

REF #9164 GYNOSAMPLER

Endometrial Curette

Important product information, read carefully before use

Disposable – discard after single use **Sterile: unless pouch is damaged or opened****Re-use may cause sexually transmitted infections****Caution: federal (USA) law restricts this device to sale by or on the order of a physician****DESCRIPTION**

The Gynosampler is an endometrial suction curette (sampling) with markings to indicate depth and has a handle with luer lock.

INDICATIONS FOR USE

The Gynosampler 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:

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

CONTRAINDICATIONS

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

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

**WARNINGS**

The Gynosampler 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.

The Gynosampler should only be used by an experienced medical practitioner, skilled in endometrial sampling.

Not sterile if pouch is damaged or opened, discard immediately.

The Gynosampler should in no case be forced, forcing may result in tissue damage/ perforation of the uterine wall.

PRECAUTIONS

Prior to insertion of the Gynosampler, 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 Gynosampler should never be forced.

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:
Gynetics Medical Products N.V.
Rembert Dodoensstraat 51
3920 Lommel, Belgium

HOW SUPPLIED:

#9164 Gynosampler

PACKAGED:

10 boxes of 25 individually sterile packed, disposable devices.

DIRECTIONS FOR USE

- Prepare the vagina and cervix using currently accepted antiseptic techniques for intrauterine procedures, use of aseptic technique during the entire procedure is essential.
- 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.
- After sounding the uterus, the depth and direction of the uterine canal should be noted. With the piston fully engaged in the sheath, the Gynosampler 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.
- 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.
- 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.
- The Gynosampler should be removed gently from the patient.
- The distal tip of the sheath should be examined for the presence of a uterine mucosa sample.
- 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.
- Safely discard after use in accordance with local regulation.



Catalogue number



Batch code



Manufacturer



Temperature limit



Consult instructions for use



CE marking of conformity



Use-by date



Sterilization using ethylene oxide



Do not use if package is damaged



Do not reuse



Medical device



Do not resterilize