

Soft-ECC[®] and Soft-ECC-S[®] a NEW simple and gentle approach to Endocervical Curettage

During clinical settings such as colposcopy or the evaluation of abnormal vaginal bleeding, a biopsy of the endocervix may be indicated. If there is a suspicion of neoplasia, the **Soft-ECC[®]** device with a patented fabric (KYLON[®]) on the tapered tip, can be used to collect tissue from the endocervix as an alternative to other curettage devices. This device is designed to provide abundant trans-epithelial histology samples. When carefully inserted, the blunted tapered shaped KYLON[®] fabric covered device head and edges are designed to fit easily and gently into the cervical canal. The Soft-ECC[®] will frictionally abrade part or all of the glandular and squamous epithelial layer of the endocervix, while simultaneously collecting the specimen within the basket rows of hooks and fabric. If all or most of the KYLON[®] pad inserts into the canal, an endocervical curettage can be performed. There are now two pad sizes available for the Soft-ECC[®]. **The Soft ECC-S[®] is a smaller pad size, designed for the shallow, short or stenotic cervix.**

WHY USE THE Soft-ECC[®] DEVICE?

- **Ease of use:** insert and rotate to gently scrape, not the old “insert and withdraw” sharp technique
- **Minimally invasive design**
- **Abundant histological sample:** simultaneous tissue collection and storage of the specimen for transport
- **Process as is customary for endocervical sample in the laboratory.**

Soft-ECC[®] Full Pad Size



Soft-ECC-S[®] Smaller Pad Size



What is KYLON?

KYLON[®] is a fabric with individually arranged hooks that gently abrade with friction and simultaneously collects the specimen within the rows of hooks and fabric (as it's basket platform).

**Soft-ECC[®]
Model SFT-2000
Soft-ECC-S[®]
Model SFT-2100
manufactured by:**

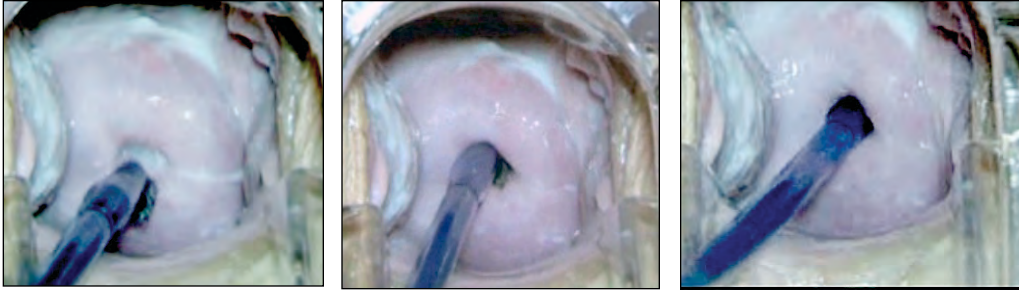
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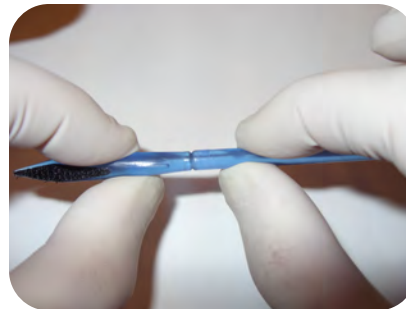
How to Perform an Endocervical Curettage with Soft-ECC®

1. Inspect the cervical os size for a proper fit. At least 1mm diameter or greater is preferred.
2. Gently introduce the tapered tip into the center of the endocervical os, until all or at least half the pad is inside the canal. **DO NOT advance the tip past the internal os. DO NOT enter the uterine cavity.**



Soft ECC® device being inserted gently and completely inside cervical canal.

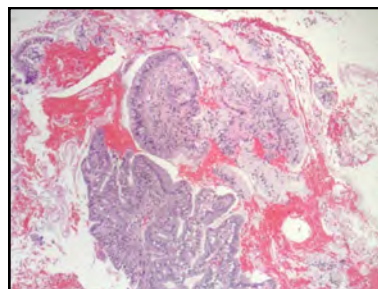
3. Once the pad is in the endocervical canal, press the fabric against the canal wall, and rotate the device 360° clockwise for three to five rotations, then 360° counter clockwise for three to five rotations.
4. Remove and inspect the KYLON® fabric pad. It should be filled with tissue and mucous. Snap the tip of the Soft-ECC® device and place the tip in a vial of (non-alcohol) fixative. Discard or recycle the acrylic plastic handle.



Separating head of device from handle



Detached device head filled with tissue in vial



Abundant Soft-ECC® histology sample

Soft-ECC® frictional specimen removal, storage and transport device system: Soft-ECC® 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.

Soft-ECC® Curette SFT-2000 and Soft-ECC-S® Curette SFT-2100

(for the shallow, short or stenotic cervix)

Indications for Use:

Bedside:

Soft-ECC® is intended to be used in clinical scenarios where endocervical curettage is desired to scrape/curette the endocervical canal. This includes, but is not limited to sampling lesions of the cervix that are suspected of being neoplastic, during the evaluation of abnormal vaginal bleeding unrelated to pregnancy, or the colposcopy examination.

Contraindications:

Soft-ECC® is contraindicated for use 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 curettage histology samples that can be removed by simply scraping the fragments off the KYLON® pad with a blunt knife blade, tweezers, or a small fine comb.