



## **LINX™ Reflux Management System**

### **Patient Information**

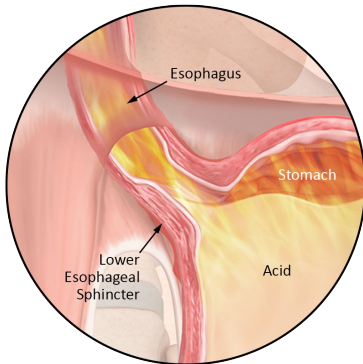
**Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.**

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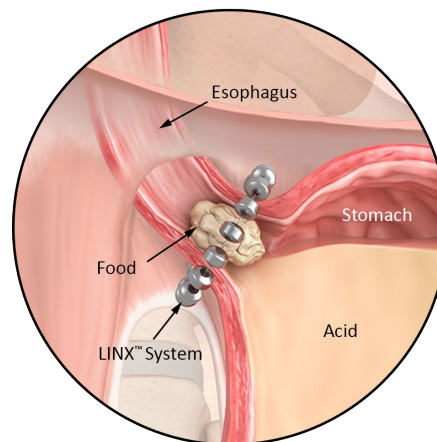
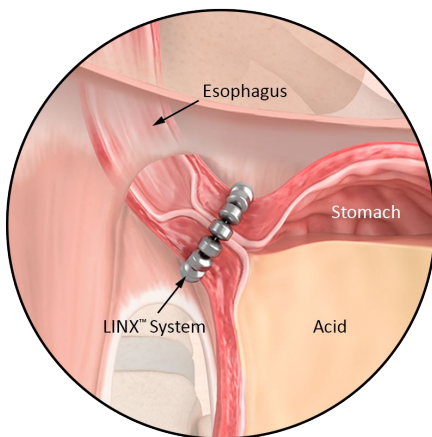
## What is the LINX Reflux Management System?

The LINX Reflux Management System is a medical device for patients 21 years and older who have been diagnosed with Gastroesophageal Reflux Disease (GERD) and continue to have heartburn or regurgitation, despite taking medication to treat GERD.



GERD occurs when the sphincter (valve) between the stomach and esophagus is weak or opens abnormally. Stomach juices reflux into the esophagus and may injure the esophagus and cause symptoms of heartburn or regurgitation.

The LINX System is designed to help the sphincter stay closed to stop the reflux. It uses a small, flexible band of beads. Each bead has a magnet inside. When placed around the outside of the esophagus, the magnetic attraction between the beads helps the sphincter stay closed to prevent reflux. Swallowing food will overcome the magnetic attraction and allow the beads to separate, allowing food and liquid to pass normally into the stomach.



## Why choose LINX?

The LINX Reflux Management System is used for treating GERD when medication no longer provides adequate symptom control. The LINX System is another option to the standard surgery for GERD, such as a fundoplication. The LINX System is designed to be:

- **Less invasive.** Placement of the LINX System does not involve significant alterations to anatomy that may limit future treatment options. With a fundoplication, the top part of the stomach is wrapped around the lower esophagus to improve the reflux barrier.
- **Removable.** If needed, the LINX System can be removed during a laparoscopic procedure similar to the implant procedure. Removal of the device generally leaves the esophagus the same as before the implant.
- **Well-tolerated.** After surgery, patients usually go home the same day or the next day. Patients are able to eat a normal diet after surgery. With a fundoplication, patients are restricted to a liquid diet that is slowly advanced over weeks to normal food.

### **Contraindications: Who cannot have the LINX System**

Patients with suspected or known allergies to titanium, stainless steel, nickel, or ferrous materials should never be implanted with the LINX System. If you have an allergy to titanium, stainless steel, nickel or ferrous materials, tell your doctor. Please note, Nickel is not a metal component of the LINX device, only the LINX Sizing Tool contains Nickel.

### **Warnings: Things you must do to avoid serious harm**

- The LINX System is considered MR Conditional in a magnetic resonance imaging (MRI) system up to 1.5-Tesla (1.5 T). Scanning under different conditions may result in serious injury to you and/or interfere with the magnetic strength and the function of the device. If a doctor prescribes an MRI examination for you, inform the doctor and MRI technologists that you have an implanted device prior to your MRI examination appointment. Full MRI safety information is available at [www.toraxmedicalmri.com](http://www.toraxmedicalmri.com).
- It is recommended that anyone implanted with the LINX System register the device with the MedicAlert Foundation ([www.medicalert.org](http://www.medicalert.org)) or a similar organization.

## Possible risks of having this done

Company-sponsored studies showed the most common complications related to the LINX device and/or procedure were:

- Dysphagia (difficulty swallowing)
- Pain (chest and upper abdominal)
- Stomach bloating

### More information about difficulty swallowing

In the pivotal clinical study, before and after treatment, patients completed GERD questionnaires. The GERD-HRQL showed that patients indicated that their symptoms of difficulty swallowing, or painful swallowing were no worse after having LINX implanted than they were before treatment. The Foregut Symptoms Questionnaire showed, the average number of times that a patient had difficulty swallowing was 1 to 2 times per week at five years.

### Other possible risks related to the LINX System may include, but are not limited to:

Achalasia (muscles of the esophagus fail to relax during swallowing), Bleeding, Cough, Death, Decreased appetite, Device erosion (device passes through esophagus wall), Device explant/re-operation, Device failure, Device migration (device does not appear to be at implant site), Diarrhea, Dyspepsia (indigestion), Early satiety (feeling full after eating a small amount of food), Esophageal spasm (contractions of the esophagus), Esophageal stricture (narrowing of the esophagus), Flatulence, Food impaction (food gets stuck), Globus sensation (feeling of having a lump in your throat), Hiccups, Inability to belch or vomit, Increased belching, Infection, Impaired gastric motility (ability to move food/liquid through your system), Injury to the esophagus, spleen, or stomach, Nausea, Odynophagia (pain or discomfort with swallowing),

Organ damage caused by device migration, Peritonitis (inflammation of the thin tissue that lines the inner wall of the abdomen), Pneumothorax (collapsed lung), Regurgitation, Saliva/mucus build-up, Ulcer, Vomiting, Weight loss, Swallow-induced syncope (fainting) and Worsening of pre-operative symptoms (including but not limited to difficulty swallowing or heartburn).

### **Possible risks of surgery and anesthesia**

Additionally, surgery and anesthesia carry risk. These risks may include, but are not limited to the following:

Adverse reaction to anaesthesia (headache, muscle pain, nausea), Anaphylaxis (life threatening allergic reaction), Cardiac arrest (blood circulation stops), Death, Diarrhea, Fever, Hypotension (low blood pressure), Hypoxemia (inadequate oxygen in blood), Infection, Myocardial infarction (heart attack), Perforation (hole in the esophagus), Pneumonia (lung infection), Pulmonary embolism (blocked artery in lungs), Respiratory distress (breathing trouble), and Thrombophlebitis (blood clot causing inflammation). Other risks reported after anti-reflux surgery include bloating, nausea, dysphagia (difficulty swallowing), odynophagia (pain or discomfort with swallowing), retching, and vomiting.

### **Possible benefits of having this done**

Benefits of treatment with the LINX System may include:

- Reduction in acid exposure to your esophagus
- Improvement in heartburn and regurgitation symptoms
- Reduction or elimination of GERD medications
- Less invasive surgery compared to the standard surgical treatment for GERD
- Ability to resume a normal diet following surgery
- Discharge the same day or the next day after surgery
- Minimal side effects, such as being unable to belch or vomit

## How to decide about this treatment

When considering the LINX System, it is important to understand the following:

- The device is a permanent implant, and limited long-term experience is available. Sustainability of effect, as assessed by quality of life scores, has not been studied past 12 years. It is possible that the device may need to be removed or replaced at a later time. If the device fails or breaks, your GERD symptoms may return or you may experience unusual pain.
- Every patient is different. There are no guarantees that your GERD symptoms will improve. It is possible you may need to continue GERD medications after treatment.
- The LINX System is only considered safe for magnetic resonance imaging (MRI) in MRI scanning machines up to 1.5 T (magnetic field strength). You should discuss the MRI scanning options with your doctor prior to deciding on treatment with the LINX System.
- The LINX System has not been studied in patients with unrepaired hiatal hernias greater than 3 cm in size, advanced esophagitis (inflammation of the esophagus), prior gastric surgeries with the exception of laparoscopic sleeve gastrectomy (LSG), metallic implants such as pacemakers or defibrillators, swallowing difficulties, or motility disorders. Please discuss your medical history with your doctor to determine if you have any conditions for which the LINX System is not recommended.
- The LINX System is not the only option available. The standard surgical treatment for GERD is a fundoplication. Your doctor will discuss this option and other options available to you, which may include treatments performed by endoscopy such as radiofrequency applications to the sphincter area and endoscopic sewing devices that sew part of the stomach to the esophagus.
- Other treatments performed in the area of lower esophagus may not be possible or will need careful consideration if the LINX System is present. These treatments may include surgical or endoscopic interventions for weight loss, Barrett's esophagus or GERD.

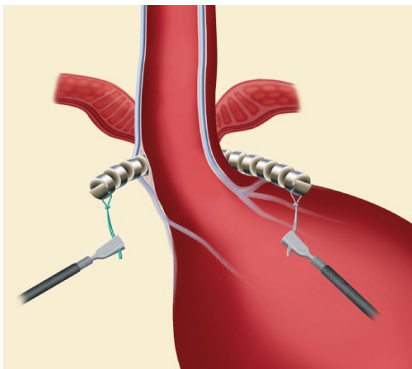
## What happens before the treatment?

You will need to have several tests to make sure you are healthy enough for the surgery and to assess your esophagus. Your doctor will explain these tests to you. These tests will likely include:

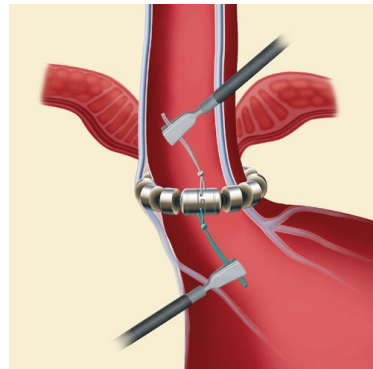
- Esophageal pH testing (tests for acid in the esophagus)
- Manometry/Motility (measures pressures in the esophagus and how many swallows are effective)
- Endoscopy (a visual examination of your esophagus using an endoscope)
- Barium esophagram (x-ray to examine the esophagus. The x-ray is performed while you drink chalky substance called contrast.)

## What happens during the treatment?

Under general anesthesia, a surgeon who has experience in anti-reflux procedures and has received specific training in the use of the LINX device, will access the esophagus using a laparoscopic approach (through several small incisions made in the abdomen). The LINX System is placed around the esophagus and the ends of the device are attached to each other. The procedure usually takes less than one hour to perform. It is unlikely that the LINX System will move from the place where it was implanted since it becomes encapsulated (covered) with tissue during the healing process.



**LINX is placed around the esophagus**



**LINX in place with the ends connected**

## What happens after the treatment?

### Return to normal diet

You should return to a normal diet as soon as tolerated after the surgery. This is important to ensure proper healing at the implant site of the LINX System.

### You may have difficulty swallowing

You may feel like you are having difficulty or pain with swallowing after the surgery. This is normal and expected. If you experience difficulty swallowing, follow these steps:

- Drink a few sips of water before taking your first bite of food and between bites as necessary.
- Take small bites of foods that can easily pass down your esophagus and into your stomach.
- Chew food well before swallowing.
- Foods like bread, pasta, rice, and meat are more likely to cause problems.

### Implant Card

You will receive a LINX Implant Card following your surgery. Carry your LINX Implant Card with you as notification to care providers that you have received a LINX System. If you lose this card, please contact your doctor's office.

## When to call your doctor

After the procedure, your doctor will provide you with instructions about when to call. In general, you should contact your doctor if you have:

- Fever over 100.4 degrees or signs of infection
- Difficulty swallowing or inability to swallow
- Painful swallowing
- Increased abdominal pain
- Return of preoperative GERD symptoms
- Nausea or vomiting
- Cough or difficulty breathing

**You should call your doctor if:**

- You are told that you need to have an MRI procedure. You must notify your physician or MRI personnel that you have been implanted with the LINX system, which is only safe to undergo scanning under certain conditions. Undergoing an MRI scan in a machine greater than 1.5 T could cause serious injury to you and/or interfere with the magnetic strength and the function of the device.
- You are told you need other surgical procedures or endoscopic treatments of your esophagus. These may be contraindicated because of the presence of the LINX System.

**Travel**

You may travel as soon as advised by your doctor. The LINX System should not interfere with airport security. You should carry your implant card when traveling so others will know you have an implanted device in case of an emergency.

**What studies showed**

The LINX System has been evaluated in multiple company-sponsored clinical studies. The following table highlights the two largest studies. Patients have been followed for 5 years in both studies.

| Name                       | Purpose   | Number of patients enrolled |
|----------------------------|---|-----------------------------|
| <b>Pivotal Study</b>       | Demonstrate the safety and effectiveness of LINX before and after the device was approved for use | 100                         |
| <b>Post-Approval Study</b> | Monitor safety and efficacy of LINX after the device was approved                                 | 200                         |

**Safety**

In the pivotal study, a total of 7.0% of patients experienced serious events related to the device or procedure. No deaths or intra-operative complications occurred. None of the reported risks discussed earlier resulted in permanent disabilities or impairment. There was one serious event (vomiting) that was reported as ongoing at the end of the study.

In the post-approval study, a total of 5.5% of patients reported serious events related to the device or procedure; all had resolved by five years except one occurrence of pain which was reported as ongoing at the end of the study. Two deaths occurred due to cancer which was determined not to be related to the device or procedure.

In both studies, devices were removed without complication if needed. In the pivotal study, 7% of patients had the LINX device removed and in the post-approval study, 13% of patients underwent a removal.

### ***Effectiveness***

Many assessments were used to evaluate how well the LINX System improved the reflux barrier to prevent reflux and improve symptoms.

#### **Testing for Acid in the Esophagus**

Evidence of an improved reflux barrier was evaluated by testing the percentage of time that stomach acid refluxed into the lower esophagus.

In the pivotal study, before treatment, the average time significant acid was detected in the esophagus was 11.6% of the time. At 12 months after treatment, the average time decreased to 5.1% of the time. Normal acid exposure time in the esophagus was defined as 4.5% of the time or less for the study. All patients had abnormal acid exposure time before treatment, and after treatment, the majority of patients had normal acid exposure time in the esophagus. In the post-approval study, testing for acid was performed annually over five years. The percentage of patients who experienced successful acid reduction ranged between 67%-78% during the five years of follow up. Successful reduction was defined as being normalized or a  $\geq 50\%$  reduction in acid as compared to acid levels prior to the device implant.

## Symptoms

Questionnaires were used to assess the frequency and severity of GERD-related symptoms before and after treatment. The table below compares GERD symptoms (moderate and severe regurgitation and heartburn) before treatment and 5 years after treatment with the LINX System.

| GERD Symptoms<br>(moderate or severe) | Pivotal Study                                |   | Post-Approval Study                          |   |
|---------------------------------------|--|---|--|---|
|                                       | % of patients<br>with symptom<br>before LINX | % of patients<br>with symptom<br>5 years after LINX | % of patients<br>with symptom<br>before LINX | % of patients<br>with symptom<br>5 years after LINX |
| Regurgitation*                        | 57%  | 1%  | 61%  | 6%  |
| Heartburn**                           | 89%  | 12%   | 82%  | 14%   |

\*including aspirations (breathing liquid into the lungs)

\*\* affecting their daily life

## Medications

The most common non-surgical treatment recommended for GERD is the use of anti-reflux medications such as proton-pump inhibitors (PPIs).

Patients in the pivotal study had been taking proton-pump inhibitors (Prilosec or Nexium, for example) for an average of 6 years before treatment and all patients were taking GERD medications on a daily basis. After treatment, about 89% no longer required daily GERD medication at 5 years.

In the post-approval study before LINX surgery, 94% of patients reported needing PPIs on a daily basis. After LINX, 90% no longer needed daily PPIs at 5 years.

## More about your condition

You can find additional information on GERD at the National Institutes of Health's website:

<http://www.nlm.nih.gov/medlineplus/gerd.html>

## Where you can find out more

Additional information about the LINX system can be found at: [www.LINXforLife.com](http://www.LINXforLife.com)

## Glossary

**Esophagus** is the tube that carries food, liquids and saliva from your mouth to the stomach.

**Fundoplication** is a surgical procedure which involves tightening the lower esophageal sphincter to prevent reflux by wrapping the very top of the stomach around the outside of the lower esophagus. There are variations depending on a individual patient factors.

**Lower esophageal sphincter (LES)** is a ring of muscle that forms a valve at the lower end of the esophagus, where it joins the stomach.

**Gastroesophageal reflux disease (GERD)** is a condition in which the stomach contents (food or liquid) leak backwards from the stomach into the esophagus (the tube from the mouth to the stomach). This action can irritate the esophagus, causing heartburn and other symptoms.

**Barrett's esophagus** is a disorder in which the lining of the esophagus (the tube that carries food from the throat to the stomach) is damaged by stomach acid and changed to a lining similar to that of the stomach.

**Intra-operative complication** is an unfavorable occurrence that affects a patient during surgery.

**Hiatal hernia** is the protrusion (bulging) of the upper part of the stomach into the chest through a tear or weakness in the diaphragm.

**Magnetic resonance imaging (MRI)** is a test that uses a magnetic field and pulses of radio wave energy to make pictures of organs and structures inside the body. In many cases MRI gives different information about structures in the body than can be seen with an x-ray, ultrasound, or computed tomography (CT) scan. MRI also may show problems that cannot be seen with other imaging methods.

**Proton-pump inhibitors (PPIs)** are a group of drugs whose main action is to stop production of stomach acid. They are the most potent inhibitors of acid secretion available today.

**Esophageal pH monitoring** is a test that measures how often and for how long stomach acid enters the tube that leads from the mouth to the stomach (esophagus).

**Endoscopy** is a procedure where a doctor is able to see the inside lining of your digestive tract. This examination is performed using an endoscope (a flexible fiberoptic tube with a tiny TV camera at the end). The camera is connected to either an eyepiece for direct viewing or a video screen that displays the images on a color TV. The endoscope not only allows diagnosis of gastrointestinal (GI) disease but treatment as well.

**Barium esophagram** or swallow is used as an initial diagnostic test for several esophageal conditions such as Barrett's esophagus, dysphagia (difficulty swallowing) as well as complications such as stricture, obstruction, narrowing, ulcers and tumors. During this procedure, the patient swallows barium, a white, chalky substance, which can then be viewed via x-ray. Using this procedure the physician can view many abnormalities associated with the esophagus.

**Esophageal manometry** is a test to measure the pressure inside the lower part of the esophagus. During the test, a thin, pressure-sensitive tube is passed through your mouth or nose and into your stomach. Once in place, the tube is pulled slowly back into your esophagus.

**Laparoscopic surgery** is a minimally invasive surgery, is a modern surgical technique in which operations in the abdomen are performed through small incisions (usually 0.5–1.5 cm) as opposed to the larger incisions needed in laparotomy (surgery where a large incision is made).

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