

Imajin® Silicone Hydrocoated Double Loop Ureteral Stent Kit

BRIEF STATEMENT

Physician Facing

Indications

Drainage of the upper urinary tract over fistulas or ureteral obstacles. Healing of the Ureter. Cicatrisation stent.

Contraindications

Untreated progressive infection of the upper urinary tract. Any known allergies to the medical device materials. These devices may particularly contain traces of silicone resulting from the manufacturing process. The evaluation of the allergic background of a patient is the healthcare professional's responsibility. Do not attempt stent placement in a patient with suspect ureteral avulsion. Do not use, when, in the judgement of the physician, such a procedure would be contrary to the best interest of the patient.

Warnings and Precautions

Reuse of this single use product may create a potential risk to the user. Reprocessing, cleaning, disinfection and sterilization may compromise product characteristics which in turn create an additional risk of physical harm to or infection of the patient. Formation of knots in lengthy stents have been reported as adverse events and may require surgical intervention to remove them.

Adverse Events

The following events have been reported although their occurrence greatly depends on patients' medical conditions. Adverse events include but are not limited to: migration or dislodgement, encrustation, infection, fragmentation, flank pain, mucosal irritation or inflammation, mucus secretion, frequency, urgency, dysuria, hematuria, reflux, stone formation, obstruction, erosion and perforation of the renal pelvis, ureter or bladder. Some events may be related to this procedure, amongst which those related to the guidewire: ureteral perforation, or burns when in contact with an electrosurgical equipment.

The risks and benefits of using Imajin® Silicone Hydrocoated Double Loop Ureteral Stent Kits should be considered in patients.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings and precautions refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company Website at www.coloplast.com.

Complications from the use of this device should be brought to the attention of your Coloplast Representative and your physician.

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

Minneapolis, MN
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