

Biomet Microfixation, Inc.
1520 Tradeport Drive
Jacksonville, Florida 32218 USA
(904)741-4400, FAX: (904)741-4500

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LactoSorb® Sheeting

ATTENTION OPERATING SURGEON

DESCRIPTION

LactoSorb® Sheeting consists of resorbable sheets of LactoSorb® available in various sizes. The sheets are designed to provide fixation in non-load bearing areas of the midface and craniofacial skeleton, as well as maintaining the position of bony fragments in mandibular and iliac crest bone graft procedures. LactoSorb® screws or rivets are recommended to fasten the LactoSorb® sheets to bone. Drill holes are placed a minimum of 2.5mm from the edge of the material and drilled at low-speed with copious irrigation.

LactoSorb® Sheeting is 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

LactoSorb® Sheeting is used as a fixation device in the following procedures:

- A. General Indication: Trauma procedures of the midface or craniofacial skeleton.

Specific Indications:

1. Comminuted fractures of the naso-ethmoidal infraorbital areas.
2. Comminuted fractures of the frontal sinus wall.
3. Pediatric midface or craniofacial trauma.
4. Orbital floor fractures.
5. Trauma of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones.

- B. General Indication: Reconstructive procedures of the midface or craniofacial skeleton.

Specific Indications:

1. Infant craniofacial surgery (i.e. craniosynostosis, congenital malformation, trauma, etc.).
2. Tumor reconstruction in midface or craniofacial skeleton.
3. Bone graft procedures in the midface or craniofacial skeleton
4. Pediatric reconstructive procedures.
5. Reconstructive procedures of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones
6. Craniotomy flap fixation.

- C. Mandible Indication: LactoSorb® Sheeting and Fasteners are used to maintain the position of bony fragments in mandibular bone graft procedures and are used in conjunction with rigid internal fixation.

- D. Used in maintaining the position of bony fragments or morselized bone graft in iliac crest autograft procedures. Lactosorb® devices are not intended for use in the spine or joint space. This product is not intended for pelvic fracture fixation.

CONTRAINDICATIONS

1. Active infection
2. Patient conditions including: blood supply limitations, insufficient quantity or quality of bone, or latent infections.
3. DO NOT USE in load bearing procedures.
4. DO NOT USE in the temporomandibular joint (TMJ).
5. DO NOT USE in the spine or joint space.

WARNINGS

1. Improper selection, placement, positioning, or fixation of the devices can cause a subsequent undesirable result. The surgeon is to be familiar with the devices, the method of application, instruments, and surgical procedure prior to performing surgery.

2. These resorbable devices provide temporary fixation and are not intended to replace normal healthy bone or withstand stress of load bearing.
3. LactoSorb® Sheeting is resorbable and does not provide permanent fixation. DO NOT USE in procedures where a permanent implant is needed.
4. LactoSorb® Sheeting can be heated and shaped as desired up to and including three times using a Lactosorb™ Heat Pack or a hot sterile saline/water bath. LactoSorb® exposure to the bath should be limited to a maximum of 15 seconds per bath with the temperature not exceeding 85° C. Screws are not to be heated or reshaped by any means.
5. Do not attempt shaping prior to heating.
6. A low-speed drill with copious irrigation should be used to create holes in the sheet. Drill holes are placed a minimum of 2.5mm from the edge of the material. Do not drill holes in heated sheets. Sheets must be at room temperature when drilling holes.
7. The devices can break or be damaged due to excessive activity or trauma. This could lead to failure of the sheets, which could require additional surgery and device removal.
8. Discard and DO NOT USE opened or damaged devices, and use only devices that are packaged in unopened and undamaged containers.
9. DO NOT USE if there is loss of sterility of the device.

PRECAUTIONS

1. The patient is to be warned that the device can break or loosen as a result of stress, excessive activity, or load bearing which may lead to additional surgery.
2. The patient is to be made aware of surgical risks and possible adverse effects prior to surgery, and warned that failure to follow postoperative care instructions can cause failure of the implant and the treatment.

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, and migration of the device 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. Inadequate healing.
6. Pain, discomfort, or abnormal sensation due to the presence of the device.
7. Necrosis of the bone or tissue.

STERILITY

LactoSorb® Sheeting is 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.

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

Authorized Representative Biomet U.K., Ltd.
Waterton Industrial Estate
Bridgend, South Wales
CF31 3XA, U.K.
Phone: (+44) 1656 655221
Fax: (+44) 1656 645454

CE 0086

European Sales Headquarters: Biomet Microfixation Europe
Toermalijnring 600
3316 LC Dordrecht
Netherlands
Phone: (+31) 78 629 29 10
Fax: (+31) 78 629 29 12