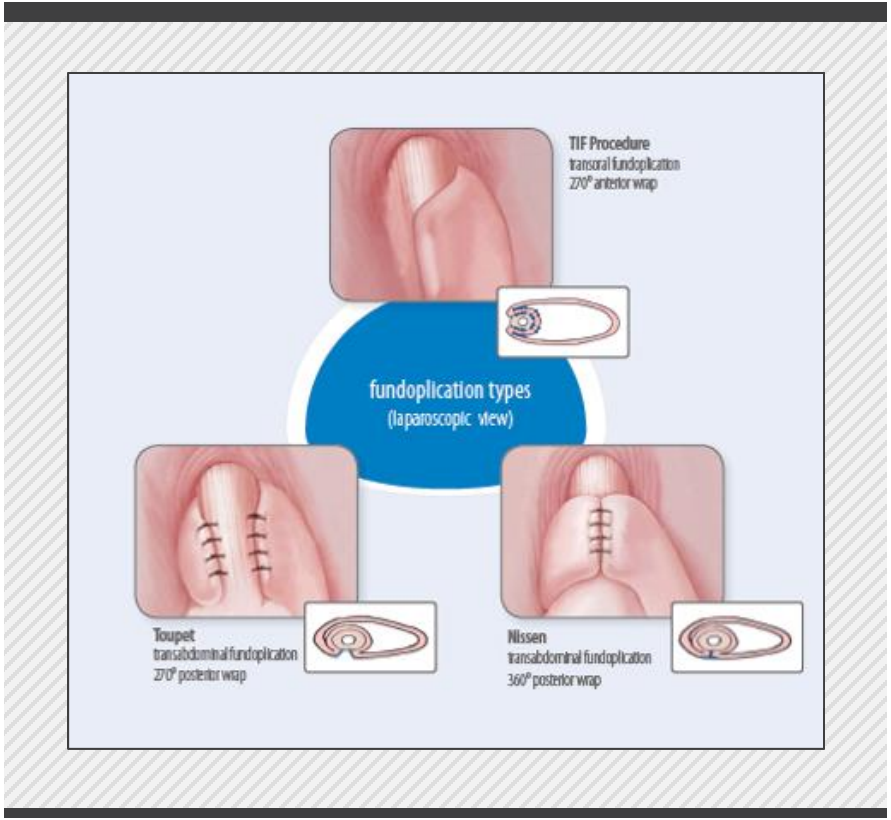
EndoGastric Solutions®

EsophyX® Z+ Device

Product Overview

EsophyX® Z+ Device and Anti-Reflux Surgery



Pioneered by Dr. Rudolph Nissen

- Reduce hiatal hernia if present
- Elongate intra-abdominal esophagus
- Recreate dynamics of the angle of His
- Restore distal high pressure zone (HPZ)
- Create fundoplication
  *(TIF= 270°, 3cm valve)

*Surgical Endoscopy (Transoral Fundoplication Offers Durable Symptom Control for Chronic GERD: 3-year Report from the TEMPO……)

ARS Principles via Transoral Approach

Tissue Mold

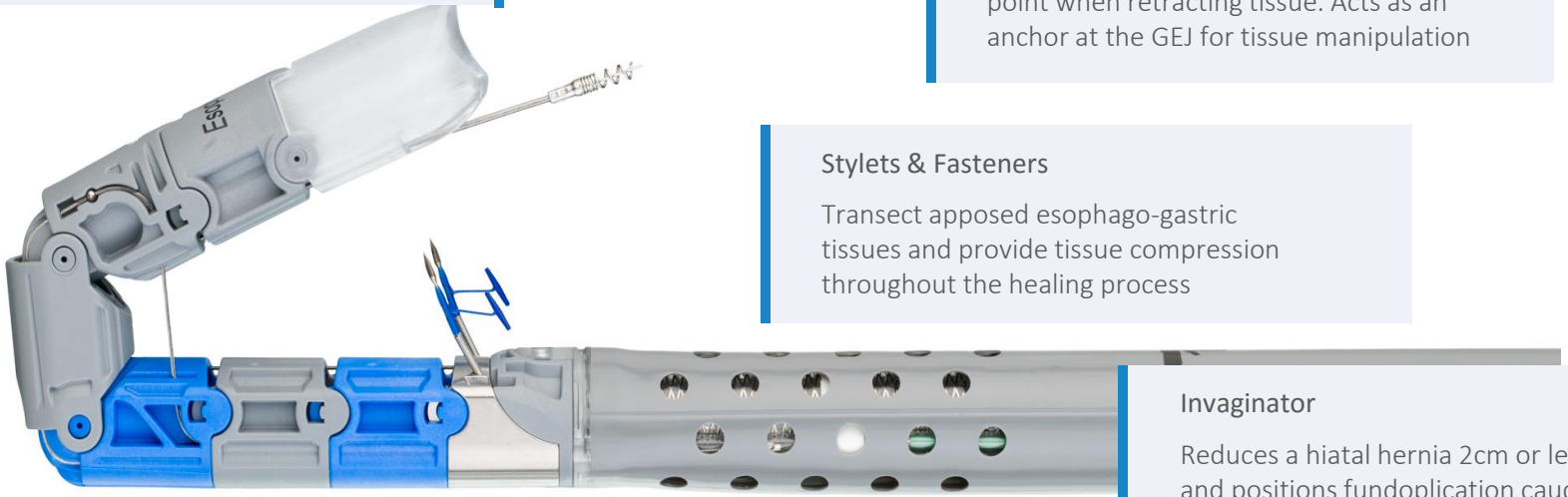
Rotates and wraps tissue around the distal esophagus superior to the z-line and compresses tissue prior to plication

Helical Retractor

Retracts gastric tissue and serves as a pivot point when retracting tissue. Acts as an anchor at the GEJ for tissue manipulation

Stylets & Fasteners

Transect apposed esophago-gastric tissues and provide tissue compression throughout the healing process



EsophyX® Z+ Device

Invaginator

Reduces a hiatal hernia 2cm or less and positions fundoplication caudal to the diaphragm

Used in concert, the elements of EsophyX® Z+ Device enable a true transoral fundoplication

EsophyX® Z+ Device Indication for Use

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 are 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.

EsophyX® Z+ Device Product Information

EsophyX Z+ Devices are used in conjunction with SerosaFuse® Fasteners to enable transoral tissue reconstruction.

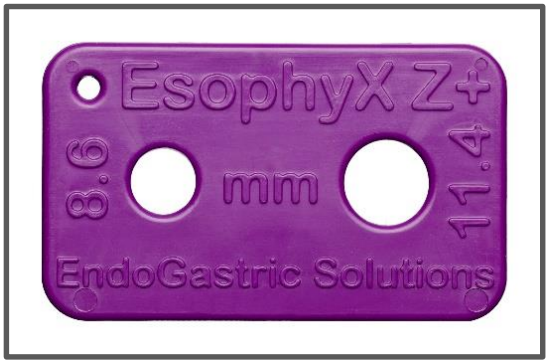
EsophyX® Z+ Device

7.5mm

EsophyX® Z+ Device –SerosaFuse® Fasteners – 7.5mm only

EsophyX® Z+ Device – Endoscope Compatibility

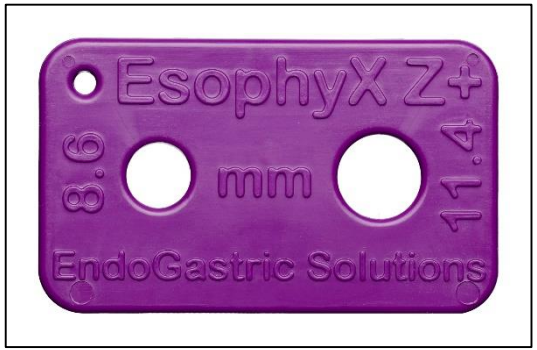
1. Use the appropriate **Endoscope Compatibility Tool** *prior* to each procedure.
2. Entire working length of scope must fit through larger opening in compatibility tool.
3. Working length of scope should not fit through smaller opening.
4. Use Purple Endoscope Compatibility Tool for EsophyX Z+ Device



EsophyX Z+ Device

EsophyX® Z+ Device Technology – Endoscope Compatibility

EsophyX Model	EsophyX Z+ Device
Example of Compatible Endoscopes	Standard and HD endoscope e.g., Olympus GIF-Q180, GIF-H190, GIF-H180J
EGS Specifications Outer Diameter Measurements	8.6mm to 11.4mm



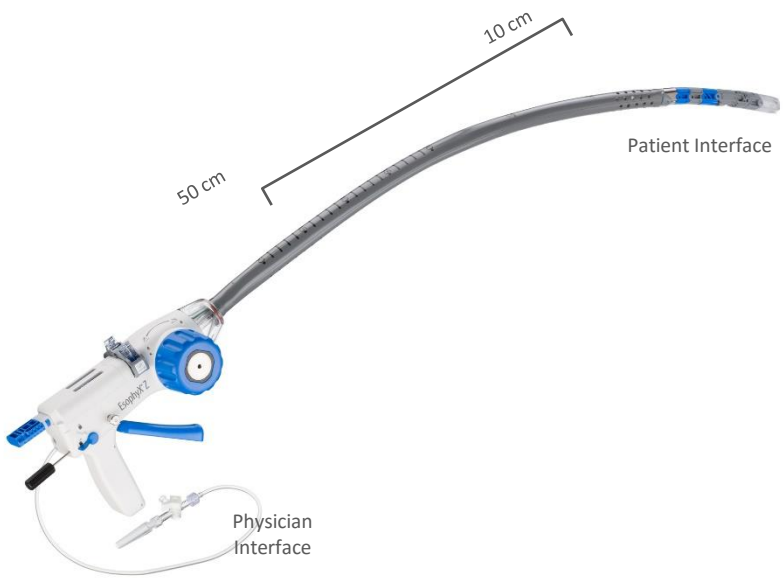
EsophyX Z+ Device Compatibility Tool

Confirm scope compatibility with measurement tool before every TIF procedure

EsophyX® Z+ Device and SerosaFuse® Fasteners Product Information

- Supplied sterile with 24 month shelf life
- Single-use only
- Do not reuse
- EsophyX Z+ Device – not MRI safe
- SerosaFuse Fasteners – MRI safe
- Remove device from packaging properly – do not use if package or device damaged
- IFU may be reviewed for more information
- Not made of natural rubber latex

Overview of EsophyX® Z+ Device



EsophyX Z+ Device

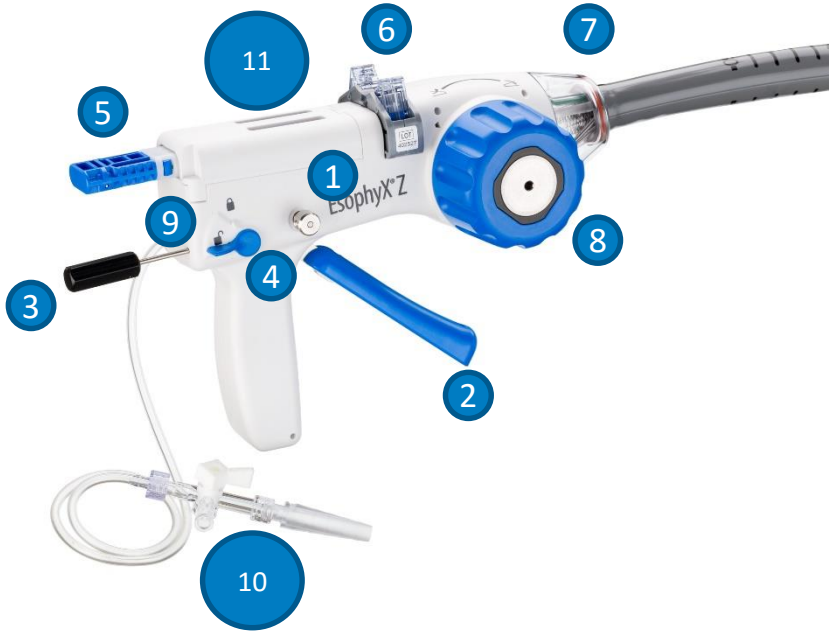
Patient Interface – consist of Invaginator, Helical Retractor, Tissue Mold, Fastener Ports, Double hinged joint, Chassis and Shaft of device.

Physician Interface – consist of Endoscope Seal, Helical Retractor Control, Helical Retractor Control Lock, Slotted Fastener Delivery Cap, Tissue Mold Knob, Fastener Delivery Trigger Release & Fastener Delivery Trigger, Fastener Cartridge, Stop-cock, Fastener Pushers, Clear Nose-cone

Markings on shaft of device are for reference only.

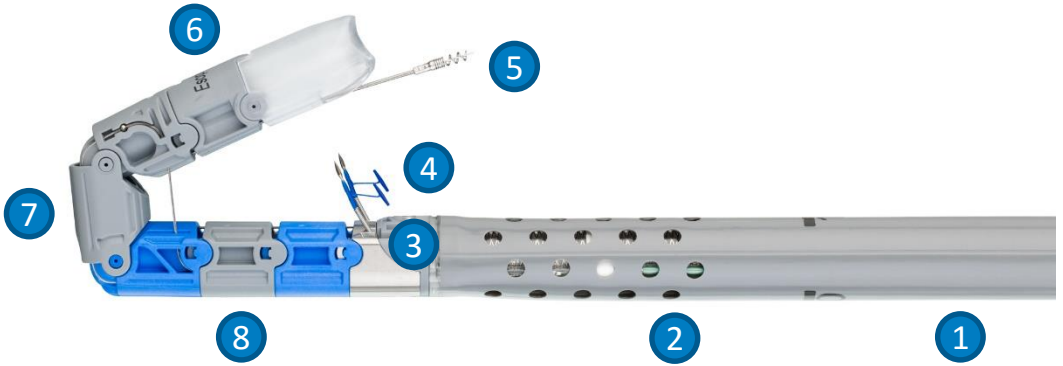
EsophyX® Z+ Device Control Overview – Physician Interface

1. Fastener Delivery Trigger Release
2. Trigger Release
3. Helical Retractor Control
4. Helical Retractor Control Lock
5. Fastener Pushers
6. SerosaFuse® Fastener Cartridge
7. Clear Nose Cone
8. Tissue Mold Knob
9. Endoscope Seal
10. Stop-cock for Invaginator
11. Slotted Fastener Delivery Cap



EsophyX® Z+ Device Control Overview – Patient Interface

1. Shaft
2. Invaginator
3. Stylet Ports
4. Stylet with SerosaFuse® Fasteners
5. Helical Retractor
6. Tissue Mold
7. Double Hinge
8. Chassis



EsophyX® Z+ Device and SerosaFuse® Fasteners Product Line

EsophyX Model	EsophyX Z+ Device
SerosaFuse® Fastener Cartridge Compatibility	7.5mm only
Diameter	20mm/60Fr
Helical Retractor	Interior Trajectory, Quick Lock
Tissue Mold	Clutch and Spring
Fastener Deliver Mechanism	Trigger and Dual Channel
Endoscope Compatibility	HD and Standard 8.6mm to 11.4mm
EGS Endoscope Compatibility Tool	Purple R4007

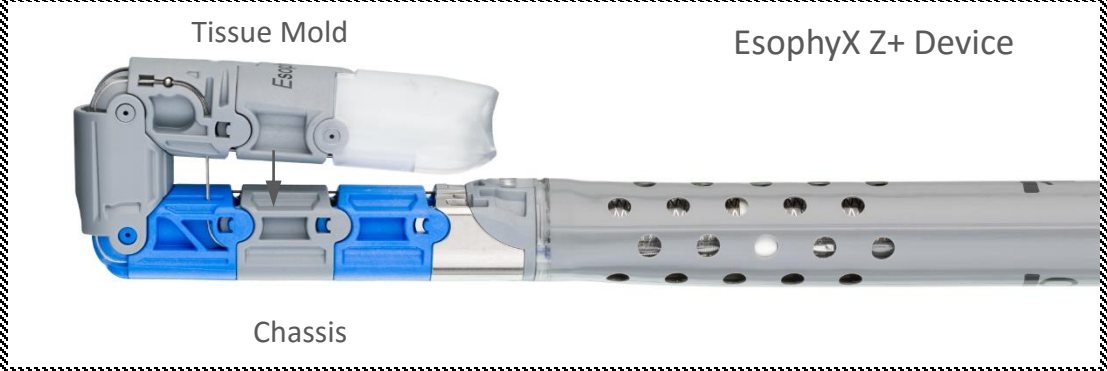
EsophyX® Z+ Device – Tissue Mold

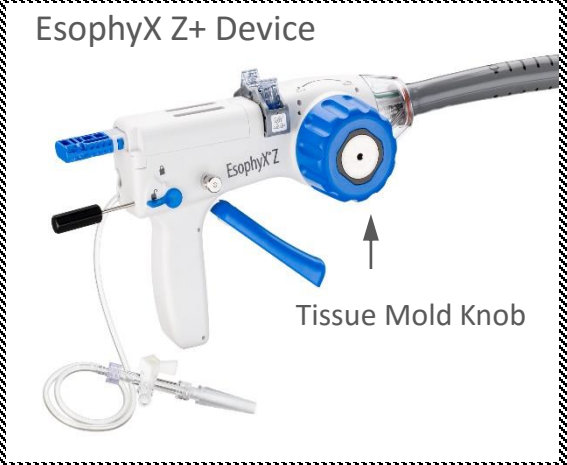
General Purpose

Determines initial trajectory and placement of the Helical Retractor, as well as compression of tissue

Standard Operation

- Open and close Tissue Mold as necessary to direct Helical Retractor toward tissue
- Tissue Mold can be used for compression of tissue and aids in wrapping tissue





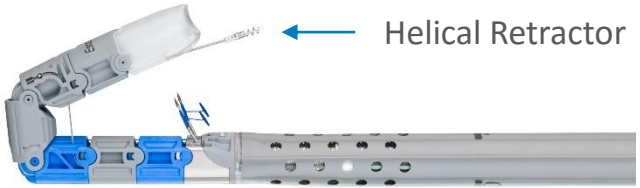
EsophyX® Z+ Device Functions – Helical Retractor

General Purpose

Engages tissue at Z line (gastric), and retracts tissue

Standard Operation

- Tissue Mold used as a guide during tissue purchase
- Engage tissue - rotate Retractor Control approximately four complete clockwise rotations **(do not over rotate)**
- Rotate Retractor Control counter clockwise when disengaging and placing in home position – apply slight tension during this maneuver
- Unlock Helical Retractor prior to unlocking or opening Tissue Mold
- May retract tissue with Helical Retractor in locked position



EsophyX® Z+ Device Functions – Helical Retractor

Note: Decrease risk of bent Helix

- After Helix is engaged into tissue – do not open Tissue Mold until the following is complete
- 1st - advance Helical Retractor control to release Helix from groove of Tissue Mold.
- 2nd – advance EsophyX Z+ device into stomach slightly – this will also assist the Helix to exit the groove of the Tissue Mold.

EsophyX Z+ Device

EsophyX® Z+ Device Functions – Helical Retractor

Note: If for any reason the Helical Retractor is bent during the TIF® procedure and cannot be returned to the “home position” for safe removal from patient –

Call EndoGastric Solutions or your local trainer/sales personnel.

EsophyX Z+ Device

EsophyX® Z+ Device Functions – Tissue Mold and Helical Retractor

General Purpose

Used simultaneously to retract, wrap, and compress tissue

Standard Operation

After Helical Retractor is engaged in tissue, advance beyond tip of Tissue Mold to free

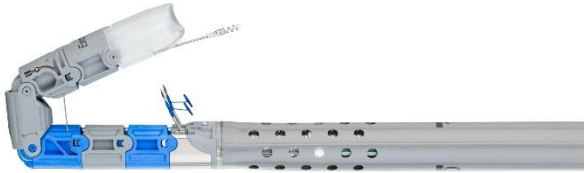
Separate retractor cable from mold by:

- Opening Tissue Mold
- Rotating away from lesser curve
- Applying tension to the Helical Retractor

NOTE: Manipulation of tissue is optimal when stomach is deflated prior to retracting tissue or wrapping tissue

After manipulation, Tissue Mold and Retractor are locked to stabilize and compress tissue

EsophyX Z+ Device



SerosaFuse® Fasteners

Molded polypropylene

Durable and biocompatible

Non-absorbable

3-0 suture strength

MRI safe

Designed to create serosal fusion

20 fasteners per cartridge (remove Red shipping holder and dispose of properly as a sharp)

7.5mm

EsophyX® Z+ Device – Fastener Loading

General Purpose

Delivers fasteners to plicate tissue and create valve

Standard Operation

- Install cartridge
- Withdraw Pushers (together)
- Click cartridge levers
- Advance Pushers (together) in short increments and observe fastener through clear nosecone
- Continue to advance Pushers until snapped into locked position

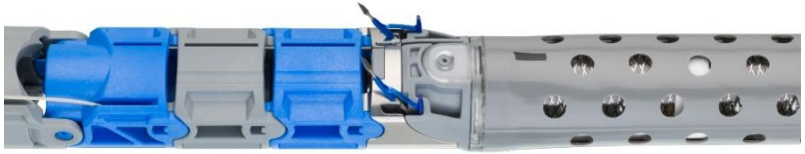
EsophyX® Z+ Device Functions – Stylets and Fasteners

General Purpose

Transect and plicate apposed tissues

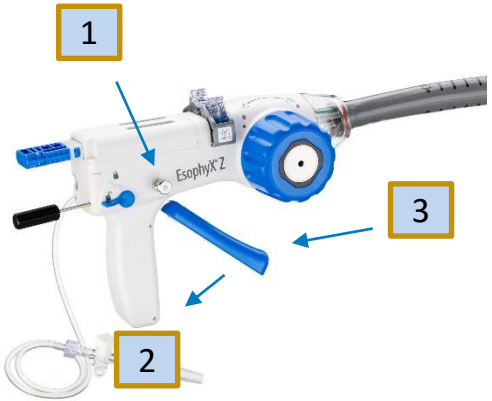
Standard Operation

- Fasteners are loaded after introduction of device and after each set of plications
- After loading fasteners onto stylet wires, continue forward motion of Pushers until loading is complete, do not retract Pushers during this process
- Deliver Stylets and Fasteners together with Trigger Handle



EsophyX Z+ Device

EsophyX® Z+ Device – Fastener Delivery



1. Depress the fastener delivery Trigger Release.
2. Squeeze the fastener delivery trigger.
3. Ensure that the trigger returns to its home position and is locked out by the Trigger Release
4. Deploy fasteners into non-fibrotic tissue

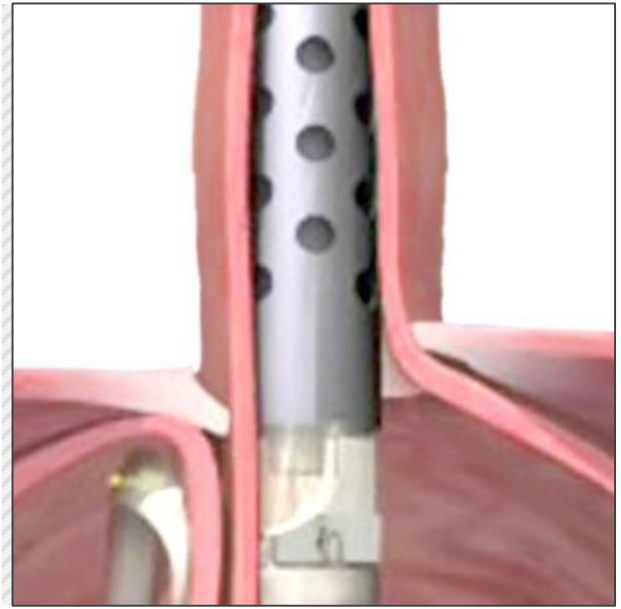
EsophyX® Z+ Device Function – Invaginator

General Purpose

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

Standard Operation

- Activated using Vacuum Stopcock
  - *Off, rotated toward device handle*
  - *On, perpendicular to vacuum tubing*
- Routinely applied after tissue manipulation to prepare construct for fastener delivery
  - *Tension distal esophagus*
  - *Counter rotate away from lesser curve - Minimizes potential of capturing diaphragm in plications*
- Invaginator is applied after Helical Retractor and Tissue Mold are locked for preparation of tissue plication



Review - ARS Principles via Transoral Approach

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EsphyX® Z+ Device – Instructions for Use (IFU)

- EsophyX Z+ Device IFU print sample provided to attendee at end of syllabus
- All Warnings within IFU reviewed with attendee

SerosaFuse® Implantable Fasteners – Instructions for Use (IFU)

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- All Warnings within IFU reviewed with attendee

EndoGastric Solutions®

Hands-on

EndoGastric Solutions®

Thank You