

ACL Reconstruction – Medial Portal

with ToggleLoc™ Fixation Device with ZipLoop™ Technology
and ComposiTCP™ Interference Screw

Surgical Technique
by Jeffrey Michaelson, M.D.

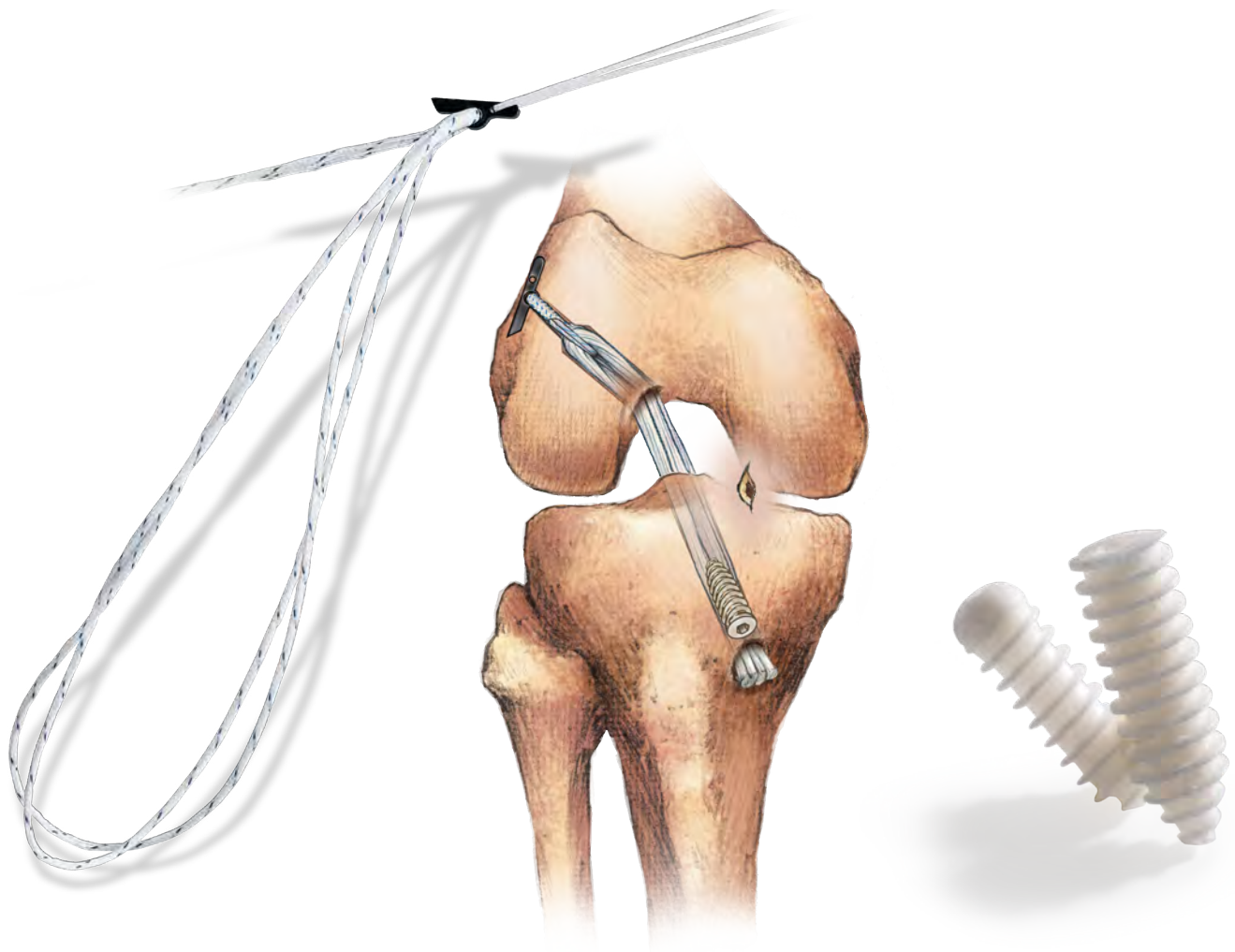
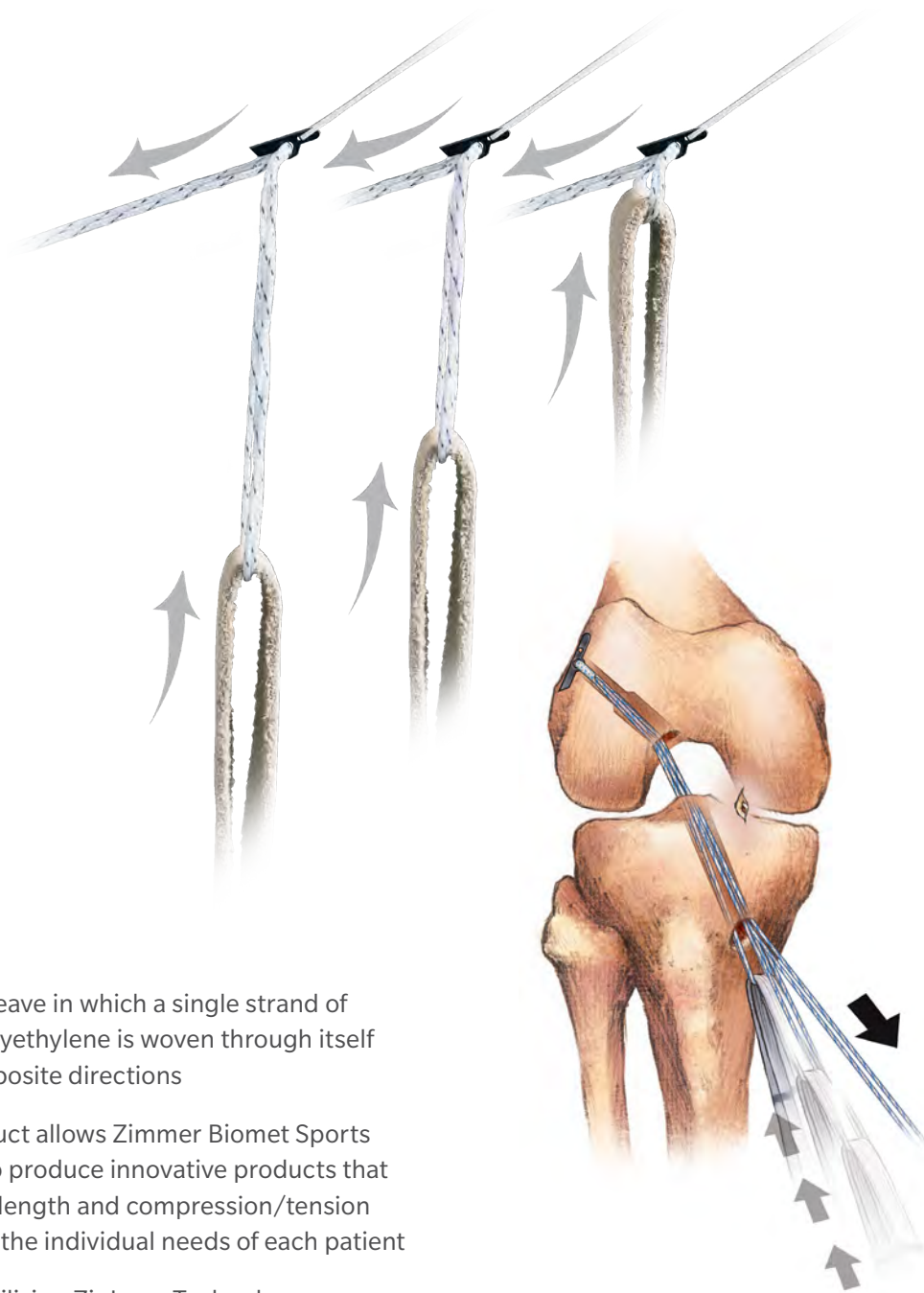


Table of Contents

- Tunnel Preparation 6
- Insert Implant into Tunnel 10
- Position Graft in Femoral Tunnel 11
- Tibial Fixation..... 12
- Sever the Zip Suture 12
- Ordering Information 13
- Indications for Use 15
- Contraindications 15

ZipLoop Technology



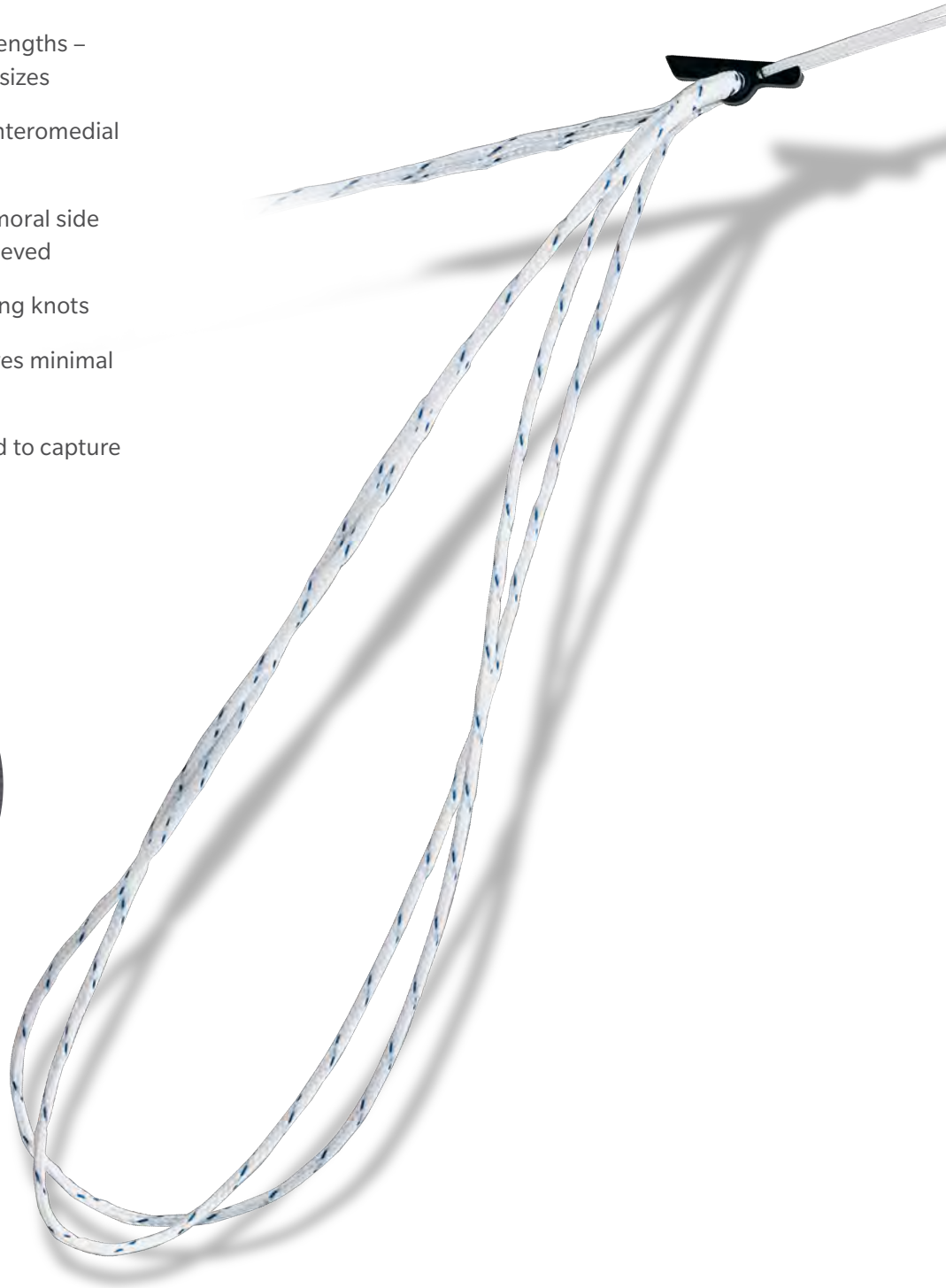
Features

- A unique weave in which a single strand of braided polyethylene is woven through itself twice in opposite directions
- This construct allows Zimmer 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

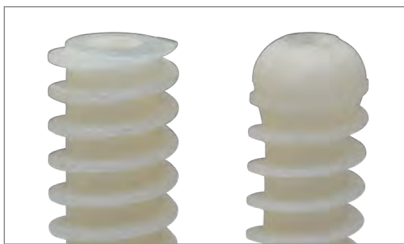
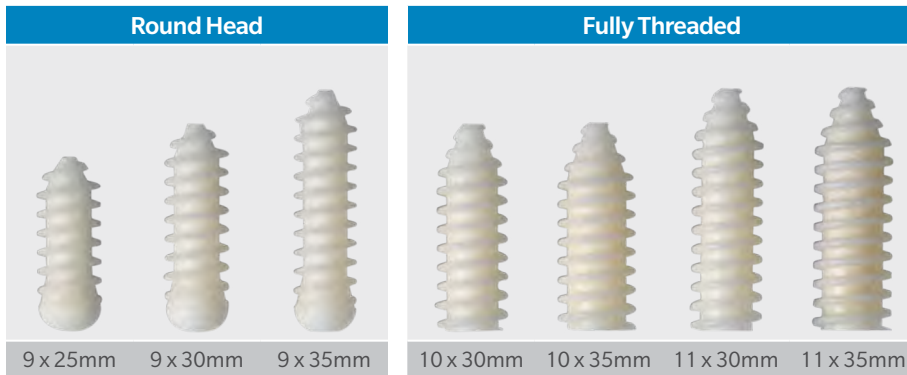
Benefits

- 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
- Resistant to slippage without tying knots
- Simple surgical technique requires minimal instrumentation
- Femoral fixation device designed to capture the cortical bone of the femur



ComposiTCP Interference Screw

Sizing



Available in fully-threaded
and round head design

Composite Material

The composite blend of 40% PLDLA and 60% beta Tri-Calcium Phosphate has been studied and the results reported in an in-vivo animal study¹ showed that "in comparison with pure PLA, TCP-containing composite materials had faster degradation kinetics, caused less inflammatory reaction, and promoted contact osteogenesis." In addition, an in-vitro study discussed how increased amounts of TCP have been shown to stimulate the proliferation of osteogenous cells¹.



Features

- Procedure-specific composite mix for anterior cruciate ligament reconstruction
- Made with a composite blend of 40% PLDLA and 60% beta Tri-Calcium Phosphate

Surgical Technique

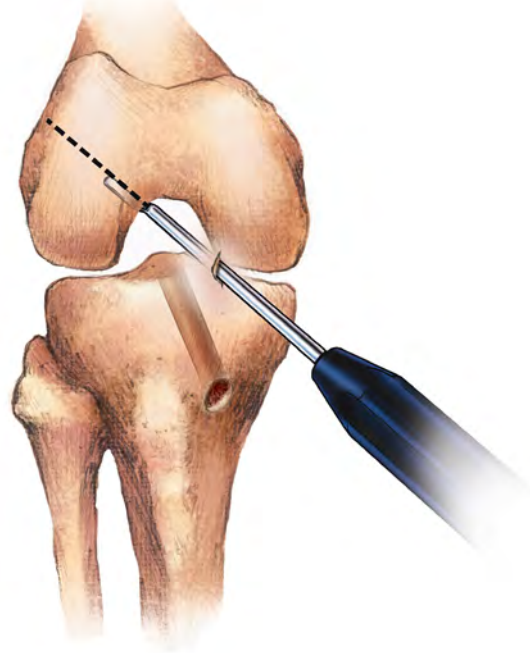


Figure 1

Tunnel Preparation

Utilizing a tibial guide that allows for optimal tunnel placement, position the tibial guide appropriately and drill the guide wire. After the graft size has been determined, ream over the guide wire with the corresponding reamer. Position a Femoral Aimer into the over-the-top position through an accessory anteromedial portal (Figure 1).

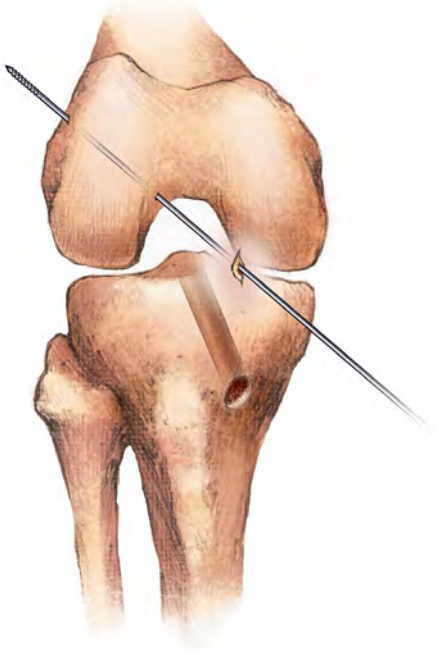


Figure 2

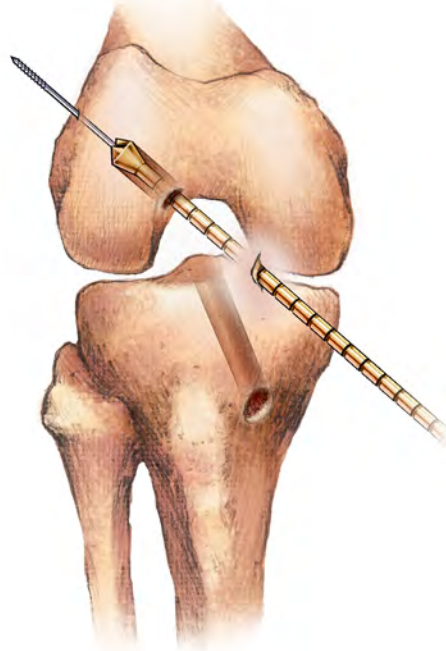


Figure 3

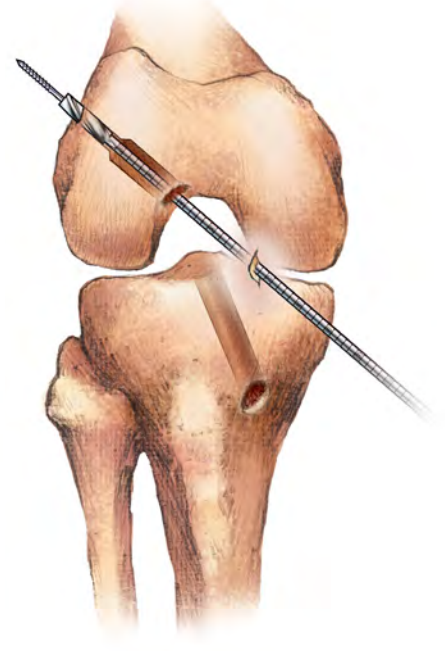


Figure 4

Tunnel Preparation (cont.)

Drill a calibrated guide wire through the Femoral Aimer and the lateral cortex of the femur (Figure 2). Consider placing the scope into the standard medial portal to check that the guide wire is placed in the 9:30 – 10:30 position for a left knee and a 1:30 – 2:30 position for the right knee.

Drill over the previously placed guide wire an endoscopic reamer corresponding to the diameter of the graft diameter and ream to the depth that will allow the desired soft-tissue graft-to-tunnel interface (typically around 25 mm) (Figure 3). Drill over the previously placed guide wire with the 4.5 mm ToggleLoc drill bit through the lateral cortex of the femur (Figure 4). Pass the 4.5 mm drill in and out of the cortex two to three times to facilitate passage of the implant.

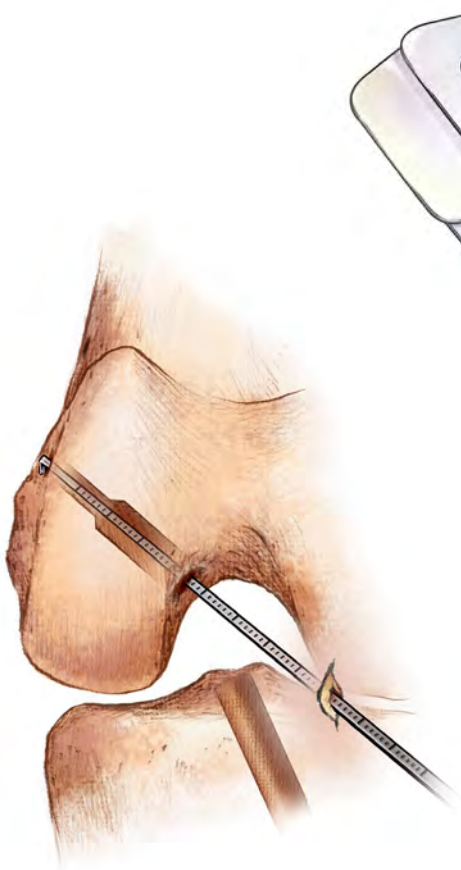


Figure 5

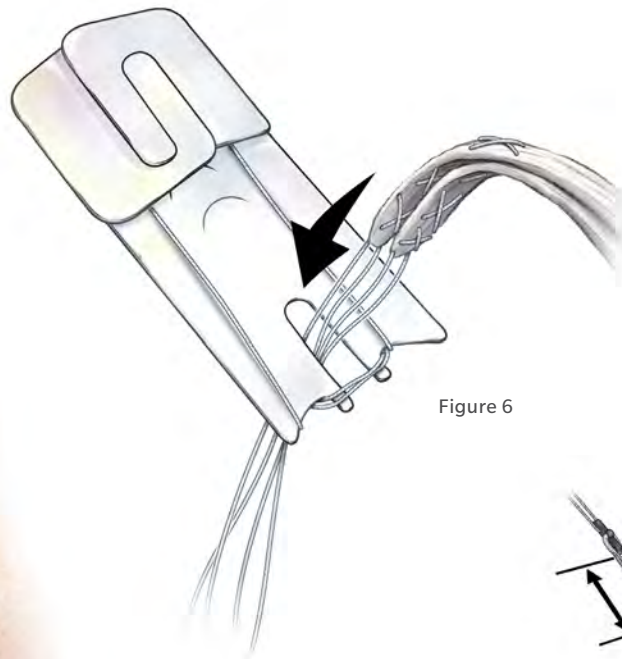


Figure 6

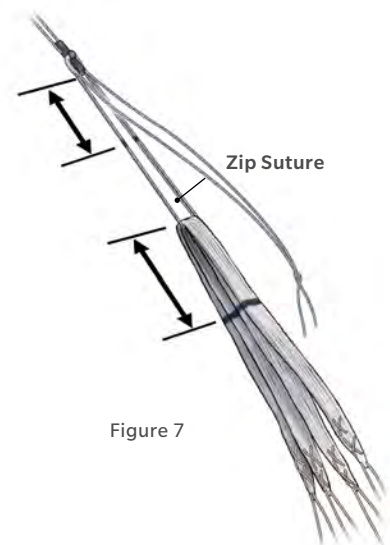


Figure 7

Tunnel Preparation (cont.)

Pass the ToggleLoc depth gauge into the femoral tunnel and measure the tunnel length from the lateral cortex of the femur to the tunnel exit point in the joint space (Figure 5). Pass the soft tissue grafts through both loops of the ToggleLoc Femoral Fixation Device with ZipLoop Technology (Figure 6). 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 loops 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 (Figure 7). Make a second mark on the graft by measuring the depth of the “graft tunnel” (typically 25 mm). This mark will aid in optimal graft positioning later in the procedure.

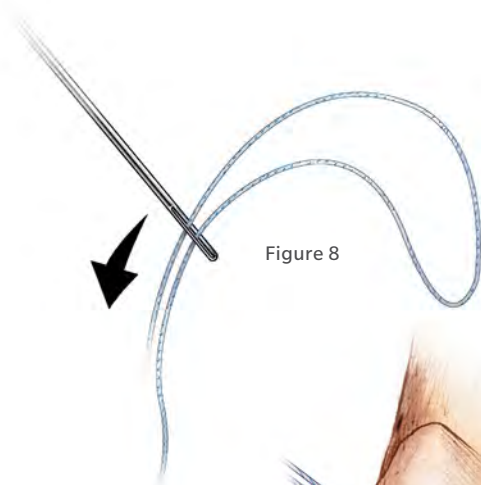


Figure 8

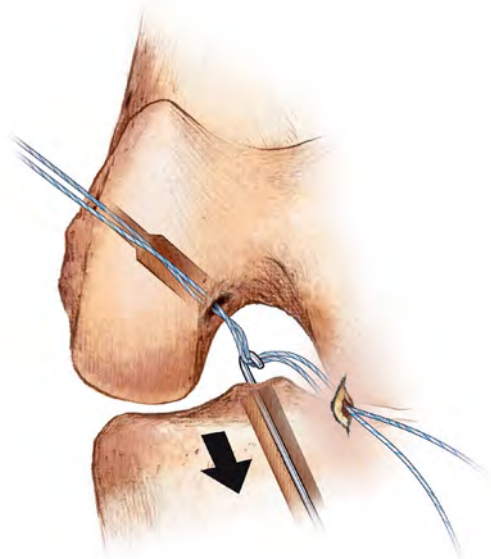


Figure 9

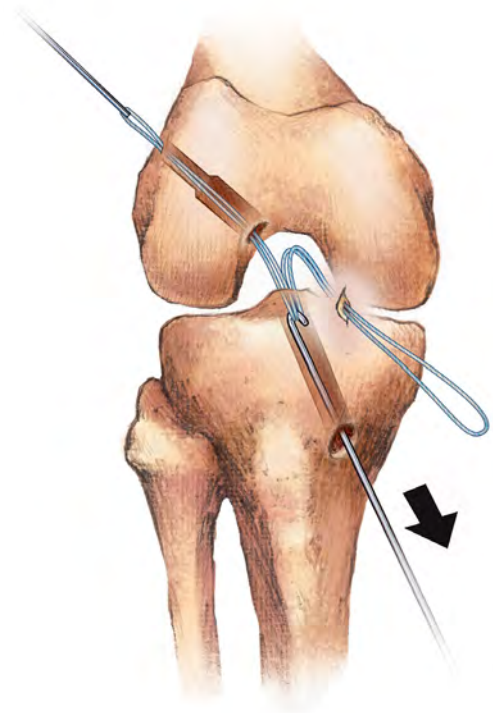


Figure 10

Tunnel Preparation (cont.)

Thread a strand of relay suture through the eyelet of the graft passing pin so that the suture forms a continuous loop (Figure 8). Pull proximally on the guide wire to pull the relay suture through the skin. Use a suture grasper or crochet hook to retrieve (Figure 9) the relay suture through the tibial tunnel (Figure 10).

Loop the passing suture (white #2 suture pre-loaded into the titanium button) of the ToggleLoc Femoral Fixation Device with ZipLoop Technology through the relay loop, 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.

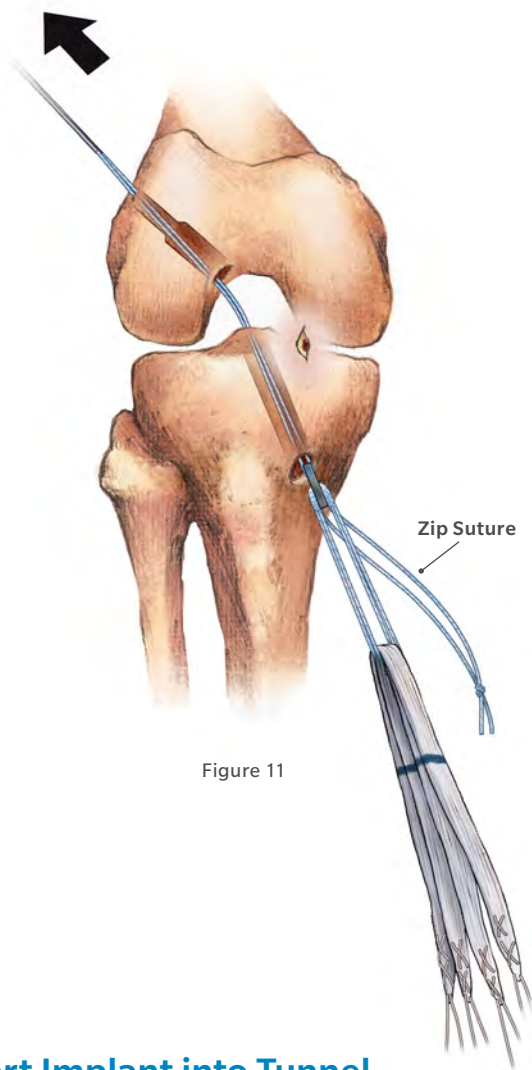


Figure 11

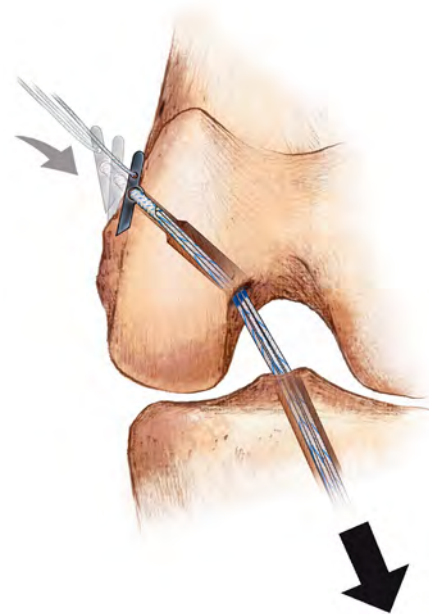


Figure 12

Insert Implant into Tunnel

Prior to fixation, 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 (Figure 11).

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 the lateral cortex of the femur (Figure 12). Pull on the distal end of the soft tissue grafts to feel the implant engage on the lateral femoral cortex, achieving femoral fixation.

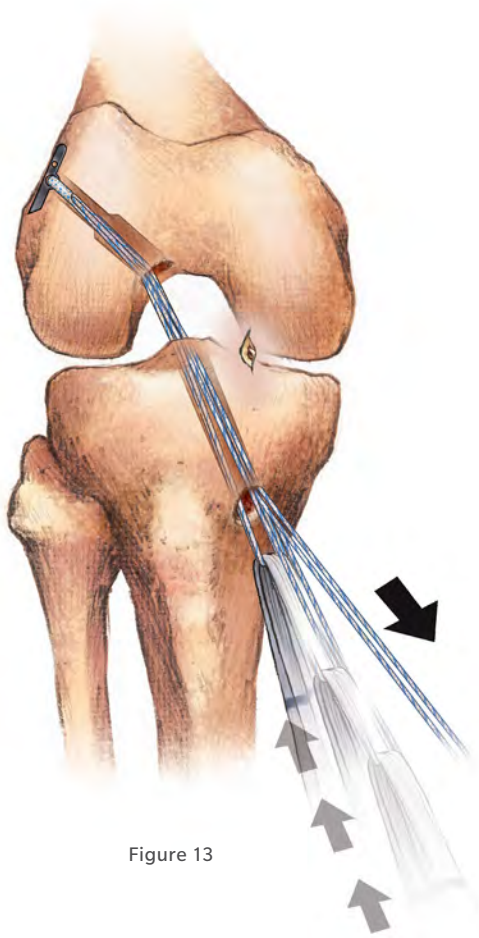


Figure 13

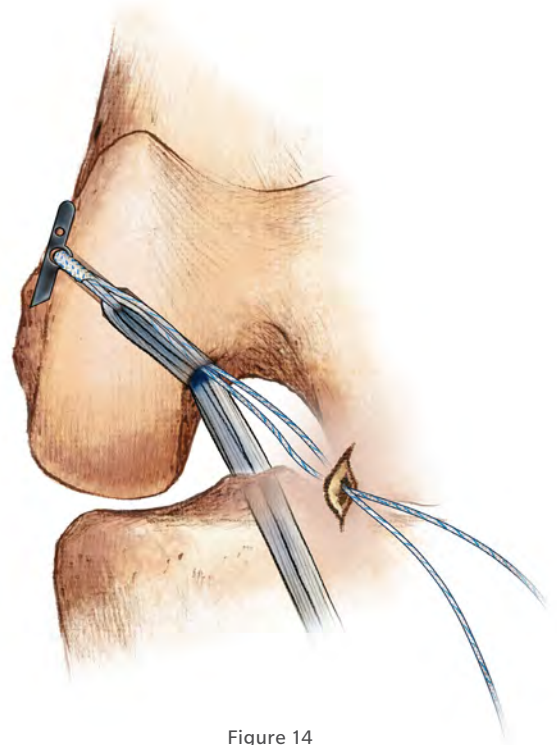


Figure 14

Position Graft in Femoral Tunnel

Ensure the “zip suture” is anterior to the graft. Place the knot of the zip strand into the ziploop puller (Figure 13) and pull distally to draw the graft through the tibial tunnel and into the 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.

Correct placement is indicated when the mark on the graft enters the femoral tunnel. Cut the knot off of the end of the “zip suture” and retrieve the cut suture limbs through the medial portal (Figure 14).

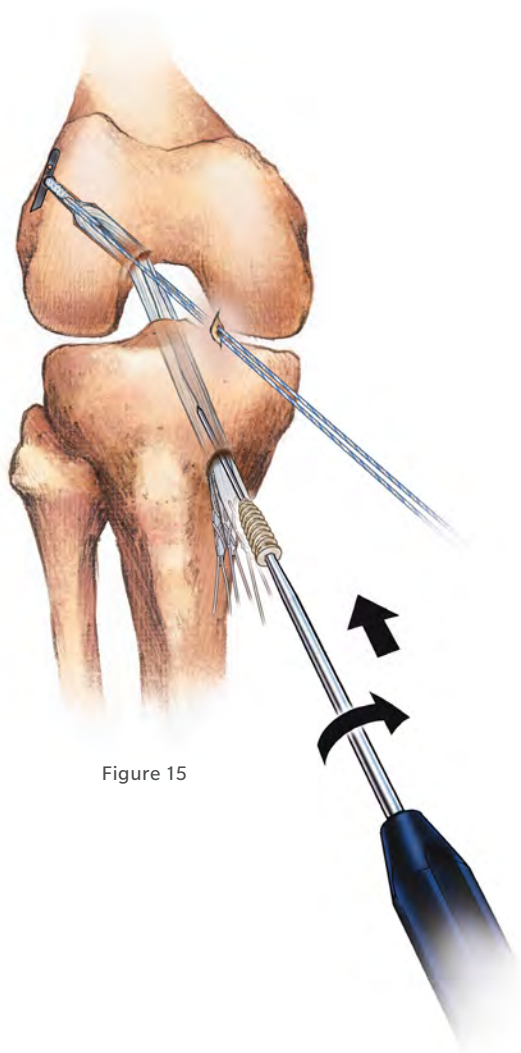


Figure 15

Tibial Fixation

Pass a 1.1mm nitinol guidewire through the tibial tunnel. Tap the tibial cortex if necessary and insert the desired ComposiTCP Interference Screw to achieve tibial fixation (Figure 15). If required, tension the femoral fixation by pulling on both limbs of the zip strand.

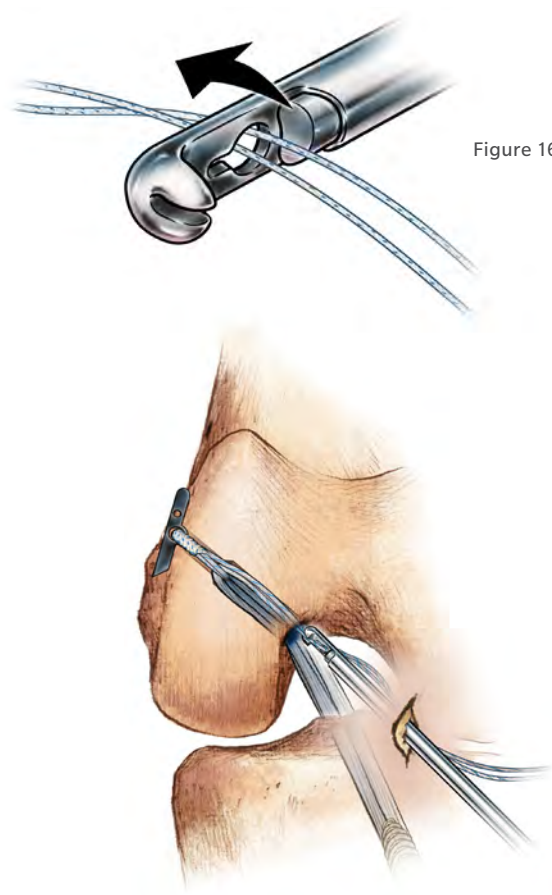


Figure 16

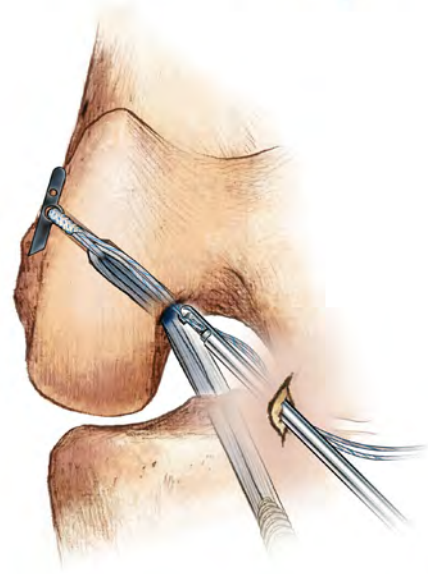


Figure 17

Sever the Zip Suture

Pass the limbs of the zip strand through the key shaped hole in the Super MaxCutter™ instrument (Figure 16). Advance the Super MaxCutter device through the medial portal and cut the suture at the entrance of the femoral tunnel in the joint space (Figure 17).

Ordering Information

Implants

Part Number	Size	Description
904755	–	ToggleLoc Femoral Fixation Device with ZipLoop Technology
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

Instrumentation

Part Number	Size	Description
909848	–	ToggleLoc Femoral Fixation Device with ZipLoop Technology Implant Kit
110007421	–	ToggleLoc Inline ACL Disposable Kit Includes: 3.2 Drill Bit ToggleLoc Inline Implant Graft Protector 4.5 mm Rigid ToggleLoc Drill Bit
		2.4 mm Drill Point K-Wire 1.1 mm Calibrated Nitinol Guide Wire Calibrated 3/32" x 16" Trocar Tip Pin
		Cannulated Bone Plug
110004607	7-8 mm	Modular Driver
905274	9-11 mm	Modular Driver
900342	–	Super MaxCutter Suture Cutter
904760	4.5 mm	Drill Bit (Disposable)
904765	4.5 mm	Drill Bit (Reuseable)
904766	–	ToggleLoc Depth Gauge
11004136	–	ToggleLoc ACL Disposable Kit Includes: 2.4 mm x 13" Drill Point K-Wire 2.4 mm x 16" Graft Passing Pin ToggleLoc 4.5 mm Drill Bit
		2.4 mm x 10" Drill Point K-Wire 1.1 mm x 14" Nitinol Guide Wire
		3.2 mm Drill Bit ACL Bone Plug
900716	–	Driver Bone Dowel Handle
900733	–	Driver Ratchet Handle
110004597	7-8 mm	Modular Tap
905278	9-11 mm	Modular Tap
905045	7-8 mm	Modular Dilator
905046	9-10 mm	Modular Dilator
906849	1.1 mm x 14"	Nitinol Wire
906852	1.1 mm x 9"	Nitinol Wire
900300	–	Instrument Case

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
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.

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 severe 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. Aunoble S; Clement D; Frayssinel P; Harmand M; Le Heuc J; "Biological performance of new B-TCP/PLLA composite material for applications in spine surgery: In-vitro and In-vivo studies" Journal of Biomedical Research Part A, January 2006. Animal testing not necessarily indicative of clinical performance in humans.

This material is intended for health care professionals and the Zimmer Biomet sales force only. Distribution to any other recipient is prohibited. All content herein is protected by copyright, trademarks and other intellectual property rights owned by or licensed to Zimmer Biomet or its affiliates unless otherwise indicated. This material must not be redistributed, duplicated or disclosed, in whole or in part, without the express written consent of Zimmer Biomet.

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 Zimmer Biomet's website.

This technique was prepared in conjunction with a licensed health care professional. Zimmer 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.

Science for Biomaterials (SBM) is the manufacturer of the ComposiTCP Interference Screws. Zimmer Biomet Sports Medicine is the distributor.

Not for distribution in France.

©2017 Zimmer Biomet



Authorized Representative

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



ZIMMER BIOMET

Your progress. Our promise.™



Legal Manufacturer

Biomet Sports Medicine
P.O. Box 587
56 E. Bell Drive
Warsaw, Indiana 46581-0587
USA

www.zimmerbiomet.com

CE 0086

CE mark on a surgical technique is not valid unless there is a CE mark on the product label.