

SUCTION CANNULA-CURETTE

with 60cc Handyvak Locking Syringe

Product Number	Cannula Size	Cannula Type
MX503	3mm	Flexible
MX504	4mm	Flexible
MX505	5mm	Flexible
MX506	6mm	Flexible
MX507	7mm	Flexible



MX603	3mm	Semi-Rigid
MX604	4mm	Semi-Rigid
MX605	5mm	Semi-Rigid
MX606	6mm	Semi-Rigid
MX607	7mm	Semi-Rigid

Product Number	Cannula Size	Cannula Type
MX622	2mm	Stainless Steel
MX623	3mm	Stainless Steel

DEVICE DESCRIPTION

This product is a sterile, disposable device consisting of a Karman-type suction curette and a 60cc Handyvak Locking Syringe. The cannula-curette provides a quiet, portable device for obtaining a histologic sample from the endometrium on an outpatient basis usually without anesthesia. The smaller sizes are especially useful in early detection of endometrial carcinoma or its precursors.

WARNINGS

- Do not depress the syringe plunger while cannula-curette is in uterus.
- If the vacuum is lost, proceed to Step 3 after resetting locking device.
- Any cervical manipulation may cause a vaso-vagal reaction. Patient should be watched for evidence of unusual pallor, nausea, vertigo or weakness. By remaining recumbent for 3 to 10 minutes, these symptoms usually disappear.
- Patients with stenotic cervices may require an anesthesia.
- In the case of an incomplete abortion, patients experiencing continued bleeding with cramps may require reaspiration. This may be an indication of retained tissue. Oral methergine should be considered.
- If patient remains febrile after the procedure, physician evaluation is required.
- Possible perforation of the uterus must be guarded against both while sounding the uterus and using this device. No undue force should be exerted at any time.
- Contents supplied sterile. Do not use if sterile barrier is damaged.

- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

CAUTION

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

INDICATIONS FOR USE

- The primary uses of this device are for early detection of endometrial cancer and periodic monitoring of those patients with a higher risk of cancer.
- The device may also be used in the following situations: infertility, investigation of menstrual irregularities, and incomplete abortion (up to 7 weeks gestation).
- This self-contained device affords a quiet, simple office procedure for obtaining an endometrial tissue sample for histologic evaluation.

CONTRAINDICATIONS

- When used for cancer screening purposes, this device is contraindicated where pregnancy is suspected. In such cases, appropriate diagnostic tests are indicated.
- Patients suffering from diseases or conditions which contraindicate outpatient surgical procedures, e.g., pelvic inflammatory disease, acute infections of the cervix, clotting mechanism deficiencies, severe anemia, heart disease or extreme anxiety.
- In general, the same criteria for regular endometrial biopsy or a D & C procedure must be followed in office curettage.
- Contraindications of conventional D & C are contraindications for office curettage. Instructions to patients should be generally similar for both procedures.

INSTRUCTIONS FOR USE

Any endometrial biopsy should be preceded by a routine bimanual examination. If no contraindications for endometrial curettage are present, the cervix and vault should be swabbed with an antiseptic solution. It may be necessary to grasp the cervix with a tenaculum and apply gentle traction to straighten endocervical canal. Request for anesthesia is rare in endometrial monitoring or with gestation below seven weeks.

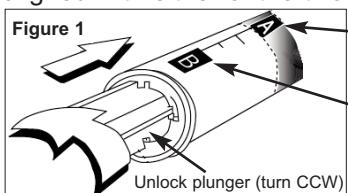
In rare cases when it remains difficult to insert the desired curette size, the Milex Dilateria™ (laminaria japonica) should be considered for prior dilation. (If the smallest size, MX200, is placed into the cervix 1 to 6 hours preceding the vacuum curettage, the cervix will be dilated and softened, and will pass the curette with ease.)

1. Carefully sound uterus to determine position and depth of uterine cavity.
NOTE: It is recommended that you transfer this measurement to patient's chart.

2. Insert curette to depth determined by uterine sounding. If a flexible curette is used, be certain the stylet is removed after curette has passed the internal cervical os.

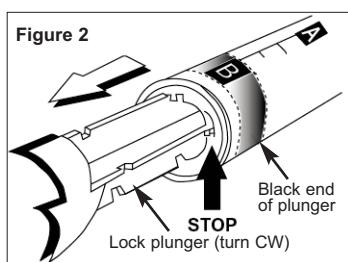
NOTE BEFORE ATTACHING SYRINGE TO CURETTE: The 60cc Handyvak Locking Syringe is shipped with the first notch engaged. To start procedure, turn plunger 1/4 turn counter-clockwise and push plunger to bottom of syringe barrel.

3. Tightly attach the syringe to the curette. Twist to lock it into place. The curette and syringe are now ready for use.
4. Hold barrel of syringe firmly. Withdraw plunger until black end of plunger is aligned with either of the two barrel markings "A" or "B".



POSITION "A": for a more sensitive cannula - curette feel.

POSITION "B": for maximum negative pressure (especially when using the larger size cannula-curettes).



- To unlock plunger: twist 1/4 turn to the left (counter-clockwise, CCW). See **Figure 1**.
- To lock plunger: twist 1/2 turn to the right (clockwise, CW). See **Figure 2**.

CAUTION: The plunger must be in a locked position before you begin the curettage.

5. Follow usual curettage procedures and precautions. Better control is achieved if the curette itself is held and manipulated, not just the syringe. On the flexible and semi-rigid models, the word "Milex" is approximately in-line with the curette edge for ease of determining which quadrant the sample is coming from. For the 2mm and 3mm stainless steel curette (MX622 and MX623), the flat portion of the curette base is approximately in-line with the curette edge.

6. If it becomes necessary to reduce or eliminate vacuum, do the following:
- a. Twist to detach the curette from the Handyvak syringe.
NOTE: If any specimen is in the syringe, it is wise to perform this step over a clean collection jar to catch the sample. A small collection jar should be half filled with fixative.
 - b. To disengage, turn plunger 1/4 turn counter-clockwise.
 - c. Press plunger to the bottom of the syringe barrel.
 - d. Collect any sample material as it is expressed. Handyvak Syringe is now in its original (unused) position.
 - e. If further curettage is required, reattach Handyvak Syringe as in Step 3 and proceed.
7. When procedure is completed:
- a. Withdraw curette from the uterine cavity.
 - b. Hold curette over the clean collection jar with fixative to catch the specimen. Withdraw plunger slightly. Turn 1/4 turn counter-clockwise.

- c. Push plunger into barrel of syringe, thus expressing sample into collection jar. Many experts recommend using the syringe to draw a small amount of fixative into curette and then expressing this into collection jar. This serves to rinse both the curette and syringe.
- d. Discard curette and syringe in accordance with all applicable Federal, State, and local Medical / Hazardous waste practices. Add additional fixative to jar containing endometrial tissue sample.

NOTE: Endometrial tissue is highly hygroscopic and requires about 10 times its volume in fixative to keep it in a satisfactory condition for a reasonable period of time. Also, if endometrial tissue is not properly fixed within one hour of the biopsy, it becomes useless for analysis by the pathologist.

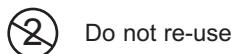
- e. Identify the sample and tightly close the collection jar. Sample is ready for delivery to the laboratory.
8. In later gestational stages, it may be necessary to dilate the cervix. A Dilateria (laminaria japonica) should be considered in these cases. Such cases generally require larger size curettes to be used with a suction pump and swivel handle.

POST OPERATIVE INSTRUCTIONS TO PATIENT

- Patient should report a fever.
- Patient should immediately report any bleeding or cramps in excess of normal menstruation.
- Patient should report any unusual pain.
- Contact physician any time you have a question.

EXPLANATION OF SYMBOLS

REF Reorder number



Do not re-use

LOT Batch code

Not made with natural rubber latex



Use-by date



Caution

STERILE EO Sterilized using ethylene oxide.



Consult instructions for use



Do not use if package is damaged



Do not resterilize

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



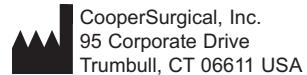
Manufacturer

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