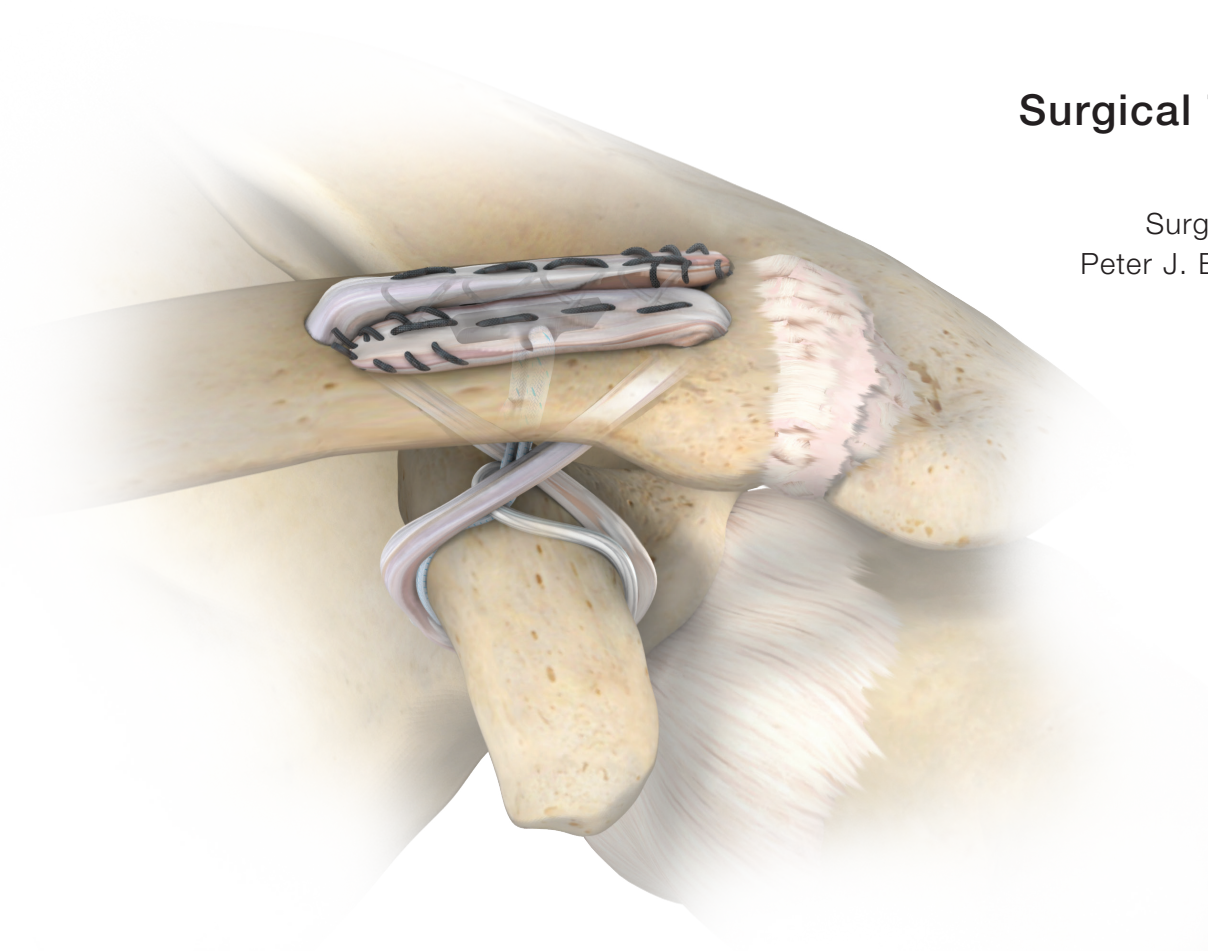


Coracoid Bone Conserving Acromioclavicular Joint Reconstruction using ToggleLoc™ Device with ZipLoop™ Technology

Surgical Technique

Surgical Protocol by
Peter J. Evans, MD, PhD



One Surgeon. One Patient.®

Over 1 million times per year, Biomet helps one surgeon provide personalized care to one patient.

The science and art of medical care is to provide the right solution for each individual patient. This requires clinical mastery, a human connection between the surgeon and the patient, and the right tools for each situation.

At Biomet, we strive to view our work through the eyes of one surgeon and one patient. We treat every solution we provide as if it's meant for a family member.

Our approach to innovation creates real solutions that assist each surgeon in the delivery of durable personalized care to each patient, whether that solution requires a minimally invasive surgical technique, advanced biomaterials or a patient-matched implant.

When one surgeon connects with one patient to provide personalized care, the promise of medicine is fulfilled.

Table of Contents

Coracoid Bone Conserving Acromioclavicular Joint Reconstruction using ToggleLoc™ Device with ZipLoop™ Technology

Acute vs. Chronic Reconstruction	1
Patient Positioning and Dissection	1
Pass the Implant	2
Create the Slip knot	3
Prepare the Clavicle	4
Reduce the AC Joint	6
Chronic Dislocation of the ACJ-Passing the Graft	6
Graft Placement	7
Closure.....	8
Post Operative Protocol	8
Indications for Use	10

Coracoid Bone Conserving Acromioclavicular Joint Reconstruction using ToggleLoc™ Device with ZipLoop™ Technology



Figure 1



Figure 2

Indications

This technique is intended for treatment of acute or chronic acromioclavicular joint (ACJ) dislocation.

Acute vs. Chronic Reconstruction

When treated within four weeks of dislocation this technique can be used with the ToggleLoc™ with ZipLoop™ technology alone, but for more chronic conditions a tendon graft used in conjunction is warranted. In very chronic cases the distal clavicle is often resected due to degenerative changes in the ACJ.

Patient Positioning and Dissection

Position the patient in a beach chair position under a general anesthesia so that fluoroscopy can be positioned to confirm ACJ reduction (Figure 1). A supraclavicular anaesthetic block can aid with postoperative pain control. A 2.5 cm oblique incision is made spanning the clavicle just superior to the coracoid in Langer's lines, which allows for cosmesis (Figure 2). A slightly longer incision is required if the distal clavicle requires excision. Alternatively a transverse incision can be made along the inferior border of the clavicle.

This brochure is presented to demonstrate the surgical technique and postoperative protocol utilized by Peter Evans, MD, and PhD. Biomet Sports Medicine, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient.

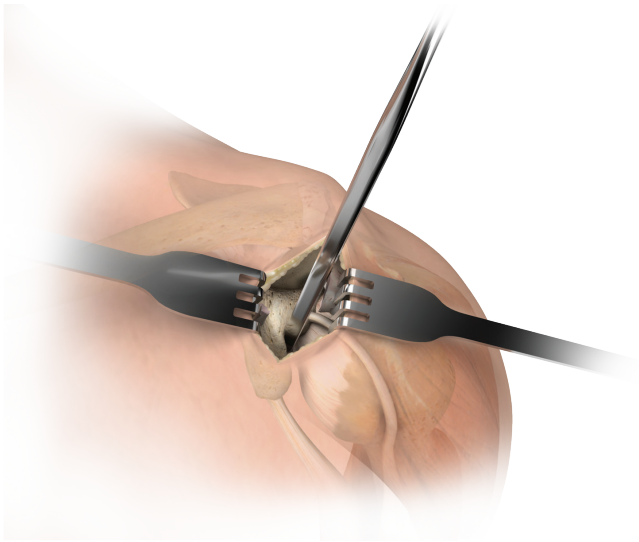


Figure 3

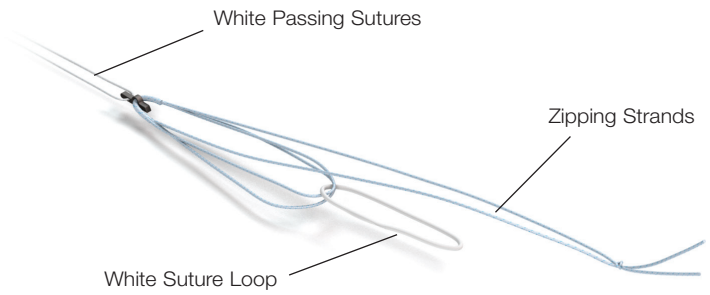


Figure 4a

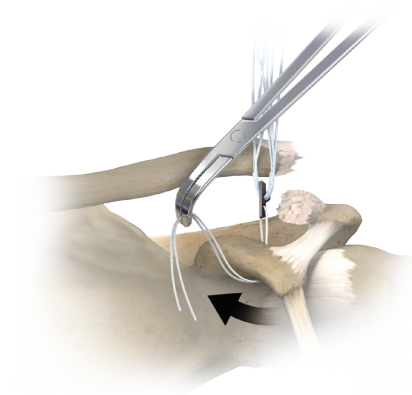


Figure 4

Patient Positioning and Dissection (cont.)

Subcutaneous sensory nerve branches are identified and protected. Elevate the skin flaps and incise the deltotrapezial fascia. Elevate the deltoid off of the clavicle to identify the subdeltoid space (Figure 3). Blunt dissection is used to identify the base of the coracoid process. Incise the fascia on the lateral and medial aspect of the coracoid.

Pass the Implant

Deliver a hemostat or other blunt curved instrument underneath the inferior aspect of the coracoid process from medial to lateral. One should feel the transition to the neck of the glenoid from the anterior scapula to assure placement at the base of the coracoid. With the curved instrument, attach the white passing sutures from the ToggleLoc™ device with ZipLoop™ Technology with continuous loop and shuttle them medially (Figure 4 & 4a).

Coracoid Bone Conserving Acromioclavicular Joint Reconstruction using ToggleLoc™ Device with ZipLoop™ Technology

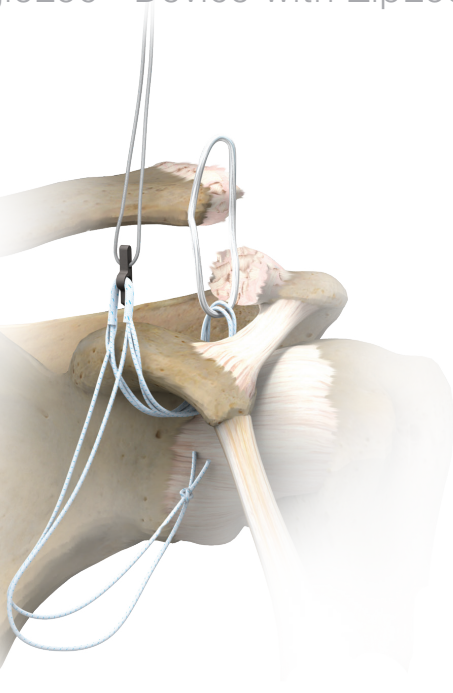


Figure 5

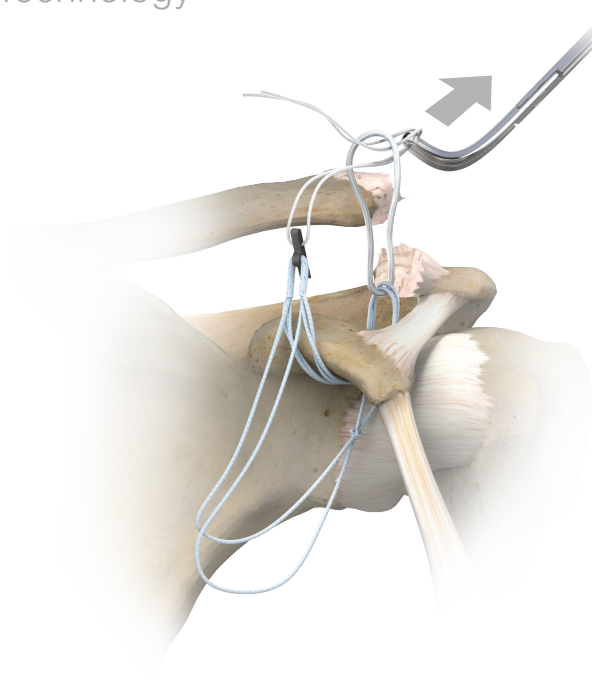


Figure 6

Pass the Implant (cont.)

Ensure the white suture loop remains on the lateral side and the MaxBraid™ zipping strands exit medially (Figure 5).

Create the Slip Knot

Next, deliver a hemostat through the solid white suture loop on the lateral side and capture the white passing sutures from the ToggleLoc™ device with ZipLoop™ Technology from the medial side. Pull the white lead sutures through the white suture loop to create the slip knot (a.k.a. “luggage tag”) around the coracoid (Figure 6).

Note: Creating the luggage tag completely eliminates the need for coracoid drilling.

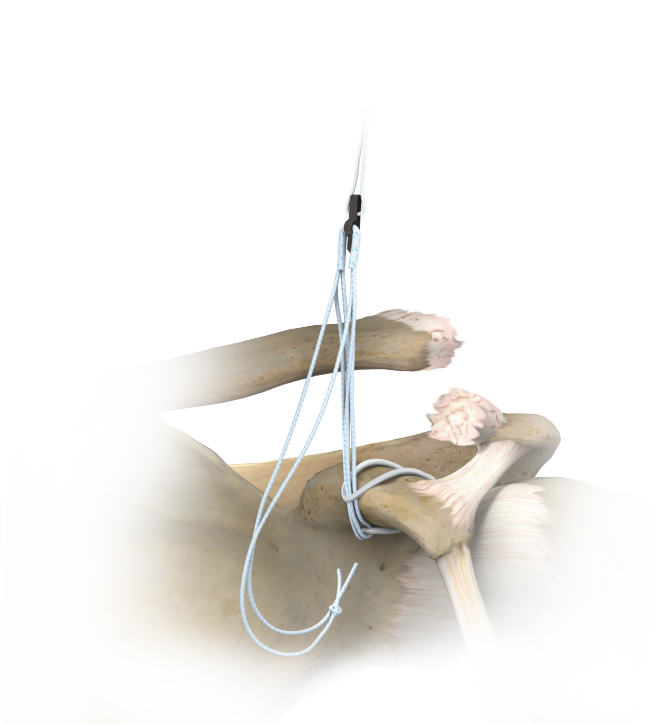


Figure 7

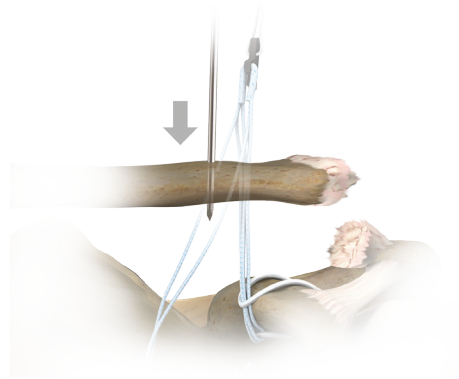


Figure 8

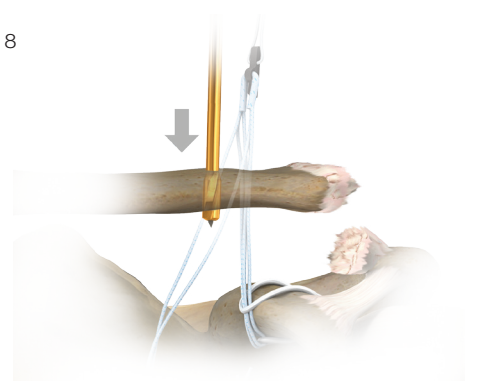


Figure 9

Create the Slip Knot (cont.)

Make sure to pass the lead sutures, ToggleLoc™ button, and zipping strands through the solid white suture loop and assure the solid white loop is positioned under the coracoid as its larger diameter will distribute forces optimally (Figure 7). Leave the hemostat clipped to the white passing suture as preparation of the clavicle takes place.

Prepare the Clavicle

Drill a 2.4 mm guide pin bicortically into the clavicle directly superior to the coracoid. Place a 4.5 mm cannulated reamer over the guide pin and drill bicortically (Figures 8 & 9). Leaving the 4.5 mm reamer in place, pass a Nitinol loop (or any monofilament suture) through the cannulation of the 4.5 mm reamer. This will be utilized to shuttle the leading passing strands of the ToggleLoc™ to the top of the clavicle.

Coracoid Bone Conserving Acromioclavicular Joint Reconstruction using ToggleLoc™ Device with ZipLoop™ Technology

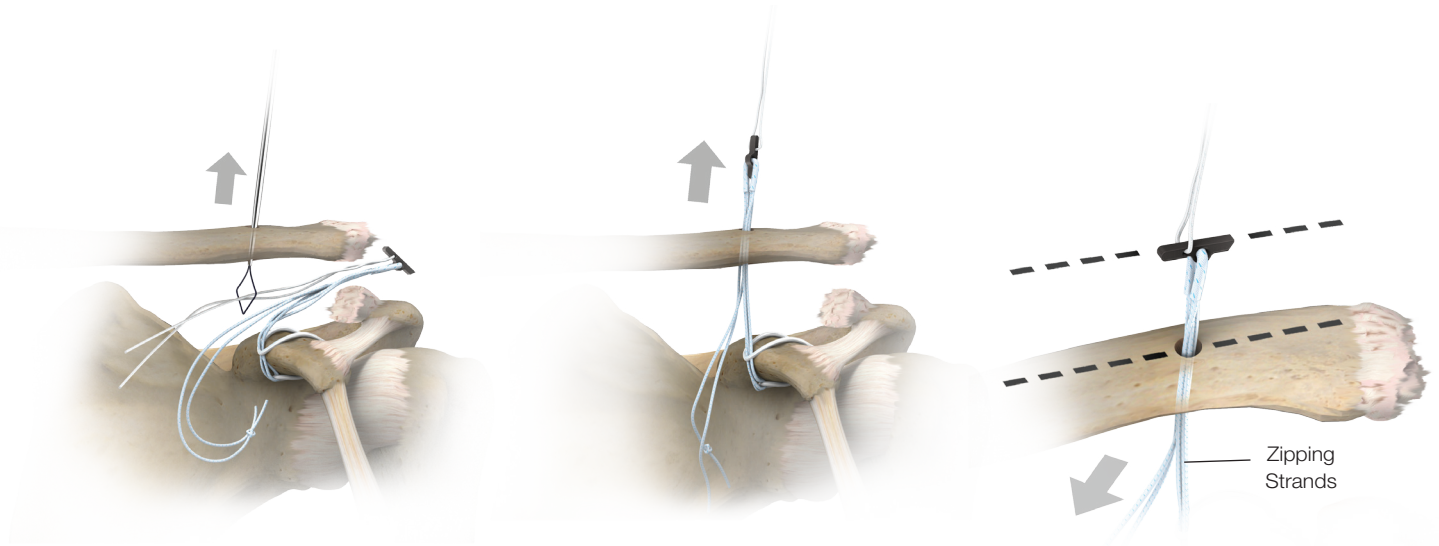


Figure 10

Figure 10a

Figure 11

Prepare the Clavicle (cont.)

Release the white passing sutures from the hemostat. Utilize the Nitinol wire to shuttle the leading white passing strand of the ToggleLoc™ device with ZipLoop™ Technology and pass them from inferior through the clavicle and out superiorly, while simultaneously pulling the ToggleLoc™ button through the clavicle (Figures 10 & 10a).

The ToggleLoc™ button should be positioned collinear to the long axis of the clavicle (Figure 11). The zipping strands of the ZipLoop™ must remain infraclavicular.

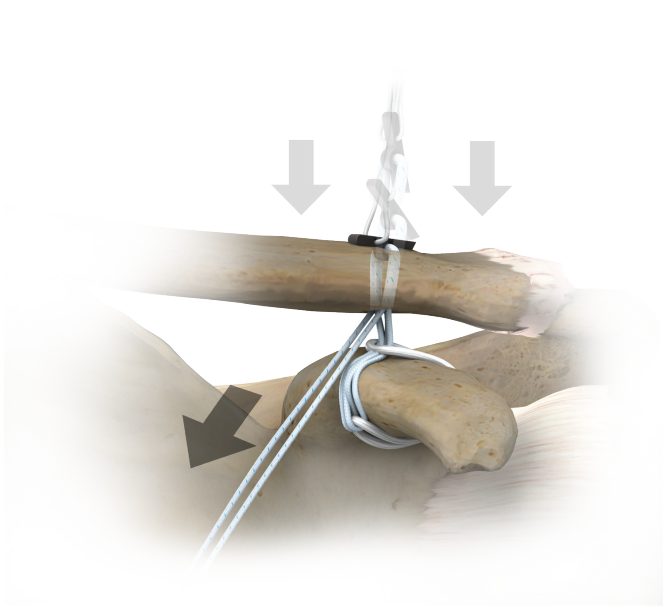


Figure 12



Figure 13

Reduce the AC Joint

Pull the ToggleLoc™ button until flush with the bone. Clavicle reduction is now performed by applying downward pressure on the clavicle and upward pressure on the elbow. The ACJ is over-reduced by 5 mm. The zipping strands of the ToggleLoc™ with ZipLoop™ are now pulled using the ZipLoop™ puller to achieve equal tension on both strands, taking up slack until desired reduction is achieved (Figure 12).

Chronic Dislocation of the ACJ—Passing the Graft

In the chronic case, a tendon graft should be passed around the coracoid. The graft can be an autograft or allograft based upon surgeon preference (Figure 13). This can be done simultaneously while the white passing sutures of the ToggleLoc™ with ZipLoop™ are shuttled from lateral to medial, as described earlier in the technique.

Coracoid Bone Conserving Acromioclavicular Joint Reconstruction

using ToggleLoc™ Device with ZipLoop™ Technology

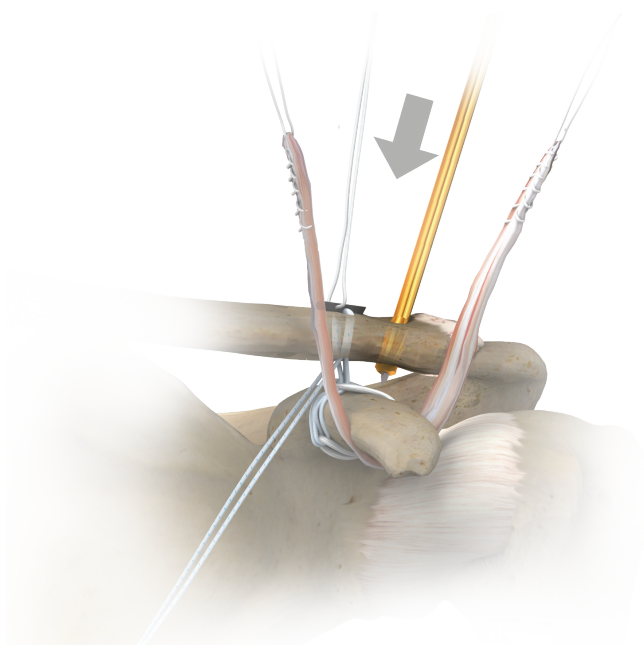


Figure 14

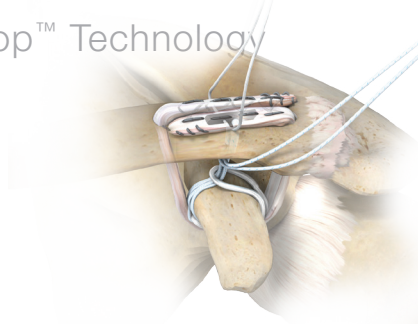


Figure 15

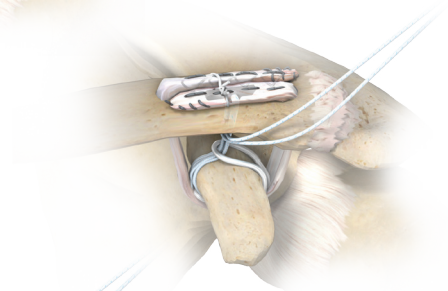


Figure 16

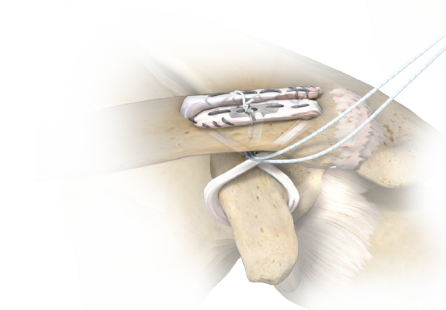


Figure 16a

Graft Placement

Two additional 3.2 mm drill holes are required to place the graft. One drill hole should be placed medial to the ToggleLoc™ with ZipLoop™ hole and the second should be placed lateral to the ToggleLoc™ with ZipLoop™ hole. Drill a 2.4 mm guide pin into the clavicle bicortically. Then drill over the pin with a 3.2 mm cannulated reamer (Figure 14).

Note: Each drill hole should be separated by 1.0-1.5 cm, recreating the anatomic locations of the coracoclavicular ligaments. Each limb of the tendon graft is passed from inferior to superior through the clavicle. A Nitinol wire can be utilized to shuttle graft suture limbs to the superior clavicle.

Once each limb of the graft is passed, the clavicle is reduced and the ZipLoop™ is tightened. The graft ends are then crossed parallel to each other over the ToggleLoc™ button. The ends should be maximally tensioned and sewn together upon exiting the clavicle with a free #2 MaxBraid™ suture in an interrupted figure-eight fashion (Figure 15).

The MaxBraid™ passing suture from the ToggleLoc™ implant can be tied over the tendon graft to secure the two limbs for additional fixation (Figure 16).

Optionally, crossing the graft limbs above the coracoid before entering the clavicle can create a more anatomic trajectory (Figure 16a). In reconstructive cases where not enough distal clavicle remains, two holes can be used, placing the ZipLoop™ and graft together through one of the holes.

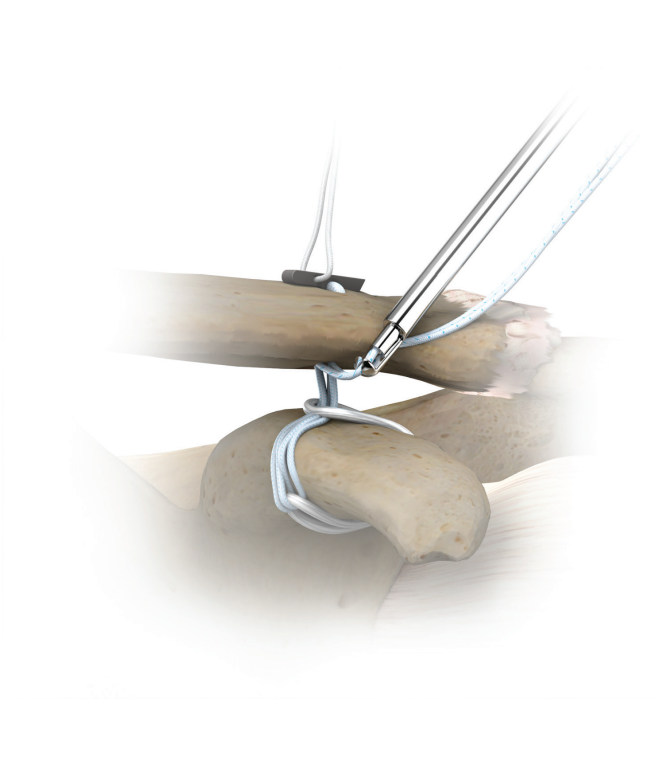


Figure 17

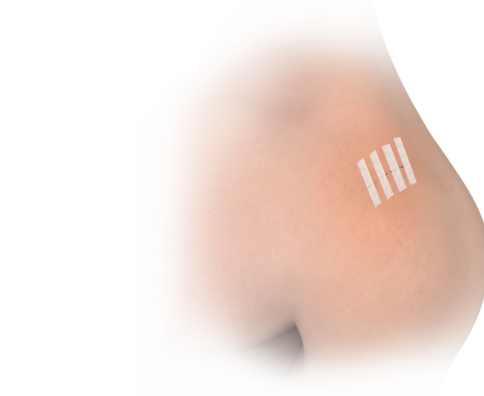


Figure 18

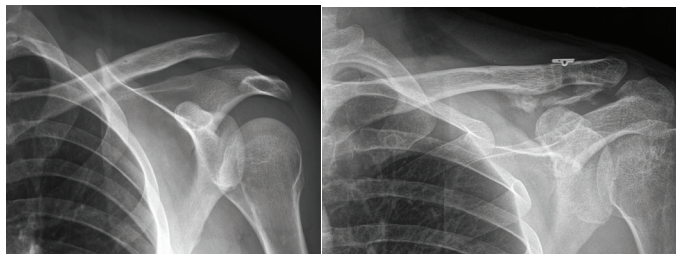


Figure 19: Pre-Op

Figure 19a: Post-Op

Closure

Insert the pull sutures into the Super MaxBraid™ cutter and advance the cutter to the inferior surface of the clavicle. Compress the trigger of the cutter until both strands of the sutures are severed (Figure 17). A layered closure is performed with absorbable sutures and a subcuticular skin closure with steri-strips for an optimal cosmetic result (Figure 18). The procedure is complete (Figures 19 & 19a).

Post Operative Protocol

A shoulder immobilizer is utilized for a period of six weeks, and waist level activities such as eating or clerical work are allowed. Range of motion is restored from week six to twelve. Progressive resistance exercises are initiated after twelve weeks. Overhead sport and impact loading activities are allowed after six months.

Part Numbers

Part Number	Size	Description
904756	-	ToggleLoc™ Device with ZipLoop™ Technology with Continuous Loop
904837	-	AC Joint Disposable Kit
904776	-	ZipLoop™ Puller
904011	-	Sterile Nitinol Loop-10pk
904004	2.3 mm	SpeedPass™ Suture Retriever Straight, Disposable
948084	3.2 mm	Cannulated Drill

INDICATIONS FOR USE

The ToggleLoc™ System devices 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 connections with trauma hardware for Weber B and C ankle fractures (only for ToggleLoc™ with Tophat)

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
Iliotibial 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

Hip

Acetabular labral repair

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 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.

All trademarks herein are the property of Biomet, Inc., and its subsidiaries unless otherwise indicated.

This material is intended for the sole use and benefit of the Biomet sales force and physicians. It is not to be redistributed, duplicated or disclosed without the express written consent of Biomet.

For complete product information, including indications, contraindications, warnings, precautions, and potential adverse effects, see the package insert and patient risk information at www.Biomet.com.



Responsible Manufacturer
Biomet Sports Medicine
P.O. Box 587
56 E. Bell Drive
Warsaw, Indiana 46581-0587
USA