

Product Design Specifications

Function

There is a demand for a more effective cervical biopsy tool needed in follow-up procedures after an abnormal PAP smear is found. A physician recommends this procedure after an abnormal PAP smear indicates 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, and easy-to-use biopsy device that will produce consistently sized biopsy samples without loss of the biopsy during the procedure.

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 as well as be able to be used for numerous procedures. This device also must be able to be autoclaved in between each patient without fear of cross patient contamination. Ideally, this tool should require minimal upkeep and be able to continuously be used to decrease the relative cost of the device with each use.

b. Safety: The device must be sterilized and then packaged in order to prepare for storage before the operation. The device must be either disposable or compatible to autoclaving for complete cleaning in between various procedures. In addition, the device should not allow accidental cutting of the surrounding tissue.

c. Accuracy and Reliability: The biopsy tool should consistently extract approximately 3 x 3 x 2 mm sample of tissue, but have a minimum sample of 4mm³.

d. Life in Service: The tool should be able to withstand up to five biopsies per patient and as many patients as possible to keep down the relative cost of the design.

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 typically used in a doctor's office and then be 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. The material will also be able to withstand any applied force required for the physician to utilize to completely take the biopsy.

k. Aesthetics, Appearance, and Finish: The device should have a smooth finish so as not to be abrasive to any tissue it may come in contact with.

2. Production Characteristics

a. Quantity: One biopsy tool will be used for one session of procedure, which may include up to five biopsies.

b. Target Product Cost: The price range for current reusable devices is about \$200 to \$1000. Often times, reusable devices require an additional maintenance cost on a yearly basis. The new device should be competitively priced within this range.

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 as well as obtaining a consistent sample size.

c. Patient-related concerns: Since the device is reusable, it should be sterilized between uses. Patient comfort should be taken into consideration during the 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.