



INSTRUCTIONS FOR USE



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

1. **SYSTEM DESCRIPTION**

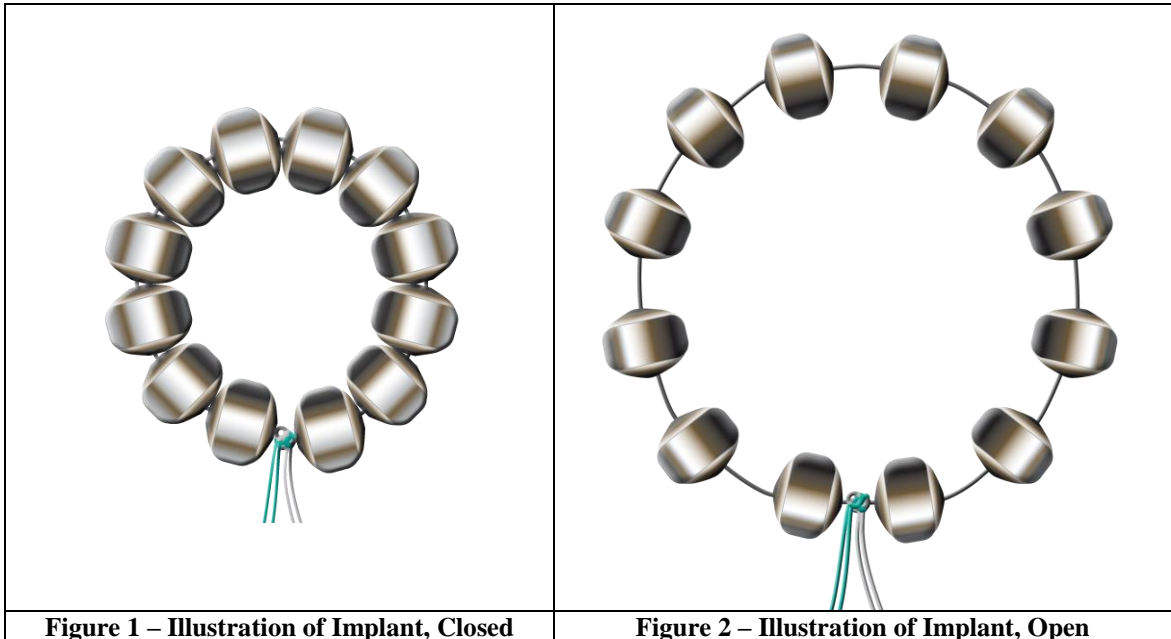
The LINX® Reflux Management System is comprised of the following components:

- 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.



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. Please note nickel is not a metal component of the LINX® implant, only the sizing tool which is a single-use instrument used only during surgical placement of the implant.

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 Conditional. Please refer to Section 6, MRI Conditional Guidelines. Exposure to an MRI environment above the MR Conditional guidelines could cause serious injury to the patient and/or interfere with the magnetic strength and the function of the device. The device is NOT safe when exposed to MRI magnetic fields of 1.5 T or 3 T. In the event alternative diagnostic procedures cannot be used and MRI is required beyond the MR Conditional guidelines, 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 packaged device should not be exposed to temperatures above 60°C (140°F) as this could adversely affect the function of the package/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. **MRI Safety Information**



Non-clinical testing has demonstrated that the LINX® System is MR Conditional. This device can be scanned safely under the following conditions:

- Static magnetic field **0.7-Tesla (0.7 T)**
- Spatial gradient field of up to 364 G/cm (3.64 T/m)
- Maximum whole body averaged specific absorption rate (SAR) of 4.0 W/kg for 15 minutes of scanning in First Level Controlled Mode
- The LINX® System contains permanent magnets. Should the patient experience discomfort or pain, immediately discontinue the scan and remove the patient from the MR environment.

RF Heating

In non-clinical testing, with body coil excitation, the LINX® System produced a temperature rise of 0.6°C at a maximum whole body averaged specific absorption rate (SAR) of 4.0 W/kg, as assessed by calorimetry for 15 minutes of scanning in a 0.7 T Hitachi Altaire Open MR scanner with software version 5.1H-1.

Caution: The RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

MR Artifact

In testing using a 0.7 T system with gradient-echo sequencing, the shape of the image artifact follows the approximate contour of the device and extends radially up to 10.3 cm from the implant.

Torax Medical recommends that the patient register the MR conditions disclosed in this IFU with the MedicalAlert Foundation (www.medicalert.org) or equivalent.

7. **ADVERSE EVENTS**

- 7.1. 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.
- 7.2. 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.
- 7.3. 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, saliva/mucus build-up, stomach bloating, vomiting, weight loss, and worsening of preoperative symptoms (including but not limited to dysphagia or heartburn).
- 7.4. Device erosion refers to at least a portion of the LINX device passing through the esophageal wall. An observed event has been reported in clinical literature.¹ Patient consultation with a surgeon who is experienced with LINX procedures and best practices is advised for proper treatment.
- 7.5. The LINX® Reflux Management System is intended to be a long-term implant, and may need to be either explanted or replaced.
- 7.6. 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.

¹ Lipham JC, Taiganides PA, Louie BE, Ganz RA, DeMeester TR. Safety Analysis of first 1000 patients treated with magnetic sphincter augmentation for gastroesophageal reflux disease. *Diseases of the Esophagus* (2014). DOI: 10.1111/dote.12199.

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 ¹	1	1% (1)

¹Adjudicated 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 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 ¹	12 Months ¹	24 Months ¹
Inability to Belch	0%	1%	0%
Inability to Vomit	0%	0%	1%
Bloating Frequency – Frequently/Continuously	40%	5%	7%
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%

Parameter	Baseline ¹	12 Months ¹	24 Months ¹
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%
	On PPI	13%	NA

¹Assessments completed off PPI therapy, unless noted

8. **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 ¹	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 ²	79.5% (31/39)	90.0% (18/20)	85.0% (17/20)

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

² 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 gastroesophageal junction (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 had persistent dysphagia treated by device removal at 226 days post-implant without incident. The dysphagia resolved and the subject went on to have a Nissen fundoplication at a later time (serious adverse event reported above).
- 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)		
Gender			
Male	52% (52/100)		
Female	48% (48/100)		
Race			
Caucasian/Non-Hispanic	96% (96/100)		
Black	0% (0/100)		
Hispanic	3% (3/100)		
Other	1% (1/100)		
BMI Class			
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 ≥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 ≥ 50% Reduction at 12 months

Primary Efficacy Endpoint	% Successful (Number of Subjects/Total)	Lower 97.5% Exact Binomial Confidence Limit	p-value ¹
Bravo pH <ul style="list-style-type: none"> • Normalization (≤4.5%) OR <ul style="list-style-type: none"> • ≥ 50% reduction from baseline 	64.0% (64/100)	53.8%	0.24

¹From one-sided, binomial exact test against the null hypothesis of ≤ 60%.

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 ± 4.7 (10.9) N=100	5.1 ± 4.8 (3.3) N=96
Upright time pH <4 (%)	6.9	14.0±7.2 (12.7) N=100	6.5 ± 5.8 (4.3) N=96
Supine Time pH <4 (%)	6.7	7.8±7.2 (6.0) N=98	2.9 ± 5.8 (0.4) N=95
# of Episodes pH <4	36.8	175.0±81.7 (161.0) N=100	82.8 ± 67.6 (67.0) N=96
# of Episodes > 5 min	1.2	12.4±6.7 (12.0) N=99	6.1 ± 6.8 (4.0) N=96
Longest Episode (min)	N/A	37.4±24.4 (29.0) N=99	19.7 ± 20.9 (13.0) N=96
DeMeester Score	<14.72	41.0±16.3 (36.6) N=97	18.7 ± 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: ≥ 50% Reduction in Daily PPI Use from Baseline

Parameter	Follow-up Time	Success Rate	95% CI
≥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: $\geq 50\%$ 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 (evaluatable 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.

9. **DIRECTIONS FOR USE**

9.1. Surgical Access

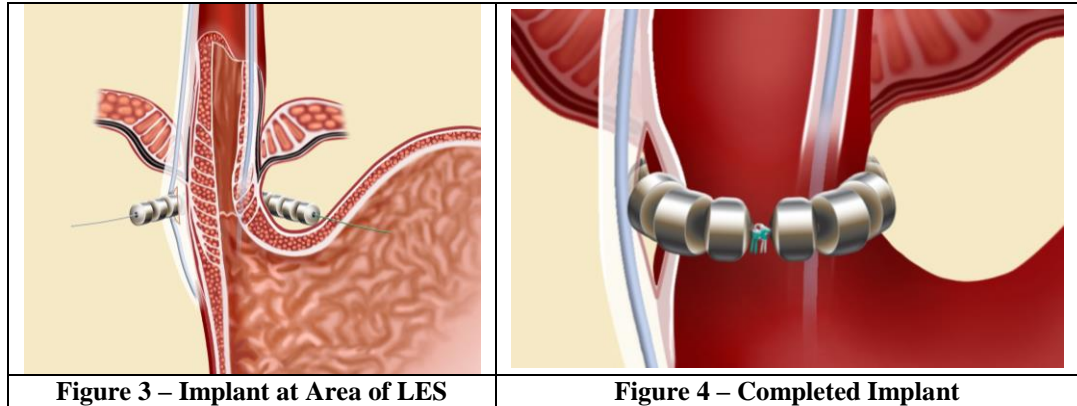
- 9.1.1. Gain surgical access through a laparoscopic port to the esophagus at the region of the gastroesophageal junction.
- 9.1.2. Dissect the soft tissues away from the outside of the esophagus at the location of the gastroesophageal junction. Tissue should be removed to expose the outer muscle of 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.

9.2. Sizing of the Esophagus

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

9.3. Placement of the LINX® Implant

- 9.3.1. Bring the chosen LINX® implant into the surgical field through a laparoscopic port of minimum internal diameter of 10 mm.
- 9.3.2. Place the device around the esophagus in the same location that was measured, reference Figure 3.
- 9.3.3. 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.
- 9.3.4. If a hiatal hernia is observed intra-operatively, repair of the hernia should be considered in conjunction with the LINX® implant procedure.



10. 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.

11. 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.

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 3089 Rev 3
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