



## FACT SHEET

### The LINX® Reflux Management System is the only available FDA-approved device to treat Gastroesophageal Reflux Disease (GERD), a debilitating disease that affects 1 in 5 U.S. adults.<sup>1</sup>

Millions of Americans suffering from GERD now have a new, safe and effective treatment alternative.



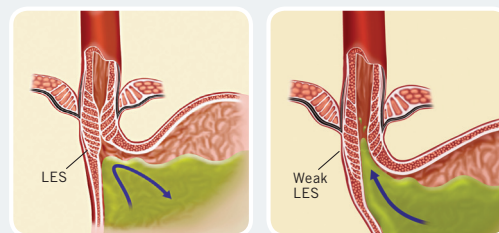
The LINX System is a small, flexible band of magnets enclosed in titanium beads. The magnetic attraction between the beads helps keep a weak esophageal sphincter closed to prevent reflux. The LINX System is implanted around the weak sphincter just above the stomach in a minimally invasive procedure that typically takes less than one hour.

- **LINX is the only available FDA-approved device for the treatment of GERD** — An FDA advisory panel voted unanimously in favor of the LINX System's safety, efficacy and clinical benefit. This positive vote was followed by FDA approval on March 22, 2012.
- **LINX study results appeared in *New England Journal of Medicine*** — The 3 year results of a 5-year clinical study assessed 100 patients with chronic GERD before and after treatment with the LINX System.
- **Results from the clinical study showed that after treatment with the LINX System:**
  - 91 percent of patients achieved freedom from daily GERD medication
  - 92 percent of patients achieved significant symptom improvement
  - 100 percent of patients eliminated severe regurgitation
  - 99 percent of patients eliminated daily sleep disruption due to heartburn
  - 94 percent of patients were satisfied with their overall condition

## 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>2</sup>

**Epidemic.** 1 in 5 U.S. adults suffers from GERD.

**Serious.** GERD can lead to serious complications like stricture, Barrett's esophagus, and esophageal cancer. Adenocarcinoma, a type of esophageal cancer, increased over 600 percent between 1973 and 2006.<sup>3</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>4</sup>

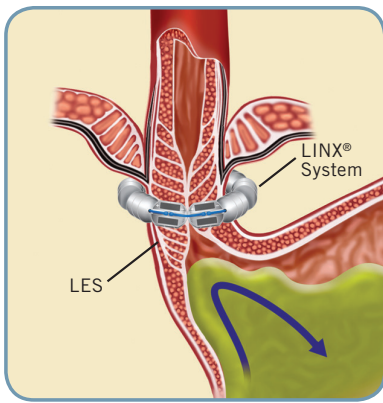


Figure 1

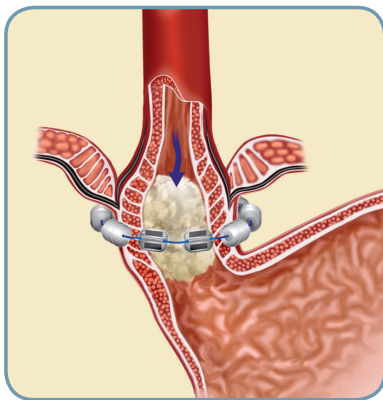


Figure 2

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

GERD is caused by a mechanical defect and requires a mechanical solution. The LINX System is a small, flexible band of magnets enclosed in titanium beads. The beads are connected by titanium wires. The LINX System is implanted around the weak esophageal sphincter, just above the stomach. The magnetic attraction between the beads keeps the weak esophageal sphincter closed to help prevent reflux. (Figure 1) Swallowing forces separate the beads temporarily to allow food and liquid to pass into the stomach. (Figure 2)

LINX is implanted laparoscopically in a minimally invasive procedure that typically takes less than one hour. 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 have symptoms while taking medications for GERD.

Current surgical treatments for GERD are performed annually on an estimated less than one-half of 1 percent of GERD sufferers in the U.S.

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

<sup>2</sup>GERD Patient Study: Patients and Their Medications (AGA Institute)

<sup>3</sup>Pohl, et al., Esophageal adenocarcinoma incidence: are we reaching the peak? *Cancer Epidemiol Biomarkers Prev*; 19 (6); 1468-70

<sup>4</sup>Wahlquist P., et al. A Systematic review: the impact of gastro-oesophageal reflux disease on work productivity. *Aliment Pharmacol Ther* 2006; 24: 259-72

## The LINX System treats a debilitating disease – GERD – at its source.

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 unsafe. 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).



Torax® Medical, Inc.

4188 Lexington Avenue North, Shoreview, Minnesota 55126, USA

[www.toraxmedical.com](http://www.toraxmedical.com) • [info@toraxmedical.com](mailto:info@toraxmedical.com)

Phone: 1 (651) 361-8900

Doc. No. 3721 Rev. 2  
Date of Issue: April 2013