

The LINX™ Reflux Management System: Over 10 years of experience for GERD patients

Unmet need in GERD

Proton pump inhibitors (PPIs) are widely prescribed to treat gastroesophageal reflux disease (GERD) symptoms, however 40% of GERD patients still experience symptoms.^{1*}

PPIs are unable to physically correct the weak esophageal sphincter seen in chronic GERD; surgical intervention may be necessary to treat such patients.²



40%
of PPI patients still had GERD symptoms.^{1*}

Nissen fundoplication is commonly used to surgically address PPI-refractory GERD, where the upper part of the stomach is wrapped around the esophagus.³ Up to 62% of patients may still need to take reflux medications in the long-term (n=37).⁴

The LINX™ Reflux Management System Mode of Action

The LINX™ Reflux Management System is an alternative to fundoplication with fewer unfavorable side effects^{5#}

LINX™ consists of a “bracelet” of magnetic beads which protect against gastroesophageal reflux events upon implantation around the esophagus, and separate to facilitate swallowing and drinking.⁶

The system is installed through a minimally invasive procedure typically allowing the patients to return to normal physical activity in less than a week.⁶

LINX™ allows for physiological mechanisms such as belching and vomiting to occur⁶- an ability which is greater following magnetic sphincter augmentation (MSA) compared to Nissen fundoplication.^{5#}

The LINX™ procedure is designed to maintain the gastroesophageal anatomy of the patient. LINX™ insertion can be reversed if required; in comparison Nissen fundoplication is permanent.

A decade of clinical evidence

Over the last 10 years there have been many examples of published, peer reviewed evidence for the LINX™ system in treating GERD. These include 1 randomised controlled trial (CALIBER), and single-arm and comparative studies and systemic reviews^{2,7,8}

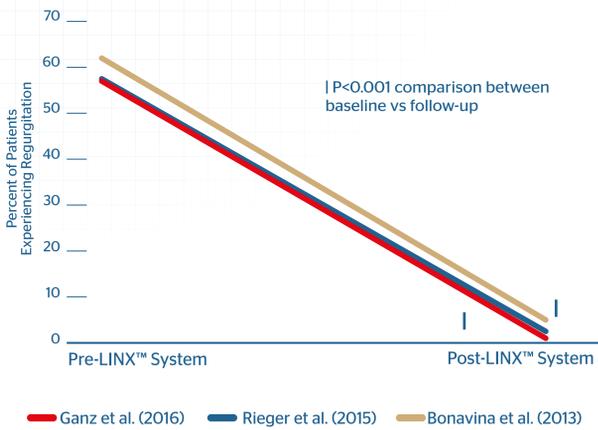
Efficacy

Long-term efficacy has been validated for LINX™ in patients with chronic GERD:

91% of patients were able to come off daily PPI use within 6 months after treatment with LINX™^{2†}

GERD patients implanted with LINX™ experienced significant and improved resolution in regurgitation⁹⁻¹¹

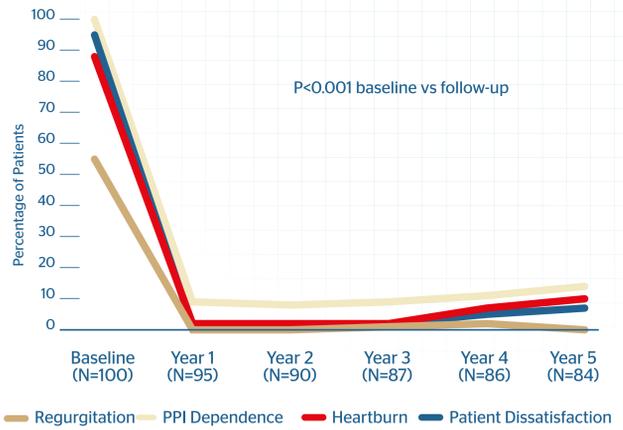
LINX™ System Patients Showed Consistent Decline in Symptoms Up to 5 Years⁹



⁹Based on 3 studies. Ganz et al. (2016): Prospective, multicenter, single-arm 5-year study; n=84. Rieger et al. (2015): Prospective, multicenter 1-year registry; n=202. Bonavina et al. (2013): Prospective, single-center 3-year case series; n=100.

GERD patients implanted with LINX™ showed a significant improvement in long-term GERD-related reflux control⁹

LINX™ System Reflux Control Through 5 Years⁹



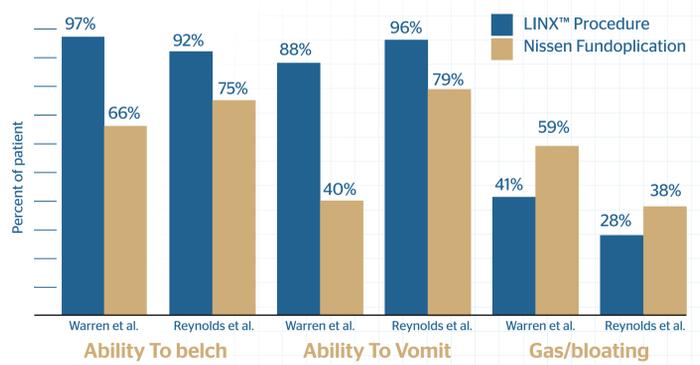
Safety

Initial LINX™ safety data from 82 institutions demonstrated a low risk profile with low overall device removal rates:¹²

Long-term data (3-5 years in over 4,000 patients) with LINX™ confirm this initial safety profile, demonstrating long-term GERD control based on symptomatic outcomes, PPI utilization, and pH studies.¹²

Studies of GERD patients having undergone the LINX™ procedure at one year demonstrated that they experienced fewer side effects compared to those that underwent Nissen fundoplication, in particular gas-bloat symptoms and higher ability to belch and vomit.^{5,14}

Propensity-matched Studies: LINX™ System vs Nissen Fundoplication Side-effect Profile^{5,14}



¹⁴ Based on 2 studies. Reynolds et al. (2015): 1-year propensity-matched comparative studies; n=47 matched pairs. Warren et al. (2016): 1-year propensity-matched comparative studies; n=114 matched pairs.

To find out more about the LINX™ Reflux Management System please visit [INSERT LOCAL LINK](#)

* Data relates to GERD symptoms in patients with large hiatal hernias.

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).

† Based on 47 patients treated with laparoscopic MSA. 91% of patients discontinued PPI use at 6 months.

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LINX™ Reflux Management System Important Safety Information

The LINX™ Reflux Management System is indicated for patients diagnosed with pathologic Gastro-oesophageal Reflux Disease (GORD) as defined by abnormal pH testing, and who continue to have chronic GORD symptoms despite maximum medical therapy.

The LINX™ Reflux Management System is labelled for use by physicians 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.

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 removal and/or replacement.

Potential Complications: Potential complications associated with the LINX™ Reflux Management System include achalasia (lower part of oesophagus does not relax), bleeding, death, device erosion (device passing through the oesophageal wall), device explant/re-operation, device failure, device migration (device does not appear to be at implant site), diarrhoea, dysphagia (difficulty swallowing), inability to belch or vomit, infection, impaired gastric motility, injury to the oesophagus, 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, vomiting, and worsening of preoperative symptoms (including but not limited to dysphagia or heartburn). (145680-200706 EMEA)