Galatea Surgical
Biologically Derived
Scaffold Collection

Strengthens Tissue*

3-Dimensional
Biologically Derived
Monofilament
Strong
Bioresorbable

GalaFLEX®
A Biodegradable
Surgical Scaffold

GalaSHAPE® 3D
A Shaped Biodegradable
Surgical Scaffold

GalaFORM® 3D
A Formed Biodegradable
Surgical Scaffold with Rim
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\(_2\)O and bioresorption is essentially complete by 18-24 months\(^{1,12}\)
Strength and Beauty.

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

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.

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.

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.\(^1\),\(^2\),\(^9\),\(^19\)
- 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.\(^2\)

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.\(^2\)

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.\(^2\),\(^23\)

Long-Term Repair Strength in a Preclinical Model\(^9\)
(per Deeken, Matthews et al.)

<table>
<thead>
<tr>
<th>Duration (Weeks)</th>
<th>Scaffold Strength</th>
<th>New Tissue Strength</th>
<th>Clinically Required Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
<td>300</td>
</tr>
<tr>
<td>6</td>
<td>50</td>
<td>250</td>
<td>250</td>
</tr>
<tr>
<td>12</td>
<td>100</td>
<td>200</td>
<td>200</td>
</tr>
<tr>
<td>18</td>
<td>150</td>
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<td>100</td>
<td>100</td>
</tr>
<tr>
<td>30</td>
<td>250</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>36</td>
<td>300</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

P4HB Scaffold Contribution
- Host Tissue Contribution
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

<table>
<thead>
<tr>
<th>TYPE I Collagen (Mature)</th>
<th>TYPE III Collagen</th>
<th>Tissue Vascularization</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Type I Collagen" /></td>
<td><img src="image2" alt="Type III Collagen" /></td>
<td><img src="image3" alt="Tissue Vascularization" /></td>
</tr>
</tbody>
</table>

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

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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

<table>
<thead>
<tr>
<th>Material</th>
<th>GalaFLEX®</th>
<th>Vicryl® Mesh</th>
<th>Seri Scaffold</th>
<th>Tigr™ Matrix</th>
<th>Strattice™</th>
<th>Alloderm</th>
</tr>
</thead>
<tbody>
<tr>
<td>P4HB</td>
<td>18-24</td>
<td>3</td>
<td>24</td>
<td>-</td>
<td>24-36</td>
<td>Remodels</td>
</tr>
<tr>
<td>Structure</td>
<td>Monofilament</td>
<td>Multifilament</td>
<td>Multifilament</td>
<td>Multifilament</td>
<td>Acellular</td>
<td>Decellularized Tissue</td>
</tr>
<tr>
<td>Absorption Time (Months)</td>
<td>22.5</td>
<td>28.6</td>
<td>17.8</td>
<td>19.0</td>
<td>65</td>
<td>Not Available</td>
</tr>
<tr>
<td>Primary Absorption Mechanism</td>
<td>Hydrolytic</td>
<td>Hydrolytic</td>
<td>Enzymatic</td>
<td>Hydrolytic</td>
<td>Enzymatic Remodeling</td>
<td>Enzymatic Remodeling</td>
</tr>
<tr>
<td>Initial Scaffold Burst Strength (kgf)²</td>
<td>&gt;70%</td>
<td>0%</td>
<td>17%</td>
<td>50%</td>
<td>21%</td>
<td>12% at 4wks</td>
</tr>
<tr>
<td>Retained Scaffold Strength at 12 weeks</td>
<td>&gt;70%</td>
<td>0%</td>
<td>17%</td>
<td>50%</td>
<td>21%</td>
<td>12% at 4wks</td>
</tr>
</tbody>
</table>

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 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, herniation, 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.

### References

1. Data on file at Tepha.
2. Preclinical data on file at Tepha; results may not correlate to clinical performance in humans.