SM301 • SelectMucus®

Endocervical aspirator

For aspiration of endocervical mucus and post-coital content

Length: 22.1 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
CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.
STERILE | EO

Device Description

The SelectMucus® is a single use, sterile, disposable endocervical aspirator. The SelectMucus® consists of a 23.0 cm long clear, flexible polypropylene sheath with a 3.1 mm O.D. (outer diameter) and a 2.6 mm I.D. (inner diameter), and a rod made of acetal copolymer. The sheath is marked at 2, 3, 4, 5, 6, 7, 8, 9, and 10 cm distance from the extreme distal rounded tip of the device.

The extreme distal tip of the device is rounded and has a circular opening of 2.2 mm diameter through which the specimen will be aspirated into the sheath lumen. An ethylene copolymer and vinyl acetate piston is molded onto the distal tip of a semi-rigid rod. This rod can be moved 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The narrower proximal end of the sheath prevents the piston from being totally withdrawn from the sheath.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

To obtain a sample of cervical mucus or post-coital content from the endocervix for evaluation of:

- Post-coital testing (Huhner Test);
- Sperm penetration in cervical mucus (Kremer Test);
- Semen to cervical mucus interaction;
- Mucus viscosity;
- Smear of Mucus trapped exfoliated cells;
- Ovulation time determination;
- Detection of antisperm antibodies in cervical secretions;
- Microscopic identification of colonizing micro-organisms.

Contraindications

The SelectMucus® 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 and
- patients known to have an endocardial lesion.

Warnings

IN NO CASE SHOULD THE DEVICE BE FORCED AGAINST RESISTANCE. A stenotic cervix may require dilation prior to insertion of the device.

Precautions

The SelectMucus® is intended for aspirating the mucus content of the endocervical canal. In most patients, insertion of the device beyond the 4 cm graduation mark will usually position the device tip beyond the internal os of the canal thus placing it within the uterine cavity. CARE SHOULD BE USED so as not to insert the SelectMucus® beyond 4 cm since such insertion could result in uterine perforation. Best clinical judgement should be used to allow for any variations from anatomical norms during insertion.

Adverse events

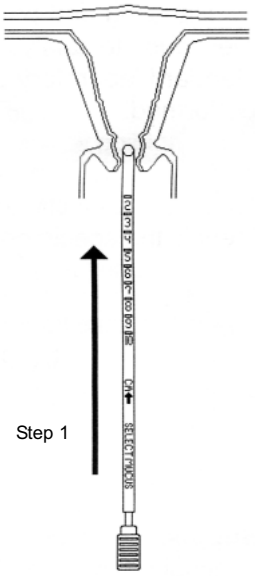
The following adverse effects or events may occur from the passage of an instrument through the cervical canal:

- Transient mild cramping and/or
- Vaso-vagal reaction.

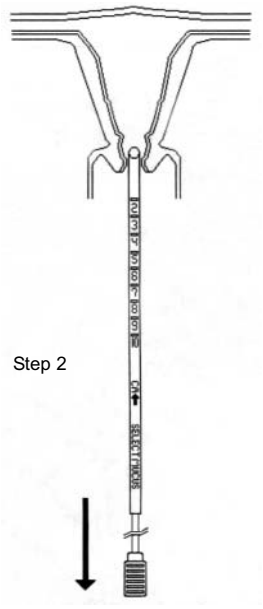
Instructions for Use

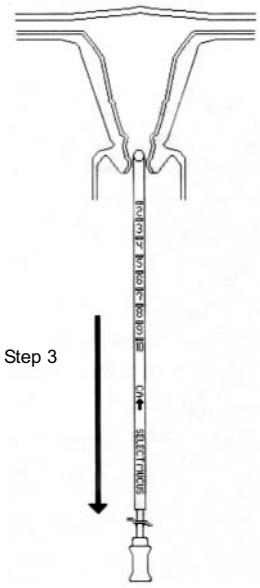
1. With the patient in the dorsal lithotomy position, expose the uterine cervix to view with a sterile vaginal speculum without artificial lubricant.
2. Wipe the external os with a swab to clean the exocervix of excess debris and to prevent vaginal contamination.
3. With the piston fully depressed at the extreme distal end of the sheath, gently insert the SelectMucus® into the cervical canal to the desired depth using the graduation marks on the device (**Step 1**).

   CARE SHOULD BE USED so as not to insert the SelectMucus® beyond the 4 cm graduation mark. Refer to PRECAUTIONS. Insertion of the SelectMucus® can usually be achieved without cervical dilation, local or topical anesthesia or the use of a tenaculum. Slight rotation of the sheath further facilitates insertion of the device.



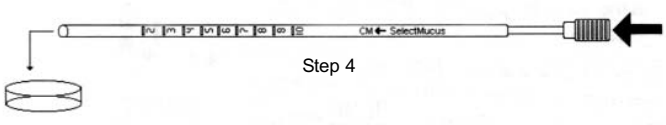
4. While one hand holds the device sheath in place, withdraw the piston rod with the other hand (**Step 2**). DO NOT interrupt the movement. Continue withdrawing towards the proximal end of the sheath until the piston rod stops thereby creating a negative pressure to aspirate the endocervical content into the sheath lumen.


Step 2


Step 3

5. SLOWLY withdraw the SelectMucus® from the cervical canal (**Step 3**).
   NOTE: Slow withdrawl of the device from the cervical canal will enable aspiration of cervical mucus through the device distal tip opening and into the sheath lumen.
6. Allow the patient to rest.
7. Handling and preparation of the cervical mucus specimen prior to analysis, should be done according to your standard laboratory procedures in relation to the test to be performed.

   While holding the device above a specimen receptacle, slide or capillary tube, push the piston rod back toward the distal tip of the SelectMucus® to expel the specimen (**Step 4**). Identify the specimen prior to sending it to the laboratory.



Step 4

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

References

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- Rohr G., Eggert-Kruse W., Pehlke A, Sahrbacher U., Runnebaum B., Kalbitzer HR. Biochemical analysis of cervical mucus by nuclear magnetic resonance spectroscopy. *Human Repro* 1992:7:7:915-917.
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Explanation of Symbols

REF Reorder Number

LOT Batch Code

Use By

ATTENTION: See instructions for use.

STERILE EO Ethylene Oxide Sterilized

Do Not Reuse

LATEX Latex Free

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SM501100 • Rev. A • 3/11