

Ureteral Injection Stent Prescriptive Information

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Caution: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. Please check availability with your local sales representative or customer service.

Warning

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/ or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Intended Use/Indications for Use

The Ureteral Injection Stent is intended to facilitate drainage from the kidney to the bladder via placement endoscopically or fluoroscopically. Additionally, the Ureteral Injection Stent is intended to inject contrast and saline into the renal collecting system.

The Ureteral Injection Stent is indicated for use with urological procedures and/or conditions such as:

- Pre-ESWL
- Post-ESWL
- Ureteral stone obstruction
- Post-ureteroscopy
- UPJ obstruction
- Ureteral trauma
- Ureteral stricture
- Ureteral carcinoma
- Retroperitoneal fibrosis
- Endopyelotomy
- Pyelotomy
- Nephrolithotomy
- Ureterolithotomy

Contraindications

The Ureteral Injection Stent is contraindicated for use with the following procedures and/ or conditions:

- Poor surgical risk patients
- Unexplained hematuria
- Unrepaired ureteral avulsion

Warnings

None known.

Precautions

1. Bending or kinking prior to placement could damage the integrity of the stent.
2. If resistance is encountered during advancement or withdrawal of the stent, **STOP. DO NOT CONTINUE** without first determining the cause of the resistance and taking remedial action.
3. Periodic radiographic, isotopic or cystoscopic examinations are recommended to evaluate stent efficacy and to observe for possible complications. When long-term use is indicated, it is recommended that indwelling time not exceed 365 days and that evaluations be performed at 90-day intervals post placement.

4. Ureteral stents are not intended to be permanent implant devices.
5. The recommendations given here are meant to serve only as a basic guide to the utilization of this stent. The insertion of a ureteral stent should not be undertaken without comprehensive knowledge of the indications, techniques and risks of the procedure. The references given below provide a broad overview of the subject of ureteral stent insertion over a pre-placed guidewire.
6. Retrieval Line indwelling time is not to exceed more than 14 days. If longer stent indwelling time is anticipated, remove retrieval line before placement or prior to day 14.

Adverse Events

The adverse events which may result from placement of ureteral stent include, but are not limited to: Reflux-GU (e.g. ureteral reflux); Occlusion/Obstruction (e.g. catheter, stent); Migration (e.g. dislodgement); Hemorrhage; Infection (e.g. sepsis, peritonitis, urinary tract infection); Perforation (e.g. bladder, ureter, kidney, renal pelvis); Extravasation; Encrustation; Loss of renal function; Edema; Urinary symptoms (e.g. frequency, urgency, incontinence, dysuria, nocturia, hematuria); Pain/discomfort; Stent fragmentation; Fistula; Hydronephrosis; Stone formation; Tissue damage; Erosion.