



# Reflux Disease

conditions, diagnosis  
and treatment options



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**The Information provided is not medical advice and is intended for educational purposes only. Talk to a Consultant or your Medical Team if you have concerns about your health.**

# 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.

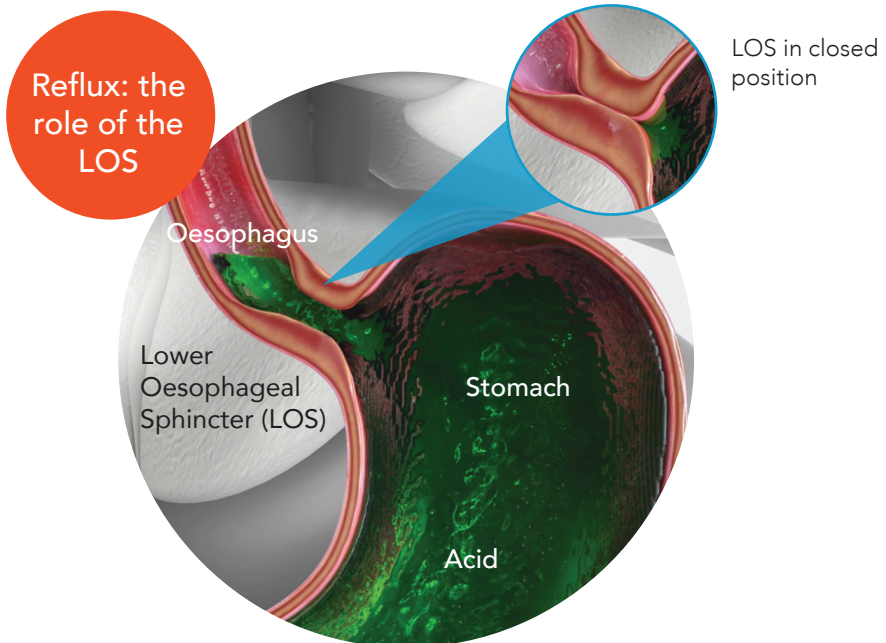
## What Causes Reflux Disease?

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.<sup>1</sup>

## Complications of Reflux Disease

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

- 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)<sup>3#</sup>



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.

\* 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.



Hoarseness

Cough

Sore  
throat

Chest pain

Asthma

Regurgitation

Difficulty  
swallowing

Heartburn

Shortness  
of breath

## Symptoms

The most common symptom of reflux disease is **heartburn**. However, reflux disease can produce a wide variety of symptoms including those listed above.<sup>2,4</sup>



## 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 monitoring

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





## 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



# 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:<sup>5</sup> headache, diarrhea, and upset stomach
- Up to 40% of patients continue to have symptoms while on medication<sup>6</sup>
- Possible side effects of long-term use of Proton Pump Inhibitors (PPI) including: possible fracture risk, low magnesium levels, and clostridium difficile-associated diarrhea<sup>5</sup>



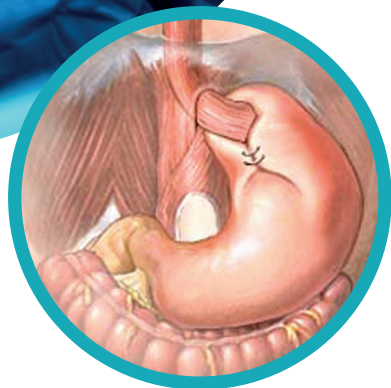
## Is Surgery Right for You?

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.



## Traditional Anti-Reflux Surgery: FUNDOPPLICATION

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 oesophagus<sup>7</sup>
- May end dependence on medication<sup>8</sup>

### 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

# 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.

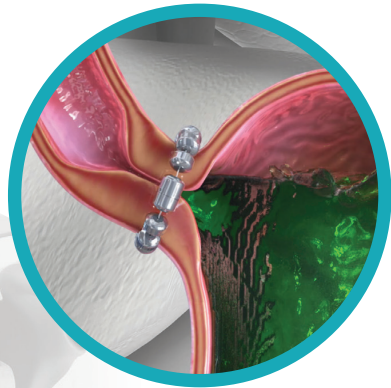
## Benefits

- Durable resolution of bothersome heartburn<sup>9\*</sup> and regurgitation<sup>9#</sup>
- Requires no alteration to the stomach anatomy

- Patients typically go home in less than 24 hours and resume a normal diet <sup>10†</sup>
- Patients are generally able to return to non-strenuous activity within a couple of days
- Reduces gassiness and bloating <sup>9‡</sup>
- Preserves the ability to belch and vomit <sup>8,9¥</sup>

## 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<0.001)
- # 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 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<0.001)
- ¥ 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).<sup>12</sup>

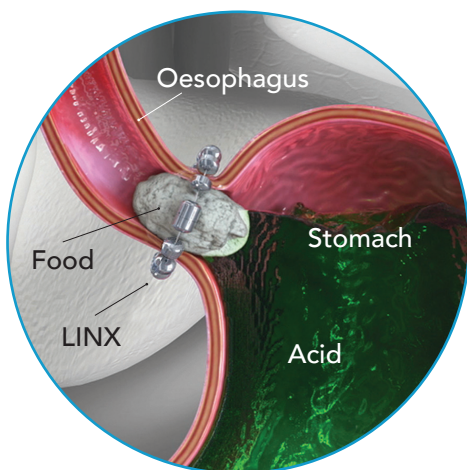
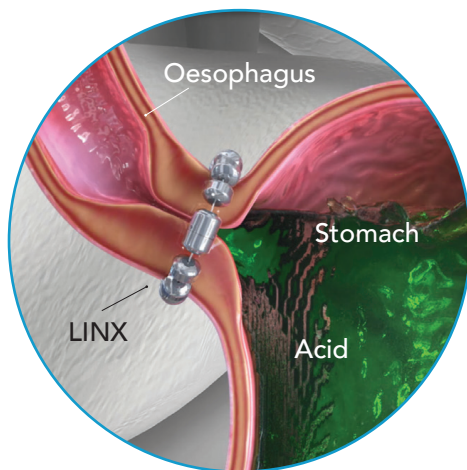
# Redefining the Surgical Treatment of Reflux Disease

## 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 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.

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™

**85%** of patients were freed from dependence on daily GORD medication <sup>9#</sup>

Bothersome regurgitation was eliminated in **99%** of patients <sup>9†</sup>

Bothersome heartburn was eliminated in **88%** of patients <sup>9‡</sup>

Patients reported a significant improvement in their **Quality of Life** <sup>9¥</sup>



\* 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 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 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, 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).



## RefluxStop™ Anti-reflux Surgery

RefluxStop™ is the latest development in anti-reflux surgery and it is creating excitement among clinicians and patients alike. Its effect is to restore the normal healthy anatomy at the base of the oesophagus, through a day case laparoscopic (keyhole) surgery procedure.

The early published results are excellent. They show normalisation of acid levels in the vast majority of patients and, as a consequence, quality of life survey scores show significant improvement.

Another attractive feature of RefluxStop™ is that it appears to negate two of the issues that cause patients concern following fundoplication and LINX®. Specifically gas bloat, excessive wind and dysphagia (difficulty swallowing) are common problems following fundoplication. Similarly dysphagia can also occur following LINX® although less commonly. These potential benefits open RefluxStop™ to a wider group of patients.



## How does it work?

RefluxStop™ treats acid reflux without affecting the oesophagus, a novel method that could eventually change the way acid reflux is treated. The ingenious RefluxStop™ device is a non-active implant that is placed on the upper part of the stomach through laparoscopic (keyhole) surgery. CE mark approval was granted in August 2018, on the strength of a multi-centre clinical investigation in which the safety and effectiveness of the device in patients was demonstrated.

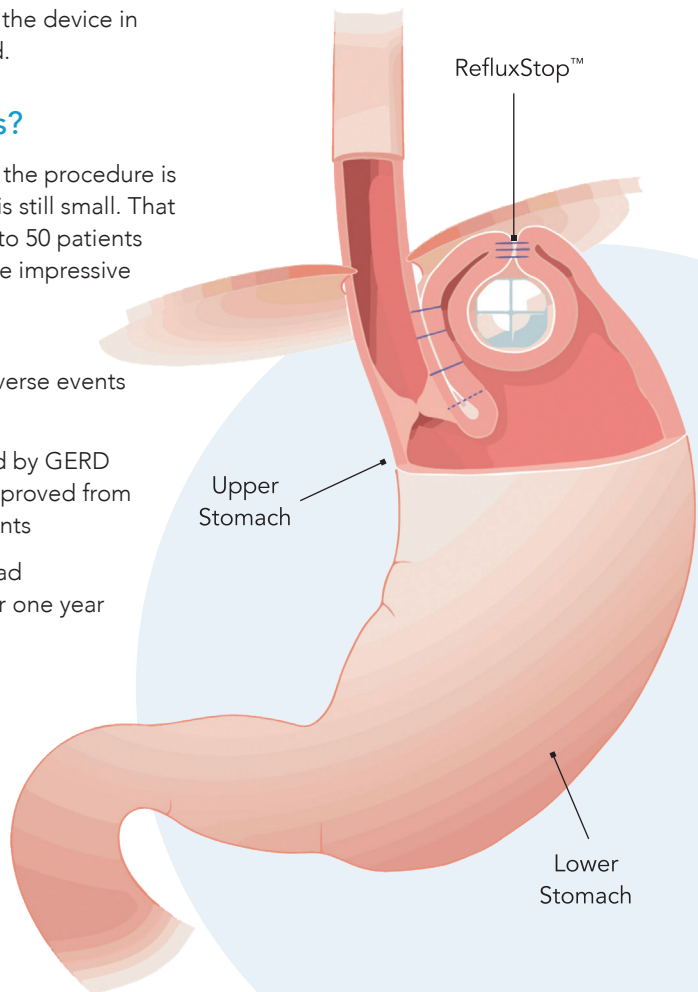
## What are the results?

It's important to stress that the procedure is new so the evidence base is still small. That said, an important study into 50 patients was published in 2020\*. The impressive headlines are as follows:

- No reported serious adverse events related to the device
- Quality of life, measured by GERD HRQL questionnaire, improved from baseline in 86% of patients
- 98% of study subjects had normal reflux levels after one year

- No dysphagia (difficulty swallowing) - sometimes a concern about other procedures
- Gas bloat symptoms were very significantly improved
- Perhaps most importantly, all 50 subjects were using PPI medication at baseline, one year later only one patient was using them

\*Bjelovic et al, BMC Surgery 2020





## What are the side effects and complications?

The current published data shows no serious side effects, either generally or specifically related to the device. It is important to remember however that the data is still thin at the moment as this is a new procedure.

All reflux surgery carries some risk and those patients who proceed to RefluxStop™™ surgery will do so in the knowledge of the following risks:

- Haemorrhage (bleeding)
- Visceral injury
- Vagal injury
- Recurring hiatal hernia

These risks and those that apply more generally to laparoscopic (keyhole) surgery would be explained by your surgeon ahead of your surgery and more specifically in the consent form you will be asked to sign.

## The Reflux Treatment Does the effect last?

Initial results for the RefluxStop™ are excellent but it's still early days. As with all new devices, it will take several years to develop a deep understanding of the long-term efficacy of a procedure and the important factors such as re-operation rates. For now however the safety and efficacy data is good.

## What about recovery following surgery?

RefluxStop™ is a day case procedure. As such there will be a short recovery period. Patients can expect to be up and about within hours of their surgery and then slowly resuming normal day to day activities over a couple of weeks. It's especially important to take things easily in the first week post op and not to overdo it during the initial healing process.

Importantly, the effect of RefluxStop™ is immediate so patients can expect to resume a normal diet within a few hours of surgery. For long suffering reflux patients this can be one of the major benefits of RefluxStop™ surgery.

## Why people choose RefluxUK for their RefluxStop™ surgery

RefluxUK is the first clinic in the UK to offer the RefluxStop™ procedure. Our team has expertise across all of the treatment options and we bring that expertise together through our reflux multi-disciplinary team. This team includes specialist reflux clinicians with backgrounds in Upper GI (gastroenterology and surgery), ENT, physiology and nursing. Together they ensure that all surgical patients benefit from in-depth and impartial scrutiny to deliver the best possible outcomes.



## References:

1. Buckley F, Bell R, Freeman K, Doggett S, Heidrick, R. Favorable results from a prospective evaluation of 200 patients with large hiatal hernias undergoing LINX magnetic sphincter augmentation. *urg Endoscopy*. 2017. 32(4):1762-1768.
2. National Institute of Diabetes and Digestive and Kidney Diseases. <https://www.niddk.nih.gov/health-information/digestive-diseases/acid-reflux-ger-gerd-adults/symptoms-causes>. Accessed June 17, 2019
3. Lenglinger J, Riegler M, Cosentini E, et al. Review on the Annual Cancer Risk of Barrett's Oesophagus in Persons with Symptoms of Gastro-oesophageal Reflux Disease. *Anticancer Res*. 2012 Dec;32(12):5465-73
4. Mayo Clinic. Gastro-oesophageal reflux disease (GORD). <https://www.mayoclinic.org/diseases-conditions/gerd/symptoms-causes/syc-20361940>. Accessed June 17, 2019
5. Katz PO, Gerson LB, Vela MF. Guidelines for the Diagnosis and Management of Gastro-oesophageal Reflux Disease. *Am J Gastroenterol*. 2013. 108:308–328; doi: 10.1038/ajg.2012.444
6. Rona K, Reynolds J, Schwameis K, et al. Efficacy of magnetic sphincter augmentation in patients with large hiatal hernias. *Surgical Endoscopy*. 2017. 31(5):2096-2102
7. Kellokumpu I, Voutilainen M, Haglund C, Färkkilä M, Roberts PJ, Kautiainen H. Quality of life following laparoscopic Nissen fundoplication: Assessing short-term and long-term outcomes. *World J Gastroenterol*. 2013 Jun 28;19(24):3810-8.
8. Reynolds JL, Zehetner J, Wu P, Shah S, Bildzukewicz N, Lipham JC. Laparoscopic Magnetic Sphincter Augmentation vs Laparoscopic Nissen Fundoplication: A Matched-Pair Analysis of 100 Patients. *J Am Coll Surg*. 2015 Jul;221(1):123-8.
9. Ganz R, Edmundowicz S, 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.
10. Ganz RA, Peters JH, Horgan S, et al. Oesophageal Sphincter Device for Gastro-oesophageal Reflux Disease. *N Engl J Med*. 2013 May 23;368(21):2039-40.s.

Email: [enquiries@opa.org.uk](mailto:enquiries@opa.org.uk)

Web: [www.opa.org.uk](http://www.opa.org.uk)

Tel: 0121 704 9860.

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OPA Cancer Charity, Unit 4, Bordesley Hall Farm Barns,

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