

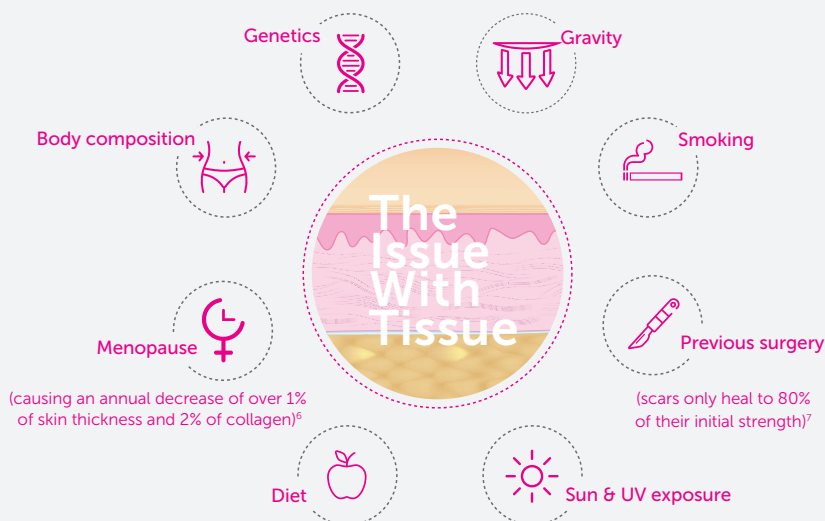
Internal Support Beyond the Procedure



GalaFLEX[®]
P4HB Scaffold

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.⁸ 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 plastic surgery procedures, compromised and/or weakened soft tissue is tightened. Unfortunately, the tissue itself will not be stronger and gravity will 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 support to newly lifted and tightened tissue immediately after surgery, but it also allows soft tissue to heal stronger.²

Why Soft Tissue Support Matters

Clinical studies show that within 10 years following surgery, somewhere between 32% - 48% of patients undergo a second surgery to revise their initial surgical results.^{10,11,12} The most commonly cited reason for these secondary procedures is a recurrence of the soft tissue weakness or deficiency.⁹



Be GalaSTRONG

Soft tissue support (STS) is used in both plastic and reconstructive procedures to repair, elevate and reinforce deficiencies where weakness or voids exist. In preclinical studies, GalaFLEX scaffold has been demonstrated to provide 3-4 times greater strength than native tissue at 12 months following implantation.^{2,4}

What Is GalaFLEX?

GalaFLEX is a temporary, absorbable scaffold used to strengthen, stabilize and support weak tissue. It was designed to provide support immediately after surgery, allowing your body the time to heal and create a healthy new tissue plane containing primarily mature collagen.

GalaFLEX scaffolds are made from a biologically derived polymer known as poly-4-hydroxybutyrate (P4HB™), which breaks down over time into carbon dioxide and water, a process much like absorbable stitches. This means that your body knows how to metabolize and completely absorb the scaffold safely and naturally.

GalaFLEX scaffolds are designed specifically for use in a variety of shapes and sizes to meet the needs of plastic and reconstructive surgery patients. Each GalaFLEX scaffold is selected by your surgeon specific to your body's shape and needs.



GalaFLEX Scaffold Integration



How Does GalaFLEX Work?

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

How Do I Know If GalaFLEX Is Right For Me?

Patients seeking to strengthen and stabilize weakened tissue in plastic and reconstructive surgery may be a candidate for GalaFLEX scaffold. Please consult your surgeon to discuss if the 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 tissue?
- Will my tissue alone provide enough strength and support?
- Does my tissue need additional soft tissue support?



The Galatea scaffolds are designed for soft tissue reinforcement in plastic and reconstructive surgery procedures.



Clinically Proven

P4HB devices have been tested in pre-clinical and clinical studies for safety and effectiveness.

- Comprehensive portfolio of biocompatibility testing reviewed by FDA during clearance process for P4HB products.^{1,3}
- Produced by a safe biological fermentation process, standard in pharmaceutical production.^{1,5}
- Implanted in more than 3 million patients worldwide.¹
- Extensively researched with more than 60 clinical and scientific publications.¹



GalaFLEX[®]

P4HB Scaffold

Indications For Use

GalaFLEX, GalaFLEX 3D and GalaFLEX 3DR scaffolds 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. This includes reinforcement of soft tissue in plastic and reconstructive surgery, and general soft tissue reconstruction. These products, referred to as Galatea scaffolds, are also indicated for the repair of fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

Important Safety Information

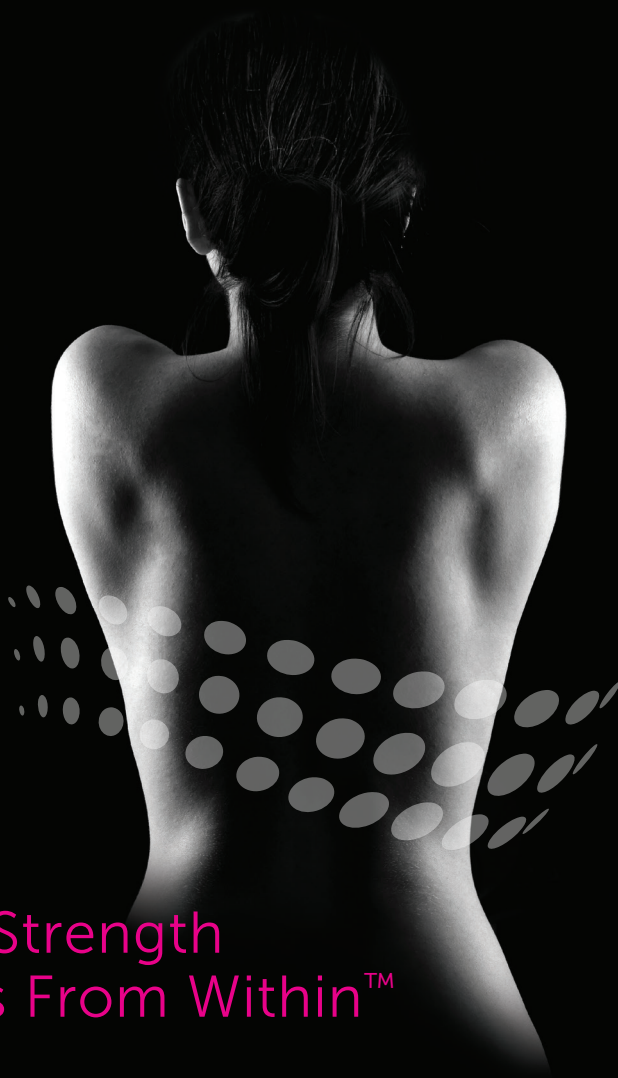
Possible complications following implantation of Galatea scaffolds include infection, seroma, pain, scaffold migration, wound dehiscence, hemorrhage, adhesions, hematoma, inflammation, extrusion, and recurrence of the soft tissue defect. The safety and product use of Galatea scaffolds for patients with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

References

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Starts From Within™**

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