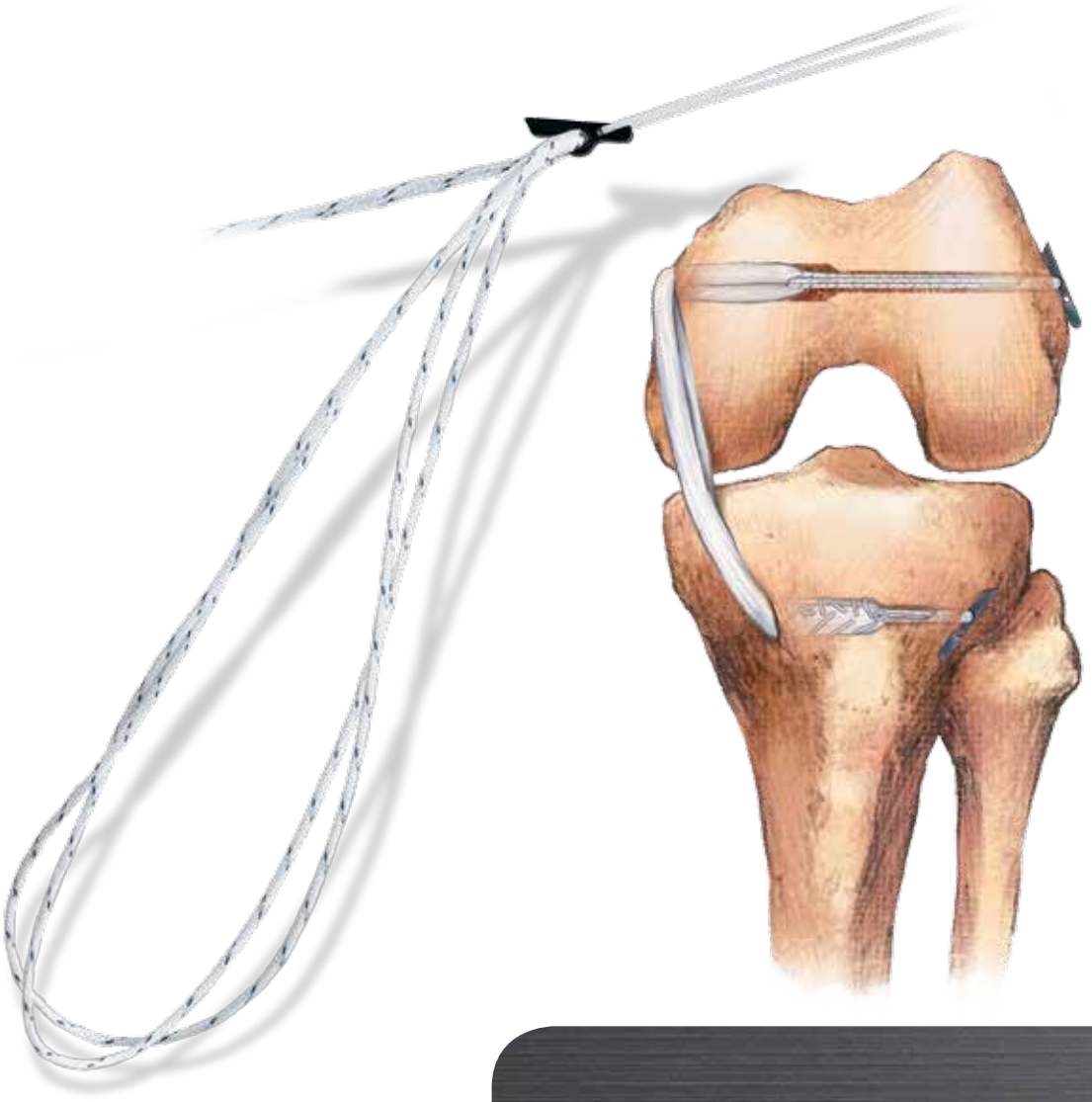
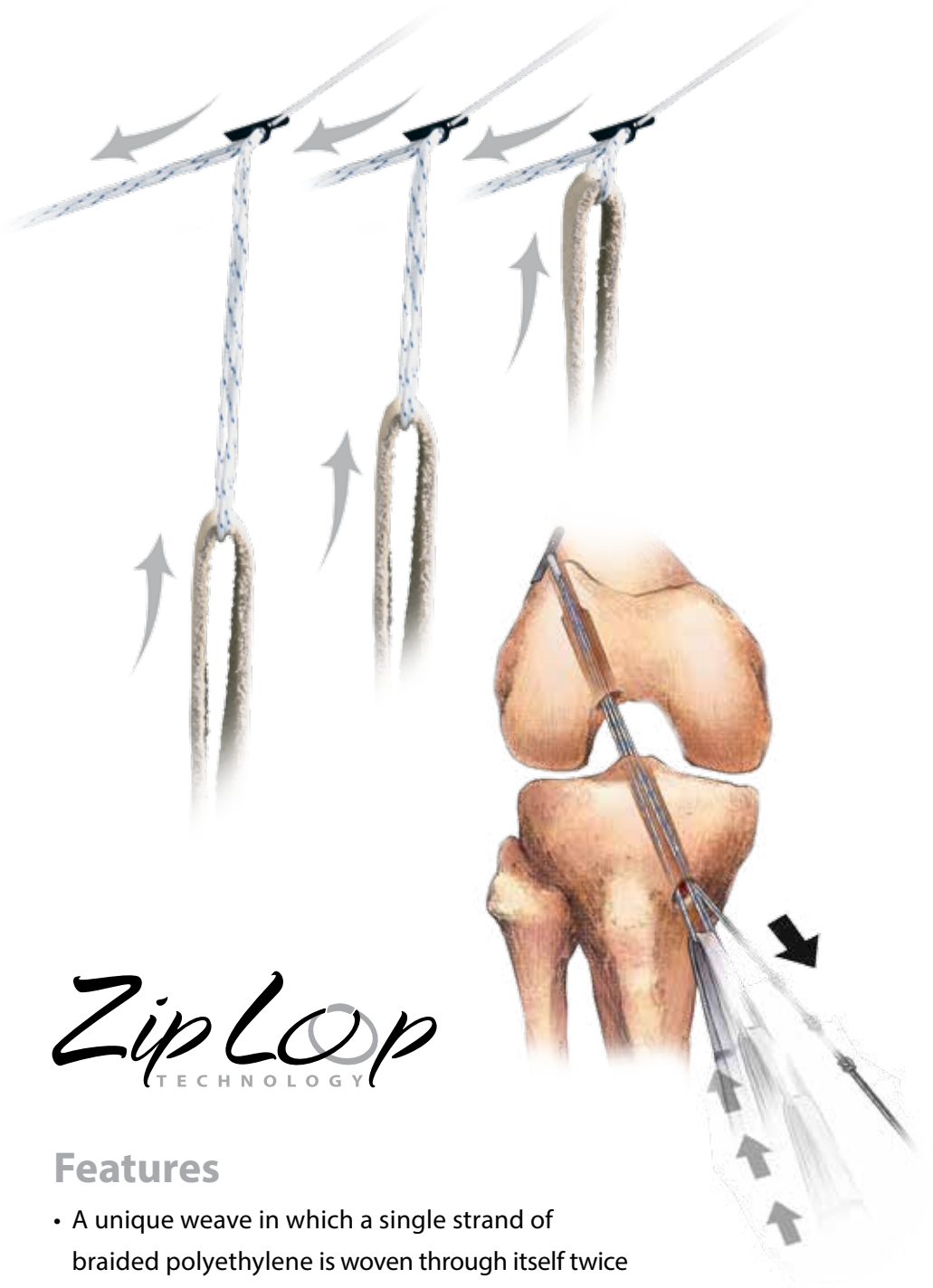
ToggleLoc
FIXATION DEVICE



MCL Reconstruction
Surgical Protocol by
Tarek Fahl, M.D.

BIOMET



ZipLoop TECHNOLOGY

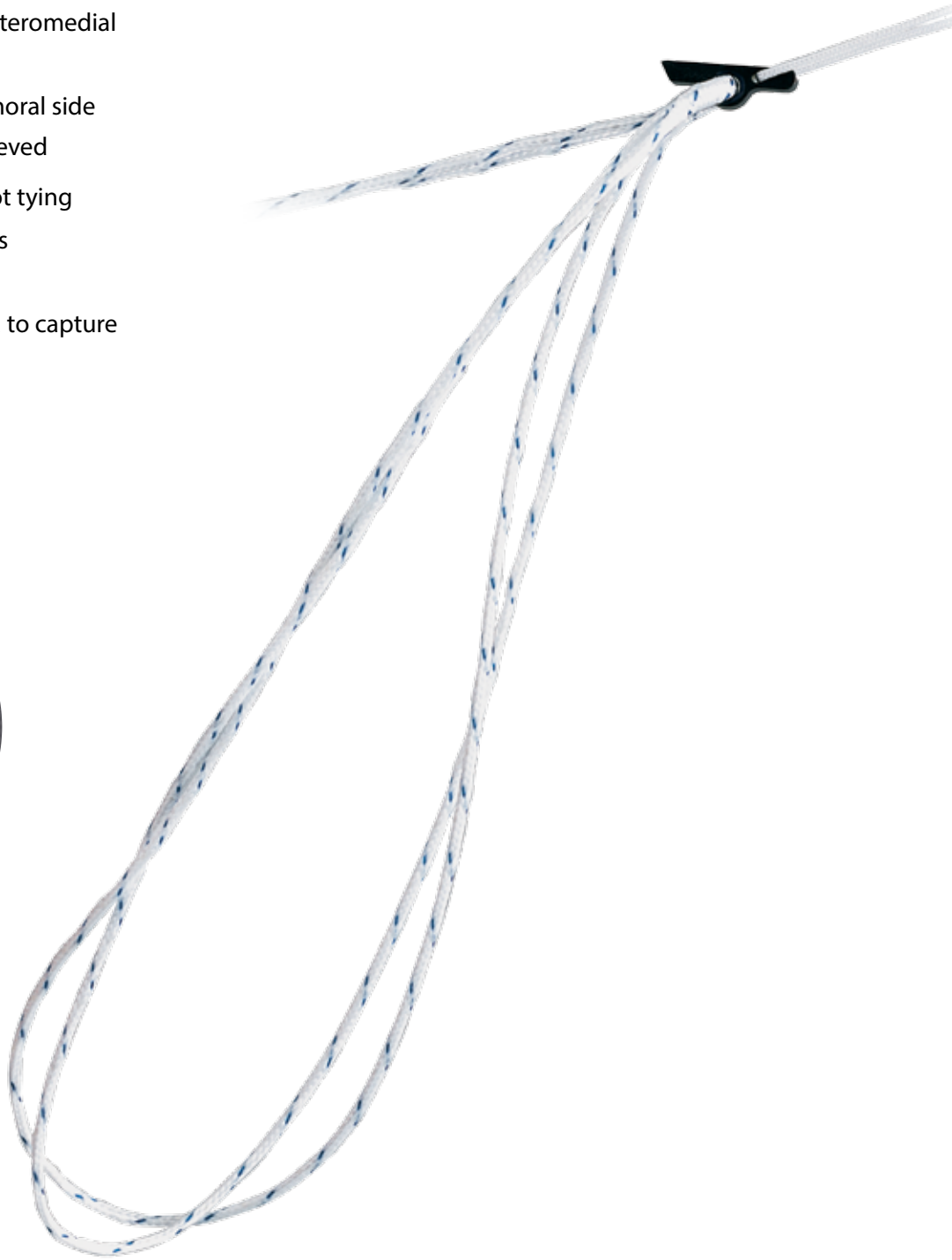
Features

- 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

Features

- 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
- Resistant to slippage with no knot tying
- Simple surgical technique requires minimal instrumentation
- Femoral fixation device designed to capture the cortical bone of the femur



Surgical Technique

Figure 1

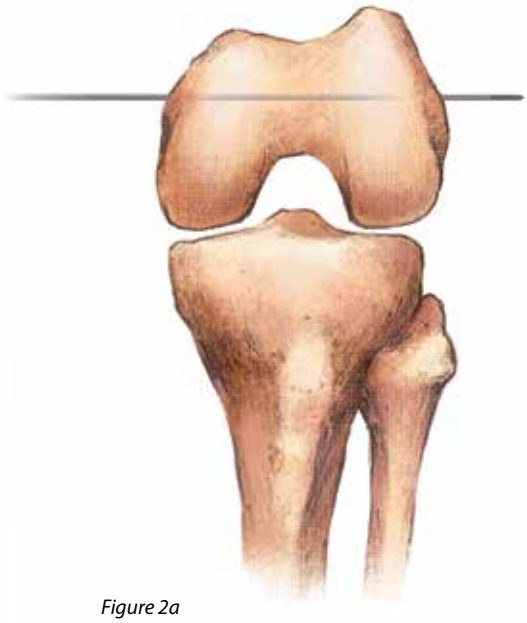


Figure 2a

Femoral Tunnel Preparation

A medial incision is made to expose the tibial and femoral footprints of the superficial medial collateral ligament (Figure 1).

The footprint of the superficial MCL origin is 3.2mm proximal and 4.8mm posterior to the medial epicondyle of the femur and inserts just anterior to the posteromedial crest of the tibia just beneath the pes anserinus.

A guidepin is drilled through the medial femoral epicondyle in a superior-lateral direction exiting just superior to the lateral femoral condyles (Figures 2a & 2b). Drilling in this direction will help to ensure that the ToggeLoc is not palpable underneath the skin.

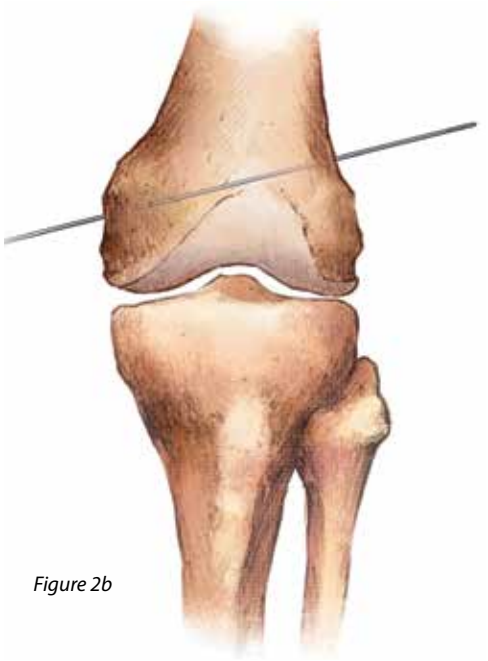


Figure 2b

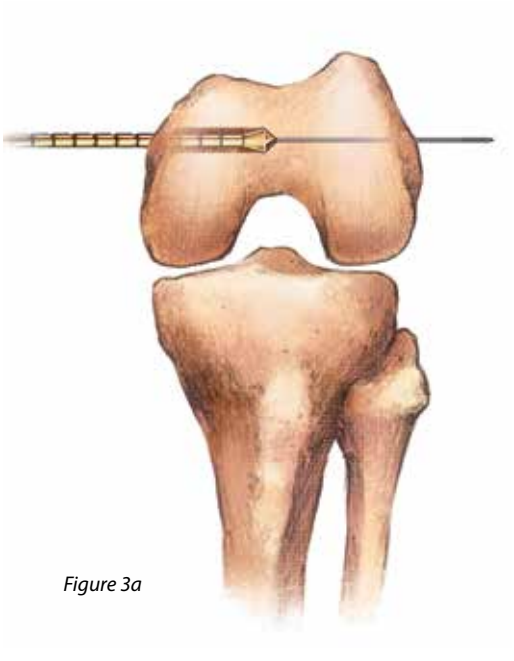


Figure 3a

A size appropriate acorn reamer is used to ream the femoral tunnel approximately 30mm. A 4.5mm reamer should then be used to break the cortex on the lateral side of the femur (Figures 3a & 3b).

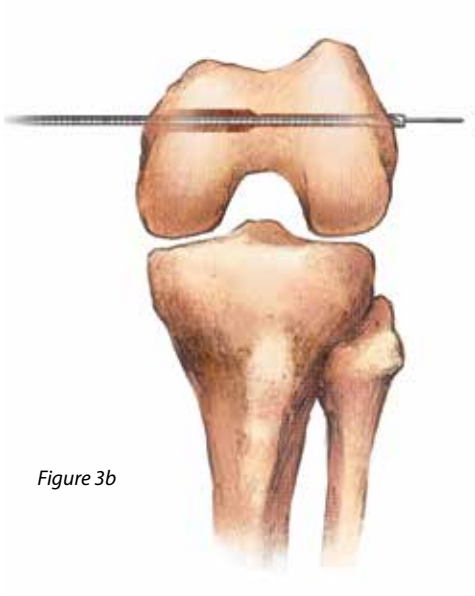


Figure 3b

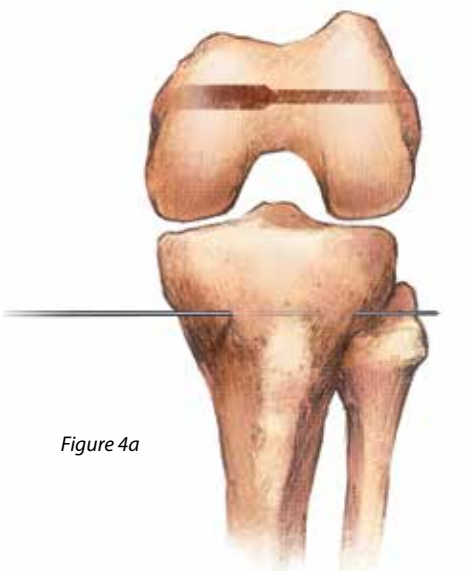


Figure 4a

Figure 4b

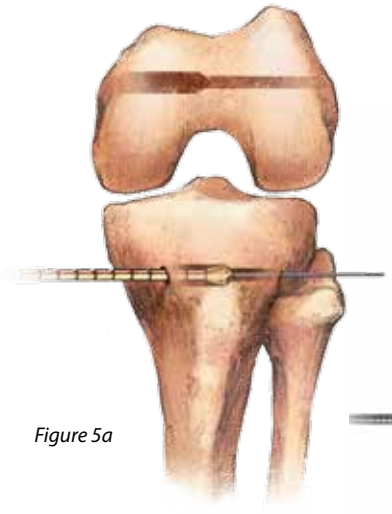


Figure 5a

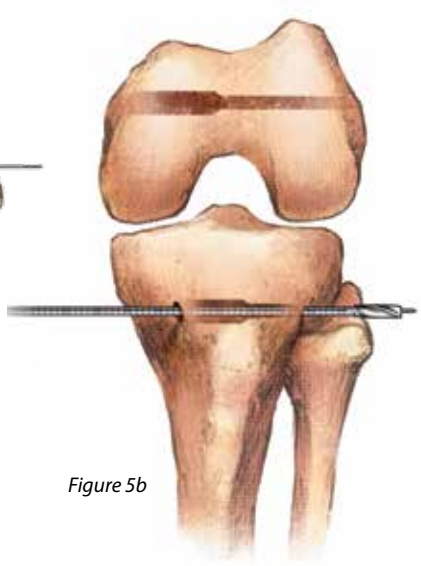


Figure 5b

Tibial Tunnel Preparation

Drill a 2.4mm guidepin through the tibial footprint of the superficial MCL, breaking the cortex on the lateral side of the tibia (Figures 4a & 4b). Ensure that this guidepin is lateral enough in order to avoid the tibial tuberosity. Drilling in this direction will help to ensure that the ToggeLoc Device is not palpable underneath the skin. Also, it is important to assure that the tibial tunnel is not drilled too far distally since it may cause injury to the anterior tibial artery or deep peroneal nerve as they pass anterior to the interasseous membrane between the tibia and fibula.

Finish preparing the tibial tunnel by drilling a 30mm tunnel with the same acorn reamer used for the femur and breaching the cortex with a 4.5mm reamer (Figures 5a & 5b).

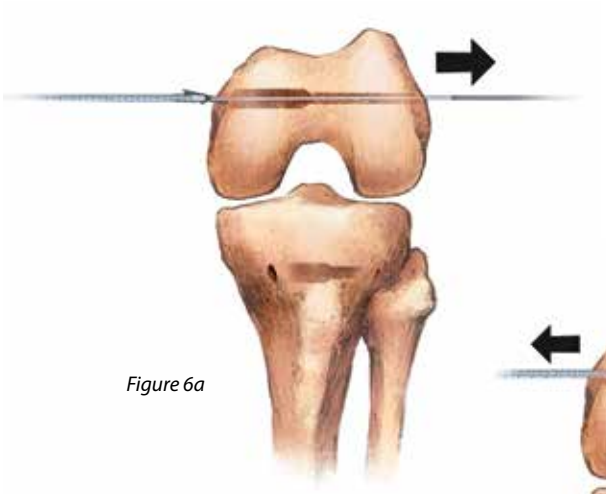


Figure 6a

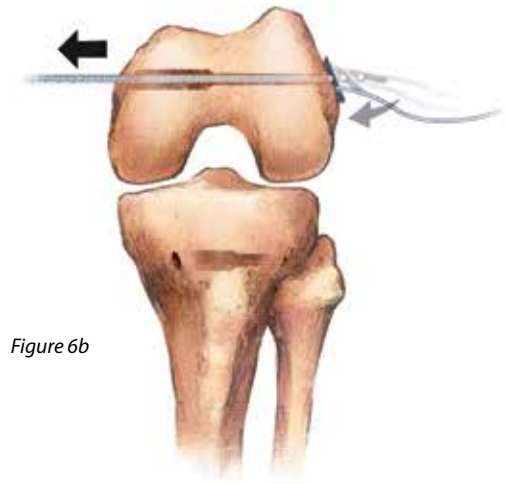


Figure 6b

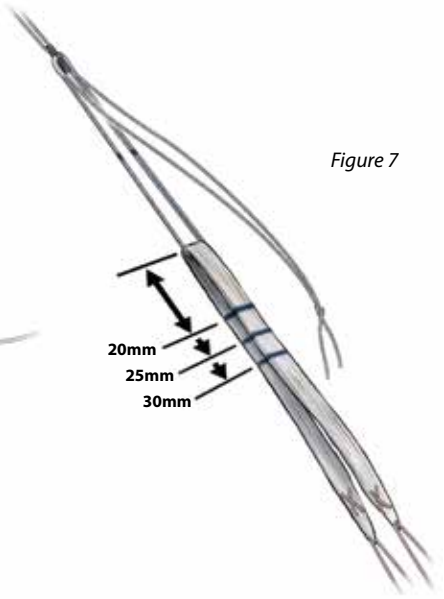


Figure 7

Prepare and Pass the ToggleLoc Fixation Device with ZipLoop into the Femur

Load the graft onto the ToggleLoc Fixation Device with ZipLoop Technology. Using a Beath pin and the ToggleLoc Device pull sutures, the ToggleLoc Device is passed and then flipped on the lateral femoral cortex (Figures 6a & 6b).

The graft can be marked with a marking pen at 20, 25 and 30mm away from the proximal end to help track the amount of graft that will be introduced into the femoral tunnel (Figure 7).

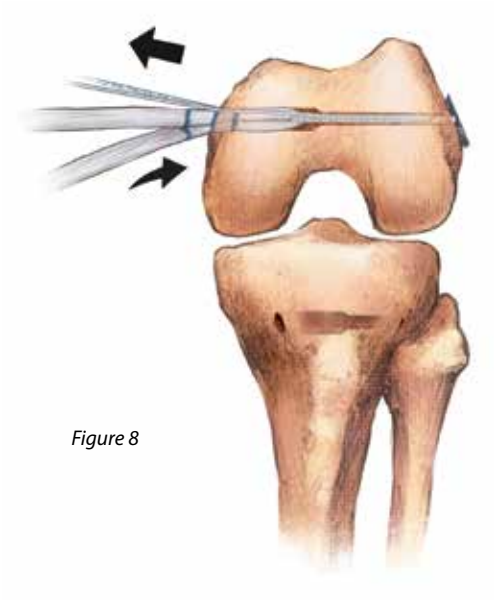


Figure 8

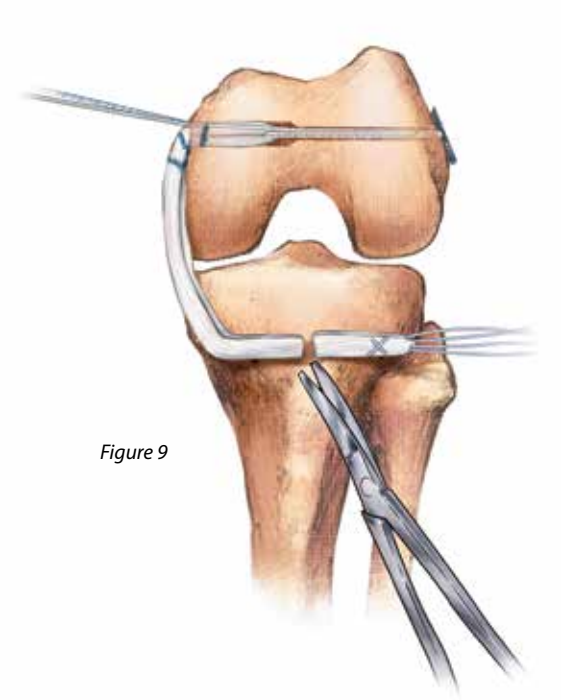


Figure 9

The zip strand of the ToggleLoc device is then pulled to introduce the proximal end of the graft into the tunnel. It is recommended to stop advancing the graft into the femoral tunnel once the 25mm mark meets the proximal cortex. This will allow further tensioning after tibial fixation. (Figure 8).

Prepare and Pass the ToggleLoc Fixation Device with ZipLoop Technology into the Tibia

The graft limbs are remeasured from the point of insertion into the medial tibial tunnel and trialed with varying amounts of length. New sutures are placed in the two free limbs for a distance that is slightly less than the length of the acorn reamed tibial tunnel. The remaining excess graft and initial tension stitches are cut away (Figure 9).

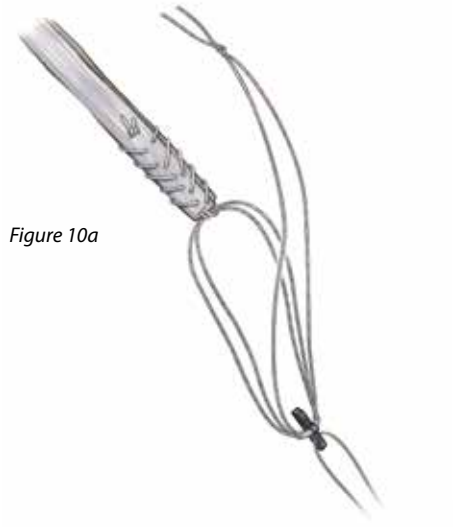


Figure 10a

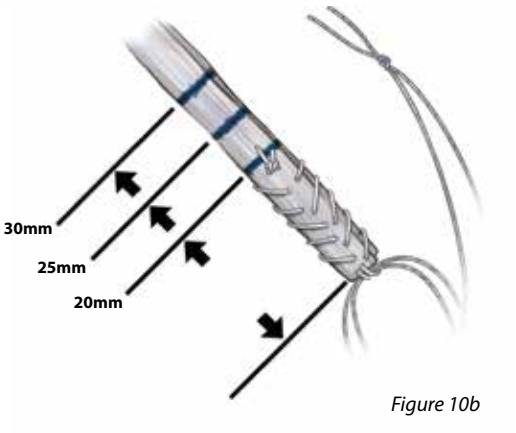


Figure 10b

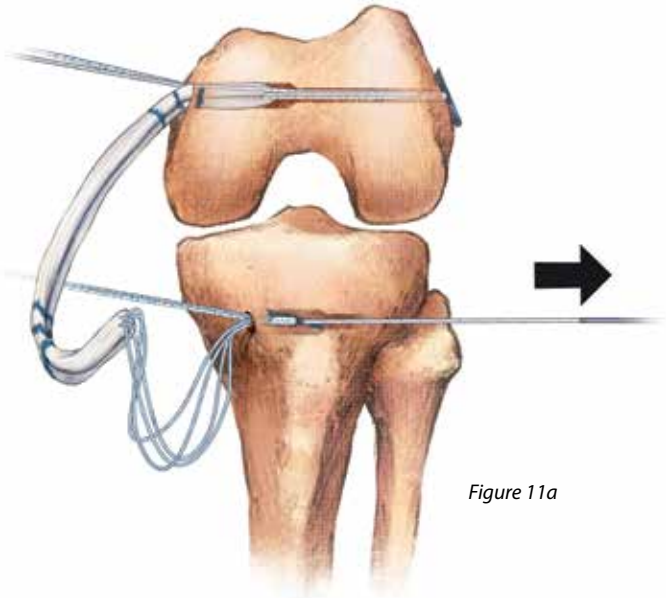


Figure 11a

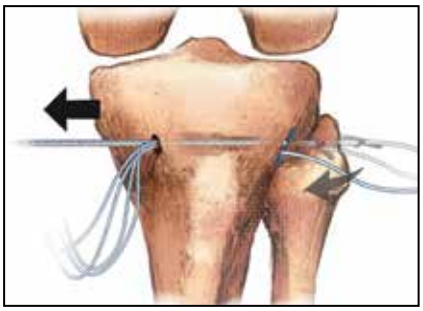


Figure 11b

The two stitches from the free limbs are tied to a second ToggleLoc device. The graft can be marked with a marking pen at 20, 25 and 30mm away from the proximal end to help track the amount of graft that will be introduced into the tibial tunnel. (Figures 10a & 10b).

The ToggleLoc device is passed and then flipped on the lateral tibial cortex (Figures 11a & 11b).

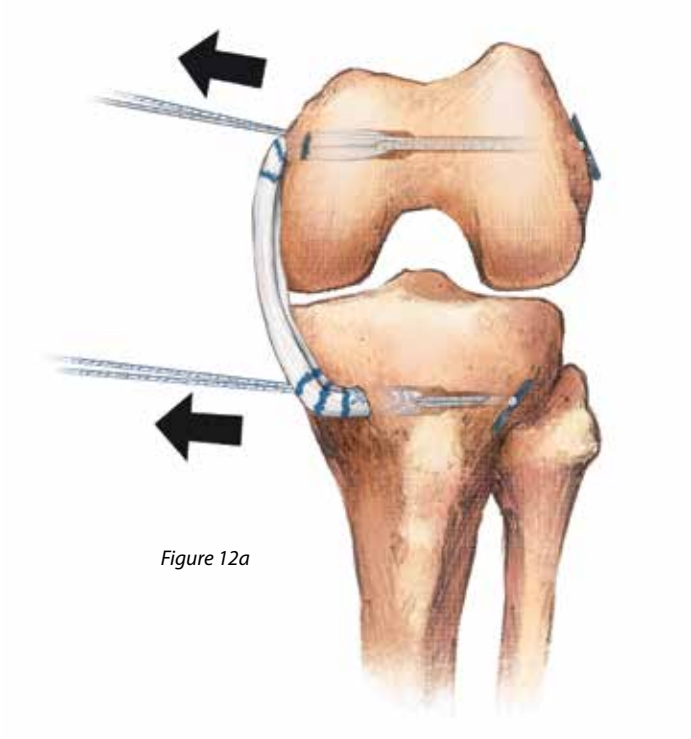


Figure 12a

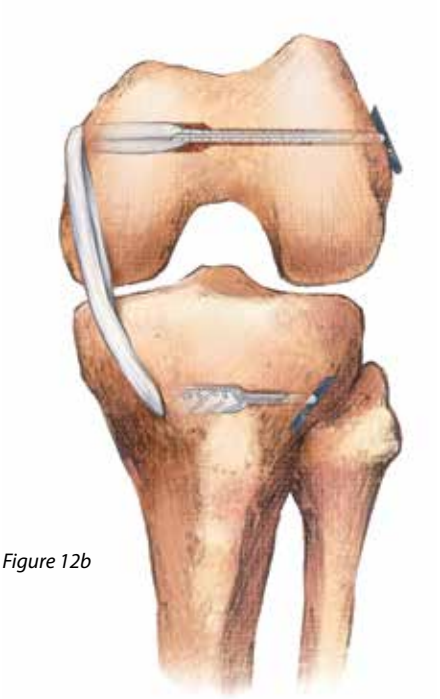


Figure 12b

The zip strands of the ToggleLoc device are then pulled to introduce the free limbs of graft into the tibial tunnel. If the 30mm mark enters the tibial tunnel and the graft is not tensioned appropriately, the femoral zip strand can be pulled until adequate tension is achieved (Figures 12a & 12b).

Ordering Information

ToggleLoc Femoral Fixation Device with ZipLoop Technology
904755

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

Super MaxCutter Suture Cutter

900342

INDICATIONS FOR USE
The ToggleLoc System devices, except the ToggleLoc XL device, 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/ZipTight Fixation Devices)

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
Illiotibial 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

The ToggleLoc XL device is used for fixation of tendons and ligaments in cases of unanticipated intraoperative complications such as cortical breaching during orthopedic reconstruction procedures, such as Anterior Cruciate (ACL) or Posterior Cruciate (PCL) Reconstruction.

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.

Check for country product clearances and reference product specific instructions for use. For complete product information, including indications, contraindications, warnings, precautions, and potential adverse effects, see the package insert and Biomet's website.

This technique was prepared in conjunction with a licensed health care professional. Biomet does not practice medicine and does not recommend any particular orthopedic implant or surgical technique for use on a specific patient. The surgeon is responsible for determining the appropriate device(s) and technique(s) for each individual patient.

Not for distribution in France.

BIOMET
SPORTS MEDICINE
One Surgeon. One Patient.

Legal Manufacturer
Biomet Sports Medicine
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581
USA

Authorised Representative
Biomet UK Ltd.
Waterton Industrial Estate
Bridgend, South Wales
CF31 3XA
UK

www.biomet.com

CE 0086