

PRODUCT NUMBER

- 30-3015 Endometrial Sampling Set

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

CAUTION

Federal law requires that this device be used by or on the order of a licensed physician.

INDICATIONS

The Endometrial Sampling Set 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 that 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.
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 Endometrial Sampling Set**, paying close attention to the embossed scale on the Endometrial Sampling Set sleeve. This will provide additional caution against perforation.
5. With the piston of the Endometrial Sampling Set's syringe completely depressed, the **Endometrial Sampling Set 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 Endometrial

Sampling Set. Please note: The "arrow" at the proximal end of the Endometrial Sampling Set is aligned with the cutting edge or sampling point of the distal end.

6. With one hand holding the proximal end of the Endometrial Sampling Set, **withdraw the piston of the syringe with your free hand**, creating a vacuum within the Endometrial Sampling Set. The withdrawal 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 Endometrial Sampling Set through all four quadrants of the endometrium** by using long, slow strokes.
8. **The Endometrial Sampling Set 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 Endometrial Sampling Set** 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 Endometrial Sampling Set. Unlock the syringe by turning the syringe piston turn counterclockwise and expel the specimen into an appropriate transfer vial.

WARNINGS

1. In general, any patient with cervical stenosis requires extreme precautions. Do not use force when using this device with these patients. You may use a topical anesthetic prior to the use of the Endometrial Sampling Set.
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 with 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.