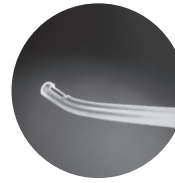


MX111 • Endocervical Curette with 12 mL Vacu-Lok Syringe

Directions for Use

DEVICE DESCRIPTION

The curette is used for endocervical tissue retrieval. The Nylon curette has a sharp Randall-type cutting edge and the outside diameter tapers to assure endocervical sampling. The Vacu-Lok Control Syringe allows adjustment of suction.



Endocervical Curette
with Vacu-Lok Control Syringe

WARNINGS

- Never introduce an instrument that has been exposed to fixative into the cervical canal.
- Any cervical manipulation may cause vasovagal reaction. Patient should be watched for evidence of unusual pallor, nausea, vertigo, or weakness. These symptoms will generally subside in about 15 minutes after rest and/or a mild analgesic.

CAUTION

- U.S. Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

- For complete histological sampling of the endocervical canal for early detection of cervical cancer
- For the evaluation of abnormal cervical cytology
- For patients who are high risk for cervical cancer

CONTRAINDICATIONS

Any endocervical curettage is contraindicated during pregnancy or in patients with certain other conditions that preclude any office procedure.

DIRECTIONS FOR USE

1. Perform the normal pelvic exam. Prepare vaginal area and cervix as you would for any sterile intracervical procedure.
2. Attach the 12 mL syringe to the curette, the curette has a Luer lock fitting. Notice that the shoulder on the curette assures that it won't be too distal.
3. Determine depth and direction of cervical canal.
4. With the syringe piston/plunger resting at base of barrel, insert the curette. Apply firm pressure on curette edge and curette four quadrants of the endocervical canal vigorously.
5. Now apply suction by withdrawing the plunger and locking it in position.

Most physicians use the full 12 mL or 20 inches of negative pressure, and curette vigorously 360°, to pick up tissue loosened or cut by step number 5. It is generally recognized that samples should be obtained from each quadrant.

Remember that the endocervical canal is composed of fibrous tissue, therefore the quantity of tissue will not be as that found in an endometrial biopsy. The suction will assure that tissue sampled is collected in the curette and syringe.

To lock plunger in place: Withdraw plunger as shown in **Figure A**. Holding plunger close to barrel, twist plunger clockwise (to the right) a ¼ of a turn until you feel it “catch”. This locks the plunger in place (test to be sure it is secure) to maintain negative suction throughout the procedure. You now have multi-stop control of curette/syringe.

You can adjust suction by pulling plunger to:

- 6 mL provides 15 inches negative pressure (approximate)(Hg)
- 9 mL provides 18 inches negative pressure (approximate)(Hg)
- 12 mL provides 20 inches negative pressure (approximate)(Hg)

6. To express tissue, first unlock syringe by twisting plunger ¼ turn counter-clockwise. Express tissue from curette directly into specimen container ½ filled with fixative.
7. Disconnect curette from syringe. Fill syringe with fixative and flush out curette directly into specimen container.
8. Clip off distal end (1"-1½") of curette and let drop directly into fixative (See **Figure B**).
9. Fill specimen jar with fixative short of top of jar.
10. Label and send to your lab.

Figure A

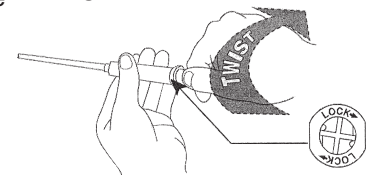
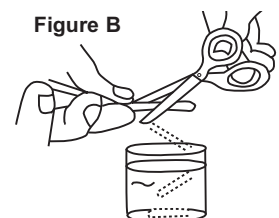


Figure B




Endocervical Curette with 12 mL Vacu-Lok Syringe • Directions for Use (continued)


EXPLANATION OF SYMBOLS


 Reorder Number

 Sterilized Using Ethylene Oxide


 Not made with natural rubber latex

 Batch Code

 Consult instructions for use.

 Do Not Reuse


 Use By

 Manufacturer

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CooperSurgical

95 Corporate Drive
Trumbull, CT 06611 USA
Phone: (800) 243-2974 • Fax: (800) 262-0105
www.coopersurgical.com
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 CooperSurgical, Inc
95 Corporate Drive
Trumbull, CT 06611 USA

International:
Phone: (203) 601-9818
Fax: (203) 601-4747

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