

Understanding Reflux Disease



Reflux Disease Overview

What is reflux disease?

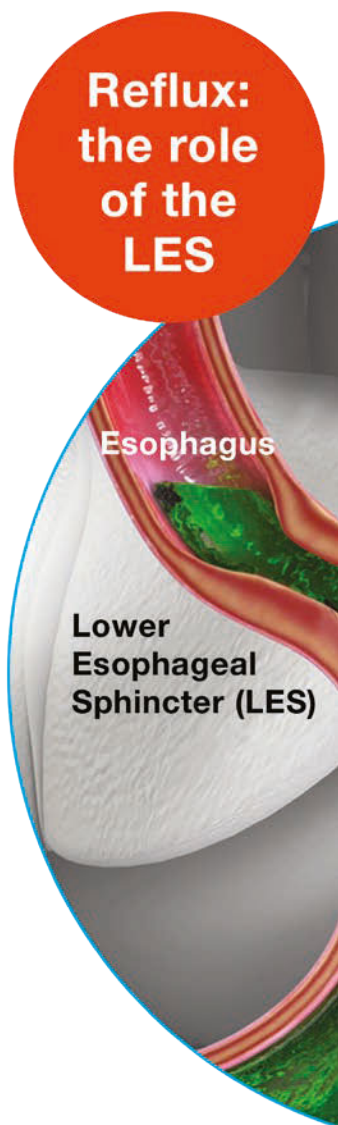
Reflux disease (also called Gastroesophageal reflux disease, or GERD) is a chronic digestive disease in which acid and bile flow back from the stomach into the esophagus, creating pain and often causing damage to the lining of the esophagus.

What causes reflux disease?

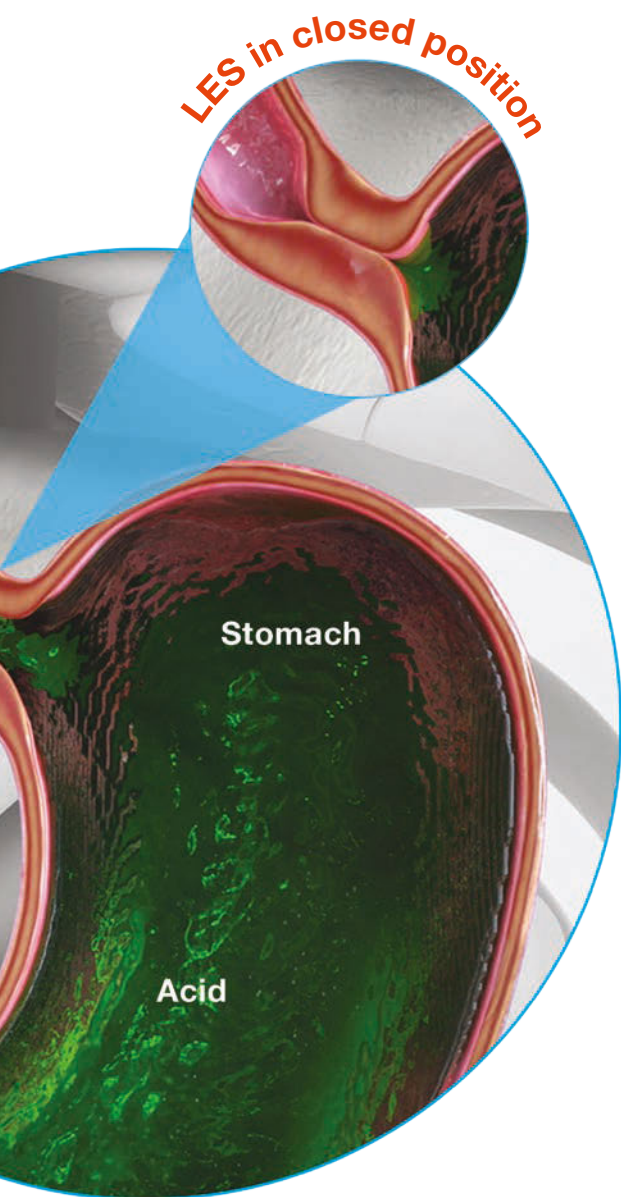
Reflux disease is caused by weakness or inappropriate relaxation in a muscle called the lower esophageal sphincter (LES). Normally the LES acts like a valve allowing food and liquid to pass into the stomach but preventing stomach contents from flowing back into the esophagus.

GERD affects
1 in 5 adults
in the U.S.¹

**Reflux:
the role
of the
LES**



In people with reflux, a weak LES allows harmful acid and bile to flow back into the esophagus.



What are the symptoms & complications of reflux?

Symptoms

The most common symptom of reflux disease is heartburn. However, reflux disease can produce a wide variety of symptoms including:

- Heartburn
- Regurgitation
- Hoarseness
- Sore throat
- Cough
- Chest pain
- Shortness of breath
- Difficulty swallowing
- Asthma



Complications*

In addition to producing a wide range of symptoms, reflux disease can lead to potentially serious complications including:

- Esophagitis (inflammation that can damage the tissue of the esophagus)
- Stricture (narrowing of the esophagus)
- Barrett's esophagus (pre-cancerous changes to the tissue lining the esophagus)
- Esophageal cancer (in rare cases)**



* LINX® Is not intended to cure, treat, prevent, mitigate or diagnose these symptoms or complications

** 0.5% of Barrett's esophagus patients per year are diagnosed with esophageal cancer

Living with reflux disease

Patients with reflux disease often experience:

- Poor quality of sleep
- Reduced work productivity
- Dietary compromises to avoid symptoms
- Concerns about the long-term effects of reflux disease
- Life-long dependence on reflux medications

Reflux disease can affect your life beyond the symptoms you feel.





How is reflux disease diagnosed?

There are several tests that your physician may use to diagnose reflux disease, including:

Response to medication: a trial of proton pump inhibitors (PPI) medication may be used to confirm diagnosis in patients with typical symptoms.

EGD: esophagogastroduodenoscopy (EGD), also known as upper Endoscopy, is a test that examines the esophagus and LES for evidence of reflux disease.

pH monitoring: a probe is used in the esophagus near the stomach to measure the level of esophageal acid exposure.

How is reflux disease treated?

Lifestyle Modifications

Diet modifications such as reducing or eliminating spicy/acidic food, caffeine, chocolate, alcohol and tobacco may help reduce reflux. Elevating the head of your bed, eliminating meals 2-3 hours before bed, and weight loss (in overweight patients) may also ease your reflux symptoms.



Medication

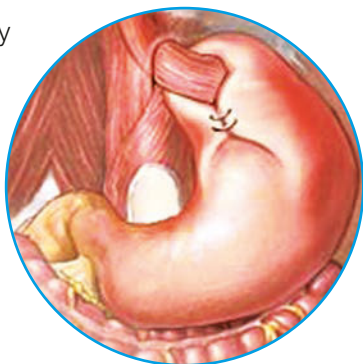


Medication is commonly used to treat heartburn and reflux. Reflux medications are designed to reduce acid production in the stomach and may provide relief from heartburn symptoms and may reduce inflammation of the esophageal lining. These medications do not address the cause of reflux (weak LES) or prevent reflux. Side effects may include headache, diarrhea, and upset stomach.² Long-term use of PPIs may also produce side effects including possible fracture risk, low magnesium levels, and clostridium difficile-associated diarrhea.² Studies have shown that up to 40% of patients continue to have symptoms while on medication.³

Fundoplication Surgery

Fundoplication involves wrapping the upper part of the stomach around the outside of the esophagus at the LES during an open, laparoscopic, or endoscopic procedure. It has been shown to reduce symptoms of heartburn and reflux, and may also end dependence on medication.⁴ Fundoplication may result in difficulty swallowing, the inability to belch or vomit when needed, bloating, and the return of symptoms over time.

This procedure permanently alters the stomach anatomy, may require a hospital stay of 1-3 days, requires a modified diet for several weeks, and may limit activity for 2-3 weeks.



LINX® Reflux Management System

A revolutionary treatment for GERD, LINX® Reflux Management System is a flexible ring of small magnets placed around the LES, right above the opening to the stomach, to help prevent reflux. LINX® has been shown to reduce heartburn and reflux, reduce gas/bloating, and improve quality of life.⁶ Some patients may experience difficulty swallowing. LINX® is intended for patients diagnosed with GERD and who are seeking an alternative to continuous acid suppression therapy.



LINX[®] Reflux Management System

Don't Compromise... Get long-term GERD relief with LINX^{®5}

LINX[®] is not a pill. It's a revolutionary treatment for GERD that is clinically shown to produce consistent, lasting results.^{3,4,6*}

After treatment with LINX[®], 99% of patients no longer experienced regurgitation.⁷ Over 85% were free of heartburn—and no longer needed daily reflux medication!⁸



88%

of patients were free of heartburn⁹



85%

were free from dependence on daily reflux medication¹⁰



99%

of patients eliminated regurgitation⁷



Significant improvement in quality of life¹¹



Significant improvement in bloating and gas¹²

*Individual results may vary



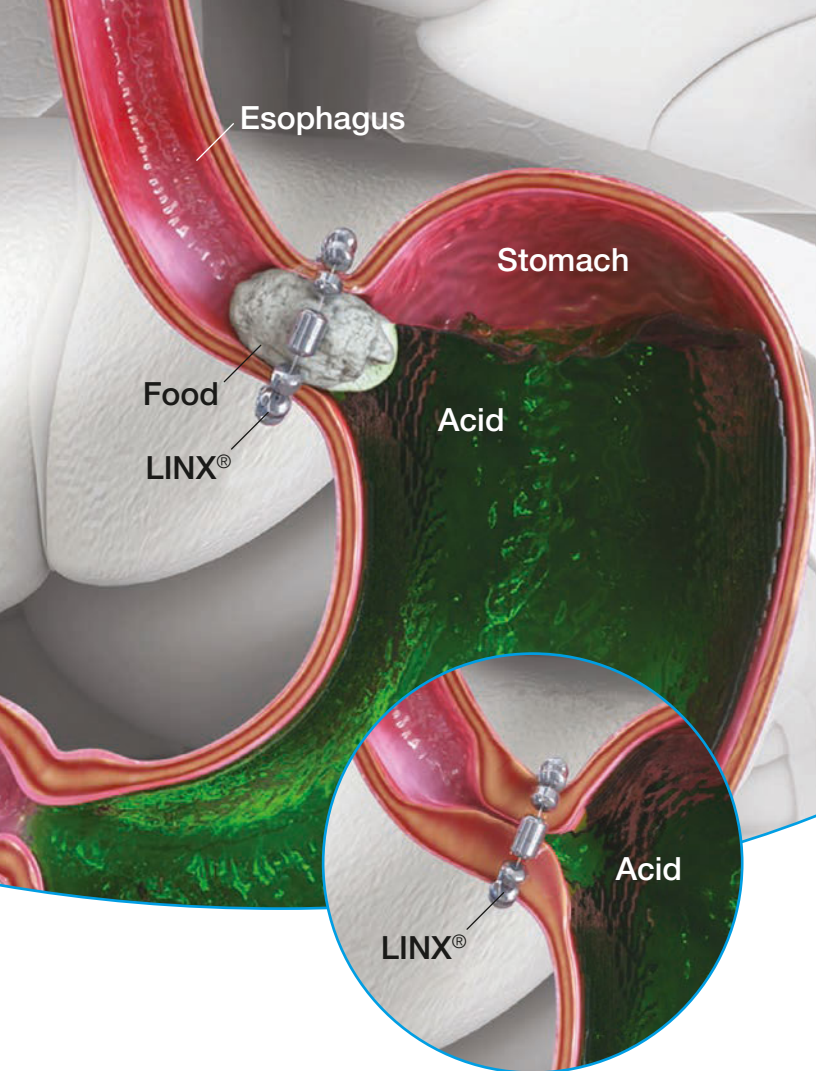
Just imagine what
long-lasting GERD relief
might be like for you.

How LINX® Works

The magnets help to keep the LES closed to help prevent harmful stomach acid from flowing back up into the esophagus, where it can cause painful heartburn and damage. When you eat or drink, the forces from swallowing cause the magnets to separate, the LINX® device to expand, and the LES to open for food or liquid to pass into the stomach.

With LINX®,
acid stays in the stomach
where it belongs.





A Short Outpatient Procedure

Unlike other surgical treatments for GERD,* LINX® does not require changes to the stomach anatomy. LINX® is implanted during a minimally invasive procedure that is generally completed in less than one hour.¹³ Patients typically go home within 24 hours, and most return to normal activities in just a few days.¹⁴

And, best of all, they can resume a regular diet.¹⁵

* As of January 28, 2020.

MRI compatible

This quarter-sized device is constructed from materials commonly used in other medical implants.¹⁶ Patients with a LINX® device can undergo a wide range of diagnostic imaging tests including: X-ray, ultrasound, PET scan, CT scan and MRI.¹⁷



Are you concerned with
a lifetime of medication,
pharmacy visits and
potential side effects?

Imagine life after LINX®

Picture being free to live in the moment again, without worrying about GERD. After treatment with LINX®, patients reported a significant improvement in their quality of life.¹¹ It's time to start your journey to controlling reflux long term.

If this sounds like you,
it may be time
to talk to a doctor.



To learn more
or find a LINX[®] surgeon visit
linxforlife.com.



Is Surgery Right for You?

There are many reasons patients consider surgery as an alternative to medical therapy.

- Are you dependent on medication to manage your reflux disease symptoms?
- Do you continue to suffer reflux disease symptoms while on medication?
- Is your reflux disease affecting your quality of life? (Examples: poor sleep, inability to tolerate certain foods, inability to participate in daily activities)
- Are you concerned about the long-term use of medication to treat your reflux disease?
- Are you concerned about the long-term risks of serious complications from your reflux disease?

Talk with your physician about your treatment options if your physician determines you are not responding to medication.

Patients who choose surgical treatment for GERD may need to undergo additional pre-surgical testing such as manometry (swallow function), EGD, or biopsy.

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 MedAlert 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.

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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3. 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.
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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.
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, regurgitation was 57% at baseline and decreased to 1.2% at 5 years. ($p<0.001$).
8. 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. Bothersome heartburn decreased to 11.9% at 5 years from 89% ($p<0.001$, $n=100$) and PPI dependence decreased to 15.3% at 5 years from 100% ($p<0.001$, $n=100$).
9. 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. ($p<0.001$).
10. 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. ($p<0.001$).
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14. Based on a pivotal IDE trial of 100 subjects at 14 clinical sites. Half of the subjects (50/100) were discharged the same day as the surgery, and the other half were discharged the next day.
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16. The LINX device consists of titanium beads with magnetic cores that are connected with independent titanium wires.
17. This device can be scanned safely under the following conditions: 1) 1.5-Tesla static magnetic field, 2) maximum spatial gradient field of 17.15 T/cm, 3) maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4.0 W/kg in First Level Controlled Operating Mode, and 4) the patient may feel pressure around the lower esophagus; should the patient experience pain, immediately discontinue the scan and remove the patient from the MR environment.

Notes



Visit linxforlife.com
to learn more about LINX.



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