GalaFLEX scaffold is a bioresorbable, monofilament scaffold, constructed of poly-4-hydroxybutyrate (P4HB) – an advanced, biologically produced polymer that was developed by MIT and Stanford scientists.

Discover the Next Generation in **Surgical Scaffolds** for **Soft Tissue Regeneration**

The 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 breast surgery procedures. Examples of medically necessary procedures include reduction mammoplasty to relieve symptoms associated with excessive breast weight as well as mastopexy to create symmetry after mastectomy. GalaFLEX scaffold may also be used in cosmetic breast procedures.

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

- **Biologically Derived:** Produced by a **safe** and **biological fermentation** process, standard in pharmaceutical production[1,2]
- **Monofilament:** Designed to minimize **risk of infection** and encourage **a healing** response[2,3,4,5,8]
- **Strong:** Provides a lattice for new tissue ingrowth and regeneration resulting in tissue **3-5x stronger** than native tissue[2,5]
- **Bioresorbable:** Naturally broken down to CO_2 and H_2O, with full bioresorption **by 18-24 months**[4]

Bruce Van Natta, MD USA

Important Safety Considerations
Possible complications include recurrence of the soft tissue defect, infection, seroma, pain, scaffold migration, wound dehiscence, adhesions, hematoma, inflammation and extrusion. Important, additional safety and risk information is located on the back cover, and at www.galateasurgical.com.

Designed to Extend the Life of your Surgical Repair.

Biologic Scaffolds: Comparative Characteristics

Property	GalaFLEX® [1,2,3]	Vicryl® Mesh[13]	Seri Scaffold[2,13]	Tigr™ Matrix[2,14]	Strattice™ [15,16]	AlloDerm[15]
Material	P4HB	PLGA	Silk	PGLATMC/ PLATMC	Porcine	Human Dermis
Structure	Monofilament	Multifilament	Multifilament	Multifilament	Extracellular Tissue Matrix	Decellularized Tissue
Absorption Time (Months)	18-24	3	24	24-36	Remodels	Remodels
Primary Absorption Mechanism	Hydrolytic	Hydrolytic	Enzymatic	Hydrolytic	Enzymatic Remodeling	Enzymatic Remodeling
Initial Scaffold Burst Strength (kfg)[2]	22.5	13.9	15.4	19.0	27.6[17]	Not Available
Retained Scaffold Strength	50% at 16wks	0% at 4wks	14% at 12wks	50% at 4wks	17% at 12wks	12% at 4wks

Disclaimer The above discussion points are in the context of the general literature, and not indicative of results from a head-to-head study.
Indications for 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.
Important Safety Considerations Possible complications include infection, seroma, pain, swelling, scaffold migration, wound dehiscence, hemorrhage, adhesions, hematoma, inflammation, extrusion and recurrence of the soft tissue defect. The safety and product use of GalaFLEX for patients with hypersensitivities to the antibiotics kanamycin sulfate and tetracycline hydrochloride is unknown. The safety and effectiveness of GalaFLEX scaffold in neural tissue and in cardiovascular tissue has not been established. The safety and effectiveness of GalaFLEX scaffold in pediatric use has not been established. Because GalaFLEX scaffold is fully bioresorbable, it should not be used in repairs where permanent support from the mesh is required.
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 & 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
	CE016S	22 x 10
	CE016M	26 x 11.9

Shape	Product Code	Size (cm)
	CE019S	14 x 7.8
	CE019M	18 x 10.1
	CE013S	22 x 9
	CE013M	26 x 10.6
	CE017S	22 x 8.6
	CE017M	26 x 10.2
	CE0104	2.5 x 10.2

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Subsidiary of Tepha, Inc.
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www.galateasurgical.com

GalaFLEX® SCAFFOLD
*A **Bioresorbable** Surgical Scaffold*

Experience the Galatea Difference in Breast Surgery

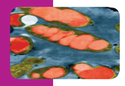
- Biologically Derived
- Monofilament
- Strong
- Bioresorbable

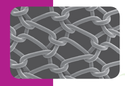
GALATEA SURGICAL

GalaFLEX® SCAFFOLD

Experience the Difference of Strength and Beauty

What is P4HB?





P4HB belongs to a large group of naturally occurring biopolymers, known as polyhydroxy-alkanoates (PHAs). PHAs exist in nature as energy reserves in microorganisms that can be stored up and broken down when needed.

In contrast to other polymers used today for soft tissue support, P4HB is produced through a proprietary biological fermentation process, rather than chemical synthesis.

P4HB has a very 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 much 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

GalaFLEX biologically derived P4HB construction

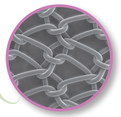
- Proprietary fermentation process designed and optimized to provide a safe, biologically friendly product that when combined with all other features encourages the patient's natural healing response.
- P4HB devices have been tested in pre-clinical and clinical studies to evaluate safety and efficacy.[1]
- More than 1 million patients worldwide have P4HB devices implanted, and results indicate a strong safety profile.[1]

Monofilament

GalaFLEX macroporous, monofilament scaffold design

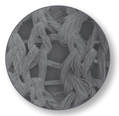
- Designed with an open pore knit pattern to encourage rapid tissue ingrowth throughout the macropores of the monofilament scaffold and to reduce risk of infection.[2,4,6,7]
- It has been reported that monofilament fibers have on average 60% less surface area than that of multifilament materials, which may improve the healing response.[7,8,9,10]
- 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.[7,8,11]

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

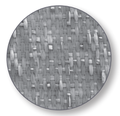


GalaFLEX Scaffolds
Monofilament
derived from P4HB
SEM Photo, 20x

SERI® Scaffold
Multifilament
SEM Photo, 20x



TIGR® Mesh
Multifilament
SEM Photo, 20x



VICRYL® Mesh
Multifilament
SEM Photo, 20x

Strong

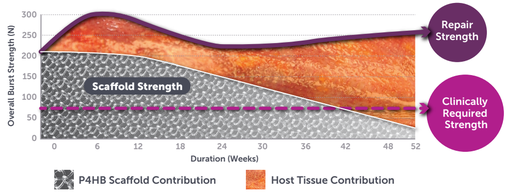
GalaFLEX strength retention

- Designed specifically for strength retention throughout critical wound healing.
- Rapid tissue regeneration resulting in tissue 3-5 times the strength of the native tissue as demonstrated in pre-clinical studies.[2]

GalaFLEX encourages new tissue ingrowth and regeneration

- Provides a lattice for new tissue ingrowth.
- Maintains ~70% of its strength at 12 weeks in vivo.[2]
- As the scaffold bioresorbs, mechanical load is transfered to the new tissue, providing strength to the repair site.
- By 26-32 weeks, the tissue from the scaffold repair site is 1 to 3mm thick and most of the repair strength is coming from new tissue.[2]

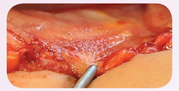
Long-Term Repair Strength in a Preclinical Model



Before Implantation

GalaFLEX scaffold is a macroporous, monofilament, bioresorbable scaffold.

After Implantation

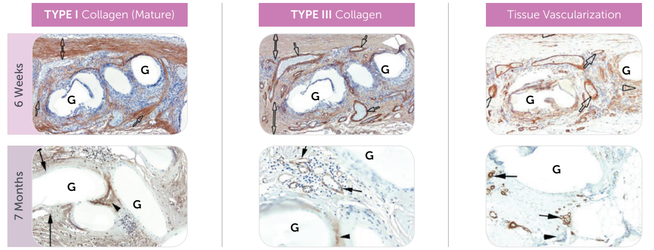


Tissue ingrowth occurs into the pores and through the GalaFLEX scaffold, such that the newly formed tissue is well integrated within the scaffold.

The newly formed tissue that infiltrates the GalaFLEX scaffold is pliable and provides strength to support the elevated tissue.

Important Safety Considerations Possible complications include recurrence of the soft tissue defect, infection, seroma, pain, scaffold migration, wound dehiscence, adhesions, hematoma, inflammation and extrusion. Important, additional safety and risk information is located on the back cover, and at www.galateasurgical.com.

By providing a lattice for tissue regeneration, the Galatea scaffold encourages cells to migrate into its pores, allowing stronger, organized collagen to build and healthy blood vessels to form.



Arrows denote new collagen formation

Arrows denote new blood vessels

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

- By 6 Weeks[1]
  - Newly formed vascularized tissue is seen in the macroporous structure of the scaffold.
  - The scaffold is embedded within mature fibrous and richly vascularized connective tissue (rich network of CD31, SMA, and Collagen III-positive blood vessels).
- By 7 Months[1]
  - Tissue thickness has increased with minimal inflammatory response.
  - Type 1 Collagen spans the entire length of the new tissue and is integrated with the scaffold.

Bioresorbable

GalaFLEX fully bioresorbable polymer

- Naturally bioresorbed, leaving behind only a strong, healthy tissue to support the surgical outcome.
- Gradually and predictably bioresorbs over the course of 18-24 months.[2,3]
- Eliminated from the body as carbon dioxide and water primarily by the process of hydrolysis.[3]
- No polymer metabolites remain after the degradation process is complete.[18]

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 device: TephaFLEX® Suture & Mesh received FDA clearance.

TephaFLEX Suture was used clinically for the first time.

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 (2009) and in the US (2010).

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.

2014 / 2015

Tepha P4HB devices achieved milestone of treating 1 million patients globally, with over 1,000 aesthetic plastic surgery patients.

GalaFLEX scaffold received CE Mark for use in medically necessary breast surgery.

2016 / 2017

GalaSHAPE 3D and GalaFORM 3D received FDA Clearance as the first and only 3-Dimensional scaffolds designed for plastic and reconstructive surgery.