

SOFTBIOPSY® - GYNECOLOGICAL DEVICE:

SoftBiopsy® is not designed or intended to perform an endocervical biopsy. If endocervical curettage is needed for complete diagnostic work-up, use a suitable instrument such as the Soft-ECC® (Endocervical Curette).

These are biopsy quality samples (not cytology). Tissue samples obtained with the SoftBiopsy® device may be interpreted using accepted biopsy classification systems such as the World Health Organization Classification of cervical disease including the CIN (cervical intraepithelial neoplasia) classification. Because the tissue obtained may include both intact epithelium and separated cellular pieces or elements, the tissue sample should not be used alone to establish invasive or microinvasive epithelial disease. If colposcopic or visual evidence for carcinoma is suspected, an excisional procedure may be advisable (cone biopsy, LEEP, LLETZ) under the guidance of a physician or clinician with expertise.

The use of SoftBiopsy® in pregnant patients has not been studied. The benefits of using SoftBiopsy® in patients who are pregnant must be weighed against any possible risks.

SOFTBIOPSY® - MICROSCOPIC INTERPRETATION:

The World Health Organization Classification System for tissue and the CIN I, II, III system should be used in interpreting and reporting analysis of tissue specimens obtained using SoftBiopsy®.

ADVERSE EVENTS: None known

CLINICAL EVIDENCE:

1. Winter M, Cestero R, Burg AC, Felix J, Han C, Raffo AM, Vasilev S. *Fabric-Based Exocervical and Endocervical Biopsy Compared With Punch Biopsy and Sharp Curettage*. Journal Lower Genital Tract Disease Vol 16, Number 2, Pages 80-87, 2012.
2. Burg AW, Felix JC, Winter M, *Trans-epithelial Exocervical and Endocervical Biopsies with Minimally Invasive Fabric Based Devices*. Abstract: Journal Lower Genital Tract Disease Vol 16, Number 2, Page S22, 2012.
3. Diedrich JD¹, Bentz J², Rathore S², *Improvement in Endocervical Yield with Fabric Curettage* Clark B., *Enhanced Colposcopic Accuracy for High Grade CIN* Clark B¹, Sitelman A², *Enhanced Inflammatory Reaction after Fabric Biopsy* Journal of Lower Genital Tract Disease, Volume 18, Number 5, 2014, S1-S27

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 SoftBiopsy® - 050-0011 Rev. C

SOFTBIOPSY® GYNECOLOGICAL TISSUE REMOVAL, COLLECTION, AND TRANSPORT DEVICE

**THE EXOCERVICAL SOFTBIOPSY® PROCEDURE**

During routine screening or a colposcopic examination, a lesion may be identified. If there is a suspicion of neoplasia, the SoftBiopsy® device can be used to collect tissue from the squamous epithelial layer of the cervix.

STEP 1 - OBTAINING AN ADEQUATE TISSUE SAMPLE

1. Locate the exocervical lesion and place the device into the vagina, with the SoftBiopsy® head firmly contacting the cervical lesion.
2. Be sure to **press the fabric on the device head firmly on the lesion similar to moderate “tooth-brushing” and rotate the SoftBiopsy® at least 3 complete rotations 360 degrees clockwise and 3 complete rotations counter-clockwise.** An alternate technique would be to **press and agitate the device 180 degrees with a rotation of the wrist back and forth, clockwise, then counterclockwise 5-6 times in each direction.** To avoid migration of the device tip from the lesion, dry the area with a cotton-tipped applicator or gauze. This will provide the best frictional removal of the trans-epithelial tissue from the target area.
3. **The Kylon® (fabric) device head will be abundantly filled with a blood-tinged mucoid sample.** Inspect the fabric and if it does not appear sample is sufficient, repeat the biopsy with a second device and send two samples in one vial.



**DEVICE PRESSED ON LESION
 AND ROTATED OR AGITATED**



**CERVICAL TISSUE
 REMOVAL SITE**

STEP 2 - TRANSFER OF THE SAMPLE TO THE PRESERVATIVE VIAL

1. The tissue accumulated has been raked into and collected between the rows of hooks which serve as a basket for transport. Inspect the black fabric pad before placing in the vial to be sure the “fabric pad” is filled with an adequate sample of tissue.
2. Place your index and thumb on the handle/shaft of the device with the scored mark between the fingers of the right and left hand.



SOFTBIOPSY®
Fabric head being
separated from handle

3. The SoftBiopsy® head will separate from the handle by bending firmly at the scored line. The handle of the device may be discarded.
4. Place the head of the SoftBiopsy® device into the formalin preservative solution in a secure manner. **Do not immerse or expose the fabric pad to alcohol preservative. Alcohol can adversely affect the integrity of the fabric-plastic bond.**



SOFTBIOPSY®
Tissue filled
fabric device head
in vial

STEP 3 - TRANSPORT TO THE LABORATORY

1. Clearly mark the first and last name, date, and patient identification number on the specimen bottle.
2. Place the vial with the sample into the bag provided.
3. Complete the Pathology Lab Requisition form and include with the specimen.

SOFTBIOPSY® - DESCRIPTION:

The SoftBiopsy® device is intended to be used once to obtain an exocervical trans-epithelial tissue specimen. The uniform disc shaped fabric covered head is designed to remove part or all of the squamous epithelial layer of the cervix. **Kylon®** is a specialized fabric with individually arranged hooks that gently, frictionally abrade and collect the specimen within the rows of hooks and fabric that serve as a basket receptacle. The head of the SoftBiopsy® is uniform and of optimal size for the average exocervical “quadrant”, allowing for the circular “face” of the SoftBiopsy® to be applied directly to an abnormality that is seen on the exocervix. The biopsy sample will contain multiple trans-epithelial fragments like that seen with multiple small punch biopsy specimens. The SoftBiopsy® head is a complete slightly convex cervical disc that is easily directed to the surface contour and maintained on the lesion because of a unique shape.

SOFTBIOPSY® - INDICATIONS FOR USE:

Bedside: SoftBiopsy® is intended to be used in the same clinical scenarios as the gynecological punch biopsy forceps. This includes, but is not limited to sampling lesions of the cervix that are suspected of being neoplastic, during a colposcopic examination.

LABORATORY: Samples of tissue should be carefully removed completely from the KYLON® fabric in the laboratory and may be processed and evaluated using a standard histologic technique. The specimen resembles a collection of multiple punch biopsy specimens, but should be evaluated by a pathologist familiar with evaluation of SoftBiopsy® exocervical samples.

CONTRAINDICATIONS:

SoftBiopsy is contraindicated for use in the following patients:

1. Patients with known bleeding disorders or those on anticoagulant therapy.
2. Patients with a suspected active cervicitis.
3. Patients with a known allergy to nylon or acrylic plastic.
4. Pregnancy or suspected pregnancy, when a cervical biopsy would not be indicated.

WARNINGS / PRECAUTIONS:

During any biopsy procedure, including SoftBiopsy®, bleeding may occur. Silver nitrate or Monsel's Solution may be applied to the bleeding site if necessary.

It is unlikely that the head of the SoftBiopsy® device will separate from the handle while in the vagina during the procedure. Use a clamp or ring forceps to retrieve it. If the procedure was completed prior to fracture and there is sufficient tissue on the device, place the device head into the specimen vial and discard the handle. If the specimen is insufficient, repeat the sampling procedure with a new device. If an intrauterine device (IUD) is present, take care to avoid tangling the string within the fabric hooks to avoid an inadvertent displacement of the IUD.