The Agile Esophageal Partially Covered Stent System is comprised of a metallic implantable stent pre-loaded inside of a flexible delivery system. The system is compatible with gastroscopes with a minimum 3.7 mm working channel. The delivery system is a co-axial tube design. The exterior tube is used by or under the supervision of physicians thoroughly trained in endoscopic techniques is active at the time of placement.

The packaging and device should be inspected prior to use. Do not use if the system has any visible signs of damage. Failure to observe this warning may result in patient injury.

The Agile Esophageal Partially Covered Stent System should only be used by or under the supervision of physicians thoroughly trained in endoscopic techniques. Clinical, applications, and risks associated with this procedure is necessary before using this device.

MRI Conditional Labeling
Non-clinical testing has demonstrated that the Agile Esophageal Stent is MR Conditional. A patient with this device can be safely scanned under the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only
- Maximum spatial gradient magnetic field of 3.0 gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤ 2.0 W/kg (Normal Operating Mode)
- Under the scan conditions defined above, the Agile Esophageal Stent is expected to produce temperature rise of less than 7.0° C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 10mm from the perimeter and 5 mm from the end of the stent when imaged with a gradient echo pulse sequence in a 3T MRI System.

INTENDED USE/INDICATIONS FOR USE
The Agile Esophageal Partially Covered Stent System is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors, and occlusion of concurrent esophageal fistulas.

CONTRAINDICATIONS
The Agile Esophageal Partially Covered Stent System is contraindicated for:

- Placement in esophageal strictures caused by benign tumors, as the long-term effects of the stent in the esophagus are unknown.
- Placement in strictures that cannot be dilated enough to pass the gastroscope or the delivery system.
- Placement of the proximal end of stent within 2 cm of the cardia or cricopharyngeal muscle.
- Placement in an esophago-jejunal anastomosis (gastroscopy), as peristalsis and altered anatomy may displace stent.
- Placement in neoplastic chronically bleeding tumors, if bleeding is active at the time of placement.
- Placement in polypoid lesions.
- Those patients for whom endoscopic techniques are contraindicated.
- Any use other than those specifically outlined under indications for use.
- Placement in patients who have an underlying bleeding diathesis.

WARNING: Stent is considered to be a permanent device. Once stent placement is permanently achieved, stent removal or repositioning is not recommended.

WARNING: Visually inspect the system for any signs of damage. DO NOT USE if the system has any visible signs of damage. Failure to observe this warning may result in patient injury.

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

WARNING: Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damaged is found, call your Boston Scientific representative.

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 diseases(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.

DEVICE DESCRIPTION

Contents:

- (1) Agile Esophageal Partially Covered Stent System

The delivery system is a co-axial tube design. The exterior tube is used to constrain the stent before deployment and to reconstrain the stent after partial deployment. The exterior tube has clear silicone covering. The system has RO markers to aid in the deployment and visualization of the stent while using fluoroscopy (Figure 2). There are five radiopaque (RO) markers to aid in the deployment and visualization of the stent while using fluoroscopy (Figure 2).

The system has a single central lumen to accommodate a 0.035 in. (0.89 mm) guidewire.

WARNING AND CAUTIONS

- The potential adverse effects associated with esophageal stent placement may include:
  - Bleeding
  - Perforation
  - Pain
  - Aspiration
  - Stent migration
  - Tumor ingrowth through uncovered portion of stent
  - Tumor overgrowth around stent ends
  - Foreign body sensation
  - Food bolus impaction
  - Reflux
  - Esophagitis
  - Edema
  - Ulceration
  - Fever
  - Infection
  - Sepsis
  - Septicemia
  - Recurrent dysphagia
  - Fistula formation
  - Tracheal compression/obstruction (or acute airway compression)
  - Hematemesis
  - Death (other than that due to normal disease progression)
  - Stent fracture

Possible Stent Complications

- Sensitivity to the metal component of the stent
- Mediastinitis
- Aspiration
- Intestinal obstruction (secondary to stent migration)
- Granulation tissue around stent ends
- Aorto and arterioesophageal fistula
- Erosion or perforation of stent into adjacent vascular structures

HOW SUPPLIED

The device is supplied sterile and intended for single use only. The packaging and device should be inspected prior to use. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in a cool, dry, dark place. See product label for expiration date.
DIRECTIONS FOR USE

Required Equipment

- Gastroscope with a minimum 3.7 mm working channel.
- Rat Tooth forceps.
- Fluoroscopic capability for pre-stent placement and stent placement confirmation.
- 0.035 in (0.89 mm), 450 cm guidewire.
- Agile™ Esophageal Partially Covered Stent System containing a stent of the appropriate length and diameter.

Pre-Procedural

Radiography of the esophagus performed no more than 10 days before the procedure should be available. Prepare for the procedure as you would an upper endoscopy. Administer a mild sedative, if necessary and a topical anesthesia to the throat to be repeated during the procedure as patient comfort warrants.

Initial preparation of delivery system

- Carefully remove the delivery system from the protective packaging.
- Visually inspect the device for damage or defects.

OPERATIONAL INSTRUCTIONS

Start of initial stent placement procedure.

1. Locate the Stricture

Intubate the patient using a standard gastroscopy per standard technique. Access the stricture location upon direct visualization. Fluoroscopy can also be used to locate the stricture with the aid of a contrast medium.

2. Examine the Stricture (Endoscopically and/or Fluoroscopically)

A. Examine Stricture Endoscopically

Endoscopically examine both the proximal and distal segments of the stricture. Using the external ruler on the gastroscope, measure the distance between the distal margin of the stricture to the patient’s incisors. Withdraw the gastroscope to the proximal margin of the stricture and measure the distance to the patient’s incisors. The stricture length is calculated as the difference between those two distances. To minimize the potential of stent migration, dilate the stricture only if passage of the gastroscope or the delivery system through the stricture lumen is not possible.

Caution: In some patients, tumor encroachment will make dilation of the stricture challenging. Physicians should use judgment based on experience in dilating esophageal strictures. Perforation or bleeding of an esophageal tumor is a risk during a tumor dilation procedure.

Warning: Placement of the Agile Esophageal Partially Covered Stent should not be attempted in patients with esophageal strictures that cannot be dilated wide enough for passage of the gastroscope or delivery system.

B. Examine the Stricture Fluoroscopically

The stricture may also be examined fluoroscopically. Leaving the gastroscope in place, observe both the proximal and distal margins of the tumor fluoroscopically. Mark the locations with either radiopaque markers or use anatomical landmarks such as ribs or vertebrae. It is recommended to re-measure the stricture length by measuring the distance between the radiopaque markers.

Warning: Physicians should use judgment based on experience when dilating esophageal strictures. Perforation or bleeding of the esophageal tumor is a risk during any dilation of the tumor.

3. Choose the Stent Size

The size of the stent must be accurately calculated to ensure the ideal stent size is used. The Agile Esophageal Partially Covered Stent should bridge the tumor and/or the fistula and should extend >1 cm above and below the stricture or fistula. For stent use with a fistula, it is critical to ensure that the covered portion of the stent completely covers the fistula to avoid leakage and facilitate healing. If stent length choice is questionable, always use the longer stent size. A second stent, the same diameter may be placed if the first stent does not cover the entire stricture length. The second stent should be placed to ensure complete tumor coverage and a smooth transition between the stents. It is recommended that the proximal stent be placed first followed by the distal stent in order to maximize luminal diameter of the interlocked stents. Care should be used when passing the delivery system through the first stent. As the stent is deployed, the stent will foreshorten. Foreshortening is defined as the percentage decrease from constrained stent length within the delivery system to deployed stent length. Benchtop testing has demonstrated the Agile Esophageal Stent will foreshorten no more than 50% from its constrained length on the delivery system. However, actual foreshortening depends on the anatomy of the lumen and stricture.

Warning: Passing the scope through a just deployed stent is not recommended and could cause the stent to dislodge.

Warning: Do not use in combination with stents from other manufacturers.

4. Insert Guidewire and Place Through Stricture

Pass a guidewire through the working channel of the gastroscope and then through the stricture and into the stomach. A floppy tip guidewire is recommended in order to reduce potential trauma from the tip of the wire. Endoscopic and fluoroscopic placement of the guidewire is also recommended to assure proper passage through the stricture and proper placement in the stomach. Maintain guidewire position throughout procedure.

Caution: A 0.035 in (0.89 mm) guidewire with a floppy tip is recommended to facilitate passage through tortuous anatomy. Dreamwire™ 0.035 in (0.89 mm) Stiff M0056141, Dreamwire 0.035 in (0.89 mm) Stiff M0056161, Jagwire™ 0.035 in (0.89 mm) Standard M0056161 or Jagwire 0.035 in (0.89 mm) Stiff M0056160 is recommended.

5. Advance the Delivery System over the Guidewire and Position Stent

There are three visual markers on the delivery system handle to aid in stent placement while using endoscopic visualization (Figure 2). The most distal visual marker indicates the stent is fully constrained on the delivery system (Figure #3), one visual marker indicates that the stent is 50% deployed (mid-point) (Figure #7), and the most proximal visual marker indicates the point at which stent reconstrainment is no longer possible (Figure #8).

There are five radiopaque (RO) markers to aid in the deployment of the stent while using fluoroscopy (Figure 3). There are two RO markers on the inner tube of the delivery system identifying the distal end of the constrained stent (Figure 2, #1 and 4). Between these RO markers are two additional RO markers. One RO marker indicates the mid-point of the stent (Figure 2 #2). One RO marker on the interior tube indicates the point at which stent reconstrainment is no longer possible (Figure 2, #3). The fifth RO marker at the leading end of the exterior tube indicates how far the stent has been deployed (Figure 2, #5).

The Agile Esophageal Stent System is passed over a guidewire and through the working channel of the gastroscope. Under direct endoscopic visualization, position the stent keeping direct endoscopic visualization of the yellow transition zone. If using fluoroscopic guidance, position the stent so marker 2 (Figure 2) is in the center of the tumor or fistula. This ensures that the stent will properly bridge the tumor. If it is not necessary to cross the Lower Esophageal Sphincter (LES), the distal end of the stent should remain above the LES in order to leave the LES functional and reduce gastric reflux. The stent can cross the LES if necessary due to tumor involvement and stricture.

6. Deploy Stent

Figure 2. Delivery System and Radiopaque (RO) Markers

Note: Once the visual reconstrainment marker cannot be seen during deployment the stent cannot be reconstrained.

Caution: Restrerelease can result in reverse direction of deployment, by holding the proximal handle (closest to the operator) steady while pulling the distal handle (farthest from the operator) away.

The stent has been designed to be reconstrained no more than two times.

Caution: Prior to full deployment, if repositingion is desired, the stent can be pulled proximally by slowly pulling back on the delivery system. The ability to pull proximally will be limited by the amount of stent deployed and the tightness of the stricture. Full reconstrainment, when possible, is always preferred and recommended over pulling the device proximally.

Caution: Pulling proximally when partially deployed could further deploy the stent if there is resistance on the stent.

Caution: Do not push the delivery system forward once deployment has begun. The delivery system can be pulled proximally if necessary. The ability to pull proximally will be limited by the amount of stent deployed and the tightness of the stricture.

Warning: Stent is considered to be a permanent device. Once stent placement is permanently achieved, stent removal or repositingion is not recommended.

If the positioning of an Agile Esophageal Partially Covered Stent is not correct and one of the following has occurred, continue to fully deploy the stent:

A. The stent has already been deployed past the reconstrainment limit

B. The stent has already been reconstrained twice

Then in either case, using rat tooth forceps, grasp the suture on the proximal or distal end of the stent (Figure 1). Gently pull the stent back with the scope to remove the stent from the device. The stent can be pulled totally through the delivery system, tightening the stent function.

Caution: Fully grasp around the suture when repositinging or removing the Agile Esophageal Partially Covered Stent.

Caution: Do not remove the stent by pulling the stent through the scope. After grasping the stent remove both the gastroscope and stent together.
7. Assess Deployed Stent Position and Remove the Delivery System

Following stent deployment, view the stent endoscopically and/or fluoroscopically to confirm stent expansion as tumor impingement may prevent the stent from achieving its maximum diameter immediately. Carefully remove the delivery system and the guidewire.

Note: A stent may require 24 hours to expand fully.

Warning: Once stent is in desired location, passing the scope through a just deployed stent is not recommended and could cause the stent to dislodge.

Caution: Never use a rigid-type dilator for post stent placement dilatation because the axial force may dislodge the stent. Physicians should use judgement based on experience when dilating.

Caution: An attempt to remove the delivery system and guidewire prior to stent expansion or when a stent is partially deployed may dislodge the stent.

If excessive resistance is felt during delivery system removal due to the stent being partially deployed, then proceed with the following steps:

A. Wait 3-5 minutes to allow further stent expansion
B. If the proximal end of the stent is pursed onto the delivery system, use the endoscope to manipulate the delivery system in a circular motion to open the proximal end of the stent.
C. Re-sheath the exterior tube of the delivery system by pushing the distal handle (Figure 3 #9) away from the operator. Slowly withdraw the delivery system and guidewire.
D. If removal is still not possible, use a balloon dilation catheter to dilate the stent. It should not be necessary for the balloon diameter/to be equal to the stent diameter. Judgement should be used when selecting the balloon size. Carefully position the balloon catheter within the stent. Inflate the balloon to its recommended pressure.
E. Deflate the balloon catheter and withdraw into the gastroscope. Slowly withdraw the delivery system and guidewire.

8. Remove Gastroscope

Withdraw gastroscope from the patient. This completes the initial stent placement procedure. Stent placement is considered permanent upon completion of initial stent placement procedure.

POST-PROCEDURE

Patients should have P-A (posteroanterior) and lateral chest films taken as a permanent record of the stent position. Observe the patient for development of any complications of endoscopy, esophageal dilation and stent placement. Vital signs should be monitored and clear liquids given in an upright position during and after meals. Patients with stents placed in the distal esophagus or across the LES should be instructed to elevate the head of the bed, and should be prescribed acid suppression therapy to minimize gastric reflux into the stent. Subsequent follow-up at 1 week and at 3 month intervals, thereafter, or for symptomatic dysphagia may be performed to verify patency and placement.

Note: Recurrence or worsening of dysphagia may occur after stent placement due to tumor in-growth or overgrowth over time, severe hyperplasia reaction or stent migration. Repeat endoscopy may be required.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC’s control directly affect the instrument and the results obtained from its use. BSC’s obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. BSC assumes no liability with respect to instruments reused, reprocessed and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.