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New Study Shows Magnetic Implant is an Important Break-Through in the Treatment of Reflux Disease

St. Paul, Minn. (September 22, 2014) Torax Medical announced today the publication of new data comparing the LINX® Magnetic Sphincter Augmentation Device and laparoscopic fundoplication surgery in 249 patients. Data from this study significantly adds to the growing body of evidence that the LINX device is a safe and effective procedure for patients suffering from gastro-esophageal reflux disease (GERD). Current surgical options (fundoplication) require the patient’s stomach tissue to be wrapped around the esophagus to create a barrier to reflux. The LINX device provides protection from reflux without compromising the patient’s stomach while minimizing the side effects commonly associated with the present surgical approaches.

Martin Riegler, MD, Department of Surgery, Medical University Vienna and an author in this prospective, multicenter study; [*Magnetic Sphincter Augmentation and Fundoplication for GERD in Clinical Practice*](#) published in *Surgical Endoscopy* commented “When patients fail acid suppression therapy for their reflux disease it presents a significant clinical problem. In this study, the majority of patients reported having reflux related symptoms that were severe enough to interfere with daily activities despite taking acid suppression medications.” Following minimally invasive laparoscopic anti-reflux surgery with either the LINX device or fundoplication, both groups demonstrated a marked improvement in their quality of life. Patients receiving the LINX device were less likely to experience bloating and were more likely to be able to belch and vomit following the procedure as compared to the fundoplication group. Discontinuation of acid suppression medications was significantly greater in the LINX group (81.8%) compared to the fundoplication group (63.0%).

“This study introduces an important break-through in the treatment options for reflux disease. LINX allows patients to have the reflux control benefits of fundoplication surgery without the significant side effects” said Dr. Riegler.

The LINX device was shown to be both safe and effective following FDA approved clinical investigations and was later approved for U.S. distribution by the FDA in early 2012. The LINX device is available in both the U.S. and European markets at centers of excellence who have received training regarding the use of the LINX system.

The Disease

Gastro-esophageal 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. Anti-reflux surgery called Nissen Fundoplication reconstructs a new reflux barrier using a portion of the patient’s stomach which is wrapped around the lower portion of the esophagus. 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 laparoscopic procedure and is an alternative to fundoplication, commonly used in surgical anti-reflux procedures. The LINX® Reflux Management System is indicated for those patients diagnosed with Gastro-esophageal 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.linxforslife.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.