

COMPLEX WOUNDS

Grafix®

ONE
viable tissue

THREE
natural components

- Living cells
- Growth factors
- Extracellular matrix

Viable cryopreserved placental membrane
for wound management.



Osiris®
THERAPEUTICS, INC.

OVERWHELMING SUCCESS in the most severe cases.¹

IDEAL for the rest.

Grafix®

THE CLINICAL TRIAL^{1,*}

OVERVIEW:

The first prospective post-market study using Grafix in the management of chronic complex diabetic foot ulcers in patients typically excluded from clinical research due to the severity of their wounds.

TITLE:

“A prospective, multicentre, open-label, single-arm clinical trial for treatment of chronic complex diabetic foot wounds with exposed tendon and/or bone: positive clinical outcomes of viable cryopreserved human placental membrane”.

PATIENT DEMOGRAPHICS & CO-MORBIDITIES:

Patients enrolled	31
Patients completed [†]	27
Age (mean)	63.5 years
Male gender	90.3%
BMI (mean)	30.0
Smoker (current or former)	61.3%
Hypertension	83.9%
Heart disease	54.8%

WOUND CHARACTERISTICS:

Wound extends through the dermis with exposed tendon, muscle, bone, or joint capsule	
Wound duration prior to study (mean)	7.5 months
Wound area at baseline (mean)	14.6 cm ²
Prior amputations	45.2%
Plantar wound	32.3%
Prior advanced wound therapy recorded	67.7%



GRAFIX IS A FLEXIBLE, CONFORMING, VIABLE CRYOPRESERVED MEMBRANE, comprised of three natural components: a collagen-rich extracellular matrix (ECM), growth factors, and living cells such as mesenchymal stem cells (MSCs).

* Negative pressure wound therapy (NPWT) and hyperbaric oxygen (HBO) therapy were excluded from use during the clinical trial.

[†] Two patients withdrew for non-compliance and two for surgical intervention.

Complex diabetic foot ulcers represent one of the most significant challenges in terms of mortality, morbidity, and cost.¹ In a recent trial, Grafix® CORE demonstrated positive outcomes for the most serious diabetic foot ulcers—those involving exposed tendon and/or bone.

THE RESULTS^{1,‡}

PRIMARY ENDPOINT:

- **96.3%** of the wounds treated exhibited 100% granulation by 16 weeks

SECONDARY ENDPOINTS:

- **92.3%** wound area reduction at 16 weeks (mean)
- **59.3%** achieved 100% re-epithelialization (wound closure) by 16 weeks
- **6.8 weeks** to achieve 100% granulation (mean)
- **6.8 applications** of Grafix CORE to achieve 100% granulation (mean)

NO GRAFIX-RELATED ADVERSE EVENTS



[‡] Per protocol analysis.

REFERENCE: 1. Frykberg, R. G., Gibbons, G. W., Walters, J. L., Wukich, D. K. and Milstein, F. C. (2016), A prospective, multicentre, open-label, single-arm clinical trial for treatment of chronic complex diabetic foot wounds with exposed tendon and/or bone: positive clinical outcomes of viable cryopreserved human placental membrane. *Int Wound J.* doi:10.1111/iwj.12649.

YOUR NATURAL CHOICE

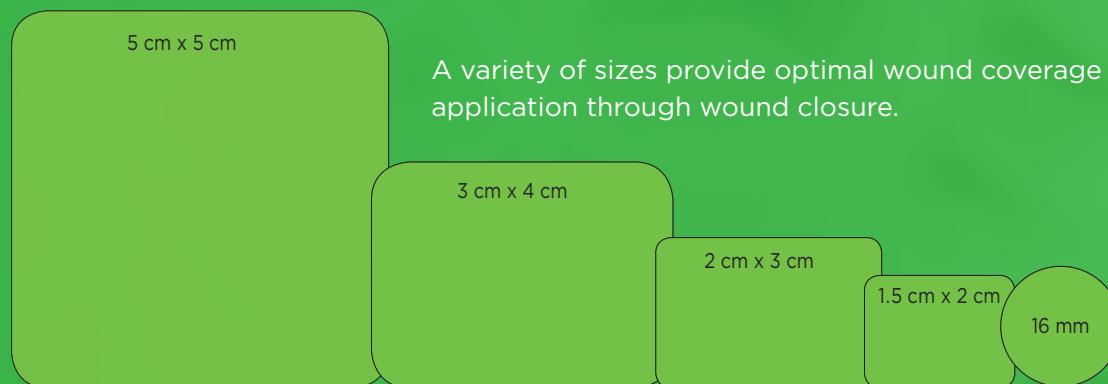
for wound care.

Grafix® is a viable cryopreserved membrane comprised of an extracellular matrix (ECM) rich in collagen, growth factors, and living cells—including mesenchymal stem cells (MSCs).

- Designed for application directly to acute and chronic wounds
- Flexible, conforming cover that adheres to complex anatomies
- May be applied over both bone and tendon
- No need for sutures or Steri-Strips®
- Suitable for a wide variety of hard-to-treat acute and chronic wounds, including:
 - Diabetic foot ulcers
 - Burns
 - Deep tunneling wounds
 - Pressure ulcers
 - Pyoderma gangrenosum
 - Surgical dehiscence
 - Trauma
 - Surgical incisions
 - Venous leg ulcers
 - Arterial ulcers

Osiris Therapeutics, Inc. is a leading cellular and regenerative medicine company focused on developing and marketing products to treat conditions in wound care, orthopaedics, and sports medicine.

GRAFIX IS AVAILABLE IN MULTIPLE SIZES, HELPING YOU REDUCE WASTE AND COST



A variety of sizes provide optimal wound coverage from initial application through wound closure.



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