

Cervical Biopsy Device

Product Design Specifications

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Function

There is a demand for a more effective cervical biopsy tool that will be used in follow-up procedures after abnormal PAP smears, which indicate the need for a colposcopy. Current surgical biopsy devices are not entirely effective in obtaining adequate tissue samples due to difficulty manipulating the device within the cervix and also anchoring the biopsy forceps due to patient anatomy. The purpose of this project is to develop a small, inexpensive, easy-to-use disposable biopsy device.

Client Requirements

- Device with a small diameter to collect the tissue sample
- Inexpensive
- Easy to handle in the cervix
- Capable of maneuvering around other surgical instruments
- Either a disposable or a reusable tool

Physical and Operational Characteristics

a. Performance requirements: The device should be capable of being used for 10 to 15 seconds to collect the specimen. Typically, one to three biopsies are performed during one exam, thus the total operation only lasts for a few minutes. The biopsy tool should be strong enough to withstand insertion and extraction from the cervix.

b. Safety: The device must be sterilized and then packaged in order to prepare for storage before the operation.

c. Accuracy and Reliability: The biopsy tool should consistently extract a 3 x 3 to 4 x 4 mm sample of tissue.

d. Life in Service: The tool should last for the minimum amount of time needed to take one biopsy sample (estimated at 15 seconds to collect the tissue). Should the device be a reusable tool, it must be capable of withstanding several operations.

e. Shelf life: The device should be able to be stored at room temperature for long periods of time.

f. Operating Environment: The device will be used in an operating room and then inserted into the vagina to extract a sample from the outer edge of the cervix. The tool must be able to withstand a temperature range of 15 degrees Celsius to 55 degrees Celsius and a pH range 3.8 to 4.5.

g. Ergonomics: The surgeon should be able to comfortably handle the biopsy device with either hand and have good control of the device's movement.

h. Size: Current tools are about 24 cm long and the new device should have a similar length.

i. Weight: Current tools have a mass of around 70 to 85 grams . Depending on whether or not the device will be disposable, the weight may vary due to the change of material used.

j. Materials: The material used to construct the device should be safe to insert into the human body and should avoid, or at the very least minimize, irritation of the biopsy site.

k. Aesthetics, Appearance, and Finish: The device should have a smooth finish so as not to be abrasive.

2. Production Characteristics

a. Quantity: One biopsy tool will be used per biopsy.

b. Target Product Cost: The price range for current disposable models is from \$10 to \$15 per device, and reusable devices typically cost anywhere between \$200 to \$1000. Often times, reusable devices require an additional maintenance cost on a yearly basis. The new device should be competitively priced, whether disposable or reusable.

3. Miscellaneous

a. Standards and specifications: FDA approval is required.

b. Customer: The client suggests that a suction-type device may be the best solution to obtain a small core type sample, similar to a punch biopsy device. She also emphasized the potential of a disposable device.

c. Patient-related concerns: The device should be sterilized between uses if reusable or discarded if disposable. Patient comfort should be taken into consideration during design and construction of the device.

d. Competition: There are numerous biopsy devices on the market, both disposable and reusable. However, there are fewer options for cervical biopsy tools.