



I want pizza...but will GERD make me pay for it later?

Reflux Disease

and your treatment options

Reflux Disease

What is Reflux Disease?

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

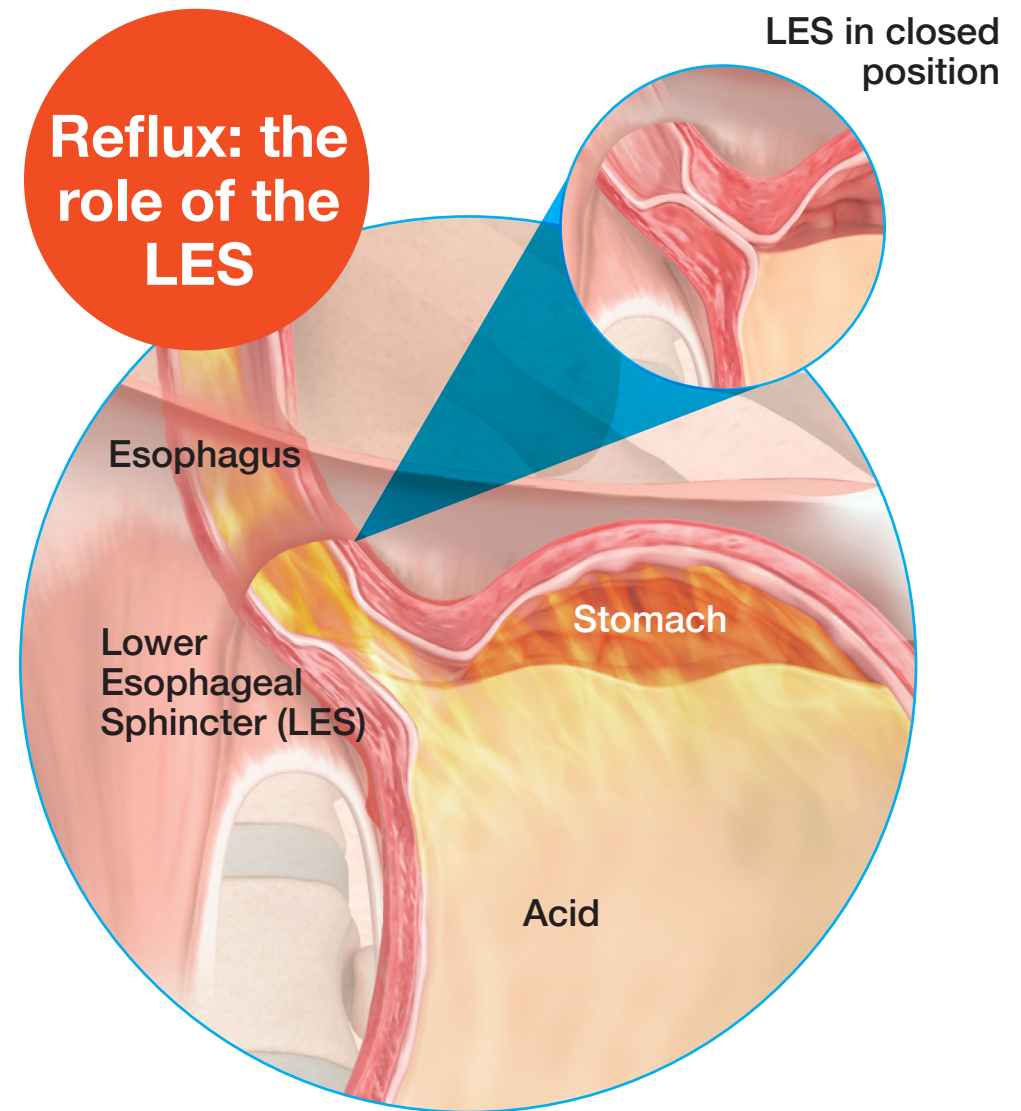
Complications of Reflux Disease*

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

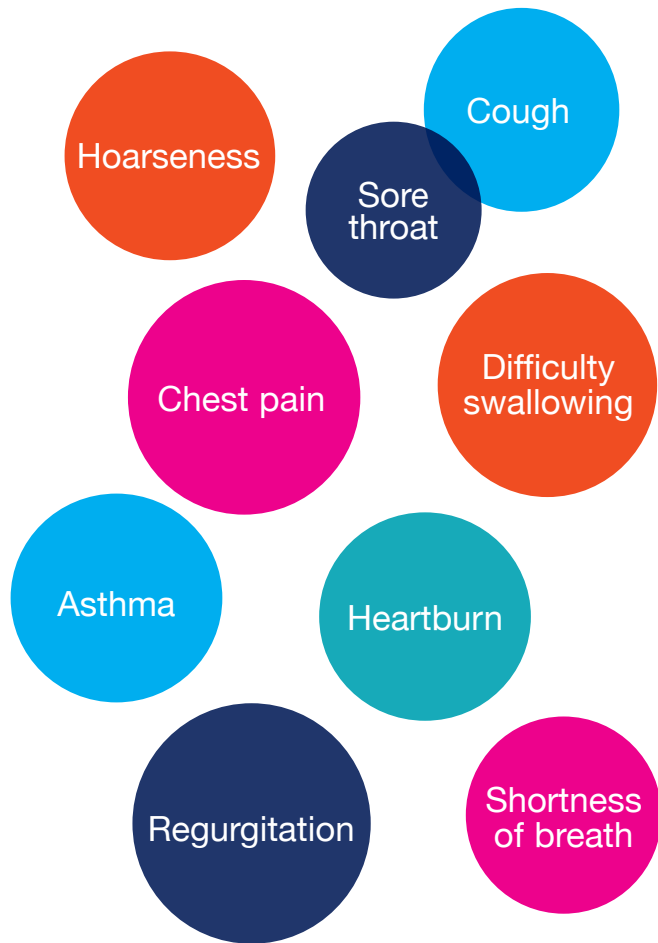
**0.5% of Barrett's Esophagus patients per year are diagnosed with esophageal cancer



In people with reflux disease, the lower esophageal sphincter is weak or relaxes inappropriately, allowing acid and bile to flow back from the stomach into the esophagus.

Symptoms

The most common symptom of reflux disease is **heartburn**. However, reflux disease can produce a wide variety of symptoms including those listed below.



Living with Reflux Disease

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

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



How is Reflux Disease Diagnosed?

There are several tests that your physician may use to diagnose reflux disease. Here are some examples.

1 Response to medication

A trial of PPI medication may be used to confirm diagnosis in patients with typical symptoms.

2 EGD

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

3 pH

pH monitoring using a probe in the esophagus near the stomach measures the level of esophageal acid exposure.



If you think you have reflux disease or have new or worsening symptoms on medication therapy, inform your physician.

Treatments

Treatment: Lifestyle Modification

Diet Modification

- Spicy/acidic food
- Caffeine
- Chocolate
- Alcohol and tobacco



Lifestyle Modifications

- Elevation of head of bed
- No meals 2 - 3 hours before bed
- Weight loss in overweight patients



Treatment: Medication

In addition to dietary and lifestyle changes, medication is commonly used to treat heartburn, the most common symptom of reflux disease.

Benefits

- Reduced stomach acid production
- Relief from heartburn symptoms
- Reduced inflammation of the esophageal lining

Limitations/Risks

- May not provide adequate symptom relief
- Does not affect the mechanical cause of reflux disease (LES)
- Does not prevent reflux disease
- Side effects include:¹ headache, diarrhea, and upset stomach
- Up to 40% of patients continue to have symptoms while on medication²
- Possible side effects of long-term use of Proton Pump Inhibitors (PPI) including: possible fracture risk, low magnesium levels, and clostridium difficile-associated diarrhea¹



Traditional Anti-Reflux Surgery: Fundoplication

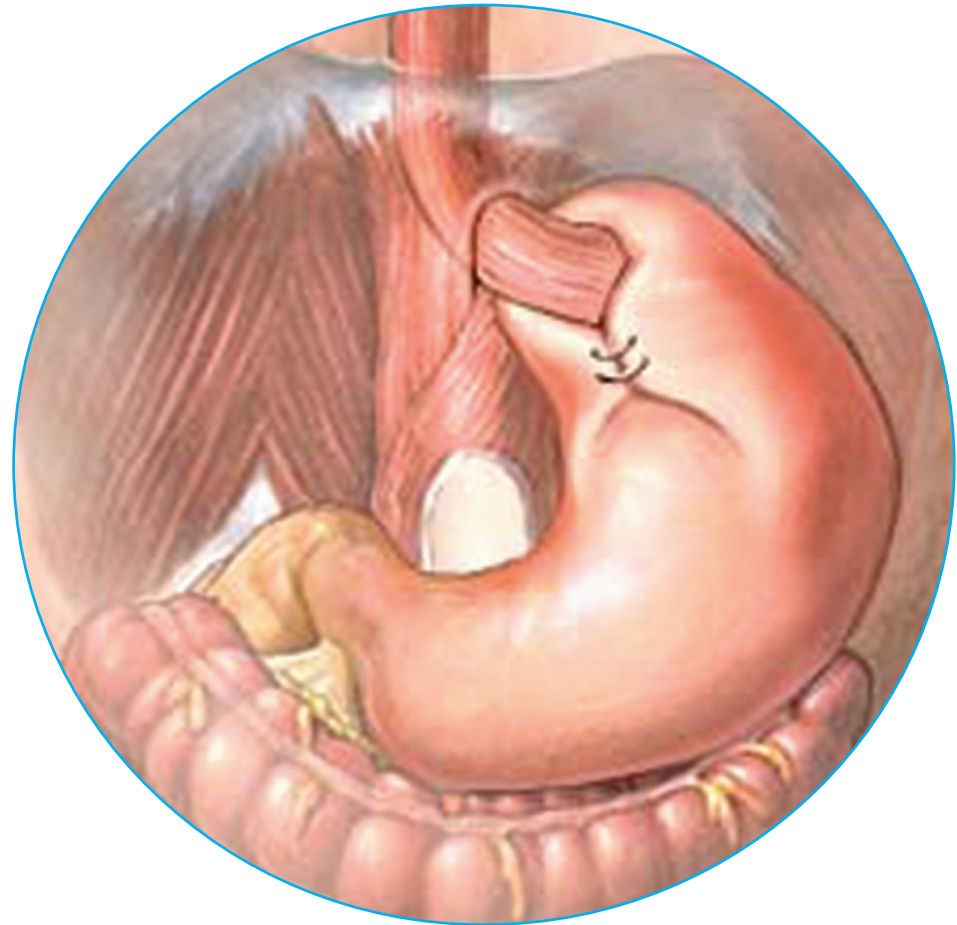
Fundoplication surgery involves wrapping the upper part of the stomach around the outside of the esophagus at the lower esophageal sphincter (LES) to help prevent reflux.

Benefits

- Reduced symptoms of heartburn, and regurgitation
- May heal damage to the esophagus³
- May end dependence on medication⁴

Limitations/Risks

- Difficulty swallowing
- Inability to belch or vomit when needed
- Permanently alters the stomach anatomy
- Typically requires hospital stay of 1-3 days
- Symptoms may return over time
- Requires a modified diet for several weeks
- May limit activity for 2-3 weeks
- Risks related to surgery and anesthesia



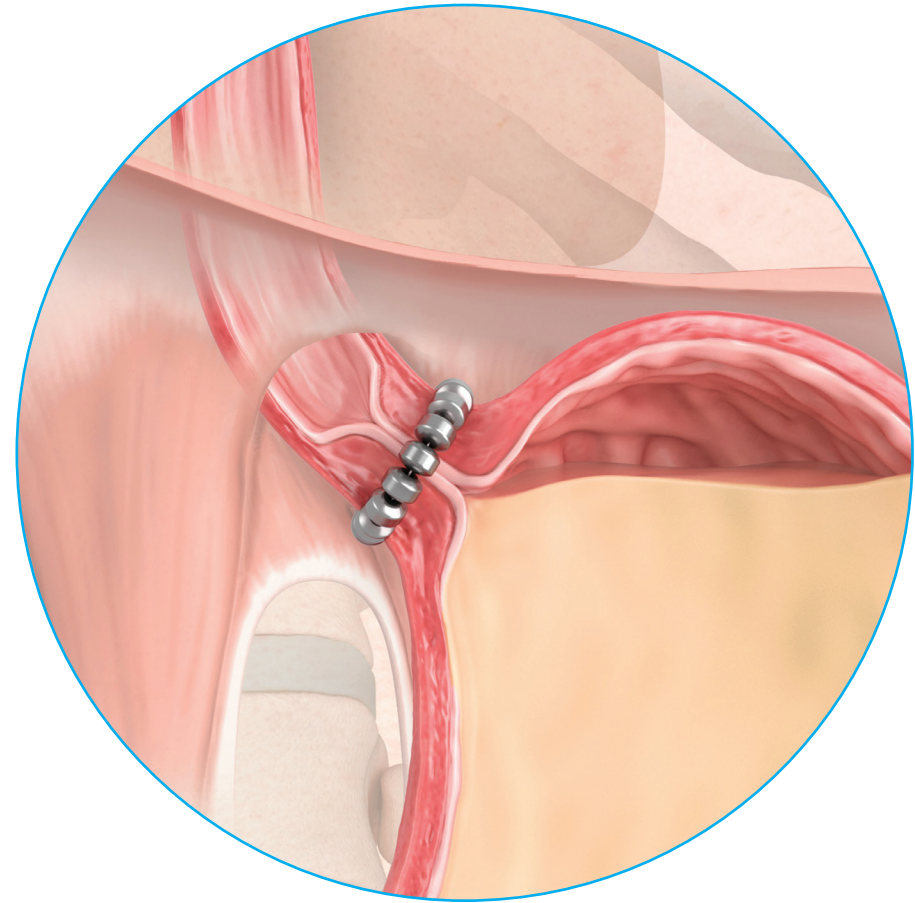
Alternative Anti-Reflux Surgery: LINX™

Benefits

- Durable resolution of bothersome heartburn and regurgitation^{5*†}
- Requires no alteration to the stomach anatomy
- Patients typically go home in less than 24 hours^{6‡} and resume a regular diet⁷
- Patients are generally able to return to non-strenuous activity within a couple of days
- Reduced gassiness and bloating^{4§}
- Preserved the ability to belch and vomit^{4,5#}

Limitations/Risks

- Incomplete symptom relief
- Difficulty swallowing
- Risks related to surgery and anesthesia
- Device failure



* Based on a 100 patient, 5 year, prospective, multi-center, single-arm study of patients who were implanted with LINX, bothersome heartburn was 89% at baseline and decreased to 11.9% at 5 years. ($p < 0.001$)

† 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. ($p < 0.001$)

‡ 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.

§ Based on a retrospective analysis of 1-year outcomes of patients undergoing MSA and LNF from June 2010 to June 2013. Matched-pair analysis of 100 patients. There were no patients with severe gas and bloating in the MSA group compared with 10.6% in the LNF group ($p = 0.022$).

Based on a prospective study of 100 adults who underwent MSA in which all patients reported the ability to belch and vomit (if necessary), and a retrospective matched-pair analysis of 1-year outcomes of 100 patients undergoing MSA and LNF from June 2010 to June 2013. After MSA 8.5% of patients were unable to belch compared to 25.5% of patients after LNF ($p = 0.028$), and 4.3% of MSA patients were unable to vomit compared to 21.3% of LNF patients ($p = 0.004$).

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 drugs 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.



LINX™ Reflux Management System

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.



Redefining the Surgical Treatment of Reflux Disease

How LINX™ Works

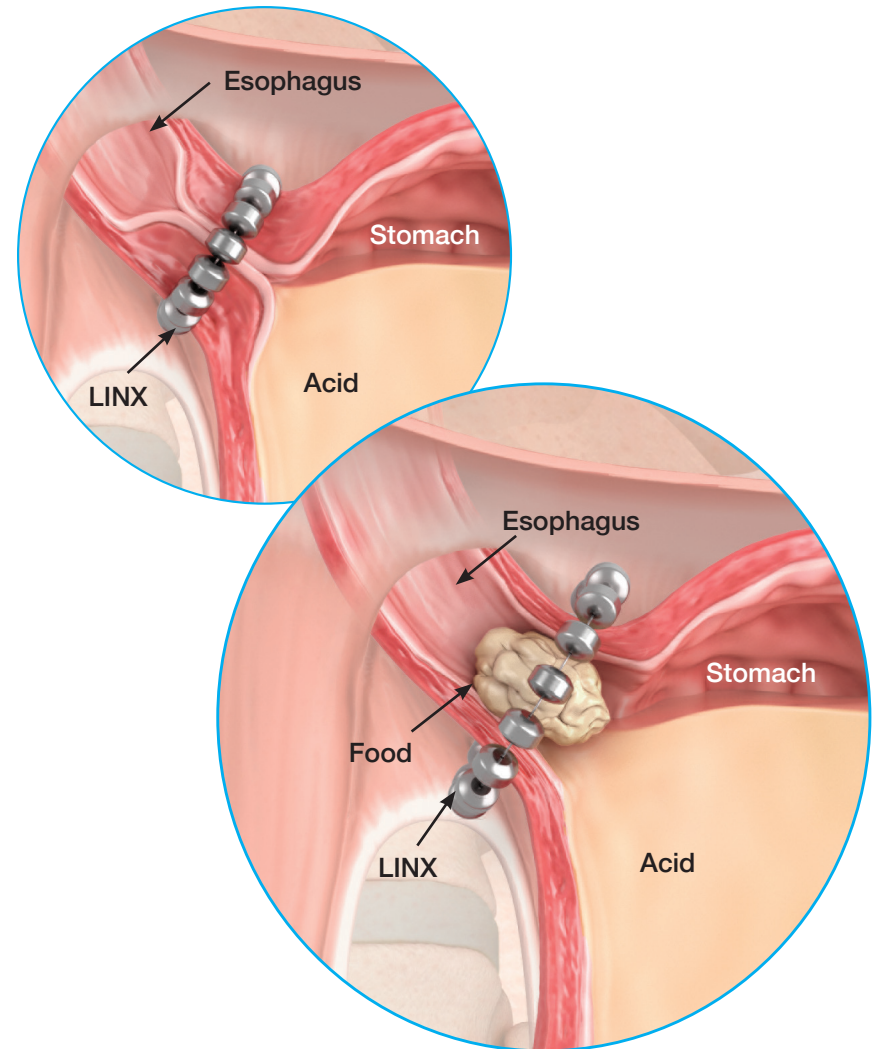
LINX is a small, flexible ring of magnets placed around the esophagus during a minimally invasive procedure.

The magnets help to keep the lower esophageal sphincter (LES) closed so that acid and bile do not flow from the stomach to the esophagus.

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.

MRI Conditional

The LINX device is MRI conditional,⁶ so patients can undergo magnetic resonance imaging up to either 0.7-Tesla (0.7T) or 1.5-Tesla (1.5T), depending on the LINX model implanted.



Control Reflux, Long Term with LINX™⁵

85% of patients were off daily reflux medications after treatment with LINX^{5*}

99% of patients experienced no regurgitation 5 years after LINX treatment^{5†}

88% of patients reported no bothersome heartburn after 5 years^{5‡}

Patients reported a significant improvement in their **Quality of Life**^{5§}



* Based on a 5 year prospective, multi-center, single-arm study observing 100 patients who were implanted with LINX, daily use of PPIs was 100% at baseline and decreased to 15.3% at 5 years. (p<0.001)

† 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)

‡ Based on a 100 patient, 5 year, prospective, multi-center, single-arm study of patients who were implanted with LINX, bothersome heartburn was 89% at baseline and decreased to 11.9% at 5 years. (p<0.001)

§ 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).

LINX™ is an effective option to treat GERD after Sleeve Gastrectomy

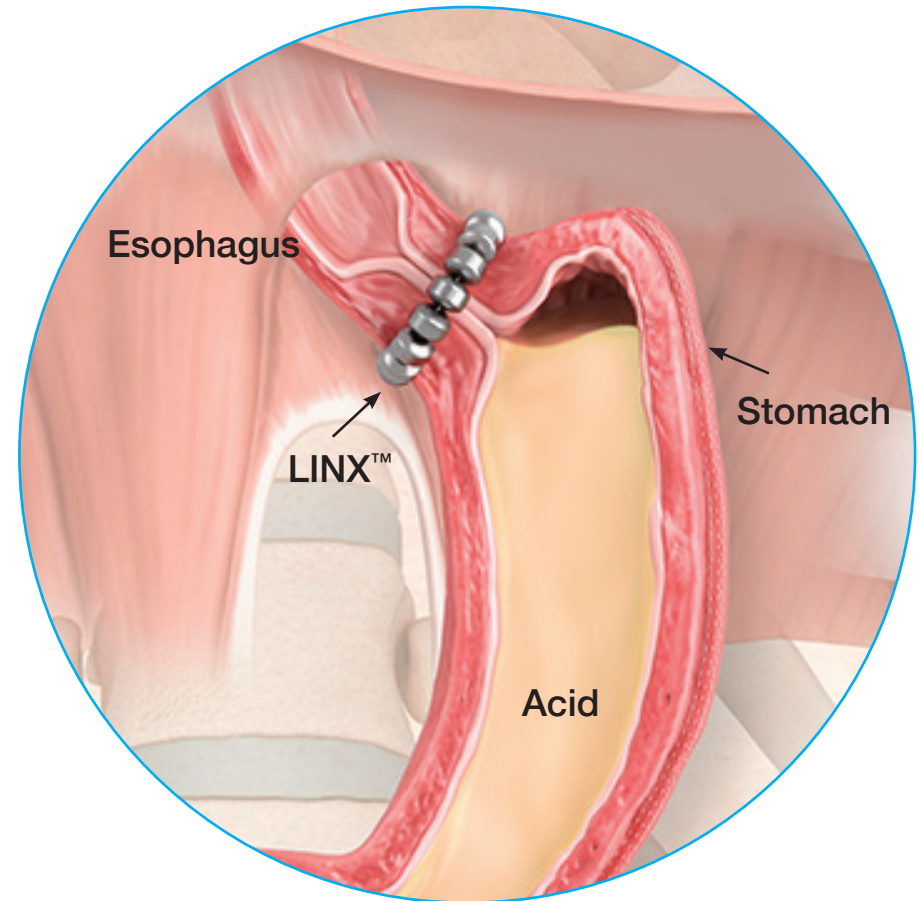
Clinical results of LINX™ in post-sleeve patients

85% of patients were free from daily PPIs at one year.^{8*}

81% of patients were free from moderate-to-severe heartburn at one year.^{9†}

92% of patients were free from moderate-to-severe regurgitation at one year.^{8‡}

81% of patients reported improved quality of life one year after LINX treatment.^{8§}



* 15.4% (4/26) of patients implanted with LINX, after laparoscopic sleeve gastrectomy, were on PPIs at 12 months vs. 100% at baseline.

† Based on Foregut Symptom Questionnaire responses at 12 months (n=26) of patients implanted with LINX after laparoscopic sleeve gastrectomy.

‡ 7.7% (2/26) of patients implanted with LINX, after laparoscopic sleeve gastrectomy, had moderate-to-severe regurgitation at 1 year vs. 80% (24/30) at baseline.

§ 80.8% (21/26) of patients implanted with LINX, after laparoscopic sleeve gastrectomy, reported ≥50% reduction in GERD-HRQL from baseline to 12-month follow-up (p<0.001)

FAQs

What is LINX™?	LINX is a flexible ring of small magnets placed around the esophagus just above the stomach during a minimally invasive procedure to help prevent reflux.
How does LINX work?	The strength of the magnets helps keep the valve between your stomach and esophagus closed to prevent reflux. When you swallow, the magnets separate temporarily to allow food and liquid to pass into the stomach.
How is LINX different from other procedures?	LINX requires no permanent anatomic alteration, reduced gas and bloating, ^{4*} preserved the ability to belch and vomit, ^{4,5†} and patients typically go home within 24 hours ^{6‡} and resume a regular diet. ⁷
How is LINX implanted?	LINX is placed around the esophagus just above the stomach using a minimally invasive surgical technique. Many patients are able to go home the same day.
Can LINX be removed if needed?	Yes. LINX can be removed using a minimally invasive procedure and preserves patients' future treatment options. ^{5§}
How do I know if I am a candidate for LINX?	Three diagnostic tests are used to determine if patients may be candidates for LINX: EGD, pH and Manometry.
What does LINX cost?	For patients with insurance, the out-of-pocket cost is based on your insurance plan, including deductibles and co-payments.
Does insurance cover LINX?	Insurance companies and Medicare are approving patients for LINX on a case-by-case basis. Once you have completed your pre-tests and are a candidate for LINX, your surgeon will start the approval process.
When can I start eating normally again?	Patients are encouraged to return to a normal diet as soon as tolerated or as directed by their physician.

* Based on a retrospective analysis of 1-year outcomes of patients undergoing MSA and LNF from June 2010 to June 2013. Matched-pair analysis of 100 patients. There were no patients with severe gas and bloating in the MSA group compared with 10.6% in the LNF group (p=0.022)

† Based on a prospective study of 100 adults who underwent MSA in which all patients reported the ability to belch and vomit (if necessary), and a retrospective matched-pair analysis of 1-year outcomes of 100 patients undergoing MSA and LNF from June 2010 to June 2013. After MSA 8.5% of patients were unable to belch compared to 25.5% of patients after LNF (p=0.028), and 4.3% of MSA patients were unable to vomit compared to 21.3% of LNF patients (p=0.004)

‡ 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

§ Based on a prospective study of the safety and efficacy of magnetic devices in 100 adults with GERD for 6 months or more, who were partially responsive to daily PPIs and had evidence of pathologic esophageal acid exposure, at 14 centers in the US and Netherlands. Three patients underwent uneventful Nissen fundoplication after LINX device removal.

FAQs continued

When can I return to normal activities?

Patients are generally able to return to non-strenuous activity within a couple of days.

How long will LINX last?

LINX is designed to be a lifelong implant.

Can I go through airport security?

LINX should not affect airport security. All patients are provided an implant card to let people know they have an implant.

Can I have an MRI?

Yes. Patients with a LINX device can undergo a wide range of diagnostic imaging tests, including: X-Ray, ultrasound, PET scan, CT scan, and MRI under certain conditions.⁶ LINX patients may undergo magnetic resonance imaging (MRI) up to 1.5-Tesla (1.5T). You should discuss the MRI scanning options with your physician prior to deciding on treatment with LINX.

What are potential risks associated with LINX?

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. Please see Important Safety Information for a full description of potential side effects and warnings.

Where can I find more information about LINX?

www.linxforlife.com or 855-276-LINX.

References: **1.** Katz, P.O., Gerson, L.B., et al. Guidelines for the Diagnosis and Management of Gastroesophageal Reflux Disease. *Am J Gastroenterol*. 2013. 108:308–328; doi: 10.1038/ajg.2012.444 **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.** Kellokumpu I, Voutilainen M, Haglund C, et al. Quality of life following laparoscopic Nissen fundoplication: Assessing short-term and long-term outcomes. *World J Gastroenterol*. 2013. 19(24):3810-18. **4.** 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. **5.** 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. **6.** LINX Reflux Management System, Instructions for Use. Ethicon, Inc. **7.** Ayazi S, Zheng P, Zaidi AH, et al. Magnetic sphincter augmentation and postoperative dysphagia: Characterization, clinical risk factors, and management. *J Gastrointest Surg*. 2020;24(1):39-49. **8.** RELIEF Study: A Prospective, Multicenter Study of Reflux Management with the LINX® System for Gastroesophageal Reflux Disease After Laparoscopic Sleeve Gastrectomy. Ethicon Inc., Internal Report. October 14, 2021. **9.** The LINX Reflux Management System IDE Study Table 17b, Foregut Symptoms Questionnaire by Visit (Off PPI). Ethicon Inc., Internal Report. October 14, 2021.

The information provided is not medical advice and is intended for educational purposes only. Talk to a physician if you have concerns about your health. Call 911 in the event of a medical emergency.

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 MedicalAlert 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.

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 with the exception of Laparoscopic Sleeve Gastrectomy (LSG) which has been evaluated for safety and efficacy.
- 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, swallow-Induced syncope (fainting), stomach bloating, ulcer, vomiting, weight loss, and worsening of preoperative symptoms (including but not limited to dysphagia or heartburn).

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For more information on LINX ask your physician or visit www.linxforlife.com

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