SM203 • SelectCells Mini®

Endometrial Sampling Device

To obtain a biopsy sample for histologic evaluation of the endometrium (uterine mucosal lining) or sample extraction of the uterine menstrual content.

R_xOnly

STERILE EO

Length: 25.6 cm (effective) 29.7 cm (overall)
O.D. 1.95 mm (distal 13 cm)
I.D. 1.5 mm (distal 13 cm)

STERILE unless package has been opened or damaged
WARNING: NEVER ATTEMPT TO RESTERILIZE.

SINGLE USE ONLY
DISPOSABLE - DISCARD AFTER USE

Device Description

The SelectCells Mini® is a single use, sterile, disposable sampling device. The SelectCells Mini consists of a clear, flexible, polypropylene sheath 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 2.5 mm from the extreme distal tip of the sheath is the device opening of 1.5 mm diameter through which the specimen will be aspirated. This sheath is a one-part tube having a total length of 26.7 cm with a 3.1 mm O.D. (outer diameter) and a 2.6 mm I.D. (inner diameter) for the proximal 13.7 cm long portion. The distal 13 cm long portion of the sheath tapers inward presenting a 1.95 mm O.D. and a 1.5 mm I.D.

An ethylene copolymer and vinyl acetate piston is molded at 13 cm of the distal end to a semi-rigid rod, which can be moved forward and backward within the proximal half-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 The piston and rod are prevented from being totally withdrawn from the sheath during manipulation by the tapered proximal lumen end of the sheath. Suction is created by the movement of the piston inside the sheath.

Indications for Use

Biopsy to obtain a sample for histologic evaluation of the endometrium (uterine mucosal lining) or sample extraction of the 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 dilation of the cervix and uterine curettage performed under general anesthesia.)
- Evaluation of luteal defect (Evaluation 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
- This device is useful for patients presenting a narrow uterine cervix or cervical canal and in postmenopausal women whose cervix might be narrower with any of the indications listed above. However, because of its smaller diameter, it should be recognized that the amount (quantity) of sample obtained with this device will be reduced.

Contraindications

The SelectCells Mini 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 for gynecologic conditions
- the presence of, or after recent Pelvic Inflammatory Disease (PID)
- patients with known coagulopathies
- patients known to have a endocardial seeding

Warnings

In case of amenorrhea, the use of the SelectCells Mini 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 anteflexion present in individual patients. In no case should the device be forced against resistance.

If passage of the SelectCells Mini through the cervical canal cannot be achieved, the device should not be forced and the possibility of the presence 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

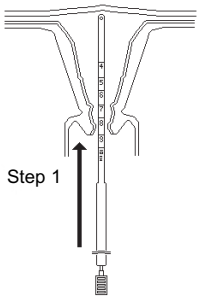
The following adverse effects or events have occasionally been reported in the literature concerning endometrial sampling devices using manually produced suction:

- Uterine wall perforation
- Transient uterine cramping
- Minimal uterine bleeding.

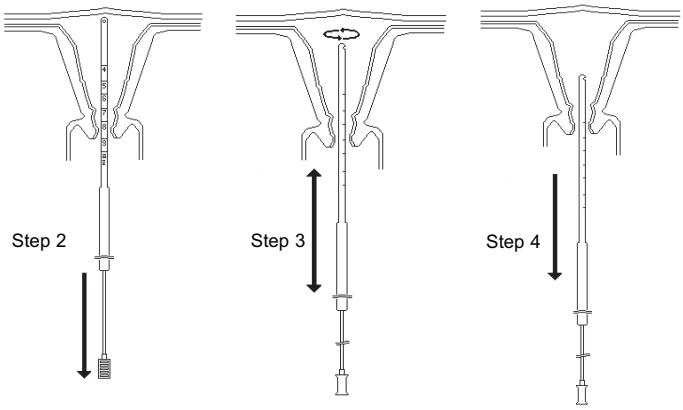
Instructions for Use

1. With the patient in the dorsal lithotomy position, disinfect 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 Mini as a 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. Withdraw the speculum by approximately 2 cm and apply a gentle traction to the forceps or tenaculum to straighten the cervical curvature.
6. With the piston rod fully depressed at the extreme distal end of the sheath, gently insert the SelectCells Mini 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 while making a gentle "to and fro" movement a few times. This procedure creates a negative pressure inside the sheath to aspirate the specimen into the sheath lumen through the device opening [**Step 3**].

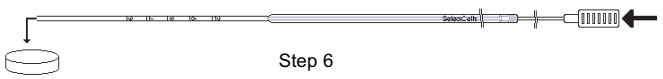


NOTE: Slow, interrupted or incomplete withdrawal of the piston rod and incomplete rotation of the sheath will not produce enough suction to obtain a sufficient sample.

9. Withdraw the SelectCells Mini from the uterus [**Step 4**] and allow the patient to rest. 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**].

Step 5

While holding the device above a specimen receptacle containing a proper preserving fluid, thread the piston rod back into the sheath to expel the specimen into the receptacle [**Step 6**].



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.

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Explanation of Symbols

REF	Reorder number	STERILE EO	Sterilized using ethylene oxide
LOT	Batch code	R_xOnly	**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	LATEX	Not made with natural rubber latex
	Consult instructions for use		Manufacturer

SelectCells Mini® is a registered trademark of CooperSurgical, Inc.

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