

About The TIF Procedure for Reflux

- The TIF 2.0 procedure with the EsophyX® device uses an incisionless approach to treat the underlying cause of gastroesophageal reflux disease (GERD) — a chronic condition caused by changes in the gastroesophageal valve (GEV) that allow acid to flow back from the stomach into the esophagus.
- TIF is an acronym for Transoral Incisionless Fundoplication:
 - **Transoral** – The procedure is performed from within the GI tract with the EsophyX device inserted through the patient’s mouth.
 - **Incisionless** – Using a transoral approach, abdominal incisions and internal dissection of other anatomy are not required.
 - **Fundoplication** – The EsophyX device enables reconstruction of the antireflux valve according to the established principles of conventional antireflux surgery.
- The purpose of the procedure is to ensure proper positioning of the stomach and esophagus below the diaphragm, to restore the angle at which the esophagus enters the stomach and to increase the high pressure zone of the chest cavity which restores one-way valve operation and prevent reflux.



How TIF 2.0 Procedure Works

- The TIF 2.0 procedure uses the EsophyX device to deliver SerosaFuse® fasteners which are used to rebuild the antireflux valve and restore the body’s natural protection against acid reflux, to repair the GEV in the digestive system so that patients can experience enduring relief from GERD symptoms.
- By accessing the gastroesophageal junction (GEJ) through the mouth, there are no scars with the TIF procedure, minimizing complications and associated with a quick recovery.
- Due to the unique approach of the TIF 2.0 procedure, most patients return to work and normal activities within a few days after the procedure, allowing them to get back to life sooner, free of the distraction and discomfort of GERD.
- While the TIF 2.0 procedure has an excellent safety profile and is less invasive than conventional laparoscopic fundoplication, it is important to note that it is still a surgical approach. There are potential risks and complications with any surgery including an endoscopic approach which include: sore throat, musculoskeletal pain, epigastric or abdominal pain and difficulty swallowing.

Understanding the Significance of TIF Procedure

- To date, the TIF 2.0 procedure has been performed in more than 18,000 patients worldwide.
- In the past 10 years, over 70 peer-reviewed papers report follow-up in over 1200 unique patients; consistent outcomes following the TIF 2.0 procedure demonstrate significant clinical efficacy across a range of outcome measurements including symptoms, quality of life scores, cessation of PPI therapy and improvements in pH measurements and LES pressure.^{1,2}
- Clinical studies demonstrate TIF patients rarely experience long-term side effects commonly associated with traditional antireflux surgery such as trouble swallowing (dysphagia), gas bloat syndrome and increased flatulence.^{1,2}
- Three-year post-procedure clinical data demonstrates that 83 percent of patients undergoing the TIF 2.0 procedure experienced elimination of regurgitation and all atypical GERD symptoms, with 70 percent of patients reporting discontinuation of PPI therapy and 87 percent of patients experiencing healing of reflux esophagitis.²

References: <http://www.gerdhelp.com/blog/topics/media-kit/>

¹Hunter, John G., et al. Efficacy of Transoral Fundoplication vs Omeprazole for Treatment of Regurgitation in a Randomized Controlled Trial, *Gastroenterology*, Volume 148(2): 324-333.e5.

²Trad, K.S., et al. *Surg Endosc*. 2016 Sept 21 [Epub ahead of print]