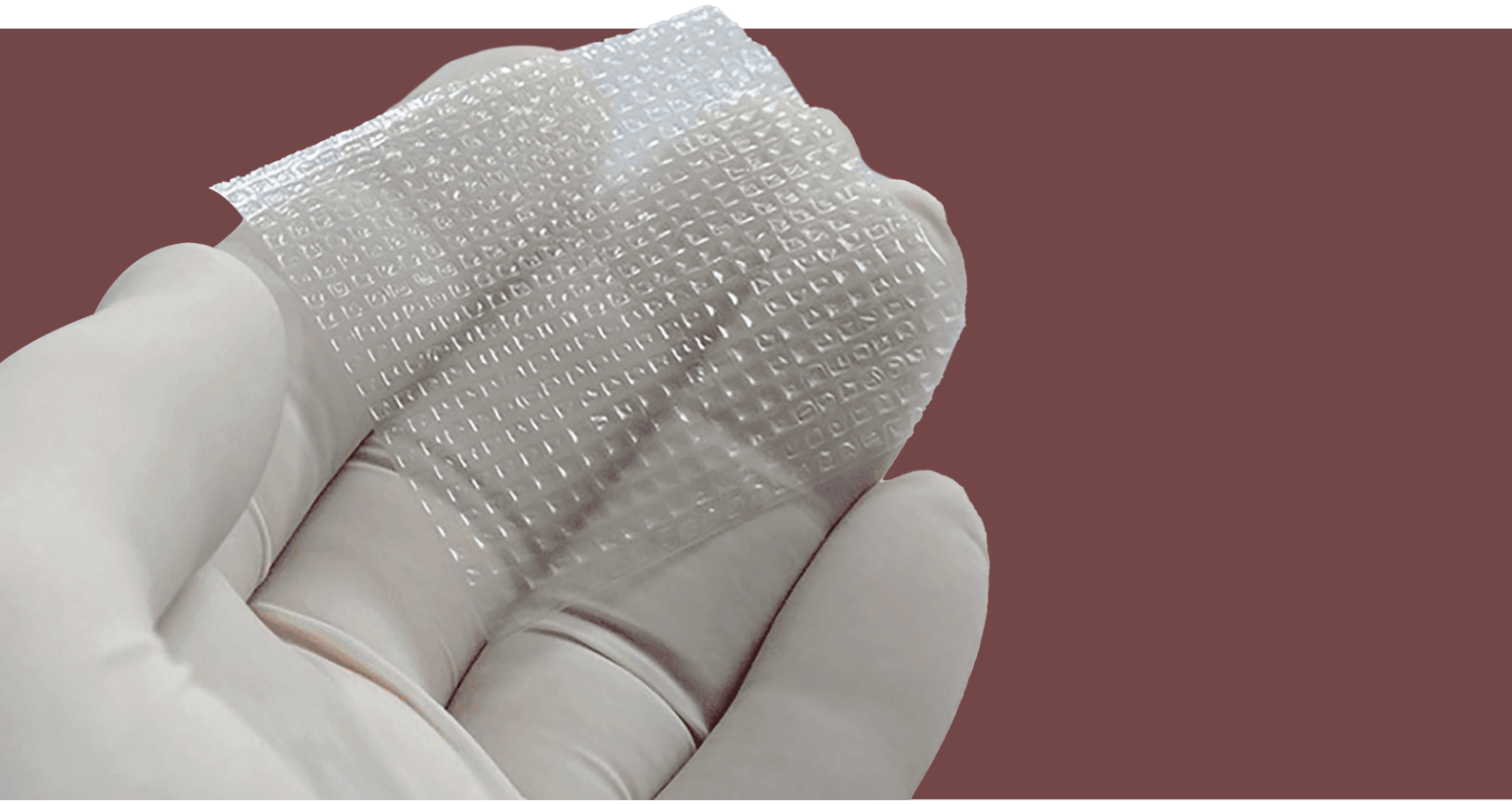
Biovance Human Amniotic Membrane

A Celularity Innovation



BIOVANCE®
Human Amniotic Membrane Allograft
A Celularity Innovation

Arthrex®

Biovance® Human Amniotic Membrane

Application of Biovance Membrane

Biovance® human amniotic membrane allograft is derived from a natural source: the placenta of a healthy, full-term human pregnancy.

Biovance Membrane Supports the Body's Natural Ability to Heal

- An intact, natural extracellular matrix (ECM) that acts as a scaffold for restoration of functional tissue
- Contains key ECM proteins that allow for the migration of host cells to permeate the graft and promote tissue repair[1]

Overview

Biovance human amniotic membrane allograft is an ECM that retains the native collagen structure of the amniotic membrane

- Devoid of cells, hormones, growth factors, and cytokines
- Contains extracellular proteins—collagen (I, III, IV, V, VII), elastin, glycosaminoglycans, fibronectin, laminin, and proteoglycans—to support the restoration of tissue
- The fibronectin found in Biovance membrane may direct movement of the patient's own fibroblasts and keratinocytes through haptotaxis
  - Scientific data was collected through *in vitro* assays to show how cells react to the inert scaffold of Biovance membrane

Biovance membrane is indicated for surgical use

- To protect the underlying tissue and preserve the tissue plane boundaries
- As a covering, wrap, or barrier at surgical sites, including those with exposed tendon, muscle, nerve, bone, or other vital structures

In vitro research has documented monocyte differentiation in the presence of Biovance membrane[2]

- Pro-inflammatory M1 macrophage cytokine signaling was suppressed (IL-12, IL1-α, IL-1β, TNF-α)
- Anti-inflammatory M2 gene expression was increased
- Monocyte release was modulated in a manner consistent with promoting vascular remodeling and tissue healing

Features and Benefits

- In a 2015 case series, Biovance membrane showed improved clinical outcomes (American Orthopedic Foot and Ankle Society Score) over tendon repairs[3]
- Animal models have shown that the Biovance membrane reduces adhesions over tendon repair[4*]
- Biovance membrane is designed for ease of use in both surgical and nonsurgical settings. It requires no preparation, can be applied in any orientation, conforms easily to irregular surfaces, and requires no sutures

Maximum Convenience

- 10 year shelf-life ensures product is readily available
- Room temperature storage; no refrigeration necessary

*Animal results are not necessarily indicative of human clinical outcomes.

Easy Application

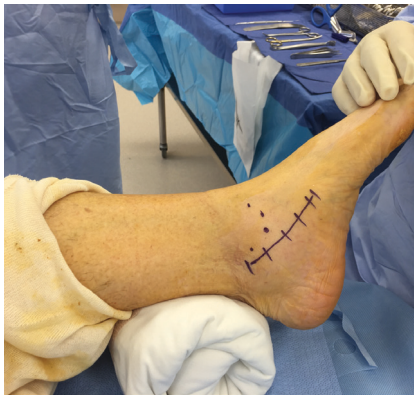
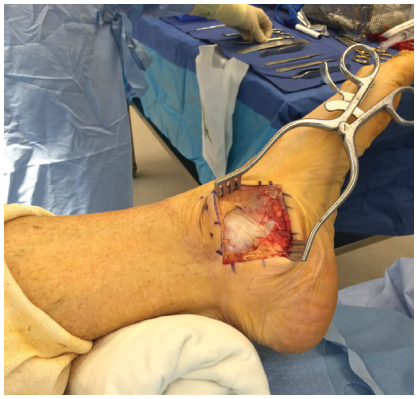
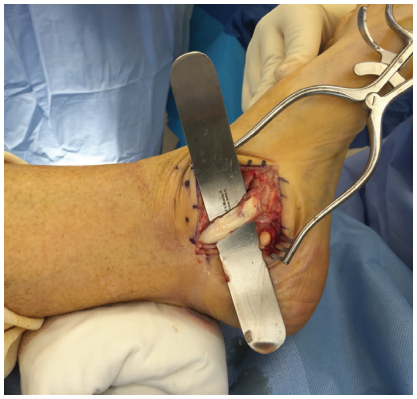
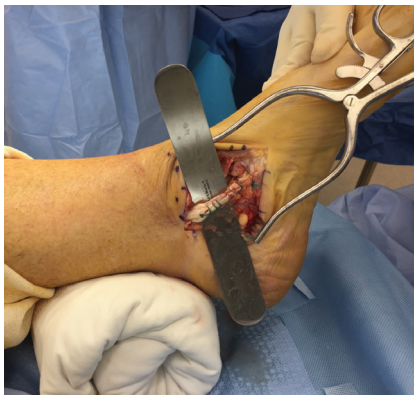
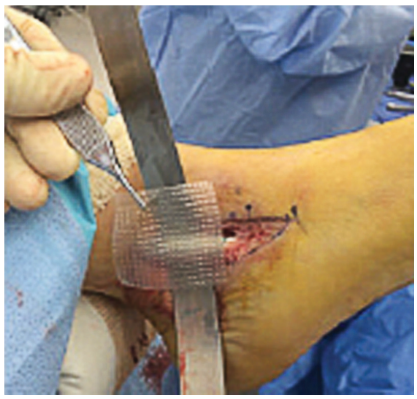
- Remove from the package and use sterile atraumatic forceps to remove Biovance® dermal matrix from its inner peel-pouch
- Apply Biovance dermal matrix over the defect. No specific orientation is required
- Adheres well without sutures

Please see accompanying package insert for full instructions.

Minimal Application Time

- **No Preparation:** No thawing, rinsing, or soaking required
- **Flexible Matrix:** Easily conforms to the surface, resulting in no additional bulk to site
- **No Orientation:** Biovance amniotic matrix can be applied with either side facing the tissue
- **Adheres Without Sutures:** Alternatively, Biovance amniotic matrix can be sutured, taped, stapled, or glued, as determined by the surgeon

Application of Biovance Membrane During Tendon Repair

Ordering Information

Product Description	Item Number
Biovance® Amniotic Membrane, 1 cm × 2 cm	**DHAM0012**
Biovance Amniotic Membrane, 2 cm × 2 cm	**DHAM0022**
Biovance Amniotic Membrane, 2 cm × 3 cm	**DHAM0023**
Biovance Amniotic Membrane, 2 cm × 4 cm	**DHAM0024**
Biovance Amniotic Membrane, 3 cm × 3.5 cm	**DHAM0035**
Biovance Amniotic Membrane, 4 cm × 4 cm	**DHAM0044**
Biovance Amniotic Membrane, 5 cm × 5 cm	**DHAM0055**
Biovance Amniotic Membrane, 6 cm × 6 cm	**DHAM0066**

Products advertised in this brochure / surgical technique guide may not be available in all countries. For information on availability, please contact Arthrex Customer Service or your local Arthrex representative.
For product information, product complaints, or adverse reaction reporting, call (844)-963-2273.

References

1. Bhatia M, Pereira M, Rana H, Stout B, Lewis C, Abramson S. The mechanism of cell interaction and response on decellularized human amniotic membrane: implications in wound healing. *Wounds*. 2007;19(8):207-217.
2. Djuretic I, Gleason J, Guo X, et al. Decellularized and dehydrated human amniotic membrane (DDHAM) in wound management: modulation of macrophage differentiation and activation. *Wound Repair Regen*. 2015;23(2):A19.
3. Mulhern J, Protzman N, Brigido S. The use of decellularized, dehydrated human amniotic membrane in tendon repair: a case series. Poster presented at: American College of Foot and Ankle Surgeons Annual Meeting; February 19-22, 2015; Phoenix, AZ.
4. Yang JJ, Jang EC, Song KS, Lee JS, Kim MK, Chang SH. The effect of amniotic membrane transplantation on tendon healing in a rabbit Achilles tendon model. *Tissue Eng Regen Med*. 2010;7(3):323-329.

Contraindications, Warnings, and Precautions

- Biovance Amniotic Membrane is contraindicated in patients with a known hyper-sensitivity to Biovance Amniotic Membrane. If a patient has an adverse reaction related to the use of Biovance Amniotic Membrane, immediately discontinue its use. Biovance Amniotic Membrane 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 Amniotic Membrane must be used prior to the expiration date on the product pouch. Biovance Amniotic Membrane should not be used together with a collagenase product on the wound.

celularity®

Biovance is a registered trademark of Celularity Inc.
Biovance is manufactured for Arthrex by Celularity Inc., 170 Park Avenue, Florham Park, NJ 07932

Please refer to package insert for complete product information.

This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Arthrex products. As part of this professional usage, the medical professional must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professional should rely on their own training and experience and should conduct a thorough review of pertinent medical literature and the product's directions for use. Postoperative management is patient-specific and dependent on the treating professional's assessment. Individual results will vary and not all patients will experience the same postoperative activity level or outcomes.

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