

Brief Summary Document

Product

Percuflex™ Ureteral Stent & Percuflex™ Plus Ureteral Stent with HydroPlus™ Coating - IFU 91125109-01

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

The Percuflex and Percuflex Plus Ureteral Stents are intended to facilitate drainage from the kidney to the bladder via placement endoscopically or fluoroscopically by a trained physician.

CONTRAINDICATIONS

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

- Contraindicated Surgical candidate
- Unexplained Hematuria
- Unrepaired Ureteral Avulsion

PRECAUTIONS

- Bending or kinking during or prior to placement could damage the integrity of the stent.
- 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.
- 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.
- 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 365 days. This stent should be evaluated by the physician on or before 90 days post placement.
- Stents are not intended to be permanent implant devices.

POTENTIAL ADVERSE EVENTS

Adverse Events associated with retrograde and 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.