

**CLINICAL OUTCOMES:
GRAFIX VERSUS EPIFIX**

Grafix®

ONE
viable tissue

THREE
natural components

- Living cells
- Growth factors
- Extracellular matrix

Cryopreserved placental membrane
for wound management



Osiris®
THERAPEUTICS, INC.

Grafix Demonstrated Superior Clinical Outcomes Versus EpiFix



The Clinical Case Series¹

TITLE:
“A Comparative Outcomes Analysis Evaluating Clinical Effectiveness in Two Different Human Placental Membrane Products for Wound Management.”

OVERVIEW:
This investigator-initiated, retrospective, single-center study analyzed 79 patients and 101 wounds treated with Grafix, an intact cryopreserved human placental membrane, or EpiFix, a dehydrated human amnion/chorion membrane. All patients who received at least one application of either Grafix or EpiFix with one follow-up measurement were included. No patients or wound types were excluded. A statistical analysis comparing patients and outcomes was performed by a blinded third party.

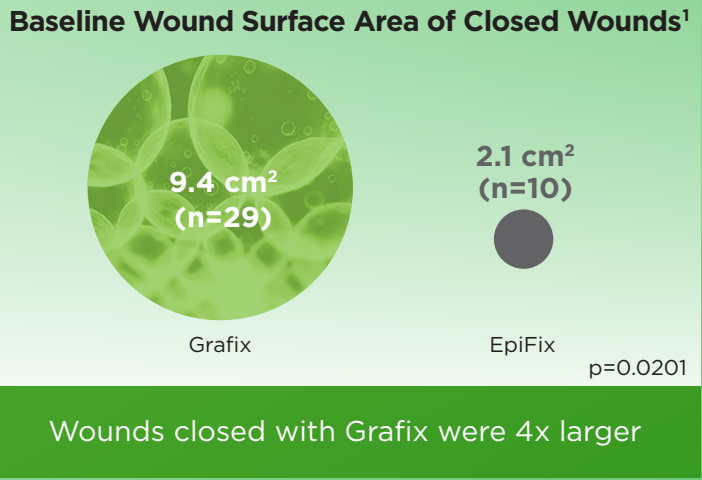
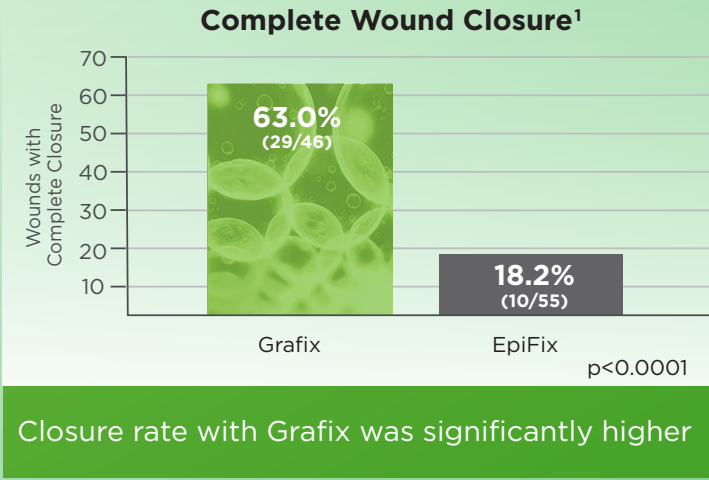
Homogeneous Treatment Cohorts:*

	Grafix	EpiFix	P-Value
Patient Demographics:			
Patients	40	39	
Age (mean)	65.9 years	67.5 years	0.649
BMI (mean)	28.0 kg/m ²	28.4 kg/m ²	0.829
Co-morbid conditions per patient (mean)	3.8	3.8	0.949
Diabetic	25.0%	35.9%	0.292
Baseline Wound Characteristics:			
Wounds	46	55	0.535
Wound area (mean)	7.7 cm ²	7.0 cm ²	0.769
Wound volume (mean)	8.3 cm ³	2.7 cm ³	0.169
Wound duration (mean)	150.9 days	212.8 days	0.107



Grafix is a flexible, conforming, cryopreserved membrane, composed of three natural components—a collagen-rich extracellular matrix (ECM), growth factors, and living cells such as mesenchymal stem cells (MSCs)—for use as a wound cover.

The Results¹



The odds ratio for complete closure for a Grafix-managed wound compared with EpiFix was 7.50 (95% CI 2.84 – 21.30).

Closed Wound Characteristics:	Grafix (n=29)	EpiFix (n=10)	P-Value
Baseline wound volume (mean)	10.3 cm ³	0.5 cm ³	0.115
Baseline wound duration (mean)	127.6 days	190.6 days	0.305
Graft applications (mean)	2.7	1.5	0.0457
Treatment duration (mean)	59.7 days	31.0 days	0.0312
Closures by week 12	26 (90%)	9 (90%)	0.444

Non-Closed Wound Characteristics:	Grafix (n=17)	EpiFix (n=45)	P-Value
Baseline wound surface area (mean)	4.8 cm ²	8.1 cm ²	0.256
Baseline wound volume (mean)	4.9 cm ³	3.2 cm ³	0.617
Baseline wound duration (mean)	190.6 days	216.8 days	0.641
Final percentage area reduction (mean)	43.1%	-72.6%	0.0382
Final percentage volume reduction (mean)	39.6%	-135.7%	0.0782

*No statistical differences in the baseline patient characteristics, wound characteristics, or etiological distribution of wound types between the two groups.

The full study is available online at <http://bit.ly/comparativeoutcomes.1>

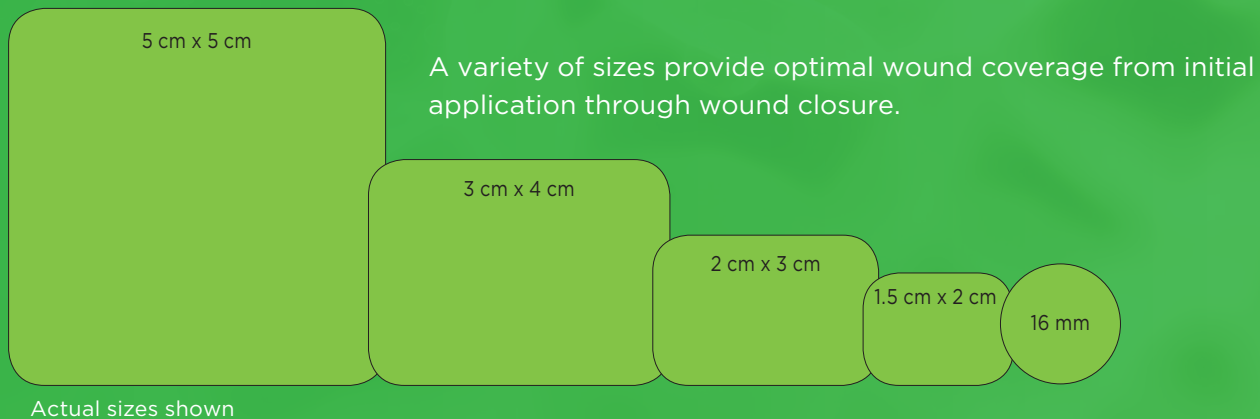
YOUR NATURAL CHOICE for wound care

Grafix is a cryopreserved placental membrane composed 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 bone, tendon, joint capsule, and muscle
- No need for sutures or Steri-Strip adhesives
- Suitable for a wide variety of hard-to-treat acute and chronic wounds, including but not limited to:
 - Diabetic foot ulcers
 - Burns
 - Deep tunneling wounds
 - Pressure ulcers
 - Pyoderma gangrenosum
 - Surgical dehiscence
 - Trauma
 - Surgical incisions
 - Venous leg ulcers
 - Arterial ulcers

Osiris Therapeutics, Inc. researches, develops, manufactures and commercializes regenerative medicine products intended to improve the health and lives of patients and lower overall healthcare costs.

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



REFERENCE: 1. Johnson E, Marshall J, Michael G. A comparative outcomes analysis evaluating clinical effectiveness in two different human placental membrane products for wound management. *Wound Repair Regen.* 2016; doi: 10.1111/wrr.12503.



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