Vortek ® Hydro-coated Ureteral Stent

BRIEF STATEMENT
Physician Facing

Indications
The Vortek® Hydro-coated Ureteral Stent is 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
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. If the stent is intended to remain implanted for more than seven days, remove the withdrawal thread prior to implantation.

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 Vortek® Hydro 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
11/16/2021

PM-19369

	Vortek Hydro **BRIEF STATEMENT** **Physician Facing**	All information is from: SH22111400 (VV-xxxxxx)

	Indications	**Include in Brief Statement - no additional decision needed.**
	Vortek Hydro-coated Double Loop Ureteral Stents are intended for:	
1	Drainage of the upper urinary tract over fistulas or ureteral obstacles.	Include Indications are required.
2	Healing of the Ureter.	

	Contraindications	**Include in Brief Statement - no additional decision needed.**
1	Untreated progressive infection of the upper urinary tract.	
2	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.	Include Contraindications are required.
3	Do not attempt stent placement in a patient with suspect ureteral avulsion.	
4	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	**RA, Mktg, Legal & CA Team's 16Nov2021 Final Decision**
1	The choice of the characteristics of the stent is under the responsibility of the physician	Don't Include
2	Any use other than stated indications is under the responsibility of the physician.	Don't Include
3	These kits must only be used by trained and experienced physicians	Don't Include
4	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	Include
5	Formation of knots in lengthy stents have been reported as adverse events and may require surgical intervention to remove them	Include
6	If the stent is intended to remain implanted for more than seven days, remove the withdrawal thread prior to implantation	Include
7	Do not resterilize this product	Don't Include
8	Do not use the products if the package is damaged.	Don't Include
9	Store the kit in a cool, dry place	Don't Include

Potential Complications	Rate	RA, Mktg, Legal & CA Team's 16Nov/2021 Final Decision
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	NA	Include
To state at the bottom of the Brief Statement:		
The risks and benefits of using Vortek Hydro Double Loop Ureteral Stent Kits should beconsidered 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.		
Complications from the use of this device should be brough to the attention of your Coloplast Representative and your physician		
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.		