

The X-Tack logo, where the letter 'X' is large and bold, with a stylized surgical instrument handle extending from its bottom right. To the right of the 'X' is the word "Tack" in a large, clean sans-serif font, with a small "TM" trademark symbol to its upper right. Below "Tack" are the words "Endoscopic HeliX" and "Tacking System" in a smaller, clean sans-serif font.

X-Tack™

Endoscopic HeliX
Tacking System

INSTRUCTIONS FOR USE

X-Tack™ Endoscopic HeliX Tacking System (160cm)
X-Tack™ Endoscopic HeliX Tacking System (235cm)
OverStitch™ Suture Cinch
Suture Cinch - Long

Product Code:

XTACK-160-H
XTACK-235-H
CNH-G01-000
CNH-C01-213-L

Caution:

Please read all instructions prior to use

STERILE EO

**SINGLE PATIENT USE
DISPOSABLE**

GRF-00538-00R02

Single use only. Disposable. Do not resterilize. Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Patent Pending.

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Table of Symbols

Description	Symbol	Description	Symbol	Description	Symbol
Consult Instructions for Use		Manufacturer		Use By	
Do Not Re-use		Caution: Federal law (USA) restricts this device to sale by or on the order of a physician		Lot Number	
Sterilized Using Ethylene Oxide		Date of Manufacture		Do not use if package is damaged	
Reference Number		Do Not Resterilize		Authorized Representative in the European Community	
Medical Device		Caution, consult accompanying documents			

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.

Information To Be Provided to Patient

The X-Tack™ System comes with a patient implant card that includes MRI Safety Information. This should be provided to the patient.

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.
- Do not use a device where the integrity of the sterile packaging has been compromised or if the device appears damaged.
- Only physicians possessing sufficient skill and experience in similar or the same techniques should perform endoscopic procedures.
- 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.
- Verify compatibility of endoscope size, endoscopic instruments and accessories and ensure performance is not compromised.
- Ensure endoscope is clean, dry, and free of lubricants prior to device installation.

- Ensure all endoscopic scopes, 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 push through or pull back on a retroflexed scope with installed HeliX Tack.
- 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.
- Reuse or reprocessing of the X-Tack™ System could result in device malfunction, patient infection or the transmission of disease.

Precautions

- The system may only be used if purchased from Apollo Endosurgery, Inc. or one of its authorized agents.

Adverse Events

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

- Pharyngitis / Sore throat
- Nausea and / or Vomiting
- Abdominal pain and / or Bloating
- Hemorrhage
- Hematoma
- Conversion to laparoscopic or open procedure
- Stricture
- Infection / Sepsis
- Pharyngeal, gastric, colonic and/or esophageal perforation
- Esophageal, gastric, colonic and/or pharyngeal laceration
- Intra-abdominal (hollow or solid) visceral injury
- Aspiration
- Wound dehiscence
- Acute inflammatory tissue reaction
- Death

NOTE: Any serious incident that has occurred in relation to the device should be reported to Apollo Endosurgery (see contact information at the end of this document) and any appropriate government entity.

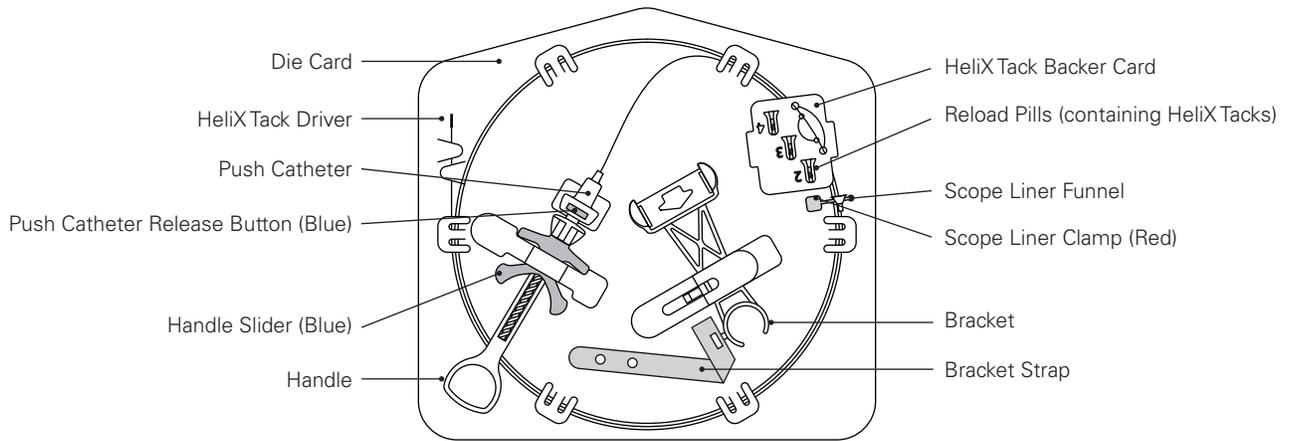
Compatibility

- The system is compatible with an endoscope (gastroscope or colonoscope) with a 2.8 mm or larger working channel. Gastric and Colonic X-Tack devices have a working length of 155 and 235 cm, respectively. The system has been verified compatible with Olympus, Pentax and Fuji gastroscopes. Note that the gastric X-Tack scope liner is approximately 2 inches shorter than the Fuji gastroscope channel. Take care when introducing X-Tack into Fuji gastroscopes.

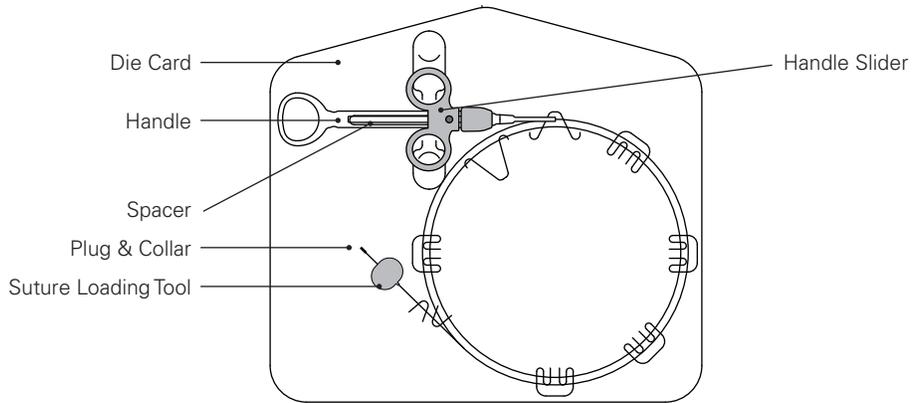
Implant Materials

- HeliX Tacks are manufactured from stainless steel.
- Cinch implants are manufactured from polyetheretherketone (PEEK).
- Suture Materials:
 - The suture is manufactured from an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polyolefin.
 - The suture pigment uses CU-Phthalocyanine Blue Dye (below 0.5 WT %) to enhance visibility.
 - The suture material meets the requirements established by USP.
- The X-Tack system contains no latex, either in the implants or the delivery system.

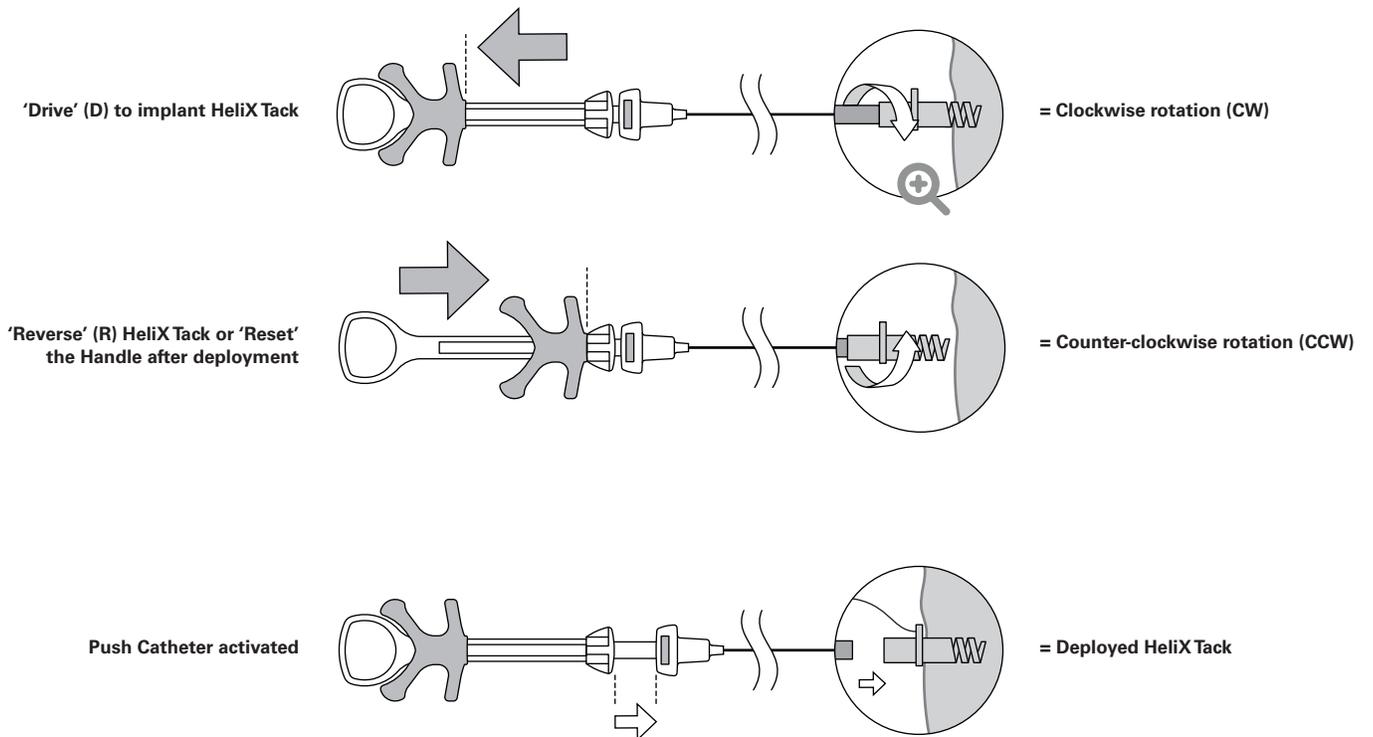
X-Tack Packaged System



Cinch Packaged System

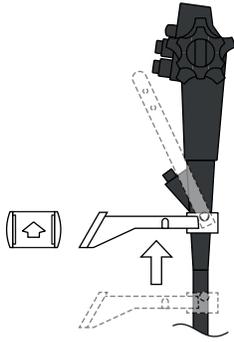


X-Tack Handle Function Overview

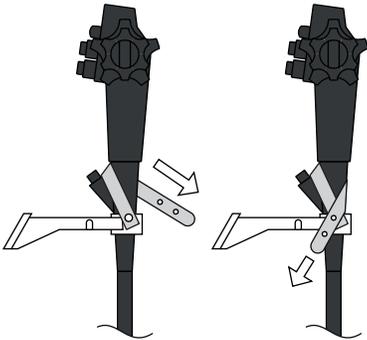


1. Assemble the system

- 1.1. Remove die card from pouch
- 1.2. Remove Bracket from die card.
- 1.3. Slide the Bracket fitting onto the scope boot (arrow pointing upwards).



- 1.4. Fix the Bracket by wrapping the Bracket Strap (blue) above the scope channel and secure using the pin on the Bracket.



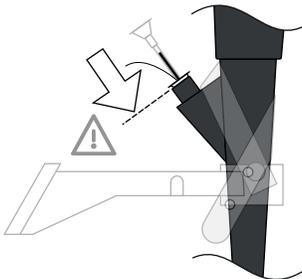
- 1.5. Remove device from die card and present distal end of device to physician.

CAUTION Control the device Handle during handover to ensure device remains clean.

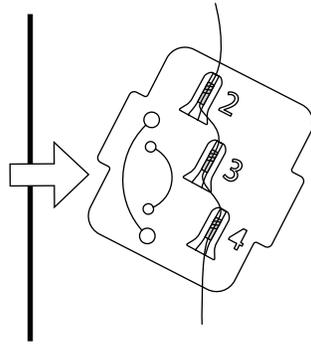
- 1.6. Insert device with Scope Liner into the working channel of the scope.

NOTE: 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.

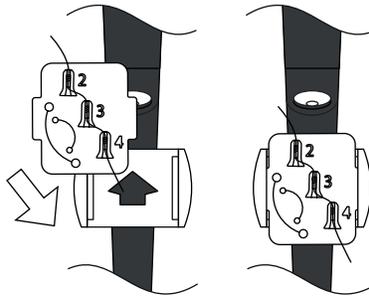
- 1.7. Fully seat Scope Liner funnel in scope cap.



- 1.8. Remove the HeliX Tack Backer Card from the device catheter.



- 1.9. Hold the Backer Card (HeliX Tack #2 top/proximal) and attach to the Bracket fitting by inserting side tabs



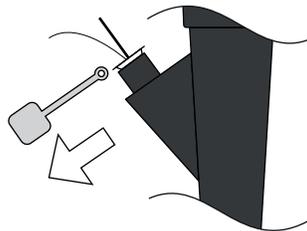
NOTE: Ensure the Suture is not captured between the Backer Card and Bracket.

- 1.10. If required, create suture slack by pulling proximal end of the Suture and allow to work through HeliX Tacks. To reduce suture slack, pull Suture tail in opposing direction.

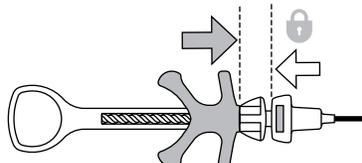
NOTE: Ensure suture slack between scope channel funnel and Backer Card is not wrapped around device catheter prior to attaching to Scope Bracket.

NOTE: Should the suture become wrapped around catheter after Backer Card attachment, it will resolve itself once catheter is removed for HeliX Tack re-loading.

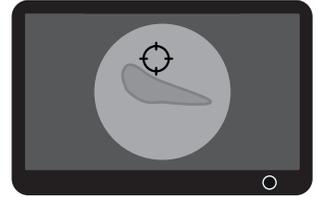
- 1.11. Remove and dispose of the Scope Liner Clamp (red) to release the Scope Liner.



CAUTION: Ensure Handle Slider is in the 'Reset' position labeled 'R' and the Push Catheter is in the initial locked position.

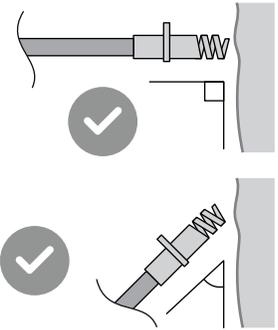


- 1.12. Maneuver scope to target site.



2. HeliX Tack Placement

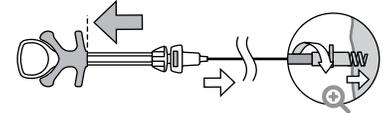
- 2.1. Advance device catheter and push HeliX Tack against tissue.



CAUTION: Ensure the Handle is in Reset position prior to driving HeliX Tack.

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

- 2.2. While applying forward pressure on the device catheter, 'Drive' the HeliX Tack into tissue by slowly PULLING Handle Slider to 'D' position until the hard stop is reached.

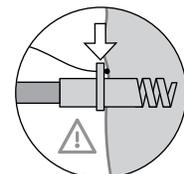


WARNING: Verify position of HeliX Tack before driving fully into tissue. Features on the HeliX Tack, used to resist back-out after surgery, may catch tissue and complicate repositioning after the Helix is driven fully into tissue.

- 2.3. Visually verify if successful placement (location and depth) was achieved.



NOTE: The HeliX Tack eyelet should be flush with the mucosal surface as an indication of correct depth.

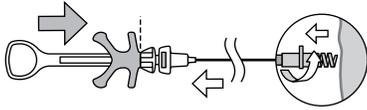


- 2.4. If the eyelet is not flush with the mucosal surface, rotate the Handle and Slider CLOCKWISE (CW) to drive HeliX Tack further into tissue.

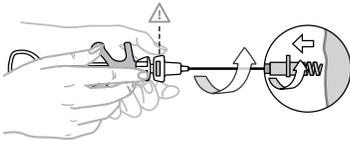
NOTE: In cases of retroflexion, manual turns may be required to fully seat the HeliX Tack.

WARNING: Excessive manual rotation could damage the device causing the HeliX Tack to slip on the driver.

- 2.5. If placement is NOT satisfactory, reverse HeliX Tack by gently pulling back on device catheter while slowly PUSHING Handle Slider to the 'R' position until the HeliX Tack is fully released from the tissue.



- 2.6. If HeliX Tack remains engaged in tissue, hold the Push Catheter with the left hand, and rotate both the Handle Slider and the Handle COUNTERCLOCKWISE (CCW) with the right hand until the HeliX Tack is fully released from tissue.



NOTE: Continue to gently pull back on device catheter and ensure the Handle Slider remains in the 'R' position throughout.

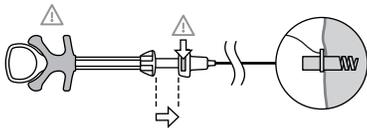
NOTE: Maintain visualization when attempting to disengage HeliX Tack from tissue to ensure it is turning CCW.

NOTE: Several turns of the Handle and Finger Slider may be required before HeliX Tack begins to rotate and can be safely removed from tissue.

- 2.7. Re-target tissue and Drive HeliX Tack according to the placement instruction above.

3. HeliX Tack Deployment

- 3.1. Ensuring that the Handle Slider is in the Drive 'D' position, press and hold the Push Catheter Release Button (blue) then advance the Pusher forward (away from Handle) until the hard stop is reached.

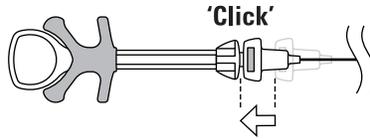


- 3.2. Visually verify correct HeliX Tack deployment.



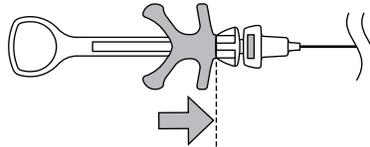
4. Reset the device

- 4.1. Reset the device by sliding the Pusher back to locked position until it 'clicks' in place.



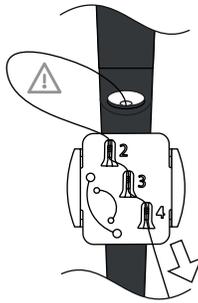
NOTE: Ensure the Push Catheter Release Button (blue) is not being pressed during this action.

- 4.2. Push Handle Slider to position 'R'.



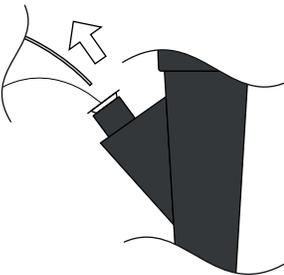
NOTE: If significant resistance is felt while advancing or retracting device, reduce scope tortuosity.

NOTE: If needed, control slack by pulling Suture.

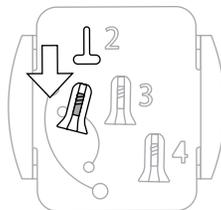


5. Reload the device

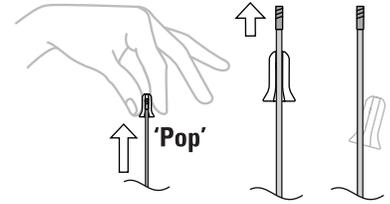
- 5.1. Remove device from working channel.



- 5.2. Remove Reload Pill #2 from Backer Card by lifting the distal end of Pill and sliding downwards.



- 5.3. Securing the Reload Pill between fingers, hold the distal end of the catheter approximately 2 inches from the tip and insert into the embedded HeliX Tack until a 'pop' is felt.

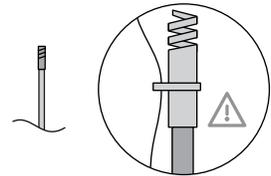


NOTE: Ensure the Push Catheter is in the locked position prior to re-loading.

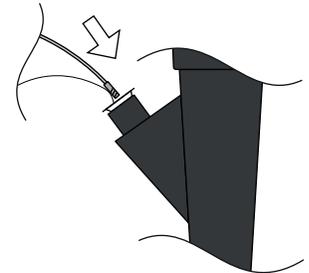
- 5.4. Continue moving the device catheter forward through the Reload Pill until the HeliX Tack is removed. Discard the Reload Pill.

CAUTION: Do not to squeeze the pill too tightly during reload as this will risk damaging the HeliX Tack.

CAUTION: 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.



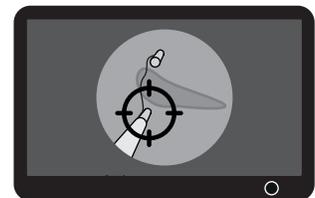
- 5.5. While holding Suture tension, slowly advance HeliX Tack along Suture and insert into working channel.



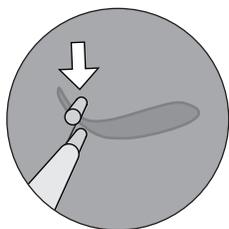
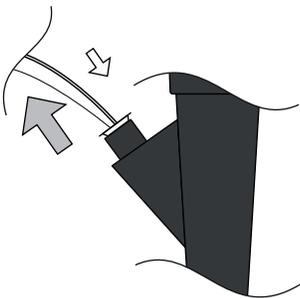
NOTE: Do not retract device catheter from the working channel whilst a HeliX Tack is installed; this could lead to device damage or inadvertent detachment.

6. Continue HeliX Tack Placement

- 6.1. Repeat steps to target tissue and implant further HeliX Tacks.

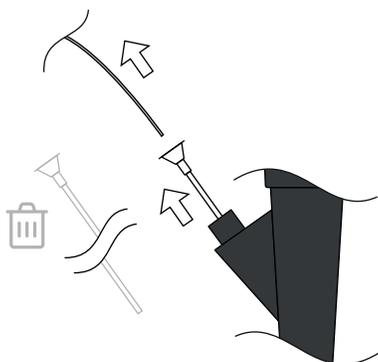


- 6.2. After placement of each additional HeliX Tack, apply tension on the suture to approximate tissue.



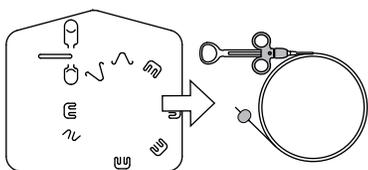
- 6.3. Remove device from Scope Liner after all HeliX Tacks have been deployed.

- 6.4. Pull Scope Liner out of biopsy valve and discard.

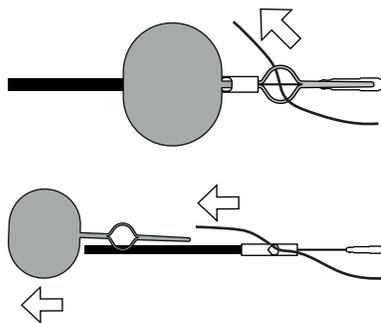


7. Secure using Cinch

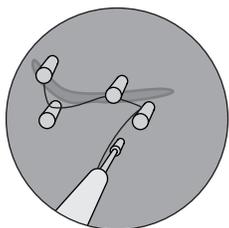
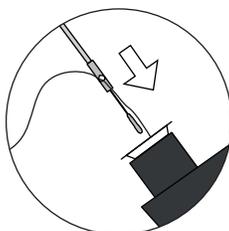
- 7.1. Remove Cinch from die card.



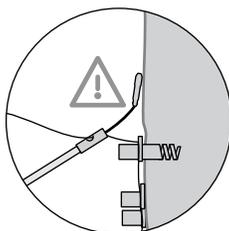
- 7.2. Feed proximal end of Suture into removable Suture Loading Loop.
- 7.3. After threading, release the proximal end of the Suture to enable loading.
- 7.4. Pull Suture Loading Loop Parallel to the device, to pull Suture into Cinch.



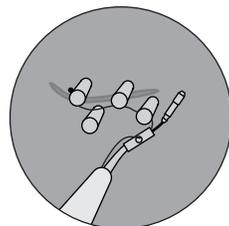
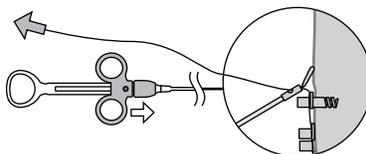
- 7.5. Holding the proximal end of the Suture, feed the Cinch down the working channel until 'Plug and Collar' can be seen on the monitor.



- 7.6. Advance Cinch to treatment location – ensure Cinch Plug is parallel to tissue.

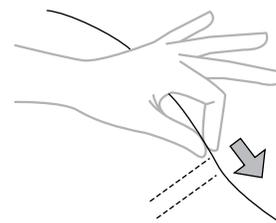


- 7.7. Pull the Suture and apply counter traction to the Cinch until the HeliX Tacks are approximated and the desired Suture tension is achieved between the Tack and the Cinch Collar.

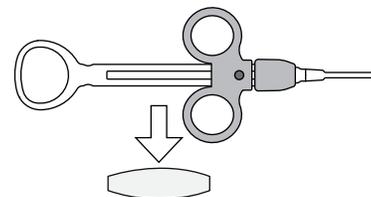


WARNING: Excessive tension may pull out HeliX Tacks or break Suture.

- 7.8. Prior to cinching, hold Suture tension gently – grasp between thumb and pointer finger allowing to slide slightly.

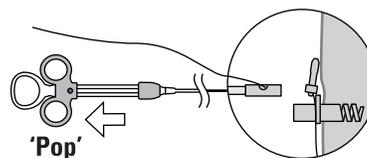


- 7.9. Remove safety spacer from Cinch Handle.



CAUTION: The safety spacer must only be removed immediately prior to deploying Cinch.

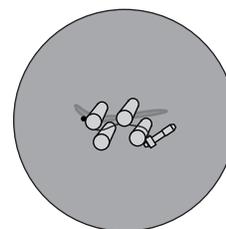
- 7.10. Firmly squeeze Cinch Handle to deploy Cinch and cut Suture.



CAUTION: Suture tension must be maintained during Cinch deployment.

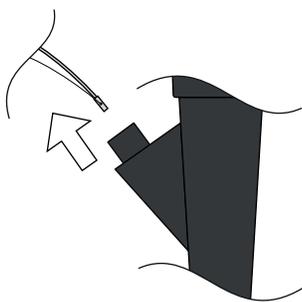
NOTE: Significant force is required to pull and lock the Plug into the Collar, a 'pop' can often be felt once the Suture is cut.

- 7.11. Visually inspect closure.

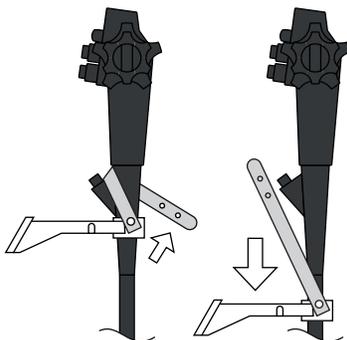


NOTE: HeliX Tack proximity shown is illustrative only; after correct Cinch deployment actual Tacks will be tightly clustered to achieve wound closure.

7.12. Remove Cinch device from scope channel.



7.13. Remove Bracket from scope.



Disposal

Dispose of any used or explanted devices or device components in accordance with any local regulations for medical waste.

MRI Safety Information



MR Conditional

Non-clinical testing has demonstrated that the X-Tack™ Endoscopic HeliX Tacking System is MR Conditional.

A patient with this device can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 1.5 -Tesla and 3-Tesla only
- Maximum spatial field gradient of 2.5 T/m (extrapolated) and less.
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (ie. per pulse sequence) in the normal operating mode.

In non-clinical testing, the X-Tack™ Endoscopic HeliX Tacking System produced a temperature rise of 1.5° C or less at a maximum extrapolated WBA SAR of 2.0 W/kg for 15 minutes of continuous MR scanning with body coil in both 1.5 T/64 MHz and 3T/128 MHz MR System Scanners.

In non-clinical testing, the image artifact caused by the Anchoring System extends approximately 16-mm from this device when imaged with a gradient echo pulse sequence and a 3-Tesla MRI system.

Troubleshooting

Channel Liner Protrudes from Scope

Cause	Resolution
Field of view obscured by protruding channel liner from scope.	<i>Retract channel liner funnel at the biopsy cap</i>

Resistance Felt During Device Insertion

Cause	Resolution
Resistance felt during device insertion.	<i>Stop advancing the catheter and straighten the scope to facilitate the device passage. Reposition scope for treatment.</i>

HeliX Tack Disengages from Driver While Inside Patient But Before Intended

Cause	Resolution
<p>If the user attempts to retract a HeliX Tack back into the scope liner, the eyelet of the HeliX Tack can catch on the scope liner and disengage the Tack from the driver.</p> <p>A HeliX Tack can disengage prematurely if the Tack is not properly loaded onto the driver.</p>	<p><i>Never attempt to withdraw a disengaged HeliX Tack through the driver because it may damage the scope.</i></p> <p><i>If the first HeliX Tack disengages, the suture can be drawn such that the HeliX Tack is held against the distal end of the scope liner. Then, withdraw the scope, scope liner, X-Tack catheter and HeliX Tack together as a single unit. Reattach the HeliX Tack, outside the patient. You should feel a pop as it engages with the driver. Pull the catheter with loaded HeliX Tack carefully back into the scope liner, taking care not to disengage the HeliX Tack, and begin again.</i></p> <p><i>If the second or third HeliX Tack disengages in the patient, adjust the suture pattern and cinch. These HeliX Tacks cannot be re-engaged with the driver. If the 4th HeliX Tack disengages, leave it and cinch the construct. If necessary, use another X-Tack device to complete the closure.</i></p>

Excessive Resistance During Device Insertion

Cause	Resolution
Excessive resistance felt during device insertion in a straight scope, scope working channel may be damaged or obstructed.	<i>Flush working channel or use different scope.</i>

(continued on next page)

Troubleshooting (continued from previous page)

Unable to Reverse HeliX Tack

Cause	Resolution
The HeliX Tack has been advanced to full depth prior to reversing. Partial placement of the HeliX Tack and verification of placement is recommended prior to fully driving the HeliX Tack into tissue.	<p>Ensure the length of catheter from the scope to the assistant is straight.</p> <p>Pull back on the catheter to assist in reversing, but care should be taken not to disengage driver. If unsuccessful with pulling, then push catheter forward.</p> <p>Move the Finger Slider to the "R" position.</p> <p>Place the entire X-Tack handle in the palm of the assistant's hand.</p> <p>While securing the finger slider with the thumb and pointer finger in the "R" position, rotate the X-Tack Handle counterclockwise while ensuring the Finger Slider does not advance while rotating.</p> <p>If cannot reverse the HeliX Tack, drop HeliX Tack and adjust closure pattern with additional HeliX Tack placements.</p>

Twisted Suture

Cause	Resolution
HeliX Tack's Bearing Eyelet is advanced too far and is not able to rotate on the Helix.	<p>Attempt to untwist suture with X-Tack driver and scope movement (care should be taken not injure surrounding tissue with the exposed driver).</p> <p>If untwisting is unsuccessful, deploy HeliX Tack and adjust closure pattern with additional HeliX Tack placements.</p>

Suture Breakage

Cause	Resolution
Suture breaks near biopsy cap and cannot be retrieved for cinch loading.	<p>Remove the scope liner and retract the scope from patient. If possible, access the suture tail and load the cinch according to the standard technique.</p> <p>Insert scope into patient and advance cinch along the outside of the scope to the closure site. Complete cinching process under direct visualization.</p>



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