WallFlex™ Colonic 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 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

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.

Intended Use/Indications for Use

Cautions

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.

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

Prescriptive Information

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

Cautions (ctd.)

MR Conditional – Non-clinical testing has demonstrated that the WallFlex™ Colonic 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 scannings
- In non-clinical testing, the WallFlex Colonic 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 Stent System with Anchor Lock Delivery System.

Potential Adverse Events

Complications associated with the use of the WallFlex Colonic Stent System with Anchor Lock

Delivery System may include:

Procedural Complications include: bleeding, pain, stent misplacement or inadequate expansion, intestinal perforation, death.

Post stent placement complications include: bleeding, perforation, pain, stent migration, stent occlusion due to tumor in-growth through stent, stent occlusion due to tumor over-growth around ends of stent, stent occlusion, foreign body sensation, bowel impaction, ulceration, fever, septicemia, death (other than that due to normal disease progression, infection, diarrhea, constipation, peritonitis, symptoms of tenesmus or urgency/incontinence.