Product Information for Patients

Agile™ Esophageal

FULLY COVERED OTW

Stent System

REF M00517750, M00517760, M00517770, M00517780

Device Information

The Agile Esophageal Fully Covered OTW Stent is a self-expanding metal stent with a Silicone cover. An esophageal metal stent is a flexible metal wire tube that is placed in the esophagus (food pipe) that expands to hold the narrowed area of the esophagus open.

The stent is intended to be used in patients with cancerous (malignant) narrowing of the food pipe (esophageal strictures) and is not intended to be removed.

The stent is designed as a device to improve difficulty swallowing (dysphagia) and maintain opening of the esophagus (esophageal patency) to allow for passage of food and liquids.

Your physician is prescribing this device as you have an abnormal connection between the esophagus and another organ in the body (stricture or fistula) hindering your ability to swallow liquids or foods.

Possible side effects may include reflux, sore throat, difficulty swallowing, and/or mild pain.

Your doctor should provide you with an implant card that identifies your stent. Always carry this card with you and present it to all health professionals (doctors, nurses, dentist, technicians).

Information on Safe Use

Follow your physician's instructions on dietary restrictions and physical activity.

- It is recommended to consume only clear liquids in an upright position during the first 24 hours after the stent has been placed.
- If you are being treated for abnormal connection between the food pipe (esophagus) and another organ in the body (fistula) you should not eat or drink until your doctor confirms the fistula is sealed.
- After physician instruction, it is recommended 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.
- After physician instruction, it is recommended to elevate the head of the bed. You may be prescribed acid suppression therapy to minimize gastric reflux (also known as heartburn, when some of the acid content of the stomach flows up into the esophagus) into the stent.
- Take your medication as instructed by your doctor.

Contact your healthcare provider immediately if any of the following occur:

- Your pain does not decrease following the instructions given to you by your doctor.
- You cough up or vomit blood.
- You have a fever of 101 °F (38.3 °C) or higher.
- You have increased difficulty swallowing.

Warnings and/or Precautions Related to Reciprocal Interference

Inform Healthcare professionals (doctors, nurses, dentist, technicians) that you have an implanted metal stent, so that they can take any necessary precautions.

The Boston Scientific Agile Esophageal Stents are MRI Conditional. This means, a patient with this device can be scanned safely only under specific conditions.

Provide MRI Conditional information below to your healthcare professionals if you have any special diagnostic tests such as an MRI.

Magnetic resonance imaging (MRI): This is a diagnostic test that uses a strong electromagnetic field to produce images of the body.

MR	
MRI Safety Information A person with the Agile Esophageal Fully Covered OTW Stent may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.	
Device Name	Agile Esophageal Fully Covered OTW 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, patient can be scanned for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	Image artifact can be produced

Expected Lifetime and Follow-up

The device has been designed to function in the body for up to one year.

The recommended post-procedure follow-up with your physician is at 1 week and at 3-month intervals.

For symptomatic dysphagia (difficulty swallowing) follow-up may be performed more frequently to verify the condition and placement of the stent.

Report any serious incident that occurs in relation to this device to Boston Scientific (https://www.bostonscientific.com) and to the relevant local regulatory authority for medical devices in your country.

For customers in Australia, report any serious incident that occurs in relation to this device to Boston Scientific and to the Therapeutic Goods Administration (https://www.tga.gov.au).

Patient Contacting Materials

The following materials are present in this stent:

Implantable Material	% Weight
Nitinol	67-75
Silicone	24-33
Polyester	<1

Warning

Nitinol is used in this device, which contains nickel. This may cause an allergic reaction in individuals with nickel sensitivity. Discuss the potential for allergy with your doctor if you have ever experienced a skin rash to jewelry, watches, or belt buckles.

Symbol Definitions

The following symbols are used for patient information:

REF Catalog Number	LOT Lot Number

EC REP

Boston Scientific Limited
Ballybrit Business Park
Galway IRELAND

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752 USA
USA Customer Service +1-888-272-1001

bostonscientific.com

CE 0344

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