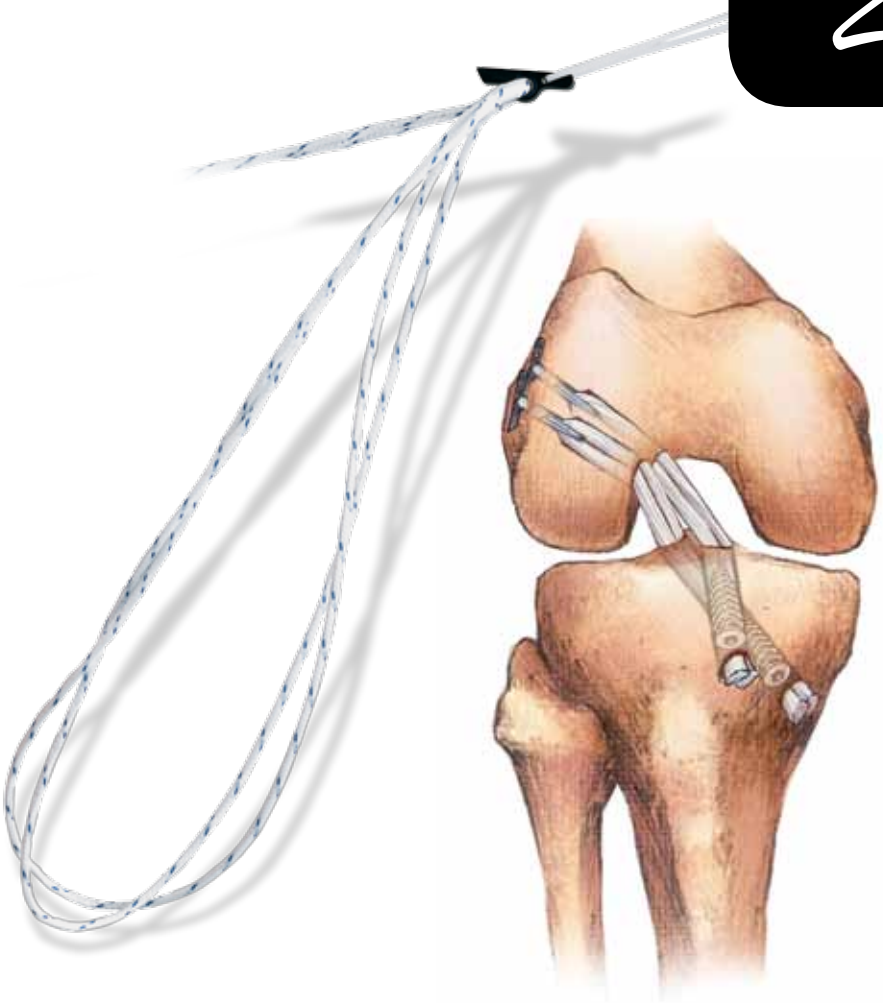
ToggleLoc™
FIXATION DEVICE

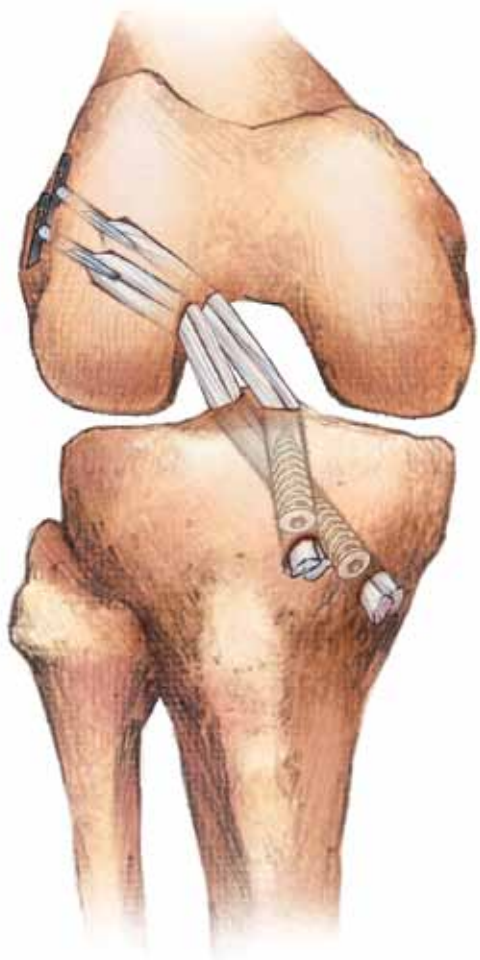
with ZipLoop™ TECHNOLOGY



ACL Reconstruction

Two Tunnel Method
Surgical Protocol by
Howard Freedberg, M.D.

BIOMET®
SPORTS MEDICINE



ZipLoop™ TECHNOLOGY

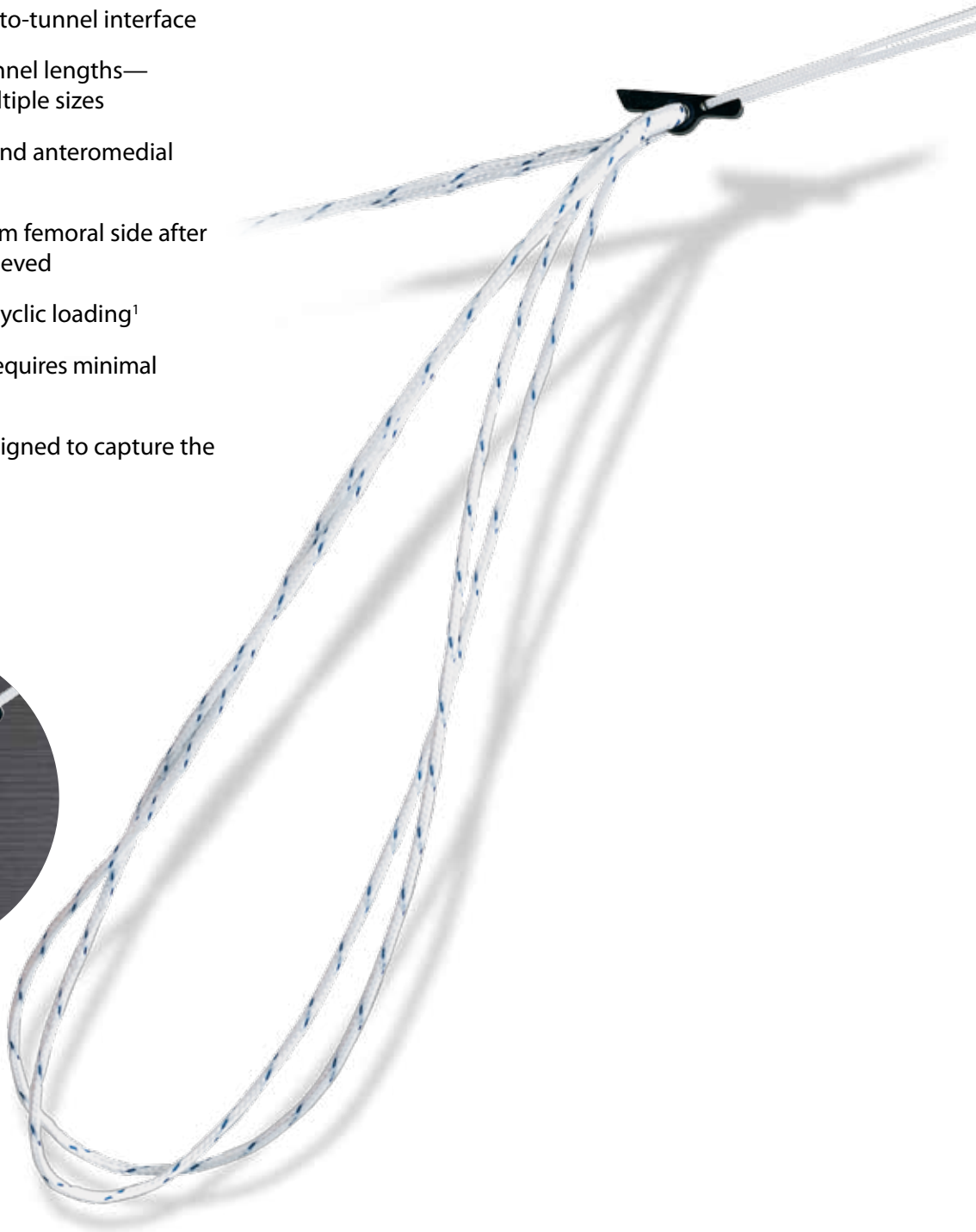
Features

- 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[1].

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[1]
- Simple surgical technique requires minimal instrumentation
- Femoral fixation device designed to capture the cortical bone of the femur



New… from Biomet Sports Medicine

ComposiTCP™
INTERFERENCE SCREW

Features

- Procedure-specific composite mix for both soft tissue and bone-tendon-bone grafts
- Unique star-shaped drive mechanism that limits stress and distributes torque evenly through the screw during insertion[1]

Unique star-shaped drive mechanism

ComposiTCP™ 30 Interference Screw

- Made with a composite blend of 70% PLDLA and 30% beta Tri-Calcium Phosphate—designed for both bone-tendon-bone and soft tissue fixation

ComposiTCP™ 60 Interference Screw

- Made from a composite material with an innovative blend of 40% PLDLA and 60% beta Tri-Calcium Phosphate—designed for soft-tissue fixation

The results reported in an *in-vivo* animal study[2] showed that "in comparison with pure PLA, TCP-containing composite materials had faster degradation kinetics, caused less inflammatory reaction, and promoted contact osteogenesis."

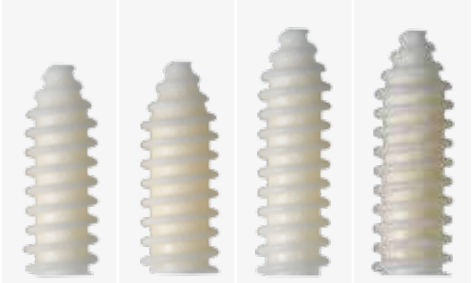
The ComposiTCP™ 60 Interference Screw has more osteoconductive material (TCP) than it does resorbable polymer. Increased amounts of TCP have been shown in an *in-vitro* study[1,2] to stimulate the proliferation of osteogenous cells.

Sizing

Round Head

7 x 20mm	7 x 25mm	8 x 25mm	8 x 30mm	9 x 25mm	9 x 30mm	9 x 35mm

Fully Threaded



10 x 30mm	10 x 35mm	11 x 30mm	11 x 35mm

Surgical Technique

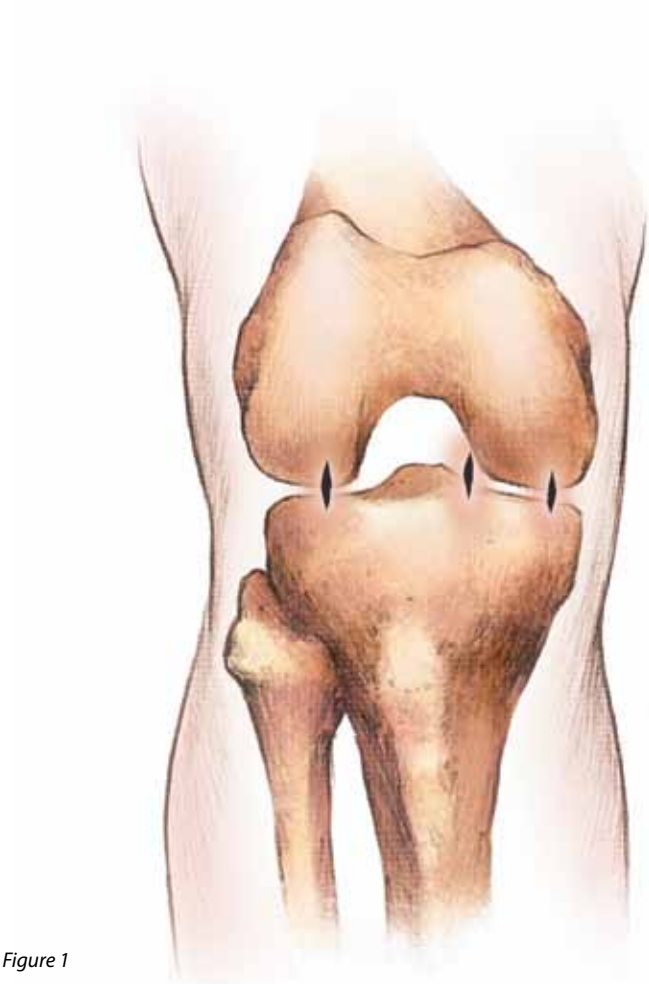


Figure 1

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 anterior medial (AM) and posterior lateral (PL) femoral tunnels. Identify the soft spot anterior to the confluence of the medial tibial plateau and medial femoral condyle. This feels like the apex of a triangle. Place a spinal needle through the soft spot and toward the notch to verify the position of the accessory medial portal (Figure 1). Next, size the grafts for both the AM and PL bundles. Typically, the AM bundle is 6–8mm in diameter, while the PL bundle is 5–7mm.

Figure 3

Figure 2a

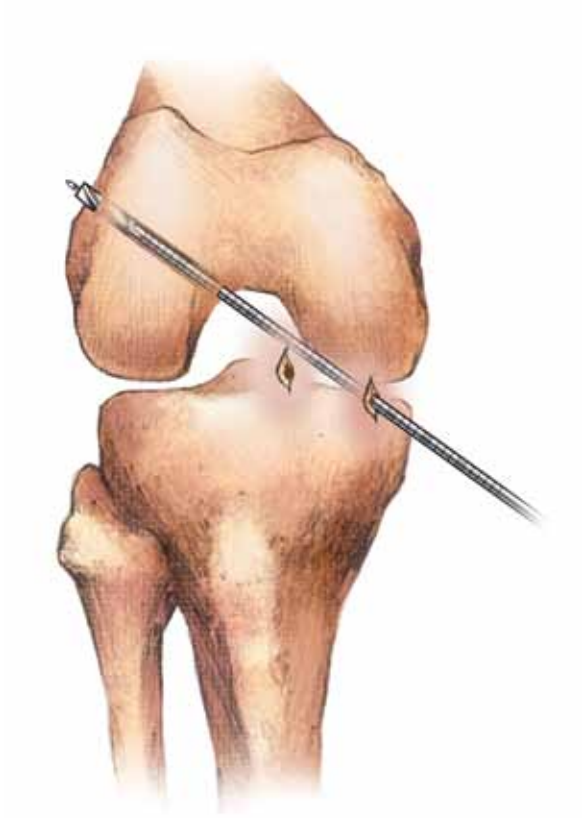


Figure 4

AM Femoral Tunnel Preparation

Clean the lateral femoral condyle by removing the stump using electrocautery. If an acute ACL rupture is identified, the stump can be left intact to aid in visualization of the AM and PL bundles. Debride any remaining soft tissue from the over-the-top position using a cupped curette or electrocautery through the medial portal or the accessory medial portal. Assess the width of the intercondular notch. A wallplasty is performed if the notch is excessively tight, which generally occurs only in the case of a chronically deficient ACL which produces a notch stenosis. Wallplasties are rarely needed with this technique.

Position an AM Tunnel Femoral Aimer into the over-the–top position through the accessory medial portal (Figures 2a & b). Position and hold the knee at 110 degrees of flexion. This will allow a 10:00 or 2:00 position of the tunnel. Additional flexion of the knee will dial the AM tunnel "down" further the clock. The arthroscope is placed into the joint through the standard medial portal to aid in visualization. Drill a calibrated guide wire through the Femoral Aimer and the lateral cortex of the femur (Figure 3). Drill over the previously placed guide wire with the 4.5mm ToggleLoc™ drill bit through the lateral cortex of the femur (Figure 4).

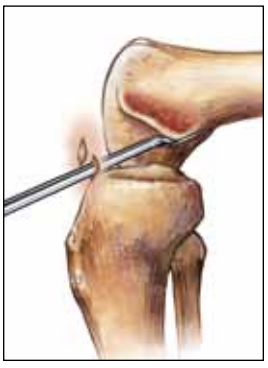


Figure 2b

Figure 5

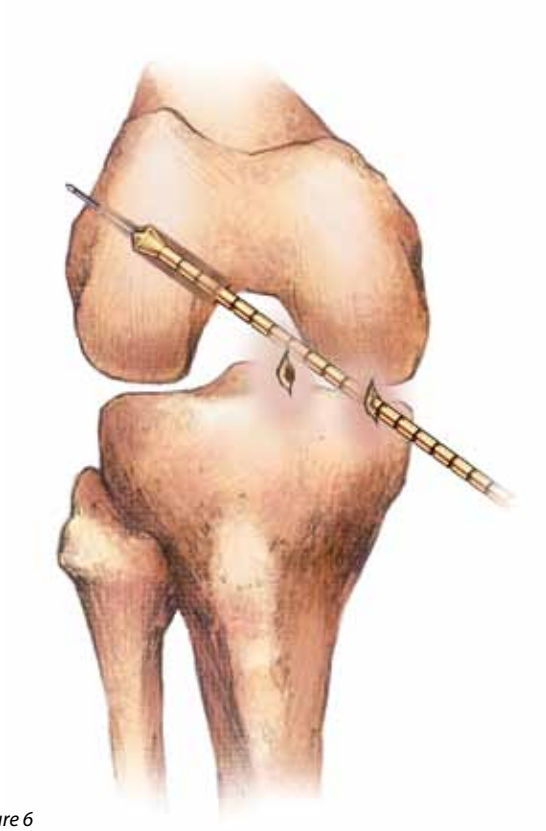


Figure 6

AM Femoral Tunnel Preparation (continued)

Remove the guidepin and measure the overall length of the AM tunnel using a depth probe (Figure 5). Insert the guidepin back into the AM 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 6). Make sure the endosopic reamer does not break the lateral cortex.

Note: When the knee is hyperflexed outflow will dramatically decrease, potentially causing poor visualization. To address this problem, either put an open mouthed shaver in the lateral portal and use as suction, or use a double port arthroscopic cannula and allow egress of fluid through the unused port when needed. If there are no guidewires in place, extending the knee will allow the egress of fluid.

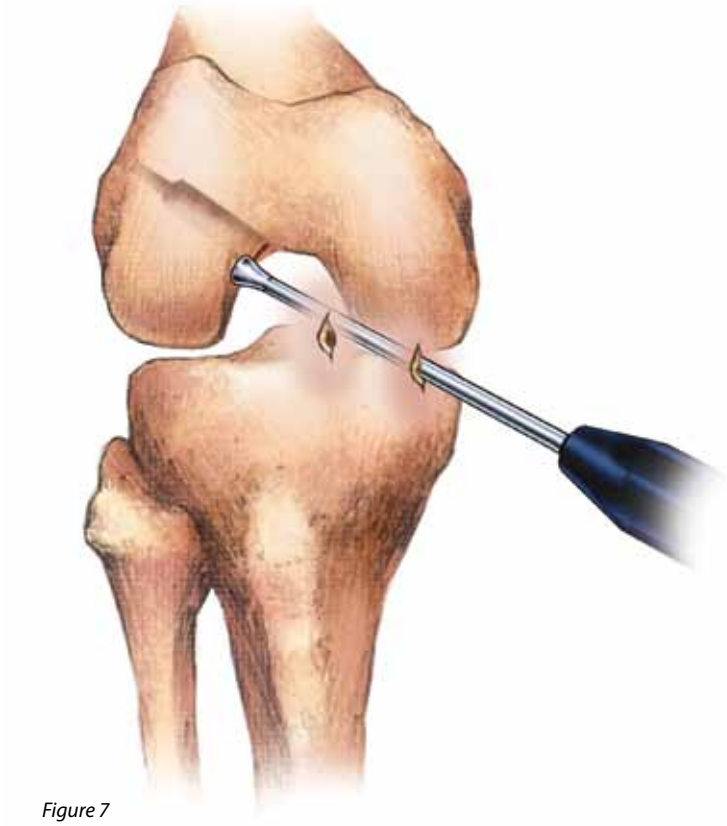


Figure 7

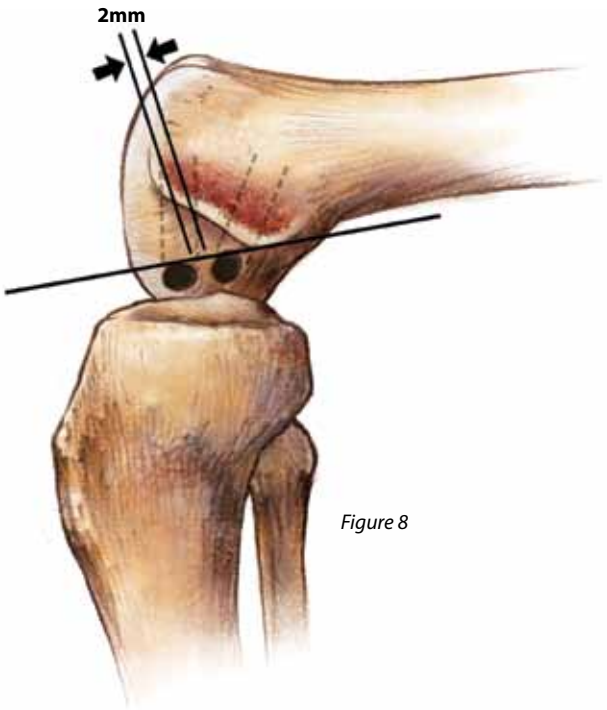


Figure 8

PL Femoral Tunnel Preparation

Position a PL Tunnel Femoral Aimer into the appropriate position on the lateral wall of the femur, utilizing the accessory medial portal (Figure 7). With the knee at 90 degrees of flexion and the thigh parallel to the ground, the PL tunnel is 10 degrees inferior to the AM femoral tunnel (Figure 8). The position is identified under direct visualization, ensuring that a 2mm bone bridge is visible between the AM and PL tunnels. Position and hold the knee at 130 degrees. Drill a calibrated guide wire through the Femoral Aimer and the lateral cortex of the femur (Figure 9).

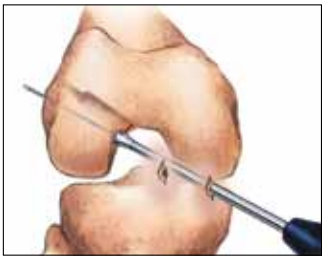


Figure 9

Drill over the previously placed guide wire with the 4.5mm ToggleLoc™ drill bit drilling through the lateral cortex of the femur. Remove the guidepin and measure the overall length of the PL Tunnel using a depth probe. 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 10). Make sure the endosopic reamer does not break the lateral cortex.

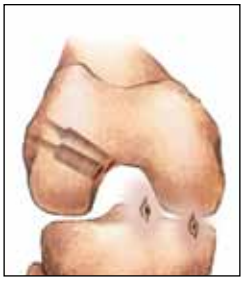


Figure 10

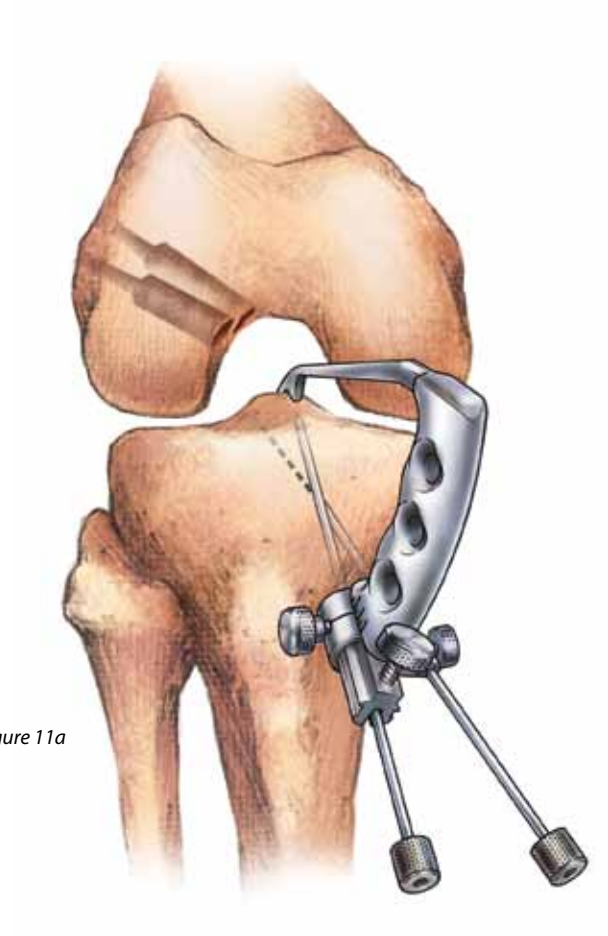


Figure 11a

Figure 11b

Tibial Tunnel Preparation

Assemble the double tunnel tibial guide by placing the outrigger on the foot of the guide. The outrigger position is set by adding the tunnel diameters for both the AM and PL femoral tunnels and setting the outrigger to etch line corresponding to the sum (Figure 11a & b). Insert the tip of the guide into the joint through the medial portal. The arthroscope will be in the standard lateral portal. Identify the anatomic insertion points of the AM and PL bundles of the ACL on the tibial plateau and place the alignment points of the guide in the center of each bundle. Note: The PL alignment point should be immediately adjacent to the anterior border of the lateral meniscus.

Make a transverse incision three finger breadths below the joint-line. This is the incision used to harvest the autogenous semitendinosus and gracilis graft. Insert the bullets for the AM and PL guidepins into the guide and place each one against the skin. Drill the AM tibial guidepin into the bone approximately 1 in. The AM tunnel should start approximately 1cm medial to the tibial tubercle. Repeat the process with the PL tunnel guidepin. The guidepin will act to stabilize the guide.

Note: The AM alignment point should be immediately adjacent to the intercondylar roof with the knee in full extension. This will ensure the AM graft will not impinge on the roof while in full extension.

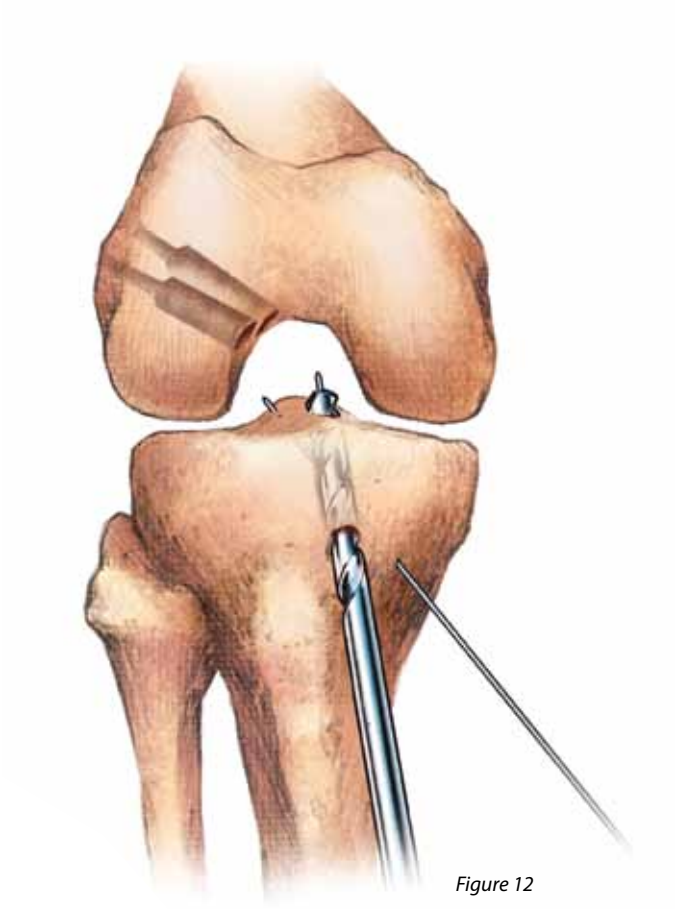


Figure 12

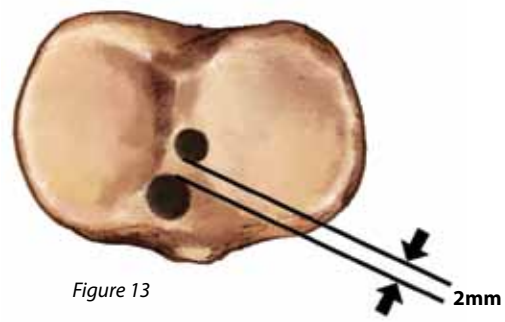


Figure 13

Check the position of the guidepin at this time and make corrections if necessary. Once each guidepin is in position, first advance the AM guidepin through the cortex followed by the PL guidepin. Remove the double tunnel tibial guide from the joint by first removing the bullets, then removing the outrigger, and finally removing the body of the tibial guide. Assess the position of each guidepin. Finally, ream the AM and PL tibial tunnels with the corresponding cannulated endoscopic reamers.

Confirm a bone bridge of approximately 2cm between the AM and the PL tunnels distally (Figure 12). Remove any debris from the aperture of the tibial tunnel to facilitate graft passage. Confirm a bone bridge of approximately 2mm between the AM and PL tibial tunnels proximally (Figure 13).

Note: The position of the AM and PL tunnels may not be indicative of the exact locations during this procedure. The distal and proximal tunnel landmarks have been illustrated for easy identifcation.

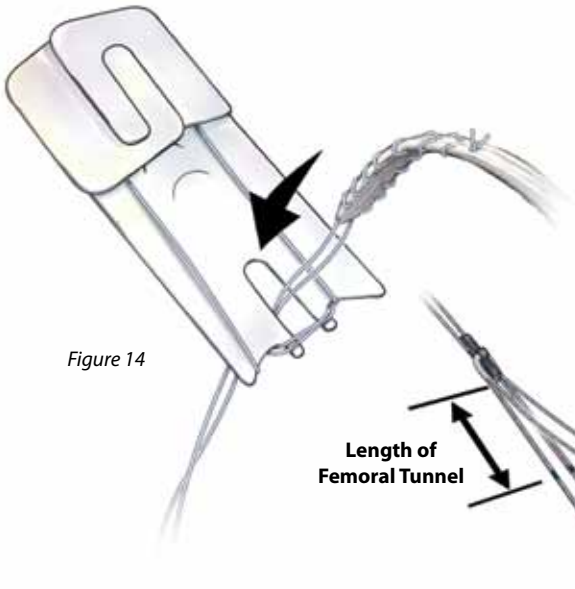


Figure 14

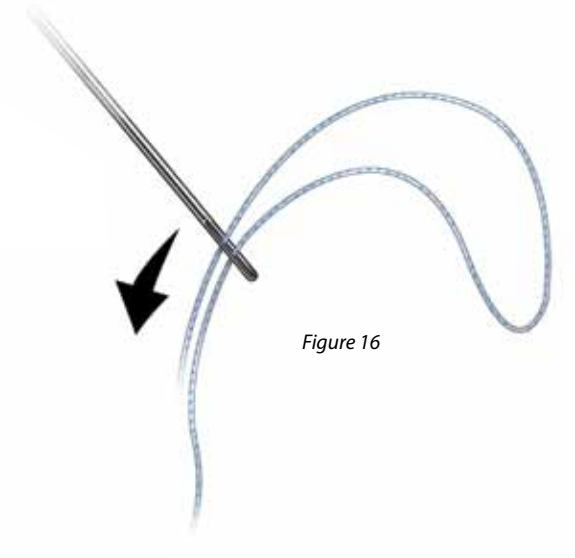


Figure 16

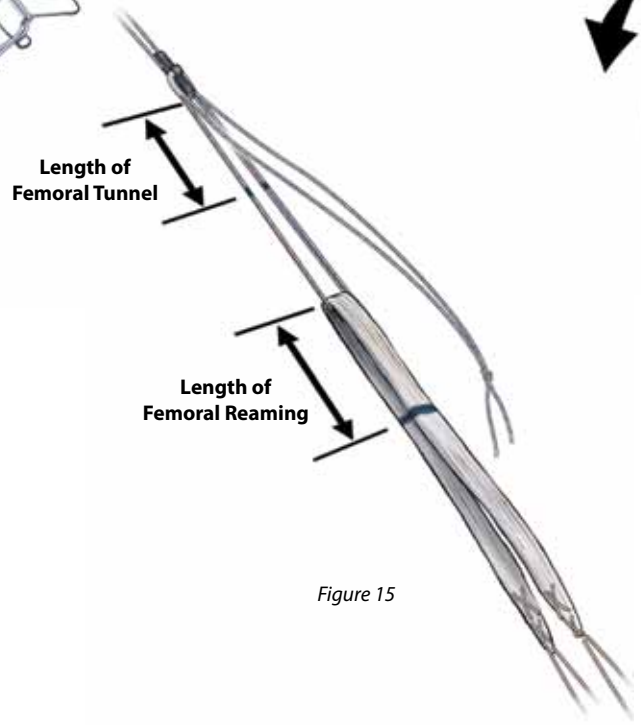


Figure 15

Prepare the Graft

Pass the soft tissue graft for the AM tunnel through both loops of the ToggleLoc™ Femoral Fixation Device with ZipLoop™ Technology (Figure 14). The implant should be left in the white 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 with a surgical marker (Figure 15).

Make a mark on the graft that corresponds to the previously reamed depth of femoral socket. This mark will aid in optimal graft positioning later in the procedure. Repeat this process with the PL soft tissue graft.

Thread a strand of relay suture through the eyelet of the graft passing pin so that the suture forms a continuous loop (Figure 16).

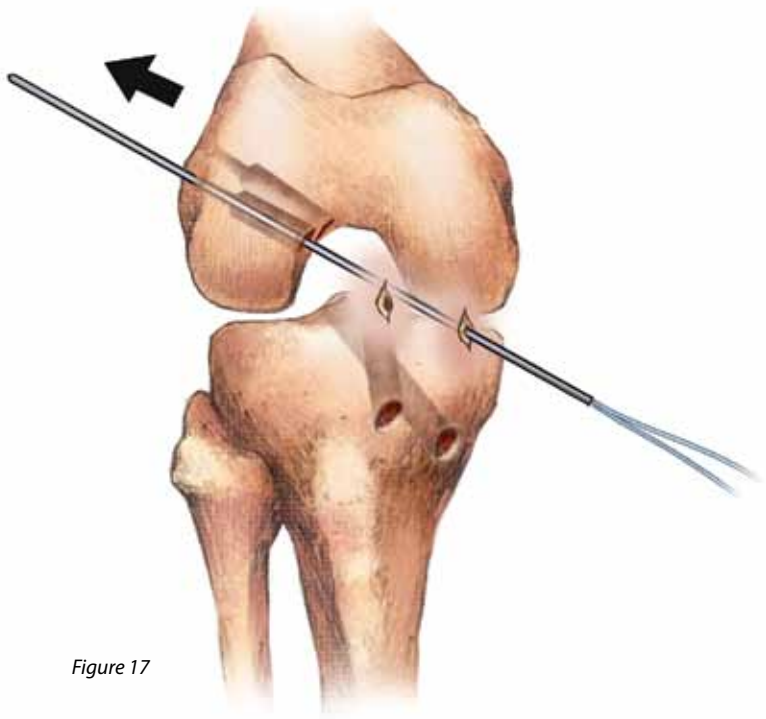


Figure 17

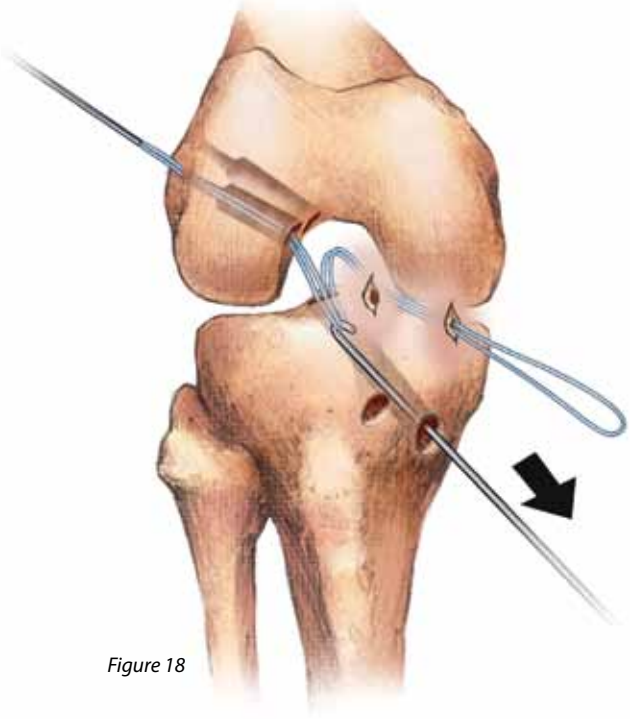


Figure 18

Passing the Relay Suture

Pass the guidepin through the accessory medial portal out the posterior lateral femoral tunnel and pull proximally on the guide wire to pull the relay suture through the skin (Figure 17).

Note: Using different colored suture for the relay suture in each portal may aid in suture management.

Use a suture grasper or crochet hook to retrieve the relay suture through the PL tibial tunnel (Figure 18). Repeat this process for the passing of the AM suture relay. 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 corresponding to the posterior lateral 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.

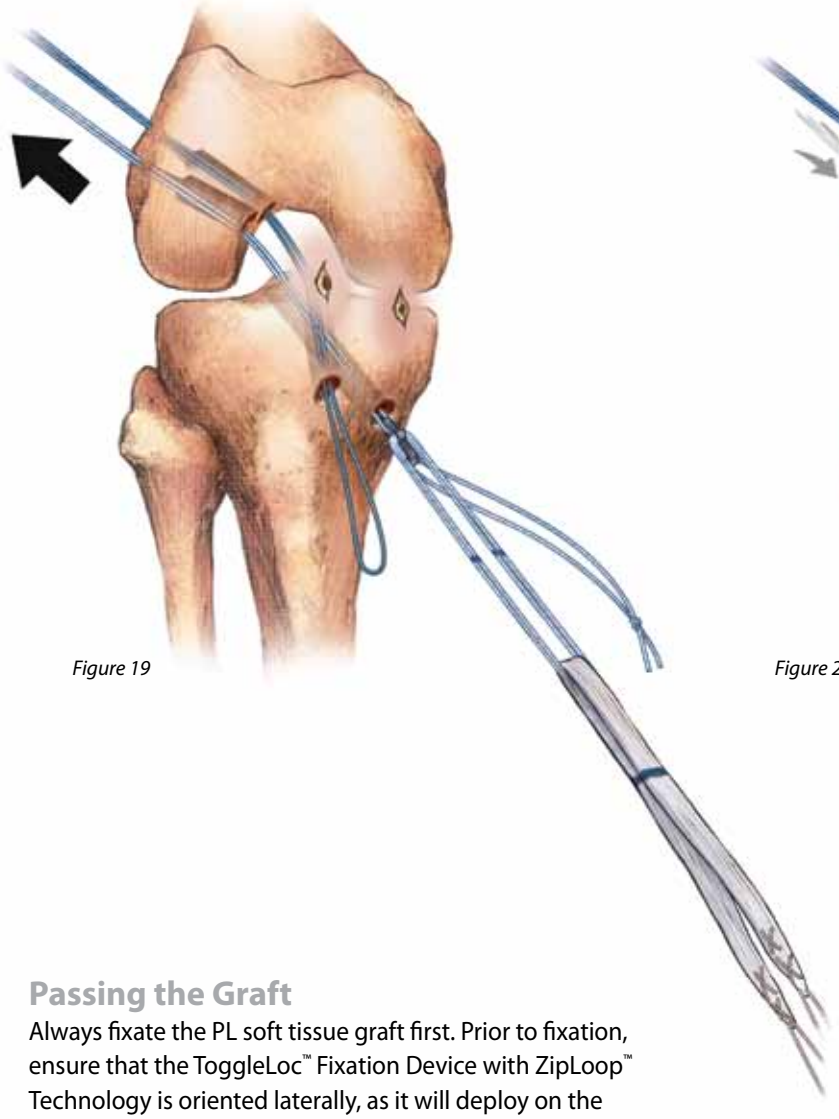


Figure 19

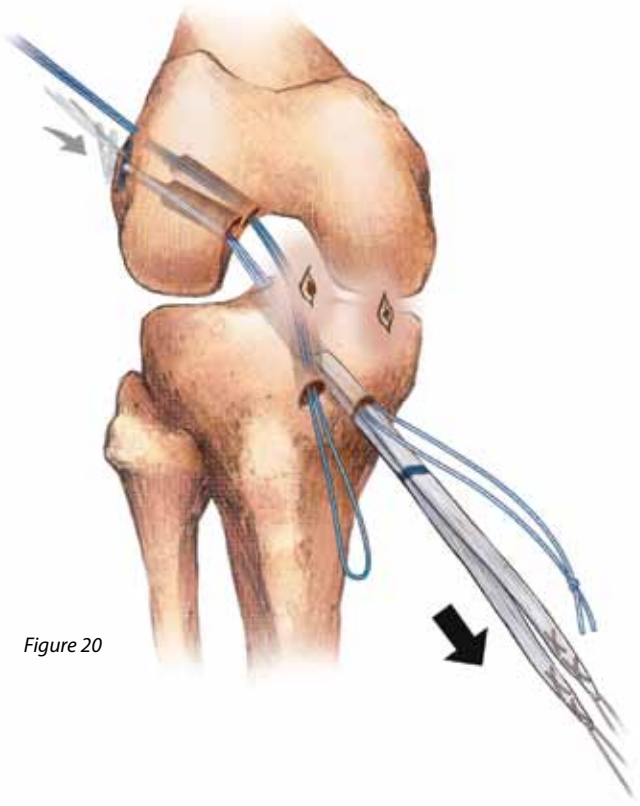


Figure 20

Passing the Graft

Always fixate the PL soft tissue graft first. Prior to fixation, ensure that the ToggleLoc™ 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 19). 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 20). Pull on the distal end of the soft tissue grafts to feel the implant engage on the lateral femoral cortex, achieving femoral fixation.

Note: Be sure to firmly hold the suture exiting the femoral tunnel as the graft is being pulled into the tunnel until the anchor deploys on the cortical bone.

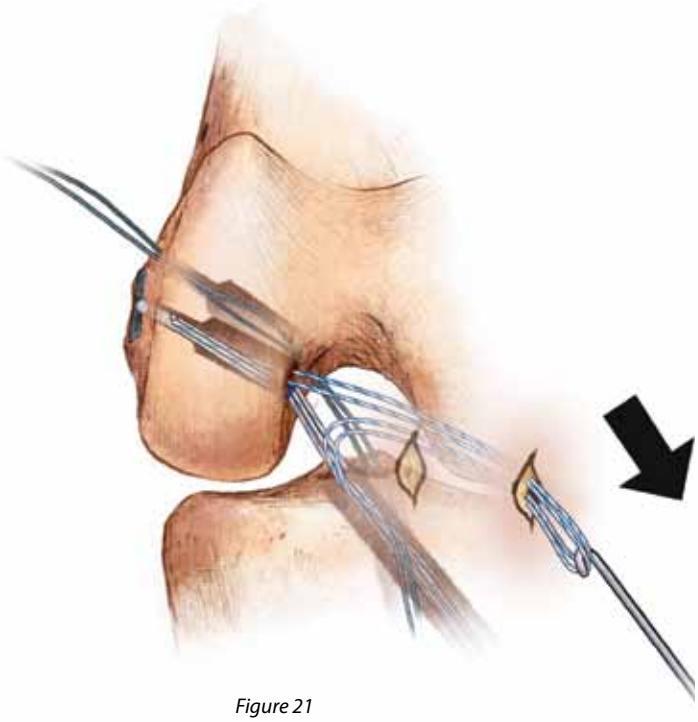


Figure 21

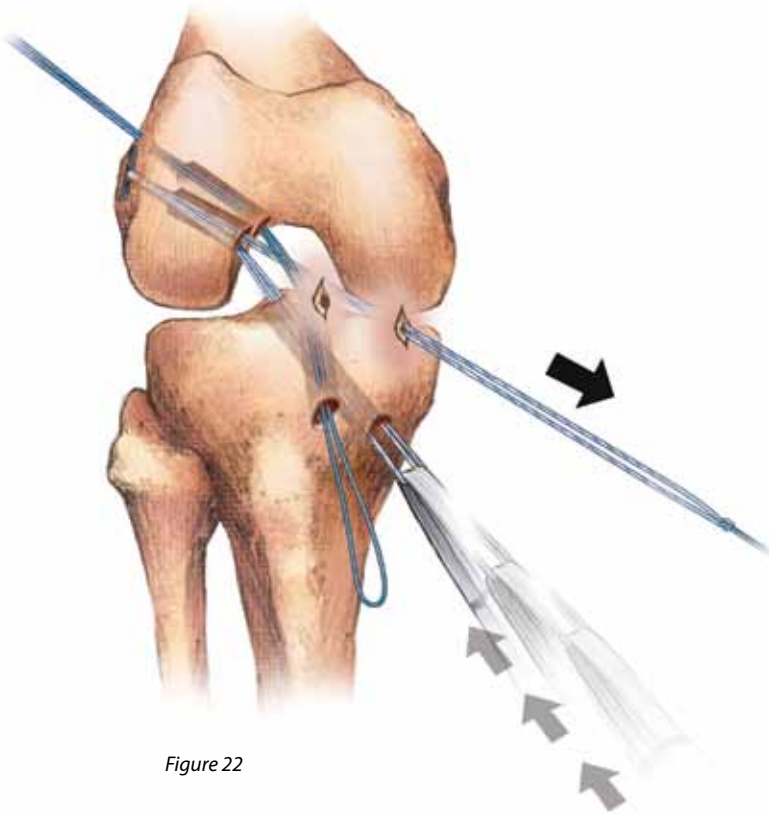


Figure 22

Retrieve the zip suture from the joint through the accessory medial portal using a suture grasping device (Figure 21). 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 (Figure 22). 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 23). Correct placement is indicated when the mark on the graft enters the femoral tunnel. If the tunnel is excessively long, the graft may be zipped just short of the mark entering the femoral tunnel. If retensioning is desired after the tibial fixation, the zip suture should remain. If not, the zip suture can be cut at this time to reduce the amount of suture in the joint space. Repeat this process for the AM soft tissue graft.

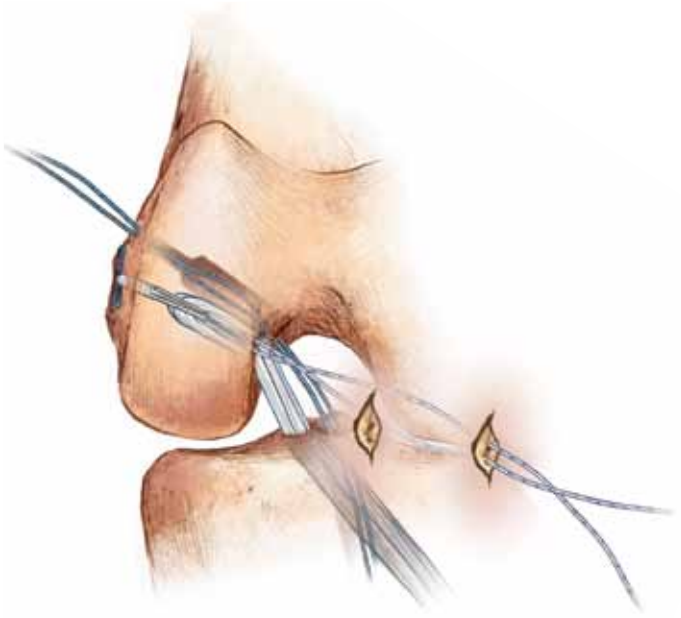


Figure 23

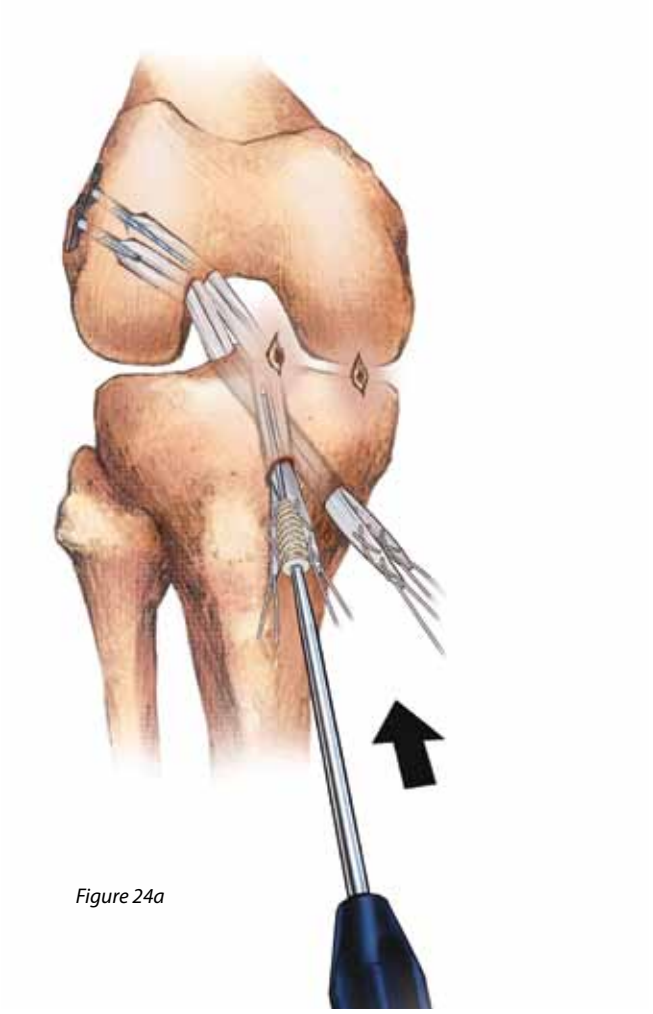


Figure 24a

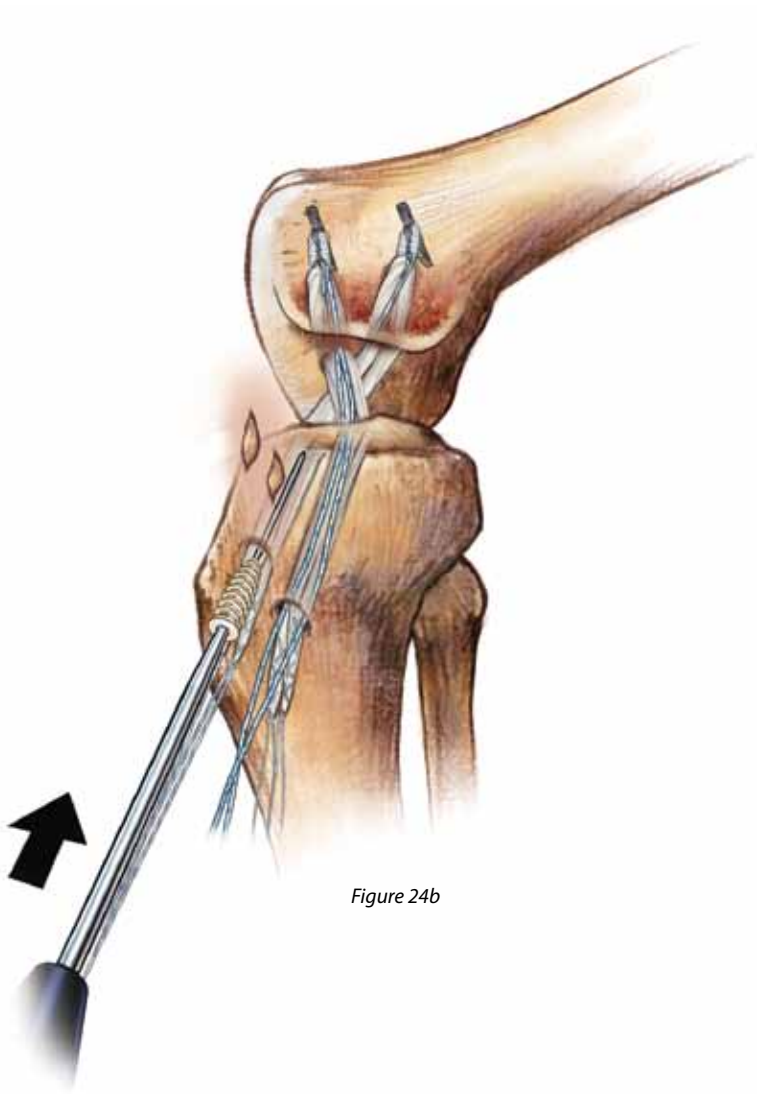


Figure 24b

Complete ACL Double Bundle Graft Fixation

Tension the AM soft tissue graft, flex the knee to 60 degrees and pass a Nitinol guidewire through the AM tibial tunnel. Insert a ComposiTCP™ Interference Screw to achieve AM tibial fixation (Figures 24a & b).

Note: For the screw in the PL tunnel, it may be necessary to dilate the tunnel to prevent cutting the graft.

Next, tension the PL soft tissue graft while fully extending the knee.

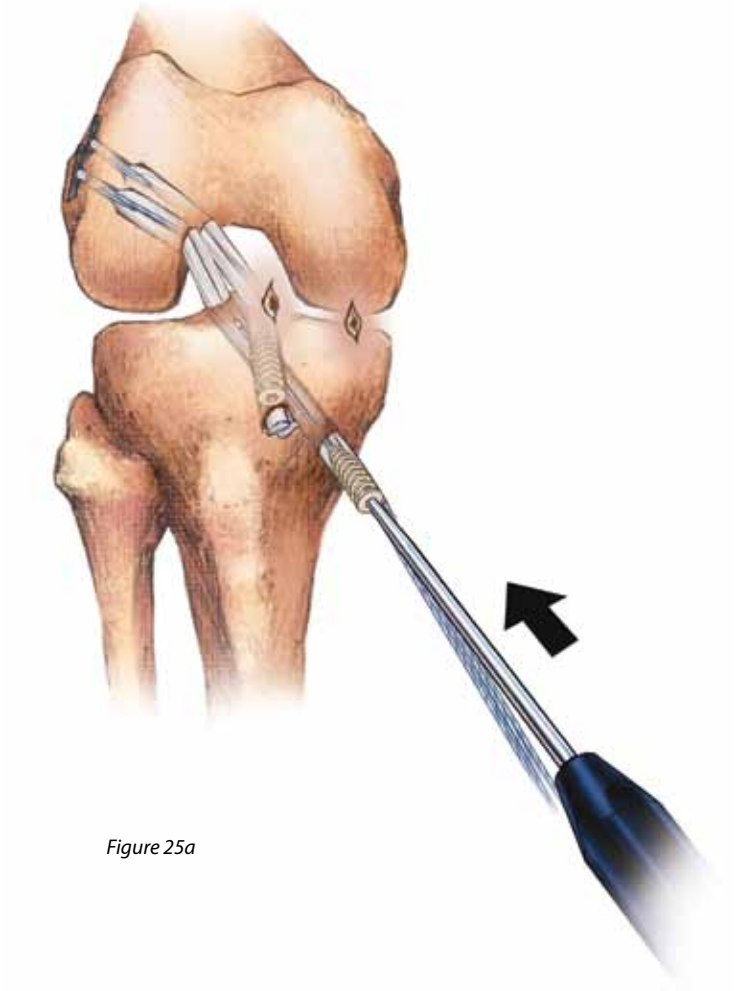


Figure 25a

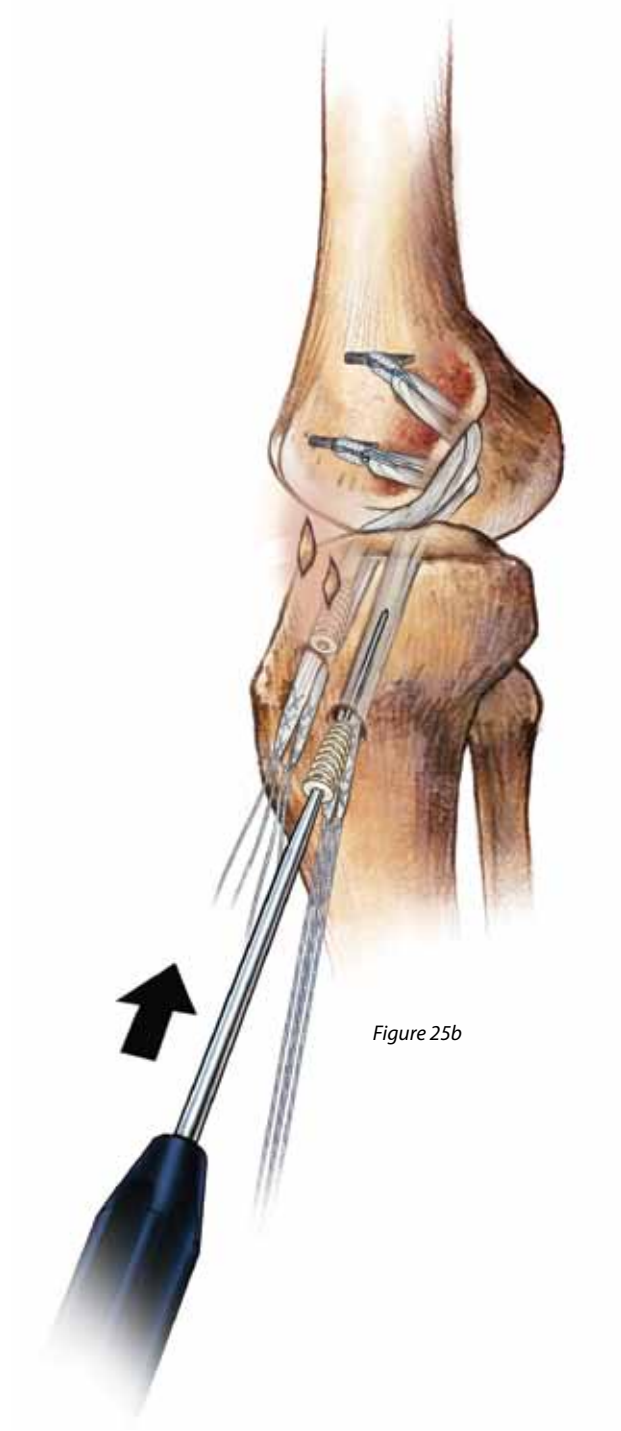


Figure 25b

Pass a nitinol guidewire through the PL tibial tunnel and insert a ComposiTCP™ Interference Screw to achieve tibial fixation (Figures 25a & b).

Optional: The free ends of the grafts my be sutured together on the exterior of the tibia to allow for adjunctive fixation.

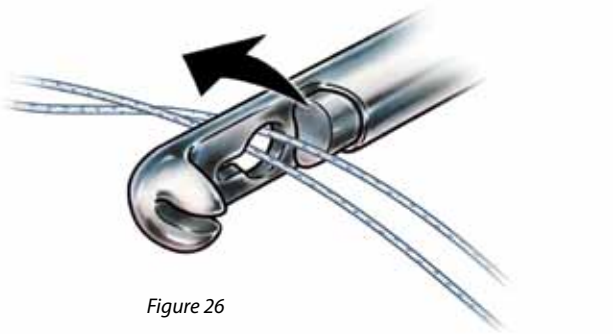


Figure 26

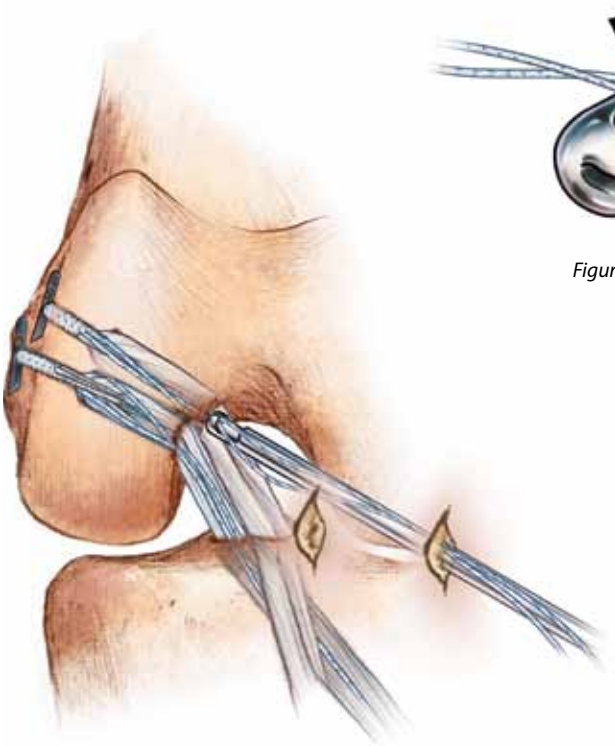


Figure 27

Trim Zip Strand

If required, the femoral fixation for either the AM or PL grafts can be re-tensioned by pulling on both limbs of the zip strand for the appropriate graft. Pass the limbs of the zip strand for the AM bundle through the key shaped hole in the Super MaxCutter™ instrument (Figure 26). Advance the Super MaxCutter™ through the medial portal and cut the suture at the entrance of the femoral tunnel in the joint space (Figure 27). Repeat this process for the PL bundle. Fixation is now complete (Figure 28).

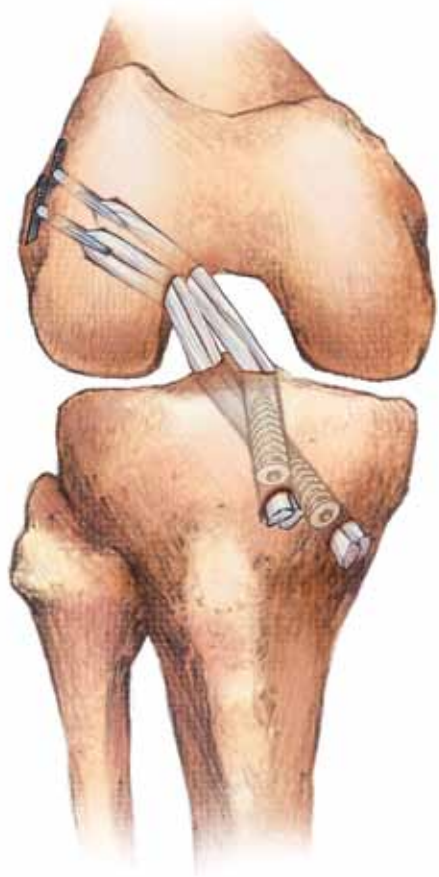


Figure 28

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
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

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.

Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estate
Bridgend, South Wales
CF31 3XA, U. K.

CE 0086
Manufacturer
Date of Manufacture
Do Not Reuse
Consult Accompanying Documents
STERILE EO Sterilized using Ethylene Oxide
STERILE R Sterilized using Irradiation
STERILE Sterile
STERILE A Sterilized using Aseptic Technique
STERILE Sterilized using Steam or Dry Heat
Expiry Date
WEEE Device
REF Catalogue Number
LOT Lot Number
Flammable

The information contained in this package insert was current on the date this brochure was printed. However, the package insert may have been revised after that date. To obtain a current package insert, please contact Biomet Sports Medicine at the contact information provided herein.

Package Insert

ComposiTCP™ 30
INTERFERENCE SCREW

Resorbable Interference Screw

User undertaking:
The user acknowledges having read these instructions, and undertakes to abide by them.

Materials:
DUOSORB™: 30% β-TriCalciumPhosphate / 70% Poly D Lactic Acid composite.

Indications:

The ComposiTCP™ 30 Interference Screw is designed for the interference fixation of bone-patellar tendon bone grafts in anterior cruciate ligament construction. 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™ 30 Interference Screw should be implanted using a dedicated screwdriver contained in the instrumentation set.

Contra-indications:
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.

Adverse side effects:
To date, no adverse effects have been observed and reported.

Surgical precautions:
The use of the ComposiTCP™ 30 Interference Screw requires sound knowledge of the anatomy and biomechanics of the knee joint, and of locomotor apparatus reconstruction surgery. Surgeons wishing to use the device must have been appropriately trained. The patient must be informed of the need for temporary restriction of activities and of the precautions to be taken following the insertion of the screw.

Recommendations for use:
1. The ComposiTCP™ 30 Interference Screws must be used only for ligament reconstruction.
2. Until graft healing is complete, fixation by means of this device should be considered to be temporary, and the construct must not be subjected to excessive loading or other stress. Early stress on the screw or premature resumption of activity may lead to backing-out, bending, breakage or displacement of the screw. For this reason, appropriate immobilization, followed by supervised mobilization, will be required for a period of 4 to 6 weeks after surgery, or until there is clinical evidence of graft healing.
3. The ComposiTCP™ 30 Interference Screws must be completely buried below the joint surface.
4. The ComposiTCP™ 30 Interference Screws must be screwed in thanks to a specific screwdriver. No other screwdriver, however similar in appearance, must be used, since doing so may lead to screw breakage.
5. The diameter of the drill hole in the bone must be chosen as a function of the diameter of the intented screw. Thus, an 8-mm ∅ screw requires a 9-mm ∅ drill hole ; a 9-mm ∅ screw, a 10-mm ∅ drill hole ; a 10-mm ∅ screw, an 11-mm ∅ drill hole ; and an 11-mm ∅ screw, a 12-mm ∅ drill hole.
6. Guide wire must not be twisted or bent prior to screw insertion, since doing so may impede screw insertion or result in screw breakage.
7. The ComposiTCP™ 30 Interference Screws must not be cut or altered under any circumstances.
8. Screwdriver must not be subjected to bending stress.

Recommendations for devices supplied sterile:
The ComposiTCP™ 30 Interference Screws have been Gamma-sterilized (dose 25 kGy). Prior to use of the device, the "sterile until" date on the packaging should be checked. SBM accepts no responsibility or liability for the use of products that are past their expiry date. The packaging should be checked for defects prior to use of the device. If inspection shows the packaging to be damaged, the product must be assumed to be non-sterile. The ComposiTCP™ 30 Interference Screws must not be re-sterilized. Any screws that have been removed from their packaging and remained unused must be discarded.

Packaging:
ComposiTCP™ 30 Interference Screws are supplied individually packaged in double peel-open packs. Prior to the use of the device, the integrity of the packaging must be checked. All the information required by law is given on the box or the label attached to the packaging.

Storage conditions:
ComposiTCP™ Interference Screws are to be stored at ambient temperature (15-30°C / 60-85°F), and normal relative humidity (50-80%). Storage conditions must be such as not to compromise the integrity of the packaging.

Instrument:
Screwdriver for ComposiTCP™ Interference Screws ø 7,8-mm is Ref. 905271, 905273 or LIG9008046.

Screwdriver for ComposiTCP™ Interference Screws ø 9,10,11-mm is Ref. 905272, 905274 or LIG9009017.

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. It is recommended that all instruments be regularly inspected for wear and disfigurement.

Guarantee:
The manufacturer's guarantee does not apply unless the device is used under the normal conditions specified in these instructions.

Reporting of adverse events:
Any person handling the device (in a commercial or a health-care capacity) that has found the service provided by SBM and/or the quality, labeling, reliability, safety, efficacy and/or the performance of SBM products wanting in any way should notify the SBM representative or distributor.

The representative or distributor should pass the complaint on to the SBM Quality Manager as quickly as possible, using an adverse event report form. The minimum information to be provided on this form should be: product description, catalogue number, batch number, the nature of the complaint or a detailed description of the adverse event and its consequences for the patient and/or the user. Any evidence that would further the investigation (the implant concerned, X-rays, etc…) should be sent with the form. If poor function or deterioration of an implant, or any fault in the instructions for use have led to a patient's or an end user's health being damaged, this event should be reported immediately by phone or fax.

Disposal:
The device should be disposed of observing the precautions that apply to operating room waste.

Distributor: Biomet, Sports Medicine, Inc., 56 East Bell Drive, PO Box 587, Warsaw, IN 46581 USA.

Manufactured By: S.B.M., ZI du Monge – 65 100 LOURDES France

Tel : +33 (0) 5 62 42 21 01 / Fax : +33 (0) 5 62 42 21 00 - www.s-b-m.fr

Caution:
Federal Law (USA) restricts this device to sale, distribution, or use by or on the order of a physician.

Date of modification: January 2008

Date of CE mark: February 2009

CE **0459**

Use by

See instructions for use

Do not re-use

STERILE R Sterilized using radiation

Date of manfacture

We cannot be held liable for any incident resulting from failure to comply with the principles described in these instructions.

The information contained in these package inserts was current on the date this brochure was printed. However, the package insert may have been revised after that date. To obtain a current package insert, please contact Biomet Sports Medicine at the contact information provided herein.

ComposiTCP™ 60
INTERFERENCE SCREW

Resorbable Interference Screw

User undertaking:
The user acknowledges having read these instructions, and undertakes to abide by them.

Materials:
DUOSORB™: 60% β-TriCalciumPhosphate / 40% Poly D Lactic Acid composite.

Indications:
The ComposiTCP™ Interference Screw is exclusively used for the fixation, by interference, of a transplant made out of pure ligament, taken out for instance from the hamstring tendon, when reconstructing the anterior cruciate ligament. The screws are cannulated and are available in different sizes, 7 thru 11-mm. They have a specific head, which allows for a more even distribution of the torsional stresses. To achieve the optimal result, the ComposiTCP™ Interference Screw 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.

Adverse side effects:
To date, no adverse effects have been observed and reported.

Surgical precautions:
The use of the ComposiTCP™ Interference Screw requires sound knowledge of the anatomy and biomechanics of the knee joint, and of locomotor apparatus reconstruction surgery. Surgeons wishing to use the device must have been appropriately trained. The patient must be informed of the need for temporary restriction of activities and of the precautions to be taken following the insertion of the screw.

Recommendations for use:

1. The ComposiTCP™ Interference Screw must be used only for ligament reconstruction.
2. Until graft healing is complete, fixation by means of this device should be considered to be temporary, and the construct must not be subjected to excessi ve loading or other stress. Early stress on the screw or premature resumption of activity may lead to backing-out, bending, breakage or displacement of the screw. For this reason, appropriate immobilization, followed by supervised mobilization, will be required for a period of 4 to 6 weeks after surgery, or until there is clinical evidence of graft healing.
3. The ComposiTCP™ Interference Screw must be completely buried below the joint surface.
4. The ComposiTCP™ Interference Screw must be screwed in thanks to a specific screwdriver. No other screwdriver, however similar in appearance, must be used, since doing so may lead to screw breakage.
5. Drilling diameter of the bone tunnel must be, at the minimum, equal to that of the screw.
6. Guide wire must not be twisted or bent prior to screw insertion, since doing so may impede screw insertion or result in screw breakage.
7. The ComposiTCP™ Interference Screw must not be cut or altered under any circumstances.
8. Screwdriver must not be subjected to bending stress.

Recommendations for devices supplied sterile:

The ComposiTCP™ Interference Screw has been Gamma sterilized (dose 25 kGy). Prior to use of the device, the "sterile until" date on the packaging should be checked. SBM accepts no responsibility or liability for the use of products that are past their expiry date. The packaging should be checked for defects prior to use of the device. If inspection shows the packaging to be damaged, the product must be assumed to be non-sterile. The ComposiTCP™ Interference Screw must not be resterilized. Any screws that have been removed from their packaging and remained unused must be discarded.

Packaging:
ComposiTCP™ Interference Screws are supplied individually packaged in double peel-open packs. Prior to the use of the device, the integrity of the packaging must be checked. All the information required by law is given on the box or the label attached to the packaging.

Storage conditions:
ComposiTCP™ Interference Screws are to be stored at ambient temperature (15-30°C / 60-85°F), and normal relative humidity (50-80%). Storage conditions must be such as not to compromise the integrity of the packaging.

Instrument:
Screwdriver for ComposiTCP™ Interference Screws ø 7,8-mm is Ref. 905271, 905273 or LIG9008046.

Screwdriver for ComposiTCP™ Interference Screws ø 9,10,11-mm is Ref. 905272, 905274 or LIG9009017.

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. It is recommended that all instruments be regularly inspected for wear and disfigurement.

Guarantee:
The manufacturer's guarantee does not apply unless the device is used under the normal conditions specified in these instructions.

Reporting of adverse events:
Any person handling the device (in a commercial or a healthcare capacity) that has found the service provided by SBM and/or the quality, labeling, reliability, safety, efficacy and/or the performance of SBM products wanting in any way should notify the SBM representative or distributor.

The representative or distributor should pass the complaint on to the SBM Quality Manager as quickly as possible, using an adverse event report form. The minimum information to be provided on this form should be: product description, catalogue number, batch number, the nature of the complaint or a detailed description of the adverse event and its consequences for the patient and/or the user. Any evidence that would further the investigation (the implant concerned, Xrays, etc…)should be sent with the form. If poor function or deterioration of an implant, or any fault in the instructions for use have led to a patient's or an end user's health being damaged, this event should be reported immediately by phone or fax.

Disposal:
The device should be disposed of observing the precautions that apply to operating room waste.

Manufactured For Distributor: Biomet, Sports Medicine, Inc., 56 East Bell Drive, PO Box 587, Warsaw, IN 46581 USA.

Manufactured By: S.B.M., ZI du Monge – 65 100 LOURDES France
–Tel : +33 (0) 5 62 42 21 01 /
Fax : +33 (0) 5 62 42 21 00 – Web site : www.s-b-m.fr.

Caution :
Federal Law (USA) restricts this device to sale, distribution, or use by or on the order of a physician.

Date of modification: September 2008.

 See instructions for use

 Do not re-use

Sterilized using radiation

We cannot be held liable for any incident resulting from failure to comply with the principles described in these instructions.

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Ordering Information

Femoral Fixation

ToggleLoc™ Fixation Device with ZipLoop™ Technology 50"
904754

Double Bundle Femoral Aimer

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

Double Tunnel Tibial Guide

909513 Guide Body
909514 Bullet (2 pack)
909515 Outrigger

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

Tibial Fixation

ComposiTCP™ 30 Interference Screw—Round Head	
905210	7 x 20mm
905211	7 x 25mm
905213	8 x 25mm
905214	8 x 30mm
905216	9 x 25mm
905217	9 x 30mm
905218	9 x 35mm

ComposiTCP™ Modular Driver

905273 7–8mm
905274 9–10mm

Universal Ratchet Driver

900733 Ratchet Handle

Modular Taps

905277 7–8mm
905278 9–11mm

Modular Dilators

905045 7–8mm
905046 9–10mm

Nitinol Wires

906849 1.1mm x 14"
906852 1.1mm x 9"
906856 0.9mm x 14"

Instrument Case

900300

ComposiTCP™ 60 Interference Screw—Round Head	
905256	9 x 25mm
905257	9 x 30mm
905258	9 x 35mm

ComposiTCP™ 60 Interference Screw—Fully Threaded	
905261	10 x 30mm
905262	10 x 35mm
905263	11 x 30mm
905264	11 x 35mm

1. Data on file at Biomet Sports Medicine. Bench test results are not necessarily indicative of clinical performance.
2. Clement D: "Evaluation of the mechanical performance of 60% TCP/40% PLLA interference screw summary of available data." SBM SA, ZI du Monge, 65100 Lourdes, France.

For product information, including indications, contraindications, warnings, precautions and potential adverse effects, see the package insert and Biomet's website.

BIOMET®
SPORTS MEDICINE

One Surgeon. One Patient.℠

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