



# Precautionary Statement (01-50-1063)

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**Biomet Sports Medicine, Inc.**

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**01-50-1063**

Date: 04/07

## **Biomet Sports Medicine™ RC Buttress**

### **Attention Operating Surgeon**

#### **Description**

The Biomet Sports Medicine™ RC (rotator cuff) Buttress is a resorbable plate comprised of LactoSorb® material. The plates are made of a resorbable copolymer, a polyester derivative of L-lactic and glycolic acids. Poly L-lactic/polyglycolic acid copolymer degrades and resorbs in vivo by hydrolysis into L-lactic and glycolic acids, which are then metabolized by the body.

#### **MATERIALS:**

Poly-L-Lactic Acid/Polyglycolic Acid

#### **INDICATIONS**

The RC Buttress is indicated for use to protect the suture during its use in transosseous bone tunneling in the repair of rotator cuff tears of the shoulder.

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 the 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 resorbable 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 proper type of implant. While proper selection can 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 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. Improper selection, placement, positioning, and fixation of the device can lead to failure of the device or the procedure. The surgeon is to be familiar with the devices, the method of application and the surgical procedure prior to performing surgery. The surgeon must select a type or types of internal fixation devices appropriate for treatment.
4. The LactoSorb® devices are resorbable and do not provide permanent fixation. DO NOT USE in procedures where a permanent implant is needed.
5. 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 a greater risk of device loosening and procedure failure.
6. Correct handling of implants is extremely important. The buttress plate can be heated and shaped as desired up to three times using the LactoSorb™ Heat Pack. Use of any other method to heat the buttress plate is NOT recommended.
7. The devices can break or be damaged due to excessive activity or trauma. This could lead to failure requiring additional surgery and device removal.
8. Discard and DO NOT USE previously opened or damaged devices. Use only devices that are packaged in unopened and undamaged containers.
9. DO NOT USE if there is a loss of sterility of the device.
10. Do not use Biomet Sports Medicine™ resorbable implants with resorbable implants made by other manufacturers, due to the probability of incompatible fits, size, and rate of resorption.
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 management.
  - o 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.
  - o The patient is to be instructed in the use of slings and braces that are intended to immobilize the shoulder and limit weight bearing or load bearing.
  - o The patients are 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.
  - o 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.
  - o The patient is to be warned that failure to follow postoperative care instructions can cause failure of the implant and the treatment.

- The patient is to be advised of the need for regular postoperative follow-up examination as long as the device remains implanted.
  - Patients that engage in stressful physical activities are to be warned that injury at or near the implant site can lead to failure of the device and/or the treatment.
12. Noncompliance with postoperative instructions could lead to failure of the device, which could require additional surgery and device removal.

**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 that have experienced extensive use or excessive force are susceptible to fracture. Surgical instruments should be only 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 devices can 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. Incomplete healing, which may lead to breakage of the implant or failure of the treatment.
6. Pain, discomfort, or abnormal sensation due to the presence of the device.

**DIRECTIONS FOR USE**

DO NOT pass sutures between holes in the same half of the plate, as this is the smallest bridge on the plate.

Example:



Do not pass through holes:

- 1 to 2 3 to 6
- 1 to 4 3 to 5
- 2 to 4 5 to 6

Sutures may be passed through buttress plate as seen.

**STERILITY**

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 by or on the order of 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

LactoSorb is a registered trademark of Biomet Manufacturing Corp. in the United States.

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