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New Study Demonstrates LINX® Safety and Efficacy Rivals Laparoscopic Nissen Fundoplication

Study authors conclude LINX is as effective as Nissen in controlling reflux with less side effects

St. Paul, Minn. (DD/MM, 2015) Torax Medical, Inc. announced today the release of new data from the University of Southern California, Keck Medical Center, a leading institution in the diagnosis and treatment of gastro-esophageal reflux disease (GERD). The retrospective study led by Dr. John C. Lipham, compared the LINX® Reflux Management System (LINX) to the standard of care, Laparoscopic Nissen Fundoplication (LNF) in similar patient populations. The results demonstrated LINX is as effective as LNF in controlling reflux but with less side effects. When compared to LNF for side effects, LINX patients reported less severe gas and bloating, while maintaining the ability to belch and vomit.

John C. Lipham, MD Chief, Division of Upper GI and General Surgery, Associate Professor of Clinical Surgery, Keck School of Medicine of USC said “This is the first propensity matched study comparing LINX to LNF assessing quality of life, proton-pump inhibitor (PPI) use, satisfaction and complications. This study validates the LINX results shown in other studies and substantiates that LINX is as effective as LNF in controlling reflux. It further supports the use of LINX as a first line therapy in patients who are failing drugs to control their reflux.” The study results were published in the Journal of the American College of Surgeons (<http://dx.doi.org/10.1016/j.jamcollsurg.2015.02.025>).

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. GERD is associated with a pre-cancerous condition known as Barrett’s esophagus, which increases the risk of esophageal cancer. 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.

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 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.