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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 in the United States.

LactoSorb® Suspension Screws

ATTENTION OPERATING SURGEON

DESCRIPTION

The LactoSorb® Suspension Screws are resorbable screws. The screws are designed with a hole placed through the screw head for suture attachment. These small anchoring devices are used in open and endoscopic brow procedures with an appropriately size suture.

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

The LactoSorb® Suspension Screws are used to assist resorbable suture in open and endoscopic brow lift procedures.

The screws are compatible for use with USP size 2-0 and/or 3-0 resorbable Vicryl®, PDS II, or comparable suture.

CONTRAINDICATIONS

1. Active Infection.
2. The devices are resorbable and should not be used where prolonged approximation of tissues (beyond six weeks) under stress is required.
3. Patient condition including: blood supply limitations, insufficient quantity or quality of bone, or latent infections.
4. Do not use in mandible.
5. Do not use in full load bearing procedures.
6. Do not use in the temporomandibular joint (TMJ).

WARNINGS

1. Improper selection, placement, and positioning of the devices and/or soft tissue can cause an undesirable result. The surgeon is to be familiar with the devices, the method of application instruments, and the surgical procedure prior to performing surgery.
2. These devices are intended to aid in reattachment of soft tissue to bone during the healing process and are not intended to replace healthy attachment mechanisms.
3. Do not heat the LactoSorb® Suspension Screws by any means prior to implantation.
4. The devices can break or be damaged due to excessive activity or trauma. This could lead to failure of the devices which could require additional surgery or removal.
5. Discard and DO NOT USE 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.

PRECAUTIONS

1. The patient is to be warned that the device and/or suture can break or loosen as a result of stress, excessive activity, or load bearing.
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. Fracture, loosening, and migration of the devices can occur as a result of excessive stress, activity, trauma, or load bearing.
4. Implantation of foreign materials can result in an inflammatory response or allergic reaction.

STERILITY

The LactoSorb® Suspension Screws are sterilized by exposure to Ethylene Oxide (ETO) Gas. Do not resterilize. Do not use past expiration date.

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