

## Brief Summary Document

### Product

Percuflex™ Locking Loop Nephrostomy Catheter- IFU 51194670-01

Percuflex™ Locking Loop with Fader Tip™ Nephrostomy Catheter- IFU 51194668-01

### Rx Statement

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

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

This Nephrostomy Catheter is intended to establish percutaneous nephrostomy access and is indicated for the following:

Diagnostic Indications:

- Antegrade pyelography
- Pressure/perfusion study (Whitaker test)

Therapeutic Indications:

- Nephrostomy catheter drainage
- Perfusion chemolysis of renal stones (**NOTE:** Percuflex Locking Loop with Fader Tip is not indicated for perfusion chemolysis or renal stones)
- Post-percutaneous nephrolithotomy
- Post-percutaneous resection and coagulation of urothelial tumors

### CONTRAINDICATIONS

The Nephrostomy Catheter is contraindicated for use in patients with blood clotting anomalies due to coagulopathies or pharmacological anticoagulations.

### PRECAUTIONS

- Bending or kinking during, prior to, or after placement (including external fixation) could damage the integrity of the catheter.
- 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.
- Periodic examinations are recommended to assess catheter patency and function.
- Catheters are not intended to be permanent implant devices.

**POTENTIAL ADVERSE EVENTS**

Potential complications which can result from the use of this Nephrostomy Catheter in urological applications include, but are not limited to:

- Hemorrhage
- Hematoma
- Perforation
- Infection
- Catheter occlusion
- Catheter dislodgement
- Tissue damage
- Inflammation
- Pain/discomfort
- Edema
- Colon injury
- Encrustation
- Pneumothorax
- Hydronephrosis
- Loss of renal function
- Fistula
- Extravasation