LINX® Reflux Management System

A favorable safety profile[1]* for the first line surgical treatment for GERD[2†]

Redefining the Surgical Treatment of Reflux Disease

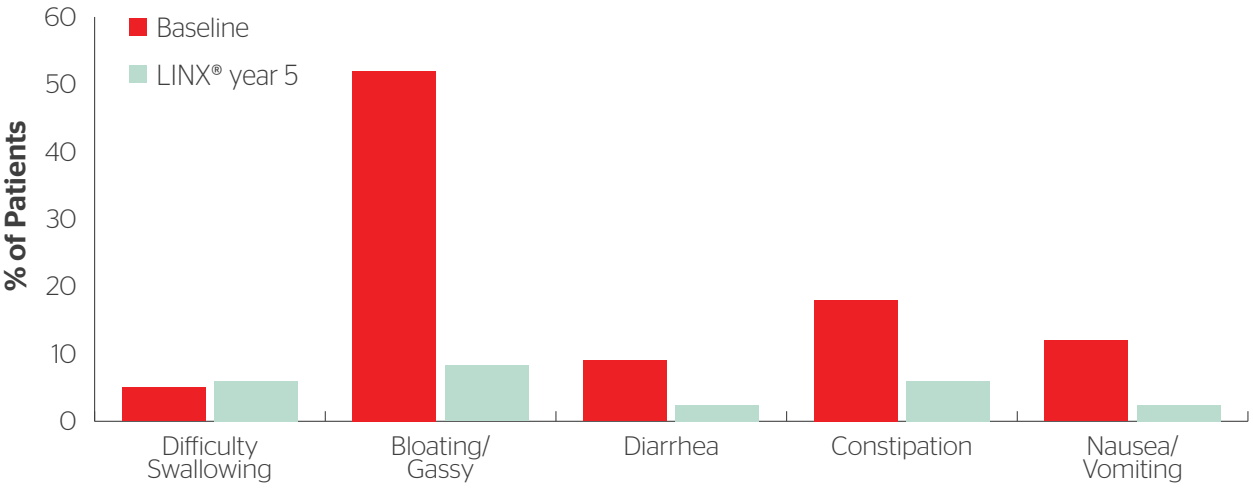
With a low rate of device removals, rare occurrence of device erosions and no migrations seen in clinical trials, the clinical evidence supports LINX Reflux Management System as an effective treatment for moderate to severe GERD with a favorable safety profile.[1*]

LINX Reflux Management System is a Premarket Approval (PMA) device, supported by clinical societies and Health Technology Assessment bodies[‡]

Safety Results Through 4 Years[3]

Safety Experience	**Occurrence Rate** (n=3,283)
Device Removal	2.7%
Device Erosion	0.15%
Device Migration	0.0%

Side Effect Profile[1]



LINX Reflux Management System augments the lower esophageal sphincter (LES) with no alteration to stomach anatomy and preserves physiologic function (belch and vomit)[2¶] and future treatment options.[1**]

Side effects commonly associated with Nissen fundoplication are largely absent.[2††]

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Rates of Erosion in Over 16,000 Implants[4]

Erosion of the LINX® Reflux Management System device is an important but rare complication. To better understand the risks of device erosion, data from 16,503 patient cases collected by Torax Medical, Inc. and the Manufacturer and User Facility Device Experience (MAUDE) database was analyzed, including 1,130 patients who had their devices implanted for over 5 years.

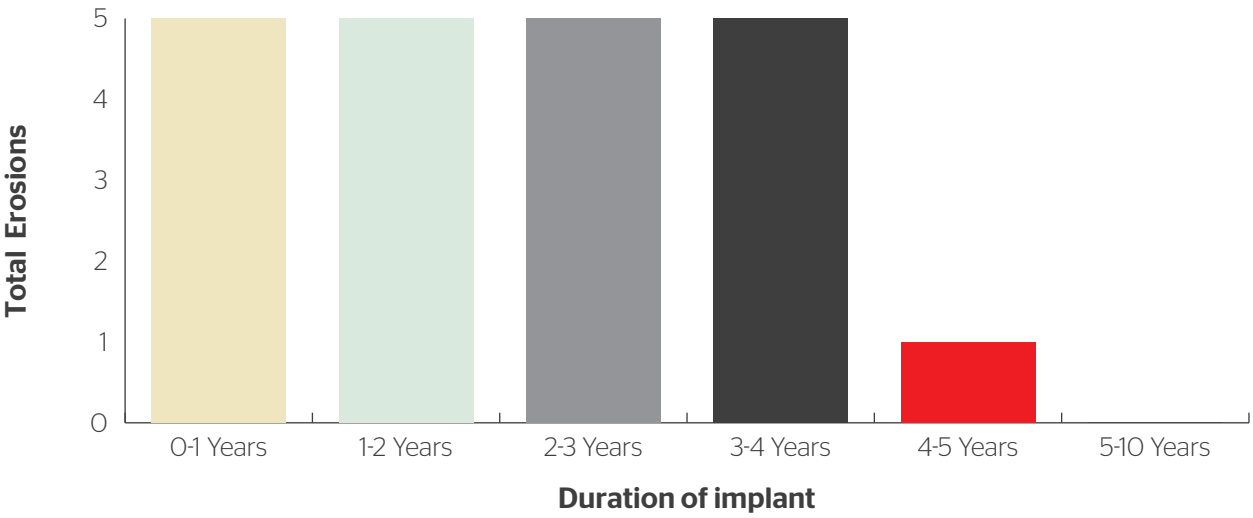
Erosion Rates by Device Size

The erosion rate for currently available LINX Reflux Management System sizes was .14% in this data set. There were no erosions in the 16-bead devices.

Device Size	Total Implanted	# of Erosions	Erosion Rate (%)
13	3008	11	0.37
14	4571	7	0.15
15	4329	3	0.07
16	2999	0	0.00
17	1596	2	0.13
Total	**16503**	**23**	**0.14**

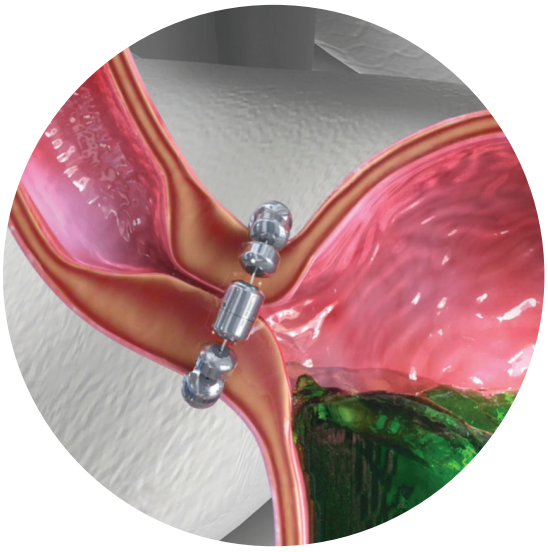
Timeframe to Erosion Presentation

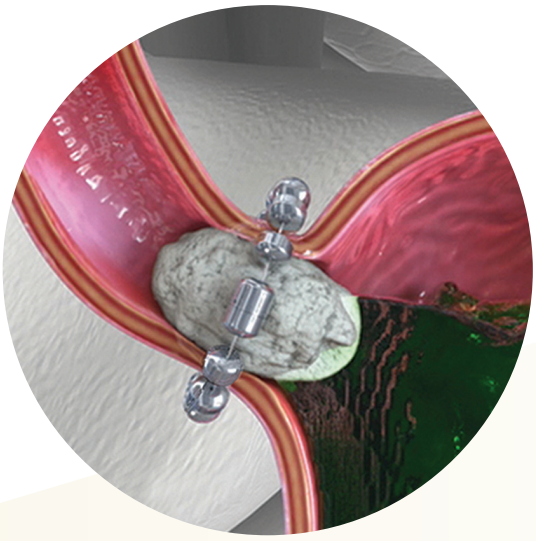
When erosions do occur, they tend to happen within the first few years following implantation. Most patients with erosions presented between 1 and 4 years after device implantation. Median time to erosion was 30 months (2.5 years). In Years 5-10, there were zero erosions.



Unique Low-Tension Design

LINX® Reflux Management System is placed around the lower esophageal sphincter (LES) in a minimally invasive procedure. It is intended to improve the barrier function of the LES without restricting its normal physiological functions. The magnetic strength is calibrated to allow the device to respond to the esophagus rather than limiting its range of motion, and its non-compressive structure avoids tension that can lead to erosion.





Potential Risk Factors for LINX Reflux Management System Device Erosion

Size mismatch/undersizing

Undersizing the device causes compression around the LES. Additional resting tension does not increase the efficacy of LINX Reflux Management System.

Endnotes

*Based on a prospective study of the safety and efficacy of magnetic devices in 100 adults. No device erosions, migrations, or malfunctions occurred in this study. Device removal occurred in 7 patients.

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

‡ SAGES (Society of American Gastrointestinal and Endoscopic Surgeons) Technology and Value Assessment Committee (TAVAC), American Society of General Surgeons, Agency for Healthcare Research and Quality

¶ 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 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). 8.5% of MSA patients were unable to belch, compared to 25.5% of LNF patients (p = 0.028). 4.3% of MSA patients were unable to vomit when necessary compared to 21.3% of LNF patients (p = 0.004).

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.
3. Smith C, Ganz R, Lipham J, et al. Lower Esophageal Sphincter Augmentation for Gastroesophageal Reflux Disease: The Safety of a Modern Implant. J Laparoendosc Adv Surg Tech. 2017. 27(6):586-591.
4. Erosion Data Set. 2019. Ethicon, Inc.

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).

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