

## Brief Summary Document

### Product

NephroMax™ High Pressure Nephrostomy Balloon Catheter – IFU 51645143-01

### Rx Statement

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

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 NephroMax Balloon Catheters are recommended for dilatation of the nephrostomy tract.

### CONTRAINDICATIONS

This product is contraindicated in the presence of conditions which create unacceptable risk during catheterization.

### PRECAUTIONS

A thorough understanding of the technical principles, clinical applications, and risks associated with Balloon Dilatation is necessary before using this product.

- If resistance is encountered during advancement of the balloon catheter, STOP. DO NOT continue without first determining the cause of the resistance and taking remedial action. Forceful insertion may result in patient injury.
- Do not inflate the balloon past the rated burst pressure stated on the label. Overinflation may result in overdistention of the patient’s nephrostomy tract and damage to the balloon catheter, resulting in device fragments that may be difficult to retrieve.
- Do not inflate the balloon dilatation catheter while the balloon is directly beside and in contact with a stone. Doing so may cause migration of the stone further up the nephrostomy tract and result in patient injury.

### POTENTIAL ADVERSE EVENTS

The complications which may result from a balloon dilatation procedure include:

- Edema
- Extravasation
- Fever
- Fistula
- Hematoma/Hemorrhage
- Infection
- Inflammation
- Laceration
- Obstruction

- Pain/Discomfort
- Perforation
- Pneumothorax/Hydrothorax
- Renal insufficiency/Failure
- Tissue Trauma
- Urgency/Urinary retention/Dysuria
- Unretrieved device fragments