OverStitch Sx™
Endoscopic Suturing System ESS

Intended Use
The Apollo Endosurgery OverStitch Sx™ Endoscopic Suture System (ESS) is intended for endoscopic placement of suture(s) and approximation of soft tissue.

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 techniques are contraindicated.
- This system is not for use with malignant tissue.

Warnings
- 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 endoscope size, endoscopic instruments and accessories and ensure performance is not compromised.
- Ensure endoscope is clean, dry, and free of lubricants prior to device installation.
- OverStitch Sx is recommended to be used in combination with an overtube having an inner diameter of at least 16.7 mm.
- 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, and Actuation Catheter slack removed, during intubation and extubation.
- Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing Synthetic Absorbable Sutures for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.
- 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.
- If 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.
- 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 device 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

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 5 mm.

Adverse Events

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

- Pharyngitis / Sore throat
- Nausea and / or Vomiting
- Abdominal pain and / or Bloating
- Hemorrhage
- Hematoma
- Conversion to laparoscopic or open procedure
- Stricture
- Infection / Sepsis
- Pharyngeal, colonic and/or esophageal perforation
- Esophageal, colonic and/or pharyngeal laceration
- Intra-abdominal (hollow or solid) visceral injury
- Aspiration
- Wound dehiscence
- Acute inflammatory tissue reaction
- Death

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.