

Instruction for Use

Nephrostomy Drainage Catheter

Device Description

A nephrostomy is a thin, plastic tube (catheter) that is inserted through the skin on back and into kidney. This is carried out using a local anaesthetic. The tube is used to drain urine from one or both kidneys into a collecting bag outside the body. It is usually recommended if there is a blockage that is preventing urine draining from the kidney into the bladder. The configurations available include:

Family	Size(Fr)	Length (Cm)
Nephrostomy Drainage Catheter (NDC)	8	30
	10	35
	12	40
	14	
	16	
	18	
	20	
	22	
	24	
	26	
	28	

Intended Purpose

Used for Nephrostomy drainage to drain urine from kidney

Intended User

This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the physician is practicing.

Medical Conditions to be Treated

- Hydronephrosis – due to obstruction of the ureter or renal pelvis.
- Ureteric obstruction – from stones, tumors, or strictures preventing normal urine flow.
- Obstructive uropathy – causing renal dysfunction or infection risk.
- Urinary fistulas or leaks – to provide external urinary diversion.
- Post-surgical urinary drainage – after urological or renal surgeries.
- Severe urinary tract infections with obstruction (pyonephrosis) – to allow urgent decompression of the kidney.

Performance Characteristics of the Device

The nephrostomy drainage catheter is designed for efficient urinary drainage from the renal pelvis, ensuring minimal resistance and reduced risk of clogging.

Indications

- Relief of Urinary Obstruction
- Diagnostic Testing
- Access for Therapeutic Interventions
- Urinary Diversion

Contraindications

Placing a nephrostomy tube is generally a safe procedure. The most common complication that you're likely to encounter is infection. You should contact your doctor immediately if you experience the following symptoms, as they may indicate an infection:

- a fever over 101°F (38.3°C)
- pain in your side or lower back
- swelling, redness, or tenderness at the site of your dressing
- chills
- urine that is very dark or cloudy, or smells bad
- urine that is pink or red

Contact doctor if any of the following occur, as it may be a sign of a blockage:

- Urine drainage is poor or no urine has collected for over two hours.

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- Urine leaks from the dressing site or from your tubing.
- You can't flush your tubing.
- Your nephrostomy tube falls out.

Precautions, Warnings & Complications

Carefully read all instructions for use and product labelling. The device shall only be applied for its intended use and in accordance with these instructions. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

Precautions

- Use only by trained healthcare professionals experienced in percutaneous nephrostomy procedures.
- Ensure correct catheter size and placement under imaging guidance (e.g., ultrasound/fluoroscopy).
- Employ strict aseptic technique to prevent infection.
- Secure catheter properly to prevent accidental dislodgement or kinking.
- Regularly monitor catheter patency, drainage, and insertion site for signs of infection or leakage.
- Device is **sterile and single-use only**; do not reuse or resterilize.

Warnings

- Do not use if sterile packaging is opened or damaged.
- Incorrect placement may cause **renal injury, hemorrhage, or peritoneal leakage**.
- Forceful insertion may lead to trauma of the renal pelvis or ureter.
- Prolonged indwelling use increases risk of infection, encrustation, or blockage.
- Contraindicated in patients with **uncorrected coagulopathy or uncontrolled infection**.
- Improper handling or dislodgement may result in **urinary leakage, sepsis, or loss of renal function**.

Intended Patient Population

- Nephrostomy Drainage Catheter is used in adult patients. The device can be used in both male and female patients.

Shelf-life of the Product

The shelf life of the Nephrostomy Drainage Catheter is 3 years (Indicated on product label with the use-by symbol and date). Store the Nephrostomy Drainage Catheter at dry, cool place. Avoid extended exposure to light.

Sterility – This product is Sterile unless the package has been opened or damaged

- The Nephrostomy Drainage Catheter have been sterilized by Exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change colour from blue to brown after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct colour.
- If the sterile package is damaged or possibly opened, do not use. Contact "Distributor" and replace the product.
- The Nephrostomy Drainage Catheter are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

Directions for Use

- Advance the Guide Wire directly from the enclosed holder.
- Introduce the flexible tip of the Guide Wire in to the urethral meatus and gently manipulate it beyond the obstruction and into the bladder. (The safety index mark, 39cm from the Guide Wire's flexible tip will be externally visible under normal circumstances)
- Note:- The Guide Wire can also be placed through a cystoscope and maintained in position as the scope is removed.
- Once the Guide Wire is placed, the Catheter is inserted through the Guide Wire with the help of imaging technology such as ultrasound, CT scan, or fluoroscopy to help them place the tube correctly.
- When the tube has been inserted, they'll attach a small disk to your skin to help hold the tube in place.
- Inspect the catheter tube on a daily basis as well as empty any urine that has collected in the drainage bag.

Flush the catheter tube at least once a day with the following procedure

- Wash your hands thoroughly. Put on gloves.
- Turn off the stopcock to the drainage bag. This is a plastic valve that controls fluid flow through your nephrostomy tube. It has three openings. One opening is attached to the tubes attached to the dressing. Another is attached to the drainage bag, and the third is attached to an irrigation port.
- Remove the cap from the irrigation port and swab thoroughly with alcohol.
- Using a syringe, push saline solution into the irrigation port. Do not pull the syringe plunger back or inject more than 5

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milliliters of saline solution.

- Turn the stopcock back to the drainage position.
- Remove the syringe from the irrigation port and recover the port with a clean cap.




















Removal Instructions

Nephrostomy tube is temporary and will eventually need to be removed. Retrieve cystoscopically by gently pulling on Catheter or retrieval line with grasping forceps or equivalent. If resistance is encountered during removal of the Metal Straightener, stop and determine cause of resistance before proceeding.

Disposal Instructions

Dispose of all equipment in appropriate containers. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations

Explanation of symbols used on label

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
	Catalogue Number		Unique Device Identifier		Do not re sterilize		Country of Manufacture		Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use		Humidity Limit
	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		

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Bibliography

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- EN ISO 20417:2020 – Medical Devices – Information to be supplied by the manufacturer.
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