

ENDOCERVICAL CURETTE - FOR THE SHALLOW, SHORT, OR STENOTIC CERVIX

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

These are histological samples (not cytological). Tissue samples obtained with the 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 carcinoma is suspected, an excisional procedure may be advisable (cone biopsy, LEEP, LLETZ) under the guidance of an 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-S®.

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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 Soft-ECC-S® Manufactured by Histologics LLC
 20409 Yorba Linda Blvd, Suite 119, Yorba Linda, CA 92886
 Toll free: 888-738-9757
 www.histologics.com • E-Mail: support@histologics.com

Soft-ECC-S® 050-0016 Rev. B

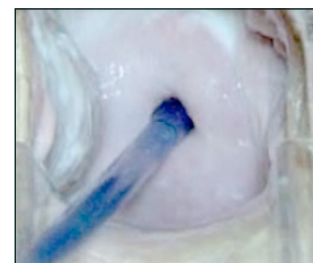
SOFT-ECC-S® ENDOCERVICAL CURETTE
TISSUE REMOVAL, COLLECTION, AND TRANSPORT DEVICE
SMALL SIZE FABRIC PAD
FOR THE SHALLOW, SHORT, OR STENOTIC CERVIX



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-S® device with a curette fabric (Kylon®) and scraping edges on the tapered tip can be used to obtain curettings (trans-epithelial tissue) from the endocervical epithelial layer. In cases where the cervix appears short, stenotic, or shallow, this version of the Soft-ECC-S® will assure the entire pad fits snugly and entirely into the endocervical canal.

STEP 1 - OBTAINING AN ADEQUATE TISSUE SAMPLE

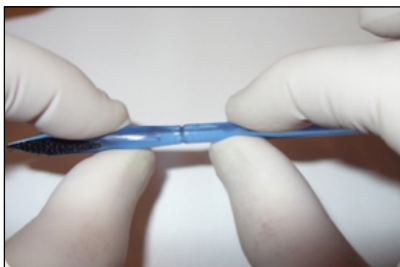
1. **Carefully and slowly** insert the tapered device head into the endocervical canal until the KYLON® fabric is not visible, or as deeply as can comfortably fit.
2. While pressing the **Kylon® pad** against the inner canal, rotate the Soft-ECC-S® device at least 3 rotations clockwise and 3 rotations counter-clockwise while pressing the fabric against the endocervical canal firmly. The marker notches on the shaft and near the head of the device can be used to count the number of rotations.
3. **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 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.



SOFT-ECC-S® HEAD INSIDE CERVICAL CANAL

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.



Separating head of device from handle

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.
3. The Soft-ECC-S® fabric-filled head will separate from the handle by bending firmly at the scored line. The handle of the device may be discarded.
4. Place the tissue-filled tip of the Soft-ECC-S® 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.**



SOFT-ECC-S®
Tissue filled device
head in the 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.

SOFT-ECC-S® - DESCRIPTION:

The Soft-ECC-S® device is intended to be used once to obtain an endocervical curettage biopsy. The tapered shaped fabric covered head is designed to remove part or all of the epithelial layer of the endocervix as curettings. 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-S® device has a tapered tip which can fit into most endocervical canals. The 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.

SOFT-ECC-S® - INDICATIONS FOR USE:

Bedside: Soft-ECC-S® is 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 fore-shortened. The Kylon® pad is triangular and more likely to fit entirely inside the canal during biopsy. Scenarios include, but is 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.

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 contains epithelial fragments as curettings and may be evaluated by a pathologist.

CONTRAINDICATIONS:

~~SOFT-ECC-S® is not intended for use in the following patients:~~ Inpatient therapy.

2. Patients with a suspected active cervicitis.
3. Patients with a known allergy to nylon or acrylic plastic.
4. Endocervical curettage or biopsy by any method is contraindicated in Pregnancy.

WARNINGS / PRECAUTIONS:

During any biopsy procedure, including 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, bleeding from the endocervical canal after biopsy is common and usually self limiting.

It is unlikely that the head of the Soft-ECC-S® 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 in the specimen vial and discard the handle. If the specimen is insufficient, repeat the sampling procedure with a new device.

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