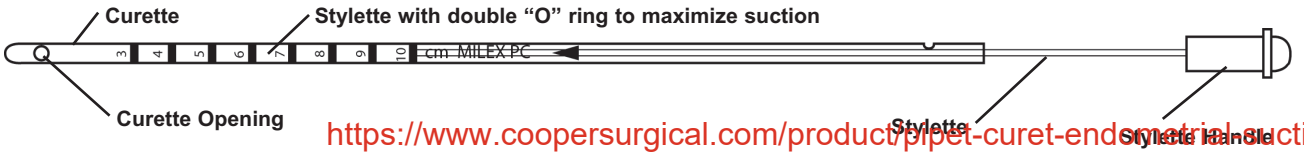
Pipet Curet™ • Endometrial Suction Curette

MX140 (3 mm OD) • MX145 (3 mm OD, Soft Yellow) • MX150 (4 mm OD)

Instructions for Use (English)

CE 0086



DEVICE DESCRIPTION

The Pipet Curet™ is a single-use, sterile, disposable, suction curette for obtaining a histologic biopsy of the uterine mucosal lining or sample extraction of uterine menstrual content for microscopic examination or culturing. The MX145 is ideal for patients with low pain threshold or hyperanxiety.

WARNINGS

- 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/orlead 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. Dispose of in accordance with all applicable Federal, State and local Medical/Hazardous waste practices.

CAUTION

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

PRECAUTIONS

- Determine depth of uterus and direction of endocervical canal prior to beginning the procedure.
- **NEVER** use force to introduce curette into canal.
- In cases where there is a marked cervical stenosis, Dilateria™ *(Laminaria japonica)* should be considered for use (to soften and dilate cervical os) prior to performing the procedure.

INDICATIONS FOR USE

- Cancer screening
- Endometrial dating
- Determine response to estrogen-replacement therapy
- Bacterial culturing
- Detection of pathology resulting in infertility
- Monitoring patients receiving tamoxifen therapy
- Secondary Amenorrhea

CONTRAINDICATIONS

- Patients where pregnancy is suspected
- Patients with, or recently recovered from pelvic inflammatory disease
- Patients with any cervical or pelvic infections *(infections should be treated and cured before performing any endometrial sampling procedure)*
- Patients suffering from any diseases or conditions which could under all circumstances contraindicate outpatient surgical treatment, e.g., severe anemia, heart disease, or clotting mechanism deficiencies

In general, the same criteria for regular hospital D&C should be followed for office suction curettage

INSTRUCTIONS FOR USE

1. Prepare vaginal area and cervix as you would for any sterile intrauterine procedure.
2. With a vaginal speculum in place and the cervical os visible, carefully sound the uterus with the sound curved in the direction of the canal, to determine both the position and the depth of the uterine cavity. In only an extremely small percentage of cases is anesthesia and/or premedication necessary. Advise patient that there may be a minimum amount of discomfort when the curette is first introduced. The discomfort can be alleviated by swabbing the internal os with a diluted topical anesthetic for approximately one minute prior to insertion of curette.
3. It may be necessary to use a tenaculum to grasp the cervix and apply gentle traction to straighten endocervical canal. To stabilize the cervix in those women with an anteverted uterus, grasp the anterior lip of the cervix with a tenaculum; if uterus is retroverted, grasp the posterior lip of the cervix and apply gentle traction to straighten the cervical curvature. If cervical canal is very dry, apply a small amount of sterile water-soluble gel to the entering end of the curette.

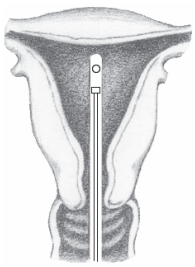


Figure 1

4. With the stylette positioned at the distal end of the curette, the Pipet Curet is gently inserted through the cervical canal and into the uterine cavity, to a depth corresponding to the depth determined by uterine sound. See **Figure 1**.
5. Release traction (remove tenaculum).
6. Hold the curette in position with one hand. With the other hand, rapidly withdraw the stylette with one swift steady motion, avoiding interruption in movement. See **Figure 2**.

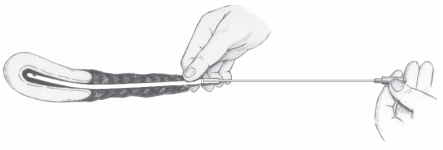


Figure 2

7. The stylette is withdrawn from curette as far as it will go. (The curette is designed to prevent total withdrawal of the stylette from the curette.) Leave the stylette fully retracted during the entire procedure.

NOTE: Hold the stylette at the base to prevent the stylette from being pulled back into the curette by suction created. See **Figure 3**. Partial, interrupted, or slow withdrawal of stylette will not provide the amount of negative pressure (suction) needed to obtain necessary tissue retrieval.

Figure 3

8. After withdrawing the stylette in Step 7, hold the stylette with two or three fingers, with the rest of the fingers on the curette (this is to prevent the build-up of negative pressure from pulling the stylette back into the curette). See **Figure 3**.
9. Immediately rotate the curette (twirl or roll) between the fingers, move from side to side at the same time you gently move the curette back and forth within the uterine cavity (3 or 4 in/out movements recommended). See **Figures 4 and 5**.
10. Gently withdraw the Pipet Curet from the uterus.
11. Cut off distal end of the Pipet Curet just above the curette opening, letting the tip drop into the container with appropriate fixative. **See Figure 6**.
12. Feed the stylette back into the curette to expel remaining tissue into the fixative.
13. Fill a specimen container with fixative.
14. Tightly close the specimen container and label.
15. Transfer the depth of uterine cavity as determined by uterine sounding to the patient's chart.
16. Dispose of the Pipet Curet in accordance with all applicable Federal, State, and local Medical Hazardous / Waste practices.

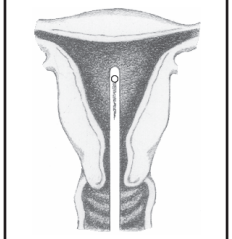


Figure 4

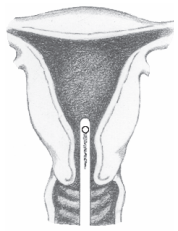


Figure 5

NOTE: Uterine mucosal specimen should be visible within the curette. Generally, little if any bleeding occurs.

Any cervical manipulation may cause a vaso-vagal reaction. The patient should be watched for evidence of unusual pallor, nausea, vertigo or weakness. These symptoms will generally respond to about 15 minutes of rest and/or mild analgesic.

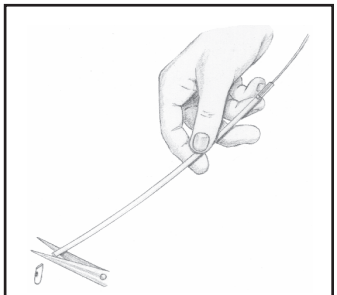


Figure 6

POST-PROCEDURE

Following the procedure, have the patient report any bleeding, low-grade fever, and/or continued cramping.

EXPLANATION OF SYMBOLS

REF — Reorder Number

LOT — Batch Code

Use-By Date

STERILE EO — Sterilized Using Ethylene Oxide

LATEX — Not made with natural rubber latex.

R_xOnly — **Caution:** U.S. Federal law restricts this device to sale by or on the order of a physician

Consult instructions for use.

EC REP — Authorized Representative in the European Community.

2 STERILIZE — Do not resterilize

Caution

2 — Do Not Re-use

Manufacturer

Do not use if package is damaged.