

SpiraBrush CX[®]

SBX-9000 Gynecological Biopsy Device

Physician and Clinician Primer: Resource Guide and Standard Lab Tissue Removal Procedure

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HISTOLOGICS LLC

**Histologics LLC
20409 Yorba Linda Blvd.
Suite 119
Yorba Linda, CA 92886**

Phone Toll Free and FAX: (888)

888-738-9757

histologics.com

support@histologics.com

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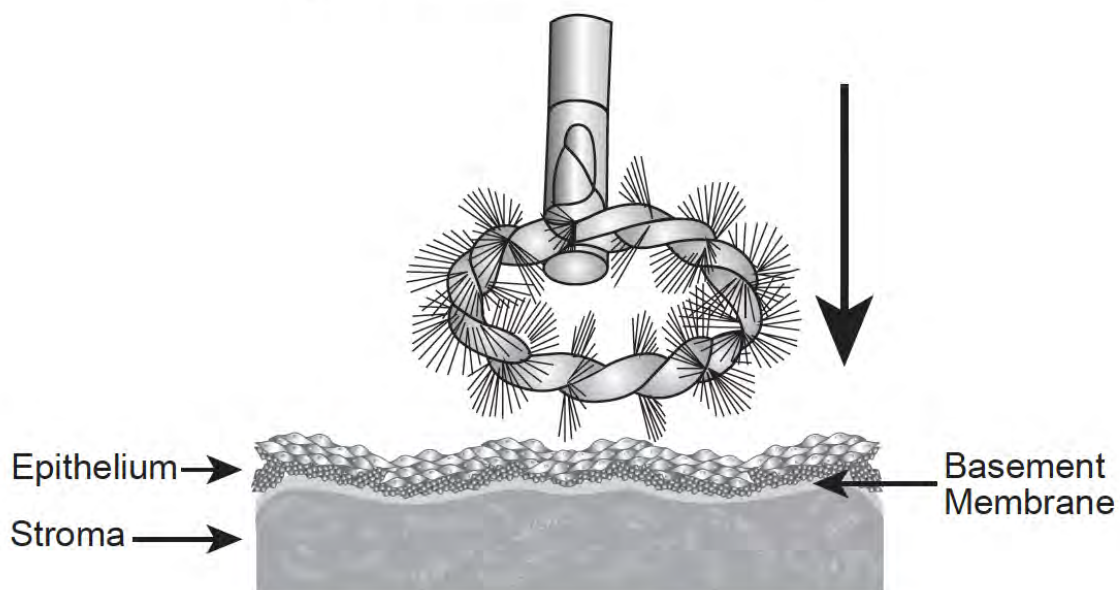
Q 1: What is SpiraBrush CX® ?

SpiraBrush CX is a non invasive instrument used to obtain a cervical biopsy when indicated in settings that include colposcopy. The twisted wire stiff bristle brush coiled into a spiral allows some bristles to be perpendicular to the axis of the handle while some are oriented parallel. The bristles puncture the tissue, and when rotated, the device is used to achieve an epithelial biopsy.



SpiraBrush CX Procedure

SpiraBrush has straight bristles. Device is pressed down into lesion.



Q 2: What is unique about the SpiraBrush CX® bristle array and how does it work to obtain a biopsy?

The bristles of the SpiraBrush are of a proprietary length, stiffness, and geometry attached to the applicator stick. When pressed on the stand tissue surface, the bristles contact the target tissue, and with pressure and rotation, penetrate through the epithelium into the submucosa. With rotation and a grinding effect, a trans-epithelial biopsy is obtained (Figure 1). The procedure of applying, pressing, and rotating the spiral bristles into the surface of the lower genital tract or cervical tissue with moderate pressure and rotating it to obtain a biopsy specimen is called a **SpiraBrush CX®** biopsy.

Q 3: How do I use the SpiraBrush® device to obtain a gynecological cervical biopsy?

Place the handle of the device in the palm and hold the handle shaft in between the thumb and first two fingers. This will permit a twirling motion during the rotational biopsy. Gently apply the spiral brush tip on the tissue surface and press with moderate firmness similar to moderate “tooth brushing”. If the tissue is excessively moist, dry the lesion or area targeted for biopsy prior to beginning the biopsy procedure to avoid skating or slippage. Twirl or rotate the device three to five complete 360 degree turns clockwise, then three to five complete revolutions counterclockwise.

Alternatively, one could press and rotationally agitate (like a washing machine effect) 6-8 times while rotating with a 180 degree twist of the wrist while pressing moderately on the surface to completely contact the lesion or target area.

Once an adequate tissue specimen is obtained, simply snap off the device head (step 3, page 5) from the shaft of the device at the junction of the thin-post/handle interface and place it in the fixative vial provided by the laboratory.



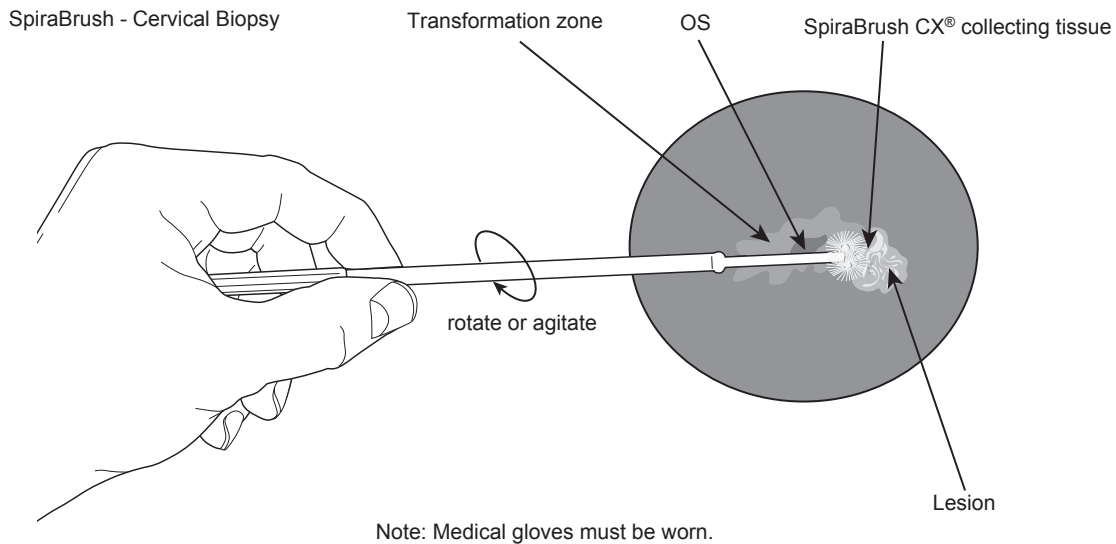
Figure 1: SpiraBrush CX applied to a lesion; post-biopsy appearance of the cervix with “micro-punctate” bleeding noted.

Q 4: Why is the tip of the SpiraBrush CX® device shaped in a larger flat spiral design?

The device is designed to cover nearly one quadrant of the cervix. It is large enough to take multiple tissue fragments of varying depths and sizes, remove cells, or larger strips or clumps of intact trans-epithelial specimens into the stroma. In the majority of cases, the biopsy will result in some slight excoriation or scratching of tissue, while removing and trapping tissue between the bristle tines.

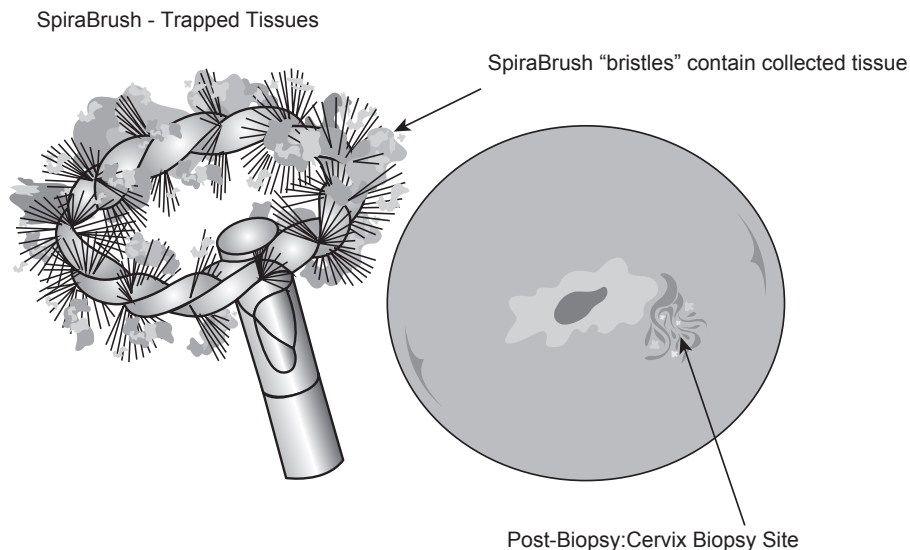
Q 5 : What steps do I take to perform a SpiraBrush CX biopsy of the cervix during colposcopy?

Step One: Apply the SpiraBrush firmly to the lesion and twirl/rotate 360 degrees clockwise for 3-5 revolutions then alternating counterclockwise for 3-5 rotations, or do agitation 180 degree half-rotations SIX to EIGHT times clockwise alternating with counterclockwise.



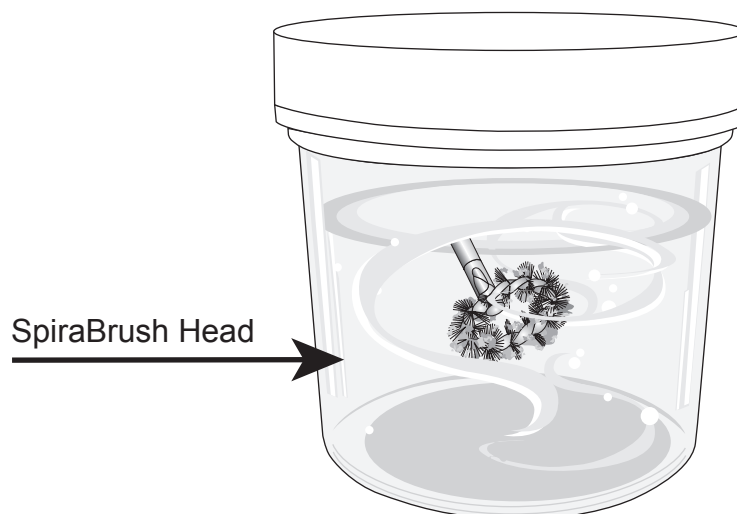
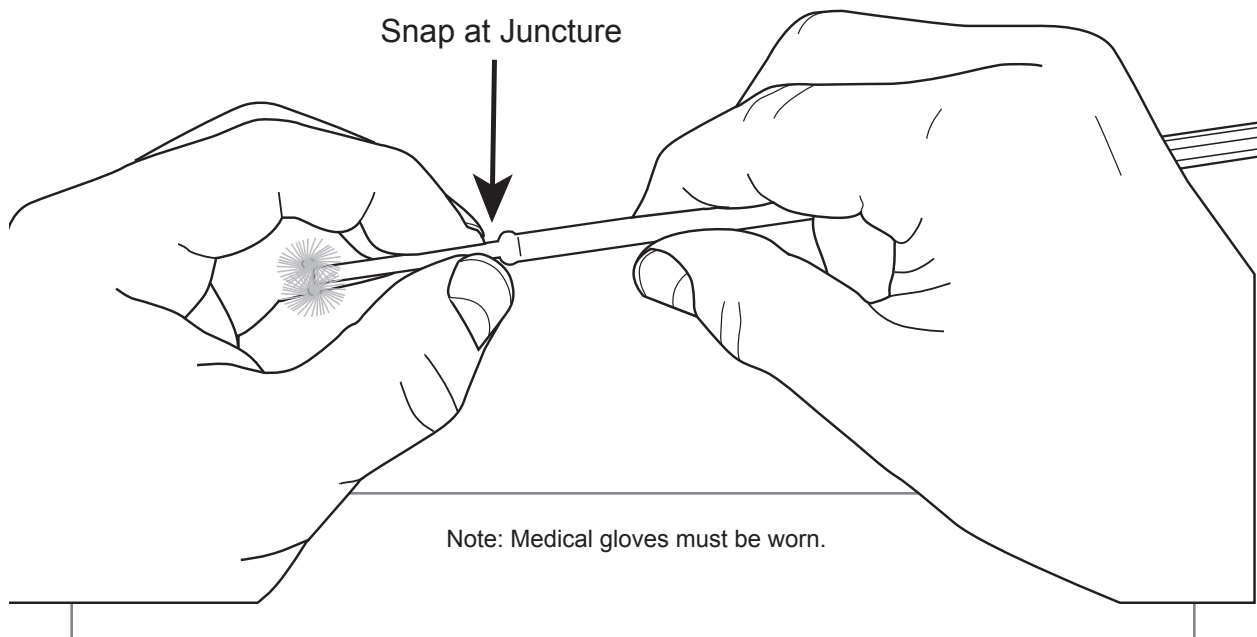
The tip is applied onto a cervical lesion and a Spiral Stiff Bristle Brush (SpiraBrush CX®) biopsy obtained.

Step Two: Remove and inspect the brush head for blood tinged mucoid tissue trapped between the bristles. There will be micro-punctate bleeding at the biopsy site.



Step Three: Snap the tip of the brush free at the junction of the narrow post and the wider diameter handle.

Snap-Off



Q 6: How do I apply the device and how much pressure do I apply when pressing the SpiraBrush CX[®] onto the tissue surface?

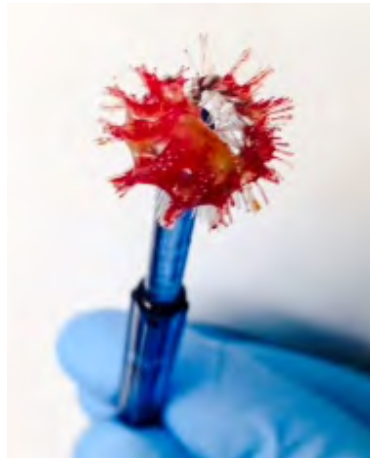
Pressure on a flat, irregular, or rounded tissue surface (like exocervix or vagina) is applied perpendicularly to the lesion or target epithelial epithelium, or radially. The amount of pressure needed to penetrate the epithelial tissue surface, equivalent to a light massage or moderate tooth brushing. Press the device into the tissue surface so it is firmly applied, but not so hard as to depress the tissue surface more than two or three millimeters.

Q 7: How do I know I have obtained a sufficient sample? How is the sample saved for analysis?

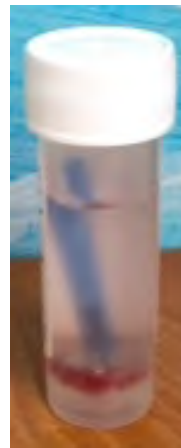
After performing the biopsy procedure, gently lift the brush head away from the tissue surface. You will note that some of the tissue and cells have recessed between the stiff spiral bristle array, and will be combined with some blood tinged mucous. The tip is designed to be released (snapped off) from the handle with moderate lateral traction and dropped in a vial of Gixative. If you do not see any tissue or mucoid material in the fabric, repeat the procedure.

SpiraBrush CX[®] tip in a vial with tissue

Tissue on brush head



Tissue in fabric head in the vial



Tissue acquisition can be confirmed visually after the biopsy obtained and the tissue can be clearly seen when the device head is submerged into the liquid fixative.

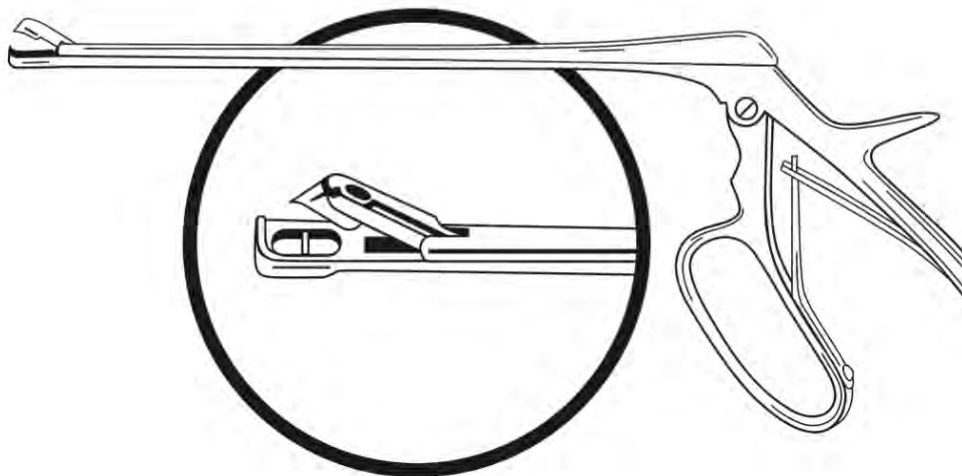
Q 8: What is the standard biopsy method for excocervical tissue removal and how does it compare with conventional punch biopsy forceps?

The conventional stainless steel “sharp” punch biopsy forceps removes single tissue pieces that range from 1mm to 4mm in size, depending on the size of the jaw assembly tip and its design. The defect left in the tissue after removal is much deeper, extending into the submucosa (stroma) and reaching the deeper blood vessel array, usually leading to bleeding. The bleeding is controlled (hemostasis) with either silver nitrate or Monsel’s solution (ferric sub-sulfate) or gel, which is time consuming and an added expense.

A clinical study proved that SpiraBrush CX® also removes a “trans-epithelial” biopsy specimen but requires less frequent need for hemostasis (control for bleeding) when compared with standard punch biopsy.

Research by Monk et al : A stiff bristled, spiral-shaped ectocervical brush: a device for transepithelial tissue biopsy. Monk BJ, Cogan M, Felix JC, Lonky NM, Bentz JS, Marshall CJ, Cestero RM, Rowe LR, Lonky SA. Obstet Gynecol. 2002 Dec;100(6):1276-84.

Conventional Punch Biopsy Forceps



Q-9: Is there evidence that the biopsy taken with SpiraBrush CX® is of a trans-epithelial thickness?

Research has shown that the biopsy sample removed with the SpiraBrush CX® spiral shaped stiff bristle brush is deep enough to remove the full thickness of the epithelium of the cervix. Please refer to these two references in the medical literature for evidence:

1. Tewari D, et al. J Low Genit Tract Dis. 2004 Oct;8(4):276-9.
2. Monk B, et al. Obstet Gynecol 2002 Dec;100(6):1276-84.

SpiraBrush CX Based Trans-epithelial Biopsy Sample



Q 10: How is the specimen taken off the bristle brush so it can be processed in the pathology lab?

The pathologist has several methods available to remove the tissue from the fabric. Tweezers or a scalpel blade can be used to gently scrape off the tissue from the untwisted spiral bristle brush. The brush must be straightened to adequately expose all the captured tissue that lies between the bristle tines.

The specimen can be collected onto filter paper or telfa. The “plucked” tissue resembles multiple small punch biopsies or conventional curettings of the transformation zone where there is glandular and squamous epithelium. The specimen can then be processed by the lab in an identical manner that is customary for the lab (tea bag or directly into cassette).

Alternatively, a cell block can be created if alcohol fixative is used, if desired.

What is the Laboratory Standard Operating Procedure?

Remove Tissue from The Bristles:

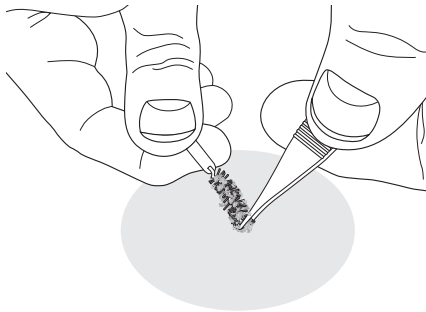
1. Unfurl the coiled brush with eye protection to prevent tissue splash back, and carefully pluck or scrape the tissue from between the bristles onto filter paper.
2. Immerse the paper into fixative until ready for histopathologic processing.

Step by step unfurling of the stiff spiral bristle brush with removal of the tissue pieces with either tweezers or scalpel.

EYE PROTECTION SHOULD BE USED



Note: Medical gloves must be worn



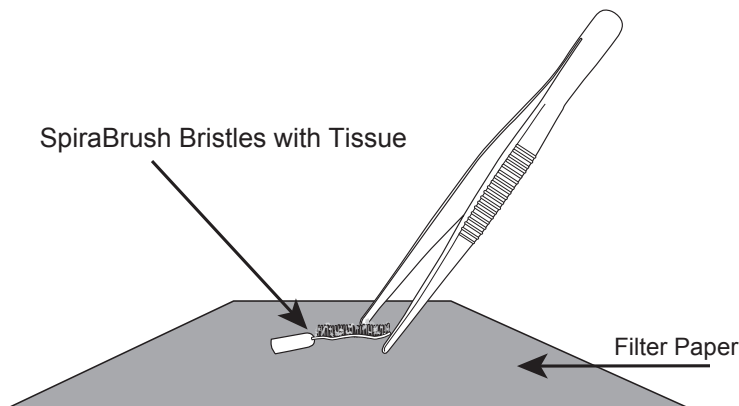
Note: Medical gloves must be worn



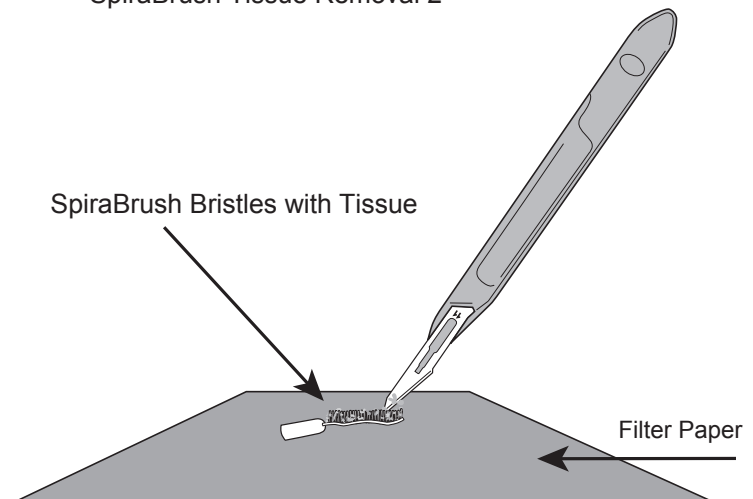
Note: Medical gloves must be worn

Unfurl and straighten the stiff bristle brush spiral using tweezers

SpiraBrush CX® - Tissue Removal Tweezer Method



SpiraBrush Tissue Removal 2



Either pluck or scrape the tissue from between the bristles onto the filter paper which can then be processed as a histological sample using conventional methods.