Precision BTB Surgical Technique utilizing the ToggleLoc™ Device

with ZipLoop™ BTB Technology and ComposiTCP™ Interference Screws

ZIMMER BIOMET

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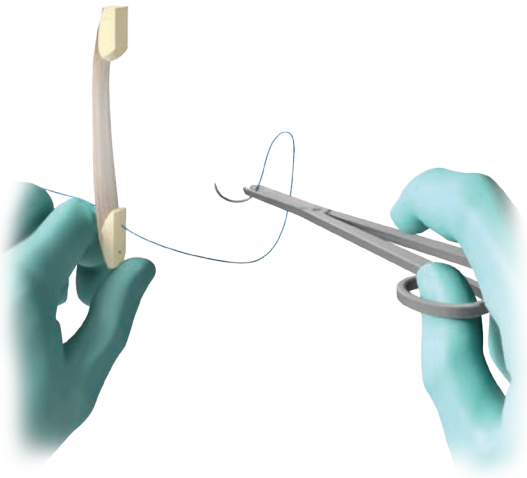


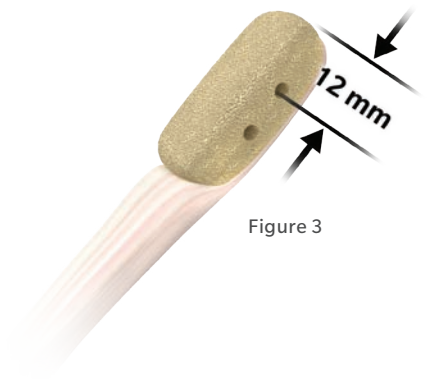
Figure 2

Graft Preparation

Harvest the middle third of the Patellar Tendon from the patient's knee.

Create small drill holes using a 2 mm drill, on shaped bone blocks, for insertion of sutures that are later used to pass graft up through the tunnels for final placement.

Size the patellar graft, using the Zimmer Biomet Tendon Sizing Block, so that the bundle passes through the sizing block with an easy fit before attaching implant.



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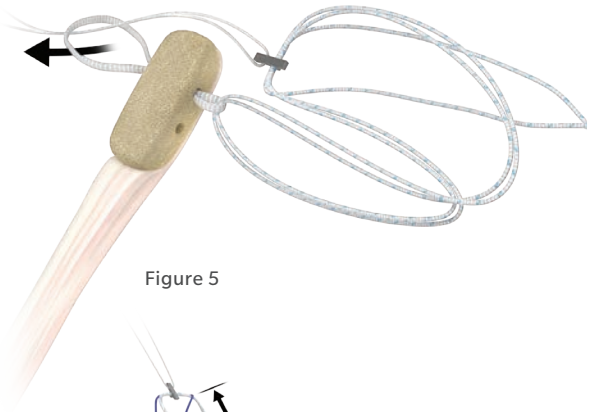

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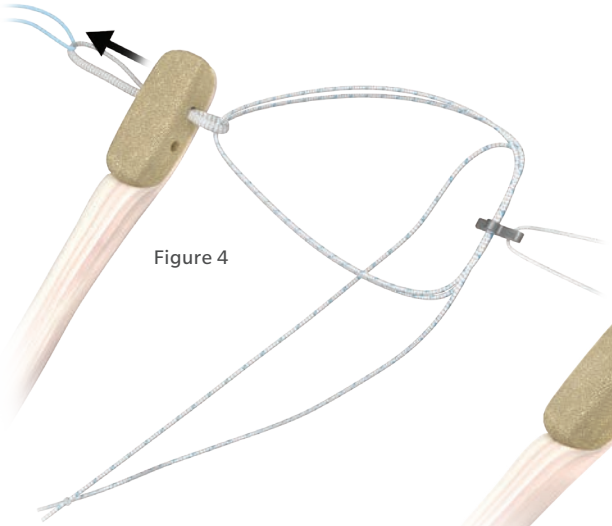

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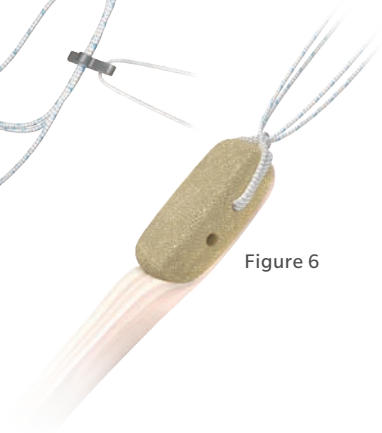

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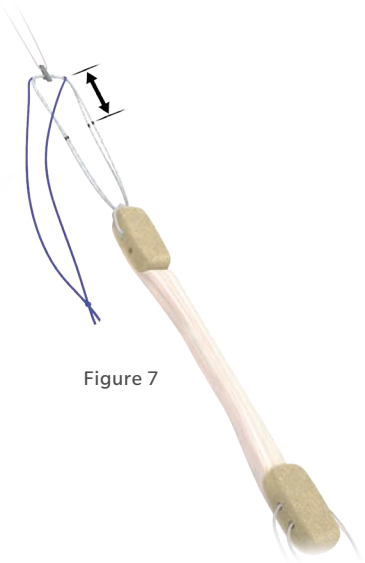


Figure 7

Prepare ToggleLoc Device

Open the BTB ToggleLoc Femoral Fixation Device with ZipLoop Technology. If not already prepared, drill a 2.0 mm hole through the bone block to aid in preparing the implant.

Note: The 2 mm hole should be 12 mm from the top of the bone block (Figure 3).

Pass a free suture through the continuous loop of the implant. Then pass both ends of the free suture through the 2 mm hole in the bone block, pulling the continuous loop with them (Figure 4). Next, pass the ToggleLoc Fixation Device through the continuous loop that was pulled through the bone block (Figure 5).

Continue pulling on the ToggleLoc Fixation Device until the continuous strand completely cinches around the bone block (like a luggage tag) (Figure 6).

Note: After the continuous strand is cinched around the bone block, resize through the graft sizing block.

Use the measurement previously obtained with the ToggleLoc depth gauge to mark the loops of the ZipLoop "zip suture" of the implant to ensure deployment on the lateral cortex. Measure from the distal end of the ToggleLoc device toward the loops and mark the "zip suture" (Figure 7).

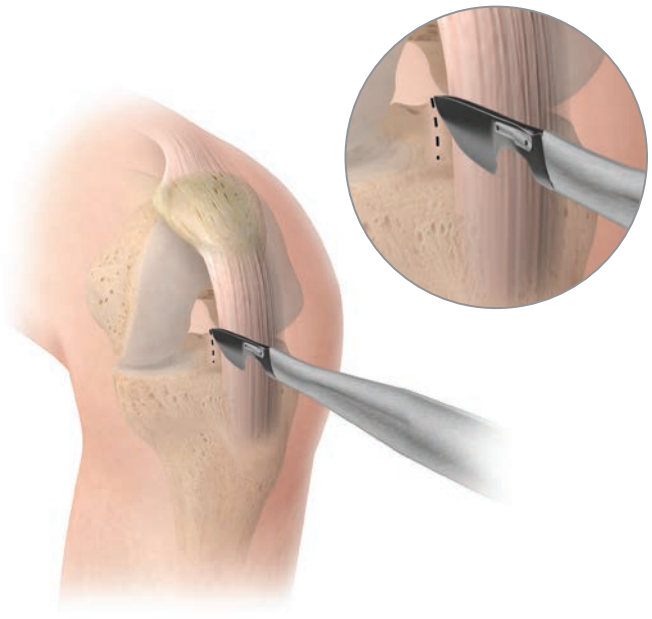


Figure 8

Portals

Make a standard lateral portal for arthroscopic visualization. The medial portal should be made at the medial edge of the patellar tendon at the joint line. The dual plane geometry of the Precision instrumentation eliminates the need for an accessory medial portal (Figure 8).

Figure 9

Femoral Tunnel

Select the appropriate Precision Curved Offset Femoral Guide dependent upon the desired margin of corico-cancellous bone at the posterior femur (Chart 1). If free-hand placement at the femoral ACL footprint is preferred, select the Precision Universal Femoral Guide.

Position the appropriate Precision Curved Offset Femoral Guide at the native ACL footprint through the medial portal (Figure 9). Orient the laser-etched line on the shaft of the guide superiorly to the anterior femur.

Back Wall Chart 1

Posterior Femoral Bone Margin (mm)				
Guide	5/6 (4 mm of Offset)	7/8 (5 mm of Offset)	9/10 (6 mm of Offset)	11/12 (7 mm of Offset)
Drill Size (mm)				
5	1.5			
6	1.0	2.0		
7	0.5	1.5		
8		1.0	2.0	
9		0.5	1.5	
10			1.0	2.0
11			0.5	1.5
12				1.0

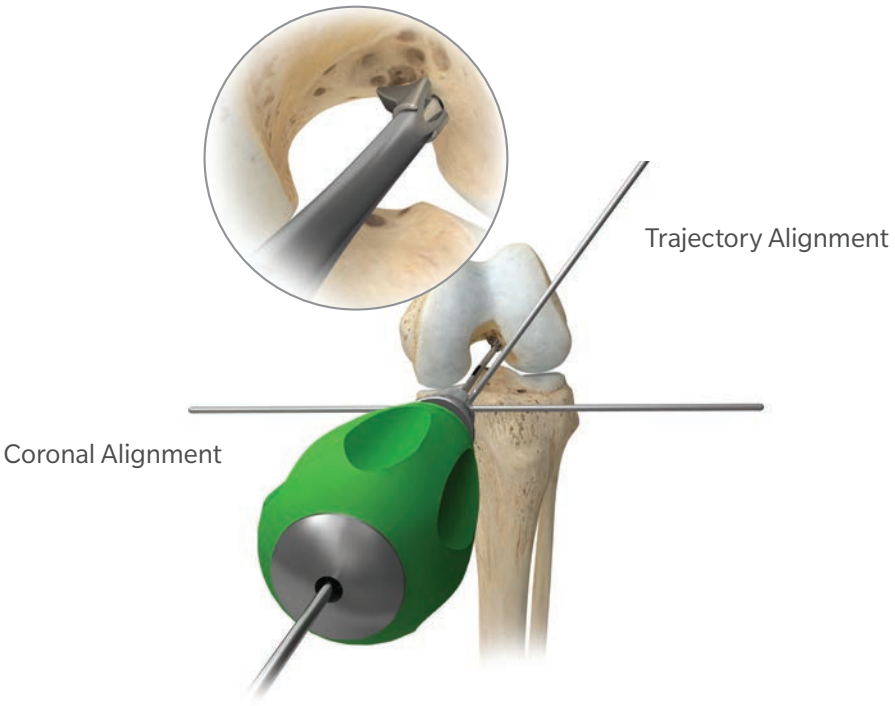


Figure 10

Femoral Tunnel (cont.)

To ensure optimal guide placement, an alignment rod may be inserted through either the coronal hole or the trajectory hole in the collar of the guide. The alignment rod placed in the coronal hole should be parallel to the joint line (Figure 10).

Alternatively, in the trajectory hole, the alignment rod indicates the exit of the Nitinol guide wire on the lateral femoral cortex.

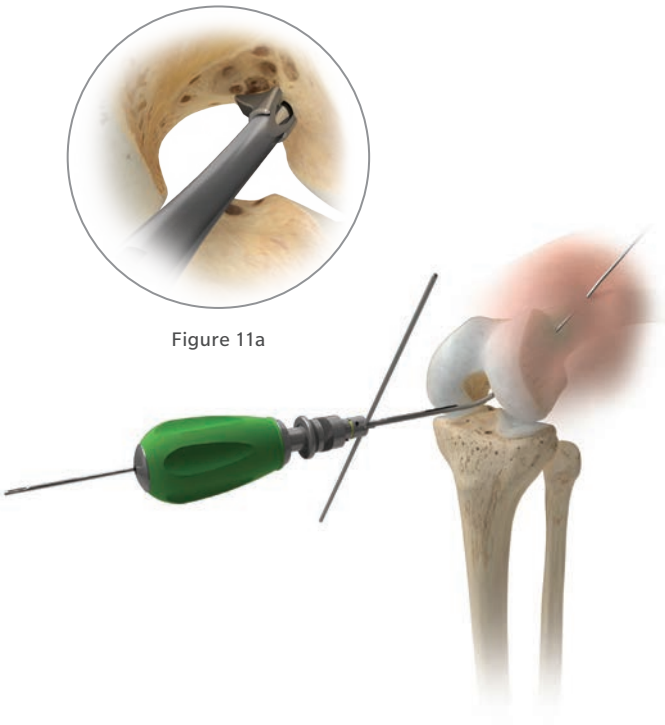


Figure 11a

Figure 11

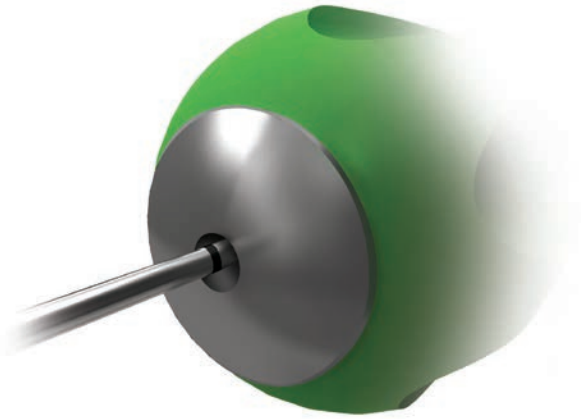


Figure 12

Placement of Nitinol Guide Wire

Once the Precision Femoral Guide is in position, use a pin driver to advance the Nitinol guide wire under power through the curved guide. Visualize the Nitinol guide wire in the window at the distal end of the guide as it enters the bone. Advance the Nitinol guide wire through the lateral femoral cortex to exit the skin on the lateral thigh (Figure 11) until the black laser line on the Nitinol guide wire meets the femoral bone in the notch (Figure 11a).

For an additional reference, match the secondary laser line on the Nitinol guide wire with the back of the green handle (Figure 12).

Figure 13

Figure 14

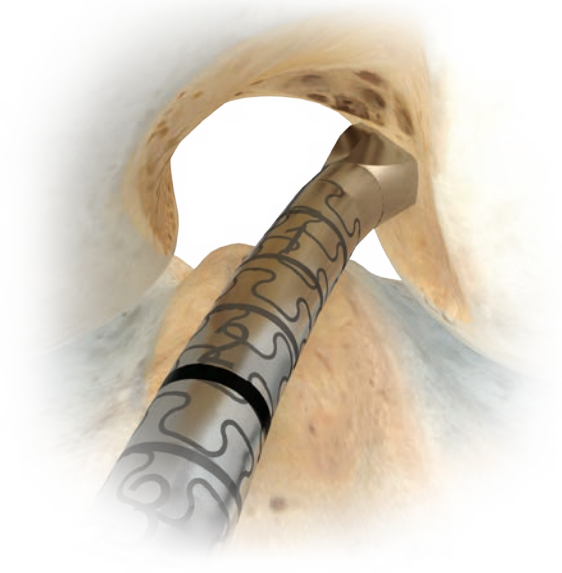
Femoral Tunnel Length

Measure the length of the femoral tunnel by sliding the Precision Depth Gauge down the Nitinol guide wire through the skin and subcutaneous tissues at the lateral thigh until contacting the femoral cortical bone. Read the tunnel length from the tip of the Nitinol guide wire (Figure 13).

Note: A minor skin incision may be required to facilitate passing of the depth gauge to the surface of the bone.

Once the femoral tunnel length measurement is determined, remove the Precision Curved Femoral Guide from the knee. Use controlled effort when removing the Precision Femoral Guide due to friction between the Nitinol guide wire and the curved section of the femoral guide. Care should be taken to avoid pulling on the release mechanism on the green handle as the guide may disengage.

Drill over the guide wire with a Precision Flexible Reamer corresponding to the diameter of the graft (Figure 14).



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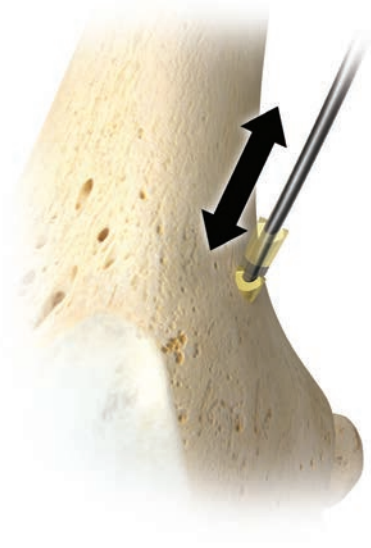
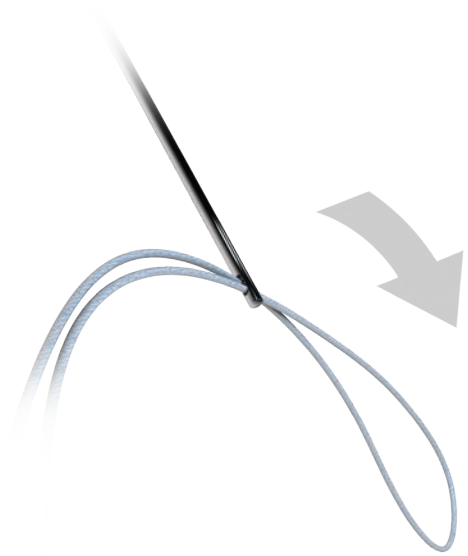


Figure 16

Femoral Tunnel Length (cont.)

Advance the Precision Flexible Reamer to the desired socket depth, leaving at least 10 mm between the end of the femoral tunnel and the lateral cortex for use with the ToggleLoc Femoral Fixation Device. Note that the bold radial etch mark on the Precision Flexible Reamer represents 25 mm depth (Figure 15).

Use the 4.5 mm Precision Flexible Reamer to ream over the Nitinol guide wire, perforating the lateral cortex of the femur. Pass the 4.5 mm reamer through the cortex two to three times to facilitate passage of the ToggleLoc device (Figure 16).



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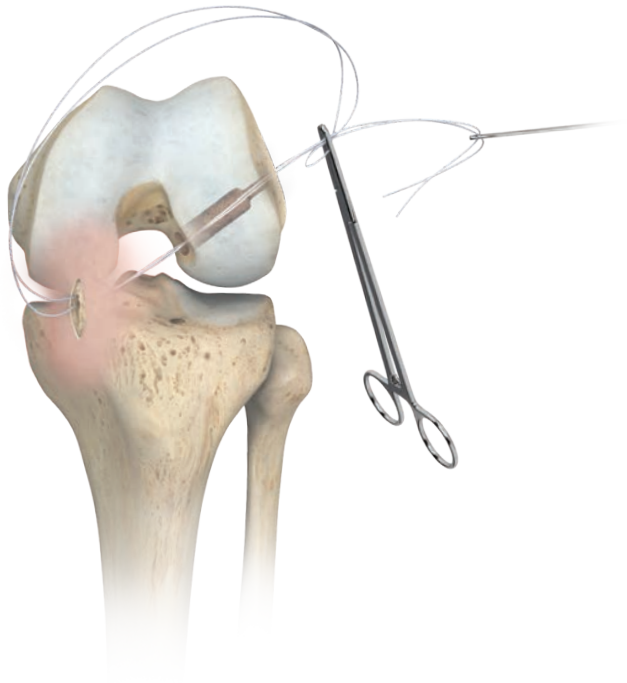
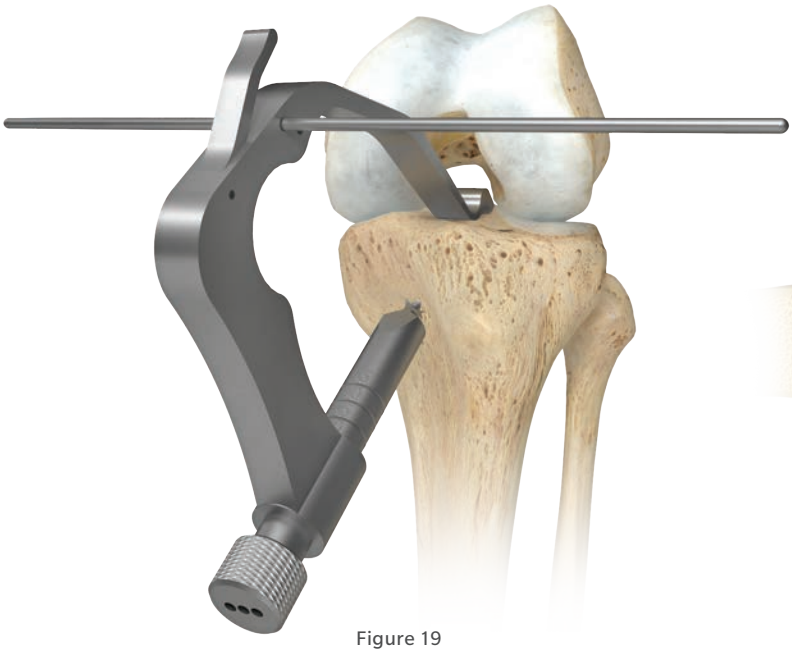


Figure 18

Prepare the Relay Stitch

Thread the free ends of a #2 MaxBraid™ suture through the eyelet of the Nitinol guide wire (Figure 17).

Pull proximally on the Nitinol guide wire to place the relay suture into the joint space and through the femoral tunnel. Using a hemostat, clamp the loop end of the relay stitch exiting the medial portal to the free ends of the relay stitch existing the skin on the lateral thigh (Figure 18).



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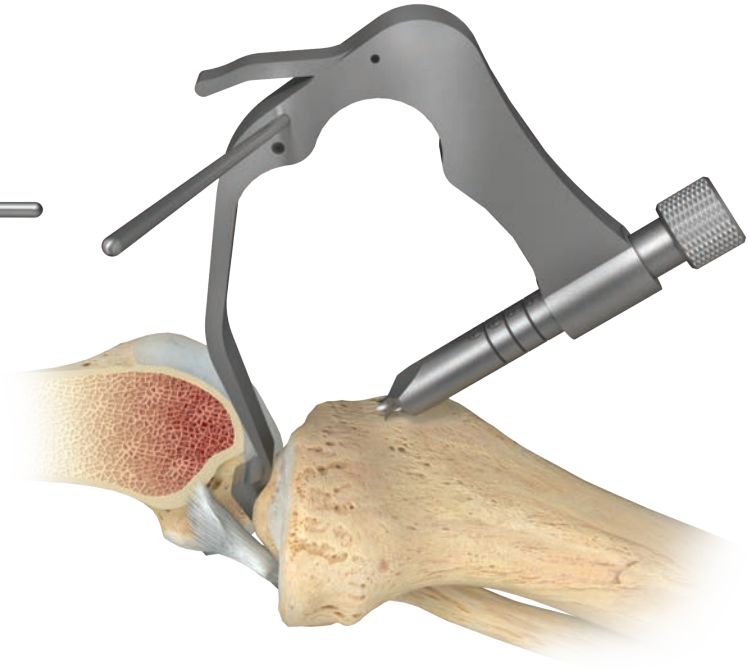


Figure 20

Insert the Anatomy Specific Tibial Guide

Insert the Anatomy Specific Tibial Guide through the medial portal. Position the tip of the guide in the space between the PCL and the lateral femoral condyle (Figure 19). Position the bump inside the notch facing the intercondylar roof.

Slowly extend the knee while arthroscopically confirming the bump on the tip of the guide remains inside the notch (Figure 20). Maintain the knee in hyperextension by placing the heel on a raised Mayo stand. Suspending the knee by placing the heel on the Mayo stand allows gravity to reduce the tibia on the femur.[1,2]

Figure 21

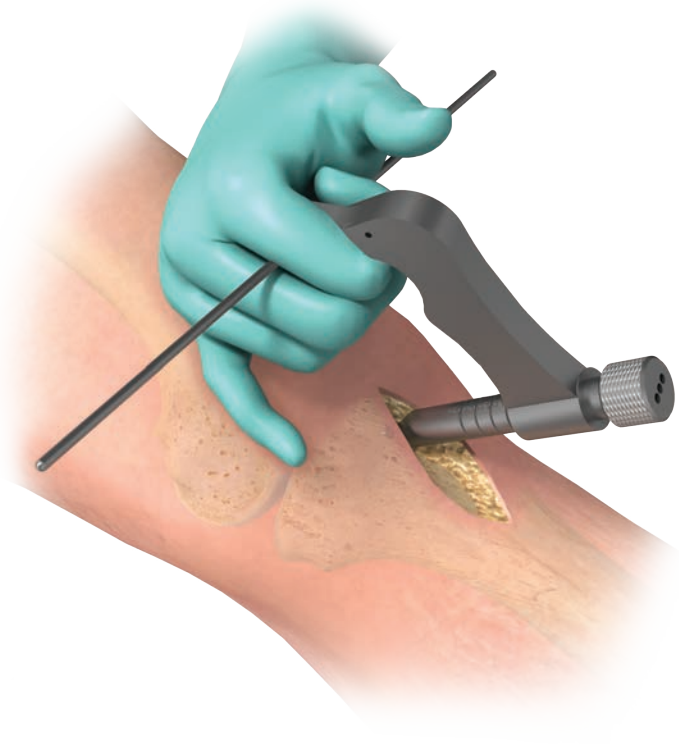


Figure 22

Position the Tibial Guide in the Sagittal Plane

Grasp the handle of the guide with the long and ring fingers and rest the hypothenar area of the hand on the patella. Seat the guide by gently lifting the handle toward the ceiling until the bump and arm of the guide abuts the trochlear groove. Simultaneously press the patella into the trochlear groove, thereby hyperextending the knee (Figure 21). This maneuver adjusts the angle and position of the guide in the sagittal plane by accommodating the specific roof angle and knee extension of the patient.

Adjust the Angle of the Tibial Guide in the Coronal Plane

From the lateral side of the guide, insert the alignment rod into the proximal hole in the handle. Position the alignment rod parallel to the joint line and perpendicular to the long axis of the tibia, which angles the tibial tunnel at 65˚ with respect to the medial joint line of the knee (Figure 22). Insert the bullet until it touches the superficial MCL overlying the posteromedial tibia. Drill a 2.4 mm drill tip guide pin through the lateral hole in the bullet until it stops at the broad tip of the guide. Remove the tibial guide.

Figure 23a

Figure 23

Assess the Position of the Tibial Guide Pin

Flex the knee, insert the arthroscope, and tap the guide pin into the notch. Assess the placement of the guide pin with the knee in 90˚ of flexion. The two checkpoints for correct placement of the guide pin are, 1) the pin is located midway between the lateral edge of the PCL and the lateral femoral condyle, and 2) the tip of the pin is equidistant from the apex and base of the notch (Figure 23 & 23a).

In the sagittal plane the checkpoint for the correct placement of the guide pin is that a 2 mm wide nerve hook pistons 2 mm between the anterior surface of the guide pin and intercondylar roof with the knee in full extension.

Once the tibial pin is in desired location, ream over the guide wire with the drill corresponding to the previously determined graft size.

Thread the passing suture of the BTB ToggleLoc Fixation Device with ZipLoop Technology through the opening of the relay stitch, which should be exiting the tibial tunnel. Pull proximally on the relay stitch to pull the passing suture through the tibial tunnel, joint space and femoral tunnel, exiting through the skin.

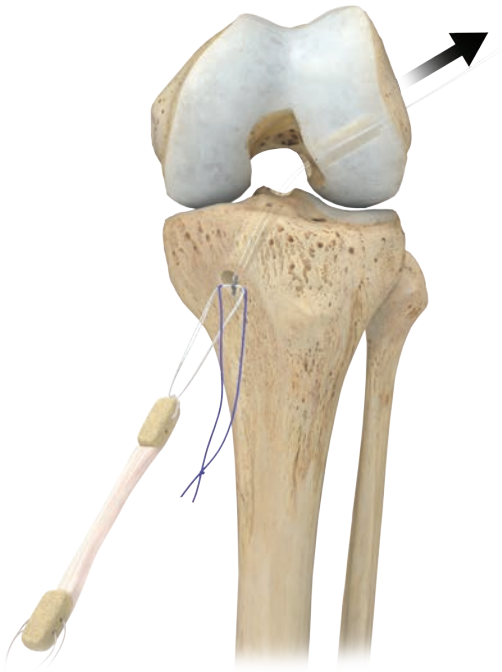


Figure 24

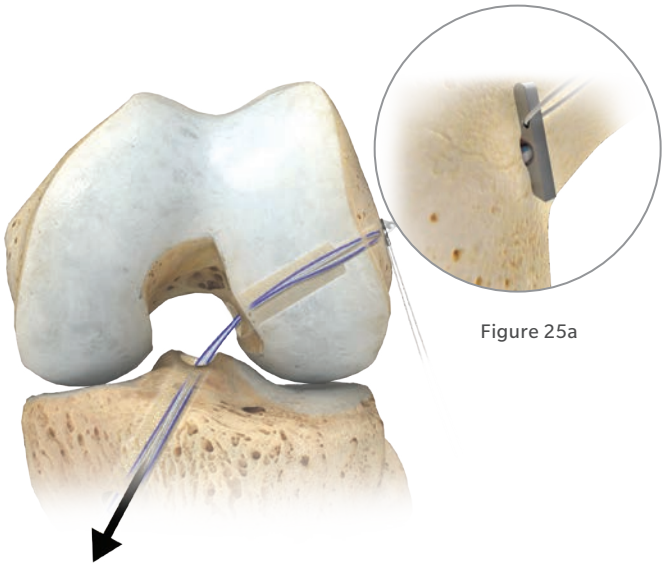


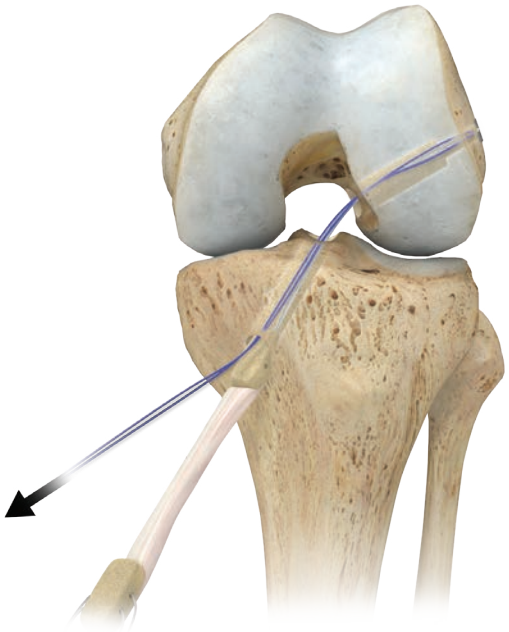
Figure 25a

Figure 25

Insert Implant into Tunnel

Prior to fixation, ensure that the BTB 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 BTB graft prior to graft placement within the femoral tunnel (Figure 24).

Pull the passing suture proximally until the mark on the "zip suture" of the BTB ToggleLoc device reaches the entrance of the femoral tunnel, which positions the implant just beyond the lateral cortex of the femur. Pull on the distal end of the BTB graft to feel the implant catch on the lateral femoral cortex, achieving femoral fixation (Figure 25).



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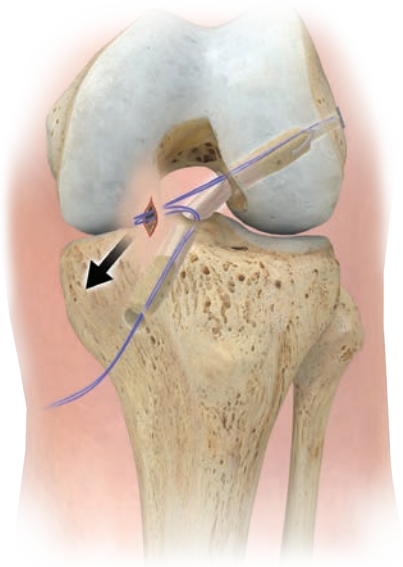
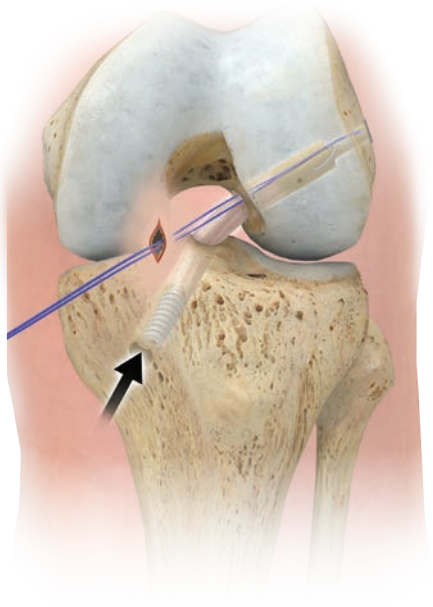


Figure 27

Insert Implant into Tunnel (cont.)

Pull distally on the zip suture to draw the graft through the tibial tunnel and into the femoral tunnel. This will shorten the loop of the BTB ToggleLoc Femoral Fixation Device with ZipLoop Technology and accurately position the BTB graft in the femoral tunnel (Figure 26).

Cut the knot off of the zip suture and retrieve the limbs through the medial portal with a crochet hook or other suture grasping device (Figure 27).



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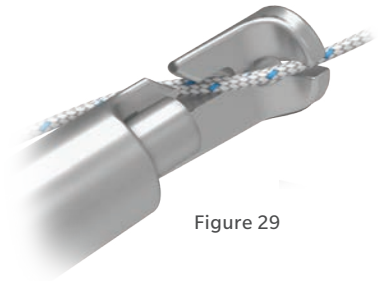

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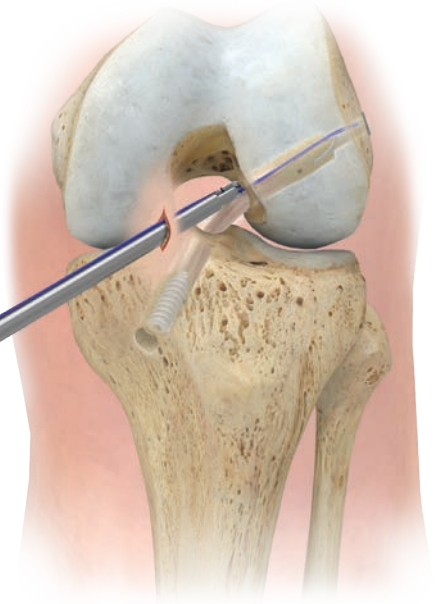

Figure 30

Complete Tibial Fixation

Tension the graft by manually pulling on the sutures attached to the patella bone plug exiting from the tibial tunnel. Cycle the knee between full extension and flexion to settle the graft, and confirm that the femoral fixation is sound. Bring the knee into full extension. Insert the 1.1 mm Nitinol wire posterior to the patellar tendon graft and insert an interference screw (Figure 28).

Note: Prior to inserting the graft or interference screw, preferred method is to tap the distal end of the tibia.

The BTB ToggleLoc device can be re-tensioned at this point if necessary. Pass the limbs of the suture through the key shaped hole in the Super MaxCutter™ instrument (Figure 29). Advance the Super MaxCutter through the medial portal and sever the suture near the entrance of the femoral tunnel in the joint space (Figure 30).

Ordering Information

Implants

Part Number	Size	Description
905256	9 x 25 mm	ComposiTCP Interference Screw 60% B-TCP—Round Head
905257	9 x 30 mm	ComposiTCP Interference Screw 60% B-TCP—Round Head
905258	9 x 35 mm	ComposiTCP Interference Screw 60% B-TCP—Round Head
905261	10 x 30 mm	ComposiTCP Interference Screw 60% B-TCP—Fully Threaded
905262	10 x 35 mm	ComposiTCP Interference Screw 60% B-TCP—Fully Threaded
905263	11 x 30 mm	ComposiTCP Interference Screw 60% B-TCP—Fully Threaded
905264	11 x 35 mm	ComposiTCP Interference Screw 60% B-TCP—Fully Threaded

Part Number	Description
904756	ToggleLoc Femoral Fixation Device with ZipLoop Technology for BTB Grafts
909849	ToggleLoc Femoral Fixation Device with ZipLoop Technology for BTB Grafts Implant System

Ordering Information

Precision Disposable Flexible Reamers

Part Number	Size
110004180	4.5 mm
110004185	7.0 mm
110010577	7.5 mm
110004186	8.0 mm
110010578	8.5 mm
110004187	9.0 mm
110010579	9.5 mm
110004188	10.0 mm
110010580	10.5 mm
110004189	11.0 mm
110010581	11.5 mm
110004190	12.0 mm

ToggleLoc Fixation Device

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

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.

ComposiTCP 60 Interference Screw

INDICATIONS FOR USE

The ComposiTCP 60 Interference Screw is exclusively used for the fixation by interference of the transplant made out of soft tissue, taken out for instance from the hamstring tendon, when reconstructing the cruciate anterior ligament. The screws are cannulated and are available in different sizes (see commercial documentation). They have a specific head, which allows for a more even distribution of the torsional stresses. To achieve the optimal result, the ComposiTCP 60 Interference Screws should be implanted using a dedicated screwdriver contained in the instrumentation set.

CONTRAINDICATIONS

Insufficient or poor-quality bone stock (including tumors and sever osteoporosis) is likely to affect screw purchase. Acute infection. Allergy to implant material. Conditions likely to limit the patient's ability and/or willingness to restrict activities and/or to adhere to instructions during the healing and rehabilitation period.

References

1. Berns, G. S., and Howell, S. M.: The effect of roofplasty and tibial hole placement on impingement of anterior cruciate ligament reconstructions. *Journal of Biomechanics,* 25(6): 653, 1992.
2. Howell, S. M.: Arthroscopic roofplasty: a method for correcting an extension deficit caused by roof impingement of an anterior cruciate ligament graft. *Arthroscopy,* 8(3): 375-9, 1992.

Notes

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, www.zimmerbiomet.com, or contact your local Zimmer Biomet Representative.

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