MINIMALLY INVASIVE FUNDOPLICATION FOR CHRONIC ACID REFLUX

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Disclosures

- Consultant and Speaker: EndoGastric Solutions
- Research support: Medigus

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ɔhageal sphincter

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Refractory GERD: Is an issue

Approximately 10 to 40 percent of patients with GERD fail to respond symptomatically, either partially or completely, to a standard dose PPI

Dorval et al. BMC Gastroenterology 2011, 11:25
J Clin Outcomes Manag. 2000;7:29
Dig Dis 2009;27:62–67
Can J Gastroenterol. 2012 Apr; 26(4): 196–204.

Proper Dosing
Aliment Pharmacol Ther. 2006;23(10):1473
Am J Gastroenterol 2009; 104: 2161-2167

Residual acid reflux
Clin Gastroenterol Hepatol. 2008;6(5):521

Nocturnal acid breakthrough
Aliment Pharmacol Ther.
1998;12(12):1231

Compliance
Curr Gastroenterol Rep. 2008;10(3):252

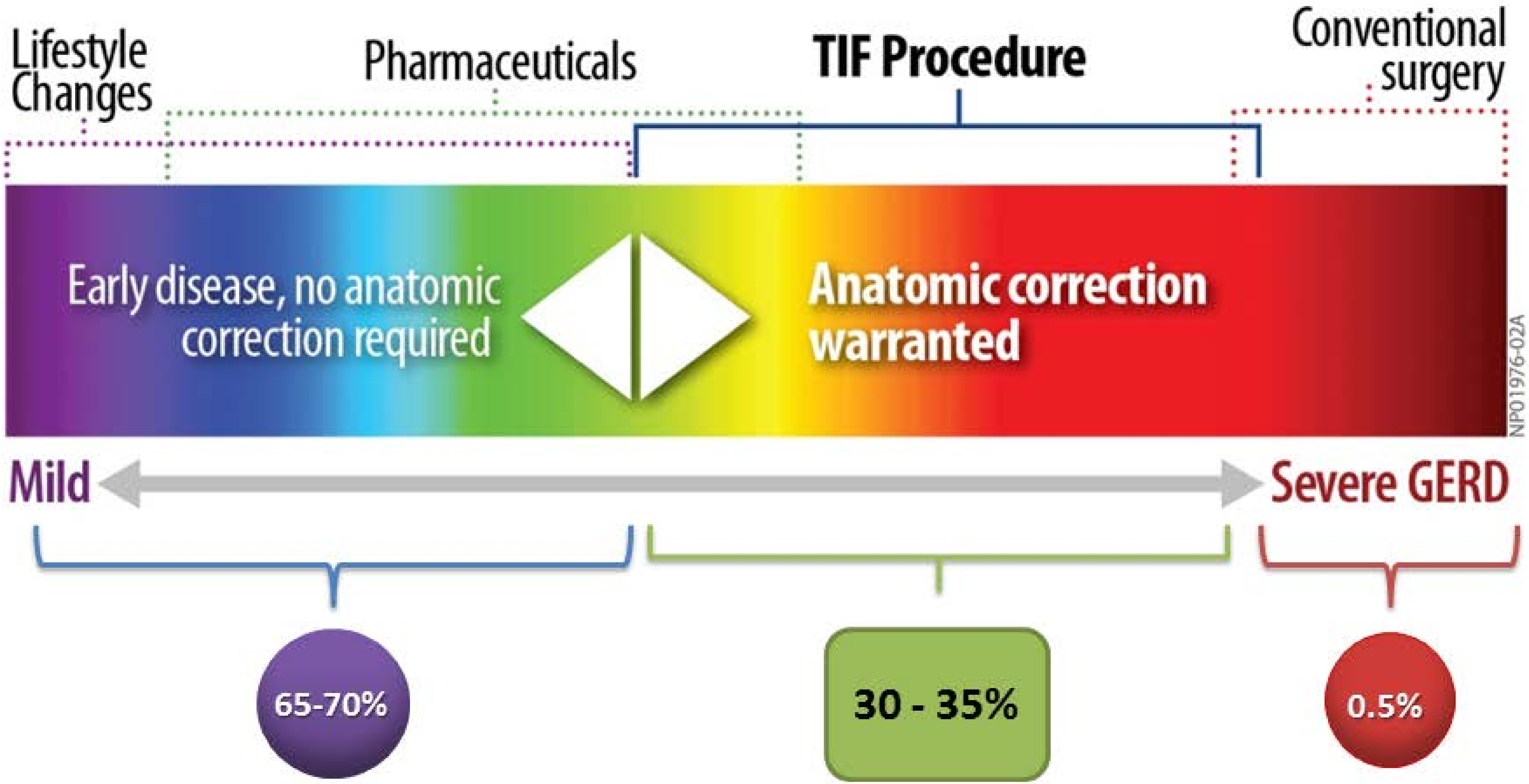
Weakly acidic or alkaline reflux
Gut. 2009;58(2):295

Functional heartburn and atypical reflux
BMJ 2006; 332: 11-17

Psychological comorbidity

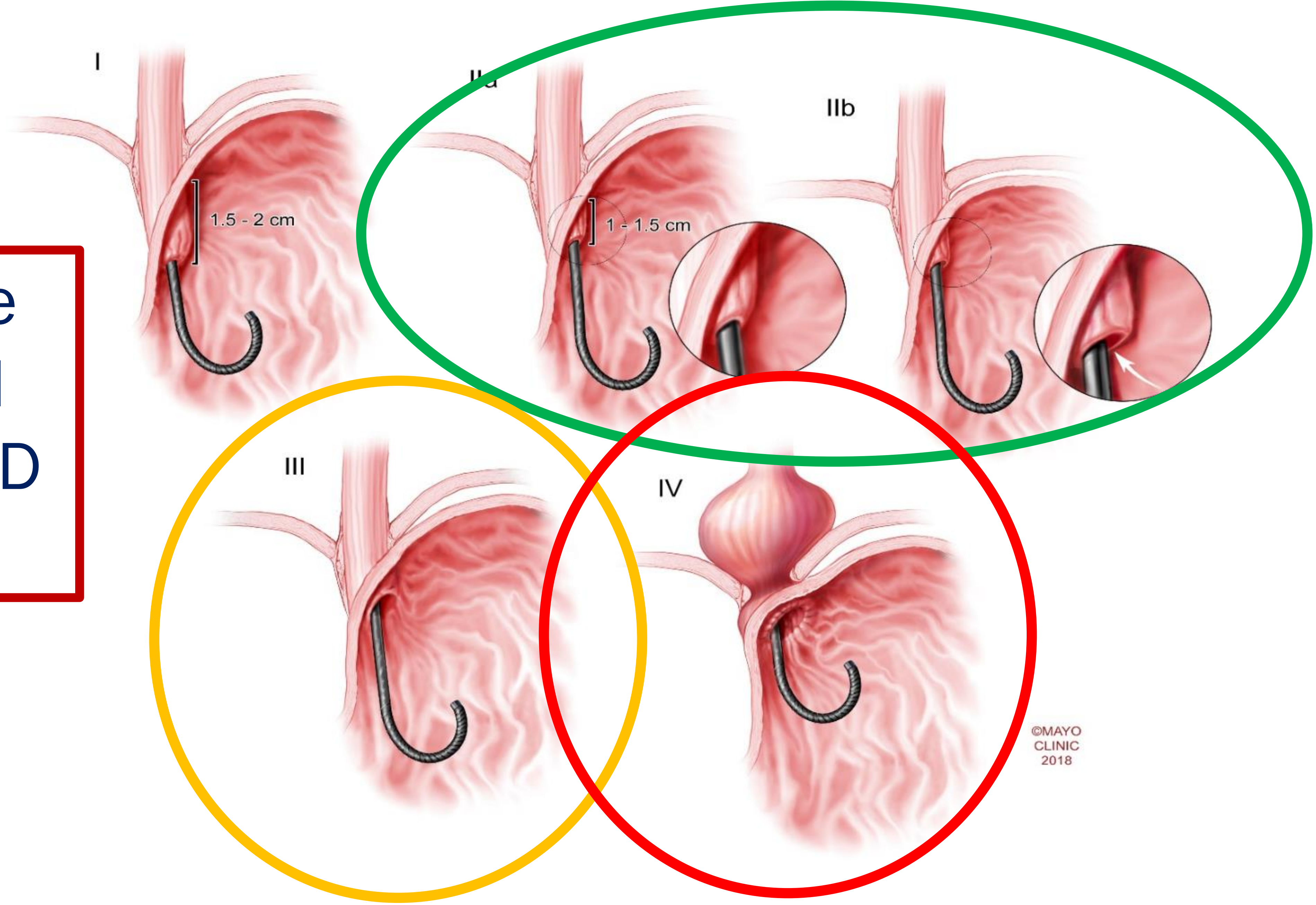
Differences in metabolism
CYP2C

GERD



Lifestyle Changes
Pharmaceuticals
TIF Procedure
Conventional surgery
Early disease, no anatomic correction required
Anatomic correction warranted
NP01976-02A
Mild
Severe GERD
65-70%
30 - 35%
0.5%

Hill Grade Revisited Endo GERD Therapy



Audience Question

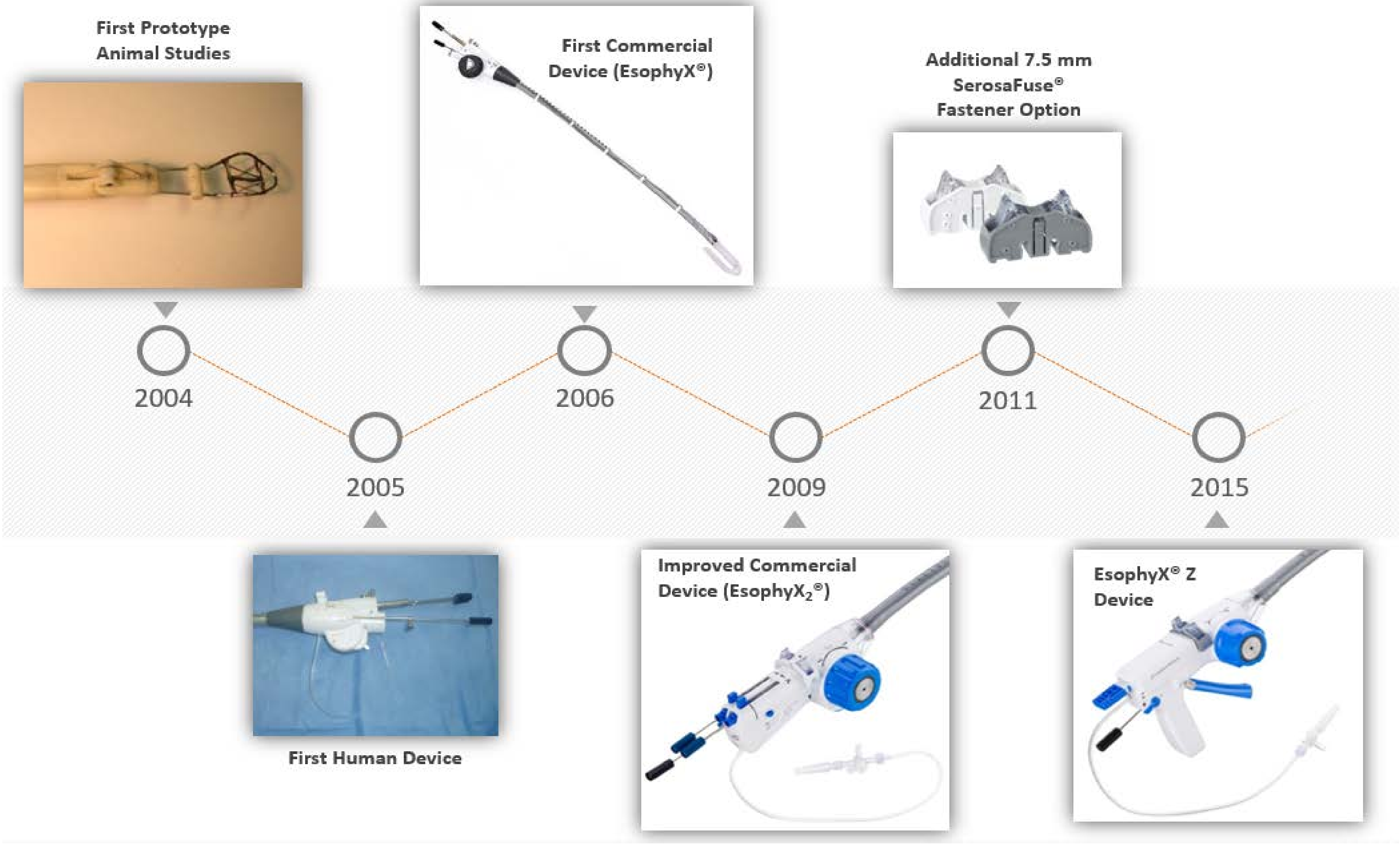
What antireflux treatments are in your reflux armamentarium? (check all that apply)

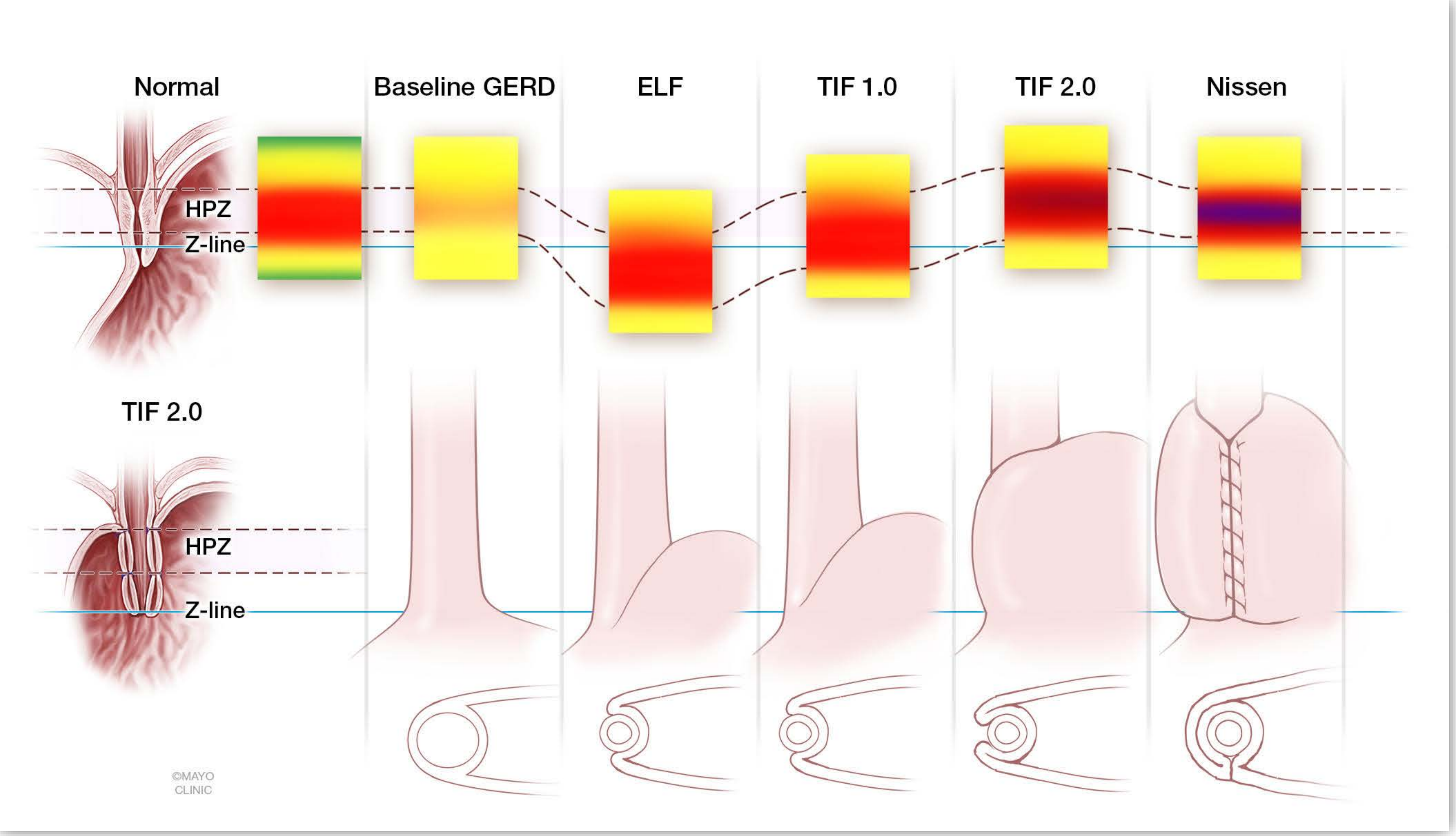
A. Nissen Fundoplication
B. Hiatal Hernia Repair
C. TIF procedure
D. LINX
E. Stretta

Emulates Traditional Surgical Principles with Endoscopic Approach

Principles Of Antireflux Surgery		Laparoscopic Fundoplication
Reduce hiatal hernia ≤ 2 cm		✓
Repair hiatal hernia > 2 cm and close crura*		✓
Elongate the intraabdominal 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		✓

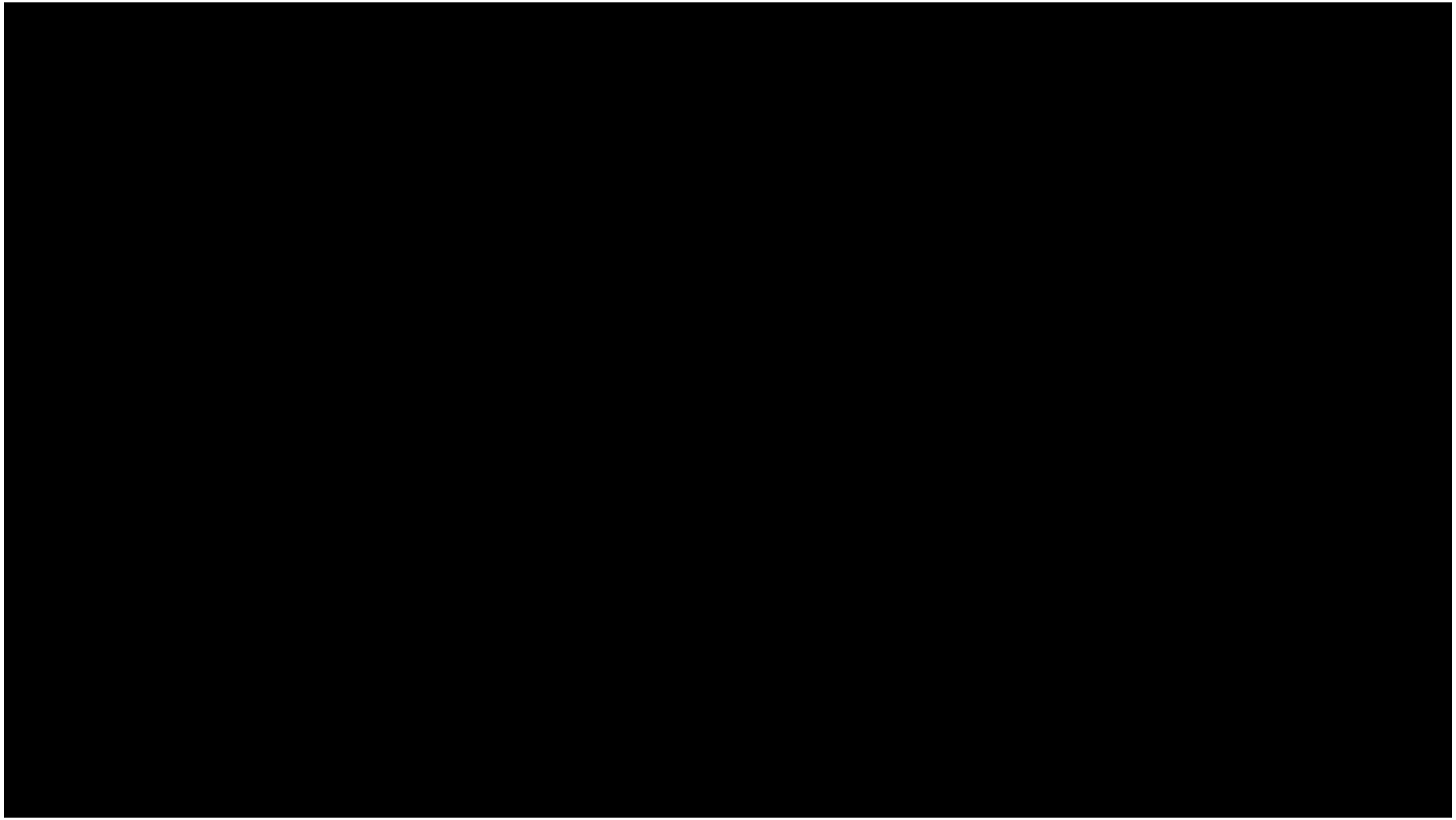
*As of June 22, 2017, EsophyX device indication was expanded to include patients with hiatal hernias larger than 2cm when a laparoscopic hiatal hernia repair (HHR) reduces the hernia to 2 cm or less.


First Prototype
Animal Studies
2004
First Human Device
2005
First Commercial
Device (EsophyX®)
2006
Improved Commercial
Device (EsophyX$_2$®)
2009
Additional 7.5 mm
SerosaFuse®
Fastener Option
2011
EsophyX® Z
Device
2015

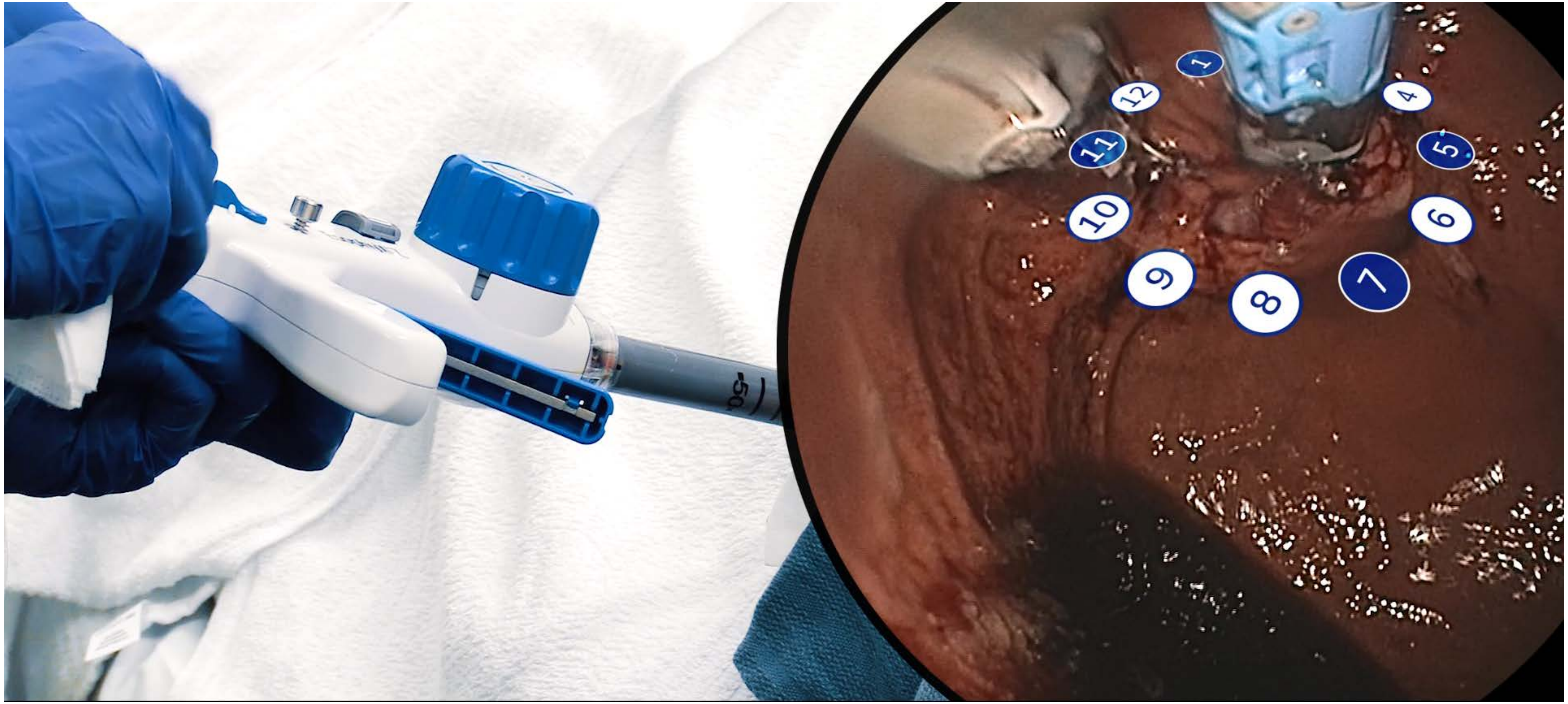


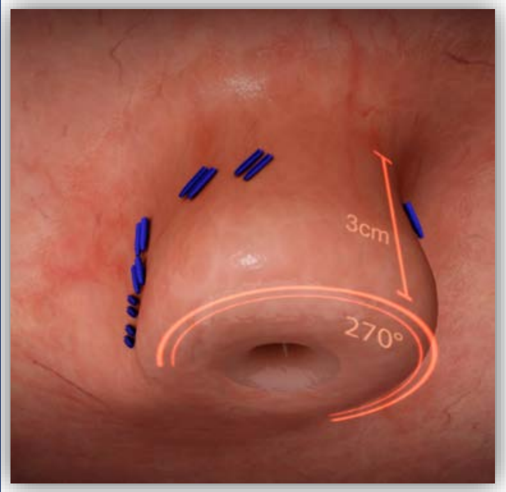
Normal
Baseline GERD
ELF
TIF 1.0
TIF 2.0
Nissen
HPZ
Z-line
TIF 2.0
HPZ
Z-line
©MAYO CLINIC

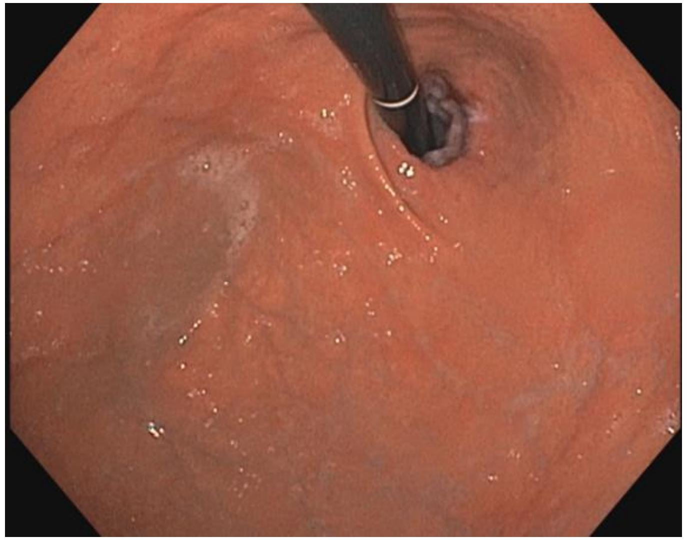
Restoring the GE Junction Valve with the TIF Procedure

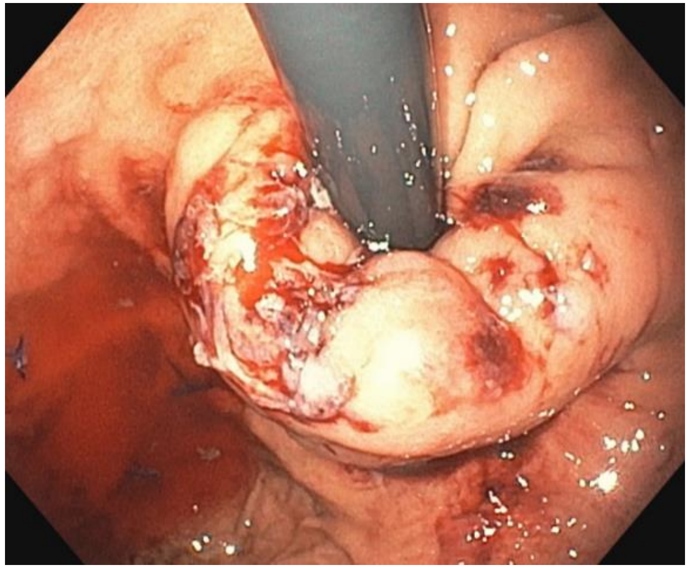


Restoring the GE Junction Valve with the TIF Procedure




3cm
270°





Emulates Traditional Surgical Principles with Endoscopic Approach

Principles Of Antireflux Surgery	TIF® Procedure	Laparoscopic Fundoplication
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Repair hiatal hernia > 2 cm and close crura*	✓ *	✓
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*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.

Data: Efficacy and Safety

Study	Study design	Characteristics	HRQL	AET	EE rates	PPI Discontinuation
Witteman et al. 2015 *The American Journal of Gastroenterology. 2015;110(4):531*	**RCT** TIF 2.0 (n=40) PPI continuation (n=20) f/u 6 months	PPI Responsive + PH off meds	TIF: 27→ 12 PPI: 28→25	TIF:10.8→7.7 PPI:11.3→6.0	TIF: 14% PPI: 10%	TIF: 74%
Hakansson et al. 2015 *Alimentary Pharmacology & Therapeutics. 2015;42(11-12):1261-70*	**Sham RCT** TIF 2.0 (n=21) Sham (n=18) f/u 6 months	PPI-Nonresponsive	QOLRAD TIF: 4.9→6.4 Sham:4.8→5.2	TIF: 7.8→3.6 Sham: 13.1→9.8		TIF: 59%
Hunter et al. 2015 *Gastroenterology. 2015;148(2):324-33*	**Double sham / placebo RCT** TIF 2.0 + placebo (n=87) Sham + PPI (n=42) f/u 6 months	PPI-Nonresponsive + PH off meds	RDQ TIF: 3.1→0.6 Sham:3.3 →0.9	TIF: 9.3→6.4 Sham:8.6→8.9	TIF: 77% Sham: 50%	TIF 72% remained off PPI at 18 months
Trad et al. 2017 *Surgical Endoscopy. 2017;31(6):2498-508*	**RCT** TIF 2.0 (n=40) PPI (n=23) f/u 3 years	PPI Responsive + PH off meds	GERD HRQL 26.4→5.0	TIF 10.5→7.8	TIF: 94%	71% at 3 years

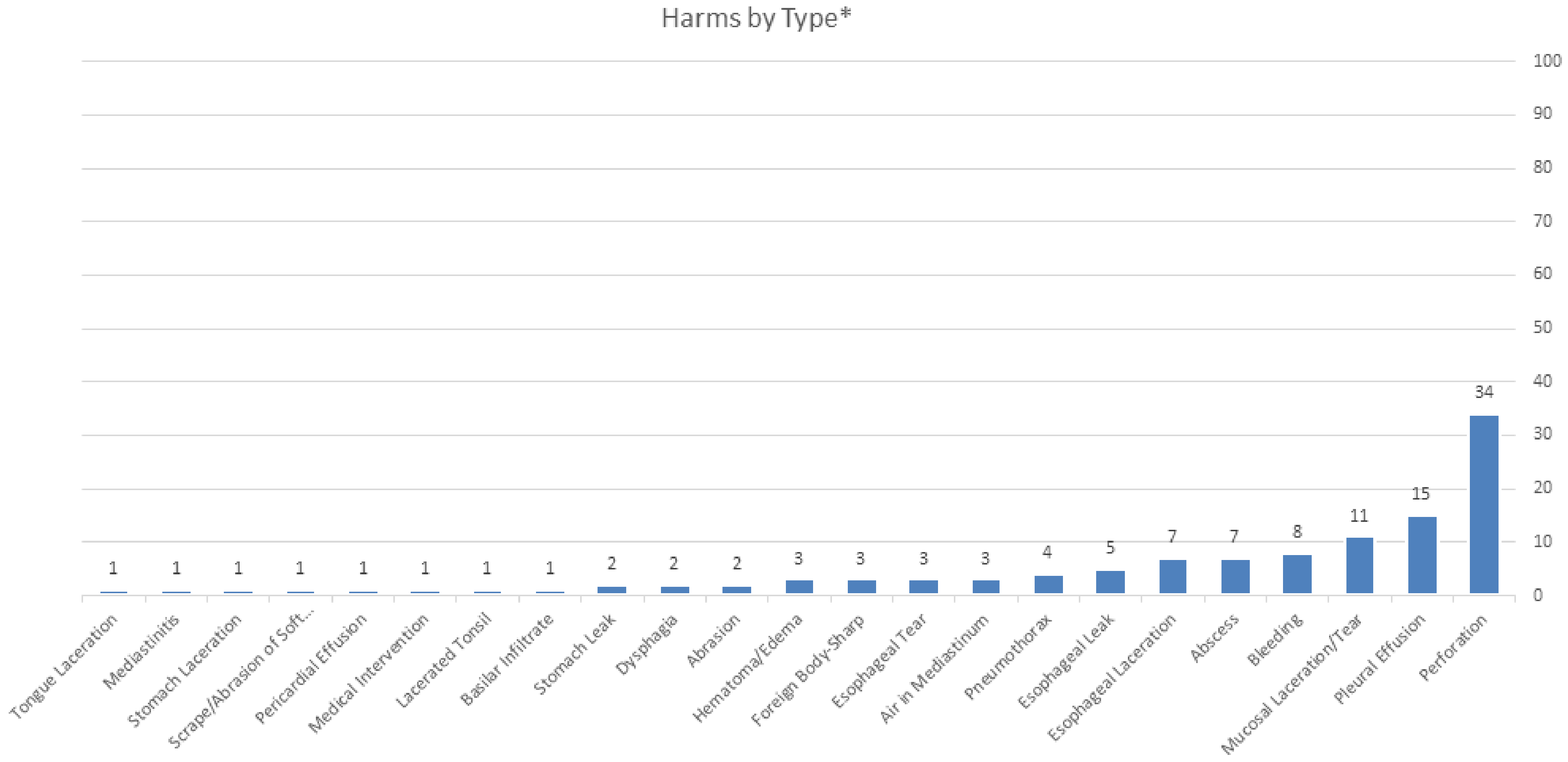
Longer-Term Studies

Study/ Parameter	Summary	TEMPO RCT 2018	Stefanidis 2016	Testoni 2019
n Follow-up	112	44 60 mo	44 59 mo	12 10 yrs
GERD-HRQL Symptoms	Significant improvement	Screening off PPI 32.8 sustained improvement 6.8	66% ≥ 50% improvement	Significant improvement (46 to 9)
PPI Use Off Daily	66%-92% OFF DAILY	66%	76%	92%
Satisfaction	62%-70% Satisfied	70%	62%	Not Reported
Durability	NS change from 6 mo – 10 Yrs	NS change 1Y/3Y/5Y	NS change from 6 mo – 24 mo	NS change from 6 mo – 10 yrs

Data from TIF 2.0 procedure technique

NS = not significant

Commercial SAE rate of 0.42% (92 in 22,000 commercial cases); last SAE case reported April 2019.



*More than one harm reported in some cases.

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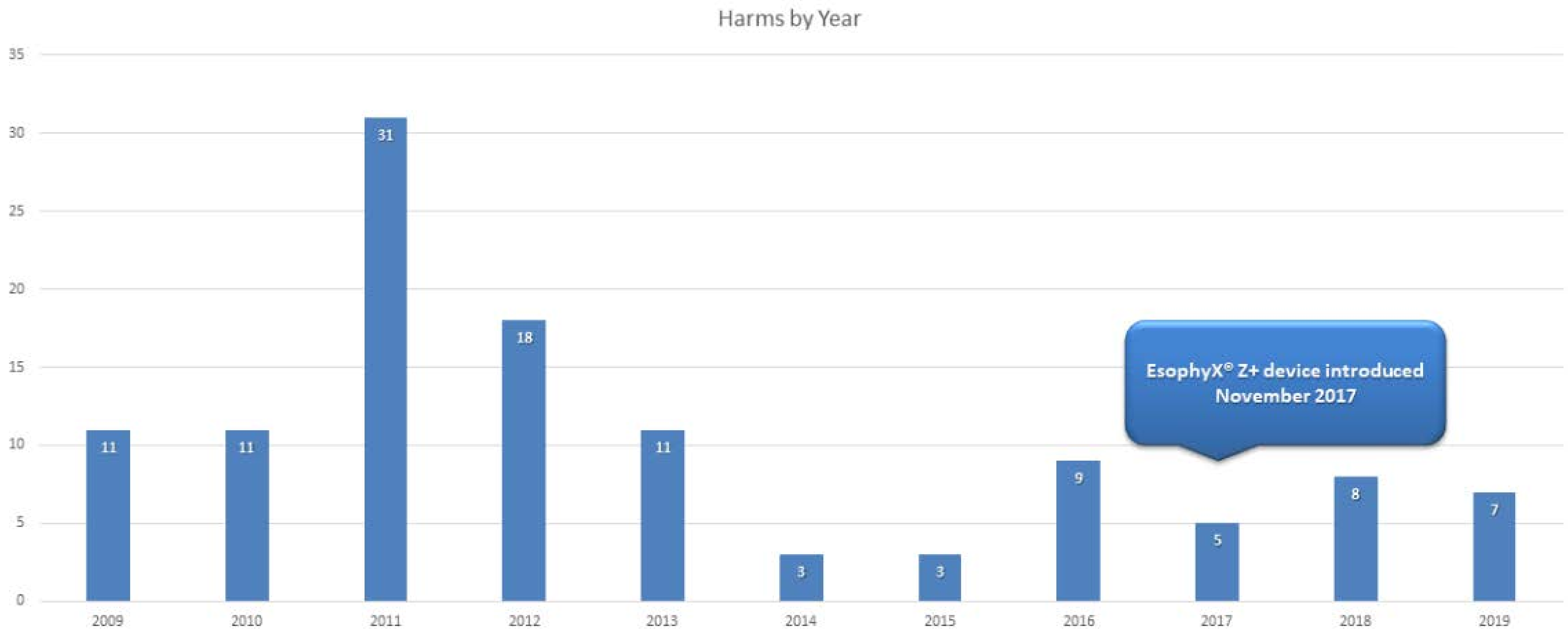
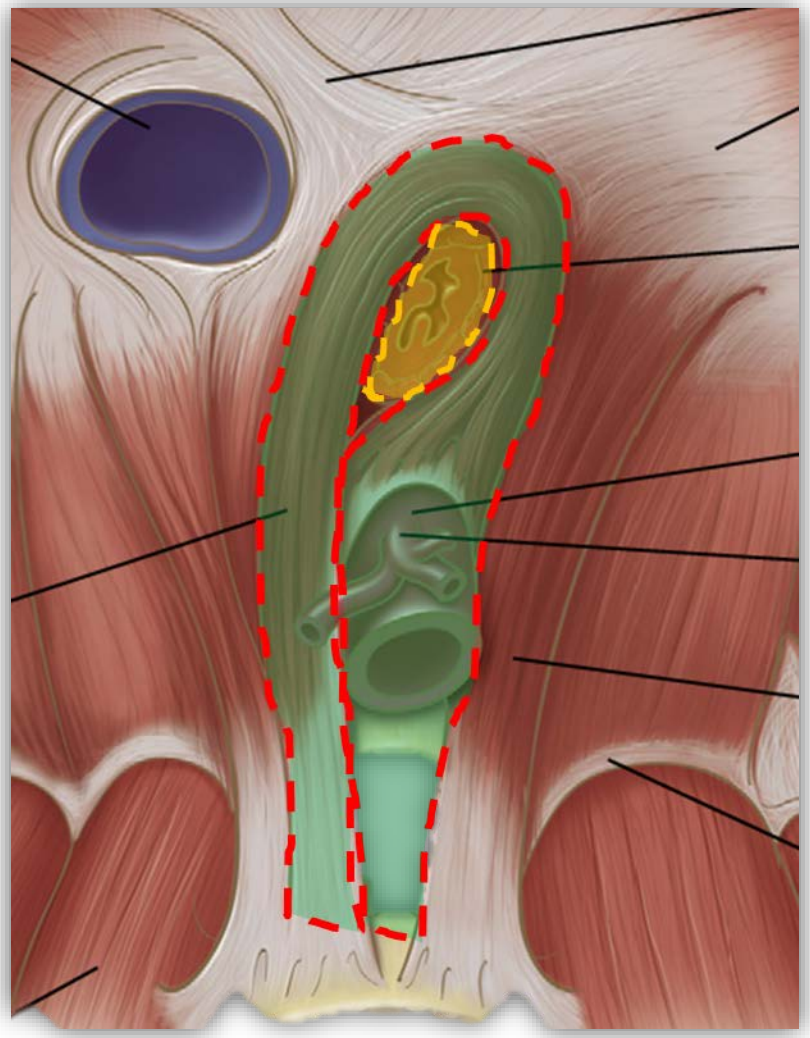
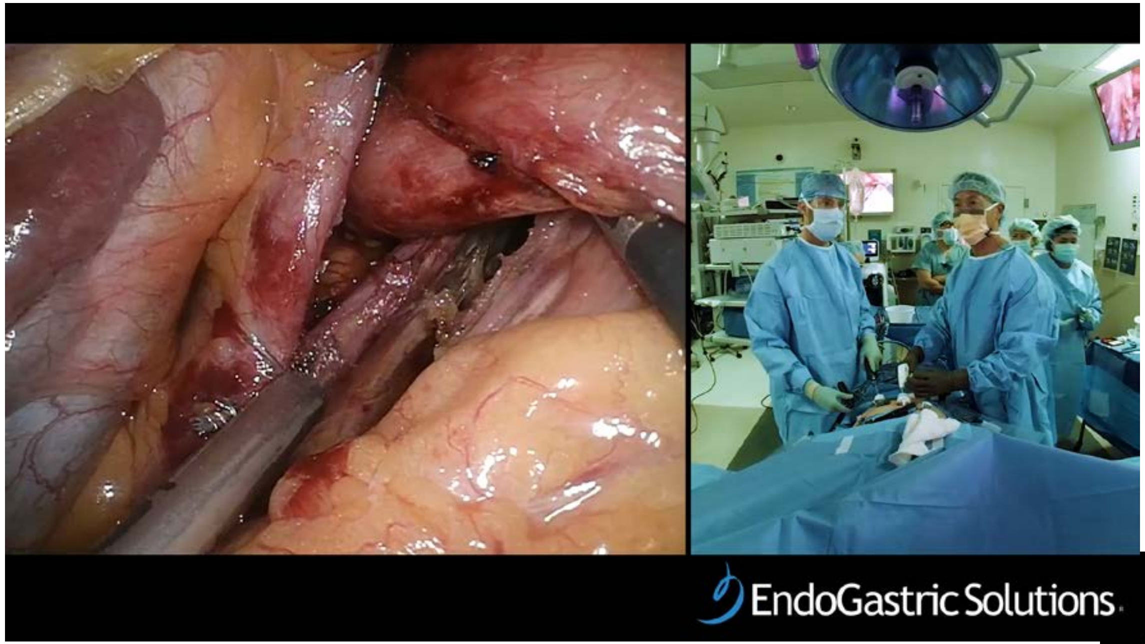


Special Considerations

Axial Height of Hiatal Hernia \ Transverse Width of Hiatal Hernia	<2cm	>2cm
>2cm	Concomitant hiatal hernia repair followed by TIF procedure	Concomitant hiatal hernia repair followed by TIF procedure
<2cm	TIF procedure	Concomitant hiatal hernia repair followed by TIF procedure




EndoGastric Solutions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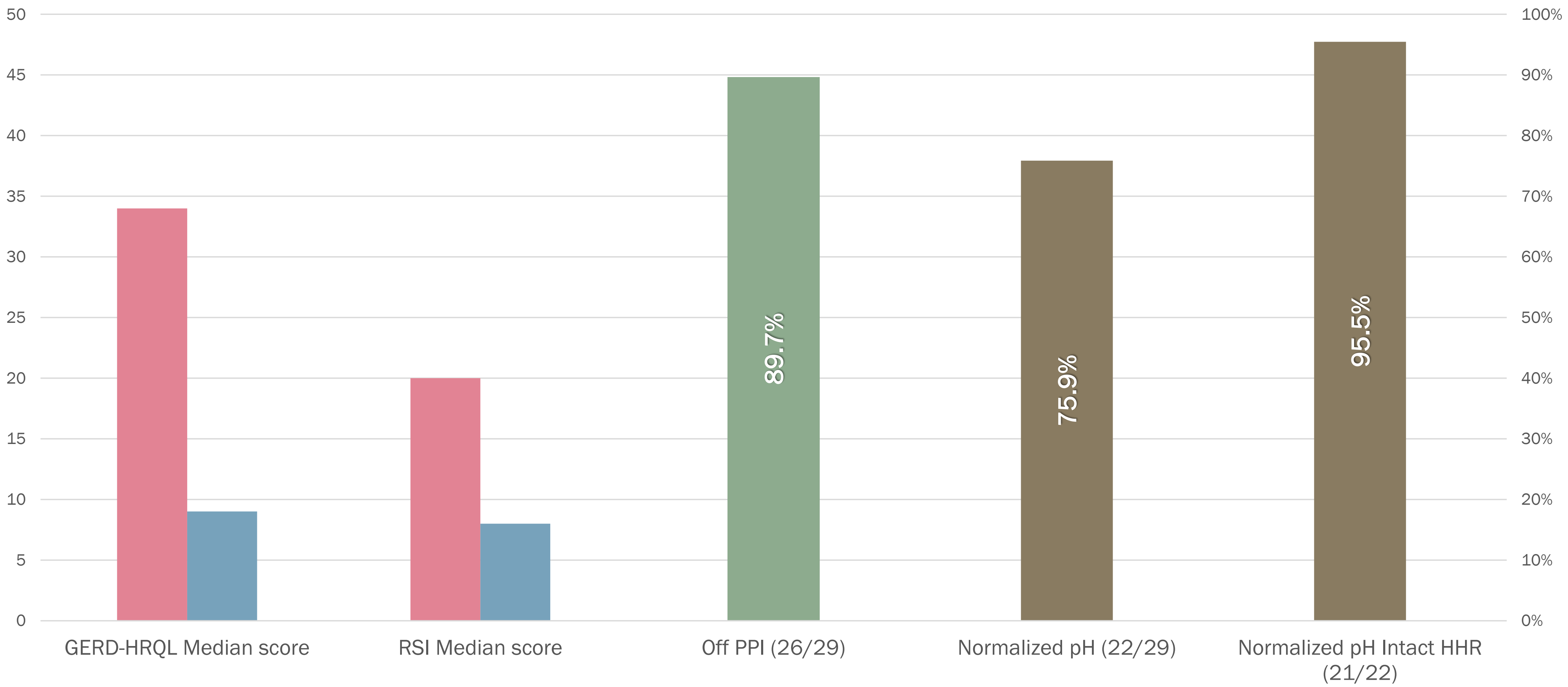
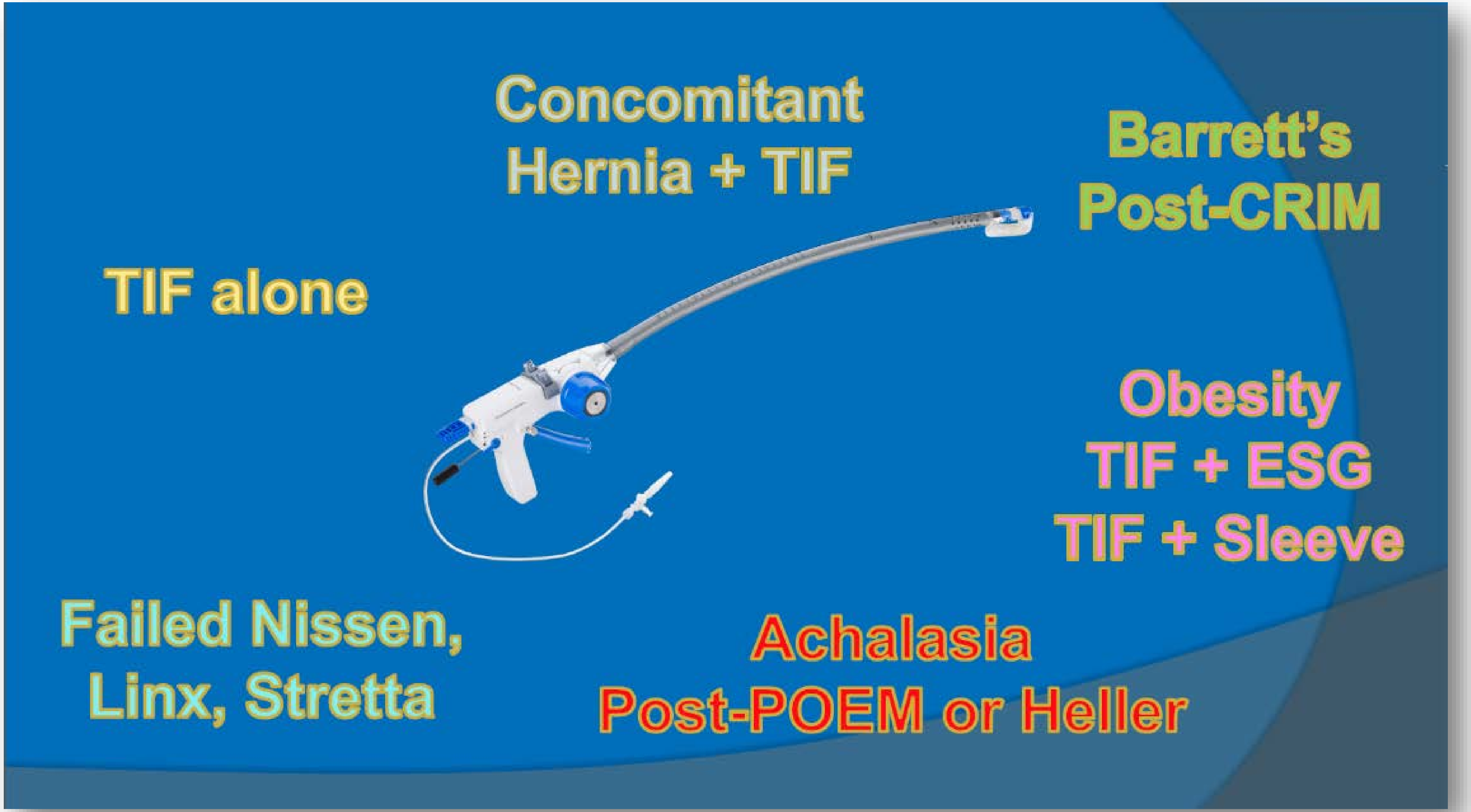
Ihde et al. 2019 JSLS

n=55 with 29 before and after pH testing



Adjunctive Patient Populations



TIF post POEM

Endoscopy International Open 2018; 06: E549–E552
N = 5, median follow-up 27 months (5-34)

	Age, years	Gender	Indication for TIF	On PPI pre-TIF	Esophagitis on EGD pre-TIF	Off PPI post-TIF	Healed esophagitis post-TIF
Patient 1	39	F	+ pH study	Y	Y, Class B	Y	Y
Patient 2	70	F	Regurgitation	Y	N	Y	n/a
Patient 3	51	M	+ pH study	Y	Y, Class D	Y	Y
Patient 4	44	M	+ pH study	Y	N	Y	n/a
Patient 5	69	M	+ pH study	Y	Y, Class B	Y	Y

Summary

- The GERD therapy gap is being filled
- Endoluminal approaches are effective
- Additional clinical investigations underway for different applications
- Coding completed! Regular reimbursement expanding

Questions?

“I look through a half opened door into the future, full of interest, intriguing beyond my power to describe.”

William J. Mayo, M.D.
1931