

INSTRUCTIONS FOR USE:

1. Prepare the vaginal area and cervix for a sterile intrauterine procedure using an antiseptic solution.
2. With a vaginal speculum in place, carefully examine the depth of uterine cavity. It may be necessary to use a tenaculum to grasp the cervix to straighten the cervical canal.
3. Gently insert the curette. If cervical canal is very dry, apply a small amount of sterile water-soluble gel to the tip of curette.
4. Attach syringe to the base of curette.
5. Withdraw the plunger fully of lock the clip in place to create a vacuum in the curette.
6. Use long slow strokes to obtain sample from the four quadrants of the endometrium. If the syringe fills with tissue and needs additional vacuum, disconnect syringe leaving the curette in place. Unlock the spring mechanism and empty the contents into a container with fixative. Reattach the syringe to curette and continue.
7. When curettage is completed, withdraw the curette from uterus and expel tissue into the container with fixative. Endometrial tissue is hygroscopic and should be placed in fixative to maintain the tissue in a satisfactory condition for the pathologist.
8. Withdraw fixative into curette and syringe and flush into container to wash out any tissue that may have lodged in curette.
9. Allow patient to remain in the same position for about 10 minutes.

SEE PRODUCT LABEL FOR:



Endosampler IFU - English
ENDOSAMP-IF4

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ENDOSAMPLER I AND II

DEVICE DESCRIPTION:

MedGyn Endosampler is a sterile, disposable catheter/cannula with a 10 ml syringe that is fitted with a locking clip. The semi-rigid cannula is 3 mm in diameter with graduated markings and is bent conveniently with a single or double slot for sampling from all areas of the endometrial cavity including the cornual areas.

INDICATIONS FOR USE:

- The device is meant for uterine diagnostic and therapeutic uses.
- The device is used for obtaining clearly differentiated endometrial tissue sample without anesthesia in an outpatient setting or as in an office setting.
- The sample is used for cytologic and histologic diagnosis.

CONTRAINDICATIONS:

CURETTAGE SHOULD NOT BE PERFORMED FOR:

- Patients where pregnancy is suspected unless a termination of pregnancy is to be carried out.
- Patients with or recently recovered from pelvic inflammatory disease.

WARNINGS:

- STERILE unless package opened or damaged
- SINGLE USE ONLY. DO NOT REUSE.
- DISPOSABLE - DISCARD AFTER USE.
- STERILIZED BY ETHYLENE OXIDE

CAUTION:

Federal law restricts this device to sale by or on the order of a physician.

PRECAUTIONS:

- This procedure is to be used by a physician who has been trained thoroughly in operative obstetrics and gynecology.
- All instructions to be carefully read prior to the use of the vacuum aspiration curette/catheter.
- Pelvic examination should be accomplished to determine size and position of the uterus.
- A thorough speculum examination of the vaginal canal is to be accomplished and indicated smears of cultures are to be obtained prior to sounding.
- Care should be exercised to avoid the possibility of uterine perforation as well as cervical lacerations with the use of any aspiration catheter, sound, canal finder, fundus locator or dilator.
- Do not re-use the Endosampler. If the device is reused it can cause a cross infection or may have loss of function.

ADVERSE REACTIONS:

- Any cervical manipulation may cause a reaction. Patient should be watched for unusual weakness or nausea.
- In rare cases there may be mild cramp or spotting. If bleeding persists, patient should be instructed to contact her physician.

PRODUCTS:

