



# Precautionary Statement (01-50-1064A)

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**Biomet Sports Medicine, Inc.**

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**01-50-1064A**

Date: 10/07

## **Biomet Sports Medicine™ Resorbable Fixation Devices ATTENTION OPERATING SURGEON**

### **DESCRIPTION**

Biomet Sports Medicine™ resorbable fixation devices include screws, sheets, mesh, plates, rivets, and pins. Biomet Sports Medicine™ resorbable fixation devices 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**

1. The LactoSorb™ Hand System is indicated for surgical fixation of closed non-comminuted diaphyseal fractures in the presence of appropriate immobilization.
2. The LactoSorb™ 5.0mm Washer is used in conjunction with the Biomet Sports Medicine™ 5.0 mm Bone Screw for ankle fractures, metatarsal fusion, and metatarsal osteotomies (Hallux Valgus) in the presence of appropriate protection or immobilization (e.g. casting, bracing, external fixator etc.).
3. The 2.0 mm, 2.5mm and 3.5mm Resorbable Bone Screws, and Resorbable Bone Pins, are indicated for use in the presence of appropriate immobilization in the following procedures: correction of Hallux Valgus (bunion) and repair of metacarpal and phalangeal fusion and fractures.
4. The resorbable mesh, sheets, 2.5mm and 3.5mm screws, and 2.5mm rivets are indicated for maintaining the position of bony fragments or morselized bone graft in iliac crest autograft procedures. The LactoSorb™ devices are not intended for use in spine or joint space. This product is not intended for pelvic fracture fixation.
5. The Resorbable Hammer Toe Pin is a resorbable device used for proximal interphalangeal joint (PIP) arthrodesis.
6. The LactoNail™ Bone Fixation is intended for use in the fixation of fragments of fractured non-load bearing bones, osteotomies, and arthrodesis. Examples include the fixation of apical fragments, osteochondral fragments and cancellous/non-load bearing fragments.

## **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, obesity, insufficient quantity or quality of bone stock or latent infection.
4. Do not use in load bearing procedures (excluding 5.0 screws and Hammer Toe Pins, see above indications).
5. Do not use LactoNail™ Bone Fixation for fractures and osteotomies of weight bearing cortical bone (except cortical bones of the foot and the hand).
6. Do not use LactoNail™ Bone Fixation for fractures and osteotomies in weight bearing cancellous bone.
7. Do not use LactoNail™ Bone Fixation in the treatment of physeal fractures in children.

## **WARNINGS**

Biomet Sports Medicine™ internal fixation devices aid the surgeon in the alignment and stabilization of skeletal fractures and provide a means of fracture management in reconstructive surgical applications. 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 resorbable aspects of the surgical implants.

1. Correct selection of the implant is extremely important. The potential for success in fracture 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. 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.
3. 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.
4. These 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 greater risk of device loosening and procedure failure.
6. Correct handling of implants is extremely important. Except as described in Warnings #7 and #8, do not modify, 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 resorbable fixation devices. 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.
8. The plates, mesh, and sheets can be heated and shaped as desired up to and including three times using the LactoSorb™ Heat Pack or a hot sterile saline/water bath. Exposure of LactoSorb™ implants to the bath should be a maximum of 15 seconds per bath with the temperature not exceeding 85 °C. Do not heat LactoSorb™ resorbable bone screws, rivets, pins or nails by any means prior to implantation.
9. Cutting of screws, pins, and nails: These devices can be cut with an oscillating or reciprocating saw. No other cutting method may be used. After implantation, screws should only be cut at the distal protrusion.
10. The devices can break or be damaged due to excessive activity or trauma. This could lead to failure requiring additional surgery and device removal.
11. Discard and DO NOT USE previously opened or damaged devices. Use only devices that are packaged in unopened or undamaged containers.
12. DO NOT USE if there is loss of sterility of the device.
13. 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.
14. When resorbable fixation devices are used to aid in the alignment and stabilization of bones in the hand, appropriate immobilization and rehabilitation is necessary for the desired outcome.
15. These resorbable devices provide temporary fixation and are not intended to replace normal healthy bone or withstand stress of load bearing.
16. 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 with senility, mental illness, alcoholism, or drug abuse may be at higher risk of device 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 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.
17. Noncompliance with postoperative instructions could lead to failure of the device, which could require additional surgery and device removal.
18. These devices should not be used for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

## **PRECAUTIONS**

Instruments are available to aid in the accurate implantation of Biomet Sports Medicine™ resorbable fixations devices. Intraoperative fracture 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 are only to 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 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. Nonunion, delayed union, or 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.
7. Disfigurement may occur due to improper alignment of bone fragments.
8. Necrosis of bone.
9. Inadequate healing.

**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 (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 USA, Fax: 574-372-3968.

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