Brief Summary Document

Product
Stretch™ VL Variable Length Flexima™ Stent with HydroPlus™ Coating - IFU 51094230-01, 51094231-01

Rx Statement
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

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

PRECAUTIONS

- Retrieval line indwelling time should not exceed fourteen (14) days to avoid possible cord encrustation.
- Avoid bending or kinking the stent during or prior to placement as to do so could damage the integrity of the stent.
- 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.
- 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.
- This stent is not intended to be a permanent implant device.
- Formation of knots in multi-length ureteral stents may occur. This may result in injury to the ureter during removal and/or the need for additional surgical intervention. The presence of a knot should be considered if significant resistance is encountered during attempts at removal.

POTENTIAL 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.