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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Introduction

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/

MKT-01441-00R01

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.

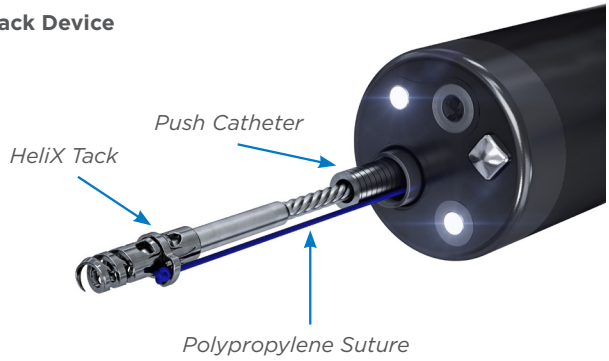
X-Tack Device Overview

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.

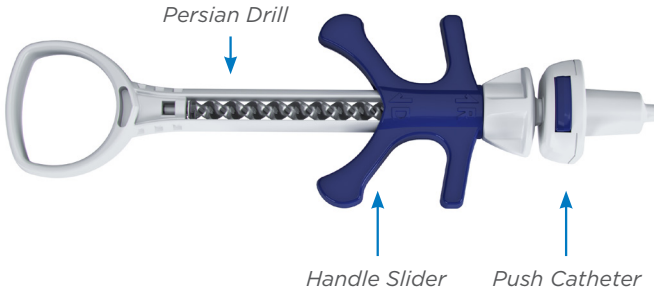
The X-Tack device enables physicians to place four (4), individual HeliX Tacks into healthy tissue adjacent to a defect using a novel Persian drill handle (Figure 1b). The HeliX Tack design includes barbs on the coil for enhanced tack fixation. The tip of the implant is in line with the pitch of the 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



b) Handle



c) HeliX Tack

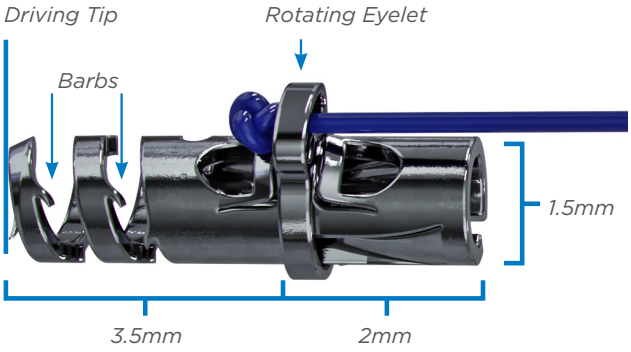


Figure 2. X-Tack HeliX Tacks Placed Around Defect

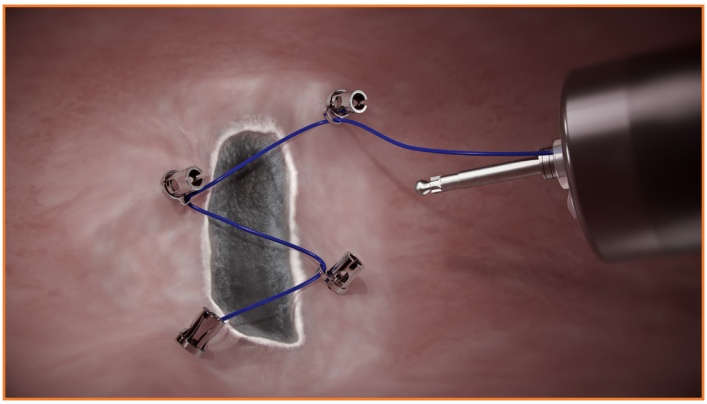
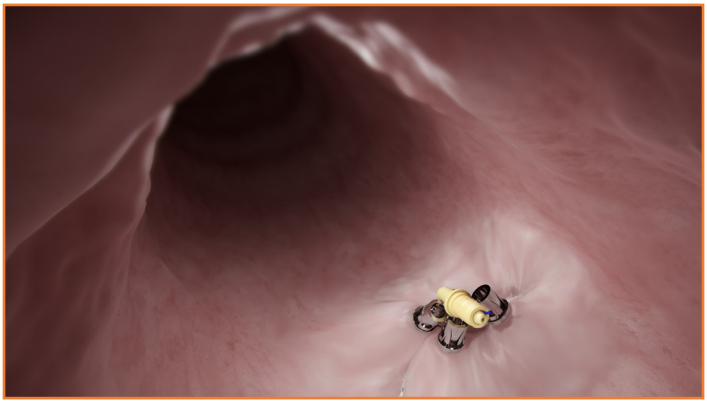


Figure 3: X-Tack Closure

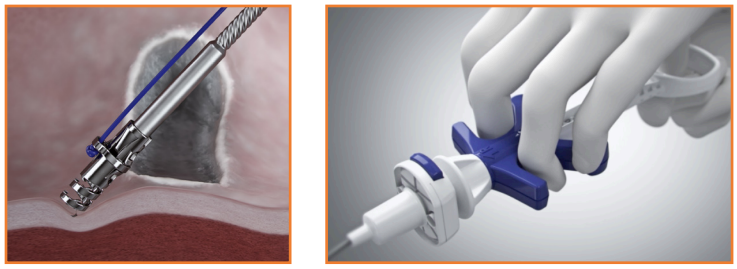


X-Tack Procedural Overview

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).

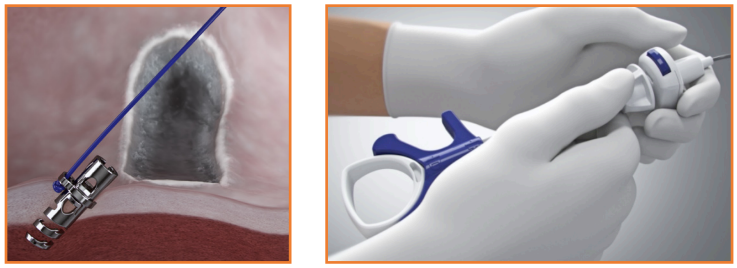
Figure 4: HeliX Tack Placement and Deployment



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

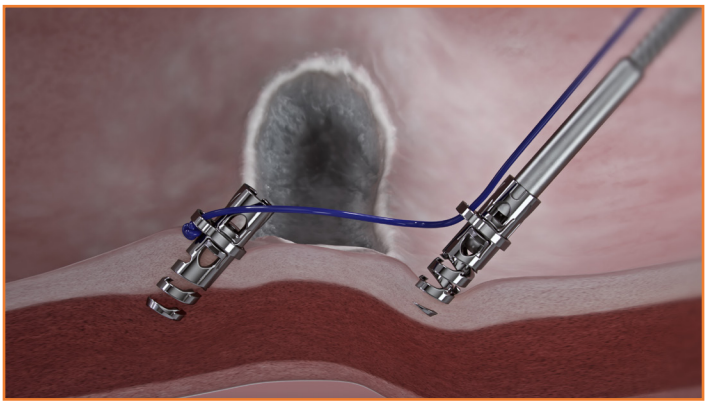
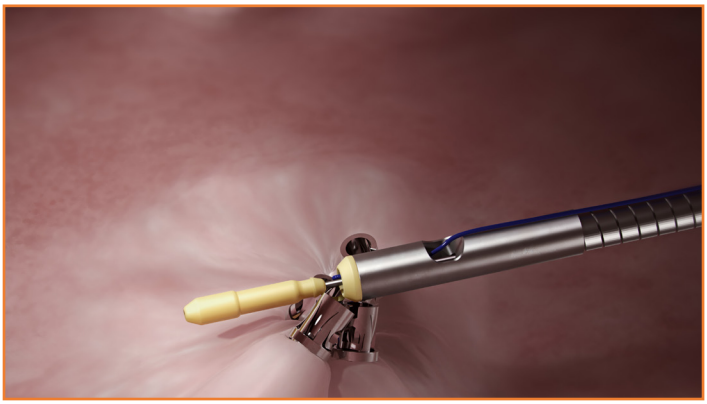
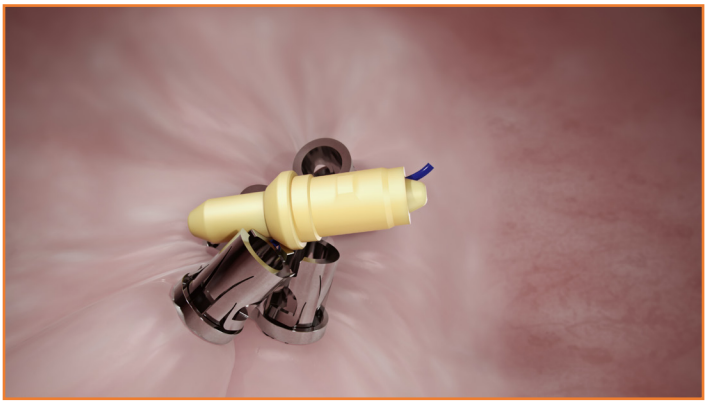


Figure 6: Suture cinch





X-Tack Development and Pre-Clinical Animal Testing

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 3.3cm and 4.2cm 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 (2.4cm) required assistance apposing the edges using an alligator forceps through the second accessory channel to close the site successfully.

Table 1. X-Tack Survival Study Data and Procedural Summary*

Gastric Closures	Rectosigmoid Closures
24 resection sites (16 X-Tack, 8 TTS Clips)	16 resection sites (8 X-Tack, 8 TTS Clips
Closure times: X-Tack = 7.69 minutes (range 5.2-11.12), TTS Clips = 5.04 minutes (range 1.25 – 12.45)	Closure times: X-Tack = 6.59 minutes (range 4.18-9.0), TTS Clips = 2.21 minutes (range 1.1 – 3.55)
X-Tack	**X-Tack**
HeliX Tacks placed 0.5cm from resection margins Overall technical closure success rate = 100% Successful closure = 16/16 (100%). 2 sites required additional accommodations, but were closed successfully without the use of an alternative device(s): • 2.8cm site – one helix was damaged and replaced for a successful closure • 3.1cm site – HeliX Tacks placed in tissue edema, operator did not advance completely. Second device was placed successfully	Largest lesion (5.0cm diameter) closed with 7 HeliX Tacks (two X-Tack devices) Overall technical closure success rate = 100% Successful closure = 8/8 (100%) • 5mm full thickness resection perforation was closed successfully with a single X-Tack device
TTS Clips	**TTS Clips**
Successful closure = 5/8 (63%). 3 sites required additional operative accommodations: • 2.4cm - needed dual channel scope for graspers; 8 clips deployed • 3.3cm site failed - needed dual channel scope for graspers; 6 clips deployed; closed with X-Tack successfully • 4.2cm site failed – needed dual channel scope for graspers; 7 clips deployed; closed with X-Tack successfully TTS Clip closures in the stomach required 3 – 8 clips (average 4.3)	Successful closure = 8/8 (100%) TTS Clip closures in the colon required 3 – 4 clips (average 3.75)

**Data submitted to FDA for 510K clearance*

Figure 7.

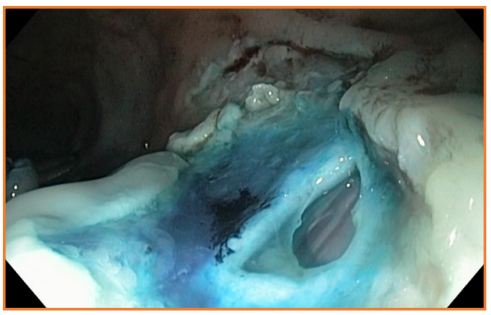
a) Porcine gastric mucosal resection (3 cm) closure

b) First HeliX Tack placed

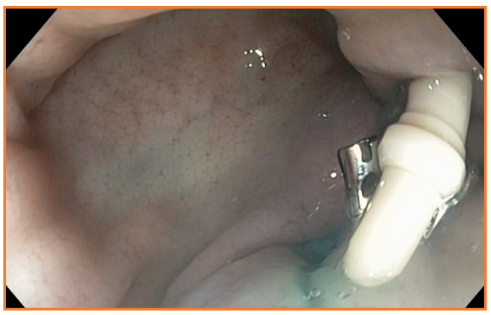
c) Second HeliX Tack placed across from first HeliX Tack

d) Closed defect after 4 HeliX Tacks placed and cinched

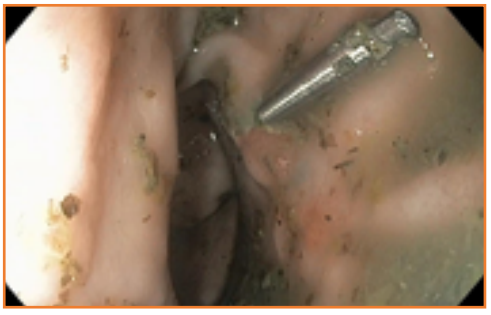
Figure 8.



a) Acute colonic perforation during EMR



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

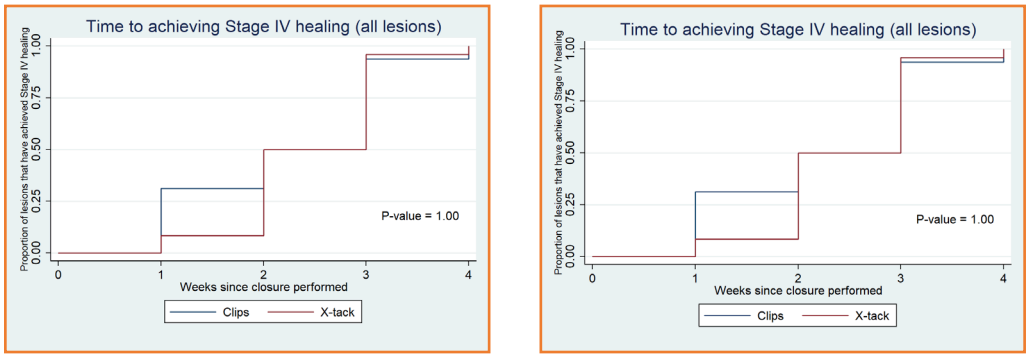


c) Site healed at 4 weeks.

What are the advantages of X-Tack?

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



Conclusion

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.

References:

1. Chukmaitov A, Bradley CJ, Dahman B, et al. Association of polypectomy techniques, endoscopist volume, and facility type with colonoscopy complications. Gastrointest Endosc. 2013 Mar;77(3):436-46.

2. Reumkens A, Rondagh EJ, Bakker CM, et al. Post-Colonoscopy Complications: A Systematic Review, Time Trends, and Meta-Analysis of Population-Based Studies. Am J Gastroenterol. 2016 Aug;111(8):1092-101

3. ASGE Standard of Practice Committee, Anderson MA, Ben-Menachem T, et al. Management of antithrombotic agents for endoscopic procedures. Gastrointest Endosc 2009;70:1060–1070.

4. Heldwein W, Dollhopf M, Rosch T, et al. The Munich Polypectomy Study (MUPS): prospective analysis of complications and risk factors in 4000 colonic snare polypectomies. Endoscopy 2005; 37:1116–1122.

5. Sawhney MS, Salfiti N, Nelson DB, et al. Risk factors for severe delayed postpolypectomy bleeding. Endoscopy 2008;40:115–119.

6. Buddingh KT, Herngreen T, Haringsma J, et al. Location in the right hemi-colon is an independent risk factor for delayed post-polypectomy hemorrhage: a multi-center case-control study. Am J Gastroenterol 2011; 106:1119–1124.

7. Qumseya BJ, Wolfsen C, Wang Y, et al. Factors associated with increased bleeding post endoscopic mucosal resection. J Dig Dis 2013;14:140–146.

8. Burgess NG, Metz AJ, Williams SJ, et al. Risk factors for intraprocedural and clinically significant delayed bleeding after wide-field endoscopic mucosal resection of large colonic lesions. Clin Gastroenterol Hepatol 2014; 12:651–661.

9. Albeniz E, Fraile M, Ibanez B, et al. A scoring system to determine risk of delayed bleeding after endoscopic mucosal resection of large colorectal lesions. Clin Gastroenterol Hepatol 2016;14:1140–1147.

10. Bahin FF, Rasouli KN, Byth K, et al. Prediction of clinically significant bleeding following wide-field endoscopic resection of large sessile and laterally spreading colorectal lesions: a clinical risk score. Am J Gastroenterol 2016;111:1115–1122.

11. Sidhu M, Tate DJ, Desomer L, et al. The size, morphology, site, and access score predicts critical outcomes of endoscopic mucosal resection in the colon. Endoscopy 2018;50:684–692.

12. Albéniz E, Gimeno-García AZ, Fraile M, et al. Clinical validation of risk scoring systems to predict risk of delayed bleeding after EMR of large colorectal lesions.Gastrointest Endosc. 2020;91(4):868-878.

13. Liaquat H, Rohn E, Rex DK. Prophylactic clip closure reduced the risk of delayed postpolypectomy hemorrhage: experience in 277 clipped large sessile or flat colorectal lesions and 247 control lesions. Gastrointest Endosc 2013;77:401–407.

14. Feagins LA, Nguyen AD, Iqbal R, et al. The prophylactic placement of hemoclips to prevent delayed postpolypectomy bleeding: an unnecessary practice? A case control study. Dig Dis Sci 2014;59:823–828.

15. Zhang QS, Han B, Xu JH, et al. Clip closure of defect after endoscopic resection in patients with larger colorectal tumors decreased the adverse events. Gastrointest Endosc 2015;82:904-9.

16. Heiko Pohl, MD, Ian S. Grimm, MD, Matthew T. Moyer, et al. Clip Closure Prevents Bleeding After Endoscopic Resection of Large Colon Polyps in a Randomized Trial. Gastroenterology 2018;157:977-984.

17. Conio M, Repici A, Demarquay JF, et al. EMR of large sessile colorectal polyps. Gastrointest Endosc 2004; 60:234–241.

18. Kantsevoy SV, Bitner M, Mitrakov AA, et al. Endoscopic suturing closure of large mucosal defects after endoscopc submucosal dissection is technically feasible, fast, and eliminates the need for hospitalization (with videos). Gastrointest Endosc. 2014;79:503-7.

19. Kothari ST., Huang RJ, Shaukat A et al. ASGE review of adverse events in colonoscopy. Gastrointest Endosc 2019;90:863-76