WALLSTENT™ Enteral Endoprosthesis

Colonic/Duodenal Stent with UNISTEP™ Plus Delivery System

Boston Scientific
Advancing science for life™

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.

Intended Use/ Indications For Use

The WALLSTENT™ Enteral Endoprosthesis Colonic/Duodenal Stent with UNISTEP™ Plus Delivery System is indicated for palliative treatment of colonic, duodenal or gastric outlet obstruction or strictures caused by malignant neoplasms, and to relieve large bowel obstruction prior to colectomy in patients with malignant strictures.

Contraindications

Contraindications associated with the use of the WALLSTENT Enteral Endoprosthesis Colonic/Duodenal Stent with UNISTEP Plus Delivery System include:

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

Warnings

- As perforation is a known risk, the stent should be used with caution and only after careful consideration in patients who are:
  1. undergoing radiation therapy and/or chemotherapy
  2. in advanced stages of cancer
- Stents cannot be repositioned after the deployment threshold has been exceeded.
- This device contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.

Precautions

- The device is intended for use by physicians who have received appropriate training.
- The system should not be resterilized.
- The sterile packaging and device should be inspected prior to use. If sterility or performance of the device is suspected to be compromised, it should not be used.
- The device is intended for single use only. Do not attempt to reload deployed stents onto the delivery system.

WALLSTENT™ Enteral Endoprosthesis

Colonic/Duodenal Stent with UNISTEP™ Plus Delivery System

Boston Scientific
Advancing science for life™

MR Conditional

Non-clinical testing has demonstrated that the WALLSTENT Enteral Endoprosthesis Colonic/Duodenal Stent with UNISTEP Plus Delivery System is MR Conditional. It can be scanned safely under the following conditions:

- static magnetic field of 1.5 Tesla or less
- maximum spatial magnetic gradient field of 450 Gauss/cm or less
- maximum whole body averaged specific absorption rate (SAR) of 1.3 W/kg for 30 minutes of scanning

In non-clinical testing, the WALLSTENT Enteral Endoprosthesis Colonic/Duodenal Stent with UNISTEP Plus Delivery System produced a temperature rise of less than or equal to 0.3 °C at a maximum whole body averaged specific absorption rate (SAR) of 1.3 W/kg, for 30 minutes of MR scanning in a 1.5 Tesla/64 Mhz Signa® General Electric Company 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 WALLSTENT Enteral Endoprosthesis Colonic/Duodenal Stent with UNISTEP Plus Delivery System.

Potential Adverse Events

Complications associated with the use of the WALLSTENT Enteral Endoprosthesis Colonic/Duodenal Stent with UNISTEP Plus Delivery System may include the usual complications reported for conventional stents and endoscopic procedures such as:

- 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)
- Diarrhea
- Constipation
- Tenesmus (e.g. symptoms of tenesmus or urgency/incontinence)
- Gastrointestinal reflux
- Stent misplacement or inadequate expansion

ENDO-1643205-AA