



## **10. Instructions for Use**

## URETERAL SEQUENTIAL DILATORS AND SET

**Device Description:**

**AMECATH URETERAL SEQUENTIAL DILATORS SET** is a sterile single use device.

Prior to any Ureteric intervention, Ureteric orifice should be dilated. The dilatation is either by **AMECATH URETERAL SEQUENTIAL DILATORS** made of Radiopaque rigid but tender material that allows dilatation without injury.

Available sizes of **AMECATH URETERAL SEQUENTIAL DILATORS** range between 6Fr. And 18Fr. Dilators are available in 70cm length

**Target patient populations:** Adults and children (Paediatric).

**Intended user:** Health Care Professionals.

**AMECATH URETERAL SEQUENTIAL DILATORS SET and its accessories:**

**AMECATH URETERAL SEQUENTIAL DILATORS SET** is available in different designs and Kit configurations to cover all customer needs

**Device construction:****List of Accessories**

There are no accessories supplied with the device

**Intended Use:**

**AMECATH URETERAL SEQUENTIAL DILATORS SET** is indicated to dilate Ureteric orifice before ureteroscopic manipulation.

**Contraindications:**

There are no known contraindications

**Warnings and Precautions**

- For single product and patient use only.
- Do not use *dilator* 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 *dilator* 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 *dilators* as it may cause its degradation.
- Do not use absolute alcohol or acetone-based product on the *dilator*. 2% chlorhexidine or Iodine based solution is recommended as antiseptic solution
- Do not use USD for more than 90 minutes.

**Complications:**

- Injury of Ureteric orifice
- Hematuria
- Delayed Stricture

**How Supplied:**

- Each **AMECATH URETERAL SEQUENTIAL DILATOR** should be protected with PE cover on overall length.
- Each **AMECATH URETERAL SEQUENTIAL DILATORS SET** is packed in a PE soft blister covered with Medical Paper
- Each carton box includes 10 **AMECATH URETERAL SEQUENTIAL DILATORS SETS**

**AMECATH URETERAL SEQUENTIAL DILATORS SET Method of Application**

After introduction of a guide wire inside the Ureteric orifice, sequentially pass the dilators starting from the 6 Fr. Dilator up to the desired Fr. Size. The dilator should be introduced inside the Ureteric orifice for at least 5 cm, to be monitored under fluoroscopic image and should be kept in place for minimum 30 seconds to ensure dilatation before its removal

**Product Variants:**

For variants of **AMECATH URETERAL SEQUENTIAL DILATORS SET**, Kindly refer to the catalogue, visit our website on:

"[www.amecathgroup.com](http://www.amecathgroup.com)", or contact your nearest **AMECATH** representative."

**Ureteric Sequential Dilators Kit:**
**A. Ureteric Sequential Dilator Set:**
**Code Structure: USD-K-H**

<b>USD</b>	: Ureteric sequential dilator.
<b>K</b>	: Complete dilators set (6,8,10,12,14,16 & 18) Fr.
<b>H</b>	: For Hydrophilic coating

Reference	Contents
USD-K	<ul style="list-style-type: none"> <li>• URETERIC SEQUENTIAL DILATOR 06 Fr 70 Cm</li> <li>• URETERIC SEQUENTIAL DILATOR 08 Fr 70 Cm</li> <li>• URETERIC SEQUENTIAL DILATOR 10 Fr 70 Cm</li> <li>• URETERIC SEQUENTIAL DILATOR 12 Fr 70 Cm</li> <li>• URETERIC SEQUENTIAL DILATOR 14 Fr 70 Cm</li> <li>• URETERIC SEQUENTIAL DILATOR 16 Fr 70 Cm</li> <li>• URETERIC SEQUENTIAL DILATOR 18 Fr 70 Cm</li> </ul>
Hydrophilic coated dilator is also available, please add "H" after the code (USD-K-H).	

**B. Separate Ureteric Sequential Dilator:**
**Code Structure: USD-XX-H**

<b>USD</b>	: Ureteric sequential dilator.
<b>XX</b>	: Dilator size in Fr
<b>H</b>	: For Hydrophilic coating

Reference	Contents
USD-XX	URETERIC SEQUENTIAL DILATOR 70 Cm
Hydrophilic coated dilator is also available, please add "H" after the code (USD-XX-H).	

**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 *dilators* 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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