

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 immediate 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.<sup>9,16,19</sup> GalaFLEX® scaffold is designed to support, repair, elevate and reinforce soft tissue in the breast during surgical procedures<sup>1-4</sup> such as:

- Reduction mammoplasty
- Mastopexy
- Breast revision surgery

**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.<sup>12,17</sup>
-  **Monofilament:** Designed to minimize risk of **infection and encourage** a natural healing response.<sup>12,17</sup>
-  **Strong:** Provides a lattice for new tissue ingrowth and regeneration resulting in tissue **3-4x stronger than native tissue.**<sup>2,17</sup>
-  **Bioabsorbable:** Naturally broken down to CO<sub>2</sub> and H<sub>2</sub>O, with **bioabsorption essentially complete by 18-24 months.**<sup>1,12,17</sup>



Bruce Van Natta, MD USA

### Comparative Scaffold Characteristics

	GalaFLEX® 2.20	VICRYL™ mesh 9,10	TIGR™ 2,7,14	STRATTICE™ 19,21
<b>Material</b>	P4HB	PLGA	PGA:PLLA:PTMC/ PLLA:PTMC	Porcine
<b>Structure</b>	Monofilament	Multifilament	Multifilament	Acellular Dermal Matrix
<b>Absorption Time (Months)</b>	18-24	3	24-36	Remodels
<b>Primary Absorption Mechanism</b>	Hydrolytic	Hydrolytic	Hydrolytic	Enzymatic Remodeling
<b>Initial Scaffold Burst Strength (kgf)<sup>2</sup></b>	22.5	28.6	19.0	65
<b>Retained Scaffold Strength at 12 weeks</b>	>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.

**Important Safety Information:** Possible complications include infection, seroma, pain or swelling, scaffold migration, wound dehiscence, haemorrhage, adhesions, haematoma, inflammation, extrusion and recurrence of the soft tissue defect. Device manufacture involves exposure to tetracycline hydrochloride and kanamycin sulfate; the safety and product use for patients with hypersensitivities to these antibiotics 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 paediatric use has not been established. Placement of the scaffold in direct contact with bowel or viscera is not recommended. Because GalaFLEX® scaffold is fully bioresorbable, it should not be used in repairs where permanent support from the scaffold is required.

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

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- 20 Williams, Simon F., Martin, David P., Moses, Arikha C. "The History of GalaFLEX P4HB Scaffold," *Aesthetic Surgery Journal*, 2016, pp. S33-S42.
- 21 "Mesh Electronic IFU," Strattice Surgical, <https://allergan-web-cdn-prod.azureedge.net>.

#### GalaFLEX®: Available Sizes and Shapes

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



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**GalaFLEX**  
P4HB Scaffold



## Strengthens Tissue in Breast Surgery

 Biologically Derived

 Monofilament

 Strong

 Bioabsorbable



# Strength and Beauty

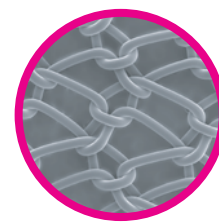
## Biologically Derived

- 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.<sup>2,12,17</sup>
- P4HB devices have been tested in pre-clinical and clinical studies to ensure safety and effectiveness.<sup>2,18,19</sup>
- More than 4 million patients worldwide have had P4HB devices implanted.<sup>1</sup>

## Monofilament

- Designed with an open pore knit pattern to encourage rapid tissue ingrowth and to reduce risk of infection.<sup>3,6</sup>
- 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.<sup>3,15</sup>
- 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.<sup>3,13</sup>

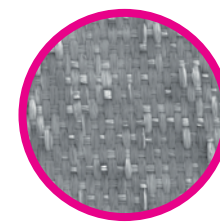
When comparing SEM images of Galatea Scaffolds and other resorbable materials, the open pores, smooth surface and monofilament structure of Galatea Scaffolds are clearly visible.



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



**TIGR™ Mesh**  
Multifilament  
SEM Photo, 20x



**VICRYL™ Mesh**  
Multifilament  
SEM Photo, 20x

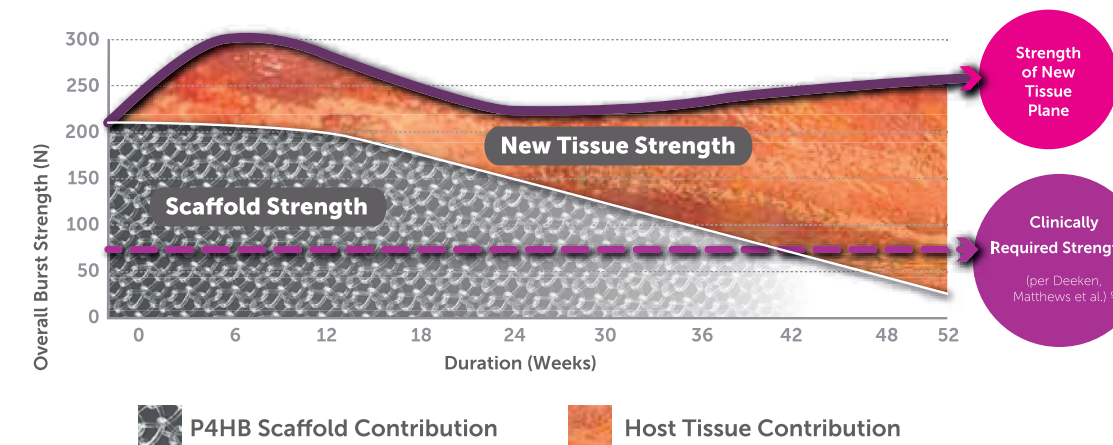
# Inside and Out

## Strong

- Designed specifically for strength retention throughout the critical wound healing period.<sup>1,16</sup>
- 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.<sup>9,19</sup>
- Maintains >70% of its strength at 12 weeks in vivo.<sup>2</sup>

## Long-Term Repair Strength in a Preclinical Model<sup>9</sup>

(per Deeken, Matthews et al.)



## Bioabsorbable

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

## Before Implantation



GalaFLEX® scaffold is a macroporous, monofilament, bioabsorbable scaffold.<sup>2</sup>

## After Implantation

(Human Breast Tissue Specimens)



Tissue rapidly grows into the pores of the GalaFLEX® scaffold, and forms a well-vascularized tissue plane.<sup>2</sup>



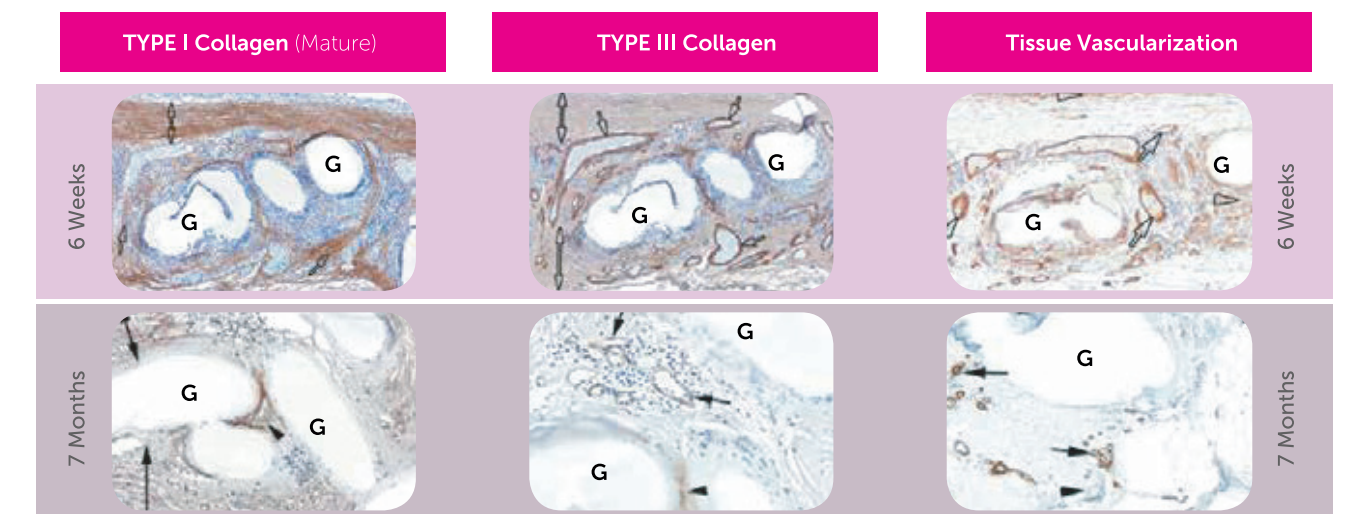
The newly formed tissue is pliable and provides strength and support to the elevated tissue.<sup>16</sup>

# GalaFLEX® encourages new tissue ingrowth and regeneration

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

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.<sup>1,16</sup>

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.<sup>1</sup>

### 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).<sup>1</sup>

## 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, Tephra, Inc. was incorporated to pursue the medical applications of PHAs.

2007 / 2008

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

2009 / 2010

Tephra 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

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

2012 / 2013

Tephra 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 Tephra, Inc. to focus on plastic and reconstructive surgery.

2014 / 2015

Tephra 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.



## What is GalaFLEX®?

GalaFLEX® is a temporary, absorbable scaffold used to strengthen, stabilize and support weakened soft tissue. It was designed to provide support immediately after breast surgery, which allows your body to heal and create a healthy new tissue plane of primarily mature collagen.

GalaFLEX® scaffolds are made from a biologically derived polymer known as poly-4-hydroxybutyrate (P4HB™), which breaks down over time into CO<sub>2</sub> and H<sub>2</sub>O, a process similar to absorbable stitches. This means that your body knows how to metabolize and completely absorb the scaffold safely and naturally.

GalaFLEX® scaffolds are offered in a variety of shapes for use in breast surgery procedures. Each GalaFLEX® scaffold is selected by your surgeon specific to your body's shape and needs.



**Intended Use:** The GalaFLEX® Family of Scaffolds 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® Family of Scaffolds 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. The GalaFLEX® Family of Scaffolds may also be used in cosmetic breast procedures.

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

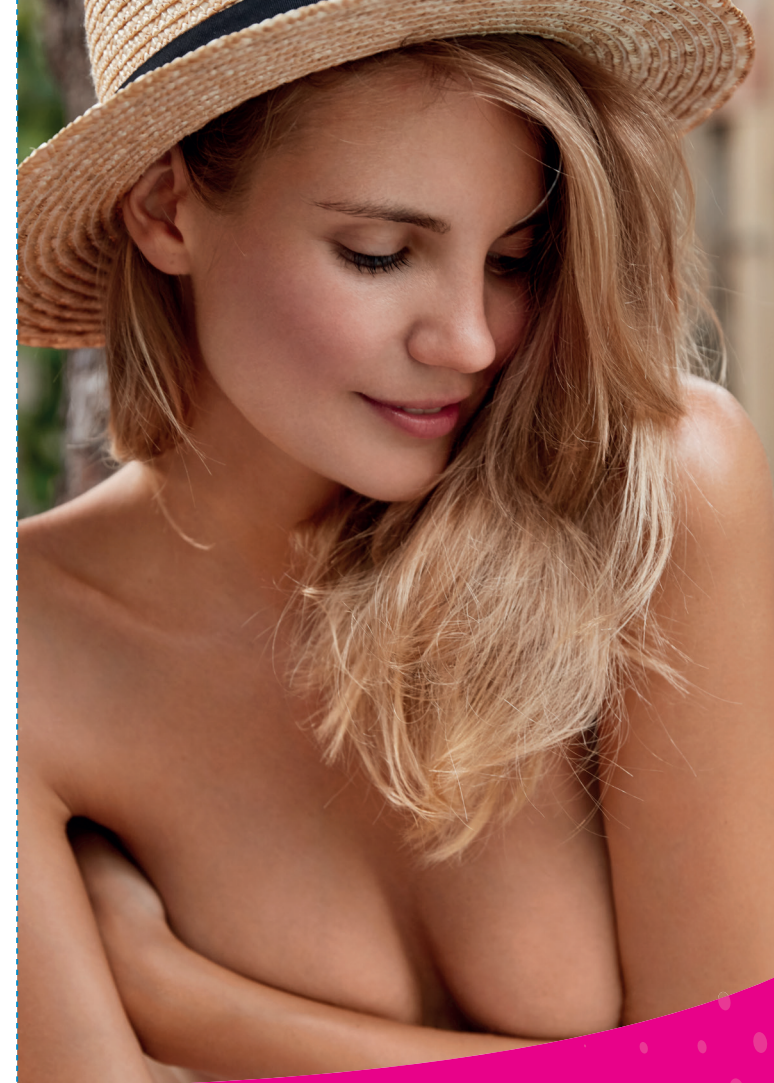
### References

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2. Preclinical Data on file at Tepha; results may not correlate to clinical performance in humans
3. 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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For more information about reinforcing your breast procedure with a GalaFLEX scaffold, please contact us at:  
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Tepha, Inc. 99 Hayden Avenue Suite 360 Lexington, MA 02421, USA



The information contained in this brochure is intended for INTERNATIONAL Health Care Professionals. Patients, please refer to your physician for information.



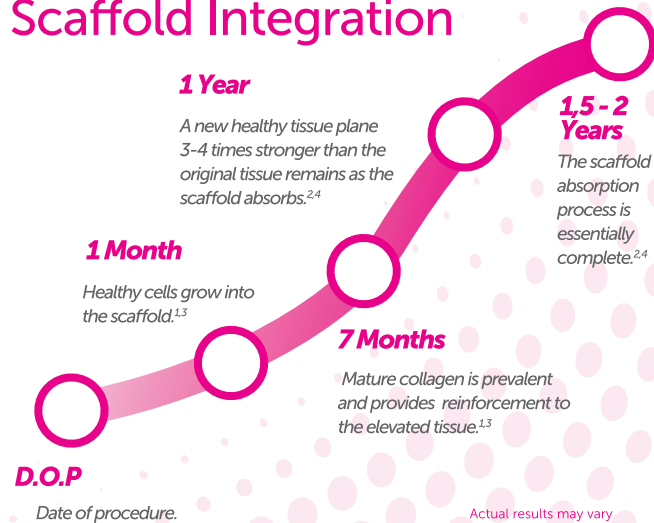
## How Does GalaFLEX® Work?

During surgery, your surgeon will place the GalaFLEX® scaffold internal bra under your tissue. The unique knit pattern of the scaffold encourages rapid cellular infiltration and the formation of new collagen<sup>1,3</sup> which is a key component of healthy skin tissue. This newly formed tissue is pliable yet provides strength, support and stability to the elevated tissue.<sup>2,4</sup> After 18-24 months, the scaffold is essentially completely absorbed and eliminated from the body as water and carbon dioxide through natural physiologic pathways.<sup>2</sup> No polymer metabolites remain after the degradation process is complete. The collagen tissue that remains is 3-4 times the original tissue strength.<sup>2,4</sup>

## Be GalaSTRONG

The GalaFLEX® Family of Scaffolds are used in patients who need additional support because of weakened or deficient soft tissue, in breast surgery procedures. The GalaFLEX® Family of Scaffolds are used in breast procedures such as reduction mammoplasty, augmentation and revision surgeries.

## GalaFLEX® Scaffold Integration



## The Issue With Tissue

As we age so does our skin. After the age of 20, our skin loses about 1% of its collagen each year.<sup>9</sup> This gradual loss of collagen is what causes skin to become thinner and less elastic, resulting in natural sagging and wrinkles. There are many factors that can accelerate this effect, including:



In most Breast surgery procedures, compromised and/or weakened soft tissue is tightened. Unfortunately, the tissue itself will not be stronger and gravity may once again cause tissue to droop or sag. This is why many surgeons choose to use a soft tissue support scaffold like GalaFLEX®. Not only does it provide internal breast support to newly lifted and tightened tissue immediately after surgery, but it also allows soft tissue to heal stronger.<sup>2</sup>

## Why Soft Tissue Support Matters

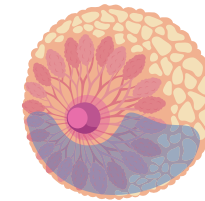
Clinical studies show that within 10 years following surgery, between 32% - 48% of patients undergo a second surgery to revise their initial surgical results.<sup>10,11,12</sup> The most frequent reason for revisionary surgery among aesthetic implant patients was the development of ptosis (42%) or sagging of the tissue.

## How Do I Know If GalaFLEX® Is Right For Me?

Patients seeking to strengthen and stabilize weakened tissue during breast surgery may be candidates for GalaFLEX® scaffold. Please consult your surgeon to discuss if GalaFLEX® scaffold may be right for you.

Here are some questions you may want to discuss with your surgeon:

- How would you describe the quality of my breast tissue?
- Do I have risk factors for weakened breast tissue?
- Will my tissue alone provide enough strength and support?
- Does my tissue need additional soft tissue support?
- Do I need a GalaFLEX® Internal Bra™?



GalaFLEX® scaffold is designed to lift, reinforce and repair soft tissue where weakness exists in breast surgery.

GalaFLEX® scaffold internal bra provides soft tissue support for cosmetic breast procedures.

## Clinically proven

- **Comprehensive portfolio** of biocompatibility testing reviewed by FDA and Notified Body during regulatory approval process for P4HB products.<sup>1,3</sup>
- **Produced by a safe biological fermentation process**, standard in pharmaceutical production.<sup>1,5</sup> Not of animal origin, Not synthetic.
- **P4HB devices implanted** in more than 4 million patients worldwide.<sup>1</sup>
- **P4HB extensively researched** with more than 60 clinical and scientific publications.<sup>1</sup>
- **GalaFLEX® does not interfere** with diagnostic mammograms or ultrasound techniques.<sup>1,3</sup>

Gala**FLEX**<sup>®</sup>  
P4HB Scaffold

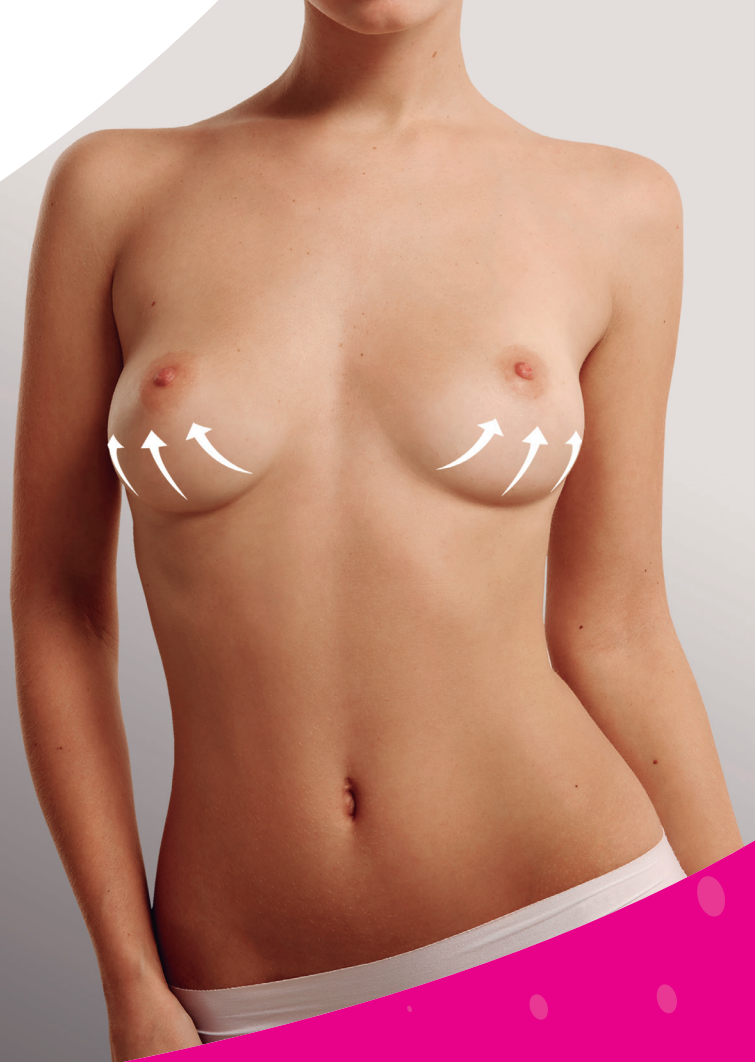
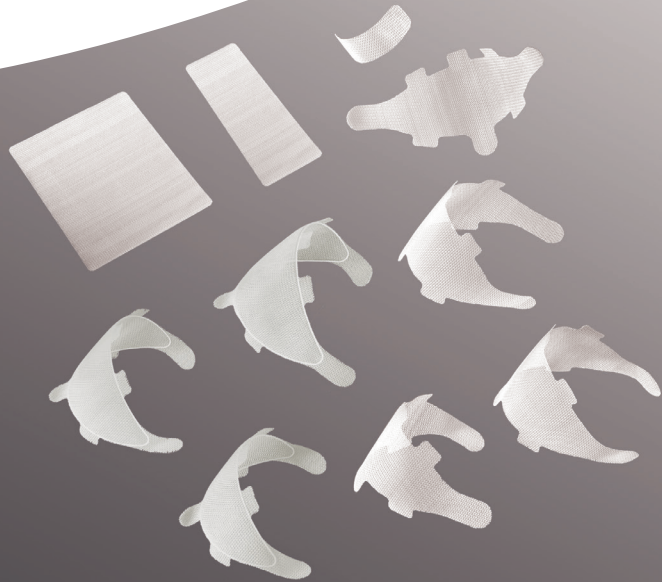






Image is not intended to represent the procedural result

# The Galatea Family of Scaffolds

Strengthen and Stabilize Tissue in Breast Surgery

-  Biologically Derived
-  Monofilament
-  Strong
-  Bioabsorbable
-  3-Dimensional options



# Strengthen and Stabilize Tissue in Breast Surgery

**GalaFLEX®**  
P4HB Scaffold



## BIOABSORBABLE

The first and only shaped bioabsorbable scaffold designed to fit and uplift the body's natural shape<sup>1</sup>



## + 4 MILLION

Patients have been implanted with P4HB devices<sup>1</sup>



## EASY PLACEMENT

Provides easier placement and reduced procedure time<sup>1</sup>



## HYDROLYSIS

Eliminated from the body as CO<sub>2</sub> and H<sub>2</sub>O primarily by the process of hydrolysis<sup>4</sup>



## 3-4 x STRONGER

Resulting in tissue 3-4 times stronger than native tissue<sup>2,3</sup>



## 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<sup>1,2,3</sup>

### Intended Use

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For more information on **elevating your surgical procedure with the Galatea Family of Scaffolds**, please contact our team.

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**The GalaFLEX® Family of Scaffolds offers you a full portfolio of sizes for each patient's surgical needs**

GalaFLEX® Scaffold		
Shape	Product Code	Size (cm)
	CE0206	5 x 15
	CE0208	5 x 20
	CE0408	10 x 20
	CE0608	15 x 20

GalaFLEX 3D™ Scaffold				
Shape	Product Code	N° per package	Size (cm)	
	CESH01	1	5.3 x 15.5	Small
	CESH03	1	6.4 x 18.5	Medium
	CESH05	1	7.5 x 21.0	Large

GalaFLEX 3DR™ Scaffold				
Shape	Product Code	N° per package	Size (cm)	
	CEFR01	1	5.3 x 15.5	Small
	CEFR03	1	6.4 x 18.5	Medium
	CEFR05	1	7.5 x 21.0	Large

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