



Ask your surgeon about the
quality of your soft tissue

Defy gravity

Support beyond the procedure

In plastic and reconstructive surgery procedures, supplemental tissue support is an important factor in achieving lasting, natural-looking results.^{1,2,3}

GalaFLEX[®]
P4HB Scaffold 

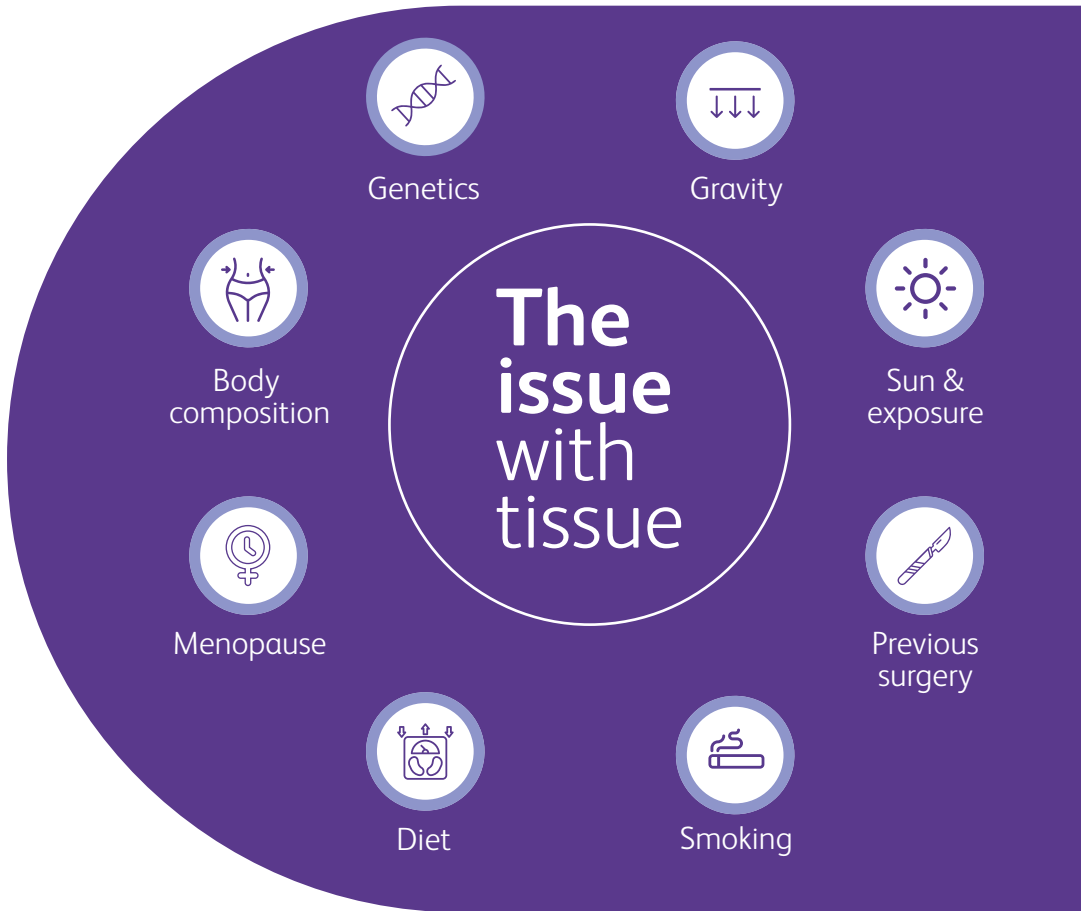
The issue with tissue

After age 20, **our skin loses about 1% of its collagen each year** - causing the soft tissue to become thinner and less elastic.

The 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:^{1,4,5}



Did you know? After surgery, native soft tissue only heals to 80% of its original strength.⁶



Why soft tissue support matters

Clinical studies show that within 10 years after plastic surgery, **32-48% of patients undergo a second procedure** to revise their initial results - most commonly citing soft tissue weakness or deficiency as the reason behind these secondary procedures.^{7,8}

What is GalaFLEX™ Scaffold?

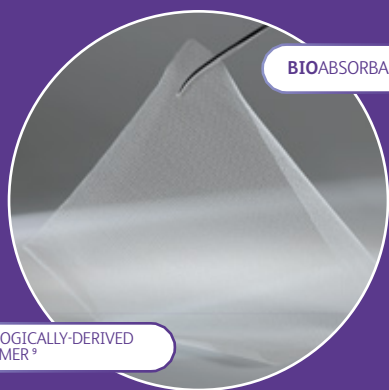
GalaFLEX™ Scaffold is a temporary, bioabsorbable scaffold used to strengthen, stabilize and support weak tissue. It was designed to provide support immediately after surgery, allowing your body the time to heal and create a healthy new tissue plane containing primarily mature collagen.⁹

Proper tissue support is an important factor in achieving lasting, natural-looking results. Plastic and reconstructive surgery patients deserve soft tissue support.

Make tissue repair stronger with GalaFLEX™ Scaffold
Reinforce your plastic and reconstructive surgery with the predictable strength of GalaFLEX™ Scaffold.⁹

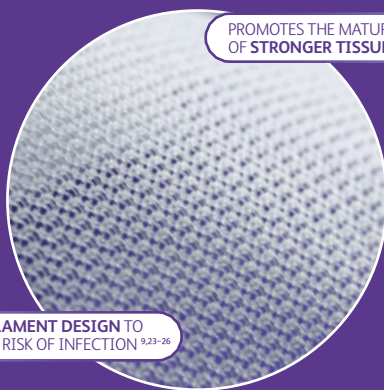
What material is GalaFLEX™ Scaffold made of?

GalaFLEX™ Scaffold is composed of 100% Poly-4-hydroxybutyrate, otherwise known as P4HB. P4HB is a polymer produced from the monomer form 4HB – a naturally occurring human metabolite found in the brain, heart, liver, kidney and muscle.¹⁵



BIOABSORBABLE

BIOLOGICALLY-DERIVED
POLYMER⁹



PROMOTES THE MATURATION
OF STRONGER TISSUE^{9,10}

MONOFILAMENT DESIGN TO
DECREASE RISK OF INFECTION^{9,23-26}



**32-48% of plastic surgery patients
undergo a second procedure** to revise
their initial results.^{7,8}

How do I know if GalaFLEX™ Scaffold is right for me?

Patients seeking to strengthen and stabilize weakened soft tissue in plastic and reconstructive surgery may be a candidate for GalaFLEX™ Scaffold.

How do I know which GalaFLEX™ Scaffold product is best for my procedure?

GalaFLEX™ Scaffold is designed for use in a variety of shapes, sizes and thicknesses 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.

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

- 1 How would you describe the quality of my tissue?
- 2 Will my tissue alone provide enough strength and support?
- 3 Does my tissue need additional soft tissue support?

Please consult your surgeon to discuss if GalaFLEX™ Scaffold may be right for you.

eXperience
the P4HB advantage



Biologically -
derived



Bioabsorbable



Monofilament



Strong



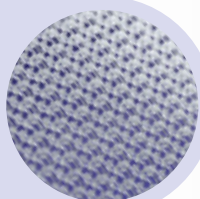
Predictable
performance



How does GalaFLEX™ Scaffold work?



During surgery, your surgeon will place the **GalaFLEX™ Scaffold** under your tissue, where it supports, repairs and reinforces soft tissue.⁹



The unique porous construction was designed to allow native tissue ingrowth and gradual transfer of load from the scaffold to the tissue.⁹

2-4_x

The new collagen formed promotes the maturation of stronger tissue. Tissue repaired with **GalaFLEX™ Scaffold** has been shown to be 2-4x stronger than native tissue.^{9-11, 22}

How long does GalaFLEX™ Scaffold remain in my body?

bioabsorbed
18-24
months

GalaFLEX™ Scaffold gradually breaks down over 18-24 months, into carbon dioxide and water, a process much like absorbable stitches.^{9,10,14}

GalaFLEX™ Scaffold performs predictably, providing immediate soft tissue reinforcement and a foundation for long-term strength.⁹⁻²⁰



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References: 1. Choi, Jae Woo. "The Influences of Skin Visco-Elasticity, Hydration Level and Aging on the Formation of Wrinkles: a Comprehensive and Objective Approach." *Skin Research and Technology*, vol. 19, no. 1, 2012. 2. Vera, Martin. "Phases of Wound Healing: The Breakdown." *Wound Source*. Accessed on Nov 13, 2020. www.woundsource.com. 3. Levenson SM, Geever EF, Crowley LV, Oates JF 3rd, Berard CW, Rosen H. The Healing of Rat Skin Wounds. *Ann Surg*. 1965;161(2):293-308. 4. Why Does Skin Wrinkle with Age? What Is the Best Way to Slow or Prevent This Process? *Scientific American*, Scientific American, 26 Sept. 2005. 5. Thornton, M. Julie. "Estrogens and Aging Skin." *Dermato-Endocrinology*, vol. 5, no. 2, 2013, pp. 264-270, doi:10.4161/derm.23872. 6. Meilang Xue and Christopher J. Jackson. "Extracellular Matrix Reorganization During Wound Healing and Its Impact on Abnormal Scarring." *Advances in Wound Care*. March 2015. 7. Mimi Y. Wu Young, Kathleen A. Holoyda, David W. Chang. Outcomes of progressive tension donor-site closure in abdominal-based autologous breast reconstruction. *Journal of Plastic, Reconstructive & Aesthetic Surgery* Volume 75, Issue 9, 2022, Pages 2991-2995. 8. Adetayo, OA MD; Salcedo, SE; Gupta, SC. 1: THE USE OF ACELLULAR DERMAL MATRIX IN BREAST AND ABDOMINAL WALL SURGERY: A META-ANALYSIS OF OUTCOMES AND RISK FACTORS PREDICTIVE OF COMPLICATIONS. *Plastic and Reconstructive Surgery* 127(0);p 9, May 2011. 9. Predclinical data on file. Results may not correlate to clinical outcomes. 10. Deeken CR, Matthews BD. 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 Surg*. 2013;2013:238067. Published 2013 May 28. doi:10.1155/2013/238067. 11. Scott JR, Deeken CR, Martindale RG, Rosen MJ. Evaluation of a fully absorbable poly-4-hydroxybutyrate/absorbable barrier composite mesh in a porcine model of ventral hernia repair. *Surg Endosc*. 2016;30(9):3691-3701. doi:10.1007/s00464-016-5057-9. 12. Martin DP, Williams SF. Medical applications of poly-4-hydroxybutyrate: a strong flexible absorbable biomaterial. *Biochem Eng J* 2003;16(2):97-105. 13. Martin DP, Badhwar A, Shah DV, et al. Characterization of poly-4-hydroxybutyrate mesh for hernia repair applications. *J Surg Res*. 2013;184(2):766-773. doi:10.1016/j.jss.2013.03.044. 14. GalaFLEX™ Scaffold Instructions for Use. 15. Williams SF, Martin DP, Moses AC. The History of GalaFLEX P4HB Scaffold. *Aesthet Surg J*. 2016;36(suppl 2):S33-S42. doi:10.1093/asj/sjw141. 16. Ireton, Jordan E. et al. "The Role of Wound Healing and Its Everyday Application in Plastic Surgery: A Practical Perspective and Systematic Review." *Plastic and reconstructive surgery*. Global open (2013). 17. Critical wound healing period adapted from Ireton 2013 (6 weeks to 3 months). 18. Stoikes NFN, Scott JR, Badhwar A, Deeken CR, Voeller GR. Characterization of host response, resorption, and strength properties, and performance in the presence of bacteria for fully absorbable biomaterials for soft tissue repair. *Hernia*. (2017) 21 (5):771-82. doi: 10.1007/s10029-017-1638-3. 19. Data on file. Results may not correlate to clinical outcomes. 20. Healthy tissue is defined by 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. 21. Guo, Kai & Martin, David. (2015). Poly-4-hydroxybutyrate (P4HB) in Biomedical Applications and Tissue Engineering. 22. Native abdominal wall tissue strength adapted from Deeken 2013 (69.7N +/- 13.6). 23. 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 Res*. 2002;63(6):765-71. 24. 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* 11.5 (2010): 449-454. 25. Engelsman, A. F., van der Mei, H. C., Ploeg, R. J., & Busscher, H. J. (2007). "The phenomenon of infection with abdominal wall reconstruction." *Biomaterials*, 28(14), 2314-2327. 26. Deeken CR, Chen DC, Lopez-Cano M, Martin DP, Badhwar A. Fully resorbable poly-4-hydroxybutyrate (P4HB) mesh for soft tissue repair and reconstruction: A scoping review. *Front Surg*. 2023;10:1157661. Published 2023 Apr 12. doi:10.3389/fsurg.2023.1157661

Indications for Use: GalaFLEX™, GalaFLEX 3D™ and GalaFLEX 3DR™ Scaffolds are indicated for use as bioresorbable scaffolds 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 the GalaFLEX™ Scaffold collection, 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.

GalaFLEX LITE™ Scaffold is intended to reinforce soft tissue where weakness exists in patients undergoing plastic and reconstructive surgery, or for use in procedures involving soft tissue repair, such as 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 the GalaFLEX™ Scaffold collection include infection, seroma, pain, scaffold migration, wound dehiscence, hemorrhage, adhesions, hematoma, inflammation, extrusion and recurrence of the soft tissue defect. For complete prescribing information, including indications for use, warnings and precautions, consult the specific GalaFLEX™ Scaffold Instructions for Use.

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