

Core Needle Biopsy Device for Breast Cancer

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INTRODUCTION

Background

- Breast cancer is the **most common cancer** among women in the US¹
- 42,000** women die from breast cancer each year²
- 60%** of breast cancer deaths occur in **low resource areas**²
- Early diagnosis** leads to better treatment outcomes

Diagnostic Methods

- Imaging Methods [i.e X-ray]: screens breast cancer
- Biopsies: **definitive diagnosis**
 - Core needle biopsy (CNB) collects sufficient amount of sample with **minimal invasiveness**

Current CNB Devices³

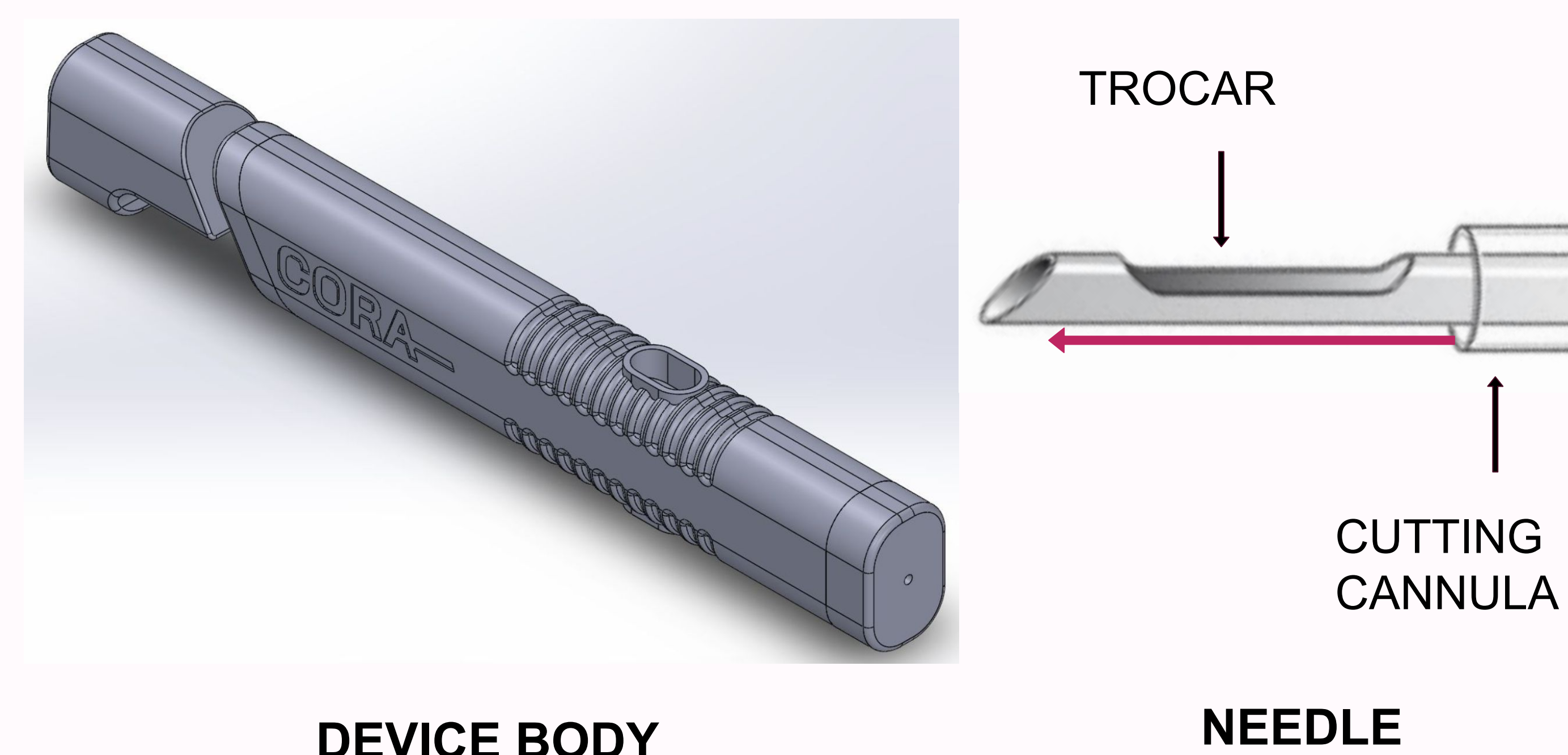


- Disadvantages: **non-reusable** and **expensive**
- Result:** inaccessible for low resource populations

Needs Statement

A more **compact** and **affordable** core needle biopsy device that is **one-hand operable** and available to healthcare workers **in low resource settings** to carry out biopsies independently.

PROPOSED SOLUTION



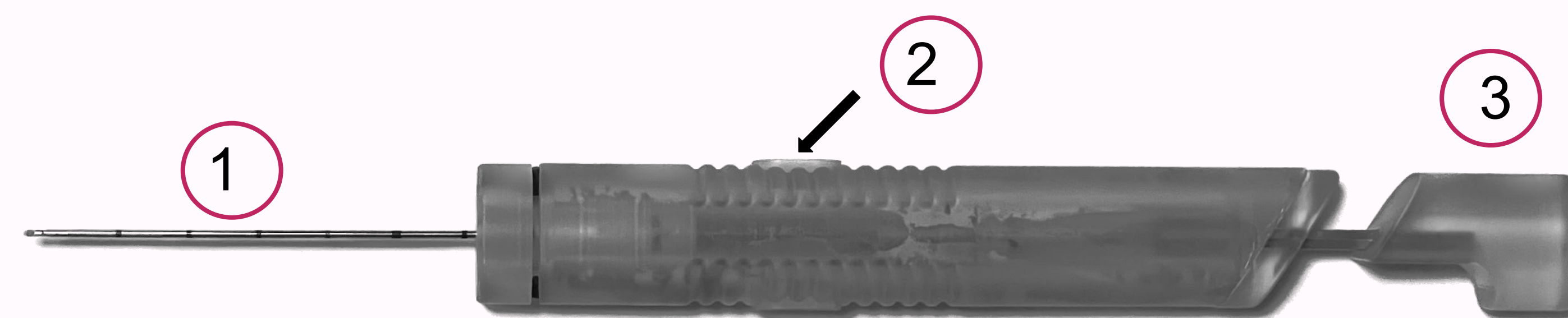
DEVICE BODY

NEEDLE

- Dimensions:** 15.5cm x 2.1cm x 1.5cm → **82% smaller** than BARD* Core Needle Biopsy (17cm x 4cm x 4cm)
- Ergonomic design:** allows **single hand** operability, **improved user maneuverability**, & **increases intuitiveness** of device
- Mechanism:** Firing the device causes the **cutting cannula** to **spring forward** over the trocar, thus **cutting the tissue** and **securing** the tissue sample.

*Existing core needle biopsy device

FINAL 3D PRINTED PROTOTYPE



- Needle: Trocar + Cutting Cannula
- Firing Trigger
- Plunger

TISSUE SAMPLE SIZE TEST

Method

- Needle inserted into banana which acted as breast tissue
- Sample mass was weighed after each trial
- 20 trials were performed

Success Criteria

- Reproducible (**std < 0.5 g**)
- Comparable to existing devices of the same gauge needle
 - tissue sample size of ~ **4mg**

Sample Type	Mass Collected (mg)
Banana	3.98 ± 0.4mg

SPRING LONGEVITY TEST

Method

- Mass Collection

Success Criteria

- Reproducible (perform **at least 5 test** cycles)

Test Result

Device successfully performed 20+ cycles

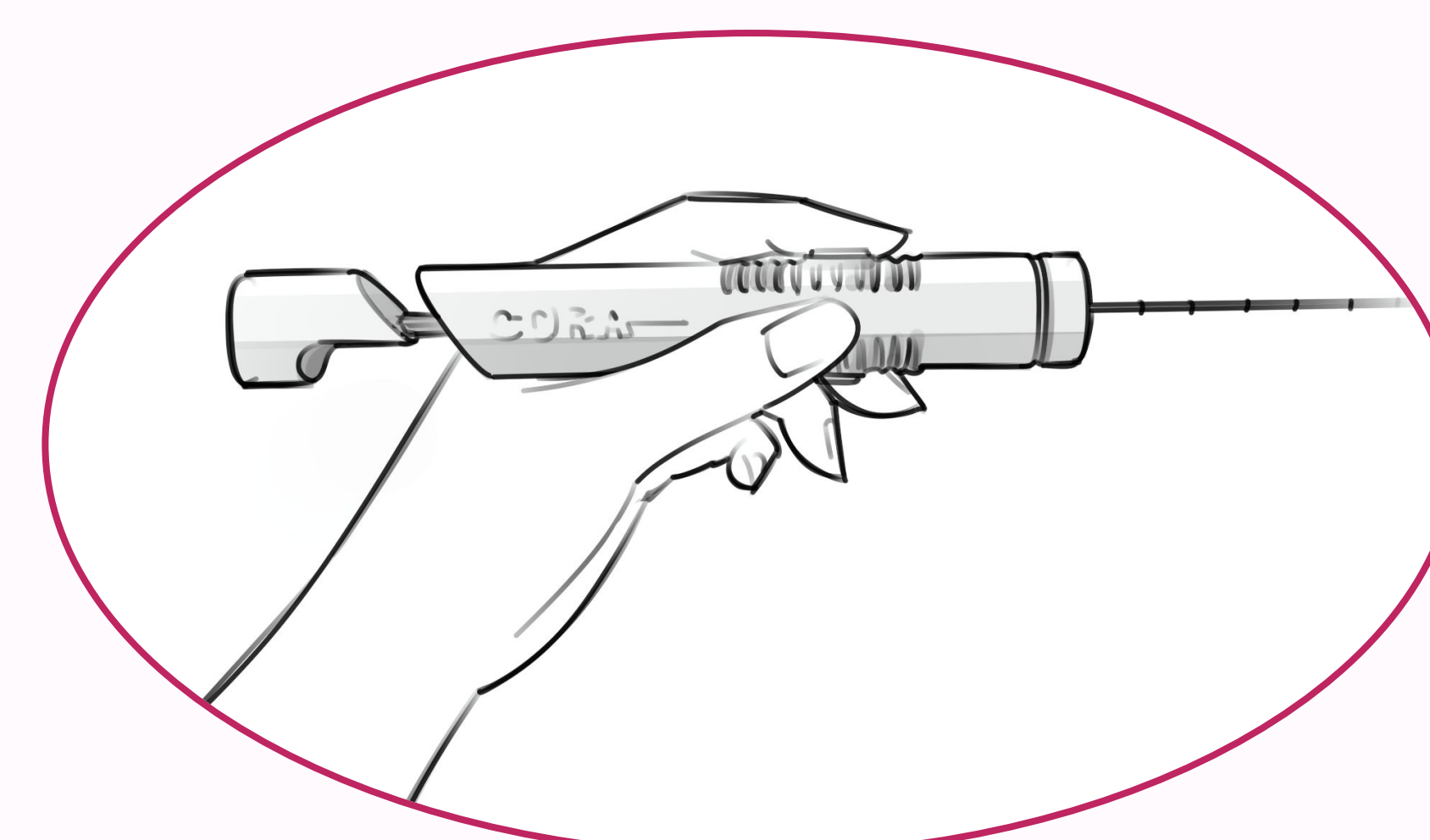
FORM FACTOR TEST

Method

- User Testing: medical professionals, potential users

Success Criteria

- ✓ One-hand operability
- ✓ Ergonomic Body Shape
- ✓ Intuitiveness
- ✓ Flexibility



Test Feedback

Rectangular body with ridged edges is most intuitive

MANUFACTURING COSTS, REGULATORY PATHWAY, PATENT & REIMBURSEMENT

Manufacturing Costs

Device	Device Retail Price (USD)
BD MC1410, 5/cs - 14G x 10cm	\$ 1,215
BD 1606MS, 5/Cs - 16G x 6cm, Needle Only	\$ 1,000
Our Device (Cost price only)	\$ 44.33

The cost price of mass manufacturing would only be \$44 which would enable a **low selling price** between the target range of **<\$100**.

Regulatory Pathway

- Class II device, **510(k) clearance needed**

Patentability

- The core working mechanism is standard and has been patented
- The external form factor is novel and can be patented

Reimbursement

- Biopsies are defined as 'medically necessary' procedures
- Breast CNBs are **covered by insurance**
- Ideally these devices would be supplied by health ministries/ government bodies and Global Health purchasers

CONCLUSION

- Ergonomic device is easy-to-use, reusable, and cost-effective (**<\$100**)
- Improving the accessibility to breast cancer diagnoses improves outcomes and **saves lives**.

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