EndoGastric Solutions®

EsophyX® Z+ Device

Product & Procedure Overview

EsophyX® Technology Indications for Use

EndoGastric Solutions

The EndoGastric Solutions EsophyX Z+ device

with **SerosaFuse® fasteners** and accessories are **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.

Emulates Traditional Surgical Principles with Endoscopic Approach

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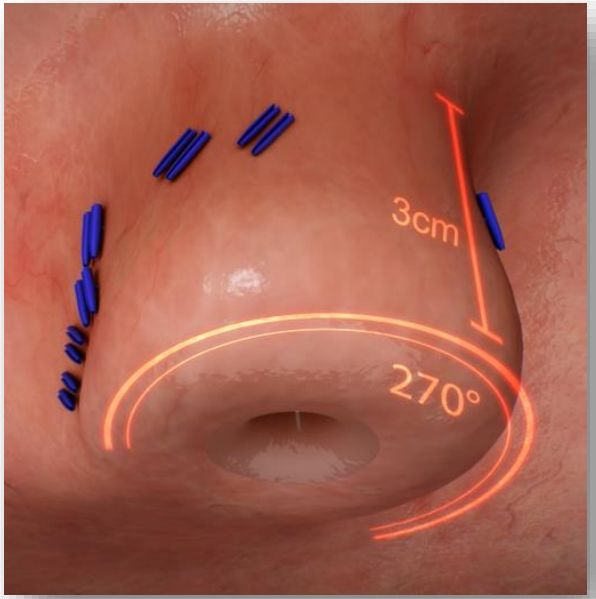
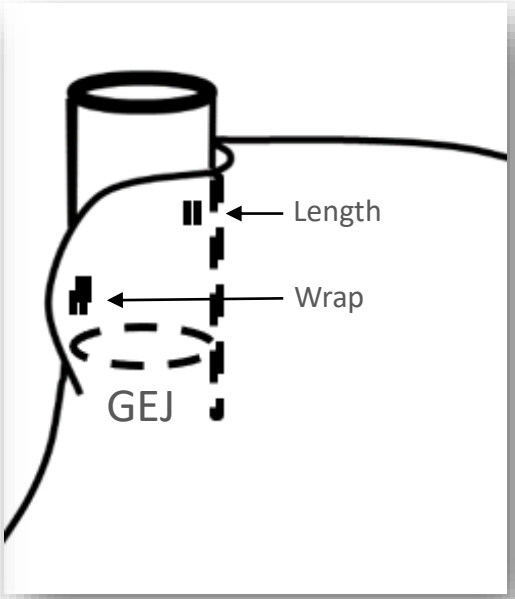
Principles Of Antireflux Surgery	TIF® Procedure	Laparoscopic Fundoplication
Reduce hiatal hernia ≤ 2 cm	✓	✓
Repair hiatal hernia > 2 cm and close crura*	✓*	✓
Elongate the intra-abdominal esophagus	✓	✓
Fundoplication	✓	✓
• Approximate and tighten the fundus around the distal esophagus	✓	✓
• Recreate the dynamics of the angle of His	✓	✓
• Restore the distal high pressure zone	✓	✓

*As of June 22, 2017, EsophyX device indication was expanded to include patients with hiatal hernias larger than 2cm when a laparoscopic hiatal hernia repair (HHR) reduces the hernia to 2 cm or less.

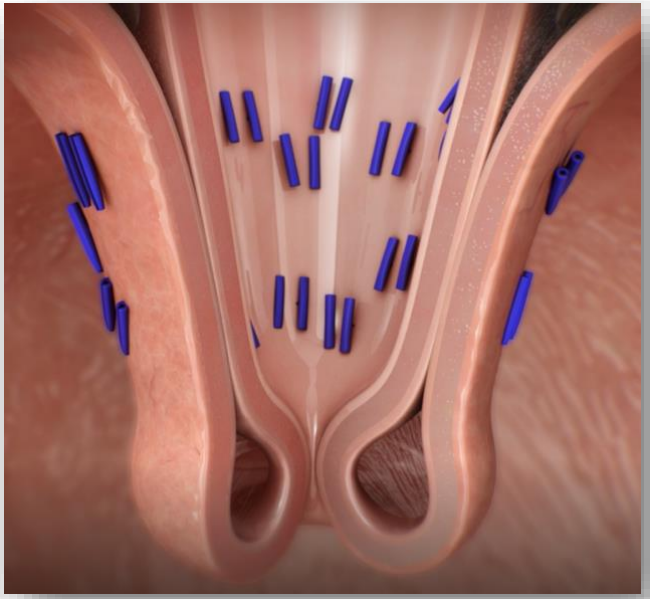
EsophyX® Z+ Device & TIF Procedure Overview



Overall Goal:
3cm length & 270° wrap

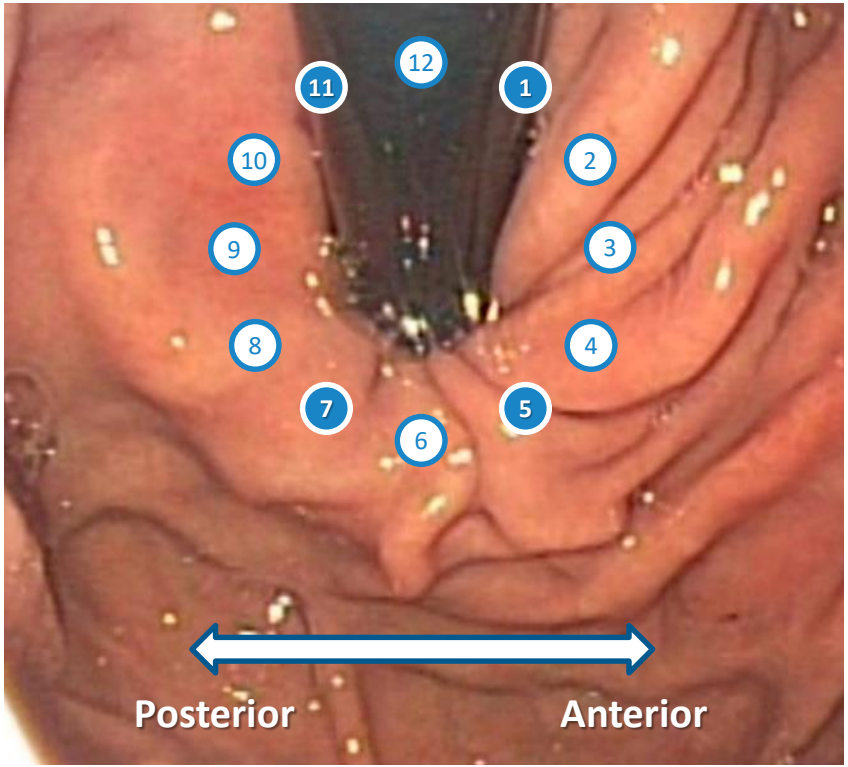


Laparoscopic View



Final Result:
Placement of 20 fasteners creates an esophagogastric plication

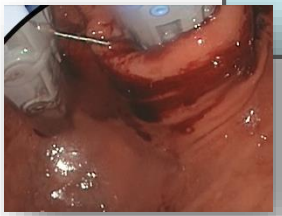
Clock Face Nomenclature & Overall Goal



11 o'clock: 6 fasteners

1 o'clock: 6 fasteners

20 fasteners
270°
1-3 cm depth



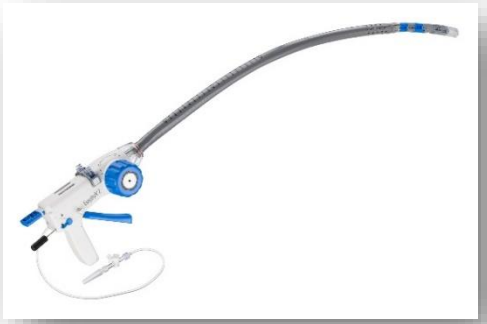
7 o'clock: 4 fasteners

5 o'clock: 4 fasteners

EsophyX® Z+ Device and SerosaFuse® Fasteners Product Line

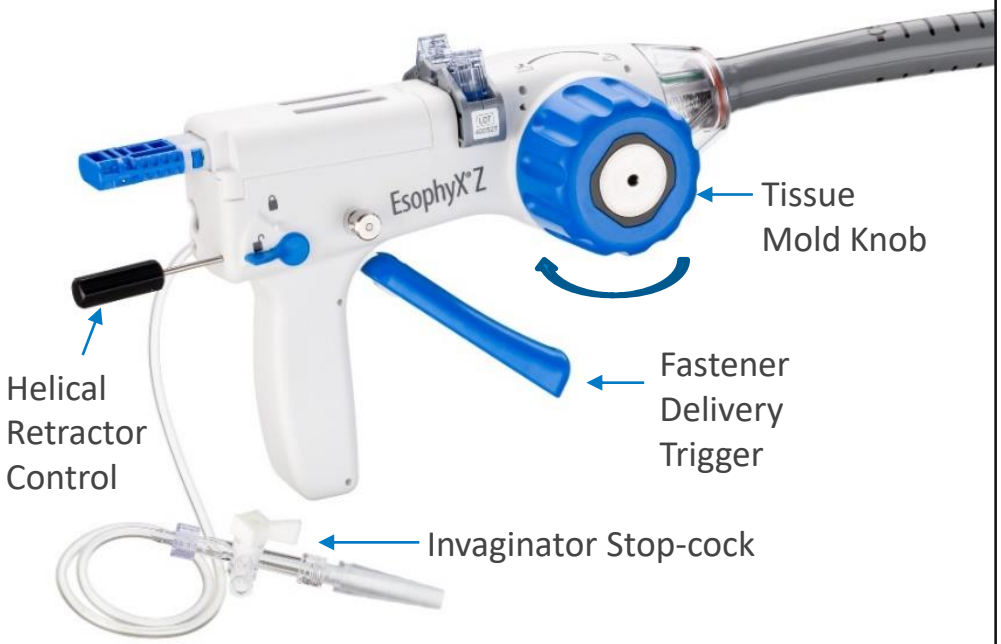
	EsophyX Z+ Device	SerosaFuse Fasteners
Supplied sterile with 24-month shelf-life	✓	✓
Single-use only (do not reuse)	✓	✓
MRI safe	✗	✓
Does not contain natural latex	✓	✓

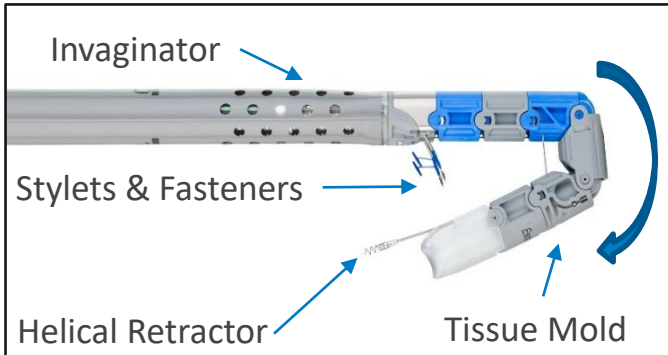
Note: EsophyX devices are single use only and cannot be re-sterilized. Check the sterility date on the packaging to make sure the device is within shelf life. Do not use if expired. EsophyX cases are not sterile as the device contacts the patients mouth; however, adhere to fundamental sterile techniques when possible to decrease risk to the patient. Consult the IFU when appropriate.



EsophyX® Z+ Device Control Overview

PHYSICIAN INTERFACE



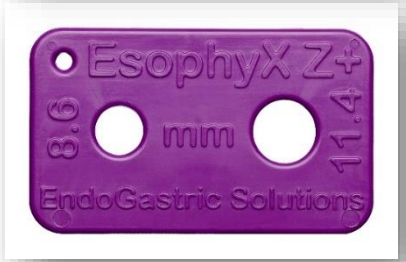


PATIENT INTERFACE

EsophyX® Device – Endoscope Compatibility

1. Use the **Endoscope Compatibility Tool** *prior* to each procedure. Flexible shaft diameters vary significantly.
2. Entire working length of endoscope must fit with very little resistance through larger opening in the endoscope compatibility tool, and should NOT fit through the smaller opening. This ensures the endoscope will fit through the device and the endoscope seal will function properly.
3. Acceptable diameter ranges are listed on the endoscope compatibility tool.

Note: The diameter ranges listed on the tools do not correlate with scope manufacturer specified diameters. The tools specify the acceptable range for the MAXIMUM diameter of the flexible portion of the endoscope.



Z+ tool is purple. For use with R2007 only.

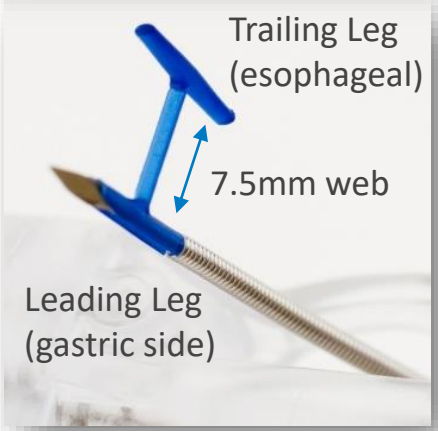
Z tool is black. For use with R2006 only.

SerosaFuse® Fasteners

Specifications:

- Molded polypropylene
- Durable and biocompatible
- MRI safe
- Non-absorbable
- 3-0 suture strength
- Designed to create serosal fusion
- 20 fasteners per cartridge
- 7.5mm web

Fastener Cartridge



Loaded Fastener

Esophagitis – Los Angeles Classification

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Esophagitis - damage to the esophageal mucosa characterized by inflammation of the tissue

Severity is characterized by the LA Classification

Grade A
at least one mucosal break, shorter than 5mm

Grade A

Grade B
at least one mucosal break, longer than 5mm

Grade B

Grade C
multiple breaks involving <75% of mucosal circumference

Grade C

Grade D
multiple breaks involving >75% of mucosal circumference

Grade D

Lundell, et al. (1999) Endoscopic assessment of oesophagitis, Gut 45, 72-80Bell, et al. (1999)
Patterns of success and failure with laparoscopic Toupet fundoplication, Surg Endosc 13: 1189-1194

Evaluating Hill Grade

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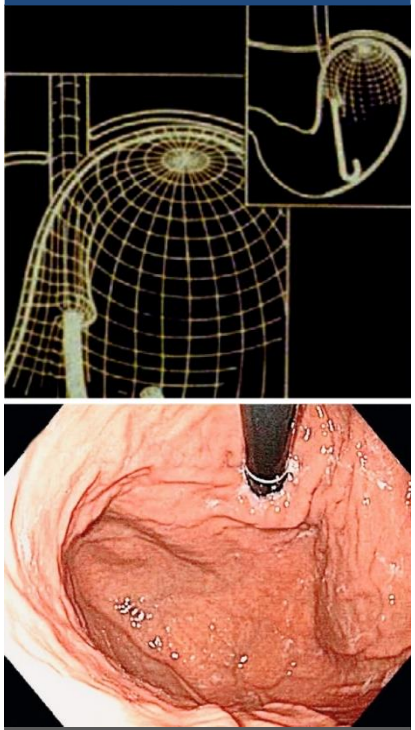
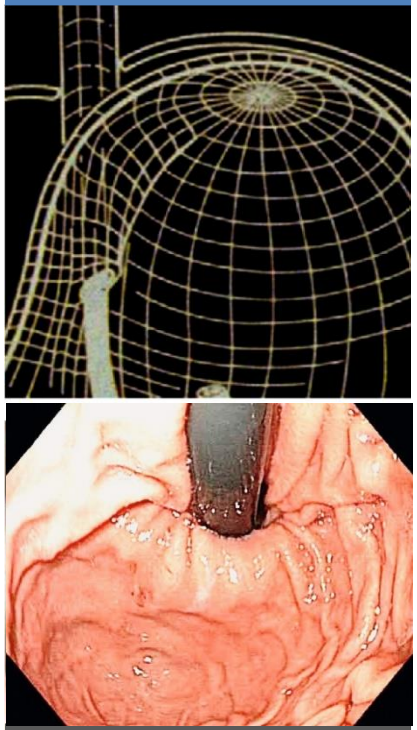
Grade I



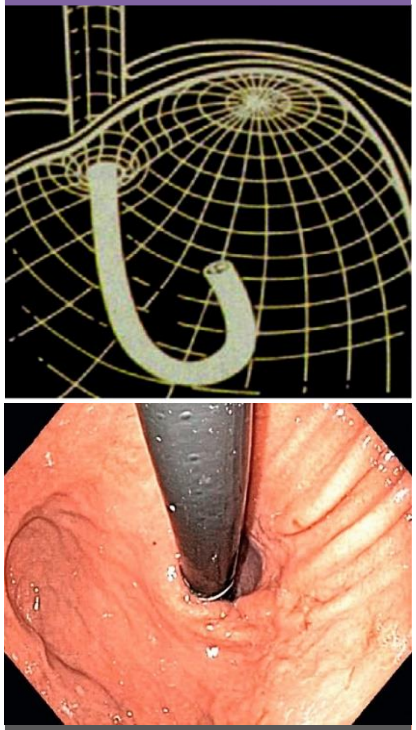
Normal ridge of tissue approximates closely to the scope

Grade II



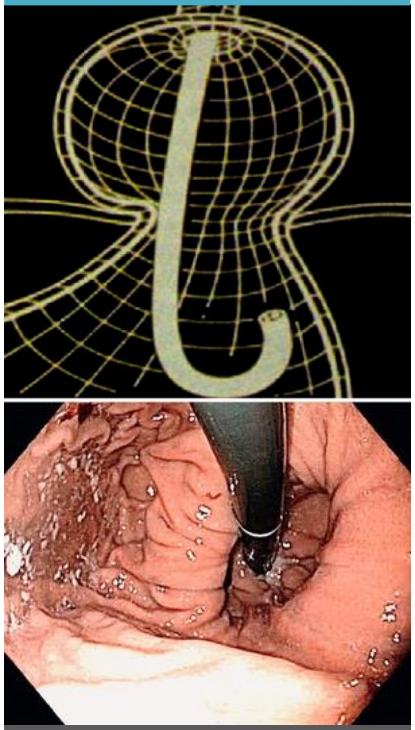
Ridge is slightly less well defined and opens with respiration

Grade III



Ridge is effaced and the hiatus is patulous

Grade IV



Hiatus is wide open at all times & sphincter is displaced axially

Device Preparation

Load first set of fasteners:

1. Pinch on both sides of the blue fastener pusher knob to free fastener pusher knob from handle.
2. Gently withdraw pushers together in short, 10cm increments until solid black lines are fully visible.

1

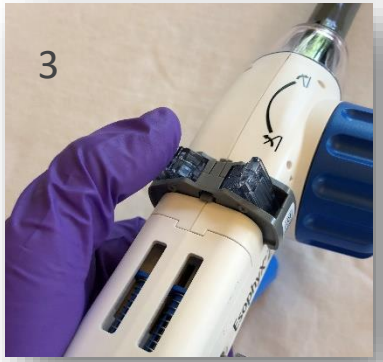
2

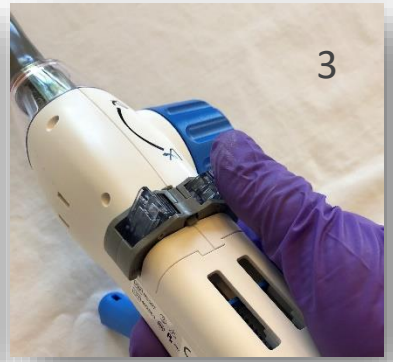
Device Preparation

Load first set of fasteners (continued):

3. Click fastener cartridge levers one at a time. Operator should feel and hear a “click.”
4. Advance pushers together in short increments until the double black lines are in-line with the device handle. Do not retract pushers during this process.
5. Observe fasteners through clear nosecone. If fasteners are confirmed to be loaded properly, continue advancing pushers until the blue fastener pusher knob is re-engaged at the handle.

Note: Do not load more than one set of fasteners per fastener delivery. This could damage the device.

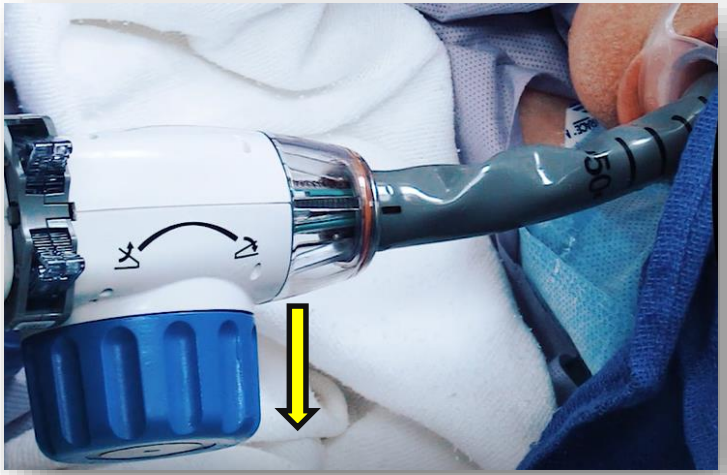




Device Insertion

Setup and orientation:

- Orient tissue mold knob to patient's left shoulder.
- Endoscope remains "hubbed" to device.
- Ensure tissue mold is fully open.
- Verify the helical retractor is locked and stowed in the safe home position (i.e. at the black line). Take care to avoid contact with the helical retractor control during device insertion.
- Introduce device under continuous visualization and keep esophageal lumen centered on the endoscope monitor. If loss of visualization occurs, stop advancing device and obtain visualization before continuing device insertion. If necessary, replace endoscope.
- Use only slight forward pressure.
- If resistance is encountered, stop and assess.
    - *Consider jaw thrust, temporary deflation of ETT cuff, and/or bougie dilation*

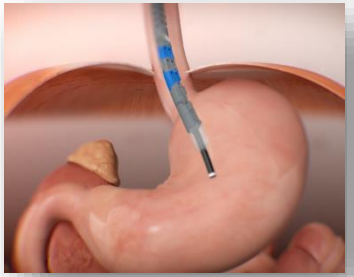


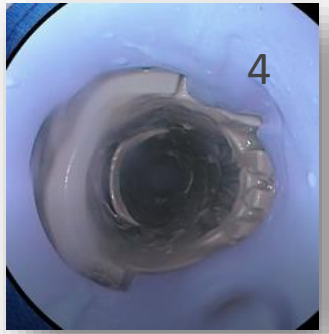
Device Insertion

Endoscope and tissue mold enter stomach:

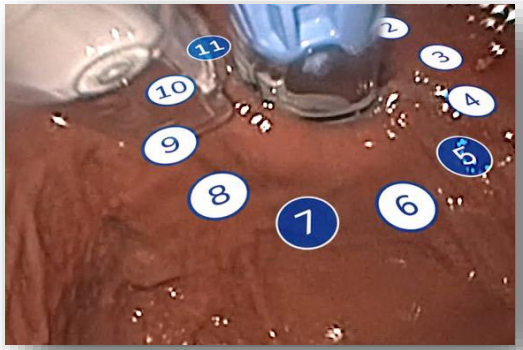
1. After endoscope enters stomach, retroflex endoscope to observe tissue mold during entry.
2. Under visualization, advance device into the stomach until at least one blue link of the chassis is exposed.

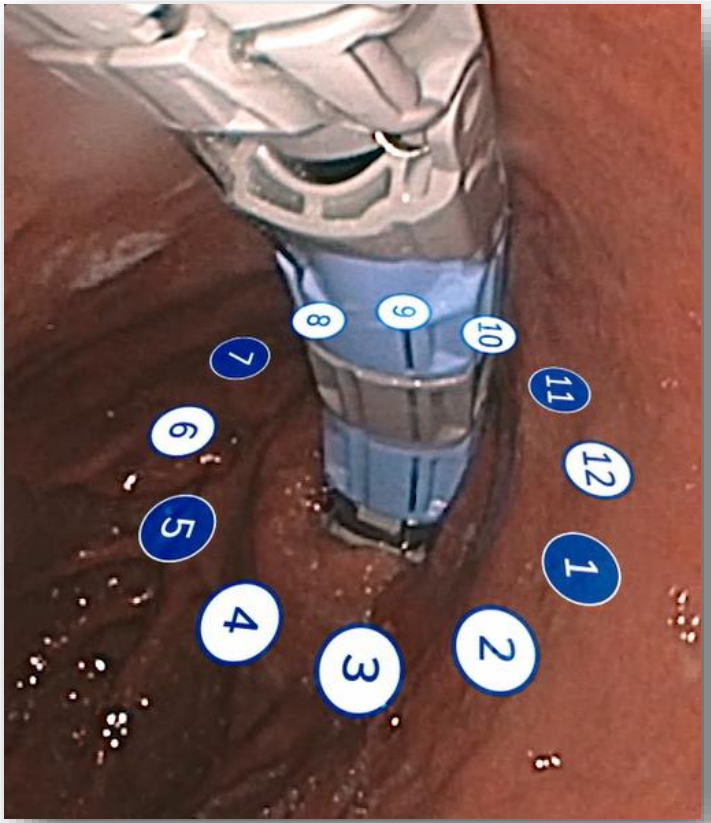
   Use insufflation to ensure distention of the stomach so there is room to close the tissue mold.
3. Orient tissue mold such that it will close/swing into the greater curve.
4. Straighten endoscope and retract endoscope back into EsophyX device until the distal blue link on the chassis is visible.





Valve Creation: Clock Face Nomenclature



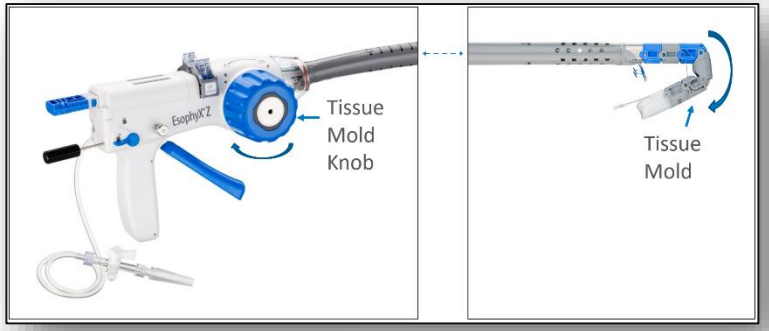


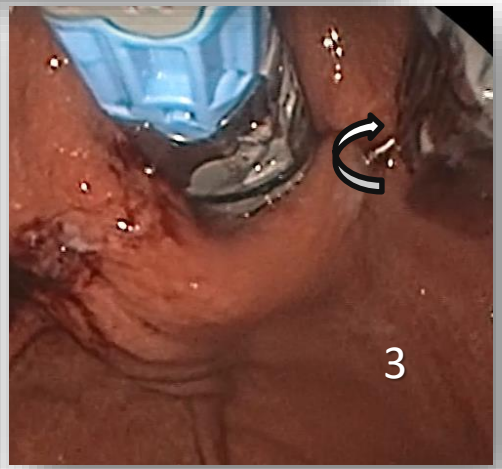
Valve Creation

Place Helical Retractor:

1. Use tissue mold to direct helical retractor towards desired position.
2. Open tissue mold slightly and gently retract device so that the tissue mold maintains contact with the valve and flattens the lip of the valve to expose the z-line.
3. Under visualization, advance helical retractor and engage tissue <u>at the z-line</u>. Rotate helical retractor control clockwise approximately 4 full rotations to fully engage the helical retractor. <u>Do not over-rotate</u>.

1



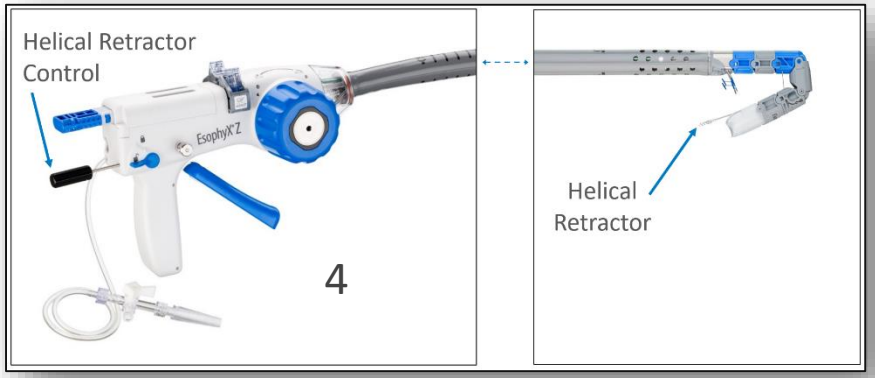


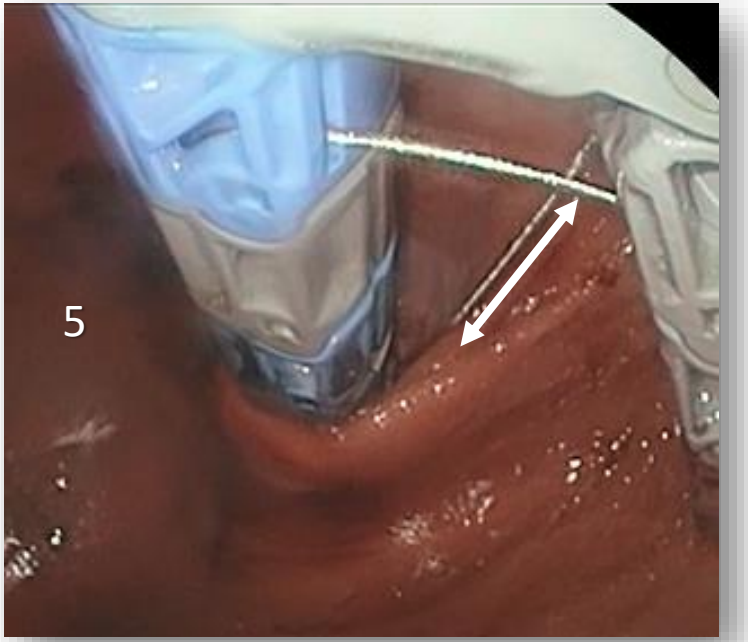
1 o'clock position shown

Valve Creation

Place Helical Retractor (continued):

4. Slowly advance helical retractor control to provide slack on the helical retractor cable.
5. Free helical retractor cable from tissue mold channel by opening tissue mold and, if in the posterior or anterior corner, rotating the tissue mold back towards the greater curve.



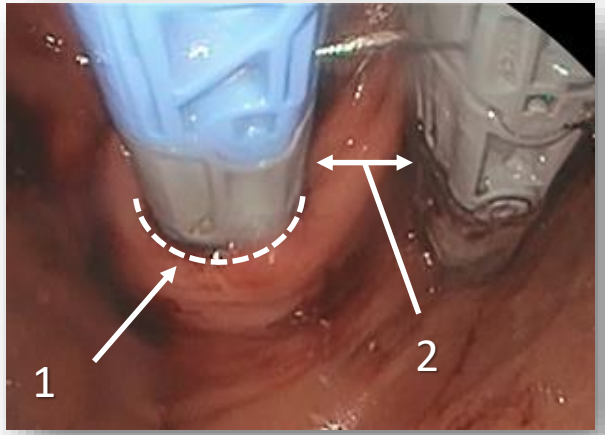


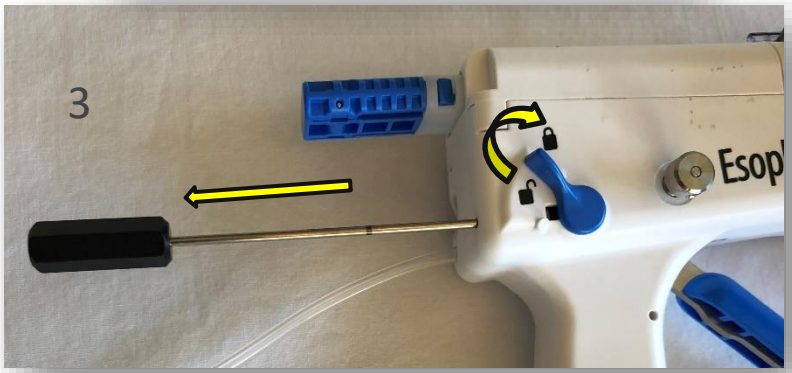
1 o'clock position shown

Valve Creation

“Set” the device:

1. Gently retract the device into the esophagus until the proximal blue link of the chassis is covered by the valve.
2. Maintain an appropriate gap between tissue mold and tissue. This allows for tissue retraction and wrap.
3. Lock the helical retractor <u>after</u> device has been properly set. Do not use excessive force when manipulating the retractor lock.
4. Maintain mild tension on the helical retractor control; only enough tension to keep the helical retractor cable free from the channel.





Valve Creation

Desufflate & Retract Tissue:

Maintain device depth during the following steps:

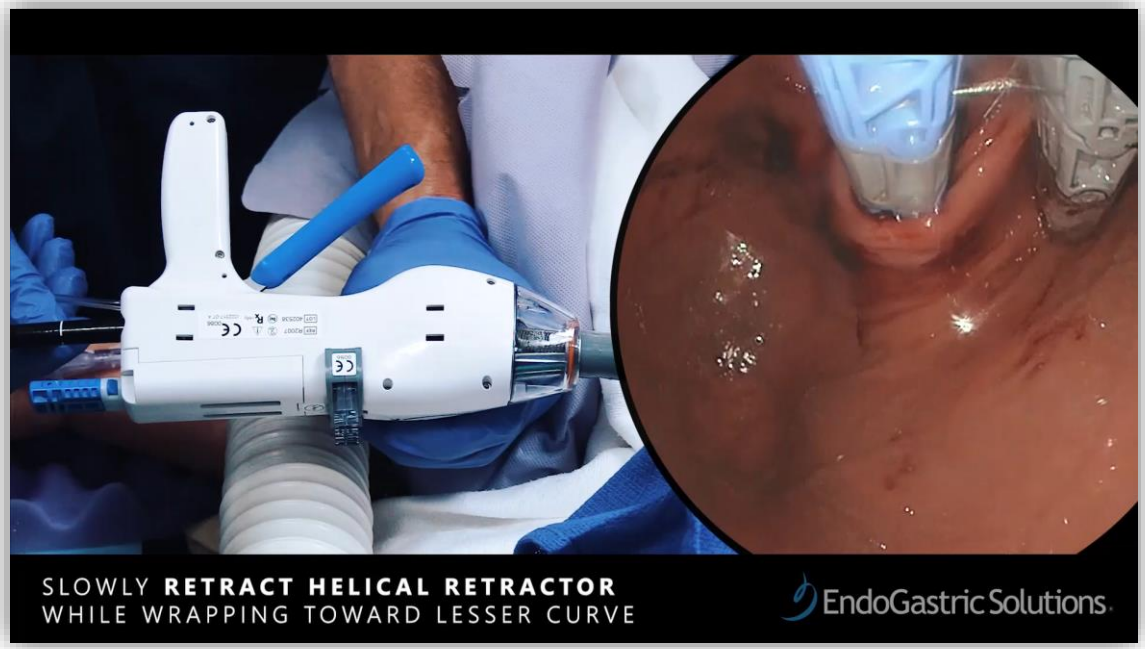
1. Scope operator provides desufflation of the stomach with the endoscope while maintaining a visual of the tissue positioned between the tissue mold and chassis.
2. After waiting for sufficient desufflation, physician provides moderate and constant retraction on the helical retractor control.
3. When helical retraction is maximized, ensure helical retractor lock is engaged and release helical retractor control (i.e. the black knob).
4. If at 5 or 7 o'clock, fully close tissue mold until the tissue mold knob clutch slips and turn the invaginator on.
5. If at 11 or 1 o'clock, continue to the next slide.

Valve Creation

Full Desufflation & Wrap
(at 11 and 1 o'clock only):

Maintain device depth during the following steps:

1. Scope operator provides desufflation, completely collapsing the gastric tissue.
2. Physician slowly rotates device towards the lesser curve to wrap tissue around the esophagus. Ensure sufficient lateral load has been applied to the tissue mold to achieve a 270° wrap.
3. When tissue wrap is maximized, fully close the tissue mold until the tissue mold knob clutch slips (i.e. no clicks are heard).
4. Invaginator on, then counter-rotate device back toward the greater curve.



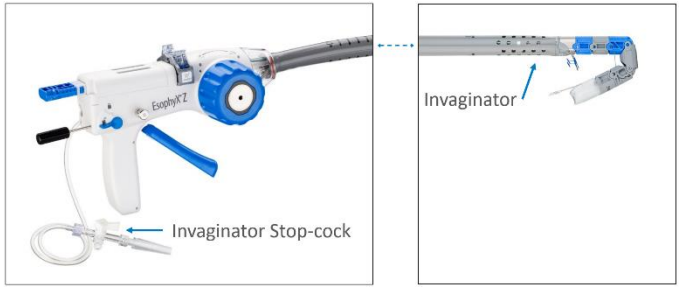
Valve Creation: EsophyX® Z+ Device Invaginator

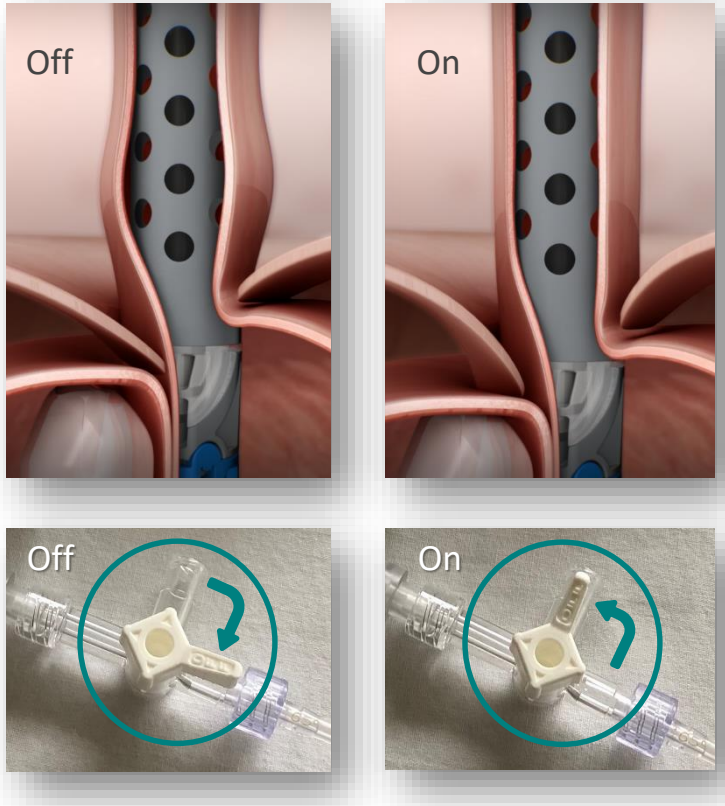
General Purpose

Provides circumferential suction of distal esophagus to position valve construct caudal to diaphragm.

Standard Operation

- Activated using invaginator vacuum stopcock, which is connected to a second, dedicated suction source
- Tensions distal esophagus to ensure fasteners will be delivered caudal to the diaphragm
- Allows for counter rotation away from lesser curve, which minimizes potential of a stylet/tissue mold strike, causing damage to the device





Valve Creation

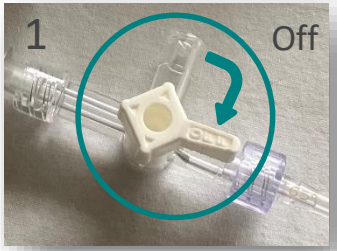
Between fastener deliveries:

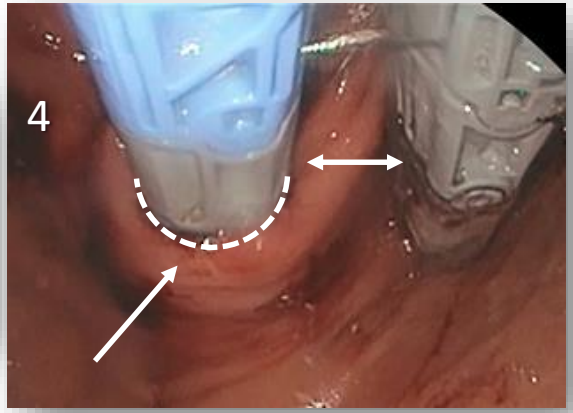
The following process ensures fasteners are not delivered on top of the previous set.

1. Invaginator off
2. Helical lock off
3. Reload fasteners
4. Open tissue mold until there is appropriate clearance for tissue manipulation, then re-set the device

Repeat previous steps until all 20 fasteners have been delivered.

Note: When repositioning tissue mold, place tissue mold plastic-to-plastic to minimize risk of tissue damage.





Post-operative EGD

Inspect valve

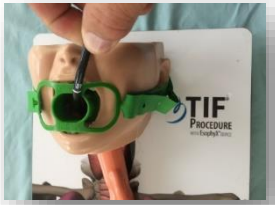
- Evaluate length, shape, and wrap.
- Confirm hemostasis.
- Inspect stomach and esophagus.
- Flush if needed.
- Suction excess fluids, especially blood.
- Suction remaining insufflation.
- Note fastener locations and quantity at each location.

CAUTION: Device and endoscope should be handled as biohazards. Avoid contact with the blue button on the scope post-procedure. Device to be disposed of properly.

Supplies & Room Set-up

Requirements

Biocompatible ≥60 Fr Bite Block (FDA approved / CE marked) placed prior to device insertion



Compatible endoscope: Reference IFU for details

CO_2 insufflator & tubing

Suction canisters & tubing x2

Insufflation adaptor for endoscope

- Examples of compatible adapters are B. Braun DP3500L and Medivators 100303

Towels & 4x4s

Gowns, gloves, drapes

Lubricant (use approved water-based or silicone lubricants compatible with endoscope)

Basin, syringe

Anesthesia, full paralysis

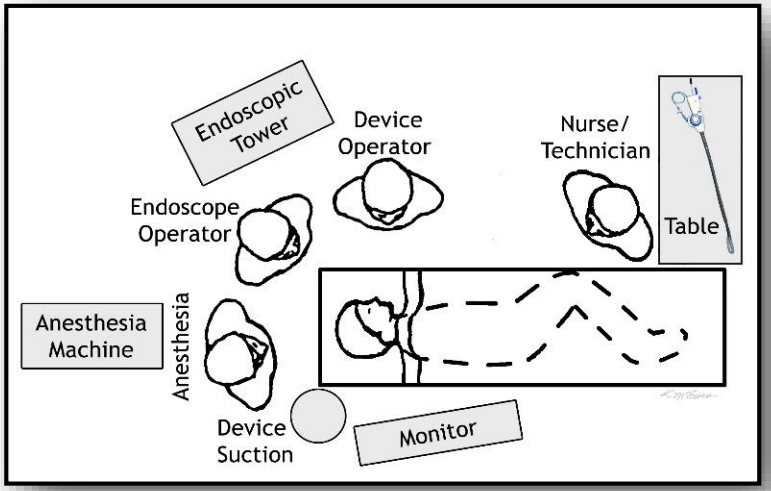
EsophyX device and 7.5mm fasteners & backups

Surgical scissors/wire cutter and scalpel

Room Setup

Patient position: Left lateral decubitus

Laparoscopic insufflator not shown below



Contraindications: TIF® procedure with EsophyX® device

Patients with:

- BMI > 35
- Hiatal hernia > 2cm
- Paraesophageal hernia
- Bleeding disorders
- Severe esophagitis
- Esophageal diverticulae
- Esophageal varices
- Esophageal infections or fungal disease
- Esophageal stenosis
- Strictures
- Obstructions
- Limited neck mobility
- Osteophytes of the spine
- Chronic cough
- Any kind of normal or abnormal esophageal anatomy which would not permit insertion of a device