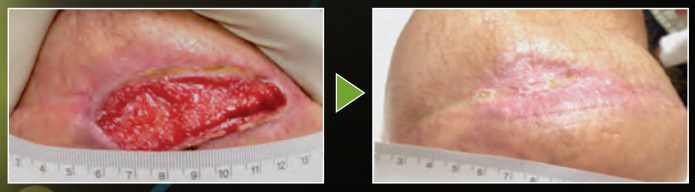
tissue reborn

Bringing the progenerative power of the amnion to tissue restoration



Acute | Chronic | Mohs surgery | Burns | Trauma | Complex Surgical | Venous leg ulcers | Exposed tendon, muscle, bone Diabetic ulcers | Pressure ulcers | Arterial ulcers

BIOVANCE®

Human Amniotic Membrane Allograft

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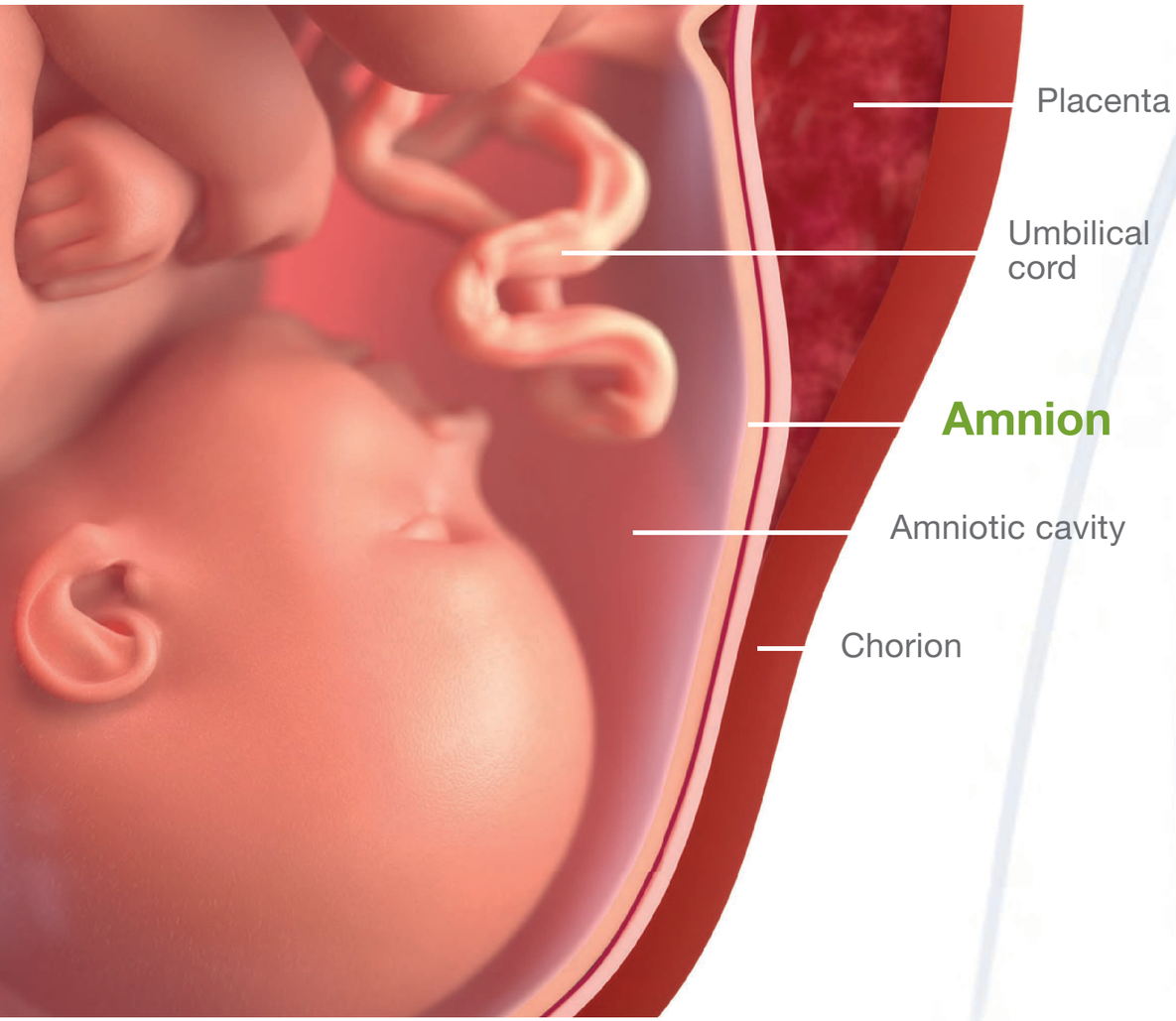
The power of the amnion reengineered for wound healing



The natural properties of the amniotic membrane support the growth and development of the fetus

For 9 months, the amniotic membrane:

- Forms the innermost lining of the placenta during gestation[1]
- Is the tissue closest to the fetus throughout development
- Serves as a barrier to minimize risk of injury to the fetus[1-3]

The progenerative power of the amniotic membrane supports the body's natural ability to restore tissue[1,2,4-7]

- Reduces inflammation[5,7]
- Provides a biological barrier to infection[7]
- Supports tissue growth[7]
- Minimizes pain upon application[1,5]

The amniotic membrane protects against desiccation and resists proteolyctic enzymes.

BIOVANCE® is an amniotic membrane allograft that supports healing[1]

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BIOVANCE contains natural substances, derived from healthy placentas, that support the body's ability to heal[1,2,7]

BIOVANCE components		Function in normal dermal tissue
Basement membrane		Anchors epithelial cells; down-regulates apoptosis of epithelial cells
Collagen protein	Types I, III, IV, V, VII	Structural support and guidance of cell migration and organization
Other proteins	Elastin	Elasticity of tissue
	Glycosaminoglycans (GAGs)	Water attraction, lubrication, and reduction of inflammation
	Glycoproteins	Cell-binding proteins in the ECM
	Proteoglycans	Matrix hydration
	Laminins and fibronectin	Collagen structure regulation; migration, differentiation, phenotype, adhesion, and survival of cells

BIOVANCE is devoid of cells, hormones, growth factors and cytokines.

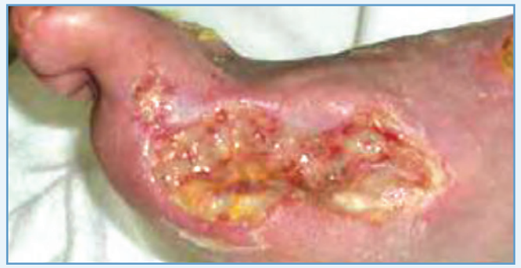
Indicated for wound management for a broad set of needs:

Acute | Chronic | Mohs surgery | Burns | Trauma | Complex Surgical | Venous leg ulcers
Exposed tendon, muscle, bone | Diabetic ulcers | Pressure ulcers | Arterial ulcers

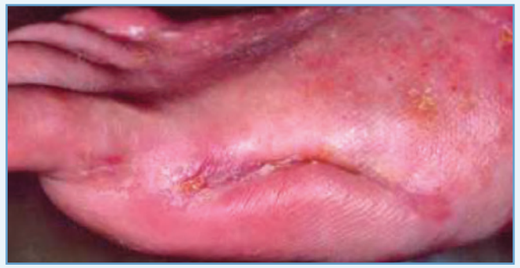
BIOVANCE® offers the potential to restore tissue to its pre-wound state with minimal scarring*[1,7]

BIOVANCE used on an ischemic ulcer and surgical wound

CASE CHARACTERISTICS: • Gangrene of the great toe • Severe ischemia following recent successful bypass • Acute transmetatarsal amputation site of the toe • Full-thickness wound with moderate exudate



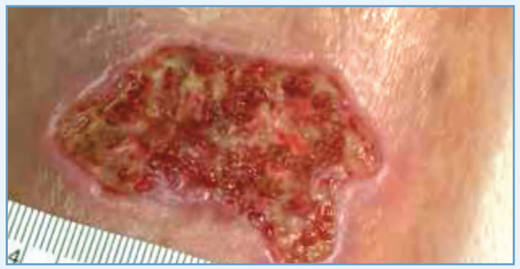
Baseline Day 1: First application of BIOVANCE
12.9 cm x 4.8 cm x 1 mm



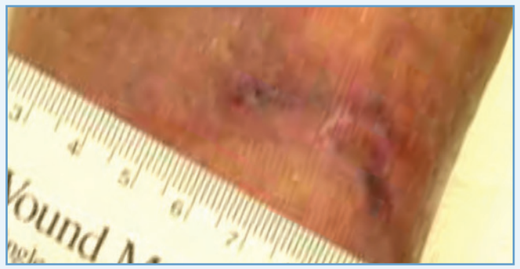
Week 25: Closed

BIOVANCE evidence in a venous leg ulcer

CASE CHARACTERISTICS: • 68-year-old female • PVD and venous stasis ulcer • Left anterior shin



Baseline Day 1: First application of BIOVANCE
3 cm x 5 cm x 1 mm



Week 12: Closed after
1 application of BIOVANCE

*Best results will be found in acute and excised chronic wounds.

BIOVANCE® has been studied from benchtop to patient[8,9]

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BIOVANCE provides the intact extracellular matrix required for appropriate healing and nothing more

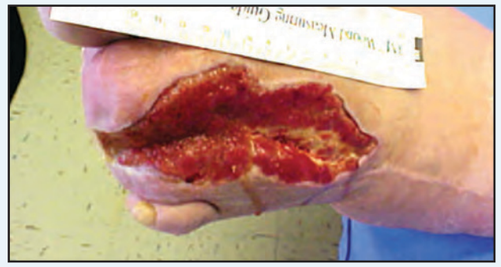
An in vitro study demonstrated[8]:

- Fibroblasts and keratinocytes readily attach to and proliferate on BIOVANCE
- BIOVANCE supports the production of an insoluble fibronectin network
- Cells attached to BIOVANCE provide G-CSF, IL-8, VEGF, and FGF which have been shown to support wound healing

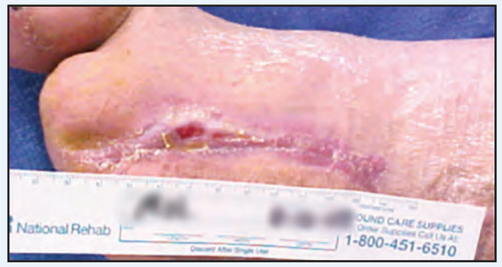
BIOVANCE is a chorion-free product. In the same study, a human amnion-chorion product containing nonviable cells and active growth factors limited cell attachment and initiated apoptosis. The release of bioactive molecules likely contributed to this negative effect.[8]

BIOVANCE® was evaluated in a real-world patient study conducted to gain clinical and safety experience[9]

- 244 wounds were treated at 19 different wound care sites
- Only patients with infected wounds or those with hypersensitivity to BIOVANCE were excluded
- Closure rate at 8 weeks was ~50% compared to historic controls of 24%-34%



Baseline Day 1: First application of BIOVANCE
12.9 cm x 4.8 cm x 1 mm



Week 25: Closed

BIOVANCE® applied to a second-degree burn of the leg[10]

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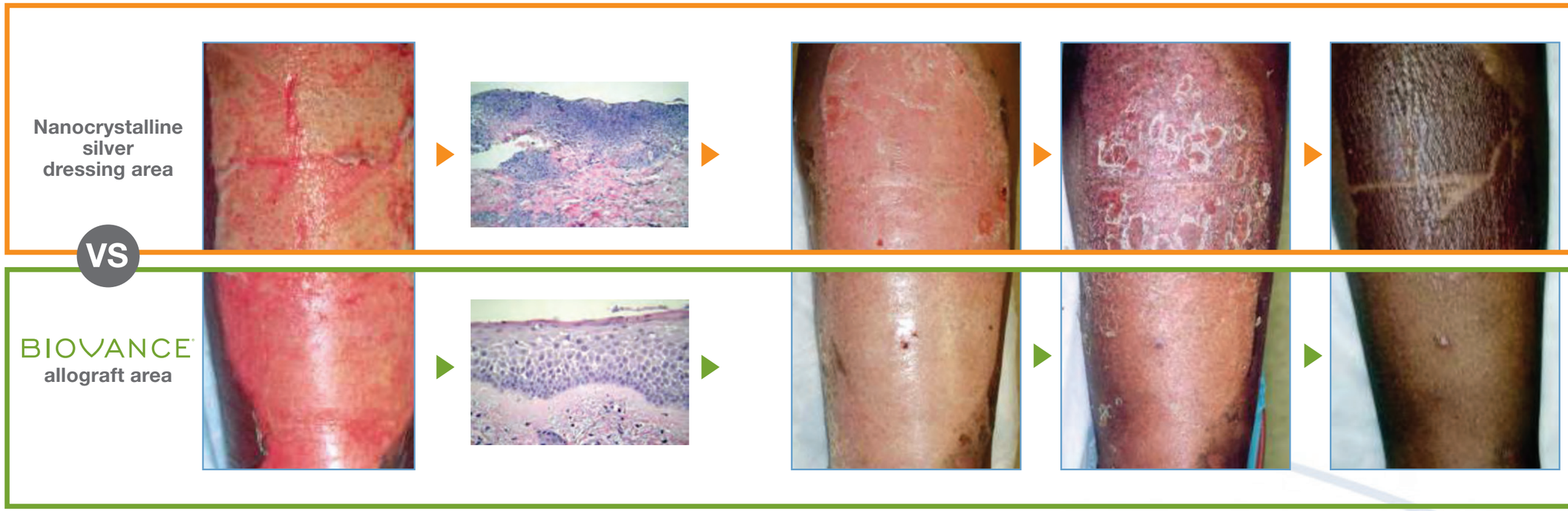
A side-by-side comparison of BIOVANCE vs nanocrystalline silver dressing*

BIOVANCE applied to lower half of burn only

VS



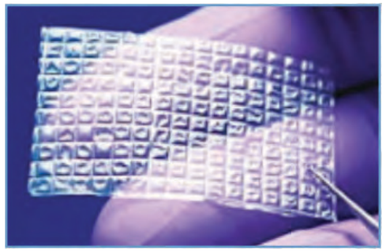
*Results may vary.

BIOVANCE® is the easy-to-use human amniotic membrane allograft

Easy application and wound visualization

- Flexible—conforms to irregular surfaces
- Adaptable—self-adheres to wounds but can be sutured, taped, stapled, or glued, as determined by the clinician
- Bidirectional—can be applied with either side facing the wound

Biovance should be applied to a clean wound and covered with an appropriate secondary, non-adherent dressing.

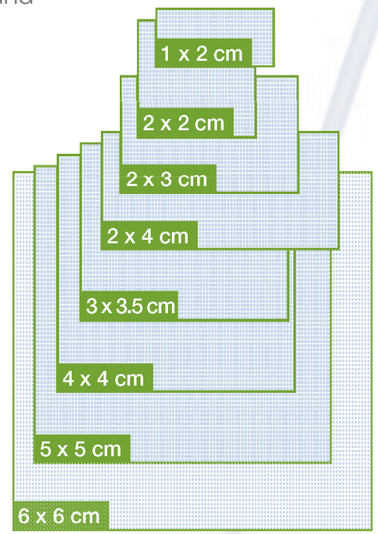


Translucent grid pattern is evident on the wound until hydration occurs to allow view of the wound's progress

Easy storage and preparation

- 5-year shelf life eliminates need for pre-ordering
- Room temperature storage—no refrigeration necessary
- No thawing, rinsing, or soaking required

Available in multiple sizes for application flexibility



Available in multiple sizes for application flexibility

1 x 2 cm	Product Code: DHAM0012
2 x 2 cm	Product Code: DHAM0022
2 x 3 cm	Product Code: DHAM0023
2 x 4 cm	Product Code: DHAM0024
3 x 3.5 cm	Product Code: DHAM0035
4 x 4 cm	Product Code: DHAM0044
5 x 5 cm	Product Code: DHAM0055
6 x 6 cm	Product Code: DHAM0066

BIOVANCE®

Human Amniotic Membrane Allograft

Minimally processed to maximize natural benefits and safety

Immunologically inert tissue

- Contains no antigens,[7] which further minimizes the risk of inflammatory response
- Tissue derived from the amniotic membrane is cleaned and preserved without altering its native matrix architecture
- Chorion layer is removed to further support the natural healing process
  - Eliminates cellular debris
  - Avoids potential addition of MMPs to the wound[3]
  - Prevents need for specific orientation for placement

Additional safety features

- Tissue used in processing is procured, processed, and tested in accordance with standards established by the AABB and the FDA
- Passed safety testing for cytotoxicity, hemolysis, irritation, endotoxins, and pyrogenicity
- Utilizes a bar-code tracking system for optimal safety monitoring and to enhance patient and practitioner confidence

Contraindications, Warnings, and Precautions

BIOVANCE® is contraindicated in patients with a known hyper-sensitivity to BIOVANCE. If a patient has an adverse reaction related to the use of BIOVANCE, immediately discontinue its use. BIOVANCE should not be used on clinically infected wounds.

The pouch contents are sterile if the pouch is unopened and undamaged. Do not use if package seal is broken. Discard material if mishandling has caused possible damage or contamination. Do not resterilize.

BIOVANCE must be used prior to the expiration date on the product pouch. BIOVANCE should not be used together with a collagenase product on the wound.

References: 1. Fetterolf DE, Synder RJ. Scientific and clinical support for the use of dehydrated amniotic membrane in wound management. *Wounds*. 2012;24(10):299-307. **2.** Bhatia M, Pereira M, Rana H, et al. Mechanism of cell interaction and response on decellularized human amniotic membrane: implications in wound healing. *Wounds*. 2007;19(8):207-217. **3.** Arechavaleta-Velasco F, Marciano D, Díaz-Cueto L, Parry S. Matrix metalloproteinase-8 is expressed in human chorion during labor. *Am J Obstet Gynecol*. 2004;190:843-850. **4.** Faulk WP, Matthews R, Stevens PJ, et al. Human amnion as an adjunct in wound healing. *Lancet*. 1980;1(8179):1156-1158. **5.** Ganatra MA. Amniotic membrane in surgery. *J Pak Med A*. 2003;v53(1):29-32. **6.** Portmann-Lanz CB, Ochsenbein-Kölble N, Marquardt K, et al. Manufacture of a cell-free amnion matrix scaffold that supports amnion cell outgrowth in vitro. *Placenta*. 2007;28(1):6-13. Epub2006. **7.** Niknejad H, Peirovl H, Jorjani M, et al. Properties of the amniotic membrane for potential use in tissue engineering. *Eur Cell Mater*. 2008;15:88-99. **8.** Guo X, Kaplunovsky A, Zaka R, et al. Modulation of cell attachment, proliferation, and angiogenesis by decellularized, dehydrated human amniotic membrane in in vitro models. *Wounds*. 1027;29(1):28-38. **9.** Smiell JM, Hahn HD, Gurney JP, Herb SE, Treadwell TA. Real world experience with a decellularized dehydrated human amniotic membrane (DDHAM) allograft. *Wounds*. 105;27(6):158-169. **10.** Treadwell T, Walker D, Nicholson B. The treatment of second-degree burns with dehydrated, decellularized amniotic membrane vs. a nanocrystalline silver dressing. http://equitiesiq.com/wp-content/uploads/2013/09/Biovance-Poster-SAWC-2014.pdf. Accessed June 19, 2018.

For product information, product complaints or adverse reaction reporting, telephone 1-844-963-2273.

Please refer to the BIOVANCE Package Insert for complete product information.

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