

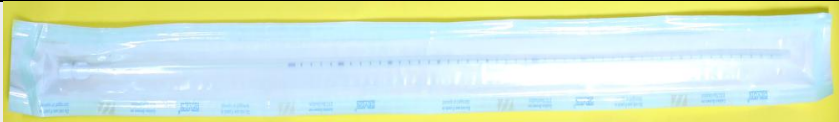




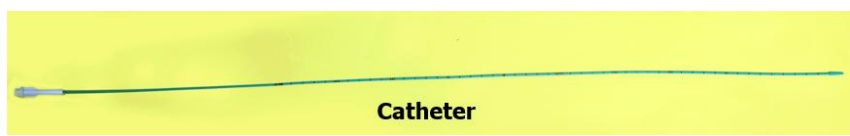







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BANGALORE**



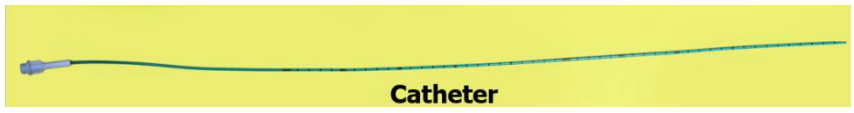
Ureteral Catheter (Open End, Round Tip Closed End, Angled Tip, Cone Tip, Whistle Tip, Pigtail Tip, Multiple hole) - With/without Hydrophilic coated

VARIANTS:

Product Name	Variant	Packing	Image
Ureteral Catheter- With/without Hydrophilic coated	Open End	With Packing	
		Without Packing	 Catheter
Ureteral Catheter- With/without Hydrophilic coated	Round Tip Close End	With Packing	
		Without Packing	 Catheter
Ureteral Catheter- With/without Hydrophilic coated	Angled Tip	With Packing	
		Without Packing	 Catheter
Ureteral Catheter- With/without Hydrophilic coated	Cone Tip	With Packing	
		Without Packing	 Catheter
Ureteral Catheter- With/without Hydrophilic coated	Whistle Tip	With Packing	
		Without Packing	 Catheter
Ureteral Catheter-	Pigtail Tip	With Packing	



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Product Name	Variant	Packing	Image
With/without Hydrophilic coated		Without Packing	 Catheter
Ureteral Catheter- With/without Hydrophilic coated	Multiple hole	With Packing	
		Without Packing	 Catheter

INTENDED PURPOSE:

Used for drainage. The open-end tip allows placement over a guide of a looped or stenotic ureter. In case of Hydrophilic coated, it is to improve the ease of insertion.

MEDICAL INDICATIONS:

Ureteral obstruction

TARGET PATIENT POPULATION:

Pediatric and Adult

INTENDED USERS:

Urologist

CLINICAL BENEFITS:

- Low Wound infection rate
- Less Postoperative morbidities
- Reduced ureteral injury
- Decreased duration of hospitalization
- More secure access
- Reduces Bleeding
- Reduce postoperative discomfort
- Better Quality of Life

SPECIFICATION:

a) Open End

Parameters	Specification
Size (F)	3F, 4F, 5F, 6F, 7F, 8F
Length (CM)	45-70 cm
Accepts Guide-Wire (inch)	0.018, 0.025, 0.035, 0.038

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b) Round Tip Closed End

Parameters	Specification
Size (F)	3F, 4F, 5F, 6F, 7F, 8F
Length (CM)	45-70 cm

c) Angled Tip

Parameters	Specification
Size (F)	4F, 5F, 6F
Length (CM)	45-70 cm
Guide- wire (Inch)	0.025, 0.035, 0.038

d) Cone Tip

Parameters	Specification
Size (F)	3F, 4F, 5F, 6F, 7F
Length (CM)	45-70 cm
Tip French Size	5F, 7F, 8F, 9F, 10F

e) Whistle Tip

Parameters	Specification
Size (F)	3F, 4F, 5F, 6F, 7F, 8F
Length (CM)	45-70 cm

f) Pigtail Tip

Parameters	Specification
Catheter Size (F)	3F, 4F, 5F, 6F, 7F, 8F
Length (CM)	45-70 cm
Guidewire (inch)	0.018, 0.025, 0.035, 0.038

g) Multiple hole

Parameters	Specification
Size (F)	3F, 4F, 5F, 6F, 7F, 8F
Length (CM)	45-70 cm
Tip French Size	0.018, 0.025, 0.035, 0.038

SHELF LIFE:

The Ureteral Catheter has a shelf life of 5 years.

RESIDUAL RISKS:

- Urinary tract infection
- Ureteral damage
- Ureteral Perforation

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- Minor Infection
- Allergic Reaction
- Bleeding

CONTRAINDICATIONS:

- Active Urinary Tract Infection (UTI).
- Known or Suspected Urethral Trauma
- Stricture or Obstruction

PRECAUTIONS:

- Carefully read all instructions for use and product labeling. 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.
- All Health care professionals is responsible for using the appropriate technique and deciding on the indication for use of this device based on own experience, training and medical judgment. The doctor must be trained in the proper use of the device.
- Do not use the catheter if the packaging is damaged or if the catheter appears bent, broken, or contaminated.

CAUTIONS:

- The sale of this device is restricted by or on the order of a Urologist.

WARNING:

- The ureteral catheters are intended for single use only.
- Do not use device if there is any indication that the sterility of the device has been compromised.
- If the catheter becomes blocked, kinked, leaks, or is accidentally removed, check its position and function using fluoroscopy. Replace or reposition the catheter as needed.
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- If the catheter has a hydrophilic coating, make sure it is properly wetted before insertion to make placement easier. Do not use if the coating looks dry or damaged.
- **Duration of Use**
 - Short term only, not for Continuous use.
- **Adverse effects:**
 - Use of this device should be based upon consideration of risk-benefit factors as they apply to your patient. Informed consent should be obtained to maximize patient compliance. Follow up procedures.
- **Reuse**
 - Reusing single-use catheter can lead to urinary tract infections in patients.

UNDESIRABLE SIDE EFFECTS:

They are bladder spasms, blood in your urine, and infections.

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DIRECTIONS FOR USE:

- Open the package carefully to avoid damaging the catheter. Incorrect removal of the catheter from the package may lead to Urinary tract infection.
- Pass the flexible end of the guidewire into the renal pelvis.
- While holding the guidewire in a set position, pass the ureteral catheter, over the guidewire through the ureter and into the pelvis.
- Verify that the catheter is in the correct position by standard radiographic procedure or fluoroscopy.
- Remove the guidewire and then the cystoscope while maintaining the catheter position.
- The supplied connector can be attached to the catheter for irrigation of a drainage system.

STERILITY:

These catheters are supplied in a package which is sterilized by using Ethylene Oxide. Do not use the catheter if the package is damaged. If used it leads to urinary tract infections.

STORAGE CONDITION:











Keep in cool and dry place. Store the Catheter at temperatures between 5°C to 40°C. Do not expose to direct sun light.

DISPOSITION:

The product shall be disposed as per medical device disposal regulation.

NOTE:



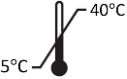





Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established;

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	MANUFACTURER		AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	DATE OF MANUFACTURE		USE-BY DATE
	BATCH CODE		COUNTRY OF MANUFACTURE
	STERILIZED USING ETHYLENE OXIDE		DO NOT RESTERILIZE
	DO NOT USE IF PACKAGE IS DAMAGED		SINGLE STERILE BARRIER SYSTEM WITH PROTECTIVE PACKAGING INSIDE

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SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	KEEP AWAY FROM SUNLIGHT		KEEP DRY
	TEMPERATURE LIMIT		DO NOT RE-USE
	CONSULT INSTRUCTIONS FOR USE		CAUTION
	MEDICAL DEVICE		UNIQUE DEVICE IDENTIFIER



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REVISION HISTORY:

Doc. No.	Revision Number	Revision Date	Description
CRP 7.2 F (9)	00	14.08.2025	INSTRUCTIONS FOR USE(IFU)

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