

Imager™ II Urology Torque Catheter Prescriptive Information

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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.

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 Imager II Urology Torque Catheter is indicated for use in facilitating access to the urinary tract, either through a retrograde or antegrade route, and may be used in conjunction with a guidewire or for the infusion of radiopaque contrast material. The Imager II Urology Torque Catheter is also indicated for the infusion of gels, such as BackStop™ Gel, intended for use in the urinary tract.

Contraindications for Use

This device is, in general, contraindicated for use in patients who are unsuitable for ureteral catheterization or the infusion of contrast material or gels, such as BackStop Gel.

Warnings

None known.

Precautions

- 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.
- The recommendations given are meant to serve only as a basic guide to the utilization of this product. The use of Imager II Urology Torque Catheter should not be undertaken without comprehensive knowledge of the indications, techniques, and risks of the procedure performed.

Adverse Events

The complications 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 bladder
- Peritonitis
- Urinary tract infection