INSTRUCTIONS FOR USE

RADA Ovum Aspiration Needle

Device Description

The RADA Ovum Aspiration Needle is a sterile, single-use medical device intended for the aspiration and collection of oocytes from ovarian follicles during assisted reproductive procedures under ultrasound or laparoscopic guidance.

The device consists of a stainless-steel needle designed to provide controlled access to ovarian follicles and features an echogenic tip to enhance ultrasound visualization.

The system includes aspiration and suction tubing for connection to a vacuum source, allowing controlled aspiration of follicular fluid.

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

Intended Use

The RADA Ovum Aspiration Needle is intended for the aspiration and collection of oocytes from ovarian follicles during assisted reproductive technology (ART) procedures under ultrasound or laparoscopic guidance.

Indications for Use

The device is indicated for:

- Ultrasound-guided transvaginal oocyte retrieval
- Laparoscopy-guided oocyte retrieval
- Assisted reproductive procedures requiring follicular aspiration

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Contraindications

Do not use the device in patients with:

- Active pelvic infection;
- Active sexually transmitted disease (STD);

- Known or suspected pregnancy;
- Severe anatomical abnormalities preventing safe access;
- Any condition in which oocyte retrieval is contraindicated according to physician judgment.

Warnings

- This device must be used only by physicians trained and experienced 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.
- Excessive force during needle insertion may result in tissue injury, bleeding, or organ perforation.

Precautions

- Oocyte retrieval procedures may be associated with pain; local anesthesia or sedation may be used according to clinical practice.
- Injury to blood vessels or the bladder may occur during transvaginal or laparoscopic access.
- Infection, including pelvic or urinary tract infection, may occur following puncture procedures.
- Mild vaginal bleeding or bleeding at the puncture site may occur and is generally managed with appropriate supportive measures.
- Vacuum pressure should be adjusted according to the clinical protocol and needle gauge.

Instructions for Use

Ultrasound-Guided Transvaginal Oocyte Retrieval

1. Position the patient in the lithotomy position.
2. Place the ultrasound probe in the vaginal fornix and identify the ovaries and follicles.
3. Insert the needle into the ultrasound needle guide.
4. Under ultrasound guidance, advance the needle into the ovarian follicle.
5. Apply controlled vacuum pressure to aspirate follicular fluid and retrieve oocytes.
6. Repeat the procedure for additional follicles as required.

7. Remove the needle and inspect the area under ultrasound guidance.
8. Discard the device after use.

Laparoscopy-Guided Oocyte Retrieval

1. Position the patient in the lithotomy position.
2. Establish laparoscopic access according to standard surgical technique.
3. Place the trocar/cannula in the appropriate position.
4. Introduce the needle through the cannula under direct visualization.
5. Advance the needle into the ovarian follicle.
6. Apply controlled vacuum pressure to aspirate follicular fluid.
7. Repeat the procedure for additional follicles as required.
8. Remove and dispose of the device after completion of the procedure.

Potential Adverse Events

Potential adverse events associated with oocyte retrieval procedures may include:

- Pelvic or abdominal pain;
- Vaginal bleeding or spotting;
- Infection (pelvic or urinary tract infection);
- Injury to adjacent organs (bladder, bowel, or blood vessels);
- Ovarian or follicular trauma;
- Hemoperitoneum (rare);
- Vasovagal reaction.

Sterility

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

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.