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Preface

The V.A.C. Ultra™ Negative Pressure Wound Therapy System is an integrated wound management system that provides V.A.C.® Therapy (negative pressure wound therapy [NPWT]) or V.A.C. VeraFlo™ Therapy (instillation therapy); it is one unit that provides two therapies for customizable wound healing. This document will provide a comprehensive overview of the V.A.C. Ultra™ Therapy System, including:

- Introduction to the V.A.C. Ultra™ Therapy System
- Wound Management with NPWT and instillation therapy
- Clinical literature review of NPWT and instillation therapy
- Description of the V.A.C. Ultra™ Therapy System
- Science supporting V.A.C. VeraFlo™ 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 healthcare expenditure and are anticipated to increase with the aging 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 instillation therapy, may facilitate earlier wound closure and be more cost effective compared to lower cost products that take longer, or fail, to heal the wound. 

Over the years wound treatment has progressed from dry gauze products to advanced moist wound therapies and further to active wound healing therapies. 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 the principles of instillation with NPWT that were developed by Fleischmann et al. Instillation helps to further promote wound healing by combining the benefits of instillation 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. Ultra™ Therapy System.

The V.A.C. Ultra™ 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. VeraFlo™ Therapy (instillation therapy using V.A.C. VeraFlo™ or V.A.C. VeraFlo 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. VeraFlo™ 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. VeraFlo™ Therapy from other commercially available instillation systems that provide instillation solutions under continuous flow (without a soak time). V.A.C. VeraFlo™ Therapy is also unique in that it uses dressings specifically designed to be less hydrophobic than current V.A.C.® GranuFoam™ Dressings. The dressings are less hydrophobic than the current V.A.C.® Therapy GranuFoam™ Dressings and provide improved fluid distribution within, and removal from, the wound bed.
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. VeraFlo™ 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™) 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.

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. 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. VeraFlo™ Therapy (Table 1).

Table 1: Indicated Wound Types

<table>
<thead>
<tr>
<th>Indicated Open Wound Types</th>
<th>Factors That May Compromise Healing</th>
<th>Benefits of V.A.C. VeraFlo™ Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute, traumatic</td>
<td>Contamination or infection</td>
<td>Instillation of topical wound cleaners and topical antimicrobial or antiseptic solutions</td>
</tr>
<tr>
<td>Dehisced</td>
<td>Susceptible host (poor immune system)</td>
<td>Removal of infectious material</td>
</tr>
<tr>
<td>Chronic</td>
<td>Comorbidities (eg, diabetes and smoking may impact patient’s ability to fight bacteria and heal)</td>
<td>Controlled, protected environment for flushing and cleansing wounds</td>
</tr>
<tr>
<td>Pressure ulcers</td>
<td>Edema</td>
<td>Protection from external contamination sources</td>
</tr>
<tr>
<td>Diabetic foot ulcers</td>
<td>Resistant bacteria</td>
<td></td>
</tr>
<tr>
<td>Venous ulcers</td>
<td>Poor hygiene or wound care</td>
<td></td>
</tr>
</tbody>
</table>

Table 1: Indicated Wound Types

Wound Management with NPWT and Instillation Therapy

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

- Debridement
- Systemic antibiotic treatment and/or 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 fluids and infectious materials. Instillation therapy 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.® 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. 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 and per fusio,n reduces edema, removes exudate and infectious material, and prepares the wound bed for closure. 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 and per fusio,n reduces edema, removes exudate and infectious material, and prepares the wound bed for closure.

Despite these well-documented benefits, there are very few randomized controlled trials (RCTs) that compare cleansing techniques and solutions. The cost effectiveness of V.A.C.® 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. More importantly, utilizing NPWT earlier in wound management (rather than later during wound therapy) has been shown to result in cost savings.

In recent years, Instillation therapy has emerged as an alternative option for patients who would benefit from vacuum-assisted closure and controlled delivery of topical cleansing solutions and suspensions, such as normal saline and wound cleansers, into the wound bed. Instillation therapy differs from irrigation (ie, practice of washing out a wound or body opening with a stream of liquid solution) and lavage (ie, process of washing out a cavity or organ [eg, bladder, bowel, or stomach] using a liquid solution for therapeutic purposes). 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 removing soluble contaminants in the wound bed followed by subsequent removal of these material during NPWT. As a result, soluble bacterial burden can be decreased, contaminants removed and the wound thus cleansed, all without direct user interaction.

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 illustration of Instillation therapy (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

<table>
<thead>
<tr>
<th>Wound Type</th>
<th>Number of Articles</th>
<th>Key References</th>
</tr>
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<tbody>
<tr>
<td><strong>Acute Wounds</strong></td>
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<tr>
<td><strong>Chronic Wounds</strong></td>
<td></td>
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<tr>
<td>Ulcers</td>
<td></td>
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<tr>
<td>Venous Insufficiency</td>
<td>8</td>
<td></td>
</tr>
</tbody>
</table>

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

Table 3: Literature Review of Negative Pressure Wound Therapy with Instillation

<table>
<thead>
<tr>
<th>Wound Type</th>
<th>Number of Articles</th>
<th>Key References</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute Wounds</strong></td>
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</table>

Literature Review of Negative Pressure Wound Therapy
Literature Review of Negative Pressure Wound Therapy with Instillation

Table 3 summarizes the literature on Instillation therapy and spans over 10 years of clinical research.

- An initial study by Fleschmann et al (1998) described the use of “Instillation-Vacuum-Sealing” for treating 27 patients with acute infections of bone and soft tissues (n=13), chronic osteomyelitis (n=8), and chronic wounds (n=6). Drainage tubes were inserted into the polyvinyl alcohol dressings, which covered the entire wound surface, and a seal was created using a transparent film dressing. A limited vacuum was applied through the foam and depending on wound type, an antiseptic or antibiotic solution was alternately instilled for 30 minutes several times a day. Following 7 days of instillation, wound closure occurred immediately or by secondary closure (n=22), skin grafting (n=3), or spontaneous epithelialization (n=2).3

- Wolvos (2004) retrospectively analyzed the use of instillation therapy with culture-directed antibiotics on 5 patients with a compromised health status and contaminated or infected wounds. The average instillation therapy time was 15 days (range: 5-24 days). Wounds that showed infection prior to instillation therapy showed no growth or only normal flora following instillation therapy. Wolvos concluded that NPWT with instillation of culture-directed antibiotics appeared to reduce the bacterial burden and assist in converting infected wounds to clean wounds.24

- Bernstein and Tam (2005) reported on a series of 5 post-surgical diabetic foot wounds treated with instillation therapy. 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.47

- More recent studies have focused on use of instillation therapy to manage larger patient groups with infected wounds. For example, Gabriel and al (2008) published a pilot study of 15 patients with complex, infected wounds treated with instillation therapy using silver nitrate compared to a retrospective historical control of 15 patients treated with moist gauze wound care (control). Study results showed that instillation therapy patients compared to Control patients required significantly fewer days of treatment (9.9 ± 4.3 vs 36.5 ± 13.1 days, p<0.001), cleared clinical infection in a shorter time (6.0 ± 1.5 vs 25.9 ± 6.6 days, p<0.001), achieved wound closure sooner (13.2 ± 6.8 vs 29.6 ± 6.5 days, p<0.001), and had shorter in-patient length of stay (14.7 ± 9.2 vs 32.9 ± 12.1 days, p<0.001). The authors concluded that “outcomes from this study analysis suggest that the use of instillation therapy may reduce cost and decrease inpatient care requirements for these complex, infected wounds.”48

- In a retrospective, case-control cohort study, Timmers et al (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 instillation therapy using polyhexanide. Control patients received “standard surgical debridement, implantation of gentamicin polymethylmethacrylate beads and long-term intravenous antibiotics.” In instillation therapy patients, infection recurrence rate was 3/30 (10%) compared to 55/93 (58.5%) for the control group (p<0.001). Moreover, for instillation therapy patients, the total duration of hospital stay was significantly shorter (36 [range: 15-75] vs 73 days [range: 6-149]; p<0.001), 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 instillation therapy reduced the need for repeated surgical interventions compared to the present standard approach.49

- An initial study by Fleschmann et al (1998) described the use of “Instillation-Vacuum-Sealing” for treating 27 patients with acute infections of bone and soft tissues (n=13), chronic osteomyelitis (n=8), and chronic wounds (n=6). Drainage tubes were inserted into the polyvinyl alcohol dressings, which covered the entire wound surface, and a seal was created using a transparent film dressing. A limited vacuum was applied through the foam and depending on wound type, an antiseptic or antibiotic solution was alternately instilled for 30 minutes several times a day. Following 7 days of instillation, wound closure occurred immediately or by secondary closure (n=22), skin grafting (n=3), or spontaneous epithelialization (n=2).3
Additionally, Schintler et al. (2009) reported on the successful instillation therapy 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 that instillation therapy 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.50

Furthermore, Leffler et al. (2009) reported on a small pilot study of 6 patients with chronic osteomyelitis that were treated with instillation therapy using a topical antiseptic solution (Polyhexanide, Lavasept®). Instillation therapy was initiated immediately after the first radical surgical bone and soft tissue debridement and continued until surgical reconstruction could be performed. After initiation of instillation therapy, all bacterial cultures were sterile; after surgical reconstruction, stable wound coverage was accomplished for all patients with no flap loss or recurrence of osteomyelitis. The authors concluded that instillation therapy can be safely and easily used in conjunction with debridement, surgical reconstruction and appropriate antibiotic therapy for the treatment of osteomyelitis.51

Beneficial clinical outcomes using instillation therapy have also been reported for wound infections after knee and hip arthroplasty. A small pilot study by Koster et al. (2009) in Germany evaluated the benefits derived from instillation therapy using antiseptic solutions (Polyhexanide, Lavasept®) in knee implant patients with documented evidence of infection. Instillation time was 10 to 20 seconds, dwell time was 10 to 15 minutes and vacuum time was 45 to 60 minutes. Instillation therapy lasted for 3 to 9 days, and all patients received systemic antibiotics for six weeks according to microbial sensitivity testing results. Patients were followed 12 to 34 months (average: 21 months) and received clinical, radiologic and laboratory examinations. There were no complications observed in the study. The authors concluded that using instillation therapy in conjunction with surgical debridement, joint lavage, and systemic antibiotic treatment represented an alternative treatment approach for preserving implants during early infection.52

In another German study, Lehrer et al. (2009) conducted a pilot study on 23 patients diagnosed with infected hip endoprostheses. After thorough surgical debridement, instillation therapy using Polyhexanide (Lavasept®) was initiated with an instillation phase up to 40 seconds, dwell time of 15 minutes and negative pressure applied at -125 mmHg for 60 minutes. The results demonstrated that 18 of 23 prosthetic hip joint infections were treated successfully using instillation therapy.53

In 2010, Raad et al. (2010) performed a retrospective review of a prospective wound care database over 2 years. Five patients with venous stasis ulcers (> 200cm²) 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 instillation therapy for 10 days with 12.5% Dakin’s solution instilled for 10 minutes every hour. After 10 days of instillation therapy, quantitative biopsies that were taken from 2 different locations in each wound tested for bacterial 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 wounds remained healed. The results suggested that instillation therapy was an effective adjunctive therapy for the management of patients with infected chronic venous stasis ulcers.54

More recently, a prospective multi-center, single-arm observational study conducted by Lehrer et al examined the impact of instillation therapy on implant retention.55 Thirty-two patients (22 with an acute and 10 with a chronic infected orthopaedic implant) received surgical debridement, lavage, systemic antibiotic treatment and instillation therapy. Although instillation therapy varied among patients, polyhexanide was instilled in 31 patients and saline in 1 patient with an instillation time of <1 minute; mean hold time was 19 minutes and negative pressure time was 70.3 minutes. The mean instillation therapy duration was 16.3 days with a mean of 16.5 cycles per day. The findings revealed that 19 acute infection patients (86.4%) and 8 (80%) chronic infection patients retained their implant at 4-6 months after treatment. The authors concluded that instillation therapy as adjunctive therapy may assist in retaining previously infected implants.56

Table 3: Literature Review of Instillation Therapy

<table>
<thead>
<tr>
<th>Author</th>
<th>Study Type and Patients</th>
<th>Instillation Therapy Parameters</th>
<th>Results/Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feilischmann et al. (1998)</td>
<td>• 27 patients with acute infections of bone and soft tissues (n=13), chronic osteomyelitis (n=8), and chronic wounds (n=6) treated with “Instillation-Vacuum-Sealing.”</td>
<td>• Polyvinyl alcohol sponges with drainage tubes were used to cover the internal or external wound surfaces and a seal was created using a transparent film dressing.</td>
<td>• Wounds that presented with infection prior to instillation therapy showed no growth or only normal flora following instillation therapy. • Authors concluded that NPWT with instillation of culture-directed antibiotics appears to reduce financial burden.</td>
</tr>
<tr>
<td>Wolvos et al. (2004)</td>
<td>• Retrospective analysis of instillation therapy with topical anesthetic or culture-directed antibiotics in 5 patients.</td>
<td>• Instillation solutions used were: lidocaine, vancomycin, gentamycin, and tobramycin • Average treatment time of instillation therapy was 15 days (range: 5-24 days).</td>
<td>• After 7 days of instillation, either immediate or delayed wound closure by second-ary suturetting (n=22), skin grafting (n=3), or sporadic epithelialization (n=2) was performed.</td>
</tr>
<tr>
<td>Bernstein and Tam (2005)</td>
<td>• A series of 5 post-surgical diabetic patients whose foot wounds were treated with Instillation therapy.</td>
<td>• 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.</td>
<td>• Authors noted a decrease in hospital stay and amputation rate. • Authors also noted that the addition of instilled solutions lowered wound fluid viscosity, facilitating more efficient removal into the canister.</td>
</tr>
<tr>
<td>Gabriel et al. (2008)</td>
<td>• A pilot study of 15 patients with complex, infected wounds treated with Instillation therapy compared to a retrospective historical control of 15 patients treated with moist gauze wound care (control).</td>
<td>• Instillation therapy consisted of instillation with silver nitrate for 30 seconds with a 1-second hold time followed by 2 hours of NPWT at -125mmHg continuously.</td>
<td>• Results showed that patients managed with Instillation therapy required fewer days of treatment (p&lt;0.001), cleared the infection earlier (p&lt;0.001), achieved wound closure sooner (p&lt;0.001), and had fewer in-hospital days (p&lt;0.001) compared to the control group. • Authors concluded that “outcomes from this study analysis suggest that the use of Instillation therapy may reduce cost and decrease inpatient care requirements for these complex, infected wounds.”</td>
</tr>
<tr>
<td>Timmers et al. (2009)</td>
<td>• 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 Instillation therapy.</td>
<td>• Control patients (n=94) received standard care (ie, debridement, implantation of gentamicin beads, and systemic antibiotics). • Instillation solution used was polyhexanide. • Soak time was 10-15 minutes. • 300mMg to 600mMg negative pressure range was used. • Dressing changes occurred every 3-4 days. • Mean duration of therapy was 19.0 ± 22.4 days.</td>
<td>• In Instillation therapy group, recurrence infection rate was 3/30 (10%) compared to 55/93 (58.5%) for the control group (p&lt;0.0001). • In Instillation therapy patients, total duration of hospital stay was significantly shorter (86 range: 15-75) vs 73 days (range: 6-149)(p&lt;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&lt;0.0001). • Authors concluded that in posttraumatic osteomyelitis negative pressure with instillation therapy reduced the need for repeated surgical interventions compared to the present standard approach.</td>
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</table>
**Table 3: Literature Review of Instillation Therapy (cont.)**

<table>
<thead>
<tr>
<th>Author</th>
<th>Study Type and Patients</th>
<th>Instillation Therapy Parameters</th>
<th>Results/Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schindler et al.</td>
<td>A series of 15 patients with skin and soft tissue infection (eg, necrotizing fasciitis) treated with Instillation therapy.</td>
<td>• Instillation solution used was polyhexanide.</td>
<td>• Results showed that infection was controlled and complete healing was achieved in all patients.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Instillation time was dependent on wound size; dwell time was 20 minutes in all cases.</td>
<td>• Authors concluded that Instillation therapy 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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Therapy duration ranged from 4-18 days with dressing changes every 2-4 days.</td>
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<tr>
<td>Leffler et al.</td>
<td>A small pilot study on 6 patients with chronic osteomyelitis treated with instillation therapy.</td>
<td>• Instillation solution used was Lavasept®.</td>
<td>• Results showed that after initiation of instillation therapy, all bacterial cultures were sterile.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2-4 instillations with NPWT were completed (mean instillation time of 20 seconds followed by a 20 minute solution dwell time).</td>
<td>• Authors concluded that instillation therapy can be easily and safely used in conjunction with debridement, surgical reconstruction and appropriate antibiotic therapy for the treatment of osteomyelitis.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Negative pressure cycle lasted 3 to 6 hours based on wound status.</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>• Dressing changes were performed every 3-7 days.</td>
<td></td>
</tr>
<tr>
<td>Koster et al.</td>
<td>A pilot study on 10 knee-implant patients with infection using instillation therapy.</td>
<td>• Instillation solution used was Lavasept®.</td>
<td>• Authors concluded that using instillation therapy in conjunction with surgical debridement, joint lavage, and systemic antibiotic treatment represented an alternative approach for preserving implants during early infection.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Instillation time was 10-20 seconds; dwell time was 10-15 minutes; vacuum time was 45-60 minutes.</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>• Instillation therapy lasted for 3-9 days and all patients received systemic antibiotics.</td>
<td></td>
</tr>
<tr>
<td>Lehner et al.</td>
<td>A pilot study on 23 patients diagnosed with infected hip endoprostheses using instillation therapy.</td>
<td>• Instillation solution used was Lavasept®.</td>
<td>• Results demonstrated that 18/23 patients retained their implant at 4-6 months follow up.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• After surgical debridement, instillation time was up to 40 seconds, dwell time was 15 minutes, and negative pressure at -125 mmHg was applied for 60 minutes.</td>
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</tr>
<tr>
<td>Raad et al.</td>
<td>A retrospective review of prospective wound care data over 2 years. 5 patients with venous stasis ulcers (&gt; 200cm²) and with colorization greater than 105 bacteria were studied.</td>
<td>• Patients were initially debrided and then treated with instillation therapy for 10 days with 12.5% Dakin's solution instilled for 10 minutes every hour. After 10 days and following negative quantitative cultures, patients received an STSG and 4 days of standard NPWT.</td>
<td>• Results showed 100% graft take at 1 month follow up.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• After 10 days and following negative quantitative cultures, patients received an STSG and 4 days of standard NPWT.</td>
<td>• Authors concluded that Instillation therapy provided an effective therapy for managing patients with infected chronic venous ulcers.</td>
</tr>
<tr>
<td>Lehner et al.</td>
<td>A prospective, multi-centre, single-arm observational study using instillation therapy as adjunctive therapy on 32 patients with infected implants.</td>
<td>• Polyhexanide was instilled in 31 patients and saline was instilled in 1 patient.</td>
<td>• Polyhexanide was instilled in 31 patients and saline was instilled in 1 patient.</td>
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<tr>
<td></td>
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<td>• Mean instillation therapy duration was 16.3 days; mean negative pressure setting was 138.3 mmHg, mean instillation time was &lt; 1 minute; mean dwell time was 19 minutes; mean vacuum time was 70.3 minutes; and a mean of 16.5 cycles (instillation + hold + vacuum) per day were applied.</td>
<td>• Mean instillation therapy duration was 16.3 days; mean negative pressure setting was 138.3 mmHg, mean instillation time was &lt; 1 minute; mean dwell time was 19 minutes; mean vacuum time was 70.3 minutes; and a mean of 16.5 cycles (instillation + hold + vacuum) per day were applied.</td>
</tr>
</tbody>
</table>

**V.A.C.Ulta™ Negative Pressure Wound Therapy System Monograph**

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. VeraFlo™ 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 system that provides two wound treatment therapies. Clinicians now have the option to use V.A.C. VeraFlo™ Therapy first to instill a suitable solution to a wound before converting to NPWT (i.e, 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. VeraFlo™ Therapy

V.A.C. VeraFlo™ 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 10 and 500 mL.
- **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. VeraFlo™ 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 changes.

There are several new system accessories designed for use with V.A.C. VeraFlo™ 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. VeraTra.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. VeraTra.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. VeraFlo™ and V.A.C. VeraFlo Cleanse™ Dressings) are available for use with V.A.C. VeraFlo™ 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. VeraFlo™ and V.A.C. VeraFlo 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. VeraFlo™ 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™ (DPC). Rather than dropping the pressure to 0mmHg between therapy cycles, DPC 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. DPC may also assist in minimizing patient discomfort from foam expansion and compression that can occur when negative pressure returns to 0mmHg. DPC is not available during V.A.C. VeraFlo™ Therapy.

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

Table 4: V.A.C.Ulta™ Therapy System Components

<table>
<thead>
<tr>
<th>Name/Description</th>
<th>Picture/Diagram</th>
</tr>
</thead>
<tbody>
<tr>
<td>V.A.C.Ulta™ Therapy System</td>
<td><img src="image" alt="Solution Container" /></td>
</tr>
<tr>
<td>Similar in style/appearance to the InfoV.A.C.® Therapy with the option of providing instillation therapy or NPWT. One therapy unit, two therapies.</td>
<td><img src="image" alt="V.A.C. VeraLink™ Cassette" /></td>
</tr>
<tr>
<td>Exudate Canisters</td>
<td><img src="image" alt="Canister Latch Release" /></td>
</tr>
<tr>
<td>Single-patient use, disposable canisters, available in three convenient sizes: 300, 500, and 1000mL.</td>
<td><img src="image" alt="V.A.C. VeraLink™ Cassette" /></td>
</tr>
<tr>
<td>V.A.C. VeraLink™ Cassette</td>
<td><img src="image" alt="Solution Delivery Line" /></td>
</tr>
<tr>
<td>Single-patient use, disposable cassette allows for irrigation solution to be used in its original container</td>
<td><img src="image" alt="Instillation Tubing" /></td>
</tr>
<tr>
<td>V.A.C. VeraT.R.A.C.™ Pad</td>
<td><img src="image" alt="V.A.C. VeraT.R.A.C.™ Pad" /></td>
</tr>
<tr>
<td>(All in One Pad with SensaT.R.A.C.™ Technology)</td>
<td><img src="image" alt="Instillation Tubing" /></td>
</tr>
<tr>
<td>This is one of two tube sets available for instillation. Single-patient use, disposable tube set with two lines:</td>
<td><img src="image" alt="Spike" /></td>
</tr>
<tr>
<td>• 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.</td>
<td><img src="image" alt="Instillation Tubing" /></td>
</tr>
<tr>
<td>• The other line delivers solution. This line attaches to the V.A.C. VeraLink™ Cassette.</td>
<td><img src="image" alt="Instillation Tubing" /></td>
</tr>
<tr>
<td>• 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.</td>
<td><img src="image" alt="Instillation Tubing" /></td>
</tr>
<tr>
<td>The V.A.C. VeraT.R.A.C.™ Pad is the standard tube set included in the V.A.C. VeraFlo™ Dressing packs.</td>
<td><img src="image" alt="Instillation Tubing" /></td>
</tr>
</tbody>
</table>

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. VeraFlo™ Therapy and V.A.C.® Therapy).
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

<table>
<thead>
<tr>
<th>Dressing Property</th>
<th>V.A.C.® GranuFoam® Dressing</th>
<th>V.A.C.® WhiteFoam Dressing</th>
<th>V.A.C.® VeraFlo™ Dressing</th>
<th>V.A.C.® VeraFlo Cleanse™ Dressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material</td>
<td>Black Polyurethane ether</td>
<td>White Polyvinyl alcohol</td>
<td>Black Polyurethane ester</td>
<td>Grey Polyurethane ester</td>
</tr>
<tr>
<td>Open cell reticulated</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Pore size</td>
<td>400-600 microns all directions</td>
<td>60-270 microns</td>
<td>400-600 microns</td>
<td>133-600 microns</td>
</tr>
<tr>
<td>Relative hydrophobicity*</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Shape</td>
<td>Variable shapes/sizes</td>
<td>Sheets</td>
<td>Spiral cut sheet</td>
<td>Rod with center perforations for ease of separation into halves</td>
</tr>
<tr>
<td>Tensile strength - Dry</td>
<td>Baseline</td>
<td>3 times greater than baseline</td>
<td>1.7 times greater than baseline</td>
<td>2.5 times greater than V.A.C.® VeraFlo™ Dressing** dry</td>
</tr>
<tr>
<td>Tensile strength - Wet</td>
<td>Baseline</td>
<td>3.7 times greater than baseline</td>
<td>1.5 times greater than baseline</td>
<td>3 times greater than V.A.C.® VeraFlo™ Dressing** wet</td>
</tr>
</tbody>
</table>

Table 6: V.A.C.Ulta™ Therapy System Components (cont.)

<table>
<thead>
<tr>
<th>V.A.C.® Therapy Dressing Kit</th>
<th>V.A.C.® Therapy</th>
<th>V.A.C.® VeraFlo™ Therapy (Saline)</th>
<th>V.A.C.® VeraFlo™ Therapy (Saline)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dressing</td>
<td>V.A.C.® Therapy</td>
<td>V.A.C.® VeraFlo™ Therapy (Saline)</td>
<td>V.A.C.® VeraFlo™ Therapy (Saline)</td>
</tr>
<tr>
<td>Therapy Applied</td>
<td>V.A.C.® Therapy</td>
<td>V.A.C.® VeraFlo™ Therapy (Saline)</td>
<td>V.A.C.® VeraFlo™ Therapy (Saline)</td>
</tr>
<tr>
<td>Results</td>
<td>Baseline</td>
<td>20% less than baseline</td>
<td>43% greater than baseline</td>
</tr>
<tr>
<td></td>
<td></td>
<td>37% greater than V.A.C.® Therapy</td>
<td>24% less than V.A.C.® VeraFlo™ Therapy</td>
</tr>
</tbody>
</table>

*Lowest value = Highest level of hydrophobicity.
**Granulation thickness based on histology; results have not yet been confirmed in human studies.

V.A.C.® Therapy Dressing Kit
The dressing systems for use with the V.A.C.Ultra™ Therapy System are the same as those currently used for V.A.C.® Therapy:
- V.A.C.® GranuFoam® Dressing Kit.
- V.A.C.® GranuFoam Silver® Dressing Kit.
- V.A.C.® WhiteFoam Dressing Kit.
- The above products are typically packaged with the V.A.C.® Drape, SensaT.R.A.C.™ Pad and a ruler.

*Note: 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.

V.A.C.® VeraFlo™ Dressing Kit
This dressing kit is designed primarily for instillation therapy and consists of the following components:
- The V.A.C.® VeraFlo™ Dressing that is similar to the V.A.C.® GranuFoam® Dressing (both are polyurethane based) but is specifically designed for V.A.C. VeraFlo™ Therapy.
- The new V.A.C.® Advanced Drape is similar to the present V.A.C.® Drape but has improved adhesive properties to assist with sealing during solution instillation.
- V.A.C. VeraT.R.A.C.™ Pad (All-in-One Pad)
- “M” Cavilon® No Sting Barrier Film
- Wound ruler

V.A.C.® VeraFlo Cleanse™ Dressing Kit
This kit, also designed primarily for instillation therapy, is comprised of the following:
- V.A.C.® VeraFlo Cleanse™ Dressing, which is similar to the V.A.C. VeraFlo™ Dressing in composition, except that it is compressed under heat in one direction. 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.
- The other disposables in this kit are the same as those included in the V.A.C. VeraFlo™ Dressing Kit.

V.A.C.® VeraT.R.A.C. Duo™ Tube Set (Two-headed Pad)
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).

Negative pressure line connects to the canister

Solution delivery line attaches to the VeraLink™ Cassette

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

<table>
<thead>
<tr>
<th>Name/Description</th>
<th>Picture/Diagram</th>
</tr>
</thead>
<tbody>
<tr>
<td>V.A.C.® VeraT.R.A.C. Duo™ Tube Set</td>
<td></td>
</tr>
<tr>
<td>(Two-headed Pad)</td>
<td></td>
</tr>
<tr>
<td>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).</td>
<td></td>
</tr>
</tbody>
</table>
Considerations for Use with V.A.C. VeraFlo Therapy

V.A.C. VeraFlo lists the contraindications for the V.A.C.Ulta Therapy System. No device-related considerations for use with V.A.C. VeraFlo Therapy.

Contraindications

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

<table>
<thead>
<tr>
<th>Generic Solution Class</th>
<th>Trade Name</th>
<th>Considerations for Use with V.A.C. VeraFlo™ Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypochlorite-based solutions (eg, Hypochlorous acid, Sodium hypochlorite)</td>
<td>Dakin’s Solution (quarter strength), DermaCyte®</td>
<td>Dakin’s Solution should not be used in concentrations greater than 0.125% (quarter strength). Consider using the fewest irrigation cycles and minimizing hold times to the lowest level that is clinically relevant.</td>
</tr>
<tr>
<td>Silver nitrate (0.5%)</td>
<td>Various</td>
<td>Silver nitrate is light sensitive. Protect V.A.C. VeraLink™ Irrigation Tubing from light during use of silver nitrate.</td>
</tr>
<tr>
<td>Sulfur-based solutions (Sulfonamides)</td>
<td>Mafenide acetate, Sulfamylon®</td>
<td>Refer to manufacturer's labeling for solution-specific considerations. No device-related considerations for use with V.A.C. VeraFlo Therapy.</td>
</tr>
<tr>
<td>Biguanides (Polyhexanide)</td>
<td>Prontosan®, Lavasept®</td>
<td>May need to be transferred to a container that can be accessed with a spike.</td>
</tr>
<tr>
<td>Cationic solutions (Octenidine, Benzalkonium Chloride)</td>
<td>Octenilin®, Zephiran®</td>
<td>Refer to manufacturer's labeling for solution-specific considerations. No device-related considerations for use with V.A.C. VeraFlo Therapy.</td>
</tr>
<tr>
<td>Isotonic Solutions</td>
<td>Normal Saline Solution, Lactated Ringer’s Solution</td>
<td>Refer to manufacturer's labeling for solution-specific considerations. No device-related considerations for use with V.A.C. VeraFlo Therapy.</td>
</tr>
</tbody>
</table>

*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. VeraFlo Therapy. (As of 01/13/2012)

Table 7: Contraindications

V.A.C.Ulta™ Therapy System

- Do not place dressings for V.A.C.® Therapy (ie, GranuFoam™ Dressing) and V.A.C.® VeraFlo® Therapy (ie, V.A.C. VeraFlo™ Dressing and V.A.C. VeraFlo Cleanse™ Dressing) directly in contact with exposed blood vessels, anastomotic sites, organs, or nerves. **NOTE:** Refer to Warnings section for additional information concerning bleeding
- V.A.C.® Therapy and V.A.C. VeraFlo® Therapy are contraindicated for patients with:
  - Malignancy in the wound
  - Untreated osteomyelitis
  - Non-enteric and unexplored fistulae
  - Necrotic tissue with eschar present
  - Sensitivity to silver (V.A.C. GranuFoam Silver® Dressing only)

V.A.C. VeraFlo® Therapy

- Do not use Octenisept®, hydrogen peroxide, or alcohol-based solutions with dressings.
- 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.
- Do not use V.A.C. VeraFlo™ Therapy unless the wound has been thoroughly explored due to the possibility of inadvertently instilling topical wound solutions into adjacent body cavities.

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-Labelling link for detailed safety information.
Science Supporting V.A.C. VeraFlo™ Therapy

The V.A.C. Ultra™ Therapy System contains improved instillation technology with V.A.C. VeraFlo™ 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. VeraFlo™ and V.A.C. VeraFlo Cleanse™. Dressings in comparison to existing V.A.C.® GranuFoam™ Dressings. Both the V.A.C. VeraFlo™ and V.A.C. VeraFlo Cleanse™ Dressings were shown to have greater tensile strength under both wet and dry conditions than V.A.C.® GranuFoam™ Dressings.

Table 8: Tensile Strength

<table>
<thead>
<tr>
<th>V.A.C.® GranuFoam™ Dressing</th>
<th>V.A.C.® WhiteFoam Dressing</th>
<th>V.A.C. VeraFlo™ Dressing</th>
<th>V.A.C. VeraFlo Cleanse™ Dressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tensile Strength Baseline</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dry: 3 times greater than V.A.C.® GranuFoam™ Dressing dry</td>
<td>1.7 times greater than V.A.C.® GranuFoam™ Dressing dry</td>
<td>2 times greater than V.A.C.® GranuFoam™ Dressing wet</td>
<td></td>
</tr>
<tr>
<td>Wet: 3.7 times stronger than V.A.C.® GranuFoam™ Dressing wet</td>
<td>Wet: 1.5 times greater than V.A.C.® GranuFoam™ Dressing wet</td>
<td>Wet: 3 times greater than V.A.C.® VeraFlo™ Dressing wet</td>
<td></td>
</tr>
</tbody>
</table>

Dressing Fluid Distribution Properties

The fluid distribution properties of the V.A.C.® GranuFoam™ and V.A.C. VeraFlo™ Dressings were compared.37

Methods:

- V.A.C.® GranuFoam™ and V.A.C. VeraFlo™ Dressings were precut and placed between 2 transparent plates; they were compressed 65% to 5.3 mm thickness.
- The plates were immersed in a clear plastic reservoir containing 15 mm 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. VeraFlo™ Dressing distributed more fluid than V.A.C.® GranuFoam™ Dressing; V.A.C. VeraFlo™ Dressing pulled more saline from the reservoir than V.A.C.® GranuFoam™ Dressing (p<0.05) (Figure 4). Also, fluid movement for V.A.C.® GranuFoam™ Dressing reached equilibrium sooner than V.A.C. VeraFlo™ Dressing. These data suggest that the V.A.C. VeraFlo™ Dressing may have enhanced fluid distribution properties.37

Effect on Granulation Tissue Formation

An in vivo porcine full-thickness wound model (n=12) was used to evaluate granulation tissue thickness.37

Methods:

- Each animal received contralateral 5 cm diameter full-thickness excisional dorsal wounds that were treated with either V.A.C. VeraFlo™ Therapy using the V.A.C. VeraFlo™ Dressing or V.A.C.® Therapy using the V.A.C.® GranuFoam™ Dressing.
- V.A.C. VeraFlo™ 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. VeraFlo™ Therapy using V.A.C. VeraFlo™ Dressings compared to V.A.C.® Therapy using V.A.C.® GranuFoam™ Dressings (4.82 ± 0.42mm and 3.38 ± 0.55mm, respectively, p<0.05). Results of the histological findings showed that the increase in granulation thickness was the result of new tissue deposition, not swelling (Figure 6).37 Optimization of Instillation therapy 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.

Notes:

- p<0.05 indicates statistical significance.
Periodic Versus Continuous Instillation

An agar wound model was used to evaluate the distribution of solutions instilled continuously versus periodically using V.A.C. VeraFlo™ Therapy. 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. VeraFlo™ 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. VeraFlo™ 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 ± 3.2% vs 30.3 ± 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.

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. VeraFlo™ Therapy with the V.A.C. VeraFlo™ Dressing (right) after 7 days of therapy.

Figure 7. Exposure assessment of instillation solution via pixilation analysis

<table>
<thead>
<tr>
<th>Method</th>
<th>% Fill</th>
<th>Periodic</th>
<th>Continuous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Fill</td>
<td>100%</td>
<td>73%</td>
<td>30%</td>
</tr>
<tr>
<td># Pixels</td>
<td>3,585,153</td>
<td>2,618,746</td>
<td>1,085,595</td>
</tr>
</tbody>
</table>
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 Instillation therapy, 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 Instillation therapy.

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**Reduction of Bacterial Aerosolization**

A bench top aerosolization study evaluating the potential for cross contamination illustrated that V.A.C. VeraFlo™ Therapy allows for controlled and contained wound irrigation as compared to lavage.59,60

**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 x 10^7 particles) and *Staphylococcus aureus* (3 x 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 splashing as the wound was cleaned using lavage or V.A.C. VeraFlo™ Therapy.
- The following commercially available products were delivered at 4-15 psi for lavage:
  - Sterile Wound Wash Saline® (Blairex Laboratories, Inc. Columbus, IN)
  - Carra-Klenz™ Wound and Skin Cleanser (Carrington Laboratories Inc., Irving, TX)
  - Ultra-Klenz™ Wound Cleanser (Carrington Laboratories, Inc., Irving,TX).
- Normal saline was used with V.A.C. VeraFlo™ 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. VeraFlo™ 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 that V.A.C. VeraFlo™ 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.59,60

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

<table>
<thead>
<tr>
<th>Method/Products</th>
<th><em>E. coli</em> Particles 3”</th>
<th><em>E. coli</em> Particles 6”</th>
<th><em>S. aureus</em> Particles 3”</th>
<th><em>S. aureus</em> Particles 6”</th>
</tr>
</thead>
<tbody>
<tr>
<td>LPL* with Blairex</td>
<td>6.3 x 10^6</td>
<td>6.0 x 10^6</td>
<td>7.7 x 10^6</td>
<td>9.6 x 10^6</td>
</tr>
<tr>
<td>LPL with Carra Klenz</td>
<td>8.5 x 10^6</td>
<td>4.9 x 10^6</td>
<td>9.0 x 10^6</td>
<td>8.4 x 10^6</td>
</tr>
<tr>
<td>LPL with Ultra Klenz</td>
<td>6.7 x 10^6</td>
<td>1.0 x 10^7</td>
<td>6.8 x 10^6</td>
<td>1.0 x 10^7</td>
</tr>
<tr>
<td>V.A.C. VeraFlo™ Therapy with V.A.C. VeraFlo™ Dressing</td>
<td>undetectable</td>
<td>undetectable</td>
<td>undetectable</td>
<td>undetectable</td>
</tr>
<tr>
<td>V.A.C. VeraFlo™ Therapy with V.A.C. VeraFlo Cleanse™ Dressing</td>
<td>undetectable</td>
<td>undetectable</td>
<td>undetectable</td>
<td>undetectable</td>
</tr>
</tbody>
</table>

* LPL: Low pressure lavage

**Figure 9.** Aerosolization of bacteria particles using commercially available wound cleansers and V.A.C. VeraFlo™ 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. VeraFlo™ Therapy using V.A.C. VeraFlo™ Dressings.60,61

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 (1 L saline within 2 minutes)
  - 10 cycles of V.A.C. VeraFlo™ 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. VeraFlo™ Therapy showed a reduction in fluorescein-dextran (95% ± 1.5% vs. 99% ± 0.6%, respectively), indicating effective wound cleansing by both therapies (Figures 10 and 11A). Changes in wound volume (-22% ± 8.3% V.A.C. VeraFlo™ Therapy vs. 4.5% ± 2.5% pulsed lavage, Figure 11B) and wound depth (-19% ± 6.4% V.A.C. VeraFlo™ Therapy vs. 4.7% ± 2.1% pulsed lavage) showed that pulsed lavage-treated wound exhibited significantly more swelling (p<0.05) than V.A.C. VeraFlo™ 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. VeraFlo™ Therapy. These data suggest that V.A.C. VeraFlo™ Therapy may provide more effective wound cleansing by causing less tissue edema compared to pulsed lavage.60,61

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

Disruption of Ex Vivo Biofilms

An ex vivo mature biofilm model evaluated the ability of V.A.C. VeraFlo™ Therapy to disrupt biofilm as compared to V.A.C.® Therapy and to Control (ie, untreated, no NPWT, and no instillation). The model consisted of a mature Pseudomonas aeruginosa biofilm, a common wound pathogen that in this model had an extracellular polymeric substance and metabolic state similar to biofilm found in chronic wounds. In addition, this biofilm was grown on porcine skin explants, which have composition and structure similar to human skin. V.A.C. VeraFlo™ Dressings were applied to biofilm explants and V.A.C. VeraFlo™ Therapy was administered for 24 hours, with instillation delivered every 4 hours with a 10-minute soak time; negative pressure was delivered at -125mmHg between instillation cycles. The instillation solutions tested included 0.9% saline and 0.1% polyhexanide. V.A.C.® Therapy was set to continuous therapy delivering -125 mmHg for 24 hours. Control samples received no NPWT or instillation.

Biofilms were evaluated after therapy by means of colony forming units (CFU/mL) and scanning electron microscopy. Upon completion of 24 hours of therapy and compared to untreated controls, there was no significant change in bacterial load in samples treated with V.A.C.® Therapy or V.A.C. VeraFlo™ Therapy with normal saline instillation. However, samples treated with V.A.C. VeraFlo™ Therapy with 0.1% polyhexanide instillation showed approximately a 3-log (99.8%) reduction in bacterial numbers compared to untreated controls (Figure 12). Although these findings have not been confirmed in human studies, they suggest that V.A.C. VeraFlo™ Therapy combined with the appropriate cleansing solution may have the ability to disrupt soluble bioburden.

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

Figure 12. Samples treated with V.A.C. VeraFlo™ Therapy combined with 0.1% polyhexanide showed approximately a 3-log (99.8%) reduction in bacterial numbers compared to untreated controls.
Table 10: Properties of V.A.C. VeraFlo™ Therapy

<table>
<thead>
<tr>
<th>Property Demonstrated</th>
<th>Study Description</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluid distribution77</td>
<td>• V.A.C.® GranuFoam™ and V.A.C. VeraFlo™ Dressings were precut and placed between 2 transparent plates. Each were compressed 65% to 5.3 mm thickness. Plates were immersed in a clear plastic reservoir containing 15 mm 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. Procedure was repeated 5 times and analyzed.</td>
<td>Data showed that V.A.C. VeraFlo™ Dressing distributed more fluid than V.A.C.® GranuFoam™ Dressing. Fluid movement for V.A.C.® GranuFoam™ Dressings reached equilibrium sooner than V.A.C. VeraFlo™ Dressings. These data suggest that the V.A.C. VeraFlo™ Dressing may have enhanced fluid distribution properties.</td>
</tr>
<tr>
<td>Effect on granulation tissue formation77</td>
<td>• In vivo porcine model (n=12) comparing V.A.C. VeraFlo™ Therapy using V.A.C.® VeraFlo™ Therapy and V.A.C.® Therapy using V.A.C.® GranuFoam™ Dressing. V.A.C. VeraFlo™ 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. V.A.C.® Therapy was set at -125mmHg continuous pressure.</td>
<td>43% (p&lt;0.05) increase in granulation tissue thickness when using V.A.C. VeraFlo™ Dressing. Data showed that V.A.C. VeraFlo™ Therapy using V.A.C.® VeraFlo™ Therapy increased wound fill over traditional V.A.C.® Therapy using V.A.C.® GranuFoam™ Dressing.</td>
</tr>
<tr>
<td>Distribution of solution across wound surface58</td>
<td>• In vitro model evaluating ability to distribute solution across a wound between Instillation therapy and continuous irrigation. Agar wound model was either instilled continuously with solution while negative pressure was applied (30 mL/hr for 3.5 hours) or with Instillation therapy (three 10-minute dwell times followed by application of NPWT). Following instillation, model was evaluated for fluid distribution across the wound surface.</td>
<td>With Instillation therapy instillation solution covered 73% of the wound surface. With continuous irrigation, solution covered 30% of the wound surface. Instillation therapy allows for better solution distribution across the wound surface, including into tunnels and undermined areas.</td>
</tr>
<tr>
<td>Prevention of bacterial aerosolization19,20</td>
<td>• In simulo wound irrigation evaluating instillation against lavage and the potential for cross contamination. Anatomical wound model was inoculated with simulated wound fluid containing inactivated common wound pathogens Escherichia coli and Staphylococcus aureus. Collection plates were placed: 3 and 6-inches around the wound to capture droplets or splashing from the wound as it was cleaned.</td>
<td>Approximately one-half of the bacteria were captured on the collection plates for lavage. Using V.A.C. VeraFlo™ Therapy with normal saline, no bacteria droplets were detected on the collection plates. Instillation therapy allows for a more controlled, contained wound irrigation while standard cleansing techniques led to bacterial aerosolization.</td>
</tr>
<tr>
<td>Ability of Instillation therapy to cleanse wound of debris59,60</td>
<td>• In vivo porcine model to evaluate clearing ability of V.A.C. VeraFlo™ Therapy vs pulsed lavage. Wounds were inoculated with fluorescent dextran solution. Wounds were cleansed with either ten 5 min hold periods of saline (V.A.C. VeraFlo™ Therapy) or 1L of saline in 2 min (pulsed lavage). Resulting fluorescence decrease and tissue swelling were measured.</td>
<td>Both pulsed lavage and V.A.C. VeraFlo™ Therapy were effective at cleansing the wound (as shown by the reduction in fluorescence following cleansing). V.A.C. VeraFlo™ Therapy resulted in significantly less tissue swelling (ie, change in wound volume; p&lt;0.05) and trauma than did pulsed lavage.</td>
</tr>
</tbody>
</table>

Table 10: Properties of V.A.C. VeraFlo™ Therapy (cont.)

<table>
<thead>
<tr>
<th>Property Demonstrated</th>
<th>Study Description</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disruption of ex vivo biofilm using instillation therapy61</td>
<td>• Ex vivo porcine skin explants biofilm model - Mature Pseudomonas aeruginosa biofilm (~10^7-10^9 organisms) grown on porcine skin explants. V.A.C. VeraFlo™ Therapy was administered for 24 hours, instillation delivered every 4 hours, 10-minute soak; negative pressure was delivered at -125mmHg between instillation cycles. Various solutions were tested including 0.1% polyhexanide and Normal Saline. Biofilms were evaluated after therapy with colony counts (CFU/mL) and scanning electron microscopy (SEM).</td>
<td>There was approximately a 3-log (99.8%) reduction in soluble bioburden using 0.1% polyhexanide with V.A.C. VeraFlo™ Therapy</td>
</tr>
</tbody>
</table>
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

An 83-year-old male presented with an open postoperative contaminated wound at a previous ileostomy site. V.A.C. VeraFlo™ Therapy was initiated using V.A.C. VeraFlo™ 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. Dressing changes occurred every 2-3 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.

Case Study 2

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. VeraFlo™ Therapy was initiated using V.A.C. VeraFlo™ Dressing. Prontosan® (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.
**Case Study 3**

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. VeraFlo™ Therapy was initiated using V.A.C. VeraFlo™ 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. VeraFlo™ Therapy
- D. After 3 days of V.A.C. VeraFlo™ Therapy, wound was ready for primary closure
- E. 2 weeks following primary closure

**Case Study 4**

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. VeraFlo™ Therapy for 9 days. V.A.C. VeraFlo™ Therapy was initiated using a V.A.C. VeraFlo™ Dressing. Saline (0.9% NaCl) was instilled until the foam was filled, followed by a soak time of 10 minutes. A thin hydrocolloid dressing was applied around the wound edges for extra skin protection. 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. 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. VeraFlo™ 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 homogenous granulation tissue with a clean appearance of the wound
- F. Day 10: Application of STSG
- G. Day 18: Complete wound closure
Case Study 5
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. VeraFlo™ Therapy was initiated using V.A.C. VeraFlo™ 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 -125 mmHg. 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
A 67-year-old male presented with an infected (moderate growth of Enterococcus faecalis) trauma wound. After adequate debridement, V.A.C. VeraFlo™ Therapy was initiated using V.A.C. VeraFlo™ 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 -125 mmHg for 7 days. The instillant 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 18.

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. VeraFlo™ Therapy
Case Study 7
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. VeraFlo™ Therapy was initiated using V.A.C. VeraFlo™ 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 -125 mmHg for 9 days. Dressing changes occurred every 2-3 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.® Therapy.

Figure 19.

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. VeraFlo™ Therapy

Case Study 8
A 56-year-old male diabetic presented with an infected (moderate growth of *Streptococci*) diabetic foot ulcer. After adequate debridement, V.A.C. VeraFlo™ Therapy was initiated using V.A.C. VeraFlo™ 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 -125 mmHg for 6 days. Dressing changes occurred every 1-2 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 20.

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. VeraFlo™ Therapy
References


(4) Abbas SM, Hill AG. Smoking is a major risk factor for wound dehiscence following negative pressure wound therapy: understanding the role of smoking. Ostomy Wound Manage 2007 September;53(9):31-8.


Important Note: Specific indications, contraindications, warnings, precautions and safety information exist for KCI products and therapies. Please consult a physician and product instructions for use prior to application. This material is intended for healthcare professionals only.

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