

SM200 • SelectCells Standard®

Endometrial Sampling Device

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



R_x Only

STERILE EO

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.

SINGLE USE ONLY

DISPOSABLE - DISCARD AFTER USE

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 The narrower proximal end of the sheath prevents the piston from being totally withdrawn from the sheath.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, postmenopausal bleeding, abnormal cytology suggesting endometrial origin
- Detection of endometrial carcinoma
(**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 of amenorrhea, the use of the SelectCells Standard should be done only after confirmation of the absence of detectable circulating levels of Human Chorionic Gonadotropin (HCG).

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 hysteroscopy may be necessary to rule out atrophic endometrium or other pathology.

Precautions

Care should be taken prior to device insertion to ascertain the depth of the uterus and any uterine retroflexion or antelexion present in individual patients. In no case should the device be forced against resistance.

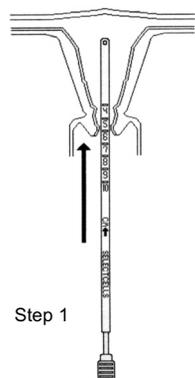
If passage of the SelectCells Standard through the cervical canal cannot be achieved, the device should not be forced and the possibility of pathologic cervical stenosis should be considered. In an elderly patient whose extremely dry cervix may cause resistance to the insertion of the device, very minimal lubrication of the device sheath with a sterile water soluble gel may facilitate its insertion.

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

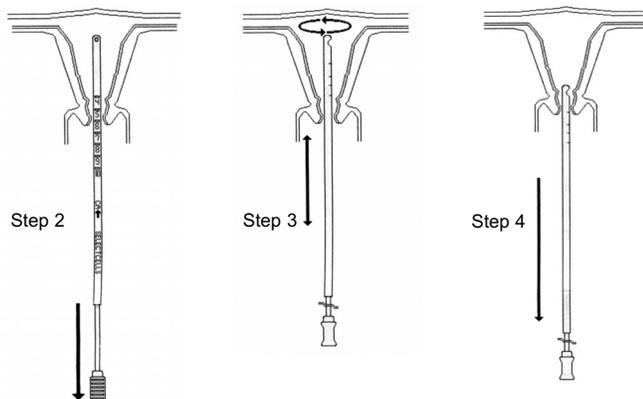
Instructions for Use

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 anteverted, 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.


Step 1
7. Release the traction applied to the cervix by the forceps or tenaculum when the device is positioned inside the uterine cavity.

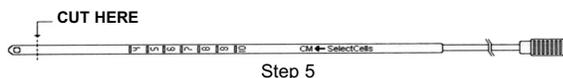
- 8. While one hand holds the device sheath in place, withdraw the piston rod with the other hand.

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

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Explanation of Symbols

- REF** Reorder number
- STERILE** Sterilized using ethylene oxide
- LOT** Batch code
- RxOnly** **CAUTION:** U.S. Federal law restricts this device to sale by or on the order of a physician.
- Use-by date
- Do Not Re-use
- Caution
- Do Not Resterilize
- Do not use if the package is damaged
- Not made with natural rubber latex.
- Consult Instructions for Use
- Manufacturer

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CooperSurgical

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

International
Phone: +1 (203) 601-9818
Fax: +1 (203) 601-4747
www.coopersurgical.com