

The Polyflex™ Airway Stent

With Delivery System

Prescriptive Information

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

Caution/Rx Only:

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

Warnings:

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.

Do not modify the Polyflex Stent, as the polyester braid, if exposed may cause mucosal damage.

The Polyflex™ Airway stent system should be used with caution and only after careful consideration in patients with:

- Elevated bleeding time or coagulopathies
- Prior pneumonectomy
- Concurrent acute inflammation in the lumen, as this may potentiate granuloma formation and fibrosis
- A tumor stricture adjacent to a major vessel, as this may potentiate fistula formation.

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

Intended Use / Indications for Use:

- Compression or strictures due to tumors (trachea and main bronchus)
- Stenosis of the central airways (such as trachea and main bronchus)
- Tracheo Esophageal fistula
- Airway complications such as anastomosis and stenosis

Contraindications:

- None in life threatening emergencies
- Obstruction of the Larynx
- Narrow or rigid stenoses that cannot be dilated sufficiently
- Patients for whom endoscopic techniques are contraindicated
- Patients with blood clotting disorders
- Bilateral recurrent laryngeal nerve paresis

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Relative Contraindications:

- Operable Tracheomalacia
- Benign operable stenosis

Cautions:

The entire directions for use should be read thoroughly before using the Polyflex Airway Stent. The Polyflex Airway Stent should only be used by or under supervision of physicians trained in airway stent placements by means of rigid bronchoscopy performed under general anesthesia with appropriate monitoring capabilities. A thorough understanding of the technical principles and risks associated with this procedure is necessary before using this device.

Visually inspect the kit for damage. If the system has any sign of damage, do not use.

Do not use mineral oil-based lubricants, silicone oils, silicone sprays or other silicone containing agents.

Avoid contacting the stent with sharp instruments, which may cause damage.

Potential Complications:

Literature states the following list of possible complications in connection with the use of airway stents. Please refer to current literature for current complications. Complications during the procedure:

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| • Mucosal Damage | • Stent occlusion due to tumor overgrowth or |
| • Pain | • granulation tissue or mucus (incrustation) |
| • Bleeding | • Mucus retention |
| • Perforation | • Infection by bacteria or fungi |
| • Failure of stricture dilation by the stent | • Pneumonia |
| • Aspiration | • Edema |
| • Hypoxia | • Fever |
| • Stent misplacement | • Development of fistula |
| • Pneumothorax | • Sepsis |
| • Complications after the stent placement: | • Halitosis |
| • Pain | • Recurrent obstructive dyspnea |
| • Bleeding | • Aphonia |
| • Perforation | • Obstructive atelectasis |
| • Stent migration | • Death |
| • Foreign body sensation | |