

INSTRUCTIONS FOR USE

RADA IUI Catheter

Device Description

The RADA IUI Catheter is a sterile, single-use device intended for the introduction of prepared spermatozoa into the uterine cavity during intrauterine insemination (IUI) procedures.

The catheter features a soft distal tip and a flexible body that facilitates smooth passage through the cervical canal and enables atraumatic delivery of the specimen into the uterine cavity.

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

Intended Use

The RADA IUI Catheter is intended for the introduction of prepared spermatozoa into the uterine cavity during intrauterine insemination (IUI) procedures.

Indications for Use

The device is indicated for intrauterine insemination procedures performed as part of infertility treatment and assisted reproductive techniques.

Contraindications

Do not use the device in patients with:

- Active pelvic infection;
- Active sexually transmitted disease;
- Recent uterine perforation;
- Severe cervical stenosis preventing safe catheter passage;
- Known or suspected pregnancy;
- Presence or suspected presence of an intrauterine device (IUD);

- Any condition in which intrauterine insemination is contraindicated according to physician judgment.
-

Warnings

- This device is intended for use only by physicians or healthcare professionals trained in assisted reproductive techniques.
 - Maintain aseptic technique throughout the procedure.
 - Do not use if the package is opened or damaged.
 - Do not use the device beyond the expiration date.
 - Reuse, reprocessing, or resterilization may compromise device integrity and increase the risk of contamination or infection.
 - Excessive force during insertion may result in cervical or uterine injury.
-

Precautions

- Manipulate the catheter gently to minimize tissue trauma.
 - Do not force the catheter if resistance is encountered.
 - Use appropriate clinical techniques when assistance is required for catheter advancement.
 - This device is intended for single use only.
-

Instructions for Use

1. Open the sterile package using aseptic technique.
 2. Attach the syringe containing the prepared sperm specimen to the proximal end of the catheter according to laboratory protocol.
 3. Gently introduce the catheter through the cervical canal.
 4. Advance the catheter to the desired intrauterine position.
 5. Slowly deliver the prepared specimen into the uterine cavity by depressing the syringe plunger.
 6. Carefully withdraw the catheter following insemination.
 7. Dispose of the device after use in accordance with applicable local regulations for medical waste.
-

Potential Adverse Events

Potential adverse events associated with intrauterine insemination procedures may include:

- Mild uterine cramping;
 - Cervical bleeding or spotting;
 - Infection;
 - Vasovagal reaction;
 - Difficulty in catheter passage;
 - Cervical trauma;
 - Uterine perforation (rare).
-

Sterility

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

Storage Conditions

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

Disposal

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