

SoftBiopsy® SFT-1000
Biopsy Device for Gynecological Use

SoftBiopsy® - Intended 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 or vagina that are suspected of being neoplastic, during a colposcopic examination.

SoftBiopsy® - Indications and Description:
The SoftBiopsy® device is indicated to be used once to obtain an ectocervical or mucosal lower genital tract biopsy. The uniform disc shaped fabric covered head is designed to remove part, or all of the mucosal squamous epithelial layer. **Kylon®** is a specialized fabric with individually arranged hooks that gently, frictionally abrade and collect the specimen within the rows of hooks and fabric. 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 or vagina optimally under colposcopy. 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 circular disc that is easily directed to the surface contour and maintained on the lesion because of its unique shape. For multifocal lesions, once the fabric array is filled with tissue, it will not trap additional lesion tissue and a new SoftBiopsy® device should be used.

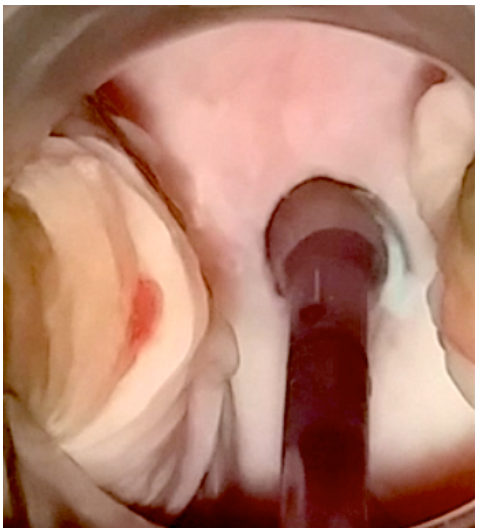
Contraindications:
SoftBiopsy is contraindicated for use in the following patients:
1. Patients with known bleeding disorders or those on anticoagulant therapy.
2. Patients with a suspected active cervicitis.
3. Patients with a known allergy to nylon or acrylic plastic.
4. Pregnancy or suspected pregnancy, when a cervical biopsy would not be indicated.

Warnings/Precautions:
• During any biopsy procedure, including SoftBiopsy®, bleeding may occur. Direct pressure with a large cotton tip applicator, silver nitrate, or Monsel's Solution may be applied to the bleeding site if necessary.
• It is unlikely that the head or part of the sampling pad of the SoftBiopsy® device will separate from the handle or fabric pile while in the vagina during the procedure. Use a forceps, 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 pad or 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 (which may result in an inadvertent displacement of the IUD).
• Eye protection is advised during the SoftBiopsy® tip detachment procedure due the tip containing fluid and particulates.

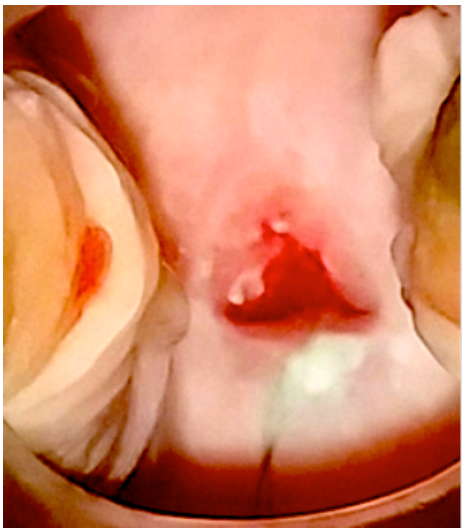
The Ectocervical/Lower Genital Tract SoftBiopsy® Procedure
During routine screening or a colposcopic examination, a lesion may be identified. If there is a suspicion of neoplasia, the SoftBiopsy® device can be used to collect tissue from the squamous epithelial layer of the cervix or vagina from a target lesion or random target.

Step 1 Obtaining an Adequate Tissue Sample

1. Locate the exocervical or vaginal lesion and place the device into the vagina, with the SoftBiopsy® head firmly contacting the target.
2. Be sure to **press the fabric on the device head firmly on the target (lesion or random biopsy site) similar to moderate "tooth-brushing" force**, **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 similar to key-turning, clockwise, then counterclockwise 5-6 times in each direction***. For best tissue yield and device tip location and placement (to avoid sliding or "skating") dry the biopsy area with a cotton tipped applicator or gauze prior to obtaining a frictional biopsy.
3. **The Kylon® (fabric) device head will be abundantly covered 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.



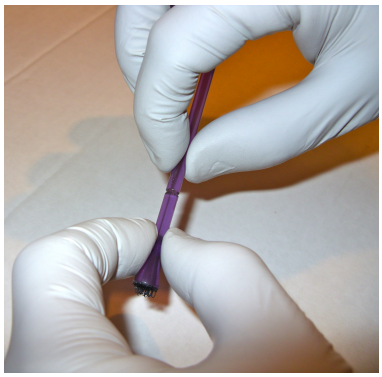
Device pressed on cervical lesion target and rotated or key-turn twisted



Post-Biopsy: Cervix Biopsy Site

Step 2 Transfer of the Sample to the Preservative Vial

1. 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.
2. The SoftBiopsy® head will separate from handle by bending firmly in a direction away from your line of sight. Shielding of the device with the hand is also helpful to avoid particulate release. The handle of the device may be discarded.
3. Eye protection is advised to avoid contact with inadvertent airborne fluid or particulates released during separation.



SoftBiopsy® head being separated from handle

4. Place the head of the SoftBiopsy® device into the preservative solution in a secure manner.

SofBiopsy ® 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.

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, and should be evaluated by a pathologist familiar with evaluation of SoftBiopsy® exocervical samples.

References:

1. Winter M, Cestero R, Burg A, et al. Fabric-based exocervical and endocervical biopsy in comparison with punch biopsy and sharp curettage. J Lower Gen Tract Dis. 16(2): 80-87, 2012.
2. Clark B, Golembeski CP, Sitelman A. High Correlation of fabric-based cervical biopsy to subsequent LEEP. J Lower Gen Tract Dis, 18, Supp 1, pS22., 2014.
3. Yetur P, Worsch L. Feasibility to diagnose cervical cancer during colposcopy using minimally invasive biopsy devices. J Lower Gen Tract Dis, 20(2): Supp 1, p S28.
4. Yetur P, Tu JJ, McClellan S, Flynn D, Worsch L. Feasibility of obtaining diagnostic trans-epithelial vaginal biopsies with frictional brush devices. . J Lower Gen Tract Dis, 20(2): Supp 1, p S28.

Glossary of Symbols

Symbol	Symbol # and Title	Explanatory Text	Standard Title
	2794 Packaging unit	To indicate the number of pieces in the package. Note: A number is inserted in the symbol to indicate the number of pieces in the package.	IEC 60417:2002 DB Graphical Symbols For Use on Equipment
	5.1.4 Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
	5.1.5 Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
	5.2.4 Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
	5.2.6 Do not resterilize	Indicates a medical device that is not to be resterilized.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
	5.2.8 Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
	5.4.2 Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
	5.4.3 Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
	5.4.4 Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
R_X ONLY	Rx Only	Caution: Federal law restricts this device to sale by or on the order of a physician.	21 CFR 801.15 (c)(1)(i)(F) Medical devices; prominence of required label statements; use of symbols in labeling.

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