



REF MDS6303010

REF MDS6303012

ENDOMETRIAL BIOPSY CANNULA

EASY FLEX OR HARD FLEX

INSTRUCTIONS FOR USE

Sterile. Single use only. Discard after using.

(ETO) sterilized Endometrial Biopsy Cannula is used to obtain a sample from the uterine mucosal lining. The Endometrial Biopsy Cannula is a 3mm(O.D.) suction curette and is sterile unless the package is opened or damaged. The endometrial biopsy cannula is designed for single use only.

PRODUCT NO.

MDS6303010 EasyFlex 3.0

MDS6303012 HardFlex 3.0

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician.
Do not reuse.

INDICATIONS

The Endometrial 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 which contraindicate an outpatient surgical procedure.

PRECAUTIONS

While sounding the uterus and using this device, care should be taken to avoid perforation of the uterine wall. Be sure not to depress the piston of the Endometrial 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 necessary to grasp the cervix with a tenaculum. If the uterus is anteverted, then the grasp should be on the anterior 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 Biopsy Cannula paying close attention to the embossed scale on the Endometrial Biopsy Cannula sleeve. This will provide additional caution against perforation.
5. With the piston completely depressed, the Endometrial 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 Endometrial Biopsy Cannula and the other hand holding the piston “paddle” rapidly withdraw the piston by pulling back on the “paddle”, creating a vacuum or suction within the Endometrial Biopsy Cannula. The withdraw motion should be smooth but quick and steady until the piston reaches the end stop built into the Endometrial Biopsy Cannula. Leave the piston in its fully withdrawn position.
7. After the piston has been retracted, immediately rotate the Endometrial Biopsy Cannula or roll between the fingers while moving the Endometrial 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 Endometrial 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 Endometrial Biopsy Cannula just above the sampling point of the device. The sampling point is the small hole at the distal end of the Endometrial Biopsy Cannula.
10. Push the piston back into the sleeve of the Endometrial Biopsy Cannula, and the specimen should be easily expelled into an appropriate transfer vial.

WARNING

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 Endometrial 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 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 patients should be instructed to notify the physician if spotting continues or if a persistent fever develops.

