

INSTRUCTIONS FOR USE

RADA Embryo Transfer Syringe

Device Description

The RADA Embryo Transfer Syringe is a sterile, single-use medical device intended for the controlled transfer of embryos into the uterine cavity during assisted reproductive technology (ART) procedures.

The device consists of a medical-grade syringe compatible with embryo transfer catheters and is designed to provide smooth, uniform, and controlled delivery of the embryo suspension while minimizing mechanical stress.

The system is intended for use in conjunction with embryo transfer catheters and is manufactured from biocompatible medical-grade materials. The device is supplied sterile.

Intended Use

The RADA Embryo Transfer Syringe is intended for the controlled transfer of embryos into the uterine cavity during in vitro fertilization (IVF) procedures under clinical or ultrasound-guided conditions.

Indications for Use

The device is indicated for:

- Embryo transfer during IVF procedures;
 - Assisted reproductive technology (ART) procedures requiring intrauterine embryo placement;
 - Controlled delivery of embryo suspension into the uterine cavity through an embryo transfer catheter.
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Contraindications

Do not use the device in patients with:

- Known or suspected pregnancy unrelated to the current treatment cycle;

- Active pelvic infection;
 - Active sexually transmitted disease (STD);
 - Any condition in which embryo transfer is contraindicated according to physician judgment.
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Warnings

- This device must be used only by physicians or healthcare professionals trained in assisted reproductive techniques.
 - 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.
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Precautions

- Verify compatibility between the syringe and the embryo transfer catheter before use.
 - Avoid the formation and introduction of air bubbles into the system.
 - Avoid mechanical stress while handling embryo-containing media.
 - Follow the protocols established by the IVF laboratory and clinical center.
 - Use only sterile, embryo-compatible media.
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Instructions for Use

1. Prepare the patient according to the standard embryo transfer protocol.
 2. Securely connect the RADA Embryo Transfer Syringe to the proximal end of the embryo transfer catheter.
 3. Load the embryo suspension into the embryo transfer catheter according to laboratory procedures.
 4. Ensure that no air bubbles are present within the system.
 5. Position the catheter tip within the uterine cavity under clinical or ultrasound guidance.
 6. Slowly and gently depress the syringe plunger to deliver the embryo suspension into the uterine cavity.
 7. Maintain smooth and controlled pressure throughout the transfer.
 8. After completion of the procedure, disconnect the syringe from the catheter.
 9. Discard the device after single use.
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Potential Adverse Events

Potential adverse events associated with embryo transfer procedures may include:

- Mild uterine cramping;
 - Vaginal spotting;
 - Infection (rare);
 - Uterine irritation;
 - Failure of embryo transfer due to improper placement or handling.
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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, 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.