# Smith-Nephew

**GRAFIX**<sup>\$</sup> Cryopreserved Placental Membrane

### GRAFIX PL<sup>◊</sup>

Lyopreserved Placental Membrane

## Evidence 🖶 Efficacy

Summary of clinical outcomes in key GRAFIX and GRAFIX PL membrane studies



### + 62% of wounds (n=97) closed with GRAFIX membrane at 12 weeks vs. 21% with SOC alone (p=0.0001)

Prospective, Multi-center, Randomized, Controlled, Blinded, DFUs<sup>1</sup>



+ 59% of wounds (n=350) closed with GRAFIX membrane Retrospective, Multi-center, WoundExpert analysis, DFUs<sup>2</sup>



+ 59% of wounds (n=27) closed with GRAFIX membrane at 16 weeks Prospective, Multi-center, Open-label, Complex DFUs<sup>3</sup>



+ 53% of VLUs (n=30) that failed to close with 12 weeks SOC went on to close with GRAFIX membrane + SOC (p<0.001)

Prospective, Single-center, Open-label,

Refractory VLUs<sup>4</sup>

76%

✤ 76% of wounds (n=67) closed with GRAFIX membrane at 12 weeks

Retrospective, Single-center, Open-label, Chronic wounds⁵



+ 63% of wounds (n=40) closed with GRAFIX membrane

+ 18% of wounds (n=39) closed with EpiFix (p<0.0001)

Retrospective, Single-center, Comparative effectiveness v. EpiFix, Chronic wounds<sup>6</sup>



+ 59% of wounds (n=98) achieved complete wound closure with GRAFIX PL membrane

Open-label, Retrospective, Chronic Wounds<sup>7</sup>

1. Lavery LA, Fulmer J, Shebetka KA, et al. The efficacy and safety of Grafix® for the treatment of chronic diabetic foot ulcers: results of a multicentre, controlled, randomised, blinded, clinical trial. *Int Wound J.* 2014; 11(5): 554-560. 2. Raspovic KM, Wukich DK, Naiman DQ, Lavery LA, Kirsner RS, Kim PJ, Steinberg JS, Attinger CE, Danilkovitch A. Effectiveness of viable cryopreserved placental membranes for management of diabetic foot ulcers in a real-world setting. *Wound Repair Regen.* 2018; 26 (2): 213-220. 3. Frykberg RG, Gibbons GW, Walters JL, et al. A prospective, multicentre, openlabel, singlearm clinical trial for treatment of chronic complex diabetic foot wounds with exposed tendon and/or bone: positive clinical outcomes of viable cryopreserved placental membrane. *Int Wound J.* 2017; 14 (3): 569-577. 4. Farivar BS, Toursavadkohi S, Monahan TS, et al. Prospective study of cryopreserved placental tissue wound matrix in the management of chronic venous leg ulcers. *J VascSurg Venous Lymphat Disord.* 2019; 7(2): 228-233. 5. Regulski M, Jacobstein DA, Petranto RD, et al. A retrospective analysis of a human cellular repair matrix for the treatment of chronic wounds. *Ostomy Wound Manage.* 2013; 59(12): 38-43. 6. 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.* 2017; 25 (1): 145-149. 7. Ananian CE, Davis DR, Johnson EL, et al. Wound closure outcomes suggest clinical equivalency between lyopreserved and cryopreserved placental membranes containing viable cells. *Adv Wound Care (New Rochelle).* 2019; 8 (11): 546–554.

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