Soft-ECC® is the new simple and gentle approach to perform 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 patent pending fabric (KYLON®) on the tapered tip can be used to collect tissue from the endocervix as an alternative 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.

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
 - Process as is customary for endocervical sample in the laboratory.

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 its basket platform).

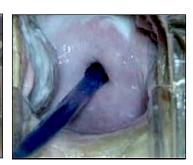
How to perform an Endocervical Curettage with Soft-ECC®

Inspect the cervical os size for a proper fit. At least 1mm diameter or greater is preferred.

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 device past the endocervical os. DO NOT enter the uterine cavity.

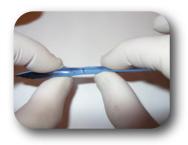






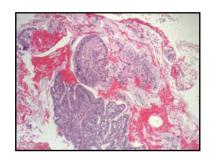
Once the pad is in the endocervical canal, press the fabric against the canal wall, and rotate the device 360° clockwise for three to five rotations, then 360° counter clockwise for three to five rotations.

Remove and inspect the KYLON® fabric pad. It should be filled with tissue and mucous. Snap the tip of the Soft-ECCTM device and place tip in the vial of fixative. Discard or recycle the acrylic plastic handle.



Endocervical Curettage specimen obtained with Soft-ECC®





Soft-ECC® Curette

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. Care should be taken if an IUD is present not to entangle and remove the IUD.

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 and may be evaluated by a pathologist and may be removed by simply scraping fragments off KYLON® pad with a knife blade, tweezers, or a small fine comb.