

VORTEK® Double Loop Ureteral Stent
BRIEF STATEMENT
Physician Facing

Indications

Vortek Double Loop Ureteral Stents are intended for:
Drainage of the upper urinary tract over fistulas or ureteral obstacles.
Healing of the Ureter.

Contraindications

Untreated progressive infection of the upper urinary tract.
These devices may particularly contain traces of silicone resulting from the manufacturing process; the evaluation of the allergic background of a patient is the health care 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

These kits must only be used by trained and experienced physicians.
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.

Potential Complications

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.

Advice to the Patient

The physician should educate the patients on their implanted stent and the need for regular monitoring. The patients should be instructed in terms that they understand to inform the physician if they are experiencing any pain, cloudy urine, bladder irritation or any sign or symptoms that they are having difficulty with urination.

The risks and benefits of using Vortek 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, precautions, and adverse events 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.

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

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