



CRITICAL DESIGN REVIEW

LMBN Surgical Neurotomy Device

Back in Action

Agathiya Tharun, Jacob Whitehouse, Joe Misenar, Cameron Mostoufi

ME463
Dr. David Cappelleri
dcappell@purdue.edu

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Executive Summary

Lumbar Medial Branch Nerve (LMBN) Surgical Neurotomy Device

Lower back pain (LBP) is a global phenomenon, experienced by 30% of the population at some point in their life. Chances are, someone in each family or each friend group has dealt with (or is currently dealing with) lower back pain. The leading cause of LBP is the irritation of the lumbar medial branch nerve in the facet joint, accounting for 25% of all lower back pain cases.

This report presents an innovative solution to facet-induced lower back pain. The proposed solution will permanently relieve said pain, as opposed to existing medical procedures which merely offer temporary relief. The solution will be also uniquely classified as minimally invasive. This separates the proposed solution from existing effective procedures, which are rather invasive. Finally, the proposed solution will entail advanced engineering principles in the development of four medical tools. For further reference, these medical tools are a Stylet, Portal, Back Stabilizer, and Denervator.

At this point in the design process, the team has developed exceptional CAD for the proposed medical tools (detailed in **Figure 1**). The Stylet was designed with a handle for axial leverage, a sharp tip to penetrate the body, and a nub to interlock with the Portal. The Portal was designed hollow as a pathway into the body for other tools, and it features a C-ring and track for the Stylet's nub to interlock these two tools. The Back Stabilizer was designed with long petals for leverage, a concave-shaped base to counteract the convex shape of a patient's back, and a clamp to constrain the Portal. Finally, the Denervator was designed with a handle for torsional leverage, a 7mm-long burred section to lesion the nerve, and a blunt end to prevent collateral damage.

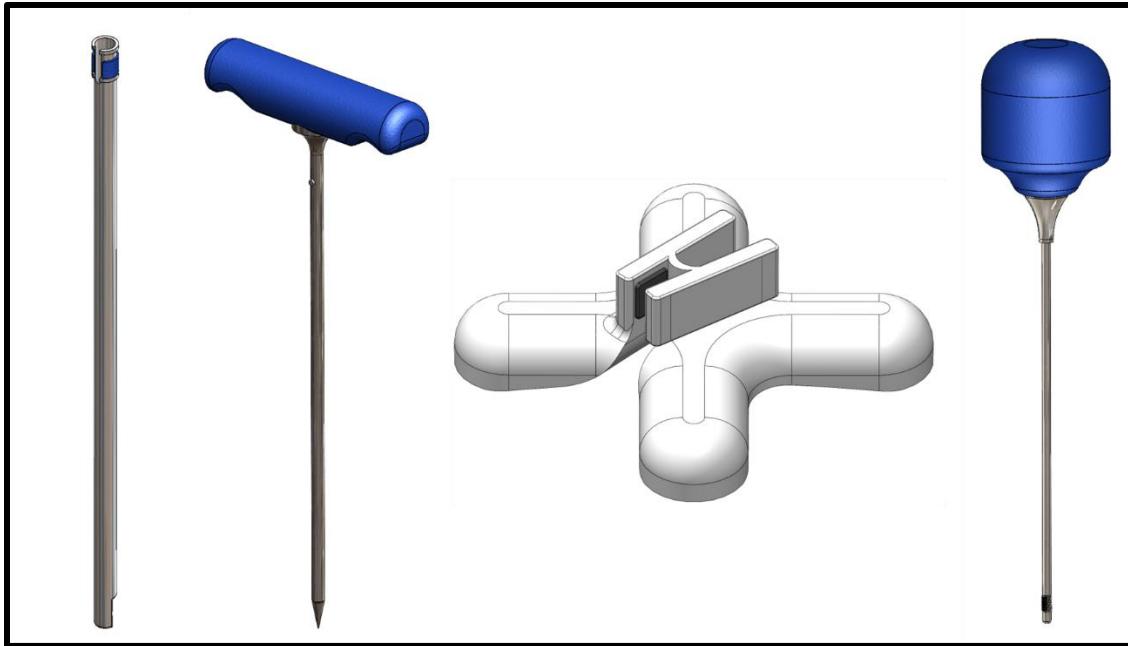


Figure 1 Final CAD of the medical tools (left to right: Portal, Stylet, Back Stabilizer, Denervator)

The team has validated the design through a variety of comprehensive engineering analyses. The relative analysis methods included bending-deformation and lever-arm calculations, FEA, thread analysis, and thermal studies. The results of these analyses drove the team to iterate their design to ensure it meets all specifications.

The team also developed a bill of materials and sourcing plan. These were heavily driven by the manufacturing plan: the team plans to outsource manufacturing of the to-scale prototype while manufacturing a macroscale prototype in-house. The BOM included medical-grade manufacturable materials, such as 316L stainless steel stock and polypropylene filament. It also included other necessary materials, such as silicone rubber pads for the clamp and heat-resistant adhesive for assembly.

Looking forward to the next phase, the team developed a comprehensive validation plan. This will test the prototype against all customer needs, engineering specifications, and desired functions. To better get this point across, the validation plan was split into three sections: customer needs tests, force tests, and functionality tests.

Through the critical design process, the team has showcased and analyzed a final design and requests to move on to the final phase of the design.

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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 amount of people with back pain, there are no patents, products, or procedure 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 Stabilize to stabilize the Portal, and a Denervator to lacerate the nerve such that it cannot regrow. The team is currently focused on a critical design phase involving design modeling, analysis, risk assessment, and developing test plans.

Extensive research was conducted to iterate on the initial design from PDR and to meet the updated engineering specifications chart (ESC). The medical grade materials were selected primarily on the basis of biocompatibility, X-ray appearance, temperature resistance (**Section G**). The material selections include SAE 316L, polypropylene, silicone rubber, and structural epoxy. Furthermore, new research into neuromas, a painful side effect of damaged nerves, gave the team insight into redesigning the ESC with more quantifiable requirements. It was ultimately decided that a cutting technique of grinding parallel to the nerve would produce the best results in preventing regrowth and neuroma formation.

Based on feedback from the preliminary prototype, customer research, and all identified critical failure points from the FMEA, the team made several updates to the CAD models (**Appendix III**) while mitigating risks based on timeline, information, budget, and functionality as detailed in the updated and project-specific Risk Register (**Section D**). Major updates to the CAD include dimension modifications to prevent yielding and deformation, tolerancing between interfacing devices, compliant mechanism implementation in the Back Stabilizer, improved manufacturability, improved functionality, and improved safety. For example, a “hood” was created at the tip of the Portal to shield the Denervator from rasping collateral flesh and the tip of the Denervator was made blunt for the same reason (**Section H**).

To ensure the designs were functional, met requirements, and would not fail to the risks identified in the FMEA, detailed analysis was performed. This included hand calculations to parameterized equations to drive design changes, thread stripping analysis, stress analysis to mitigate against yielding, and thermal analysis to ensure all devices could withstand the high temperatures of sterilization (**Section I**). The results of the analyses drove design changes as part of an iterative process; final dimensions and design features were honed in.

To ensure that the product will meet all requirements, a detailed test plan was updated to validate customer needs, basic functionality, force identification. Major customer needs include verifying procedural effectiveness through length of nerve damage, heat resistance, and X-ray appearance. Basic functionality tests include ergonomics, ease-of-use, and device integration. Finally, force identification tests will ensure procedural loads will not damage the devices (**Section L**). Such testing will improve the robustness and dependability of the product.

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 on the order of millions. The market size and demand, in addition to the BOM and budget, was leveraged to update the initial price estimation for the product, taking inspiration from how similar competitors have done so (**Appendix II**). To remain competitive to the competitor procedure, RF Ablation, the team priced its kit at \$1500 which yields an annual gross profit of \$4,584,050.

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 move into

the next phase of Final Design Review and hone the leading designs. Moving forward, the team plans to place orders, begin in-house manufacturing, and perform validation testing.

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 included a rewriting of the following sections for conciseness: 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. The following information was reviewed and slightly modified from PDR to CDR. 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, the Purdue Bechtel Innovation Design Center (BIDC), and Discovery Park Laboratories. The team also plans to use outsourced manufacturing companies such as Xometry to create a to-scale prototype. 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, and Edward Null.

 ME 463 Senior Design					
Project Title: LMBN Surgical Nuerotomy Device Team Name: Back in Action Team Members: Cameron Mostoufi, Joseph Misenar, Jacob Whitehouse, Agathiya Tharun	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.				
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.	Key Stakeholders (Role, Influence, Interest) All patients with facet-induced lower back pain All professionals who treat facet-induced lower back pain (PM&R specialists, physiatrists) Insurance companies covering this procedure.				
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.	Project Scope <table border="1"> <tr> <th>IN Scope (for this class)</th><th>OUT of Scope</th></tr> <tr> <td>Development of to-scale prototype Proof of concept on macro-scale prototype Mechanical/software testing/analysis Soft body modeling Procedural testing</td><td>Regulatory pathway ie. establishment registration, medical device listing, PMA, etc. sourcing manufacturers.</td></tr> </table>	IN Scope (for this class)	OUT of Scope	Development of to-scale prototype Proof of concept on macro-scale prototype Mechanical/software testing/analysis Soft body modeling Procedural testing	Regulatory pathway ie. establishment registration, medical device listing, PMA, etc. sourcing manufacturers.
IN Scope (for this class)	OUT of Scope				
Development of to-scale prototype Proof of concept on macro-scale prototype Mechanical/software testing/analysis Soft body modeling Procedural testing	Regulatory pathway ie. establishment registration, medical device listing, PMA, etc. sourcing manufacturers.				
Key Milestones <ol style="list-style-type: none"> Assess clinical need for a new lower back pain device, analyze current treatments, and design a superior solution. Develop design plans, build prototypes, conduct software and bench tests for functionality and safety, and perform soft body modeling. Conduct preclinical tests and mannequin trials to verify efficacy and safety. 	Key Assumptions & Risks Key Assumptions: The Lumbar Medial Branch Nerve (LMBN) surgical neurotomy procedure is no more invasive than radiofrequency (RF) ablation, the LMBN procedure will work at an efficient rate according to the design of our tools, our procedure falls under the open surgical code Risks: Patented procedure and tools, lack of IRB approval/certification, FDA non-approval/certification, negative side effects, ineffective or damaging procedure/tools				
Team Members & Roles Cameron Mostoufi: Project Manager, Chief Engineer, Business Lead Jacob Whitehouse: Buyer, Electronics Lead, Analysis Lead, Validation Lead Joseph Misenar: Manufacturing Manager, Mechanical Design Lead, CAD lead Agathiya Tharun: Project Manager, Chief Engineer	Key Resources Required Our team will utilize internal resources at Purdue. For example, EDM Machining with Professor Titus at Kepner, ME Machine Shop, Purdue Rapid Prototyping Lab, ME Labs, BIDC, and Discovery Park Laboratories. We also plan to utilize external resources such as Xometry Manufacturing and McMaster-Carr. Our team will also make use of colleagues and other people. This includes, Dr. S Ali Mostoufi Spine Interventionalist, Professor Cappelleri, Professor Hirleman, FDA POC's, Kyle Baer, and Mark Baldwin (biomedical fellow from LM), Martin Jun, Edward Null, Beth Hess (former bioengineer)				
Version: 2.0.0	Last Updated: 3/3/2024 Rewrote Key milestones, business/society, risks for conciseness				

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 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 PDR report. CDR fidelity, however, has significantly improved since then.

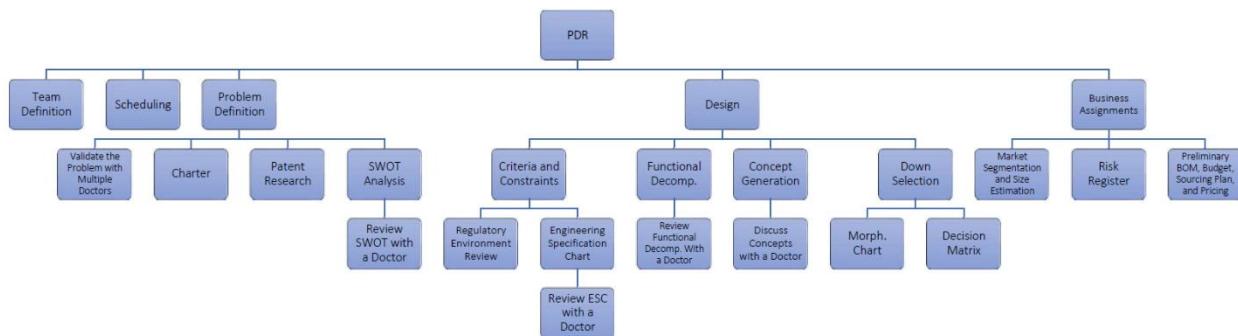


Figure B.1 WBS chart used for the PDR phase

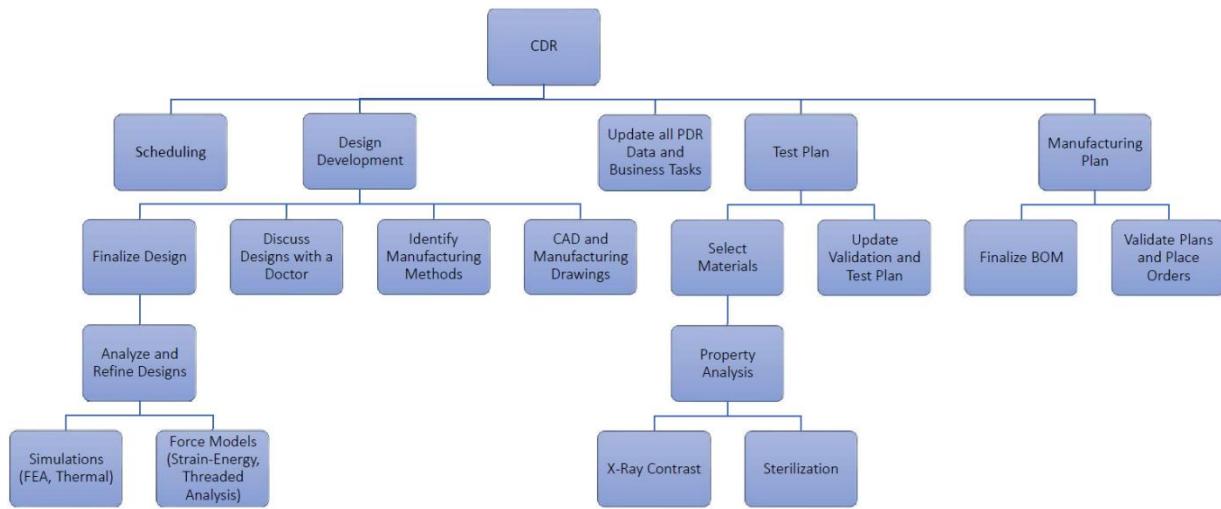
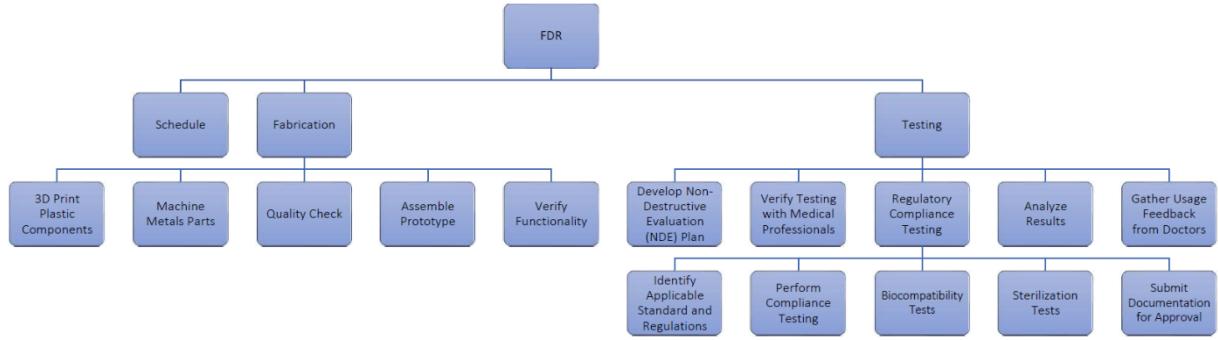
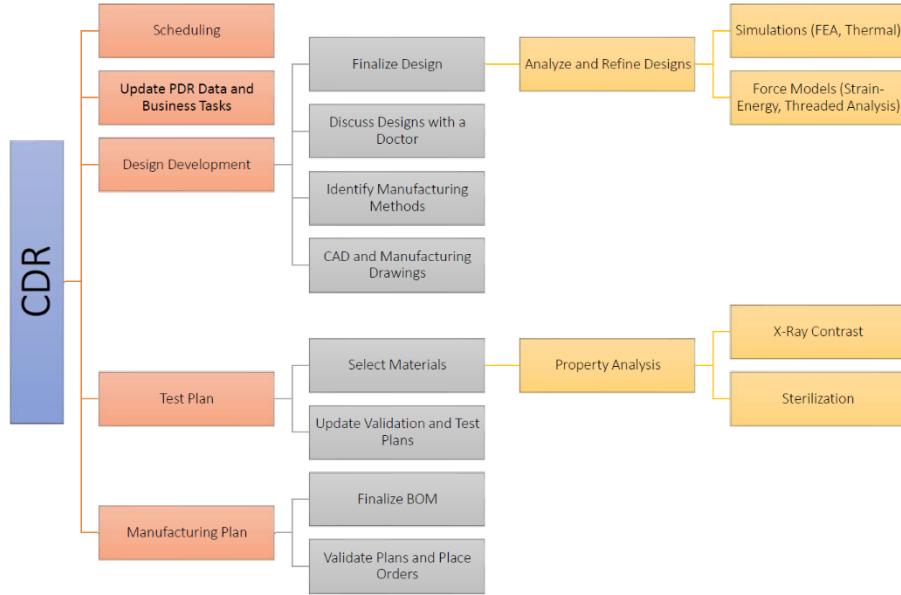
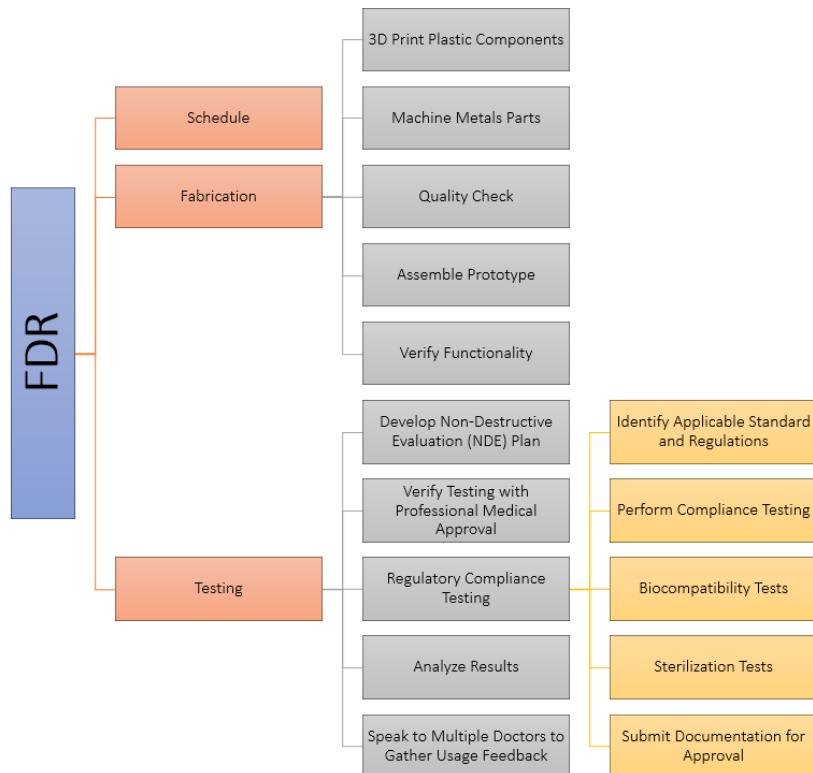


Figure B.2 WBS chart for the CDR phase

**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

Due to limited information, the chart for the FDR phase yields limited fidelity. 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**. Hence, the FDR phase is not as accurate as the PDR and CDR phases. Some tasks in this checklist, in addition to the "Independent Market Analysis" 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 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 <ul style="list-style-type: none"> 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 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"> 3D Print Plastic Components Fabricate Metal Parts with Machining Quality Check all Fabricated Parts Assemble Prototype Verify Basic Functionality Iterate on CDR Tasks as Needed <p>Testing</p> <ul style="list-style-type: none"> Develop Non-Destructive Evaluation (NDE) Plan Modularity/Interactivity Ease of Use Mishandling Cases Initial Sterilization Procedural Functionality (on Dummy) <ul style="list-style-type: none"> Appearance on X-rays Doctor Procedural Approval Verify Testing with Medical Approval Customer Feedback <ul style="list-style-type: none"> Speak to a Professional for Usage Feedback Analyze Test Results and Iterate as Needed <p>Regulatory Compliance Testing</p> <ul style="list-style-type: none"> Identify Applicable Standards and Regulations <ul style="list-style-type: none"> Speak to Professionals Perform Compliance Testing Biocompatibility Tests Sterilization and Cleanliness Tests Submit Regulatory Documentation for Approval <p>Report Deliverables</p> <ul style="list-style-type: none"> Written Report Presentation <p>Independent Market Analysis:</p> <p>Industry Analysis</p> <ul style="list-style-type: none"> Macro-environmental Factor 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 CDR 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 PDR phase have not changed since the PDR report.

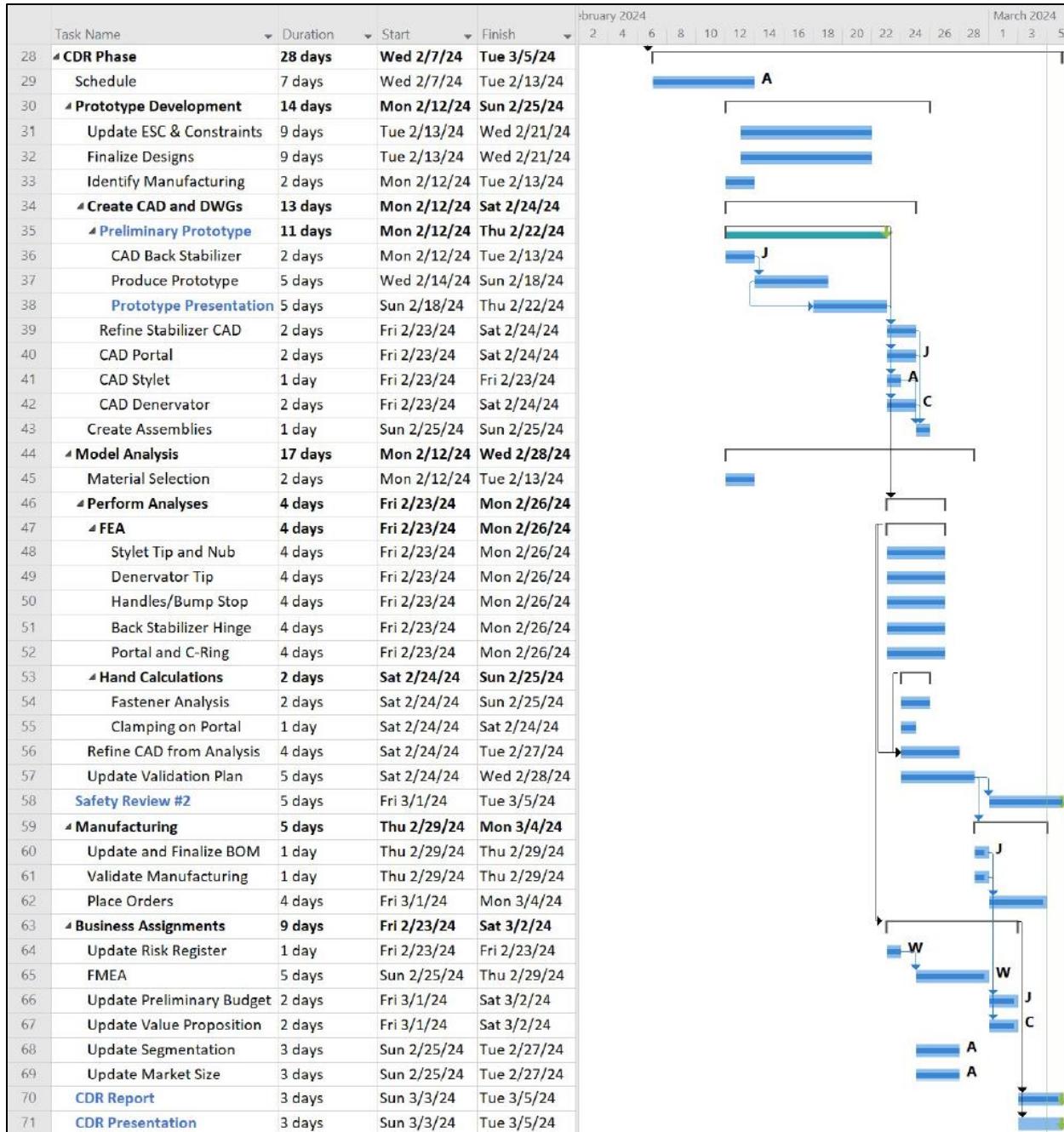


Figure B.8 CDR Gantt Chart

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 a few items in the BOM can either be sourced for free via the ME Machine Shop or ME463 resources. In addition, all parts needing to be 3D printed can be done using free services through the ME 3D Print Lab. The only incurred cost for 3D printing will be from the purchase of polypropylene filament, which will be implemented into the prototype due to its high mechanical strength. Certain items that can be sourced for free were not included in the Preliminary Budget as seen below in **Figure C.1**.

Figure C.1 Preliminary budget

Due to the nature of this project, certain parts will require near-micro-scale manufacturing, which is difficult to machine with the team's available resources. After creating the preliminary prototype and reviewing engineering drawings and specifications, the team decided that they cannot make one of the medical tools: the Portal. Thus, the team will use a third-party manufacturing service, called Xometry, to produce the unique geometries of the

Portal. Xometry offers a wide range of materials and manufacturing processes. A major benefit of using this company is their very fast lead times and instant quoting for any CAD model input onto their website. They also give the option to supply part certifications and supplier qualifications, ensuring the quality of the desired part. The preliminary budget also reflects service costs and sourcing from manufacturers. Given that only 50% of the team's budget is to be expended, it can be safely assumed that any additional manufacturing services or supplies the team may utilize will remain within the budget.

The rest of the budget offers the team protection for handling unexpected issues, mitigating risks, and optimizing the design to a higher and medical-grade quality. The team also included the medical-grade materials for manufacturing, including grade 316L stainless steel, and polypropylene filament. The team will also take into consideration comfort and ease of use into their design budget. Furthermore, the team will continuously make updates to this chart as new information is acquired and as the project develops. Thus, this large buffer allows for price fluctuations and other uncertainties as well.

D. Risk Register

It's important to reiterate 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 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 risk. 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 RAISED	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	E	I	Residual Ris	Commentary	Last Updat	
Select overall approach to treatment (Mitigate or Accept)	Summary of the treatment responses (actions, controls, fallback) 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

For the sake of the CDR phase, a comprehensive list of all relative risks can be seen in **Figures D.3 and D.4**. A few of the highest-rated risks, where a high-rated risk has its CRS highlighted in red, will be explicitly discussed. The first high-rated risk that's important to note is the slow response times from the doctors that the team is consulting with. Considering the team is developing these medical tools for doctors, they have been in contact and consultation with multiple back-specialized doctors. The team, however, cannot put much reliance on these doctors to follow through, considering the doctors are not a part of the team nor the class. For

this reason, if the doctors take too long to communicate with the team (e.g. if the team is reaching a deadline and has not heard back from a nerve doctor about nerve-related questions), then the team will have to accept this and move on with their deliverables by making decisions based on their best judgment and intuition. This would reduce the impact of the risk otherwise, such that the team would wait too long for the doctors and subsequently get behind schedule.

Another high-rated risk that is important to discuss is if the FEA and hand calculations reveal failures or shortcomings of the design. The entire purpose of the CDR phase is to prove that the design is viable; therefore, if the design doesn't satisfy the analysis, then it is not viable and cannot be presented as a convincing solution. The team has decided that this risk can be mitigated through design iteration. The team will complete the CAD early within the CDR phase to give themselves sufficient time to iterate on the design. Based on the results of hand calculations, material property analysis, FEA, and thermal analysis, the team will update the CAD accordingly. Implementing an engineering concept like design iteration into the design process allows the team to greatly mitigate this risk, as noted by the CRS dropping by 9 points to the RRS.

The last high-rated risk to be noted in this report is if the prototype doesn't meet the engineering specifications. If this happens, then the prototype will fail to meet the customers' needs. There would be no point in doing this project and putting in so much work only if the prototype cannot meet the customer needs. The team has already spoken with multiple doctors to establish thorough customer needs and done medical research to set engineering specifications. From the CDR phase and on, the team will need to perform appropriate analysis and validation testing for each of the engineering specifications. If each specification can be analyzed or tested, then the team can iterate the design as needed. Having results for each engineering specification will help the team ensure that the prototype does indeed meet all the customers' needs, which will reduce the impact of the risk. The rest of the relative risks from the CDR phase and the entire project can be found in the Risk Register document attached to this report.

Critical Design Review

21

1. IDENTIFICATION										2. CURRENT ASSESSMENT			3. TREATMENT			4. RESIDUAL ASSESSMENT			5. REVIEW, CONTROL, COMMUNICATE		
Raised	Date Raised	Cause (If...)		Effect (Then...)		Risk Owner	P	I	Current Risk Score	Strategy	Treatment Description		F	Residual Risk Score	Commentary	Last Update					
		When the risk was first identified		If uncertain event occurs due to (or because of) specified root cause(s). Tip: ask "why, why... to drill down to root cause."		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 meet 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			
1	Jacob Whitehouse	23-Feb-24	The originator of the risk		Team members are not available to complete work due to extracurricular commitments		Work will get pushed back, not completed, or completed in a non-comprehensive manner		Agathya Thanun	M	L	5	Mitigate	Each member needs to map their extracurricular schedule to the rest of the team at least a week in advance. Work can get reassigned depending on availability.	L	L	1	This was somewhat of an issue in the PDR phase; however, the team has implemented a new system during CDR to ensure that everybody can meet their workload. During the first meeting of every week, every team member discusses their time off plans for the week, and if anything arises later in the week, the team is sure to communicate this.		23-Feb-24	
2	Jacob Whitehouse	23-Feb-24	Medical standards (according to the FDA) impose a lot of constraints		Material selection and prototype designs will be strongly constrained		Jacob Whitehouse	M	M	10	Mitigate	Medical research must be done to identify all medical standards prior to brainstorming (the team should also have a medical review). Then, extensive material research must be done to identify materials that comply with all medical standards to prevent recalls.	L	L	1	The team had to look into the FDA medical standards in order to design their medical tools appropriately.		23-Feb-24			
8	Cameron Mostoufi	6-Feb-24	The team roles are misaligned		Work won't be done in an expert manner and team members may not enjoy the work that they get assigned		Agathya Thanun	M	M	10	Mitigate	All team members should discuss their areas of expertise as well as their areas of passion prior to any role assignment. The team should also make sure to assign responsibilities thoroughly before matching person with role.	L	M	6	Jacob updated the wording for this risk to make it more applicable to the team's specific project. The team is flexible to realignment during the length of the project, if necessary.		23-Feb-24			
9	Cameron Mostoufi	6-Feb-24	Unrealistic timelines are set		The team is at risk of getting behind on project milestones and deliverables		Agathya Thanun	L	M	6	Mitigate	Understand the entire semester-long scope of deliverables, establish all team members availability, and then develop a cumulative timeline. Then, check-in and review at each meeting to determine its accuracy.	L	M	6	Jacob updated the wording for this risk to make it more applicable to the team's specific project. The schedule is being reviewed every meeting to ensure that the team is on pace and to ensure that the future schedule is set realistic.		23-Feb-24			
10	Cameron Mostoufi	6-Feb-24	The sources used throughout the research process are unreliable		This will create skewed and inaccurate understandings		Agathya Thanun	M	L	5	Mitigate	At least one other team member should review the research to ensure it is both reliable and the correct takeaways have been defined.	L	L	1	Jacob updated the wording for this risk to make it more applicable to the team's specific project. Heavy research validation was done between Aggy, Jacob, and Cam. Also, doctors were consulted to ensure that the research made sense.		23-Feb-24			
11	Cameron Mostoufi	6-Feb-24	There are slow responses from the doctors that the team is consulting with		The team may get behind their schedules if they do not move on at some point and they might have questions unanswered		Cameron Mostoufi	M	H	15	Accept	The team will eventually have to move on to the next part of the project if they do not move on. The team will have to use their best judgment to temporarily answer any questions they had for now.	M	M	10	Jacob updated the wording for this risk to make it more applicable to the team's specific project. The team is currently facing this problem. Jacob updated the wording for this risk to make it more applicable to the team's specific project. Heavy research validation was done between Aggy, Jacob, and Cam. Also, doctors were consulted to ensure that the research made sense.		23-Feb-24			
13	Cameron Mostoufi	6-Feb-24	FEA analysis and hand calculations reveal failures or shortcomings of the design		The design will not accomplish the desired functions		Jacob Whitehouse	M	H	15	Mitigate	The team will iterate on their designs in order to accommodate for any issues that arise during analysis	L	M	6	Jacob updated the wording for this risk to make it more applicable to the team's specific project. FEA will be performed by Jacob and Aggy in order to have two sets of eyes on it.		23-Feb-24			

Figure D.3 First section of relative risks to the CDR phase

A	B	C	D	E	F	G	H	I	2. CURRENT ASSESSMENT	K	L	M	N	P	Q	R		
Raised	Date Raised	CAUSE (IF...)	Effect (Then...)	Risk Owner	P	I	Current Risk Score	Strategy	Treatment Description	F	Residual Risk Score	Commentary	Last Update					
		When the risk was first identified		If uncertain event occurs due to (or because of) specified root cause(s). Tip: ask "why, why... to drill down to root cause."		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 meet 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
14	Jacob Whitehouse	23-Feb-24	The team is not able to afford medical grade materials (e.g. SS316L, polypropylene, or silicone)		The team will not be able to test the temperature and pressure (sterilization testing) resistance of the medical tool		Jacob Whitehouse	M	M	10	Mitigate	assigned to the CAD models and throughout analysis to get valid results. Also, the final prototype will be manufactured out of similar materials to the CAD model.	L	M	6	The materials themselves (316L, polypropylene, and silicone) are not drastically expensive. It more of a question of how expensive outsourcing manufacturing is. The team will be sure to evaluate costs of materials prior to choosing a final design/material.		23-Feb-24
16	Jacob Whitehouse	23-Feb-24	Manufacturing processes for the debrider and portal are not identified prior to CAD		The CAD will not be designed according to manufacturing, which makes it a level harder to manufacture.		Joe Miseran	L	M	6	Mitigate	Discuss with professors and machine shop faculty to identify possible methods to manufacture the debrider and portal prior to CAD.	L	L	1	The team plans to talk with Darrin Wilcockson and Mike Sherwood to identify manufacturing methods for the small geometries of the designs. This will be discussed with the team so the team knows how to perform the CAD to reflect manufacturing processes.		23-Feb-24
17	Jacob Whitehouse	23-Feb-24	The team gets caught up trying to perfect the design before creating CAD		Project progress will get stagnant and the team will get behind		Agathya Thanun	M	L	5	Mitigate	The schedule should emphasize a hard deadline for the design such that the CAD can begin on time.	L	L	1	Jacob and Aggy tend to try and perfect everything before moving on. This will be worked on with the customer and achieve the best possible design before the deadline in the schedule.		23-Feb-24
18	Jacob Whitehouse	23-Feb-24	The team does not have access to rubber pads		The preliminary prototype of the back stabilizer will be ineffective		Jacob Whitehouse	H	L	9	Mitigate	The team will collect materials to simulate the functionality of the rubber pads (e.g. rubber bands).	L	L	1	There are many common materials to simulate the friction of a rubber pad, such as rubber bands.		23-Feb-24
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 patient needs. Then, the team will research relevant engineering specifications out of 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 how well each customer need is satisfied.		23-Feb-24
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 has refined the ESC to make each customer need testable. This was done through input from Professor Capellen and Mike Sherwood.	M	L	5	The team has refined the ESC to make each customer need testable. This was done through input from Professor Capellen and Mike Sherwood.		23-Feb-24

Figure D.4 Second section of relative risks to the CDR 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 preliminary 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, taking into account 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 cutting-edge medical solutions.

E.2 Market Size Estimation

The following information regarding the market size estimation has been reviewed since the PDR phase, though the team didn't find updates necessary.

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 determined with the aid of various AI software. 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.3 Competitor Analysis

E.3.1 Patent Research

The following information regarding the patent research has been reviewed since the PDR 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 PDR 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.3.1**



Figure E.3.1 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**

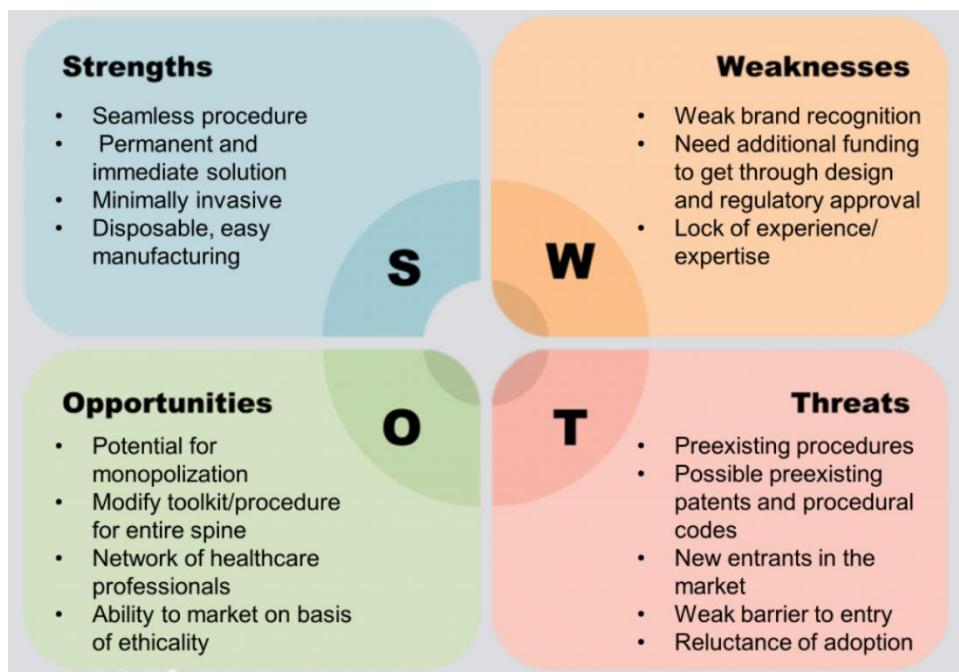


Figure E.3.2 Project-specific SWOT analysis

E.3.3 Regulatory Environment Review (RER)

The following information regarding the Regulatory Environment Review analysis has been reviewed since the PDR phase, though the team didn't find updates necessary.

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

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, assuming 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, with an 80% adjustment applied for 5000 units/year for items like the Stylet Shaft. This method ensures that the costs are scaled appropriately, benefiting from 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 Portal Hollow Tube, which necessitates 0.5 hours of labor, resulting in a \$30 labor cost. This is then combined with the adjusted component cost and a specific overhead rate, which in the case of the Portal Hollow Tube, amounts to 35% overhead. This eventually leads to a final component cost of \$289.68.

For materials used in smaller quantities, such as epoxy and threaded inserts, 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.

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's 3D printing filament at \$42.80, with an additional \$20 for 20 hours of printing labor. This culminates in a final cost of \$62.80 for the component.

The final cost per toolkit, \$583.19, 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 and F.1.2** provide continued detailed cost analyses for other components such as the Stylet Shaft, the Back Stabilizer, and various fasteners and inserts. This level of detail in the cost breakdown is essential for maintaining transparency and accuracy in financial planning and pricing strategies.

Component #1 - Stylet Shaft		Component #2 - Portal Hollow Tube		Component #3 - Denervator Shaft	
Description	Stylet Shaft body	Description	Portal Hollow Tube Body	Description	Denervator Shaft Body
Vendor	McMaster-Carr	Vendor	McMaster-Carr	Vendor	McMaster-Carr
Retail Cost	\$33.28	Retail Cost	\$230.72	Retail Cost	\$33.28
Units / yr	5000	Units / yr	5000	Units / yr	5000
Volumized % of retail	80%	Volumized % of retail	80%	Volumized % of retail	80%
Part Cost	\$26.62	Part Cost	\$184.58	Part Cost	\$26.62
Machining	0.2 hr.	Machining hrs.	0.5 hr.	Machining	0.3 hr.
Labor rate	60 \$/ hr.	Labor rate	60 \$/ hr.	Labor rate	60 \$/ hr.
Labor cost	\$12.00	Labor cost	\$30.00	Labor cost	\$18.00
Part + Lab	\$38.62	Part + Labor	\$214.58	Part + Lab	\$44.62
Overhead	35%	Overhead	35%	Overhead	35%
Component Cost	\$52.14	Component Cost	\$289.68	Component Cost	\$60.24
ss					
Component #4 - C-Clip		Component #5 - Back Stabilizer		Component #6 - Epoxy Coating	
Description	C Clip	Description	Denervator Body	Description	Epoxy Coating Spray
Vendor	Matter Hackers	Vendor	McMaster-Carr	Vendor	McMaster-Carr
Retail Cost	\$0.01	Retail Cost	\$1.11	Retail Cost	\$21.47
Units / yr	5000	Units / yr	5000	Units / yr	2000
Volumized % of retail	80%	Volumized % of retail	80%	Volumized % of retail	90%
Part Cost	\$0.01	Part Cost	\$0.89	Part Cost	\$19.32
Overhead	8.5%	Overhead	8.5%	Overhead	8.5%
Component Cost	\$0.01	Component Cost	\$0.96	Component Cost	\$20.97

Figure F.1.1 Cost of components 1 through 6

Component #7 - Denevator Handle		Component #8 - Misc. Fasteners		Component #9 - Threaded Inserts	
Description	3D Printed Handle	Description	M2x6mm Stainless Fasteners	Description	M2 Threaded Inserts
Vendor	Matterhackers	Vendor	McMaster-Carr	Vendor	McMaster-Carr
Retail Cost	\$2.09	Retail Cost	\$7.29	Retail Cost	\$0.07
Units / yr	5000	Units / yr	2000	Units / yr	10000
Volumized % of retail	80%	Volumized % of retail	90%	Volumized % of retail	70%
Part Cost	\$1.67	Part Cost	\$6.56	Part Cost	\$0.05
Overhead	8.5%	Overhead	8.5%	Overhead	8.5%
Component Cost	\$1.81	Component Cost	\$7.12	Component Cost	\$0.05
Component #10 - 3D Printing Filament		Component #11 - Stylet Handle		Component #12 - Structural Epoxy	
Material: PP		Description	Handle for Assy	Description	M2 Threaded Inserts
Filament cost	0.069 in	Vendor	Matterhackers	Vendor	McMaster-Carr
Filament length	2164 ft	Retail Cost	\$0.47	Retail Cost	\$89.09
Filament cost	0.049 lb. / cu. in.	Units / yr	5000	Units / yr	1000
Filament volume	4.755568 lb. / cu. in.	Volumized % of retail	80%	Volumized % of retail	90%
Price	\$ 9.00 /lb.	Part Cost	\$0.38	Part Cost	\$80.18
Material cost	\$ 42.80	Overhead	8.5%	Overhead	8.5%
Units/yr	100	Component Cost	\$0.41	Component Cost	\$87.00
Labor & Machine Cost (added to all materials)					
Printing time	20 hrs.				
Cost / hr.	\$ 1.00 / hr.				
Labor & M	\$ 20.00				
Component Cost	\$62.80				
Total	\$583.19				

Figure F.1.2 Cost of components 1 through 6

F.2 Product Price

The product pricing for the proposed medical tools has been updated since the PDR. Previously, the team had priced out the medical procedure. However, the team is not selling the procedure; the team is selling the medical tools. Pricing has been appropriately updated to 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 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 \$583.19 per performed procedure (**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 PDR 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 procedure is a crucial indicator of its financial health and the effectiveness of its pricing strategy. The meticulous approach to calculating the production cost of each component, considering the intricacies of manufacturing, labor, and overhead, results in a comprehensive total cost of \$583.19 per unit. 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 procedural 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 procedure 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 \$583.19, the gross profit per unit stands at \$916.81. 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 \$4,584,050.

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. Numerous NIH and NCBI articles 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**.

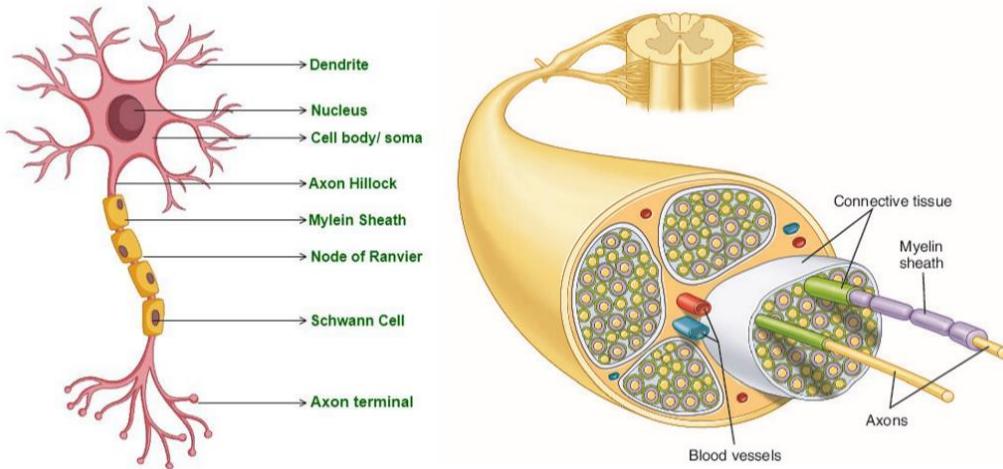


Figure G.1.1 Anatomy of a nerve

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 reapproximate (reconnect). 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 helps 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 provided the team with critical insight into how a nerve should be severed to prevent permanent regrowth. A mutually exclusive characteristic of 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 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, 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

Axonal regeneration requires an intact endoneurium¹⁸ to reestablish 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 denervation for the team.

All aforementioned research has undergone insignificant changes since PDR. During the CDR phase, the team continued research in this domain to identify how neuromas can be prevented. 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.

With regards to the influence of a cutting method on neuroma formation, other 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 judgement 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**.

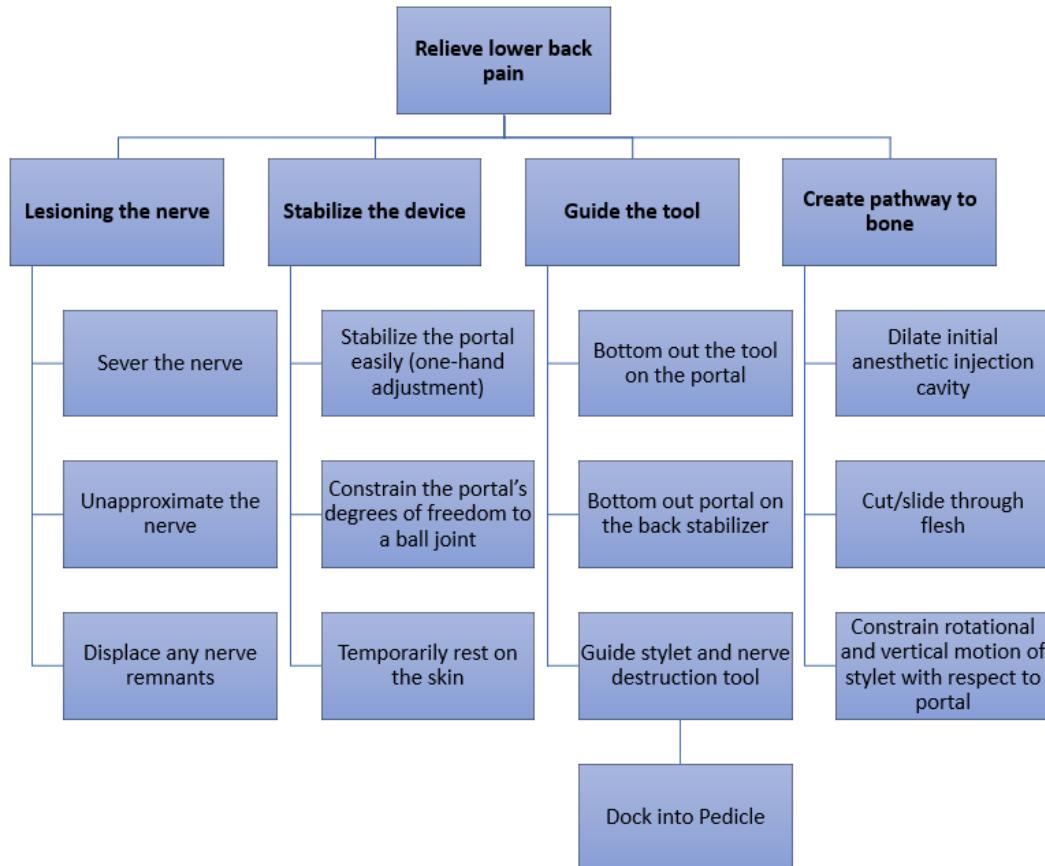


Figure G.1.3 Functional Decomposition chart

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.

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, and 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 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, 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 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.3.2**). 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 Critical Design Review (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 PDR. In order to establish a stronger 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 an 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)

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 (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 constraint 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.

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. 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.

H. CAD Models

The team spent much time finalizing the concept in the most optimal way to fulfill the customer's needs. **Figures H.1 through H.4** resemble the toolkit's final chosen concept in four main components. In order, the Portal, Stylet, Back Stabilizer, and Denervator. The Portal will be outsourced; therefore, it's considered a buy-part. Meanwhile the Stylet, Back Stabilizer and Denervator are to be manufactured in-house, which means they are considered make-parts (though they are manufactured from a slew of 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 from 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 note that the blue and white components are made from polypropylene 3D filament and the rest of the components are made from stainless steel 316L. The functional requirements of the components are discussed below.

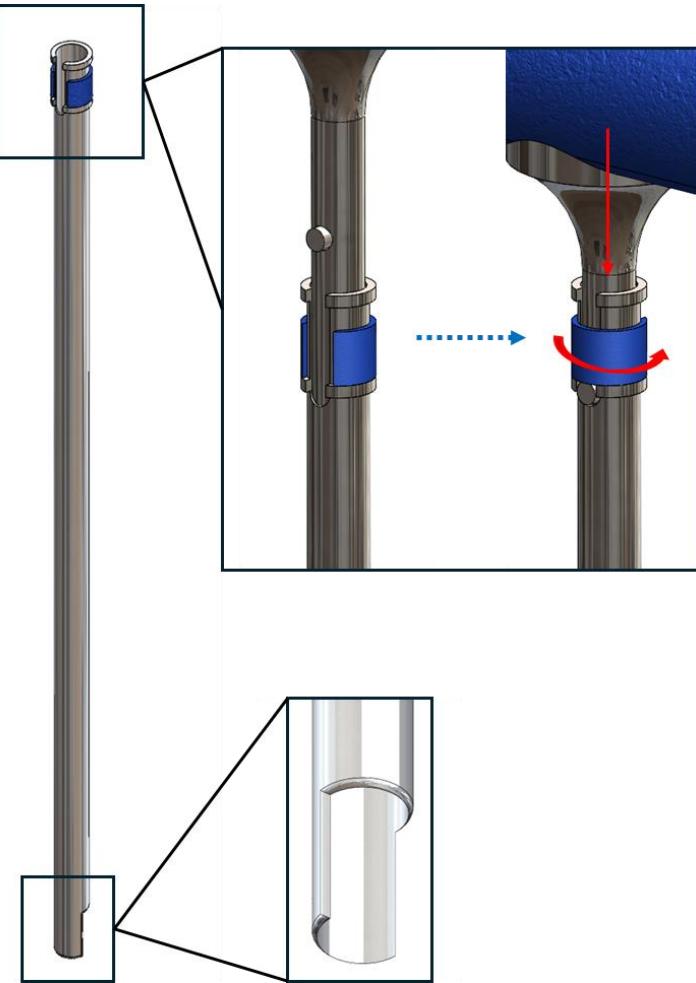


Figure H.1 Portal CAD model

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 the Denervator tool to slide in and out. Additionally, the Portal was tolerance in order 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 in order to avoid laceration to any structure or tissue other than the nerve by acting as a shield. The nerve sits in the groove of the facet joint which means the only location that needs to be in contact with 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. The Portal also must temporarily connect to the Stylet tool while inserting the Portal and Stylet combination into the patient's body. The two tools act as one when the top locking

mechanism is in use. The blue plastic C-Clip is pressed on to the Portal shaft and is free to rotate and lock the Stylet nub in the recess shown in **Figure H.1** with the help of the doctor.

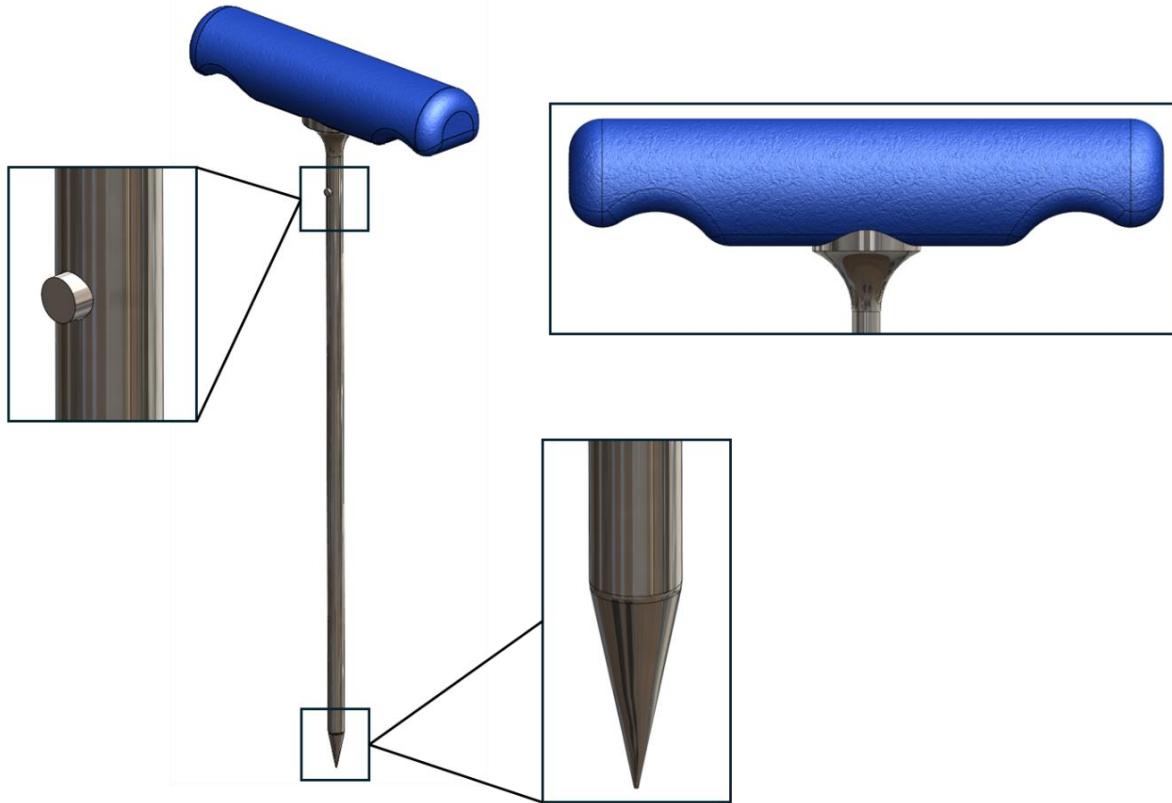


Figure H.2 Stylet CAD model

The Stylet as seen in **Figure H.2** consists of a solid shaft with a conical bottom end and an ergonomic handle on the top. The nub highlighted above is used as part of the locking mechanism between the Portal described previously. The functional requirement of the bottom is to help guide the Portal into the body at the beginning of the procedure. The point was made to have a sharp incline but still have a blunt tip to limit minimize 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, which 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 conical shape's simplicity allows for the entire 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. The connection between the Stylet shaft and the handle is made with threads and a high strength epoxy for extra security. The handle was perfected for an ergonomic fit for the average sized person's hand to grasp and easily rotate in order to be pushed down into the body and dock onto the bone.

The Back Stabilizer is shown below 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 to 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, eliminating 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.

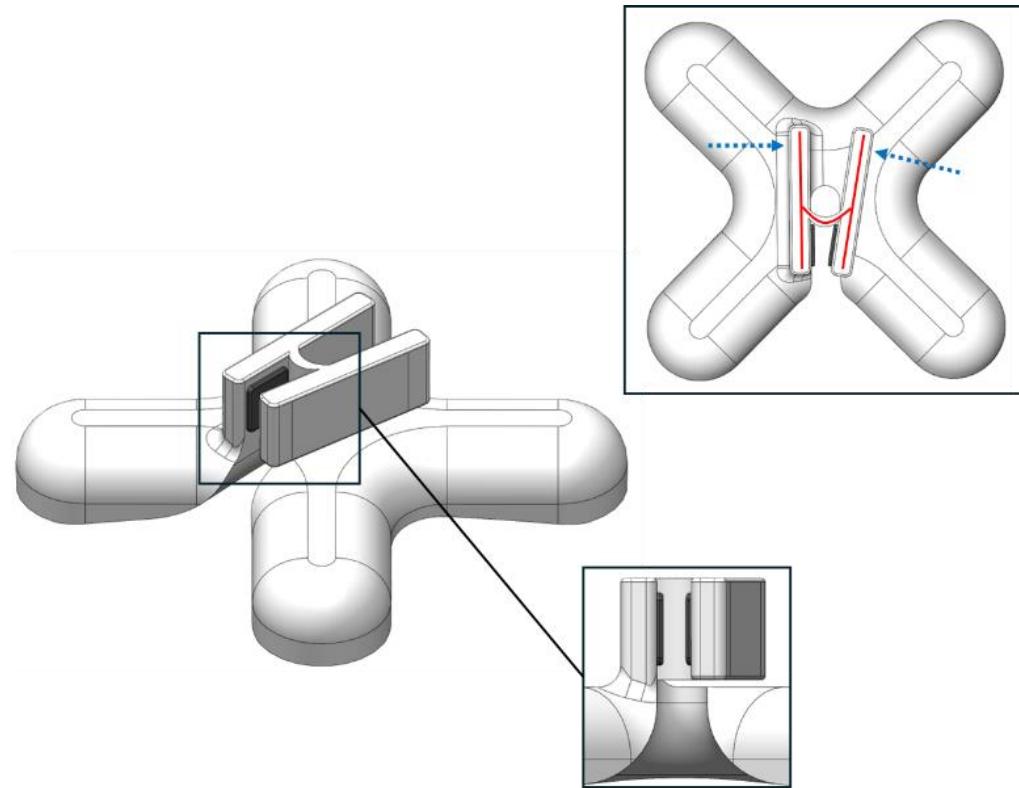


Figure H.3 Back Stabilizer CAD model

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. Incorporating adjustments made during the Critical Design Review (CDR) phase, 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. As seen in black, there are rubber pads epoxied to the inside face of the clamp arms to help restrict the Portal from moving. 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. The team was able to find a good middle ground for these dimensions that worked best.

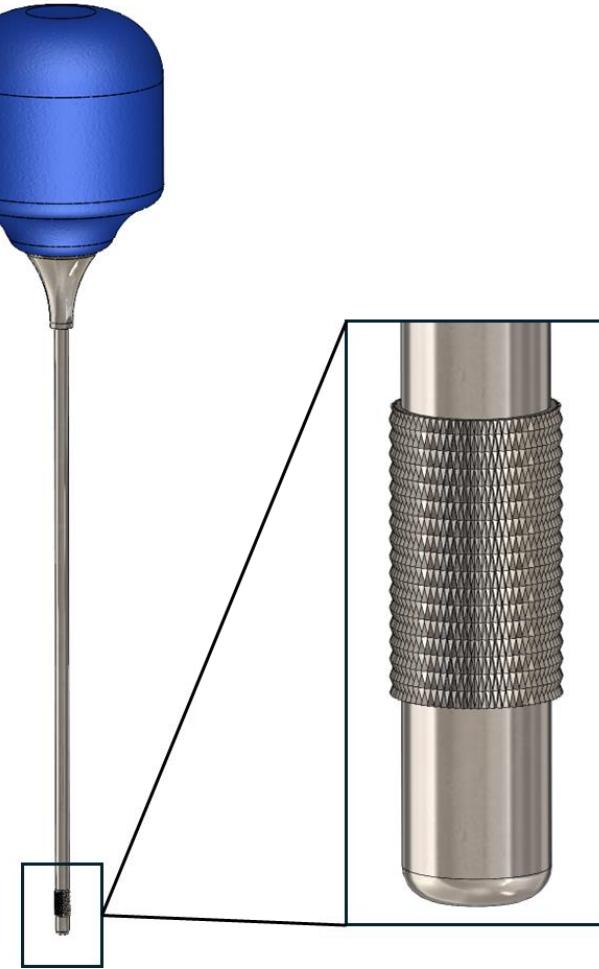


Figure H.4 Denervator CAD model

Lastly, the Denervator can be seen above in **Figure H.4** with a unique rasping bottom end and a handle on top. The functional requirement for the bottom of the tool is to help destroy the nerve with the rasp-like end. The Denervator will be used on an angle, therefore the end of the tool needs to be smooth so that it does not harm the body around the nerve, while the rasp edge does its job. The opposite end of the tool has yet again an ergonomic handle for the customer that can be twisted in any such way the customer desires. 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. Similar to the Stylet, the connection between the Denervator shaft and the handle is made with threads and a high strength epoxy for extra security. The use of a threaded insert has been discussed, however, the additional labor and complexity associated with the threaded insert has led the team to avoid use in the current prototype. This may change in the

future after testing. The Denervator is 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, active cutting section, is 7mm and protrudes from the Denervator shaft in order to lacerate 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. 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.

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, threaded analysis, 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:

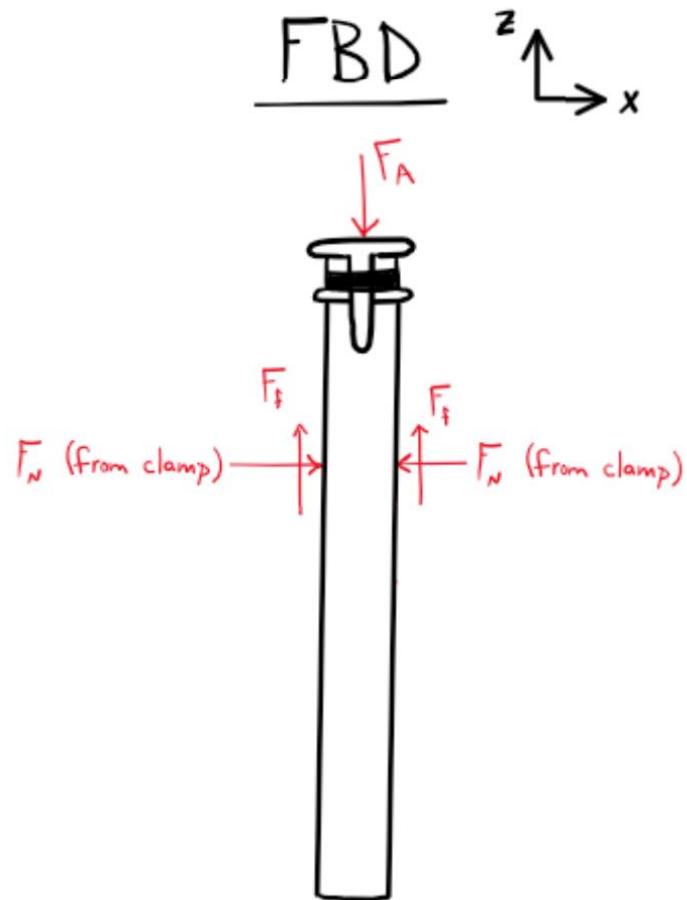


Figure I.1.1.1 FBD of the Portal when being clamped by the clamping mechanism and having an applied axial load

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 0.64⁹.
 - 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 10N. The axial force on the Portal will be greatest while the doctor is cutting the nerve, and it is assumed that the doctor doesn't put more than 50% of their force in the axial direction since they are grinding the nerve through torque. Since it is known that the doctor doesn't use more than 20N of force throughout the procedure, 10N is assumed as the maximum axial force exhibited on the Portal while it is clamped.
- 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 axial force being designed to is 20N 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:

- $\mu_s = 0.64$
- $F_A = 20N$

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:

$$F_N = \frac{20N}{2(0.64)}$$

$$F_N = 15.625N \text{ (on either side; total clamping force is therefore 30.25N)}$$

As noted in **Section I.1.1**, the clamping force required to prevent the Portal from slipping, according to a factor of safety of two, is 30.25N. The team now knows that the clamp must be designed to provide a clamping force of 30.25N; 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:

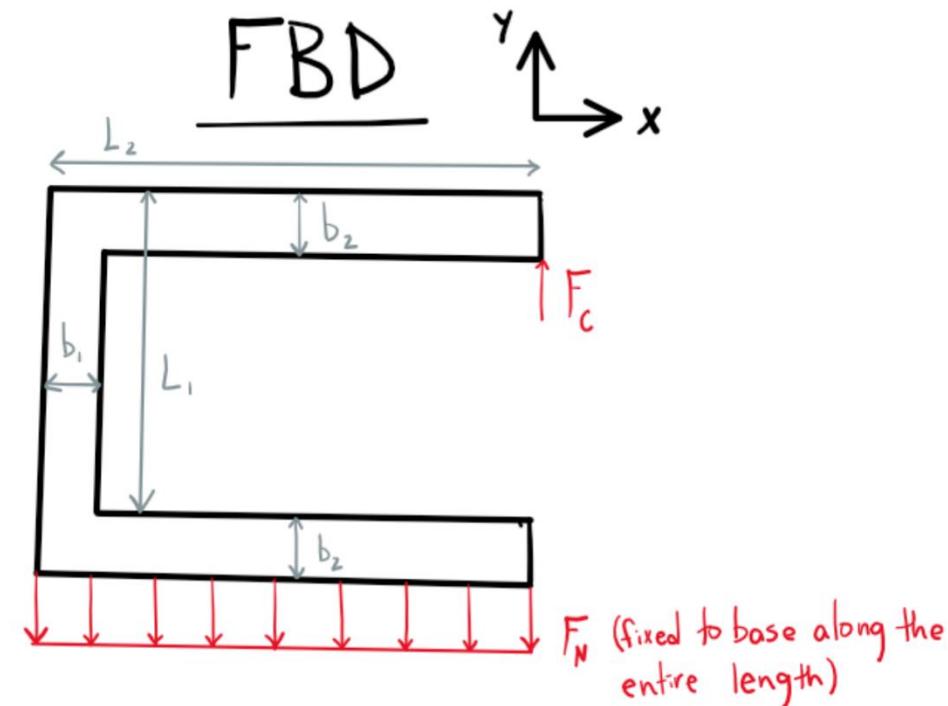


Figure I.1.2.1 FBD of the rectangularly-simplified clamping mechanism with an applied force to deflect it open and a reactionary load due to the fixture to the base of the Back Stabilizer

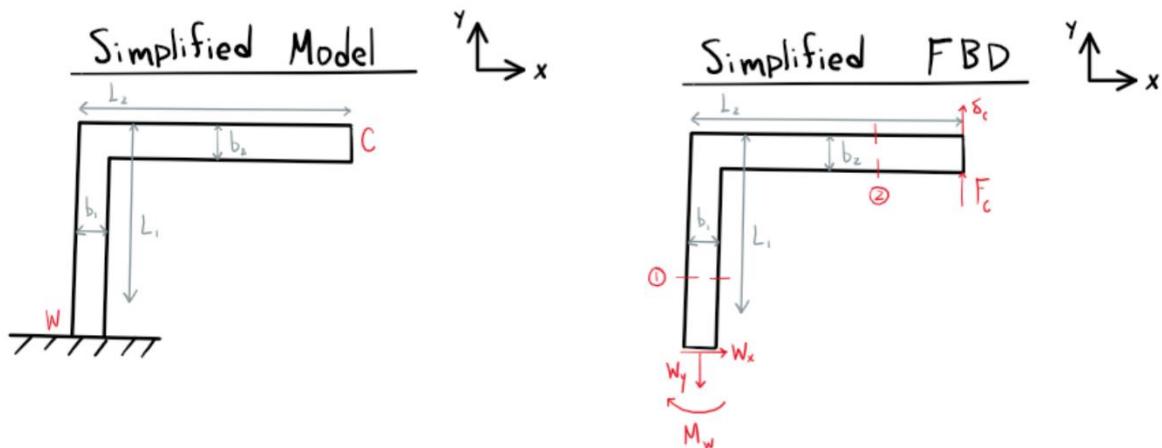


Figure I.1.2.2 Simplified model and FBD of the clamping mechanism (including locations for cuts)

Internal FBD's

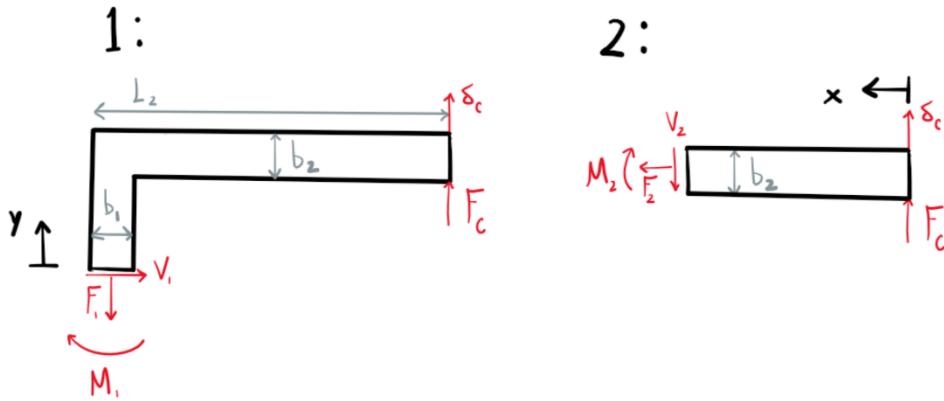


Figure I.1.2.3 Internal FBD's according to the two cuts

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, 4.46mm (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:

$$U_1 = \frac{1}{2EA_1} \int_0^{L_1} F_1^2 dy + \frac{1}{2EI_1} \int_0^{L_1} M_1^2 dy$$

$$U_2 = \frac{1}{2EI_2} \int_0^{L_2} M_2^2 dx$$

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

Solving Displacement:

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

$$\delta_C = \frac{F_1}{EA_1} \int_0^{L_1} dy + \frac{M_1}{EI_1} \int_0^{L_1} L_2 dy + \frac{1}{EI_2} \int_0^{L_2} M_2 x dx$$

$$\delta_C = \frac{F_1 L_1}{EA_1} + \frac{M_1 L_2 L_1}{EI_1} + \frac{1}{EI_2} \int_0^{L_2} M_2 x dx$$

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

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

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:

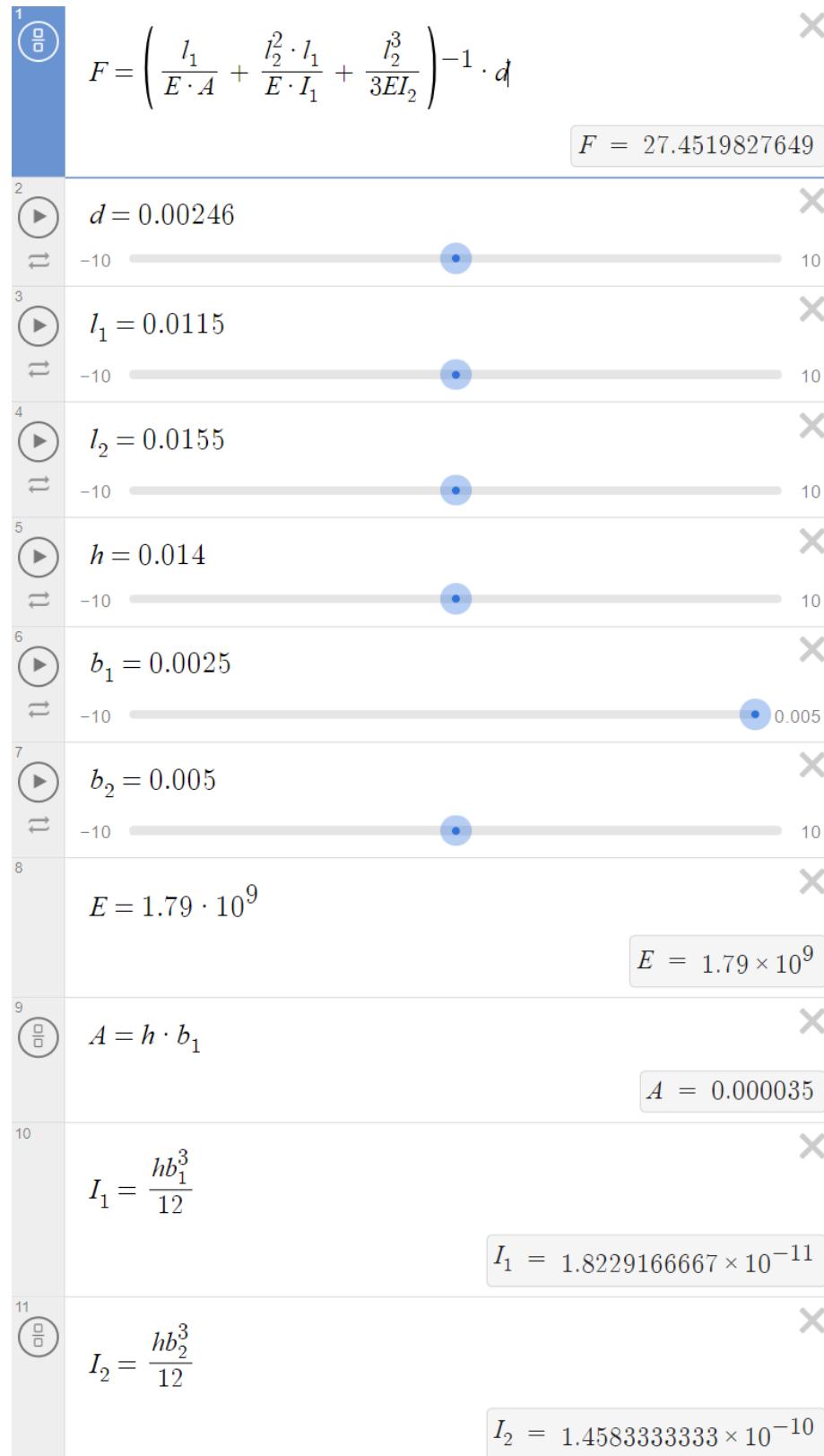
$$F_c = \left(\frac{L_1}{(0.0135m)(1.3 \times 10^9 Pa)b_1} + \frac{L_2^2 L_1}{(1.3 \times 10^9 Pa)((0.0135m)b_1^3/12)} \right.$$

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

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

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

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:

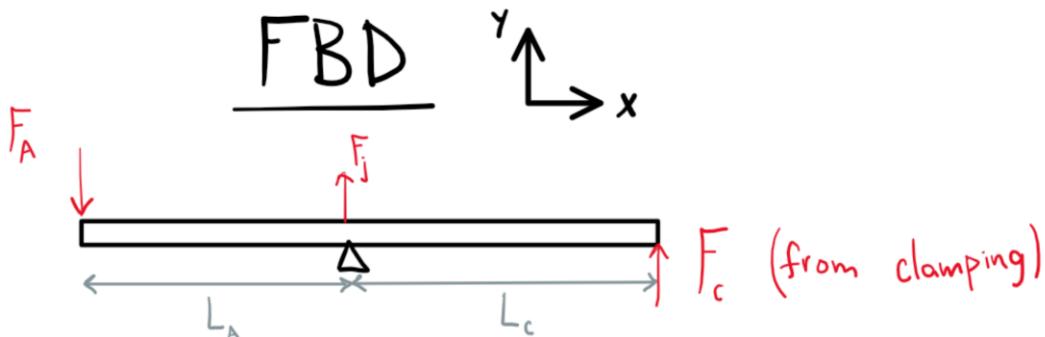


Figure I.1.3.1 FBD of the lever-simplified clamping arm

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 Threaded Analysis

As discussed in **Appendix H**, the Stylet and Denervator shafts are connected to the handles via threads. Threads are fine geometries which produce stress concentrations; therefore, it was important for the team to perform proper thread analysis. The first thing to note is that this is thread analysis rather than fastener analysis. This is because the threads are not fastening any external bodies. Another thing to note is that thread stripping is the only concern for thread failure in the procedural application of the medical tools. More specifically, stripping of the threaded plastic hole is the most imminent failure (if failure were to occur due to threading). For these reasons, the team chose to analyze the stripping of the internal threads due to transverse shear stress. This analysis can be seen as follows.

FBD:

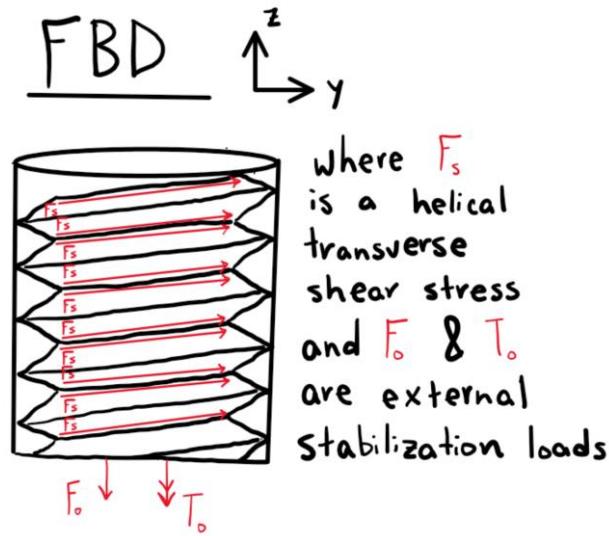


Figure I.2.1 FBD of the internal threading due to helical shear forces

Assumptions:

- The threads will strip on the internal threads before the screw, since the internal threads are made of plastic and have a drastically lower yield strength (15MPa⁵¹), while the screw is made of metal and has a much larger yield strength (205MPa²)
 - The team is analyzing the internal threads.
- The threads are at biggest risk when tightening the handle to the shafts. Therefore, transverse shear stress is the only stress that is of concern.

- 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 axial force being designed to is 40N to account for this).
- The external load applied is taken evenly by the screw and internal threads.

Variable Definitions:

- H_{Stylet} : height of the fastener in the Stylet handle
- $H_{Denervator}$: height of the fastener in the Denervator handle
- P_n : external applied load
- d : nominal diameter
- p : pitch
- S_y : yield strength
- τ_s : transverse shear stress
- F_n : force within the fastener (preload and external)
- $A_{s,n}$: stripping area
- N_{th} : number of engaged threads
- F_i : preload

Known Values/Properties:

- $H_{Stylet} = 10mm = 0.010m$
- $H_{Denervator} = 20mm = 0.020m$
- $P_n = 20N$
- $d = 16mm = 0.016m$
- $p = 2mm = 0.002m$
- $S_y = 15MPa = 15 \times 10^6 \frac{N}{m^2}$

Calculations:

General definitions:

$$\tau_s = \frac{F_n}{A_{s,n}N_{th}}$$

$$F_n = F_i + P_n$$

$$A_{s,n} = 0.88\pi dp$$

$$N_{th} = H/p$$

Derivation:

$$S_y = \tau_{s,max} = \frac{F_{n,max}}{A_{s,n}N_{th}}$$

$$S_y = \frac{F_{i,max} + P_n}{(0.88\pi dp)(H/p)}$$

$$S_y = \frac{F_{i,max} + P_n}{0.88\pi dH}$$

$$F_{i,max} = 0.88\pi dHS_y - P_n$$

Plug and solve:

$$F_{i,max,Stylet} = 0.88\pi(0.016m)(0.010m)(15 \times 10^6 \frac{N}{m^2}) - 20N$$

$$F_{i,max,Stylet} = 6,615.044N$$

$$F_{i,max,Denervator} = 0.88\pi(0.016m)(0.020m)(15 \times 10^6 \frac{N}{m^2}) - 20N$$

$$F_{i,max,Denervator} = 13,230.087N$$

Through the results of **Section I.2**, the team discovered that the maximum preload for both the Stylet and Denervator threading is thousands of newtons. This is much larger than any sort of experimental or intended preload force. Therefore, if the threads can handle such a large preload, it demonstrates that the threads are designed to be very strong, and they should not strip nor pose any other failure concern.

I.3 FEA Simulations

I.3.1 Stylet

The Stylet, as seen in **Figure I.3.1.1**, 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.3.1.1 CAD model of the Stylet assembly

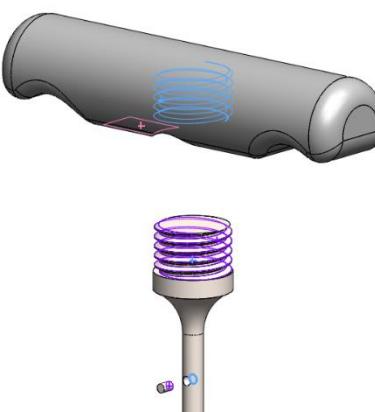
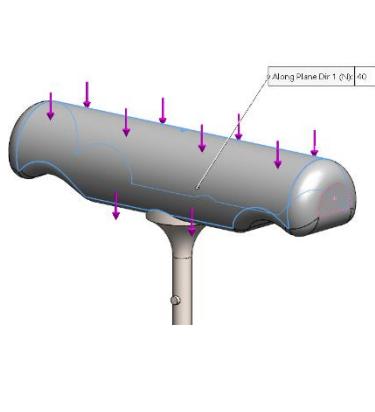
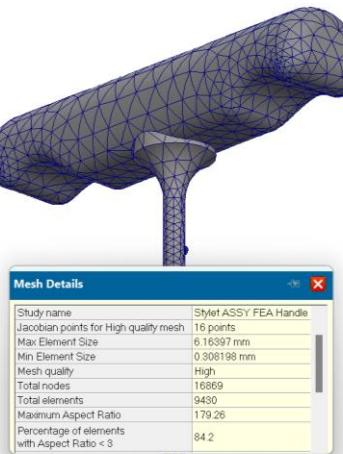
To configure the static structural simulations, materials were assigned, local interactions were created, a load was applied, and a resulting mesh was generated. The material assignments can be seen below in **Table I.3.1.1**.

Table I.3.1.1 Stylet Material Assignments

Stylet Body and Nub	Stylet 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="Save model type in library"/> Units: SI - N/m^2 (Pa) Category: Steel <input type="button" value="Create stress-strain curve"/> Name: AISI 316 Stainless Steel Sheet (SS) Default failure criterion: Max von Mises Stress Description: Source: 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>1.929999974e+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>8000.0000133</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	1.929999974e+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	8000.0000133	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="Save model type in library"/> Units: SI - N/m^2 (Pa) Category: 463Materials Name: PP Homopolymer Default failure criterion: Unknown Description: PP- Homopolymer,unfilled Source: Sustainability: PP Homopolymer in SOLIDWORKS Materi <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>1790000000</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	1790000000	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 and nub were assigned to SAE 316L. The remaining specifics regarding the configuration of the simulations can be found below in **Table I.3.1.2**.

Table I.3.1.2 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 is 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.3.1.2**.

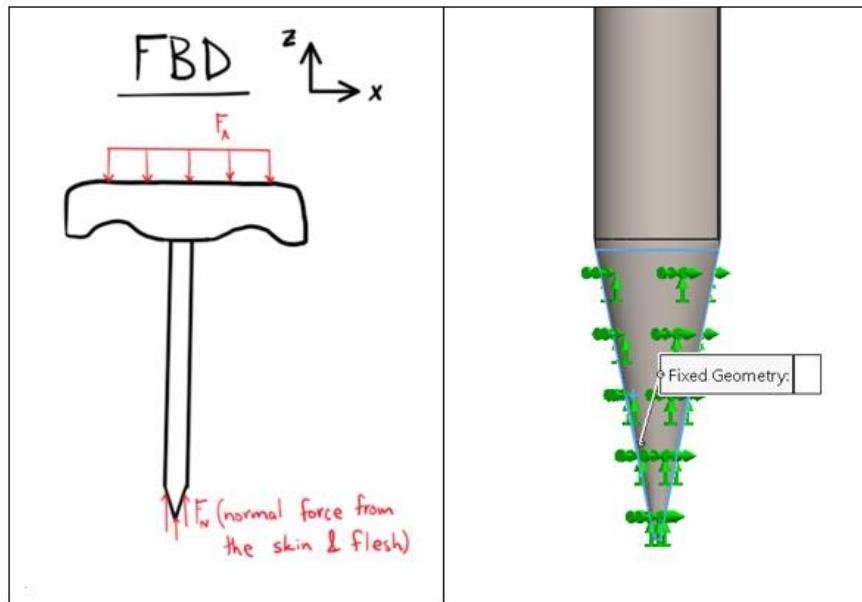
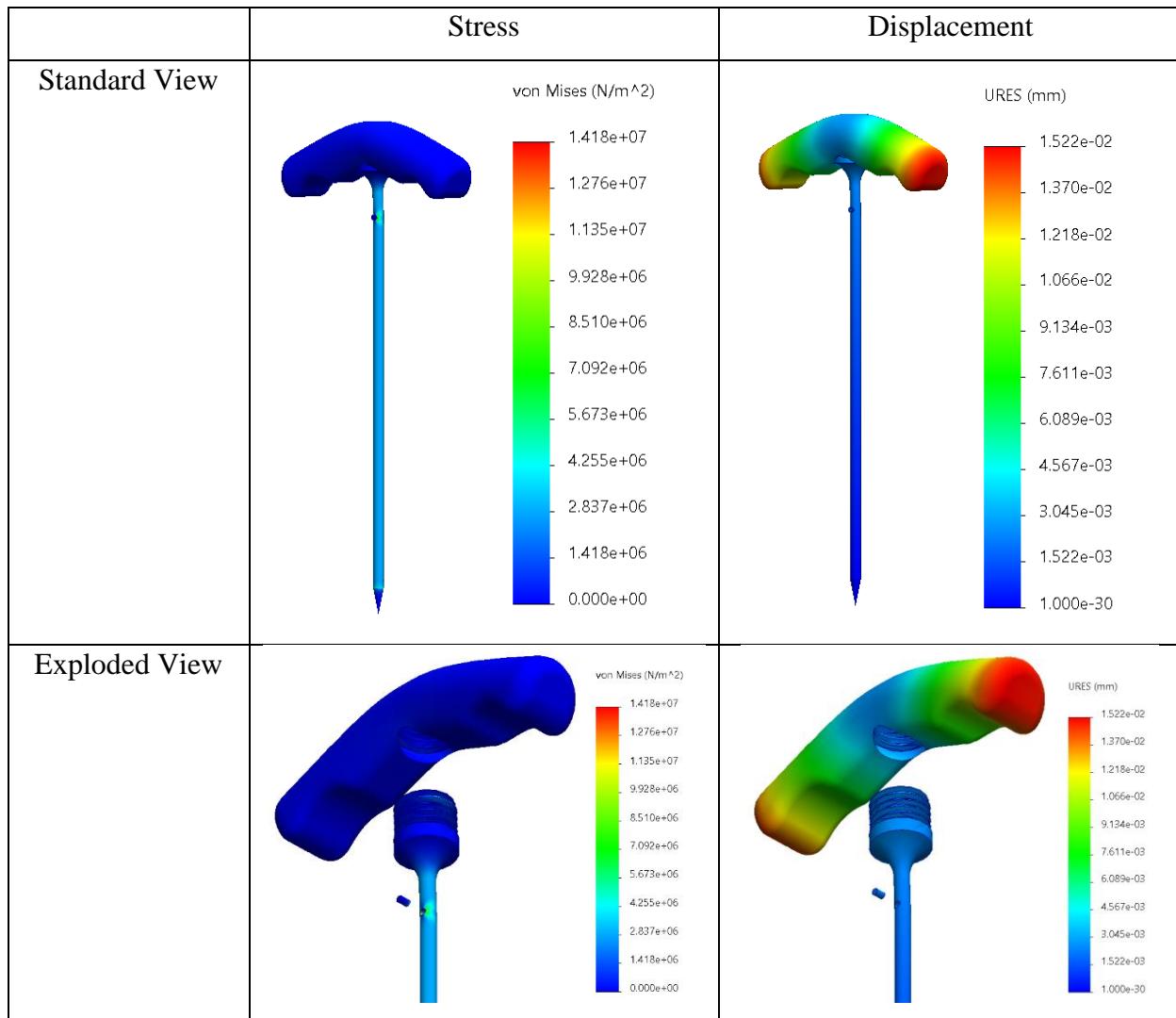


Figure I.3.1.2 A fixed geometry constraint being applied at the tip to simulate the Stylet's FBD

The stress and displacement results of this simulation, along with exploded views to see within the assembly, can be seen below in **Table I.3.1.3**.

Table I.3.1.3 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.3.1.3**.

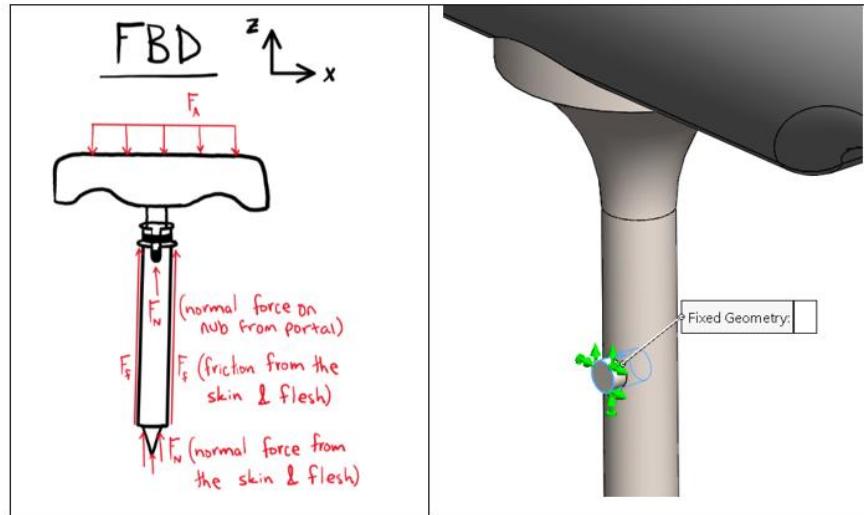
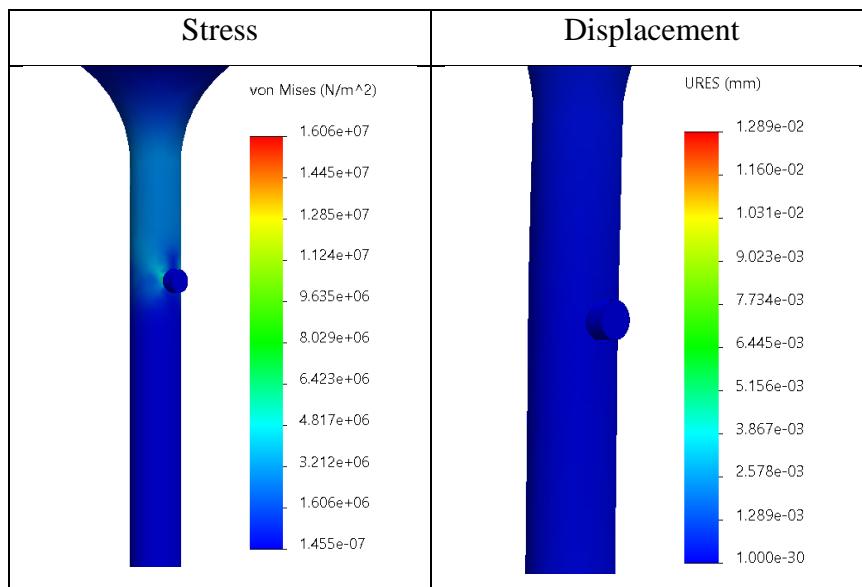


Figure I.3.1.3 A fixed geometry constraint being applied at the nub to simulate the Stylet's FBD

The stress and displacement results of simulating a normal force on the Stylet's nub can be seen below in **Table I.3.1.4**.

Table I.3.1.4 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.3.2 Portal

The Portal, as seen in **Figure I.3.2.1**, 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 to lock the nub in place. The C-Ring is slightly pried open at the expense of elastic deformation to assemble it on to the Portal – this is a one-time action. Thus, the team expressed concerns on ensuring the required deflection to expand the jaws of the C-Ring to fit around the Portal diameter would not induce yielding. By subtracting the nominal gap between the idle C-Ring from the Portal diameter, a deflection requirement was found. Through an iterative process, the minimum force required to achieve such a deflection was found through FEA simulations.

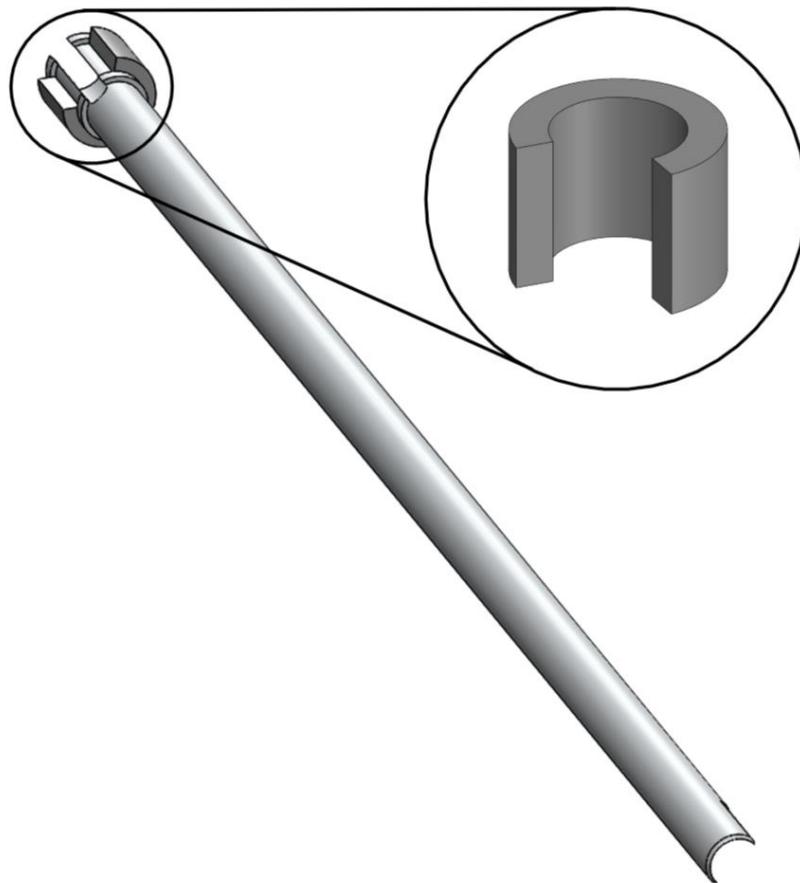
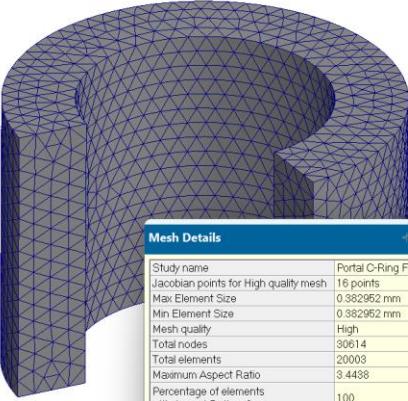
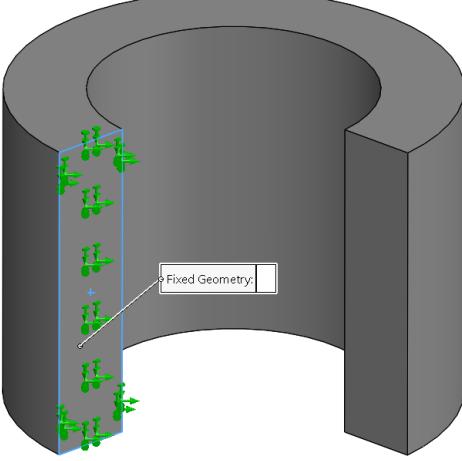
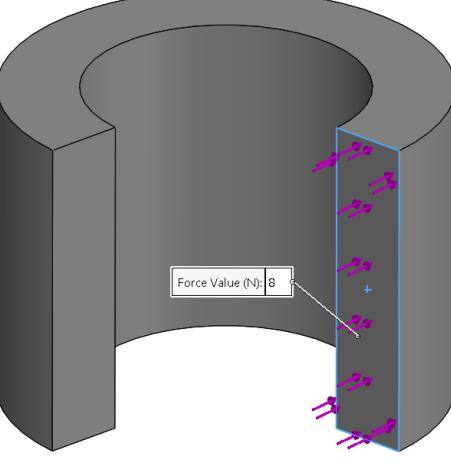


Figure I.3.2.1 CAD model of the Portal assembly and the C-Ring

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.3.2.1**.

Table I.3.2.1 C-Ring Simulation Configuration

Material	Generated Mesh																																																												
<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> <table border="1" data-bbox="279 587 776 1106"> <tr><td>Model Type:</td><td>Linear Elastic Isotropic</td><td><input type="checkbox"/> Save model type in library</td></tr> <tr><td>Units:</td><td>SI - N/m^2 (Pa)</td><td></td></tr> <tr><td>Category:</td><td>463Materials</td><td></td></tr> <tr><td>Name:</td><td>PP Homopolymer</td><td></td></tr> <tr><td>Default failure criterion:</td><td>Unknown</td><td></td></tr> <tr><td>Description:</td><td>PP- Homopolymer, unfilled</td><td></td></tr> <tr><td>Source:</td><td></td><td></td></tr> <tr><td>Sustainability:</td><td>PP Homopolymer in SOLIDWORKS Materi</td><td>Select...</td></tr> </table> <table border="1" data-bbox="279 846 776 1106"> <thead> <tr><th>Property</th><th>Value</th><th>Units</th></tr> </thead> <tbody> <tr><td>Elastic Modulus</td><td>1790000000</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>	Model Type:	Linear Elastic Isotropic	<input type="checkbox"/> Save model type in library	Units:	SI - N/m^2 (Pa)		Category:	463Materials		Name:	PP Homopolymer		Default failure criterion:	Unknown		Description:	PP- Homopolymer, unfilled		Source:			Sustainability:	PP Homopolymer in SOLIDWORKS Materi	Select...	Property	Value	Units	Elastic Modulus	1790000000	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	 <div data-bbox="1008 819 1312 1015" style="border: 1px solid black; padding: 5px;"> Mesh Details Study name: Portal C-Ring FEA Jacobian points for High quality mesh: 16 points Max Element Size: 0.382952 mm Min Element Size: 0.382952 mm Mesh quality: High Total nodes: 30614 Total elements: 20003 Maximum Aspect Ratio: 3.4438 Percentage of elements with Aspect Ratio < 3: 100 </div>
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As seen above, 8N of force was required to pry open the C-Ring to a deflection of the required deflection of approximately 1mm. The loads and fixtures were applied to be consistent with the FBD depicting this event as seen below in **Figure I.3.2.2**.

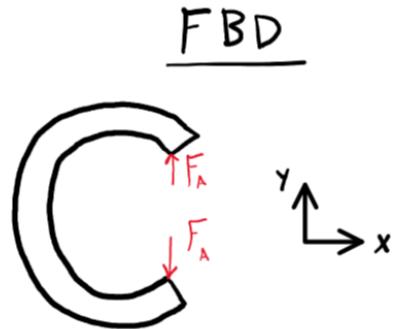
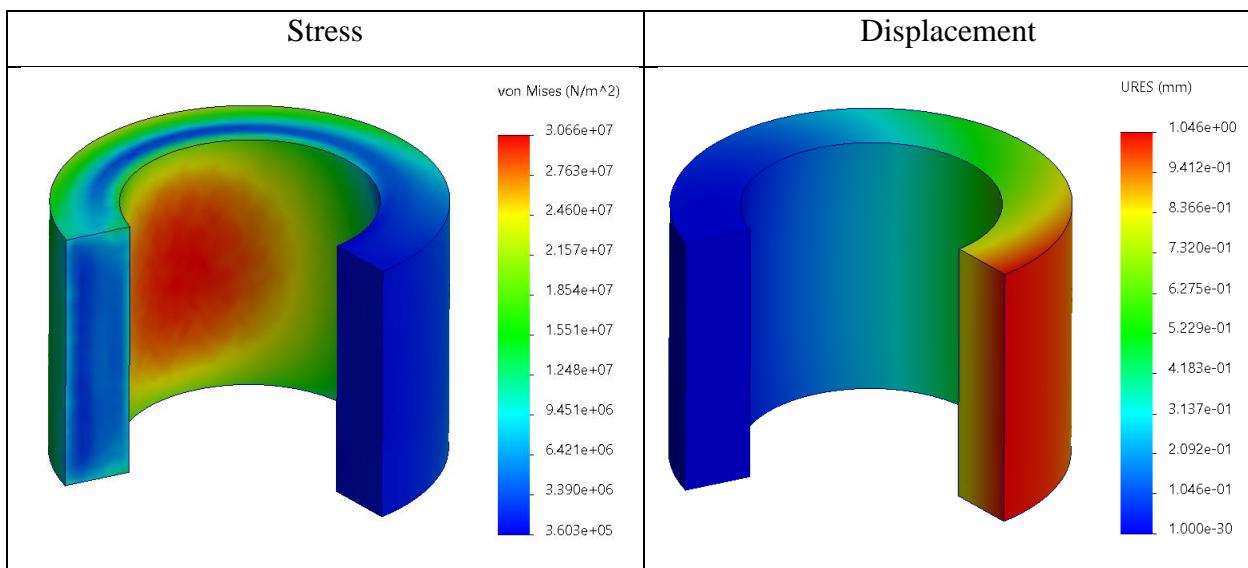


Figure I.3.2.2 An FBD of the C-Ring when being pried open

The team decided that a factor of safety of 1 was sufficient as there is 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.3.2.2**.

Table I.3.2.2 Stylet Deformation Results



These results prove that to achieve the required 1mm deflection in the C-Ring to expand the gap, an 8N 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 inserted onto the Portal 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 30.25N 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 onto 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.3.2.3**, depicting this event.

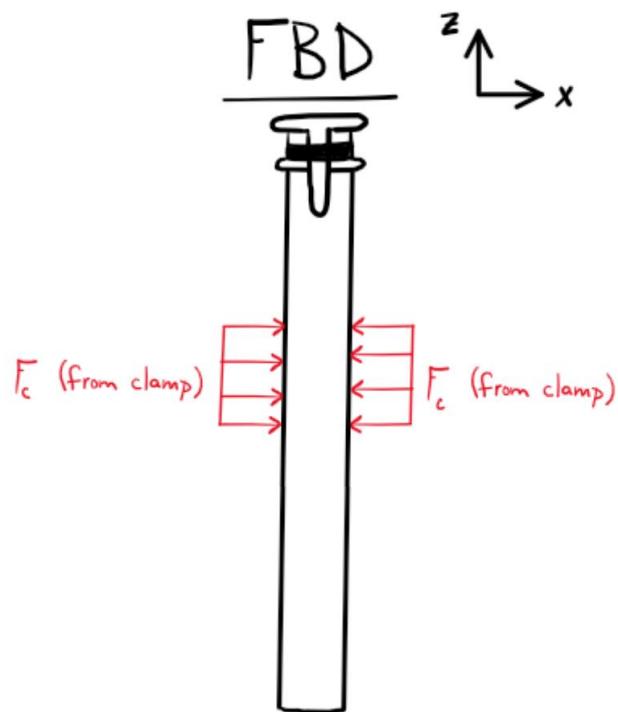
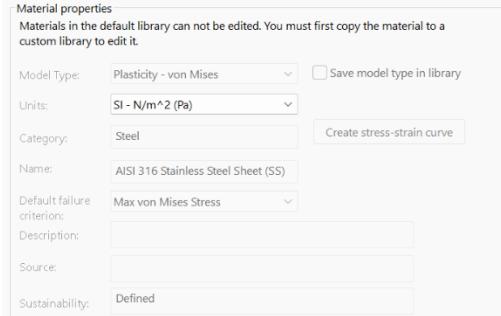
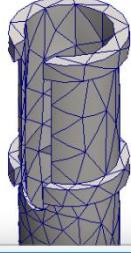
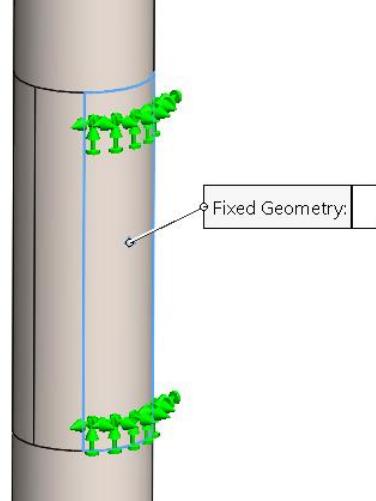
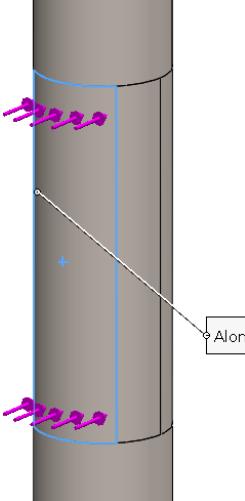


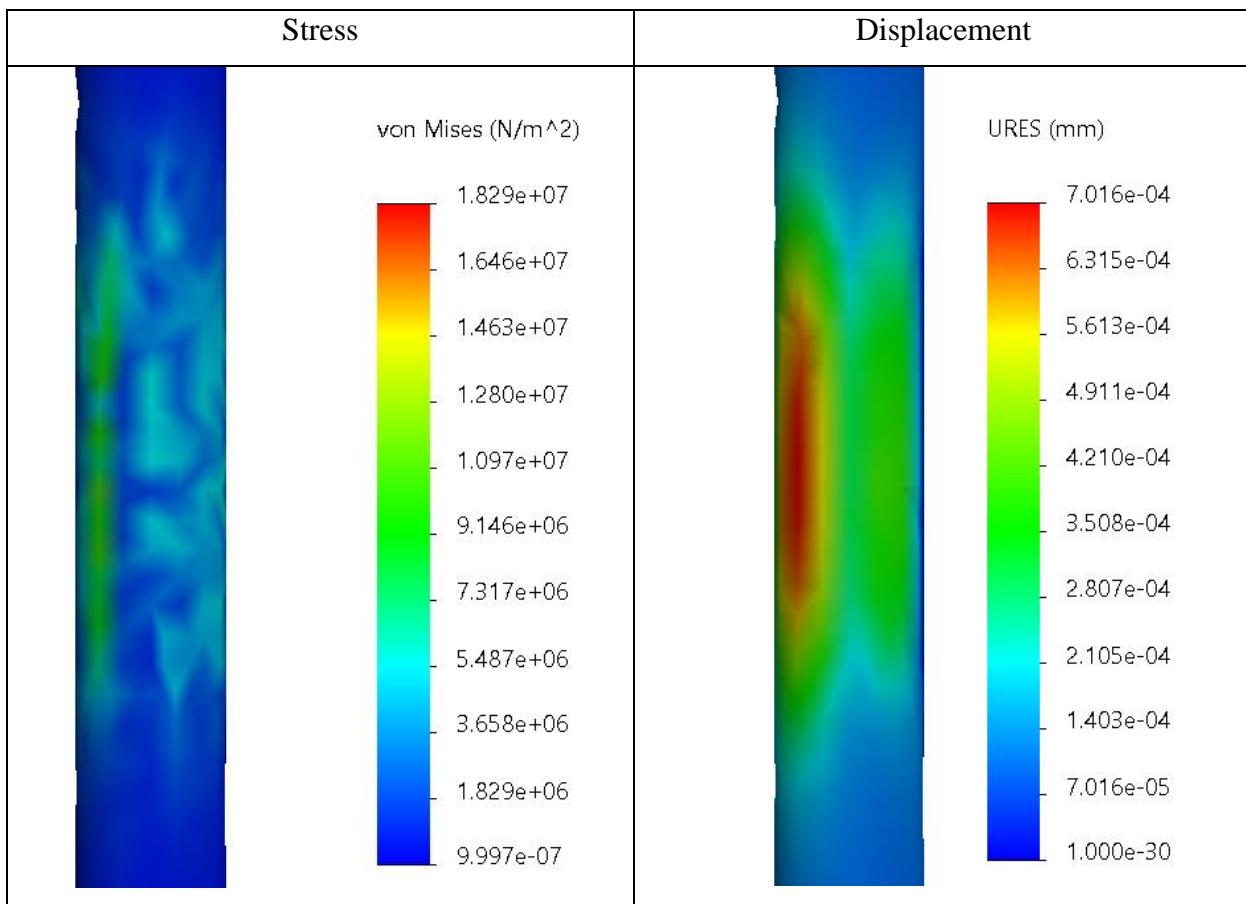
Figure I.3.2.3 An FBD of the Portal when being clamped on by the Back Stabilizer

To configure this simulation, a material was assigned, a load and fixture were applied, and a resulting mesh was generated. The specifics of this configuration can be found below in **Table I.3.2.3**.

Table I.3.2.3 Portal Simulation Configuration

Material	Generated Mesh																																													
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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.3.2.4**.

Table I.3.2.4 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 0.0007mm 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.3.3 Back Stabilizer

The Back Stabilizer, as seen in **Figure I.3.3.1**, 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 towards the force required to open the jaws.

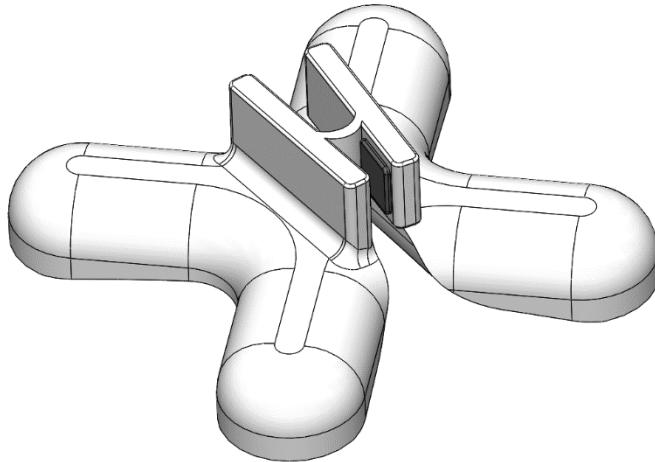


Figure I.3.3.1 CAD model of the Back Stabilizer assembly

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 doctors and 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. Lastly, the team plans to add stoppers by the arms to prevent any accidental misuse from over-opening the jaws. This is a design change planned for the next phase.

To configure this static structural simulation, materials were assigned, local interactions were created, a fixture was applied, and a resulting mesh was generated. The specifics of this configuration can be found below in **Table I.3.3.1**.

Table I.3.3.1 Back Stabilizer Jaw Displacement Simulation Configuration

Back Stabilizer Material	Rubber Pads Material																																																																								
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To simulate pinching the arms to open the jaws, as depicted by the adjacent FBD, a load was applied, as seen in **Figure I.3.3.2**, to test if this would achieve the necessary displacement required to fit the Portal in the jaws of the clamp.

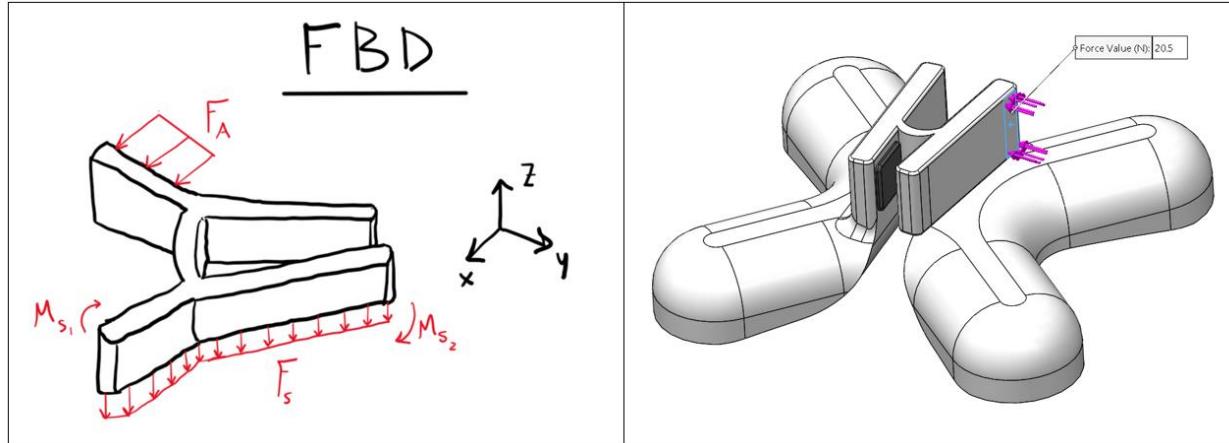
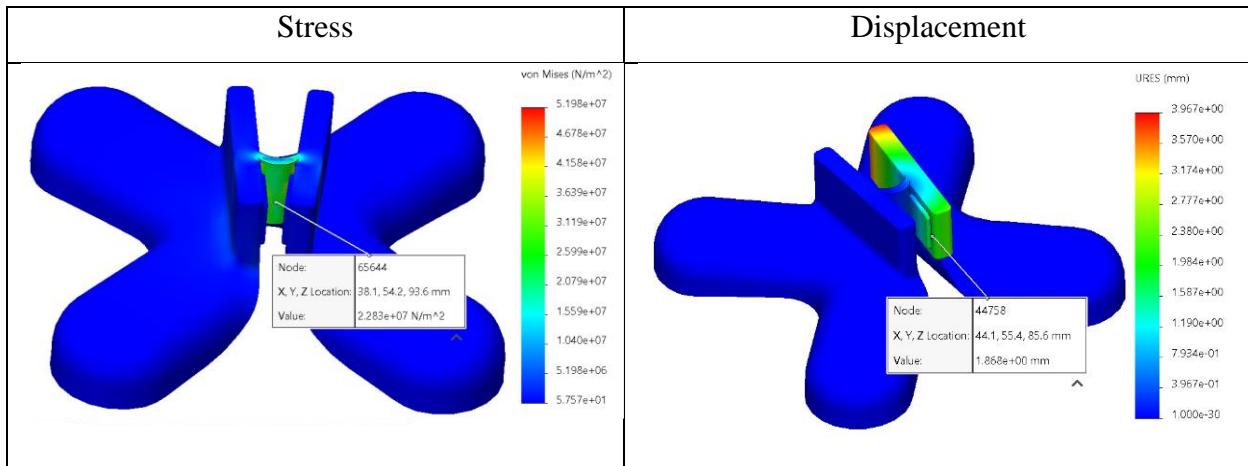


Figure I.3.3.2 Load applied to the clamp to simulate the FBD (left)

The stress and displacement results of simulating this applied force on the Back Stabilizer can be seen below in **Table I.3.3.2**.

Table I.3.3.2 Back Stabilizer Jaw Displacement Simulation Results



As seen above, the simulation proves that the 20.5N of applied force at the arms was enough to create a 1.87mm displacement at the tip. This is enough to increase the 3.15mm relaxed jaw gap to at least 5mm to allow the Portal to easily slip in between the jaws.

Furthermore, the critical features of the Back Stabilizer were under the yield point of the material. Therefore, it can safely be concluded that the device can withstand 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 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.3.3.3**.

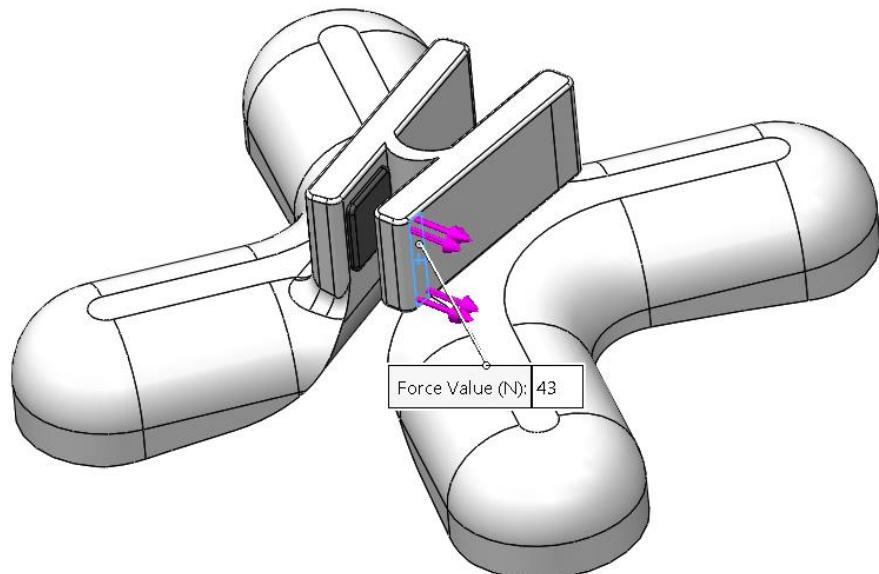


Figure I.3.3.3 Produceable clamping force being tested at required displacement

The displacement results corresponding to the clamping force produced can be seen below in **Figure I.3.3.4**.

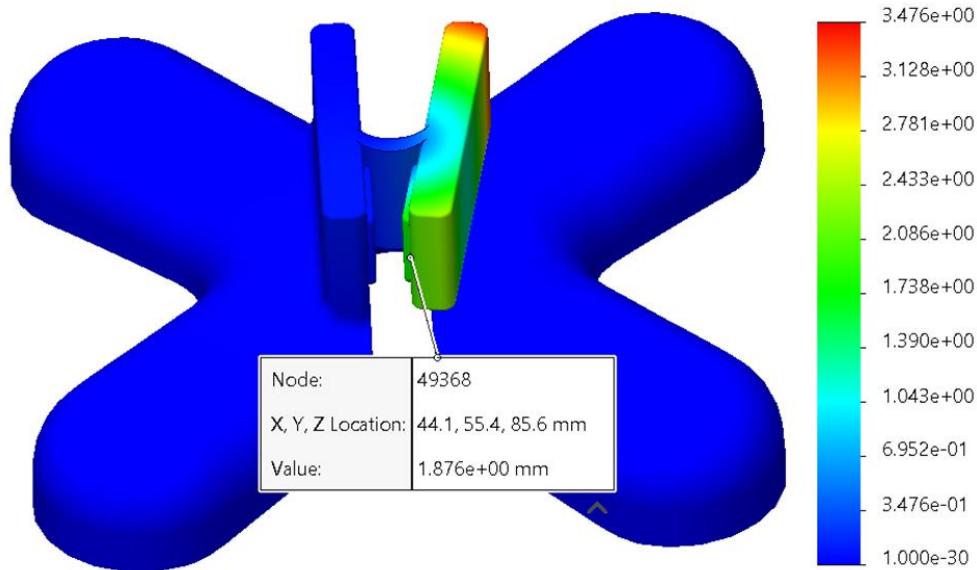


Figure I.3.3.4 Resulting displacement corresponding to the clamping force being tested

As seen above, the simulation proves that for a 1.88mm displacement, 43N of clamping force is produced. This 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 30.25N.

In summary, these results confirm that 20.5N of applied force at the arms will allow the Back Stabilizer to open its jaws enough to accept a 5mm-diameter Portal and produce 43N of clamping force without yielding at any of the critical features.

I.3.4 Denervator

The Denervator, as seen in **Figure I.3.4.1**, 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 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 shaft of the Denervator. As a result, the team's primary concerns were ensuring such stresses would not induce yielding under the procedural force.



Figure I.3.4.1 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.

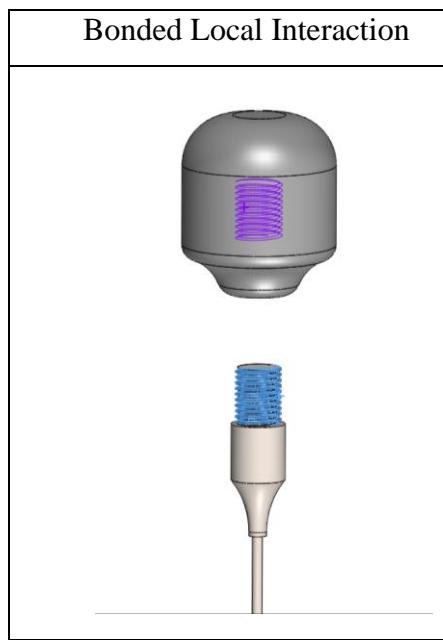
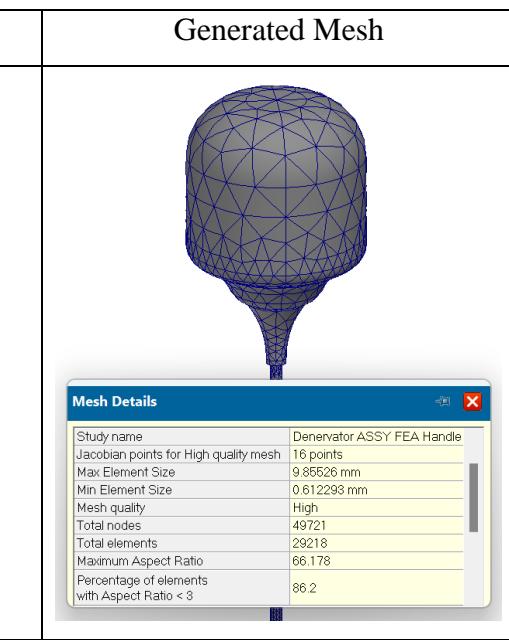
To configure the static structural simulations, materials were assigned, local interactions were created, and a resulting mesh was generated. The material assignments can be seen below in **Table I.3.4.1**.

Table I.3.4.1 Denervator Material Assignments

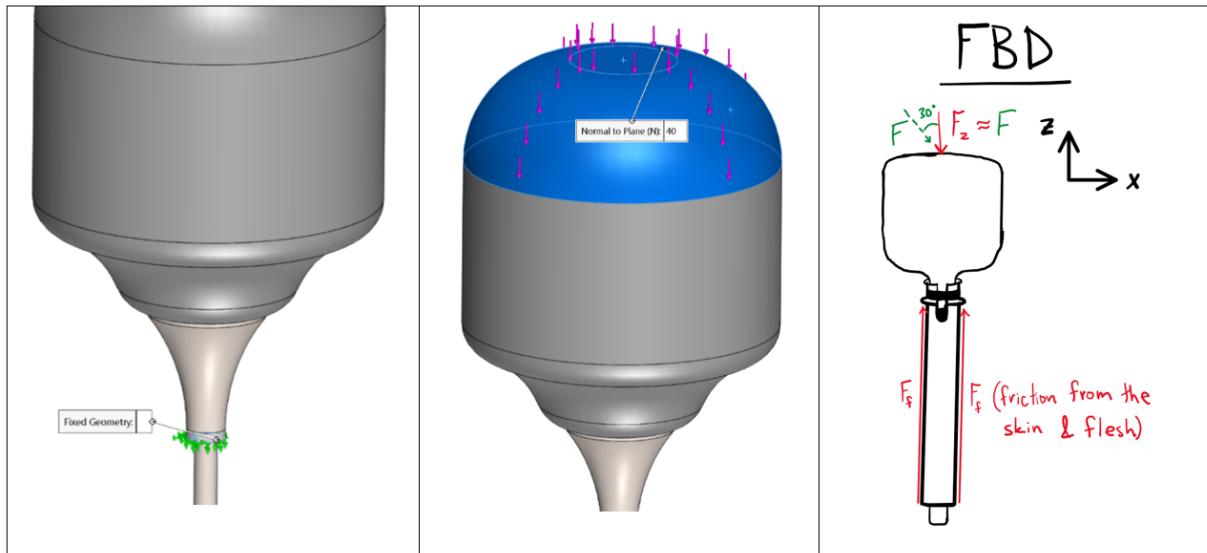
Denervator Body	Denervator Handle																																																															
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As seen above, the handle was assigned to PP homopolymer, and the body was assigned to SAE 316L. The remaining specifics regarding the configuration of the simulations can be found below in **Table I.3.4.2**.

Table I.3.4.2 Denervator Simulations Configuration

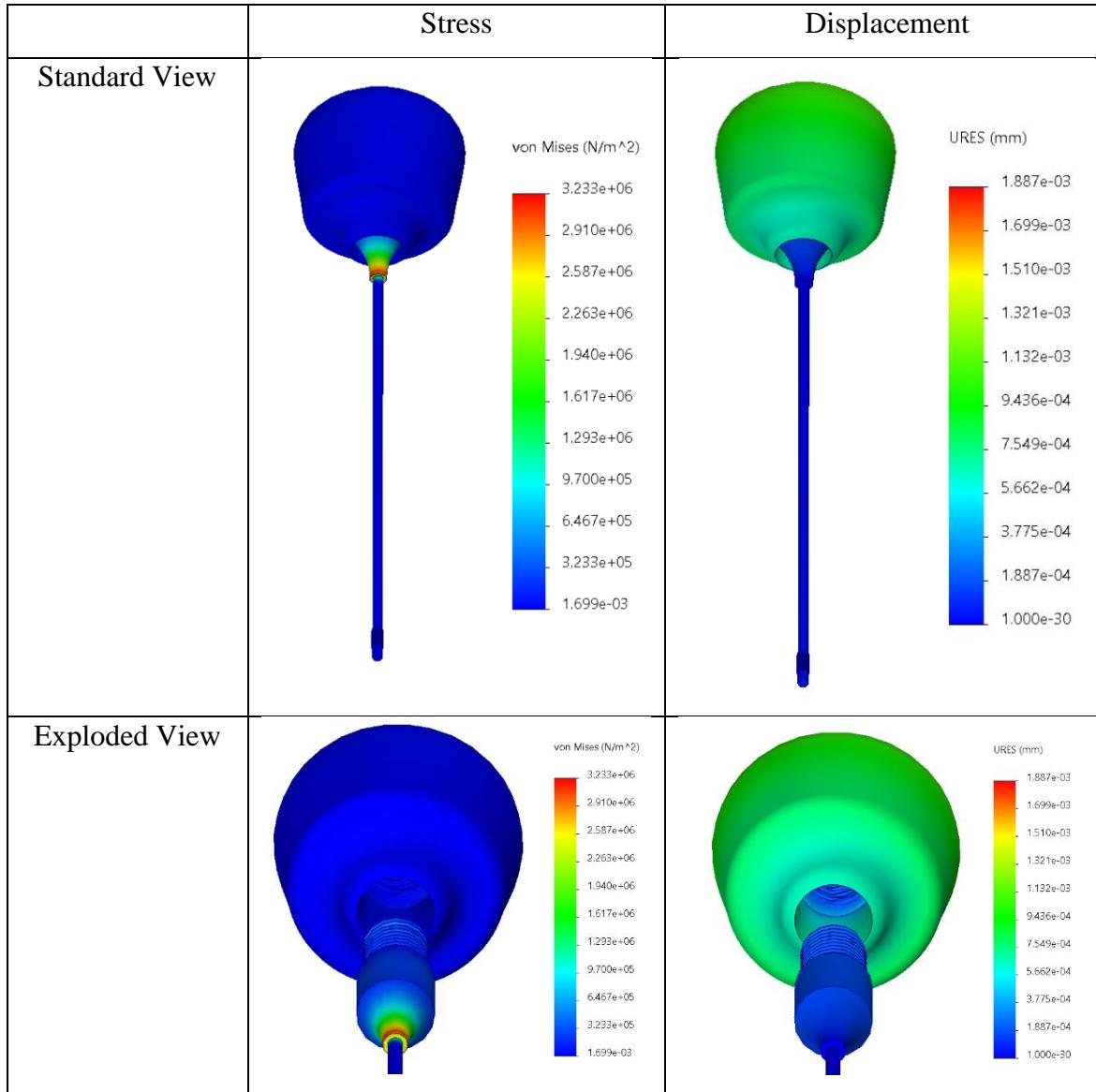
Bonded Local Interaction	Generated Mesh
	

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 to simulate a normal force from bottoming out on the shell 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.3.4.2**.

**Figure I.3.4.2** 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.3.4.3.**

Table I.3.4.3 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 faced frictional resistance from the flesh and thus 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.3.4.3.

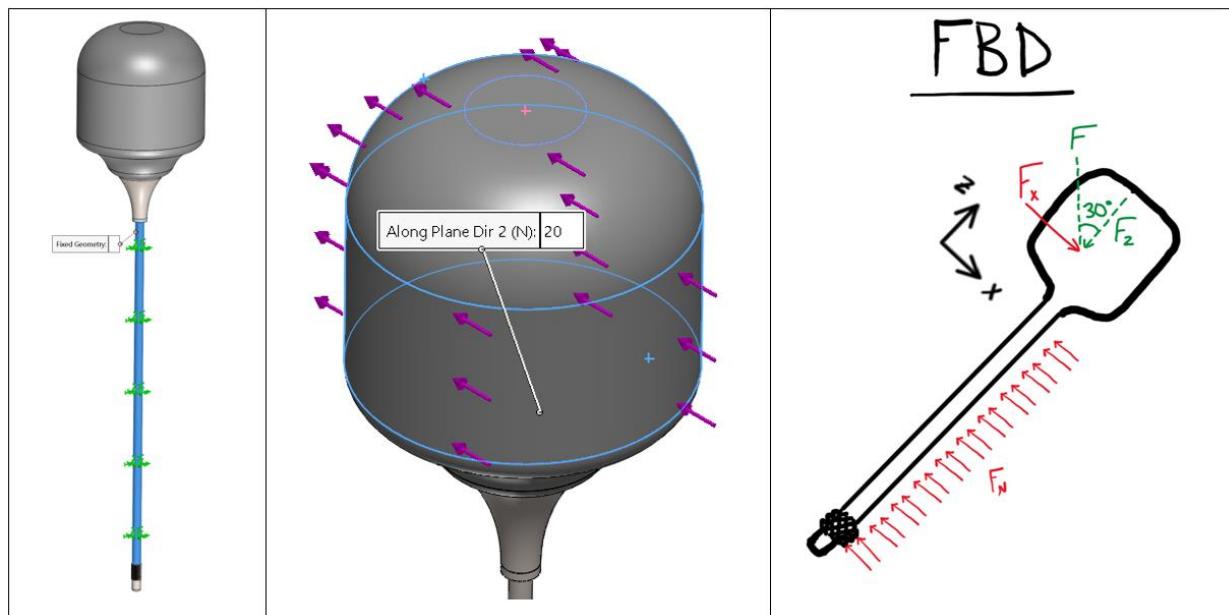
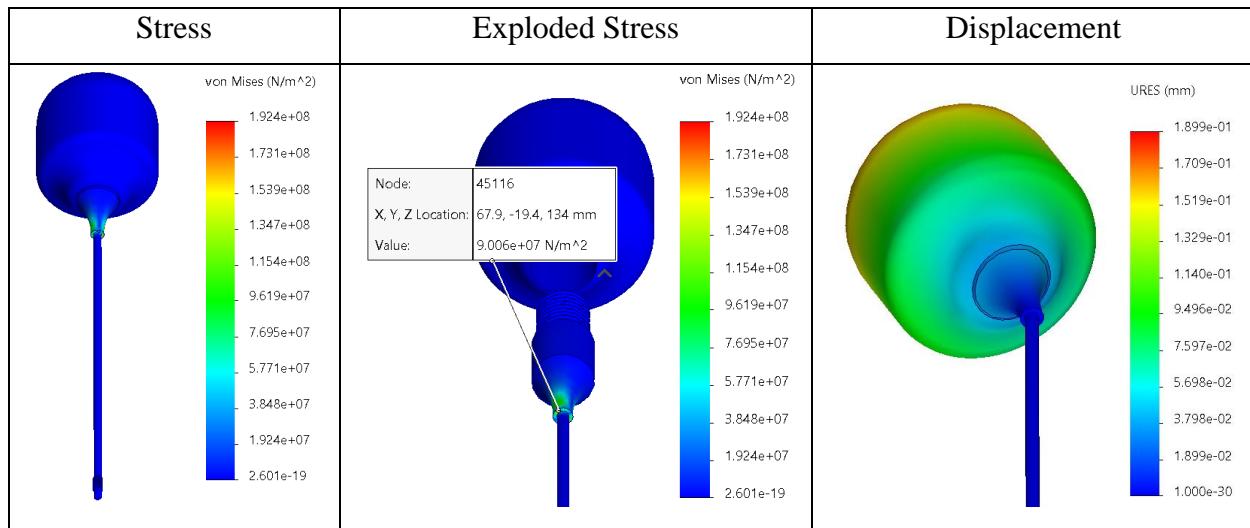


Figure I.3.4.3 A fixed geometry constraint (1) and transverse load (2) applied to simulate the Denervator's FBD (3).

The stress and displacement results of simulating this bending force on the Denervator can be seen below in **Table I.3.4.4**.

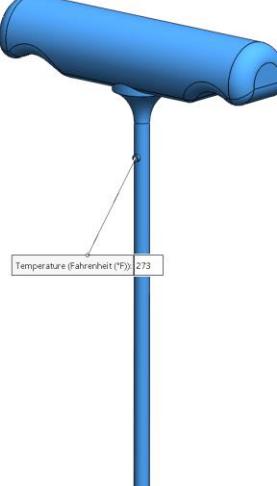
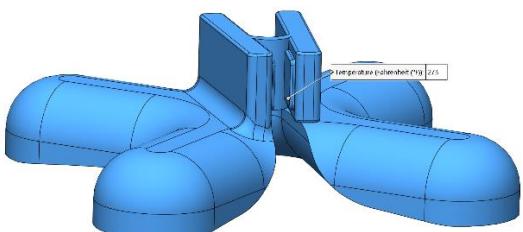
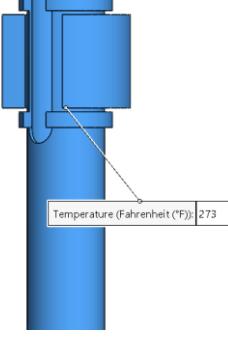
Table I.3.4.4 Denervator Bending Deformation Results

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. Though some stresses in noncritical areas were a little concerning, the team realized that minor geometry changes, such as adding a chamfer, would resolve the issue. Such changes are planned for the next phase. 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.

I.4 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.3**, 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.4.1**.

Table I.4.1 Thermal Loads Applied

Stylet	Denervator
	
Back Stabilizer	Portal
	

The respective fixtures applied for each device can be seen below in **Table I.4.2**.

Different fixtures were applied to each device to best simulate how they would be fixed during sterilization. Some would be held on a rack (and thus had fixed constraints applied) while others would be free to slide around (and thus had roller constraints applied).

Table I.4.2 Fixtures Applied

Stylet	Denervator
Back Stabilizer	Portal

Note that unlike in **Section I.3.2**, 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.4.1** below.

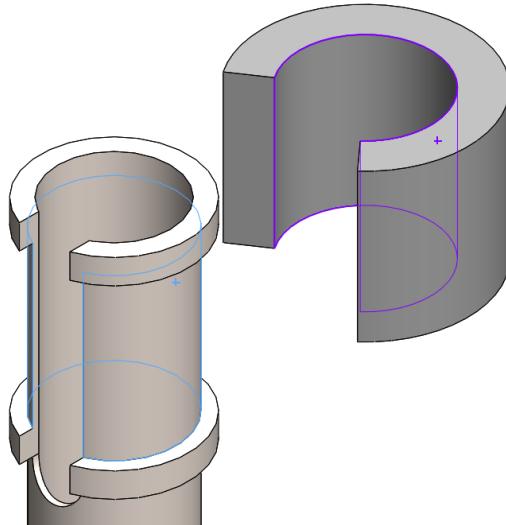
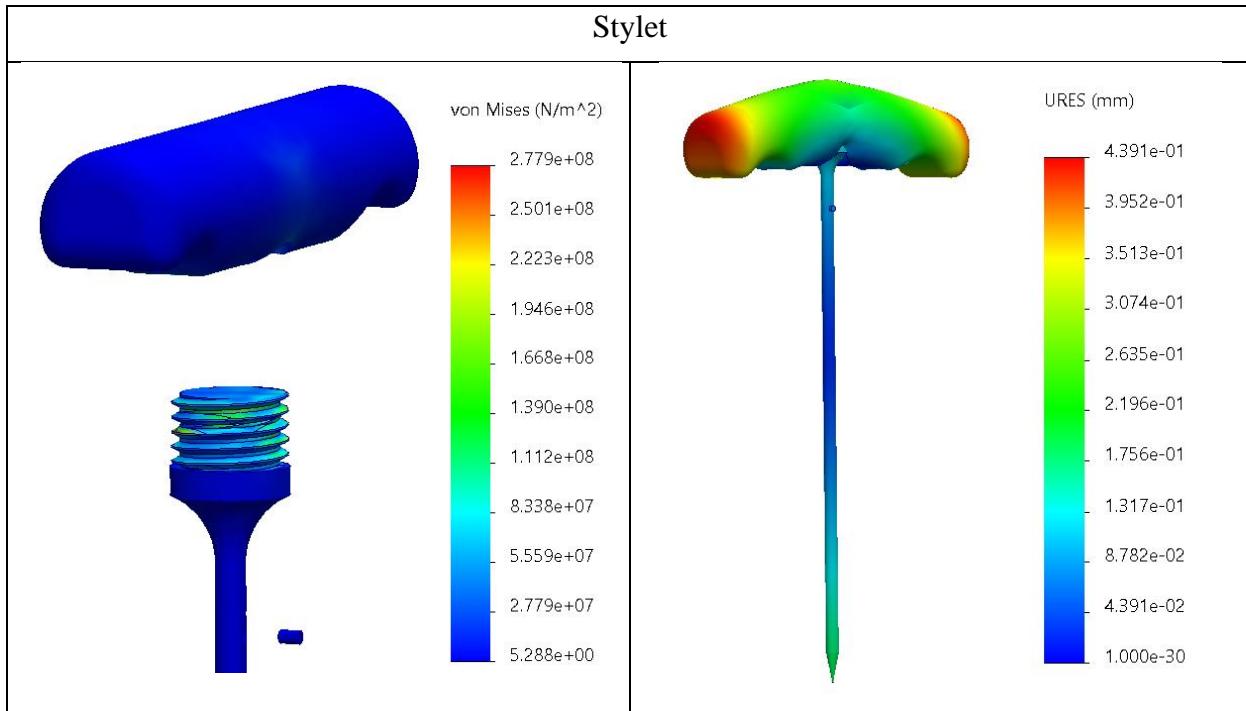
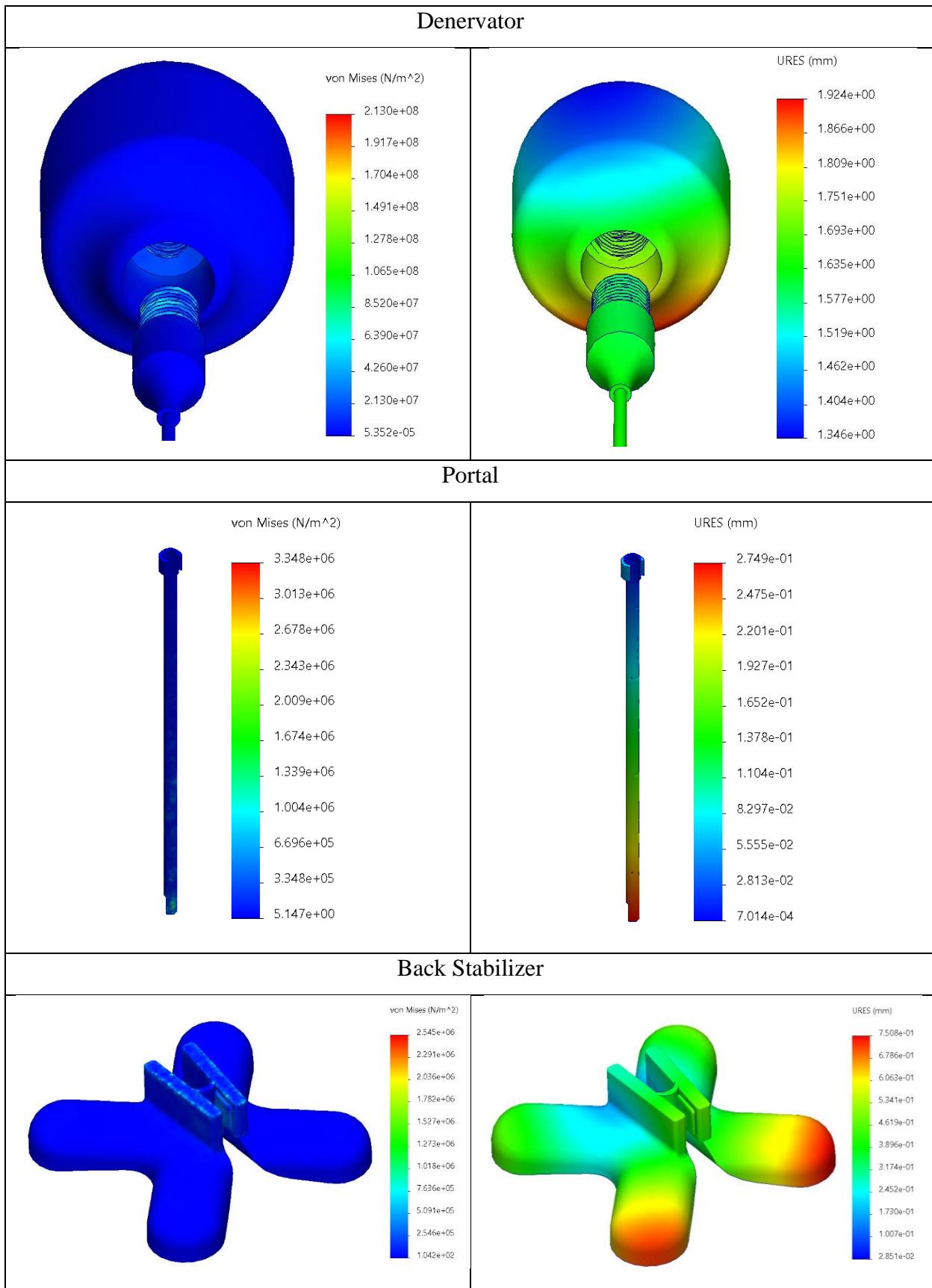


Figure I.4.1 A contact based local interaction between the C-Ring and Portal that was included in its thermal analysis simulation

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.4.3**. Stress results can be seen on the left column with displacement results on the right column.

Table I.4.3 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.

The team noticed concerning stresses in the results of the Stylet and Denervator. Minor areas, on the order of 0.5 square millimeters or less, had yielding. Due to the negligible area and the affected features not being critical, the team dismissed this as it didn't warrant a redesign. Furthermore, overwhelming support and mass adoption of these materials in the medical industry hinted at the fact 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. It was thus concluded that the negligible yielding may have been due to errors and discrepancies in the simulation causing it to not produce an accurate estimate or representation of sterilization. Regardless, the plans to investigate this further and alleviate these concerns with more research in the upcoming phase.

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 no previous FMEA had taken place in the PDR phase). Therefore, this is not an update, but rather an introduction to the FMEA performed in the scope of this project.

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 one 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 one 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 one 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, an updated severity, occurrence, and detection ranking is 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, 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 RCC U	N DET U	N 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 reamers 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 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 denervators, to either in-house or outsourcing 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 insufficient 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 shafts will break because there 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 insufficient 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

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. 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	New SEV	New OCC	New DET	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 pads do not provide enough friction force (via friction between the Back Stabilizer and the Portal). Another cause is that the Back Stabilizer does not provide enough grip force on the Portal.	5	The team on the Back Stabilizer provides a suitable clamping 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 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

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, this plastic 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). 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	COST (\$)
1	Stylet					
1a	Shaft Body	0.75 in Diameter x 2 foot Length shaft made from 316L Stainless Steel with a small cylindrical extrusion for interlocking mechanism and a threaded end for attaching the handle. The opposite end is a sharp point with unique geometry	2 ft	#8936K18	McMaster-Carr	133.11
1b	Handle	24130 mm^3 volume T-Handle made from PP 3D printer filament	22.51 grams	#M-Y6C-YEZM	MatterHackers	0.47
2	Portal					
2a	Hollow Tube Body	5mm OD x 4.55mm ID x 157.5mm Length hollow shaft made from 316L Stainless Steel with one small machined vertical slits for locking mechanism and opened opposite end for denervator end.	1	Quote Q74-0484-0533	Xometry	230.72
2b	C-Clip	31.05 mm^3 volume C-clip with same size slit as hollow cylinder made from PP 3D printer filament	0.03 grams	#M-Y6C-YEZM	MatterHackers	0.01
3	Denervator					
3a	Shaft Body	0.75 in Diameter x 2 foot Length shaft made from 316L Stainless Steel with a threaded end for attaching handle. Opposite end has a machined unique geometry for cutting nerve. Uses portion of 2 foot length from Stylet	2 ft	#8936K18	McMaster-Carr	n/a
3b	Handle	107238 mm^3 volume bulb shape made from PP 3D printer filament	100 grams	#M-Y6C-YEZM	MatterHackers	2.09
4	Back Stabilizer					
4c	Base & Clamp	56909 mm^3 volume ergonomical base that incorporates with the compliant clamp mechanism. Made from PP 3D printer filament	53.15 grams	#M-Y6C-YEZM	MatterHackers	1.11
5	Miscellaneous					
5a	Epoxy Coating Spray	Epoxy Antislip aerosol can for coating handles and portions not inserted into the body for increased traction	1 can	#63825T74	McMaster-Carr	21.47
5b	Structural Epoxy	Structural epoxy adhesive compatible with PP. Temperature range: -50F to 350F. Shear Strength: 300 lbs./sq. in.	1 cartridge	#7513A1	McMaster-Carr	89.09
5c	Fasteners/Nuts etc.	M2 x 6mm fasteners for attaching handles to shaft bodies if not like current version	1 pack	#B07HGNCLV	Amazon	7.29
5d	Threaded Inserts	M2 threaded inserts for attaching handles to shaft bodies if the shaft bodies are not drilled and tapped	1 pack	# B0C2HGNYLY	Amazon	19.88
5e	Filament	Polypropylene 3D filament	1 spool	#YS-PP-1.75MM-1KG-WHITE	Amazon	39.99
					Total (\$)	545.23

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 the team thinks are essential. 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 will be either manufactured in-house or outsourced. Many of the items that the team needs for their toolset are sourced from McMaster-Carr. 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 Denervator will be manufactured using a lathe and a form cutter in order to create the fillet, knurl and thread tool. The Back Stabilizer will be 3D printed using Polypropylene. The Stylet will be manufactured in house using a lathe and a drill press to create the hole that the nub will fit into. The nub will also be metal and will be cut out of an extruded rod to size using band saw in low quantities and flying or rotary sheer in mass manufacturing. It's also important to note that the Portal will be outsourced using a company named Xometry whom will likely use a drill press in order to hollow out the portal and band saw in order to cut down to size. Xometry is an on-demand manufacturing company that can produce custom parts within a few days. Just like McMaster-Carr, Xometry is a highly reputable vendor. They are used within industry, provide good service, and have quick lead times. Most remaining items are to be 3D printed, and the required filament to create each individual part is documented in grams on the BOM. The plastic pieces are created with the help of Purdue's Rapid Prototyping Lab.

The rest of the items included in the BOM are much less of a proportion of the proposed prototype. Excess parts will be 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 \$133.58, the Portal costs \$230.73, the Back Stabilizer costs \$1.11, and the Denervator has a cost of \$2.09. The miscellaneous components aggregate to cost \$177.72, which includes cost for epoxy, filament, threaded inserts, and excess parts.

L. Validation Plan

At this point in the design process, the team has developed and iterated CAD based on customer needs and analysis results. The team believes that there is sufficient evidence that the CAD is finalized and will satisfy all engineering specifications and functional requirements. Looking forward to the final design review (FDR) phase, the immediate steps for the team are to place purchase orders, begin manufacturing the prototype, and get in contact with the Purdue medical school (as further described in **Section L.1**). Future plans within the scope of the FDR phase includes the team validating the final prototype through testing and iterating on the prototype accordingly. The validation plan will comprehensively test the prototype against each function and engineering specification, such that the team can deem it as a viable solution to all customer needs.

The validation plans set forth, as seen in **Sections L.1 through L.3**, fit within three major categories: there is customer need testing, force testing, and functionality testing. With regards to customer need testing (**Section L.1**), the team will perform quantifiable tests to determine how well the medical tools satisfy the engineering requirements. For example, the incision test will determine the length of incision created by these medical tools and will compare this to the pre-established target value of 5mm.

For force testing (**Section L.2**), it's important to note that this does not include fatigue strength or failure. Since all of the proposed medical tools are designed to be disposable (and therefore used one time), fatigue is a negligible concern. Force testing will be 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 this CDR phase, these force tests will not be extensive and will rather 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 will be testing simple things such as tool fits. This will ensure that the manufactured prototype is up to the desired standard of the team and is usable. After all, if the team cannot develop a usable prototype, then it will be

useless. These tests will not require hardly any extensive planning, as they merely require the medical tools.

L.1 Customer Need Testing

L.1.1 Temperature Test

Purpose: This test will be performed to determine if the medical tools can withstand the high temperatures of autoclave sterilization.

Procedure: The oven will be heated to 280 degrees Fahrenheit (giving 7-degree leeway to the 273 degrees that autoclaves operate at in case the oven temperatures are not exact). Once it reaches this temperature, the medical tools will be inserted into the oven. They will remain in the oven for another 30 minutes. After this 30-minute period, the medical tools will be removed, and any melting/deformation will be evaluated.

Tested Function/Customer Need: Initial sterilization.

Measurement System: The temperature inside the oven will be measured by the internal thermometer.

Assessment: The medical tools will pass this test if there is no noticeable melting or deformation after the 30 minutes in the oven.

Location: This test will be performed at Aggy's apartment.

Resources: This test requires the Stylet, Portal, Denervator, and Back stabilizer, as well as a kitchen oven, a cooking tray, and oven mitts.

L.1.2 X-ray Imaging Test

Purpose: This test will determine which materials show up on X-ray images.

Procedure: The team will reach out to the medical school at Purdue University. If the team can get in contact with the medical school and get permission to their X-ray labs, then the team will follow through with this test. If not, then the team will scrap this test, considering X-ray appearance is trivial considering it is a material property and this test is being done for luxury. If the team gets permission to the X-ray labs, then they will have lab faculty assist them in taking X-ray images of the 4 medical tools. X-ray images will be taken from a side and top view to ensure comprehensive testing.

Tested Function/Customer Need: Tool appearance on X-ray.

Measurement System: N/A.

Assessment: The grade 316L stainless steel will pass this test if it shows up on X-ray images. The polypropylene will pass this test if it does not show up on X-ray images.

Location: This test will be performed in X-ray labs in medical buildings at Purdue University.

Resources: This test requires the Stylet, Portal, Denervator, and Back Stabilizer as well as an X-ray lab and a computer (to check images).

L.1.3 Incision Test

Purpose: This test will determine the incision size produced from the medical tools.

Procedure: The team will use a scalpel to cut a small (~2mm) incision in the skin of a rotisserie chicken. After the incision is made, the team will insert the Stylet-Portal module into the incision and bore at least 40mm into the flesh and muscle of the chicken. The Stylet-Portal module will then be held in this position for another 5 minutes before the team pulls it out. After the team pulls out the Stylet-Portal module, they will measure the final length of the incision with a ruler.

Tested Function/Customer Need: Cut/slide through flesh. Minimally invasive (no general anesthesia or stitches are needed).

Measurement System: The length of the incision will be measured in millimeters by a ruler.

Assessment: The Portal will pass this test if the incision is no longer than 5mm.

Location: This test will be performed in Aggy's apartment.

Resources: This test requires the Stylet and Portal as well as a rotisserie chicken, a scalpel, and a ruler.

L.1.4 Lesion Test

Purpose: This test will be performed to determine how effective the Denervator is at lesioning the nerve.

Procedure: A thin rubber band will be stapled down to a chunk of wood to simulate the medial branch nerve resting on the facet joint. The experimenter will then spend 1 minute grinding on the nerve with the Denervator, like how the doctor would in procedure. After this minute is up, the team will measure the length of cut along the rubber band.

Tested Function/Customer Need: Lesioning the nerve. Pain should be relieved effectively for long periods. Avoidance of neuromas.

Measurement System: The length of cut along the rubber band will be measured in millimeters by a ruler.

Assessment: The Denervator will pass this test if it creates a cut at least 7mm long.

Location: This test will be performed in Aggy's apartment.

Resources: This test requires the Denervator as well as a thin (~1.5mm in diameter) rubber band, a block of wood, a stapler, and a ruler.

L.1.5 Ease-of-Use Test

Purpose: This test will be performed to identify the ease-of-use rating of the medical tools.

Procedure: The team will reach out to the medical school at Purdue University. If the team can get in contact with the medical school, then they will follow through with this test. If not, then the team will scrap this test, considering ease-of-use ratings are very subjective and this test is being done for luxury. If the medical school is available, then the team will get in contact with 10 medical students. The team will set up a time with the medical students to explain the medical tools and procedure, and then let the medical students play around with them. At the end of each session, the team will survey the medical student to get an ease-of-use rating.

Tested Function/Customer Need: Ease of use/inability for mishandling.

Measurement System: The team will use a scale from 1 to 10 to get an ease-of-use rating.

They will then average out all the individual ratings to determine an average rating.

Assessment: The medical tools will pass this test if the average ease-of-use rating is at least 75%.

Location: This test will be performed in different buildings across campus at Purdue University.

Resources: This test requires the Stylet, Portal, Denervator, and Back Stabilizer.

L.2 Force Testing

L.2.1 Penetrating Force Test

Purpose: This test will determine the amount of force required to penetrate through the skin, flesh, and muscle.

Procedure: The team will hold a force gauge against the handle of the Stylet-Portal module. They will then penetrate the skin and bore through the flesh and muscle of a rotisserie chicken. The maximum force recorded by the force gauge will be noted.

Tested Function/Customer Need: Cut/slide through flesh. Strong enough to withstand procedural force.

Measurement System: The force to penetrate the rotisserie chicken will be measured in newtons by a force gauge.

Assessment: The Stylet and Portal will pass this test if they do not deform or yield from the applied force.

Location: This test will be performed in Aggy's apartment.

Resources: This test requires the Stylet and Portal as well as a rotisserie chicken, a force gauge, and a computer (to record the force gauge data).

L.2.2 Clamping Force Test

Purpose: This test will determine the amount of force required to overcome the clamp on the Portal.

Procedure: The Portal will be inserted into the clamp on the Back Stabilizer. A force gauge will also be held against the Portal. The team will then apply axial force on the Portal until it slips in the clamp. The force at slipping will be recorded by the force gauge.

Tested Function/Customer Need: Constrain the Portal's degrees of freedom. Strong enough to withstand procedural force.

Measurement System: The force to cause slipping will be measured in newtons by a force gauge.

Assessment: The Back Stabilizer will pass this test if it takes greater than 30N to cause slipping.

Location: This test will be performed in Aggy's apartment.

Resources: This test requires the Portal and Back Stabilizer, as well as a force gauge and a computer (to record the force gauge data).

L.2.3 Stabilization Force Test

Purpose: This test will determine the amount of frictional force supporting the Back Stabilizer.

Procedure: One of the team members will take off their shirt and lay flat on their stomach. The experimenter will then place the Back Stabilizer on the exposed back. With the Back Stabilizer on the bare back, the experimenter will position their non-dominant hand on the Back Stabilizer to mimic how a doctor would leverage the Back Stabilizer during the procedure. With this setup, the experimenter will then use a force gauge to put lateral force on the Back Stabilizer until the Back Stabilizer slips on the exposed back. When this happens, the measured force will be recorded.

Tested Function/Customer Need: Temporarily test on skin. Strong enough to withstand procedural force.

Measurement System: The force to cause slipping will be measured in newtons by a force gauge.

Assessment: The Back Stabilizer will pass this test if it takes greater than 20N to cause slipping.

Location: This test will be performed in Agathiya's apartment.

Resources: This test requires the Back Stabilizer as well as a force gauge and a computer (to record the force gauge data).

L.3 Functionality Testing

L.3.1 Stylet-Portal Fit Test

Purpose: This test will determine if the Stylet can fit within the Portal.

Procedure: The Stylet will be inserted into the Portal. It will be noted whether the Stylet fits within the Portal or not.

Tested Function/Customer Need: Guide Stylet and nerve destruction tool.

Measurement System: N/A.

Assessment: The Stylet and Portal will pass this test if the Stylet fits within the Portal without any interference.

Location: This test will be performed in Aggy's apartment.

Resources: This test requires the Stylet and Portal.

L.3.2 Denervator-Portal Fit Test

Purpose: This test will determine if the Denervator can fit within the Portal.

Procedure: The Denervator will be inserted into the Portal. It will be noted whether the Denervator fits within the Portal or not.

Tested Function/Customer Need: Guide Stylet and nerve destruction tool.

Measurement System: N/A.

Assessment: The Denervator and Portal will pass this test if the Denervator fits within the Portal without any interference.

Location: This test will be performed in Aggy's apartment.

Resources: This test requires the Denervator and Portal.

L.3.3 Stylet-Portal Interlocking Test

Purpose: This test will determine whether the Portal can interlock the Stylet to create a module.

Procedure: The Stylet will be inserted into the Portal. The C-ring will then be slid around the Portal to lock the Stylet nub into the Portal shaft. It will be noted whether the C-ring can effectively be turned to block the Stylet nub into the Portal track.

Tested Function/Customer Need: Constrain rotational and vertical motion of Stylet with respect to Portal.

Measurement System: N/A.

Assessment: The Stylet and Portal will pass this test if the C-ring can properly be twisted around and block the Stylet from being removed from the Portal.

Location: This test will be performed in Aggy's apartment.

Resources: This test requires the Stylet and Portal.

L.3.4 Back Stabilizer-Portal Mate Test

Purpose: This test will determine whether the Back Stabilizer can be inserted around the Portal.

Procedure: The team will use a scalpel to create an incision in a chicken breast. The Portal will then be inserted into the chicken breast. With the Portal fixed in the chicken breast, the Back Stabilizer will be slid on the Portal, making sure to clamp the Portal. It will be analyzed whether the Back Stabilizer can successfully be slid and clamped on the Portal.

Tested Function/Customer Need: Stabilizer the Portal easily (one-hand adjustments).

Measurement System: N/A.

Assessment: The Back Stabilizer will pass this test if it can successfully slide and clamp onto the Portal.

Location: This test will be performed in Aggy's apartment.

Resources: This test requires the Portal and the Back Stabilizer, as well as a scalpel and a chicken breast.

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