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.

AMECATH URETERAL SEQUENTIAL DILATORS should be used for not more than 90 minutes.

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 lodine based solution is recommended as antiseptic solution
- Do not use USD for more than 90 minutes.

Complications:

- Injury of Ureteric orifice
- Heamaturea
- Delayed Stricture

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How Supplied:

- Each AMECATH URETERAL SEQUENTIAL DILATOR 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", or contact your nearest AMECATH representative."

Ureteric Sequential Dilators Kit:

A. Ureteric Sequential Dilator Set:

Code Structure: USD-K-H

USD: Ureteric sequential dilator.

K: Complete dilators set (6,8,10,12,14,16 & 18) Fr.

H: For Hydrophilic coating.

Reference	Contents
USD-K	URETERIC SEQUENTIAL DILATOR 06 Fr 70 Cm
	URETERIC SEQUENTIAL DILATOR 08 Fr 70 Cm
	URETERIC SEQUENTIAL DILATOR 10 Fr 70 Cm
	URETERIC SEQUENTIAL DILATOR 12 Fr 70 Cm
	URETERIC SEQUENTIAL DILATOR 14 Fr 70 Cm
	URETERIC SEQUENTIAL DILATOR 16 Fr 70 Cm
	URETERIC SEQUENTIAL DILATOR 18 Fr 70 Cm
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

USD: Ureteric sequential dilator.

XX: Dilator size in Fr
H: 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).

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Instructions for use

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 quiries, 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.



















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