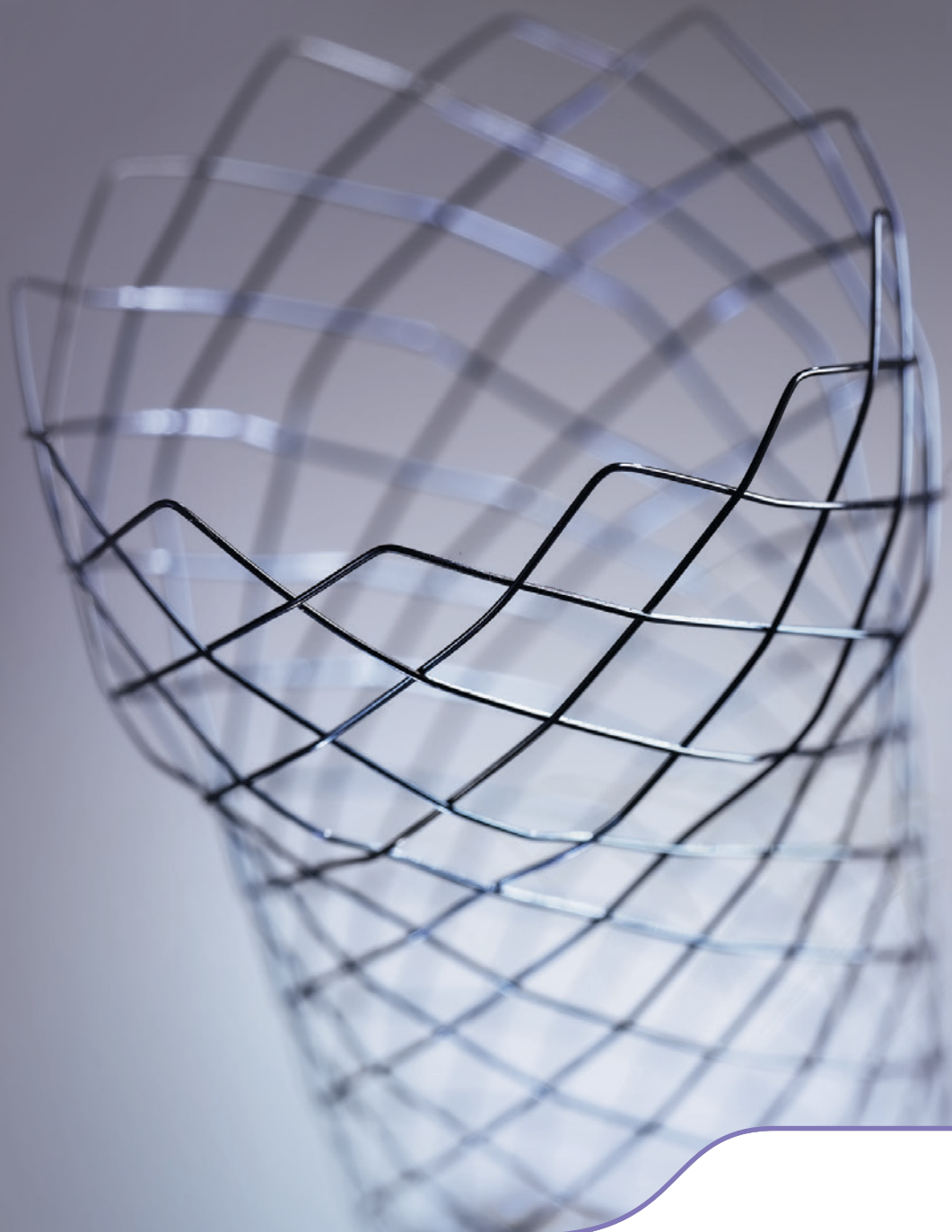


WallFlex™ Colonic Stent

Boston
Scientific



WallFlex™ Colonic Stent

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

Visualization

The Nitinol construction allows for clear visualization under fluoroscopy.

Access

Constructed as a 10Fr Through the Scope (TTS)/Over the Wire (OTW) delivery system, it may enable access and passage in anatomical areas of high tortuosity.

Migration Resistance

Dedicated flared stent design available in large diameters, is intended to improve obstruction relief and aid in reducing the risk of migration.^{1,2,3,4}

Control

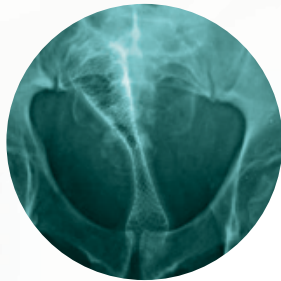
TTS/OTW delivery system is designed to gain procedural support and control during access, manipulation and deployment.

Stent Placement Accuracy

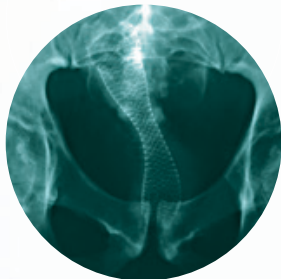
The delivery system is created to allow physicians to recapture and reposition the stent up to approximately 70% of stent deployment.

Treatment

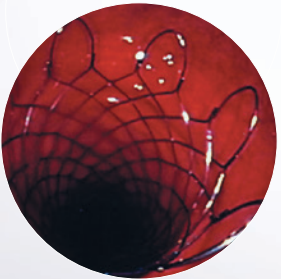
Stents offer an alternative treatment option for palliation and are associated with low morbidity and mortality rates as compared to colostomy.^{5,6} Moreover, cost-effectiveness of stenting has been reported in several studies.^{7,8}



Initial post-stent placement



20 hours post-stent placement



Looped ends may reduce risk of tissue trauma⁴

Place Your Trust in Clinical Evidence

Results from a European **prospective** multi-center study demonstrate that the WallFlex Colonic Stent provided effective treatment of malignant colonic strictures in patients requiring palliative therapy to potentially eliminate the need for stoma creation.¹⁰

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).

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)

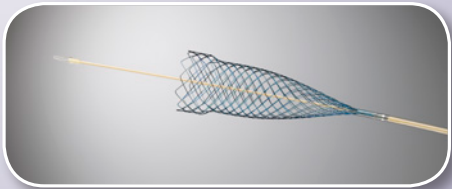
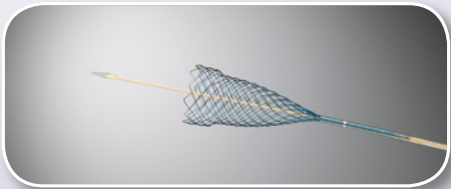
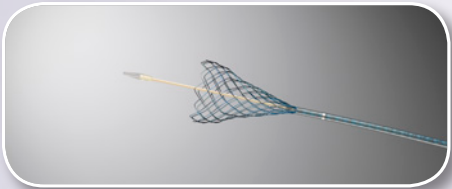
Procedural failures:

- 16** stents could not be placed
- 8** patients received a stent but failed procedural success

Successful “bridge” to elective surgery with primary anastomosis: 89.8% (150/182)

- 7** emergency surgery as treatment to a procedural or post-procedural complication
- 15** lost to follow-up or died
- 10** no surgery

“This largest multi-center prospective study of colonic SEMS demonstrates that colonic SEMS 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.”¹⁰



WallFlex™ Colonic Stent



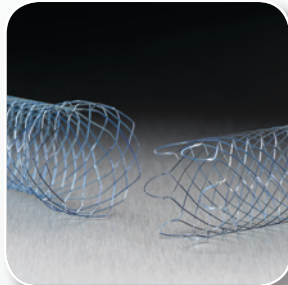
**Magnetic Resonance
Conditional***

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 Instructions For Use.

Ordering Information

WallFlex Colonic Stent



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

NOTES

1. 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
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3. Gastrointestinal Stenting, Zollikoffer et al. European Radiology 10, 2000
4. Varadarajulu S, Banerjee S, Barth B, et al. Enteral stents. Gastrointest Endosc. 2011/09/01/ 2011;74(3):455-464. doi:https://doi.org/10.1016/j.gie.2011.04.011
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6. van Hooft Jeanin E et al. SEMSs for obstructing colonic and extracolonic cancer: ESGE Guideline – Update 2020
7. 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
8. The cost effectiveness of self-expanding metal stents in the management of malignant left sided large bowel obstruction, H. S. Osman; Colorectal Disease, 2000
9. Quinn PL, Arjani S, Ahlawat SK, Chokshi RJ. Cost-effectiveness of palliative emergent surgery versus endoscopic stenting for acute malignant colonic obstruction. Surg Endosc. 2021;35(5):2240-2247. doi:10.1007/s00464-020-07637-x
10. 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
11. Images provided courtesy of Nuri Ozden, MD, Metro Nashville General Hospital, Nashville, Tennessee and Todd Threadgill, MD, Baptist Memorial Hospital, Oxford, Mississippi

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