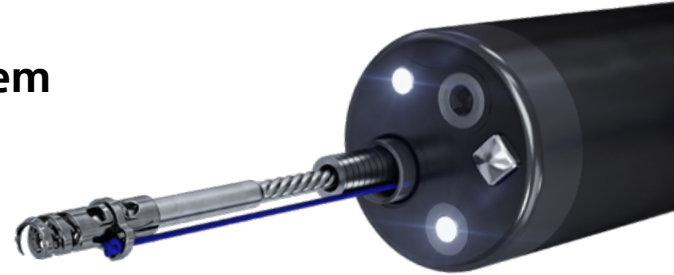




## Clinical Data on the use of the X-Tack System

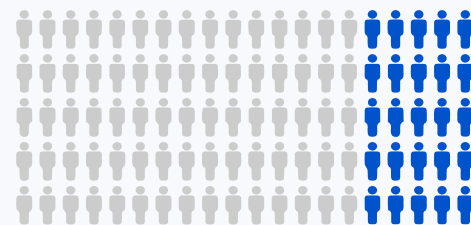
For Closing Defects in the Upper and Lower Gastrointestinal Tract<sup>1</sup>



The following is a summary of the study by Dr. Mahmoud on using the X-Tack, tack and suture system for challenging GI defect closure.

The X-Tack Endoscopic HeliX Tacking System addresses a significant, unmet clinical need. Closure with an alternative device was determined to not be possible in 24.7% of studied patients due to location, size, or shape of the defect.

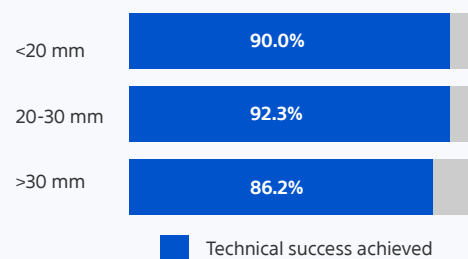
- Standard closure with X-Tack
- Closure only possible with X-Tack



### X-Tack was successful in closing defects of various shapes and sizes

- Overall success rate was 89.2%
- No serious adverse events
- Mild/moderate AEs occurred in 2.2.% of the cases

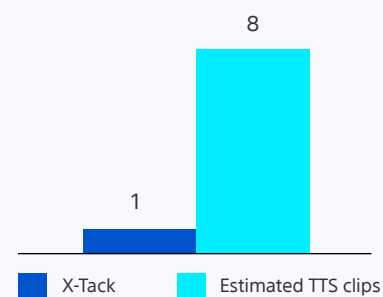
Technical Success Rate by Size of Defect



### X-Tack was cost-effective and time-effective

- 68.8% closures were completed with 1 X-Tack System
- 18% of defects were closed with 2 X-Tack systems and 12% were closed with 3-4 X-Tack Systems
- Supplemental closure systems was used in 24% of patients with a mean defect size of 41.6 mm with an average of 4 TTS clips\*
- Endoscopists estimated the number of TTS clips they would have needed to perform the same closure

Median Number of Devices for Closure



## Methods

- Retrospective, multicenter study with 93 patients
- Eight centers in the US, both academic and private centers
- The study focused on various defect closures, including those difficult or impossible to close with alternative devices
  - Large and/or irregularly shaped
  - Hard to reach anatomy
  - Upper and lower gastrointestinal defects
- The primary outcomes were efficacy (technical success) and safety

## Results

- Mean defect size was 37 mm  $\pm$  20 mm
- Technical success was achieved in 89.2% of patients
- Closure achieved with X-Tack was determined not to be possible with clips or endoscopic suturing devices in 24.7% of patients
- A median of only one X-Tack device was needed to successfully close defects of all sizes compared to a median 8 TTS clips for defects of similar sizes
- No serious adverse events occurred

## Conclusion

The novel, endoscopic, through-the-scope, X-Tack system is safe, efficient, and permits closure of large, irregularly-shaped, and proximal colon defects that were not possible with predicate devices.

## X-Tack was used successfully for defect closure in the following applications:



- Endoscopic Mucosal Resections (EMR)
- Endoscopic Sub-mucosal Dissections (ESD)
- Fistulas
- Perforations
- Peroral Endoscopic Myotomies (POEM)
- Ulcers
- Post-polypectomy repairs
- Full Thickness Resections
- Mucosal Tears

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<sup>1</sup> Mahmoud T, Initial Multicenter Experience Using a Novel Endoscopic Tack and Suture System for Challenging GI Defect Closure and Stent Fixation, Gastrointestinal Endoscopy (2021), doi: <https://doi.org/10.1016/j.gie.2021.10.018>.

\* All these cases were performed at only one of the participating centers in the study, which may be due to operator preference for double layer closure as confidence is accumulated with use of the device.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at <https://apolloendo.my.site.com/dfu/s/>.

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