WallFlex™ Esophageal Fully and Partially Covered Stent Systems

Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

Caution

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

Warning

Contents supplied NON-STERILE. Do not use if damaged. If damage is found, call your Boston Scientific representative.

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 injection 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. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Intended Use/Indications for Use

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

Contraindications

The WallFlex Esophageal Fully and Partially Covered Stent Systems is contraindicated for: placement in esophageal strictures caused by benign tumors, as the long-term effects of the stent in the esophagus are unkown. Placement in strictures that cannot be dilated enough to pass the endoscope or the delivery system. Placement of the proximal end of the 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 bleedng 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

Stent is considered to be a permanent device. Once stent placement is permanently achieved, stent removal or repositioning is not recommended.

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 endoscope or delivery system.

The WallFlex Esophageal Fully and Partially Covered Stent Systems 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

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.

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MR Conditional

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

- Static magnetic field of 3 Tesla or less
- Spatial gradient field of 720 Gauss/cm or less
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning

In non-clinical testing, the WallFlex Esophageal Stent produced a temperature rise of less than 0.6 C at a maximum whole body averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of MR scanning in a 3 Tesla MR scanner (Excite™, General Electric).

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the WallFlex Esophageal Stent.

Potential Adverse Events

The potential adverse effects associated with esophageal stent placement may include: bleeding, perforation, pain, aspiration, stent migration, tumor ingrowth through uncovered portion of stent (for WallFex Partially Covered Esophageal Stent only), tumor overgrowth around stent ends, foreign body sensation, food boulus impaction, reflux, esophagitis, edema, ulceration, fever, infection, sepsis, septicemia, recurrent dysphagia, fistula formation, tracheal compression/obstruction (or acute airway compression), hematemesis, death (other than that due to normal disease progression).

Possible post sent complications include: sensitivity to the metal component of the stent, mediastinitis, aspiration, intestinal obstruction (secondary to stent migration), and granulation of tissue around stent ends.