WasherLoc Tibial Fixation Devices and the No-Profile Screw and Washer System

ATTENTION OPERATING SURGEON

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 the WasherLoc Tibial Fixation Devices and the No-Profile Screw and Washer System.

MATERIALS
Titanium Alloy (Ti-6Al-4V)

INDICATIONS
Soft tissue fixation to bone, specifically during ligament reconstructive procedures.

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.

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 washers.
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 if there is a loss of sterility of the device.
9. DO NOT USE opened or damaged devices, and use only devices that are package in unopened or undamaged containers.
10. 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.
11. 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.
   a. Patients affected 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.
   b. 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.
   c. The patient is to be made fully aware and warned that the implant does not replace normal healthy bone, and that the implant can break, bend or be damaged as a result of stress, activity, load bearing, or weight bearing.
   d. 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.
   e. The patient is to be warned that failure to follow postoperative care instructions can cause failure of the implant and the treatment.
   f. The patient is to be advised of the need for regular postoperative follow-up examinations as long as the implant remains implanted.
   g. Patients that engage in stressful physical activities are to be warned that injury at or near the implant site can lead to subsequent failure of the implant and/or the treatment.
12. 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.
13. Device is single use only. After use, the device may be a potential biohazard. Reuse of devices labeled for single-use may result in product contamination, patient infection and/or failure of the device to perform as intended.
14. Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.
15. Excessive, unusual and/or awkward movement and/or activity, trauma, excessive weight, and obesity have been implicated with premature failure of certain implants by loosening, fracture, dislocation, subluxation and/or wear.

PRECAUTIONS
Specialized instruments are designed for Biomet® Internal Fixation Device systems to aid in the accurate implantation of the components. The use of instruments or implant components from other systems can result in inaccurate fit, incorrect sizing, excessive wear and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments that 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.

All trial, packaging, and instrument components must be removed prior to closing the surgical site. Do not implant.
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.
10. Early or late postoperative infection and/or allergic reaction.

Biomet® WasherLoc and No-Profile Screw in the Magnetic Resonance (MR) Environment

Biomet® WasherLoc and No-Profile Screws are composed of non-ferromagnetic Titanium (Ti-6Al-4V). Biomet has performed bench testing and numerical simulations on these components in a Magnetic Resonance Imaging (MRI) environment. These tests determined the non-clinical effects of MRI based on scientifically relevant characteristics of the WasherLoc components.

MR Conditions
The WasherLoc and No-Profile Screws are determined to be MR Conditional in accordance to ASTM F2503-08 Standard Practice for Marking Devices and Other Items for Safety in the Magnetic Resonance Environment. MR Conditional refers to an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.

Safety information for the use of MRI procedures (i.e. imaging, angiography, functional imaging, spectroscopy, etc.) pertains to shielded MRI systems under the following specifications:
- Static magnetic field of 1.5-Tesla (1.5T) and 3.0-Tesla (3.0T)
- Spatial gradient field of 2500-Gauss/cm or less
- Maximum MR System reported, whole-body-averaged specific absorption rate (SAR) of 2 W/kg for up to 15 minutes of scanning
- Normal Operating Mode,
- The effects of local RF transmit coils have not been tested and are not recommended in the area of the implant
- Recommended Good Clinical Practices
  o The use of porous insulation between the patient and the edge of the bore
  o Prevention of patient’s legs from touching each other and arms/hands from touching body

MR Information
Temperature evaluations of WasherLoc components yielded the following in-vitro rises.

1.5T MR Systems
- A temperature rise in a test performed according to ASTM F2182-11a of less than 7.0°C was calculated when scaled to phantom whole-body-averaged SAR of 2 W/kg for 15-minutes of RF power application.

3.0T MR Systems
- A temperature rise in a test performed according to ASTM F2182-11a of less than 8.0°C was calculated when scaled to phantom whole-body-averaged SAR of 2 W/kg for 15-minutes of RF power application.

Image Artifacts
In testing performed per ASTM F-2119-07, the Washerloc and No-Profile Screws exhibited artifacts which extend about 27mm beyond the implant. Therefore, it may be necessary to optimize MR imaging parameters for the presence of these implants.

Other: Testing of materials used in the WasherLoc and No-Profile Screws indicated no known risks of magnetically induced displacement force or torque for the field conditions given above.

STERILITY
Biomet Sports Medicine internal fixation implants are supplied sterile and are sterilized by exposure to a minimum dose of 25kGy of gamma radiation. Do not resterilize. Single Use Only. Do Not Reuse. Do not use past expiration date.

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

Comments regarding this device can be directed to ATTN: Regulatory Dept., Biomet, Inc., P.O. Box 587, Warsaw, IN 46581, Fax: 574-372-3968.

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

CE Mark on the package insert (IFU) is not valid unless there is a CE Mark on the product (description) label.

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

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Authorized representative in the European Community