SAPLINX CATH Fallopian Tube Recanalization Catheter

Description:

- SC-FTR-M SALPINX CATH Fallopian Tube Recanalization Catheter
- SC-FTR-M-G SALPINX CATH Fallopian Tube Recanalization Catheter with Malleable Stylet & Hydrophilic Guidewire

Intended use:

Used for fallopian tube recanalization under radiological fluoroscopy control.

Contraindications:

- Uterine bleeding
- Recent surgery
- Active pelvic infection
- Current pregnancy
- Gynecology malignancy.
- Known allergy to dye or contrast medium

Complications:

- Perforation
- Ectopic pregnancy
- Mild bleeding
- Infection
- Contrast reaction
- Damage to normal fallopian tubes.
- Tubal dissection
- Pain or discomfort
- Extravasation

Caution:

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

Warning/ Precaution:

- Do not use if package is opened or damaged.
- Dispose in accordance with recognized medical practice and under observance of applicable law and regulation.
- Single use only.
- Attempt to resterilize a single use device may compromise its structural integrity and/or lead to device failure which may result in patient injury or illness.
- Only experienced surgeon should use this device.
- Storage temperature between 5ºC to 30ºC.
- The Guide wires in the fallopian tube catheterization sets are intended only to facilitate placement of the inner catheters. They are not intended for tubal recanalization and should not be advanced beyond the tubal isthmus.

Instruction for Use:

- The Fallopian tube recanalization procedure begins with standard hysterosalpingogram to evaluate the patency of the fallopian tubes.
- A speculum is inserted into the vagina to see the cervix.
- The cervix is then prepped & cleaned.
- The outer catheter is used for selective salpingiography.
- On finding the tubal block, the inner Malleable Stylet is advanced through the catheter into the tubal OS.
- A 0.018” floppy tip PTFE coated guide wire is advanced to cannulate the tubal OS to free it from mucus or debris forming the block.
- Contrast is then injected to demonstrate spillage into the peritoneal cavity and tubal patency is confirmed.

Do not reuse, reprocess & resterilize:

Reuse, Reprocessing & resterilization may compromise the structural integrity, can also create risk of contamination & may not give desired result or create complications, infections which may result in injury, illness or death.

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.

REF Catalogue Number | LOT Batch Code | Date of Manufacture | Use By | Do not re-use | Do not Re-Sterilize | Rx only | Caution : Federal (USA) law restricts device to sale by or on the order of a physician.

Consult Instruction for use | Do not use if Packing is damaged | Caution | Keep out of sunlight | Keep Dry | STERILE EO | Sterilized using ethylene oxide | Temperature Limit

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