

## Brief Summary Document

### Overview

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#### Product

Imager™ II Urology Torque Catheter

IFU 51322156-01

#### Rx Statement

*CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.*

*Prior to use, please refer to all applicable “Instructions for Use” for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator’s Instructions.*

#### 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.

#### CONTRAINDICATIONS

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

#### 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.

#### POTENTIAL 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