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GRAFIX®
Placental Membrane

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GRAFIX clinical evidence collection

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Level 1 DFU evidence

Significantly more patients with chronic diabetic foot ulcers (DFUs) achieved complete wound closure in a shorter time with GRAFIX◊ Cryopreserved Placental Membrane than with standard care

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 multi-centre, controlled, randomised, blinded, clinical trial. *Int Wound J.* 2014;11(5):544-560.[1]

Key points

~3X
Increase in wound closure with GRAFIX Membrane versus standard care (62.0 vs 21.3%; p=0.0001)

27.5 days
Faster complete wound closure with GRAFIX Membrane versus standard care (42.0 vs 69.5 days; p=0.019)

67.8%
Probability of **complete wound closure** with addition of GRAFIX Membrane to standard care in the open-label phase

Overview

- Prospective, multicenter, randomized, single-blinded study
- Patients with DFUs (duration 4–52 weeks) received once weekly GRAFIX Membrane (n=50) or standard care of off-loading and non-adherent dressings (n=47) for up to 84 days
  - All wounds were appropriately cleaned and surgically debrided at each weekly visit
- Patients receiving standard care whose wounds had not closed by the end of the blinded treatment phase were able to receive GRAFIX Membrane in an open-label treatment phase (84 days)

Results

- GRAFIX Membrane use significantly increased the number of DFUs that achieved complete closure compared with standard care (p=0.0001; Figure)
  - DFUs remained closed at 12-week follow-up in 82.1% of patients with GRAFIX Membrane and 70.0% of patients with standard care
- Median time to complete wound closure was significantly faster with GRAFIX Membrane versus standard care (42.0 vs 69.5 days; p=0.019)
- Complete wound closure was achieved with 50% fewer study visits with GRAFIX Membrane than with standard care (6 vs 12 visits; p<0.001)
- For patients who had failed to heal with standard care alone and added GRAFIX Membrane (n=26), the probability of DFU closure was 67.8% with a mean closure time of 42 days

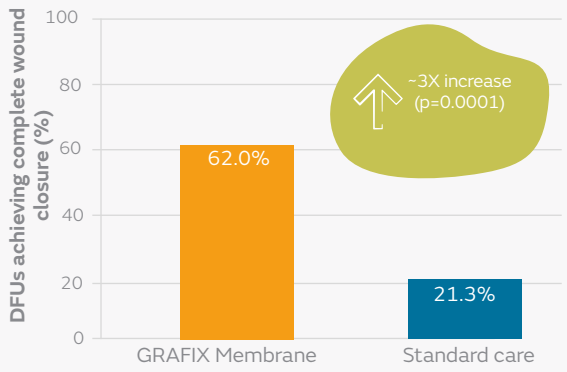

Figure. Complete wound closure (%) in patients with DFUs managed with GRAFIX Membrane and standard care

Conclusions

Significantly more patients with chronic DFUs achieved complete wound closure in a shorter time using GRAFIX Membrane compared with standard care.

Level 1 VLU evidence

GRAFIX◊ PL PRIME significantly reduces venous leg ulcer (VLU) size and increases the probability of total wound closure versus standard of care (SOC)

Dhillon Y, Levine L, Tovmassian G, et al. A multicenter, randomized, controlled, clinical trial evaluating a lyopreserved amniotic membrane in the treatment of venous leg ulcers. *Health Sci Rep.* 2025;8(5):e70819.

Key points

Versus SOC, patients receiving GRAFIX PL PRIME had:

Significantly greater reduction in VLU size after **8 and 12 applications** ($p<0.05$)

72% **greater probability of complete VLU closure** for wounds initially 3–25cm² ($p<0.05$)

Significantly greater **5-fold improvement** in quality of life ($p<0.05$)

Overview

- A prospective, multicenter, open-label, randomized controlled trial conducted in the United States for patients with VLUs. Patients received either:
  - SOC, defined as compression therapy (n=100)
  - GRAFIX PL PRIME + SOC (n=100)
- Key inclusion criteria included:
  - Adult patients ≥18 years old
  - Lower extremity VLU present for >4 weeks but <52 weeks
  - Open ulcer size between 1cm² and 25cm², but not exceeding 10cm at the longest dimension
  - Compression therapy previously received for >2 weeks
- Patients received treatment weekly for up to 12 weeks or until VLU closure. A closed VLU was defined as:
  - 100% re-epithelialization without drainage or dressing, confirmed at two separate visits 2 weeks apart
- Primary outcome measure of the study was complete closure of the VLU. Other secondary outcomes included:
  - Time to initial ulcer closure
  - Percentage area reduction in ulcers that did not close
  - Incidence of adverse events and serious adverse events
- Exploratory outcomes included quality of life measures

Results

Patients receiving GRAFIX PL PRIME vs SOC had:

- Significantly greater mean size reduction (Figure)
- Significant reduction in VLU wound area was observed after 8 applications (3.46cm² vs 2.46cm²; $p<0.05$)
  - Significant reduction also observed after 12 applications (4.38cm² vs 2.56cm²; $p<0.05$)
- Significantly greater probability of complete wound closure (1.72; $p<0.05$) vs SOC for VLUs initially 3–25cm²
  - Probability of complete wound closure increased to 2.31 for wounds initially 4–25cm² ($p<0.05$) and to 2.74 for wounds 5–25cm² ($p<0.05$)
- Significantly greater 5-fold improvement in quality of life (physical symptoms and daily life; $p<0.05$)
- GRAFIX PL PRIME was able to close statistically larger sized wounds vs SOC
- GRAFIX PL PRIME closed wounds 70% faster than SOC

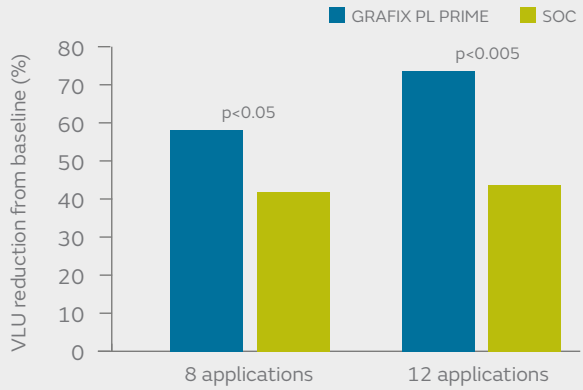

Figure. VLU size reduction from baseline was significantly greater for patients receiving GRAFIX PL PRIME versus SOC

Conclusions

In a multicenter, randomized controlled trial, patients receiving GRAFIX PL PRIME had a significantly greater reduction in venous leg ulcer size and significantly greater probability of complete wound closure versus patients receiving standard of care. Quality of life was also significantly improved for patients receiving GRAFIX PL PRIME versus standard of care.

Real-world DFU evidence

The application of GRAFIX◊ cryopreserved placental membrane resulted in total wound closure for the majority of diabetic foot ulcer (DFU) wounds

Raspovic KM, Wukich DK, Naiman DQ, et al. 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]

Available at: Journal of Wound Repair and Regeneration

Key points

Overview

- Retrospective analysis was performed to evaluate the effectiveness of GRAFIX Membrane for treatment of DFUs using the Wound Expert Electronic Health Records database
  - Treatment records for patients that received GRAFIX for DFUs from July 1, 2012 and June 30, 2016 were extracted from the database
- DFU wounds (n=441) were located on the foot, toe, heel, metatarsal head, toe web space, toe amputation site, or transmetatarsal amputation site
  - Mean wound size of 5.1cm^2 and 3.9mm deep, with an average wound duration of 102 days prior to treatment with GRAFIX
  - Wounds <0.25cm^2 were excluded and majority of wounds (72.5%) were 0.25–5cm^2

Results

- Wound closure at the end of treatment with GRAFIX Membrane was 59.4%
  - With a median treatment duration of 42 days and 4 applications of GRAFIX
- During the treatment period, the following adverse events were observed:
  - 3.0% of wounds required amputation
  - 2.0% of wounds developed an infection

Table. Median time to wound closure and required number of GRAFIX applications on various size DFU wounds

Wound size	Median time to wound closure	Number of GRAFIX applications
0.25–2cm^2	21 days	4
2–5cm^2	49 days	4
5–10cm^2	63 days	5
Overall	42 days	4

Conclusions

At the end of treatment, the majority of DFU wounds closed with application of GRAFIX Membrane (59.4%).

Real-world DFU evidence

Likelihood of new or recurrent diabetic foot ulcers (DFUs) was significantly reduced after application of GRAFIX◊ Membrane compared with other cellular- and tissue-based products in an analysis of Medicare claims

DaVanzo J, Hartzman A, Surfield C, Dobson A. Cryopreserved placental membrane allograft reduces the likelihood of developing a new or recurring foot ulcer and all-cause mortality in diabetic patients, when compared to other cellular- and tissue-based products. *Adv Wound Care (New Rochelle)*. 2022;12(4):169-176.[4]

Key points

After application of GRAFIX Cryopreserved Placental Membrane, compared with other cellular- and tissue-based products:

Significant reduction in likelihood of a new or recurrent DFU (all time points; p<0.05)

Favorable indirect effect on average mortality rate at 1 year*

Lower occurrences of cellulitis/abscess of the foot and toe (versus other cellular products; most time points)

Overview

- A Medicare claims-based observational study comparing effectiveness of GRAFIX Membrane with other cellular- and tissue-based products (cellular and acellular) in an outpatient setting
- Any new or recurrent DFUs, mortality and DFU-related infections were assessed at 30, 90, 180 and 365 days after completing treatment
- Data from 7,869 Medicare beneficiaries, with confirmed DFUs who were treated for 90 days and had at least one Medicare outpatient claim, were included (2013 to 2017):
  - GRAFIX Membrane, n=786
  - Another cellular product, n=4,546
  - An acellular product, n=2,537

Results

- At all time points, the likelihood of a new or recurrent DFU was significantly reduced after treatment with GRAFIX Membrane compared with the other cellular or acellular products (Figure; p<0.05)
  - Relative reductions ranged from 36.7% after 30 days (other cellular products) to 58.5% after 365 days (acellular products)
- At day 365, average mortality rate was lower with GRAFIX Membrane (12.3%) than with other cellular (17.7%) or acellular products (18.1%)*
- For GRAFIX Membrane compared with other cellular products, there were significant reductions (p<0.05) in occurrences of:
  - Cellulitis/abscess of the foot at 30, 90, 180 and 365 days
  - Cellulitis/abscess of the toe at 180 and 365 days
- There were no significant differences between groups in occurrences of gangrene, osteomyelitis or paronychia

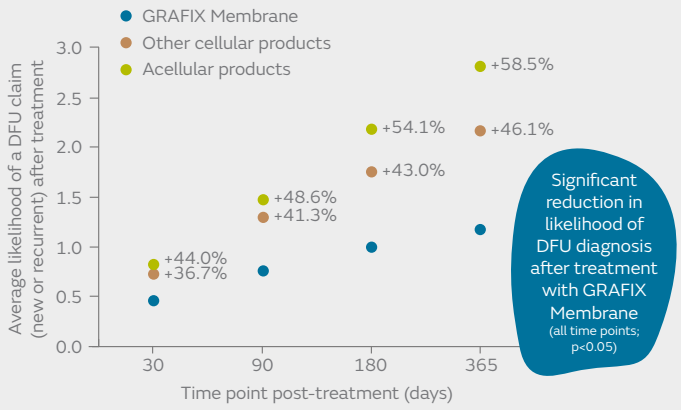

Figure. Average likelihood of a DFU diagnosis with GRAFIX Membrane, other cellular products or acellular products (differences are reported as relative percentage increases with other products vs GRAFIX Membrane)

Conclusions

After completion of treatment, the likelihood of a claim for a new or recurrent DFU was significantly reduced with GRAFIX Membrane versus other cellular and acellular products used in outpatient settings (relative reductions ranged from 36.7% to 58.5%, depending on comparator and time point).

*GRAFIX Membrane cannot save lives and instead may have an indirect effect on mortality.

Real-world DLEU & VLU evidence

GRAFIX◊ PL PRIME and GRAFIX PRIME are associated with lower wound recurrence, adverse outcomes, and 1-year mortality for patients with diabetic lower extremity ulcers (DLEU) and venous leg ulcers (VLU), compared to standard care

Padula WV, Ramanathan S, Cohen BG. Comparative effectiveness of placental allografts in the treatment of diabetic lower extremity ulcers and venous leg ulcers in U.S. Medicare beneficiaries: a retrospective observational cohort study using real-world evidence. *Advances in Wound Care (New Rochelle).* 2024;13(7):350-362.[5]

Available at: Advances in Wound Care

Key points

Application of GRAFIX PL PRIME for DLEUs, and GRAFIX PL PRIME or GRAFIX PRIME for VLUs resulted in:

91% (DLEU) and 80% (VLU) reduction for wound recurrence versus SOC

71% (DLEU) and 67% (VLU) reduction in adverse outcomes (amputation, 1-year mortality and wound recurrence)

26% (DLEU) and 23% (VLU) reduction for 1-year mortality

Overview

- Retrospective, observational, cohort study of Medicare beneficiaries for DLEUs and VLUs between 2016–2020
  - 333,362 DLEU episodes among 261,101 beneficiaries
  - 122,012 VLU episodes among 80,415 beneficiaries
- Three cohorts of patients were evaluated:
  - Viable cryopreserved placental membrane (vCPM) or viable lyopreserved placental membrane (vLPM)
  - Other cellular tissue products (CTP)
  - Standard of care (SOC)
- Patients that received vCPM or vLPM were treated with GRAFIX PRIME or GRAFIX PL PRIME, respectively
- The following outcomes were assessed:
  - Recurrence
  - Adverse outcomes
  - 1-year mortality

Results

- For patients with DLEUs (Table), GRAFIX PL PRIME was associated with:
  - A relative risk ratio (RRR) reduction of 91% for wound recurrence versus SOC, and a RRR reduction of 49% for wound recurrence versus other CTPs
  - An odds ratio (OR) of 2.42 (70.8% reduction) for adverse outcome prevention compared to SOC
  - A RRR of 0.74 for reduced 1-year mortality versus SOC
- For patients with VLUs (Table):
  - GRAFIX PL PRIME was associated with a relative risk reduction for wound recurrence compared to SOC (80%) and other CTPs (73%)
  - GRAFIX PL PRIME or GRAFIX PRIME were associated with a 67% reduction in adverse outcomes compared to SOC
  - GRAFIX PL PRIME or GRAFIX PRIME was associated with a RRR of 77% for 1-year mortality compared to SOC

Table. Outcomes assessed for DLEU and VLU cohorts.

	DLEU cohort		VLU cohort	
	GRAFIX PL PRIME vs CTPs	GRAFIX PL PRIME vs SOC	GRAFIX PL PRIME and GRAFIX PRIME vs CTPs	GRAFIX PL PRIME and GRAFIX PRIME vs SOC
Wound recurrence	0.51 RRR	0.09 RRR	0.27 RRR	0.20 RRR
Adverse outcome prevention	0.99 OR	2.42 OR	0.88 OR	2.01 OR
1-year mortality	1.07 RRR	0.74 RRR	1.21 RRR	0.77 RRR

Conclusions

Diabetic lower extremity ulcers and venous leg ulcers treated with GRAFIX PL PRIME and GRAFIX PRIME allografts are associated with lowered wound recurrence, adverse outcomes, and 1-year mortality compared to standard care.

Note: "DLEU" in this study included pressure ulcers of the lower extremity with diabetic etiology.

Additional DFU evidence

260 patients across 10 publications

Level	Reference	Product	HCPCS Code	Patients (n)	Wound closure (%)	Time to wound closure (days)
2	Davis KE, Killeen AL, Farrar D, et al. *Int Wound J.* 2020;17(6):1893–1901.[6]	GRAFIX◊ PRIME	Q4133	40	48	40
2	Reyzelman AM, Vartivarian M, Danilkovitch A, Saunders MC. *Wounds*. 2019;31(4):97–102.[7]	GRAFIX PL PRIME	Q4133	5	60	56
2	Lavery L, Fulmer J, Shebetka KA, et al. *Wounds*. 2018;30(9):283–289.[8]	GRAFIX PRIME	Q4133	26	65	34
4	Johnson EL, Marshall JT, Michael GM. *Wound Repair Regen*. 2017;25(1):145–149.[9]	GRAFIX PRIME	Q4133	7	14	-
4	Ananian CE, Davis RD, Johnson EL, et al. *Adv Wound Care (New Rochelle)*. 2019;8(11):546–554.[10]	GRAFIX PL PRIME	Q4133	41	63	65
4	D'Costa WF, Kurtz Phelan DH. *Wounds*. 2018;30(11):324 328.[11]	GRAFIX PRIME	Q4133	10	66	-
4	Smedley J, Michael GM, Tamire YG. *Int J Low Extrem Wounds*. 2016;15(4):360–365.[12]	GRAFIX PRIME	Q4133	6	100	55
4	Gibbons GW. *Adv Wound Care (New Rochelle)*. 2015;4(9):534–544.[13]	GRAFIX PRIME	Q4133	1	100	42
4	Regulski M, Jacobstein DA, Petranto RD, Migliori VJ, Nair G, Pfeiffer D. *Ostomy Wound Manage*. 2013;59(12):38–43.[14]	GRAFIX PRIME	Q4133	27	85	43
4	Nuccio EJ, Lavery LA, Min S. *J Clin Diabetes Pract*. 2016;6(4):76–81.[15]	GRAFIX PRIME	Q4133	97	-	-

Additional VLU evidence

104 patients across 6 publications

Level	Reference	Product	HCPCS Code	Patients (n)	Wound closure (%)	Time to wound closure (days)
2	Reyzelman AM, Vartivarian M, Danilkovitch A, Saunders MC. *Wounds*. 2019;31(4):97–102.[7]	GRAFIX◊ PL PRIME	Q4133	5	60	42
2	Farivar BS, Toursavadkohi S, Monahan TS, et al. *J Vasc Surg Venous Lymphat Disord*. 2019;7(2):228–233.[16]	GRAFIX PRIME	Q4133	30	53	76
4	Johnson EL, Marshall JT, Michael GM. *Wound Repair Regen*. 2017;25(1):145–149.[9]	GRAFIX PRIME	Q4133	10	70	-
4	Ananian CE, Davis RD, Johnson EL, et al. *Adv Wound Care (New Rochelle)*. 2019;8(11):546–554.[10]	GRAFIX PL PRIME	Q4133	19	47	30
4	D'Costa WF, Kurtz Phelan DH. *Wounds*. 2018;30(11):324–328.[11]	GRAFIX PRIME	Q4133	6	100	25
4	Regulski M, Jacobstein DA, Petranto RD, Migliori VJ, Nair G, Pfeiffer D. *Ostomy Wound Manage*. 2013;59(12):38–43.[14]	GRAFIX PRIME	Q4133	34	68	37

Published evidence beyond DFU and VLU

GRAFIX◊ PL PRIME and GRAFIX PRIME (Q4133) have been shown to improve healing outcomes for patients across multiple separate publications for non DFU and non VLU wounds, including surgical or trauma related wounds, pressure ulcers, and other lower extremity wounds.[7,9,10,13,14,17–29] In addition, wound recurrence and other adverse outcomes were measured for 333, 362 DLEU for Medicare beneficiaries, where GRAFIX was shown to have significant benefit versus SOC.[5]

Other lower extremity wounds

8 patients across 4 publications

Level	Reference	Product	HCPCS Code	Patients (n)	Wound closure (%)	Time to wound closure (days)
4	Johnson EL, Marshall JT, Michael GM. *Wound Repair Regen.* 2017;25(1):145–149.[9]	GRAFIX PRIME	Q4133	3	33	-
4	Anselmo DS, McGuire JB, Love E, Vlahovic T. *Wounds.* 2018;30(3):57–61.[17]	GRAFIX PRIME	Q4133	1	100	28
4	Suzuki K, Michael G, Tamire Y. *J Wound Care.* 2016;25(Sup10):S25–S31.[18]	GRAFIX PRIME	Q4133	3	100	96
4	Regulski MJ, Danilkovitch A, Saunders MC. *Clin Case Rep.* 2019;7(3):456–460.[19]	GRAFIX PRIME	Q4133	1	100	98

Surgical or trauma wounds

59 patients across 11 publications

Level	Reference	Product	HCPCS Code	Patients (n)	Wound closure (%)	Time to wound closure (days)
4	Johnson EL, Marshall JT, Michael GM. *Wound Repair Regen.* 2017;25(1):145–149.[9]	GRAFIX◊ PRIME	Q4133	11	82	-
4	Johnson EL, Saunders M, Thote T, Danilkovitch A. *Wounds.* 2021;33(2):34–40.[20]	GRAFIX PRIME	Q4133	19	84	40
4	Ananian CE, Davis RD, Johnson EL, et al. *Adv Wound Care (New Rochelle).* 2019;8(11):546–554.[10]	GRAFIX PL PRIME	Q4133	10	70	60
4	Ang J, Liou C-K D, Schneider HP. *Clin Podiatr Med Surg* 2018;35(3):311–321.[21]	GRAFIX PRIME	Q4133	2	100	-
4	Lavor MA, Michael GM, Tamire YG, Dorofee ND. *Eplasty.* 2018;18:e22.[22]	GRAFIX PRIME	Q4133	6	100	-
4	Suzuki K, Michael G, Tamire Y. *J Wound Care.* 2016;25(Sup10):S25–S31.[18]	GRAFIX PRIME	Q4133	6	100	52
4	Fife TA, Thote T, Saunders MC. *Clin Case Rep.* 2020;8(4):757–760.[23]	GRAFIX PRIME	Q4133	1	100	21
4	Dress CM, Tassis EK. *J Surg Case Rep.* 2018;2018(3):rjy055.[24]	GRAFIX PRIME	Q4133	1	100	-
4	Sun XP, Wilson AG, Michael GM. *J Foot Ankle Surg.* 2018;57(3):583–586.[25]	GRAFIX PRIME	Q4133	1	100	-
4	Gupta RJ, Connelly ST, Silva RG, Gwilliam NR. *Plast Reconstr Surg Glob Open.* 2018;6(1):e1638.[26]	GRAFIX PRIME	Q4133	1	100	-
4	Bain MA, Vincent J. *Plast Reconstr Surg Glob Open.* 2016;4(12):e1132.[27]	GRAFIX PRIME	Q4133	1	100	168

Pressure injuries

9 patients across 5 publications

Level	Reference	Product	HCPCS Code	Patients (n)	Wound closure (%)	Time to wound closure (days)
2	Reyzelman AM, Vartivarian M, Danilkovitch A, Saunders MC. *Wounds*. 2019;31(4):97–102.[7]	GRAFIX◊ PL PRIME	Q4133	1	100	35
4	Johnson EL, Marshall JT, Michael GM. *Wound Repair Regen*. 2017;25(1):145–149.[9]	GRAFIX PRIME	Q4133	3	33	-
4	Anselmo DS, McGuire JB, Love E, Vlahovic T. *Wounds*. 2018;30(3):57–61.[17]	GRAFIX PRIME	Q4133	1	100	28
4	Suzuki K, Michael G, Tamire Y. *J Wound Care*. 2016;25(Sup10):S25–S31.[18]	GRAFIX PRIME	Q4133	3	100	77
4	Gibbons GW. *Adv Wound Care (New Rochelle)*. 2015;4(9):534–544.[13]	GRAFIX PRIME	Q4133	1	100	35

Other wounds

58 patients across 8 publications

Level	Reference	Product	HCPCS Code	Patients (n)	Wound closure (%)	Time to wound closure (days)
4	Johnson EL, Marshall JT, Michael GM. *Wound Repair Regen.* 2017;25(1):145–149.*[9]	GRAFIX◊ PRIME	Q4133	12	83	-
4	Johnson EL, Saunders M, Thote T, Danilkovitch A. *Wounds.* 2021;33(2):34–40.†[20]	GRAFIX PRIME	Q4133	7	75	90
4	Ananian CE, Davis RD, Johnson EL, et al. *Adv Wound Care (New Rochelle).* 2019;8(11):546–554.‡[10]	GRAFIX PL PRIME	Q4133	28	57	60
4	Anselmo DS, McGuire JB, Love E, Vlahovic T. *Wounds.* 2018;30(3):57–61.§[17]	GRAFIX PRIME	Q4133	1	0	-
4	Gibbons GW. *Adv Wound Care (New Rochelle).* 2015;4(9):534–544.¶[13]	GRAFIX PRIME	Q4133	1	100	70
4	Regulski M, Jacobstein DA, Petranto RD, Migliori VJ, Nair G, Pfeiffer D. *Ostomy Wound Manage.* 2013;59(12):38–43.‖[14]	GRAFIX PRIME	Q4133	6	83	41
4	Johnson EL, Danilkovitch A. *Clin Case Rep.* 2018;6(11):2163–2167.**[28]	GRAFIX PRIME	Q4133	1	100	21
4	Johnson EL, Tassis EK, Michael GM, Whittinghill SG. *Medicine (Baltimore).* 2017;96(49):e9045.††[29]	GRAFIX PRIME	Q4133	2	100	52.5

*Wounds included trauma , burn, pyoderma, polyneuropathic, dog bite, and vasculitis. †Wounds included burns, pressure injury, chronic ulcer, necrotizing fasciitis, and pilonidal cyst. ‡Wounds included pressure injury, arterial wound, chronic wound, open hematoma, gangrenous wounds and other undisclosed wound types. §Wounds included chronic ulcer, arterial ulcer, pressure ulcer, and pyoderma gangrenosum ulcer. ¶Shrapnel wound. ‖Wounds included pressure ulcers and non venous vascular. **Nasal wound. ††Burn wounds.

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References:

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 multi centre, controlled, randomised, blinded, clinical trial. *Int Wound J*. 2014;11(5):554–560. **2.** Dhillon Y, Levine L, Tovmassian G, et al. A multicenter, randomized, controlled, clinical trial evaluating a lyopreserved amniotic membrane in the treatment of venous leg ulcers. *Health Sci Rep*. 2025;8(5):e70819. **3.** Raspovic KM, Wukich DK, Naiman DQ, et al. 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. **4.** DaVanzo J, Hartzman A, Surfield C, Dobson A. Cryopreserved placental membrane allograft reduces the likelihood of developing a new or recurring foot ulcer and all cause mortality in diabetic patients, when compared to other cellular and tissue based products. *Adv Wound Care (New Rochelle)*. 2022;12(4):169–176. **5.** Padula WV, Ramanathan S, Cohen BG. Comparative effectiveness of placental allografts in the treatment of diabetic lower extremity ulcers and venous leg ulcers in U.S. Medicare beneficiaries: a retrospective observational cohort study using real world evidence. *Adv Wound Care (New Rochelle)*. 2024;13(7):350–362. **6.** Davis KE, Killeen AL, Farrar D, Raspovic KM, Berriman Rozen ZD, Malone M. Lyopreserved amniotic membrane is cellularly and clinically similar to cryopreserved construct for treating foot ulcers. *Int Wound J*. 2020;17(6):1893–1901. **7.** Reyzelman AM, Vartivarian M, Danilkovitch A, Saunders MC. A prospective, single center, open label case series evaluating the clinical outcomes of lyopreserved placental membrane containing viable cells in the treatment of chronic wounds. *Wounds*. 2019;31(4):97–102. **8.** Lavery L, Fulmer J, Shebetka KA, et al. Open label extension phase of a chronic diabetic foot ulcer multicenter, controlled, randomized clinical trial using cryopreserved placental membrane. *Wounds*. 2018;30(9):283–289. **9.** Johnson EL, Marshall JT, Michael GM. 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. **10.** Ananian CE, Davis RD, 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. **11.** D'Costa WF, Kurtz Phelan DH. Surgical application of viable cryopreserved placental membrane for the treatment of chronic wounds in 12 high risk patients. *Wounds*. 2018;30(11):324–328. **12.** Smedley J, Michael GM, Tamire YG. Wound closure in smoking peripheral arterial disease patients with treatment refractory ulcerations: a 12 month follow up case series. *Int J Low Extrem Wounds*. 2016;15(4):360–365. **13.** Gibbons GW. GRAFIX, a cryopreserved placental membrane, for the treatment of chronic/stalled wounds. *Adv Wound Care (New Rochelle)*. 2015;4(9):534–544. **14.** Regulski M, Jacobstein DA, Petranto RD, Migliori VJ, Nair G, Pfeiffer D. A retrospective analysis of a human cellular repair matrix for the treatment of chronic wounds. *Ostomy Wound Manage*. 2013;59(12):38–43. **15.** Nuccio EJ, Lavery LA, Min S. Innovative treatment of chronic diabetic foot ulcer in a controlled randomized clinical trial produces fewer adverse events, faster wound closure, and lower costs. *J Clin Diabetes Pract*. 2016;6(4):76–81. **16.** 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 Vasc Surg Venous Lymphat Disord*. 2019;7(2):228–233. **17.** Anselmo DS, McGuire JB, Love E, Vlahovic T. Application of viable cryopreserved human placental membrane grafts in the treatment of wounds of diverse etiologies: a case series. *Wounds*. 2018;30(3):57–61. **18.** Suzuki K, Michael G, Tamire Y. Viable intact cryopreserved human placental membrane for a non surgical approach to closure in complex wounds. *J Wound Care*. 2016;25(Sup10):S25–S31. **19.** Regulski MJ, Danilkovitch A, Saunders MC. Management of a chronic radiation necrosis wound with lyopreserved placental membrane containing viable cells. *Clin Case Rep*. 2019;7(3):456–460. **20.** Johnson EL, Saunders M, Thote T, Danilkovitch A. Cryopreserved placental membranes containing viable cells result in high closure rate of nonhealing upper and lower extremity wounds of non diabetic and non venous pathophysiology. *Wounds*. 2021;33(2):34–40. **21.** Ang J, Liou C K D, Schneider HP. The role of placental membrane allografts in the surgical treatment of tendinopathies. *Clin Podiatr Med Surg*. 2018;35(3):311–321. **22.** Lavor MA, Michael GM, Tamire YG, Dorofee ND. Meshed split thickness autograft with a viable cryopreserved placental membrane overlay for lower extremity recipient sites with increased risk of graft failure. *Eplasty*. 2018;18:e22. **23.** Fife TA, Thote T, Saunders MC. Management of a complex scalp defect with cryopreserved placental membrane containing viable cells resulted in rapid wound closure. *Clin Case Rep*. 2020;8(4):757–760. **24.** Dress CM, Tassis EK. A case of Dupuytren's disease managed with viable cryopreserved placental membrane adjunct to open palmar fasciectomy. *J Surg Case Rep*. 2018;2018(3):rjy055. **25.** Sun XP, Wilson AG, Michael GM. Open surgical implantation of a viable intact cryopreserved human placental membrane for the treatment of recalcitrant plantar fasciitis: case report with greater than 2 year follow up duration. *J Foot Ankle Surg*. 2018;57(3):583–586. **26.** Gupta RJ, Connelly ST, Silva RG, Gwilliam NR. Use of viable cryopreserved placental membrane as an adjunct to facial keloid resection. *Plast Reconstr Surg Glob Open*. 2018;6(1):e1638. **27.** Bain MA, Vincent J. Management of a complex excoriation disorder induced wound with a viable cryopreserved placental membrane. *Plast Reconstr Surg Glob Open*. 2016;4(12):e1132. **28.** Johnson EL, Danilkovitch A. Nonsurgical management of a large necrotic nasal tip wound using a viable cryopreserved placental membrane. *Clin Case Rep*. 2018;6(11):2163–2167. **29.** Johnson EL, Tassis EK, Michael GM, Whittinghill SG. Viable placental allograft as a biological dressing in the clinical management of full thickness thermal occupational burns: two case reports. *Medicine (Baltimore)*. 2017;96(49):e9045.

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