

NephroMax™ High Pressure Nephrostomy Balloon Catheter 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 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.

Adverse Events

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

- Tissue trauma
- Bleeding
- Perforation
- Urine leakage
- Infection
- Pneumothorax/Hydrothorax
- Fistula
- Fever
- Renal colic
- Urinary tract obstruction