Polyflex®
Esophageal Stent

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

**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.

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**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.

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Offer multiple stent options

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

*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® Esophageal Stent are generally performed.*
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.

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.

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.

Resist migration
- Proximal flare designed for improved stent fixation.

Allow for stent repositioning post-deployment
- Thin stent wall is engineered to elongate when stretched lengthwise.

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Please refer to the Directions For Use for complete stent loading instructions.
## Polyflex® Esophageal Stent

### Polyflex Stent for the Esophagus

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<th>Order Number</th>
<th>Stent Body I.D. (mm)</th>
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### Package contents

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

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.

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