OverStitch NXT™

Endoscopic Suture System

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℞ 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 sterilize. Reuse, reprocessing or sterilization 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 sterilization 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 NXT Endoscopic Suturing System is a sterile, single use device that is used with single channel endoscopes for the endoscopic placement of suture(s) and approximation of soft tissue including Endoscopic Sleeve Gastroplasty (ESG) and bariatric revision procedures. The OverStitch NXT 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) or NXT Tissue Helix Pro (NXT Helix) can be used to manipulate and position tissue in a way that facilitates the desired suture placement, and the Suture Cinch provides a means for securing and cutting the suture once placement is complete.

2.1 Description of the Endoscopic Sleeve Gastroplasty (ESG) Procedure

Endoscopic Sleeve Gastroplasty is an endoscopic procedure that involves the creation of plications in the stomach, through a series of stacked suture-based plications, to reduce stomach volume. The plications form a sleeve, which reduces stomach capacity and slows gastric emptying. Over time, there will be scarring and bridging tissue to maintain the reduced gastric volume. Patients receiving ESG should be advised to adopt a healthy lifestyle including proper diet and exercise.

The mechanism of action of ESG is a reduction in stomach volume. Data from a subset of the MERIT Trial patients indicate that ESG is also associated with a delay of gastric emptying, which may alter appetite related regulatory pathways.

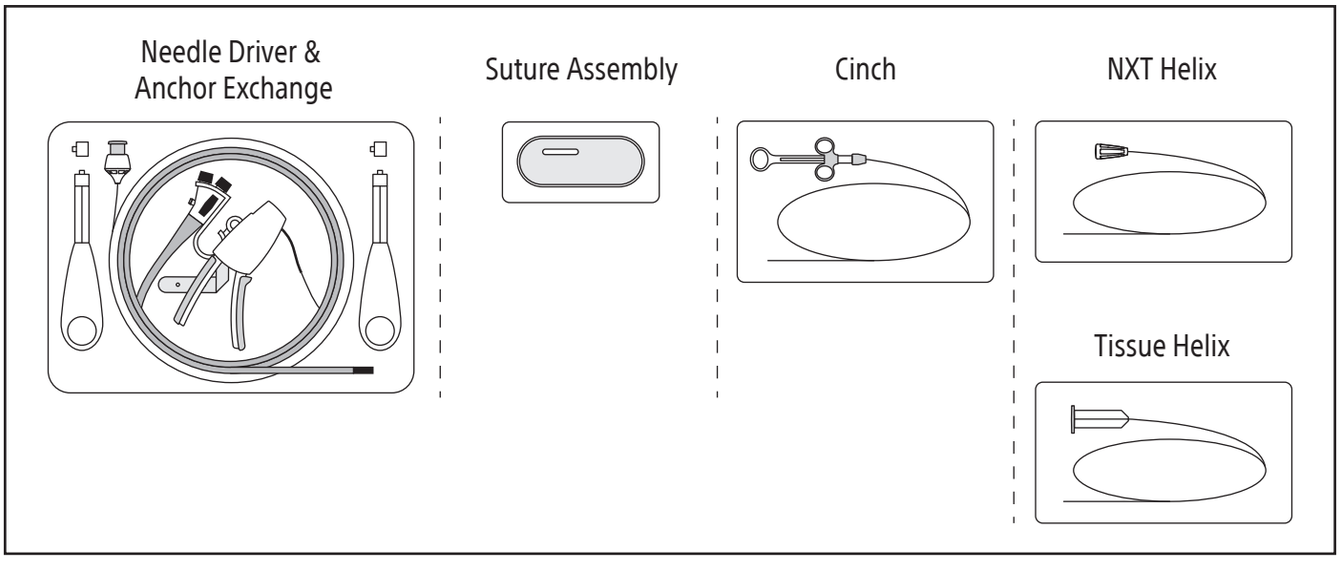
In some cases, the plications can fail and come apart. This is most likely to occur with sutures that were not placed "full-thickness" or through sutures breaking over time. This may compromise the effectiveness of the sleeve and patients may report a loss of satiety. In such cases, the sleeve can be revised with new plications or converted to a laparoscopic sleeve gastrectomy, or LSG. See Section 16 for additional information on this procedure.

BSC (MB eIFU Template 8.2677 x 11.6929 A4, 925243241), eIFU, MB, OverStitch NXT US only, en, 51931761-01A

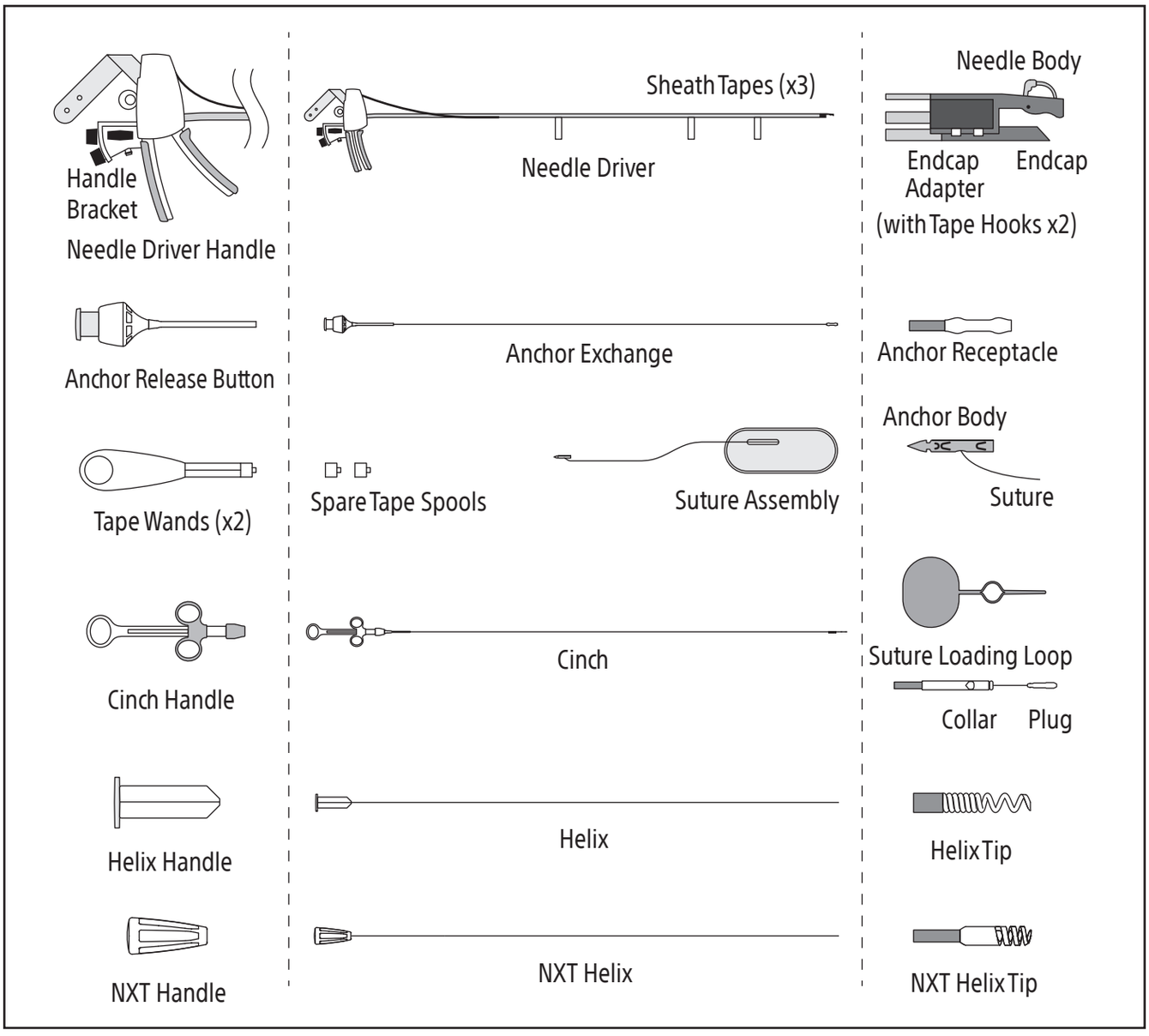
2.2 Description of the Bariatric Revision Procedures

Revision procedures are indicated when a patient who undergoes an initial bariatric procedure loses weight, but then reports a loss of satiety, and begins to regain weight. This can be due to dilation of the gastric outlet following gastric bypass or a previous gastric sleeve. The OverStitch NXT Endoscopic Suturing System is used to perform Transoral Outlet Reduction (TORe) (applying 1 or 2 suture-anchors to reduce the size of the outlet) and is often combined with the placement of 1 to 4 suture-anchors in the stomach to reduce a dilated pouch. See Section 17 for additional information on this procedure.

3. CONTENT



4. NOMENCLATURE



5. OPERATING PRINCIPLE

The OverStitch NXT Endoscopic Suturing System (OverStitch NXT Device) consists of the Needle Driver Assembly and the Anchor Exchange. The OverStitch NXT Endoscopic Suture System functions by delivering a proprietary Anchor and Suture through the Anchor Exchange channel of the OverStitch NXT Device. 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 NXT Helix channel of the OverStitch NXT Device 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 Anchor Exchange 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 NXT 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 NXT Endoscopic Suturing System (ESS) is intended

- for endoscopic placement of suture(s) and approximation of soft tissue.
- to be used by trained gastroenterologists or surgeons that perform bariatric procedures to facilitate weight loss by reducing stomach volume through endoscopic sleeve gastroplasty in adult patients with obesity with BMI between 30-50 kg/m^2 who have not been able to lose weight, or maintain weight loss, through more conservative measures.
- to be used by trained gastroenterologists or surgeons that perform bariatric procedures to facilitate weight loss in adult patients with obesity with BMI between 30-50 kg/m^2 by enabling transoral outlet reduction as a revision to a previous bariatric procedure.

Intended Users

The OverStitch NXT 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.

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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.

The following contraindications apply to the use of OverStitch for bariatric procedures:

- Large hiatal hernia.
- Potential bleeding gastric lesions (e.g. ulcers; erosive gastritis; varices; or vascular malformations).
- Affective disorders not under medical supervision or refractory to medical therapy and all eating disorders (e.g. anorexia nervosa; binge eating disorder; specified feeding and eating disorders; avoidant restrictive food intake; rumination).
- Women who are pregnant.
- Coagulopathy and antiplatelet/anticoagulant therapy that cannot be corrected.

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 or NXT Tissue Helix Pro is recommended to retract the tissue intended to be sutured away from these unseen structures.
- 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.
- 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.
- 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, use the minimum tension necessary. 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. If this occurs, remove the suture and Anchor (if possible).
- Patients who develop significant persistent upper abdominal pain at any time after a procedure, 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.

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.

- Take care when using plasma coagulation marking. Perforation could occur while using plasma coagulation and/or coagulated tissue may slough off later, resulting in delayed gastrointestinal bleeding.
- During a revision procedure, the physician should carefully consider the specific anatomy being revised and the presences of previous devices that may have been placed during the original procedure. Failure to do so may result in patient injury.
- Placing the patient in a supine to modified (semi supine) left lateral decubitus position, creates additional safety margin between the stomach and surrounding structures prevent patient injury.

11. PRECAUTIONS

- With the Endoscopic Suturing System installed, the endoscope's effective outer diameter is increased by approximately 7 mm.
- An overtube with an internal diameter of at least 17.5 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.
- The Tissue Helix must be kept clean from debris during use; this may require periodic debridement of the helix coil during use.

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 NXT 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 NXT ESS is compatible with PLY-G02-020-APL/M00505451 sutures.

The NXT Tissue Helix PRO is only compatible with the device channel of OverStitch NXT ESS.

The system is compatible with Olympus, Fuji, and Pentax reusable gastroscopes having an insertion tube and distal diameter between 8.8 mm and 9.8 mm, a working length up to 110 cm, and using overtubes having an inner diameter of at least 17.5 mm.

Disposable endoscopes have not been evaluated for compatibility.

Device Compatibility:

BSC UPN	Apollo SKU	Description
M00505451	PLY-G02-020-APL	OverStitch 2-0 Polypropylene Suture
M00505460	THX-165-028	Tissue Helix
M00505490	NXT-THXP-130	NXT Tissue Helix Pro
M00505530	CNH-G01-000	OverStitch Suture Cinch
M00505560	OVT-027-160	OverTube Endoscopic Access System

15. ASSEMBLY

15.1 Prepare for Procedure

Warning: Use of an appropriate overtube (with an inner diameter of at least 17.5 mm) is recommended for transoral procedures. Confirm the installed device is of compatible size with overtube prior to use.

When using an overtube with OverStitch NXT, a thorough application of lubricant is recommended prior to intubation. To achieve adequate coverage, generously apply lubricant to the proximal opening of the overtube. Transfer this lubricant along the full length of the overtube's inner walls by fully inserting the endoscope through the lubricated overtube, while rotating it multiple times.

Warning: Ensure that the endoscope's distal end and insertion tube are free of any lubricants or residue and then dried prior to device installation.
Failure to adequately remove excess lubricant or residue may impact the adhesive properties of the end cap tape and cause the device to slip off the endoscope during use.

Lay the endoscope straight, with the distal end pointed toward the dominant hand.

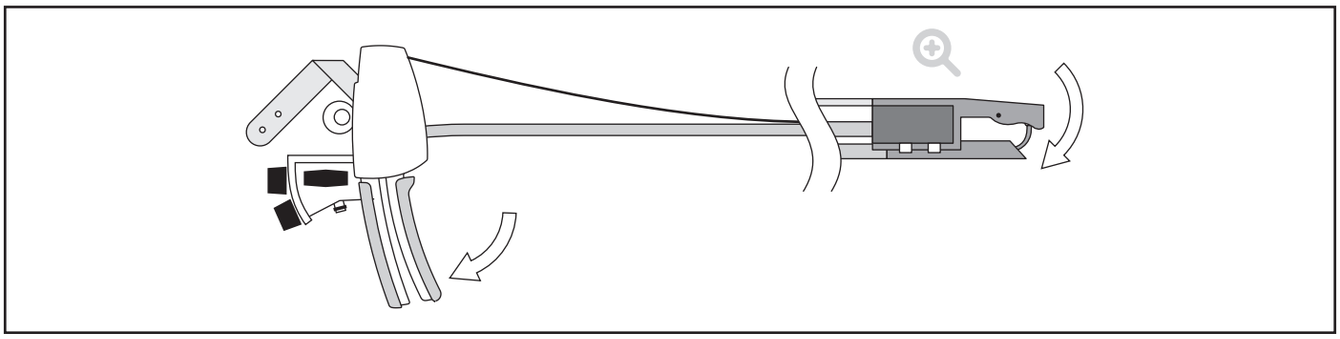
15.2 Prepare Device

Remove the Needle Driver from the packaging by first undoing the loop tab at the bottom left of the die card. Release the Catheter Sheath and Endcap before removing the Handle.

Caution: Take care not to crush or damage the catheters near the Endcap.

Caution: Ensure the Endcap is not dropped or damaged.

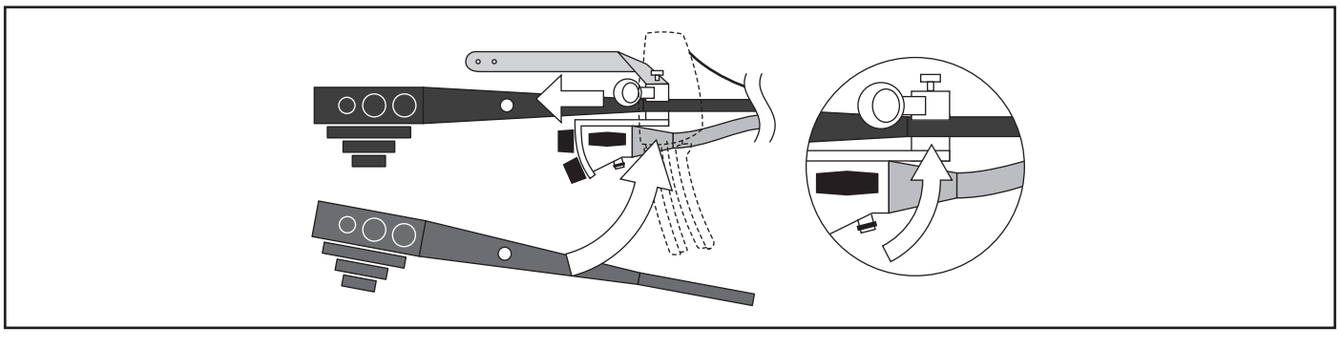
Close the Needle Body



Lay the Needle Driver next to the scope.

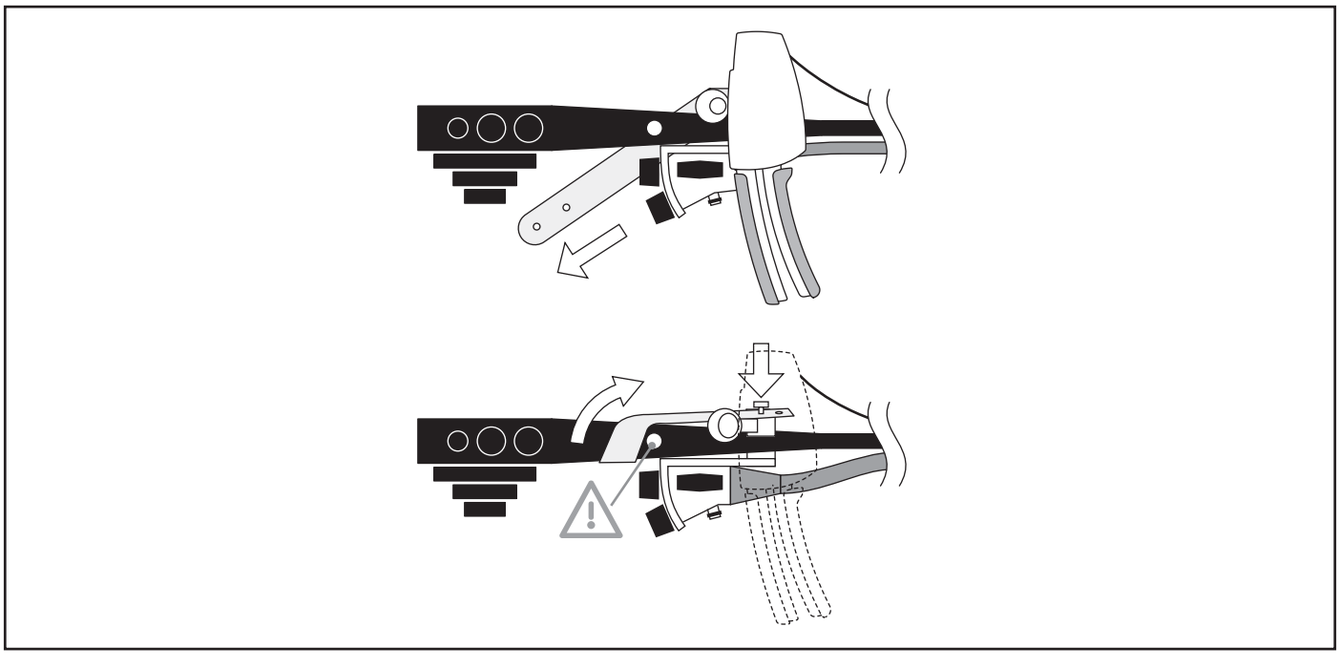
15.3 Assemble Handle

Insert the scope insertion tube behind the handle and into the open C-shape slot of the Needle Driver Handle Collar. Slide the Handle up the endoscope until it is fully seated. Ensure the channel ports are aligned under the scope knobs, as shown.



Secure by stretching the rubber Handle Strap around the rear of the endoscope, over the top of endoscope channel port, and fitting back onto the attachment peg.

Caution: Ensure the Handle Strap is secured above the endoscope channel port.

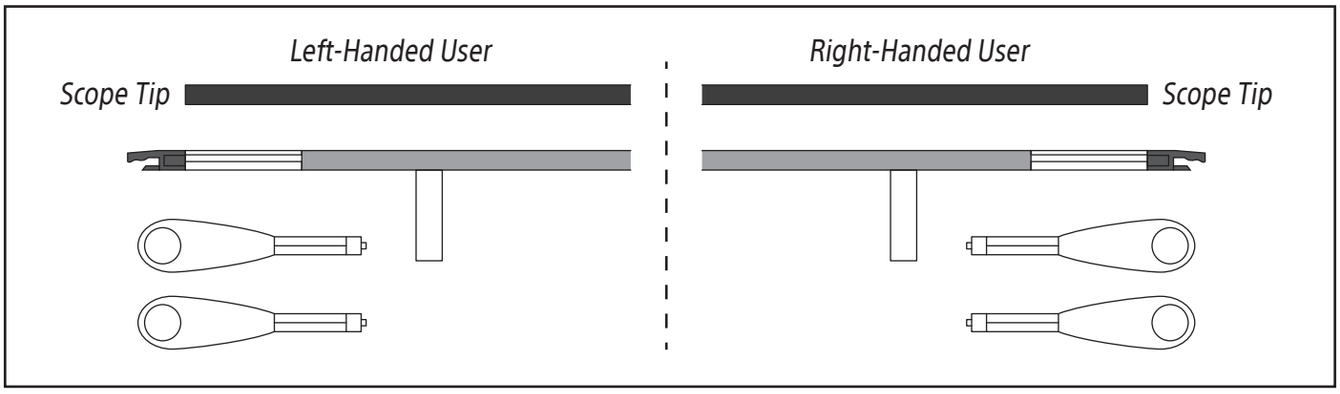


15.4 Assemble Endcap

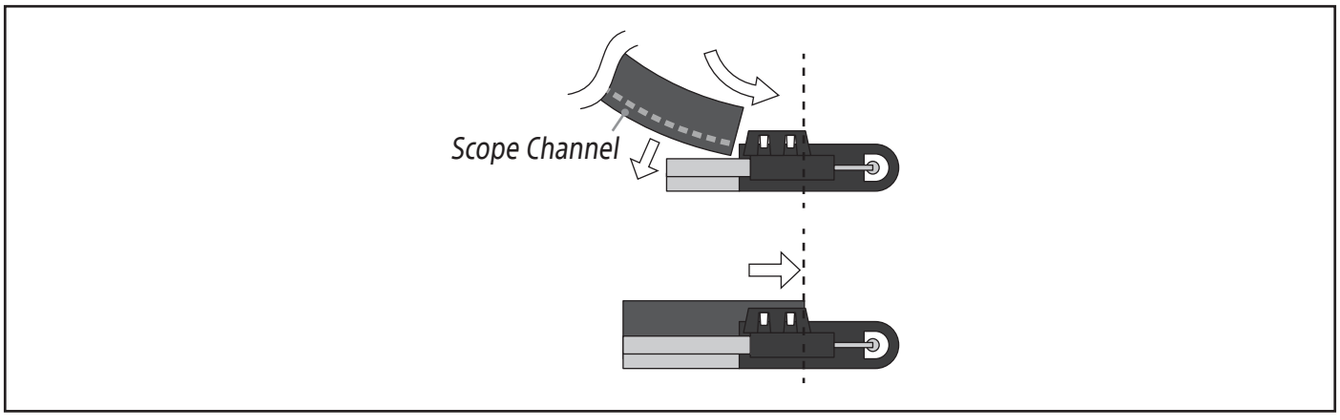
Note: Images show assembly performed by a right-hand dominant user. For left-handed users, images would be mirrored.

Remove both Tape Wands from the packaging and lay them next to the distal end of the device.

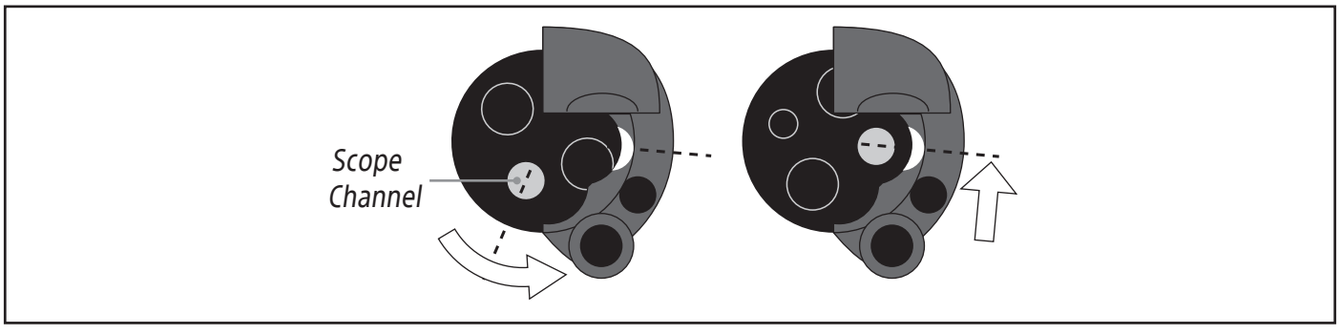
Caution: Ensure the Sheath is not twisted along the length of the scope and that the endcap and distal insertion tube continue to be dry and free of any lubricants.



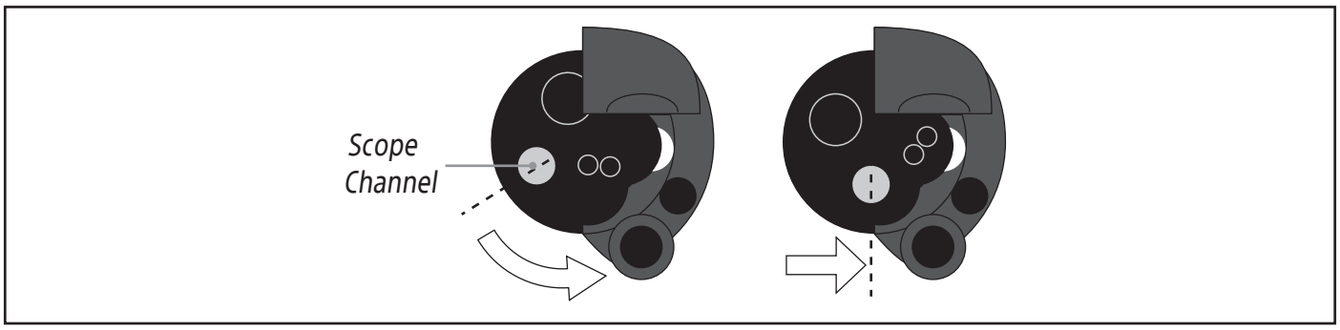
With the scope channel oriented toward the inside of the Endcap, insert the distal end of the scope at an approximate 45 ° angle into the middle of the Endcap Adapter and push the scope forward until fully bottoms out on the roof of the Endcap Adapter.



For Olympus and Fuji endoscopes, rotate to align the scope channel with White Alignment Dot.

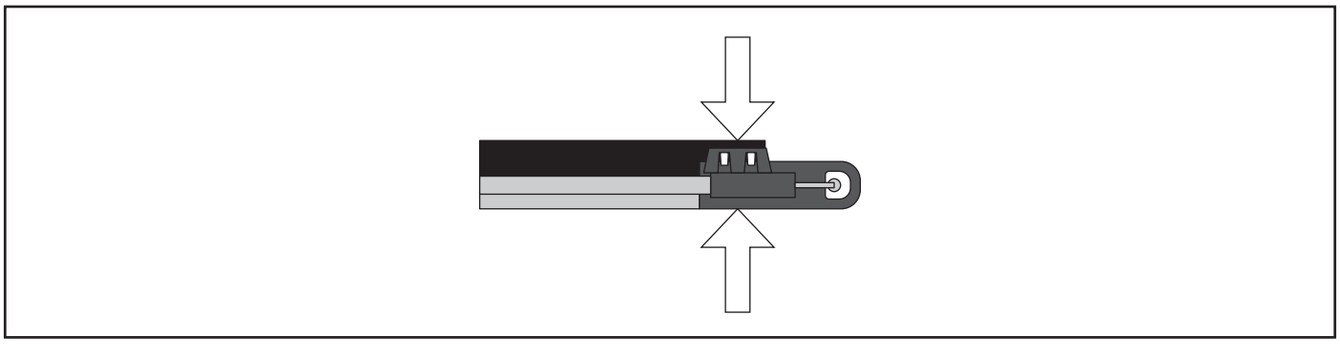


For Pentax endoscopes, rotate to align the scope channel at the bottom edge of the Endcap Adapter.

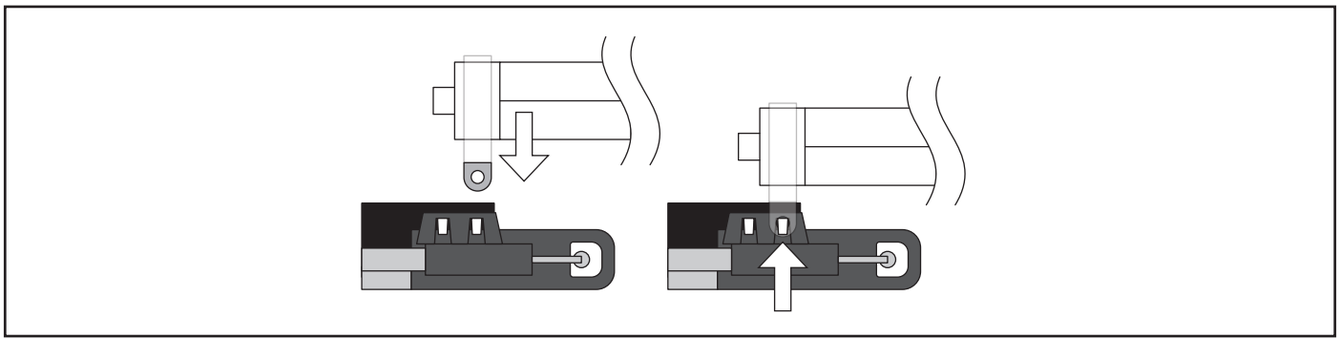


With the non-dominant hand, secure the scope position by pinching the scope and Endcap.

Caution: The scope should be fully seated and held securely until after the first tape is fully applied.

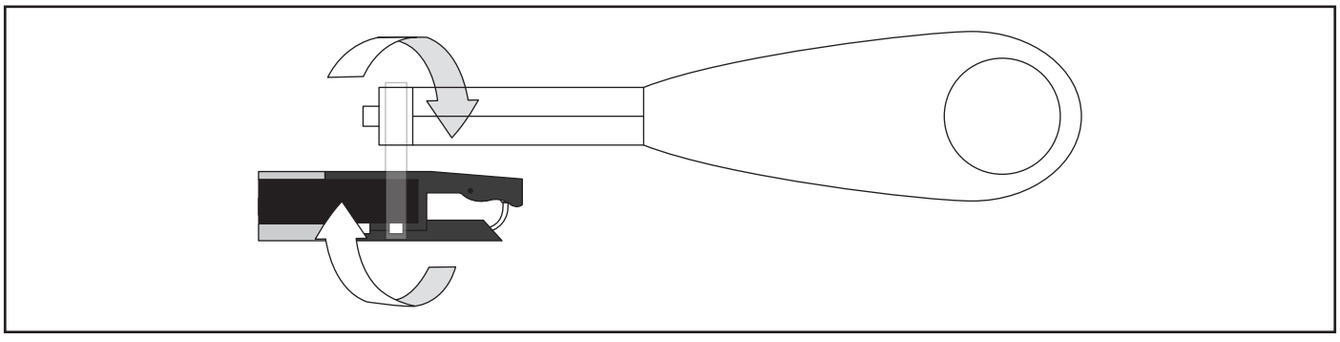


Pick up a Tape Wand with the dominant hand and place the Tape eyelet hole over the distal Hook of the Endcap Adapter.



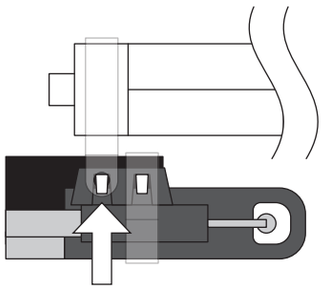
Wrap Tape around the scope, maintaining high-tension until the tape has been fully applied. Do not rotate the wand while wrapping tape. Ensure not to tape over the other tape hook.

Note: If the initial tape application fails, unscrew the used Tape Spool from the Tape Wand tip, screw on a spare Tape Spool and repeat the step.



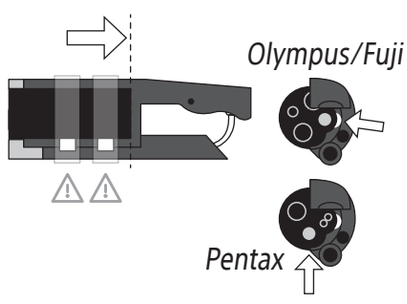
Press to secure the tape tail down.

Repeat for the second Tape Wand on the Endcap Adapter's proximal Hook.



Confirm the scope is fully seated against the roof of the Adapter and that the scope's working channel is set to the position indicated in Step 17.4. If not, remove the Tape as per the Disassembly section 15.22 and repeat the Endcap Assembly with the Spare Tape Spools.

Warning: Confirm both hooks are fully covered by tape and that the tape is wrapped tightly to scope with no gaps or folds.

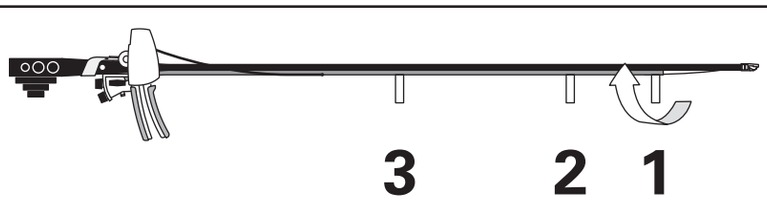


15.5 Assemble Catheter Sheath

Lubricate the distal 50 cm of the inner concave surface of the catheter sheath, insert the scopes insertion tube and remove any excess lubricate/residue. Working distal to proximal, remove the white backing from the Sheath Tape and wrap each Sheath Tape securely around both the scope and the Sheath.

Warning: Ensure Tape lays smoothly with no gaps or folds, and that taped portions of device lay flat against the scope.

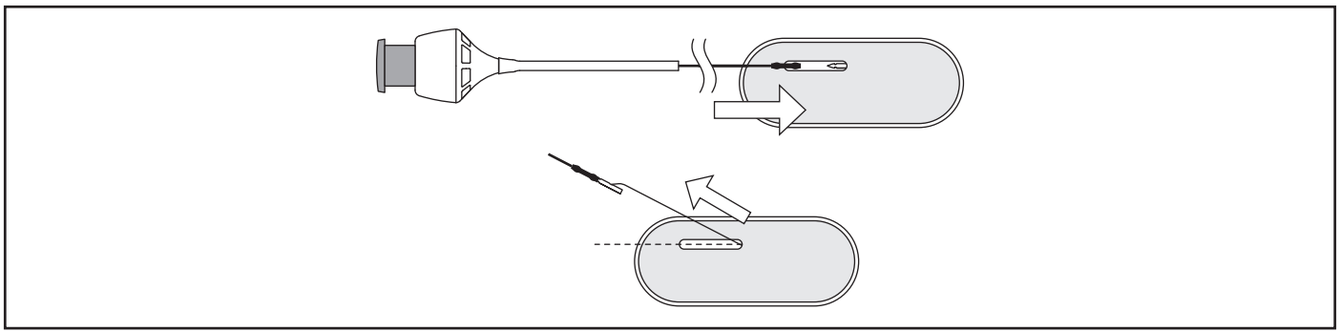
Note: Depending on the scope manufacturer, there may be excess scope insertion tube length between Sheath Tape #3 and the Handle. This is normal and should not affect device performance.



15.6 Load Anchor

Remove the Suture Assembly and Anchor Exchange from the packaging.

Load the Anchor onto the Anchor Exchange.



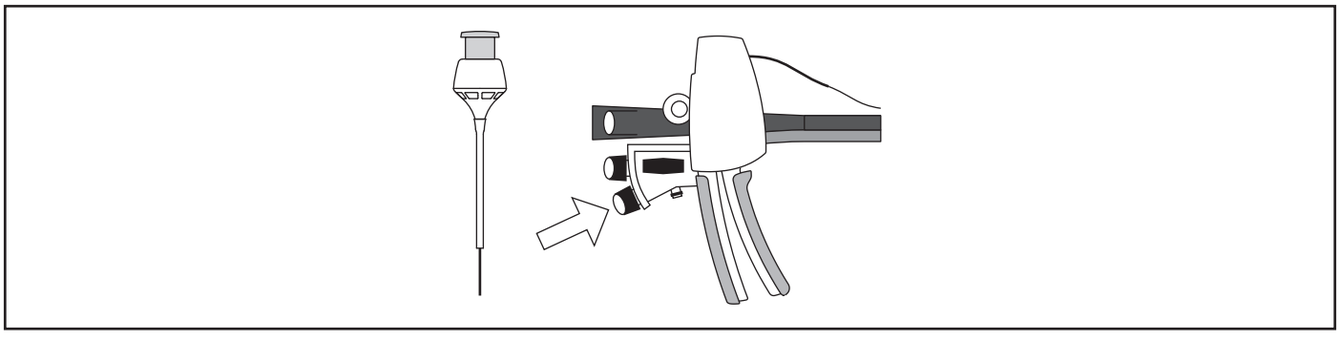
Remove the Suture from Suture Racetrack by holding and pulling the Suture, not the Anchor or Anchor Exchange.

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.

Open the valve covers and insert the Anchor Exchange into the open Anchor Exchange (outside) channel of the device.

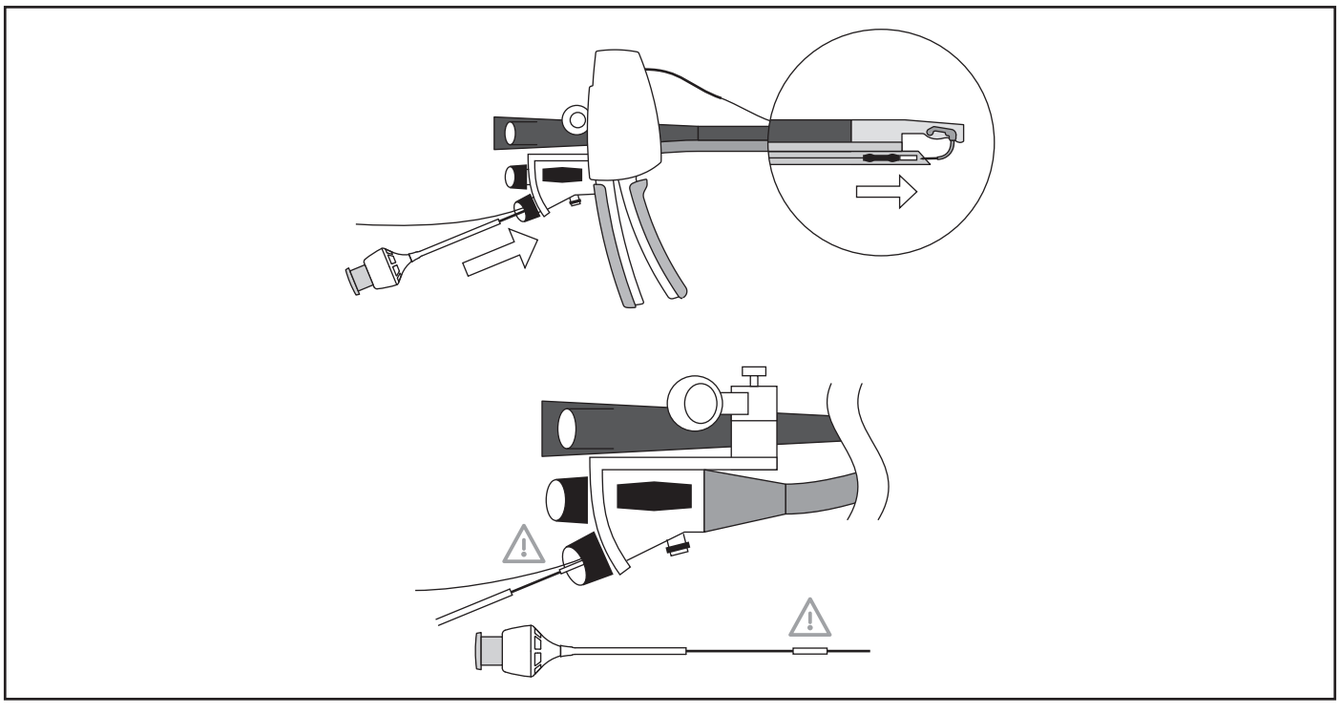
Caution: Do not use when valve covers are closed as Suture drag will be increased.



Using a `pencil-grip' on the catheter and placing the remaining fingers of the same hand on the Endoscope housing, advance the Anchor Exchange until the orange marker band is partially inside the channel port; this reference places the Anchor safely within the Endcap.

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 Anchor Exchange Channel, reduce the endoscope angulation until the device passes smoothly.



15.7 Lubricate and insert device

Add lubricant to the distal 2 sheath tapes as well as the flexible catheters and then fully spread the lubricant over the distal 50 cm of the device and endoscope.

Insert the endoscope into the patient.

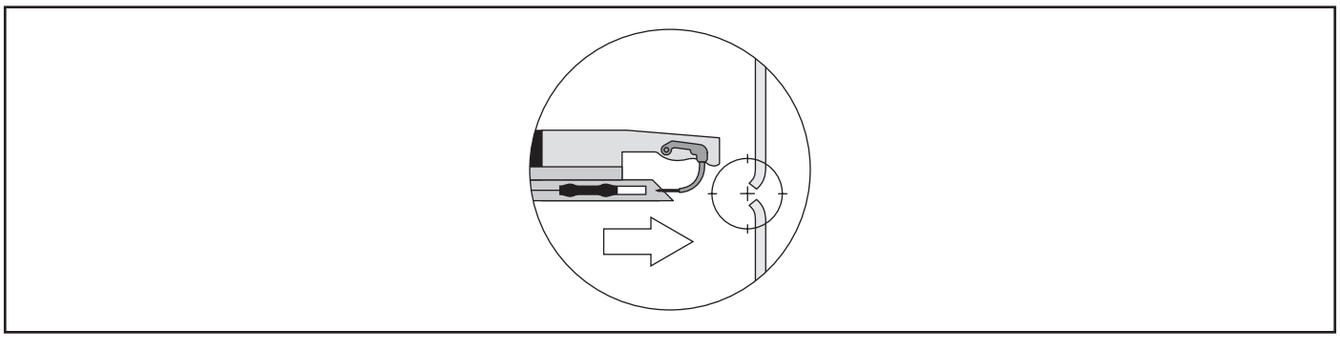
Warning: Do not introduce the device with the Needle Body in its open position. Doing so may cause damage to the device and/or injury to the patient.

15.8 Preparing to Suture

Advance scope

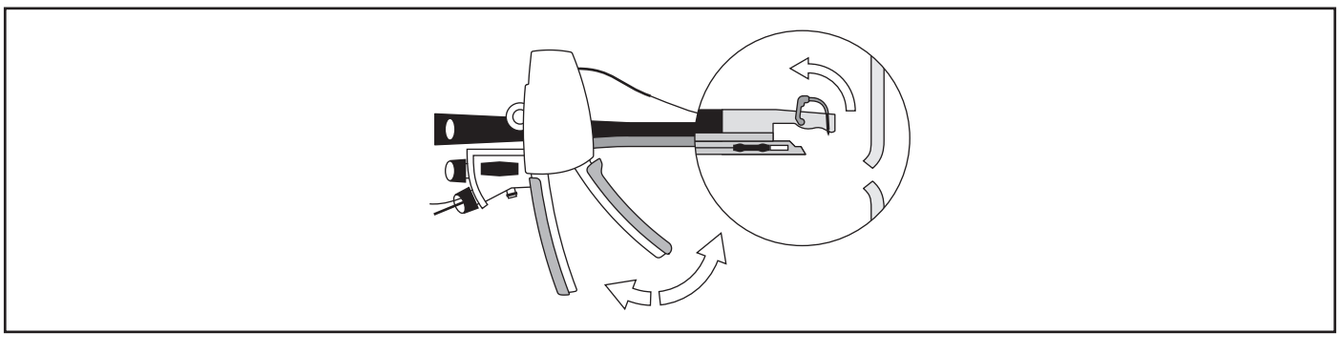
Advance until the target anatomy is located. Ensure any device accessories in use are fully inserted up to the Endcap prior to retroflexing the scope.

Warning: When intubating or extubating ensure that the working length of the endoscope and the external Sheath are advanced or retracted together. Ensure the Pull String is not in use and any slack from distal end is removed prior to device removal from the patient. Doing otherwise may cause patient injury.

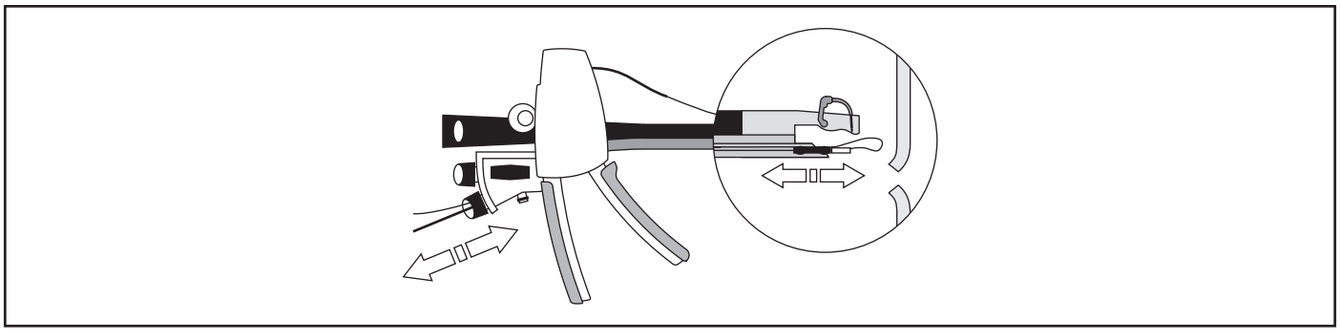


15.9 Transfer Anchor

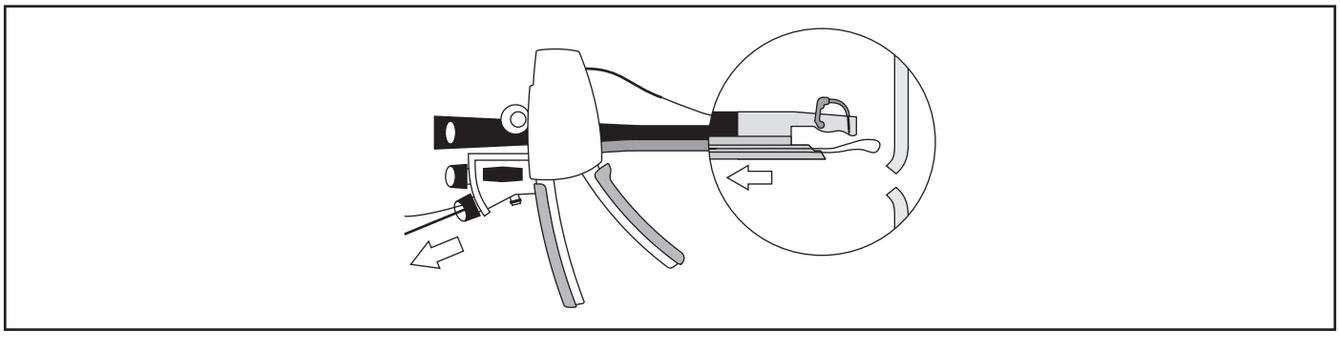
Open the Needle Body.



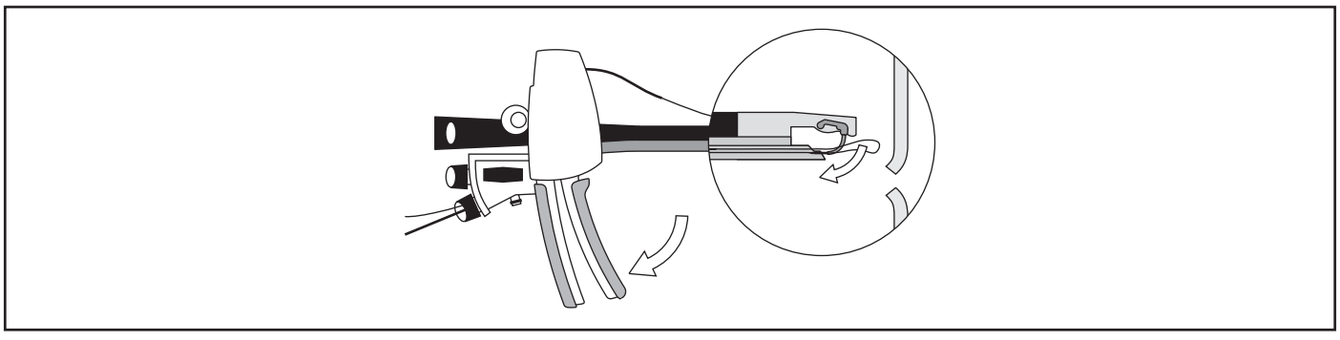
Advance the Anchor Exchange and/or manipulate the endoscope to create Suture slack.



Once sufficient slack has been created, retract the Anchor Exchange into the device.

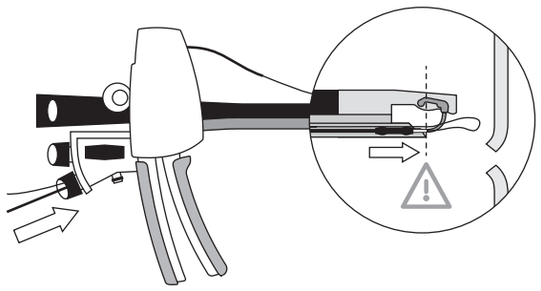


Close the Needle Body.

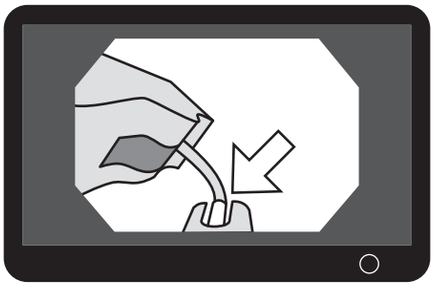


Using a 'pencil-grip' on the white portion of the cable and placing the remaining fingers of the same hand on the Endoscope housing for optimum control, advance the Anchor Exchange until the Anchor fully seats onto the Needle Body.

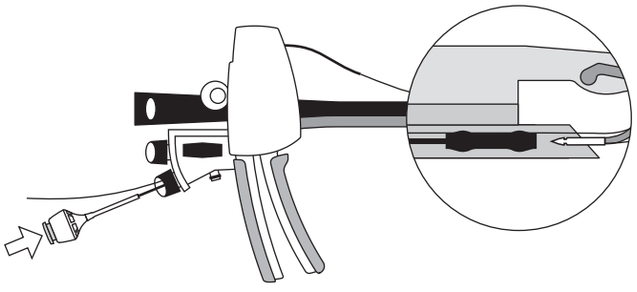
Note: A tactile 'click' or firm stop may be felt as the Anchor seats fully onto the Needle Body.



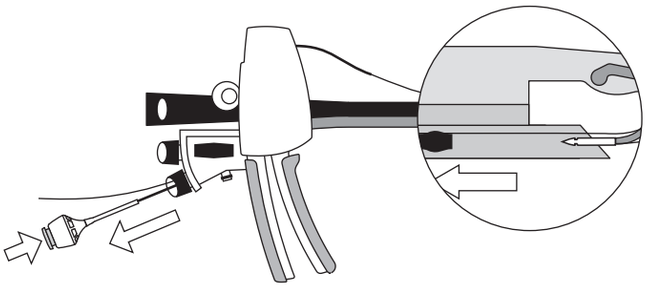
Check the monitor image to ensure the Anchor is properly installed on the Needle Body.



Ensure that the proximal end of the Suture is visible beyond the Handle channel valves.
Fully depress the Anchor Release Button to release the Anchor.



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 the Anchor Exchange until the distal end of the orange marker band is just inside the channel port.



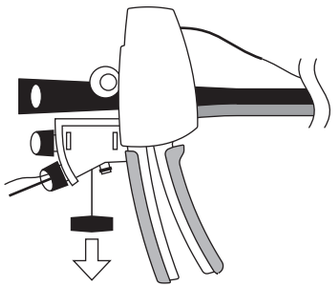
15.10 Pull String scope retroflex assist (Optional)

Caution: The Pull String is designed to be used on Olympus, Fuji and Pentax compatible scopes with the Endcap mounted as instructed to ensure the added articulation is only in the scope's primary ('Up') direction. Use in orientations other than the scope's 'Up' direction may result in damage to the endoscope or device.

Fully articulate the scope using primary ('Up') dial and hold the dial to maintain this position. Do not lock the scope wheel.

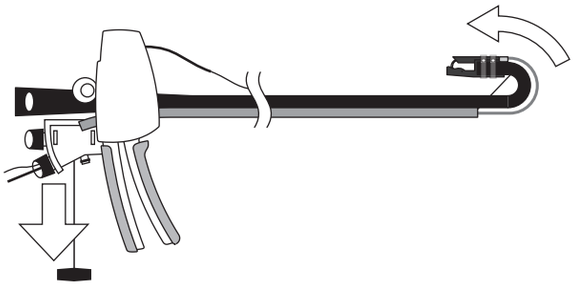
Caution: Failure to fully articulate scope prior to use of Pull String may result in damage to scope or device.

Keep the suture in the primary channel out of the way by holding in the endoscope hand.
Disengage the Pull String Handle from underneath the device Handle.



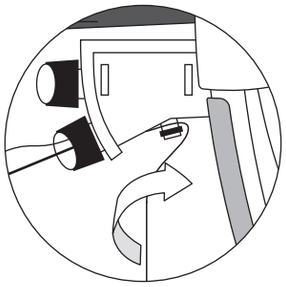
Pull the Pull String straight from the device to increase articulation (i.e. small increments to full retroflexion). After the pull string is engaged, the scopes left/right dials can be used to refine position.

Caution: If significant resistance is encountered when pulling on Pull String, release tension on string and do not proceed with use of pull string.



Wrap the Pull String around the brake washer on the side of the device a minimum of 2 times to secure the device position (if desired).

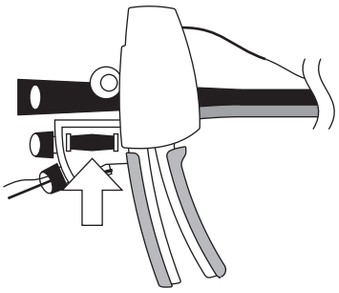
Warning: When the pull string is engaged, ensure no tissue or anatomy comes into contact within the retroflexed area of scope. Doing so may cause damage to the device and/or injury to the patient.



Once the Pull String use is complete, hold the endoscope 'Up' dial at its fully articulated position and then release the Pull String by unwrapping it from the brake washer and letting go of the tension in the string in a slow controlled manner to prevent the device from springing back. Do not release the hold on endoscope's 'Up' dial.

Caution: An uncontrolled release of the pull string could cause an uncontrolled movement of the endoscope and damage tissue.

Secure the Pull String Handle back underneath the device, ensuring the string is not wrapped around the handle.



Release the scope dial.

Warning: Ensure no tension remains on the pull string and confirm on monitor that the scope has returned to a straight configuration prior to navigating to new areas of anatomy. Doing so may cause damage to the device and/or injury to the patient.

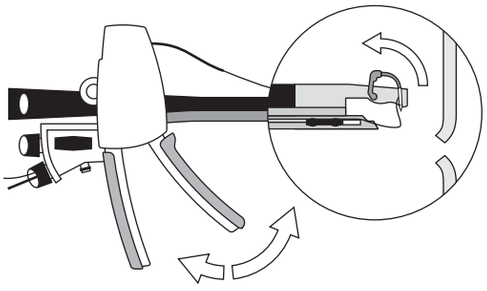
15.11 Tissue Management

Prepare to acquire tissue

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



Position tissue in appropriate location for suturing, using Tissue Helix, NXT Tissue Helix Pro or other 2.8 mm compatible accessory if required.

15.12 Use of NXT Helix (Use of Tissue Helix or NXT Helix is optional for Defect Closure but required for ESG and TORe)

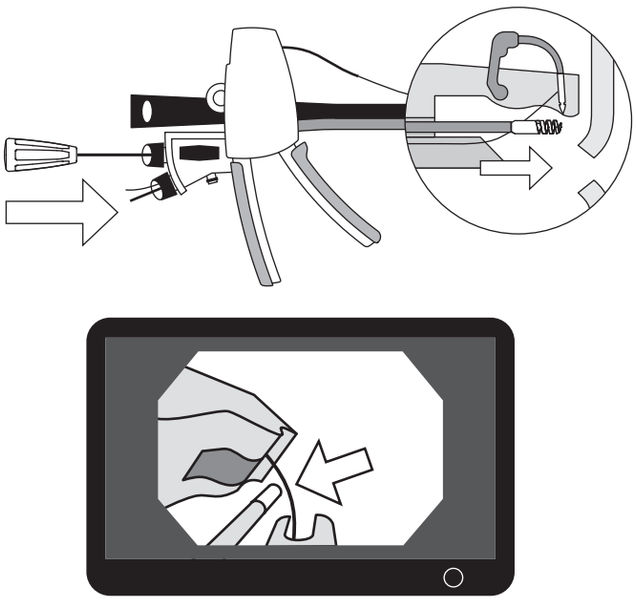
Caution: The NXT Tissue Helix Pro is for use in the NXT Helix Channel only. Do not use in endoscope channels as the unshielded tip can damage the endoscope's working channels.

Remove the tissue helix from its packaging as well as the clear protective cap from the end of the device.

Ensure the NXT Biopsy Cap is open.

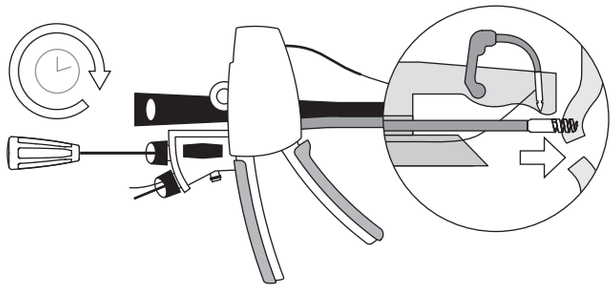
Advance the Helix into the NXT Helix Channel until orange depth marker band is at the entry of Biopsy Cap, or until the distal tip is visible on the monitor.

Caution: If resistance is encountered when advancing the Helix through the NXT Helix Channel, reduce the endoscope angulation until the device passes smoothly, and ensure that the device's secondary working channel is not obstructed.

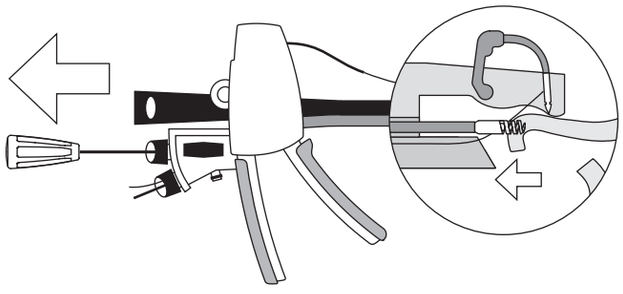


Acquire tissue by rotating the Helix Catheter or Handle clockwise until desired tissue depth is achieved.

Note: Maintain gentle forward pressure during the tissue acquisition.



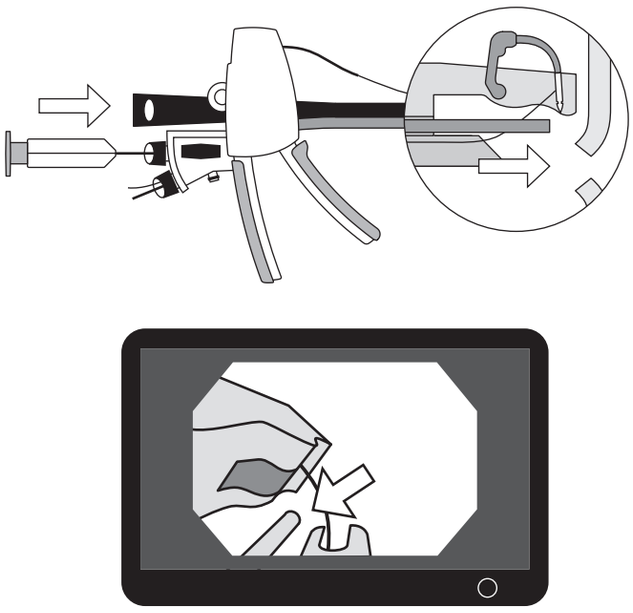
Advance / retract the Helix to position the tissue into desired location.



15.13 Use of Tissue Helix (Use of Tissue Helix or NXT Helix is optional for Defect Closure but required for ESG and TORe)

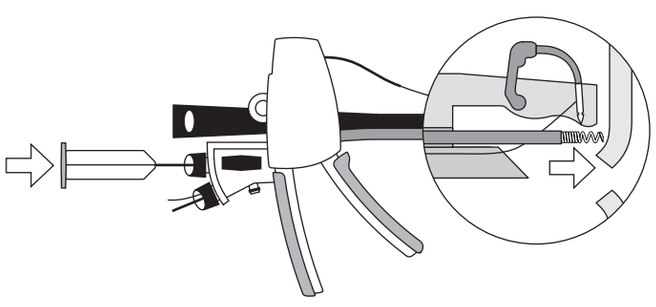
Advance the Helix into the Helix Channel while in the retracted position, until the distal tip is visible on the monitor.

Caution: If resistance is encountered when advancing the Helix through the Helix Channel, reduce the endoscope angulation until the device passes smoothly, and ensure that the device's secondary working channel is not obstructed.

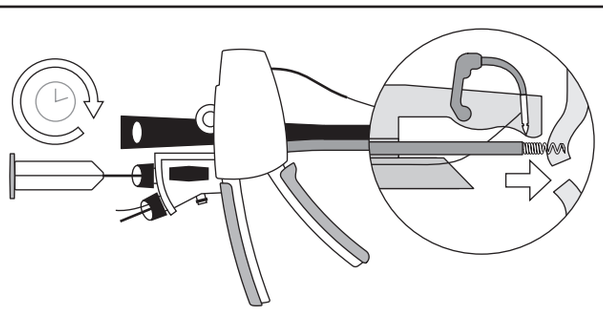


Fully depress the Helix Handle button to expose the Helix Tip.

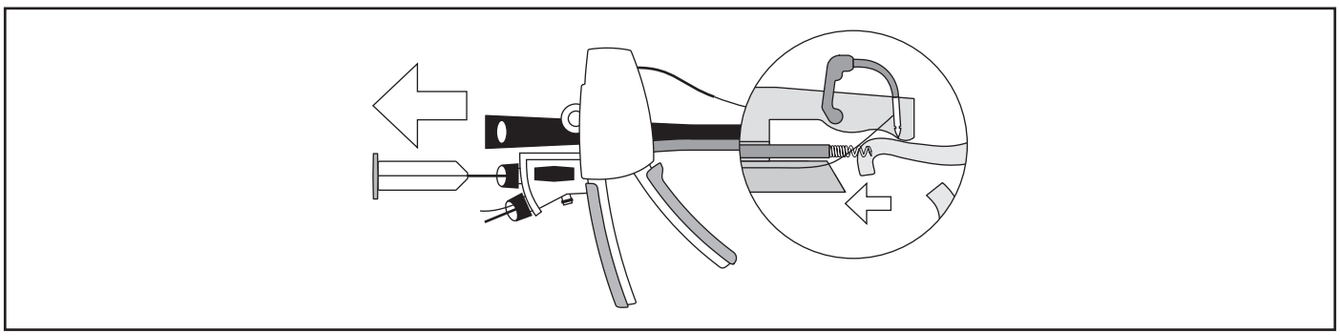
Caution: Do not depress the Helix Handle button while advancing Helix through the device.



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



Maintain gentle forward pressure during the tissue acquisition.
Advance / retract Helix to position tissue into the desired location.

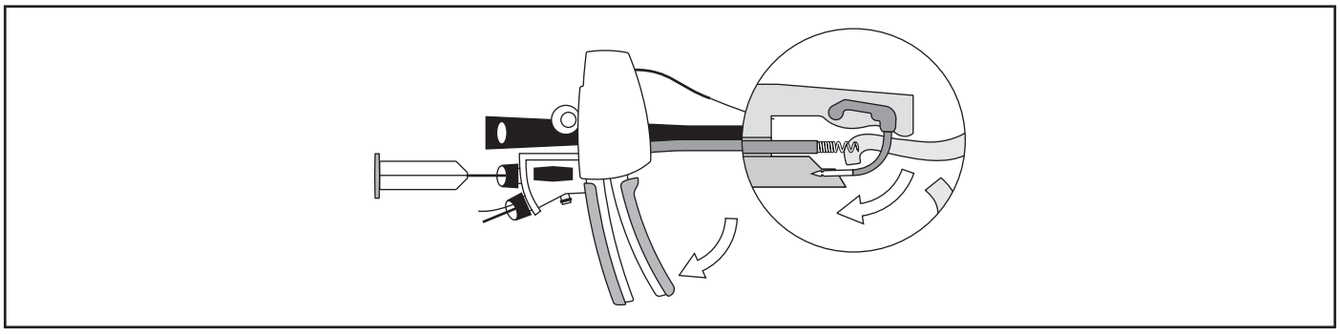


15.14 Suturing

Place stitch

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

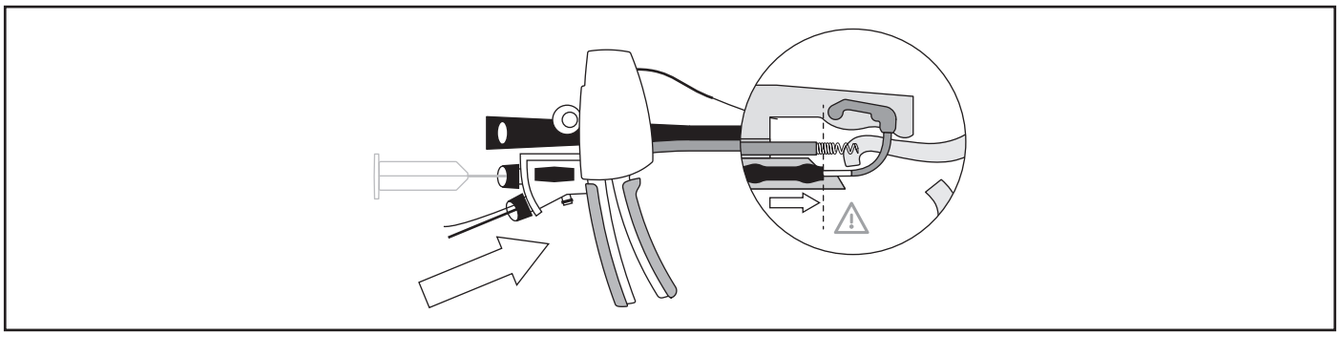
Caution: Ensure that the Needle Arm does not inadvertently close on any foreign object or device. Doing so may damage the device.



15.15 Retrieve Anchor

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 scope.

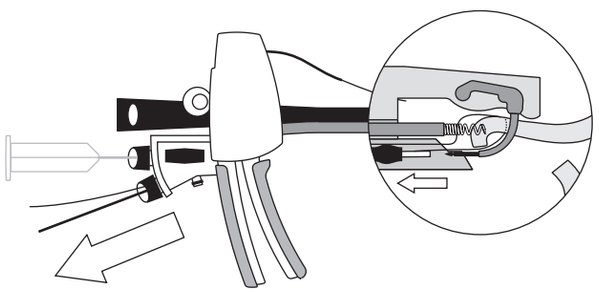


Retract the Anchor Exchange to acquire Anchor.

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

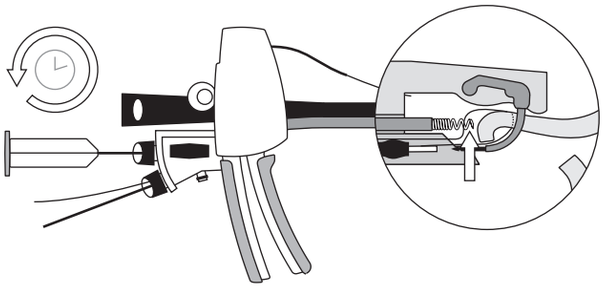
Caution: Do not press the Anchor Release Button, as this may cause an inadvertent drop of the Anchor.

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 20. If Troubleshooting is unsuccessful, additional intervention may be required.



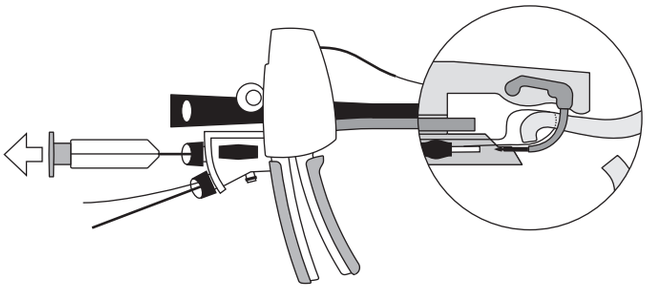
15.16 Release tissue

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

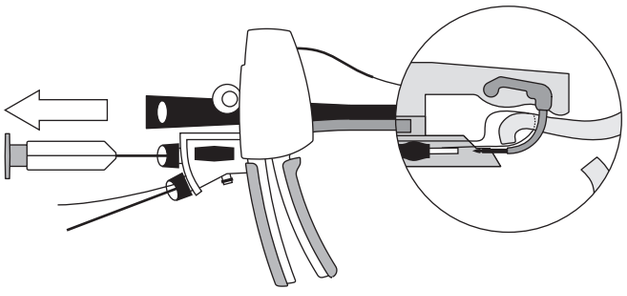


If using the Tissue Helix, return the Helix handle button.

Caution: Check monitor to ensure tip is fully retracted into shaft before withdrawing into the accessory Channel. Failure to retract tip could cause damage to NXT channel.



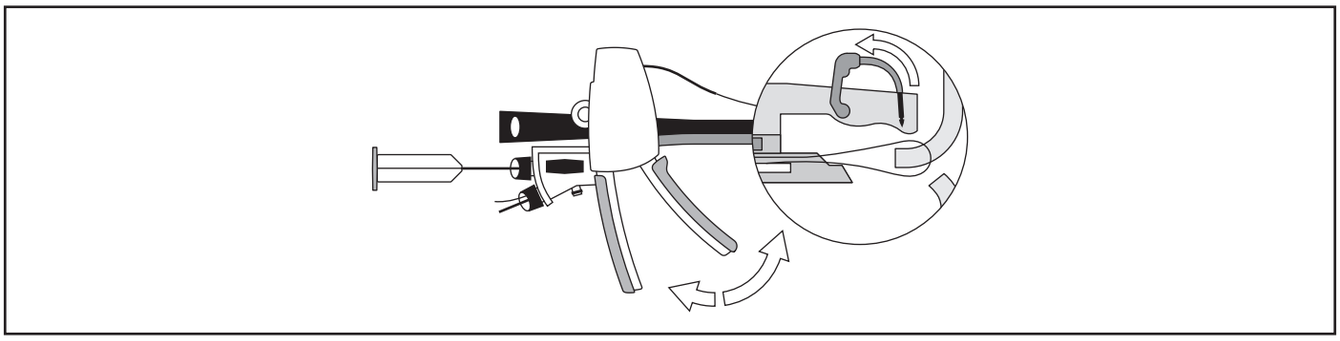
Withdraw the accessory a short distance into the Channel.



15.17 Release tissue from Needle Body

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.



15.18 Repeat stitches

To continue placing stitches with this Anchor, repeat sections 15.8-15.14.

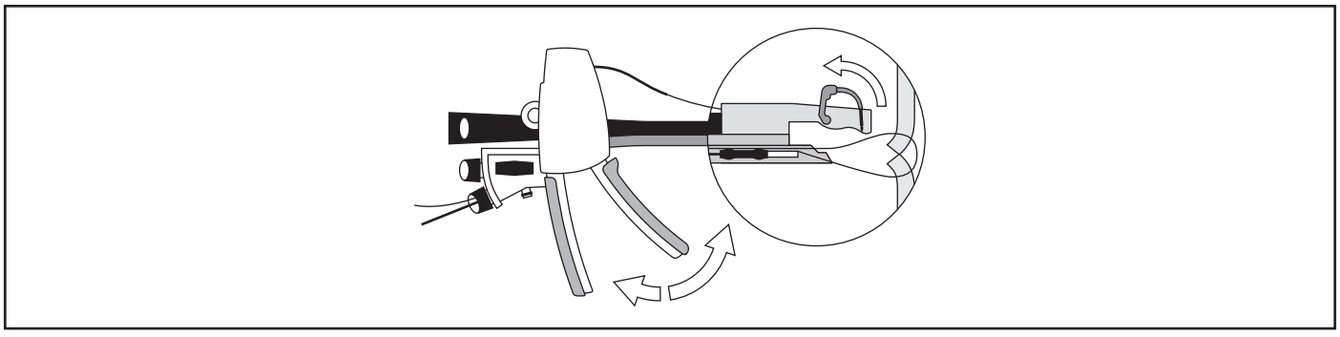
If stitching is complete for this Anchor, proceed to approximate tissue, secure and cut the Suture.

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

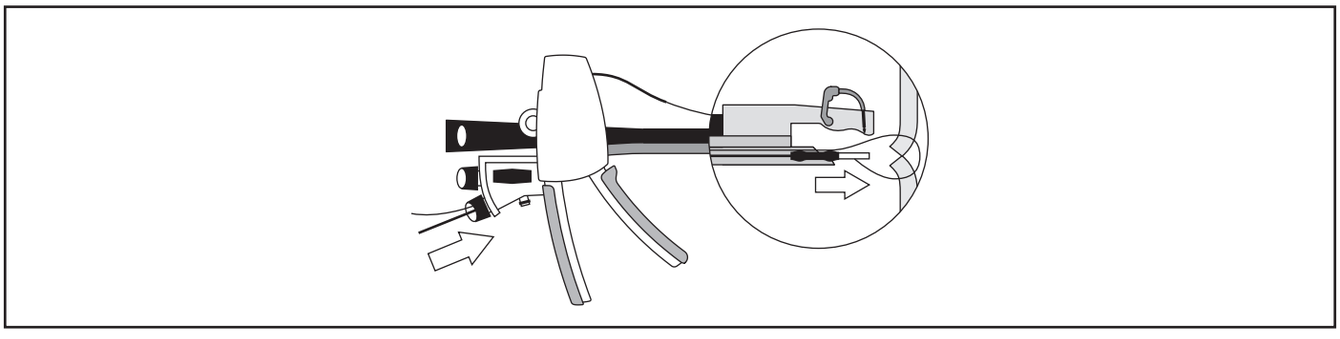
15.19 Securing and Cutting Suture

Remove the Anchor Exchange

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

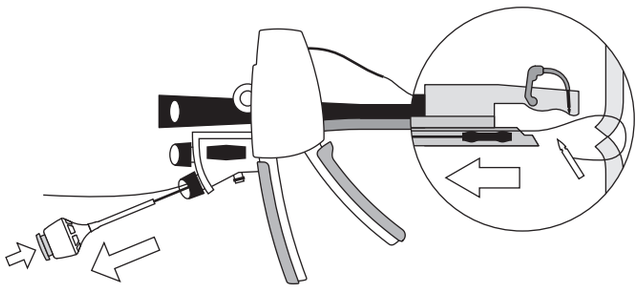


Advance the Anchor distal of the device until it is visible on the monitor.



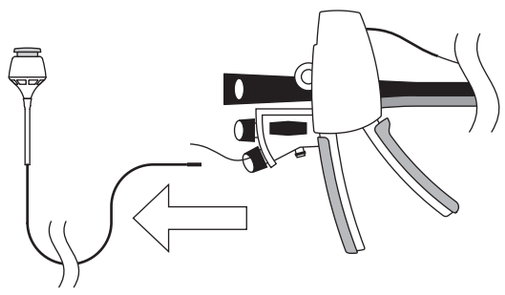
Fully depress the Anchor Release Button and retract the Anchor Exchange to release the Anchor.

Caution: Do not release the Anchor inside the Anchor Exchange channel. Doing so may cause damage to the NXT channel.



Fully remove the Anchor Exchange.

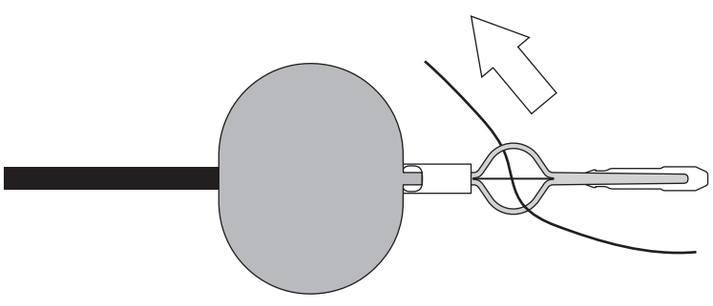
Note: The Anchor Exchange can be utilized for additional sutures.



15.20 Use of the Cinch to secure Suture

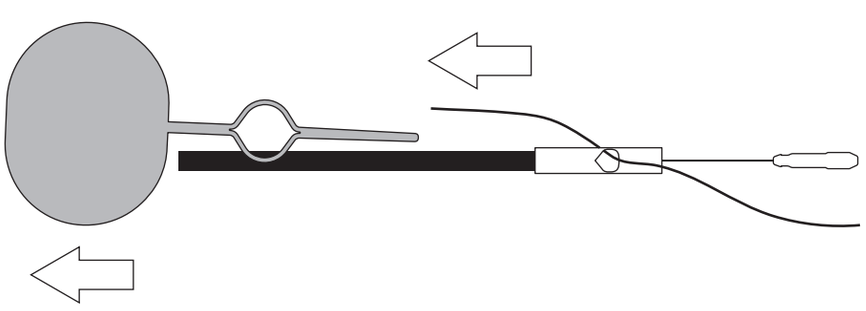
Unpack the Cinch, identify the Suture Loading Loop at the distal end of the Cinch device.

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

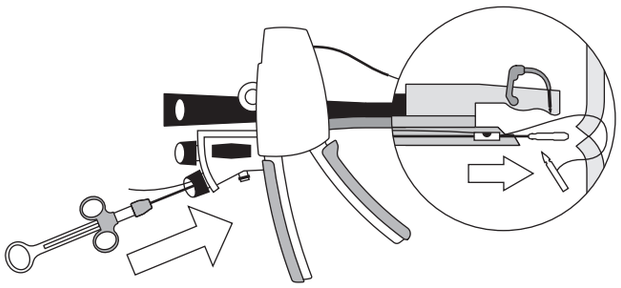


After threading, release the proximal end of the Suture to enable loading.

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



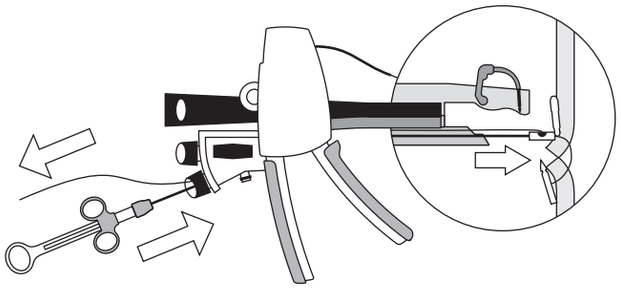
Holding the proximal end of the Suture, feed the Cinch down the Anchor Exchange channel until the 'Plug and Collar' can be seen on the monitor.



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.

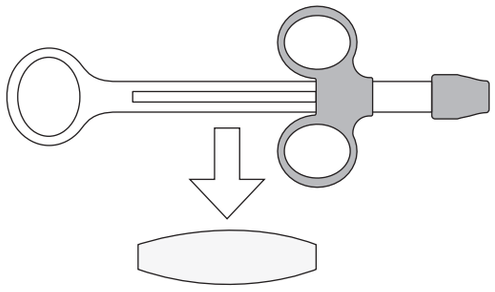
Note: It is the Collar that sets the final position of the Cinch, not the Plug.

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



While holding suture tension, remove the safety spacer from the Cinch handle.

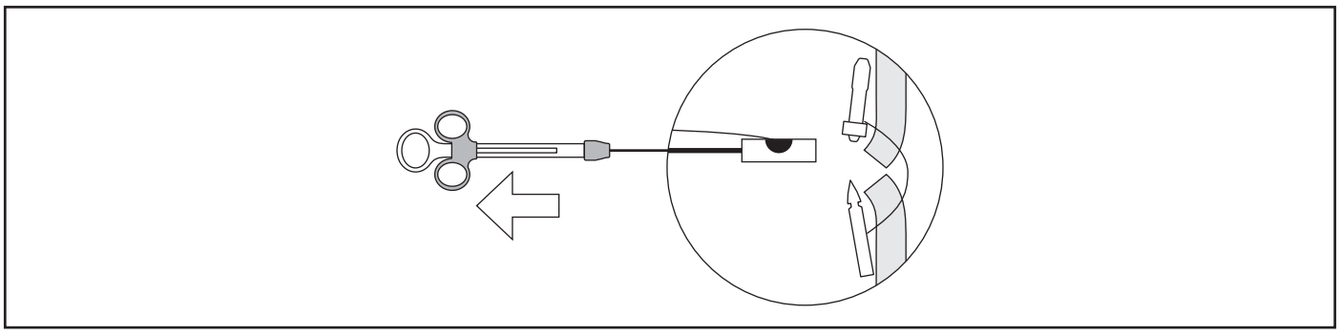
Caution: The safety spacer must only be removed immediately prior to deploying the Cinch in order to avoid inadvertent suture cutting.



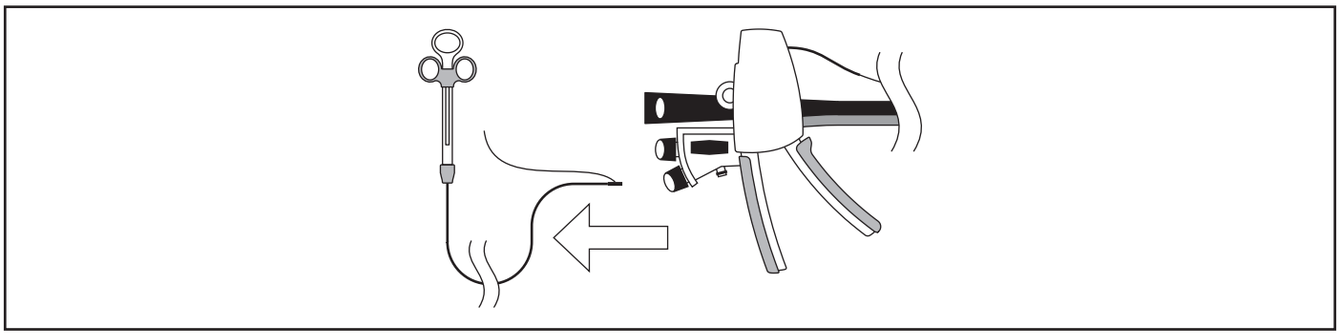
Firmly squeeze the Cinch Handle to deploy the Cinch and cut the Suture.

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

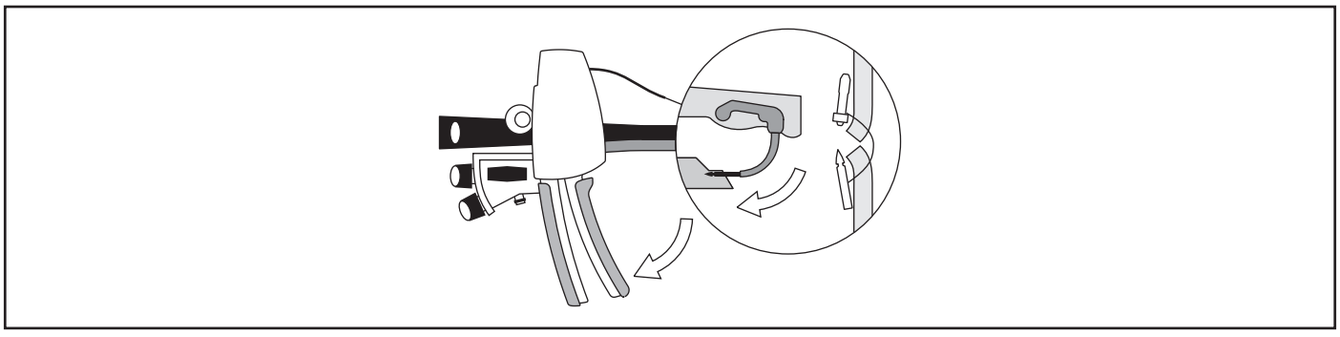
Note: Significant force is required to pull and lock the Plug into the Collar, a 'pop' can often be felt once the Suture is cut. Do not over deploy Cinch - only squeeze the handle until the Suture is cut.



Remove both the Cinch and Suture.



Close the Needle Body.



15.21 Multiple Sutures

The Anchor Exchange and the 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 secure to the endoscope before the next intubation. Otherwise, the Endcap can dislodge and cause patient injury.

To use another Suture Assembly, return to step 15.6 for Anchor loading and follow all subsequent steps.

If suturing is complete, proceed to section 15.22 for removal of the device.

15.22 Disassembly

Remove scope

Remove any accessory devices.

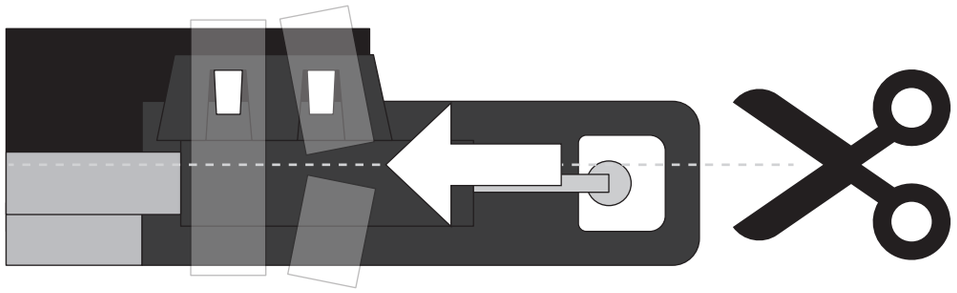
Ensure the Needle Body is closed and retract the endoscope from the patient, making sure the external Sheath is retracted together with the endoscope.

Warning: Ensure the Pull String is not in use and any slack from distal end is removed prior to device removal from the patient, otherwise patient injury may result.

15.23 Remove endcap

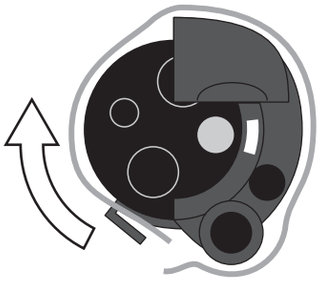
Use a pair of scissors to cut through both Endcap Tapes. Cut below the tape hooks (along white area of Endcap Adapter) so scissors are not next to the scope.

Caution: Ensure scissors do not contact scope. Cutting the tape at any other location may result in scope damage.



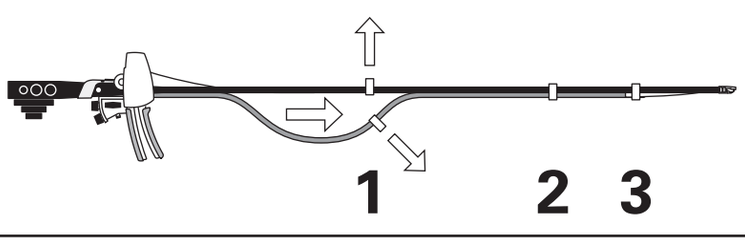
If reloading of the Endcap is required (using the spare tape spools provided), remove fitted tape by unwrapping counter-clockwise.

If device use is complete, unwrap the Tape from the Tape Hooks of the Endcap Adapter in a clockwise direction to break the Tape Hooks and unwrap Tape.

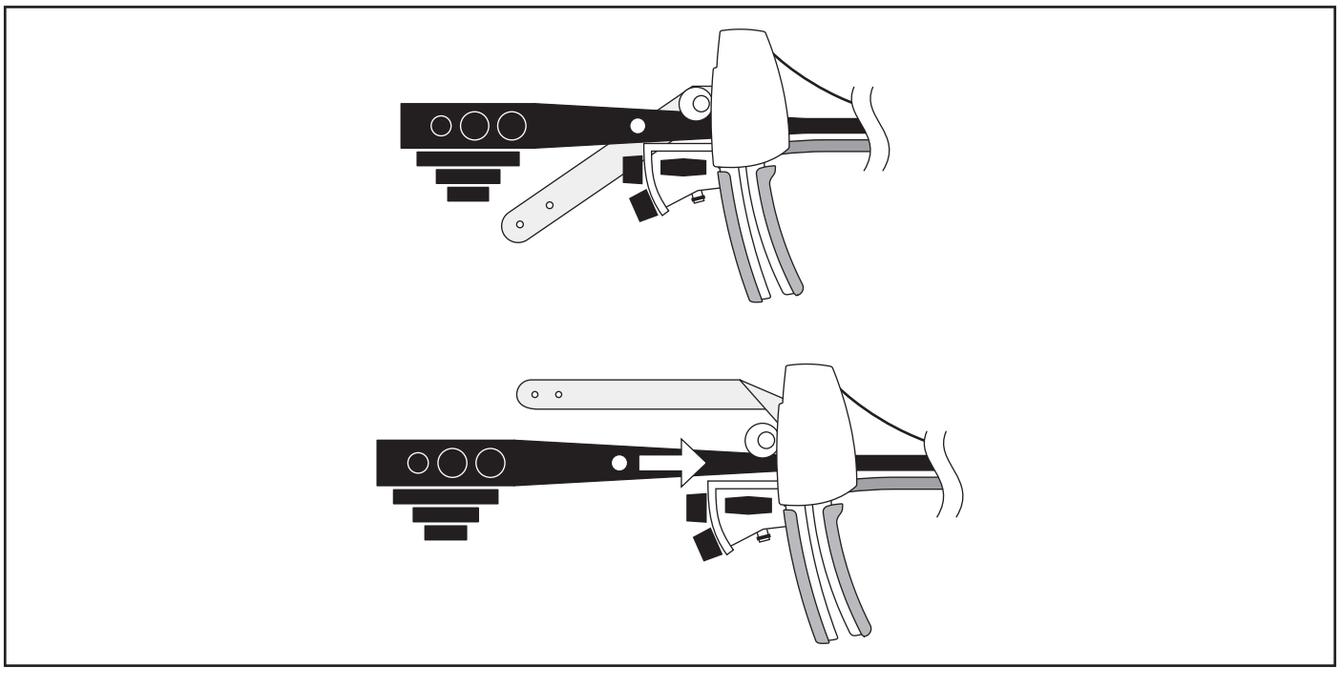


15.24 Remove Catheter Sheath and Handle

Each Sheath Tape is perforated for removal. Start at the proximal end where the endoscope and Sheath come together and gently pull apart the Sheath from the scope to release the proximal most Sheath Tape. Continue for remaining tapes. Alternatively tape can be unwrapped or scissors can be used to release the tape.



Undo the Handle Strap and slide the Handle Bracket off the endoscope.



16. ESG TECHNIQUE

16.1. Procedural Setup and Ancillary Equipment

Endoscopic sleeve gastroplasty (ESG) should be performed under general anesthesia with the patient positioned in a supine or semi supine left position to facilitate a safety margin between the stomach and surrounding structures.

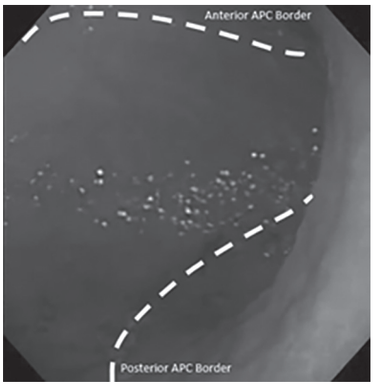
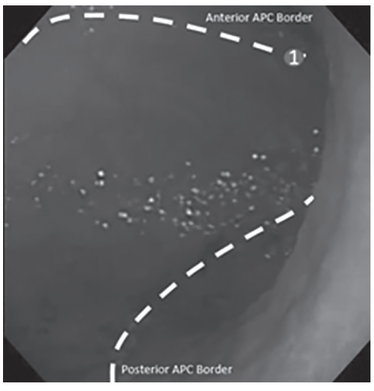
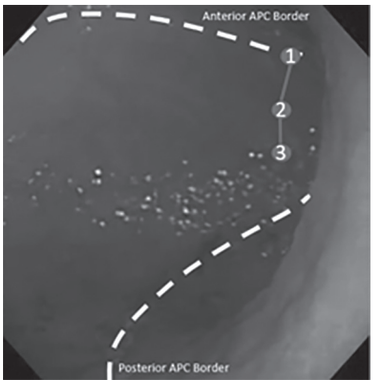
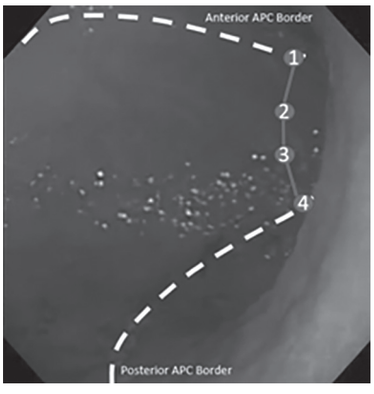
If using an overtube, verify compatibility between the overtube and the suturing device, as mounted on the specific endoscope. Lubricate the overtube and endoscope liberally. Place the overtube following the overtube manufacturer's directions.

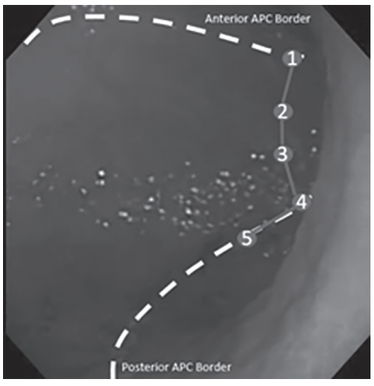
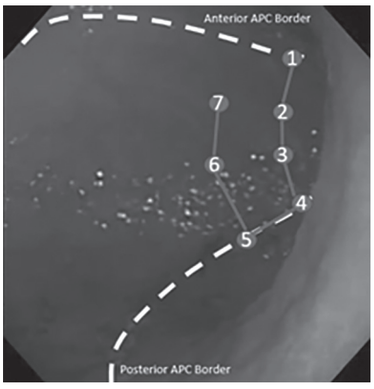
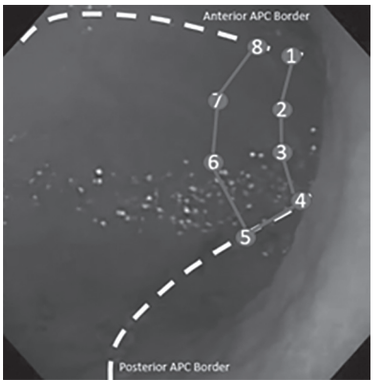
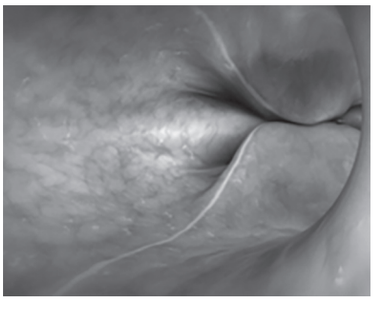
Coagulation marking on the mid-anterior and mid-posterior walls of the stomach is recommended to guide placement of stitches. Take care when using plasma coagulation marking. Perforation could occur while using plasma coagulation and/or coagulated tissue may slough off later, resulting in delayed gastrointestinal bleeding.

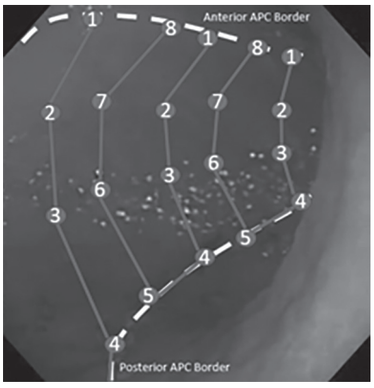
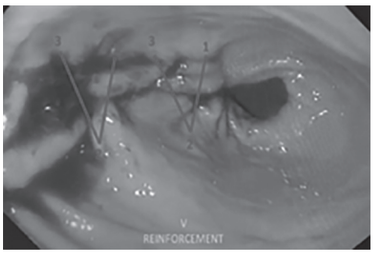
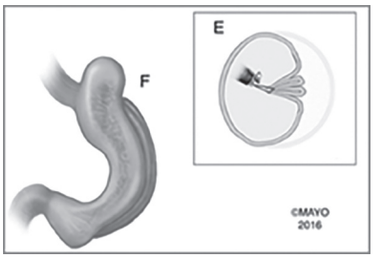
Carbon Dioxide (CO^2) is required for insufflation. Room air must not be used and can contribute to serious adverse events including pneumoperitoneum, pneumothorax, pneumomediastinum, and death.

16.2. Endoscopic Sleeve Gastroplasty Procedure

Important factors for a successful procedure include properly operating the OverStitch device, successfully placing full thickness sutures at each position listed below, avoiding the fundus, and shortening the stomach length while decreasing the lumen diameter. Specific suture patterns are at the discretion of the physician but should begin in the distal stomach at the level of incisura and end proximally, before the fundus, the latter in order to reduce risk of an adverse event. Reinforcement sutures overlying the main plications are optional depending on the appearance of the stacked plications and sleeve lumen. The endoscopist should use the Helix to capture the muscle layer only (and not beyond), by avoiding excessive forward pressure and rotations of the Helix.

1. Prior to suturing, it is recommended to use an endoscope and a coagulation device to mark the mid-anterior and mid-posterior borders of the stomach.	
2. The first bite or stitch should start at the level of incisura. The first stitch should target the mid-anterior wall of the stomach with deliberate maneuvering of the endoscope tip and the gastric wall (captured by the Helix) to fill the suturing device tower to enable a full thickness bite. A gap of at least 1-1.5 cm between the exit point and return point of suture at a bite or stitch site provides a visual affirmation that a full thickness stitch has been placed.	
3. The second and third suture positions should be placed along the greater curvature of the stomach.	
4. The fourth position targets the mid-posterior wall of the stomach.	

5. Move 1 - 2cm proximal to the fourth stitch or bite along the mid-posterior wall to place the fifth stitch.	
6. Stitch position six and seven and target the greater curvature of the stomach moving towards the anterior border.	
7. Final stitch position returns to the anterior wall of the stomach in line with the first stitch.	
8. The anchor is dropped from the anchor exchange in the lumen and the suture cinch is loaded with the proximal end of the suture.	
9. The suture cinch is advanced into the scope and into the lumen to the first stitch site. The suture is tensioned against the cinch slowly to allow tissue approximation. Care should be taken not to over tension the suture and risk breakage. When appropriately snug tissue approximation is achieved, the cinch is deployed. The cinch catheter and excess suture is removed from the scope channel.	

10. The suture pattern is repeated moving proximal approximately up to 2cm for each new plication, until the fundus is reached.	
11. Final inspection of the lumen is performed, and full thickness reinforcement sutures may be placed with care not to interfere with the first row of sutures.	
Illustration of the final sleeve.	

16.3. Prophylaxis Techniques to Consider

The endoscopist should use the Helix to capture the muscle layer only (and not beyond), by avoiding excessive forward pressure and rotations of the Helix.

To minimize the risk of early post-procedure dehydration, intravenous fluid hydration should be continued during the postoperative recovery period and based on the patient medical history.

To reduce the risk of infection, it is recommended to administer intravenous antibiotic prophylaxis before the procedure.

To reduce the risk of thromboembolic events, patients should receive prophylaxis with low-molecular weight heparin, if the procedure is expected to be prolonged. In selected cases, intermittent pneumatic compression devices should be placed on the lower extremities during the procedure.

To reduce the risk of post-procedure bleeding, avoid non-steroidal anti-inflammatory drugs before and after the procedure.

Patients on chronic antithrombotic therapy should be on a prescribed regimen established by the medical team managing these medications before, during and after the procedure.

16.4. ESG follow-up care

Most patients having ESG can be discharged the same day, though some may require a hospital stay to manage early symptoms of accommodation (e.g dehydration, pain, nausea or bleeding).

Following ESG, patients should be prescribed a clear liquid diet for several days with a gradual dietary progression and encouragement to maintain hydration, especially during the early post-procedure period.

Post-procedural abdominal pain and nausea are common and are expected to be self-limiting. These tend to resolve in the first week. These can be minimized with oral analgesics and anti-emetics. In some cases, more severe abdominal pain may require hospitalization with parenteral opioids. Rarely, post procedure discomfort with pain and nausea may be unrelenting and debilitating enough such that the plications should be endoscopically removed.

Upper GI bleeding has been reported post-procedure, as have hematemesis and melena. These typically present within the first week of the procedure but have been reported out to one month. In patients presenting with post-procedure

bleeding and a drop in hematocrit or hemoglobin, perform endoscopy to inspect the sleeve. If bleeding is identified, it can be treated with conventional techniques or oversewing the bleeding site. 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 would warrant investigation with an imaging study, e.g. CT. Treatment includes the use of antibiotics, per-cutaneous drainage, or, if the leak can be identified, surgery.

Gastric perforation is a rare event and may be diagnosed by clinical presentation with peritonitis with free air and fluid in the abdominal cavity on imaging. These must be repaired either endoscopically or surgically.

Patients should progress to a full liquid diet, including 60 grams of protein per day, followed by progression to soft, then full low-fat diet over several week intervals, e.g. 2 weeks, depending on accommodation to the sleeve. Patients are encouraged to drink sufficient non-alcoholic fluids per day to avoid dehydration, e.g., 48-64 oz. Overeating is likely to induce a sensation of bloating and should be avoided. Patients should be advised to maintain a healthy lifestyle, including both diet and exercise. Weight loss is typically reported to increase progressively over the first one to two years after the ESG procedure. Most of the weight loss will happen within the first six months. If a patient reports a loss of satiety or weight regain, they should be advised to consult with their doctor. The sleeve may need to be revised.

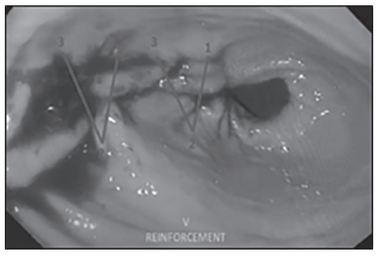
17. BARIATRIC REVISION: ADDRESSING WEIGHT REGAIN FOLLOWING ESG, LSG OR GASTRIC BYPASS.

Some patients will lose weight after a bariatric procedure and then begin to regain weight. They may report that they can consume more food during a meal and no longer feel full after eating. Depending on the previous procedure, this can be an indication of plications coming apart, dilation of the sleeve or dilation of the gastric outlet and the gastric pouch. The following sections describe revision strategies for each of these situations.

17.1. ESG Retightening

These revision procedures require adherence to the same operating principles described for a primary ESG procedure. These general techniques include placement of full thickness bites, creation of lumen-narrowing, and multi-bite plications in a distal to proximal progression beginning at the incisura. Deep fundal plications must be avoided to reduce the risk for leak.

- Inspect the stomach to determine whether all or some plications have completely disappeared and if plications have loosened with exposed lengths of suture between stitch sites.
- Identify exposed needle anchors and cinches. These should be avoided or removed.
- In those cases where plications are absent, new plications are placed using the same suture pattern from the index procedure, with the first stitch or bite on the anterior wall.
- Extra care is taken to be certain that each stitch or bite is full thickness (1-1.5 cm gap between suture exit and entrance with each bite).
- It is recommended to place a second overlying reinforcing "V" set of 3 stitches (anterior, greater curve, posterior) in these cases.



- In cases where plications are intact but "loosened" with exposed lengths of suture, new plications are placed next to the loosened plications using the extra measures of second layer reinforcing suturing. The loosened plications are first released by cutting the exposed suture and removing suture to expose the area for the new plication.
- The new plications are created using the same technique as described above (*Endoscopic Sleeve Gastroplasty Procedure*).

17.2. Revision of LSG to Tighten the Sleeve

- The initial endoscopic inspection assesses whether the sleeve is dilated along the entire length or proximally, with an accompanying enlarged fundal remnant.
- Identify the staple line. Suturing through the staple line is to be avoided as it can damage the suture-anchor or suturing instrument.
- Coagulation marks can be made on the anterior and posterior walls. This can prevent closing the sleeve lumen beyond a desirable diameter (<1.5 cm).
- Fewer stitches are needed within the dilated sleeve to create plications. This is influenced by the starting lumen diameter and the staple line.
- Suturing is initiated on the anterior wall of the sleeve, incisura level.
- Extra care is taken to obtain full thickness bites. The tissue grasped by the Helix should be pulled into the device slowly to observe whether or not the grasped tissue is readily drawn into the device. If the grasped tissue is immobile, a deep tear can occur. In this setting, a different site should be selected for stitch placement.
- Plications are started distally.
- The dilated fundal remnant can be reduced with a plication. Care is taken to avoid the thinner cephalad or deeper portion of the remnant fundus to prevent leak.

Prophylactic Techniques and Follow-Up Care are consistent with the advice given in the section on ESG.

17.3. Conversion to Laparoscopic Sleeve Gastrectomy (LSG)

Patients receiving ESG may be converted to LSG if they begin to regain weight after achieving some or all of their weight loss goals. This can occur if the sleeve dilates, or the plications fail. An endoscopy is performed to identify and remove sutures, cinches and suture-anchors prior to performing the conversion. There is a risk of stapling over the original ESG hardware, which can damage the staples or jam the stapling instrument. Once the original ESG hardware is removed, the sleeve gastrectomy can be performed per the routine procedure.

17.4. Transoral Outlet Reduction (TORe)

Patients having previous Roux-en-Y gastric bypass bariatric surgery may experience dilation of the gastrojejunostomy outlet and the gastric pouch, followed by weight gain. This can be addressed by reducing the diameter of the gastric outlet by suturing. Often, the physician may elect to use additional suturing to reduce the dilated areas of the pouch. This procedure is often referred to as Transoral Outlet Reduction (TORe).

The TORe procedure is appropriate when a previous bypass patient demonstrates a stoma diameter greater than 20 mm (Abu Dayyeh 2011, Jaruvongvanich 2020) and is regaining weight. Jaruvongvanich (2020) conducted a meta-analysis and reported that the TORe procedure with full thickness suturing (n=737 patients), reduced the stoma diameter to 8-10 mm and delivered an average of 8.1-11.0% TBWL through 6 months and 4.3-7.1 %TBWL at 12 months. This was consistent with the experience in a registry conducted by the American Gastroenterological Society through 12 months as well as Jirapinyo (2020), which reported weight loss of 8.8% TBWL at 5 years. The most common risks associated with the TORe procedure are bleeding (associated with the use of plasma coagulation) and stricture of the outlet, which can be addressed with endoscopic dilation using a balloon.

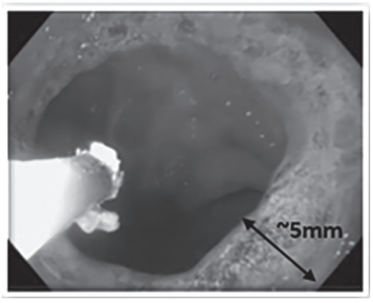
The sources of this information on TORe include the following.

- A multicenter registry on endoscopic suturing conducted as a partnership between Apollo Endosurgery and the American Gastroenterological Association. That study included 39 subjects having the TORe procedure.
- An ongoing single site registry made available to Apollo Endosurgery, including 201 subjects enrolled at a private bariatric practice.
- Abu Dayyeh BK, Lautz DB, Thompson CC. Gastrojejunal stoma diameter predicts weight regain after Roux-en-Y gastric bypass. Clinical Gastroenterology and Hepatology 2011; 9: 228-233.
- Jirapinyo P, Kumar N, AlSamman MA et al. Five-year outcomes of transoral outlet reduction for the treatment of weight regain after Roux-en-Y gastric bypass. Gastrointest Endosc 2020; May;91(5):1067-1073.
- Jaruvongvanich V, Vantanasiri K, Laoveeravat P et al. Endoscopic full thickness suturing plus argon plasma coagulation versus argon plasma mucosal coagulation alone for weight regain after gastric bypass: a systematic review and meta-analysis. Gastro Endo 2020; 92(6): 1164-1175.

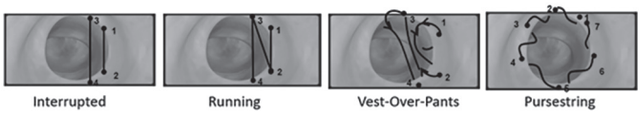
Important factors for a successful procedure include properly operating the device, successfully placing full thickness sutures at each position listed below, avoiding previously placed hardware, reducing the diameter of the gastric outlet

and then decreasing the pouch diameter (if applicable). Specific suture patterns are at the discretion of the physician but should begin with reducing the gastric outlet then reducing the gastric pouch, as necessary.

- Inspect the pouch to assess the size. A normal pouch is approximately 2 cm in length and no more than 2 cm in width.
- Inspect the gastrojejunal anastomosis. A normal anastomosis diameter should be < 1.5 cm.
- Reduce the dilated anastomosis first.
- Start by thoroughly coagulating the margin of the anastomosis and the pouch mucosa within 1 cm of the margin to destroy the mucosa. Alternatively, a circumferential endoscopic mucosal resection (EMR) can be per-formed to remove the mucosa to the edge of the anastomosis.



- Reduce the anastomosis at one side by placing full thickness stitches across from the jejunal to gastric side using the suture pattern of choice. The reduced lumen should be less than 1 cm.



- The anastomosis can be reduced by placing an 8- or 10-mm dilating balloon first, then tensioning the suture and cinching around the balloon.
- If the pouch is dilated, plications can be created to close the lumen to a diameter of less than 2 cm. Fewer stitches are needed compared to a primary ESG plication and are determined by the beginning size of the pouch.
- Stitch placement is guided by the shape of the pouch.
- More than one plication may be needed for the pouch reduction. A plication can be placed to a level just below the squamocolumnar junction.
- When creating a plication below the squamocolumnar junction, placing stitches within the lesser curve should be avoided to reduce the risk for bleeding.
- Prophylactic Techniques and Follow-Up Care are consistent with the advice given in the section on ESG.

18. 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.

19. 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).

20. TROUBLESHOOTING

Endcap assembly does not result in the Endcap being installed at the specified location:

Cause	Resolution
Tape Hook of Endcap Adapter bends backwards while applying Tape, or Endcap Tape slips from Tape Hook during assembly.	*i. Bend the Tape Hook back to its original position* *ii. Repeat section (Assemble endcap), ensuring to fully seat the eyelet of the Endcap Tape to the bottom of the Tape Hook and wrapping the Tape Wand around the scope as close to the scope as possible at all times – do not apply Tape upward or outward from the scope.*
Endcap Tape breaks or is not applied as specified:	*i. Remove any applied tape to the device.* *ii. Unscrew the used Tape Spool from the Tape Wand tip, screw on a spare Tape Spool, and repeat section (Assemble endcap).*
Scope is not fully seated on the roof of the Adapter, or Scope orientation is not set correctly:	*i. Remove Tape per Disassembly Section 15.22* *ii. Unscrew the used Tape Spool(s) from the Tape Wand tip(s), screw on the spare Tape Spool(s), and repeat section (Assemble endcap).*

Difficulty passing installed device through overtube:

Cause	Resolution
Insufficient lubricant applied:	*i. Fully lubricate the device and the inside of the overtube. Apply a twisting motion of the endoscope with the installed device during intubating and extubating.*
Endoscope and/or overtube sizing not compatible:	*i. Exchange overtube selected with a larger sized overtube.*
Device does not lay flat against scope:	*i. Maneuver the scope and device to lay flat against each other. Apply a twisting motion of the endoscope with the installed device during intubating and extubating.*

Distal end of scope is inserted past the roof of Endcap Adapter causing the scope not to be fully seated within Endcap Adapter	*i. Remove Endcap Tapes per Disassembly Section 15.22* *ii. Clean the distal end of the scope so it is free of any lubricants. Ensure the scope tip is clean and dry.* *iii. Unscrew the used Tape Spool(s) from the Tape Wand tip(s), screw on spare Tape Spool(s), and repeat section (Assemble endcap).*

Pull string does not result in increased articulation:

Cause	Resolution
Incorrect setup:	*i. Ensure the scope is compatible, and the endcap is mounted in the specified location. Scope manufacturers other than Olympus, Fuji, or Pentax may require alternate endcap orientations. Incorrect endcap orientation will result in the pull string pulling in a direction that is not in the scope's `UP' direction.* *ii. Discontinue use of the Pull String and complete scope maneuvering without the use of the Pull String.*
Scope dial is not rotated to maximum 'Up' position prior to beginning use of Pull String	*i. If in use, release Pull String per Steps 17.10.* *ii. Fully articulate the scope using the primary ('Up') dial and hold the dial to maintain this position prior to using the Pull String per Section 15.10.*
Unknown Cause	*i. If issue persists, remove scope from patient and ensure the Pull String is not entangled and there is no device damage. Confirm the Pull String functions as intended.* *ii. If issue persists, discontinue use of the Pull String and complete the scope maneuvering without use of the Pull String.*

Pull string brake does not hold scope position:

Cause	Resolution
Brake does not prevent string from slipping:	*i. Wrap the additional turns of the string around the brake washer in same manner as Step 17.10.* *ii. If issue persists, the Pull String tension may be held in the opposite hand, against the scope handle.*

Pull String does not release and allow scope back to neutral position:

Cause	Resolution
After releasing Pull String from Brake, tension remains in Pull String:	*i. Ensure the endoscope's brake is released.* *ii. Ensure the Pull String is not wrapped around or inhibited by any objects at both the proximal end and the distal end.* *iii. If issue persists, cut the pull string with scissors to release tension.*

Difficulty passing catheters through device channels:

Cause	Resolution
Scope retroflexion bend radius is too tight or catheters are kinked	*i. Straighten the endoscope from its retroflexed state (Note: if the Pull String is in use, the Pull String must be released), and maneuver the scope handle ± 90 ° to alleviate any twisting that could have occurred.* *ii. Pass device accessory through device up to the Endcap* *iii. Retroflex the endoscope to desired position.*

Needle body will not open:

Cause	Resolution
Needle obstructed:	*i. Assess the space in which you are working and maneuver the Sheath and endoscope as a system, straighten the endoscope to the non-Retroflexed position.*

Suture movement restricted:	*If the Anchor is on the Needle Body, ensure the suture is not held proximally near the handle during the opening operation.* *i. 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.*
Sheath or Actuation Catheter looped or kinked:	*i. Check to ensure that the Sheath and Actuation Catheter running down the outside of the endoscope are not looped or kinked.* *ii. Straighten the endoscope to the non-Retroflexed position.* *iii. Advance the endoscope forward and slightly pull any slack from the Sheath and Actuation Catheter proximally until minimal resistance is felt.* *iv. Grasp both the Sheath and endoscope and adjust by advancing and retracting as a system.*
Foreign body obstruction:	*i. Remove the Anchor Exchange only:* *a. Transfer the Anchor to the Needle Body and remove the Anchor Exchange from the device.* *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 device.* *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.*
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.* *ii. 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.*

Needle Body will not close:

Cause	Resolution
General obstruction:	*i. Follow steps (Needle Body will not open).* *ii. Ensure the Needle Driver handle is locked closed and:* *a. Stretch the Actuation Catheter to change the effective length of the Needle Body drive cable.* *b. Remove the Anchor Exchange and use graspers (through the device primary channel) to grab the Needle Body.* *c. Cut the Suture if necessary.*
Needle Driver cable broken:	*i. Deploy the Anchor and Cinch. Advance grasper through endoscope and secure Needle Driver. Pull the Needle Driver closed while removing the device. 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.*

Anchor Exchange will not exchange

Cause	Resolution
Anchor Exchange will not install Anchor onto the Needle Body:	*i. Ensure there is sufficient Suture slack and the Suture outside the device is not entangled.* *ii. Ensure the Anchor Exchange is properly positioned in the Endcap of the Needle Driver.* *iii. If the Anchor and Suture are through tissue, either drop the Anchor and deploy the Cinch per Section 15.19 of Instructions for Use or drop the Anchor and use a suitable accessory to cut and remove the Suture.* *iv. If Anchor and Suture are not through tissue, close the handle of the Needle Driver. Remove device. Replace the Anchor and/or Anchor Exchange.*
Anchor Exchange will not release an Anchor:	*i. Ensure there is sufficient Suture slack and the Suture outside the device is not entangled.* *ii. Ensure the Anchor Exchange Release Button is FULLY depressed while retracting the Anchor Exchange.* *iii. Reduce the articulation / tortuosity of the endoscope (if possible) and try to release the Anchor.* *iv. Use accessories compatible with device secondary channel or endoscope working channel to cut and remove the Suture.* *v. Replace the Anchor Exchange.*
Anchor Exchange will not retrieve Anchor from Needle Body:	*i. Ensure there is sufficient Suture slack and the Needle Driver handle is in the closed position.* *ii. Use a 'pencil-grip' to advance the Anchor Exchange until the Anchor is engaged and resistance is felt. Retract Anchor Exchange to acquire Anchor.* *iii. If the Anchor cannot be retrieved, replace the Anchor Exchange. Alternatively, use a suitable accessory to cut and remove the Suture.* *vi. Replace the Anchor and resume suturing per Section 15.14.*

Cinch does not cut the Suture when fired:

Cause	Resolution
Suture not cut	*i. Use a suitable accessory through the device's secondary channel or endoscope working channel to cut the Suture and remove the Cinch.* *ii. Use standard endoscopic techniques to remove the cut Suture.*

Inadvertent drop of Anchor:

Cause	Resolution
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 device channel, use the Anchor Exchange or 3.2 mm compatible grasper to push the Anchor out through the device.* *Do not attempt to pull the Anchor back through the device as it may get stuck in the channel or the y-junction at the handle.*

Suture entanglement:

Cause	Resolution
Suture outside field of view:	*i. Close the Needle Driver Handle and manipulate the endoscope back to release.*

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.*
Suture twisted:	*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.* ***Note:** If the twist was noted immediately after articulation of the endoscope, first try to articulate in reverse order to remove.* *ii. If the Anchor has been deployed, use the Cinch to push and guide the Suture free.*

Endcap detachment from endoscope:

Cause	Resolution
Detached during use:	*i. Close the Needle Body, remove any slack in Catheter Sheath and Pull String and slowly remove the device from the patient. If using an overtube, advance the overtube as far distally as possible and withdraw the endoscope and device into the overtube, maintaining a tight hold of the Sheath to keep the Endcap flush with the endoscope.*

Helix does not unscrew

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

21. CLINICAL EVALUATION OF ESG (MERIT TRIAL)

Study Purpose

The Multi-center ESG Randomized Interventional Trial (MERIT-Trial) evaluated the effectiveness and safety of ESG as an adjunct to life-style intervention for weight loss and improvement in obesity-related comorbidities compared to lifestyle intervention alone, in participants 21-65 years of age with BMI ≥30 and ≤40 kg/m^2 and who have failed to achieve and maintain weight loss with a non-surgical program. The study aimed to enroll up to 200 subjects (80 ESG and 120 controls) and to enroll at least 50 patients with hypertension, at least 50 with Type II diabetes mellitus (T2DM), and to enroll no more than 50 patients with no weight-related comorbidities.

Study Design

This was a prospective, randomized, multicenter study and subjects were followed for two years. Patients were randomized in a 1:1.5 ratio of treatment (ESG + lifestyle modification) to controls (lifestyle modification). At one year, patients in the control group were allowed to cross-over to ESG if they had not responded to lifestyle modification (defined as not having achieved ≥25% Excess Weight Loss (EWL)) and had completed their follow-up visits.

Study Population

There were 85 Treatment and 124 Control subjects randomized. Eight subjects in the Treatment group did not receive treatment and were removed from the study. Twelve subjects in the Control group did not complete a single visit and 2 additional Control subjects were determined to be ineligible prior to starting the study. As a result, 77 Treatment and 110 Control subjects received the assigned treatment. Of these, 55 and 113 had baseline comorbidities of Type II Diabetes or hypertension, respectively, defined as a having a pre-existing diagnosis from their primary care physician and currently taking medications specifically for that comorbidity. Of those, 37 subjects had both baseline diagnosis of both diabetes and hypertension. Three Treatment subjects withdrew consent prior to the 52 week visit

and six were lost to follow-up. In the Control group, 13 withdrew consent and eight were lost to follow-up prior to completing the 52 week visit. As a result, there were 68 Treatment and 89 Control subjects with effectiveness data at 52 weeks. Of the subjects with data at 52 weeks; 45 and 92 subjects had baseline comorbidities of Type II diabetes and hypertension, respectively.

Data Source

This multicenter study was sponsored by the MAYO Clinic (Rochester, MN) and financial support was provided by Apollo Endosurgery, Inc. as part of a collaborative research agreement. Institutional Review Board (IRB) approval was obtained by all sites prior to enrolling subjects for the study. The study data were compiled by the MAYO Clinic, provided to Apollo Endosurgery for independent analysis, and submitted for FDA review.

Key Study Endpoints

The primary effectiveness endpoint of Apollo's analysis was to assess the responder rate, defined as at least 10% Total Body Weight Loss (%TBWL), at 52 weeks. The %TBWL was derived at each post-placement study visit for each subject where a weight measurement was collected. The primary effectiveness endpoint was summarized for the effectiveness population and included 95% confidence intervals. Secondary effectiveness endpoints collected as part of the investigational plan included %Excess Weight Loss (EWL) and change in BMI from baseline. Along with %TBWL, these data were collected at each visit and used to evaluate the effectiveness of Treatment and Control, retightening of an ESG, and crossing over from lifestyle modification to ESG, over time.

All adverse events were recorded. Serious adverse events (defined as a death, a life-threatening event, or hospitalization of at least 24 hours), and select adverse events deemed notable by the clinical sites, were reviewed by an independent Data Monitoring Committee and categorized using the Clavien-Dindo classification. Adverse events graded as Clavien-Dindo Class III or higher were identified for reporting as safety failures. The primary safety endpoint was the percentage of adverse events with Clavien-Dindo Grade III or higher, including a one-sided confidence interval.

Analysis Population

The population for the effectiveness analysis was the mITT population, which included all eligible subjects regardless of adherence to follow-up visits or the treatment program. The mITT population was defined as follows:

- Subjects in both groups that met the eligibility criteria for the study.
    - Treatment group subjects that had an EGD with confirmation of satisfying anatomical and medical criteria and completed the ESG were included in the mITT.
    - Treatment and Control group subjects that were confirmed ineligible based upon baseline visit information, were excluded from study analysis, even if the subject completed study visits prior to exclusion.
- Subjects in the Control group that completed at least one follow-up visit following randomization.

The population for the safety analysis included all mITT patients that were assigned to have an ESG procedure, either as randomized or as a cross-over from lifestyle intervention alone to the ESG group.

Total Number of Enrolled Subjects and Patient Demographics

Nine sites enrolled a total of 187 subjects that made up the modified Intent to Treat (mITT) population. See Table 1 below for details on sample sizes and demographics at enrollment. There were 157 subjects that completed the study through 52 weeks.

Table 1: Demographics for mITT Population by Randomized Treatment Group

Description	Control (Lifestyle Modification)	Treatment (ESG + Lifestyle Modification)	p-value
N	110	77	
Weight (kg)			
Mean ± StdDev	99.2 ± 12.775	98.1 ± 12.346	0.641
Median	97.5	95.3	
Min, Max	73.8, 138.7	74.4, 130.0	
95 % CI	96.7, 101.6	95.3, 100.9	
BMI (kg/m^2)			
Mean ± StdDev	35.74 ± 2.6167	35.37 ± 2.5654	0.357
Median	35.78	35.52	
Min, Max	30.12, 39.88	31.01, 39.83	
95 % CI	35.25, 36.24	34.79, 35.96	
Age (years)			
Mean ± StdDev	45.7 ± 10.072	47.3 ± 9.323	0.269
Median	45.5	49.0	
Min, Max	23, 65	22, 64	
95 % CI	43.8, 47.6	45.22, 49.45	
Gender			
Male	17 (15.5 %)	9 (11.7 %)	0.525
Female	93 (84.5 %)	68 (88.3 %)	
Race			
White	62 (56.4 %)	53 (68.8 %)	0.136
African American	14 (12.7 %)	11 (14.3 %)	
Asian	3 (2.7 %)	0 (0.0 %)	
Hispanic / Latino	18 (16.4 %)	11 (14.3 %)	
Other	9 (8.2 %)	1 (1.3 %)	
Deferred	4 (3.6 %)	1 (1.3 %)	
Weight Related Comorbidities*			
Type II Diabetes	36 (32.7 %)	19 (24.7 %)	0.234
Hypertension	72 (65.5 %)	41 (53.2 %)	0.931

*For Apollo's analysis, the assignment to Type II diabetes and/or hypertension was based on an existing diagnosis from the patient's primary healthcare provider combined with taking medication specifically for that diagnosis. Subjects could be identified as having both type II diabetes and hypertension.

Study Visits and Follow-Up Rates

Visits reported in this study were baseline, 1 week, 4 week, 8 weeks, 12 weeks, 24 weeks, and 52 weeks for the initial randomization groups (Treatment and Control). Additional visits for the Treatment group were at 60 weeks, 72 to 76 weeks and 104 weeks. Control subjects were then allowed to cross-over to ESG. Controls were then followed for 52 weeks following crossover to ESG, in the same schedule as the initial randomization of the Treatment group (1, 4, 8, 12, 24 and 52 weeks after crossover).

The follow-up rates are provided for Control and Treatment groups in Table 2 and Table 3, respectively.

Table 2: Accountability by Follow-up Visit, Primary Endpoint: Control Subjects

	1 week	4 weeks	8 weeks	12 weeks	24 weeks	52 weeks
Theoretical #	110	110	110	110	110	110
Withdrawn	-	2	6	6	8	13
Lost to Follow-up	-	-	1	2	5	8
Expected*	110	108	104	104	102	97
Visit Weight Data	103	92	90	89	85	89@
Missed Visit	7	16	13	13	11	0
% Follow-up – Effectiveness Data^	93.6 %	84.3 %	86.5 %	85.6 %	83.3 %	91.8 %

Subjects in the mITT population
* Expected = Theoretical – Withdrawn
^ % Follow-up = Visit Weight Data / Expected *100
@ Theoretical subjects for cross-over portion of the study

Table 3: Accountability by Follow-up Visit, Primary Endpoint: Treatment Subjects

	1 week	4 weeks	8 weeks	12 weeks	24 weeks	52 weeks
Theoretical #	77	77	77	77	77	77
Withdrawn	-	-	-	-	1	3
Lost to Follow-up	-	-	-	-	-	6
Expected*	77	77	77	77	76	74
Visit Weight Data	76	72	70	62	70	68@
Missed Visit	1	5	7	15	6	0
% Follow-up – Effectiveness Data^	98.7 %	93.5 %	90.9 %	79.2 %	92.1 %	91.9 %

Subjects in the mITT population
* Expected = Theoretical – Withdrawn
^ % Follow-up = Visit Weight Data / Expected *100
@ Theoretical subjects for 52-104 months of the study. One additional subject had known safety information available

Due to the Covid-19 pandemic, starting in March 2020, accommodations were made to permit self-reported weight measurements. Based on an analysis by Apollo Endosurgery, it is estimated that 10% and 13% of the weight measurements at 52 weeks were self-reported, in the Control and Treatment groups, respectively. Previous visits were not impacted. Nine percent of visits 52 weeks after cross-over are likely to have been self-reported. Earlier visits, following cross-over, may have had as high as 40% of the weight related measurements self-reported. This reflects the timing of the most stringent pandemic lock down conditions at the study site locations.

Final Effectiveness Findings

The primary effectiveness analysis is reported in Table 4. Responder rates at 52 weeks, as defined by achieving ≥10 % TBWL, in the completers population were 64.7% and 4.5% in Treatment and Control groups, respectively. Sensitivity analysis, including Last Observation Carried Forward, and Best and Worst Case Scenarios for missing data imputation, all showed a higher responder rate in the Treatment group compared to Control group.

Table 4: Responder rates at 52 weeks, based on achievement of 10 % TBWL in the mITT population.

Population	Control	Treatment	Difference	Standard Error of Difference	95 % CI*	p-value
Completers Rate CI (95 %)	 4/89 (4.5 %) 1.2, 11.1	 44/68 (64.7 %) 52.2, 75.9	 -60.2	 6.2	 -71.0, -46.6	 <0.001
LOCF# Rate CI (95 %)	 5/110 (4.5 %) 1.5, 10.3	 48/77 (62.3 %) 50.6, 73.1	 -57.8	 5.9	 -68.2, -45.2	 <0.001
Best Case Scenario# Rate CI (95 %)	 25/110 (22.7 %) 15.3, 31.7	 53/77 (68.8 %) 57.3, 78.9	 -46.1	 6.6	 -58.0, -32.2	 <0.001
Worst Case Scenario# Rate CI (95 %)	 25/110 (22.7 %) 15.3, 31.7	 44/77 (57.1 %) 45.4, 68.4	 -34.4	 6.9	 -47.2, -20.3	 <0.001

LOCF = last observation carried forward. Best case was calculated assuming that all Treatment and Control subjects lost to follow up were responders. Worst case scenario was that all Treatment subjects lost to follow-up were non-responders, but all control subjects lost to follow-up were responders.

* Confidence interval was obtained based on the Agresti-Caffo confidence interval method, without multiplicity adjustment made.

Additional analyses were performed to report responder rates at 52 weeks (10 % TBWL) by various subgroups. Table 5 below shows that responder rates across the subgroups defined by age, gender, race, BMI, type II diabetes, and hypertension at baseline in the completers population were all higher in the Treatment group than in the Control group.

Table 5: Sub-group responder rates at 52 weeks based on achievement of at least 10 % TBWL in the Completers population.

Comparison	Sub-Group	Control	Treatment	Difference	Standard Error of Difference	95 % CI
Age	< 50 years	3/66 (4.5 %)	22/37 (59.5 %)	-54.9	8.5	-69.5, -36.7
	≥ 50 years	1/23 (4.3 %)	22/31 (71.0 %)	-66.6	9.2	-80.6, -42.8
Gender	Male	0/11 (0 %)	6/9 (66.7 %)	-66.7	15.7	-87.8, -24.0
	Female	4/78 (5.1 %)	38/59 (64.4 %)	-59.3	6.7	-70.9, -44.5
BMI	<35 kg/m^2	3/41 (7.3 %)	24/31 (77.4 %)	-70.1	8.5	-83.5, -49.5
	≥ 35 kg/m^2	1/48 (2.1 %)	20/37 (54.1 %)	-52.0	8.4	-66.4, -33.3
Race	Caucasian	3/51 (5.9 %)	34/47 (72.3 %)	-66.5	7.3	-78.4, -49.4
	Non-Caucasian	1/38 (2.6 %)	10/21 (47.6 %)	-45.0	11.2	-64.3, -21.3
Type II Diabetes	Yes	0/27 (0 %)	11/18 (61.1 %)	-61.1	11.5	-79.0, -34.1
	No	4/62 (6.5 %)	33/50 (66.0 %)	-59.5	7.4	-72.1, -43.1
Hypertension	Yes	1/55 (1.8 %)	22/37 (59.5 %)	-57.6	8.3	-71.6, -39.3
	No	3/34 (8.8 %)	22/31 (71.0 %)	-62.1	9.5	-77.3, -39.8

* Confidence interval was obtained based on the Agresti-Caffo confidence interval method, without multiplicity adjustment made.

The mean % TBWL is shown for each follow up visit in Table 6. Subjects in the Treatment group began to lose weight as early as the one-week visit. Weight loss steadily progressed through 24 weeks (14.70, SD 5.62 % TBWL) then plateaued, with minimal weight regain at 52 weeks (13.86, SD 8.06 % TBWL). Comparatively, subjects in the Control group experienced very little weight loss through 52 weeks (0.76, SD 4.97 % TBWL).

Table 6: % TBWL by Randomized Group and Visit for the mITT Population

Weeks	Descriptive	Control	Treatment	Difference*
1	Mean ± StdDev N Median Min, Max 95 % CI	0.43 ± 1.7946 103 0.11 -4.94, 4.89 0.08, 0.78	-5.08 ± 3.9745 76 -4.61 -29.00, 1.89 -5.99, -4.17	5.51 ± 0.4890 4.54, 6.48
4	Mean ± StdDev N Median Min, Max 95 % CI	-0.08 ± 2.2065 92 0.00 -7.79, 5.86 -0.54, 0.37	-8.47 ± 3.9968 72 -8.03 -33.36, -1.32 -9.41, -7.53	8.39 ± 0.5242 7.35, 9.43
8	Mean ± StdDev N Median Min, Max 95 % CI	-0.42 ± 2.7118 90 -0.17 -7.32, 6.06 -0.99, 0.15	-11.09 ± 4.4888 70 -10.96 -35.36, -3.64 -12.16, -10.02	10.67 ± 0.6079 9.47, 11.88
12	Mean ± StdDev N Median Min, Max 95 % CI	-0.94 ± 3.1050 89 -0.55 -8.81, 4.44 -1.59, -0.28	-13.14 ± 4.9838 62 -11.83 -37.18, -3.88 -14.41, -11.88	12.21 ± 0.6588 10.79, 13.62
24	Mean ± StdDev N Median Min, Max 95 % CI	-1.36 ± 4.5586 85 -0.80 -14.31, 7.49 -2.34, -0.38	-14.70 ± 5.6167 70 -13.51 -29.03, 0.36 -16.04, -13.36	13.34 ± 0.8172 11.73, 14.96
52	Mean ± StdDev N Median Min, Max 95 % CI	-0.76 ± 4.9711 89 -0.39 -17.62, 9.91 -1.81, 0.29	-13.86 ± 8.0585 68 -12.88 -40.91, 6.84 -15.81, -11.91	13.10 ± 1.1102 10.89, 15.30
60	Mean ± StdDev N Median Min, Max 95 % CI	NA	-14.72 ± 7.9433 57 -13.66 -34.09, 1.08 -16.82, -12.61	NA
72-76	Mean ± StdDev N Median Min, Max 95 % CI	NA	-13.93 ± 7.4285 61 -12.40 -37.00, 0.05 -15.84, -12.03	NA
104	Mean ± StdDev N Median Min, Max 95 % CI	NA	-12.20 ± 8.5461 59 -11.29 -34.91, 8.13 -14.43, -9.97	NA

* Difference = Control – Treatment and 95% CIs are not adjusted for multiplicity.

The mITT populations also observed the same type of changes in % EWL and changes in BMI. At the 52-week visit, Treatment and Control subjects reported a loss of 49.81 (SD, 31.40) and 2.98 (SD, 17.97) % EWL, respectively. Similarly, BMI in Treatment and Control subjects reduced by 4.76 (SD, 2.57) and 0.26 (SD, 1.77) kg/m², respectively, at 52 weeks.

Table 7 presents the % TBWL at each follow up visit in patients that were assigned to the Control group but crossed over to the Treatment group at 52 weeks. As early as the 1-week visit, subjects that crossed over to ESG lost more weight than they had with lifestyle modification. Weight loss steadily progressed through 24 weeks then plateaued, with minimal weight regain at 52 weeks. This was the same pattern demonstrated by subjects randomized to ESG. After 52 weeks of lifestyle modification alone, these crossover subjects lost 0.18 (SD, 4.47) % TBWL. Then, 52 weeks after crossing over to ESG, these same subjects had lost 12.95 (SD, 8.64) % TBWL.

Table 7: % TBWL: Control and Cross-Over

Weeks	Description	Control	Cross-Over	Difference*
1	Mean ± StdDev N Median Min, Max 95 % CI	0.38 ± 1.494 67 0.24 -3.89, 4.89 0.01, 0.74	-4.38 ± 2.165 71 -4.32 -10.27, 0.50 -4.89, -3.87	4.75 ± 0.315 4.13, 5.38
4	Mean ± StdDev N Median Min, Max 95 % CI	0.12 ± 1.820 63 0.00 -4.37, 4.78 -0.34, 0.57	-7.70 ± 2.978 70 -7.38 -16.05, 6.43 -8.41, -6.99	7.82 ± 0.423 6.98, 8.66
8	Mean ± StdDev N Median Min, Max 95 % CI	-0.34 ± 2.518 64 -0.55 -6.49, 5.09 -0.97, 0.29	-10.35 ± 2.855 68 -10.45 -17.68, -4.05 -11.04, -9.66	10.74 ± 0.610 9.07, 10.93
12	Mean ± StdDev N Median Min, Max 95 % CI	-0.77 ± 2.936 67 -0.55 -8.58, 4.44 -1.48, -0.05	-11.50 ± 4.097 69 -10.29 -28.77, -4.27 -12.49, -10.52	10.91 ± 4.786 9.53, 11.94
24	Mean ± StdDev N Median Min, Max 95 % CI	-0.69 ± 3.910 64 -0.14 -12.97, 7.49 -1.67, 0.28	-13.35 ± 5.77 69 -12.28 -32.36, -3.83 -14.74, -11.97	12.66 ± 0.849 10.98, 14.34
52	Mean ± StdDev N Median Min, Max 95 % CI	-0.18 ± 4.473 72 -0.02 -17.62, 7.11 -1.23, 0.87	-12.95 ± 8.636 59 -12.17 -36.64, 4.09 -15.20, -10.70	12.77 ± 1.242 10.30, 15.24

* Difference = Control – Treatment and 95% CIs are not adjusted for multiplicity.

The cross-over population also demonstrated the same type of changes in % EWL and changes in BMI. At the 52 week visit after cross-over, subjects reported a loss of 46.85 (SD, 37.97) compared to 0.44 (SD, 15.34) % EWL over the 52 weeks of lifestyle modification prior to crossing over. Similarly, BMI reduced by 4.59 (SD, 2.10) 52 weeks after crossing over, compared to a reduction of just 0.07 (SD, 1.61) kg/m^2, after the 52 weeks of lifestyle modification prior to crossing over. The weight loss from subjects following crossover was consistent with the amount of weight loss in subjects randomized to the Treatment group.

Retightening of ESG

Fourteen (14) ESG patients had a secondary procedure to retighten the original ESG procedure. At 52 weeks prior to the retightening procedure, mean weight loss was 3.84 (SD, 4.31) % TBWL in 9 subjects that had not experienced at least 25 % EWL, and 10.94 (SD, 3.02) % TBWL in 5 subjects that had lost more than 25 % EWL. This is compared to 15.8 (SD, 7.5) % TBWL in the 54 Treatment subjects still under study at 52 weeks that were not retightened. At 104 weeks, 52 weeks after retightening, the mean weight loss from baseline (index ESG procedure) was 7.10 (SD, 5.1) % TBWL in

the < 25 % EWL group (9 subjects) and 11.6 (SD, 7.6) % TBWL in the > 25 % EWL group (5 subjects). Similarly, % EWL and change in BMI were greater for the subjects with >25 % EWL prior to the retightening procedure. No adverse events were associated with the retightening procedure. If retightening is performed, subjects may demonstrate weight maintenance or modest incremental weight loss following the retightening procedure. Retightening of the ESG has the same adverse event profile as the primary ESG procedure.

Final Safety Findings

The safety population includes subjects from both the initial ESG group and cross-over ESG group for a total of 150 subjects. Of these 150 subjects, 146 and 131 subjects had complete safety data through 24 and 52 weeks since the ESG, respectively. The observed rate of device or procedure related, Clavien-Dindo Grade III or higher, events was 2.3 % (3/131) and the upper limit of the 1-sided 95 % confidence interval was 6.5 %. Table 8 summarizes the primary safety endpoint analysis and imputations associated with the study.

Table 8: Primary Safety Endpoint: Incidence of Device and/or Procedure Related, Clavien-Dindo Grade III or higher, through 52 Weeks.

Analysis Population	Weeks	SAE Incidence Rate	Upper Limit of 1-sided 95 % CI
Completers	52	3 / 131 (2.3 %)	6.5 %
Imputation (Best Case)	52	3 / 150 (2.0 %)	5.7 %
Imputation (Worst Case)^	52	22 / 150 (14.7 %)	21.4 %

^ Worst case scenario assumed that subjects with missing data had a safety endpoint event. Subjects that continue in active follow-up and have completed their 24-week visit were not reported as an SAE in Worst Case as all reported SAEs occurred prior to the 12 week visit. This ensures that subjects that continue to be followed but are not yet due for their expected visits to not negatively impact the imputation.

* Confidence interval was obtained based on the Agresti-Caffo confidence interval method, without multiplicity adjustment made.

The three adverse events rated Clavien-Dindo Grade III or higher were as follows. One patient presented with an abdominal abscess and plural effusion two weeks after ESG. One patient was admitted at 11 weeks following ESG with weakness, dehydration, altered mental status and was suspected of malnutrition. This case was treated by endoscopically cutting sutures to open the sleeve. One patient was kept in the hospital after the ESG due to abdominal pain, nausea and vomiting. It was determined that this patient had bleeding associated with the use of Argon Plasma Coagulation to mark the intended suture locations. Upon follow-up EGD, this patient was found to have an amount of clotted blood, which was located in the cardia (between the stomach and esophagus). All three cases resolved with medical intervention.

An additional safety analysis was performed using FDA's traditional definition of a Serious Adverse Event (SAE). There were 21 device or procedure related SAEs reported from 11 of the 150 subjects receiving ESG (including primary and cross-over subjects). This represents an SAE rate of 7.3 % (11/150; 95 % CI: 3.7-12.7 %) See Table 9. The most frequently reported SAEs were nausea, abdominal pain and vomiting. The FDA definition resulted in a higher SAE rate because the investigational plan aimed to discharge patients the day of the procedure, and 7 patients were hospitalized to address early post-operative symptoms associated with accommodation to the sleeve, primarily nausea and vomiting. Treatments consisted of IV fluids, pain medications and anti-emetics and all adverse events resolved prior to discharge. There was also a device related adverse event that resulted in a mucosal tear in the esophagus. The decision was made not to complete the procedure. The patient was kept in the hospital for three days and then discharged.

Table 9: Overview of Device and/or Procedure Related Serious Adverse Events by Subject

Serious Adverse Event[1]	# Subjects (% Subjects)	# Events	Onset (days to event)
Abdominal Abscess	1/150 (0.7 %)	1	15
Abdominal Pain	3/150 (2.0 %)	3	Mean = 1.7 Median = 2 Range = 0-3
Bloody Stools	1/150 (0.7 %)	1	0
Bowel Impaction	1/150 (0.7 %)	1	81
Dehydration	1/150 (0.7 %)	1	5
Esophageal Mucosal Tear	1/150 (0.7 %)	1	0
GI bleeding at Argon Plasma Coagulation site	1/150 (0.7 %)	1	0

Malnutrition[2]	1/150 (0.7 %)	1	77
Nausea	5/150 (3.3 %)	5	Mean = 0.8 Median = 1 Range = 0-2
Pleural Effusion	1/150 (0.7 %)	1	20
Pneumonitis	1/150 (0.7 %)	1	4
Sore Throat	1/150 (0.7 %)	1	8
Vomiting	3/150 (2.0 %)	3	Mean = 0.3 Median = 0 Range = 0-1
Total	11/150 (7.3 %)	21	Mean = 11 Median = 2 Range = 0-81

[1] A serious adverse event is one that:
- Led to death
- Resulted in serious deterioration in the health of the subjects that results in:
  - o Life-threatening illness or injury
  - o Permanent impairment of a body structure or a body function
  - o The need for in-patient care or prolongation of hospitalization (this does not include the optional 23 hours observation admission after ESG or re-tightening procedure)
  - o Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function
- Planned hospitalization for a pre-existing condition, or a procedure required by the trial protocol, without serious deterioration in health, is not considered a serious adverse event

[2]This patient was treated by endoscopically cutting sutures to open the sleeve.

Considering gastrointestinal adverse events that could be attributed to the device or procedure, the most common events were nausea, abdominal pain, constipation, eructation, constipation, heartburn and diarrhea. See Table 10. All of these types of events tended to initiate within the first week of the procedure and to resolve within 30-60 days.

Table 10: All Gastrointestinal Device and/or Procedure Related Adverse Events Occurring in > 10% of Subjects

Adverse Event	**Number of Subjects (% subjects) N=150**	**Date of Onset: Median (Mean) Range**	**Duration in Days[1]: Median (Mean) Range**	**Severity[2] n/N (%): Mild[3] Moderate[4] Severe[5] Unknown[6]**	**# Subjects with onset <= 3 days post-procedure (% Subjects)**	**# Subjects with onset <= 3 post-procedure with duration > 14 days and <= 30 days (% Subjects)**	**# Subjects with onset <= day 3 post-procedure with duration > 30 days (% Subjects)**
Abdominal Pain[7]	102 (68.0 %)	0 (37.5) 0-704	4 (16.1) 1-162	77/102 (75.5 %) 22/102 (21.6 %) 3/102 (2.9 %) 0/102 (0 %)	82/102 (80.4 %)	8/82 (9.8 %)	6/82 (7.3 %)
Constipation[7]	68 (45.3 %)	7 39.5 0-567	26 51.5 1-368	51/68 (75.0 %) 17/68 (25.0 %) 0/68 (0 %) 0/68 (0 %)	30/68 (44.1 %)	3/30 (10.0 %)	12/30 (40.0 %)
Diarrhea[7]	23 (15.3 %)	8 65.3 0-427	8 25.7 1-296	20/23 (87.0 %) 2/23 (8.7 %) 0/23 (0 %) 1/23 (4.3 %)	9/23 (39.1 %)	1/9 (11.1 %)	1/9 (11.1 %)

Eructation[7]	77 (51.3 %)	1 19.1 0-366	27 45.8 1-403	67/77 (87.0 %) 10/77 (13.0 %) 0/77 (0 %) 0/77 (0 %)	55/77 (71.4 %)	5/55 (9.1 %)	24/55 (43.6 %)
Heartburn / Reflux	55 (36.7 %)	2 40.1 0-550	10 44.5 1-253	40/55 (72.7 %) 14/55 (25.5 %) 0/55 (0 %) 1/55 (1.8 %)	34/55 (61.8 %)	4/34 (11.8 %)	9/34 (26.5 %)
Nausea	105 (70.0 %)	0 9.5 0-365	3 7.7 1-89	76/105 (72.4 %) 24/105 (22.8 %) 5/105 (4.8 %)	92/105 (87.6 %)	3/92 (3.3 %)	3/93 (3.3 %)
Vomiting	74 (49.3 %)	0 23.5 0-541	2 8.1 1-368	54/74 (73.0 %) 16/74 (21.6 %) 3/74 (4.1 %) 1/74 (1.3 %)	60/74 (81.1 %)	0/60 (0 %)	1/60 (1.7 %)

[1] Duration in Days = Date of Resolution – Date of Onset +1. Thus, an event that resolved the same day as onset will have a day of resolution = 1.
[2] Subjects with multiple events of the same type are reported by first occurrence with the highest severity.
[3] Mild = awareness of sign or symptom, but easily tolerated, although not specifically defined in the study protocol.
[4] Moderate = discomfort enough to cause interference with usual activity, although not specifically defined in the study protocol.
[5] Severe = incapacitating with inability to work or do usual activity, although not specifically defined in the study protocol.
[6] Unknown = no response was recorded in the electronic database.
[7] The following events did not have a resolution date recorded and were excluded from the duration calculations (1 report of Abdominal pain, 3 reports of constipation, 1 report of diarrhea, and 1 report of eructation).

There were 935 device or procedure related adverse events reported in the study. See Table 11. Of the 150 subjects that had an ESG (including primary and cross over subjects), 138 (92%) experienced at least one device or procedure related adverse event and 132 (88%) experienced at least two. Some subjects reported multiple instances of a given type of adverse event. These types of adverse events were most likely to be abdominal pain, eructation, constipation, and nausea.

Table 11: All Device and/or Procedure Related Adverse Events

Adverse Event[1]	**# Subjects[2] with Events (% Subjects)**	**# Events[3] (% Events)**	**# Subjects with Event Occurrence > 1 (% Subjects)**
Abdominal Abscess	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Abdominal Pain	102 (68.0 %)	143 (15.3 %)	28 (18.7 %)
Abdominal Spasm	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Back Pain	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Bloody Stools	8 (5.3 %)	10 (1.1 %)	2 (1.3 %)
Blurred Vision	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Bowel Impaction	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Burning	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Chest Pain	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Chills	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Concentrated Urine	22 (14.7 %)	28 (3.0 %)	3 (2.0 %)
Constipation	68 (45.3 %)	102 (10.9 %)	23 (15.3 %)
Cough	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Cramping	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Dehydration	6 (4.0 %)	8 (0.9 %)	1 (0.7 %)
Diarrhea	23 (15.3 %)	29 (3.1 %)	3 (2.0 %)
Dizziness	40 (26.7 %)	44 (4.7 %)	4 (2.7 %)

Epigastric Pain	2 (1.3 %)	2 (0.2 %)	0 (0 %)
Eructation	77 (51.3 %)	107 (11.4 %)	25 (16.7 %)
Esophageal Mucosal Tear	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Fever	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Gagging on Uvula	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Gas Pain	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Halitosis	32 (21.3 %)	35 (3.7 %)	3 (2.0 %)
Headache	35 (23.3 %)	43 (4.6 %)	6 (4.0 %)
Heartburn / Reflux	55 (36.7 %)	75 (8.0 %)	15 (10.0 %)
Hiccups	33 (22.0 %)	43 (4.6 %)	6 (4.0 %)
Intraoperative Bleeding	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Low Iron	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Malnutrition	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Metallic Taste in Mouth	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Nausea	105 (70.0 %)	140 (15.0 %)	22 (14.7 %)
Night Sweats	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Pleural Effusion	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Pneumonitis	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Rash	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Rectal bleed	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Shortness of Breath	2 (1.3 %)	2 (0.2 %)	0 (0 %)
Shoulder Pain	3 (2.0 %)	3 (0.3 %)	0 (0 %)
Sore Throat	2 (1.3 %)	2 (0.2 %)	0 (0 %)
Syncope	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Tremors	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Vomiting	74 (49.3 %)	93 (9.9 %)	10 (6.7 %)
White Tongue	1 (0.7 %)	1 (0.1 %)	0 (0 %)
Grand Total	138 (92.0 %)	935 (100 %)	132 (88.0 %)

[1] Adverse Events reported in the CSR as a combination (i.e., Nausea and Vomiting) were separated into 2 events to ensure all related symptoms are reported together
[2] Subjects: N = 150
[3] Events: N = 935

Study Conclusions

The primary effectiveness analysis showed a higher responder rate in the Treatment group compared to Control group. A responder was defined as a patient who achieved at least 10 % TBWL at 52 weeks after treatment or initiation of the lifestyle modification program. Weight loss was largely maintained over 104 weeks and the rate of device- and/or procedure-related SAEs was 7.3 % (11/150; 95 % CI: 3.7-12.7 %). The observed rate of device or procedure related, Clavien-Dindo Grade III or higher, events was 2.3 % (3/131) and the upper limit of the 95% confidence interval was 6.5 %. Adverse events were mostly associated with symptoms of early accommodation to the sleeve (e.g., abdominal pain, eructation, nausea and vomiting) and resolved with medical intervention. The MERIT Trial demonstrated a favorable benefit:risk profile.

22. WARRANTY

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

23. SYMBOL DEFINITIONS

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

24. 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.

25. 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.

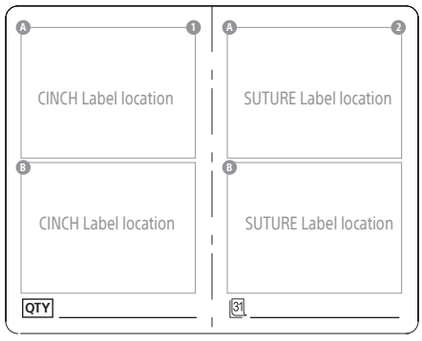


Table 1. Symbol Definitions

	Contents
	For Use with
	Gastric

REF

Boston Scientific Legal Manufacturer	Apollo Legal Manufacturer
M00505430 OverStitch NXT Endoscopic Suture System 1pk	ESS-G02-NXT ESS-ESG-NXT
M00505451 OverStitch 2-0 Polypropylene Suture 12pk	PLY-G02-020-APL
M00505530 OverStitch Suture Cinch 1pk	CNH-G01-000
M00505460 Tissue Helix 1pk	THX-165-028
M00505490 NXT Tissue Helix Pro 1pk	NXT-THXP-130

AR REP

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

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BSC (MB eIFU Template 8.2677 x 11.6929 A4, 925243241), eIFU, MB, OverStitch NXT US only, en, 51931761-01A

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