GalaFLEX
P4HB Scaffold 3D™

Strength and Beauty
Inside and Out

The only shaped scaffold 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 3D™

BIOABSORBABLE
The first and only shaped 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 approximately 2.4 mm thick and provides a majority of strength to the repair site[1,2,3]

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.

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

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

Shape	Product Code	Nº per package	Size (cm)	
	CESH01	1	5.3 x 15.5	Small
	CESH02	2		
	CESH03	1	6.4 x 18.5	Medium
	CESH04	2		
	CESH05	1	7.5 x 21.0	Large
	CESH06	2		

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