SerosaFuse®
Implantable Fasteners

EN **INSTRUCTIONS FOR USE**

MERITMEDICAL®

SerosaFuse®
Implantable Fasteners

INSTRUCTIONS FOR USE

READ THE FOLLOWING INFORMATION BEFORE USE. PRODUCT TO BE OPERATED ONLY BY HEALTHCARE PROFESSIONALS TRAINED IN THE PROPER USE OF THE PRODUCT. SEE SYMBOLS GLOSSARY FOR EXPLANATION OF SYMBOLS.

CAUTION: These instructions are designed to explain the operation of this device and its controls. This document is not a reference to surgical techniques.

POTENTIAL ADVERSE EVENTS
Foreseeable adverse events (AE) and adverse device effects (e.g., serious/ non-serious device related/non-related) are as follows:

Typical known risks or discomforts anticipated as a result of an endoscopic procedure:
- Crepitus
- Endoluminal Gas Bubbles
- Gagging
- Globus Pharyngis
- Hoarseness
- Inflammation reaction from lubricant
- Temporary dysphagia (difficulty swallowing) or odynophagia (painful swallowing) due to swelling or tissue manipulation
- Other temporary pain which responds to standard pain medication

Unusual risks or discomforts as a result of an endoscopic procedure:
- Abrasion
- Bite Block Related Injury
- Bleeding
- Diarrhea
- Dyspepsia
- Esophageal Tear
- Fistulae Between Inner Organs
- Gas Bloat
- Hematoma/ Edema
- Hiccups
- Infection
- Injury Of Mouth and/or Teeth
- Laceration
- Lesions
- Limited Neck Mobility
- Nose Bleeding from Nasal Intubation
- Perforation
- Persistent Odynophagia or Dysphagia Requiring Intervention
- Vocal Cord Nodules Due to Intubation
- Vomiting

Rare risks as a result of an endoscopic procedure and of this particular procedure:

- Achalasia
- Acute Abdomen
- Aspiration/Aspiration Pneumonia
- Atelectasis
- Bleeding Requiring Blood Transfusion
- Bowel Obstruction
- Cardiac Event
- Chest Pain
- Death
- Embolism
- Focal Necrosis
- Gastrointestinal and Pancreatic Leaks
- Hypoxia
- Lockjaw
- Mediastinitis
- Medical or Surgical Treatment as a Result of the Occurrence of Complication
- Nerve Damage
- Pancreatitis
- Peritonitis
- Pericardial Effusion
- Pneumoabdomen
- Pneumomediastinum
- Pneumothorax
- Pleural Effusion
- Serious Burns from use of Endoscope
- Surgery for Uncontrolled Bleeding and/or Perforation
- Thoracic, Mediastinal, or Abdominal Abscess
- Tissue Damage
- Ulceration/Ulcer
- Capture of other inner organs which may neighbor the suturing site or resulting from adhesions from previous abdominal infections or surgical procedures, potentially resulting in fistulae between inner organs or the inner organs and the abdominal or thoracic cavity.
- Procedure related failure requiring medical intervention or surgical conversion.

WARNINGS AND PRECAUTIONS

Do not use equipment that is not CE marked or cleared by the U.S. FDA, and/or is not properly functioning. Repeated attempts to use any device component that fails to properly function could damage product and may cause patient injury.

- The SerosaFuse Implantable Fastener Cartridge is a single use product. DISCARD AFTER USE. DO NOT RESTERILIZE. Risk of reuse includes disease transmission from the inability to clean all components of the Cartridge.
- These devices are not intended for use except as indicated.
- The cartridge is supplied sterile; handle in accordance with sterile device procedures. Do not use if package is damaged.
- To avoid potential biohazard, handle and dispose of the cartridge after use in accordance with accepted medical practice and applicable local, state, and national/federal laws and regulations.
- Ensure the patient is adequately anesthetized and paralyzed prior to starting the TIF® procedure.
- Report any serious incidents and/or product malfunctions to the product manufacturer and the authority which has jurisdiction in the locale.

INDICATIONS FOR USE CLINICAL DATA SUMMARY

The indications are supported by clinical outcomes in the literature on 163 patients who have undergone the procedure of HHR before TIF with favorable results. This literature is summarized briefly below.

1. Ihde, G et al. Short-term safety and symptomatic outcomes of transoral incisionless fundoplication with or without hiatal hernia repair in patients with chronic gastroesophageal reflux disease. The American Journal of Surgery, 2011 Dec; 202 (6):740-6.

Forty-eight (48) patients underwent TIF using the EsophyX® device. Patients who presented with a hiatal hernia 3 cm or more in the greatest transverse diameter underwent laparoscopic HHR before TIF (n=18). There were no long-term postoperative complications. At the median follow-up of 6 months, 73% of patients normalized the GERD-HRQL score ($p<.001$), 73% of patients eliminated the heartburn, 76% of patients eliminated the regurgitation, 67% of patients reported elimination of atypical symptoms, 76% of patients were off daily proton pump inhibitors (PPIs) and 88% of patients were satisfied with their current health condition.

2. Chang, C et al. Laparoscopic Hiatal Hernia Repair in 221 Patients: Outcomes and Experience. Journal of the Society of Laparoendoscopic Surgeons, January-March 2016 Volume 20 Issue 1 e2015.00104.

This analysis included patients who underwent HHR with a simultaneous bariatric procedure (n=122), TIF (n=46), Nissen fundoplication (n=10) or HHR alone (n=33). The greatest GERD-HRQL score improvement (average 20.5 points) was observed in patients who underwent HHR with a fundoplication procedure (Nissen/TIF) and was statistically significant. Most complications were minor (dysphagia, nausea and vomiting).

3. Janu, P et al. Laparoscopic Hiatal Hernia Repair Followed by Transoral Incisionless Fundoplication With EsophyX Device (HH + TIF): Efficacy and Safety in Two Community Hospitals. Surgical Innovation. 2019;26(6):675-86.

A total of 99 patients underwent the TIF procedure with the EsophyX device following HHR and were given GERD-HRQL, RSI, and GSRS questionnaires at screening, 6 months and 12 months post-procedure. HRQL scores were improved 85% for all six heartburn questions and 7 regurgitation questions, while 50% improvement was noted for bloating, dysphagia and odynophagia. The RSI scores for hoarseness, throat clearing, excess mucus, coughing and chest pain also improved as well, from 50% to 80%. The GSRS questions on heartburn and regurgitation showed 80% improvement while bloating and dysphagia improved by more than 50%. All these results were durable at 6 and 12 months follow up. There were no adverse effects reported.

INDICATIONS FOR USE

The Merit Fastener Delivery Device with SerosaFuse Fastener and accessories is indicated for use in transoral tissue approximation, full thickness plication and ligation in the GI tract and is indicated for the treatment of symptomatic chronic gastroesophageal reflux disease in patients who require and respond to pharmacological therapy. It is also indicated to narrow the gastroesophageal junction and reduce hiatal hernia ≤ 2cm in size in patients with symptomatic chronic gastroesophageal reflux disease. Patients with hiatal hernias larger than 2cm may be included, when a laparoscopic hiatal hernia repair reduces the hernia to 2cm or less.

CONTRAINDICATIONS
Patients with bleeding disorders, strictures, severe esophagitis, esophageal diverticulae, obstructions, paraesophageal hernia, limited neck mobility, osteophytes of the spine, esophageal varices, esophageal infections or fungal disease, esophageal stenosis and any kind of normal or abnormal esophageal anatomy which would not permit insertion of a device of this size, chronic cough, or BMI > 35.

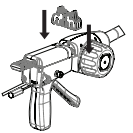
CONTENTS OF CARTRIDGE PACKAGE

R2175	SerosaFuse Implantable Fasteners Cartridge Qty: (1) 7.5mm (20 fasteners per cartridge)
R2375	SerosaFuse Implantable Fasteners Cartridge Qty: (2) 7.5mm (20 fasteners per cartridge)

OTHER ITEMS REQUIRED
EsophyX Fastener Delivery Device

DEVICE PREPARATION

Cartridge Installation
Remove cartridge from packaging by peeling back tray lid and gently lifting cartridge from tray. Load the cartridge directly into the EsophyX device handle by first aligning the tab on the cartridge with the notch in the device handle. Insert the cartridge directly into the handle; an audible click confirms correct insertion (Figure 1).



EsophyXZ+

Figure 1

Cartridge Removal
To remove a cartridge from an EsophyX device handle, push gently on the release tab adjacent to the top of the device handle. Simultaneously lift the cartridge away from the handle (Figure 2).

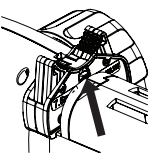


Figure 2

	Caution
	Do not use if package is damaged and consult instruction for use
REF	Catalog number
LOT	Batch code
MD	Medical Device
UDI	Unique Device Identifier
	Single use
	Do not resterilize
STERILE EO	Sterilized using ethylene oxide
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Single sterile barrier system
	Use by date: YYYY-MM-DD
	Date of manufacture: YYYY-MM-DD
	Manufacturer
	Temperature limitation
	Humidity limitation
MR	MR Safe
	MR Unsafe
	Importer

MERIT MEDICAL
ENDOTEK®

www.merit.com

Manufacturer:
Merit Medical Systems, Inc.
1600 West Merit Parkway, South Jordan, Utah 84095 U.S.A.
1-801-253-1600
U.S.A Customer Service 1-800-356-3748

408149001_001 2024-10-03