

**GASTROESOPHAGEAL REFLUX DISEASE (GERD) AND  
BARRETT'S ESOPHAGUS**

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5/16, 11/16, 11/17, 11/18

Date Of Origin: February 25, 2004

Status: Current

**I. POLICY/CRITERIA**

**A. Transoral incisionless fundoplication (TIF) for GERD for individuals with normal esophageal motility (by either manometry or video esophagogram) is a covered benefit for any of the following indications:**

1. Persistent GERD symptoms despite PPI therapy.
2. Anatomic disruption of the GE flap valve to a Hill Grade II-III.
3. Evidence of one of the following while on PPI therapy:
  - a. Erosive esophagitis (erosions or ulcerations during endoscopy)
  - b. Abnormal ambulatory pH study
  - c. Biopsy confirmed changes characteristic of reflux esophagitis
4. Contraindications for TIF include:
  - a. BMI  $\geq$  35
  - b. Hiatal hernia > 2 cm
  - c. Esophagitis grade D or Barrett's esophagitis
  - d. Esophageal ulcer
  - e. Fixed esophageal stricture or narrowing
  - f. Portal hypertension and/or varices
  - g. History of previous resective gastric or esophageal surgery, cervical spine fusion, Zenker's diverticulum, esophageal epiphrenic diverticulum, achalasia, scleroderma or dermatomyositis, eosinophilic esophagitis, > 2 dilations for esophageal stricture, or cirrhosis
  - h. Active esophago-gastro-duodenal ulcer disease
  - i. Gastric outlet obstruction or stenosis
  - j. Gastroparesis or delayed gastric emptying confirmed by solid-phase gastric emptying study if patient complains of postprandial satiety during assessment

**B. The Stretta radiofrequency energy procedure for the treatment of GERD may be considered medically necessary for patients 18 years or older when the following clinical criteria are met (must meet 1 or 2 and 3 below):**

1. Patient must have all of the following:
  - a. Daily gastroesophageal reflux disease (GERD) > 6 months as evidenced by **one** of the following:

- i. pH study (performed off medication) showing pathologic acid exposure (pH <4 more than 4% of a 24- hour period OR DeMeester score >14.7), **OR**
- ii. upper GI endoscopy showing Grade A or B esophagitis (Los Angeles classification), **OR**
- iii. abnormal reflux as determined by impedance testing, **OR**
- iv. biopsy confirmed reflux esophagitis
- b. Esophageal manometry demonstrating **both** of the following:
  - i. normal peristalsis (e.g. lack of frequent large breaks in peristaltic propagation, or bolus clearance > 70%, or contractility > 500), **AND**
  - ii. normal sphincter relaxation (i.e. residual pressure  $\leq$ 8 mmHg)
- c. Symptoms of heartburn refractory to daily appropriate dose anti-secretory therapy.

**OR**

2. Patient has been diagnosed with:
  - a. reflux related aspiration pneumonia, OR
  - b. laryngopharyngeal reflux

**AND**

3. Patient does not have any of following:
  - a. American Society of Anesthesiologists (ASA) IV classification
  - b. Barrett's esophagus,
  - c. Esophagitis grade C or D (Los Angeles classification)
  - d. Hiatal hernia >2cm
  - e. Autoimmune disease
  - f. Collagen vascular disorder
  - g. Coagulation disorder
  - h. Current anticoagulant therapy
  - i. Life threatening disorder with life expectancy <1 year
  - j. Achalasia
  - k. Current pregnancy

Credentialing:

1. Physician must be privileged in EGD and have completed the manufacturer's training program for Stretta.
2. Documentation of training must be available upon request.

The Stretta procedure was reviewed by the Priority Health Technology Assessment Committee in September 2015. This policy reflects the recommendation of the committee.

**C. Magnetic sphincter augmentation (MSA) with the LINX device may be a covered benefit for the treatment of GERD when all of the following are met:**

1. 18 -74 years of age
2. Body Mass Index (BMI)  $\leq 35$
3. Documented typical symptoms of gastroesophageal reflux disease (GERD) for longer than 6 months (regurgitation or heartburn which is defined as a burning epigastric or substernal pain which responds to acid neutralization or suppression)
4. Patient is refractory to ideal medical management (requires twice daily proton pump inhibitor or other anti-reflux drug therapy, diet and lifestyle change discussed).
5. Hiatal hernia  $\leq 3$  cm as determined by endoscopy
6. Total Distal Ambulatory Esophageal pH must meet the following criteria: pH < 4 for  $\geq 4.5\%$  of the time with discontinuation of any GERD medications for at least 7 days prior to testing.
7. Distal esophageal motility (average of sensors 3 and 4) is  $\geq 35$  mmHg peristaltic amplitude on wet swallows or  $\geq 70\%$  (propulsive) peristaltic sequences
8. Symptomatic improvement on proton-pump inhibitor (PPI) therapy demonstrated by a GERD-Health-Related Quality of Life (GERD-HRQL) score of  $\leq 10$  on proton-pump inhibitors and  $\geq 15$  off PPIs, or a  $\geq 6$  point improvement when comparing their on PPI and off PPI GERD-HRQL score
9. None of the following:
  - a. History of gastroesophageal surgery, anti-reflux procedures, including endoscopic anti-reflux procedures
  - b. Suspected or confirmed esophageal or gastric cancer
  - c. Esophagitis - Grade C or D (LA Classification)
  - d. Symptoms of dysphagia more than once per week within the last 3 months.
  - e. Diagnosed with Scleroderma
  - f. Diagnosed with an esophageal motility disorder such as but not limited to Achalasia, Nutcracker Esophagus, or Diffuse Esophageal Spasm or Hypertensive LES
  - g. History of or known esophageal stricture or gross esophageal anatomic abnormalities (Schatzki's ring, obstructive lesions, etc.)
  - h. Esophageal or gastric varices
  - i. History of or known Barrett's esophagus

- j. Pregnant or breastfeeding
  - k. Life expectancy less than 3 years
  - l. Diagnosed psychiatric disorder (e.g. bipolar, schizophrenia, etc.), not including depression on appropriate medication(s), would require statement of clearance from the treating Behavioral Health team
  - m. Suspected or known allergies to titanium, stainless steel, nickel or ferrous materials
  - n. Current electrical implant or metallic abdominal implant
10. Prior authorization by Priority Health.

Credentialing:

- 1. Physician must be privileged in foregut procedures and have completed the manufacturer's device specific training and device specific proctoring from designated LINX Preceptor (Torax Medical).
- 2. Documentation of training must be available upon request.

**D. Priority Health does not provide coverage for other treatments\* for GERD for the following reasons:**

- 1. The evidence does not permit conclusions on whether endoscopic suturing or implantation of inert polymers for treatment of gastroesophageal reflux disease improves health outcomes or is as beneficial as established alternatives. Case series data are inadequate to demonstrate improvement in health outcome. The procedures have not been compared to Nissen fundoplication in controlled trials, and the risks and benefits of the procedures compared to Nissen fundoplication are not established. Non-covered procedures include, but are not limited to the following:
  - a. Bard EndoCinch Suturing System (C.R. Bard Inc., Murray Hill, NJ) Angelchik anti-reflux prosthesis
  - b. Enteryx
  - c. Endoscopic Plicator System (NDO Surgical, Inc., Mansfield, MA) and the Syntheon ARD Plicator (Syntheon, Miami, FL)
  - d. Durasphere (Carbon Medical Technologies, St Paul, MN), the Gatekeeper Reflux Repair System (Medtronic, Inc., Minneapolis, MN), an endoscopically-implanted injectable esophageal prosthesis, and the Plexiglas polymethylmethacrylate (PMMA) microspheres (Arkema Inc., Bristol, PA)
- 2. There is no long-term outcome data to show the durability of these procedures.

***\*These procedures are Non-Covered Services under "Experimental, Investigational, or Unproven Services" as outlined in the plan documents.***

**E. Endoscopic Mucosal Resection and/or Thermal Ablation Treatment (i.e. BARRX) or Photodynamic Therapy for Barrett's Esophagus (BE) is a covered benefit when the following is present:**

1. Dysplastic Barrett's esophagus and/or early esophageal adenocarcinoma (EAC)
2. The data available at present is insufficient to support these modalities in non-dysplastic Barrett's esophagus.

**F. Any of the following ablative or surgical interventions are considered experimental and investigational for the treatment of members with Barrett's Esophagus:**

1. Argon plasma coagulation
2. Chemoradiation therapy
3. Cryotherapy
4. Laser therapy
5. Multi-polar electro-coagulation
6. Ultrasonic therapy

**G. Any of the following tests are considered experimental and investigational for the diagnosis or management of Barrett's Esophagus:**

1. Methylation biomarkers and microRNA tests.
2. Capsule endoscopy of the esophagus
3. Confocal laser endomicroscopy and Fuji Intelligent Chromo Endoscopy (FICE)
4. Genetic mutation analysis

**H. The following device is considered experimental and investigational and not a covered benefit for the treatment of GERD or any other condition:**

1. Reza Band Upper Esophageal Sphincter Assist Device

**II. MEDICAL NECESSITY REVIEW**

Required\*                       Not Required                       Not Applicable

\*Prior authorization is only required for magnetic sphincter augmentation (MSA) with the LINX device.

### III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*
- ❖ **PPO:** *This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*
- ❖ **MEDICARE:** *Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.*
- ❖ **MEDICAID/HEALTHY MICHIGAN PLAN:** *For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: [http://www.michigan.gov/mdch/0,1607,7-132-2945\\_42542\\_42543\\_42546\\_42551-159815--,00.html](http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html). If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: [http://www.michigan.gov/mdch/0,1607,7-132-2945\\_5100-87572--,00.html](http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html), the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.*

### IV. DESCRIPTION

A. Endoscopic, or endoluminal, therapies for GERD are designed to alter structures at the gastroesophageal junction to prevent reflux of gastric contents. Current endoscopic therapies may be classified into three basic categories: (1) radiofrequency energy or radiofrequency thermal ablation; (2) endoscopic or plication suturing; and (3) polymer injection and implantation techniques.

- 1. Radiofrequency Energy or Radiofrequency Thermal Ablation:**  
Thermal energy is delivered to the lower esophageal sphincter (LES) using endoscopically placed needles. Proposed mechanism of action is unknown, although it is likely that there is a resultant scarring or neurolysis in the lower esophageal sphincter.

An example is the Stretta<sup>®</sup> System. Mederi Therapeutics, Inc.

- 2. Plication/Suturing Techniques:** This procedure is also referred to as Endoluminal Gastric Plication (ELGP). A needle puncture device attached to the endoscope creates pleats through a series of sutures passed by a needle through adjoining proximal fundic folds at the

gastroesophageal junction. The proposed action is providing a physical barrier to gastric reflux, possibly by increasing the length of the lower esophageal sphincter (LES), decreasing the esophageal luminal diameter, or decreasing the frequency of transient relaxations of the LES (tLESRs).

An example of a suture plication gastroplasty device is the EndoCinch<sup>™</sup> or Bard Endoscopic Suturing System (BESS) (Bard Endoscopic Technologies, Billerica, MA, a subsidiary of C.R. Bard Inc., Murray Hill, NJ).

The full-thickness Endoscopic Plication<sup>™</sup> System (EPS; NDO Surgical, Inc., Mansfield, MA) is a semiflexible tube that retroflexes upon itself within the stomach and creates a transmural, full-thickness plication. Its proposed mechanism of action is to inhibit gastroesophageal reflux by placing a transmural plication near the gastroesophageal junction.

The EndoGastric Solutions (EGS) EsophyX<sup>™</sup> System with Serofuse<sup>™</sup> Fastener is indicated for use in endoluminal, transoral tissue approximation, full thickness plication and ligation in the GI tract and is indicated for the treatment of symptomatic chronic gastroesophageal reflux disease in patients who require and respond to pharmacological therapy. It is also indicated to narrow the gastroesophageal junction and reduce hiatal hernia  $\leq 2\text{cm}$  in size in patients with symptomatic chronic gastroesophageal reflux disease

- 3. Polymer Injection/Implantation Techniques:** These are referred to as bulking techniques as their proposed mechanism of action is to provide bulking support to the sphincter keeping stomach fluids and acids from backing up into the esophagus. It does not affect the stomach's ability to produce acid or other digestive fluids. The procedure is not reversible.

An example is Enteryx<sup>™</sup> which is a liquid polymeric material that is injected into the muscle of the lower esophageal sphincter (LES), through an endoscope. Enteryx<sup>™</sup> forms a soft, spongy permanent implant in the sphincter muscle.

\*On October 14, 2005 the FDA issued a preliminary public health notification recall of all Enteryx<sup>™</sup> Procedure Kits and Single Pack Enteryx<sup>™</sup> Injectors to health care practitioners stating serious adverse events, including death, occurred in patients treated with Enteryx<sup>™</sup> for GERD (FDA, 2005).



B. Endoscopically based therapies for Barrett's esophagus (BE) are designed to destroy the damaged tissue in the esophagus associated with BE and thus reduce the risk of esophageal cancer in these individuals. There are currently two endoscopically based therapies for BE: (1) Photodynamic Therapy (PDT); (2) Thermal Ablation.

**1. Photodynamic Therapy (PDT):** PDT using porfimer sodium (Photofrin) is an FDA approved treatment for Barrett's esophagus with high grade dysplasia. Porfimer sodium is a light-sensitizing drug (a photosensitizer) which is administered intravenously or by mouth. The drug concentrates in the Barrett's tissues. The esophageal tissue is then exposed to modified laser light. Photoactivation of the drug then destroys the cells in which it has been absorbed.

**2. Thermal Ablation (TA):** The goal of this therapy is to ablate dysplastic tissue, reversing the histopathological changes characteristic of BE, and initiating squamous re-epithelialization of the esophagus. Using a controller to limit the amount of heat energy generated, a high-frequency electric current is passed through a heater element for less than a second to destroy the innermost layer of esophageal tissue. The HALO<sup>360</sup> Coagulation System, which is also referred to as the BARRX device, is an example of this technology.

C. Reza Band Upper Esophageal Sphincter Assist Device: The Reza Band is a non-medication, non-surgical medical device that is externally worn and applies a slight, external pressure to the cricoid cartilage to generate added intraluminal UES pressure to stop reflux from rising above the UES. There is no evidence in the peer-reviewed medical literature to support its effectiveness.

## V. CODING INFORMATION

### Transoral Incisionless Fundoplication (TIF) for GERD

#### ICD-10 Codes:

K20.8	Other esophagitis
K20.9	Esophagitis, unspecified
K21.0	Gastro-esophageal reflux disease with esophagitis
K21.9	Gastro-esophageal reflux disease without esophagitis

#### CPT/HCPCS Codes:

*The following procedures are covered only for the gastroesophageal reflux disease (GERD) dx above:*



- 43210 Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed (*when billed for EsophyX System*)
- 43257 Esophagogastroduodenoscopy, flexible, transoral; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease (*when billed for Stretta System*)

*The following procedures are not covered for the GERD diagnoses above:*

- 43211 Esophagoscopy, flexible, transoral; with endoscopic mucosal resection
- 43229 Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)
- 43254 Esophagogastroduodenoscopy, flexible, transoral; with endoscopic mucosal resection
- 43270 Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)

**Endoscopic Mucosal Resection, Thermal Ablation Treatment or Photodynamic Therapy for Barrett's Esophagus**

**ICD-10 Codes:**

- K22.710 Barrett's esophagus with low grade dysplasia
- K22.711 Barrett's esophagus with high grade dysplasia
- K22.719 Barrett's esophagus with dysplasia, unspecified

**CPT/HCPCS Codes:**

*The following procedures are covered only for the Barrett's esophagus (BE) diagnoses above:*

- 43211 Esophagoscopy, flexible, transoral; with endoscopic mucosal resection
- 43229 Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)
- 43254 Esophagogastroduodenoscopy, flexible, transoral; with endoscopic mucosal resection
- 43270 Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)
- 96570 Photodynamic therapy by endoscopic application of light to ablate abnormal tissue via activation of photosensitive drug(s); first 30 minutes (List separately in addition to code for endoscopy or bronchoscopy procedures of lung and esophagus)
- 96571 Photodynamic therapy by endoscopic application of light to ablate abnormal tissue via activation of photosensitive drug(s); each additional 15 minutes (List separately in addition to code for endoscopy or bronchoscopy procedures of lung and esophagus)
- J9600 Injection, porfimer sodium, 75 mg

**Magnetic sphincter augmentation (MSA) - LINX device:**

**ICD-10 Codes:**

K20.8	Other esophagitis
K20.9	Esophagitis, unspecified
K21.0	Gastro-esophageal reflux disease with esophagitis
K21.9	Gastro-esophageal reflux disease without esophagitis

**CPT/HCPCS Codes:**

*The following procedures are covered only for the gastroesophageal reflux disease (GERD) dx above:*

43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e., magnetic band), including cruroplasty when performed <b>Prior Authorization Required – Not Covered for Priority Health Medicare and Priority Health Medicaid</b>
43285	Removal of esophageal sphincter augmentation device <b>No Prior Authorization</b>

**CPT/HCPCS Codes:**

*The following procedures are not covered:*

43201	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance ( <i>when billed for Gatekeeper™ System, Enteryx™, PMMA beads, Duraspheres or other GERD /BE treatment not listed as covered</i> )
43206	Esophagoscopy, flexible, transoral; with optical endomicroscopy
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed ( <i>when billed for EndoCinch™, Endoscopic Plication™ System</i> )
43229	Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed) ( <i>when billed for cryo or laser ablation techniques</i> )
43236	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance ( <i>when billed for Gatekeeper™ System, Enteryx™, PMMA beads, Duraspheres or other GERD or BE treatment not listed as covered</i> )
43252	Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy
43254	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic mucosal resection
E1399	Durable medical equipment, miscellaneous
L8499	Unlisted procedure for miscellaneous prosthetic services
43289	Unlisted laparoscopy procedure, esophagus
43499	Unlisted procedure, esophagus
43999	Unlisted procedure, stomach

*(Explanatory notes must accompany claims billed with unlisted codes. Not covered if billed for GERD or BE for treatments listed in this policy as non-covered or not listed as covered.)*

## VI. BACKGROUND

Gastroesophageal reflux disease (GERD), also known as reflux esophagitis, is probably the most prevalent clinical condition that arises from the gastrointestinal (GI) tract. There are two principal factors involved in esophageal reflux: (i) the GI contents and (ii) the anti-reflux mechanism, which is comprised of the lower esophageal sphincter (LES) and the anatomic configuration of the gastroesophageal junction. Reflux occurs when the gradient between the LES pressure and the intragastric pressure is compromised as a result of a transient or sustained reduction in the former, or an elevation in the latter. Most patients with GERD have decreased LES pressures. However, some patients have normal LES pressures, but their sphincters relax inappropriately, thus resulting in refluxes.

The initial treatment of GERD is geared toward reducing esophageal refluxes. Antacids, H<sub>2</sub>-receptor antagonists, as well as dietary and lifestyle modifications have been used for such purposes. For patients who fail initial treatment, proton pump inhibitors (e.g., lansoprazole and omeprazole) should be tried. When these standard medical therapies fail, surgery may be considered.

Traditional procedures were designed to raise the pressure within the LES by wrapping a portion or all of the cardia stomach around the esophagus. With the advent of laparoscopic anti-reflux surgery, the two most common procedures are the Nissen fundoplication and the Toupet partial fundoplication. Anti-reflux surgery has been reported to have an efficacy rate of 90%. These operations are usually performed on the same day of hospital admission and take approximately 90 minutes. In general, patients are discharged from the hospital on the second postoperative day and can return to work in 7 to 10 days. Anti-reflux surgery can be associated with complications. The most common complications are dysphagia and an inability to belch or vomit, occurring in 4 to 11% of patients. The ideal candidates for anti-reflux surgery should be young, have typical GERD symptoms (heartburn and regurgitation) with or without a hiatal hernia, have an abnormal ambulatory pH test, have normal esophageal motility studies, and have responded, at least partially, to PPI therapy.

Limitations to the use of fundoplication include the need for surgical expertise, the need for hospitalization and several weeks of postoperative recovery, and the risk of complications and development of new symptoms not present before the surgery. Additionally, many patients treated surgically will need to resume pharmacologic therapy over time as often the surgery does not cure their disease or permanently modify their need for medication use. It is because of the

invasiveness, costs, and inherent risks of surgery that an interest in alternative, endoscopic therapies for GERD, has emerged

Endoscopic, or endoluminal, therapies for GERD are designed to alter structures at the gastroesophageal junction to prevent reflux of gastric contents. Current endoscopic therapies may be classified into three basic categories: (1) radiofrequency energy or radiofrequency thermal ablation; (2) endoscopic or plication suturing; and (3) polymer injection and implantation techniques.

The Stretta® System is an example of radiofrequent (RF) thermal energy delivered to the LES using endoscopically placed needles. RF thermal injury purportedly results in ablation of nerve pathways responsible for tLESRs and/or tissue tightening or remodeling of the gastroesophageal junction due to heat-induced collagen contraction. Thus, RF energy may improve LES compliance and inhibit tLESRs.

Examples of suture plication (gastroplasty) devices are EndoCinch™ (Bard™ Endoscopic Technologies, Billerica, MA) and the Endoscopic Suturing Device® (ESD; Wilson-Cook Medical, Winston-Salem, and NC), also called Sew-Right. These devices sometimes are referred to as miniature or endoscopic “sewing machines.” With this technology, which uses a transoral flexible endoscopic suturing device to create pleats in the gastroesophageal junction, a needle puncture device attached to the endoscope creates pleats through a series of sutures passed by a needle through adjoining proximal fundic folds, thus, providing a barrier to gastric reflux. A third suture plication device, the full-thickness Endoscopic Plication™ System (EPS; NDO Surgical, Inc., Mansfield, MA) has been designed to inhibit gastroesophageal reflux by placing a transmural plication near the gastroesophageal junction under direct endoscopic visualization to enhance the competency of the gastric cardia. The EPS is an enlarged flexible tube that forms a fundic fold fixation with a single pretied suture implant delivered by the instrument, while retroflexed within the stomach and visually monitored through an inserted endoscope. Thus, plication devices may act by restoring the flap mechanism.

The newest plication procedure is The EndoGastric Solutions (EGS) EsophyX™ System with Serofuse™ Fastener is indicated for use in endoluminal, transoral tissue approximation, full thickness plication and ligation in the GI tract and is indicated for the treatment of symptomatic chronic gastroesophageal reflux disease in patients who require and respond to pharmacological therapy. It is also indicated to narrow the gastroesophageal junction and reduce hiatal hernia  $\leq 2$ cm in size in patients with symptomatic chronic gastroesophageal reflux disease.

There are several polymer injection techniques under investigation, including Enteryx™ injection therapy (Boston Scientific Corp., Natick, MA), in which inert polymer material is injected deep into the submucosal zone beneath the LES to form a ring like “bulking” zone to augment sphincter pressure and decrease

tLESRs; the Gatekeeper™ Reflux Repair System (Medtronic, Inc., Minneapolis, MN), which allows endoscopic introduction of an expandable hydrogen prosthesis into the submucosa of the LES zone; and the Plexiglas (polymethylmethacrylate [PMMA]) implantation procedure (Röhm GmbH & Co. KG, Darmstadt, Germany), in which PMMA microspheres are injected endoscopically by needle under high pressure into the submucosa of the proximal LES zone to provide “bulking” support to the sphincter. At this time, neither Gatekeeper nor PMMA are FDA approved.

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