COOK MEDICAL

# Echosight Jansen-Anderson Intratubal Transfer Set

Instructions for Use

T_K-J-ITS_REV3

# Echosight Jansen-Anderson Intratubal Transfer Set

**CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).**

## DEVICE DESCRIPTION

The Intratubal Transfer Set consists of a polymer curved guide catheter, stainless steel malleable obturator, stainless steel wire guide and a polymer transfer catheter.

## INTENDED USE

This device is intended to inject sperm, gametes, or embryos into the uterine ostium of the fallopian tube via ultrasound guidance.

## CONTRAINDICATIONS

- Active vaginal or intrauterine infection
- Sexually transmitted disease
- Recent uterine perforation
- Recent or current pregnancy
- Presence of intrauterine device

## WARNINGS

None Known

## PRECAUTIONS

- The assisted reproduction catheter (and any other accessories used during this procedure) should be constructed of embryo-compatible materials.
- Infection may occur due to bacterial contamination of the catheter during vaginal and transcervical manipulation and may result in urinary tract infection (UTI), pelvic inflammatory disease (PID), or uterine infection. To minimize occurrrence of these infections, Cook recommends that you use only embryo-compatible materials; flush the catheter (and any accessories used) with sterile, compatible culture media; administer prophylactic antibiotics; and closely adhere to sterile techniques.
- Trauma from inserting the catheter through the cervix may result in bleeding, which has been associated with a lower pregnancy rate. A simple and atraumatic transfer method has been noted to offer the best conditions for success.
- This product is intended for use by physicians trained and experienced in assisted reproduction techniques. Standard techniques should be employed.

## INSTRUCTIONS FOR USE

**NOTE: It is important to determine the exact catheter volume prior to use. To determine catheter volume, aspirate transfer media or other appropriate liquid into the catheter, utilizing a calibrated syringe.**

**NOTE: The media column may be interrupted by unintended air during aspiration due to inherent properties of the media used to support the embryo.**

1. Under ultrasound guidance, pass the preassembled malleable obturator and guiding catheter transvaginally through the uterus and into the tubal ostium.
   **NOTE: The obturator can be withdrawn to manipulate the preset curve on the catheter and facilitate placement.**
2. Once in position, remove the malleable obturator.
3. If desired, the wire guide may be introduced into the guiding catheter to facilitate cannulation of the proximal fallopian tube.
4. Introduce the preloaded delivery catheter into the guiding catheter, advance the delivery catheter approximately 2 cm into the fallopian tube and instill the desired samples.

5. Remove the device and discard.

**NOTE: One cell MEA tested and passed with 80% or greater blastocyst development within 96 hours. USP Endotoxin (LAL) tested and passed with 20 EU or less per device.**

## HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened and undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from the package, inspect the product to ensure no damage has occurred.

## REFERENCES

These instructions for use are based on experience from physicians and (or) their published literature. Refer to your local Cook sales representative for information on available literature.

**A symbol glossary can be found at cookmedical.com/symbol-glossary**

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