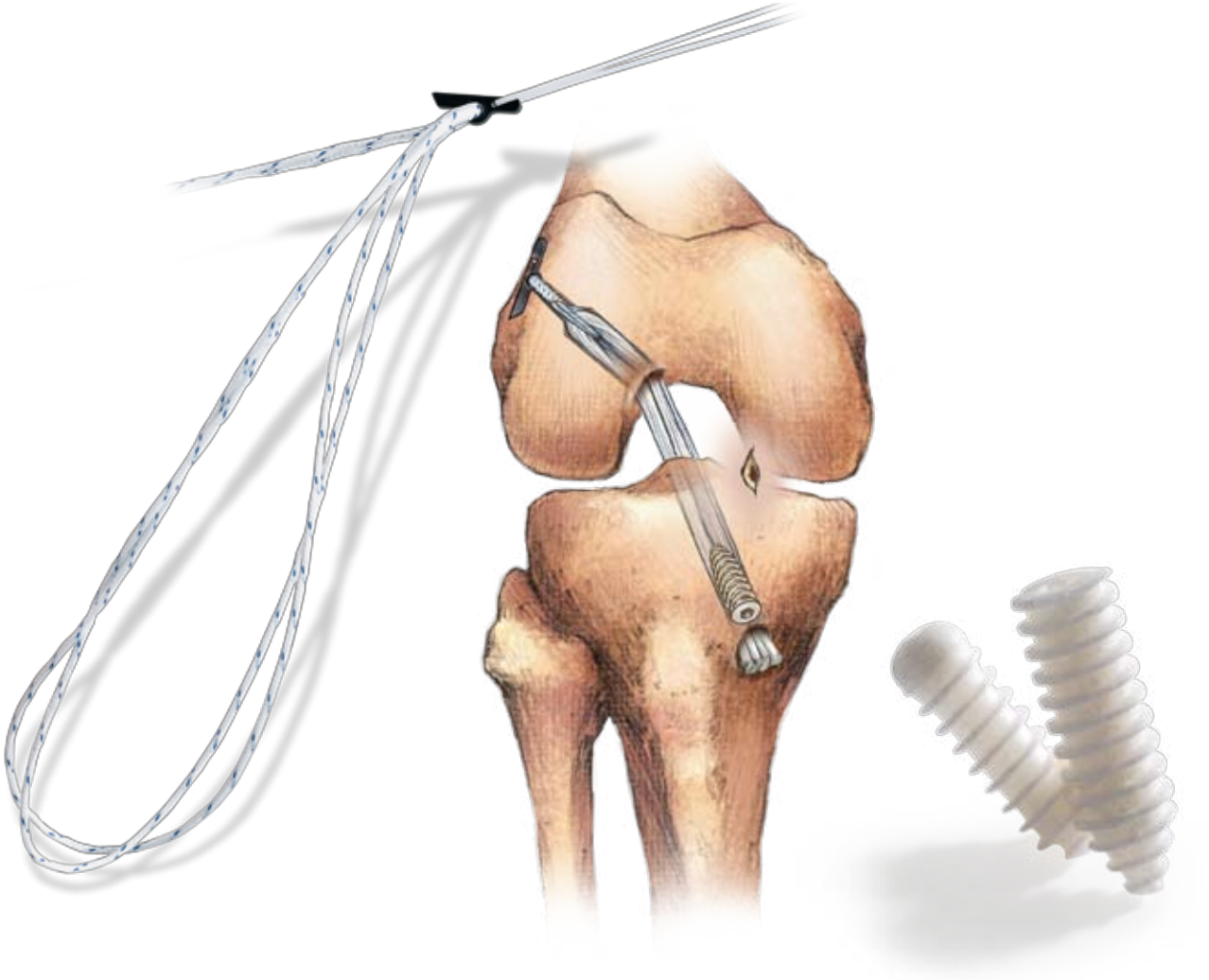
ToggleLoc™
FIXATION DEVICE
with ZipLoop™ Technology

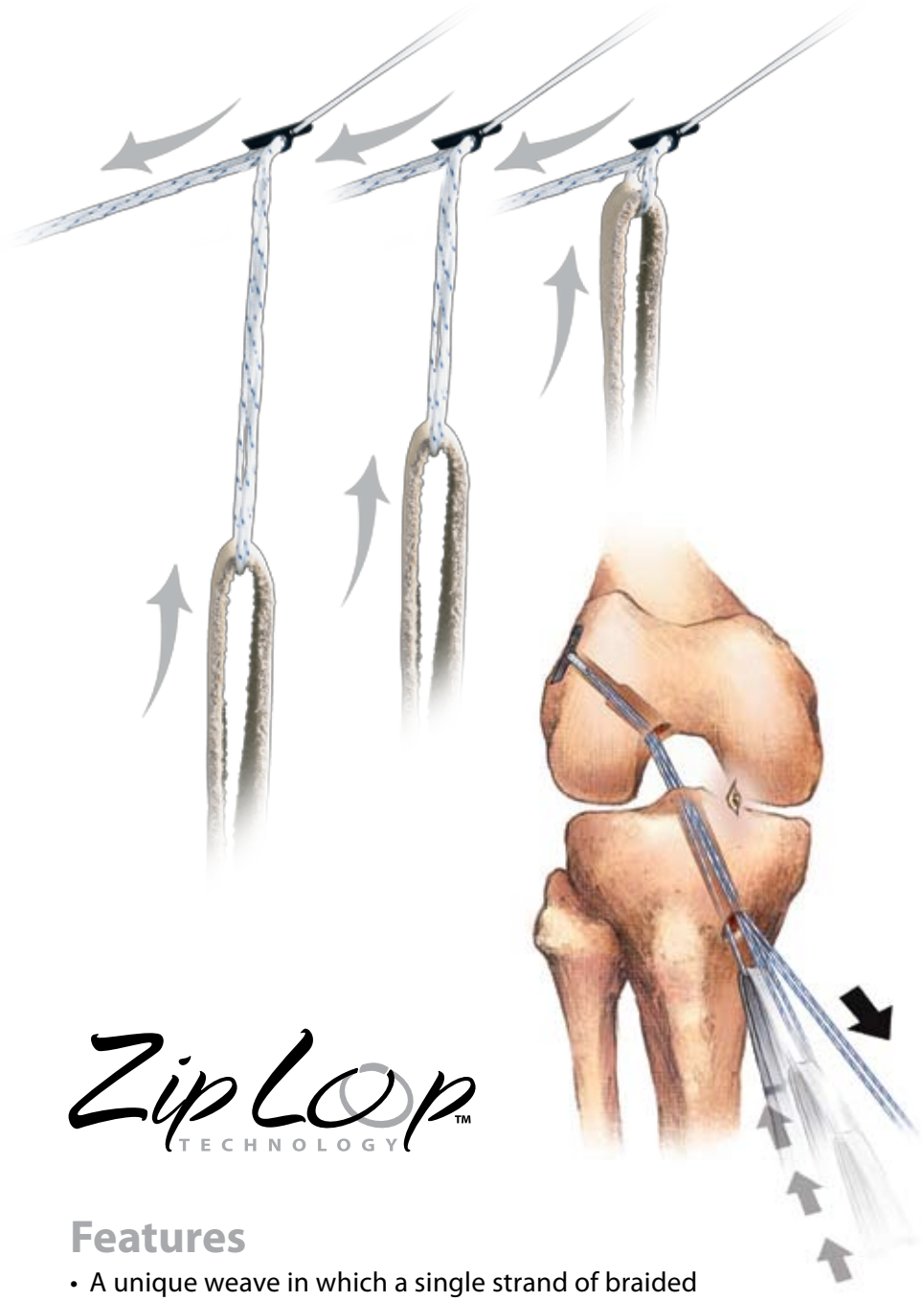
CompositCP™
INTERFERENCE SCREW
For ACL Reconstruction



ACL Reconstruction—
Medial Portal

Surgical Protocol by
Jefferey Michaelson, M.D.

BIOMET®
SPORTS MEDICINE



ZipLoop™ TECHNOLOGY

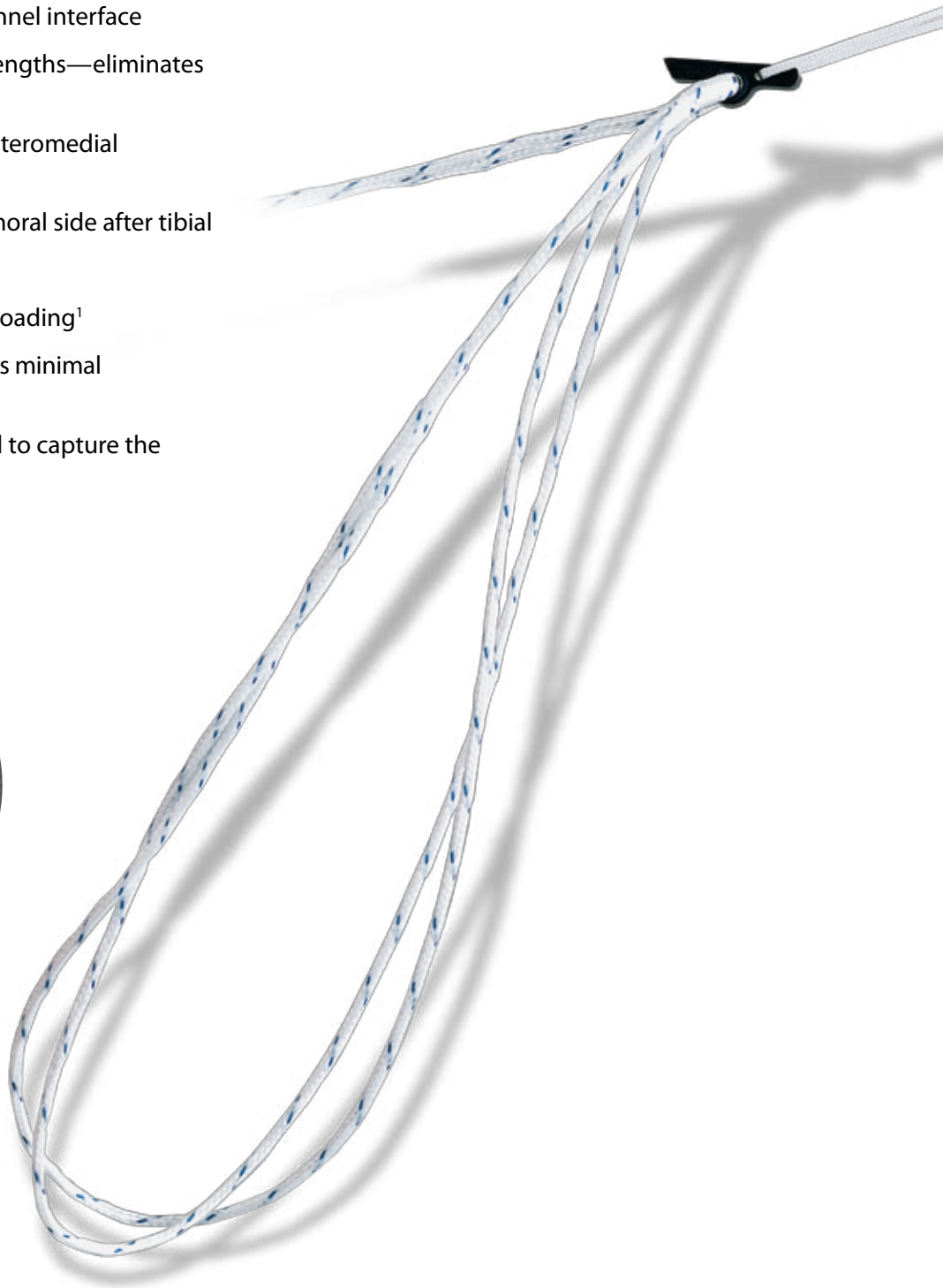
Features

- 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

Features

- Made from a composite material with an innovative blend of 40% PLDLA and 60% beta Tri-Calcium Phosphate that is designed for soft-tissue fixation
- Unique star-shaped drive mechanism that limits stress and distributes torque evenly on the screw during insertion[1]

ComposiTCP™
INTERFERENCE SCREW

Composite Material

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.[1]

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

Sizing

Round Head			Fully Threaded			
						
9 x 25mm	9 x 30mm	9 x 35mm	10 x 30mm	10 x 35mm	11 x 30mm	11 x 35mm

Available in fully-threaded and round head design

Surgical Technique

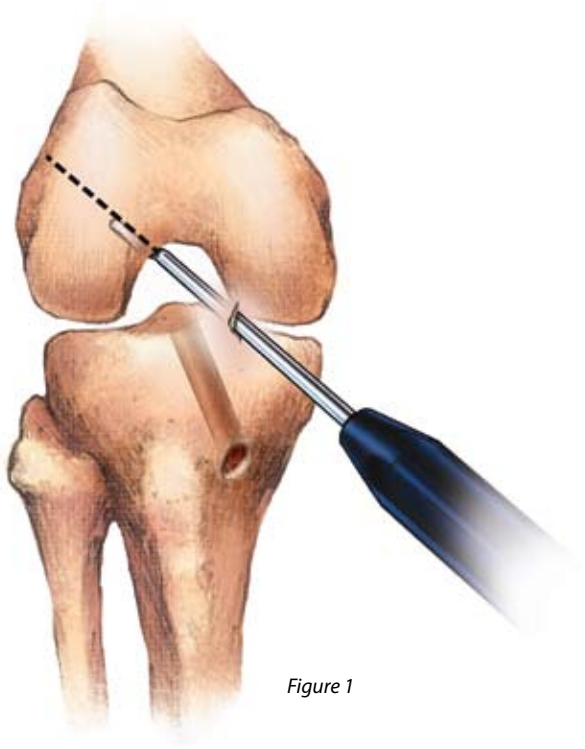


Figure 1

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).

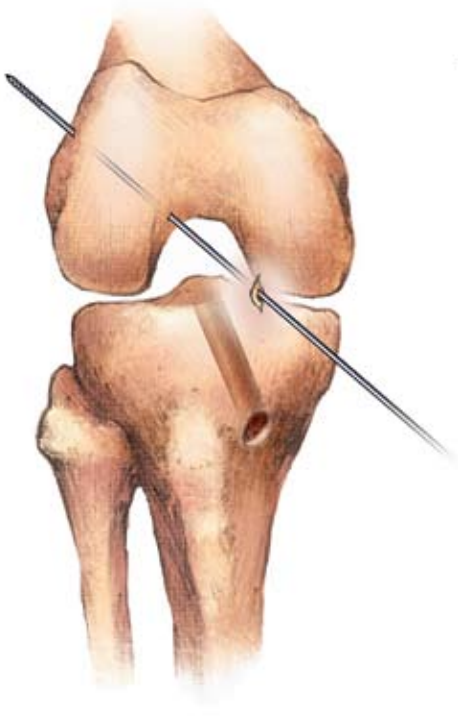


Figure 2

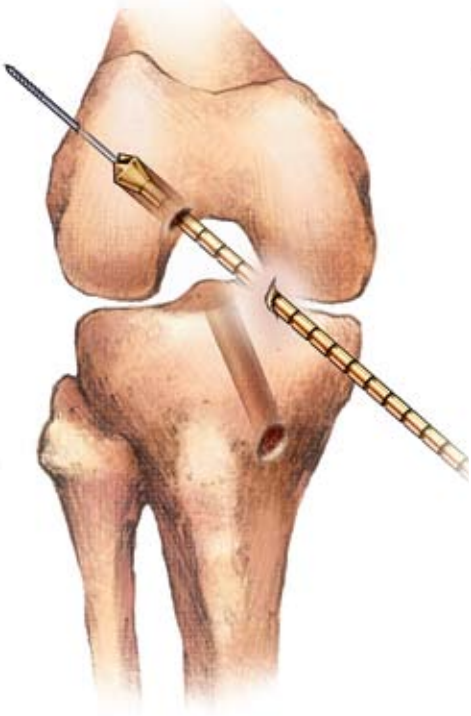


Figure 3

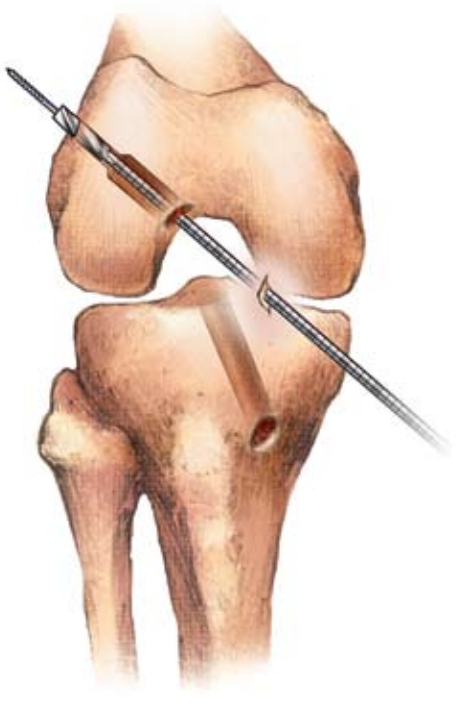


Figure 4

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 25mm) (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). Pass the 4.5mm drill in and out of the cortex two to three times to facilitate passage of the implant.

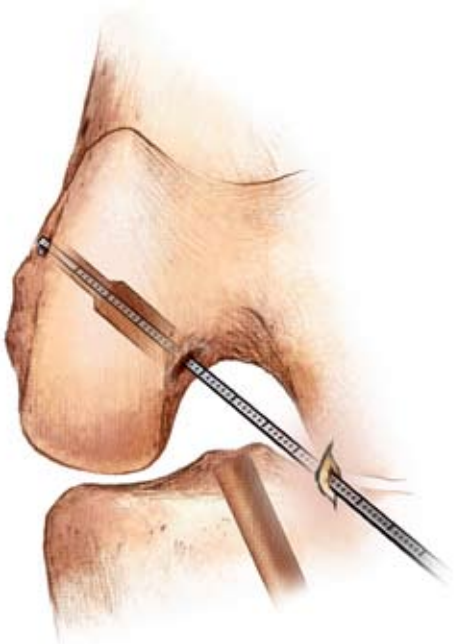


Figure 5

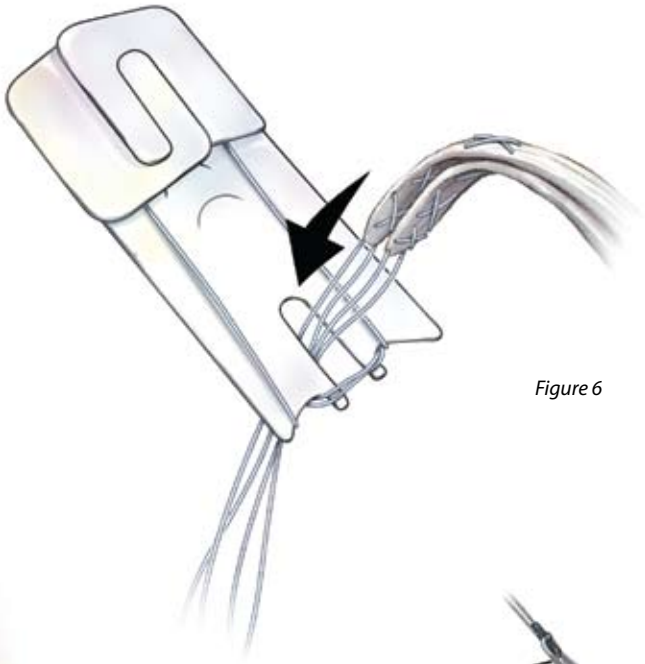


Figure 6

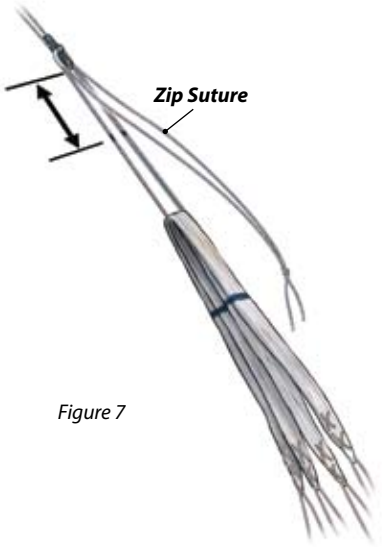


Figure 7

Prepare ToggleLoc™ Femoral Fixation Device with ZipLoop™ Technology

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 with a surgical marker (Figure 7). Make a second mark on the graft by measuring the depth of the "graft tunnel" (typically 25mm). This mark will aid in optimal graft positioning later in the procedure.

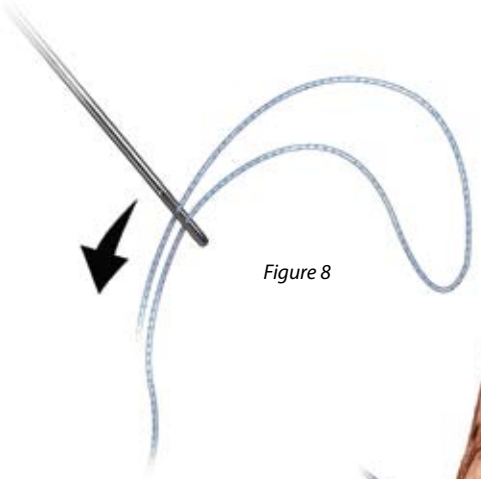


Figure 8

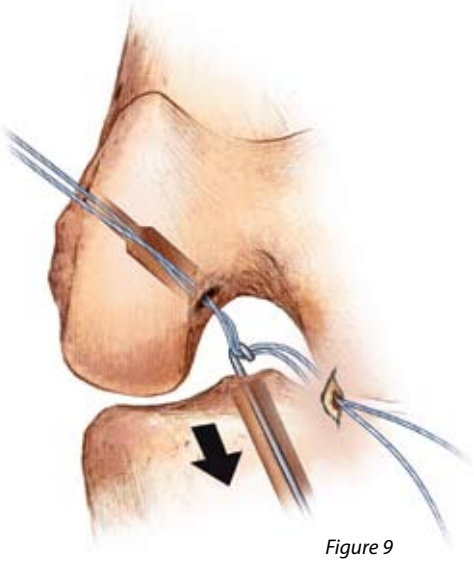


Figure 9

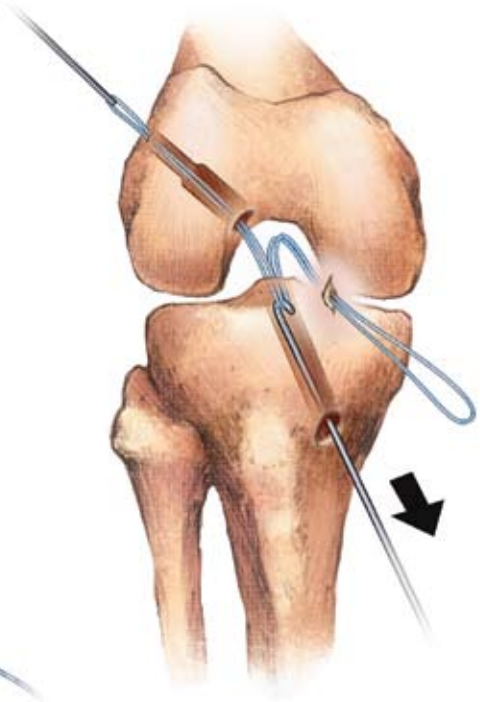


Figure 10

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.

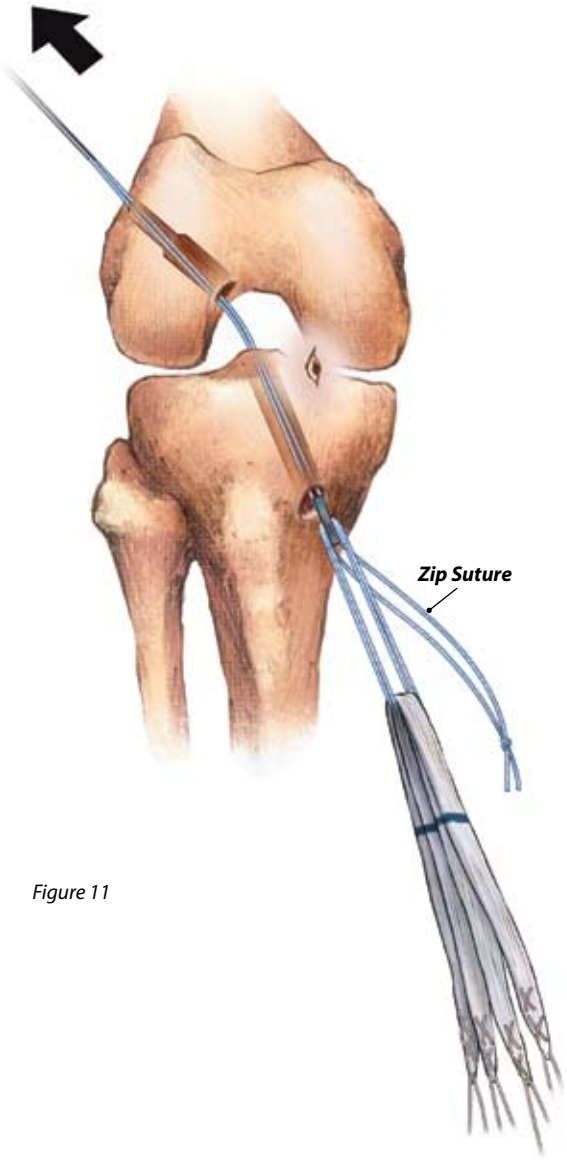


Figure 11

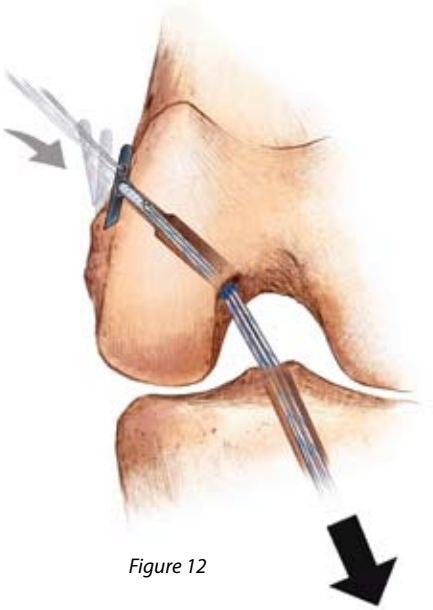


Figure 12

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.

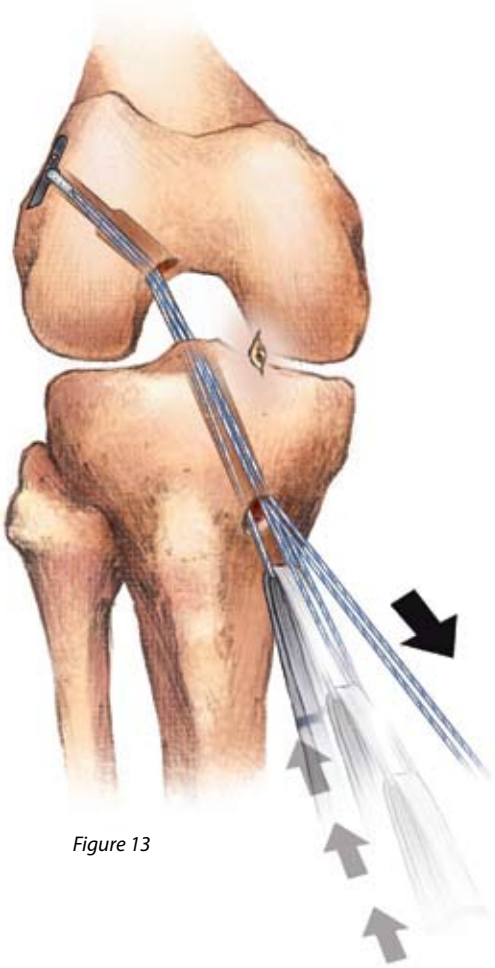


Figure 13

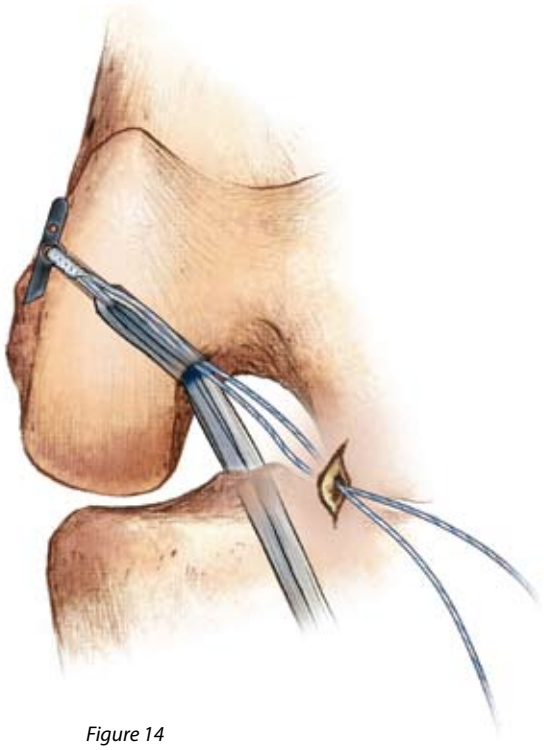


Figure 14

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).

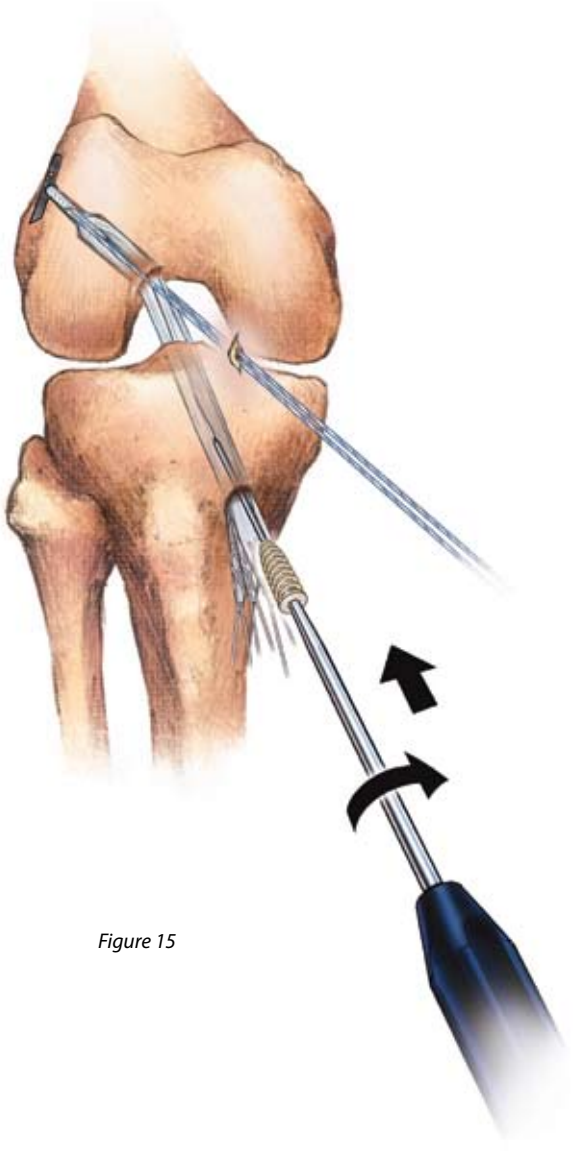


Figure 15

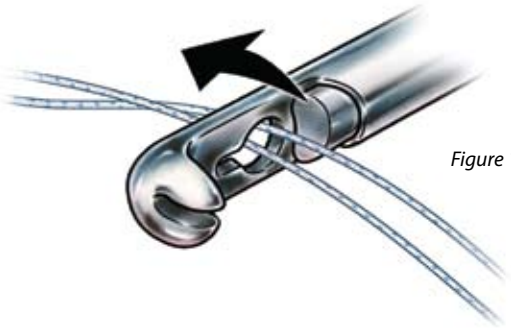


Figure 16

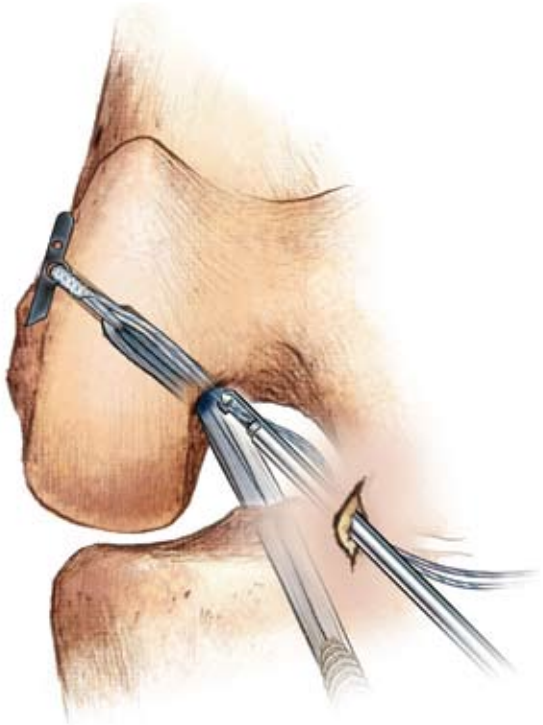


Figure 17

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.

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).

Package Insert

Biomet Sports Medicine
4861 E. Airport Dr.
Ontario, CA 91761, USA

21282015
Rev. A
Date: 01/09

Biomet Sports Medicine™ Toggleloc™ Systems

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 of 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 insure 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 of implants 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.

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.

ComposiTCP™
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 instruction 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.

Ordering Information

ToggleLoc™ Fixation Device

ToggleLoc™ Femoral Fixation Device with ZipLoop™ Technology
904755

ToggleLoc™ Femoral Fixation Device with ZipLoop™ Technology System
909848

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
- 1.1mm x 14" Nitinol Guide Wire
- 3.2mm Drill Bit
- ACL Bone Plug
- Marking Pen
- 6" Ruler

Super MaxCutter™ Suture Cutter

900342

CompositCP™ Interference Screw

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

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

Modular Driver

905274

Driver Handle

900716	Bone Dowel Handle
900733	Ratchet Handle

Modular Taps

905049	7mm
905050	8mm
905051	9mm
905052	10mm

Modular Dilators

905045	7–8mm
905046	9–10mm

Nitinol Wires

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

Instrument Case

900300

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.

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