

## Endometrial Cell Samplers

For use with MFR # 543.

### Instructions for Use

#### ATTENTION

Read this information and all instructions before using this product.

#### WARNING

- McKesson Argent<sup>®</sup> Endometrial Cell Sampler should not be used on patients with acute pelvic inflammatory disease (PID) or blood clotting disorders.
- McKesson Argent<sup>®</sup> Endometrial Cell Sampler should not be used on patients who are or may be pregnant.
- **DO NOT USE FORCE IN ANY WAY DURING THIS PROCEDURE!** If force is used, or sounding is not properly done, perforation of the uterine wall may occur.
- Cervical stenosis, extraordinary uterine flexion or other restrictions may inhibit the use of this device.

#### CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician.

#### PRECAUTIONS

- Be sure to use a uterine sound to gauge the direction and depth before using the McKesson Argent<sup>®</sup> Endometrial Cell Sampler.
- Discontinue use immediately if the McKesson Argent<sup>®</sup> Endometrial Cell Sampler causes cramping, uterine spasms, or if perforation of the uterine wall is suspected.
- Lubrication with a water soluble gel may help to facilitate the insertion of the sheath.
- All actions associated with this procedure should be done gently – no force should be used at any time.

#### ADVERSE REACTIONS

- Cramping
- Uterine Spasms
- Endometrial Aspiration

#### INDICATIONS FOR USE

Extraction of uterine tissue sample for:

- Cancer Screening and pre-cancerous conditions
- Endometrial tissue response to hormones
- Fertility testing and diagnosis of pathology associated with infertility
- Bacterial culturing to identify uterine pathogens

#### CONTRAINDICATIONS FOR USE

See Warning section above.

#### PRODUCT DESCRIPTION

The McKesson Argent<sup>®</sup> Endometrial Cell Sampler is a device designed to extract tissue from the uterine mucosal lining, or to extract a tissue sample of uterine menstrual content, for histological examination. The outer sheath is made of a latex free plastic and is 23 cm long and 3 mm in outside diameter, with sounding marks at every 1 cm (starting at 2 cm). The endometrial cell sampler has a collection port that is 4 mm from the distal end and draws the sample into that port via vacuum. This product is sterile (EO), single use only and disposable.

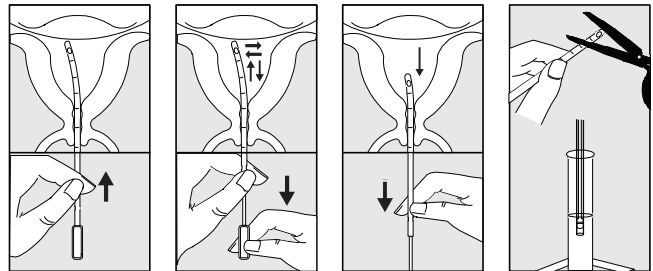


Figure 1 (steps 1 - 4)

Figure 2 (steps 5 - 6)

Figure 3 (step 7)

Figure 4 (steps 8 - 9)

#### DIRECTIONS FOR USE

1. Prepare the vagina and cervix for an intrauterine procedure.
2. Using a vaginal speculum, open and expose the uterine cervix. Gently probe the uterine canal for depth and direction using an McKesson Argent<sup>®</sup> UTERINE SOUND. **DO NOT** use an endometrial cell sampler for uterine sounding.
3. Steady the cervix and straighten any cervical curvature.
4. Remove the protective packaging from the endometrial cell sampler, keeping the plunger completely forward in its sheath. Without force, lightly insert the endometrial cell sampler through the cervical canal into the uterine cavity. **DO NOT USE FORCE.** Use the sounding marks as a guide for depth.
5. Once in place, discontinue any traction. Maintaining device position within the canal, hold the sheath in one hand and pull the plunger back to the stop [this is done to create a vacuum within the sheath]. Do not pull the plunger from its sheath – this will discontinue the vacuum.
6. Rotate the sheath between the thumb and forefinger. At the same time, gently stroke in and out between the internal cervical os and the fundus of the uterus. Perform these motions 3 - 4 times. The vacuum created in the sheath will draw the tissue into the collection port at the distal end. Do not pull the device out or allow it to exit the canal while performing the in and out motions.
7. When the rotating/stroking motions are completed, leave the plunger withdrawn and pull the entire device out of the canal. The tissue sample should be clearly visible. There should be little to no bleeding.
8. With a sterile pair of McKesson Argent<sup>®</sup> scissors, cut off the distal end of the sheath (immediately next to the distal opening). By pushing the plunger forward to its original position in the sheath, express the accumulated tissue into an appropriate transport vessel.
9. Dispose of the endometrial cell sampler in accordance to local medical hazardous waste practices and the facility's guidelines.

Questions? Call 1-800-777-4908

#### Satisfaction Guaranteed

If you are not completely satisfied with any McKesson Brands product, you may return it for a full refund or credit.

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