GalaFLEX® scaffold is a bioabsorbable, monofilament surgical scaffold, constructed of poly-4-hydroxybutyrate (P4HB) – an advanced, biologically derived polymer that was developed by scientists at MIT.

GalaFLEX®
P4HB Scaffold

Discover the Next Generation of **Soft Tissue Regeneration in Breast Surgery**

GalaFLEX® scaffold is a biologically derived surgical scaffold that provides inmediate mechanical support to the repair site. Over the course of approximately 24 months, GalaFLEX® bioabsorbs and encourages rapid tissue integration into the macropores of the monofilament design, strengthening tissue and resulting in a neotissue plane that is 3-4 times stronger than native tissue.[9,16,19] GalaFLEX® scaffold is designed to support, repair, elevate and reinforce soft tissue in the breast during surgical procedures[1-4] such as:

- Reduction mammoplasty
- Mastopexy
- Breast revision surgeryi

GalaFLEX® scaffold offers a unique combination of properties that are optimal for soft tissue support in both medically necessary and cosmetic breast procedures:

Biologically Derived: Produced by a **safe biological fermentation** process, standard in pharmaceutical production.[12,17]

Monofilament: Designed to minimize risk of **infection and encourage** a natural healing response.[12,17]

Strong: Provides a lattice for new tissue ingrowth and regeneration resulting in tissue **3-4x stronger than native tissue.**[2,17]

Bioabsorbable: Naturally broken down to CO_2 and H_2O, with **bioabsorption essentially complete by 18-24 months.**[1,12,17]

Bioabsorbable GalaFLEX® scaffold support outcomes over time on an Augmentation Mastopexy

Pre-OP **2 Years** **5 Years**

Bruce Van Natta, MD USA

Comparative Scaffold Characteristics

	GalaFLEX® [2,20]	VICRYL™ mesh [9,10]	TIGR™ [2,7,14]	STRATTICE™ [19,21]
Material	P4HB	PLGA	PGLATMC/ PLATMC	Porcine
Structure	Monofilament	Multifilament	Multifilament	Acellular Dermal Matrix
Absorption Time (Months)	18-24	3	24-36	Remodels
Primary Absorption Mechanism	Hydrolytic	Hydrolytic	Hydrolytic	Enzymatic Remodeling
Initial Scaffold Burts Strength (kgf)[2]	22.5	28.6	19.0	65
Retained Scaffold Strength at 12 weeks	>70%	0%	50%	21%

Disclaimer The above discussion points are in the context of the general literature, and not indicative of results from a head-to-head study.

Intended Use GalaFLEX® 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® 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® scaffold may also be used in cosmetic breast procedures.

Consult the GalaFLEX® Instructions for Use for complete prescribing information; including its indications for use, warnings and precautions.

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GalaFLEX®: Available Sizes and Shapes

Shape	Product Code	Size (cm)
	CE0103	2.5 x 7.6
	CE0206	5 x 15
	CE0208	5.0 x 20.0
	CE0408	10 x 20
	CE0608	15.0 x 20.0

GALATEA INTERNATIONAL

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GalaFLEX®
P4HB Scaffold

Strengthens Tissue in Breast Surgery

- Biologically Derived
- Monofilament
- Strong
- Bioabsorbable

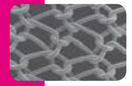
GALATEA INTERNATIONAL

GalaFLEX® P4HB Scaffold

Strength and Beauty

What is P4HB?

P4HB belongs to a large group of naturally occurring biopolymers, known as polyhydroxyalkanoates (PHAs). PHAs exist in nature as energy reserves in microorganisms that can be stored and utilized when needed. In contrast to other polymers used today for soft tissue support, P4HB is biologically derived through a proprietary biological fermentation process, rather than chemical synthesis. P4HB has a unique set of properties, particularly in comparison to other polymers commonly used in resorbable medical devices, such as polyglycolide (PGA) and polylactide (PLA), which are inherently stiffer materials. The properties of P4HB make it possible to produce high strength biomaterial, without sacrificing elasticity, to yield strong, pliable monofilament fibers.



Biologically Derived

- Proprietary fermentation process designed and optimized to provide a biocompatible product that when combined with all other features encourages the patient's natural healing response.[2,12,17]
- P4HB devices have been tested in pre-clinical and clinical studies to ensure safety and effectiveness.[2,18,19]
- More than 3 million patients worldwide have had P4HB devices implanted.[1]

Monofilament

- Designed with an open pore knit pattern to encourage rapid tissue ingrowth and to reduce risk of infection.[3,6]
- It has been reported that monofilament materials have on average 60% less surface area than that of multifilament materials, which may improve the healing response.[3,15]
- With less surface area, monofilament scaffolds have fewer recesses that bacteria can use as a haven from the body's natural defense systems or antibiotic treatments.[3,13]

When comparing SEM images of Galatea Scaffolds and other resorbable materials, the open pores, smooth surface and monofilament structure of Galatea Scaffolds are clearly visible.

GalaFLEX® Scaffold
Monofilament
derived from P4HB
SEM Photo, 20x

TIGR™ Mesh
Multifilament
SEM Photo, 20x

VICRYL™ Mesh
Multifilament
SEM Photo, 20x

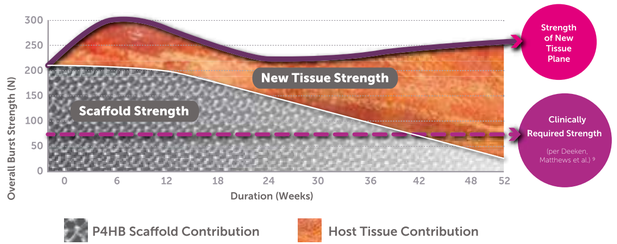
Inside and Out

Strong

- Designed specifically for strength retention throughout the critical wound healing period.[1,16]
- Rapid tissue regeneration resulting in a new tissue plane approximately 3-4 times the strength of the native tissue as demonstrated in pre-clinical studies.[9,19]
- Maintains >70% of its strength at 12 weeks in vivo.[2]

Long-Term Repair Strength in a Preclinical Model[9]

(per Deeken, Matthews et al.)



Bioabsorbable

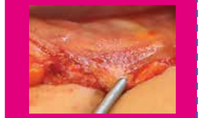
- Naturally bioabsorb, leaving behind only strong, healthy tissue to support the surgical outcome.[2,12]
- Gradually and predictably bioabsorbs over the course of approximately 18-24 months.[12]
- Eliminated from the body as carbon dioxide and water primarily by the process of hydrolysis.[9,12]
- No polymer metabolites remain after the degradation process is complete.[2]

Before Implantation

GalaFLEX® scaffold is a macroporous, monofilament, bioabsorbable scaffold.[2]

After Implantation

(Human Breast Tissue Specimens)



Tissue rapidly grows into the pores of the GalaFLEX® scaffold, and forms a well-vascularized tissue plane.[2]

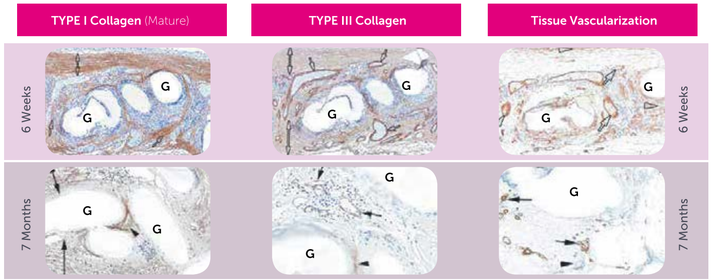
The newly formed tissue is pliable and provides strength and support to the elevated tissue.[16]

GalaFLEX® encourages **new tissue ingrowth and regeneration**

- Provides a lattice for new tissue ingrowth.[16]
- As the scaffold bioabsorbs, the new ingrown tissue provides strength to the repair site.[19]
- By 52 weeks the new ingrown tissue is approximately 2.4 mm thick and provides a majoritiy of strength to the repair site.[2]

By providing a lattice for tissue regeneration, GalaFLEX® encourages cells to migrate into its pores, allowing stronger, organized collagen to build and healthy blood vessels to form.[1,16]

G = GalaFLEX® scaffold • Human Tissue Specimen • Images shown at 100x magnification



Arrows denote new collagen formation

Arrows denote new blood vessels

By 6 Weeks:
New tissue with abundant mature collagen
(as indicated by positive type I collagen staining) and vascularization
(as shown by positive CD31 and smooth muscle actin stains) has quickly integrated into the scaffold.[1]

By 7 Months:
A fully integrated tissue plane of primarily type I collagen throughout the scaffold
indicates collagen maturationand soft tissue regeneration
(minimal inflammatory response with no evidence of encapsulation).[1]

History of **P4HB** Products

1980s

Researchers at MIT developed a recombinant system to produce Polyhydroxyalkanoates (PHAs) in microorganisms.

1990s

Researchers at Metabolix further developed recombinant systems for the industrial production of PHAs. In 1998, Tepha, Inc. was incorporated to pursue the medical applications of PHAs.

2007 / 2008

The first P4HB medical devices: TephaFLEX® Suture & Mesh received FDA clearance.

2009 / 2010

Tepha partnered with B. Braun Medical who received the CE Mark for the P4HB device: MonoMax® Suture. MonoMax Suture was the first commercial launch of a P4HB device in Europe and the US.

2011

TephaFLEX Mesh received FDA clearance for soft tissue reinforcement in Plastic Surgery
and was first used for Plastic Surgery.
Tepha partnered with Tornier® and commercially launched: BioFiber™ for soft tissue reinforcement in the US.

2012 / 2013

Tepha partnered with Bard/Davol® to commercially launch the P4HB device: Phasix™ mesh for Hernia Repair in the US.
Galatea Surgical, Inc.® became a wholly owned subsidiary of Tepha, Inc. to focus on plastic and reconstructive surgery.

2014 / 2015

Tepha P4HB devices achieved milestone of treating 1 million patients globally, with over 1,000 aesthetic plastic surgery patients.
Galatea Surgical received CE Mark for use of GalaFLEX scaffold in breast surgery.

2016 / 2017

Galatea Surgical received FDA Clearance as the first and only 3-Dimensional scaffolds designed for plastic and reconstructive surgery.