

The Journal of the American College of Surgeons Publishes on Major Advancement in
Surgery for Gastroesophageal Reflux Disease

ST. PAUL, Minn., July 15, 2013 – An estimated 1 in 5 U.S. adults suffer from Gastroesophageal Reflux Disease (GERD), a chronic, often progressive disease that can cause debilitating symptoms and in certain cases lead to esophageal cancer. GERD is caused by a weak esophageal sphincter muscle that opens abnormally allowing harmful gastric fluids from the stomach to reflux into the esophagus. Acid reflux medications such as Prevacid®, Nexium®, and Prilosec®, are designed to reduce the amount of acid in the stomach, but they do not prevent reflux from occurring. The Journal of the American College of Surgeons (JACS) reports on a study from a leading medical center that implanted the LINX® Reflux Management System, an FDA-approved medical device for the treatment of GERD. Based on the results of this study, this center has adopted LINX as the standard of care.

In the study, over a period of six years, 100 consecutive patients suffering with GERD who had been on daily reflux medications for several years underwent laparoscopic surgery to have the LINX System implanted. The primary reasons cited for undergoing the procedure were the ineffectiveness of acid reflux medications, poor quality of life, and fear of cancer. At a median follow-up of 3 years post implant, 93% of patients reported significant improvement in their quality of life, and 85% reported complete cessation of their acid reflux medication. There were no intraoperative complications related to the LINX System. For more information, please visit [http://www.journalacs.org/article/S1072-7515\(13\)00356-6/abstract](http://www.journalacs.org/article/S1072-7515(13)00356-6/abstract).

These results were consistent with the results from a multicenter prospective trial of the LINX System published this year in the New England Journal of Medicine, conducted as part of the FDA pre-market approval process.

The LINX System offers an alternative to the Nissen fundoplication, a surgical procedure in which part of the stomach is wrapped around the esophagus in order to reconstruct the sphincter. This procedure permanently alters the normal anatomy and, compared to implanting the LINX System, is more invasive. During a LINX procedure, a surgeon implants a small device comprised of magnetic beads around the weak sphincter, while leaving the stomach intact. The magnets support the weak sphincter to help prevent reflux. In the study, both the LINX System and the Nissen fundoplication were offered to each patient; all but one patient elected the LINX procedure at post procedure follow up, 91% of patients responded that they would undergo the LINX procedure again.

Philip O. Katz, M.D., Chairman of Gastroenterology at Albert Einstein Medical Center and past president of the American College of Gastroenterology, commented, “Currently we have limited options for treatment of patients who have incomplete symptom relief with acid suppression medications. The reflux inhibitor Baclofen is limited by side effects and is not FDA approved. Antireflux surgery has been underutilized due to concern for waning of initial success and potential side effects. Endoscopic options such as Endocinch, radio frequency application, and TIF have met with limited success in selected patients. As such, there is a real therapy gap between medical therapy and fundoplication. Magnetic sphincter augmentation offers an exciting and needed new surgical option for these patients.”

The Disease

Gastroesophageal Reflux Disease (GERD) is a chronic, often progressive disease resulting from a weak lower esophageal sphincter that allows harmful gastric fluid to reflux into the esophagus, resulting in both pain and injury to the esophageal lining. Symptoms of GERD include heartburn and regurgitation, often associated with the inability to sleep and dietary constraints. Acid reflux medications, such as Prevacid®, Nexium®, and Prilosec®, affect gastric acid production, but do not repair the sphincter defect, allowing continued reflux. GERD is associated with a pre-cancerous condition known as Barrett’s esophagus, which increases the risk of esophageal cancer.

The LINX® Reflux Management System

The LINX System is a small implant comprised of interlinked titanium beads with magnetic cores. The magnetic attraction between the beads augments the existing esophageal sphincter's barrier function to prevent reflux. The device is implanted with a standard minimally invasive laparoscopic procedure and is an alternative to the more anatomically disruptive fundoplication, commonly used in surgical anti-reflux procedures. The LINX® Reflux Management System is indicated for those patients diagnosed with Gastroesophageal Reflux Disease (GERD) as defined by abnormal pH testing, and who continue to have chronic GERD symptoms despite maximum medical therapy for the treatment of reflux.

For more information on the LINX System, including a statement of risks, please visit www.linxforlife.com.

About Torax Medical

Torax Medical, Inc. is a privately-held medical device company headquartered in St. Paul, Minnesota that develops and markets products designed to treat sphincter disorders utilizing its technology platform, Magnetic Sphincter Augmentation (MSA). Torax Medical is currently marketing the LINX® Reflux Management System for the treatment of GERD in the U.S. and Europe and the FENIX™ Contenance Restoration System for the treatment of Fecal Incontinence (FI) in Europe.

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