UroMax Ultra™ High Pressure Balloon Catheter

Prescriptive Information

Refer to the operator's manual for complete instructions for use.

Indications

Balloon Dilatation Catheters are recommended for dilatation of the urinary tract.

Contraindications

None known.

Warnings

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 patient 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.

Potential Adverse effects

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

- Tissue trauma
- Tissue perforation

Cautions

Do not inflate balloon dilatation catheter while the balloon is directly beside and in contact with a stone.

Federal (USA) law restricts these devices to sale by or on the order of a physician.