

# Polyflex<sup>®</sup> Airway Stent

*Self-expanding Silicone Airway Stent*

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## POLYFLEX AIRWAY STENTS

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Order Number	Stent ID (mm)	Length (mm)	Delivery System Diameter (mm)	Scope Minimum I.D. (mm)
M00570000	8	20	7	7.5
M00570010	8	30	7	7.5
M00570020	10	20	8	8.5
M00570030	10	30	8	8.5
M00570040	10	40	8	8.5
M00570050	10	50	8	8.5
M00570060	12	20	9	9.5
M00570070	12	30	9	9.5
M00570080	12	40	9	9.5
M00570090	12	50	9	9.5
M00570100	14	20	9	9.5
M00570110	14	30	9	9.5
M00570120	14	40	9	9.5
M00570130	14	50	9	9.5
M00570140	14	60	9	9.5
M00570150	16	30	10	10.5
M00570160	16	40	10	10.5
M00570170	16	50	10	10.5
M00570180	16	60	10	10.5
M00570190	16	70	10	10.5
M00570200	18	30	11	13
M00570210	18	40	11	13
M00570220	18	50	11	13
M00570230	18	60	11	13
M00570240	18	70	11	13
M00570250	18	80	11	13
M00570260	20	40	12	13
M00570270	20	50	12	13
M00570280	20	60	12	13
M00570290	20	70	12	13
M00570300	20	80	12	13
M00570310	22	50	13	13
M00570320	22	60	13	13
M00570330	22	80	13	13

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### **INSTRUCTIONS FOR USE**

Refer to the operator's manual for complete instructions for use.

### **INDICATIONS**

Indicated for compression or strictures due to tumors (trachea and main bronchus), stenosis of the central airways (such as trachea and main bronchus), tracheoesophageal fistula, and 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

Relative contraindications include: operable tracheomalacia, or benign operable stenosis.

### **WARNINGS**

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization 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 resterilization 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 the stent loader/soft positioner, delivery tube, stopper and packaging in accordance with hospital, administrative and/or local government.

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, or a tumor stricture adjacent to a major vessel, as this may potentiate fistula formation.

### **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: mucosal damage, pain, bleeding, perforation, failure of stricture dilation by the stent, aspiration, hypoxia, stent misplacement, and pneumothorax.

Complications after the stent placement: pain, bleeding, perforation, stent migration, foreign body sensation, stent occlusion due to tumor overgrowth or granulation tissue or mucus (encrustation), mucus retention, infection by bacteria or fungi, pneumonia, edema, fever, development of fistula, sepsis, halitosis, recurrent obstructive dyspnea, aphonia, obstructive atelectasis and death.

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.

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Ordering Information  
1.800.225.3226

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