Polaris™ Ultra Double Pigtail Percuflex™ Ureteral Stents and Stent Sets 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. This 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 stents are intended to facilitate drainage from the kidney to the bladder via placement endoscopically or fluoroscopically or during an open surgical procedure by a trained physician.

Contraindications
The double pigtail Percuflex Ureteral Stents are contraindicated for use with the following procedures and/or conditions:

- Poor surgical risk patients
- 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. Recommended for one time use only.
3. Bending or kinking during or prior to placement 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 the resistance and taking remedial action.
5. 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 not exceed 365 days*. This stent should be evaluateby the physician on or before 90 days postplacement.
   *Biocompatibility data on file.

6. Stents are not intended to be permanent implant devices.
7. 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 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.