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

**Intended Use/Indications for Use**

- Stenting esophageal stenoses, such as stenting refractory benign strictures and malignant strictures
- Esophago-respiratory-fistula
- Maintaining esophageal lumen patency in esophageal strictures caused by intrinsic or extrinsic tumors.

**Contraindications**

- Serious blood clotting disorders
- Placement in necrotic chronically bleeding tumors
- Placement in polypoid lesions
- Extremely narrow and rigid strictures that cannot be dilated to allow passage of the delivery system
- Esophageal perforation or fistula without stenose, which can contribute to improper anchoring
- Placement of the stent’s proximal end within 2 cm of the upper esophageal sphincter
- Patients, with whom endoscopic techniques cannot be performed and/or are contraindicated

**Warnings**

For single patient 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 or reprocessing 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.

The Polyflex Stent should be used with caution only after careful consideration in patients with significant preexisting pulmonary or cardiac disease.

The safety and effectiveness of removing a stent from a benign lesion beyond 9 months has not been established.

The Polyflex Esophageal Stent should not be contacted by a laser or argon.

Placing a stent in a position that is too proximal may cause symptoms of globus or discomfort.

Exercise care when removing a stent that has significant overgrowth around the stent ends.

It is suggested not to remove a stent from a malignant lesion once original placement has been completed and confirmed.

Note: MRI (Magnetic Resonance Imaging) and CT are possible.

Caution should be used in conditions where esophageal stenting may cause a secondary stenosis.
Refer to the device directions for use for complete instructions on device use.

**Warnings (ctd.)**

The migration rate may be increased by the absence of a tumor abutment in benign esophageal stenosis, wrong sizing of the stent, or in cases of malignant stenosis where radiotherapy and/or chemotherapy is employed.

Stenting across the gastro esophageal junction may increase the risk of migration.

Stent revision or removal may be difficult in patients who have had prior gastric pull up operations.

To date, there has been no published experience with stents placed one inside the other.

**Potential Adverse Events**

Literature states the following list of possible complications in connection with the use of esophageal stents. Please consult current medical literature for any additional complications.

Potential Adverse Effects may include, but are not limited to:

During intubation: perforation, aspiration, bleeding, stent migration, pain and tracheal, bronchial compression, vomiting, and respiratory compromise.

Following intubation: perforation, bleeding, stent migration, pain/sensation of a foreign body, tumor growth around the ends of the stent, stent occlusion due to a bolus of food, reflux, esophagitis, edema, mucous membrane ulceration, fever, fistula development, sepsis, vomiting and aspiration, tracheal and bronchial compression, mediastinitis, emphysema, and death.

Warning: Caution should be used in conditions where esophageal stenting may cause a secondary tracheal stenosis.

Please be aware that potential adverse effects may arise even with the proper use of medical devices. Accordingly, this device should only be used by persons qualified in the procedures for which it is indicated.

**Cautions**

Cautions can be found in the product labeling supplied with each device. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

The migration rate may be increased by the absence of a tumor abutment in benign esophageal stenoses, wrong sizing of the stent, or in cases of malignant stenosis where radiotherapy and/or chemotherapy is employed.

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