New Technology Changes how Gastroesophageal Reflux Disease is Treated

ST. Paul, Minn. (July 1, 2014) Torax Medical today announced the release of new data from two leading U.S. medical centers that further establishes the LINX Reflux Management System as a safe and effective procedure for patients suffering from gastroesophageal reflux disease (GERD).

Chronic GERD, when not completely responsive to medical therapy, can progress to serious complications including precancerous Barrett’s esophagus and esophageal cancer. Symptoms are often debilitating and may include daily pain, difficulty swallowing and sleep disruption. The disease is also associated with upper respiratory problems including asthma and bronchitis/pneumonia. Medical therapy (acid suppression medications) commonly prescribed to address GERD symptoms do not address the underlying cause of the disease which is a weak sphincter (valve) between the stomach and esophagus.

C. Daniel Smith, MD, Professor of Surgery, Mayo Clinic Jacksonville, Florida recently published his experience with the LINX Magnetic Sphincter Augmentation System in the Journal of the American College of Surgeons. “Our clinical experience with the LINX System matches what has been observed in controlled trials. Importantly, we are seeing LINX as a new treatment option for patients who suffer from GERD despite continuous drug use. The ability to offer patients a minimally invasive treatment which restores their esophageal sphincter without major side effects has been a long-term clinical need which it appears LINX can fulfill.” said Dr. Smith.

A second study, recently published in the Annals of Thoracic Surgery presents LINX outcomes by Brian Louie, MD, Director, Thoracic Research and Education and colleagues from the Swedish Cancer Institute and Medical Center in Seattle, Washington. The team evaluated sphincter augmentation with LINX with case matched sphincter reconstruction using the patient’s gastric fundus (Nissen fundoplication). Study results demonstrated that both LINX and fundoplication provided significant improvement in GERD symptoms such as heartburn, regurgitation and cough. However, patients implanted with LINX had a greater ability after the procedure to belch and experienced less bloating and gassy feelings, which are commonly associated with laparoscopic Nissen fundoplication surgery.

“The LINX device appears to restore the sphincter barrier function and preserve normal physiology which enables belching and vomiting” said Dr. Brian Louie. “LINX is an important new surgical treatment option for patients who fail medical therapy and have worsening GERD.”
The LINX device has been clinically studied for over 7 years. These studies add to the growing body of evidence that the LINX system is an effective and medically necessary treatment in the continuum of care for patients suffering from GERD.

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 lifestyle 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.