping force exhibited by the Back Stabilizer contains a factor of safety.

The hand calculations described in **Section I.1.2** gave the team good insight into which critical geometry influenced the clamping force the most. Several FEA simulations were run as part of an iterative process to identify the clamping force produced by the Back Stabilizer based on the new dimensions. The same configuration as mentioned earlier was leveraged for this simulation as well, with the only difference being the loads applied. While clamping, the Portal will exhibit an equal and opposite reactionary normal force on the jaws equaling the clamping force applied on the Portal. Thus, by simulating the outward normal force on the jaws, the magnitude of the equivalent clamping force can be determined. The loads being applied can be seen below in **Figure I.2.3.3**.

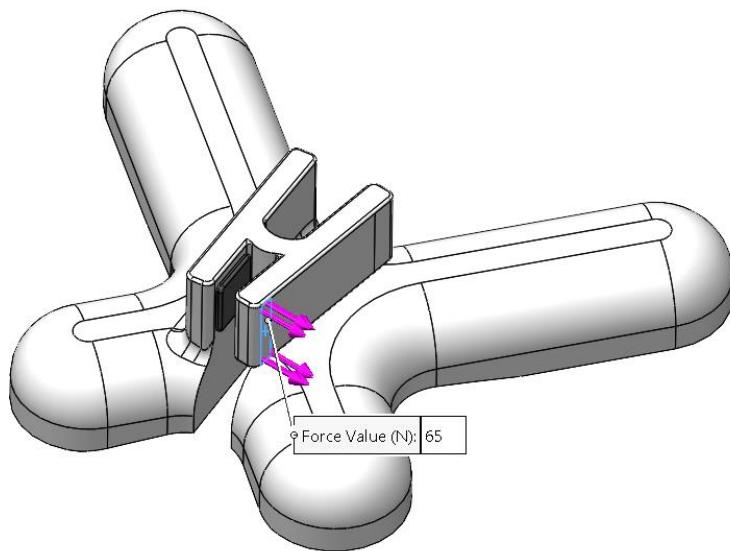


Figure I.2.3.3 Produceable clamping force being tested at required displacement

The displacement results corresponding to the clamping force produced can be seen below in **Figure I.2.3.4**.

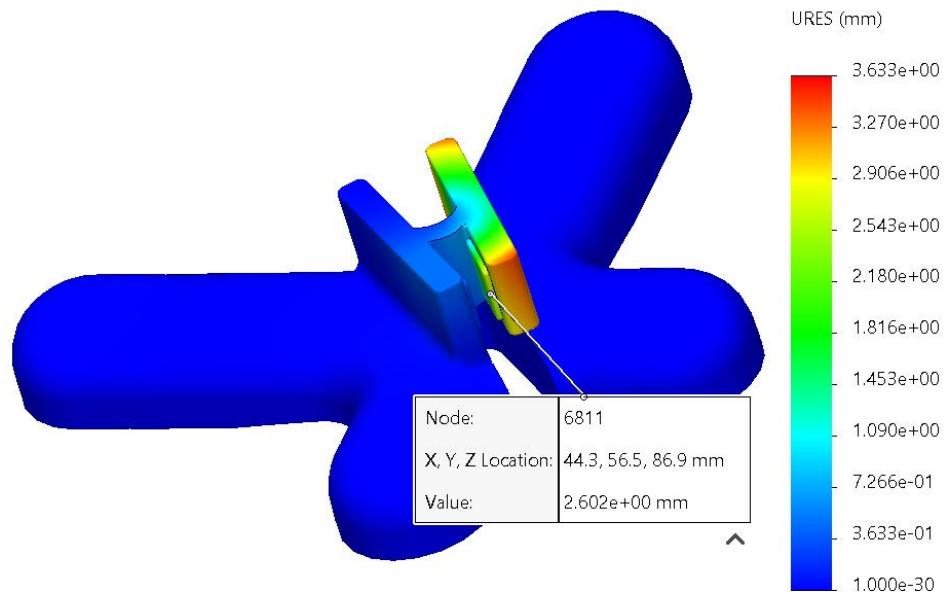


Figure I.2.3.4 Resulting displacement corresponding to the clamping force being tested

As seen above, the simulation proves that for a 2.6mm displacement, 65N of clamping force is produced. Thus, the clamping force is larger than needed. However, this force was applied at the tip of the jaw and is not a good representation of where the Portal will typically be clamped – near the center. The effective clamping force at the center will thus be lower and closer to the target value of 62.5N.

In summary, these results confirm that 27N of applied force at the arms will allow the Back Stabilizer to open its jaws enough to accept a 5.15mm-diameter Portal and produce 65N of clamping force without yielding at any of the critical features.

I.2.4 Denervator

The Denervator, as seen in **Figure I.2.4.1**, is primarily responsible for grinding the medial branch nerve (MBN). As per the research highlighted in **Section G.1**, the team decided that the most effective option would be to grind the nerve, as opposed to a perpendicular transection, and target the pedicle parallel to the nerve. This method would thus induce axial and bending stresses on the Denervator. As a result, the team's primary concerns were ensuring such stresses would not induce yielding under the procedural force.

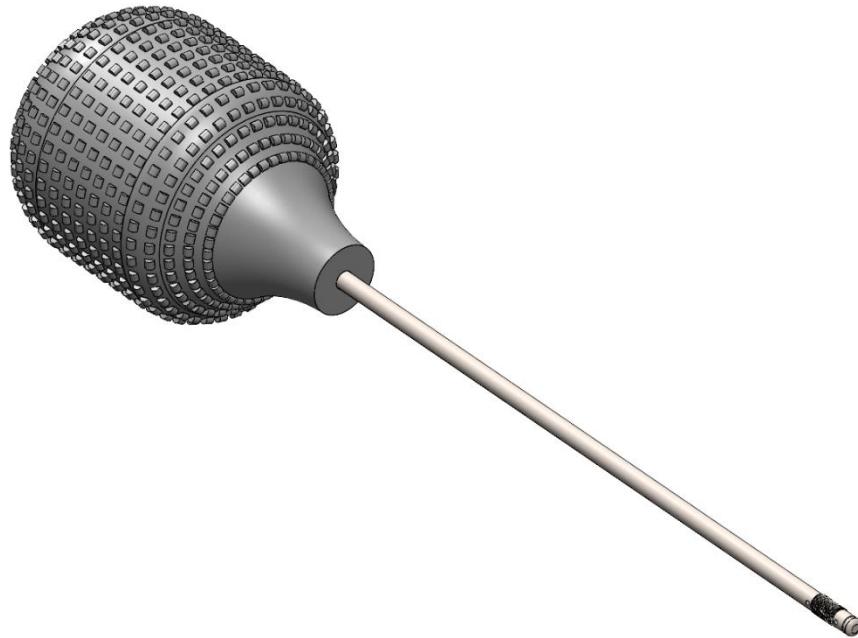


Figure I.2.4.1 CAD model of the Denervator assembly

As per the procedural loads defined in **Section G.3**, 40N of force is to be applied axially while considering a factor of safety of 2. Since using the Denervator is the most delicate and intricate part of the procedure, as it is severing a nerve and mistakes to this may induce severe collateral damage, it can be assumed the environment is controlled with minimal uncertainty as the doctor would be very focused and intentional with their actions. Thus, a factor of safety of 2 is very conservative. The Denervator will also be at a conservative angle of around 30° from an axis perpendicular to the back. Thus, the true bending force seen by the Denervator's shaft is a component of the total applied force, in other words: $F_x = 40 \sin 30 = 20N$. On the contrary, to test the axial strength of the device, the axial force seen would be $F_z = 40 \cos 30 = 35N$.

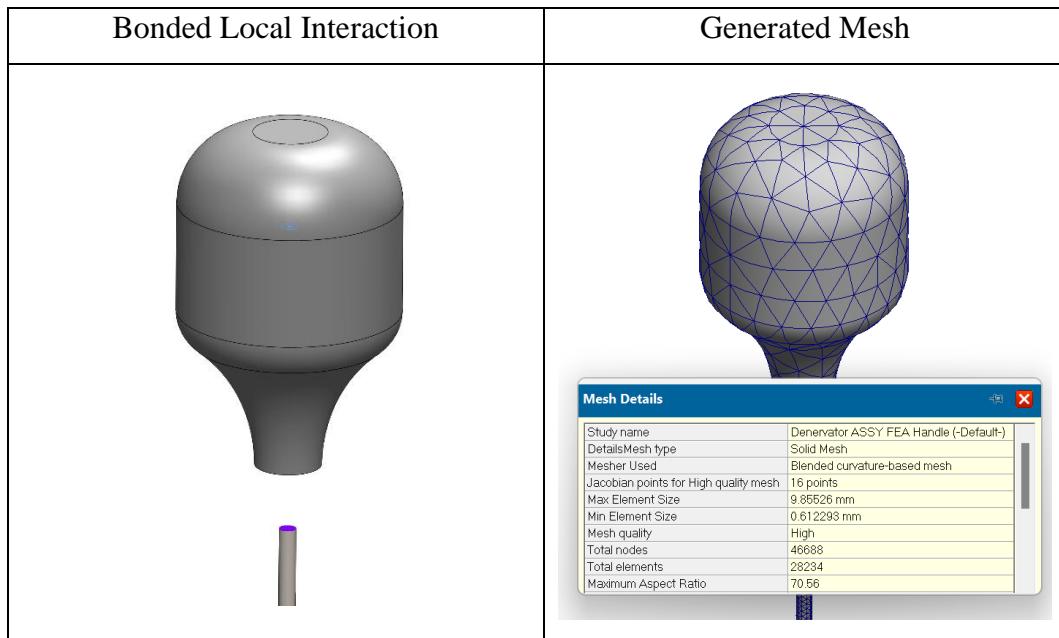
However, the team kept this force as $F_z = 40N$ to allow for a conservative estimate in testing the axial strength. Due to the large bulbous shape of the handle, the team wanted to run simulations to confirm the strength of the device, despite the many fillets incorporated attempting to alleviate various stress concentrations. The Denervator model would be deemed effective as long as the FEA-measured stresses of its critical features were anywhere under the yield points of their corresponding materials.

To configure the static structural simulations, materials were assigned, local interactions were created, and a resulting mesh was generated. The material assignments can be seen below in **Table I.2.4.1**.

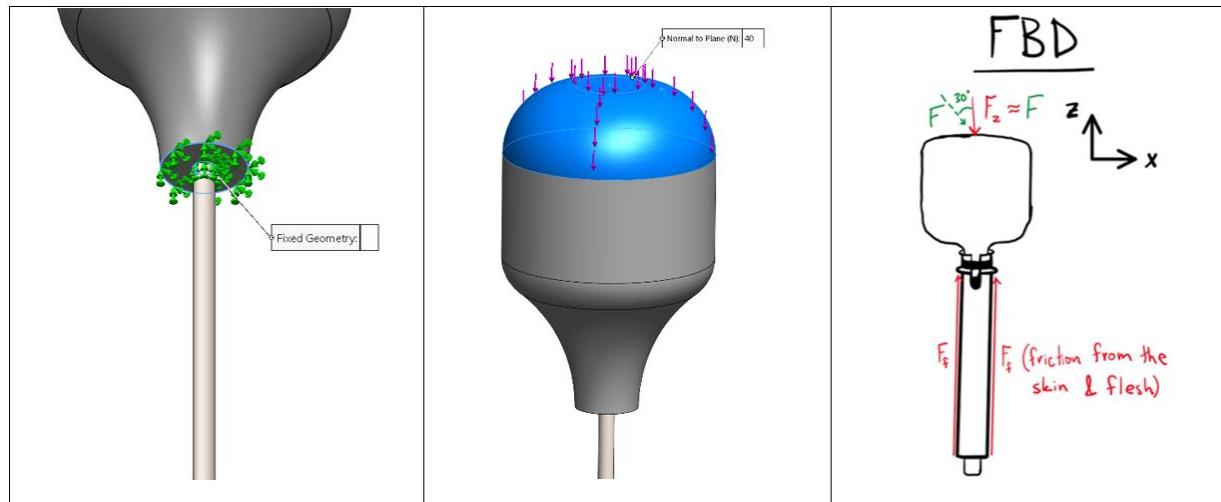
Table I.2.4.1 Denervator Material Assignments

Denervator Body	Denervator Handle																																																															
<p>Material properties Materials in the default library can not be edited. You must first copy the material to a custom library to edit it.</p> <p>Model Type: Plasticity - von Mises <input type="button" value="▼"/> <input type="checkbox"/> Save model type in library</p> <p>Units: SI - N/m^2 (Pa) <input type="button" value="▼"/></p> <p>Category: Steel <input type="button" value="Create stress-strain curve"/></p> <p>Name: AISI 316 Stainless Steel Sheet (SS)</p> <p>Description:</p> <p>Source:</p> <p>Sustainability: Defined</p> <table border="1"> <thead> <tr> <th>Property</th><th>Value</th><th>Units</th></tr> </thead> <tbody> <tr> <td>Elastic Modulus</td><td>1.92999974e+11</td><td>N/m^2</td></tr> <tr> <td>Poisson's Ratio</td><td>0.27</td><td>N/A</td></tr> <tr> <td>Tensile Strength</td><td>580000000.8</td><td>N/m^2</td></tr> <tr> <td>Yield Strength</td><td>172368932.3</td><td>N/m^2</td></tr> <tr> <td>Tangent Modulus</td><td></td><td>N/m^2</td></tr> <tr> <td>Thermal Expansion Coefficient</td><td>1.6e-05</td><td>/K</td></tr> <tr> <td>Mass Density</td><td>8000.000133</td><td>kg/m^3</td></tr> <tr> <td>Hardening Factor</td><td>0.85</td><td>N/A</td></tr> </tbody> </table>	Property	Value	Units	Elastic Modulus	1.92999974e+11	N/m^2	Poisson's Ratio	0.27	N/A	Tensile Strength	580000000.8	N/m^2	Yield Strength	172368932.3	N/m^2	Tangent Modulus		N/m^2	Thermal Expansion Coefficient	1.6e-05	/K	Mass Density	8000.000133	kg/m^3	Hardening Factor	0.85	N/A	<p>Material properties Materials in the default library can not be edited. You must first copy the material to a custom library to edit it.</p> <p>Model Type: Linear Elastic Isotropic <input type="button" value="▼"/> <input type="checkbox"/> Save model type in library</p> <p>Units: SI - N/m^2 (Pa) <input type="button" value="▼"/></p> <p>Category: 463Materials</p> <p>Name: PP Homopolymer</p> <p>Default failure criterion: Unknown <input type="button" value="▼"/></p> <p>Description: PP- Homopolymer, unfilled</p> <p>Source:</p> <p>Sustainability: PP Homopolymer in SOLIDWORKS Materials : Plastics <input type="button" value="Select..."/></p> <table border="1"> <thead> <tr> <th>Property</th><th>Value</th><th>Units</th></tr> </thead> <tbody> <tr> <td>Elastic Modulus</td><td>1300000000</td><td>N/m^2</td></tr> <tr> <td>Poisson's Ratio</td><td>0.42</td><td>N/A</td></tr> <tr> <td>Shear Modulus</td><td></td><td>N/m^2</td></tr> <tr> <td>Mass Density</td><td>933</td><td>kg/m^3</td></tr> <tr> <td>Tensile Strength</td><td>33000000</td><td>N/m^2</td></tr> <tr> <td>Compressive Strength</td><td>39300000</td><td>N/m^2</td></tr> <tr> <td>Yield Strength</td><td>33000000</td><td>N/m^2</td></tr> <tr> <td>Thermal Expansion Coefficient</td><td>9e-05</td><td>/K</td></tr> <tr> <td>Thermal Conductivity</td><td>0.117</td><td>W/(m·K)</td></tr> <tr> <td>Specific Heat</td><td></td><td>J/(kg·K)</td></tr> <tr> <td>Material Damping Ratio</td><td></td><td>N/A</td></tr> </tbody> </table>	Property	Value	Units	Elastic Modulus	1300000000	N/m^2	Poisson's Ratio	0.42	N/A	Shear Modulus		N/m^2	Mass Density	933	kg/m^3	Tensile Strength	33000000	N/m^2	Compressive Strength	39300000	N/m^2	Yield Strength	33000000	N/m^2	Thermal Expansion Coefficient	9e-05	/K	Thermal Conductivity	0.117	W/(m·K)	Specific Heat		J/(kg·K)	Material Damping Ratio		N/A
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As seen above, the handle was assigned to PP homopolymer, and the body was assigned to SAE 316L. In addition, the grip on the handle and fine geometries at the tip were suppressed as they were not critical for the results of the simulation and would induce negligible effects. The model used for the simulation can be seen in **Table I.2.4.2** where specifics of the simulation configuration, such as local interactions and meshing, are highlighted.

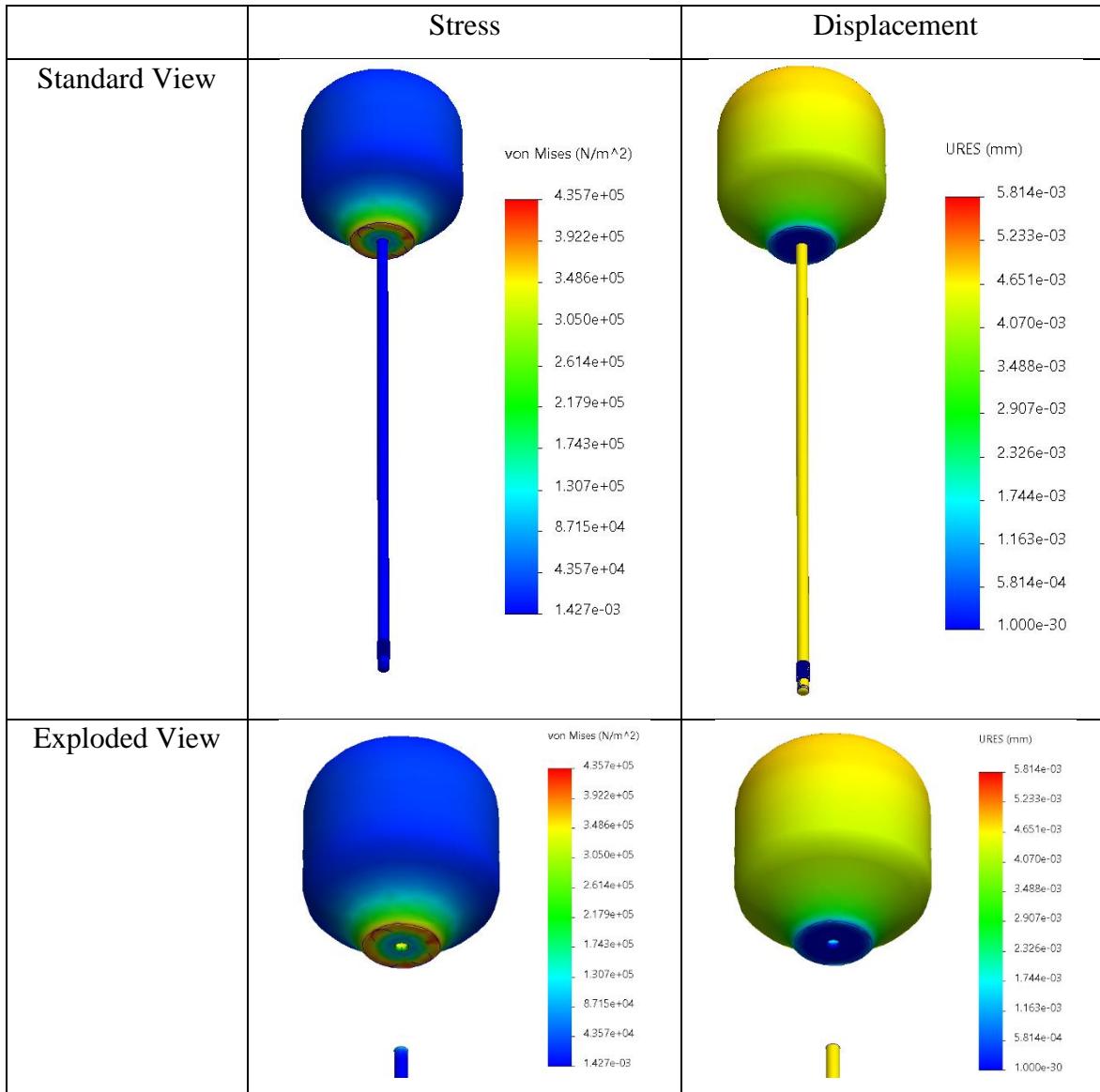
Table I.2.4.2 Denervator Simulations Configuration

The first question the team needed to answer was if an axially applied load would deform the handle, shaft, or tip when boring through the body. To test this, a fixture was applied at the lip of the handle to simulate the normal force from bottoming out on the Sleeve of the Portal and an axial load (F_z) was applied on the handle to simulate the procedural load (F), as shown in the adjacent free body diagram (FBD) depicting this situation, as seen below in **Figure I.2.4.2**.

**Figure I.2.4.2** A fixed geometry constraint (1) and axial load (2) applied to simulate the Denervator's FBD (3)

The stress and displacement results of this simulation, along with exploded views to see within the assembly, can be seen below in **Table I.2.4.3**.

Table I.2.4.3 Denervator Axial Deformation Results



These results prove that the displacement and deformation are negligible under this situation. It also highlights that all critical features of this device are within the yield limits of both materials. Thus, it can be safely concluded that the device can withstand the procedural force in addition to a factor of safety.

The next question the team wanted to answer is if this applied procedural load would induce significant bending and deform the shaft. Unlike in the first test where the Portal acted as a fixture on which the Denervator could bottom out on, in this test, the entire shaft of the Denervator is to be supported within the Portal shell due to the direction of bending and the tight clearance within the Portal. To test this concern, a fixture was applied along the shaft to simulate support from the Portal and a transverse load (F_x) equaling a component of the procedural load (F) was applied at the handle, as shown in the adjacent free body diagram (FBD) depicting this situation, as seen below in **Figure I.2.4.3**.

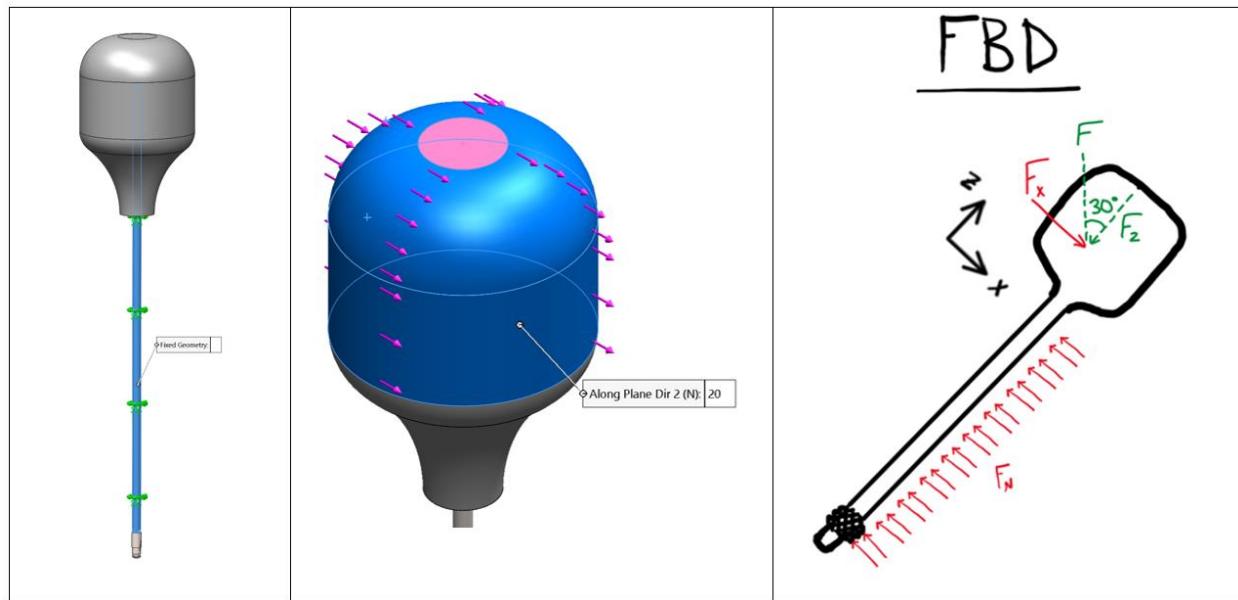
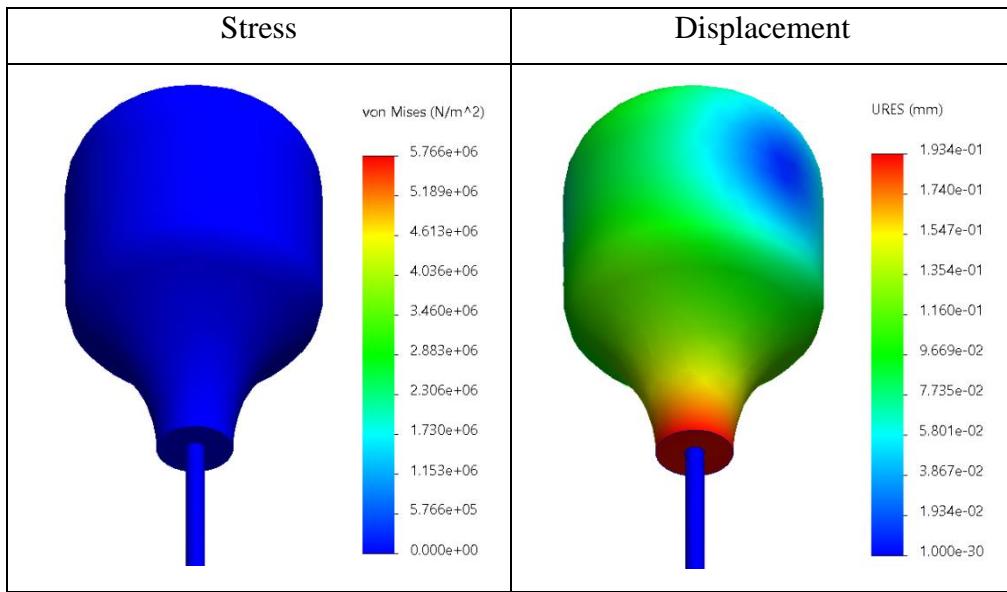


Figure I.2.4.3 A fixed geometry constraint (1) and transverse load (2) applied to simulate the Denervator's FBD (3)

The stress and displacement results of simulating this bending force on the Denervator can be seen below in **Table I.2.4.4**.

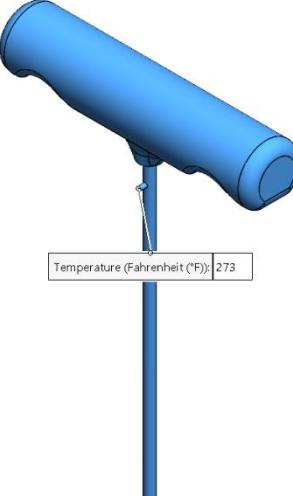
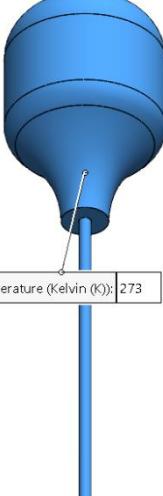
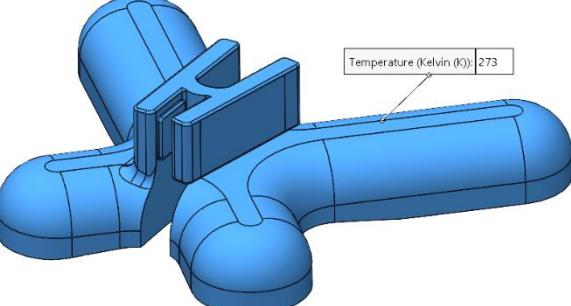
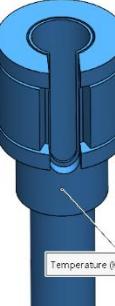
Table I.2.4.4 Denervator Bending Deformation Results

The conclusions of these results are the same as before: deformation is negligible, and all critical features remain under the yield points of both materials. Stress-related issues from the previous phase were also addressed and geometry was updated accordingly to resolve threats of yielding, such as removing stress concentrations. In conclusion, when a bending load is put on the Denervator while it is in the Portal, it is safe to conclude that the device will not yield and can withstand a factor of safety of 2. Since CDR, minor changes have been made to the analysis setup and method itself. Simulations were rerun to ensure the updated CAD models still met all requirements.

I.3 Thermal Stress Analysis

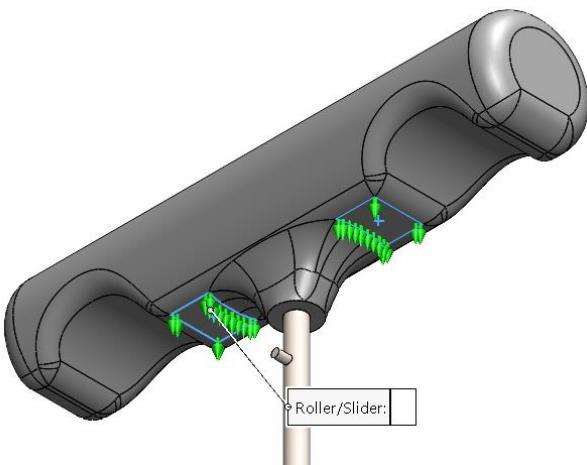
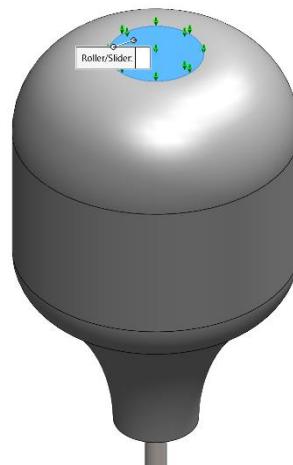
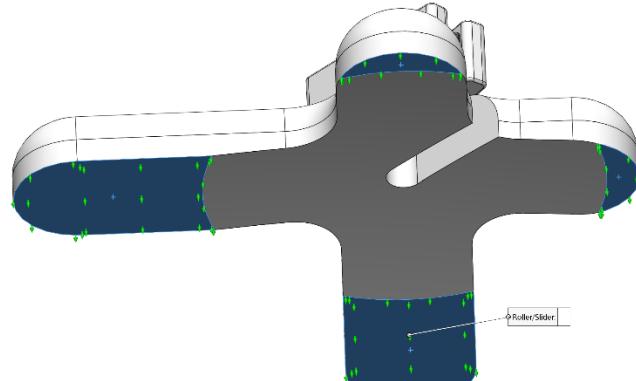
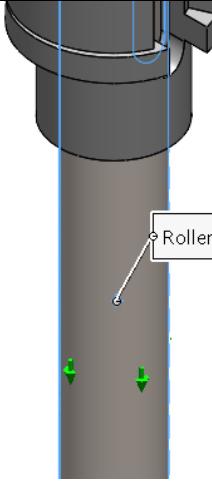
One of the primary engineering requirements of this project is that the devices must withstand initial sterilization at temperatures of 273 degrees Fahrenheit. To ensure none of the devices deform or experience significant thermal stress, the team conducted thermal stress analysis. This was done by applying a thermal load to all exposed faces of all the device assemblies and then transferring this load data into a static structural simulation to investigate thermal stresses. While retaining the same material assignments, mesh settings, and local interactions for each device assembly as described in **Section I.2**, only the loading and fixtures were changed for the thermal analysis. The thermal loads applied for each device can be seen below in **Table I.3.1**.

Table I.3.1 Thermal Loads Applied

Stylet	Denervator
	
Back Stabilizer	Portal
	

The respective fixtures applied for each device can be seen below in **Table I.3.2**. All models had roller constraints applied to simulate their freedom to move around while in the autoclave/oven. The setups of these fixtures have changed since CDR. Besides this, negligible other changes have been made to the thermal analysis setup and method itself. Simulations were rerun to ensure the updated CAD models still met all requirements.

Table I.3.2 Fixtures Applied

Stylet	Denervator
	
Back Stabilizer	Portal
	

Note that unlike in **Section I.2.2**, the Portal assembly was now under investigation and not just the individual parts (C-Ring and Portal Body). A new local interaction was thus added to simulate contact between the faces, as seen in **Figure I.3.1** below.

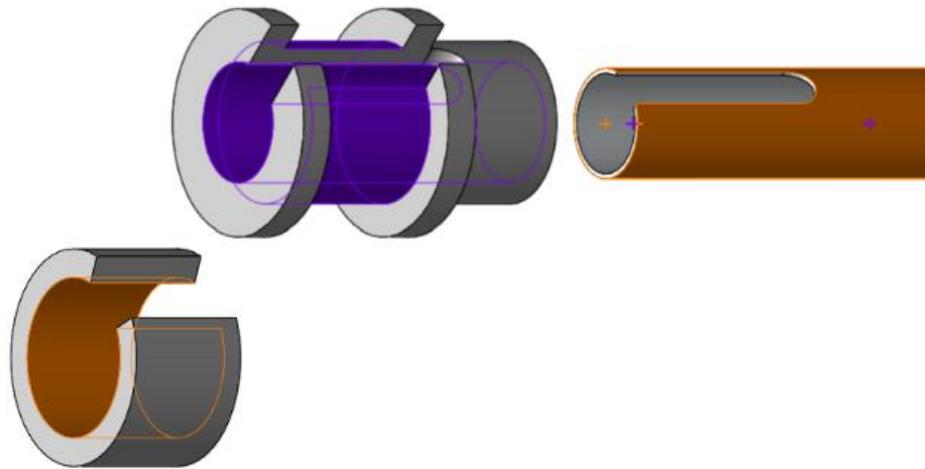
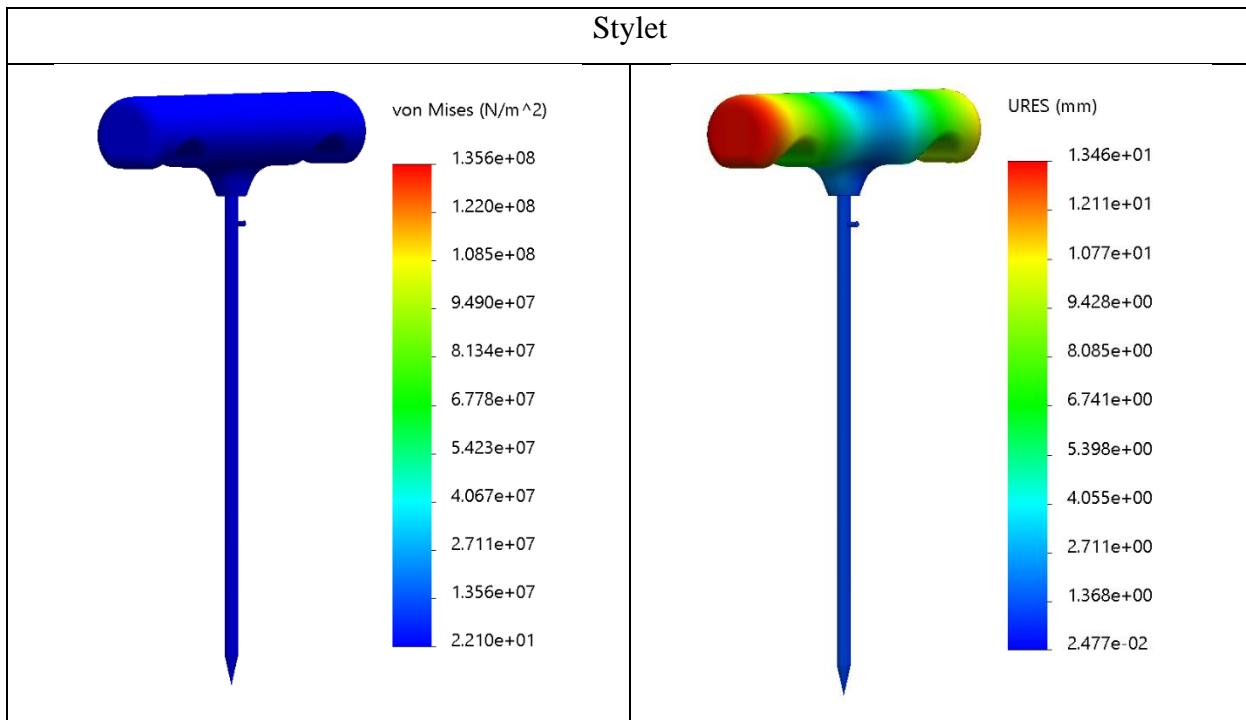
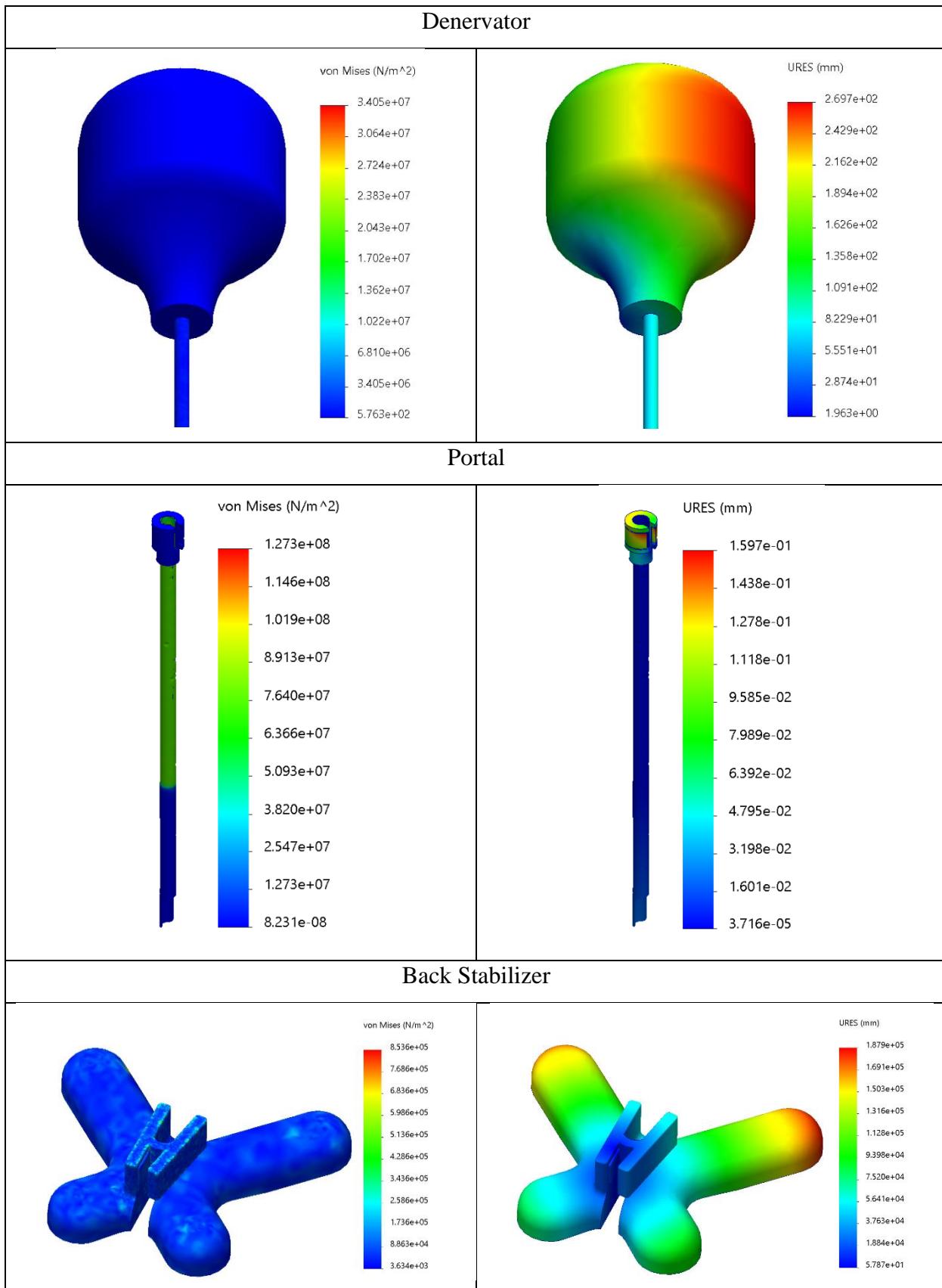


Figure I.3.1 A contact-based local interaction between the C-Ring, Sleeve, and Portal that was included in its thermal analysis simulation

After all details of the simulations had been configured, the thermal analysis simulations were run, and the following deformation and stress results were found, as shown in **Table I.3.3**. Stress results can be seen on the left column with displacement results on the right column.

Table I.3.3 Thermal Stress Results





As seen above, negligible deformation was seen and none of the device's critical features experienced yielding. This did not come as a surprise as the glass transition temperature and melting temperatures of these materials were much higher than the temperature at which sterilization testing would occur.

It is important to note that though stresses above the yield point of PP homopolymer are displayed as a maximum in some of the charts, no areas of components using this material experienced stresses above its yield point – only the metallic components saw such stresses. In addition, the overwhelming support and mass adoption of these materials in the medical industry supported the results of the simulation in that such tools should be able to safely withstand sterilization at high temperatures just as millions of other tools in the industry have already done.

In conclusion, the thermal stress analysis has proved to the team that all devices are safe for sterilization and will not deform to a point where the viability of the procedure is put at risk.

J. FMEA

To evaluate all possible modes of failure during the operational use of the medical tools and procedure, the team performed Failure Mode and Effects Analysis (commonly referred to as FMEA). FMEA analysis entails the analyzation of how the design fails to satisfy the desired functional or customer needs. Considering this type of risk management is so design-focused, the team did not perform FMEA until they had finalized their design in the CDR phase (hence why FMEA had not taken place during the PDR phase). The team then updated the FMEA during the FDR phase to keep up with the development of the prototype and the project. Before getting to these updates, the FMEA will be introduced as it was in the CDR phase.

It's important to understand how FMEA works before diving into its impact on this project. The team can identify a potential failure mode, which is how the prototype fails at what it is supposed to do. They then identify the worst-case effects of this failure and rank its severity on a scale of 1 to 10 (where a ranking of 1 has no effect). The team follows this up by identifying the potential causes of the failure mode and ranking the occurrence of these causes on a scale of 1 to 10 (where a ranking of 1 means it never occurs). The team then details the current methods to control the failure and ranks the detection of failure via these methods of control on a scale from 1 to 10 (where a ranking of 1 means the method will reliably detect a failure mode). This generates a risk priority number (RPN), which can be thought of as the risk rating for each failure mode. The RPN is calculated as the product of the three rankings: multiply the severity, occurrence, and detection together. The remaining few columns of the FMEA document then prompt the team to establish an action to further mitigate the risk of each failure mode. The goal of this action is to reduce one (or many) of the severity, occurrence, and detection. This action is then assigned to a member on the team and given a due date. Finally, updated severity, occurrence, and detection rankings are made and a new RPN is generated. The goal is to implement strong mitigating actions to heavily reduce the RPN of each failure mode.

Now that a general understanding of the FMEA process is established, the project-specific results can be discussed. There were a multitude of mitigating actions which had no impact on the design during the CDR phase, but rather reduced the risk of each failure mode. These failure modes and mitigating actions are detailed in **Figure J.1**.

Line No.	Item / Function	Potential Failure Mode	Potential Effect(s) of Failure	S E V	Potential Cause(s) / Mechanism(s) of Failure	O C C	Current Controls	D E T	R P N	Mitigation Action (s)	by Who	by Who	U SE V	N H OCC	N H DET	N H RPN
2	Module Assembly / Disassembly / Service	Portal deforms	The Stylet and Denervator will not fit within the Portal, and therefore the procedure cannot be performed	10	The clamping force from the Back Stabilizer is too strong for the Portal's geometry and material	2	Pick a strong material to manufacture the Portal from and ensure reasonably smalls (difference between the OD and ID)	8	160	Perform FEA on the Portal with double the clamping force (accounting for a factor of safety of 2) to determine if any deformation will occur	Agathya Tharun	2/28/2024	10	1	1	10
3	Module Assembly / Disassembly / Service	Nerve isn't cut effectively	The pain will either remain the same or worsen. Neurams can also form due to ineffective cutting	8	The burrs might not be sharp enough or long enough. Also, the nerve may not have been found	6	Reference pre-existing solutions; such as the reamer from the Veritas project, to remove geometry off of. Also, perform extensive research to understand the thickness of the nerve well as well as the nerve cutting length. Finally, use x-rays and other medical tools as best as possible with the nerve	6	288	Discuss with ME machine shop faculty effective manufacturing processes for denervator shafts. Consider whether to outsource the manufacturing for higher quality results. Finally, research materials which will and won't show up on x-rays	Cameron Mostoufi	2/23/2024	8	2	2	32
4	Module Assembly / Disassembly / Service	Shaft of the Denervator deforms inside the Portal	The end effector will move within the body and cause collateral damage and the Denervator won't be able to come back out of the Portal	6	The shaft is too narrow, and insufficient grip will result in procedural force (especially with the inside surface of the Portal providing a reactionary force against the shaft)	2	Pick a strong material to manufacture the Denervator shaft from and ensure a big enough shaft, while still fitting within the Portal	7	84	Perform FEA on the Denervator with double the procedural force accounting for a factor of safety of 2 to determine if any deformation will occur	Agathya Tharun	2/28/2024	6	1	1	6
6	Module Assembly / Disassembly / Service	Threads deform/strip	The handles will break off of the shafts (for either the Stylet or Denervator) and the tools will not be usable	10	The handle threads are too few threads. Another cause is that the threads are too narrow	3	Make the threads relatively thick in the CAD	8	240	Perform thread stripping analysis via hand calculations to determine whether or not the threads will strip	Jacob Whitehouse	2/28/2024	10	1	3	30
7	Module Assembly / Disassembly / Service	Shaft of the Stylet deforms inside the Portal	The Stylet tip will move within the body and cause collateral damage and the Stylet won't be able to come back out of the Portal	6	The shaft is too narrow, and insufficient grip will result in procedural force (especially with the inside surface of the Portal providing a reactionary force against the shaft)	2	Pick a strong material to manufacture the Stylet shaft from and ensure a big enough shaft, while still fitting within the Portal	7	84	Perform FEA on the Stylet with double the procedural force accounting for a factor of safety of 2 to determine if any deformation will occur	Agathya Tharun	2/28/2024	6	1	1	6
8	Module Assembly / Disassembly / Service	Stylet detaches from the Portal during skin/ flesh penetration	The incision will be jagged and cause excess bleeding	4	The C-ring is too loose around the Portal	2	Tolerancing is being done to ensure the fit between the C-ring and the Portal	3	24	Perform FEA on the C-ring to determine how much force it requires to open it to the width of the Portal (a higher force indicates a tighter fit)	Agathya Tharun	2/28/2024	4	2	2	16
9	Pack Assembly / Disassembly / Service	Stylet and/or Denervator don't fit within the Portal	The procedure cannot be performed	10	Poor CAD design or poor manufacturing	2	Tolerancing is being done to ensure the fit between the Stylet/Denervator and the Portal	3	60	Talk to ME machine shop faculty to identify reasonable tolerances to manufacture. Also, 3D print the CAD to ensure tolerancing	Cameron Mostoufi	2/23/2024	10	1	1	10

Figure J.1 FMEA table for the mitigating actions which were not design-driving during the CDR phase

Starting off with the Portal deforming, this failure mode would inhibit the procedure from being performed. If the Portal deforms, tools wouldn't be able to slide in and out, which renders the procedure impossible. With the CAD already developed, the team wanted to understand the occurrence of this failure mode during procedural use. Therefore, the team performed finite element analysis (FEA) on the Portal and determined that it doesn't deform due to the clamping force from the clamping mechanism of the Back Stabilizer. From these results, the team decided that this mitigating action nullified the likelihood of this failure mode. Although important to the scope of this project, this mitigating action did not drive any design updates or changes.

The second of these failure modes is the nerve not being cut effectively. The nerve being cut effectively directly affects how well the team accomplishes the goal of the procedure. Therefore, to ensure that the Denervator is designed up to the ability to cut the nerve effectively, the team analyzed the manufacturing methods for the burrs. In-house manufacturing was discussed with Darrin Wilcoxson, who provided insight as to what machines to us. Similarly, research was done into outsourcing the manufacturing with vendors such as Xometry. Both analyses found it viable to manufacture sharp burrs as intended, which meant that the current Denervator design was plausible. This heavily reduced the risk of ineffective nerve cutting, however, didn't drive any design plans.

The next two failure modes which were analyzed, yet didn't impact the design, include the Stylet and Denervator Shafts deforming inside the Portal. If either tool were to deform within the Portal during operational use, the tools would get stuck in the Portal and would make a difficult extraction from the body. Considering CAD had already been developed, the team then implemented a mitigating action to perform FEA on the Stylet and Denervator. It was found that

no significant deformation will occur for either of the medical tools while within the Portal, which validates the design and reduces the occurrence of the risk.

Another mode of failure that passed inspection was the threads stripping. If the threads within the handles stripped, then the tool would be rendered unusable. Therefore, hand calculations were performed according to the geometry and chosen threads for the CAD. The results from this thread analysis indicated that thread stripping won't even remotely be a concern, which further validated the current design.

The sixth failure mode with no design-driving impact was the Stylet detaching from the Portal. This would cause an inconsistent bore through the skin and flesh. Though not a drastic effect, it was still important to analyze. FEA was performed on the CAD of the C-ring, which determined that the C-ring will provide a strong clamping force around the Portal (hence making it more difficult for the C-ring to slip and the Stylet to come out of the Portal unintentionally). As with the other aforementioned mitigating actions, this merely nullified the risk rather than driving any design updates.

Finally, the last failure mode which didn't drive any design updates was the Stylet and Denervator not fitting within the Portal. If either one of these medical tools didn't fit within the Portal, then the procedure would be impossible to perform. Due to this, the team analyzed the tolerances through assembly in CAD. It was found that there existed strong clearance fits between the medical tools, confirming the tolerances and current design.

Each of these just-discussed failure modes and mitigating actions validated the existing design. This being said, the risks of failure modes were much reduced, yet no part of the design was updated, changed, or driven by these mitigating actions. This is in no way a bad thing, as the team still benefitted by reducing the risk of failure modes. However, there also existed some failure modes and mitigating actions which did directly drive the design of the medical tools during the CDR phase. These failure modes and mitigating actions are detailed in **Figure J.2**.

S #	Item / Function	Potential Failure Mode	Potential Effect(s) of Failure	S E V	Potential Cause(s) / Mechanism(s) of Failure	O C -	Current Controls	D E T	R P N	Mitigation Action (s)	by Who	by Whe	Non-SEV	Non-OCC	Non-DET	Non-RPN
				V		C		E	P							
1	Module Assembly / Disassembly / Service	Portal slips from the clamp grip	The Portal will go further into the patient's body, which can cause auxiliary damage	10	One cause is that the rubber pads do not provide enough friction resistance (via friction) between the Back Stabilizer and the Portal. Another cause is that the Back Stabilizer does not provide enough grip force to hold the Portal in place.	5	The team on the Back Stabilizer provides a qualitative strength force and rubber pads will be adhered to the interior of the clamp to provide significant friction resistance	8	400	Perform hand calculations to determine the clamping force required from the Back Stabilizer and rubber pads to prevent any Portal slippage according to a factor of safety of 2	Jacob Whitehouse	2/25/2024	10	2	1	20
5	Module Assembly / Disassembly / Service	Back Stabilizer wobbles/slips on the patient's back during procedural use	The medical tools tear the incision open wider and cause collateral damage within the body due to sharp and unstable movement	8	Every patient's back is different in shape and there isn't much friction between plastic and skin	3	Create a concave base for the Back Stabilizer so that it has point-focused stabilization and matches well with the convex shape of the back	8	192	Make the petals and base of the Back Stabilizer larger to provide the doctor with greater leverage	Joe Misener	2/23/2024	8	2	6	96
10	Pack Assembly / Disassembly / Service	Tools deform/melt during sterilization	The medical tool kit cannot be sold and the procedure cannot be brought to market	10	The material does not have a high enough melting temperature or strong enough thermal resistance	5	Extensive research into standard medical materials which can withstand sterilization (high temperatures and pressures)	5	150	Perform thermal studies on CAD to verify the strength of the medical tools	Agathya Thanu	2/28/2024	10	1	1	10
11	Module Assembly / Disassembly / Service	Tool either don't show up on x-rays when they should, or do show up on x-rays when they shouldn't	The doctor cannot identify where the medical tools are within the body and either causes collateral damage or cannot perform the procedure	9	The material either does x-ray diffraction or it shouldn't, or it doesn't x-ray diffraction when it should	1	Extensive research into whether or not the chosen medical materials show up on x-ray	2	18	Plan x-ray testing for the final prototype	Jacob Whitehouse	3/30/2024	9	1	1	9
12	Module Assembly / Disassembly / Service	Incision is too big	The incision has to be closed with sutures and staples, which are not considered minimally invasive	5	The tools are too large to fit within a small incision	5	Extensive research into what defines a procedure as minimally invasive, specifically, how small the incision must be	5	125	Plan incision size testing to determine the required incision size to fit the medical tools within the body	Jacob Whitehouse	3/30/2024	5	5	2	50

Figure J.2 FMEA table for the mitigating actions which were design-driving during the CDR phase

The first failure mode which drove design for this project was the Portal slipping within the clamp mechanism on the Back Stabilizer. If the Portal were to slip from this grip, it could cause collateral damage which could be detrimental to the patient. The team decided to perform friction hand calculations to determine the clamping force required to prevent the Portal from slipping within the grip. The clamping force determined from these calculations were then designed according to bending-deformation hand calculations. These bending-deformation hand calculations were parametrized in terms of the Back Stabilizer geometry, such that the team could easily yield clamping forces based on design changes. Through playing around with different geometrical sizing, the team eventually decided to decrease the length of the clamp arms and the thickness of the clamp arms. Doing this increased the clamping force significantly, enough such that the required clamping force to prevent the Portal from slipping was met. In driving this design change, the hand calculation mitigating action also significantly reduced the risk of this failure mode.

Another failure mode which led to a design change is the Back Stabilizer wobbling or slipping during procedural use. This could cause the medical tools inside the body to similarly slip, which would inflict collateral damage. After developing the preliminary prototype for the Back Stabilizer, the team found the Back Stabilizer to be very small. Being so small, the team was unsure how well the Back Stabilizer resisted slippage on the back. Though there is no great way to analyze this, the team decided that the failure mode could be mitigated by increasing the length and size of the petals on the Back Stabilizer. These sizes were therefore increased on the CAD to cover a larger surface area of the back and provide more leverage. Large area and greater leverage are two ways to sufficiently increase stability and friction, which is what the team intended on doing by this design update. Considering this was not an analysis or test plan,

the risk for this failure mode wasn't reduced as greatly as it was possible. Despite this, the risk was still reduced.

The third and fourth failure modes happen with regards to the material. These include the medical tools melting or deforming during sterilization and the medical tools not showing up (or showing up when they shouldn't) on X-ray imaging. To ensure that the medical tools met the specifications for sterilization and X-ray imaging (therefore not posing any failure risks), the team performed extensive material property analysis research. Through this research, it was determined that the metal parts will be made from grade 316L stainless steel, and the plastic parts will be made from polypropylene. To withstand sterilization, these medical tools must be able to withstand temperatures as high as 273 degrees Fahrenheit⁴⁷. Grade 316L stainless steel is known to be safe for steam sterilization⁸, supported by its melting temperature of approximately 2500 degrees Fahrenheit⁴⁶. This material is also one of the most common metals used in medical settings, specifically prevalent in surgical devices and implants⁵⁷. With regards to polypropylene, it is one of the most common medical-grade plastics, being seen in applications such as syringes and surgical devices⁵⁸. It's also important to note that polypropylene is deemed suitable for steam sterilization⁴⁹, supported by its glass transition temperature of 338 degrees Fahrenheit¹³. From the specifications of these two materials, both should be well-suited for steam sterilization at high temperatures. However, it's also important to make sure that the metal parts show up on X-ray imaging and the plastic parts do not. From further material property analysis research, it was found that all stainless steels should show up on X-rays³, and engineering plastics (including polypropylene) do not show up well on X-rays⁵⁹. These are the exact results desired for the design, which further validates material selection. Overall, this material research drove the material selection for the design of the medical tools. This also significantly reduced any risk of failure during sterilization or X-ray imaging.

The last failure mode which drove the design of the medical tools was the incision being too big. If the incision is too big, then it would require stitches to close and the procedure wouldn't be considered minimally invasive. From previous research, it had been determined that 7mm was a maximum incision size, considering this size is considered minimally invasive³⁸ and this size is when stitches start to become optional⁵⁵. Considering a target value of 5mm had been set by the team in their engineering specifications and constraints, they designed the tools to fit

within a 5mm incision. This constraint and research drove the sizing of the design, which coincidentally reduced any risk of the incision being too big.

As can be noted from these failure modes and mitigation actions, not everything drove the design of the team's medical tools. Some actions were set in place purely to validate the design and eliminate any risk. Some actions were instead developed to truly drive the design, which took place in many ways (geometry, sizing, and material). After a final design was settled on which encompassed all mitigation action, the team moved onto the FDR phase.

The FDR phase of the project entailed the manufacturing and testing of the final prototype. During this phase, the team felt that it was important to update the FMEA as necessary. After a comprehensive review of the FMEA, the team ended up reframing two of the existing failure modes, updating the other 10 existing failure modes to align with the progress of the project, and appending two new failure modes. The two reframed failure modes are detailed in **Figure J.3**.

Line	Item / Function	Potential Failure Mode	Potential Effect(s) of Failure	S V	Potential Cause(s) / Mechanism(s) of Failure	O C	Current Controls	D T	R N	Mitigation Action (s)	by Who	by When	REV	CC	DET	PR
6	Module Assembly / Disassembly / Service	Epoxy fails to keep the shafts connected to the handles	The handles will break off of the shafts (for either the Styler or Generator) and the tools will not be usable	10	One cause is that the epoxy is not rated for the procedural stresses. Another cause is if there is not enough epoxy applied	2	Make the fit between the shafts and handles transition fits such that it is already tight pre-epoxy	8	160	Perform hand calculations to determine the shear stress between the shafts and handles, find epoxy that meets these ratings	Jacob Whitehouse	3/19/2024	10	1	3	30
11	Module Assembly / Disassembly / Service	Tools don't properly show up on X-ray	The doctor cannot identify where the medical tools are within the body and either causes collateral damage or cannot perform the procedure	9	The material or geometry either does X-ray diffraction when it shouldn't, or it doesn't X-ray diffraction when it should	1	Extensive research into whether or not the chosen materials will show up on X-ray. Also planned X-ray testing for the final prototypes via the Veterinary School	4	36	Perform X-ray testing with the Veterinary School	Jacob Whitehouse	4/14/2024	9	1	1	9

Figure J.3 FMEA table for the two failure modes which were reframed during the FDR phase

The first thing that stuck out to the team while reviewing the FMEA was the failure mode regarding thread deformation and stripping. Considering the final design had been changed to remove all threading, this failure mode was not applicable anymore. However, the idea of this failure mode (that the connection between the shafts and handles would fail) remained relevant, only now the epoxy was responsible for this connection. The team took this opportunity to reframe the failure mode and potential cause to focus on the epoxy. The new potential failure mode focuses on the epoxy failing to keep the shafts connected to the handles, which could be caused by not enough epoxy or a choice of poorly rated epoxy.

The other failure mode that was reframed during the revision of the FMEA was that regarding the X-ray appearance of the tools. During the CDR phase, the team had identified this failure mode as whether the materials correctly showed up (or didn't show up) on X-ray images. However, through further discussion, the team realized that the material was not the only

important thing dictating successful X-ray images; the geometry of the medical tools must also show up on the X-ray images as desired. Because of this realization, the team updated the potential failure mode to encompass both the material and geometry as possible causes. The team now considers failure if the tools don't properly show up on the X-ray images, which is a generalized way of encompassing both causes. Due to the increased requirements, the detection was increased by a factor of 2. Similarly, the RPN was increased two-fold from 18 to 36 to reflect the increased difficulty for detection.

While these two failure modes were reframed to better fit the scope of this project, the team did not find it necessary to change any other failure modes or causes. In fact, the team did not change any effects, including the effects of the reframed failure modes. Being that the severity ranking is driven by the effects of failure, it did not change for any of the existing failure modes. However, for the 10 existing failure modes that were not changed, the team made significant changes to their occurrence and detection rankings. These updates, along with further discussed updates to these 10 failure modes, are detailed in **Figures J.4 and J.5**.

Line	Item / Function	Potential Failure Mode	Potential Effect(s) of Failure	S V	Potential Cause(s) / Mechanism(s) of Failure	O C	Current Controls	D T	R N	Mitigation Action (s)	by Who	by When	P-REV	P-OCC	N-W DEF	New RPN
1	Module Assembly / Disassembly / Service	Portal slips from the clamp grip	The Portal will go further into the patient's body, which can cause auxiliary damage	10	One cause is that the rubber does not grip enough and the resistance (friction) between the Back Stabilizer and the Portal. Another cause is that the Back Stabilizer does not provide enough normal force on the Portal	3	The clamp on the Back Stabilizer needs a qualitative strong force and rubber pads will be adhered to the interior of the clamp to provide significant friction resistance. Performed numerical analysis to determine the clamping force required from the Back Stabilizer clamp in order to prevent any Portal slippage according to a factor of safety of 2	3	90	Perform force tests to determine the maximum force required for the Portal to slip from the clamp grip. Then compare this value to the estimated procedural force and determine the factor of safety	Jacob Whitehouse	4/14/2024	10	1	1	10
2	Module Assembly / Disassembly / Service	Portal deforms	The Stylet and Deneravator will not fit within the Portal, and therefore the procedure cannot be performed	10	The clamping force from the Back Stabilizer is too strong for the Portal's geometry and material	1	Pick a strong material to manufacture the Portal from and ensure reasonably high clamping force (accounting for ID and OD). Perform FEA on the Portal with double the clamping force (accounting for a factor of safety of 2) to determine if any deformation will occur	2	20	Test the Portal according to its procedural use	Jacob Whitehouse	4/14/2024	10	1	1	10
3	Module Assembly / Disassembly / Service	Nerve isn't cut effectively	The pain will either remain the same or worsen. Neuromas can also form due to ineffective cutting	8	The burrs might not be sharp enough or long enough. Also, the nerve may not have been found	3	Reference pre-existing solutions, such as the reamer from the Vertiflex procedure, to model the geometry off of. Also, perform extensive research to understand the thickness of the nerve as well as effective cutting lengths. Use x-rays to align the medical tools as best as possible to ensure alignment with ME machine shop faculty effective manufacturing processes for deep and sharp burrs while burring precision high quality manufacturing processes. Finally, research materials which will and won't show up on x-rays	3	72	Test the Deneravator according to a simulated nerve and according to a bone in order to determine the effectiveness and length of cut	Jacob Whitehouse	4/14/2024	8	2	2	32
4	Module Assembly / Disassembly / Service	Shaft of the Deneravator deforms inside the Portal	The end effector will move within the body and cause collateral damage and the Deneravator won't be able to come back out of the Portal	6	The shaft is too narrow, and therefore too weak, to withstand procedural force (especially with the inside surface of the Portal providing a reactionary force against the shaft)	2	Pick a material to manufacture the Deneravator shaft from and ensure a big enough shaft, while still fitting within the Portal. Perform FEA on the Deneravator shaft to determine the procedure force (accounting for a factor of safety of 2) to determine if any deformation will occur	2	24	Test the Deneravator and Portal according to its procedural use	Jacob Whitehouse	4/14/2024	6	1	1	6

Figure J.4 First half of the FMEA table for the 10 failure modes which were updated during the FDR phase

Item / Function	Potential Failure Mode	Potential Effect(s) of Failure	S I V	Potential Cause(s) / Mechanism(s) of Failure	O C	Current Controls	D I	R F N	Mitigation Action (s)	by Who	by When	SEV	OCC	DET	RPN
5 Module Assembly / Disassembly / Service	Back Stabilizer wobbles/slips on the patient's back during procedural use	The medical tools tear the incision open larger and cause collateral damage within the body due to sharp and unstable movements	8	Every patient's back is different in shape and there isn't much friction between plastic and skin	3	Create a concave base for the Back Stabilizer so that it has point-focused stabilization and it mates well with the convex shape of the back	8	192	Make the petals and base of the Back Stabilizer larger to provide the device with greater grip. Perform the Back Stabilizer to determine the amount of force it requires to overcome the friction of the back.	Joe Misner	4/2/2024	8	2	3	48
7 Module Assembly / Disassembly / Service	Shaft of the Styret deforms inside the Portal	The Styret tip will move within the body and cause collateral damage and the Styret won't be able to come back out of the Portal	6	The shaft is too narrow and therefore too weak, to withstand procedural force (especially with the inside surface of the Portal providing a reactionary force against the shaft)	2	Pick a strong material to manufacture the Styret shaft from and ensure a big enough shaft, while still fitting within the Portal. Perform FEA on the Styret with double the procedural force (multiplying for a factor of safety of 2) to determine if any deformation will occur	2	24	Test the Styret and Portal according to its procedural use	Jacob Whitehouse	4/14/2024	6	1	1	6
8 Module Assembly / Disassembly / Service	Styret detaches from the Portal during skin/flesh penetration	The incision will be jagged and cause excess bleeding	4	The C-ring is too loose around the Portal	2	Tolerancing is being done to ensure the fit between the C-ring and the Portal	3	24	Perform FEA on the C-ring to determine how much force it requires to open it to the width of the Portal (a higher force indicates a tighter fit)	Agathiya Tharun	4/2/2024	4	2	2	16
9 Pack Assembly / Disassembly / Service	Styret and/or Generator don't fit within the Portal	The procedure cannot be performed	10	Poor CAD design or poor manufacturing	2	Tolerancing is being done to ensure the fit between the Styret/Generator and the Portal. Talk to ME machine shop faculty to identify reasonable tolerances to implement in the 3D model. The CAD to ensure tolerancing. Order tightly-toleranced, high quality, pre-manufactured stock or reliable medical grade stainless steel C-rings	2	40	Test the fit between the Styret/Generator and the Portal	Jacob Whitehouse	4/14/2024	10	1	1	10
10 Pack Assembly / Disassembly / Service	Tools deform/melt during sterilization	The medical tool kit cannot be sold and the procedure cannot be brought to market	10	The material does not have a high enough melting temperature or strong enough thermal resistance	2	Extensive research into standard medical materials which can withstand sterilization temperatures (temperatures and pressures). Perform thermal analyses on CAD to verify the strength of the medical tools	2	40	Perform a temperature test by heating the tools up to autoclave temperatures and analyse any deformation or melting	Jacob Whitehouse	4/14/2024	10	1	1	10
12 Module Assembly / Disassembly / Service	Incision is too big	The incision has to be closed with stitches and the procedure is not considered minimally invasive	5	The tools are too large to fit within a small incision	6	Extensive research into what defines a procedure as minimally invasive, specifically: how small the incision must be. Plan incision size testing to determine the required incision size to fit the medical tools within the body	2	50	Perform incision test to determine the typical size and size ranges of incisions due to these medical tools	Jacob Whitehouse	4/14/2024	5	3	2	30

Figure J.5 Second half of the FMEA table for the 10 failure modes which were updated during the FDR phase

As of the time that the FMEA was updated, the prescribed mitigation actions had been performed for all 10 remaining failure modes from the CDR phase. Due to this progress, the team appended these mitigation actions to the current controls for these failure modes. To account for the updated control methods, the team then adjusted the occurrence and detection rankings for these 10 failure modes. The largest decrease in RPN was by 310 points and occurred for the failure mode regarding the Portal slipping from the clamp grip. The other notably large decreases in RPN were by 216 and 140 points, occurring for the failure modes of the nerve not being cut effectively and the portal deforming, respectively.

After the mitigation actions were appended to the current controls for the remaining failure modes, the team developed new mitigation actions to take their place. The updated mitigation actions all revolve around validation testing, considering this is the next step in both the project and the risk assessment process. Since Jacob is the validation lead, all these updated mitigation actions were assigned to him. They were also updated to be completed by April 14th, aligning with the timeline set forth by the team for their validation testing. Finally, considering the new risk rankings are all driven by the mitigation actions, the team updated the new severity, occurrence, and detection rankings for each of the 10 remaining failure modes. This helped generate a revised new RPN for each failure mode, yielding positive change in the direction of risk reduction. At this point, all 12 existing failure modes had been reframed or updated. This is when the team appended two additional failure modes to the FMEA, as noted in **Figure J.6**.

Row ID	Item / Function	Potential Failure Mode	Potential Effect(s) of Failure	S I V	Potential Cause(s) / Mechanism(s) of Failure	O C	Current Controls	D I	R F N	Mitigation Action(s)	by Who	by When	SEV	OCC	DEI	RPN
13	Module Assembly / Disassembly / Service	Handle slips from the doctor's grip	The doctor can lose control of the tools and accidentally cause collateral damage.	I	There is no effective grip to the handles	5	There is a T-grip for the handle of the Stylet, which includes grooves for the fingers.	5	250	Implement grooves/small bumps onto the Denervator handle CAD to provide grip points.	Agathya Tharun	4/2/2024	10	2	3	60
14	Pack Assembly / Disassembly / Service	Tools are inserted too deep into the body	Collateral damage, bleeding, and unnecessary cutting could occur	I	There is no visual understanding of the depth of the tools for the doctors	3	The X-ray imaging should help doctors identify where the tools are within the body	3	90	Etch, engrave, or paint on measurement lines on the outside of the Portal so that doctors know the depth that they are at within the body	Agathya Tharun	4/7/2024	10	2	2	40

Figure J.6 FMEA table for the two failure modes which were appended during the FDR phase

As noted earlier, two new potential failure modes were realized by the team in addition to the reframing and updating of the existing failure modes during the FDR phase. The first of these new failure modes is if the handle slips from the doctor's grip. This failure mode could lead to the doctor losing control of the tools, causing accidental collateral damage. The cause behind this would be if there exists no effective grip on the handles. When framing this failure mode in this way, it directly relates to the ease of use of the medical tools. The team already accounted for this failure mode when designing the Stylet handle, as it was designed as a T-grip with grooves for fingers. However, this risk had not been considered when designing the Denervator handle. Therefore, to mitigate this failure, the team implemented small bumps on the Denervator handle to provide grip points. This significantly reduced the RPN by 190 points, proving it to be a worthwhile change.

The other newly identified failure mode is if the tools are inserted too deep into the body. This could have horrible effects, including collateral damage, bleeding, and unnecessary cutting. Such failure would occur if the doctors had no visual understanding of the depth of the tools, which is currently not too much of an issue due to the X-ray imaging. However, the team has identified further mitigation actions that would reduce the risk. They plan on etching, engraving, or painting measurement lines onto the outer surface of the Portal, which would give doctors an understanding of the tool depth within the body. Paired with X-ray guidance, this mitigation plan would practically ensure that no tool goes too deep or anywhere else in the body other than the facet joint.

During the FDR phase, the FMEA was heavily revised to reflect the status of the project and prototype development. For a comprehensive understanding of the FMEA, the file has been attached to this report. The results of the FMEA proved that significant risk has been reduced via the actions taken by the team, and this should help to prove the viability of the medical tools and procedure.

K. BOM & Sourcing Plan

The BOM and Sourcing Plan, as seen below in **Figure K.1**, lists every buy-item needed to complete the team's toolkit.

ITEM ID	ITEM NAME	DESCRIPTION	QUANTITY	PART #	SOURCING	MFG	COST (\$)
1 Stylet							
1a	Stylet Nub	2mm diameter x 1 foot length stock shaft made from 316L Stainless Steel to be cut to size and press fit into a hole on the Shaft Body to create a protrusion for the interlocking mechanism .	1ft	#2959N14	McMaster-Carr	Yes	12.08
1b	Shaft Body	4.5mm OD x 2ft length stock shaft made of 316 Stainless Steel to be cut into a Stylet with tip and press fit into the shaft adapter.	2ft	#91c453c14fd9	Alcobra Metals	Yes	21.54
1c	Handle	60293 mm^3 volume T-Handle made from PP 3D printer filament (1.75mm)	37.5 grams	#B09VZ154Q4	Amazon	Yes	1.74
2 Portal							
2a	Hollow Tube Body	0.203" OD x 0.01" ID x 2' Length 316 Stainless Steel Shaft to get machined with a cutout for the Denervator.	1	#89935K27	McMaster-Carr	Yes	39.23
2b	Portal Sleeve	Sleeve that slides on to the Portal to offer bounding lips for the C-Ring	1.58 grams	#B09VZ154Q4	Amazon	Yes	0.06
2c	C-Ring	197 mm^3 volume C-Ring with same size slit as hollow cylinder made from PP 3D printer filament (1.75mm)	0.44 grams	#B09VZ154Q4	Amazon	Yes	0.02
3 Denervator							
3a	Shaft Body	4mm OD x 3ft length stock shaft made of 316 Stainless Steel to be knurled and press fit into the shaft adapter.	3ft	#1335T24	McMaster-Carr	Yes	30.77
3b	Handle	128520 mm^3 volume bulb shape made from PP 3D printer filament (1.75mm)	79.8 grams	#B09VZ154Q4	Amazon	Yes	3.68
4 Back Stabilizer							
4a	Base & Clamp	68861 mm^3 volume ergonomic base that incorporates a compliant clamp mechanism. Made from PP 3D printer filament (1.75mm)	48.22 grams	#B09VZ154Q4	Amazon	Yes	2.22
4b	Silicone Pads	Silicone Rubber Sheet, Heat Resistant, Heavy Duty, High-Grade 60A, 12 x 12 Inch, 1/25 Inch Thickness; Anti-Vibration, Anti-Slip	0.04" thick	#B0B2QZVFL3	Amazon	Yes	8.99
5 Miscellaneous							
5a	Structural Epoxy	Structural epoxy adhesive compatible with PP. Temperature range: -50F to 350F. Shear Strength: 360 lbs./sq. in.	1 cartridge	#7513A1	McMaster-Carr	No	89.09
5b	Magigoo PP	Bed adhesion for PP filament	1 bottle	#B07JQFMCWQ	Amazon	No	24.99
5c	AquaSys 120	Dissolvable 3D filament compatible with PP (1.75mm)	1 spool	#B08RWTWYS9	Amazon	No	100
5d	PP Packing Tape	Scotch 373 Tape to aid with bed adhesion when printing PP	1 roll	#B00AQ2BHBS	Amazon	No	11.09
					Total (\$)		345.5

Figure K.1 BOM for all tools in the toolkit

The table is separated out by the four main components of the toolset plus miscellaneous parts that are essential to manufacturing and assembling the final prototype. Under each main component is its corresponding item. Each item is provided with a thorough description and their item number. The quantity of each item is listed in addition to the corresponding units. Each item is assigned with a part number that is correlated to the sourcing that the item would be purchased from.

The bulk of the medical tools were manufactured in-house with the purchase of supplementary material to assist in manufacturing. Many of the items that the team needed for their toolset were sourced from McMaster-Carr and Amazon. Similarly, McMaster-Carr is a reputable hardware and raw-material vendor, as they are commonly used in industry. The items that are purchased from McMaster-Carr are then machined using machines in the Purdue ME Machine Shop. The team decided to purchase stainless steel rod stock with exact outer diameters that match their Denervator and Stylet. The team decided to do this to simplify the manufacturing process, eliminating the need to turn down the stock using a lathe. This also eliminated the risk of bending the stock while turning it down. The Denervator was manufactured using a mill, lathe, and a form cutter in order to create the fillet, knurl, and holes. The Back Stabilizer was 3D printed with polypropylene filament, using a P1S printer in the Bambu Lab of the Bechtel Innovation and Design Center (BIDC). The Stylet was manufactured in-house using a lathe and a mill to create the hole that the Nub will fit into. The Nub is also grade 316L stainless steel and was cut out of an extruded rod to size using a band saw. It's also important to note that the team decided not to use Xometry to outsource the Portal. Metal 3D printing was not capable of producing such a thin-walled part. Instead, the Portal started as a hollow metal stock and was then laser etched for its unique features. Most remaining items, like handles, were 3D printed, and the required filament to create each individual part is documented in grams on the BOM. The Polypropylene pieces were created with the help of the BIDC.

The rest of the items included in the BOM are much less of a proportion of the proposed prototype. Excess and miscellaneous parts were sourced through Amazon in order for the team to have parts on hand as needed. Excluding these excess parts, the cost per item for the quantity needed is listed. The Stylet has a cost of \$35.36, the Portal costs \$39.31, the Back Stabilizer costs \$11.21, and the Denervator has a cost of \$34.45. The miscellaneous components aggregate to cost \$225.17, which includes cost for epoxy, filament, threaded inserts, and excess parts. The BOM accounts for all materials purchased, though only a singular toolkit was manufactured. To understand the adjusted product cost by volume and utilization of material, see **Section F.1**.

K.1 Manufacturing Drawings

The report contains detailed manufacturing drawings for each component as well as for the complete toolset, which are located at the end of the document. These drawings illustrate the individual parts and their assembly process, showing how they combine to create each tool in the toolset. The drawings maintain specific tolerances for surface finishes, holes, and edges, typically achieving a precision of +/- 0.5mm for edges and centricity, although some deviations may occur based on manufacturing feasibility. Stainless steel components are required to have a minimum surface roughness of 0.4µm. For polypropylene materials, only essential maximum and minimum tolerances are specified, since these materials do not necessitate stringent surface finishes. In contrast, 3D printed parts are depicted only with critical dimensions; the .STL files used for printing already include all necessary geometric and manufacturing parameters, unlike stainless steel parts which require detailed dimensions for traditional manufacturing processes.

The manufacturing drawings for the stylet include critical dimensions, such as the length from one end to the start of the inclined conical end. The dimensions of the hole and the corresponding nub are crucial to ensure that the nub can be press-fit securely into the stylet's body. Additionally, the outer diameter of the stylet must be sized to slip fit into the portal. All dimensions and tolerances for the handles of both the Stylet and the Denervator are specified in the drawings. The external portions of these parts have less stringent tolerances because they are not as critical to the function of the devices.

The critical dimensions of the portal are located at both ends of the part. At one end, the dimension includes a slot near the handle, which is essential because the Stylet Nub must slide into this slot and reach the end when the base of the handle is fully inserted. At the opposite end, the half-cutout must be precisely dimensioned to ensure that the Denervator's knurls are visible on one side without protruding past the end. The inner diameter of the portal is crucial; thus, the team has opted to purchase material stock that already meets this dimension. Additionally, the Portal sleeve and C-ring require tight tolerances, as most of the fittings are slip fits and must operate smoothly during use.

The Back Stabilizer is quite complicated, but the manufacturing sheets include all dimensions necessary for manufacturing. The critical dimensions lie at the clamp. The relaxed shape and gaps are critical for the compliant mechanism to work properly in the procedure. One side of the clamp is fixed at the base of the Back Stabilizer and the other is free to move.

Therefore, the section between the fingers that acts like a spring must have well dimensioned thickness. The team also decided to extend the rear legs for more support which can be seen in the manufacturing drawings. The lower curvature of the base is also dimensioned in the sheet, along with the rubber pads that are adhered to the inside face of each finger.

The Denervator end has a unique geometry that is specified in the manufacturing drawing. The knurl length, the distance between the through holes, and the location of the groove are all critical dimensions for this part, because the doctor is relying on their sizing during the procedure. There must be tight tolerance to eliminate discrepancy and fluctuation between procedures. Every part in the manufacturing drawings is to scale, and the final prototype is to scale for the procedure.

K.2 Operation Sheets

The team compiled operation sheets for each tool, essential for the manufacturing planning since most tools are to be custom-made. These sheets, shown in **Figure K.2.1** to **Figure K.2.4**, detail the manufacturing steps for each tool component. They include the specific action to be taken, the method to be used, and the machinery and tools required. Material specifications and any necessary speeds, feed rates, or setup instructions are also provided. For a quality finish, all stainless-steel components were polished with diamond compounds to achieve the desired surface roughness.

Below, **Figure K.2.1** illustrates the manufacturing workflow for the Stylet, which is composed of three distinct parts: the shaft, the handle, and the Nub. To fabricate the majority of the Stylet's shaft, the team primarily used a lathe and complemented this with a band saw to trim the shaft to the required length. The Nub was also initially cut with a band saw and then finely shaped with a lathe. The handle's manufacturing process is more intricate, including all the necessary specifications to be accurately produced using a Bambu Lab P1S 3D printer. Achieving the correct print for the 3D printed components required multiple revisions of the operation sheet. The 3D printing process with Polypropylene (PP), a plastic known for its low surface energy and preference for self-adhesion, requires precise control and specific materials to ensure successful prints. To start, Magigoo PP is used for bed adhesion; it is applied when the bed is heated to 90°C, although the rest of the print proceeds at 85°C. After printing, the bed is reheated to between 90°C to 100°C to facilitate the removal of the print. While PP Scotch Packing Tape can also be laid down as a build surface to aid in bed adhesion, with Magigoo PP applied on top of it, this method has proven less effective. The nozzle temperature is meticulously maintained between 230°C to 260°C, with the print speed moderated at 30-55mm/s. A brim, measuring 25-30mm with 1-5 layers, is applied to bolster the print's stability. In instances where a raft is used, a single layer gap is maintained between the raft and the first layer of the print, and the use of glue may be avoided if an AquaSys raft is created. The AquaSys 120 filament is printed with a gyroid structure at a temperature range of 230°C to 245°C. Post-printing, hot water is used to dissolve the AquaSys material. Throughout the process, layer height is minimized to achieve the best print quality and dimensional accuracy. This refinement process was consistent across the manufacturing of all the handles and the Back Stabilizer. Notably, the operation sheet for the Stylet has undergone several changes during the Final

Design Review (FDR) phase. The team encountered difficulties in manufacturing threads for attaching the shaft to the handle. As a result, they opted to engineer a slip-fit connection for these parts, securing them together with adhesive epoxy. This design change was applied to the Denervator as well.

Shaft				
Step	Operation	Description	Equipment	Notes
1	Face end	Face end for threaded end	Lathe	S=130; F=Hand
2	Turn (outer body)	Ø11.4mm X 191.9mm Length	Lathe	S=130; F=Hand
3	Turn (inner body)	Ø4.25mm X 160.27mm Length	Lathe	S=130; F=Hand
4	Radius	Ø10mm; 90 degrees	Lathe (Radius tool)	S=60; F=Hand
5	Turn (chamfer end)	Ø.2mm to Ø4.25mm X 10.18mm Length	Lathe	S=60; F=Hand
6	Raw stock	Ø.75 X 191.9mm Length Stainless Steel 316L rod	Bandsaw	
7	Drill	Ø1.9mm X 1.875mm Length	Mill	S=1200; F=Hand
8	Hand debur	Remove all sharp edges	Hand tool	
9	Finish	Deburr, sand, and finish surface	Micropolish and buff wheel	
Handle				
Step	Operation	Description	Equipment	Notes
1	Load PP filament	1.75mm	Rerapper PP	
2	Set support structure	Set to Gyroid	Bambu Labs P1S	
3	Set infill	15%, Gyroid	Bambu Labs P1S	
4	Set brim	5mm	Bambu Labs P1S	
5	Set print speed	30mm/s	Bambu Labs P1S	
6	Set wall thickness	3 mm	Bambu Labs P1S	
7	Set layer height	0.18 mm	Bambu Labs P1S	
8	Set nozzle temperature	240 C (0.4mm)	Bambu Labs P1S	
9	Set bed temperature	85C	Bambu Labs P1S	
10	Set fan power	10% part fan, 50% chamber fan	Bambu Labs P1S	
11	Begin print	Send to a Bambu Labs P1S printer	Bambu Labs P1S	Print vertical/standing tall
12	Apply bed adhesion	Apply at 90C	Magigoo PP	
13	Reheat bed to 90-100C	Helps separate part from bed	Bambu Labs P1S	
14	Remove structures	Use removal tools	Structures removal kit	
Nub				
Step	Operation	Description	Equipment	Notes
1	Raw stock	Ø.75" X 2' Stainless Steel 316L rod	Bandsaw	
2	Face end	Face end for cleanliness	Lathe	S=130; F=Hand
3	Turn (Shape body)	Ø1.9mm X 2.189mm Length	Lathe	S=130; F=Hand
4	Hand debur	Remove all sharp edges	Hand tool	

Figure K.2.1 Stylet operational sheet

Figure K.2.2 below shows the operation sheet for the manufacturing process of creating the Portal. This part was separated out into three components: the hollow shaft, C-Ring, and Sleeve. The manufacturing process of the portal consists of a six-step procedure.

Initially, the material is cut to the desired length with an additional two-inch excess using a hacksaw. Following the initial cut, the ends are wrapped in thick tape until the effective diameter exceeds 1 centimeter, which helps in handling and prevents damage to the ends. The third step involves using a non-metal rotary laser cutter to etch out specific features on the Portal. To securely hold the material for this precision work, the portal is then wrapped in a thick cloth

and clamped in a vice. After the features are etched, a fine-bit Dremel tool is used to finish the cutout features and trim the portal to the exact size required. The final step in the process includes deburring, sanding, and polishing the surface with a micro-polish and buff wheel to ensure a smooth finish.

Hollow Shaft				
Step	Operation	Description	Equipment	Notes
1	Cut to length	Approximately cut to length with +2" excess	Hacksaw	Cut by hand to avoid damaging
2	Wrap in tape	Wrap ends until effective diameter exceeds 1cm	Thick tape	To fit into laser cutter
3	Run etching sequence	Cut out features on the Portal	Non-metal rotary laser cutter	Maximum power settings (etch)
4	Support in vice	Wrap tool in thick cloth to support it in a vice	Vice	
5	Finish features	Finish cut out features and trim to size	Fine-bit Dremel	
6	Finish	Deburr, sand, and finish surface	Micropolish and buff wheel	
C-Clip				
Step	Operation	Description	Equipment	Notes
1	Load PP filament	1.75mm	Reprapper PP	
2	Set support structure	Set to Gyroid	Bambu Labs P1S	
3	Set infill	15%, Gyroid	Bambu Labs P1S	
4	Set brim	5mm	Bambu Labs P1S	
5	Set print speed	30mm/s	Bambu Labs P1S	
6	Set wall thickness	3 mm	Bambu Labs P1S	
7	Set layer height	0.18 mm	Bambu Labs P1S	
8	Set nozzle temperature	240 C (0.4mm)	Bambu Labs P1S	
9	Set bed temperature	85C	Bambu Labs P1S	
10	Set fan power	10% part fan, 50% chamber fan	Bambu Labs P1S	
11	Begin print	Send to a Bambu Labs P1S printer	Bambu Labs P1S	Print without structures
12	Apply bed adhesion	Apply at 90C	Magigoo PP	
13	Reheat bed to 90-100C	Helps separate part from bed	Bambu Labs P1S	
14	Remove structures	Use removal tools	Structures removal kit	
Sleeve				
Step	Operation	Description	Equipment	Notes
1	Load PP filament	1.75mm	Reprapper PP	
2	Set support structure	Set to Gyroid	Bambu Labs P1S	
3	Set infill	15%, Gyroid	Bambu Labs P1S	
4	Set brim	5mm	Bambu Labs P1S	
5	Set print speed	30mm/s	Bambu Labs P1S	
6	Set wall thickness	3 mm	Bambu Labs P1S	
7	Set layer height	0.18 mm	Bambu Labs P1S	
8	Set nozzle temperature	240 C (0.4mm)	Bambu Labs P1S	
9	Set bed temperature	85C	Bambu Labs P1S	
10	Set fan power	10% part fan, 50% chamber fan	Bambu Labs P1S	
11	Begin print	Send to a Bambu Labs P1S printer	Bambu Labs P1S	
12	Apply bed adhesion	Apply at 90C	Magigoo PP	
13	Reheat bed to 90-100C	Helps separate part from bed	Bambu Labs P1S	
14	Remove structures	Use removal tools	Structures removal kit	

Figure K.2.2 Portal operation sheet

Figure K.2.3 below shows the operation sheet for the manufacturing process of creating the Back Stabilizer. This part was separated out into two components: the base and pads. A major difference in printing the Back stabilizer was how the part was oriented to print. It is shown in the notes section of the operation sheet to print the part facing upside down, which was

critical in printing a Back Stabilizer that would not warp. The team did extensive research on how to properly print with polypropylene filament, driving all manufacturing decisions. Much iteration was done to determine the ideal way to manufacture the Back Stabilizer, but the final method can be detailed in **Figure K.2.3**.

Base				
Step	Operation	Description	Equipment	Notes
1	Load PP filament	1.75mm	Reprapper PP	
2	Set support structure	Set to Gyroid	Bambu Labs P1S	
3	Set infill	15%, Gyroid	Bambu Labs P1S	
4	Set brim	5mm	Bambu Labs P1S	
5	Set print speed	30mm/s	Bambu Labs P1S	
6	Set wall thickness	3 mm	Bambu Labs P1S	
7	Set layer height	0.18 mm	Bambu Labs P1S	
8	Set nozzle temperature	240 C (0.4mm)	Bambu Labs P1S	
9	Set bed temperature	85C	Bambu Labs P1S	
10	Set fan power	10% part fan, 50% chamber fan	Bambu Labs P1S	
11	Begin print	Send to a Bambu Labs P1S printer	Bambu Labs P1S	Print upside down (clamp down)
12	Apply bed adhesion	Apply at 90C	Magigoo PP	
13	Reheat bed to 90-100C	Helps separate part from bed	Bambu Labs P1S	
14	Remove structures	Use removal tools	Structures removal kit	

Pads				
Step	Operation	Description	Equipment	Notes
1	Rubber stock	12" x 12" x 1/25" rubber sheet	Purchased	
2	Cut sheet	Cut into two 10mm x 10mm pieces	Scissors	Hand
3	Radius	Ø1mm; 90 degrees 4 corners	Scissors	Hand
4	Radius	Ø0.5mm; 90 degrees 4 sides	Scissors	Hand
5	Hand debur	Remove all loose edges	Hand tool	

Figure K.2.3 Back Stabilizer operational sheet

Figure K.2.4 below shows the operation sheet for the manufacturing process of creating the Denervator. This part was separated out into two components: the shaft and handle. The team found challenges manufacturing threads for the connection between the shaft and handle, therefore the team decided to create a slip-fit and use an adhesive epoxy to secure the two parts. Machining requires precision and attention to detail at every step, from setup to the final operations. When setting up a lathe for knurling, the workpiece is secured in a collet closer with exactly 19.45mm exposed, ensuring proper grip without bending or misalignment. The piece is then brought to the sander where it is fine tuned to a surface finish between 0.05 and 0.01 microns.

The next phase involves filing and channel cutting, bringing the workpiece to within a +/- 0.05mm tolerance and creating a 1mm-wide channel 0.5mm from the tip. This is followed by smoothing with a file while the lathe runs at 650rpm. Milling setup requires the workpiece to be

transferred to a hexagonal collet block under the milling machine, finding the center with an edge finder, and performing center drilling at specified distances from the tip.

Finally, during drilling operations, precision is paramount. A small drill chuck equipped with a drill press return spring makes 1mm holes at marked locations. The speed is set between 1500-2000rpm, with Molybdenum Disulfide oil as a lubricant, ensuring smooth operation and long-lasting tool life. Both hands are used to apply consistent pressure throughout the drilling, maintaining the quality and integrity of the workpiece.

Denervator

Shaft

Step	Operation	Description	Equipment
1	Install Collet Closer	5/32" Collet installation with collet closer	Collet Closer
2	Face end	Face End	Lathe
3	Knurl	knurl; 40 LPI Ø4.0 X 7mm Length	Lathe (Knurling wheel)
4	Sand	Sand Tip Until 5mm Tip to Knurl	Belt Sander
5	Turn	Ø3.5mm X 1mm	Lathe
6	Mill	2X Ø1mm hole	Mill
7	Finishing pass	Finish entire surface to specification	Lathe
8	Hand debur	Remove all sharp edges	Hand tool
9	Finish	Deburr, sand, and finish surface	Micropolish and buff wheel

Handle

Step	Operation	Description	Equipment
1	Load PP filament	1.75mm	Reprapper PP
2	Set support structure	Set to Gyroid	Bambu Labs P1S
3	Set infill	15%, Gyroid	Bambu Labs P1S
4	Set brim	5mm	Bambu Labs P1S
5	Set print speed	30mm/s	Bambu Labs P1S
6	Set wall thickness	3 mm	Bambu Labs P1S
7	Set layer height	0.18 mm	Bambu Labs P1S
8	Set nozzle temperature	240 C (0.4mm)	Bambu Labs P1S
9	Set bed temperature	85C	Bambu Labs P1S
10	Set fan power	10% part fan, 50% chamber fan	Bambu Labs P1S
11	Begin print	Send to a Bambu Labs P1S printer	Bambu Labs P1S
12	Apply bed adhesion	Apply at 90C	Magigoo PP
13	Reheat bed to 90-100C	Helps separate part from bed	Bambu Labs P1S
14	Remove structures	Use removal tools	Structures removal kit

Figure K.2.4 Denervator Operational Sheet

The fit between the Denervator and the stylet within the portal was evaluated by the team using visual inspection and feel. They inserted each component into the portal and observed two key factors: the ease with which the component could be inserted, and the absence of significant lateral movement once in place. Moreover, the team opted for lathe machining to create knurls,

as this method allows for automation, facilitating mass production.

L. Validation Plan

During the FDR phase of this project, the team manufactured a final prototype for each of the four proposed medical tools. Though a developed prototype was great, the team was not able to deem the project successful unless the prototype was able to achieve the desired functions and performance. Specifically, the team had to ensure that the prototype met all functional requirements and customer needs. To clarify how each customer need was tested, the team put together a test-specifying engineering specification chart (ESC), which is depicted in **Figure L.1**.

Priority (1 - most, 5 - least)	Customer Need	Technical Need	Technical Requirement	Target Value	Validation Plan
3	Ease of use/inability for mishandling	Ease-of-use ratings	The average ease-of-use rating from those who use or test the medical tools must be at least 75% . This number is very subjective, hence it being a conservative percentage.	75%	Ease-of-Use Test
1	Minimally invasive (no general anesthesia or stitches are needed)	Diameter	The outer diameter of the portal should be no larger than 12.7mm to fit within a small incision.	5mm	Incision Test
3	Disposable (one-time use)	Reprocessing rate	0% rate for reprocessing the device (cleaning, disinfecting, or sterilizing).	0%	Given (Doctors' Control)
1	Initial sterilization	Temperature	The medical tools should all be able to withstand steam sterilization at temperatures of 250-273°F	273°F	Temperature Test
1	Initial sterilization	Pressure	The medical tools should all be able to withstand steam sterilization at pressures of 15-30psi .	30psi	Analysis (FEA)
1	Tool appearance on X-ray	Validation score	The X-ray images must get a cumulative score of 5 when being evaluated by the four members of the engineering team and a doctor, where each person can give a rating of 1 (the tools show up as desired) or 0 (the tools do not show up as expected).	5	X-ray Imaging Test
1	Pain should be relieved effectively for long periods	Length of displaced distal ends	The destructive tool must create a lesion in the myelin sheath and displace the ends of the nerve by at least 5mm .	7-8mm	Lesion Test
3	Avoidance of neuromas	Length of displaced distal ends	The destructive tool must create a lesion in the myelin sheath and displace the ends of the nerve by at least 7mm .	10mm	Lesion Test
1	Strong enough to withstand procedural force	Force	The medical tools should withstand at least 20N .	40N	Analysis (FEA) and Force Identification Testing
4	Sustainability	Recycling rate	At least 50% of the material volume in the kit should be recyclable to be repurposed.	75%	Given (Material Selection)

Figure L.1 ESC with an appended column to define the validation plan for each customer need (some needs have been previously validated via design decisions or analysis)

From this chart, it's first important to note that the disposable customer need is a given; the customer controls whether the medical tools will be disposed of. Therefore, if the customers desire disposable medical tools, they can control that by disposing of the tools themselves. Another important thing to note is that the sustainability customer need had already been proven through research. As discussed in **Section G.2**, grade 316L stainless steel and polypropylene are both completely recyclable^{15,58}. For this reason, approximately 99% of the material volume in the

medical tools is recyclable, satisfying the technical requirement and target value for the sustainability customer need. A third thing to note about the test-specifying ESC in **Figure L.1** is that the initial sterilization customer need was split into two different rows, such that one row focused on temperature and the other on pressure. The reason for this was that it was practically impossible to physically test the pressure specification, and it had already been proven through analysis (FEA), further described in **Appendix I**. Meanwhile, despite the temperature specification having also passed the analyses previously performed (thermal stress studies), it was feasible to physically test this specification. For this reason, the *Temperature Test* was performed, as discussed in further detail in **Section L.1**. A final thing to note was that, as discussed with the pressure specification, the team was able to meet a few customer needs during the CDR phase through design iteration and performed analyses. These analysis-proven customer needs are noted in the test-specifying ESC in **Figure L.1**. The specific analyses performed to satisfy the associated customer needs are further discussed in **Appendix I**. While previous design decisions and analyses helped the team validate a few customer needs, many remained to be satisfied or even tested against. Therefore, the team developed a variety of tests, as were outlined in the CDR report. During the FDR phase, the team was able to carry out these tests to validate the prototype against the remaining customer needs. Each test is listed in its associated row for the customer need in the test-specifying ESC in **Figure L.1**.

The validation plans undergone, as described in **Sections L.1 through L.3**, fit within three major categories: there is customer need testing, force identification testing, and modularity testing. With regards to customer need testing (**Section L.1**), the team performed quantifiable tests to determine how well the medical tools satisfy the engineering specifications. For example, the incision test determined that the length of incision created by these medical tools was about 4.24mm, which proved successful when compared to the pre-established target for the incision length to be less than or equal to 5mm.

For force identification testing (**Section L.2**), it's important to note that this did not include fatigue strength or failure. Since all the proposed medical tools were designed to be disposable (and therefore used one time), fatigue was a negligible concern. Force identification testing was done for the team to identify procedural force limits (to advise doctors of) and simultaneously test the customer need that the medical tools need to be strong enough to withstand the procedural force. Considering hand calculations and further FEA were performed

during the CDR phase, these force tests were not extensive and rather served the purpose to identify the forces that could not be prior analyzed (such as the force required to overcome the friction between the Back Stabilizer and the skin).

Finally, for functionality testing (**Section L.3**), the team tested simple things such as tool fits. This ensured that the manufactured prototype is up to the desired standard of the team and is usable. After all, if the team was not able to develop a usable prototype, then it would have been useless. These tests did not require any extensive planning, as they merely required the medical tools.

From a general perspective, the medical tools were able to satisfy all engineering specifications. In fact, the design did not require immediate iteration to overcome a failure or satisfy a requirement. All design and iteration previously done during the CDR method proved valuable, as the prototypes lived up to expectations. A result-defining ESC details the specific results for each physically performed test, as depicted in **Figure L.2**. Further understanding and explanation for each test, as well as future iteration suggestions, can be found in **Sections L.1 through L.3**.

Priority (1 - most, 5 - least)	Customer Need	Technical Need	Technical Requirement	Target Value	Result
3	Ease of use/inability for mishandling	Ease-of-use ratings	The average ease-of-use rating from those who use or test the medical tools must be at least 75% . This number is very subjective, hence it being a conservative percentage.	75%	81.25%
1	Minimally invasive (no general anesthesia or stitches are needed)	Diameter	The outer diameter of the portal should be no larger than 12.7mm to fit within a small incision.	5mm	4.24mm
1	Initial sterilization	Temperature	The medical tools should all be able to withstand steam sterilization at temperatures of 250-273°F	273°F	300°F
1	Tool appearance on X-ray	Validation score	The X-ray images must get a cumulative score of 5 when being evaluated by the four members of the engineering team and a doctor, where each person can give a rating of 1 (the tools show up as desired) or 0 (the tools do not show up as expected).	5	5
1	Pain should be relieved effectively for long periods	Length of displaced distal ends	The destructive tool must create a lesion in the myelin sheath and displace the ends of the nerve by at least 5mm .	7-8mm	6.46mm
3	Avoidance of neuromas	Length of displaced distal ends	The destructive tool must create a lesion in the myelin sheath and displace the ends of the nerve by at least 7mm .	10mm	6.46mm

Figure L.2 ESC with an appended column to define the result of each physically performed customer need test

L.1 Customer Needs Testing

L.1.1 Incision Test

Purpose: It has previously been discussed that a desire for these medical tools and the associated medical procedure is that stitches will not be required post-procedure. To achieve this, the medical tools must be classified as minimally invasive, which approximately occurs for incisions less than 12.7mm in length³⁸. Since invasiveness is driven by incision size, this test will determine the incision size produced from the medical tools.

Tested Function/Customer Need: The tested customer need is that the medical tools should be minimally invasive, which is further described in **Figure L.1.1.1**.

Priority (1 - most, 5 - least)	Customer Need	Technical Need	Technical Requirement	Target Value
1	Minimally invasive (no general anesthesia or stitches are needed)	Diameter	The outer diameter of the portal should be no larger than 12.7mm to fit within a small incision.	5mm

Figure L.1.1.1 Further description of the minimally invasive customer need tested in the *Incision Test*

Expected Results: The average incision length is expected to be approximately 5mm, considering the outer diameter of the Portal was designed to be 5mm.

Materials:

- Oven tray
- Aluminum foil
- Pork shoulder ribs
- Stylet
- Portal
- Force gauge
- Craft knife

- Disposable gloves
- Ruler

Location: This test was performed in Jacob's apartment.

Setup: A sketched schematic for the test setup is depicted in **Figure L.1.1.2**, while a picture of the physical test setup is depicted in **Figure L.1.1.3**.

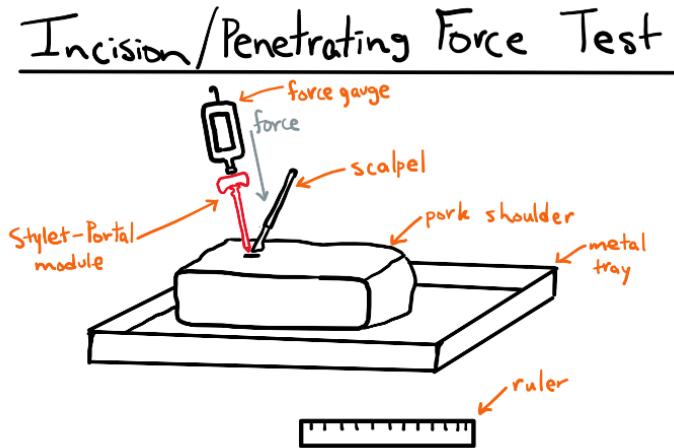


Figure L.1.1.2 Sketched schematic for the setup of the *Incision Test*



Figure L.1.1.3 Picture of the physical setup of the *Incision Test*

Procedure:

1. The tester begins by putting on the disposable gloves to prevent any contact with the raw meat.
2. The oven tray is lined with aluminum foil.
3. A pork shoulder rib (used to best represent the human body, as advised to the team by Dr. Mostoufi) is placed on the oven tray.
4. The Stylet is interlocked with the Portal.
5. The craft knife is used along with a ruler to cut an initial incision of approximately 2mm in length.
6. The Stylet-Portal module is inserted into the initial incision, then the force gauge is used to drive the Stylet-Portal all the way into the pork.
7. The Stylet-Portal module is held in the pork for 5 minutes, before removing them from the pork.
8. A ruler is used to measure the length of the remaining incision.
9. Repeat to gather 10 total samples.

Measurement System: The incision length is measured in millimeters using a ruler.

Results: The *Incision Test* yielded an average incision length of 4.24mm. The raw data (from which was averaged) for each sample can be seen in **Table L.1.1.1**.

Table L.1.1.1 Raw data from the *Incision Test*

Sample	Length (mm)
1	3.8
2	4.9
3	4.0
4	4.1
5	4.8
6	3.7
7	4.5
8	4.3
9	4.3
10	4.0

Justification: The prototype satisfies the customer need of being minimally invasive. This is because the average incision length due to the medical tools is 4.24mm, which satisfies the technical requirement by being less than 12.7mm, and also hits the target value by being less than 5mm. This result aligns with the expected results, considering the outer diameter of the Portal was designed to be 5mm. Therefore, the incision length was not expected to be any larger than this considering the elasticity of the meat.

Future Suggestions: During this test, it was hard to tell how deep the medical tools were within the pork. Although X-ray imaging will help guide the tools during procedural use, this will not provide the doctor with an understanding of the depth of the tools. Because of this, the team believes that etches, engravings, or paintings should be made on the Portal to signify depth lines as well as orientation lines.

L.1.2 Lesion Test

Purpose: It has previously been discussed that these medical tools should effectively relieve pain for long periods of time, while avoiding neuroma generation. To achieve this, the medical tools must displace the distal ends of the lumbar medial branch nerve by a significant length. Therefore, this test will determine the distance of nerve separation that can be produced by the medical tools.

Tested Function/Customer Need: The two tested customer needs are that the medical tools should relieve pain effectively for long periods of time and the medical tools should avoid neuromas. These customer needs are further described in **Figure L.1.2.1**.

Priority (1 - most, 5 - least)	Customer Need	Technical Need	Technical Requirement	Target Value
1	Pain should be relieved effectively for long periods	Length of displaced distal ends	The destructive tool must create a lesion in the myelin sheath and displace the ends of the nerve by at least 5mm .	7-8mm
3	Avoidance of neuromas	Length of displaced distal ends	The destructive tool must create a lesion in the myelin sheath and displace the ends of the nerve by at least 7mm .	10mm

Figure L.1.2.1 Further description of the effective pain relief over long periods and neuroma avoidance customer needs, which were tested in the *Lesion Test*

Expected Results: The average distance of nerve separation is expected to be approximately 7mm, considering the length of the knurled section of the Denervator was designed to be 7mm.

Materials:

- Block of wood
- Stapler (loaded with staples)
- 1.5mm rubber bands
- Denervator
- Ruler

Location: This test was performed in Jacob's apartment.

Setup: A sketched schematic for the test setup is depicted in **Figure L.1.2.2**, while a picture of the physical test setup is depicted in **Figure L.1.2.3**.

Lesion Test

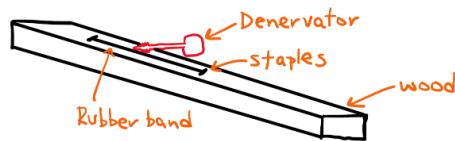


Figure L.1.2.2 Sketched schematic for the setup of the *Lesion Test*



Figure L.1.2.3 Picture of the physical setup of the *Lesion Test*

Procedure:

1. A rubber band is ripped at one point in the circle such that it becomes a singular strand. The rubber band will be used to represent the lumbar medial branch nerve, as supported by their similar elastic and tensile properties.

2. The rubber band strand is stapled to either end of the wood block. The wood block represents the bone backing of the nerve in this test.
3. The tester grinds the rubber band with the Denervator until it cuts the rubber bands.
4. A ruler is used to measure the length of the displaced rubber band ends.
5. Repeat to gather 10 total samples.

Measurement System: The distance of rubber band separation is measured in millimeters using a ruler.

Results: The *Lesion Test* yielded an average rubber band separation of 6.46mm. The raw data (from which was averaged) for each sample can be seen in **Table L.1.2.1**.

Table L.1.2.1 Raw data from the *Lesion Test*

Sample	Length (mm)
1	7.4
2	5.2
3	7.1
4	6.1
5	5.4
6	7.6
7	5.8
8	8.4
9	5.4
10	6.2

Justification: The prototype satisfies the customer need of relieving pain effectively for long periods. This is because the average rubber band separation due to the medical tools is 6.46mm, which satisfies the technical requirement by being greater than 5mm. This unfortunately falls short of the target value, which was set at 7-8mm of separation. The prototype also fails to satisfy the customer need of neuroma avoidance, considering the

average rubber band separation was 6.46mm and the technical requirement required at least 7mm of rubber band separation. These results do actually make sense: the length of the knurled section for the Denervator prototype was manufactured as 6.54mm. Prior to the test, it was assumed that the distance of separation would be 1:1 with the length of the knurled section. After performing the test and measuring the length of the knurled section, this assumption is proven true. This doesn't change the fact that the prototype failed to satisfy these values, though it does bring clarification as to why the tools failed. It's also important to note that these tests were performed for only one pass of the Denervator. During the procedure, the Denervator would be passed to the lumbar medial branch nerve multiple times to lesion it. Therefore, the technical requirements and target values were developed to reflect multiple passes. Considering this, the technical requirements and target values for a singular pass can be divided by two (being conservative, such that only two passes would occur). When comparing the results of this test to the adjusted technical requirements and target values, the prototype would satisfy both customer needs completely. Because of this, it can be said that the prototype satisfies the effective pain relief for long periods customer need and falls within the acceptable range for a singular pass to satisfy the neuroma avoidance customer need. This gives context as to why the result cell was highlighted yellow for the neuroma avoidance customer need in **Figure L.2**.

Future Suggestions: Two future suggestions have arisen due to the results of this test. The first suggestion is to increase the length of the knurled section to 10mm. Considering the distance of nerve displacement is 1:1 with the length of the knurled section and the target value for neuroma avoidance is 10mm, the knurled section should be manufactured 10mm long to completely satisfy this customer need. The other suggestion for the design of the prototype is to increase the sharpness of the knurls. It took a while to create the lesion in the rubber band, which signified that the knurls were not as sharp as desired. If the knurls are to be made sharper, then it would be easier and quicker to cut the nerve.

L.1.3 Temperature Test

Purpose: It has previously been discussed that a desire for these medical tools is that they can withstand sterilization. To achieve this, the medical tools must be able to withstand autoclave sterilization, which happens for up to 30 minutes at temperatures up to 273°F⁴⁷. Therefore, this test will determine if the medical tools can withstand the high temperatures of autoclave sterilization.

Tested Function/Customer Need: The tested customer need is that the medical tools should be able to withstand initial sterilization, which is further described in **Figure L.1.3.1**.

Priority (1 - most, 5 - least)	Customer Need	Technical Need	Technical Requirement	Target Value
1	Initial sterilization	Temperature	The medical tools should all be able to withstand steam sterilization at temperatures of 250-273°F	273°F

Figure L.1.3.1 Further description of the initial sterilization customer need tested in the *Temperature Test*

Expected Results: The tools are expected to withstand temperatures of at least 300°F without deformation, discoloration, or structural weakening.

Materials:

- Oven
- Oven tray
- Oven mitts
- Stylet
- Portal
- Back Stabilizer
- Denervator

Location: This test was performed in Aggy and Cameron's apartment.

Setup: A sketched schematic for the test setup is depicted in **Figure L.1.3.2**, while a picture of the physical test setup is depicted in **Figure L.1.3.3**.

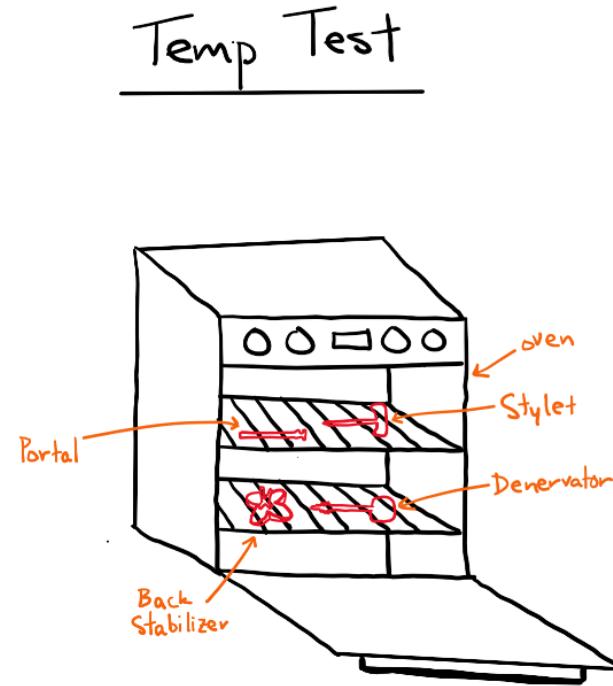


Figure L.1.3.2 Sketched schematic for the setup of the *Temperature Test*



Figure L.1.3.3 Picture of the physical setup of the *Temperature Test*

Procedure:

1. The oven is heated to 300°F, to be conservative since there is no exact setting to ensure 273°F and the tools should have no difference withstanding 300°F versus 273°F.
2. Once the oven indicates that it has heated up to 300°F, the medical tools are all placed on an oven tray and inserted into the oven.
3. The medical tools are left in the oven for 30 minutes.
4. After the 30 minutes are up, the medical tools are removed from the oven.
5. Any deformation or discoloration is visually observed.
6. After the tools cool down, considerable efforts are made to deform them. Any structural weakening is observed.

Measurement System: The oven temperature is measured by an internal thermometer in degrees Fahrenheit, while the deformation, discoloration, and structural weakening are all qualitatively observed.

Results: The *Temperature Test* proved that the tools withstood 300°F without any sort of noticeable deformation, discoloration, or structural weakening.

Justification: The prototype satisfies the customer need of withstanding initial sterilization. This can be credited to the material choices. The prototype features grade 316L stainless steel, polypropylene, structural epoxy, and silicone rubber, all of which have melting temperatures well above 300°F. These material choices are further elaborated in **Section G.2**.

Future Suggestions: No future suggestions arose during this test.

L.1.4 X-ray Imaging Test

Purpose: It has previously been discussed that a desire for these medical tools is that they will properly show up on X-ray imaging. While the procedure is being performed, X-ray imaging will help the doctor guide the medical tools within the body. To achieve effective X-ray guidance, the materials and specific geometries of the medical tools must

show up properly on the X-ray images. Therefore, this test will determine whether the medical tools show up properly on X-ray images.

Tested Function/Customer Need: The tested customer need is the tool appearance on X-ray images, which is further described in **Figure L.1.4.1**.

Priority (1 - most, 5 - least)	Customer Need	Technical Need	Technical Requirement	Target Value
1	Tool appearance on X-ray	Validation score	The X-ray images must get a cumulative score of 5 when being evaluated by the four members of the engineering team and a doctor, where each person can give a rating of 1 (the tools show up as desired) or 0 (the tools do not show up as expected).	5

Figure L.1.4.1 Further description of the tool appearance on X-ray images customer need tested in the *X-ray Imaging Test*

Expected Results: The medical tools will properly show up on X-ray images, both with respect to the materials and well as the specific geometry. This will earn them a passing score from all five individuals who judge the X-ray images, aggregating to a validation score of 5.

Materials:

- Stylet
- Portal
- Back Stabilizer
- Denervator
- X-ray machines and equipment
- Model pelvis
- Gelatin

Location: This test was performed at the Purdue Veterinary School.

Setup: A sketched schematic for the test setup is depicted in **Figure L.1.4.2**, while a picture of the physical test setup is depicted in **Figure L.1.4.3**.

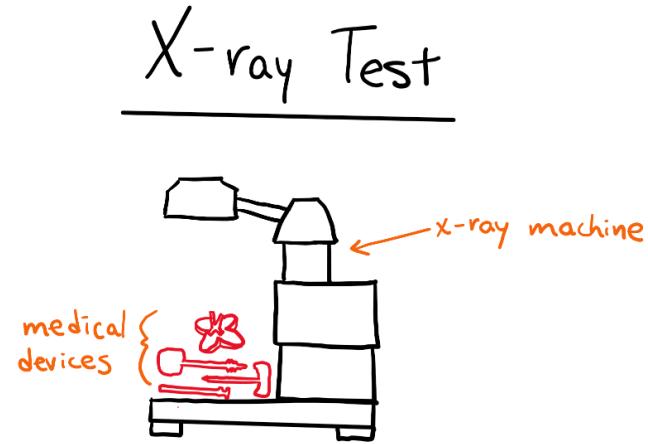


Figure L.1.4.2 Sketched schematic for the setup of the *X-ray Imaging Test*

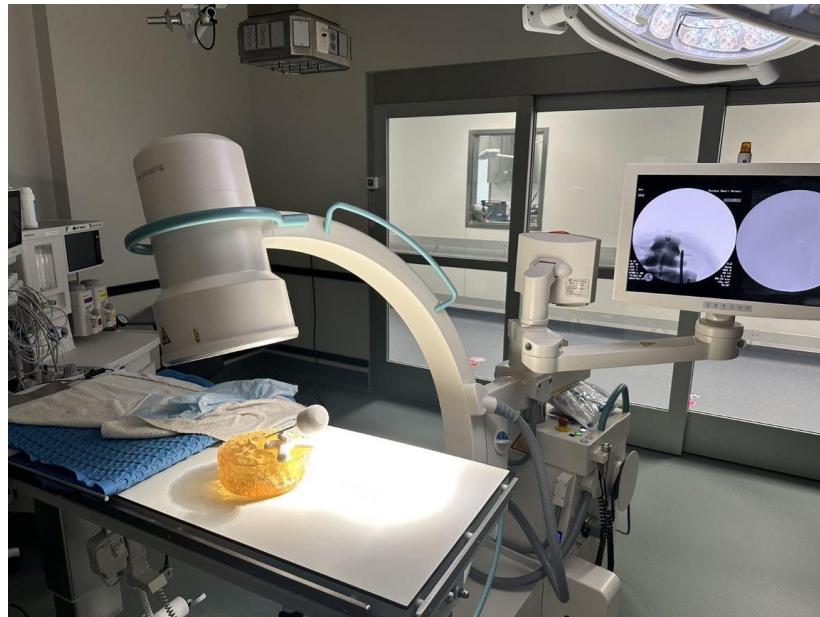


Figure L.1.4.3 Picture of the physical setup of the *X-ray Imaging Test*

Procedure:

1. Reach out to the Purdue Veterinary School to get their approval to perform X-ray imaging on the medical tools.
2. Set up an appointment with an X-ray technician.

3. Before the appointment, set a model pelvis in a tub of gelatin.
4. Show up for the appointment with a plan.
5. Work with the X-ray technician to capture the desired X-ray images.
6. Have the entire team, along with an industry expert, analyze the X-ray images to determine whether the tools show up properly.
7. Have all five people give these images a score of 0 (fail) or 1 (pass).

Measurement System: The X-ray images are judged as either passing or failing to show up properly on X-ray images. This has been converted to a binary pass/fail scale, where a score of 0 indicates that the tools failed to show up properly, while a score of 1 indicates that the tools passed to show up properly.

Results: The *X-ray Imaging Test* yielded a cumulative validation score of 5 from the four members on the engineering team and the one industry expert. In this case, Dr. Mostoufi was the industry expert who helped the team determine whether the medical tools showed up properly on the X-ray images. Notably, the metal materials (grade 316L stainless steel) showed up on the X-ray images, while the plastic and adhesive materials (polypropylene, silicone rubber, and structural epoxy) did not show up on the X-ray images. This can be seen in **Figures L.1.4.4 through L.1.4.6**. **Figures L.1.4.4 and L.1.4.5** demonstrate the Stylet and Denervator, respectively. The metal shafts are very noticeable on the X-ray images, while the structural epoxy and polypropylene handles only very barely show up and are translucent (you can see the metal shafts inside of the handles on the images, despite not being able to physically see them). **Figure L.1.4.6** demonstrates the Stylet and Denervator, where the Stylet is distinguishable on the X-ray image. However, the Back Stabilizer is again very barely noticeable and is translucent, demonstrating the proper material appearance on the X-ray images. Along with the proper material appearance, the specific geometry of the medical tools properly showed up on the X-ray images. A few examples of this can be seen in **Figures L.1.4.6 through L.1.4.8**. In **Figure L.1.4.6**, the pointy tip of the Stylet can be easily depicted. This is important to visualize, considering X-ray imaging will guide the doctors when penetrating the Stylet to the facet joint. **Figure L.1.4.7** then demonstrates the Portal

shield. This is important to visualize for the doctors to understand the orientation of the medical tools, as incorrect orientation could lead to unnecessary collateral damage.

Finally, **Figure L.1.4.8** demonstrates the end of the Denervator. It is very important to be able to visualize the two 1mm-diameter holes, considering these indicate the active cutting section. The doctor needs to know the active cutting section of the Denervator to again prevent any unnecessary collateral damage.

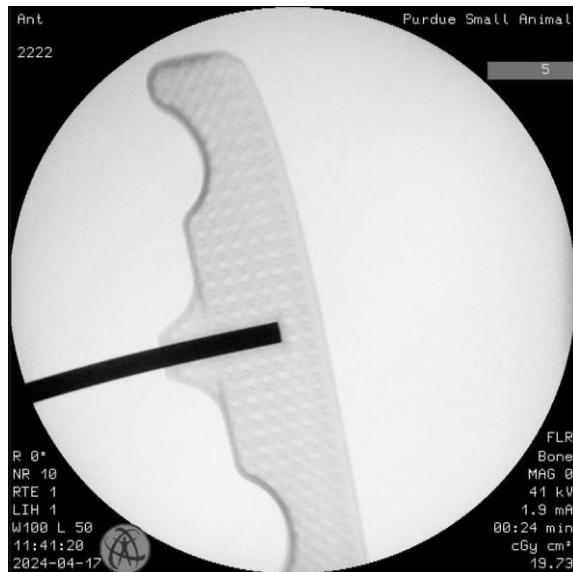


Figure L.1.4.4 X-ray image of the Stylet

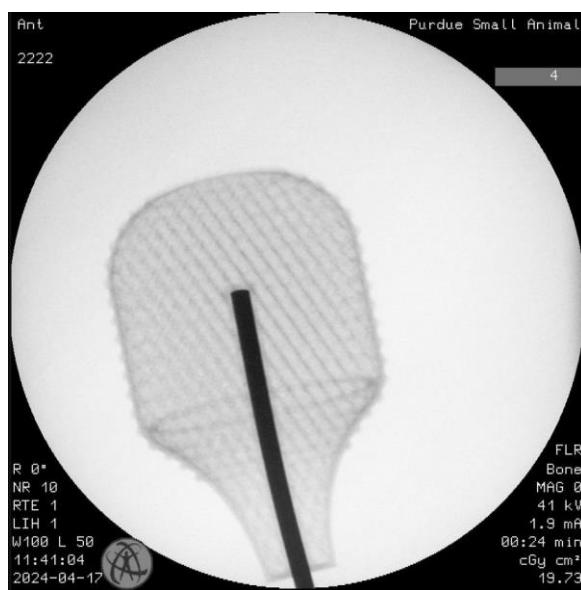


Figure L.1.4.5 X-ray image of the Denervator



Figure L.1.4.6 X-ray image of the Stylet being inserted into the pelvis, while being clamped by the Denervator

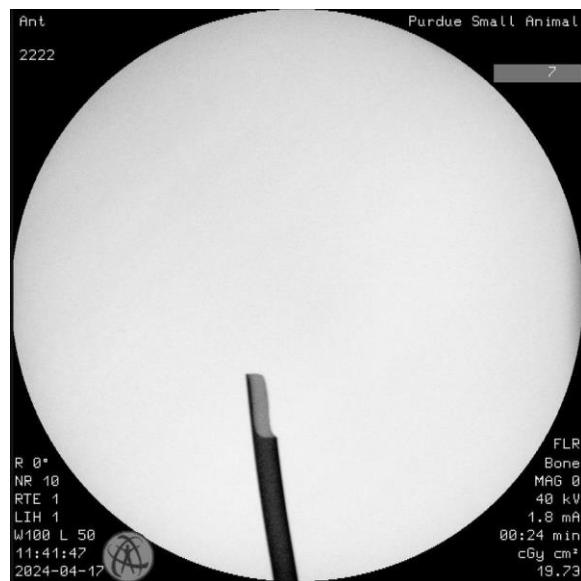


Figure L.1.4.7 X-ray image of the end of the Portal

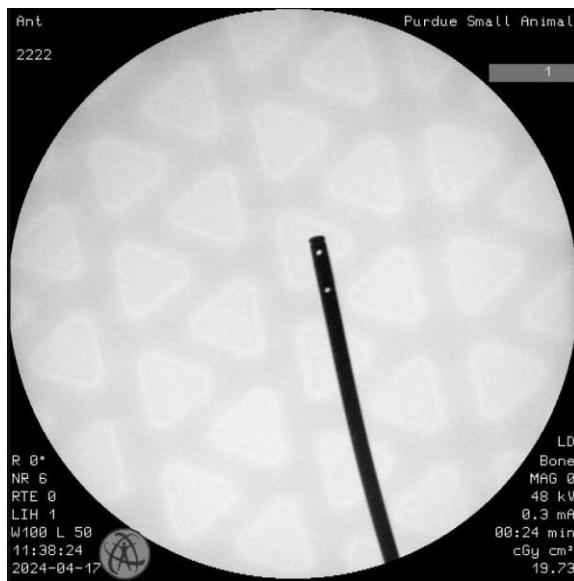


Figure L.1.4.8 X-ray image of the end of the Denervator

Justification: The prototype satisfies the customer need of proper X-ray appearance. This can be credited to the material choices and design decisions. The prototype features grade 316L stainless steel, polypropylene, structural epoxy, and silicone rubber, which have all been researched to show up on X-rays as much (or as little) as desired. These material choices are further elaborated in **Section G.2**. Similarly, this prototype features specific geometry such as the 1mm-diamtere holes at the end of the Denervator as well as the Portal shield. These geometries facilitate proper X-ray appearance, and are further elaborated in **Appendix H**.

Future Suggestions: No future suggestions arose during this test.

L.1.5 Ease-of-Use Test

Purpose: It has previously been discussed that a desire for these medical tools is that they are both easy to use and hard to mishandle. To achieve this, the medical tools must be considered easy to use during procedural use. Therefore, this test will determine the ease-of-use rating for the medical tools.

Tested Function/Customer Need: The tested customer need is the ease of use of the medical tools, which is further described in **Figure L.1.5.1**.

Priority (1 - most, 5 - least)	Customer Need	Technical Need	Technical Requirement	Target Value
3	Ease of use/inability for mishandling	Ease-of-use ratings	The average ease-of-use rating from those who use or test the medical tools must be at least 75% . This number is very subjective, hence it being a conservative percentage.	75%

Figure L.1.5.1 Further description of the ease-of-use customer need tested in the *Ease-of-Use Test*

Expected Results: The medical tools are expected to yield an average ease-of-use rating of 75%. This is because ergonomics and usability were heavily considered while designing the medical tools.

Materials:

- Stylet
- Portal
- Back Stabilizer
- Denervator
- Oven tray
- Aluminum foil
- Pork shoulder ribs
- Disposable gloves

Location: This test was performed in Jacob's apartment.

Setup: A sketched schematic for the test setup is depicted in **Figure L.1.5.2**, while a picture of the physical test setup is depicted in **Figures L.1.5.3 and L.1.5.4**.

Ease-of-Use Test

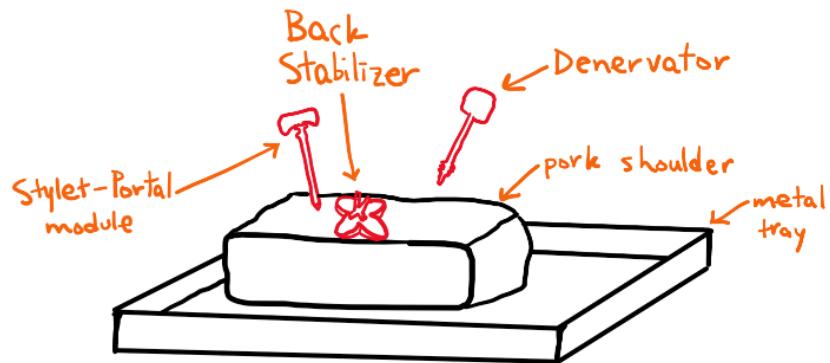


Figure L.1.5.2 Sketched schematic for the setup of the *Ease-of-Use Test*



Figure L.1.5.3 Picture of the physical setup of the *Ease-of-Use Test* during the insertion of the Stylet-Portal module



Figure L.1.5.4 Picture of the physical setup of the *Ease-of-Use Test* during the clamping of the Back Stabilizer around the Portal

Procedure:

1. The tester begins by putting on the disposable gloves to prevent any contact with the raw meat.
2. The oven tray is lined with aluminum foil.
3. A pork shoulder rib (used to best represent the human body, as advised to the team by Dr. Mostoufi) is placed on the oven tray.
4. The Stylet is interlocked with the Portal.
5. The Stylet-Portal modules are inserted into the pork.
6. The Stylet is removed from the Portal.
7. The Back Stabilizer is clamped around the Portal and set to rest on the pork.
8. The Denervator is inserted into the Portal and twisted to simulate nerve lesioning.
9. The tools are removed from the pork.
10. The tester gives the tools an ease-of-us rating between 0% and 100%.
11. Repeat this process for each member of the team.

Measurement System: The ease-of-use ratings are on a scale of 0% to 100% but are subjective to each user.

Results: The *Ease-of-Use Test* yielded an average ease-of-use rating of 81.25%. The ratings (from which was averaged) from each person can be seen in **Table L.1.5.1**.

Table L.1.5.1 Individual ratings from the *Ease-of-Use Test*

Person	Rating
Jacob	80%
Cameron	95%
Aggy	80%
Joe	70%

Justification: The prototype satisfies the customer need of being easy to use. This is because the medical tools were heavily designed with ergonomics in mind. The team consulted multiple doctors to ensure that their design provided proper ergonomics, which specifically regarded the clamp of the Back Stabilizer and the grips on the Denervator handle. The team also used existing solutions in industry to mimic ergonomic designs, specifically with regards to the shape of the Stylet handle. Further discussion on the ergonomics and details of the design can be found in **Appendix H**.

Future Suggestions: During this test, each team member noted that the handles were a bit big. Therefore, it might be useful to reduce the handle size in the future to provide users with a more leveraged design. Similarly, each team member noted that the Back Stabilizer was a bit un-ergonomic. Specifically, they found it tough to rest a hand on. For this reason, the team plans to continually improve the ergonomics of the Back Stabilizer.

L.2 Force Identification Testing

L.2.1 Penetrating Force Test

Purpose: During customer need identification with doctors, the team was informed that the maximum procedural force that these medical tools would be used under would be approximately 5lbs (or 20N). To design these tools to a factor of safety (FOS) of 2, the team set a benchmark for these tools to be able to withstand 40N of procedural force. This test will be performed to both validate the assumed procedural force as well as ensure that the tools can withstand the desired procedural force.

Tested Function/Customer Need: The tested customer need is that the medical tools should be strong enough to withstand procedural force, which is further described in **Figure L.2.1.1**. The tested function is the procedural force applied to the medical tools.

Priority (1 - most, 5 - least)	Customer Need	Technical Need	Technical Requirement	Target Value
1	Strong enough to withstand procedural force	Force	The medical tools should withstand at least 20N .	40N

Figure L.2.1.1 Further description of the strong enough to withstand procedural force customer need tested in the *Penetrating Force Test*

Expected Results: The penetrating force should be approximately 20N, and the tools should withstand this without any issues.

Materials:

- Oven tray
- Aluminum foil
- Pork shoulder ribs
- Stylet
- Portal
- Force gauge
- Craft knife

- Disposable gloves
- Ruler

Location: This test was performed in Jacob's apartment.

Setup: A sketched schematic for the test setup is depicted in **Figure L.2.1.2**, while a picture of the physical test setup is depicted in **Figure L.2.1.3**.

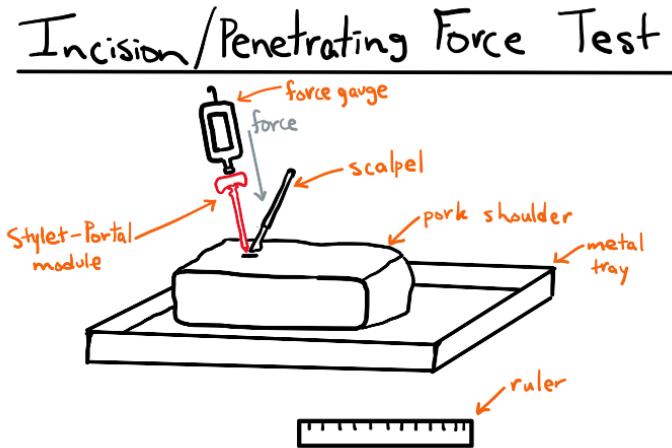


Figure L.2.1.2 Sketched schematic for the setup of the *Penetrating Force Test*



Figure L.2.1.3 Picture of the physical setup of the *Penetrating Force Test*

Procedure:

1. The tester begins by putting on the disposable gloves to prevent any contact with the raw meat.
2. The oven tray is lined with aluminum foil.
3. A pork shoulder rib (used to best represent the human body, as advised to the team by Dr. Mostoufi) is placed on the oven tray.
4. The Stylet is interlocked with the Portal.
5. The craft knife is used along with a ruler to cut an initial incision of approximately 2mm in length.
6. The Stylet-Portal module is inserted into the initial incision, then the force gauge is used to drive the Stylet-Portal all the way into the pork.
7. The peak force measured by the force gauge is recorded.
8. Repeat to gather 10 total samples.

Measurement System: The penetrating force is measured in Newtons by the force gauge.

Results: The *Penetrating Force Test* yielded an average penetrating force of 25.9N. The raw data (from which was averaged) for each sample can be seen in **Table L.2.1.1**. It's also important to note that the tools did not deform during this test.

Table L.2.1.1 Raw data from the *Penetrating Force Test*

Sample	Force (N)
1	23.5
2	26.1
3	26.0
4	23.6
5	31.1
6	22.9
7	22.7
8	27.1
9	27.6
10	28.4

Justification: The prototype satisfies the customer need of being able to withstand procedural force. This is because the average force applied to and withstood by the tools during penetration was 25.9N, which satisfies the technical requirement by withstanding at least 20N. This test failed to test the target value, so no conclusion can be made regarding this. However, the analysis performed in **Appendix I** can be used as evidence to support that the tools satisfy the target value. In fact, the satisfaction of the technical requirement aligns with the expected results, considering extensive analysis had been previously performed to validate the strength of the design. From this test, the prototype also further clarified the procedural force. This test helped the team determine that the penetrating force is approximately 25.9N, as opposed to 20N. This didn't align exactly with what Dr. Mostoufi had informed the team of, though it was relatively close. Identifying the procedural force gives the team valuable information to inform the doctors, as well as to make future design changes as needed.

Future Suggestions: The team wished to reduce the required penetrating force. To do this, the Stylet tip needs to be made sharper. The Stylet tip had been dulled-down ever-so-slightly in the design and manufacturing processes because the team wanted to limit danger from the tool. However, if the Stylet tip was made sharper, it would reduce the force required to penetrate the body. With a reduced force, the factor of safety for the medical tools would then increase.

L.2.2 Stabilization Force Test

Purpose: During customer need identification with doctors, the team was informed that the maximum procedural force that these medical tools would be used under would be approximately 5lbs (or 20N). To design these tools to a factor of safety (FOS) of 2, the team set a benchmark for these tools to be able to withstand 40N of procedural force. This test will be performed to both validate the assumed procedural force as well as ensure that the tools can withstand the desired procedural force.

Tested Function/Customer Need: The tested customer need is that the medical tools should be strong enough to withstand procedural force, which is further described in

Figure L.2.2.1. The tested function is the procedural force applied to the medical tools.

Priority (1 - most, 5 - least)	Customer Need	Technical Need	Technical Requirement	Target Value
1	Strong enough to withstand procedural force	Force	The medical tools should withstand at least 20N .	40N

Figure L.2.2.1 Further description of the strong enough to withstand procedural force customer need tested in the *Stabilization Force Test*

Expected Results: The stabilization force should be no greater than 20N, and the tools should withstand this without any issues.

Materials:

- Back Stabilizer

- Human back
- Force gauge

Location: This test was performed in Aggy and Cameron's apartment.

Setup: A sketched schematic for the test setup is depicted in **Figure L.2.2.2**, while a picture of the physical test setup is depicted in **Figure L.2.2.3**.

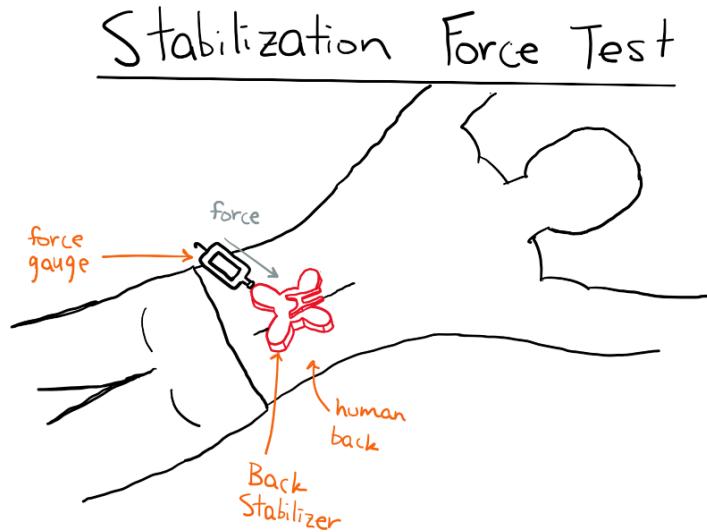


Figure L.2.2.2 Sketched schematic for the setup of the *Stabilization Force Test*



Figure L.2.2.3 Picture of the physical setup of the *Stabilization Force Test*

Procedure:

1. The Back Stabilizer is placed on the human back.
2. The tester puts 10N of downward force on the Back Stabilizer with their non-dominant hand, as calibrated with the force gauge.
3. The force gauge is reset.
4. The tester pushes on the Back Stabilizer with the force gauge, using their dominant hand, until the Back Stabilizer slips.
5. The force at slip is recorded.
6. Repeat to gather 10 total samples.

Measurement System: The stabilization force is measured in Newtons by the force gauge.

Results: The *Stabilization Force Test* yielded an average stabilization force of 14.4N. The raw data (from which was averaged) for each sample can be seen in **Table L.2.2.1**. It's also important to note that the tools did not deform during this test.

Table L.2.2.1 Raw data from the *Stabilization Force Test*

Sample	Force (N)
1	13.8
2	14.1
3	16.1
4	14.2
5	16.4
6	13.3
7	14.9
8	13.7
9	14.1
10	13.8

Justification: This test failed to test both the technical requirement and target value for the customer need, so no conclusion can be made regarding them. However, with regards to the customer need, it can be stated that the prototype does withstand procedural force. This is because the prototype did not deform due to any of the applied forces, which were applied to simulate the procedural forces. This aligns with the expected results that the tools were expected to withstand all applied forces. Despite this test failing to directly test the technical requirement and target value, the analysis performed in **Appendix I** can be used as evidence to support that the tools satisfy both these values. From this test, the prototype also further clarified the procedural force. This test helped the team determine that the stabilization force is approximately 14.4N, which is well under 20N. This aligned with what the team expected, considering stabilization is not the most force-necessitating action. Identifying the procedural force gives the team valuable information to inform the doctors, as well as to make future design changes as needed.

Future Suggestions: The team plans on continually improving the ergonomics of the Back Stabilizer. This is the most uniquely shaped tool, and its entire purpose is to provide ease of use. Therefore, the team will continue to work towards optimizing the ergonomics of this design to require even less stabilization force.

L.2.3 Clamping Force Test

Purpose: During customer need identification with doctors, the team was informed that the maximum procedural force that these medical tools would be used under would be approximately 5lbs (or 20N). To design these tools to a factor of safety (FOS) of 2, the team set a benchmark for these tools to be able to withstand 40N of procedural force. Also, during the analysis, it was desired that the Back Stabilizer provides 62.5N of clamping force on the Portal to prevent slipping due to procedural force. This test will be performed to validate the assumed procedural force to ensure that the tools can withstand the desired procedural force, and to determine if the Back Stabilizer can provide 62.5N of clamping force.

Tested Function/Customer Need: The tested customer need is that the medical tools should be strong enough to withstand procedural force, which is further described in

Figure L.2.3.1. The tested function is the procedural force applied by the medical tools.

Priority (1 - most, 5 - least)	Customer Need	Technical Need	Technical Requirement	Target Value
1	Strong enough to withstand procedural force	Force	The medical tools should withstand at least 20N.	40N

Figure L.2.3.1 Further description of the strong enough to withstand procedural force customer need tested in the
Clamping Force Test

Expected Results: The clamping force should be approximately 62.5N (equating to 40N of applied frictional force) according to the design of the Back Stabilizer, and the tools should withstand this without any issues.

Materials:

- Back Stabilizer
- Portal
- Force gauge

Location: This test was performed in Jacob's apartment.

Setup: A sketched schematic for the test setup is depicted in **Figure L.2.3.2**, while a picture of the physical test setup is depicted in **Figure L.2.3.3**.

Clamping Force Test

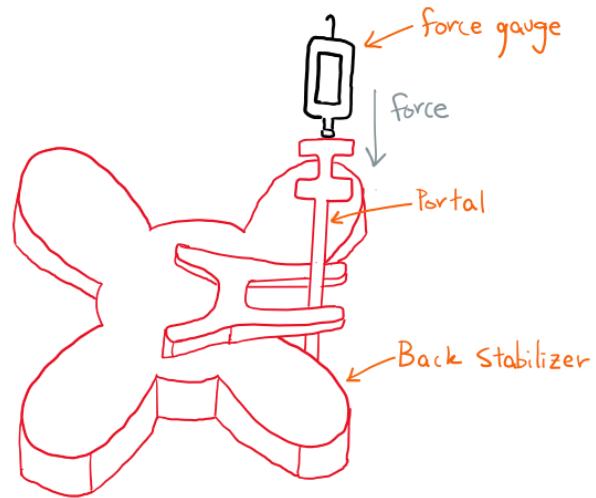


Figure L.2.3.2 Sketched schematic for the setup of the *Clamping Force Test*



Figure L.2.3.3 Picture of the physical setup of the *Clamping Force Test*

Procedure:

1. The Back Stabilizer is placed on the edge of a counter such that the clamp hangs over the edge.
2. The Portal is inserted into the clamp grips of the Back Stabilizer.
3. The force gauge is driven into the top of the Portal until it slips.
4. The force at slip is recorded from the force gauge.
5. The force at slip, which demonstrates the frictional force, is divided by the coefficient of friction to calculate the clamping force.
6. Repeat to gather 10 total samples.

Measurement System: The frictional force is measured in Newtons by the force gauge, before being converted to the clamping force, also in Newtons.

Results: The *Clamping Force Test* yielded an average frictional force of 13.3N. The raw data (from which was averaged) for each sample can be seen in **Table L.2.3.1**. This frictional force was then divided by the coefficient of friction between stainless steel and silicone, which is 0.64⁹. The average clamping force provided by the Back Stabilizer was therefore determined to be 20.8N. It's also important to note that the tools did not deform during this test.

Table L.2.3.1 Raw data from the *Clamping Force Test*

Sample	Force (N)
1	13.0
2	13.5
3	12.5
4	13.9
5	13.8
6	13.3
7	13.5
8	12.9
9	13.5

10	13.2
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Justification: This test failed to test both the technical requirement and target value for the customer need, so no conclusion can be made regarding them. However, with regards to the customer need, it can be stated that the prototype does withstand procedural force. This is because the prototype did not deform due to any of the applied forces, which were applied to simulate the procedural forces. This aligns with the expected results that the tools were expected to withstand all applied forces. Despite this test failing to directly test the technical requirement and target value, the analysis performed in **Appendix I** can be used as evidence to support that the tools satisfy both these values. From this test, the prototype also further clarified the procedural force. This test helped the team determine that the clamping force generated by the Back Stabilizer is approximately 20.8N. Unfortunately, this falls short of the 62.5N of clamping force that was expected and that the Back Stabilizer was designed to. This does not align with what the team expected, which can be justified because the Portal was not clamped directly at the tip of the Back Stabilizer clamp. It was hard to get a good hold on the Portal when trying to grip it by the tip of the clamp, therefore, the Portal was instead clamped towards the center. Considering the analysis that yielded 65N of clamping force was performed entirely at the tip of the Back Stabilizer clamp, this doesn't accurately reflect the procedural use of the clamp. When reviewing this analysis at the center of the clamp, it was discovered that the clamping force generated was only 21N. This aligns almost exactly with the results of this test and helps explain the discrepancies. Therefore, the mathematical model was validated by these tests. According to the validated mathematical model, it can be noted that the current prototype is able to provide up to 65N of clamping force as needed. However, it's important to note that this would happen exactly at the tip of the Back Stabilizer clamp.

Future Suggestions: To increase the clamping force of the Back Stabilizer, the height of the clamp can be increased. This will increase the cross-sectional area and the second moments of the inertia, which will consequently increase the clamping force.

L.3 Modularity Testing

L.3.1 Stylet-Portal Fit Test

Purpose: During the penetration into the body, the Stylet must be inserted into the Portal to create a module. Therefore, this test will determine if the Stylet can fit within the Portal.

Tested Function/Customer Need: The tested function is the Stylet's ability to fit within the Portal.

Expected Results: The Stylet should be able to fit within the Portal without any interference.

Materials:

- Stylet
- Portal

Location: This test was performed in Jacob's apartment.

Setup: A sketched schematic for the test setup is depicted in **Figure L.3.1.1**, while a picture of the physical test setup is depicted in **Figure L.3.1.2**.

Stylet-Portal Fit Test

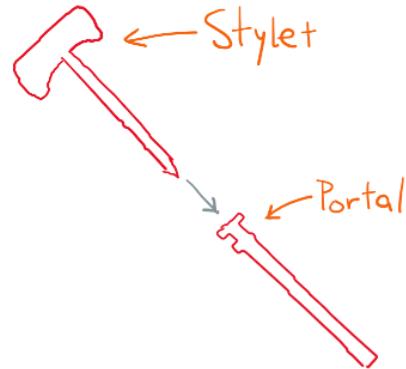


Figure L.3.1.1 Sketched schematic for the setup of the *Stylet-Portal Fit Test*



Figure L.3.1.2 Picture of the physical setup of the *Stylet-Portal Fit Test*

Procedure:

1. Attempt to insert the Stylet into the Portal.
2. Decide whether the medical tools pass or fail the test.

Measurement System: The Stylet fitting into the Portal is judged as pass or fail by the tester.

Results: The *Stylet-Portal Fit Test* was successful, such that the Stylet was able to fit within the Portal without interference. **Figure L.3.1.3** depicts the Stylet-Portal module.

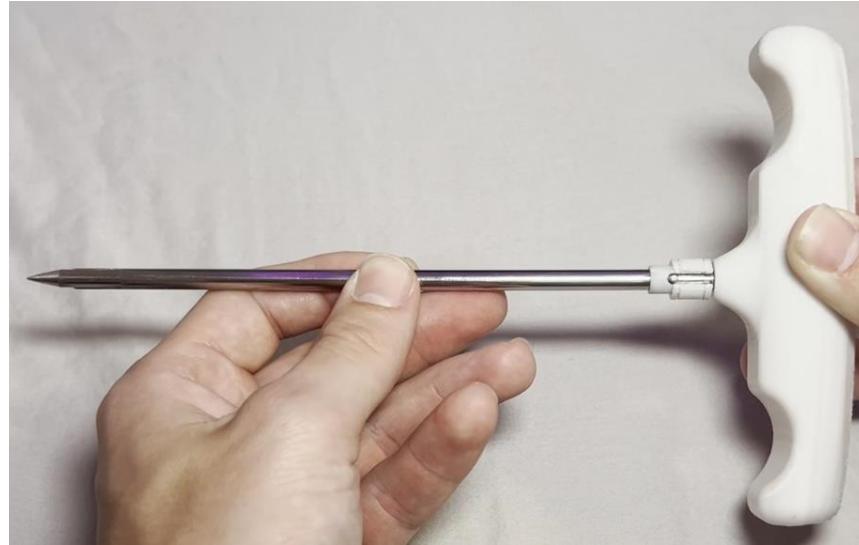


Figure L.3.1.3 Stylet-Portal module

Justification: The Stylet successfully fit within the Portal due to the dimensions of the design. The Stylet shaft was designed with an outer diameter of 4.50mm, while the Portal was designed with an inner diameter of 4.65mm. Due to the 0.01mm tolerance of the design, there was approximately 0.08mm of radial clearance between the Stylet and Portal. This allowed the Stylet to fit within the Portal.

Future Suggestions: No future suggestions arose during this test.

L.3.2 Denervator-Portal Fit Test

Purpose: During the lesioning of the nerve, the Denervator must be inserted into the Portal to access the lumbar medial branch nerve. Therefore, this test will determine if the Denervator can fit within the Portal.

Tested Function/Customer Need: The tested function is the Denervator's ability to fit within the Portal.

Expected Results: The Denervator should be able to fit within the Portal without any interference.

Materials:

- Denervator
- Portal

Location: This test was performed in Jacob's apartment.

Setup: A sketched schematic for the test setup is depicted in **Figure L.3.2.1**, while a picture of the physical test setup is depicted in **Figure L.3.2.2**.

Denervator-Portal Fit Test

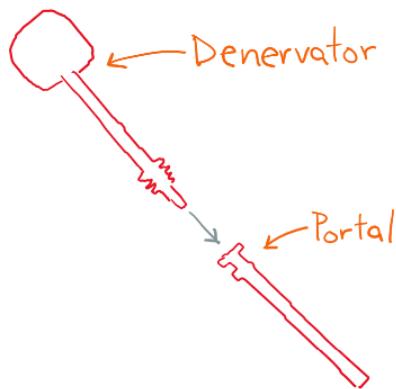


Figure L.3.2.1 Sketched schematic for the setup of the *Denervator-Portal Fit Test*



Figure L.3.2.2 Picture of the physical setup of the *Denervator-Portal Fit Test*

Procedure:

1. Attempt to insert the Denervator into the Portal.
2. Decide whether the medical tools pass or fail the test.

Measurement System: The Denervator fitting into the Portal is judged as pass or fail by the tester.

Results: The *Denervator-Portal Fit Test* was successful, such that the Denervator was able to fit within the Portal without interference. **Figure L.3.2.3** depicts the Denervator-Portal module.



Figure L.3.2.3 Denervator-Portal module

Justification: The Denervator successfully fit within the Portal due to the dimensions of the design. The Denervator shaft was designed with an outer diameter of 4.00mm, however, the knurls added approximately an extra 0.5mm in diameter. This means the maximum diameter of the Denervator was designed to be 4.5mm, while the Portal was designed with an inner diameter of 4.65mm. Due to the 0.01mm tolerance of the design, there was approximately 0.08mm of radial clearance between the Denervator and Portal. This allowed the Denervator to fit within the Portal.

Future Suggestions: No future suggestions arose during this test.

L.3.3 Stylet-Portal Interlocking Test

Purpose: During the penetration into the body, the Stylet must interlock with the Portal. Interlocking is necessary, considering the doctor must insert and guide the two tools as a single instrument. Therefore, this test will determine if the Stylet can interlock with the Portal.

Tested Function/Customer Need: The tested function is the Stylet's ability to interlock with the Portal.

Expected Results: The Stylet should be able to interlock with the Portal successfully, and the interlocked module should be able to withstand significant resistance.

Materials:

- Stylet
- Portal

Location: This test was performed in Jacob's apartment.

Setup: A sketched schematic for the test setup is depicted in **Figure L.3.3.1**, while a picture of the physical test setup is depicted in **Figure L.3.3.2**.

Stylet - Portal Interlocking Test

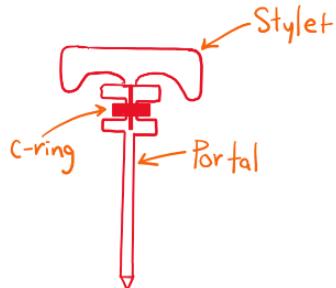


Figure L.3.3.1 Sketched schematic for the setup of the *Stylet-Portal Interlocking Test*



Figure L.3.3.2 Picture of the physical setup of the *Stylet-Portal Interlocking Test*

Procedure:

1. Insert the Stylet into the Portal until the Nub makes it to the bottom of the Portal cutout.
2. Turn the Portal C-ring on the track until it completely blocks the Nub from being removed.
3. Apply a reasonable amount of force to try and pull the Stylet out of the Portal.
4. Turn the Portal C-ring on the track until it creates a path for the Nub to be removed.

5. Remove the Stylet from the Portal.
6. Decide whether the medical tools pass or fail the test.

Measurement System: The Stylet interlocking with the Portal is judged as pass or fail by the tester.

Results: The *Stylet-Portal Interlocking Test* was successful, such that the Stylet was able to interlock with the Portal. Furthermore, these tools remained interlocked despite significant force applied to remove the Stylet from the Portal (effectively trying to break the interlocking mechanism). **Figure L.3.3.3** depicts the interlocked Stylet-Portal module.

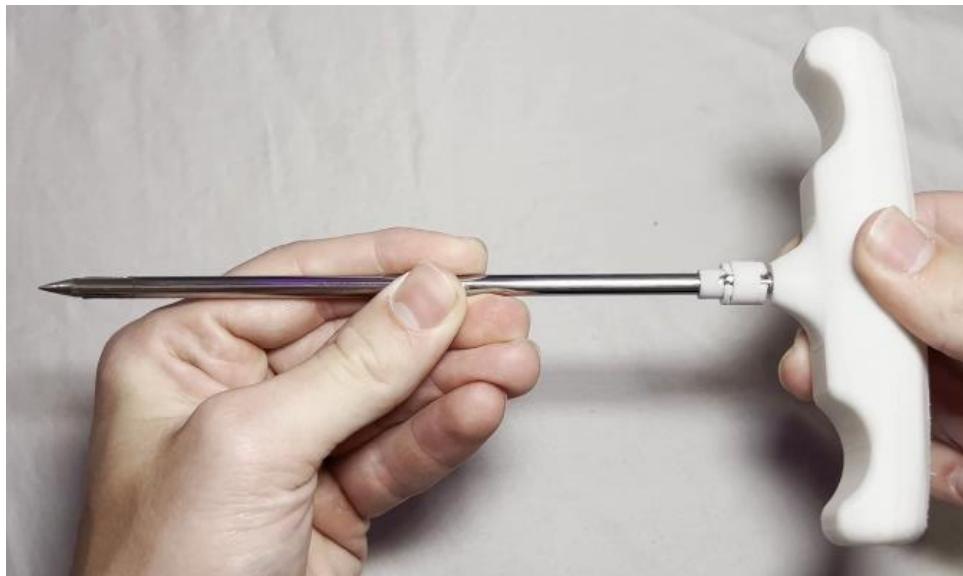


Figure L.3.3.3 Interlocked Stylet-Portal module

Justification: The Stylet successfully interlocked with the Portal due to the dimensions of the design. The Stylet Nub was designed with an outer diameter of 2mm, while the Portal cutout was designed with an inner diameter of 2.50mm. Due to the 0.03mm tolerance of the design, there was approximately 0.25mm of radial clearance between the Stylet Nub and Portal cutout. This allowed the Stylet Nub to fit within the Portal cutout. With the Stylet Nub in the Portal cutout, the Portal C-ring was then slid around the Portal

track. The clearance between the Portal C-ring and track was 0.10mm, which allowed the mechanism to withstand large forces without breaking.

Future Suggestions: No future suggestions arose during this test.

L.3.4 Back Stabilizer-Portal Mate Test

Purpose: While the Portal is in the body, it must be stabilized to constraint vertical, lateral, and rotational motion. This is the purpose of the Back Stabilizer, to stabilize the Portal while it's within the body. Therefore, this test will determine if the Back Stabilizer can clamp around the Portal.

Tested Function/Customer Need: The tested function is the Back Stabilizer's ability to clamp around the Portal.

Expected Results: The Back Stabilizer should be able to clamp around the Portal successfully.

Materials:

- Back Stabilizer
- Portal

Location: This test was performed in Jacob's apartment.

Setup: A sketched schematic for the test setup is depicted in **Figure L.3.4.1**, while a picture of the physical test setup is depicted in **Figure L.3.4.2**.

Back Stabilizer - Portal Mate Test

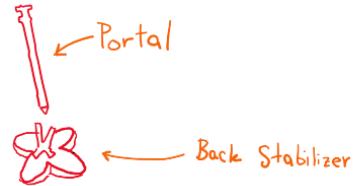


Figure L.3.4.1 Sketched schematic for the setup of the *Back Stabilizer-Portal Mate Test*



Figure L.3.4.2 Picture of the physical setup of the *Back Stabilizer-Portal Mate Test*

Procedure:

1. Open the clamp of the Back Stabilizer.
2. Place the Portal in between the clamp grips of the Back Stabilizer, then release the clamp.
3. Ensure that the Portal does not fall out of the clamp grip.
4. Open the clamp of the Back Stabilizer and remove the Portal.
5. Decide whether the medical tools pass or fail the test.

Measurement System: The Back Stabilizer clamping around the Portal is judged as pass or fail by the tester.

Results: The *Back Stabilizer-Portal Mate Test* was successful, such that the Back Stabilizer was able to clamp around the Portal and constrain it in all directions. **Figure L.3.4.3** depicts the Back Stabilizer clamped around the Portal.



Figure L.3.4.3 Back Stabilizer clamped around the Portal

Justification: The Back Stabilizer successfully clamped around the Portal due to the dimensions of the design. The Portal was designed with an outer diameter of 5.16mm, while the Back Stabilizer clamp was designed with a clamp separation of 4.5mm. This would appear as if the Portal would not fit within the Back Stabilizer clamp. However, since the clamp was designed as a compliant mechanism, it was able to open up to account for wider clamp separation. This increased the applied force on the Portal, which further constrained the Portal. These design features allowed the Back Stabilizer to successfully clamp around the Portal.

Future Suggestions: No future suggestions arose during this test.

M. List of Standards

During the course of this project, the team kept a running list of all standards that they had to adhere to. These standards primarily regarded the medical device industry, but also had to do with manufacturing, risk management, and testing. These standards, which must be adhered to in order to bring the medical toolkit to market, will be further discussed in detail.

The first standard to be discussed is ISO 13485:2016. This focuses on the quality management system (QMS) requirements specific to the medical device field. It ensures that manufacturers can consistently produce devices that not only meet customer expectations, but also comply with international regulatory guidelines. To comply with this standard, manufacturers must set up a QMS that covers all stages of a medical device's lifecycle, from design to post-market activities. This includes maintaining rigorous control over the design process to ensure that all functional, performance, and regulatory requirements are met. The team applied this standard by performing a functional decomposition, an engineering specification chart, and a Regulatory Environment Review. These pieces of work helped the team manage quality and set benchmarks for the design. This standard also involves selecting and monitoring suppliers and subcontractors to ensure they meet necessary quality standards, implementing robust manufacturing processes, and maintaining detailed records that track the device from conception through to distribution. The team applied this to the project by carefully choosing their material sources according, such that each vendor was proven, reliable, and consistent. Finally, with regards to this standard, effective post-market surveillance must be established to continually assess and enhance product safety and effectiveness. The team plans on implementing this part of the standard when they finally take their product to market, which will help them iterate towards a more perfect design.

Similar to the previous standard, ISO 14971:2019 provides a comprehensive approach to risk management specifically tailored to medical devices. It begins at the device design phase, where potential hazards are identified and assessed for their severity and probability. This assessment helps prioritize which risks to address through design modifications or other mitigation strategies. This aspect of the standard was applied during the PDR phase through the development of the Risk Register document. Considering the Risk Register was periodically updated throughout the CDR and FDR phases, this standard saw constant application by the team identifying potential risks and their probabilities. This standard continues to enforce effective

risk management, such that it includes ongoing monitoring of the device after it has entered the market to ensure that the risk controls are functioning as intended and to identify any new risks that might emerge over time. Documentation plays a crucial role throughout this process, creating an audit trail that supports transparency and regulatory review. Similar to ISO 13485:2016, the team plans to implement this aspect of the standard when they eventually take their medical tools to industry. This will allow them to manage the livelihood of their product and ensure that it has no harmful effects.

Next up is ISO 10993-1:2018, which is pivotal for evaluating the biocompatibility of medical devices. It requires a rigorous assessment of the materials used in a device to ensure they do not harm the body. For a device using components like 316 stainless steel and polypropylene, it's crucial to understand whether they are biocompatible or not. Through research, the team has determined that these materials meet the biocompatibility standards of medical devices, validating their design. The findings from this research should be integrated into a risk management process, aligning with ISO 14971, to evaluate potential biological effects and determine the need for further testing or modifications. Documentation of these assessments must be meticulous, providing a clear trace of decisions and outcomes for regulatory review. Driven by comprehensive, the team ensured that documentation was very thorough during the entire course of the project, so the team meets this standard well.

Another standard applied to this project is IEC 60601-1-2, which focuses on the electromagnetic compatibility of medical electrical equipment. Although primarily relevant for electronic devices, its principles are critical for non-electrical devices used near sensitive equipment, like an X-ray C-arm. It ensures that a device neither emits nor is susceptible to electromagnetic disturbances that could affect medical equipment functionality. This was a focus for the team, considering they performed the *X-ray Imaging Test* as described in **Subsection L.1.4**. Through material research, the team was able to ensure that the chosen materials are safe during X-ray use. This research allowed the team to satisfy IEC 60601-1-2, further strengthening the case for their product.

Moving onto ISO 17665-1:2006, this standard is relevant for devices using steam sterilization. It provides comprehensive guidelines for autoclaving, ensuring that sterilization is achieved and maintained. For a device sterilized by autoclaving, this involves validating the sterilization process to confirm its reliability, using biological indicators to monitor

effectiveness, and maintaining strict routine controls. This standard necessitates meticulous documentation of all process validations and controls to verify compliance and facilitate regulatory audits. The team partially applied this standard to their medical devices, as they were designed to withstand autoclave sterilization. The tools were then tested according to autoclave sterilization parameters to validate the design, as described by the *Temperature Test* in **Subsection L.1.3**. The team has not had the chance to perform actual autoclave sterilization, so they plan to further apply this standard in the future when they perform autoclave sterilization on their medical tools.

The next standard has not played a role in this project currently, though the team intends to apply it during future endeavors. ISO 14155:2020 outlines the standards for conducting clinical investigations of medical devices involving human subjects. This standard emphasizes ethical and scientific rigor in clinical trials. It requires obtaining necessary approvals from ethics committees, ensuring informed consent from all participants, and designing trials that provide valid and reliable data. It also mandates rigorous management of data integrity, adverse event reporting systems, and comprehensive documentation and reporting of trial processes and results. This ensures not only the protection of participants but also the credibility of the clinical data collected. The team plans to apply this standard during the clinical testing stage of these medical tools, which is still far in the future.

Another notable standard which has not been applied, though the team has future plans to apply is ISO 15223-1:2021. This standard plays a crucial role in enhancing the communication clarity of medical device labeling through standardized symbols that transcend language barriers. This standard is vital for ensuring that essential safety and operational information is universally understood, thereby facilitating safe device operation in diverse healthcare settings. For the LMBN device, adopting this standard involves selecting appropriate symbols that convey critical information such as sterilization method, handling precautions, expiration dates, and manufacturer details. These symbols are integrated into the device's labels, instructions for use, and packaging to ensure visibility and recognition. It's also important to educate users on the meaning of these symbols, especially those that may not be immediately obvious. This can be achieved through detailed user manuals or quick-start guides. Regular compliance checks are essential to maintain alignment with the latest standards, as these symbols and labeling requirements are subject to updates.

Furthering the discussion of standards and compliances, the FDA 510(k) premarket submission is essential for introducing the LMBN surgical neurotomy device to the U.S. market. To be classified as a Class II device, the medical toolkit requires demonstration of substantial equivalence to a legally marketed predicate device. This process involves a detailed device description, including intended use, technical specifications, and any accessories. A direct comparison with a predicate device establishes that the new device matches or exceeds the safety and effectiveness of the existing one. The 510(k) submission must also include comprehensive data from preclinical tests, such as biocompatibility and sterilization validation, and, if applicable, data from clinical trials. All labeling materials must comply with ISO 15223-1 and FDA labeling regulations to ensure all safety, warning, and instructional content is clearly communicated. Documentation of any regulatory correspondences with the FDA, such as pre-submission meetings, should also be included to provide context and support for the review process.

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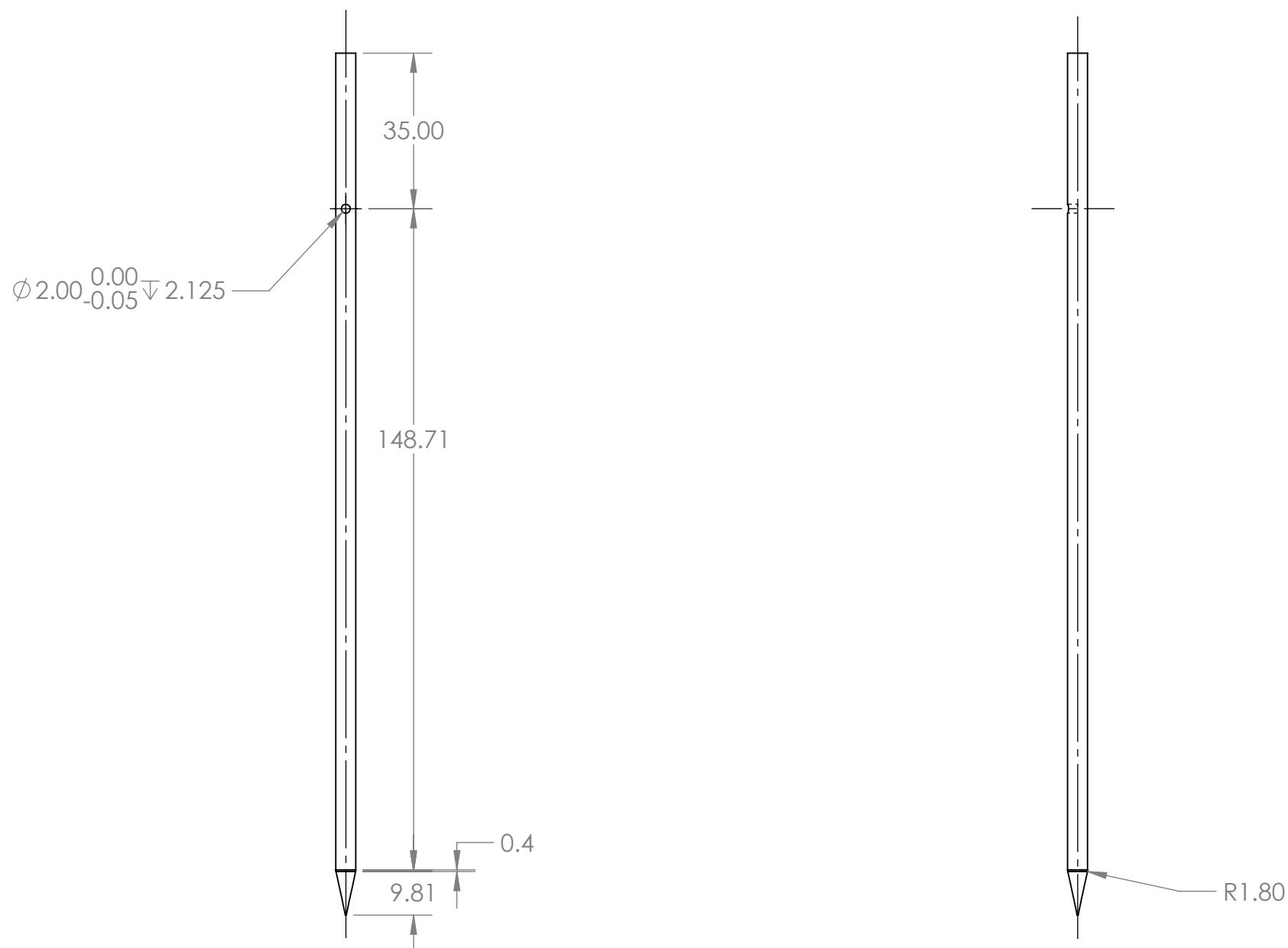
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3

2

1

REVISIONS		
SYMBOL	DESCRIPTION	DATE



NOTES

- 1. MATERIAL 316 STAINLESS STEEL
- 2. FINISH ALL OVER: 0.4µM
- 3. REMOVE ALL SHARP EDGES

A technical drawing showing a circle divided into four quadrants by two intersecting lines. A horizontal line segment extends from the left side of the circle to a dimension line labeled $\phi 4.42$. Another horizontal line segment extends from the right side of the circle to a dimension line labeled $\phi 0.2$. The intersection of the lines forms a small circle in the center.

SCALE 2:

GÉNÉRAL TOI FRANCES

X.X ± 0.1mm
X.XX ± 0.05mm
X.XXX ± 0.005mm

$X^\circ \pm 0.5^\circ$

ALL DIMENSIONS IN MILLIMETERS

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		PC NO	PART NAME	QTY
FIRST ISSUED	3/18/24	BACK IN ACTION		
DRAWN BY	JBW			
CHECKED BY	AT	TITLE:		
APPROVED BY		STYLET BODY		
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SCALE: 1:1.3			SHEET 1 OF 1	

4

3

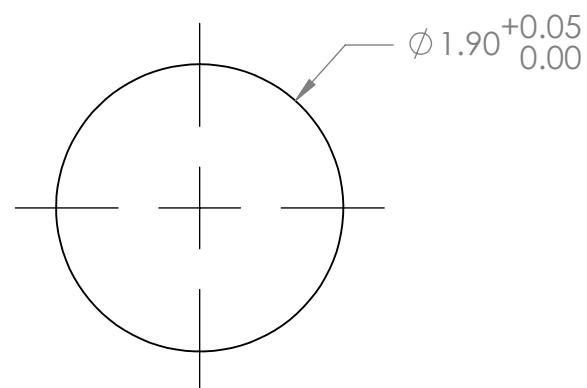
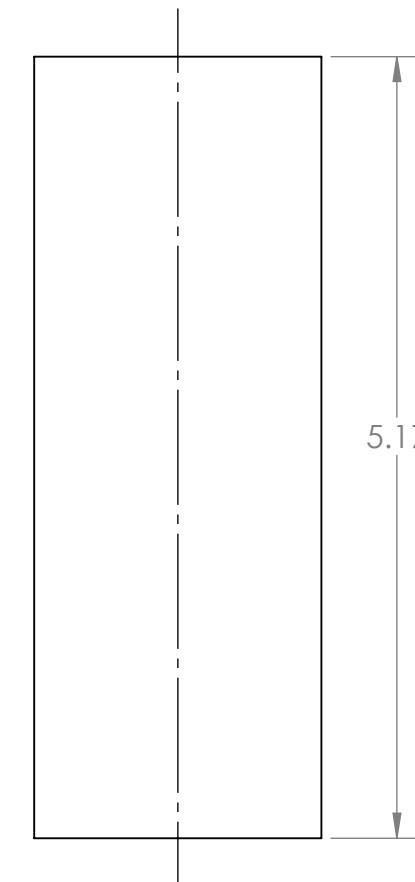
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1

REVISIONS		
SYMBOL	DESCRIPTION	DATE

B

B



GENERAL TOLERANCES

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 $X.XXX \pm 0.005\text{mm}$

$X^\circ \pm 0.5^\circ$

ALL DIMENSIONS IN MILLIMETERS

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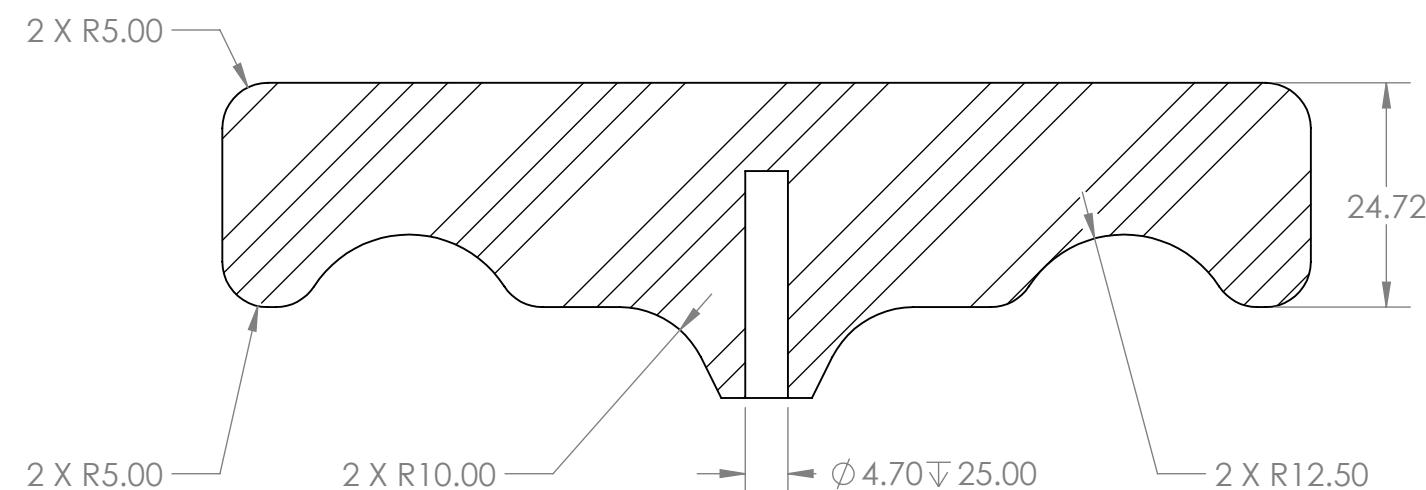
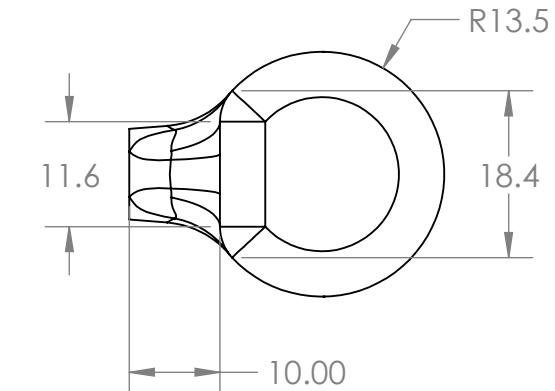
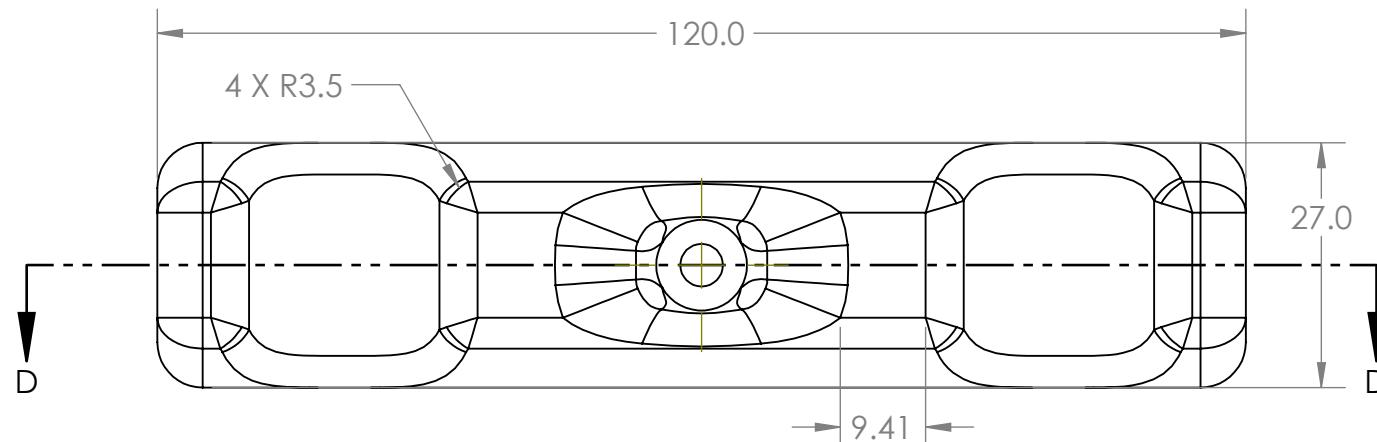
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3

2

1

REVISIONS		
SYMBOL	DESCRIPTION	DATE



SECTION D-D
SCALE 1:1
SCALE 1.2 : 1

GENERAL TOLERANCES
 $X.X \pm 0.1\text{mm}$
 $X.XX \pm 0.05\text{mm}$
 $X.XXX \pm 0.005\text{mm}$

$X^\circ \pm 0.5^\circ$

ALL DIMENSIONS IN MILLIMETERS

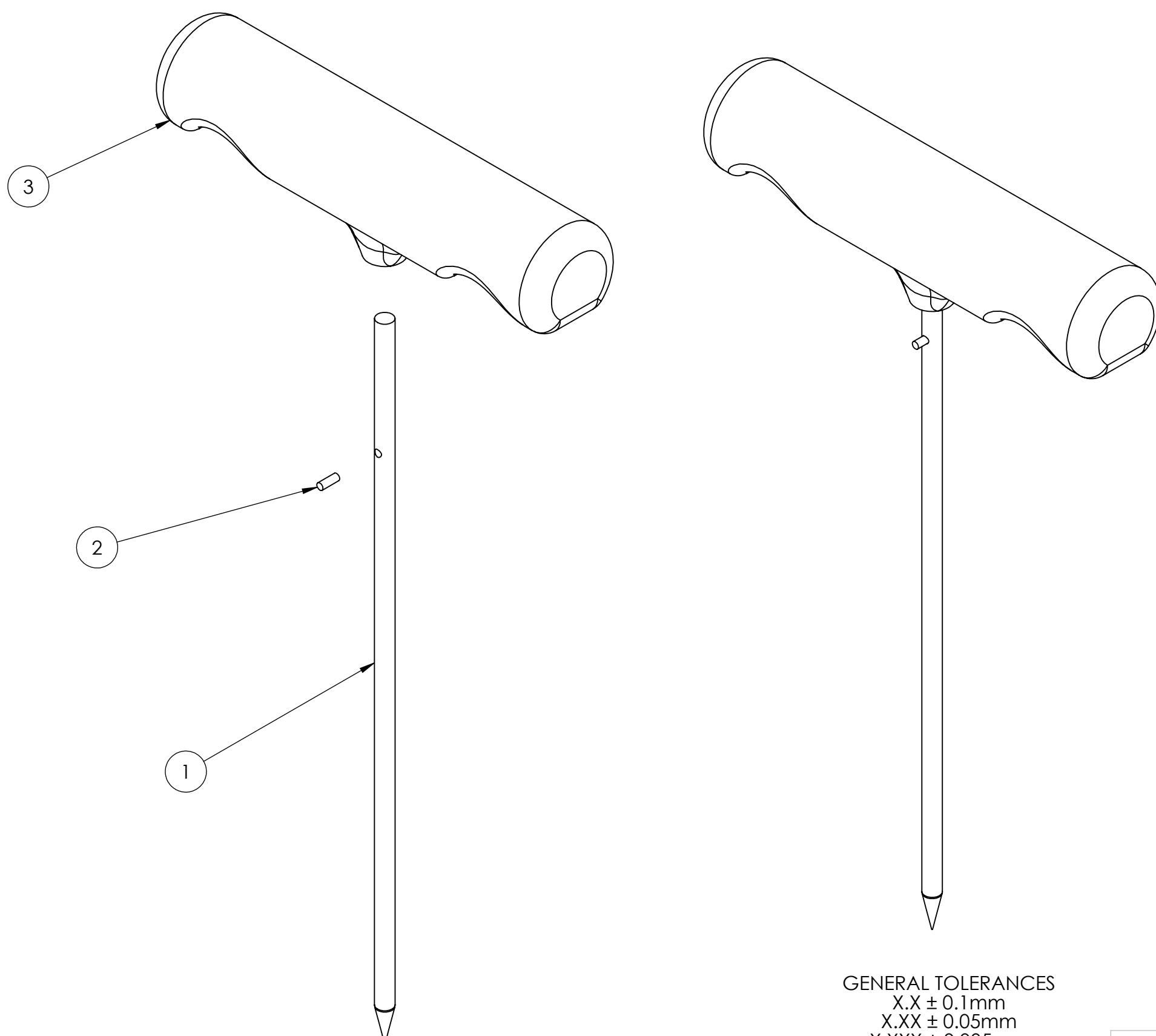
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CHECKED BY	JBW				
APPROVED BY					
COMMENTS:	ONLY CRITICAL DIMENSIONS HAVE BEEN IDENTIFIED AS THIS PART WILL BE 3D PRINTED. COMPREHENSIVE DIMENSIONS CAN BE FOUND IN THE RESPECTIVE .SLDPRT FILE.				
SIZE	DWG. NO.	REV			
B	S.3	B			
SCALE: 1.2:1			SHEET 1 OF 1		

4

3

2

1



GENERAL TOLERANCES

$X.X \pm 0.1\text{mm}$
 $X.XX \pm 0.05\text{mm}$
 $X.XXX \pm 0.005\text{mm}$

 $X^\circ \pm 0.5^\circ$

ALL DIMENSIONS IN MILLIMETERS

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3	S.3	CONNECTING HANDLE	1
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1	S.1	STYLET BODY	1
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FIRST ISSUED	3/18/24
DRAWN BY	JBW
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APPROVED BY	

COMMENTS:

SIZE	DWG. NO.	REV
B	S.1.2.3	B

SCALE: 1:1	SHEET 1 OF 1
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REVISIONS		
SYMBOL	DESCRIPTION	DATE

BACK IN ACTION

STYLET ASSEMBLY

4

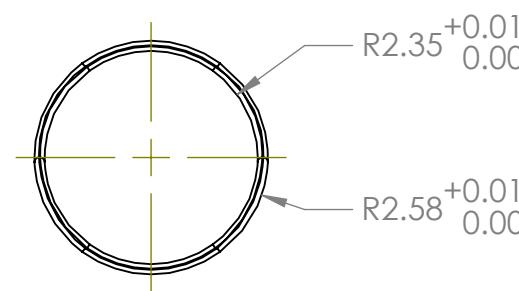
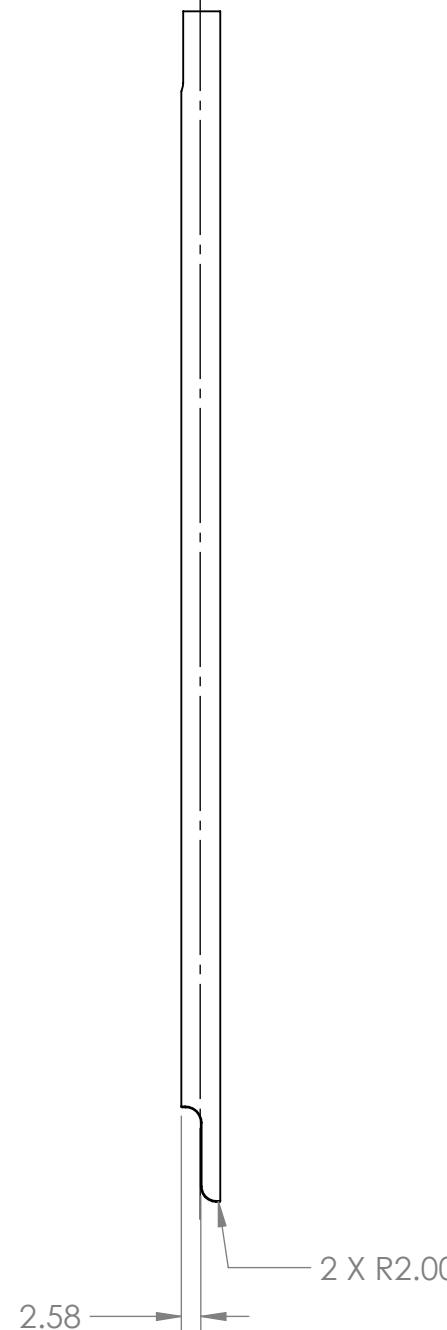
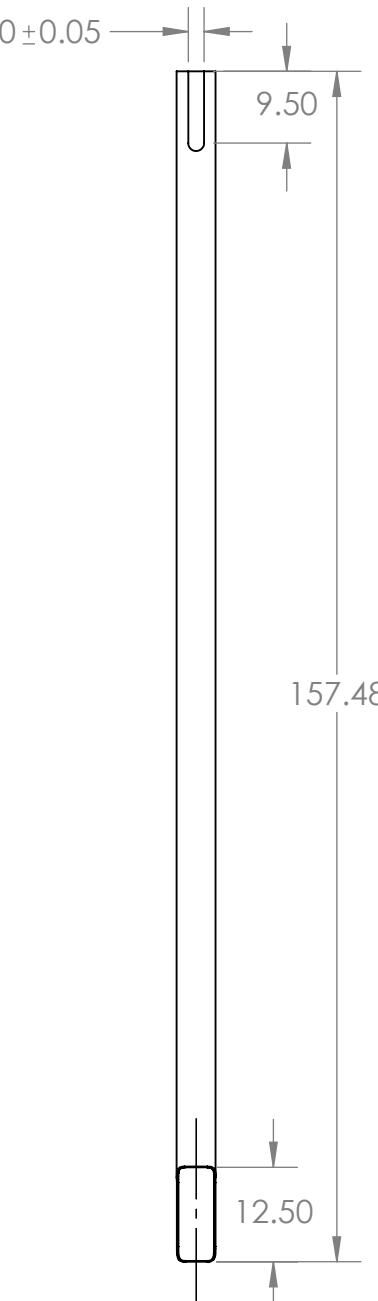
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2

1

B

B



SCALE: 6:1

GENERAL TOLERANCES

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 $X.XX \pm 0.05\text{mm}$
 $X.XXX \pm 0.005\text{mm}$

 $X^\circ \pm 0.5^\circ$

ALL DIMENSIONS IN MILLIMETERS

REVISIONS

SYMBOL	DESCRIPTION	DATE

NOTES
1. MATERIAL 316 STAINLESS STEEL
2. FINISH ALL OVER: 0.4 μm
3. REMOVE ALL SHARP EDGES

PC NO	PART NAME		QTY
	BACK IN ACTION		
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DRAWN BY	PORTAL BODY		
CHECKED BY			
APPROVED BY			
COMMENTS:			
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SCALE: 1:1		SHEET 1 OF 1	

4

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2

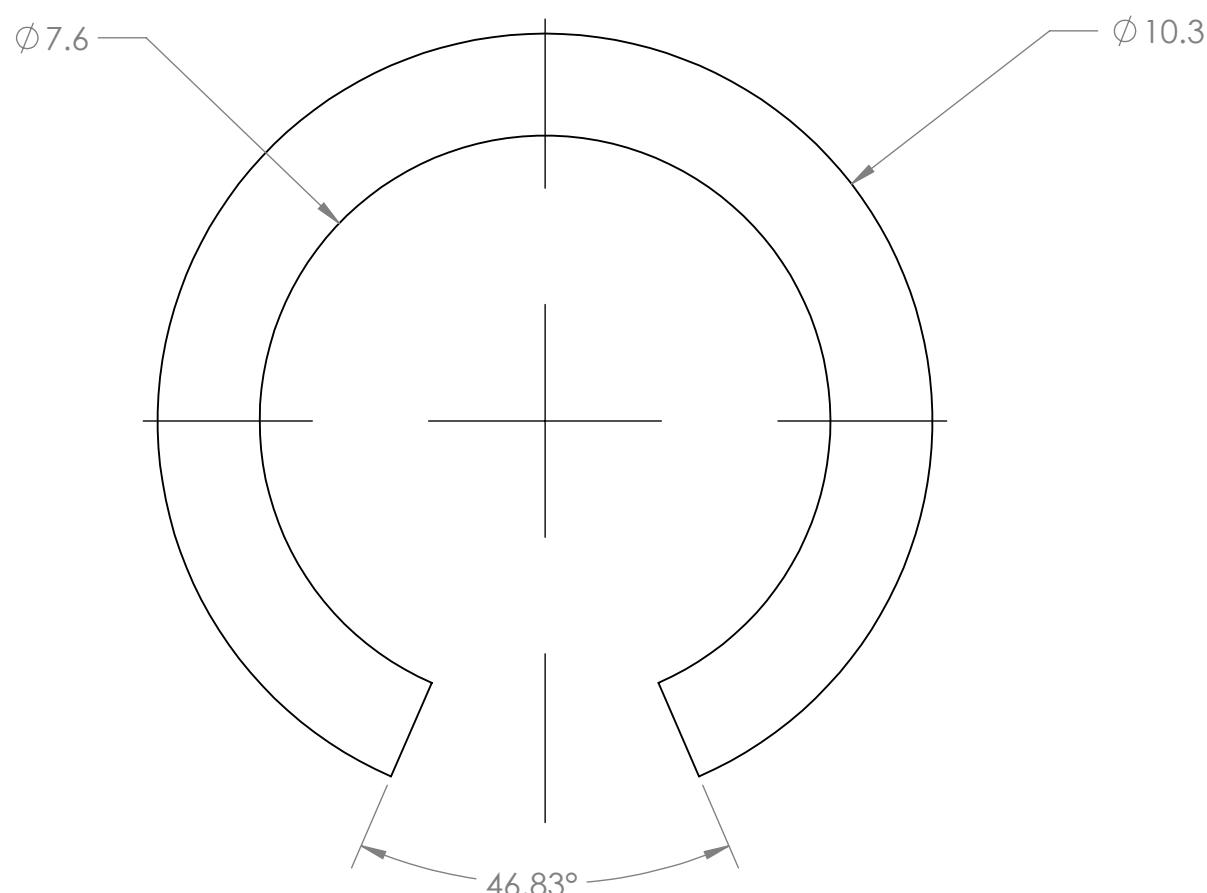
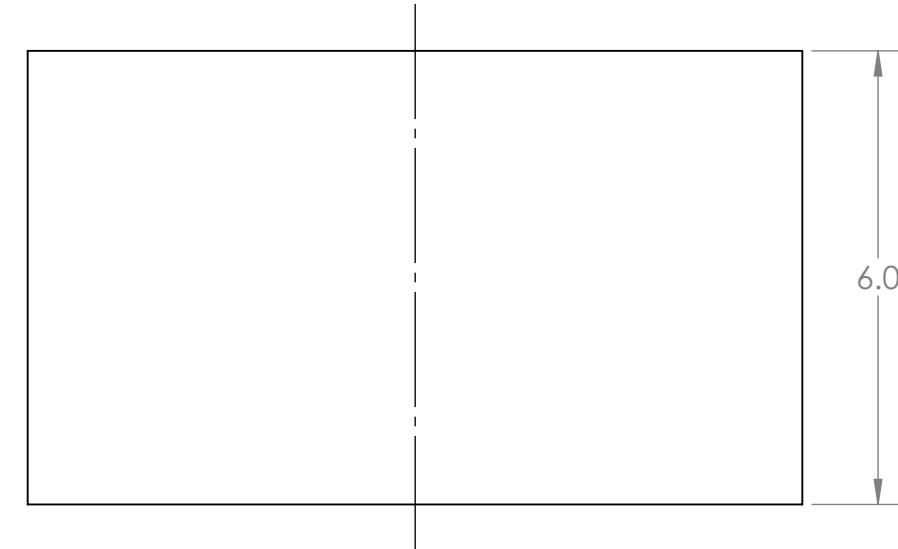
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REVISIONS

SYMBOL	DESCRIPTION	DATE

B

B



GENERAL TOLERANCES

$X.X \pm 0.1\text{mm}$
 $X.XX \pm 0.05\text{mm}$
 $X.XXX \pm 0.005\text{mm}$

 $X^\circ \pm 0.5^\circ$

ALL DIMENSIONS IN MILLIMETERS

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CHECKED BY	JBW	APPROVED BY	
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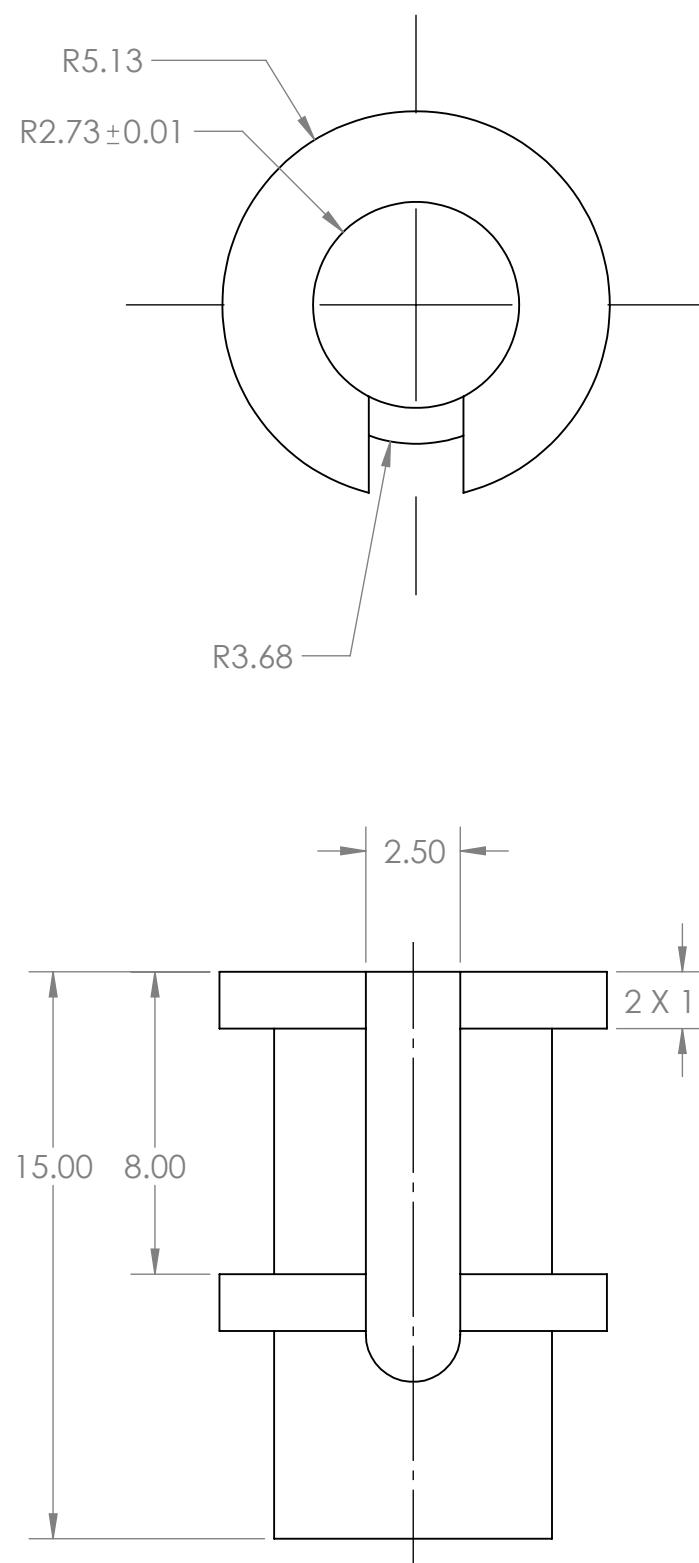
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REVISIONS		
SYMBOL	DESCRIPTION	DATE



GENERAL TOLERANCES
 $X.X \pm 0.1\text{mm}$
 $X.XX \pm 0.05\text{mm}$
 $X.XXX \pm 0.005\text{mm}$

$X^\circ \pm 0.5^\circ$

ALL DIMENSIONS IN MILLIMETERS

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COMMENTS:

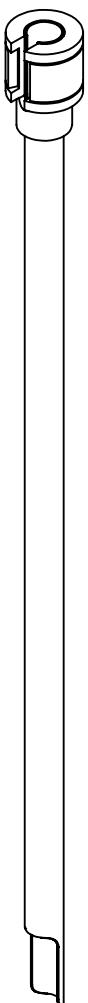
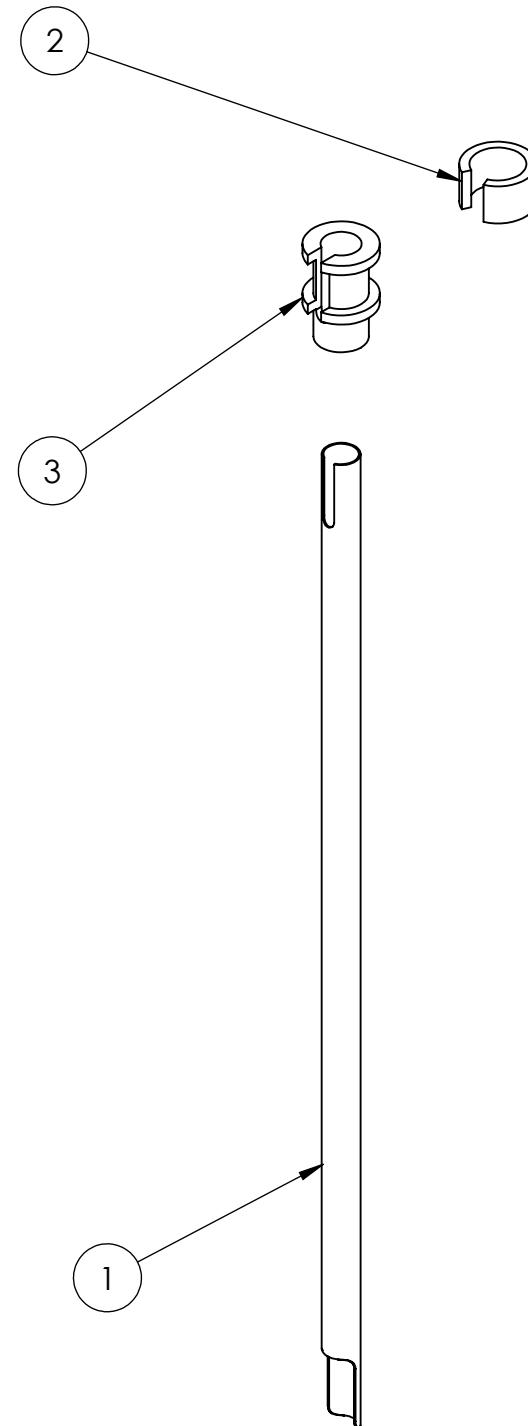
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B	P.3	A
SCALE: 5:1		SHEET 1 OF 1

4

3

2

1



GENERAL TOLERANCES

$X.X \pm 0.1\text{mm}$
 $X.XX \pm 0.05\text{mm}$
 $X.XXX \pm 0.005\text{mm}$

$X^\circ \pm 0.5^\circ$

ALL DIMENSIONS IN MILLIMETERS

REVISIONS		
SYMBOL	DESCRIPTION	DATE

3	P.3	C-RING SLEEVE	1
2	P.2	C-RING ATTACHMENT	1
1	P.1	PORTAL BODY	1
NO	DWG NO	DESCRIPTION	QTY

FIRST ISSUED	3/18/24	TITLE: PORTAL ASSEMBLY
DRAWN BY	JBW	
CHECKED BY	AT	
APPROVED BY		
COMMENTS:		
SIZE	DWG. NO.	REV
B	P.1.2.3	B
SCALE: 1:1		SHEET 1 OF 1

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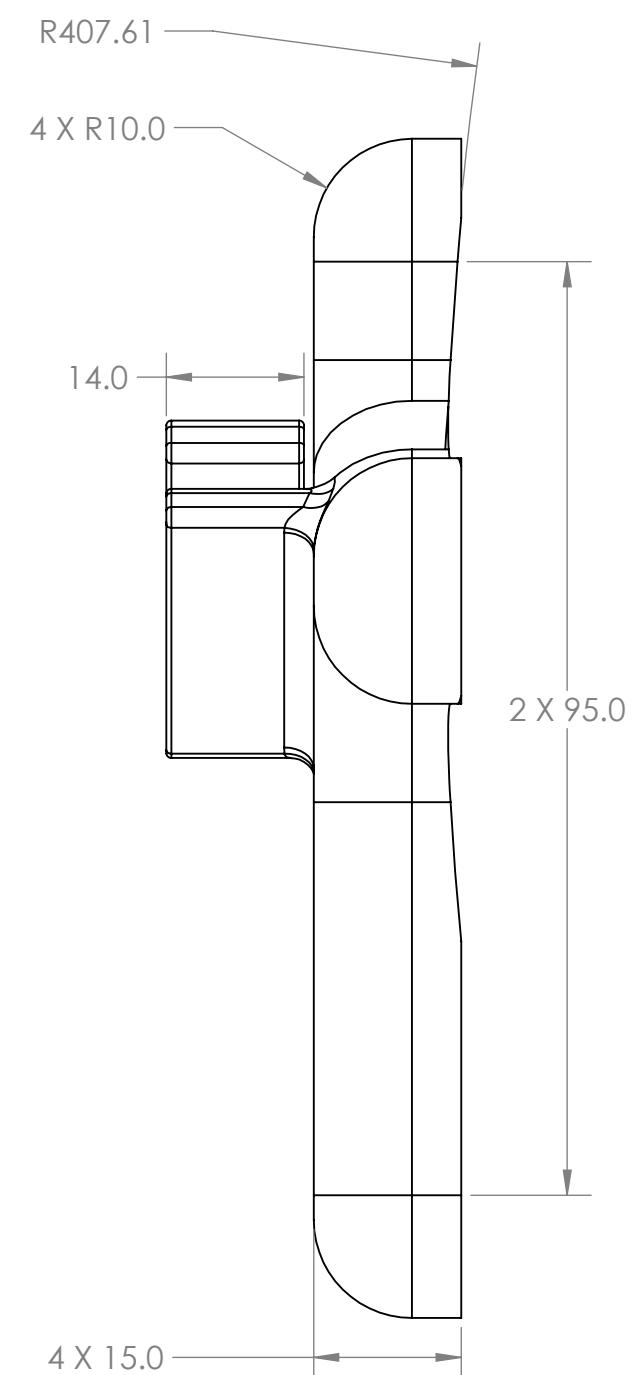
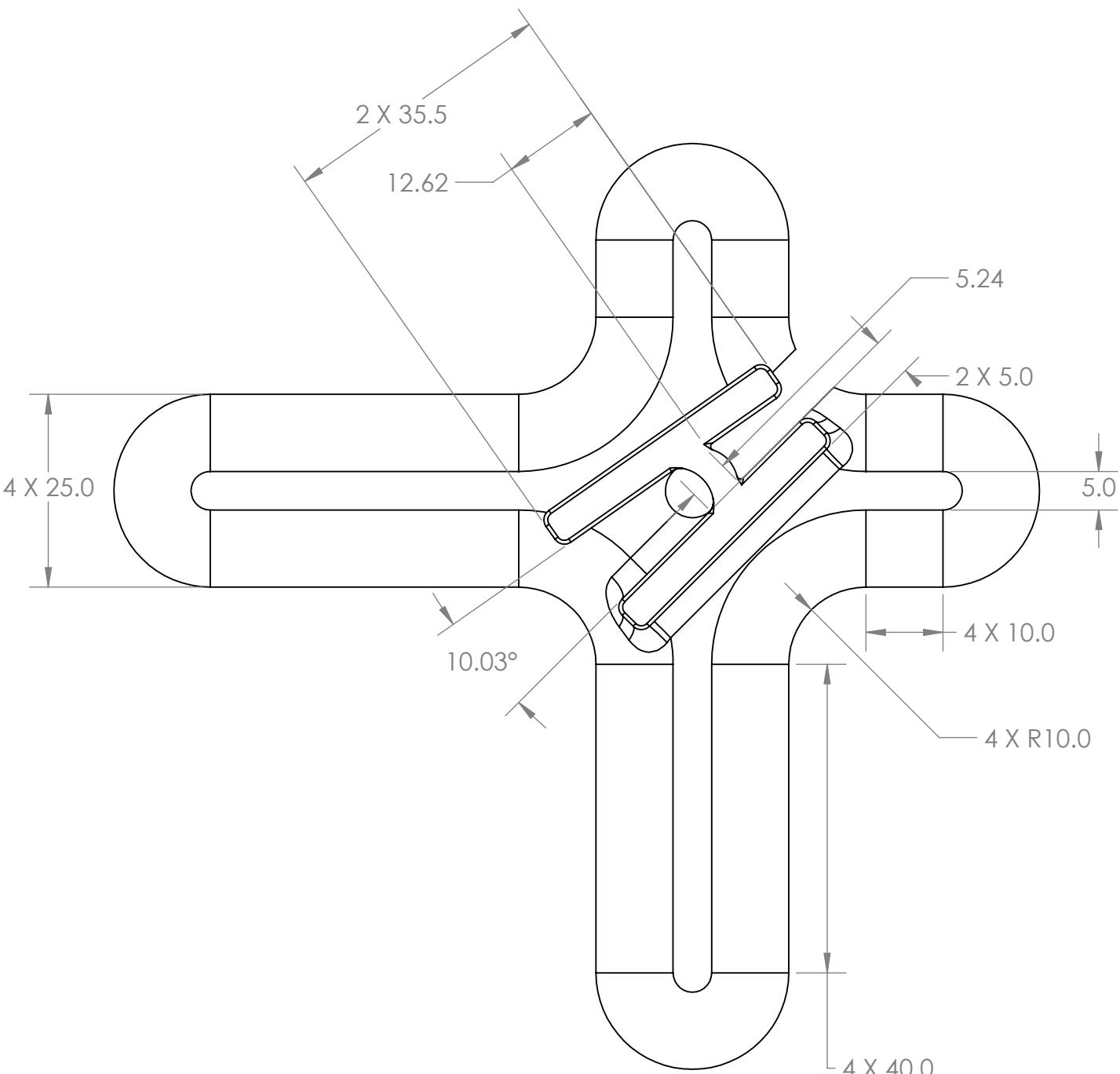
4

3

2

1

REVISIONS		
SYMBOL	DESCRIPTION	DATE



NOTES
 1. MATERIAL POLYPROPYLENE
 2. FINISH ALL OVER: 50µM
 3. REMOVE ALL STRUCTURES

GENERAL TOLERANCES

X.X ± 0.1mm
 X.XX ± 0.05mm
 X.XXX ± 0.005mm

X° ± 0.5°

ALL DIMENSIONS IN MILLIMETERS

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PC NO	PART NAME	QTY
FIRST ISSUED 3/18/24	DRAWN BY AT	BACK IN ACTION
CHECKED BY JBW	APPROVED BY	TITLE: BACK STABILIZER BASE
		SIZE DWG. NO. B B.1 REV B
	SCALE: 1.3:1	SHEET 1 OF 1

4

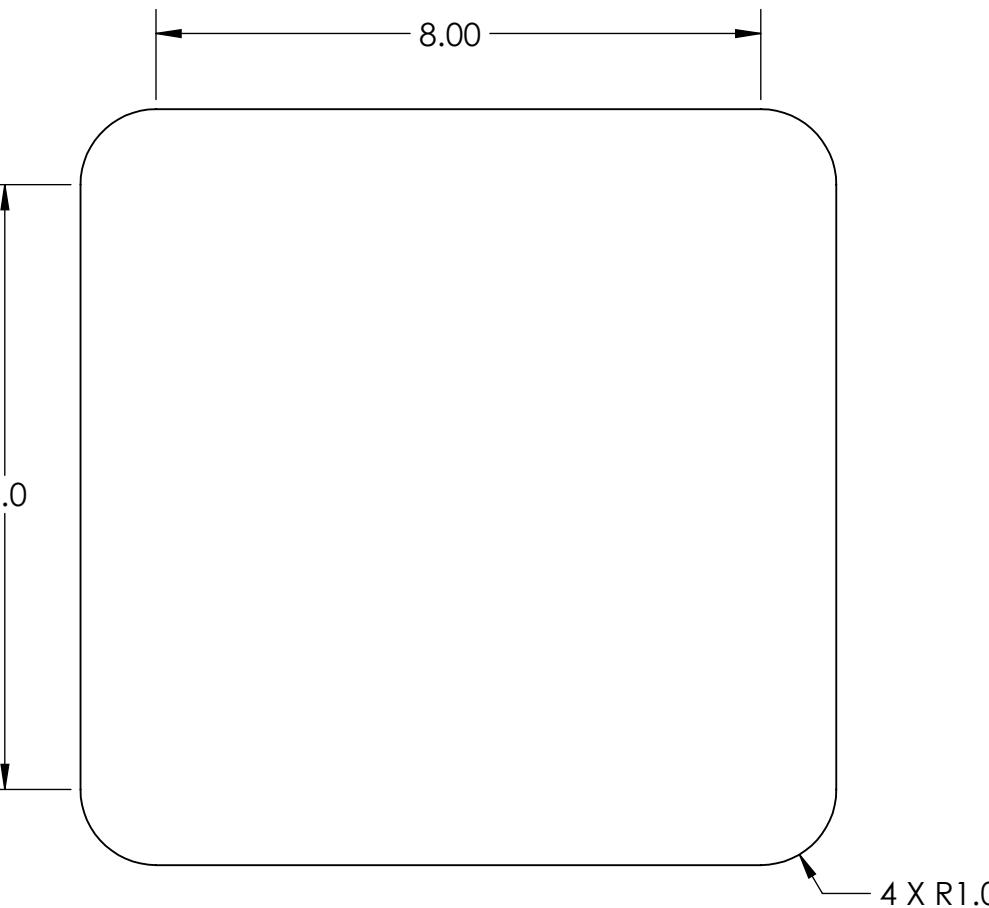
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2

1

REVISIONS		
SYMBOL	DESCRIPTION	DATE

B



NOTES
 1. MATERIAL SILICONE RUBBER
 2. FINISH ALL OVER: 3µM

GENERAL TOLERANCES

X.X ± 0.1mm
 X.XX ± 0.05mm
 X.XXX ± 0.005mm

X° ± 0.5°

ALL DIMENSIONS IN MILLIMETERS

PC NO	PART NAME	QTY
	BACK IN ACTION	
TITLE:		RUBBER PADS
FIRST ISSUED	3/18/24	
DRAWN BY	CM	
CHECKED BY	JBW	
APPROVED BY		
COMMENTS:		
SIZE	DWG. NO.	REV
B	B.2	B
SCALE: 10:1		SHEET 1 OF 1

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4

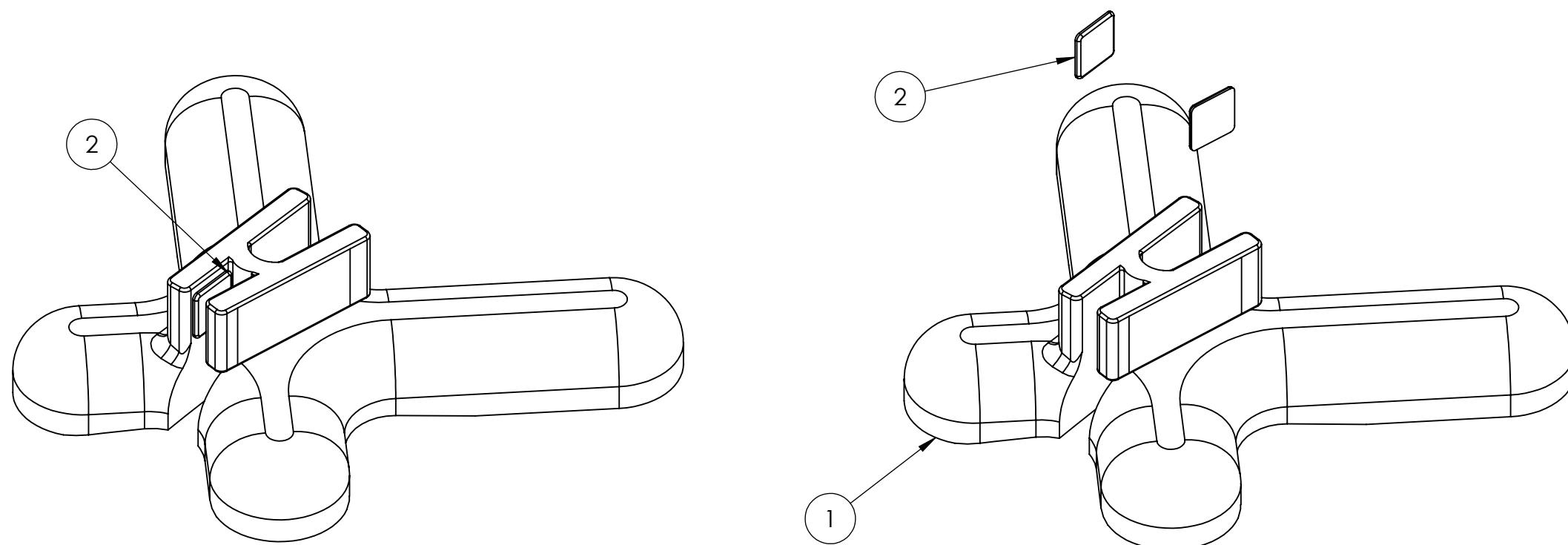
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2

1

REVISIONS

SYMBOL	DESCRIPTION	DATE



B

B

A

A

GENERAL TOLERANCES

$X.X \pm 0.1\text{mm}$
 $X.XX \pm 0.05\text{mm}$
 $X.XXX \pm 0.005\text{mm}$

 $X^\circ \pm 0.5^\circ$

ALL DIMENSIONS IN MILLIMETERS

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2	B.2	RUBBER PADS	2
1	B.1	BACK STABILIZER BASE	1
NO	DWG NO	DESCRIPTION	QTY

BACK IN ACTION

BACK STABILIZER ASSEMBLY

SIZE	DWG. NO.	REV
B	B.1.2	B
SCALE: 1:1		SHEET 1 OF 1

4

3

2

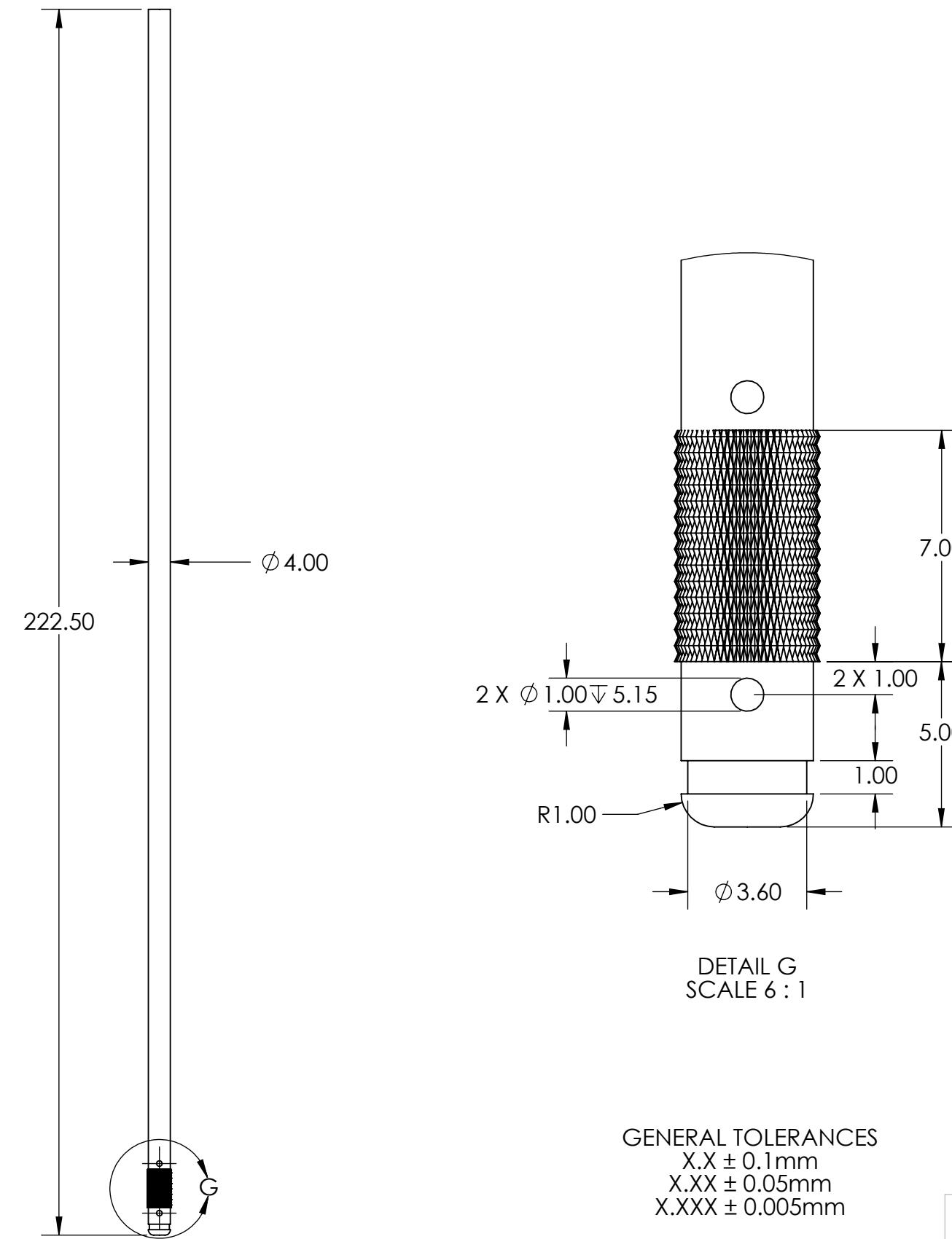
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REVISIONS

SYMBOL	DESCRIPTION	DATE

B

B



PC NO	PART NAME		QTY
FIRST ISSUED	BACK IN ACTION		
DRAWN BY	CM		
CHECKED BY	AT		
APPROVED BY			
COMMENTS:			
SIZE	DWG. NO.	REV	
B	D.1	B	
SCALE: 1:1			SHEET 1 OF 1

4

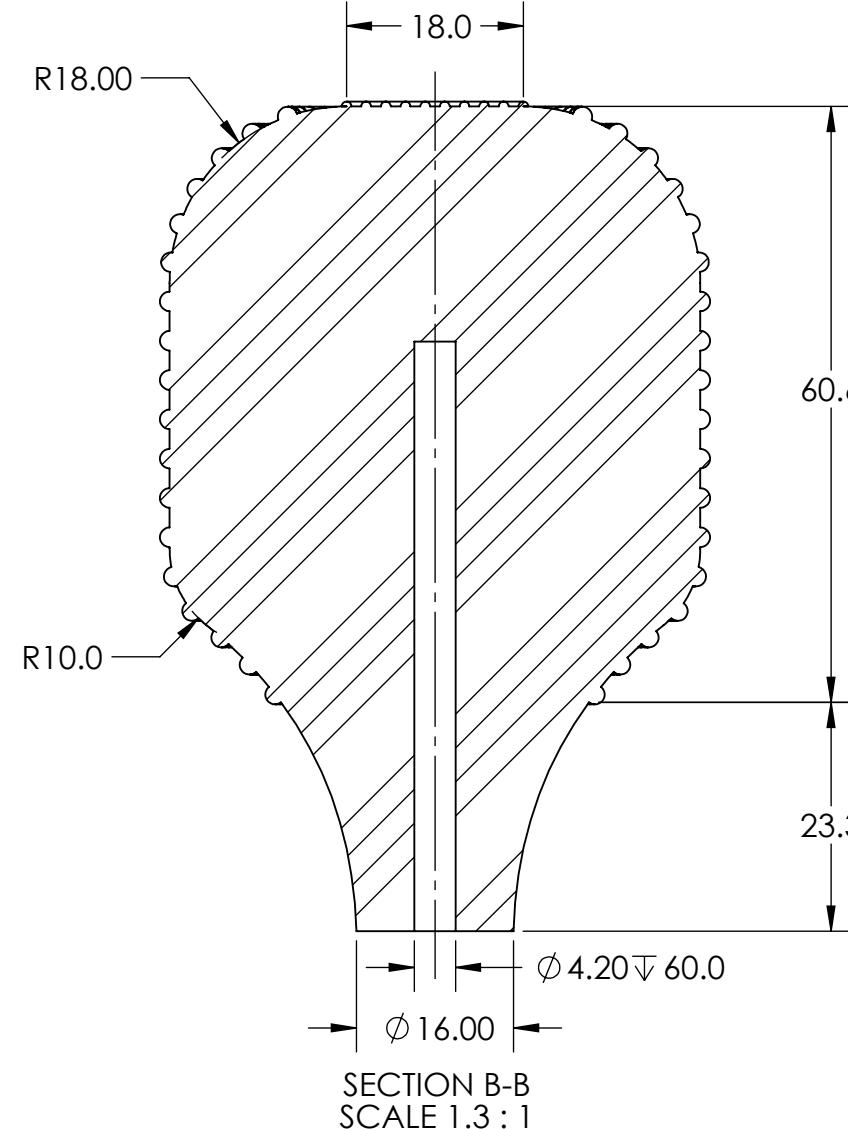
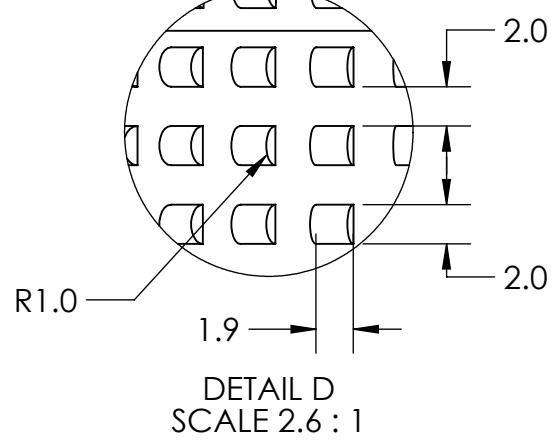
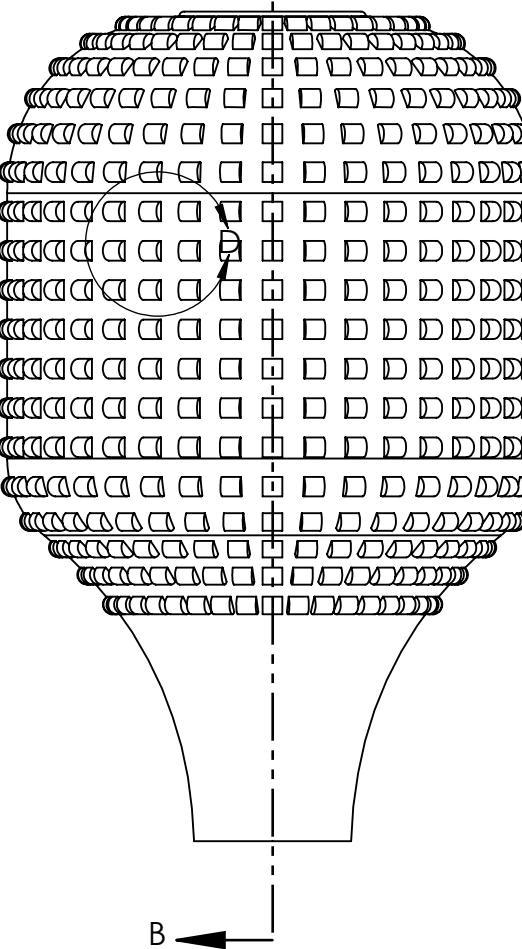
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2

1

REVISIONS		
SYMBOL	DESCRIPTION	DATE

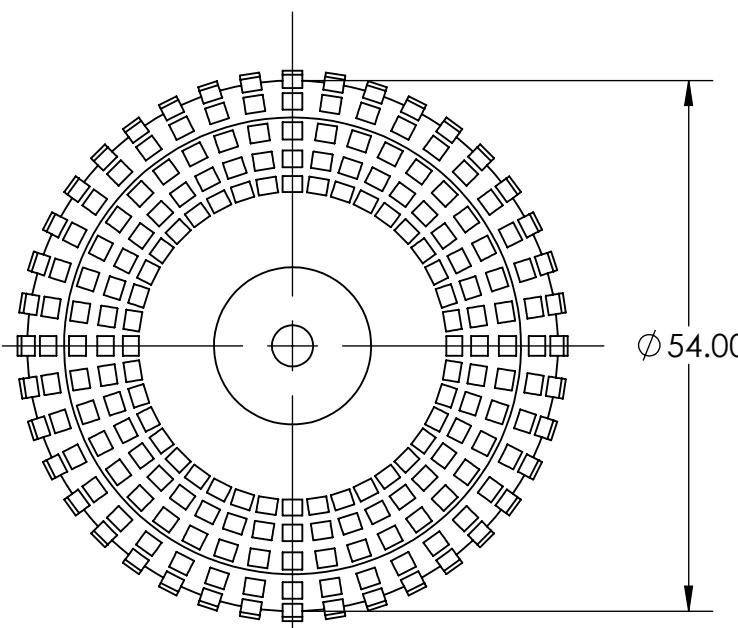
B



NOTES
 1. MATERIAL POLYPROPYLENE
 2. FINISH ALL OVER: 50µM
 3. REMOVE ALL STRUCTURES

B

B



GENERAL TOLERANCES
 $X.X \pm 0.1\text{mm}$
 $X.XX \pm 0.05\text{mm}$
 $X.XXX \pm 0.005\text{mm}$

$X^\circ \pm 0.5^\circ$

ALL DIMENSIONS IN MILLIMETERS

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PC NO	PART NAME	QTY
	BACK IN ACTION	
	TITLE:	
	DENERVATOR	
	HANDLE	
SIZE	DWG. NO.	REV
B	D.2	B
SCALE: 1.3:1		SHEET 1 OF 1

4

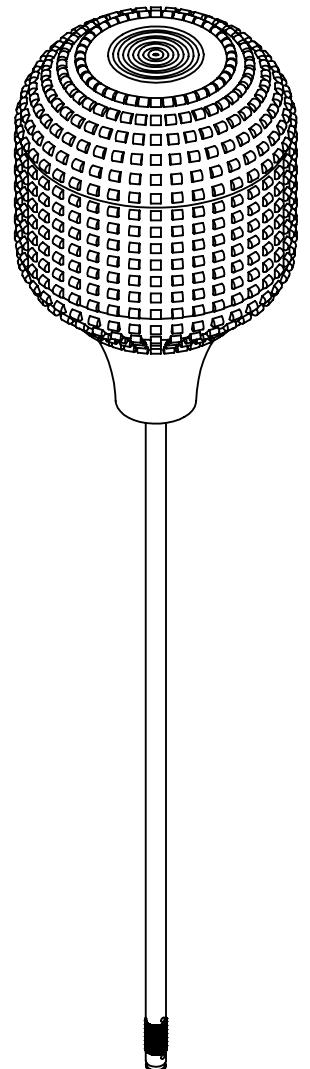
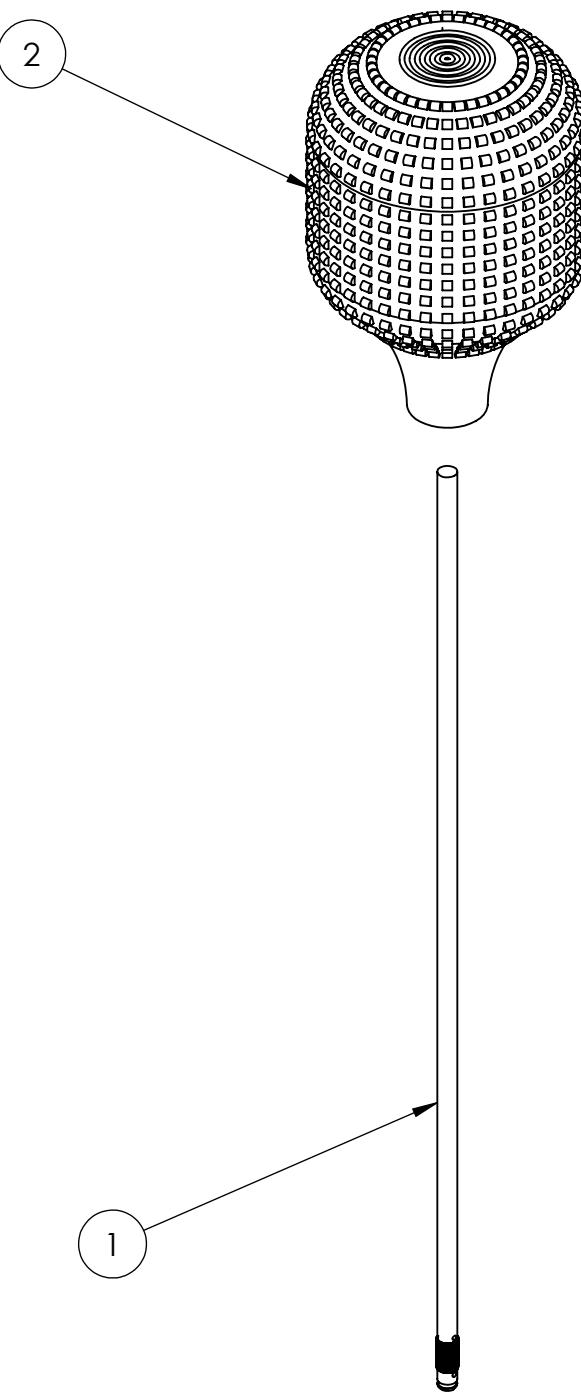
3

2

1

REVISIONS

SYMBOL	DESCRIPTION	DATE



GENERAL TOLERANCES

$X.X \pm 0.1\text{mm}$
 $X.XX \pm 0.05\text{mm}$
 $X.XXX \pm 0.005\text{mm}$

 $X^\circ \pm 0.5^\circ$

ALL DIMENSIONS IN MILLIMETERS

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FIRST ISSUED	3/18/24	BACK IN ACTION
DRAWN BY	JBW	TITLE:
CHECKED BY	AT	DENERVATOR ASSEMBLY
APPROVED BY		
COMMENTS:		
SIZE	DWG. NO.	REV
B	D.1.2	B
SCALE: 1:1.5		SHEET 1 OF 1