OverStitch™ NXT
Endoscopic Suturing System

Intended Use

The Apollo Endosurgery OverStitch™ NXT Endoscopic Suturing System (ESS) is intended for:

- Endoscopic placement of suture(s) and approximation of soft tissue.
- 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 between30-50 kg/m² who have not been able to lose weight, or maintain weight loss, through more conservative measures.
- 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

Contraindications include those specific to use of an endoscopic suturing system, and any endoscopic procedure, which may include, but not limited to, the following:

- This system is not for use where endoscopic interventions are contraindicated.
- This system is not for use on malignant tissue.

The following contraindications apply to the use of OverStitch for bariatric procedures:

- 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

- Only gastroenterologists or surgeons trained to use OverStitch for bariatric procedures to facilitate weight loss should perform the bariatric procedure covered in the instructions for use.
- Do not use a device where the integrity of the sterile packaging has been compromised or if the device appears damaged.
- Only physicians possessing sufficient skill and experience in similar or the same techniques should perform endoscopic procedures.
- 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 confirm to original specifications.
- Ensure that there is sufficient space for the Needle 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 OverStitch system could result in device malfunction or patient consequences to include:
    - Infection or the transmission of disease
    - Failure of the handle mechanism causing the device to become locked on tissue that may require surgical intervention
    - Reduced retention on the Endoscope, causing the Endcap to detach during use that 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
    - 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 trapped in the foreign body, requiring surgical intervention.
- 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 or NXT Tissue Helix Pro is recommended to retract the tissue intended to be sutured away from these unseen structures.
- It is important to ensure the Tissue Helix and NXT Helix Tissue Helix Pro are 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/NXT Tissue Helix Pro. 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.
- 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 as this region is relatively thin walled and located close to the spleen and diaphragm. Caution/ care should be used when placing plications in the fundus. For ESG procedures, this region should be avoided.
- 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, use the minimum tension necessary. Excessive tension may increase the risk of gastrointestinal bleeding or creating a leak. Excessive tension, exceeding 1.1kgf, may also increase the risk of the suture- anchor breaking. If this occurs, remove the suture and Anchor (if possible).
- Patients who develop significant persistent upper abdominal pain at any time after a procedure involving OverStitch, with radiation to the back or supraclavicular area along with pleuritic symptom 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.
- 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.

Precautions

- The System may only be used if purchased from Apollo Endosurgery, Inc. or one of its authorized agents.
- With the Endoscopic Suturing System installed, the endoscope's effective outer diameter is increased by approximately 7 mm.
- An overtube with an internal diameter of at least 17.5 mm may be used with the system to protect the esophagus.

For Bariatric Procedures:

- 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 couldoccur while using plasma coagulation and/or coagulated tissue may slough off later, resulting in delayed gastrointestinal bleeding.
- The Tissue Helix or NXT Tissue Helix Pro 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

Possible complications that may result from using the Endoscopic Suturing System include, but may not be limited to:

- Acute inflammatory tissue reaction
- Aspiration
- Bloating
- Bowel obstruction
- Conversion to laparoscopic or open procedure
- Constipation
- Death
- Deep Vein Thrombosis
- Dehydration and/or nutritional deficiency requiring hospital admission (Specific to Bariatric Procedures)
- Fever
- Gall bladder suture
- Gastrointestinal bleeding (with or without melena or hematemesis)
- Generalized weakness after procedure
- GERD
- Heartburn
- Hematoma
- Hemoperitoneum
- Hemorrhage
- Infection/sepsis
- Intra-abdominal (hollow or solid) visceral injury
- Laceration of the gastrointestinal tract
- Leak
- Liver abscess
- Moderate abdominal pain more than 24 hours after procedure. In some cases, abdominal pain may be severe and require medical intervention
- Nausea and / or Persistent Vomiting
- Paresthesia
- Perforation of the gastrointestinal tract
- Perigastric fluid collection
- Peritonitis
- Pharyngitis / Sore throat
- Pleural effusion
- Pneumomediastinum
- Pneumoperitoneum
- Pneumothorax
- Pulmonary Embolism
- Shortness of breath
- Spleen Laceration
- Stricture

MR Conditional

Non-clinical testing has demonstrated that the Sutures, Cinches and Anchors (collectively termed Anchoring System) deployed by the OverStitch Endoscopic Suturing System are MR Conditional. A patient with this Anchoring System can be safely scanned immediately after placement in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T or 3.0 T
- Maximum spatial field gradient of 2,000 gauss/cm (20 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg

Under the scan conditions defined above, the Anchoring System is expected to produce a maximum temperature rise of less than 2°C after 15 minutes of continuous scanning.
In non-clinical testing, the image artifact caused by the Anchoring System extends approximately 10 mm from this device when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

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

As a condition of the FDA De Novo Authorization of the Overstitch NXT and Overstitch Endoscopic Suturing System for endobariatric procedures (formerly referred to as the Apollo ESG and Apollo REVISE Systems), the devices should only be used for Endoscopic Sleeve Gastroplasty (ESG) or to enable transoral outlet reduction (TORe) as a bariatric revision procedure by gastroenterologists and surgeons who have undergone specific training by the device manufacturer.

To fulfill the FDA requirement and special controls for these devices, Boston Scientific is required to independently host courses with consistent training curricula. More information regarding the referenced ESG and TORe revision procedure training courses is available through Boston Scientific