Endourology *your way*

Ureteral Stent

Catalog | 2024

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.

Whether 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

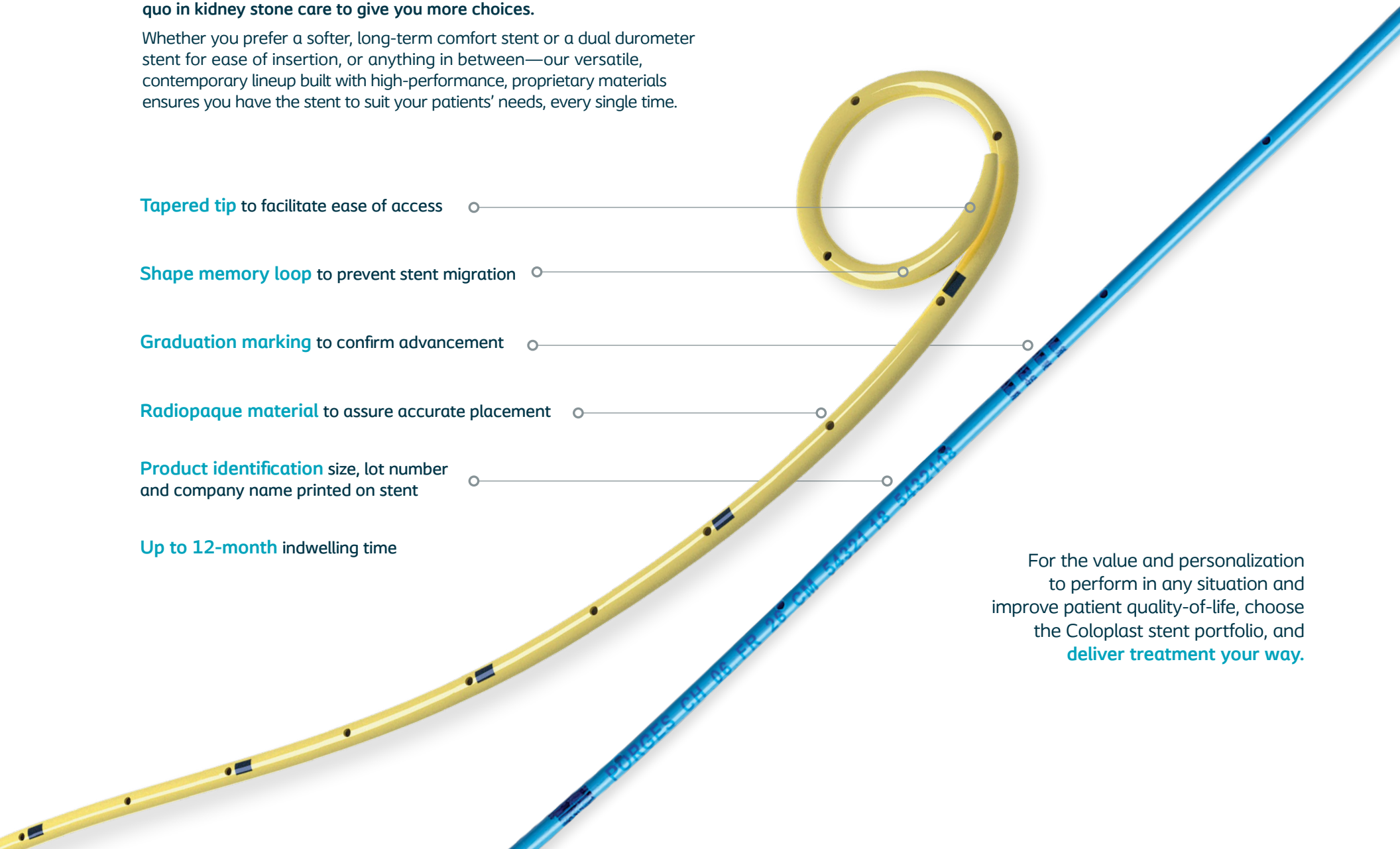
Shape memory loop to prevent stent migration

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.**

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

25%
More comfortable*[1]

36%
Less encrustation*[2]

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

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 is Coloplast's softer go-to ureteral stent that combines firmness with flexibility. The flexible biocompatible polymer of Biosoft softens at body temperature and is softer than Vortek® stents allowing for patient comfort. The loops on the proximal and distal end have excellent shape memory that prevents risk of migration during indwell.

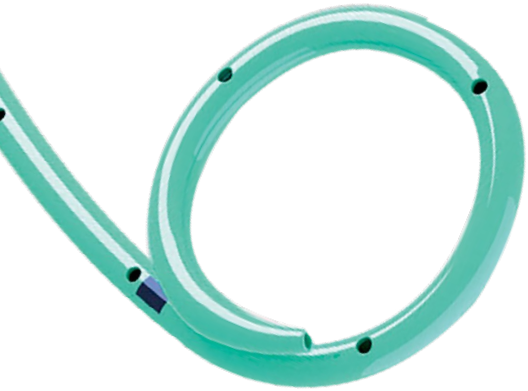
Indwelling time of up to 6 months

The Biosoft® difference

In an observational, retrospective, multicenter study at mean indwell time approximately 20 weeks, Biosoft demonstrated a lower global encrustation rate (5.5%) than severe encrustation rate estimated at the same time from literature (11%).[1]

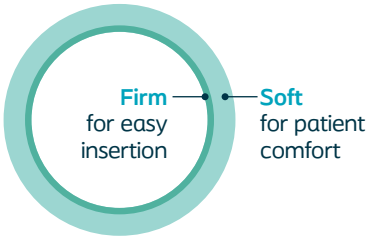
Biosoft is well tolerated in daily practice, while showing long term integrity as reported in literature

- Biosoft® duo is composed of a soft polymer blend for enhanced patient comfort
- Shape memory to prevent risk of migration during indwell



Kit composition:

- Biosoft duo double loop ureteral stent
- 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
6	20	BCAA62	BCAF62
	22	BCAA67	BCAF67
	24	BCAA63	BCAF63
	26	BCAA64	BCAF64
	28	BCAA65	BCAF65
	30	BCAA66	BCAF66
7	20	BCAA72	BCAF72
	22	BCAA77	BCAF77
	24	BCAA73	BCAF73
	26	BCAA74	BCAF74
	28	BCAA75	BCAF75
	30	BCAA76	BCAF76
8	26	BCAA84	BCAF84
	28	BCAA85	BCAF85
	30	BCAA86	BCAF86
9	26	BCAA94	--
	28	BCAA95	--
	30	BCAA96	--

1. Legrand F, Saussez T, Ruffion A, Celia A, Djouhri F, Musi G, Kalakech S, Desriac I, Roumeguere T. Double Loop Ureteral Stent Encrustation According to Indwelling Time: Results of a European Multicentric Study. *J Endourol.* 2021 Jan;35(1):84-90. doi: 10.1089/end.2020.0254. Epub 2020 Nov 6. PMID: 32799700.

Vortek® Hydro

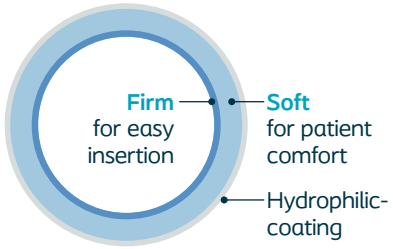
Hydrophilic-coated double loop ureteral stent kit

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:

- Vortek Hydrophilic-coated double loop ureteral stent
- Steerable or non-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	22	BCFA47	BCFD47
	24	BCFA43	BCFD43
	26	BCFA44	BCFD44
	28	BCFA45	BCFD45
6	22	BCFA67	BCFD67
	24	BCFA63	BCFD63
	26	BCFA64	BCFD64
	28	BCFA65	BCFD65
	30	BCFA66	BCFD66
7	22	BCFA77	BCFD77
	24	BCFA73	BCFD73
	26	BCFA74	BCFD74
	28	BCFA75	BCFD75
	30	BCFA76	BCFD76

Vortek®

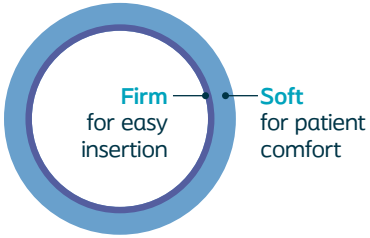
Double loop ureteral stents

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:

- Vortek double loop ureteral stent
- Steerable or non-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 comfort**.

Indwelling time of up to 12 months

Kit composition:

- Stenostent double loop ureteral stent
- 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

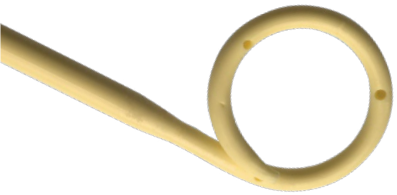
Diameter (Ch/Fr)	Length (cm)	1 Each
12	16	AJ4W81
	24	AJ4W83
	26	AJ4W84
	28	AJ4W85
	30	AJ4W86

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:

- Pyelostent double loop ureteral stent
- Steerable pusher
- Fixed core 0.035" guidewire

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

NovoFlow™

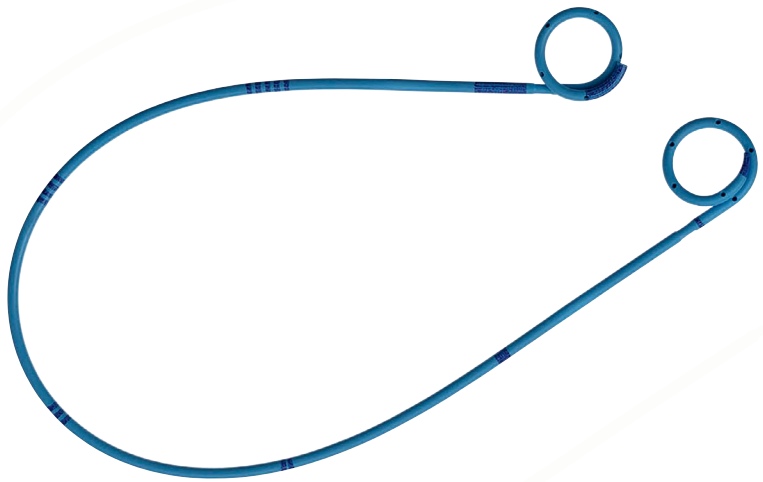
Reinforced ureteral stent

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



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

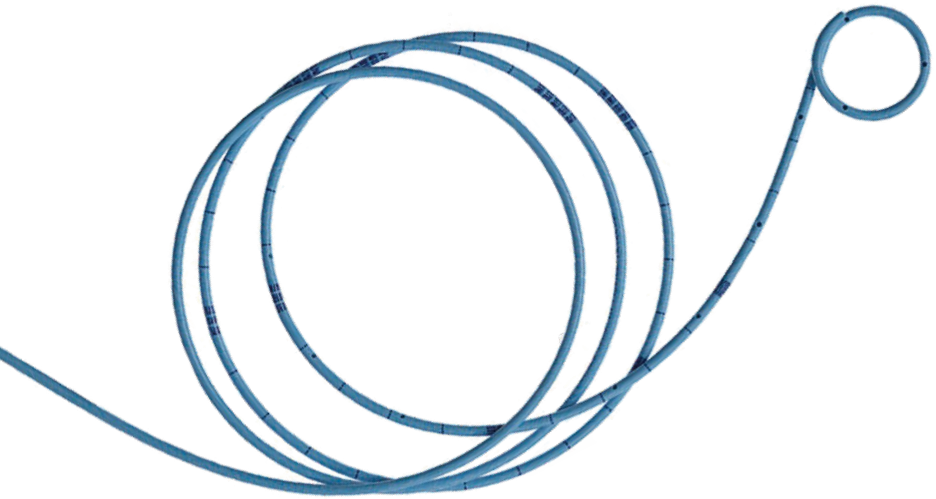
Single loop stent for short-term drainage of the upper urinary tract in ureterostomy or vesical replacement and for short-term drainage from the upper urinary tract over fistulas or ureteral obstacles. Retention coil strength avoids the risk of migration while the double layer structure of Vortek is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

- Vortek single loop ureteral stent
- Seldinger fixed-core 0.035" guidewire
- Clamp
- Connector for urine bag



Stent accessories

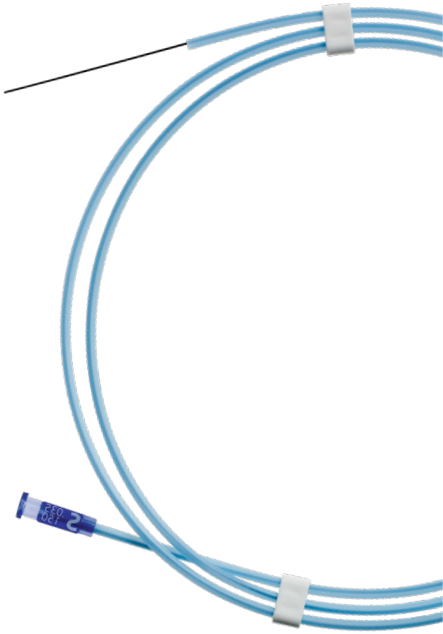
Steerable/connectable pusher

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

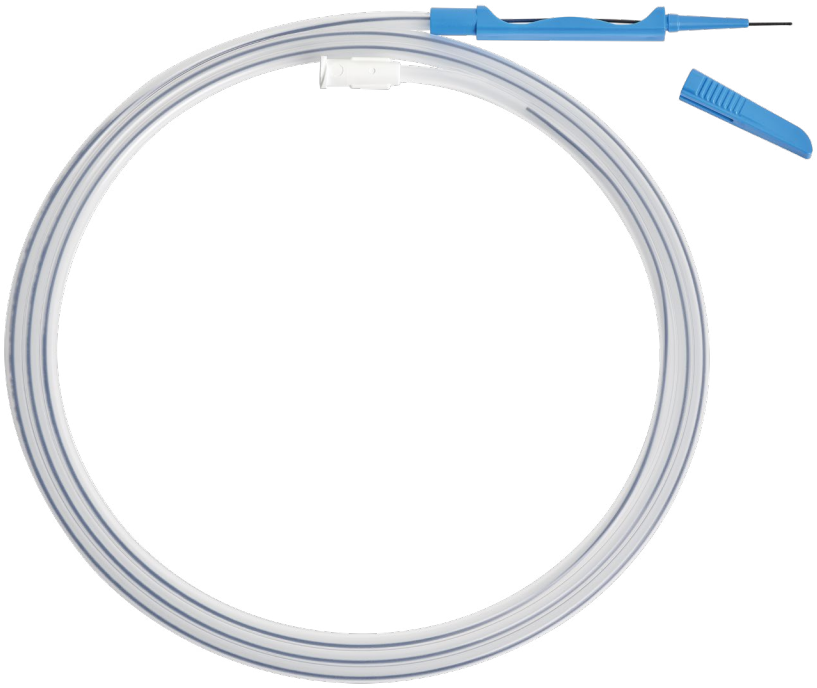
- 0.035″ guidewire
- PTFE coating offers a smooth wire surface to facilitate advancement
- Precise control and positioning
- Flexible tip to limit risk of trauma during advancement
- Radiopaque for fluoroscopic visualization

Soprano®

Hybrid guidewire

Pitch perfect design

The hydrophilic-coated tip of the Soprano hybrid guidewire is designed not only to ease insertion and instrument passage, but also to enhance responsiveness, maneuverability and precision in navigation. The core provides an ideal blend of stiffness and flexibility, for effective torque and enhanced control.



Item	Diameter (in)	Length (cm)	Distal Tip	Proximal Tip	EA/Sales UOM
Soprano®					
AEHA35	0.035"	150 cm	Straight	Standard	5 per box
Soprano® Dual Flex					
AEHB35	0.035"	150 cm	Straight	Dual Flex	5 per box

Available exclusively in boxes of 5

Soprano®

The hydrophilic flexible tip reduces surface friction, and its round distal tip creates a lubricious surface for ease of insertion and navigation.

Soprano® Dual Flex

The Soprano Dual Flex features a flexible proximal end designed to ease passage and to minimize the risk of scope damage.

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 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.

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.com.

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.com.

Complications from the use of this device should be brought 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.

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.

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.

ImaJin® Pyelostent® Silicone Double Loop Ureteral Stent Kit Brief Statement

Indications:
Drainage of the upper urinary tract and/or ureteral healing during management of ureteral stenosis:Partial enlargement of the stent diameter, for localized stenosis of the ureteropelvic junction in adult and pediatric (adolescents) patients. The Pyelostent® 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:
The choice of the characteristics and the size of the stent is under the responsibility of the physician. It should be appropriate to the patient's anatomy, as evidenced, for example, through imaging during surgery. 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.

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. Recommendations to maintain adequate fluid intake and, if needed, advice on diet to follow after surgery should be given to the patients. The physician should provide the patients with the medical device implant card and advise them to keep this card with them during the whole implantation period and to inform other healthcare professionals.

The risks and benefits of using ImaJin® Pyelostent® 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.

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 (USA) law 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.

Seldinger PTFE Guidewires Brief Statement

Indications:
All endourologic procedures or percutaneous urologic procedures requiring a guidewire. Stiff guidewires are particularly indicated for the insertion of a percutaneous nephrostomy.

Contraindications:
- These guidewires are not intended for use other than for endourologic procedures.
- Do not use, when, in the judgement of the physician, such a procedure would be contrary to the best interest of the patient.
- Any contraindication of the endourological procedure (untreated urinary tract infection, uncorrected haemostasis disorder).

Warnings and Precautions:
- The Seldinger guidewires are P.T.F.E coated.
- Do not kink the guidewire. If the guidewire becomes kinked it cannot be used. Do not try to straighten the guidewire if it has become kinked.
- Do not resterilize this product.
- The risks and benefits of using Seldinger guidewire should be considered in patients.
- Do not use if the patient has an allergy to device components.

Potential Complications:
- Do not use this guidewire with any electrosurgical equipment such as an electric scalpel to avoid the risk of iatrogenic burns.
- Perforation of the ureter is a classic 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.

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.

For Rx Only

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

Soprano®/Soprano® Dual Flex Brief Statement

Intended use:
This device is intended to be used to facilitate the placement of endourological instruments during diagnostic or interventional procedures.

Indications:
Endourological guidewires are used to facilitate the insertion of endoscopic and/or consumable devices or to keep the path of an access once a ureteral or a percutaneous access has been established.

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

Untreated urinary tract infections.

Uncorrected haemostasis disorders.

The safety of some endourologic procedures should be evaluated in pregnant women.

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:
This device must only be used by trained and experienced physicians with a thorough understanding of the technical basics, clinical applications, and risks of using guidewires to prevent damage to the guidewires and patient harm. The users should be familiar with the appropriate techniques to manage the potential complications associated with the use of the device.

Failure to abide by the following warnings might result in abrasion of the hydrophilic coating, release of fragments from the guidewire, damage to or breakage/separation of the guidewire, or perforation of tissue that may necessitate intervention.

Any use other than the stated intended use is under the responsibility of the physician.

Potential Complications:
The following side effects have been reported although their occurrence greatly depends on patients' medical conditions. Side effects include but are not limited to: mucosal irritation, tissue lesion, bleeding (e.g., hematuria, hemorrhage), perforation of the urinary tract or close organs, infection (e.g., urinary tract infection, pyelonephritis, severe infection…), burns when in contact with an electrosurgical equipment, ureteral avulsion, and foreign object in body (which may additionally cause pain, dysuria, or frequency). Other unusual side effects may include allergic reactions to guidewire materials.

Advice to the Patient:
The physician should educate the patient on his/her diagnostic or interventional procedure. The patient should be advised to inform the physician immediately if any side effect (e.g., blood in the urine, signs of infection) occurs.

The risks and benefits of using Soprano®/Soprano® Dual Flex 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 (USA) law restricts this device to sale by or on the order of a physician.

Notes:

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 & Skin Care, Interventional Urology and Voice & Respiratory Care. 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
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