

Recommended in the 2022 ACG GERD Guideline



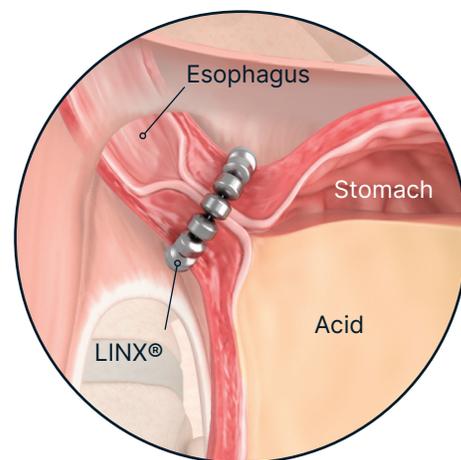
“ We recommend consideration of Magnetic Sphincter Augmentation (MSA) as an alternative to laparoscopic fundoplication for patients with regurgitation who fail medical management (strong recommendation, moderate level of evidence). -Katz et al. ”

In the 2022 **American College of Gastroenterology (ACG) Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease (GERD)**, the authors provide updated recommendations and practical guidance for the evaluation and management of GERD.¹

LINX® Reflux Management System

The Guideline compared MSA (LINX) to laparoscopic fundoplication (LF). The Guideline stated:

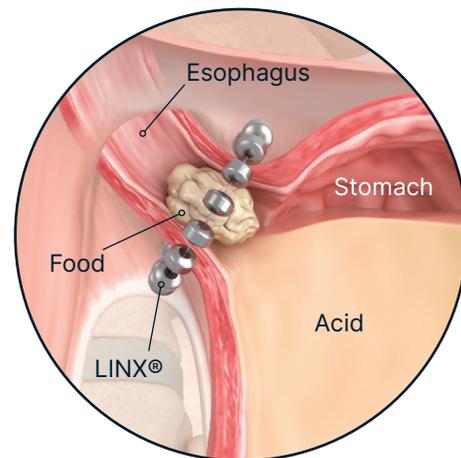
- ACG **strongly recommend MSA (LINX) as an alternative to LF** for GERD patients with regurgitation, who fail medical management
- There were no significant differences in rates of symptom control, postoperative PPI usage, and major complications
- MSA (LINX) results in less gas-bloat and greater ability to belch and vomit
- MSA (LINX) has shown shorter hospital stays



Candidates for Antireflux Surgery

Antireflux surgery may be an option for the long-term treatment of patients with objective evidence of GERD who meet any of the following criteria:

- Have LA grade C/D esophagitis, large hiatal hernias, and/or persistent, troublesome GERD symptoms
- Fail to respond to medical therapy
- Are uncomfortable with lifelong PPI treatment
- Present with regurgitation as a primary complaint



Read the 2022
ACG Guideline

<https://bit.ly/33MsOa7>



Learn more
about LINX®

<https://bit.ly/3M1vdPq>

References:

1. Katz PO, Dunbar K, Schnoll-Sussman FH, Greer KB, Yadlapati R, Spechler SJ. ACG Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease. *Amer J Gastroenterol.* 2022;117(1):27-56.

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. 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:

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