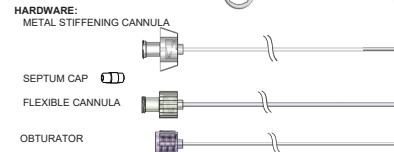


UreSil® NEPHRO-STENT™ Nephroureteral Stent Catheter

Intended use: For percutaneous internal / external nephroureteral drainage
This product is intended for short-term use (more than 24 hours and less than 30 days).

See the pouch label on this product for specific contents

LOCKING CATHETER:
NEPHROURETERAL STENT CATHETER
WITH LOCKING PIGTAIL AND RO MARKER



INSTRUCTIONS FOR USE:

- Selected and prepare the insertion site using standard technique. Using standard technique a 0.038" diameter guidewire percutaneously through the renal pelvis, ureter into the bladder.
- Determine the appropriate Nephroureteral Stent Catheter pigtail-to-pigtail length using one of two techniques:
 - Measure the ureter on x-ray and select the appropriate Nephroureteral Stent Catheter pigtail-to-pigtail length. The stent catheter length should be sufficient to allow the proximal pigtail to form in the renal pelvis, while the distal pigtail forms in the bladder.
 - Insert an angiographic catheter or other appropriate device over the guidewire and into the bladder. Mark the device at the skin site. Slowly withdraw the device until the end is located in the renal pelvis. Again, mark the device at the skin site. The distance between the two marks plus an additional 2 cm is the approximate pigtail-to-pigtail length required for the Nephroureteral Stent Catheter. NOTE: The guidewire can also be used to determine the pigtail-to-pigtail length using the same procedure.
- To ease introduction of the Nephroureteral Stent Catheter, the tract may be dilated. Reserve slack in the retention suture by pulling it out gently until slight resistance is felt.
- Straighten the pigtails prior to advancing the stenting cannula into the stent catheter. If using the flexible cannula for insertion, first insert the supplied obturator into the flexible cannula. Then, gently advance the reinforced flexible cannula into the stent catheter.
- Lock the stenting cannula into the stent catheter hub. If the flexible cannula was used, remove the obturator.
- Advance the stent catheter with stenting cannula over the guidewire into the superficial part of the renal pelvis. At the point of entry into the renal pelvis, the cannula is unlocked and held stationary while the stent catheter is advanced further until the distal tip is in the bladder.
- Remove the stenting cannula.
- Remove the guidewire while rotating the stent catheter clockwise to form the pigtails.
- Pull the suture to fully close the locking pigtail. Depending upon whether or not suture storage is desired, lock the pigtail as follows:
 - Option A:** Locking the pigtail proximally with suture: Mow the locking slide proximally until an audible "click" is heard. The suture is now locked. Trim away excess suture at the proximal end of the hub.
 - Option B:** Locking the pigtail with suture storage: Wind approximately 15 cm of suture into the suture channel for later use when removing or repositioning the catheter. To wrap the suture, pull it straight and then hook it in the notch at the bottom of the suture channel. After making the last wind, wrap the suture around the suture retention post. Move the locking slide proximally until an audible "click" is heard. The suture is now locked.
- To remove the catheter, gently pull the catheter hub. To unlock the mechanism, depress the tab using an instrument and move the slide distally. If no suture was stored, the suture will now be released. If suture was stored, unwind the suture to complete the release. Cut the suture at the exit point at the proximal end of the hub and pull the catheter cut off the patient. In order to maintain control of the hub and pull the catheter cut off the patient.
- Internal drainage can be achieved by placing the septum cap on the stent catheter hub. The septum cap contains a self-sealing needle puncture port for flushing.

CAUTION:

- When engaging the catheter luer lock, do not overlighten. Overtightening the luer can result in luer crack which may require catheter replacement.
- The stent catheter may rapidly obstruct where chronic stone formers more rapidly cause encrustations.



Rx Only

Sterile if package is unopened and undamaged. The reuse of this single-use device can lead to patient infection and/or device malfunction. NEPHRO-STENT is a trademark of UreSil, LLC, and URESEL is a registered trademark of UreSil, LLC, U.S. patent nos. 8,177,773 and 9,079,069.

TO REORDER: Call 1-800-538-7374 (U.S. only) Fax: 1-847-982-0106
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NEPHRO-STENT Cathéter à stent Néphro-uréteral

L'utilisation prévue: Pour le drainage percutané néphrourétal interne / externe Ce produit est destiné à un usage de courte durée (plus de 24 heures et moins de 30 jours).

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