

How to Perform an Exocervical Biopsy with the SoftBiopsy® Gynecological Biopsy Device

1. Inspect the cervix as is customary for colposcopy after staining or application of acetic acid. Identify lesions or other areas for biopsy (occasional random biopsy as indicated). Lesions that extend onto the vaginal mucosa can also be biopsied using SoftBiopsy®.
2. Gently press the round tip onto the center of the lesion or cervical quadrant involved. Use pressure similar to tooth brushing. You may use a one handed or two handed technique to maintain the tip of the device on the biopsy target.



One and two handed technique on applying the device and guiding the biopsy procedure.

Softbiopsy® being applied, pressed and rotated gently.

3. Once the fabric pad is pressed firmly against the cervix target area, rotate the device 360° clockwise for three to five rotations, then 360° counter clockwise for three to five rotations. Alternatively, 6-10 half (180°) rotations (like key turning) in each direction may be used. Dry the lesion area with a cotton applicator or gauze prior to biopsy for the best tissue yield and placement.

4. Remove and inspect the KYLON® fabric pad. It should be filled with tissue and mucous. Snap the tip of the SoftBiopsy® device and place tip in a (non-alcohol) vial of fixative. Discard or recycle the acrylic plastic handle.



Separating head of device from handle



SoftBiopsy® head with tissue in vial

SoftBiopsy® Device SFT-1000

Indications for Use:

Bedside:

SoftBiopsy® is intended to be used in clinical scenarios where exocervical or vaginal biopsy is indicated. This includes, but is not limited to sampling lesions of the cervix that are suspected of being neoplastic during the colposcopy examination.

Contraindications:

SoftBiopsy® should **not** be used in clinical scenarios where exocervical biopsy is contraindicated during pregnancy or suspected pregnancy.

Laboratory:

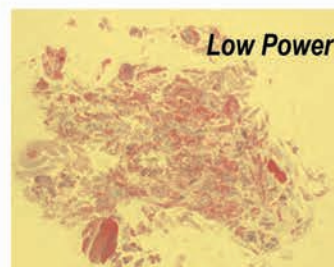
Samples of tissue should be carefully and completely removed from the KYLON® fabric in the laboratory and may be processed and evaluated using a standard histologic technique. The specimen contains abundant multiple histology samples that can be removed by simply scraping the fragments off the KYLON® pad with a small fine comb, knife blade, or tweezers.



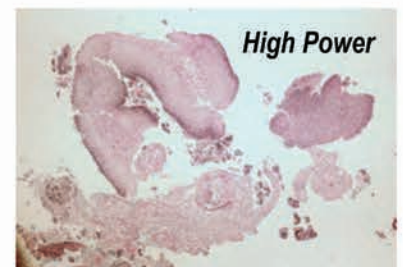
Application and Rotation



Post-Biopsy



Low Power



High Power

Full thickness and abundant histology sample

Exocervical Biopsy with SoftBiopsy®

SoftBiopsy® frictional specimen removal, storage and transport device system: SoftBiopsy® employs a Kylon® fabric that has a dual function: when pressed and rotated on the target tissue it frictionally de-bonds the epithelium from the underlying stroma at or just below the basement membrane. It also sweeps and retains the tissue inside the fabric hooks and holds (contains) the specimen, so when placed in (non-alcohol) preservative, the entire specimen is transported back to the lab. This dual tissue removal and storage system is registered with the Food and Drug Administration.

SoftBiopsy[®] is the NEW simple and gentle approach to perform a cervical or lower genital tract biopsy

During clinical settings such as colposcopy, a biopsy of the exocervix or lower genital tract may be indicated. If there is a suspicion of neoplasia, the **SoftBiopsy[®]** device, with a patented fabric (KYLON[®]) on the round tip, can be used to collect tissue from the cervix as an alternative to other punch biopsy devices. This device is designed to provide abundant trans-epithelial histology samples. When carefully applied to the lesion, pressed, and rotated, the round flat platform tip (just under 1/2 inch in diameter) KYLON[®] fabric will excavate numerous full thickness tissue pieces like multiple small punch biopsies. The **SoftBiopsy[®]** microscopically lifts, removes, and simultaneously collects the specimen within the basket rows of hooks and fabric. The KYLON[®] pad and distal device head can be simply snapped from the handle after the biopsy and placed in a (non-alcohol) liquid fixative vial for transport to the lab.

WHY USE THE SoftBiopsy[®] DEVICE?

- **Ease of use: Apply with moderate pressure to the cervical or vaginal lesion and rotate to gently biopsy**
- **No pinching or cutting tissue**
- **Minimally invasive design**
- **Abundant histological sample: simultaneous tissue collection and storage of the specimen for transport**
- **Process as is customary for exocervical biopsy sample in the laboratory.**

What is KYLON?

KYLON[®] is a fabric with hooks that gently biopsies by compressing and frictionally lifting intact tissue fragments and simultaneously collects the specimen within the rows of hooks and fabric.



SoftBiopsy[®]
Model SFT-1000
manufactured by:

HISTOLOGICS

4095 E. La Palma Ave., Ste. N
Anaheim, CA 92807
Phone and FAX: (888)-738-9757

histologics@gmail.com
www.histologics.com
Twitter: @Histologics LLC