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 to stabilize it during tissue ingrowth.

HOW SUPPLIED

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

STORAGE

Store at room temperature. Avoid prolonged exposure to elevated temperatures.

REF	Product Code	Rx ONLY	Prescription Use Only
LOT	Lot Number	STERILE EO	Sterilized Using Ethylene Oxide
	Use By Expiration Date		Do Not Resterilize
	Do Not Reuse		Attention, See Instructions For Use

For respective patents, visit galateasurgical.com/patents

400108-Rev L

GALATEA SURGICAL

INSTRUCTIONS FOR USE

GalaFLEX® Scaffold

A Bioresorbable Surgical Scaffold

Galatea Surgical Inc. is a subsidiary of Tepha, Inc.

Manufactured by Tepha, Inc.

99 Hayden Avenue

Lexington, MA 02421

Tel: 781-357-1750

Made in the USA

DESCRIPTION

GalaFLEX scaffold is a bioresorbable surgical mesh manufactured from poly-4-hydroxybutyrate (P4HB). P4HB is produced from a naturally occurring monomer and is processed into monofilament fibers and knitted into a surgical scaffold. P4HB bioresorbs through a process of hydrolysis and hydrolytic enzymatic digestion. It has been developed to optimize resorption 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 GalaFLEX scaffold retains approximately 70% of its strength at 12 weeks. Bioresorption of the scaffold material will be essentially complete within 18-24 months.

INDICATIONS FOR USE

GalaFLEX scaffold is indicated for use as a bioresorbable scaffold for soft tissue support and to repair, elevate and reinforce deficiencies where weakness or voids exist that require the addition of material to obtain the desired surgical outcome. This includes reinforcement of soft tissue in plastic and reconstructive surgery, and general soft tissue reconstruction. GalaFLEX scaffold is also indicated for the repair of fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

PRECAUTIONS

Only physicians skilled in 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 GalaFLEX scaffold can cause subsequent undesirable results. No special handling is required prior to use. Prepare as per institutional standards.

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, GalaFLEX scaffold elicited a minimal tissue reaction characteristic of foreign body response to a substance. The tissue reaction resolved as the scaffold was resorbed.

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 scaffold in neural tissue and in cardiovascular tissue has not been established.
3. The safety and effectiveness of GalaFLEX 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 scaffold is fully resorbable, it should not be used in repairs where permanent support from the mesh is required.
6. The safety and effectiveness of GalaFLEX scaffold in operative laparoscopy has not been established.
7. GalaFLEX 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 scaffold is supplied sterile. Inspect the device and packaging prior to use to be sure they are intact and undamaged.
10. GalaFLEX scaffold is for single use only. Do not re-sterilize or re-use any portion of the GalaFLEX 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.

DIRECTIONS FOR USE

Using aseptic technique, GalaFLEX 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. (continued)