

GYNEX[®]

Instructions For Use:

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Endometrial Curette

STERILE EO Single-Use 

Not made with natural rubber latex.

DESCRIPTION

The ETO Sterilized curette is used to obtain a sample of differentiated endometrial tissue. The curette is a 3mm (O.D.) endometrial suction curette with a Randall-like cutting edge at its distal end and packaged with a twist-and-lock syringe. The syringe provides the vacuum or suction during the procedure. The curette is sterile unless the package is opened or damaged. It is designed for single patient use only.

INDICATION

The curette is a device used to remove samples of materials from the uterus and from the mucosal lining of the uterus by scraping or vacuum suction. These devices obtain tissue samples for purposes of biopsy precancer screening or they can be used for menstrual extraction.

CAUTION

Federal law restricts this device to sale by or on the order of a physician. Do not reuse for avoiding user may be infected by the microorganism.

CONTRAINDICATIONS

The procedure is contraindicated in suspected pregnancy or in women with acute pelvic inflammatory disease. It is also contraindicated in women with chronic cervical infections or any conditions which contraindicate an outpatient surgical procedure.

PROCEDURES

While sounding the uterus and using this device, care should be taken to avoid perforation of the uterine wall. Do not depress the syringe's piston while it is in the uterus.



WARNINGS

- In general, any patient with cervical stenosis requires extreme precaution. Do not use force when using this device with these patients. You may use a topical anesthetic prior to the use of the curette.
- Be aware of and look for adverse reactions that are occasionally encountered in any intrauterine procedure.

ADVERSE REACTIONS

- Patients should be carefully watched for evidence of unusual paleness, nausea, vertigo or weakness. Any cervical manipulation may cause a vasovagal reaction. These symptoms typically subside in about 15 minutes of rest and/or a mild analgesic.
- In some cases, there may be spot bleeding or mild cramps after this procedure has been performed. The patient should be instructed to notify the physician if spotting continues or if a persistent fever develops.

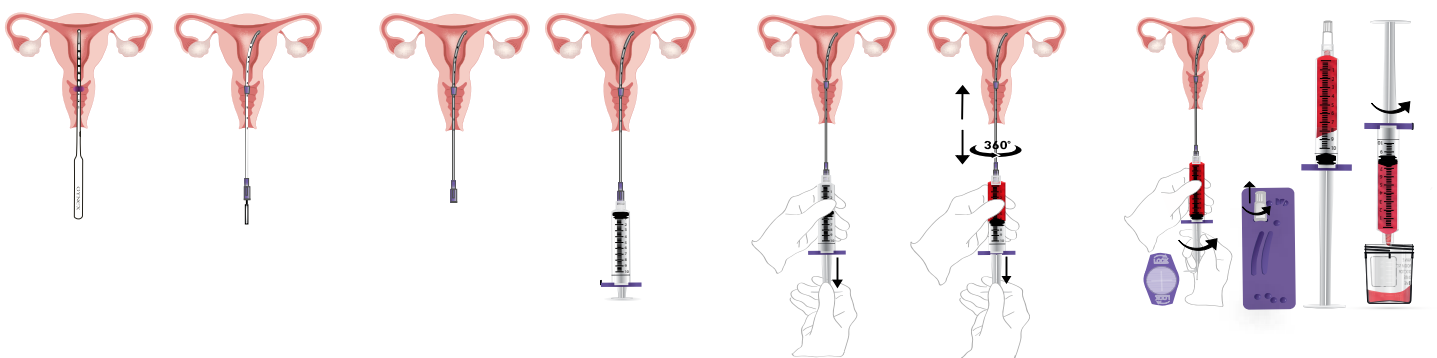
STORAGE

Store at room temperature.



DIRECTIONS FOR USE

1. Prepare the vagina and cervix as you would for any sterile intrauterine procedure.
2. Expose the cervix using a suitable speculum.
3. Gently insert a uterine sound to determine the depth and direction of the uterine cavity. It may be necessary to grasp the cervix with a tenaculum. If the uterus is anteverted, the grasp should be on the anterior lip of the cervix. If the uterus is retroverted, the grasp should be on the posterior lip of the cervix. Apply gentle traction to straighten any cervical curvature.
4. After the depth of the cervix has been determined, insert the curette paying close attention to the embossed scale on the curette sleeve or use the enclosed "stopette." This will provide additional protection from perforation.
5. With the piston of the curette's syringe completely depressed, the curette should be inserted and gently passed through the cervical canal and into the cavity of the uterus. Discontinue any traction applied with a tenaculum. Carefully attach the syringe to the base of the curette. Please note, that the "arrow" at the proximal end of the curette is aligned with the cutting edge or sampling point of the distal end.
6. With one hand holding the proximal end of the curette, withdraw the piston of the syringe with your free hand creating a vacuum within the curette. The withdraw motion should be smooth and steady until the piston reaches the end stop of the syringe. Now grasp the piston syringe close to the blue locking mechanism and lock the piston in place by turning the piston 1/4-turn clockwise. Test to be sure the piston is secured in its locked position. When locked, the syringe will provide adequate vacuum or suction during the procedure.
7. After the piston has been retracted and locked to provide a vacuum or suction, rotate the curette through all four quadrants of the endometrium by using long slow strokes.
8. The curette should be gently removed from the uterus. Upon examination of the device, you should see a specimen or sample from the endometrium of histological quality. Bleeding is usually minimal, if it occurs at all.
9. Cut off the tip of the curette just above the sampling point of the device. The sampling point is the entrance port with the Randall-like cutting edge at the distal end of the curette. Unlock the syringe by turning the syringe piston 1/4 turn counterclockwise and expel the specimen into an appropriate transfer vial.



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