Enluxtra™ Humifiber™
Self-Adaptive Wound Dressing

Case Studies

OSNovation Systems, Inc.
www.EnluxtraWoundCare.com

OSNovation Systems, Inc. 500 Laurelwood Rd, Ste 1, Santa Clara, CA 95054 (888)519-2297

Case study 1: Chronic lower extremity venous stasis ulcer

Enluxtra® Humifiber® Wound Dressing Clinical Results

Patient:

A 53-year-old male presented with a draining lateral venous stasis ulcer on his left lower leg that had been present for several months. Patient is a heavy smoker (1pack a day) with a history of untreated hypertension, arterial compromise, and refused revascularization (ankle/brachial index: .82).

Wound Description:

Upon presentation to the clinic, the venous stasis ulcer appeared weepy and stalled in the inflammation phase of wound healing. Healing was further complicated by frequent recurrence of fungal/yeast infection on the periwound skin, which caused constant pruritus and inflammation. Patient complained of sleep loss due to itching and discomfort throughout the day. Initial goals in this case were to reduce wound drainage and edema.

Initial Wound Treatment:

In addition to triamcinolone, anti-fungal ointments and topical antibiotics, a variety of dressings were applied to the wound during the first four months of treatment, including foams, alginates, silver alginates, and polymeric membrane dressings. Unfortunately, the quantity and consistency of drainage from the wound did not change with application of any of these dressings. After 4 months of advanced wound care, the ulcer remained weepy and hypergranulated with raised wound edges above peri-wound skin level. Condition of the periwound skin was bright red, erythematous, edematous, and with scaly dry drainage adding to the pruritus (Fig. A).

Application of Enluxtra:

Prior to the first application of Enluxtra® Humifiber wound dressing, following debridement, the ulcer measured 4.0 x 4.0 x 0.5 cm. Topical antibiotics and anti-fungal ointment were applied. Enluxtra was placed over the ulcer, overlapping 2 to 3 cm onto intact skin, and secured with circumferential gauze wrap.

Wound Progression with Enluxtra:

Two weeks following initial application of Enluxtra, drainage was noticeably reduced, the periwound erythema was resolved, and the wound was granulating normally with only a small, slightly raised area (Fig. B). The dressing prevented transfer of exudate to the peri-wound skin, ending prolonged skin irritation and itching after only one week of Enluxtra.

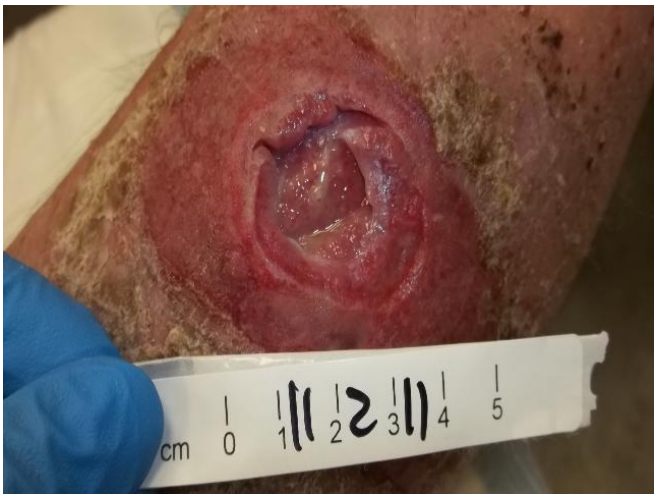


Fig. A. Chronic venous leg ulcer with edematous raised bed after 4 months of advanced wound care and prior to Enluxtra application

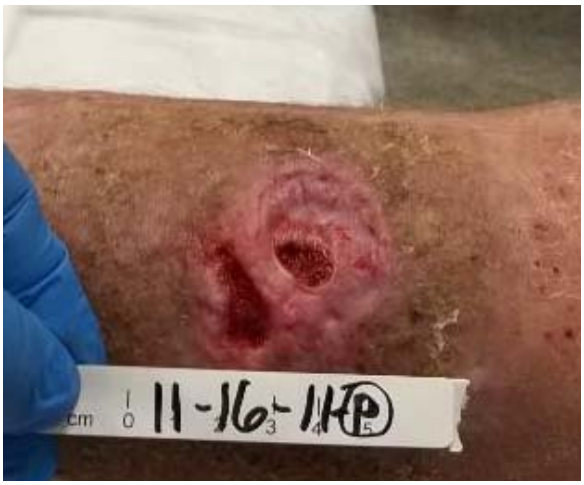


Fig. B. Two weeks following initial use of Enluxtra, drainage is considerably decreased and peri-wound erythema is completely resolved. Signs of inflammation are no longer present and the wound is nearly level with the peri-wound skin.

After 4 weeks of Enluxtra, the wound bed was completely level with the periwound skin and re-epithelializing normally. The wound measured only 0.5 x 0.25 x 0.25 cm with no periwound edema (Fig. C). No dressing adjustment or cutting was required during course of wound healing. After 2 months, the wound was completely closed and re-epithelialized (Fig. D). Dressings were discontinued and the patient was released from care.

User Experience:

The patient was very satisfied with the Enluxtra dressing, particularly with respect to painless, non-adherent dressing removal and the rapid rate of erythema resolution and wound closure. Patient reported no dressing leakage or fluid strike-through. Itchiness stopped within one week of application, and the patient was relieved to finally sleep through the night. His wound that had been open and draining for 4 months was nearly closed within 1 month of Enluxtra use, allowing him to return to his normal daily activities.

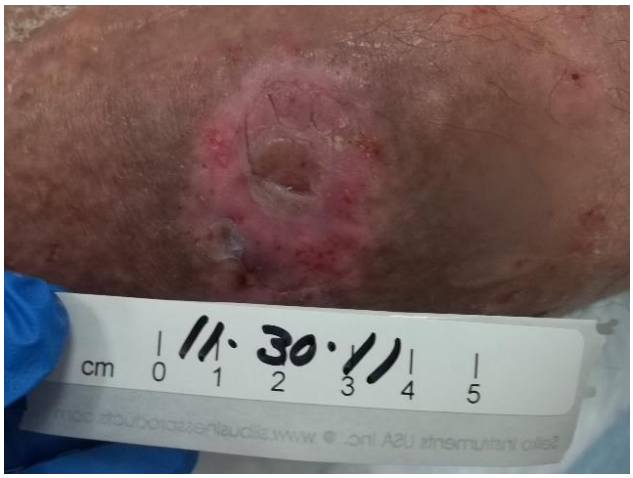


Fig. C. After 1 month of Enluxtra, wound size was reduced to 0.5 x 0.25 x 0.25 cm with no edema or drainage. The wound appeared optimally moist and mostly re-epithelialized.

Clinical Outcomes/Conclusion:

In this case, Enluxtra appeared to contain all the properties needed to reverse the impediments in ulcer healing that were evident during the previous four months, including edema, uncontrolled drainage, and moisture imbalances. Compared to all previous dressings used in this chronic ulcer, Enluxtra was the only dressing that facilitated effective and efficient wound closure.

Drainage was controlled, locked in and reduced with this dressing, resulting in edema reduction and optimal moisture balance throughout the wound and peri-wound skin. The dressing appeared to absorb exudate from the central area of the draining wound while maintaining moist wound edges, and to provide a moist healing environment during the low-/non-exuding final stages of wound healing. The final cosmetic appearance of the healed wound was excellent.

From a clinician's perspective, Enluxtra greatly simplifies the tedious process of choosing appropriate wound care dressings, because this one dressing type is suited for the entire wound healing continuum and does not need to be switched according to changing wound conditions. Enluxtra was effective throughout all conditions and dimensions of the wound in this case.

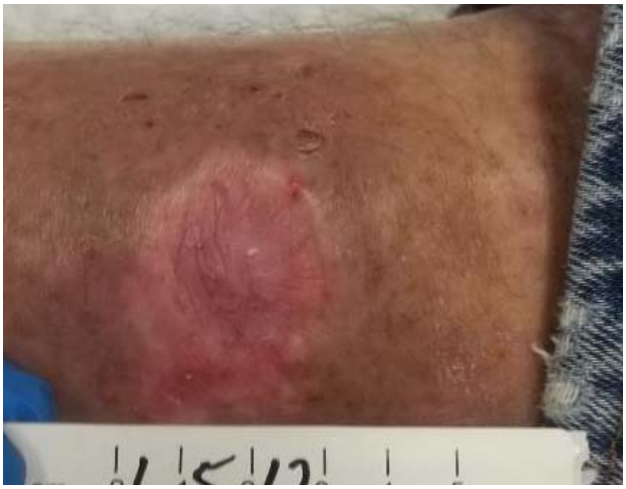


Fig. D. Venous stasis ulcer is completely closed with excellent aesthetic result after 2 months of Enluxtra dressings

Reference:

Vicki Fischenich, GNP-BC;
Dr. Randall Wolcott
Southwest Regional Wound Care Center, Lubbock, TX

Case study 2: Basal cell carcinoma of the temporal region

Enluxtra® Humifiber® Wound Dressing Clinical Results

Patient:

A 62-year-old male presented with a nonhealing soft tissue radionecrosis wound of the left facial and temporal region following severe radiation damage post basal cell carcinoma. Patient's medical history also included hypertension and stage II chronic kidney disease.

Wound Description:

Continual drainage from the exposed frontal sinus was contaminating and causing inflammation to the surrounding soft tissue, prolonging wound healing process. Wound healing was further complicated by desiccation of wound edges and non-exudative portions of the wound, as well as formation of necrotic tissue and biofilms.

Initial Wound Treatment:

A range of absorbent dressings, including hydrocellular and self-adherent polyurethane foams, were tried in the wound and were unsuccessful in controlling drainage of the sinus fluid and necrotic tissue formation. The wound required weekly debridements to remove necrotic tissue, which was increasing the wound size and traumatizing the wound edges, exposed bone, and the fragile thin tissue layer over the brain. Brain pulsating movement could be observed in the center of the wound. Continual debriding of this fragile area due to drainage deterred the healing process.

Application of Enluxtra:

Ten weeks after the patient initially presented to our clinic, the wound measured 10.0 x 13.0 x 1.0 cm with exposed bone (Fig. A). Debridement was performed, and Enluxtra was placed on the wound, overlapping 2 to 3 cm onto intact skin, and secured with non-woven cotton tape at the first dressing change. On follow-up visit, additional folded gauze was added to the outer Enluxtra dressing and cotton tape to ensure wound bed contact with the Enluxtra and aid drainage absorption and biofilm elimination.

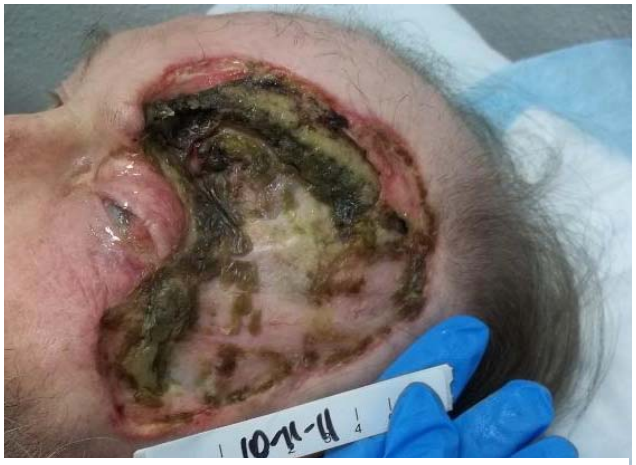


Fig. A. Chronic soft tissue radionecrosis wound prior to use of Enluxtra is filled with necrotic tissue and contaminated with sinus fluid

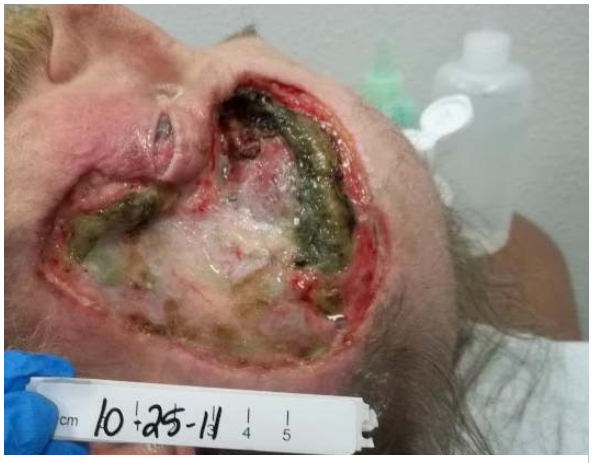


Fig. B. Two weeks following initial use of Enluxtra, sinus drainage is controlled and pink granulation buds are present in the wound bed

Wound Progression with Enluxtra:

Two weeks following initial placement of Enluxtra, the wound displayed marked signs of improvement. Drainage was controlled and isolated within the dressing, and healthy pink tissue was present in the wound bed and on wound edges (Fig. B).

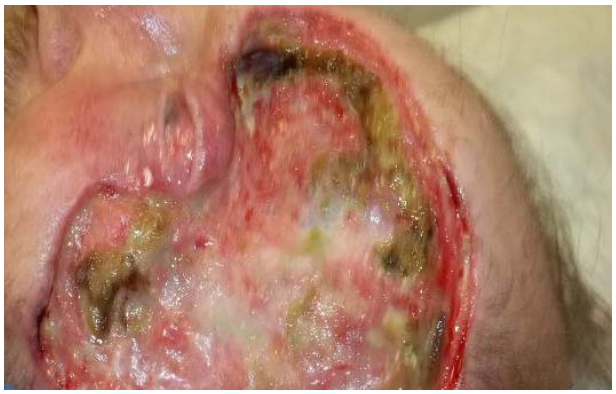
Exudate containment and maintenance of correct moisture balance throughout the entire wound led to a drastic reduction in sharp debridements and associated trauma to the exposed bone and healing tissues. The layer of tissue covering brain tissue continuously retained its moisture, and appeared strengthened within one month of Enluxtra use (Fig. C).

After 3 months of Enluxtra, wound size was decreased, sinus fluid remained contained, and granulation buds were present throughout the wound bed (Fig. D).

Fig.C. After 1 month's use of Enluxtra, the need for debridement was drastically reduced and the thin tissue over the brain remained optimally moist and granulated

User Experience:

The patient reported increased comfort with the dressing, particularly with respect to painless dressing removal, leak-free dressing and decreased debridement frequency. Other dressings applied prior to Enluxtra leaked drainage into the eye and inner ear, requiring frequent debridement and use of antibiotic eye drops for inflammation and irritation.



Fig,D. After 3 months of Enluxtra, wound edges appear healthy, and all dimensions are smaller

Clinical Outcomes/Conclusion:

All areas of this complex soft tissue radionecrosis wound responded positively underneath the Enluxtra dressing throughout the 12-week application period. Improved moisture balance and considerably reduced necrotic tissue and biofilm formation were observed with application of Enluxtra, compared to previous dressings used in this wound. Enluxtra appeared to assist in autolytic debridement, which greatly decreased the need for sharp debridement and allowed the underlying healthy tissue to consistently remain on a positive wound-healing trajectory.

Reference:

Vicki Fischenich, GNP-BC
Dr. Randall Wolcott
Southwest Regional Wound Care Center
Lubbock, TX

Case study 3: Fourth metatarsal head following amputation

Enluxtra® Humifiber® Wound Dressing Clinical Results

Patient:

A 67-year-old male presented with a diabetic wound of the right foot fourth metatarsal head following toe amputation. Patient was a healthy, insulin-dependent diabetic with hypertension.

Wound Description:

Patient with a diabetic wound of the right foot fourth metatarsal had been unsuccessfully treated by a local physician for 1 month. Patient was admitted to a local hospital for amputation of foot and intravenous antibiotics. Patient sought second opinion from our wound clinic and it was determined that amputation of only the fourth digit was necessary. Three days after amputation, the incision dehisced and the wound began producing copious amounts of drainage. At initial presentation post dehiscence, wound edges were macerated and erythematous, due to the uncontrolled wound drainage.

Application of Enluxtra:

Following debridement, the ulcer measured 3.0 x 1.5 x 1.0 cm with exposed bone (Fig. A). A small piece of Enluxtra was cut and placed between the toes and over the wound, overlapping 2 to 3 cm onto intact skin (Fig. B), then secured with gauze wrap. The aim of the dressing was to absorb and reduce wound drainage as well as facilitate recovery of the macerated periwound skin.

Wound Progression with Enluxtra:

The drainage was well absorbed by the dressing. After one week of Enluxtra application, drainage was reduced and maceration around the wound was decreased (Fig. C). The periwound area was healthy and completely recovered at week 3 (Fig. D).

After 6 weeks of Enluxtra, edema and erythema were no longer present and the wound appeared optimally moist. The wound was smaller (0.5 x 0.5 x 1.0 cm) and well-granulated, including over previously exposed bone (Fig. E). The wound was

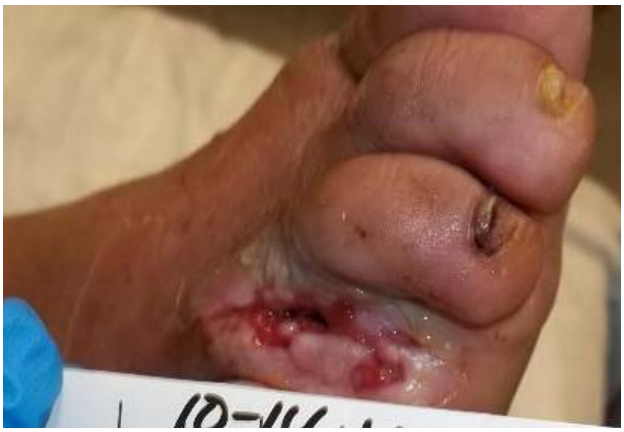


Fig.A. Diabetic wound post amputation and debridement with copious drainage and wound edge maceration

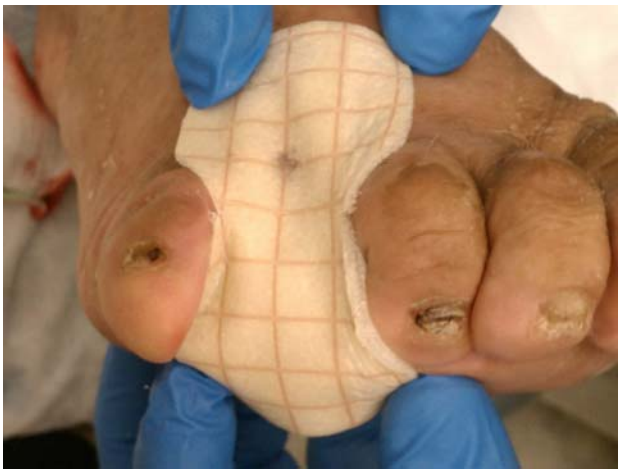


Fig.B. Enluxtra dressing applied between toes and overlapping onto intact skin

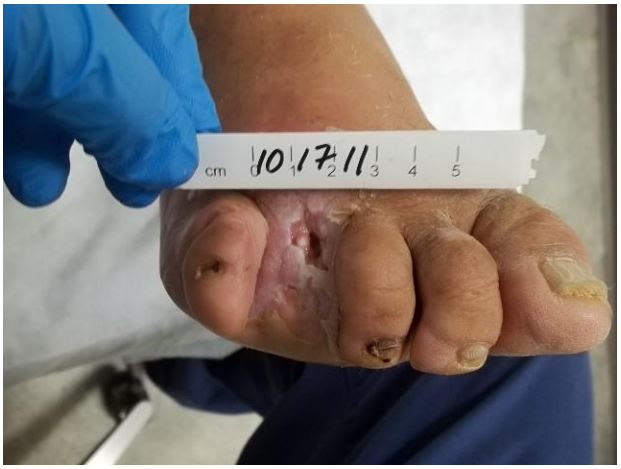


Fig. C. After 1 week of Enluxtra, wound edge maceration is resolving due to dressing absorption capabilities. Slight erythema is present at the wound

completely closed after 4 months of Enluxtra application (Fig. F), and the patient was discharged from wound care services.

User Experience:

The patient appreciated the ease of application and removal of the Enluxtra dressing, and was encouraged at each dressing change by consistent progress toward closure.

Clinical Outcomes/Conclusion:

The diabetic foot ulcer showed steady progression toward closure at each dressing change with use of Enluxtra, and was completely closed at 4 months. Drainage and edema were decreased and periwound maceration was eliminated with this dressing. Enluxtra appears to be a viable, simplified dressing option for diabetic wounds due to its effectiveness over different tissue types and throughout the wound healing continuum.

Reference:

Vicki Fischenich, GNP-BC
Dr. Randall Wolcott
Southwest Regional Wound Care Center
Lubbock, TX

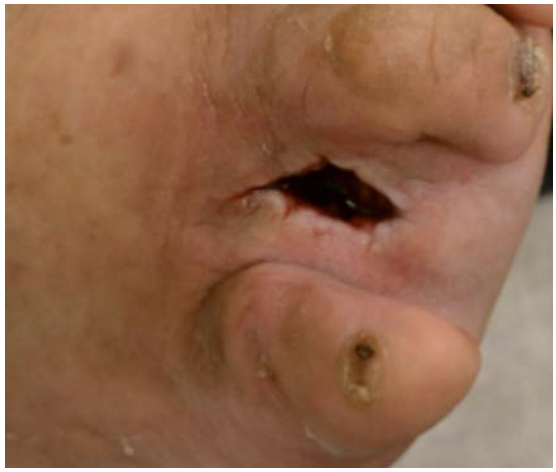


Fig. D. Peri-wound is free of maceration and erythema after 3 weeks of Enluxtra. Wound edges remain moist and begin coming together

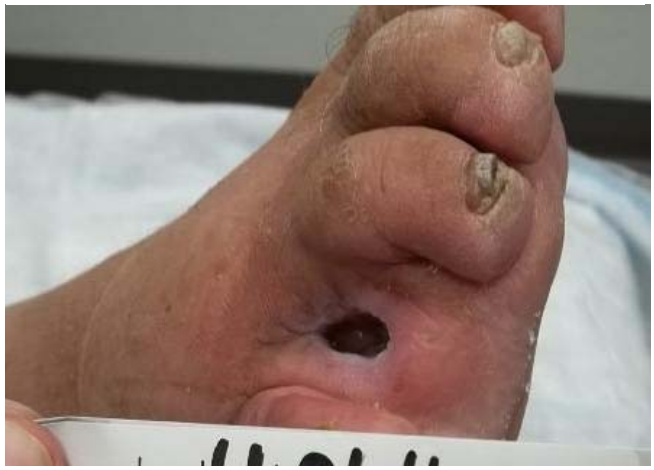


Fig. E. After 6 weeks of Enluxtra, the wound was well granulated over tissue and bone

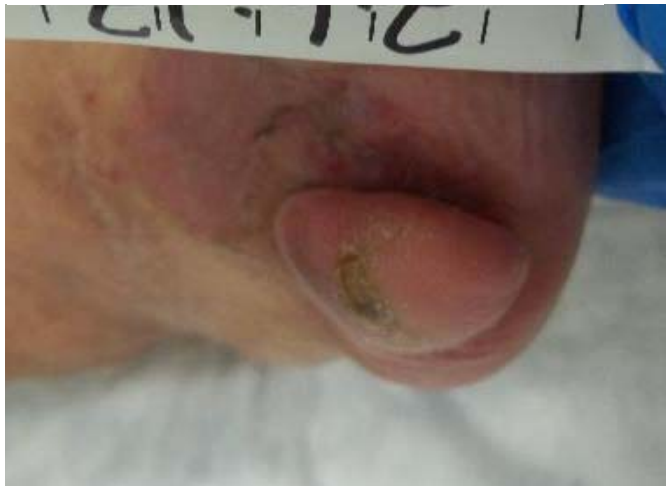


Fig. F. At 4-months, the diabetic wound is completely closed

Novel Humifiber Advanced Wound Dressing Study

Dr. Randall D. Wolcott, NP & Pas, Vicki Fischenich, GNP
The Southwest Regional Wound Care Center, Lubbock, TX

Abstract of presentation at The Symposium on Advanced Wound Care (SAWC) Spring 2012

The purpose of this study was to determine the effectiveness of a novel humifiber advanced wound dressing* for achieving optimal moisture balance in multiple wound types. The subject dressing had the unique property of being able to sequester large amounts of exudate or conversely prevent desiccation of a dry wound. This allowed the dressing to be used throughout the healing of a wound. A total of 15 patients from a variety of settings (clinic and nursing homes) were selected. The types of wounds in the study included venous, diabetic, and decubitus ulcers as well as acute traumatic and chronic wounds. The dressing was applied one to three times per week either in clinic or in home settings, based on the wound and in conjunction with local best practices throughout the entire study. Our overall approach was to use this dressing on any wound regardless of etiology or the amount of exudate, and to decrease dressing changes to a minimum (once a week) until the wound was completely re-epithelialized.

Our conclusion was that this dressing was effective on all types of wounds with minimal to heavy exudate and with no need for dressing customization. We observed notable improvements of wound edge conditions. The dressing demonstrated excellent properties with regard to preservation of peri-wound skin. Dressing removal was painless and non-traumatic. It also seemed that this dressing minimized formation of biofilm, therefore reducing the need for debridement. We had promising results with extended use in patients with once a week dressing changes with moderate drainage. The utilization of one-fit-all dressing for multiple wound types, which exhibit minimal to severe exudate, simplified wound care. This dressing improved the quality consistency of practical moist wound healing and facilitated care continuum in the clinic, home and facility settings.

* Enluxtra™ Humifiber™ Wound Dressing, OSNovation Systems, Inc., BASF,Inc.