

# Polyflex™ Esophageal Stent with Delivery System

REFER TO THE DEVICE DIRECTIONS FOR USE FOR COMPLETE INSTRUCTIONS ON DEVICE USE. RX ONLY.  
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 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.

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

## Caution

Read the Directions for Use thoroughly before using the Polyflex Esophageal Stent. The Polyflex Esophageal Stent should only be used by or under the supervision of physicians trained in esophageal stent 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

- 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

## Possible Complications

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.

### During Intubation

- Perforation
- Tracheal or bronchial compression
- Pain
- Respiratory compromise
- Bleeding
- Vomiting and aspiration
- Stent migration

### Following Intubation

- Perforation, especially in situations where there is severe esophageal compromise (e.g. unhealed burns)
- Bleeding, especially in situations where there is severe esophageal compromise (e.g. unhealed burns)
- Vomiting and aspiration
- Stent migration
- Reflux
- Stent occlusion due to a bolus of food
- Edema
- Fever
- Mediastinitis, empyema and Sepsis
- Tracheal or bronchial compression
- Pain/Sensation of a foreign body
- Tumor growth around the ends of the stent
- Esophagitis
- Mucous membrane ulceration
- Fistula development
- Death

## Warning

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

**Warning:** The Polyflex Esophageal Stent should not be contacted by a laser or argon due to ignition of the silicone, which may result in tissue injury.

**Warning:** The safety and effectiveness of leaving this stent in place in, or removing this stent from a benign lesion beyond 9 months has not been established.

**Warning:** Placing the stent in a position, which is too proximal may cause symptoms of globus or discomfort.

## Caution

**Caution:** 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.

**Caution:** Stenting across the gastroesophageal junction may increase the risk of migration.

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

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

**Caution:** Do not use sharp instruments in or near this stent. The stent may be punctured or torn.