



WallFlex™ Colonic Stent System with Anchor Lock Delivery System

Prescriptive Information

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

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 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.

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, coagulopathies, or in patients with radiation colitis or proctitis.

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.

To minimize pain and tenesmus, the proximal stent end should be placed 2 cm above the anal canal or 6 cm from the anus.

Indications for Use

The device is indicated for the palliative treatment of Colonic strictures caused by malignant neoplasm and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

Contraindications

Contraindications associated with the use of the WallFlex™ Colonic Stent System with Anchor Lock Delivery System include:

- Enteral ischemia
- Suspected or impending perforation
- Intra-abdominal abscess/perforation

- Strictures that do not allow passage of a guidewire
- Patients for whom endoscopic techniques are contraindicated
- Any use other than those specifically outlined under indications for use

Precautions

Read the entire directions for use thoroughly before using the WallFlex Colonic Stent System with Anchor Lock Delivery System. The WallFlex Colonic Stent System with Anchor Lock Delivery System should only be used by or under the supervision of physicians thoroughly trained in the placement of colonic 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.

Potential Adverse Events

Complications associated with the use of the WallFlex Colonic Stent System with Anchor Lock Delivery System may include:

- Hemorrhage (e.g. bleeding)
- Perforation
- Pain (e.g. discomfort, foreign body sensation)
- Migration
- Obstruction (e.g. occlusion)
- Erosion (e.g. ulceration)
- Fever
- Infection (e.g. local infection, peritonitis, septicemia)
- Death (other than that due to normal disease progression)
- Diarrhea
- Constipation
- Tenesmus (e.g. symptoms of tenesmus or urgency/incontinence)
- Gastrointestinal reflux
- Stent misplacement or inadequate expansion