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	Rx	Prescription Use Only
	Used by Date		Consult Instructions
STERILE EO	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.

The stent is not intended as a permanent indwelling device. The indwelling time should not exceed thirty (30) days.

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

DEVICE DESCRIPTION:

The RELIEF™ Ureteral Stents are sterile, single-use devices. The stents are available in 6Fr, with lengths of 24cm and 26cm. The ureteral stent is constructed of a radiopaque polymer tube with a central lumen with side holes positioned along its length to provide drainage of urine from the kidney to the bladder and includes hydrophilic coating. Along the stent are printed insertion markers throughout its length. The 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 orifice, thereby preventing vesicoureteral reflux**. 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, thus precluding any tension on the tether or coil. The RELIEF™ Ureteral Stent package contents consist of:

- RELIEF™ Ureteral Stent
- Stent pusher tube with radiopaque tip
- Pigtail straightener

The RELIEF™ Ureteral Stent is not intended as a permanent indwelling device and is labeled for indwell time not to exceed thirty (30) days.

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 onto 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 onto 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 **thereby preventing vesicoureteral reflux (VUR)** 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 tether segment of the stent resides in the intramural segment allowing the normal function of the ureteral orifice **to prevent vesicoureteral reflux** and 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

SUMMARY OF CLINICAL TESTING:

Clinical data collected from 19 patients were provided to verify that the design of the suture tether does not impede the normal functioning of the urinary orifice to prevent vesicoureteral reflux. This data were obtained from a prospective, open label study called 'Clinical Evaluation of RELIEF ™ Stent study' which was conducted in the University Hospital Cleveland Medical Center. The study enrolled 26 patients who were assessed for eligibility based on the inclusion criteria. Seven patients were excluded based on the exclusion criteria. Total 19 patients were evaluated in the study, including 10 male and 9 female patients. Eleven of the evaluated subjects underwent previous stent placement. Four and 15 of the evaluated patients had renal and ureteral calculi, respectively. The demographics and anatomical height of the subjects, inclusion, and exclusion criteria used for the study are listed below:

Demographic

The patient demographics for the clinical performance testing is referenced below:

Gender	Number of participants	Ethnicity
Male	10	All Caucasian
Female	9	Asian (1) Afro-American (2) Caucasian (6)

The age range for the subjects was 39 to 84 years.

Anatomical Height criteria:

The patient's anatomical height in relation to the RELIEF™ Ureteral Stent length utilized as referenced below:

Anatomical Height	Stent Length
5' 3" – 5' 7"	24 cm
5' 8" – 5' 10"	26 cm

Inclusion criteria:

1. Male and female patients
2. Over 18 years of age and willing and able to provide informed consent
3. Renal or ureteral stone of 5-25 mm measured on plain abdomen X-ray KUB (Kidney Ureter Bladder) or CT (computed tomography)
4. Upper or middle third ureteral stricture or stone AND/OR stone located in the renal pelvis
5. Patient agrees to participate in the study and signs the informed consent form
6. Able to complete self-rated questionnaires

Exclusion criteria:

1. Patients with distal ureteral obstruction
2. Patients with urinary reflux (assessed by pre-stent cystogram)
3. Patients requiring bilateral surgical stone management procedure or patients with active urinary tract infection (UTI) or sepsis

Study Results:

Across the 19 patients evaluated in the study, no patients experienced adverse complications. All cystograms, pre- and post-stent implant, were graded at No Reflux. The comparison of the cystogram images of the RELIEF™ Ureteral Stent verified that the low-profile tether segment of the subject device placed in the intramural segment of the ureter to the bladder did not impede the urinary orifice's one-way valve function. The normal function of the urinary orifice's one way valve is to close and seal off during micturition, thereby preventing vesicoureteral reflux.

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

Manufactured for:
Ureteral Stent Company

Made in the USA

RELIEFSTENT

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www.RELIEFStent.com