stryker

Artelon® FlexBand®
Twist Anchor System

Operative technique

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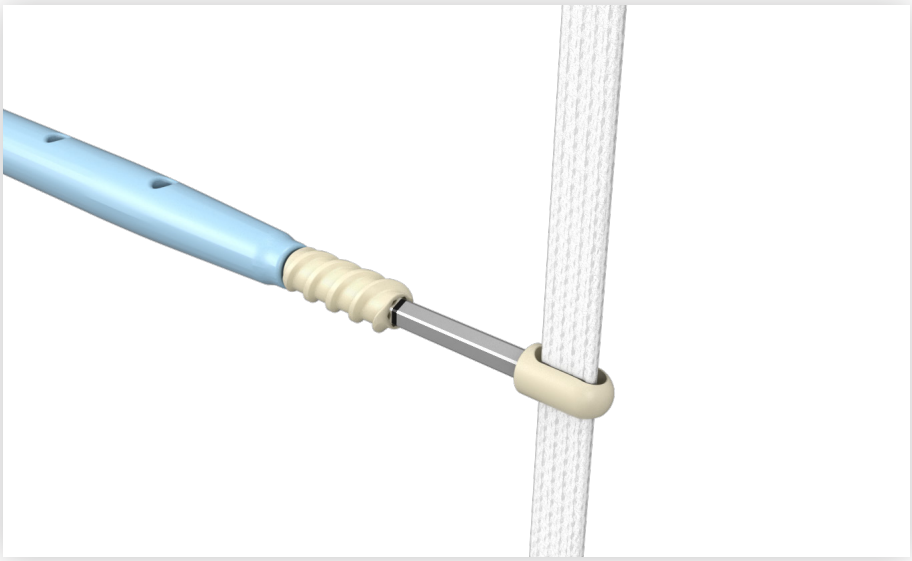


This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

Indications and contraindications

Indications

FlexBand®, FlexPatch®, and FlexBand® Plus are intended for use in surgical procedures for reinforcement of soft tissue where weakness exists. FlexBand®, FlexPatch®, and FlexBand® Plus are also intended for reinforcement of soft tissues that are repaired by suture or other fixation devices during tendon and ligament repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps tendons, medial collateral ligament, lateral collateral ligament, spring ligament, deltoid ligament, ulnar collateral ligament or other tendons or extra-articular ligaments. FlexBand®, FlexPatch®, and FlexBand® Plus are not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff, patellar, Achilles, biceps, quadriceps tendons, medial collateral ligament, lateral collateral ligament, spring ligament, deltoid ligament, ulnar collateral ligament or other tendons or extra-articular ligaments. Sutures, used to repair the tear, and sutures or other fixation devices, used to attach the tissue to the bone, provide mechanical strength for the tendon repair. The products reinforce soft tissue and provides a degradable scaffold that is incorporated into the patient's own tissue.

The ATL Anchors are indicated for attachment of soft tissue to bone. This product is intended for the following indications:

- Shoulder: Rotator Cuff Repair, Acromioclavicular Separation Repair, Bankart Repair, Bankart Lesion Repair, Biceps Tenodesis, Capsular Shift or Capsulolabral Reconstruction, Deltoid Repair, SLAP Lesion Repair.
- Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Illiotibial Band Tenodesis, Patellar Ligament and Tendon Avulsion Repair.
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Midfoot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair.
- Elbow: Tennis Elbow Repair, Biceps Tendon Reattachment.
- Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, TFCC.
- Hip: Acetabular labral repair.

Contraindications, including but not limited to

Artelon FlexBand is contraindicated for use in patients with:

- Active or latent infection,
- Decreased vascularity,
- Pathologic soft tissue conditions that would prevent secure fixation.

Artelon FlexBand is contraindicated for use in any patient with mental or neurological conditions who is unwilling or incapable of following postoperative care instructions.

Artelon FlexBand is contraindicated for uses that require rolling, folding, or layering, and which may create a space impermeable to fluid, cells, and blood vessels. Such uses may result in excessive inflammation, drainage, extrusion, or infection.

ATL Anchors are contraindicated in the following clinical scenarios:

- Any active infection;
- Blood supply limitations or other systemic conditions that may retard healing;
- Foreign body sensitivity, if suspected should be identified and precautions observed;
- Insufficient quality or quantity of bone. Suture anchor performance is directly related to the quality of bone into which the anchor is placed;
- Patient's inability or unwillingness to follow the surgeon's prescribed postoperative regimen;
- Any situation that would compromise the ability of the user to follow the directions for use or using the device for an indication other than those listed; and
- Risks due to anesthesia.

⚠ CAUTION

Use of this product in applications other than those intended for implantation to reinforce soft tissue where weakness exists has the potential for serious complications. The patient is to be made aware of the potential complications as listed.

MR

Artelon® anchors, FlexBand®, FlexPatch®, and FlexBand Plus® are MR safe.

System general considerations

TW012 FlexBand Twist.12 kit

- 0.5×12cm FlexBand Plus pre-loaded on driver with 3.85 anchor and eyelet
- 1.4mm K-wires (2)
- Drill Guide
- 4.5mm Cannulated Drill Bit
- Anchor caddy with 3.85 anchor (1) and 5.0 anchor (1)

TW030 FlexBand Twist.30 kit

- 0.5×30cm FlexBand Plus pre-loaded on driver with 3.85 anchor and eyelet
- 1.4mm K-wires (2)
- Drill Guide
- 4.5mm Cannulated Drill Bit
- Anchor caddy with 3.85 anchor (2) and 5.0 anchor (1)

System general considerations (continued)

- Consult Instructions for Use for a complete list of potential adverse effects and adverse events, contraindications, warnings and precautions.
- Do not resterilize. Discard all open and unused portions of FlexBand product.
- The device is sterile if the package is unopened and undamaged. Do not use if the package seal is broken.
- Discard the device if mishandling has caused possible damage or contamination, or if the device is past its expiration date.
- Ensure that device is hydrated prior to anchoring.
- Aseptic technique must be adhered to throughout the procedure.
- Single patient use only. Reuse of product may result in cross contamination or infection.
- The ATL Anchors come pre-loaded onto a driver. Do not remove the anchor from the driver.
- The devices are preloaded with size USP 0 ultra-high molecular weight polyethylene (UHMWPE) suture. Needles may also be provided for convenience.
- The fixation provided by this device should be protected until healing is complete. Failure to follow the postoperative regimen prescribed by the surgeon could result in the failure of the device and compromised results.
- Size selection of the implant should be made with care taking into consideration the quality of the bone into which the implant is to be placed.
- Any decision to remove the device should take into consideration the potential risk of a second surgical procedure. Adequate postoperative management should be followed after implant removal.
- Pre-operative planning and evaluation, surgical approaches and technique, and familiarity of the implant, including its instrumentation and limitations are necessary components in achieving a good surgical result.
- This device must never be reused. Reuse or re-sterilization may lead to changes in material characteristics such as deformation and material degradation which may compromise device performance. Reprocessing of single use devices can also cause cross-contamination leading to patient infection.
- This device must never be re-sterilized.
- Appropriate instrumentation (drill, drill bit, mallet) should be used to implant this device.

The following complications are possible with the use of surgical graft material. If any of these conditions occur, the device may need to be removed at the surgeon's discretion:

- Infection
- Acute or chronic inflammation (Initial application of surgical graft materials may be associated with transient, mild, localized inflammation.)
- Tissue erosion
- Product extrusion.

Operative technique

1. Preparation of FlexBand

FlexBand shall be soaked in sterile saline (0.9% NaCl) at room temperature for at least 5 minutes before use. If the FlexBand is pre-loaded on the driver, the entire driver and FlexBand can soak in saline while it is still loaded on the driver as long as the FlexBand is submerged.

⚠CAUTION

Do not skip soaking step. Soaking is integral for promotion of tissue integration.

2. Exposure

Physician preference can be utilized to expose the operative site. Care should be taken to avoid injuring tendons, blood vessels and peripheral nerves.

3. Isolation and preparation of tendons or ligaments for reinforcement

Dissection is performed to identify and define tendons or extra-articular ligaments that are to be reinforced. The primary repair of the tendon or ligament should be completed using sutures to repair the tear or other fixation devices, used to re-attach the tissue to the bone, which will provide mechanical strength for the tendon/ligament repair.

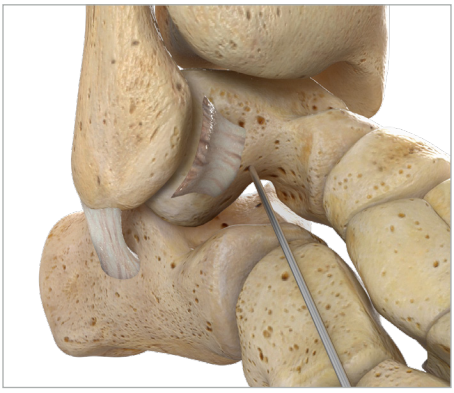
The FlexBand system described here is intended to reinforce soft tissue on conjunction with the primary repair.

4. Preparation of distal pilot hole

The bone is prepared for anchor placement. The surgeon can determine the number of anchors needed per their standard protocol and tissue requirements. The bone is drilled by placing the K-wire and using the provided cannulated drill bit and drill guide.

The drill guide should be fully seated against the bone anatomy and the drill bit should be advanced into the guide until the drill bit fully seats against the back of the drill guide.

The anatomical site may be prepared for additional implants based on surgeon determination per their standard protocol.



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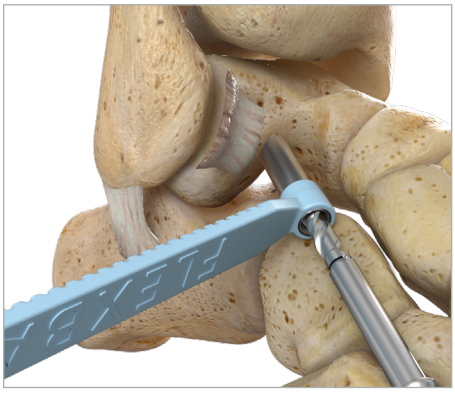

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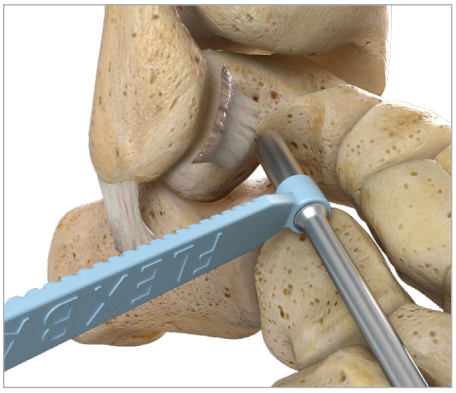

4C

5. Implanting the anchor

Insert the FlexBand Twist anchor into the prepared pilot holes. Place the tip of the inserter containing the eyelet and pre-loaded FlexBand into the pilot hole. Align the driver with the trajectory of the prepared hole. Using a mallet, tap the back of the driver until the anchor body engages with the surface of the bone.

Then hold the paddle and rotate the driver handle clockwise until the anchor is fully seated and flush with the bone. Unwind the sutures from the paddle cleats and remove the inserter by gently pulling straight back.

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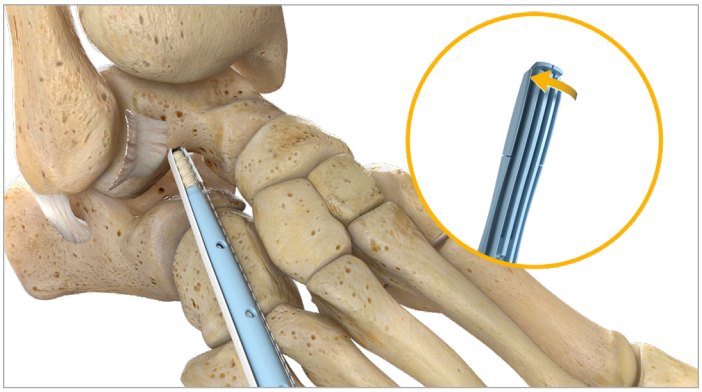
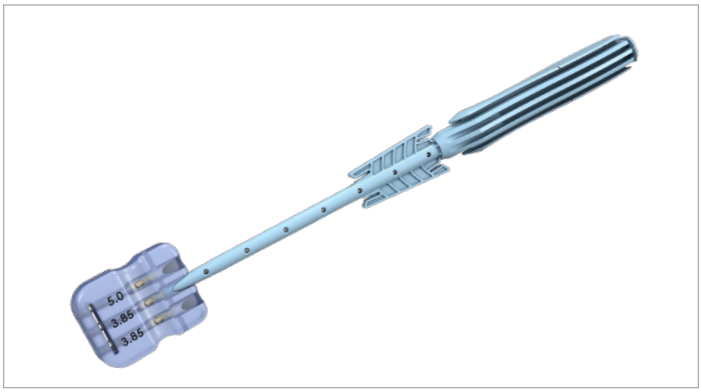


5B

6. Re-load additional anchors

Using the caddy, re-load an additional eyelet and anchor on the driver. Reload the inserter with a standard 3.85mm anchor. The 5.0mm anchor may be selected at the surgeon's discretion based on softer bone or variable patient anatomy. Align the driver with the angle of selected slot and advance the shaft into the slot. Apply firm pressure and remove the driver from the caddy slot. When the driver is removed, the shaft will be re-loaded with an eyelet and the selected anchor size. Ensure the eyelet is secure and fully flush on the driver shaft before proceeding to next step. If the eyelet is not flush, return the shaft back into the caddy slot and apply additional firm pressure.



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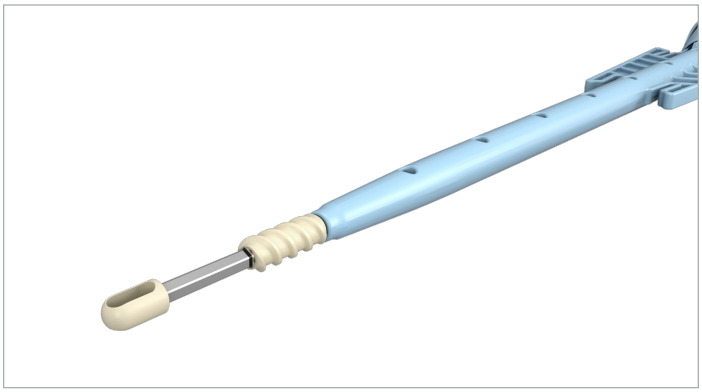

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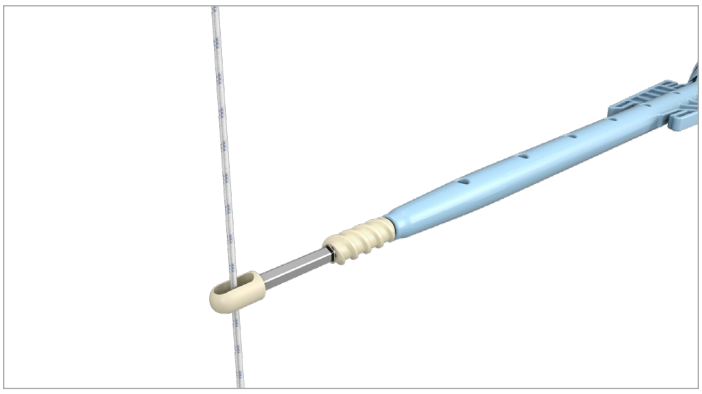
7. Load the FlexBand in the anchor

Using the suture, thread the FlexBand through the re-loaded eyelet on the end of the driver.



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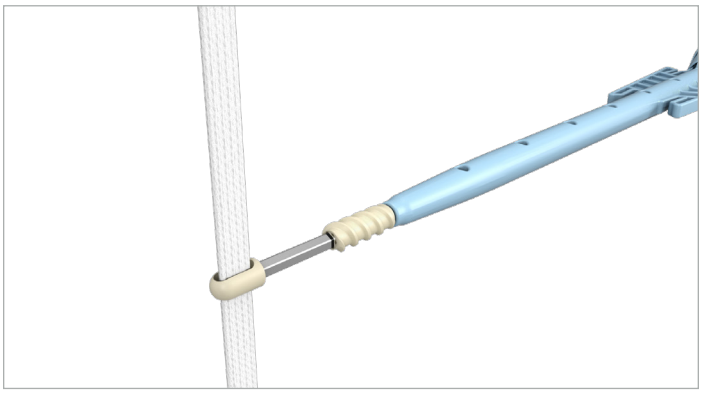


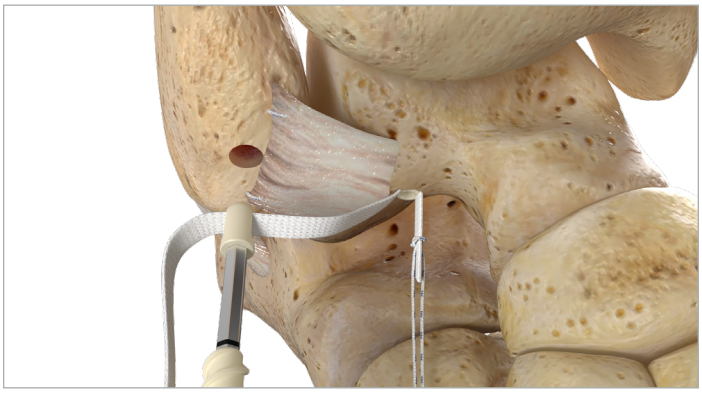
7B

8. Implant FlexBand and additional anchor

The anatomy should be placed in optimal position for each specific augmentation procedure before implanting additional anchors.

Remove the slack out of the FlexBand so the material is taut and place the tip of the inserter containing the eyelet and pre-loaded FlexBand into the next prepared pilot hole. Using a mallet, tap the back of the driver until the distal end of the anchor body threads engage with the surface of the bone.

Then hold the paddle and rotate the driver handle clockwise until the anchor is fully seated and flush with the bone.



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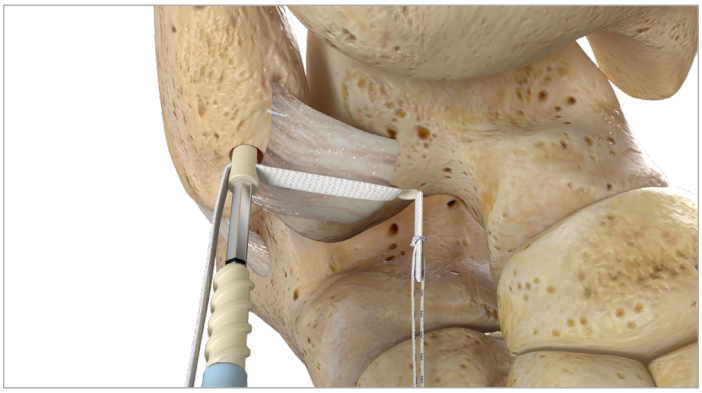

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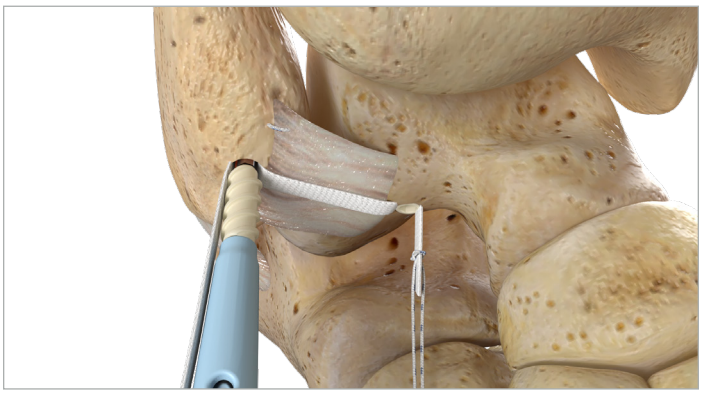

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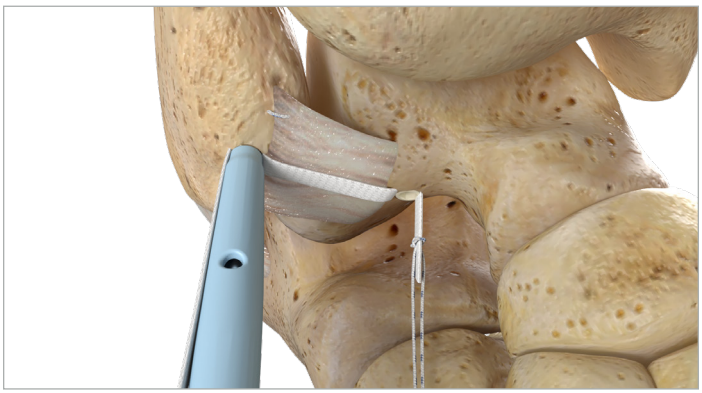

8D

9. Completing the augmentation, trim excess and close

After completing the insertion of the final FlexBand Twist implant, use a sharp instrument to trim any excess FlexBand at the level of the cortex. Ensure to avoid damaging soft tissue or the implanted FlexBand.

Wound closure is then performed according to the surgeon's standard protocol.

9A

Removal

If, for any reason, the clinician determines that the implant should be removed after it has been seated, the driver can be used to unscrew the anchor by turning counterclockwise and the FlexBand can be manually pulled to remove the implant and eyelet.

Notes

Notes

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Foot & Ankle

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for cleaning and sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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