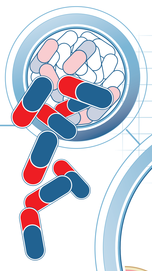
The LINX™ Reflux Management System: Over 10 years of experience for GORD patients

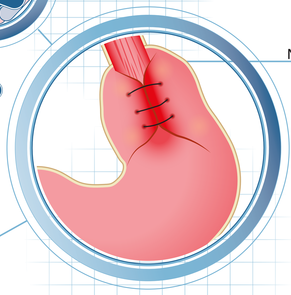
Unmet need in GORD

Proton pump inhibitors (PPIs) are widely prescribed to treat gastro-oesophageal reflux disease (GORD) symptoms, however 40% of GORD patients still experience symptoms.[1*]

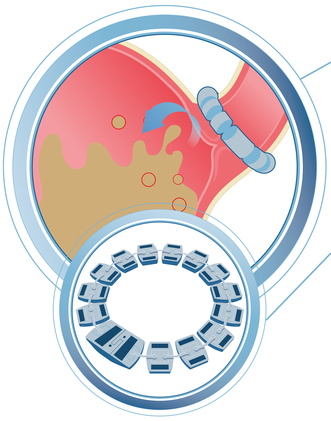
PPIs are unable to physically correct the weak oesophageal sphincter seen in chronic GORD; surgical intervention may be necessary to treat such patients.[2]



40%
of PPI patients still had GORD symptoms.[1*]



Nissen fundoplication is commonly used to surgically address PPI-refractory GORD, where the upper part of the stomach is wrapped around the oesophagus.[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 gastro-oesophageal reflux events upon implantation around the oesophagus, 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 occur[6]– an ability which is greater following magnetic sphincter augmentation (MSA) compared to Nissan fundoplication.[5#]

The LINX™ procedure is designed to maintain the gastro-oesophageal 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 GORD. These include 1 randomised controlled trial (CALIBER), and single-arm and comparative studies and systemic reviews[2,7,8]

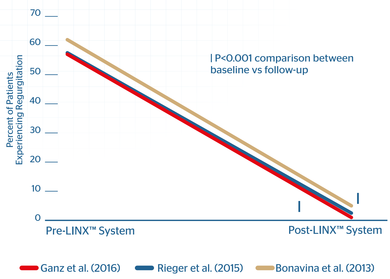
Efficacy

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

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

GORD patients implanted with LINX™ experienced significant and improved resolution in regurgitation[9-11]

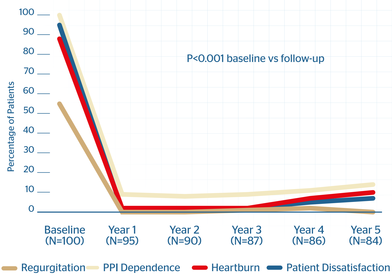
LINX™ System Patients Showed Consistent Decline in Symptoms Up to 5 Years[6]



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

GORD patients implanted with LINX™ showed a significant improvement in long-term GORD-related reflux control[9]

LINX™ System Reflux Control Through 5 Years[8]



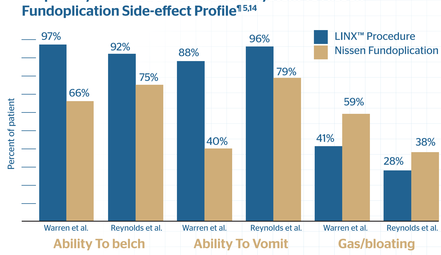
Safety

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 GORD control based on symptomatic outcomes, PPI utilization, and pH studies.[12]

Studies of GORD 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]



¶ 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: https://www.linxforlife.co.uk/

* Data relates to GORD 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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4. Spechler SJ, Lee E, Ahnen D, et al. Long-term outcome of medical and surgical therapies for gastroesophageal reflux disease: follow-up of a randomized controlled trial. *JAMA.* 2001;285:2331-2338.
5. Reynolds J, Zehetner J, Wu P, et al. Laparoscopic magnetic sphincter augmentation vs laparoscopic nissen fundoplication: A matched-pair analysis of 100 patients. *J Am Coll Surg.* 2015;221:123-128.
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12. Lipham J, Taiganides P, Louie B, et al. Safety analysis of first 1000 patients treated with magnetic sphincter augmentation for gastroesophageal reflux disease. *Dis Esophagus.* 2015;28:305-311.
13. Telem D, Wright A, Shah P, et al. SAGES Technology and Value Assessment Committee (TAVAC) safety and effectiveness analysis: LINX Reflux Management System. *Surg Endosc.* 2017;31:3811-3826.
14. Warren H, Reynolds J, Lipham J, et al. Multi-institutional outcomes using magnetic sphincter augmentation versus Nissen fundoplication for chronic gastroesophageal reflux disease. *Surg Endosc.* 2016;30:3289-3296.

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).

Please refer always to the Instructions for Use / Package Insert that come with the device for the most current and complete instructions.

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