Wallflex™ Fully and Partially Covered Esophageal Stents

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.

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

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.

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.

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