

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**
- **Less need for hemostasis following biopsy**
- **Trans-epithelial histological sample**
- **Process as is customary for exocervical biopsy sample in the laboratory or as cell block**



SpiraBrush CX[®] is an FDA-cleared cytology device and FDA compliant gynecological biopsy device, providing specimens equivalent to the cervical punch biopsy.

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.

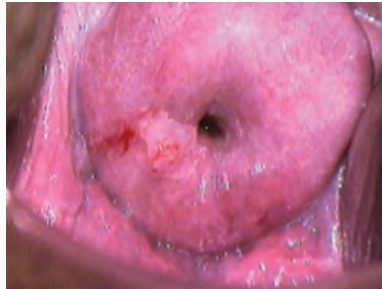


SpiraBrush CX[®] being applied, pressed and rotated gently.

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

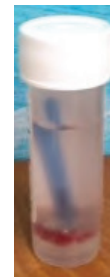


Micro-punctate bleeding at the brushed biopsy site

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[®]

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 KYLON[®] pad with a small fine comb, knife blade, or tweezers.