

## Stretch™ VL Variable Length Flexima™ Stent with HydroPlus™ Coating Prescriptive Information

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### 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 ureteral stent are:

- Extrinsic compression of ureter
- Ureteral obstruction
- Ureteral trauma
- Ureteral manipulation
- Preparation for ureteral manipulation
- Assistance with stone fragment passage

### 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. Retrieval line indwelling time should not exceed fourteen (14) days to avoid possible cord encrustation.
2. This device is supplied sterile and recommended for onetime use **only**.
3. Avoid bending or kinking the stent during or prior to placement as to do so could damage the integrity of the stent.
4. 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.
5. Periodic radiographic, isotopic, or cystoscopic examinations are recommended to evaluate stent efficiency and to observe for possible complications. Where long term use is indicated, it is recommended that indwelling time not exceed 90 days. This stent should be evaluated by the physician on or before 90 days post-placement.
6. This stent is not intended to be a permanent implant device.
7. 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 below provide a broad overview of the subject of ureteral stent insertion over a preplaced 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.