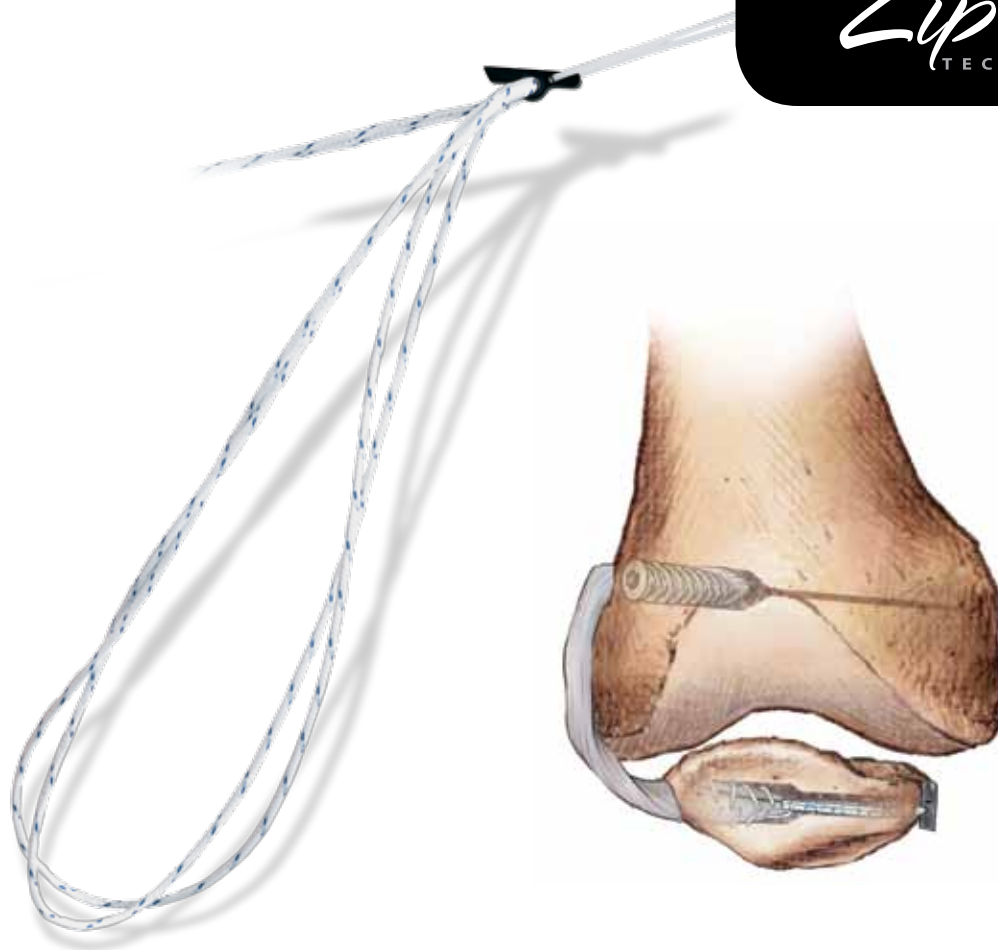


ToggleLoc™
FIXATION DEVICE

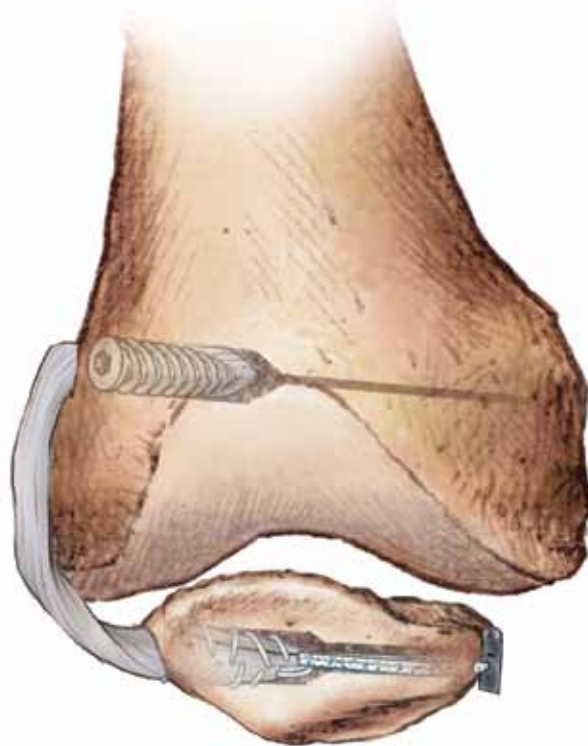
with **ZipLoc™**
TECHNOLOGY



Medial Patellofemoral Ligament (MPFL) Reconstruction

Surgical Protocol by
Ronald Navarro, 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!

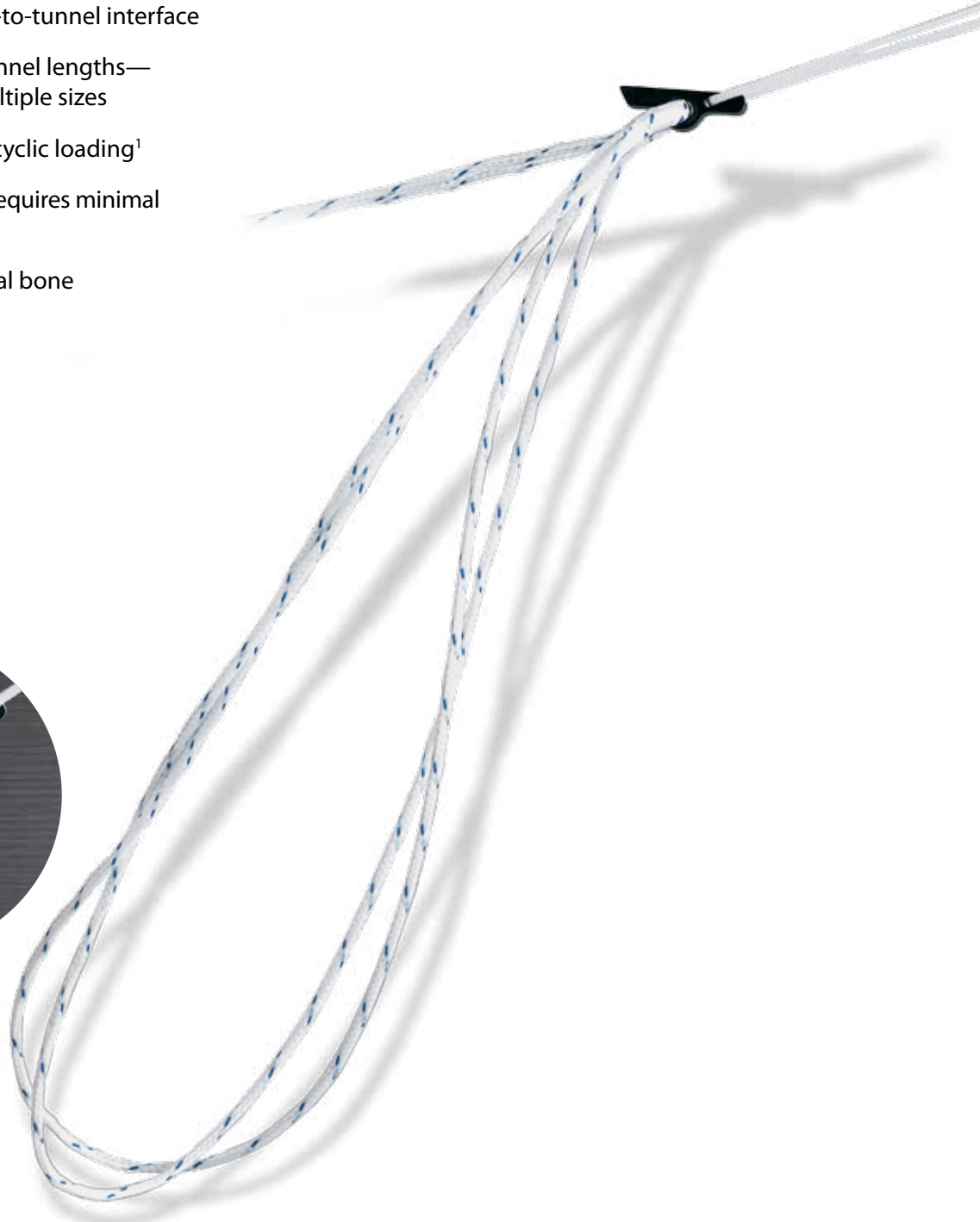


ToggleLoc™

FIXATION DEVICE

Benefits

- Maximizes soft tissue graft-to-tunnel interface
- One implant for varying tunnel lengths—eliminates the need for multiple sizes
- Virtually no slippage after cyclic loading¹
- Simple surgical technique requires minimal instrumentation
- Designed to capture cortical bone



Surgical Technique

Indications for Surgery

- Severe instability of the patella
- Subluxation of the patella

Contraindications

If patellar instability is only due to these differential diagnoses

- Trochlear hypoplasia
- Generalized ligamentous laxity
- Patella alta
- Patellar facet dysplasia

General Positioning

The patient is brought to the operating theater and placed in the supine position on a split leg table if possible. After adequate anesthesia is obtained the patient's involved lower extremity has a thigh high tourniquet placed but it is not inflated. After sterile prep and drape, 1% lidocaine and epinephrine is injected inferomedially and inferolaterally (if diagnostic arthroscopy is to be performed) as well as medially at the femoral epicondyle, medially at the insertion of the MPFL and in and around the hamstrings insertions of the tibia.

Diagnostic Arthroscopy/Possible Trochleoplasty

If deemed appropriate due to the possibility of underlying intra-articular pathology or the need for trochleoplasty or lateral release, a diagnostic arthroscopy is performed. Incisions are made inferomedially and inferolaterally in the typical portal locations for knee arthroscopy. The arthroscope is introduced. Evidence of chondral change is assessed on the patella. This can then be debrided using a shaver. More elaborate cartilage restoration methods are described separately in the literature. All other intra-articular meniscal and chondral pathology can be assessed and treated as dictated by prior informed consent.

If on preoperative assessment including CT scan, a supra-trochlear bump is seen this may deviate the patella out of the central track in the trochlea. There may be a benefit to take down this bump and deepen the trochlea. An arthroscopic burr or bone cutting shaver can be used to perform this task. Any anterior femoral cortical outcropping can be taken down while being careful not to create a stress riser in this region. If relative trochlear hypoplasia is present with flattening of the normal trochlear concavity, typical capture of the patella in early knee flexion cannot occur. The trochlear central groove is deepened in this setting with the use of a bone cutting shaver directly on the most proximal trochlear articular cartilage. The goal is to deepen only the most proximal trochlea and not remove the entire articular surface.

An arthroscopic lateral release is performed if negative patellar tilt exists (where the lateral patella cannot be tilted medially in the coronal plane to a position where the patella could be parallel to the floor if the patient is in the supine position and the toes are in the up pointing or 12 o'clock position). The arthroscopy is then terminated and the knee decompressed to begin the medial patellar femoral ligament reconstruction.

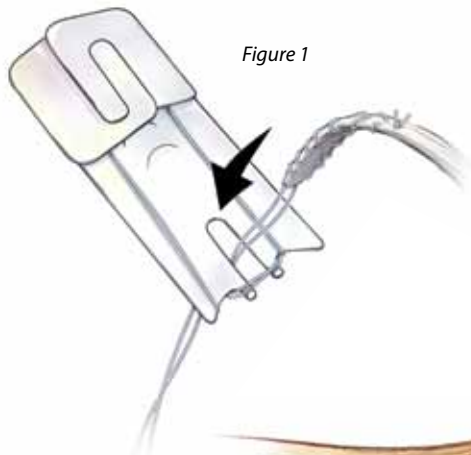


Figure 1

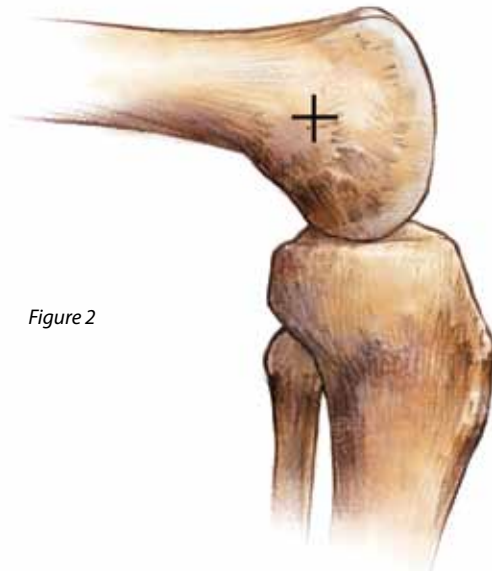


Figure 2

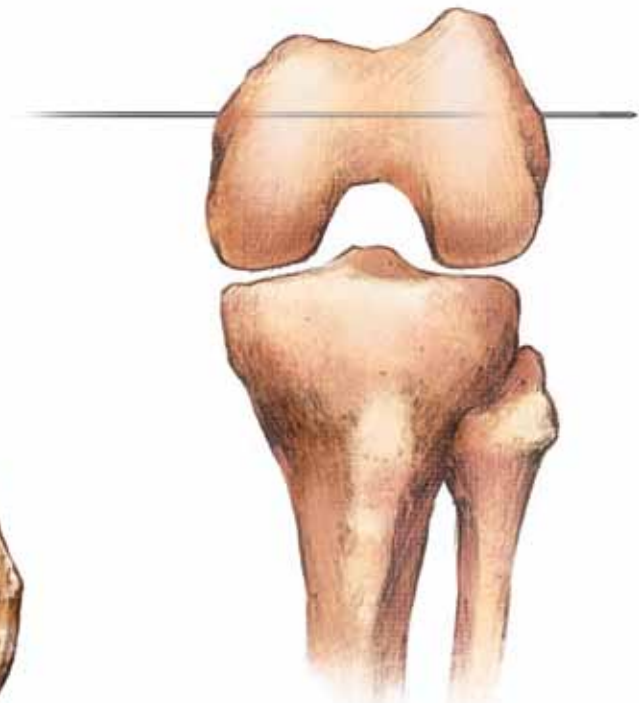


Figure 3

Graft Preparation

A doubled graft of 5.5 – 7.0mm doubled diameter is required. If an allograft is chosen as the graft choice, usually a soft tissue graft is chosen. If a hamstrings autograft is chosen, an incision is made at the anterior medial aspect of the tibia. The sartorial fascia is visualized. It is then cut in line with the underlying tendons. The semitendinosus is removed and tagged using a closed end tendon stripper after its tibial insertion and attachments to the medial gastrocnemius are released. The sartorial fascia is closed with a running stitch. The semitendinosus or soft tissue allograft is taken to the back table and doubled over a passing stitch if using the CompositTCP™ Interference Screw (where the looped end is placed) or the looped end of a ToggleLoc™ Fixation Device with ZipLoop™ Technology (Figure 1). The resultant doubled graft is run through a tendon sizer to obtain its largest diameter. The diameter is noted for later drilling.

The free ends of the graft are then tagged with provisional tension stitches and the graft is placed on a graft board in tension on the back table. It is wrapped in a moist lap sponge, awaiting its use in the reconstructive effort.

Femoral Preparation

If a split leg table is used, the uninvolved extremity is abducted so medial work can ensue. A 1cm incision is made over the medial epicondyle prominence and the incision is taken down to bone through multiple medial layers. The medial epicondyle is palpated and a position just superior and slightly posterior to the tip of the epicondylar eminence is chosen for placement of a guide pin (Figure 2). The pin is drilled to the lateral surface of the femur, being careful not to deviate too anteriorly into the articular surface of the trochlea (Figure 3).

Surgical Technique (continued)

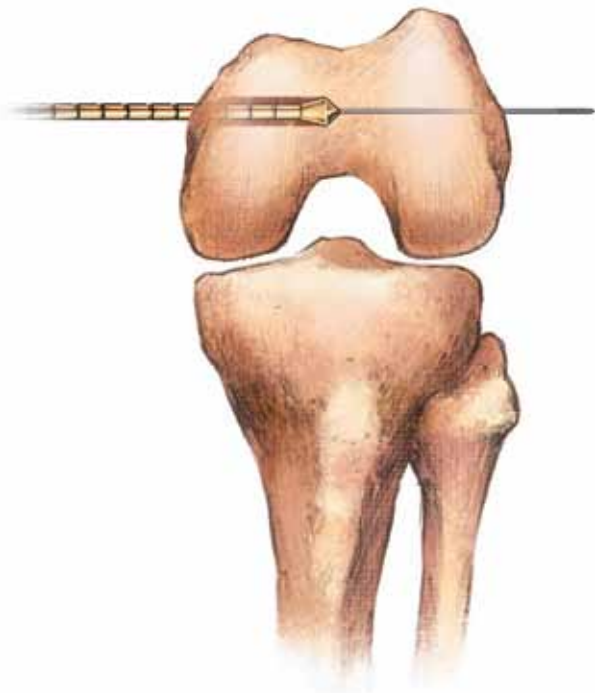


Figure 4

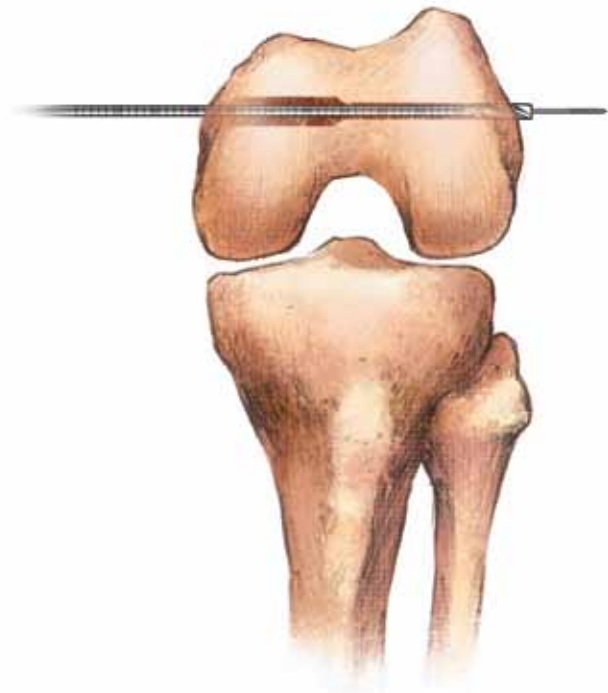


Figure 5

Isometry

A suture can be placed around the pin and passed between Layer 2 and Layer 3 of the medial anatomy of the knee to a small incision on the superomedial patella for isometry testing. It is important to avoid excessive medial patellar facet tension in flexion (femoral point too proximal) and medial patellar displacement in extension (femoral point too distal).

Femoral Drilling

The pin in the femur is over-drilled with an acorn reamer bit of diameter corresponding to the diameter of the graft prepared and sized earlier to a distance of 30–35mm (Figure 4). The remaining tunnel length is over-drilled with the 4.5mm drill bit to accommodate the passage of the ToggleLoc™ Device (Figure 5) or left alone if utilizing a ComposiTCP™ Screw. Fluoroscopic guidance can help simplify this step.

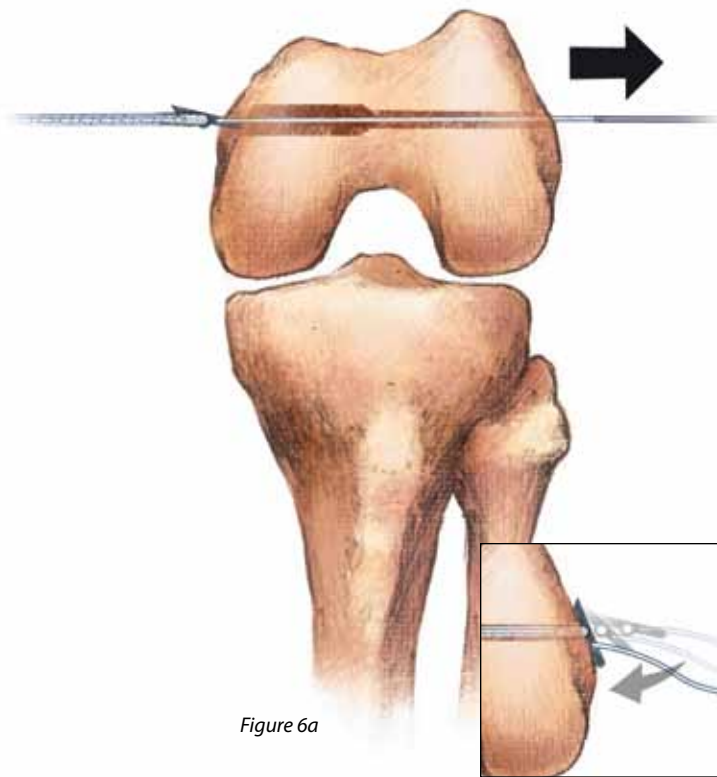


Figure 6a

Figure 6b

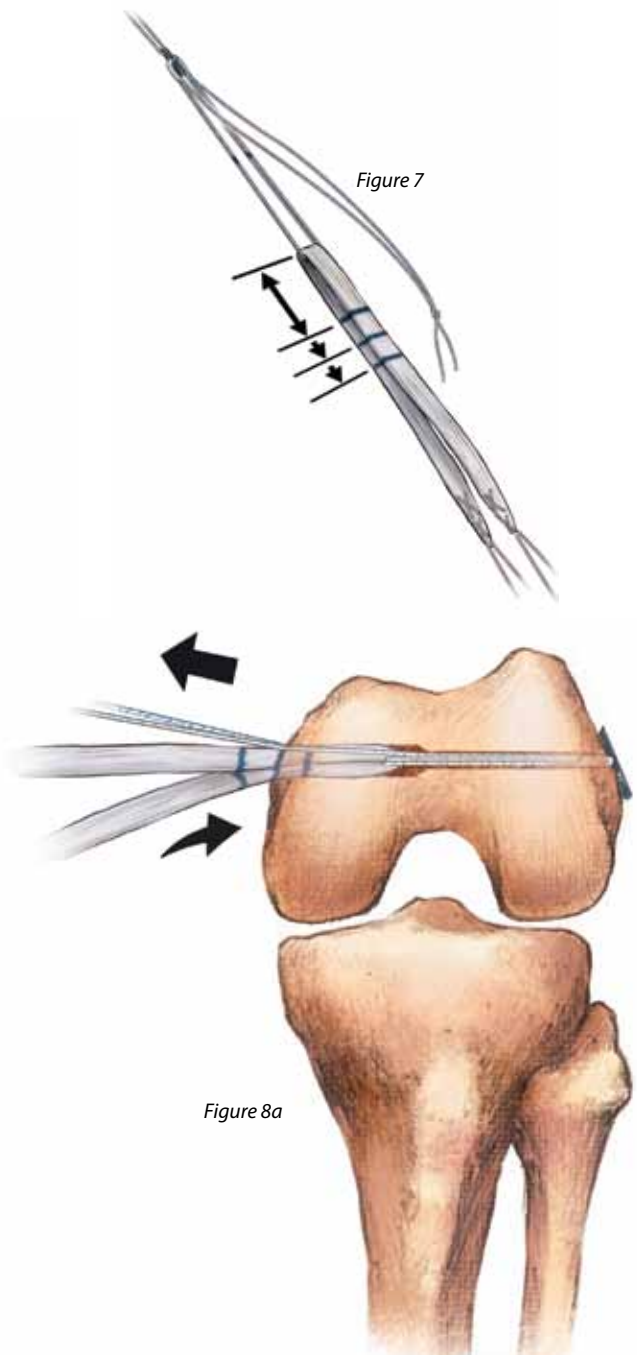


Figure 7

Figure 8a

Femoral Graft Delivery

The graft is delivered into the closed end femoral tunnel using the Beath pin. The ToggleLoc™ Device is passed and then flipped on the lateral femoral cortex (Figure 6a & b). The zip strand of the ToggleLoc™ device is then pulled to introduce the looped end of the graft into the tunnel. The graft can be marked with a marking pen at 25, 30 and 35mm away from the butt end to help track the amount of graft that has been introduced into the femoral tunnel (Figure 7). It is recommended that less than the full length of graft that can be introduced on the femoral side initially be introduced (Figure 8a). If using the ComposiTCP™ Interference Screw, the graft is introduced to 30mm and the ComposiTCP™ Interference Screw of appropriate size and length is placed in line with the graft while placing tension on either side of the graft (Figure 8b).

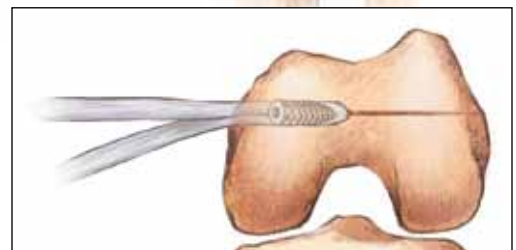


Figure 8b

Surgical Technique (continued)

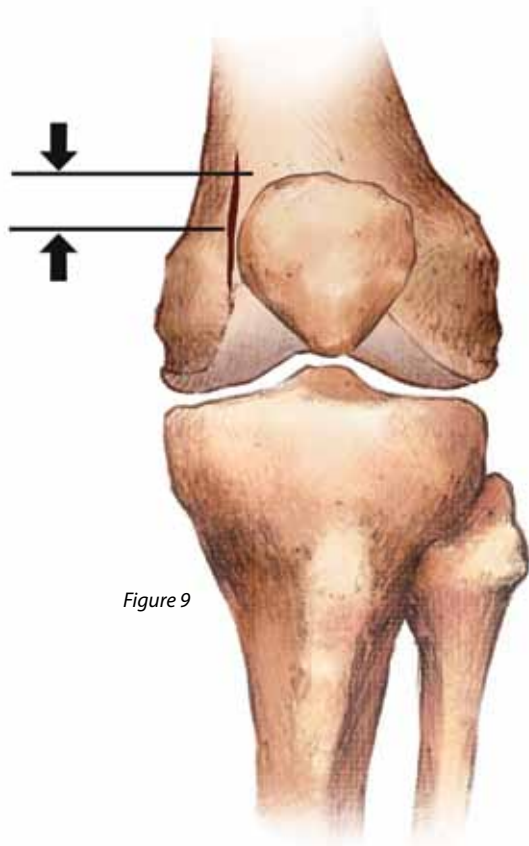


Figure 9

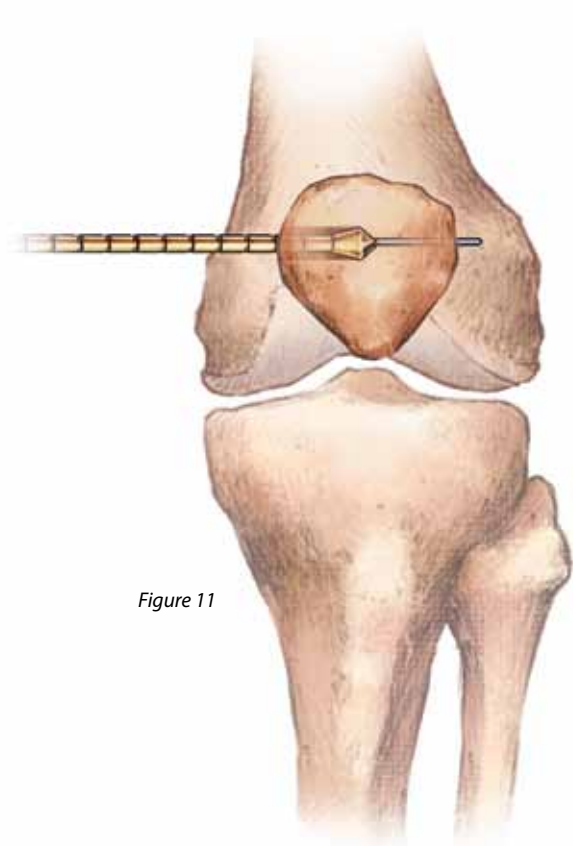


Figure 11

Patellar Preparation

An incision is made just medial to the patella. As the typical patellar insertion site of the MPFL is 6 mm distal to the superior pole of the patella, the focus is superomedially on the patella (Figure 9). Anatomical Layer 2 of the medial knee is incised and Layer 3 is spared unless open patellar cartilage restoration procedures are contemplated. This same superomedial patella position is chosen for placement of a guide pin. The pin is drilled to the lateral surface of the patella, being careful not to deviate too anteriorly into the nonarticular surface of the patella or posteriorly into the patellar articulating facets (Figure 10).



Figure 10

Patellar Drilling

The pin in the patella is overdrilled with an acorn reamer of the diameter corresponding to the diameter of the graft prepared and sized earlier to a distance of 15–25mm (Figure 11). The remaining tunnel length is overdrilled with the 4.5mm drill bit to accommodate the passage of the ToggleLoc™ Device (Figure 12). Fluoroscopic guidance can help simplify this step.



Figure 12

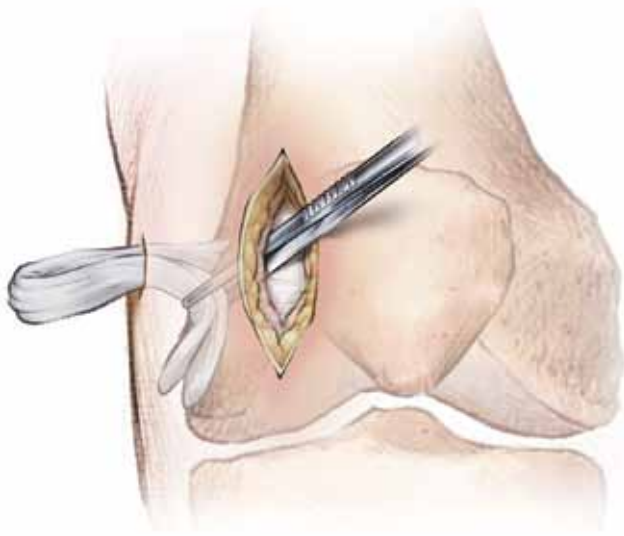


Figure 13

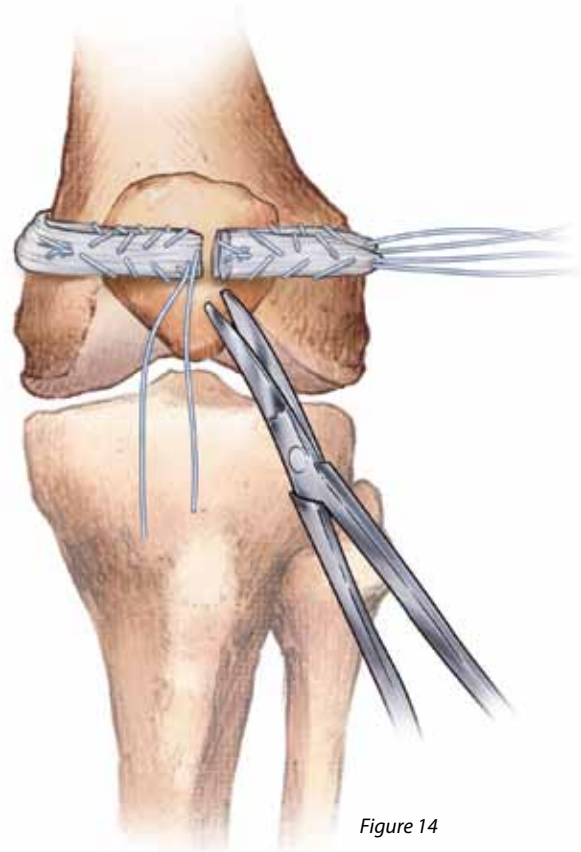


Figure 14

Graft Limb Cutting

The graft is passed from the medial femoral incision to the anterior medial patellar incision underneath Layer 2 (Figure 13). The graft limbs are remeasured from the point of insertion into the medial patellar tunnel and trialed with varying amounts of “MPFL” length. Lateral patellar laxity is checked with each of the lengths to find a length where the patella can glide one quadrant laterally in full extension. This is the point where the checkrein effect of the MPFL reconstruction would block any further abnormal lateral displacement.

New sutures are placed in the two free limbs for a distance that matches the length of the acorn reamed patellar tunnel and the remaining excess graft and initial tension sutures are cut away (Figure 14).

Surgical Technique (continued)

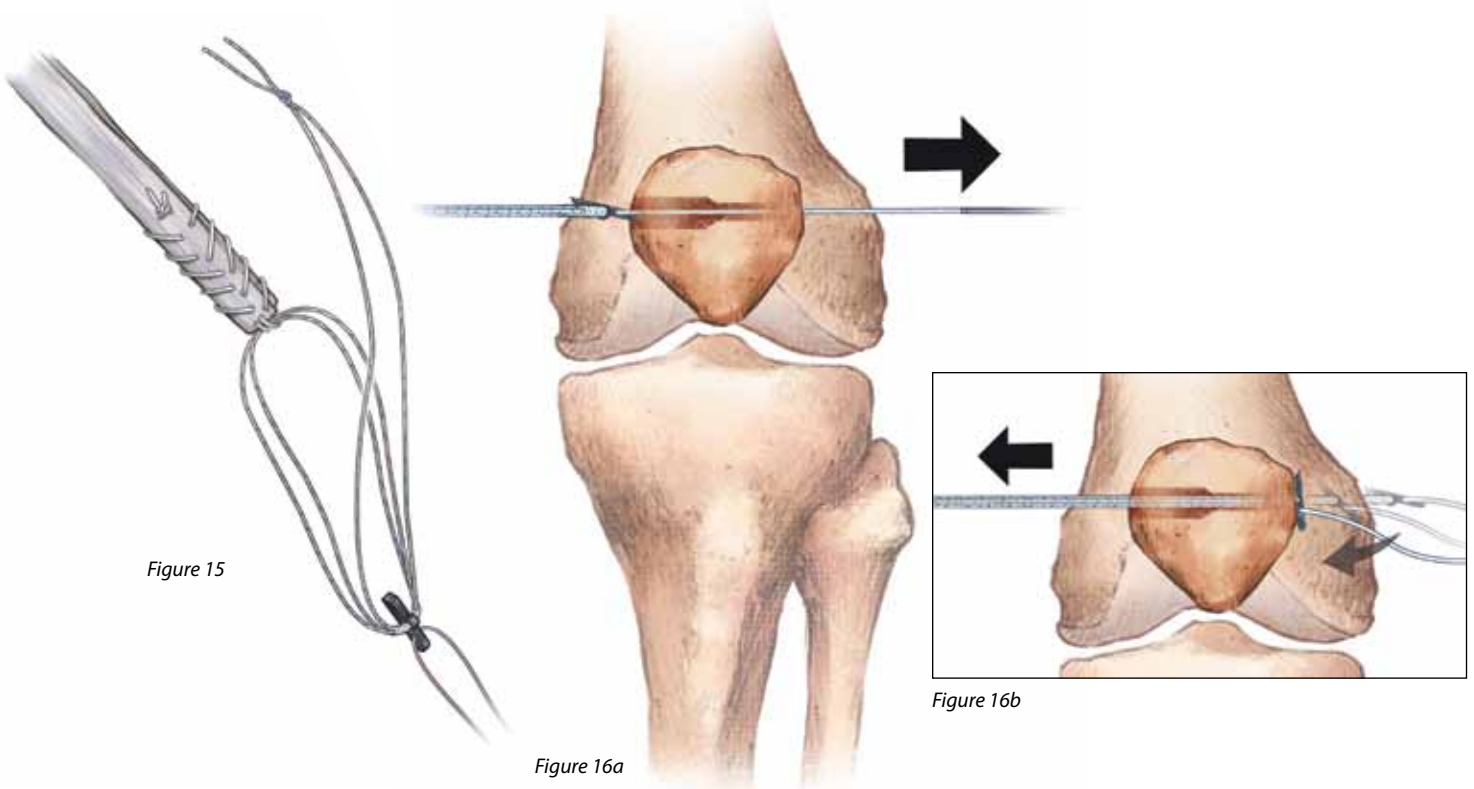


Figure 15

Figure 16a

Figure 16b

Patellar Graft Delivery

The two stitches from the free limbs are tied to a second ToggleLoc™ Device via the ZipLoop™ suture looped ends (Figure 15). The ToggleLoc™ Device is passed and then flipped on the lateral patellar cortex (Figure 16a & b). The suture pulling strands of the ToggleLoc™ Device are then pulled upon to introduce the free limbs of graft into the tunnel. The graft can be marked with a marking pen at 15, 20 and 25mm away from the ends of the graft to help track the amount of graft that has been introduced into the patellar tunnel (Figure 17).

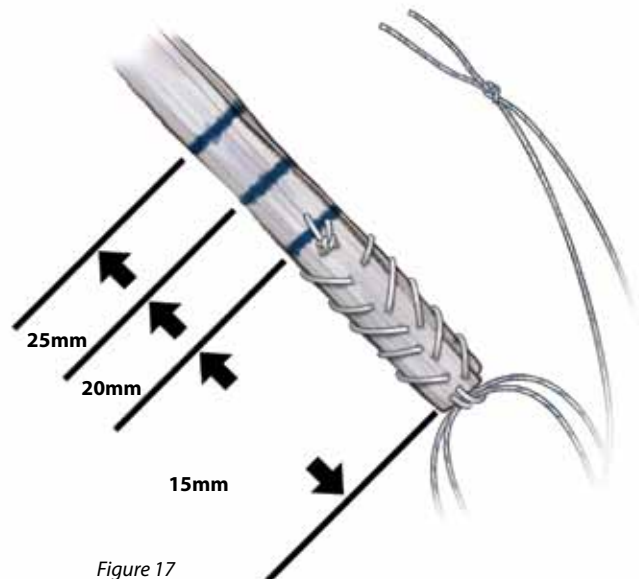


Figure 17

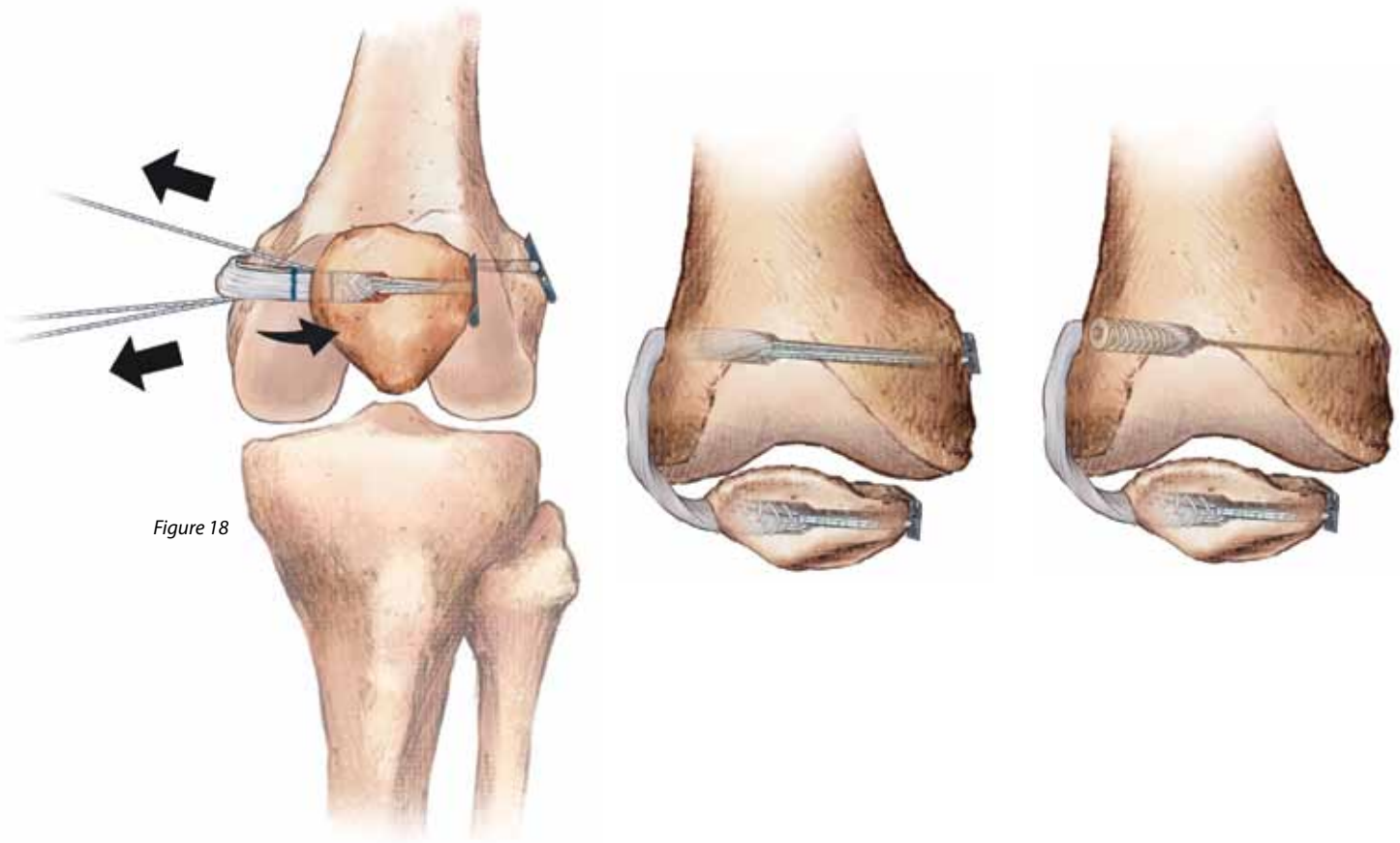


Figure 18

Customizable Final Tensioning of Patella

At this point, the final tensioning of the patella can take place. Because of the ZipLoop™ Technology, tensioning can take place on both the patella side and the femoral side to ensure the patella has normal lateral glide in full extension, trochlear engagement of the patella in 30 to 45 degrees of flexion and the ability to achieve full flexion without graft stretch (Figure 18).

Closure and Rehabilitation

The incisions are then irrigated freely and closed in layers. Sterile dressings are applied. A hinged knee brace is placed. The patient can weight bear in full extension immediately with crutch aide. Range of motion is initiated from 0 to 30 degrees of range immediately (non-weight bearing). Progressive increase in flexion should occur over the next 4-6 weeks to achieve full flexion and weaning of the crutches and brace. Progressive strengthening of the quadriceps and hamstrings with increase in functional movements helps facilitate recovery. Patients can typically return to sports activities in 4-6 months.

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
Illiotalibial 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.

All trademarks herein are the property of Biomet, Inc. or its subsidiaries unless otherwise indicated.

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



Manufacturer

Date of Manufacture

Do Not Reuse

Consult Accompanying Documents

STERILE EO Sterilized using Ethylene Oxide

STERILE IR Sterilized using Irradiation

STERILE Sterile

STERILE A Sterilized using Aseptic Technique

STERILE S 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.

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 intended screw. Thus, an 8-mm Ø screw requires a 9-mm Ø drill hole ; a 9-mm Ø screw, a 10-mm Ø drill hole ; a 10-mm Ø screw, an 11-mm Ø drill hole ; and an 11-mm Ø screw, a 12-mm Ø 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



Use by



See instructions for use



Do not re-use



Sterilized using radiation



Date of manufacture

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.

Package Insert

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 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™ 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.

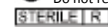
Date of modification: September 2008.



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.

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.

Ordering Information

ToggleLoc™ Fixation Device

ToggleLoc™ Fixation Device with ZipLoop™ Technology 50"
904755

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

ComposiTCP™ Interference Screw

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

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

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
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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

1. Warren LF, Marshall JL; "The supporting structures and layers on the medial side of the knee: an anatomical analysis." *The Journal of Bone and Joint Surgery*, Vol. 61 Issue 1 5662, 1979.
2. Davis and Fithian; "Techniques of Medial Retinac Repair and Reconstruction," *CORR*, 402 September, pp 38 – 52, 2002.
3. Colvin AC, West RV; "Patellar Instability" *The Journal of Bone and Joint Surgery*," Vol. 90: 2751 – 2762, 2008.
4. Redziniak DE, et al.; "Patellar Instability" *The Journal of Bone and Joint Surgery*," Vol. 91: 2264 – 2275, 2009.

1. Data on file at Biomet Sports Medicine. Bench test results are not necessarily indicative of clinical performance.

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

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