10. INSTRUCTIONS FOR USE

URETERAL ACCESS SHEATH

Device Description:
AMECATH URETERAL ACCESS SHEATH is a sterile single use device.

AMECATH URETERAL ACCESS SHEATH consists of an inner tapered dilator and an outer sheath. The Ureteral Access Sheath Set may be advanced over a 0.035 in. (0.89 mm) or 0.038 in. (0.97 mm) guidewire. The sheath is designed to create a conduit for urological procedure instruments. Refer to package label for sheath dimensions.

Range of size 11Fr. And 14Fr.

Range of length between 24cm to 54cm.

*Hydrophilic coating is applied as an option that when activated, attracts and holds water and other liquids to the device, creating a low-friction surface. The material used in hydrophilic coating is specially designed for urinary catheters.

Target patient populations: Adults and children
Intended user: Health Care Professionals

AMECATH URETERAL ACCESS SHEATH and its accessories:
AMECATH URETERAL ACCESS SHEATH is available in different designs and Kit configurations to cover all customer needs

Device construction:

AMECATH URETERAL ACCESS SHEATH Types:

- URETERAL ACCESS SHEATH
- Hydrophilic Coated URETERAL ACCESS SHEATH

List of Accessories

There are no accessories supplied with the device

Intended Use:
AMECATH URETERAL ACCESS SHEATH is indicated for use in endoscopic procedures to facilitate the passage of endoscopes, urological instruments and for the injection of fluids into the urinary tract.

Contraindications:

- Patients who are contraindicated for RETROGRADE urologic procedures.
- Presence of tight strictures which would limit use of the device.
- Presence of large obstructing distal ureteral stone.

Warnings and Precautions

- For single product and patient use only.
- Do not use 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 product and affect its integrity which when re-used may lead to possible deterioration in health and safety of patients.
- The recommendations given are meant to serve only as a basic guide to the utilization of this access sheath set. The ureteral sheath Set should not be used without comprehensive knowledge of the indications, techniques and risks of the procedure.
- 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 device size and length is the responsibility of the physician considering the patient's anatomy.

Complications:

Potential complications associated with the use of the transurethral access device include, but are not limited to

- Mucosal irritation, inflammation and edema
- Urethral strictures
- Acute bleeding or hemorrhage
- Urethral, bladder, or ureteral perforation
- Other injury to the urinary tract

How Supplied:

- Each **AMECATH URETERAL ACCESS SHEATH** is packed in a PETG hard blister with blister cover then packed in Breathable bag (window bag).
- Each carton box includes 10 **AMECATH URETERAL ACCESS SHEATH**.

AMECATH URETERAL ACCESS SHEATH Method of Application

1. Place a 0.035 in. (0.89 mm) or 0.038 in. (0.97 mm) guidewire into the desired location within the urinary tract.
2. Prior to use, place the dilator and sheath into a container of saline or sterile water to activate the hydrophilic coating.
3. Insert the dilator fully inside the sheath and secure by pushing the dilator hub until it snaps into the sheath hub.
4. Advance the dilator/sheath assembly over the guidewire to the desired location.
5. Once positioned, gently withdraw the dilator while maintaining sheath position.
   DO NOT advance the sheath without ensuring that the dilator is in place.
6. Introduce desired instrumentation through the sheath as needed.
7. To perform a retrograde pyelogram, reinsert the dilator into the sheath (see Step 3) and inject contrast through the luer fitting of the dilator.
8. Remove dilator as desired per Step 5.
9. Upon completion of the access procedure, gently withdraw the device.

Product Variants:

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

Code Structure: UAS-XX-YY

UAS	Ureteral Access Sheath (Saflex)
XX	Outer diameter in Fr. (11 or 14) Sheath
YY	Length in Cm
Note: Inner diameter in Fr	9.5 Fr for Sheath 11 Fr 12 Fr For Sheath 14 Fr

Reference	Contents
UAS-XX-YY	Ureteral Access Sheath

* All UAS are suitable with guide wire 0.035" (0.89 mm) and 0.038" (0.97 mm)

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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