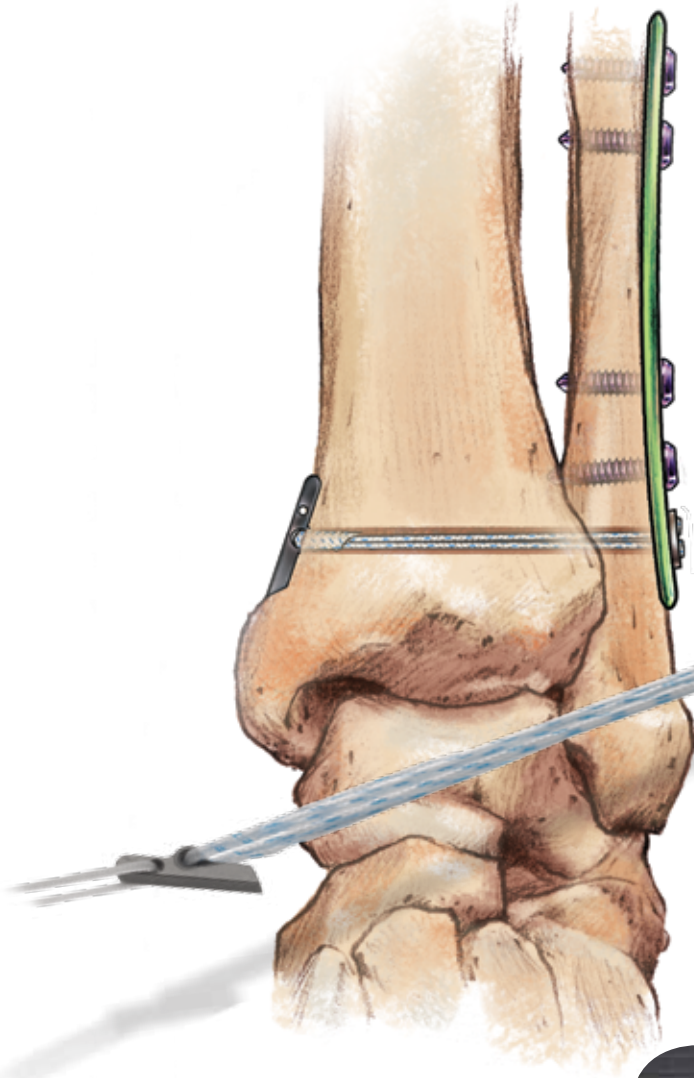


ZIPTIGHT™

FIXATION SYSTEM FOR ANKLE SYNDESMOSIS

Featuring... *ZipLop*™
TECHNOLOGY



Ankle Syndesmosis

Surgical Protocol by
Timothy Charlton, M.D.

BIOMET®
SPORTS MEDICINE

ZipLoop™ TECHNOLOGY



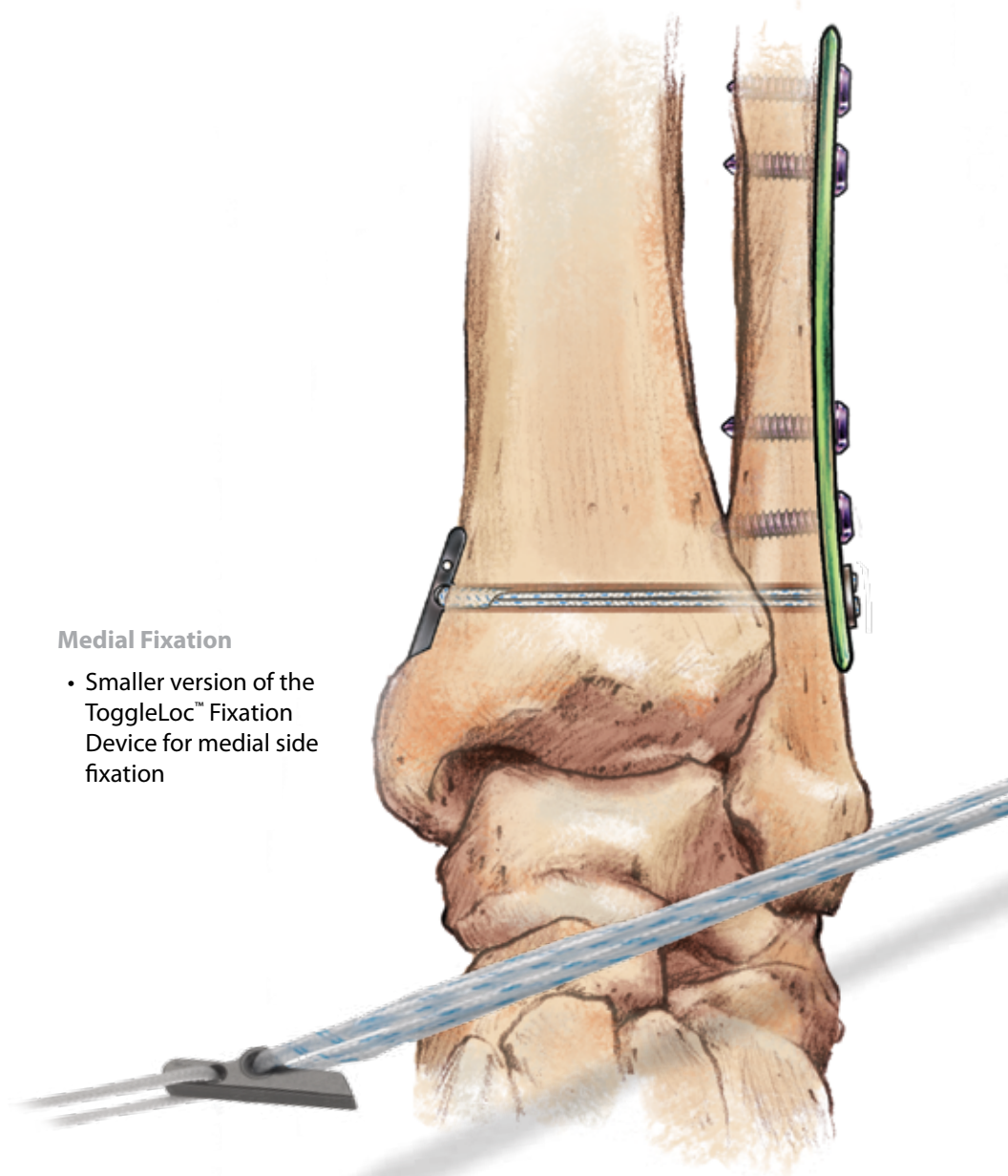
ZipLoop™ Technology is a unique weave in which a single strand of braided polyethylene is woven through itself twice in opposite directions. This construct allows Biomet Sports Medicine to produce innovative products that can vary in length and compression/tension addressing the individual needs of each patient. Products utilizing ZipLoop™ Technology are resistant to slippage without tying knots.¹ Procedure-specific animations, surgical protocols and surgery videos are available at www.ziploop.net.



www.ziploop.net

Medial Fixation

- Smaller version of the ToggleLoc™ Fixation Device for medial side fixation



Material

- Available with either titanium or stainless steel buttons to correspond with the surgeon's preferred plating system

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

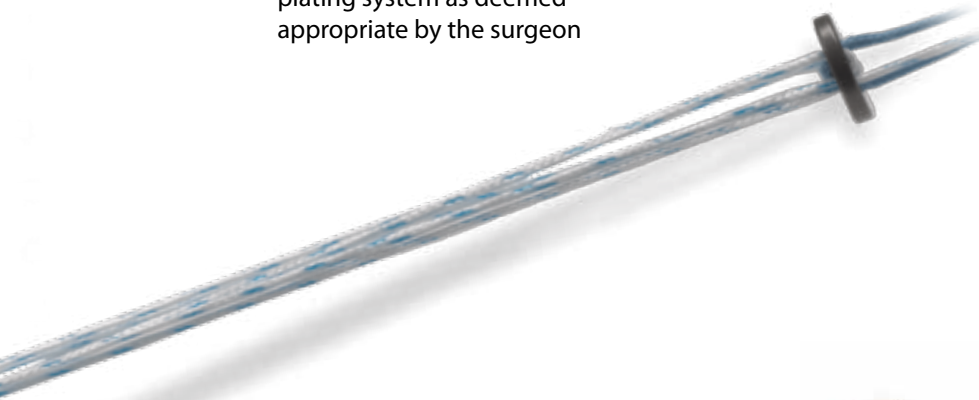
This brochure is presented to demonstrate the surgical technique and postoperative protocol utilized by Timothy Charlton, M.D. Biomet Sports Medicine, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient.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

ZIPTIGHT™

FIXATION SYSTEM FOR ANKLE SYNDESMOSIS

Lateral Fixation

- Round top hat button for lateral fixation
- Can be used directly on the lateral cortex of the fibula or in conjunction with a plating system as deemed appropriate by the surgeon

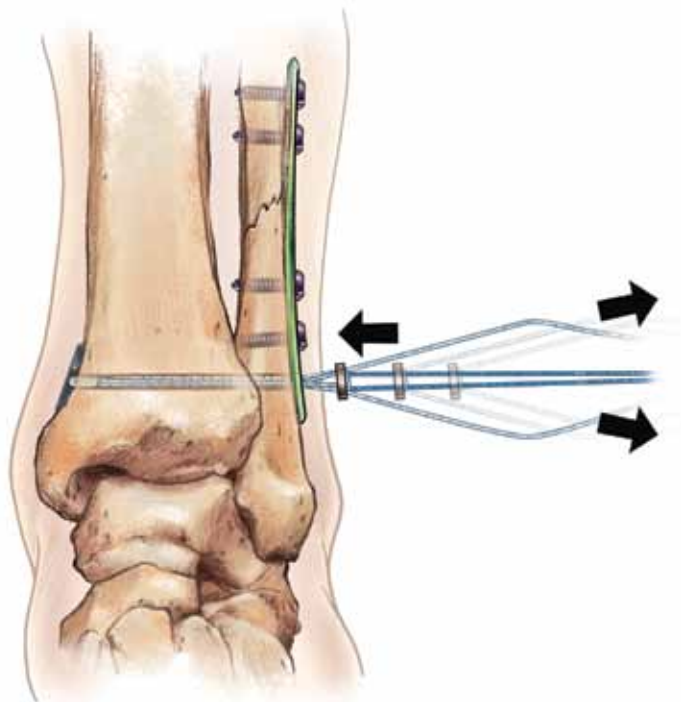


MaxBraid™ Suture

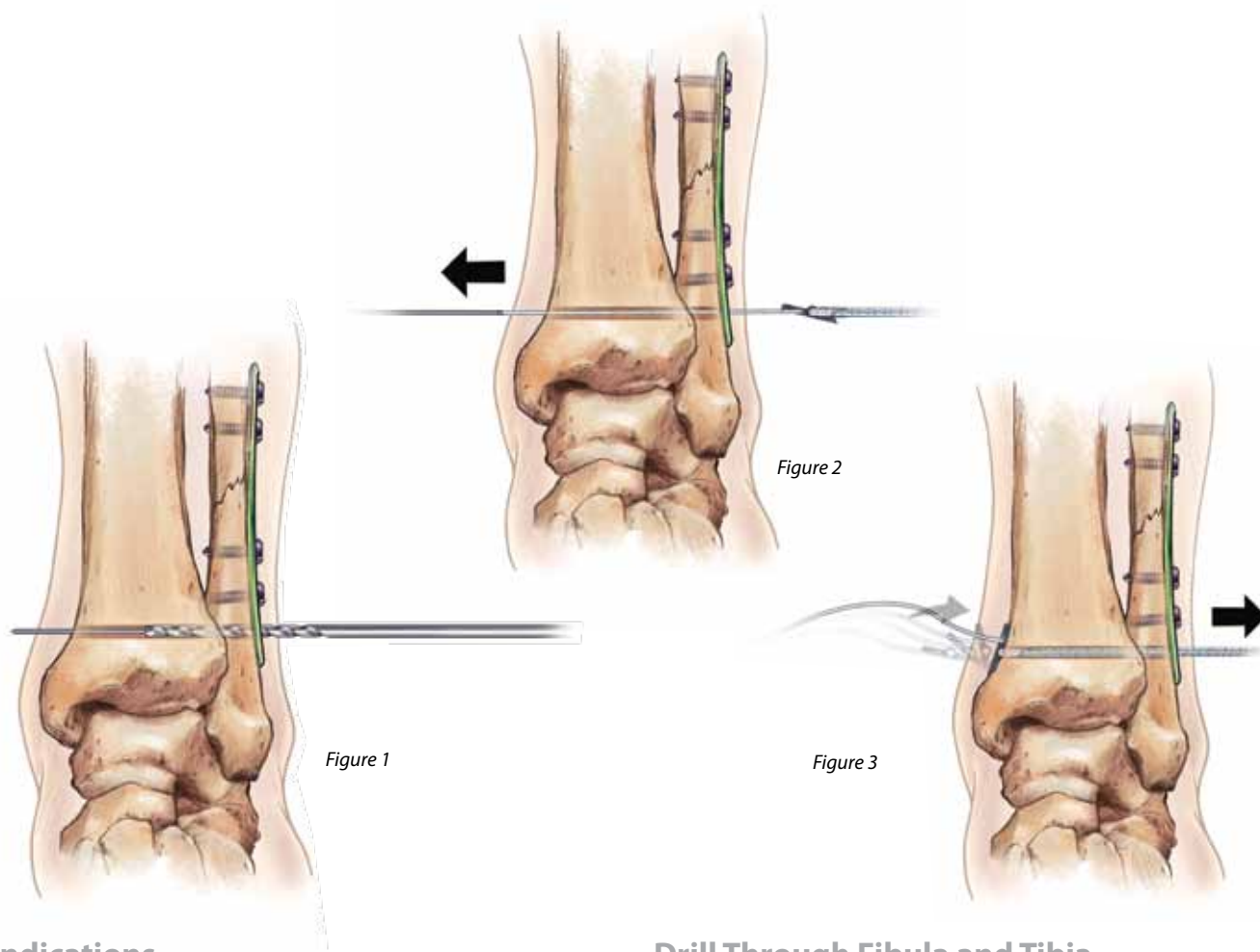
- Medial and lateral fixation devices connected with MaxBraid™ Suture

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 surgeon's preferred plating system
- 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 to repair 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 Device 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 Device

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

Carefully continue pulling the ZipTight™ Fixation Device pull strand (white MaxBraid™ suture) until the ToggleLoc™ button exits the bone tunnel on the medial side of the tibia. Keeping the device taught 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).

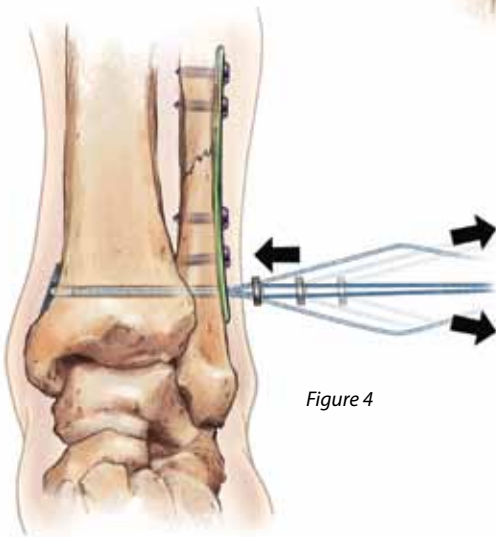


Figure 4

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).

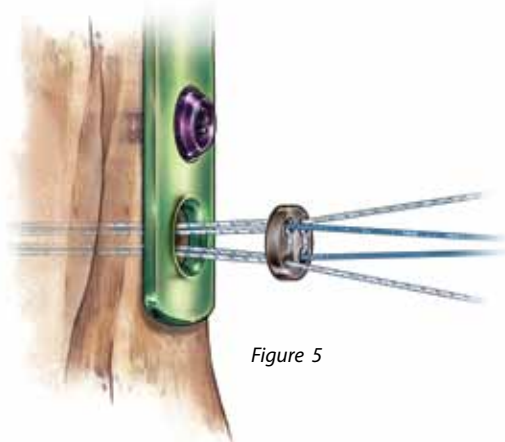


Figure 5

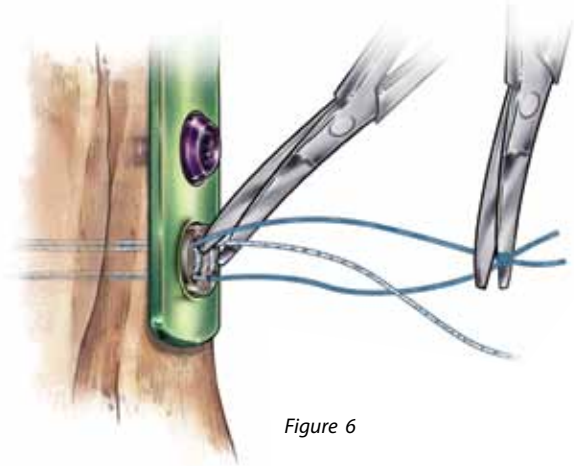


Figure 6

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, the Super MaxCutter™ Suture Cutter or the Disposable Cutter may be used (Figure 6). **Note: No knots need to be tied because the construct utilizes ZipLoop™ Technology.**

Surgical Technique (continued)

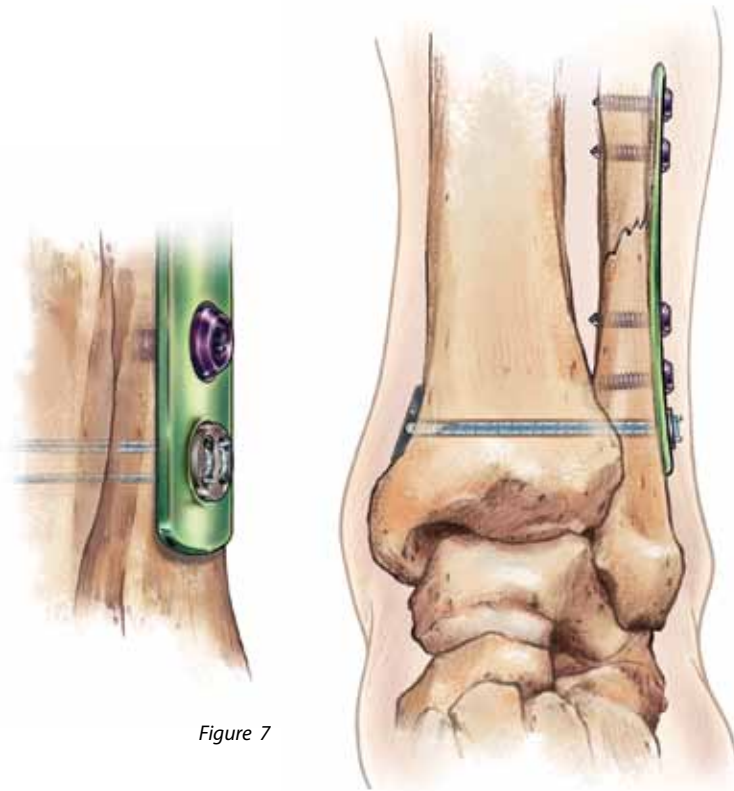


Figure 7

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.

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
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 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
Bridgford, 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

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)

Cannulated Drill Bit

948086	3.7mm x 5" (Non-Sterile)
948084	3.2mm x 5" (Non-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

Super MaxCutter™ Suture Cutter

900342

Disposable Cutter

905732

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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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SPORTS MEDICINE
One Surgeon. One Patient.™

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