ENGLISH

DESCRIPTION

GalaFLEX 3D™ scaffold is a single layer, bioresorbable surgical mesh made from poly-4-hydroxybutyrate (P4HB) P4HB is produced from a naturally occurring monomer and is processed into monofilament fibres and knitted into a surgical scaffold. The scaffold has a slight 3D curvature designed to promote better conformance with a patient's anatomy in locations in which a flat design does not easily conform. P4HB bioresorbs through a process of hydrolysis and hydrolytic enzymatic digestion. It has been developed to optimise 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.

INTENDED USE

GalaFLEX 3D™ scaffold is intended for use, as an adjunct to sutures, for the reinforcement and repair of soft tissue where weakness exists and where the addition of a reinforcing material is needed to obtain the desired surgical result in patients undergoing breast surgery. The GalaFLEX 3D™ scaffold is designed to be used in patients undergoing soft tissue repair and reinforcement in medically necessary breast surgery procedures where the existing soft tissue is deficient to support the surgical repair. Examples of such breast surgery applications include reduction mammoplasty and breast revision surgery to correct a medical condition. GalaFLEX 3D™ scaffold may also be used in cosmetic breast procedures.

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 3D™ scaffold in neural tissue and in cardiovascular tissue has not been established.
3. The safety and effectiveness of GalaFLEX 3D™ scaffold in paediatric use has not been established.
4. Placement of the scaffold in direct contact with bowel or viscera is not recommended.
5. If an infection develops, treat the infection aggressively. An unresolved infection may require removal of the scaffold.
6. Because GalaFLEX 3D™ scaffold is fully bioresorbable, it should not be used in repairs where permanent support from the scaffold is required.
7. GalaFLEX 3D™ scaffold is supplied sterile. Inspect the device and packaging prior to use to be sure they are intact and undamaged.
8. GalaFLEX 3D™ is for single use only. Do not re-sterilise or re-use any portion of GalaFLEX 3D™ scaffold. Never re-use a scaffold, even if it seems

to be in perfect condition, in order to prevent risk of cross-contamination or risk of reduced performance. Do not re-sterilise the scaffold. Once the package has been opened, any unused scaffold should be discarded.

9. Unused scaffold must be discarded according to the institution's procedures for handling of biohazardous materials.
10. Any decision to remove the scaffold should take into account potential risks associated with a second surgical procedure. This may include difficulty to remove the scaffold due to the ingrowth of tissue or degradation of the scaffold. Scaffold removal should be followed by adequate post-operative management.

PRECAUTIONS

Only doctors qualified in the appropriate surgical techniques should use this device. Users should be familiar with surgical procedures and techniques, including strength requirements and scaffold size choices. Improper selection, placement, positioning and fixation of GalaFLEX 3D™ can cause subsequent undesirable results. Patient should be provided with instructions regarding post-operative care, i.e. lifting, hygiene, activity limitations and any other specific patient/procedure requirements. The GalaFLEX 3D™ scaffold is bioresorbable and therefore any initial palpability of the scaffold decreases over time.

ACTIONS

GalaFLEX 3D™ scaffold degrades through a process of hydrolysis and hydrolytic enzymatic digestion.

It has been developed to minimise the variability of resorption rate and strength and provide support throughout the expected period of healing.

Pre-clinical implantation studies indicate that GalaFLEX 3D™ scaffold retains approximately 70% of its strength at 12 weeks. Absorption of the scaffold material will be essentially complete within 18-24 months.

ADVERSE REACTIONS

Possible complications of using GalaFLEX 3D™ scaffold include infection, seroma, pain or swelling, scaffold migration, wound dehiscence, haemorrhage, adhesions, haematoma, inflammation, extrusion and recurrence of the soft tissue defect. In pre-clinical testing, GalaFLEX 3D™ scaffold elicited a minimal tissue reaction characteristic of foreign body response to a substance. The tissue reaction resolved as the scaffold was resorbed.

IMAGING COMPATIBILITY

GalaFLEX 3D™ scaffold is made from fully resorbable P4HB and is temporary in nature. This material is non-conducting, non-metallic and non-magnetic. Therefore, in accordance with the definition stated in ASTM F-2503-13, Standard Practice for Marking Devices and Other Items for Safety in the Magnetic Resonance Environment, the device is determined to be "MR Safe - an item that poses no known hazards in all MR environments."

DIRECTIONS FOR USE

1. Prior to implanting GalaFLEX 3D™ scaffold, complete repair using appropriate suture technique.
2. GalaFLEX 3D™ scaffold should be prepared for placement using standard surgical preparation technique.
3. Using aseptic technique, GalaFLEX 3D™ scaffold may be cut to the shape or size desired for a specific application and fixation tabs may be cut if desired for each specific application.
4. To ensure the scaffold remains curved, minimise pulling and stretching of the scaffold prior to implantation.
5. Transfer the scaffold to the surgical site. Implant the scaffold so that the contour of the scaffold follows the natural contours of the implantation site and the edge of the scaffold extends beyond the margins of the defect. Suture the scaffold into place, avoiding excessive tension and without the expectation of stretch.
6. It is recommended that suture fixation be placed 6 mm to 12 mm apart at a distance approximately 6 mm from the edge of the scaffold using an interrupted suturing technique.
7. If using a resorbable suture to fixate the scaffold, please ensure the strength retention of the suture 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 assure proper closure under correct tension and to stabilise it during tissue ingrowth.
8. Close the incision site using standard surgical technique.
9. Discard any unused portions of the scaffold per your institution's procedures for biohazardous materials.

HOW SUPPLIED

GalaFLEX 3D™ scaffold is available as a sterile, undyed scaffold of varying widths and lengths.

STERILISATION

GalaFLEX 3D™ scaffold is sterilised using Ethylene Oxide. GalaFLEX 3D™ scaffold is supplied sterile and is for SINGLE USE ONLY.

DO NOT clean, re-sterilise or re-use as this may damage or compromise performance of devices and may expose patient to risk of transmitting infectious disease.

STORAGE

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

SYMBOLS KEY

REF	Catalogue Number
LOT	Batch Code
	Use By – year, month and day
	Do Not Re-use
	Do not use if package is damaged
	Temperature limitation
R_x Only	Rx ONLY Prescription Use Only
STERILE EO	Sterilised by Ethylene Oxide
	Do Not Re-sterilise
	CAUTION - Consult Instructions for Use
	Manufacturer
EC REP	European Union Authorised Representative
CE 2797	CE mark and identification number of Notified Body
MR	MR Safe

CONTACT INFORMATION

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

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