SM200 • SelectCells Standard®

Endometrial Sampling Device
For histologic biopsy of the endometrium or for sampling the uterine menstrual content.

Length: 21.7 cm (effective) 26.1 cm (overall)
O.D 3.1 mm
I.D. 2.6 mm

STERILE unless package has been opened or damaged
WARNING: NEVER ATTEMPT TO RESTERILIZE.
CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

Device Description
The SelectCells Standard® is a single use, sterile, disposable sampling device. The SelectCells Standard® consists of a 23 cm long clear, flexible, polypropylene sheath with a 3.1 mm O.D. and a 2.6 mm I.D., and a rod made of acetal copolymer. The sheath is marked at 4, 5, 6, 7, 8, 9, and 10 cm distance from the extreme distal, rounded tip of the device. The sheath has an arrow. Its tip points to the position of the device opening. At 3.5 mm from the extreme distal tip of the sheath is the device opening of 2.2 mm diameter through which the specimen will be aspirated. An ethylene copolymer and vinyl acetate piston is molded onto the distal end of the semi-rigid rod which can be moved forward and backward through almost the full length of the sheath lumen. This is accomplished by pulling the proximal tip of the piston rod that protrudes from the proximal end of the sheath. The narrower proximal end of the sheath prevents the piston from being totally withdrawn from the sheath. Suction is created by the movement of the piston inside the sheath.

Indications for Use
Histologic biopsy of the uterine mucosal lining or sample extraction of uterine menstrual content for:
- Evaluation of infertility conditions, menstrual disorders, post-menopausal bleeding, abnormal cytology suggesting endometrial origin
- Detection of endometrial carcinoma
  \( \text{(Note: The most reliable method for the detection of endometrial carcinoma is diagnostic hysteroscopy followed by dilation of the cervix and uterine curettage performed under general anesthesia.)} \)
- Diagnosis of luteal defect (Diagnosis of luteal defect is visually determined histologically from endometrial tissue obtained only during the secretory [progestational] phase of the menstrual cycle.)
- Endometrial dating
- Microscopic examination

Contraindications
The SelectCells Standard® should not be used in:
- pregnant patients or in patients suspected of being pregnant
- the presence of chronic or acute cervical infection
- the presence of vaginitis until infection is controlled
- patients currently under antimicrobial therapy
- the presence of or after recent Pelvic Inflammatory Disease (PID)
- patients with known coagulopathies
- patients known to have an endocardial seeding

Warnings

IN CASE AN INADEQUATE TISSUE SAMPLE IS OBTAINED, CAREFUL PATIENT FOLLOW-UP IS MANDATORY. IN SUCH A CASE, THE ENDOMETRIAL SAMPLING PROCEDURE SHOULD BE REPEATED USING MULTIPLE SAMPLING AND MULTIPLE DEVICES, OR A DILATION AND CURETTAGE OR HYSTEROLOGY MAY BE NECESSARY TO RULE OUT ATROPHIC ENDOMETRIUM OR OTHER PATHOLOGY.

Precautions
Due to its flexibility and rounded tip the SelectCells Standard® can be introduced in the uterus with minimal risk of uterine wall perforation. However, care should be taken prior to device insertion to ascertain the depth of the uterus and any uterine retroflexion or anteflexion present in individual patients. In NO CASE should the device be forced against resistance.

Adverse Events
The following adverse effects or events have occasionally been reported in the literature concerning endometrial sampling devices using manually produced suction:
- Uterine wall perforation
- Transient uterine cramping
- Minimal uterine bleeding

Instructions for Use
1. With the patient in the dorsal lithotomy position, proceed to the disinfection of the vagina and cervix using currently accepted disinfection techniques with a suitable antiseptic.
2. Expose the uterine cervix to view with a vaginal speculum.
3. Gently probe the uterus for depth and direction with a uterine sound. DO NOT USE the SelectCells Standard® as an uterine probe.
4. Grasp the anterior lip of the cervix if the uterus is antverted, or the posterior lip of the cervix if the uterus is retroverted, with a single tooth tenaculum or very fine forceps. Endometrial sampling may be accomplished without the use of tenaculum or forceps if the uterus does not present any flexion.
5. Apply a gentle traction to the forceps or tenaculum to straighten the cervical curvature.
6. With the piston fully depressed at the extreme distal end of the sheath, gently insert the SelectCells Standard® through the cervix and into the uterine cavity up to the fundus, as previously...
determined by the uterine probe (Step 1). IN NO INSTANCE SHOULD FORCE BE USED against resistance to achieve insertion of the device. Although, a slight friction may be felt while the device passes through the internal os.

7. Release the traction applied to the cervix by the forceps or tenaculum when the device is positioned inside the uterine cavity.

8. While one hand holds the device sheath in place, withdraw the piston rod with the other hand.

DO NOT interrupt the movement. Continue withdrawing towards the proximal end of the sheath until the piston rod stops (Step 2). Then, rotate the device sheath continuously through 360 degrees with a gentle “to and fro” movement a few times, creating a negative pressure to aspirate the specimen into the device lumen (Step 3).

Note: Slow, interrupted or incomplete withdrawal of the piston and incomplete rotation of the sheath will not produce enough suction to obtain a sufficient sample.

9. Withdraw the SelectCells Standard® from the uterus and allow the patient to rest (Step 4). The uterine mucosa specimen should be clearly visible within the sheath. Bleeding, should it occur, would usually be minimal.

10. Cut off the tip of the device sheath at the site of the distal perforation (Step 5).

While holding the device above a specimen receptacle containing a proper preserving fluid, push the piston rod back to expel the specimen into the receptacle (Step 6).

Identify the specimen receptacle and send it to the laboratory for analysis.

Dispose of device in accordance with Federal, State and local Medical / Hazardous waste practices.

References


Smith S. Determining the Time of the Urinary Luteinizing Hormone Surge Does It facilitate the Interpretation of Endometrial Biopsy Results? J Repro Med 1992;37:9,785-788


Smith S. Determining the Time of the Urinary Luteinizing Hormone Surge Does It facilitate the Interpretation of Endometrial Biopsy Results? J Repro Med 1992;37:9,785-788


Smith S. Determining the Time of the Urinary Luteinizing Hormone Surge Does It facilitate the Interpretation of Endometrial Biopsy Results? J Repro Med 1992;37:9,785-788


Explanation of Symbols

**REF** Reorder Number

**STERILE EO** Ethylene Oxide Sterilized

**LOT** Batch Code

**Latex Free**

**Use By, Year-Month**

**Do Not Reuse**

**See instructions for use**

**OperSurgical**

95 Corporate Drive
Trumbull, CT 06611 USA
Phone: (800) 243-2974
Fax: (800) 262-0105