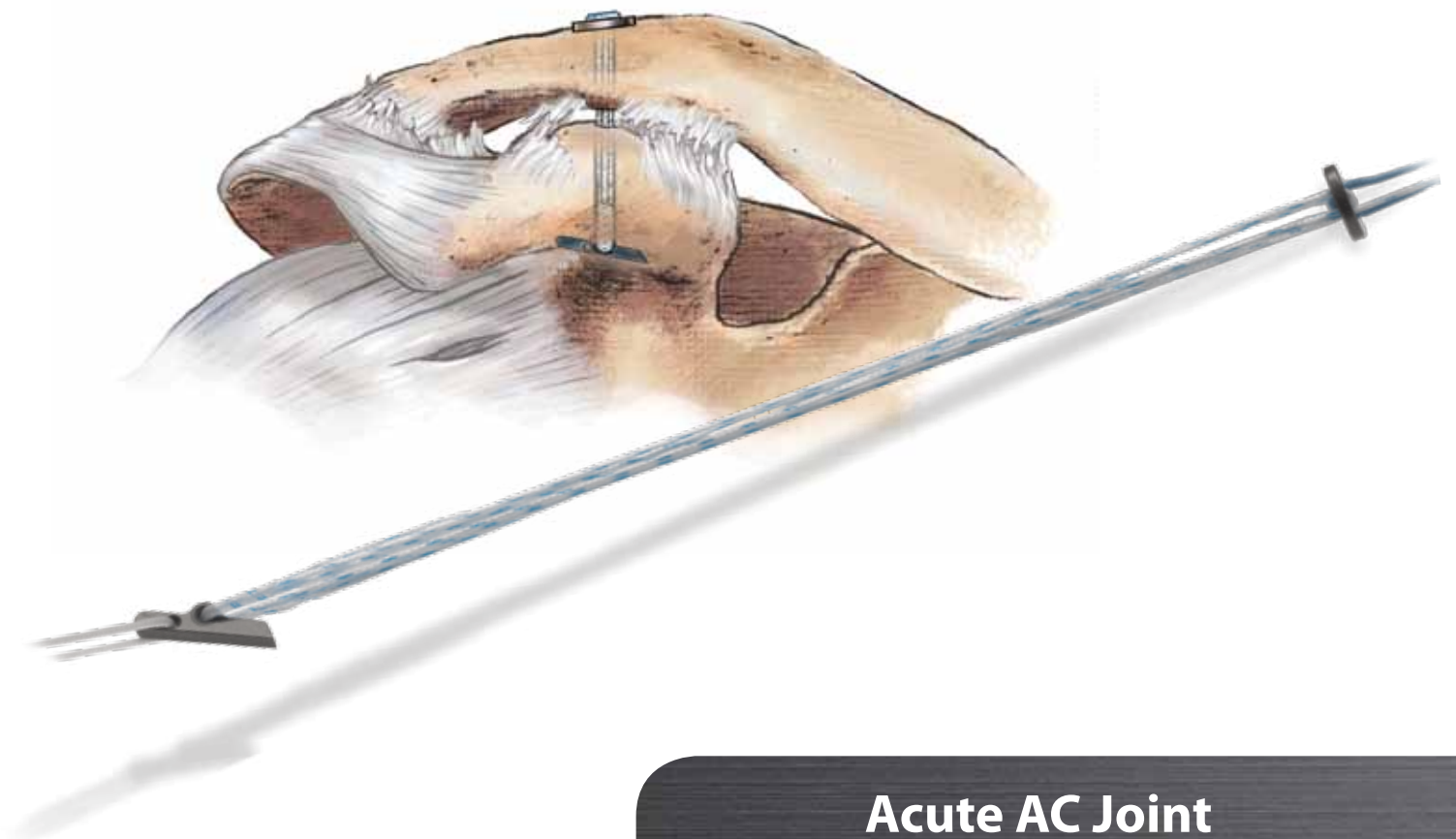


# ZIPTIGHT™

FIXATION SYSTEM

Featuring... *Zip Loop*™  
TECHNOLOGY



## Acute AC Joint Reconstruction

Surgical Protocol by  
Eric McCarty, M.D.

# ZipLoop™

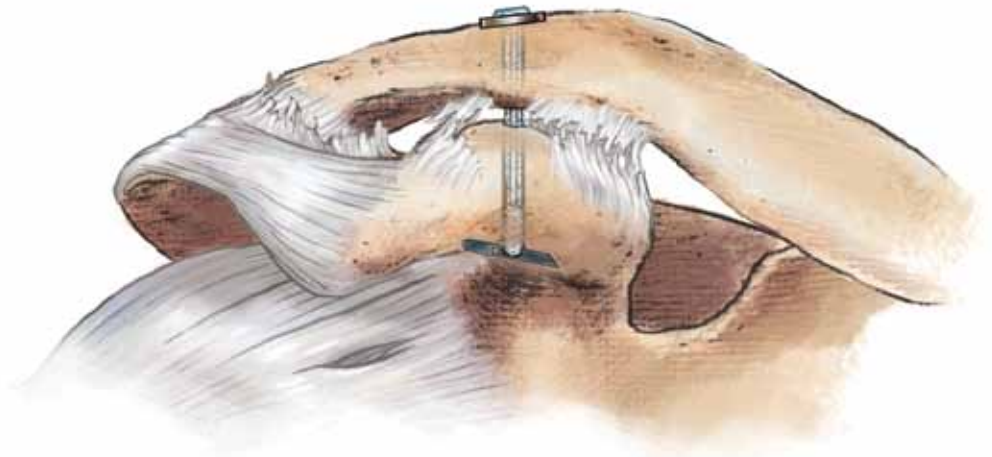
TECHNOLOGY



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. Products utilizing ZipLoop™ Technology are resistant to slippage without tying knots.<sup>1</sup> Procedure-specific animations, surgical protocols and surgery videos are available at [www.ziploop.net](http://www.ziploop.net).

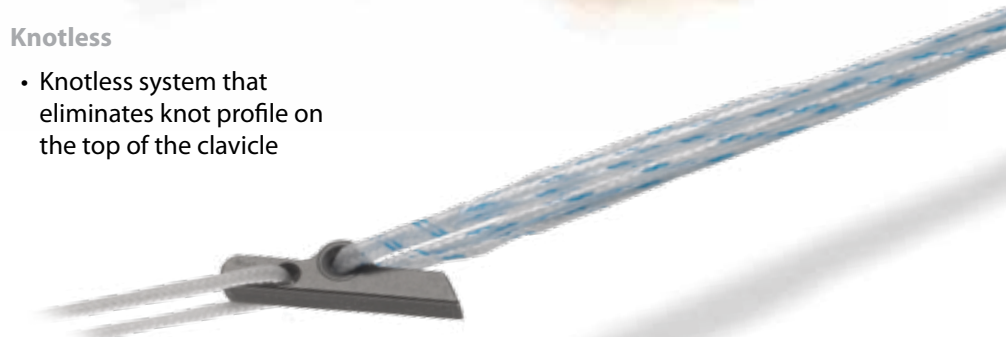


[www.ziploop.net](http://www.ziploop.net)



#### Knotless

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



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

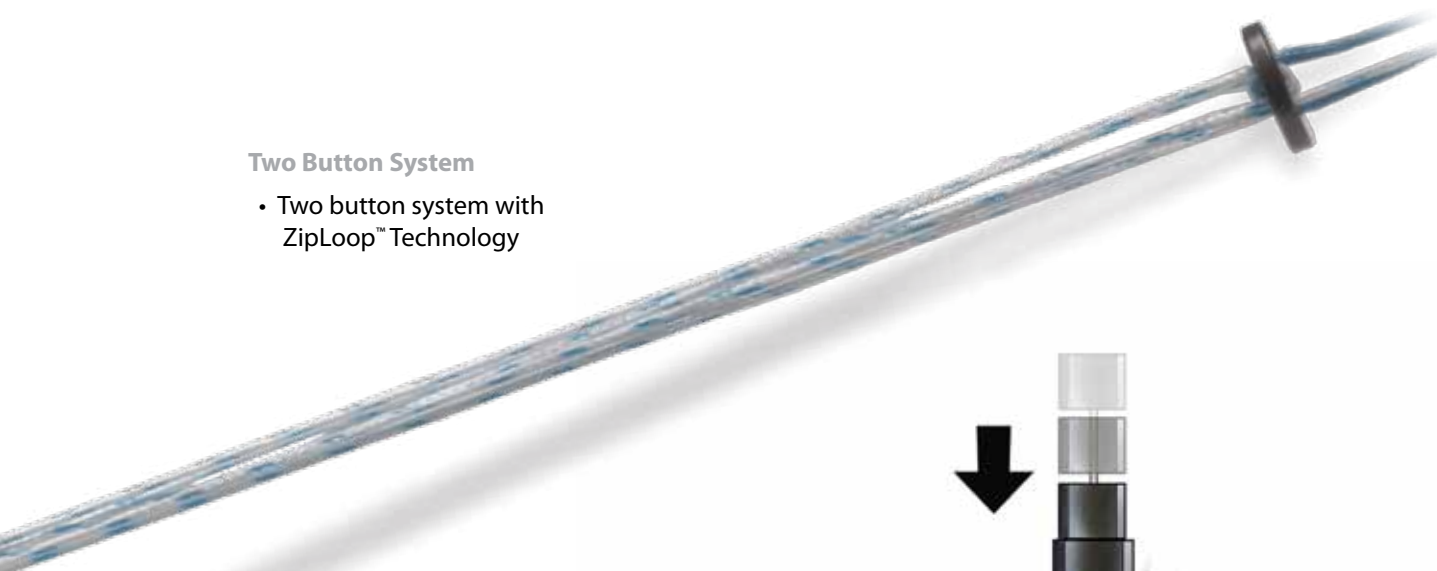
This brochure is presented to demonstrate the surgical technique and postoperative protocol utilized by Eric McCarty, M.D. Biomet Sports Medicine, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and utilizing the appropriate techniques for such procedure for each individual patient.

# ZIPTIGHT™

FIXATION SYSTEM

## Two Button System

- Two button system with ZipLoop™ Technology

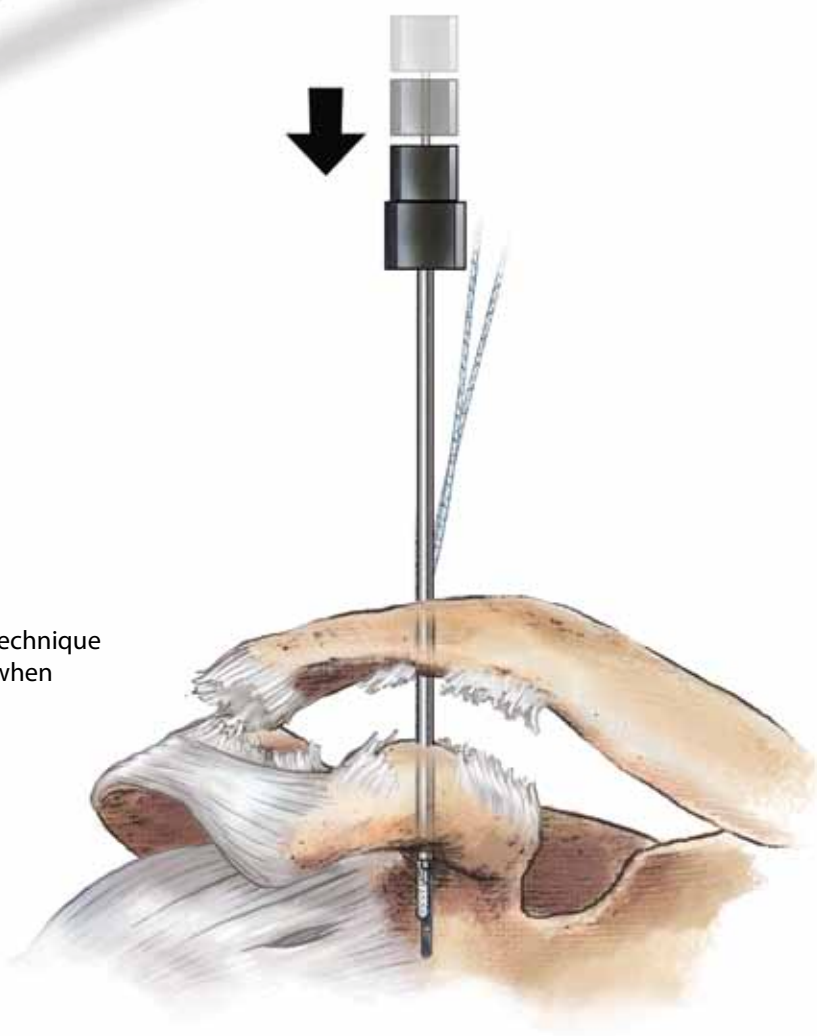


## MaxBraid™ Suture

- Coracoid and clavicle fixation devices connected with #7 MaxBraid™ Suture
- 376 lbs. of strength<sup>1</sup>

## Simple Technique

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



# Surgical Technique



Figure 1

## Indication

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 posterior portal. Create subsequent anterior portal utilizing a spinal needle for desired positioning of the portal. This portal should be on 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 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.

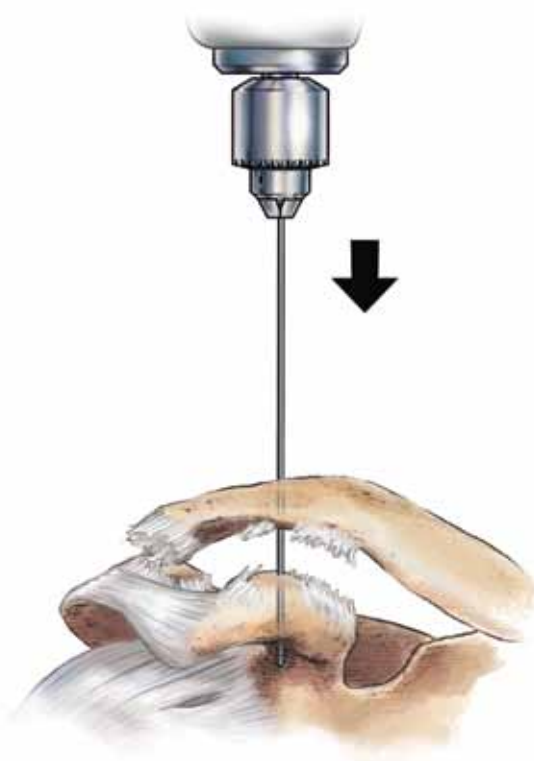


Figure 2

Once the coracoid is visualized with the arthroscopic camera, the tip can be exposed with an alternating combination of shaver and ablation device. 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 is exposed and its posterior curve is 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, sometimes 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 it 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

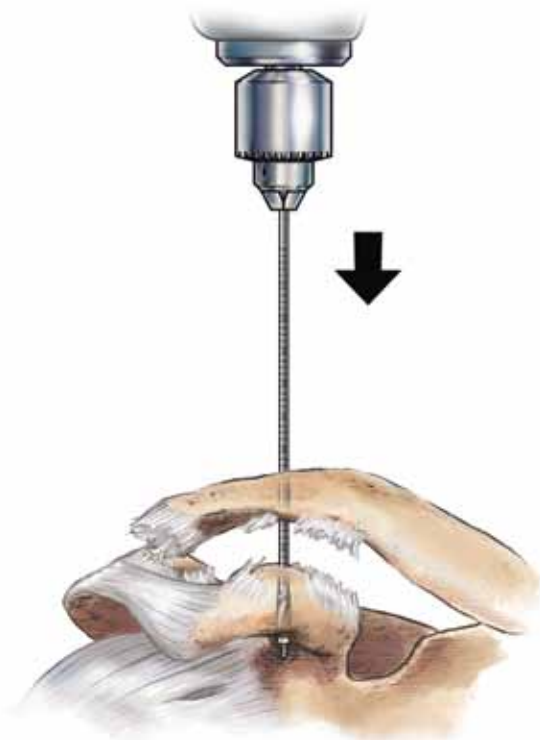


Figure 3

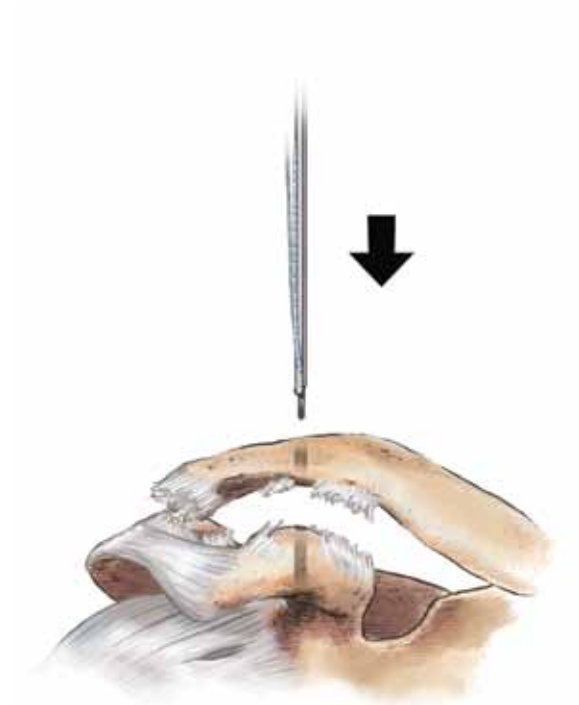


Figure 4

## Drill the Coracoid and Clavicle (continued)

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

Check guide pin under direct visualization under coracoid and redrill if placement was incorrect. Next, 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).

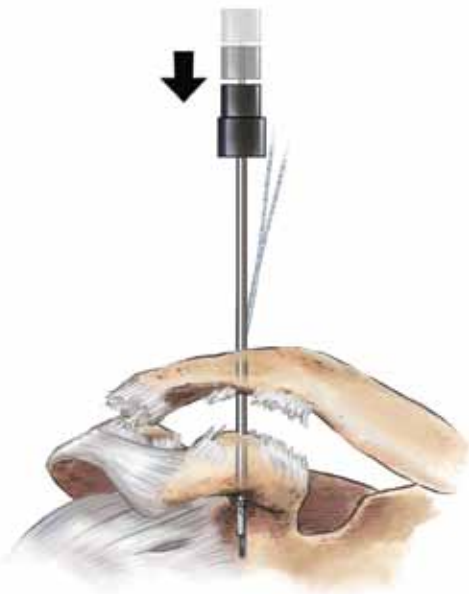


Figure 5

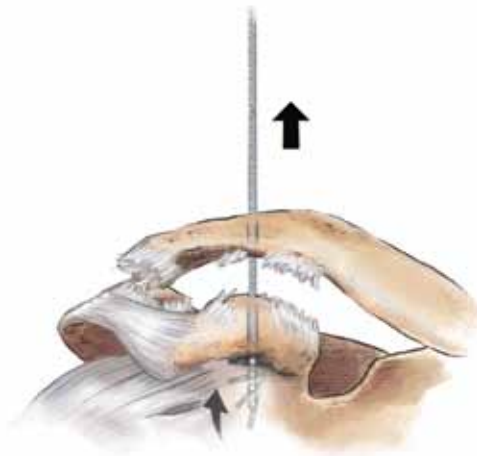


Figure 6

The ZipLoop™ and zip strand will already be through the clavicle and ready to be placed through the round button.

# Surgical Technique



Figure 7

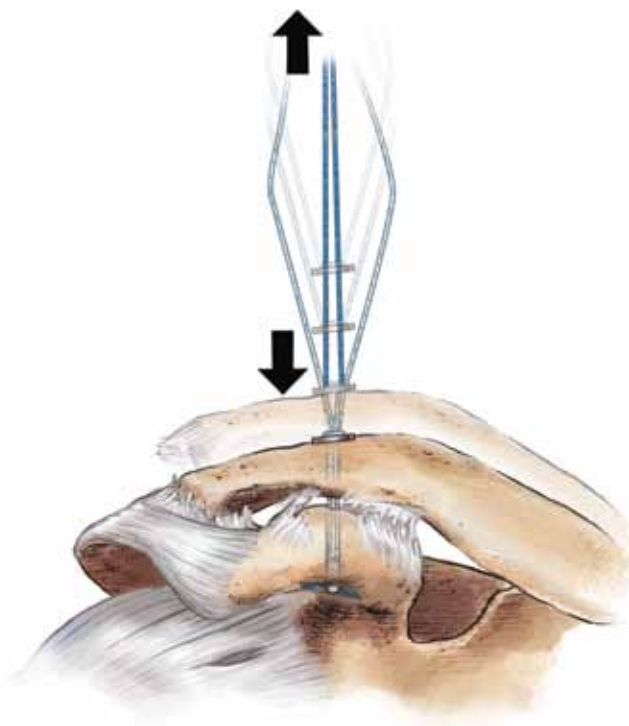


Figure 8

## 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. Also, this can 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).

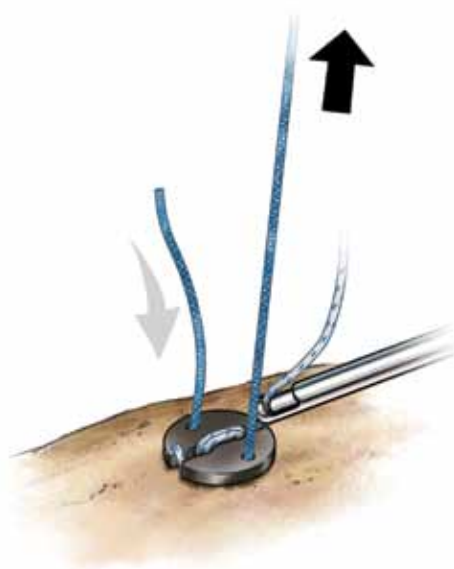
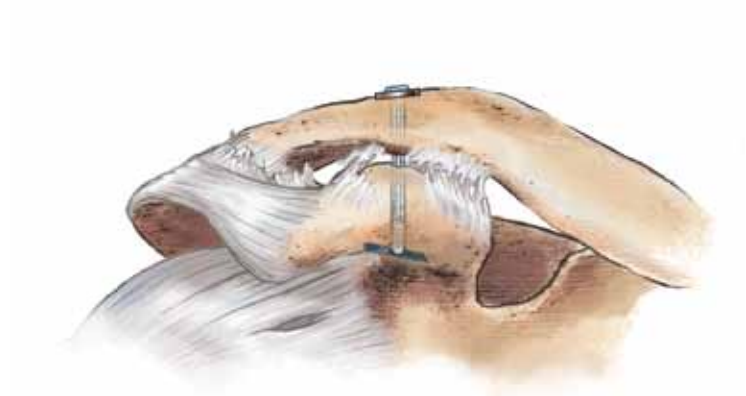


Figure 9





### **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 full return to activities 4 – 6 months following the surgery.

# Package Insert

## Biomet Sports Medicine

56 East Bell Drive  
P.O. Box 587  
Warsaw, Indiana 46581 USA



**01-50-1186**  
Date: 03/09

### Biomet Sports Medicine ToggleLoc™ System ATTENTION OPERATING SURGEON

#### DESCRIPTION

The ToggleLoc™ System is a non-resorbable system intended to aid in arthroscopic and orthopedic reconstructive procedures requiring soft tissue fixation, due to injury or degenerative disease.

#### MATERIALS

Titanium Alloy  
Ultra-High Molecular Weight Polyethylene (UHMWPE)  
Polypropylene  
Nylon  
Polyester  
Stainless Steel

#### 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 connection 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  
Illiotal 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 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.

#### WARNINGS

The ToggleLoc™ System devices provide the surgeon with a means to aid in the management of soft tissue to bone reattachment procedures. While these devices are generally successful in attaining these goals, they cannot be expected to replace normal healthy bone or withstand the stress placed upon the device by full or partial weight bearing or load

bearing, particularly in the presence of nonunion, delayed union, or incomplete healing. Therefore, it is important that immobilization (use of external support, walking aids, braces, etc.) of the treatment site be maintained until healing has occurred. Surgical implants are subject to repeated stresses in use, which can result in fracture or damage to the implant. Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the service life of the implant. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but also must be aware of the mechanical and metallurgical aspects of the surgical implants.

Patient selection factors to be considered include: 1) need for soft tissue to bone fixation, 2) ability and willingness of the patient to follow postoperative care instructions until healing is complete, and 3) a good nutritional state of the patient

1. Correct selection of the implant is extremely important. The potential for success in soft tissue to bone fixation is increased by the selection of the proper type of implant. While proper selection can help minimize risks, neither the device nor grafts, when used, are designed to withstand the unsupported stress of full weight bearing, load bearing or excessive activity.
2. The implants can loosen or be damaged and the graft can fail when subjected to increased loading associated with nonunion or delayed union. If healing is delayed, or does not occur, the implant or the procedure may fail. Loads produced by weight bearing and activity levels may dictate the longevity of the implant.
3. Inadequate fixation at the time of surgery can increase the risk of loosening and migration of the device or tissue supported by the device. Sufficient bone quantity and quality are important to adequate fixation and success of the procedure. Bone quality must be assessed at the time of surgery. Adequate fixation in diseased bone may be more difficult. Patients with poor quality bone, such as osteoporotic bone, are at greater risk of device loosening and procedure failure.
4. Implant materials are subject to corrosion. Implanting metals and alloys subjects them to constant changing environments of salts, acids, and alkalis that can cause corrosion. Putting dissimilar metals and alloys in contact with each other can accelerate the corrosion process that may enhance fracture of implants. Every effort should be made to use compatible metals and alloys when marrying them to a common goal, i.e., screws and plates.
5. Care is to be taken to ensure adequate soft tissue fixation at the time of surgery. Failure to achieve adequate fixation or improper positioning or placement of the device can contribute to a subsequent undesirable result.
6. The use of appropriate immobilization and postoperative management is indicated as part of the treatment until healing has occurred.
7. Correct handling of implants is extremely important. Do not modify implants. Do not notch or bend implants. Notches or scratches put in the implant during the course of surgery may contribute to breakage.
8. DO NOT USE if there is a loss of sterility of the device.
9. Discard and DO NOT USE opened or damaged devices, and use only devices that are package in unopened or undamaged containers.
10. Adequately instruct the patient. Postoperative care is important. The patient's ability and willingness to follow instructions is one of the most important aspects of successful fracture management. Patients effected with senility, mental illness, alcoholism, and drug abuse may be at a higher risk of device or procedure failure. These patients may ignore instructions and activity restrictions. The patient is to be instructed in the use of external supports, walking aids, and braces that are intended to immobilize the fracture site and limit weight bearing or load bearing. The patient is to be made fully aware and warned that the device does not replace normal healthy bone, and that the device can break, bend or be damaged as a result of stress, activity, load bearing, or weight bearing. The patient is to be made aware and warned of general surgical risks, possible adverse effects, and to follow the instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examinations as long as the device remains implanted.

#### PRECAUTIONS

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat with implants that have been, even momentarily, placed in a

different patient.

Instruments are available to aid in the accurate implantation of internal fixation devices. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet Sports Medicine recommends that all instruments be regularly inspected for wear and disfigurement.

If device contains MaxBraid™ suture, refer to manufacturer package insert for further information.

#### POSSIBLE ADVERSE EFFECTS

1. Nonunion or delayed union, which may lead to breakage of the implant.
2. Bending or fracture of the implant.
3. Loosening or migration of the implant.
4. Metal sensitivity or allergic reaction to a foreign body.
5. Pain, discomfort, or abnormal sensation due to the presence of the device.
6. Nerve damage due to surgical trauma.
7. Necrosis of bone or tissue.
8. Inadequate healing.
9. Intraoperative or postoperative bone fracture and/or postoperative pain.

#### STERILITY

The ToggleLoc™ System devices are supplied sterile and are sterilized by exposure to Ethylene Oxide Gas (ETO) if device contains MaxBraid™ PE suture. Do not resterilize. Do not use any component from an opened or damaged package. Do not use past expiration date.

**Caution:** Federal law (USA) restricts this device to sale, distribution, or use by or on the order of a physician.

Comments regarding the use of this device can be directed to Attn: Regulatory Affairs, Biomet, Inc., P.O. Box 587, Warsaw IN 46581 USA, Fax: 574-372-3968.

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Authorized Representative: Biomet U.K., Ltd.  
Waterton Industrial Estate  
Bridgend, South Wales  
CF31 3XA, U. K.



Manufacturer



Date of Manufacture



Do Not Reuse



Consult Accompanying Documents



Sterilized using Ethylene Oxide



Sterilized using Irradiation



Sterile



Sterilized using Aseptic Technique



Sterilized using Steam or Dry Heat



Expiry Date



WEEE Device



Catalogue Number



Lot Number



Flammable

The information contained in this package insert was current on the date this brochure was printed. However, the package insert may have been revised after that date. To obtain a current package insert, please contact Biomet Sports Medicine at the contact information provided herein.

## Ordering Information

<b>ZipTight™ Fixation Device</b>
<b>904834</b>

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

**ZipLoop™ Puller**

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**904776**

**Super MaxCutter™ Suture Cutter**

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**900342**

Illustrations in this surgical technique are intended to highlight steps of the procedure and may not be to scale.

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For product information, including indications, contraindications, warnings, precautions and potential adverse effects, see the package insert and Biomet's website.

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