



LMBN Surgical Neurotomy Device

Capstone Senior Design Project • Spring 2024

Back in Action



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Vision Statement

We strive to develop a simple and effective functional medical tool kit and related procedure, to be used by operating specialists, thereby permanently relieving pain caused by the facet joint in every patient's lumbar region.

Problem Definition

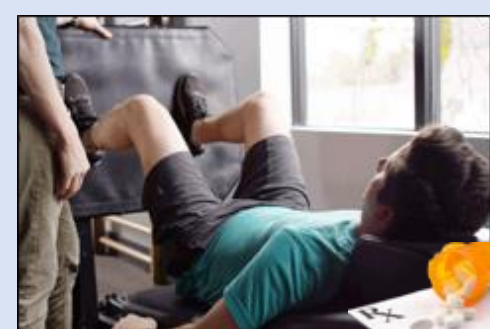
80% of all people experience some sort of back pain in their life

#1 cause of disability worldwide is back pain

25% of all lower back pain is induced by the facet joint

Market

Physical Therapy and Medication



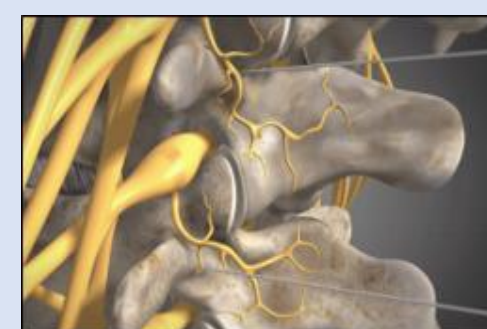
- Continuous treatment
- Not invasive
- Not very effective

Cortisone Injections



- Lasts ~3 months
- Very repetitive
- Can get expensive and tiring

Radio-frequency (RF) Ablation



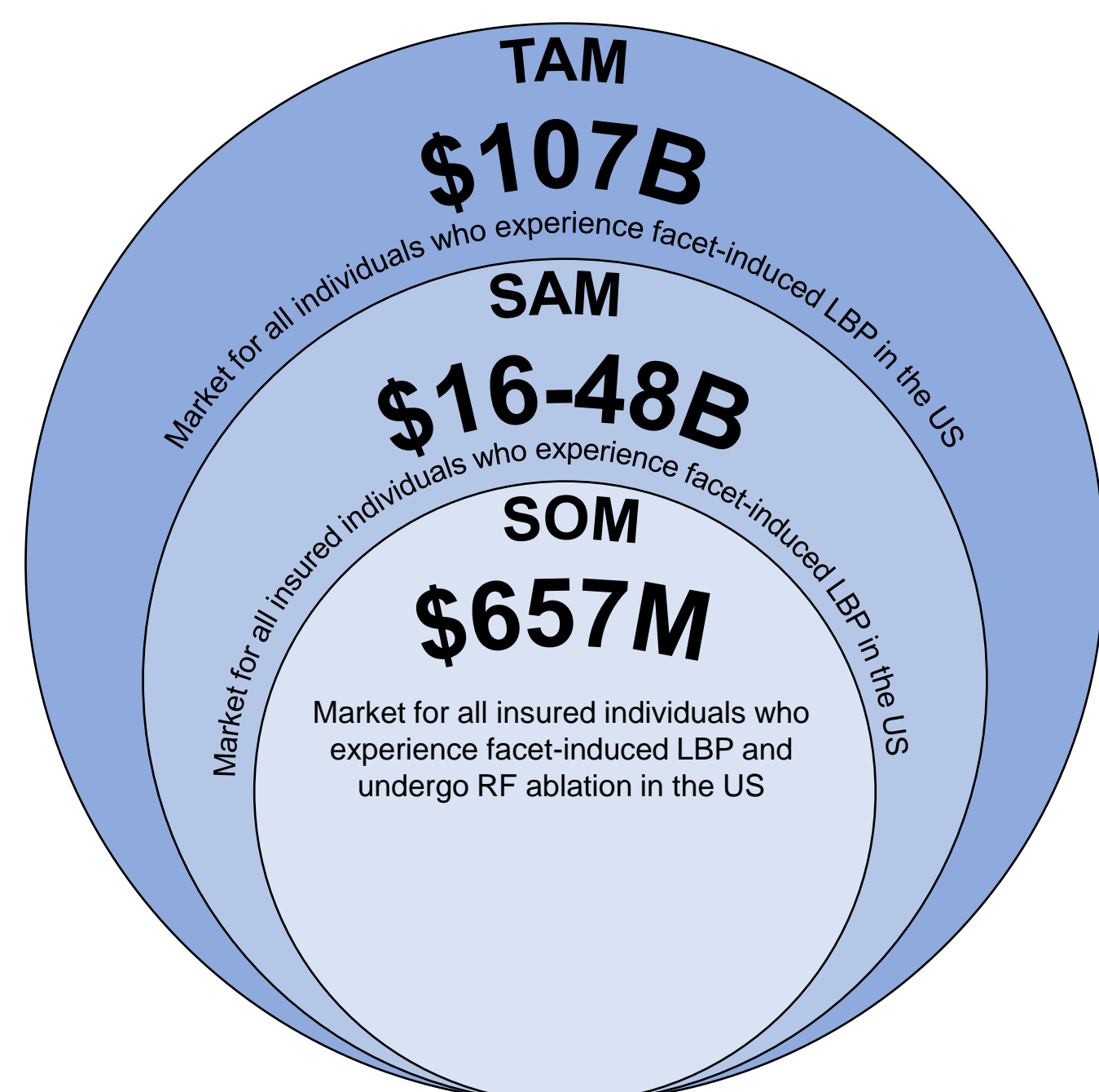
- Lasts 6-12 months
- Minimally invasive
- Can get expensive and tiring

Spinal Fusion



- Not permanent
- Very invasive
- Only 60% effective

Business Case

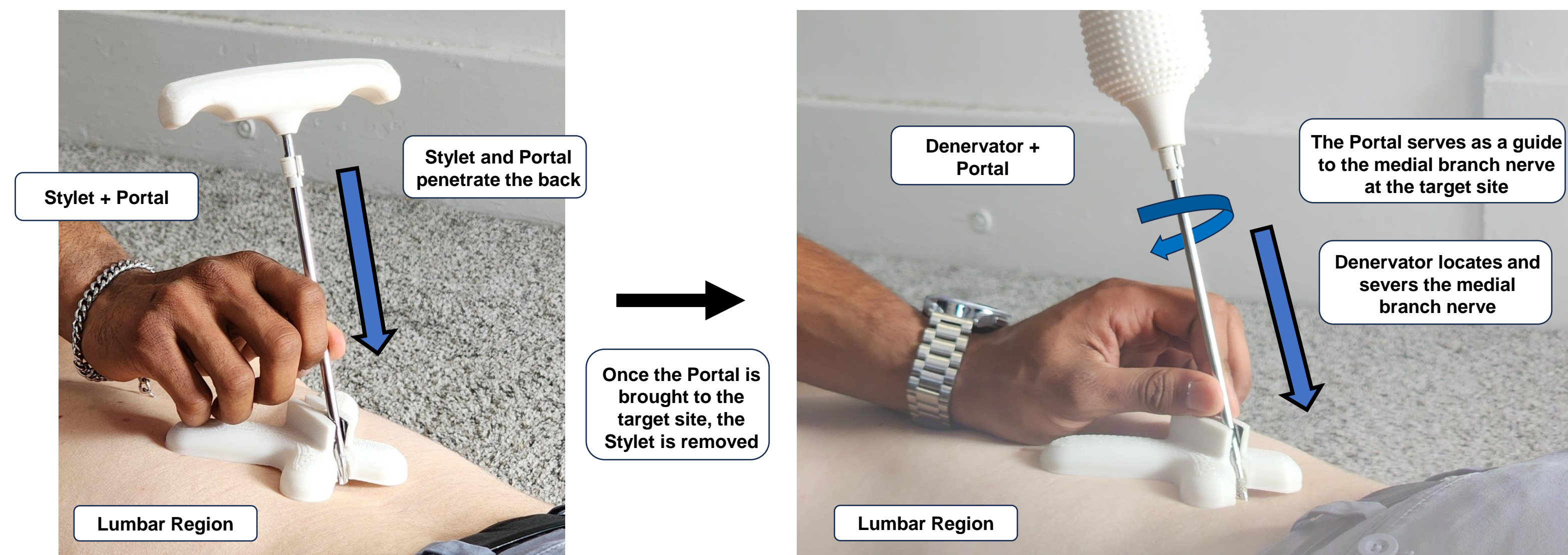


Unit Cost: \$288.07

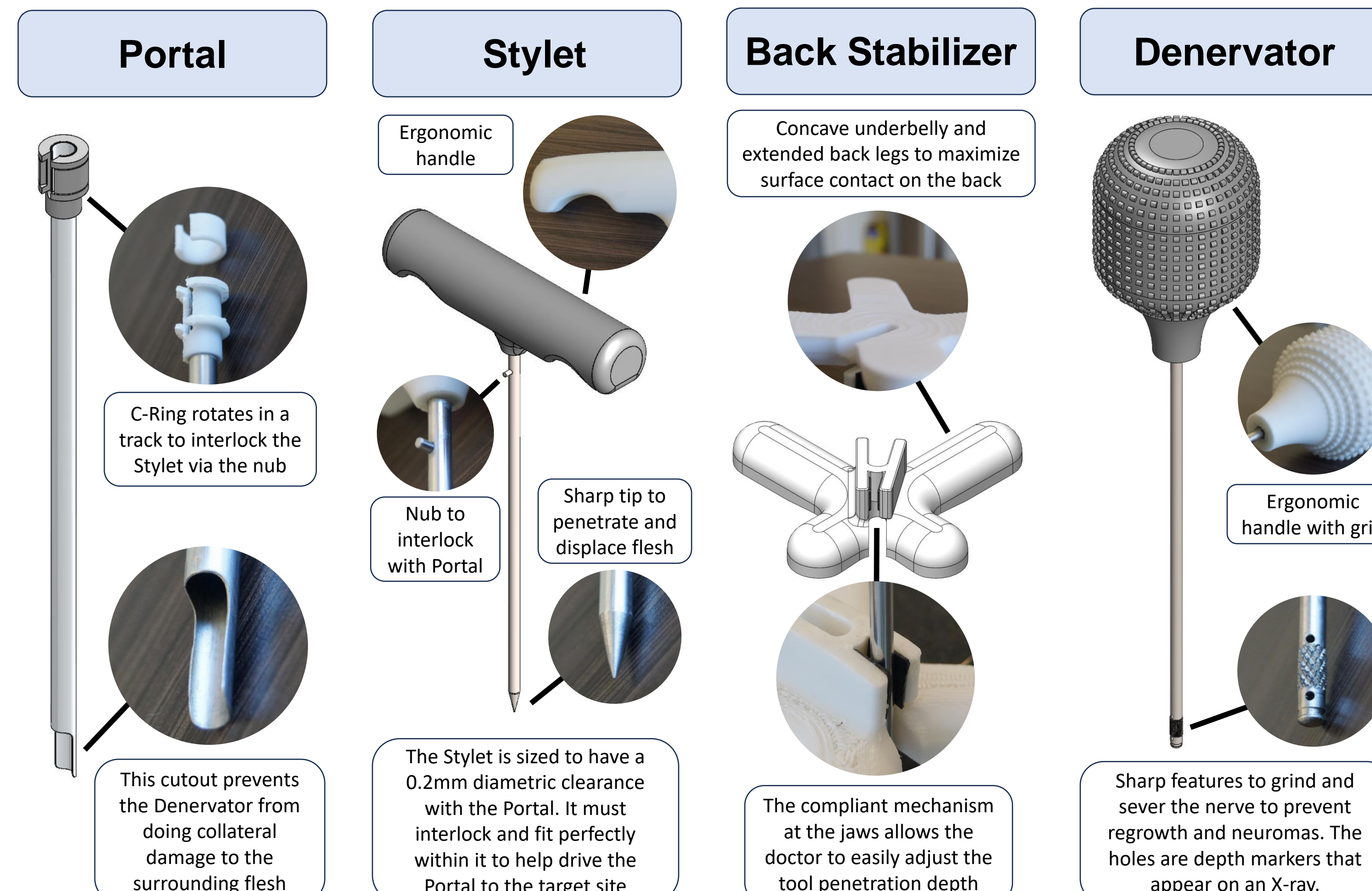
Sales Price: \$1,500

Annual Expected Profit: \$6.06M

Prototype



Design



Analysis

Thermal Analysis: The toolkit needs to be sterilized at high temperatures. Thermal stress analyses reveal that the devices will not deform and retain a high factor of safety.

FEA: Stress simulations were run to ensure all devices could withstand procedural loads with a factor of safety of 2. The compliant mechanism was also tested in conjunction with hand calculations to optimize the geometry for elastic but not plastic deformation.

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

Material Properties: Polypropylene and SAE316L were specifically selected for their biocompatibility and compliance with FDA regulations and ISO standards. They also had high thermal resistance, were easily manufacturable, and met ductility requirements.

Functionality: Clearances, interlocking tools, and fits were meticulously tested to ensure the proposed mass manufacturing process yields high-precision results. The ergonomics and feasibility of the procedure were deeply investigated through intensive research:

Validation Testing

Customer Requirement	Technical Need	Technical Requirement	Target Value	Result
Minimally invasive	Incision diameter	$\leq 12.7\text{mm}$	5mm	4.24mm
Initially sterilizable	Temperature withstood without deformation	$\geq 273^\circ\text{F}$	273°F	300°F
Correctly appears on X-ray	Validation score on a scale of 1-5	5	5	5
Effective and long-term pain relief	Length of displaced distal ends	$\geq 5\text{mm}$	7-8mm	6.46mm
Avoid neuromas	Length of displaced distal ends	$\geq 7\text{mm}$	10mm	6.46mm
Withstands procedural force	Force withstood without deformation	$\geq 20\text{N}$	40N	40N



Prototype and procedure demo

tinyurl.com/biapapd



Validation testing for customer requirements

tinyurl.com/biavtfc

Future

Preclinical and Clinical Testing: Continue testing and proceed to clinical trials to prepare for the FDA's 510(k) submission process.

Professional Consultation: Collaborate with medical professionals to refine and enhance our product design.

Market Entry Strategy: Consider licensing the product or leveraging distribution channels of established device manufacturers to introduce our product to the market effectively and minimize risk.

Furthered Medical Research: Continue investigating medical risks and optimal designs for preventing neuromas (benign tumors) and ensuring nerve unapproximation to yield a safe and permanent solution.

Sunderland Grade	Seddon	Site of Pathology				
		Myelin	Axon	Endoneurium	Perineurium	Epineurium
1	Neurapraxia	+	-	-	-	-
2	Axonotmesis	+/+	+	-	-	-
3	Axonotmesis	+/+	+	+	-	-
4	Axonotmesis	+/+	+	+	+	-
5	Neuritis	+	+	+	+	+

Key: + means affected, - means unaffected

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