

Biomet Microfixation

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LactoSorb™ Trauma Plating System

ATTENTION OPERATING SURGEON

DESCRIPTION

The LactoSorb™ Trauma Plating System consists of resorbable fixation devices (plates, meshes, screws, and rivets). The system is used in trauma and reconstructive surgical procedures in the midface and craniofacial skeleton.

The 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

A. General Indications: trauma procedures of the midface or craniofacial skeleton.

Specific Indications:

1. comminuted fractures of the naso-ethmoidal and intraorbital area.
2. comminuted fractures of the frontal sinus wall.
3. pediatric midface or craniofacial trauma.
4. LeFort (I, II, III) fractures.
5. orbital floor fractures.
6. fractures of the maxilla, zygoma, zygomatic arch, orbital rim, nasal, ethmoid, and lacrimal bones.
7. trauma of the craniofacial skeleton, including frontal, parietal, temporal, sphenoid, and occipital bones.

B. General Indications: reconstructive procedures of the midface or craniofacial skeleton.

Specific Indications:

1. infant craniofacial surgery (i.e. craniosynostosis, congenital malformation, trauma, etc.)
2. LeFort (I, II, III) osteotomies.
3. tumor reconstruction in midface or craniofacial procedures.
4. bone graft procedures in the midface or craniofacial skeleton.
5. pediatric reconstructive procedures.
6. reconstructive procedures of the craniofacial skeleton including, frontal, parietal, temporal, sphenoid, and occipital bones.
7. craniotomy flap fixation.

C. Mandibular Indication (2.5mm diameter screws):

The 2.5mm LactoSorb™ Screws are indicated for use as fixation in mandibular osteotomy procedures, including but not limited to:

1. sagittal split osteotomy
2. vertical ramus osteotomy
3. inferior border osteotomy
4. subapical osteotomy
5. genioplasty

D. Orthopedic Indication: Used in maintaining the position of bony fragments or morselized bone graft in iliac crest autograft procedures. The 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 stock or latent infection.
3. DO NOT USE in full load bearing procedures.
4. DO NOT USE in the temporomandibular joint (TMJ).

WARNINGS

1. Improper selection, placement, positioning, or fixation of the implant can cause a subsequent undesirable result. The surgeon is to be familiar with the devices, the method of application and the surgical procedure prior to performing surgery.
2. These resorbable devices provide fixation and are not intended to replace normal healthy bone or withstand stress of full load bearing.
3. These devices are resorbable and do not provide permanent fixation. DO NOT USE in procedures where a permanent implant is needed.
4. The plates/meshes 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. Exposure of LactoSorb™ to the bath should be a maximum of 15 seconds per bath with the temperature not exceeding 85° C. Screws and rivets are not to be heated or reshaped by any means.
5. The devices can break or be damaged due to excessive activity or trauma. This could lead to failure of the plates and/or screws which could require additional surgery and device removal.
6. Discard and DO NOT USE previously opened or damaged devices. Use only devices that are packaged in unopened and undamaged containers.
7. DO NOT USE if there is loss of sterility of the device.
8. When utilizing the Direct Drive LactoSorb™ push screw, do not rotate implant on insertion.

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.
2. The patient is to be made aware of the 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.
3. Do not use LactoSorb™ implants with resorbable implants made by other manufacturers due to the probability of incompatible fits, size and rate of resorption.
4. Instruments are available to aid in the accurate implantation of LactoSorb™ fixation 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. All instruments are to be regularly inspected for wear and disfigurement.
5. Templates are made of aluminum and are to be used to assist in contouring the plates. Do not drill through templates.

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.

STERILITY

The Lactosorb 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.

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