PRESCRIPTIVE INFORMATION

WallFlex™ Colonic & Duodenal Soft Stent Systems with Anchor Lock Delivery System

Boston Scientific
Advancing science for life™

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.

WallFlex Colonic Soft Stent System

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.

MRI Conditional Labeling

Non-clinical testing has demonstrated that the WallFlex™ Colonic Soft 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 gradient magnetic 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 Colonic Soft 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 Colonic Soft Stent System with Anchor Lock Delivery System.

Intended Use/Indications For Use

The device is indicated for the palliative treatment of colonic strictures produced 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 Soft 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

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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.

Precautions

• 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.

Adverse Events

Complications associated with the use of the WallFlex Colonic Soft 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

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- 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.

Precautions

- 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.

Adverse Events

Complications associated with the use of the WallFlex Duodenal Soft 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. biliary obstruction, occlusion)
- Erosion (e.g. ulceration)
- Fever
- Infection (e.g. local infection, peritonitis, septicemia)
  Death (other than that due to normal disease progression)
- Gastrointestinal reflux
- Stent misplacement or inadequate expansion