

CAUTION

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

PRODUCT DESCRIPTION

ET-S, ET-SI, ET-A. The Embryo Transfer Catheter is composed of transfer catheter and a guide catheter (some with obturator)

INDICATION FOR USE

Used in conjunction with a syringe to transfer embryos or fertilized eggs that have undergone in vitro fertilization (IVF) into the uterine cavity.

CONTRAINDICATION

Patients with acute inflammation of the whole body and reproductive system should be prohibited.

WARNING

- 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 slipping out of the embryo by bending, squeezing or damaging the transfer catheter.
- 3) This product has been sterilized by ethylene oxide, since the sterilization date, the service life is 3 years, do not use expired.
- This product is sterilized packaging, if damaged, do not use.
- 5) This product is for one-time use only. Please read the instructions carefully before use.

 After use, the product should be disposed of in accordance with 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) The patient was taken from the lithotomy position and inserted into a vaginal speculum 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.

- 2) If applicable, insert the obturator into guide catheter to increase the hardness of the guide catheter.
- 3) Insert guide catheter through cervix.
- 4) 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 absorb appropriate amount of culture medium to wash the catheter, discard the medium;
- 5) Follow laboratory produce for loading embryos into the transfer catheter.
- 6) If applicable, remove obturator before insert of transfer catheter.

- 7) Place the tip of transfer catheter into the appropriate position in the uterine cavity through the guide catheter, and the embryo was injected into the uterine cavity by slowly pushing the rod of the syringe.
- 8) 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 of symbol	Symbols	Title of symbol
5.1.1	—	Manufacturer
5.1.3	سا	Date of manufacture
5.1.4		Use-by date
5.1.5	LOT	Batch code
5.2.3	STERILEEO	Sterilized using ethylene oxide
5.3.2		Keep away from sunlight
5.3.7	1	Temperature limit
5.4.2	2	Do not re-use



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