

INSTRUCTIONS FOR USE

RADA Hystrometer

Device Description

The RADA Disposable Hystrometer is a sterile, single-use medical device intended for measuring uterine cavity depth and determining uterine orientation prior to gynecological and assisted reproductive procedures.

The device consists of a flexible catheter manufactured from biocompatible medical-grade materials with a smooth, atraumatic pre-formed distal tip and graduated depth markings to facilitate accurate measurement of the uterine cavity.

The device is manufactured from biocompatible medical-grade materials and is supplied sterile.

Intended Use

The RADA Disposable Hystrometer is intended for measuring uterine cavity depth and determining uterine orientation prior to diagnostic, therapeutic, gynecological, and assisted reproductive procedures.

Indications for Use

The device is indicated for:

- Measurement of uterine cavity depth;
 - Determination of uterine orientation (anteverted or retroverted uterus);
 - Preparation for intrauterine procedures;
 - Assisted reproductive procedures (ART);
 - Intrauterine insemination (IUI);
 - Embryo transfer (ET);
 - Endometrial biopsy procedures;
 - Insertion of intrauterine devices (IUDs).
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Contraindications

Do not use the device in patients with:

- Known or suspected pregnancy;
 - Active pelvic infection;
 - Active sexually transmitted disease (STD);
 - Acute cervical or uterine inflammation;
 - Any condition in which intrauterine instrumentation is contraindicated according to physician judgment.
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Warnings

- This device must be used only by physicians or trained healthcare professionals.
 - Strict aseptic technique must be maintained throughout the procedure.
 - Do not use the product if the package is opened, damaged, or beyond the expiration date.
 - Reuse, reprocessing, or resterilization is prohibited.
 - Excessive force during insertion may result in cervical trauma, uterine injury, or uterine perforation.
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Precautions

- Assess cervical alignment and orientation before advancing the device.
 - Advance the device gently and discontinue insertion if resistance is encountered.
 - Patients may experience transient discomfort or uterine cramping during the procedure.
 - Use caution in patients with cervical stenosis or abnormal uterine anatomy.
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Instructions for Use

1. Position the patient according to standard gynecological practice.
2. If necessary and according to physician preference, use a vaginal speculum to provide adequate visualization and access to the cervix.
3. Prepare the vagina and cervix using aseptic technique.
4. Gently introduce the distal tip of the hystrometer through the cervical canal.
5. Advance the device carefully until the uterine fundus is reached.
6. Read the graduated markings to determine uterine cavity depth.
7. Assess uterine orientation based on the direction of insertion.
8. Gently withdraw the device after completion of the measurement.

9. Discard the device after use.
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Potential Adverse Events

Potential adverse events associated with hystrometer use may include:

- Pelvic discomfort or cramping;
 - Vaginal spotting or minor bleeding;
 - Cervical trauma;
 - Uterine perforation (rare);
 - Infection.
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Sterility

- Sterilized using Ethylene Oxide (EO).
 - Do not use the product if the package has been opened or damaged.
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Storage Conditions

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

Disposal

Dispose of the device after use in accordance with applicable local regulations for biohazardous medical waste.