

## **Malecot Nephrostomy Catheter Set Re-Entry™ Malecot Nephrostomy Catheter Set Prescriptive Information**

**Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician.

**CAUTION:** The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. This material not intended for use in France. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. Please check availability with your local sales representative or customer service.

### **Warning**

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/ or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

### **Intended Use/Indications for Use**

The Malecot Nephrostomy Catheter Set is intended to establish percutaneous nephrostomy drainage 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
- Percutaneous nephrolithotomy
- 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.

### **Warnings**

None Known.

### **Precautions**

The recommendations given are meant to serve only as a basic guide to the utilization of this catheter. The performance of percutaneous nephrostomy should not be undertaken without comprehensive knowledge of the indications, techniques, and risks of the procedure. The references given below provide a broad overview of the subject.

### **Adverse Events**

- Hemorrhage
- Subcapsular renal hematoma

- Bleeding from iatrogenic arteriovenous-caliceal fistulas
- Edema
- Extravasation
- Loss of renal function
- Sepsis