

Dual Lumen Ureteral 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. 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

Ureteral Catheters are indicated for use for catheterization of the urinary tract during interoperative procedures, including but not limited to the following applications:

- Ureteral occlusion for injection of contrast media
- Delivery of irrigation fluids to the ureter
- Drainage of fluids from the urinary tract
- Access, advancement or exchange of ancillary devices including guidewires.

Contraindications

Ureteral catheters are in general contraindicated for use in patients unsuitable for catheterization.

Precautions

- Do not use this product without reading and understanding the complete instructions herein.
- Avoid bending or kinking the catheter prior to placement. To do so could damage the integrity of the catheter and result in patient injury.
- If resistance is encountered during advancement or withdrawal of the catheter, STOP. DO NOT CONTINUE without first determining the cause of the resistance and taking remedial action.

Warnings

None known.

Adverse Events

The adverse events which may result from ureteral catheter placement include, but are not limited to:

- Extravasation
- Hemorrhage
- Sepsis
- Edema
- Loss of renal function
- Perforation of kidney, renal pelvis, ureter and/or bladder
- Peritonitis
- Urinary tract infection

Caution: Indwelling time not to exceed 24 hours