

Utepreva LLC

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Utepreva Endometrial Biopsy Device

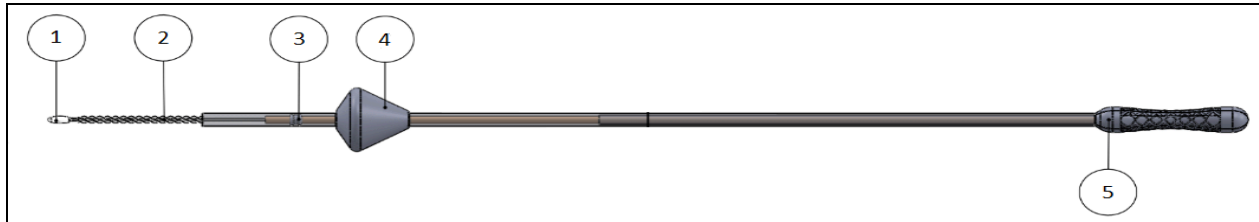
Instructions for Use #1
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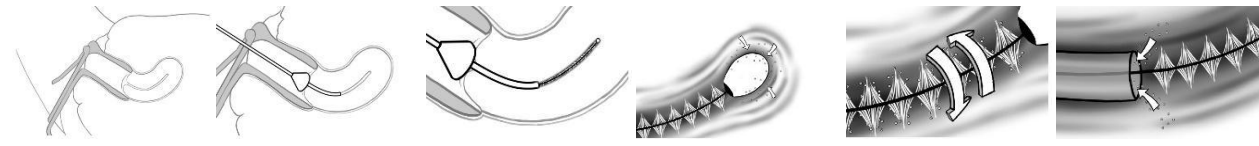
CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner)

Intended Use

Utepreva is used to obtain endometrial cytological and histological samples.

Description

The Utepreva is a single-use, sterile device designed to maximize cell collection during the endometrial biopsy process. The distal end of the device includes a cell collection brush (2) as well as a small foam (1) piece to absorb fluid and additional cells. Once the cell retrieval is complete, the brush/foam assembly is retracted into a plastic sheath. Just proximal to the brush/foam assembly is a small plunger (3) which causes suction when the brush assembly is retracted into the sheath. This suction mechanism increases the ability to retain cells during the procedure and gives the clinician a larger cell count to evaluate. At the proximal end of the device, an ergonomic handle (5) is bonded to the biopsy brush tubing for easy handling. Finally, on the external surface of the sheath is a “hard-stop” feature – skirt (guard), (4) to ensure insertion to the appropriate depth in the uterus.

Procedure:

Place the patient in lithotomy position.

Gently insert the speculum and open to expose the uterine cervix. (Figure 1)

Assure that the brush is completely retracted into the outer sheath. Gently insert the outer sheath of the device through the cervix into the uterus and stop when the skirt (guard) touches the cervix. (Figure 2)

Extend the brush by gently pushing the handle until resistance is felt upon the tip meeting the fundus of the uterus. (Figure 3)

The sponge on the tip protects the fundus from piercing and creates additional tissue sampling by absorption of the fluid and the cells from the uterus. (Figure 4)

Rotate the sampler in a clockwise or counterclockwise manner and complete up four or five 360° rotations. (Figure 5)

Pull the handle back. The suction created by the plunger located inside of the sheath provides aspiration of the cells and prevents loss of the sample from the brush. (Figure 6)

Immediately immerse the sample from the brush, sponge and any fluid that was aspirated into the preservative solution. Handle the sample and brush as directed by the pathology lab.

Contraindications:

The device should not be used when patient:
 Is pregnant
 Has a sexually transmitted disease
 Has an active pelvic infection
 Has a confirmed or suspected intrauterine device
 Has a history of uterine perforation
 Has had a recent cesarean section

Precautions:

In patients with postmenopausal bleeding who are at known increased risk of carcinoma, and when an inadequate tissue sample has been removed by a biopsy device, consider 1) obtaining additional transcervical cytological samples by an endometrial sampler in a physician's office, or 2) dilation and curettage under general anesthesia in a hospital.

The patient should experience only mild discomfort and little or no pain during the procedure. If the patient experiences significant pain, the endometrial sampler should be withdrawn immediately.

Adverse Reactions:

The following adverse reactions can be suspected or reported:








Injury to the uterus (perforation)
 Cramping
 Uterine spasms







How Supplied

Supplied sterilized by In peel-open package. Sterile if package is unopened or undamaged. Intended for one-time use only. Do not use the product if there is a doubt as to whether the product is sterile. Store in dry, dark, cold place. Upon removal from the package, inspect the product to ensure no damage has occurred.

General Comments

Once all the symbols used have been defined, you need a section that has a table that has the symbol and what it means. Something like this:

Symbol	Explanation
	Single-patient, single-procedure device. Do not re-use
	Manufacturer
	Sterilized using ethylene oxide
	Consult instructions for use
	Caution, Consult Accompanying Documentation
	Catalogue Number
	Do not use if Package is Damaged

	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Use By Date
	Batch number
	Unique Device Identifier
	Do not resterilize
	Upper Limit of Temperature