

# V.A.C.ULTA™

THERAPY SYSTEM



## V.A.C.ULTA™ Negative Pressure Wound Therapy System

MONOGRAPH

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## Preface

The V.A.C.ULTA™ Negative Pressure Wound Therapy System is an integrated wound management system that provides negative pressure for three therapy systems: 1) V.A.C.® Therapy using V.A.C.® GRANUFOAM™ and V.A.C. WHITEFOAM™ Dressings, 2) V.A.C. VERAFLOR™ Instillation Therapy using V.A.C. VERAFLOR™ and V.A.C. VERAFLOR CLEANSE™ Dressings, and 3) ABTHERA™ Open Abdomen Negative Pressure Therapy using the ABTHERA™ SENSAT.R.A.C.™ Dressing.

Although the V.A.C.ULTA™ Negative Pressure Wound Therapy System provides three therapies for customizable wound healing, this document will focus only on the V.A.C.® Therapy and V.A.C. VERAFLOR™ Instillation Therapy Systems, including:

- Introduction to the V.A.C.ULTA™ Therapy System
- Wound Management with NPWT and NPWTi-d
- Clinical literature review of NPWT and NPWTi-d
- Description of the V.A.C.ULTA™ Therapy System
- Science supporting V.A.C. VERAFLOR™ Therapy
- Instillation therapy case studies describing clinical outcomes

## Introduction

The management of acute and chronic wounds requires a comprehensive assessment of both the patient and wound to determine the optimal treatment plan for achieving wound care goals. Direct and indirect costs related to wound care contribute to the overall health-care expenditure and are anticipated to increase with the aging US population. Moreover, wound treatment costs can increase when wound complications, such as infection, edema, and poor perfusion, develop, causing further delays in wound healing. It is critical to balance the benefits of lower costs of wound healing dressings against those of advanced technologies. The use of advanced technologies, such as NPWT and NPWTi-d, may facilitate earlier wound closure and be more cost effective compared to lower cost products that take longer, or fail, to heal the wound.<sup>1</sup>

Over the years wound treatment has progressed from dry gauze products to advanced moist wound therapies and further to active wound healing therapies.<sup>2</sup> One such active therapy is V.A.C.® Therapy, a clinically proven advanced therapy system that was cleared for commercialization in 1995. Since that time, a variety of therapies and dressings have been developed in order to better meet the needs of wound patients. For example, in 2003, V.A.C. INSTILL™ Wound Therapy introduced to the US the principles of instillation with NPWT that were developed by Fleischmann et al.<sup>3</sup> Instillation helps to further promote wound healing by combining the benefits of irrigation using topical wound solutions with the advantages of NPWT. Currently, the latest development in V.A.C.® Therapy technology incorporates both NPWT and instillation features, including a new volumetric pump and dressings designed for instillation therapy, into one system: the V.A.C.ULTA™ Therapy System.

The V.A.C.ULTA™ Therapy System (**Figure 1**) is an integrated wound management system that provides both V.A.C.® Therapy (NPWT using V.A.C.® GRANUFOAM™ or V.A.C. WHITEFOAM™ Dressings) and V.A.C. VERAFLOR™ Therapy (NPWTi-d using V.A.C. VERAFLOR™ or V.A.C. VERAFLOR CLEANSE™ Dressings).

- V.A.C.® Therapy is the form of NPWT that uses a hydrophobic reticulated open cell foam under subatmospheric pressure to promote wound healing. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure, and venous insufficiency), flaps and grafts.
- V.A.C. VERAFLOR™ Therapy consists of NPWT coupled with automated, controlled delivery to and removal of topical wound treatment solutions from the wound bed. The soak time and automated volumetric delivery differentiate V.A.C. VERAFLOR™ Therapy from other commercially available instillation systems that either provide instillation solutions under continuous flow (without a soak time) or use gravity to instill solution into the wound. V.A.C. VERAFLOR™ Therapy is also unique in that it uses dressings specifically designed for instillation therapy with NPWT. The dressings are less hydrophobic than the current V.A.C.® Therapy Dressings and provide improved fluid distribution within, and removal from, the wound bed.



**Figure 1.** V.A.C. ULTA™ Therapy System

The V.A.C. ULTA™ Therapy System is designed to provide therapeutic options that can be customized for different wound care needs. With V.A.C. VERAFLU™ Therapy, the user can select the appropriate topical wound solution needed for each wound to be treated (such as normal saline or wound irrigation solutions and cleansers) as well as adjust the instillation fill volume and soak time. NPWT parameters, such as negative pressure settings, and duration of negative pressure therapy between instillation cycles, can also be customized. With V.A.C.® Therapy, customers can select continuous or intermittent (called DYNAMIC PRESSURE CONTROL™ Therapy) application of negative pressure.

More importantly, the system can potentially be used for a variety of indicated wound types (Table 1). Because these are open wounds, it is not uncommon for them to become contaminated or infected. Such wounds may benefit from removal of infectious materials and controlled instillation of topical wound cleansers, topical antimicrobial or antiseptic solutions. Additionally, the controlled instillation of topical anesthetic solutions may provide patient comfort during therapy and at dressing changes.

Wounds differ not only in size and shape, but also in amount of exudate, edema, and presence of inflammatory mediators, pathogens, or physical contaminants. Wound severity and comorbidities of the host (eg, immunocompromised, malnourished, poor perfusion, smoking, chronic medical conditions, and advanced age) also influence wound healing.<sup>4,5</sup> All of these factors influence the healing rate and should be considered in selecting optimal wound therapy for each patient. V.A.C. ULTA™ Therapy can be a helpful tool in managing a wide variety of wounds through application of V.A.C.® Therapy and/or V.A.C. VERAFLU™ Instillation Therapy (Table 1).

**Table 1:** Indicated Wound Types

Indicated Open Wound Types	Factors That May Compromise Healing	Benefits of V.A.C. VERAFLU™ Therapy
<ul style="list-style-type: none"> <li>• Acute, traumatic</li> <li>• Dehisced</li> <li>• Chronic</li> <li>• Pressure ulcers</li> <li>• Diabetic foot ulcers</li> <li>• Venous ulcers</li> </ul>	<ul style="list-style-type: none"> <li>• Contamination or infection</li> <li>• Susceptible host (poor immune system)</li> <li>• Comorbidities (eg, diabetes and smoking may impact patient's ability to fight bacteria and heal)</li> <li>• Edema</li> <li>• Resistant bacteria</li> <li>• Poor hygiene or wound care</li> </ul>	<ul style="list-style-type: none"> <li>• Instillation of topical wound cleansers, topical anesthetic solutions and topical antimicrobial or antiseptic solutions</li> <li>• Removal of infectious material</li> <li>• Controlled, protected environment for flushing and cleansing wounds</li> <li>• Protection from external contamination sources</li> <li>• Dressing Soak Tool allows the dressing to be soaked with fluid before removal, allowing for easier dressing removal and increased patient comfort</li> </ul>

Given the extensive amount of published evidence supporting V.A.C.® Therapy as a proven therapy for acute and chronic wounds, this document will primarily focus on instillation using V.A.C. VERAFLU™ Therapy as part of the V.A.C. ULTA™ Therapy System. It will describe wound management using NPWT and NPWTi-d, review the literature relating to NPWT and NPWTi-d, provide scientific evidence supporting the V.A.C. ULTA™ Therapy System, and present the results of instillation therapy in case studies.

## Wound Management with NPWT and NPWTi-d

All wounds can be categorized as unclean (ie, potentially contaminated with bacteria). Health and wound status of the host can also contribute to the probability of developing a wound infection.<sup>6</sup> There is widespread acceptance that wound cleansing is necessary in wound therapy;<sup>7</sup> however, there are very few randomized controlled trials (RCTs) that compare cleansing techniques and solutions.<sup>8</sup> Current wound treatment practice<sup>9</sup> includes some or all of the following:

- Debridement
- Antibiotic treatment and local application of antiseptics or antimicrobials
- Delayed wound closure (when necessary)
- Use of drains
- Repeated wound cleansing

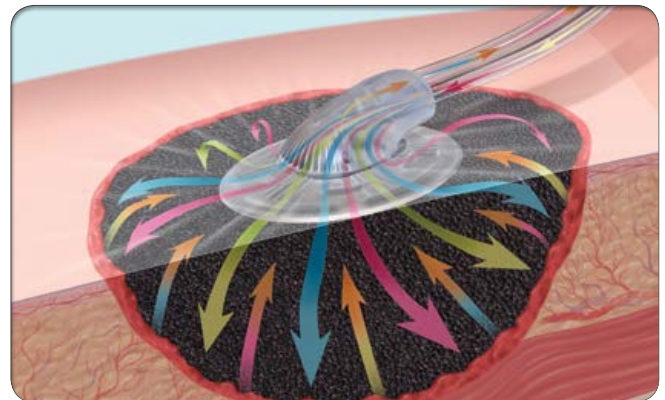
NPWT provides adjunctive therapy that helps prepare the wound bed for closure and remove wound fluid and infectious materials. NPWTi-d also offers additional benefits such as controlled, automated wound cleansing through instillation of topical antiseptic or antimicrobial wound solutions over the wound bed.

Over the past 15 years, NPWT (as delivered by V.A.C.<sup>®</sup> Therapy) has been successfully established in clinical practice for treating acute and chronic wounds and has been increasingly used to manage complex and difficult-to-treat wounds.<sup>10-13</sup> NPWT creates a closed, moist wound-healing environment, promotes granulation tissue formation and perfusion, reduces edema, removes exudate and infectious material, and prepares the wound bed for closure.<sup>11, 12, 14-18</sup> The negative pressure transmitted through the reticulated open cell foam (ROCF) dressing delivers mechanical stress to the tissue, drawing wound edges together, and to the cells, stretching them as tissue is pulled up into the open pores of the ROCF. Cell stretch triggers mitosis, resulting in proliferation and ultimately granulation tissue formation.<sup>14, 15, 19-21</sup> The cost effectiveness of V.A.C.<sup>®</sup> Therapy has been related to positive clinical outcomes in a variety of wound types, including reduced time to wound closure and less complex reconstructive methods of closure.<sup>11, 12, 22-24</sup> More importantly, utilizing NPWT earlier in wound management (rather than later during wound therapy) has been shown to result in cost savings.<sup>1, 25-28</sup>

In recent years, NPWTi-d has emerged as an alternative option for patients who would benefit from vacuum-assisted drainage and controlled delivery of topical cleansing solutions and suspensions, such as normal saline and wound cleansers, into the wound bed.<sup>6, 29</sup> NPWTi-d differs from irrigation (ie, practice of washing out a wound or body opening with a stream of liquid solution<sup>8</sup>) and lavage (ie, process of washing out a cavity or organ [eg, bladder, bowel, or stomach] using a liquid solution for therapeutic purposes).<sup>30</sup> Instilled fluid is slowly introduced into the wound and remains in the wound bed for a defined period of time before being removed by applying negative pressure (**Figure 2**). Automated instillation helps with wound cleansing by loosening soluble contaminants in the wound bed followed by subsequent removal of infectious material during NPWT. As a result, soluble bacterial burden can be decreased, contaminants removed and the wound thus cleansed, all without user interaction. Furthermore, if topical anesthetic solutions are used, patient comfort may be increased during therapy<sup>29</sup> and at dressing changes.<sup>31,32</sup> Two different randomized controlled trials demonstrated that the use of lidocaine either injected retrograde up the suction tube into the foam or instilled through the tubing into the foam for 20 or 30 minutes, respectively, before dressing removal was associated with a decrease in pain during dressing removal compared to control patients who received saline.<sup>31,32</sup>

**V.A.C. VERAFLO™ Therapy** combines the benefits of V.A.C.® Therapy with automated solution distribution and removal. It can help:

- ↑ **Cleanse**  
the wound with instillation of topical wound cleansers in a consistent, controlled manner
- ↑ **Treat**  
the wound with the instillation of appropriate topical antimicrobial and antiseptic solutions and the removal of infectious material
- ↑ **Heal**  
the wound and prepare for primary or secondary closure



**Figure 2.** Schematic of NPWTi-d (V.A.C. VERAFLO™ Therapy)

## Literature Review of NPWT

NPWT (as delivered by V.A.C.® Therapy) is an established advanced wound therapy system for the treatment of acute and chronic wounds across all care settings. There are >700 peer-reviewed publications, including more than 30 RCTs, reporting the use of V.A.C.® Therapy.

**Table 2** lists a number of key references by wound type. These studies have demonstrated several benefits of NPWT, including reduction of wound volume, preparation of wound bed for skin grafting, promotion of healing in acute, chronic and complex diabetic wounds, and promotion of granulation tissue in complex venous leg ulcers as well as in a variety of wound types.

**Table 2:** Key evidence supporting the use of V.A.C.® Therapy

Wound Type	Number of Articles	Key References
<b>Acute Wounds</b>		
Surgical Wounds	195	<sup>33</sup> Zannis et al 2009 (PCT) <sup>34</sup> Siegel et al 2007 (CRS) <sup>35</sup> Yang et al 2006 (CRS) <sup>36</sup> Moues et al 2004 (RCT)
General Trauma	23	<sup>37</sup> Machen et al 2007 (CSE) <sup>38</sup> Labler et al 2007 (CST)
Grafts	70	<sup>39</sup> Blume et al 2010 (RS) <sup>40</sup> Vidrine et al 2005 (CRS) <sup>41</sup> Moisisidis et al 2004 (RCT) <sup>42</sup> Scherer et al 2002 (CSE)
Diabetic Foot Amputations	11	<sup>43</sup> Lavery et al 2008 (RCT-P) <sup>11</sup> Armstrong and Lavery 2005 (RCT) <sup>44</sup> Paola 2010 (RCT) <sup>2</sup> Eginton et al 2003 (RCT)
<b>Chronic Wounds</b>		
<b>Ulcers</b>		
Pressure	38	<sup>45</sup> Wanner et al 2003 (RCT) <sup>46</sup> Ford et al 2002 (RCT) <sup>47</sup> Joseph et al 2000 (RCT)
Diabetic Foot	38	<sup>12</sup> Blume et al 2008 (RCT)
Venous Insufficiency	8	<sup>48</sup> Vuerstaek et al 2006 (RCT)

CRS: Comparative Retrospective Study; CSE: Case Series; CST: Case Study; PCT: Prospective Controlled Trial; RCT: Randomized Controlled Trial; RCT-P: Post hoc Analysis of previously published RCT; RS: Retrospective Study

## Literature Review of NPWTi-d

**Table 3** summarizes the literature on NPWTi-d and spans over 10 years of clinical research.

- In a retrospective analysis of a 5-patient case series, Wolvos<sup>29</sup> (2004) evaluated the use of instillation therapy with topical anesthetics or culture-directed antibiotics. All patients presented with painful, contaminated or infected wounds with overall compromised health. Instillation parameters included instillation of solution ranging 15-60 seconds, with a 5-minute soak time for all patients, followed by NPWT (-125mmHg). The instillation/NPWT cycle was repeated every three hours for all patients. Average treatment time of instillation therapy was 15 days (range: 5-24 days). Several instillation solutions were used including lidocaine, vancomycin, gentamycin, and tobramycin. Results showed wounds that presented with infection prior to instillation therapy showed no growth or only normal flora following instillation therapy. Author concluded that NPWT with instillation of culture-directed antibiotics appeared to reduce the bacterial burden and assist in converting infected wounds to clean wounds. Additionally, the instillation of an anesthetic solution effectively minimized the pain in these patients.<sup>29</sup>
- Bernstein and Tam<sup>49</sup> (2005) reported on a series of 5 post-surgical diabetic foot wounds treated with NPWTi-d. One therapy cycle consisted of instilling solution (composed of saline, polymyxin B, and bacitracin) into the wound for 90 seconds, holding it in the wound for 5 minutes, and applying NPWT at -125mmHg for 6 hours. The authors noted a decrease in hospital stay and amputation rate and reported that the addition of instilled solutions lowered wound fluid viscosity, facilitating more efficient removal into the canister.<sup>49</sup>
- More recent studies have focused on use of NPWTi-d to manage larger patient groups with infected wounds. For example, Gabriel et al<sup>50</sup> (2008) published a pilot study of 15 patients with complex, infected wounds treated with NPWTi-d using silver nitrate compared to a retrospective historical control of 15 patients treated with moist gauze wound care (control). Study results showed NPWTi-d patients compared to Control patients required significantly fewer days of treatment ( $9.9 \pm 4.3$  vs  $36.5 \pm 13.1$  days,  $p < 0.001$ ), cleared clinical infection in a shorter time ( $6.0 \pm 1.5$  vs  $25.9 \pm 6.6$  days,  $p < 0.001$ ), achieved wound closure sooner ( $13.2 \pm 6.8$  vs  $29.6 \pm 6.5$  days,  $p < 0.001$ ), and had shorter in-patient length of stay ( $14.7 \pm 9.2$  vs  $39.2 \pm 12.1$  days,  $p < 0.001$ ). The authors concluded that "outcomes from this study analysis suggest the use of NPWTi-d may reduce cost and decrease inpatient care requirements for these complex, infected wounds."<sup>50</sup>
- In a retrospective, case-control cohort study, Timmers et al<sup>51</sup> (2009) evaluated the clinical outcome of 30 patients diagnosed with osteomyelitis of the pelvis or lower extremity and treated with debridement and systemic antibiotics followed by adjunctive NPWTi-d using polyhexanide. Control patients received "standard surgical debridement, implantation of gentamicin polymethylmethacrylate beads and long-term intravenous antibiotics." In NPWTi-d patients, infection recurrence rate was 3/30 (10%) compared to 55/93 (58.5%) for the control group ( $p < 0.0001$ ). Moreover, for NPWTi-d patients, the total duration of hospital stay was significantly shorter ( $36$  [range: 15-75] vs  $73$  days [range: 6-149];  $p < 0.0001$ ), and number of surgical procedures was significantly smaller compared to the control group ( $2$  [range: 1-4] vs  $5$  [range: 2-42];  $p < 0.0001$ ). The authors concluded that, in posttraumatic osteomyelitis, adjunctive NPWTi-d reduced the need for repeated surgical interventions compared to the present standard approach.<sup>51</sup>
- Additionally, Schintler et al<sup>52</sup> (2009) reported on the successful NPWTi-d treatment of 15 patients with complicated skin and soft tissue infection (eg, necrotizing fasciitis). Polyhexanide was instilled in all wounds; instillation time was dependent on wound size and dwell time was 20 minutes in all cases. Therapy duration ranged from 4-18 days with dressing changes every 2 to 4 days. Infection was controlled and complete healing was achieved in all patients. The authors concluded NPWTi-d may be a viable option for infection control when dealing with challenging wound locations and in cases of incomplete debridement when treating complicated skin and soft tissue infections.<sup>52</sup>

- In 2010, Raad et al<sup>53</sup> performed a retrospective review of a prospective wound care database over 2 years. Five patients with venous stasis ulcers (> 200cm<sup>2</sup>) and with colonization greater than 105 bacteria (2 patients had multi-drug-resistant *Pseudomonas* and 3 patients had methicillin-resistant *Staphylococcus aureus*) were initially debrided and then treated with NPWTi-d for 10 days with 12.5% Dakin's solution instilled for 10 minutes every hour. After 10 days of NPWTi-d, quantitative biopsies that were taken from 2 different wound locations for each patient tested negative for bacteria growth. Patients then received a split-thickness skin graft (STSG) followed by 4 days of standard NPWT. At 1-month follow up, there was 100% graft take. At one year, all patient wounds remained healed. The results suggested NPWTi-d was an effective adjunctive therapy for the management of patients with infected chronic venous stasis ulcers.<sup>53</sup>

**Table 3:** Literature Review of Instillation Therapy

Author	Study Type and Patients	Instillation Therapy Parameters	Results/Conclusions
Wolvos <sup>29</sup> (2004)	<ul style="list-style-type: none"> <li>• Retrospective analysis of instillation therapy with topical anesthetic or culture-directed antibiotics in 5 patients.</li> </ul>	<ul style="list-style-type: none"> <li>• Average treatment time of instillation therapy was 15 days (range: 5-24 days).</li> <li>• Instillation solutions used were: lidocaine, vancomycin, gentamycin, and tobramycin.</li> <li>• All solutions were instilled for 15-60 seconds, with a 5 minute soak time followed by continuous NPWT set at -125mmHg.</li> </ul>	<ul style="list-style-type: none"> <li>• Wounds that presented with infection prior to instillation therapy showed no growth or only normal flora following instillation therapy.</li> <li>• Author concluded NPWT with instillation of culture-directed antibiotics appeared to reduce the bacterial burden.</li> <li>• Additionally, instilling an anesthetic was associated with a decrease in pain in these patients.</li> </ul>
Bernstein and Tam <sup>49</sup> (2005)	<ul style="list-style-type: none"> <li>• A series of 5 post-surgical diabetic patients whose foot wounds were treated with NPWTi-d.</li> </ul>	<ul style="list-style-type: none"> <li>• 6 hours of NPWT at -125mmHg followed by instillation of a solution composed of saline, polymyxin B, and bacitracin for 90 seconds and a dwell time of 5 minutes.</li> </ul>	<ul style="list-style-type: none"> <li>• Authors noted a decrease in hospital stay and amputation rate.</li> <li>• Authors also noted the addition of instilled solutions lowered wound fluid viscosity, facilitating more efficient removal into the canister.</li> </ul>
Gabriel et al <sup>50</sup> (2008)	<ul style="list-style-type: none"> <li>• A pilot study of 15 patients with complex, infected wounds treated with NPWTi-d compared to a retrospective historical control of 15 patients treated with moist gauze wound care (control).</li> </ul>	<ul style="list-style-type: none"> <li>• NPWTi-d consisted of instillation with silver nitrate for 30 seconds with a 1-second hold time followed by 2 hours of NPWT at -125mmHg continuously.</li> </ul>	<ul style="list-style-type: none"> <li>• Results showed patients managed with NPWTi-d required fewer days of treatment (<math>p &lt; 0.001</math>), cleared the infection earlier (<math>p &lt; 0.001</math>), achieved wound closure sooner (<math>p &lt; 0.001</math>), and had fewer in-hospital days (<math>p &lt; 0.001</math>) compared to the control group.</li> <li>• Authors concluded "outcomes from this study analysis suggest that the use of NPWTi-d may reduce cost and decrease inpatient care requirements for these complex, infected wounds."</li> </ul>



**Table 3:** Literature Review of Instillation Therapy (cont.)

Author	Study Type and Patients	Instillation Therapy Parameters	Results/Conclusions
Timmers et al <sup>51</sup> (2009)	<ul style="list-style-type: none"> <li>A retrospective, case–control cohort study of 30 patients diagnosed with osteomyelitis of the pelvis or lower extremity and treated with debridement, systemic antibiotics and adjunctive NPWTi-d.</li> <li>Control patients (n=94) received standard care (ie, debridement, implantation of gentamicin beads, and systemic antibiotics).</li> </ul>	<ul style="list-style-type: none"> <li>Instillation solution used was polyhexanide.</li> <li>Soak time was 10-15 minutes.</li> <li>300mmHg to 600mmHg negative pressure range was used.</li> <li>Dressing changes occurred every 3-4 days.</li> <li>Mean duration of therapy was 19.0 - 22.4 days.</li> </ul>	<ul style="list-style-type: none"> <li>In NPWTi-d group, recurrence infection rate was 3/30 (10%) compared to 55/93 (58.5%) for the control group (<math>p&lt;0.0001</math>).</li> <li>In NPWTi-d patients, total duration of hospital stay was significantly shorter (36 [range: 15-75] vs 73 days [range: 6-149]; <math>p&lt;0.0001</math>) and number of surgical procedures was significantly smaller compared to the control group (2 [range: 1-4] vs 5 [range: 2-42]; <math>p&lt;0.0001</math>).</li> <li>Authors concluded in posttraumatic osteomyelitis negative pressure with instillation therapy reduced the need for repeated surgical interventions compared to the present standard approach.</li> </ul>
Schintler et al <sup>52</sup> (2009)	<ul style="list-style-type: none"> <li>A series of 15 patients with skin and soft tissue infection (eg, necrotizing fasciitis) treated with NPWTi-d.</li> </ul>	<ul style="list-style-type: none"> <li>Instillation solution used was polyhexanide.</li> <li>Instillation time was dependent on wound size; dwell time was 20 minutes in all cases.</li> <li>Therapy duration ranged from 4-18 days with dressing changes every 2-4 days.</li> </ul>	<ul style="list-style-type: none"> <li>Results showed infection was controlled and complete healing was achieved in all patients.</li> <li>Authors concluded NPWTi-d may be a viable option for infection control in complicated anatomical regions and in cases of incomplete debridement in complicated skin and soft tissue infections.</li> </ul>
Raad et al <sup>53</sup> (2010)	<ul style="list-style-type: none"> <li>A retrospective review of prospective wound care data over 2 years.</li> <li>5 patients with venous stasis ulcers (&gt;200cm<sup>2</sup>) and with colonization greater than 10<sup>5</sup> bacteria were studied.</li> </ul>	<ul style="list-style-type: none"> <li>Patients were initially debrided and then treated with NPWTi-d for 10 days with 12.5% Dakin's solution instilled for 10 minutes every hour.</li> <li>After 10 days and following negative quantitative cultures, patients received an STSG and 4 days of standard NPWT.</li> </ul>	<ul style="list-style-type: none"> <li>Results showed 100% graft take at 1-month follow up.</li> <li>Authors concluded that NPWTi-d provided an effective therapy for managing patients with infected chronic venous stasis.</li> </ul>

## V.A.C.ULTA™ Therapy System

The V.A.C.ULTA™ Therapy System is an innovation in NPWT, combining V.A.C.® Therapy with automated instillation features upgraded from the V.A.C. INSTILL™ Therapy Unit. One unit, two therapies, allows clinicians the flexibility to alternate between two negative pressure wound therapies:

- V.A.C.® Therapy, which provides NPWT.
- V.A.C. VERAFLOR™ Therapy, which instills and suspends topical solutions across the wound bed.

The V.A.C.ULTA™ Therapy System is the next-generation replacement for INFOV.A.C.™, V.A.C. ATS™, and V.A.C. INSTILL™ Therapy Units in acute care hospitals.

### V.A.C.ULTA™ Therapy Technology

The V.A.C.ULTA™ Therapy System is a customizable single system that provides two wound treatment therapies. Clinicians now have the option to use V.A.C. VERAFLOR™ Therapy first to instill a suitable solution to a wound before converting to NPWT (ie, V.A.C.® Therapy) for the remainder of treatment, eliminating the need for a separate NPWT unit, as well as the need for manual instillation of topical wound solutions between NPWT cycles. After the therapy parameters are entered into the V.A.C.ULTA™ Therapy unit, wound instillation and NPWT are under the control of the therapy unit, without the need for caregiver intervention until need for dressing change, replacement of the solution container or attention to alarms.

### V.A.C. VERAFLOR™ Therapy

V.A.C. VERAFLOR™ Therapy allows the users to select a variety of therapy parameters:

- Instillation solution: per clinician preference, although solution container must accept a standard spike for connection to the therapy unit.
- Fill volume: between 6 and 500ml
- Soak time: 1 sec to 30 min
- Negative pressure time between instillation cycles:
  - 3 min to 12 hrs
  - Negative pressure range: -50 to -200mmHg

The V.A.C.ULTA™ Therapy Unit has three new advanced software features that facilitate instillation and dressing changes:

- **Fill Assist Tool** allows the clinician to visually determine the correct instillation volume. Once determined, the desired volume will automatically be delivered for each subsequent instillation phase of V.A.C. VERAFLOR™ Therapy.
- **Test Cycle Tool** runs an abbreviated instillation cycle to ensure that the system is set up and functioning as intended.
- **Dressing Soak Tool** allows the clinician to soak the dressing with instillation solution before removal. This allows easier dressing removal and increased patient comfort. Refer to Table 6 for compatible topical anesthetic solutions.

There are several new system accessories designed for use with V.A.C. VERAFLOR™ Therapy.

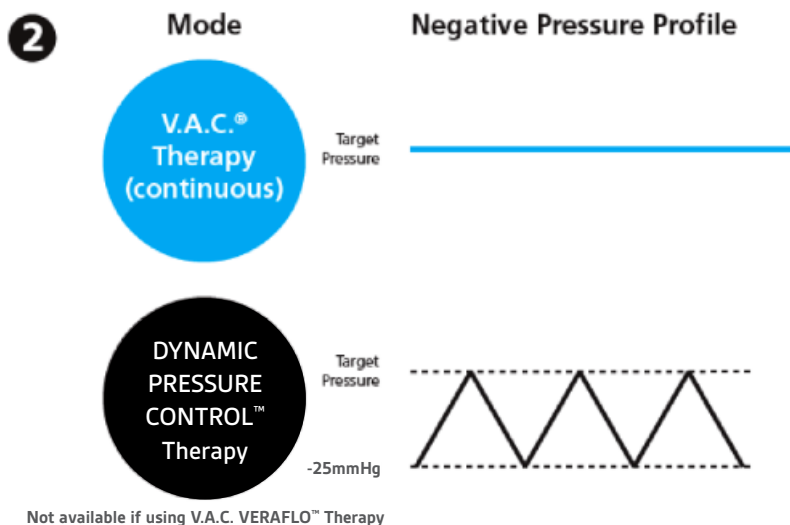
- The V.A.C. VERALINK™ Cassette is an instillation cassette that connects the solution bag/bottle and dressing tubing to the V.A.C.ULTA™ Therapy Unit. The cassette holds and delivers user-provided wound solutions to the wound bed.
- The V.A.C. VERAT.R.A.C.™ Pad is a single pad that incorporates tubing for fluid delivery and tubing for exudate/fluid removal. It also works with SENSAT.R.A.C.™ Technology to monitor and adjust pressure at the wound site.
- The V.A.C. VERAT.R.A.C. DUO™ Tube Set contains two pads: the Instill pad for fluid instillation and the SENSAT.R.A.C.™ Pad for exudate/fluid removal and pressure sensing at the wound site. It also works with SENSAT.R.A.C.™ Technology to monitor and adjust pressure at the wound site.

Newly engineered dressings (V.A.C. VERAFLOR™ and V.A.C. VERAFLOR CLEANSE™ Dressings) are available for use with V.A.C.VERAFLOR™ Therapy. These new dressings are similar to the V.A.C.® GRANUFOAM™ Dressing in pore size, but are less hydrophobic with improved mechanical properties. Although V.A.C. VERAFLOR™ and V.A.C. VERAFLOR CLEANSE™ Dressings are specifically designed to be used for instillation, they can also be used with V.A.C.® Therapy, if the clinician decides to switch from V.A.C. VERAFLOR™ Therapy to V.A.C.® Therapy before the next dressing change is due.

## V.A.C.® Therapy

Although the V.A.C.® Therapy delivered by the V.A.C.ULTA™ Therapy Unit is the same as that provided by all other KCI V.A.C.® Therapy Systems, several new features have been added.

- The V.A.C.® Therapy option offers two therapy modes (**Figure 3**):
  - Continuous mode.
  - The next evolution of intermittent therapy, DYNAMIC PRESSURE CONTROL™ Therapy. Rather than dropping the pressure to 0mmHg between therapy cycles, DYNAMIC PRESSURE CONTROL™ Therapy maintains a low level of negative pressure (-25mmHg) between cycles (**Figure 3**), which helps to prevent leaks and fluid accumulation that can occur when there is no negative pressure at the wound site. DYNAMIC PRESSURE CONTROL™ Therapy may also assist in minimizing patient discomfort from foam expansion and compression that can occur when negative pressure returns to 0mmHg. DYNAMIC PRESSURE CONTROL™ Therapy is not available during V.A.C. VERAFLU™ Therapy. DYNAMIC PRESSURE CONTROL™ Therapy



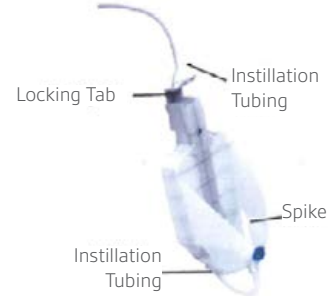
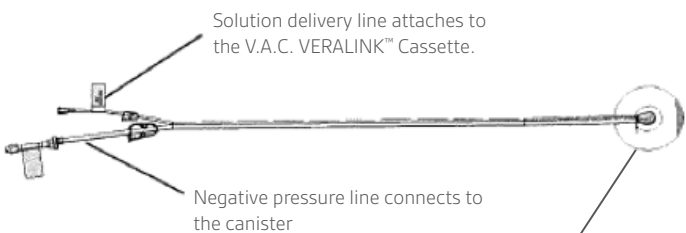


**Figure 3.** V.A.C.® Therapy (With Two Modes)

The V.A.C.® Therapy cycle is compatible with all current V.A.C.® Therapy dressings (V.A.C.® GRANUFOAM™, V.A.C.® GRANUFOAM SILVER™, and V.A.C. WHITEFOAM™ Dressings), SENSAT.R.A.C.™ Technology, drapes and INFOV.A.C.™ Therapy canisters.

**Table 4** describes the components of the V.A.C.ULTA™ Therapy System (ie, V.A.C. VERAFLU™ Therapy and V.A.C.® Therapy).

**Table 4:** V.A.C.ULTA™ Therapy System Components





Name/Description	Picture/Diagram
<p><b>V.A.C.ULTA™ Therapy System</b>            Similar in style/appearance to the INFOV.A.C.™ Therapy System with the option of providing NPWTi-d or NPWT. One therapy unit, two therapies.</p>	 <p>Solution Container Hanger Arm</p> <p>Instillation Cassette (V.A.C. VERALINK™ Cassette)</p> <p>Canister</p>
<p><b>Exudate Canisters</b>            Single-patient use, disposable canisters, available in three convenient sizes: 300, 500, and 1000ml.</p>	 <p>500ml</p> <p>300ml</p> <p>Canister Latch Release</p>
<p><b>Instillation Cassette (V.A.C. VERALINK™ Cassette)</b>            Single-patient use, disposable cassette allows for irrigation solution to be used in its original container</p>	 <p>Locking Tab</p> <p>Instillation Tubing</p> <p>Spike</p> <p>Instillation Tubing</p>
<p><b>V.A.C. VERAT.R.A.C.™ Pad (All in One Pad with SENSAT.R.A.C.™ Technology)</b>            This is one of two tube sets available for instillation. Single-patient use, disposable tube set with two lines:</p> <ul style="list-style-type: none"> <li>• One line delivers negative pressure to and monitors pressure at the wound site. This line connects to the tubing leading to the exudate canister in the therapy unit.</li> <li>• The other line delivers solution. This line attaches to the V.A.C. VERALINK™ Cassette.</li> <li>• These lines are applied over the foam dressing in the wound via a pad that is similar in appearance to the SENSAT.R.A.C.™ Pad.</li> </ul> <p>The V.A.C. VERAT.R.A.C.™ Pad is the standard tube set included in the V.A.C. VERAFLU™ Dressing packs.</p>	 <p>Solution delivery line attaches to the V.A.C. VERALINK™ Cassette.</p> <p>Negative pressure line connects to the canister</p> <p>Provides delivery of solutions and negative pressure and exudate removal through a single pad.</p>

**Table 4: V.A.C.ULTA™ Therapy System Components (cont.)**

Name/Description	Picture/Diagram
<p><b>V.A.C. VERAT.R.A.C. DUO™ Tube Set (Two-headed Pad)</b></p> <p>This is the second configuration available for instillation. This set is equipped with two separate pads that are placed over the dressing, one for instilling fluids and the other for delivering negative pressure. This design allows clinicians the option of selecting different sites in the wound where the solution is instilled and where it is removed (through the negative pressure line).</p>	
<p><b>V.A.C. VERAFLU™ Dressing Kit</b></p> <p>This dressing kit is designed primarily for instillation therapy and consists of the following components:</p> <ul style="list-style-type: none"> <li>• The <b>V.A.C. VERAFLU™ Dressing</b> which is similar to the V.A.C.® GRANUFOAM™ Dressing (both are polyurethane based) but is specifically designed for V.A.C. VERAFLU™ Therapy.</li> </ul> <p>This dressing is less hydrophobic with improved mechanical properties. It is available in three sizes: small, medium and large.</p> <ul style="list-style-type: none"> <li>• The new <b>V.A.C.® Advanced Drape</b> is similar to the present V.A.C.® Drape but has improved adhesive properties to assist with sealing during solution instillation.</li> <li>• <b>V.A.C. VERAT.R.A.C.™ Pad (All-in-One Pad)</b></li> <li>• <b>3M™ Cavilon™ No Sting Barrier Film</b></li> <li>• <b>Wound ruler</b></li> </ul>	
<p><b>V.A.C. VERAFLU CLEANSE™ Dressing Kit</b></p> <p>This kit, also designed primarily for instillation therapy, is comprised of the following:</p> <ul style="list-style-type: none"> <li>• <b>V.A.C. VERAFLU CLEANSE™ Dressing</b>, which is similar to the V.A.C. VERAFLU™ Dressing in composition, except that it is compressed under heat in one direction.</li> </ul> <p>In swine granulation studies, it was generally less granulating than other V.A.C.® Therapy Dressings. It is less hydrophobic with improved mechanical properties. Due to its tubular shape and design, it can be configured for a variety of wound geometries.</p> <p>The other disposables in this kit are the same as those included in the V.A.C. VERAFLU™ Dressing Kit.</p>	
<p><b>V.A.C.® Therapy Dressing Kit</b></p> <p>The dressing systems for use with the V.A.C.ULTA™ Therapy System are the same as those currently used for V.A.C.® Therapy:</p> <ul style="list-style-type: none"> <li>• V.A.C.® GRANUFOAM™ Dressing Kit.</li> <li>• V.A.C.® GRANUFOAM SILVER™ Dressing* Kit.</li> <li>• V.A.C. WHITEFOAM™ Dressing kit.</li> </ul> <p>The above products are typically packaged with the V.A.C.® Drape, SENSAT.R.A.C.™ Pad and a ruler.</p> <p><b>*Note:</b> V.A.C.® GRANUFOAM SILVER™ Dressing is not intended to be used with Instillation Therapy as instillation solutions may have a negative impact on the benefits of the V.A.C.® GRANUFOAM SILVER™ Dressing.</p>	

The properties of the above dressings are compared in **Table 5** below, and the instillation solutions with which they are compatible are provided in **Table 6**.

**Table 5:** V.A.C.ULTA™ Therapy System Components

Dressing Property	V.A.C.® GRANUFOAM™ Dressing	V.A.C. WHITEFOAM™ Dressing	V.A.C. VERAFLU™ Dressing	V.A.C. VERAFLU CLEANSE™ Dressing
				
Material	Black Polyurethane ether	White Polyvinyl alcohol	Black Polyurethane ester	Grey Polyurethane ester
Open cell reticulated	Yes	No	Yes	Yes
Pore size	400-600 microns all directions	60-270 microns	400-600 microns	133-600 microns depends on direction
Relative hydrophobicity* (lowest value = highest level of hydrophobicity)	1	4	2	3
Shape	Variable shapes/sizes	Sheets	Spiral cut sheet	Rod with center perforations for ease of separation into halves
Tensile strength - Dry	Baseline	3 times greater than baseline	1.7 times greater than baseline	2.5 times greater than V.A.C. VERAFLU™ Dressing dry
Tensile strength - Wet	Baseline	3.7 times greater than baseline	1.5 times greater than baseline	3 times greater than V.A.C. VERAFLU™ Dressing wet
7 day granulation tissue formation** (Swine model data) <sup>52</sup>	<b>Therapy Applied</b>			
	V.A.C.® Therapy	V.A.C.® Therapy	V.A.C. VERAFLU™ Therapy (Saline)	V.A.C. VERAFLU™ Therapy (Saline)
	<b>Results</b>			
	Baseline	20% less than baseline	43% greater than baseline	<ul style="list-style-type: none"> <li>• 37% greater than V.A.C.® WHITEFOAM™ Dressing with V.A.C.® Therapy</li> <li>• 24% less than V.A.C. VERAFLU™ Dressing with V.A.C. VERAFLU™ Therapy</li> </ul>

\*Lowest value = highest level of hydrophobicity.

\*\*Granulation thickness based on histology; results have not yet been confirmed in human studies.

**Table 6:** Solutions Compatible with V.A.C. VERAFLOR™ Therapy\*

Generic Solution Class	Trade Name	Considerations for Use with V.A.C. VERAFLOR™ Therapy
Hypochlorite-based solutions (eg, Hypochlorous acid, Sodium hypochlorite)	Dakin's Solution (quarter strength), Dermacyn®, Microcyn®	<ul style="list-style-type: none"> <li>Dakin's Solution should not be used in concentrations greater than 0.125% (quarter strength).</li> <li>Consider using the fewest irrigation cycles and minimizing hold times to the lowest level that is clinically relevant.</li> </ul>
Silver nitrate (0.5%)	Various	<ul style="list-style-type: none"> <li>Silver nitrate is light sensitive. Protect V.A.C. VERALINK™ Instillation Tubing from light during use of silver nitrate.</li> </ul>
Sulfur-based solutions (Sulfonamides)	Mafenide acetate, Sulfamylon®	<ul style="list-style-type: none"> <li>Refer to manufacturer's labeling for solution-specific considerations. No device-related considerations for use with V.A.C. VERAFLOR™ Therapy.</li> </ul>
Biguanides (Polyhexanide)	PRONTOSAN®	<ul style="list-style-type: none"> <li>May need to be transferred to a container that can be accessed with a spike.</li> </ul>
Cationic solutions (Octenidine, Benzalkonium Chloride)	Octenilin®	<ul style="list-style-type: none"> <li>Refer to manufacturer's labeling for solution-specific considerations. No device-related considerations for use with V.A.C. VERAFLOR™ Therapy.</li> </ul>
Isotonic Solutions	Normal Saline Solution, Lactated Ringer's Solution	<ul style="list-style-type: none"> <li>Refer to manufacturer's labeling for solution-specific considerations. No device-related considerations for use with V.A.C. VERAFLOR™ Therapy</li> </ul>
Local Anesthetic (topical wound cleanser additive)	Lidocaine®	<ul style="list-style-type: none"> <li>Lidocaine hydrochloride without any other additives should only be used in concentrations equal to or less than 0.1%.</li> <li>Refer to manufacturer's labeling for solution-specific considerations. No device-related considerations for use with V.A.C. VERAFLOR™ Therapy.</li> <li>Toxicity concerns may exist; consult with your Pharmacist for solution and patient specific considerations when using lidocaine hydrochloride as an additive to topical wound cleansing solutions.</li> </ul>

**\*Caution: Listing of the above solutions is neither an endorsement nor an indication of a solution's clinical efficacy.** These solutions are included based on KCI in-house testing of disposables, mechanical properties, biocompatibility, and solution interaction and found to be compatible with the V.A.C. ULTA™ Therapy System components. If wound healing goals are not being achieved, consider an alternate instillation frequency, solution concentration, or solution type deemed appropriate by a physician. Please follow solution manufacturer's Instructions for Use prior to use with V.A.C. VERAFLOR™ Therapy. (As of 12/2013)

## Indications for Use

The V.A.C. ULTA™ NPWT System is an integrated wound management system that provides Negative Pressure Wound Therapy (V.A.C.® Therapy) with an instillation option (V.A.C. VERAFLOR™ Therapy).

NPWT in the absence of instillation is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material.

The instillation option is indicated for patients who would benefit from vacuum-assisted drainage and controlled delivery of topical wound solutions over the wound bed.

The V.A.C. ULTA™ Therapy System with and without instillation is indicated for patients with chronic, acute, traumatic, sub-acute, and dehisced wounds, partial-thickness burns, ulcers (eg, diabetic, pressure and venous insufficiency), flaps, and grafts.

The V.A.C. ULTA™ Therapy System is not intended for home use. If the need arises for V.A.C.® Therapy to be continued when a patient transitions home, other KCI Therapy Systems approved for the post-acute care environment should be considered.

## Contraindications

**Table 7** lists the contraindications for the V.A.C. ULTA™ Therapy System, including contraindications specific to V.A.C. VERAFLOR™ Therapy.

## Warnings, Precautions, and Limitations

It is important to read and follow all instructions and safety information prior to use for any NPWT device. Please refer to the KCI e-labeling link for detailed safety information.

**Table 7:** Contraindications

V.A.C. ULTA™ Therapy System	V.A.C. VERAFLOR™ Therapy
<ul style="list-style-type: none"><li>Do not place dressings for V.A.C.® Therapy (ie, V.A.C.® GRANUFOAM™ Dressing) and V.A.C. VERAFLOR™ Therapy (ie, V.A.C. VERAFLOR™ Dressing and V.A.C. VERAFLOR CLEANSE™ Dressing) directly in contact with exposed blood vessels, anastomotic sites, organs, or nerves. <b>NOTE:</b> Refer to Warnings section for additional information concerning bleeding</li><li>V.A.C.® Therapy and V.A.C. VERAFLOR™ Therapy are contraindicated for patients with:<ul style="list-style-type: none"><li>Malignancy in the wound</li><li>Untreated osteomyelitis <b>NOTE:</b> Refer to Warnings section for Osteomyelitis information</li><li>Non-enteric and unexplored fistulae</li><li>Necrotic tissue with eschar present <b>NOTE:</b> After debridement of necrotic tissue and complete removal of eschar, V.A.C.® Therapy may be used</li><li>Sensitivity to silver (V.A.C.® GRANUFOAM SILVER™ Dressing only)</li></ul></li></ul>	<ul style="list-style-type: none"><li>Do not use Octenisept®, hydrogen peroxide, or alcohol-based solutions with dressings. (Note: Octenisept® is not available in the United States.)</li><li>Do not deliver fluids to the thoracic or abdominal cavity due to the potential risk to alter core body temperature and the potential for fluid retention within the cavity.</li><li>Do not use V.A.C. VERAFLOR™ Therapy unless the wound has been thoroughly explored due to the possibility of inadvertently instilling topical wound solutions into adjacent body cavities.</li></ul>



## Science Supporting V.A.C. VERAFLOR™ Therapy

The V.A.C.ULTA™ Therapy System contains improved instillation technology with V.A.C. VERAFLOR™ Therapy; therefore, several analyses were conducted to evaluate different properties of this therapy. Results of the preclinical studies have not yet been verified in human trials.

### Dressing Strength Properties

A series of bench tests (**Table 8**) evaluated the physical characteristics of the V.A.C. VERAFLOR™ and V.A.C. VERAFLOR CLEANSE™ Dressings in comparison to existing V.A.C.® GRANUFOAM™ Dressings. Both the V.A.C. VERAFLOR™ and V.A.C. VERAFLOR CLEANSE™ Dressings were shown to have greater tensile strength under both wet and dry conditions than V.A.C.® GRANUFOAM™ Dressings

### Dressing Fluid Distribution Properties

**Table 8:** Tensile Strength<sup>54</sup>

	V.A.C.® GRANUFOAM™ Dressing	V.A.C. WHITEFOAM™ Dressing	V.A.C. VERAFLOR™ Dressing	V.A.C. VERAFLOR CLEANSE™ Dressing
Tensile Strength	Baseline	<ul style="list-style-type: none"> <li>Dry: 3 times greater than V.A.C.® GRANUFOAM™ Dressing dry</li> <li>Wet: 3.7 times stronger than V.A.C.® GRANUFOAM™ Dressing wet</li> </ul>	<ul style="list-style-type: none"> <li>Dry: 1.7 times greater than V.A.C.® GRANUFOAM™ Dressing dry</li> <li>Wet: 1.5 times greater than V.A.C.® GRANUFOAM™ Dressing wet</li> </ul>	<ul style="list-style-type: none"> <li>Dry: 2.5 times greater than V.A.C. VERAFLOR™ Dressing dry</li> <li>Wet: 3 times greater than V.A.C. VERAFLOR™ Dressing wet</li> </ul>

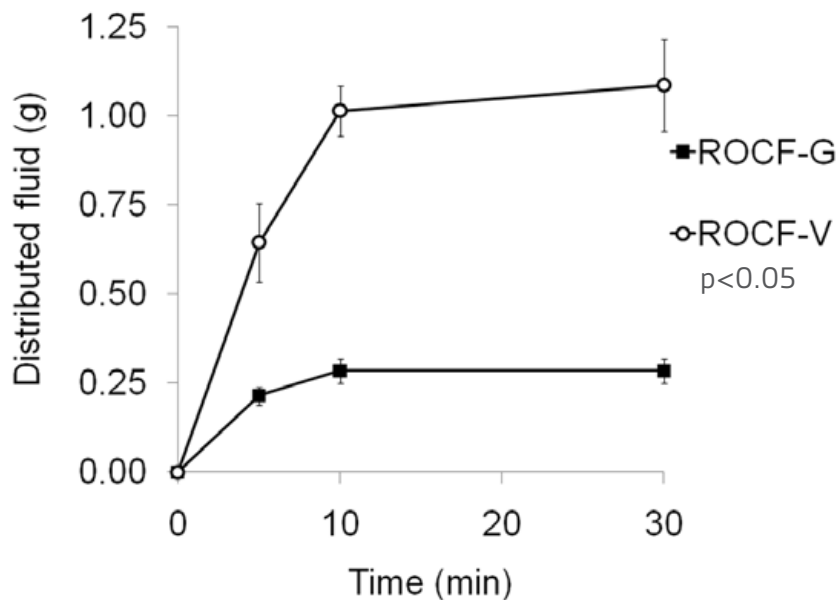
The fluid distribution properties of the V.A.C.® GRANUFOAM™ and V.A.C. VERAFLOR™ Dressings were compared.<sup>55</sup>

#### Methods:

- V.A.C.® GRANUFOAM™ and V.A.C. VERAFLOR™ Dressings were precut and placed between 2 transparent plates; they were compressed 65% to 5.3mm thickness.
- The plates were immersed in a clear plastic reservoir containing 15mm of saline and removed after 6-, 15-, or 30-minute exposure times.
- They were then weighed and the amount of saline wicked by each dressing was measured.
- The procedure was repeated 5 times and analyzed.

#### Results

Data showed that V.A.C. VERAFLOR™ Dressing distributed more fluid than V.A.C.® GRANUFOAM™ Dressing; V.A.C. VERAFLOR™ Dressing pulled more saline from the reservoir than V.A.C.® GRANUFOAM™ Dressing ( $p < 0.05$ ) (**Figure 4**). These data suggest that the V.A.C. VERAFLOR™ Dressing may have enhanced fluid distribution properties.<sup>55</sup>



**Figure 4.** Time course of fluid distribution of saline throughout both dressings ( $p < 0.05$ ). (ROCF-G: V.A.C.® GRANUFOAM™ Dressing; ROCF-V: V.A.C. VERAFLOR™ Dressing)

### Effect on Granulation Tissue Formation

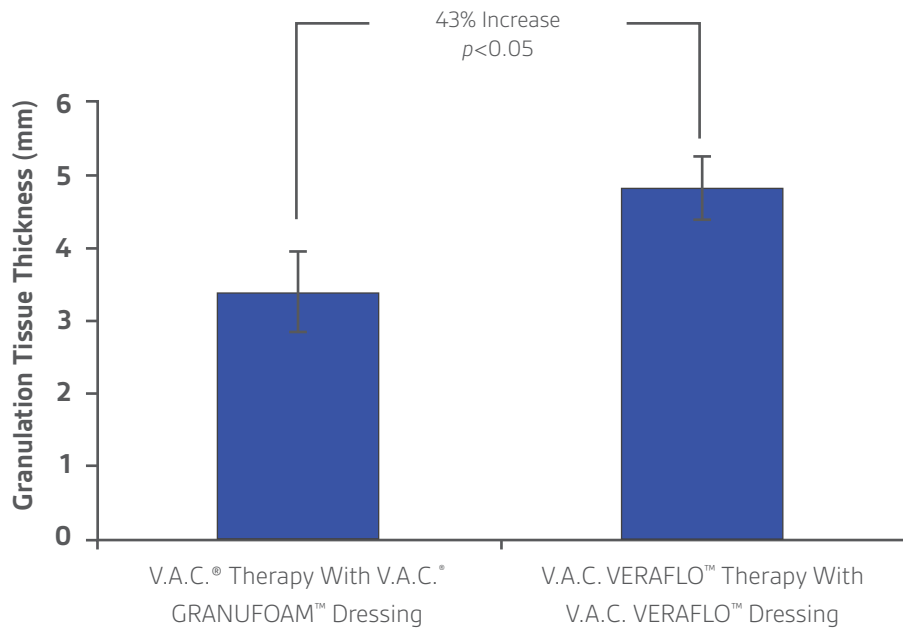
An *in vivo* porcine full-thickness wound model ( $n=12$ ) was used to evaluate granulation tissue thickness.<sup>55</sup>

#### Methods:

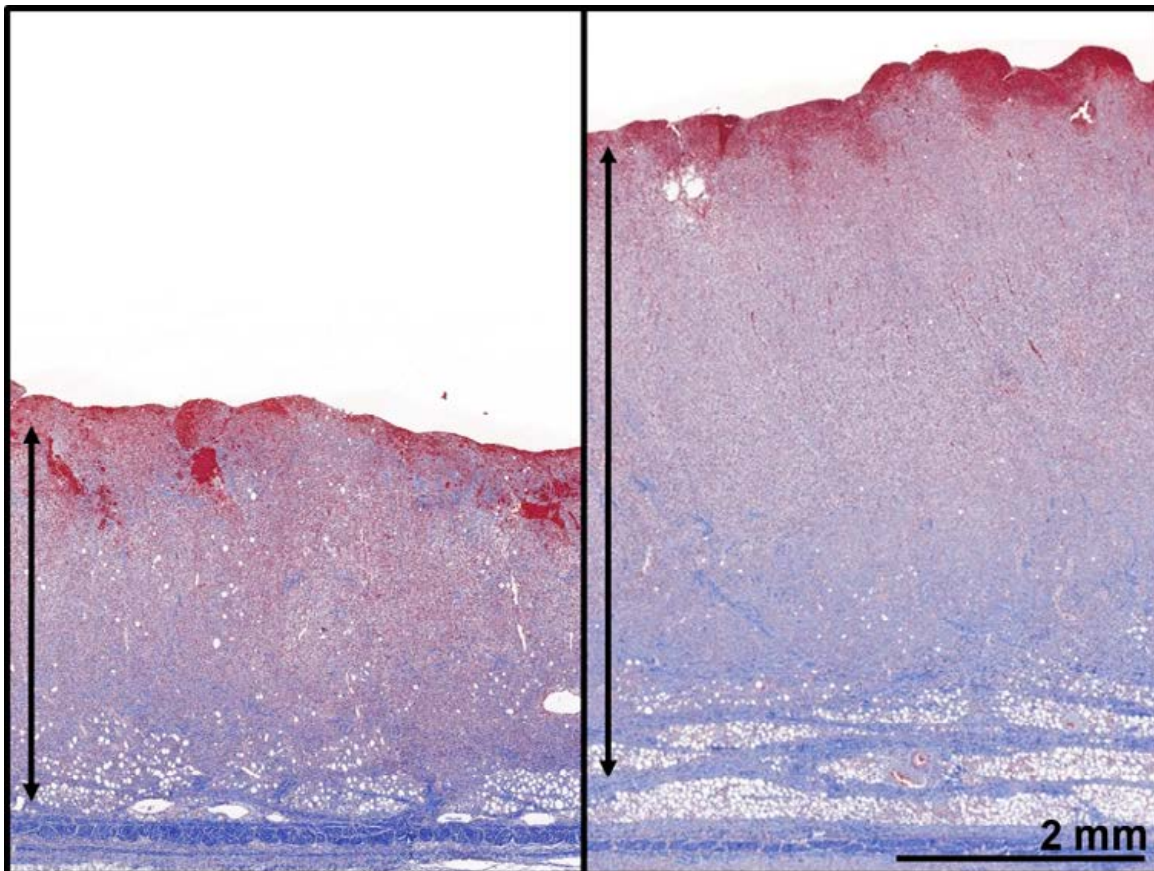
- Each animal received contralateral 5cm diameter full-thickness excisional dorsal wounds that were treated with either V.A.C. VERAFLOR™ Therapy using the V.A.C. VERAFLOR™ Dressing or V.A.C.® Therapy using the V.A.C.® GRANUFOAM™ Dressing.
- V.A.C. VERAFLOR™ Therapy was set to instill 20ml of normal saline, soak for 5 minutes and apply negative pressure of -125mmHg continuously for 2.5 hours for 10 cycles per day.
- V.A.C.® Therapy was set at -125mmHg continuous pressure.
- After 7 days, tissue samples were processed for histology and stained with Masson's tri-chrome.
- Granulation tissue thickness was measured from the base of the wound to the surface of the wound.

#### Results

A significant increase in granulation thickness (43%,  $p < 0.05$ ; **Figure 5**) was observed with V.A.C. VERAFLOR™ Therapy using V.A.C. VERAFLOR™ Dressings compared to V.A.C.® Therapy using V.A.C.® GRANUFOAM™ Dressings ( $4.82 \pm 0.42\text{mm}$  and  $3.38 \pm 0.55\text{mm}$ , respectively,  $p < 0.05$ ).<sup>55</sup> Results of the histological findings showed that the increase in granulation thickness was the result of new tissue deposition, not swelling (**Figure 6**).<sup>55</sup> Optimization of NPWTi-d parameters, such as instillation volume, soak time, and cycle frequency may allow for further improvement in tissue granulation. However, it is uncertain how these swine results may correlate to human results.



**Figure 5.** Granulation tissue thickness



**Figure 6.** Histological images from swine study showing a difference in granulation tissue thickness between V.A.C.® Therapy with the V.A.C.® GRANUFOAM™ Dressing (left) and V.A.C. VERAFLOR™ Therapy with the V.A.C. VERAFLOR™ Dressing (right) after 7 days of therapy.

### Periodic Versus Continuous Instillation

An agar wound model was used to evaluate the distribution of solutions instilled continuously versus periodically using V.A.C. VERAFLOR™ Therapy.<sup>56</sup> Continuous instillation is a method of instillation therapy that is provided by other manufacturers of wound instillation therapy. It consists of fluid delivered continuously (at a constant rate) to the wound bed, with removal by negative pressure; there is no time when the solution is held or allowed to stand in the wound bed. Because recent publications have alluded to positive outcomes with continuous instillation, a method was developed to assess and compare differences in fluid distribution capabilities for continuous instillation and periodic instillation provided by V.A.C. VERAFLOR™ Therapy.

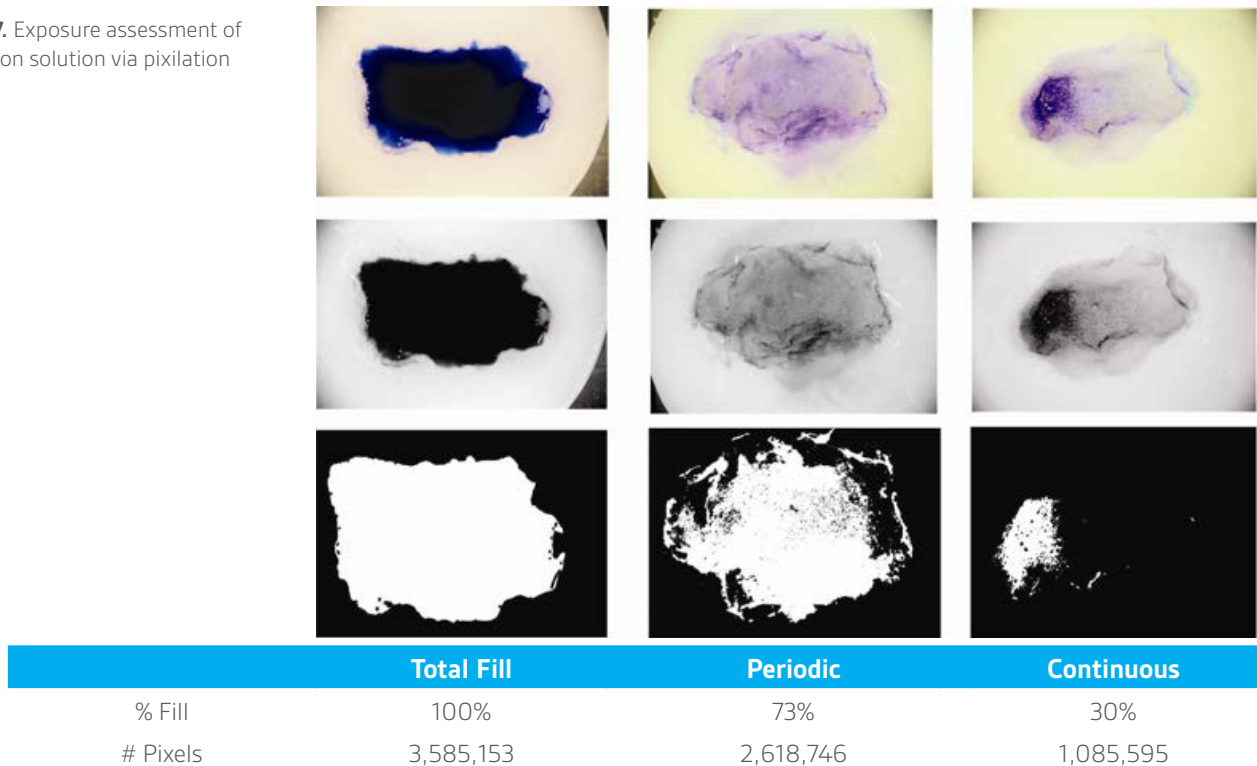
#### Method:

- Agar wound models were developed to assess the ability of the instillation methods to distribute instillation solutions containing water soluble dyes throughout the simulated wound bed.
- Continuous therapy instilled solutions at a continuous rate of 30ml/hr for 3.5 hours. Periodic therapy instilled solutions with three 10-minute soak times followed by NPWT at -125mmHg. V.A.C. VERAFLOR™ Dressing was used with both therapies.
- Controls consisted of manually filling to saturation the simulated wound bed with the dye solutions (total fill method).
- The results were assessed with digital photography followed by pixel analysis of black and white images.

#### Results

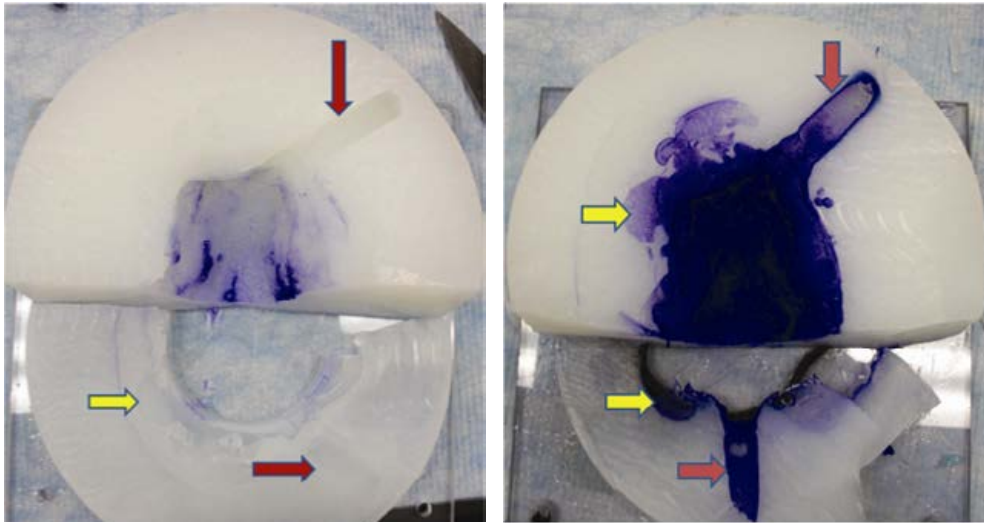
The results showed that periodic instillation demonstrated uniform distribution of solutions throughout the entire wound bed, while continuous instillation therapy displayed limited delivery of solutions throughout the wound bed (**Figure 7**). There was significantly more coverage of the wound bed when the solution was delivered using periodic versus continuous instillation ( $73.0 \pm 3.2\%$  vs  $30.3 \pm 10.7\%$ ;  $p < 0.05$ ). This suggests that periodic instillation therapy with the less hydrophobic foam delivers uniform distribution of solutions to the wound bed.<sup>56</sup>

**Figure 7.** Exposure assessment of instillation solution via pixilation analysis



The agar wound model was also sectioned to visualize exposure of instillant to tunneled (red arrows, **Figure 8**) and undermined (yellow arrows, **Figure 8**) regions. It visually appears that following continuous instillation there was little solution exposure to the tunneled and undermined regions. However, following the application of three 10-min soak times per NPWTi-d, there was visual evidence that tunneled and undermined regions in the model had been exposed to instilled solutions.

**Figure 8.** Left is lateral section of agar wound model following 3.5h continuous irrigation. Right is lateral section of agar wound model following three 10-minute soak times with NPWTi-d.



### Reduction of Bacterial Aerosolization

A bench top aerosolization study evaluating the potential for cross contamination illustrated that V.A.C. VERAFLOR<sup>TM</sup> Therapy allows for controlled and contained wound irrigation as compared to lavage.<sup>57, 58</sup>

#### Method:

- An anatomical wound care model (Seymour II, VATA Anatomical Models, Canby, OR) was inoculated with simulated wound fluid containing inactivated common wound pathogens *Escherichia coli* ( $3 \times 10^7$  particles) and *Staphylococcus aureus* ( $3 \times 10^7$  particles).
- The bacterial particles were fluorescently labeled to allow for visualization.
- Collection plates were arranged in a 6-inch zone radially around the simulated wound to capture aerosolized droplets or plashing as the wound was cleaned using lavage or V.A.C. VERAFLOR<sup>TM</sup> Therapy.
- The following commercially available products were delivered at 4-15 psi for lavage:
  - Sterile Wound Wash Saline<sup>®</sup> (Blair Laboratories, Inc. Columbus, IN),
  - Carra-Klenz<sup>™</sup> Wound and Skin Cleanser (Carrington Laboratories Inc., Irving, TX)
  - Ultra-Klenz<sup>™</sup> Wound Cleanser (Carrington Laboratories, Inc., Irving, TX).
- Normal saline was used with V.A.C. VERAFLOR<sup>TM</sup> Therapy (5 cycles, each cycle consisting of 20 minutes continuous negative pressure at -125mmHg, instillation, and 60 seconds of soak time).

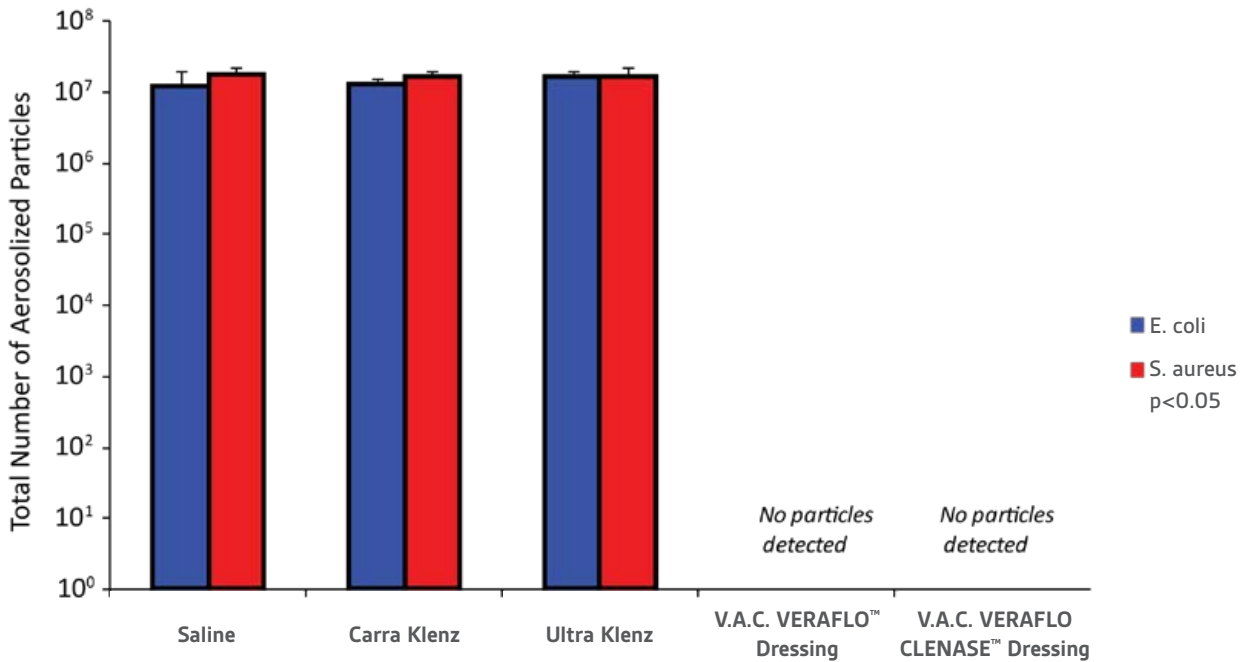
#### Results

The results showed that lavage wound cleansing caused significantly more aerosolization of the wound fluid and bacteria ( $p < 0.05$ ). With these techniques, approximately one-half of the inoculated bacteria were captured outside of the wound bed on the collection plates. The remaining bacteria not accounted for may have aerosolized further than the collection plates. In contrast, when using V.A.C. VERAFLOR<sup>TM</sup> Therapy with normal saline, no bacteria were captured on the collection plates, and 100% of the inoculated bacteria were sequestered to the exudate canister. Results are shown below in **Table 9** and in **Figure 9**. This study reported V.A.C. VERAFLOR<sup>TM</sup> Therapy allows for a more controlled, contained wound irrigation compared to standard techniques, potentially reducing the likelihood of cross-contamination of patients, healthcare workers, and the surrounding environment.<sup>57, 58</sup>

**Table 9:** Number of aerosolized bacterial particles recovered at 3 and 6 inches from the wound model

Method/Products	<i>E.coli</i> Particles 3"	<i>E.coli</i> Particles 6"	<i>S.aureus</i> Particles 3"	<i>S.aureus</i> Particles 6"
LPL* with Blairex	$6.3 \times 10^6$	$6.0 \times 10^6$	$7.7 \times 10^6$	$9.6 \times 10^6$
LPL with Carra Klenz	$8.5 \times 10^6$	$4.9 \times 10^6$	$9.0 \times 10^6$	$8.4 \times 10^6$
LPL with Ultra Klenz	$6.7 \times 10^6$	$1.0 \times 10^7$	$6.8 \times 10^6$	$1.0 \times 10^7$
V.A.C. VERAFLOR <sup>TM</sup> Therapy with V.A.C. VERAFLOR <sup>TM</sup> Dressing	undetectable	undetectable	undetectable	undetectable
V.A.C. VERAFLOR <sup>TM</sup> Therapy with V.A.C. VERAFLOR CLEANSE <sup>TM</sup> Dressing	undetectable	undetectable	undetectable	undetectable

\*LPL: Low pressure lavage



**Figure 9.** Aerosolization of bacteria particles using commercially available wound cleansers and V.A.C. VERAFLOR<sup>TM</sup> Therapy

## Effects on Wound Cleansing and Tissue Damage

A porcine study was used to compare wound cleansing and tissue damage between pulsed lavage and V.A.C. VERAFLOR™ Therapy using V.A.C. VERAFLOR™ Dressings.<sup>58, 59</sup>

### Method

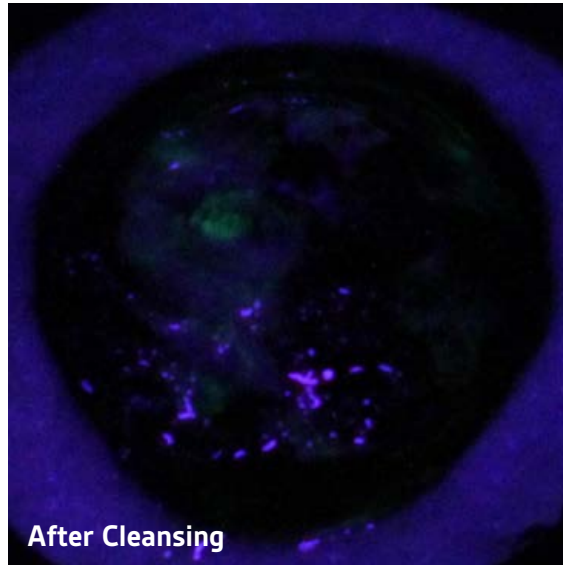
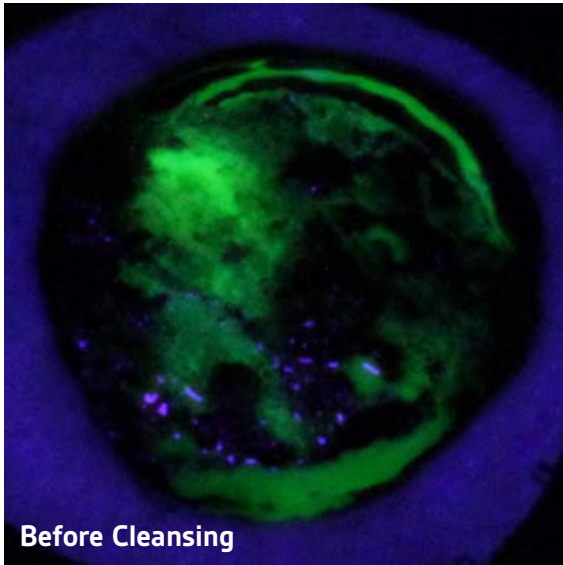
- Three adult swine received 8 full-thickness excisional wounds that were allowed to granulate for 4 days.
- A solution containing fluorescein-dextran particles was used to simulate debris and applied to all wounds on day 4.
- Wounds received either:
  - Pulsed lavage (1L saline within 2 minutes)
  - 10 cycles of V.A.C. VERAFLOR™ Therapy (40 second instillation of saline, 5 minute soak, and 5 min NPWT over 2 hours).
- To determine cleansing efficacy, fluorescent images of wounds were collected before and after cleansing.
- Tissue damage (ie, immediate tissue swelling) was assessed by changes in wound volume and depth using a 3-D camera and histology.

### Results

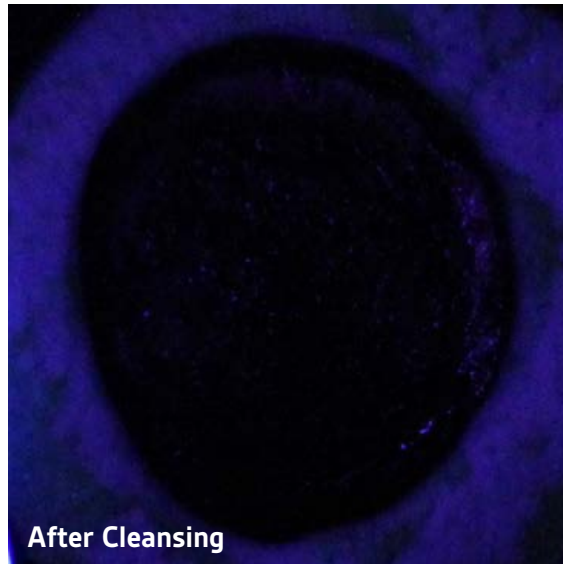
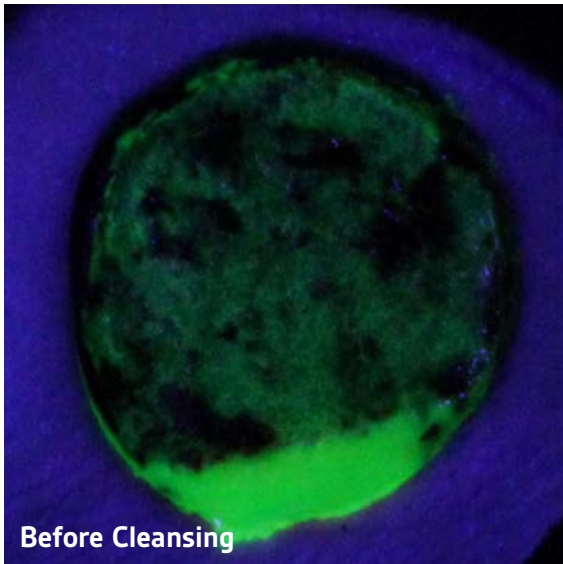
Results showed that both pulsed lavage and V.A.C. VERAFLOR™ Therapy showed a reduction in fluorescein-dextran ( $95\% \pm 1.5\%$  vs  $99\% \pm 0.6\%$ , respectively), indicating effective wound cleansing by both therapies (**Figures 10** and **11A**). Changes in wound volume ( $-22\% \pm 8.3\%$  V.A.C. VERAFLOR™ Therapy vs  $4.5\% \pm 2.5\%$  pulsed lavage; **Figure 11B**) and wound depth ( $-19\% \pm 6.4\%$  V.A.C. VERAFLOR™ Therapy vs  $4.7\% \pm 2.1\%$  pulsed lavage) showed that pulsed lavage-treated wound exhibited significantly more swelling ( $p < 0.05$ ) than V.A.C. VERAFLOR™ Therapy-treated wounds, indicating that pulsed lavage may damage tissue during cleansing. Similarly, histology results showed that pulsed lavage had a slightly higher edema score compared to V.A.C. VERAFLOR™ Therapy. These data suggest that V.A.C. VERAFLOR™ Therapy may effectively remove debris, causing less tissue edema compared to pulsed lavage.<sup>58, 59</sup>



### Pulsed Lavage Therapy

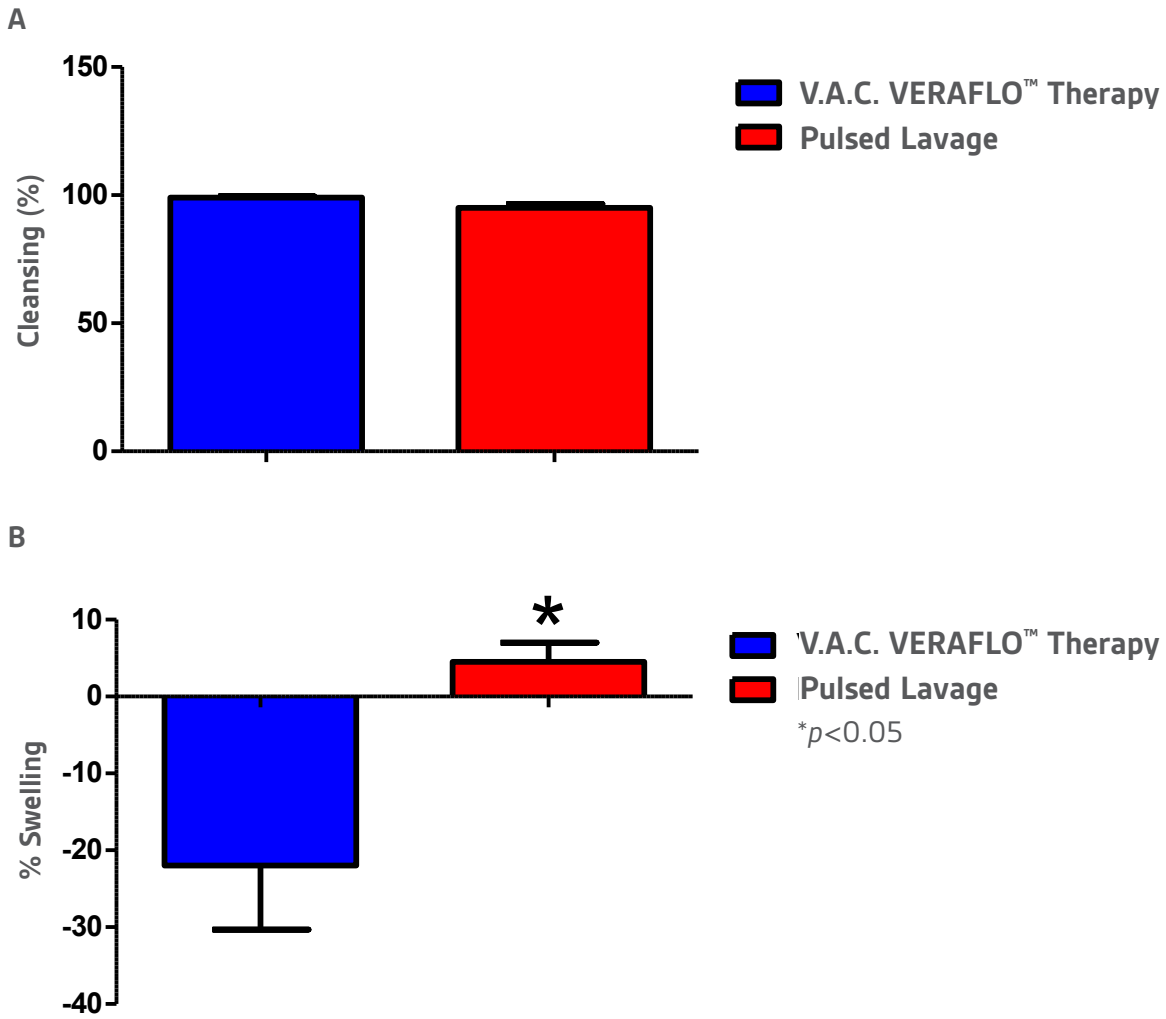


### V.A.C. VERAFLU™ Therapy



**Figure 10.** Wound images before and after cleansing with pulsed lavage (top) or V.A.C. VERAFLU™ Therapy (bottom). The green represents the fluorescein-dextran particle fluorescence in the wound. Virtually all fluorescence is removed following cleansing with either modality.





**Figure 11.** **A.** Cleansing efficacy evaluated as reduction in fluorescence between V.A.C. VERAFLOR™ Therapy and pulsed lavage. **B.** Swelling evaluated as change in wound volume between V.A.C. VERAFLOR™ Therapy and pulsed lavage ( $p < 0.05$ ).

### Effect of Dressing Soak on Dressing Removal

This study was to determine the removal characteristics of dressing removal from porcine full-thickness excisional wounds after 5 days of NPWT.<sup>60</sup>

#### Methods

- Each pig (n=3) received 12 wounds that were pretreated using V.A.C.® Therapy with V.A.C.® GRANUFOAM™ Dressing for 3 days prior to placement of V.A.C. VERAFLU CLEANSE™ Dressings.
- On Day 3, wounds were treated using V.A.C. VERAFLU™ Therapy with V.A.C. VERAFLU CLEANSE™ Dressings for 5 days. Each cycle consisted of instilling saline (20-25ml per wound) with a 10 minute soak time followed by 4 hours of negative pressure.
- Peel testing was performed after 5 days of therapy. Briefly, the peel tester was mounted on a tilting stand and the pig was mounted on a tilting operating table, allowing for a 90° angle to be achieved between the peel tester and the dressing. The grip region of the dressing was gripped by the peel tester, and the peel testing was initiated at the maximum speed of the motorized test stand (approximately 500mm/min).
- The force required to remove the dressing was measured with and without a 30 minute saline soak.

#### Results

Our results showed that soaking the dressing with saline for 30 minutes prior to removal reduced the mean peel force by 61% (Figure 12).<sup>60</sup>

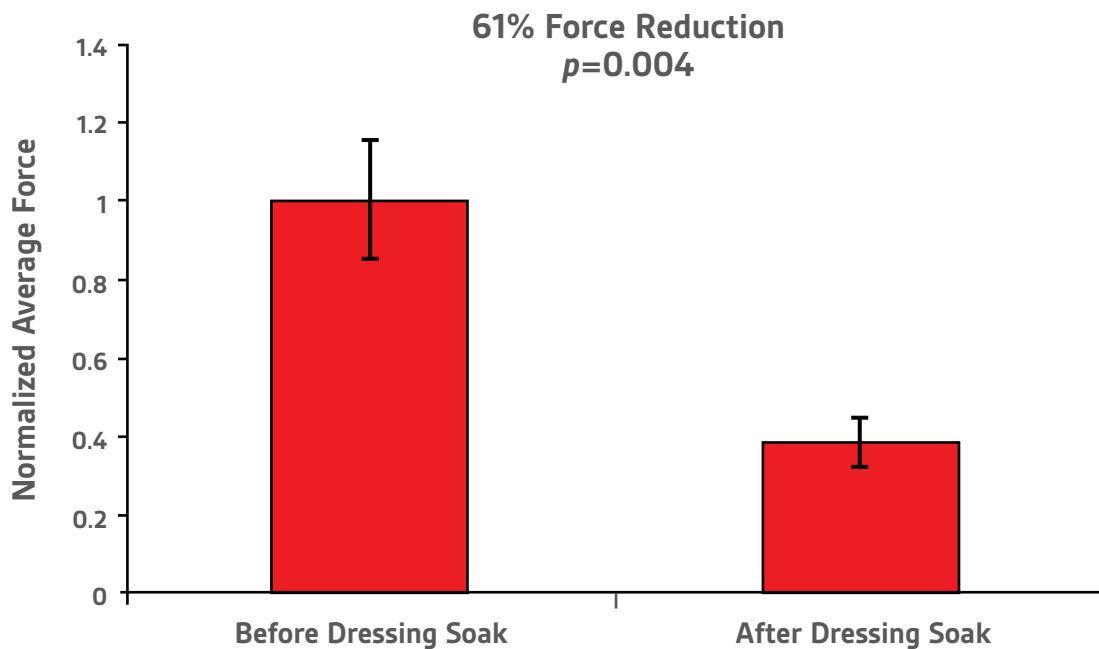


Figure 12. Soaking the dressing with saline for 30 minutes reduced the mean peel force. (Data are normalized to pre-soak force.)

**Table 10:** Properties of V.A.C. VERAFLOR™ Therapy

Property Demonstrated	Study Description	Results
Fluid distribution <sup>55</sup>	<ul style="list-style-type: none"> <li>V.A.C.® GRANUFOAM™ and V.A.C. VERAFLOR™ Dressings were precut and placed between 2 transparent plates.</li> <li>Each were compressed 65% to 5.3mm thickness.</li> <li>Plates were immersed in a clear plastic reservoir containing 15mm of saline and removed after 6-, 15-, or 30-minute exposure times.</li> <li>They were then weighed and the amount of saline wicked by each dressing was measured.</li> <li>Procedure was repeated 5 times and analyzed.</li> </ul>	<ul style="list-style-type: none"> <li>Data showed that V.A.C. VERAFLOR™ Dressing distributed more fluid than V.A.C.® GRANUFOAM™ Dressing.</li> <li>V.A.C. VERAFLOR™ Dressing pulled more saline from the reservoir than V.A.C.® GRANUFOAM™ Dressing (<math>p&lt;0.05</math>).</li> <li>Fluid movement for V.A.C.® GRANUFOAM™ Dressings reached equilibrium sooner than V.A.C. VERAFLOR™ Dressings.</li> <li>These data suggest the V.A.C. VERAFLOR™ Dressing may have enhanced fluid distribution properties.</li> </ul>
Effect on granulation tissue formation <sup>55</sup>	<ul style="list-style-type: none"> <li><i>In vivo</i> porcine model (n=12) comparing V.A.C. VERAFLOR™ Therapy using V.A.C. VERAFLOR™ Dressing and V.A.C.® Therapy using V.A.C.® GRANUFOAM™ Dressing. <ul style="list-style-type: none"> <li>V.A.C. VERAFLOR™ Therapy included Instillation of 20ml of normal saline held for 5 minutes with negative pressure at -125mmHg for 2.5 hours continuously for 10 cycles daily.</li> <li>V.A.C.® Therapy was set at -125mmHg continuous pressure.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>43% (<math>p&lt;0.05</math>) increase in granulation tissue thickness when using V.A.C. VERAFLOR™ Dressing.</li> <li>Data showed V.A.C. VERAFLOR™ Therapy using V.A.C. VERAFLOR™ Dressing increased wound fill over traditional V.A.C.® Therapy using V.A.C.® GRANUFOAM™ Dressing,</li> </ul>
Distribution of solution across wound surface <sup>56</sup>	<ul style="list-style-type: none"> <li><i>In vitro</i> model evaluating ability to distribute solution across a wound between NPWTi-d and continuous irrigation.</li> <li>Agar wound model was either instilled continuously with solution while negative pressure was applied (30ml/hr for 3.5 hours) or with NPWTi-d (three 10-minute dwell times followed by application of NPWT).</li> <li>Following instillation, model was evaluated for fluid distribution across the wound surface.</li> </ul>	<ul style="list-style-type: none"> <li>With NPWTi-d instillation solution covered 73% of the wound surface.</li> <li>With continuous irrigation, solution covered 30% of the wound surface.</li> <li>NPWTi-d allows for better solution distribution across the wound surface, including into tunnels and undermined areas.</li> </ul>
Prevention of bacterial aerosolization <sup>57, 58</sup>	<ul style="list-style-type: none"> <li><i>In simulo</i> wound irrigation evaluating instillation against lavage and the potential for cross contamination. <ul style="list-style-type: none"> <li>Anatomical wound model was inoculated with simulated wound fluid containing inactivated common wound pathogens <i>Escherichia coli</i> and <i>Staphylococcus aureus</i>.</li> <li>Collection plates were placed: 3 and 6-inches around the wound to capture droplets or splashing from the wound as it was cleaned.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Approximately one-half of the bacteria were captured on the collection plates for lavage.</li> <li>Using V.A.C. VERAFLOR™ Therapy with normal saline, no bacteria droplets were detected on the collection plates.</li> <li>Instillation therapy allows for a more controlled, contained wound irrigation while standard cleansing techniques led to bacterial aerosolization.</li> </ul>
Ability of NPWTi-d to cleanse wound of debris <sup>58, 59</sup>	<ul style="list-style-type: none"> <li><i>In vivo</i> porcine model to evaluate cleansing ability of V.A.C. VERAFLOR™ Therapy vs pulsed lavage.</li> <li>Wounds were inoculated with fluorescent dextran solution.</li> <li>Wounds were cleansed with either ten 5 min hold periods of saline (V.A.C. VERAFLOR™ Therapy) or 1L of saline in 2 min (pulsed lavage).</li> <li>Resulting fluorescence decrease and tissue swelling were measured.</li> </ul>	<ul style="list-style-type: none"> <li>Both pulsed lavage and V.A.C. VERAFLOR™ Therapy were effective at cleansing the wound (as shown by the reduction in fluorescence following cleansing).</li> <li>V.A.C. VERAFLOR™ Therapy resulted in significantly less tissue swelling (ie, change in wound volume; <math>p&lt;0.05</math>) and trauma than did pulsed lavage.</li> </ul>
Effect of dressing soak on dressing Removal <sup>60</sup>	<ul style="list-style-type: none"> <li>Each pig (n=3) received 12 wounds that were pretreated using V.A.C.® Therapy with V.A.C.® GRANUFOAM™ Dressing for 3 days prior to V.A.C. VERAFLOR™ Therapy.</li> <li>On Day 3, wounds were treated using V.A.C. VERAFLOR™ Therapy with V.A.C. VERAFLOR CLEANSE™ Dressings for 5 days. Each cycle consisted of instilling saline (20-25ml per wound) with a 10 minute soak time followed by 4 hours of negative pressure.</li> <li>Peel testing was performed after 5 days of therapy. The force required to remove the dressing was measured with and without a 30 minute saline soak.</li> </ul>	<ul style="list-style-type: none"> <li>Our results showed that soaking the dressing with saline for 30 minutes prior to removal reduced the mean peel force by 61%.</li> </ul>

## Case Studies

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 the patient's circumstances and condition.

### Case Study 1: *Contaminated Ileostomy Site*

An 83-year-old male presented with an open postoperative contaminated wound at a previous ileostomy site. V.A.C. VERAFLOR™ Therapy was initiated using V.A.C. VERAFLOR™ Dressing. Microcyn® (Oculus Innovative Sciences, Petaluma, CA) was instilled until the foam was filled followed by a soak time of 10 minutes. Instillation was repeated every 4 hours followed with continuous negative pressure at -125mmHg for 12 days. Therapy was discontinued when patient transitioned out of the acute care setting and the wound could be treated with local wound care alone. No complications occurred during therapy.

**Figure 13.**



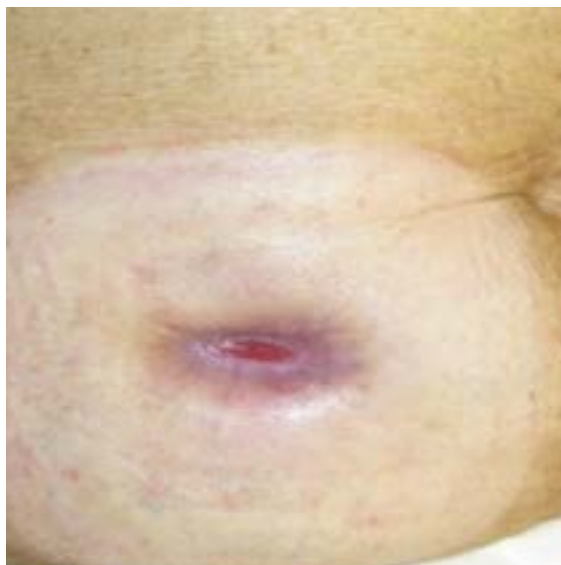
**A.** Immediate postoperative, right lower quadrant wound



**B.** Application of V.A.C. VERAFLOR™ Therapy with instillation of Microcyn®



**C.** Day 10 of V.A.C. VERAFLOR™ Therapy at 4th dressing change



**D.** Follow up on postoperative Day 34

## Case Study 2: Infected Chest Wound

A 43-year-old female presented with an infected chest wound after radiation. Prior to debridement, the wound was visually assessed for infection. Punch-wound biopsy cultures were positive for bacterial bioburden. Patient received systemic antibiotics and wound was debrided. V.A.C. VERAFLOR<sup>TM</sup> Therapy was initiated using V.A.C. VERAFLOR<sup>TM</sup> Dressing. Prontosan<sup>®</sup> (B.Braun Medical Inc., Bethlehem, PA) was instilled until the foam was filled followed by a soak time of 3 minutes. Instillation was repeated every hour followed by continuous negative pressure at -125mmHg for 3 days. No complications occurred during therapy, and granulation tissue was present with negative cultures at the time of coverage with a latissimus flap.

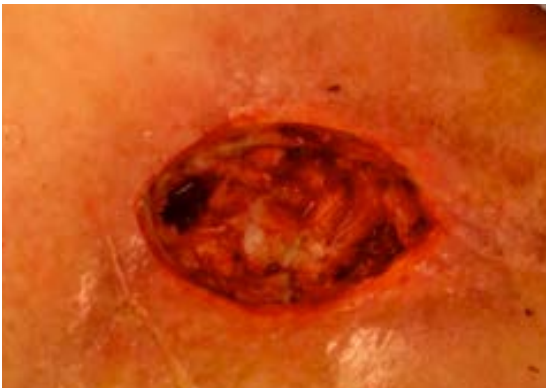
**Figure 14.**



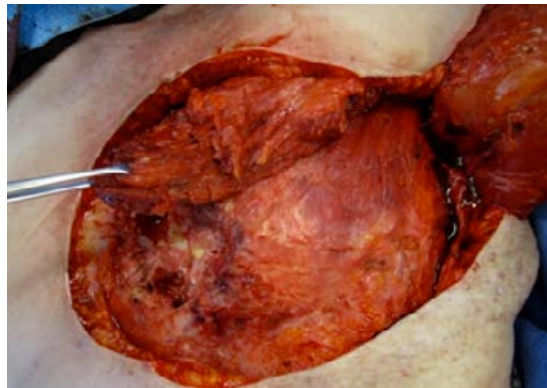
**A.** Radiated chest wound



**B.** Initial presentation of chest wound



**C.** Wound after debridement of rib and cartilage and 4 days of V.A.C. VERAFLOR<sup>TM</sup> Therapy



**D.** Excision of radiated skin



**E.** 6 weeks following chest wall reconstruction with latissimus flap



### Case Study 3: Infected Foot Abscess

An 86-year-old female diabetic with peripheral vascular disease presented with a left foot abscess. Prior to debridement, the wound was visually assessed for infection. Punch-wound biopsy cultures were positive for bacterial burden. Patient received systemic antibiotics and wound was debrided. V.A.C. VERAFLOR<sup>™</sup> Therapy was initiated using V.A.C. VERAFLOR<sup>™</sup> Dressing. Saline was instilled until the foam was filled followed by a soak time of 3 minutes. Instillation was repeated every 2 hours followed by continuous negative pressure at -125mmHg for 3 days. No complications occurred during therapy, and granulation tissue was present with negative cultures at the time of primary closure.

**Figure 15.**



**A.** Left foot abscess at presentation



**B.** Abscess was drained and the wound debrided



**C.** Application of V.A.C. VERAFLOR<sup>™</sup> Therapy



**D.** After 3 days of V.A.C. VERAFLOR<sup>™</sup> Therapy, wound was ready for primary closure



**E.** 2 weeks following primary closure

### Case Study 4: Trauma of the Ankle

Patient was a 69-year-old female, with a history of arterial hypertension, who presented with an open fracture of the left lateral malleolus. An initial large surgical debridement was performed, followed by V.A.C. VERAFLOR™ Therapy for 9 days. V.A.C. VERAFLOR™ Therapy was initiated using a V.A.C. VERAFLOR™ Dressing. Saline (0.9% NaCl) was instilled until the foam was filled, followed by a soak time of 10 minutes. Instillation was repeated every 6 hours, followed by continuous negative pressure at -125mmHg. Dressing changes occurred on Days 3 and 6, with final removal on Day 9. A thin hydrocolloid dressing was applied around the wound edges for extra skin protection. After 9 days of therapy, there was rapid development of homogeneous granulation tissue and a clean appearance of the wound. A split-thickness skin graft (STSG) was applied on Day 10, and by Day 18, wound was completely closed.

Figure 16.



A. Day 0: Presentation of an open fracture of the lateral malleolus of the left ankle



B. Day 0: Application of V.A.C. VERAFLOR™ Therapy



C. Day 3: Wound after first dressing change



D. Day 3: A thin hydrocolloid dressing applied around the wound edges for extra skin protection



E. Day 9: Rapid development of homogeneous granulation tissue with a clean appearance of the wound



F. Day 10: Application of STSG



G. Day 18: Complete wound closure

### Case Study 5: Trauma of the Knee

Patient was a 22-year-old male, with no history of concomitant diseases, who presented with an open fracture of the left knee (comminuted fracture of the tibial plateau) with a skin defect on the anterior knee caused by a motorcycle accident. Extensive debridement was performed, followed by reconstruction of the bone with screws. Standard treatment, including pulsatile lavage and intravenous antibiotics, was initiated, but on Day 3, patient developed a skin infection with necrotizing bacteria based on both microbiologic data (ie, wound swabs and tissue samples) and clinical (eg, fever, redness, swelling, and pus) confirmation. On Day 6, debridement and articular lavage were performed, and V.A.C. VERAFLOR™ Therapy was initiated using V.A.C. VERAFLOR™ Dressings for 12 days. Saline (0.9% NaCl) was instilled until the foam was filled, followed by a soak time of 10 minutes. Instillation was repeated every 6 hours, followed by continuous negative pressure at -125mmHg. Dressing changes occurred every 3 days with final dressing removal on Day 12 of therapy. Complete wound closure occurred 12 days after therapy was discontinued.

**Figure 17.**



**A.** Initial presentation of open fracture of the left knee (comminuted fracture of the tibial plateau) with a skin defect on the anterior knee



**B.** Development of skin infection with necrotizing bacteria



**C.** Complete wound closure occurred 12 days after therapy was discontinued



### Case Study 6: Infected Foot Wound

A 74-year-old male with hypertension presented with an infected (limited growth of *Morganella morganii* and *Staphylococcus aureus* along with moderate growth of *Bacteroides fragilis*) neuropathic wound located on his right foot. After adequate debridement, V.A.C. VERAFLOR<sup>™</sup> Therapy was initiated using V.A.C. VERAFLOR<sup>™</sup> Dressing. Lactated Ringer's Solution (10ml) was instilled, followed by a soak time of 15 minutes. Instillation was repeated every 3.5 hours, followed by continuous negative pressure at -125mmHg for 9 days. No complications occurred during therapy, and granulation tissue was present with no signs of infection based on clinical and culture results. The wound was then treated with V.A.C.<sup>®</sup> Therapy.

Figure 18.



A. Wound at initial presentation



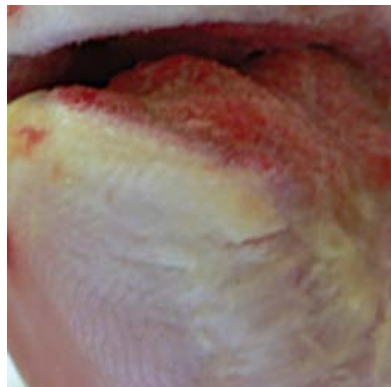
B. First dressing change



C. Second dressing change



D. Third dressing change

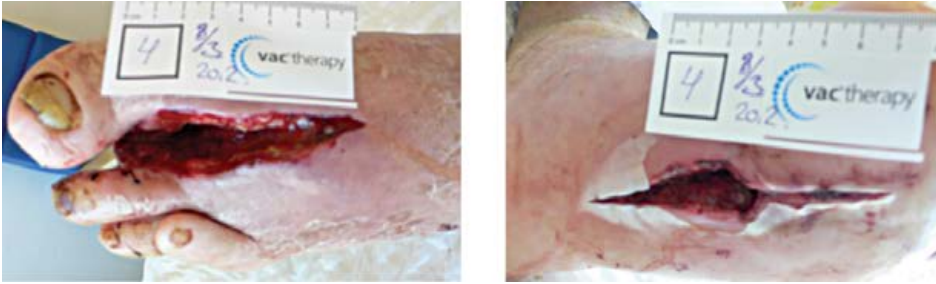


E. Wound after 9 days of V.A.C. VERAFLOR<sup>™</sup> Therapy

### Case Study 7: Infected Diabetic Foot Wound

A 56-year-old male diabetic presented with an infected (moderate growth of *Streptococci*) diabetic foot ulcer. After adequate debridement, V.A.C. VERAFLOR™ Therapy was initiated using V.A.C. VERAFLOR™ Dressing. Lactated Ringer's Solution (22ml) was instilled, followed by a soak time of 15 minutes. Instillation was repeated every 3.5 hours, followed by continuous negative pressure at -125mmHg for 6 days. No complications occurred during therapy, and granulation tissue was present with no signs of infection based on clinical and culture results. The wounds were then treated with V.A.C.® Therapy.

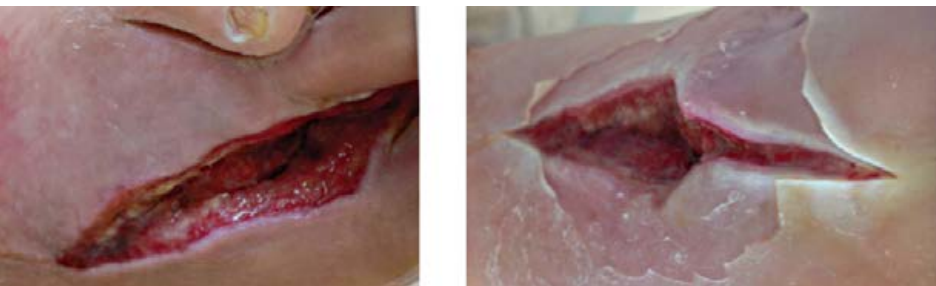
Figure 19.



A. Wounds on top of foot (left) and bottom of foot (right) at initial presentation



B. Second dressing change on top of foot (left) and bottom of foot (right)



C. Wounds on top of foot (left) and bottom of foot (right) after 6 days of V.A.C. VERAFLOR™ Therapy

### Case Study 8: Infected Trauma Wound

A 67-year-old male presented with an infected (moderate growth of *Enterococcus faecalis*) trauma wound. After adequate debridement, V.A.C. VERAFLOR<sup>TM</sup> Therapy was initiated using V.A.C. VERAFLOR<sup>TM</sup> Dressing. Normal saline was initially used; 10ml was instilled, followed by a soak time of 15 minutes. Instillation was repeated every 3.5 hours, followed by continuous negative pressure at -125mmHg for 7 days. The instillate was changed to Lactated Ringer's Solution at first dressing change. No complications occurred during therapy, and the wound was clean and closed by primary intention.

Figure 20.



A. Wound at initial presentation



B. First dressing change followed by surgical debridement



C. Second dressing change followed by surgical debridement



D. Wound after 7 days of V.A.C. VERAFLOR<sup>TM</sup> Therapy

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