Retromax™ Plus Endopyelotomy Stent with HydroPlus™ Coating 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
Some of the indications for placement of a Retromax Plus Stent are:

- Extrinsic compression of ureter
- Ureteral incision
- Ureteropelvic junction incision
- Stricture dilatation

Contraindications
The use of ureteral stents should be reconsidered if the following conditions exist:

- Poor surgical risk
- Unexplained hematuria
- Unrepaired ureteral avulsion

Warnings
None known.

Precautions

1. This device is supplied sterile and recommended for one-time use only.
2. Avoid bending or kinking the stent during or prior to placement as to do so 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 resistance and taking remedial action.
4. Periodic radiographic, isotopic, or cystoscopic examinations are recommended to evaluate stent efficiency and to observe for possible complications. When long term use is indicated, it is recommended that indwelling time not exceed 365 days. The stent should be evaluated for replacement at three (3) month intervals.
5. This stent is not intended to be a permanent implant device.
6. The recommendations given herein are meant to serve only as a basic guide to the utilization of this device. Use of this device should be restricted to physician specialists with comprehensive knowledge of the indications, techniques and risks of the procedure. The references given herein provide a broad overview of the subject of ureteral stent insertion over a pre-placed guidewire.

Adverse Events
Adverse events associated with retrograde and antegrade positioned indwelling ureteral stents: 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.