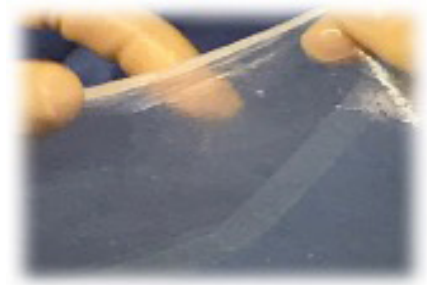


LevaGRAF™



Human Amniotic Membrane-

Material of Choice Augmenting Better Results in Tissue Regeneration and Repair

LevaGRAF™ is a terminally sterilized, naturally-derived, bioengineered placental collagen matrix that acts as a mechanically robust and biologically active barrier. LevaGRAF™ has been cross-linked with a controlled-release mechanism to prevent premature absorption, further sustaining the “native” beneficial properties following allogeneic transplant.^{Data on file}

Mechanical Properties¹

Permeability • Stability • Elasticity • Flexibility • Plasticity • Resorbability

Published Properties and Benefits of Birth Tissues

Accelerates Healing

...Effective in tissue regeneration and guided bone regeneration, prevents fibrous tissue invasion^{2,3}

Immunoprivileged Tissue

... absence of inducing an immune reaction³

Reduces Pain

...Increased blood supply and oxygen^{5,9,10}

Reduces Scar Formation

...Facilitates migration of epithelial cells^{5,9}

Remodels Tissue

... Mimics function of native Extracellular Matrix, promoting cell migration, replication and angiogenesis¹⁰

Anti-Inflammatory

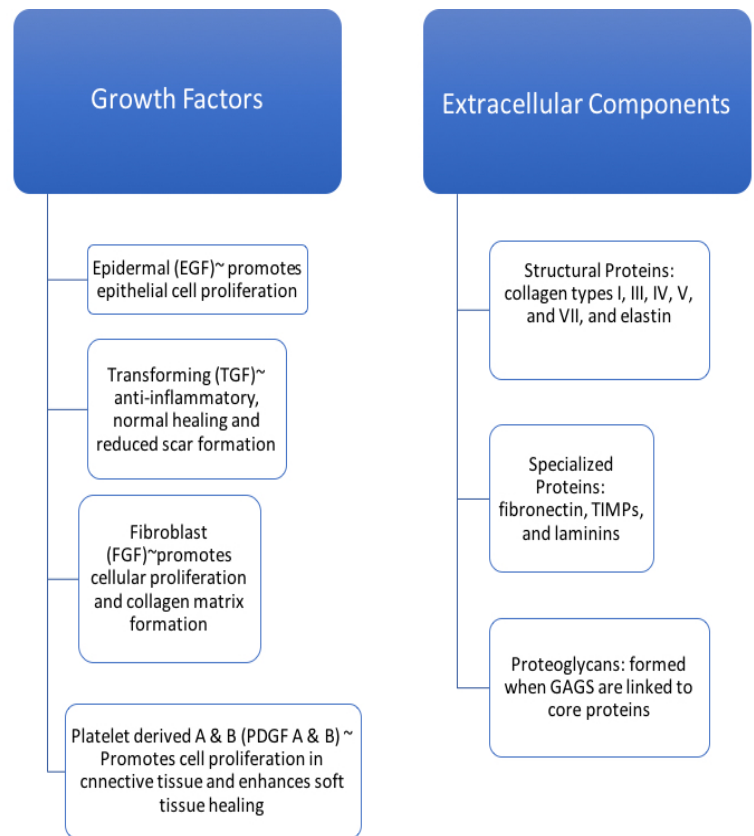
...Modulates Inflammation^{9,10,11}

Anti-Bacterial/Anti-Microbial

...Cleanses and protects, prevents infection^{9,10,11}

Extracellular Matrix Composition

...Collagen types I, III, IV, VI, fibronectin, nidogen, laminin, proteoglycans¹¹



LevaGRAF™ - a cryoprotectant-free, gamma-irradiated (terminally sterilized), chorion-free human Amniotic Membrane Allograft tissue prepared from birth tissues donated after Cesarean section delivery from a screened and qualified volunteer donor. Terminal Sterilization has been proven to retain maximum biological activity, while ensuring maximum patient safety.^{7,8,9}



Levana
BIOLOGICS

The Evolution of Medicine

LevaGRAF™ = More Growth Factors

Potential Uses - Therapeutic and Regenerative Applications¹⁰

Wound Care	Ophthalmology	Spine/ Sports Orthopedics Medicine	Oral & Periodontal	Internal	General Uses
Infected and Contaminated Wounds	Ocular Surface Reconstruction	Tendon and Nerve Wraps following Anastomosis	Grafted Extraction Sockets	Ulcers	Anti-Adhesion Barriers (post-laminectomy, post-surgery)
Immunosuppressed wounds (Graft vs. Host)	Corneal Surface Disorders	Flexor Tendon Injury	Mucosal Surgical Defects	Liver Diseases and Fibrosis	Surgeries Where the Formation of Scar Tissue are a Concern
Burn Coverings	Symptomatic Bullous Keratopathy	Osteoarthritis	Covers Sinus Lateral Window	Myocardial Infarctions	Alternative to Absorbable Collagen and Synthetic Coverings
Dermatitis	Band Keratopathy	Plantar Fasciitis	Sinus and Schneiderian Membrane Perforations	Intrapulmonary Applications	Alternative to Cadaveric Coverings
Diabetic Foot Ulcers	Conjunctival Surface Reconstruction	Spinal Stenosis	Ridge Augmentations	Intra-Abdominal Applications	Alternative and/or Supplement to Autologous Skin Grafts
Venous Leg Ulcers or Amputation Wounds	As an Alternative to Allogeneic Limbal Epithelium Stem Cells	Tendon Tears	Mild Gingival Recession	Intrauterine Adhesions/ Vaginal Reconstruction	Non-Surgical Approach to Tissue Reconstruction
Raynaud's Syndrome	Glaucoma	Spinal Stenosis and Herniated Disk	Adhesion Barrier in TMJ Surgery	Post-operative Atrial Fibrillation	Cosmetic Indications
	Dry Eye Syndrome		Bone Grafted Apioectomy and retrofilled Sites	Scleroderma	
				Dorsal cheilectomy for Hallux Rigidus	

This list is not inclusive of all potential applications. Not all uses and applications listed above have successfully completed IRB approvals. Some of these applications are currently in pre-clinical trial stage. It is up to the user clinician to determine its' usefulness and effectiveness.

Quality & Safety

- Non-Invasive and Safe
- Over 226 growth factors, cytokines and chemokines present post-preservation
- Available in terminally sterilized hydrated or dehydrated formats
- Excess can be folded onto itself for a more customized fit
- Easy to handle and apply
- Guaranteed stability at room temperature for 2 years from date of packaging
- Levana Biologics provides practitioners with a complimentary consultation with our Chief Scientific Officer
- Over 4,000 LevaGRAF™ units have been successfully transplanted
- Some indications may qualify for third-party reimbursement

Sizes

- 1 x 1 -cm (1 cm²)
- 2 x 2 -cm (4 cm²)
- 2 x 4 -cm (8 cm²)
- 4 x 4 -cm (16 cm²)
- 4 x 6 -cm (24 cm²)
- 4 x 8 -cm (32 cm²)
- 7 x 15-cm (105 cm²)

All sizes are available in hydrated and dehydrated formats, with the exception of the 7 x 15 cm (105 cm²) which is only offered in a hydrated format.

Manufacturer

Levana Biologics is partnered with a world-renowned Cell Therapy and Regenerative Medicine Academic Institution and University to manufacture LevaGRAF™ and other biomaterials. LevaGRAF™ qualifies as a human tissue allograft (HCT/P) as outlined in 21 CFR 1271 under Section 361 of the Public Health Service Act. Collection, processing, preservation and storage are performed utilizing a proprietary process (patent pending) by an FDA registered, AATB, FACT, CAP accredited, CLIA certified laboratory.

References: (1)Mohan R, Bajaj A, Gundappa M (2017) J Int Soc Prev Community Dent 7:15-21(1) (2) Li W, et al. (2015) Langmuir 31:8642-53. (3)Aral N, et al. (2012) J Oral Maxillofac Surg 70:2221-8 (4) Velez I et al. (2010) J Periodontol 81:1797-804 (5)Kaigler D, et al. (2006) Expert Opin Drug Deliv 3:647-662 (6)Gupta A, Kedige SD, Jain K (2015) Int J of Biomater doi:10.1155/2015/274082 (7) Koob TJ, Rennert R, Zabeck N, Masseur M, Lim JJ, Temenoff JS, et al. Biological properties of dehydrated human amnion/chorion composite graft: implications for chronic wound healing. International Wound Journal. 2013;10(5):493-500. (8) Zelen CM, Serena TE, Denozziere G, Fetteroff DE. A prospective randomised comparative parallel study of amniotic membrane wound graft in the management of diabetic foot ulcers. International Wound Journal. 2013;10(5):502-507. (9) Jeremy J. Lim and Thomas J. Koob (2016) Worldwide Wound Healing - Innovation in Natural and Conventional Methods; Placental Cells and Tissues: The Transformative Rise in Advanced Wound Care Chapter 7 doi: 10.5772/65321 (10) Antonietta R. Siliini et al., (July 2015) Frontiers in Bioengineering and Biotechnology 3:162. doi: 10.3389/fbioe.2015.00162

©2017 Levana Biologics. All rights reserved. Printed in U.S.A. 9/17. LevaGRAF™ is a trademark of Levana Biologics. LevaGRAF™ may not be re-sold or used for commercial purposes, which both require a specific license.

For inquiries or to place an order:

Direct: 303-500-5151

Toll Free: 1-888-328-1383

Fax: 720-941-6865

sales@levanabiologics.com

Visit us online at: Levanabiologics.com



Levana
BIOLOGICS