allwin® Medical Devices

TRIAL TRANSFER CATHETER

Description:

Code	Description
TT-EB-ETC18	Trial Transfer Catheter for Embryo Trans (18 cm)
TT-EB-ETC23	Trial Transfer Catheter for Embryo Trans (23 cm)

TT-ET-ETC18	Trial Transfer Catheter for Echo Trans (18 cm)
TT-ET-ETC23	Trial Transfer Catheter for Echo Trans (23 cm)

Indication for use:
Allwin Embryo Transfer Catheters are used to introduce in vitro fertilized (IVF) embryos into the uterine cavity.

Contraindications:
This catheter should not be used on a patient with an active vaginal or intrauterine infection, a intra – fallopian procedure, a sexually transmitted disease, uterine perforation, a recent pregnancy (or is currently pregnant), or confirmed or suspected intrauterine device.

Complications:
- Urinary tract Infection
- Pelvic inflammatory disease
- Uterine infection
- Bleeding
- Endometrial / Endocervical damage
- Endometrial lesions

Caution:
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- The visibility of catheter may be compromised with use of low resolution ultrasound equipment.
- The patients should be with a full bladder for performing transabdominal Ultrasound.

Warning / Precaution:
- Do not use if package is opened or damaged.
- To reduce the risk of perforation, if any resistance is felt while inserting the stylet, soft obturator, or catheter, do not force the device against the resistance.
- Confirm the specification (length) of the catheter prior to use.
- During insertion do not pull back further than the last graduation of the inner catheter, as removing the inner catheter from the r catheter. may result in damage to the endometrial tissue and bleeding
- This device is supplied sterile and intended for single use only.
- Do not re-sterilize.
- Only experienced practitioners should use this device.
- The assisted reproduction catheter (and any other accessories used during this procedure) should be comprised of embryo compatible materials.
- Infection may occur due to bacterial contamination of the device during vaginal manipulation, and result in urinary tract infection (UTI), pelvic inflammatory disease (PID), or uterine infection.
- Recommendations to minimize infection include the use of only embryo compatible materials, flushing the catheter (an any other accessories used) with sterile, compatible culture media, and closely adhering to sterile techniques.
- Bleeding may occur as a result of the trauma due to insertion of the catheter through the cervix and has been reported to be associated with a lower pregnancy rate. A simple and atraumatic transfer method has been noted to offer the best condition for success.
- Dispose in accordance with recognized medical practice and under observance of applicable law and regulation.
- Storage temperature between 5ºC to 30ºC.

Instruction for Use:
For

1. Place patient in a lithotomy.
2. Insert vaginal speculum to expose cervix and clean with a cotton swab moistened with normal saline or medium.
3. Shape the outer catheter to complement the patient's anatomy and pass the catheter till it reaches the internal orifices.
4. Advance the catheter so that the inner catheter passes through the external and internal os, into the mid-uterine cavity. (It may be necessary to twist the catheter as it negotiates the cervical canal)
5. In case of difficulty in negotiating the cervical canal, use appropriate stylets as under

Length	For use with	Code
18 cm	TT-EB-ETC18, TT-ET-ETC18	STY18
23 cm	TT-EB-ETC18, TT-ET-ETC23	STY23

6. Place the tip of catheter approximately 1cm from the fundus. Assess the passage of the catheter in preparation for embryo transfer.
7. Remove and dispose of the catheter in accordance with local medical hazardous waste practices.

Limited Express Warranty:
The limited express warranty as set forth herein is exclusive and in lieu of all warranties of merchantability and fitness for use, remedies, obligations and liabilities for consequential damages. The products are being sold only for the purpose described herein and such limited express warranty runs only to the original user. In no event shall ALLWIN be liable for any breach of warranty in any amount exceeding the purchase price of the product. ALLWIN reserves the right to make design changes to products without liability to incorporate said changes in ALLWIN products previously designed or sold.

Note
Bacterial endotoxin (LAL - limulus amoebocyte lysate) assay ≤ 20 EU/device. Test conducted to ensure efficiency and safety of the device(s) for its intended use.

REF Catalogue Number | LOT Batch Code | Date of Manufacture | Use By | Do not re-use | Do not Re-Sterilize | Rx only Caution: Federal Law restricts this device to sale by or on the order of a physician or a practitioner trained in its use.

Consult Instruction for use | Do not use if Packing is damaged | Caution | Keep out of sunlight | Keep Dry | MD Medical Device | STERILE EO Sterilized using ethylene oxide | Not made with natural rubber latex | Temperature Limit

EU REP
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