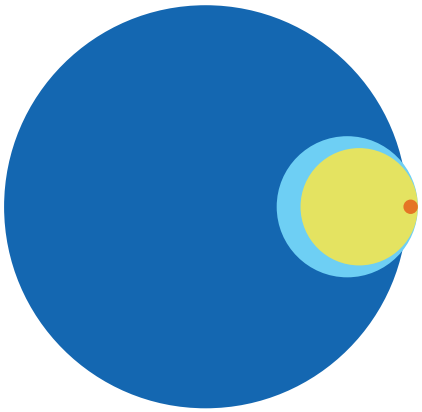
TIF® Procedure with EsophyX® device

GERD has taken a lot from your patients.

The TIF® procedure will help your patients get back to living.

EndoGastric Solutions.

Gastroesophageal Reflux Disease (GERD)[1,2]

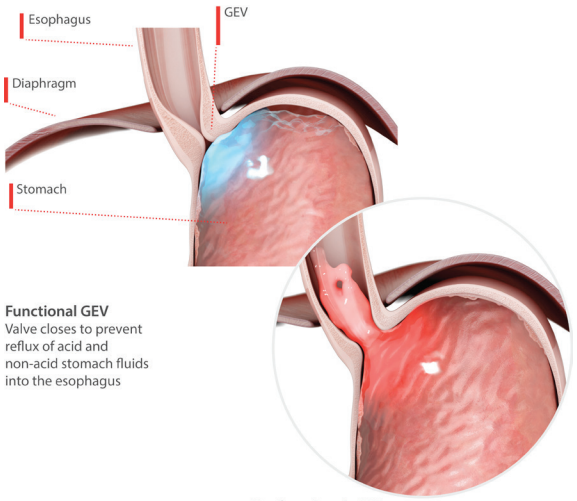


81 Million Americans suffer with symptoms

10 million see a doctor

6.7 million receive a diagnosis

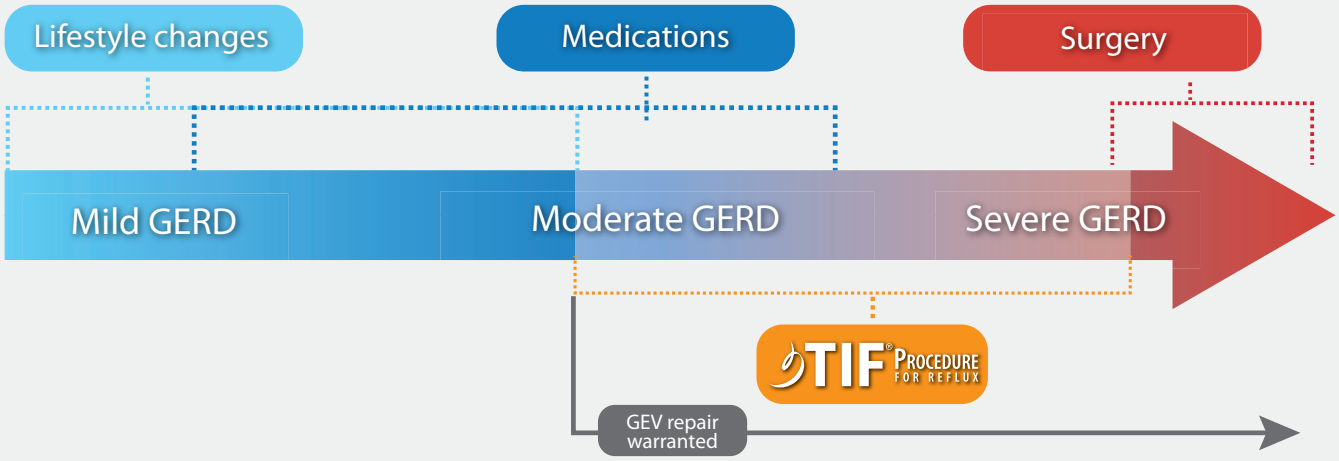
Only 30,000 choose traditional surgery as treatment



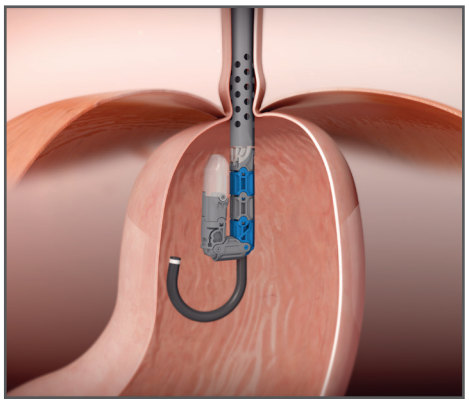
Functional GEV
Valve closes to prevent reflux of acid and non-acid stomach fluids into the esophagus

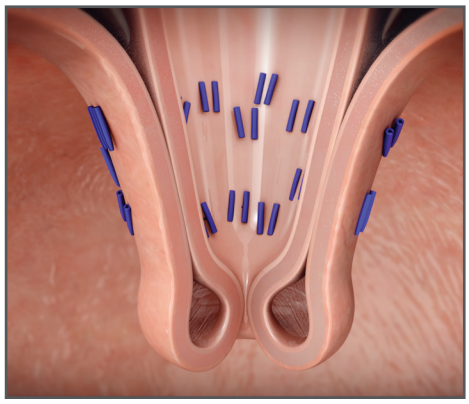
Dysfunctional GEV
Valve no longer functions properly and allows stomach fluids to reflux into esophagus

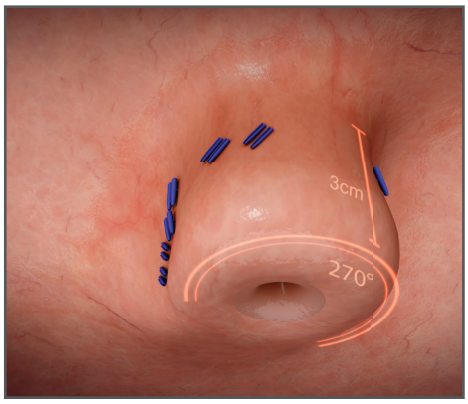
Most patients treat their GERD with OTC or Rx medications—most frequently proton pump inhibitors (PPIs). For some patients, these medications don't adequately control symptoms or may stop working after extended use. These patients are considered refractory to PPIs. Other patients are uncomfortable with side-effects and long-term dependence. Patients are increasingly uncomfortable with traditional anti-reflux surgery (ARS). The treatment gap for GERD patients refractory to PPIs is significant. Patients are interested in a procedure that improves symptom control and reduces medication dependence.[3]



TRANSORAL INCISIONLESS FUNDOPLICATION - the TIF procedure, fills the refractory GERD treatment gap. Using an endoscopic approach - similar to diagnostic EGD - the gastroesophageal valve (GEV) is reconstructed without incisions following principles of traditional fundoplication. The TIF procedure maintains an exemplary safety profile with minimal side-effects.



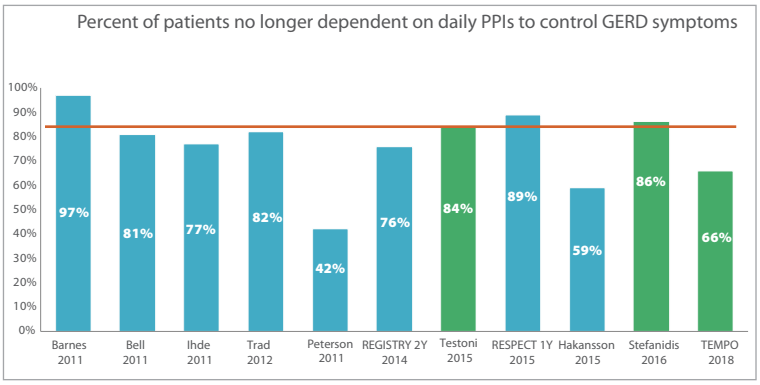




Data Supports GERD Treatment Gap Option [4-19]

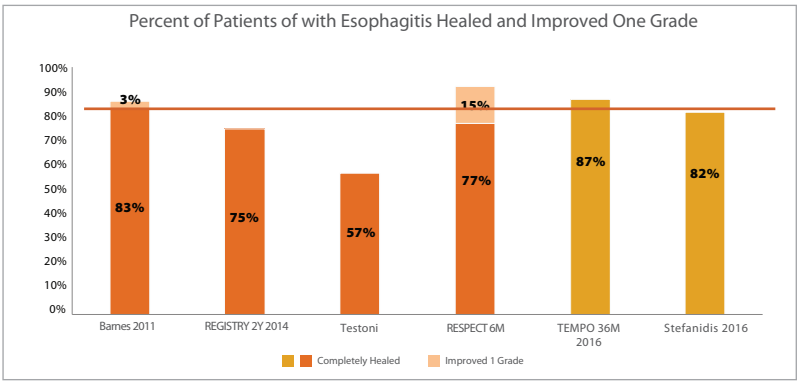
81% of TIF patients no longer use PPIs daily

84% Esophagitis healed or improved one grade



Weighted incidence is 81.41% across 11 studies with follow-up > 6mo in 568 patients

Weighted incidence is 78.35% across 3 studies follow-up > 59 mo in 120 patients

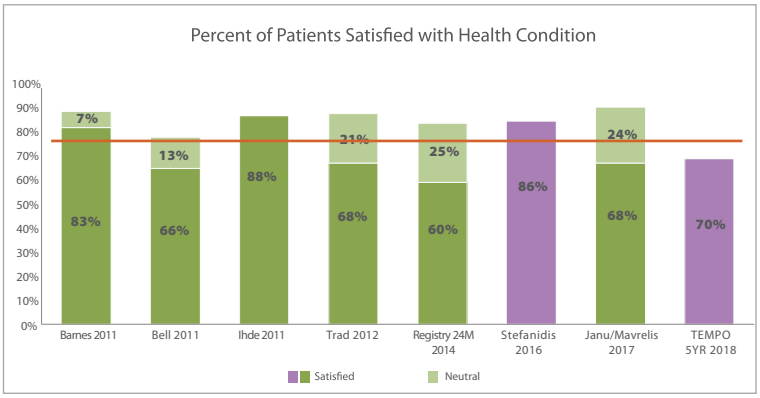


Weighted incidence is 80.25% across 6 studies follow-up > 6mo in 122 patients)

Weighted incidence is 83.94% across 2 studies follow-up > 36mo in 56 patients)

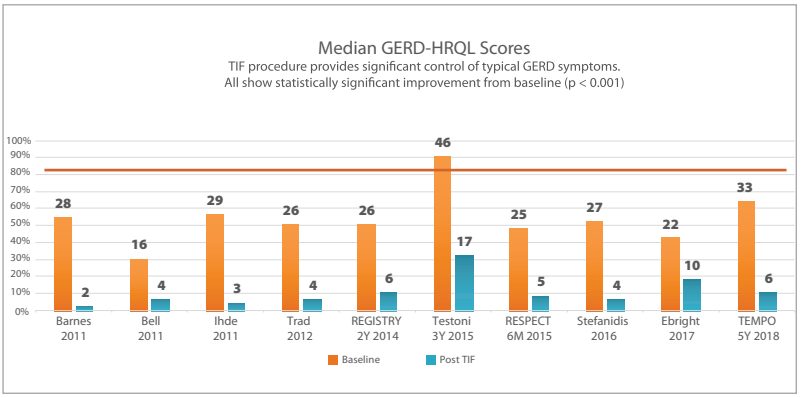
78% of TIF patients were satisfied with their health condition

81% Significantly improved quality of life scores



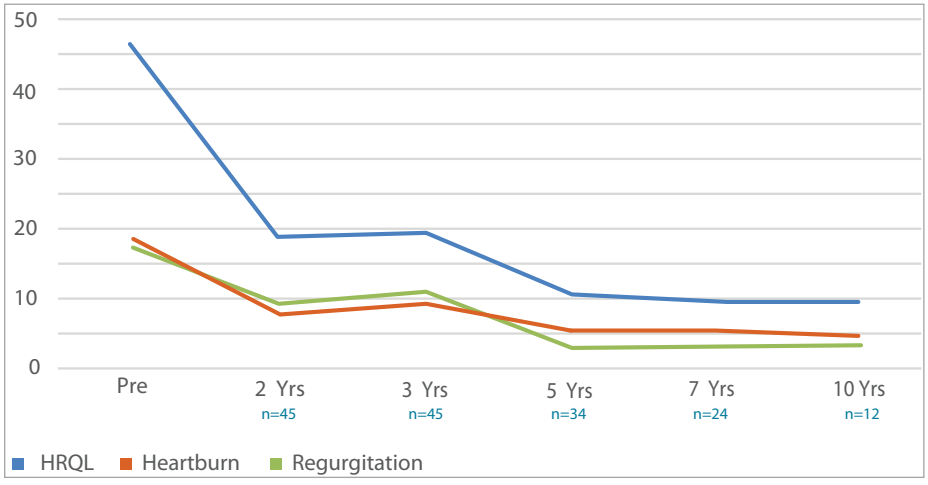
Weighted incidence is 73.1% across 8 studies follow-up > 6mo in 495 patients)

Weighted incidence is 78.4% across 2 studies follow-up > 59mo in 88 patients)



In the 10 studies where the follow-up was >=6 months, the weighted average percent reduction in the median score from the pre-study median baseline was 80.81%

TIF Procedure Delivers 10-Year Durability[19]

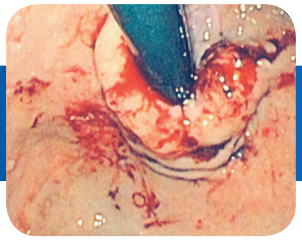


TIF 2.0 Procedure Follows Principles of Antireflux Surgery[20]

	TIF® Procedure	Laparoscopic Fundoplication
Reduce hiatal hernia ≤ 2 cm	✓	✓
Repair hiatal hernia ≤ 2 cm and close crura[21]	✓	✓
Elongate the intrabdominal 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	✓	✓

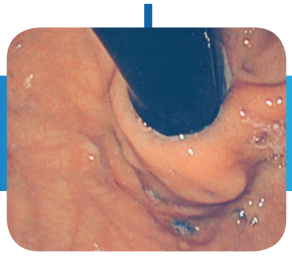
Date of TIF Procedure

EGD at the start of TIF procedure



EGD after completion of TIF procedure

Five Years Post TIF Procedure



"This patient reports his symptoms are completely controlled and he remains off PPIs five years after the TIF procedure."

- Peter Janu, M.D., Chilton, WI

22,000+	1500	100+	4	Cat 1
procedures worldwide since original EsophyX® device clearance in 2007	unique patients studied in 75 centers with consistent outcomes	peer-reviewed clinical papers in respected gastroen-terology and surgical journals in the past 12 years	published randomized controlled trials; two with sham-controlled arms	CPT® Code Esophagogastric Fundoplasty Trans-Orifice procedures effective 1/1/2016

References: www.gerdhelp.com/blog/references/references-tif-procedure-brochure/.

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21. 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.

INDICATIONS

The EndoGastric Solutions EsophyX Z 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 ≤ 2 cm 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.

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