

# Six to Twelve Year Outcomes of Magnetic Sphincter Augmentation for Gastroesophageal Reflux Disease



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## Source

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## Overview<sup>1</sup>

This single-center, retrospective, single-arm study demonstrates the long-term safety and effectiveness of magnetic sphincter augmentation (MSA) in a cohort of patients implanted greater than 6 years and up to 12 years (median 9 years). Of the 335 subjects implanted with MSA between March 2007 and March 30, 2020, 124 subjects were followed long term, and their results are presented here. All adverse events were assessed from the time of implant through the last visit. To assess efficacy, gastro-oesophageal reflux disease health-related quality of life (GORD-HRQL) scores, proton-pump inhibitor (PPI) usage, and oesophageal acid exposure were compared to baseline. Favorable outcomes were defined as a  $\geq 50\%$  reduction in GORD-HRQL score and PPI cessation. Predictors of long-term clinical success were also identified. It is notable that during the study period, the surgical procedure evolved from minimal to full crural dissection. This is the first report of a cohort of patients who have completed 6 to 12 years of follow-up after MSA.

## Results<sup>1</sup>

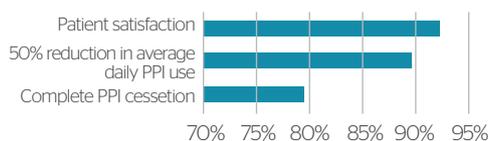
### Long-term outcomes in 124 patients with 6 to 12 years follow-up, median follow-up of 9 years (IQR2)

- There were no erosions or migrations
- 3 patients required device removal, for a rate of 2.4%
- 89% of patients met the criteria for favorable outcomes
- 89% patients who completed pH monitoring at 6-12 years follow up achieved either normal oesophageal acid exposure or had at least a 50% reduction from baseline

### Primary reasons for MSA device removal by length of follow-up

	6-12 years (n=124)
Erosions	0
Regurgitation	0
Heartburn	1
Dysphagia	1
Need for MRI	1

### Long-term (6-12 years) Efficacy Outcomes



	Baseline n=124	6-12 yrs n=91	P value
Mean total percent time with pH<4 (Oesophageal pH off PPI)	9.70	4.20	<0.001
DeMeester score	40.70	16.30	<0.001
Grade 2-4 regurgitation	59.60%	9.60%	<0.01
Total mean GORD-HRQL score	19.90	4.01	<0.001

## Predictors<sup>1</sup>

Utilizing a multivariate analysis, independent predictive variables of successful outcome were confirmed to be age <40 years and a baseline GORD-HRQL score of >15.

### Complete cohort adverse events (n=335)<sup>1</sup>

- 9.2%** (n=31; 28 in the 1-5 years; 3 in the 6-12 years follow up) device removal rate, majority within 6 years of follow-up
- 1.8%** (n=6; 6 in the 1-5 years; 0 in the 6-12 years follow up) erosion rate
- No** device migrations
- 2.4%** (n=8) required a single pneumatic dilation due to persistent dysphagia at 11, 13, 21, 23, 28, 53, 60, 65 months respectively

Most complications requiring MSA removal occurred in those patients with 12\*- and 13-bead devices.

Note: Two different sizer tools were used over the course of this study. Please consult the Instructions For Use for the appropriate use of the current sizer tool

## Conclusion<sup>1</sup>

The authors concluded that the incidence of adverse events was low during the study time frame, providing reasonable assurance that the risk of MSA complications does not increase with longer implant duration. Efficacy outcomes were observed to be sustained up to 12 years post-implantation.

## LINX™ Reflux Management System Important Safety Information

The LINX™ Reflux Management System is indicated for patients diagnosed with pathologic Gastro-oesophageal Reflux Disease (GORD) as defined by abnormal pH testing, and who continue to have chronic GORD symptoms despite maximum medical therapy.

The LINX™ Reflux Management System is labelled for use by physicians 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.

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

### 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 removal and/or replacement.

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 3 cm should be considered on the basis of each patient's medical history and severity of symptoms.

The safety and effectiveness of the LINX™ device has not been evaluated in patients with Barrett's oesophagus or Grade C or D (LA classification) or Grade IV (Savary-Miller) oesophagitis.

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™ device has not been evaluated in patients with major motility disorders.

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

- Scleroderma
- Suspected or confirmed oesophageal or gastric cancer
- Prior oesophageal or gastric surgery or endoscopic intervention
- Distal oesophageal motility less than 35 mmHg peristaltic amplitude on wet swallows or <70% (propulsive) peristaltic sequences or a known motility disorder such as achalasia, nutcracker oesophagus, and diffuse oesophageal spasm or hypertensive LOS
- Symptoms of dysphagia more than once per week within the last 3 months
- Oesophageal stricture or gross oesophageal anatomic abnormalities (Schatzki's ring, obstructive lesions, etc.)
- Oesophageal or gastric varices
- Lactating, pregnant or plan to become pregnant
- Morbid obesity (BMI >35)

### Potential Side Effects:

Potential complications associated with the LINX™ Reflux Management System include achalasia (lower part of oesophagus does not relax), bleeding, death, device erosion (device passing through the oesophageal wall), device explant/re-operation, device failure, device migration (device does not appear to be at implant site), diarrhoea, dysphagia (difficulty swallowing), inability to belch or vomit, infection, impaired gastric motility, injury to the oesophagus, 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, vomiting, and worsening of preoperative symptoms (including but not limited to dysphagia or heartburn).

**Reference: 1.** Ferrari D, Asti E, Lazzari V, Siboni S, Bernardi D, Bonavina L. Six to 12-year outcomes of magnetic sphincter augmentation for gastroesophageal reflux disease. *Sci Rep.* 2020;10:13753. doi:10.1038/s41598-020-70742-3.

LINX™ Reflux Management System is manufactured by Torax® Medical Inc.  
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**Please refer always to the Instructions for Use / Package Insert that come with the device for the most current and complete instructions.**

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