

Dynamic™ (Y) Stent

Bifurcated Tracheobronchial Stent

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The Dynamic (Y) Stent is a tracheobronchial stent designed specifically for the airway anatomy. The stent, which consists of a single piece construction bifurcated tube, is designed to simultaneously secure the trachea, left mainstem and right mainstem bronchus.

The Dynamic (Y) Stent is intended to maintain patent airways in tracheal stenosis and seal tracheoesophageal fistulas. In addition, the stent is applicable to the following conditions, including:

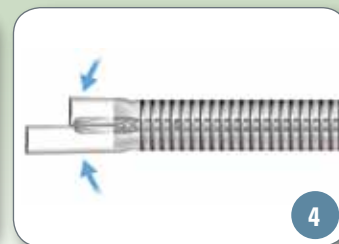
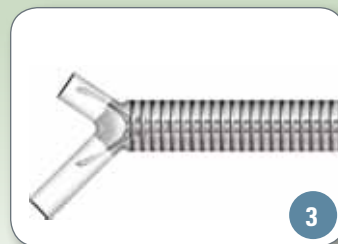
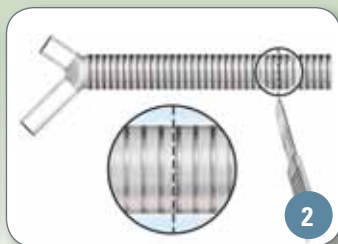
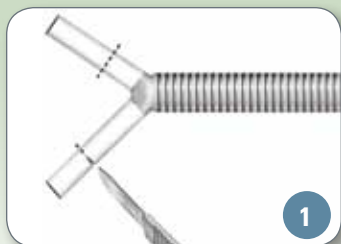
- Tracheomalacia
- Stenosis secondary to lung transplantation

➤ *Instructions on how to remove the stent can be found in the Directions for Use.*



DYNAMIC™ (Y) STENT PLACEMENT

*The following is an abbreviated description of the insertion technique for the Dynamic (Y) Stent. For a complete set of detailed instructions, please see the Directions for Use. The Dynamic (Y) Stent is designed for use by a physician trained in stent insertion of tracheobronchial stents under laryngoscopic control or rigid bronchoscopy.

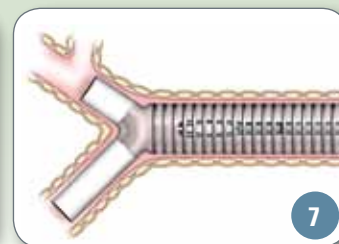
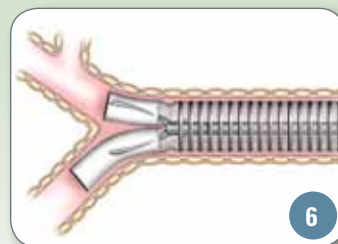


MODIFYING STENT LENGTH Using a long surgical knife, make a straight continuous cut at a right angle through the bronchial limb to be shortened. Incision edges must be rounded and care taken to ensure smoothness of terminal stent edges. (Figures 1 and 2)

STEP 1 The cut-to-fit and rounded off stent is fixed with the stent forceps. (Figures 3 and 4)

Placement of the stent can be accomplished using rigid grasping forceps, such as the Freitag forceps (10510N) produced by Karl Storz GmbH & Co. KG.

Note: The stent should be introduced as soon as the bronchoscope has been removed to take advantage of the dilating effect of the bronchoscope.



STEP 2 The vocal cords are visualized in the usual manner.

STEP 3 The stent is inserted directly into the airway with forceps. (Figure 5)

Note: Slight turning of the stent forceps as well as having both silicone stent limbs maximally pressed together facilitate passage through the vocal cords.

Caution: Care should be taken so that stent insertion does not damage vocal cords.

Caution: Careful insertion of stent is required to avoid perforation of the tracheal wall, especially through the lesion.

STEP 4 The stent is carefully rotated into its appropriate axial position so that the anterior and posterior portions of the stent are aligned with the anterior and posterior airway.

STEP 5 Using forceps with jaws slightly opened, the stent is advanced to the carina. The stent is held in its final position as the forceps are withdrawn. (Figures 6 and 7)

Note: Complete expansion of the strut reinforced tracheal part of the stent may occasionally require several days.

INDICATIONS

- Airway complications such as anastomosis and stenosis following lung transplantation
- Tracheo-malacia
- Tracheoesophageal fistula

CONTRAINDICATIONS

- None in life threatening emergencies
- Laryngeal obstruction
- Bilateral paralysis of recurrent laryngeal nerve
- Patent tracheal stoma
- Need for artificial ventilation

WARNING

Do not use on patients with:

- Operable stenosis
- Mature, open tracheostoma
- Patients who need artificial respiration because of indications other than stenosis
- Compression of airway by vascular anomalies (e.g. aortic aneurysm)

APPLICATION

The stent is designed for use by a physician trained in stent insertion of tracheobronchial stents under laryngoscopic, or rigid bronchoscopy.

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CLINICAL CASE

**Gaetane Michaud,
MS, MD, FRCP(C), FCCP**

Assistant Professor of Medicine
Thoracic Interventional Program
Pulmonary and Critical Care Medicine
Yale School of Medicine

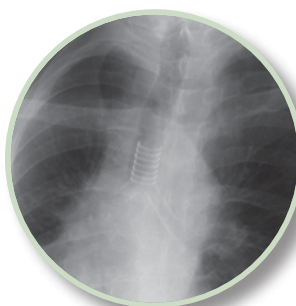
A 43-year-old man presented with non-small cell lung cancer. He had a malignant airway obstruction of the trachea and right main bronchus. A Dynamic (Y) Stent was inserted into the airway.



Intra-operative mid-stent
view of the carina via
bronchoscopy



Intra-operative view of the
anatomically shaped proximal end
of the stent via bronchoscopy



Post-operative chest
radiograph confirming proper
stent position



Post-operative 3-D Computed
Tomography reconstruction
confirming proper stent position

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

ORDERING INFORMATION

Dynamic™ (Y) Stent

Order Number	Tracheal Width (I) (mm)	Bronchial Width (I) (mm)	Tracheal Length (mm)	Bronchial Lengths (R/L) (mm)	Units
M00570670	11	8	110	25 / 40	Each
M00570680	13	10	110	25 / 40	Each
M00570690	15	12	110	25 / 40	Each

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Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
www.bostonscientific.com/endo-resources

Ordering Information
1.888.272.1001

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Indications, Contraindications, Warnings and Instructions for Use 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.