GalaFLEX
P4HB Scaffold 3DR™

Strength and Beauty
Inside and Out

The only formed scaffold with a reinforcing rim that supports, elevates and reinforces the breast tissue.

- 3-Dimensional
- Biologically Derived
- Monofilament
- Strong
- Bioabsorbable

GALATEA
INTERNATIONAL

Image is not intended to represent the procedural result.

Strengthen and Stabilize
Tissue in Breast Surgery

GalaFLEX P4HB Scaffold 3DR™

BIOABSORBABLE
The first and only formed and rimmed bioabsorbable scaffold designed to fit and uplift the body's natural shape[1]

+ 3 MILLION
Patients have been implanted with P4HB devices[1]

EASY PLACEMENT
Provides easier placement and reduced procedure time[1]

HYDROLYSIS
Eliminated from the body as CO_2 and H_2O primarily by the process of hydrolysis[4]

3-4 x STRONGER
Resulting in tissue 3-4 times stronger than native tissue[2,3]

THICK TISSUE
By 52 weeks the new ingrown tissue is approxi- mately 2.4 mm thick and provides a majority of strength to the repair site[1,2,3]

Intended Use

GalaFLEX 3DR™ 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 3DR™ scaffold is designed to be used in patients undergoing soft tissue repair and reinforcement in medically neces- sary 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 3DR™ scaffold may also be used in cosmetic breast procedures.

The GalaFLEX 3DR™ Family of Scaffolds offers you a full portfolio of sizes and shapes for each patient's surgical needs.

Shape	Product Code	N° per package	Size (cm)	
Oval 	CEFR01	1	5.3 x 15.5	Small
	CEFR02	2		
	CEFR03	1	6.4 x 18.5	Medium
	CEFR04	2		
	CEFR05	1	7.5 x 21.0	Large
	CEFR06	2		

Consult the GalaFLEX 3DR™ Instructions for Use for complete prescribing information, including its indications for use, warnings and precautions.

1. Data on file at Tepha.
2. Preclinical data on file at Tepha.
3. Deeken, Corey R., and Brent D. Matthews. "Characterization of the Mechanical Strength,Resorption Properties, and Histologic Characteristics of a Fully Absorbable Material (Poly-4-Hydroxybutyrate—PHASIX Mesh) in a Porcine Model of Hernia Repair." ISRN surgery, 2013.
4. "Chapter 7: Poly-4-hydroxybutyrate (P4HB) in Biomedical Applications and Tissue Engineering."Biodegradable Polymers Volume 2, by Kai Guo and David Martin, 2015 Nova Science Publishers, Inc, 2015.

GALATEA INTERNATIONAL

Tepha, Inc.
99 Hayden Avenue, Suite 360
Lexington, MA 02421, USA

www.galateasurgicalinternational.com
contact-international@galateasurgical.com