The Agile Esophageal Fully 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 stent is made from braided Nitinol wires which form a self-expanding, radiopaque braided Nitinol wires which form a self-expanding, radiopaque structure. The system has a single central lumen to accommodate a 0.035 in guidewire. The system has RO markers on the inner tube of the delivery system identifying the stent ends each have a continuous suture threaded around their circumferences. The suture is intended to aid in removal of a metallic implantable stent pre-loaded inside of a delivery system.


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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 Fully 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 stricture must be accurately calculated to ensure the ideal size of stent is used. The Agile Esophageal Fully 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 stent completely covers the fistula to avoid leakage and facilitate healing. If stent length choice is questionable, always use the longer stent. A second stent of 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 forestall. Forestalling 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 forestall no more than 50% from its constrained length on the delivery system. However, actual forestalling 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/or 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. The Dreamwire™ 0.035 in (0.89 mm) Standard M0056141, Dreamwire 0.035 in (0.89 mm) Stiff M0056161, Jagwire™ 0.035 in (0.89 mm) Standard M0056681 or Jagwire 0.035 in (0.89 mm) Stiff M0056681 is recommended.

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

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

There are five radiopaque (RO) markers to aid in the deployment of the stent while using fluoroscopic visualization (Figure 2). There are two RO markers on the inner tube of the delivery system identifying the ends 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 #3). 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 3. Delivery System, Visual Markers and Handles

Caution: Do not twist the delivery system or use a boring motion during stent deployment as this may affect stent positioning and ultimately, the stent function.

Begin stent deployment by holding the distal handle (farthest from the operator, (Figure 3 #9) of the delivery system with one hand, and holding the proximal handle (closest to the operator, Figure 3 #10) and hold this handle stationary. Between the handles is a hypotube with visual markers. These visual markers are intended to aid in stent deployment. Prior to deploying the stent, you can visualize a marker at the fully constrained/undeployed position (Figure 3 #6). In order to deploy the stent, hold the distal handle (farthest from the operator, Figure 3 #9) with one hand and the proximal handle (handle closest to the operator, Figure 3 #10) with the other hand. To deploy the stent, slowly pull the distal handle toward the proximal handle while holding the proximal handle stationary. Monitor the stent release fluoroscopically and/or endoscopically, keeping the markers on the delivery system between the identified stricture margins. If necessary, it is possible to stop deployment and adjust the stent position proximally without reconstraining the stent prior to passing the reconstrainment marker (Figure 3 #8). Refer to the reconstrainment technique section. If satisfied with stent placement, proceed with full deployment.

Reconstrainment Technique

- The stent can be reconstrained at any point up to the reconstrainment markers (radioopaque Figure 2, #3 and visual Figure 3, #8).

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

- Reconstrainment is done by reversing the direction of deployment, by holding the proximal handle (closest to the operator) steady while pushing the distal handle (farthest from the operator) away.

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

- Prior to full deployment, if reposisioning 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.

Note: The stent is fully constrained if visual marker (Figure 3, #8) is fully visible.

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.

If the positioning of an Agile Esophageal Fully 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 (Figure 3, #8)

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 during the initial stent placement procedure.

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

Caution: Fully grasp around the suture when repositioning or removing the Agile Esophageal Fully 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 dilation 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/size 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 the first 24 hours post-stent placement. Patients being treated for fistula should have no fluids or foods orally until successful sealing of the fistula has been confirmed. Post 24 hours, the patient should be instructed to eat only in an upright sitting position, to chew food thoroughly, to avoid certain foods (such as meats, raw vegetables, and breads), and to drink fluids 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 ingrowth 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 or sterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.