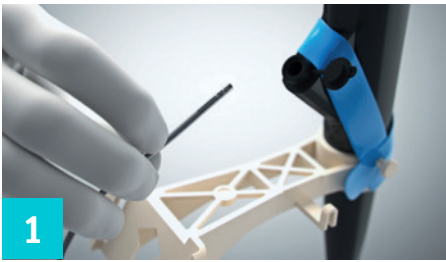




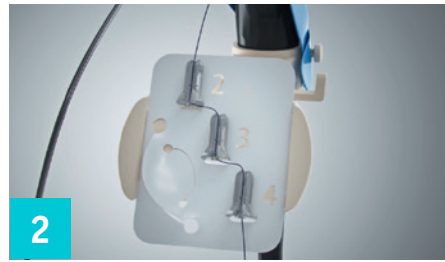
X-Tack™

Endoscopic HeliX Tacking System

Quick Reference Guide



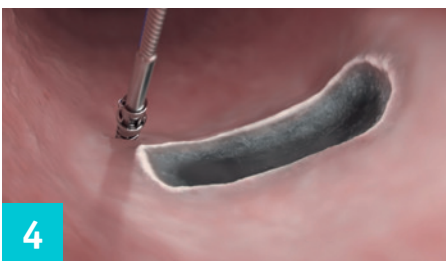
1 Insert the X-Tack device with pre-loaded HeliX Tack and Scope Liner into the scope channel. Ensure the biopsy cap is open.



2 Position the Backer Card with the #2 proximal and attach by inserting both side tabs. Release red Scope Liner Clamp.



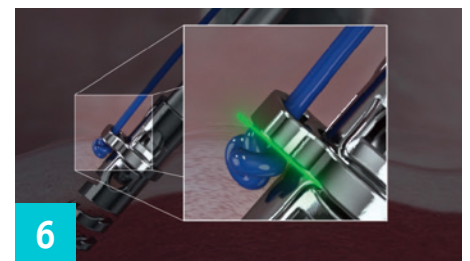
3 Ensure the Handle Slider is in the **Reset** position labeled **R** and the Push Catheter is in the initial locked position.



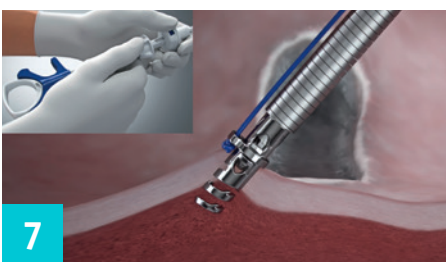
4 Maneuver to target site. Recommended HeliX Tack placement is approximately 5-10 millimeters from the defect margin.



5 Apply forward pressure to the catheter and pull Handle Slider to the **D** position.



6 Verify eyelet is flush with tissue. Pull back on catheter to verify HeliX Tack engagement.*



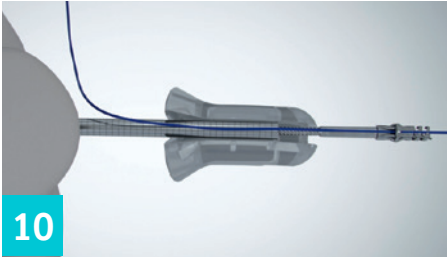
7 To deploy HeliX Tack, press and hold the blue Release Button while advancing the Push Catheter forward until the hard stop is reached.



8 Reset the Handle by sliding the Push Catheter back to the locked position until it **clicks**.

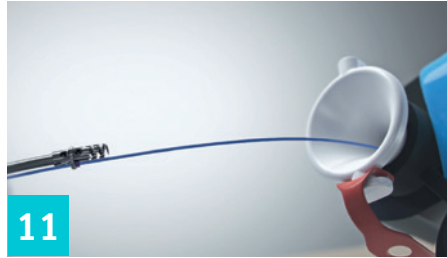


9 Move the Handle Slider to the **R** position.



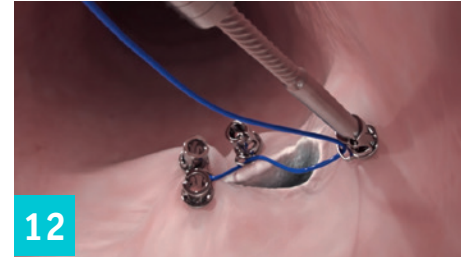
10

Re-load HeliX Tack by securing the distal end of the catheter and advance the driver into the Reload Pill until the driver engages. Continue to advance.



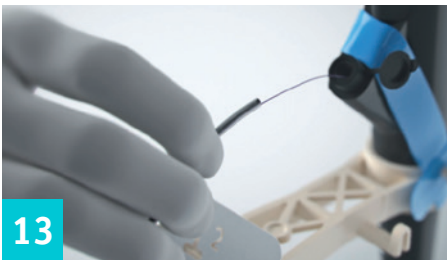
11

While holding tension on the suture, slowly advance the HeliX Tack along the suture into the working channel.



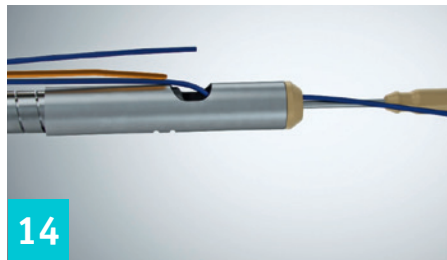
12

Repeat technique for each additional HeliX Tack.



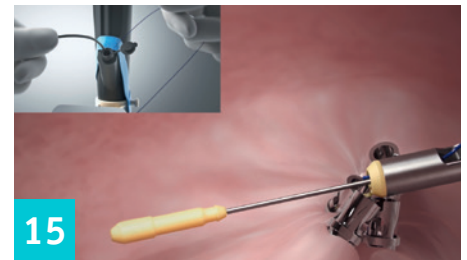
13

Remove device catheter and Scope Liner from the working channel leaving the suture in place.



14

Thread suture through gold tab of cinch. Pull tab along axis of the cinch catheter.



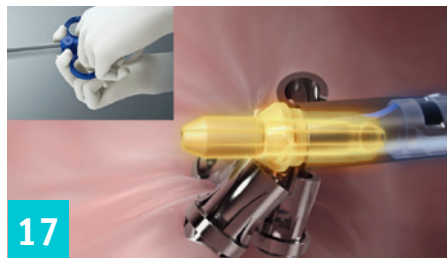
15

Hold slight suture tension and introduce cinch through scope channel. Ensure cinch is parallel to the tissue. While holding the cinch catheter in place, apply tension to approximate tissue.



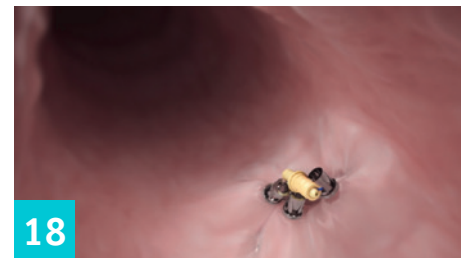
16

Prior to deploying the cinch, hold suture tension gently – grasp between thumb and pointer finger allowing the suture to slide.



17

Open the cinch handle with the palm facing down to release the safety mechanism. Squeeze handle to lock the suture, deploy the cinch and cut the suture.



18

Remove all devices and visually inspect closure.

* Refer to the X-Tack IFU for instructions on reversing and repositioning HeliX Tack if applicable.

The 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.

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