

**REDEFINING BREAST BIOPSIES**

# **BREAST WE CAAN**

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# Background

## Breast Biopsies

- Facilitates diagnosis of breast cancer
- Minimally-invasive tool for breast biopsy procedures



## Hologic SERTERA®

- Spring-loaded
- Improved User Interface
- Reduced Patient Discomfort



# Regulatory Assessment

- Class II Medical Device
- 510(k) Premarket Notification

<i><b>Predicate Device</b></i>	<i><b>Holder</b></i>	<i><b>Device</b></i>
<b>Achieve</b> Programmable Automatic Biopsy Needle	(Bauer Medical) CareFusion (Cardinal Health)	
<b>Monopt</b> Disposable Core Biopsy Instrument	C.R. Bard, Inc.	

# Clinical Strategy

## Post-Marketing Comparative Study



### Primary Endpoint

15% increase in usability score

### Secondary Endpoints

10% reduction in procedure time

5-10% greater accuracy

# Relevant Patents

<i>US Patent #</i>	<i>Description</i>	<i>Assignees</i>	<i>Relevance</i>
2004/0171989 A1	Biopsy Needle Device	Specialized Health Products, Inc.	Shield apparatus that includes housing to actuate cannula
6022362A	Excisional Biopsy Devices and Methods	Encapsule Medical LLC	Distal tip window for biopsy excision
<b>5368045</b>	<b>Biopsy Needle Instrument</b>	<b>Boston Scientific Corp.</b>	One-handed operable needle
<b>4953558</b>	<b>Tissue Sampling Device</b>	<b>C.R. Bard, Inc.</b>	Pre-tensioned, dual cannula structure

## Medium Risk

*(Disclaimer: Patents Pending for Hologic's SERTERA® Design)*

# Product Protection




**Defensive Strategy** - defend against patent infringement lawsuits

*Protected Technologies include:*

- User Interface Ergonomics
- Material Selection
- Actuation Mechanisms



# Risk Assessment

<i><b>Potential Failure Mode</b></i>	<i><b>Cause(s)</b></i>	<i><b>Effect(s)</b></i>	<i><b>Risk</b></i>	<i><b>Mitigation</b></i>
<b>External cannula improperly cuts tissue</b>	Actuator malfunction; Dull needle tip	Improper sample collection		Design verification; IQC and QC
<b>Non-sterile device</b>	Improper sterilization dosage; Loss of sterile barrier	Minor, localized infection		Sterilization validation; Distribution validation
<b>Cannula punctures internal organ</b>	Over-displacement of spring	Internal organ injury		Design verification and validation



Acceptable



Acceptable with Review

# Cost to Manufacture

Cost per Device: **\$23.34**

- Burdened Labor: **\$3.48\***
- Materials: **\$19.86**
  - (12) Parts for Assembly
  - (4) Parts for Packaging

*\*Burdened Labor Rate: \$15.00 / hr*

## DFMA Improvements:

- 1) Redesign Packaging



- 2) Stronger Snap Features



- 3) Standardize Spring Selection



# Value Proposition

SERTERA® provides the physician with *improved functionality* at a *reduced cost* for obtaining breast biopsy samples in patients.



# Reimbursement

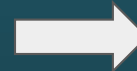
<i>CPT(R) / HCPCS Code</i>	<i>Description</i>	<i>Site of Service</i>
19083	Breast localization device(s) and imaging	Hospital
19084	Biopsy collection	Clinic



\$683.68 + \$559.15



\$1236.62 + Packaged



**\$2479.45**

# Summary

## **SERTERA® to Physician:**

- Ease-of-Use
- Confidence in Procedure

## **Physician to Patient:**

- Reduced Procedure Time
- Quality Biopsy Samples

## **Patient to SERTERA®:**

- Trust in Breast Biopsies
- Improved Compliance

