

## Brief Summary Document

### Product

Malecot Nephrostomy Catheter Set  
Re-Entry™ Malecot Nephrostomy Catheter Set  
IFU 50549798-01

### 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

The Malecot Nephrostomy Catheter Set 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
- Post-percutaneous nephrolithotomy
- Post-percutaneous resection and coagulation of urothelial tumors

### CONTRAINDICATIONS

The Malecot Nephrostomy Catheter Set is not indicated 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.
- Where long-term use is indicated, it is recommended that indwelling time for catheter not exceed 90 days. This catheter should be evaluated by the physician on or before 90 days postplacement.
- Periodic examinations are recommended to assess catheter patency and function.
- Catheters are not intended to be permanent implant devices.

## **POTENTIAL ADVERSE EVENTS**

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