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

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

- 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.

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.

Sample Collected (mg)

<table>
<thead>
<tr>
<th>Sample Collected on Prototype 3</th>
<th>Sample Collected on Bard Monopty Disposable Core Biopsy</th>
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</thead>
<tbody>
<tr>
<td>6.4 ± 2.9 mg</td>
<td>6 mg</td>
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- Density of a banana: −1 g/cm³
- Density of human breast tissue3: 0.950 - 1.020 g/cm³

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

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Manufacturing Cost and Market Analysis

- Manufacturing Info
  - One-time cost of 6 total molds: $30,000
  - Large scale manufacturing cost breakdown (50,000 units)

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<thead>
<tr>
<th></th>
<th>ABS</th>
<th>PC</th>
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<tbody>
<tr>
<td>Injection Molding Cost</td>
<td>1.30</td>
<td>2.30</td>
</tr>
<tr>
<td>Cost of Springs ($/device)</td>
<td>4.30</td>
<td></td>
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<tr>
<td>Cost of Needles ($/device)</td>
<td>19</td>
<td></td>
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<tr>
<td>Unit-Device Cost ($/device)</td>
<td>25.19</td>
<td>25.41</td>
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- Market Analysis
  - Breast biopsy and device market estimated at $528.7 million with a CAGR of 8.3% through 20273
  - 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 limited resources and healthcare services.

References

6. Finding the optimal lubricant to use within the device to allow for a smoother firing mechanism.