MERIT MEDICAL ENDOTEK®

cTIF®

Consecutive Hiatal Hernia Repair + TIF 2.0®

CREATING THE

Optimal AntiReflux Barrier

WITH THE ESOPHYX® Z+ DEVICE

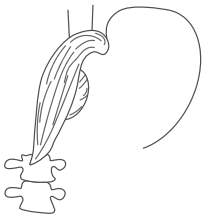
Merit Medical defines the term "cTIF" as a **consecutive** Transoral Incisionless Fundoplication which consists of a Hiatal Hernia Repair (HHR) followed by a Transoral Incisionless Fundoplication (TIF) procedure under a single anesthesia setting.

cTIF

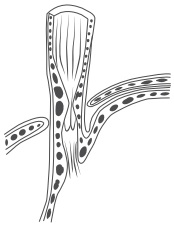
cTIF (consecutive Transoral Incisionless Fundoplication) is a TIF 2.0 procedure preceded by a hiatal hernia repair for patients with a hernia greater than 2 cm.[4]

GERD is an Anatomical Issue

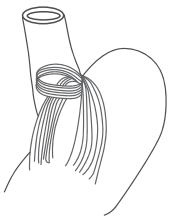
GERD is caused by a gradual deterioration of the antireflux barrier. The antireflux barrier (ARB) consists of the crural diaphragm, the LES and its sling fibers, and the gastroesophageal flap valve.[5] These three factors contribute to the mechanical and physiologic barriers to reflux. cTIF resolves the root cause of reflux by addressing all three components of the ARB.



The Crura

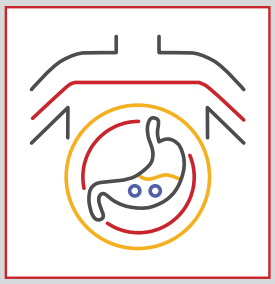


The GE Flap Valve



The LES and its Sling Fibers

cTIF Creates the Optimal AntiReflux Barrier by Restoring Anatomy to Its Natural State With Less Risk For Side Effects[1]

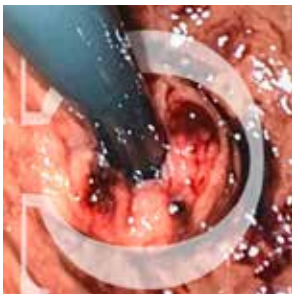


- Hernia reduced if more than 2cm
- Crural defect fixed[4]
- Lower esophageal sphincter tightened without disrupting the sling fibers[4]
- Gastroesophageal flap valve recreated[4]

- Creates an omega shaped valve, helping to restore native anatomy
- Recreates the Angle of His with an anterior and posterior wrap, up to 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 and preserving blood supply
- Spares the fundus preserving the accommodation function
- No twisting or torquing of gastric folds

Laparoscopic View of Completed cTIF[6]

Laparoscopic View of Nissen Fundoplication[6]



Endoscopic View of the Newly Constructed GEFV after cTIF, resembling the configuration of an omega sign[7]

cTIF Follows the Principles of Traditional Fundoplication with Fewer Side Effects than Conventional AntiReflux Surgery[1]

		TIF 2.0	cTIF	ARS
Principles of AntiReflux Surgery	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 the optimal flap valve and is as effective as traditional surgical options

73% Decrease in GERD frequency & severity[4]

83% Decrease in regurgitation[4]

74% Decrease in or discontinued PPI use[5]

90% Improvement in DeMeester score[4]

> *In a multicenter comparative study of hiatal hernia repair with transoral incisionless fundoplication versus Nissen fundoplication, in the cTIF group, results demonstrated significantly lower rates of bloating (13.8% vs 30% at 6 months).*[8]

cTIF Restores the GEFV Without Esophageal Torsion

Endoscopic view of completed cTIF

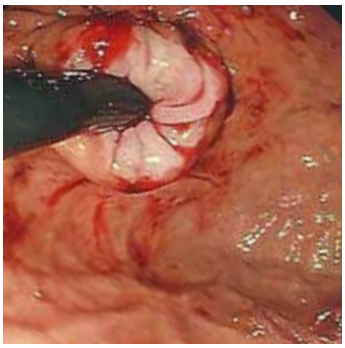
Endoscopic view of Laparoscopic Nissen

	cTIF	Nissen	Toupet	Dor
Wrap	270° cardia esophageal plication	360° total fundoplication	270° partial fundoplication	180° partial fundoplication
View of Valve	Endoscopically	Laparoscopically		
Diameter	60 French (Built around device)	Diameter varies based on surgeon 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[9]

- Significant Reduction in Subject Reported Symptoms of GERD[1]
- Lower Rate of Early and Serious Adverse Events When Compared to Laparoscopic NISSEN Fundoplication (LNF)[9]
- Higher Rate of Decreased or Discontinued PPI Use At Six And Twelve Months when Compared to LNF[9]
- Fewer reports of Dysphagia and Gas Bloat Associated with Traditional AntiReflux Procedures[1]

Open Hiatus before Hernia Repair



Omega-shaped GEFV after cTIF

1,500

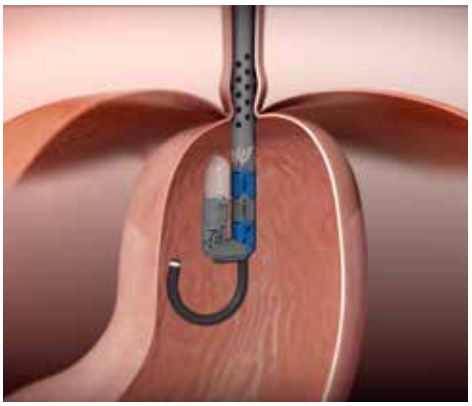
Unique patients studied in over 75 centers with consistent outcomes[10]

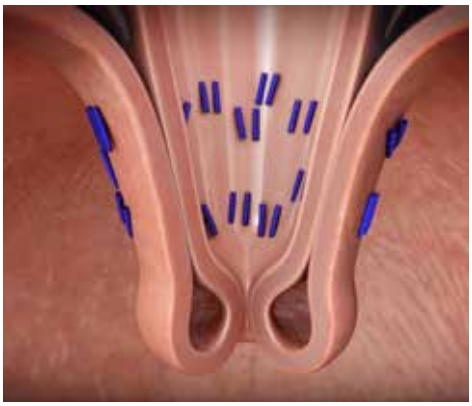
100+

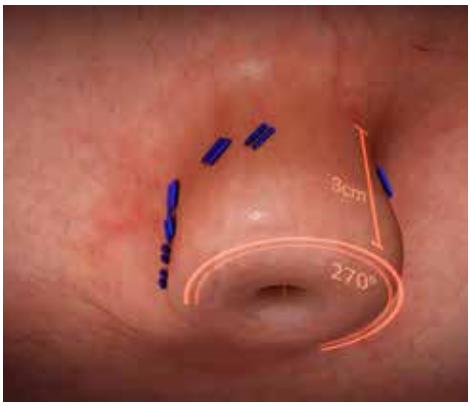
Peer-reviewed clinical papers in respected gastroenterology and surgical journals[10]

4

Published randomized control trials; two with sham controlled arms[10]







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

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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. Patients with hiatal hernias larger than 2cm may be included, when a laparoscopic hiatal hernia repair reduces the hernia to 2cm or less.

References: 1. Janu, P. et al., Laparoscopic Hiatal Hernina Repair Followed by Transoral Incisionless Fundoplication with EsophyX Device (HH + TIF): Efficacy and Safety in Two Community Hospitals. **2.** Ihde GM. The evolution of TIF: transoral incisionless fundoplication. Therap Adv Gastroenterol. 2020 May 21;13:1756284820924206. doi: 10.1177/1756284820924206. PMID: 32499834; PMCID: PMC7243382. **3**. https://www.endogastricsolutions.com/providers/support/data/ **4**. 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 **5**. Nguyen NT, Thosani NC, Canto MI, et al. The American Foregut Society White Paper on the Endoscopic Classification of Esophagogastric Junction Integrity. Foregut. 2022;2(4):339-348. doi:10.1177/2634516122112696l **6**. Ninh Nguyen, MD – UC Irvine, Michael Murray, MD – Northern Nevada Medical Center **7**. Nguyen, N.T., Chinn, J. & Chang, K. Collaboration between GI surgery & Gastroenterology improves understanding of the optimal antireflux valve—the omega flap valve. **8**. 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. **9**. 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 **10**. Merit Medical, data on file.

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