Endourology your way

Ureteral Stent

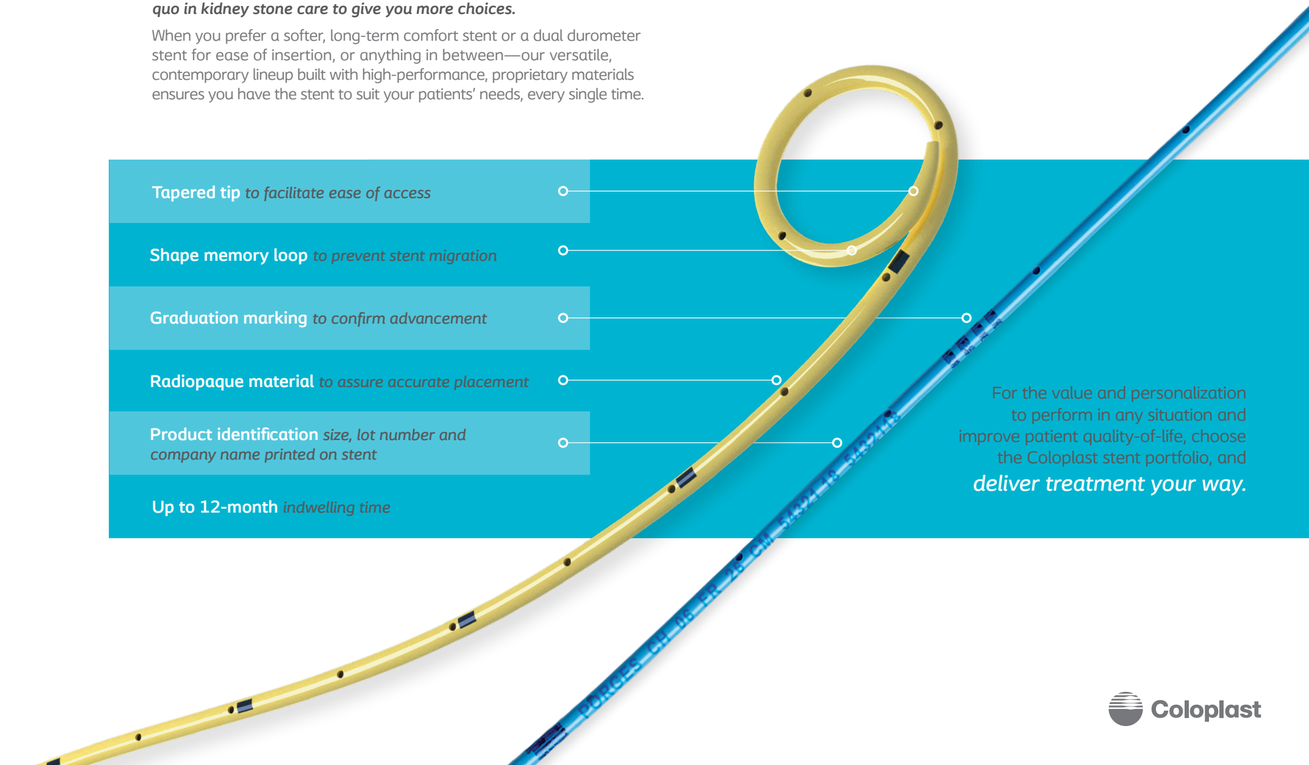
Catalog | 2023

Coloplast

A fitting solution.

No two patients are alike—That's why we're disrupting the status quo in kidney stone care to give you more choices.

When you prefer a softer, long-term comfort stent or a dual durometer stent for ease of insertion, or anything in between—our versatile, contemporary lineup built with high-performance, proprietary materials ensures you have the stent to suit your patients' needs, every single time.



Tapered tip *to facilitate ease of access*

Shape memory loop *to prevent stent migration*

Graduation marking *to confirm advancement*

Radiopaque material *to assure accurate placement*

Product identification *size, lot number and company name printed on stent*

Up to 12-month *indwelling time*

For the value and personalization to perform in any situation and improve patient quality-of-life, choose the Coloplast stent portfolio, and ***deliver treatment your way.***

Coloplast

ImaJin® Hydro

Hydrophilic-coated silicone double loop ureteral stent kits

The remarkable biocompatibility of silicone makes it the material of choice for long-term implantation: improved patient comfort and less encrustation material compared to Polyurethane. Hydro-coated stents to facilitate advancement.

Indwelling time of up to 12 months

Kit composition:

- ImaJin Hydro Hydrophilic-coated silicone stent
- Steerable pusher
- Choice of with or without guidewire

There's a more comfortable option for your patients. The ImaJin® Hydro ureteral stent is a clinically differentiated, precisely placeable, long-lasting option with a hydrophilic coating and steerable pusher to facilitate easier advancement in the urinary tract. Imagine fewer patient visits to the ER and fewer phone calls to your office.

- Clinically proven for greater patient comfort over leading competitor[1]
- The remarkable biocompatibility and flexibility of silicone makes it the material of choice for long-term implantation
- Greater resistance to encrustation than alternative materials[2]
- Stents made of silicone are soft and smooth for improved patient comfort
- Silicone stents cause less superficial epithelial destruction and host reaction

25%
More comfortable[1]*

36%
Less encrustation[2]*

Diameter (Ch/Fr)	Length (cm)	With Orchestra® Guidewire 0.035″	Without Guidewire
		1 Each	1 Each
6	16	BCHS61	BCHF61
	20	BCHS62	BCHF62
	22	BCHS67	BCHF67
	24	BCHS63	BCHF63
	26	BCHS64	BCHF64
	28	BCHS65	BCHF65
	30	BCHS66	BCHF66
7	16	BCHS71	BCHF71
	20	BCHS72	BCHF72
	22	BCHS77	BCHF77
	24	BCHS73	BCHF73
	26	BCHS74	BCHF74
	28	BCHS75	BCHF75
	30	BCHS76	BCHF76
8	16	BCHS81	BCHF81
	20	BCHS82	BCHF82
	24	BCHS83	BCHF83
	26	BCHS84	BCHF84
	28	BCHS85	BCHF85
	30	BCHS86	BCHF86

*Compared to a leading competitor's hydrophilic polymer ureteral stent

1. Wiseman O, Ventimiglia E, Doizi S, Kleinclauss F, Letendre J, Cloutier J, Traxer O. Effects of Silicone Hydrocoated Double Loop Ureteral Stent on Symptoms and Quality of Life in Patients Undergoing Flexible Ureteroscopy for Kidney Stone: A Randomized Multicentre Clinical Study. *J Urol.* 2020 Oct;204(4):769-777.
2. Barghouthy Y, Wiseman O, Ventimiglia E, Letendre J, Cloutier J, Daudon M, Kleinclauss F, Doizi S, Corrales M, Traxer O. Silicone-hydrocoated ureteral stents encrustation and biofilm formation after 3-week dwell time: results of a prospective randomized multicenter clinical study. *World J Urol.* 2021 Sep;39(9):3623-3629.

Biosoft® Duo

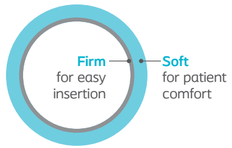
Double loop ureteral stents

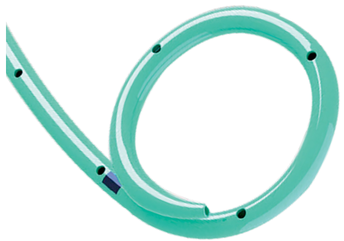
Biosoft duo was designed for easy insertion, while retaining great flexibility for patient comfort. Produced by coextrusion of a flexible material and a rigid material.

Indwelling time of up to 6 months

Kit composition:

- Steerable pusher, with or without radiopaque ring
- Choice of with or without guidewire
- Individually packaged





Diameter (Ch/Fr)	Length (cm)	With Seldinger Guidewire 0.035″	With Orchestra® Guidewire 0.035″	Without guidewire
		1 Each	1 Each	1 Each
6	20	BCAA62	BCAS62	BCAF62
	22	BCAA67	BCAS67	BCAF67
	24	BCAA63	BCAS63	BCAF63
	26	BCAA64	BCAS64	BCAF64
	28	BCAA65	BCAS65	BCAF65
	30	BCAA66	BCAS66	BCAF66
7	20	BCAA72	BCAS72	BCAF72
	22	BCAA77	BCAS77	BCAF77
	24	BCAA73	BCAS73	BCAF73
	26	BCAA74	BCAS74	BCAF74
	28	BCAA75	BCAS75	BCAF75
	30	BCAA76	BCAS76	BCAF76
8	26	BCAA84	BCAS84	BCAF84
	28	BCAA85	BCAS85	BCAF85
	30	BCAA86	BCAS86	BCAF86
9	26	BCAA94	--	--
	28	BCAA95	--	--
	30	BCAA96	--	--

Vortek® Hydro

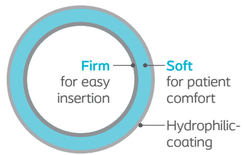
Hydrophilic-coated double loop ureteral stent kit

Improved glide and facilitated insertion with Hydrophilic-coating.
Dual durometer material for easy insertion and placement while retaining great flexibility for patient comfort. Thermosensitive material is firm for advancement but softens at body temperature for increased patient comfort.

Indwelling time of up to 6 months

Kit composition:

- Steerable pusher
- Choice of with or without guidewire
- Individually packaged



Diameter (Ch/Fr)	Length (cm)	With Seldinger Guidewire 0.035″	With Orchestra® Guidewire 0.035″	Without Guidewire
		1 Each	1 Each	1 Each
Stent 4.8Ch/Fr + Pusher 6Ch/Fr 40 cm	22	BCFA47	BCFS47	BCFD47
	24	BCFA43	BCFS43	BCFD43
	26	BCFA44	BCFS44	BCFD44
	28	BCFA45	BCFS45	BCFD45
6	22	BCFA67	BCFS67	BCFD67
	24	BCFA63	BCFS63	BCFD63
	26	BCFA64	BCFS64	BCFD64
	28	BCFA65	BCFS65	BCFD65
	30	BCFA66	BCFS66	BCFD66
7	22	BCFA77	BCFS77	BCFD77
	24	BCFA73	BCFS73	BCFD73
	26	BCFA74	BCFS74	BCFD74
	28	BCFA75	BCFS75	BCFD75
	30	BCFA76	BCFS76	BCFD76

Vortek®

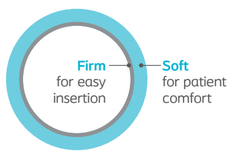
Double loop ureteral stents

The material of choice to ease insertion through narrow ureteral paths. Dual durometer material for easy insertion and placement while retaining great flexibility for patient comfort. Thermosensitive material is firm for advancement but softens at body temperature for increased patient comfort.

Indwelling time of up to 6 months

Kit composition:

- Steerable pusher
- Choice of with or without guidewire
- Individually packaged



Diameter (Ch/Fr)	Length (cm)	With Seldinger Guidewire 0.035″	Without Guidewire
		1 Each	1 Each
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

Stenostent®

Double loop ureteral stents for ureteral stenosis

Comprised of soft, smooth silicone material which has demonstrated greater patient comfort over Percuflex™[3]. Coils taper to 8 Fr, leaving less material in the bladder. 12 Ch/Fr ***reinforced body for maximum resistance to stenosis*** and 8 Ch/Fr loops ***for patient comfor***t.

Indwelling time of up to 12 months

Kit composition:

- Steerable pusher
- Fixed core 0.035" guidewire

3. El-Nahas et al, Self-Retaining Ureteral Stents: Analysis of Factors Responsible for Patients' Discomfort. *J of Endourology*, Jan 2006, 20(1):33-7

Diameter (Ch/Fr)	Length (cm)	
		1 Each
12	16	AJ4W81
	24	AJ4W83
	26	AJ4W84
	28	AJ4W85
	30	AJ4W86

Pyelostent®

Double loop ureteral stents for pyeloplasty

12 Ch/Fr reinforced part in renal pelvis ***for better healing***, 8 Ch/Fr loops for ***patient comfort***.

Indwelling time of up to 12 months

Kit composition:

- Steerable pusher
- Fixed core 0.035" guidewire

Diameter (Ch/Fr)	Length (cm)	
		1 Each
8/12	26	AJ4Y84
	28	AJ4Y85
	30	AJ4Y86

NovoFlow™

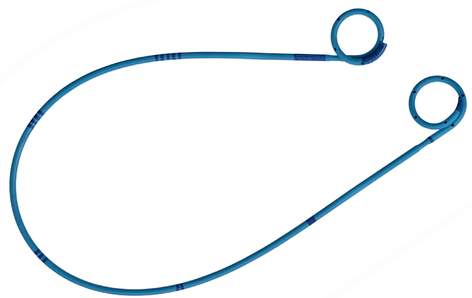
Reinforced Ureteral Stent

NovoFlow™ reinforced ureteral stent features a reinforced layer compared to Vortek® ureteral stents. This layer allows for passing through stricture and has an ***excellent resistance to compression***. There are no drainage holes on the straight section to prevent tumoral tissue ingrowth, and is designed to maintain flow rate through ureteral stenosis or tumoral compressions.

Indwelling time of up to 6 months

Kit composition:

- Steerable pusher
- Open-open double loop ureteral stent
- Choice of with or without guidewire
- Individually packaged
- Available in certain kits: A radiopaque 0.035 inch (0.89 mm) diameter hydrophilic nitinol guidewire



Diameter (Ch/Fr)	Length (cm)	With Orchestra Guidewire 0.035″	Without Guidewire
		1 Each	1 Each
7	26	BCCU74	BCCJ74
	28	BCCU75	BCCJ75
	30	BCCU76	BCCJ76
8	26	BCCU84	BCCJ84
	28	BCCU85	BCCJ85
	30	BCCU86	BCCJ86

Vortek® Single Loop Ureteral Stents

Device for drainage and urine collection

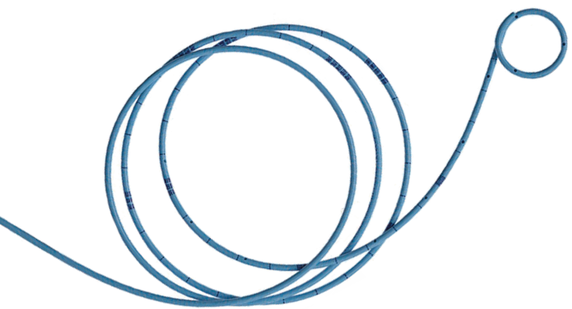
Single loop stent for short-term drainage of the upper urinary tract in ureterostomy or vesical replacement and for short-term drainage from the upper urinary tract over fistulas or ureteral obstacles. Retention coil strength avoids the risk of migration while the double layer structure of Vortek is a good compromise between glide over the wire and patient comfort.

Indwelling time of <30 days

Diameter (Ch/Fr)	Length (cm)	O/C Eyes on loop and body	O/O Eyes on loop and body	O/O Eyes on loop only
		1 Each	1 Each	1 Each
6	90	AC4406	ACA206	ACA106
7	90	AC4407	ACA207	ACA107
8	90	AC4408	ACA208	ACA108

Kit composition:

- Seldinger fixed core 0.035" guidewire
- Clamp
- Connector for urine bag



Stent accessories

Steerable/connectable pusher

For stent placement

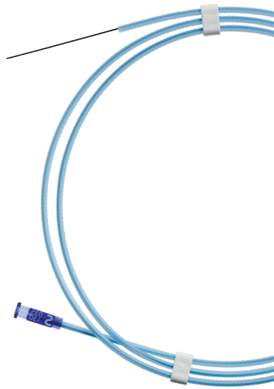
- ***Steerable/connectable pusher*** to retract or reposition the stent any time during insertion to facilitate precise placement
- With or without ***radiopaque ring***. The radiopaque ring at the extremity of the pusher provides a ***better visualization*** under fluoroscopy. Cystoscopy is not required to place the stent
- Can be used as a ***standard positioner***

Orchestra®

Hydrophilic nitinol guidewire

To gain ureteral access and to facilitate instrument exchange or placement

- 0.035˝ guidewire
- Kink-resistant elastic Nitinol core provides an ideal blend of stiffness and flexibility, for atraumatic navigation and optimal performance
- Durable hydrophilic coating on the entire length of the wire creates a lubricious surface to reduce friction and allow for greater efficiency, even after multiple instrument exchanges



PTFE-Coated Seldinger Guidewires

Facilitates the placement of devices during interventional procedures

- 0.035˝ guidewire
- PTFE coating offers a smooth wire surface to facilitate advancement
- Precise control and positioning
- Flexible tip to limit risk of trauma during advancement
- Radiopaque for fluoroscopic visualization

ISIRIS® Stent Removal System

Consistent ***quality***. Consistent ***sterilization***. At the ready, ***every time.***

There's an easier way to manage stent removal than large, expensive reusable cystoscope systems. Reach for the ISIRIS® single-use flexible cystoscope for consistent quality and sterilization—reducing concerns about scope availability or contamination. ISIRIS has an ergonomic lightweight handle, excellent scope deflection, and high-quality visualization, with integrated grasper for efficient stent capture (no assistant needed) plus advanced digital CMOS camera with bright LED illumination. The portable plug-and-play LCD monitor can be attached to IV pole, reducing footprint in crowded healthcare settings. It all adds up to convenience and safety.

Item	Description	EA / Sales UOM
ALFA01	Single-Use ISIRIS Devices	5 EA
MN0001	ISIRIS Monitor	1 EA

IMAJIN® SILICONE HYDRO-COATED DOUBLE LOOP URETERAL STENT KIT BRIEF STATEMENT

Indications:
Silicone Hydro-Coated 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. 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:
These kits must only be used by trained and experienced physicians. 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 must inform the patient of the risks associated with the use of the device.

The risks and benefits of using Imajin® Silicone Hydro-Coated Double Lop Ureteral Stent Kit 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.

BIOSOFT® DUO DOUBLE LOOP URETERAL STENT BRIEF STATEMENT

Indications:
Biosoft duo Double Loop Ureteral Stents can be used for:
- Drainage of the upper urinary tract over fistulas or ureteral obstacles
- Healing of the Ureter

Target population are Patients requiring ureteral stenting for drainage and/or healing of the ureter. Duration of Use: Biosoft duo Double Loop Ureteral Stent may remain implanted for up to 6 months.

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.

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.

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.

The risks and benefits of using Biosoft Duo Double Loop Ureteral Stent Kit 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.us.

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

VORTEK® HYDRO-COATED URETERAL STENT BRIEF STATEMENT

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.us.

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.

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.us.

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

IMAJIN® STENOSTENT® SILICONE DOUBLE LOOP URETERAL STENT KIT BRIEF STATEMENT

Indications:
Drainage of the upper urinary tract and/or ureteral healing during management of ureteral stenosis. Total enlargement of the stent diameter, for ureteral stenosis in adult and pediatric (children and adolescents) patients. Stenostent® Silicone double loop ureteral stents may remain implanted for up to 12 months.

Contraindications to the Medical Device:
Do not attempt stent placement in a patient with suspected ureteral avulsion. Allergy to any component of the device. Violent sports or strenuous physical activities are not recommended during stenting period. The practice of sport should be evaluated by the physician. Do not use, when, in the judgement of the physician, such a procedure would be contrary to the best interest of the patient.

Contraindications to the Endourological Procedure:
Untreated progressive infections of the upper urinary tract. Uncontrolled haemostasis disorder (relative contraindication). The safety of some endourological procedures should be evaluated in pregnant women.

Warnings and Precautions:

These devices must only be used by trained and experienced physicians. Physicians must inform patients of the possible undesirable side effects.

Potential Complications:

The following events have been reported with double loop ureteral stents although their occurrence greatly depends on patients' medical conditions. Adverse events include but are not limited to: pain, discomfort, sexual dysfunction, infection (e.g., urinary tract infection, pyelonephritis, severe infection, sepsis), tissue lesion (e.g., mucosal irritation, erosion, laceration, perforation of the renal pelvis, ureter or bladder), urinary symptoms (e.g., frequency, urgency, dysuria…), migration, encrustation, obstruction, hematuria, hemorrhage, fragmentation, reflux, knot, and hydronephrosis.

Some other events may be related to the procedure, particularly if the devices are not used as recommended amongst which:

- related to the guidewire: perforation of the urinary tract or close organs, bleeding, hemorrhage, mucosal irritation, tissue lesion, breakage, foreign object in the body, infection, guidewire knotting or looping or kinking, guidewire entrapment, or ureteral avulsion.

- related to the pusher: mucosal irritation, perforation, foreign object in the body, infection or prolonged procedure in case of difficult detachment from the stent.

The risks and benefits of using ImaJin® Stenostent® Silicone Double Loop Ureteral Stent Kit 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.

PYELOSTENT® URETERAL STENT BRIEF STATEMENT

Indications:
Drainage of the upper urinary tract over fistulas or ureteral obstacles. (e.g., periureteral tumour) Cicatrisation stent.

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 healthcare professional's responsibility.

Warnings and Precautions:
This type of kits must only be used by trained and experienced professionals. Reuse of this single use product may create a potential risk to the user.

Potential Complications:
The following events have been reported although their occurrence greatly depends on patients' medical conditions: infection, encrustation, obstruction, rupture, migration, bladder irritation symptoms, pain, hematuria, erosion.

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 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.us.

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

NOVOFLOW™ REINFORCED URETERAL STENT BRIEF STATEMENT

Indications for use:
The NovoFlow™ Reinforced Ureteral Stents are intended for patients 12 years of age (40 kg) and over for drainage of the upper urinary tract over fistulas or ureteral obstacles and/or for healing of the ureter. These stents may remain implanted for up to 6 months.

Contraindications:
Do not attempt stent placement in a patient with suspected ureteral avulsion.

Allergy to any component of the device.

Violent sports or strenuous physical activities are not recommended during stenting period. The practice of sport should be evaluated by the physician.

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 infections of the upper urinary tract.

Uncontrolled haemostasis disorder (relative contraindication).

The safety of some endourological procedures should be evaluated in pregnant women

Warnings and Precautions:
These devices must only be used by trained and experienced physicians. Physicians must inform patients of the possible undesirable side effects.

Physicians should evaluate the allergic background of the patient before use.

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 with double loop ureteral stents although their occurrence greatly depends on patients' medical conditions. Adverse events include but are not limited to: pain, discomfort, sexual dysfunction, infection (e.g., urinary tract infection, pyelonephritis, severe infection, sepsis), tissue lesion (e.g., mucosal irritation, erosion, laceration, perforation of the renal pelvis, ureter or bladder), urinary symptoms (e.g., frequency, urgency, dysuria…), migration, encrustation, obstruction, hematuria, hemorrhage, fragmentation, reflux, knot, and hydronephrosis.

Some other events may be related to the procedure, particularly if the devices are not used as recommended amongst which:

- related to the guidewire: perforation of the urinary tract or close organs, bleeding, hemorrhage, mucosal irritation, tissue lesion, breakage, foreign object in the body, infection, guidewire knotting or looping or kinking, guidewire entrapment, or ureteral avulsion.

- related to the pusher: mucosal irritation, perforation, foreign object in the body, infection or prolonged procedure in case of difficult detachment from the stent.

Advice to the Patient:
The physician should educate the patients on their implanted stent, the need for regular monitoring and the planned removal date. Practice of strenuous activities or violent sport should be avoided.

The patients should be informed on potential side effects (e.g., discomfort during physical activities or urination, frequent or urgent needs to urinate, or sexual dysfunction…). They should be advised to immediately contact the attending physician if any of the following symptoms are noted: any sustained pain, cloudy urine, bladder irritation, blood in the urine or any sign or symptoms that they are having difficulty with urination.

The risks and benefits of using NovoFlow™ Reinforced Ureteral Stent 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.

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.

ORCHESTRA® BRIEF STATEMENT

Indications:
The hydrophilic guidewire is intended to facilitate the placement of devices through the urinary tract during endourologic procedures.

Contraindications:
The hydrophilic guidewire is not intended for use other than for endourologic procedures.

Warnings and Precautions:
The hydrophilic guidewire should be used only by a physician, who is well trained in manipulation and observation of guidewires.

Perforation of the ureter is a risk connected with the use of a guidewire. It is advisable to proceed slowly and with caution to avoid it, inserting the guidewire flexible tip first. When using a drug or a device concurrently with the wire, the operator should have a full understanding of the properties/characteristics of the drug or device so as to avoid damage to the hydrophilic guidewire. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.

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

ISIRIS® STENT REMOVAL BRIEF STATEMENT

Indications:
ISIRIS is a sterile single use flexible cystoscope designed for removal of double loop ureteral stents accessible in the bladder via an urethral insertion in adults. ISIRIS has been designed to be used with
the reusable ISIRIS monitor to visualize the observations obtained by ISIRIS.

Warnings and Precautions:
Do not use active endoscopic accessories such as laser probes and electrosurgical equipment in conjunction with the ISIRIS system, as this may result in patient injury or damage to the ISIRIS system. Alert the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the ISIRIS system. The ISIRIS system is neither MRI safe nor MRI compatible. Do not use the Isiris system during defibrillation. Only to be used by skilled physicians trained in clinical endoscopic techniques and procedures. Passive deflection and retrovision maneuvers may be hazardous as it may affect the device, especially the grasper functionality. The distal end of the endoscope may get warm due to heating from the light emission part. Avoid long periods of contact between the tip of the device and the mucosal membrane as long, sustained contact with the mucosal membrane may cause mucosal injury. Do not enter any part of ISIRIS into the ureter. Do not activate the grasper when the distal end is inside the urethra. Do not activate the grasper during suctioning. Do not attempt to clean and reuse ISIRIS as it is a single-use device. Reuse of the product can cause contamination, leading to infections.

The risks and benefits of using ISIRIS® stent removal 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.us.

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.

Coloplast develops products and services that make life easier for people with very personal and private medical conditions. Working closely with the people who use our products, we create solutions that are sensitive to their special needs. We call this intimate healthcare.

Our business includes Ostomy Care, Continence Care, Wound and Skin Care and Interventional Urology. We operate globally and employ about 14,000 employees.

Scan here to learn more about Coloplast Interventional Urology's Endourology offerings.

Ostomy Care | Continence Care | Wound and Skin Care | Interventional Urology | Voice and Respiratory Care

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

Coloplast