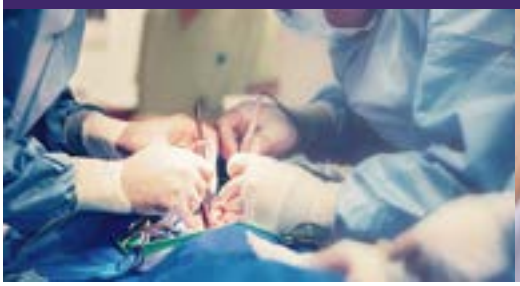
CELLUTION BIOLOGICS

Cellution Biologics

AmchoPlast Information Packet

AmchoPlast™

Cellution Biologics Corporate Information



Leading Biomedical Innovations With Cutting-Edge Human Tissue Based Products.

Ordering Process

Email: orders@cellutionbiologics.com
Phone: 888-575-7357

Corporate Information

Tax ID Number: 93-4096118

Payment

Payment Terms can be found on the website at https://www.cellutionbiologics.com/termsconditions.

CELLUTION BIOLOGICS

4000 Northfield Way, Suite 400
Roswell, GA 30076
888-575-7357
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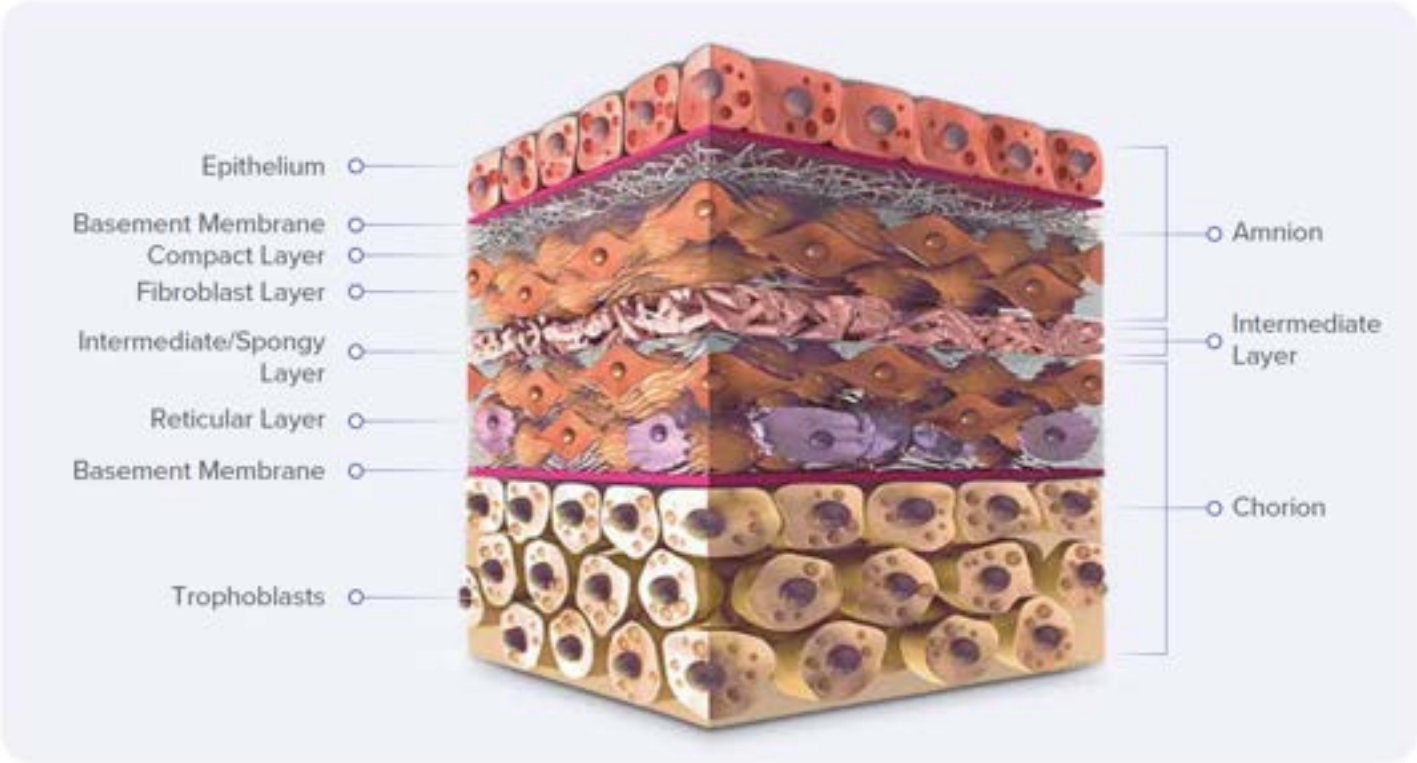
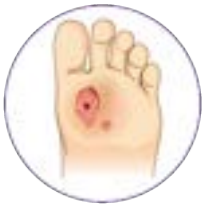
AmchoPlast™

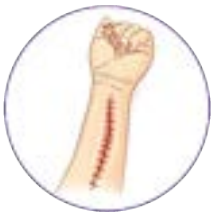
AmchoPlast is a natural biological wound cover made from human placental tissue donated during healthy delivery. Using our proprietary AGNES process, we dehydrate and sterilize this product while retaining all the structural properties of the placental tissue along with its key growth factors to provide a protective matrix for the wound.





Chronic Wounds

Diabetic Foot Ulcers
Pressure Ulcers
Venous Ulcers



Surgical Reconstruction

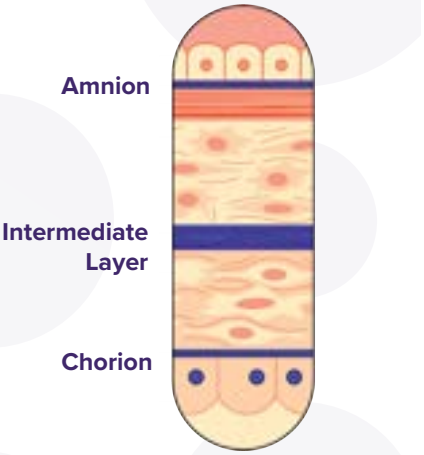
Surgical Wounds
Soft Tissue Reconstruction
Donor Sites

Traumatic Wounds

First & Second Degree Burns
Lacerations
Cuts, Abrasions

AmchoPlast™

Sterile dehydrated Human Amnion - Intermediate Layer - Chorion Membrane Allograft dHAICM



AmchoPlast is a cutting-edge, sterile, minimally manipulated, dehydrated allograft designed to support homologous use in clinical applications. It is meticulously derived from human placental membranes, specifically the amnion, intermediate layer, and chorion, obtained from healthy, consenting donors. The allograft incorporates a basement membrane and a stromal matrix collagen layer, providing structural integrity and biological compatibility for therapeutic purposes.

Procurement and Donor Screening

The placental tissues used in AmchoPlast are procured under stringent aseptic conditions to ensure the highest level of safety and quality. Informed consent is obtained from donors after a thorough review of their health history. Each donor undergoes extensive screening for a broad spectrum of infectious diseases (as detailed in Table 1), minimizing the risk of pathogen transmission to recipients.

Beyond standard laboratory testing, donors are also subjected to a comprehensive physical examination by qualified medical professionals to identify any signs or symptoms of undetected illnesses. This dual-layer screening process ensures that only tissues from donors meeting the most rigorous eligibility criteria are selected for processing.

Manufacturing Excellence

AmchoPlast is produced following strict guidelines to maintain the sterility and integrity of the tissues. The manufacturing process involves careful dehydration, a method that preserves the biological properties of the placental membranes while enhancing their shelf life and handling convenience. By minimizing manipulation, the process retains the inherent structural and biochemical properties of the tissue, ensuring its efficacy in homologous applications.

Clinical Applications and Benefits

The unique composition of AmchoPlast, which includes a basement membrane and stromal matrix collagen, supports a variety of clinical applications. It provides an optimal scaffold for tissue regeneration and repair, promoting wound healing and cellular integration. Its biocompatible properties make it ideal for use in managing acute and chronic wounds, surgical procedures, and other tissue repair scenarios.

AmchoPlast represents a significant advancement in regenerative medicine, offering a reliable and safe solution for clinicians seeking effective tools to enhance patient outcomes.

Manufacturing Excellence

CELLUTION BIOLOGICS

AMCHOPLAST: AMNION-INTERMEDIATE LAYER-CHORION MEMBRANE ALLOGRAFT

Amnion, intermediate layer, chorion membranes are procured from healthy donors under aseptic conditions with necessary informed consent and health history of the donor. Donors are screened for various infectious diseases (Table 1), to minimize risk to patients. In addition, donors are physically examined by the physicians for signs and symptoms of any untested illness.

AmchoPlast is a sterile minimally manipulated, dehydrated, human amnion, chorion membrane allograft intended for homologous use. The allograft is derived from human placental membrane collected from consenting donors. It consists of a basement membrane and stromal matrix collagen layer.

Only tissues from donors meeting the prescribed criteria are processed for manufacturing of **AmchoPlast**.

TABLE 1: Infectious disease screened in blood specimens of donor

HIV - I & II (Antibody)	HIV - I & HCV (NAT)	Anti HTLV - I & Anti HTLV - II
Anti - HBC	Anti - HCV	CMV - IgM & CMV - IgG
HBsAg	Syphilis	Malaria

APPLICATIONS FOR USE OF AMCHOPLAST

AmchoPlast can be used for non-infected, acute & chronic wounds that occur due to conditions such as:

- **Diabetes**[1]
- **Peripheral vascular arterial disease**[2]
- **Chronic venous insufficiency post traumatic wounds**[3]
- **Burns**[4]
- **Post-operative wounds.**[5, 6]

USAGE GUIDELINES

- The wound site should be assessed and prepared for wound debridement
- The site bed should be cleared of all necrotic tissue and cleared of possible infections.

References

1. Lakmal, K., Basnayake, O., & Hettiarachchi, D. (2021, February 15). Systematic review on the rational use of amniotic membrane allografts in diabetic foot ulcer treatment. BMC Surgery. https://doi.org/10.1186/s12893-021-01084-8
2. Horváth, V., Svobodová, A., Cabral, J. V., Štádler, P., Lindner, J., Mrstinova, M. B., Balogh, L., & Jirsová, K. (2023, November 9). Cryopreserved amniotic membrane in chronic nonhealing wounds: a series of case reports. Cell and Tissue Banking. https://doi.org/10.1007/s10561-023-10100-5
3. Barr, S. M. (2014, December 1). Dehydrated Amniotic Membrane Allograft for Treatment of Chronic Leg Ulcers in Patients With Multiple Comorbidities: A Case Series. Journal of the American College of Clinical Wound Specialists. https://doi.org/10.1016/j.jccw.2016.01.002
4. Yang, C., Xiong, A. B., He, X. C., Ding, X. B., Tian, X., Li, Y., & Yan, H. (2020, December 7). Efficacy and feasibility of amniotic membrane for the treatment of burn wounds: A meta-analysis. Journal of Trauma and Acute Care Surgery. https://doi.org/10.1097/ta.0000000000003050
5. Rezazadeh, D., Aliabad, R. A., & Norooznezhad, A. H. (2020, April 1). Autologous amniotic membrane: An accelerator of wound healing for prevention of surgical site infections following Cesarean delivery. Medical Hypotheses. https://doi.org/10.1016/j.mehy.2019.109532
6. Rahavian, A., Hazrati, E., Azar, D. A., Allameh, F., Hojjati, S. A., Javanmard, B., & Hamidi, R. (2021, May 25). Using Dry Human Amniotic Membranein Secondary Intention Wound Healing After Urological Cancer Surgery: The First Randomized Clinical Trial in Iran. International Journal of Cancer Management. https://doi.org/10.5812/ijcm.111421

Q-4316

Available in Sizes:

14mm disc
18mm disc
2x2cm
2x3cm
2x4cm
2x6cm
3x3cm
3x5cm
4x4cm
4x6cm
4x7cm
4x8cm
5x5cm
6x8cm
6x12cm
7x7cm
10x10cm
10x20cm
20x20cm

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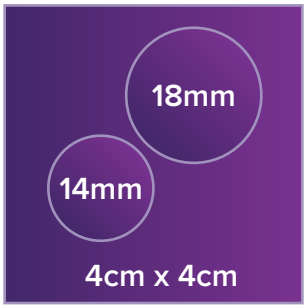
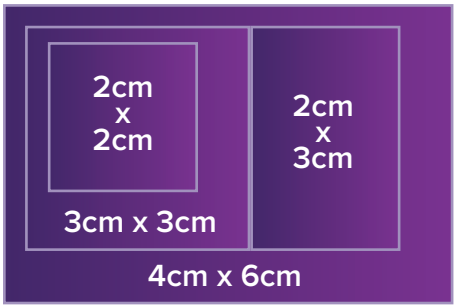
AmchoPlast™

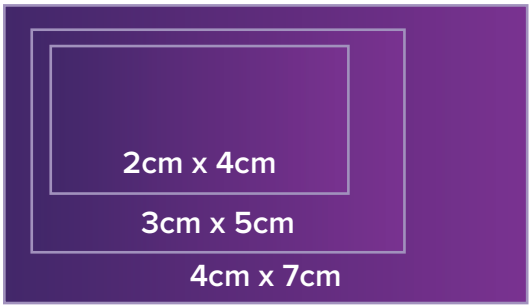
Q-4316

Product Size Guide

SKU	Dimension	Description	Area SQ CM
ACM0014	14mm disc	AmchoPlast (14mm disc) Sterile dehydrated human amnion chorion membrane allograft	1.54
ACM0018	18mm disc	AmchoPlast (18mm disc) Sterile dehydrated human amnion chorion membrane allograft	2.54
ACM0202	2cm x 2cm	AmchoPlast (2cm x 2cm) Sterile dehydrated human amnion chorion membrane allograft	4
ACM0203	2cm x 3cm	AmchoPlast (2cm x 3cm) Sterile dehydrated human amnion chorion membrane allograft	6
ACM0204	2cm x 4cm	AmchoPlast (2cm x 4cm) Sterile dehydrated human amnion chorion membrane allograft	8
ACM0303	3cm x 3cm	AmchoPlast (3cm x 3cm) Sterile dehydrated human amnion chorion membrane allograft	9
ACM0305	3cm x 5cm	AmchoPlast (3cm x 5cm) Sterile dehydrated human amnion chorion membrane allograft	15
ACM0404	4cm x 4cm	AmchoPlast (4cm x 4cm) Sterile dehydrated human amnion chorion membrane allograft	16
ACM0406	4cm x 6cm	AmchoPlast (4cm x 6cm) Sterile dehydrated human amnion chorion membrane allograft	24
ACM0407	4cm x 7cm	AmchoPlast (4cm x 7cm) Sterile dehydrated human amnion chorion membrane allograft	28
ACM0408	4cm x 8cm	AmchoPlast (4cm x 8cm) Sterile dehydrated human amnion chorion membrane allograft	32
ACM0505	5cm x 5cm	AmchoPlast (5cm x 5cm) Sterile dehydrated human amnion chorion membrane allograft	25
ACM0608	6cm x 8cm	AmchoPlast (6cm x 8cm) Sterile dehydrated human amnion chorion membrane allograft	48
ACM0612	6cm x 12cm	AmchoPlast (6cm x 12cm) Sterile dehydrated human amnion chorion membrane allograft	72
ACM0707	7cm x 7 cm	AmchoPlast (7cm x 7cm) Sterile dehydrated human amnion chorion membrane allograft	49
ACM1010	10cm x 10cm	AmchoPlast (10cm x 10cm) Sterile dehydrated human amnion chorion membrane allograft	100
ACM1020	10cm x 20cm	AmchoPlast (10cm x 20cm) Sterile dehydrated human amnion chorion membrane allograft	200
ACM2020	20cm x 20cm	AmchoPlast (20cm x 20cm) Sterile dehydrated human amnion chorion membrane allograft	400

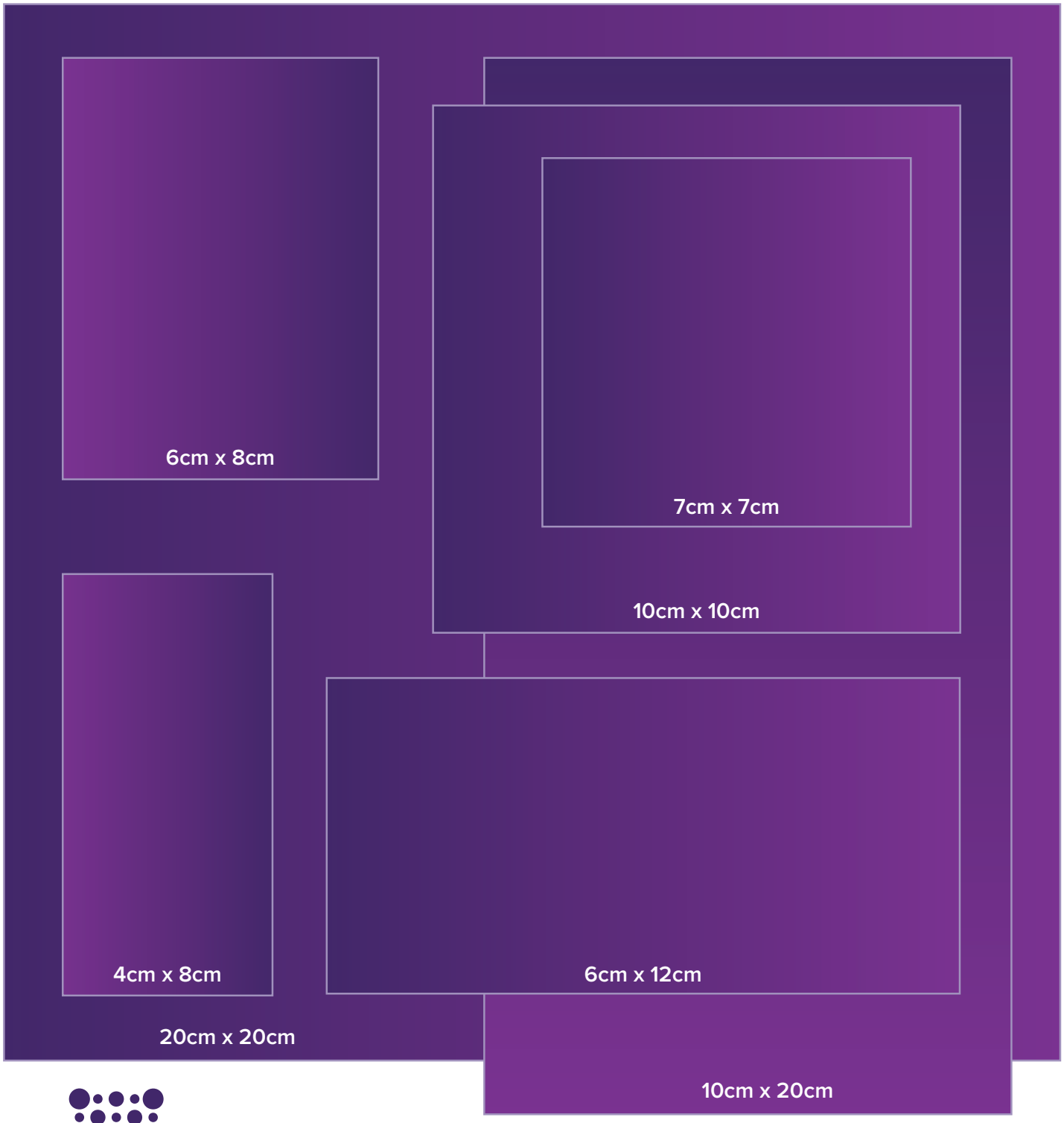






AmchoPlast™

Size Guide Continued



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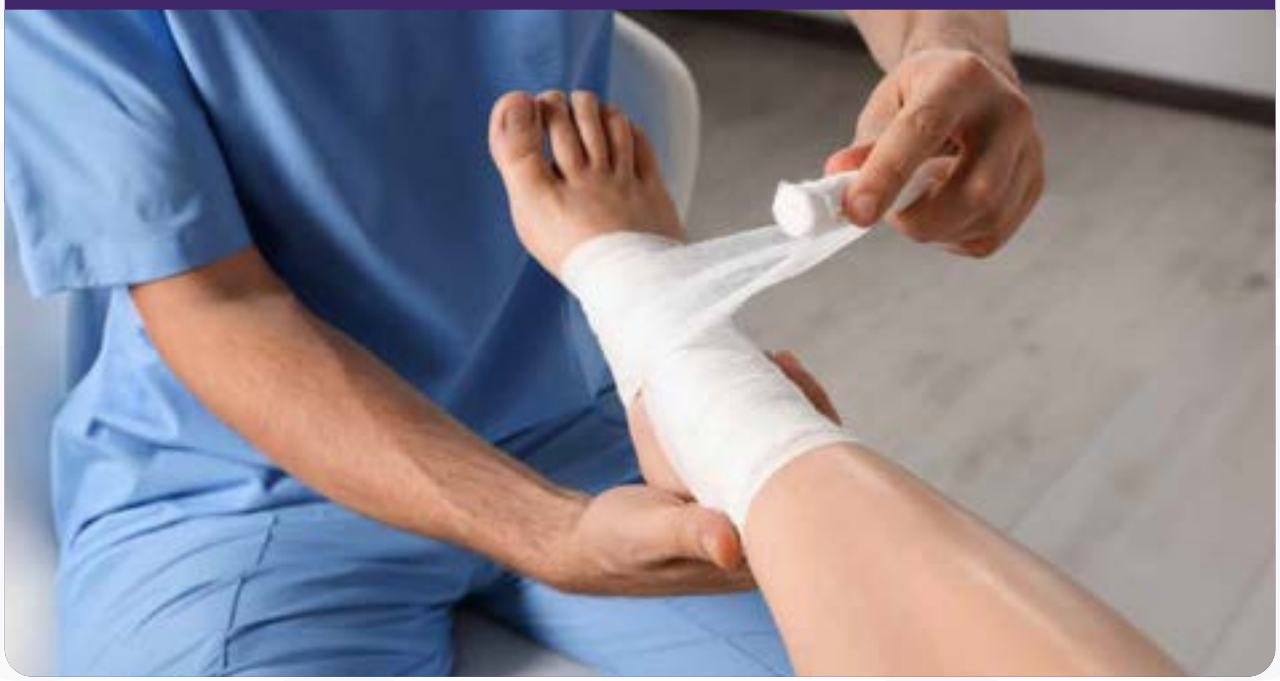
AmchoPlast™

Sterile dehydrated Human
Amnion - Intermediate Layer - Chorion
Membrane Allograft
dHAICM

CLINICAL REVIEW AND CASE STUDIES



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AmchoPlast™

AmchoPlast is a sterile, minimally manipulated, dehydrated human amnion, intermediate layer, and chorion membrane allograft derived from the human placental tissues of consenting donors. This dehydrated allograft is processed aseptically and gamma sterilized.

ADVANTAGES OF AMCHOPLAST

1. Easy to use
2. Simple, single-step rehydration
3. Optimized sizes for different needs
4. Easy determination of orientation
5. Compatible with Compression Therapy, Negative Pressure Wound Therapy (NPWT), and Hyperbaric Oxygen Therapy (HBOT)
6. Terminally sterilized
7. Produced using AGNES proprietary processing method that preserves the structural integrity of the ECM and the quality of growth factors found in native placental tissue.
8. Long shelf life of 3 years
9. Can be stored at room temperature for off-the-shelf convenience

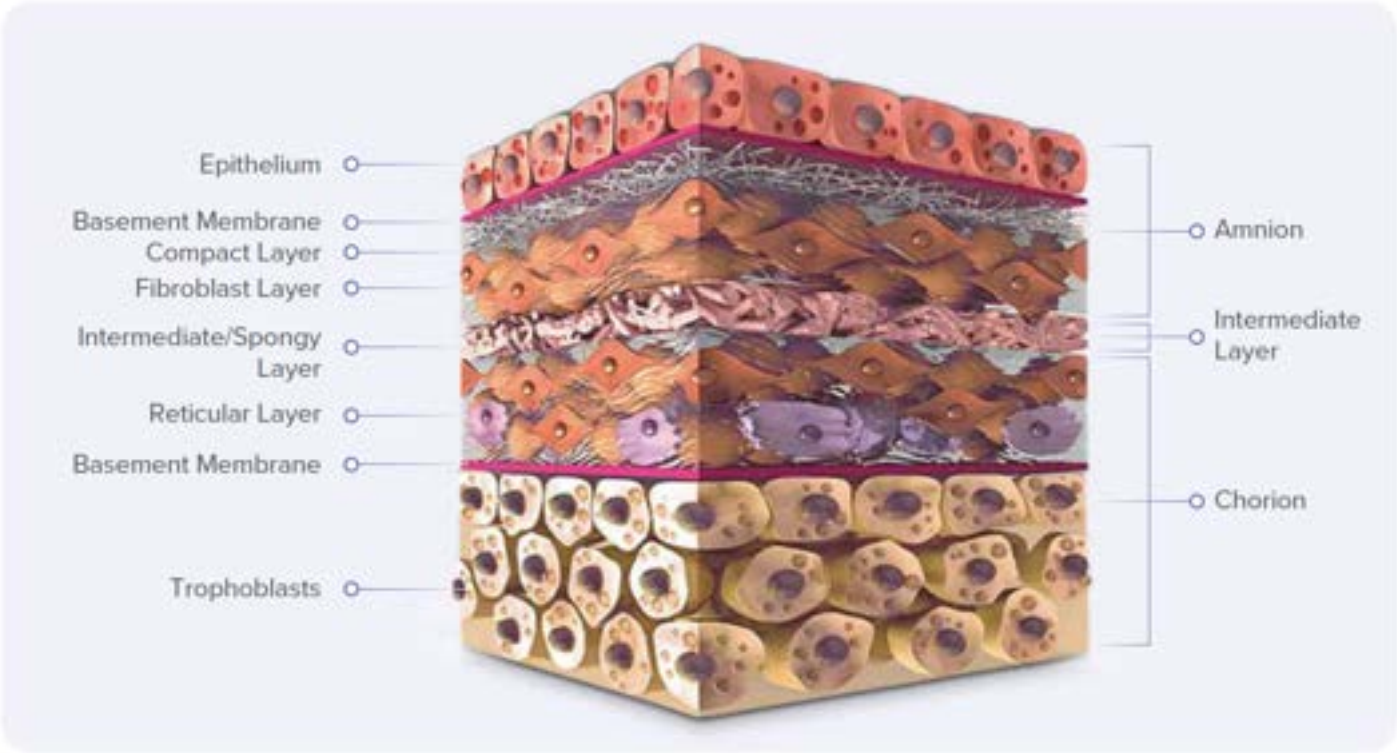
KNOWN PRESENCE OF GROWTH FACTORS & CYTOKINES IN THE EXTRACELLULAR MATRIX OF HUMAN PLACENTAL TISSUE AND THEIR FUNCTIONS:

Growth Factors and Cytokines	Native Function	AmchoPlast
IL-1ra, IL-4, IL-6, IL-10	Anti-Inflammatory	✔
VEGF	Angiogenic	✔
bFGF		✔
TGF-Beta		✔
PDGF		✔
EGF		✔
IGF-1	Cell Proliferation and Remodeling	✔
KGF		✔
MIP	Anti-Bacterial	✔

AGNES PROCESSING TECHNOLOGY

The proprietary AGNES Processing Technology retains the spongy layer along with the amnion and chorion layers and preserves the inherent biological components of native placental tissue.

- Structural components: collagen I, III, IV; elastin
- Cell-binding domains: fibronectin, collagen V, VII; hyaluronic acid
- ECM binding domains: proteoglycans, laminin
- 300+ regulatory proteins



CLINICAL USES

CASE STUDIES

EXPLORE THE EFFICACY OF AmchoPlast THROUGH THE FOLLOWING CASE STUDIES:

DIABETIC FOOT ULCER:

INTRODUCTION:

Poorly controlled diabetes mellitus often leads to diabetic foot ulcers, a prevalent complication resulting from factors such as inadequate glycemic control, neuropathy, peripheral vascular disease, or insufficient foot care. These ulcers frequently cause osteomyelitis and lower extremity amputations, typically occurring in areas of the foot subject to repetitive trauma and pressure. Staphylococcus commonly infects these ulcers, which tend to be chronic.

An interprofessional approach involving podiatrists, endocrinologists, primary care physicians, vascular surgeons, and infectious disease specialists yields the best outcomes. This scenario is commonly encountered in both outpatient and inpatient settings.

Diabetic foot ulcers are a leading cause of hospital admissions among diabetic complications and contribute significantly to non-traumatic amputations in the US. Approximately 5% of patients with diabetes mellitus develop foot ulcers, with 1% ultimately requiring amputation.

Successfully treating these ulcers demands a careful and innovative approach to wound care. Amid the urgency of addressing these complex wounds, amniotic membrane therapy stands out as a promising solution, utilizing regenerative properties to improve healing in diabetic foot ulcers (DFUs). This brief study delves into the effectiveness of amniotic membrane therapy on DFUs, providing a comprehensive evaluation of its efficacy. Through detailed case analyses, this study aims to significantly contribute to the discussion on advanced interventions for treating diabetic foot ulcers, emphasizing the need for deeper insights to enhance patient outcomes.

DIABETIC FOOT ULCER (CONTINUED):

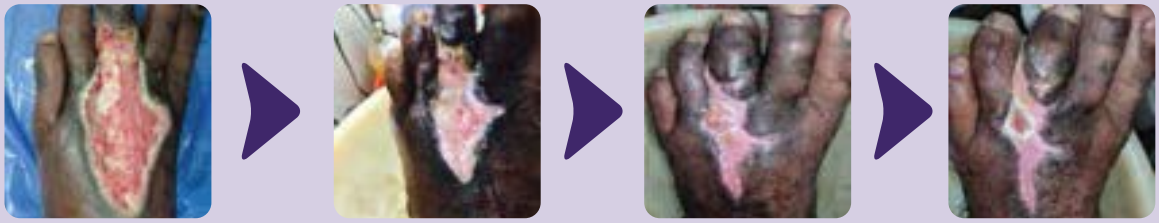
STUDY DESIGN:
This research comprised a case series including four patients diagnosed with DFUs, who underwent treatment with dehydrated human amnion, intermediate layer, chorion membrane (dHAICM) allograft. The treatment regimen consisted of debridement followed by routine wound irrigation and application of dHAICM every five days. Each application was then carefully secured with a suitable moisture-retaining dressing to ensure the allograft remained in place and effective.

CASE REPORTS: ULCERS ON DORSAL SURFACE

CASE STUDY 1:

Patient History, Diagnosis & Initial Treatment: A 62-year-old man with diabetes mellitus presented to the clinic with a chronic, non-healing diabetic foot ulcer (7.5 cm x 5 cm in size) on the dorsal side of the left foot which persisted for 9 weeks. A nail prick caused the wound in between the third and the fourth toe. He reported increasing pain, redness and discharge despite treatment with conventional wound care measures, including regular dressing changes, offloading, and antibiotic therapy for 4 weeks.

Wound Treatment with dHAICM: dHAICM was applied on the patient every 5 days till complete closure of the ulcer was achieved. A total of 8 dHAICM's were applied. 1st and 2nd applications were 7cm x 4cm in size, 3rd and 4th applications were 6cm x 4cm in size, 5th and 6th applications were 3cm x 3cm in size, 7th and 8th applications were 2cm x 2cm in size. Pain, redness and discharge reportedly diminished. No complications were reported.



CASE STUDY 2:

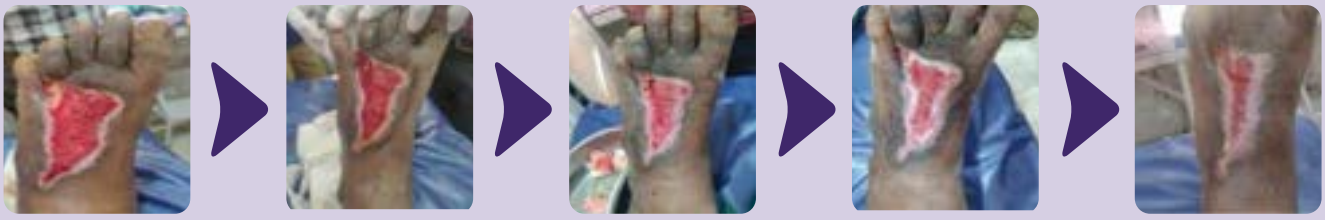
Patient History, Diagnosis & Initial Treatment: A 52-year-old man with diabetes mellitus presented to the clinic with a chronic, non-healing diabetic foot ulcer (8cm x 7cm in size) on the dorsal side of the right foot which initially resulted from farming related injury, and persisted for the past 10 weeks. He reported increasing pain, redness and discharge despite treatment with conventional wound care measures, including regular dressing changes, offloading, and antibiotic therapy for 6 weeks.

Wound Treatment with dHAICM: dHAICM was applied on the patient every 5 days till complete closure of the ulcer was achieved. A total of 8 dHAICM's were applied, 1st and 2nd applications were 7cm x 7cm in size, 3rd and 4th were 5cm x 5cm in size, 5th and 6th were 3cm x 3cm in size, 7th and 8th were 2cm x 2cm in size. Pain, redness and discharge reportedly diminished. No complications were reported.

CASE STUDY 3:

Patient History, Diagnosis & Initial Treatment: A 58-year-old male presented to the clinic with a non-healing ulcer (7.5cm x 5cm in size) on the dorsal aspect of the left foot. The patient had a history of diabetes mellitus and varicose veins. He reported increasing pain, redness and discharge despite treatment with conventional wound care measures, including regular dressing changes, offloading, and antibiotic therapy for 4 weeks.

Wound Treatment with dHAICM: He received an application of dHAICM every 7 days till complete closure of the ulcer was achieved. A total of 8 dHAICM's were applied, 1st application was 7.5cm x 5cm in size, 2nd application was 7cm x 5cm in size, 3rd and 4th application was 6cm x 4.5cm in size, 5th and 6th application were 4.5cm x 2.5cm in size, 7th application was of 4cm x 2cm in size, 8th was of 4cm x 2cm in size. Pain, redness and discharge reportedly diminished. No complications were reported.



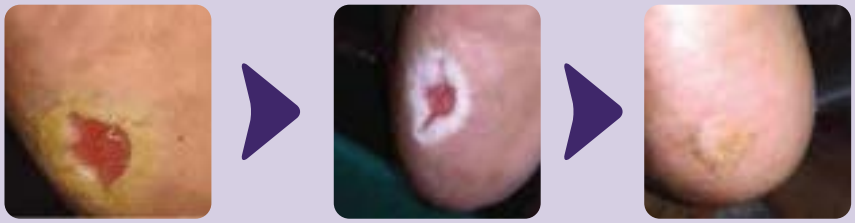
ULCERS ON PLANTAR SURFACE

INTRODUCTION:
Diabetic foot ulcers on the weight-bearing sole (plantar region) present unique challenges compared to those on the non-weight-bearing surface (dorsal region). Constant pressure and mechanical stress during walking delay healing, compounded by reduced blood flow in the plantar area. These factors create a challenging microenvironment, hindering optimal wound healing.

CASE STUDY 1:

Patient History, Diagnosis & Initial Treatment: A 54-year-old woman with type 1 diabetes mellitus presented to the clinic with a chronic, non-healing diabetic foot ulcer (2.2cm x 1.5cm in size) on the heel of the left foot which persisted for 16 weeks. She reported increasing pain, redness and discharge despite treatment with conventional wound care measures, including regular dressing changes, offloading, and antibiotic therapy.

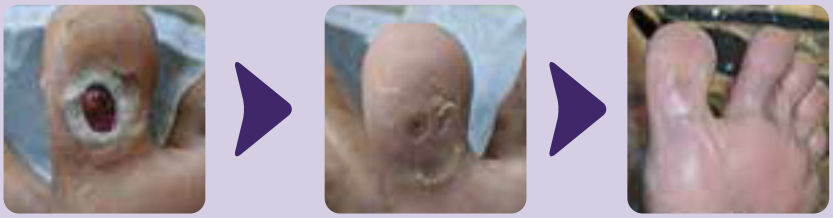
Wound Treatment with dHAICM: dHAICM was applied on the patient every 5 days till complete closure of the ulcer was achieved. A total of 5 dHAICM's of the size 2cm x 2cm were applied. Pain and redness subsided. No complications were reported.



CASE STUDY 2:

Patient History, Diagnosis & Initial Treatment: A 70-year-old man with type 1 diabetes mellitus presented to the clinic with a chronic, non-healing diabetic foot ulcer (1.5cm x 1cm in size) on the plantar surface of the hallux of left foot, which persisted for the past 16 weeks. He reported increasing pain, redness and discharge despite treatment with conventional wound care measures, including regular dressing changes, offloading, and antibiotic therapy.

Wound Treatment with dHAICM: dHAICM was applied on the patient every 5 days till complete closure of the ulcer was achieved. A total of 3 dHAICM's of the size 18mm diameter disks were applied. Pain and redness subsided. No complications were reported.



RESULTS: All wounds were observed to be completely closed one week after the final application of dHAICM. The required number of applications varied between three and eight, averaging at six applications. During the healing process, changes included decreased redness, increased formation of granulation tissue, partial re-epithelialization, and eventual complete coverage of the wound with a thin layer of fragile, pink-colored skin. Additionally, reductions in pain and discharge were observed. No adverse events or severe side effects related to dHAICM were reported, and there has been no recurrence in any patients for six months.

DISCUSSION: This case series demonstrates that incorporating dHAICM with standard of care can accelerate the closure of diabetic wounds and prevent complications. Wound closure time with dHAICM was notably shorter compared to traditional methods, particularly for wounds persisting for 9-16 weeks with no improvement before dHAICM application. dHAICM usage could reduce prolonged healing time and associated healthcare expenses. Further research through randomized controlled trials is necessary for a thorough assessment of its effectiveness compared to conventional approaches.

FASCIOTOMY FOR COMPARTMENT SYNDROME

INTRODUCTION:

Compartment syndrome, marked by elevated pressure within a closed anatomical space, poses a serious threat to tissue health and function. Fasciotomy, a surgical procedure aimed at relieving this pressure, is vital and often life-saving. However, post-fasciotomy care presents new challenges, including wound management and complications. Exploring innovative interventions is crucial in this context. Amniotic membrane therapy shows promise in addressing various aspects of wound healing, inflammation, and tissue regeneration. This case study investigates the application of amniotic membrane therapy in post-fasciotomy care, focusing on its effects on wound healing, inflammation reduction, and complication prevention. Through specific cases and outcomes, the study provides valuable insights into improving post-fasciotomy care. This exploration emphasizes the importance of advancing therapeutic approaches to enhance the quality of care and functional recovery in individuals undergoing fasciotomy for compartment syndrome.

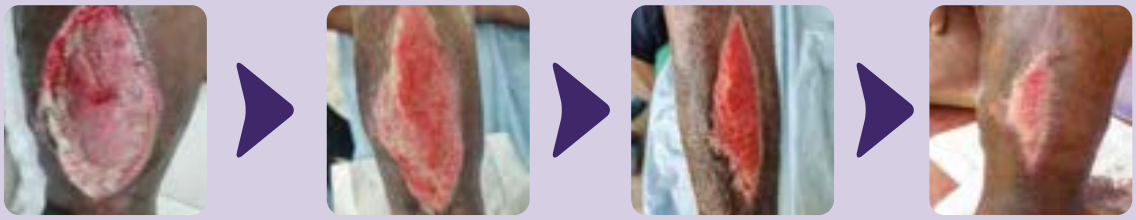
STUDY DESIGN:

In this case series, two patients underwent treatment with dehydrated human amnion, intermediate layer, chorion membrane (dHAICM) allograft after fasciotomy. The treatment plan involved meticulous debridement, routine wound irrigation, and (dHAICM) application every five days until the wounds healed. Each application was carefully secured with a suitable moisture-retaining dressing to prevent allograft displacement.

CASE STUDY 1:

Patient History, Diagnosis & Initial Treatment: A 43-year-old man presented with escalating pain, swelling and erythema in his right lower extremity, one week after undergoing fasciotomy for acute compartment syndrome. The fasciotomy site measured 8 cm x 6 cm in size.

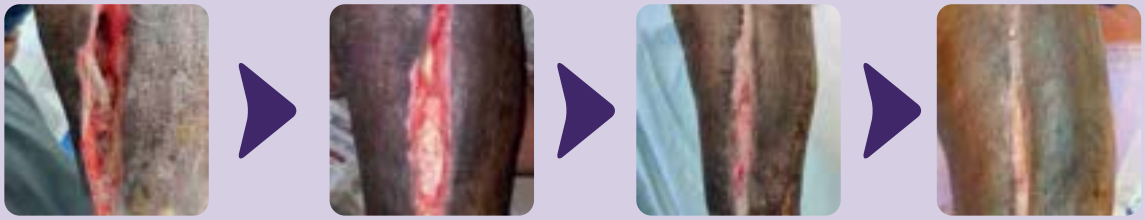
Wound Treatment with dHAICM: Surgical debridement preceded the application of dHAICM at the incision site. dHAICM was applied on the patient every 5 days. There were a total of 8 dHAICM applications, 1st and 2nd applications were 8cm x 6cm in size, 3rd and 4th were 6cm x 4cm in size, 5th and 6th were 5cm x 3cm in size, 7th and 8th were 3cm x 2cm in size. After the last application of dHAICM, complete wound closure was achieved, pain and swelling subsided. No complications were reported.



CASE STUDY 2:

Patient History, Diagnosis & Initial Treatment: A 50-year-old man presented with escalating pain, swelling and erythema in his left lower extremity, one week after undergoing fasciotomy for acute compartment syndrome, The fasciotomy site measured 8cm x 2cm in size. Incision site displayed signs of cellulitis, including local warmth, redness and swelling.

Wound Treatment with dHAICM: Surgical debridement preceded the application of dHAICM at the incision site. dHAICM was applied on the patient every 5 days. There were a total of 6 dHAICM applications. 1st and 2nd applications were 2 allografts (4cm x 2cm in size), 3rd and 4th were 2 allograft (3cm x 2cm in size), 5th and 6th were of 2 allograft (2cm x 2cm in size). After the last application of dHAICM, complete wound closure was achieved, pain and swelling subsided. No complications were reported.



RESULTS: One week after the last dHAICM application, both Case 1 and Case 2 showed complete wound closure. Case 1 resolved after eight applications, while Case 2 resolved after six applications. Both patients experienced reductions in pain and swelling. The healing process included erythema reduction, granulation tissue formation, patchy re-epithelialization, and eventual coverage by thin, pink skin. No adverse events or severe side effects related to dHAICM were reported in either case.

DISCUSSION: This case series underscores the effectiveness of amniotic membrane therapy in improving the treatment of post-fasciotomy wounds in patients with cellulitis and compartment syndrome. The regenerative properties of the amniotic membrane play a crucial role in accelerating wound healing and reducing complications. Amniotic membrane therapy demonstrates potential in addressing the intricate issues of post-fasciotomy care and serves as a valuable addition to standard treatments. Further research and clinical investigation are necessary to fully understand its scope of application and optimize its incorporation into post-surgical care protocols.

DISCUSSION:

Chronic venous ulcers are a significant burden on patients and healthcare systems, characterized by slow healing, high recurrence rates, and associated morbidity. dHAICM o ers several potential benefits in this context. This case series illustrates the e cacy of dHAICM in promoting wound healing, as evidenced by the reduction in ulcer size and improvement in healing observed over the treatment period. Moreover, the ability of dHAICM to modulate pain and reduce inflammation can significantly enhance patient comfort and quality of life. However, further research is needed to elucidate the long-term outcomes and comparative e ectiveness of dHAICM compared to standard treatments for chronic venous ulcers, such as compression therapy and wound dressings.

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CELLUTION BIOLOGICS

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10

FEI: 3031041395

Other FDA Registrations:
Blood:
Devices:
Drugs:

Reason For Last Submission: Change in Information
Last Annual Registration Year: 2025
Last Registration Receipt Date: 11/27/2024
Summary Report Print Date: 12/05/2024

Legal Name and Location:

Cellution Biologics LLC
4000 Northfield Way
4000 Northfield Way
Suite 400

Roswell, Georgia 30076
USA

Phone: 888-575-7357 **Ext.:**

Reporting Official:

Pallavi Misra, Sr. VP Corporate Quality and Regulatory
4000 Northfield Way
4000 Northfield Way
Roswell, Georgia 30076
USA
Phone: 888-575-7357 Ext.
pallavi.a@lifecell.in

Satellite Recovery Establishment: No
Parent Manufacturing Establishment FEI No.:
Testing For Micro-Organisms Only: No

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane							X	X	X			***See full text on next page.
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

FDA information collection OMB Control number: 0910-0543, expiration date: 08/31/2026

Additional Information: No additional information provided.

Proprietary Name(s):	Amniotic Membrane	AmchoMatrix (formerly ¿AmchoPlast"), TriCoreMatrix, AmCoreMatrixBurn, AmCoreMatrixWound, AmCoreMatrixSurgical

FEI: 3031041395

Legal Name: Cellution Biologics LLC

Form **W-9**
(Rev. March 2024)
Department of the Treasury
Internal Revenue Service

Request for Taxpayer Identification Number and Certification

Go to *www.irs.gov/FormW9* for instructions and the latest information.

Give form to the requester. Do not send to the IRS.

Before you begin. For guidance related to the purpose of Form W-9, see *Purpose of Form*, below.

Print or type. See ***Specific Instructions*** on page 3.

1 Name of entity/individual. An entry is required. (For a sole proprietor or disregarded entity, enter the owner's name on line 1, and enter the business/disregarded entity's name on line 2.)

CELLUTION BIOLOGICS LLC

2 Business name/disregarded entity name, if different from above.

3a Check the appropriate box for federal tax classification of the entity/individual whose name is entered on line 1. Check only **one** of the following seven boxes.

☐ Individual/sole proprietor ☐ C corporation ☐ S corporation ☐ Partnership ☐ Trust/estate

☒ LLC. Enter the tax classification (C = C corporation, S = S corporation, P = Partnership) C

Note: Check the "LLC" box above and, in the entry space, enter the appropriate code (C, S, or P) for the tax classification of the LLC, unless it is a disregarded entity. A disregarded entity should instead check the appropriate box for the tax classification of its owner.

☐ Other (see instructions)

3b If on line 3a you checked "Partnership" or "Trust/estate," or checked "LLC" and entered "P" as its tax classification, and you are providing this form to a partnership, trust, or estate in which you have an ownership interest, check this box if you have any foreign partners, owners, or beneficiaries. See instructions . . . . . ☐

4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3):

Exempt payee code (if any)

Exemption from Foreign Account Tax Compliance Act (FATCA) reporting code (if any)

(Applies to accounts maintained outside the United States.)

5 Address (number, street, and apt. or suite no.). See instructions.

4000 NORTHFIELD WAY STE 400

6 City, state, and ZIP code

ROSWELL, GA 30076-4945

Requester's name and address (optional)

7 List account number(s) here (optional)

Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN*, later.

Note: If the account is in more than one name, see the instructions for line 1. See also *What Name and Number To Give the Requester* for guidelines on whose number to enter.

Social security number

			–		–				

or

Employer identification number

9	3	–	4	0	9	6	1	1	8

Part II Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
2. I am not subject to backup withholding because (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
3. I am a U.S. citizen or other U.S. person (defined below); and
4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and, generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

Sign Here **Signature of U.S. person** A. [signature] **Date** 01/07/2025

General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to *www.irs.gov/FormW9*.

What's New

Line 3a has been modified to clarify how a disregarded entity completes this line. An LLC that is a disregarded entity should check the appropriate box for the tax classification of its owner. Otherwise, it should check the "LLC" box and enter its appropriate tax classification.

New line 3b has been added to this form. A flow-through entity is required to complete this line to indicate that it has direct or indirect foreign partners, owners, or beneficiaries when it provides the Form W-9 to another flow-through entity in which it has an ownership interest. This change is intended to provide a flow-through entity with information regarding the status of its indirect foreign partners, owners, or beneficiaries, so that it can satisfy any applicable reporting requirements. For example, a partnership that has any indirect foreign partners may be required to complete Schedules K-2 and K-3. See the Partnership Instructions for Schedules K-2 and K-3 (Form 1065).

Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS is giving you this form because they

AmchoPlast™ ™

DEHYDRATED, HUMAN AMNION/CHORION MEMBRANE ALLOGRAFT

Package Insert (Instructions for Use)

FOR SINGLE PATIENT USE ONLY.

FOR SINGLE USE ONLY.

TO BE USED BY & ON ORDER OF REGISTERED PHYSICIAN.

IMPORTANT NOTICE TO END-USER

Please record the tracking label (provided along with the tissue) in your records and in the patient's file.

THIS ALLOGRAFT COLLECTED FROM
A DONOR WITH WRITTEN CONSENT.

PROCESSING AND PACKAGING
PERFORMED UNDER ASEPTIC CONDITIONS.

TERMINAL STERILIZATION PERFORMED
USING GAMMA IRRADIATION.

PASSES USP <71> STERILITY TEST.
DO NOT RESTERILIZE

DESCRIPTION

AmchoPlast is a sterile minimally manipulated dehydrated human amnion, intermediate layer, and chorion membrane allograft. The allograft is derived from human placental tissue collected from consenting donors. This dehydrated allograft is processed aseptically and is terminally gamma sterilized to achieve a sterility assurance level (SAL) of 1×10^{-6}. AmchoPlast is packaged as a sterile product in sealed, single-use pouches.

INDICATION FOR USE

AmchoPlast is restricted to homologous use. It acts as a barrier and provide a protective coverage from the surrounding environment for acute and chronic wounds such as partial and full thickness wounds, pressure sores/ ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/ undermined wounds, surgical wounds (e.g., donor site/grafts, post-laser surgery, post-Mohs surgery, podiatric wounds, wound dehiscence), trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears), and draining wounds.

DOSAGE

The dosage and application of AmchoPlast are determined by the treating physician based on individual patient factors and the specific condition being treated.

DONOR SCREENING AND TESTING

AmchoPlast is manufactured from “DONATED HUMAN TISSUE”. All tissue recovered meets stringent specifications during donor screening and laboratory testing to reduce the risk of transmitting infectious disease.

The Medical Director has assessed the results of infectious disease testing, consent documentation, the donor's current medical history interview and behavior risk assessment, physical examination, and relevant medical records, including past medical history, laboratory tests, and other pertinent information regarding donor suitability. Based on this evaluation, it has been determined that the donor meets the criteria for suitability in

accordance with the current standards established by the American Association of Tissue Banks and FDA regulations outlined in 21 CFR Part 1271 on Human Cells, Tissues, and Cellular and Tissue-Based Products, where applicable as well as relevant international laws and regulations.

The donor's blood samples are screened negative/non-reactive for the following infectious diseases:

- HIV-1/2 antibody
- Hepatitis B surface antigen
- Hepatitis B core antibody (Total)
- Hepatitis C antibody
- HTLV I/II antibody
- HIV (NAT)
- HBV (NAT)
- HCV (NAT)
- Malaria
- Syphilis
- WNV (NAT)

CONTRAINDICATIONS

AmchoPlast should not be used with known hypersensitivity to ofloxacin, vancomycin, and amphotericin B. It should not be used on (1) areas with active or latent infection and/or (2) a patient with a disorder that would create an unacceptable risk of post-operative complications.

RECOMMENDED INSTRUCTIONS FOR USE

These recommendations are designed only to serve as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

Prior to use, carefully follow the AmchoPlast Allograft preparation steps as mentioned below using aseptic technique.

AmchoPlast is aseptically packaged in primary and secondary tear-pouches and tertiary outer cover to ensure allograft integrity.

THE INNER POUCH IS CONSIDERED STERILE. USE CAUTION WHEN OPENING.

Step 1 : Remove the allograft from the outer packaging.
Step 2 : Inspect the pouch packaging. DO NOT USE if the packaging is damaged, if elements are missing or appear to have been tampered with, if the labeling is illegible, or if the expiration date occurs in the past.
Step 3 : Utilizing aseptic technique, peel open the outer pouch and place the inner pouch to the sterile field.
Step 4 : Wait to open the inner pouch until ready to place the graft. Locate the tear notch on the pouch, and tear open.
Step 5 : Using sterile non-toothed forceps, remove the graft and place it directly at the surgical or wound site. Allograft can be trimmed with a sterile sharp scissor in its dry state if there is a requirement.
Step 6 : Apply AmchoPlast on the wound gently with sterile forceps and spread the membrane to maximize the contact with the wound surface. If needed, prior to application, the membrane can be hydrated with sterile saline solution. When necessary secure using the physician's choice of fixation.
Note: Allografts are human tissue products and appearance may vary between donors. Variations in color, opacity, and thickness are normal due to the nature of human tissue.

RECIPIENT TRACKING

The authorized medical professional is required to maintain tissue recipient records to trace the tissue post-transplantation. The responsible entity should use provided peel-off tracking labels on the patient record and enclosed Tissue Utilization Card. The card must be completed and mailed to the distributors. The authorized medical professional shall be solely responsible for determining the adequacy and appropriateness of the allograft for all uses to which the user shall apply the

allograft. Copies of this information should be retained by the transplant facility for future reference.

WARNINGS AND PRECAUTIONS

1. Do not resterilize, keep away from sunlight, do not use if package is damaged and consult instructions for use, Keep dry, keep out of reach of children. Do not re-use. Contains biological material of human origin.
2. Caution should be used when treating patients with a known sensitivity to ofloxacin, vancomycin, and amphotericin antibiotics. Expert opinion is required before use on babies and pregnant women.
3. The graft is intended for single-patient use only.
4. Strict donor screening and laboratory testing, along with dedicated processing and sterilization methods are employed to reduce the risk of any disease transmission. However, as with all biological implants, an absolute guarantee of tissue safety is not possible. As with any allograft, complications at the graft site may occur post operatively that are not readily apparent.
   These include, but are not limited to:
   - Transmission of communicable diseases, including those of unknown etiology
   - Transmission of infectious agents such as viruses, bacteria and fungi
   - Immune rejection of, or allergic reaction to, implanted HCT/Ps
5. Discard all damaged, mishandled or potentially contaminated tissue.
6. This product has not been tested in combination with other products.
7. AmchoPlast shall not be offered, distributed or dispensed for veterinary use.

COMPLAINTS, ADVERSE EVENTS, AND RETURNS:

As with any procedure the possibility of infection exists. Proprietary processing and validated sterilization methods are

employed to eliminate potential deleterious components of the allograft. However with biological implants, the possibility of rejection still exists. Complaints or adverse events, including the suspected transmission of diseases attributable to this allograft, should be reported immediately.
Please contact your local sales representative, authorized distributor, or at customerservice@cellutionbiologics.com for information on returns. All products being returned must be in original unopened container, packaging, original label and in resalable condition.

STORAGE REQUIREMENTS

Store in a clean and dry environment at ambient temperature. DO NOT FREEZE.
The distributor, intermediary and/or end-user clinician or facility is responsible for storing product under appropriate conditions prior to further distribution or implantation.

SHELF LIFE

Refer package label for expiration date.

PACKAGING & HANDLING

AmchoPlast is aseptically packaged in a sterilized hermetically sealed aluminum-PVC foil pouch. The aluminum-PVC foil pouch containing allograft is additionally packed in another aluminum-aluminum foil pouch. The foil pouch is sealed and then packed in a pre-printed tertiary pack.

- Please inspect the integrity of the package upon receipt. If the package and contents appear defective or damaged in any way, immediately contact the distributor.
- After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and applicable local, state and national laws and regulations.
- Discard all damaged, mishandled or potentially contaminated tissue.

AVAILABLE SIZES:

AmchoPlast is available in multiple sizes, ranging from 14mm disc to 18mm disc, and 2cmx2cm to 20cmx20cm based on the size of the wound.

DEFINITIONS OF LABEL SYMBOLS

Consult instructions for use	Do not resterilize	Do not re-use	Caution
Rx only Prescription Use Only	Expiration Date	LOT Lot Number	SN Serial Number
Do not Use If package is damaged	Storage Temperature Limits	STERILE R Sterilized Using Irradiation	REF Catalogue Number
Manufacturer			

FOR MORE INFORMATION OR TO PLACE AN ORDER, PLEASE CONTACT

Distributed by:

Cellution Biologics Inc.
4000 Northfield Way, Suite 400, Roswell, GA 30076
Phone : 888-575-7357
E-mail : customerservice@cellutionbiologics.com
www.cellutionbiologics.com

USFDA Facility Registration No. : 3031041395

CB/IFU/ACP V2 03/25

Manufactured by:

LifeCell International Pvt. Ltd.
No. 26, Vandalur-Kelambakkam Main Road, Keelakottaiyur,
Chennai, 600127, Tamil Nadu

USFDA Facility Registration No. FEI: 3007953176

AATB Accredited Member #00323

DISCLOSURE
Cellution Biologics Inc. makes no claims concerning the biological properties of allograft tissue. All tissue has been collected, processed, stored, and distributed in compliance with the AATB, FDA regulations governing HCT/Ps. Although every effort has been made to ensure the safety of allograft material, current technologies may not preclude the transmission of disease. Due to the inherent variability of allograft tissue, biological and biomechanical properties cannot be guaranteed by Cellution Biologics Inc.

Cellution Biologics Inc. excludes all warranties, whether expressed or implied, including but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Cellution Biologics Inc. shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from use of this product. Cellution Biologics Inc. neither assumes nor authorizes any person to assume for it any other or additional liability or responsibility in connection with these products.

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