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Lower Esophageal Magnetic Sphincter Augmentation

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Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Lower esophageal magnetic sphincter augmentation (MSA) **may be considered medically necessary** when ALL the following conditions are met:

- Patient is diagnosed with gastroesophageal reflux disease (GERD) defined by abnormal pH testing in which acid exposure time (AET) is greater than 6%; and
- Patient has undergone appropriate endoscopic and esophageal manometric evaluation to rule out extragastrointestinal etiology of symptoms; and
- Patient has chronic GERD symptoms despite maximum medical therapy for the treatment of reflux defined as maximum (or maximum tolerated) dose of proton pump inhibitors (PPI) for at least 6 months; and
- Implantation of the device is performed by a surgeon with experience in laparoscopic anti-reflux procedures and has received product specific training.

Lower esophageal magnetic sphincter augmentation **is considered experimental, investigational and/or unproven** for the following, as safety and efficacy has not been established:

- Patients with suspected or known allergies to titanium, stainless steel, nickel, or ferrous materials;
- Patients with electrical implants such as pacemakers and defibrillators, or other metallic, abdominal implants;
- Unrepaired hiatal hernia >3 cm or a paraesophageal hernia;
- Barrett's Esophagus or esophagitis Los Angeles (LA) class C or D;
- 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 (e.g., achalasia, nutcracker esophagus, and diffuse esophageal spasm or hypertensive lower esophageal sphincter [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 (body mass index [BMI] >35); or
- Age <21.

Policy Guidelines

The Los Angeles (LA) Classification of gastroesophageal reflux disease (GERD):

- Grade A - One (or more) mucosal break no longer than 5 mm that does not extend between the tops of 2 mucosal folds.
- Grade B - One (or more) mucosal break more than 5 mm long that does not extend between the tops of 2 mucosal folds.
- Grade C - One (or more) mucosal break that is continuous between the tops of 2 or more mucosal folds, but which involve less than 75% of the circumference.
- Grade D - One (or more) mucosal break which involves at least 75% of the esophageal circumference. (2)

Description

The LINX® Reflux Management System is a magnetic sphincter augmentation device designed to prevent reflux due to abnormal opening of the lower esophageal sphincter (LES). The system is a laparoscopically implanted ring composed of a small flexible band of interlinked titanium beads with magnetic cores that was developed for the treatment of gastroesophageal reflux disease (GERD). The device is placed around the esophagus at the level of the gastroesophageal junction. The magnetic attraction between the beads is intended to augment the LES to prevent

gastric reflux into the esophagus without compressing the esophageal wall. The magnetic attraction increases the LES closure pressure but permits food passage when swallowing. (3)

Gastroesophageal Reflux Disease

The Montreal Consensus defines GERD as "a condition which develops when the reflux of stomach contents causes troublesome symptoms and/or complications." (4) It includes a spectrum of symptoms, including heartburn, regurgitation, dysphagia, laryngitis, dental problems, adult-onset asthma, and aspiration pneumonia. The prevalence of GERD is high and increasing globally. (5)

Lifestyle modification and medications are the mainstay of treatment for GERD. Despite proper medical therapy, 10 to 40% of patients continue to have significant symptoms. (6, 7) Surgical intervention is generally reserved for patients who have persistent symptoms or develop complications despite optimal medical therapy. Fundoplication is a well-established surgical intervention that dates to the 1950's. Since then, multiple variations of the fundoplication have been established. The laparoscopic fundoplication (LF) and its variations are considered highly effective and durable but also associated with significant potential for adverse effects, including dysphagia, difficulty in vomiting, and gas bloating. (8)

Since the advent of fundoplication, other less invasive options that do not alter the gastric fundus have been developed. Magnetic sphincter augmentation is 1 of those options. It is performed using the LINX Reflux Management System. This device treats GERD by augmenting the LES with an extraluminal ring consisting of a series of magnets. The magnetic attraction increases the LES closure pressure but permits food passage when swallowing.

Regulatory Status

In 2012, the LINX® Reflux Management System (Ethicon; formerly Torax Medical) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process (P100049) for patients diagnosed with GERD, as defined by abnormal pH testing, and who continue to have chronic GERD symptoms despite maximal therapy for the treatment of reflux. The FDA initially required a 5-year follow-up of 100 patients from the investigational device exemption (IDE) pivotal study to evaluate safety and efficacy of the device, which was completed in March 2016. In 2018, the manufacturer initiated a device recall due to a possible separation of the bead component with the adjacent wire link causing a potential discontinuous or open LINX device. (3) This recall was terminated on November 4, 2020. FDA product code: LEI.

In March 2018, the FDA approved an update of the LINX® Reflux Management System precautions statement, stating that the use of the system "in patients with a hiatal hernia larger than 3 cm should include hiatal hernia repair to reduce the hernia to less than 3 cm and that the LINX Reflux Management System has not been evaluated in patients with an unrepaired hiatal hernia greater than 3 cm, add a hiatal hernia clinical data summary in the instructions for use, update the instructions for use section to highlight the recommendation to repair a hiatal hernia, if present, at the time of the LINX Reflux Management System implantation, and update

the patient information booklet to align with the instructions for use and include 5 year clinical study results." (9)

In February 2024, the FDA revised the labeling for the LINX® Reflux Management System. They removed a precautionary statement about Barrett's Esophagus (BE) from the instructions for use. However, the updated labeling now includes this guidance: "LINX has not been proven to effectively treat BE by causing regression or preventing progression to cancer. Patients with BE who use LINX to manage GERD symptoms should consult their physician about ongoing BE treatment, which may include continued use of proton pump inhibitors (PPIs)." (10)

Rationale

This policy is based on a review of coverage guidance from the Centers for Medicare and Medicaid Services (CMS) specific to lower esophageal magnetic sphincter augmentation. (1)

Safety and Efficacy

Since the U.S. Food and Drug (FDA) approval in 2012, numerous studies have evaluated the safety and efficacy of magnetic sphincter augmentation (MSA) using the LINX ®device. Multiple short to moderate-term studies (6 months to 5 years) have demonstrated reduced gastroesophageal reflux disease (GERD) symptoms, improved GERD-related quality of life scores, cessation of proton pump inhibitor (PPI) use, and normalization of objective GERD measurements. More recently, studies have been published with data extending beyond 5 years.

In 2012, Lipham et al. performed a multicenter, prospective, single-arm study of 44 patients who underwent laparoscopic placement of the LINX System. (11) The acid exposure time (AET) reduced from 11.9% at baseline to 3.8% at 3 years, with 80% (18/20) of patients achieving pH normalization. At ≥ 4 years, 100% of the patients reported improved quality-of-life measures for GERD, and 80% had complete cessation of PPIs. There were no reported deaths or long-term device-related complications such as migration or erosion.

A retrospective case-control study was done in 2014 by Louie et al. It involved consecutive patients undergoing either laparoscopic Nissen fundoplication (LF) or MSA who had chronic GERD, and a hiatal hernia of less than 3 cm. (12) Sixty-six patients underwent operations (34 MSA and 32 LF) and were followed for at least 6 months. The groups were similar in reflux characteristics and hernia size. MSA resulted in less gassy and bloated feelings and enabled belching in 67% compared with none of the LF patients. The AET normalized in both groups but was statistically better in the LF group. MSA resulted in similar objective control of GERD, symptom resolution, and improved quality of life compared with LF.

Saino et al. (2015) evaluated the safety and efficacy of the MSA for 5 years during a prospective, multicenter study. (13) Forty-four patients (ages 18-75 years) had a LINX device implanted by laparoscopy, and 33 patients were followed to 5 years. At 5 years, GERD Health-

Related Quality of Life (HRQL) questionnaire score, esophageal pH, PPI use, and complications were evaluated. Complete discontinuation of PPIs was achieved by 87.8% of patients. No device erosions or migrations were reported. However, 11 (25%) of the study patients were not followed to the 5-year endpoint. Three patients had device removal.

A 2015 prospective, multicenter study by Riegler et al. compared MSA and LF in clinical practice. (14) Two hundred forty-nine patients (202 MSA patients and 47 LF patients) had completed one-year follow-up. Discontinuation of PPIs was achieved by 81.8% of patients after MSA and 63.0% after LF. Excessive gas and abdominal bloating were reported by 10.0% of patients after MSA and 31.9% following LF. Following MSA, 91.3% of patients were able to vomit if needed, compared with 44.4% of those undergoing LF. The reoperation rate was 4.0% following MSA and 6.4% following LF.

Ganz et al. (2016) performed a prospective study on 100 subjects ages 18-75 years old that underwent the LINX placement, 85 of which were followed for 5 years to evaluate quality of life, reflux control, use of PPIs, and side effects. (15) All patients used PPIs at baseline; this decreased to 15.3% at 5 years. Moderate or severe regurgitation occurred in 57% of subjects before the procedure and 1.2% at 5 years post-surgery. All patients reported the ability to belch and vomit if needed. Bothersome dysphagia was present in 5% at baseline and 6% at 5 years. No device erosions, migrations, or malfunctions were reported in this study. Device removal occurred in 7 patients.

Bell et al. (2019) prospectively studied 152 patients with GERD and moderate-to-severe regurgitation despite 8 weeks of once-daily PPI therapy. (16) These results indicate 89% (42/47) of treated patients with MSA reported relief of regurgitation compared with 10% (10/101) of the twice a day PPI group at the 6-month primary endpoint. The same authors published another study in 2020 that offered MSA to patients in the PPI arm of the study who had persistent moderate to severe regurgitation and excess reflux episodes during impedance or pH testing on medication. (17) In this study, 70% (48/69) of patients had pH normalization at study completion. MSA was not associated with peri-operative events, device explants, erosions, or migrations.

The 2019 multicenter, prospective study by Louie et al. evaluated patients with pathologic acid reflux confirmed by esophageal pH testing undergoing MSA. (18) A total of 200 patients, ages ranging from 19.7-71.6 years. At 1 year, the mean total AET decreased from 10.0% at baseline to 3.6% and 74.4% of patients had normal esophageal AET. The device removal rate at 1 year was 2.5%. One erosion was reported.

In a long-term retrospective study, Ferrari et al. (2020) reported on the course of 335 patients, 124 of which were followed from 6 to 12 years after surgery (median 9 years). (19) The mean total GERD-HRQL score significantly improved from 19.9 to 4.01, and PPI use was discontinued by 79% of patients. The mean total percent time with pH < 4 decreased from 9.6% at baseline to 4.1%, with 89% of patients achieving pH normalization. The rate of procedure-related adverse events was 11.6%, with 2.4% requiring a single endoscopic pneumatic dilation due to

persistent dysphagia. Thirty-one patients (9.2%) required laparoscopic device removal for the following reasons: erosion [6], regurgitation [6], heartburn [5], dysphagia [5], foreign body sensation [2], odynophagia [1], pharyngodynia [1], chronic cough [1], need for magnetic resonance imaging (MRI) [1].

Addressing postoperative dysphagia, Ganz et al. (2013) prospectively assessed 100 patients with GERD before and after sphincter augmentation. (20) The study did not include a concurrent control group. The most frequent adverse event was dysphagia (in 68% of patients postoperatively, in 11% at 1 year, and 4% at 3 years). Serious adverse events occurred in 6 patients, and the device was removed in 6 patients. Ayazi et al. (2020) performed a retrospective review of prospectively collected data of patients who underwent MSA over 5 years. (21) The preoperative objective evaluation included upper endoscopy, esophagram, high-resolution impedance manometry, and esophageal pH testing. A total of 380 patients underwent MSA; at a mean follow-up of 11.5 months, 15.5% of patients were experiencing persistent dysphagia. The overall response rate to dilation therapy was 67%, and the efficacy of dilation reduced with each subsequent procedure.

Regarding the risk of erosion, Alicuben et al. (2018) examined data for all devices placed worldwide from February 2007 through July 2017 using the device registry. (22) In total, 9453 devices were placed, and there were 29 reported cases of erosion. The median time to presentation of erosion was 26 months, most occurring between 1 and 4 years after placement. The risk of erosion was 0.3% at 4 years after device implantation. In this series, smaller devices were associated with higher rates of erosion. Notably, the smaller 12-bead device was responsible for 18/29 (62%) of erosions.

Effectiveness compared to fundoplication

In a systematic review and meta-analysis of 688 patients (273 fundoplication and 415 MSA), Skubleny et al. (2017) found MSA was statistically superior to LF in preserving patient's ability to belch and vomit. (23) There was no statistically significant difference between MSA and LF in gas/bloating, postoperative dysphagia, and PPI elimination.

Aiolfi et al. (2018) examined 7 observational cohort studies, including 1211 patients, 686 MSA and 525 LF. (24) Postoperative morbidity ranged from 0 to 3% in the MSA group and from 0 to 7% in the LF group, and there was no mortality reported. Dysphagia requiring endoscopic dilatation occurred in 9.3% of MSA and 6.6% of LF patients. Postoperative PPI use, dysphagia requiring dilatation, and quality of life are similar in the 2 patient groups. MSA was associated with less gas/bloat symptoms and an increased ability to vomit and belch.

Chen et al. (2017) conducted a meta-analysis of 4 trials that included 624 patients and aimed to evaluate the differences in PPI use, complications, and adverse events. (25) MSA had a shorter operative time and length of stay. Similar PPI use, complication rate, and severe dysphagia for dilation was shown in both groups. Although there was no difference between the MSA and LF in the number of adverse events, the incidence of postoperative gas or bloating favored the MSA group. There was no significant difference in the ability to belch and vomit.

The systematic review by Guidozzi et al. (2019) identified 6 comparative studies of MSA versus fundoplication and 13 single-cohort studies. (26) Collectively, the study included 1099 patients, 632 receiving MSA and 467 receiving fundoplication. Following MSA, only 13.2% required postoperative PPI therapy, 7.8% dilatation, 3.3% device removal or reoperation, and esophageal erosion was seen in 0.3%. There was no significant difference between the groups in the requirement for postoperative PPI therapy, GERD-HRQOL score, dysphagia, and reoperation. However, when compared to fundoplication, MSA was associated with significantly less gas bloating and a greater ability to belch. Regarding safety, 3.3% of the MSA patients required device removal.

Patient selection

Rona et al. performed a retrospective review of 192 patients. (27) Median follow-up was 20 months (ranging from 3-75 months). Fifty-two patients had a hiatal hernia >3cm. This study reports MSA in patients with large hiatal hernias showed decreased postoperative PPI requirement and mean GERD-HRQL scores compared to patients with smaller hernias.

Buckley et al. (2018) conducted a 3-year multicenter, prospective study of consecutive patients undergoing MSA with the LINX device with concurrent repair of paraesophageal and hernias over 3 cm. (28) Non-permanent mesh reinforcement of hiatal repair was performed in 83% of the patients. At 9-month median follow up, complete PPI independence was achieved in 94%, 9.5% required dilation, GERD-HRQL scores improved from 26 preoperatively to 2 post-operatively. There were no device explants, erosions, or migrations reported.

In a retrospective review, Dunn et al. (2021) evaluated 79 patients with GERD and hiatal hernias ≥ 3 cm who underwent MSA and hiatal hernia repair over a 7-year period. (29) Seventy-nine patients, with a median age of 65.56 years were included, median follow up was 2.98 years. Five (6.3%) hiatal hernia recurrences occurred, and 1 required re-operation. Median GERD-HRQL scores improved from 21 to 2.

Alicuben et al. (2019) and Dunn et al. (2021) published very similar retrospective studies showing MSA to be effective at preventing progression of metaplasia/Barrett's esophagus to dysplasia or neoplasia. (30, 31) The studies involved 86 and 87 patients, respectively. In both studies, the effect remained consistent even after 2 years of follow-up.

Warren et al. (2018) retrospectively studied clinical, endoscopic, manometric, pH data, and intraoperative factors of 170 patients. (32) Manometric data pre- and post-MSA demonstrated that LESs with 1 defective component were restored to normal in 77% of patients; however, those with 2 or 3 defective components can only be restored to normal in 56%. MSA appears to provide less control of GERD in patients with lower esophageal sphincter (LES) with multiple defects. Using a multivariable analysis, body mass index (BMI) >35, structurally defective LES, and preoperative LES residual pressure were independent negative predictors of excellent/good outcome.

In a 3-year retrospective cohort study, James et al. (2022) evaluated the outcomes of 621 consecutive patients who underwent laparoscopic MSA. (33) Patients were grouped into 4 cohorts according to the World Health Organization BMI classification: BMI < 25 (normal weight), BMI 25-29.9 (overweight), BMI 30-34.9 (obese class I), and BMI >35 (obese class II-III). Follow-up with endoscopy or video esophagram was available for 361 patients (58%) with a median follow-up of 15.4 months. There were no significant differences in outcomes between normal weight, overweight, and obese patient groups undergoing MSA.

Analysis of Evidence (Rationale for Determination)
With fundoplication considered the gold standard for surgical treatment of GERD refractory to medical management, numerous studies have evaluated MSA versus fundoplication. Current evidence shows MSA to have similar safety and efficacy when used in appropriately selected patients. The data shows similar quality-of-life improvement scores and rates of PPI cessation in both groups. In contrast, more fundoplication patients are unable to belch and vomit. Compared to fundoplication, MSA generally has shorter operative times and duration of hospital stays. (23-26)

Dysphagia is a common adverse symptom that generally decreases over time and has been successfully treated with dilation therapy. (20, 21) The risk of erosion was addressed in a large 2018 study, which found the incidence to be 0.3%. (22) Persistent or recurrent adverse effects such as heartburn, regurgitation, dysphagia, chest pain, and device erosion have resulted in explantation. The likelihood of explantation generally ranges from 3-7% and should be included in the preoperative risk/benefit discussion. (15, 34)

The criteria for patient selection undergoing MSA are primarily based on the manufacturer's FDA-approved instructions for use, as these guidelines have been used in the majority of studies. Although use outside these parameters is reported, it has only been evaluated in a small number of studies, has limited objective data, and lacks adequate long-term follow-up.

There is limited study in patients with an unrepaired hiatal hernia >3m. However, there are multiple studies that show the effective use of MSA in patients who have a hiatal hernia concurrently repaired at the time of placement. (27-29)

Thus far, there is limited data regarding use in patients with more severe GERD including esophagitis LA class C or D and Barrett's esophagus. Two small retrospective studies evaluated the outcomes of MSA in patients with Barrett's and showed promising results. (30, 31) However, these studies were from the same institutions, had nearly identical numbers, and occurred over a similar timeframe. Although published separately, the results appear consistent with data used from an overlapping patient population. Authors involved in both articles disclosed a paid consulting relationship with the manufacturer, adding limitation to the studies.

The literature suggests that endoscopy and esophageal manometry are valuable in the preoperative evaluation to rule out alternative pathology including cancer, motility disorders, stricture, and anatomic abnormalities. The 2018 Warren study showed structurally defective

LES and preoperative LES residual pressure were independent negative predictors of excellent/good outcome. (32)

The initial trials that led to the approval of the LINX device excluded patients with a BMI >35, and most studies since then have followed this criterion. James et al. examined the effect of preop BMI on outcomes and found no significant differences between normal weight patients, overweight, and different classes of obesity. (33) However, the 2018 study by Warren et al. suggests a higher BMI may be a negative predictor. (32) Currently, there is not sufficient evidence for use outside this parameter.

It is important to note that patients >75 years old were excluded from the original FDA trials. Since then, no significant study has addressed its use for patients >75 years old. Although studies have suggested that younger age is a predictor of positive outcomes, age is not listed as an exclusionary criterion. Careful patient selection is critical for both success and safety. (22)

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	43284, 43285
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

References

Local Coverage Determination

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
01/01/2026	Document updated. Coverage criteria revised to be consistent with coverage guidance from the Centers for Medicare and Medicaid Services. Added references 1, 2, 4-8, 10-34; others removed. Title changed from: “Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease (GERD).”
10/15/2024	Document updated with literature review. Coverage unchanged. References added: 6, 7, 11-13, 28-31, 33, 35, 39, and 41; others updated/revised.
09/15/2023	Document updated with literature review. The following change was made to Coverage: Removed “Hiatal hernias greater than 3 cm in size” from experimental, investigational and/or unproven list. Added references 22, 23, 28, and 32.
06/15/2022	Document updated with literature review. Coverage unchanged. The following references were added: 1-3, 7, 8, 14-16, 19-22, and 24-27; others removed.
09/15/2021	Reviewed. No changes.
01/01/2021	Document updated with literature review. Coverage unchanged. Added references 1, 2, and 21.
04/01/2019	Reviewed. No changes.
05/01/2018	Document updated with literature review. Coverage unchanged. References 1-2, 11-12 and 15-19.
12/01/2017	Reviewed. No changes.
06/01/2017	Document updated with literature review. The following statement was added to the coverage section of the medical policy: Removal of an esophageal sphincter augmentation device may be considered medically necessary when all the following criteria are met: 1) Patient met all the

	criteria for initial placement of the device, AND 2) Complications such as erosion, device migration, or difficulty swallowing.
04/01/2016	New medical document originating from a topic previously addressed on medical policy MED201.016. Coverage has changed to the following: 1) A laparoscopically implantable magnetic esophageal ring (LINX™ Reflux Management System) is considered medically necessary as a treatment alternative to laparoscopic Nissen fundoplication when the patient has chronic gastroesophageal reflux disease (GERD) symptoms refractory to maximum medical therapy, 2) The safety and effectiveness of a laparoscopically implantable magnetic esophageal ring (LINX™ Reflux Management System) has not been established and/or is contraindicated and therefore considered experimental, investigational and/or unproven for patients with the following conditions: Suspected or known allergies to metals such as iron, nickel, titanium, or stainless steel; Hiatal hernias greater than 3 cm in size; Barrett's esophagus or Grade C or D (LA classification) esophagitis; 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 (e g. 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), or Age <21.