WALLACH®

ENDOCELL™ Endometrial Cell Sampler

REF 908014A - Box of 35 (English)
REF 908015 - Case of 210
REF 908016 - Case of 525

Not made with natural rubber latex

CE 0086

Read all safety information and instructions before using this product!

WARNING

- Endocell™ should not be used on patients who are pregnant or suspected of being pregnant.
- Endocell™ should not be used on patients with acute pelvic inflammatory disease or blood clotting disorders.
- Extraordinary uterine flexion, cervical stenosis or other restrictions may preclude the use of this device.
- Perforation of the uterine wall may result if uterus is not properly sounded.
- In no event should force be used when inserting Endocell™.
- Contents supplied sterile. Do not use if sterile barrier is damaged.
- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/orlead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. Dispose of in accordance with all applicable Federal, State and local Medical/Hazardous waste practices.

CAUTION

U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

PRECAUTIONS

Use a sounding device prior to inserting the Endocell™ Endometrial Cell Sampler. If entry or passage of the Endocell™ Endometrial Cell Sampler is difficult, or causes spasms or cramping, or suspected perforation of the uterine wall, discontinue use immediately. In patients with an extremely dry cervix, slight lubrication of the sheath with a water soluble gel may facilitate its insertion. All movements of the device should be performed gently and with ease.

ADVERSE REACTIONS

- Cramping
- Uterine spasm
- Endometrial aspiration may be associated with or followed by vaso-vagal symptoms and signs.

PRODUCT DESCRIPTION

The Wallach Endocell™ Endometrial Cell Sampler is a single-use, sterile, disposable plastic device designed to extract sample tissue from the uterine mucosal lining, or to extract a sample of uterine menstrual content, for histological examination.

The device consists of a clear, flexible outer sheath 24.3 cm long and 3.1 mm OD (outside diameter), marked with sounding marks 1 cm apart starting at 3 cm, with a circular collection port 3.4 mm from the distal end.

The Endocell™ Endometrial Cell Sampler is packaged in an individual EtO sterilized pouch. The device draws tissue through a distal collection port by means of a vacuum, created when the inner plunger is pulled through the outer sheath.

INDICATIONS FOR USE

Extraction of uterine content for:

- Detection of endometrial carcinoma and precancerous conditions
- Determination of endometrial tissue response to hormonal influences
- Diagnosis of pathology associated with infertility
- Bacterial culturing to identify causative uterine pathogens

INSTRUCTIONS

1. Prepare the vagina and cervix for the intrauterine procedure.
2. Expose the uterine cervix with an open vaginal speculum in place. Using a uterine sound, gently probe the uterine canal for depth and direction. Do not use the Endocell™ Endometrial Cell Sampler for sounding.
3. Stabilize the cervix and straighten any cervical curvature.
4. Remove the Endocell™ Endometrial Cell Sampler from its protective package, keeping the plunger fully forward in its sheath. Gently admit the Endocell™ Endometrial Cell Sampler through the cervical canal into the uterine cavity.
   IN NO EVENT SHOULD FORCE BE USED. The sounding marks are a guide to depth.
5. Once in position, discontinue any traction applied. Then, hold the sheath in one hand, and smoothly draw back the plunger to the stop, thus creating a vacuum within the sheath (maintain device position within the canal). Do not withdraw the plunger from the sheath as this will eliminate the vacuum.
6. The sheath is then rotated between the thumb and forefinger, while at the same time it is gently stroked in and out between the internal cervical os and the fundus of the uterus. This combined movement is performed 3-4 times, as the vacuum created in the sheath draws in the tissue through the collection port at the distal end. Do not allow the device to exit the canal while moving it in and out.
7. Upon completion of the rotating/stroking motions, leave the plunger withdrawn and remove the entire device from the canal. Examination of the sheath should reveal a specimen of uterine content clearly visible. Bleeding should be minimal or non-existent.
8. Snip the distal end of the sheath immediately proximal to the distal opening with a sterile pair of scissors. Express the accumulated material into an appropriate transport medium by pushing the plunger forward to its original position in the sheath.
9. Dispose of Endometrial Cell Sampler in accordance with local medical hazardous waste practices.

EXPLANATION OF SYMBOLS

REF	Reorder Number
LOT	Lot number
	Use-by
	Consult instructions for use
2 STERILIZE	Do not resterilize
2	Do not re-use
	Do not use if package is damaged
LATEX	Not made with natural rubber latex
STERILE EO	Sterilized using ethylene oxide
R_x Only	U.S. Federal law restricts this device to sale by or on the order of a physician.
CE 0086	Product conforms to the Medical Device Directive 93/42/EEC
EC REP	Authorized Representative in the European Community
	Manufacturer

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