

**10.1. Nephrostomy Catheter and Kits Instructions for Use**

PERCUTANEOUS NEPHROSTOMY CATHETERS

Device Description:

AMECATH Percutaneous Nephrostomy Catheter is a catheter that perforates the skin, passes through the body wall and renal parenchyma, and terminates in the renal pelvis or a calyx.

AMECATH Percutaneous Nephrostomy Catheter has multiple functions but is used most frequently to provide urinary drainage when the ureter is obstructed and retrograde access is inadvisable or impossible.

AMECATH Percutaneous Nephrostomy Catheter placement is a prime interventional procedure used mainly in the decompression of the renal collecting system (Percutaneous Nephrostomy Catheter placement has been the prime procedure for the temporary drainage of an obstructed collecting system).

AMECATH Percutaneous Nephrostomy Catheters are single lumen for adult and pediatric use, 25-30-35 Cm length and 4 - 22 FR range in diameters. Hydrophilic coating added is an option.

AMECATH Percutaneous Nephrostomy Catheter is supplied either single catheter or in kits.

Target patient populations: Adults and children (Paediatric)

Intended user: Health Care Professionals

AMECATH Percutaneous Nephrostomy Catheter and its accessories:

AMECATH Percutaneous Nephrostomy Catheter is available in different designs and Kit configurations to cover all customer needs

Device construction:**Catheter Types**

- Nephrostomy Catheter J type (Pigtail)
- Nephrostomy Catheter Malecot
- One step Nephrostomy Catheter
- Nephrostomy Catheter J type or Malecot with string lock
- Re-entry Nephrostomy Catheter Malecot

List of Accessories:

The basic kits contain the following accessories:

- Connection Tube (12Fr or 16Fr).
- Puncture Trocar, Cannula.
- Chiba Needle.
- Fascial Dilators.
- Scalpel.
- J- End Guide Wire.
- Fixation Wings.

The Optional accessories:

- Stopcock.
- Urine Bag
- Lunderquist guide wire (only in Nephrostomy catheters kit with Lunderquist guide wire)

Intended Use:

AMECATH Percutaneous Nephrostomy Catheters are used 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 non-dilated 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 (e.g., benign stricture dilatation, antegrade ureteral stent placement, stone retrieval, pyeloureteroscopy, endopyelotomy).
- Decompression of nephric or perinephric fluid collections (eg, abscesses, urinomas).

Contraindications:

- Bleeding diathesis (most commonly uncontrollable coagulopathy) and an uncooperative patient.
- Severe hyperkalemia (>7 mEq/L) should be corrected with hemodialysis prior to the procedure.

Warnings and Precautions

- For single product and patient only.
- Do not use if any sign of product damage is visible.
- Do not re-use, reprocess or re-sterilize. Re-use may lead to infection and Pyrogenicity. 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.
- The methods of application are variable and could be modified by the physician according to his own experience.
- Short term catheter should not be 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 considering the patient's anatomy.
- HCP must be experienced or trained on the proper use of the device
- Do not use absolute alcohol or acetone-based product on the catheter. 2% chlorhexidine or Iodine based solution is recommended as antiseptic solution.
- It is not recommended to use ointments on catheters as it may cause its degradation.

Complications:

- **Common:**
 - Bleeding
 - Sepsis
 - Injury to an adjacent organ
 - Microscopic hematuria
 - Inability to remove Nephrostomy Catheter due to crystallization around the catheter site
 - Pain
- **Rare:**
 - Massive hemorrhage requiring transfusion, surgery, or embolization
 - Urine extravasation
 - Sepsis
- **Very Rare:**
 - Death
 - Pneumothorax

How Supplied:

- **AMECATH Percutaneous Nephrostomy Catheters** is a sterile, single-use Medical device
- Each carton box includes 10 **AMECATH Percutaneous Nephrostomy Catheters** kits packed in PETG hard blister covered with Tray Cover.

AMECATH Percutaneous Nephrostomy Catheter method of application

1. The patient is commonly placed in a prone or prone-oblique position, the side to be punctured is elevated. The body site where the device will be inserted should be evaluated with sonography, CT, or fluoroscopy and also should be marked. This body site 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 anaesthetic, usually 1% lidocaine to anesthetize the skin.
2. A small skin incision is made to facilitate passage of the needle into the skin.
3. Puncture site selection is crucial in minimizing the risk of haemorrhage. 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 haemorrhage.
4. 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 manoeuvres 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.
5. 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 to inject is the same as the amount of urine removed.
6. Once access into the collecting system is obtained, successful wire exchanges should occur until a 0.035" J-tip wire is placed into the renal pelvis or down the ureter.
7. The tract should be dilated with dilators.
8. The drainage catheter should be flushed, and the Straightener that comes with the kit should be used.
9. 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 be fixed with the fixation wings and tied to the skin with suture and attached to an external drainage bag.

- 9.1 **N.B.** For One Step nephrostomy application the most dilated portion of the kidney is assed 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.
10. 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 further information on luer connections, please refer to latest version of BS EN ISO 80369-7**

Product Variants:

For variants of **AMECATH Percutaneous Nephrostomy Catheter**, Kindly refer to the catalogue, visit our website on:

"www.amecathgroup.com", or contact your nearest **AMECATH** representative."

Code Key

NEP:	Nephrostomy Catheter
XX:	Size in Fr
LL:	Catheter Length 25cm Or 30 Cm and 35cm
T:	Type of Catheter Tip. (M) For Malecot, (J) J type (Pigtail)
K:	For Complete kit.
H:	For Hydrophilic coated catheter
OS:	For One Step Catheter.
x/ XX	Re Entry Tube Size In Fr/Catheter Size In Fr. for Re-entry Nephrostomy Catheter
Q	Lunderquist Guide Wire
L	For string Lock

Add (SB) at the code end in case of Stopcock + Urine Bag.

For Nephrostomy Catheters

Type	Reference	Contents
Nephrostomy Catheter	NEP-XX-LL-J Nephrostomy Catheter J type	<ul style="list-style-type: none"> •Nephrostomy Catheter •Connection Tube •Fixation Wings
	NEP-XX-LL-M Nephrostomy Catheter Malecot type	
	NEP-XX-LL-T-L Nephrostomy Catheter with String Lock (J-Type or Malecot Type)	
RE-ENTRY NEPHROSTOMY MALECOT CATHETER	NEP- x/ XX -LL-M	<ul style="list-style-type: none"> •Re-entry Nephrostomy Catheter Malecot Type •Connection Tube •Fixation Wings
	NEP- x/ XX -LL-M-SB	<ul style="list-style-type: none"> •Re-entry Nephrostomy Catheter Malecot Type •Connection Tube •Fixation Wings •3-Way Stopcock •Urine Bag
One Step Nephrostomy Catheter with String Lock	NEP-XX-LL-T-OS-L	<ul style="list-style-type: none"> •One Step Nephrostomy Catheter with String Lock J-Type or Malecot Type •Connection Tube •Fixation Wings
	NEP-XX-LL-T-OS-L-SB	<ul style="list-style-type: none"> •One Step Nephrostomy Catheter with String Lock J-Type or Malecot Type •Connection Tube •Fixation Wings •3-Way Stopcock •Urine Bag

One Step Nephrostomy Catheter	NEP-XX-LL-T-OS	<ul style="list-style-type: none"> •One Step Nephrostomy Catheter J-Type or Malecot Type •Connection Tube •Fixation Wings •Scalpel
	NEP-XX-LL-T-OS-SB	<ul style="list-style-type: none"> •One Step Nephrostomy Catheter J-Type or Malecot Type •Connection Tube •Fixation Wings •Scalpel •3-Way Stopcock •Urine Bag
Add "H" for Hydrophilic Coating		

For Nephrostomy Catheter Kits

Type	Reference	Contents
Nephrostomy Catheter Kit	NEP-XX-LL-J-K Nephrostomy Catheter J type	<ul style="list-style-type: none">•Nephrostomy Catheter•Connection Tube•Puncture Trocar, Cannula•Chiba Needle•Fascial Dilators•Scalpel•J-End Guide Wire•Fixation Wings
	NEP-XX-LL-M-K Nephrostomy Catheter Malecot type	
	NEP-XX-LL-T-K-L Nephrostomy Catheter with String Lock (J-Type or Malecot Type)	
Nephrostomy Catheter Kit with urine bag and 3-way stopcock	NEP-XX-LL-J-K-SB Nephrostomy Catheter J type	<ul style="list-style-type: none">•Nephrostomy Catheter•Connection Tube•Puncture Trocar, Cannula•Chiba Needle•Fascial Dilators•Scalpel•J-End Guide Wire•Fixation Wings•3-Way Stopcock•Urine Bag
	NEP-XX-LL-M-K-SB Nephrostomy Catheter Malecot type	
	NEP-XX-LL-T-K-L-SB Nephrostomy Catheter with String Lock (J-Type or Malecot Type)	
Nephrostomy Catheter Kit with Lunderquist Guide Wire	NEP-XX-LL-J-K-Q Nephrostomy Catheter J type	<ul style="list-style-type: none">•Nephrostomy Catheter•Connection Tube•Puncture Trocar, Cannula•Chiba Needle•Fascial Dilators•Scalpel•Lunderquist Guide Wire•Fixation Wings
	NEP-XX-LL-M-K-Q Nephrostomy Catheter Malecot type	
	NEP-XX-LL-T-K-L-Q Nephrostomy Catheter with String Lock (J-Type or Malecot Type)	
Nephrostomy Catheter Kit with Lunderquist Guide Wire, urine bag and 3-way stopcock	NEP-XX-LL-J-K-Q-SB Nephrostomy Catheter J type	<ul style="list-style-type: none">•Nephrostomy Catheter•Connection Tube•Puncture Trocar, Cannula•Chiba Needle•Fascial Dilators•Scalpel•Lunderquist Guide Wire•Fixation Wings•3-Way Stopcock•Urine Bag
	NEP-XX-LL-M-K-Q-SB Nephrostomy Catheter Malecot type	
	NEP-XX-LL-T-K-L-Q-SB Nephrostomy Catheter with String Lock (J-Type or Malecot Type)	
Add” H” for Hydrophilic Coating		

Storage and Product Safe Disposal

- Store between 5°C to 30°C.
- Do not expose to organic solvents, ionizing radiation or ultraviolet light.
- Rotate inventory so that catheters are used prior to expiration date on the package label.
- Used product should be disposed in sanitary container to prevent possible contamination and cross infection.

❖ **N.B. please provide patients by the instructions of home care attached to this document.**

❖ *In case of any questions or queries, Kindly contact the local Authorised Representative or visit AMECATH website on : "www.amecathgroup.com".*

❖ **In case of any Adverse event, Contact your local Health Authority immediately.**

❖ ***Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established***

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