



Precautionary Statement (01-50-1001)

Biomet Sports Medicine, Inc. 01-50-1001

P.O. Box 587

Date: 03/07

56 East Bell Drive

Warsaw, Indiana 46581 USA

Biomet Sports Medicine™ Bio-Phase™ Resorbable Suture Anchor

ATTENTION OPERATING SURGEON

DESCRIPTION:

The Biomet Sports Medicine™ Bio-Phase™ Suture Anchor is a resorbable repair device used to attach soft tissue to bone using sutures. The resorbable anchor is implanted into a prepared hole in the bone and secures a suture used to reattach damaged soft tissue. The suture anchors are made of a resorbable copolymer, a polyester derivative of lactic acid and glycolic acid. Polylactic/polyglycolic acid copolymer degrades and resorbs in vivo by hydrolysis to lactic and glycolic acids that are then metabolized by the body.

MATERIALS:

Poly-L-Lactic Acid/Polyglycolic Acid

Polyester

INDICATIONS:

1. 3.0mm Resorbable Suture Anchor Shoulder Indications:
 - Bankart Repair
 - SLAP Lesion Repair
 - Acromio-clavicular Separation
 - Rotator Cuff Repair
 - Capsule Repair and Capsulolabral Reconstruction
 - Biceps Tenodesis
 - Deltoid Repair
2. 2.0mm Resorbable Suture Anchor Wrist/Hand Indications:
 - Wrist: Scapholunate Ligament Reconstruction
 - Hand: Ulnar Collateral Ligament Reconstruction
 - Radial Collateral Ligament Reconstruction

CONTRAINDICATIONS:

1. Active infection.
2. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.

3. Patient conditions including: blood supply limitations, insufficient quantity or quality of bone, or latent infections.
4. Pathologic soft tissue conditions that would prevent secure fixation.

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 soft tissue or withstand the stress placed upon the device by full or partial weight bearing or load bearing, particularly in the presence of incomplete healing. Therefore, it is important that immobilization (use of external support, sling, 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 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 polymeric 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, the device is not designed to withstand the unsupported stress of full weight bearing, load bearing or excessive activity.
2. The implants can loosen or be damaged when subjected to increased loading associated with inadequate healing. 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. 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.
5. The use of appropriate immobilization and postoperative management is indicated as part of the treatment until healing has occurred.
6. 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 devices can occur if excessive force (torque) is applied while seating.
7. 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 or awl.
8. DO NOT USE if there is loss of sterility of the device.
9. Discard and DO NOT USE opened or damaged devices, and use only devices that are packaged in unopened or undamaged containers.
10. DO NOT USE with other resorbable implant materials.
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 soft tissue 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 that are intended to immobilize the repair 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 tissue, 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 examination as long as the device remains implanted.

PRECAUTIONS:

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.

POSSIBLE ADVERSE EFFECTS:

1. Infection can lead to failure of the procedure.
2. Neurovascular injuries can occur due to surgical trauma.
3. Bending, fracture, loosening, rubbing, and migration of the implant may occur as a result of excessive activity, trauma, or load bearing.
4. Implantation of foreign materials can result in an inflammatory response or allergic reaction.
5. Inadequate healing.
6. Pain, discomfort, or abnormal sensation due to the presence of the device.
7. Necrosis of the bone or tissue.

STERILITY:

Biomet Sports Medicine™ resorbable implants are sterilized by exposure to Ethylene Oxide (ETO) Gas. Do not resterilize. Do not use past expiration date.

STORE AT OR BELOW ROOM TEMPERATURE. DO NOT EXPOSE PRODUCT TO TEMPERATURES GREATER THAN 120°F OR 49°C.

Caution: Federal Law (USA) restricts this device to sale, distribution, or use 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: 574-372-1683

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