

## **PCN Set Pigtail Catheter with locking mechanism/ Nephrostomy Drainage Catheter with Locking Mechanism/Percutaneous Nephrostomy Set Pigtail Catheter**

### **Device Description**

It is a percutaneous drainage catheter used for the drainage of fluid collections. The catheter is made from a soft, biocompatible plastic. The distal end of catheter contains a pigtail and drainage holes. A suture is used to lock the distal pigtail in place which helps secure the catheter in place and decrease the risk of displacement. The configurations available include:

Family	Accessories	Size(Fr)	Length (Cm)
PCN Set pigtail catheter with locking mechanism/ Nephrostomy drainage catheter with locking mechanism/Percutaneous Nephrostomy Set Pigtail Catheter	Guide wire,	6.0	
	Fascial Dilator, IPN.	7.0	22
	Urine Bag Connector (UBC),	8.0	30
	Metal Straightener,	8.5	
	Stop Cock	9.0	
	Connector, Skin	10.0	
	Stitching Clamp,	12.0	
	Suture, Scalpel	14.0	
	Blade/ Surgical	16.0	
	Blade, Locking	18.0	
	Mechanism, Pigtail	20.0	
	Straightener	22.0	
		24.0	

### **Intended Purpose**

The PCN Locking Drainage Catheter with locking pigtail is intended for percutaneous drainage of abscess fluid from body cavities.

### **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**

- Temporary or permanent relief of obstruction caused by calculi (kidney stones), strictures, or tumors.
- Drainage of urine to relieve kidney swelling caused by obstruction or infection.
- Drainage of pus from the renal collecting system to manage infection and prevent sepsis.
- Temporary drainage for patients undergoing urological surgery or awaiting definitive treatment.

### **Performance Characteristics of the Device**

The Device is manufactured in such a way that the distal end of the device consists of a pigtail tip and locking mechanism towards the proximal end. The pigtail tip aids in the retention of distal end in renal pelvis and the locking mechanism prevents the accidental slippage of the catheter. The eye holes are provided for better drainage.

### **Condition of Use**

- Used in patients diagnosed with large kidney Stones, blocking more than one branch of the collecting system of the kidney (known as staghorn kidney stones) and presence of larger stones in ureter.
- Urine Drainage is poor or no urine collected for two years.
- Urine leaks from the dressing site or from your tubing.
- You can't flush your tubing.
- Nephrostomy tube falls out.

### **Indications**

- Urinary decompression for urinary obstruction
- Calculi
- Urinary tract strictures
- Urothelial neoplasia
- Extrinsic compression

### **Contraindications**

- Bleeding Diathesis, most commonly uncontrollable coagulopathy.
- Severe hyperkalemia
- Severe metabolic acidosis
- Uncooperative patient.

### **Precautions & Warnings**

Carefully read all instructions for use and product labelling. Do not use this product without reading and understanding the complete instructions enclosed herein. 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:**

- The Intended User of the device must be a Urologist specializing in the treatment of urinary system disorders and related urological procedures authorized by the Competent Authority of the Country in which the physician is practicing.
- Each Physician is responsible for using the appropriate technique and deciding on the indication for use of this device.
- Confirm the information on the label and that the product has not reached its expiration date and there is no damage to the packaging or device.
- Device is not recommended for use in patients with the above-mentioned contraindicated conditions.
- Store the PCN Set Pigtail Catheter with Locking Mechanism at a temperature between 12-35°C and a Humidity range of 30-70%.
- Store in a dry, cool place. Avoid extended exposure to sun light.

#### **Warnings:**

- All the components of the device are for single use only.

### **PCN Set Pigtail Catheter with locking mechanism/ Nephrostomy Drainage Catheter with Locking Mechanism/Percutaneous Nephrostomy Set Pigtail Catheter with Locking Mechanism**

- The product must not be re-used. Reusing single-use device can lead to potentially serious consequences for the patient such as bio-contamination due to release of the infectious agents from the device into the body which further may result in Urinary Infection.
- Do not use the device if there is any indication that the sterility of the device has been compromised. If the sterile package is damaged or possibly opened, do not use. Contact "Manufacturer or Distributor" and replace the product.
- Do not reprocess or re-sterilize, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to failure which, in turn, may result in patient injury.

#### **Intended Patient Population**

- The device is intended for use in adult patients having the above-mentioned conditions.

#### **Shelf-life and Storage condition of the Product**

- The shelf life of the PCN Set pigtail catheter with locking mechanism/ Nephrostomy drainage catheter with locking mechanism is 3 years (Indicated on product label with the following use-by date symbol).

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

- The PCN Set pigtail catheter with locking mechanism/ Nephrostomy drainage catheter with locking mechanism 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.
- Exposure to high levels of Ethylene Oxide may result in presence of residual ETO which leads to toxic reaction in the body resulting in tissue damage of Urinary System.
- The PCN Set pigtail catheter with locking mechanism/ Nephrostomy drainage catheter with locking mechanism are packed single. Product in each pack must be utilized immediately when opened.

#### **Directions for Use**

- Open the Package from the Chevron Side ('V' Notch) of the pouch.
- By preliminary plain film, I.V.P., retrograde pyelogram, ultrasound, or CAT scan, localize the kidney to be drained. A prone or slightly oblique position is preferred. Under fluoroscopic control, identify and anesthetize the skin site overlying the collecting system.
- Pass the 18-gauge needle vertically through a small incision in the skin (made with a scalpel blade) insert the needle into the appropriate part of the pyelocaliceal system. Free flow of fluid from the needle after removing the obturator confirms a satisfactory location for the tip of the needle cannula.
- Pass the flexible end of the guide wire through the hub of the 18-gauge needle cannula; insert the guide wire three (3) more inches into the collecting system. Confirm the position fluoroscopically. Maintain the position of the guide wire as the needle cannula is withdrawn over it.
- Care must be exercised to avoid withdrawal of the guide wire itself.
- To facilitate passage of the nephrostomy catheter, dilate the musculofascial tract by progressing from the smallest to the largest dilator provided.
- Pass the pigtail end of the catheter over the external end of the guide wire, gradually advance the pigtail end well into the collecting system. Confirm the position fluoroscopically. While the shaft of the pigtail catheter is held securely in position with one hand, the guide wire is withdrawn with the other and lock the distal loop in place.
- Use the urine bag connector to connect the pigtail catheter to a drainage bag or leg bag.



















#### **Removal Instructions**

PCN Set pigtail catheter with locking mechanism/ Nephrostomy drainage catheter with locking mechanism 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		
	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		



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- Contraindications: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3312169/>
- Single Use Medical Device:  
[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/956268/Single\\_use\\_medical\\_devices.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956268/Single_use_medical_devices.pdf)
- EN ISO 15223-1:2021 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
- EN ISO 20417:2020 – Medical Devices – Information to be supplied by the manufacturer.