



HISTOLOGICS

THE FUTURE IS ... COMPASSIONATE COLPOSCOPY® EXOCERVICAL BIOPSY AND ENDOCERVICAL CURETTAGE

Choose the Patient-Friendly “Gentle” Approach to Biopsy and ECC

High Quality Colposcopic Biopsy and Curettage with the Patient Care Experience in Mind!

- **ABUNDANT BROAD SAMPLE**
- **AFFORDABLE**
- **HIGHLY EFFICIENT TISSUE TRAPPING**
- **DIAGNOSTIC TRANSEPITHELIAL SAMPLES**

EXOCERVICAL BIOPSY DEVICES

SoftBiopsy®

The Kylon® fabric both removes and traps abundant transepithelial (full thickness) samples.
EASY, RAPID, GENTLE, ABUNDANT SAMPLE from a broad area of the exocervix.



Spirabrush cx®

Stiff bristles in spiral array remove abundant transepithelial (full thickness) samples.
EASY, RAPID, GENTLE, ABUNDANT SAMPLE from a broad area of the exocervix.



EXOCERVICAL BIOPSY METHOD FOR BOTH DEVICES

1. Visualize the cervix under colposcopy, choose the target area for biopsy
2. Press on the cervical lesion with moderate pressure to create friction.
3. Six half wrist rotations like “key turning” in clockwise, then counter-clockwise.

ENDOCERVICAL CURETTE DEVICE

Soft ECC® & Soft ECC-S®

The Kylon® fabric both removes and traps abundant transepithelial (full thickness) samples.
RAPID, GENTLE, ABUNDANT SAMPLE from the endocervical canal. No retrieval needed - FAST & EASY.



ENDOCERVICAL CURETTAGE METHOD FOR BOTH DEVICES

1. Clinical decision to perform endocervical curettage for colposcopy or bleeding problem.
2. Gently insert fabric tip in to canal with moderate pressure.
3. Six half wrist rotations like “key turning” in clockwise, then counter-clockwise.

YES! There is a high quality patient-friendly frictional alternative to the conventional stainless steel “cutting” punch biopsy forceps and sharp scraping curettes!



ORDER NOW (Order Form on back)

How to Perform an Exocervical Biopsy with the SoftBiopsy® Gynecological Biopsy Device

1. Inspect the cervix as is customary for colposcopy after staining or application of acetic acid. Identify lesions or other areas for biopsy (occasional random biopsy as indicated). Lesions that extend onto the vaginal mucosa can also be biopsied using SoftBiopsy®.
2. Gently press the round tip onto the center of the lesion or cervical quadrant involved. Use pressure similar to tooth brushing. You may use a one handed or two handed technique to maintain the tip of the device on the biopsy target.

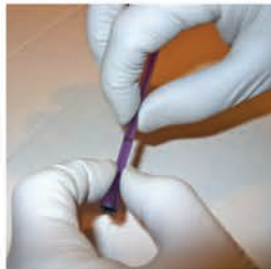


One and two handed technique on applying the device and guiding the biopsy procedure.

Softbiopsy® being applied, pressed and rotated gently.

3. Once the fabric pad is pressed firmly against the cervix target area, rotate the device 360° clockwise for three to five rotations, then 360° counter clockwise for three to five rotations. Alternatively, 6-10 half (180°) rotations (like key turning) in each direction may be used. Dry the lesion area with a cotton applicator or gauze prior to biopsy for the best tissue yield and placement.

4. Remove and inspect the KYLON® fabric pad. It should be filled with tissue and mucous. Snap the tip of the SoftBiopsy® device and place tip in a (non-alcohol) vial of fixative. Discard or recycle the acrylic plastic handle.



Separating head of device from handle



SoftBiopsy® head with tissue in vial

SoftBiopsy® Device SFT-1000

Indications for Use:

Bedside:

SoftBiopsy® is intended to be used in clinical scenarios where exocervical or vaginal biopsy is indicated. This includes, but is not limited to sampling lesions of the cervix that are suspected of being neoplastic during the colposcopy examination.

Contraindications:

SoftBiopsy® should not be used in clinical scenarios where exocervical biopsy is contraindicated during pregnancy or suspected pregnancy.

Laboratory:

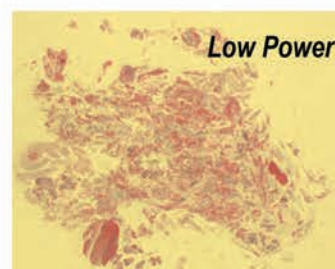
Samples of tissue should be carefully and completely removed from the KYLON® fabric in the laboratory and may be processed and evaluated using a standard histologic technique. The specimen contains abundant multiple histology samples that can be removed by simply scraping the fragments off the KYLON® pad with a small fine comb, knife blade, or tweezers.



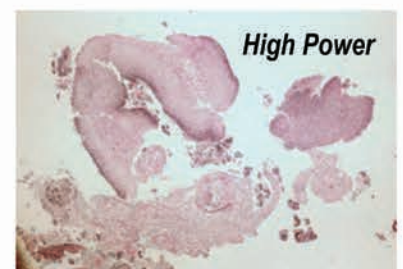
Application and Rotation



Post-Biopsy



Low Power



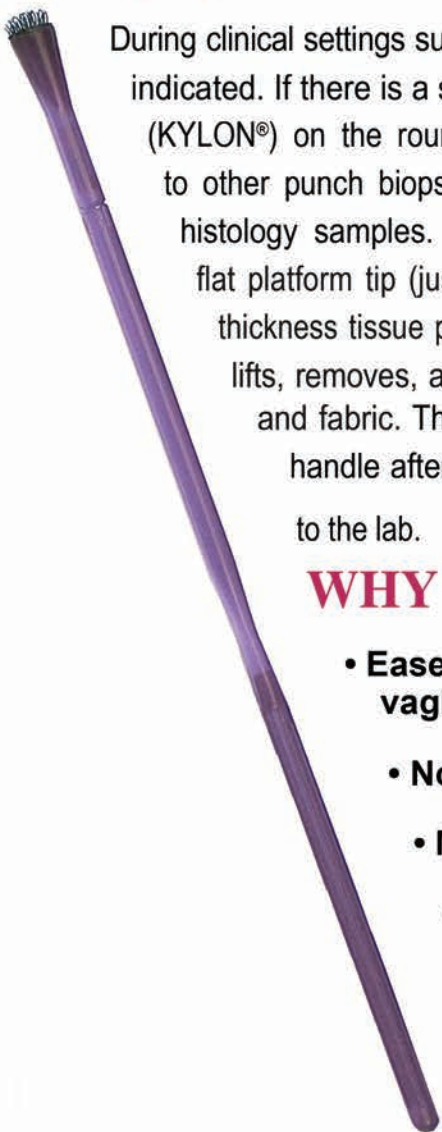
High Power

Full thickness and abundant histology sample

Exocervical Biopsy with SoftBiopsy®

SoftBiopsy® frictional specimen removal, storage and transport device system: SoftBiopsy® 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.

SoftBiopsy® is the NEW simple and gentle approach to perform a cervical or lower genital tract biopsy



During clinical settings such as colposcopy, a biopsy of the exocervix or lower genital tract may be indicated. If there is a suspicion of neoplasia, the **SoftBiopsy®** device, with a patented fabric (KYLON®) on the round tip, can be used to collect tissue from the cervix as an alternative to other punch biopsy devices. This device is designed to provide abundant trans-epithelial histology samples. When carefully applied to the lesion, pressed, and rotated, the round flat platform tip (just under 1/2 inch in diameter) KYLON® fabric will excavate numerous full thickness tissue pieces like multiple small punch biopsies. The **SoftBiopsy®** microscopically lifts, removes, and simultaneously collects the specimen within the basket rows of hooks and fabric. The KYLON® pad and distal device head can be simply snapped from the handle after the biopsy and placed in a (non-alcohol) liquid fixative vial for transport to the lab.

WHY USE THE SoftBiopsy® DEVICE?

- **Ease of use:** Apply with moderate pressure to the cervical or vaginal lesion and rotate to gently biopsy
- **No pinching or cutting tissue**
- **Minimally invasive design**
- **Abundant histological sample:** simultaneous tissue collection and storage of the specimen for transport
- **Process as is customary for exocervical biopsy sample in the laboratory.**

What is KYLON®?

KYLON® is a fabric with hooks that gently biopsies by compressing and frictionally lifting intact tissue fragments and simultaneously collects the specimen within the rows of hooks and fabric.



SoftBiopsy®
Model SFT-1000
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.

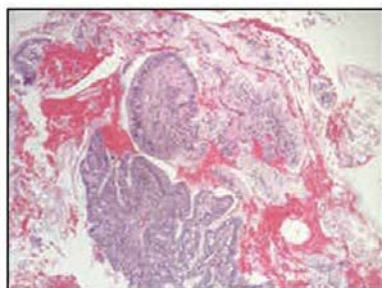
3. Once the pad is in the endocervical canal, press the fabric against the canal wall, and rotate the device 360° clockwise for three to five rotations, then 360° counter clockwise for three to five rotations.
4. Remove and inspect the Kylon® fabric pad. It should be filled with tissue and mucous. Snap 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**

...

**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.

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.**

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® Full Pad Size



Soft-ECC-S® Smaller Pad Size



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

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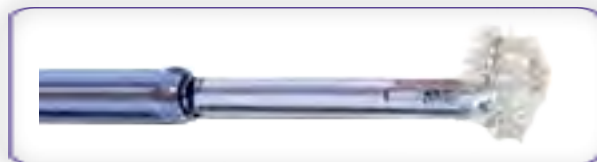
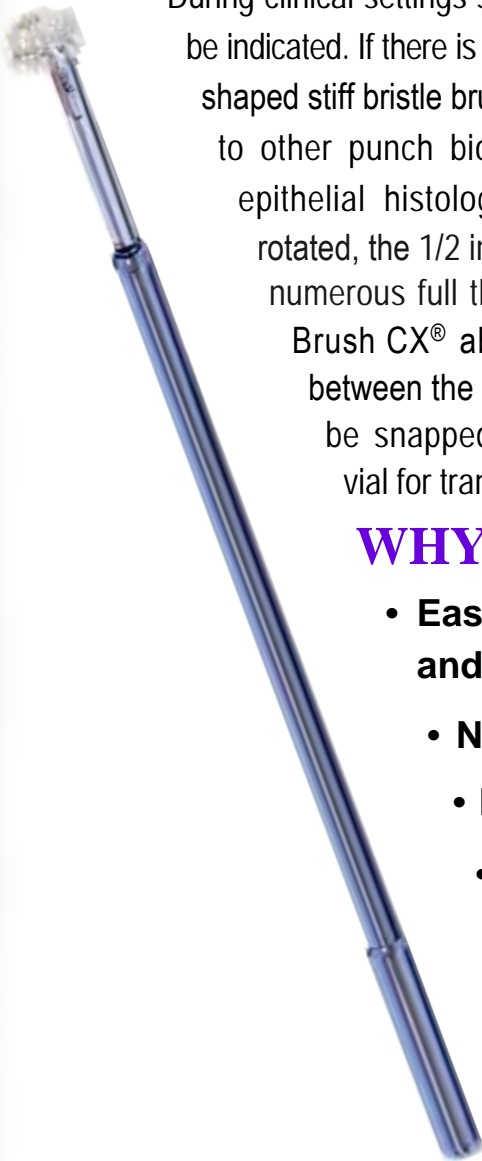
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SpiraBrush CX[®] is a time-honored device used to perform a cervical or lower genital tract biopsy

During clinical settings such as colposcopy, a biopsy of the exocervix or lower genital tract may be indicated. If there is a suspicion of neoplasia, the SpiraBrush CX[®] device, with a patented spiral shaped stiff bristle brush, can be used to collect tissue from the cervix as an alternative to other punch biopsy devices. This device is designed to provide abundant trans-epithelial histology samples. When carefully applied to the lesion, pressed and rotated, the 1/2 inch diameter bristle array, will gently micro-puncture the tissue and trap numerous full thickness tissue pieces like multiple small punch biopsies. The SpiraBrush CX[®] abrades the epithelium into the submucosa and traps the specimen between the straight stiff bristle array. Once tissue is collected, the device head can be snapped from the handle after the biopsy and placed in the liquid fixative vial for transport to the lab.

WHY USE THE SpiraBrush CX[®] DEVICE?

- **Ease of use: Gently press on cervical or vaginal lesion and rotate to obtain a biopsy specimen**
- **No pinching or cutting tissue - Minimally invasive**
- **Not to be used as a cytologic sampling device.**
- **Trans-epithelial histological sample**
- **Process as is customary for exocervical biopsy sample in the laboratory or as cell block**



Although SpiraBrush CX[®] is an FDA-cleared sampling device, it sold as an FDA compliant gynecological biopsy device, providing specimens equivalent to the cervical punch biopsy.

SpiraBrush CX[®]

Model SBX-9000
manufactured by:

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How to perform an Exocervical Biopsy with the SpiraBrush CX®

1. Inspect the cervix as is customary for colposcopy after staining or application of acetic acid. Identify lesions or other areas for biopsy (occasional random biopsy as indicated). Lesions that extend onto the vaginal mucosa can also be biopsied using SpiraBrush CX®
2. Gently press the SpiraBrush CX® tip on to the center of the lesion or cervical quadrant involved. Use pressure similar to tooth brushing. Try to maintain the tip of the device on the biopsy target.

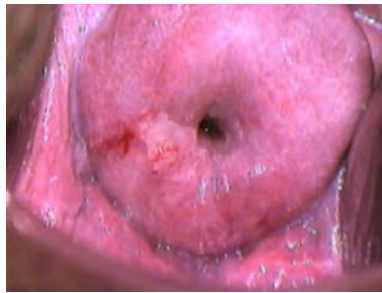


SpiraBrush CX® being applied, pressed and rotated gently.

3. Once the bristles are pressed firmly against the cervix target area, rotate the device 360° clockwise for three to five rotations, then 360° counter clockwise for three to five rotations. Alternatively 6-10 half (180°) rotations (like key turning) in each direction may be used.



Brush head with tissue trapped between bristles

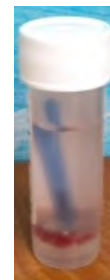


Micro-punctate bleeding at the brushed biopsy site

4. Remove and inspect the brush head. It should be filled with tissue and mucous. Snap the tip off the SpiraBrush CX® device and place tip in the vial of fixative. Medically discard or recycle the acrylic plastic handle.



Separating head of device from handle



SpiraBrush CX® head with tissue in vial

SpiraBrush CX® **Device: SBX-9000** **Indications for Use:**

Bedside:

SpiraBrush CX is intended to be used in clinical scenarios where exocervical or vaginal biopsy is indicated. This includes, but is not limited to sampling lesions of the cervix that are suspected of being neoplastic during the colposcopy examination.

Contraindications:

SpiraBrush CX is contraindicated for use in clinical scenarios where exocervical biopsy is contraindicated, including pregnancy or suspected pregnancy.

Laboratory:

Samples of tissue should be carefully and completely removed from the un-wound brush head using eye protection in the laboratory and may be processed and evaluated using a standard histologic technique. The specimen contains abundant multiple histology samples and may be evaluated by a pathologist and may be removed by scraping fragments off the bristle brush head using a knife blade, or tweezers.

Order information:

SpiraBrush CX® is distributed by authorized laboratories, hospitals, and distributors. Sample packs of all Histologic's minimally invasive tissue sampling devices are available for sale.

Call 888-738-9757 to request additional information or visit us at: www.histologics.com
Email us at: histologics@gmail.com

We will respond to your product request in a timely manner.