

1. INTENDED PURPOSE:

The **UROMED™** Stone Basket Retrieval Intended for use in minimally invasive endoscopic urological procedures to capture, secure, and remove urinary calculi from the ureter, urinary bladder, and renal pelvis via a transurethral endoscopic approach.



2.DEVICE DESCRIPTION

Basic –UDI-DI : 890615570SBYR

The **UROMED™** Stone Retrieval Basket Single-use, sterile, endoscopic stone retrieval device consisting of a proximal actuation handle, a flexible shaft, and a distal expandable multi-wire metallic basket manufactured from medical-grade stainless steel or Nitinol. The basket is deployed and retracted via controlled handle actuation to capture and remove urinary calculi under endoscopic visualization.

Sizes: 1.2Fr, 1.4Fr, 1.7Fr, 1.8Fr, 1.9Fr, 2.0Fr, 2.2Fr, 2.5Fr, 2.8Fr, 3.0Fr, 3.5Fr, 4.0Fr, 5.0Fr, 6.0Fr, 7.0Fr, 8.0Fr, 9.0Fr.

Length: 35cm, 40cm, 45cm, 50cm, 60cm, 65cm, 70cm, 90cm, 110cm, 115, 120cm, 150cm, 200cm, 400cm

- 1.9F and 2.4F baskets ideal for proximal and renal calculi
- 3.0F baskets accommodate larger stones

Compatible with rigid, semirigid and flexible endoscopes having a working channel sufficient to accommodate the selected basket

Stone Retrieval Basket Size Range	Working Channel Diameter	Working Channel Length	Scope Outer Diameter
1.2–2.9 Fr	≥ 3.6 Fr (≥ 1.2 mm)	650–700 mm (65–70 cm)	7.5–9.2 Fr
3.0–3.9 Fr	≥ 4.0 Fr (≥ 1.33 mm)	650–700 mm (65–70 cm)	7.5–9.2 Fr
4.0–4.9 Fr	≥ 5.0 Fr (≥ 1.67 mm)	650–700 mm (65–70 cm)	7.5–9.2 Fr
5.0–5.9 Fr	≥ 6.0 Fr (≥ 2.0 mm)	650–700 mm (65–70 cm)	7.5–9.2 Fr
6.0–6.9 Fr	≥ 7.0 Fr (≥ 2.33 mm)	650–700 mm (65–70 cm)	7.5–9.2 Fr
7.0–7.9 Fr	≥ 8.0 Fr (≥ 2.67 mm)	650–700 mm (65–70 cm)	8.0–10.0 Fr
8.0–8.9 Fr	≥ 9.0 Fr (≥ 3.0 mm)	650–700 mm (65–70 cm)	9.0–11.0 Fr
9.0 Fr	≥ 10.0 Fr (≥ 3.33 mm)	650–700 mm (65–70 cm)	10.0–12.0 Fr

Duration of Use : Transient use (≤60 minutes). The device is intended for temporary use during an endoscopic procedure for retrieval of urinary tract stones and is removed immediately following completion of the procedure.

3. INDICATIONS

The **UROMED™** Stone Retrieval Basket is indicated for the endoscopic capture and retrieval of urinary calculi and stone fragments from the ureter, renal pelvis, and urinary bladder during minimally invasive urological procedures via a transurethral endoscopic approach. The device is intended to be introduced through the working channel of a compatible endoscope and used under direct endoscopic visualization by appropriately trained healthcare professionals.

Target Patient Population

The **UROMED™** Stone Retrieval Basket is intended for adult patients with urinary calculi or stone fragments located in the ureter, renal pelvis, or urinary bladder who are suitable for endoscopic stone retrieval.

4. CONTRAINDICATIONS:

- **Anatomical Abnormalities:** Significant anatomical distortions or strictures in the urinary tract that may impede the insertion or effective use of the Stone Basket.
- **Active Infection:** Presence of an active urinary tract infection (UTI) or other infections in the urinary tract, which could be exacerbated by the procedure.
- **Bleeding Disorders:** Patients with significant bleeding disorders or those on anticoagulant therapy, as this increases the risk of bleeding during or after the procedure.
- **Pregnancy:** Use during pregnancy is generally contraindicated due to potential risks to the foetus and complications that might arise from the procedure.
- **Severe Urethral or Bladder Injury:** Existing severe trauma or injury to the urethra or bladder that could be aggravated by the device.
- **Inaccessible Stones:** Stones that are not accessible or visible for effective retrieval using the Stone Basket. located in parts of the urinary tract that

5. WARNINGS AND PRECAUTIONS

- **Risk of Injury:** There is a risk of injury to the urinary tract or surrounding tissues during the procedure. Proper technique and care should be taken to avoid damaging the ureter, bladder, or renal pelvis.
- **Risk of Infection:** Although the device is used in a sterile environment, there is still a risk of infection. Follow strict aseptic techniques to minimize this risk.
- **Device Malfunction:** In the event of device malfunction, such as a failure of the basket to deploy or close properly, immediate action should be taken to prevent harm.
- **Inadequate Visualization:** Proper endoscopic visualization is necessary to ensure effective use of the Stone Basket. Poor visibility may hinder the successful retrieval of stones.
- **Patient Selection:** Ensure that patients meet the selection criteria for the device. Use in inappropriate cases or conditions not covered by the indications may lead to complications.
- **Training and Expertise:** The Stone Retrieval Basket should only be used by trained and experienced healthcare

professionals. Inadequate knowledge or skill can lead to improper use and adverse outcomes.

6. INSTRUCTIONS FOR USE

Pre-Procedure Preparation

- Verify the device model, size, and specifications to ensure compatibility with the selected endoscope (e.g. ureteroscope or cystoscope) and the intended clinical application.
- Inspect the sterile packaging prior to use. Do not use the device if the packaging is damaged, opened, compromised, or if the expiration date has passed.
- Open the package using aseptic technique in a sterile field.
- Prior to patient insertion, actuate the handle outside the patient to confirm that the basket opens and closes smoothly and that no mechanical malfunction is present.

System Requirements

Compatible with flexible or rigid ureteroscopes.

Selection Parameter	Selection Criteria
Basket Size	Select according to the size of the stone/fragment to be

	retrieved and the endoscope working-channel diameter.
Basket Length	Select according to the endoscope working length and the anatomical location of the stone.
Endoscope	Select a compatible rigid, semirigid or flexible endoscope appropriate for the intended anatomical location.
Compatibility	Ensure the endoscope working channel is sufficient to accommodate the selected basket and that the working length is sufficient for the selected basket length.

Components of Stone Basket

- Handle
- Catheter Shaft
- Nitinol core / Stainless steel (SS 304)
- Stone Basket (4-wire / 5- wire)

Patient and Access Preparation

- Position the patient in accordance with the planned endoscopic procedure and institutional clinical practice.
- Establish endoscopic access to the urinary tract using standard urological techniques.
- Insert the endoscope (e.g. ureteroscope) and advance to the target site to visualize the stone under direct endoscopic visualization and/or fluoroscopic guidance, as clinically indicated.

Device Insertion

- Ensure that the basket is fully retracted within the catheter sheath prior to insertion.
- Introduce the stone retrieval basket through the working channel of the endoscope.
- Advance the device carefully until the distal tip is visible under direct endoscopic visualization.
- Position the distal tip of the device adjacent to or distal to the stone, as clinically appropriate.

Basket Deployment

- Slowly actuate the handle to deploy the basket from the catheter sheath.
- Deploy the basket only under direct endoscopic visualization to minimize the risk of mucosal injury.
- Manipulate the basket carefully to position it around the stone.
- Once the stone is centrally positioned within the basket, gently close the basket to securely capture the stone.
- Do not apply excessive force during basket deployment or closure.

Stone Retrieval

- Confirm secure capture of the stone under direct visualization.

- Withdraw the basket slowly and in a controlled manner, maintaining visualization whenever possible.
- If resistance is encountered during withdrawal, stop immediately and reopen the basket to reposition or release the stone as clinically appropriate.
- Retrieve the stone through the endoscope or by withdrawing the device and endoscope together, based on clinical judgment.

Completion of Procedure

- Fully retract the basket into the catheter sheath prior to removing the device from the patient.
- Remove the stone retrieval basket from the endoscope.
- Dispose of the device in accordance with hospital procedures for single-use medical devices.

7.INTENDEDUSER:

Healthcare Professionals:

- Urologists
- Endourologists
- Surgeons specializing in minimally invasive urological procedures

Qualifications:

- Trained and experienced in endoscopic techniques
- Knowledgeable in handling endoscopic equipment and retrieval devices

Setting:

Clinical environments such as hospitals or surgical centres

8. POTENTIAL COMPLICATIONS

- Ureteral or bladder injury during insertion or retrieval
- Stone migration during manipulation
- Basket failure or entrapment
- Incomplete removal of the stone or foreign body
- Post-procedural infection or bleeding

9. PRINCIPLE OF OPERATION:

The UROMED™ Stone Basket Retrieval Device operates as follows:

Insertion: The device is introduced through the working channel of an endoscope (flexible or rigid) and navigated to the location of the stone or foreign body within the urinary tract under the fluoroscopic guidance.

Deployment: The control handle is used to advance the device and deploy the basket. The basket, which is initially collapsed, expands once the sheath is

retracted. This allows the basket to open and encircle the stone or foreign body.

Capture: The basket is maneuvered around the stone or foreign body. Using the control handle, the operator carefully closes the basket by retracting the sheath, ensuring that the stone or foreign body is securely captured within the mesh.

Retrieval: With the stone or foreign body captured, the device is withdrawn from the urinary tract along with the endoscope. The basket remains closed during withdrawal to ensure that the captured object is not released.

Removal: Once outside the body, the device and the captured stone or foreign body are removed from the endoscope. The device is then disposed of according to medical waste protocols.

10. CLINICAL BENEFITS:

Minimally Invasive Procedure: The stone basket allows for the removal of kidney stones or foreign bodies from the urinary tract without the need for open surgery. This results in less trauma to the patient and a faster recovery time.

Precise Stone Removal: The device enables precise capture and removal of stones, reducing the likelihood of incomplete removal and minimizing the need for repeat procedures.

Adaptability: Available in various sizes, the stone basket can accommodate different stone sizes and anatomies, making it a versatile tool in urological procedures.

Compatibility with Endoscopic Systems: The device is designed to work seamlessly with flexible and rigid ureteroscopes, facilitating efficient and effective stone retrieval.

Safe and Effective: post-market data generally show that stone basket retrieval devices have a high success rate in removing stones with a low incidence of serious complications.

Performance characteristics

The performance characteristics of the UROMED™ Stone Retrieval Basket are described in the **Device Description, Compatibility/System Requirements, Principle of Operation, and Instructions for Use** sections of this IFU.

11. DESCRIPTION OF PACKAGING AND CONTENTS

Packaging:

Primary Packaging:

Sterile Pouch: The device is enclosed in a sterile, sealed pouch to ensure it remains free from contamination until it is used. The pouch is typically made from medical-grade Tyvek materials

that maintain sterility and integrity of the device.

Outer Packaging:

Labeling:

Product Label: Clearly indicates the product name, model number, lot number, expiration date, and any relevant symbols or instructions for use. Includes handling and storage conditions.

Sterility Indicator: Provides a visual or mechanical indicator to confirm that the packaging has not been compromised and remains sterile with Single Sterile Barrier System.

12. STORAGE

Store the device in its original packaging in a clean, dry environment at room temperature. Avoid exposure to extreme temperatures or humidity, which may affect the integrity of the device.

Temperature Limit : 0°C – 45°C

13. DISPOSAL INSTRUCTIONS:

Single-Use Device: The stone basket retrieval device is intended for single use only. It should not be reused, reprocessed, or re-sterilized.

Biohazardous Waste: After use, the device should be considered biohazardous due to its contact with

bodily fluids and tissues. Dispose of the device in accordance with local regulations for biohazardous medical waste.

Environmental Impact: Where possible, dispose of the device in a way that minimizes environmental impact. Follow any applicable regulations regarding the disposal of medical plastics or metal components.

Serious Incident Reporting

Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

For reporting a serious incident to the manufacturer, please use the manufacturer contact details provided in this IFU.

14. MANUFACTURER'S INFORMATION:

(LEGAL MANUFACTURER)

 **MANISH MEDI INNOVATION PVT LTD**

SY No. 150/2, No. 53,54, 55, 68, 69 and 70, Bannerghatta Main Road, ABT Layout, Hullahalli Village, CK Palya,

Bannerghatta, Bengaluru Urban, Bengaluru – Karnataka 560083, INDIA.

(MANUFACTURING SITE)

 **MANISH MEDI INNOVATION**

10/9, 3rd Main, 24th Cross Sri Krishna Layout, Hulimavu, Bannerghatta Road Bangalore, Karnataka 560076, India

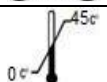
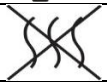


CMC Medical Device

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15. SYMBOLS & GLOSSARY

Sr. No.	Symbol	Meaning
1.		Sterilised with ethylene oxide
2.		Do not re-sterilize
3.		Do not use if package is damaged
4.		Consult electronic instruction for use
5.		Temperature limit
6.		Single use only
7.		Keep In clean and dry condition
8.		Keep away from straight rays from sun
9.		Non-pyrogenic
10.		CE Mark with notified body number
11.		Symbol for "Reference number"
12.		Symbol for "Batch code"
13.		Symbol for "Date of manufacture"
14.		Symbol for "Use Before"
15.		Symbol for "Manufacturer"
16.		Symbol for Medical device
17.		Symbol for Single Sterile Barrier System with protective Packing inside