

▶▶ CYGNUS® SOLO AMNIOTIC MEMBRANE TISSUE ALLOGRAFT

CYGNUS® SOLO

CHRONIC DIABETIC FOOT ULCER CASE STUDY

The patient is a 47-year-old obese diabetic male presenting a diabetic foot ulceration in the right plantarflexed metatarsal, which had been existent for 16 weeks prior to the first application of CYGNUS® Solo amniotic membrane tissue allograft. The wound had been caused by pressure due to severe hammertoe and the otherwise healthy patient was given conservative treatment of weekly wound debridement, medicinal honey, oral antibiotics, and offloading and the wound remained open.

▶▶ APPLICATION OF VIVEX® BIOLOGICS CYGNUS® SOLO AMNION TISSUE ALLOGRAFT AND OUTCOME

CYGNUS Solo amniotic membrane tissue allografts were applied to the diabetic foot ulcer as a wound covering, providing protection while retaining endogenous growth factors.^{1,2} ADAPTIC™ Non-Adhesive Silicone Dressing, cotton padding, and Steri Strips were applied as a dressing. The patient was successful at keeping weekly dressings intact and, throughout the 8 weeks of treatment with CYGNUS Solo, continued to use an off-loading adjunct therapy.



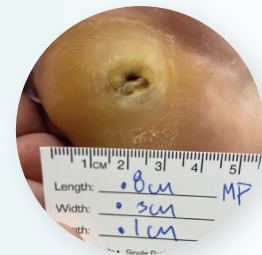
**PRE-APPLICATION
OF CYGNUS SOLO**

Wound Dimensions:
1.5cm L x 0.5cm W x 0.5cm D



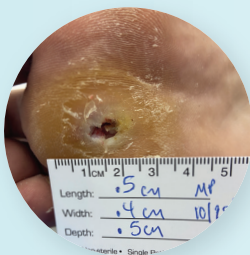
**AFTER 1ST APPLICATION
OF CYGNUS SOLO**

Wound Dimensions:
0.5cm L x 0.2cm W x 0.02cm D



**AFTER 2ND APPLICATION
OF CYGNUS SOLO**

Wound Dimensions:
0.8cm L x 0.2cm W x 0.2cm D



**AFTER 3RD APPLICATION
OF CYGNUS SOLO**

Wound Dimensions:
0.4cm L x 0.5cm W x 0.5cm D



**AFTER 4TH APPLICATION
OF CYGNUS SOLO**

Wound Dimensions:
0.7cm L x 0.2cm W x 0.5cm D



**AFTER 6TH APPLICATION
OF CYGNUS SOLO**

Wound Dimensions:
Wound Closure

After 6 CYGNUS Solo applications over the course of 8 weeks, and despite continued pressure from the orthopedic deformity, the patient achieved complete wound closure without drainage or dressing requirements.

The patient had previously been treated with traditional wound care including medicinal honey, oral antibiotics, offloading, and weekly debridement. These methods did not work. Utilizing CYGNUS Solo in conjunction with the use of an off-loading Cam Boot achieved **complete wound closure**.

▶▶ CONCLUSION

This case study demonstrates the use of VIVEX CYGNUS Solo amniotic membrane tissue allograft as a wound covering to help close a chronic full-thickness Wagner Grade 2 diabetic foot ulcer. The CYGNUS tissue allograft is easy to apply, is available in multiple sizes, and will conform to wounds

▶▶ CYGNUS SOLO

CYGNUS Solo is a single-layer amnion membrane allograft. VIVEX's Integrity Processing™ preserves the inherent properties of amniotic tissues, maintaining key extracellular matrix molecules, proteins, carbohydrates, collagen, growth factors, and cytokines.^{1,2}

▶▶ SAFE AND TRUSTED PARTNER

VIVEX Biologics is a regenerative solutions company focused on patient care through the innovation of tissue-based therapies in Wound Care, Ortho-Fusion, and Interventional Pain. With more than 50 years of highly safe and effective operations, VIVEX aims to provide advanced regenerative solutions.

- Amniotic tissue is recovered from healthy mothers at live births.
- Amniotic tissue is handled and processed in accordance with both FDA regulations and AATB standards.
- VIVEX maintains the trend of safely delivering over 2 million allografts with no disease transmission.

VIVEX has used reasonable efforts to provide accurate and complete information herein, but this information should not be construed as providing clinical advice, dictating reimbursement policy, or as a substitute for the judgment of a health care provider. It is the health care provider's responsibility to determine the appropriate treatment, codes, charges for services, and use of modifiers for services rendered and to submit coverage or reimbursement-related documentation.

This research study is designed to test a product manufactured by VIVEX. The physician leading this research receives compensation from VIVEX for work that is related to and unrelated to this study, including consulting, writing, and/or speaking engagements. If you would like more information, please contact a VIVEX representative.

1. Delcroix Gaetan J. R., et. al. "Preserving the Natural Regenerative Potential of Amniotic Membrane." VIVEX Biologics, 2017.

2. Niknejad, Hassan, et. al. "Properties of the Amniotic Membrane for Potential Use in Tissue Engineering." *European Cells and Materials*, 2008, vol. 15, pp. 88-89.



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