

## Brief Summary Document

### Product

Percuflex™ Urinary Diversion Stent Set- IFU 51413325-01

### Rx Statement

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a skilled and licensed practitioner with experience in urological surgery.

Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

### INTENDED USE/INDICATIONS FOR USE

The Urinary Diversion Stent Sets are intended to provide external drainage of urine after urinary diversion surgeries.

### PRECAUTIONS

Not adhering to the following precautions could result in patient injury:

- Use only compatible accessories (connecting catheter, drainage bag, tube, or accessories compatible with the stent). Failure to do so may result in extended procedure time or urine leaks.
- If resistance is encountered during advancement or withdrawal of the catheter, STOP. DO NOT CONTINUE without first determining the cause of the resistance and taking remedial action.
- Bending or kinking during or prior to placement could damage the integrity of the stent.
- Periodic visual, radiographic or isotopic examinations are recommended to evaluate stent efficiency and to observe for possible complications. This stent should be evaluated by the physician on or before 90 days post placement.
- Stents are not intended to be permanent implant devices.
- In patients with unexplained hematuria, placement of a ureteral stent may complicate evaluation of the existing hematuria.

### POTENTIAL ADVERSE EVENTS

Adverse events associated with Urinary Diversion Stents include but are not limited to and may require additional medical or surgical intervention:

- Allergic Reaction
- Avulsion
- Discomfort
- Dislodgement
- Edema
- Encrustation
- Erosion
- Extravasation

- Fistula
- Hematoma
- Hematuria
- Hemorrhage
- Hydronephrosis
- Infection
  - Peritonitis
  - Sepsis
  - Urinary Tract Infection
- Inflammation
- Loss of Renal Function
- Migration
- Obstruction
- Occlusion
- Pain
- Perforation
- Reflux, Genitourinary (GU) (includes Ureteral Reflux)
- Stone Formation
- Tissue Damage
- Unretrieved Device Fragments
- Urine Leak