WasherLoc™

TIBIAL FIXATION DEVICE

and the Bone Dowel Harvester:
A slippage resistant, stiff, strong fixation combination for the tibia.

BIOMET®
SPORTS MEDICINE
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 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.

The WasherLoc™ Tibial Fixation Device and the EZLoc™ Femoral Fixation Device were developed in conjunction with Stephen M. Howell, M.D., Sacramento, California.

Proven Strategies for ACL Reconstruction

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Rationale and Technique for Fixing a Soft-Tissue ACL Graft to the Tibia with the WasherLoc™ Device and Autogenous Bone Dowel

At the time of implantation, the WasherLoc™ Tibial Fixation Device and autogenous bone dowel have the mechanical advantage of providing the most slippage resistant, stiffest, and strongest fixation combination for tibial fixation of a soft tissue anterior cruciate ligament graft. 4,12,17,20,21

After implantation, the WasherLoc™ Device and autogenous bone dowel used together have the biologic advantage of encouraging circumferential tendon-tunnel healing,22 reducing the potential for tunnel widening,18 maintaining stability in the face of the obligatory tension loss in the graft,7 and lowering the tension in the graft during open-chain exercise,13 all of which can allow for brace-free, aggressive rehabilitation.

Combining the EZLoc™ Femoral Fixation Device with the WasherLoc™ Tibial Fixation Device and autogenous bone dowel provides a comprehensive fixation combination to resist slippage of the soft-tissue graft with respect to the fixation device and slippage of the fixation device in bone during the first month of brace-free, aggressive rehabilitation.23

Although the WasherLoc™ and EZLoc™ devices are considered “distal fixation devices,” they have demonstrated restoration of the same anterior laxity16 and provide better stiffness than intratunnel devices.16 Distal fixation devices have less slippage,2,14 less tunnel widening,1,18 and provide greater surface area (i.e. circumferential contact) for tendon-tunnel healing, than intratunnel devices.12,18,22
Advantages of Soft Tissue ACL Grafts

The double-looped semitendinosus and gracilis (DLSTG) hamstring graft is the strongest and stiffest autogenous graft available,\textsuperscript{8,17} and the single-looped tibialis allograft is the strongest and stiffest allograft available.\textsuperscript{9,19} Both of these soft-tissue grafts have less harvest morbidity compared to other autogenous graft sources. The DLSTG autograft and the tibialis allograft are not normally associated with the complications of a bone-patellar tendon-bone graft which include quadriceps weakness, patellar fracture, patellar tendon rupture, anterior knee pain, and degeneration of the articular surface of the patella-femoral joint. Most surgeons prefer the soft-tissue ACL graft because of its structural properties, minimal or non-existent harvest morbidity, and ease of rehabilitation.\textsuperscript{10,11}

Limitation of Tendon-Tunnel Healing

Ways to improve the fixation strength of a tendon graft are needed because the biologic bond is only half as strong as a bone-patellar tendon-bone graft at three weeks.\textsuperscript{24} By four weeks the tendon-tunnel interface provides most of the fixation strength offloading the mechanical strength provided by the fixation device.\textsuperscript{25} However, it isn’t until six weeks that the strength of the biologic bond of the tendon-tunnel interface equals that of the bone-patellar tendon-bone graft.\textsuperscript{24} Therefore, during the first six weeks of implantation, the fixation method of a soft-tissue graft must provide more slippage resistance, stiffness, and strength than the fixation used with a bone-patellar tendon-bone graft.\textsuperscript{24}

Enhancing Tendon Tunnel Healing

There are several ways to improve the healing, strength, and stiffness of the tendon-tunnel biologic bond within the first six weeks of the reconstruction that might benefit clinical outcome.\textsuperscript{18,22,24} The use of a longer tunnel provides more surface area for bonding.\textsuperscript{6,22} The addition of autogenous biologic material inside the tunnel alongside the soft-tissue graft tightens the fit and improves tendon-tunnel contact.\textsuperscript{15} Finally, the use of distal fixation devices instead of intratunnel fixation devices, allows circumferential rather than one-sided healing of the tendon to the tunnel wall.\textsuperscript{22} Each one of these factors is known to improve the healing, strength, and stiffness of the biologic bond.\textsuperscript{6,15,16,22} These findings suggest that the principles for improving early healing and biologic fixation include the use of slippage resistant, stiff, and strong distal fixation devices in conjunction with compaction of bone into the tunnel alongside the soft tissue graft. Collectively, the fixation combination of the WasherLoc™ Device, EZLoc™ Device, and Bone Dowel provide long, tight fitting tunnels that allow circumferential tendon-tunnel healing.

Reducing the Need for Hardware Removal

Removal of painful prominent hardware continues to be the most common reason for additional surgery using a hamstring graft, with the incidence ranging from 12 to 26%.\textsuperscript{3,11,21} The WasherLoc™ Device may minimize discomfort with kneeling or impact,\textsuperscript{11} because the average prominence of the WasherLoc™ Device is only 2mm, which is significantly less than other tibial fixation methods such as staples (7mm) and washers (7 to 8mm).\textsuperscript{17}
Surgical Technique

Harvest a Bone Dowel from the Tibial Tunnel

Place the 2.4 mm 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. 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).
Disengage the collet from the handle. Read the calibrated plunger and determine the length of the bone plug (typically 25–35 mm) (Figure 7). If the guidepin was removed with the Bone Dowel Harvester, then re-insert the guidepin into the notch by inserting an 8mm femoral reamer into the tibial tunnel and then passing a guidepin through the cannulation and through the tibial plateau (Figure 8). Finish drilling the tibial tunnel with the cannulated reamer that matches the diameter of the graft (Figure 9).
Prepare the Pilot Hole for the Counter Bore

Use electrocautery and a ronguer to remove a 17 x 17mm section of the superficial layer of the MCL from the cortical opening of the tibial tunnel. The majority of the superficial MCL fibers are retained and the deep fibers of the MCL are undisturbed. Insert the counter bore guide into the tibial tunnel until the vertical sleeve is compressed against the distal end of the anterior edge of the tibial tunnel. Rotate the counter bore guide until the sleeve for the awl is pointing from anteromedial to posterolateral towards the fibula (Figure 10). Impact the awl through the sleeve until it is fully seated (Figure 11). Remove the guide and replace the awl in the pilot hole to maintain orientation. The long axis of the awl should be perpendicular to the posterior wall of the tibial tunnel and pointing posterolateral toward the fibula.

Ream the Counter Bore

Memorize the orientation of the awl, remove it, and insert the tip of the counter bore into the pilot hole at the same angle. Maintain the cutting surface of the counter bore parallel to the posterior wall of the tibial tunnel. Ream until the counter bore is flush with the posterior wall of the tibial tunnel and save the reamings (Figure 12).
**Select the Correct Size WasherLoc™ Device**

Select the 16mm Extended Spike WasherLoc™ for a 7 or 8mm diameter graft. Select the 18mm Extended Spike WasherLoc™ for a 9 or 10mm diameter graft. Thread the WasherLoc™ Device on the drill guide and thread the drill guide on the awl (Figure 13).

**Tension the Graft and Impact the WasherLoc™ Device**

After fixing the graft to the femur with the EZLoc™ Femoral Fixation Device, manually tension the graft and cycle the knee full extension to maximum flexion. Tensioning the graft and cycling the knee seats the EZLoc™ Device and removes slack in the graft. Place the knee in maximum hyperextension and maintain this position by resting the heel on Mayo stand. Place an impingement rod between the sutures attached to the tendons and have an assistant tension the graft in line with the tibial tunnel by pulling on the rod (Figure 14). Rotate the WasherLoc™ Device so that the flat edge faces the distal end of the tibial tunnel (Figure 15). Place the tip of the awl between the limbs of each tendon and use a right-angle clamp to maneuver the graft under the WasherLoc™ Device so that all four bundles are contained within the four longer extended spikes (Figure 16). Impact the WasherLoc™ Device using a mallet (Figure 17).
Drill, Measure and Insert the Cancellous Compression Screw

Maintain tension on the graft. Unscrew and remove the awl from the drill guide. Insert a 3.2mm drill bit through the drill guide and push the cutting tip past the tendons (Figure 18). Protect the neurovascular structures by carefully drilling toward the fibula and through the LATERAL tibial cortex without plunging into the soft tissues. Unscrew the drill guide, insert the depth gauge, and measure the length of the tunnel (Figure 19). Momentarily leave the depth gauge in place and adjust the overhead light until the depth gauge casts a shadow on the thigh. Mark the long axis of the shadow casted by the depth gauge. Screw the appropriate sized self-tapping cancellous compression screw into the tibia. Keep the shadow of the shaft of the screwdriver in line with axis of the depth gauge while advancing the compression screw (Figures 20 and 21).
Compact Bone Dowel into the Tibial Tunnel

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 22). 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 23). Reinsert the arthroscope into the joint and confirm that bone graft has not been impacted into the joint through the tibial tunnel.

Completed technique with WasherLoc™ Device and added bone dowel.
The WasherLoc™ compression screw should course toward the fibula from anteromedial to posterolateral and exit through the LATERAL cortex of the tibia (open circle), which avoids neurovascular structures. On the AP view the WasherLoc™ Device should be parallel to the back wall of the tibial tunnel. The bone dowel should fill the anteromedial section of the tibial tunnel (irregular line).

References

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Date: 02/07
Biomet Sports Medicine® Internal Fixation Devices

DESCRIPTION
Biomet 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. Specially implants are available for specialized treatments.

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

INDICATIONS
Bone Mulch™ Screws are intended for use in fixation of semitendinous and/or gracilis 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
Biomet 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 alkalies 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. Notch or bend can weaken the implant, allowing the device to break or migrate, leading to device or procedure failure.

8. Do not use excessive force when inserting anchors. Excessive force (e.g., long, hard hammer blow) can cause fracture or bending of the device. Prior to insertion of the implant, predril, 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 package in unopened or undamaged containers. DO NOT OVERTIGHTEN the screw. Structural damage to the tissue and implant may occur if the screw is overtightened.

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. 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
- Nonunion or delayed union, which may lead to breakage of the implant.
- Bending or fracture of the implant.
- Loosening or migration of the implant.
- Metal sensitivity, or allergic reaction to a foreign body.
- Pain, discomfort, or abnormal sensation due to the presence of the device.
- Nerve damage due to surgical trauma.
- Necrosis of bone or tissue.
- Inadequate healing.
- Intraoperative or postoperative bone fracture and/or postoperative pain.

STERILITY
Biomet 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: Biomet UK, Ltd. Waterton Industrial Estates, Bridgend, South Wales CF31 3XA, U.K.
### WasherLoc™ Tibial Fixation Device

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### WasherLoc™ Cancellous Screw

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### Bone Dowel Harvester

#### Harvesting Tubes (Disposable)

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