Biomet Sports Medicine™ Metal Suture Anchors

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. Metal suture anchors are used to provide soft tissue fixation to bone during healing.

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

INDICATIONS
Metal suture anchors are indicated for use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, and knee. Specific indications are 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 – 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.

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.

CONTRAINdications
1. Active 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™ metal suture anchors 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.

CONTRAINDICATIONS
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.

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 metal suture anchors. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments should be used for their intended purpose. Instruments, which have experienced extensive use or excessive torque, may cause fracture or bending of the device. When encountering hard cortical bone, predrill with a 3/32 or 1/8 inch drill prior to inserting suture anchors.

7. 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 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. The patient is to be instructed in the use of external supports, walking aids, and braces that are intended to limit weight bearing or load bearing. The patient is to be made fully aware and warned that the device does not replace normal soft tissue attachment and that the device can break, bend or be damaged as a result of stress, activity, load bearing, and/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 examination as long as the device remains implanted.

POSSIBLE ADVERSE EFFECTS
1. Nerve damage due to surgical trauma.
2. Necrosis of bone or tissue.
3. Inadequate healing.
4. Intraoperative or postoperative bone fracture and/or postoperative pain.
Biomet Sports Medicine™ metal suture anchors 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™ suture. Do not resterilize.

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

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