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# Identifying the LINX® Reflux Management System Patient

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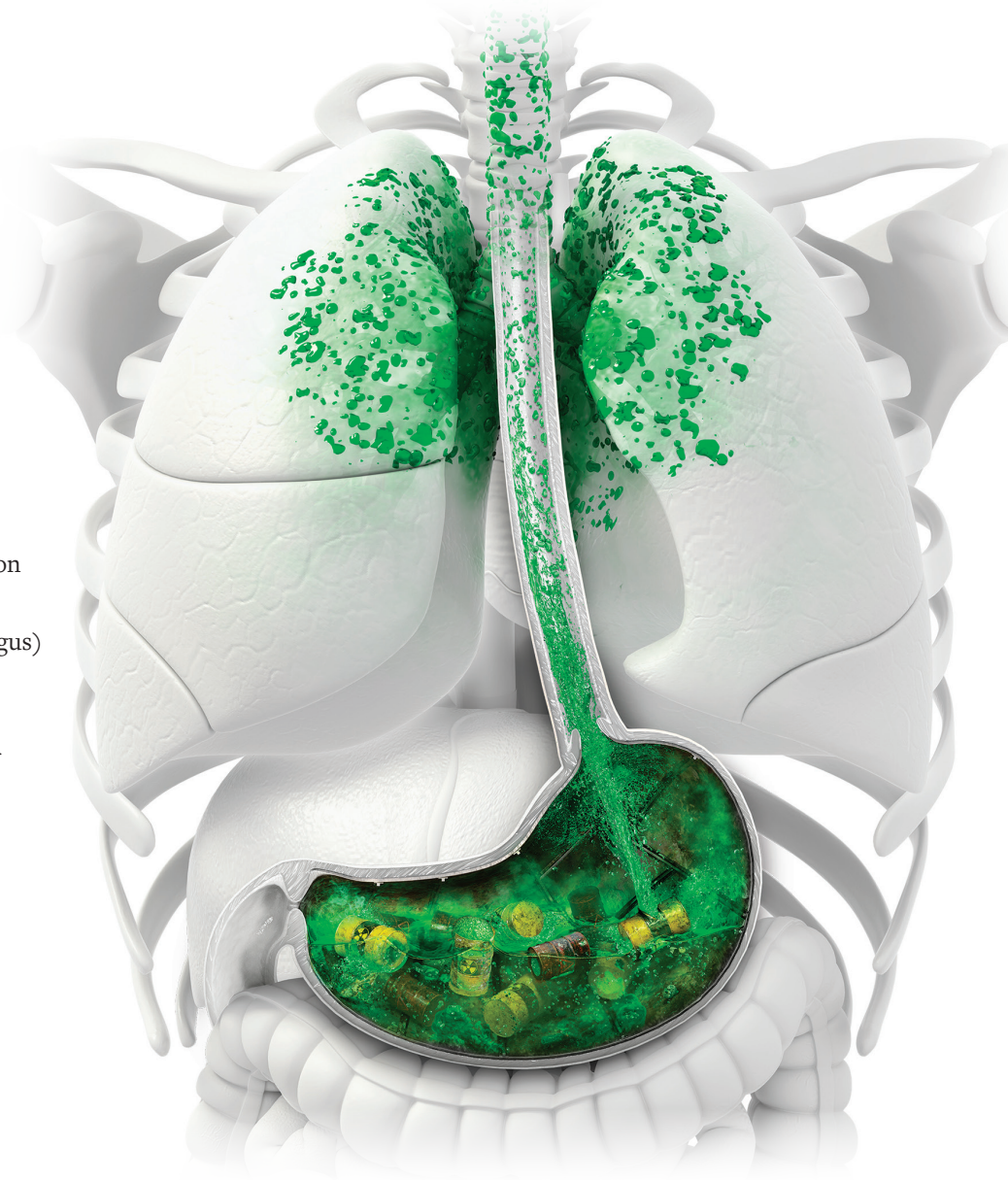
# What is GERD?

Gastroesophageal Reflux Disease, or GERD is a chronic digestive disease, caused by weakness or inappropriate relaxation in a muscle called the lower esophageal sphincter (LES). Normally, the LES behaves like a one-way valve, allowing food and liquid to pass through to the stomach, but preventing stomach contents from flowing back into the esophagus.

## Symptoms of GERD

- Heartburn
- Chest pain
- Regurgitation
- Dysphagia (difficulty swallowing)
- Dental erosion and bad breath
- Cough
- Hoarseness
- Sore throat
- Asthma



## Complications *

GERD can lead to potentially serious complications including:

- Esophagitis (inflammation, irritation or swelling of the esophagus)
- Stricture (narrowing of the esophagus)
- Barrett's esophagus (precancerous changes to the esophagus)
- Esophageal cancer (in rare cases)**

## Diagnosing GERD

- Response to medication
- Endoscopy/EGD
- Bravo pH monitoring

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

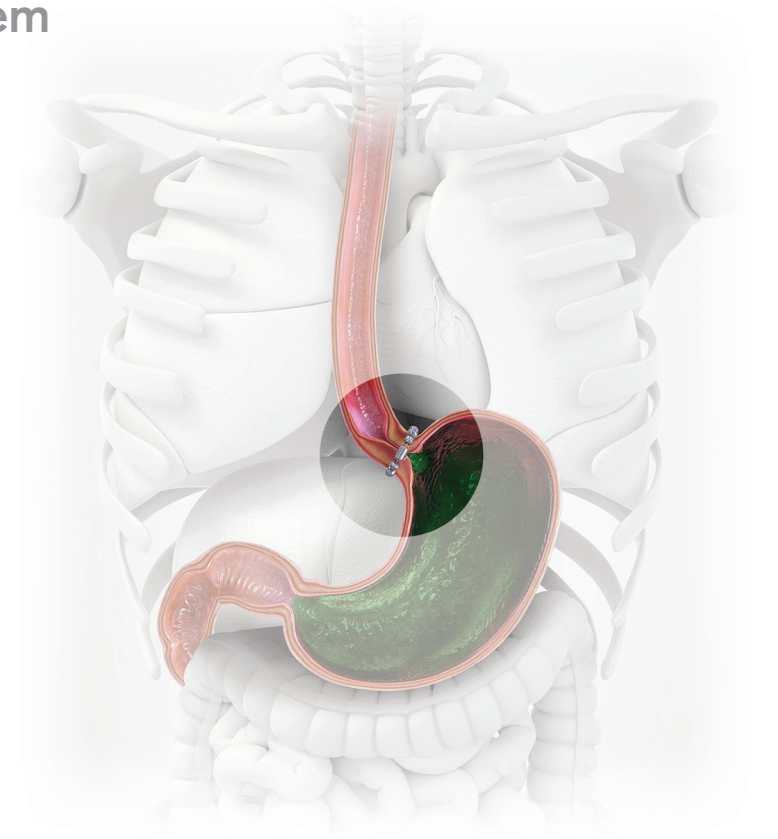
**0.5% of Barrett's esophagus patients per year are diagnosed with esophageal cancer

# Who is the LINX® Reflux Management System patient?

- Diagnosed with GERD as defined by abnormal pH testing
- Patients seeking an alternative to continuous acid supression therapy

## LINX Reflux Management System patient workup

- Objective reflux – pH testing
- Anatomy – EGD
- Esophageal function – Manometry



## Restore don't reconstruct[1*]

- Requires no alteration to stomach anatomy
- Preserved ability to belch and vomit[2†]
- Removable
- Preserves future treatment options[1‡]

## Patient benefits at 5 years[1]

- 85% of patients were off daily reflux medications after treatment with LINX Reflux Management System[§]
- Elimination of regurgitation in 99% of patients[¶]
- 88% elimination of bothersome heartburn[**]
- Patients reported significant improvement in quality of life[††]
- Patients reported a significant improvement in symptoms of bloating and gas[€]

### References


1. 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.
2. 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.


* Based on a 5-year tudy observing 100 patients who were implanted with LINX. Bothersome heartburn was 89% at baseline and decreased to 11.9% at 5 years($p<0.001$), bothersome regurgitation was 57% at baseline and decreased to 1.2% at 5 years ($p<0.001$), PPI dependence decreased to 15.3% at 5 years ($p<0.001$).

† 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. More LNF patients were unable to belch (8.5% of MSA and 25.5% of LNF; $p= 0.028$) or vomit (4.3% of MSA and 21.3% of LNF; $p=0.004$).

‡ 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.

§ 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 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. ($p<0.001$)

†† 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 ($p<0.001$).

€ Based on a 5 year prospective, multi-center, single-arm study observing 100 patients who were implanted with LINX, symptoms of bloating/gas decreased from 52% at baseline to 8.3% 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.

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).



**Manufactured by:**
Torax® Medical, Inc.
4188 Lexington Avenue North
Shoreview, Minnesota 55126, USA

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