

Instructions for Use

Tucker Embryo Catheter™, Tucker Embryo Trial Catheter™ and Tucker Stylettes™ for Embryo Transfer

Product Description:

The Tucker Embryo Catheter™ (TEC) (Part #'s ftr120 and ftr123) are single use, sterile, disposable, soft, flexible catheters for the replacement of embryos into the uterine cavity following *in vitro* fertilization. Each catheter has a matte finish on tip for visibility under ultrasound. The embryo passes through the clear, pellethane catheter, which is open on the end. The catheters have a working length of 20cm (light green hub) or 23cm (dark green hub) including Luer Lock adaptors that are affixed. The color coded hubs indicate the different lengths. Each TEC comes with a guide sheath providing smooth passage into the uterus. Five black graduator markings are located on the distal portion of the outer sheath at 1cm increments to indicate the degree of advancement into the cervix. Five black graduation markings located on the proximal portion of the inner catheter at 1cm increments indicate the degree of advancement into the uterus. The TEC is protected within a petrothane protective sheath in a sterile, peelable pouch, which is discarded before use.

The optional Stylet (accessory) is intended for use only with the TEC. The Stylet is sold separately in a peelable pouch. There is a 20cm (ftr220) length with a color coordinated light green hub and 23cm (ftr223) length with color coordinated dark green hub.

Indications For Use:

This product is designed for introduction of embryos into the uterine cavity.

Contraindications:

Procedures requiring the use of these products are contraindicated in the presence of chronic cervical infection or in the presence of or after recent Pelvic Inflammatory disease. The products are not intended for intrafallopian tube procedures.

Sterile:

By Ethylene Oxide gas (ETO)-Unless peel pouch package has been opened or damaged.

Endotoxin Assay:

LAL endotoxin testing used the gel-clot method. Testing is performed in a manner consistent with the requirements of U.S.P. XXII and the FDA Guideline on Validation of the LAL test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products and Medical Devices December, 1987. Endotoxin levels may not exceed 20 EU/device for lot acceptance.

MEA (Mouse Embryo Assay) 96- hour One-Cell:

Each lot of the TEC is subject to the 1-cell mouse embryo bioassay. Test articles that score greater than or equal to 80% development to blastocyst at 96 hours are considered non-toxic.

Warning:

Before use examine each pouch for damage or perforations. Discard product if package is damaged or broken, or if beyond the expiration date on the package.

Precautions/cautions:

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

Single use only. After use, discard per local hazardous waste procedures. **DO NOT** resterilize and reuse due to potential risk of infection.

- In no case should the catheter be forced against manually felt resistance while inside the uterine cavity.
- The outer sheath should **not** be advanced further than the internal os, and should never enter the uterine cavity.
- To be used by, or under the direction of a qualified person in line with local guidelines governing *in vitro* fertilization if applicable.
- Embryo can be ejected early somewhere other than the uterus.
- Embryo can be left in the catheter, not delivered.
- Embryo can be damaged and become non-viable.

- Inner Catheter can fold back on itself during introduction, kink, and the embryo can be delivered into the cervical canal. (Sometimes it can be difficult under ultrasound to visualize exactly where the catheter tip is located.)
- If catheter is placed too close to fundus, embryo can be delivered into a Fallopian tube, resulting in an ectopic pregnancy.
- Interior smoothness of noodle is important, especially at the tip, so no obstruction is damaging embryos during delivery.

Adverse Reactions:

No adverse reactions to the use of the catheter have been reported. However, as with any catheter which is passed through the internal cervical os, mild cramping may be expected. In every case the Directions for Use should be followed, taking note of any CONTRAINDICATIONS, PRECAUTIONS AND WARNINGS.

Instructions for Use:

Below are suggested directions for use. The final decision on the technique used is the responsibility of the physician in charge.

1. Place patient in the dorsal lithogeny position.
2. Expose the cervix with a vaginal speculum and gently swab with cotton moistened with normal saline or embryo culture media.
3. In accordance with your standard protocol, load the embryo(s) into the inner catheter using a syringe attached to the Luer Lock.
4. With the hubs attached, 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 gently rotate the catheter as it negotiates the cervical canal.
5. If difficulty is experienced, withdraw the catheter and advance the outer sheath several centimeters, or to the position where the tip of the inner catheter with the hub of the outer sheath ensures a smooth radius protrudes. Pre-shape the outer sheath to complement the patient's anatomy and pass the catheter in this position to the internal os (should be performed prior to retracing the inner catheter). Advance the inner catheter into the mid-uterine cavity.
6. Place tip of the catheter approximately 1cm from the fundus using the graduations as a guide. Gently rotate the catheter to remove excess mucus from the tip.
7. Expel the embryos.
8. Leave time for the uterine environment to stabilize and slowly remove the catheter.
9. Hand catheter back to embryologist to confirm that no embryos remain.
10. Repeat embryo transfer, if necessary.
11. Dispose of the catheter in accordance with local medical hazardous waste practice.

The white outer sheath stabilizes the inner catheter and makes for better handling and ideally should not have to be introduced into the internal os. However, on occasion, resistance to the easy passage of the inner catheter is encountered, usually at the level of the internal os. In such a situation, the white outer sheath should be released from the catheter hub and advanced to the external os, thus assisting the soft inner catheter in its passage through the canal. If resistance persists, a malleable stylet (ftr220 and ftr223) can be used to cannulate the cervix and allow easy passage.

Products

Ref. No

Tucker Embryo Catheter™ 23 cm	FTR123
Tucker Stylettes™ 20 cm	FTR220
Tucker Stylletes™ 23 cm	FTR223
Tucker Embryo Trial Catheter™ 23 cm	FTR323

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