OverStitch™
Endoscopic Suturing System

TABLE OF CONTENTS

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

1. REUSE WARNING

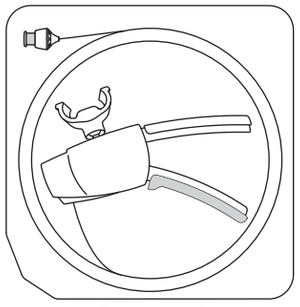
For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

2. DEVICE DESCRIPTION

The OverStitch Endoscopic Suturing System is a sterile, single use device that is used with dual channel endoscopes for the endoscopic placement of anchor sutures. Anchor-sutures can be placed for defect closure (e.g., perforation, ESD/EMR, and fistula/leak), stent fixation to reduce migration rates in the upper GI tract, endoscopic sleeve gastroplasty, and transoral outlet reduction.The OverStitch Endoscopic Suturing System consists of the Needle Driver Assembly and the Anchor Exchange which is used in conjunction with the "suture assembly" to create full-thickness bites when approximating soft tissue. The Tissue Helix (Helix) can be used to manipulate and position tissue in a way that facilitates the desired suture placement, and the Suture Cinch (Cinch) provides a means for securing and cutting the suture once placement is complete.

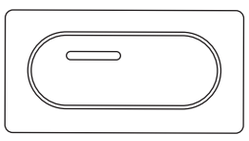
3. CONTENTS

3.1. Packaged System (All available separately)



Package 1

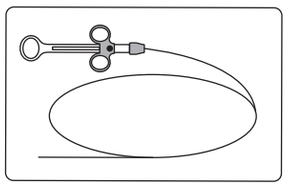
Needle Driver & Anchor Exchange



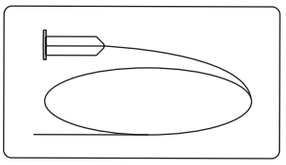
Package 2

Suture Assembly

Polypropylene (nonabsorbable) - BLUE

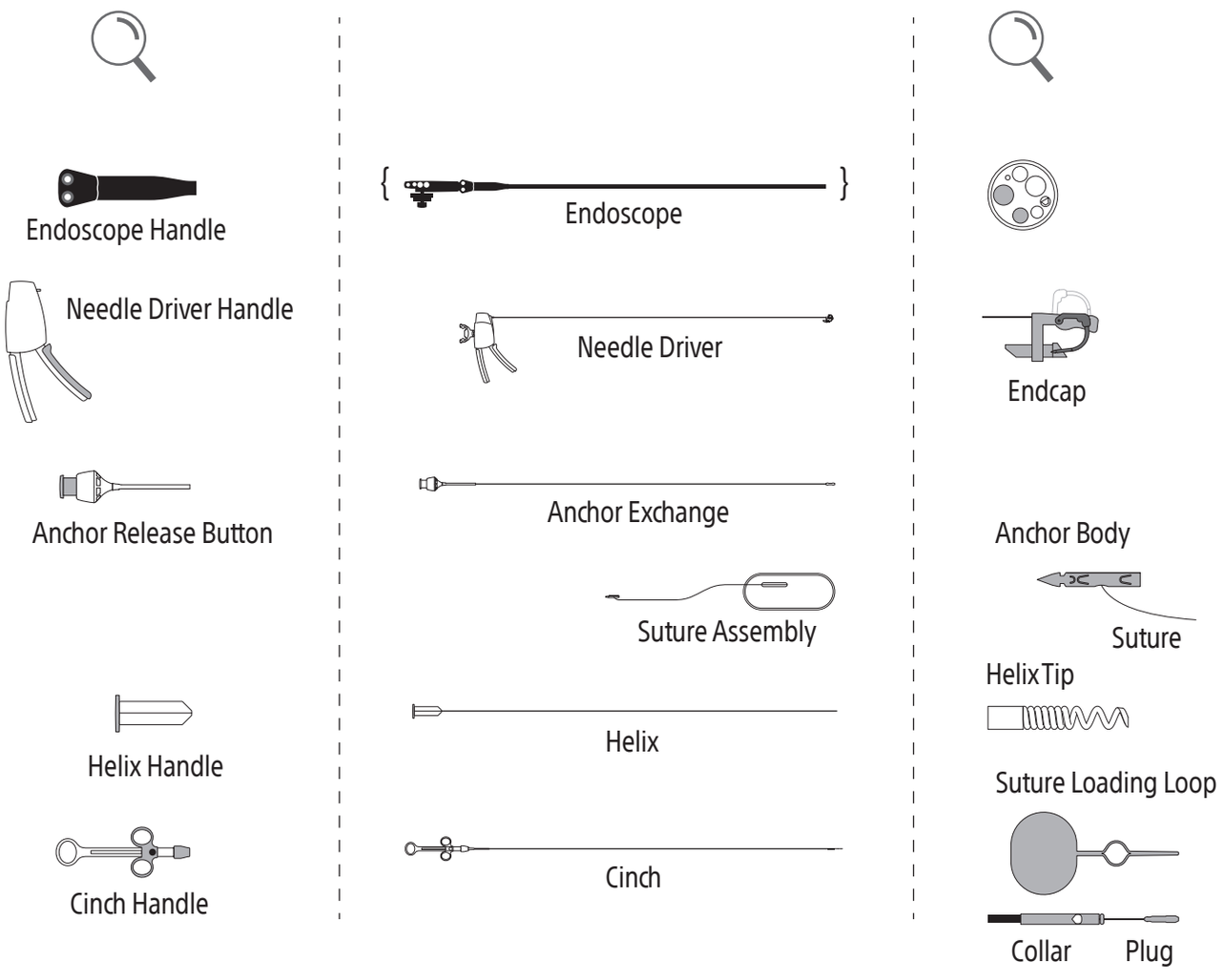


Package 3
Cinch



Package 4
Helix
(AVAILABLE SEPARATELY)

4. NOMENCLATURE



5. OPERATING PRINCIPLE

The OverStitch Endoscopic Suturing System (Overstitch Device) consists of the Needle Driver Assembly and the Anchor Exchange. The OverStitch Endoscopic Suture System functions by delivering a proprietary Anchor and Suture through the primary channel of the endoscope. The Anchor-Suture assembly is then passed back and forth from the Anchor Exchange to the Needle Driver assembly to create full-thickness bites when approximating soft tissue. As necessary, a Tissue Helix can be advanced down the endoscope's secondary channel to manipulate and position tissue.

The Suture Cinch provides a means to secure and cut the suture once tissue approximation is complete. Suture is threaded into the Suture Cinch device, using the suture loading tool, and the device is advanced down the scope working channel. The finger slide is actuated as the desired amount of suture tension is applied by the user to deploy the cinch. The cinch device crimps the suture between two Polyetheretherketone (PEEK) components (i.e. collar and

plug) and shears the excess suture against the metal housing as the cinch is released from the delivery system. The crimped suture maintains suture tension, completing tissue approximation while the device and excess suture are removed from the patient's body.

6. MATERIALS

6.1. Information on materials and substances to which patients can be exposed.

Each implant construct, consisting of an Anchor-Suture and Cinch, consists of 1. A polypropylene suture (typically less than 5 cm long) with an anchor (made from 316 L stainless steel (0.011 g), cobalt chrome alloy (0.006 g)) and 2. A Cinch to hold the implant in place (made from PEEK (0.020 g).

Anchor-Suture/Cinch*	
Implantable material	% weight (total assembly weight is 0.0421 g)
Polyetheretherketone (PEEK)*	51 %
Stainless steel	26 %
Cobalt-Chrome	14 %
Polypropylene	9 %
* Implant is comprised of Anchor-Suture and Cinch. Cinch is supplied separately.	

- All implants and patient contacting delivery instruments have been tested and evaluated in accordance with appropriate ISO-10993 standards for suitable biocompatibility.
- The suture-anchor materials have been subject to a toxicological risk assessment that supports the use of eight suture-anchors in a single patient.
- The OverStitch Endoscopic Suturing systems, including the implants and delivery system, are not made from natural rubber latex.

6.2. Hazardous substance information

CMR Statement – The stainless steel and cobalt alloy components within this device contain the following substance(s) defined as a CMR (carcinogenic, mutagenic or toxic to reproduction) 1A/1B and/or endocrine disrupting in a concentration above 0.1 % weight by weight:
Cobalt (CAS No. 7440-48-4; EC No. 231-158-0).
Current scientific evidence supports medical devices manufactured from these cobalt alloys or stainless steels containing cobalt do not cause increased risk of cancer or adverse reproductive effects.

7. USER INFORMATION

Only physicians possessing sufficient skill and experience in similar or the same techniques should perform endoscopic procedures.

8. INTENDED USE/INDICATIONS FOR USE

The OverStitch Endoscopic Suture System is indicated for the endoscopic placement of anchor-sutures. Anchor-sutures can be placed for defect closure (e.g. perforation, ESD/EMR and fistula/leak), stent fixation to reduce migration rates in the upper GI tract, endoscopic sleeve gastroplasty, and transoral outlet reduction.

Intended Users

The OverStitch Endoscopic Suturing System is operated by the physician (e.g., doctors performing endoscopic procedures) and supported by allied health personnel (e.g., nurses, physician assistants). Boston Scientific offers basic training on the use of OverStitch and supplemental training on endoscopic sleeve gastroplasty and transoral outlet reduction. This training covers patient selection, potential adverse events, prophylactic techniques, how to perform the procedure, and after care for the patient. Physicians performing bariatric procedures should have this supplemental training. Contact your local Boston Scientific (BSC) representative to inquire about training.

Intended Patient Population

The system is designed to operate in the gastrointestinal (GI) tract. Prospective patients are from the general adult population who have a pathology in their gastrointestinal tract or have obesity, except for those from whom endoscopic procedures are contraindicated.

Clinical Benefit Statement

The intended clinical benefit of the OverStitch Endoscopic Suturing System is to place endoscopic suture(s) within the gastrointestinal tract to aid in defect closure, stent fixation, and facilitate in weight loss in adults with obesity by reducing the volume of the stomach or reducing a dilated gastric outlet.

Summary of Safety and Clinical Performance

For customers in the European Union, use the device name found in the labeling to search for the device's Summary of Safety and Clinical Performance, which is available on the European database on medical devices (EUDAMED) website: (https://ec.europa.eu/tools/eudamed).

9. CONTRAINDICATIONS

Contraindications include those specific to use of an endoscopic suturing 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.

10. WARNINGS

- Contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.
- 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.
- Ensure that the Handle Grip of the Endoscopic Suturing System is closed and locked during intubation and extubation. Failure to do so may result in patient injury.
- It is possible for the needle to become trapped in a foreign body which could require surgical or medical intervention.
- In situations where the operative site poses a risk of harm to adjacent anatomic structures, use of endoscopic accessories such as the OverStitch Tissue Helix is recommended to retract the tissue intended to be sutured away from these unseen structures.
- It is important to ensure the Tissue Helix is carefully deployed and correctly retracted to avoid entrapping tissue and potentially causing trauma. Avoid using excessive pressure or applying excess turns when deploying the Tissue Helix. Performing more turns than necessary to retract tissue may increase the risk of capturing and suturing an adjacent organ and the risk of the helix entrapping tissue, complicating removal of the instrument.
- For bariatric cases, Carbon Dioxide (CO_2) is required for insufflation. Room air should not be used to insufflate and could contribute to serious adverse events including pneumoperitoneum, pneumothorax, pneumomediastinum, and death.
- Sutures placed in the fundus may increase the risks of leakage and inadvertent suturing of the adjacent organs as this region is relatively thin walled and located close to the spleen and diaphragm. Caution/care should be used when placing plications in the fundus. For ESG procedures, this region should be avoided.
- Maintain awareness of the potential to disrupt a short gastric artery along the greater curve. Post procedure pain with any hemodynamic instability should immediately raise concern for extra-gastric bleeding and/or hematoma formation. These symptoms warrant further investigation.
- When cinching the suture anchor to form the plications, use the minimum tension necessary to maintain the plication. Excessive tension may increase the risk of gastrointestinal bleeding or creating a leak. Excessive tension may also increase the risk of the suture-anchor breaking and compromising the gastric sleeve. If this occurs, remove the suture and Anchor (if possible).
- Patients who develop significant persistent upper abdominal pain at any time after an ESG, with radiation to the back or supraclavicular area along with pleuritic symptoms or even dyspnea, may have developed a needle puncture site leak with the development of a sterile or infected fluid collection and inflammatory pleural effusion. These symptoms warrant further investigation.
- An overtube device can be used to protect the esophagus. When using an overtube, mount the suturing device onto the scope and verify compatibility with the overtube prior to use. Scope refurbishment may

impact compatibility. Thoroughly lubricate the endoscope and overtube prior to use. Never advance or retract the endoscope in an overtube against significant resistance as this may result in esophageal perforation or laceration.

11. PRECAUTIONS

- With the Endoscopic Suturing System installed, the endoscope's primary channel effectively becomes a 3.2 mm channel.
- An overtube with an internal diameter of at least 16.7 mm may be used with the system to protect the esophagus.
- Verify compatibility of endoscopic instruments and accessories and ensure performance is not compromised.

Note: Refurbished scopes may no longer confirm to original specifications.

- Ensure that there is sufficient space for the Needle to open.

12. ADVERSE EVENTS

Possible complications that may result from using the Endoscopic Suturing System include, but may not be limited to:

- Acute inflammatory tissue reaction
- Aspiration
- Bowel obstruction
- Conversion to laparoscopic or open procedure
- Death
- Dehydration and/or nutritional deficiency requiring hospital admission
- Gastrointestinal symptoms such as nausea and vomiting
- Hemoperitoneum
- Hemorrhage
- Inadvertent stent dislodgement
- Infection/sepsis
- Intra-abdominal (hollow or solid) visceral injury
- Laceration
- Leak
- Liver abscess
- Moderate abdominal pain more than 24 hours after procedure. In some cases, abdominal pain may be severe and require medical intervention
- Paresthesia
- Perforation
- Perigastric fluid collection
- Pleural effusion, Pneumomediastinum, and Pneumothorax
- Pneumoperitoneum
- Respiratory Distress
- Stricture
- Tissue Damage to surrounding organs
- Wound dehiscence

13. HOW SUPPLIED

Device Details

The OverStitch Endoscopic Suturing System is supplied sterile using an ethylene oxide (EO) process.

Do not use if package is damaged or unintentionally opened before use.

Do not use if labeling is incomplete or illegible.

Handling and Storage

This product has no special handling or storage requirements.

14. COMPATIBILITY

The OverStitch ESS is compatible with PLY-G02-020-APL/M00505441 sutures.

The OverStitch is compatible with the following dual channel endoscopes:

- Olympus GIF2T240
- Olympus GIF2T160
- Olympus GIF2TH180
- Fuji EI-740D/S

Availability of compatible devices may vary depending on geography.

Device Compatibility:

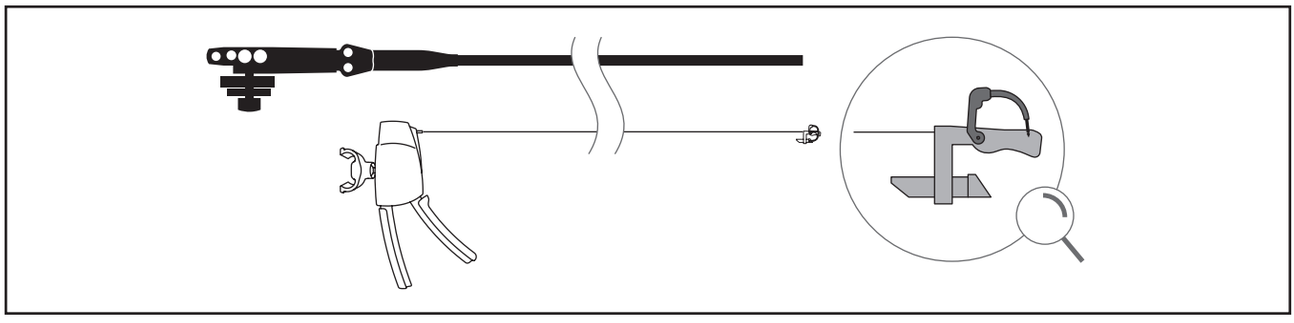
BSC UPN	Apollo SKU	Description
M00505441	PLY-G02-020-APL	OverStitch 2-0 Polypropylene Suture
M00505470	THX-165-028	Tissue Helix
M00505540	CNH-G01-000	OverStitch Suture Cinch
M00505560	OVT-027-160	OverTube Endoscopic Access System

15. ASSEMBLY

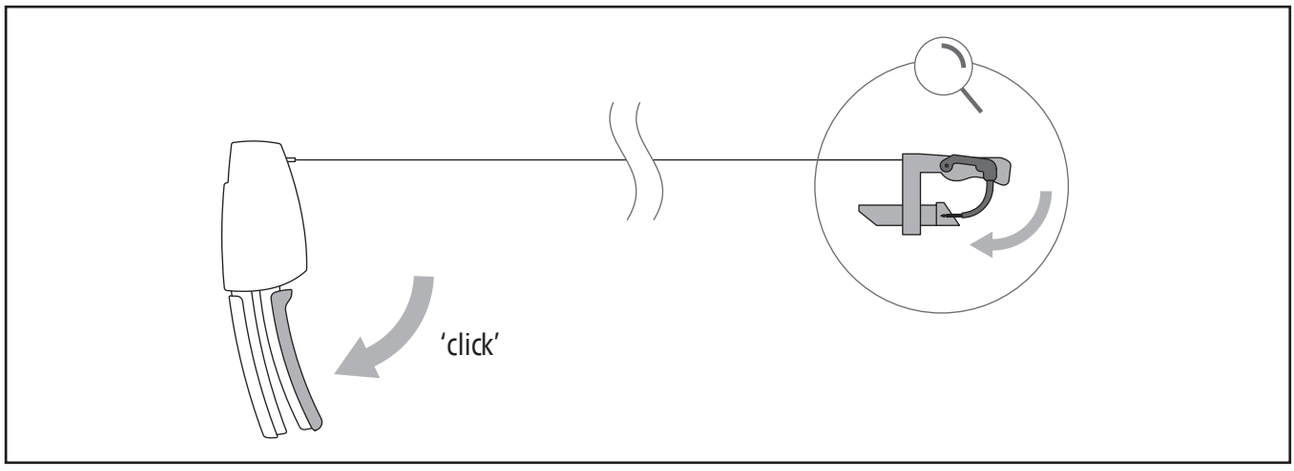
15.1 Place the compatible endoscope on a suitable surface for assembly.

Caution: Ensure standard channel valves are fitted to the working channels.

15.2 Remove the Needle Driver from packaging.

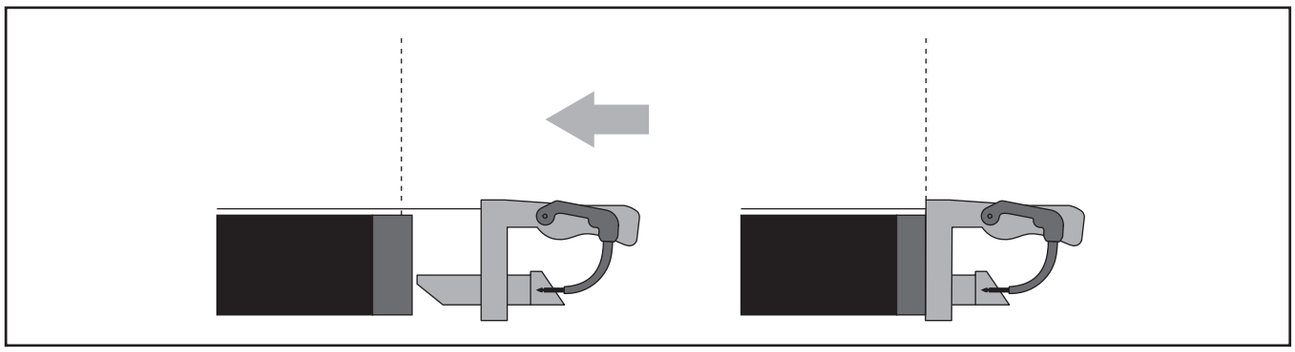


15.3. Close the Needle Body.



Caution: Ensure the Endcap is not dropped or otherwise damaged.

15.4. Push the alignment tube into the primary working channel of the endoscope until the Endcap is flush with the Endoscope face.

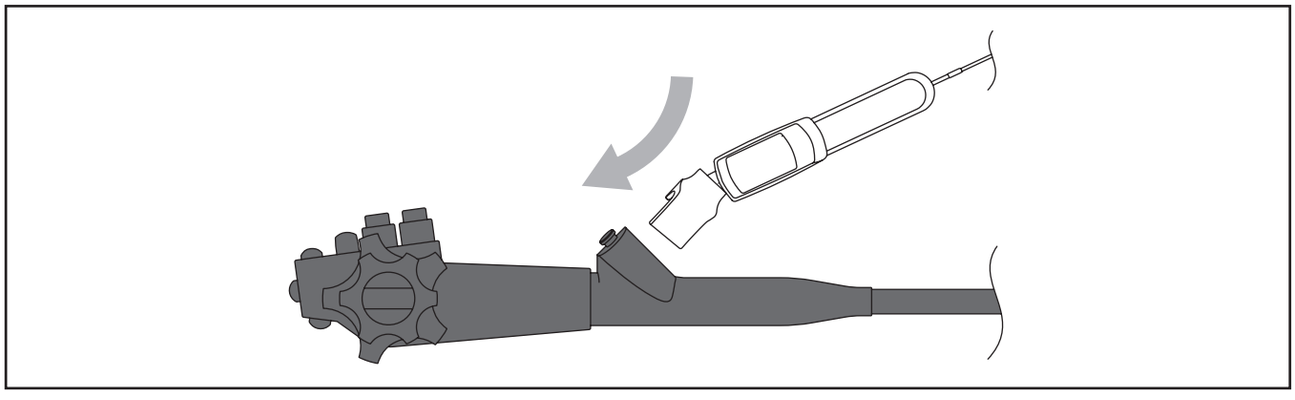


Note: Resistance should be felt when attaching the Endcap to the endoscope as this indicates correct attachment.

Note: Ensure that the secondary working channel is not obstructed on the Endoscope.

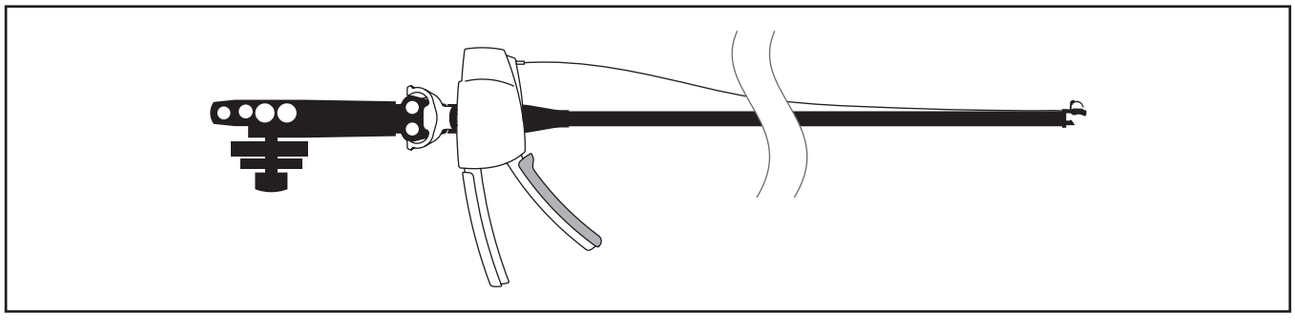
Warning: Ensure that the Endcap is fully seated on the Endoscope, otherwise the endcap can dislodge and cause patient injury.

15.5. Assemble the Needle Driver handle onto the Endoscope.



Caution: Ensure the external cable is not twisted around Endoscope.

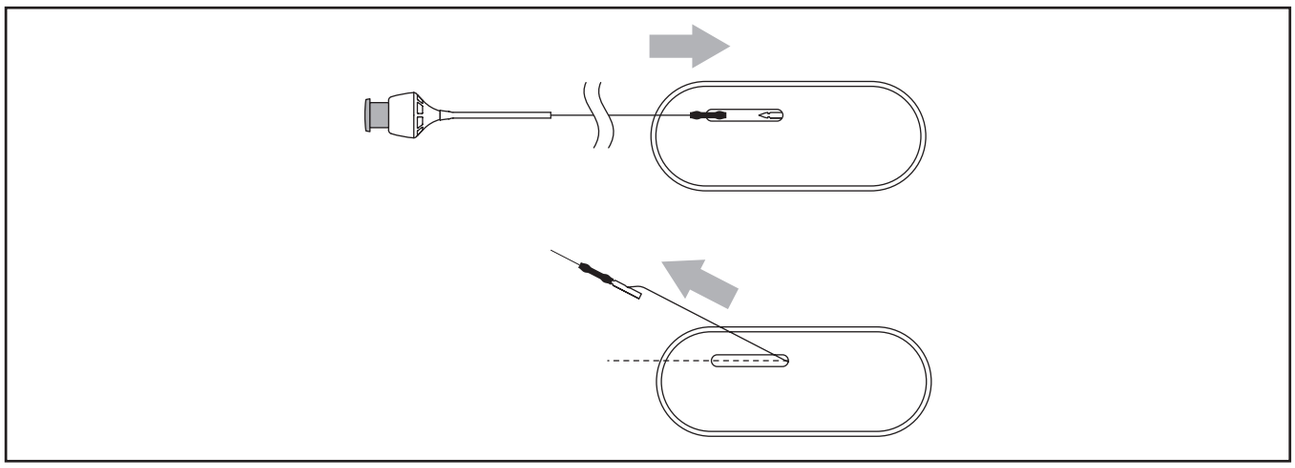
15.6. Connect the Endoscope to the Tower.



Load Anchor

15.7. Remove the Suture Assembly and Anchor Exchange from packaging.

15.8. Load the Anchor.



15.9. Remove the Suture from the Suture Racetrack by holding and pulling the Suture, not the Anchor or Anchor Exchange.

Caution: Ensure the Suture is not tangled after removal from the Racetrack as this may result in deployment difficulties.

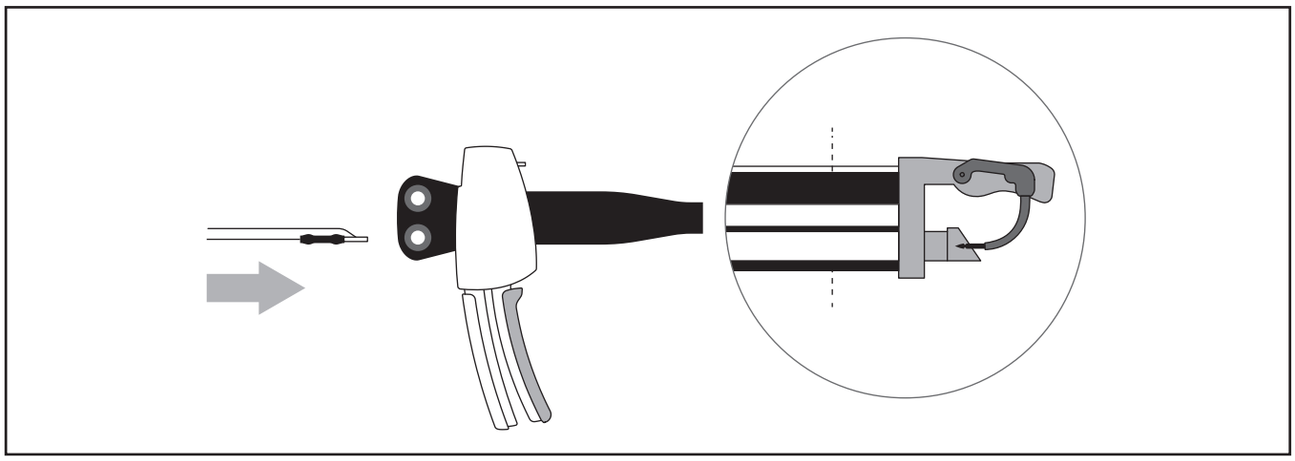
Note: If excessive resistance is encountered when unspooling the Suture from the Racetrack, remove paper and unwrap the Suture from the Racetrack.

15.10. Open the valve cover and insert the Anchor Exchange into primary channel of Endoscope.

Caution: Do not use when valve covers are closed as suture drag will be increased.

15.11. Using a `pencil-grip' on the catheter and placing the remaining fingers of the same hand on the Endoscope housing for optimum control, advance Anchor Exchange until Anchor is positioned near distal end of Endoscope, just inside the Endoscope working channel.

Caution: Apply tension to Suture at proximal end while advancing the Anchor Exchange to prevent Suture entanglement. Excessive tension may damage/break the suture.



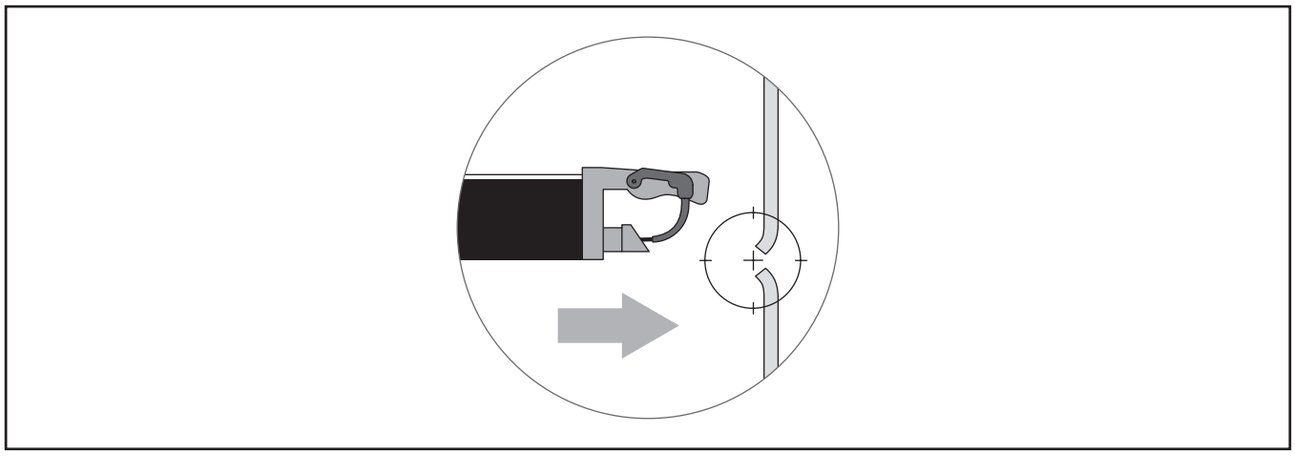
Caution: If resistance is encountered when advancing the Anchor Exchange through the working channel of the Endoscope, reduce the Endoscope angulation until the device passes smoothly.

15.12. Insert the Endoscope into the patient.

Warning: Do not introduce the device with the Needle Body in its open position. Doing so may cause damage to the device and/or injury to the patient.

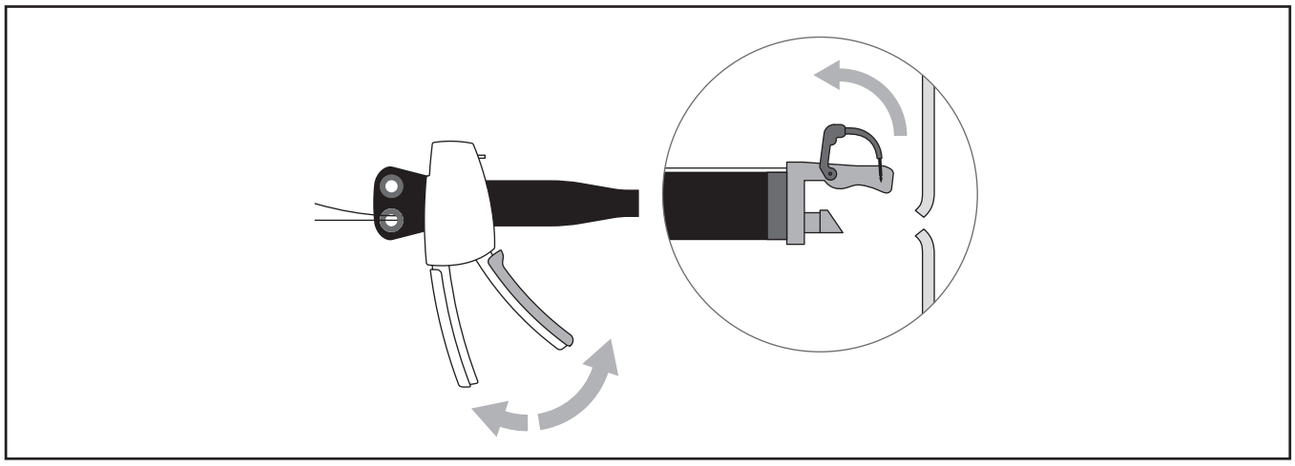
16. NAVIGATING TO TARGET ANATOMY

16.1. Advance the device until the target anatomy is located.

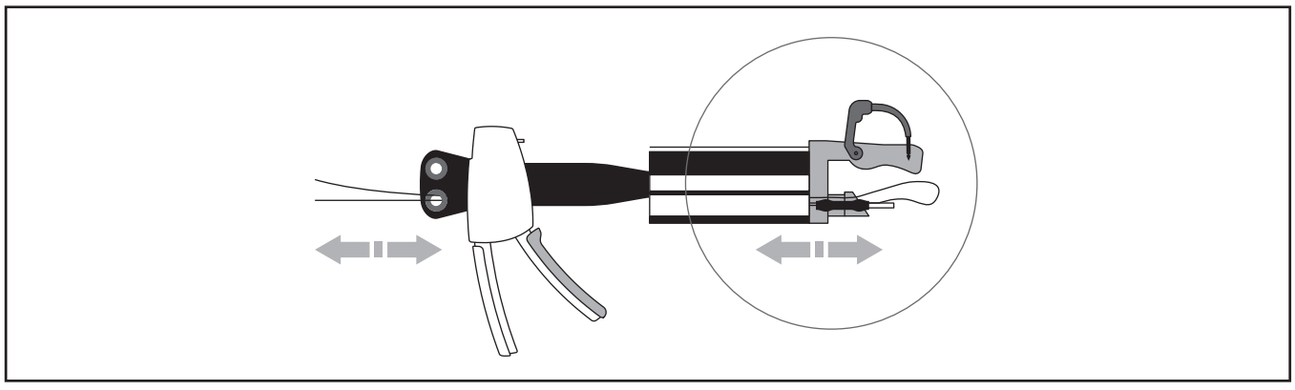


Warning: When intubating or extubating with the Endoscopic Suturing System, ensure that the working length of the Endoscope and the actuation cable are advanced and retracted together. Ensure Endcap is fully seated on Endoscope or the endcap can dislodge and cause patient injury.

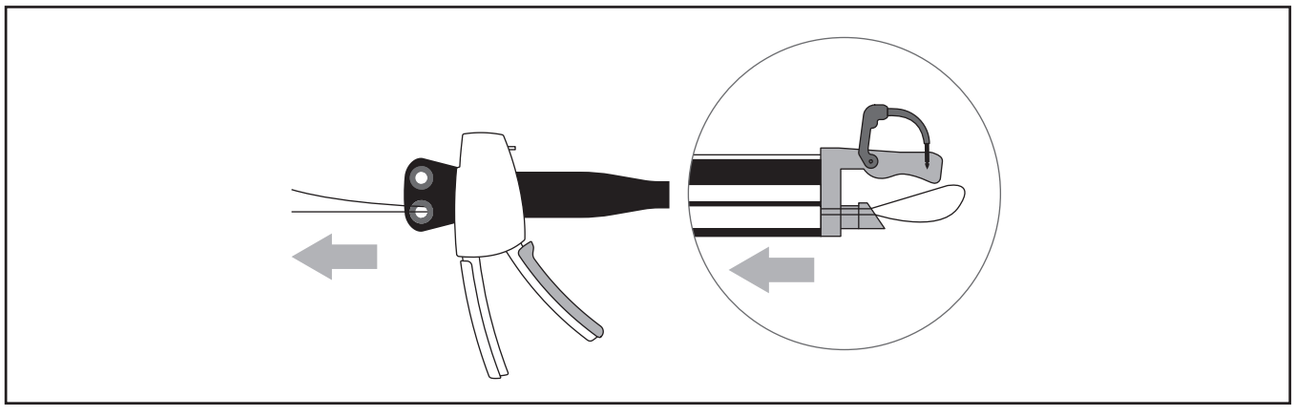
16.2. Open the Needle Body.



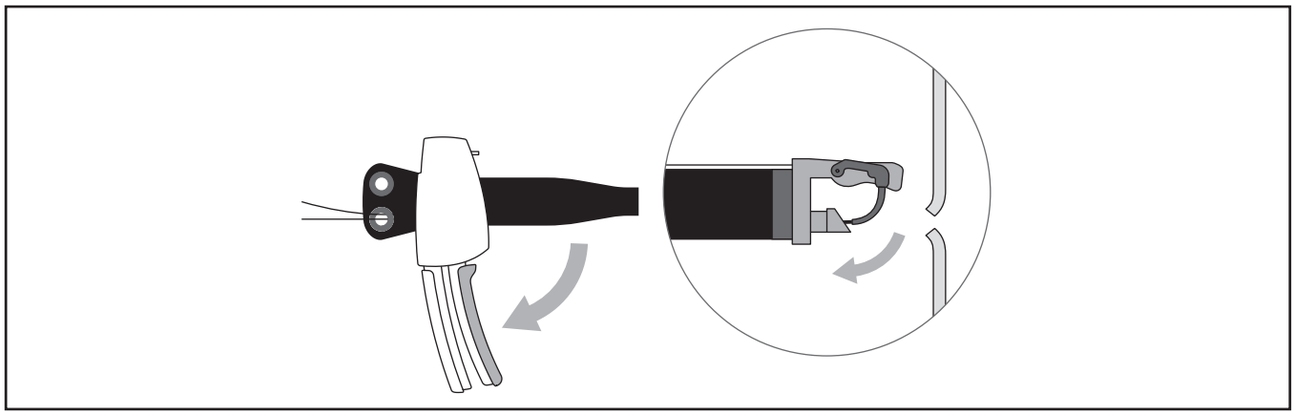
16.3. Advance the Anchor Exchange and/or manipulate the Endoscope to create Suture slack.



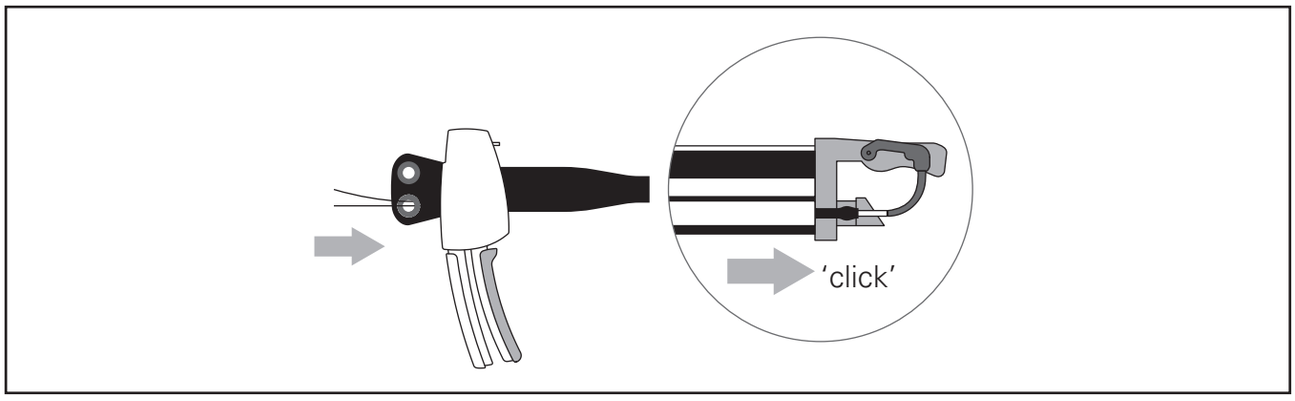
16.4. Once sufficient slack has assessed been created, retract the Anchor Exchange into the Endoscope.



16.5. Close the Needle Body.

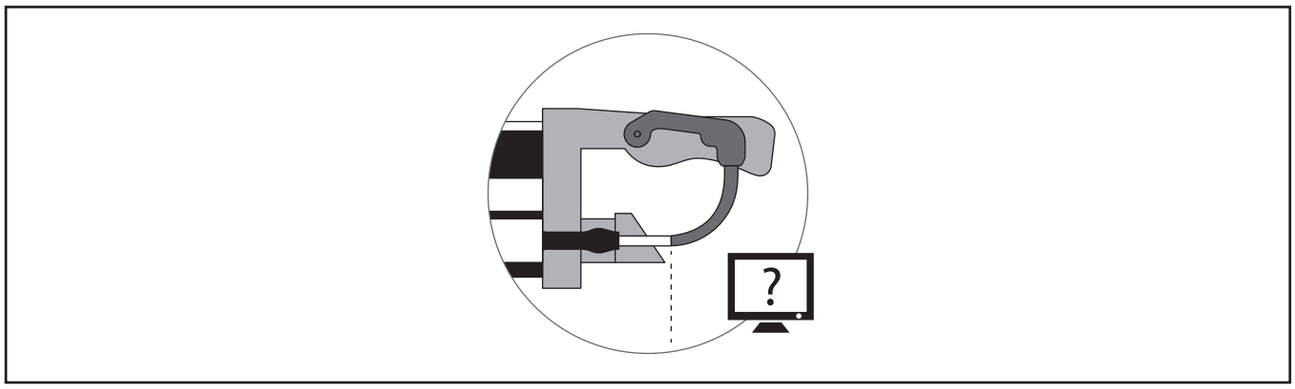


16.6. Using a 'pencil-grip' on the white portion of the cable and placing the remaining fingers of the same hand on the Endoscope housing for optimum control, advance the Anchor Exchange until the Anchor fully seats onto the Needle Body.



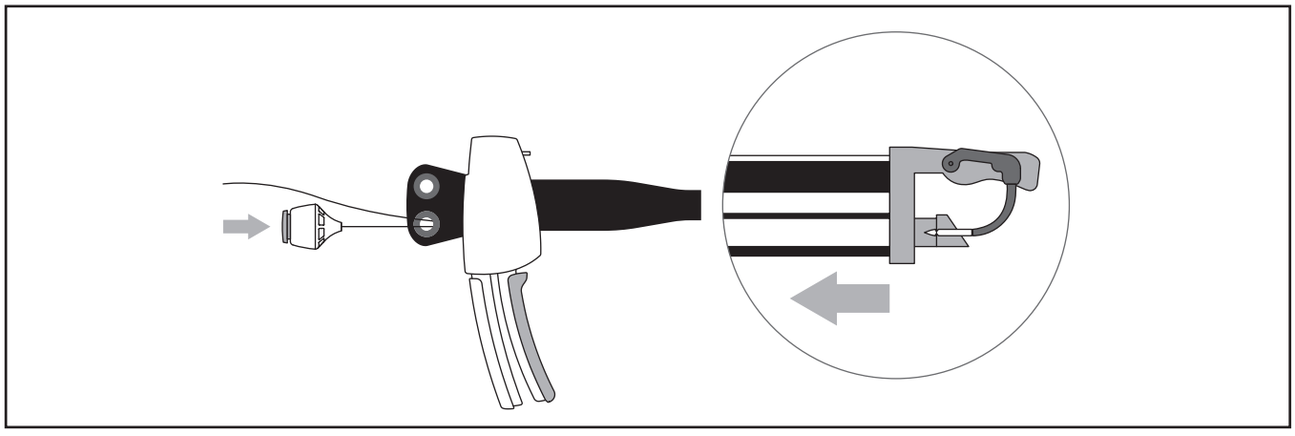
Note: A tactile 'click' or firm stop may be felt as the Anchor seats fully onto the Needle Body.

16.7. Check the monitor image to ensure that the Anchor is properly installed on the Needle Body.

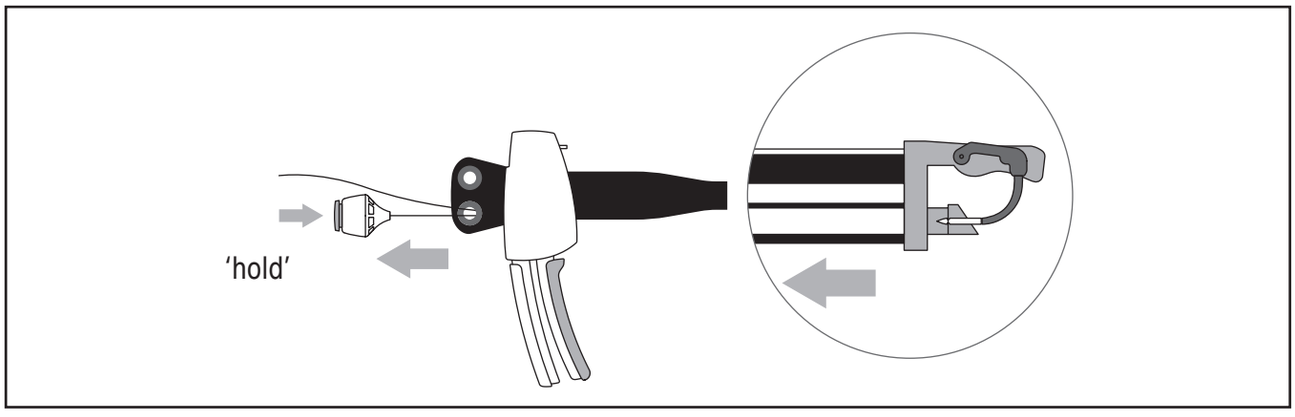


16.8. Ensure that the proximal end of the Suture is visible beyond the Endoscope channel valves.

16.9. Fully depress Anchor Release Button to release Anchor.



16.10. With the Anchor Release Button still fully depressed, using a 'pencil-grip' on the white portion of the cable and placing the remaining fingers of the same hand on the Endoscope housing for optimum control, slightly retract Anchor Exchange until it is just inside the Endoscope working channel.



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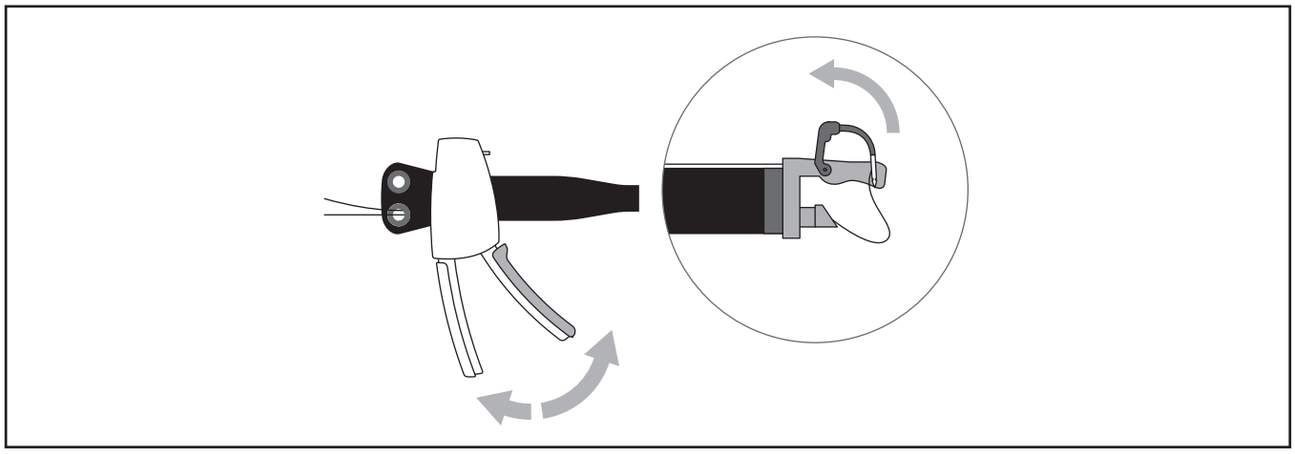
17. TISSUE AND SUTURE MANAGEMENT

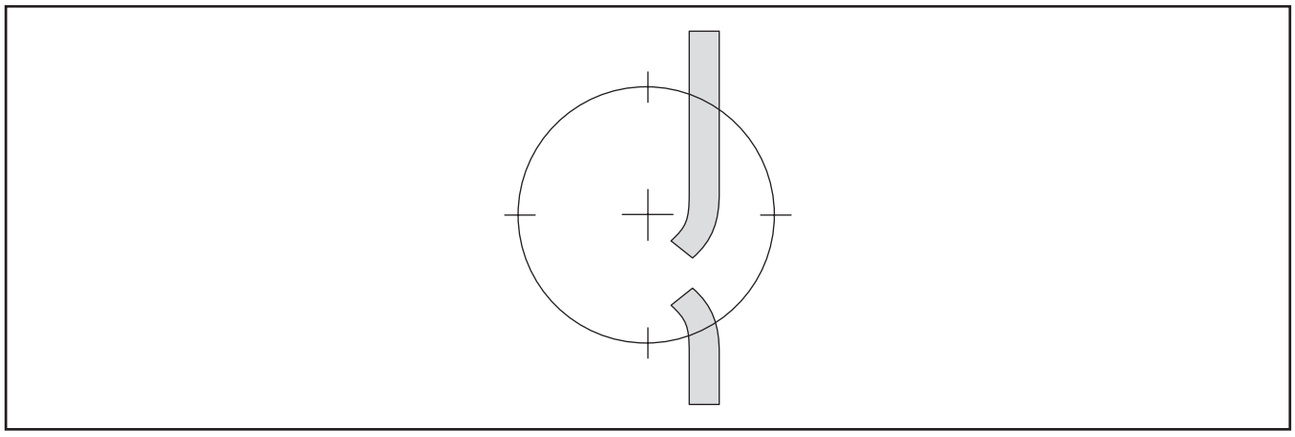
17.1. Open the Needle Body.



Caution: If the Needle Body does not open, ensure that the Anchor has been released from the Anchor Exchange.

Warning: Ensure that appropriate Suture slack has been created for the desired Suture path and pattern. Advance Anchor Exchange and/or manipulate Endoscope to create Suture slack. Not doing so could result in suture breakage or patient injury.

17.2. Position tissue in the appropriate location for suturing, using Tissue Helix or Endoscope compatible accessory if required.

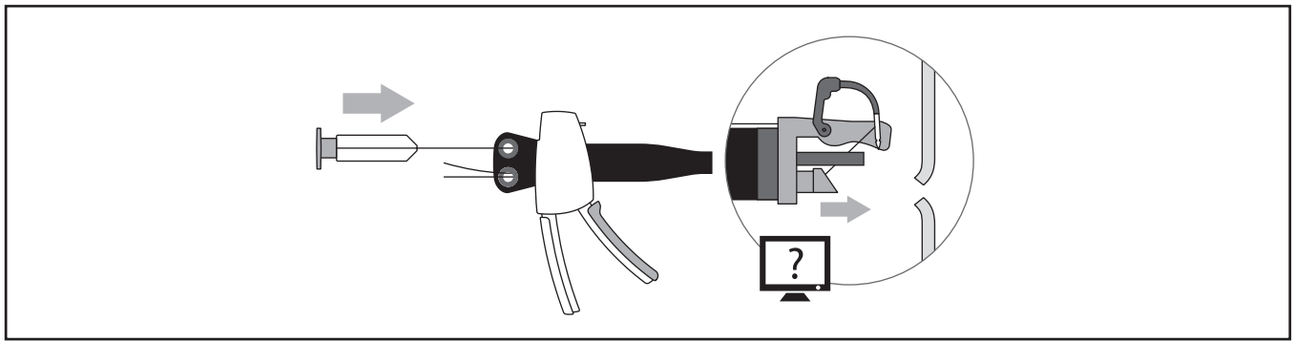


Caution: The NXT Tissue Helix Pro is only compatible with OverStitch NXT and should not be inserted within the channel of the Endoscope.

18. USE OF TISSUE HELIX (OPTIONAL FOR DEFECT CLOSURE BUT REQUIRED FOR ENDOSCOPIC SLEEVE GASTROPLASTY AND TRANSORAL OUTLET REDUCTION)

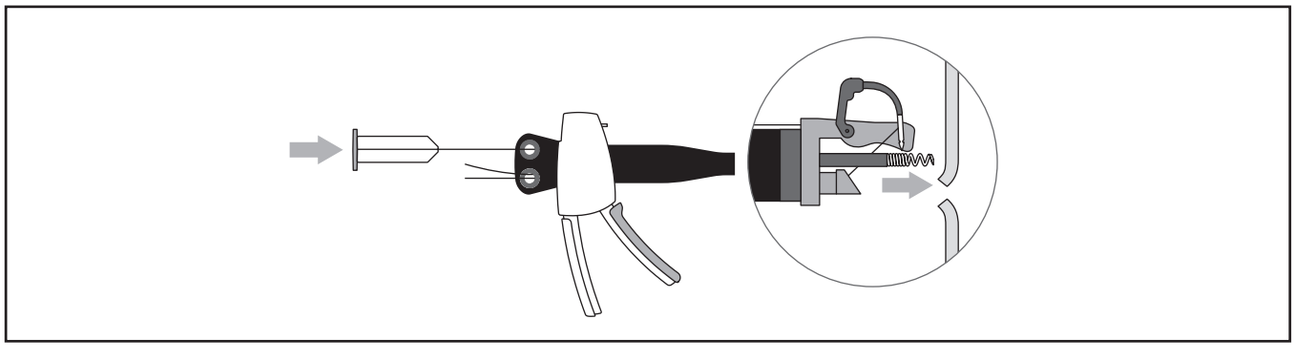
18.1. Remove the Tissue Helix from the packaging.

18.2. Advance the Helix into the secondary channel of the Endoscope, while in the retracted position, until distal tip is visible on the monitor.



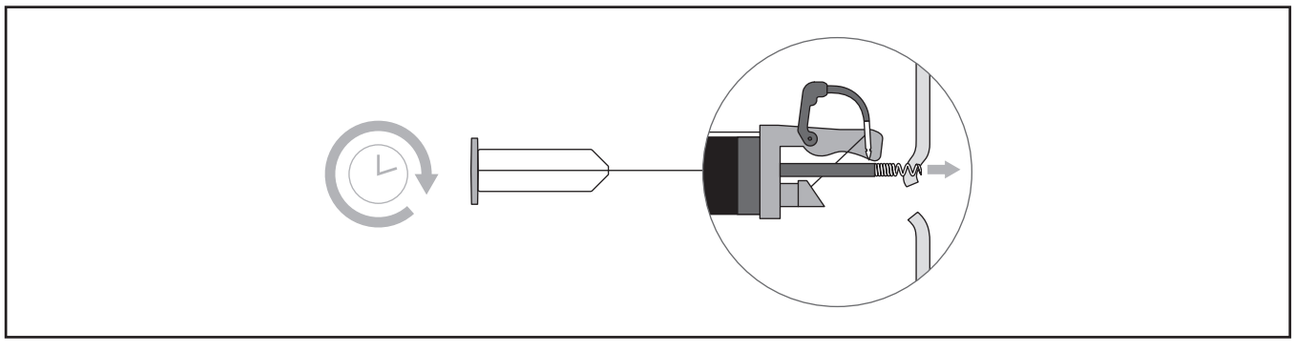
Caution: If resistance is encountered when advancing the Helix through the working channel of the Endoscope, reduce the Endoscope angulation until the device passes smoothly, and ensure that the secondary working channel is not obstructed on the Endoscope.

18.3. Fully depress the Helix Handle button to expose the Helix Tip.



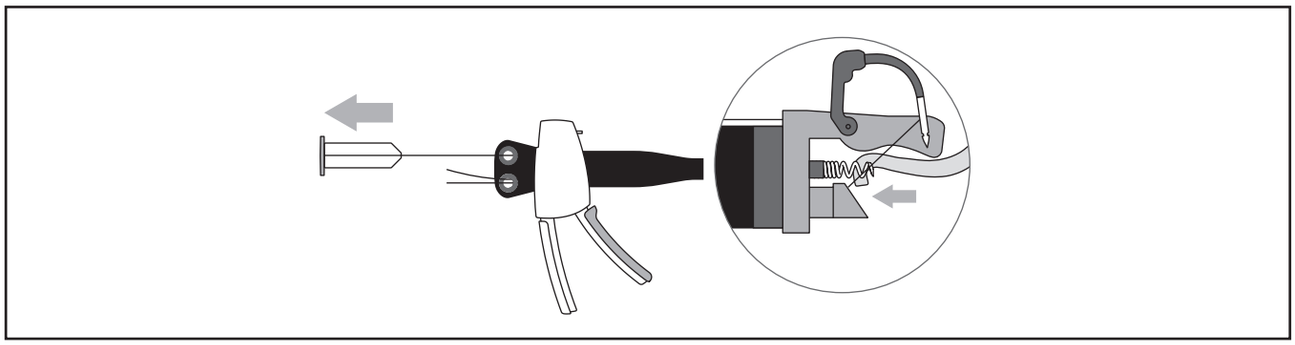
Caution: Do not depress the Helix Handle button while advancing the Helix through the Endoscope, otherwise the tip of the helix may damage the lining of the endoscope channel.

18.4. Acquire tissue by rotating the Helix Handle clockwise until the correct tissue depth is achieved.



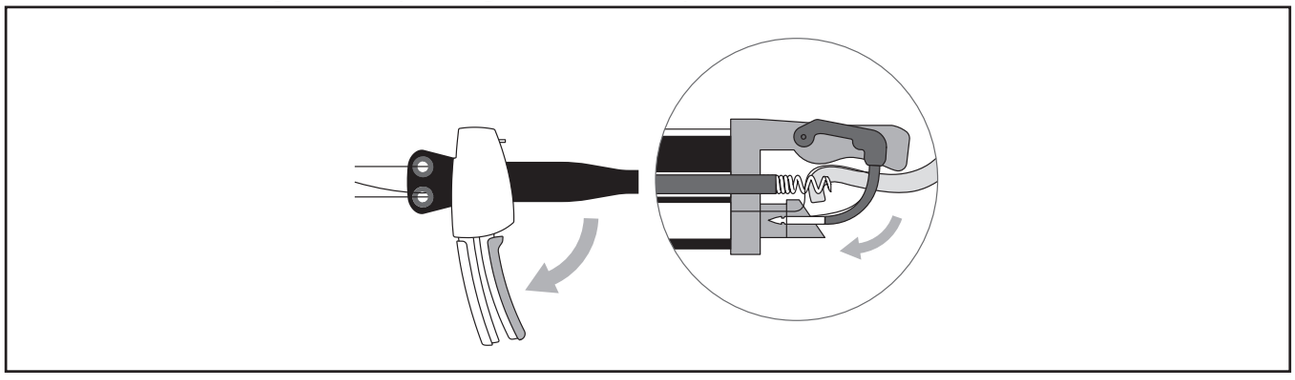
Note: Maintain gentle forward pressure during tissue acquisition.

18.5. Advance / retract the Helix to position tissue into the desired location.



19. SUTURING

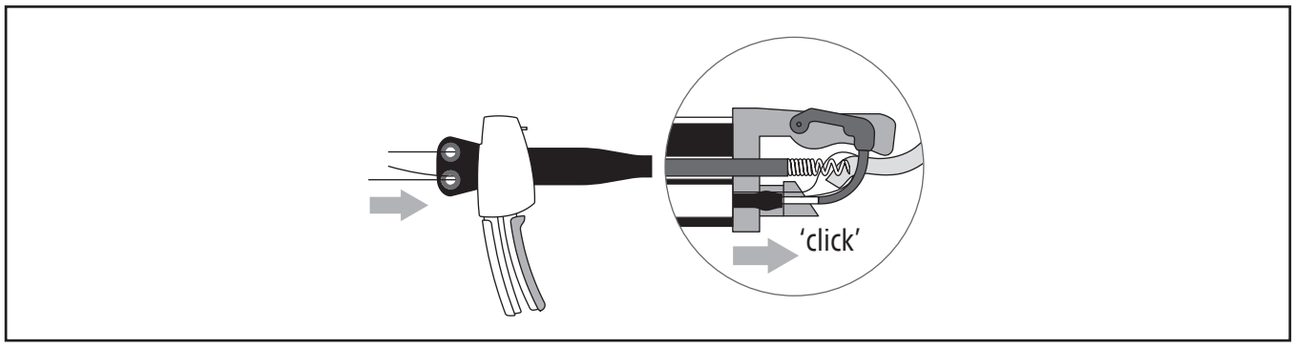
19.1. Drive the Needle through tissue by closing the Needle Body.



Caution: Ensure that the Needle Arm does not inadvertently close on any foreign object or device. Doing so may damage the device.

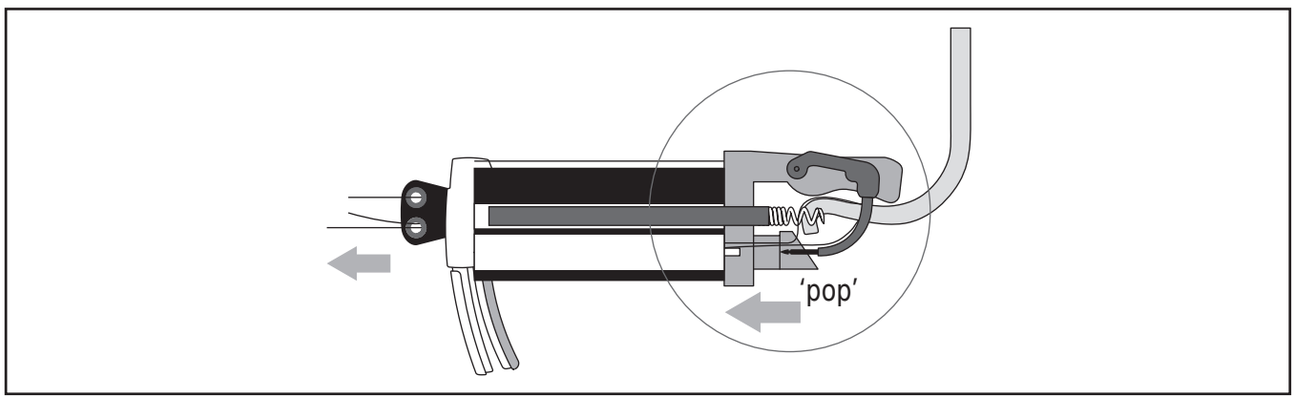
Retrieve Anchor

19.2. Use a 'pencil-grip' to advance the Anchor Exchange until the Anchor is engaged and resistance is felt.



Note: Resistance may vary due to the position of the Endoscope.

19.3. Retract the Anchor Exchange in order to acquire the Anchor.



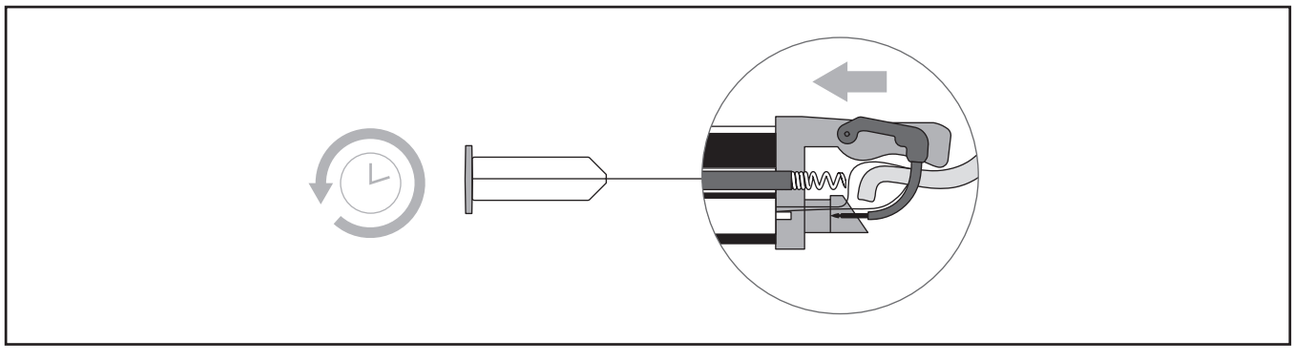
Warning: Use a 'pencil-grip' on the white section of the cable and place the remaining fingers of the same hand on the Endoscope housing to prevent damage to the Suture or tissue once the Anchor 'pops' off the Needle Body.

Caution: Do not press the Anchor Release Button, as this may cause an inadvertent drop of the Anchor.

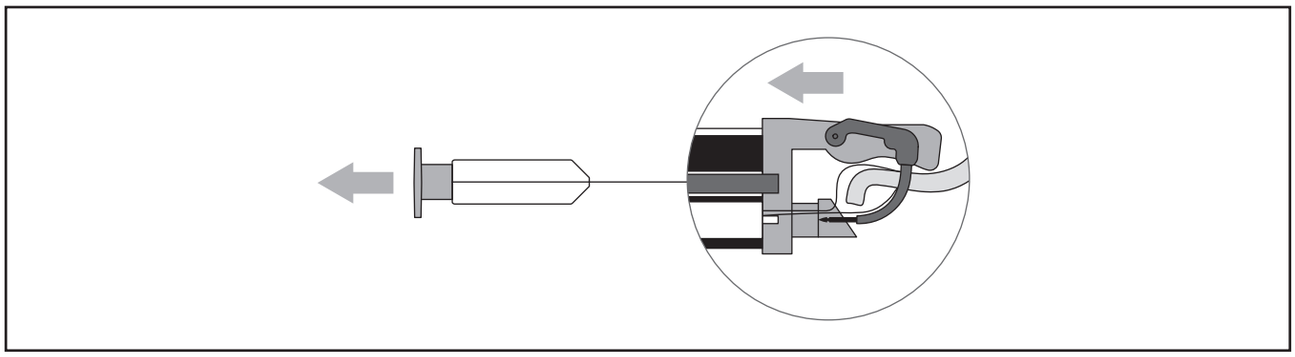
Warning: If sufficient slack has not been created prior to driving the Anchor through tissue, retraction of the Anchor Exchange may be difficult and the Anchor may not release correctly from the Needle Body. This may result in prolonged procedure time following Troubleshooting steps in Section 25. If Troubleshooting is unsuccessful, additional intervention may be required.

Release Tissue

19.4. Rotate the Helix handle counter-clockwise until the device is free from tissue.

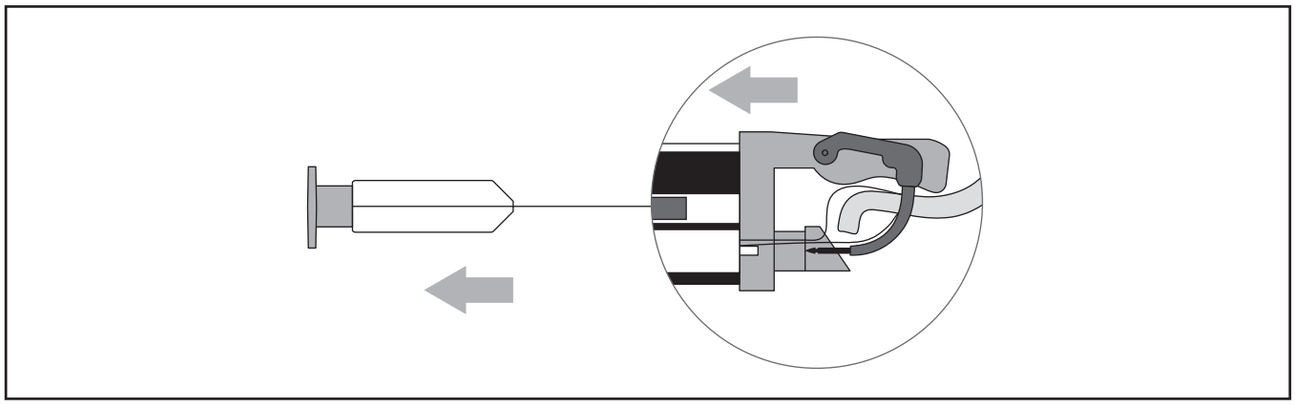


19.5. Return the Helix handle button.

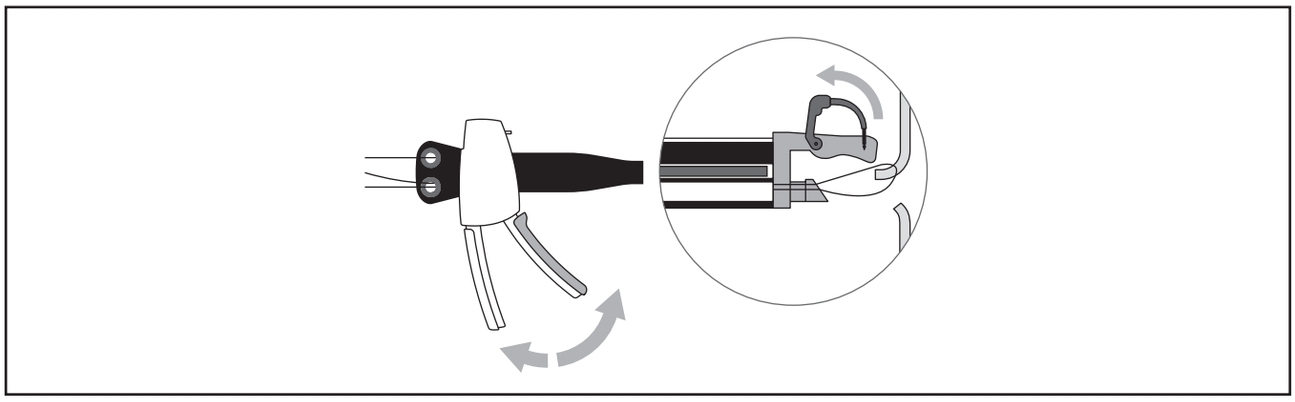


Caution: Check the monitor to ensure that the tip of the helix is fully retracted within its shaft before withdrawing into Endoscope. Failure to retract the tip could cause damage to the endoscope channel.

19.6. Withdraw the Helix a short distance within the Endoscope.



19.7. Open the Needle Body.



Caution: Do not tension the Suture with the Anchor in the Needle Body. This could result in inability to complete suture sequence or suture breakage.

19.8. To **continue** placing stitches with this Anchor, repeat **sections 16-19**.

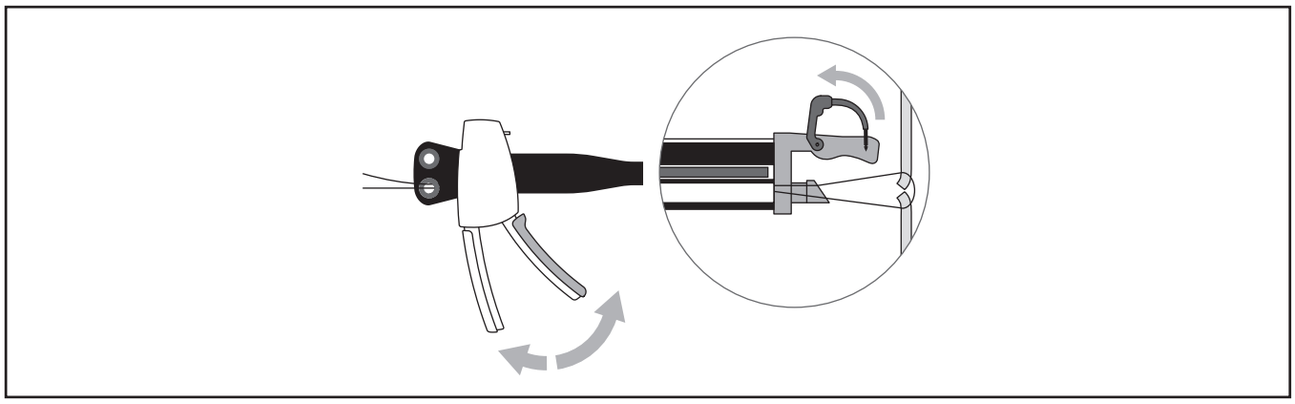
19.9. If stitching is **complete** for this Anchor, proceed to **section 20** to approximate tissue, secure and cut the Suture.

Note: Multiple Anchors can be utilized with each Needle Driver and Anchor Exchange.

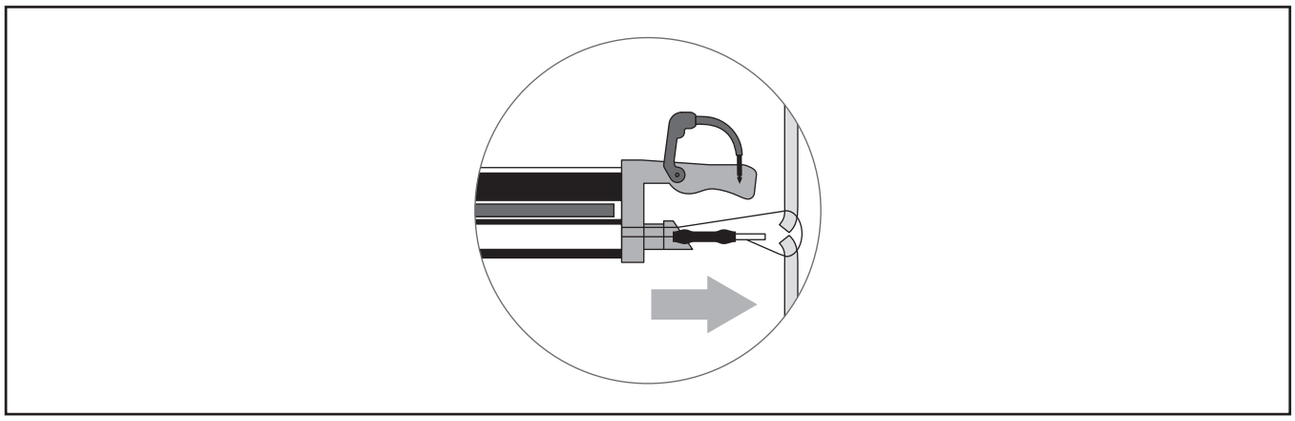
20. SECURING AND CUTTING SUTURE

20.1. Remove accessories (Tissue Helix or similar) from Endoscope.

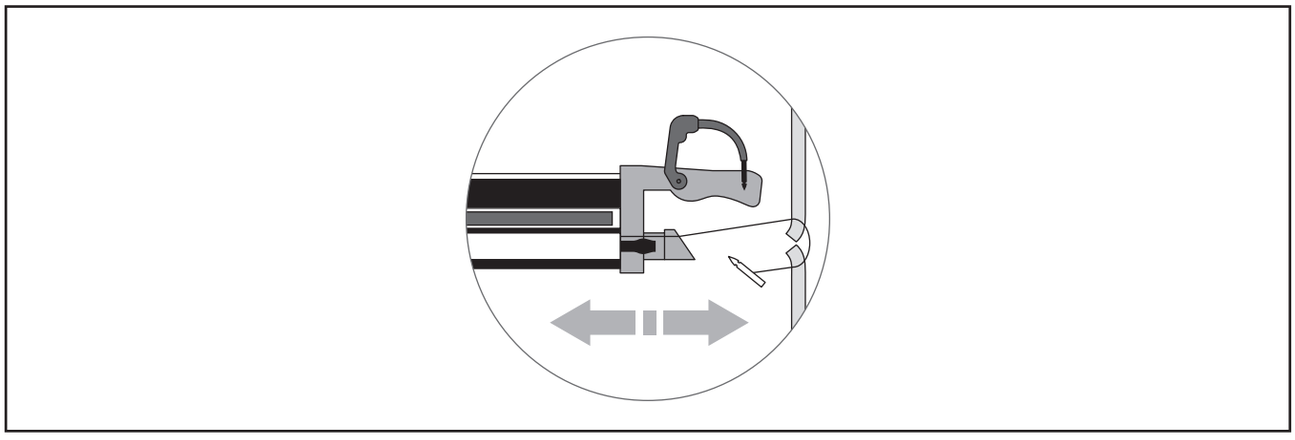
20.2. Ensure the Anchor is in the Anchor Exchange and open the Needle Body.



20.3. Advance the Anchor distal of the alignment tube.

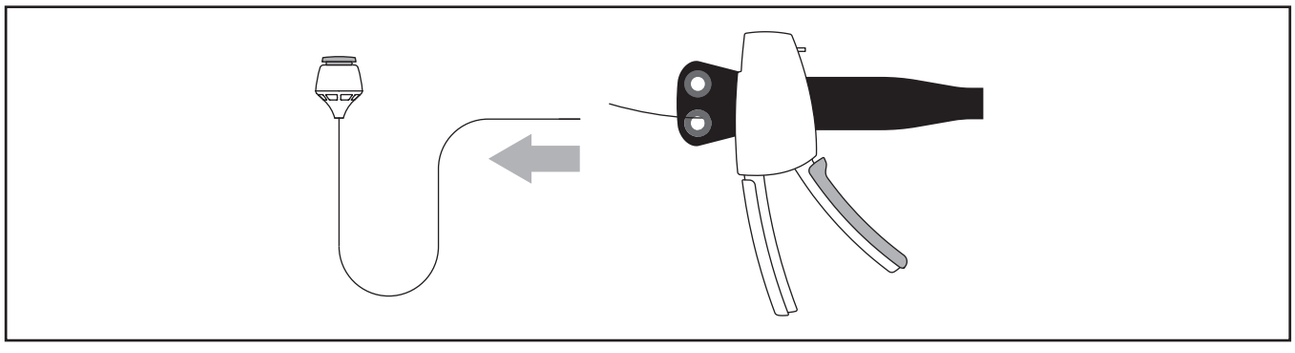


20.4. Fully depress the Anchor Release Button and retract the Anchor Exchange to release the Anchor.



Caution: Do not release the Anchor inside the Endoscope's working channel. Doing so may cause damage to the scope.

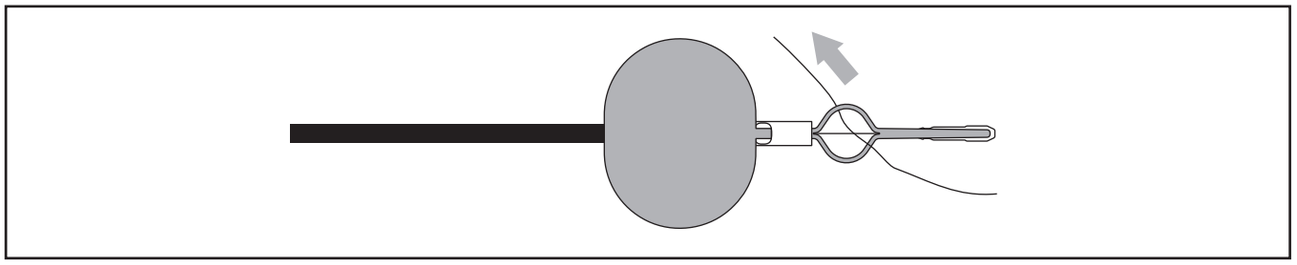
20.5. Remove the Anchor Exchange from the Endoscope.



Note: The Anchor Exchange can be utilized for additional sutures.

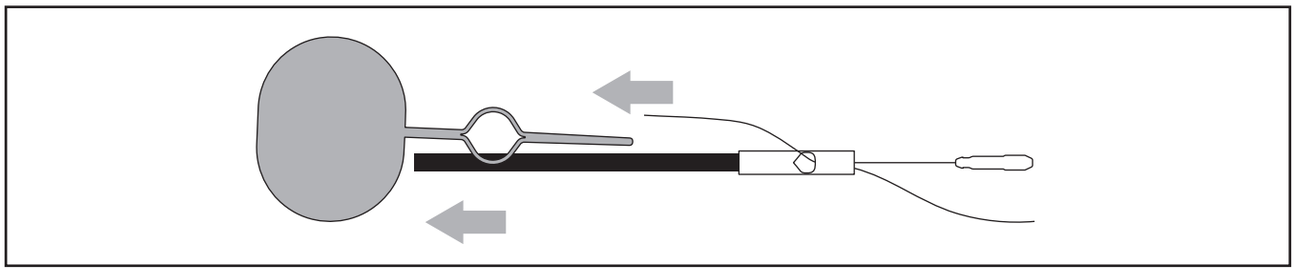
20.6. Remove the Cinch from its packaging.

20.7. Feed the proximal end of the Suture into the removable Suture Loading Loop.

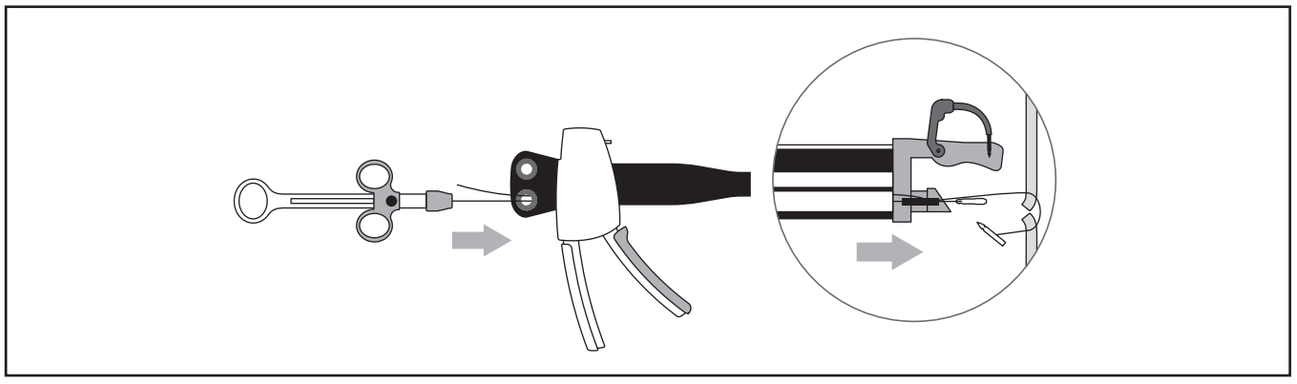


20.8. After threading, release the proximal end of the Suture to enable loading.

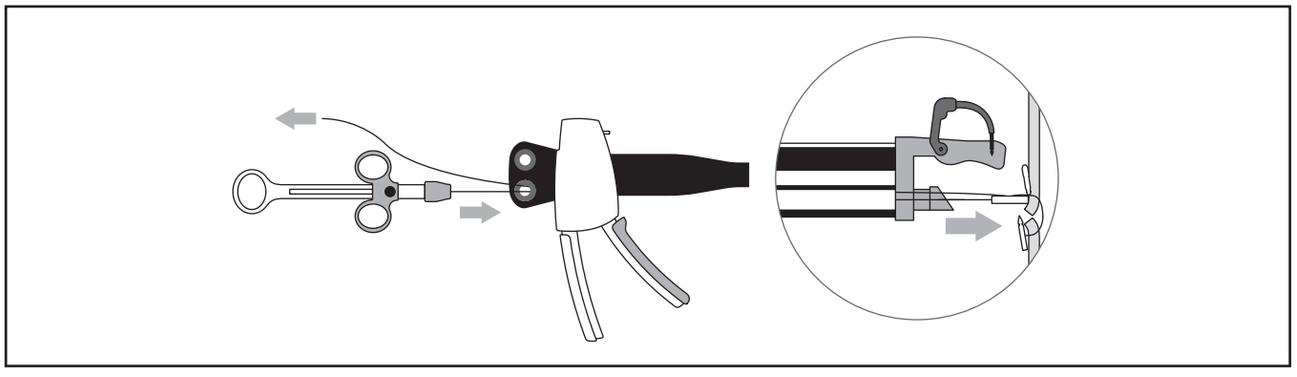
20.9. Pull the Suture Loading Loop parallel to the device in order to pull the Suture into the Cinch.



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



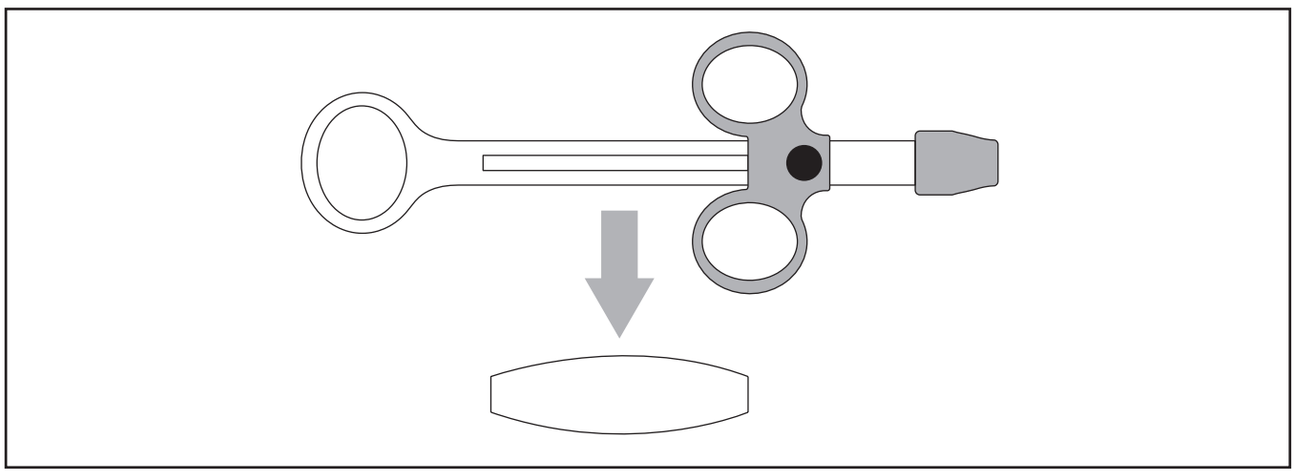
20.11. Pull the Suture and apply counter traction to the Cinch until the tissue is approximated and the desired Suture tension is achieved between the Anchor and the Cinch Collar.



Note: It is the Collar that sets the final position of the Cinch, not the Plug.

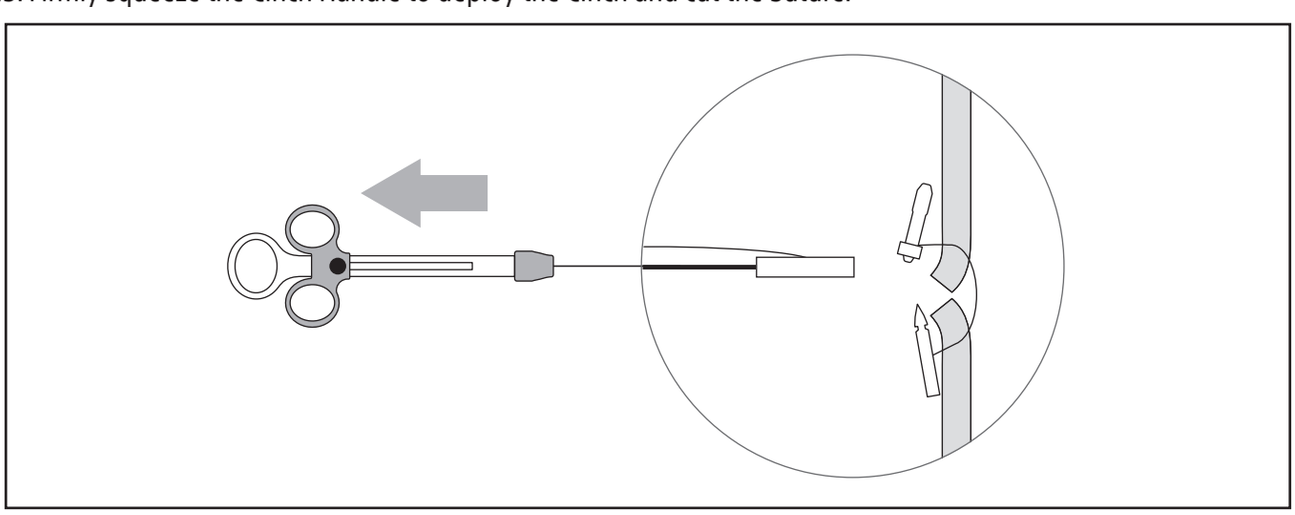
Warning: Excessive tension may damage tissue and/or damage/break the suture.

20.12. Remove the safety spacer from the Cinch handle while maintaining Suture tension.



Caution: The safety spacer must only be removed immediately prior to deploying Cinch in order to avoid inadvertent suture cutting.

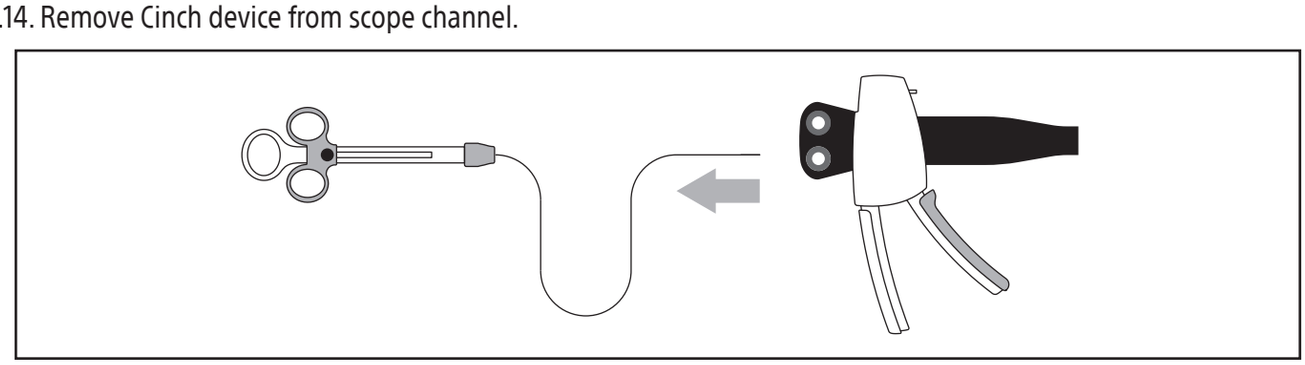
20.13. Firmly squeeze the Cinch Handle to deploy the Cinch and cut the Suture.



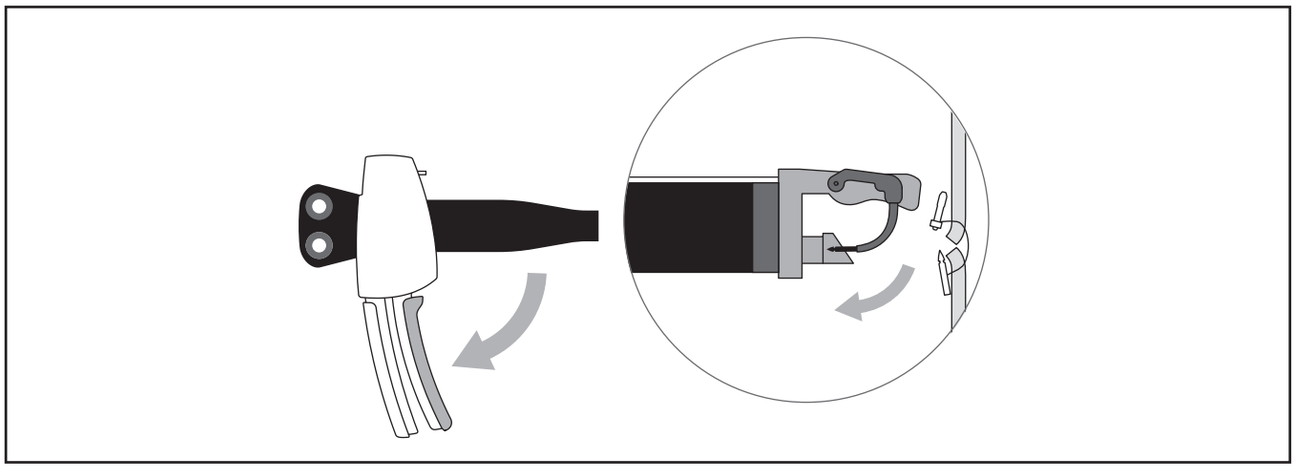
Caution: Suture tension must be maintained during Cinch deployment. Otherwise, tissue approximation may be lost.

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. Do not over deploy Cinch-only squeeze the handle until the Suture is cut.

20.14. Remove Cinch device from scope channel.



20.15. Close the Needle Body.



21. MULTIPLE SUTURES

21.1. The Anchor Exchange and Needle Driver can be utilized with multiple sutures. Removal of the Endoscope after cinching is not required if further sutures are to be deployed.

Warning: If the Endoscope is removed between stitching for cleaning, ensure the Endcap is fully seated before the next intubation. Reseat if necessary. Otherwise, the Endcap can dislodge and cause patient injury.

Note: If removed and reinstalled, ensure that the secondary working channel is not obstructed on the Endoscope.

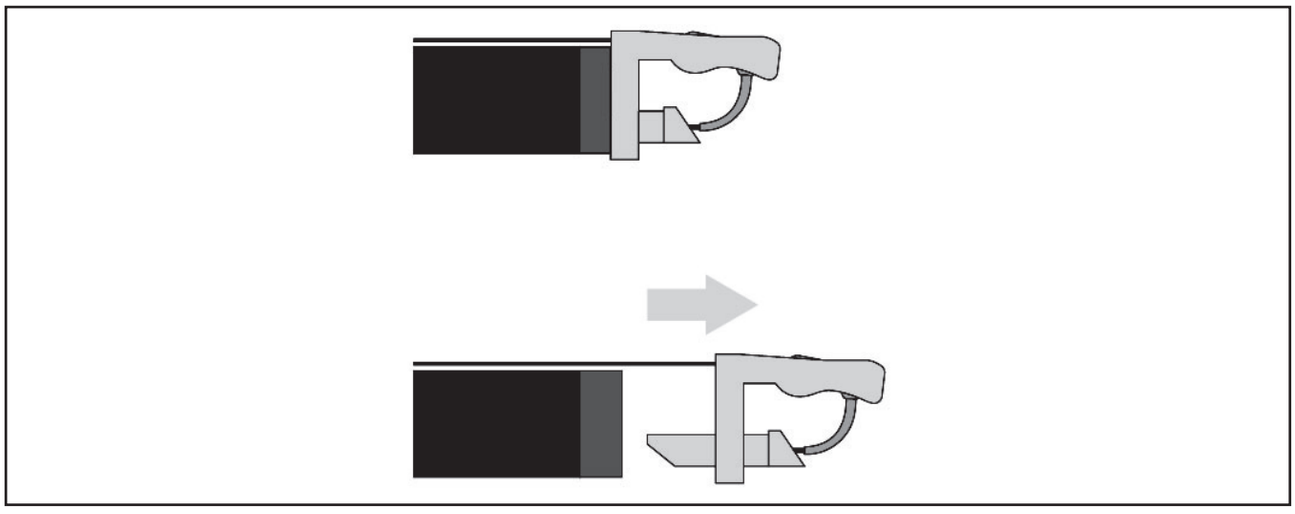
21.2. To use another Suture Assembly, return to **step 15.7** for Anchor loading and follow all subsequent steps. If suturing is complete, proceed to **section 22** for removal of the device.

22. REMOVAL OF DEVICE

22.1. Remove any accessory devices from the Endoscope.

22.2. Ensure the Needle Body is closed and retract the Endoscope from the patient, making sure the external cable is retracted together with the Endoscope.

22.3. Remove the Endcap from the Endoscope.



Caution: Do not hold the Needle Arm when removing the Endcap as this may damage the device.

22.4. Remove the Needle Driver from the Endoscope by flexing the scope attachment bracket around the working channels.

23. MRI SAFETY INFORMATION

MR Conditional

Non-clinical testing has demonstrated that the Sutures, Cinches and Anchors (collectively termed Anchoring System) deployed by the OverStitch Endoscopic Suturing System are MR Conditional.

A patient with this Anchoring System can be safely scanned immediately after placement in an MR system meeting the following conditions:

Static Magnetic Field

- Static magnetic field of 1.5 T or 3.0 T.
- Maximum spatial field gradient of 2,000 gauss/cm (20 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg.

Under the scan conditions defined above, the Anchoring System is expected to produce a maximum temperature rise of less than 2° C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the Anchoring System extends approximately 10 mm from this device when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

Disposal

To minimize the risk of infection or microbial hazards after use, dispose device and packaging as follows:

After use, device may contain biohazardous substances. The device and packaging should be treated and disposed of as biohazardous waste or have them treated and disposed of in accordance with any applicable hospital, administrative, and/or local government regulations. Use of a biohazardous container with biological hazard symbol is recommended. Untreated biohazardous waste should not to be disposed of in the municipal waste system.

This device contains a sharps hazard. Take precautions to ensure that sharps are handled properly. Dispose of all sharps directly into a sharps disposal container labeled with a biological hazard symbol. Sharps waste should be safely disposed of using available sharps waste channels in accordance with hospital, administrative, and/or local government policy.

Post-Procedure

Any serious incident that occurs in relation to this device should be reported to the manufacturer and relevant local regulatory authority.

24. PATIENT COUNSELING INFORMATION

Brief the patient on any relevant post-procedure instructions, contraindications, warnings, precautions and/or adverse events found within this Instructions for Use (IFU), pertaining to the patient.

Implantable Device Patient Information

Advise the patient that additional information may be available to them on the Boston Scientific website (www.bostonscientific.com/patientlabeling).

25. TROUBLESHOOTING

25.1. Needle Body will not open:

Cause	Resolution
25.1.1. Needle obstructed:	i. Assess the space in which you are working and maneuver the catheter and Endoscope as a system. Straighten the Endoscope to the non-Retroflexed position.
25.1.2. Suture movement restricted:	i. If the Anchor is on the Needle Body, ensure the suture is not held proximally near the handle during the opening operation. ii. Transfer the Anchor to the Anchor Exchange. Open the Needle Body. Slowly retract the Anchor Exchange proximally and then advance the Needle Body distally to free the Suture.

25.1.3. Needle Driver catheter looped or kinked:	i. Check to ensure that the catheter running down the outside of the Endoscope is not looped or kinked. Straighten the Endoscope to the non-Retroflexed position. Advance the Endoscope forward and slightly pull any slack from the actuation cable proximally until minimal resistance is felt. Grasp both the actuation cable and Endoscope and adjust by advancing and retracting as a system.
25.1.4. Foreign body obstruction:	i. Remove the Anchor Exchange only: a. Transfer the Anchor to the Needle Body and remove the Anchor Exchange from the Endoscope. b. Load a grasper through the primary channel and push the Needle Body open. ii. Remove the Anchor and Anchor Exchange, cutting the Suture if necessary: a. Transfer the Anchor to the Needle Body and remove the Anchor Exchange from the Endoscope. b. Through either channel, use an appropriate accessory to cut the Suture. c. Use an accessory to push open the Needle Body d. Use appropriate means to remove the cut Suture. iii. Once standard endoscopic techniques have been exhausted, utilize laparoscopic techniques to remove the device.
25.1.5. Needle Driver actuation cable broken:	i. Deploy the Anchor and Cinch. Advance grasper through endoscope and secure Needle Driver. Pull Needle Driver closed while removing the device. a. If using an overtube, advance the overtube as far distally as possible and withdraw the endoscope and device into the overtube, using the distal tip of the overtube to close the Needle Body.

25.2. Needle Body will not close:

Cause	Resolution
25.2.1. General obstruction:	i. Follow steps 25.1.1, 25.1.2, 25.1.3 above (Needle Body will not open). ii. Ensure the Needle Driver handle is locked closed and: a. Pull the Needle Driver actuation cable proximal to change the length of the Needle Body drive cable. b. Remove the Anchor Exchange and use graspers (through the primary channel) to grab the Needle Body. Cut the Suture if necessary.
25.2.2. Needle Driver cable broken:	i. Deploy the Anchor and Cinch. Advance grasper through endoscope and secure Needle Driver. Pull Needle Driver closed while removing the device. a. If using an overtube, advance the overtube as far distally as possible and withdraw the endoscope and device into the overtube, using the distal tip of the overtube to close the Needle Body.

25.3. Anchor Exchange will not exchange:

Cause	Resolution
25.3.1. Anchor Exchange will not install Anchor onto the Needle Body:	i. Ensure there is sufficient Suture slack and the Suture outside Endoscope is not entangled. ii. Ensure Anchor Exchange is properly positioned in alignment tube of Needle Driver. iii. If Anchor and Suture are through tissue, either drop Anchor and deploy Cinch per Section 20 of Instructions for Use or drop Anchor and use a suitable accessory to cut and remove the Suture. iv. If Anchor and Suture are not through tissue, close handle of Needle Driver. Remove Endoscope. Replace Anchor and/or Anchor Exchange.

25.3.2. Anchor Exchange will not release an Anchor:	i. Ensure there is sufficient Suture slack and the Suture outside Endoscope is not entangled. ii. Ensure the Anchor Exchange Release Button is FULLY depressed while retracting Anchor Exchange. iii. Reduce the articulation / tortuosity of the Endoscope (if possible) and try to release the Anchor. iv. Use accessories compatible with Endoscope secondary working channel to cut and remove the Suture. v. Replace the Anchor Exchange.
25.3.3. Anchor Exchange will not retrieve Anchor from Needle Body:	i. Replace the Anchor Exchange. Alternatively, use a suitable accessory to cut and remove the Suture. Replace the Anchor and resume suturing per Section 19 of Instructions for Use. ii. Remove the Anchor Exchange from the working channel. Using a suitable accessory in the working channel, partially close the Needle Body and pull Anchor off. If Anchor cannot be pulled off, proceed to cut and cinch Suture. Replace the Anchor and resume suturing per Section 19 of Instructions for Use.

25.4. Cinch does not cut the Suture when fired:

Cause	Resolution
25.4.1. Suture not cut:	i. Use a suitable accessory through the secondary working channel to cut the Suture and remove the Cinch and/or Suture.

25.5. Inadvertent drop of Anchor:

Cause	Resolution
25.5.1. Anchor Exchange button depressed out of sequence:	i. Retrieve the Anchor as a foreign body or follow the procedure to Cinch in place. If the Anchor is dropped inside the working channel, use the Anchor Exchange or 3.2 mm compatible grasper to push the Anchor out through the Endoscope. ii. DO NOT attempt to pull the Anchor back through the Endoscope as it may get stuck in the channel or y-junction at the Endoscope handle.

25.6. Suture entanglement:

Cause	Resolution
25.6.1. Suture outside field of view:	i. Close the Needle Driver Handle and manipulate the Endoscope back to release.
25.6.2. Suture behind Tissue Guard:	i. Slightly close the Needle Body while retracting the Endoscope. ii. If necessary, transfer the Anchor to the Anchor Exchange. iii. Open the Needle Body and advance the Anchor Exchange beyond the Endcap to push the Suture free.
25.6.3. Suture twisted:	**Note:** If the twist was noted immediately after articulation of the Endoscope, first try to articulate in reverse order to remove. i. If the Suture is twisted, move the Endoscope and transfer the Anchor between the Needle Body and Anchor Exchange, on the opposite side of the suture thread, as needed to untwist. ii. If the Anchor has been deployed, use the Cinch to push and guide the Suture free.

25.7. Endcap detachment from Endoscope:

Cause	Resolution
25.7.1. Pushed off during use:	i. Close the Needle Body. Using a rat-toothed grasper, capture the alignment tube "zigzag" cutout and remove any slack in the Actuation Cable and slowly remove the device from the patient. a. If using an overtube, advance the overtube as far distally as possible, withdraw the endoscope and device into the overtube, and remove all devices as one unit.

25.8. Helix does not unscrew:

Cause	Resolution
25.8.1. Helix stuck in tissue:	i. Use a suitable accessory through the primary channel to apply counter traction to the tissue around the Helix and pull the Helix free. ii. Once endoscopic techniques have been exhausted, utilize laparoscopic techniques to remove the Helix.

26. WARRANTY

For device warranty information, visit (www.bostonscientific.com/warranty).

27. SYMBOL DEFINITIONS

Commonly used medical device symbols that appear on the labeling are defined at www.bostonscientific.com/SymbolsGlossary.

28. INSTRUCTIONS FOR USE

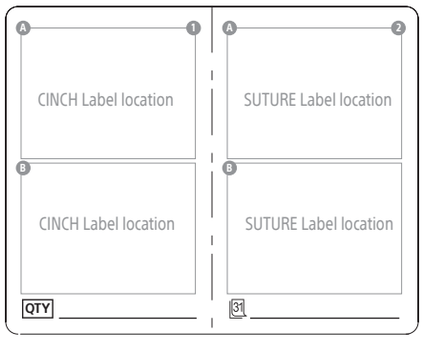
The Instructions for Use (IFU) for this product are supplied in electronic form over the Internet. Visit www.IFU-BSCI.com to access the IFU in Adobe® Portable Document Format (PDF), and be sure to have the product label available for reference. If you have difficulty accessing the IFU online, or would prefer to receive a paper copy, please contact Boston Scientific Customer Service or your local country contact. A copy will be sent to you at no charge and should arrive within seven days.

29. IMPLANT CARD INSTRUCTIONS

Record the institution name, patient details, and implant date. Locate the peel-off labels from the OverStitch 2-0 Polypropylene Suture(s) and Cinch(es) and follow the instructions below.

Place the Suture peel-off on the implant card face identified with the number '1' in the spot identified with the letter 'A'. This card can accommodate two distinct lots of Sutures. If all sutures are from the same lot then one peel-off is sufficient. STOP and draw a line through the 'B' position to indicate that only one lot of Suture was implanted. If a second lot is used, locate a peel-off from a Suture within that lot and apply it to the 'B' position on the card. Record the total number of Sutures implanted in the 'QTY' field.

Place the Cinch, also called Suture Cinch, on the implant card face identified with the number '2'. This card can accommodate two distinct lots of Cinches. If all Cinches are from the same lot then one peel-off is sufficient. STOP and draw a line through the 'B' position to indicate that only one lot of Cinches was implanted. If a second lot is used, locate a peel-off from a Cinch within that lot and apply it to the 'B' position on the card. Record the total number of Cinches implanted in the 'QTY' field.



Provide completed implant card to patient.

Table 1. Symbol Definitions

	Contents
	For Use with
	Gastric

REF

Boston Scientific Legal Manufacturer	Apollo Legal Manufacturer
M00505400 OverStitch Endoscopic Suture System 1pk	ESS-G02-160
M00505441 OverStitch 2-0 Polypropylene Suture 12pk	PLY-G02-020-APL
M00505540 OverStitch Suture Cinch 1pk	CNH-G01-000
M00505470 OverStitch Tissue Helix 1pk	THX-165-028

AR REP

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link bostonscientific.com/arg

AU REP

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY NSW 1455 Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

EC REP

Boston Scientific Limited
Ballybrit Business Park
Galway IRELAND

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752 USA
USA Customer Service +1-888-272-1001

www.bostonscientific.com

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