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M00516700	M00516730
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M00516720	M00516750

AR REP

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link bostonscientific.com/arg

AU REP

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY NSW 1455 Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

EC REP

Boston Scientific Limited
Ballybrit Business Park
Galway IRELAND

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752 USA
USA Customer Service +1-888-272-1001
www.bostonscientific.com

CE 0344

WallFlex™ Esophageal

FULLY COVERED

Stent System

℞ ONLY

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

REUSE WARNING

For single use only. Do not reuse, reprocess or sterilize. Reuse, reprocessing or sterilization 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. Reuse, reprocessing or sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

DEVICE DESCRIPTION

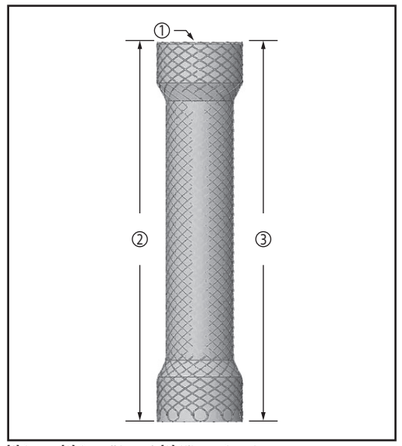
Contents

The package includes:

One (1) WallFlex Esophageal Fully Covered Stent System

Operating Principle

The WallFlex Esophageal Fully Covered Stent System consists of a flexible delivery system preloaded with a self-expanding esophageal metal stent. The stent is made from a metallic radiopaque material that is formed into a cylindrical mesh (Figure 1). It is fully covered with a translucent silicone polymer to restrict tumor ingrowth through the wire mesh and to occlude concurrent esophageal fistulas. A suture is threaded through the proximal end of the stent and is intended to aid in removal during the initial stent placement procedure, to be used in the event of incorrect placement. The stent has flares at both extremities to aid in minimizing migration after the stent has been placed in the esophagus. The delivery system is a coaxial tube design. The exterior tube is used to constrain the stent before deployment and reconstrain the stent, if desired, after partial deployment. The exterior tube has a clear section so that the constrained stent is visible. There are four radiopaque (RO) markers to aid in the deployment of the stent while using fluoroscopy (Figure 2). There are RO marker bands on the inner tube of the delivery system identifying the ends of the constrained stent (Figure 2, #1 and #3). Between these marker bands is an additional RO marker band to indicate at what point reconstrainment is no longer possible (Figure 2, #2). The fourth radiopaque marker band at the distal end of the exterior tube indicates up to what point the stent has been deployed (Figure 2, #4). The tip and interior tube are also radiopaque for use with fluoroscopy. There are two visual markers on the interior tube between the handles to aid in the deployment of the stent (Figure 3, #5 and #6). Visual marker #5 indicates the start position and marker #6 indicates the point at which reconstrainment is no longer possible. The interior tube has a single central lumen to accommodate a 0.038 in (0.97 mm) guidewire.



[1] Suture [2] Overall Length [3] Silicone Covering

Figure 1. WallFlex Esophageal Fully Covered Stent

Materials

Materials and substances for which the patient can be exposed to, by the implantable portion of the medical device, are the following:

Implantable Material	% Weight
Nitinol	67-76
Silicone	24-33
Polyester	<1

Contains cobalt: CAS No. 7440-48-4; EN No. 231-158-0. Defined as a 1B carcinogen and reproductive toxicant according to the European Commission in a concentration above 0.1% weight by weight.

Note: The Delivery System is made with stainless steel which contains cobalt. Current scientific evidence supports that stainless steels used in medical devices, do not cause an increased risk of cancer or adverse reproductive effects.

Warning: This device contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.

User Information

Read the entire Instructions for Use thoroughly before using the WallFlex Esophageal Fully Covered Stent System. The WallFlex Esophageal Fully Covered Stent System should only be used by or under the supervision of physicians thoroughly trained in esophageal prosthesis placement. A thorough understanding of the technical principles, clinical applications, and risks associated with this procedure is necessary before using this device.

INTENDED USE / INDICATIONS FOR USE

The WallFlex Esophageal Fully Covered Stent System is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors, and occlusion of concurrent esophageal fistulas.

Clinical Benefit Statement

The clinical benefit of the WallFlex Esophageal Fully Covered Stent is to maintain esophageal patency and structure of the esophagus in patients with malignant strictures, with or without concurrent esophageal fistulas.

Summary of Safety and Clinical Performance

For customers in the European Union, use the device name found in the labeling to search for the device's Summary of Safety and Clinical Performance, which is available on the European database on medical devices (EUDAMED) website: (https://ec.europa.eu/tools/eudamed).

The Summary of Safety and Clinical Performance for the WallFlex Esophageal Fully Covered Stent System can be found on the EUDAMED website using the following search term: WallFlex Esophageal.

CONTRAINDICATIONS

The WallFlex Esophageal Fully Covered Stent System is contraindicated for:

- Placement in esophageal strictures caused by benign tumors, as the long-term effects of the stent in the esophagus are unknown.
- Placement in strictures that cannot be dilated enough to pass the gastroscope or the delivery system.
- Placement of the proximal end of stent within 2 cm of the cricopharyngeal muscle.
- Placement in an esophago-jejunostomy (following gastrectomy), as peristalsis and altered anatomy may displace stent.
- Placement in necrotic chronically bleeding tumors, if bleeding is active at the time of placement.
- Placement in polypoid lesions.
- Those patients for whom endoscopic techniques are contraindicated.
- Any use other than those specifically outlined under indications for use.
- Placement in patients who have an underlying bleeding diathesis.

WARNINGS

- The risk of perforation and erosion into adjacent vascular structures or aortoesophageal and arterioesophageal fistulas may be increased with pre- or post-operative chemotherapy and radiation, longer implantation times, aberrant anatomy, and/or mediastinal contamination or inflammation.
- As perforation is a known risk, the stent should be used with caution and only after careful consideration in patients who are:
  - undergoing radiation therapy and/or chemotherapy
  - in advanced stages of cancer

The WallFlex Esophageal Fully Covered Stent System should be used with caution and only after careful consideration in patients with:

- Strictures exceeding 12 cm in length
- Significant preexisting pulmonary or cardiac disease

Stent is considered to be a permanent device. Once stent placement is permanently achieved, stent removal or repositioning is not recommended. Post procedure stent migration may occur and would require appropriate management as per physician discretion.

ADVERSE EVENTS

These include, but are not necessarily limited to:

- Allergic Reaction
- Aorto and arterioesophageal fistula
- Aspiration
- Bleeding
- Death (other than that due to normal disease progression)
- Edema
- Erosion or perforation of stent into adjacent vascular structures
- Esophagitis
- Fever
- Fistula formation
- Food bolus impaction
- Foreign body sensation
- Gastrointestinal symptoms
- Granulation tissue around stent ends
- Hematemesis
- Infection
- Inflammation
- Intestinal obstruction (secondary to stent migration)
- Mediastinitis
- Pain
- Perforation
- Recurrent dysphagia
- Reflux
- Sepsis
- Septicemia
- Stent fracture
- Stent migration
- Tracheal compression/obstruction (or acute airway compression)

BSC (MB IFU Template 16.5354 x 11.6929 A3, 92310061K), IFU, MB, Wallflex Esophageal FC, en, 51033363-01A

- Tumor overgrowth around stent ends
- Ulceration

HOW SUPPLIED

The WallFlex Esophageal Fully Covered Stents are supplied non-sterile in single pack configuration.

Device Details

Do not use if package is damaged or unintentionally opened before use.

Do not use if labeling is incomplete or illegible.

Handling and Storage

This product has no special handling or storage requirements. Check device label for expiration date.

OPERATIONAL INSTRUCTIONS

Required Equipment

- Gastroscope
- 0.038 in (0.97 mm), stiff-bodied 260 cm guidewire with floppy tip
- WallFlex Esophageal Fully Covered Stent System containing a stent of the appropriate length and diameter
- Fluoroscopic capability for pre-stent placement and stent placement confirmation
- Rat Tooth forceps

Pre-Procedure

Radiography of the esophagus performed no more than 10 days before the procedure should be available.

Prepare for the procedure as you would an upper endoscopy.

Initial Preparation of Delivery System

- Carefully remove the delivery system from the protective packaging.

Warning: Visually inspect the system for any signs of damage. DO NOT USE if the system has any visible signs of damage. Failure to observe this warning may result in patient injury.

Procedure

Start of Initial Stent Placement Procedure

1. **Locate the Stricture**

   If using a gastroscope, intubate the patient using a standard gastroscope per standard technique. Access the stricture location upon direct visualization. Fluoroscopy can also be used to locate the stricture with the aid of a contrast medium.

2. **Examine the Stricture (Endoscopically and/or Fluoroscopically)**

   A. Examine Stricture Endoscopically

   Endoscopically examine both the proximal and distal segments of the stricture. Using the external ruler on the gastroscope, measure the distance between the distal margin of the stricture to the patient's incisors. Withdraw the gastroscope to the proximal margin of the stricture and measure the distance to the patient's incisors. The stricture length is calculated as the difference between those two distances. To minimize the potential of stent migration, dilate the stricture ONLY if passage of the gastroscope or the delivery system through the stricture lumen is not possible.

   Warning: In some patients, tumor encroachment will make dilation of the stricture challenging. Physicians should use judgment based on experience in dilating esophageal strictures. Perforation or bleeding and/or migration could result from dilatation of an esophageal tumor.

   Warning: Placement of the WallFlex Esophageal Fully Covered Stent should not be attempted in patients with esophageal strictures that cannot be dilated wide enough for passage of the gastroscope or delivery system in order to avoid patient injuries such as perforation, hemorrhage and/or obstruction.

   B. Examine the Stricture Fluoroscopically

   The stricture may also be examined fluoroscopically. Leaving the gastroscope in place, observe both the proximal and distal margins of the tumor fluoroscopically. Mark the locations with either radiopaque markers or use anatomical landmarks such as ribs or vertebras. It is recommended to re-measure the stricture length by measuring the distance between the radiopaque markers.

3. **Choose the Stent Size**

   The size of the stricture must be accurately calculated to ensure the ideal stent size is used. The WallFlex Esophageal Fully Covered Stent should bridge the tumor and/or the fistula and should extend >1 cm above and below the stricture or fistula. For stent use with a fistula, it is critical to ensure that the stent completely covers the fistula to avoid leakage and facilitate healing. If stent length choice is questionable, always use the longer stent. A second stent of the same diameter may be placed if the first stent does not cover the entire stricture length. The second stent should be placed to ensure complete tumor coverage and a smooth transition between the stents. It is recommended that the proximal stent be placed first followed by the distal stent in order to maximize luminal diameter of the interlocked stents. Care should be used when passing the delivery system through the first stent.

   Warning: Passing the scope through a just deployed stent is not recommended and could cause the stent to dislodge, resulting in patient injury.

   Precaution: Boston Scientific has not evaluated the use of the Wallflex Esophageal Stent in combination with other stents.

4. **Insert Guidewire and Place Through Stricture**

   Pass a guidewire through the working channel of the gastroscope and then through the stricture and into the stomach. A floppy tip guidewire is recommended in order to reduce potential trauma from the tip of the wire. Endoscopic and fluoroscopic placement of the guidewire is also recommended to assure proper passage through the stricture and proper placement in the stomach. Maintain guidewire position throughout procedure.

   Precaution: A stiff bodied 0.038 in (0.97 mm) guidewire with a floppy tip is recommended to facilitate passage through tortuous anatomy. Jagwire Guidewire M00556621 is recommended.

5. **Advance the Delivery System over the Guidewire and Position Stent**

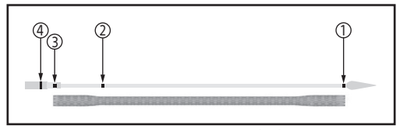


Figure 2. Delivery System and Radiopaque (RO) Markers

There are four radiopaque (RO) markers to aid in the deployment of the stent while using fluoroscopy. Radiopaque marker bands attached to the inner tube indicate the length of the constrained stent on the delivery system (Figure 2, #1 and #3). A marker band on the inner catheter between the constrained stent markers indicates at what point reconstrainment is no longer possible, Figure 2, #2. Up to this point, the stent can be reconstrained and repositioned if desired, no more than two times. The fourth radiopaque marker band at the distal end of the exterior catheter indicates up to what point the stent has been deployed (Figure 2, #4). The tip and inner tube are also radiopaque for use with fluoroscopy. After placing the guidewire, remove the gastroscope from the patient leaving the guidewire in place. Reinsert the gastroscope alongside the guidewire if direct visualization of stent deployment is desired. Tilt the patient's head to provide the straightest pathway for advancement of the delivery system over the guidewire. Lubrication can be applied if desired.

Using fluoroscopic guidance, position the stent with the proximal RO marker above the proximal tumor margin and the distal RO marker below the distal tumor margin, centering the tumor between the markers (Figure 2, #1 and #3). This ensures that the stent will properly bridge the tumor. If it is not necessary to cross the Lower Esophageal Sphincter (LES), the distal end of the stent should remain above the LES in order to leave the LES functional and reduce gastric reflux. The stent can cross the LES if necessary due to tumor involvement and stricture.

6. **Deploy Stent**

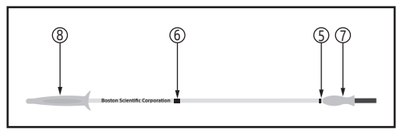


Figure 3. Delivery System, Visual Markers and Handles

Precaution: Do not twist the delivery system or use a boring motion during stent deployment as this may affect stent positioning and ultimately, the stent function.

Begin stent deployment by holding the distal handle (farthest from the operator, Figure 3, #7) of the delivery system with one hand, and using the other hand, grasp the proximal handle (closest to the operator, Figure 3, #8) and hold this handle stationary. Between the handles is a yellow segment with visual markers. These visual markers are intended to aid in stent deployment. Prior to deploying the stent, you can visualize a marker at the fully constrained/undeployed position (Figure 3, #5).

In order to deploy the stent, hold the distal handle (farthest from the operator, Figure 3, #7) with one hand and the proximal handle (handle closest to the operator, Figure 3, #8) with the other hand. To deploy the stent, slowly pull the distal handle toward the proximal handle while holding the proximal handle stationary. Monitor the stent release fluoroscopically and/or endoscopically, keeping the fluoroscopic markers on the delivery system between the identified stricture margins. If necessary, it is possible to stop deployment and adjust the stent position proximally prior to passing the reconstrainment marker (Figure 3, #6). Refer to the reconstrainment technique section. If satisfied with stent placement, proceed with full deployment.

Reconstrainment Technique

- The stent can be reconstrained at any point up to the reconstrainment markers (radiopaque Figure 2, #2 and visual Figure 3, #6).

Note: Once the visual reconstrainment marker cannot be seen during deployment the stent cannot be reconstrained.

- Reconstrainment is done by reversing the direction of deployment, by holding the proximal handle (closest to the operator) steady while pushing the distal handle (farthest from the operator) away.
- The stent has been designed to be reconstrained no more than two times.
- Prior to full deployment, if repositioning is desired, the stent can be pulled proximally by slowly pulling back on the delivery system. The ability to pull proximally will be limited by the amount of stent deployed and the tightness of the stricture. Full reconstrainment, when possible, is always preferred and recommended over pulling the device proximally.

Note: The stent is fully constrained if visual marker (Figure 3, #5) is fully visible.

Warning: Pulling proximally when partially deployed could further deploy the stent if there is resistance on the stent, which could lead to positioning issues and/or patient injury.

Precaution: Do not push the delivery system forward once deployment has begun. The delivery system can be pulled proximally if necessary. The ability to pull proximally will be limited by the amount of stent deployed and the tightness of the stricture.

If the positioning of a WallFlex Esophageal Fully Covered Stent is not correct and one of the following has occurred, continue to fully deploy the stent:

A. The stent has already been deployed past the reconstrainment limit

OR

B. The stent has already been reconstrained twice

Then in either case, using rat tooth forceps, grasp the suture on the proximal end of the stent (Figure 1). Gently pull the stent back with the scope to remove the stent during the initial stent placement procedure.

Note: In a limited evaluation of the WallFlex Esophageal Fully Covered Stent in a porcine model, 6 stents were successfully removed during the initial stent placement procedure from 6 separate animals using the methods described above.

Warning: Stent is considered to be a permanent device. Once stent placement is permanently achieved, stent removal or repositioning is not recommended. Post procedure stent migration may occur and would require appropriate management as per physician discretion.

7. **Assess Deployed Stent Position and Remove the Delivery System**

   Following stent deployment, view the stent endoscopically to confirm stent expansion as tumor impingement may prevent the stent from achieving its maximum diameter immediately.

   Carefully remove the delivery system and the guidewire.

   Precaution: An attempt to remove the delivery system and guidewire prior to stent expansion or when a stent is partially deployed may dislodge the stent. If excessive resistance is felt during delivery system removal, wait 3-5 minutes to allow further stent expansion then proceed with the following steps:

   A. Slowly withdraw the delivery system and guidewire.
   B. If removal is still not possible, use a balloon dilation catheter to dilate the stent. It should not be necessary for the balloon diameter/size to be equal to the stent diameter. Judgement should be used when selecting the balloon size. Carefully position the balloon catheter within the stent. Inflate the balloon to its recommended pressure.
   C. Deflate the balloon catheter and withdraw into the gastroscope. Slowly withdraw the delivery system and guidewire.

   Warning: A stent may require 24-72 hours to expand fully. Physicians should use judgement based on experience when dilating esophageal strictures. Perforation or bleeding of the esophageal tumor is a risk during any dilation of the tumor. Never use a rigid-type dilator for post stent placement dilation because the axial force may dislodge the stent and could lead to patient injury.

   Warning: Once stent is in desired location, passing the scope through a just deployed stent is not recommended and could cause the stent to dislodge, which may lead to patient injury.

8. **Remove Gastroscope**

   Withdraw gastroscope from the patient.

This completes the initial stent placement procedure. Stent placement is considered permanent upon completion of initial stent placement procedure.

Disposal

To minimize the risk of infection or microbial hazards after use, dispose device and packaging as follows: After use, device may contain biohazardous substances. The device and packaging should be treated and disposed of as biohazardous waste or have them treated and disposed of in accordance with any applicable hospital, administrative, and/or local government regulations. Use of a biohazardous container with biological hazard symbol is recommended. Untreated biohazardous waste should not be disposed of in the municipal waste system.

Post-Procedure

Any serious incident that occurs in relation to this device should be reported to the manufacturer, and to the relevant local regulatory authority.

Patients should have P-A (posteroanterior) and lateral chest films taken as a permanent record of the stent position. Observe the patient for development of any complications of endoscopy, esophageal dilation and stent placement. Vital signs should be monitored, and clear liquids given in an upright position during the first 24 hours post-stent placement. Patients being treated for fistula should have no fluids or foods orally until successful sealing of the fistula has been confirmed. Post 24 hours, the patient should be instructed to eat only in an upright sitting position, to chew food thoroughly, to avoid certain foods (such as meats, raw vegetables, and breads), and to drink fluids during and after meals. Patients with stents placed in the distal esophagus or across the Lower Esophageal Sphincter (LES) should be instructed to elevate the head of the bed and should be prescribed acid suppression therapy to minimize gastric reflux into the stent. Subsequent follow-up at 1 week and at 3-month intervals, thereafter, or for symptomatic dysphagia may be performed to verify patency and placement.

Note: Recurrence or worsening of dysphagia may occur after stent placement due to tumor in-growth or overgrowth over time, severe hyperplasia reaction or stent migration. Repeat endoscopy may be required.

MRI SAFETY INFORMATION

MRI Safety Information

A person with the *WallFlex Stent(s)* may be safely scanned under the following conditions. Failure to follow these conditions may result in injury

Device Name	*WallFlex Stent*
Static Magnetic Field Strength (B_0)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Cylindrical Whole-body Coil Cylindrical Head Coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration / Temperature Rise	Under scan conditions defined above, WallFlex Stent is expected to have a temperature rise of less than 4°C and can be used for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	Image artifact caused by device may extend approximately 20 mm from the perimeter and 5 mm from the end of the stent with a spin and gradient echo pulse sequence

PATIENT COUNSELING INFORMATION

Brief the patient on any relevant post-procedure instructions, contraindications, warnings, precautions and/or adverse events found within this Instructions for Use (IFU), pertaining to the patient.

Implantable Device Patient Information

Advise the patient that additional information may be available to them on the Boston Scientific website (www.bostonscientific.com/patientlabeling).

Implant Card Instructions

- Apply the peel-off label from the product onto the supplied patient implant card
- Fill in the implant date, patient name, healthcare institution and/or physician information
- Give the completed card to the patient

WARRANTY

For device warranty information, visit (www.bostonscientific.com/warranty).

SYMBOL DEFINITIONS

Commonly used medical device symbols that appear on the labeling are defined at www.bostonscientific.com/SymbolsGlossary.

Additional symbols are defined at the end of this document.

BSC (MB IFU Template 16.5354 x 11.6929 A3, 92310061K), IFU, MB, WallFlex Esophageal FC, en, 51033363-01A

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