ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use

PCN Catheter with Needle

CE 2803

Device Description

The PCN Catheters with Needle are provided for use in Urology procedures to provide temporary urinary diversion associated with urinary obstruction secondary to calculi. The PCN Catheter consists of a Radiopaque pigtail catheter, matching hollow needle obturator, Urine Bag connector and catheter straightener. The configurations available include:

Family	Accessories	Size (Fr.)	Length (cm)	Catalogue Number	Color
PCN Catheter with Needle (PCNN)	Needle, Needle Obturator, Straightener, Urine Bag Connector	8.5 9.0 10.0 12.0 14.0 16.0 18.0	22	AMPLCT005	Blue

Intended Purpose

PCN Catheters with Needle are used for percutaneous placement of a pigtail catheter in the renal pelvis for nephrostomy drainage.

Performance Characteristics of the Device

PCN Catheter with Needle is used for temporary or permanent drainage and irrigation of urine from the kidney by direct puncture, in the presence of distal obstruction. The Catheter used 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 beg outside the body.

Indications

- Used in patients diagnosed with blockage in ureter which leads to blockage of urine flow from kidney to bladder and eventually results in kidney failure.
- Permanent or temporary Nephrostomy Drainage by direct puncture.
- Irrigation of Urine from kidney.

Contraindications

- Bleeding Diathesis (most commonly, uncontrollable coagulopathy or pharmacological anticoagulation)
- Severe hyperkalemia
- Severe metabolic acidosis
- Uncooperative patient.

Precautions & Warnings

Carefully read all instructions for use and product labeling. 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 with Needle/ Nephrostomy Catheter with Needle at a temperature between 12°-35°C and a Humidity range of 30%-75%.
- Store in a dry, cool place. Avoid extended exposure to sun light.

Warnings:

- All components of the PCN Catheter with Needle/ Nephrostomy Catheter with Needle 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 use the device if there is any indication that the sterility of the device has been compromised. If the sterile package is damaged or 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 patients of all age groups.

Shelf-life

The shelf life of the PCN Catheter with Needle/ Nephrostomy Catheter with Needle is 3 years (Indicated on product label with the following use-by symbol).

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

- The PCN Catheters with Needle 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.

- The PCN Catheters with Needle/ Nephrostomy Catheter with Needle are packed single. Product in each pack must be utilized immediately when opened.

Directions for Use

Open the package from the Chevron Side ('V' Side) of the pouch.

- Straighten the PCN catheter with the help of catheter straightener and guide the needle obturator into the catheter tip. Secure its position with the luer lock to close the malecot wings.
- 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 flexible end of the J guide wire through the hub of the PCN catheter with needle, the guide wire three (3) more inches into the collecting system. Confirm the position fluoroscopically. Maintain the position of the guide wire
- To facilitate passage of the PCN catheter with needle, dilate the musculofascial tract by progressing from the smallest to the largest dilator provided.
- Pass the pigtail end of the catheter with needle 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, first remove the needle obturator, then remove the guide wire 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
REF	Catalogue Number	CE 2803	CE Mark	2 STERILIZE	Do not Re sterilize	CC	Country of Manufacture	MD	Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
LOT	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use	UDI	Unique Device Identifier
STERILE EO	Sterilized using ethylene oxide		Consult Instructions for Use	35°C 12°C	Temperature Limit		Do Not Use if Package is Damaged	EC REP	Authorized Representative in the European community
75% 30%	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.