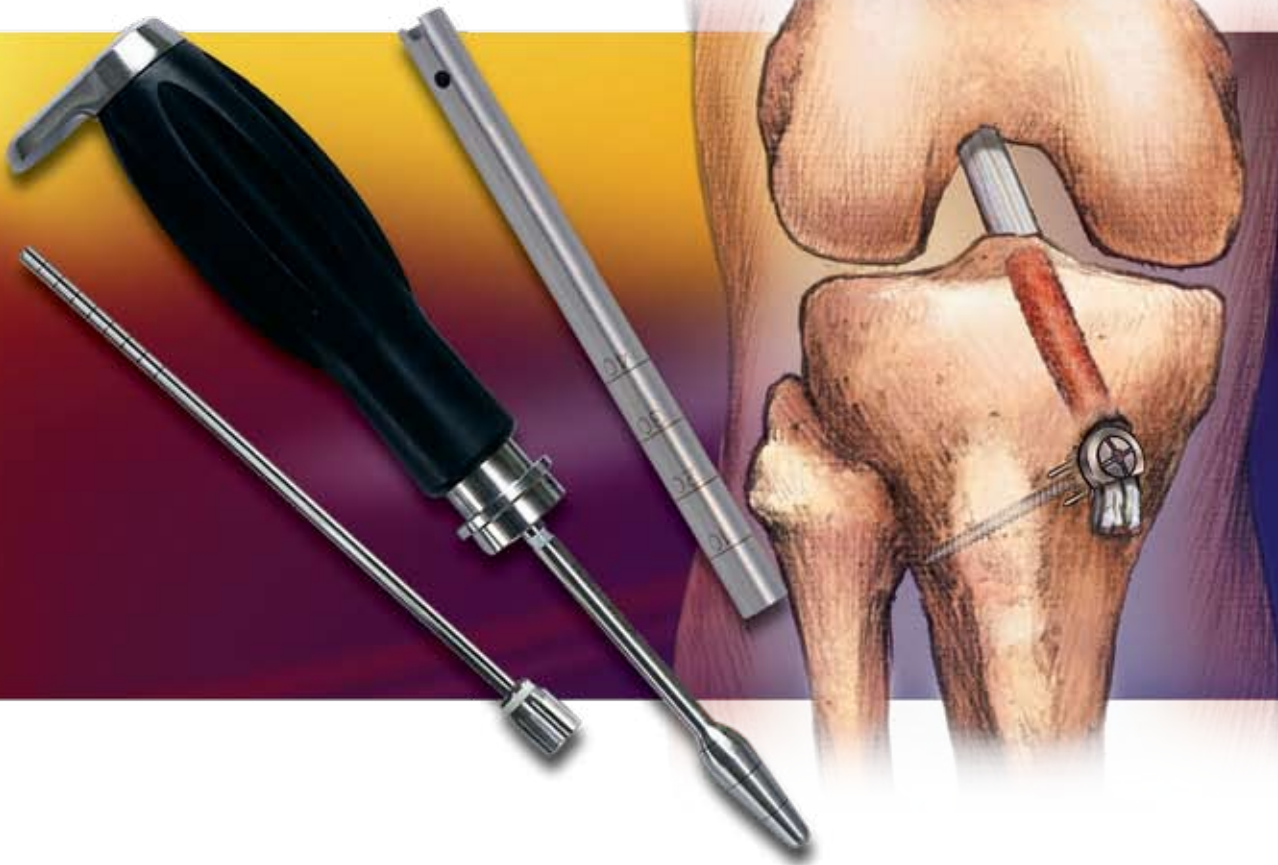


Bone Dowel Harvester

Developed in conjunction with Stephen M. Howell M.D.



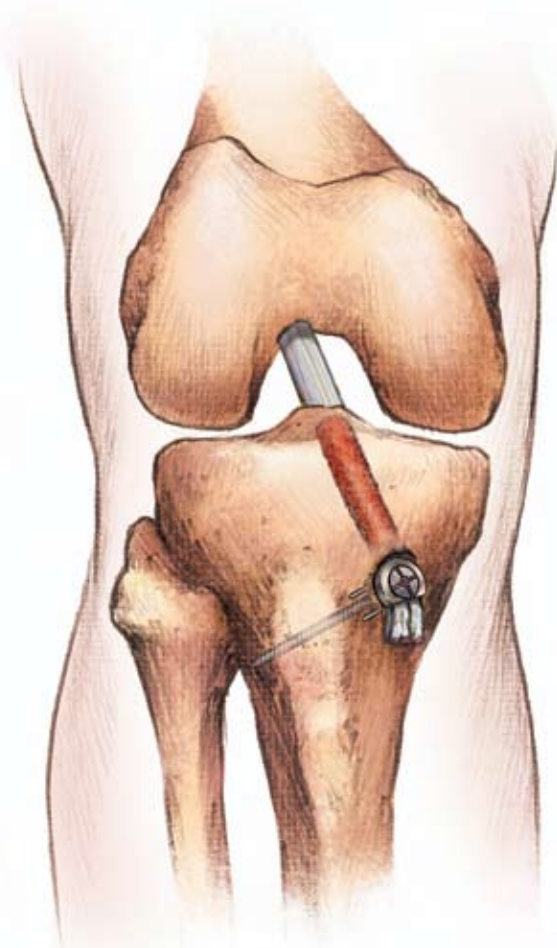
***Compacting a Bone Dowel in the Tibial Tunnel:
Can accelerate healing, minimize tunnel expansion
and improve fixation when used with the
WasherLoc™ Tibial Fixation System***

BIOMET®
SPORTS MEDICINE



Proven Strategies for ACL Reconstruction

Proven strategies. Combining the EZLoc™ Femoral Fixation Device with the WasherLoc™ Tibial Fixation Device (905N, 273N/mm), and with the compaction of a bone dowel in the tibial tunnel (58N/mm), creates one of the strongest, stiffest and most slippage resistant ACL graft constructs available. The excellent fixation properties of this ACL graft construct, and the ability of the graft to heal circumferentially to all sides of the tunnel, has allowed an early, aggressive, brace-free rehabilitation which has returned patients back to sport as early as four months.¹⁻¹⁴



Challenges in ACL Reconstruction

Tunnel Widening

Extensive tunnel widening after ACL reconstruction complicates revision surgery. Tunnel widening is greatest with intratunnel devices because the insertion of large interference screws not only compresses the graft in the bone tunnel but also significantly enlarges the bone tunnel itself.³ Compacting an autogenous bone dowel into the tibial tunnel alongside a soft tissue ACL graft that is fixed distally with the WasherLoc™ device prevents tunnel widening and simplifies revision surgery.¹⁶

Need to Stiffen ACL Graft Construct

The surgeon interested in a stiff ACL graft construct can use a bone dowel in series with a distal device of high fixation stiffness (*ie*, WasherLoc, tandem washers and screws) instead of joint line fixation with an interference screw. A bone dowel, harvested from the tibial tunnel, and compacted alongside a soft tissue graft increases the stiffness of the ACL graft construct (58 N/mm) at the time of implantation.¹² High stiffness distal fixation in the tibia with either the WasherLoc™ or tandem washers alone provides greater or at least similar stiffness to joint line fixation with a wide variety of metal and bioabsorbable interference screws, even though the graft is lengthened with distal fixation.^{15,21} These studies refute the opinion that a soft tissue graft must be fixed at the joint line to stiffen the graft construct.¹⁴

Slow Tendon-Tunnel Healing

The healing rate of a soft tissue ACL graft in a bone tunnel is slower than a bone-patellar tendon-bone (BPTB) graft during the first six weeks of implantation.²² The healing rate is even more of a problem in the tibia than the femur because the marrow is fattier¹⁰ and the bone is softer.⁷ Therefore, a soft-tissue graft requires better fixation technique than a BPTB graft²² especially in the tibia.¹⁰ The consequence of not addressing the slow tendon-tunnel healing is slippage during early rehabilitation.⁹ Slippage is more likely with a soft tissue ACL graft than with a BPTB graft because early-on pain is less, and motion, weight-bearing and function are more quickly restored.⁸

Developed in conjunction with Stephen M. Howell, M.D., Sacramento, California.

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This brochure is presented to demonstrate the surgical technique utilized by Stephen M. Howell, M.D. Biomet Sports Medicine, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and utilizing the appropriate techniques and products for each individual patient. Biomet Sports Medicine is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.

Rehabilitation activities vary depending on the individual patient and physician's recommendations.



Proven Strategies for ACL Reconstruction

Use Long, Snug Tunnels

The healing of a tendon graft is stronger and stiffer when the tunnel is lengthened and the fit between the tendon and tunnel wall is snug.¹¹ Lengthening the tunnel requires placement of the fixation device at the end of the tunnel and not inside (i.e. intratunnel device).¹⁹ A snug fit requires compaction of autogenous bone between the tendon and tunnel wall to fill voids caused by the non-uniform, tapering shape of the graft as it courses along the tunnel.^{21,23}

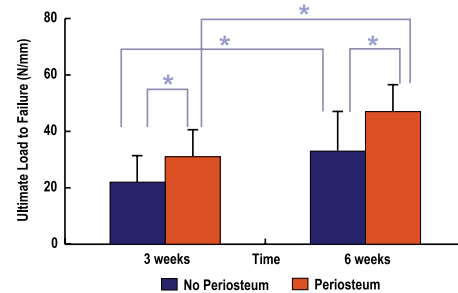
Allow Circumferential and Avoid One-Sided Healing

The healing of a tendon graft is stronger and stiffer when the tendon heals to the tunnel circumferentially and not to only one side, which can occur with interference screw fixation.¹⁹ Circumferential healing requires placement of the fixation device at the end of the tunnel so that the entire surface area of the tunnel can heal to the graft and the strands of the graft can heal to each other.¹⁹

Surround Tendon Graft with Biologically Active Substance

Healing of a tendon is accelerated and stronger when a biologically active substance is inserted in the tunnel with the graft. Wrapping periosteum around the graft accelerates the healing process of a tendon in a bone tunnel and leads to better biomechanical fixation in a shorter period of time.¹³ Adding bone morphogenetic protein accelerates the healing process when a tendon graft is transplanted into a bone tunnel.¹⁷ The acceleration of healing by periosteum and bone morphogenetic protein suggests that compaction of autogenous bone into the tunnel might also benefit healing.¹³ Autogenous cancellous bone has viable osteoblasts that might initiate, regulate, and accelerate the ingrowth of bone into the tendon.

Periosteum, A Biologically Active Substance, Accelerates Tendon Tunnel Healing at Three and Six Weeks¹³



Use a Distal Fixation Device (WasherLoc™ Tibial Fixation Device)

Bone grafting the tibial tunnel and promoting circumferential healing requires that the fixation device be placed at the end of the tibial tunnel. Distal fixation with a WasherLoc™ device provides a slippage resistant, stiff, and strong, means of fixation.^{2,15,18,20} The superior fixation properties of the WasherLoc™ device are from purchasing cortical bone (which is 50 times stronger than cancellous bone¹), and from the 13 tines of the WasherLoc™ device, which provide multiple sites of fixation. Multiple sites of fixation in cortical bone with the WasherLoc™ device is in sharp contrast to other fixation options that rely on shallow, dull threads in soft cancellous bone to grip the graft.¹⁵

Impact a Dowel of Biologically Active Autogenous Cancellous Bone in the Tunnel

Impactting a dowel of bone improves the fixation stiffness (~58N/mm) of the WasherLoc™ device fixation at time of implantation.¹² Compacting a dowel of autogenous cancellous bone prevents tunnel widening, a problem that has not yet been solved for many other tibial fixation devices.¹⁶

Surgical Technique

The following technique is designed to accelerate tendon-tunnel healing, minimize tunnel expansion, and improve fixation of a soft tissue ACL graft in a tibial tunnel. The technique is simple, quick, and effective; requiring only two instruments and three steps.



Figure 1

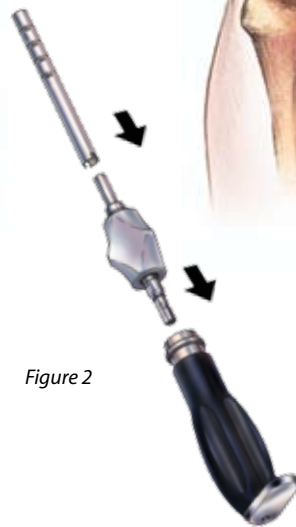


Figure 2

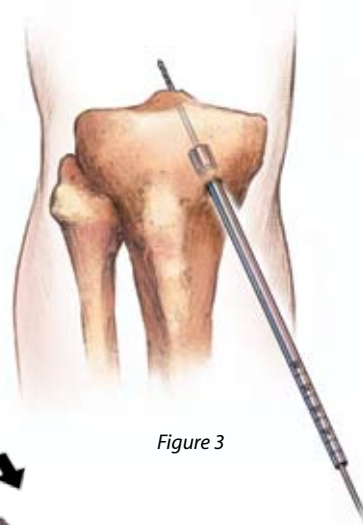


Figure 3

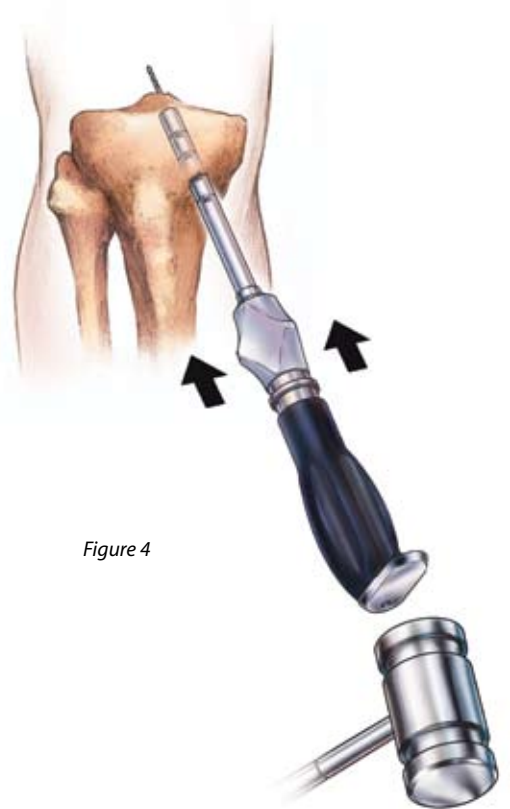


Figure 4

Harvest a Bone Dowel from the Tibial Tunnel

Place the 2.4mm guidepin for the tibial tunnel. Choose a cannulated reamer matching the diameter of the soft tissue ACL graft. Advance the cannulated reamer until it just breaks through the distal tibial cortex (Figure 1).

Assemble the Bone Dowel Harvester by locking the collet in the quick release handle. Next, lock the 8mm in diameter harvester tube into the collet (Figure 2). Slide the calibrated plunger over the tibial guidepin until it rests inside the tibia (Figure 3). Slide the 8mm in diameter harvester tube over the plunger until it rests on cancellous bone (Figure 4 & 5). Impact the Bone Dowel Harvester over the guidepin to subchondral bone (Figure 4 & 5). Rotate the Bone Dowel Harvester several times clockwise and counterclockwise to break-off the cylindrical bone dowel and then pull to remove (Figure 6).



Figure 5

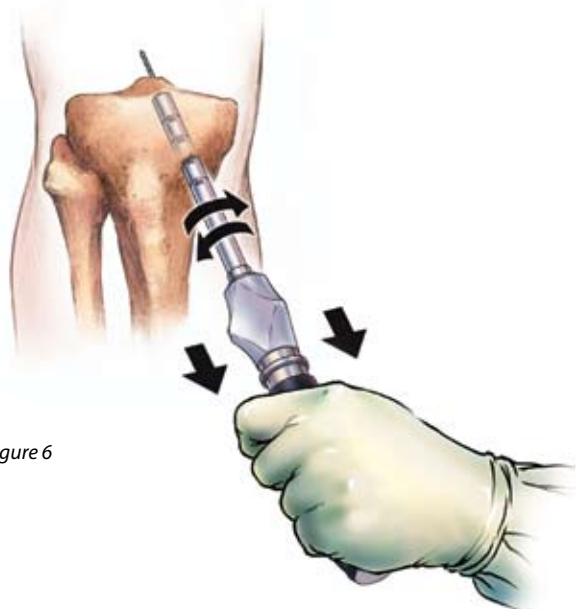


Figure 6

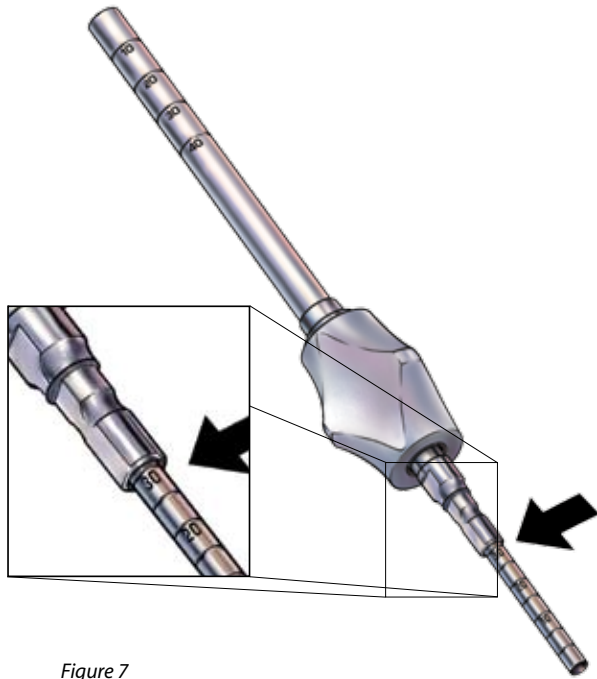


Figure 7



Figure 8

Disengage the collet from the handle. Determine the length of the bone plug by reading the mark on the calibrated plunger (typically 25–35 mm) (Figure 7). If the guidepin inadvertently came out with the bone dowel, then reinsert the guidepin into the notch by first inserting an 8mm one-inch femoral reamer into the tibia and then pass the guidepin into the notch through the cannulation in the reamer (Figure 8). Finish drilling the tibial tunnel with the cannulated reamer that matches the diameter of the graft (Figure 9).



Figure 9

Surgical Technique

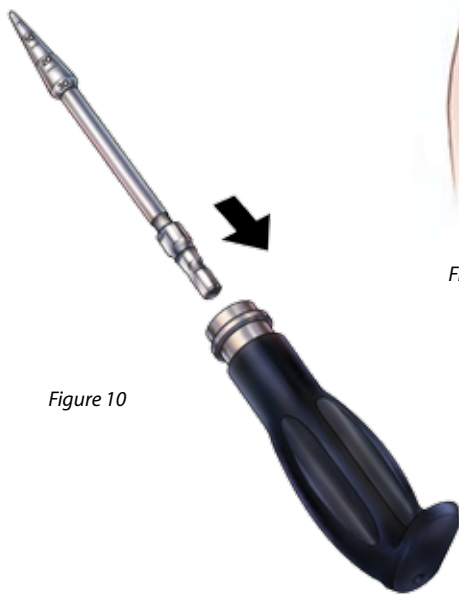


Figure 10

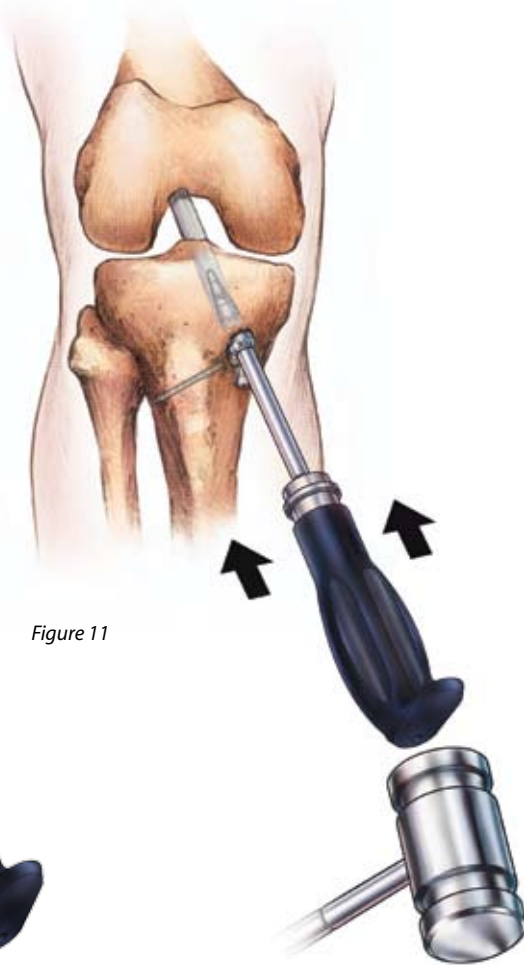


Figure 11

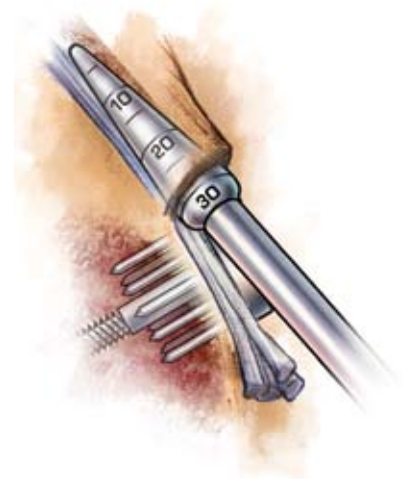


Figure 12

Dilate the Tibial Tunnel

Dilate the tibial tunnel after fixing the soft tissue ACL graft to the tibia with the WasherLoc™ device and compression screw. Insert the dilator into the handle (Figure 10). Place the tip of the dilator between the anterior surface of the soft tissue graft and tibial tunnel. Gently impact the dilator to the level of the joint line, (typically 25mm) (Figures 11 & 12).

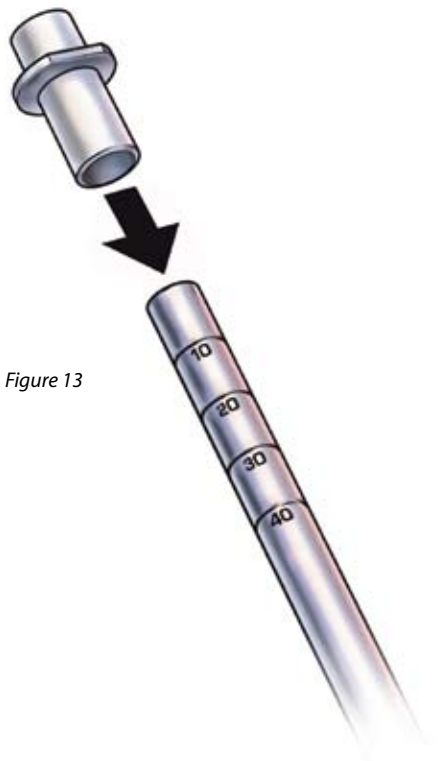


Figure 13

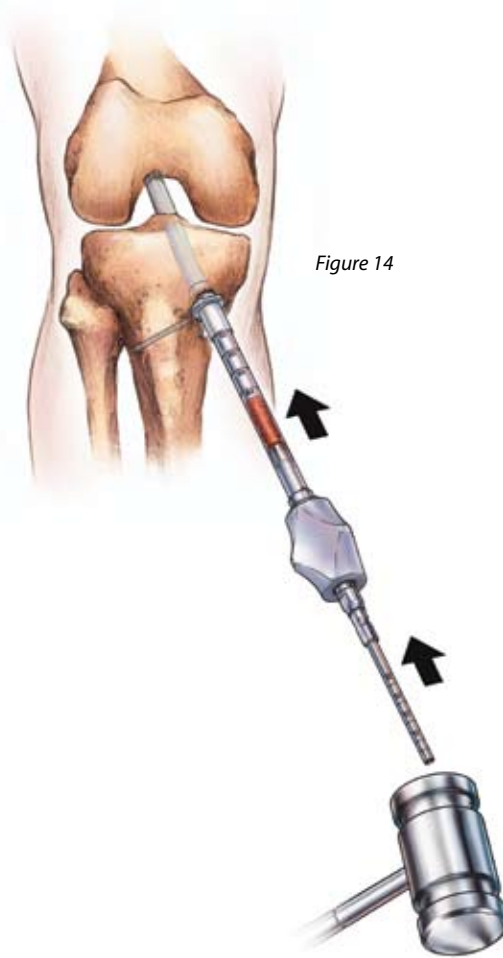
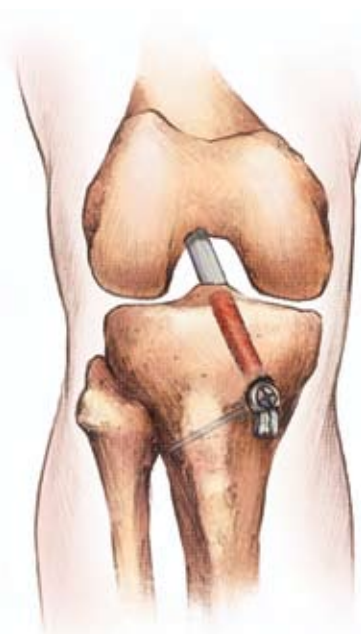


Figure 14

Compact the Bone Dowel

Compact any notchplasty remnants and bone reamings into the dilated opening with the dilator or an impingement rod. Place the plastic graft protection sleeve over the cutting tip of the harvester tube (Figure 13). Position the harvester tube over the dilated opening of the tibial tunnel. Impact the calibrated end of the plunger with a mallet until it is flush with the collet, compacting the cylindrical bone dowel into place (Figure 14). Reinsert the arthroscope into the joint and confirm that bone dowel has not been driven into the joint.



Completed technique with WasherLoc™ device and added bone dowel.

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Package Insert

Biomot Sports Medicine, Inc.

4861 E. Airport Dr.
Ontario, CA 91761, USA

21282002

Rev.D
Date: 02/07

Biomot Sports Medicine™ Internal Fixation Devices

ATTENTION OPERATING SURGEON

DESCRIPTION

Biomot Sports Medicine manufactures a variety of internal fixation devices intended to aid in arthroscopic and orthopedic reconstructive procedures requiring soft tissue fixation, due to injury or degenerative disease. Implants used for this application include: screws, washers, anchors, pins, and suture. Specialty implants are available for specialized treatments.

Materials

316 LVM Stainless Steel
Titanium Alloy
Ultra-High Molecular Weight Polyethylene (UHMWPE)
Polyester
Polypropylene

INDICATIONS

Bone Mulch™ Screws are intended for use in fixation of semitendinous and/or gracile tendon grafts in ACL reconstruction only.

Interference Screws and Set Screws are intended for use in fixation of patellar bone-tendon-bone grafts in ACL reconstruction.

Screw and Washers are indicated for soft tissue fixation to bone, and bone-to-bone fixation in orthopedic procedures specifically during Ligament reconstruction.

Toggle anchors (i.e., ToggleLoc™ ToggleLoc™ buttons and EZLoc™) are indicated for use for fixation of tendons and ligaments during orthopedic reconstruction procedures such as Anterior Cruciate Ligament (ACL) reconstruction.

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.

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

Biomot Sports Medicine™ internal fixation 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.

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. Intraoperative fracture of screws can occur if excessive force (torque) is applied while seating bone screws.
8. Do not use excessive force when inserting suture anchors. Excessive force (e.g., long, hard hammer blows) may cause fracture or bending of the device. Prior to insertion of the implant, predrill, awl, or tap.
9. DO NOT USE if there is a loss of sterility of the device.
10. Discard and DO NOT USE opened or damaged devices, and use only devices that are packaged in unopened or undamaged containers.
11. Ensure contact of tissue to bone when implanting. DO NOT OVERTIGHTEN the screw. Structural damage to the tissue and implant may occur if the screw is overtightened.
12. 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.
13. The ToggleLoc™ Buttons are used with a size #2 polyester suture or one of equivalent or greater strength, unless otherwise indicated.

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. Biomot 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

Biomot Sports Medicine™ internal fixation implants are supplied sterile and are sterilized by exposure to a minimum dose of 25kGy of gamma radiation or by Ethylene Oxide Gas (ETO) if device contains MaxBraid™ PE suture. Do not resterilize.

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

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

CE 0086

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

Ordering Information

WasherLoc™ Tibial Fixation

WasherLoc™ Tibial Fixation Device	
908469	16mm Extended Spike
908468	18mm Extended Spike

WasherLoc™ Cortical Screw	
908624	24mm
908626	26mm
908628	28mm
908630	30mm
908632	32mm
908634	34mm
908636	36mm
908638	38mm
908640	40mm
908642	42mm
908644	44mm
908646	46mm
908648	48mm
908650	50mm
908652	52mm
908654	54mm
908656	56mm
908658	58mm
908660	60mm

WasherLoc™ Cancellous Screw	
908824	24mm
908826	26mm
908828	28mm
908830	30mm
908832	32mm
908834	34mm
908836	36mm
908838	38mm
908840	40mm
908842	42mm
908844	44mm
908846	46mm
908848	48mm
908850	50mm
908852	52mm
908854	54mm
908856	56mm
908858	58mm
908860	60mm

Bone Dowel Harvester

Bone Dowel Handle

900716

Collets

900717 7mm
 900718 8mm
 900719 9mm
 900720 10mm
 900721 11mm

Plunger

900722 7mm
 900723 8mm
 900724 9mm
 900725 10mm
 900726 11mm

Drill Tip K-Wire

909827

Harvesting Tubes

900737 7mm
 900738 8mm
 900739 9mm
 900740 10mm
 900741 11mm

Dilators

900742 7mm
 900743 8mm
 900744 9mm
 900745 10mm
 900746 11mm

Step Drills

900747 7mm
 900748 8mm
 900749 9mm
 900750 10mm
 900751 11mm

Instrument Case

900710





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