AMNIOREPAIR ALLOGRAFT

Zimmer Biomet is your trusted partner in providing you with innovative solutions for treating wounds and tendon ruptures. AmnioRepair Allograft delivers a concentrated volume of growth factors directly where they are needed, to best fit your needs in these clinical applications.

Patients with comorbidities, such as diabetes, have reduced healing potential, frequently resulting in chronic wound healing defects.[1] Routine care for chronic, diabetic wound healing complications has an economic cost estimated in billions of dollars annually, and also an increased mortality risk for diabetic patients.[2]

In vitro results suggest that sustained application of growth factors can heal wounds,[3] which may reduce costs from repeat hospitalizations, and better manage mortality risk.*

AmnioRepair uses a proprietary freeze-drying solution during lyophilization to preserve protein structures and **maintain bioactive capabilities** of important wound healing elements such as **EGF and bFGF.**

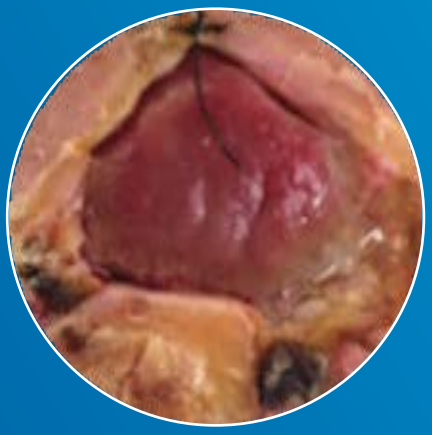
APPLICATIONS FOR PLACENTAL ALLOGRAFTS

SURGICAL

Enables rapid, non-pathologic healing and remodeling of surgical and reconstructive wounds[3]

NON-HEALING

Maintains a consistent application of growth factors to support wound closure[3]



WOUND COVER

Serves as a protective barrier for severely damaged, vulnerable tissue[4]

*In vitro testing is not necessarily indicative of clinical performance.

Convenient Size Options

AmnioRepair is available in both a disc and rectangular sizes, ranging from 4 cm^2 to 24 cm^2.

Conclusion

Zimmer Biomet is your trusted partner in providing you with innovative solutions for treating wounds and tendon ruptures. AmnioRepair Allograft contains the growth factors,[5]* convenient sizes and streamlined handling characteristics to fit your clinical needs in surgical, chronic non healing, and limb salvage applications.

Adverse Effects & Reporting

- Potential adverse effects that may result from placement of AmnioRepair include but are not limited to wound or systemic infection, seroma, dehiscence, hypersensitivity, allergic or other immune response, sloughing or failure of the graft and disease transmission.
- AmnioRepair is processed using sodium chloride solution, povidone iodine, Dulbecco's phosphate buffered saline, sodium chloride irrigation solution, anticoagulant acid citrate dextrose-formula A, glycerol, mannitol and trehalose and trace amounts of these solutions may be present in the product.
- Any adverse effect should be reported immediately to Zimmer Biomet at 800-348-9500.

Ordering Information

Description	Size	Part Number
AMNIOREPAIR	16 mm DISC	00561800416
	2 x 2 cm	00561800422
	2 x 3 cm	00561800423
	2 x 4 cm	00561800424
	3 x 3 cm	00561800433
	4 x 4 cm	00561800444
	4 x 6 cm	00561800446

References

1. Kolluru GK, *et al.* Endothelial Dysfunction and Diabetes: Effects on Angiogenesis, Vascular Remodeling, and Wound Healing. *International Journal of Vascular Medicine.* Art ID 918267: 1-30, 2012.
2. Kruse I., *et al.* Evaluation and Treatment of Diabetic Foot Ulcers. *Clinical Diabetes.* 24(2): 91-3, 2006.
3. Barrientos, S., *et al.* Growth factors and cytokines in wound healing. *Wound Repair and Regeneration.* 16: 585-601, 2008.
4. AmnioRepair Allograft, Instructions for Use.
5. Data on file Aziyo Biologics. Composition and cellular Effects Comparison of AltiPly and EpiFix, report number REP-0154. Aug 20, 2020.
6. Losi, P., *et al.* Fibrin-based scaffold incorporating VEGF- and bFGF-loaded nanoparticles stimulates wound healing in diabetic mice. *Acta Biomaterialia.* 9:7814-7821, 2013. LT-0019 Rev. 01, 2018.
7. Brown, G. L., *et al.* Enhancement of Wound Healing by Topical Treatment with Epidermal Growth Factor. *The New England Journal of Medicine.* 321:76-79, 1989.

For indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert or contact your local representative; visit www.zimmerbiomet.com for additional product information. Check for country product clearances and reference product specific instructions for use. Zimmer Biomet does not practice medicine. This technique was developed in conjunction with health care professional. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure. Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

*In vitro testing is not necessarily indicative of clinical performance.

***Animal testing is not necessarily indicative of performance in humans.*

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ZIMMER BIOMET

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www.zimmerbiomet.com

ZIMMER BIOMET

AmnioRepair® Allograft

OUR SOLUTION

AmnioRepair Allograft is a lyophilized placental membrane allograft that is aseptically processed to preserve the native extracellular matrix and endogenous proteins. AmnioRepair is indicated for use as a biological barrier or wound cover. AmnioRepair is a Human Cellular and Tissue Based Product (HCT/P) per 21 CFR Part 1271.

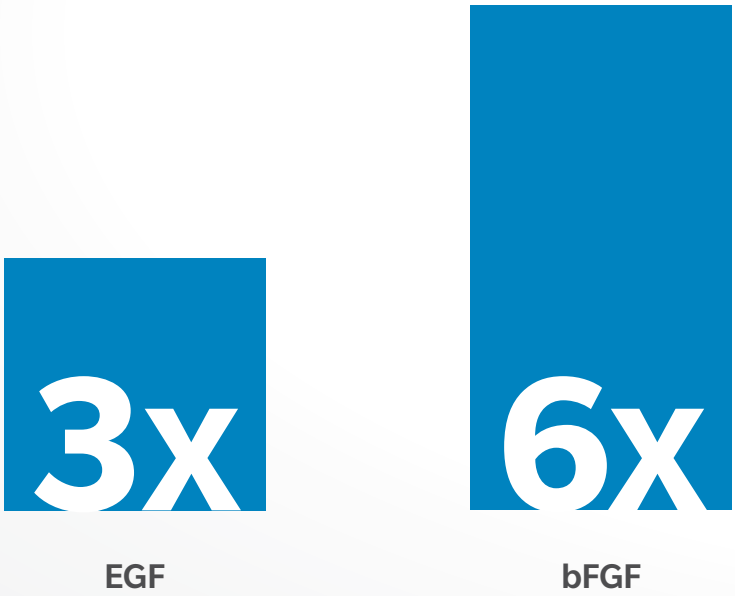
Each allograft is restricted to homologous use for use in procedures on a single occasion by a licensed physician or surgeon.

Growth factors preserved to aid the healing process

AmnioRepair is a placental allograft processed with proprietary methods to maximize the retention and preservation of growth factors and other extracellular matrix (ECM) components. Several steps are taken to avoid tissue degradation during processing. AmnioRepair is processed via freeze drying (lyophilization) rather than oven drying to remove water and stabilize for long-term room temperature storage. Lyophilization avoids the damage or destruction heat can have on sensitive molecules of the tissue product like specific growth factors.

This proprietary process results in more growth factors preserved in AmnioRepair compared to a competitive allograft.[5]*

Growth Factor Level Comparison AmnioRepair vs. EpiFix®



In a review of EGF, several studies demonstrated increased epithelization and decreased healing time in several types of wounds.[3,7]* In an animal study, bFGF was a key factor that helped induce re-epithelialization.[6]**

AmnioRepair contains 3 times more mean epidermal growth factor (EGF) and 6 times more mean basic fibroblast growth factor (bFGF) than a competitive allograft.[5]*

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Hyaluronic Acid Comparison
AmnioRepair vs. EpiFix®

4x

ECM

The proprietary lyophilization process used to produce AmnioRepair retained 4.5 times more of the structural extracellular matrix (ECM) hyaluronic acid than a competitive allograft.[5]*

These results indicate AmnioRepair creates a barrier option with greater levels of ECM than a competitive allograft.[5]*

Simple handling characteristics and easy to identify orientation allow for ease of application

- Bilayer composition of human amnion and chorion
- Room temperature storage
- User friendly texture, flexibility, and thickness
- No rehydration required

Epithelial

Stromal

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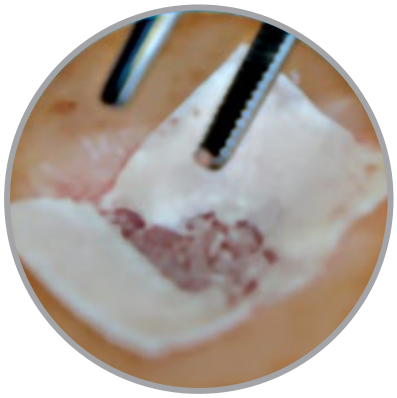
How to apply

AmnioRepair has two distinct sides: an epithelial side and a stromal side. The epithelial side is smooth while the stromal side is dull. In addition, the graft has a 2-3 mm vertical orientation guide slit that when in the upper right corner, the epithelial side is facing upward.

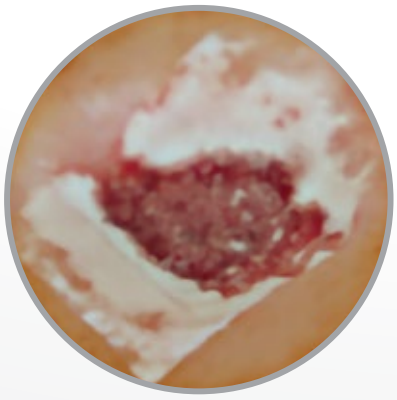
Apply the graft with the epithelial side facing up and the stromal side directly against the wound bed. Trim or push excess graft into the wound as necessary.

Cover the treated wound with a sterile non-adherent dressing followed by sterile saline moistened gauze to fill but not pack the wound.

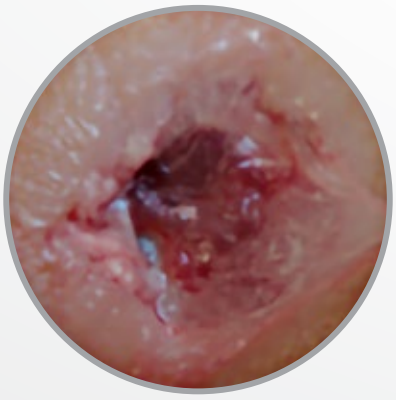
Easy to visualize and handle at room temperature



Ready to apply



No rehydration required



Conforming