

GRAFIXPL PRIME CLINICAL CASE STUDIES

GrafixPL PRIME Case Study – Diabetic Foot Ulcer

Patient and Diagnosis: 67 year old male with non-healing diabetic ulceration on the plantar surface of the right foot. Relevant past medical history includes the following: Type II diabetes, chronic kidney disease, hypertension, peripheral arterial disease, and end-stage renal disease with dialysis.

Prior Treatment: BlastX antimicrobial gel, PROMOGREN, and Drawtex.

Wound Treatment and Outcome: There was an 80% surface area reduction in wound size demonstrated after 2 applications of GrafixPL PRIME. In addition to standard of care, 4 serial weekly applications of GrafixPL PRIME achieved complete closure at week 5.



Application #1

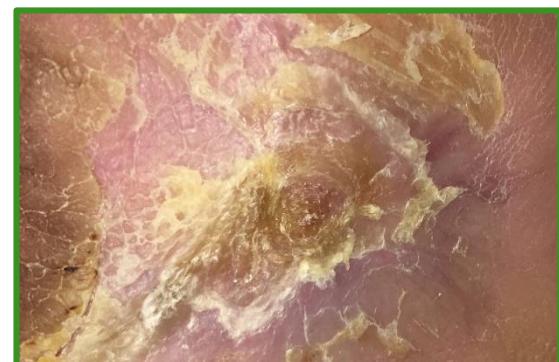
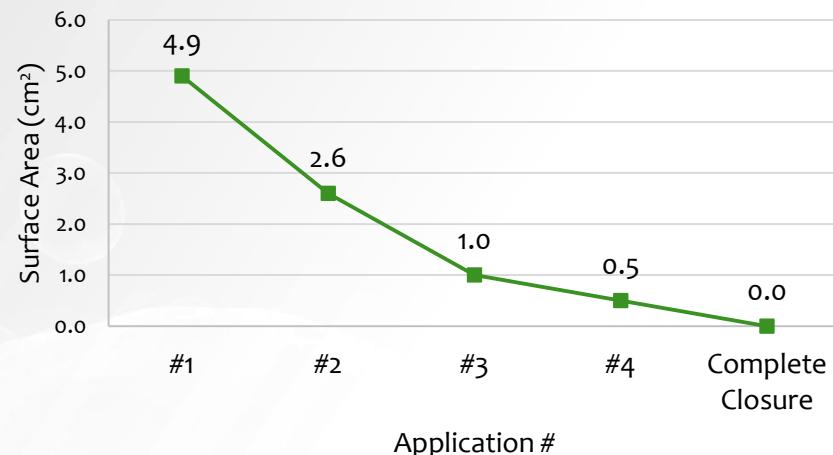
Length: 2.5 cm Width: 2.0 cm Depth: 0.2 cm



Application #3

Length: 0.8 cm Width: 1.2 cm Depth: 0.2 cm

Wound Size at Each Visit



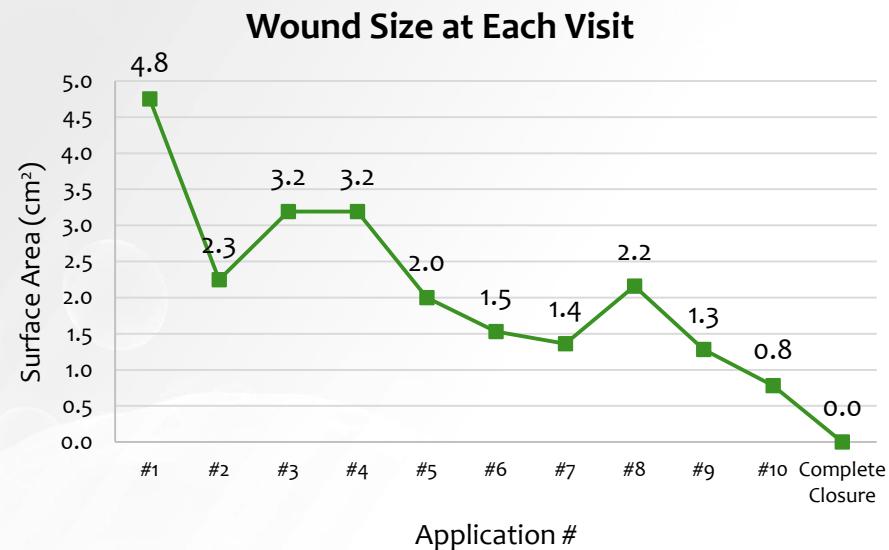
Complete Closure

Length: 0 cm Width: 0 cm Depth: 0 cm

GrafixPL PRIME Case Study – Diabetic Foot Ulcer

Patient and Diagnosis: 54 year old male with non-healing diabetic ulceration with an over 2 year duration on the dorsal aspect of the right foot. Relevant past medical history includes: Type II diabetes, hypertension, and previous transmetatarsal and toe amputations.

Wound Treatment and Outcome: There was a 58% surface area reduction in wound size demonstrated after 4 applications of GrafixPL PRIME. In addition to standard of care, 10 serial applications of GrafixPL PRIME achieved complete closure at week 12.



Application #1

Length: 1.9 cm Width: 2.5 cm Depth: 0.2 cm



Application #5

Length: 2.0 cm Width: 1.0 cm Depth: 0.1 cm



Complete Closure

Length: 0 cm Width: 0 cm Depth: 0 cm

GrafixPL PRIME Case Study – Venous Leg Ulcer

Patient and Diagnosis: 93 year old female with non-healing venous ulceration on the anterior aspect of the left leg.

Prior Treatment: PolyMem dressing and BlastX antimicrobial gel.

Wound Treatment and Outcome: In addition to standard of care and compression, 2 serial weekly applications of GrafixPL PRIME achieved complete closure of the 7.7 cm² chronic wound at week 4 in this patient.



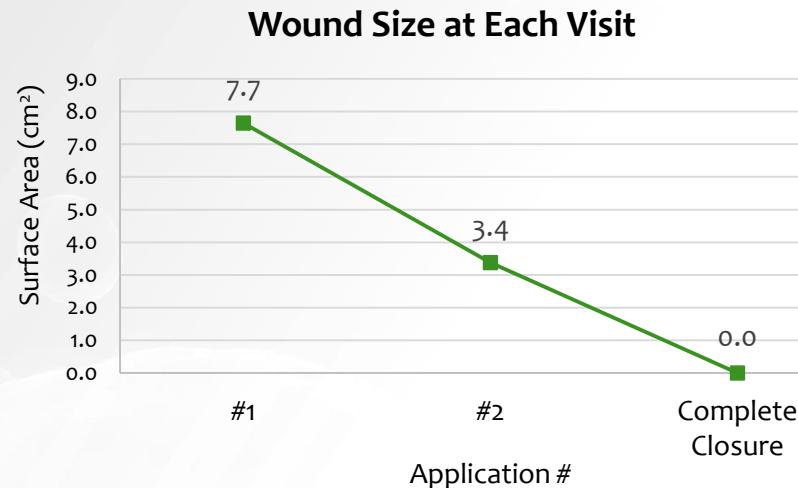
Application #1

Length: 3.5 cm | Width: 2.2 cm | Depth: 0.2 cm



Application #2

Length: 2.3 cm | Width: 1.5 cm | Depth: 0.2 cm



Complete Closure

Length: 0 cm | Width: 0 cm | Depth: 0 cm

GrafixPL PRIME Case Study – Venous Leg Ulcer

Patient and Diagnosis: 62 year old male with a venous ulceration on the right leg. Relevant past medical history includes: HIV, deep vein thrombosis, and anti-coagulant therapy.

Wound Treatment and Outcome: There was an 87% surface area reduction in wound size demonstrated after 2 applications of GrafixPL PRIME. In addition to standard of care and multi-layer compression, 3 serial applications of GrafixPL PRIME achieved complete closure at week 5.



Application #1

Length: 2.6 cm Width: 1.5 cm Depth: 0.1 cm



Application #3

Length: 1.2 cm Width: 0.4 cm Depth: 0.1 cm



Complete Closure

Length: 0 cm Width: 0 cm Depth: 0 cm

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Case study provided by Alexander Reyzelman, DPM
Center for Clinical Research, San Francisco, CA

GrafixPL PRIME Case Study – Venous Leg Ulcer

Patient and Diagnosis: 59 year old female with non-healing venous ulceration on the lateral aspect of the right leg. Relevant past medical history includes the following: osteoarthritis, hypertension, and lymphedema.

Prior Treatment: BlastX antimicrobial gel, PROMOGRAN, and Drawtex.

Wound Treatment and Outcome: There was a 68% surface area reduction in wound size demonstrated after 1 application of GrafixPL PRIME. In addition to standard of care and multi-layer compression, 2 serial weekly applications of GrafixPL PRIME achieved complete closure at week 3.



Application #1

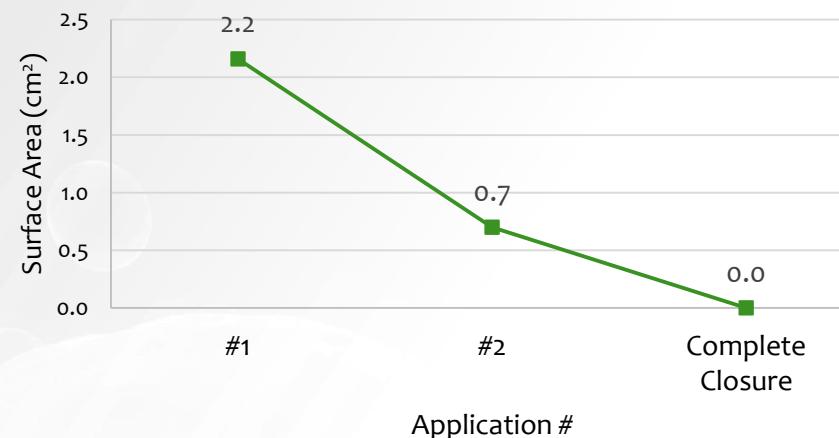
Length: 2.0 cm Width: 1.1 cm Depth: 0.2 cm



Application #2

Length: 1.2 cm Width: 0.6 cm Depth: 0.2 cm

Wound Size at Each Visit



Complete Closure

Length: 0 cm Width: 0 cm Depth: 0 cm

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BlastX is a trademark of Next Science. PROMOGRAN is a trademark of KCI USA, Inc. Drawtex is a trademark of Beier Drawtex Healthcare.

Case study provided by Matthew Regulski, DPM
Ocean County Foot and Ankle Surgical Associates, Toms River, NJ

GrafixPL PRIME Case Study – Pressure Ulcer

Patient and Diagnosis: 59 year old male with non-healing pressure ulceration on the medial aspect of the posterior left heel with a 1 year duration. Relevant past medical history includes: Type II diabetes, end-stage renal disease, deep vein thrombosis, and obesity.

Wound Treatment and Outcome: There was a 60% surface area reduction in wound size demonstrated after 1 application of GrafixPL PRIME. In addition to standard of care and multi-layer compression, 3 serial applications of GrafixPL PRIME achieved complete closure at week 5.



Application #1

Length: 1.0 cm Width: 1.0 cm Depth: 0.2 cm



Application #2

Length: 0.5 cm Width: 0.8 cm Depth: 0.2 cm



Complete Closure

Length: 0 cm Width: 0 cm Depth: 0 cm

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Case study provided by Alexander Reyzelman, DPM
Center for Clinical Research, San Francisco, CA

GrafixPL PRIME Case Study – Dehiscence Following Transmetatarsal Amputation

GP18019/REV01

Patient and Diagnosis: 60 year old male with a 6 month duration dehiscence wound on the lateral aspect of the left foot following a transmetatarsal amputation. Relevant past medical history includes: Type II diabetes, hypertension, osteomyelitis, and peripheral arterial disease.

Wound Treatment and Outcome: There was an 83% surface area reduction in wound size and a 70% reduction in depth demonstrated after 3 applications of GrafixPL PRIME. In addition to standard of care, 7 serial applications of GrafixPL PRIME achieved complete closure at week 10.



Application #1

Length: 2.0 cm Width: 1.5 cm Depth: 1.0 cm



Application #3

Length: 0.9 cm Width: 0.6 cm Depth: 0.3 cm



Complete Closure

Length: 0 cm Width: 0 cm Depth: 0 cm

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Case study provided by Charles Ananian, DPM
New Hope Podiatry Group, Los Angeles, CA

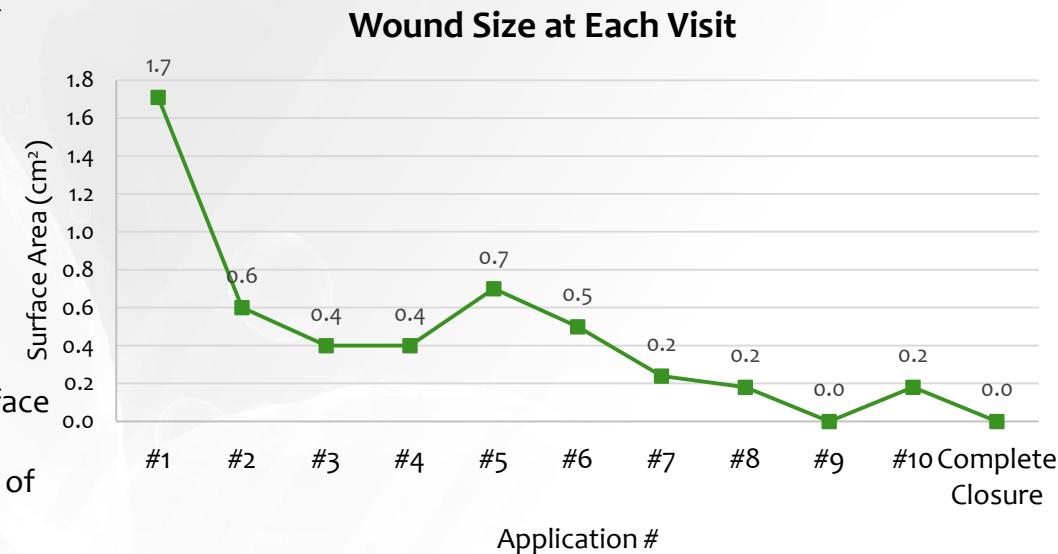
GrafixPL PRIME Case Study – Dehiscence Wound Following Metatarsal & Hallux Amputation

GP18019/REV01

Patient and Diagnosis: 59 year old male with an 8 week duration dehiscence wound over exposed bone on the distal left foot following amputation of the 4th metatarsal and hallux. Relevant past medical history includes: Type II diabetes, hypertension, obesity, and osteomyelitis.

Prior Treatment: V.A.C. was applied for 3 weeks to granulate the wound prior to application of GrafixPL PRIME.

Wound Treatment and Outcome: There was an 71% surface area reduction in wound size demonstrated after 6 applications of GrafixPL PRIME. In addition to standard of care, 10 serial applications of GrafixPL PRIME achieved complete closure at week 14.



Application #1

Length: 1.9 cm

Width: 0.9 cm



Application #4

Length: 2.3 cm

Width: 1.3 cm



Complete Closure

Length: 0 cm

Width: 0 cm

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® V.A.C. is a trademark of KCI.

Case study provided by Charles Ananian, DPM
New Hope Podiatry Group, Los Angeles, CA

GrafixPL PRIME Case Study – Dehiscence Wound Following Trauma

GP18019/REV01

Patient and Diagnosis: 62 year old male with a dehiscence wound on the left leg over the tibia following trauma. Relevant past medical history includes: Type II diabetes, neuropathy, hypertension, arterial disease, and chronic venous insufficiency.

Prior Treatment: Trauma wound from falling off an exercise bike was stitched 1 week after injury. Wound dehisced, and V.A.C. was applied for one month prior to application of GrafixPL PRIME.

Wound Treatment and Outcome: There was a 60% surface area reduction in wound size demonstrated after 3 applications of GrafixPL PRIME. In addition to standard of care, 7 serial applications of GrafixPL PRIME achieved complete closure at week 8.



Application #1

Length: 3.0 cm

Width: 2.5 cm



Application #4

Length: 2.3 cm

Width: 1.3 cm

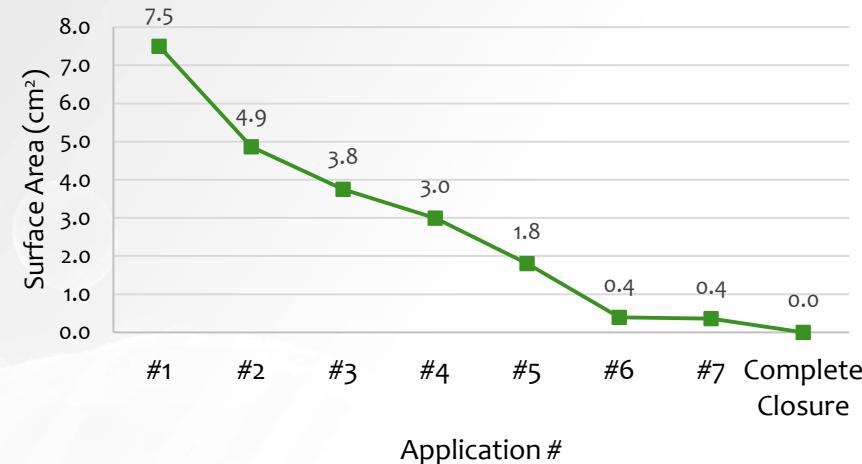


Complete Closure

Length: 0 cm

Width: 0 cm

Wound Size at Each Visit



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Case study provided by Charles Ananian, DPM
New Hope Podiatry Group, Los Angeles, CA

GrafixPL PRIME Case Study – Trauma Wound

Patient and Diagnosis: 38 year old male with a plantar wound secondary to trauma with exposed fascia on the plantar aspect of the right foot following an abscessed blister. Relevant past medical history includes: Type II diabetes, neuropathy, hypertension, and amputation of the hallux and 2nd toe.

Prior Treatment: V.A.C. was applied for one month to granulate the surgical wound prior to application of GrafixPL PRIME.

Wound Treatment and Outcome: There was an 89% surface area reduction in wound size demonstrated after 4 applications of GrafixPL PRIME. In addition to standard of care, 7 serial applications of GrafixPL PRIME achieved complete closure at week 9.



Application #1

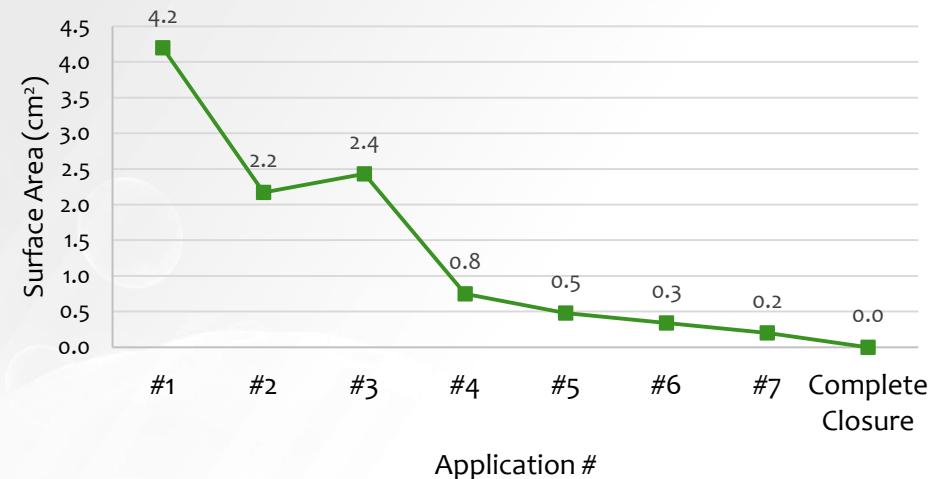
Length: 3.5 cm | Width: 1.2 cm | Depth: 0.1 cm



Application #5

Length: 2.4 cm | Width: 0.2 cm | Depth: 0.2 cm

Wound Size at Each Visit



Complete Closure

Length: 0 cm | Width: 0 cm | Depth: 0 cm

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® V.A.C. is a trademark of KCI.

Case study provided by Charles Ananian, DPM
New Hope Podiatry Group, Los Angeles, CA

GrafixPL PRIME Case Study – Radiation Wound

Patient and Diagnosis: 73 year old female with a 6 month duration radiation wound to the right medial ankle as a result of cancer treatment after tumor excision. Relevant past medical history includes the following: Rheumatoid Arthritis, systemic sclerosis, lymphedema, mild chronic venous insufficiency, and squamous cell carcinoma.

Prior Treatment: Collagen, honey-impregnated dressings, and topical antibiotics.

Wound Treatment and Outcome: In addition to standard of care and multi-layer compression, 11 serial weekly applications of GrafixPL PRIME achieved complete closure at week 14. The wound remained closed after 3 months from initial closure.



Application #1

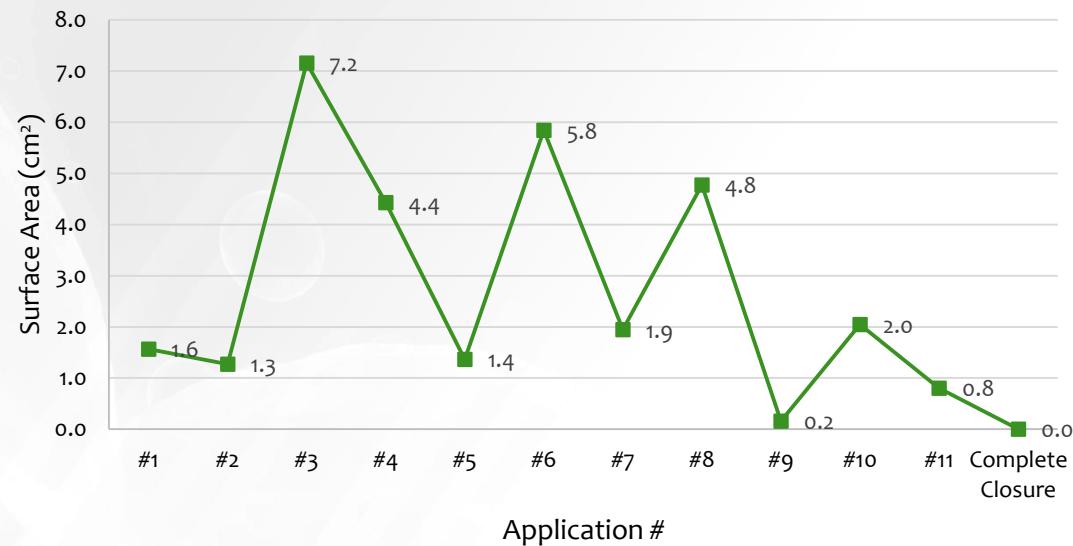
Length: 1.4 cm Width: 1.1 cm Depth: 0.2 cm



Application #6

Length: 2.6 cm Width: 2.2 cm Depth: 0.2 cm

Wound Size at Each Visit



Complete Closure

Length: 0 cm Width: 0 cm Depth: 0 cm

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Case study provided by Matthew Regulski, DPM
Ocean County Foot and Ankle Surgical Associates, Toms River, NJ

GrafixPL PRIME Case Study – Surgical Wound Following Pilonidal Cyst Removal

GP18019/REV01

Patient and Diagnosis: 25 year old male with a 16 week duration surgical wound following pilonidal cyst excision. No relevant past medical history reported.

Prior Treatment: Wound V.A.C., Tegaderm Ag mesh, AQUACEL, collagen dressings, IODOSORB, & Iodoform packing.

Wound Treatment and Outcome: In addition to standard of care, 3 serial applications of GrafixPL PRIME achieved complete closure at week 7.



Application #1

Length: 2.0 cm Width: 1.5 cm Depth: 0.2 cm



Application #3

Length: 3.5 cm Width: 0.7 cm Depth: 0.1 cm



Complete Closure

Length: 0 cm Width: 0 cm Depth: 0 cm

V.A.C. is a trademark of KCI USA, Inc. Tegaderm is a trademark of 3M. AQUACEL is a trademark of Convatec, Inc. IODOSORB is a trademark of Smitih & Nephew.

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Case study provided by Eric Johnson, MD
Bozeman Deaconess Wound Clinic, Bozeman, MT