**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.

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