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# A PROVEN TREATMENT FOR CHRONIC REFLUX

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Doc no 3393-1 Rev 3
Date of Issue OCT 15

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**This booklet is for patients who have discussed the LINX® Reflux Management System during a consultation with their surgeon. It will answer some of the questions that are often asked before surgery – how chronic reflux or Gastro Oesophageal Reflux Disease (GORD) is caused, what the LINX® System is, what the procedure involves, how it can treat GORD and the recovery process.**

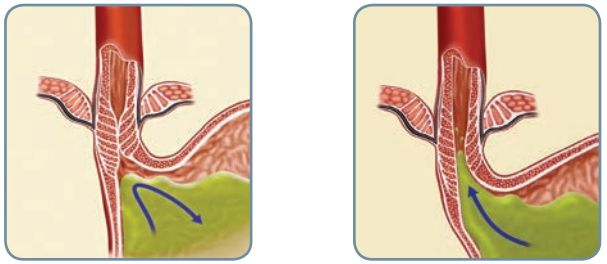
## HOW COMMON IS GORD?

GORD is the most common diagnosis made by doctors in gastroenterology outpatient clinics and it is thought to affect at least 10% of the adult population in Western Countries. Heartburn is the most common symptom of GORD and 12% of Western populations experience heartburn at least once a week, with 5% having daily heartburn. However, some GORD patients never experience heartburn but may have other less common symptoms such as pain when swallowing, nausea and excess saliva. For many sufferers the symptoms of GORD can impact significantly on the ability to perform daily activities and can have a negative effect on their quality of life.[1-3]

GORD is "a condition which develops when the reflux of stomach contents causes troublesome symptoms and/or complications"[3]

## WHAT CAUSES REFLUX/GORD?

Reflux occurs when acid and bile from the stomach enters the oesophagus, causing symptoms such as burning and regurgitation. In healthy individuals, a muscle at the junction of the oesophagus and stomach called the lower oesophageal sphincter (LOS) acts as a valve to stop this occurring. In people with GORD, the LOS is weak and allows reflux back into the oesophagus.



Over time, if left untreated, reflux can cause damage to the lining of the oesophagus and in some cases can lead to ulcers, scar tissue build up (stricture) and inflammation. Chronic or long-term reflux can cause changes to the cells in the oesophagus which lead to Barrett's oesophagus, and possibly oesophageal cancer. Because of these possible dangers, it is important to control reflux symptoms and avoid long-term damage.

*"My reflux symptoms were terrible – it left me with 10 years of burning in the throat, asthma, hoarseness and excess mucus after eating, as well as being prone to sinus infections. The symptoms really knocked my confidence and made me not want to socialise; I couldn't eat out with friends as I would feel the food coming back up, and I had to avoid a lot of lunch meetings with work. I love intense sport, but had to stop playing football and weight training because I felt so bad."*[4]

# TREATMENT OPTIONS

In the early stages of reflux disease or in mild cases, patients are usually prescribed medication by their doctor to control the symptoms, such as antacids or PPIs (proton pump inhibitors). The aim of PPIs is to reduce the acidity of the reflux and therefore reduce irritation and inflammation in the oesophagus.[3] Unfortunately for many people, their symptoms persist despite the medication. There is growing concern about the long-term use of PPIs as there is evidence of a possible link with increased bone fracture rates, *Clostridium difficile*-associated diarrhoea (CDAD) and oesophageal cancer.[5,6,7]

## GORD occurs with varying degrees of severity:

In **MILD GORD**, the symptoms are controlled by medication. In very mild cases the medication may only be needed from time to time. However in mild to moderate GORD, the medication may have to be taken every day for long periods to control the symptoms.

**MODERATELY SEVERE GORD**, sufferers may obtain incomplete relief from medication and may experience symptoms occurring at night, or suffer from additional symptoms as well as heartburn.

In **SEVERE GORD** one or more complications may occur. These include:

- Ulcerative oesophagitis – a condition in which the oesophagus (gullet) becomes inflamed and ulcers develop in the lining of the oesophagus
- Stricture – a narrowing of the oesophagus caused by the build-up of scar tissue following repeated damage
- Barrett's oesophagus – changes to the wall of the gullet caused by prolonged inflammation and which increase the risk of developing oesophageal cancer
- Oesophageal cancer

# TREATMENT OPTIONS

In severe cases of GORD that cannot be treated with medication, individuals may be referred to a surgeon who may recommend a complex surgical procedure called fundoplication.

Fundoplication involves wrapping the upper part of the stomach (fundus) around the lower end of the oesophagus and stitching it in place to artificially reinforce a weak lower oesophageal sphincter. When performed by expert surgeons in specialised centres, fundoplication is generally acknowledged as an effective and durable therapy for advanced GORD or patients with a large hiatus hernia. Often there are unwanted side effects such as the inability to belch or vomit, which can cause some patients to be reluctant to proceed with this surgery.[3]

The LINX® System is suitable for chronic GORD sufferers who do not respond fully to medication. The LINX® System is a simple procedure designed to provide a permanent solution to GORD by stopping reflux at its source. The operation does not alter the anatomy of the stomach and may be reversible if necessary.

# WHAT IS THE LINX® REFLUX MANAGEMENT SYSTEM?


*Actual size*

The LINX® System is a medical device which is placed around the Lower Oesophageal Sphincter (LOS) using a simple technique called laparoscopy (keyhole surgery). The device consists of a small flexible band of interlinked titanium beads with magnetic cores and is placed around the LOS in the closed position (see diagram 1). The beads will separate temporarily as the force of a swallow allows food and drink to pass into the stomach (see diagram 2). The magnetic attraction between the beads then brings the device back to the closed position to prevent reflux occurring. The magnets are calibrated to allow higher gastric pressures to open the device, but will not open for the lower gastric pressure of reflux. This means that the device will also open if there is a need to release increased pressure in the stomach (when belching or vomiting).

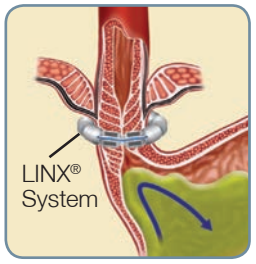


Diagram 1

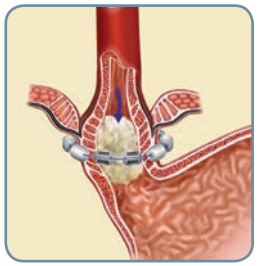
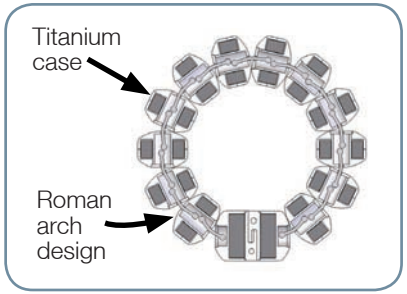
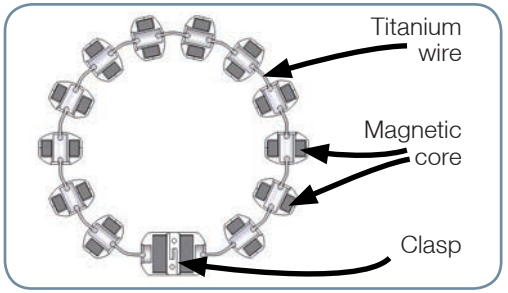


Diagram 2

The LINX® System is made with neodymium permanent rare earth magnets. The magnets are cased in titanium and each bead is joined by individual titanium wires. The Roman arch design means that the device does not compress the tissue around the oesophagus and a specially designed clasp securely locks one end of the device to the other so it will not come undone. The device is positioned so it will not move from its location inside the body.




Both the titanium and other materials used in the device are inert and are commonly used in medical devices.

# WHO IS THE LINX® SYSTEM SUITABLE FOR?

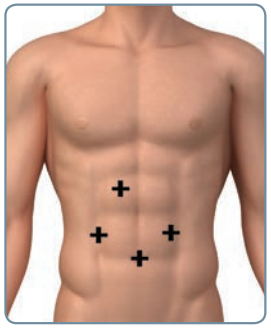
The LINX® System is not suitable for every patient with reflux. It is suitable for people who have suffered from GORD for a number of years, who respond partially to medication. In addition, the individual should be able to swallow normally and have a healthy oesophagus. Patients are assessed for their eligibility following a series of tests. Two of the key tests are pH Monitoring and Manometry.

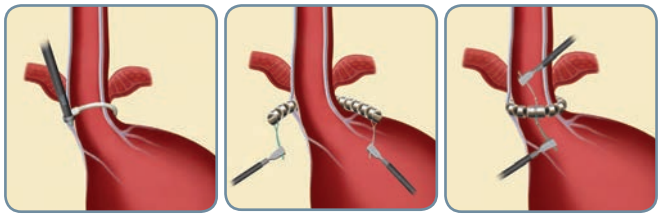
- ## pH Monitoring
  pH monitoring measures the presence of acid in the oesophagus over a 24 or 48 hour period. The results of this monitoring are expressed as a DeMeester score. The DeMeester score takes into account the amount of time there is acid in the oesophagus (upright and lying down), the number of reflux episodes that occur and how long they last. A normal DeMeester score is less than 14.7.

- ## Manometry
  This procedure assesses the muscle functioning of the oesophagus and will show any swallowing disorders that are present. To be eligible for the LINX® System you need to have a normal manometry result so that your oesophagus functions well enough to allow the device to open and close.

# THE PROCEDURE

Before the procedure begins, you will be placed under general anaesthesia. The surgeon will then make 4 or 5 small incisions in your stomach to gain access to the lower oesophageal sphincter (LOS). The surgeon will perform a small amount of dissection to the tissue surrounding the LOS, to create a small tunnel in which the LINX® device will be placed. A sizing tool is passed around the LOS to measure the diameter of the oesophagus, before the appropriate sized device is introduced into the tunnel created.





The procedure generally takes less than an hour and starts working immediately. Your surgeon will normally discharge you the following day and you will be encouraged to start eating normal food immediately. Typically, you will be able to resume your normal daily activities in less than a week.

*"The whole process was straightforward and I was functioning normally within a few days of the operation. In fact, I sat enjoying solid food in the hospital on the same night as I had the procedure without any reflux symptoms at all![4]"*

# ARE ANY SIDE EFFECTS LIKELY?

## SHORT-TERM SIDE EFFECTS

Following surgery, most patients will experience difficulty when swallowing (dysphagia) and some patients may also experience discomfort or pain whilst eating (odynophagia). This can occur as your body adjusts to the LINX® System opening and closing and can also be caused by scar tissue forming around the device as your body heals. Dysphagia normally peaks at around 6 weeks and all side effects tend to be mild and resolve without treatment within 12 weeks.[1]

## HOW TO MANAGE DYSPHAGIA

If you experience dysphagia, try to eat frequent, smaller meals throughout the day. Drinking water before and during meals can help, as can taking smaller bites of food and chewing thoroughly before swallowing.

If a piece of food does cause discomfort, have some water or a fizzy drink. Try to eat a normal diet as soon as tolerated, including solid foods like meat and vegetables so that your body learns to accept the device opening and closing. You will be given specific dietary advice to manage any dysphagia you may experience after surgery.

## LONG-TERM SIDE EFFECTS

The procedure requires no alteration to your anatomy and no significant complications have been reported during surgery. Some patients have reported persistent dysphagia and odynophagia which is usually resolved without intervention, however, occasionally some patients have required a dilatation for dysphagia. This involved the inflation of a small balloon in the gullet to expand the LINX® device under x-ray guidance. This has the effect of opening the capsule that has formed around the LINX® device and eases the passage of food. Additionally, some patients have been re-admitted to hospital for nausea or vomiting. Currently 5.6% of patients require dilatation. In a study of the first 1000 patients the readmission rate was 1.3% for minor morbidity, such as dysphagia, pain, nausea and vomiting[8].

In some patients these complications cannot be resolved and the LINX® device needs to be removed, this is done laproscopically. As the procedure is reversible there are no permanent changes to internal organs or tissues. It is often possible for the surgeon to perform a traditional anti-reflux procedure (fundoplication) at the same time as the LINX® removal should this be desired by the patient. This type of LINX® removal has been required in 3.4%[8] of patients.

Lastly, there have been reports of the LINX® device moving through the wall of the gullet and being visible inside. In all cases, the LINX® was removed in a planned procedure without any adverse consequences for the patients. To date this represents about 0.25%[9] of the number of patients treated with the LINX® System worldwide since February 2007.

# HOW EFFECTIVE IS THE LINX® SYSTEM?

A clinical study looked at the extent to which the LINX® System had helped patients five years after it had been implanted. The results showed that the GORD symptoms had improved significantly, and that 85% of patients were able to stop daily PPI medication. Reassuringly, these patients also said their quality of life had improved.[1]

The graphs below show (1) the results of how patients felt following the LINX® System implant and (2) how doctors assessed its effectiveness.

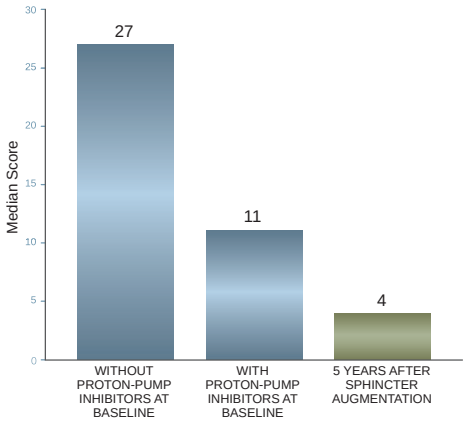
## (1) PATIENTS

### Quality of Life Improved by over 85%[10]

This graph shows the GORD - HRQL (Health-Related Quality of Life) score.

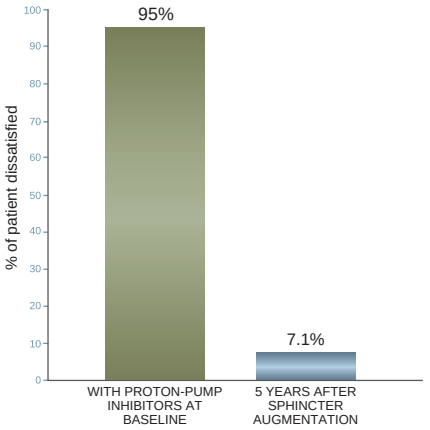
Before having the LINX® System implanted, the average score was 27.

Five years later it was down to just 4.




### Patient Satisfaction: 95% of patients dissatisfied[10]

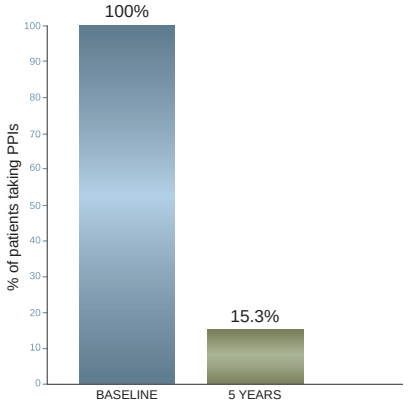
Patient dissatisfaction prior to treatment was 95% and decreased to 7.1% at 5 years.




## (2) DOCTORS

### Most patients no longer required medication[10]

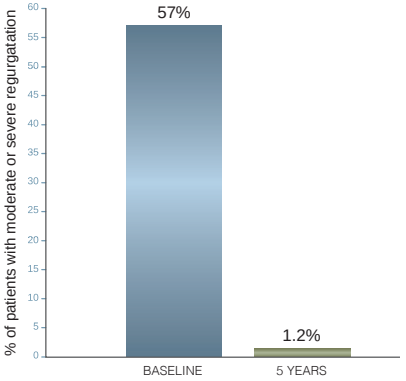
After 5 years, 85% of patients were able to stop daily PPI medication.




### Regurgitation score was reduced[10]

The assessment of regurgitation symptoms, according to the Foregut Symptom Questionnaire rated the severity of regurgitation before and after treatment.

The proportion of patients reporting moderate-to-severe regurgitation decreased, from 57% before implantation to 1.2% at 5 years.



# FREQUENTLY ASKED QUESTIONS

## Q. Will I be cured?

The LINX® Reflux Management System is designed to work with your lower oesophageal sphincter to reduce the symptoms of GORD. But there is a small chance you may still have some symptoms of reflux, such as heartburn, after the implant. Even normal, healthy people can suffer from heartburn or reflux at times. Your doctor or nurse can advise you on how to avoid this, such as eating smaller meals.

## Q. When can I start eating normally again?

Try to return to a normal diet as quickly as you feel able to do so. This helps your body adapt to the LINX® Reflux Management System.

## Q. When can I return to normal physical activities?

Generally, patients can return to non-strenuous activity within a couple of days. However, as with any surgical procedure, you should consult your doctor about what activities you can do and how soon you can do them after the insertion of the LINX® System.

## Q. Is there a risk of my body rejecting the LINX® Reflux Management System?

The LINX® System is designed to minimize the risk of rejection. All areas of the device that contact the body are made of materials that are used frequently in medical devices and have proven to be very stable. However, if you have a medical history that suggests you may be at increased risk of your body rejecting a medical device, it is important that you tell your doctor about this before receiving a LINX® Reflux Management System.

# FREQUENTLY ASKED QUESTIONS

## Q. Will the magnets wear out?

The LINX® Reflux Management System uses permanent magnets and therefore will not wear out.

## Q. Can I go through airport security?

The LINX® Reflux Management System should not affect airport security. However, all patients will be provided with an implant card to have available in case an issue arises.

## Q. Can I have an MRI test after receiving the LINX® Reflux Management System?

If you are told you need an MRI procedure, please contact your LINX® physician. It is important to know which LINX® device you have. The LX models of LINX® are considered MR Conditional in a magnetic resonance imaging (MRI) system up to 0.7 Tesla. The LXM models of LINX® are considered MR Conditional in a MRI system up to 1.5 Tesla. Scanning under different conditions may interfere with the magnetic strength and function of the device. LINX® implants **PRIOR** to September 10, 2015 have the LX model. If your LINX® implant was **AFTER** September 10, 2015, contact your LINX® physician.

## Q. Will I need a follow-up endoscopy?

An endoscopy is not required after the LINX® procedure.

*“The LINX® System has very much helped me from day one – I have no reflux symptoms and I feel a lot better now that I can eat whatever I want. It has been 7 weeks since the operation and I am getting a bit of dysphagia and I am not taking any medication for GORD. I feel in control now and I can focus on other things such as business lunches and sport, without the constant worry of GORD.[4]”*

# REFERENCES


1. Bonavina L, DeMeester T, Fockens P, *et al*: Laparoscopic sphincter augmentation device eliminates reflux symptoms and normalizes esophageal acid exposure: one and two year results of a feasibility trial. Annals of Surgery 2010; 252: 857-62.
2. Moayyedi P, Axon ATR: Review article: gastro-oesophageal reflux disease – the extent of the problem. Aliment Pharmacol Ther 2005; 22: 11-19.
3. Kahrilas P: Gastroesophageal Reflux Disease. The New England Journal of Medicine; 359: 1700-07.
4. Data on file, Torax Medical document 3281-1.
5. Gray S, *et al*: Proton Pump Inhibitor Use, Hip Fracture, and Change in Bone Mineral Density in Postmenopausal Women. Arch Intern Med 2010; 170; 765-71.
6. Dial S, *et al*: Use of Gastric Acid-Suppressive Agents and the Risk of Community-Acquired *Clostridium difficile*-Associated Disease. JAMA 2005; 294; 2989-95.
7. Nason K, *et al*: Gastroesophageal Reflux Disease Symptom Severity, Proton Pump Inhibitor Use, and Esophageal Carcinogenesis. Archives of Surgery 2011; 146: 851-58.
8. Lipham J C, Taiganides P A, Louie B E, *et al*: Safety analysis of first 1000 patients treated with magnetic sphincter augmentation for gastroesophageal reflux disease. Diseases of the Esophagus 2014.
9. Data on File, Torax Medical.
10. Ganz, *et al*: Long-Term Outcomes of Patients Receiving a Magnetic Sphincter Augmentation Device for Gastroesophageal Reflux, Clin Gastroenterol Hepatol. 2015 Jun 2. [Epub ahead of print].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