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10. INSTRUCTIONS FOR USE



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Revo-Trapper URETERAL STONE BASKET

Device Description:

Nowadays Endoscopic treatment of ureteral stone has become very popular, carrying the benefits of shortening hospital stay and early recovery are major advantages.

AMECATH Revo-Trapper Ureteral Stone Basket is used for stone retrieval. **AMECATH Revo-Trapper Ureteral Stone Basket** is made of a special type nitinol or stainless steel wires that resists breaking or damage on frequent use.

AMECATH Revo-Trapper Ureteral Stone Basket has either helical expandable wires that allow firm grip on small stones or straight wires to grip on large stones Both types of tipped or tipples are also available for different indications.

The system of **AMECATH Revo-Trapper Ureteral Stone Basket** allows for easy application and separation of its parts by the endoscopist.

Ureteral Stone Basket is available with different number of wires (3, 4, 5 and 6 wires)

Range of tube diameter from 1.8 to 5Fr.

AMECATH Revo-Trapper Ureteral Stone Basket and its accessories:

AMECATH Revo-Trapper Ureteral Stone Basket is available in different designs and Kit configurations to cover all customer needs

Device construction:

- Wire number: 3 to 6 wires
- Helical or straight basket
- Tipped or tipples basket
- Nitinol or Stainless

List of Accessories

There are no accessories supplied with the device

Intended Use:

- Extraction of small ureteric stones not more than 1cm.
- Extraction of pelvic or calyceal stones.
- Fixation of large stone prior to intraluminal lithotripsy.

Contraindications:

- Impassable urethral structure.
- Bleeding tendencies.

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.
- Trauma to the urethra could occur during insertion.
- Procedures should be aborted if any difficulties observed during insertion.
- Extra force may lead to outer sheath damage.

Complications:

• The most common complication from the Basket use are Ureteral injury, Perforation or even avulsion.

How Supplied:

- AMECATH Revo-Trapper Ureteral Stone Basket is a sterile, single-use Medical device
- Each carton box includes 10 AMECATH Revo-Trapper Ureteral Stone Basket packed in a PETG hard blister tray with blister cover in a window bag

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AMECATH Revo-Trapper Ureteral Stone Basket method of application

- Through the working channel of the ureteroscope, the basket is introduced until it becomes few mm above the stone or just beside it.
- Push the sliding thumb control of the basket handle till the wires expand inside the ureter, or inside the renal calyx.
- Slowly withdraw the handle thumb control until the wires grip on the stone. No need to force the handle thumb control back to its original place, once you grip the stone stop moving the handle thumb control
- Rotate the basket 360 degree to ensure that no tissue is gripped inside the wires.
- Lithotripsy may be applied at this stage.
- Gradually, withdraw the Basket and the ureteroscope to outside.

Product Variants:

For variants of **AMECATH Revo-Trapper Ureteral Stone Basket**, Kindly refer to the catalogue, visit our website on www.amecathgroup.com", or contact your nearest **AMECATH** representative.

Description	Reference	Contents
Revo-Trapper Ureteral Stone Basket	USB-X-Y-N-T-H	 Ureteal Stone Basket Nitinol, Tipped, Helical X-wires Y FR. Tube Diameter
Revo-Trapper Ureteral Stone Basket	USB-X-Y-N-T-S	 Ureteal Stone Basket Nitinol, Tipped, Straight X-wires Y FR. Tube Diameter
Revo-Trapper Ureteral Stone Basket	USB-X-Y-N-0-H	 Ureteal Stone Basket X-wires Y FR. Tube Diameter Nitinol, Tipless, Helical
Revo-Trapper Ureteral Stone Basket	USB-X-Y-N-0-S	 Ureteal Stone Basket X-wires Y FR. Tube Diameter Nitinol, Tipless, Straight
Revo-Trapper Ureteral Stone Basket	USB-X-Y-S-T-H	Ureteal Stone Basket Stainless Steel, Tipped, Helical X-wires Y FR. Tube Diameter

Storage and Product Safe Disposal

- Store at room controlled temperature.
- 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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