#9164 GYNOSAMPLER

Endometrial Curette

HOW SUPPLIED:

REF #9164 Gynosampler

Important product information, read carefully before use
Disposable – discard after single use
Re-use may cause sexually transmitted infections
Caution: federal (USA) law restricts this device to sale by or on the order of a physician
Sterile: unless pouch is damaged or opened.

DESCRIPTION

The device is an endometrial suction curette (sampling) with markings to indicate depth. Intended patient population: women.

INDICATIONS FOR USE

The device is a single-use, sterile, disposable curette for obtaining histological biopsy of the glandular epithelium and superficial chorionic layers of the uterine endometrial wall or sample extraction of uterine menstrual content for any of the following:

a) Routine screening for early detection of endometrial carcinoma or other precancerous conditions which could make estrogen therapy inadvisable.
b) Evaluation of endometrial tissue response in patients receiving estrogen replacement therapy for menopausal symptoms.
c) Endometrial dating and evaluation of uterine pathology associated with infertility, luteal insufficiency, or functional metrorrhagia.
d) Identification of specific uterine pathogens by bacterial culturing of uterine samples.

CONTRAINDICATIONS

The device should not be used when one or more of the following conditions exist:

1. Pregnancy or suspicion of pregnancy.
2. Acute pelvic inflammatory disease (PID) or recent treatment for PID.
3. Untreated acute cervicitis, chronic cervicitis, or vaginitis, including bacterial vaginosis, until infection is controlled.

WARNINGS

The device should not be used to obtain an endometrial biopsy in patients with amenorrhoea unless a laboratory test has confirmed the absence of detectable circulating HCG levels. Not sterile if pouch is damaged or opened, discard immediately. Forcing may result in tissue damage/perforation of uterine wall. The device should be used by healthcare professionals trained in endometrial biopsy procedures. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State.

PRECAUTIONS

Prior to insertion of the device, the uterus should be carefully sounded to determine the degree of patency of the endocervical canal and the internal os, and the direction and depth of the uterine cavity. If resistance is felt at any time in the procedure, the device should never be forced. Slight lubrication of the sheath with a water soluble gel may aid the insertion.

ADVERSE REACTIONS

The adverse reactions cited as having been reported to occur are not listed in any order of frequency or severity. Reported adverse reactions from endometrial sampling procedures include perforation of the uterus, pain and cramping, uterine spasm, vasovagal syncope, and vaginal bleeding.

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Manufactured by:
Gynétics Medical Products N.V.
Rembert Dodoensstraat 51
3920 Lommel, Belgium

PACKAGED:

3 boxes of 25 individually sterile packed, disposable devices.

DIRECTIONS FOR USE

1. Check the expiry date of the device.
2. Position the patient in the lithotomy position. Insert vaginal speculum to expose the cervix.
3. Prepare the vagina and cervix using currently accepted antiseptic techniques for intrauterine procedures, use of aseptic technique during the entire procedure is essential.
4. With a speculum in place, gently insert a sterile uterine sound to determine the depth and direction of the uterine canal. If the uterus is anteverted or retroverted, it may be advisable to use very fine forceps or a tenaculum to correct the angulation and stabilize the cervix.
5. After sounding the uterus, the depth and direction of the uterine canal should be noted. With the piston fully engaged in the sheath, the device is gently inserted through the cervical canal into the uterine cavity until wall contact is felt. If resistance is encountered, no attempt should be made to force the insertion. In patients with an extremely dry or narrow cervical canal, slight lubrication of the sheath with a water soluble gel may aid the insertion.
6. When the sheath is correctly positioned in the uterine cavity, the piston should be pulled back as far as possible with one hand while the sheath is held in position with the other hand. A quick and steady motion will create the maximum negative pressure within the sheath and result in an optimal tissue sample.
7. After pulling back the piston, the sheath should be rolled between the fingers while simultaneously moving it laterally as well as back and forth inside the uterus three (3) to four (4) times for comprehensive sampling.
8. The device should be removed gently from the patient.
9. The distal tip of the sheath should be examined for the presence of a uterine mucosa sample.
10. To expel the sample into the transport container, the distal tip is cut just below the side hole and the piston is pushed into the sheath to expel the sample.
11. Safely discard after use.in accordance with local regulation

REF Catalogue number
LOT Batch code
Manufacturer
30°C 86°F / 0°C 32°F Temperature limit
Consult instructions for use
CE marking of conformity
Use-by date
STERILE EO Sterilization using ethylene oxide
Do not use if package if damaged
Do not reuse
MD Medical device
Do not resterilize
Single sterile barrier system
Single sterile barrier system with protective packaging
UDI Unique device identifier
Keep dry
Date of manufacture

REF: 02803j
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