Wallflex™ Duodenal Stent

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

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 tumore 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.

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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

Cautions can be found in the product labeling supplied with each device. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.