LINX® more effective than Omeprazole at controlling regurgitation and improving quality of life in patients with Gastroesophageal Reflux Disease (GERD)

Preliminary Results from a Landmark Clinical Trial Comparing the LINX® Reflux Management System and Omeprazole Presented at Digestive Disease Week

St. Paul, Minn. (May 24, 2017) Torax Medical, Inc. announced preliminary results from the CALIBER Trial that were presented at Digestive Disease Week (DDW) in Chicago, Il. The CALIBER Trial compared LINX®, a revolutionary solution for GERD, and omeprazole, an acid suppression medication (sold under the brand name Prilosec®) to determine which treatment was more effective for managing regurgitation.

CALIBER Trial

The standard of care for GERD is treatment with acid suppression medications known as proton pump inhibitors (PPIs). Studies suggest 80% of GERD patients experience regurgitation, an often debilitating symptom that occurs when stomach contents flow back into the esophagus or throat. Although acid suppression medication is helpful for heartburn symptoms, it has limited impact on regurgitation.

The CALIBER Trial is a multi-center randomized controlled trial comparing LINX to acid suppression medication (omeprazole) in patients with troublesome regurgitation. All patients had a diagnosis of GERD as confirmed by abnormal acid exposure time and moderate to severe regurgitation despite taking once-daily omeprazole. Patients were randomized to treatment with twice a day omeprazole or LINX. The primary endpoint of the trial was elimination of moderate to severe regurgitation at 6 months after treatment. Preliminary results reported at DDW showed*:

- 92.6% of patients treated with LINX achieved the primary endpoint success criteria versus 8.6% of patients treated with twice a day omeprazole.
- Significant improvement in quality of life was achieved in 88.9% of patients treated with LINX versus 6.8% of patients treated with twice a day omeprazole.
- Normal levels of reflux were restored in 92% of patients treated with LINX compared to 36% of patients treated with twice a day omeprazole.

**This data was presented at Digestive Disease Week 2017 (DDW) in Chicago, IL, by Dr. Reginald Bell, SurgOne Foregut Institute, Englewood, CO.*

"PPI's are intended for acid suppression, not reflux control. The CALIBER study is effectively showing that patients with troublesome regurgitation appear to significantly benefit from the reflux control provided

by LINX over omeprazole which primarily affects gastric acidity", commented Todd Berg CEO, Torax Medical.

Reginald Bell MD, one of the study Principal investigators, commented *"Current practice for GERD patients with troublesome regurgitation is to increase the dose of acid suppression therapy. The preliminary results of this study demonstrate a 10-fold better resolution of regurgitation with LINX compared to increases in acid-suppression therapy. If the significant disparity in outcomes observed in this preliminary analysis continues to favor LINX, the medical community will need to recognize that increasing PPI dosing for these patients is largely ineffective. A paradigm shift will occur that will greatly favor the reflux control provided by LINX."*

A total of 150 patients were enrolled in the CALIBER trial. All patients will be followed out to one year after treatment. Additional results from the trial will be available in late 2017.

About GERD

Gastroesophageal Reflux Disease (GERD) is a chronic, often progressive disease which affects more than 20 million Americans. GERD results 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®, work to suppress normal gastric acid production, but do not repair the sphincter defect, allowing continued reflux. Traditional anti-reflux surgery called Nissen fundoplication requires a portion of the patient's stomach to be wrapped around the esophagus.

**Prevacid is a registered trademark of DEXILANT, Nexium is a registered trademark of AstraZeneca, Prilosec is a registered trademark of AstraZeneca.*

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 are seeking an alternative to continuous acid suppression therapy. For more information about LINX, or to find a physician, visit www.linxforlife.com.

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., part of the Ethicon family of companies, is headquartered in St. Paul, Minnesota, 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. For more information, please visit www.toraxmedical.com.