

Landmark Publication Affirms Safety of LINX®, a New Treatment Option for Gastro-esophageal Reflux Disease

ST. PAUL, MN, April 2, 2014 – Millions of Americans suffer from Gastroesophageal Reflux Disease (GERD), a chronic, often progressive disease that can cause debilitating symptoms and lead to serious complications including pre-cancerous Barrett's esophagus and esophageal cancer. A study of over 1000 patients published in the journal *Diseases of the Esophagus* confirms the safety of the LINX® Reflux Management System, the only available device approved by the FDA to be both safe and effective in the treatment of GERD. LINX is intended to treat patients with a chronic history of GERD and an incomplete response to GERD medications.

The study examined the safety profile of LINX in the first 1,048 patients treated during a six year period in over 80 centers worldwide. Laparoscopic implantation of LINX is a minimally invasive procedure utilizing a mechanical device as an alternative to the current surgical method which reconstructs a portion of the patient's stomach around the esophagus to create a barrier for reflux, often leading to patients losing the ability to vomit and effectively belch. As reported in this safety review of the LINX procedure, there were no intraoperative complications and no adverse events leading to any serious long-term complications or deaths.

In this review, the effectiveness of LINX from controlled studies with between 3 and 5 years follow-up was cited. The clinical evidence shows that LINX provides relief of GERD symptoms with minimal long-term side effects; nearly all patients preserve the ability to belch and vomit. Importantly, regurgitation, a reflux symptom not addressed by acid suppression medications, was resolved in nearly all patients. Over 85% of patients studied have completely eliminated their use of proton-pump inhibitor drugs.

"This is one of the largest reviews of safety for anti-reflux surgery ever published. It provides further clinical evidence that LINX is a safe, minimally invasive option for patients who are concerned about the progression of their reflux disease and need an alternative to life-long medications," stated John C. Lipham, M.D., Chief, Division of Upper GI and General Surgery, Associate Professor of Surgery at the University of Southern California and lead author of the study. "Overall, LINX had a remarkable safety profile, even from the earliest experiences with this new technology."

Dr. Paul Taiganides, Director of the Heartburn Treatment Center at Knox Community Hospital and co-author, emphasized the importance of this study to patients who are failing medical therapy for their GERD. "Based on these excellent safety results, patients with GERD should no longer be afraid of surgery, especially with a less invasive option like the LINX procedure now available. It is important for patients to understand that GERD medications do not address the cause of reflux. Actually, it has been recently shown that long-term use of GERD medications is associated with significantly higher risk of esophageal cancer. The LINX procedure provides patients an option intended to correct the sphincter defect that allows the reflux to occur."

LINX is available in specially trained Centers of Excellence medical centers in the U.S. and Europe. To learn more about LINX and to find a listing of centers in the U.S. offering LINX, please visit www.linxforld.com.

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 chronic sleep disruption, and may also include persistent cough, excessive throat clearing, hoarseness and a feeling of a “lump” in the throat. 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

LINX 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 using 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.

LINX does require a surgical procedure and is associated with potential risks, contraindications and life style modifications. For more information on LINX, 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™ Continence Restoration System for the treatment of Fecal Incontinence (FI) in Europe. For more information, please visit www.toraxmedical.com.

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