PRESCRIPTIVE INFORMATION

Agile™ Esophageal Fully Covered/Partially Covered Stent Systems

REFER TO THE DEVICE DIRECTIONS FOR USE FOR COMPLETE INSTRUCTIONS ON DEVICE USE. RX ONLY.
CAUTION: 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 damage is found, call your Boston Scientific representative. For single use only. Do not reuse, reprocess or resterilise. Reuse, reprocessing or resterilisation 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 resterilisation 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. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

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 3,000 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 5mm 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 and Fully Covered Stent Systems are intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumours, and occlusion of concurrent esophageal fistulas.

Contraindications

The Agile Esophageal Partially Covered Stent System is contraindicated for:

- Placement in esophageal strictures caused by benign tumours, 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 2cm of the cricopharyngeal muscle.
- Placement in an esophago-jejunostomy (following gastrectomy), as peristalsis and altered anatomy may displace stent.
- Placement in necrotic chronically bleeding tumours, 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.

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Warnings and Cautions

- 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 Partially Covered Stent System should be used with caution and only after careful consideration in patients with:
  - Strictures exceeding 12cm in length
  - Significant preexisting pulmonary or cardiac disease
- This device contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.

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

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.

Adverse Events

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

- Bleeding
- Perforation
- Pain
- Aspiration
- Stent migration
- Tumour ingrowth through uncovered portion of stent
- Tumour 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 post 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 strictures

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 labelling is incomplete or illegible.

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