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CND Life Sciences

SBHSE School of Biological and Health Systems Engineering

Automated Skin Punch Biopsy Tool

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BioCut SKIN PUNCH BIOPSY

Clinical Need

Background: Skin punch biopsies are commonly performed by dermatologists to diagnose skin cancer and inflammatory diseases. Recently, an innovative method for diagnosing synucleinopathies with skin punch biopsy samples was developed, leading neurologists to begin performing the procedure. However, neurologists typically lack experience with the procedure as it is not routine for their specialty.

Clinical Problem: Many of the biopsy samples received for diagnostic purposes have poor integrity and cannot be used. These samples may have been **pinched**, obtained with **insufficient volume,** or collected at an **incorrect angle** and often result in the patient undergoing another biopsy procedure. Feedback from these clinician suggests that the issue stems from difficulties with the biopsy tool kit.

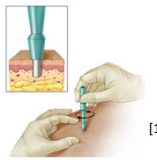

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Figure 1: Skin punch biopsy procedure.

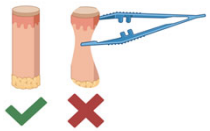


Figure 2: Effective vs Ineffective biopsy sample.

Mission Statement: BioCut is committed to innovation, precision, and compassion by developing diagnostic solutions that enhance patient care and support clinicians.

Market Analysis

2.5 million patients diagnosed with synucleinopathy, approximately **180,000** new patients diagnosed every year

The U.S. holds the highest market share in the neurodiagnostic segment, holding around **26%** of the worldwide market.

This device falls under the neurodiagnostic market. This market has a reported size of **$17.54 billion** and has a **CAGR of 3.8%** in the United States.

Design Inputs & Specifications

Customer Needs	Metrics	Specifications
Reduced sample damage	Syn-One Test/diagnostic sensitivity	>95% sensitivity
Usability	Number of steps in procedure	5 steps
Easy to use	Physician feedback	80% survey approval rate
Low cost	Cost per kit (≤$8)	≤$4/tool
Can produce at least 3 equal samples	Number of usable samples per procedure	≥3 equal samples
Consistent sample proportions	No deviations from current procedure	Depth: 5 mm Diameter: 3 mm

Table 1: Table shows customer needs, metrics, and specifications that are part of the design criteria.

Product Concept & Design

Tool Component	Calculation
Spring constant	0.0001 N/mm
Plunger activation force	5 N
Vacuum pressure	Suction: -125mmHg Ejection: 1.2 N

Table 2: Technical Specifications

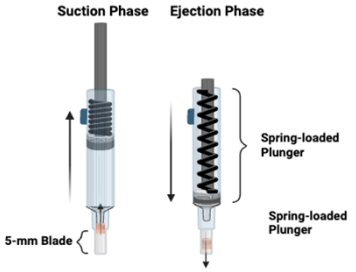


Figure 4: Vacuum-spring mechanism for extraction & ejection of sample.

This tool **replaces the tweezers and metal push rod** with a s**pring-loaded, negative-pressure mechanism** that gently retrieves and ejects biopsy samples without deformation. Clinicians will **only need this tool and scissors** to trim excess connective tissue. By standardizing applied forces, clinician variability is reduced.

Technical Modeling

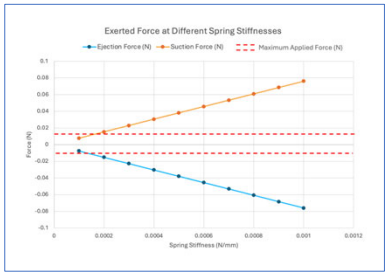
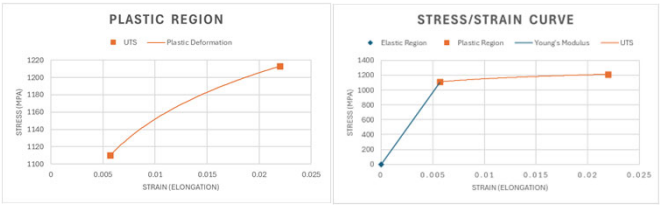


Figure 5. Exerted Force on Skin Sample at Varying Spring Stiffnesses.

Figure 5 shows how spring stiffness affects force applied to the sample. The red dotted lines indicate maximum allowable force that can be applied without tissue damage. Stiffness values within this boundary are safe for the spring design.



Figures 6 & 7: Stress-strain curve of stainless steel used for the blade. The model is used to determine that the force for insertion will not reach the plastic region.

Equations

Spring	Syringe	Plunger
$F = -k \times \Delta x$ Hooke's Law based on sample displacement	$P = \frac{F}{A}$ 1mm diameter Force applied > 125 mmHg to maintain sample integrity	$F_{Friction} = F_{Applied} + F_{Adhesion}$ Activation will require sum of forces in the system

Manufacturing Cost

Manufacturing Costs					
Body	Spring	Plunger	Syringe	Stainless Steel Blade	Total
$0.40	$0.20	$0.10	$0.30	$2.16	$3.16

All component costs were verified during the concept analysis verification of this tool. The body and plunger will be fabricated in 3D printing (PLA filament). The cost per unit will be $0.40 and $0.10 respectively, taking into consideration the amount of filament needed. The spring per unit can be bought in bulk by spring manufacturers and has an average cost of $0.20. Syringes can also be found in the market, amounting to $0.30 per unit when purchased in large quantities. The stainless-steel blade must be ordered from medical-grade manufacturers and amounts to $2.16 per unit given our specifications. This blade is sterilized and ready for use in packaging. 3D printer and assembly costs were not considered in this analysis.

Future Directions

Regulatory Pathway: The proposed pathway follows **Class II FDA classification** due to the invasive nature of the device. Existing market equivalents make an argument for a **510k Premarket Notification** pathway. To benchmark and test safety and efficacy we plan to run further tests to verify mechanical strength, sterility, and edge retention/sharpness of the blade to ensure satisfactory sample production, patient safety and a more efficient procedure.

Gantt Chart

Future Challenges: The physical design will present several key challenges, including ensuring consistent cutting performance and developing a structure that is both durable and easy to operate. Additionally, integrating the punch tool into a complete kit, along with clear instructional materials, will require careful consideration of usability, packaging, and reproducibility. We anticipate iterating on these aspects to meet our project goals and fully satisfy stakeholder requirements

Acknowledgements

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[1] "Punch Biopsy." Mayo Clinic, Mayo Foundation for Medical Education and Research, www.mayoclinic.org/tests-procedures/skin-biopsy/multimedia/punch-biopsy/img-20005764. Accessed 15 Nov. 2025.