EndoGastric Solutions Announces AMA Assignment of CPT Code and Short Form Descriptor

New CPT Code for the TIF Procedure Becomes Effective January 1, 2016

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REDMOND, Wash.--(BUSINESS WIRE)--EndoGastric Solutions® (EGS), a leader in incisionless procedural therapy to treat Gastroesophageal Reflux Disease (GERD), announced today assignment of Category I Current Procedural Terminology (CPT®) code number 43210 with short form descriptor esophagogastroduodenoscopy, flexible, transoral with esophagogastric fundoplasty, partial or complete, includes duodenoscopy. The code and descriptor will be used for EGS' Transoral Incisionless Fundoplication (TIF®) procedure for reflux starting January 1, 2016.

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"We are pleased by the AMA's decision to create a unique category I CPT code for the TIF procedure which represents another milestone for GERD patients," said Skip Baldino, President and CEO of EndoGastric Solutions. "The AMA has acknowledged the significant clinical evidence, including two randomized clinical trials and multi-year outcome data for the TIF procedure."

"We extend our deep appreciation to the AGA, ACG, ASGE, ASGS, and SAGES societies for their continued leadership efforts to advocate on behalf of their members and the patients they serve," continued Baldino. "I am especially proud that EGS is the sole sponsor of multiple randomized-controlled trials and prospective registries demonstrating durable outcomes of transoral procedures for the treatment of GERD."

The TIF procedure is backed by superior medical evidence from more than 50 peer-reviewed clinical publications encompassing over 40 study centers documenting outcomes on more than 800 unique study patients and features two randomized controlled trial:

> RESPECT (Randomized EsophyX® vs. Sham/Placebo Controlled Trial) study, the first-ever blinded, randomized, sham- and placebo-controlled study for TIF® procedure. The study found that a majority of patients who underwent the TIF procedure experienced significant elimination of troublesome regurgitation and healed esophagitis compared to the sham – controlled group.[1]
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> TEMPO (TIF® versus Medical PPI Management of Refractory GERD symptoms) trial demonstrated elimination of daily troublesome regurgitation and atypical symptoms as evaluated by two validated instruments—Reflux Disease Questionnaire and Reflux Symptom Index; secondary outcomes included healing of esophagitis, normalization of esophageal acid exposure and PPI use in the TIF treated patients at 6 and 12 months.[2]

Over 17,000 TIF patients have been treated worldwide since EsophyX® device clearance in 2007. For more information, visit www.GERDHelp.com.

About Current Procedural Terminology (CPT®)

CPT codes are a listing of descriptive terms and identifying codes for reporting medical services and procedures. The purpose of CPT is to provide a uniform language that accurately describes medical, surgical, and diagnostic services, and thereby serves as an effective means for reliable nationwide communication among physicians and other healthcare providers, patients, and third parties. CPT® is registered trademark of the American Medical Association.

About GERD

Gastroesophageal reflux disease (GERD) is a chronic condition in which the gastroesophageal valve (GEV) allows gastric contents to wash back up into the esophagus, causing heartburn and possible injury to the esophageal lining. The stomach produces hydrochloric acid and other digestive enzymes after a meal to aid in the digestion of food. The cells that line the stomach are coated with a protective mucus that can withstand gastric contents, while the cells that line the esophagus lack the same protection.

GERD is the most common gastrointestinal-related diagnosis made by physicians during clinical visits in the U.S. It is estimated that pain and discomfort from acid reflux impacts over 40 million people at least once per month in the U.S. The standard recommendations for symptomatic GERD patients include lifestyle changes (e.g., diet, scheduled eating times, and sleeping positions) and escalating doses of prescription medications for prolonged periods of time. Long-term, maximum-dose usage of prescription medications has been linked to a variety of other health complications.

About Transoral Incisionless Fundoplication (TIF®) procedure for reflux

Performed without the need for external incisions through the skin, the TIF procedure offers patients who require an anatomical repair another treatment option to correct the underlying cause of GERD. Studies show that for up to three years after the TIF procedure esophageal inflammation (esophagitis) is eliminated and most patients are able to stop using daily PPI medications to control symptoms.

About EsophyX® technology

The original EsophyX device was cleared by the FDA in 2007. EGS launched the third generation EsophyX device, the EsophyX Z in 2015. The technology has continued to evolve and is a clinically-backed tool for physician use in the treatment of GERD. The EsophyX technology now enables surgeons and gastroenterologists to use a wider selection of endoscopes–including low profile and larger high-definition models—to treat the underlying anatomical cause of GERD. The EsophyX technology is used to reconstruct the gastroesophageal valve (GEV) and restore its function as a barrier, preventing stomach acids from washing back up into the esophagus. The device is inserted through the patient's mouth with direct visual guidance from an endoscope.

About EndoGastric Solutions®

Based in Redmond, WA, EndoGastric Solutions, Inc. (www.endogastricsolutions.com), is a medical device company focused on developing and commercializing innovative, evidence-based, incisionless surgical technology for the treatment of gastroesophageal reflux disease (GERD). EGS has combined the most advanced concepts in gastroenterology and surgery to develop the Transoral Incisionless Fundoplication (TIF®) procedure—a barely invasive solution that addresses a significant unmet clinical need.

References

[1]Hunter JG, et al., Transoral Fundoplication Provides Better GERD Symptom Control Than PPIs in Patients with Troublesome Regurgitation: A Multicenter Sham Gastroenterology. 2015 Feb;148(1):324-33.

[2]Trad KS, et al., Efficacy of transoral fundoplication for treatment of chronic gastroesophageal reflux disease incompletely controlled with high-dose proton-pump inhibitors therapy: a randomized, multicenter, open label, crossover study BMC Gastroenterology 2014; 14:174.

Indications:

The EsophyX device with SerosaFuse fasteners 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 < 2cm in size in patients with symptomatic chronic gastroesophageal reflux disease.

Contacts

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