















Directions for Use: RELIEF™ Stent – Ureteral Stent

RS-001 (6 French x 24 cm), RS-002 (6 French x 26 cm)

 REF	Catalogue Number		Do not use if package is damaged
 LOT	Lot Number		Do not re-sterilize
	Date of Manufacture		Prescription Use Only
	Used by Date		Consult Instructions
	Sterilization: Ethylene Oxide		Keep Dry
	Caution		Keep away from sunlight
	No Reuse		Manufacturer

INTENDED USE & INDICATIONS FOR USE

The RELIEF™ Ureteral Stent is intended for temporary drainage from the ureteropelvic junction to the bladder in a variety of benign, malignant, and post- traumatic conditions of the ureter. These conditions include stones and/or stone fragments or other ureteral obstructions such as those associated with ureteral stricture, malignancy of abdominal organs, retroperitoneal fibrosis or ureteral trauma, or in association with Extracorporeal Shock Wave Lithotripsy (ESWL). The stent may be placed using endoscopic surgical techniques or percutaneously using standard radiographic technique. It is recommended that the indwelling time not exceed 30 days. The stent is not intended as a permanent indwelling device.

CONTRAINDICATIONS:

- Patients who are contraindicated for surgical procedures
- Patients with distal ureter stones or obstruction
- Patients with unknown hematuria
- Ureteral avulsion

CAUTIONS:

- **Federal (USA) law restricts this device to sale by or on the order of a physician.**
- **Do not use if sterile pouch barrier is damaged**
- **Do not clean, reprocess, or re-sterilize.** Cleaning, reprocessing, or re-sterilizing may compromise the device ability to perform as intended.
- **Do not reuse.** Reuse could cause cross contamination and transmission of infectious disease from one patient to another resulting in patient injury or death.
- **Do not force, bend, or kink Pusher Tube or RELIEF™ Stent during or prior to placement.** This could lead to inability to deliver the RELIEF™ Stent or other complications.
- A pregnant patient may require close monitoring for stent encrustation due to potential use of calcium supplements.

ADVERSE EVENTS

As with all standard-of-care ureteral stents, the expected potential adverse events include:

- Flank pain/loin discomfort
- Lower abdominal pain
- Suprapubic pain
- Flank pain when voiding, reflux
- Trigonal irritation
- Dysuria
- Urinary Tract Infection
- Bacteriuria
- Incontinence
- Stent encrustation / occlusion
- Extravasation
- Hematuria
- Urinary urgency
- Urinary frequency
- Urethral discomfort
- Signs of ureter trauma
- Nocturia
- Stent migration
- Additional stent specific procedures
- Perforation of urethra, ureter, bladder, renal pelvis, kidney

DEVICE DESCRIPTION

RELIEF™ Ureteral Stent includes a radiopaque soft polymeric proximal tubular coil and body segment attached to a 4 cm tether of suture material that is placed along the ureter intramural segment, allowing natural opening and closing of the ureteral opening. The tether is attached to a radiopaque distal bladder coil constructed of a monofilament (non-lumened), polymeric segment, allowing it to float in the bladder.

The package contents consist of:

- RELIEF™ Ureteral Stent
- Stent pusher tube with 4 cm black marker band and radiopaque tip
- Pigtail straightener

PRIOR TO USE

- Immerse the entire stent in sterile water or isotonic saline to activate the hydrophilic coating on the stent to absorb fluid so that it becomes slippery which will aid with insertion.

DIRECTIONS FOR USE

- RELIEF™ Stent indwell time: ≤ 30 days
- Pullout Suture indwell time: ≤ 14 days

1. Perform cystoscopy and position the flexible end of .038 ureteral guidewire into the ureter and up to the renal pelvis. Use an open-end catheter in conjunction with the guidewire to resolve tortuosity in the obstructed ureter.
2. Perform baseline pyelogram to assess length of ureter in order to determine length of stent for patient. Add 1 cm to the estimated length to ensure ample length.
3. Using the pigtail coil straightener, load the proximal coil of the ureteral stent on to the guidewire and advance until the guidewire exits the distal end of the proximal stent body. Remove the pigtail coil straightener off the guidewire and discard.
4. Next, load the radiopaque tip end of the pusher tube on to the guidewire and advance the stent into the cystoscope.

Note: The distal coil of the stent is not loaded on to the guidewire like conventional double pigtail stents. The distal coil will uncoil and trail alongside the pusher tube during advancement into position. Have an assistant maintain migration of the guidewire during advancement of the stent to prevent the guidewire from advancing into the renal parenchyma.

Note: If resistance is encountered during placement or withdrawal do not continue until first determining the source of the resistance and resolving this completely.

5. Continue to advance the stent over the guidewire until the proximal tip of the stent enters the ureteral orifice. Continue to advance the pusher tube until the suture portion of the stent and the radiopaque tip of the pusher tube enters the ureteral orifice.

Note: There is a black marker band 4 cm from the end of the radiopaque tip of the pusher tube.

Continue to advance the pusher tube until the black marker band is in contact with the ureteral orifice. This will now position the suture portion of the stent into the intramural segment of the ureter and positions the bladder coil of the stent into the bladder. At this point the bladder coil should be floating freely in the fluid filled bladder.

6. Hold the pusher tube in position while the guidewire is partially removed to uncoil the proximal stent coil in the renal pelvis. Confirm via fluoroscopy that the proximal coil is properly positioned in the renal pelvis.
7. Once position is confirmed remove the guidewire from the cystoscope while holding the position of the stent with the pusher tube. Remove the pusher tube from the cystoscope.
8. Confirm that the distal bladder coil is freely floating in the bladder.

Note: It is recommended that periodic evaluation of the stent after placement using cystoscopy, radiographic or ultrasonic techniques to assess the function and condition of the stent.

9. If required final distal adjustment of the stent position can be made with grasping forceps.
10. Pull out suture can either remain extended out of the patient for stent removal within 14 days, or if longer term placement is anticipated, the pullout suture should be removed. The suture can be removed by cutting off the knot and gently pulling on one of the suture strands until the balance of the suture is removed.
11. Remove cystoscope to complete the stent placement.

PHYSICIAN INSTRUCTIONS TO PATIENT:

- Provide ureteral stent care instructions to the patient, including follow-up care.
 - Inform patient **not** to remove pullout suture until directed by physician.
- Inform the patient about online resources that will provide additional sources of information about kidney stones, treatment options and post procedure care and maintenance of ureteral stents. Helpful websites include:
 - American Urology Association: <https://www.urologyhealth.org/urology-a-z/k/kidney-stones>
 - National Institute of Health: <https://www.niddk.nih.gov/health-information/urologic-diseases/kidney-stones?dkrd=hispt0421>
- Additional online resources may be searched using key words such as:
 - Kidney Stone Treatments
 - Ureteral Stent Care
 - Ureteral Stent Removal

Note: In case of serious injury (incident) in relation to use of product, contact your local distributor or manufacturer.

Manufactured for:
Ureteral Stent Company



45 Glenridge Court
Chagrin Falls, Ohio 44022
(216) 258-8047