X-Tack Endoscopic HeliX Tacking System:
The Through-the-Scope Closure System That Offers the Precision of Suturing and Addresses the Challenges of TTS Clips and OTSC Devices

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The endoscopic removal of foregut and colorectal neoplasia carries up to 2.2% risk of perforation and up to 8.4% risk of delayed bleeding (1,2,19). These two serious adverse events often result in additional endoscopic as well as surgical interventions, hospitalizations, expanded health care costs, and significant distress for both patients and their physicians. Additionally, with the aging U.S. population, there is an increasing number of individuals taking anti-thrombotic medications who are recognized to be at increased risk for bleeding after mucosal resection procedures such as polypectomy (3). Bleeding and perforation may occur during the removal of a mucosal lesion or in a delayed fashion post-procedure. Risk factors for these adverse events have been identified in the clinical literature (4-12). The use of prophylactic closure of resection site defects has been reported to significantly reduce the incidence of these two adverse events and has generated strong advocacy among treating physicians (13-16).

Mucosal neoplasia can be removed using a variety of methods, most of which involve electrosurgical energy for both cutting and coagulation of tissue (17). This is accomplished using a snare or electrosurgical knife. Depending on the size, shape, and location of the lesion, targeted tissue is removed as a single resected specimen or in several pieces during either polypectomy, endoscopic mucosal resection (EMR), or endoscopic submucosal dissection (ESD). All these methods leave a defect which extends through the submucosal layer of the gut wall near the thin muscle layer. As a result of tissue removal, considerations for prophylactic closure include:

- **The base and margins of the defect contains exposed arterial blood vessels that predispose to acute or delayed bleeding, or the resection size is very large leading to increased risk of hemorrhage.**
- **The muscle layer is inadvertently damaged by thermal injury which will result in delayed perforation.**
- **The resection involved accidental or intentional full-thickness tissue resection resulting in a perforation of the bowel wall and requires immediate endoscopic closure or surgical repair.**

The Apollo Endosurgery X-Tack™ Endoscopic HeliX Tacking 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). X-Tack is not intended for hemostasis of acute bleeding ulcers. For X-Tack safety information reference IFU PN# GRF-00538-00 https://apolloendo.com/dfus/
Prophylactic closure of mucosal resection site defects can be accomplished by means of applying Through-the-Scope (TTS) metallic (hemostatic) clips, Over-the-Scope (OTSC) large metallic clips, or endoscopic suturing. Each of these closure methods have limitations which lend themselves to selective use:

- **TTS-** superficial mucosal capture; limited defect diameter and shape; high rate of failed individual clip application; multiple clips required for acceptable closure.

- **OTSC-** 2 cm maximal defect limitation; precise placement necessary; the gastroscope or colonoscope must be removed from the patient in order to mount the device; placing multiple end-to-end implants to close a larger defect is technically challenging; removal can be challenging.

- **Suturing-** requires use of a gastroscope, limiting access to proximal colon; the gastroscope or colonoscope must be removed from the patient in order to mount the device; physician access to endoscopic suturing skill set is limited (18).

The X-Tack closure device is designed to resolve the aforementioned limitations of TTS clips, OTSC and endoscopic suturing by offering functionality through the working channel of any standard gastroscope or colonoscope with precise HeliX Tack placement and tight closure of defects of varying shapes and sizes. X-Tack is not designed to treat acutely bleeding ulcers, ulcers with stigmata or any ulcers with a visible vessel.

Designed for compatibility with market-leading gastroscopes and colonoscopes, X-Tack can be implanted using any working channel of at least 2.8mm diameter (Figure 1a). Therefore, physicians will have on-demand access to the benefits of through-the-scope, suture-based fixation during their upper or lower gastrointestinal therapeutic procedures. Furthermore, the X-Tack System eliminates the need to withdraw the scope from the patient prior to applying therapy.

The X-Tack device enables physicians to place four (4), individual HeliX Tacks into healthy tissue adjacent to a defect using a novel Persian drill handle (Figure 1b). The HeliX Tack design includes barbs on the coil for enhanced tack fixation. The tip of the implant is in line with the pitch of the coil and does not have a protruding point. Additionally, the length of the implant is designed to reach a depth permitting entry into but not through the muscularis propria (Figure 1c). Each HeliX Tack is tethered with a single polypropylene suture (Figure 2). Pulling tension on the suture approximates the HeliX Tacks and, in turn, closes the tissue defect. A suture cinch is then used as the final step to secure the suture in place (Figure 3). Because it offers multiple points of fixation, the X-Tack enhances a physician’s ability to overcome challenges of closing large or irregularly shaped defects.
Figure 1.

a) X-Tack Device

- Push Catheter
- HeliX Tack
- Polypropylene Suture

b) Handle

- Persian Drill
- Handle Slider
- Push Catheter

c) HeliX Tack

- Flat Driving Tip
- Rotating Eyelet
- Barbs

Measurements:
- 1.5mm
- 3.5mm
- 2mm
HeliX Tacks are placed into the bowel wall 5-10mm from the margin of a defect. Applying forward pressure on the X-Tack catheter and pulling the Handle Slider rotates the driver and engages the attached HeliX Tack into tissue. (Figure 4 a,b)

At this stage, if initial placement is less than desirable, the HeliX Tack is designed to be reversed out of the tissue and repositioned. Once the first Helix Tack is fully embedded, it is deployed using the Push Catheter at the handle (Figure 4 c,d). The deployment catheter is then withdrawn from the endoscope, and the second HeliX Tack is loaded onto the catheter tip. With tension on the suture running alongside the catheter, the HeliX Tack is positioned at the second desired location for placement (Figure 5). After the second Helix Tack is placed, the suture is tensioned to approximate the HeliX Tacks and in turn begin defect closure. Next, the second HeliX Tack is deployed, and the technique is repeated for all remaining HeliX Tacks. After the fourth and final HeliX Tack is placed and the edges of the defect have been drawn together, the X-Tack catheter and scope liner are removed. The suture is loaded into the cinching device, and the cinch is then advanced over the suture through the scope channel. Final suture tension is applied, and the cinch is deployed to lock the construct and cut the suture (Figure 6).
**Figure 4: HeliX Tack Placement and Deployment**

a) Tissue targeted 5-10mm from defect margin

b) HeliX Tack placement is initiated by pulling Handle Slider

c) HeliX Tack is placed at full depth

d) Push Catheter is advanced to deploy HeliX Tack
Figure 5: Second HeliX Tack Placement

Figure 6: Suture cinch
This novel closure device underwent a robust development program beginning with computer simulation efforts to a final rigorous animal study performed at the Mayo Clinic Developmental Endoscopy Research Unit. Devices were tested in multiple acute and survival studies (1, 2 and 4 week), initially in the stomach and then in the porcine rectosigmoid colon. Gastric closure sites included 2 cm full thickness excision closures. Gastric closures, both mucosal defects and full thickness defects, were monitored by laparoscopy, chiefly to identify inadvertent capture of surrounding organs or structures and secure full thickness closures. The outcomes of these studies allowed for refinement of the HeliX Tack design, placement and cinching techniques, identification of the average number of HeliX Tacks needed for closure of 2-4 cm defects, and limitations for closure of full thickness defects. The final Mayo Clinic run 4-week porcine survival study involved closure of mucosal defects up to 5 cm in both the stomach (Figure 7) and rectosigmoid (distal 30 cm to within 5 cm of the anus) using the production version of the X-Tack system.

With the standard four (4) HeliX Tacks included in the X-Tack system, most of the defects in this study were reliably closed with one device. A few larger sites required a second adjacent device, but closure was achieved easily and successfully.

Additionally, a 5 mm perforation occurred in the rectosigmoid during the creation of a defect. This was closed using the X-Tack device without any sequelae. The subsequent necropsy after 4 weeks demonstrated healing without evidence of any peri-colonic inflammation or abscess (Figure 8).

In this final Mayo Clinic study, the X-Tack device was compared to a TTS clip (Resolution Clip, Boston Scientific Corporation, Natick MA). The X-Tack system was used for successful closure of all the intended 2-5 cm mucosal defects, while technical closure of large and irregular defects was challenging with clips [Table 1]. Histological evaluation was performed to analyze all defect sites at one month. The results, from both gastric and rectosigmoid sites, were consistent with complete mucosal healing.

Technical closure with X-Tack was overall successful in 24/24 (100%). Technical closure with clips was successful in 13/16 (81.3%) [Table 1]. Two clip failures involved gastric defects of 3.3 cm and 4.2 cm where 6 and 7 clips were attempted, respectively. Failure was attributed to size and shape of the defects. In both cases, successful salvage closure with X-Tack was performed. An additional TTS clip site (2.4 cm) required assistance apposing the edges using an alligator forceps through the second accessory channel to close the site successfully.
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<thead>
<tr>
<th>Gastric Closures</th>
<th>Rectosigmoid Closures</th>
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<tbody>
<tr>
<td>24 resection sites (16 X-Tack, 8 TTS Clips)</td>
<td>16 resection sites (8 X-Tack, 8 TTS Clips)</td>
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<tr>
<td>Closure times: X-Tack = 7.69 minutes (range 5.2-11.12), TTS Clips = 5.04 minutes (range 1.25 – 12.45)</td>
<td>Closure times: X-Tack = 6.59 minutes (range 4.18-9.0), TTS Clips = 2.21 minutes (range 1.1 – 3.55)</td>
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<tr>
<th>X-Tack</th>
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<tr>
<td>HeliX Tacks placed 0.5cm from resection margins</td>
<td>Largest lesion (5.0cm diameter) closed with 7 HeliX Tacks (two X-Tack devices)</td>
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<tr>
<td>Overall technical closure success rate = 100%</td>
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<tr>
<td>Successful closure = 16/16 (100%). 2 sites required additional accommodations, but were closed successfully without the use of an alternative device(s):</td>
<td>Successful closure = 8/8 (100%)</td>
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<tr>
<td>• 2.8cm site – one helix was damaged and replaced for a successful closure</td>
<td>• 5mm full thickness resection perforation was closed successfully with a single X-Tack device</td>
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<td>• 3.1cm site – HeliX Tacks placed in tissue edema, operator did not advance completely. Second device was placed successfully</td>
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<th>TTS Clips</th>
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<tr>
<td>Successful closure = 5/8 (63%). 3 sites required additional operative accommodations:</td>
<td>Successful closure = 8/8 (100%)</td>
</tr>
<tr>
<td>• 2.4cm - needed dual channel scope for graspers; 8 clips deployed</td>
<td>TTS Clip closures in the colon required 3 – 4 clips (average 3.75)</td>
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<tr>
<td>• 3.3cm site failed - needed dual channel scope for graspers; 6 clips deployed; closed with X-Tack successfully</td>
<td></td>
</tr>
<tr>
<td>• 4.2cm site failed – needed dual channel scope for graspers; 7 clips deployed; closed with X-Tack successfully</td>
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<td>TTS Clip closures in the stomach required 3 – 8 clips (average 4.3)</td>
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*Data submitted to FDA for 510K clearance*
**Figure 7.**

a) Porcine gastric mucosal resection (3 cm) closure

b) First HeliX Tack placed

c) Second HeliX Tack placed across from first HeliX Tack

d) Closed defect after 4 HeliX Tacks placed and cinched

**Figure 8.**

a) Acute colonic perforation during EMR

b) EMR completed (25 mm) and site with perforation closed using 4 HeliX Tacks

c) Site healed at 4 weeks.
The TTS clip is limited by the width of the jaws of the opened clip and the amount of tissue-edge opposing force that can be generated from a “pinching” mechanism. Orientation, despite rotational capability of TTS clips, is challenged by access to a defect. Access can be compromised by surface irregularity, angle of approach, configuration of a defect, and finally, defect width. The total number of clips needed to close a defect is unpredictable and may be dependent on defect size, shape, location, and clip misplacement. Limitations caused by access and numbers of clips needed to close any size lesion are eliminated by the accuracy of HeliX Tack placement along the edges of a defect, regardless of width, shape, and comparable size. The rate of complete (Stage IV Mayo scoring system) defect healing up to 3 cm is comparable between the TTS clip closure and X-Tack closure (Figure 9). This study demonstrated that X-Tack closures achieve expected levels of tissue healing when compared to the standard of care and provided physicians with a more efficient option for closure, especially for larger or irregularly shaped resections.

**Figure 9. Stage IV Mayo Scoring System**

The X-Tack Endoscopic HeliX Tacking System meets the needs for simple direct defect closures of high risk resection sites without removing the endoscope from the patient, which may be especially important in the colon. In the colon, high risk defects include polyps > 1 cm, resection location proximal to the splenic flexure, and patients who take blood thinning and antiplatelet medications. Most importantly, the X-Tack system is a simple addition to the endoscopy toolbox and may be applied without the need for special endoscopes and requires only simple training to achieve competence in use of the device for the benefit of patients and their treating physicians.

**Conclusion**

What are the advantages of X-Tack?
References:


