

WallFlex™ Duodenal Stent System with Anchor Lock Delivery System

Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

Intended Use/Indications for Use

The device is indicated for the palliative treatment of gastroduodenal obstructions produced by malignant neoplasms.

Contraindications

Contraindications associated with the use of the WallFlex Enteral Duodenal Stent include:

- Enteral ischemia
- Suspected or impending perforation
- Intra-abdominal abscess/perforation
- Strictures that do not allow passage of a guidewire
- Patients for whom endoscopic technique are contraindicated
- Any use other than those specifically outlines under indications for use

Warnings

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 device should be used with caution and only after careful consideration in patients with elevated bleeding times or coagulopathies.

Stents cannot be repositioned after complete deployment.

The safety and effectiveness of this device for use in benign strictures have not been established.

Chemoradiation therapy or radiotherapy alone may lead to tumor shrinkage and subsequent stent migration.

The stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.

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 patient 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.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

MR Conditional

Non-clinical testing has demonstrated that the WallFlex Duodenal Stent System with Anchor Lock Delivery System is MR Conditional. A patient with this device may undergo MRI immediately under the following conditions.

- Static magnetic field of 3 Tesla or less
- Maximum spatial magnetic gradient field of 720 Gauss/cm or less
- Maximum whole body averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning

In non-clinical testing, the WallFlex Duodenal Stent System with Anchor Lock Delivery System produced a temperature rise of less than or equal to 0.6 °C at a maximum whole body averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of MR scanning in a 3 Tesla Excite®, G3.0-052B, General Electric Medical Systems, Milwaukee, WI; active-shielded, horizontal field MR scanner. MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the WallFlex Duodenal Stent System with Anchor Lock Delivery System.

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WallFlex™ Duodenal Stent System with Anchor Lock Delivery System (ctd.)

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Refer to the device directions for use for complete instructions on device use.

Potential Adverse Events

Complications associated with the use of the WallFlex Enteral Duodenal Stent may include:

Procedural Complications

- Bleeding
- Pain
- Stent misplacement or inadequate expansion
- Intestinal perforation
- Death

Post Stent Placement Complications

- Bleeding
- Stent occlusion
- Foreign body sensation
- Ulceration
- Septicemia
- Infection
- Perforation
- Pain
- Stent migration
- Stent occlusion due to tumor in-growth through stent
- Stent occlusion due to tumor over-growth around ends of stent
- Bowel impaction
- Fever
- Death (other than that due to normal disease progression)

Please be aware that potential adverse effects may arise even with the proper use of medical devices. Accordingly, this device should only be used by persons qualified in the procedures for which it is indicated.

Cautions

Read the entire directions for use thoroughly before using the WallFlex Duodenal Stent System with Anchor Lock Delivery System should only be used by or under the supervision of physicians thoroughly trained in the placement of duodenal stents. A thorough understanding of the techniques, principles, clinical applications and risks associated with this procedure is necessary before using the device.

The system must not be resterilized.

The packaging and the device should be inspected prior to use. Do not use the device if the product is damaged in shipping.

The device is intended for single use only. Do not attempt to reload deployed stents onto the delivery system.

Use of fluoroscopy is recommended. Not using fluoroscopy can result in misplacement of the stent.