Overview

Product

Agile™ Esophageal Fully Covered Stent System (TTS) IFU 51627816
Agile™ Esophageal Partially Covered Stent System (TTS) IFU 51627817
Agile™ Esophageal Fully Covered Stent System (OTW) IFU 51627819
Agile™ Esophageal Partially Covered Stent System (OTW) IFU 51627820

Rx Statement

CAUTION**:** Federal Law (USA) restricts this device to sale by or on the order of a *licensed practitioner.*
Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

Content

INTENDED USE/INDICATIONS FOR USE
The Agile Esophageal Partially Covered and Fully Covered Stent Systems are 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 Fully Covered Stent System and Fully Covered Stent Systems are 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 cricopharyngeal muscle.
- Placement in an esophago-jejunostomy (following gastrectomy), as peristalsis and altered anatomy may displace stent.
- Placement in necrotic chronically bleeding tumors, if bleeding is active at the time of placement.
- Placement in polypoid lesions.

- Placement in patients who have an underlying bleeding diathesis.
- Those patients for whom endoscopic techniques are contraindicated.
- Any use other than those specifically outlined under indications for use.

WARNINGS

REUSE WARNING

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 disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

GENERAL WARNINGS

- This device contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.
- The risk of perforation and erosion into adjacent vascular structures or aortoesophageal and arterioesophageal fistulas may be increased with pre- or post-operative chemotherapy and radiation, longer implantation times, aberrant anatomy, and/or mediastinal contamination or inflammation.
- As perforation is a known risk, the stent should be used with caution and only after careful consideration in patients who are:
  – Undergoing radiation therapy and/or chemotherapy
  – In advanced stages of cancer
- The Agile Esophageal Fully Covered Stent System and the Agile Esophageal Partially Covered Stent System should be used with caution and only after careful consideration in patients with:
  – Strictures exceeding 12 cm in length
  – Significant preexisting pulmonary or cardiac disease
- The stent is considered to be a permanent device when used in malignant tumors and concurrent fistulas. Once stent placement is permanently achieved, stent removal or repositioning is not recommended as this may lead to patient injury. Post-procedure stent migration may occur and would require appropriate management as per physician discretion.
- 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.
- 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.
- Placement of the Agile Esophageal Fully Covered Stent or 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 in order to avoid patient injuries such as perforation, hemorrhage and/or obstruction.
- Passing the scope through a just deployed stent is not recommended and could cause the stent to dislodge resulting in patient injury.

- Pulling proximally when partially deployed could further deploy the stent if there is resistance on the stent which could lead to positioning issues and/or patient injury.
- Once stent is in desired location, passing the scope through a just deployed stent is not recommended and could cause the stent to dislodge which may lead to patient injury.
- Never use a rigid-type dilator for post stent placement dilation because the axial force may dislodge the stent and could lead to patient injury. Physicians should use judgment based on experience when dilating.
- Carefully remove the delivery system and the guidewire. An attempt to remove the delivery system and guidewire prior to stent expansion or when a stent is partially deployed may dislodge the stent and could lead to patient injury.

PRECAUTIONS

- Boston Scientific has not evaluated the use of the Agile Esophageal Stent in combination with stents from other manufacturers.
- (OTW models only) A stiff bodied 0.038 in (0.97 mm) guidewire with a floppy tip is recommended to facilitate passage through tortuous anatomy. The Jagwire Guidewire M00556621 is recommended.
- 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.
- 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.
- Fully grasp around the suture when repositioning or removing the Agile Esophageal Fully Covered Stent or the Agile Esophageal Partially Covered Stent in order to avoid positioning issues with the stent.
- (Through-the-Scope models only) Do not remove the stent by pulling the stent through the scope. After grasping the stent remove both the gastroscope and stent together or damage to the scope may occur.

Note: The Agile Esophageal Fully Covered and Partially Covered OTW Stent Systems are not intended to be used through the working channel of any endoscope.
Note: A stend may require 24 hours to expand fully.

POTENTIAL ADVERSE EVENTS

The potential adverse effects associated with esophageal stent placement may include:

- Allergic reaction
- Aspiration
- Death (other than that due to normal disease progression)
- Dysphagia
- Edema/Inflammation
- Fistula (Including Aorto and arterioesophageal fistulas)
- Food bolus impaction
- Foreign body sensation
- Gastrointestinal Symptoms
- Hematemesis
- Hemorrhage
- Infection

- Mediastinitis
- Obstruction
- Pain
- Perforation
- Respiratory distress/Insufficiency
- Stent fracture
- Stent migration
- Tissue Damage
- Tissue overgrowth or ingrowth
- Tracheal compression/obstruction (or acute airway compression)
- Ulceration/Erosion

MRI SAFETY INFORMATION

A person with the Agile Stent(s) may be safely scanned under the following conditions. Failure to follow these conditions may result in injury	
Device Name	Agile Stent
Static Magnetic Field Strength (B_0)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Cylindrical Whole-body Coil Cylindrical Head Coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	Under scan conditions defined above, Agile Stent can be used for 60 minutes of continuous RF (a sequence or back-to-back series/ scan without breaks)
MR Image Artifact	Image artifact caused by device may extend approximately 20 mm from the perimeter and 5 mm from the end of the stent with a gradient echo pulse sequence

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.IFU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.