## What is your experience with esophageal spasm post-op?

Esophageal spasm occurs in less than 10% of patients, most often in the early postoperative period, and can be quite painful.[1] Most patients describe it as a crampy, sharp, or stabbing pain in the mid chest and epigastric area. Some will say that it feels as though they are having a heart attack. Occasionally this pain can radiate up into the neck and jaw. Most associate the spasm with eating but some will experience it in between meals.

It is probably a response to increased outflow resistance of the esophagus because of inflammation and edema. It usually resolves on its own after the patient is fully recovered. Reassuring and reminding patients to eat slowly, take small bites, and chew thoroughly, will help. Medications may be helpful.

Some patients describe intermittent spasm out beyond the 3-4 months of recovery. This can be recurrent spasm from the early period or rarely de novo late onset spasm. Medications may be useful in these patients. If the spasm persists or does not respond to medical therapy, EGD and balloon dilatation (15mm under flouro as described for dysphagia) may be used. If the spasm doesn't improve with medical therapy or dilatation then device removal may be considered.

## When would you consider explanting a patient?

Removing a device for dysphagia or esophageal spasm is typically not considered until a patient is at least 3-4 months post-op, since most will improve with time. Patients often improve out to 6 months and beyond, so patience, reassurance, and waiting is usually the best approach for these patients. If a patient has seen no improvement by 4 months post-op despite medical therapy as outlined above and / or dilatation, consider device removal.

## LINX® Reflux Management System Important Safety Information

The LINX® Reflux Management System is a laparoscopic, fundic-sparing anti-reflux procedure indicated for patients diagnosed with Gastroesophageal Reflux Disease (GERD) as defined by abnormal pH testing, and who are seeking an alternative to continuous acid suppression therapy (i.e. proton pump inhibitors or equivalent) in the management of their GERD.

### Rx Only

### Contraindications

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

### Warnings

The LINX device is considered MR Conditional in a magnetic resonance imaging (MRI) system up to either 0.7 Tesla (0.7T) or 1.5 Tesla (1.5T), depending on the LINX model implanted. Scanning under different conditions may result in serious injury to you and/or interfere with the magnetic strength and the function of the device. In the event alternative diagnostic procedures cannot 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. It is recommended that patients receiving the LINX device register their implant with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

Failure to secure the LINX device properly may result in its subsequent displacement and necessitate a second operation.

Laparoscopic placement of the LINX device is major surgery and death can occur.

### General Precautions

The LINX device is a long-term implant. Explant (removal) and replacement surgery may be indicated at any time. Management of adverse reactions may include explantation and/or replacement.

The use of the LINX device in patients with a hiatal hernia larger than 3 cm should include hiatal hernia repair to reduce the hernia to less than 3 cm. The LINX device has not been evaluated in patients with an unrepaired hiatal hernia greater than 3 cm.

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.

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.

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 High Resolution Manometry equivalent, and/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

### Potential Side Effects

Potential adverse events associated with laparoscopic surgery and anesthesia include adverse reaction to anesthesia (headache, muscle pain, nausea), anaphylaxis (severe allergic reaction), cardiac arrest, death, diarrhea, fever, hypotension (low blood pressure), hypoxemia (low oxygen levels in the blood), infection, myocardial infarction, perforation, pneumonia, pulmonary embolism (blood clot in the lung), respiratory distress, and thrombophlebitis (blood clot). Other risks reported after anti-reflux surgery procedures include bloating, nausea, dysphagia (difficulty swallowing), odynophagia (painful swallowing), retching, and vomiting.

Potential risks associated specifically with the LINX Reflux Management System include achalasia (lower part of esophagus does not relax), bleeding, cough, death, decreased appetite, device erosion, device explant/re-operation, device failure, device migration (device does not appear to be at implant site), diarrhea, dyspepsia (indigestion), dysphagia (difficulty swallowing), early satiety (feeling full after eating a small amount of food), esophageal spasms, esophageal stricture, flatulence, food impaction, globus sensation (sensation of a lump in the throat), hiccups, inability to belch or vomit, increased belching, infection, impaired gastric motility, injury to the esophagus, spleen, or stomach, nausea, odynophagia (painful swallowing), organ damage caused by device migration, pain, peritonitis (inflammation of the peritoneum), pneumothorax (collapsed lung), regurgitation, saliva/mucus build-up, stomach bloating, ulcer, vomiting, weight loss, and worsening of preoperative symptoms (including but not limited to dysphagia or heartburn).

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For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

Manufactured by:

Torax® Medical, Inc.
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**1.** Reynolds J, Zehetner J, Bildzukewicz N, et al. Magnetic Sphincter Augmentation with the LINX Device for Gastroesophageal Reflux Disease after U.S. Food and Drug Administration Approval. The American Surgeon. 2014;80(10):1034-38. **2.** Bonavina L, Saino G, Bona D, et al. One Hundred Consecutive Patients treated with Magnetic Sphincter Augmentation for Gastroesophageal Reflux Disease: 6 Years of Clinical Experience from a Single Center. J Am Coll Surg. 2013;217(4):577-85. **3.** LINX® Reflux Management System, Instructions for Use. **4.** Reynolds J, Zehetner J, Wu P, et al. Laparoscopic Magnetic Sphincter Augmentation vs Laparoscopic Nissen Fundoplication: A Matched-Pair Analysis of 100 Patients. J American College of Surgeons. 2015;221(1):123-128. **5.** Ayazi S, Zheng P, Zaidi AH, et al. Magnetic sphincter augmentation and postoperative dysphagia: Characterization, clinical risk factors, and management. Journal of Gastrointestinal Surgery. 2020;24(1):39-49. **6.** Wehrli NE, Levine MS, Rubesin SE, et al. Secondary achalasia and other esophageal motility disorders after laparoscopic Nissen fundoplication for gastroesophageal reflux disease. AJR Am J Roentgenol. 2007;189(6):1464-8. **7.** Smith CD. Surgical therapy for gastroesophageal reflux disease: Indications, evaluation, and procedures. Gastrointest Endosc Clin N Am. 2009;19(1):35-48. **8.** Ganz R, Peters J, Horgan S, et al. Esophageal Sphincter Device for Gastroesophageal Reflux Disease. N Engl J Med. 2013;368(8):719-727. **9.** Reynolds JL, Zehetner J, Bildzukewicz, et al. Magnetic sphincter augmentation with the LINX device for gastroesophageal reflux disease after U.S. Food and Drug Administration approval. Am Surg. 2014;80(10):1034-8. **10.** Warren HF, Reynolds JL, Lipham JC, et al. Multi-institutional outcomes using magnetic sphincter augmentation versus Nissen fundoplication for chronic gastroesophageal reflux disease.

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# LINX® Reflux Management System Post-Op Patient Management Guide

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## What do patients commonly experience after LINX surgery?

LINX Magnetic Sphincter Augmentation is generally a short, minimally invasive operative procedure generally completed in less than an hour.[1,3*] It is an outpatient procedure for most patients, and patients typically go home within 24 hours.[3†] Patients are started on a soft mechanical diet in the recovery room and told that they should eat a few tablespoons of soft food every 2-3 hours while awake. They are instructed to avoid taking only liquids and are sent home with oral pain medications.

Despite the minimally invasive approach and minimal disruption of the native anatomy with LINX, the full healing process takes several months. This should be stressed to patients. Patients are generally able to return to non-strenuous activity within a couple days.

Setting expectations pre-operatively will help tremendously with the recovery period.

## What is the most important aspect of LINX post-operative management?

The most important aspect in managing LINX patients is understanding that their recovery and management are very different from the Nissen patients. It is important to set expectations with these patients pre-operatively. Discussing the dysphagia timeline is exceedingly important and will decrease unnecessary patient concerns and numerous phone calls to your office. It is also important to thoroughly discuss the need to stay on a soft mechanical diet immediately post- op and eat every 2-3 hours as "physical therapy" for the device. This should be reinforced multiple times both pre and post-operatively as it can impact dysphagia rates.

Reassurance in the post-operative period is also very important with LINX patients. Patients may think that something must be wrong because they could eat normally for the first week or two and but then develop dysphagia.

Reminding them and assuring them that this is normal goes a long way. Patients may will also worry if they have the sensation of reflux in the early period; however this most likely represents pooling and poor bolus clearance. Taking the time to explain this possibility and that it will improve with time may help alleviate patient concerns. LINX patients may need a little more reassurance and attention in the early post-op period, but in the long term are typically happier and have fewer side effects than Nissen patients.[4‡]

## Why does dysphagia occur for LINX patients?

Dysphagia during the recovery period is common after LINX and has been reported to occur in up to 60% of patients.[5] It occurs for two main reasons: The first and probably most significant reason is the normal inflammation and edema that occur around the GE junction and hiatus in response to the placement and encapsulation of the LINX device. The second reason for the dysphagia appears to be due to a temporary alteration in esophageal motility.

Barium Esophagrams (VEG) obtained during the first 3 months post-op frequently will show an element of dysmotility and in extreme cases may even look like achalasia. This has also been shown to occur in Nissen fundoplication patients post-operatively when Barium Esophagrams (VEG) have been obtained during the same period.[6, 7]

Once the edema and inflammation has resolved the Barium Esophagrams (VEG) generally return to normal.

## Is there a predictable timeline for LINX post-op dysphagia?

The dysphagia timeline is fairly predictable, although there is patient to patient variability. Some patients will experience dysphagia from the beginning, whereas others may experience a "honeymoon" period immediately post-op where they are able to swallow solid food without any difficulty or sensation of dysphagia. In general, this period will last for 1-3 weeks.[1]

After 1-3 weeks, dysphagia may worsen due to increasing inflammation, which may range from mild to severe.

The dysphagia generally peaks at about 6-8 weeks post-op before it then starts to resolve. Full resolution of the dysphagia was reported in 79% of patients at a median of 8 weeks in the FDA post-approval study.[1] Continued improvement in the dysphagia has been seen in patients up to a year post-op without intervention.[8]

* Median operative time for 67 patients was 60 minutes[2], for 100 patients was 47 minutes[1], and for 100 patients was 39 minutes[3]

† Based on a pivotal IDE trial of 100 subjects at 14 clinical sites. Half of the subjects (50/100) were discharged the same day as the surgery, and the other half were discharged the next day.

‡ Based on a retrospective analysis of 1-year outcomes of patients undergoing MSA and LNF from June 2010 to June 2013. Matched-pair analysis of 100 patients. There were no patients with severe gas and bloating in the MSA group compared with 10.6% in the LNF group (p=0.022). 8.5% of MSA patients were unable to belch, compared to 25.5% of LNF patients (p = 0.028). 4.3% of MSA patients were unable to vomit when necessary compared to 21.3% of LNF patients (p = 0.004).

## What is the concept of using a solid foods diet as physical therapy for LINX patients during the post-operative period?

Probably the most important aspect of reducing dysphagia both short and long-term is for patients to follow the practice of eating a soft mechanical diet as provided in their post-up instructions. In a published series, the authors reported that patients who mistakenly went home on a liquid diet experienced persistent dysphagia at 4 months post-op and all subsequently needed an endoscopic dilatation.[9] As the esophagus heals, a fibrous capsule forms around each bead of the device. As the capsule formation occurs, it is imperative that the device opens and closes frequently so the device does not get trapped in frozen scar tissue (i.e. the fibrous capsule).

Liquids do not seem to get the device to open and close enough. Instruct patients to stay on a regular or soft mechanical diet so a formed bolus passes through the device, causing the device to expand and then close again. In many ways it is similar to physical therapy for the device. Patients that get a knee or hip replacement start physical therapy immediately to prevent the new joint from getting trapped by the scar tissue formation. The LINX patient also needs to start this immediately. The best physical therapy for the LINX is a solid food bolus every 2-3 hours post-op while awake.

## How soon do you return patients to a normal diet?

Once the dysphagia starts to improve/resolve, patients are instructed to advance to a normal diet. They are told that it is a trial and error process at this stage and that there is no way to accurately predict when they will be able to eat certain foods. Remind patients that taking smaller bites and chewing well can help to reduce dysphagia as well. If it doesn't go down well they are told to hold off on that particular food and try it again in a week or so. Usually by 3-4 months patients are able to tolerate most foods without difficulty.

## PPI Discontinuation

It is important that patients are given instructions about post-operative medication usage. Patients are often tapered off anti-reflux medications following surgery. The course of the taper should be done at the surgeon's discretion. Instructions around discontinuation of anti-reflux medications should be discussed with the patient prior to surgery for best results.

## What is your routine follow up schedule for LINX patients?

Routine follow-up for the LINX patients is generally at 2 weeks, 6 weeks, 3 months and at one year. It's important to bring them into the clinic around post-op day 14 since that is when the majority of patients will begin to experience dysphagia.

Reassurance at this stage that this is a normal part of the healing process and that it may worsen over the next few weeks helps patients cope with this dysphagia period. At 6 weeks the dysphagia is generally at its peak or will be starting to resolve. Again, reassurance at this stage seems to help. Patients are then brought back at 3 months to make sure their diet has progressed back to normal and the dysphagia is resolving.

## What options do you have if a specific patient is having more trouble with the dysphagia period or is more sensitive to it?

For the great majority of patients, the dysphagia will resolve with watchful waiting and time. Setting expectations with patients pre-operatively about the timeline of their recovery, especially regarding dysphagia, helps significantly with patients tolerating this recovery period. Severe dysphagia with difficulty tolerating even liquids, regurgitation, and severe pooling sensations is uncommon but does occur in some of the patients.[10] In this group of patients, the most important thing is to get them back on a soft mechanical diet. Long-term dysphagia is more common in patients that remain on a liquid only diet.

Medication, such as steroids, may be very helpful in patients with severe dysphagia. EGD/dilatation is not recommended in the first 3 months. It does not seem to help at this stage and may even make the dysphagia worse by increasing the edema and inflammation around the GE junction and hiatus.

## When and how do you dilate a patient?

Starting patients on a soft mechanical diet immediately post-op, and eating every 2-3 hours, can help to reduce the need for dilatation. Starting the mechanical diet immediately helps to create the space for the device to expand as encapsulation occurs. For patients that have significant dysphagia at 3-4 months post-op, EGD/dilatation is an option. By this time, the capsule around the LINX should be fully formed and the most plausible explanation for the patient's persistent dysphagia at this stage is that the device is trapped in scar tissue preventing it from fully actuating/opening. Gentle dilatation should help disrupt some of this scar tissue and allow the device to actuate better.

The recommended method for dilatation is with a 15mm balloon under fluoroscopy, visualizing bead separation and ensuring that at least 3 beads remain unseparated.[3] Most patients respond to a single dilatation but some will need repeated dilatations.

## In what situations would you get a Barium Esophagram (VEG)?

Barium Esophagram (VEG) is a good test to assess the position of the device, device actuation, and esophageal bolus transport and motility. If a Barium esophagram (VEG) is obtained in the early post-operative period (< 3months), it may show poor bolus transport and dysmotility. This seems to be a transient finding as motility and bolus transport generally appear normal after the recovery period (>3-4 months).

In patients with persistent dysphagia beyond 3-4 months, the VEG can help to confirm that the device is in good position and that there is not a structural reason for the patient's symptoms. Barium tablet hold-up at the device can, and frequently is, a normal finding as the volume of a barium tablet is insufficient to generate sufficient peristalsis to actuate (separate) the magnets.

## Can patient non-compliance with the Post-Op diet affect the success of their recovery?

The most important part of the recovery period for LINX seems to be adherence to a solid foods or soft mechanical diet every 2-3 hrs. For patients where there may be problems with non-compliance to the diet and post-operative instructions, the success of the procedure may be compromised.

## When would you get a pH test post-operatively and why?

The symptoms attributed to reflux are numerous and nonspecific. Symptoms have been shown to poorly correlate with the amount of reflux. In the early post-operative period, some patients may complain of recurrent reflux. This usually represents pooling in the esophagus from impaired clearance, sometimes with acidification, rather than true reflux. Reassurance that this can be normal and should resolve is appropriate.

In patients with persistent symptoms after the recovery period, pH testing is an option. Ideally, this testing would be not be done until at least 6 months post-op, but could be considered at 3-4 months out. An EGD to evaluate for esophagitis, the position of the LINX, and other causes of symptoms is appropriate. Minor esophagitis can be due to stasis; the pH test is the best test for reflux.