

# **Axolotl Biologix**

Creating products that improve health and quality of life.

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## **Axolotl DualGraft**

An amniotic wound covering and structural barrier

## Product Overview:

**Axolotl DualGraft™** is a bi-layered dehydrated human amnion membrane allograft (dhAM) derived from the amniotic lining of the placenta. **Axolotl DualGraft™** is indicated as a wound covering and structural barrier. **Axolotl DualGraft™** simplifies the application process by positioning the epithelial surfaces facing outwards, eliminating application placement limitations.

**Axolotl DualGraft™** is marketed under Section 361 of the PHS act and regulated under 21 CFR Part 1271. The amniotic components used in **Axolotl DualGraft™** create a natural 3-D extracellular matrix to act as a structural barrier and wound covering. **Axolotl DualGraft™** is processed through minimally manipulated techniques, retaining the native qualities of the amniotic membrane.

Proteins found in **Axolotl DualGraft™** include:

- Collagen I, III, IV, V and VII
- Fibronectin
- Laminin

The donor tissue is recovered and processed under sterile conditions, in accordance with all FDA guidelines and quality assurance standards in a controlled environment. **Axolotl DualGraft™** allograft tissue products are terminally irradiated in the final package. **Axolotl DualGraft™** is only intended for use in the domestic United States.

1. Rocha, S. C. M., & Baptista, C. J. M. (2015). Biochemical properties of amniotic membrane. In *Amniotic Membrane* (pp. 19-40). Springer, Dordrecht.  
2. Lintzeris, D., Yarrow, K., Johnson, L., White, A., Hampton, A., Strickland, A., ... & Cook, A. (2015). Use of a Dehydrated Amniotic Membrane Allograft on Lower Extremity Ulcers in Patients with Challenging Wounds: A Retrospective Case Series. *Ostomy/wound management*, 61(10), 30-36.

**Axolotl DualGraft™** is a dual layer amniotic membrane that can be used as a barrier based patch or as a wound covering. Clinicians have used the Axolotl DualGraft™ in a variety of cases and scientific literature supports the use of amniotic tissues for reduction of inflammation and promotion of soft tissue healing.

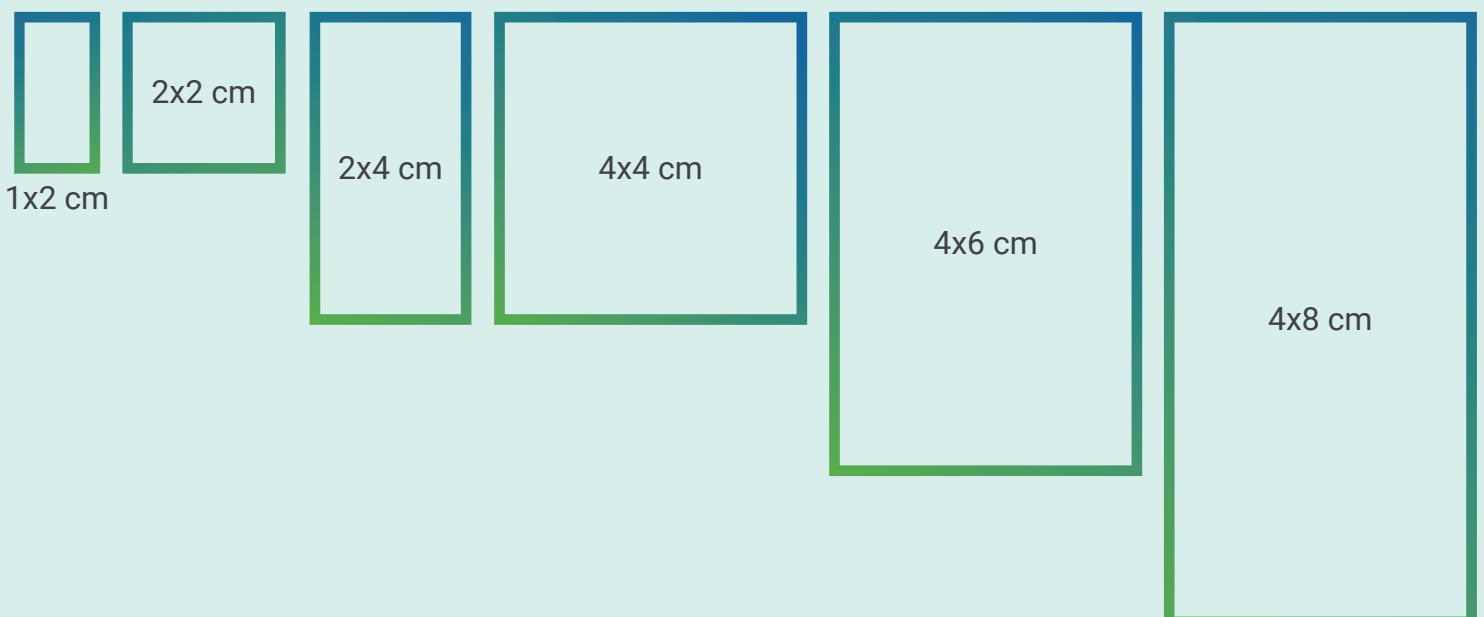
## Features & Benefits

- Simple: No suturing is required
- Versatile: Available in multiple sizes
- Easy to Use: Membrane is orientation neutral
- Chorion-Free: Preferred in Orthopedics

## Storage & Handling

- Axolotl DualGraft™ can be stored at ambient room temperatures
- Has a 5 year shelf life
- Comes in a variety of sizes
- Package includes an allograft tracking record, patient labels for clinical use, and an Instruction for Use
- Axolotl DualGraft™ is a sterilized single use structural membrane

## Sizing



## Instruction for Use



1 Open carton containing the product and remove the outer tray using aseptic technique. The outer tray is not sterile and should not be placed directly onto the sterile field. The package includes product tray, IFU, chart labels and allograft tracking record.



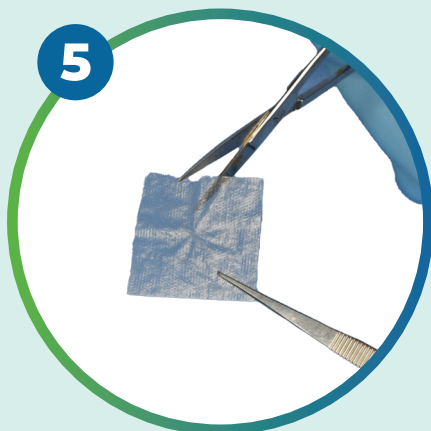
2 Peel open the outer tray, and remove the inner tray, using aseptic technique. The inner tray is sterile and may be placed onto the sterile field.



3 Open the inner tray, using aseptic technique and aseptically remove the pouch containing the Axolotl Biologix DualGraft.



4 Using sterile scissors, cut open the package. Always use sterile gloves or sterile forceps when handling the Amniotic Membrane.



5 If needed, the clinician may cut the membrane with sterile scissors to fit their size needs for their procedure.

## Overview

**Axolotl DualGraft™** is a human amniotic allograft that is processed using minimally-manipulated techniques. These techniques preserve the natural extracellular membrane characteristic serving as an ideal structural barrier.

## Structural Qualities Preserved

**Axolotl DualGraft™** is an allograft that contains hyaluronic acid, Collagen I, III, V & IV, laminin, fibronectin and varying proteoglycans. This protein rich membrane offers a low risk of immunogenicity. Additionally it offers optimal mechanical properties mimicking the native tissues including elasticity, flexibility, stability and permeability.



Available Sizes	Product Code	Product Identifier
1x2	ADG12	50038-072630
2x2	ADG22	50038-072607
2x4	ADG24	50038-072608
4x4	ADG44	50038-072609
4x6	ADG46	50038-072610
4x8	ADG48	50038-072611



## Product Summary

- Physical covering protects the tissue in vivo
- Easy to apply
- Simple, sutureless allograft placement
- Amniotic membrane has low risk of immunogenicity
- Applications for wound covering and structural barrier
- Stored at ambient temperature

## Donor Screening

Quality systems and validated processes ensures patient safety from the initial donor consultation to the surgeon's transplantation of Axolotl Dualgraft™.

- Comprehensive medical and social histories are thoroughly reviewed by trained, qualified personnel on every donor.
- All donations are reviewed for eligibility by donor and processor Medical Director.
- Donor acceptance criteria follows FDA regulations and American Association Tissue Banking (AATB) guidelines

## Safety Testing

Communicable disease testing was performed by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens in accordance with Clinical Laboratory Improvement Amendments (CLIA) and 42 CFR Part 493, or that has equivalent requirements as determined by the Centers for Medicare and Medicaid Services. Names and addresses of testing laboratories, interpretation of all required infectious disease tests, and a listing of the documents reviewed as part of the relevant medical records are kept on file at the processing facility and are available to the end-user upon request, except as prohibited by law. Donor blood samples taken prior to or at the time of recovery were tested and found negative/nonreactive using FDA licensed tests for, at minimum:

- HBsAg: Hepatitis B Surface Antigen
- HBcAb: Hepatitis B Core Antibody
- HCVAb: Hepatitis C Antibody
- HIV 1/2/Ab: Human Immunodeficiency Virus Types 1/2 and O
- HCV NAT: Hepatitis C Virus
- HIV NAT: Human Immunodeficiency Virus
- HBV NAT: Hepatitis B Virus
- RPR/STS or Equivalent: Syphilis
- HTLV I/II: Human T-Cell Lymphotropic Virus
- WNV: West Nile

## Regulatory

**Axolotl DualGraft™** line of reimbursement-eligible human allograft is regulated by the FDA Center for Biologics Evaluation and Research (CBER) which regulates HCT/Ps under 21 CFR Parts 1270 and 21 CFR Part 1271 and Section 361 of the Public Health Service Act; accordingly, all of our allograft meet the definitions of "minimally manipulated" and "homologous use" requirements.

1. Fénelon, M.; Catros, S.; Meyer, C.; Fricain, J.-C.; Obert, L.; Auber, F.; Louvrier, A.; Gindraux, F. Applications of Human Amniotic Membrane for Tissue Engineering. *Membranes* 2021, 11, 387. <https://doi.org/10.3390/membranes11060387>
2. Dadkhah Tehrani F, Firouzeh A, Shabani I and Shabani A (2021) A Review on Modifications of Amniotic Membrane for Biomedical Applications. *Front. Bioeng. Biotechnol.* 8:606982. doi: 10.3389/fbioe.2020.606982
3. Agathe Grémare, Sarah Jean-Gilles, Pauline Musqui, Laure Magnan, Yoann Torres, Mathilde Fénelon, Stéphanie Brun, Jean-Christophe Fricain, Nicolas L'Heureux, Cartography of the mechanical properties of the human amniotic membrane, *Journal of the Mechanical Behavior of Biomedical Materials*, Volume 99, 2019, Pages 18-26, ISSN 1751-6161, <https://doi.org/10.1016/j.jmbm.2019.07.007>.
4. Rocha, S. C. M., & Baptista, C. J. M. (2015). Biochemical properties of amniotic membrane. In *Amniotic Membrane* (pp. 19-40). Springer, Dordrecht.
5. Lintzeris, D., Yarrow, K., Johnson, L., White, A., Hampton, A., Strickland, A., ... & Cook, A. (2015). Use of a Dehydrated Amniotic Membrane Allograft on Lower Extremity Ulcers in Patients with Challenging Wounds: A Retrospective Case Series. *Ostomy/wound management*, 61(10), 30-36

