Contour Soft Percuflex™ 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
The Ureteral Stent is 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:

- Contra-indicated surgical candidate
- Unexplained hematuria
- Unrepaired ureteral avulsion.

Warnings
None known.

Precautions

Note: 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 radiographic, isotopic or cystoscopic examinations are recommended to evaluate stent efficiency and to observe for possible complications.

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 postplacement.
*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.

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.