



# Precautionary Statement (01-50-1078)

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**Biomet Sports Medicine, Inc.**

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**01-50-1078**

Date: 04/07

## **Biomet Sports Medicine™ Non-Resorbable, Soft Tissue Anchoring Devices**

### **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: 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

Polyetheretherketone (PEEK)

Polypropylene

Tantalum

**INDICATIONS** The Metal Screw Anchor and ALLthread™ PEEK Suture Anchor are indicated for use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, and knee. Specific indications as follows:

Shoulder Indications - Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, deltoid repair.

Wrist/Hand Indications - Scapholunate ligament reconstruction (not including Allthread™ Ti Suture Anchors), ulnar/radial collateral ligament reconstruction.

Ankle/Foot Indications - Lateral stabilization, medial stabilization, Achilles tendon repair/reconstruction, hallux valgus reconstruction, mid- and forefoot reconstruction.

Elbow Indications - Ulnar or radial collateral ligament reconstruction, biceps tendon reconstruction

Elbow Indications (ALLthread™ PEEK Suture Anchor Only) - Lateral epicondylitis repair

Knee Indications - Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis, and patellar ligament/tendon repair.

The Hitch™ PEEK Suture Anchors are indicated for use in soft tissue reattachment procedures. Specific Indications are:

Shoulder Indications - Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, deltoid repair.

Wrist - Scapholunate ligament reconstruction

Elbow - Biceps tendon reattachment, Ulnar or radial collateral ligament reconstruction.

Knee Indications - Extracapsular Repair: Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis reconstruction, and patellar ligament and tendon repair, vastus medialis obliquus (VMO) muscle advancement.

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 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 assure 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.

## **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**

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). Do not resterilize.

**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, P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-1683.

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