Overview

Product

WallFlex™ Duodenal Stent System with Anchor Lock Delivery System – IFU 51619451-01A & 51619453-01A

Rx Statement

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.*

Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

Content

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 outlined under indications for use

WARNINGS

REUSE WARNING

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.

GENERAL WARNINGS

- The stent contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.
- 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 cancerThe device should be used with caution and only after careful consideration in patients with elevated bleeding times or coagulopathies as this may result in bleeding.
- Stents cannot be repositioned after complete deployment as this may result in a patient injury such as perforation.
- 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.
- Do not push forward or pull backward on the hub handle with the stent partially deployed. The hub handle must be securely immobilized. Inadvertent movement of the hub handle may cause misalignment of the stent and possible intestinal wall damage.
- The stent should deploy easily. Do not deploy the stent if unusual force is required. Using such force may cause patient injury such as perforation, bleeding, or tissue damage. To reconstrain and remove the device, see the Caution in Step 11 below.
- Do not dilate the stent after placement, this may result in perforation.

PRECAUTIONS

- 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.

- Visually inspect the entire system for damage. Visually check that the exterior tube covers the leading end of the stent. Ensure that the delivery system does not have any kinked sections.
- Do not reconstrain around tortuous anatomy as it may cause damage to the device.
- A stent cannot be repositioned after the Deployment Limit Marker Band has been passed.
- If the stent cannot be fully deployed or fully reconstrained, the entire delivery system can be pulled into the endoscope, using the working channel of the endoscope to reconstrain the stent. This may cause damage to the working channel of the endoscope. In addition, the stent could inadvertently be forced off of the delivery system.
- Do not place stents end to end (without overlap) as this may cause kinking. Do not use in combination with stents from other manufacturers.
- If the delivery system is not fully closed prior to withdrawal, there is a possibility that the tip of the delivery system will get caught in the stent.

POTENTIAL ADVERSE EVENTS

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

- Allergic Reaction
- Death (other than that due to normal disease progression)
- Erosion (e.g. ulceration)
- Gastrointestinal symptoms

- Hemorrhage
- Infection
- Inflammation
- Migration
- Obstruction
- Pain (e.g. discomfort, foreign body sensation)
- Pancreatitis
- Perforation
- Peritonitis
- Stent misplacement or inadequate expansion
- Tissue Damage
- Tissue Overgrowth/Ingrowth