GalaFLEX
P4HB Scaffold LITE™

INSTRUCTIONS FOR USE

For respective patents, visit galateasurgical.com/patents

REF Product Code	Do Not Use When Package Is Damaged	Attention, See Instructions For Use
LOT Lot Number	Rx Only Prescription Use Only	MR MR Safe
Use By Expiration Date	STERILE EO Sterilized Using Ethylene Oxide	25°C / 15°C Temperature Limit
Do Not Reuse	Do Not Resterilize	

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GALATEA® SURGICAL

INSTRUCTIONS FOR USE

GalaFLEX LITE™ Scaffold

A P4HB Surgical Scaffold

DESCRIPTION

GalaFLEX LITE scaffold is a bioabsorbable surgical mesh manufactured from poly-4-hydroxybutyrate (P4HB™). P4HB is a biologically derived polymer which is extruded into monofilament fibers and knitted into a surgical scaffold. P4HB bioabsorbs through a process of hydrolysis and hydrolytic enzymatic digestion. It has been developed to optimize absorption rate and prolong strength retention in order to provide support throughout the expected period of healing. Although the scaffold loses strength with time, its porous construction was designed to allow native tissue ingrowth and gradual transfer of load from the scaffold to the tissue.

Pre-clinical implantation studies indicate that the GalaFLEX LITE scaffold retains approximately 54% of its strength at 12 weeks. Bioabsorption of the scaffold material will be essentially complete in 18-24 months.

INDICATIONS FOR USE

GalaFLEX LITE scaffold is intended to reinforce soft tissue where weakness exists in patients undergoing plastic and reconstructive surgery, or for use in procedures involving soft tissue repair, such as the repair of fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

CONTRAINDICATIONS

None known.

WARNINGS

1. Device manufacture involves exposure to tetracycline hydrochloride and kanamycin sulfate. The safety and product use for patients with hypersensitivities to these antibiotics is unknown.
2. The safety and effectiveness of GalaFLEX LITE scaffold in neural tissue and in cardiovascular tissue has not been established.
3. The safety and effectiveness of GalaFLEX LITE scaffold in pediatric use has not been established.
4. Placement of the scaffold in direct contact with bowel or viscera is not recommended.
5. Because GalaFLEX LITE scaffold is fully resorbable, it should not be used in repairs where permanent wound or organ support is required.
6. The safety and effectiveness of GalaFLEX LITE scaffold in laparoscopic surgery has not been established.
7. GalaFLEX LITE scaffold has not been studied for use in breast reconstructive surgeries.
8. If an infection develops, treat the infection aggressively. An unresolved infection may require removal of the scaffold.
9. GalaFLEX LITE scaffold is supplied sterile. Inspect the device and packaging prior to use to be sure they are intact and undamaged.
10. GalaFLEX LITE scaffold is for single use only. Do not re-sterilize or re-use any portion of the GalaFLEX LITE scaffold.
11. Unused scaffold must be discarded according to the institution's procedures for handling of biohazardous materials.
12. Any decisions to explant the scaffold should take into account potential risks associated with a second surgical procedure. Scaffold removal should be followed by adequate post-operative management.

PRECAUTIONS

Only physicians qualified in the appropriate surgical techniques should use this device. Users should be familiar with strength requirements and scaffold size choices for the repair. Improper selection, placement, positioning, and fixation of the GalaFLEX LITE scaffold can cause subsequent undesirable results. No special handling is required prior to use. Prepare as per institutional standards.

The safety and effectiveness of GalaFLEX LITE scaffold in the proximity of existing or excised cancer has not been established.

ADVERSE REACTIONS

Possible complications include infection, seroma, pain, scaffold migration, wound dehiscence, hemorrhage, adhesions, hematoma, inflammation, extrusion and recurrence of the soft tissue defect. In pre-clinical testing, the GalaFLEX LITE scaffold elicited a minimal tissue reaction characteristic of foreign body response to a substance. The tissue reaction resolved as the scaffold was absorbed.

DIRECTIONS FOR USE

Using aseptic technique, GalaFLEX LITE scaffold may be cut to the shape or size desired for each specific application. The scaffold is to be positioned so its edges extend beyond the margins of the defect. It is recommended that surgical fixation be placed ¼ to ½ inches (6 to 12mm) apart at a distance approximately ¼ inch (6mm) from the edge of the scaffold. The edges are then fixated to assure proper closure under correct tension. When anchoring the scaffold, use the type of suture that is appropriate for your application. The edges or corners of the scaffold should be fixated with suture such that it lies flat against the tissue of the repair site. The scaffold should be sufficiently anchored without the expectation of stretch, to stabilize it during tissue ingrowth.

HOW SUPPLIED

GalaFLEX LITE scaffold is available as a sterile, undyed scaffold in single sheet sizes of varying widths, lengths and shapes.

STORAGE

Store at room temperature, 15° to 25°C. Avoid prolonged exposure to elevated temperatures.

MRI SAFETY INFORMATION

The GalaFLEX LITE scaffold is MR safe.

400246 Rev C

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