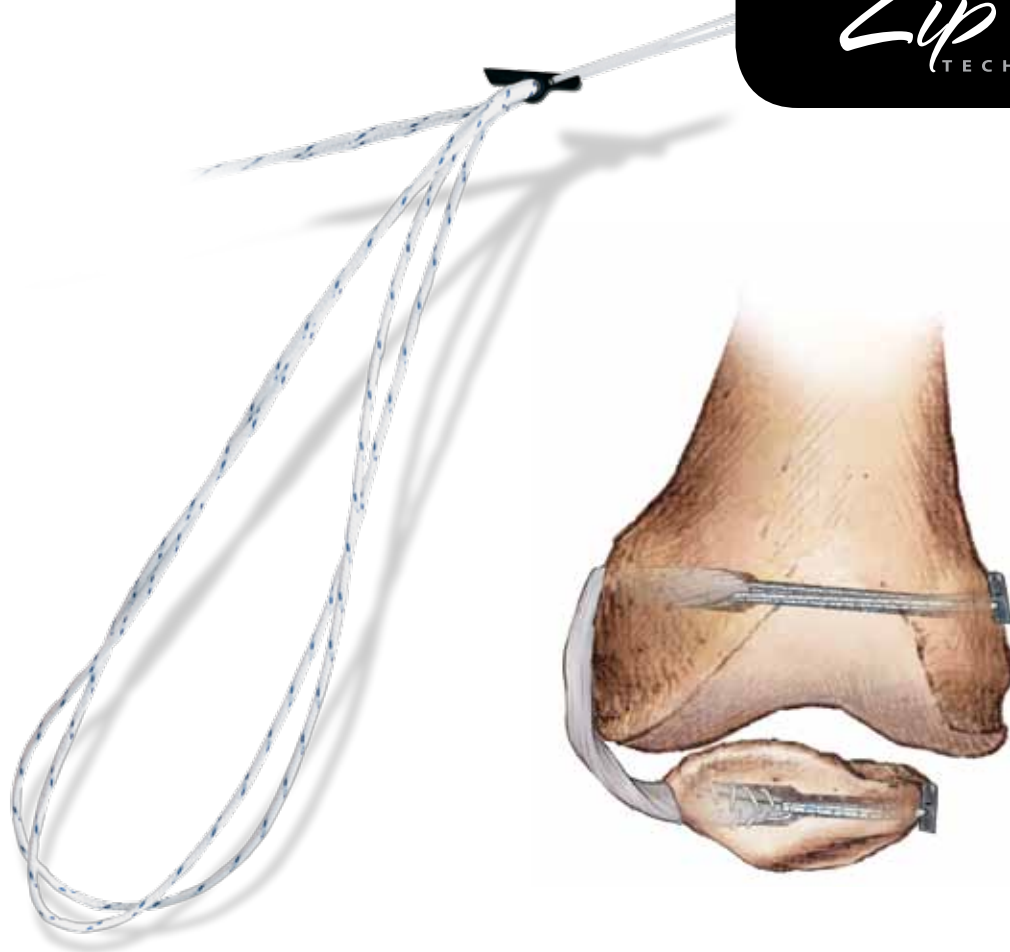


**ToggleLoc™**  
FIXATION DEVICE

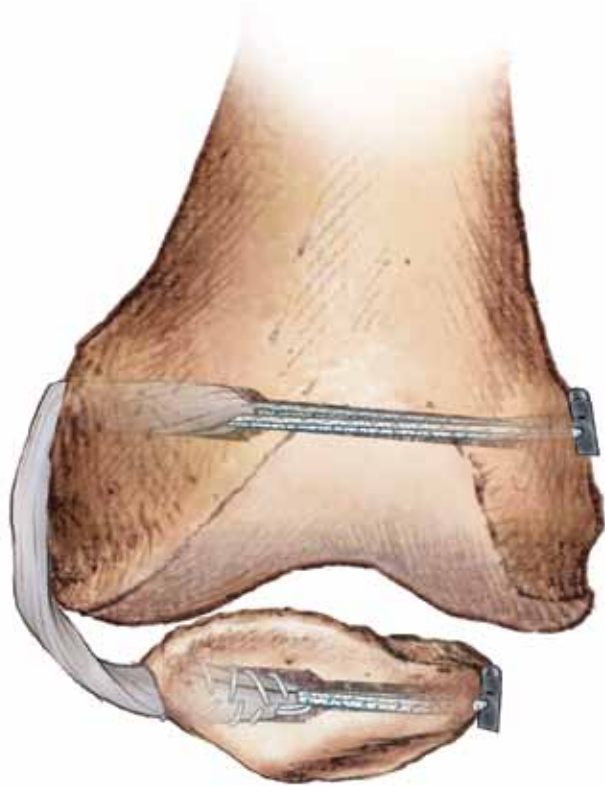
with **ZipLoc™**  
TECHNOLOGY



## Medial Patellofemoral Ligament (MPFL) Reconstruction

Surgical Protocol by  
Ronald Navarro, M.D.

**BIOMET®**  
SPORTS MEDICINE



*ZipLoop*  
TECHNOLOGY™

## Features

- 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 knots¹.

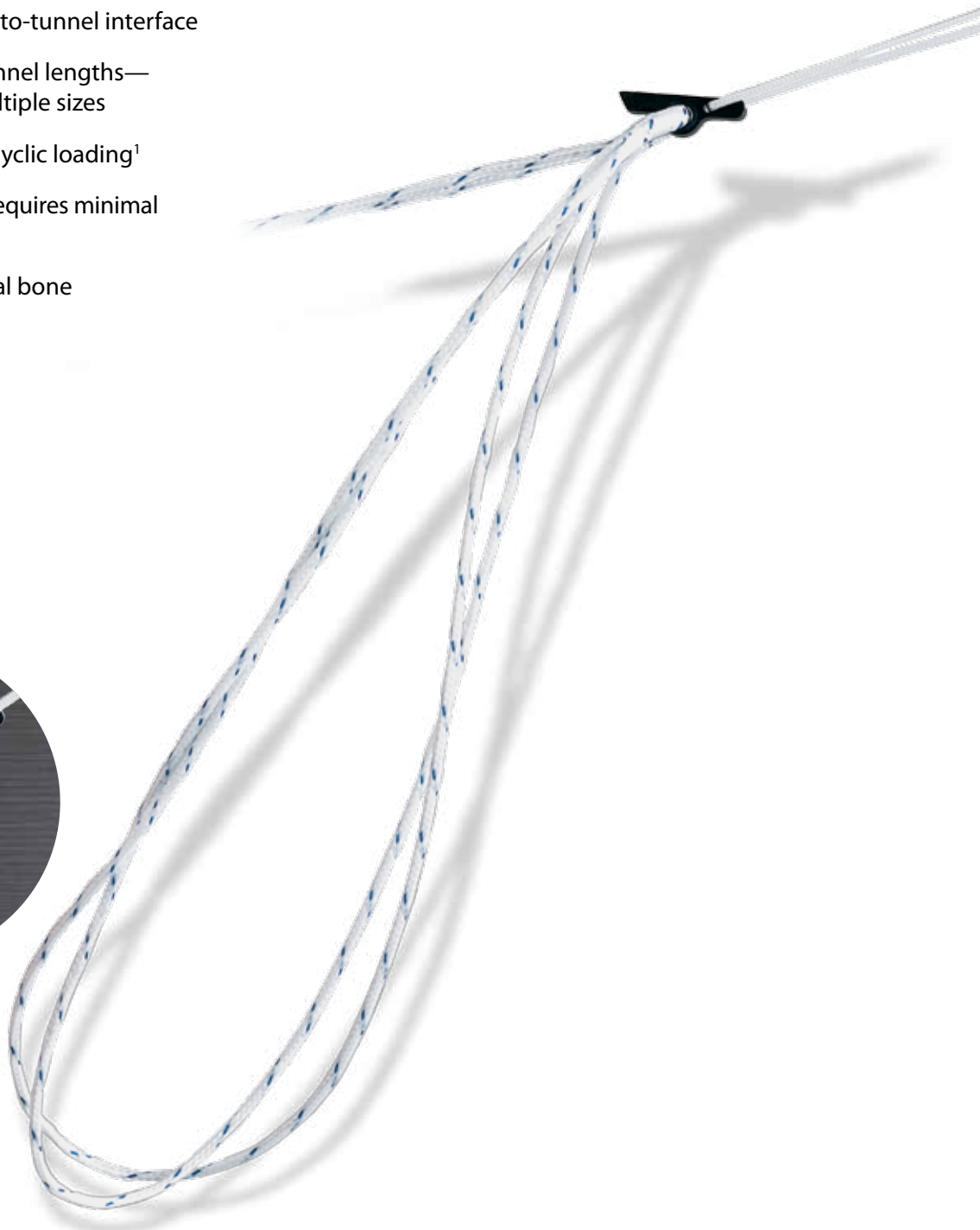


# ToggleLoc™

FIXATION DEVICE

## Benefits

- Maximizes soft tissue graft-to-tunnel interface
- One implant for varying tunnel lengths—eliminates the need for multiple sizes
- Virtually no slippage after cyclic loading<sup>1</sup>
- Simple surgical technique requires minimal instrumentation
- Designed to capture cortical bone



# Surgical Technique

## Indications for Surgery

- Severe instability of the patella
- Subluxation of the patella

## Contraindications

If patellar instability is only due to these differential diagnoses

- Trochlear hypoplasia
- Generalized ligamentous laxity
- Patella alta
- Patellar facet dysplasia

## General Positioning

The patient is brought to the operating theater and placed in the supine position on a split leg table if possible. After adequate anesthesia is obtained the patient's involved lower extremity has a thigh high tourniquet placed but it is not inflated. After sterile prep and drape, 1% lidocaine and epinephrine is injected inferomedially and inferolaterally (if diagnostic arthroscopy is to be performed) as well as medially at the femoral epicondyle, medially at the insertion of the MPFL and in and around the hamstrings insertions of the tibia.

This brochure is presented to demonstrate the surgical technique and postoperative protocol utilized by Ronald Navarro, 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 procedure for each individual patient.

### **Diagnostic Arthroscopy/ Possible Trochleoplasty**

If deemed appropriate due to the possibility of underlying intra-articular pathology or the need for trochleoplasty or lateral release, a diagnostic arthroscopy is performed. Incisions are made inferomedially and inferolaterally in the typical portal locations for knee arthroscopy. The arthroscope is introduced. Evidence of chondral change is assessed on the patella. This can then be debrided using a shaver. More elaborate cartilage restoration methods are described separately in the literature. All other intra-articular meniscal and chondral pathology can be assessed and treated as dictated by prior informed consent.

If on preoperative assessment including CT scan, a supra-trochlear bump is seen this may deviate the patella out of the central track in the trochlea. There may be a benefit to take down this bump and deepen the trochlea. An arthroscopic burr or bone cutting shaver can be used to perform this task. Any anterior

femoral cortical outcropping can be taken down while being careful not to create a stress riser in this region. If relative trochlear hypoplasia is present with flattening of the normal trochlear concavity, typical capture of the patella in early knee flexion cannot occur. The trochlear central groove is deepened in this setting with the use of a bone cutting shaver directly on the most proximal trochlear articular cartilage. The goal is to deepen only the most proximal trochlea and not remove the entire articular surface.

An arthroscopic lateral release is performed if negative patellar tilt exists (where the lateral patella cannot be tilted medially in the coronal plane to a position where the patella could be parallel to the floor if the patient is in the supine position and the toes are in the up pointing or 12 o'clock position). The arthroscopy is then terminated and the knee decompressed to begin the medial patellar femoral ligament reconstruction.

## Surgical Technique (continued)

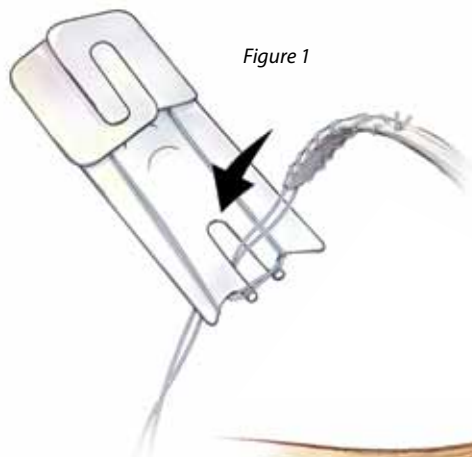


Figure 1

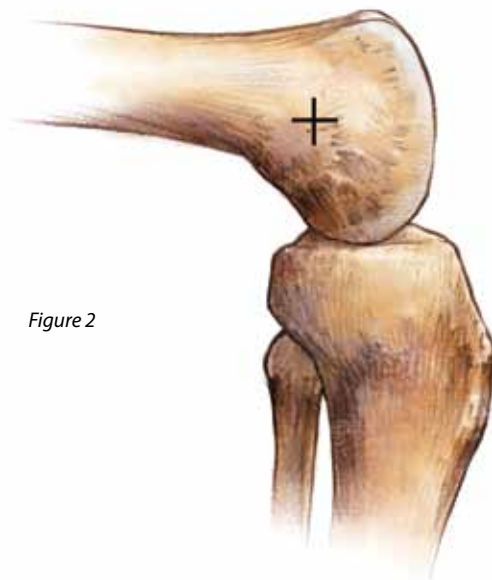


Figure 2

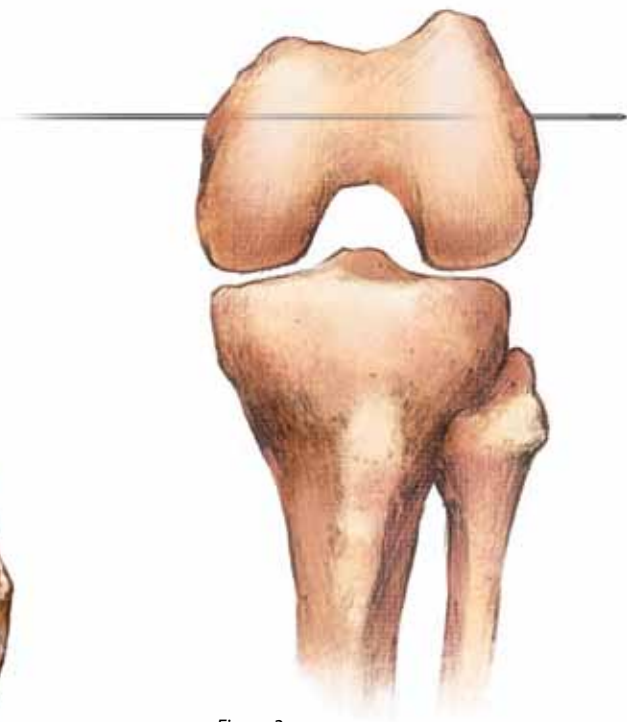


Figure 3

### Graft Preparation

A doubled graft of 5.5–7.0mm doubled diameter is required. If an allograft is chosen as the graft choice, usually a soft tissue graft is chosen. If a hamstrings autograft is chosen, an incision is made at the anterior medial aspect of the tibia. The sartorial fascia is visualized. It is then cut in line with the underlying tendons. The semitendinosus is removed and tagged using a closed end tendon stripper after its tibial insertion and attachments to the medial gastrocnemius are released. The sartorial fascia is closed with a running stitch. The semitendinosus or soft tissue allograft is taken to the back table and doubled over a passing stitch if using the CompoSiTCP™ Interference Screw (where the looped end is placed) or the looped end of a ToggleLoc™ Fixation Device with ZipLoop™ Technology (Figure 1). The resultant doubled graft is run through a tendon sizer to obtain its largest diameter. The diameter is noted for later drilling.

The free ends of the graft are then tagged with provisional tension stitches and the graft is placed on a graft board in tension on the back table. It is wrapped in a moist lap sponge, awaiting its use in the reconstructive effort.

### Femoral Preparation

If a split leg table is used, the uninvolved extremity is abducted so medial work can ensue. A 1cm incision is made over the medial epicondyle prominence and the incision is taken down to bone through multiple medial layers. The medial epicondyle is palpated and a position just superior and slightly posterior to the tip of the epicondylar eminence is chosen for placement of a guide pin (Figure 2). The pin is drilled to the lateral surface of the femur, being careful not to deviate too anteriorly into the articular surface of the trochlea (Figure 3).

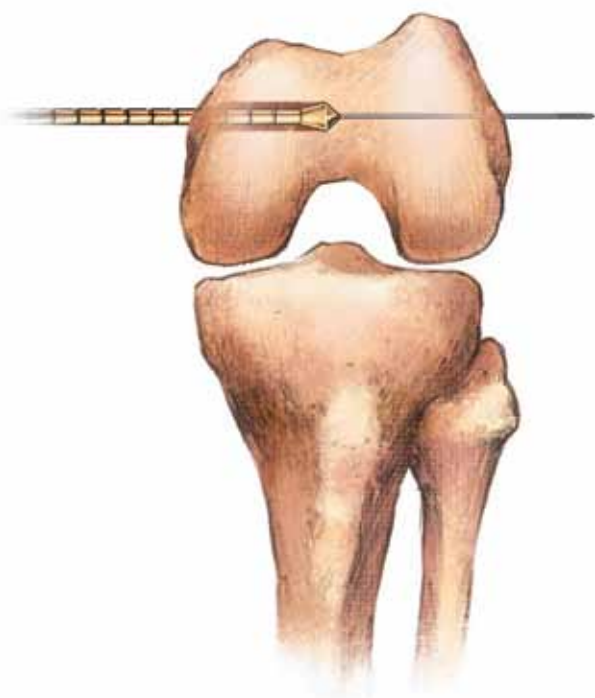


Figure 4

### Isometry

A suture can be placed around the pin and passed between Layer 2 and Layer 3 of the medial anatomy of the knee to a small incision on the superomedial patella for isometry testing. It is important to avoid excessive medial patellar facet tension in flexion (femoral point too proximal) and medial patellar displacement in extension (femoral point too distal).

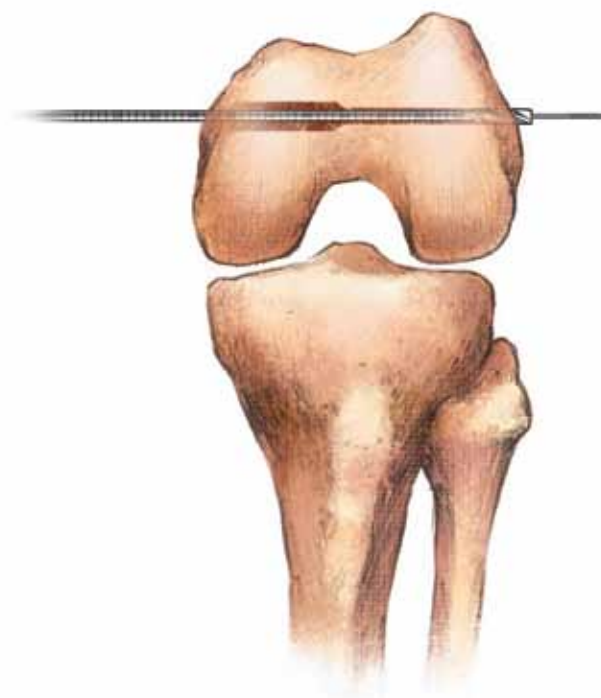


Figure 5

### Femoral Drilling

The pin in the femur is over-drilled with an acorn reamer bit of diameter corresponding to the diameter of the graft prepared and sized earlier to a distance of 30 – 35mm (Figure 4). The remaining tunnel length is over-drilled with the 4.5mm drill bit to accommodate the passage of the ToggleLoc™ Device (Figure 5) or left alone if utilizing a ComposiTCP™ Screw. Fluoroscopic guidance can help simplify this step.

## Surgical Technique (continued)

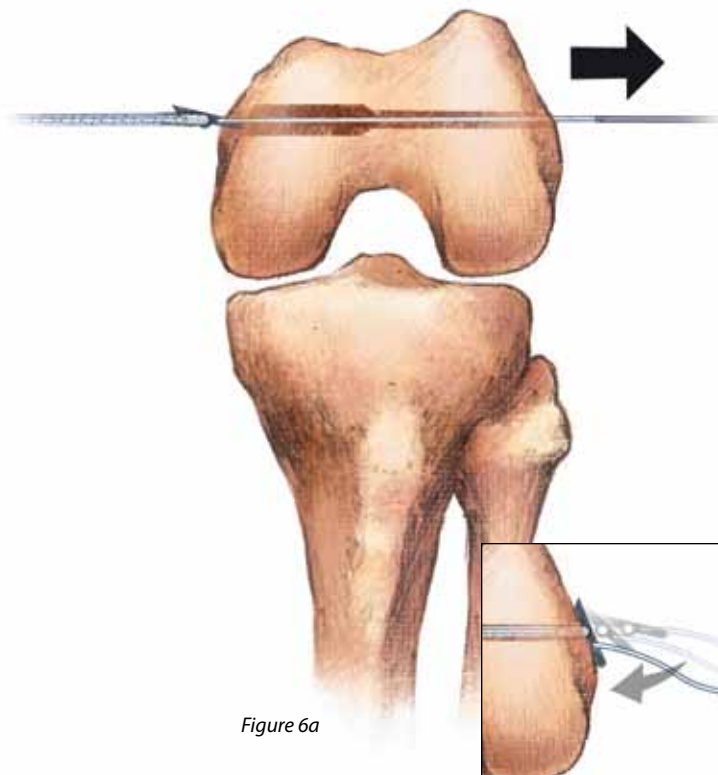


Figure 6a

Figure 6b

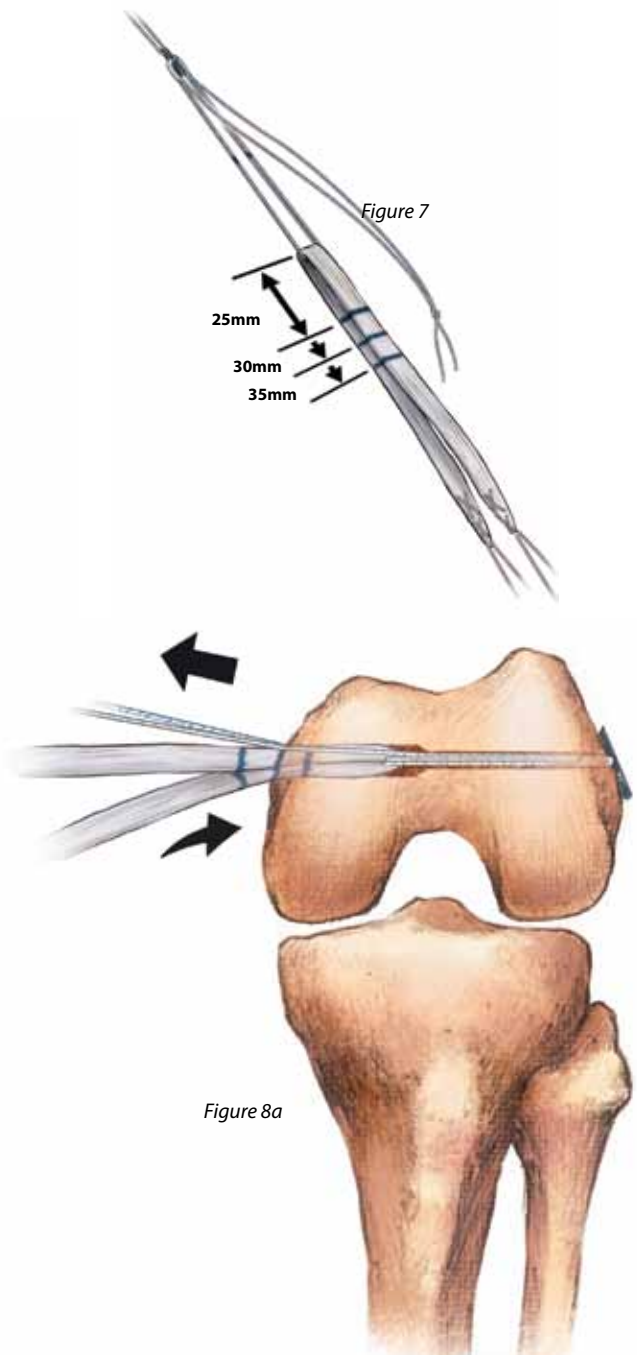


Figure 8a

### Femoral Graft Delivery

The graft is delivered into the closed end femoral tunnel using the Beath pin. The ToggleLoc™ Device is passed and then flipped on the lateral femoral cortex (Figure 6a & b). The zip strand of the ToggleLoc™ device is then pulled to introduce the looped end of the graft into the tunnel. The graft can be marked with a marking pen at 25, 30 and 35mm away from the butt end to help track the amount of graft that has been introduced into the femoral tunnel (Figure 7). It is recommended that less than the full length of graft that can be introduced on the femoral side initially be introduced (Figure 8a). If using the ComposiTCP™ Interference Screw, the graft is introduced to 30mm and the ComposiTCP™ Interference Screw of appropriate size and length is placed in line with the graft while placing tension on either side of the graft (Figure 8b).

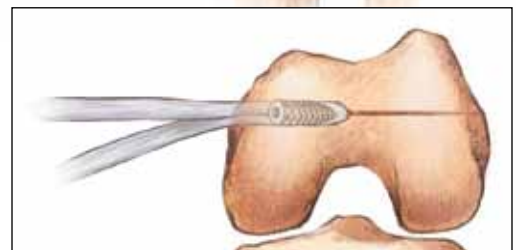


Figure 8b

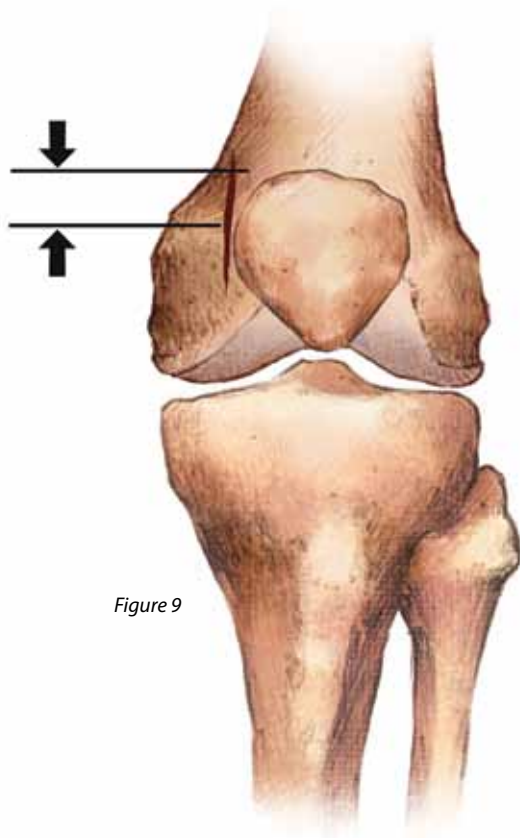


Figure 9

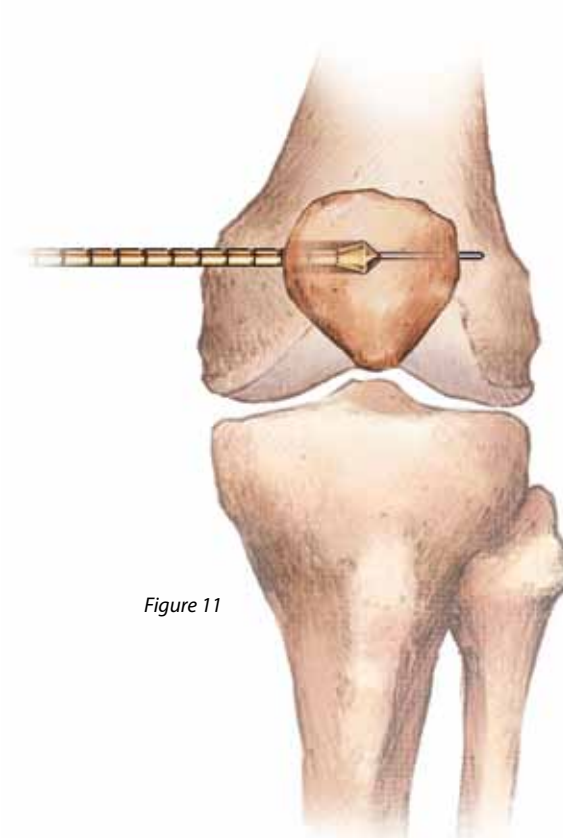


Figure 11

### Patellar Preparation

An incision is made just medial to the patella. As the typical patellar insertion site of the MPFL is 6 mm distal to the superior pole of the patella, the focus is superomedially on the patella (Figure 9). Anatomical Layer 2 of the medial knee is incised and Layer 3 is spared unless open patellar cartilage restoration procedures are contemplated. This same superomedial patella position is chosen for placement of a guide pin. The pin is drilled to the lateral surface of the patella, being careful not to deviate too anteriorly into the nonarticular surface of the patella or posteriorly into the patellar articulating facets (Figure 10).



Figure 10

### Patellar Drilling

The pin in the patella is overdrilled with an acorn reamer of the diameter corresponding to the diameter of the graft prepared and sized earlier to a distance of 15–25mm (Figure 11). The remaining tunnel length is overdrilled with the 4.5mm drill bit to accommodate the passage of the ToggleLoc™ Device (Figure 12). Fluoroscopic guidance can help simplify this step.



Figure 12

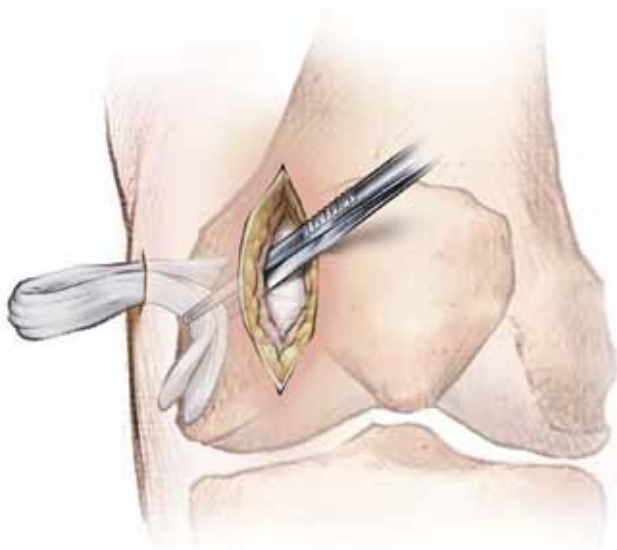


Figure 13

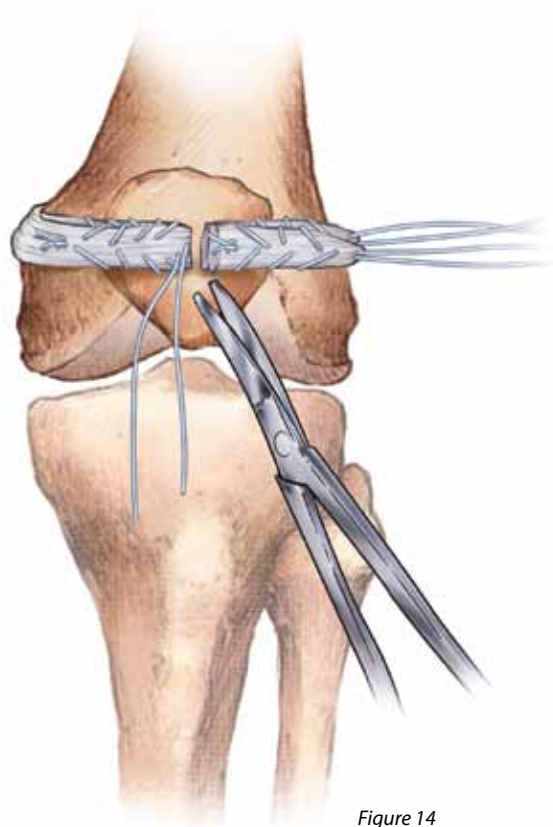


Figure 14

### Graft Limb Cutting

The graft is passed from the medial femoral incision to the anterior medial patellar incision underneath Layer 2 (Figure 13). The graft limbs are remeasured from the point of insertion into the medial patellar tunnel and trialed with varying amounts of "MPFL" length. Lateral patellar laxity is checked with each of the lengths to find a length where the patella can glide one quadrant laterally in full extension. This is the point where the checkrein effect of the MPFL reconstruction would block any further abnormal lateral displacement.

New sutures are placed in the two free limbs for a distance that matches the length of the acorn reamed patellar tunnel and the remaining excess graft and initial tension stitches are cut away (Figure 14).

## Surgical Technique (continued)

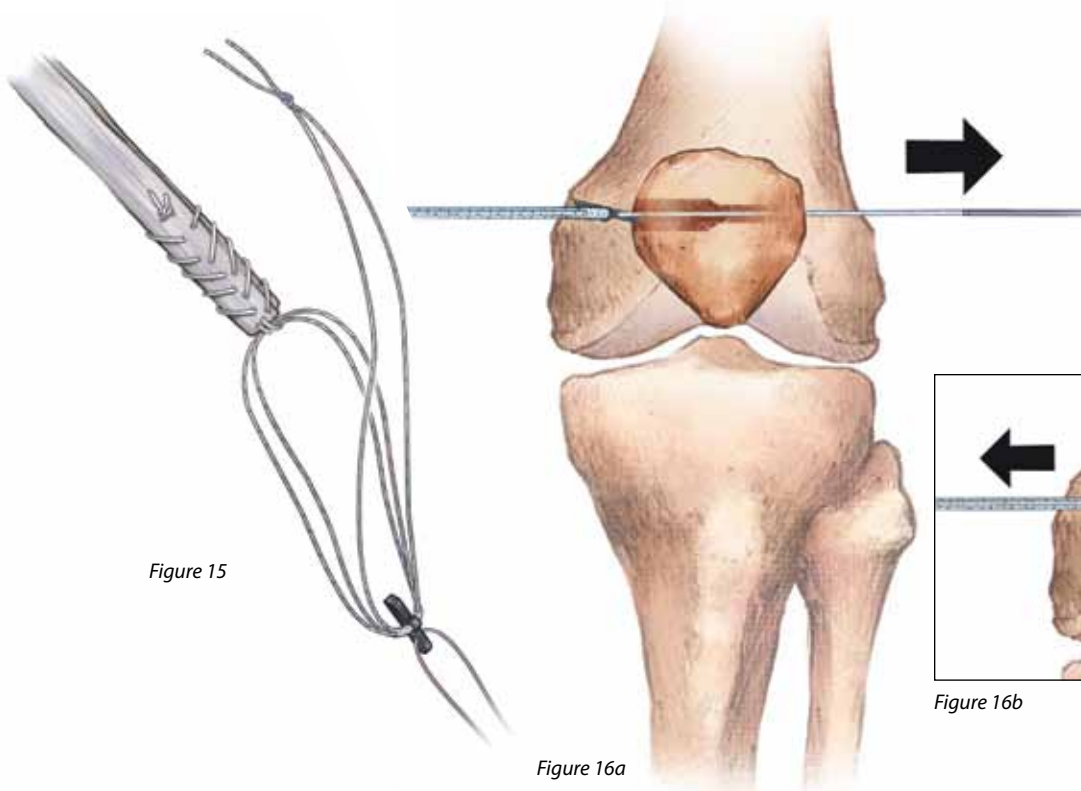


Figure 15

Figure 16a



Figure 16b

### Patellar Graft Delivery

The two stitches from the free limbs are tied to a second ToggleLoc™ Device via the ZipLoop™ suture looped ends (Figure 15). The ToggleLoc™ Device is passed and then flipped on the lateral patellar cortex (Figure 16a & b). The suture pulling strands of the ToggleLoc™ Device are then pulled upon to introduce the free limbs of graft into the tunnel. The graft can be marked with a marking pen at 15, 20 and 25mm away from the ends of the graft to help track the amount of graft that has been introduced into the patellar tunnel (Figure 17).

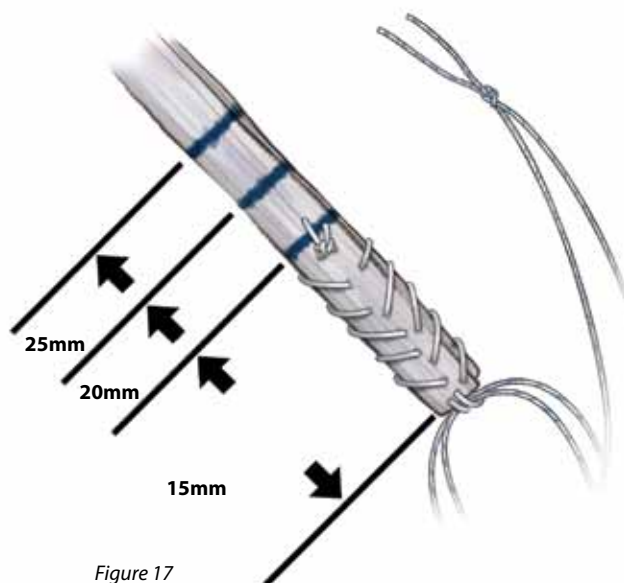


Figure 17

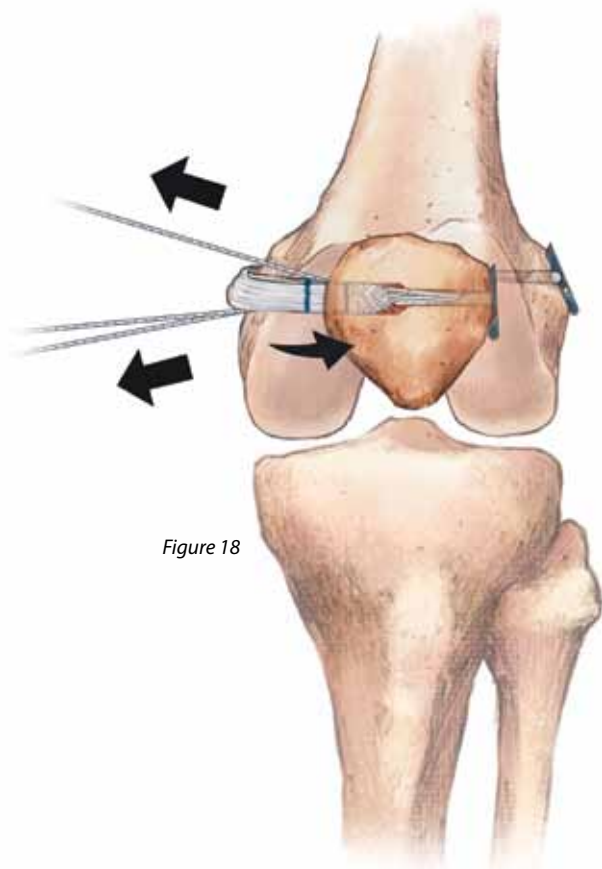


Figure 18

### Customizable Final Tensioning of Patella

At this point, the final tensioning of the patella can take place. Because of the ZipLoop™ Technology, tensioning can take place on both the patella side and the femoral side to ensure the patella has normal lateral glide in full extension, trochlear engagement of the patella in 30 to 45 degrees of flexion and the ability to achieve full flexion without graft stretch (Figure 18).



### Closure and Rehabilitation

The incisions are then irrigated freely and closed in layers. Sterile dressings are applied. A hinged knee brace is placed. The patient can weight bear in full extension immediately with crutch aid. Range of motion is initiated from 0 to 30 degrees of range immediately (non-weight bearing). Progressive increase in flexion should occur over the next 4–6 weeks to achieve full flexion and weaning of the crutches and brace. Progressive strengthening of the quadriceps and hamstrings with increase in functional movements helps facilitate recovery. Patients can typically return to sports activities in 4–6 months.

# 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  
Bridgend, South Wales  
CF31 3XA, U. K.



Manufacturer

Date of Manufacture

Do Not Reuse

Consult Accompanying Documents

STERILE EO Sterilized using Ethylene Oxide

STERILE IR Sterilized using Irradiation

STERILE Sterile

STERILE A Sterilized using Aseptic Technique

STERILE S Sterilized using Steam or Dry Heat

Expiry Date

WEEE Device

REF Catalogue Number

LOT 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

## ToggleLoc™ Fixation Device

<b>ToggleLoc™ Fixation Device with ZipLoop™ Technology 50"</b>
<b>904755</b>

### ToggleLoc™ Disposable Kit

- 909846** Includes:
- 2.4mm x 13" Drill Point K-Wire
  - 2.4mm x 16" Graft Passing Pin
  - ToggleLoc™ 4.5mm Drill Bit
  - 2.4mm x 10" Drill Point K-Wire
  - 3.2mm Drill Bit
  - ACL Bone Plug
  - Marking Pen
  - 6"Ruler

### ZipLoop™ Puller

**904776**

### Super MaxCutter™ Suture Cutter

**900342**



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

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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.<sup>™</sup>**

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