Vortek®

Double Loop Ureteral Stent

Essential value, reliable performance

The Value of Vortek®

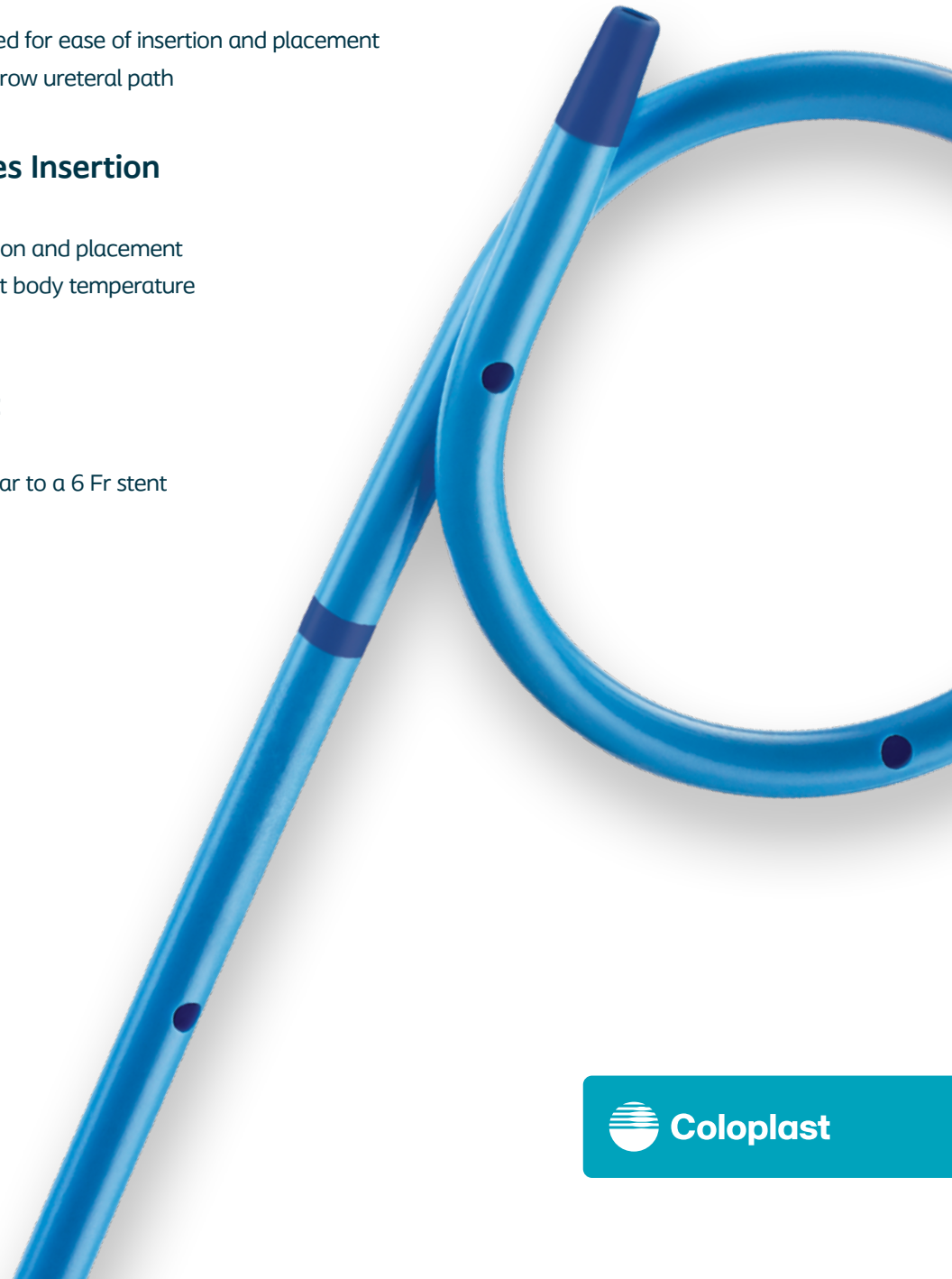
- Comprised of Vortek material, designed for ease of insertion and placement
- Ideal material for passing through narrow ureteral path

Dual-Layer Design Balances Insertion and Patient Comfort

- Firm inner layer allows for easy insertion and placement
- Thermosensitive outer layer softens at body temperature for increased patient comfort

Smaller Size with Excellent Urinary Flow Rate

- 4.8 Fr size has drainage capacity similar to a 6 Fr stent



Coloplast

Ordering Information

Coloplast Interventional Urology Service Support **800-258-3476**

Diameter (Ch/Fr)	Length (cm)	With Seldinger Guidewire 0.035″	Without Guidewire
Stent 4.8Ch/Fr + Pusher 6Ch/Fr 40 cm	12	ACB1C0	ACBM50
	16	ACB1C1	ACBM51
	20	ACB1C2	ACBM52
	22	ACB1C7	ACBM57
	24	ACB1C3	ACBM53
	26	ACB1C4	ACBM54
	28	ACB1C5	ACBM55
	30	–	ACBM56
6	20	ACB162	ACBM62
	22	ACB167	ACBM67
	24	ACB163	ACBM63
	26	ACB164	ACBM64
	28	ACB165	ACBM65
	30	ACB166	ACBM66
7	20	ACB172	ACBM72
	22	ACB177	ACBM77
	24	ACB173	ACBM73
	26	ACB174	ACBM74
	28	ACB175	ACBM75
	30	ACB176	ACBM76
8	24	ACB183	ACBM83
	26	ACB184	ACBM84
	28	ACB185	ACBM85
	30	ACB186	ACBM86

Vortek® Double Loop Ureteral Stent Brief Statement

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.

Minneapolis, MN
12/10/2021

PM-19678

Coloplast Corp. Minneapolis, MN 55411 / Interventional Urology Surgical Support 1-800-258-3476

Coloplast