

**10. INSTRUCTIONS FOR USE**

URETERAL BALLOON DILATOR

Device Description:

AMECATH Ureteral balloon dilator is a sterile single use, dual lumen shafts with inflation and guide wire lumens and dilation balloon on the distal end. The dilator balloon had two radiopaque bands which define the balloon working length and facilitate radiographic visualization and placement.

Range of balloon size between 4 to 7 mm and length 40 mm or 60 mm

Target patient populations: Adults and children (Paediatric)

Intended user: Health Care Professionals

AMECATH Ureteral balloon dilator and its accessories:

AMECATH Ureteral balloon dilator is available in different designs and Kit configurations to cover all customer needs

Device construction:
List of Accessories:

The kits contain the following accessories:

- 10cc Syringe
- 3 ways Stopcock

Intended Use:

AMECATH Ureteral balloon dilator is used for Ureteral dilation prior to ureteroscopy and intramural ureter before ureteroscopic manipulation either for stone endoreterival or for diagnostic ureteroscopy to facilitate the passage of the ureteroscope through the ureter.

Contraindications:

- Do not use this device to treat obstruction that is due to extrinsic factors.

Warnings and Precautions

- For single product and patient use only.
- Do not use device 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 device and affect its integrity which when re- used may lead to possible deterioration in health and safety of patients.
- It is not recommended to use antimicrobial ointments on devices as it may cause its degradation.
- Do not use absolute alcohol or acetone-based product on the device. 2% chlorhexidine or Iodine based solution is recommended as antiseptic solution
- Always inflate the balloon with sterile water.
- Balloon Ureteric Dilator is intended for use by highly qualified & well trained Urologist.
- Inspection of the catheter prior to usage to ensure no damage has occurred during shipment.
- Don't preinflate the balloon.
- Pass the balloon catheter over the guide wire under direct vision or fluoroscopic imaging.
- Advance the catheter so the entire balloon extends beyond the end of the cystoscope before inflating the balloon.
- Don't try to over inflate the balloon. Time, rather than excessive pressure, is the key factor in transluminal dilatation. Find the table below for maximum balloon inflation pressure of each balloon size

Size of balloon	Length of balloon	Maximum Balloon inflation pressure
4 mm	4 cm	800 kpa
5 mm	4 cm	1000 kpa
5 mm	6 cm	
6 mm	4 cm	1000 kpa
6 mm	6 cm	
7 mm	4 cm	1100 kpa
7 mm	6 cm	

- The proper size selection for the device size and length is the responsibility of the physician considering the patient's anatomy.

Complications:

- Abdominal or back discomfort.
- Bleeding or hemorrhage
- Infection leading to septicemia.

How Supplied:

- **AMECATH Ureteral balloon dilator** is a sterile, single-use Medical device
- Each balloon dilator of **AMECATH Ureteral balloon dilator** is packed in a PETG hard blister covered with Tyvek.
- Each carton box includes 10 **AMECATH Ureteral balloon dilator** kits

AMECATH Ureteral balloon dilator method of application

1. Remove the catheter from its packaging and place in the sterile field.
 2. Inspect the balloon catheter to ensure no damage has occurred during shipment.
 3. Connect a stopcock to the connector of the balloon lumen and flush thoroughly. Connect a 10ml syringe partially filled with contrast medium and saline solution to the stopcock. Never use air or any gaseous medium to inflate the balloon.
 4. Hold the catheter with the distal tip pointing down and apply negative pressure with the syringe to evacuate all air from the balloon. Maintain the suction for 20 to 30 seconds and make sure that no bubbles are seen passing through the diluted contrast medium. Close the stopcock, release the plunger carefully and disconnect the syringe.
 5. Carefully remove the protection tubing from the balloon and discard.
 6. Connect the prepared prefilled inflation device or 10 ml syringe to the stopcock and hand-tight the hubs securely.
 7. Open the stopcock and ensure that a meniscus of contrast medium is seen in balloon port.
 8. Use cystoscopy to identify the ureteric orifice.
 9. Introduction of the appropriate straight guide wire through the cystoscope to the ureter under image.
 10. Pass of the Balloon Catheter over the guide wire while its' balloon is deflated and immersed with water soluble lubricant. Position the tip of the balloon inside the distal ureter leaving small part of the balloon in the ureteral orifice.
 11. Inflate the balloon with sterile diluted contrast liquid & maintain pressure not more than the specified in the table below according to the size, to a time variable according to surgeon experience.
 12. Deflate the balloon completely & advance the balloon catheter dilator over the straight guide wire for further dilatation according to the ureteric condition.
 13. Deflation of the balloon & remove it while preserve the straight guide wire inside the ureter.
 14. Pass the ureterscope through the ureter guided with the straight guide wire for further management either for stone endoreterival or diagnostic ureteroscopy.
- ❖ Balloon deflation and withdrawal
- Aspirate the balloon completely.
 - When the balloon is completely deflated. Removal of the catheter is facilitated by rotating the shaft counterclockwise during withdrawal. Using excessive force to withdraw the balloon can inflict trauma to tissue and/or damage the cytoscope.

N.B for further information on luer connections, please refer to latest version of BS EN ISO 80369-7

Product Variants:

For variants of **AMECATH Ureteral balloon dilator**, Kindly refer to the catalogue, visit our website on ["www.amecathgroup.com"](http://www.amecathgroup.com), or contact your nearest **AMECATH** representative.

Code Structure: UBD-XX-TT

UBD: Ureteral Balloon Dilator.
XX: Balloon Size in mm.
TT: Balloon Length in Cm.

Reference	Contents
UBD-XX-TT	<ul style="list-style-type: none"> • Ureteral Balloon Dilator • 10cc Syringe • Three Way Stopcock

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"](http://www.amecathgroup.com)*

❖ *In case of any Adverse event, Contact your local Health Authority immediately.*



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