



VitaVitro

Embryo Transfer Catheter

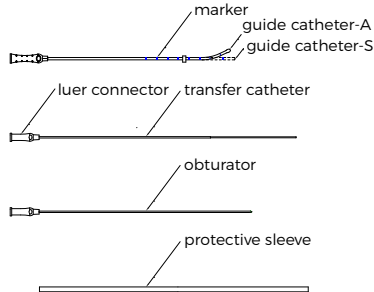


CAUTION

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

PRODUCT DESCRIPTION

The Embryo Transfer Catheter is composed of transfer catheter and a guide catheter (some with obturator). See below the engineering schematic diagram of the catheters and components for each model.



INDICATION FOR USE

VitaVitro Embryo Transfer Catheter is used to place in vitro fertilized (IVF) embryos into the uterine cavity.

CONTRAINDICATION

Patients with infection, sexually transmitted disease, intra fallopian procedure, recent pelvic inflammation, pregnancy, confirmed or suspected intrauterine device and acute inflammation of the whole body and reproductive system should be prohibited from using the device.

WARNING

- 1) This product is for the use of assisted reproduction specialists only.
 - 2) When performing the embryo transfer procedure, care should be taken to avoid damage to the cervical canal and uterine cavity, or to avoid releasing the embryo from the catheter early by bending, squeezing or damaging the transfer catheter.
 - 3) The shelf-life of this EO sterilized product is 3 years. Do not use the product beyond the expiration date
 - 4) This product is sterilized. Do not use if the package is open or damaged.
 - 5) This product is for single use only. Please read the instructions carefully before use.
 - 6) After use, the product should be disposed in accordance with relevant regulations of medical waste.
 - 7) When the product passes through the vagina or uterus, it may cause trauma and bleeding, which will affect the embryo implantation rate and pregnancy rate.
 - 8) This device may be infected with bacteria in the vagina or uterus during operation, causing uterine infection, urinary tract infection and pelvic inflammation.
- Recommendations to reduce infection: use materials with good embryo compatibility and strictly abide by the requirements of aseptic operation technique to ensure the sterility of the product.

PRECAUTIONS

- 1) Please read the manual carefully before use. Pay attention to all warnings and precautions in the manual, otherwise, accidents may occur.
- 2) All equipment and accessories involved in this operation must be made of embryo compatible materials.
- 3) Make sure to flush the transfer catheter with culture medium before embryo aspiration; carefully check the transfer catheter under the microscope after completing the operation to ensure that no embryos are left.
- 4) The catheter tip is flexible, please handle it with care during placement to prevent loss of samples.

- To reduce the risk of perforation, if any resistance is felt while inserting the catheter, do not force the catheter against the resistance.
- The size of the matched syringe is 1 ml and the syringe is not provided with catheter.

POTENTIAL ADVERSE EVENTS

- Contractions can be observed when the device enters the vagina or uterus, which may cause pain, trauma or bleeding, and affect the implantation.
- Improper operation may damage the embryo.
- Improper operation may contaminate bacteria in the vagina or uterus and cause infection, leading to uterine infection, urinary tract infection or pelvic inflammation.

QUALITY CONTROL TESTING

Provided sterile (SAL 10⁻⁶) for single use

Endotoxin per USP <85> < 5EU/device











One-cell MEA: ≥80% embryos developed to expanded blastocyst at 96 hours.

INSTRUCTION FOR USE

- The patient was taken from the lithotomy position and a speculum is inserted into the vaginal to expose the cervix. The condition of the cervix and endometrium is examined, and the depth and Angle of insertion of the guide and transfer catheter are estimated in advance.
- If applicable, insert the obturator into guide catheter to increase the hardness of the guide catheter.
- Insert guide catheter through cervix.
- Remove the protective sleeve and take out the transfer catheter, connect the Luer connector of the transfer catheter to the syringe, pull the syringe rod to fill 1ml culture medium and eject any air bubbles, discard the medium;
- Follow laboratory produce for loading embryos into the transfer catheter.
- If applicable, remove obturator before inserting the transfer catheter.
- Place the tip of transfer catheter into the appropriate position in the uterine cavity through the guide catheter, and the embryo is injected into the uterine cavity by slowly pushing the rod of the syringe. The adjustable marker on the outer sheath can be set to indicate the desired cervical length/depth.
- Remove catheters and check for embryo retention.

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	5.2.3		Sterilized using ethylene oxide
5.1.3		Date of manufacture	5.2.8		Do not use if package is damaged
5.1.4		Use-by date	5.3.2		Keep away from sunlight
5.1.5		Batch code	5.4.2		Do not re-use
5.1.6		Catalog number	5.7.7		Medical device



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