

Soft-ECC® and Soft-ECC®-S Endocervical Curette(s)

Regular Canal Length and Small Length Fabric Pad for the Shallow, Short, or Stenotic Cervix

Tissue Removal, Collection, and Transport System

Soft-ECC® ***for Regular Canal Length***

Soft-ECC®-*s for Shallow, Short or Stenotic Cervix*

PACKAGE INSERT - Endocervical Curette

Soft-ECC® and Soft-ECC-S® - Intended Use:

Bedside: Soft-ECC® and Soft-ECC-S® are intended to be used in clinical scenarios where endocervical biopsy is desired to scrape/curette the endocervical canal, especially in cases where the cervical canal is foreshortened. The Kylon® pad is triangular and more likely to fit entirely inside the canal during biopsy. Scenarios include, but are not limited to sampling lesions of the cervix that are suspected of being neoplastic, during the evaluation of abnormal vaginal bleeding, or as part of the colposcopy examination.

Soft-ECC® and Soft-ECC-S® - Description:

The **Soft-ECC-S®** device is intended to be used once to de-bond endocervical epithelium and superficial stroma and simultaneously collect and store the tissue in the fabric base for storage and transport back to the laboratory. The tapered shaped fabric covered head is designed to remove part or the entire epithelial layer of the endocervix as curettage specimens. **Kylon®** is a fabric with individually arranged hooks that gently, frictionally abrade and collect the specimen within the rows of hooks and serves as a "basket", much like conventional endocervical curettes. The head of the **Soft-ECC® and Soft-ECC-S®** device is has a tapered tip which can fit into most endocervical canals. The **Soft-ECC® and Soft-ECC-S®** head comes to a tapered blunt tip that must be carefully inserted into the endocervical canal, not forced. If all or part of the **Kylon®** pad inserts into the canal, a curettage biopsy can be performed.

During a gynecological examination or a colposcopic examination, curettage of the endocervix may be indicated (abnormal bleeding, lesion in canal, unsatisfactory colposcopy, routine use in colposcopy). If there is a suspicion of neoplasia, the **Soft-ECC® orSoft-ECC-S®** device with a curette fabric **(Kylon®)** and scraping edges on the tapered tip can be used to obtain curettage samples (biopsy tissue) from the endocervical epithelial layer. In cases where the cervix appears short, stenotic, or shallow, this version of the Soft-ECC® devices will assure the entire pad fits snugly and entirely into the endocervical canal.

Contraindications:

Soft-ECC® and Soft-ECC-S® 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. **Endocervical curettage or biopsy is contraindicated in Pregnancy.**

Step 1 - Obtaining an Adequate Tissue Sample

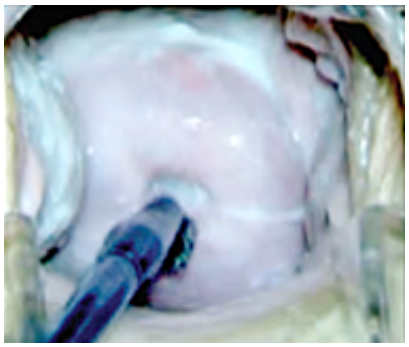
1. **Carefully and slowly** insert the tapered device head into the endocervical canal until the **KYLON®** fabric is not visible, or as deeply as can comfortably fit.

2. While pressing the **Kylon®** pad against the inner canal, rotate the **Soft-ECC® or Soft-ECC-S®** device at least 3 rotations clockwise and 3 rotations counter-clockwise while assuring pressure of the fabric hooks flattening them against the endocervical canal firmly and exposing the curette short

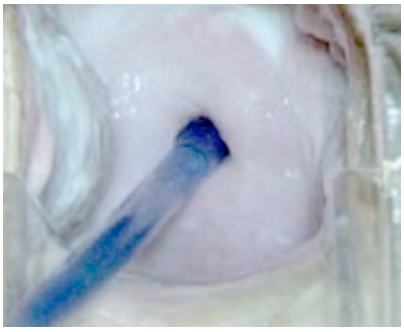
tips enabling penetration into the mucosa. The marker notches on the shaft and near the head of the device can be used to count the number of rotations.

3. **Warning: DO NOT FORCE DEVICE INTO A STENOTIC OS, OR INSERT THE DEVICE PAST THE INTERNAL ENDOCERVICAL OS.**

4. **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.



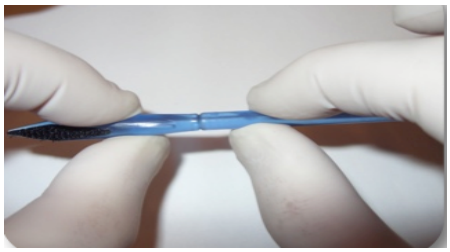
Soft-ECC® head entering the cervical canal



Soft-ECC® head inside cervical canal

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.



Separating Head of Device from Handle

2. The **Soft-ECC® and Soft-ECC-S®** head will separate from handle by bending firmly at the scored mark. Shielding the tip during separation to avoid splatter is advised. 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.
4. Place the head of the **Soft-ECC® and Soft-ECC-S®** device into the preservative solution in a secure manner. The tissue accumulated should be filled with mucoid tissue to be considered abundant in quality.

Soft-ECC® tissue filled device in vial

Soft-ECC® and Soft-ECC®-s tissue filled tips

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.

Warnings/Precautions:

• During any biopsy procedure, including **Soft-ECC® and Soft-ECC-S®**, bleeding may occur. Silver nitrate or Monsel's Solution may be applied to the bleeding site if necessary. As with other devices used for curettage, bleeding from the endocervical canal after biopsy is common and usually self-limiting.

• It is very unlikely that the head or fabric pad of the **Soft-ECC® and Soft-ECC-S®** device will separate from the handle or tip 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 in the specimen vial and discard the handle. If the specimen is insufficient, repeat the sampling procedure with a new device.

• **Soft-ECC® and Soft-ECC-S® and the Intrauterine Device (IUD) –** it is possible that the IUD string can become entangled in the hooked fabric and when the device is withdrawn, the IUD may be inadvertently removed. Take great care to slide the string free from the device on withdrawal OR avoid using **Soft-ECC® and Soft-ECC-S®** in patients with an intact IUD and IUD string.

• **Soft-ECC® and Soft-ECC-S®** is not designed or intended to perform an ectocervical biopsy. If biopsy of an exocervical lesion is needed for complete diagnostic work-up, use a suitable instrument.

• To repeat: Eye protection is advised during the **Soft-ECC or Soft-ECC-S®** tip detachment procedure due the tip containing fluid and particulates.

Laboratory Information: 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 contains epithelial curettage strips and fragments and may be evaluated by a pathologist. These biopsy-quality (not cytology) tissue samples obtained with the **Soft-ECC® and Soft-ECC-S®** 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 biopsy should not be used alone to establish invasive or microinvasive epithelial disease. If colposcopic or visual evidence for invasive carcinoma is suspected, an excisional procedure may be advisable (cone biopsy, LEEP, LLETZ) under the guidance of a physician or clinician with expertise.

Soft-ECC-S® -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 **Soft-ECC® and Soft-ECC-S®**.

Adverse Events:

None known

Clinical Evidence

1. Burg, et al. Trans-Epithelial Endocervical and Exocervical Biopsy with Minimally Invasive Fabric Based Devices. J. Lower Gen Tract Dis, Vol. Sixteen, Number Two, April 2012 Supplement pg. S22
2. Winter, et al. Fabric-Based Exocervical and Endocervical Biopsy in Comparison with Punch Biopsy and Sharp Curettage. J. Lower Gen Tract Dis., Vol. Sixteen, Number Two, April 2012 pg. 80-87.
3. Diedrich et al. Improvement in Endocervical Yield with Fabric Curettage J. Lower Gen Tract Dis, April 2014 - Volume 18 - Supplement 1 5, p-S19.
4. Clark et al. High Correlation of Fabric-based Cervical Biopsy to Subsequent LEEP. J. Lower Gen Tract Dis, April 2014 - Volume 18 - Supplement 1 5, p-S22.
5 Clark et al. Observation of a Robust Immune Inflammatory Response Following Frictional Fabric Biopsy During Colposcopy. J Lower Gen Tract Dis, April 2014 - Volume 18 - Supplement 1 5, p-S21.

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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Soft-ECC® and KYLON® are trademarks of: Histologics LLC,
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