

## Product Design Specifications

September 12, 2002

Elizabeth Burnside – Client  
John Webster - Advisor  
Janie Goldsworthy – Communications  
Kristi Hinner - BSAC  
Nick Kortan – Team Leader  
Crystal Marshek - BWIG

**Title:** Improvement for fine needle aspiration (FNA) used during breast cell biopsies.

**Function:** A 20-25-gauge aspiration needle is inserted into the breast to extract questionable cells found during ultrasound mammography. Using ultrasound, the needle is positioned at the site where it is used to break up and disperse the cells. Even after the cells are loosened, it is unlikely that the hollow of the needle will collect a sufficient sample. Thus, the client suggested modifying the needle and/or the FNA technique in order to remove more cells.

A drill bit housed in the tip of the needle is currently being pursued as the method for extracting more cells. After the introducer needle is inserted into the breast, the inner drill bit is extended out past the tip of the introducer needle. Cells will travel up the threading of the drill bit and into the needle as the drill bit is turned.

**Client requirements:** The client would like us to modify the needle, so FNA could gain more confidence by medical professionals as a more effect, minimally-invasive means of obtaining cells samples over more invasive procedures such as core biopsy. For FNA to gain popularity among breast cancer specialists, a larger undamaged cell sample must be obtained on the first attempt.

**Design requirements:**

### **Physical and Operational Characteristics**

*Performance requirements:*

- Device will be used 1 time.
- Obtain greater number of cells from a mass of approximately 1 cm diameter.
- Constrained to standard 20-25-gauge needle, client prefers 23-gauge.
- Drill bit insert must be longer than introducer needle.
- Drill bit insert cannot extend 1cm past the tip of the needle.
- Needle should remain steady during the procedure.
- Large clumps of cells should be avoided due to problems with analysis.
- Minimal noise during procedure as to not startle the patient.
- Remain minimally invasive.
- Should not cause additional pain.
- Cells cannot be damaged during the procedure.

*Safety:*

- No part of the device should remain in the body after the procedure.
- When dislodging cells, device shouldn't spread cells a large distance from the needle.

*Accuracy and Reliability:*

- The device should obtain cells from varying density masses.

*Life in Service:*

- One use.

*Shelf Life:*

- Should be the same as current needle shelf life.

*Operating Environment:*

- Biological components (blood, fat, tissue).
- Body Temperature.
- Operator should be a medical professional able to judge distance using an ultrasound machine.
- If electrical component added to the device, shock could be a hazard.

*Ergonomics:*

- Similar to normal needle.
- Operator manipulation of the drill bit and introducer needle should be minimal.
- Drill bit should be easily rotated by the operator.

*Size:*

- Needle gauge should be 20-25.
- Drill bit insert must fit within the hollow of the needle.
- Drill bit insert must be longer than the introducer needle.

*Weight:*

- Needle should not increase more than 3 times its original weight.

*Materials:*

- Hypoallergenic
- Non-corrosive
- Not brittle
- Semi-hard

*Aesthetics, Appearance, and Finish:*

- Outside of needle should remain smooth

**Production Characteristics**

*Quantity:*

- Client currently only wants one device for testing. If device were successful, a medical company would need to mass-produce the product.

*Target Product Cost:*

- Less than \$5.00 per needle.

**Miscellaneous**

*Standards and Specifications:*

- Must be FDA approved

*Customer:*

- Affordable
- User- friendly
- Effective – short time required to perform aspiration or cell sample (i.e. – less than 20 minutes)

*Patient-related concerns:*

- Does not cause procedure to be more painful or more difficult

*Competition:*

- No known variations to the standard 20+ gauge needle for FNA use with breasts
- May be variation in technique that is more efficient