WallFlex™ Esophageal
Fully Covered Stent System
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
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. This device contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.

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.

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.

Potential 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)
- Tumor overgrowth around stent ends
- Ulceration

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