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RAPIDFLAP™ LS
Resorbable Cranial Flap Fixation System

ATTENTION OPERATING SURGEON

DESCRIPTION

The RapidFlap™ LS Cranial Fixation System is designed to reattach the bone flap after a craniotomy procedure. Each device is comprised of an inner plate and an outer plate. The inner plate consists of a circular disk, with a post extending from the center of the disk. The outer plate consists of a circular disk with a threaded hole to accept the post. The post is rotated by hand which forces the clamps together capturing the cranial bone. When applied, the clamps tightly grip the bone flap, and provide rigid attachment and coplanar alignment to the surrounding bone (see the following Instructions For Use.).

The RapidFlap™ LS Cranial Fixation System 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

The RapidFlap™ LS Cranial Fixation System is indicated for use in pediatric craniotomy flap 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 patients with a decompression flap.

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 device, 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 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 devices can break or be damaged due to excessive activity, load bearing upon insertion *in vivo*, or trauma. This could lead to failure of the device, which could require additional surgery and/or device removal.
5. Discard and **DO NOT USE** previously opened or damaged devices. Use only devices that are packaged in unopened and undamaged containers.
6. **DO NOT USE** if there is loss of sterility of the device.
7. Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been, even momentarily, placed in a different patient.

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.

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.

INSTRUCTIONS FOR USE

To maintain proper stability of the bone flap, the clamp must be 2 - 4mm larger in diameter than the burr hole to securely attach to the surrounding bone. The minimum size burr hole for this device is 5mm.

1. Before replacing the bone flap, position a minimum of three (3) LactoSorb® RapidFlap™ LS clamps around the craniotomy line in order to achieve optimum stability.

NOTE: The clamps should be placed equidistant from each other around the flap. Therefore, if using three clamps, they should be positioned 120° apart. If using four clamps, they should be positioned 90° apart.

2. Replace the bone flap.
3. Tighten the clamps against the cranium by turning the clamp post clockwise while holding the upper disc.
4. After all clamps have been tightened, remove the excess clamp posts by cutting with the cutting tip of the LactoSorb™ Heat/Contouring Pen approximately 2mm above the upper disc. **DO NOT HEAT THIS DEVICE BY ANY OTHER MEANS.**
5. Flatten the approximate 2mm of post remaining above the upper disc using the contouring tip of the LactoSorb™ Heat/Contouring Pen. **DO NOT HEAT THIS DEVICE BY ANY OTHER MEANS.**

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 OR 49° C.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

RapidFlap™ is a trademark of Biomet Microfixation, Inc.

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