WallFlex[™] Esophageal Stents

Fully and Partially Covered Self Expanding Metal Stents

Ordering Information

WallFlex Fully Covered RMV Esophageal Stents

| | Order Number | Stent O.D. (mm) | Proximal / Distal Flares O.D. (mm) | Stent Length (cm) | Catheter Diameter (F) / (mm) | System Length (cm) |
|-------------|------------------------|--------------------|--|-------------------------|------------------------------------|--------------------------|
| | M00516210 [†] | 18 | 25 / 23 | 10.3 | 18.5 / 6.2 | 78 |
| AREAS | M00516220 ⁺ | 18 | 25 / 23 | 12.3 | 18.5 / 6.2 | 78 |
| ATTA | M00516230 ⁺ | 18 | 25 / 23 | 15.3 | 18.5 / 6.2 | 78 |
| | M00516240 ⁺ | 23 | 28 / 28 | 10.5 | 18.5 / 6.2 | 78 |
| SAL SAL | M00516250 ⁺ | 23 | 28 / 28 | 12.5 | 18.5 / 6.2 | 78 |
| Manuel Real | M00516260 ⁺ | 23 | 28 / 28 | 15.5 | 18.5 / 6.2 | 78 |

Packaged one per box. † Product commercialised only in countries where refractory benign indication is approved. Recommended Guidewire: .038in (0.97mm) 260cm Jagwire[™] Guidewire, M00556621



| | Order Number | Stent O.D. (mm) | Proximal / Distal Flares O.D. (mm) | Stent Length (cm) | Catheter Diameter (F) / (mm) |
|---|--------------|--------------------|--|-------------------------|------------------------------------|
| A | M00516270 | 18 | 25 / 23 | 10.3 | 18.5 / 6.2 |

| \searrow | M00516270 | 18 | 25 / 23 | 10.3 | 18.5 / 6.2 | 78 |
|------------|-----------|----|---------|------|------------|----|
| | M00516280 | 18 | 25 / 23 | 12.3 | 18.5 / 6.2 | 78 |
| | M00516290 | 18 | 25 / 23 | 15.3 | 18.5 / 6.2 | 78 |
| 2 | M00516300 | 23 | 28 / 28 | 10.5 | 18.5 / 6.2 | 78 |
| | M00516310 | 23 | 28 / 28 | 12.5 | 18.5 / 6.2 | 78 |
| | M00516320 | 23 | 28 / 28 | 15.5 | 18.5 / 6.2 | 78 |

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ged one per box. Limited availability in all European countries (except UK and France). Please contact your local Terr **nmended Guidewire:** .038in (0.97mm) 260cm Jagwire™ Guidewire, M00556621

WallFlex Partially Covered Esophageal Stents with Permalume[™] Covering

| - | | | | | - | | |
|---|--------------|--------------------|--|-------------------------|---------------------------|------------------------------------|--------------------------|
| | Order Number | Stent O.D. (mm) | Proximal / Distal Flares O.D. (mm) | Stent Length (cm) | Covered Length (cm) | Catheter Diameter (F) / (mm) | System Length (cm) |
| | M00516900 | 18 | 23 / 23 | 10.3 | 7.1 | 18.5 / 6.2 | 78 |
| | M00516910 | 18 | 23 / 23 | 12.3 | 9.1 | 18.5 / 6.2 | 78 |
| | M00516920 | 18 | 23 / 23 | 15.3 | 12.1 | 18.5 / 6.2 | 78 |
| 2 | M00516930 | 23 | 28 / 28 | 10.5 | 7.2 | 18.5 / 6.2 | 78 |
| | M00516940 | 23 | 28 / 28 | 12.5 | 9.2 | 18.5 / 6.2 | 78 |
| | M00516950 | 23 | 28 / 28 | 15.5 | 12.2 | 18.5 / 6.2 | 78 |

Packaged one per box. Recommended Guidewire: .038in (0.97mm) 260cm Jagwire[™] Guidewire, M00556621



MR Conditional - Non-clinical testing has demonstrated that the WallFlex Esophageal Stent System is MR Conditional. It can be scanned safely under the conditions outlined in the

View case studies and clinical information on WallFlexTM Esophageal Stent at Boston Scientific's Peerto-Peer Education Resource website: www.endosuite.com

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CAUTION: The 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 use only in countries with applicable health authority registrations. Material not intended for use in France.

Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. Please check availability with your local sales representative or customer service.

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System Length (cm)

WallFlex[™] Esophageal Stents

Fully and Partially Covered Self Expanding Metal Stents









WallFlex[™] Esophageal Stents

Fully and Partially Covered Self Expanding Metal Stents

Place your trust in over 20 years of research and development. Boston Scientific is a leading developer of advanced stent technologies, and remains committed to high quality standards and collaboration with physicians.



"The Esophageal WallFlex is of interest in my practice as the flexibility of the stent allows it to conform to the anatomy and enables placement in different types of malignant strictures with or without fistulas. In my experience, the 23mm diameter stent option offers an optimal balance of esophageal adherence and patency."*

Peter D. Siersema, MD, PhD

Professor of Endoscopic Gastrointestinal Oncology, Head Endoscopy Center, Dept. of Gastroenterology and Hepatology, Radboud University Medical Center, Nijmegen, The Netherlands

"The flared ends design of the WallFlex Fully Covered Esophageal Stent helps anchor the stent and may reduce the risk of migration in benign strictures while the full Permalume covering has helped prevent tumor in-growth and reduce food impaction."*

Alessandro Repici, MD

Director of Digestive Endoscopy, Istituto Clinico Humanitas, Milan, Italy

"I like the 18.5F (6.2mm) low profile delivery system because it facilitates placement through difficult strictures without the need of pre-dilation. Additionally, the high radiopacity of the stent allows full control and ultimately confidence during deployment."*

Richard P. Sturgess, MD

Consultant Gastroenterologist, Clinical Director Digestive Diseases Directorate, University Hospital Aintree, Liverpool, UK

"Our study is the first prospective case series to report the outcomes of treatment with a fully covered WallFlex stent. This stent is easy to implant and can be safely removed."^{†*}

Jorge M.T. Canena, MD, PhD

Professor of Gastroenterology, University Center of Gastroenterology-Faculty of Medical Sciences, Cuf Infante Santo Hospital, Lisbon, Portugal

Canena et al. BMC Gastroenterology 2012, 12:70
 * Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.
 WallFlex[™] Esophageal Stents are approved for benign indication in EU only.



1-3mm malignant esophageal stricture



Pre-dilation was not required

Boston Scientific stent technology is built on science and innovation to expand options available for patient treatment and management.

Stent

Migration Resistance

The progressive step flared ends may assist in anchoring the stent within the esophageal lumen.

Stricture Resolution

The multiple wire braided construction is engineered to allow the stent to adjust to forces from the esophageal anatomy such as strictures and peristalsis. The design allows for gradual stent expansion, which is typically complete after 24-72 hours.

Tissue In-growth Prevention

The Permalume[™] silicone covering extends the entire length of the stent in the fully covered version and is designed to prevent tumor in-growth as well as stent concurrent esophageal fistulas.

Fluoroscopic Visualization

The Nitinol construction allows for clear visualization during fluoroscopy, ensuring accurate stent placement.

Removability and Adjustability

The coated polyester removal suture facilitates removal during the initial stent placement procedure and from benign strictures for up to 8 weeks.



Delivery System

Pre-dilation Avoidance

The 18.5 French (6.2mm), low profile delivery system is designed to traverse tight strictures.*

Endoscopic Placement

The endoscopic transition zone is designed to aid in stent placement accuracy when deployed using endoscopic visualization.

Stent Placement Accuracy

The coaxial delivery system is designed to result in 1:1 stent deployment.

The fully covered stent may be reconstrained up to 75% of deployment and 2 times during the initial stent placement procedure.**

* Pre-dilation may not be required, depending on stricture lumen diameter.
** A stent can not be reconstrained after the reconstrainment limit has been exceeded

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Proximal Reposition Marker





Endoscopic Transition Zone

4 Radiopaque Markers