PERCUTANEOUS NEPHROSTOMY CATHETERS

Guides & Instruction for use

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

INTRODUCTION:
Percutaneous nephrostomy or nephropyleostomy is an interventional procedure used mainly in the decompression of the renal collecting system. Since Goodwin et al published a report of the first series involving this procedure in 1955, percutaneous nephrostomy catheter placement has been the prime procedure for the temporary drainage of an obstructed collecting system.

INDICATIONS:
The main reason that percutaneous nephrostomy tubes are placed is for temporary urinary diversion due to urinary obstruction secondary to calculi. Other common indications include the following:

- Diversion of urine from the renal collecting system in an attempt to heal fistulas or leaks due to traumatic or iatrogenic injury, malignant or inflammatory fistulas, or hemorrhagic cystitis.
- Treatment for nondilated obstructive uropathy.
- Treatment for urinary tract obstruction related to pregnancy.
- Treatment for complications related to renal transplants.
- Access for interventions such as direct infusion of substances for dissolving stones, chemotherapy, and antibiotic or antifungal therapy.
- Access for other procedures (eg, benign stricture dilatation, antegrade ureteral stent placement, stone retrieval, pyeloureteroscopy, endopyelotomy).
- Decompression of nephric or perinephric fluid collections (eg, abscesses, urinomas).

HOW SUPPLIED:
The devices are sterilized by ethylene oxide. Contents are sterile, non-pyrogenic in unopened or undamaged package. Do not use if package has been damaged or has been opened.

STORAGE:
Store at room controlled temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to expiration date on the package label.

WARNING:
- For single product and patient use only.
- Do not use if any sign of product damage is visible.
- Do not re-use, reprocess or re-sterilize. Reuse may lead to infection and Pyrogencity. Reprocessing or Re-sterilization may damage the product and affect its integrity which when re-used may lead to possible deterioration in health and safety of patients.

COMPLICATIONS:
The only real contraindications are a bleeding diathesis (most commonly uncontrollable coagulopathy) and an uncooperative patient. Severe hyperkalemia (>7 mEq/L) should be corrected with hemodialysis prior to the procedure. Major complications with percutaneous nephrostomy tube placement include bleeding, sepsis, and injury to an adjacent organ. Other major complications, though somewhat rare, have been reported to occur in as many as 5% of patients. Complications of percutaneous nephrostomy may include the following:

- Massive hemorrhage requiring transfusion, surgery, or embolization (1-3%)
- Pneumothorax (<1%)
- Microscopic hematuria (common)
- Pain (common)
- Urine extravasation (<2%)

Ref: URO-NEP
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- Inability to remove nephrostomy tube due to crystallization around the tube site
- Death (0.2%)
- Sepsis (1.3%)
- Catheter dislodgement in first month (<1%)

**PRECAUTIONS:**
- The methods of application are variable, and could be modified by the physician according to his own experience.
- Short term catheter should not left inside the body for more than 30 days.
- The proper size selection for the catheter size and length is the responsibility of the physician.

**METHOD OF APPLICATION:**
- The patient is commonly placed in a prone or prone-oblique position, the side to be punctured is elevated. The region should be evaluated with sonography, CT, or fluoroscopy and the site marked. This region should then be prepared (e.g., cleansed with Betadine solution) and draped in the usual manner. The patient is given an appropriate medication for conscious sedation (e.g., fentanyl and Versed) and a local anesthetic, usually 1% lidocaine to anesthetize the skin.
- A small skin nick is made to facilitate passage of the needle into the skin.
- Puncture site selection is crucial in minimizing the risk of hemorrhage. The best route for needle entry into the renal collecting system is through an oblique posterolateral approach along the Brödel line and into the end of a posterior calix. This line is near the posterior axillary line and is about 2-3 cm below the 12th rib. A percutaneous nephrostomy tract that approaches along Brödel line has the smallest risk of causing substantial arterial injury and subsequent hemorrhage.
- The needle is angled toward a posterior lower or middle pole calix. Once the needle is inserted into the calix and into the collecting system, the stylet is removed, and urine is returned if an obstruction is present. If no urine is present, a few maneuvers can be used. A 10-mL syringe should be attached to the needle hub, and the needle and syringe should be retracted slightly. If urine is aspirated, the tip is likely within the collecting system. Otherwise, a 0.018” wire can be used to probe the region, or a small amount of contrast agent can be injected to check the position.
- Contrast material should be gently injected into the collecting system to confirm the location. Over distension of the system with contrast material or the withdrawal of too much urine for culturing should be avoided. In commonly practice, the amount of contrast agent used inject is the same as the amount of urine removed.
- Once access into the collecting system is obtained, successful wire exchanges should occur until a 0.035-in J-tip wire is placed into the renal pelvis or down the ureter.
- The tract should be dilated with dilators.
- The drainage catheter should be flushed, and the Straightener that comes with the kit should be used.
- The catheter should be advanced into the proximal renal parenchyma over a 0.035” guide wire, the trocar should be loosened, and the catheter should be slipped off the trocar into the renal pelvis. The internal wire should be pulled to lock the pigtail catheter, and the catheter should be seated appropriately within the renal pelvis. The catheter position should be confirmed with the use of contrast material, and the catheter should fixed with the fixation wings and tied to the skin with suture and attached to an external drainage bag.
- **N.B.** For One Step nephrostomy application the most dilated portion of the kidney is assessed ultrasonographically and with its puncture needle is applied on the puncture line to the kidney in only one step then with removal of the trocar and passage of urine to be sure that the catheter is in the renal pelvis, then the cannula is removed and the catheter will re-coil to take its original pig tail shape.
- It's more rapid easy procedure for rapid access to the renal pelvis in urgent cases with obstructed kidney that in need for rapid urinary diversion or can't withstand major procedure up to improving the general condition of the patient.
- **N.B.** For Nephrostomy catheter With LOCK (See the mechanism instruction at the end of this instruction).

**DEVICE DESCRIPTION:**
Percutaneous Nephrostomy Catheters are single lumen for adult and pediatric use, 30 Cm in standard length and 4 - 24 FR in diameters. Hydrophilic coating added is an option. Percutaneous Nephrostomy is supplied either single catheter or in kits.
## CODE KEY/PACKAGE INCLUDES:

<table>
<thead>
<tr>
<th>Code key</th>
<th>Single catheter package includes</th>
<th>Complete Kit Package includes</th>
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<tbody>
<tr>
<td><strong>Nephrostomy catheter J type and kit</strong>&lt;br&gt;Ref. code key: NEP-XX-YY-J-K</td>
<td>- Nephrostomy Catheter.&lt;br&gt;- Connection tube.&lt;br&gt;- Fixation wings.</td>
<td>- Nephrostomy Catheter.&lt;br&gt;- Connection Tube.&lt;br&gt;- Puncture Trocar, Cannula.&lt;br&gt;- Chiba Needle.&lt;br&gt;- Fascial Dilators.&lt;br&gt;- Scalpel.&lt;br&gt;- J-End Guide Wire.&lt;br&gt;- Fixation Wings.&lt;br&gt;- Stopcock. (Optional)</td>
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<tr>
<td>NEP : Nephrostomy Catheter&lt;br&gt;XX : Size in Fr.&lt;br&gt;YY : Catheter Length&lt;br&gt;J : For J type (Pigtail)&lt;br&gt;K : For Complete kit.</td>
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| **Nephrostomy catheter Malecot type and kit**<br>Ref. code key: NEP-XX-YY-M-K | - Nephrostomy Catheter.<br>- Connection tube.<br>- Fixation wings. | - Nephrostomy Catheter.<br>- Connection Tube.<br>- Puncture Trocar, Cannula.<br>- Chiba Needle.<br>- Fascial Dilators.<br>- Scalpel.<br>- J-End Guide Wire.<br>- Fixation Wings.<br>- Stopcock. (Optional) |
| NEP : Nephrostomy Catheter<br>XX : Size in Fr.<br>YY : Catheter Length<br>M : For Malecot type<br>K : For Complete kit. | | |

| **Nephrostomy catheters kit with Lunderquist guide wire.**<br>Add (Q) at the end of code for the types above. | - Nephrostomy Catheter.<br>- Connection tube.<br>- Fixation wings. | - Nephrostomy Catheter.<br>- Connection Tube.<br>- Puncture Trocar, Cannula.<br>- Chiba Needle.<br>- Fascial Dilators.<br>- Scalpel.<br>- J-End Guide Wire.<br>- Fixation Wings.<br>- Stopcock. (Optional) |

| **One step Nephrostomy catheters**<br>Ref. code key: NEP-XX-YY-T-OS | - Nephrostomy Catheter.<br>- Puncture Trocar and Cannula.<br>- Connection Tube.<br>- Fixation wings. | - Nephrostomy Catheter.<br>- Connection Tube.<br>- Puncture Trocar, Cannula.<br>- Chiba Needle.<br>- Fascial Dilators.<br>- Scalpel.<br>- Lunderquist Guide Wire.<br>- Fixation Wings.<br>- Stopcock. (Optional) |
| NEP : Nephrostomy Catheter One Step<br>XX : Size in Fr.<br>YY : Catheter Length.<br>T : Type Of Catheter Tip. (M)For Malecot, (J) For J type (pigtail).<br>OS : One Step Catheter. | | |

| **Nephrostomy catheter J type or Malecot with String lock.**<br>Add (L) at the end of code for the types above. | - Nephrostomy Catheter.<br>- Connection Tube.<br>- Fixation Wings. | - Nephrostomy Catheter.<br>- Connection Tube.<br>- Puncture Trocar, Cannula.<br>- Chiba Needle.<br>- Fascial Dilators.<br>- Scalpel.<br>- Lunderquist Guide Wire.<br>- Fixation Wings.<br>- Stopcock. (Optional) |

| **Re-entry nephrostomy catheter malecot**<br>Ref. code key: NEP-x/XX-YY-M | - Nephrostomy Catheter.<br>- Connection Tube.<br>- Fixation Wings. | - Nephrostomy Catheter.<br>- Connection Tube.<br>- Puncture Trocar, Cannula.<br>- Chiba Needle.<br>- Fascial Dilators.<br>- Scalpel.<br>- Lunderquist Guide Wire.<br>- Fixation Wings.<br>- Stopcock. (Optional) |
| NEP : Re Entry Nephrostomy Catheter<br>x/XX : Re Entry Nephrostomy Catheter Size In Fr/Catheter Size In Fr.<br>YY : Catheter Length.<br>M : For Malecot Type. | | |

**Note:** Add (H) At The End Of Code In Case Of Hydrophilic Coating

**PRODUCT SAFE DISPOSAL:**

Used products should be disposed in sanitary container to prevent possible contamination and cross infection.
Nephrostomy catheter with lock mechanism instruction:

While insertion, ring’s leg is kept as in the shown position

Catheter end is straightened

Straightener is unlocked and pulled out

The catheter end retains its original shape

Thread is pulled and ring is rotated clockwise, till latching and locking the thread

Ring is rotated anticlockwise to free the thread and release the catheter