

WallFlex™ Colonic Stent

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WallFlex™ Colonic Stent

Place your trust in the WallFlex Colonic Stent, a system designed to offer an exceptional combination of delivery system access and stent construction to expand options available for patient treatment and management.

Visualization

Expertise in combining stent materials has resulted in a product combining the benefits of Nitinol with the radial force and visibility characteristics of Elgiloy.¹

Access

Constructed as a highly trackable 10F / 3.3mm Through the Scope (TTS)/Over the Wire (OTW) delivery system, enabling access and passage even in anatomical areas of high tortuosity.¹

Migration Resistance

Dedicated flared stent design available in large diameters, is intended to improve obstruction relief and aid in reducing the risk of migration.^{2, 3, 4, 5, 6}

Control

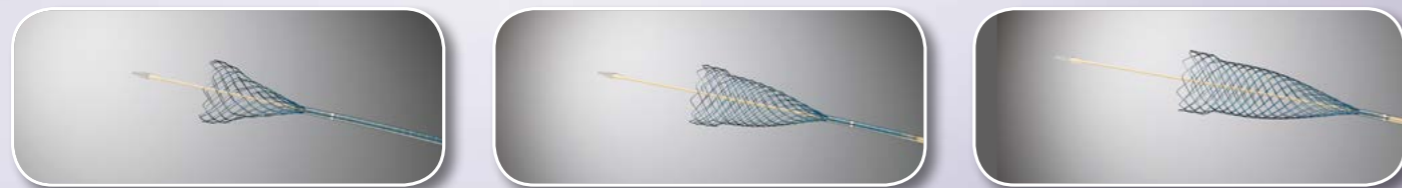
TTS/OTW delivery system is designed to gain procedural support and control during access, manipulation and deployment.¹

Stent Placement Accuracy

The delivery system is created to allow physicians to recapture and reposition the stent up to approximately 70% of stent deployment.¹

Treatment

Stents offer an alternative treatment option for both palliation and as bridge to elective surgery, and are associated with low morbidity and mortality rates as compared to colostomy.^{6, 8} Moreover, cost-effectiveness of stenting has been reported in several studies.^{6, 7, 8, 9, 10}



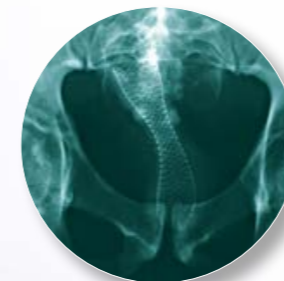
The largest diameter stent into a 10F TTS/OTW delivery system*

"The WallFlex™ [Colonic] Stent is a tremendous advancement in stent technology...these stents go around strictures very well without kinking...The lumen of the stent is not compressed by the stricture whatsoever and will follow the course of the lumen."

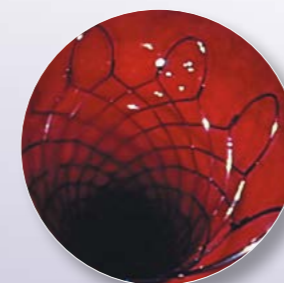
Douglas Pleskow, MD
Beth Israel Deaconess Medical Center, Boston, MA



Initial post-stent placement¹¹



20 hours post-stent placement¹¹



Looped ends may reduce risk of tissue trauma¹¹

Place Your Trust in Clinical Evidence

**"Self-expandable metal stents for relieving malignant colorectal obstruction: short-term safety and efficacy within 30 days of stent procedure in 447 patients".
Gastrointest Endosc 2011;74:876-84**

Objective: To document performance, safety, and effectiveness of colorectal stents used per local standards of practice in patients with malignant large-bowel obstruction to avoid palliative stoma surgery in incurable patients (PAL) and facilitate bowel decompression as a bridge to surgery for curable patients (BTS).

Main Outcome Measurements: The primary endpoint was clinical success at 30 days, defined as the patient's ability to maintain bowel function without adverse events related to the procedure or stent. Secondary endpoints were procedural success, defined as successful stent placement in the correct position, symptoms of persistent or recurrent colonic obstruction, and complications.

WallFlex Colonic Stent Registries Conducted:

At **39 centers**

In **13 countries**

With **447 patients**

Clinical success: 90.5% (313/346)

BTS group = **94.0%** (141/150)

PAL group = **87.8%** (172/196)

Procedural success: 94.8% (439/463)

Successful "bridge" to elective surgery: 89.8% (150/182)

"This largest multi-center prospective study of colonic SEMS placement demonstrates that colonic SEMSs are safe and highly effective for the short-term treatment of malignant colorectal obstruction, allowing most curable patients to have one-step resection without stoma and providing most incurable patients minimally invasive palliation instead of surgery. Risk of complications including perforation was low."¹²

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The WallFlex Colonic Stent is indicated for the palliative treatment of colonic strictures caused by malignant neoplasm and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

*Non-clinical testing has demonstrated that the WallFlex Colonic Stent System with Anchor Lock Delivery System is MR Conditional. It can be scanned safely under the conditions outlined in the Directions For Use.

Ordering Information

WallFlex Colonic Stent



Order Number	Diameter (mm) Flare/Body	Stent Length (cm)	Working Length (cm)	System Length (cm)	Catheter Diameter (F/mm)	Guidewire Diameter (Inches/mm)
M00565040	30 / 25	6	230	270	10/3.3	0.035/0.89
M00565050	30 / 25	9	230	270	10/3.3	0.035/0.89
M00565060	30 / 25	12	230	270	10/3.3	0.035/0.89
M00565070	30 / 25	6	135	175	10/3.3	0.035/0.89
M00565080	30 / 25	9	135	175	10/3.3	0.035/0.89
M00565090	30 / 25	12	135	175	10/3.3	0.035/0.89
M00565100	27 / 22	6	230	270	10/3.3	0.035/0.89
M00565110	27 / 22	9	230	270	10/3.3	0.035/0.89
M00565120	27 / 22	12	230	270	10/3.3	0.035/0.89
M00565130	27 / 22	6	135	175	10/3.3	0.035/0.89
M00565140	27 / 22	9	135	175	10/3.3	0.035/0.89
M00565150	27 / 22	12	135	175	10/3.3	0.035/0.89

Recommended Guidewires

Wallstent™ Super Stiff Guidewire 0.035" (0.89mm) – 500cm

Order Number: H965180010

NOTES

†acc. to the current market

1. Data on File Boston Scientific Corporation: Internal Testings and Limited Launch Results
2. "A practical guide for choosing an expandable metal stent for GI malignancies: is a stent by any other name still a stent", T. H. Baron; Gastrointestinal Endoscopy vol.54, no2, 2001
3. "Palliative treatment of malignant colorectal strictures with metallic stents", L. Paul et al.; Cardiovascular and Interventional Cardiology, 22. 1999
4. "Gastrointestinal Stenting", Zollkoffer et al. European Radiology 10, 2000
5. "Metal Stents for decompression of acute colorectal obstruction", A. Repici; UEGW 2001
6. "Systematic review of the efficacy and safety of colorectal stents", U.P. Khot et al.; British Journal of Surgery, 2002-89
7. "Self-Expanding Metal Stents in the Treatment of Malignant Colorectal Obstructions", S. Meisner; Business Briefing, European Pharmacotherapy 2005
8. "Clinical Evidence on Colorectal Stenting. Systematic Literature Review", M. Parker, E. Tejero, L. Petruzzello; Boston Scientific Corporation, 2004
9. "Acute colonic obstruction: clinical aspects and cost effectiveness of preoperative and palliative treatment with self-expanding metallic stents: a preliminary report", C. A. Binkert et al.; Radiology 1998
10. "The cost effectiveness of self-expanding metal stents in the management of malignant left sided large bowel obstruction", H. S. Osman; Colorectal Disease, 2000
11. Images courtesy of Nuri Ozden, MD, Metro Nashville General Hospital, Nashville, Tennessee and Todd Threadgill, MD, Baptist Memorial Hospital, Oxford, Mississippi
12. "Self-expandable metal stents for relieving malignant colorectal obstruction: short-term safety and efficacy within 30 days of stent procedure in 447 patients", S. Meisner et al.; Gastrointestinal Endoscopy vol. 74, no 4, 2011

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CAUTION: Law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for the use only in countries with applicable health authority product registrations.

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