Galatea Surgical Biologically Derived Scaffold Collection

Strengthens Tissue*

- 3-Dimensional
- Biologically Derived
- Monofilament
- Strong
- Bioresorbable

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

GalaSHAPE® 3D
*A **Shaped** Bioresorbable Surgical Scaffold*

GalaFORM® 3D
*A **Formed** Bioresorbable Surgical Scaffold with Rim*

GALATEA SURGICAL

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

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

The Galatea Collection of biologically derived scaffolds provides the ability to strengthen and stabilize plastic and reconstructive soft tissue repairs by enabling new tissue generation in a targeted manner. This scaffold collection offers a unique combination of properties that are optimal for soft tissue reinforcement in plastic and reconstructive surgery:

3-Dimensional: The first and only **formed absorbable scaffold** designed to fit and uplift the body's natural shape, providing easier placement and reduced procedure time[1]

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**[3,15]

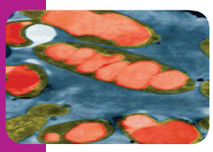
Strong: Provides a lattice for new tissue ingrowth and regeneration resulting in tissue **3-4x stronger than native tissue**[9,16,19]

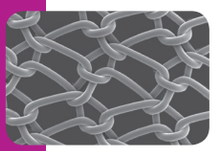
Bioresorbable: Naturally broken down to CO_2 and H_2O and **bioresorption is essentially complete by 18-24 months**[1,12]

Galatea Surgical Bioresorbable Scaffold Collection

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.

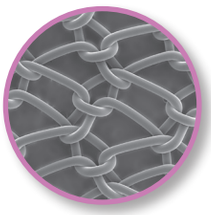
Biologically Derived

- 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 evaluate safety and effectiveness.[2,18,19]
- More than 3 million patients worldwide have P4HB devices implanted.[1]

Monofilament

- The monofilament scaffold was designed with an open pore knit pattern to encourage rapid tissue ingrowth and to reduce risk of infection.[3,6,9]
- 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]

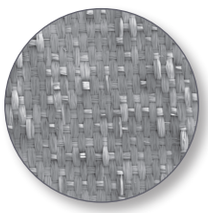
When comparing SEM images of Galatea Scaffolds and other resorbable materials, the open pores, the smooth surface, and the monofilament structure of Galatea Scaffolds are clearly visible.



Galatea Scaffolds
Monofilament
derived from P4HB
SEM Photo, 20x

SERI® Scaffold
Multifilament
SEM Photo, 20x

TIGR® Mesh
Multifilament
SEM Photo, 20x



Woven VICRYL® Mesh
Multifilament
SEM Photo, 20x

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.

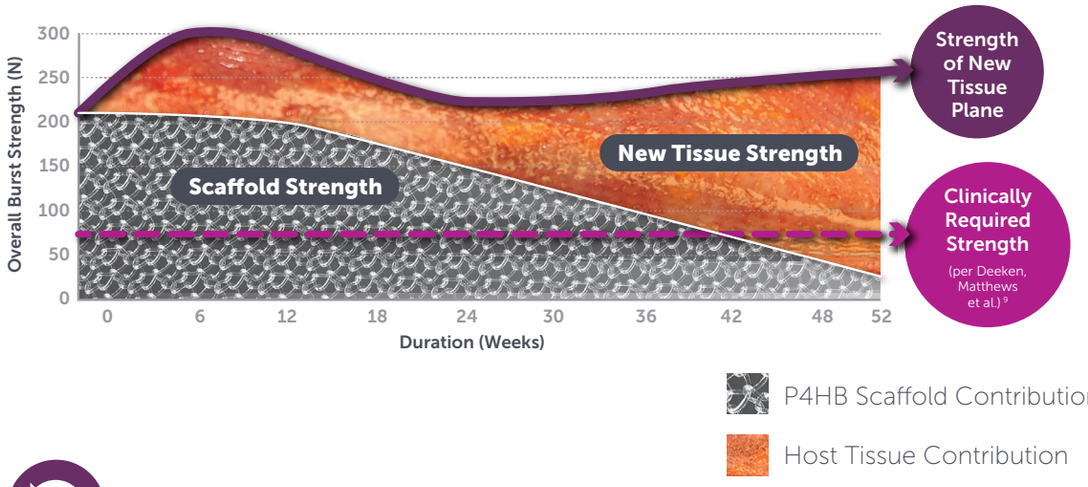
Inside and Out.

Strong

- Designed specifically for strength retention throughout the critical wound healing period.[1,19]
- 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.)



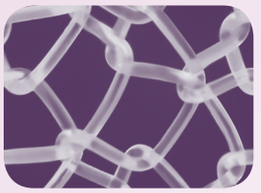
P4HB Scaffold Contribution

Host Tissue Contribution

Bioresorbable

- Naturally bioresorbed, leaving behind only strong, healthy tissue to support the surgical outcome.[2,12]
- Gradually and predictably bioresorbs over the course of 18-24 months.[2,12]
- 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]

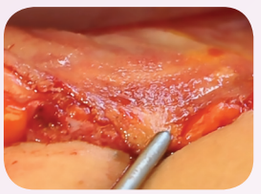
Before Implantation



Galatea scaffold is a macroporous, monofilament, bioresorbable scaffold.[2]

After Implantation

(Human Tissue Specimens)



Tissue rapidly grows into the pores of the Galatea 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 bioresorbs, the new ingrown tissue provides strength to the repair site.[19]
- By 26-52 weeks, the tissue from the scaffold repair site is 2 to 3mm thick and provides the majority of repair strength.[2,23]

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.

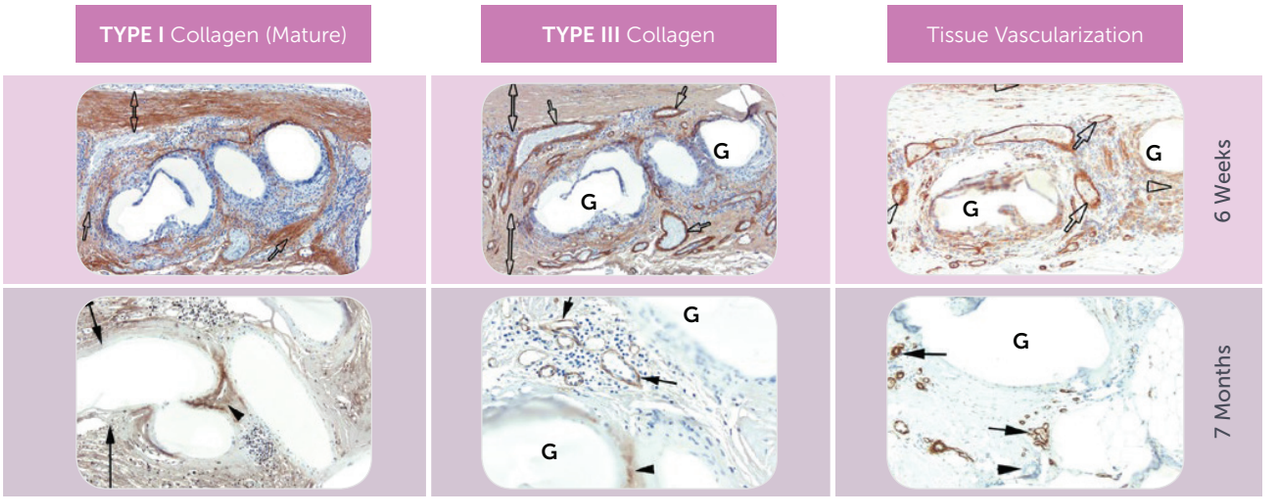
2011

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.

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.[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 maturation and soft tissue regeneration (minimal inflammatory response with no evidence of encapsulation).[1]

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.

Comparative Scaffold Characteristics

	GalaFLEX® [2,23]	Vicryl® Mesh [9,10]	Seri Scaffold [7,11,20]	Tigr™ Matrix [2,14,22]	Strattice™ [19,21]	Alloderm [2,5,8]
Material	P4HB	PLGA	Silk	PGLATMC/ PLATMC	Porcine	Human Dermis
Structure	Monofilament	Multifilament	Multifilament	Multifilament	Acellular Dermal 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 (kgf)²	22.5	28.6	17.8	19.0	65	Not Available
Retained Scaffold Strength at 12 weeks	>70%	0%	17%	50%	21%	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, GalaSHAPE 3D and GalaFORM 3D (Galatea scaffold) are indicated for use as a bioresorbable scaffold for soft tissue support and to repair, elevate, and reinforce deficiencies where weakness or voids exist that require the addition of material to obtain the desired surgical outcome.

Important Safety Information

Possible complications include recurrence of the soft tissue defect, infection, seroma, pain, scaffold migration, wound dehiscence, adhesions, hematoma, inflammation and extrusion. The safety and product use of Galatea scaffold for patients with hypersensitivities to the antibiotics kanamycin sulfate and tetracycline hydrochloride is unknown. Galatea scaffold has not been studied for use in breast reconstructive surgeries. The safety and effectiveness of Galatea scaffold in neural tissue and in cardiovascular tissue has not been established. The safety and effectiveness of Galatea scaffold in pediatric use has not been established. **Consult Instructions for Use for complete prescribing information; including indications for use, warnings and precautions.**

References

1. Data on file at Tepha.
*2. Preclinical data on file at Tepha; results may not correlate to clinical performance in humans.
3. Engelsman, A. F., van der Mei, H. C., Ploeg, R. J., & Busscher, H. J. "The Phenomenon of Infection with Abdominal Wall Reconstruction." *Biomaterials*, vol. 28 no. 14, 2018, pp. 2314-2327.
4. Loh, Q. L., Choong, C.. "Three-dimensional scaffolds for tissue engineering applications: Role of porosity and pore size." *Tissue Engineering* Part B: Reviews, vol. 19, no. 6, 2013, pp. 485-502. doi:http://dx.doi.org.portal.lib.fit.edu/10.1089/ten.teb.2012.0437
5. Alloderm Regenerative Tissue Matrix, Lifecell Electronic IFU. https://allergan-web-cdn-prod.azureedge.net/actavis/.
6. Amid, P. K. . "Classification of Biomaterials and Their Related Complications in Abdominal Wall Hernia Surgery." *Hernia*, vol. 1, no. 1, 1997, pp. 15-21.
7. Bengtson, B., Baxter, R. A., Clemens, M. W., & Bates, D.C50. "A 12-month Survey of Early Use and Surgeon Satisfaction With a New Highly Purified Silk Matrix: SERI Surgical Scaffold." *Plastic and Reconstructive Surgery Global Open*, vol. 2, no. 7, 2014.
8. Corey R Deeken, PhD, et al. "Histologic and Biomechanical Evaluation of Crosslinked and Non-Crosslinked Biologic Meshes in a Porcine Model of Ventral Incisional Hernia Repair." 23 Mar. 2011. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3782991/
9. 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.
10. "Wound Closure Manual." Ethicon, Inc. PDF file. 2005.
11. Gross, John E., et al. "An Evaluation of SERI Surgical Scaffold for Soft-Tissue Support and Repair in an Ovine Model of Two-Stage Breast Reconstruction." *Plastic and Reconstructive Surgery*, vol. 134, no. 5, 2014, pp. 700e-704e.
12. "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.
13. Halaweish, Ihab, et al. "Novel In Vitro Model for Assessing Susceptibility of Synthetic Hernia Repair Meshes to Staphylococcus Aureus Infection Using Green Fluorescent Protein-Labeled Bacteria and Modern Imaging Techniques." *Surgical Infections*, vol. 11, no. 5, 2010, pp. 449-454.
14. Hjort, H., et al. "Three-Year Results From a Preclinical Implantation Study of a Long-Term Resorbable Surgical Mesh with Time-Dependent Mechanical Characteristics." *Hernia*, vol. 16, no. 2, 2012, pp. 191-197.
15. Klinge U, Junge K, Spellerberg B, Piroth C, Klosterhalfen B, Schumpelick V. "Do Multifilament Alloplastic Meshes Increase the Infection Rate? Analysis of the Polymeric Surface, the Bacteria Adherence, and the In Vivo Consequences in a Rat Model." *J Biomed Mater Reserve*, vol. 63, no. 6, 2002, pp. 765-71.
16. Martin, D P, et al. "Characterization of Poly-4-Hydroxybutyrate Mesh for Hernia Repair Applications." *Journal of Surgical Research*, vol. 184, no. 2, 2013, pp. 766–773.
17. Martin, David P., and Simon F. Williams. "Medical Applications of Poly-4-Hydroxybutyrate: a Strong Flexible Absorbable Biomaterial." *Biochemical Engineering Journal*, vol. 16, no. 2, 2003, pp. 97-105.
18. Roth, J. S., et al. "Prospective Evaluation of Poly-4-Hydroxybutyrate Mesh in CDC Class L/High-Risk Ventral and Incisional Hernia Repair: 18-Month Follow-Up." *Surgical Endoscopy*, vol. 32 no. 4, 2013, pp. 1929-1936.
19. Scott, J. R., Deeken, C. R., Martindale, R. G., Rosen, M. J. "Evaluation of a Fully Absorbable Poly-4-Hydroxybutyrate/Absorbable Barrier Composite Mesh in a Porcine Model of Ventral Hernia Repair." *Surgical Endoscopy*, vol. 30, no. 9, 2016, pp. 3691-3701.
20. "Scaffold Electronic IFU." SERI Surgical. https://www.allergan.com/.
21. "Mesh Electronic IFU." Strattice Surgical. https://allergan-web-cdn prod.azureedge.net.
22. "Surgical Mesh Electronic IFU." TIGR Surgical. http://novusscientific.com.
23. Williams, Simon F., Martin, David P., Moses, Arikha C. "The History of GalaFLEX P4HB Scaffold." *Aesthetic Surgery Journal*, 2016, pp. S33–S42.

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