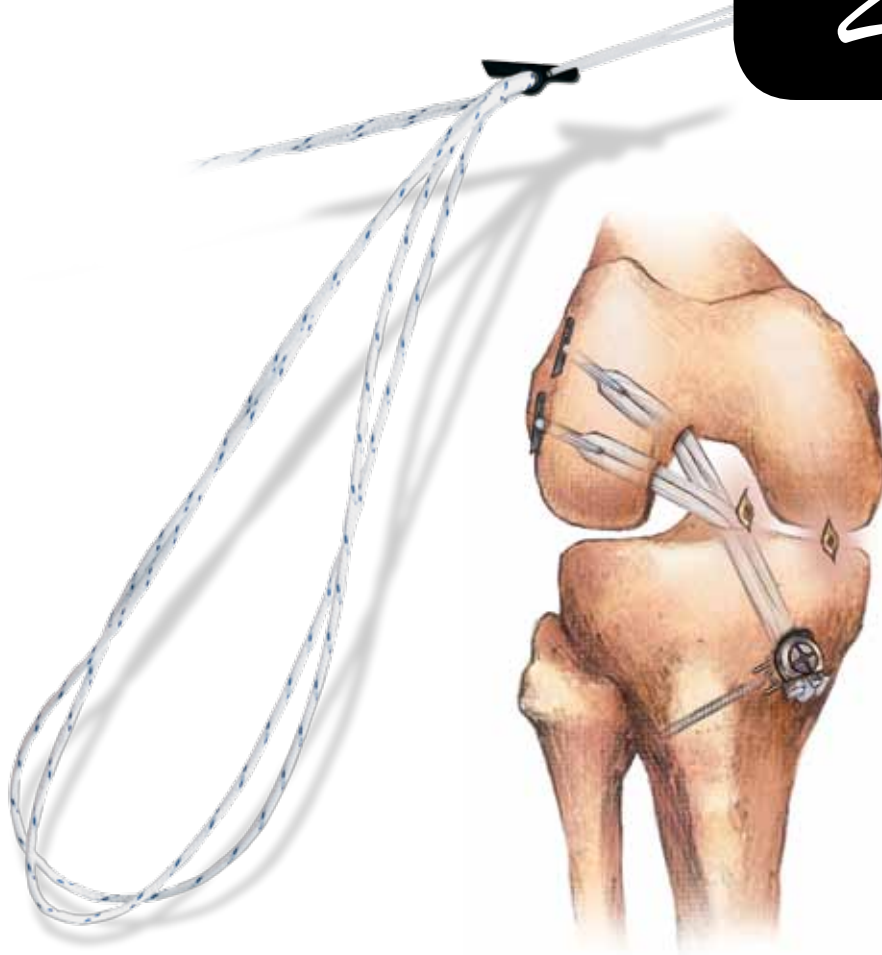


**ToggleLoc™**  
FIXATION DEVICE

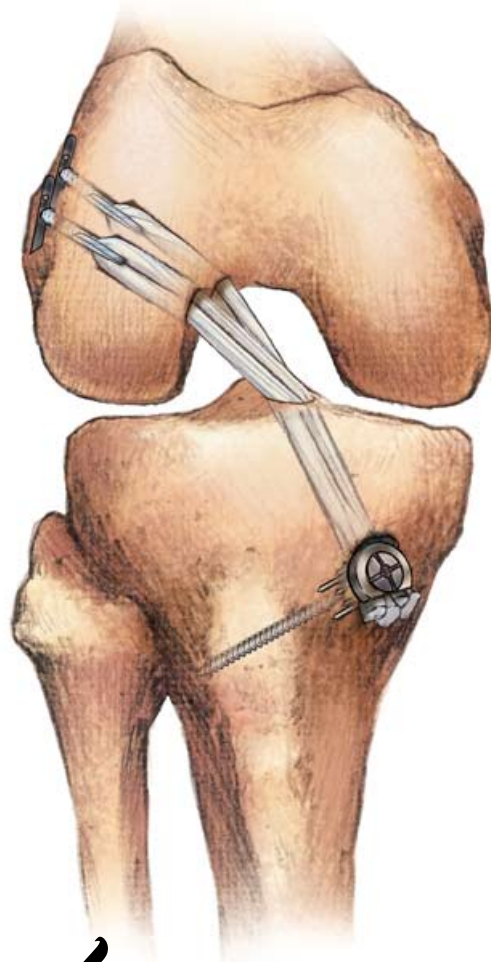
with **ZipLoop™**  
TECHNOLOGY



## ACL Reconstruction

Single Tibial Tunnel Double Bundle  
Surgical Protocol by  
Eric McCarty, 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 knots!

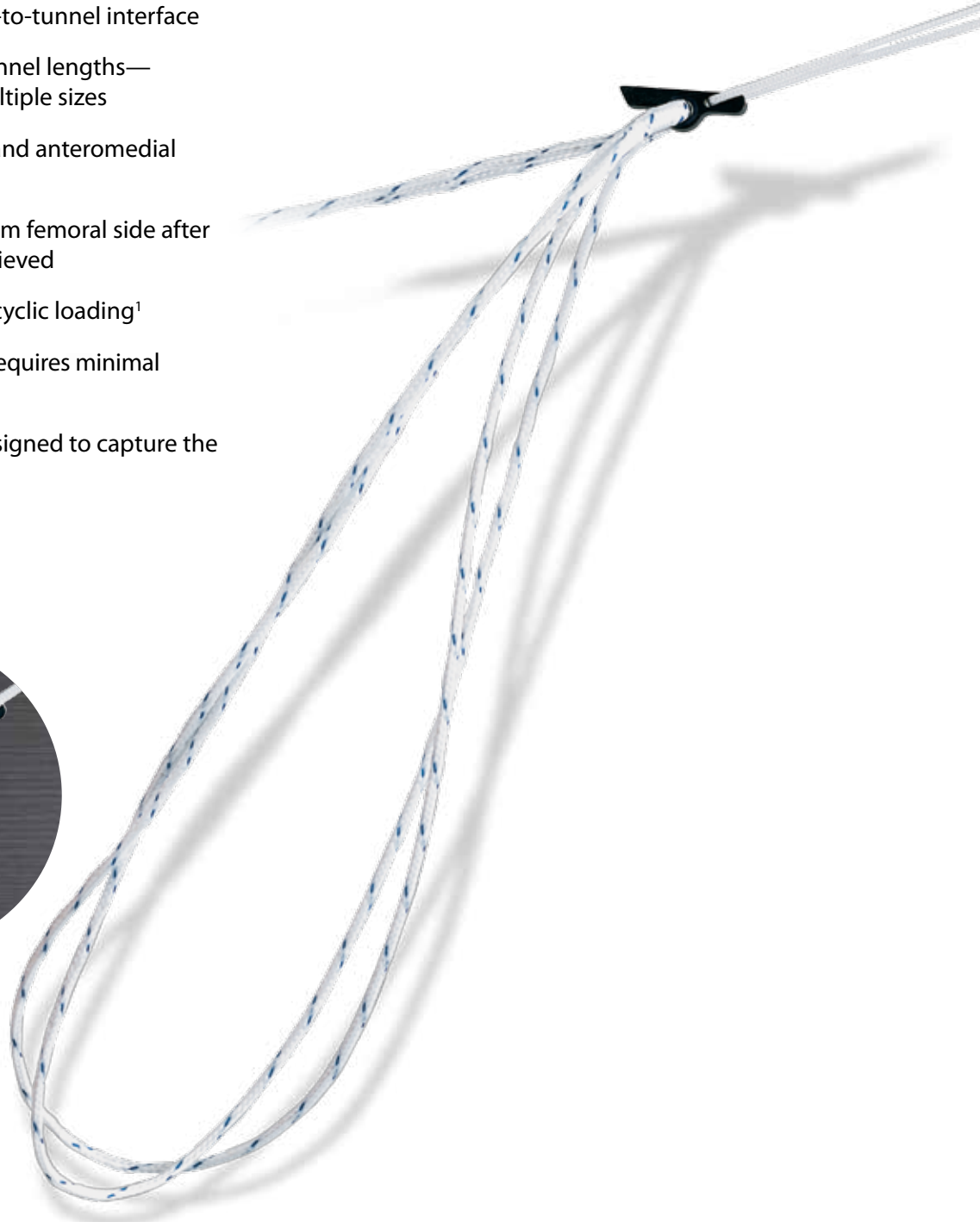


# ToggleLoc™

FIXATION DEVICE

## Benefits

- Maximizes soft tissue graft-to-tunnel interface
- One implant for varying tunnel lengths—eliminates the need for multiple sizes
- For use in both transtibial and anteromedial portal ACL reconstruction
- Tension may be applied from femoral side after tibial fixation has been achieved
- Virtually no slippage after cyclic loading<sup>1</sup>
- Simple surgical technique requires minimal instrumentation
- Femoral fixation device designed to capture the cortical bone of the femur



## Surgical Technique

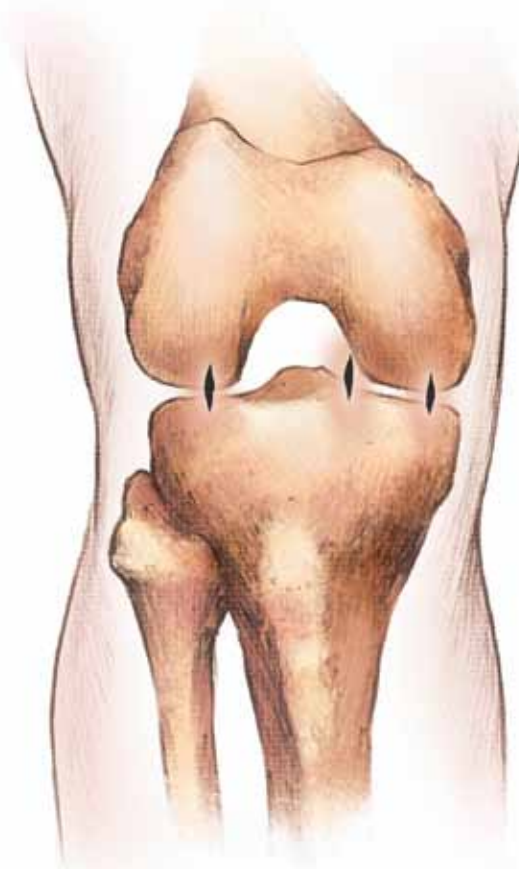


Figure 1

### Portal Position and Sizing of Grafts

Create medial and lateral arthroscopic portals immediately adjacent to the edge of the patella tendon just distal to the inferior pole of the patella. The use of an accessory medial portal is recommended for preparation of both the AM and PL femoral tunnels (Figure 1). Next, size the grafts. The two femoral grafts should be sized individually. Typically, the AM bundle is 7–8mm in diameter, while the PL bundle is 6–7mm. The AM and PL grafts should then be sized together to determine the tibial tunnel diameter.

This brochure is presented to demonstrate the surgical technique 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.

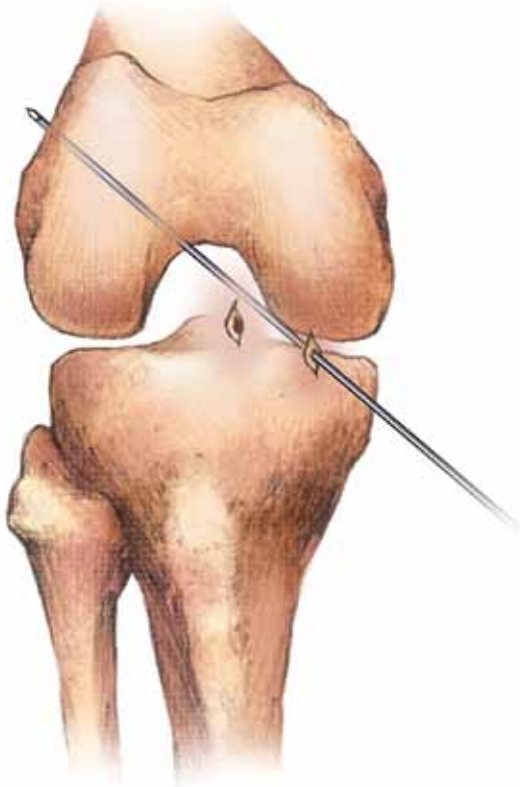


Figure 2

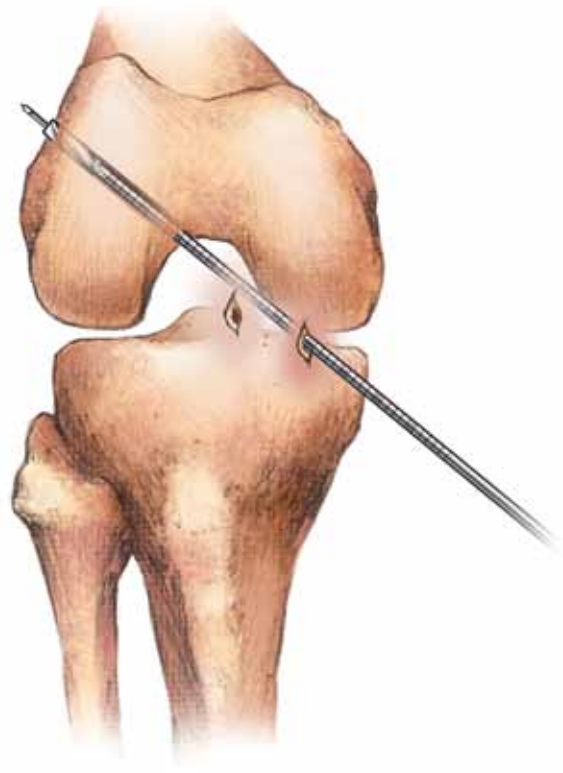


Figure 3

### AM Femoral Tunnel Preparation

Clean the posterior lateral femoral condyle by removing the stump using a shaver or electrocautery. Debride any remaining soft tissue from the over-the-top position using a cupped curette.

Position the knee at 90 degrees of flexion. Place the arthroscope in the medial portal and identify the center of the AM bundle insertion point on the lateral wall of the femur. Create a pilot hole for the femoral guidepin with a microfracture pick or similar instrument via the accessory medial portal.

The knee is then hyperflexed and using either freehand technique or a drill guide, drill a calibrated guide wire through the lateral cortex. Check that the guidewire is placed in the 10:00 position for a left knee and a 2:00 position for a right knee (Figure 2).

Drill over the previously placed guide wire with the 4.5mm ToggleLoc™ drill bit through the lateral cortex of the femur (Figure 3).

## Surgical Technique (continued)

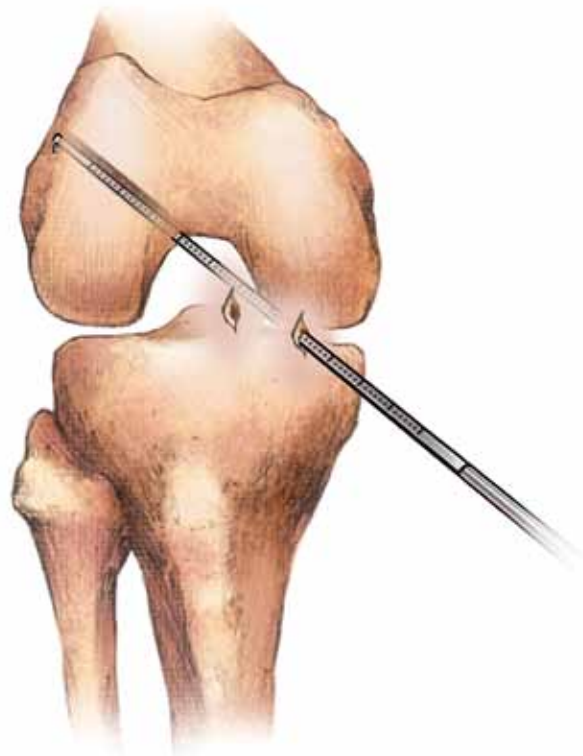


Figure 4



Figure 5

### AM Femoral Tunnel Preparation (continued)

Pass the 4.5mm drill in and out of the cortex two to three times to facilitate passage of the implant. Remove the guidepin and measure the overall length of the AM Tunnel using a depth probe (Figure 4). Insert the guidepin back into the AM tunnel through the accessory medial portal. Drill over the guide wire with an endoscopic reamer corresponding to the diameter of the graft and ream to the depth that will allow the desired soft-tissue graft-to-tunnel interface (Figure 5). Make sure the endoscopic reamer does not break the lateral cortex.

**Note: When the knee is hyperflexed, outflow will dramatically increase causing poor visualization. To address this problem, put an open mouthed shaver in the lateral portal and use as suction.**



Figure 6

### PL Femoral Tunnel Preparation

Flex the knee to 90 degrees. Position a PL Tunnel Femoral Aimer into the appropriate position on the lateral wall of the femur, utilizing the accessory anteromedial portal (Figure 6). The position is identified under direct visualization, ensuring that a 2–4 mm bone bridge is visible between the AM and PL tunnels (Figure 7). The area of the PL tunnel should be just above the apex of the curve of the lateral condyle with the knee flexed at 90 degrees.

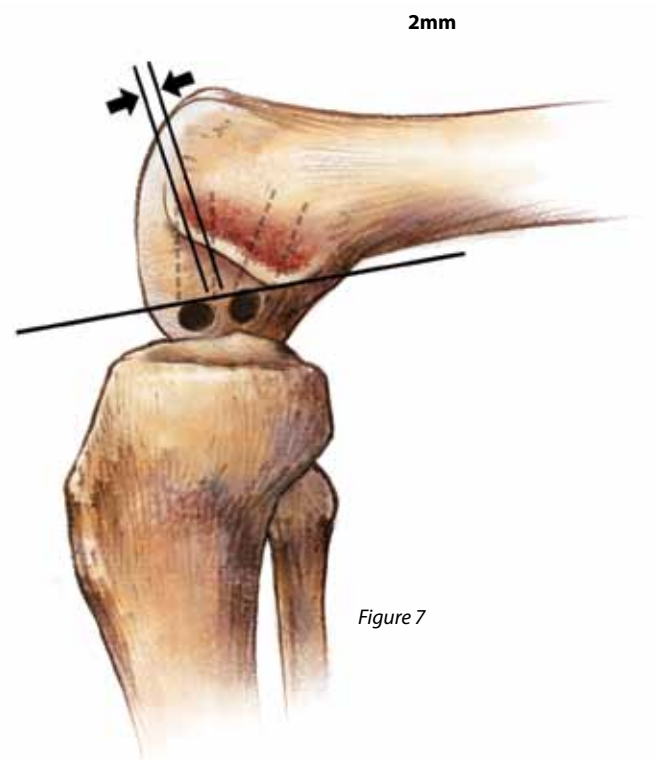


Figure 7

## Surgical Technique *(continued)*



Figure 8

### **PL Femoral Tunnel Preparation** *(continued)*

With the knee hyperflexed, drill a calibrated guide wire through the Femoral Aimer and the lateral cortex of the femur (Figure 8). Drill over the previously placed guide wire with the 4.5mm ToggleLoc™ drill bit through the lateral cortex of the femur. Pass the 4.5mm drill in and out of the cortex two to three times to facilitate passage of the implant. Remove the guidepin and measure the overall length of the PL tunnel using a depth probe. The PL tunnel is typically shorter than the AM tunnel, approximately 20–30mm in length.



Figure 9

Insert the guidepin back into the PL tunnel. Drill over the guide wire with an endoscopic reamer corresponding to the diameter of the graft and ream to the depth that will allow the desired soft-tissue graft-to-tunnel interface (Figure 9). Make sure the endoscopic reamer does not break the lateral cortex.



Figure 10

### **Tibial Tunnel Preparation**

Utilizing a tibial guide that allows for optimal tunnel placement, position the tibial guide appropriately and drill the guide wire. Determine the appropriate tunnel diameter based on the diameter of the AM and PL grafts. A tibial tunnel with a diameter of at least 9mm is typical. Once the appropriate diameter has been established, ream over the guide wire with the corresponding reamer (Figure 10). If using a WasherLoc™ device for tibial fixation, prepare the counterbore at this time.

## Surgical Technique (continued)

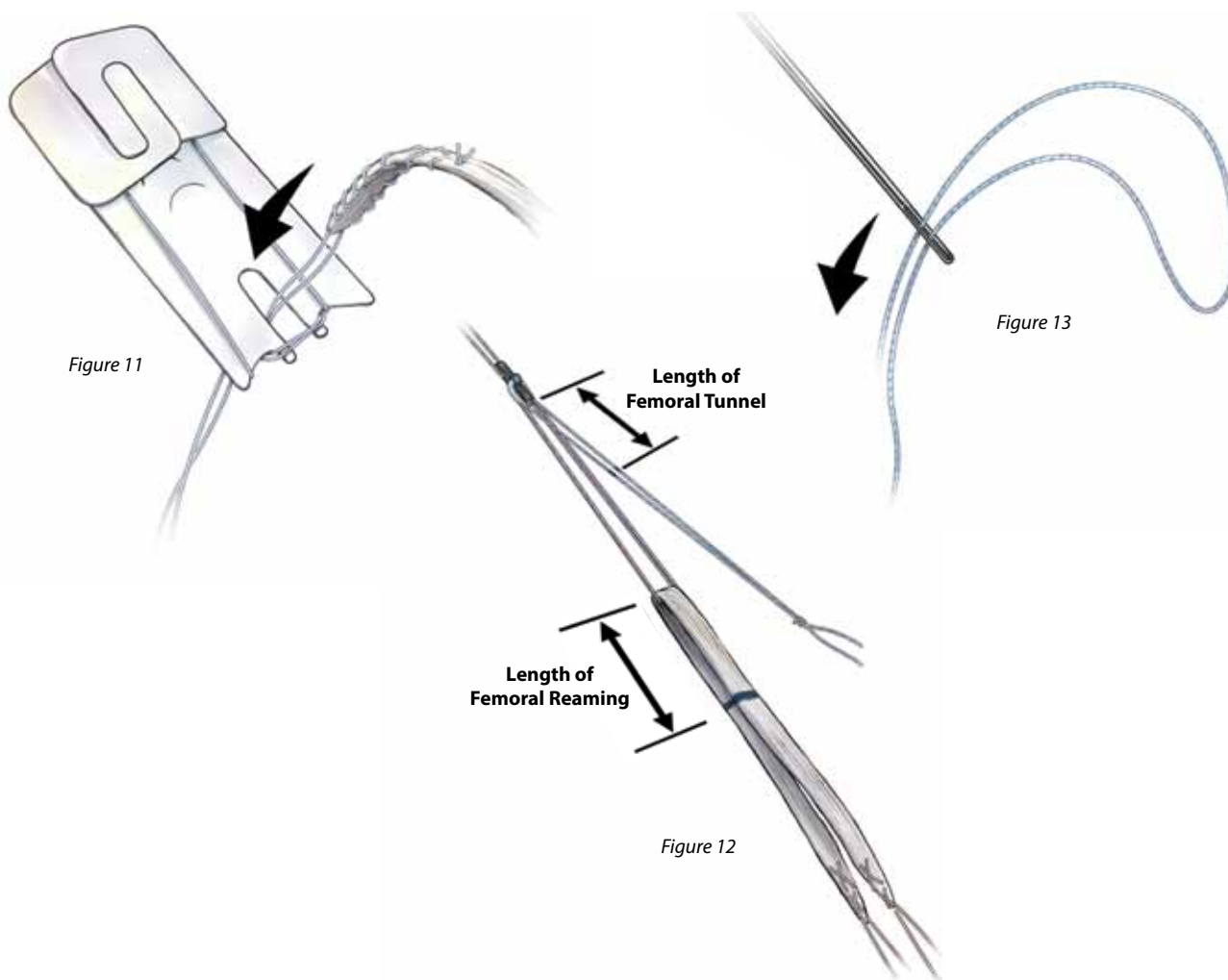


Figure 11

Figure 13

Figure 12

### Prepare ToggleLoc™ Device

Pass the soft tissue graft for the AM tunnel through both loops of the ToggleLoc™ Femoral Fixation Device with ZipLoop™ Technology (Figure 11). The implant should be left in the white cardboard packaging. This will facilitate passing the soft tissue graft through the correct loops. Place the graft through the hole in the package. Balance the soft tissue grafts in the loops of the implant to allow equal amounts of the soft tissue on either side of the loop.

Use the measurement previously obtained with the ToggleLoc™ depth gauge to mark the zip strands of the implant to ensure deployment on the lateral cortex. Measure from the distal end of the ToggleLoc™ device toward the graft and mark the length with a surgical

marker (Figure 12). Make a second mark on the graft by measuring the depth of the “graft tunnel.” **The mark must be 5mm less than the length of the graft tunnel for the AM soft tissue graft.** For example, if the graft tunnel is 25mm, the graft should be marked 20mm from the top of the graft loop. This mark will aid in optimal graft positioning later in the procedure. **Repeat this process with the PL soft tissue graft, however mark the PL soft tissue graft the same length as the graft tunnel.** For example, if the graft tunnel is 25mm, the graft should be marked at 25mm from the top of the graft loop.

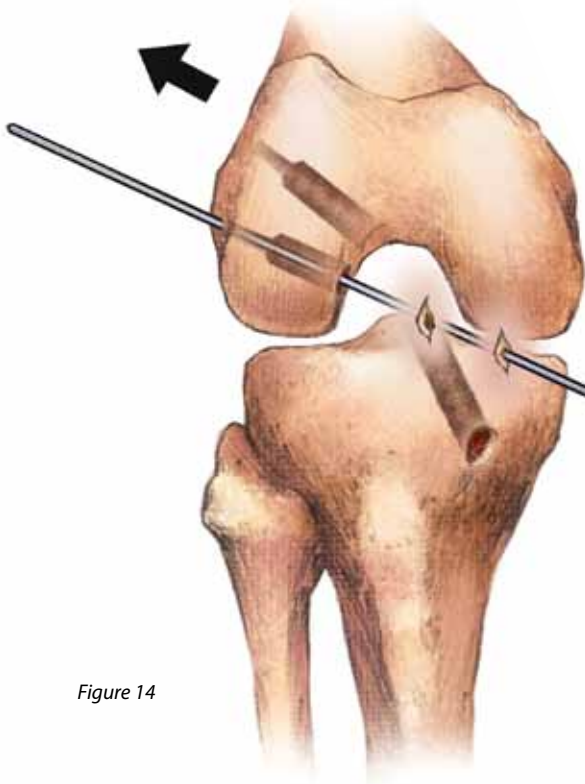


Figure 14

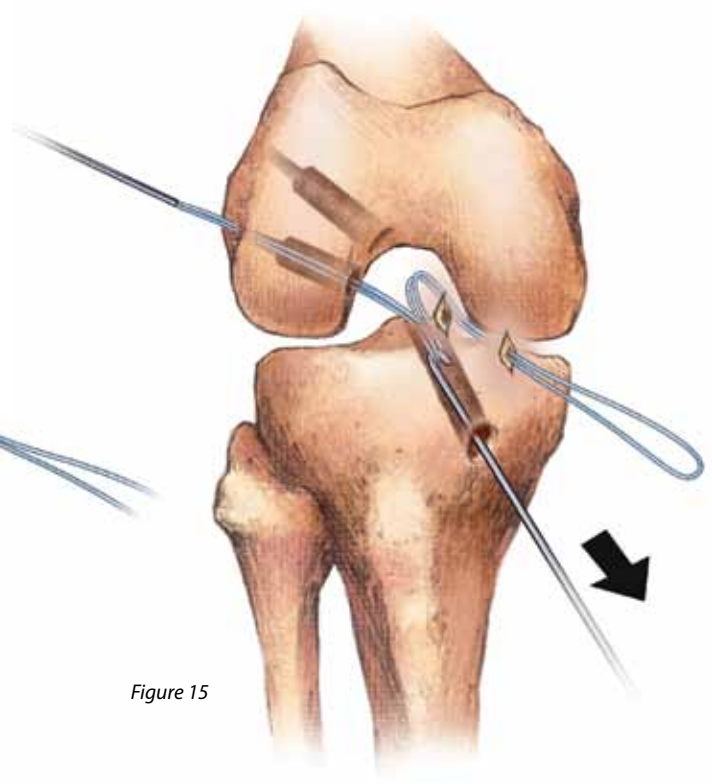


Figure 15

### Passing the ToggleLoc™ Device

Thread a strand of relay suture through the eyelet of the graft passing pin so that the suture forms a continuous loop (Figure 13). Hyperflex the knee and pass the guidepin through the PL femoral tunnel and pull proximally on the guide wire to pull the relay suture through the skin (Figure 14). Use a suture grasper or crochet hook to retrieve the relay suture through the tibial tunnel (Figure 15).

Loop the implant passing suture (white #2 suture pre-loaded into the titanium button) of the ToggleLoc™ Femoral Fixation Device with ZipLoop™ Technology through the relay loop corresponding to the PL soft tissue graft, which should be exiting the tibial tunnel. Pull proximally on the relay suture to pull the passing suture through the tibial tunnel, joint space and femoral tunnel, exiting through the skin (Figure 16).

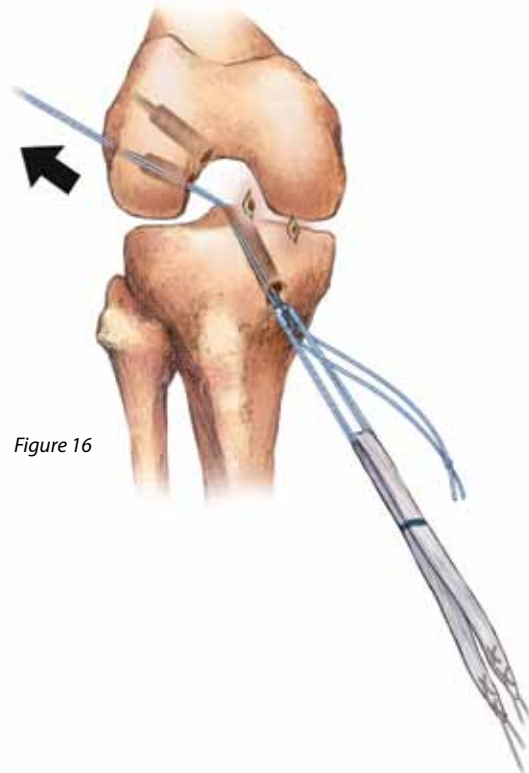


Figure 16

## Surgical Technique (continued)

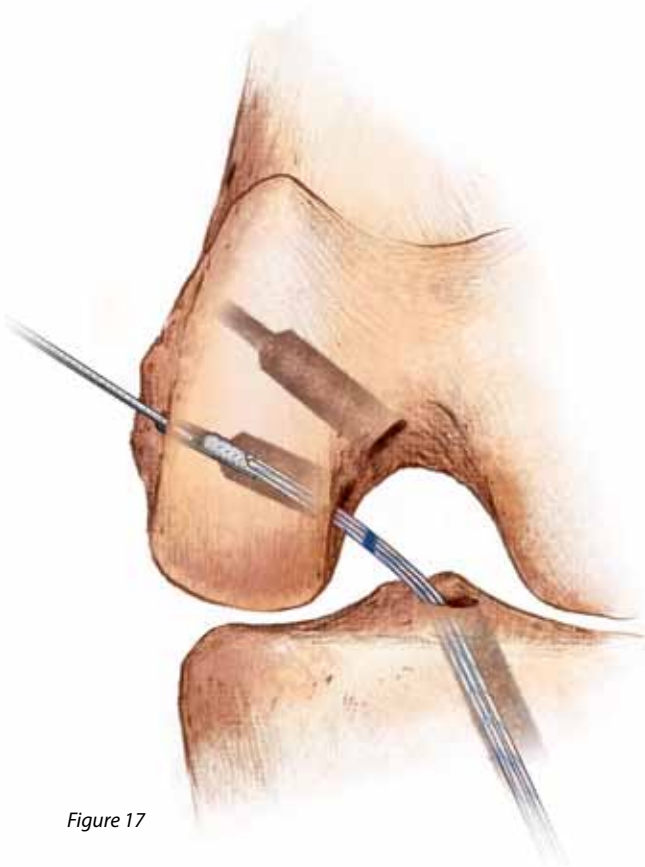


Figure 17

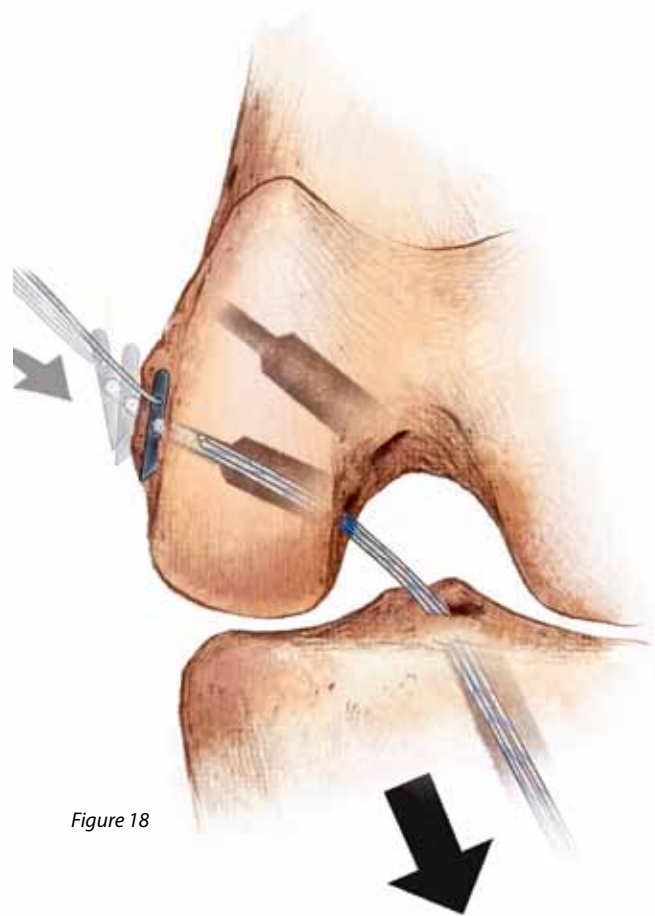


Figure 18

### Passing the ToggleLoc™ Device (continued)

Pass the PL soft tissue graft. Prior to passing, ensure that the ToggleLoc™ Femoral Fixation Device with ZipLoop™ Technology is oriented laterally, as it will deploy on the femur's lateral cortex. The "zip suture" should be on the anterior side of the soft-tissue graft prior to graft placement within the femoral tunnel. Pull the passing suture proximally until the mark on the loops of the ToggleLoc™ device reach the entrance of the femoral tunnel.

Position the implant just beyond the lateral cortex of the femur (Figure 17). Pull on the distal end of the soft tissue grafts to feel the implant engage on the lateral femoral cortex, achieving femoral fixation (Figure 18).

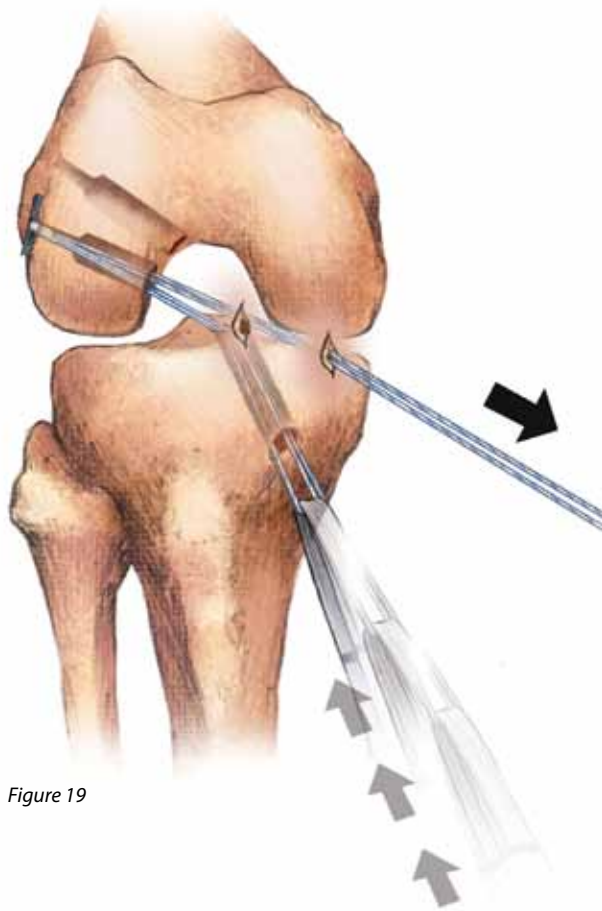


Figure 19

Retrieve the zip suture from the joint through the medial portal using a suture grasping device (Figure 19). Place the knot of the zip strand into the ZipLoop™ puller and pull distally to draw the graft through the PL tibial tunnel and into the PL femoral tunnel. This will shorten the loop of the ToggleLoc™ Femoral Fixation Device with ZipLoop™ Technology and accurately position the soft-tissue graft in the femoral tunnel (Figure 20).

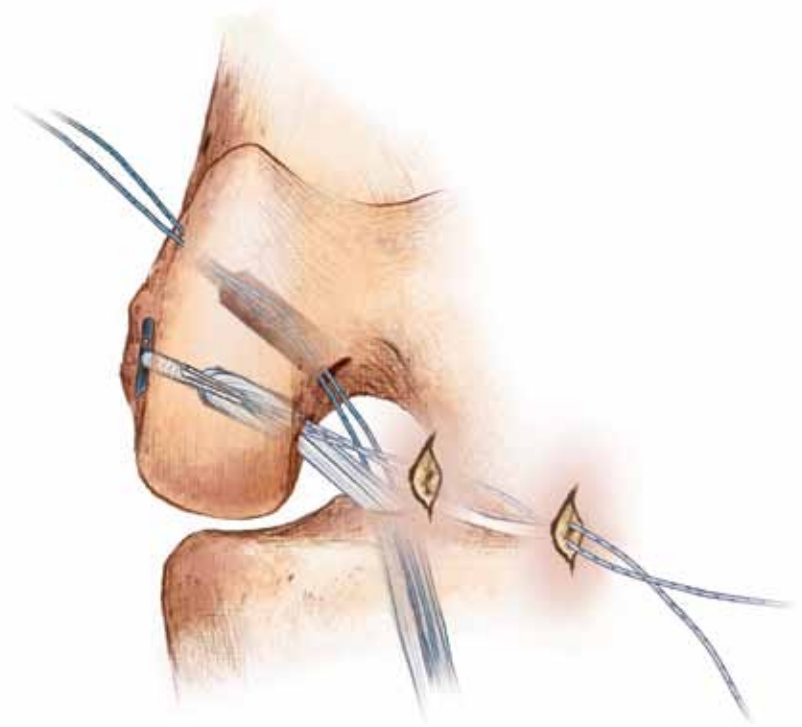


Figure 20

Correct placement is indicated when the mark on the graft enters the femoral tunnel. Sever the zip suture with the MaxCutter™ Suture Cutter. Repeat this process for the AM soft tissue graft. Tension should be applied to the PL bundle when zipping the AM tunnel to ensure the PL bundle does not bunch in the tibial tunnel. Make sure the AM soft tissue graft is zipped only to the point where the mark on the graft enters the femoral tunnel, so that after tibial fixation it can be zipped further.

## Surgical Technique (continued)

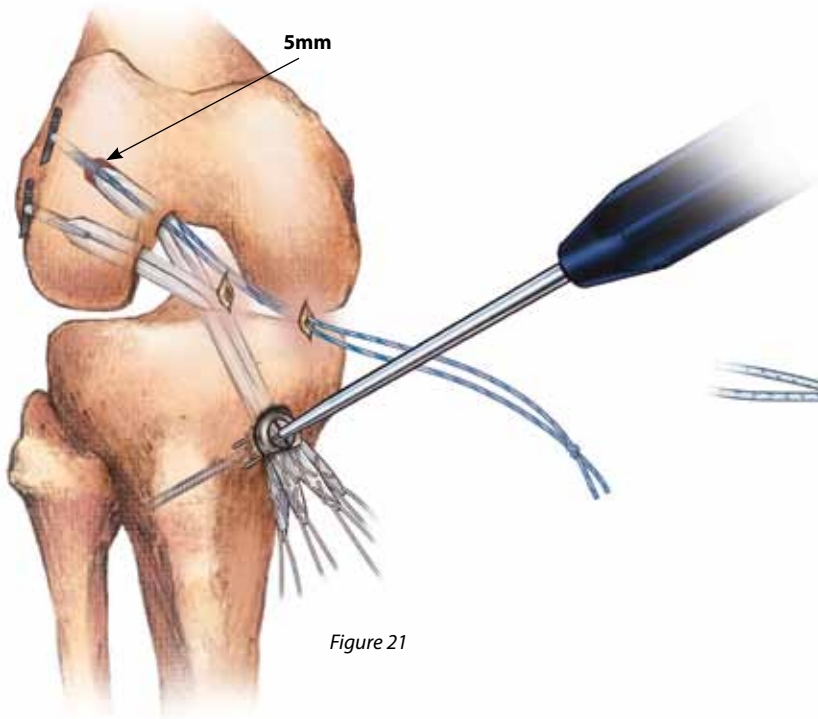


Figure 21

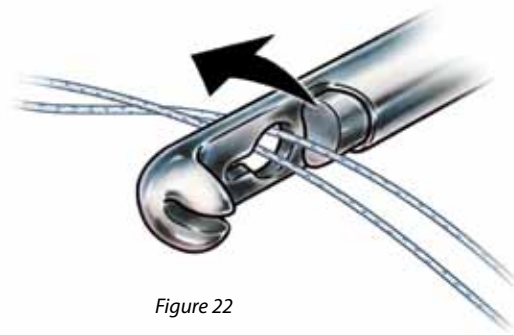


Figure 22

### Complete ACL Double Bundle Graft Fixation

Tension both the AM and PL soft tissue grafts in full extension and fixate with the selected tibial fixation device. Flex the knee to 45 degrees and pull the limbs of the zip strand for the AM bundle until the desired tension of the AM bundle is met (Figure 21).

Pass the limbs of the zip strand for the AM bundle through the key shaped hole in the Super MaxCutter™ instrument (Figure 22). Advance the Super MaxCutter™ through the medial portal and cut the suture at the entrance of the femoral tunnel in the joint space. Repeat this process for the PL bundle. Reconstruction of the grafts is now complete (Figure 23).

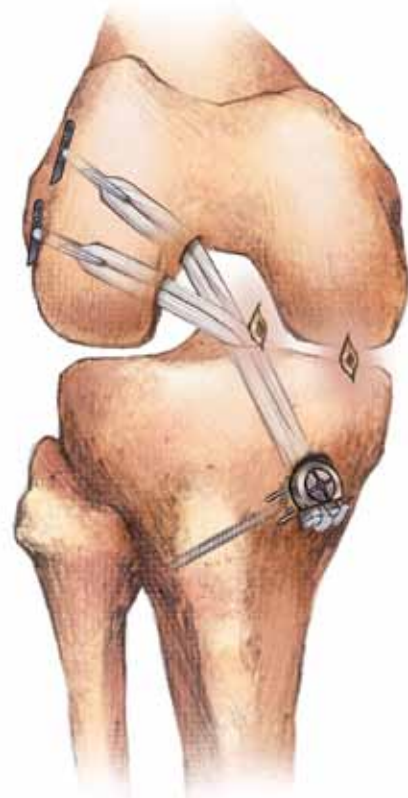


Figure 23

# 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  
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

##### 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

# Ordering Information

<b>ToggleLoc™ Fixation Device with ZipLoop™ Technology 50"</b>
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<b>904754</b>
---------------

## Double Bundle Femoral Aimer

**909753** 5mm  
**909754** 6mm  
**909747** 7mm  
**909748** 8mm  
**909749** 9mm

## Medial Portal Femoral Aimer

**909590** 6mm  
**909591** 7mm  
**909592** 8mm  
**909593** 9mm  
**909594** 10mm

## 4.5mm Drill Bit

**904760** Disposable  
**904765** Reusable

## ToggleLoc™ Depth Gauge

**904766**

## 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**

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

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.™**

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