INSTRUCTIONS FOR USE

RADA® Endometrial Suction Catheter

Device Description

The RADA® Endometrial Suction Catheter is a sterile, single-use device intended for atraumatic aspiration and collection of endometrial tissue samples from the uterine cavity.

The device consists of a 23 cm flexible catheter and an internal piston used to generate negative pressure for specimen collection. The catheter features a soft, rounded, tip-formed distal end designed to minimize tissue trauma during insertion.

A distal side sampling opening located adjacent to the catheter tip facilitates efficient aspiration of endometrial tissue. Centimeter depth markings along the catheter assist in uterine positioning and insertion control.

The catheter is manufactured from biocompatible medical-grade materials and is intended for single-patient use only.

Intended Use

The RADA® Endometrial Suction Catheter is intended for atraumatic aspiration and collection of endometrial tissue samples from the uterine cavity for histologic and/or microbiologic examination.

Indications for Use

The device is indicated for obtaining endometrial samples for diagnostic evaluation, including:

- Investigation of abnormal uterine bleeding;
- Evaluation of endometrial pathology;
- Assessment of infertility;
- Evaluation of recurrent implantation failure, when clinically indicated;
- Histologic examination of endometrial tissue;
- Microbiologic examination of endometrial specimens.

Contraindications

Do not use the device in patients with:

- Known or suspected pregnancy;
- Acute pelvic inflammatory disease;
- Active cervical, vaginal, or uterine infection;
- Severe cervical stenosis preventing safe insertion;
- Any condition in which endometrial biopsy is contraindicated according to physician judgment.

Warnings

- Excessive force during insertion may result in uterine perforation or patient injury.
- Use only by qualified healthcare professionals trained in gynecologic procedures.
- Maintain aseptic technique throughout the procedure.
- Do not use if the sterile package is damaged or opened.
- Reuse, reprocessing, or resterilization may compromise device integrity and increase the risk of infection or cross-contamination.

Precautions

- Do not force the device if resistance is encountered.
- Use only minimal lubrication when clinically necessary.
- Verify the absence of pregnancy before performing endometrial biopsy in amenorrheic patients.
- This device is intended for single use only.
- Do not reuse, reprocess, or resterilize.

Preparation

1. Prepare the vagina and cervix using standard antiseptic techniques.
2. Determine uterine depth and orientation using a uterine sound or ultrasound guidance, if clinically indicated.
3. Stabilize the cervix with appropriate forceps or a tenaculum when necessary.
4. Ensure that the piston is fully inserted before introducing the catheter.

Procedure

1. Gently advance the RADA® Endometrial Suction Catheter through the cervical canal into the uterine cavity to the desired depth using the depth markings as guidance.
2. Completely withdraw the piston to create negative pressure and aspirate tissue into the catheter lumen.
3. Rotate the catheter while moving it gently back and forth several times to obtain an adequate specimen.
4. Carefully remove the catheter from the uterus.

Histologic Examination

Advance the piston to expel the collected tissue into an appropriate fixative solution according to laboratory procedures.

Microbiologic Examination

Handle and transfer the collected specimen according to institutional laboratory protocols.

Potential Adverse Events

Potential complications associated with endometrial biopsy may include:

- Uterine perforation;
- Pelvic cramping or abdominal pain;
- Uterine spasm;
- Vaginal bleeding or spotting;
- Vasovagal reaction;
- Infection.

Sterility

- Sterile unless package is opened or damaged.
- Sterilized using Ethylene Oxide (EO).

Storage Conditions

Store in a clean, dry environment away from direct sunlight, excessive heat, and humidity.

Disposal

After use, dispose of the device in accordance with applicable local regulations and institutional procedures for biohazardous medical waste.

Symbol Definitions

Refer to the package label for applicable symbols, including:

- Single Use Only
- Sterile EO
- Do Not Reuse
- Do Not Use if Package is Damaged
- Consult Instructions for Use
- Keep Dry
- Manufacturer
- Date of Manufacture
- Batch Code
- Use-By Date