X-Tack™ Endoscopic
HeliX Tacking System

Intended Use

The X-Tack™ System is intended for approximation of soft tissue in minimally invasive gastroenterology procedures (e.g. closure and healing of ESD/EMR sites, and closing of fistula, perforation or leaks). The X-Tack™ System is not intended for hemostasis of acute bleeding ulcers.

Contraindications

Contraindications include those specific to use of an endoscopic tacking 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

- The device should not be used to treat acutely bleeding ulcers, ulcers with stigmata of recent bleeding or any ulcers with a visible vessel.
- X-Tack utilizes a 3-0 polypropylene suture with a nominal tensile force of approximately 1.5 lb. If the force applied to the suture exceeds that, the suture may break. If the suture breaks, cut the suture using endoscopic scissors and leave the deployed Helix Tacks in place. Closure can be performed using another X-Tack device or an alternative closure device.
- If a Helix Tack is not fully embedded into the muscle layer, it may be pulled free from the tissue when tension is applied to the suture. If this happens, continue to place the remaining Helix Tacks and then cinch in the usual procedure. Evaluate the integrity of the closure. If needed, supplemental fixation may be applied using another X-Tack device or an alternative device.
- Do not retract the X-Tack device into or through the scope while a Helix Tack is present on the distal end. This can prematurely disengage the Helix Tack from the coil catheter. If this does happen, withdraw the X-Tack and continue with the next Helix Tack. Complete the closure in the normal process with the remaining Helix Tacks embedded in the tissue. The detached Helix Tack will be on the suture but not contributing to the closure. Evaluate the integrity of the closure. If needed, supplemental fixation may be applied using another X-Tack device or an alternative device.
- If a Helix Tack disengages while in the scope and becomes stuck in the channel liner, first try to push the tack down the channel with the coil catheter. If this cannot be done, remove the X-Tack catheter and channel liner, leaving the suture in place. Cinch the construct if Helix Tacks have already been placed in tissue. Evaluate the integrity of the closure. If needed, supplemental fixation may be applied using another X-Tack device or an alternative device.

- 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.
- Ensure all endoscopic scopes, including scope channels, are in good working condition prior to use.
- Suction operation through endoscope may be significantly reduced when the scope channel liner is in proper position.
- Do not advance or retract the X-Tack device through a retroflexed scope (a scope that is curved more than 180 degrees). This can damage the device and/or the endoscope. If there is excessive resistance to moving the device through the scope, reduce the curvature in the scope (tortuosity) before proceeding. This should reduce resistance.
- Applying excessive force to the distal end of the X-Tack™ device could compress or damage the HeliX Tack when installed.
- Do not retract device into scope whilst a HeliX Tack is installed.
- Reuse or reprocessing of the X-Tack™ System could result in device malfunction, patient infection or the transmission of disease.

Precautions

- The system may only be used if purchased from Apollo Endosurgery, Inc. or one of its authorized agents.

Adverse Events

Possible complications that may result from using the X-Tack™ System include, but may not be limited to:

- Pharyngitis / Sore throat
- Nausea and / or Vomiting
- Abdominal pain and / or Bloating
- Pericardial tamponade
- Delayed bleeding
- Hemorrhage
- Hematoma
- Conversion to laparoscopic or open procedure
- Stricture
- Inflammation
- Infection / Sepsis
- Pharyngeal, gastric, colonic and/or esophageal perforation
- Esophageal, gastric, colonic and/or pharyngeal laceration
- Intra-abdominal (hollow or solid) visceral injury
- Pancreatitis
- 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.