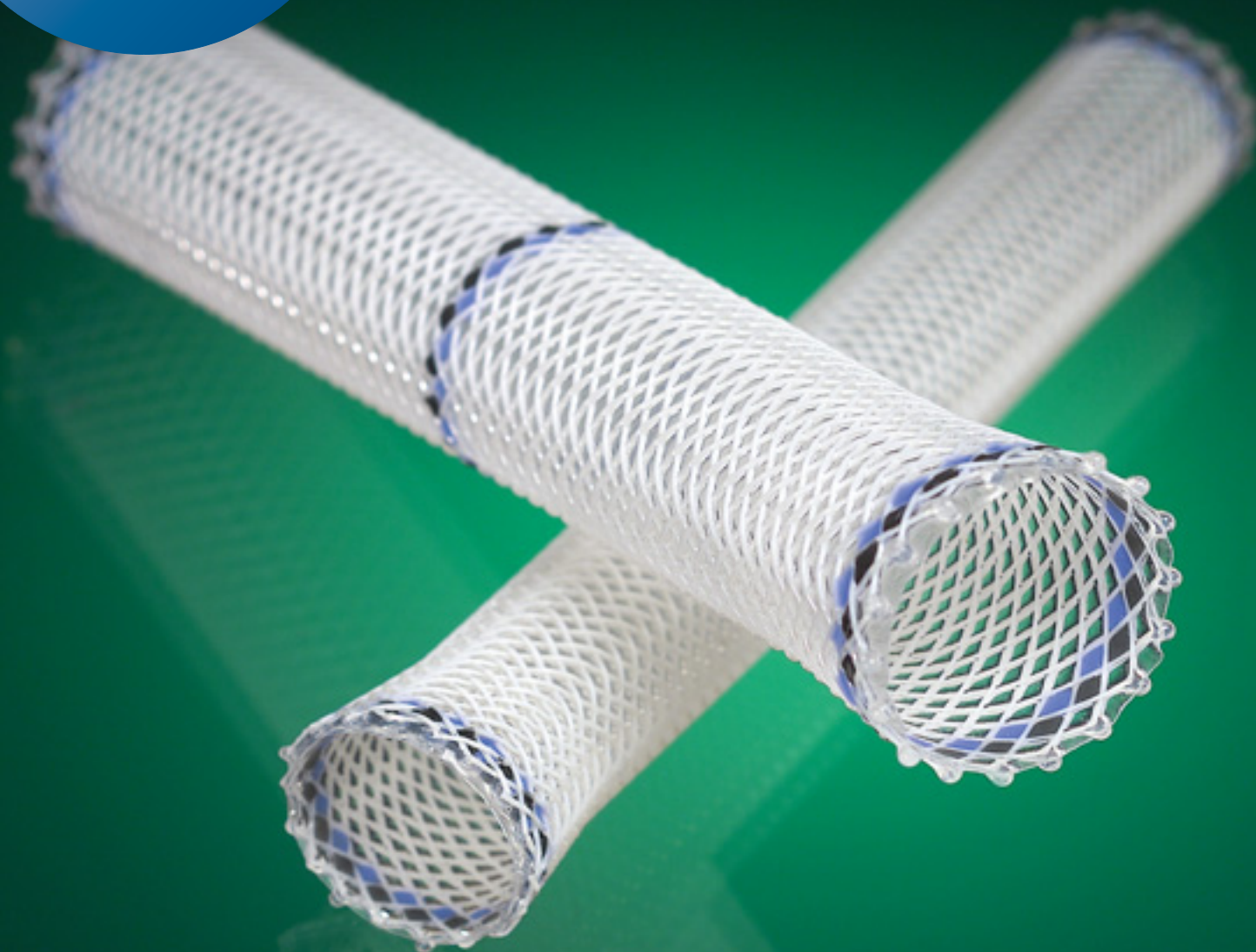


# ***Polyflex***<sup>®</sup>

Esophageal Stent

**Boston  
Scientific**

**Indicated for  
Refractory Benign and  
Malignant Esophageal  
Strictures**



# Polyflex<sup>®</sup>

## Esophageal Stent

Indicated for refractory benign and malignant esophageal strictures

The Polyflex Esophageal Stent is indicated for refractory benign and/or malignant esophageal stenosis and concurrent tracheoesophageal fistulas. The stent is engineered to maintain luminal patency in both intrinsic and extrinsic tumors.

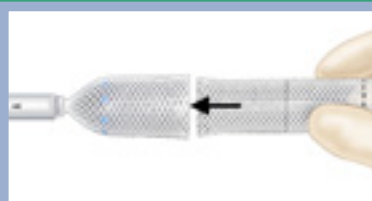
In a limited evaluation of the Polyflex Esophageal Stent in 37 benign stenoses, stents were successfully removed in 36 cases. One stent was removed at 270 days, with an average time to removal of 67 days.

**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.

### Offer multiple stent options

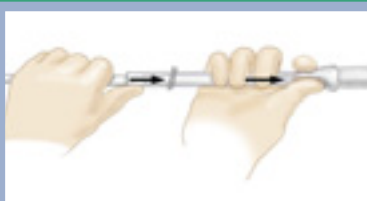
- Choice of stent diameter length accommodate a variety of different patient conditions.

## Esophageal Stent Device Set-Up Steps\*



### Step one

The funnel end of the stent is inserted into the basket of the stent loader as far as the marker.



### Step two

The stent loader is grasped with one hand while the other hand is used to grasp and pull back on the basket sleeve with the basket. The basket with the stent must be lengthened simultaneously in order to achieve a narrowing or funnel-like effect where the stent is being pulled into the delivery system.

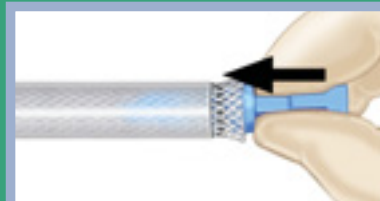
**CAUTION:** If stent infolding or collapsing is observed through the delivery system, it is important to release and reload the stent and increase the pull force. If stent infolding cannot be corrected, a second stent should be selected for the procedure.



### Step three

The delivery system is slid over the basket while the Polyflex Stent is held with the thumb until only 1 mm (black marker) of it projects from the transparent delivery system.

**CAUTION:** If the stent is pulled too far into the delivery system, the basket loaded stent should be pulled out of the delivery system and the insertion process should be started again.



### Step four

The stopper is inserted firmly into the end of the stent to prevent the stent from moving.

\* This overview is provided for illustrative purposes only and is intended only as a brief summary of how the set up procedures for the Polyflex<sup>®</sup> Esophageal Stent are generally performed.



### Promote smooth interface with mucosa

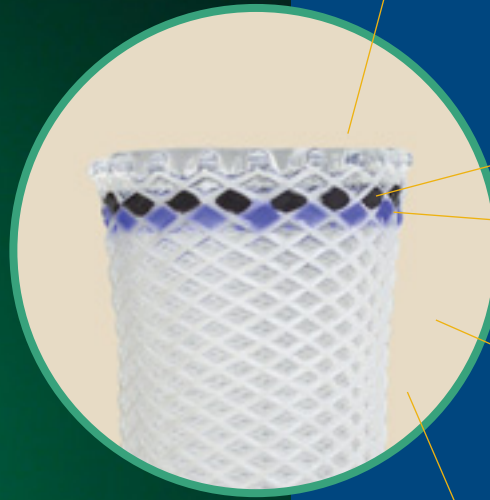
- Silicone reinforced ends help resist hyperplasia.

### Potentially enhance patient comfort

- Thin wall promotes full use of lumen diameter for greater patency.
- Smooth inner surface helps facilitate passage of foods and fluid.

### Maintain luminal patency

- Silicone construction is engineered to exert constant, gentle pressure on tumors and to help adapt to normal esophageal peristalsis.



### Resist migration

Proximal flare designed for improved stent fixation.

### Facilitate accurate positioning

Black radiopaque markers assist in fluoroscopic stent positioning and monitoring.

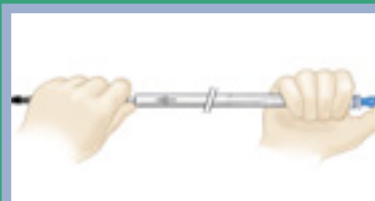
Blue endoscopic markers help facilitate direct visualization.

### Resist tumor ingrowth and seal tracheoesophageal fistulae

Silicone coating enhances patency and palliation.

### Allow for stent repositioning post-deployment

Thin stent wall is engineered to elongate when stretched lengthwise.



#### Step five

The stopper is pressed with the thumb of one hand while the stent loader is grasped with the other hand. The stent loader is pulled backwards until it is removed.



#### Step six

The stopper is removed. The stent is pushed fully into the delivery system up to the marker with the aid of the soft positioner.



#### Step seven

The end of the insertion tube is inserted into the delivery system and the stent until the dilator is closing the end of the tube. The insertion tube's free end is then threaded into the soft positioner end with the arrow first. Threading is continued and soft positioner is advanced until it touches the stent in the introducer sleeve.

NOTE: If the dilator tip falls out of the delivery system, the dilator tip should be pushed back into the sleeve and threading should be continued.

#### Step eight

Onto the free end of the insertion tube, the stent clamp is threaded, orange end first, until the clamp reaches the positioner. The blue end should then be tightened clockwise until the system does not move.


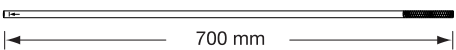
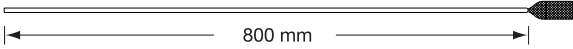
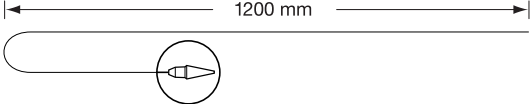


# Polyflex<sup>®</sup>

## Esophageal Stent

### Polyflex Stent for the Esophagus

Order Number	Stent Body I.D. (mm)	Stent Flare I.D. (mm)	Stent Lengths (mm)	Delivery System O.D. (mm)
M005 <b>14270</b>	16	20	90	12
M005 <b>14280</b>	16	20	120	12
M005 <b>14290</b>	16	20	150	12
M005 <b>14300</b>	18	23	90	13
M005 <b>14310</b>	18	23	120	13
M005 <b>14320</b>	18	23	150	13
M005 <b>14330</b>	21	25	90	14
M005 <b>14340</b>	21	25	120	14
M005 <b>14350</b>	21	25	150	14

### Package contents

(1) Polyflex Stent	
(2) Delivery System with Stent Clamp	
(3) Loading Basket	
(4) Insertion Tube with Dilator	
(5) Soft Positioner	
(6) Stopper	

**Boston  
Scientific**

*Delivering what's next.™*

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

**Ordering Information**  
**1.800.225.3226**

© 2005 Boston Scientific Corporation  
or its affiliates. All rights reserved.

BVG8050 5M 05/05

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.

Polyflex is a trademark of Willy Rusch GmbH or its affiliates.