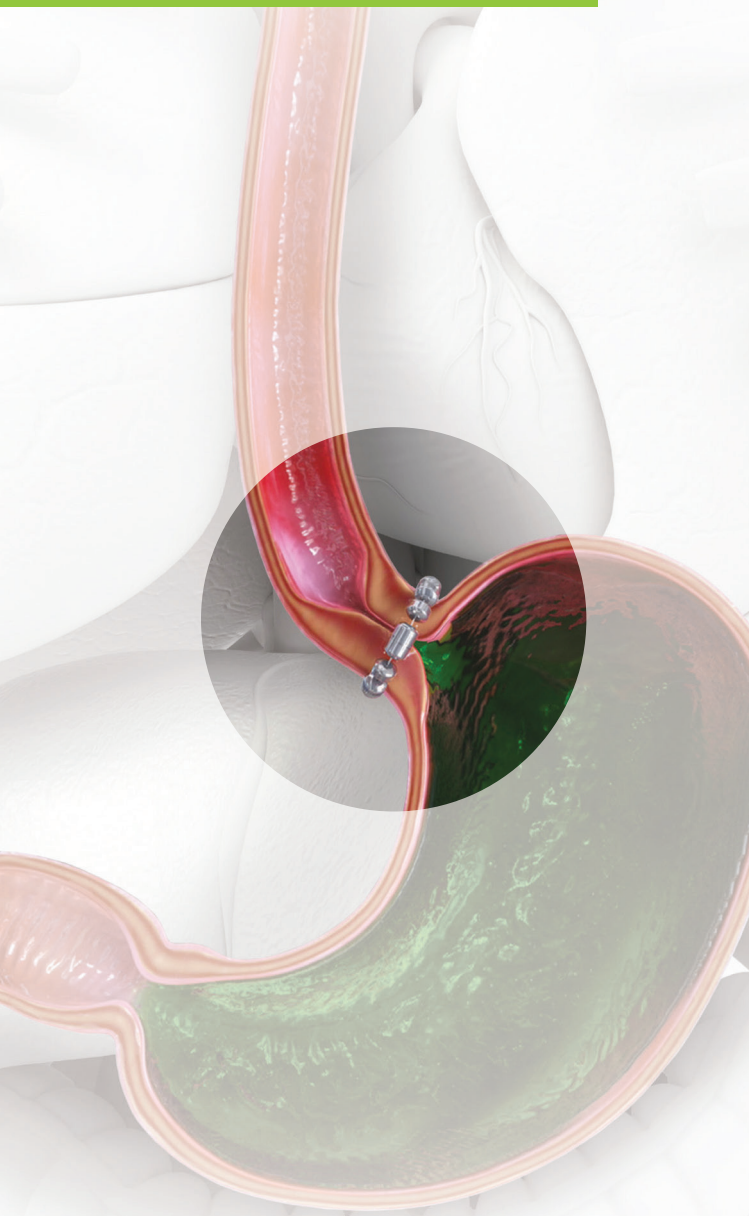


LINX™ A revolutionary
treatment for reflux disease



Restore*, don't reconstruct.

No alteration to stomach anatomy.

LINX is implanted during a minimally invasive laparoscopic procedure. Unlike other procedures to treat reflux disease, LINX requires no permanent anatomic alteration.

Reduced gas and bloating.^{2†}

LINX preserved the ability to belch and vomit.^{1-2†} The titanium beads open and close to let food down, and if it needs to come up, it can.



MRI conditional.

LINX will not affect airport security, and is MRI conditional.[∞]

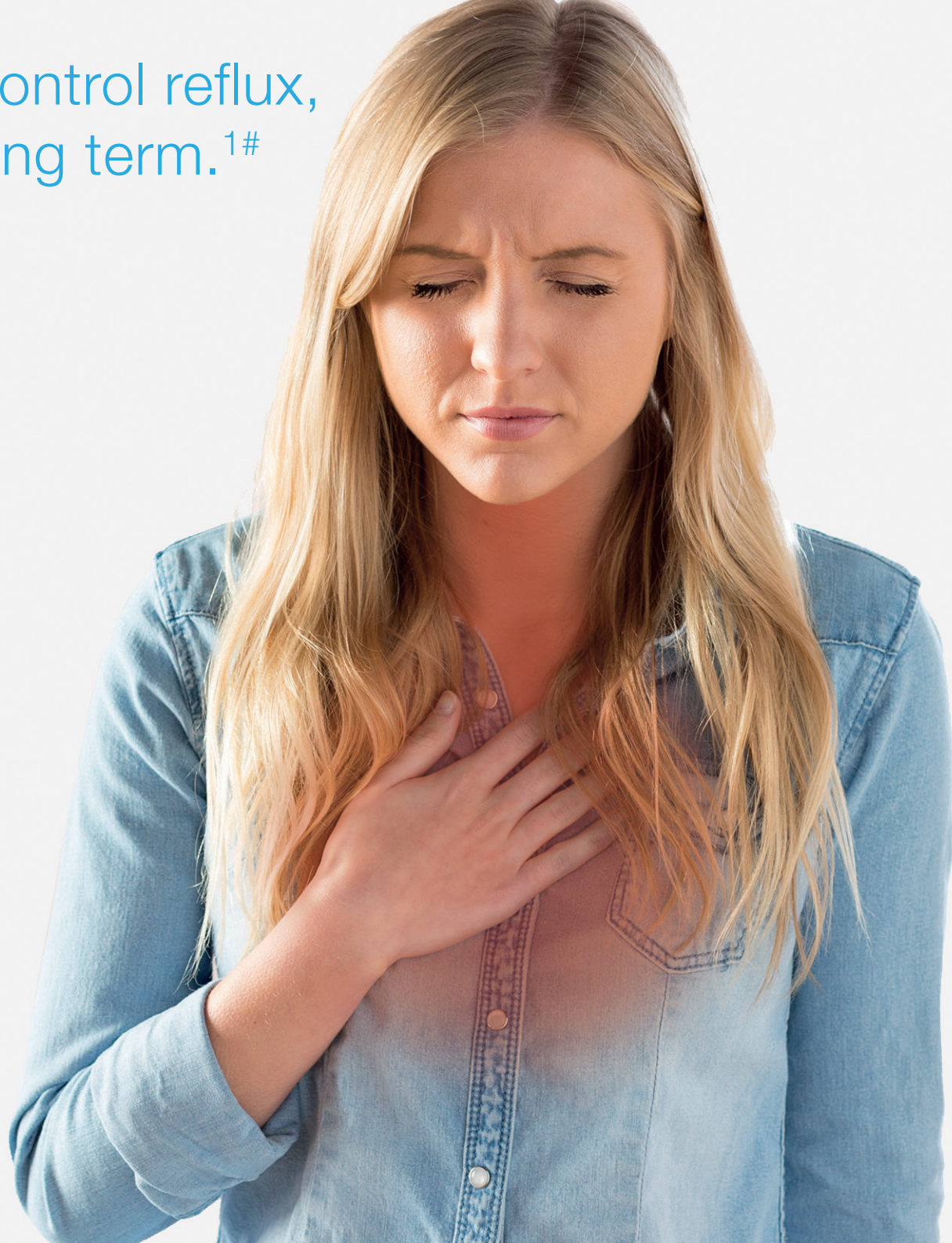
Actual size.



[∞] This device can be scanned safely under the following conditions:

1) 1.5-Tesla static magnetic field, 2) maximum spatial gradient field of 17.15 T/m, 3) maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4.0 W/kg in First Level Controlled Operating Mode, and 4) the patient may feel pressure around the lower oesophagus; should the patient experience pain, immediately discontinue the scan and remove the patient from the MR environment. Refer to IFU for warnings/MRI safety information.

Control reflux,
long term.^{1#}



Is LINX right for you?

LINX is intended for patients diagnosed with reflux disease who want an alternative to medication. Are you concerned with a lifetime of medication, pharmacy visits and potential side effects? It's time to learn more about LINX.



Reduced Medication.

85% of patients were free from dependence on daily reflux medication after treatment with LINX.^{1§}



Durable resolution of bothersome heartburn.

88% of patients reported that bothersome heartburn had been eliminated after treatment with LINX.^{1¶}



Durable resolution of regurgitation.

99% of patients eliminated bothersome regurgitation after treatment with LINX.^{1¶}



Significantly less gas and bloating.^{2†}

Patients reported significant improvement in gassiness and bloating after treatment with LINX.^{1**}



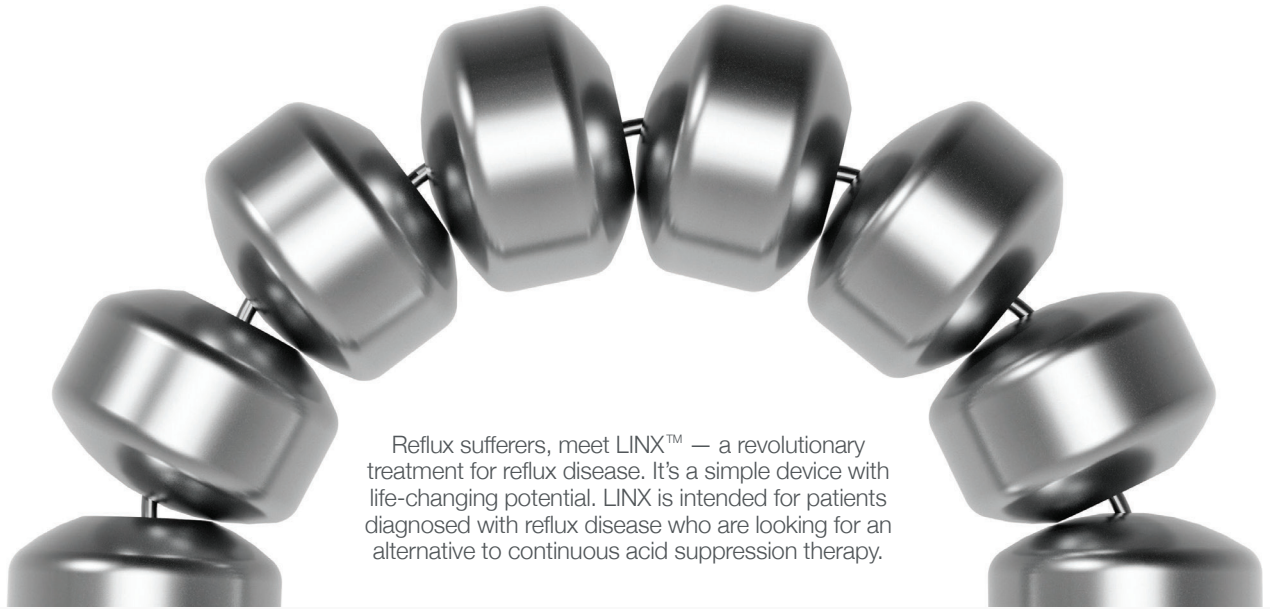
Improved quality of life.

Patients reported significant improvement in their quality of life after surgical treatment with LINX.^{1##}

It's time to win the battle against reflux.^{1#}

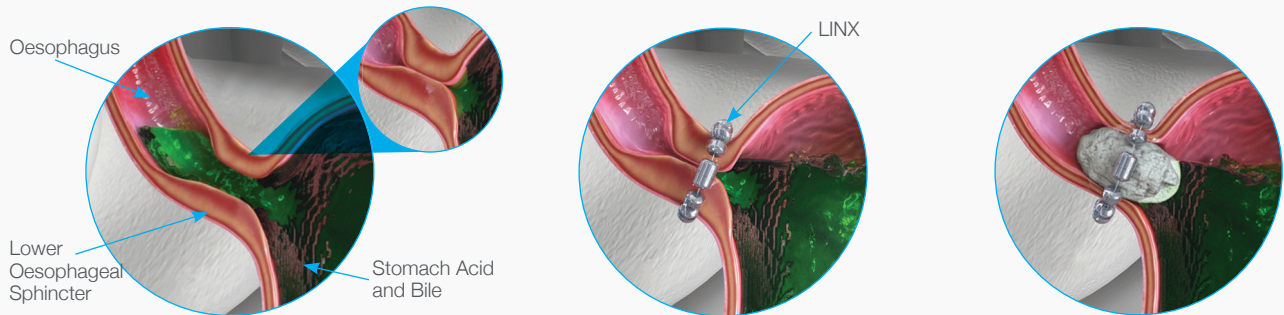
For more information on the LINX Reflux Management System, contact your physician.

Simply designed to be simple.



Reflux sufferers, meet LINX™ — a revolutionary treatment for reflux disease. It's a simple device with life-changing potential. LINX is intended for patients diagnosed with reflux disease who are looking for an alternative to continuous acid suppression therapy.

How LINX works



Reflux (also called Gastro-oesophageal Reflux Disease, or GORD) is caused by a muscle in your oesophagus called the Lower Oesophageal Sphincter (LOS) that is weak or relaxing inappropriately. This allows acid and bile to flow back from the stomach into the oesophagus, causing damage to the lining of the oesophagus, throat and lungs.

LINX is a small, flexible ring of magnets placed around the oesophagus during a minimally invasive procedure. The magnets help to keep the LOS closed so that acid and bile do not flow from the stomach to the oesophagus. When you eat or drink, the forces from swallowing cause the magnets to separate, the LINX device to expand, and the LOS to open for food or liquid to pass into the stomach.



* The LINX device is placed in the area of the Lower Oesophageal Sphincter (LOS) designed to augment a weak LOS.

Based on observation of 100 patients implanted with LINX. Bothersome heartburn decreased to 11.9% at 5 years from 89%(p<0.001), bothersome regurgitation decreased to 1.2% at 5 years from 57% (p<0.001), PPI dependence decreased to 15.3% at 5 years from 100% (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. There were no patients with severe gas and bloating in the MSA group compared with 10.6% in the LNF group (p=0.022).

‡ Based on a prospective study of 100 adults who underwent MSA in which all patients reported the ability to belch and vomit (if necessary), and a retrospective matched-pair analysis of 1-year outcomes of 100 patients undergoing MSA and LNF from June 2010 to June 2013. After MSA 8.5% of patients were unable to belch compared to 25.5% of patients after LNF (p=0.028), and 4.3% of MSA patients were unable to vomit compared to 21.3% of LNF patients (p=0.004).

§ Based on a study observing 100 patients who were implanted with LINX, daily use of PPIs 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, 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, 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, symptoms of bloating/gas decreased from 52% at baseline to 8.3% 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, there was a significant improvement in the median GORD-HRQL score at 5 years, as compared with baseline, both with and without PPI use, 4 vs 11 and 27 respectively (p<0.001).

1. Ganz R, Edmundowicz S, Taiganides P, et al. Long-term Outcomes of Patients Receiving a Magnetic Sphincter Augmentation Device for Gastro-oesophageal 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.

Although many patients benefit from LINX™, results may vary. Please talk to your physician to see if LINX is right for you. Your physician can discuss the benefits and risks with you.

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).