Endourology your way

Endourology

Product Catalog | 2023

Coloplast

The Coloplast History

Coloplast has a long history of providing quality, innovative products to support endourologists and their patients. Our story began in 1893 in Sarlat, France where Porges Laboratories specialized in the manufacturing of catheters and medical devices for urology. Today, the Coloplast endourology brand is recognized globally for delivering differentiated and clinically-focused disposable stone management products that help make life easier for people with intimate healthcare needs.

Coloplast's business includes Ostomy Care, Continence Care, Wound and Skin Care and Interventional Urology. We work closely with people who have intimate healthcare needs. We listen to their needs and respond with products that help make their lives easier.

With a world class innovative spirit and the ultimate objective of always being able to make life easier, Coloplast Interventional Urology presents its latest dedicated Endourology product catalog. Coloplast is proud to provide you with the highest level of services, products and support.

Our Customer Service and Sales Representatives are available whenever you need them to help you find the right solutions to your specific requirements.

To Order Call Toll-Free 800.258.3476
These products may be ordered directly from Coloplast.

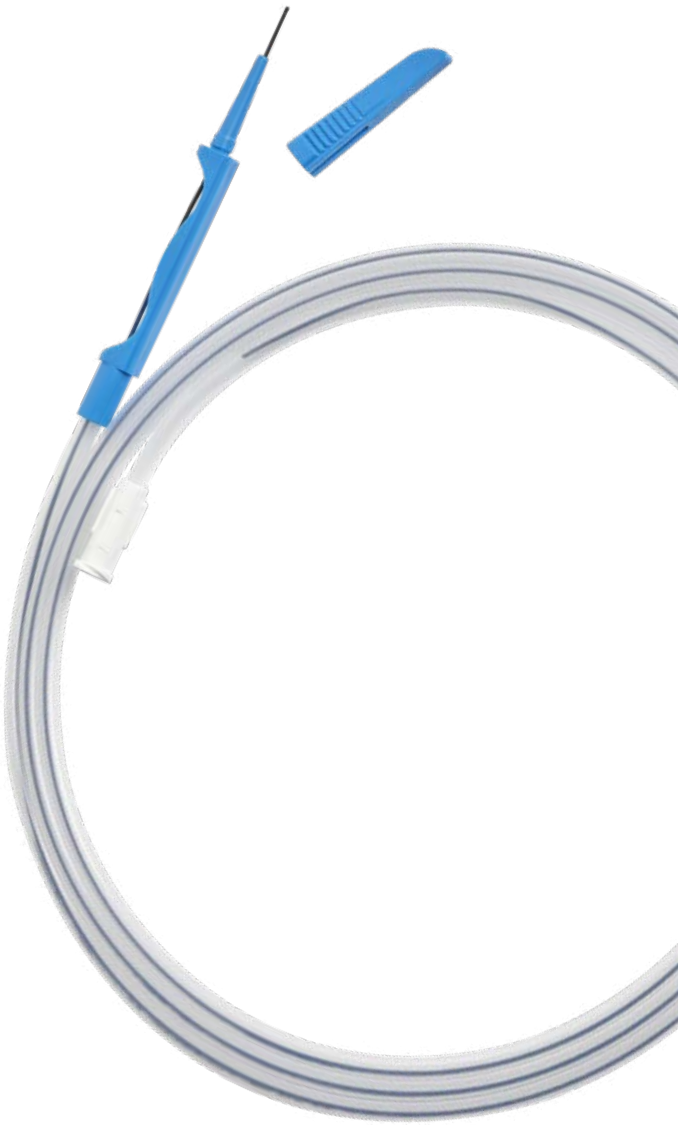
Table of Contents

Guidewires

Soprano® Hybrid Guidewire

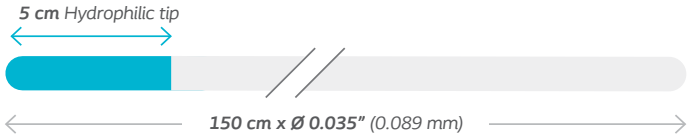
*Tuned for **peak** performance*

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.



Soprano®

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

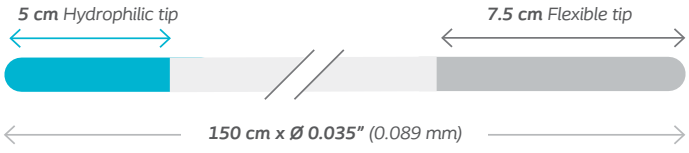


Diameter (inch)	Length (cm)	Tip	Item
0.035"	150 cm	Straight	AEHA35

5 per box

Soprano® Dual Flex

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



Diameter (inch)	Length (cm)	Tip	Item
0.035"	150 cm	Straight	AEHB35

5 per box

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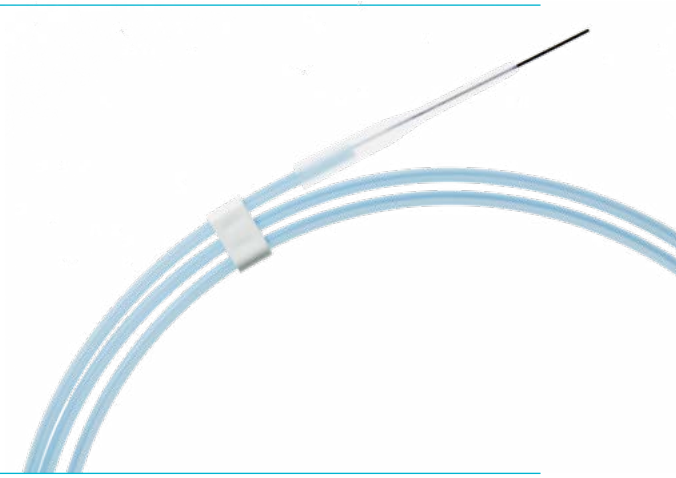
Orchestra® Hydrophilic Nitinol Guidewires

Diameter (inch)	Length (cm)	Shaft	Tip	Item
0.035	150	Standard	Straight	AEAD35
0.035	150	Standard	Angled	AEAE35
0.035	150	Stiff	Straight	AECD35
0.035	150	Stiff	Angled	AECE35

5 per box



Fixed Core PTFE-Coated Seldinger Guidewires

Diameter (inch)	Length (cm)	Shaft	Tip	Item
0.032	150	Standard	Straight	AE0032
0.035	150	Standard	Straight	AE0035
0.038	150	Standard	Straight	AE0038
0.032	90	Standard	Straight	AE0E32
0.038	90	Standard	Straight	AE0E38
0.035	150	Stiff	Straight	AE0C35
0.038	80	Stiff	J Tip	AE1138

5 per box

Movable Core PTFE-Coated Seldinger Guidewires

Diameter (inch)	Length (cm)	Shaft	Tip	Item
0.032	150	Standard	Straight	AE0A32
0.035	150	Standard	Straight	AE0A35
0.038	150	Standard	Straight	AE0A38
0.035	150	Stiff	Straight	AE0D35

5 per box

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Ureteric Catheters

Hydrophilic-Coated Floppy Tip Ureteral Catheter

Diameter (Fr)	Length (cm)	Guidewire Compatibility (inch)	Item
5	70	0.035	ACR205
6	70	0.035	ACR206
7	70	0.035	ACR207

5 per box

Chevassu Ureteral Catheters for Retrograde UreteroPyelography (RUP)

Diameter (Fr)	Cone/Bulb Diameter (Fr)	Length (cm)	Guidewire Compatibility (inch)	Item
3	4	70	–	AC5904
3	5	70	–	AC5905
4	6	70	–	AC5906
5	7	70	–	AC5907
5	8	70	–	AC5908
6	9	70	–	AC5909
7	10	70	–	AC5910
7	11	70	–	AC5911
7	12	70	–	AC5912

5 per box

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Flush Ureteral Catheter

Diameter (Fr)	Length (cm)	Side Eyes	Guidewire Compatibility (inch)	Item
Straight Open Tip				
4.8	74	–	0.038	ACP205
6	74	–	0.038	ACP206
7	74	–	0.038	ACP207
8	74	–	0.038	ACP208
Straight Open Tip with Side Eyes				
3	74	2	0.021	ACP303
4	74	2	0.035	ACP304
4.8	74	2	0.038	ACP305
6	74	2	0.038	ACP306
7	74	2	0.038	ACP307
Coude Open Tip				
3	74	–	0.021	ACP603
4	74	–	0.035	ACP604
4.8	74	–	0.038	ACP605
6	74	–	0.038	ACP606
7	74	–	0.038	ACP607
Coude Open Tip with Side Eyes				
3	74	2	0.021	ACP403
4	74	2	0.035	ACP404
4.8	74	2	0.038	ACP405
6	74	2	0.038	ACP406
7	74	2	0.038	ACP407

5 per box

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Dilation

ReTrace® Access Sheath

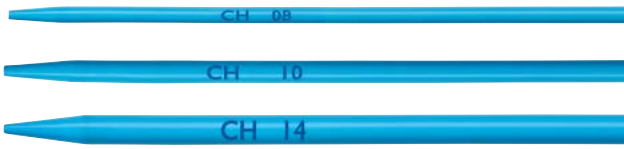
Efficiency + safety: You ***can*** have it all.

Now you don't have to give up procedural efficiency to gain safe, secure access. The ReTrace® ureteral access sheath has a flexible introducer designed to respect the anatomy and reduce injury—a real win for patients. Its unique single wire design lets you convert working guidewire into safety guidewire—and vice versa if you need to reintroduce the sheath. That reduces the number the number of steps, improving procedure time and reducing cost—a big win for clinical efficiency, too.

Diameter (Fr)	Length (cm)	Item
10-12	28	ASXL10
	35	ACXL10
	45	AXXL10
	55	ALXL10
12-14	28	ASXL12
	35	ACXL12
	45	AXXL12
	55	ALXL12

1 each

Ureteral Dilators



Diameter (Ch)	Diameter (Fr)	Length (cm)	Item
8	10	48	RBD010
12	14	48	RBD014

10 per box

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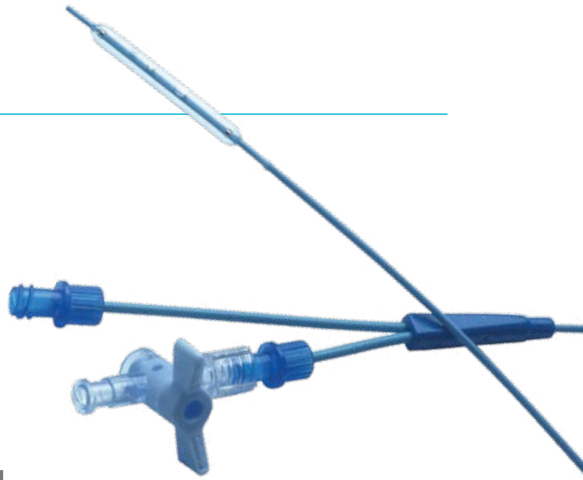
In-Ka® Ureteral Balloon Dilatation Catheters

PET balloon for an effective and uniform dilatation of the ureteral meatus or stenosis during endoscopic procedures. Compatible with a 0.035" guidewire.



Catheter		Balloon			
(Ch/Fr)	Length (cm)	(Ch/Fr)	Diameter (mm)	Length (cm)	Item
Inflating Device: Screw syringe with a manometer					
5	75	12	4	4	BD4044
		15	5		BD4045
		18	6		BD4046
Inflating Device: Screw syringe with luer-lock					
5	75	12	4	4	BD4144
		15	5		BD4145
		18	6		BD4146

1 each

Manometer

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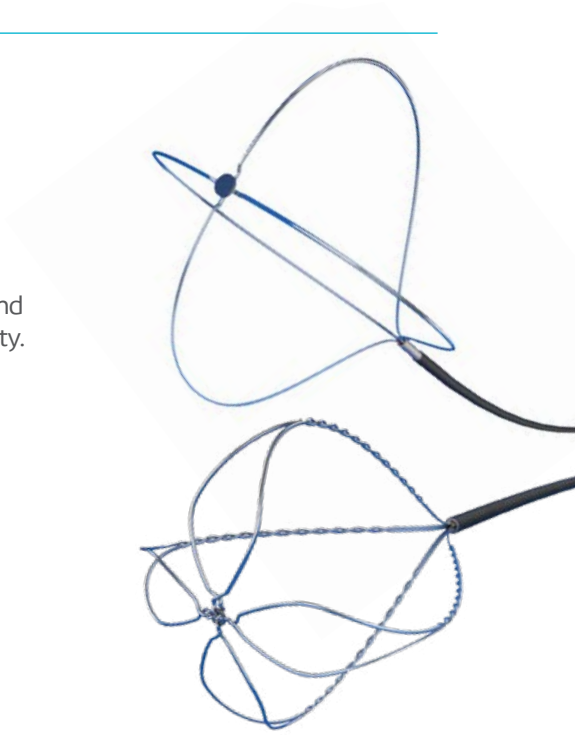
Dormia® Nitinol Stone Baskets



Full line of stone management solutions.

The Dormia® line of nitinol stone baskets—including No-Tip, Front, and N. Stone options—gives you real choice and selection for stone management. Available in options for use during flexible, semi-rigid and rigid ureteroscopy within the ureter and kidney. Nitinol alloy provides excellent compromise between strength and flexibility.

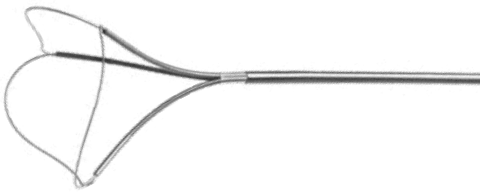
Dormia® No Tip Stone Retrieval Devices

Diameter (Ch/Fr)	Length (cm)	Basket Size (mm)	Item
1.5	120	9	EXN934
2.2	120	11	EXN734
3	90	14	EXN434

Dormia No Tip 1.5 and 2.2 for use in the kidney and in the ureter, during flexible, semi rigid or rigid ureteroscopy.
Dormia No Tip 3.0 for use in the ureter during semi rigid and rigid ureteroscopy.

1 each

Dormia® Front Nitinol Hybrid Grasper

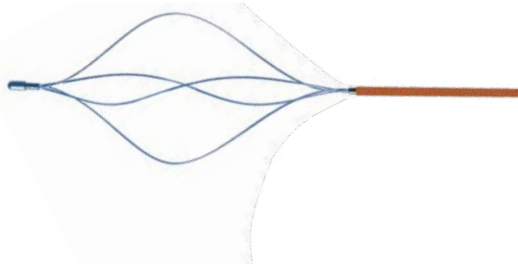


Diameter (Ch/Fr)	Length (cm)	Basket Size (mm)	Item
1.5	120	8	DOF158
1.5	120	11	DOF151
2	120	8	DOF208
2	120	11	DOF201

Dormia Front for use in the kidney and the ureter during flexible, semi rigid or rigid ureteroscopy.

1 each

Dormia® N. Stone Retrieval Devices



Diameter (Ch/Fr)	Length (cm)	Basket Size (mm)	Item
2.5	90	12.5	EXT624
3	90	15	EXT424
4	90	15	EXT224

Dormia N. Stone for use in the ureter, during semi-rigid and rigid ureteroscopy.

1 each

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Holmium Laser Fibers & Accessories

SabreGuard® Holmium Laser Fibers

Core Size (µm)	Tip	Item
150	Round	SUN150
200	Round	SUN200

3 each

SabreLine® Single-Use Holmium Laser Fibers

Core Size (µm)	Tip	Item
200	Radius	SUE200
272	Radius	SUE272
365	Radius	SUE365
550	Straight	SUD550
940	Straight	SUD940

3 each

SabreLine® Reusable Holmium Laser Fibers

Core Size (µm)	Tip	Item
272	Straight	RUS272
365	Straight	RUS365
550	Straight	RUS550
940	Straight	RUS940

1 each

Holmium Laser Fibers Accessories

Description	Size (µm)	Item
150 Series Laser Fiber Stripper	150	STR150
200 Series Laser Fiber Stripper	200	STR200
272 Series Laser Fiber Stripper	272	STR272
365 Series Laser Fiber Stripper	365	STR365
550 Series Laser Fiber Stripper	550	STR550
940 Series Laser Fiber Stripper	940	STR940
Laser Fiber Cleaving Pen	–	CLPENS
Laser Fiber Cleaving Tool - Box of 5	–	CLTOOL

1 each

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Thulium Fiber Laser, Fibers & Accessories

Coloplast TFL Drive Thulium Fiber Laser (TFL)

The Coloplast TFL Drive Thulium Fiber Laser is an all-in-one solution for lithotripsy, benign prostatic hyperplasia (BPH) and precise soft tissue surgery. The system features an intuitive graphical user interface that assists navigation with built-in safety precautions.

Description	Item
Coloplast TFL Drive 60W Thulium Fiber Laser *Includes double footswitch, safety goggles (2), power cord, user manual, and accessory case containing fiber stripper for optical fibers 300 to 1000 µm, Fiber stripper for optical fibers 100 to 400 µm, interlock connector, optical blast shield and key for use with Coloplast TFL Drive Laser (TFL).*	TFLD01

Coloplast TFL Drive Accessories

Description	Item
Coloplast TFL Drive Accessory Case *Includes: Fiber stripper for optical fibers 300 to 1000 µm, Fiber stripper for optical fibers 100 to 400 µm, interlock connector, optical blast shield and key for use with Coloplast TFL Drive.*	CPCASE
300 to 1000 µm optical fiber stripper	FS0310
100 to 400 µm optical fiber stripper	FS0104
Key	KEY001
Interlock connector	CPIC01
Optical Blast Shield	CPOBS1
Protecting safety goggles (2 sets)	CPGL01
Double footswitch	CPDFS1
Removable Power Cord (16A plug)	PLUGUS

1 each

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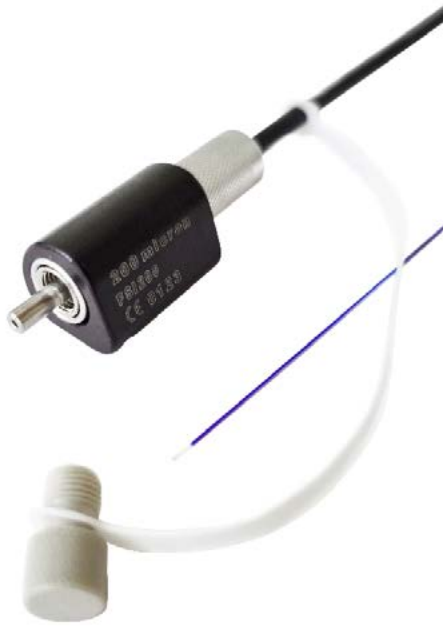
Coloplast TFL Drive Optical Fibers

Description	Size (µm)	Item
Single Use	150	FSI150
	200	FSI200
	272	FSI272
	272 Ball Tip	FBI272
	365	FSI365
	550	FSI550
	600 Lateral	FLI600
	800	FSI800
	1000	FSI000
5x Reusable	200	FSV200
	272	FSV272
	365	FSV365
	550	FSV550
	800	FSV800
	1000	FSV000
10x Reusable	200	FSX200
	272	FSX272
	365	FSX365
	550	FSX550
	800	FSX800
	1000	FSX000



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ImaJin® Hydro Ureteral Stent Kits

More comfort. *Less* encrustation. *Longer* indwell.

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.

Indwelling time of up to 12 months
Packaged with steerable pusher

Diameter (Ch/Fr)	Length (cm)	With Orchestra® Guidewire 0.035″	Without Guidewire
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

1 each

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Biosoft® Duo Stent Kits

Indwelling time of up to 6 months
Packaged with steerable pusher

Diameter (Ch/Fr)	Length (cm)	With Seldinger Guidewire 0.035″	With Orchestra® Guidewire 0.035″	Without guidewire
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	--	--

1 each

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Vortek® Hydro Double Loop Ureteral Stent Kits

Improved glide and facilitated insertion with ***Hydrophillic-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
Packaged with steerable pusher

Diameter (Ch/Fr)	Length (cm)	With Seldinger Guidewire 0.035″	With Orchestra® Guidewire 0.035″	Without Guidewire
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

1 each

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Vortek® Ureteral Stent Kits

Indwelling time of up to 6 months
Packaged with steerable pusher

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

1 each

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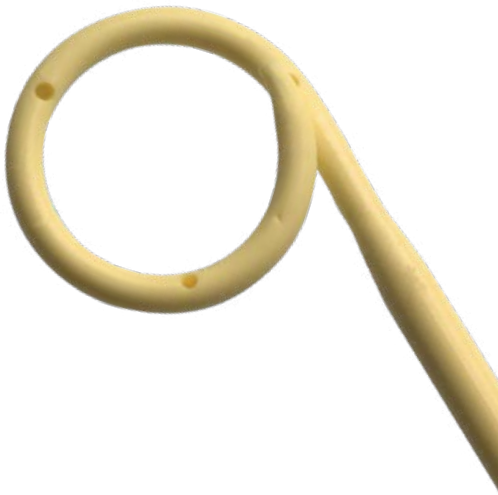
Specialty Ureteral Stents

Stenostent® Ureteral Stent

The ***comfortable*** way to treat stenosis.

Patients want relief and comfort and now you can really deliver. The Stenostent® silicone specialty stent is designed for maximum patient comfort—its soft, smooth material has demonstrated greater patient comfort over Percuflex.™ And the coil tapers to 8 Fr, so there's less material in the bladder (and less "ouch" for your patients). Stenostent is easy to place and withdraw, too—it's inserted and removed like a traditional double loop stent—and paired with a unique steerable positioner designed for precise placement.



Indwelling time of up to 12 months

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

1 each

Pyelostent® Ureteral Stent

Indwelling time of up to 12 months
Packaged with steerable pusher

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

1 each

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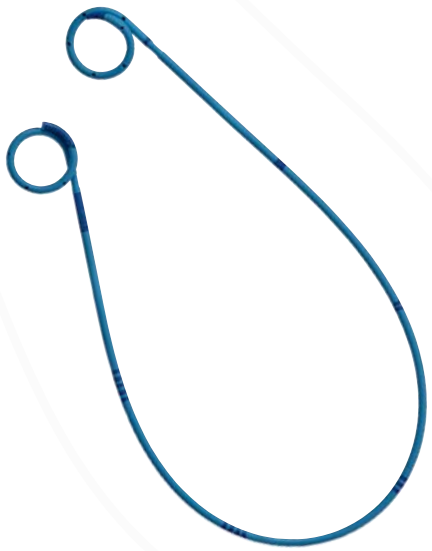
Novoflow™ Reinforced Ureteral Stent

The inner layer is reinforced compared to the standard Vortek ureteral stent. It allows passing through stricture and the stiffness of material offers an excellent resistance to compression.

Indwelling time of up to 6 months
Packaged with steerable pusher

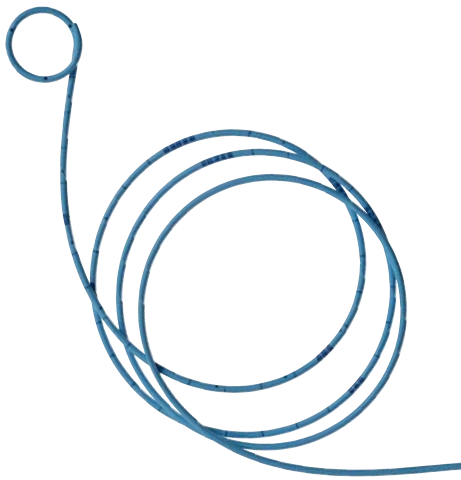


Diameter (Ch/Fr)	Length (cm)	With Orchestra® Guidewire	Without Guidewire
7	26	BCCU74	BCCJ74
	28	BCCU75	BCCJ75
	30	BCCU76	BCCJ76
8	26	BCCU84	BCCJ84
	28	BCCU85	BCCJ85
	30	BCCU86	BCCJ86

1 each

Vortek® Single Loop Stent Kits

Indwelling time of up to 30 days
Packaged with a .035 PTFE fixed-core guidewire, a clamp, a connector with a leur end and latex leur-bag connector



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
6	90	AC4406	ACA206	ACA106
7	90	AC4407	ACA207	ACA107
8	90	AC4408	ACA208	ACA108

1 each

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Stent Removal

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.

Description	Item
Single-Use ISIRIS Devices *5 per box*	ALFA01
ISIRIS Monitor *1 each*	MN0001

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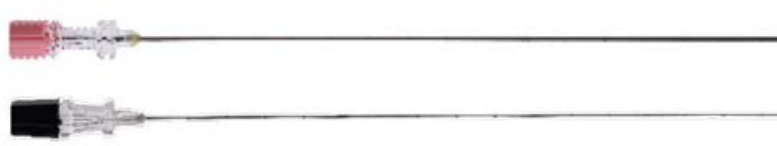
Nephrostomy

Percutaneous Access Needles

Diameter	Tip	Item
18 G	Chiba	RAC018
22 G	Chiba	RAC022

5 per box



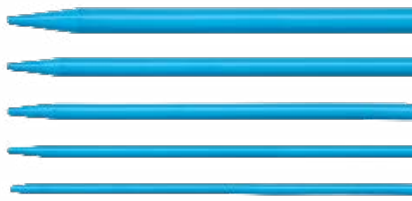
Percutaneous Nephrostomy Dilators

Dilators	Item
8F Simple Dilator	RBA008
10F Simple Dilator	RBA010
12F Simple Dilator	RBA012

5 per box

Dilator Sets	Item
6F, 8F, 10F, 12F, 14F Dilator Set	RBB014
6F, 8F Dilator Set with Splittable Working Sheath	RBC008
6F, 8F, 11F Dilator Set with Splittable Working Sheath	RBC010
6F, 8F, 10F Dilator Set Set 1	RBB010

1 set per box



In-Ka® Nephrostomy Balloon Catheters

Catheter		Balloon		Amplatz Sheath		
Diameter (Fr)	Length (cm)	Diameter (Fr)	Length (cm)	Inner Diameter (Fr)	Length (cm)	Item
Inflating Device: Screw Type Syringe						
7	55	30	12	30	17	BD3010
Inflating Device: Screw Type Syringe						
7	55	30	12	30	17	BD3020

1 each

Amplatz Sheaths

Inner Diameter (Fr)	Length (cm)	Item
30	17	RF3017
30	19	RF3019

5 per box

To Order Call Toll-Free 800.258.3476

These products may be ordered directly from Coloplast.

Images are not to scale and are for illustrative purposes only.

Drainage Catheters

X-Flow® Silicone Prostatic Catheters

Balloon (mL)	Ways	Diameter (Fr)	Length (cm)	Item
Dufour Tip				
30	3	18	42	AB6A18
		20		AB6A20
		22		AB6A22
		24		AB6A24
50	3	18	42	AB6318
		20		AB6320
		22		AB6322
		24		AB6324
	2	18	42	AB6418
		20		AB6420
		22		AB6422
		24		AB6424
Couvelaire Tip				
50	3	18	42	AB6118
		20		AB6120
		22		AB6122
		24		AB6124
	2	18	42	AB6518
		20		AB6520
		22		AB6522
		24		AB6524

5 per box

To Order Call Toll-Free 800.258.3476

These products may be ordered directly from Coloplast.

Images are not to scale and are for illustrative purposes only.

Balloon (mL)	Ways	Diameter (Fr)	Item
Straight Tip			
50	2	18	AB6618
		20	AB6620
		22	AB6622
		24	AB6624
30	3	18	AB6C18
		20	AB6C20
		22	AB6C22
		24	AB6C24
50		18	AB6018
		20	AB6020
		22	AB6022
		24	AB6024
Delinotte Tip			
50	2	18	AB6718
		20	AB6720
		22	AB6722
		24	AB6724
	3	18	AB6218
		20	AB6220
		22	AB6222
		24	AB6224

5 per box

To Order Call Toll-Free 800.258.3476

These products may be ordered directly from Coloplast.

Images are not to scale and are for illustrative purposes only.

Drainage Catheters

Folysil® Pediatric Silicone Foley Catheters

Length (cm)	Balloon (mL)	Eyes	Diameter (Ch/Fr)	Item
Pediatric Straight				
30	1.5	2	6	AA6106
30	3	2	8	AA6108
34	3	2	10	AA6110
Pediatric Tiemann				
30	3	1	8	AA6308
34	3	1	10	AA6310
Pediatric Open (Over Guidewire)				
30	3	2 + tip	8	AA6408
34	3	2 + tip	10	AA6410

5 per box

To Order Call Toll-Free 800.258.3476

These products may be ordered directly from Coloplast.

Images are not to scale and are for illustrative purposes only.

Folysil® Silicone Foley Catheters

Length (cm)	Balloon (mL)	Eyes	Diameter (Ch/Fr)	Item
Male Straight				
41	10	2	12	AA6112
			14	AA6114
41	15	2	16	AA6116
			18	AA6118
			20	AA6120
			22	AA6122
			24	AA6124
41	30	2	18	AA6C18
			20	AA6C20
			22	AA6C22
			24	AA6C24
Open (Over Guidewire)				
40	10	2 + tip	12	AA6412
			14	AA6414
40	15	2 + tip	16	AA6416
			18	AA6418
			20	AA6420
			22	AA6422
			24	AA6424
Tiemann				
40	10	1	12	AA6312
			14	AA6314
40	15	1	16	AA6316
			18	AA6318
			20	AA6320
			22	AA6322
			24	AA6324
Neobladder 3-Way				
42	30	6 + tip	20	AA6820
			22	AA6822

5 per box

To Order Call Toll-Free 800.258.3476

These products may be ordered directly from Coloplast.

Images are not to scale and are for illustrative purposes only.

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 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.

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.

URETERIC CATHETERS BRIEF STATEMENT

Indications:
Drainage catheters: bevel, olive or cylindrical tip straight catheters, olive tip elbowed catheters. Catheters for Retrograde Uretero-Pyelography (R.U.P.): Chavassu, cone or Braasch catheters. International catheters: flush, open straight, open elbowed and open floppy tip catheters.

Contraindications:
Those for ureteral catheterization.

The evaluation of the allergic background of a patient is the health care professional's responsibility.

Warnings and Precautions:
This type of device 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, migration, bladder irritation systems, pain and erosion. Some events may be related to this procedure, amongst which those related to the guidewire: ureteral perforation, or burns when in contract with an electrosurgical equipment.

Advice to Patient:
Physicians should educate patients on their catheter and the need for regular monitoring of their catheter and to follow up with their doctor if any anomaly or dysfunction is noted.

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.

RETRACE® URETERAL ACCESS SHEATH BRIEF STATEMENT

Indications:
To establish a continuous conduit during urological endoscopic procedures facilitating the in and out passage of endoscopes and other instruments into the urinary tract.

Contraindications:
All usual contraindications to ureteroscopic procedures. Any known allergies to the medical device materials. The evaluation of the allergic background of a patient is the health care professional's responsibility.

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.

The risks and benefits of using ReTrace® ureteral access sheath 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.

URETERAL DILATORS BRIEF STATEMENT

Indications:
Dilation of the ureter during ureteroscopic procedures.

Contraindications:
Same as for ureteral dilatation.
Any contraction to endoscopy.
Any known allergies to the medical device materials.

Warnings and Precautions:
This type of device 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:
Hematuria due to local ureteral bleeding may occur.

As with any dilation procedure, the use of a ureteral dilator may cause traumatic tissue lesions.

There is a risk of injury to the urinary tract, particularly if the instructions for use have not been complied with, and especially if the dilator has been positioned without radioscopic control.

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.

IN-KA® URETERAL BALLOON DILATATION CATHETERS BRIEF STATEMENT

Indications:
In-Ka® ureteral balloon dilatation catheters are intended for:

- Dilation of ureteral meatus and/or ureteral canal during endoscopic procedures.
- Treatment of ureteral stenosis.

Contraindications:
- Any contraindication to endoscopy (untreated urinary tract infection).
- 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 having a thorough understanding of the technical principles, clinical applications, and risks associated with ureteral dilation.
- The risks and benefits of In-Ka® Ureteral Balloon Dilation Catheters should be considered in patients, including pregnant women.

Potential Complications
As with any dilation procedure, the use of a dilatation balloon may be associated with several risks including, but not limited to:

- Hematuria.
- Damage to the urinary tract (tissue trauma, ureteral perforation), particularly if the instructions for use have not been complied with, and especially if the catheter has been positioned without fluoroscopic control.

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.

DORMIA® NO-TIP BRIEF STATEMENT

Indications:
Extraction of urinary tract calculi.

Contraindications:
Any conditions contraindicating the use of a stone extractor. Any known allergies to the medical device materials. Extraction of biliary duct calculi.

Warnings and Precautions:

This type of instrument must only be used by trained and experienced professionals.

Adverse Events:
Lesions of the urinary tract if the operating procedure and the warnings set out below are not observed.

The risks and benefits of using Dormia® No-Tip 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.

DORMIA® FRONT STONE EXTRACTOR BRIEF STATEMENT

Indications:
For stone removal during the course of rigid and flexible ureterorenoscopy, cystoscopy, endoscopic retrograde cholangioscopy (ERC), endoscopi retro- grade cholangiopancreatography (ERCP).

Intended Purpose:
Stone retrieval devices serve for the endoscopic removal of stones and their fragments from the urogenital and gastroenterological tract during the course of retrograde interventions.

Contraindications:
The contraindications of the above endoscopic interventions apply. The stone retrieval devices may not be used for Percutaneous Nephrolithotomy (PCNL). Stone retrieval devices may not be used for intravascular applications or other application areas, as sufficient clinical experience is lacking for this.

Warnings and Precautions:
If used improperly, stone retrieval devices can cause the perforation of tissue, in particular if the stones are lodged on the vessel wall. The stone bed is then frequently very fragile. The use of contrast media can lead to adhesions that can limit the functionality of the stone retrieval device. Some stones may be too large to be removed with the stone retrieval device through the endoscope because the stone could get stuck in the working channel of the endoscope during removal. Therefore, always the complete system of endoscope and retrieval device shall be removed and the retrieval device shall be emptied outside the human body. Stone retrieval devices may not be used for mechanical stone crushing (lithotripsy). This type of device must be used only by trained and experienced professionals. Do not use the stone retrieval device if the stone is too large. If excessive force is used, there is a potential for vessel wall tear.

Potential Complications:
The following complications are possible when using stone retrieval devices for stone removal:

- Entrapment of large stones
- Inability to disengage the dislodger from irretrievable stones requiring the application of other interventions
- Tissue perforation
- Breakage of the stone retrieval device
- Infection
- Non-retrievable stones

The risks and benefits of using Dormia® Front Stone Extractor 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.

DORMIA® NO-TIP, N. STONE BRIEF STATEMENT

Indications:
Extraction of urinary tract calculi.

Contraindications:
Any conditions contraindicating the use of a stone extractor. Any known allergies to the medical device materials. Extraction of biliary duct calculi.

Warnings and Precautions:
Do not use with a flexible endoscope. This type of instrument must only be used by trained and experienced professionals.

Adverse Events:
Lesions of the urinary tract if the operating procedure and the warnings set out below are not observed.

The risks and benefits of using Dormia® No-Tip, N. Stone 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.

SABREGUARD® SABRELINE® LASER FIBERS BRIEF STATEMENT

Indications:
The Coloplast SabreGuard® and SabreLine® Laser Fibers are indicated for use in all surgical specialties in which compatible laser systems with operational wavelengths between 500 nm – 2200 nm have received regulatory clearance.

The laser delivery devices are intended for use with any cleared surgical laser with a SMA-905 connector.

Contraindications:
The laser fibers are contraindicated for treatment of patients for whom endoscopic procedures are contraindicated. Refer to the laser User Manual for contraindications related to the laser system.

Warnings and Precautions:
Before attempting to use the laser fiber, the physician should fully understand the use of the laser, safety considerations, tissue interaction, and proper technique specific to the treatment for which the physician intends to use this product.

Single-use fibers are not to be reused. Reuse may compromise device integrity and lead to malfunction or failure which may result in patient or user injury.

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.

COLOPLAST TFL DRIVE BRIEF STATEMENT

Indications:
The Coloplast TFL Drive laser device and its accessories are intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissue with or without an endoscope, in the following indications: Urology, Lithotripsy, Gastroenterological Surgery and Gynecological Surgery.

Contraindications:
The use of the laser is contraindicated:

- In patients whose general medical condition contraindicates surgical intervention.
- When appropriate anaesthesia is contraindicated by patient history or inability to receive anesthesia.
- Where tissue (especially tumors) is calcified.
- For hemostasis of vessels with diameters over approximately two millimeters.
- Where laser therapy is not considered the treatment of choice.
- In patients who have recently undergone radiotherapy. Such patients may be at greater risk of tissue perforation or erosion.
- In patients unable to receive endoscopic treatment.
- In patient suffering from bleeding disorders and coagulopathy.
- Diagnosed with acute or chronic prostatitis, prostate cancer, or severe urethral stricture.
- Diagnosed at the time of treatment with acute or chronic urinary tract infection.
- Patients with compromised renal function or upper urinary tract obstructive diseases.

- Patients who still wish to have children.
- Patients with an ASA classification of physical status 5.
- Patients with a prostate gland > 120g.

Warnings and Precautions:
Clinical studies have shown that patients who have undergone radiation therapy present a greater risk of perforation or tissue erosion. The Coloplast Drive Laser System is a surgical device that should be used only by physicians or surgeons who have been thoroughly trained in laser surgery. Surgeons using Coloplast TFL Drive Laser System must understand the laser's unique properties prior to using the device.

As with conventional endoscopic surgery, the possibility of complications and adverse events (such as chills, fever, edema, hemorrhage, inflammation, tissue necrosis or infection) may occur following treatment. In extreme cases, death may occur due to procedural complications or concurrent illness. The laser may not be effective for coagulation in massive haemorrhage situations. The surgeon must be prepared to control haemorrhages with alternative non-laser techniques, such as ligature or cautery. The risk of infection and scarring associated with any surgical procedure has to be taken into account. Tissue perforation may result if excessive laser energy is applied. This could occur through the use of excessive laser power or the application of a correct power for excessive periods, particularly in diseased tissue. The use of mechanical pressure on the Single-Use and Reusable Optical Fiber devices does not increase its cutting or vaporization effects but may induce bleeding, thermal damage and fiber destruction.

The manufacturer has no clinical information or experience concerning the use of the Laser System on pregnant women or nursing mothers. There is no guarantee that treatment with the Laser System will entirely eliminate the disease. Repeated treatment or alternative therapies may subsequently be required.

Potential Complications:
Complications and risks are the same of the conventional laser surgery. Acute pain may occur immediately following laser therapy and may persist for as long as 48 hours. Immediately following laser therapy, the patient may experience fever and leucocytosis, which are commonly associated with tissue destruction. These generally resolve without treatment. Laser ablated tissue may become necrotic or infected after treatment. In case of concerns about any possible infection, appropriate treatment should be carried out. Acute complications and non-thermal risks include induced hemorrhage, ulceration, perforation, edema, pain, fever, leukocytosis, and chills. Critical complications and thermal risks include healing delay, perforation, stenosis, delayed hemorrhage, sepsis, and embolism.
The following complications could be serious and could result in death:

- Patients may experience bleeding at the site of laser therapy. Haematocrit analysis after treatment is recommended to identify this potential complication.
- Sepsis can result from performing any surgical procedure. In case of concerns about any possible sepsis, appropriate evaluations should be made.
- Perforation may occur as a result of laser treatment. In order to diagnose perforations, patients must be carefully followed post-operatively with appropriate tests.

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.

COLOPLAST TFL DRIVE LASER FIBERS BRIEF STATEMENT

Indications – Single Use Lateral and 150µm Optical Fibers:
Single Use Lateral and 150µm Optical Fibers are intended to be used to deliver the laser radiation to the target tissue when used with any cleared/certified surgical laser with operational wavelengths between 532 nm – 2200 nm equipped with SMA 905 or SMA 906 or compatible connector, as per the indications of the laser device used with.

Indications – Single Use and Reusable Optical Fibers:
Single Use and Reusable Optical Fibers are intended to be used in conjunction with any cleared surgical laser distributed by Coloplast equipped with SMA 905 or SMA 906 or compatible connector for use in general surgical applications (incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in contact or non-contact mode). Optical Fibers are also indicated for use in open or closed endoscopic applications where incision, excision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors or lesions, tissue vaporization, hemostasis and or coagulation may be indicated.

The Optical Fibers are indicated for use in general surgery, urology, gastroenterology, gynecology, dermatology, vascular surgery, neurosurgery, plastic surgery, ENT/otolaryngology, endovenous occlusion of the greater saphenous vein in the patient with superficial vein reflux and laser assisted lipolysis. Optical Fibers are also intended as an aid for otologic procedures, for use in incision, excision, coagulation and vaporization of soft and fibrous tissue including osseous tissue, and for use in lithotripsy.

Optical Fibers are indicated for use with laser devices emitting radiation from 532 nm to 2100 nm, with pulsed and continuous wave (CW) emission mode, and, but not limited, for use with Diode laser, Argon, KTP/532, Ho:YAG, Nd:YAG, Tm:YAG pulsed and continuous wave CW laser devices.

Optical Fibers may be used in surgical specialties or procedures for which compatible lasers have received regulatory clearance: for a complete information about applications, contraindications, precautions and warnings when using Optical Fibers it is necessary to refer to the applicable laser device User Manual.

Warnings and Precautions - Single Use, Single Use 150µm and Reusable Optical Fibers:
Optical Fibers shall be used by trained and qualified users only. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to a device failure which, in turn, may result in patient injury, illness or death (For Single Use Fibers Only). On patients with confirmed or suspected Transmissible spongiform encephalopathies (TSEs), also known as prion disease, use only Single-use Sterile Optical fibers.

Potential Complications - Single Use, Single Use 150µm and Reusable Optical Fibers:

Complications that could occur during laser treatments include local and/or systemic infection, thermal changes to the surrounding structures, local hematoma, dissection and perforation, tissue adhesion, distal tip detachment, and discomfort during and/or after (laser) energy application. In the unlikely event of a detached tip, it may be visually located through an appropriate scope and removed using forceps. Irrigate the area thoroughly to remove any traces of the tip.

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® SILICONE HYDROCOATED DOUBLE LOOP URETERAL STENT KIT BRIEF STATEMENT

Indications:
Drainage of the upper urinary tract over fistulas or ureteral obstacles. Healing of the Ureter. Cicatrisation stent.

Contraindications:
Untreated progressive infection of the upper urinary tract. Any known allergies to the medical device materials. 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. 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.

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 ImaJin® Silicone Hydrocoated 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.

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 (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.com.

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

STENOSTENT® URETERAL STENTS BRIEF STATEMENT

Indications:
Management of ureteral stenosis:
- Partial enlargement of the diameter: localized stenoses connected with ureteropelvic junction syndrome
- Total enlargement of the diameter: stenoses over all or part of the ureter

Contraindications:
Untreated progressive infection of the upper urinary tract. Any known allergies to the medical device materials.

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.

Adverse Events:
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 risks and benefits of using 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.

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.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:
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:
Surgical indication: The Vortek® Single Loop Ureteral Stent is intended for use in ureterostomy or vesical replacement in adult and pediatric (adolescents, children, and infants) patients requiring endourological procedure and/or short-term (less than 30 days) drainage of the upper urinary tract.
Endoscopic indication: The Vortek® Single Loop Ureteral Stent is intended for short-term (less than 30 days) drainage of urine from the upper urinary tract over fistulas or ureteral obstacles in adult and pediatric.

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:
The urine bag connectors contain natural latex which may cause allergic reactions. Formation of knots in lengthy stents have been reported as adverse events and may require surgical intervention to remove them. 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.

Adverse Events:
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.

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 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.

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.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.

PERCUTANEOUS ACCESS NEEDLES/CHIBA NEEDLE® BRIEF STATEMENT

Indications:
Puncture of the renal cavities.

Contraindications:
Some percutaneous renal procedures may be contraindicated in the following situations (unless the anticipated benefits outweigh the potential risks):

Uncontrolled haemostasis disorders.

Untreated urinary tract infection.

Malignant kidney or urinary tract tumor.

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 type of device must only be used by trained and experienced professionals having a thorough understanding of the technical principles, clinical applications, and risks associated with percutaneous renal access procedures.

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

Do not resterilize this product. Reuse of this single use product may create a potential risk to the patient.

Potential Complications:
The use of this device may be associated with several risks including, but not limited to: Bleeding/hematuria.

Damage (perforation) to the kidney, urinary tract or neighboring organs, particularly if the instructions for use have not been complied with, and especially if the procedure has been performed without image guidance control.

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.

IN-KA® PERCUTANEOUS BALLOON DILATATION CATHETER BRIEF STATEMENT

Indications:
For dilation of the tract to create a percutaneous renal access.

Contraindications:
Some percutaneous renal procedures may be contraindicated in the following situations (unless the anticipated benefits outweigh the potential risks):

- Uncontrolled haemostasis disorders.
- Untreated urinary tract infection.
- Malignant kidney or urinary tract tumor.

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 type of device must only be used by trained and experienced professionals having a thorough understanding of the technical principles, clinical applications, and risks associated with balloon dilation of the nephrostomy tract. The risks and benefits In-Ka® Percutaneous Balloon Dilatation Catheter should be considered in patients, including pregnant women.

Potential Complications:
As with any dilation or percutaneous access creation, the use of the dilatation balloon and Amplatz sheath may be associated with several risks including, but not limited to:

- Damage (perforation, tissue trauma) to the urinary tract, kidney, or neighboring organs, particularly if the instructions for use have not been complied with, and especially if the catheter or the sheath has been positioned without fluoroscopic control.
- Bleeding when withdrawing the sheath.

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.

AMPLATZ SHEATH BRIEF STATEMENT

Indications:
Used during renal dilatation to provide and maintain a nephrostomy tract.

Contraindications:
Some percutaneous renal procedures may be contraindicated in the following situations (unless the anticipated benefits outweigh the potential risks):

- Uncontrolled haemostasis disorders.
- Untreated urinary tract infection.
- Malignant kidney or urinary tract tumor.

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 type of device must only be used by trained and experienced professionals having a thorough understanding of the technical principles, clinical applications, and risks associated with percutaneous renal procedures.
- The risks and benefits Amplatz should be considered in patients, including pregnant women.

Potential Complications:
As with any dilatation or percutaneous access creation, the use of the Amplatz sheath may be associated with several risks including, but not limited to:

- Damage (perforation, tissue trauma) to the urinary tract, kidney, or neighboring organs, particularly if the instructions for use have not been complied with, and especially if the sheath has been positioned without fluoroscopic control.
- Bleeding when withdrawing the sheath.

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.

BALLOON URINARY CATHETERS BRIEF STATEMENT

Indications:
Foley catheters: urethral urinary catheterization. Only straight 2-way Foley catheters with a maximum balloon volume of 15 ml may be used for the suprapubic approach (except for ribbed catheters).

3-way Foley catheters: urethral urinary catheterization and postoperative bladder irrigation-lavage.

Prostate catheters:
- Short-term drainage of bladder urine
- Postoperative bladder irrigation-lavage
- After prostate surgery: hemostasis of the prostatic fossa

Contraindications:
Same as for urethral urinary catheterization and supra-pubic bladder drainage, and generally, known allergic reactions due to the device material (e.g. latex). Where indicated, some products contain latex, which may cause allergic reactions. The evaluation of the allergic background of a patient is the health care professional's responsibility.

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.

Adverse Events:
Bladder irritation symptoms, pain, urinary tract infection, incrustation, stone formation, urinary tract trauma, leakage, balloon burst or deflation, hematuria, skin irritation, migration of the catheter, catheter knotting, peritoneal perforation with or without bowel perforation, and misplacement/displacement.

The risks and benefits of using balloon urinary catheters 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.

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