Polaris™ Loop Ureteral Stents

Prescriptive Information
Refer to the device directions for use for complete instructions on device use.

Intended Use/Indications for Use
The Polaris Loop Ureteral Stents are intended to facilitate drainage from the kidney to the bladder via placement endoscopically, fluoroscopically, or during an open surgical procedure by a trained physician.

Contraindications
The Polaris Loop Ureteral Stents are contraindicated for use with the following procedures and/or conditions:
- Antegrade Placement
- Poor surgical risk patients
- Unexplained hematuria
- Unrepaired ureteral avulsion

Warnings
None known.

Precautions
- Retrieval line indwelling time should not exceed fourteen (14) days to avoid possible cord encrustation.
- Recommended for one time use only.
- Bending or kinking during or prior to placement 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 the resistance and taking remedial action.
- It is recommended that when long term use is indicated the stent should be evaluated every 90 days.
    - Results from laboratory testing demonstrate that the stent material (Percuflex™ Material) is biocompatible for up to 365 days.
- During cystoscopic placement the Polaris Loop Stent requires a 12F (4.0 mm) or greater bridgeport in conjunction with a 19.5F (6.5 mm) or larger sheath.
- During stent removal it is recommended to grasp both loops prior to extracting the stent.
- The recommendations given here are meant to serve only as a basic guide to the utilization of this stent. The insertion of the ureteral stent should not be undertaken without comprehensive knowledge of the indications, techniques and risks of the procedure.

Adverse Events
Adverse Events associated with retrograde 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

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.