



VitaVitro

Oocyte Retrieval Needle



CAUTION

Federal (U.S.) law restricts this device to sale by or on the order of a physician.

PRODUCT DESCRIPTION

ORNS-17G, ORNS-18G, ORND-17G. The Oocyte Retrieval Needle is composed of a needle protection sleeve, needle, handle, suction catheter, silicone plug, vacuum catheter, flushing catheter and taper joint.

INDICATION FOR USE

The device is intended for flushing and/or aspiration of oocytes from ovarian follicles under ultrasonic guidance.

CONTRAINDICATION

- 1) Prohibited during pelvic inflammation or convalescence.

- 2) Patients with active vaginal or intrauterine infections are prohibited.
- 3) Prohibited for those with sexually transmitted diseases.
- 4) Patients with recent uterine perforation, cesarean section or current pregnancy are prohibited.

WARNING

- 1) This product should only be performed by persons having adequate training and familiarity with oocyte retrieval techniques.
- 2) When performing oocyte retrieval procedure, operators should be careful during the process to avoid damage to the vaginal wall and uterine cavity, or oocyte deformation, loss, or influence on oocyte fertilization and embryonic development potential due to bending, squeezing or damaging the tube.

- 3) This product has been sterilized by ethylene oxide, since the sterilization date, the service life is 3 years, do not use expired.
- 4) This product is sterilized packaging, if damaged, do not use it.
- 5) This product is for one-time use only. Please read the instructions carefully before use.
- 6) After use, the product should be disposed of following relevant regulations of medical waste.

QUALITY CONTROL TESTING

Sterility tested Passed
LAL Endotoxin < 5EU/device
1-cell Mouse Embryo Assay (MEA)
≥ 80% blastocysts by 96h

INSTRUCTION FOR USE

- 1) Patients were given general or local anesthesia, lithotomy was taken, and the vulva and vagina were routinely disinfected.

- 2) According to the routine procedure of transvaginal ultrasound, the ultrasound probe is placed in the vaginal fornix to observe the position of the uterus and the number and location of follicles to be aspirated.
- 3) Remove the package, take out the Oocyte Retrieval Needle, and insert the needle into the needle guide of the ultrasound transducer, ensuring that there is smooth movement along its length.
- 4) For single-lumen needle
 - 4.1 The vacuum tube conical connector was connected to the vacuum pump and the silicone plug was fitted to a sterile follicular fluid collection tube. Test the piping system with flushing medium to ensure that all connections are intact and that full flow can be achieved.

4.2 An ultrasound probe was placed into the vagina to detect the ovaries and mature follicles at the posterior dome. The follicles were punctured under the guidance of transvaginal ultrasound.

4.3 Using a vacuum pump, the suction pressure is adjusted to the appropriate value, and the follicle is aspirated to collect oocytes. When the collection tube is full, the collection tube should be removed and replaced with a new sterile collection tube.

4.4 Repeat steps 4.2 to 4.4 for the other ovary. When the required oocytes have been collected, the vaginal probe and needle are withdrawn to check for bleeding or hematoma symptoms. If the above symptoms occur, appropriate treatment should be carried out according to the requirements of the oocyte retrieval procedure.

5) For dual-lumen needle

5.1 The vacuum catheter conical connector was connected to the vacuum pump, and the silicone plug was fitted to a sterile follicular fluid collection tube. The conical connector at the end of the flush tube was connected to a sterile syringe.









5.2 An ultrasound probe was placed into the vagina to detect the ovaries and mature follicles at the posterior dome. The follicles were punctured under the guidance of transvaginal ultrasound.

5.3 Using a vacuum pump, adjust the suction pressure to a suitable value, and aspirate/flush the follicles to collect oocytes. If the follicles need to be flushed, connect the syringe with flushing medium to the connector at the end of the flushing tube and rinse. Continue pumping the follicles until they empty.

5.4 Repeat steps 4.2 to 4.4 for the other ovary. When the required oocytes have been collected, the vaginal probe and needle are withdrawn to check for bleeding or hematoma symptoms. If the above symptoms occur, appropriate treatment should be carried out according to the requirements of the oocyte retrieval procedure.

DESCRIPTION OF ISO SYMBOLS

The symbol glossary is in line with the SDO-developed standard ANSI/AAMI/ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General requirements.

Reference number of symbol	Symbols	Title of symbol
5.1.1		Manufacturer
5.1.3		Date of manufacture
5.1.4		Use-by date
5.1.5		Batch code
5.2.3		Sterilized using ethylene oxide
5.3.2		Keep away from sunlight
5.3.7		Temperature limit
5.4.2		Do not re-use



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