

## PRODUCT NUMBERS

- 30-3010 SoftFlex Endo Biopsy Cannula
- 30-3012 FirmFlex Endo Biopsy Cannula
- 25/box

Either of the sterile (ETO) Endo Biopsy Cannula is used to obtain a sample from the uterine mucosal lining. The Endo Biopsy Cannula is a 3mm (O.D.) suction curette and is sterile unless the package is opened or damaged. The Endo Biopsy Cannula is designed for single use only. Although the SoftFlex construction is more commonly used – it is the preference of the clinician as to which of the two versions is suitable for the patient.

## CAUTION

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

## INDICATIONS

The Endo Biopsy Cannula is used to obtain a sample of the mucosal lining for histological study in cancer screening, endometrial dating or bacterial culturing.

## 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 piston of the Endo Biopsy Cannula 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 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 Endo Biopsy Cannula** paying close attention to the embossed scale on the Endo Biopsy Cannula sleeve. This will provide additional caution against perforation.
5. With the piston of the Endo Biopsy Cannula's syringe completely depressed, the **Endo Biopsy Cannula should be inserted and gently passed through the cervical canal and into the cavity of the uterus**. Discontinue any traction applied with a tenaculum.

6. With one hand holding the proximal end of the Endo Biopsy Cannula and the other hand holding the piston handle **rapidly withdraw the piston by pulling back on the handle**, creating a vacuum or suction within the Endo Biopsy Cannula. The withdrawal motion should be smooth but quick and steady until the piston reaches the end-stop built into the Endo Biopsy Cannula. Leave the piston in its fully withdrawn position.
7. After the piston has been retracted, immediately **rotate the Endo Biopsy Cannula** (either twirl or roll) between the fingers while moving the Endo Biopsy Cannula back and forth and side to side within the uterine cavity. Continue this sweeping motion at least three or four times to obtain an adequate sample.
8. **The Endo Biopsy Cannula should be gently removed from the uterus**. Upon examination of the device, you should see a specimen or sample from the uterine mucosal lining. Bleeding is usually minimal, if it occurs at all.
9. **Cut off the tip of the Endo Biopsy Cannula** just above the sampling point of the device. The sampling point is the small hole at the distal end of the Endo Biopsy Cannula.
10. **Now push the piston back into the sleeve of the Endo Biopsy Cannula**, and the specimen should be easily expelled 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 Endo Biopsy Cannula.
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.