EXPLANATION OF SYMBOLS

REF Reorder Number

LOT Batch Code

Use by date

Caution

LATEX Not made with natural rubber latex

Do not use if package is damaged

2 STERILIZE Do not resterilize

R_x Only U.S. Federal law restricts this device to sale by or on the order of a physician.

STERILE EO Sterilized Using Ethylene Oxide

Consult instructions for use

2 Do not re-use

Manufacturer

Made in the USA

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

8700-IFU • Rev. A • 05/17

Model 8700
ASPIRETTE®

Endocervical Aspirator
For aspiration of endocervical mucus and post-coital content

DEVICE DESCRIPTION

The Aspirette® Endocervical Aspirator is a single-use, sterile, disposable, plastic aspirating catheter for sampling the contents of the endocervical canal.

The device consists of a clear, flexible, polypropylene sheath (A) that is 23.5 cm in length with a 3.1 mm OD (outside diameter) and a 2.6 mm ID (inside diameter). The sheath is marked with a graduated scale in centimeter intervals starting at 2 cm and ending at 10 cm distance from its distal tip. These markings indicate both the depth of insertion of the sheath into the endocervical canal and the amount of aspirate obtained during use. The extreme distal tip of the sheath is smoothly shouldered and has a 2 mm diameter circular opening (B) that is a direct axis portal to the lumen of the sheath.

A polystyrene piston (C) and piston rod (D) can be advanced and retracted within almost the full length of the lumen of the sheath (A). This is accomplished by digital manipulation of the piston knob (E) which extends beyond the proximal end of the sheath. The piston is prevented from being totally pulled from within the sheath by means of a polystyrene stop (F) which is friction fitted onto the proximal end of the sheath. Steady retraction of the piston within the sheath from its fully inserted position to its maximum retracted position creates a negative pressure (suction) within the lumen of the sheath. When this suction is created while the instrument is within the endocervical canal, such negative pressure draws the mucus and any post-coital contents present through the distal tip opening of the sheath and into its lumen.

WARNINGS

- 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/or lead 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.
- To avoid unnecessary patient discomfort and possible cervical trauma, NEVER force the instrument against cervical resistance during insertion.
- A stenotic cervix may require dilation prior to insertion of the Aspirette.

CAUTION

U.S. Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

Aspiration of endocervical mucus and its post-coital contents for such subsequent analysis as:

- Huhner Test (evaluation of post-coital condition and penetration of sperm in cervical mucus).
- Kremer Test (sperm into cervical mucus penetration test).
- Semen to cervical mucus interaction tests.
- Mucus viscosity evaluation.
- Ovulation time determination.
- Smear evaluation of mucus-trapped exfoliated cells.
- Microscopic identification of mucus-trapped organisms.

CONTRAINDICATIONS

The Aspirette should not be used in patients who are pregnant or in patients suspected of being pregnant.

PRECAUTIONS

The Aspirette is intended for aspiration of the mucus content of the endocervical canal. In most patients, insertion of the instrument beyond the 4 cm mark on its sheath will usually position the distal tip of the sheath beyond the internal os of the canal and thus place it within the uterine cavity. While minimal insertion of the instrument past the internal cervical os usually will not cause any adverse patient effects, care should be used so as not to insert the aspirator 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 REACTIONS

As with any instrument that is passed into or through the cervical canal, mild cramping may be expected and the patient should be observed for possible vaso-vagal reactions.

DIRECTIONS FOR USE

1. Remove the sterile instrument from its protective peel-apart package.
2. With the patient in the dorsal lithotomy position, expose the uterine cervix to view with a vaginal speculum.
3. With its piston fully advanced to the extreme distal end of the sheath, gently insert the aspirator into the cervical canal to the desired depth by observing the scale printed on the sheath. Care should be used so as not to insert the instrument further than the 4 cm mark; beyond which, in most patients, the length of the cervical canal would be exceeded and the uterine cavity entered by the distal tip of the sheath. See PRECAUTIONS. Insertion of the aspirator can usually be achieved without cervical dilation, local or topical anesthesia or the use of a tenaculum. Slight rotation of the sheath between the thumb and forefinger as insertion is performed further facilitates the ease of entry.
4. When the desired depth is achieved, stabilize the sheath between the thumb and forefinger of one hand, while, with the other hand, retracting the piston in one motion toward the proximal end of the sheath as far as it will go. (A stop at the proximal end of the sheath will prevent total withdrawal of the piston from within the sheath.) This action creates the negative pressure (suction) within the sheath that is necessary to draw the mucus sample into the lumen of the sheath.
5. With the negative pressure created within the sheath, SLOWLY withdraw the sheath from the cervical canal so that as the surrounding mucus is passed, it is drawn through the distal tip opening and into the lumen of the sheath where it is trapped.
6. The desired aspirate, now contained within the lumen of the sheath, can be partly or completely expelled as required for analysis by simply advancing the piston to force the contents out through the distal tip opening of the sheath.
7. Discard in accordance with Federal, State and local Medical/Hazardous waste practices.