

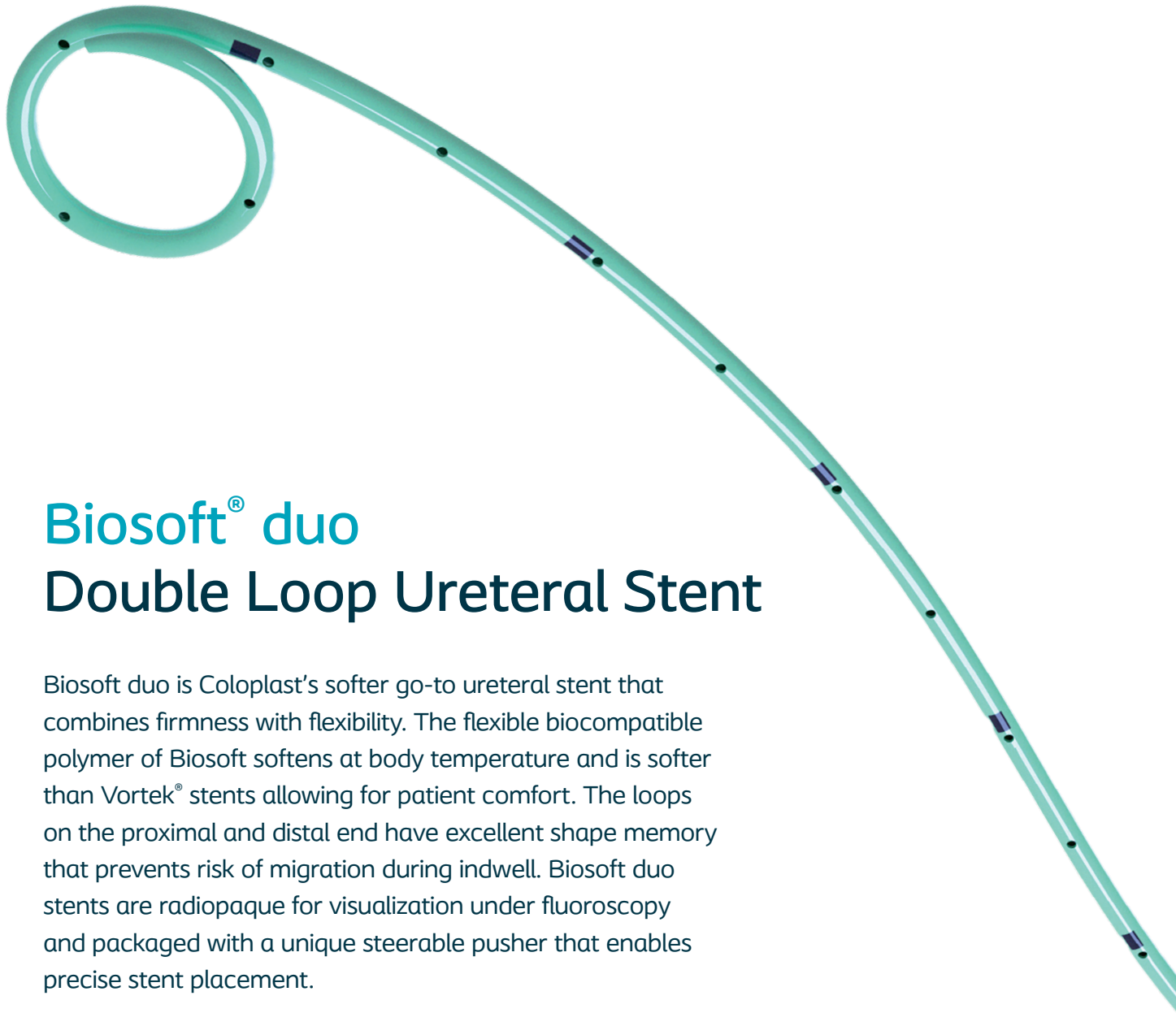
Biosoft® duo

Double Loop Ureteral Stent

The softer stent solution
combining firmness
and flexibility



Coloplast



Biosoft[®] duo Double Loop Ureteral Stent

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. Biosoft duo stents are radiopaque for visualization under fluoroscopy and packaged with a unique steerable pusher that enables precise stent placement.

Biosoft duo was designed for **easy insertion**, while retaining **great flexibility** for patient comfort.

Produced by coextrusion of a flexible material and a rigid material.

Indwelling time of
up to 6 months



The Biosoft difference

Biosoft demonstrated a lower global encrustation rate (5.5%) than severe encrustation rate estimated at the same time from literature (11%).¹

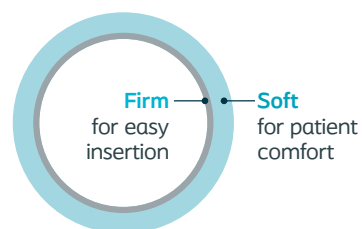
Biosoft is well tolerated in daily practice, while showing long term integrity as reported in literature.

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



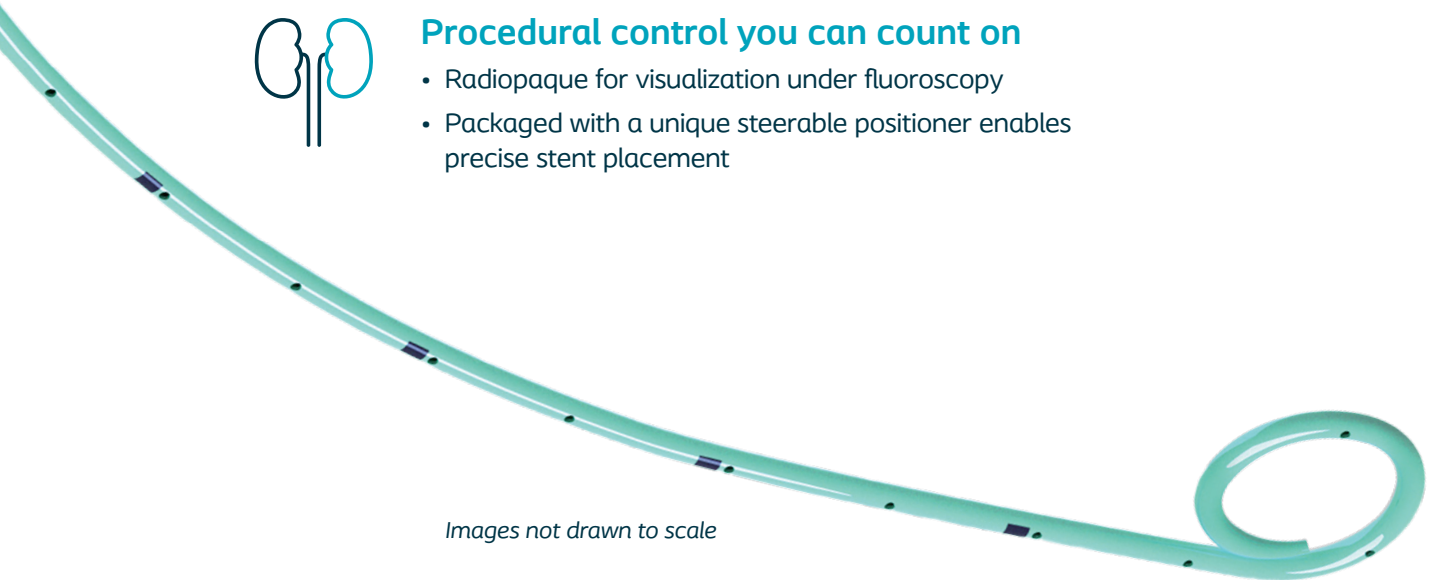
Dual-layer design for easy placement and patient comfort

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



Procedural control you can count on

- Radiopaque for visualization under fluoroscopy
- Packaged with a unique steerable positioner enables precise stent placement



Images not drawn to scale

Kit composition

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

Ordering Information

Coloplast Interventional
Urology Service Support
800-258-3476

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

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.

Biosoft® duo Double Loop Ureteral Stent BRIEF STATEMENT

Indications

Biosoft duo Double Loop Ureteral Stents can be used for:

- Drainage of the upper urinary tract over fistulas or ureteral obstacles
- Healing of the Ureter

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

Contraindications

Untreated progressive infection of the upper urinary tract.

These devices may particularly contain traces of silicone resulting from the manufacturing process. The evaluation of the allergic background of a patient is the health care professional's responsibility.

Do not attempt stent placement in a patient with suspect ureteral avulsion.

Do not use, when, in the judgement of the physician, such a procedure would be contrary to the best interest of the patient.

Warnings and Precautions

These kits must only be used by trained and experienced physicians.

Reuse of this single use product may create a potential risk to the user.

Formation of knots in lengthy stents have been reported as adverse events and may require surgical intervention to remove them.

If the stent is intended to remain implanted for more than seven days, remove the withdrawal thread prior to implantation.

Potential Complications

The following events have been reported although their occurrence greatly depends on patients' medical conditions.

Adverse events include but are not limited to: migration or dislodgement, encrustation, infection, fragmentation, flank pain, mucosal irritation or inflammation, mucus secretion, frequency, urgency, dysuria, hematuria, reflux, stone

formation, obstruction, erosion, and perforation of the renal pelvis ureter or bladder.

Some events may be related to this procedure, amongst which those related to the guidewire: ureteral perforation, or burns when in contact with an electrosurgical equipment.

The risks and benefits of using Biosoft duo Double Loop Ureteral Stent Kit should be considered in patients.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company website at www.coloplast.us.

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

Minneapolis, MN
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