Steerable Biopsy Needle

Product Design Specifications

October 24, 2006

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Function : Design a biopsy needle that can be steered into the correct place when the desired location is missed while keeping current standards for core biopsy relatively the same. The operation of the needle must be intuitive to the user.

Client requirements : Our client requirements are as follows:

- Must be less than a 14 gauge needle
- Externally controlled
- Compatible with Ultrasound and Computed Tomography
- Core biopsy sample acquired from needle of quality close to current methods
- Ability to steer must not corrupt the tissue sample
- Realignment of needle must not require complete retraction of needle out of body
- Must not cause more damage than current biopsy needles
- Biopsies must be repeatable and predictable

Design requirements :

1. Physical and Operational Characteristics

a. *Performance requirements:* Must withstand internal body conditions and be strong enough not to break when inserted into the patient. However, it must be able to puncture soft tissue. Core biopsy standards similar to current non-steerable needles.
b. *Safety:* Needle user must have complete control of the mechanism and sterilized.
c. *Accuracy and Reliability:* Biopsy taken using this steerable needle must be easily taken. The steerable portion of the needle must react, in the same environment, the same every time.
d. *Life in Service:* Disposable.
e. *Operating Environment:* Our device will be exposed to normal hospital conditions. Needle will be used inside the body, so it must be able to be sterilized.
f. *Ergonomics:* Must be easy to use and the movement of the needle must be intuitive (turn left to make the needle go left)
g. *Size:* Must not exceed the size of a typical 14 gauge needle.

h. *Weight:* The weight will not be factored into our design, as it will be limited by the size of the unit, but must still be within reasonable standards.
i. *Materials:* All material used in this design, metal and polymers, must be compatible with environment of the human body and still me our design standards. .

2. Product Characteristics

a. *Quantity:* Only one unit will be necessary to meet the requirements of a successful design. This design should be reproducible, however.
b. *Target Product Cost:* Current needles cost approximately $150, so for our steerable needle will cost between $200 to $250

3. Miscellaneous

a. *Competition:* A group at the University of British Columbia is developing a steerable biopsy needle but it has not gone into clinical testing yet. Also, PneumRx have developed a steerable FNA needle that they are currently testing and marketing.