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

- For single use only. Do not reuse, reprocess or resterilize.
- Warnings can be found in the product labeling supplied with each device.

Potential Adverse Events

Adverse Events associated with retrograde positioned indwelling ureteral stents:

- Edema
- Extravasation
- Fistula formation
- Hemorrhage
- Hydronephrosis
- Infection
- Loss of renal function
- Pain/discomfort
- Perforation of kidney, renal pelvis, ureter, and/or bladder
- Peritonitis
- Stent dislodgement/fragmentation/migration/occlusion
- Stent encrustation
- Stone formation
- Ureteral erosion
- Ureteral reflux
- Urinary symptoms (frequency, urgency, incontinence, dysuria, hematuria)

Precautions

- Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.
- 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.
- Precautions can be found in the product labeling supplied with each device.