OverStitch

Endoscopic Suturing System

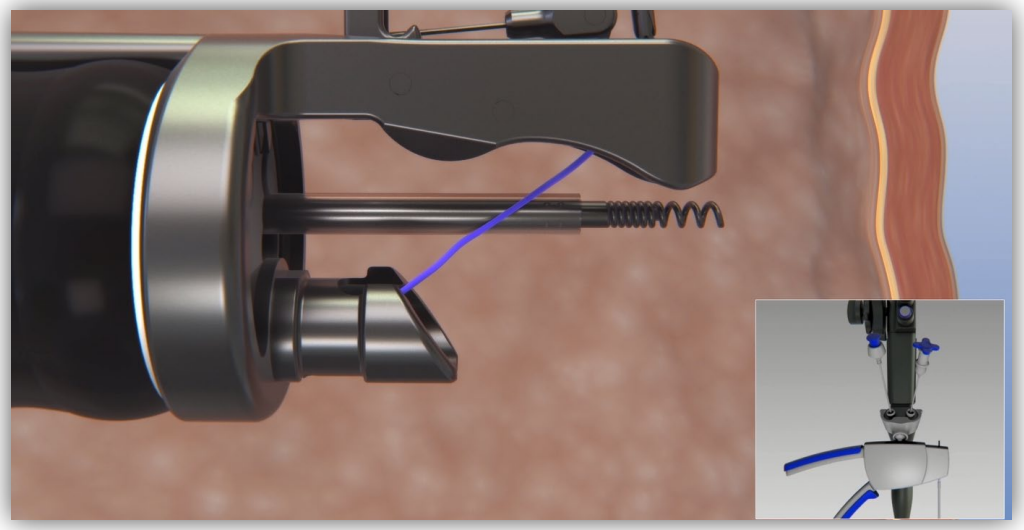
SINGLE-USE INTRALUMINAL CLOSURE SYSTEM FOR GASTROINTESTINAL PROCEDURES

MARCH 9, 2021

ICD-10 Coordination and Maintenance Committee Meeting

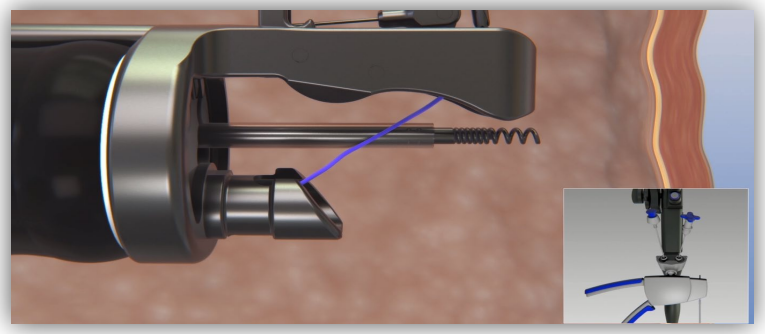
apollo endosurgery

Single Use Intralumenal Closure System for Gastrointestinal Procedures



- ***System for incisionless endolumenal surgical procedures enabling approximation of soft tissue within the gastrointestinal tract and stomach volume reduction***
  - An incisionless alternative to traditional open or laparoscopic surgery
  - Catheter system which deploys anchors and cinches to perform permanent surgical procedure.
  - Enables closure of defects, anastomosis, surgical sites and stent fixation.
  - FDA approvals 2008, 2017
  - FDA *de novo* approval for ESG Weight loss procedure expected 2021

Device and Procedure Description



➢ *Unique Design Features*

- The system comes in two versions:
  - Overstitch for upper and lower endoscopic gastrointestinal tract procedures
  - ESG for the endoluminal sleeve gastroplasty in the stomach and bariatric revision procedures.
- Device attaches to either single and dual channel endoscope for access to and viewing of target surgical site
- Physician operates hand controls outside the body, which operate the mechanical catheter system in the gastrointestinal tract to control and deploy the tissue anchor and cinch.

➢ *Mechanical Endoscopic Surgical system*

- The catheter system which advances the anchor and cinch down the scopes' principal chamber to secure and stabilize the closure process.
- The implanted cinch fixation devices remain permanently within the gastrointestinal tract lumen securing the tissue closure.
- The cinch device is an implant comprised of thermoplastic and stainless-steel materials to maintain suture position in situ and maintain the tension to allow tissue apposition.

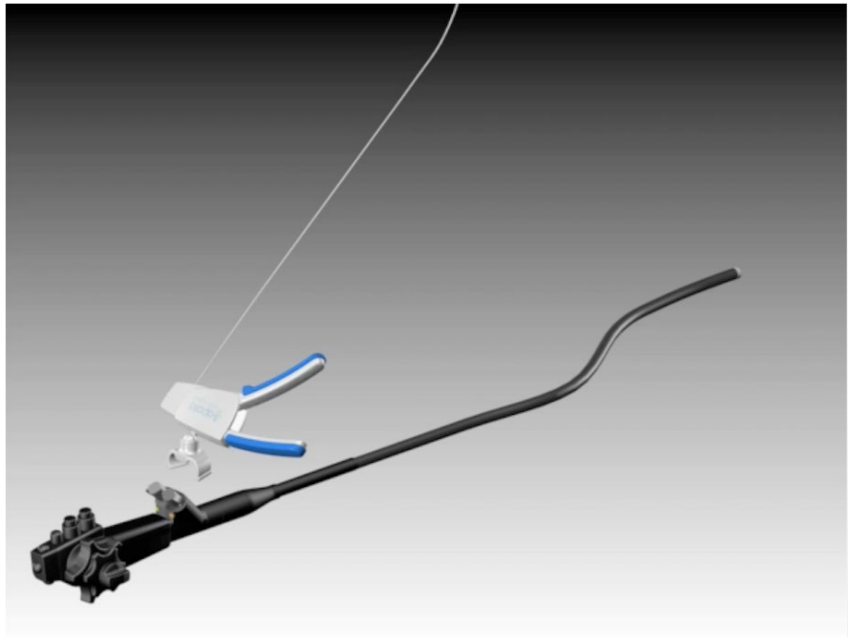
Closure System Key Components

Cinch Implant

Cinch loaded on Anchor Cutting Device

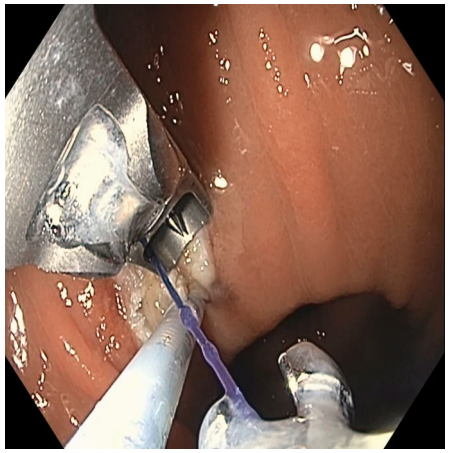
Cinch Handle

Device Use Procedural Steps

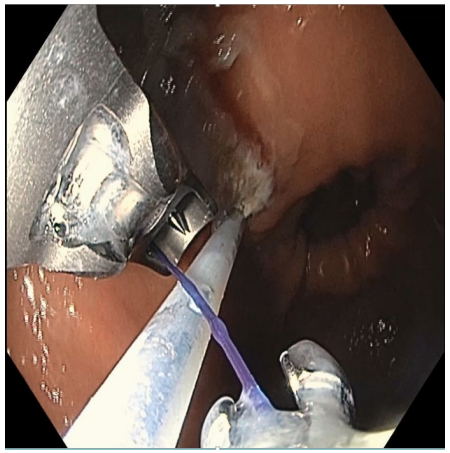


- ***What are the procedural steps involved?***
  - Loading the device onto the endoscope tip
  - Pulling targeted tissue into the device with the Helix tissue retractor
  - Driving the needle arm and needle tissue anchor through the targeted tissues one or more times for closure. Weight loss procedures on the stomach can require 8-10 passes with needle tissue anchor transfers with each pass.
  - Installing the cinch implant within the lumen to maintain tissue apposition at the end of the closure, fixation, or plication cycle.
  - Once the surgery is completed the inserted mechanical catheter system is removed, leaving behind he cinch fixation devices to secure the surgical procedure.
  - The devices are used in both the Inpatient and Outpatient setting.

Full–Thickness Bite Technique

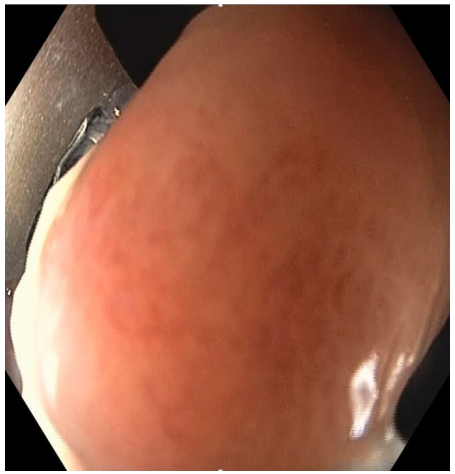


Ensure secure helix engagement: 3-4 full revolutions recommended at targeted suturing site

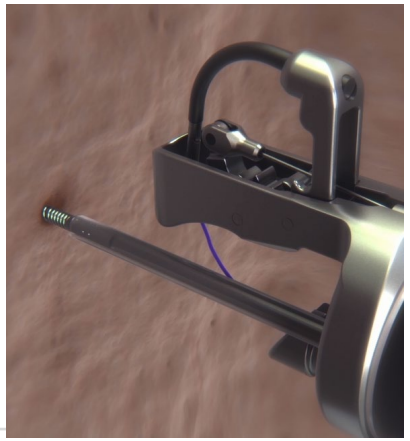


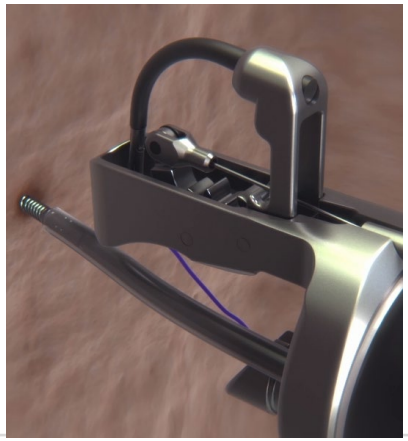
Roll scope left so that the helix is slightly right of the tower

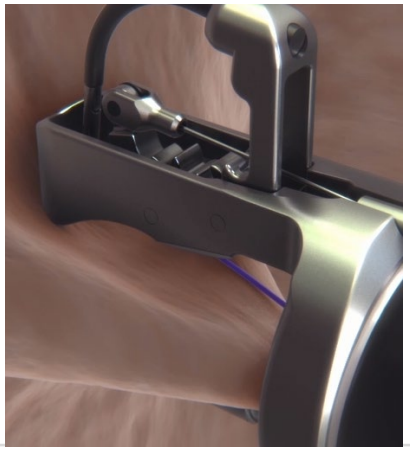
Pull tissue left of the tower



Tissue will pull into camera view. Engage needle driver





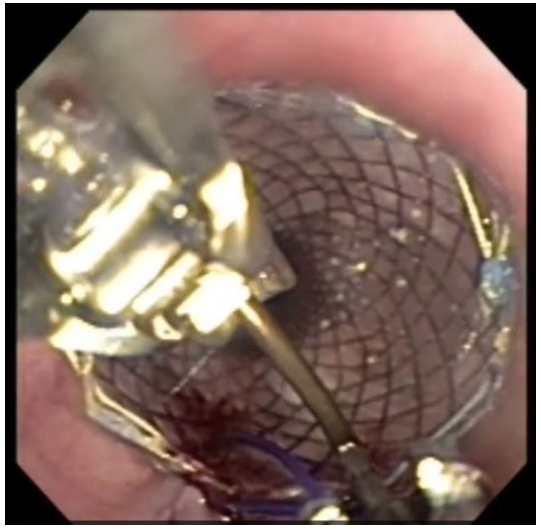


Examples of Indicated Gastrointestinal Applications

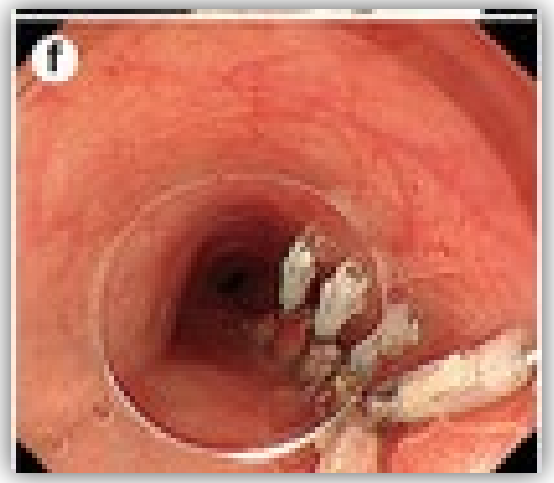
- ***Procedures performed by GI Closure and Fixation System***
  - Upper endoscopy with stent fixation
  - Upper endoscopy with musculoplasty
  - Upper endoscopy with myotomy
  - Upper endoscopy or colonoscopy with closure of mucosal defect for the prevention of bleeding
  - Upper endoscopy or colonoscopy with closure of mucosal defect for the prevention of delayed perforation
  - Upper endoscopy or colonoscopy with closure of acute perforation
  - Upper endoscopy or colonoscopy repair of ulcer for hemostasis
  - Upper endoscopy or colonoscopy with repair of fistula
  - Upper endoscopy or colonoscopy with full thickness resection of neoplasia
- ***Bariatric Weight Loss and Revision procedures performed by ESG System***
  - Upper endoscopy with endoscopic sleeve gastroplasty (restrictive gastroplasty)
  - Upper endoscopy with reduction of dilated gastric pouch (restrictive gastroplasty)
  - Upper endoscopy with repair of anastomosis
  - Upper endoscopy with reduction of dilated sleeve gastrectomy (restrictive gastroplasty)

Examples of Procedures Performed

- ***Endoscopic closure and fixation:***
  - Mucosal defects after polypectomy, mucosal resection, endoscopic submucosal resection
  - Adenomatous polyps; dysplasia in the setting of inflammatory bowel disease; early cancer
  - Full thickness defects after resection of neoplastic lesions
  - Submucosal epithelial tumors; GIST; Leiomyoma; Carcinoid; Schwannoma; metastases
  - Mucosal tunnel entry sites after POEM, G-POEM, and STER
  - Achalsia; gastroparesis; subepithelial tumor
  - Fistulas
  - Perforations
  - Refractory bleeding ulcers
  - Lower esophageal sphincteroplasty for control of acid or non-acid reflux
  - Fixation of self expanding metal stents (fully covered) to prevent migration in the setting of benign refractory strictures, fistulas, and perforations.



Fixation of Stent



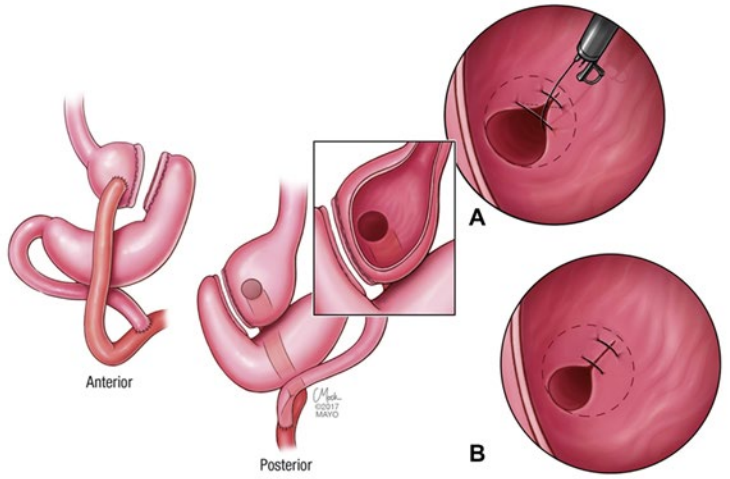
POEM Closure

Endoscopic Sleeve Gastroplasty Procedure Description

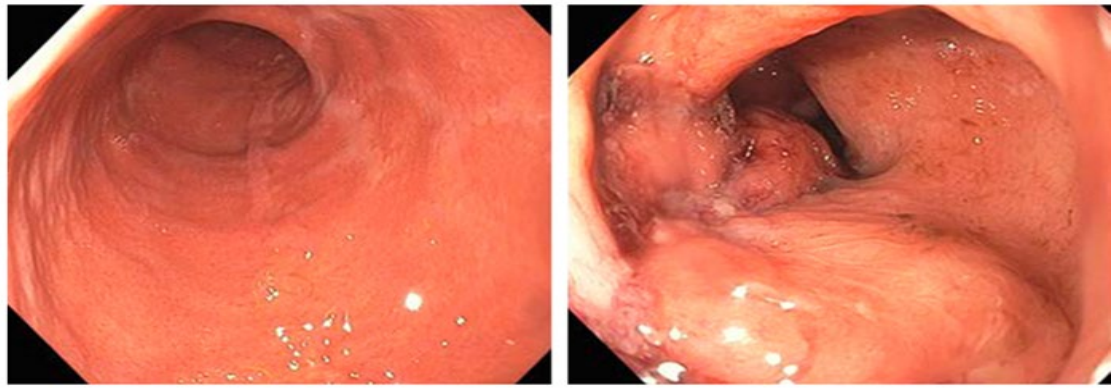
- ***Endoscopic sleeve gastroplasty (ESG) is an oral endolumenal flexible endoscopic incisionless bariatric procedure developed to treat morbid obesity.***
  - Incisionless way to create a restrictive gastric sleeve.
  - ESG reduces the volumetric capacity of the stomach between 70-80%.
  - Accomplished by approximating the anterior and posterior walls and greater curvature of the stomach using a mechanical catheter-based cinch system.
  - Large plications are constructed drawing the stomach walls and greater curve together along the length of the stomach form a gastroplasty with a lumen of 1-2 cm diameter running along the lesser curvature, from the antrum up to but not including the fundus of the stomach.
  - The gastroplasty is similar in shape, but not identical, to a sleeve gastrectomy. The significant difference between the ESG technique and the laparoscopic sleeve gastrectomy (LSG) technique is that the ESG draws the intact stomach in on itself while the LSG technique partitions the stomach into a sleeve from the outside with removal of the excluded stomach.

ESG and Bariatric Revision Procedures

ESG Primary Procedure



Roux-en-Y Gastric Bypass Revision



Laparoscopic Sleeve Gastrectomy Revision

Safety Profile

- ***Have there been any associated complications/sequela/adverse events? If yes, how many and what did they consist of? (E.g. dislodgement, failure, loosening, etc.)***
  - Cinch device malfunction
    - Documented rates of malfunction:
      - Anchor/ cinch deployment 0.10%
      - Anchor / cinch handle breaking during deployment 0.02%
  - Serious adverse events (< 2 %) have been associated with ESG and anastomotic revision after RYGB:
    - Perigastric fluid collection
    - Splenic tear
    - Gastric perforation
    - Pneumoperitoneum
    - Pneumothorax
    - Pneumomediastinum
    - Esophageal perforation

Procedure Documentation

- Fistula Repair, Perforation Repair, Stent fixation, ESG Weight Loss and Bariatric Revision Procedures are standalone procedures.
- Both the Endoscopic Surgical System (OverStitch or ESG), the endoscope, and related procedures would be documented in an endoscopic surgical procedure report.
- These would be formatted into commercial programs such as Provation and linked to the electronic medical record, e.g. Epic.

- The closure and stent fixation procedures are standalone procedures which may be performed as either primary or secondary procedures.

  Example:

  Primary Procedure: Fistulas or Perforation

  Secondary Procedure: Stent Fixation

- ESG Weight Loss and Bariatric Revision Procedures are standalone primary procedures every time.