



Ensula Curette

US Patent # 5217024 and #5358497

The ETO Sterilized **Ensula Curette** is used to obtain a sample of differentiated endometrial tissue. The **Ensula 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 **Ensula Curette** is sterile unless the package is opened or damaged. It is designed for single patient use only.

PRODUCT NUMBER : RD003

CAUTION

Federal law requires that this device be ordered by a physician.

Do not reuse for avoiding user may be infected by the microorganism.

INDICATION

The **Ensula Curette** is used to obtain endometrial tissue lining and superficial layers of the uterine endometrial wall for histological study.

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.

DIRECTIONS FOR USE

1. Prepare the vagina and cervix as you would for any sterile intrauterine procedure.

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STERILE EO



EC REP

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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 **Ensula Curette** paying close attention to the embossed scale on the **Ensula Curette** sleeve or use the enclosed "stopette." This will provide additional protection from perforation.
5. With the piston of the **Ensula Curette's** syringe completely depressed, the **Ensula 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 **Ensula Curette**. Please note, that the "arrow" at the proximal end of the **Ensula Curette** is aligned with the cutting edge or sampling point of the distal end.
6. With one hand holding the proximal end of the **Ensula Curette** withdraw the piston of the syringe with your free hand creating a vacuum within the **Ensula 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 **Ensula Curette** through all four quadrants of the endometrium by using long slow strokes. from the uterus. Upon examination of the device,
8. The **Ensula Curette** should be gently removed 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 **Ensula 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 **Ensula Curette**. Unlock the syringe by turning the syringe piston 1/4 turn counterclockwise and expel the specimen into an appropriate transfer vial.

WARNINGS

1. 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 **Ensul Curette**.
2. Be aware of and look for adverse reactions that are occasionally encountered in any intrauterine procedure.

ADVERSE REACTIONS

1. 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.
2. 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.