Percuflex™ Plus Ureteral Stent with HydroPlus™ Coating

Prescriptive Information

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

Intended Use/Indications for Use

The Percuflex Plus Ureteral Stent is intended to facilitate drainage from the kidney to the bladder via placement endoscopically or fluoroscopically by a trained physician.

Contraindications

- 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 and antegrade positioned indwelling ureteral stents:

- Ureteral reflux
- Extravasation
- Stent occlusion
- Stent dislodgement
- Hemorrhage
- Sepsis
- Perforation of kidney, renal pelvis, ureter and bladder
- Peritonitis

Precautions

- Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
- Suture 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.
- Periodic radiographic, isotopic or cystoscopic examinations are recommended to evaluate stent efficiency and to observe for possible complications. Where long-term use is indicated, it is recommended that indwelling time not exceed 365 days. This stent should be evaluated by the physician on or before 90 days post placement.
- Stents are not intended to be permanent implant devices.
- The insertion of a ureteral stent should not be undertaken without comprehensive knowledge of the indications, techniques and risks of the procedure.
- Precautions can be found in the product labeling supplied with each device.