



cTIF[®]

Consecutive Hiatal Hernia
Repair + TIF 2.0[®]

CREATING THE
Optimal Anti-Reflux Barrier

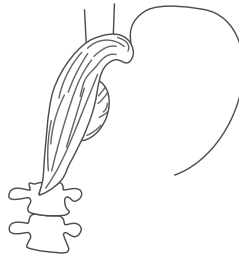


WITH THE
ESOPHYX[®] Z+ DEVICE

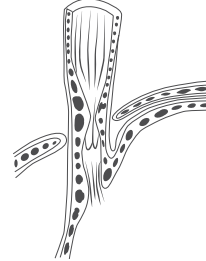
Merit Medical defines the term "cTIF" as a consecutive Transoral Incisionless Fundoplication which consists of a Hiatal Hernia Repair (HHR) followed by a Transoral Incisionless Fundoplication (TIF) procedure under a single anesthesia setting.

GERD is an anatomical issue.

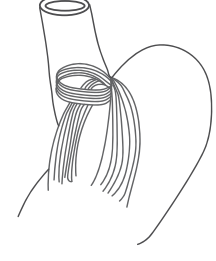
Gastroesophageal reflux disease (GERD) is caused by a gradual deterioration of the anti-reflux barrier (ARB). The ARB consists of the crural diaphragm, the lower esophageal sphincter (LES) and its sling fibers, and the gastroesophageal flap valve (GEFV).¹ These three factors contribute to the mechanical and physiological barriers to reflux. cTIF resolves the root cause of reflux by addressing all three components of the ARB.



The crura

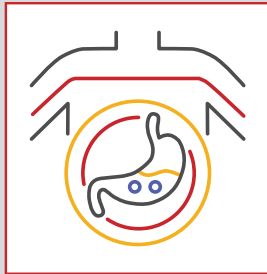


The GEFV



The LES and its sling fibers

cTIF creates the optimal anti-reflux barrier designed to restore anatomy to its natural state with less risk for side effects.²



- ✓ Hernia reduced if more than 2 cm
- ✓ Crural defect repaired³
- ✓ LES tightened without disrupting the sling fibers³
- ✓ GEFV recreated³

- Creates an omega-shaped valve, helping to restore native anatomy
- Recreates the angle of His with an anterior and posterior wrap, averaging 270°, depending on patient's anatomy
- Elongates the distal esophagus and restores the distal high-pressure zone
- Avoids disruption of the lesser curvature of the stomach
- Potentially less dissection of short gastric vessels, preserving blood supply
- Spares the fundus, preserving the accommodation function
- No twisting or torquing of gastric folds



Laparoscopic view of completed cTIF⁴



Laparoscopic view of Nissen fundoplication⁴



Endoscopic view of the newly constructed GEFV after cTIF, resembling the configuration of an omega sign⁵

cTIF follows the principles of traditional fundoplication with fewer side effects than conventional anti-reflux surgery (ARS).²

		TIF 2.0	cTIF	ARS
Principles of ARS	Reduce hiatal hernia (≤ 2 cm)	✓		✓
	Repair hiatal hernia (> 2 cm) and close crura ⁶		✓	✓
	Elongate the intra-abdominal 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	✓	✓	✓

The cTIF procedure creates an optimal flap valve and is as effective as traditional surgical options.

73%
Decrease in GERD
frequency & severity³

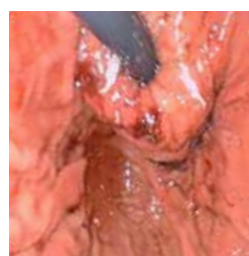
83%
Decrease in
regurgitation³

74%
Decrease in or
discontinued use of
proton-pump
inhibitors (PPI)²

89%
Improvement in
DeMeester score³

// In a multicenter comparative study of hiatal hernia repair with transoral incisionless fundoplication (cTIF) versus Nissen fundoplication, in the cTIF group, results demonstrated significantly lower rates of bloating (13.8% vs 30% at 6 months).⁷ //

cTIF restores the GEFV
without esophageal torsion.



Endoscopic view of
completed cTIF



Endoscopic view of
laparoscopic Nissen

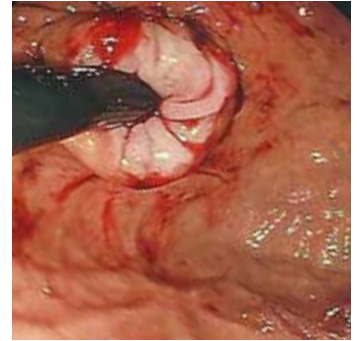
	cTIF	Nissen	Toupet	Dor
Wrap	270° Cardia esophageal plication	360° Total fundoplication	270° Partial fundoplication	180° Partial fundoplication
View of valve	Endoscopically	Laparoscopically		
Diameter	60F (built around device)	Diameter varies based on surgeon's technique		
Fasteners/Sutures	20+ Fasteners	3–4 Anterior plication sutures	6 Anterior plication sutures	3–4 Sutures, no posterior wrap

cTIF effectively and safely improves chronic GERD.⁷

- Significant reduction in subject-reported symptoms of GERD²
- Lower rate of early and serious adverse events when compared to laparoscopic Nissen fundoplication (LNF)⁷
- Fewer reports of dysphagia and gas bloat associated with traditional anti-reflux procedures²



Open hiatus before
hernia repair



Omega-shaped
GEFV after cTIF

1,500

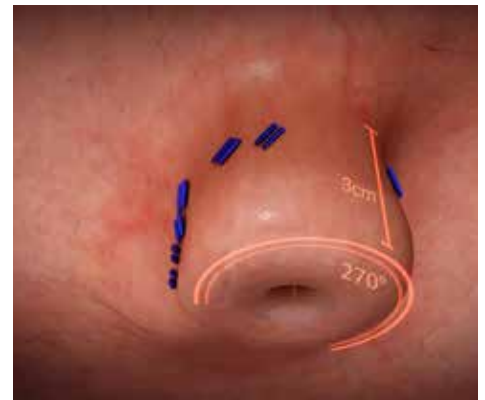
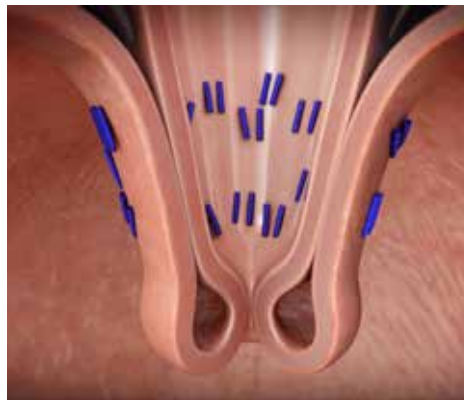
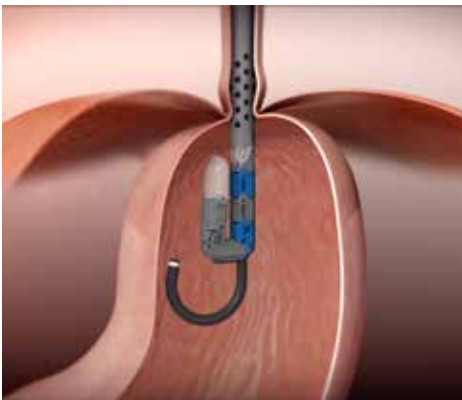
Unique patients studied in over 75 centers with consistent outcomes⁸

100+

Peer-reviewed clinical papers in respected gastroenterology and surgical journals⁸

4

Published randomized control trials, two with sham controlled arms⁸



Before using, refer to Instructions for Use for indications, contraindications, warnings, precautions, and directions for use.

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INDICATIONS

The Merit Medical Systems 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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2. Janu P, Shughoury AB, Venkat K, et al. Laparoscopic Hiatal Hernia Repair Followed by Transoral Incisionless Fundoplication With EsophyX Device (HH + TIF): Efficacy and Safety in Two Community Hospitals. *Surgical Innovation*. 2019;26(6):675-686. doi:10.1177/1553350619869449. <https://pubmed.ncbi.nlm.nih.gov/31431138/>
3. Choi AY, Rocco MK, Samarasekera JB, Kolb JM, Lee DP, Lee RH, Daly S, Hinojosa MW, Smith BR, Nguyen NT, Chang KJ. Novel Interdisciplinary Approach to GERD: Concomitant Laparoscopic Hiatal Hernia Repair with Transoral Incisionless Fundoplication. *J Am Coll Surg*. 2021 Mar;232(3):309-318. doi: 10.1016/j.jamcollsurg.2020.11.021. Epub 2020 Dec 17. PMID: 33346082. <https://pubmed.ncbi.nlm.nih.gov/33346082/>
4. Courtesy of Ninh Nguyen, UC Irvine, and Michael Murray, Northern Nevada Medical Center.
5. Nguyen NT, Chinn J, Chang K. Collaboration between GI surgery & Gastroenterology improves understanding of the optimal antireflux valve-the omega flap valve. *Surg Endosc*. 2021 Jun;35(6):3214-3220. doi: 10.1007/s00464-021-08416-y. Epub 2021 Mar 11. PMID: 33709228. <https://pubmed.ncbi.nlm.nih.gov/33709228/>
6. 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.
7. Jaruvongvanich, Veeravich, et al. "881 Multicenter Comparative Study of Hiatal Hernia Repair with Transoral Incisionless Fundoplication versus Nissen Fundoplication for the Treatment of Gastroesophageal Reflux Disease." *Gastrointestinal Endoscopy*, vol. 91, no. 6, 2020, <https://doi.org/10.1016/j.gie.2020.03.609>. [https://www.giejournal.org/article/S0016-5107\(20\)30849-X/fulltext](https://www.giejournal.org/article/S0016-5107(20)30849-X/fulltext)
8. Merit Medical, data on file.

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