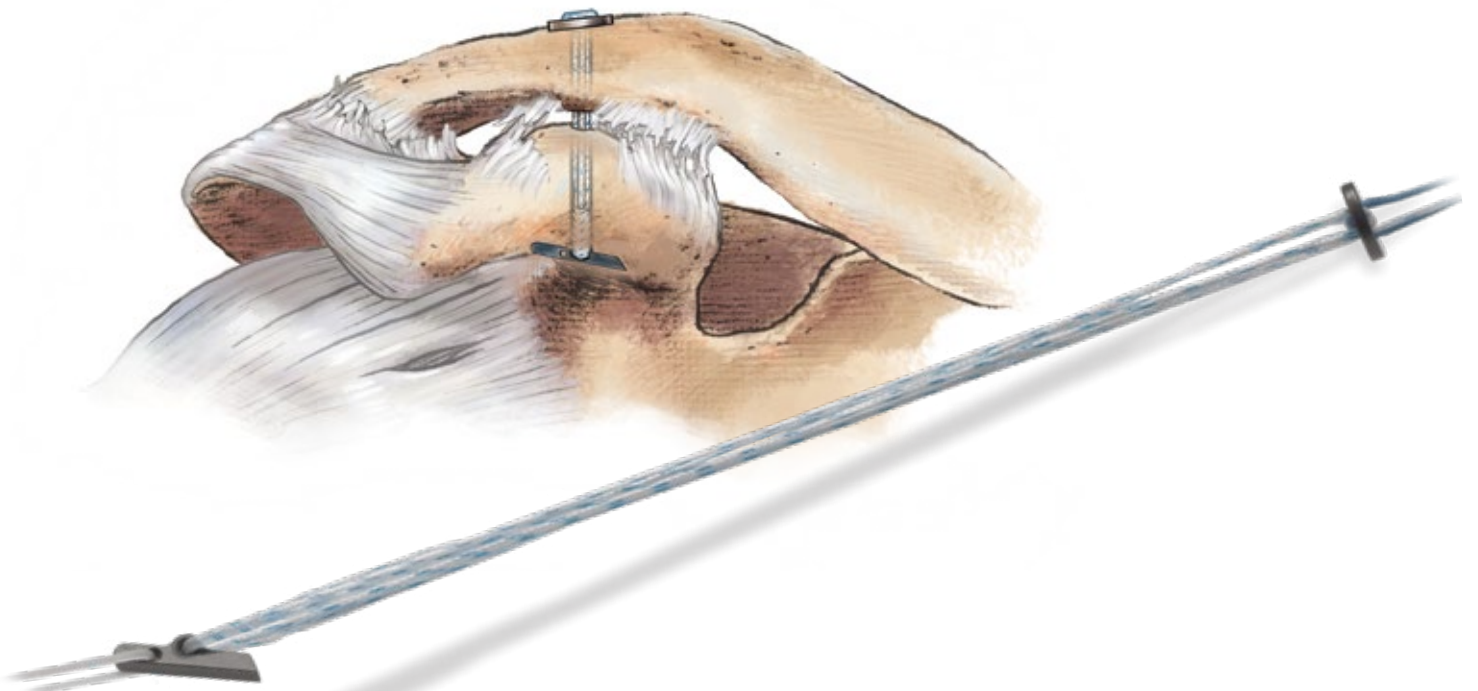


ZIPTIGHT™

FIXATION SYSTEM

Featuring... *Zip Loop*®
TECHNOLOGY

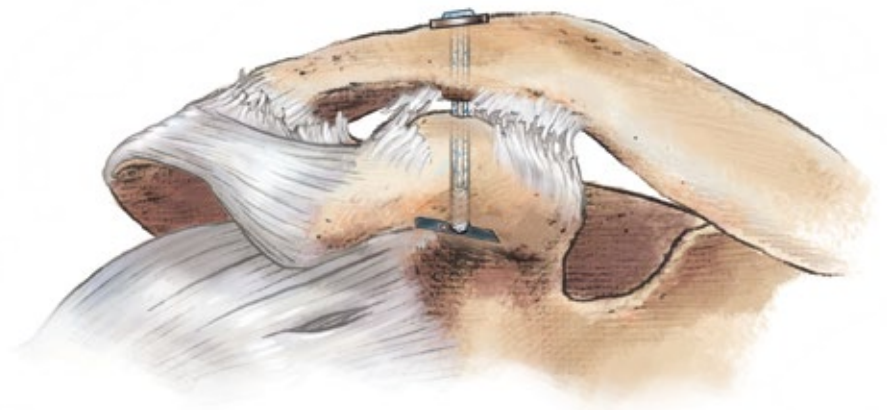


Acute AC Joint Reconstruction

ZipLoop TECHNOLOGY



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.



Knotless

- Knotless system that eliminates knot profile on the top of the clavicle

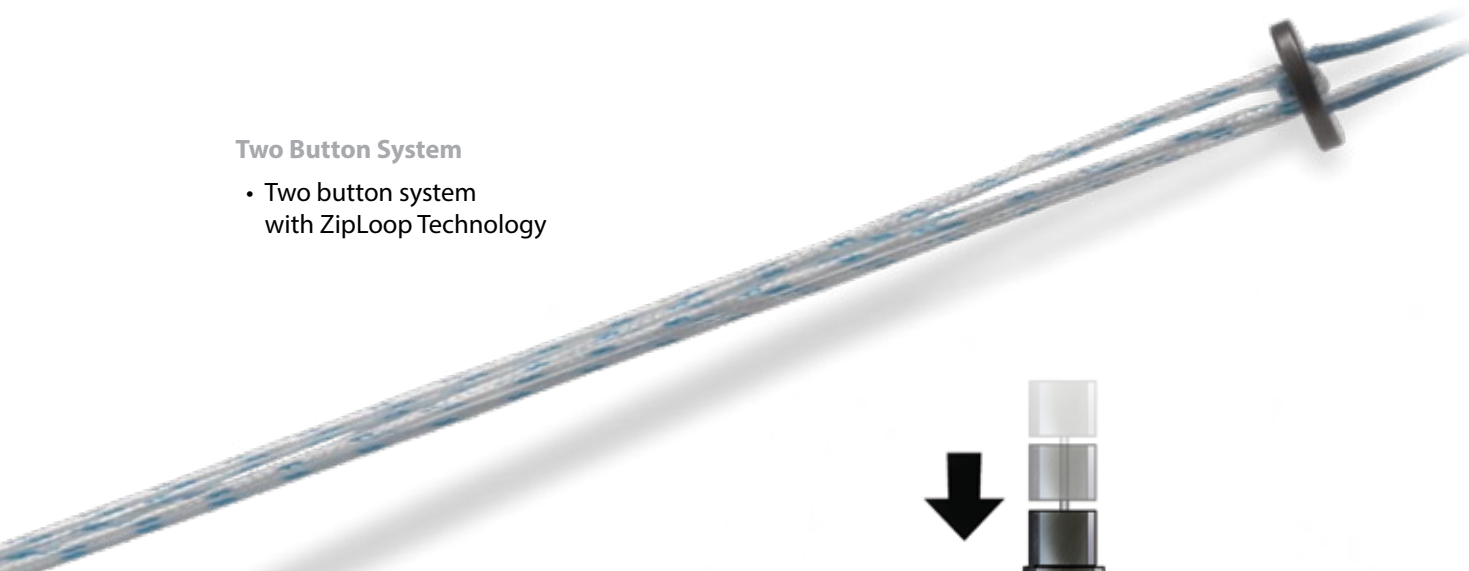


ZIPTIGHT

FIXATION SYSTEM

Two Button System

- Two button system with ZipLoop Technology

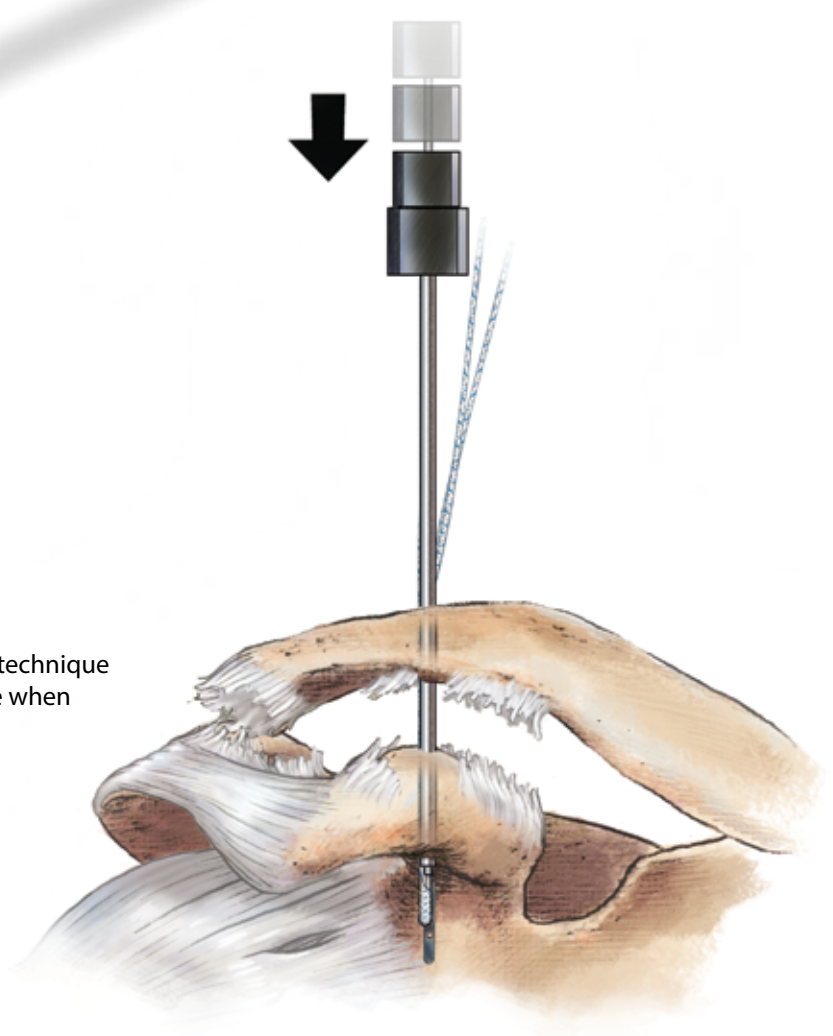


MaxBraid Suture

- Coracoid and clavicle fixation devices connected with #7 MaxBraid Suture

Simple Technique

- ToggleLoc device pusher/plunger technique eliminates having to shuttle suture when fixating the initial coracoid button



Surgical Technique



Figure 1

Acute Reconstruction

This technique is indicated for acute acromioclavicular joint dislocation of less than four weeks duration (Figure 1).

Preliminary Technique

Position the patient in the preferred beach chair or lateral decubitus position.

A general diagnostic arthroscopy is done via a posterior portal. Create a subsequent anterior portal utilizing a spinal needle for desired positioning of the portal. This portal should be on the same level as the coracoid tip, but at least 2cm lateral to it. A cannula can be introduced into the glenohumeral joint. Once the glenohumeral joint is examined and any pathology addressed, the coracoid will then need to be exposed.

The coracoid can be exposed by approaching it through either the rotator interval (the area between the supraspinatus and subscapularis anteriorly) or from the subacromial space.

Exposing the coracoid through the rotator interval involves having the arthroscopic camera in the glenohumeral joint viewing from the posterior portal toward the rotator interval. The rotator interval is then taken down with either an arthroscopic shaver or an ablation device. Once the rotator interval is taken down, the tip of the coracoid will be visualized medially just above the subscapularis.

Exposing the coracoid from the the subacromial space involves placing the arthroscopic camera into the anterior aspect of the subacromial space from the posterior portal. In this area there is typically very little bursa and the space is easily visualized. An anterior lateral portal is then made lateral and inferior to the anterolateral tip of the acromion. A spinal needle can be utilized to ensure an adequate location. Next, the coracoacromial (CA) ligament is identified anteriorly and this is followed in its course down medial and inferior to its attachment on the coracoid tip. Some bursa may need to be debrided to follow the ligament.

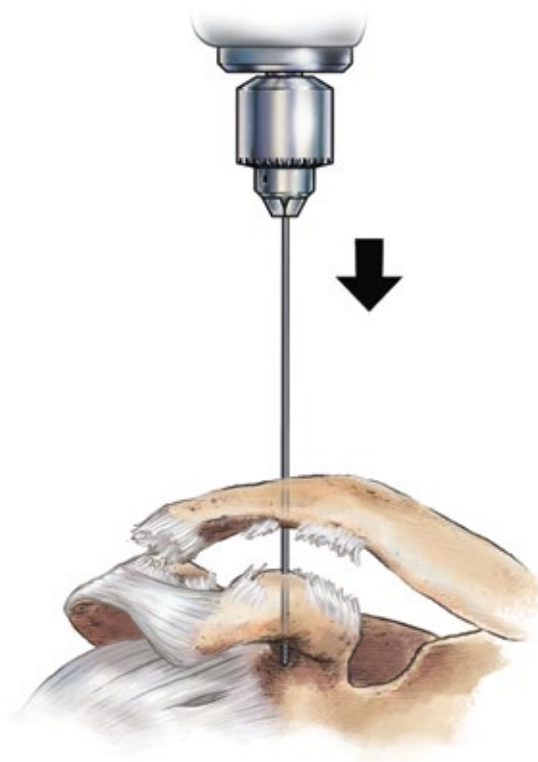


Figure 2

Once the coracoid is visualized with the arthroscopic camera, the tip can be exposed with an alternating combination of shaver and ablation devices. Visualization of the coracoid can continue with the arthroscope in this position from the posterior portal with either the 30 or 70 degree lens. At some point the camera is then placed into the lateral portal so that the entire coracoid can be visualized. Care must be taken to keep the ablation unit on bone as the coracoid is exposed and as the coracoid curves posteriorly.

The bursa in this area will also need to be debrided. To avoid potential injury to the axillary nerve, the shaver and ablation device should not drop inferiorly below the level of the bottom of the coracoid process. Once the coracoid bone and its posterior curve are exposed, the area on top and just inferior along the curve must be exposed. This area will be referred to as the arch. Utilize the ablation device on the bone to expose the superior and inferior aspect of the arch. In the acute repair, care must also be taken not to ablate the coracoid attachments of the coracoclavicular ligaments which are just posterior to the arch on top of the coracoid base.

Drill the Clavicle and Coracoid

Create a 1.5cm longitudinal incision over the clavicle approximately 2.5cm from the distal clavicle. The deltotracheal fascia will then need to be incised to expose the clavicle. Preserve the fascia as this will aid in completing the closure after the procedure. Additionally, to aid in reduction, it may be necessary to resect 5 – 8mm of the distal clavicle.

Next utilizing the guide, the clavicle and coracoid will be drilled (Figure 2). These can be drilled either together if proper alignment can be achieved with reduction of the clavicle, or, as is often the case, the bones may need to be drilled independently.

If drilling both, visualize arthroscopically as the guide is placed in the inferior mid aspect of the coracoid arch. The clavicle then needs to be reduced down and the bullet placed in the mid aspect of the clavicle at approximately 30–35mm from the end of the clavicle. **Note: This corresponds to midway between the attachments of the conoid and trapezoid coracoclavicular ligaments.**

Surgical Technique

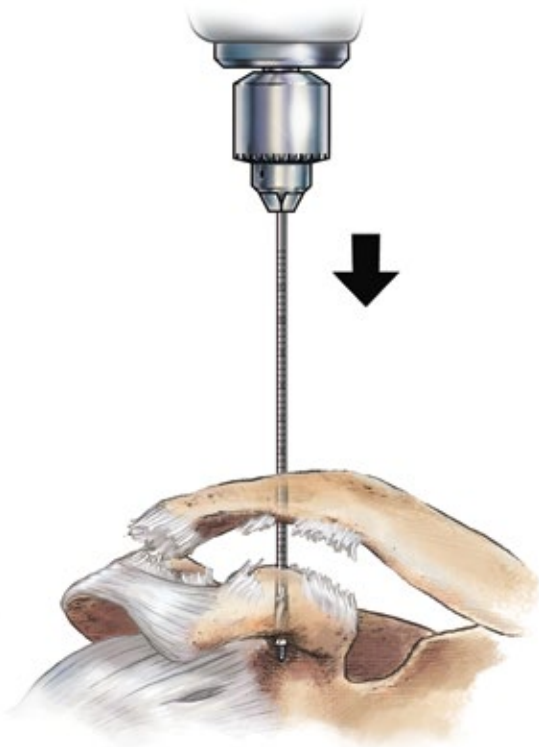


Figure 3

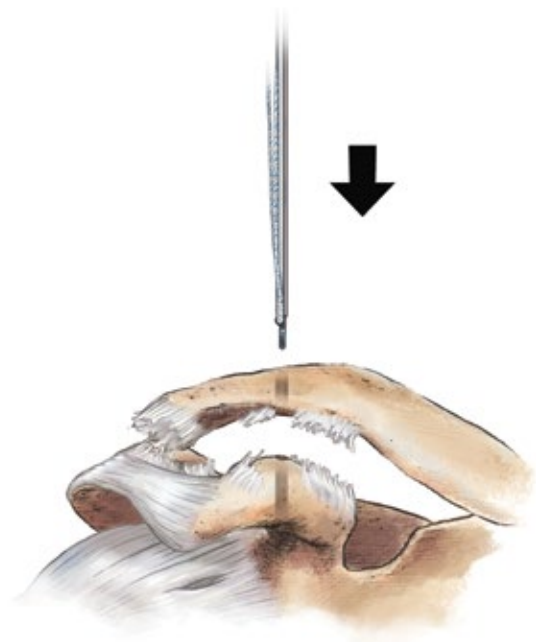


Figure 4

Drill the Coracoid and Clavicle (cont.)

Next, the 2.4mm guide pin is power drilled through the clavicle and the coracoid. If there is any difficulty, drill these independently.

Check the guide pin under direct visualization under the coracoid and redrill if placement was incorrect. If satisfied with position of the pin, leave guide pin in place. Slowly drill 4.5mm ToggleLoc Device Reamer over the guide pin through the clavicle and coracoid (Figure 3).

Insert ToggleLoc Fixation Device

If the clavicle and coracoid were drilled together, the ToggleLoc Device can be inserted from the top by using the ToggleLoc pusher (Figure 4). Push ToggleLoc Device down through the clavicle and coracoid and deploy the ToggleLoc Device on the undersurface of the coracoid under direct arthroscopic visualization (Figure 5).

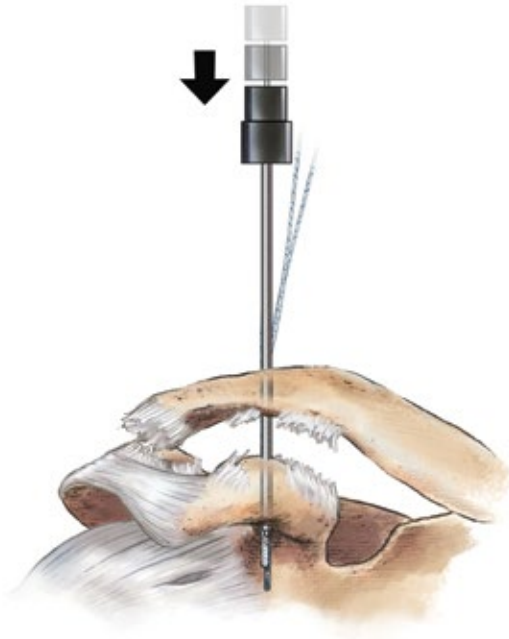


Figure 5

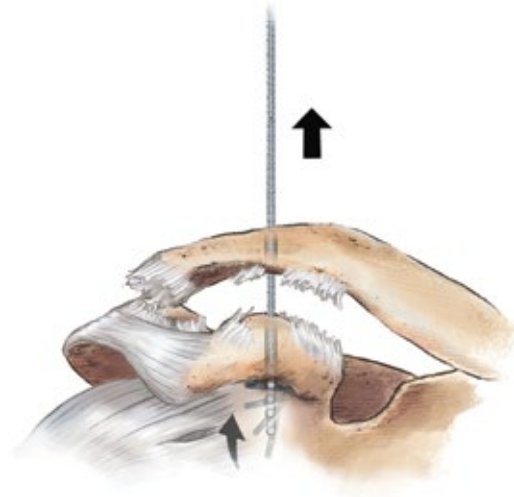


Figure 6

The ZipLoop and zip strand will already be through the clavicle and ready to be placed through the round button (Figure 6).

Surgical Technique



Figure 7

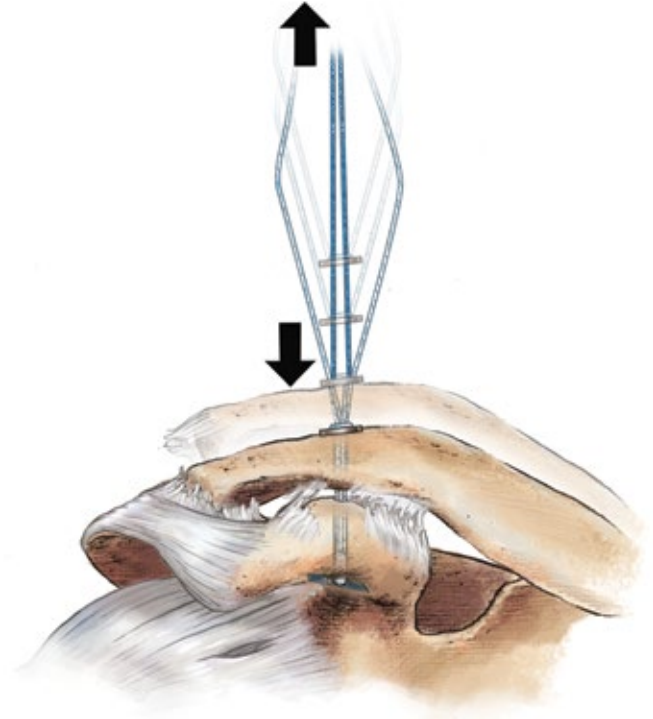


Figure 8

Reduce Clavicle

Next, loop the zip strand of the ToggleLoc Device onto the round button (Figure 7). Pull on blue back tensioning strand while pulling zip strand to tighten both buttons together utilizing ZipLoop Technology (Figure 8). Reduce clavicle under direct visualization while zipping both buttons together. This can also be viewed with fluoroscopically. After adequate reduction has been achieved, cut sutures with MaxCutter Suture Cutter. The blue back tensioning strands can be cut and removed (Figure 9).

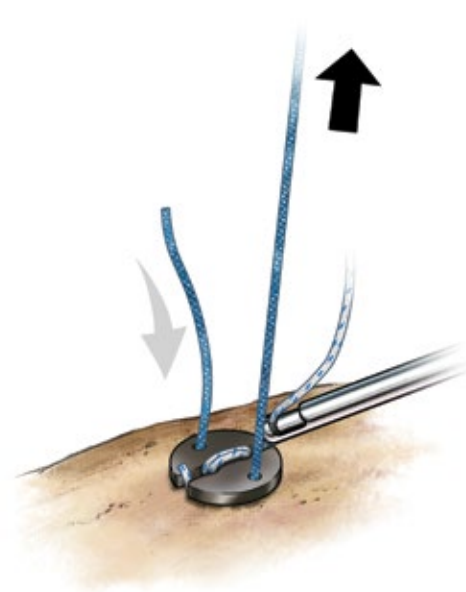
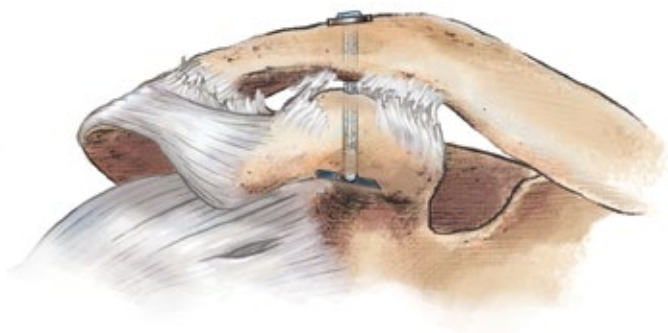


Figure 9



Post Operative Protocol

Patient should be immobilized for at least 4 – 6 weeks to avoid stress on the healing tissue around the acromioclavicular joint. Then, motion and gentle strengthening exercises can be initiated with plan on return to activities 4 – 6 months following the surgery.

Indications & Contraindications

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
Illiotalibial 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 in cases of unanticipated intraoperative complications such as cortical breaching during orthopedic reconstruction procedures, such as Anterior Cruciate (ACL) or Posterior Cruciate (PCL) Reconstruction.

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
904834

ZipTight Fixation Device Disposable Kits
904837
Sterile Kit Includes: ToggleLoc pusher and plunger, 6" Beath pin, 4.5mm ToggleLoc cannulated drill, 2.4mm drill point K-wire (10")

ZipLoop Puller

904776

Super MaxCutter Suture Cutter

900342

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