



LINX[®] Reflux Management System

Patient Information

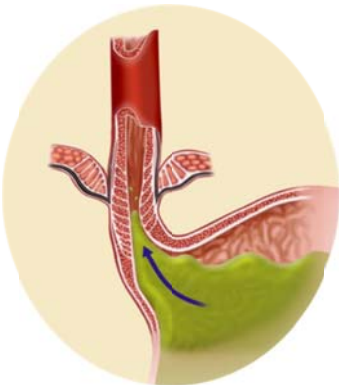
Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.

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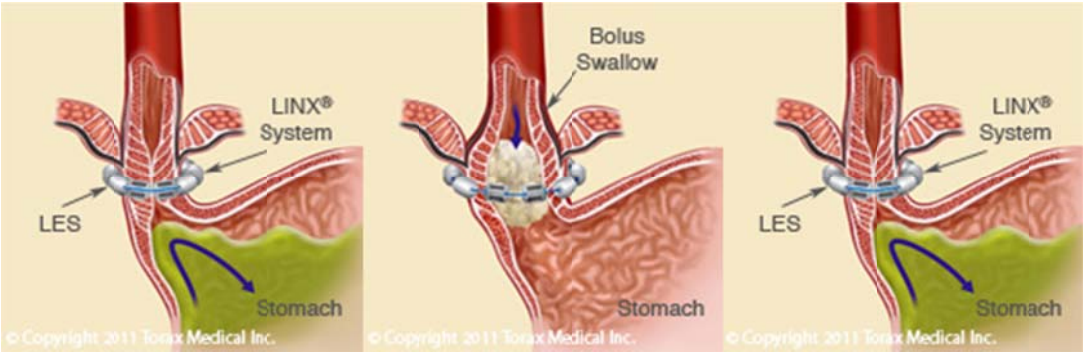
What is the LINX Reflux Management System?

The LINX Reflux Management System is a medical device for patients 21 years and older who have been diagnosed with 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.

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Why doctors use it

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 Nissen fundoplication. The LINX System is:

- **Less invasive.** Placement of the LINX System does not involve significant alterations to anatomy that may limit future treatment options. With the Nissen 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 Nissen 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.

Warnings: Things you must do to avoid serious harm

- The LINX System is not considered safe for magnetic resonance imaging (MRI). You must avoid having a MRI test if you are treated with the LINX System. The MRI could cause serious injury to you and/or interfere with the magnetic strength and the function of the device. It is recommended that anyone implanted with the LINX System register the device with the MedicAlert Foundation (www.medicalert.org) or a similar organization.
- The LINX System should not be used with electrical implants (pacemakers or implantable defibrillators, for example) or metallic implants in the abdomen.

Risks of having this done

A clinical study of 100 patients showed that difficulty swallowing, pain, and stomach bloating were the most common risks associated with the LINX System (summarized below). If you are planning to have the LINX System, your doctor will review these risks with you.

Risk	% of Patients	Clinical Experience
Difficulty swallowing	68%	Treatment included dilation (stretching lower esophagus with a balloon) or removal of device in 3% of patients. Difficulty swallowing resolved when the device was removed. After dilation, the difficulty swallowing improved but sometimes returned and required having the dilation repeated. See below for more information about difficulty swallowing.
Pain	24%	Most cases were mild and resolved by 3 months after the procedure. Treatment included pain medications.
Stomach Bloating	14%	Stomach bloating was mild to moderate and resolved in nearly all patients.

More information about difficulty swallowing

Before and after treatment, patients completed a questionnaire that included a question about difficulty swallowing. Before treatment, 69% of patients reported no symptoms related to difficulty swallowing compared to 55% at 6 months, 64% at 1 year and 59% at 2 years. Before treatment, difficulty swallowing that bothered patients every day or worse was 5% compared to 7% at 6 months, 5% at 1 year and 4% at 2 years. The average number of times per week that a patient had difficulty swallowing was 1 to 2 times per week after treatment. Data about difficulty swallowing is reported below.

Do you have difficulty swallowing?*

	Before Treatment	After Treatment		
		6 Months	1 Year	2 Years
0 = No Symptoms	69%	55%	64%	59%
1 = Symptoms noticeable, but not bothersome	11%	15%	18%	15%
2 = Symptoms bothersome, but not everyday	15%	22%	14%	22%
3 = Symptoms bothersome everyday	2%	7%	5%	4%
4 = Symptoms affect daily activities	3%	0%	0%	0%
5 = Symptoms are incapacitating, unable to do activities	0%	0%	0%	0%
Average number of times per week with difficulty swallowing	1	2	2	1

*Questionnaire completed while off GERD medications

Other risks of the LINX System reported less frequently included:

- Painful swallowing – 8%
- Hiccups – 8%
- Nausea – 7%
- Inability to belch or vomit – 6%
- Decreased Appetite – 4%
- Increased belching – 2%
- Flatulence – 2%
- Weight loss – 2%
- Vomiting – 1%
- Food impaction – 1%
- Lump in throat – 1%
- Upset stomach or indigestion – 1%
- Regurgitation of sticky mucus – 1%
- Uncomfortable feeling in chest – 1%
- Vomiting – 1%

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
- Death
- Device erosion (device passes through esophagus wall)
- Device failure
- Device migration (device does not appear to be at implant site)
- Device removal or re-operation
- Esophageal spasm
- Diarrhea
- Infection
- Impaired gastric motility (ability to move food/liquid through your system)
- Injury to the esophagus, spleen, or stomach
- Organ damage caused by device migration
- Peritonitis (inflammation of the thin tissue that lines the inner wall of the abdomen)
- Pneumothorax (collapsed lung)
- Perforation
- Regurgitation
- Retching
- Worsening of pre-operative symptoms (including but limited to difficulty swallowing or heartburn)

Risks of general surgery and anesthesia

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

- Adverse reaction to anesthesia (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)
- Nausea
- Odynophagia (pain or discomfort with swallowing)

(Risks of general surgery and anesthesia – continued)

- Pneumonia (Lung infection)
- Pulmonary embolism (Blocked artery in lungs)
- Respiratory distress (breathing trouble)
- Thrombophlebitis (Blood clot causing inflammation)
- Vomiting

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 2 years. It is possible that the device may need to be removed or replaced at a later time (for example, in 10 years). If the device fails or breaks, your GERD symptoms may return or you may experience unusual pain.

(How to decide about this treatment – continued)

- 90% of patients reported improvement in GERD symptoms or elimination of GERD medications in a clinical study at 1 and 2 years after treatment. Every patient is different. There are no guarantees you will have the same results. It is possible you may need to continue GERD medications after treatment.
- MRI is not allowed while the device is implanted as it may cause serious injury to you and/or the device. This may be an issue if you currently have or may develop a disease or condition where MRI is the appropriate diagnostic test. You should discuss the MRI restriction with your doctor prior to deciding on treatment with the LINX System.
- The LINX System has not been studied in patients with hiatal hernias greater than 3 cm in size, Barrett's esophagus, advanced esophagitis (inflammation of the esophagus), 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 the Nissen 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 laparoscopic 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.



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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 to receive a replacement card.

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
- Nausea or vomiting
- Cough or difficulty breathing

(When to call your doctor – continued)

You should call your doctor if:

- You are told that you need to have an MRI procedure. You should not be exposed to an MRI environment. The MRI could cause injury to you and/or damage to the LINX System.
- 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 two clinical studies enrolling a total of 144 patients. The largest clinical study enrolled 100 patients. Patients have been followed for at least 2 years and as long as 5 years.

Safety

No deaths or intra-operative complications occurred. None of the reported risks discussed earlier resulted in permanent disabilities or impairment. If needed, the device was safely removed without complications.

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. Before treatment, the average time significant acid was detected in the esophagus was 11.6% of the time. After treatment, the average time decreased to 5.1% of the time. Normal acid exposure time in the esophagus was 4.5% 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. After treatment, the likelihood of achieving any reduction in acid exposure time in the esophagus was 90%.

- **Symptoms**

Questionnaires were used to assess the frequency and severity of GERD-related symptom before and after treatment. The table below compares GERD symptoms before treatment and 2 years after treatment with the LINX System.

% of patients with symptom before LINX	GERD Symptom	% of patients with symptom 2 years after LINX
70%	Reflux affecting sleep on a daily basis	2%
76%	Reflux affecting what food they could eat every day	2%
57%	Moderate or severe regurgitation including aspirations (breathing liquid into the lungs)	1%
55%	Severe heartburn affecting their daily life	1%
40%	Esophagitis	11%

- **GERD Medications**

Patients in the 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 90% no longer required daily GERD medication at 1 and 2 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.toraxmedical.com

Glossary

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

Nissen 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.

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.

(Glossary – continued)

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.

(Glossary – continued)

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 and 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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