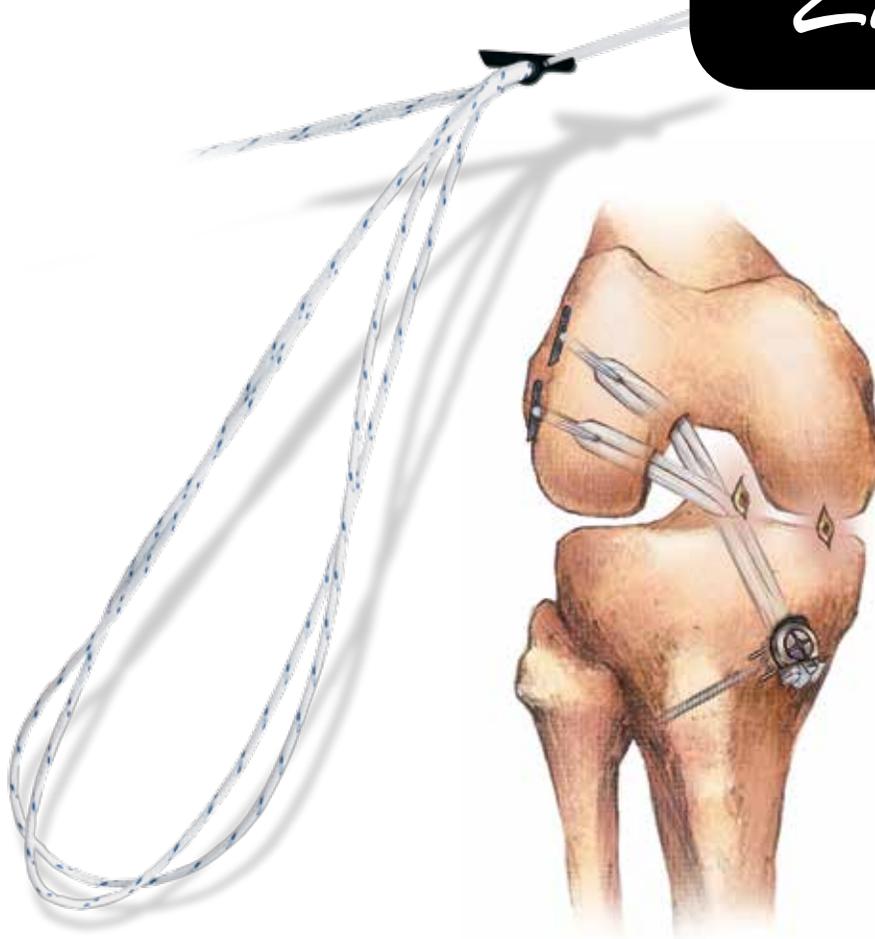


ToggleLoc
FIXATION DEVICE

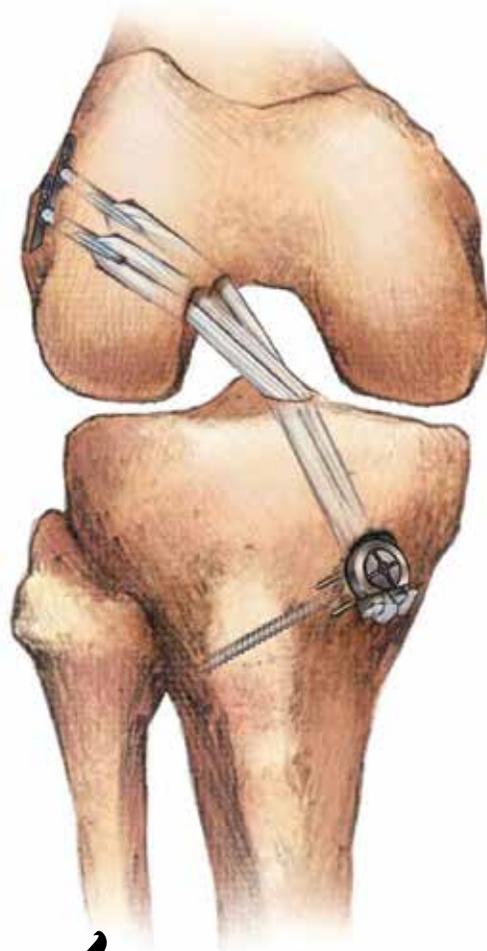
with ***Zip Loop***
TECHNOLOGY



ACL Reconstruction

Single Tibial Tunnel Double Bundle
Surgical Protocol by
Eric McCarty, M.D.

BIOMET



Zip Loop

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.

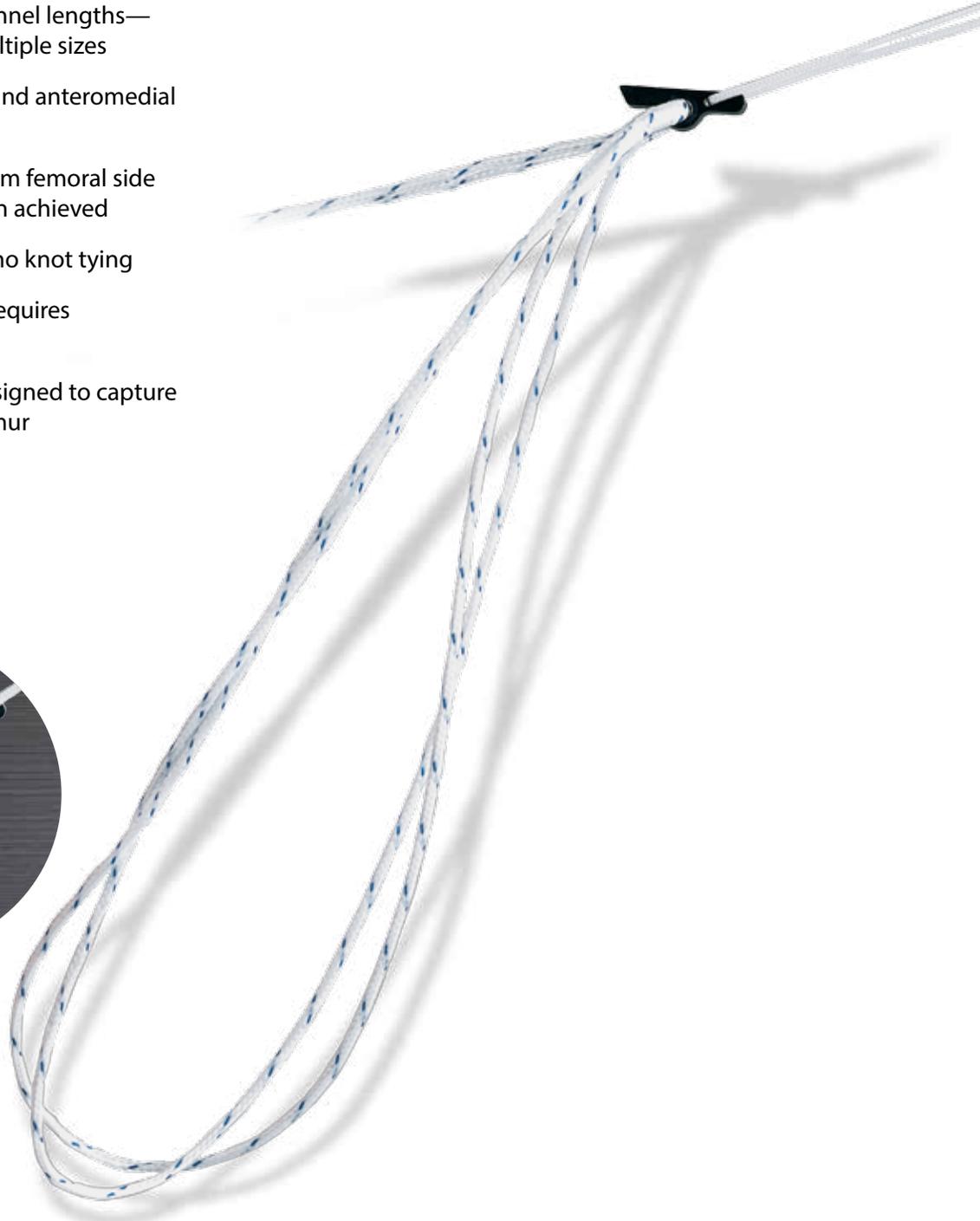


ToggleLoc

FIXATION DEVICE

Benefits

- 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

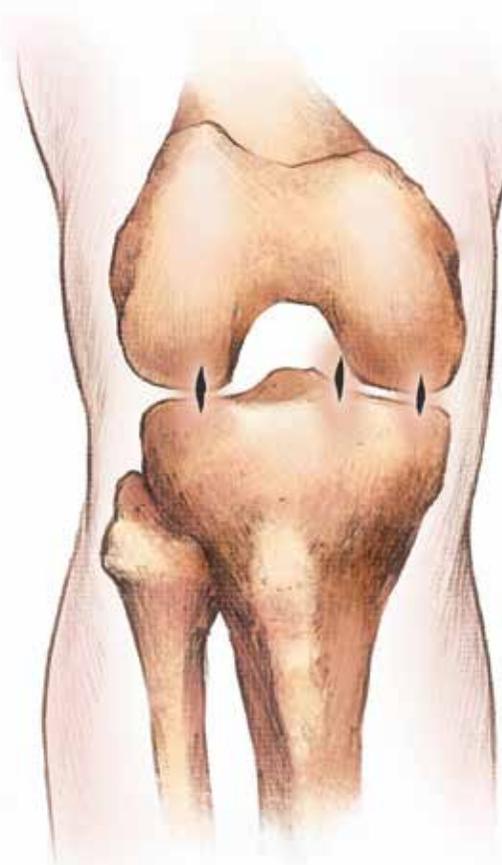


Figure 1

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 material represents the surgical technique utilized by Eric McCarty, M.D. Biomet does not practice medicine. The treating surgeon is responsible for determining the appropriate treatment, technique(s), and product(s) for each individual patient.

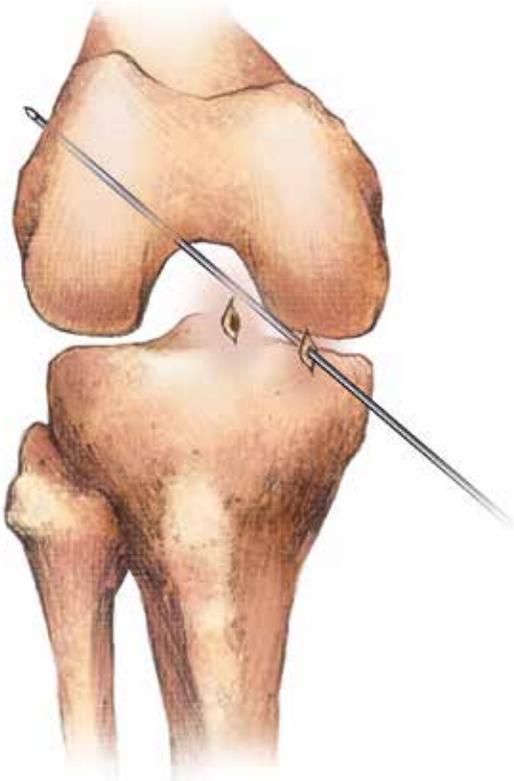


Figure 2

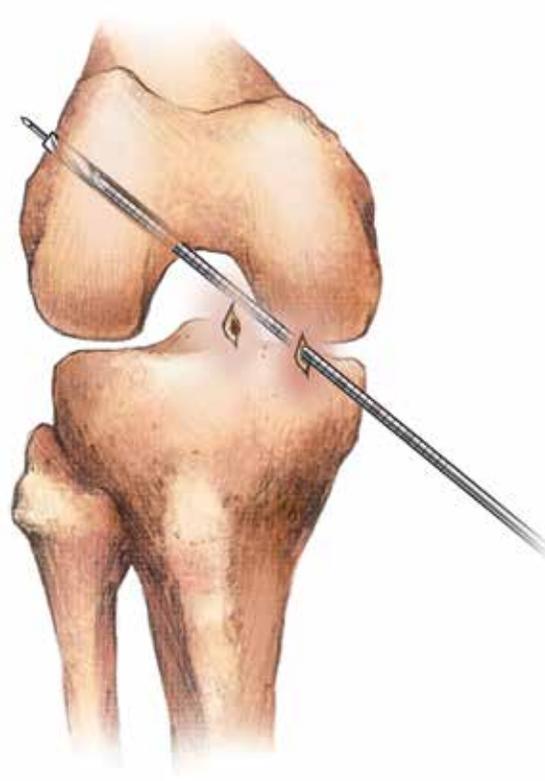


Figure 3

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)

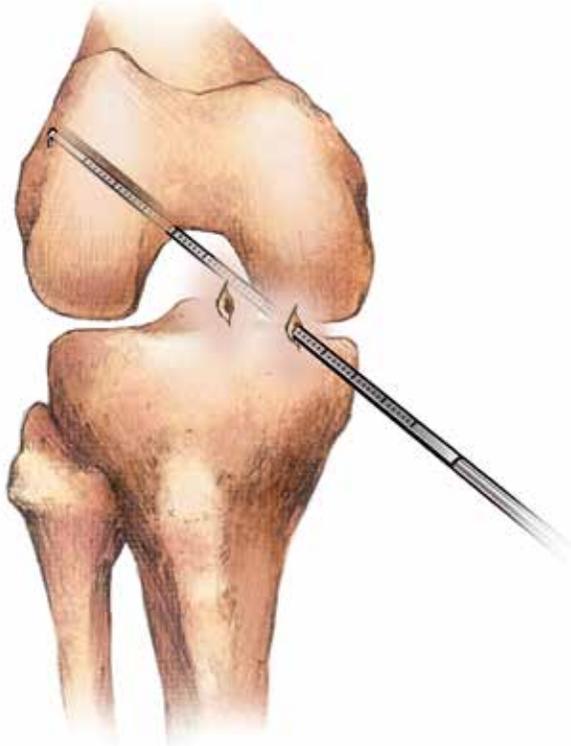


Figure 4



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

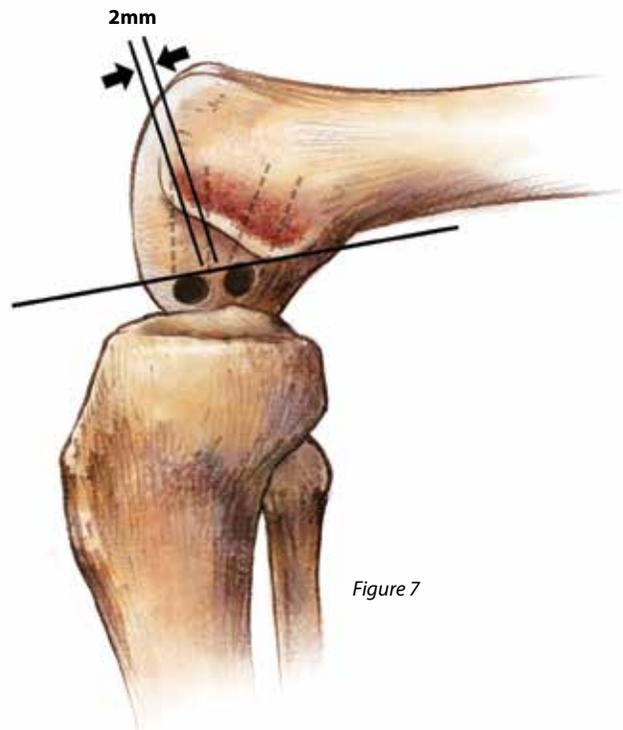


Figure 7

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.

Surgical Technique *(continued)*

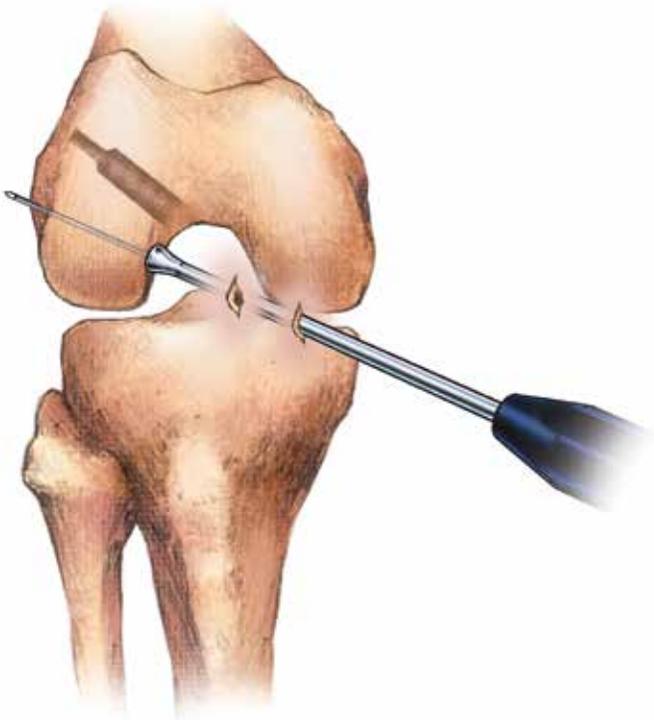


Figure 8



Figure 9

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.

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)

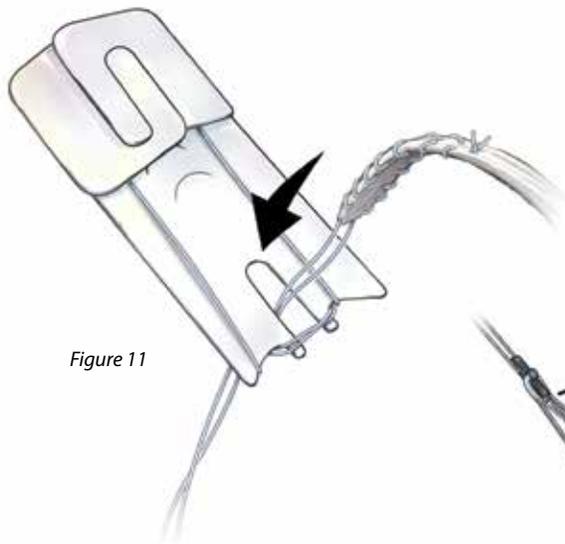


Figure 11

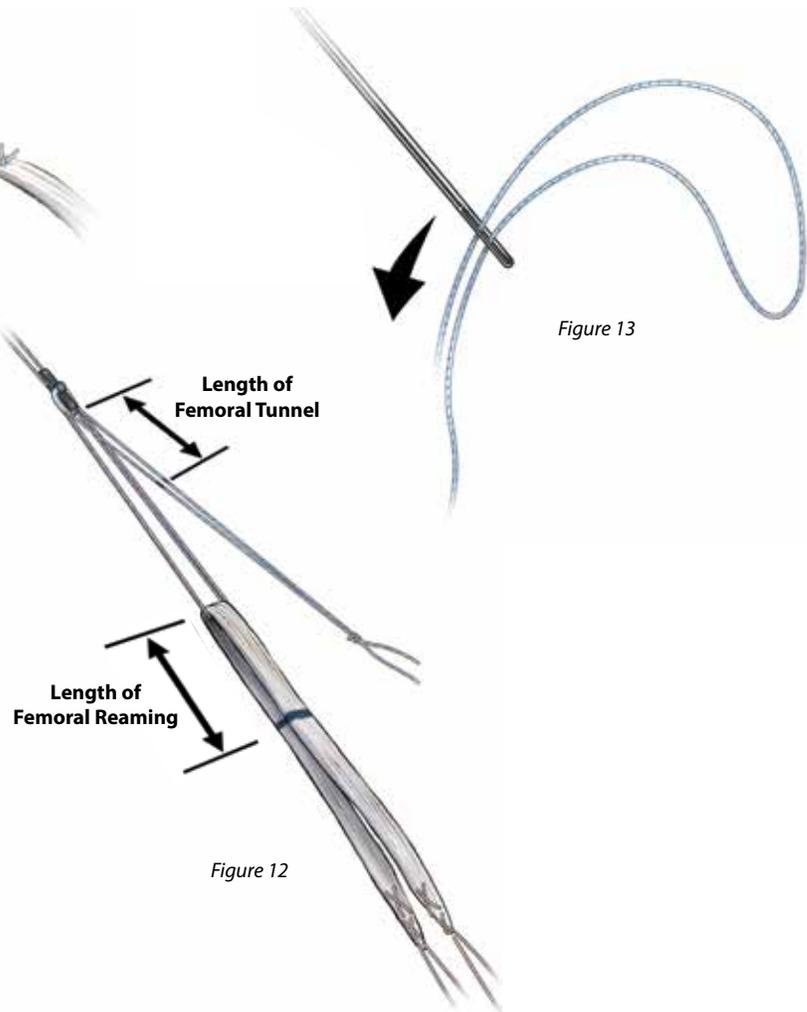


Figure 12

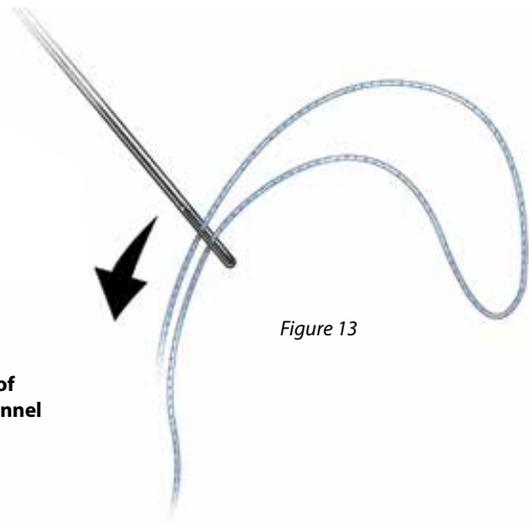


Figure 13

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

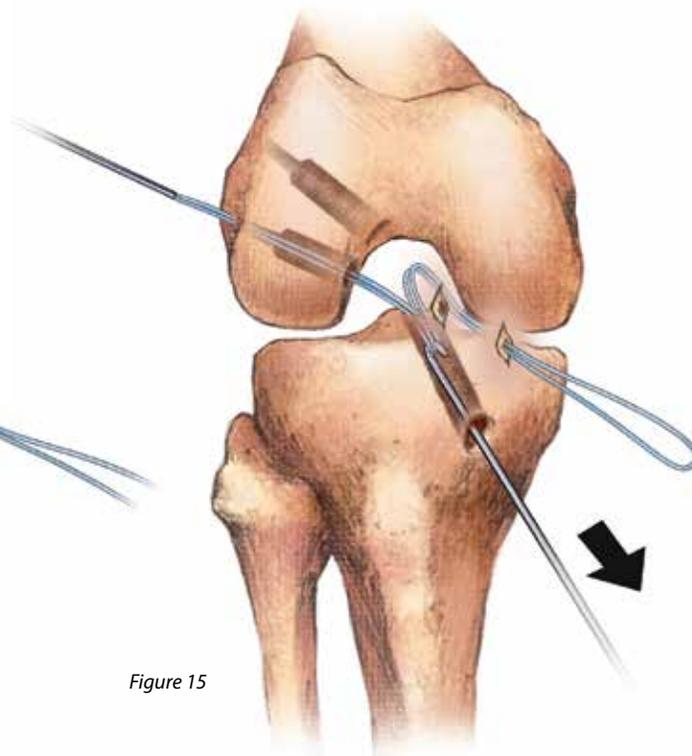


Figure 15

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).

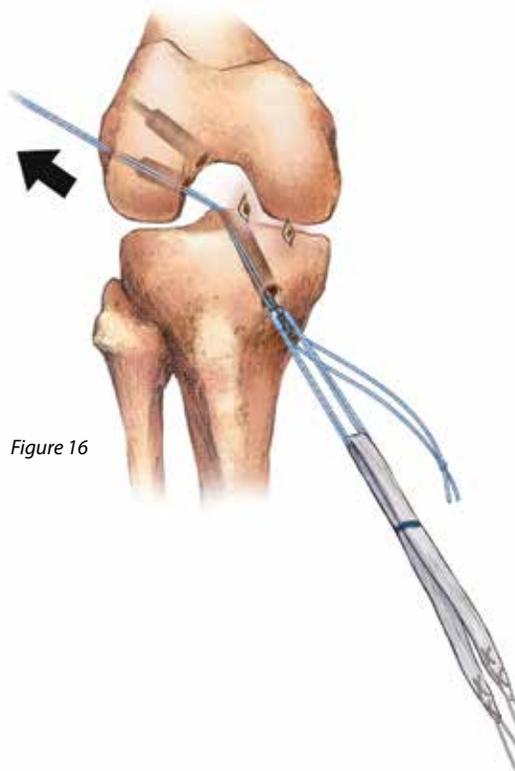


Figure 16

Surgical Technique *(continued)*

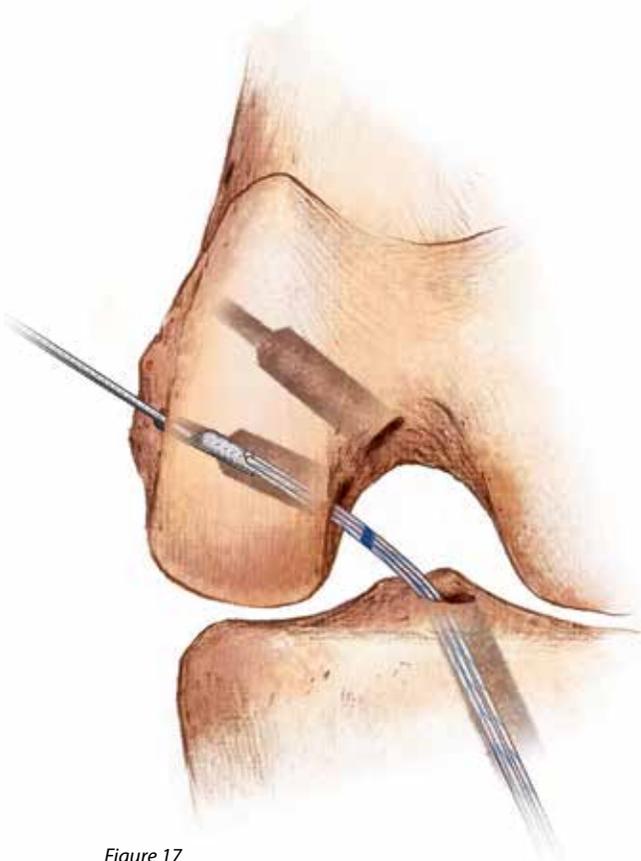


Figure 17

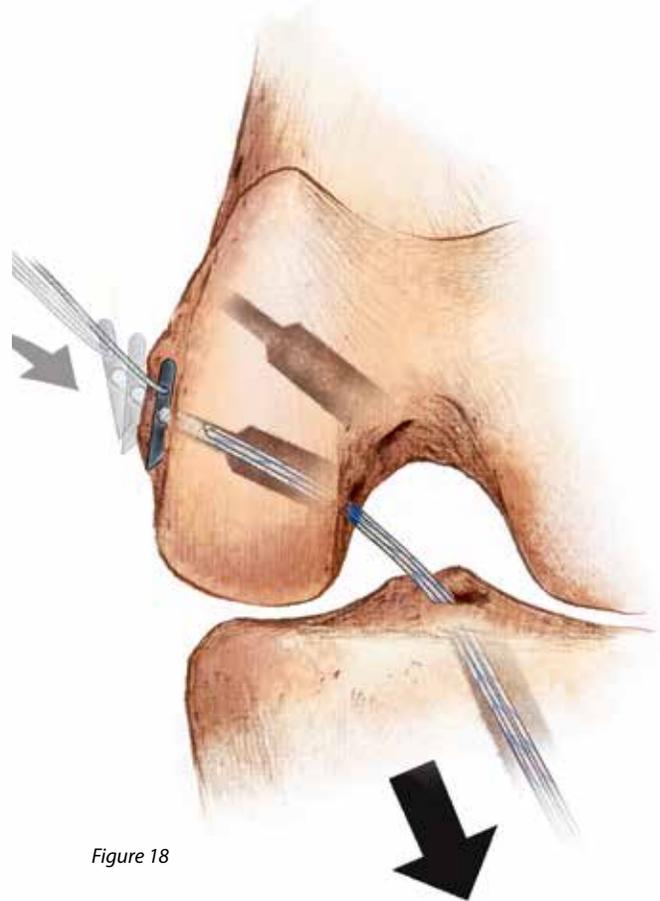


Figure 18

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).

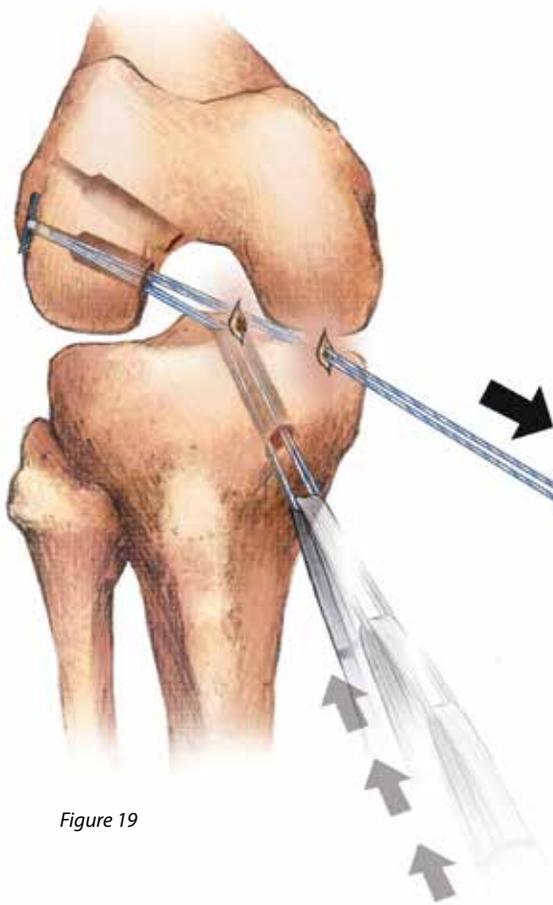


Figure 19

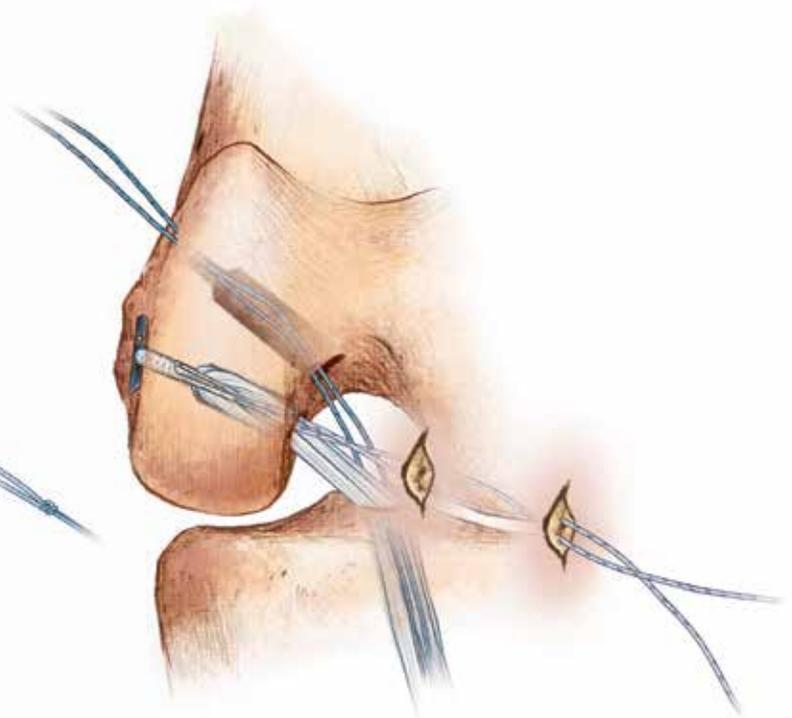


Figure 20

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).

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)

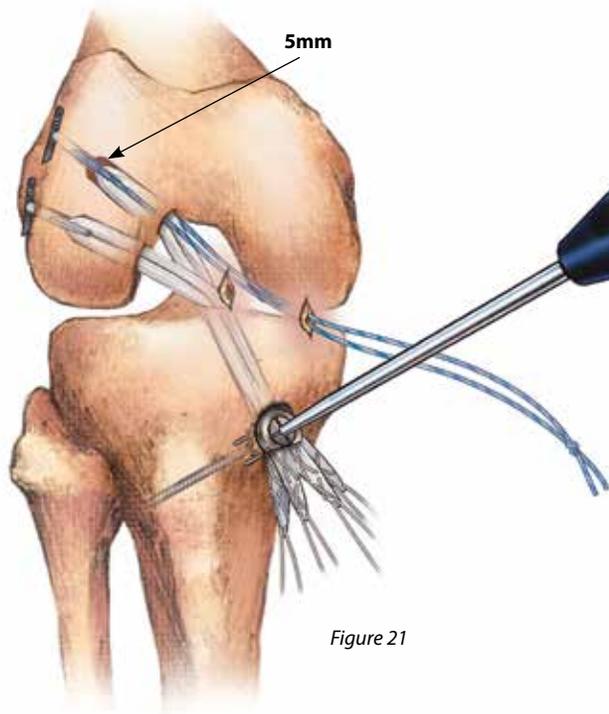


Figure 21

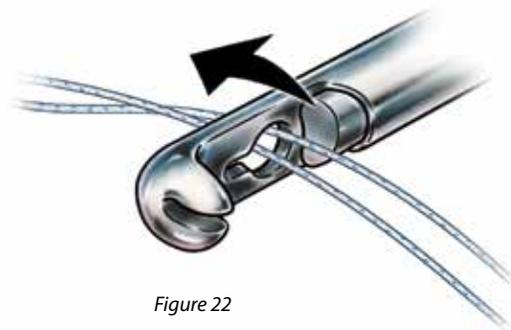


Figure 22

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).

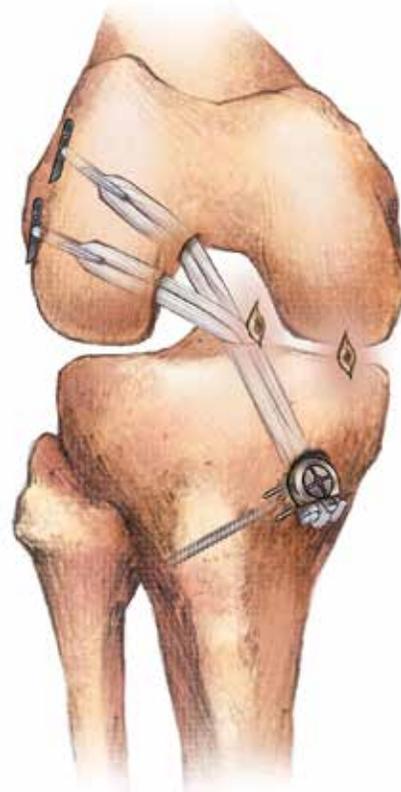


Figure 23

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
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

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.

Ordering Information

ToggleLoc Fixation Device with ZipLoop Technology

904754

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

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