

ZipTight[™] Ankle Syndesmosis

Surgical Technique

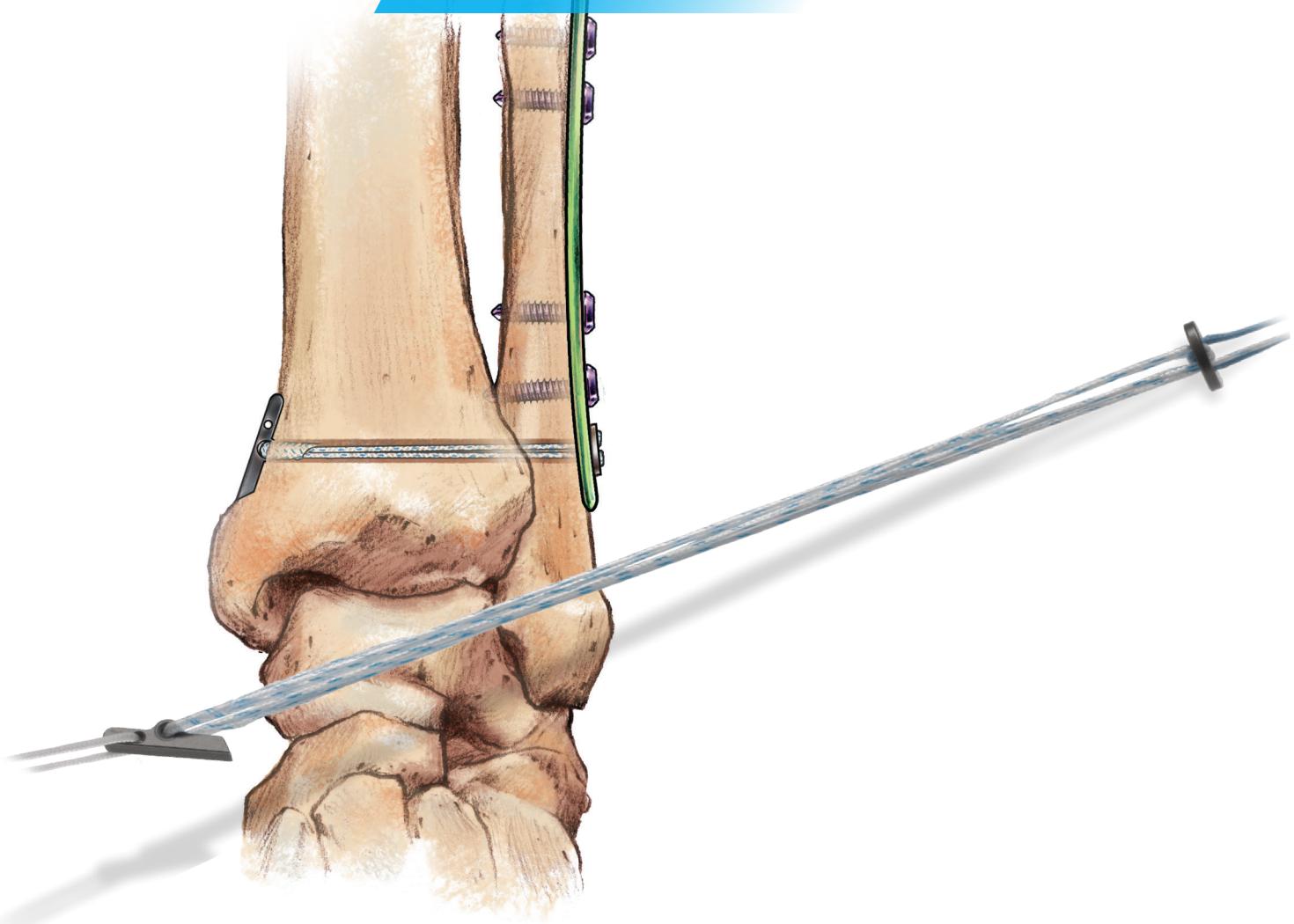
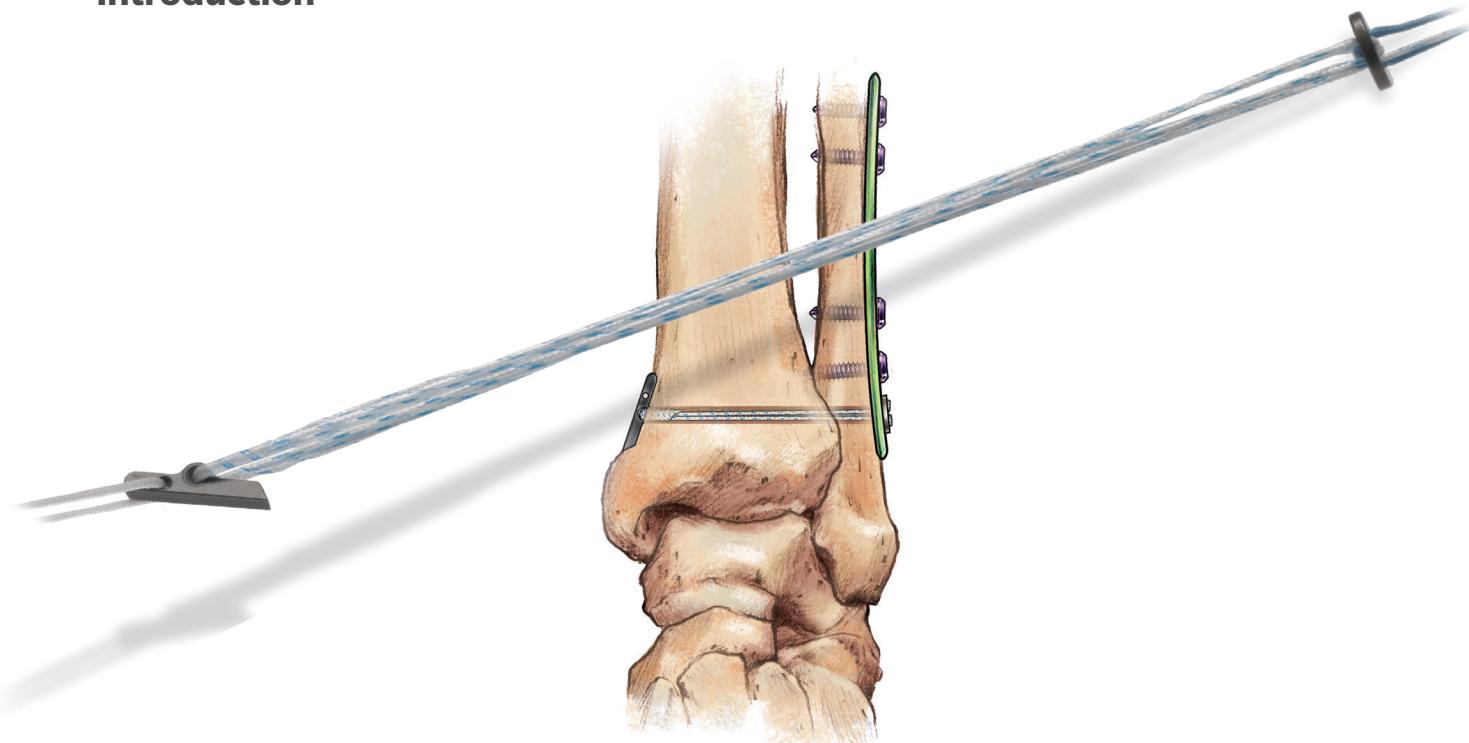


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Introduction



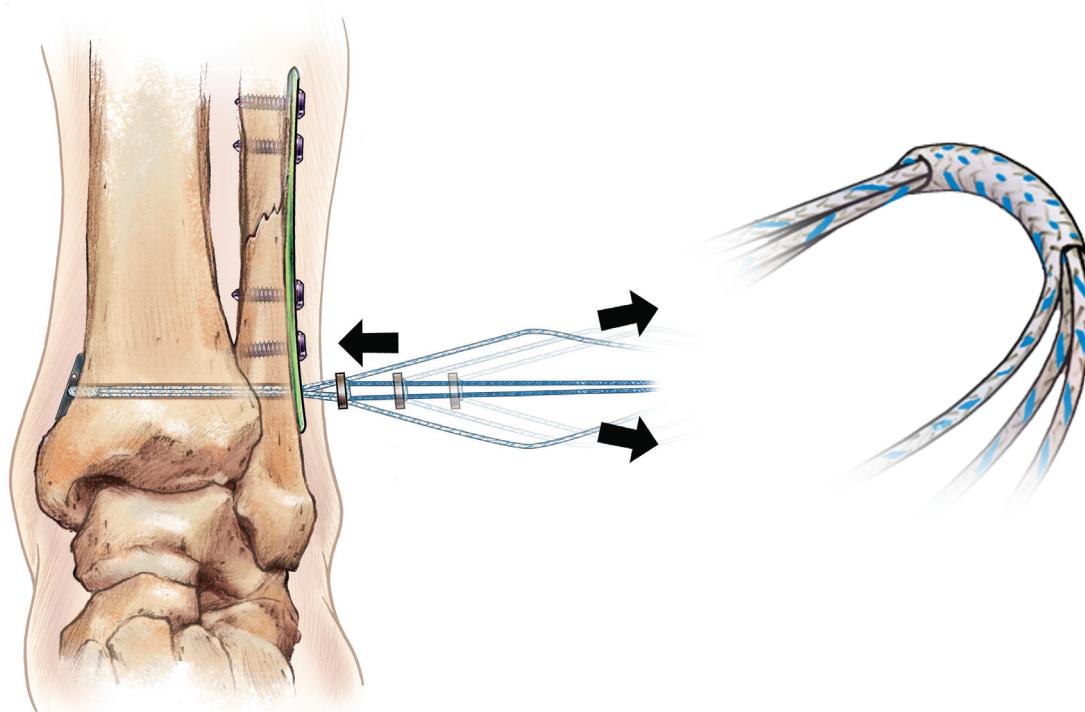
Medial Fixation

ZipLoop® Technology is a unique weave in which a single strand of braided polyethylene is woven through itself twice in opposite directions. This construct allows Biomet Sports Medicine to produce innovative products that can vary in length and compression/tension addressing the individual needs of each patient. Products utilizing ZipLoop Technology are designed to be resistant to slippage¹.

Material

- Available with either titanium or stainless steel buttons to correspond with the titanium A.L.P.S.® Distal Fibula Plate or the stainless steel Zimmer® Periarticular Locking Distal Fibula Plate.

1. Data on file at Biomet Sports Medicine. Bench test results are not necessarily indicative of clinical performance



Lateral Fixation

- Round top hat button for lateral fixation
- Can be used directly on the lateral cortex of the fibula or in conjunction with the titanium A.L.P.S. Distal Fibula Plate or the stainless steel Zimmer Periarticular Locking Distal Fibula Plate as deemed appropriate by the surgeon.

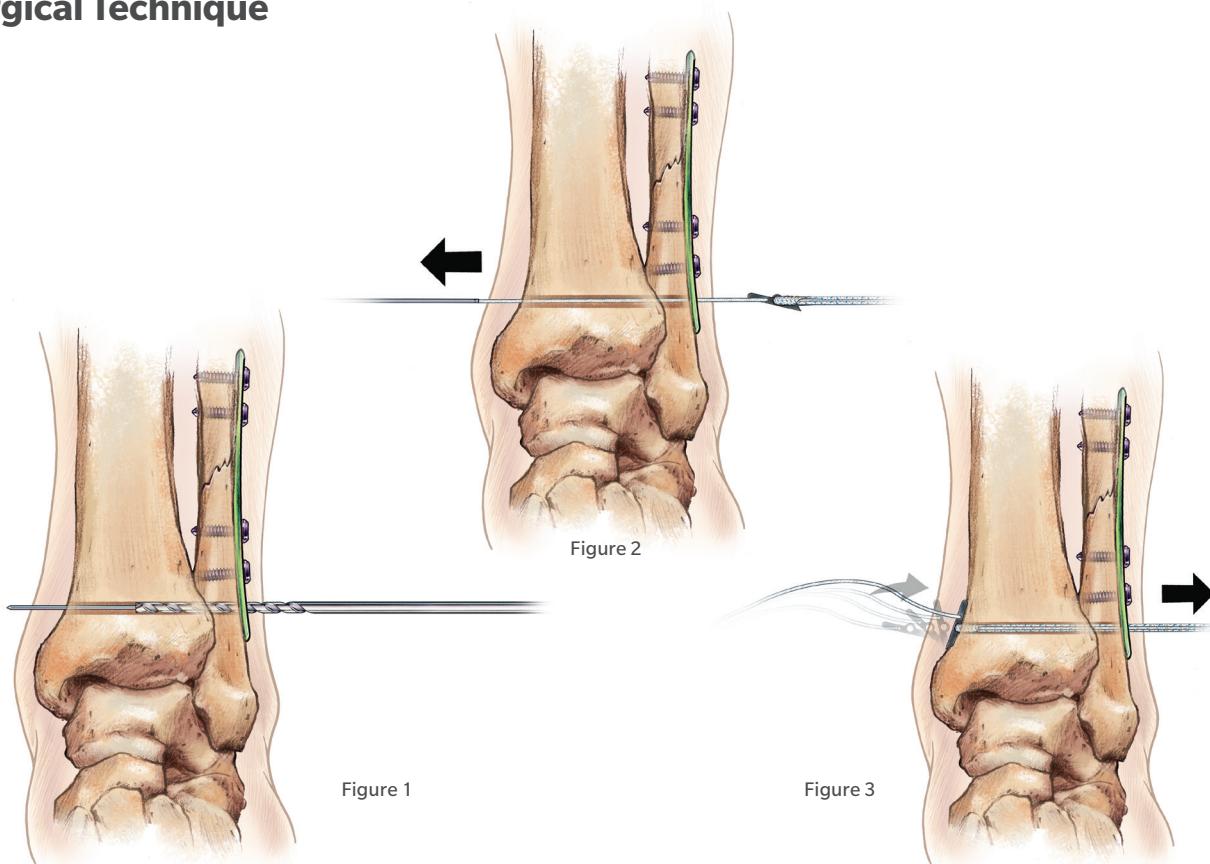
MaxBraid™

- Medial and lateral fixation devices connected with MaxBraid Suture

Features

- Low profile, knotless suture fixation system featuring ZipLoop Technology
- Fixation alternative to rigid stainless steel screws for repairing ankle syndesmosis joint disruptions
- Available with either titanium or stainless steel buttons to correspond with the titanium A.L.P.S. Distal Fibula Plate or the stainless steel Zimmer Periarticular Locking Distal Fibula Plate
- Allows for micromotion during healing which more closely mimics the patient's true joint mechanics

Surgical Technique



Indications

The ZipTight Fixation System for Ankle Syndesmosis is indicated for fixation of ankle syndesmosis disruptions and as an adjunct in connection with trauma hardware for Weber B and C ankle fractures.

Note: This surgical technique shows the ZipTight Fixation Device used in conjunction with trauma hardware. However, the device can also be used without trauma hardware in length stable fractures as determined appropriate by the surgeon.

Reduce Fracture

Reduce fracture to obtain correct length, rotation, and alignment. Reduce the syndesmosis joint as required to achieve anatomical correction, utilizing bone clamp(s). As determined appropriate by the surgeon, place the surgeon preferred trauma hardware plate and screws, in balanced fixation, on to fibula leaving an additional one or two screw holes empty, where ZipTight Fixation system may be placed to repair the ankle syndesmosis disruption.

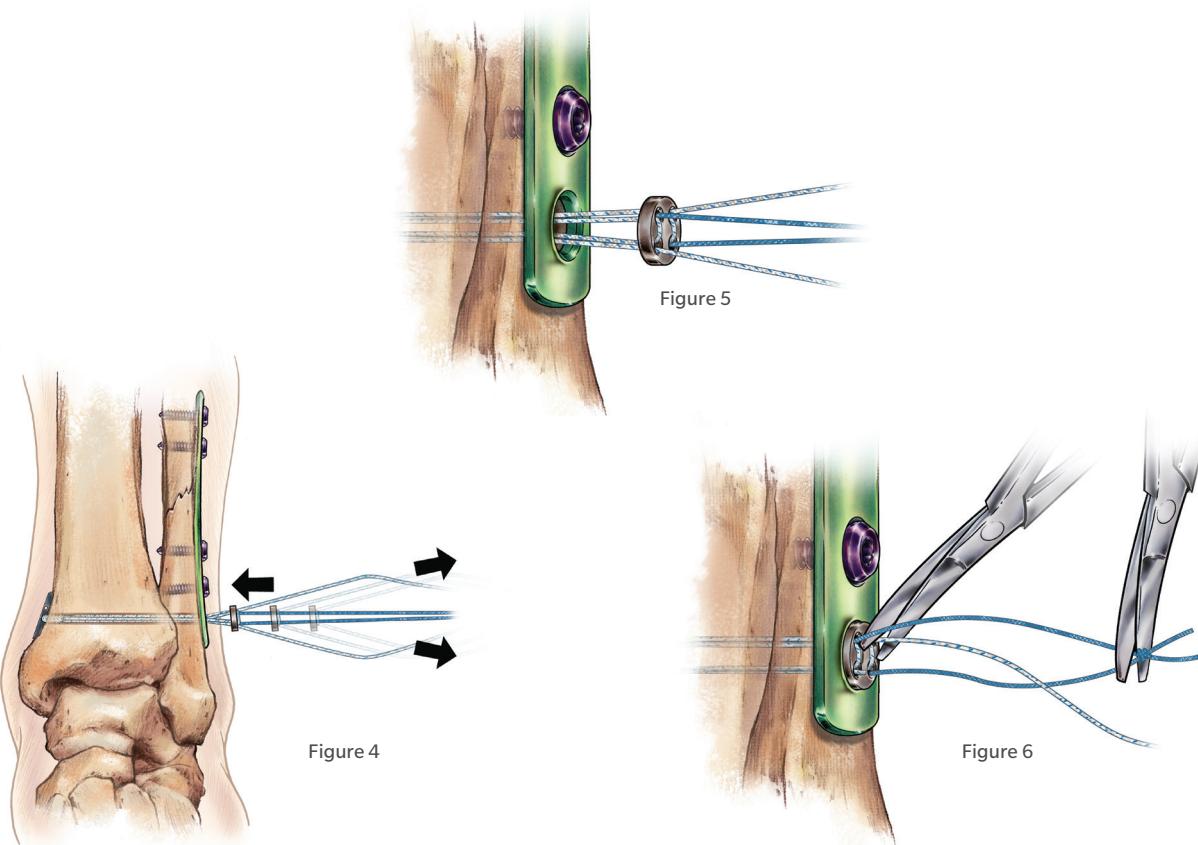
Drill Through Fibula and Tibia

Using either a solid or cannulated 3.2mm drill, create a drill pathway at or slightly above the incisura of the tibia at the distal tib-fib joint. Penetrate both tibial cortices with the 3.2mm drill (Figure 1).

Pass the ZipTight Fixation System

After the bone tunnels have been prepared, pass the ZipTight Fixation System pull strands through the tunnels from lateral to medial using the guide pin (Figure 2).

Carefully continue pulling the ZipTight Fixation System pull strand (white MaxBraid suture) until the ToggleLoc button exits the bone tunnel on the medial side of the tibia. Keeping the device taut from both ends keeps the ToggleLoc button angled so that it will easily flip on the medial cortex. As the button exits out of the medial tibial cortex, directing the hand inferiorly may aid in flipping the ToggleLoc button. Under fluoroscopic imaging, once the button appears to be out of the medial tibial cortex, pull the device back in the lateral direction so that the ToggleLoc button will flip and rest closely against the medial cortex of the tibia (Figure 3).



Zip the Top Hat Button Into Place

Pull on the blue/white 'zip' strands (blue/white MaxBraid suture) while maintaining tension on the solid blue back-tension strand (blue polyester suture). The solid blue back-tension strand provides slight counterforce to help keep the ZipLoop sutures organized (Figure 4).

Continuing to pull the blue/white 'zip' strands will bring the round top hat button down against the plate (or lateral fibular cortex if no plate is used) to its final deployed position on the lateral side of the fibula (Figure 5).

Final Tensioning

After the round top hat button is seated, the solid blue back-tension strand can be released and the surgeon can provide final tensioning by pulling on each leg of the blue/white 'zip' strand to equalize tension of the legs of the ZipLoop strand. A ZipLoop puller can be used to assist in final tensioning of the fixation device.

The strands and guide pin can be removed on the medial side. The solid blue 'back-tension' strand can be cut and removed and the 'zip' strands can be carefully cut down near the round top hat button with scissors or the Super MaxCutter™ Suture Cutter. (Figure 6).

Note: No knots need to be tied because the construct utilizes ZipLoop Technology.

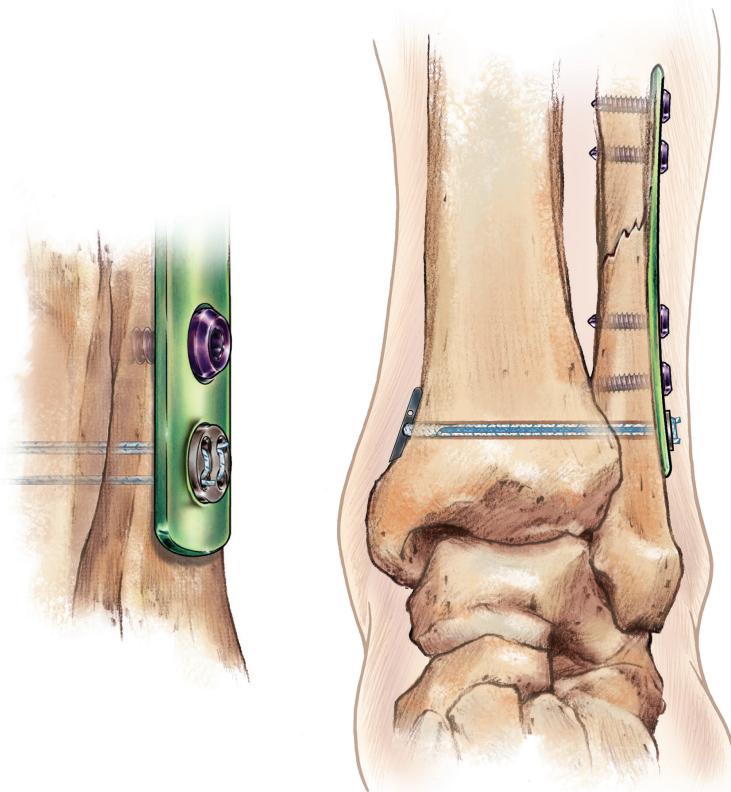


Figure 7

Postoperative Protocol

Fixation is complete (Figure 7). The patient is placed in a post-operative splint, non-weightbearing until suture removal. Non-weight bearing is maintained for a minimum of four weeks or until sufficient callus ensures length stability of the fibula. A compliant patient can be allowed to do gentle range of motion non-weightbearing at four weeks. In the presence of sufficient fibula healing, protected weightbearing can be started on week six. Advancement to full weightbearing is progressed as clinically indicated.

Removal

The need for removal will be determined by the surgeon. If removal is desired, a small incision over the ToggleLoc button on the medial tibia is made to expose the button. Similarly, a small incision is made over the round top hat button on the lateral fibula. Using a blade or cautery, cut both legs of the ZipLoop suture at the round top hat button. The round top hat button can be removed. The ToggleLoc button and suture can then be removed from the medial side of the tibia.

INDICATIONS FOR USE

The ToggleLoc System devices, except the ToggleLoc XL device, are intended for soft tissue to bone fixation for the following indications:

SHOULDER

- Bankart lesion repair
- SLAP lesion repairs
- Acromio-clavicular repair
- Capsular shift/capsulolabral reconstruction
- Deltoid repair
- Rotator cuff tear repair
- Biceps Tenodesis

FOOT AND ANKLE

- Medial/lateral repair and reconstruction
- Mid- and forefoot repair
- Hallux valgus reconstruction
- Metatarsal ligament/tendon repair or reconstruction
- Achilles tendon repair
- Ankle Syndesmosis fixation (Syndesmosis disruptions) and as an adjunct in connection with trauma hardware for Weber B and C ankle fractures (only for ToggleLoc with Tophat/ZipTight Fixation Devices)

ELBOW

- Ulnar or radial collateral ligament reconstruction
- Lateral epicondylitis repair
- Biceps tendon reattachment

KNEE

- ACL/PCL repair / reconstruction
- ACL/PCL patellar bone-tendon-bone grafts
- Double-Tunnel ACL reconstruction
- Extracapsular repair: MCL, LCL, and posterior oblique ligament
- Illiotibial band tenodesis
- Patellar tendon repair
- VMO advancement
- Joint capsule closure

HAND AND WRIST

- Collateral ligament repair
- Scapholunate ligament reconstruction
- Tendon transfers in phalanx
- Volar plate reconstruction
- The ToggleLoc XL device is used for fixation of tendons and ligaments during orthopedic reconstruction procedures, such as Anterior Cruciate (ACL) or Posterior Cruciate (PCL)
- Reconstruction, as well as in cases of unanticipated intraoperative complications, such as cortical breaching.

CONTRAINDICATIONS

1. Infection.
2. Patient conditions including blood supply limitations, and insufficient quantity or quality of bone or soft tissue.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

Ordering Information

ZipTight Fixation Device for Ankle Syndesmosis with ZipLoop Technology	
904759	Titanium
909856	Stainless Steel

ZipTight Fixation Device for Ankle Syndesmosis with ZipLoop Technology Disposable Kits	
909853	Titanium
909857	Stainless Steel
Sterile Kit Includes: Implant, 0.062" (1.57mm) x 6" needle crimped onto passing suture, two 0.062" (1.57mm) x 9" K-wires, one 3.2mm x 7.5" cannulated drill bit, and one 3.2mm x 5" solid drill bit	

K-wire

951549	.045 (1.1mm) x 9" — Pkg. 2 (Non-Sterile)
945019	.045 (1.1mm) x 9" — Partially Threaded (Sterile)

Solid Drill Bit

904301	3.2mm x 5" (Non-Sterile)
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Guide Pin

909634	3/32" x 16" (Non-Sterile)
909540	3/32" (Sterile)

ZipLoop Puller

904776	(Non-Sterile)
904794	(Sterile)

Super MaxCutter Suture Cutter

900342	(Non-Sterile)
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Zimmer Biomet does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Animations and virtual reality are provided as a visual guide based on surgical techniques; a written copy of the surgical technique is available at www.zimmerbiomet.com or from your local representative. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure. Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

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