

PUBLISHED STUDY SUPPORTS TWO-YEAR SAFETY AND EFFICACY OF INCISIONLESS TIF SURGERY FOR THE TREATMENT OF GERD

Redwood City, CA (March 26, 2009) — [EndoGastric Solutions \(EGS\)](#), the recognized leader in the emerging field of Natural Orifice Surgery (NOS), today announced publication of a two-year study of [TIF \(Transoral Incisionless Fundoplication\)](#) procedure for the surgical treatment of GERD (gastroesophageal reflux disease) confirming the procedure's safety and efficacy. The study, conducted at [Centre Hospitalier Universitaire St. Pierre, Brussels, Belgium](#), by [Professor Guy-Bernard Cadière](#), was published in the [March 14, 2009 edition of Surgical Endoscopy](#).

The results from the study showed stability of the TIF-created valve and resultant long-term improvement in the patients' symptoms. At two years after TIF1 (first generation TIF technique) patients reported having experienced cessation of heartburn, elimination of daily pharmaceutical therapy (proton pump inhibitors) and improved quality of life superior to pharmaceutical therapy. Key trial results include:

- 93% of patients reported a cessation of heartburn
- 71% of patients were completely off daily PPIs
- 64% of patients had a $\geq 50\%$ improvement in GERD HRQL (health related quality of life) scores compared with baseline on their PPIs
- 79% of patients experienced a complete cure or remission of their GERD
- 86% of patients were satisfied with TIF
- At 2 years no adverse events related to TIF were reported

"Surgeons and patients having been waiting for an effective and low-risk surgical remedy for GERD without the complications associated with the Lap Nissen," explained Pr. Cadière. "Although limited by the small study population, this study substantiates that the TIF procedure is safe and effective long-term, with no long-term complications, and results that are similar to the results of a large multi-center, 86 patient study awaiting publication. The fact that clinical effects are sustained from one to two years verifies that TIF achieves serosa-to-serosa fusion, resulting in a robust and durable antireflux valve. Additionally, in the two years since we started the study, the procedure has continued to evolve and improve. We are now performing a third-generation TIF2 procedure with the second-generation EsophyX2 device, which results in a tighter wrap and better efficacy."

"EGS is continuing to build a foundation of research and clinical data to support long-term safety and efficacy of TIF," said [Thierry Thauere, Chief Executive Officer of EndoGastric Solutions](#). "Over 1200 TIF procedures have been performed worldwide to date with no long-term complications. TIF delivers the efficacy of partial fundoplication such as Toupet or Belsey procedures without the associated long-term complications of a Lap Nissen."

About GERD

Over 21 million Americans suffer from GERD. Typical symptoms include painful heartburn, chronic cough, regurgitation, sleep disorders, asthma, and sore throat,

which occur when stomach acids break through a dysfunctional one way valve and backwash up into the esophagus or are inhaled. The standard of care, acid suppressive pharmaceutical therapies with PPIs (proton pump inhibitors), can be effective at masking the condition and eliminating symptomatic heartburn for some patients. However, new studies linking long-term use of PPIs to hip fractures, the adverse interaction of PPIs with Plavix, and other adverse conditions have some patients and their physicians rethinking their treatment strategy. In addition, for a large patient population, persistent breakthrough reflux, non-acid related symptoms of reflux, nighttime reflux (which disrupts sleep), or even the promise of being shackled to a lifelong regimen of daily drug therapy is motivation for them to seek a more permanent anatomical correction for their GERD.

Although antireflux surgery has been shown to be more effective than PPIs in long-term management of chronic GERD, patients are reluctant to undergo open or laparoscopic surgery because of associated risks and side effects. Both the laparoscopic antireflux surgery such as the Nissen procedure and the incisionless TIF procedure reconstruct the deteriorated antireflux valve, creating a robust physical barrier to reflux. The laparoscopic Nissen procedure, while effective, is more invasive, involving as many as five small incisions and substantial internal cutting and dissection. The Nissen procedure not only requires considerable patient recovery but also has significant associated risks, including dysphagia (difficulty swallowing) and gas bloat. The incisionless TIF procedure with the EsophyX device was developed to create a similar antireflux barrier as the Nissen procedure, but from within the body with the device inserted through the mouth and without incisions or internal dissection. Results are similar. Because TIF is incisionless, recovery and risk of complications are reduced and patient satisfaction is generally higher.

About the TIF Procedure and the EsophyX Device

The TIF (Transoral Incisionless Fundoplication) surgical procedure corrects the root cause of GERD, an anatomic defect at the gastroesophageal junction. Inserted through the mouth, under visual guidance of an endoscope, the EsophyX device is used to construct a robust antireflux valve, reestablishing a barrier to reflux and restoring the competency of the gastroesophageal junction. The result is the effective elimination of GERD.

About EndoGastric Solutions

EndoGastric Solutions (EGS) is a privately held corporation located in Redmond, Washington and Redwood City, California. EGS is a pioneer in developing incisionless transoral procedures for the treatment of upper gastrointestinal conditions, including gastroesophageal reflux disease (GERD). EsophyX® is cleared by the FDA, CE marked, and available for sale in the U.S. and other parts of the world.

For more information about EndoGastric Solutions, Inc., and EsophyX, please visit:

US: <http://www.endogastricsolutions.com/>

EU: <http://www.egseurope.eu/>

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