EsophyX® Z+
Fastener Delivery Device

EN **INSTRUCTIONS FOR USE**

MERITMEDICAL®

EsophyX® Z+
Fastener Delivery Device

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.

INDICATIONS
The EsophyX® Z+ 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
Qty: One (1) EsophyX Z+ Fastener Delivery Device

OTHER ITEMS REQUIRED
- 7.5mm SerosaFuse® Implantable Fasteners For Use With EsophyX® device
- Endoscope (CE-marked, FDA cleared, 8.6-11.4mm Dia.)
- Endoscope Compatibility Tool (R4007, Purple Color)
- ≥ 20mm (60Fr) Bite Block
- Surgical scissors/wire cutter and scalpel
- Surgical lubricant (any water-based lubricant; ensure any lubricants used are also compatible with the endoscope)
- Vacuum Pumps (CE-marked)
- Vacuum Hose

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/UIcer
- 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
- Significant bleeding may occur in patients with hypertension and/or patients taking platlet function inhibitors or anti-coagulants.
- Vomiting and/or high physical activity post-TIF® procedure may cause fasteners to break or pull out of tissue.
- The device is intended to be used only with the 7.5mm SerosaFuse Fastener Cartridge.
- Ensure that the patient's esophagus is of sufficient dimension to accommodate the EsophyX Z+ device before beginning the procedure.
- The device is supplied sterile; handle in accordance with sterile device procedures. Do not use if package is damaged.
- Helical retractor and stylets are sharp. Handle with care.
- Do not use equipment or items which are not functioning properly. Repeated attempts to use any device component that fails to properly function could damage product and may cause patient injury. Should a malfunction occur, safely remove device under direct visualization.
- Do not use equipment that is not CE-marked or has not been cleared by the U.S. FDA.
- Verify the endoscope intended for use is compatible with the device. Compatibility is verified by using the appropriate Endoscope Compatibility Tool prior to insertion (insert the endoscope intended for use through the larger hole present on the compatibility tool; the entire working length of the endoscope should fit comfortably through the larger hole; the endoscope should not be able to fit through the smaller hole present on the compatibility tool).
- The device contains ferromagnetic metallic components that should be kept away from live voltages and/or protective earth portions of devices as they could present a shock hazard to the patient.
- Do not use in a Magnetic Resonance environment. This device is MR unsafe.
- Remove endoscope from device and replace if experiencing a loss of visualization related to endoscopy equipment.
- The amount of tissue to be approximated and fastened should be carefully chosen to ensure appropriate and suitable plications are achieved. An attempt to approximate too little or too much tissue could result in bleeding, focal necrosis, or plication failure.
- Helical retractor must be locked and positioned at the black line during device insertion and removal. The tissue mold must be partially or fully closed to advance the helical retractor into the tissue mold from the fully retracted position.
- The retractor lock only prevents forward motion of the helical retractor. Do not retract the retractor control during device insertion or withdrawal.
- Visually confirm that helical retractor, stylets, and fastener pushers are retracted and safely stowed in the device prior to insertion and removal; failure to do so could result in device damage and injury to patient anatomy.
- Always deploy the helical retractor under direct visualization.
- The tissue mold must be fully opened and unlocked (tactile and audible feedback from the knob ceases) during device insertion and removal.
- The tissue mold must be fully closed and locked (tactile and audible feedback from the knob ceases) when delivering fasteners.
- The device is a single use product. Do not re-sterilize. Risk of reuse includes disease transmission from inability to clean all components of the device.
- To avoid potential biohazard handle and dispose of the device and all associated components after use in accordance with accepted medical practice and applicable local, state, and national / federal laws and regulations.
- Do not press any endoscope buttons during device removal and during endoscope removal from the device.
- This device is not intended for use except as indicated.
- Repetitive use may result in pathophysiological risks and injuries.
- 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 Laparo-endoscopic 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.

PATIENT SELECTION

Individuals that have GERD with a hiatal hernia ≤ 5 cm and Hill grade II, III, or IV. A hiatal hernia ≤ 5 cm is defined as maximum axial height from end of the esophagus to the diaphragm by any study including upper endoscopy esophagram and/or at time of surgery.

Careful deliberation should be given to patients who have had previous anti-reflux surgery or other gastric surgical procedures and the TIF procedure is performed only when the benefits outweigh the risks.

When a hiatal hernia repair (HHR) is completed in the same anesthesia setting as a TIF procedure, careful deliberation should be conducted around the results of the HHR.

Physicians should note that a combined Hiatal Hernia Repair and TIF 2.0® (cTIF®) procedure can extend anesthesia time over a TIF 2.0 alone procedure by approximately 30 minutes. The exact time is dependent on clinical factors associated with the patient's anatomy and repair technique chosen by the operating physician. The procedural plan should be discussed in detail with the anesthesiologist, surgeon, and gastroenterologist. The procedural time would be clinically comparable to that of laparoscopic fundoplication which has a well-established safety profile. All perioperative risks, both procedural and anesthesia related, should be taken into consideration for each patient and the benefits of performing a cTIF procedure should outweigh the risks.

INSTRUCTIONS FOR USE

Device Removal from Tray

1. Remove device from tray by pulling up on the six black buttons which free the top sheet from the bottom tray. Remove and discard the top sheet to expose the device (Figure 3), lift the device out of the tray by grasping the tissue mold control knob (Figure 4) and carefully releasing the vacuum stopcock from the tray. Carefully release the distal end from the tray and exercise caution to prevent device controls from bending.
2. Generously lubricate the distal two-thirds of the device.

Cartridge Installation

3. Load the cartridge directly into the handle by aligning the tab on the cartridge with the notch in the handle. Insert the cartridge directly into the handle (Figure 5); an audible click confirms proper installation.
4. Gently withdraw the pushers by squeezing the sides of the fastener pusher knob. Retract the pusher knob out of the device and pull the pushers in short, 10cm increments until three black bands are visible on each of the fastener pushers and confirm that two thin single wires are visible in the cartridge loading slot in the device handle.
   NOTE: There are two sets of markings on each fastener pusher. With the pusher tubing fully withdrawn, the single black marking just proximal to the device handle indicates the fastener loading position. Moving towards the fastener pusher knob, the double black markings indicate the position where loaded fasteners should be visible in the nosecone.
5. Slowly and deliberately press each fastener lever until a tactile and audible click is felt and heard.
6. To confirm successful loading of fasteners, gently re-insert the fastener pushers using only forward motion into the device until the double black bands on the fastener pushers are adjacent to the device handle. Look through the top of the nosecone to verify the fasteners have loaded into the respective lumens. If no fasteners are visible, repeat steps 4 and 5.
7. Continue to re-insert the fastener pushers using only forward motion into the device until the pusher knob snaps back into place in the device handle.

Device Inspection

8. Confirm the vacuum stopcock is in the off position - the white lever points towards the device handle. Rotate the white lever if necessary.
9. Confirm that the helical retractor is contained within the helical retractor channel on the tissue mold and locked with the black line on the retractor control shaft adjacent to the device handle. If not, unlock the helical retractor and position the helical retractor within the helical retractor channel, with the black line on the retractor control adjacent to the device handle. Lock the retractor.
10. Confirm the tissue mold is fully open by rotating it in the open direction until the mold is fully extended (until tactile and audible feedback from the knob ceases).

Pre-Operative EGD

11. Insert the endoscope into the patient and using the depth markings on the endoscope, measure both the Z-line and diaphragmatic pinch starting from the patient's incisors. If the measurements are different, note the greater of the two measurements. Failure to measure properly may result in fastener placement into the mediastinum.
    CAUTION: The device shaft depth markings are for reference only.
12. Verify the stomach is free of food contents and note any anatomical abnormalities which may affect the appropriateness of the TIF procedure.
13. Remove the endoscope from the patient. Lay the endoscope next to the EsophyX device and place the endoscope lens where the stylets exit the EsophyX device.
14. Mark the EsophyX device shaft at the same location as the noted measurement on the endoscope.

Endoscope Insertion

15. Liberally coat the surface of the endoscope with lubricant.
16. Insert the endoscope through the endoscope seal and advance the endoscope until the endoscope boot is flush with the proximal aspect of the device handle (the endoscope should extend approximately 10-15cm beyond the distal end of the device).

Device Insertion

17. Place the bite block into the patient's mouth.
18. With the device operator and the endoscope operator in optimal position for proper procedure visualization, introduce the device assembly through the bite block, through the patient's oral cavity, and esophagus slowly and with care.
    CAUTION: The device is most flexible with the tissue mold knob facing the patient's left shoulder and the fastener cartridge aligned with the patient's hard palate and nares.
    CAUTION: Do not exert any excess force while attempting device insertion.
    CAUTION: Maintain direct endoscopic visualization, keeping oropharynx, hypopharynx and esophageal lumen centered at all times during insertion.
    CAUTION: Assess the gastric lumen size making sure it is large enough to safely close the tissue mold.
19. As the endoscope enters the stomach, retroflex the endoscope and then advance the device under direct visualization.
20. Once the chassis of the device enters the stomach, rotate the device so that the back of the tissue mold is aligned with the lesser curvature of the stomach and then withdraw the endoscope into the distal aspect of the chassis.
21. Fully close the tissue mold and advance the endoscope through the chassis and back into the stomach.
22. Retroflex the endoscope and observe the device and the gastro-esophageal junction through the panoramic view.
23. Connect the vacuum stopcock to external vacuum.
24. Ensure that the device is in the stomach far enough to close the tissue mold completely, so that the tissue mold touches the chassis and is fully retroflexed.

Tissue Plication

25. Gently withdraw the fastener pushers by squeezing the sides of the fastener pusher knob and retracting the pushers in short, 10cm increments until three black bands are visible on each of the fastener pushers.
26. Slowly and deliberately press each fastener lever until a tactile and audible click is felt and heard.
27. To confirm successful loading of fasteners, gently re-insert the fastener pushers using only forward motion into the device until the double black bands on the fastener pushers are adjacent to the device handle. Look through the top of the nosecone to verify the fasteners have loaded into the respective lumens. If no fasteners are visible, repeat steps 25 and 26.
    CAUTION: Do not load more than one fastener per channel prior to delivery.
28. Continue to re-insert the fastener pushers using only forward motion into the device until the pusher knob snaps back into place in the device handle.
29. Rotate the device to the desired fastener delivery location on the gastroesophageal junction.

30. Insufflate stomach. Position tissue mold at the gastroesophageal junction while maintaining sufficient insufflation and visualization. Maintain contact between the tissue mold tip and the gastroesophageal junction, unlock and advance the helical retractor while rotating the helical retractor control counterclockwise until the retractor is in contact with tissue. Rotate the helical retractor control clockwise approximately four (4) rotations to fully engage tissue.
CAUTION: Only insufflate the stomach until adequate procedure visualization is achieved, do not over-insufflate.
CAUTION: Do not engage the helical retractor into undesirable tissue such as thin or scar tissue, the diaphragm, or crura.
CAUTION: Do not over-engage the helical retractor into tissue. Tissue may bind and become unable to disengage from tissue.
31. Gently advance the helical retractor control, open the tissue mold slightly, and then gently retract the helical retractor control to disengage the helical retractor from the center of the tissue mold. If in the posterior or anterior corner, gently rotate tissue mold towards the greater curve.
32. Set the device by gently retracting the device into the esophagus until the proximal blue link of the chassis is covered by the valve. Lock the helical retractor leaving enough slack to avoid the helical retractor from pulling out of tissue (slack can still be taken in when retractor is locked).
CAUTION: Do not prematurely lock the helical retractor.
33. Deflate the stomach and retract tissue between the tissue mold and chassis by pulling the helical retractor control away from the device handle. If in the anterior or posterior corners, rotate the device towards the lesser curve while deflating the stomach, being careful not to over-rotate the device.
34. Fully rotate the tissue mold control in the closed direction to its auto-lock position (until tactile and audible feedback from the knob ceases).
CAUTION: Cautiously manipulate the helical retractor during tissue engagement, helical retractor rotation, tissue retraction, and tissue disengagement, to avoid the helical retractor from pulling out of tissue and/or damaging the helical retractor.
35. Activate the invaginator by turning the vacuum stopcock to the on position (rotate the white lever perpendicular to the line of flow). If in the posterior or anterior corner, counter rotate the device back towards the greater curve.
36. Confirm that the shaft of the device collapses from vacuum and then advance the device distally in a gentle and careful manner to the measured level noted on shaft of device, taking note not to pull the helix from the tissue.
37. Deliver fasteners by (1) depressing the fastener delivery trigger release (Figure 6); (2) pulling the fastener delivery trigger fully until the trigger contacts the handle of the device and resistance is felt; (3) completely releasing the fastener delivery trigger in one rapid motion. Ensure the fastener delivery trigger is not depressed and is locked out by the fastener delivery trigger release (Figure 7).
CAUTION: Do not deliver fasteners in the same location as previously deployed fasteners as an adverse event such as fasteners breaking or pulling through tissue, or, in rare cases, perforation or pleural effusion may occur.
38. Deactivate the invaginator by turning the vacuum stopcock to the off position by rotating the white lever toward the device handle. Confirm the shaft of the device is no longer collapsed.
39. Disengage the device from tissue by unlocking the helical retractor, slightly open the tissue mold (rotate in the open direction until the tissue mold disengages auto-lock and slightly opens) and unlock the helical retractor allowing enough slack to avoid pulling the helical retractor from tissue.
40. Reload fasteners following steps 25 through 28 as necessary.
41. When removing the helical retractor from tissue, place slight tension on the helical retractor control while rotating the helical retractor counterclockwise to release tissue. Fully withdraw the helical retractor into the tissue mold channel, advance the helical retractor control until the black line on the retractor control is adjacent to the handle, and lock the helical retractor.
42. Repeat steps 25 through 40 as necessary.

Device Removal

43. With the stomach insufflated, ensure the fastener delivery trigger is locked out by the fastener delivery trigger release, the stylets are safely stowed inside the device, the vacuum line is disconnected, the helical retractor is in its home position by pulling the retractor control all the way back and then advancing so that the black line on the helical retractor control is aligned with the handle of the device. Lock the helical retractor.
44. Position the tissue mold at the center of the greater curve, partially open the tissue mold, retract the endoscope into the device so the distal blue link of the chassis is seen, and fully open the tissue mold (until tactile and audible feedback from the knob ceases).
45. Advance the endoscope until the endoscope lens is located in the clear tissue mold tip.
46. Orient device so the tissue mold knob is facing the patient's left shoulder.
47. Slowly withdraw the device ensuring no device or endoscope controls are bumped or manipulated. If resistance is encountered during device removal, stop and reassess device distal end orientation.
48. With the device removed from the patient, verify the helical retractor control is positioned at the black line and locked, and the stylets remain safely stowed inside the device prior to removing the endoscope from the device.

TROUBLESHOOTING

Should you experience a jammed fastener channel(s), the following actions are recommended:

1. Ensure that the helical retractor is not affixed to tissue and return it to its home position by pulling the retractor control all the way back and then advancing so that the black line on the helical retractor control is aligned with the handle of the EsophyX Z+ device.
2. Under endoscopic view, open the tissue mold and advance the EsophyX Z+ device into the stomach such that the chassis is distal to the gastroesophageal junction and one or more invaginator holes on the shaft are visible within the lumen of the stomach.
3. Gently withdraw the fastener pushers by squeezing the sides of the fastener pusher knob and retracting the pushers in short, 10cm increments until three black bands are visible on each of the fastener pushers and then gently re-insert the fastener pushers back into the device until the pusher knob snaps back into place in the EsophyX Z+ handle.
4. Dry fire the EsophyX Z+ device by (1) depress the fastener delivery trigger release; (2) pull the fastener delivery trigger fully until the trigger is close to the handle of the device and resistance is felt; (3) maintaining that position, observe the stylets and pushers exiting the distal end of the device between the chassis and tissue mold; (4) release the fastener delivery trigger and observe the stylets and pushers retracting into the device. All components should move freely without resistance.

Should you experience loss of control of the tissue mold and failure of the device to open freely, the following actions are recommended to enable safe removal:

1. Verify tissue mold auto-lock is in the unlocked position by rotating tissue mold control knob towards the open direction.
2. If the tissue mold fails to respond, perform steps 3-14 listed below. Exercise additional care when performing these steps if tissue is captured in the tissue mold.

Secure Sharps and Disconnect Invaginator:

3. Unlock the helical retractor.
4. Rotate the helical retractor counterclockwise to release the engaged tissue and place the helical retractor is in its home position by pulling the retractor control all the way back and then advancing so that the black line on the helical retractor control is aligned with the handle of the EsophyX Z+ device. Lock the helical retractor.
5. Ensure that the fastener deployment trigger is fully extended and locked out by the fastener delivery trigger release.
6. Turn the vacuum stopcock to the off position by rotating the white lever toward the EsophyX Z+ handle and disconnect the vacuum line.

Using Anatomy to Open the Tissue Mold:

7. Position the tissue mold at the center of the greater curve.
8. Under direct visualization, pull the device against the gastroesophageal junction to attempt to open the tissue mold using the anatomy.
CAUTION: Do not exert any excess force while attempting to open the tissue mold using anatomy.
9. When the mold is perpendicular to the device shaft stop, withdraw the endoscope into the distal aspect of the chassis and proceed to step 15.

Expose and Cut Cables:

10. Make a complete circumferential cut through the gray outer tube approximately 2 cm distal to the clear nose cone with a scalpel (Figure 8).
11. Using scissors cut the gray outer tube longitudinally along the shaft of the device to the 50cm tube marking (Figure 9) and peel back the tube to expose the device cabling.
12. Identify 4 internal device cables (Figure 9):
    a. One small silver coiled cable (identified by the circle in the nose cone)
    b. Two green cables in larger clear plastic tubing (not to be cut)
    c. One silver cable in smaller clear plastic tubing (not to be cut)
13. Position the tissue mold at the center of the greater curve and withdraw the endoscope into the distal aspect of the chassis.
14. Insufflate the stomach and cut completely through the silver coiled cable housing with scissors or other available cutters to release the tissue mold. The tissue mold will now spring open. **Do not cut any of the cables in clear plastic tubing (two larger green and one small silver) and ensure the endoscope is retracted into the distal aspect of the chassis prior to cutting.**

Remove Device:

15. Ensure the fastener delivery trigger is locked out by the fastener delivery trigger release, the vacuum line is disconnected, the helical retractor is in its channel and the black line on the helical retractor control is aligned with the handle of the EsophyX Z+ device. Lock the helical retractor.
16. Advance the endoscope until it is located in the clear tissue mold tip.
17. Withdraw the fastener pushers until three black bands are visible on each of the fastener pushers.
18. Slowly withdraw the device and rotate so that tissue mold knob is facing the patient's left shoulder; deflate the stomach with the endoscope during removal.

	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
55°C -30°C	Temperature limitation
90% 0%	Humidity limitation
MR	MR Safe

MR	Magnetic Resonance Unsafe
	Importer
	Indicates the direction to rotate the Tissue Mold Knob to open the Tissue Mold
	Indicates the direction to rotate the Tissue Mold Knob to close the Tissue Mold
	Helical Retractor is locked
	Helical Retractor is unlocked

A. Fastener Cartridge
B. Nosecone
C. Shaft
D. Tissue Mold Control
E. Fastener Delivery Trigger Release
F. Fastener Delivery Trigger
G. Retractor Lock
H. Helical Retractor Control
I. Endoscope Channel and Seal
J. Invaginator Vacuum Stopcock
K. Fastener Pusher Knob

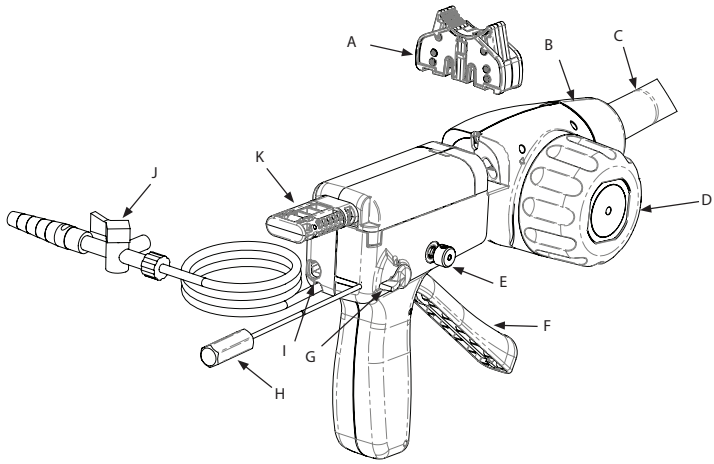

Figure 1

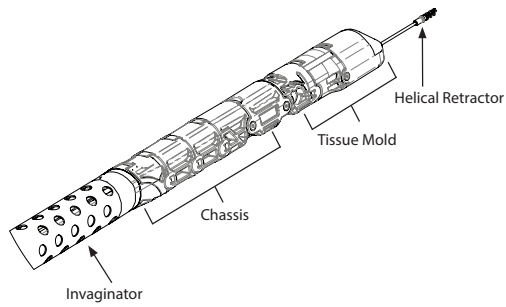

Figure 2

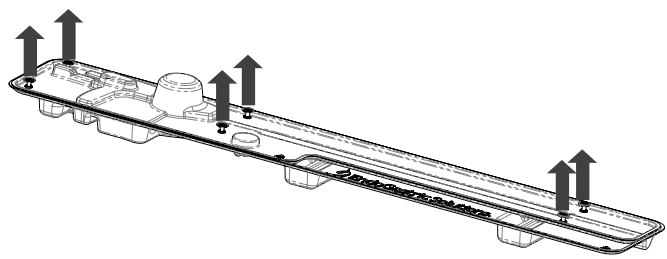

Figure 3

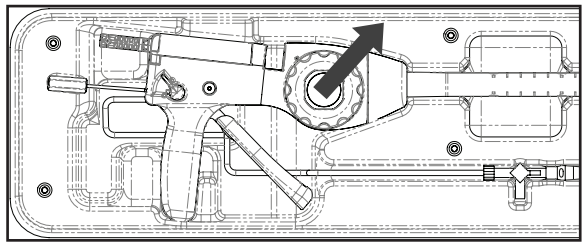

Figure 4

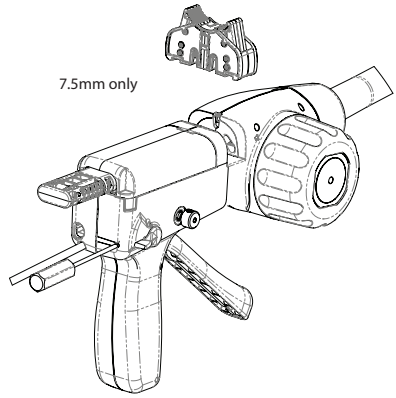

Figure 5

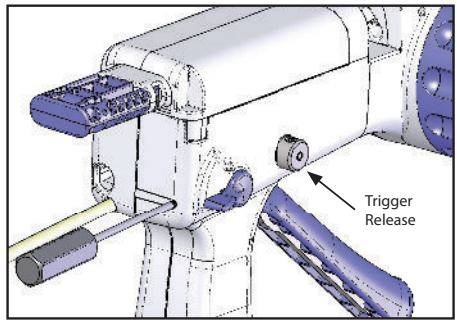

Figure 6
Fastener Delivery Trigger Release - Unlocked

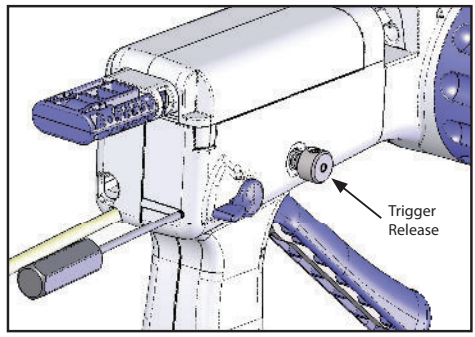

Figure 7
Fastener Delivery Trigger Release - Locked

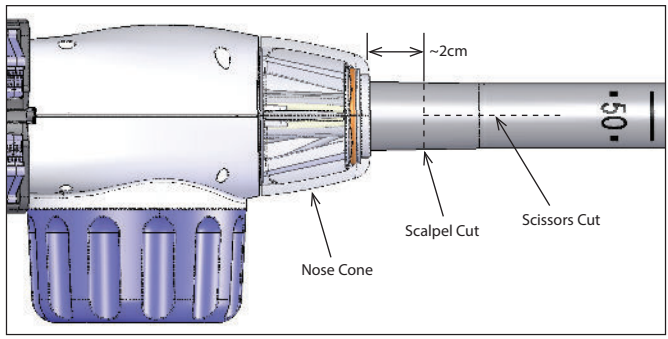

Figure 8

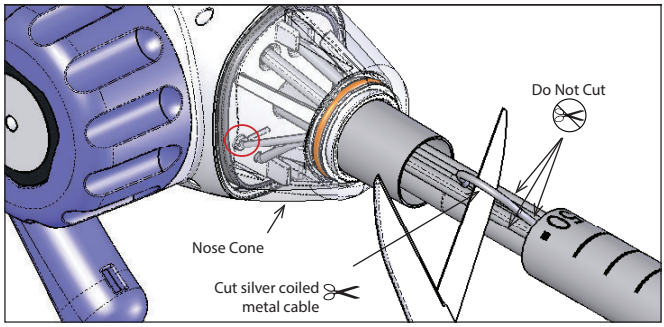

Figure 9

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