

Instruction for Use
PCN Catheter Set
Device Description

The PCN Catheter Sets are used in Urology procedures for the percutaneous placement of a pigtail catheter in the renal pelvis for nephrostomy drainage. PCN Catheter sets consist of 18-gauge Initial Puncture Needle, 0.038" diameter PTFE coated stainless steel guide wire 150cm long with tip, Radiopaque dilators, Radiopaque pigtail catheter, Scalpel blade and Urine bag connector. Sterile and intended for single use. Duration of contact with the body is not more than 30 days. The configurations available include:

Family	Accessories	Size (Fr.)	Length (cm)	Guide Wire J Tip	IP Needle	Fascial Dilators	Scalpel	UBC	Catalogue Number
PCN Catheter Sets (PCNS)	Fascial Dilator,	8.0	30	0.966"	18G	6	1	1	AMPLCT006
	I.P.Needle,	10.0	36			8			
	Guide Wire,	12.0				10			
	Pigtail	14.0				12			
	Straightener,					14			
	Locking Pigtail,					16			
	Scalpel,								
	Urine Bag Connector								

Intended Purpose

PCN Catheter Sets are used for Percutaneous placement of a pigtail catheter in the renal pelvis for nephrostomy drainage.

Performance Characteristics of the Device

The device is used for temporary or permanent drainage and irrigation of urine from the kidney by direct puncture.

Percutaneous Nephrostomy (PCN) tube is a catheter that is inserted through your skin into the kidney.

The nephrostomy tube placed is sterile and radiopaque for better visualization. The pigtail tip configuration aids in the retention of the distal tip in the renal pelvis to drain urine from the body into a collecting bag outside the body.

Indications

- 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.
- Uretero-Pelvic Junction Obstruction
- Decompression of the renal collecting system
- Irrigation of Urine from kidney

Contraindications

- Bleeding diathesis, most commonly uncontrollable coagulopathy.
- Severe metabolic acidosis
- Severe hyperkalemia
- 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 Catheter Set/ Drainage Puncture Set with Pigtail Catheter/ Suprapubic Drainage Catheter Set at a temperature between 12-350C and a Humidity range of 30-75%.
- Store in a dry, cool place. Avoid extended exposure to sunlight.

Warnings:

- All components of the "PCN Catheter Set/ Drainage Puncture Set with Pigtail Catheter/ Suprapubic Drainage Catheter Set" are for single use only.
- The product must not be re-used. Reusing single-use devices can lead to potentially serious consequences for the patient such as bio-contamination due to release of infectious agents from device into the body which further may result in Infection.
- 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 patients of all age groups.

Shelf-life

The shelf life of the PCN Catheter Set 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 Catheter Sets have been sterilized by exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change color from blue to brown after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct color.
- 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.

Instruction for Use

PCN Catheter Set

- The "PCN Catheter Sets/ Drainage Puncture Set with Pigtail Catheter/ Suprapubic Drainage Catheter Set" 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 CT scan, localize the kidney to be drained. A prone or slightly oblique position is preferred. Prepare and drape the flank in the usual fashion. Under fluoroscopic control, identify and anesthetize the skin site overlying the collection 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 J 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.
- Use the urine bag connector to connect the pigtail catheter to a drainage bag or leg bag.


















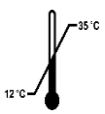


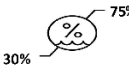
Removal Instructions

- Retrieve cystoscopically by gently pulling on Catheter or retrieval line with grasping forceps or equivalent.
- If resistance is encountered during removal of the Catheter, 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		CE Mark		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		Unique Device Identifier
	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		Authorized Representative in the European community
	Humidity Limit								

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Bibliography

- 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
- 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.