allwin® Medical Devices

NephroTrack Nephrostomy Track Balloon Dilator

Description:
The NephroTrack Nephrostomy Track Balloon Dilator is a coaxial catheter with a balloon mounted on its proximal tip. The lumen marked 'balloon' is for balloon inflation and the other lumen permits insertion of a stiffening stylet or a 0.018" guidewire through the proximal tip. The balloon is designed to provide a distensible segment, which inflates to a known diameter and length at a specific pressure.

Configuration:
See brochure

Intended use:
NephroTrack Nephrostomy Track Balloon Dilators are recommended for dilatation of the nephrostomy tract.

Contraindications:
This product is contraindicated in the presence of conditions which create unacceptable risk during the catheterization.

Complications:
- Ureteral Perforation
- Tissue trauma

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

Maintaining vacuum on the balloon may cause the sides to flatten, impeding withdrawal and removal.

Warning/ Precaution:
- This device should be used only by physicians thoroughly trained in the technique of catheter dilation.
- Inflation in excess of recommended balloon capacity may cause balloon to burst or the catheter bond to fail.
- It is important that NephroTrack Nephrostomy Track Balloon Dilator not be inflated beyond recommended rated burst pressure of 17atm.
- Storage temperature between 5ºC to 30ºC.
- For a 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.
- Dispose in accordance with recognized practice and under observance of applicable law & regulation.
- Do not use if package is opened or damaged.

Instruction prior to use:
1. Prior to use and while using aseptic technique, remove the catheter from its package. Visually inspect the catheter for bends or kinks. Do not use if product is damaged.
2. It is recommended that the stopcock in use be hand-tightened prior to operation.
3. Purge air from the inflation lumen before use. Do so by first attaching a stopcock and an empty 50cc Syringe to the inflation lumen, labeled "Balloon". Then with the balloon- folding tool still in place, and with the stopcock in the open position, draw back on the plunger as far as comfortably possible. After one minute and while plunger is still drawn back, close stopcock to maintain the vacuum within the balloon.
4. Replace empty syringe with another, which has been filled with an appropriate inflation fluid. Inflation fluid should include a sterile contrast agent.

Instruction for Use:
Catheter Insertion Technique:
The catheter may be placed over a 0.035" I 0.038" Guidewire in the pelvicalyceal system. The balloon catheter is advanced over the guidewire until the most distal radiopaque marker is seen fluoroscopically inside the system.

Balloon Inflation:
When the balloon has been positioned within the section of ureter to be dilated, the balloon can be inflated by means of a hand-held syringe (a 20cc syringe is recommended). To ensure proper positioning of the balloon, the dilation catheter can be inflated with sterile dilute contrast medium as previously described. Proper dilation however can be performed with sterile normal saline solution. The balloon should be fully inflated. The use of a pressure manometer to monitor intraluminal balloon pressure is strongly recommended.

Balloon Deflation and Withdrawal:
For deflating the balloon, reopen stopcock and deflate the balloon by emptying most of the fluid with the syringe. Then remove syringe to allow ambient pressure to completely relax the balloon. Gently withdraw the catheter. As the balloon exits the scope, use a gentle, steady counterclockwise motion.

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 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 | STERILE EO | Sterilized using ethylene oxide

EC REP
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CE 0123

Temperature Limit

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