

LINX Reflux Management System

A revolutionary treatment for reflux disease.

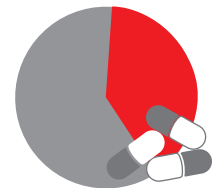
A simple device with life-changing potential.

Up to 1 in 5 U.S. adults suffer from gastroesophageal reflux disease (GERD).¹

Millions of patients rely on medications to treat GERD, medications for GERD are designed to control or suppress acid production in the stomach. They do not address the mechanical cause of GERD, a weak sphincter muscle.

Approximately 40% of GERD sufferers continue to suffer symptoms while taking medications for GERD.²

LINX Reflux Management System is a revolutionary treatment for GERD demonstrated to reduce dependence on medication and improve quality of life.^{3,4}



Demonstrated consistent symptom improvement.⁵

5-Year results of a landmark study confirm LINX® as a beneficial treatment for Gastroesophageal Reflux Disease:

- 85% of patients were free from dependence on daily GERD medication.⁴
- Elimination of regurgitation in 99% of patients.⁶
- Elimination of heartburn in 85% of patients.⁷
- Patients reported a significant improvement in their quality of life.³

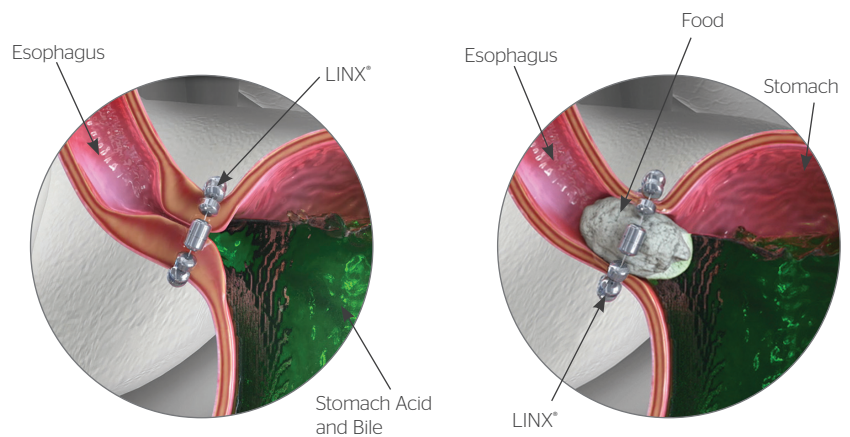


Simply designed to be simple.

LINX® is easy to understand and love because it is simple. LINX is a small, flexible ring of magnets that opens to allow food and liquid down, then closes to prevent stomach contents from moving up.

Simple as that.

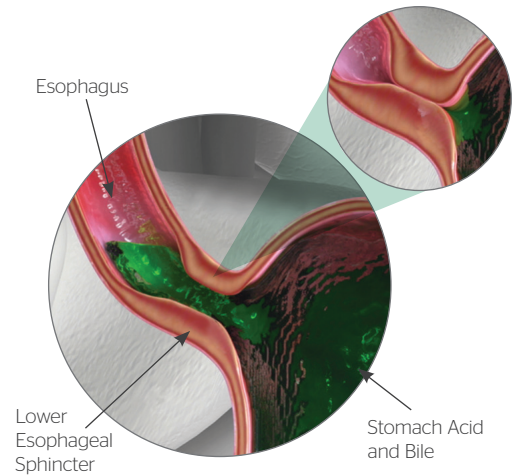
LINX® is implanted using a minimally invasive procedure and patients generally go home within one day.



GERD: The backstory.

Reflux disease is more than heartburn.

Whether you call it heartburn, acid reflux, or GERD, gastroesophageal reflux disease can spell misery for millions of adults in the U.S. Reflux (also called Gastroesophageal Reflux Disease, or GERD) is caused by a weak muscle in your esophagus called the Lower Esophageal Sphincter (LES). The LES is your body's Reflux Barrier. Normally your Reflux Barrier acts like a one-way valve, allowing food and liquid to pass into the stomach, but preventing stomach contents from flowing back into the esophagus. In people with reflux, the Reflux Barrier allows harmful acid and bile to flow back into the esophagus.



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 mechanical cause of GERD, a weak sphincter muscle. Approximately 40 percent of GERD sufferers continue to have symptoms while taking medications for GERD.²

Epidemic.

Up to 1 in 5 U.S. adults suffers from GERD.¹

Serious.

GERD can lead to serious complications like stricture, Barrett's esophagus, and esophageal cancer.

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.⁸

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.^{9,10,11}

1. El-Serag HB, Sweet S, Winchester C, et al. Update on the epidemiology of gastro-oesophageal reflux disease: a systematic review. *Gut*. 2014. 63(6): 871-80. Poisson regression model of 16 studies yielded a sample size-weighted mean of 19.8% for the prevalence of GERD in the US.
2. Rona K, Reynolds J, Schwameis K, et al. Efficacy of magnetic sphincter augmentation in patients with large hiatal hernias. *Surgical Endoscopy*. 2017. 31(5):2096-2102.
3. Ganz R, Edmundowicz S, Taiganides P, et al. Long-term Outcomes of Patients Receiving a Magnetic Sphincter Augmentation Device for Gastroesophageal Reflux. *Clin Gastroenterol Hepatol*. 2016. 14(5):671-7. Based on a 5 year prospective, multi-center, single-arm study observing 100 patients who were implanted with LINX, there was a significant improvement in the median GERD-HRQL score at 5 years, as compared with baseline, both with and without PPI use, 4 vs 11 and 27 respectively (p<0.001).
4. Ganz R, Edmundowicz S, Taiganides P, et al. Long-term Outcomes of Patients Receiving a Magnetic Sphincter Augmentation Device for Gastroesophageal Reflux. *Clin Gastroenterol Hepatol*. 2016. 14(5):671-7. Based on a study observing 100 patients who were implanted with LINX, daily use of PPIs decreased to 15.3% at 5 years. (p<0.001)
5. Rona K, Reynolds J, Schwameis K, et al. Efficacy of magnetic sphincter augmentation in patients with large hiatal hernias. *Surgical Endoscopy*. 2017. 31(5):2096-2102. Reynolds J, Zehetner J, Wu P, et al. Laparoscopic Magnetic Sphincter Augmentation vs Laparoscopic Nissen Fundoplication: A Matched-Pair Analysis of 100 Patients. *J American College of Surgeons*. 2015. 221(1):123-128. Ganz R, Edmundowicz S, Taiganides P, et al. Long-term Outcomes of Patients Receiving a Magnetic Sphincter Augmentation Device for Gastroesophageal Reflux. *Clin Gastroenterol Hepatol*. 2016. 14(5):671-7. Based on 192 patients who underwent MSA with LINX as well as a matched pair analysis in which 47 patients underwent MSA. 98.1% (p=0.118) and 97.8% of patients, respectively, reported symptom improvement or resolution. In a study of 100 patients implanted with LINX, bothersome heartburn decreased to 11.9% (p<0.001) and bothersome regurgitation decreased to 1.2% (p<0.001).
6. Ganz R, Edmundowicz S, Taiganides P, et al. Long-term Outcomes of Patients Receiving a Magnetic Sphincter Augmentation Device for Gastroesophageal Reflux. *Clin Gastroenterol Hepatol*. 2016. 14(5):671-7. Based on a 5 year prospective, multi-center, single-arm study observing 100 patients who were implanted with LINX, regurgitation was 57% at baseline and decreased to 1.2% at 5 years. (p<0.001)
7. Based on a 5 year prospective, multi-center, single-arm study observing 100 patients who were implanted with LINX, bothersome heartburn was 89% at baseline and decreased to 11.9% at 5 years. (p<0.001)
8. Wahlqvist P, et al. A Systematic review: the impact of gastro-oesophageal reflux disease on work productivity. *Aliment Pharmacol Ther* 2006; 24: 259-72
9. Fractures: <https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm213206.htm>
10. Magnesium: <https://www.fda.gov/Drugs/DrugSafety/ucm245011.htm>
11. Clostridium: <https://www.fda.gov/Drugs/DrugSafety/ucm290510.htm>

LINX[®] is prescribed by your physician. It is not for everyone. Please talk to your physician to see if it is right for you. Your physician should discuss any potential benefits and risks with you. Although many patients benefit from LINX[®], results may vary. All surgical procedures carry risk. LINX[®] does not treat gastric or esophageal cancer, Barrett's esophagus, pain, anxiety or sleep disorders.

The LINX Reflux Management System is a laparoscopic, fundic-sparing anti-reflux procedure indicated for patients diagnosed with Gastroesophageal Reflux Disease (GERD) as defined by abnormal pH testing, and who are seeking an alternative to continuous acid suppression therapy (i.e. proton pump inhibitors or equivalent) in the management of their GERD. **Rx Only. 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:** belching, decreased appetite, device erosion, device migration (device does not appear to be at implant site), dysphagia (difficulty swallowing), flatulence, hiccups, inability to belch or vomit, infection, nausea, odynophagia (painful swallowing), pain, regurgitation, stomach bloating, weight loss, 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.linxforlife.com or www.toraxmedical.com.

Manufactured by:

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