

INSTRUCTIONS FOR USE:

1. Prepare the vaginal area and cervix for sterile intrauterine procedure using an antiseptic solution
2. Use a vaginal speculum to view the cervix
3. Gently insert a uterine sound to measure the depth of the uterus. **DO NOT USE** the MedGyn Pipette as a uterine probe
4. Grasp the cervix with a single tooth tenaculum
5. Turn the cervix to insert the Pipette
6. With the piston fully depressed, gently insert the MedGyn Pipette through the cervix into the uterine cavity up to the fundus as previously determined by uterine sound. **DO NOT USE FORCE** to achieve insertion
7. Release the traction applied to the cervix by the tenaculum when the device is positioned inside the uterine cavity
8. Hold the Pipette in place with one hand and withdraw the piston rod with the other hand until the piston rod stops. Then rotate the device continuously through 360 degrees with a gentle "to and fro" movement to aspirate the specimen into the Pipette
9. Withdraw the MedGyn Pipette from the uterus and allow the patient to rest. The uterine mucosa specimen should be very clearly visible in the Pipette. Bleeding, if any, should be minimal.
10. Cut the tip of the Pipette at the site of the distal hole and expel tissue into a specimen container with fixative

SEE PRODUCT LABEL FOR:



Pipette I, II and IV IFU - English
PIPET124-IF6

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PIPETTE, PIPETTE II AND PIPETTE IV

DEVICE DESCRIPTION:

MedGyn Pipette is a sterile, disposable sampling device. It consists of a 23.5 cm long clear, flexible tube with a 3.1 mm O.D. and an inside piston rod. The outer tube is marked at 2,3,4,5,6,7,8,9,10,11 and 12 cm distance from the distal rounded tip of the device. There is one opening of approximately 3 mm at approximately 3 mm from the distal tip in MedGyn Pipette through which the speculum will be aspirated. There are two openings of approximately 2.2 mm in MedGyn Pipette II one at approximately 3 mm and the other at approximately 9 mm from the distal tip on the opposite side. There are four openings of approximately 2.2 mm in MedGyn Pipette IV two openings at approximately 3 mm and the other two openings at approximately 9 mm from the distal tip. Both sets of openings are at 90 degrees to each other for ease of aspiration.

INDICATIONS FOR USE:

The device is meant for uterine diagnostic use. 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 a histological and cytological diagnosis.

CONTRAINDICATIONS:

MedGyn Pipette should not be used in:

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

WARNINGS:

- CONTENTS STERILE IN UNOPENED, UNDAMAGED PACKAGE
- 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 device is to be used by a physician thoroughly trained in operative obstetrics and gynecology
- All instructions to be carefully read prior to use
- Depth of the uterus should be determined before inserting the device to prevent uterine wall perforation
- If the insertion of the device is difficult, it should not be forced. The patient should be checked for pathologic cervical stenosis.
- In elderly patients, who might have dry cervix, slight lubrication of the exterior of the device with a sterile, water soluble gel will facilitate insertion.

ADVERSE REACTIONS:

Adverse reactions include occasional transient uterine cramping and minimal uterine bleeding.