

# PRELIMINARY DESIGN REVIEW

## *LMBN Surgical Neurotomy Device*

**Back in Action**

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February 5<sup>th</sup>, 2024

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## Executive Summary

### **Lumbar Medial Branch Nerve (LMBN) Surgical Neurotomy Device**

This report presents an innovative solution to address the pervasive issue of lower back pain, specifically pain caused by the facet joint. This project, led by a dedicated team, aims to develop a biomedical toolkit that offers a permanent solution to this problem, contrasting the temporary relief provided by existing treatments.

The report outlines the significant impact of lower back pain globally, emphasizing its prevalence as a leading cause of disability and its substantial economic burden due to healthcare costs and lost productivity. The proposed solution targets a market that includes Interventional Pain Management Specialists and spine doctors, offering a unique, cost-effective, and convenient treatment option.

The product, designed with advanced engineering principles, integrates features like a Portal, an interlocking Stylet with a diamond-shaped tip for precise nerve severance, a de-nerving tool, and a stabilizing unit for safety and efficacy during procedures. The product's disposable nature enhances its appeal by reducing sterilization needs and facilitating office-based procedures. Manufacturing plans for the product include 3D printing for plastic parts and microfabrication for metal components, ensuring medical-grade quality. Rigorous testing protocols are outlined to adhere to FDA standards and optimize the product's functionality.

The societal impact of the project is profound, potentially alleviating 25% of all lower back pain cases. It also promises a safer alternative to existing long-term treatments like radiofrequency ablation and spinal fusion. Business-wise, the project envisions a sustainable model by selling comprehensive, disposable tool kits, creating a symbiotic relationship within the medical community.

This report marks a significant advancement in the field of pain management and spinal health. Its innovative approach, grounded in rigorous research and engineering, positions it as a promising solution to a long-standing medical challenge. Through the preliminary design process the team has showcased an initial design and requests to move to a critical phase of the design.

## Main Body

Lower back pain (LBP) is the leading cause of disability worldwide and the second most common reason to visit a doctor after the common cold. Nearly 80% of all people will experience some form of back pain and 30% will experience chronic LBP in their lives. 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 is a lack of a toolset and procedure that will permanently destroy the nerve and prevent regrowth so that pain is permanently relieved. Based on market research, there is no product or patent that strictly relieves lower back pain for long periods of time and requires only a minimally invasive procedure. Currently, alternative solutions for relieving back pain include physical therapy, cortisone shots, radiofrequency ablation, and spinal fusion. All these solutions are temporary, and the stress of repeatability is apparent (**Section E.3**).

Given that this is such a pressing and influential problem, the team decided to tackle this with a revolutionary product and minimally invasive procedure that seeks to permanently relieve facet-induced lower back pain for patients. The proposed solution will focus on facet-induced LBP but can also be implemented on a smaller scale in other areas of the spine in the future.

With only four individuals on the Back in Action team, different roles were strategically assigned to each group member to assign responsibilities and maximize efficiency. Tasks were thoroughly assigned to accommodate each member's skills and interests. A problem charter was developed to define the expectations for the project, as well as understand the problem statement, project scope, vision statement, and key milestones, as seen in the preliminary project schedule (**Appendix I**). The team is currently focused on a preliminary design phase involving market research, medical research, initial concept generation, risk assessment, and test plan feasibility.

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 market size for this issue is thus very large. The team conducted extensive research

on various statistics, documented all critical assumptions, and developed conservative estimates to arrive at a general market size of 10-30 million patients and a target market size of around 400,000 patients per year (**Appendix II**). In addition, a preliminary BOM was developed to create an initial price estimation for the product based on the additional value the team's solution offers beyond what competitors offer. In addition to also considering the market size, the gross profit for the product is thus predicted to be around \$11,367.87 per kit.

The team conducted extensive research, through interviewing professionals and article review, on factors that influence sensory nerve regrowth and how those factors can be countered while inhibiting neuroma development – this is the crux of the product as it contributes to the team's primary selling point of a permanent solution to facet-induced lower back pain. Another key feature that distinguishes the team from competitors is the fact that this proposed solution is to be minimally invasive and suitable for a non-surgical and office setting. It is also disposable meaning that repeated sterilization is not required – this further reduces cost which can be reflected to cost seen by the patient. The product is to be sold as a kit containing all devices necessary to perform the procedure. Such key characteristics were kept in mind during the concept generation and design selection stages of this project. A detailed test plan was also derived to ensure product manufacturability, functionality, ease of use, and seamless integration amongst other devices in the kit (**Appendix III**).

The team's proposed solution can yield monumental societal benefits, saving the lives of millions. Many have had to make severe lifestyle changes, sacrifice activities that they cannot do because of their LBP, and partake in expensive and ineffective procedures. The team's initial prediction of project success and feasibility is very promising. The team is thus ready to move into the next phase of Critical Design Review and perfect the leading designs. Plans have developed for creating physical prototypes and analyzing leading designs. The team's proposed solution has great potential to become a well-crafted and medically-certified product to save the lives of millions.

## Appendix I – Project Management

### A. Problem Charter

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, manufacturing, testing, analysis, soft body modeling, and procedural 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.

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 EDM Machining, ME Machine Shop, Rapid Prototyping Lab, ME Labs, BIDC, and Discovery Park Laboratories. 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

<b>Project Title:</b> LMBN Surgical Nuerotomy Device	<b>Vision Statement:</b> 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.	
<b>Team Name:</b> Back in Action		
<b>Team Members:</b> Cameron Mostoufi, Joseph Misenar, Jacob Whitehouse, Agathiya Tharun		
<b>Problem Statement (Current State)</b>		
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.		
<b>Business / Society Benefit (Future State)</b>		
The business vision for our team is such that we can develop a company out of our product. This will be accomplished by developing and selling a package of medical tools. The unique tool developed to permanently sever the lumbar medial branch nerve will be manufactured and packaged with all other tools required to perform the LMBN surgical neurotomy. In doing so, doctors will be required to buy the entire kit of tools to perform the procedure. This will increase the revenue we earn, considering doctors will be buying a kit of tools as opposed to a		
<b>Key Stakeholders (Role, Influence, Interest)</b>		
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.		
<b>Project Scope</b>		
<b>IN Scope (for this class)</b>	<b>OUT of Scope</b>	
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.	
<b>Key Assumptions &amp; Risks</b>		
Key Assumptions: The Lumbar Medial Branch Never (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: Procedure is patented, supplementary tools are patented, the procedure doesn't get approved/certified by the Industrial Review Board (IRB), the medical device doesn't get approved/certified by the FDA, there are negative side effects from the procedure/medical tools, the		
<b>Key Resources Required</b>		
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		
<b>Version:</b>	1.0.3	
	1.0.2	
	1.0.1	
	1.0.0	
<b>Last Updated:</b>	1/23/2024	Added "Edward Null" to the Key Resources box.
	1/16/2024	Filled out every other box in the document besides the "Team Members & Roles"
	1/15/2024	Inserted the vision statement
	1/12/2024	Started document by filling out the team members & roles and team/project information box

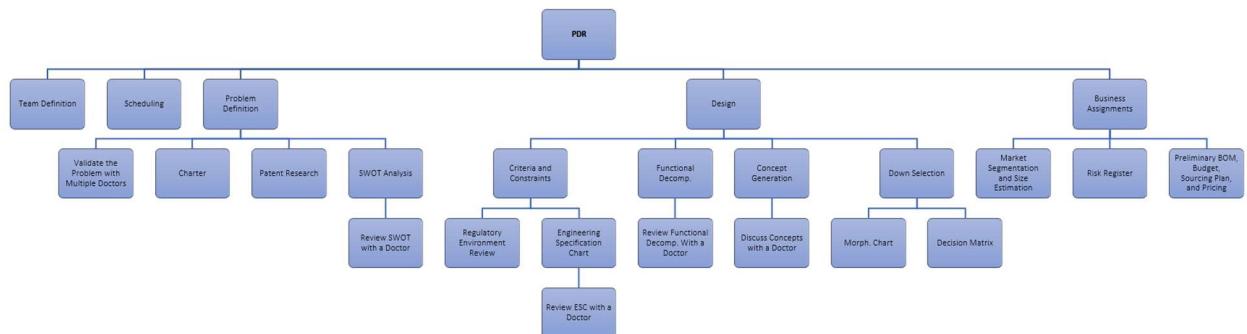
**Figure A.1 Project Charter**



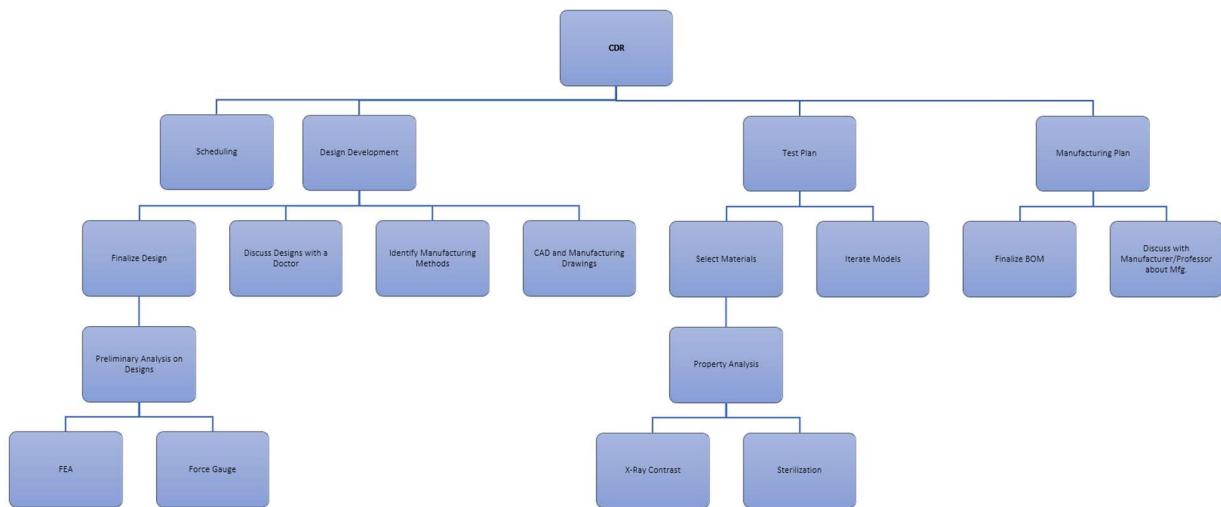
**Figure A.2** Team Photo

## B. Schedule

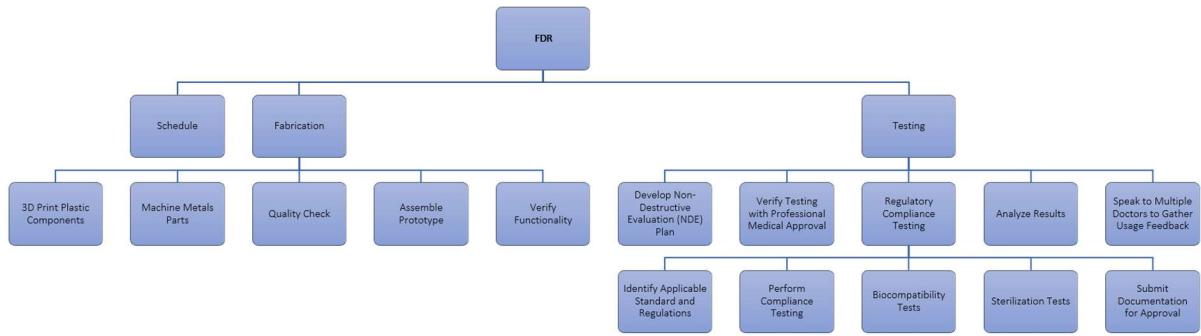
A project schedule was defined following a thorough overview of the scope and feasibility of the project. Along with extensive research, medical professionals were consulted to identify all steps along the process with regard to ensuring the project meets medical standards and has potential to get approval 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**.



**Figure B.1** WBS chart for the PDR phase

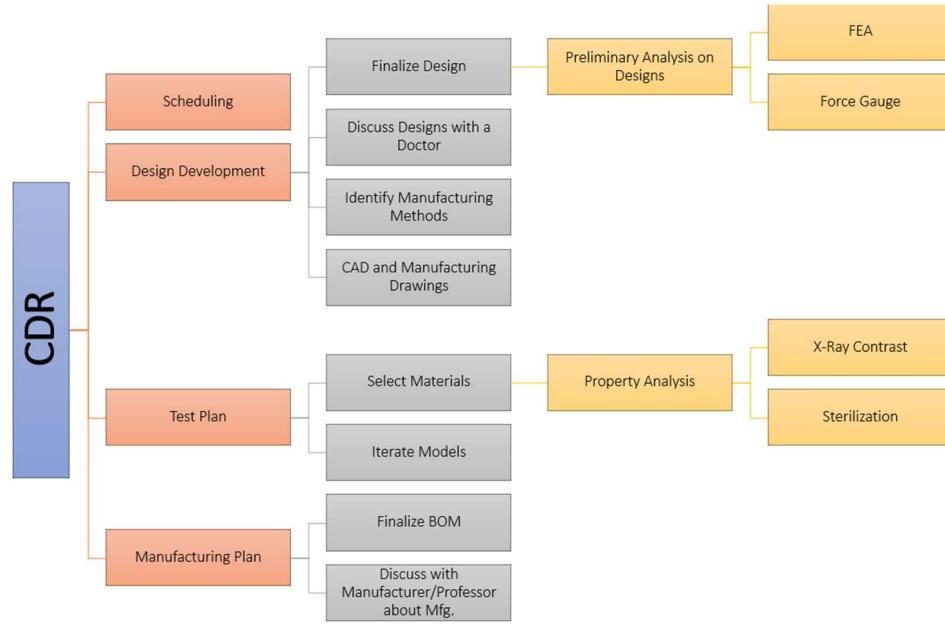
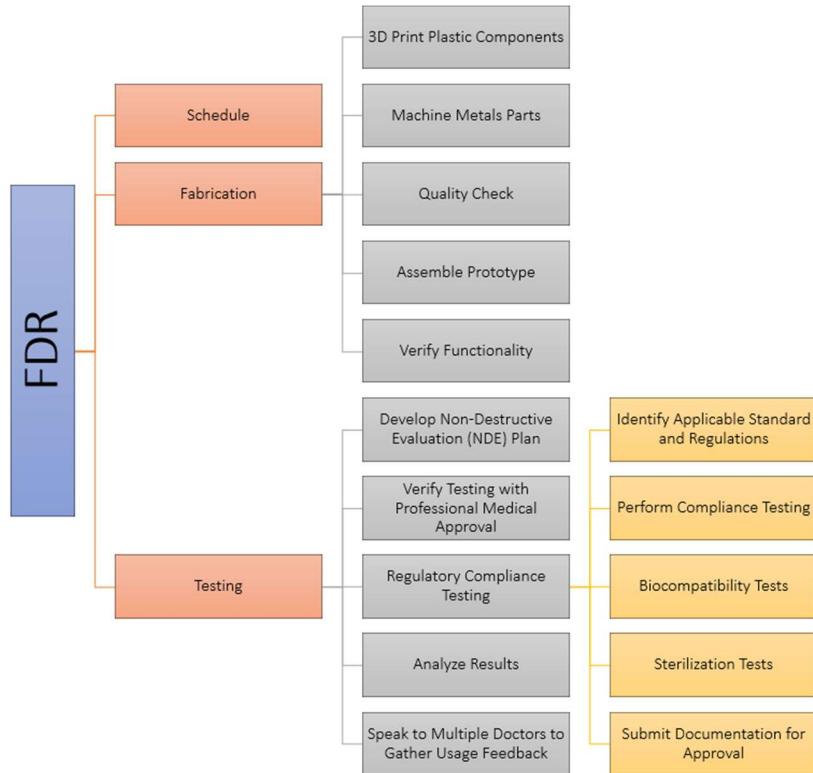


**Figure B.2** WBS chart for the CDR phase

**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 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, these charts yield limited fidelity regarding tasks within the CDR or FDR phase. In addition, a master checklist, off which the team's Gantt Chart is driven,

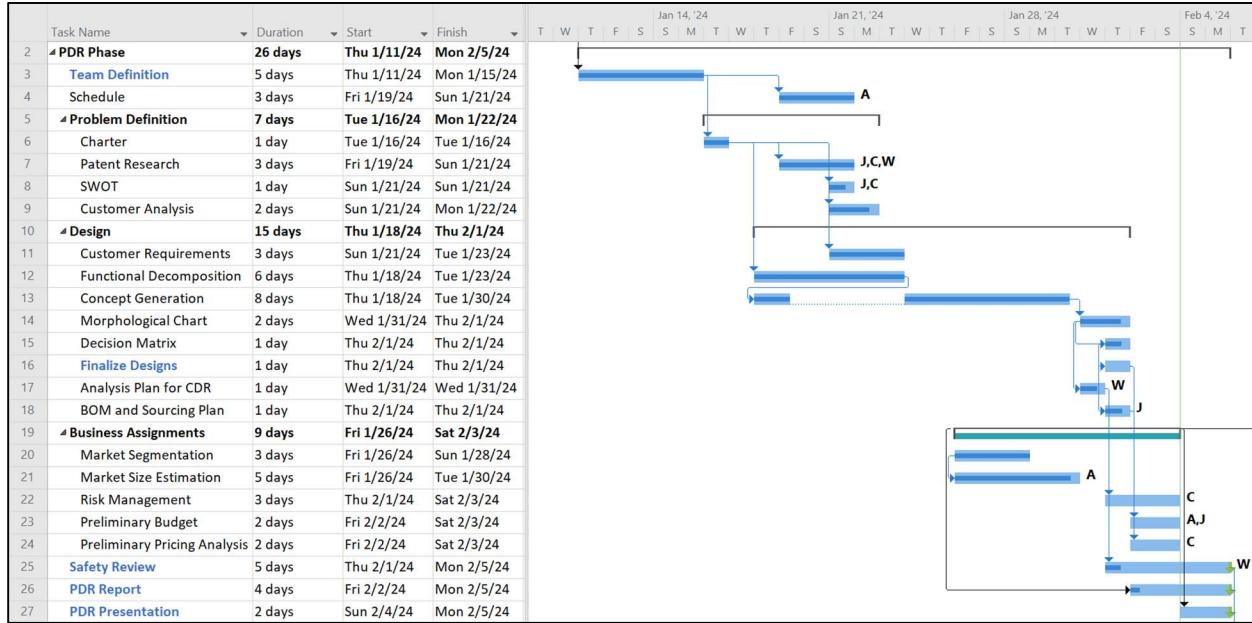
was created to have a complete project schedule. It is a live document where tasks will be edited with time, as can be seen in **Figure B.7**. Hence, the CDR and FDR phases are not as accurate as the PDR phase. Some tasks in this checklist, in addition to the “Independent Market Analysis” section, are tasks beyond the scope of the course rubric that the team plans to complete in order to guarantee project success.

PDR:	CDR:	FDR:
<b>Team Definition</b> Vision & Mission Team Roles Project/Team Name Company Name	<b>Schedule</b> Update Roadmap Update Gantt Chart	<b>Schedule</b> Update Roadmap Update Gantt Chart
<b>Schedule</b> WBS Network Diagram Timelines	<b>Prototype Development</b> Finalize Design Validate Final Design with a Doctor Identify Suitable Manufacturers Create CAD Models and Engineering Drawings Design for Manufacturability Leverage Parametric Modeling Create Assemblies	<b>Fabrication</b> 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
<b>Problem Definition</b> Charter Problem Statement Patent Research (Google Patents) <b>SWOT Analysis</b> Talk with a Doctor About SWOT <b>Customer Analysis</b> Problem Verification	<b>Model Analysis</b> Select Materials via Material Property Analysis Rockwell Hardness X-ray Diffraction Sterilization Biocompatibility Perform Analyses as Needed Stress and Finite Element Analysis (FEA) Friction and Threads/Fasteners, etc. Interpret Results and Refine Models as Necessary	<b>Testing</b> Develop Non-Destructive Evaluation (NDE) Plan Modularity/Interactivity Ease of Use Mishandling Cases Initial Sterilization Procedural Functionality (on Dummy) Appearance on X-rays Doctor Procedural Approval Verify Testing with Medical Approval Customer Feedback Speak to a Professional for Usage Feedback Analyze Test Results and Iterate as Needed
<b>Design</b> 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 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	<b>Manufacturing Plan</b> Update and Finalize BOM Discuss Mfg. Process with a Manufacturer Finalize Process Flowcharts as Needed	<b>Regulatory Compliance Testing</b> Identify Applicable Standards and Regulations Speak to Professionals Perform Compliance Testing Biocompatibility Tests Sterilization and Cleanliness Tests Submit Regulatory Documentation for Approval
<b>Business Assignments</b> Risk Register Preliminary Budget Value Proposition Product Cost/Value Preliminary Pricing Analysis Societal Benefit Gross Revenue Market Segmentation Market Size Estimation Sales Quantity	<b>Report Deliverables</b> Written Report Presentation	<b>Report Deliverables</b> Written Report Presentation
<b>Report Deliverables</b> Written Report Presentation Safety Review #1		<b>Independent Market Analysis:</b> Industry Analysis 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 PDR with dates and deadlines can be seen below in **Figure B.8**

**B.4.** The Gantt Chart has slightly less fidelity than the master checklist found in **Figure B.3**. The team will continuously update all scheduling documents as more information becomes available.



**Figure B.8** PDR Gantt Chart

## C. Preliminary Budget

The BOM and Sourcing Plan, as described in detail in **Section J**, describes a preliminary yet extensive list of all parts needed for a final prototype. However, many 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 for free through the ME 3D Print Lab. Thus, filament and other items that can be sourced for free were not included in the Preliminary Budget as seen below in **Figure C.1**.

**Figure C.1** Pending orders for the preliminary budget

Due to the nature of this project, many parts will require near-micro-scale manufacturing that cannot easily be done at the machine shops available on campus. Thus, the team may also consider third-party manufacturing services to produce certain parts based on engineering drawings and specifications. Various details that exist beyond the scope of PDR have not been finalized and thus an accurate estimate for these services, if leveraged at all, cannot be predicted. Thus, the preliminary budget does not reflect service costs of sourcing from manufacturers. Given that only 20% of the team's budget is to be expended, it can be safely assumed that any manufacturing services the team may utilize will remain within the budget.

The remainder of the budget offers the team a safe cushion for mitigating risks, handling unexpected issues, and optimizing the design to a higher and medical-grade quality. 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

The Risk Register is a critical tool in project management, documenting potential risks throughout various phases of a project, such as PDR (Preliminary Design Review), CDR (Critical Design Review), and FDR (Final Design Review). These risks encompass a wide array of issues ranging from general team misalignment to project-specific regulatory compliance and manufacturing challenges. Each identified risk is thoroughly analyzed, detailing its cause, probable effect, the assigned risk owner, and its probability and impact on the project, quantified through a scoring system. For instance, team misalignment risks are attributed to the misalignment of team roles and communication, potentially leading to inefficiencies and project delays, with the project manager being responsible for mitigating these risks through regular team meetings and clear role documentation. The risk score, derived from the product of probability and impact, guides the prioritization and mitigation strategies. Mitigation plans are then devised to lower the residual risk, with continuous monitoring and adjustments to ensure project alignment with its objectives.

Moreover, the Risk Register is not static; it evolves with the project, incorporating new risks and updating mitigation strategies as necessary. For example, schedule delay risks, attributed to inaccuracies in the Work Breakdown Structure (WBS) and unrealistic timelines, have high probability and impact, necessitating regular schedule reviews and the inclusion of buffer times. Similarly, risks related to inadequate problem definition, regulatory compliance, and budget underestimation are systematically addressed through enhanced research, regulatory reviews, and budget reassessment, respectively. This dynamic document serves not only as a guide for proactive risk management but also as a communication tool, ensuring all stakeholders are informed of potential risks and the measures in place to mitigate them, thereby fostering transparency and collaborative problem-solving within the project team.

Calculating risk in the Risk Register involves a systematic approach where the risk score is derived by multiplying the risk's probability (P) with its impact (I). Probability, defined as the likelihood of the risk occurring, is categorized as low, medium, or high. Impact measures the severity of the risk's consequences on project parameters such as schedule, budget, and product requirements, and is similarly classified. The resulting risk score, a numerical value, provides a quantifiable measure of the risk's overall significance to the project. For example, a risk with a

high probability (P) and high impact (I) would yield a high risk score (e.g., High x High = 9), indicating a critical risk that demands immediate attention and mitigation efforts. Conversely, a risk with low probability and low impact results in a low risk score (e.g., Low x Low = 1), identifying it as less critical. This calculation enables prioritization, guiding project managers and teams in focusing their efforts and resources on mitigating the most significant risks to maintain project alignment with its objectives and timelines.

Some specific examples from the register are as follows: there is a medium risk score with regards to team misalignment. This is because the team may communicate ineffectively creating a decrease in efficiency and leading to deliverables being rushed or incomplete. This is an ongoing task that will require the team to maintain consistent and open communication. Additionally, the team has run into research inconsistencies which are on the Risk Register. This has served as a critical blocker and has stopped progress for about a week, the risk score was a 6 as seen in **Figure D.1** which became an issue for the team during the PDR phase. Further comprehensive risks are described in the attached Risk Register document.

1. IDENTIFICATION			2. CURRENT ASSESSMENT			3. TREATMENT			4. RESIDUAL ASSESSMENT			5. REVIEW, CONTROL, COMMUNICATE	
RAISED BY	DATE RAISE	CAUSE (IF...)	EFFECT (THEN...)	RISK OWNER	Probability of the event occurring	STRATEGY	TREATMENT DESCRIPTION	Probability of the treatment to occur	Worst Impact	Residual Risk Score	Commentary	Last Update	
he originator of the risk	When the risk has been identified	If uncertain event occurs due to (or because of) root cause(s). Tip: ask "so what, so what,..." to drill down to root cause	Then the ultimate impact to our objectives are:	Single named owner	Worst Impact	Calculated risk score	Select course of action to treat the risk	Summary of the treatment responses (actions, controls, fallbacks) that treat the risk	Probability of the event occurring	Worst Impact	Calculated risk score	Any additional notes, comments or actions	Enter the last risk or update date for now
1 Cameron	6-Feb-24	Misalignment of team roles and communication inefficiencies and project delays	Project Manager	Medium	Medium	Mitigate	Implement regular team meetings and clear documentation	Low	Low	Low	Ongoing team alignment needed	6-Feb-24	
2 Cameron	6-Feb-24	Inaccuracies in WBS and unrealistic timelines	Impact on project milestones and deliverables	Project Manager	High	High	Mitigate	Develop a realistic schedule with buffer times and review	Medium	Medium	Schedule reviewed bi-weekly	6-Feb-24	
3 Cameron	6-Feb-24	Incomplete or inaccurate problem statement	Flawed project foundation and potential rework	Analysis Lead	Medium	High	Mitigate	Enhance research and validate the problem statement	Low	Medium	Validation of research critical	6-Feb-24	
4 Cameron	6-Feb-24	Failure to review regulatory environment	Risk of non-compliance and design changes	Business Manager	Low	High	Mitigate	Conduct regulatory review early and engage with relevant stakeholders	Low	Medium	Regulatory checks are continuous	6-Feb-24	
5 Cameron	6-Feb-24	Inaccurate preliminary budgeting	Financial shortfalls and scope adjustments	Buyer	Medium	High	Mitigate	Review budget assumptions, include contingency plan	Low	Medium	Budget monitored monthly	6-Feb-24	
6 Cameron	6-Feb-24	Variability in research quality or sources	Additional research time and delays in conception	Analysis Lead	Medium	High	Mitigate	Standardize research processes and validate sources	Low	Medium	Ongoing monitoring of research quality is needed	6-Feb-24	

**Figure D.1** Risk Register lines related to the PDR phase

## Appendix II – Business/Marketing

### E. Market Analysis

#### *E.1 Market Segmentation*

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**

To better understand the market at hand, the team performed a high-level analysis on 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.

### *General Demographic Market Size Calculation:*

- 1) The total US population as of February 4, 2024:
  - 336,019,747<sup>18</sup> people
- 2) Number of people covered by some medical insurance in the US as of 2022:
  - 92%<sup>23</sup> 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%<sup>2</sup> 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%<sup>4</sup> 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.

*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%<sup>22</sup> 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***

#### *Patent Research:*

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 20120226301, 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 5429138, 4356828, 4266555, and 4262676. 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 #10201267 and application #20170340194, 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.

### *SWOT:*

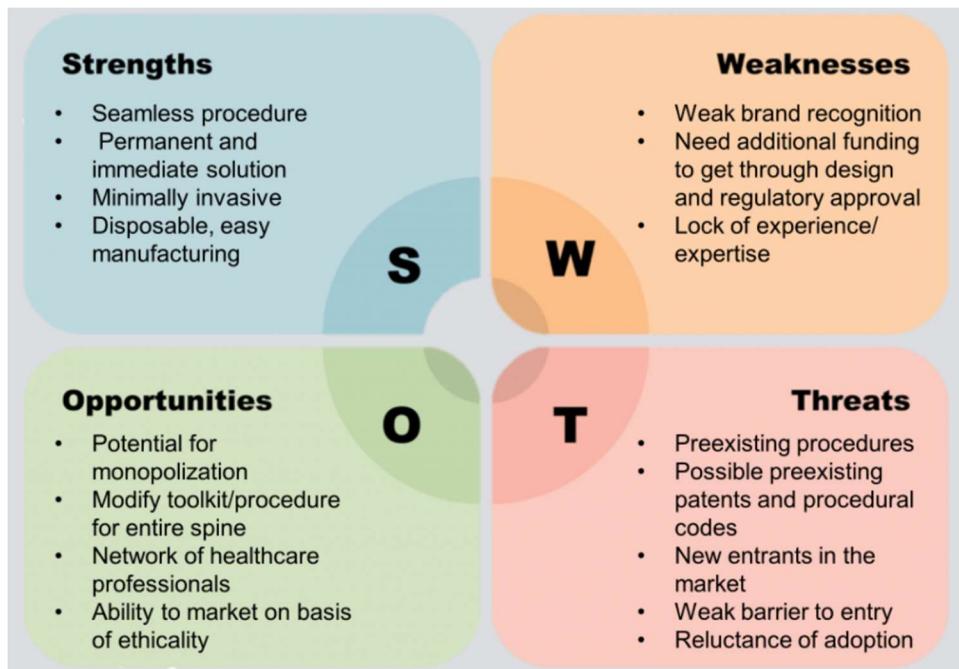
SWOT stands for Strengths, Weaknesses, Opportunities, and Threats. It represents a succinct framework for evaluating any situation, whether in a business context, personal sphere, or other scenarios, by examining internal aspects such as strengths and weaknesses, alongside external factors like opportunities 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

their 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

*Regulatory Environment Review (RER):*

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 product cost breakdown calculates each component's cost by integrating various factors such as retail cost adjustments, labor, and overhead rates.

The "Stylet Shaft" component starts with a retail cost of \$6.89. However, considering a volumized percentage of retail at 70%, the part cost is adjusted to \$4.82. Adding to this, machining labor, calculated at 0.2 hours with a labor rate of \$60/hr, contributes an additional \$12.00 to the part cost. When combined, the part and labor cost sum to \$16.82. The inclusion of a 35% overhead rate further elevates the component cost to \$22.71.

Similarly, the cost for "3D Printing Filament" is derived from its material cost and labor & machine costs. The filament's material cost is calculated based on its weight, which is determined from its length, diameter, and density, resulting in a cost of \$42.80. The printing process, taking 20 hours at a cost rate of \$1.00/hr, adds a labor and machine cost of \$20.00, culminating in a component cost of \$62.80. This approach to cost calculation is consistent across all components, ensuring a comprehensive and detailed cost breakdown for the product, with the total cost summing to \$347.13. The entire product costs calculation for each component is broken down in **Figures F.1.1 through F.1.3**.

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	\$6.89	Retail Cost	\$50.39	Retail Cost	\$6.89
Units / yr	10000	Units / yr	4000	Units / yr	6566
Volumized % of retail	70%	Volumized % of retail	90%	Volumized % of retail	80%
Part Cost	\$4.82	Part Cost	\$45.35	Part Cost	\$5.51
Labor	Machining hrs. Labor rate Labor cost	Labor	Machining hrs. Labor rate Labor cost	Labor	Machining hrs. Labor rate Labor cost
	0.2 hr. \$60 / hr. \$12.00		0.5 hr. \$60 / hr. \$30.00		0.3 hr. \$60 / hr. \$18.00
Part + Labor	\$16.82	Part + Labor	\$75.35	Part + Labor	\$23.51
Overhead	35%	Overhead	35%	Overhead	35%
Component Cost	\$22.71	Component Cost	\$101.72	Component Cost	\$31.74

**Figure F.1.1** Product cost calculations for the Stylet Shaft, Portal Hollow Tube, and Denervator Shaft components

Component #4 - Spherical Bearing		Component #5 - Aluminum Stock		Component #6 - Epoxy Coating	
Description	Spherical Bearing	Description	Aluminum Cube Stock	Description	Epoxy Coating Spray
Vendor	McMaster-Carr	Vendor	McMaster-Carr	Vendor	McMaster-Carr
Retail Cost	\$47.80	Retail Cost	\$35.70	Retail Cost	\$21.47
Units / yr	4000	Units / yr	3000	Units / yr	2000
Volumized % of retail	90%	Volumized % of retail	90%	Volumized % of retail	90%
Part Cost	\$43.02	Part Cost	\$32.13	Part Cost	\$19.32
Overhead	8.5%	Overhead	8.5%	Overhead	8.5%
Component Cost	\$46.68	Component Cost	\$34.86	Component Cost	\$20.97
<hr/>					
Component #7 - Superglue		Component #8 - Misc. Fasteners		Component #9 - Threaded Inserts	
Description	High Strength Superglue	Description	M2x6mm Stainless Fasteners	Description	M2 Threaded Inserts
Vendor	McMaster-Carr	Vendor	McMaster-Carr	Vendor	McMaster-Carr
Retail Cost	\$8.99	Retail Cost	\$7.29	Retail Cost	\$9.99
Units / yr	2000	Units / yr	2000	Units / yr	4000
Volumized % of retail	90%	Volumized % of retail	90%	Volumized % of retail	90%
Part Cost	\$8.09	Part Cost	\$6.56	Part Cost	\$8.99
Overhead	8.5%	Overhead	8.5%	Overhead	8.5%
Component Cost	\$8.78	Component Cost	\$7.12	Component Cost	\$9.76

**Figure F.1.2** Product cost calculations for the Spherical Bearing, Aluminum Stock, Epoxy Coating, Superglue, Threaded Inserts, and Miscellaneous Fastener components

Component #10 - 3D Printing Filament		
<b>Material: PET</b>		
Filament diameter	0.069	in
Filament length	2164	ft
Filament density	0.049	lb. / cu. in.
Filament weight	4.75556827	lb. / cu. in.
Price	\$ 9.00	\$/lb.
<b>Material cost</b>	<b>\$ 42.80</b>	
Units/yr	100	
<b>Labor &amp; Machine Cost (added to all materials)</b>		
Printing time	20	hrs.
Cost / hr.	\$ 1.00	\$/ hr.
<b>Labor &amp; Machine cost</b>	<b>\$ 20.00</b>	
<b>Component Cost</b>	<b>\$62.80</b>	

**Figure F.1.3** Product cost calculations for the 3D Printing Filament

Each subsequent component's cost is uniquely calculated by considering specific factors relevant to the component, such as machining hours for parts requiring labor-intensive processes or material costs for those reliant on specific raw materials. Overhead rates are applied differently based on the nature of the component, reflecting the indirect costs associated with production, such as facility costs, utilities, and management expenses. This structured and detailed approach ensures an accurate and transparent cost breakdown, essential for financial planning and product pricing strategies.

### ***F.2 Preliminary Pricing Analysis***

The proposed surgical solution introduces a minimally invasive technique for addressing lumbar medial branch nerve pain through a targeted surgical neurotomy product. This product boasts a design prioritizing precision, necessitating only a 4-5mm incision and promising rapid healing within 5-10 days. It functions by effectively severing and isolating the medial branch nerve from the facet joint, offering a singular and non-repetitive intervention. Notably, the procedure's execution on the structurally dense pedicle minimizes risk by avoiding essential anatomical structures.

The value-based pricing model reflects the cost benefits associated with the product, which eliminates the need for recurrent Radiofrequency (RF) ablation treatments. As the product is projected to alleviate nerve pain for up to five years, the pricing is based on the cumulative cost savings compared to ongoing RF ablations. Considering the annual expense of RF ablation per patient at \$1,943, a five-year cost avoidance translates to \$9,715. To incentivize practitioners, an additional \$2,000 has been factored in for the procedural execution, setting the preliminary product price at \$11,715.

This pricing structure is strategically crafted to resonate with both insurance entities and medical professionals. By aligning with reimbursement rates for open surgical codes, typically higher than those for less invasive procedures, the solution attracts insurance coverage. Simultaneously, the competitive price encourages medical professionals to adopt this novel and safer method for treating lumbar medial branch nerve discomfort.

### ***F.3 Societal Benefit***

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**

Gross profit, a critical financial metric, indicates the profitability of a product by highlighting the difference between sales revenue and the cost of goods sold (COGS). In the case of the discussed product, analyzing gross profit is indispensable for evaluating its financial health and the effectiveness of its pricing strategy. The product's production cost is meticulously calculated at \$347.13, accounting for each component's cost (including, but not limited to, the "Stylet Shaft" and "3D Printing Filament"). This comprehensive total includes considerations for retail cost adjustments, labor, overhead, and material costs, providing a detailed view of production expenses.

The product, to be sold as a kit of devices, is to be priced at \$11,715 per unit, adopting a value-based pricing model that capitalizes on the product's ability to eliminate the need for ongoing RF ablation treatments. This price is reflective of the total cost savings of \$9,715, attributed to avoiding five years of RF ablation treatments, with an additional \$2,000 added for procedural execution costs.

Gross profit per product was determined by subtracting the cost of production from the selling price, as seen in **Equation F.4.1** below:

$$\textbf{Gross Profit per Product} = \textit{Selling Price per Product} - \textit{Cost of Production per Product}$$

**Equation F.4.1** Gross Product Model

For this product, applying the figures translates to a gross profit of \$11,367.87 per kit, calculated by taking the \$11,715 selling price and deducting the \$347.13 production cost. This significant gross profit of \$11,367.87 per product emphasizes the product's financial viability and the strategic soundness of its pricing model. The substantial profit margin demonstrates the product's value in offering a permanent solution to lumbar medial branch nerve pain, thus eliminating the economic and physical strain of repeated RF ablation treatments. Moreover, this profit margin ensures that the pricing strategy is balanced, making the product affordable and accessible to patients while providing sufficient funds for reinvestment into further research, development, and market expansion.

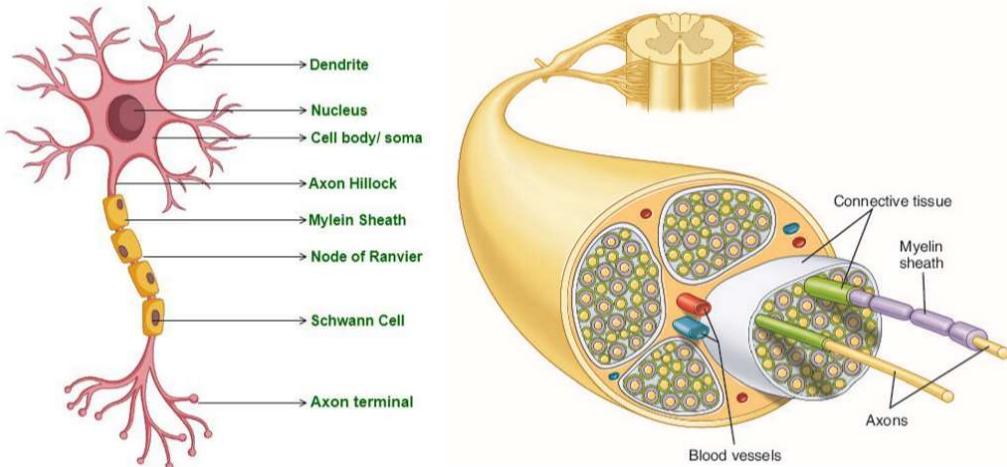
## Appendix III – Design Process

### 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 axons<sup>13</sup>. These axons are contained within a protective myelin sheath<sup>11</sup> 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 gap<sup>5</sup> between severed ends<sup>12</sup> of the nerve discourages the nerve from reconnecting.
- **General Health:** Younger age and better health helps a severed nerve heal.
- **Scar Tissue:** Collagen<sup>1</sup> based scar tissue may inhibit the development of neuromas and pain. Scar tissue may create dense physical barriers<sup>16</sup> to inhibit<sup>7</sup> regrowth but may also serve as scaffolding<sup>12</sup> to promote regrowth.
- **Time:** A critical window (~18 months<sup>17</sup>) exists within which axon regrowth from the distal stump is most receptive<sup>12</sup> to growth signals from the proximal (healthy) portion. With more time, regeneration potential decreases<sup>7</sup>. When intervention is delayed, Schwann cells undergo apoptosis<sup>17</sup> 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 neuromas<sup>6</sup>, 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**.

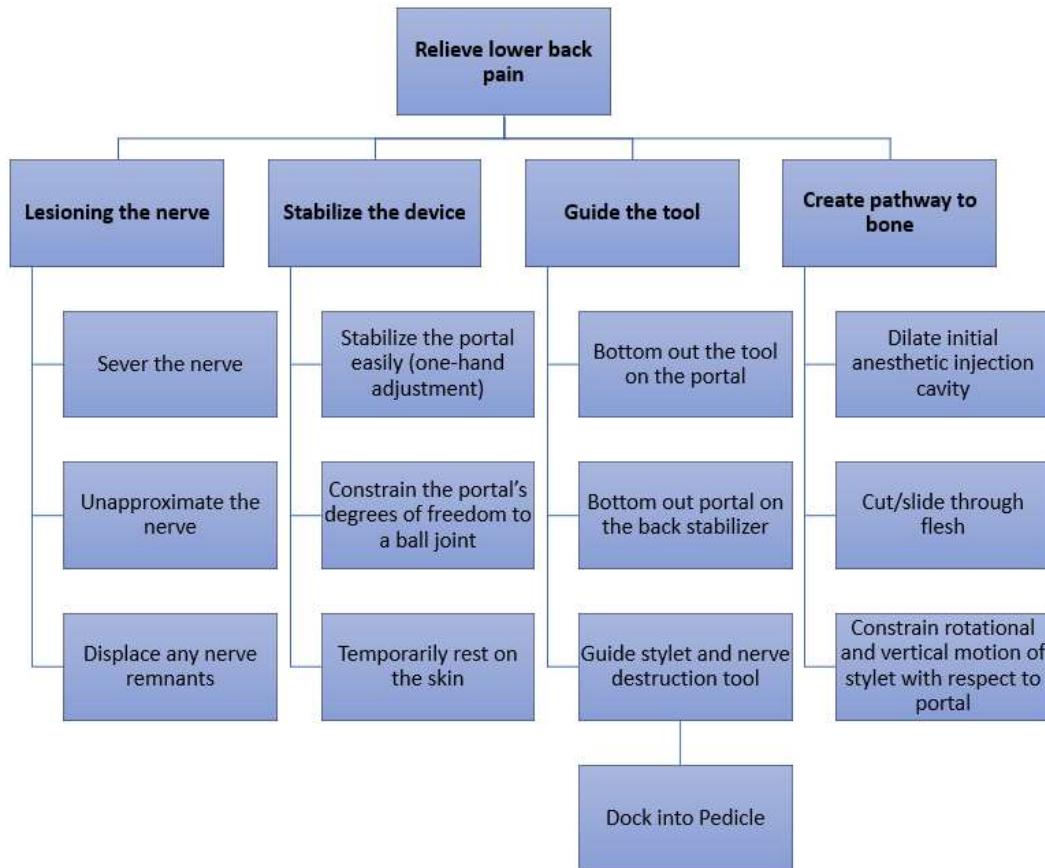
Classification of Peripheral Nerve Injury						
Sunderland Grade	Seddon	Site of Pathology				
		Myelin	Axon	Endoneurium	Perineurium	Epineurium
1	Neurapraxia	+	-	-	-	-
2	Axonotmesis	+/-	+	-	-	-
3	Axonotmesis	+/-	+	+	-	-
4	Axonotmesis	+/-	+	+	+	-
5	Neurotmesis	+	+	+	+	+

Key: + means affected, - means unaffected

**Figure G.1.2** Denervation injury severities

Axonal regeneration requires an intact endoneurium<sup>7</sup> 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.

The team's functional decomposition chart was thus developed with this knowledge in mind. The results of this can be seen below in **Figure G.1.3**.



**Figure G.1.3** Functional Decomposition chart

## ***G.2 Determining Engineering Specifications***

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 with 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.2.1**.

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.2.1**). The first customer need listed in **Figure G.2.1** 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.2.1** 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) wide<sup>10</sup>. 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 7mm<sup>24</sup>. 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 use<sup>20</sup>. 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 15-30psi<sup>21</sup>. 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 ratio<sup>8</sup>. 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<sup>3,19</sup>. 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 years<sup>24</sup>. 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 capabilities<sup>15</sup>. 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 sessions<sup>6</sup>. 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 procedures<sup>14</sup>. 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)<sup>9</sup>. 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 <b>at least 75%</b> . 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 <b>no larger than 12.7mm</b> to fit within a small incision.	4-5mm
3	Disposable (one-time use)	Reprocessing rate	<b>0%</b> 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 <b>250-273°F and 15-30psi</b> .	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 <b>at least 3:1</b> with bone	5:1
1	Relief of pain	Extent and effectiveness	The medical tools and procedure should successfully relieve <b>50% of pain, 80% of the time.</b>	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 <b>at least 5 years.</b>	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 <b>at least 5mm.</b>	7-8mm
3	Avoidance of neuromas	Percentage of cases	Neuroma generation should not happen for <b>any more than 10% of all patients.</b>	5%
1	Strong enough to withstand procedural force	Force	The medical tools should withstand <b>at least 20N.</b>	40N
4	Sustainability	Recycling rate	<b>At least 50%</b> of the tools in the kit should be recyclable to be repurposed.	75%

**Figure G.2.1** 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. These include design, information, anatomical, resource, and market constraints. While the team will have to deal with them in their own ways, each constraint is just as important as the next.

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.

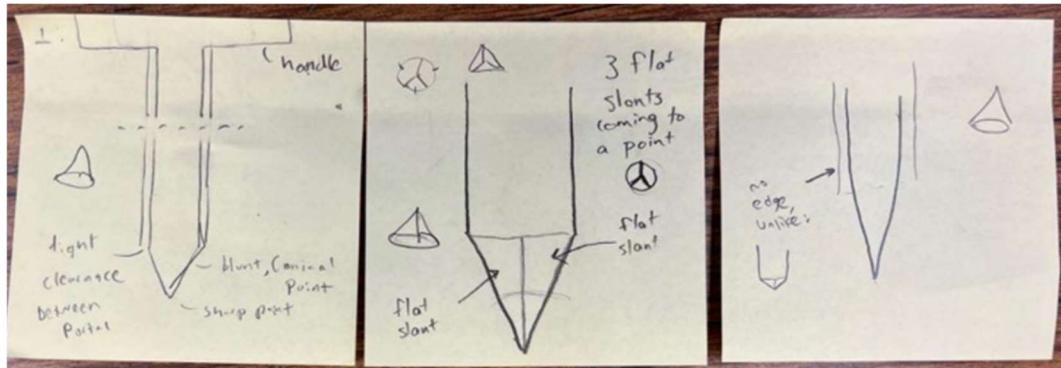
## H. Concept Sketches

Following extensive research, consultations with medical professionals, and defining engineering specifications, the team leveraged timed Group Passing brainstorming strategies to ideate several ideas for each function required of the product. Functional requirements and engineering specifications were kept in mind throughout this process. The key features for which concepts were developed include:

- Stylet:
  - Flesh-cutting mechanism
  - Ergonomic handle
- Portal:
  - Vertical and rotational interlocking mechanism
  - Docking into pedicle
- Back Stabilizer:
  - Easy-use clamping mechanism
- Denervator:
  - Bottom out the Denervator on the Portal
  - Ergonomic handle
  - Unapproximate the nerve
    - Prevent neuroma formation
    - Interrupt distal ends

A Group Passing brainstorming session was held for each of the aforementioned subfunctions. The team would take 1 minute to come up with a concept and pass on their ideas to the next team member who would then come up with another concept after considering/taking inspiration from the concept idea that was just passed to them. This was repeated until each member had seen everyone's ideas. Redundant ideas and infeasible ideas were discarded and photographic documentation was recorded of all remaining ideas. The team then discussed all created ideas and further honed the selection based on estimated effectiveness, ease-of-manufacturing and mass-producibility, and other defining characteristics inherent to the device, as described in detail in **Section I.**

The first device considered was the Stylet. The results of the brainstorming sessions for its functions and key features can be seen below in **Figures H.1 through H.2**. The flesh-cutting mechanisms, as seen below, were ideated such that they minimize collateral damage to nearby flesh. Various tip shapes were developed.



**Figure H.1** Flesh cutting mechanism concepts for the Stylet

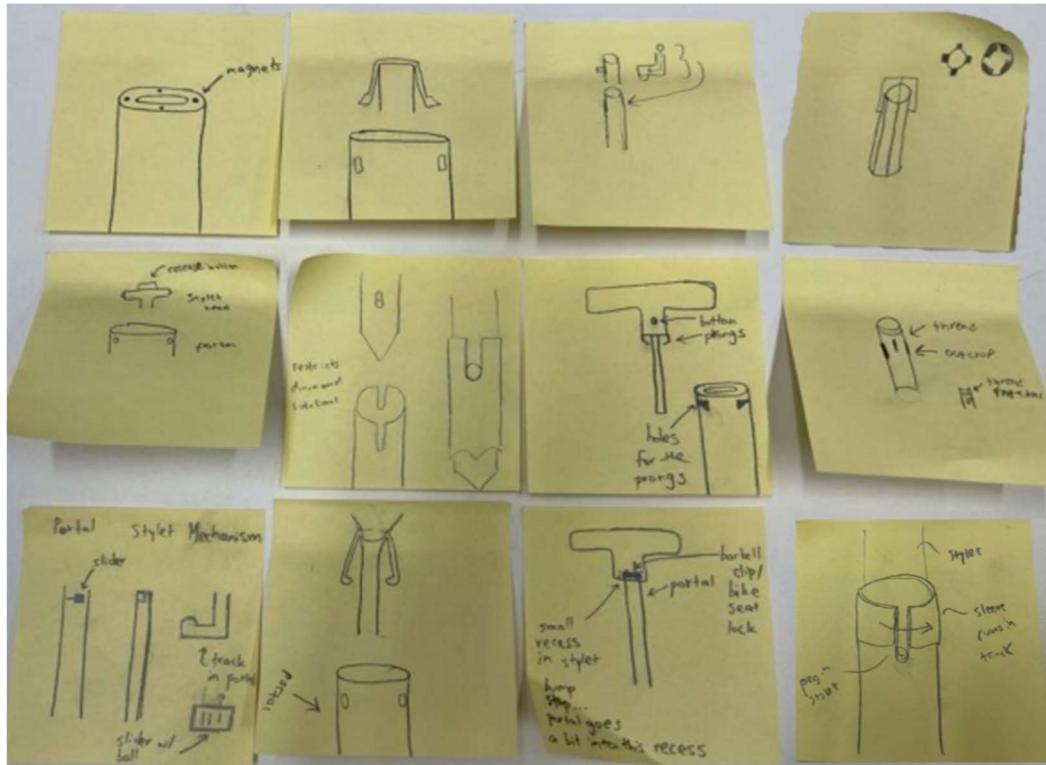
The handles, as seen below, were ideated to allow for an ergonomic and easy-to-handle grip that would offer the user maximized dexterity, control, and leverage when operating the device. Note that the concepts for the ergonomic handle were leveraged for both the Stylet and Denervator, though different criteria were used during concept refinement and down selection.



**Figure H.2** Ergonomic handle concepts for the Stylet and Denervator

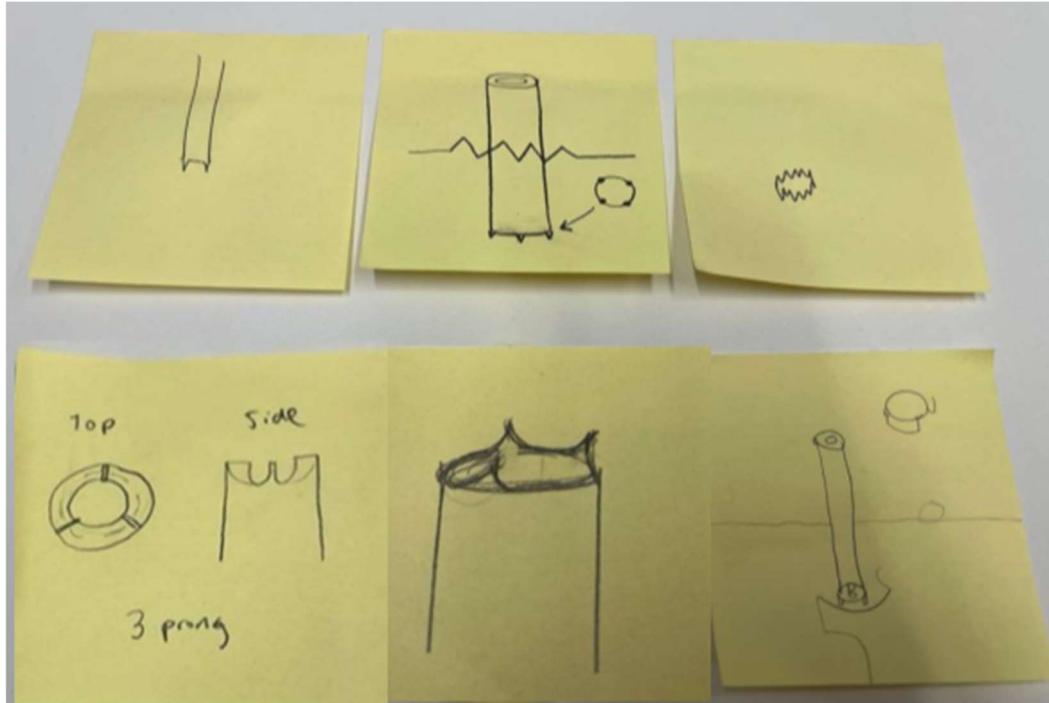
The next device investigated was the Portal. The results of its brainstorming session can be found below in **Figures H.3 through H.4**. As seen below, the concepts generated for the interlocking mechanism of the Portal needed to be simple, easy to manufacture, easy to use such that the Stylet can easily be removed from the Portal in 1-2 steps, and robust such that the Stylet

is rotationally and vertically constrained with the Portal. This is important as the doctor will drive the Portal-Stylet system into the body using the ergonomic handle of the Stylet.



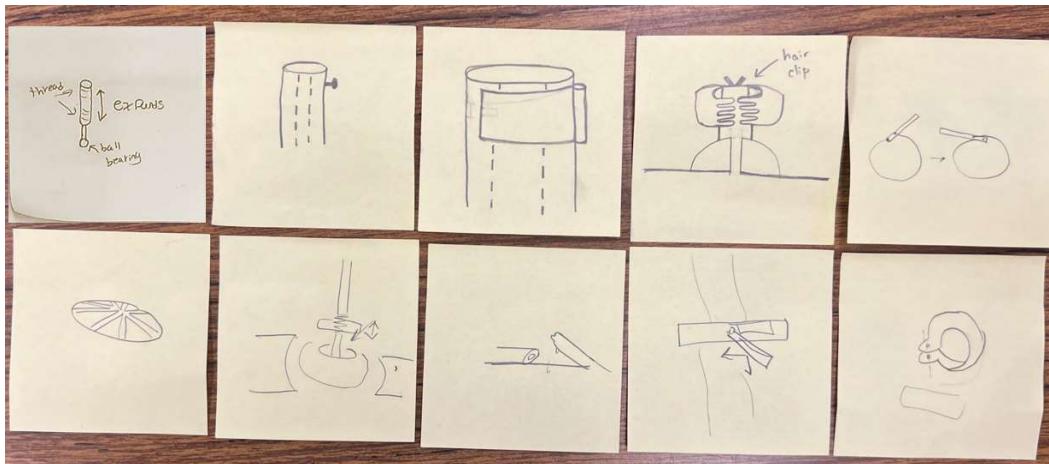
**Figure H.3** Interlocking mechanism concepts for the Portal

The concept generation for the pedicle-docking mechanism, as seen below, was less technically intensive. The primary focus was to ensure that the Portal can be docked securely, and the docking teeth can be manufactured easily. It was also important for the team to note that the teeth would be extremely small and sharp – a hotspot for stress concentration factors. Thus, it was crucial to design them in a way where strength is retained. The projected manufacturing process must also cut the part in a way such that teeth's integrity isn't compromised.

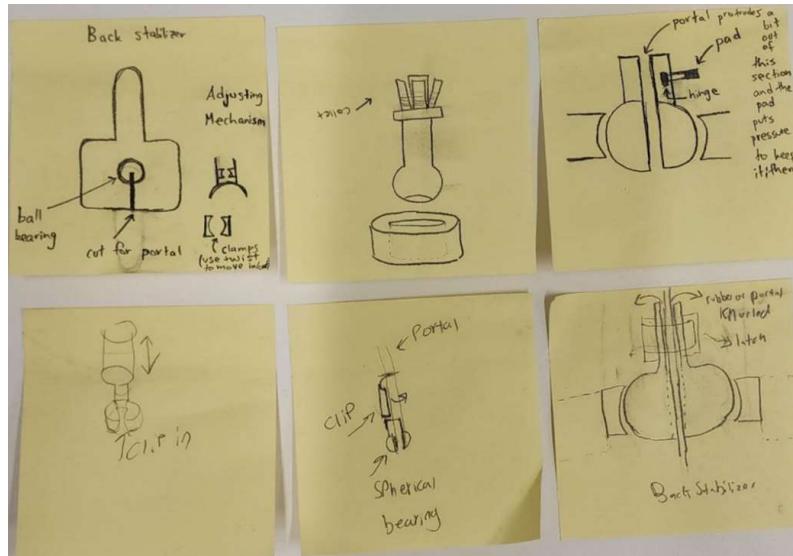


**Figure H.4** Pedicle docking concepts for the Portal

The team then studied the Back Stabilizer. Its most complex and crucial feature is its ability to prevent the Denervator from slipping too far into the body and accidentally causing collateral damage. Thus, an adjustable clamping mechanism integrated into a multi-axis Portal stabilizing mechanism (such as a ball bearing) was to be ideated. The results of this feature's concept generation can be seen below in **Figures H.5 through H.6**.

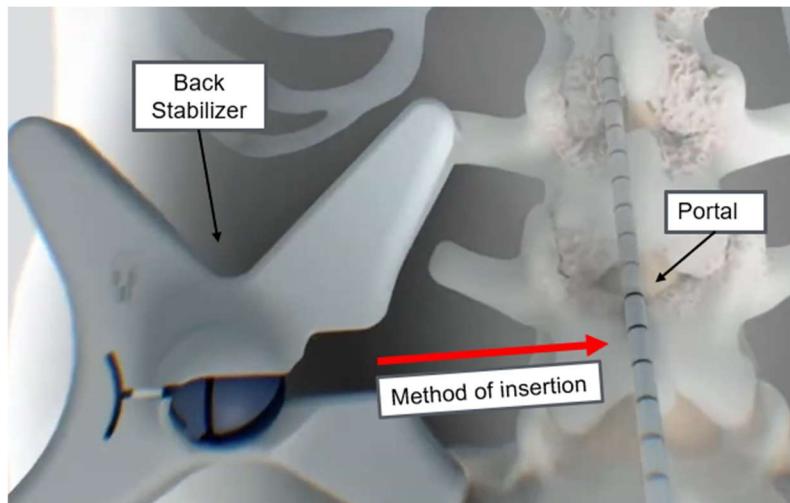


**Figure H.5** Multi-axis clamping concepts for the Back Stabilizer (Part 1 of 2)



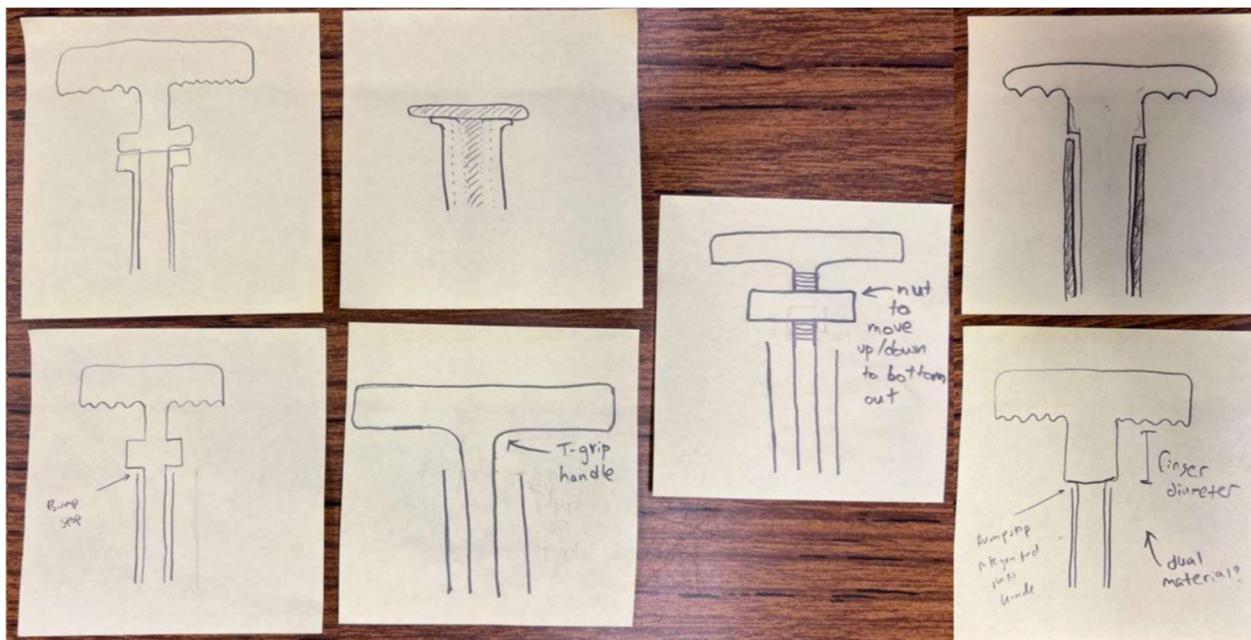
**Figure H.6** Multi-axis clamping concepts for the Back Stabilizer (Part 2 of 2)

The most critical characteristic in these concepts is that the Back Stabilizer must be easy to use such that minimal jostling/vibration occurs when the clamping mechanism is activated/disengaged. In addition, the Back Stabilizer must provide adequate support to the Portal, regardless of its orientation in any axis. It must also display some friction-based adherence properties with the skin so that it does not move around. Furthermore, the device must also be compatible with sliding onto the Portal laterally. This is because, in most cases, the Portal will already be in the body and the Back Stabilizer will need to slide into place afterwards, as pictured below in **Figure H.7**.



**Figure H.7** Pictorial depiction of an example Back Stabilizer sliding into a Portal to stabilize it

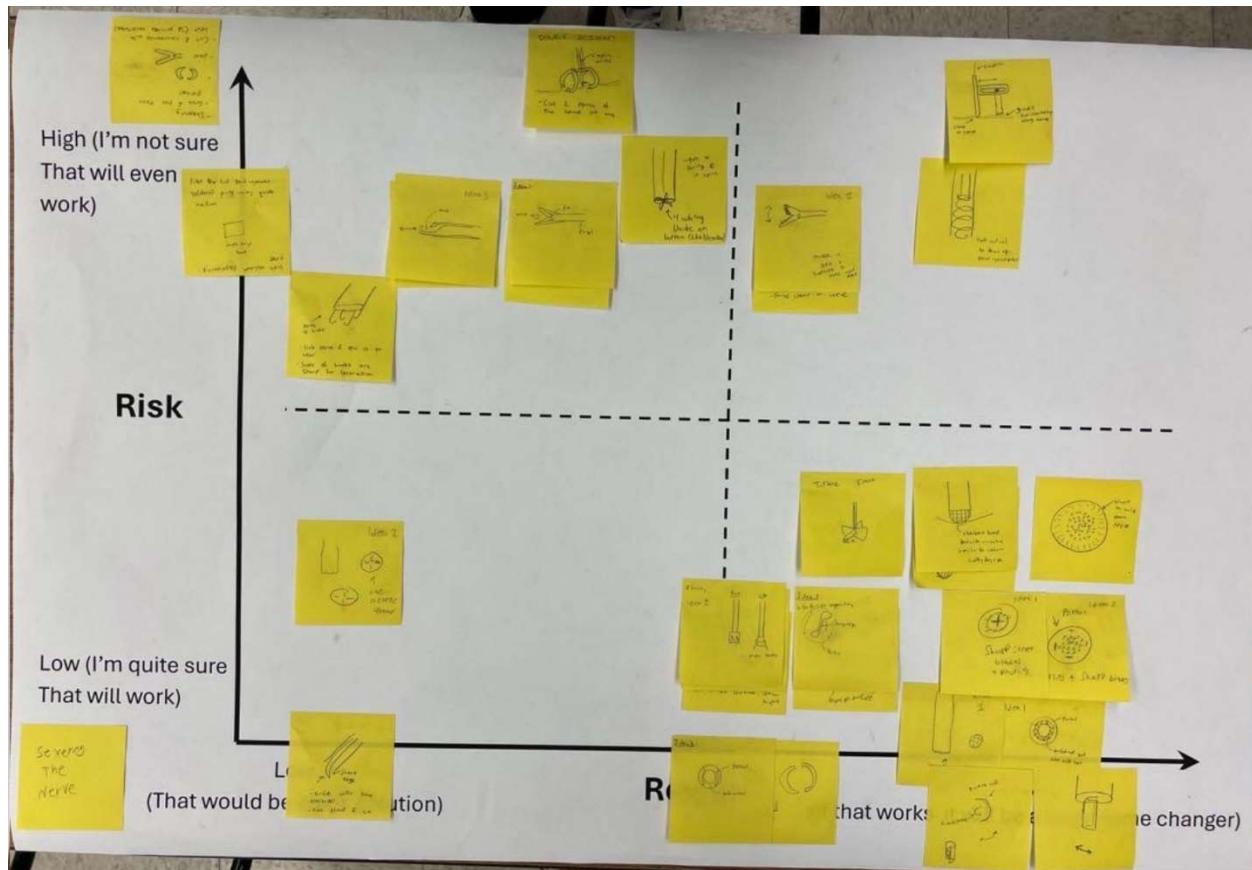
The last device investigated was the Denervator. This concept generation process was the most complex as the Denervator has three significant subfunctions to design for. The device must be ergonomic at the handle, bottom out against the Portal, and unapproximate the nerve. The results of the concept generations for each of these functions, in order, can be seen in **Figure H.2** and **Figures H.8 through H.9**.



**Figure H.8** Bump stop concepts for the Denervator

Note that a T-Grip handle, as seen above across all the sketches, was used as a general placeholder for the true handle, for which concepts were ideated based on ergonomics and handling as previously shown in **Figure H.2**. During ideation, it was highlighted that the key characteristic of a successful concept for bottoming out the Denervator against the Portal is that it must be structurally feasible and minimize stress concentrations that may arise from a large force being applied on the handle. The force flow from this would ultimately culminate at the thin body of the Portal and create risk of fracture. This feature is critical – if the Denervator does not bottom out against the Portal, it could slip too far into the body and cause unintended collateral damage.

The last function investigated by the team was unapproximating the nerve. As seen below, a plethora of concepts were ideated to sever the nerve and displace or interrupt the distal ends. Manufacturability, procedural effectiveness, and patient safety were the team's primary concerns during this ideation process.



**Figure H.9** Unapproximation concepts for the Denervator plotted on a risk vs. reward map

Concepts ranged from combinations of clean cutting vs. grinding to a parallel vs. perpendicular entry approach. The entry type defines how the tool is oriented with respect to the medial branch nerve (MBN). During ideation, the team considered the pros and cons of each method when ideating cut type + entry type combinations to inspire the concepts generated. For example, concepts that chose a perpendicular clean-cut approach often leveraged designs like that of an X-Acto knife and included a feature to displace the distal ends. The pros and cons of these methods considered can be seen below in **Table H.1**.

**Table H.1** Pros and Cons of Unapproximation Methods

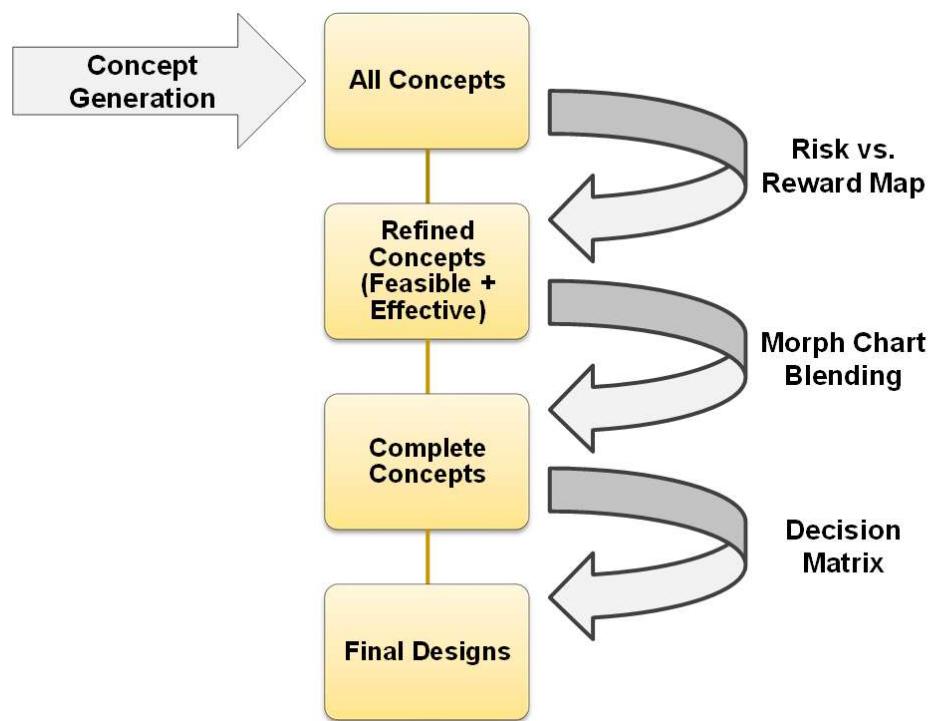
Method		Pros	Cons
Type of Cut	Clean Cut	Inhibits neuroma growth	Promotes nerve regeneration
	Grinding	<ul style="list-style-type: none"> <li>• Interrupts distal ends</li> <li>• Can pull out nerve debris</li> </ul>	Risk of neuromas
Type of Entry w.r.t MBN	Perpendicular	Targeted MBN destruction	Harder to locate the MBN
	Parallel	<ul style="list-style-type: none"> <li>• Attacks a larger area</li> <li>• Similar to RF Ablation</li> </ul>	Harder to damage the MBN

Further analysis and research is required to identify the optimal approach (cut + entry type) to unapproximating the nerve. Thus, the top designs of the top approaches were selected, as described in detail in **Section I**, as opposed to a singular design and approach.

Of all of these subfunctions from all of the devices, the team plans to develop preliminary prototypes of the Portal's interlocking mechanism and the Back Stabilizer's clamping and stabilization mechanisms. These are the most functionally complex mechanisms that can be tested within the scope of the preliminary prototype phase. The team plans to test the remaining functions through detailed analyses and by leveraging the test plans highlighted in **Section K**.

## I. Down Selection

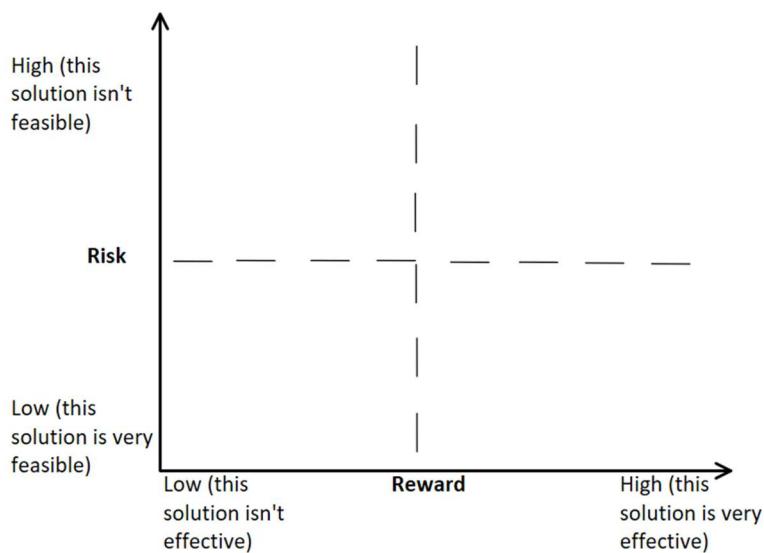
After concept generation, the team had an abundant number of concepts for each function. The end goal of this phase was to develop a few final designs through the process of down selection. This process involved narrowing the concepts down in a sensible fashion, developing a morphological chart of the reasonable concepts, blending individual concepts into complete concepts, and finally using decision matrices to settle on a few final designs. This down selection process can be visualized by **Figure I.1**.



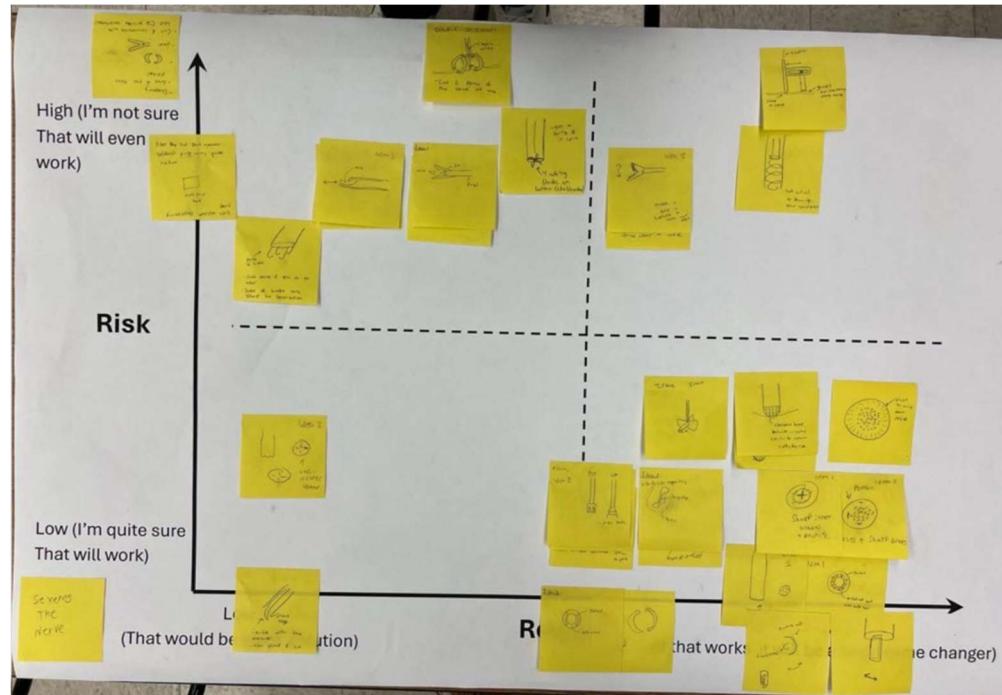
**Figure I.1** Down selection process

As noted in **Figure I.1**, the first step in the down selection process involved narrowing down all concepts. Concept evaluation was heavily driven by engineering factors such as feasibility and effectiveness, as well as business factors such as the estimated cost of manufacturing, design simplicity, ergonomics, and ease of use. In order to accomplish this, the team used a risk versus reward map (**Figure I.2**). The risk axis of the graph was used to determine the feasibility (how reasonable is this concept and how well can it be manufactured) of the concepts. The reward axis of the graph was used to determine the effectiveness (how well

would this concept accomplish the desired function) of the concept. For each round of concept generation, the developed concepts were placed on the risk versus reward map. The goal was to place each concept on the map independently of the other concepts in order to prevent any bias. Considering the bottom right quadrant of the map communicated all feasible and effective solutions, the team focused on evaluating only concepts in this quadrant. The team's goal was to narrow down each function to a final six (or less) concepts. For some functions, such as "cut/slide through flesh", there weren't even six concepts in the bottom right quadrant. However, other functions, such as "lesioning the nerve", had several concepts in this bottom right quadrant. In these cases, the team used intuition and logical reasoning to narrow down those functions. An example of the application of the risk versus reward map can be seen in **Figure I.3**, for which the team evaluated all Denervator concepts that were designed to lesion the nerve.

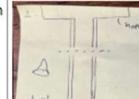
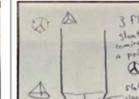
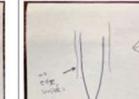
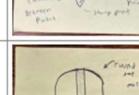
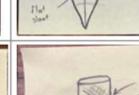
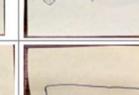


**Figure I.2** Risk versus reward map



**Figure I.3** An example of the application of the risk versus reward map for “lesioning the nerve”

After concepts were narrowed down for each function, the team developed morphological charts. This involved no more than just filling out the charts with the previously selected concepts. Considering there are four proposed medical tools which each have unique functions, the team developed four morphological charts – one for each tool. The leftmost column defines the function(s) encapsulated by the generated concepts, while the rest of the columns represent a different individual concept. **Figures I.4 through I.7** detail the morphological charts for each medical tool.

Function(s)	Option 1	Option 2	Option 3	Option 4	Option 5
• Cut/slide through flesh					
• Ease of use (handle)					

**Figure I.4** Morphological chart for the Stylet and its associated functions

Function(s)	Option 1	Option 2	Option 3	Option 4
• Constrain rotational and vertical motion of stylet with respect to portal (interlocking mechanism)				
• Dilate initial anesthetic injection cavity • Dock into pedicle • Guide stylet and nerve destruction tool				

**Figure I.5** Morphological chart for the Portal and its associated functions

Function(s)	Option 1	Option 2	Option 3	Option 4	Option 5
• Stabilize the device • Bottom out portal on the back stabilizer • Stabilize the portal easily (one-hand adjustment) • Constrain the portal's degrees of freedom to a ball joint					 Does not use spherical bearing

**Figure I.6** Morphological chart for the Back Stabilizer and its associated functions

Function(s)	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6
• Bottom out the tool on the portal (bump stop)						
• Bottom out the tool on the portal (handle)						
• Lesioning the nerve • Sever the nerve • Unapproximate the nerve • Displace any nerve remnants						

**Figure I.7** Morphological chart for the Denervator and its associated functions

The next step in the down selection process involved blending the morphological charts to develop complete concepts. A complete concept is a design composed of a singular concept from each row of the morphological chart to satisfy all desired functions. An example of the blending process for one of the Denervator complete concepts is detailed in **Figure I.8**.

Function(s)	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6
• Bottom out the tool on the portal (bump stop)						
• Bottom out the tool on the portal (handle)						
• Lesioning the nerve • Sever the nerve • Unapproximate the nerve • Displace any nerve remnants						

**Figure I.8** An example of the blending process for complete concept generation

The team developed as many complete concepts for each medical tool as felt necessary. It is important to note that not all concepts in the morphologic chart were integrated into complete concepts. Complete concepts were chosen as the best possible combinations of the existing concepts, therefore some concepts worked better with others and some concepts didn't work at all with others. The complete concepts developed by the team can be seen in **Figures I.9 through I.12.**

Functions	Concept S1	Concept S2	Concept S3
• Cut/slide through flesh			
• Ease of use (handle)			

**Figure I.9** Complete concepts for the Stylet

Functions	Concept P1	Concept P2	Concept P3
<ul style="list-style-type: none"> <li>Constrain rotational and vertical motion of stylet with respect to portal (interlocking mechanism)</li> </ul>	2 	1 	1 
<ul style="list-style-type: none"> <li>Dilate initial anesthetic injection cavity</li> <li>Dock into pedicle</li> <li>Guide stylet and nerve destruction tool</li> </ul>	3 	1 	3 

**Figure I.10** Complete concepts for the Portal

Functions	Concept B1	Concept B2	Concept B3	Concept B4	Concept B5
<ul style="list-style-type: none"> <li>Stabilize the device           <ul style="list-style-type: none"> <li>Bottom out the tool on the back stabilizer</li> <li>Stabilize the portal easily (one-hand adjustment)</li> <li>Constrain the portal's degrees of freedom to a ball joint</li> </ul> </li> </ul>	1 	2 	3 	4 	5 

**Figure I.11** Complete concepts for the Back Stabilizer

Functions	Concept D1	Concept D2	Concept D3	Concept D4	Concept D5	Concept D6
<ul style="list-style-type: none"> <li>Bottom out the tool on the portal (bump stop)</li> </ul>	2 	2 	3 	2 	3 	2 
<ul style="list-style-type: none"> <li>Bottom out the tool on the portal (handle)</li> </ul>	1 	1 	2 	1 	3 	1 
<ul style="list-style-type: none"> <li>Lesioning the nerve           <ul style="list-style-type: none"> <li>Sever the nerve</li> <li>Unapproximate the nerve</li> <li>Displace any nerve remnants</li> </ul> </li> </ul>	1 	4 	6 	2 	5 	3 

**Figure I.12** Complete concepts for the Denervator

The final step in the down selection process is applying decision matrices to the complete concepts. The decision matrix is a tool used to score and compare complete concepts to each other and market solutions. **Figure I.13** demonstrates a template of the decision matrix used by the team. Considering that there is a group of complete concepts to represent each medical tool,

the team created four decision matrices based on the four medical tools: there was an individual decision matrix for the Stylet, the Portal, the Back Stabilizer, and the Denervator. On the left-hand side of each decision matrix, the previously defined customer needs and functionalities are listed for each tool. These requirements were weighed on a scale of 1 to 3, where 1 represents the least important requirements and 3 represents the most important requirements. These weights were determined by the emphasis that the doctors (Dr. Mostoufi, Dr. George, and Dr. Hamouda) put on each customer's need, along with the engineering team's collaborative intuition. One the top of each decision matrix was the name of each complete concept being scored. This top row also listed a market competitor to be scored, if one existed. The rest of the space in between the requirements and concepts is where the scoring happened. Each concept (and competitor, if applicable) was scored with respect to each requirement on a scale of 0 to 5. In this case, a score of 0 meant the concept did not satisfy the requirement at all, while a score of 5 meant the concept satisfied the requirement perfectly. The scoring for each concept was done collectively by the team by applying their intuition, knowledge, and logical reasoning. The bottom row of the decision matrix applied the individual weights and score to determine a cumulative score for each concept. The four previously mentioned decision matrices (one for each medical tool) are detailed in **Figure I.14 through I.17**.

**Figure I.13** A template for the decision matrices used in the down selection process

		Concepts	Concept S1	Concept S2	Concept S3	Jamshidi Needle
Requirements	Weight (1-3)					
Ease of use/inability for mishandling	2		3	3	3	3
Effectiveness in cutting through flesh	3		5	3	5	5
Minimize collateral damage	2		4	3	4	4
Ease of manufacturing	1		4	2	2	3
		Total score	33	23	31	32

**Figure I.14** Decision matrix for the Stylet

		Concepts	Concept P1	Concept P2	Concept P3	Jamshidi Portal
Requirements	Weight (1-3)					
Docking into pedicle	2		4	3	4	0
Effectiveness of interlocking with stylet	3		4	4	4	5
Ease of disengaging of interlocked stylet	2		3	3	3	2
Ease of manufacturing	1		3	5	4	3
		Total score	29	29	30	22

**Figure I.15** Decision matrix for the Portal

		Concepts	Concept B1	Concept B2	Concept B3	Concept B4	Concept B5	MILD© Stabilizer
Requirements	Weight (1-3)							
Ease of adjustment for vertical constraint	2		4	3	4	5	5	0
Stabilize the portal	2		5	5	5	5	2	5
Vertically constrain portal via clamping	3		5	4	5	4	2	0
Ease of manufacturing	1		2	5	2	2	5	3
		Total score	35	33	35	34	25	13

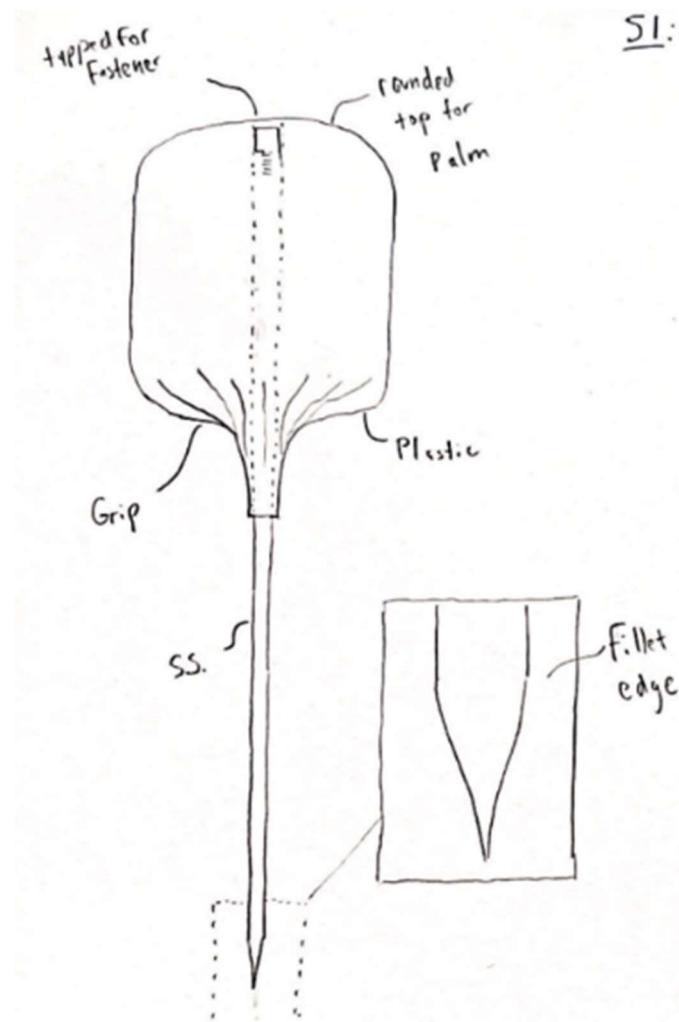
**Figure I.16** Decision matrix for the Back Stabilizer

		Concepts	Concept D1	Concept D2	Concept D3	Concept D4	Concept D5	Concept D6
Requirements	Weight (1-3)							
Ease of use/inability for mishandling	1		4	3	2	4	3	2
Minimizes collateral damage	2		3	3	3	4	3	3
Number of cuts produced	1		4	5	3	2	3	2
Interrupting distal ends	3		4	3	3	4	4	3
Bottom out the denervator on the portal	2		5	5	4	5	4	5
Length of nerve attacked	3		2	4	2	2	2	4
Ease of manufacturing	1		3	2	3	4	2	3
		Total score	45	47	37	46	40	44

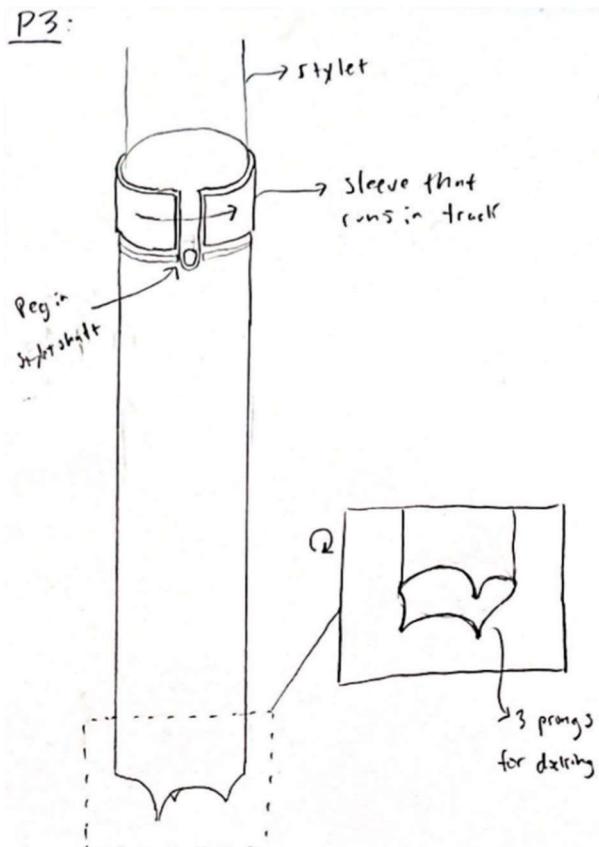
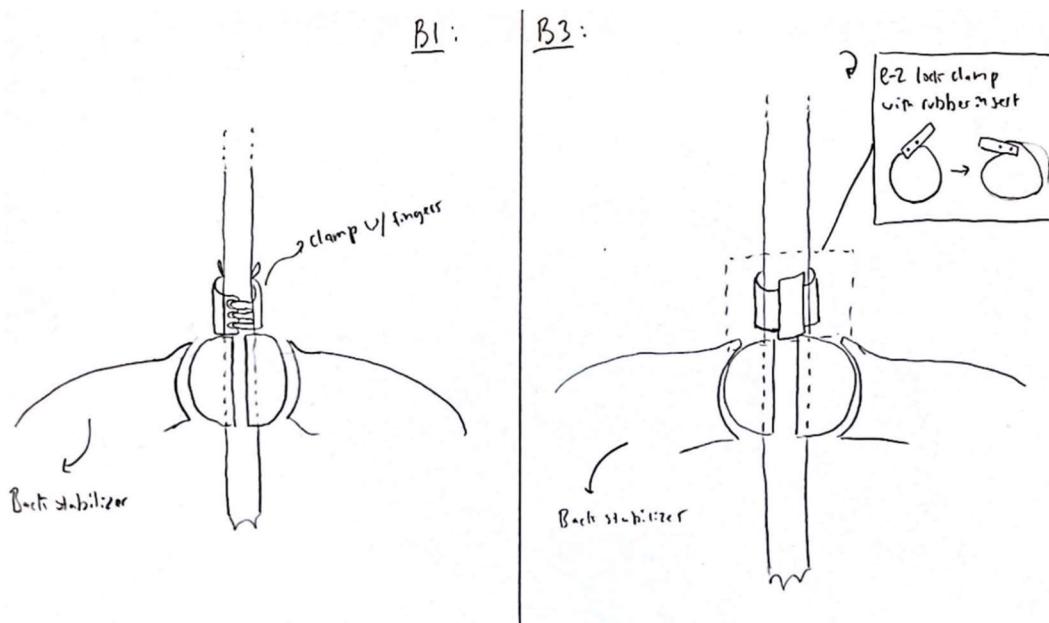
**Figure I.17** Decision matrix for the Denervator

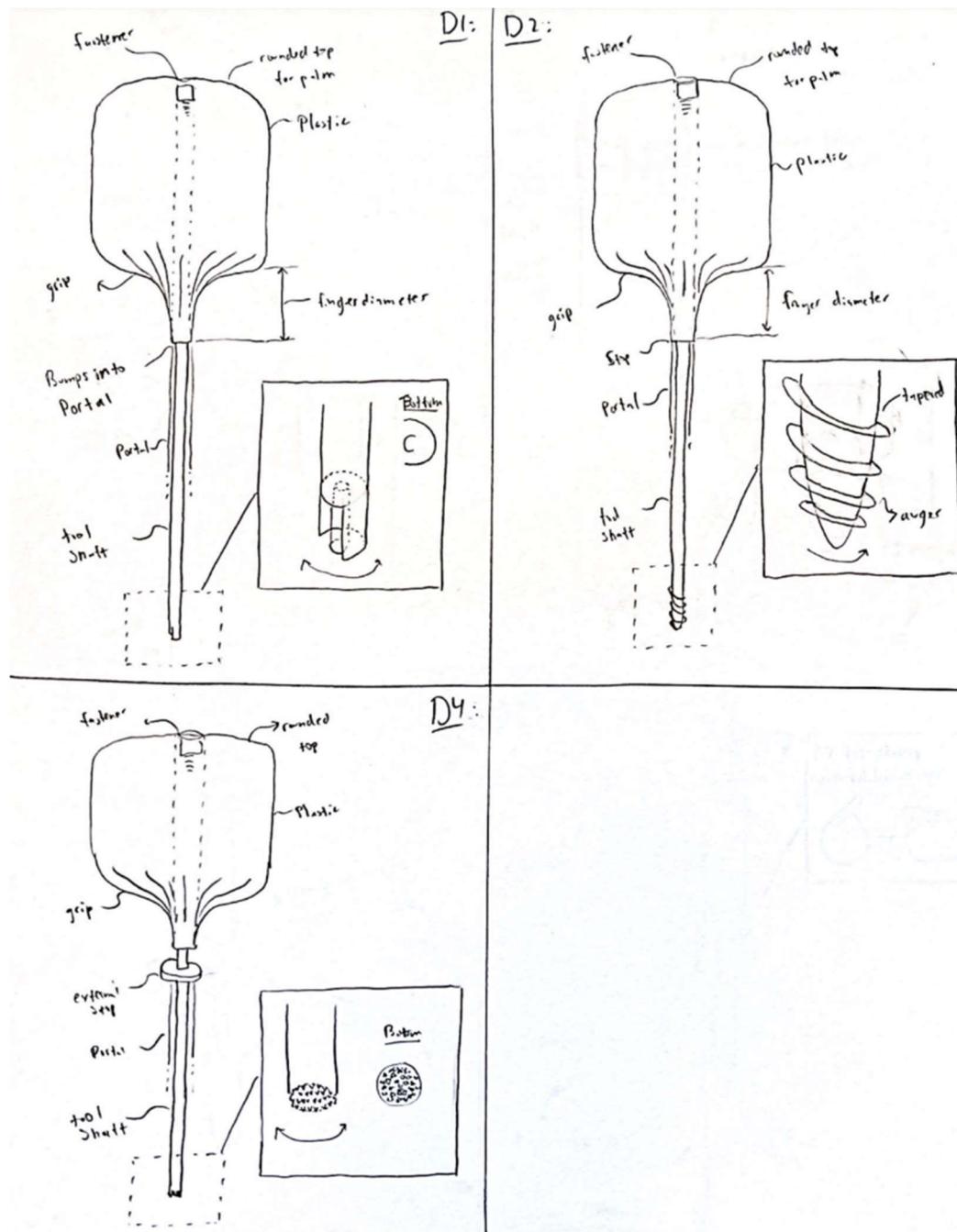
With comprehensive decision matrices, the team then made decisions on the final designs for each medical tool. To choose the final designs, the team had to properly score each complete concept as previously described. The scoring for the complete concepts was heavily driven by a multitude of general requirements. These general requirements include the ability to perform desired functions, the ease of use, the ease of manufacturing, the simplicity of the design, the integration between medical tools, and the minimized collateral damage. The priority of these general requirements is as listed (ability to perform desired functions is most important, minimized collateral damage is least important), which was previously discussed in **Section G**. These general requirements mostly overlap with the listed requirements, though the listed requirements are a bit more specific to each medical tool. After evaluating and scoring the medical tools based on this criterion, the team felt confident in choosing the complete concepts with the highest total score in the decision matrix.

For both the Stylet and Portal, three complete concepts were evaluated. Therefore, the team decided on a singular final design for each of these medical tools based on the results of their decision matrices. The final designs of the Stylet and Portal are detailed in **Figures I.18 and I.19**. For the Back Stabilizer, five complete concepts were evaluated in the decision matrix. From these five concepts, the top two were chosen as the final designs. These two designs are detailed in **Figure I.20**. Finally, for the Denervator, three of the six evaluated complete concepts were chosen as the final design. These three concepts are shown in **Figure I.21**.



**Figure I.18** Final design for the Stylet

**Figure I.19** Final design for the Portal**Figure I.20** Final designs for the Back Stabilizer



**Figure I.21** Final designs for the Denervator

The next phase of design revolves around analyzing and validating the final designs. Although the analysis hasn't begun yet, the team has established a plan for each medical tool. The first step of the analysis plan for all medical tools is to consult doctors about their opinions on the proposed final designs. After all, doctors are the direct customer, so it's important to ensure that the designs satisfy their needs as best as the team thinks they do. The team will then

perform technical analysis on each individual medical tool. It is important to note that all force-related tests will involve free body diagram analysis to ensure proper force distribution.

In order to analyze the final design of the Stylet, the team will perform FEA on the tip. The amount of force that the tip can withstand will communicate how efficient the design is with regards to cutting through skin and flesh. The desired results from this analysis are that the Stylet and Stylet tip can withstand 40N of direct force. This value would justify the final design of the Stylet.

The Portal has two pressing analyses which are important to perform to justify the design. To understand the strength of the Portal and its ability to dock into the pedicle, the team will perform FEA to analyze the stress on the prongs. Considering the prongs are stress concentrations, it is important to know how well they can withstand force. Similar to the Stylet, the goal is for the prongs to be able to withstand 40N of direct force. The other important method of analysis to be performed for the Portal is with regards to its manufacturability. The team will create a CAD model of the proposed final design and send this file off to a manufacturer. The goal is to gather insight from the manufacturer about how easy the tool will be to manufacture. It is desired that the manufacturer deems the Portal as “easy to manufacture”. If the Portal does not pass either of these analyses, then other concepts may need to be revisited.

With regards to the Back Stabilizer, the only aspect that can be analyzed as of now is the ease of use. The functions of the Back Stabilizer are all trivial to achieve, the only difference between the concepts is with regards to usability. Therefore, the analysis of the final designs will take place as discussions with doctors. The team will get doctors to rate the usability of the design on a scale from 1 to 5, where 1 is the hardest to use and 5 is the easiest to use. The goal is that one of the designs will have an average rating of at least 3.75, which would be sufficient to meet the target value defined in the engineering specifications chart.

The last medical tool to be analyzed is the Denervator. Considering it is near-impossible to analyze the effectiveness of nerve cutting pre-prototype, the team will focus on analyzing the strength, manufacturability, and effectiveness of the Denervator. Like the Portal, the Denervator will be created in CAD. With a functional cad model, the team will perform FEA to understand how much force the Denervator can withstand. The goal of this is for the Denervator to be able to withstand at least 40N of direct force. The CAD model will also be sent to a manufacturer to gather insight into how easy it will be to manufacture the Denervator. Like with the Portal, the

team's goal is that the manufacturer will deem this medical tool as "easy to manufacture". The last thing with regards to the Denervator to be analyzed is the effectiveness of the cutting method. Due to limited medical resources and expertise, the team hasn't been able to come up with a final method to cut the nerve. In order to understand this aspect of the project, the team will consult nerve doctors. The team has already discussed with them to set up a time, so there will be no issue connecting with the nerve doctors. Once the team is able to gain a deeper understanding about the proper nerve cutting method, they will be able to finalize the Denervator design.

## J. BOM & Sourcing Plan

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

ITEM ID	ITEM NAME	DESCRIPTION	QUANTITY	PART #	SOURCING	COST (\$)
1	<b>Stylet</b>					
1a	Shaft Body	4mm Diameter x 255mm Length shaft made from austenitic SAE 316 with a small cylindrical extrusion for interlocking mechanism and a tapped and threaded end for attaching the handle. The opposite end is a sharp point with unique geometry.	1 ft	#1325T2	McMaster-Carr	6.89
1b	Handle	roughly 100mm x 100mm x 100mm bulb shape made from PETG 3D printer filament	313 grams	#M-Y6C-YEZM	MatterHackers	6.53
2	<b>Portal</b>					
2a	Hollow Tube Body	6mm OD x 4mm ID x 250mm Length hollow shaft made from austenitic SAE 316 with two small machined vertical slits for locking mechanism.	0.5 m	#9811T12	McMaster-Carr	50.39
2b	C-Clip	10mm OD x 5mm ID x 20mm length C-clip with same size slit as hollow cylinder made from PETG 3D printer filament	0.34 grams	#M-Y6C-YEZM	MatterHackers	0.01
3	<b>Derenvator</b>					
3a	Shaft Body	4mm Diameter x 260mm Length shaft made from austenitic SAE 316 with a tapped and threaded end for attaching handle. Opposite end has a machined unique geometry for cutting nerve	1 ft	#1325T2	McMaster-Carr	6.89
3b	Handle	roughly 40mm x 40mm x 100mm bulb shape made from PETG 3D printer filament	50 grams	#M-Y6C-YEZM	MatterHackers	1.04
4	<b>Back Stabilizer</b>					
4a	Spherical Bearing	Corrosion-Resistant Swivel Joint, Lubrication-Free, 6 mm ID, 16 mm OD.	1	#63215K112	McMaster-Carr	47.8
4b	Latch Mechanism	6mm ID shaft collar with slit for portal to slide into then latch to restrict vertical movement. Made from PETG 3D printer filament	0.5 grams	#M-Y6C-YEZM	MatterHackers	0.01
4c	Base	Roughly 150mm x 150mm x 100mm ergonomical base that incorporates with 4a and 4b. Made from PETG 3D printer filament	700 grams	#M-Y6C-YEZM	MatterHackers	14.61
5	<b>Miscellaneous</b>					
5a	Aluminum Stock	3in x 3in x 3in block used for various fixes and minor features throughout all subassemblies	1	#9140T273	McMaster-Carr	35.7
5b	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
5c	Superglue	Loctite Professional High Strength Glue Super Glue 0.71 oz.	1 bottle	#1415645	Ace Hardware	8.99
5d	Fasteners/Nuts etc.	M2 x 6mm fasteners for attaching handles to shaft bodies	1 pack	#B07HGNCLV	Amazon	7.29
5e	Threaded Inserts	M2 threaded inserts for attaching handles to shaft bodies if the shaft bodies are not drilled and tapped	1 pack	#B088QJG676	Amazon	9.99

**Figure J.1** Preliminary BOM for all devices in the kit

The table is separated out by the five main components of the toolset. 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 majority of the items that the team needs for their toolset are sourced from McMaster-

Carr. The items that are purchased from this reputable company are then machined using the Purdue ME Machine Shop. The remaining items are 3D printed and the required filament to create the part is documented in grams for each item. The plastic pieces are created with the help of Purdue's Rapid ProtoTyping Lab. Finally, the cost per item for the quantity needed is listed.

## K. Test of Feasibility

Once the team develops preliminary prototypes, testing must be conducted to understand how well the prototypes accomplish the desired functionality. Although neither the prototype nor testing are within the current phase, it is important to begin planning the tests as early as possible. If the team can, at an early stage, identify what testing needs to be performed, then they can mold their testing around the feasibility of their tests and the availability of resources. This will set the team up to be equipped and well-prepared when it comes time to perform the tests.

Each medical tool will be tested in its own, unique way. The methods of testing are described below in **Sections K.1 through K.2**. Most tests revolve around the basic functionality and strength of the medical tools. However, it's important to note that strength analysis does not include fatigue strength. Since all the proposed medical tools are disposable (and therefore used one time), fatigue is a negligible concern. It is also important to note that the design is in the preliminary stages. Therefore, it is unclear how components will be assembled during prototype manufacturing. For this reason, fastener analysis, weldment strength, and epoxy strength tests will only be conducted as needed to verify the strength of each medical tool. Finally, the test plan will be considered an entirely non-destructive evaluation (NDE). This means that no physical prototype will be destroyed for test purposes. All destruction will occur via simulations, if at all.

## K.1 Strength Testing

### K.1.1 Stylet – Force required to cut through skin and flesh

**Test Purpose:** This test will determine the effectiveness of the Stylet at penetrating the body and whether the chosen design and material can withstand the required force.

**Test Assessment:** The Stylet will pass this test if it is able to penetrate skin and flesh without breaking and without exceeding 40N of applied force. If neither of these conditions are achieved, then the Stylet has failed this test.

**Test Resources:** This test will require a force gauge to measure the applied force and a mannequin to test on.

**Test Feasibility:** This test is feasible for the team to perform. A force gauge is easy to come by and can likely be found in labs across Purdue University. The team is also able to acquire a mannequin model from the doctors they have previously conversed with.

### K.1.2 Portal – Force required to overcome the interlocking mechanism

**Test Purpose:** This test will determine the effectiveness and strength of the interlocking mechanism regarding its ability to lock the Stylet and Portal together.

**Test Assessment:** The Portal will pass this test if the interlocking mechanism breaks at a force threshold above the previously discovered force required for the Stylet to penetrate skin and flesh. If the interlocking mechanism breaks under this force threshold, then the Portal will have failed this test.

**Test Resources:** This test will only require a virtual model of the Portal and FEA software.

**Test Feasibility:** This test is feasible for the team to perform. The Portal will already have been virtually modeled by the time the test will be run. Also, FEA software is readily available on computers at Purdue University.

### K.1.3 Back Stabilizer – Force required to overcome the clamping mechanism

**Test Purpose:** This test will determine the effectiveness and strength of the clamping mechanism regarding its ability to constrain the vertical motion of the Portal.

**Test Assessment:** The Back Stabilizer will pass this test if the clamping mechanism can withstand 40N of applied force. If the Portal slips within the clamping mechanism or if the

Back Stabilizer breaks prior to 40N of applied force, then the Back Stabilizer will have failed this test.

**Test Resources:** This test will require a force gauge to measure the applied force.

**Test Feasibility:** This test is feasible for the team to perform. A force gauge is easy to come by and can likely be found in labs across Purdue University.

#### *K.1.4 Back Stabilizer – Force required to overcome friction between the medical tool and skin*

**Test Purpose:** This test will determine the effectiveness of the Back Stabilizer's adherence to the skin via friction.

**Test Assessment:** The Back Stabilizer will pass this test if it does not move with respect to the skin with 40N of force applied. If the Back Stabilizer moves with respect to the skin with sub-40N of force applied, then it will have failed this test.

**Test Resources:** This test will require a force gauge to measure the applied force and a mannequin to test on.

**Test Feasibility:** This test is feasible for the team to perform. A force gauge is easy to come by and can likely be found in labs across Purdue University. The team is also able to acquire a mannequin from the doctors they have previously conversed with.

#### *K.1.5 Back Stabilizer – Forces required to break the spherical joint bearing*

**Test Purpose:** This test will determine the radial and thrust forces required to break the spherical joint bearing.

**Test Assessment:** The Back Stabilizer will pass this test if it takes more than 40N of radial and thrust force to break the bearing. If the spherical bearing joint breaks within 40N of radial or thrust force, then it will have failed this test.

**Test Resources:** This test will only require a virtual model of the bearing and FEA software.

**Test Feasibility:** This test is feasible for the team to perform. The bearing will already have been virtually modeled by the time the test will be run. Also, FEA software is readily available on computers at Purdue University.

## K.2. Functionality Testing

### K.2.1 Stylet – Ability of the Stylet to fit within the Portal

**Test Purpose:** This test will determine the ability of the Stylet to fit within the Portal.

**Test Assessment:** The Stylet will pass this test if it fits within the Portal without any interference. The Stylet will fail this test if interference exists between the Stylet and Portal.

**Test Resources:** The only resources required for this test are the Stylet and Portal.

**Test Feasibility:** This test is feasible for the team to perform. This is because the only resources required are the medical tools, which will have been manufactured by the time the tests will be performed.

### K.2.2 Portal – Usability of the interlocking mechanism

**Test Purpose:** This test will determine the relative ease-of-use of the interlocking mechanism.

**Test Assessment:** The Portal will pass this test if the average ease-of-use rating from doctors is at least 75%.

**Test Resources:** The only resources required for this test are the Stylet, Portal, and a few doctors.

**Test Feasibility:** This test is feasible for the team to perform. This is because the only resources required are the medical tools, which will have been manufactured by the time the tests will be performed, and doctors, three of which have already been identified.

### K.2.3 Portal – Ability of the Portal to dock into the facet joint

**Test Purpose:** This test will determine the ability of the Portal to dock into the facet joint.

**Test Assessment:** The Portal will pass this test if it can successfully dock into the pedicle under 40N of applied force. If the Portal isn't able to dock into the pedicle (such that it slides on the surface of the bone) under 40N of applied force, then the Portal will fail this test.

**Test Resources:** This test will require a force gauge to measure the applied force and a bone model of the facet joint.

**Test Feasibility:** This test is feasible for the team to perform. A force gauge is easy to come by and can likely be found in labs across Purdue University. The team is also able to acquire a bone model from the doctors they have previously conversed with.

#### *K.2.4 Portal – Ability of the Portal to fit within a 4mm incision*

**Test Purpose:** This test will determine the ability of the Portal to fit within a 4mm incision.

**Test Assessment:** The Portal will pass this test if it is able to both fit within a 4mm incision and not stretch the incision. If the Portal either doesn't fit within the incision or stretches the incision, then it will fail this test.

**Test Resources:** This test will require a mannequin to test on.

**Test Feasibility:** This test is feasible for the team to perform. The team is able to acquire a mannequin from the doctors they have previously conversed with.

#### *K.2.5 Back Stabilizer – Usability of the clamping mechanism*

**Test Purpose:** This test will determine the relative ease-of-use of the clamping mechanism.

**Test Assessment:** The Back Stabilizer will pass this test if the average ease-of-use rating from doctors is at least 75%. If the average ease-of-use rating is less than 75%, then the Back Stabilizer will fail this test.

**Test Resources:** The only resources required for this test are the Back Stabilizer, the Portal, a mannequin to test on, and a few doctors.

**Test Feasibility:** This test is feasible for the team to perform. This is because the only resources required are the medical tools (which will have been manufactured by the time the tests will be performed), doctors (three of which have already been identified), and a mannequin (which the doctors will have access to).

#### *K.2.6 Back Stabilizer – Range of motion of the spherical joint bearing*

**Test Purpose:** This test will determine the range of motion of the spherical joint.

**Test Assessment:** The Back Stabilizer will pass this test if the range of motion of the spherical joint bearing is 60 degrees from the vertical. If the range of motion is less than 60 degrees from the vertical, then the Back Stabilizer will fail this test.

**Test Resources:** The only resources required for this test are the Back Stabilizer and a protractor.

**Test Feasibility:** This test is feasible for the team to perform. This is because the only resources required are the medical tools, which will have been manufactured by the time the tests will be performed, and a protractor, which the team already has.

#### *K.2.7 Denervator – Ability of the Denervator to fit within the Portal*

**Test Purpose:** This test will determine the ability of the Denervator to fit within the Portal.

**Test Assessment:** The Denervator will pass this test if it fits within the Portal without any interference. The Denervator will fail this test if interference exists between the Denervator and Portal.

**Test Resources:** The only resources required for this test are the Denervator and Portal.

**Test Feasibility:** This test is feasible for the team to perform. This is because the only resources required are the medical tools, which will have been manufactured by the time the tests will be performed.

#### *K.2.8 Stylet and Denervator – Ergonomics of the handle*

**Test Purpose:** This test will determine how ergonomic the handle of the Stylet and Denervator is.

**Test Assessment:** The handle will pass this test if the average ergonomic rating is at least 75%. If the average ergonomic rating is less than 75%, then it will fail this test.

**Test Resources:** The only resources required for this test are the medical tools (the Stylet and Denervator) and a few doctors.

**Test Feasibility:** This test is feasible for the team to perform. This is because the only resources required are the medical tools, which will have been manufactured by the time the tests will be performed, and doctors, three of which have already been identified.

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