LINX® Reflux Management System
Fact Sheet
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 Reflux Management System 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 bothersome heartburn in 88% of patients.⁷
- Patients reported a significant improvement in their quality of life.³

Simply designed to be simple.

LINX Reflux Management System is easy to understand and love because it is simple. LINX Reflux Management System 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 Reflux Management System 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

References

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)
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. 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, bothersome heartburn was 89% at baseline and decreased to 11.9% at 5 years. (p<0.001)
LINX® Reflux Management System Important Safety Information

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 Reflux Management 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. Scanning under different conditions may result in serious injury to you and/or interfere with the magnetic strength and the function of the device. In the event alternative diagnostic procedures cannot be used and MRI is required, the LINX device can be safely removed utilizing a laparoscopic technique that does not compromise the option for traditional anti-reflux procedures. It is recommended that patients receiving the LINX device register their implant with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

Failure to secure the LINX device properly may result in its subsequent displacement and necessitate a second operation. Laparoscopic placement of the LINX device is major surgery and death can occur.

General Precautions: The LINX device is a long-term implant. Explant (removal) and replacement surgery may be indicated at any time. Management of adverse reactions may include explantation and/or replacement.

The use of the LINX device in patients with a hiatal hernia larger than 3 cm should include hiatal hernia repair to reduce the hernia to less than 3 cm. The LINX device has not been evaluated in patients with an unrepaired hiatal hernia greater than 3 cm.

The safety and effectiveness of the LINX device has not been evaluated in patients with Barrett’s esophagus or Grade C or D (LA classification) esophagitis.

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The safety and effectiveness of the LINX device has not been evaluated in patients with a hiatal hernia larger than 3 cm.

The safety and effectiveness of the LINX device has not been evaluated in patients with electrical implants such as pacemakers and defibrillators, or other metallic, abdominal implants.

The safety and effectiveness of the LINX Reflux Management System has not been established for the following conditions:

- Scleroderma
- Suspected or confirmed esophageal or gastric cancer
- Prior esophageal or gastric surgery or endoscopic intervention
- Distal esophageal motility less than 35 mmHg peristaltic amplitude on wet swallows or <70% (propulsive) peristaltic sequences or High Resolution Manometry equivalent, and/or a known motility disorder such as Achalasia, Nutcracker Esophagus, and Diffuse Esophageal Spasm or Hypertensive LES
- Symptoms of dysphagia more than once per week within the last 3 months
- Esophageal stricture or gross esophageal anatomic abnormalities (Schatzki’s ring, obstructive lesions, etc.)
- Esophageal or gastric varices
- Lactating, pregnant or plan to become pregnant
- Morbid obesity (BMI >35)
- Age < 21

Potential Side Effects: Potential adverse events associated with laparoscopic surgery and anesthesia include adverse reaction to anesthesia (headache, muscle pain, nausea), anaphylaxis (severe allergic reaction), cardiac arrest, death, diarrhea, fever, hypotension (low blood pressure), hypoxemia (low oxygen levels in the blood), infection, myocardial infarction, perforation, pneumonia, pulmonary embolism (blood clot in the lung), respiratory distress, and thrombophlebitis (blood clot). Other risks reported after anti-reflux surgery procedures include bloating, nausea, dysphagia (difficulty swallowing), odynophagia (painful swallowing), retching, and vomiting.

Potential risks associated specifically with the LINX Reflux Management System include achalasia (lower part of esophagus does not relax), bleeding, cough, death, decreased appetite, device erosion, device explant/re-operation, device failure, device migration (device does not appear to be at implant site), diarrhea, dyspepsia (indigestion), dysphagia (difficulty swallowing), early satiety (feeling full after eating a small amount of food), esophageal spasms, esophageal stricture, flatulence, food impaction, globus sensation (sensation of a lump in the throat), hiccups, inability to belch or vomit, increased belching, infection, impaired gastric motility, injury to the esophagus, spleen, or stomach, nausea, odynophagia (painful swallowing), organ damage caused by device migration, pain, peritonitis (inflammation of the peritoneum), pneumothorax (collapsed lung), regurgitation, saliva/mucus build-up, stomach bloating, ulcer, vomiting, weight loss, and worsening of preoperative symptoms (including but not limited to dysphagia or heartburn).

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