



Core Biopsy Device for Low Resource Areas

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Introduction

Background

- 2.3 million women diagnosed with breast cancer and 685,000 deaths due to breast cancer in 2020¹.
- 60% of all breast cancer deaths occur in developing countries².

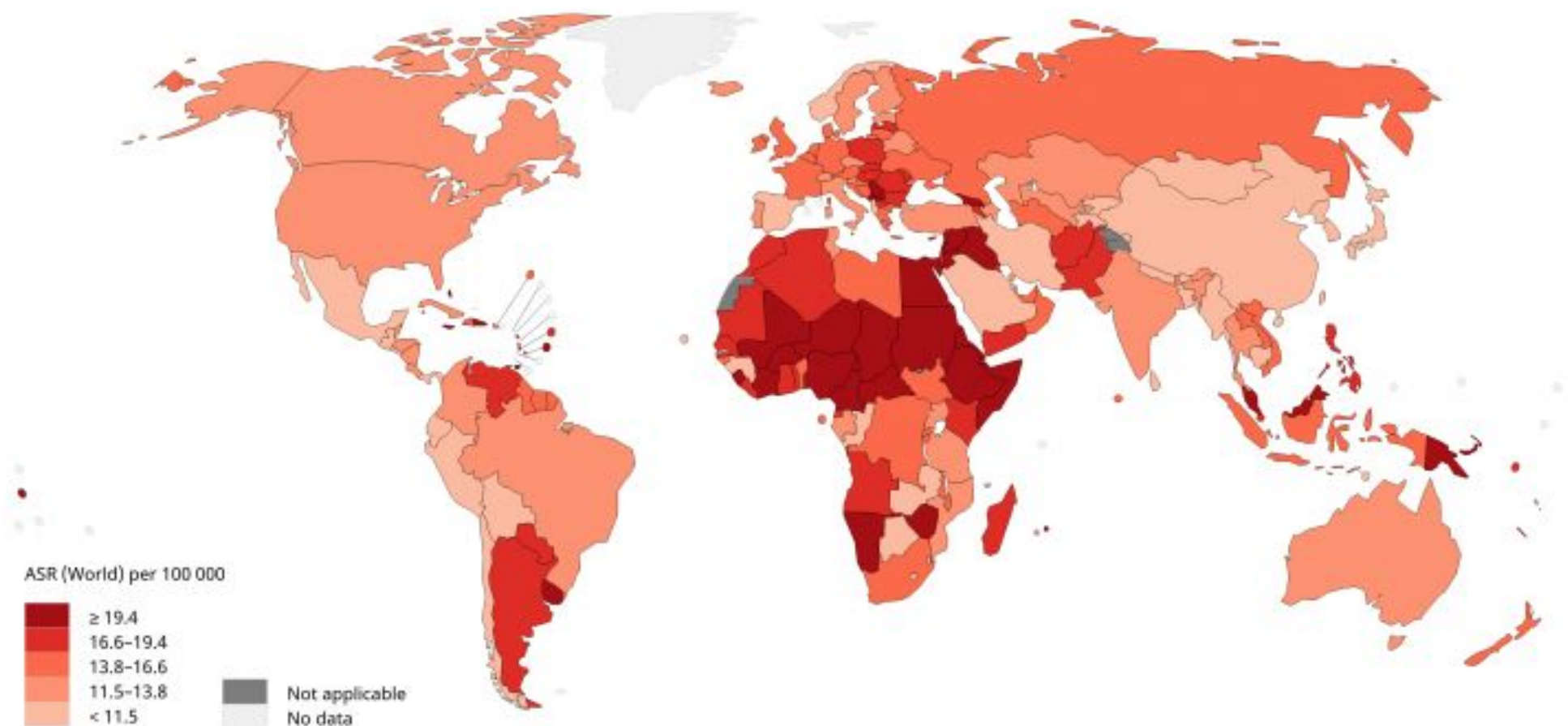


Figure 1. Mortality rates of breast cancer across the globe. Deeper red correlates to a higher mortality rate.³

Problems

- Difficult to use for physicians without extensive medical training.
- Mean cost for patient per core biopsy procedure is \$4,346.

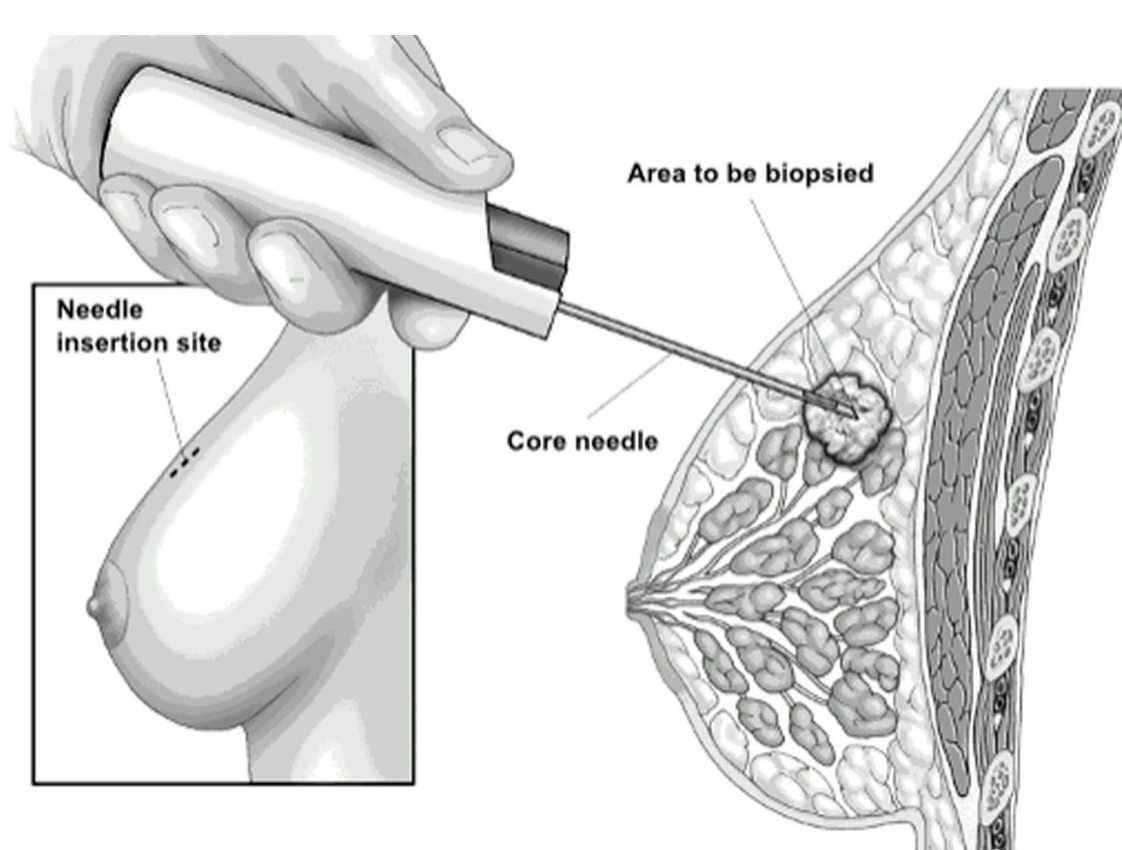


Figure 2. Core needle breast biopsy diagram.

Needs Statement

A **more affordable** core needle biopsy device that is **easy to use for healthcare providers** within **low resource areas**.

Current Devices

- Most devices are one-time use, leading to extra costs and waste.
- Average cost of a core biopsy device: \$243
- Bard is the current top producer of core biopsy devices



- Ithemba: patented by a Johns Hopkins student group.
 - Core biopsy targeting low resource areas.
 - Our device features a distinct launching mechanism.

Device Mechanism

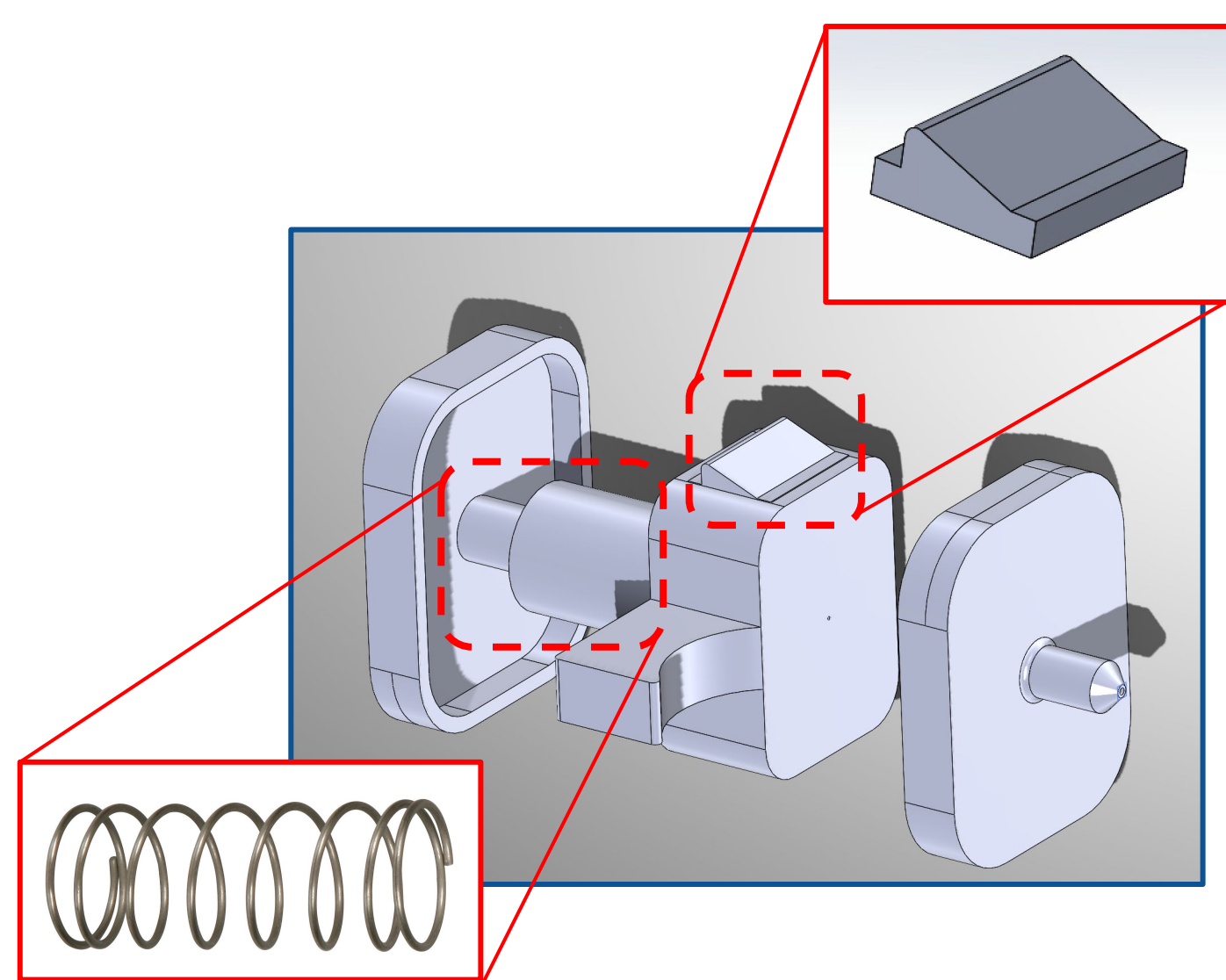


Figure 3. SolidWorks Model of Device Mechanism.

Components:

- 2 spring types (1 around shaft, 4 below button)
- Button

How it works:

- Pressing button decompresses the spring around shaft, which fires the device.
- Button slides underneath body and up through second hole.

Final Design

- Our main need is to create a reusable device that is easy to use and is more affordable, for low resource communities.
- With a press fit and multi component design, our final prototype can be easily taken apart, replaced, and repaired.
- The button mechanism provides a simple, mechanical way to launch the replaceable needles.

Prototype 0 → 1 → 2 → 3

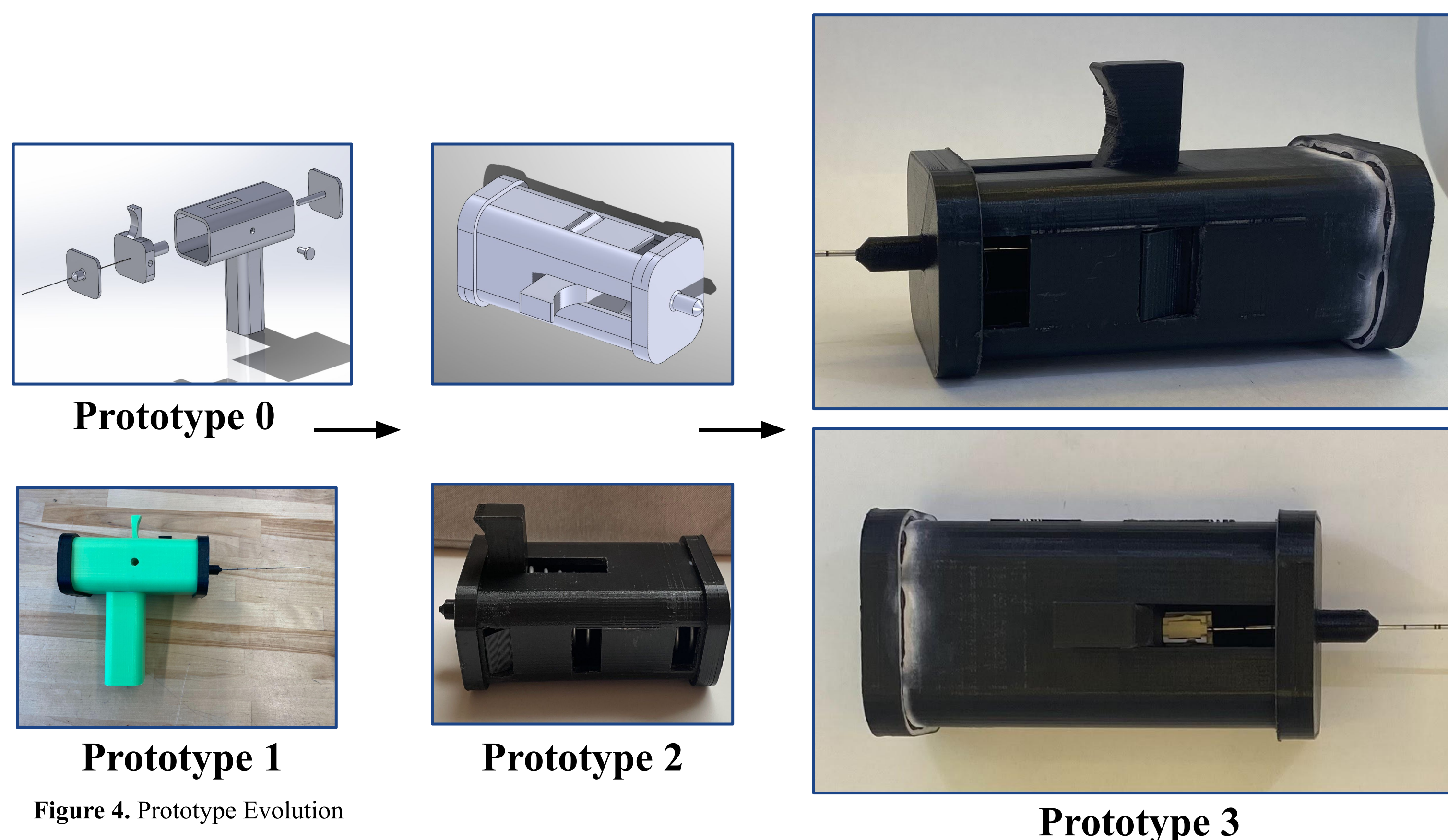


Figure 4. Prototype Evolution

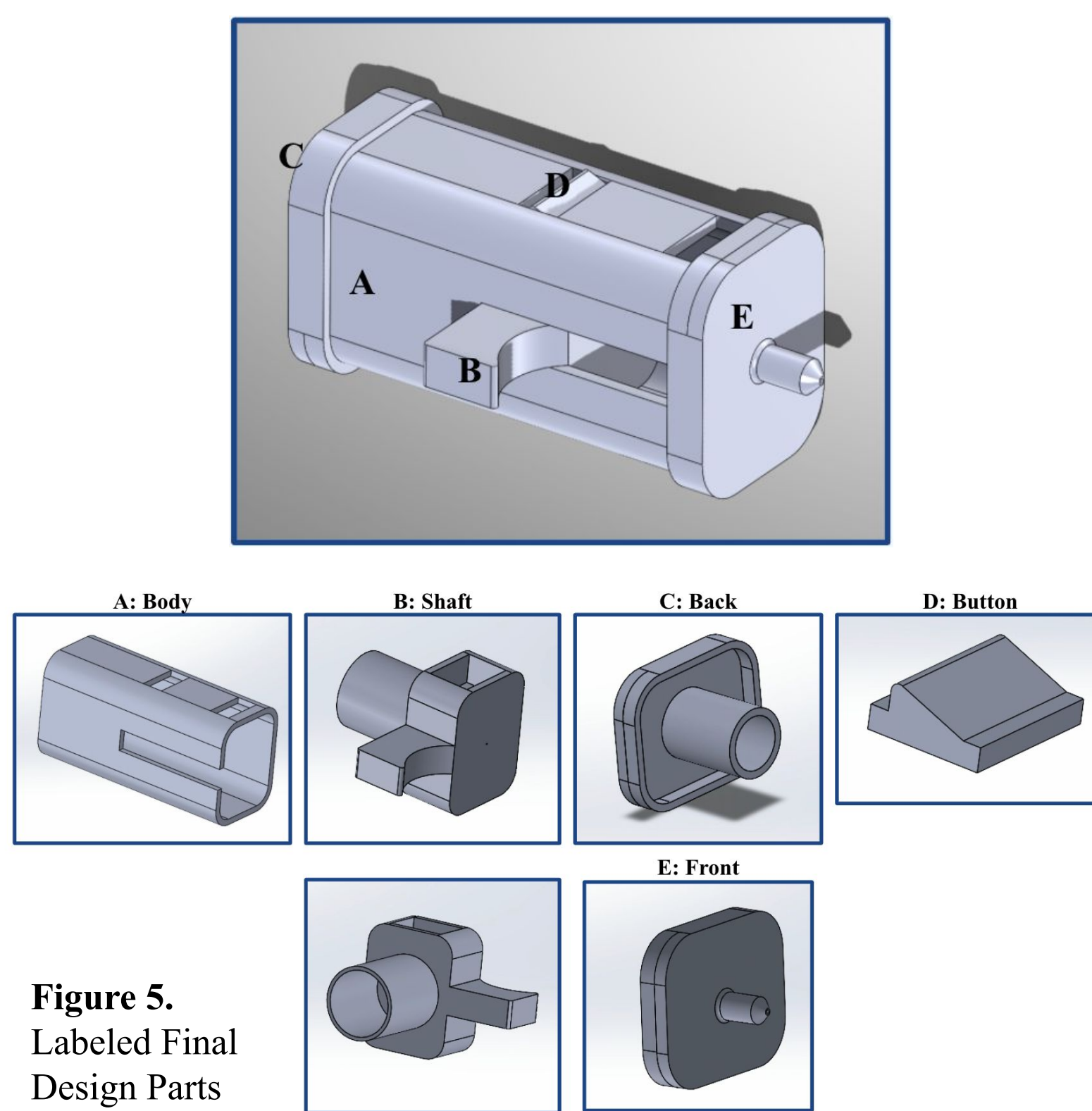


Figure 5. Labeled Final Design Parts

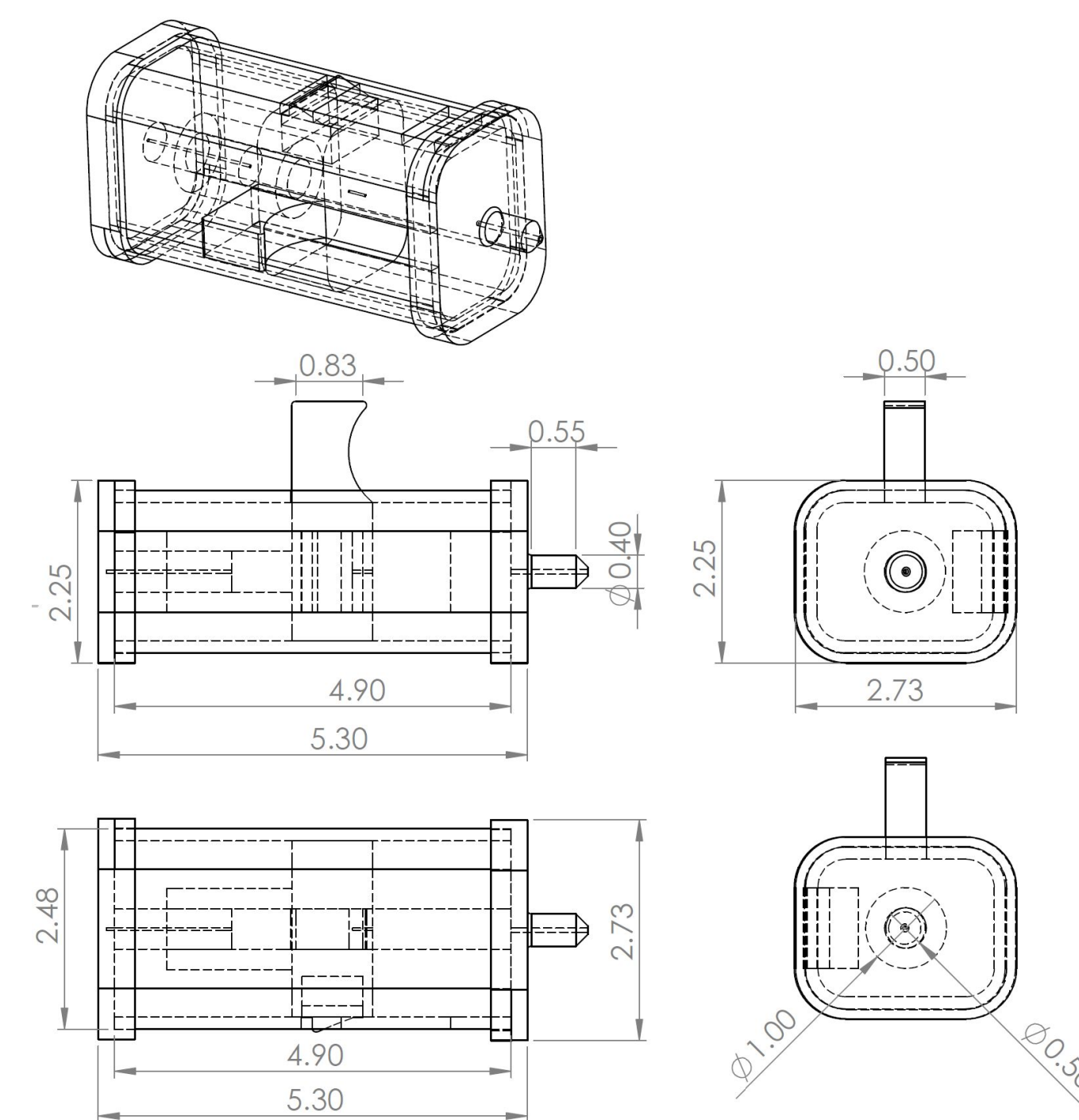


Figure 6. CAD Drawing of Inner Parts

Manufacturing Cost and Market Analysis

Manufacturing Info

One-time cost of 6 total molds: \$30,000

Large scale manufacturing cost breakdown (50,000 units)

	ABS	PC
Injection Molding Cost ^{5,6,7} (\$/lb)	1.30	2.30
Cost of Springs (\$/device)	4.30	
Cost of Needles (\$/device)	19	
Unit-Device Cost (\$/device)	25.19	25.41

Market Analysis

- Breast biopsy and device market estimated at \$528.7 million with a CAGR of 8.3% through 2027.⁹
- Target market: health care facilities/hospitals with limited resources and healthcare services.

Reimbursement and Patents

Patentability

- Ithemba – reusable core biopsy device, but lacks launching mechanism
- Bard, BD – reusable core biopsy device, but requires vacuum assistance
- Our device is patentable – presents a reusable device with a novel and low-cost mechanism for sample collection

Reimbursement

- Medicare and Medicaid fully cover core needle biopsies
- Outpatient: covered under Part B
- Inpatient: covered under Part A
- Reimbursement code: 19100
 - Biopsy of breast; percutaneous, needle core, not using image guidance.

Testing

- Prototype fired into a banana (n=15) to test effectiveness.
- Throughout these trials, the needle cavity was emptied and cleaned of remnants between each individual fire.

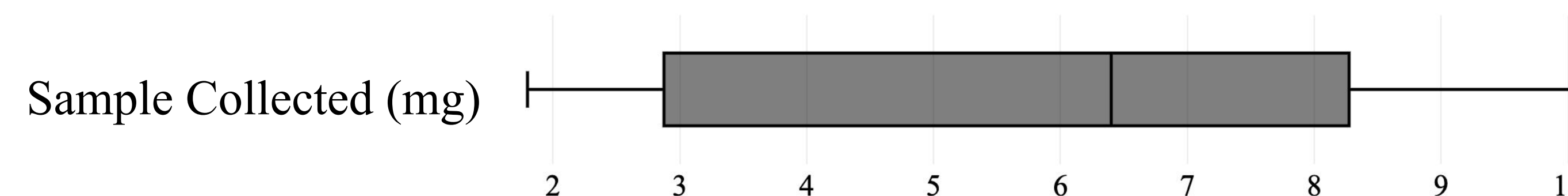


Figure 7. Box plot displaying results of banana testing (n=15) in terms of sample collected (mg).

Median Sample Collected on Prototype 3	Sample Collected on Bard Monopty Disposable Core Biopsy
6.4 ± 2.9 mg	6 mg

- Density of a banana: ~1 g/cm³
- Density of human breast tissue⁸: 0.950 - 1.020 g/cm³



Figure 8. (A) Image of prototype being inserted into a banana. (B) Sample collected in needle well after firing device.

Conclusion and Future Work

- In comparison to current devices, our prototype has been able to function properly and yield sample sizes with a comparable mass.
- Our testing has shown us that our prototype is able to function properly over several uses without showing signs of wear or damage.

Future Work

- Testing ethylene oxide sterilization as an effective method to sterilize the device between uses.
- Finding the optimal lubricant to use within the device to allow for a smoother firing mechanism.

Acknowledgements

We would like to thank Dr. Conrad Zapanta, Dr. Howard Edington, Alefia Kothambawala, and the Carnegie Mellon Undergraduate Research Office for their assistance on this project.

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