Fine Needle Aspiration (FNA) Device

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Function: Fine needle aspiration is a biopsy method of collecting tissue samples. The procedure is currently manual and requires repetitive low yield sampling to collect enough viable cells for testing. The goal of our project is to maximize tissue sample size in a single, timely procedure. We propose to develop a device that automates the current biopsy procedure, and tests the sample yield by varying the frequency and needle stroke. The test results will determine the optimal operating frequency at various stroke lengths to provide a maximum cell yield. The automation of the device will reduce operating time, cost and discomfort for the patient.

Client requirements: The device must:

- be reusable
- be durable
- be user-friendly
- be sanitary to clients standards
- comply with given hospital safety standards
- be dependable and precise
- test variations in frequency and needle stroke

Design requirements:

1) Physical and Operational Characteristics

a) Performance Requirements:
   i) Reusable
   ii) Withstand constant oscillation
   iii) Withstand multiple procedures
   iv) Withstand sterilization methods
   v) Needle force requirements
   vi) Vacuum mechanism to draw cells into needle easily operated by second person

b) Safety:
   i) No risk of electric shock
   ii) Non-toxic and non-allergenic
   iii) Preserve needle integrity

c) Accuracy and Reliability:
   i) Variable needle insertion depth (10mm to 20mm)
   ii) Frequency must be variable and measurable
   iii) Biopsy sample must be retained within needle shaft

d) Life in Service: Device must be operable over 30 minute interval

e) Operating Environment:
i) Sterile hospital environment
ii) 23°C standard room temperature

f) Ergonomics:
   i) Functional at varying angles of operation without losing maneuverability
   ii) Controls must be easily accessible

g) Size:
   i) Small and slender
   ii) Must not restrict maneuverability and accessibility

h) Weight:
   i) Must not strain arm and hand
   ii) Light weight

i) Materials:
   i) Light weight materials
   ii) Easily sanitized, especially materials potentially in contact with patient

j) Aesthetics, Appearance, and Finish:
   i) Marketable (aesthetically pleasing to patient and doctor)
   ii) Maintains professional medical device appearance

2) Production Characteristics
   a) Quantity: 1 prototype

   b) Target Product Cost: minimal, constrained by budget

3) Miscellaneous
   a) Standards and Specifications: FDA approval (human testing standards)

   b) Customer:
      i) Minimal training
      ii) Low production costs
      iii) User-friendly

   c) Patient-related concerns:
      i) Sterilized between uses
      ii) Minimal time, cost and pain
      iii) Professional aesthetics

   d) Competition
      i) Manual fine needle aspiration technique
      ii) Cameco Syringe Gun
      iii) Vacuum needle
      iv) Fine Needle Gun (Patent 7008383)