

## LINX®. A Revolutionary Solution for GERD.

Up to 1 in 5 U.S. adults suffer from gastroesophageal reflux disease (GERD).<sup>1</sup> Americans suffering from GERD now have a safe and effective treatment alternative.

LINX is a revolutionary solution for GERD proven to eliminate dependence on medication and improve quality of life.

- LINX is the only available FDA-approved device for the treatment of GERD.

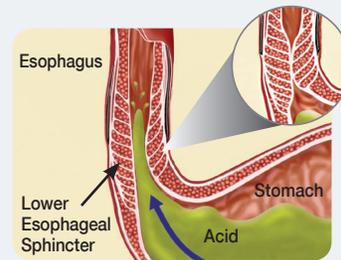


- **5-Year results of a Landmark Study Confirm LINX Procedure as a Beneficial Treatment for Gastroesophageal Reflux Disease:**<sup>2</sup>
  - 85 percent of patients remained free from dependence on daily GERD medication.
  - Bothersome regurgitation, a debilitating symptom of GERD, was eliminated in 99 percent of patients.
  - Bothersome heartburn, was significantly reduced from 89% at baseline to 11.9% at five years.
  - Patients reported a significant improvement in their quality of life.

## GERD: The backstory

### GERD spells misery for millions of U.S. adults.

Whether you call it heartburn, acid reflux, or GERD, gastroesophageal reflux disease can spell misery for millions of adults in the U.S. GERD is caused by a weak muscle in the esophagus called the Lower Esophageal Sphincter (LES) that allows acid and bile to splash up from the stomach into the esophagus, often causing injury to the lining of the esophagus and symptoms like heartburn, chest pain, regurgitation, sore throat, and cough.



### GERD is:

#### Caused by a mechanical defect and requires a mechanical solution.

Medications for GERD are designed to control or suppress acid production in the stomach. They do not address the cause of GERD, a weak sphincter muscle, and can't prevent reflux. Approximately 40 percent of GERD sufferers continue to have symptoms while taking medications for GERD.<sup>3</sup>

#### Epidemic.

Up to 1 in 5 U.S. adults suffers from GERD.<sup>1</sup>

#### Serious.

GERD can lead to serious complications like stricture, Barrett's esophagus, and esophageal cancer. Adenocarcinoma, a type of esophageal cancer, increased over 700 percent between 1973 and 2006.<sup>4</sup>

#### Debilitating.

GERD can cause daily pain, lead to poor sleep, affect food tolerance, and limit daily activities.

#### Costly.

The cost of GERD to U.S. employers has been estimated at \$75 billion per year.<sup>5</sup>

*The United States Food and Drug Administration (FDA) has issued a series of statements on possible side effects of long-term use of Proton Pump Inhibitors (PPI) including: possible fracture risk, low magnesium levels, and clostridium difficile-associated diarrhea.<sup>6</sup>*

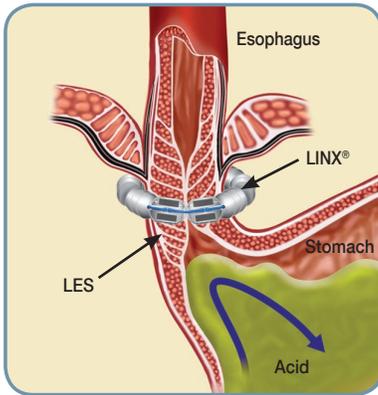


Figure 1

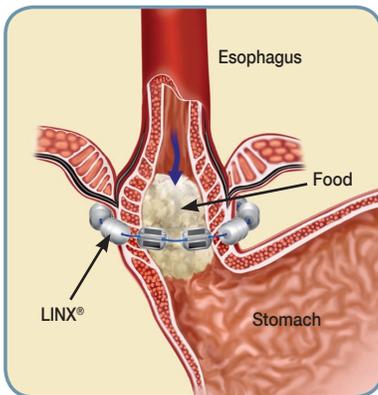


Figure 2

### How It Works: LINX is designed to STOP REFLUX AT ITS SOURCE.

GERD (Gastroesophageal Reflux Disease) is caused by a weak muscle called the lower esophageal sphincter (LES) that allows acid and bile to flow back from the stomach into the esophagus, creating pain and often causing damage to the lining of the esophagus. LINX is a flexible ring of small magnets placed around the LES during a minimally invasive procedure. The strength of the magnets helps keep the weak LES closed to prevent reflux. (Figure 1) When patients swallow, LINX opens temporarily to allow food and liquid to pass into the stomach. (Figure 2)

LINX is implanted using a minimally invasive procedure and patients generally go home within one day.

### Current Treatments: Patients need an alternative.

Medications for GERD are designed to control or suppress acid production in the stomach. They do not address the cause of GERD, a weak sphincter muscle, and can't prevent reflux. Approximately 40 percent of GERD sufferers continue to suffer symptoms while taking medications for GERD.<sup>3</sup>

<sup>1</sup>International Foundation for Functional Gastrointestinal Disorders (IFFGD)

<sup>2</sup>Ganz, et al., Long-Term Outcomes of Patients Receiving a Magnetic Sphincter Augmentation Device for Gastroesophageal Reflux: *Clin Gastroenterol Hepatol: Article in Press*, published online June 01, 2015.

<sup>3</sup>GERD Patient Study: Patients and Their Medications (AGA Institute)

<sup>4</sup>Pohl, et al., Esophageal adenocarcinoma incidence: are we reaching the peak? *Cancer Epidemiol Biomarkers Prev*; 19 (6); 1468-70

<sup>5</sup>Wahlqvist P., et al. A Systematic review: the impact of gastro-oesophageal reflux disease on work productivity. *Aliment Pharmacol Ther* 2006; 24: 259-72

<sup>6</sup>[www.fda.gov/Drugs/DrugSafety/informationbydrugclass/ucm213259.htm](http://www.fda.gov/Drugs/DrugSafety/informationbydrugclass/ucm213259.htm)

## LINX. A Revolutionary Solution for GERD.

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.

**Caution:** Federal law (USA) restricts these devices to sale by or on the order of a physician.

**Contraindications:** Do not implant the LINX System in patients with suspected or known allergies to titanium, stainless steel, nickel or ferrous materials.

**Warnings:** The LINX device is considered MR Conditional in a magnetic resonance imaging (MRI) system up to either 0.7 Tesla (0.7T) or 1.5-Tesla (1.5T), depending on the LINX model implanted. Laparoscopic placement of the LINX device is major surgery.

**General Precautions:** The LINX device is a long-term implant for use in patients 21 years or older. Medical management of adverse reactions may include explantation and/or replacement.

**Potential Risks Associated with LINX System:** dysphagia, stomach bloating, nausea, odynophagia, increased belching, decreased appetite, inability to belch or vomit, flatulence, early satiety, device erosion, device migration, infection, pain, and worsening of preoperative symptoms.

For more information on the LINX Reflux Management System, contact your physician or Torax Medical, Inc.

For full patient information visit [www.linxforslife.com](http://www.linxforslife.com) or [www.toraxmedical.com](http://www.toraxmedical.com).



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Doc. No. 4888 Rev4  
Date of Issue: Sept 2015