

The SpiraBrush CX biopsy brush is a patented, FDA cleared, sterile, disposable, single-use, cervical, biopsy device designed to be used in place of the traditional punch or forceps cervical biopsy instrument to obtain tissue from areas of the cervix appearing to be abnormal during vaginal examination to test for abnormal, precancerous conditions or cervical cancer. The unique, stiff-bristled, spiral-shaped design of the SpiraBrush CX makes possible the removal of a layer of squamous epithelial tissue of the cervix for the biopsy with minimal trauma for the patient and less bleeding.



TESTIMONIALS

I have been using Spirabrush CX with great success. Spirabrush CX is easier to use than the punch method, especially when the lesion is in a more difficult location to sample, such as the outer area of the ectocervix. Also, there is less pain and less bleeding post-procedure.

- *Steven R. Drosman, M.D., San Diego, CA*

The results with SpiraBrush CX have been excellent.

- *Robin Wedberg, M.D., San Diego, CA*

We have now seen thousands of SpiraBrush CX samples and are confident that we can accurately diagnose both low and high grade squamous dysplasia using this excellent, patient friendly device. In our pathology practice, we view SpiraBrush CX diagnoses as equivalent to cervical punch biopsy diagnoses.

- *Alfred Lui, M.D., Medical Director Pathology Inc., a Medical Corporation*

SpiraBrush CX will make a huge impact on a physician's ability to insure a more definitive diagnosis by making the biopsy process more comfortable for the patient and easier for the clinician to perform.

- *Jack Rowland, M.D., Encinitas, CA*

SpiraBrush ex

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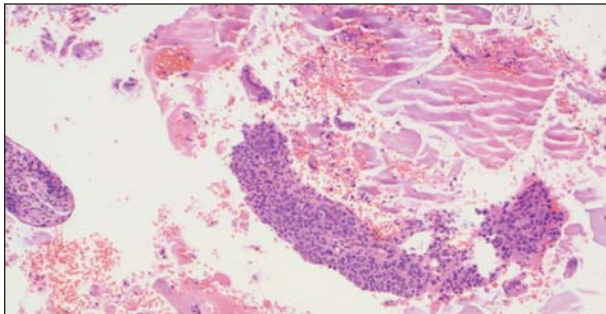
SpiraBrush CX

**PATENTED - FDA CLEARED
CERVICAL BIOPSY BRUSH**

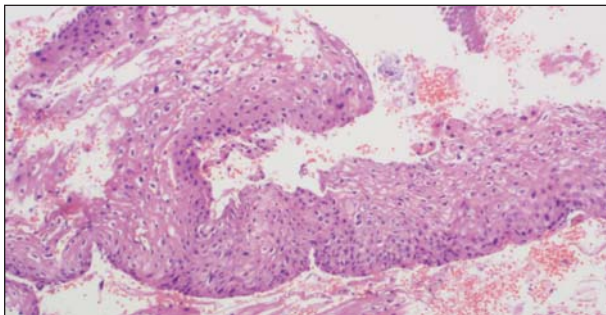
SPIRABRUSH CX AT A GLANCE

- FDA cleared to be used in place of the punch biopsy
- Patented nationally and internationally
- Less bleeding
- Less need for hemostasis
- Full transepithelial tissue samples
- CPT Codes are the same as for punch biopsy
 - Cervical Biopsy: 57454
 - Lab Processing: 88305
- SpiraBrush CX saves time
- SpiraBrush CX is cost effective
 - Single use disposable device
 - No maintenance by office staff
 - No need for cleaning, repairing, sharpening, or sterilizing

SPIRABRUSH CX SLIDE SAMPLES



Fragment of highly cellular, atypical squamous cells diagnostic of CIN 3



Strip of squamous epithelium showing the characteristic koilocytes of CIN 1

SPIRABRUSH CX vs. PUNCH BIOPSY

- Study patients already scheduled for LEEP, which provides the definitive tissue sample.
- Diagnostic accuracy of SpiraBrush CX was evaluated using LEEP as the gold standard, and the resulting correlation was compared to that of the punch biopsy.
- Lesion partially sampled with SpiraBrush CX, remainder sampled with the punch.
- Pain and bleeding recorded.
- Biopsy results compared to LEEP sections.
- Pathologists completely masked.
- Results published in the Journal of Obstetrics and Gynecology (Obstet Gynecol 2002;100:1276-1284. and compared to other studies of punch biopsy accuracy appearing in peer reviewed literature.



FREQUENTLY ASKED QUESTIONS

Can I use the SpiraBrush CX during a patient's menses?
Yes.

Can the SpiraBrush CX be used during pregnancy?
The SpiraBrush CX is not contraindicated in pregnant patients.

Do I still need to do an ECC?
Yes. SpiraBrush CX replaces only the punch biopsy. The rest of your routine remains the same.

Do I need to anesthetize the cervix before getting a specimen?
That is up to you, it's not necessary. Patients have said it feels about the same as a Pap smear.

Can I use Lugol's solution prior to taking a biopsy?
You can use whatever protocol you normally use when preparing the patient for biopsy.

I use acidic acid (vinegar) solution to prep the cervix prior to taking the biopsy. Will I also do this with the SpiraBrush CX?
Yes. You would use the same protocol you use now.

How can I be sure that I have an adequate tissue sample when using the SpiraBrush CX?
First, confirm visually that the brush head is loaded with bloody mucoid material. Then check for micropunctate bleeding at the site of the lesion. Follow up with a visual inspection of the site with your colposcope if you prefer.

Should I take a punch biopsy after I've taken a SpiraBrush CX biopsy?
No. The SpiraBrush CX has been cleared by the FDA to replace the punch biopsy.

Will I still need Monsels or silver nitrate to stop the bleeding?
Rarely. A cotton swab is usually enough to tidy up.

What are the CPT codes?
Use the same CPT code you normally use for a punch biopsy (Colpo with biopsy #57454). There is no change in the code when using the SpiraBrush. The lab processing is the same as well (#88305).

