



Registered Charity No. 1062461

Reflux Disease

and your treatment options



Reflux Disease

What is Reflux Disease?

Reflux (also called Gastro-oesophageal reflux disease, or GORD) is a chronic digestive disease in which acid and bile flow back from the stomach into the oesophagus, creating pain and often causing damage to the lining of the oesophagus.

What Causes Reflux Disease?

Reflux disease is caused by inappropriate relaxation or weakness in a muscle called the lower oesophageal sphincter (LOS). Normally the LOS acts like a one-way valve, allowing food and liquid to pass through to the stomach, but preventing stomach contents from flowing back into the oesophagus.¹

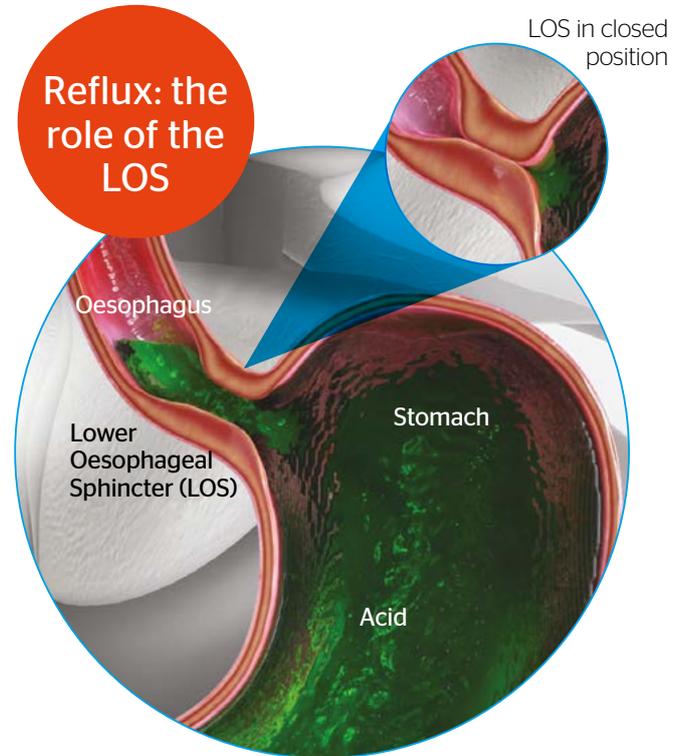
Complications of Reflux Disease*

In addition to producing a wide range of symptoms, reflux disease can lead to potentially serious complications including:²

- Oesophagus (Inflammation that can damage the tissue of the oesophagus)
- Stricture (Narrowing of the oesophagus)
- Barrett's oesophagus (Pre-cancerous changes to the tissue lining the oesophagus)
- Oesophageal cancer (in rare cases)^{3#}

* LINX is not intended to cure, treat, prevent, mitigate or diagnose these symptoms or complications

The annual cancer risk of NDBE [non-dysplastic Barrett's Oesophagus] varies between countries and ranges from 0.12% to 0.5% and 0.33% to 0.7% in population-based studies and in meta-analyses, respectively.



In people with reflux disease, the lower oesophageal sphincter is weak or relaxes inappropriately, allowing acid and bile to flow back from the stomach into the oesophagus.

Symptoms

The most common symptom of reflux disease is **heartburn**. However, reflux disease can produce a wide variety of symptoms including those listed below.²⁴



Living with Reflux Disease

Reflux disease can affect your life beyond the symptoms you feel.

Patients with Reflux Disease Often Experience:

- Poor quality of sleep
- Reduced work productivity
- Dietary compromises to avoid symptoms
- Concerns about the long-term effects of reflux disease
- Life-long dependence on reflux medications



How is Reflux Disease Diagnosed?

There are several tests that your consultant may use to diagnose reflux disease. Here are some examples.

1 Response to medication

A trial of PPI medication may be used to confirm diagnosis in patients with typical symptoms.

2 OGD

Oesophagogastroduodenoscopy (OGD), also known as upper Endoscopy, is a test that examines the oesophagus and LOS for evidence of reflux disease.

3 pH

pH monitoring using a probe in the oesophagus near the stomach measures the level of oesophageal acid exposure.



If you think you have reflux disease or have new or worsening symptoms on medication therapy, inform your consultant.

Treatments

Treatment: Lifestyle Modification

Diet Modification

- Spicy/acidic food
- Caffeine
- Chocolate
- Alcohol and tobacco

Lifestyle Modifications

- Elevation of head of bed
- No meals 2 - 3 hours before bed
- Weight loss in overweight patients



Treatment: Medication

In addition to dietary and lifestyle changes, medication is commonly used to treat heartburn, the most common symptom of reflux disease.

Benefits

- Reduced stomach acid production
- Relief from heartburn symptoms
- Reduced inflammation of the oesophageal lining

Limitations/Risks

- May not provide adequate symptom relief
- Does not affect the mechanical cause of reflux disease (LOS)
- Does not prevent reflux disease
- Side effects include:⁵ headache, diarrhea, and upset stomach
- Up to 40% of patients continue to have symptoms while on medication⁶
- Possible side effects of long-term use of Proton Pump Inhibitors (PPI) including: possible fracture risk, low magnesium levels, and clostridium difficile-associated diarrhea⁵



Traditional Anti-Reflux Surgery: Fundoplication

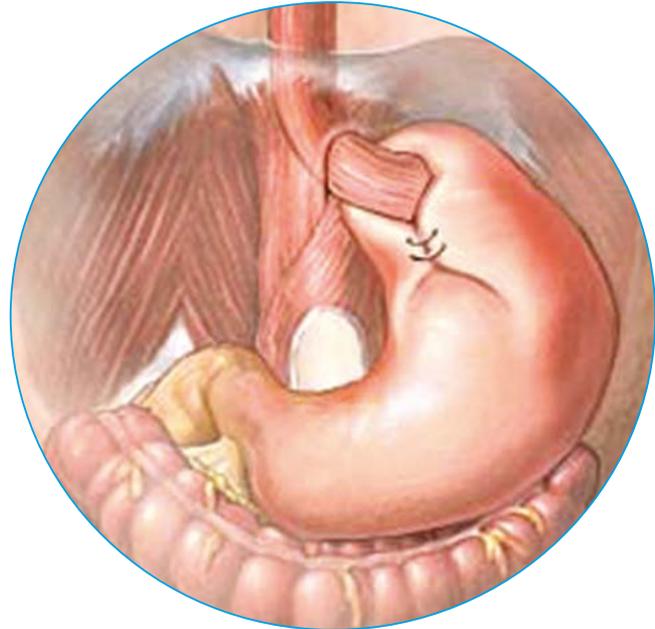
Fundoplication surgery involves wrapping the upper part of the stomach around the outside of the oesophagus at the lower oesophageal sphincter (LOS) to help prevent reflux.

Benefits

- Reduced symptoms of heartburn, reflux and bloating
- May heal damage to the oesophagus⁷
- May end dependence on medication⁸

Limitations/Risks

- Difficulty swallowing
- Inability to belch or vomit when needed
- Permanently alters the stomach anatomy
- Typically requires hospital stay of 1-3 days
- Symptoms may return over time
- Requires a modified diet for several weeks
- May limit activity for 2-3 weeks
- Risks related to surgery and anesthesia



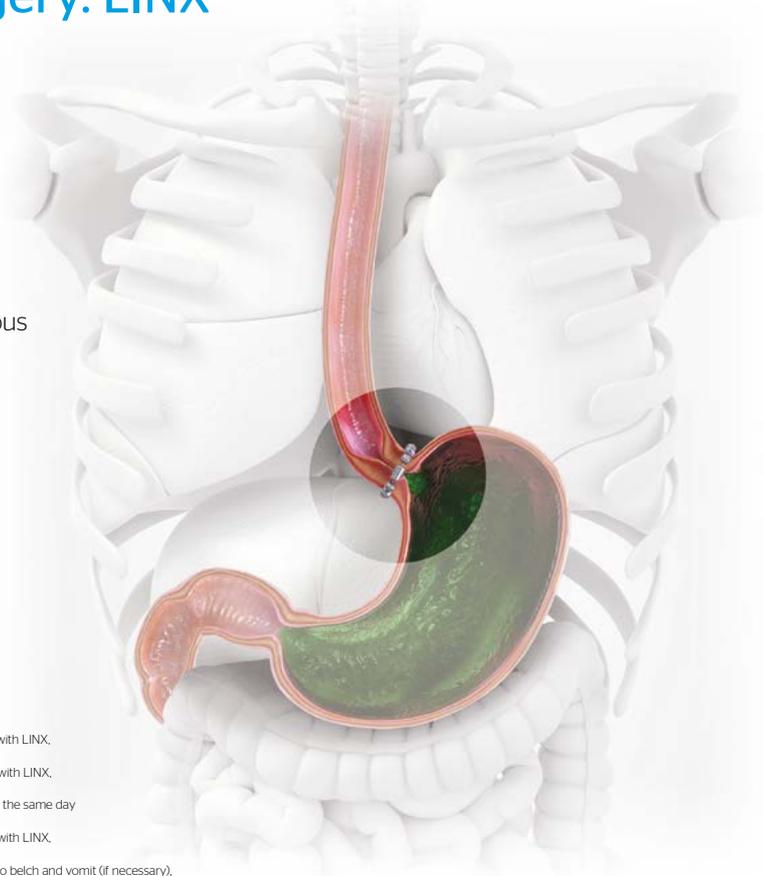
Alternative Anti-Reflux Surgery: LINX™

Benefits

- Durable resolution of bothersome heartburn^{9*} and regurgitation^{9#}
- Requires no alteration to the stomach anatomy
- Patients typically go home in less than 24 hours and resume a normal diet^{10†}
- Patients are generally able to return to non-strenuous activity within a couple of days
- Reduces gassiness and bloating^{9‡}
- Preserves the ability to belch and vomit^{8,9¥}

Limitations/Risks

- Incomplete symptom relief
- Difficulty swallowing
- Risks related to surgery and anesthesia
- Device failure



* 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<0.0001)

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 pivotal IDE trial of 100 subjects at 14 clinical sites. Half of the subjects (50/100) were discharged the same day as the surgery, and the other half were discharged the next day.

‡ 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<0.0001)

¥ 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).

Is Surgery Right for You?

There are many reasons patients consider surgery as an alternative to medical therapy.

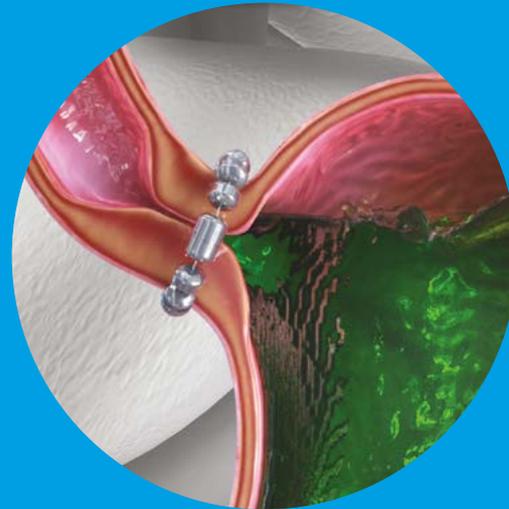
- Are you dependent on medication to manage your reflux disease symptoms?
- Do you continue to suffer reflux disease symptoms while on medication?
- Is your reflux disease affecting your quality of life? (Examples: poor sleep, inability to tolerate certain foods, inability to participate in daily activities).
- Are you concerned about the long term use of drugs to treat your reflux disease?
- Are you concerned about the long term risks of serious complications from your reflux disease?

Talk with your consultant about your treatment options if your consultant determines you are not responding to medication.



LINX™ Reflux Management System

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.



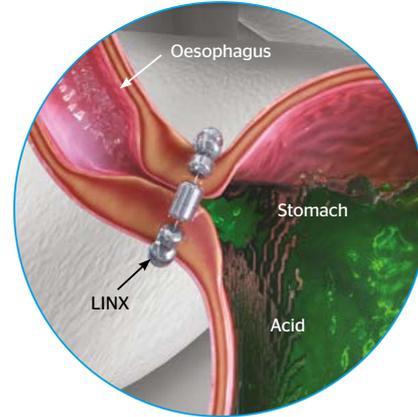
Redefining the Surgical Treatment of Reflux Disease

How LINX™ Works

LINX is a small, flexible ring of magnets placed around the oesophagus during a minimally invasive procedure.

The magnets help to keep the lower oesophageal sphincter (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.



MRI Conditional*

The LINX device is MRI conditional, so patients can undergo magnetic resonance imaging up to either 0.7-Tesla (0.7T) or 1.5-Tesla (1.5T), depending on the LINX model implanted.

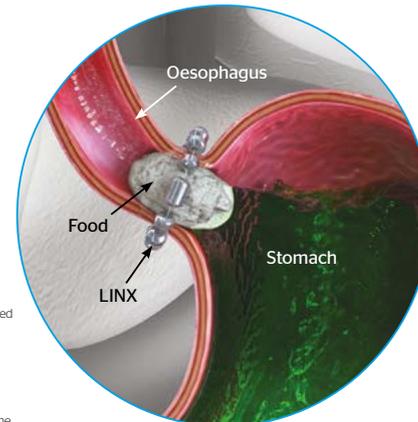
*This device can be scanned safely under the following conditions:

LINX model MRI conditional up to 1.5-Tesla (1.5T)

1) 1.5-Tesla static magnetic field, 2) maximum spatial gradient field of 1715 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.

LINX model MRI conditional up to 0.7-Tesla (0.7T)

1) 0.7-Tesla static magnetic field, 2) spatial gradient field up to 364 G/cm, 3) maximum whole body averaged specific absorption rate (SAR) of 4.0 W/kg for 15 minutes of scanning in First Level Controlled Mode, and 4) immediately discontinue the scan and remove the patient from the MR environment should the patient experience discomfort or pain.



Control Reflux, Long Term with LINX™9*

85% of patients were freed from dependence on daily GORD medication^{9#}

Bothersome regurgitation was eliminated in **99%** of patients^{9†}

Bothersome heartburn was eliminated in **88%** of patients^{9‡}

Patients reported a significant improvement in their **Quality of Life**^{9¥}



* 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 12% 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 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, regurgitation was 57% at baseline and decreased to 12% 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, 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).

FAQs

What is LINX™?	LINX is a flexible ring of small magnets placed around the oesophagus just above the stomach during a minimally invasive procedure to help prevent reflux.
How does LINX work?	The strength of the magnets helps keep the valve between your stomach and oesophagus closed to prevent reflux. When you swallow, the magnets separate temporarily to allow food and liquid to pass into the stomach.
How is LINX different from other procedures?	LINX requires no permanent anatomic alteration, reduces gas and bloating ^{8*} , preserves the ability to belch and vomit ^{8,9#} , and patients typically go home within 24 hours and resume a normal diet. ^{10†}
How is LINX implanted?	LINX is placed around the oesophagus just above the stomach using a minimally invasive surgical technique. Many patients are able to go home the same day.
Can LINX be removed if needed?	Yes. LINX can be removed using a minimally invasive procedure and preserves patients' future treatment options. ^{9‡}
How do I know if I am a candidate for LINX?	Three diagnostic tests are used to determine if patients may be candidates for LINX: EGD, pH and Manometry.
When can I start eating normally again?	Patients are encouraged to return to a normal diet as soon as tolerated or as directed by their consultant.

* 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 85% of patients were unable to belch compared to 25.5% of patients after LNF (p=0.026), and 4.3% of MSA patients were unable to vomit compared to 21.3% of LNF patients (p=0.004).

† Based on a pivotal IDE trial of 100 subjects at 14 clinical sites.

‡ Based on a prospective study of the safety and efficacy of magnetic devices in 100 adults with GORD for 6 months or more, who were partially responsive to daily PPIs and had evidence of pathologic oesophageal acid exposure, at 14 centers in the US and Netherlands. Three patients underwent uneventful Nissen fundoplication after LINX device removal.

FAQs continued

When can I return to normal activities?

Patients are generally able to return to non-strenuous activity within a couple of days.

How long will LINX last?

LINX is designed to be a lifelong implant.

Can I go through airport security?

LINX should not affect airport security. All patients are provided an implant card to let people know they have an implant.

Can I have an MRI?

LINX patients may undergo magnetic resonance imaging (MRI) up to either 0.7-Tesla (0.7T) or 1.5-Tesla (1.5T), depending on the LINX model implanted. You should discuss the MRI scanning options with your consultant prior to deciding on treatment with LINX. LINX patients can also undergo: CT scan, x-ray, ultrasound and PET scan.*

What are potential risks associated with LINX?

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*).

*This device can be scanned safely under the following conditions:

LINX model MRI conditional up to 1.5-Tesla (1.5T)

1) 1.5-Tesla static magnetic field, 2) maximum spatial gradient field of 1715 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.

LINX model MRI conditional up to 0.7-Tesla (0.7T)

1) 0.7-Tesla static magnetic field, 2) spatial gradient field up to 364 G/cm, 3) maximum whole body averaged specific absorption rate (SAR) of 4.0 W/kg for 15 minutes of scanning in First Level Controlled Mode, and 4) immediately discontinue the scan and remove the patient from the MR environment should the patient experience discomfort or pain.

The information provided is not medical advice and is intended for educational purposes only. Talk to a consultant if you have concerns about your health.

Indications, Safety and Warnings

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 consultants 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.

The LINX device has not been evaluated in patients with a hiatal hernia larger than 3 cm. Use of LINX device in patients with a hiatal hernia larger than 3 cm should be considered on the basis of each patient's medical history and severity of symptoms.

The safety and effectiveness of the LINX device has not been evaluated in patients with Barrett's oesophagus or Grade C or D (LA classification) or Grade IV (Savary-Miller) 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 device has not been evaluated in patients with major motility disorders.

The safety and effectiveness of the LINX Reflux Management System has not been established for the following conditions:

- Scleroderma
- Suspected or confirmed oesophageal or gastric cancer
- Prior oesophageal or gastric surgery or endoscopic intervention
- Distal oesophageal motility less than 35 mmHg peristaltic amplitude on wet swallows or <70% (propulsive) peristaltic sequences or a known motility disorder such as achalasia, nutcracker oesophagus, and diffuse oesophageal spasm or hypertensive LOS
- Symptoms of dysphagia more than once per week within the last 3 months
- Oesophageal stricture or gross oesophageal anatomic abnormalities (Schatzki's ring, obstructive lesions, etc.)
- Oesophageal or gastric varices
- Lactating, pregnant or plan to become pregnant
- Morbid obesity (BMI >35)

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).

For more information on LINX ask your consultant

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