

# **3M<sup>™</sup> Promogran<sup>™</sup> Matrix Family** Monograph

3M<sup>™</sup> Promogran<sup>™</sup> Collagen Matrix with ORC

3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver





# 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 3M<sup>™</sup> Promogran<sup>™</sup> Collagen Matrix with ORC and 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver help maintain a physiologically moist microenvironment that is conducive to granulation tissue formation, epithelialization, and can significantly increase the number of wounds closed. This document will provide the following:

- Introduction to Promogran Matrix and Promogran Prisma Matrix
- Clinical literature review of Promogran Matrix and Promogran Prisma Matrix
- Description of Promogran Matrix and Promogran Prisma Matrix
- Science supporting Promogran Matrix and Promogran Prisma Matrix
- Science supporting Promogran Prisma Matrix with 3M<sup>™</sup> ActiV.A.C.<sup>™</sup> Negative Pressure Wound Therapy System
- Case studies

# Introduction

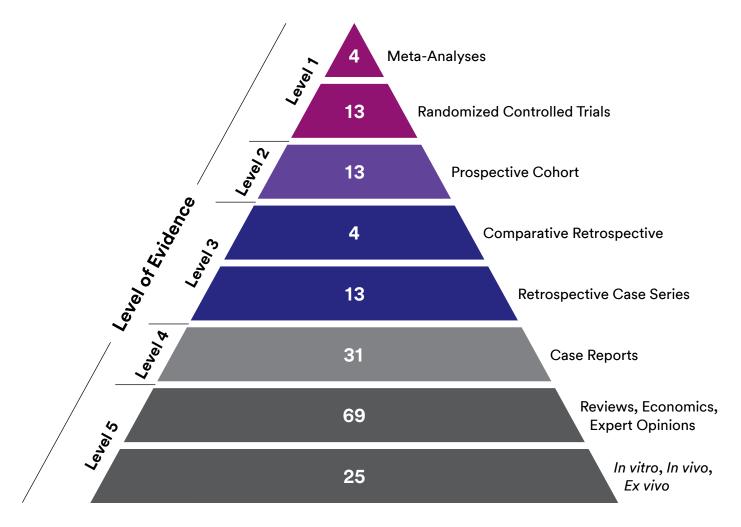
Healthcare systems in the United States and in other countries are being challenged to manage an increasing number of wounds that have failed to complete an orderly process of healing despite treatment with standard therapies. Factors contributing to these nonhealing (chronic) wounds include aging populations, 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 reepithelialization. The microenvironment of a chronic nonhealing wound is characterized 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 Matrix and Promogran Prisma 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.

Promogran Matrix and Promogran Prisma 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). 3M<sup>™</sup> Promogran<sup>™</sup> Matrix Family has demonstrated its effectiveness through multiple clinical studies including Randomized Controlled Trials (RCTs) that were systematically reviewed in meta-analysis.

**Figure 1.** 3M<sup>™</sup> Promogran<sup>™</sup> Collagen Matrix with ORC and 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver published clinical literature.



A literature search performed in February of 2024 was used to compile publications reporting on use of Promogran and/or Promogran Prisma. 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 3M<sup>™</sup> Promogran<sup>™</sup> Collagen Matrix with ORC and/or 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver to standard care **(Table 1)**. These studies have shown that the use of 3M<sup>™</sup> Promogran<sup>™</sup> 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 Matrix/Promogran Prisma Matrix.

Year/Author/ Evidence Level	Wound Type	Study Type and Patients	Results/Conclusions
2022 Chen et al <sup>1</sup>	VLUs, DFUs	<ul> <li>A meta-analysis of chronic skin wounds</li> <li>Promogran Matrix and Promogran Prisma Matrix (<i>n</i>=763) vs. Control (standard of care; <i>n</i>=758)</li> </ul>	<ul> <li>Compared to Control, the Promogran Matrix and Promogran Prisma Matrix treated group had:</li> <li>Significantly higher complete wound healing (<i>p</i>=0.03; odds ratio (OR), 1.74; 95% confidence interval (CI), 1.06–2.85)</li> <li>Higher wound relative reduction percent</li> </ul>
			<ul> <li>(p=0.02, mean difference (MD) 13.50; 95% CI, 2.39–24.61)</li> <li>Lower adverse events (p=0.04; OR, 0.63; 95% CI 0.41–0.98)</li> </ul>
2022 Shu et al <sup>2</sup>	VLUs, DFUs, PU	<ul> <li>A meta-analysis of chronic wounds</li> <li>Collagen dressing (n=485) vs. Control (saline moistened dressing) (n=476)</li> </ul>	<ul> <li>The collagen dressing treatment group had a higher wound healing rate (risk ratio [RR]=1.53; 95% Cl, 1.33–1.77), and a higher healing velocity (MD, 2.69; 95% Cl, 0.87–4.51), compared to Control</li> <li>Similar adverse events related to dressings were reported (RR=0.67; 95% Cl, 0.44–1.01)</li> </ul>
2017 Cullen et al <sup>3</sup>	VLUs	<ul> <li>A 12-week RCT involving VLU patients</li> <li>Promogran Prisma Matrix in conjunction with standard of care (n=22) vs. Control (standard of care alone; n=27)</li> </ul>	<ul> <li>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</li> <li>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%)</li> </ul>
2015 Kloeters et al <sup>4</sup>	Pls	<ul> <li>A 12-week RCT involving PI patients</li> <li>Promogran Matrix (n=23) vs. Control (Foam Dressing; n=10)</li> </ul>	• Compared to the Control group, the Promogran Matrix treated group showed a significantly faster ( <i>p</i> <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 <sup>5</sup>	DFUs	<ul> <li>A 14-week multicenter RCT involving DFU patients</li> <li>Promogran Prisma Matrix (n=24) vs. Control (best standard of care; n=15)</li> </ul>	<ul> <li>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</li> <li>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)</li> <li>At week 14, the number of wounds completely healed was 52% vs. 31%, respectively</li> </ul>
2011 Motzkau et al <sup>6</sup>	Diabetic foot lesions	<ul> <li>An RCT involving chronic diabetic foot lesion patients</li> <li>Promogran Matrix (n=13) vs. Control (standard good wound care; n=6)</li> </ul>	<ul> <li>No differences in the mRNA levels of MMPs, IL-1β and TNF-α were observed between both groups</li> </ul>
2011 Ulrich et al <sup>7</sup>	DFUs	<ul> <li>A 12-week RCT measuring wound area reduction and biochemistry in DFU patients (Wagner Status 2–4)</li> <li>Promogran Matrix (n=22) vs. Control (hydrocolloid dressing; n=10)</li> </ul>	<ul> <li>The group treated with Promogran Matrix showed significant differences (<i>p</i>&lt;0.05) in wound area reduction on days 14 and 28 compared to Control</li> <li>Wound fluid biochemistry data also indicated a more favorable environment in wounds to which Promogran Matrix was allocated</li> </ul>
2008 Smeets et al <sup>8</sup>	VLUs	<ul> <li>A 12-week RCT involving VLU patients</li> <li>Promogran Matrix (n=17) vs. Control (hydrocolloid dressing; n=10)</li> </ul>	• Wound fluid biochemistry data indicated a more favorable environment in wounds to which Promogran Matrix was allocated
2007 Kakagia et al <sup>9</sup>	DFUs	<ul> <li>An 8-week RCT involving DFU patients</li> <li>Promogran Matrix (n=17) vs. autologous growth factors (n=17) vs. combination Promogran Matrix + autologous growth factors (n=17)</li> </ul>	• 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 <sup>10</sup>	DFUs	<ul> <li>A 6-week single center RCT involving DFU patients</li> <li>Promogran Matrix (n=20) vs. Control (moist wound healing — standard wound care protocol; n=20)</li> </ul>	<ul> <li>Significantly more wounds achieved complete healing with Promogran Matrix vs. Control (63% vs. 15%; p&lt;0.03)</li> <li>Mean time to achieve healing was 23.3 days in the Promogran Matrix group compared with 40 days in the Control group (p&lt;0.01)</li> </ul>

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
2006 Lobmann et al <sup>11</sup>	DFUs	<ul> <li>A single-blinded RCT measuring wound size reduction and biochemistry in DFU patients over an 8-day period</li> <li>Promogran Matrix (<i>n</i>=18) vs. Control (standard good wound care; <i>n</i>=15)</li> </ul>	<ul> <li>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</li> <li>MMP levels in wound tissue (analyzed by ELISA) were not significantly different between both groups</li> </ul>
2005 Nisi et al <sup>12</sup>	Pls	<ul> <li>A 6-week RCT involving PI patients</li> <li>Promogran Matrix (n=40) vs. Control (moist wound healing — Vaseline gauze and hydropolymer patch; n=40)</li> </ul>	<ul> <li>More patients with pressure injuries completely healed in the Promogran Matrix group compared to the Control group (90% vs. 70%, respectively)</li> <li>The time to complete healing was shorter and more cost effective in the Promogran Matrix group (360 days overall hospitalization vs. 1,164 days in the Control group)</li> </ul>
2005 Wollina et al <sup>13</sup>	VLUs	<ul> <li>A 2-week RCT involving chronic VLU patients</li> <li>Promogran Matrix + good ulcer care (<i>n</i>=30) vs. Control (good ulcer care only; <i>n</i>=10)</li> </ul>	<ul> <li>A significantly greater mean wound area reduction was achieved in the Promogran Matrix group compared to Control (p&lt;0.05)</li> <li>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&lt;0.05)</li> </ul>
2002 Veves et al <sup>14</sup>	DFUs	<ul> <li>A 12-week multicenter RCT involving DFU patients</li> <li>Promogran Matrix (n=138) vs. saline-moistened gauze (n=138)</li> </ul>	• More wounds achieved complete healing with Promogran Matrix, especially in wounds of <6 months duration (45% vs. 33%, <i>p</i> =0.056)
2002 Vin et al <sup>15</sup>	VLUs	<ul> <li>A 12-week multicenter RCT involving VLU patients</li> <li>Promogran Matrix + compression (n=37) vs. Control (nonadherent dressing + compression; n=36)</li> </ul>	<ul> <li>47.6% more wounds (62% vs. 42%, p=0.0797) were characterized as healing or improved (≥ 50% wound area reduction at week 12) in the Promogran Matrix + compression group than in the Control group</li> <li>A significant reduction in wound areas was achieved in the Promogran Matrix + compression group compared to Control (54.4% vs. 36.5%, p&lt;0.0001)</li> </ul>
2010 Snyder et al <sup>16</sup>	Chronic wounds, PU, postsurgical wounds, locally infected wounds, DFUs, VLUs	<ul> <li>A retrospective chart study of sequential treatment with Promogran Prisma Matrix and Promogran Matrix dressings</li> <li>Sequential Promogran Prisma Matrix and Promogran Matrix (<i>n</i>=873) vs. Control (saline gauze dressing; <i>n</i>=101)</li> </ul>	<ul> <li>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</li> <li>After 6 months, 43% of saline-treated wounds healed at a total cost of \$22,050</li> </ul>

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

# 3M<sup>™</sup> Promogran<sup>™</sup> Collagen Matrix with ORC and 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver

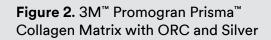
### **Product Descriptions**

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

Promogran Prisma Matrix consists of 44% ORC, 55% collagen, and 1% silver/ORC of which 1/4 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) of collagen and ORC compared to the Promogran Matrix.

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. Depending on wound exudate levels, the collagen and ORC in the Promogran Prisma Matrix may take a longer time to biodegrade in 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 secure with elastic or cohesive wrap, tape or 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 molded to fit the wound. Residual matrix from both dressings does not need to be removed during dressing changes.



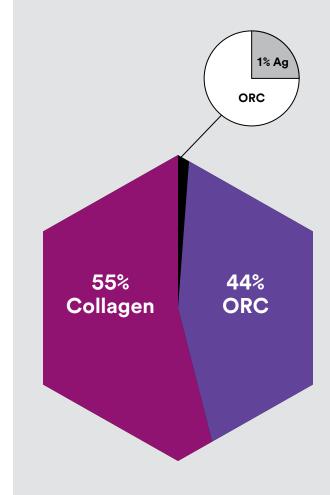


Figure 3. Dressing application: 3M<sup>™</sup> Promogran<sup>™</sup> Collagen Matrix with ORC and 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver.

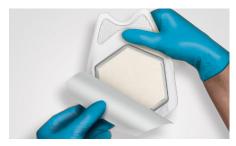


Figure 3A. Removal from package.



Figure 3B. Placement over wound.



Figure 3C. Application of secondary dressing.

# 3M<sup>™</sup> Promogran<sup>™</sup> Collagen Matrix with ORC and 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver

### **Indications for Use**

The Promogran Matrix and Promogran Prisma Matrix are intended for the management of exudating wounds including:

- Diabetic ulcers
- Venous ulcers
- Pressure injuries
- Ulcers caused by mixed vascular etiologies
- Full-thickness and partial-thickness wounds
- Donor sites and other bleeding surface wounds
- Abrasions
- Traumatic wounds healing by secondary intention
- Dehisced surgical wounds

### Contraindications

Promogran Matrix is not indicated for wounds with active vasculitis, third-degree burns, or patients with known sensitivity to ORC or collagen. Promogran Prisma Matrix is not indicated for third-degree burns or patients with known sensitivity to silver, ORC, or collagen.

### Precautions

Promogran Prisma 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.

### 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver combined <u>with</u> the 3M<sup>™</sup> ActiV.A.C.<sup>™</sup> Negative Pressure Wound Therapy System

### **Indications for Use**

Promogran Prisma Matrix can be combined with the 3M<sup>™</sup> ActiV.A.C.<sup>™</sup> Therapy System and used with 3M<sup>™</sup> V.A.C.<sup>®</sup> Granufoam<sup>™</sup> Dressing Kits, 3M<sup>™</sup> V.A.C.<sup>®</sup> Simplace<sup>™</sup> Dressing Kits, 3M<sup>™</sup> V.A.C.<sup>®</sup> Drape, and 3M<sup>™</sup> Dermatac<sup>™</sup> Drape. Under the supervision of a health care professional, Promogran Prisma Matrix can be combined with ActiV.A.C. Therapy System to manage exudating wounds, including:

- Diabetic ulcers
- Venous ulcers
- Pressure injuries
- Partial-thickness wounds
- Traumatic wounds healing by secondary intention
- Dehisced surgical wounds

### **Contraindications and Warnings\***

- Compression therapy may not be used when Promogran Prisma Matrix is used with ActiV.A.C. Therapy System
- Do not use Promogran Prisma Matrix with ActiV.A.C. Therapy System over closed incisions
- 3M<sup>™</sup> V.A.C.<sup>®</sup> Granufoam Silver<sup>™</sup> Dressing should not be used in conjunction with Promogran Prisma Matrix due to unknown potential cumulative effect of silver

### Precautions

Please review the Instructions for Use and product labeling for complete safety information. As described in the product labeling, when used with the ActiV.A.C. Therapy System, seven slits are cut into the Promogran Prisma by the health care provider before applying the dressing and the components of the ActiV.A.C. Therapy System.

# Science Supporting 3M<sup>™</sup> Promogran<sup>™</sup> Collagen Matrix with ORC and 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver

# 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 >1cm<sup>2</sup> and duration >30 days.<sup>17</sup> 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.<sup>17</sup>

Another preclinical study also demonstrated that ORC/collagen has a positive role in promoting cell proliferation.<sup>18</sup> 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.<sup>18</sup>

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.<sup>19</sup> 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 reepithelialization than wounds treated with hydrocolloid alone (Control). Furthermore, ORC/collagentreated 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.<sup>19</sup>

# Science Supporting 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver combined with the 3M<sup>™</sup> ActiV.A.C.<sup>™</sup> Negative Pressure Wound Therapy System

A retrospective analysis by Hou et al examined wound outcomes when NPWT was used alone (NPWT-only; n=485) or in combination with Promogran Prisma Matrix (NPWT+ORC/C/Ag; n=485).<sup>20</sup> The NPWT-only cohort did not receive any type of collagen dressings, while ORC/collagen/silver dressings were applied beginning on the first day of NPWT in the NPWT+ORC/C/Ag cohort. Wounds treated with the NPWT+ORC/C/Ag combination therapy were significantly more likely to heal compared to NPWT-only (p=0.0158; NPWT+ORC/C/Ag (191 [39.4%]) vs. NPWT-only (155 [32.0%])). The relative wound area reduction was 40% for the NPWT+ORC/C/Ag cohort vs. 9% for NPWT-only (p=0.0099). The NPWT+ORC/C/Ag cohort vs. 9% for NPWT-only (p=0.0099). The NPWT+ORC/C/Ag cohort signed to NPWT-only (p=0.0037). A higher percentage of NPWT+ORC/C/Ag patients, compared to NPWT-only patients, attained 75–100% granulation tissue coverage with no measurable depth at 1 week (p=0.0307; 14.4% vs. 9.9%), 2 weeks (p=0.0460; 22.9% vs. 17.7%), and 12-weeks (p=0.0290; 53.6% vs. 46.6%).

A case series presented by Napolitano et al described the outcomes of 3M<sup>™</sup> ActiV.A.C.<sup>™</sup> Therapy System with Promogran Prisma Matrix on five patients with lower extremity wounds.<sup>21</sup> The authors compared the observations made during this study to their prior experiences with NPWT and foam dressings. This study showed that combining NPWT with Promogran Prisma Matrix resulted in positive healing outcomes. No significant wound complications, including infection, were observed in patients while receiving this combined therapy. Health care providers noted that compared to NPWT with foam dressings alone, NPWT with Promogran Prisma Matrix resulted in decreased healing time.

Desvigne et al reported the benefits of adding NPWT over Promogran Prisma Matrix.<sup>22</sup> They combined ActiV.A.C. Therapy System with Promogran Prisma Matrix for wound bed preparation. Dressings were applied to wounds every 24-72 hours, and a non-adherent layer was placed over it to provide continuous pressure at -125 mmHg. This case series examined the outcomes of this combination therapy in four patients with pressure injury (n=3) or diabetic foot ulcer (n=1) wounds. No complications resulted from NPWT use with Promogran Prisma Matrix. This combination therapy helped promote wound healing through secondary intention. Results indicate using NPWT with Promogran Prisma Matrix should be considered for patients with chronic wounds or wounds that demonstrate delayed healing.

### **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.

### **Reference Clinical Case Studies**

### **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 fullthickness 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 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver. 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 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver, wound size was notably decreased.



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



**Figure 4D.** After 3 months of 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver 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.

The patient was a 59-year-old female hospitalized with the diagnosis of nonhealing left transmetatarsal amputation site. Past medical history was significant for chronic obstructive pulmonary disease, hypertenstion, hypothyroidism, renal failure requiring hemodialysis 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 (3M<sup>™</sup> V.A.C.<sup>®</sup> 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. 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver 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 reepithelialization were noted. The surrounding dermatitis had also improved (Figure 5D).



Figure 5A. STSG over wound.



**Figure 5C.** Hydropolymer foam dressing applied over 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver, which covered the donor site.



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



Figure 5D. Donor site postoperative day 14 after removing the 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver and hydropolymer foam dressings.

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

### Case Study 2 (cont.)

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 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver 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 reepithelialized 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 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver and hydropolymer foam dressings.



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

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

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. 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver 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 reepithelialized (Figure 6C).



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



Figure 6B. Wound at week 4.



**Figure 6C.** Wound fully reepithelialized at week 14.

A 77-year-old male was referred to the wound care clinic after emergency amputation of the first ray of the left foot due to a diabetic foot infection. His previous medical history included diabetes, chronic obstructive pulmonary disease, acute kidney injury, obesity, coronary heart disease, hypertension, bacteremia, agent orange exposure, and diabetic neuropathy. The patient presented with a diabetic foot infection 20 days after amputation. Despite previous use of negative pressure wound therapy (NPWT) after surgery, the wound had not healed (Figure 7A).

The treatment goal was to prepare the wound bed for a skin graft. Antibiotic therapy was initiated, and sharp debridement performed. A fenestrated 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver was placed in the wound bed followed by application of the 3M<sup>™</sup> ActiV.A.C.<sup>™</sup> Therapy System using a 3M<sup>™</sup> V.A.C.<sup>®</sup> Granufoam<sup>™</sup> Dressing (Figure 7B). The ActiV.A.C. Therapy System delivered continuous negative pressure at -125 mmHg. Dressings were changed every 48–72 hours. Any residual Promogran Prisma Matrix was removed from the wound before applying new dressings.

The wound progressively improved with the use of Promogran Prisma Matrix in conjunction with Acti.V.A.C. Therapy System. Within 16 days of treatment, the wound bed showed significant development of healthy, granulation tissue (Figure 7C). The patient received a split-thickness skin graft (STSG) approximately 30 days after treatment (Figure 7D). The Wound 7 days after application, the STSG failed due to patient non-compliance (Figure 7E). Wound care was resumed using Promogran Prisma Matrix and a secondary dressing.



Figure 7A. Diabetic foot infection at presentation.



**Figure 7B.** Application of fenestrated 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver.



Figure 7C. Wound after 16 days of 3M<sup>™</sup> ActiV.A.C.<sup>™</sup> Therapy System use in combination with 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver.



**Figure 7D.** Wound after approximately 30 days of therapy.



**Figure 7E.** Wound 7 days after split-thickness skin grafting.

A 56-year-old female presented for care with an abscessed chronic diabetic neuropathic ulcer on the plantar surface of the right foot. The ulcer had been present for over two years. Since incision and drainage of the abscess, 63 days prior to presentation, the wound had been treated with debridement and collagen dressings. Previous medical history included congestive heart failure, diabetes mellitus with neuropathy, obesity, coronary artery disease, and cardiomyopathy. The patient presented with a non-healing diabetic foot infection of the right foot (Figure 8A).

The treatment goal was wound preparation for an allograft. After sharp debridement, the wound dimensions were 2.7cm x 4.4cm x 0.6cm (Figure 8B). A fenestrated 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver was applied to the wound followed by application of 3M<sup>™</sup> ActiV.A.C.<sup>™</sup> Therapy System with 3M<sup>™</sup> V.A.C.<sup>®</sup> Granufoam<sup>™</sup> Dressing (Figure 8C). Continuous negative pressure at -125 mmHg was utilized, and dressings occurred every 48–72 hours. Any residual Promogran Prisma Matrix was removed from the wound before applying new dressings.

The combined use of ActiV.A.C. Therapy System and Promogran Prisma Matrix resulted in increased granulation tissue and less wound depth (Figure 8D). Human bioactive allografts were applied after 29 days of treatment. After three allograft applications, the wound showed improvement (Figure 8E). The patient was transferred to another provider to continue wound care.



Figure 8A. Wound at presentation.



**Figure 8B.** Wound after sharp debridement.



Figure 8C. Application of fenestrated 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver.



Figure 8D. Wound after 29 days 3M<sup>™</sup> ActiV.A.C.<sup>™</sup> Therapy System use in combination with 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver.



**Figure 8E.** Wound after three applications of human bioactive allografts.

A 51-year-old male presented for care with a chronic wound after a hallux amputation of the left foot. The wound was present for over 1 year. Previous medical history included poorly controlled diabetes mellitus, hypertension, osteomyelitis, methicillin-sensitive *Staphylococcus aureus* and methicillin-resistant *Staphylococcus aureus* infections, and below-the-knee amputation of the right leg. The patient presented with a chronic wound of the left foot 3 days after ulcer excision and a partial resection of the first ray (Figure 9A).

Three days after the operative procedure, fenestrated 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver was applied to the wound followed by application of 3M<sup>™</sup> ActiV.A.C.<sup>™</sup> Therapy System with 3M<sup>™</sup> V.A.C.<sup>®</sup> Granufoam<sup>™</sup> Dressing (**Figure 9B**). Continuous negative pressure at -125 mmHg was utilized, and dressings were changed every 48–72 hours. Any residual Promogran Prisma Matrix was removed from the wound before applying new dressings.

Wound healing progress was visible within 3 weeks of therapy (Figure 9C). ActiV.A.C. Therapy System use was discontinued after 4 weeks (Figure 9D). Use of Promogran Prisma Matrix with a secondary dressing continued for an additional 2 weeks. Six weeks after the surgical procedure, the wound was fully healed (Figure 9E).



Figure 9A. Chronic wound at presentation.



after ulcer excision and partial resection of the first ray, fenestrated 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver in combination with 3M<sup>™</sup> ActiV.A.C.<sup>™</sup> Therapy System with 3M<sup>™</sup> V.A.C.<sup>®</sup> Granufoam<sup>™</sup> Dressing was initiated.



Figure 9C. Wound after 3 weeks.



**Figure 9D.** Wound after 4 weeks of continued treatment, 3M<sup>™</sup> ActiV.A.C.<sup>™</sup> Therapy System was discontinued.



Figure 9E. Wound fully healed 6 weeks after surgery.

A 74-year-old male presented for care 18 days after amputation of the second and third toes. He had a previous medical history of diabetes, peripheral vascular disease, hypertension, lymphedema, and neuropathy. The patient presented with a diabetic foot infection of the left foot (Figure 10A). Wound dimensions were 4.4cm x 3.5cm by 1.1cm.

Antibiotic therapy was initiated, followed by sharp debridement. Fenestrated 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver dressings were applied to the wound followed by application of 3M<sup>™</sup> ActiV.A.C.<sup>™</sup> Therapy System with 3M<sup>™</sup> V.A.C.<sup>®</sup> Granufoam<sup>™</sup> Dressing (Figure 10B). Therapy goals included wound bed preparation, granulation tissue formation, and removal of infectious materials. The ActiV.A.C. Therapy System provided continuous negative pressure at -125 mmHg. Dressings were changed every 48–72 hours. Any residual Promogran Prisma Matrix was removed from the wound before applying new dressings.

After 25 days of treatment (Figure 10C), ActiV.A.C. Therapy System use was discontinued. Promogran Prisma Matrix and a secondary dressing were applied and the wound continued to show improvement after 10 days of treatment (Figure 10D). Full wound closure was observed after 14 days and treatment was discontinued.



Figure 10A. At presentation.



**Figure 10B.** Application of 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver.



Figure 10C. Wound after 25 days of combination therapy, 3M<sup>™</sup> ActiV.A.C.<sup>™</sup> Therapy System was discontinued.



Figure 10D. Wound after an additional 10 days of 3M<sup>™</sup> Promogran Prisma<sup>™</sup> Collagen Matrix with ORC and Silver and a secondary dressing.

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