

## **UroMax Ultra™ Balloon Dilatation Catheter Prescriptive Information**

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

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### **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**

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

### **Contraindications**

None known.

### **Precautions**

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

### **For Catheters with HydroPlus™ Coating**

The Urological Balloon Dilatation Catheters with HydroPlus Coating are coated with exclusive hydrophilic coating. To activate the HydroPlus Coating, the balloon should be immersed in a physiological solution such as saline after the wing form tool is removed for approximately 30 seconds.

### **Adverse Events**

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

- Tissue trauma
- Tissue perforation

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

**Caution:** Care should be exercised when passing a balloon coated with HydroPlus Coating through any metal containing system. Do not wrap gauze around the balloon. Minimize excessive handling. Do not wipe balloon with dry gauze or gauze wet with any solvent other than sterile water or saline.

**Caution:** Do not advance the guidewire or the balloon dilatation catheter if resistance is met, without first determining the cause of resistance and taking remedial action.

**Caution:** Inflation devices and syringes are capable of attaining very high pressures with minimal effort. The use of an inflation device or syringe with a high pressure gauge is strongly recommended.

**Caution:** If loss of pressure within the balloon occurs during inflation or if balloon ruptures during dilatation, immediately discontinue the procedure. Deflate the balloon carefully. Do not reinflate.

**Caution:** If resistance is encountered when removing a guidewire through a catheter or if resistance is encountered when removing a catheter through a scope, STOP and remove them as a complete unit to prevent damage to the guidewire, catheter or anatomy.