Percuflex™ Urinary Diversion Stent Set

Prescriptive Information

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

Intended Use/Indications for Use

For drainage following percutaneous, endoscopic, or operative procedures.

Contraindications

The Percuflex Urinary Diversion Stent is contraindicated for use with the following procedures and/or conditions:

- 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 urinary diversion stents include:
Stent occlusion

- Stent dislodgment
- Hemorrhage
- Sepsis
- Perforation of kidney, bladder, renal pelvis or ureter
- Extravasation
- Peritonitis
- Encrustation
- Loss of renal function
- Urinary tract infection
- Edema
- Pain/discomfort
- Occlusion
- Stent fragmentation
- Hydronephrosis
- Stone formation
- Erosion

Precautions

- Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
- Recommended for single 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 visual, radiographic or isotopic 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 90 days. This stent should be evaluated by the physician on or before 90 days post placement and at intervals.

- 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.