

## **The New England Journal of Medicine Publishes Clinical Study of Minimally-Invasive Device for Treatment of Reflux Disease**

ST. PAUL, Minn., February 21, 2013 – For the millions who suffer from Gastroesophageal Reflux Disease (GERD), a study published today in the New England Journal of Medicine (NEJM) provides clinical evidence of safety and effectiveness for a new, FDA-approved medical device. Torax Medical's LINX<sup>®</sup> Reflux Management System was studied in a controlled, prospective, multicenter trial involving 14 U.S. and European medical centers as part of the FDA pre-market approval process. The patients were evaluated before and after treatment to determine the effect of the LINX System on their GERD using pre-defined success criteria, which included reduction of esophageal acid, improvement in quality of life and elimination of reflux medications.

Last year, an FDA advisory panel evaluated the study and voted unanimously in favor of the medical device's safety, efficacy, and clinical benefit. This positive vote was followed by FDA approval of the device on March 22, 2012. The data published today in the NEJM reports three-year results from this clinical investigation.

The patients in the study reported suffering from reflux symptoms for a median of 10 years and taking reflux medications for a median of five years, underscoring the chronicity of GERD and the long-term dependence on medications to manage symptoms. "Despite continuous use of reflux medications, and having modified their lifestyles to reduce reflux triggers, some of my patients continue to experience debilitating symptoms and substantial compromise in their daily quality of life," said Robert A. Ganz, M.D., Associate Professor of Medicine at the University of Minnesota and lead author of the study. "In severe cases, patients are unable to lie flat in bed because reflux interferes with their sleep or causes them to choke or cough."

Numerous studies have shown that reflux symptoms persist in up to 40% of patients who receive acid suppression medications and that these symptoms have a negative impact on quality of life and healthcare utilization. "The biggest challenge in treating patients with GERD over the last 20 years is that the medicines available alleviate the symptoms but are unable to treat the underlying problem – a weak sphincter," said C. Daniel Smith, M.D., Professor of Surgery and Chair of the Department of Surgery at Mayo Clinic in Florida. "The only other surgical option, Nissen fundoplication, was developed decades ago and involves wrapping the stomach around the esophagus like a collar. While this operation can be effective, it is tricky to perform and get good results, and some of the side effects can be quite distressing to patients. Patients need another alternative."

The LINX System, developed by Torax Medical, is a new approach to treating GERD and an alternative to the more invasive Nissen fundoplication. The LINX System allows surgeons to leave the stomach intact and support the weak sphincter with a small device placed around the sphincter. The device uses magnetic attraction to help prevent the sphincter from opening to reflux.

As reported in the study, after sphincter augmentation with the LINX System, the majority of patients were able to substantially reduce or resolve their reflux symptoms, while eliminating use of their reflux medications. Severe regurgitation was eliminated in 100% of patients, and nearly all patients (93%) reported a significant decrease in the need for medication. More than

9 in 10 patients (94%) reported satisfaction with their overall condition after having the LINX System, compared to 13% before treatment while taking medication.

Founder and CEO of Torax Medical, Todd Berg, stated, “The LINX System is the result of a 10-year collaboration with experts in medicine and industry and a patient-centered focus on medical innovation. This device represents a needed advancement for a disease that not only presents life-long debilitating symptoms for many people, but also has created a tremendous economic burden on our healthcare system. We are proud to be part of this innovative breakthrough in the treatment of GERD, which is supported by clinical evidence, addresses an important chronic disease, and may yield important economic benefits.”

The LINX<sup>®</sup> Reflux Management System is available in leading medical centers in the U.S and Europe. For more information and to read the full study, please visit the NEJM website [hyperlink: <http://www.nejm.org/doi/full/10.1056/NEJMoa1205544>].

### **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 suppression drugs, such as Prevacid<sup>®</sup>, Nexium<sup>®</sup>, and Prilosec<sup>®</sup>, 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. Approximately 7% of adults in western countries suffer daily from symptoms of GERD.

### **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<sup>®</sup> 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 brief statement of risks, please visit [www.toraxmedical.com](http://www.toraxmedical.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<sup>®</sup> Reflux Management System for the treatment of GERD in the U.S. and Europe and the FENIX<sup>™</sup> Continence Restoration System for the treatment of Fecal Incontinence (FI) in Europe. For more information, please visit [www.toraxmedical.com](http://www.toraxmedical.com).

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