

Instruction for Use Suprapubic Catheter

Device Description

The Suprapubic Catheters are provided for use in Urology procedures to provide drainage following open renal or bladder surgeries. It is a sterile, self-retaining, radiopaque catheter with a flower at the tip intended for single use. Duration of Contact with the body is not more than 30days. The device consists of Malecot Catheter, matching hollow needle obturator and Urine bag connector. The configurations available include:

Family	Accessories	Size (Fr.)	Length (cm)	Catalogue Number	Color
Suprapubic Catheter (SPC)	Needle, Needle Obturator, Urine Bag Connector	10.0 12.0 14.0 16.0 18.0	25	AMPLCT008	Blue

Intended Purpose

Suprapubic Catheters are used to provide bladder drainage by percutaneous placement of a Malecot catheter.

Performance Characteristics of the Device

It is used to provide drainage following an open renal or bladder surgery. The flowers are employed to provide enhanced drainage and promote catheter retention and prevents its accidental removal. Suprapubic Catheter provides maximum softness for enhanced patient comfort and provides a useful alternative to latex catheters.

Indications

- Used for drainage of urine from bladder in patients diagnosed with kidney stone, urinary incontinence, urinary retention, pelvic organ prolapses or other health conditions.
- Urinary Retention (Can't Urinate on your own)
- Urinary Incontinence (Leakage)

Contraindications

- Bleeding Diathesis (most commonly uncontrollable coagulopathy or pharmacological anticoagulation)
- Active skin Infection
- Coagulopathy
- Osteomyelitis of the pubis
- 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 Suprapubic Catheter 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 Suprapubic Catheters 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 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 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 Suprapubic Catheter 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

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- The Suprapubic Catheters 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 Suprapubic Catheters 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. Suggested instructions for using Suprapubic Catheters:

- The Percutaneous Seldinger technique is a common method used. Distention of the urinary bladder is imperative for this approach; it can be done physiologically (urinary retention) or with the aid of a cystoscope.
- Straighten the Suprapubic catheter and guide the needle obturator into the catheter tip. Secure its position with the luer lock to close the Suprapubic wings.
- In an area, roughly 2 fingerbreadth or 1-2 inches above the symphysis pubis, a large bore needle is inserted until urine returns.
- Sterile saline can be added to the bladder at this point if necessary. X-ray guidance is also optional as contrast can be added to better visualize the urinary bladder.
- Insert the catheter vertically at a 30-degree angle toward the symphysis pubis. Gradually advance the catheter 4-5cm beyond the first sign of bladder fluid. The catheter midpoint is an approximation.
- If bladder pressure is low and urine fails to flow spontaneously through the hollow obturator, withdraw urine to ascertain that the catheter is within the bladder.
- After releasing the luer lock in order to open the Suprapubic wings, carefully remove the hollow needle obturator. The catheter must be stabilized and the needle rotated while pulling or removing. Care must be exercised to avoid jerking the catheter forward.
- Use the urine bag connector to connect the Suprapubic catheter to a drainage bag.
- Allow the bladder to empty.
- Withdraw the Suprapubic catheter until the Suprapubic wings meet the resistance of the bladder dome. Advance the catheter approximately 2cm back into the bladder to allow for movement.













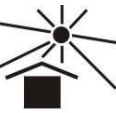




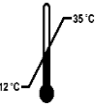



Removal Instructions

- 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								

**Instruction for Use
Suprapubic Catheter**



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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 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.