

Instruction for Use

Drainage Puncture Set with Pig tail Catheter

Device Description

The Drainage puncture set consist of a 2-way shaft and proximal tube, a blocking valve, and distally the blocking balloon, for a safe retention in the urinary bladder, puncture sets for the first placement of a catheter, exchange sets also contain a PFTE-coated guide wire which is used for drainage of urine in the bladder, which are equipped with a balloon for blocking the catheter. The configurations available include:

Family	Accessories	Size(Fr)	Length (Cm)	Catalogue Number
Drainage puncture set with Suprapubic balloon catheter/ Pigtail Catheter	Pigtail Straightener, Guide Wire, Metal Trocar/ Plastic Trocar, Scalpel Blade/ Surgical Blade, UBC, Stop	10	40	AMPLCT022
	Cock Connector, Skin	12	42	
	Stitching Clamp, Urine Bag	14		
		16		
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Intended Purpose

The Drainage puncture set is used in drainage of the bladder after surgery, in case of bladder dysfunction, urinary retention, acute prostatitis, abnormal urethral anatomy, in pelvic trauma, for diagnostic purposes or monitoring of diuresis.

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

- Drainage of pleural effusion, ascites, or localized fluid collections in thoracic or abdominal cavities.
- Relief of obstructed fluid accumulation caused by infection, trauma, or post-surgical complications.
- Management of abscesses or cystic lesions by providing continuous drainage.
- Temporary drainage support in patients requiring minimally invasive intervention for fluid evacuation.

Performance Characteristic of the Device

Drainage Puncture Set with Suprapubic Balloon Catheter-Drainage Puncture Set with Suprapubic balloon Catheter has a drainage lumen and inflation channel. It has an integrated balloon towards the tip of the Catheter which is symmetrical in shape, and when inflated, helps to maintain retention of the catheter in the bladder.

Drainage Puncture Set with Pig tail Catheter- 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 suffering from Bladder Dysfunction, Acute Prostatitis, Abnormal Urethral Anatomy and Diuresis.
- Urinary Retention (Can't Urinate on your own)
- Urinary Incontinence (Leakage)
- Decreased Urinary Stream

Contraindications

- Carcinoma of the bladder
- Uncorrected coagulopathy
- Inappropriate bladder filling (at least 300 ml), skin infection at the designated puncture site)
- Previous lower abdominal surgery
- Prosthetic devices in lower abdomen (e.g. Hernia mesh, vascular bypass).

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 Drainage Puncture Set with Suprapubic balloon Catheter/ with Pigtail Catheter 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:

- The device is intended 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 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

The shelf life of the Drainage Puncture Set with Suprapubic Balloon Catheter/Pigtail Catheter is 3 years (Indicated on product label with the following use-by symbol).

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

- The Drainage Puncture Set 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 Drainage Puncture 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.
- Prepare the set components on a sterile area.
- In accordance with current guidelines and recommendations, the bladder must be filled properly (at least 300 ml) and should be palpable before puncture.
- If in doubt or in obese patients use ultrasound for bladder tracking and to ensure that the planned puncture track is free from interposing bowel loops.
- Anesthetize the skin at the puncture site when the procedure is not done under general or regional anaesthetic.
- Make a small incision on the median line of the body, 2-3 cm above the symphysis pubis with the enclosed scalpel.
- Puncture vertically the abdominal wall at this position at an angle of 15° to 20° with the prepared needle and syringe while injecting anaesthetic during the passage of the different layers.
- Once the needle has passed the bladder wall urine can be freely drawn through the needle.
- Disconnect the syringe from the needle while maintaining the needle in place.
- Introduce the soft tip of the guide wire via the needle into to the bladder.
- Gently withdraw the needle while keeping the guide wire in place.

Exchange of catheter with dilation

- Place the dilator and sheath over the guide wire and push them with gentle pressure down into the bladder without moving the guide wire.
- While maintaining the outer sheath in place, withdraw the dilator and guide wire.
- Insert the catheter inside the sheath and push half of its length into the body (the 16 cm mark must be hidden in the track).

Inflate the balloon

- Inflate the balloon with the 5ml of adequate fluid prepared in the syringe.
- Withdraw the sheath along the catheter track, split it and discard the halves. Apply an appropriate dressing to the skin around the catheter.
- Deflate the balloon (if appropriate) and withdraw the catheter.
- Proceed as described above, but after removal of the old catheter dilate the puncture track with a dilator and sheath of appropriate diameter.
- Remove the dilator and the guide wire from the sheath, insert the catheter into the sheath and push half of its length into the body (the 16 cm mark must be hidden in the track).
- Withdraw the sheath along the catheter track, split it and discard the halves. Apply an appropriate dressing to the skin around the catheter.













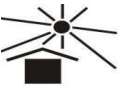

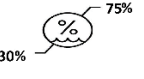


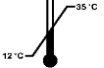

Removal Instructions

- Deflate the balloon completely.
- When the balloon is completely deflated, remove the catheter by withdrawing slowly.
- If resistance is encountered during removal of the device, stop and determine the 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

- Contraindications:
<https://www.ncbi.nlm.nih.gov/books/NBK482179/#:~:text=Relative%20contraindications%20for%20suprapubic%20cystotomy,hardware%20of%20the%20pubic%20symphysis.>
- 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.