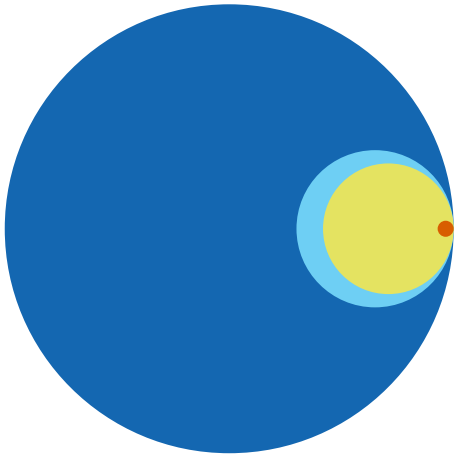
TIF® Procedure
FOR REFLUX

EndoGastric Solutions®

TIF® Procedure for Reflux

Gastroesophageal Reflux Disease (GERD)[1,2]

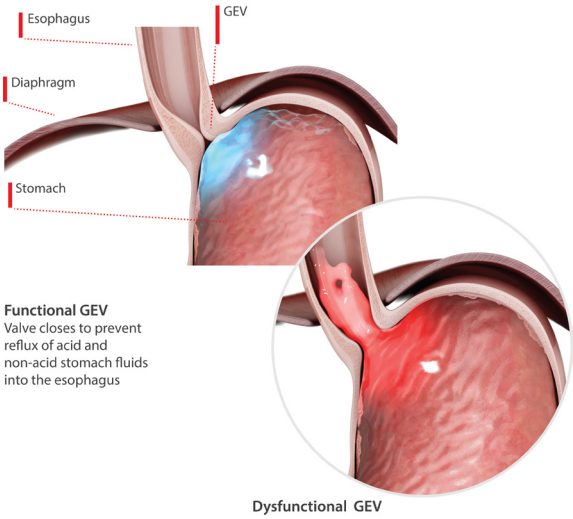


81 Million Americans suffer with symptoms

10 million see a doctor

6.7 million receive a diagnosis

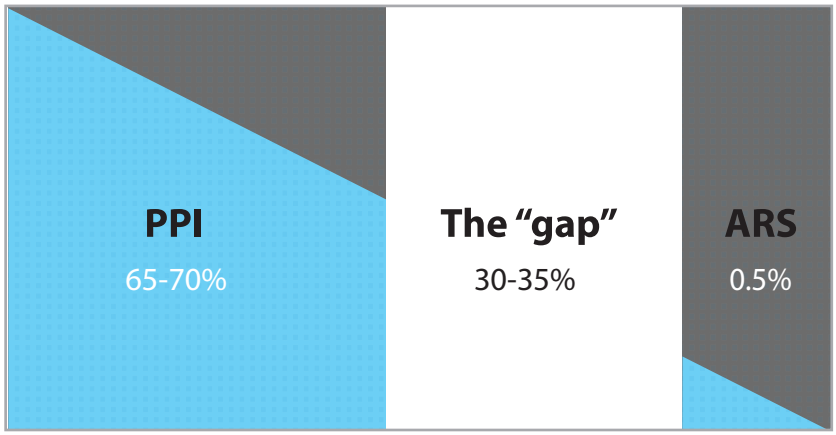
Only 30,000 choose traditional surgery as treatment



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. Clinical studies report a less than 3% occurrence of gas bloat and dysphagia. Clinical studies evaluating feasibility, safety and initial learning curve have reported a serious adverse event (SAE) rate of <3%. The commercial SAE rate in more than 18,000 procedures is very low, <0.5% (1 in every 250 cases).[4]

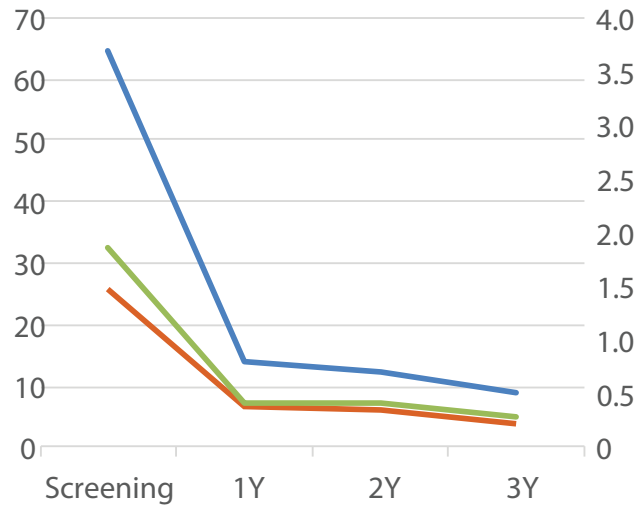
LOTUS RCT 5-yr[5]	PPI	ARS
Serious Adverse Events (SAE)	24.1%	28.6%
Dysphagia	11%	5%
Gas Bloat	28%	40%
Flatulence	40%	57%

Data Supports GERD Treatment Gap Option

3 Year TIF Procedure Durability

In the randomized controlled trial TEMPO at three year follow-up[7]

- All symptom scores improved significantly after the TIF procedure as measured by validated questionnaires off PPIs
- No significant change between 1, 2 or 3 year follow-up points
- Number of TEMPO patients evaluated: 60 at 1 year, 55 at 2 year, 52 at 3 year



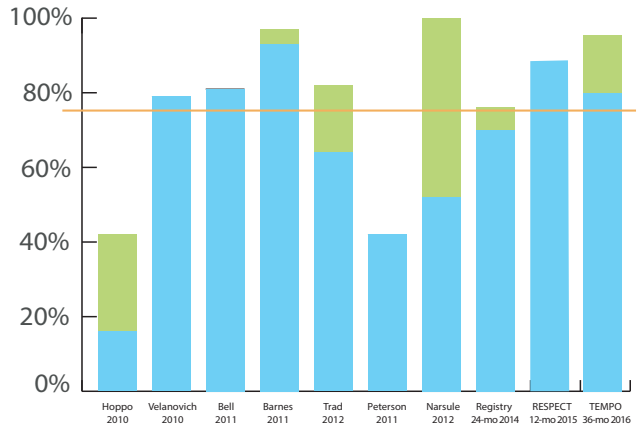
RDQ = Reflux Disease Questionnaire (right-side axis)

GERD-HRQL = GERD Health Related Quality of Life (left-side axis)

RSI = Reflux Symptom Index (left-side axis)

75% of TIF Patients Off PPIs [6-14,16]

- Weighted average % of patients completely off PPIs
- 75% completely off PPIs; 8% occasional use
- 10 studies; n=527 patients (weighted average follow-up at 13 mos.)

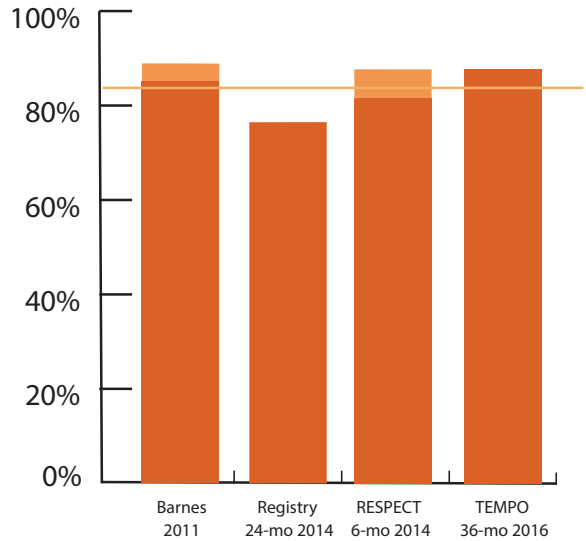


Post-TIF PPI Use (Completetly Off)

Post-TIF PPI Use (Occasional)

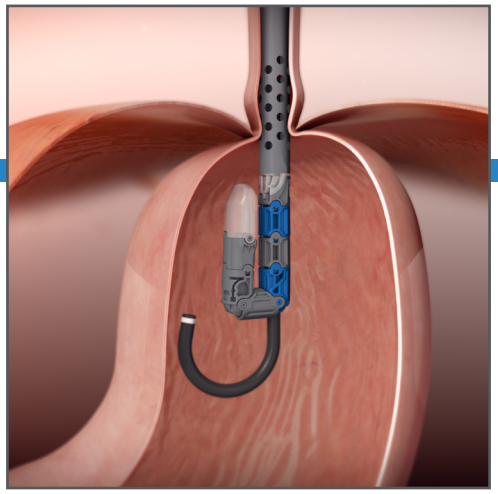
82% of TIF Patients' Esophagitis Healed [6, 7, 11, 15]

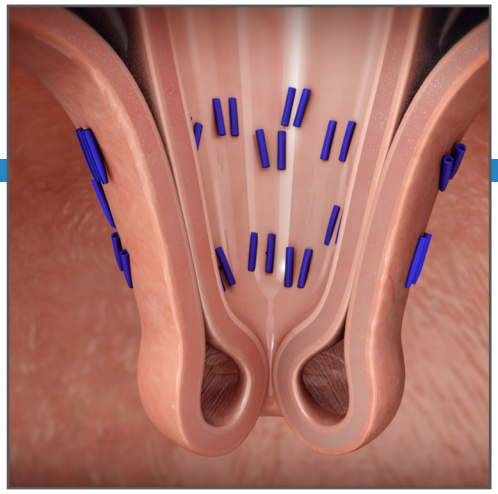
- Weighted average % of patients esophagitis completely healed
- 82% completely healed; 4% improved
- 4 studies; n=82 patients (weighted average follow-up at 18 mos.)

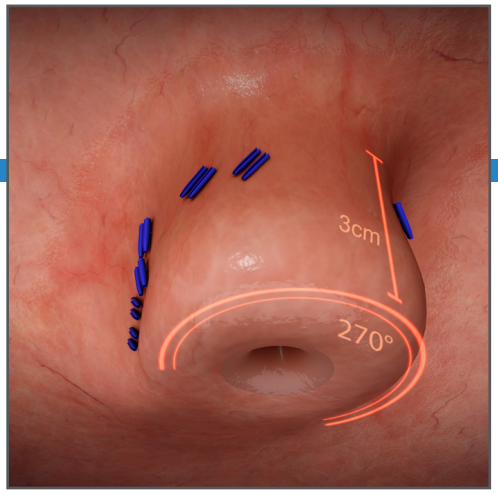


Completely Healed

Improved 1 Grade







Step 1
The EsophyX® device is inserted through the mouth into the esophagus with an endoscope down the center channel of the device. The endoscope is retroflexed and device is positioned at the gastroesophageal junction (GEJ) to rebuild the valve.

Step 2
A full thickness tissue fold at the GEJ is retracted, wrapped and secured using SerosaFuse® implantable fasteners - equivalent to 3-0 sutures - to create an esophagogastric plication.

Step 3
The valve is extended and approximately 20 fasteners are delivered to form a 270˚ wrap. The TIF® procedure reconstructs the primary components of the antireflux barrier, creating a tight 3 cm length valve enveloping the distal esophagus below the diaphragm.

18,000+	1200+	70+	4	Cat 1
procedures worldwide since original EsophyX® device clearance in 2007	unique patients studied in 50+ centers with consistent outcomes	peer-reviewed clinical papers in respected gastroenterology and surgical journals in the past 10 years	published randomized controlled trials featuring 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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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.

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