APOLLO ESG™ System
APOLLO REVISE™ System

Intended Use

The Apollo ESG System is intended to be used by trained gastroenterologists or surgeons that perform bariatric procedures to facilitate weight loss by reducing stomach volume through endoscopic sleeve gastroplasty in adult patients with obesity with BMI between 30-50 kg/m2 who have not been able to lose weight, or maintain weight loss, through more conservative measures. The Apollo REVISE System is intended to be used by trained gastroenterologists or surgeons that perform bariatric procedures to facilitate weight loss in adult patients with obesity with BMI between 30-50 kg/m2 by enabling transoral outlet reduction as a revision to a previous bariatric procedure.

Contraindications

- This System is not for use where endoscopic interventions are contraindicated.
- This System is not for use on malignant tissue.
- Large hiatal hernia.
- Potential bleeding gastric lesions (e.g. ulcers; erosive gastritis; varices; or vascular malformations).
- Affective disorders not under medical supervision or refractory to medical therapy and all eating disorders (e.g. anorexia nervosa; binge eating disorder; specified feeding and eating disorders; avoidant restrictive food intake; rumination).
- Women who are pregnant.
- Coagulopathy and antiplatelet/anticoagulant therapy that cannot be corrected.

Warnings

- Do not use a device where the integrity of the sterile packaging has been compromised or if the device appears damaged.
- Only physicians trained to use OverStitch devices for bariatric procedures should perform the procedures covered in this Instructions for Use.
- Contact of electrosurgical components with other components may result in injury to the patient and/or operator as well as damage to the device and/or endoscope.
- Verify compatibility of endoscopic instruments and accessories and ensure performance is not compromised.
- NOTE: Refurbished scopes may no longer conform to original specifications.
- An overtube device can be used to protect the esophagus. When using an overtube, mount the suturing device onto the scope and verify compatibility with the overtube prior to use. Scope refurbishment may impact compatibility. Thoroughly lubricate the endoscope and overtube prior to use. Never advance or retract the endoscope in an overtube against significant resistance, as this may result in esophageal perforation or laceration.

- Ensure that there is sufficient space in the lumen for the Needle arm to open.
- Ensure that the Handle Grip of the Endoscopic Suturing System is closed and locked during intubation and extubation.
- Reuse or reprocessing of the APOLLO ESG or APOLLO REVISE System components could result in device malfunction or adverse patient consequences, which include:
- Infection or the transmission of disease.
- Failure of the handle mechanism causing the device to become locked onto the tissue, which may require surgical intervention.
- Reduced retention on the endoscope, causing the endcap to detach during use, which may require surgical intervention to retrieve.
- Reduced retention of the anchor to the needle body, resulting in an inadvertent Anchor drop causing procedural delay or requiring subsequent intervention.
- Bending of the needle body, preventing the physician from driving the needle correctly or performing the intended procedure; and/or,
- Failure of the helix to extend fully, limiting the ability to acquire tissue and perform intended procedure.
- If the subject device is used to oversew foreign objects, such as staples, stents, clips, or mesh, it is possible for the needle to become bent, or trapped in the foreign object, requiring surgical intervention for proper removal.
- In situations where the operative site poses a risk of harm to adjacent anatomic structures, use of endoscopic accessories such as the OverStitch Tissue Helix is recommended to retract the tissue intended to be sutured away from these unseen structures.
- It is important to ensure the Tissue Helix is carefully deployed and correctly retracted to avoid entrapping tissue and potentially causing trauma. Avoid using excessive pressure or applying excess turns when deploying the Tissue Helix. Performing more turns than necessary to retract tissue may increase the risk of capturing and suturing an adjacent organ and the risk of the helix entrapping tissue, complicating removal of the instrument.
- Carbon Dioxide (CO2) is required for insufflation. Room air should not be used to insufflate and could contribute to serious adverse events including pneumoperitoneum, pneumothorax, pneumomediastinum, and death.
- Avoid placing plications in the fundus. The fundus is relatively thin walled and located close to the spleen and diaphragm. Sutures placed in the fundus may increase the risks of leakage and inadvertent suturing of the adjacent organs
- Maintain awareness of the potential to disrupt a short gastric artery along the greater curve. Post procedure pain with any hemodynamic instability should immediately raise concern for extra gastric bleeding and/or hematoma formation. Management of this should include imaging, e.g. with CT along with serum hemoglobin measurements.
- When cinching the suture anchor to form the plications, use the minimum tension necessary to maintain the plication. Excessive tension, exceeding 1.1kgf, may increase the risk of gastrointestinal bleeding or creating a leak. Excessive tension may also increase the risk of the suture-anchor breaking and compromising the gastric sleeve. If this occurs, remove the suture and Anchor (if possible).
- Patients who develop significant persistent upper abdominal pain at any time after an ESG, with radiation to the back or supraclavicular area along with pleuritic symptoms or even dyspnea, may have developed a needle puncture site leak with the development of a sterile or infected fluid collection and inflammatory pleural effusion. These symptoms warrant investigation with an imaging study, e.g. CT.

Precautions

- The System may only be used if purchased from Apollo Endosurgery, Inc. or one of its authorized agents.
- With the dual channel OverStitch Endoscopic Suturing System installed, the second available channel is the diagnostic 2.8 mm diameter channel.
- Placing the patient in a supine to modified (semi supine) left lateral decubitus position, creates additional safety margin between the stomach and surrounding structures.
- Take care when using plasma coagulation marking. Perforation could occur while using plasma coagulation and/or coagulated tissue may slough off later, resulting in delayed gastrointestinal bleeding.
- The Tissue Helix must be kept clean from debris during use; this may require periodic debridement of the helix coil during use.
- During a revision procedure, the physician should carefully consider the specific anatomy being revised and the presence of previous devices that may have been placed during the original procedure.

Adverse Events

Adverse events are generally ordered by decreasing anticipated frequency.

- Pharyngitis / Sore throat
- Vomiting
- Nausea
- Moderate abdominal pain more than 24 hours after procedure. In some cases, abdominal pain may be severe and require medical intervention
- Constipation
- Generalized weakness after procedure
- Heartburn
- Fever
- Gastrointestinal bleeding (with or without melena or hematemesis)
- Pharyngitis / Sore throat
- Vomiting
- Dehydration and/or nutritional deficiency requiring hospital admission
- Perigastric fluid collection
- Leak
- Hemoperitoneum
- Hematoma
- Paresthesia
- GERD
- Peritonitis
- Pneumoperitoneum
- Pulmonary Embolism
- Perforation (gastric or esophageal)
- Pneumothorax
- Pneumomediastinum
- Gall bladder suture
- Spleen Laceration
- Deep Vein Thrombosis
- Esophageal tear
- Pleural effusion
- Persistent Vomiting

- Bowel obstruction
- Infection/sepsis
- Bloating
- Stricture
- Liver abscess
- Intra-abdominal (hollow or solid) visceral injury
- Aspiration
- Shortness of breath
- Acute inflammatory tissue reaction
- Death

NOTE: Any serious incident that has occurred in relation to the APOLLO ESG or APOLLO REVISE Systems should be reported to Apollo Endosurgery (see contact information at the end of this document) and any appropriate government entity.