Overview

Product

OverStitch™ NXT Endoscopic Suturing System – IFU # 51931761

℞ ONLY

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

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.

Intended Use/Indications for Use

The Endosurgery 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/m² 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/m² by enabling transoral outlet reduction as a revision to a previous bariatric procedure.

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 interventions are contraindicated.
- This system is not for use on 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.

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 and NXT Helix Tissue Helix Pro are 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/NXT Tissue Helix Pro. 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 involving OverStitch, 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.
- 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.
- 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.
- Confirm both hooks are fully covered by tape and that the tape is wrapped tightly to scope with no gaps or folds.
- Ensure Tape lays smoothly with no gaps or folds, and that taped portions of device lay flat against the scope.
- 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.
- 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.
- 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.
- 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.
- 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.

- 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.
- 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. If Troubleshooting is unsuccessful, additional intervention may be required.
- Excessive tension may damage tissue and/or damage/break the suture.
- 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.
- 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.

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.

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.
- Take care not to crush or damage the catheters near the Endcap.
- Ensure the Endcap is not dropped or damaged.
- Ensure the Handle Strap is secured above the endoscope channel port.
- 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.
- The scope should be fully seated and held securely until after the first tape is fully applied.
- Ensure the Suture is not tangled after removal from the Racetrack as this may result in deployment difficulties.
- Do not use when valve covers are closed as Suture drag will be increased.
- Apply tension to Suture at proximal end while advancing the Anchor Exchange to prevent Suture entanglement. Excessive tension may damage/break the suture.
- If resistance is encountered when advancing the Anchor Exchange through the Anchor Exchange Channel, reduce the endoscope angulation until the device passes smoothly.
- 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.
- Failure to fully articulate scope prior to use of Pull String may result in damage to scope or device.
- If significant resistance is encountered when pulling on Pull String, release tension on string and do not proceed with use of pull string.

- An uncontrolled release of the pull string could cause an uncontrolled movement of the endoscope and damage tissue.
- If the Needle Body does not open, ensure that the Anchor has been released from the Anchor Exchange.
- 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.
- 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.
- 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.
- Do not depress the Helix Handle button while advancing Helix through the device.
- Ensure that the Needle Arm does not inadvertently close on any foreign object or device. Doing so may damage the device.
- Do not press the Anchor Release Button, as this may cause an inadvertent drop of the Anchor.
- 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.
- Do not tension the Suture with the Anchor in the Needle Body. This could result in inability to complete suture sequence, or suture breakage.
- Do not release the Anchor inside the Anchor Exchange channel. Doing so may cause damage to the NXT channel.
- The safety spacer must only be removed immediately prior to deploying the Cinch in order to avoid inadvertent suture cutting.
- Suture tension must be maintained during Cinch deployment. Otherwise, tissue approximation may be lost.
- Ensure scissors do not contact scope. Cutting the tape at any other location may result in scope damage.

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 (Specific to Bariatric Procedures)
- 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

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 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 2ºC 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.

As a condition of the FDA De Novo Authorization of the Overstitch NXT and Overstitch Endoscopic Suturing System for endobariatric procedures (formerly referred to as the Apollo ESG and Apollo REVISE Systems), the devices should only be used for Endoscopic Sleeve Gastroplasty (ESG) or to enable transoral outlet reduction (TORe) as a bariatric revision procedure by gastroenterologists and surgeons who have undergone specific training by the device manufacturer.

To fulfill the FDA requirement and special controls for these devices, Boston Scientific is required to independently host courses with consistent training curricula. More information regarding the referenced ESG and TORe revision procedure training courses is available through Boston Scientific