

URETERIC CATHETER

Device Description:

AMECATH Ureteric Catheter is a single use device. It is a tube that extends from the kidney to outside the body passing through the ureter, bladder and the urethra. It is applied through cystoscope.

AMECATH Ureteric Catheter is made of medical radiopaque polyurethane.

AMECATH Ureteric Catheter may have different diameters ranging from 3 Fr. to 8 Fr. with patent inner diameter and opened versus closed upper end according to customer specifications. Catheter length is standard 70cm graduated every 5cm

As known, drainage of the kidney after a stent application is through and around the stent so form ally the flow inside the stent does not affect much the function of the catheter.

AMECATH Ureteric Catheter material is biocompatible enough for the maximum period of insertion which should not exceed 3 days for application.

AMECATH Ureteric Catheter exists in Different rigidity for easy introduction and dilatation.

Target patient populations: Adults and children (Paediatric)

Intended user: Health Care Professionals

AMECATH Ureteric Catheter and its accessories:

AMECATH Ureteric Catheter is available in different designs and Kit configurations to cover all customer needs .

Device construction:

AMECATH ureteric catheter has different tip shapes::

- Round closed tip for direct application.
- Open tapered tip for application over guide wire.
- Cone and chevasaeu tips for contrast injection.
- Whistle tip for better drainage.
- Olive, angle and curved tips for easy insertion.

List of Accessories:

- Adaptor (Catheter connector).
- Monofilament Stylet.

Intended Use:

Ureteric catheter intended for Retrograde Pyelogram, navigation of tortuous ureter and for urine drainage from the renal pelvis to outside through the urethral.

Common indications include the following:

- **Diagnostic**
 - ☐ To do ascending pyelourethrography.
 - ☐ To take urine sample.
- **Therapeutic**
 - ☐ To drain obstruction.
 - ☐ To inject chemotherapy.

- ❑ After ureteral endoscopic or open surgery.

Contraindications:

- In general, ureteric catheters are contraindicated in patients unsuitable for catheterization.

Warnings and Precautions:

- For single product and patient use only.
- Do not use catheter if any sign of product damage is visible.
- Do not re-use, reprocess or re-sterilize. Reuse may lead to infection. Reprocessing or Re-sterilization may damage the catheter and affect its integrity which when re- used may lead to possible deterioration in health and safety of patients.
- Catheter should not be left inside the body for more than three days to avoid risk of ascending infection.
- It is not recommended to use antimicrobial ointments on catheters as it may cause its degradation.
- Do not use absolute alcohol or acetone-based product on the catheter. 2% chlorhexidine or Iodine based solution is recommended as antiseptic solution.
- The proper size selection for the catheter size and length is the responsibility of the physician considering the patient's anatomy.

Complications:

- Ureteral perforation.
- Hematuria.
- Ascending infection.

How Supplied:

- **AMECATH Ureteric Catheters** is a sterile, single use medical device.
- Each **AMECATH Ureteric Catheters** is packed in a PE soft blister covered with Medical Paper.
- Each carton box includes 10 **AMECATH Ureteric Catheters**.

AMECATH Ureteric Catheter method of application

General

1. Catheterize the patient in the usual manner.
2. Ureteric Catheter to be connected via its end to the extension line or the stopcock.
3. Extension line or stopcock to be connected to the measuring equipment.

CLOSED TIP

- Introduce the catheter through the cystoscope channel till reaches the bladder.
- Introduce the catheter through the ureter opening about 4 cm.
- Remove the inner stylet.
- Advance the catheter till renal pelvis.

OPEN TIP

- Advance the catheter over the suitable guide wire under vision or fluoroscopy.
- Ensure that the catheter is inside the renal fluoroscopy by injecting dye through the lower end.

Product Variants:

For variants of **AMECATH Ureteric Catheter**, Kindly refer to the catalogue, visit our website on : "www.amecathgroup.com" , or contact your nearest **AMECATH** representative.

Code Structure: UC-XX-T-S-C

UC:	Ureteric Catheter.
XX:	Size in Fr.
T:	Tip Configuration: (TO) Tapered Opened Tip (CL) Closed Round Tip (WH) Whistle Tip (CO) Cone Tip (OL) Olive Tip (CH) Chevassu Tip (CU) Curved tip (AO) Angel Tip
S:	Stiffness: yellow (Y) Soft white (W) Semi-Soft Blue (B) Firm
C:	Type of Coating: (O) No Coating (H) Hydrophilic Coating

Reference	Contents
UC-XX-T-S-C	<ul style="list-style-type: none"> • Ureteric Catheter • Adaptor (Catheter Connector) • Monofilament Stylet

Storage and Product Safe Disposal

- Store between 5°C to 30°C.
 - Do not expose to organic solvents, ionizing radiation or ultraviolet light.
 - Rotate inventory so that catheters are used prior to expiration date on the package label.
 - Used product should be disposed in sanitary container to prevent possible contamination and cross infection.
- ☐ In case of any questions or queries, Kindly contact the local Authorised Representative or visit AMECATH website on : “ www.amecathgroup.com ,
- ☐ In case of any Adverse event, Contact your local Health Authority immediately.
- ☐ 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



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