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. Doing so may cause patient injury.
- 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. Helix Tacks not fully embedded may be pulled free and cause patient injury.
- 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. Ineffective closure may cause patient injury.

- 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. Ineffective closure may cause patient injury.

- 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.

- Contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.

- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

- Verify position of HeliX Tack before driving fully into tissue. Features on the HeliX Tack, used to resist back-out after surgery, may catch tissue and complicate repositioning after the Helix is driven fully into tissue.

- If tack is fully seated, attempting to disengage may result in patient injury.

- Excessive tension may pull out HeliX Tacks or break Suture.

Precautions

- 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.

- Ensure all endoscopes, 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.

- Federal Law (USA) restricts this device to sale by or on the order of a physician.

- Ensure biopsy valve is OPEN and scope is not retroflexed. Do not kink the catheter during insertion as this might compromise control of the HeliX Tack.

- If the Scope Liner funnel is not fully seated against the biopsy cap, the full length of the scope working channel may not be covered. This can damage the device and/or the endoscope.

- Do not retract device catheter from the working channel whilst a HeliX Tack is installed; this could lead to device damage or inadvertent detachment.

- Manual rotation after the tack is fully seated increases the risk that the HeliX Tack may skip on the driver and impact performance.

- Visually verify that HeliX Tack is installed to device. If Helix appears not fully seated carefully hold Helix between thumb and index finger and insert distal end of device into the HeliX Tack until a ‘pop’ is felt.

- The safety spacer must only be removed immediately prior to deploying Cinch in order to avoid inadvertent suture cutting.

- Suture tension must be maintained during Cinch deployment.

Adverse Events

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

- Pain

- Delayed bleeding

- Hemorrhage
- Conversion to laparoscopic or open procedure
- Stricture
- Inflammation
- Infection / Sepsis
- Perforation
- Laceration
- Aspiration
- Wound dehiscence
- Acute inflammatory tissue reaction
- Death
- Erosion
- Migration
- Tissue Damage