

# **American Foregut Surgery Statement on Appropriate Patient Selection and Use of Magnetic Sphincter Augmentation (LINX).**

Magnetic sphincter augmentation (MSA) of the lower esophageal sphincter (LINX<sup>®</sup> or the LINX<sup>®</sup> procedure) is an important contribution in the management of gastroesophageal reflux disease. The procedure and device are unique in that there is a standardized technique to place a functionally dynamic magnetic sphincter with few of the long-term sequelae of traditional operations. The excellent 5-year data from the FDA/PMA trial are compelling, but the challenge is to ensure that this success can be replicated as the procedure becomes more accepted by the medical community and desired by patients. This position statement from the American Foregut Society (AFS) will focus on preoperative work-up for not only the LINX procedure but anti-reflux surgery (ARS) in general, specific procedural steps, and quality standards for foregut surgeons. We believe these to be critical for successful patient outcomes in both the short and long-term. The relevance and utility of ARS in the treatment of GERD is dependent on these outcomes. Patient-perceived outcomes are a central component in the value based care equation (Value= Outcomes that matter to patients/ cost of care episode). Innovation in healthcare will have to impact a least one of these variables in order to be sustainable.

## **Patient Selection for Anti-Reflux Surgery (ARS)**

Patient selection is crucial to ensuring ARS success. Evaluation begins with a detailed history and physical and culminates with appropriate pre-operative endoscopy, imaging, and objective reflux testing. The patient selection criteria for MSA do not differ in principle from those of any other surgical procedure for reflux disease.

### **Indications for ARS**

1. Typical GERD symptoms (i.e. heartburn, regurgitation) with break-through symptoms, intolerance to medical therapy, and/or unwillingness to take anti-reflux medications long term.
2. Regurgitation despite optimized medical therapy and lifestyle modification.
3. Extraesophageal symptoms with objective evidence of significant reflux disease (i.e. endoscopic evidence of LA Class C or D esophagitis, Barrett's esophagus or positive pH study).

### **Patient History**

#### *1. Symptom characterization*

A careful history should allow for symptom characterization as typical or atypical/extraesophageal. Symptom characterization impacts ARS candidacy and helps guide preoperative testing. GERD symptoms, often multiple and coexisting, should be ranked according to severity and the degree of dependence on medical therapy to control these symptoms should be gauged.

*Typical:* heartburn, regurgitation

*Atypical/Extraesophageal:* cough, laryngitis, globus sensation, throat clearing, dental erosions, and dysphonia.

ARS should be considered in patients with typical symptoms who are intolerant or refractory to anti-reflux medications. ARS for isolated extraesophageal symptoms (i.e. in the absence of concomitant typical reflux symptoms) should be approached cautiously and requires objective documentation of significant reflux through impedance or pH testing and, often times, a multidisciplinary approach.

### *2. Proton pump inhibitor (PPI) response*

Symptom improvement with PPI predicts ARS success. Appropriate PPI dosing and proper administration before meals should be emphasized. Heartburn improvement is typically noted within days whereas extraesophageal symptom resolution with PPI may take several months or may be entirely ineffective in the face of small volume reflux events. PPI response has been shown to predict ARS success. ARS should be approached cautiously in those without PPI response (after ensuring appropriate dosing and compliance).

### *3. Additional GI symptomatology*

Presence of so-called “red flag” or alarm symptoms such as progressive dysphagia, anorexia, weight loss, and early satiety suggests underlying malignancy. A history of functional gastrointestinal disorders (FGIDs) such as functional dyspepsia and irritable bowel syndrome (IBS) may indicate a functional etiology to esophageal symptoms (i.e. functional heartburn, acid-sensitive esophagus). Underlying eczema, asthma, and allergies could indicate presence of eosinophilic esophagitis (EoE), particularly when dysphagia is the primary symptom. The presence of bloating, abdominal distention, excessive belching, nausea/vomiting, and early satiety may indicate need for pre-operative gastric emptying assessment and could impact choice of ARS. A detailed patient history prior to ARS is needed to screen for underlying malignancy, functional heartburn, eosinophilic esophagitis, and delayed gastric emptying.

## **Preoperative Testing**

### *Mandatory*

#### **1. Upper endoscopy to determine-**

- Presence of esophagitis (Los Angeles Classification Class A-D)
- Barrett’s esophagus: Prague C & M criteria and histologic level of dysplasia
- Presence and size of hiatal hernia (Hill grade classification I-IV) as measured from the crural pinch to the top of the gastric folds
- Exclusion of eosinophilic esophagitis, esophageal stricture, or malignancy through biopsy

#### **2. Esophageal motility-**

- High-resolution esophageal manometry (HRM) is required to exclude achalasia, esophagogastric junction (EGJ) outflow obstruction and to assess esophageal body motility

(presence/absence of peristalsis, contractile amplitude as expressed by mean wave amplitude, distal contractile integral (DCI), and adequacy of bolus transit). Mean contractile amplitude of >30 mm Hg or DCI > 450 mmHg-s-cm in 70% of swallows is recommended prior to magnetic sphincter augmentation. In patients with ineffective motility, alternative treatments should be considered (i.e., partial fundoplication).

- HRM is the preoperative test of choice for esophageal motility assessment and access to HRM is required. In cases where HRM is not possible (i.e. patient intolerance), a video-esophagram (VEG) with a solid phase in a prone position can be substituted. The only situation where this is an acceptable alternative is when a specific protocol is followed and there is excellent coordination between an experienced surgeon and radiologist.

- EndoFLIP® is a new diagnostic modality performed during upper endoscopy that may help facilitate preoperative motility evaluation in secondary peristalsis. Further studies are needed to validate its use prior to ARS to extrapolate primary peristalsis function from secondary peristalsis.

### **3. pH testing-**

All patients who lack endoscopic LA Class C/D esophagitis or Barrett's esophagus (at least 1 cm in length) should undergo objective pH testing via wireless or catheter-based modalities prior to ARS. Patients with intestinal metaplasia limited to the esophagogastric junction should undergo objective pH testing prior to anti-reflux surgery.

- Patients should be assessed *off* anti-reflux medications to establish reflux severity and degree of symptom correlation. Both impedance pH and traditional pH testing are acceptable when testing is performed *off* anti-reflux medication.

- Traditional pH study findings of increased overall esophageal acid exposure, supine reflux, and good symptom correlation predict ARS success.

- In rare instances patients may be tested *on* anti-reflux medication. These patients should undergo impedance pH testing to assess for ongoing non-acid reflux. Traditional pH testing *on* anti-reflux medication is NOT recommended.

### *Optional*

#### **1. Gastric emptying study**

Patients with additional upper gastrointestinal symptoms such as bloating, nausea, vomiting, and early satiety should undergo pre-operative gastric emptying assessment with 4- hour scintigraphy. Gastric emptying analysis should also be considered in patients with underlying diabetic neuropathy. Though data is limited, the presence of symptomatic gastroparesis may increase gas-bloat symptoms following laparoscopic fundoplication.

## **2. Video Esophagram**

A video Esophagram offers additional information regarding esophageal length, hiatal hernia size, and functional assessment of esophageal motility. The latter may be further evaluated with administration of a barium-coated solid food bolus (i.e. marshmallow or bread).

## **Magnetic Sphincter Augmentation (MSA)**

MSA candidacy largely mirrors that for laparoscopic fundoplication. Low dysphagia rates for MSA have been found when performed in patients with normal esophageal motility. MSA is contraindicated in patients with allergy to titanium, stainless steel, nickel, or iron. Caution should be utilized in patients who require frequent MRI testing. Though the current device is compatible with 1.5 Tesla MRI scanners, it is important to know that the original device was compatible with 0.7 Tesla MRIs.

## **Special considerations Obesity**

Patients with morbid obesity and GERD should strongly consider Roux-en-Y gastric bypass (RYGB). RYGB has been shown to achieve weight loss while controlling GERD symptoms. Sleeve gastrectomy, conversely, can worsen underlying GERD and accelerate progression of Barrett's esophagus. MSA's efficacy in management of post-sleeve gastrectomy GERD requires further study (only small, short term studies to date).

## **MSA Procedure & Technique**

The LINX device applies magnetic force to augment the barrier function of the LES. For reflux to occur, the intragastric pressure must overcome both the patient's native LES pressure and the magnetic bonds of the device, creating a resistance to opening. The LINX device, while augmenting the LES, allows for expansion to accommodate a swallowed bolus or the escape of elevated gastric pressure associated with belching or vomiting. [[Ganz et al. 2013](#)].

The LINX device consists of a series of titanium beads with magnetic cores hermetically sealed inside. The beads are interlinked with independent titanium wires to form a flexible and expandable ring with a 'Roman arch' configuration. Interestingly, each bead can move independently of the adjacent beads, creating a dynamic implant that mimics the physiological movement of the esophagus without limiting its range of motion ([Figure 1](#)). The strength of the magnetic core contained in each bead is calibrated by mass to provide a resisting force that precisely augments the sphincter's function. This attractive force between closed beads is approximately 40 g; this decreases exponentially with distance such that attractive force at full separation is approximately 7 g. The device is manufactured in different sizes, from 10 to 18 beads, and is capable of nearly doubling its diameter when all beads are separated.

## **Historical Background**

The MSA device was FDA approved in 2012. It consists of a series of titanium beads with a magnetic core. The beads are linked together with independent titanium arms to form a flexible

ring that is placed around the distal esophagus in what has been described as a ‘Roman arch’. The design does not exert pressure on the esophagus unless the LES begins to expand during effacement and or during a swallow. The device expands to accommodate a swallowed bolus, and the magnetic force between the beads is exponentially reduced with distension of the sphincter. Each bead is able to move independently of each other. This provides control of reflux without compromising the physiologic function of the LES. The device is manufactured in sizes ranging from 13 to 17 beads, with an 18 bead device coming soon.

In total, over 50 peer-reviewed articles have been published on MSA, including 1 newly published randomized controlled trial, 7 comparative, 11 single-arm and 3 meta-analysis. Recently, the FDA restriction of the device to hiatal hernias less than 3cm was lifted based on 3 publications demonstrating its safety. MSA continues to show its safety, efficacy, and flexibility in the treatment of GERD.

Anti-reflux surgery with MSA is generally a two-part procedure. The first component of the operation is to address the hiatus, and the subsequent component is to address the LES. A thorough understanding of the history of anti-reflux surgery supports the need for both parts of the operation. Publications dating back several years emphasize the conclusion that only about half of the symptoms and abnormal acid exposure are improved with addressing only one component. This led to the recognition that both components need to be addressed giving rise to the “two-sphincter hypothesis” term. Original MSA implantation was with minimal dissection addressing only the LES, but subsequent studies where the hiatal hernia and crus was addressed demonstrated even better results. The GERD barrier is still being understood, but currently recommendations are to address both components, even in patients without a recognizable hiatal hernia in their preoperative workup. In all cases of surgical intervention, it is recommended that a full hiatal dissection and cruroplasty be performed prior to implantation of the MSA device.

### **Part 1: Hiatus**

The proper repair of the hiatus includes a circumferential dissection of the phrenoesophageal membrane permitting entrance into the mediastinum. The complete phrenoesophageal membrane access will entail incision of the gastrohepatic ligament, and potentially the hepatic branches of the vagus nerve. Opening the phrenoesophageal membrane will allow for proper evaluation of the gastroesophageal junction to identify the anterior and posterior vagus nerves so they can be carefully spared, as well as assess for intra-abdominal esophageal length. The mediastinal dissection should move deep into the mediastinum to identify all the relevant anatomical structures such as the pleura bilaterally, aorta, vagus nerves, and in some cases this dissection can extend to the inferior pulmonary vein. This dissection will allow for the proper esophageal length to be obtained into the peritoneal cavity to allow for a cruroplasty leaving enough length for safe MSA implantation around the distal esophagus. The consensus on the amount of esophageal length is still to be determined, however, it is acceptable to have at least 2 cm of intra-abdominal length following the cruroplasty. Some surgeons recommend greater than 3 cm of intra-abdominal length or may routinely dissect the mediastinum as high as possible.

The mediastinal dissection follows an avascular plane along the esophagus. Entrance through the phrenoesophageal membrane gains access to this plane. Care must be taken to safely identify and

spare the anterior and posterior vagus nerves. The dissection can now follow these nerves, as well as the avascular plane, to safely complete the dissection. Encountering bleeding or difficulty seeing the avascular plane should prompt immediate re-evaluation of the dissection. The dissection can typically be done bluntly, but cauterization can be used to prevent small blood vessels from bleeding. Upper endoscopy can be used to aid in the identification of these important anatomical landmarks.

In the instance of a paraesophageal hernia, these dissection planes are less obvious, and the plane between the hernia sac and the mediastinum will guide the dissection to the level of the gastroesophageal junction. Recognition of the hernia sac and its relationship to the phrenoesophageal membrane is essential. The hernia sac is contiguous with the peritoneum overlying the crura and is an elongated phrenoesophageal membrane projecting up into the mediastinum as the herniation becomes more prominent. This relationship means the apex of the hernia sac arises from the insertion on the gastroesophageal junction. Entering the mediastinum should be in the same fashion as those cases with minimal hiatal hernias, at the interface of the hernia sac and crura. This can be done on either side, or at the location preference of the surgeon. Continued caudal retraction of the hernia sac creates tension at the level of the dissection plane. Care must be taken as larger paraesophageal hernias with large amounts of the stomach in the mediastinum because this makes the dissection more difficult and can obscure the normal location of mediastinal structures. When the mediastinal dissection is completed, the esophageal length must be assessed.

The cruroplasty is performed next. There is considerable debate as to technique in its performance, but approximation of the crura should be done to create a new hiatus to surround the distal esophagus. Approximating the hiatus to the esophagus should act to completely fill the new hiatus with the esophagus leaving essentially no open areas. Using a bougie to size the hiatus can be done, but caution needs to be maintained to prevent too patulous of a hiatus. The approximation of the crura to the wall of the esophagus is thought to be critical in reconstruction of the GERD barrier. Use of mesh, configuration of suturing method, and location of sutures is to the discretion of the surgeon.

## **Part 2: LES and MSA Implantation**

After the hiatus is closed, there should be at least 2 cm of esophageal length for MSA implantation. The posterior vagus nerve has been spared and has its native attachments to the posterior aspect of the esophagus. This is essential for MSA implantation. Since the LES can't be seen grossly, placement of the MSA device needs to be placed with care and based on landmarks. Intra-operative endoscopy is recommended to act as a final visual que that the device is at the level of the LES. With a full mediastinal dissection, the Angle of His, truncal vagus nerves, and transition of the esophagus into the stomach at the attachment of the phrenoesophageal membrane should be grossly apparent. It is important to note that the MSA device must be placed on the distal esophagus and not on the stomach. The ideal location for the MSA device is found with identification of the posterior vagus nerve and proximal to the gastroesophageal junction. A dissection plane is created between the esophagus and posterior vagus nerve bluntly until access to the left upper quadrant is obtained. The plane is preserved by placing a Penrose drain. This allows for passage of the sizing device.

The proper size MSA device is determined with the sizing device. Nothing should be within the lumen of the esophagus such as a nasogastric tube or bougie, that will give a false measurement. Using the Penrose drain to allow for passage through this plane already created, the sizing device is passed. Deployment of the sizer will project a flexible tip that will attract to the shaft of the device with a magnetic force. Once encircling the esophagus, the device will be incrementally closed around the esophagus to find the proper measurement for the number of beads used in MSA device selection. As the device closes, the tissue will eventually be contacted with the device correlating to numbers on the device shaft indicating the number of beads on a corresponding MSA device.

Several passes with the device should be done to find the appropriate size. The device aperture should be observed not compressing the esophagus. The value on the shaft of the device will provide a number that corresponds to the number of beads in the MSA device. The proper size is where the device doesn't put any pressure on the esophageal wall. Once the esophageal surface starts to demonstrate indentation, the aperture becomes too small. As the sizer continues to close and pinch the esophagus, the pressure will eventually overcome the magnetic force and break the connection to the shaft. This has been termed as the "pop off" size. It appears that the selection of the device size will either be 2 or 3 sizes larger than the "pop off" size based on surgeon preference.

Once the device size is selected, it can pass through an appropriate trocar into the peritoneal cavity. It is important to recognize that the device should not come in contact with the skin. The Penrose drain should be removed by placing a grasper through the plane behind the esophagus. The MSA device can be handed to the grasper and pulled through the posterior plane and clasped anteriorly. The clasp has undergone an update, but the current device needs to demonstrate the features that it is locked and cannot be displaced. Its final appearance should be free of pressure on the esophageal wall.

In conclusion, MSA is a novel advancement in the field of anti-reflux surgery. The dynamic nature, objective sizing, and procedural standardization of the device has several potential benefits over classic ARS. There is an ever-growing body of evidence that supports its application as first-line procedural therapy for patients with clear objective evidence of GERD and normal esophageal motility. MSA addresses the two key structural components of the anti-reflux barrier- namely the LES and hiatus. Optimal outcomes will be obtained when the proper selection criteria and meticulous technique are followed by an experienced foregut surgeon\*\*\*. It is also critical to understand the device's indications, contraindications, and precautions. Essential to patient and procedure success beyond proper selection and surgical technique are post-operative care of the patient (not discussed here) and a commitment to long term follow-up.

\*\*\* Per the LINX FDA Indications For Use (IFU) item number one under Precautions states- "*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.*" The statement is clear that experience matters when it comes to the outcomes of anti-reflux surgery (ARS) and the LINX procedure in particular. Specific requirements as to what constitutes appropriate experience in foregut surgery can be found in the AFS statement on the definition of a foregut surgeon. We believe that a surgeon performing MSA and a foregut surgeon are one in the same.

*Consensus Statement of the American Foregut Society Board*

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