



REFLUX MANAGEMENT SYSTEM

## INSTRUCTIONS FOR USE

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



## 1. **SYSTEM DESCRIPTION**

The LINX® Reflux Management System is comprised of the following components:

- LINX® Reflux Management System Implant
- LINX® Reflux Management System Esophagus Sizing Tool (packaged separately)

The Esophagus Sizing tool is a single use disposable device provided non-sterile, that must be cleaned and sterilized prior to use (Refer to the LINX® Reflux Management System Esophagus Sizing Tool Instructions for Use).

The LINX® Reflux Management System Implant consists of a series of titanium beads with magnetic cores that are connected with independent titanium wires to form an annular shape. The attractive force of the magnetic beads is designed to provide additional strength to keep a weak LES closed (Figure 1). During swallowing, the magnetic beads slide away from each other on the independent titanium wire "links" to allow esophageal distention as the bolus passes by (Figure 2).

The implant device is offered in multiple sizes to accommodate variation in esophagus size. The sizes are denoted by the model number (e.g., LS12 = 12 Bead Implant). The LINX® Reflux Management System Esophagus Sizing Tool, packaged separately, is utilized to associate the esophagus size to an appropriate LINX® implant device. An illustration of a "12 Bead" size LINX® implant is provided in Figures 1 and 2.

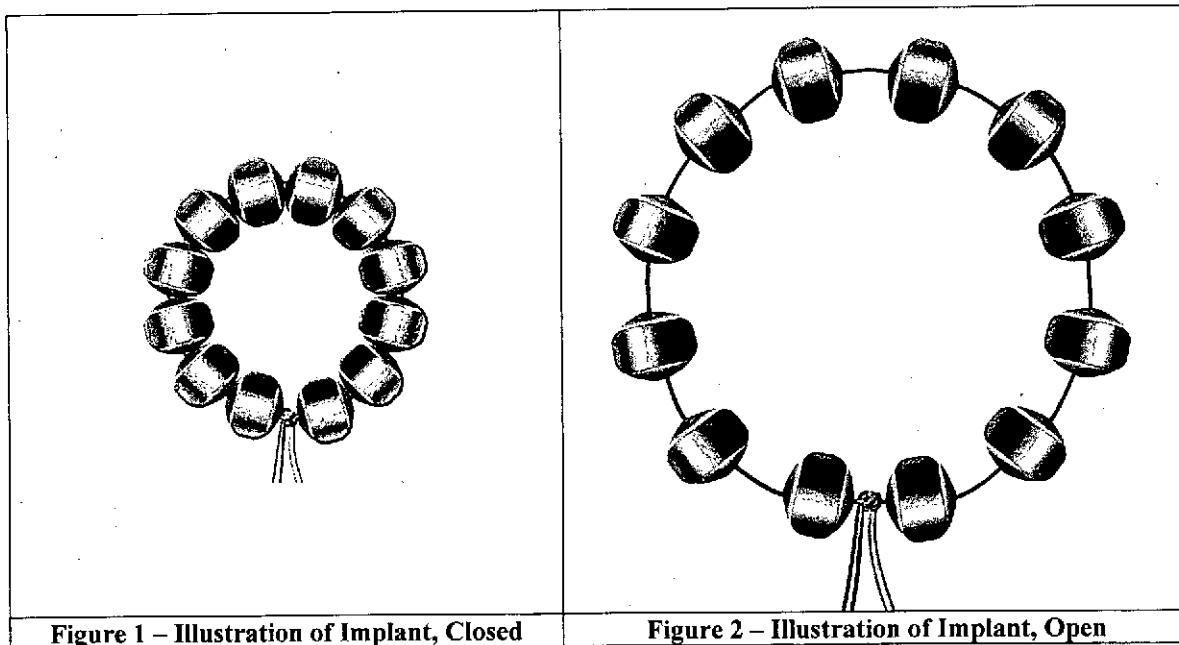


Figure 1 – Illustration of Implant, Closed

Figure 2 – Illustration of Implant, Open

## 2. **INDICATION FOR USE**

The LINX™ Reflux Management System is indicated for patients diagnosed with Gastroesophageal Reflux Disease (GERD) as defined by abnormal pH testing, and who continue to have chronic GERD symptoms despite maximum medical therapy for the treatment of reflux.

### **3. CONTRAINDICATIONS**

- 3.1. Do not implant the LINX® Reflux Management System in patients with suspected or known allergies to titanium, stainless steel, nickel, or ferrous materials.

### **4. WARNINGS**

- 4.1. The device is to be placed around the esophagus including the anterior and excluding the posterior vagus nerve bundle. The device should never be placed outside both vagus nerve bundles.
- 4.2. The LINX® Implant is considered MR Unsafe. After implantation, the patient should not be exposed to an MRI environment. The MRI environment could cause serious injury to the patient and/or interfere with the magnetic strength and the function of the device. A recommendation should be made to patients receiving the LINX® device to register their implant with the MedicAlert Foundation ([www.medicalert.org](http://www.medicalert.org)) or equivalent organization. In the event alternative diagnostic procedures can not 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.
- 4.3. Failure to secure the LINX® device properly may result in its subsequent displacement and necessitate a second operation.
- 4.4. Laparoscopic placement of the LINX® Reflux Management System is major surgery and death can occur.
- 4.5. The device should not be exposed to temperatures above 100°C (212°F) as this could adversely affect the magnets and the function of the device.

### **5. PRECAUTIONS**

- 5.1. Implantation of the device should only be performed by a surgeon who has experience in laparoscopic anti-reflux procedures and has received product specific training.
- 5.2. It is the responsibility of the surgeon to advise the patient of the known risks and complications associated with the surgical procedure and implant.
- 5.3. The sterile package and device should be inspected prior to use. If sterility or performance of the device is suspect or compromised, it should not be used.
- 5.4. The device is intended for single use only. Do NOT re-sterilize the device. Functionality and sterility of the device can not be assured if re-used.
- 5.5. The device is magnetic and will be attracted to ferrous objects in the surgical field and other surgical instruments that are ferromagnetic.
- 5.6. 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 3cm should be considered on the basis of each patient's medical history and severity of symptoms.
- 5.7. Patients should be advised that the LINX® Reflux Management System is a long-term implant. Explant (removal) and replacement surgery may be indicated at any time. Medical management of adverse reactions may include explantation and/or replacement.
- 5.8. The safety and effectiveness of the LINX® device has not been evaluated in patients with Barrett's esophagus or Grade C or D (LA classification) esophagitis.
- 5.9. 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.
- 5.10. The safety and effectiveness of the LINX® device has not been evaluated in patients with major motility disorders.

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

- Scleroderma
- Suspected or confirmed esophageal or gastric cancer
- Prior esophageal or gastric surgery or endoscopic intervention
- Distal esophageal motility less than 35 mmHg peristaltic amplitude on wet swallows or <70% (propulsive) peristaltic sequences or a known motility disorder such as Achalasia, Nutcracker Esophagus, and Diffuse Esophageal Spasm or Hypertensive LES.
- Symptoms of dysphagia more than once per week within the last 3 months.
- Esophageal stricture or gross esophageal anatomic abnormalities (Schatzki's ring, obstructive lesions, etc.).
- Esophageal or gastric varices.
- Lactating, pregnant or plan to become pregnant.
- Morbid obesity (BMI >35).
- Age < 21

## 6. **ADVERSE EVENTS**

- 6.1. Adverse events that may result from use of the LINX® Reflux Management System are both those commonly associated with general surgical procedures as well as those associated with the device specifically.
- 6.2. Potential adverse events associated with laparoscopic surgery and anesthesia include adverse reaction to anesthesia (headache, muscle pain, nausea), anaphylaxis, cardiac arrest, death, diarrhea, fever, hypotension, hypoxemia, infection, myocardial infarction, perforation, pneumonia, pulmonary embolism, respiratory distress, and thrombophlebitis. Other risks reported after anti-reflux surgery procedures include bloating, nausea, dysphagia, odynophagia, retching, and vomiting.
- 6.3. Potential risks associated specifically with the LINX® Reflux Management System include achalasia, bleeding, death, decreased appetite, device erosion, device explant/re-operation, device failure, device migration (device does not appear to be at implant site), diarrhea, dysphagia, early satiety, esophageal spasms, flatulence, food impaction, hiccups, inability to belch or vomit, increased belching, infection, impaired gastric motility, injury to the esophagus, spleen, or stomach, nausea, odynophagia, organ damage caused by device migration, pain, peritonitis, pneumothorax, regurgitation, stomach bloating, vomiting, weight loss, and worsening of preoperative symptoms (including but not limited to dysphagia or heartburn).
- 6.4. The LINX® Reflux Management System is intended to be a long-term implant, and may need to be either explanted or replaced.
- 6.5. Following are summary safety results from the pivotal clinical study:

The analysis of safety in the clinical study was based on 100 subjects.

There were no cases of esophageal erosion or device migration as assessed by upper endoscopy and chest x-rays in any of the subjects that were evaluated up to the 24 month time point. The majority of subjects evaluated with barium esophagram had normal swallow function; there were three subjects with abnormal function, one of whom required dilation.

Manometry was performed at baseline and 12 months. At 12 months, 31 out of the 32 subjects who had a hypotensive LES at baseline were evaluated and three remained hypotensive. Fifteen of 93 subjects had <70% effective swallows, and four had distal esophageal amplitude <35 mmHg. One subject was reported to have ongoing complaints

of dysphagia and abnormal motility. No other significant differences were seen in measures between baseline and 12 months.

Seventy-six (76) of the 100 subjects (76.0%) implanted with the LINX® device experienced a total of 162 adverse events related to the device and/or procedure, as shown in Table 1.

**Table 1: Adverse Events Related to or Relationship to Device or Procedure Unknown**

Adverse Event	Related or Unknown		Mild		Moderate		Severe	
	AEs (n)	Subj. % (n)	AEs (n)	Subj. % (n)	AEs (n)	Subj. % (n)	AEs (n)	Subj. % (n)
Total	162	76% (76)	108	65% (65)	42	28% (28)	12	10% (10)
Dysphagia	76	68% (68)	54	49% (49)	17	16% (16)	5	5% (5)
Pain	25	24% (24)	8	8% (8)	13	13% (13)	4	4% (4)
Stomach Bloating	15	14% (14)	13	12% (12)	2	2% (2)	0	0%
Nausea	8	7% (7)	4	3% (3)	2	2% (2)	2	2% (2)
Odynophagia	8	8% (8)	4	4% (4)	3	3% (3)	1	1% (1)
Other: Hiccups	8	8% (8)	7	7% (7)	1	1% (1)	0	0%
Inability to belch or vomit	6	6% (6)	5	5% (5)	1	1% (1)	0	0%
Decreased Appetite	4	4% (4)	4	4% (4)	0	0%	0	0%
Belching	2	2% (2)	2	2% (2)	0	0%	0	0%
Flatulence	2	2% (2)	2	2% (2)	0	0%	0	0%
Weight Loss	2	2% (2)	2	2% (2)	0	0%	0	0%
Food Impaction	1	1% (1)	0	0%	1	1% (1)	0	0%
Globus Sensation	1	1% (1)	1	1% (1)	0	0%	0	0%
IBS/Dyspepsia	1	1% (1)	1	1% (1)	0	0%	0	0%
Regurgitation of Sticky Mucus	1	1% (1)	0	0%	1	1% (1)	0	0%
Uncomfortable Feeling in Chest	1	1% (1)	1	1% (1)	0	0%	0	0%
Vomiting	1	1% (1)	0	0%	1	1% (1)	0	0%

The most common adverse event experienced by subjects was dysphagia (76 events in 68 subjects). Eighteen (18) subjects at seven sites underwent esophageal dilation for dysphagia, odynophagia, regurgitation or burning sensation in throat. Twelve (12) of these subjects had at least two dilations and 10 of these subjects continued to have symptoms. The second most common event experienced by subjects was pain (25 events in 24 subjects). Unanticipated adverse events included hiccups, belching, food impaction, and pain.

There were nine serious device-or procedure-related adverse events reported in six subjects (Table 2).

**Table 2: Serious Adverse Events – Related or Unknown (as determined by either the Investigator or CEC)**

Serious Adverse Event	Events (n)	Subjects % (n)
Total	9	6% (6)
Dysphagia	3	3% (3)
Nausea	2	2% (1)
Vomiting	2	2% (2)
Odynophagia	1	1% (1)
Pain <sup>1</sup>	1	1% (1)

<sup>1</sup>Adjudicated with a relationship of Unknown to device and/or procedure

Regarding the time to onset, of the adverse events, there were 149 device or procedure related adverse events that occurred between 0 and 180 days. After 180 days, there were 13 events considered related to the device/procedure or of unknown relationship; one of these events was considered serious. This subject experienced chest pain, nausea, and symptoms of indigestion (day 235 post implant). This is shown in Table 3.

**Table 3: Days to Onset of Adverse Event**

Adverse Event Type	0 – 90 Days	90-180 Days	>180 Days
All Adverse Events	70% (218/310)	10% (32/310)	19% (60/310)
Related to device/procedure or unknown relationship	84% (136/162)	8% (13/162)	8% (13/162)
Serious	41% (7/17)	35.3% (6/17)	24% (4/17)
Serious related to device/procedure or unknown relationship	78% (7/9)	11% (1/9)	11% (1/9)

There were five subjects who had the device explanted. Three subjects had the device explanted for dysphagia. Two subjects elected to have a Nissen fundoplication following device removal. Details of the five explants are given below:

- One subject with history of severe heartburn, severe regurgitation, and frequent and prolonged nausea, experienced nausea coupled with dysphagia within two weeks of device implantation. The subject underwent balloon dilation in the region of the gastroesophageal junction without resolution of symptoms and the subject requested to have the device removed at thirty days post-implant. The subject underwent a Nissen fundoplication at a later date.
- One subject with history of GERD started with dysphagia within five days of device implantation. The subject underwent esophageal dilation without resolution of symptoms. Subsequent manometry/motility testing was performed and showed loss of esophageal motility. The device was removed on post-operative day 21.
- One subject started with dysphagia within five days post-implant and odynophagia within seven days post-implant. Esophageal dilations of the gastroesophageal junction (GEJ) were performed without resolution of symptoms and the device was removed 93 days post implant.
- One subject with recurrent GERD symptoms elected to have the device removed so a Nissen fundoplication could be performed. This occurred 489 days post-implant.
- One subject started with intermittent vomiting within three months of device implantation. The subject was subsequently diagnosed with a *Helicobacter pylori* infection and started on medication. The vomiting episodes continued and the device was explanted at 357 days post-implant.

Side effects associated with antireflux surgery were minimal after the LINX® implant. Additionally, other GERD-related outcomes as assessed by the unvalidated Foregut questionnaire, (bloating, regurgitation, extra-esophageal symptoms) showed long-term improvement (Table 4).

**Table 4: Side Effects and Additional Clinical Outcomes**

Parameter	Baseline <sup>1</sup>	12 Months <sup>1</sup>	24 Months <sup>1</sup>
Inability to Belch	0%	1%	0%
Inability to Vomit	0%	0%	1%
Bloating Frequency – Frequently/Continuously	40%	5%	7%

Parameter	Baseline <sup>1</sup>	12 Months <sup>1</sup>	24 Months <sup>1</sup>
Heartburn – Severe or Moderate	89%	3%	6%
Heartburn – Mean frequency/week	79	2	2
Regurgitation – Severe or Moderate	57%	2%	1%
Regurgitation – Mean frequency/week	28	1%	1%
Absence of Extra-Esophageal Symptoms	49%	86%	88%
Chest Pain	69%	20%	16%
Difficulty Swallowing	23%	44%	46%
Difficulty Swallowing – requiring liquids for clearing	4%	7%	12%
Difficulty Swallowing – Mean frequency/week	1	2	1
Patient Satisfied with Present Condition			
Off PPI	0%	95%	90%
On PPI	13%	NA	NA

<sup>1</sup>Assessments completed off PPI therapy, unless noted

## 7. CLINICAL STUDIES

The LINX System has been evaluated in two prospective, single-arm, multicenter clinical trials with a combined enrollment of 144 subjects.

### Feasibility Study

The first study enrolled 44 subjects at four clinical sites (2 US and 2 OUS) as part of a feasibility IDE trial. Performance outcomes for symptom improvement, reduction of PPI dependence and esophageal acid reduction have been reported through three years (Table 5).

**Table 5: Long-Term Feasibility IDE Trial Performance Outcomes**

Performance Outcomes <sup>1</sup>	12 Months % (n/N)	24 Months % (n/N)	36 Months % (n/N)
Improvement in GERD-HRQL scores by $\geq 50\%$	97.4% (38/39)	88.6% (31/35)	96.3% (26/27)
Reduction in PPI therapy by $\geq 50\%$	89.7% (35/39)	82.9% (29/35)	87.5% (28/32)
pH normalization or $\geq 50\%$ reduction in distal acid exposure <sup>2</sup>	79.5% (31/39)	90.0% (18/20)	85.0% (17/20)

<sup>1</sup>Compared to the subject's baseline data and assessed while off proton pump inhibitors

<sup>2</sup>pH monitoring is not performed in US subjects beyond the 12-month follow-up.

A total of 24/44 (54.5%) subjects experienced adverse events related to the device and/or procedure. The most common adverse event experienced by subjects was dysphagia (22 events in 20 subjects). Although most cases resolved within approximately three months, two subjects required dilation in the area of the GEJ, and one subject had the device removed. Other common adverse events included pain, nausea and vomiting. No intra-operative complications, deaths, life-threatening events, device erosions, device migrations or infections were reported. Two subjects had serious adverse events related to the device and procedure that included one device removal for dysphagia and one hospitalization for chest pain <30 days following the device implant procedure. Both events resolved without clinical sequelae.

There were three subjects who had the device explanted. Reasons for explant included ongoing dysphagia (serious adverse event reported above) and elective removal due to recurrent heartburn and need for an MRI study.

- One subject experienced neurological and vascular symptoms unrelated to the device and procedure. The study subject requested removal of the device in order to undergo this MRI procedure. The Investigator complied with this request and removed the device 468 post-implant without incident.
- Another subject continued to experience recurrent heartburn. A decision was made to remove the device and perform a Nissen fundoplication. The device was removed 1302 days post-implant without incident.

### Pivotal Study

The second study, a pivotal IDE trial, enrolled a total of 100 subjects at 14 clinical sites (13 US and 1 OUS). All 100 subjects were implanted with the LINX device during a laparoscopic procedure with a mean duration of 39 minutes (range 7 to 125 minutes). Half the subjects (50/100) were discharged the same day as surgery, and the other half (50/100) were discharged the next day. Follow-up data is available for 12 and 24 months.

The average age of subjects implanted was 50.4 years. Fifty-two percent (52%) were male and 48% female. Fifty-five percent (55%) were overweight (BMI 25-30) and 26% were obese (BMI > 30). Baseline summary statistics for selected demographics and Body Mass Index (BMI) are shown in Table 6.

**Table 6: Baseline Demographics**

Characteristic	N	Mean±SD (Median)	Range
Age (years)	100	50.4±12.4 (53.0)	18.3, 74.7
Body Mass Index (BMI)	100	27.9±3.4 (27.9)	19.8, 34.7
Characteristic	% (n/N)		
<b>Gender</b>			
Male	52% (52/100)		
Female	48% (48/100)		
<b>Race</b>			
Caucasian/Non-Hispanic	96% (96/100)		
Black	0% (0/100)		
Hispanic	3% (3/100)		
Other	1% (1/100)		
<b>BMI Class</b>			
Normal (<25)	19% (19/100)		
Overweight (≥25 and <30)	55% (55/100)		
Obese (≥30)	26% (26/100)		

In the pivotal IDE trial, a subject met the primary endpoint at 12 months if either of the following criteria were met:

- there was normalization of pH, with normalization defined as pH < 4 for ≤ 4.5% of monitoring time, or
- there was a reduction of at least 50% in total time that pH <4, relative to baseline.

This endpoint would be met if the lower bound of a 97.5% confidence interval for the success rate was at least 60%.



At 12 months, 64% of subjects had pH normalization or a  $\geq 50\%$  reduction in distal esophageal acid exposure, and the mean total acid exposure (percent time pH<4) was reduced from 11.9% at baseline to 5.4%. Since the lower limit of the 97.5% confidence interval fell below the 60% success threshold (53.8%), the primary endpoint of the study was not met. See Table 7.

**Table 7: Primary Effectiveness Endpoint: Bravo pH Normalization or  $\geq 50\%$  Reduction at 12 months**

Primary Efficacy Endpoint	% Successful (Number of Subjects/Total)	Lower 97.5% Exact Binomial Confidence Limit	p-value <sup>1</sup>
<b>Bravo pH</b> • Normalization ( $\leq 4.5\%$ ) OR • $\geq 50\%$ reduction from baseline	64.0% (64/100)	53.8%	0.24

In obtaining the primary endpoint of pH testing, other components of the DeMeester Score as well as the composite score were also able to be examined. It is the composite score, which is made up of these individual components pertaining to acid exposure time, frequency, and duration, that has been reported to be the most reliable measurement of a therapeutic acid suppression regimen or an effective antireflux operation, with sensitivity and specificity for GERD at 96%. There was improvement in the composite DeMeester score in 93% of subjects that had pH testing at 12 months, and 52% had a normalized DeMeester score. This is shown in the Table 8.

**Table 8: pH Parameters of Esophageal Acid Exposure**

DeMeester Components	Normal Values	Baseline	12-Months
Total time pH <4 (%)	5.3	11.6 $\pm$ 4.7 (10.9) N=100	5.1 $\pm$ 4.8 (3.3) N=96
Upright time pH <4 (%)	6.9	14.0 $\pm$ 7.2 (12.7) N=100	6.5 $\pm$ 5.8 (4.3) N=96
Supine Time pH <4 (%)	6.7	7.8 $\pm$ 7.2 (6.0) N=98	2.9 $\pm$ 5.8 (0.4) N=95
# of Episodes pH <4	36.8	175.0 $\pm$ 81.7 (161.0) N=100	82.8 $\pm$ 67.6 (67.0) N=96
# of Episodes > 5 min	1.2	12.4 $\pm$ 6.7 (12.0) N=99	6.1 $\pm$ 6.8 (4.0) N=96
Longest Episode (min)	N/A	37.4 $\pm$ 24.4 (29.0) N=99	19.7 $\pm$ 20.9 (13.0) N=96
DeMeester Score	<14.72	41.0 $\pm$ 16.3 (36.6) N=97	18.7 $\pm$ 17.3 (13.5) N=95
Percentage of subjects with normal DeMeester score		0%	52%

Elimination of daily PPIs was achieved in 91% and 92% of subjects at 12 and 24 months, respectively. The proportion of subjects achieving at least a 50% reduction in daily use of PPIs from baseline was 93% (93/100) at 12 months and 86% (86/100) at 24 months based on the entire treatment group and 96% (86/90) based on evaluable subjects at 24 months. See Table 9.

**Table 9: Secondary Efficacy Endpoint:  $\geq 50\%$  Reduction in Daily PPI Use from Baseline**

Parameter	Follow-up Time	Success Rate	95% CI
$\geq 50\%$ reduction in daily PPI use (secondary endpoint)	12 months	93% (93/100)	86%, 97%
	24 months (treatment group)	86% (86/100)	78%, 92%
	24 Months (evaluable subjects)	96% (86/90)	89%, 98%
Elimination of daily PPI use	12 months (evaluable subjects)	91% (88/97)	83%, 96%
	24 Months (evaluable subjects)	92% (83/90)	85%, 97%

A validated questionnaire called the GERD-HRQL Questionnaire was one method used to assess improvement in GERD-related symptoms. The questionnaire consists of a total of 10 questions that include 6 heartburn questions, 2 swallowing questions, 1 bloating/gas question and one question about GERD medications. Each question is scored on a scale of 0 (no symptoms) to 5 (incapacitating). The best possible score is 0 and the worst score is 50. The mean total GERD-HRQL score at baseline was 26.6 assessed off PPIs and 12.0 assessed on PPIs. At 12 and 24 months, the mean GERD-HRQL scores assessed off PPIs improved to 3.8 and 4.3, respectively.

The proportion of subjects achieving at least a 50% reduction compared to baseline score was 92% (92/100) at 12 months and 84% at 24 months (treatment group) and 93% (84/90) at 24 months based on evaluable subjects. See Table 10.

**Table 10: ≥ 50% Reduction in GERD-HRQL Total Score from Baseline (Off PPI)**

Follow-up Time	Success Rate	95% CI
12 months	92% (92/100)	85%, 97%
24 months (treatment group)	84% (84/100)	78%, 92%
24 Months (evaluable subjects)	93% (84/90)	86%, 98%

The percentage of subjects with no esophagitis increased from 60.0% at baseline to 87.6% at 12 months and 88.7 % at 24 months. Grade B esophagitis decreased from 18% at baseline to 3.4 % at 24 months. Twenty-two subjects had Grade A at baseline while ten had Grade A at 12 months, and 7 at 24 months. One subject developed Grade D esophagitis at 12 months, which was resolved at 24 months. Esophagitis grade by study visit is provided in Table 11.

**Table 11: Esophagitis Grade by Visit**

Esophagitis Grade	Baseline % (n/N)	Month 12 % (n/N)	Month 24 % (n/N)
None	60.0% (60/100)	87.6% (85/97)	88.7% (79/89)
Grade A	22.0% (22/100)	10.3% (10/97)	7.9% (7/89)
Grade B	18.0% (18/100)	1.0% (1/97)	3.4% (3/89)
Grade C	0.0% (0/100)	0.0% (0/97)	0.0% (0/89)
Grade D	0.0% (0/100)	1.0% (1/97)	0.0% (0/89)

Adverse event and safety information for the clinical study is presented above in Section 6.

## 8. **DIRECTIONS FOR USE**

### 8.1. Surgical Access

8.2. Gain surgical access through a laparoscopic port to the esophagus at the region of the gastroesophageal junction.

8.3. Dissect the soft tissues away from the outside of the esophagus at the location of the gastroesophageal junction. Tissue should be removed to expose the outer muscle of the esophagus. Create a tunnel under the posterior vagus nerve through the peri-neural tissue. The anterior vagus nerve will be included within the implant. Care should be taken to avoid injuring the vagus nerve bundles.

### 8.4. Sizing of the Esophagus

Refer to the LINX® Reflux Management System Esophagus Sizing Tool Instructions for Use.

The Esophagus Sizing tool is a single use disposable device provided non-sterile, that must be cleaned and sterilized prior to use.

### 8.5. Placement of the LINX® Implant

8.5.1. Bring the chosen LINX® implant into the surgical field through a laparoscopic port of minimum internal diameter of 10 mm.

8.5.2. Place the device around the esophagus in the same location that was measured, reference Figure 3.

8.5.3. Using the suture provided, secure the ends of the device with a hand tied knot or a Top-Knot® device such that the eyelets of the device are touching or overlapping. Complete this method of securement for each set of white and green sutures for a total of two secured knots. Once secured, trim sutures, reference Figure 4.

- 8.5.4. If a hiatal hernia is observed intra-operatively, repair of the hernia should be considered in conjunction with the LINX® implant procedure.

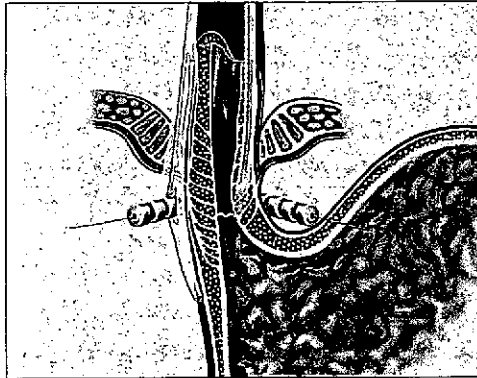


Figure 3 – Implant at Area of LES

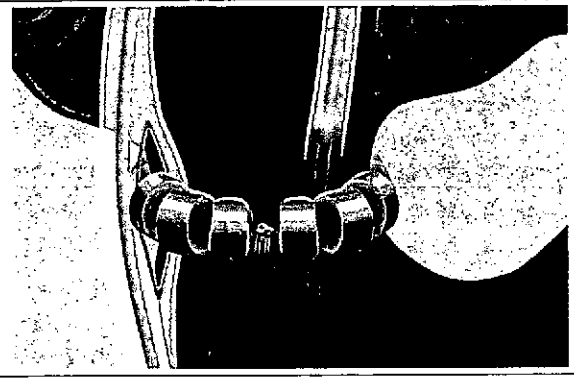


Figure 4 – Completed Implant

## 9. **PACKAGING/STORAGE**

The LINX® device is provided sterile and designed to remain sterile unless the primary product pouch has been opened or damaged. Store in a cool, dry place. If opened and not used, discard device or return device to Torax Medical Inc. Do Not Resterilize.

## 10. **LIMITED WARRANTY**

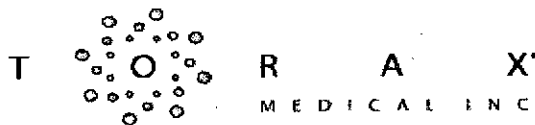
(a) Torax warrants that the product shall be free from material defects in materials and/or workmanship, and shall perform substantially in accordance with the written specifications, through the earlier of (i) the expiration of the shelf-life as specified on the applicable product labeling or (ii) the date on which the products are used or implanted.

(b) This limited warranty does not extend to damage caused by (i) abuse or misuse of any product, (ii) accident or neglect by you or a third party; (iii) use of the product other than in accordance with Torax's instructions or specifications; or (iv) any alterations made to the product after shipment.

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4188 Lexington Avenue North  
Shoreview, Minnesota 55126 USA  
Phone: (651) 361-8900  
Fax: (651) 361-8910  
[www.toraxmedical.com](http://www.toraxmedical.com)

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3089 Rev 1  
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REFLUX MANAGEMENT SYSTEM

ESOPHAGUS SIZING TOOL

## INSTRUCTIONS FOR USE

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



## 1. **SYSTEM DESCRIPTION**

The LINX® Reflux Management System Esophagus Sizing Tool is an accessory to the LINX® Reflux Management System (packaged separately). See the Instructions for Use provided with the LINX® Reflux Management System.

The Esophagus Sizing tool is a single use disposable device provided non-sterile, that must be cleaned and sterilized prior to use.

The device consists of a series of titanium beads with magnetic cores that are connected on a continuous stainless steel cable so that it can form an annular shape. The beads of the device are color coded to correspond with the size range of the LINX® Reflux Management System Implants. An illustration of the LINX® Reflux Management System Esophagus Sizing Tool is provided in Figure 1.



**Figure 1 – Illustration of Sizing Tool**

## 2. **DIRECTIONS FOR USE**

### 2.1 Clean and Sterilize Before Use

2.1.1 Every sizing tool must be cleaned and sterilized before it is used. The Esophagus Sizing Tool was developed for sterilization by autoclave.

### 2.2 Cleaning Before Use

2.2.1 Every sizing tool must be disinfected and thoroughly cleaned before use. Clean and inspect the sizing tool carefully. Sterilize the sizing tool before surgery. Clean the instrument as follows:

2.2.2 Do not use corrosive cleaning agents. Cleaning solutions and rinses at or near a neutral pH (7.0) are best. Use of an enzymatic cleaning solution intended specifically for surgical instruments is recommended.

2.2.3 Do not use abrasive cleaners.

2.2.4 Rinse thoroughly with tap water or equivalent (distilled water, etc.).

2.2.5 Only a soft brush should be used.

2.2.6 Rinse the sizing tool with tap water for two minutes while brushing with a soft bristled cleaning brush to remove most or all of the visible gross debris.

2.2.7 Place the sizing tool into an enzymatic bath for five (5) minutes following the enzymatic cleaner manufacturer's directions. Scrub the sizing tool with a soft bristled cleaning brush to remove any remaining debris from the instrument.

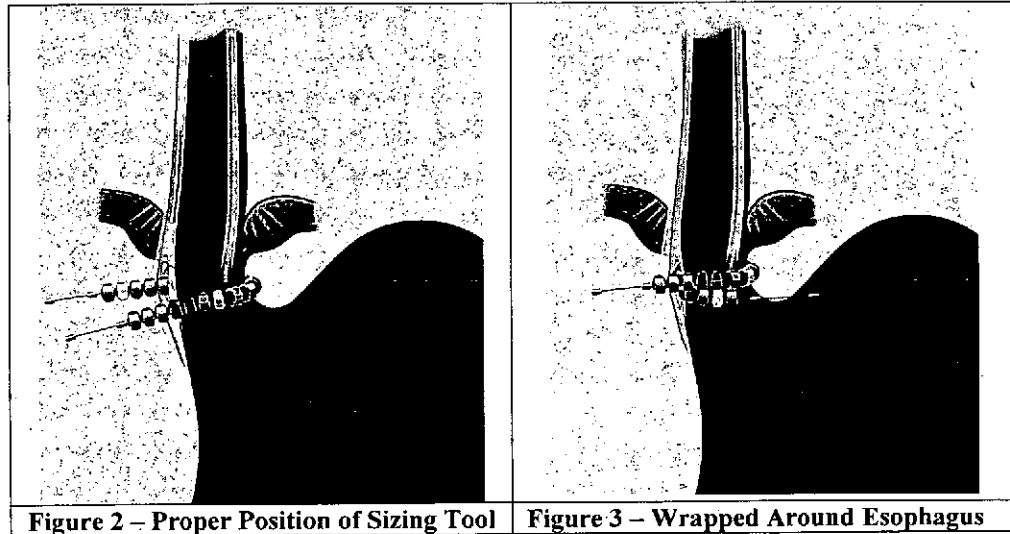
2.2.8 Rinse the sizing tool for two minutes using tap water.

2.2.9 Visually inspect the sizing tool under normal lighting to verify cleanliness. Thoroughly dry the sizing tool carefully with compressed air, or allow the sizing tool to air dry.

### 2.3 Sterilization Before Use

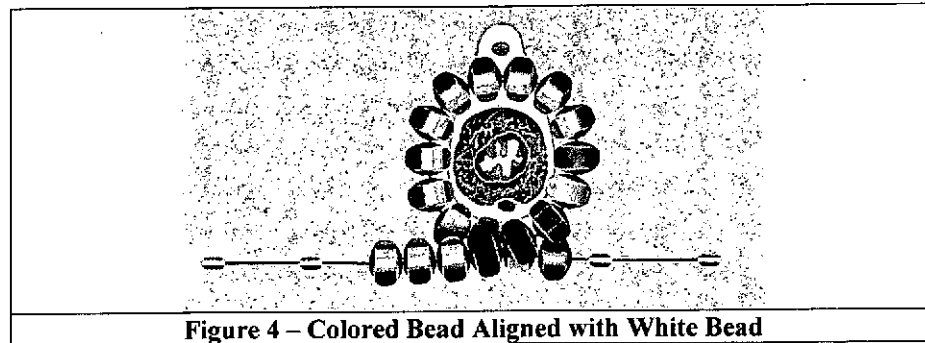
2.3.1 Steam autoclave sterilization is recommended. Do not sterilize in hot air.

- 2.3.2 Standard **gravity** autoclave steam cycle 132°C - 135°C for 30 minutes.
- 2.3.3 Standard **pre-vacuum** autoclave steam cycle 132°C - 135°C for 4 minutes.
- 2.4 Inspection and Functional Check
  - 2.4.1 It is very important to carefully examine each sizing tool for breaks, cracks, loose or faded color coding, corrosion, broken wires, or other malfunctions before use. **DO NOT USE DAMAGED INSTRUMENTS. DO NOT REPLACE COLOR CODING.**
- 2.5 Surgical Access
  - 2.5.1 Gain surgical access through a laparoscopic port to the esophagus at the region of the gastroesophageal junction.
  - 2.5.2 Dissect the soft tissues away from the outside of the esophagus at the location of the gastroesophageal junction. Tissue should be removed to expose the outer muscle of the esophagus. Create a tunnel under the posterior vagus nerve through the peri-neural tissue. The anterior vagus nerve will be included within the implant. Care should be taken to avoid injuring the vagus nerve bundles.
- 2.6 Sizing of the Esophagus
  - 2.6.1 Use the LINX® Esophagus Sizing Tool to determine the LINX® Implant size. The LINX® implant sizes are denoted by the model number (e.g., LS12 = 12 Bead Implant).
  - 2.6.2 Bring the LINX® Esophagus Sizing Tool into the surgical field through a laparoscopic port of a minimum internal diameter of 10 mm.
  - 2.6.3 Place the sizing tool around the esophagus in the dissected space around the exposed outer muscle and through the tunnel created under the posterior vagus nerve bundle, reference Figure 2.
  - 2.6.4 Hold opposite ends of the sizing tool and wrap the sizing tool into a circular shape around the esophagus, reference Figure 3.



- 2.6.5 There is a white bead near the end of the sizing tool. With the sizing tool wrapped around the esophagus, align the white bead with the remaining colored beads of the sizing tool, reference Figure 4.





- 2.6.6 Determine the color that aligns with the white bead and referring to the sizing chart in Table 1, select the appropriate device for implantation.

**Table 1 – Sizing Chart**

<b>Bead Color</b>	<b>Associated LINX® Implant Device</b>
1 <sup>st</sup> Bead Pre-Orange	10-Bead
Orange	11-Bead
Yellow	12-Bead
Green	13-Bead
Blue	14-Bead
Purple	15-Bead
1 <sup>st</sup> Bead Post-Purple	16-Bead
2 <sup>nd</sup> Bead Post-Purple	17-Bead
3 <sup>rd</sup> Bead Post-Purple	18-Bead

- 2.6.7 Should the white bead align between two colors, choose the device with the higher number of beads.

## **1. PACKAGING/STORAGE**

The LINX® Sizing Tool is provided non-sterile. Store in a cool, dry place. If opened and not used, discard device or return device to Torax Medical Inc.

## **2. LIMITED WARRANTY**

(a) Torax warrants that the product shall be free from material defects in materials and/or workmanship, and shall perform substantially in accordance with the written specifications, through the earlier of (i) the expiration of the shelf-life as specified on the applicable product labeling or (ii) the date on which the products are used or implanted.

(b) This limited warranty does not extend to damage caused by (i) abuse or misuse of any product, (ii) accident or neglect by you or a third party; (iii) use of the product other than in accordance with Torax's instructions or specifications; or (iv) any alterations made to the product after shipment.

(c) Torax's entire liability and your exclusive remedies under this limited warranty are, at Torax's option, for Torax to use commercially reasonable efforts to fix or replace the defective product.

(d) EXCEPT AS EXPRESSLY STATED ABOVE, TORAX MAKES NO WARRANTIES, EXPRESS OR IMPLIED, WRITTEN OR ORAL, BY OPERATION OF LAW OR OTHERWISE, OF ANY PRODUCTS OR SERVICES FURNISHED UNDER OR IN CONNECTION WITH THIS AGREEMENT. TORAX DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND THOSE WARRANTIES ARISING BY STATUTE OR OPERATION OF LAW, OR FROM A COURSE OF DEALING OR USAGE OR TRADE.

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4188 Lexington Avenue North  
Shoreview, Minnesota 55126 USA  
Phone: (651) 361-8900  
Fax: (651) 361-8910  
[www.toraxmedical.com](http://www.toraxmedical.com)

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## **LINX<sup>®</sup> Reflux Management System**

### **Patient Information**

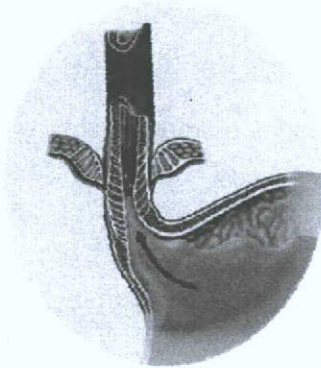
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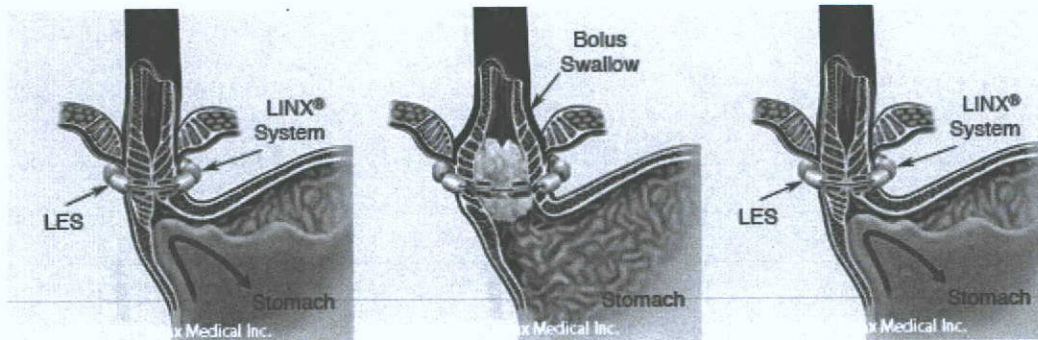
## What is the LINX Reflux Management System?

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.

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 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](http://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 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)
- 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.

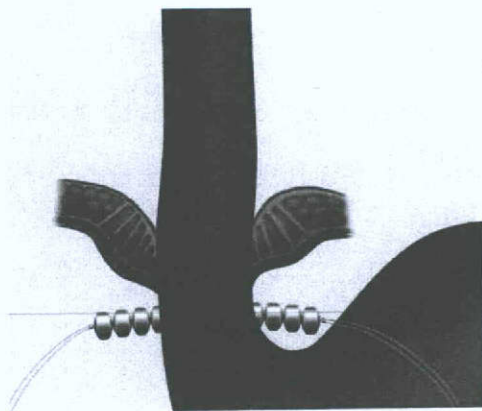
## What happens before the treatment?

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:

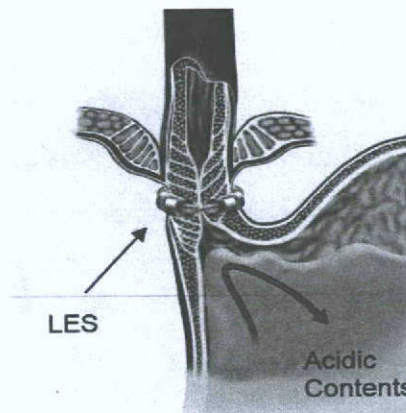
- Esophageal pH testing (tests for acid in the esophagus)
- Manometry/Motility (measures pressures in the esophagus and how many swallows are effective)
- Endoscopy (a visual examination of your esophagus using an endoscope)
- Barium esophagram (x-ray to examine the esophagus. The x-ray is performed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



LINX is placed around the esophagus at the sphincter



LINX in place with ends attached

## 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.

<b>% of patients with symptom before LINX</b>	<b>GERD Symptom</b>	<b>% of patients with symptom 2 years after LINX</b>
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](http://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).

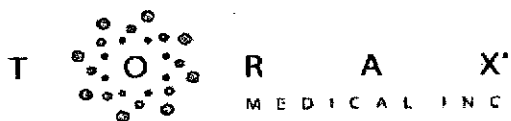
**Endoscopy** is a procedure where a doctor is able to see the inside lining of your digestive tract. This examination is performed using an endoscope (a flexible fiberoptic tube with a tiny TV camera at the end). The camera is connected to either an eyepiece for direct viewing or a video screen that 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, 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).



4188 Lexington Avenue North  
Shoreview, Minnesota 55126 USA  
Phone: (651) 361-8900  
Fax: (651) 361-8910  
[www.toraxmedical.com](http://www.toraxmedical.com)

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