Tria™ Ureteral Stent

INTENDED USE/INDICATION FOR USE
The Ureteral Stent is intended to facilitate drainage from the kidney to the bladder via placement endoscopically, fluoroscopically or during an open surgical procedure by a trained physician.

CONTRAINDICATIONS
No known contraindications.

WARNINGS
None known.

PATIENT SELECTION

WARNINGS
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.

PRECAUTIONS
To avoid possible retrieval line encrustation, it is recommended that indwelling time not exceed fourteen (14) days if the retrieval line is left attached to the stent.

1. Recommended for one time use only.
2. Bending or kinking during or prior to placement could damage the integrity of the stent.
3. 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.
4. Periodic upper urinary tract examinations are recommended to ensure the stent is draining adequately. Evaluation for stent encrustation should be performed periodically.

Note: Where long-term use is indicated, it is recommended that indwelling time for stent (with retrieval line removed) not exceed 365 days*. This stent should be evaluated by the physician on or before 90 days post-placement.

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*Biocompatibility data on file.

5. Stents are not intended to be permanent implant devices.
6. The recommendations given are meant to serve only as a basic guide to the utilization of this set. 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 preplaced guidewire.
7. Stent placement may complicate the subsequent work-up/evaluation of unexplained hematuria.
8. Patients who are poor surgical risk should be managed appropriately.

ADVERSE EVENTS

Adverse events associated with retrograde or antegrade positioned indwelling ureteral stents 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.

CAUTIONS

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

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