Vortek® Single Loop Ureteral Stents
BRIEF STATEMENT

Indications
The Vortek® Single Loop Ureteral Stent can be temporarily used for the indications below:

•Surgical indication
For short-term (less than 30 days) drainage of the upper urinary tract in ureterostomy or vesical replacement in adult and pediatric (adolescents, children, and infants) patients.
•Endoscopic indication
For short-term (less than 30 days) drainage from the upper urinary tract over fistulas or ureteral obstacles in adult and pediatric (adolescents, children, and infants) patients.

Contraindications
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. Untreated progressive infection of the upper urinary tract. Do not use the latex Luer-bag connector on patients with a known latex allergy. Do not use in patients who have allergy to silicone, as these devices may contain traces of silicone resulting from the manufacturing process.

Warnings and Precautions
This kit must only be used by trained and experienced professionals. 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, reflux, stone formation, obstruction, erosion, and perforation of the renal pelvis, ureter or bladder.
Additional procedural related adverse events from the guidewire could include: ureteral perforation, or burns when in contact with an electrosurgical equipment.

Advice to the Patient
The physician must inform the patient of the risks associated with the use of the device

The risks and benefits of using Vortek® Single Loop Ureteral Stents 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.

Minneapolis, MN
February 21, 2023
PM 15966