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TRANSMYOMETRIAL EMBRYO TRANSFER SET

Used for transferring IVF embryo(s) into the endometrial cavity. Intended for one time use.

NOTE: One cell mouse embryo tested and passed with 75% or greater blastocyst rate. USP endotoxin (LAL) tested and passed with 20 EU's or less per device. Testing is conducted on a lot-to-lot (batch) basis.

CAUTION: Sterile if the package is unopened or undamaged. Do not use if package is broken.

CAUTIONS: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. This procedure should only be performed by physicians trained in IVF procedures.

CONTRAINDICATIONS

The Transmyometrial Embryo Transfer Set should not be used on a patient with an active vaginal or intrauterine infection, a sexually transmitted disease, a recent uterine perforation, a recent cesarean section, a recent pregnancy (or who is currently pregnant), or if the patient currently has an intrauterine device.

CAUTIONS:

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 occurrence include use of only embryo compatible materials, flushing the catheter (and any other accessories used) with sterile, compatible culture media, and closely adhering to sterile techniques.

Bleeding may occur as a result of trauma due to insertion of the device through the myometrium and has been reported to be associated with a lower pregnancy rate. Reference article: Y. Englert, F. Puissant, M. Camus, et al: "Clinical study on embryo transfer after human in vitro fertilization," Journal of in vitro Fertilization and Embryo Transfer, 1986:3 (4), pages 243-246.

SUGGESTED INSTRUCTIONS FOR USING TRANSMYOMETRIAL EMBRYO TRANSFER SET

1. Place the patient in knee/chest or lithotomy position.
2. Place an ultrasound transducer into the vaginal fornix to visualize the endometrial lining.
3. Advance the guide needle through the myometrium to the endometrial lining.
NOTE: If only a single needle is used, advance the needle directly into the endometrial cavity.
4. If desired, advance the inner needle through the guide needle and into the endometrial cavity.
5. With the embryos loaded in the catheter, advance the catheter through the guide needle (or inner needle, if appropriate).
6. Expel the embryos into the endometrial cavity.
7. Remove catheter and needle(s). Check catheter for retention of embryos.
8. Discard needle(s) and catheter.



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