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Solventum™ Promogran™ Matrix Family Monograph

Solventum™ Promogran Prisma™ Collagen Matrix with ORC and Silver and Solventum™ Promogran™ Collagen Matrix with ORC



Preface

The increasing prevalence of wounds that fail to heal with standard therapies has led to the development of advanced wound dressings designed to target wound environments that can delay healing. Both Solventum™ Promogran Prisma™ Collagen Matrix with ORC and Silver and Solventum™ Promogran™ Collagen Matrix with ORC help maintain a physiologically moist microenvironment that is conducive to granulation tissue formation, epithelialisation and can significantly increase the number of wounds closed.

This document will provide the following:

- Introduction to Promogran Prisma Matrix and Promogran Matrix
- Clinical literature review of Promogran Prisma Matrix and Promogran Matrix
- Description of Promogran Prisma Matrix and Promogran Matrix
- Science supporting Promogran Prisma Matrix and Promogran Matrix
- Case studies

Introduction

Healthcare systems are being challenged to manage an increasing number of wounds that have failed to complete an orderly process of healing despite treatment with standard therapies. Factors contributing to these nonhealing (chronic) wounds include ageing populations, increasing prevalence of comorbid conditions (e.g., diabetes, obesity) that can impair a patient's healing capability and imbalances within the wound microenvironment.

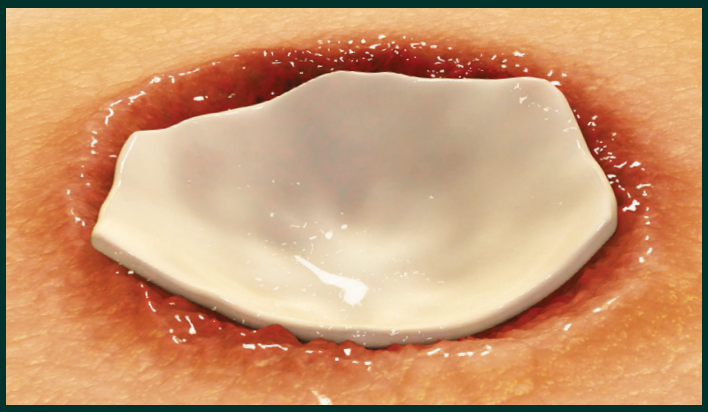
Research into the pathophysiology of wound healing has provided insight into the distinctions between healing and nonhealing wound environments. In an acute wound that achieves healing, there is an orderly transition through the repair processes starting with removal of damaged tissue and ultimately leading to new tissue formation and reepithelialisation. The microenvironment of a chronic nonhealing wound is characterised by a prolonged inflammatory phase, in which proteases (especially human neutrophil-derived elastase [HNE] and matrix metalloproteinases [MMPs]) degrade the growth factors and extracellular matrix required to transition to the proliferative phase of healing.

Promogran Prisma Matrix and Promogran Matrix advanced wound dressings are uniquely formulated with collagen and oxidized regenerated cellulose (ORC). Promogran Prisma Matrix has the added benefit of silver, a well-known antimicrobial agent.

How the dressings work

In the presence of exudate, Promogran Prisma Matrix and Promogran Matrix transform into a soft, conformable, biodegradable gel, allowing contact with all areas of the wound. Promogran Prisma Matrix and Promogran Matrix modulate and re-balance the wound environment by the unique combination of:

1. Binding and inactivation of proteases (i.e. matrix metalloproteases, elastase and plasmin) which have been shown to be detrimental in excess in chronic wounds.
2. Binding and protection of naturally occurring growth factors against degradation by these excess proteases.



These naturally occurring, protected, growth factors are released back into the wound, while the detrimental proteases remain inactive upon bio-degradation of the Promogran Prisma Matrix and Promogran Matrix. During dressing changes, it is not necessary to remove any residual Promogran Prisma Matrix or Promogran Matrix.

Promogran Prisma Matrix and Promogran Matrix have been on the market for over 20 years. In that time, they have been the subject of multiple clinical and preclinical studies (Figure 1). Promogran Matrix Family has demonstrated its effectiveness through multiple clinical studies including Randomised Controlled Trials (RCTs) that were systematically reviewed in meta-analysis.

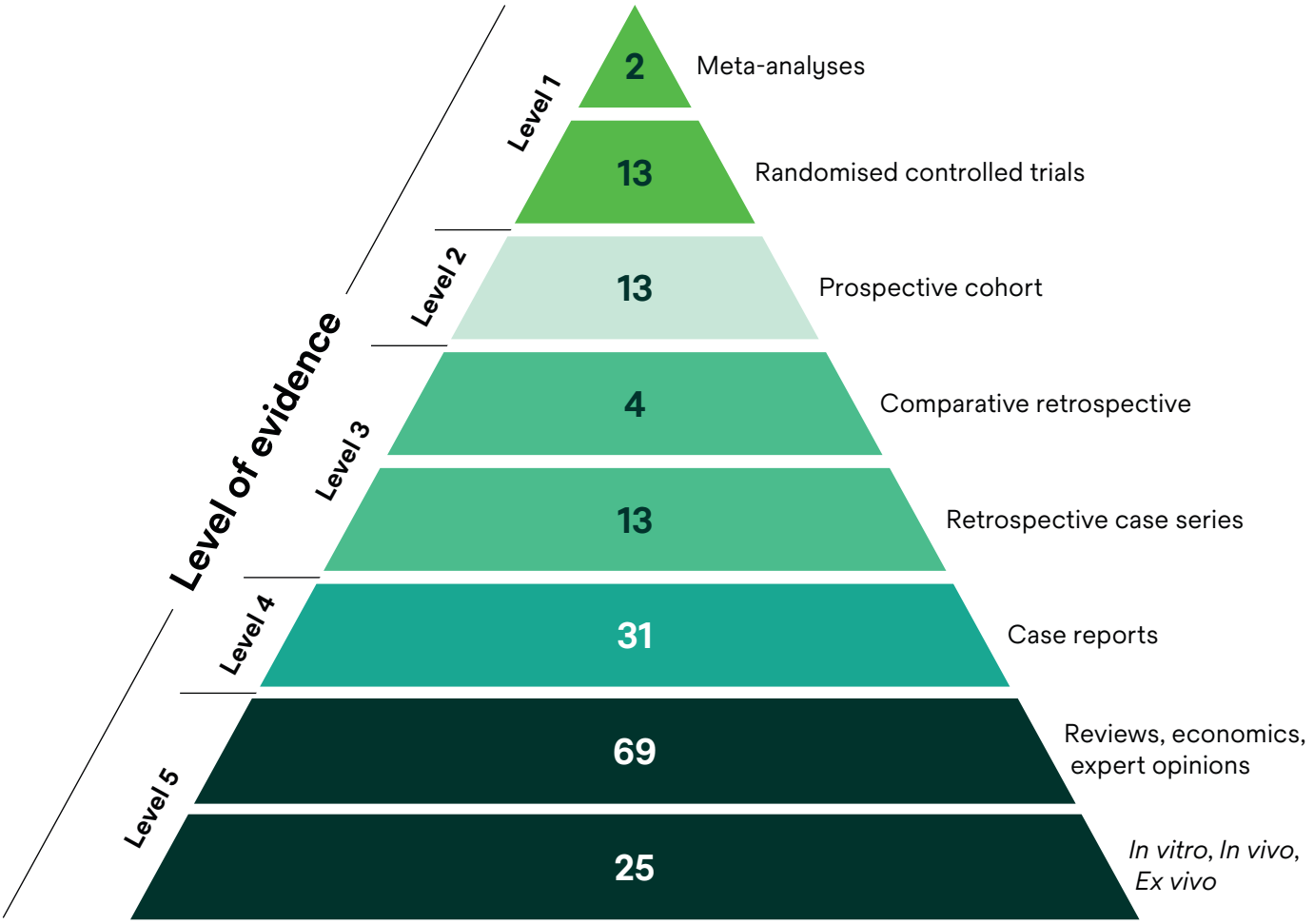


Figure 1. Promogran Prisma Matrix and Promogran Matrix published clinical literature.

A literature search performed in February of 2024 was used to compile publications reporting on use of Promogran Prisma Matrix and/or Promogran Matrix. Off-topic articles, veterinary studies, study protocols, letters, conference abstracts and posters, and articles published in languages other than English were excluded.

Clinical evidence review

Key clinical studies, including RCTs, meta-analyses, and retrospective studies, have compared Promogran Prisma Matrix and/or Promogran Matrix to standard care **(Table 1)**. These studies have shown that the use of Promogran Matrix Family results in higher rates of wound closure, improved wound management success rates and lower total cost of treatment.

Table 1. Key Clinical Evidence supporting the use of Promogran Prisma Matrix/Promogran Matrix.

Year/author/ evidence level	Wound type	Study type and patients	Results/conclusions
2021 Chowdhry[1] 1	DFU VLU PI	• A meta-analysis of chronic wounds • Promogran Matrix and Promogran Prisma Matrix (*n*=1224) vs. Control (standard of care; *n*=443)	Compared to standard care, wounds receiving Promogran Matrix Family dressings: • were 3.4 times more likely to achieve closure (95% CI 1.15, 10.1; *p*=0.027) (10-study comparison) • had a significantly greater percent reduction in the wound area (*p*=0.006) (4-study comparison) • had a significantly higher wound area reduction (*p*=0.017) (2-study comparison)
2022 Shu *et al*[2] 1	VLU DFU PU	• A meta-analysis of chronic wounds • Collagen dressing (*n*=485) vs. Control (saline moistened dressing) (*n*=476)	• The collagen dressing treatment group had a higher wound healing rate (risk ratio [RR]=1.53; 95% CI, 1.33–1.77) and a higher healing velocity (MD, 2.69; 95% CI, 0.87–4.51), compared to Control • Similar adverse events related to dressings were reported (RR=0.67; 95% CI, 0.44–1.01)
2017 Cullen *et al*[3] 1	VLU	• A 12-week RCT involving VLU patients • Promogran Prisma Matrix in conjunction with standard of care (*n*=22) vs. Control (standard of care alone; *n*=27)	• Intent-to-treat analysis showed a mean percentage wound area reduction at 12 weeks of 85.6% for the intervention group vs. 72.5% for the control group • A higher healing rate was reported in the intervention group compared with patients who received standard of care only at both week 4 (23% vs. 11%) and week 12 (64% vs. 59%)
2015 Kloeters *et al*[4] 1	PI	• A 12 week RCT involving PI patients • Promogran Matrix (*n*=23) vs. Control (Foam Dressing; *n*=10)	• Compared to the Control group, the Promogran Matrix treated group showed a significantly faster (*p*<0.05) healing rate

DFU: Diabetic Foot Ulcer; **PI:** Pressure Injury; **VLU:** Venous Leg Ulcer; **PU:** Pressure Ulcer

Clinical evidence review (cont.)

Year/author/ evidence level	Wound type	Study type and patients	Results/conclusions
2013 Gottrup *et al*[5] 1	DFU	• A 14-week multicentre RCT involving DFU patients • Promogran Prisma Matrix (*n*=24) vs. Control (best standard of care; *n*=15)	• Significantly more responders (≥50% reduction in wound area measured by the Margolis index) in the Promogran Prisma Matrix group compared with the Control group (79% vs. 43%, respectively; *p*=0.035) at week 4 • There were significantly fewer withdrawals due to infection in the Promogran Prisma Matrix group compared with the Control group (0% vs. 31%, respectively; *p*=0.012) • At week 14, the number of wounds completely healed was 52% vs. 31%, respectively
2011 Motzkau *et al*[6] 1	Diabetic foot lesions	• An RCT involving chronic diabetic foot lesion patients • Promogran Matrix (*n*=13) vs. Control (standard good wound care; *n*=6)	• No differences in the mRNA levels of MMPs, IL-1β and TNF-α were observed between both groups
2011 Ulrich *et al*[7] 1	DFU	• A 12 week RCT measuring wound area reduction and biochemistry in DFU patients (Wagner Status 2–4) • Promogran Matrix (*n*=22) vs. Control (hydrocolloid dressing; *n*=10)	• The group treated with Promogran Matrix showed significant differences (*p*<0.05) in wound area reduction on days 14 and 28 compared to Control • Wound fluid biochemistry data also indicated a more favourable environment in wounds to which Promogran Matrix was allocated
2008 Smeets *et al*[8] 1	VLU	• A 12 week RCT involving VLU patients • Promogran Matrix (*n*=17) vs. Control (hydrocolloid dressing; *n*=10)	• Wound fluid biochemistry data indicated a more favorable environment in wounds to which Promogran Matrix was allocated
2007 Kakagia *et al*[9] 1	DFU	• An 8 week RCT involving DFU patients • Promogran Matrix (*n*=17) vs. autologous growth factors (*n*=17) vs. combination Promogran Matrix + autologous growth factors (*n*=17)	• Promogran Matrix was more effective at reducing ulcer size than autologous growth factors; however, the combination was significantly better than the other groups (*p*<0.001)
2007 Lazaro-Martinez *et al*[10] 1	DFU	• A 6 week single centre RCT involving DFU patients • Promogran Matrix (*n*=20) vs. Control (moist wound healing — standard wound care protocol; *n*=20)	• Significantly more wounds achieved complete healing with Promogran Matrix vs. Control (63% vs. 15%; *p*<0.03) • Mean time to achieve healing was 23.3 days in the Promogran Matrix group compared with 40 days in the Control group (*p*<0.01)

Clinical evidence review (cont.)

Year/author/ evidence level	Wound type	Study type and patients	Results/conclusions
2006 Lobmann *et al*[11] 1	DFU	• A single-blinded RCT measuring wound size reduction and biochemistry in DFU patients over an 8 day period • Promogran Matrix (*n*=18) vs. Control (standard good wound care; *n*=15)	• No differences detected between both groups and at the 3 time points for the mRNA levels of MMPs as well as of IL-1β and TNF-α • MMP levels in wound tissue (analysed by ELISA) were not significantly different between both groups
2005 Nisi *et al*[12] 1	PI	• A 6 week RCT involving PI patients • Promogran Matrix (*n*=40) vs. Control (moist wound healing — Vaseline gauze and hydropolymer patch; *n*=40)	• More patients with pressure injuries completely healed in the Promogran Matrix group compared to the Control group (90% vs. 70%, respectively) • The time to complete healing was shorter and more cost effective in the Promogran Matrix group (360 days overall hospitalisation vs. 1,164 days in the Control group)
2005 Wollina *et al*[13] 1	VLU	• A 2 week RCT involving chronic VLU patients • Promogran Matrix + good ulcer care (*n*=30) vs. Control (good ulcer care only; *n*=10)	• A significantly greater mean wound area reduction was achieved in the Promogran Matrix group compared to Control ($p<0.05$) • Wounds allocated to the Promogran Matrix group reported a significant reduction in pain scores at week 2 (baseline mean pain score was 8.72 compared to 3.84 at week 2, $p<0.05$)
2002 Veves *et al*[14] 1	DFU	• A 12-week multicentre RCT involving DFU patients • Promogran Matrix (*n*=138) vs. saline-moistened gauze (*n*=138)	• More wounds achieved complete healing with Promogran Matrix, especially in wounds of <6 months duration (45% vs. 33%, $p=0.056$)
2002 Vin *et al*[15] 1	VLU	• A 12-week multicentre RCT involving VLU patients • Promogran Matrix + compression (*n*=37) vs. Control (nonadherent dressing + compression; *n*=36)	• 47.6% more wounds (62% vs. 42%, $p=0.0797$) were characterised as healing or improved (≥ 50% wound area reduction at week 12) in the Promogran Matrix + compression group than in the Control group • A significant reduction in wound areas was achieved in the Promogran Matrix + compression group compared to Control (54.4% vs. 36.5%, $p<0.0001$)
2010 Snyder *et al*[16] 3	Chronic wounds, PU, postsurgical wounds, locally infected wounds, DFU, VLU	• A retrospective chart study of sequential treatment with Promogran Prisma Matrix and Promogran Matrix dressings • Sequential Promogran Prisma Matrix and Promogran Matrix (*n*=873) vs. Control (saline gauze dressing; *n*=101)	• After 2 months, 95% of the Promogran Matrix and Promogran Prisma Matrix treated wounds closed at a total cost of $2,145 vs. 7.2% and a total cost of $7,350 for Control • After 6 months, 43% of saline-treated wounds healed at a total cost of $22,050

Product descriptions

Promogran Prisma Matrix and Promogran Matrix

Promogran Prisma Matrix consists of 44% ORC, 55% collagen and 1% silver/ORC of which 25% of the total weight of the silver-ORC is silver **(Figure 2)**. Promogran Prisma Matrix also has an increased density (approximately twice as much collagen and ORC) compared to the Promogran Matrix.

Promogran Matrix is composed of 45% ORC and 55% collagen.

There are many similarities between the two matrix dressings. In the presence of fluid/exudate in the wound, both dressings transform into a soft, conformable, biodegradable gel that allows contact with all areas of the wound. In a wound with low or no exudate, the matrix dressing should be hydrated with saline solution to initiate the transformation of the dressing into a gel matrix. Both matrix dressings must be covered with a semiocclusive or nonocclusive secondary dressing and secured with an elastic or cohesive wrap, tape or by other methods **(Figure 3)**.

With the supervision of a healthcare professional, both dressings may be used under compression bandages. Also, both dressings can be cut with sterile scissors to fit the wound shape or premoistened to form a gel that can be moulded to fit the wound. Residual matrix from both dressings does not need to be removed during dressing changes.

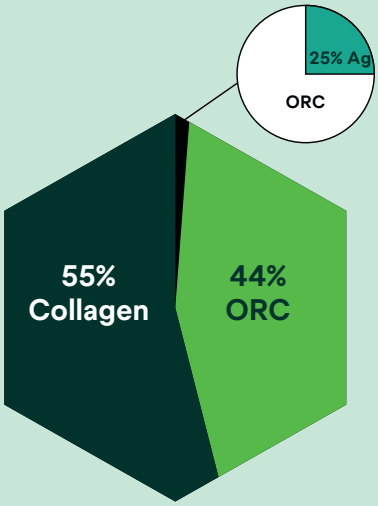


Figure 2. Promogran Prisma Matrix composition

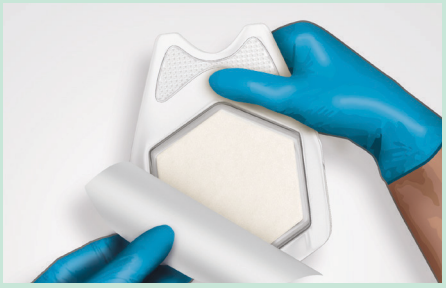


Figure 3A. Removal from package.

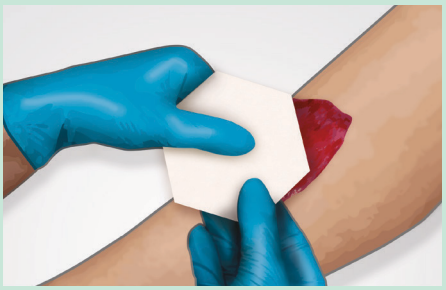


Figure 3B. Placement over wound.



Figure 3C. Application of secondary dressing.

Figure 3. Dressing application: Promogran Prisma Matrix and Promogran Matrix.

Indications for use

Promogran Prisma Matrix is intended to be used for the management of wounds which are clear of necrotic tissue, and is indicated for use with full-thickness and partial thickness wounds such as:

- Diabetic ulcers
- Venous ulcers
- Pressure ulcers
- Ulcers caused by mixed vascular aetiologies
- Traumatic and surgical wounds
- Donor sites

Promogran Prisma Matrix can be used under compression therapy.

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- Diabetic ulcers
- Venous ulcers
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- Ulcers caused by mixed vascular aetiologies
- Traumatic and surgical wounds

Promogran Matrix can be used under compression therapy.



Contraindications

Promogran Prisma Matrix is contraindicated in patients with known hypersensitivity to the components of this product, i.e., ORC, collagen and silver. Discontinue use if signs of sensitivity appear.

Promogran Prisma Matrix is not indicated for patients with extensive burns.

Promogran Matrix is contraindicated in patients with known hypersensitivity to the components of this product, i.e., ORC and collagen. Discontinue use if signs of sensitivity appear.

Please refer to the Instructions for Use for the full list of contraindications, warnings and precautions.

Precautions

Promogran Prisma Matrix and Promogran Matrix may be used when visible signs of infection are present in the wound area only when proper medical treatment addresses the underlying cause.

Promogran Prisma Matrix is not intended to be a substitute for appropriate treatment of infection. Clinicians and healthcare professionals should be aware that there are very limited data on prolonged and repeated use of silver containing dressings, particularly in children and neonates.

Promogran Matrix should be checked at regular intervals. If the condition of the wound deteriorates or adverse reaction observed, discontinue use and consult a health care professional.

Supporting science

Promogran Prisma Matrix and Promogran Matrix

The following summaries are preclinical descriptions of benchtop *in vitro,* laboratory animal *in vivo* and *ex vivo* studies supporting ORC/collagen dressing technology.

An *in vitro* study evaluated the effect of an ORC/collagen dressing on wound fluid taken from patients with diabetic foot ulcers (DFUs) with surface area >1cm² and duration >30 days.[17] Compared to Control samples (wound fluid only), samples exposed to ORC/collagen showed a marked decrease in collagenase-like activity during the first hour of testing, an effect that was maintained for the rest of the 28 hour test. MMP-2 and MMP-9 levels were also significantly reduced in wound fluid incubated with ORC/collagen. Other tests demonstrated that ORC/collagen was more effective at scavenging oxygen-free radicals than collagen/alginate or carboxymethyl-cellulose and that ORC was able to bind iron and zinc ions. Compared to ORC and collagen tested separately, the combination of ORC/collagen was able to bind and protect a significantly greater amount of growth factors in wound fluid. This *in vitro*, non-clinical study demonstrated that ORC/collagen was able to bind and inactivate proteases while also having no detrimental effect on growth factors in chronic wound fluid.[17]

Another preclinical study also demonstrated that ORC/collagen has a positive role in promoting cell proliferation.[18] This study investigated the effects of ORC/collagen on fibroblast migration and proliferation *in vitro* and its effects on accelerated wound repair in a diabetic mouse model. *In vitro* results showed that ORC/collagen was found to promote fibroblast proliferation and cell migration. *In vivo* studies demonstrated that ORC/collagen significantly ($p<0.01$) accelerated wound closure in a mouse model of diabetic wound healing and resulted in a measurable improvement in the histological appearance of wound tissues.[18]

An *in vivo* rat model was used to investigate the effects of ORC/collagen on dermal and epidermal healing and growth factor concentration in acute wounds.[19] Full-thickness excision wounds were created, and each wound received either an ORC/collagen plus a hydrocolloid dressing or a hydrocolloid dressing alone. Results showed that rat wounds treated with ORC/collagen displayed a significantly ($p>0.05$) greater area of reepithelialisation than wounds treated with hydrocolloid alone (Control). Furthermore, ORC/collagen-treated wounds showed significantly higher levels of platelet-derived growth factor and increased dermal and epidermal insulin-like growth factor-I protein concentration compared to Control wounds. No significant differences were found in collagen morphology or deposition, neoangiogenesis or vascular endothelial growth factor concentration between both groups. The authors concluded that in this model, ORC/collagen enhanced epidermal regeneration and increased specific growth factor concentrations, which had beneficial effects on acute wounds.[19]

Reference clinical case studies

Cited case studies

The following represent real-world product applications. As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary, depending on patient circumstances and conditions.

Case study 1

Patient was a 70-year-old white male with a history of long-standing diabetes mellitus and diabetic peripheral neuropathy who presented with a chronic, nonhealing DFU on the right foot **(Figure 4A)**. Multiple treatments, debridements and antibiotic topical therapy were provided by other physicians but with no success. The DFU remained a noninfected full-thickness wound with hypergranulation on the first submetatarsal head with minimal exudate drainage. There was no gross deformity or bony involvement. A gastrocnemius equinus contracture was noted on patient's right lower extremity that increased the forefoot pressures. Upon vascular examination, patient had intact pedal pulses with adequate ankle brachial index and digital pressures, but there was loss of protective sensation. Management consisted of a full-thickness, sharp excisional debridement into and through the subcutaneous tissue, which removed any fibrotic tissue. Wound was debrided down to a healthy pink granular base, followed by application of Promogran Prisma Matrix. An offloading boot was also provided to reduce the forefoot pressures. At 3 and 7 weeks post initiation of Promogran Prisma Matrix **(Figures 4B and 4C)**, the DFU continued to heal. At 3 months, the DFU was fully closed **(Figure 4D)**.



Figure 4A. DFU at presentation.



Figure 4B. 3 weeks post sharp excisional debridement and initiation of Promogran Prisma Matrix, wound size was notably decreased.



Figure 4C. At 7 weeks, DFU was nearly reepithelialised.



Figure 4D. After 3 months of Promogran Prisma Wound Balancing Matrix and offloading, DFU was closed.

Patient data and photos courtesy of Lawrence A. DiDomenico, DPM, FACFAS, FACFAOM, CWS, FCCWS; Ankle and Foot Care Centers/Ohio College of Podiatric Medicine, Youngstown, Ohio.

Reference clinical case studies

Case study 2

The patient was a 59-year-old female hospitalised with the diagnosis of nonhealing left transmetatarsal amputation site. Past medical history was significant for chronic obstructive pulmonary disease, hypertension, hypothyroidism, renal failure requiring haemodialysis 3 times per week, and peripheral vascular disease. Past surgical history was significant for: right below the knee amputation, left femoral-popliteal bypass, and a left transmetatarsal amputation, due to nonhealing toe wounds.

Upon admission, the left transmetatarsal amputation was debrided via pulse lavage and Negative Pressure Wound Therapy System (Solventum™ V.A.C.® Therapy) to prepare the wound for a split-thickness skin graft (STSG). Nine days after presentation, the patient underwent surgical debridement of the left transmetatarsal amputation and fourth metatarsal resection with placement of a STSG over the defect **(Figure 5A)**.

The donor site on the left lateral thigh measured 10cm x 7cm and was covered initially with a thin film dressing left in place until postoperative day 5, and was changed and ordered to be changed weekly. On postoperative day 11, the donor site had become more exudative, requiring an increased frequency of dressing changes by the staff daily. The donor site was reevaluated and found to have a gelatinous slough covering the base. The measurements remained the same from the initial harvest. The skin surrounding the donor site developed dermatitis **(Figure 5B)**.

The donor site was cleansed with antibacterial soap and normal saline, rinsed, and then patted dry with the application of skin prep to protect the surrounding skin. Promogran Prisma Matrix was applied over the donor site and covered with a hydropolymer foam dressing **(Figure 5C)**. On postoperative day 14, the dressing was changed. There was an increase in healthy granulation tissue, and new areas of reepithelialisation were noted. The surrounding dermatitis had also improved **(Figure 5D)**.



Figure 5A. STSG over wound.

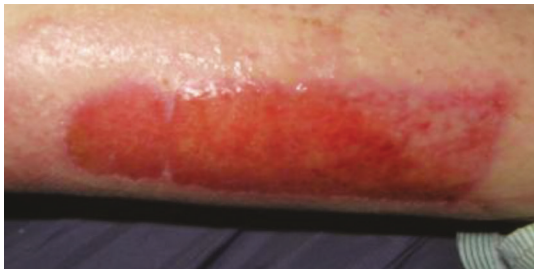


Figure 5B. Left lateral thigh donor site with dermatitis.



Figure 5C. Hydropolymer foam dressing applied over Promogran Prisma Matrix, which covered the donor site.



Figure 5D. Donor site postoperative day 14 after removing the Promogran Prisma Matrix and hydropolymer foam dressings.

Patient data and photos courtesy of Patricia Brennan RN, BSN, CWOCN; South Seminole Hospital, Longwood, FL.

Reference clinical case studies

Case study 2 continued

On postoperative day 15, the surgeon evaluated the donor site, so the dressing was changed. The wound continued to improve with more epithelial islets noted **(Figure 5E)**. The Promogran Prisma Matrix and the hydropolymer foam dressings were left in place and changed on postoperative day 17, prior to the patient's discharge to an extended care facility **(Figure 5F)**.

The patient's donor site reepithelialised completely by the next dressing change on postoperative day 20.

The dressing maintained a moist wound environment without maceration of the peri-donor skin, and the improved exudate management with the combination of the Promogran Prisma Matrix and the hydropolymer foam dressings helped the dermatitis resolve.



Figure 5E. Donor site postoperative day 15 after removal of Promogran Prisma Matrix and hydropolymer foam dressings.



Figure 5F. Donor site postoperative day 17 at time of hospital discharge.

Reference clinical case studies

Case study 3

A 74-year-old male presented with a 2.5cm, 7-month-old diabetic foot ulcer (DFU) on the bottom of the right foot **(Figure 6A)**. The patient had a history of diabetes mellitus and had previously undergone a transmetatarsal amputation.

Wound fluid and measurements were taken at wound presentation and every 2 weeks up to 14 weeks. Promogran Prisma Matrix was applied over the wound. Wound fluid was tested for elastase and MMP-9 activity using either a fluorogenic substrate or immunocapture activity assay.

At presentation, MMP-9 activity was measured at 227.2 relative fluorescence units (RFU)/minute/mL and elastase measured at 568.6 RFU/minute/mL. At week 4, the wound showed a healthy pink granulation bed and slight enlargement of the wound **(Figure 6B)**. At week 12, MMP-9 and elastase activity measured 5.4 RFU/minute/mL and 277.1 RFU/minute/mL, respectively. This decrease in activity was calculated to a 97.6% reduction of MMP-9 activity and 51.3% reduction in elastase activity. By week 14, the wound was fully reepithelialised **(Figure 6C)**.

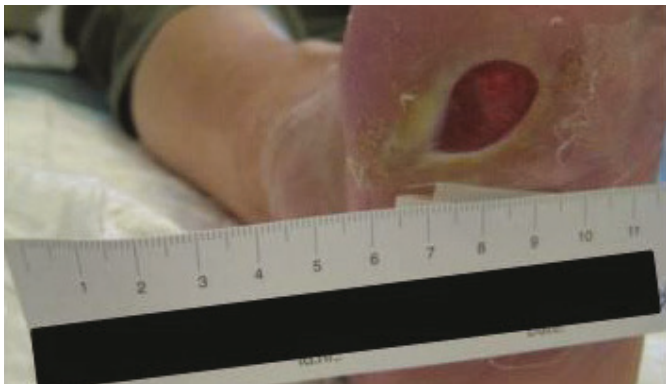


Figure 6A. Diabetic foot ulcer on bottom of right foot at presentation.



Figure 6B. Wound at week 4.

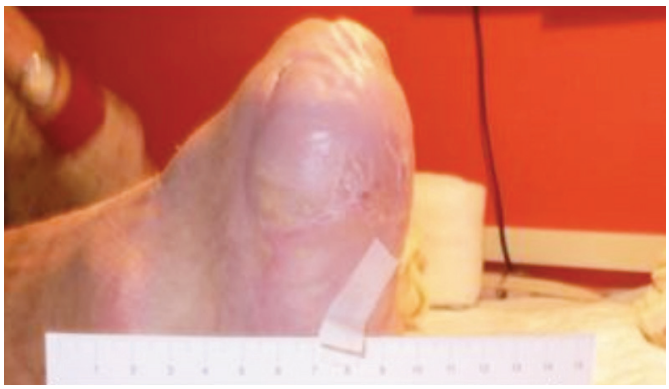


Figure 6C. Wound fully reepithelialised at week 14.

Patient data and photos courtesy of Finn Gottrup, Professor of Surgery, MD, DMSci.
Copenhagen Wound Healing Center, Department of Dermatology, Bispebjerg University Hospital, Copenhagen, Denmark.

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