Oocyte Retrieval Needle

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

PRODUCT DESCRIPTION

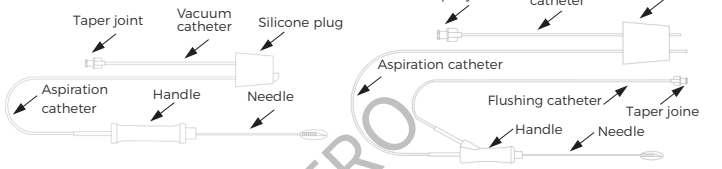
ORNS-17G, ORNS-18G, ORND-17G.
The Oocyte Retrieval Needle is composed of a needle protection sleeve, needle, handle, suction catheter, silicone plug, vacuum catheter, flushing catheter, and taper joint.

NEEDLE GAUGE
17G or 18G

SILICONE PLUG DIAMETER
14.3-18.0mm

SINGE LUMEN NEEDLE LENGTH
33cm

DOUBLE LUMEN NEEDLE LENGTH
35cm



Single Lumen Oocyte Retrieval Needle

Double Lumen Oocyte Retrieval Needle

INDICATION FOR USE

VitaVitro Single Lumen Oocyte Retrieval Needle is intended for ultrasound guided transvaginal aspiration of oocytes from ovarian follicles for patients undergoing Assisted Reproductive procedures. VitaVitro Double Lumen Oocyte Retrieval is intended for ultrasound guided transvaginal aspiration and flushing of oocytes from ovarian follicles for patients undergoing Assisted Reproductive procedures.

CONTRAINDICATION

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

WARNING

1) Do not use device if it is beyond its expiration date.
2) This product is sterilized packaging, if damaged, do not use it.
3) This product is for one-time use only. Please read the instructions carefully before use.
4) Hematuria may occur due to the needle penetrating a filled bladder during transvaginal ultrasound aspiration. This complication typically resolves spontaneously within a day.
5) Extravasation of urine may occur within the abdominal cavity if a needle puncture traverses the bladder. Patients should be monitored for evidence of this known complication; however, there is typically no associated discomfort or adverse effects.
6) Infection may be introduced via needle puncture and result in urinary tract infection (UTI), pelvic inflammatory disease (PID), uterine infection or cystitis.
7) Failure to use ultrasound to locate the follicles or incorrect needle guidance may result in failure to obtain the required sample and/or tissue damage.
8) Read the complete directions for use before use. Failure to properly follow the instructions, warnings and cautions may lead to serious surgical consequences or injury to the patient.
9) These procedures should only be performed by persons having adequate training and familiarity with these techniques. Consult medical literature regarding techniques, complications and hazards prior to performance of these procedures.
10) To be used by, or under the direction of, qualified persons in line with local guidelines governing in vitro fertilization, if applicable.
11) The sharp needle must be handled carefully to avoid needle-stick injury, which may result in tissue damage or cross-infection.

PRECAUTIONS

1) Federal (US) law restricts this device to sale by or on the order of a physician or practitioner trained in its use.
2) These procedures should only be performed by persons having adequate training and familiarity with these techniques. Consult medical literature regarding techniques, complications and hazards prior to performance of these procedures.
3) Aseptic technique should be adhered to during use of the device.
4) Test tubes used should be comprised of embryo compatible materials.
5) Vaginal bleeding has been reported to be associated with the transvaginal route for oocyte retrieval via needle aspiration. Bleeding is typically easily controlled with direct pressure.
6) Use with care to avoid damaging the needle tip.
7) 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) Keep the patient in the lithotomy position. Perform local or general anesthesia as needed, and the vulva and vagina were routinely disinfected.
2) According to the routine procedure of transvaginal ultrasound, place the ultrasound probe in the vagina fornix to observe the position of the uterus and the number and location of follicles to be aspirated.
3) Open the package and remove the Oocyte retrieval needle. Inspect the device to ensure it is not damaged and suitable to use (e.g., inspect needle tip to assess sharpness, tubing kinking, other visible damage.).
4) For single-lumen needle

4.1 The vacuum tube taper joint is connected to the vacuum pump and the silicone plug is fitted to a sterile follicular fluid collection tube. Test the piping system with flushing medium (an FDA- cleared medium indicated for follicle flushing procedures) to ensure that all connections are intact and that full flow can be achieved. Vacuum pressure for aspiration procedures should be no more than 175 mmHg, If the device is clogged, remove the device from the patient and use a vacuum pressure of no more than 500 mmHg to clear the clog.

4.2 Place the ultrasound probe in the vagina to detect the ovaries and mature follicles at the posterior dome and presence of blood vessels in and around the ovary to determine a direct path into the ovarian follicles to be aspirated. Following visualization of the follicle to be aspirated, line up the follicle using the needle guide on the ultrasound monitor and advance the needle tip into the center of the ovarian follicle via a rapid, stabbing motion. The combination of the needle bevel and echogenic marker enhances visualization of the position of the needletip.

4.3 Using a vacuum pump, the aspiration 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 double lumen needle

5.1 The vacuum catheter taper joint is connected to the vacuum pump, and the silicone plug is fitted to a sterile follicular fluid collection tube. The taper joint at the end of the flushing catheter is connected to a 20 mL sterile syringe full of sterile, FDA-cleared flushing medium that is indicated for follicle flushing procedures. Test the piping system with flushing medium to ensure that all connections are intact and that full flow can be achieved. Vacuum pressure for aspiration procedures should be no more than 150 mmHg, If the device is clogged, remove the device from the patient and use a vacuum pressure of no more than 500 mmHg to clear the clog.

5.2 Place the ultrasound probe in the vagina to detect the ovaries and mature follicles at the posterior dome and presence of blood vessels in and around the ovary to determine a direct path into the ovarian follicles to be aspirated. Following visualization of the follicle to be aspirated, line up the follicle using the needle guide on the ultrasound monitor and advance the needle tip into the center of the ovarian follicle via a rapid, stabbing motion. The combination of the needle bevel and echogenic marker enhances visualization of the position of the needle tip.

5.3 Using a vacuum pump, adjust the aspiration pressure to a suitable value, and aspirate/flush the follicles to collect oocytes. If the follicles need to be flushed, stop the vacuum and use the 20mL syringe connected to the flushing catheter to rinse the follicle with 2-4 mL of flushing medium. Resume aspiration to collect the flushing fluid. When the collection tube is full, the collection tube should be removed and replaced with a new sterile collection tube.

5.4 Repeat steps 5.2 to 5.4 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.

6) Removal of the device from the body and disassembly the needle guide of the ultrasound transducer when the procedure is finished. Discard the aspiration needle according to standard clinical practice for medical hazardous waste.

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	Symbols	Title of symbol	Reference number	Symbols	Title of symbol
5.1.1		Manufacturer	5.2.8		Do not use if package is damaged
5.1.3		Date of manufacture	5.3.2		Keep away from sunlight
5.1.4		Use-by date	5.4.2		Do not re-use
5.1.5	LOT	Batch code	5.4.3		Consult instructions for use or consult electronic instructions for use
5.1.6	REF	Catalog number	5.7.7	MD	Medical device
5.2.3	STERILE EO	Sterilized using ethylene oxide			

VitaVitro

Shenzhen VitaVitro Biotech Co., Ltd.

R601,Building B, Hai Ke Xing Tech Park,
Baoshan Road No.16,
Pingshan District, Shenzhen,
Guangdong, 518118, CHINA

Phone: +86 755 84511813

www.vitavitro.com

IU132503008 V01