

Brief Summary Document

Overview

Product

Malecot Nephrostomy Catheter Set Re-Entry™ Malecot Nephrostomy Catheter Set IFU-51682189-01

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.
- Pregnant patients require more frequent examinations for catheter patency and function and may require subsequent catheter exchange.
- Catheters are not intended to be permanent implant devices.
- These recommendations are meant to serve only as a basic guide to the utilization of this device. The performance of percutaneous nephrostomy should not be undertaken without comprehensive knowledge of the indications, techniques and risks of the procedure.

POTENTIAL ADVERSE EVENTS

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

There are no known **WARNINGS** associated with the use of this device.