Objectives

The learner will be able to:

- List key functions of the V.A.C.Ulta™ Therapy System
- Define instillation therapy and irrigation therapy
- Understand science behind the technology
- Discuss pertinent clinical literature on the use of instillation therapy
- Examine case studies and assess beneficial clinical techniques for application

Important Safety Information

- In most cases, unless otherwise indicated, these slides will reference indications and safety information generally applicable to V.A.C.® Therapy and V.A.C. VeraFlo™ Therapy.
- Before using V.A.C.® Therapy and V.A.C. VeraFlo™ Therapy, read all safety information which is provided with the therapy unit, as well as in dressing and canister cartons.
- Certain unique indications, contraindications, warnings, and precautions apply for products within KCI Negative Pressure Therapy Systems, including the V.A.C.Ulta™ NPWT System. Prior to use, read the instructions for use provided for the specific therapy unit or disposables for specific product information.
- Please refer to the V.A.C.® Therapy Clinical Guidelines, A Reference Source for Clinicians (available at www.kci1.com), for additional information when establishing patient-specific NPWT treatment protocols.
- Additional information and education on KCI Negative Pressure Therapy topics, including V.A.C.® Therapy, can be found on www.kci1.com. Clicking on the Education & Training link will provide information on these educational opportunities.
- KCI recommends that clinicians participate in device-in-service and training prior to use.
- V.A.C.® Therapy Systems are available by Rx only.
- 3M and Cavilon are trademarks of 3M Company. Unless otherwise indicated, all other trademarks are proprietary to KCI Licensing, Inc., its affiliates and/or licensors.
Product Overview

The V.A.C.Ultra™ Negative Pressure Wound Therapy System is an integrated wound therapy system that delivers:

- Proven V.A.C.® Therapy (Negative Pressure Wound Therapy) as practiced today
- V.A.C. VeraFlo™ Therapy, which consists of V.A.C.® Therapy coupled with automated, controlled delivery to and removal of topical wound solutions from the wound bed

Product Overview

The V.A.C.Ultra™ Therapy Unit utilizes trusted, proven V.A.C.® Technology:

- Customizable options: V.A.C.® Therapy or V.A.C. VeraFlo™ Instillation Therapy
- Efficient and easy to use
- V.A.C.® Therapy: Compatible with all:
  - V.A.C.® Therapy Dressings
  - SensaT.R.A.C.™ Technology
  - InfoV.A.C.® Canisters
- V.A.C. VeraFlo™ Therapy: New dressings and disposables will be used

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>Installation of topical wound cleaners and topical antimicrobial or antiseptic solutions.</td>
</tr>
<tr>
<td>Dehisced</td>
<td>Susceptible host (poor immune system)</td>
<td></td>
</tr>
<tr>
<td>Chronic</td>
<td>Comorbidities (eg, diabetes and smoking may affect patient’s ability to fight bacteria and heal)</td>
<td></td>
</tr>
<tr>
<td>Pressure ulcers</td>
<td>Edema</td>
<td>Removal of infectious material.</td>
</tr>
<tr>
<td>Diabetic foot ulcers</td>
<td>Resistant bacteria</td>
<td>Controlled, protected environment for flushing and cleansing wounds.</td>
</tr>
<tr>
<td>Venous ulcers</td>
<td>Poor hygiene or wound care</td>
<td>Protection from external contamination sources.</td>
</tr>
</tbody>
</table>
Instillation Therapy

Background

Current wound treatment protocol includes some or all of the following:

- Debridement
- Antibiotic treatment (both local and systemic for infected wounds)
- Local application of antiseptics or antimicrobials
- Delayed wound closure (when necessary)
- Use of drains
- Repeated wound cleansing


Instillation vs Irrigation

**Irrigation**
- Practice of washing out a wound or body opening with a stream of liquid solution

**Instillation**
- Solution 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.
- Instillation helps with wound cleansing by loosening soluble contaminants in the wound bed followed by subsequent removal of infectious material during NPWT.
- In automated instillation, the cleansing cycle can be automatically repeated.


### Observational

- 27 patients treated with "Instillation-Vacuum-Sealing"
  - \( n=13 \), acute infections of bone and soft tissues
  - \( n=8 \), chronic osteomyelitis
  - \( n=6 \), chronic wounds

### Results

After 7 days of instillation with antibiotic and antiseptic solutions, either immediate or delayed wound closure by secondary suturing \( (n=22) \), skin grafting \( (n=3) \), or spontaneous epithelialization \( (n=2) \) was performed.

### Volumetric Fluid Delivery

**Utilizing a pump for reliable fluid delivery**

Automatic volumetric fluid delivery with V.A.C. VeraFlo™ Therapy differs from other systems that provide instillation solutions under continuous flow or use gravity to instill solution.

### Product Testing and Analysis
Science Supporting V.A.C. VeraFlo™ Therapy

- Materials testing
- Benchtop testing
- In vitro testing
- In vivo testing

The following results have not been confirmed in human studies

V.A.C. VeraFlo™ Therapy Can Help:

- **Cleanse**
  - V.A.C. VeraFlo™ Therapy combines the benefits of V.A.C.® Therapy with automated solution distribution and removal.
  - **Cleanses** the wound with instillation of topical wound cleansers in a consistent, controlled manner.

- **Treat**
  - **Treats** the wound with the instillation of appropriate topical antimicrobial and antiseptic solutions and the removal of infectious material.

- **Heal**
  - **Heals** the wound and prepares for primary or secondary closure.

Cleanses: Reduction of Bacterial Aerosolization

- In a bench top model
  - Low pressure lavage caused aerosolization or splashing of wound fluid bacteria more than 6 inches (15 cm) from model
  - V.A.C. VeraFlo™ Therapy provided containment
    - No wound fluid bacteria detected outside the wound model
    - Wound fluid bacteria found inside canister
  - Suggests V.A.C. VeraFlo™ Therapy may help reduce likelihood of cross-contamination during cleansing.
Cleanses: Wound Cleansing and Tissue Damage

- Contralateral porcine wounds were inoculated with a fluorescent solution and treated either with pulsed lavage or V.A.C. VeraFlo™ Therapy
- Pulsed lavage was shown to cleanse wounds, but caused swelling
- V.A.C. VeraFlo™ Therapy equivalently cleansed wounds without causing swelling
- V.A.C. VeraFlo™ Therapy may cleanse wounds as effectively as pulsed lavage, but may cause less tissue damage than other techniques

Cleanses: Dressing Strength

- V.A.C. VeraFlo™ Dressings have greater tensile strength than V.A.C.® GranuFoam™ Dressings under wet and dry conditions
- Better ability to withstand tearing at removal, even when wet

Cleanses: Dressing Fluid Distribution

- Compared to V.A.C.® GranuFoam™ Dressings, V.A.C. VeraFlo™ Dressings:
  - Are less hydrophobic
  - Provide enhanced fluid distribution through foam
- This may enable:
  - Even fluid delivery during instillation
  - Enhanced removal of fluids and exudates from wound
**Treats: Periodic vs. Continuous Instillation**

- Benchtop wound anatomical model
- Continuous Instillation (akin to SVED™ system) did not provide even wound coverage
- Periodic Instillation (V.A.C. VeraFlo™ Therapy) provided uniform coverage of wound with irrigation solution
  - Reached tunneled and undermined regions

**Treats: Bioburden Management**

- Mature Pseudomonas aeruginosa biofilm grown on pig skin in vitro
- After 24 hours of treatment, samples treated with V.A.C. VeraFlo™ Therapy and Polyhexamethylene Biguanide (PHMB) showed ~3-log (99.8%) reduction in bacteria compared to untreated controls

**Heals: Granulation Tissue Formation**

- Porcine wound healing model with 7 days of therapy
- Contralateral non-infected wounds
- Wounds with V.A.C. VeraFlo™ Therapy with saline instillation had 43% more granulation tissue than V.A.C.® Therapy wounds
Review of Clinical Literature

NPWTi Literature Review*

<table>
<thead>
<tr>
<th>Wound Type</th>
<th>Number of Articles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute wounds</td>
<td></td>
</tr>
<tr>
<td>Surgical Wounds</td>
<td>195</td>
</tr>
<tr>
<td>General Trauma</td>
<td>23</td>
</tr>
<tr>
<td>Grafts</td>
<td>70</td>
</tr>
<tr>
<td>Diabetic Foot Amputations</td>
<td>11</td>
</tr>
<tr>
<td>Chronic wounds</td>
<td></td>
</tr>
<tr>
<td>Pressure Ulcers</td>
<td>38</td>
</tr>
<tr>
<td>Diabetic Foot Ulcers</td>
<td>38</td>
</tr>
<tr>
<td>Venous Insufficiency Ulcers</td>
<td>8</td>
</tr>
</tbody>
</table>

* As of 03/12

Negative pressure wound treatment with polyvinyl alcohol foam and polyhexanide antiseptic solution instillation in posttraumatic osteomyelitis Timmers et al, 2009

Retrospective, case-control cohort study
- 30 patients with osteomyelitis of the pelvis or lower extremity and treated with adjunctive NPWTi
- Control patients (n=94) received standard care (i.e., debridement, implantation of gentamicin beads and systemic antibiotics)
- Instillation solution used was polyhexanide
- Soak time was 10-15 minutes
- 300-600 mmHg negative pressure range was used
- Dressing changes occurred every 3-4 days
- Mean therapy duration = 19.6-22.4 days

*This negative pressure setting is not achievable with V.A.C.® Therapy Units.

Results
- In NPWTi group, recurrence infection rate was 3/30 (10%) compared to 55/93 (58.5%) for the control group (p<0.0001).
- Total duration of hospital stay and number of surgical procedures was significantly lower in the NPWTi group compared to the control (p<0.0001 for both).

Conclusions
- In post traumatic osteomyelitis, negative pressure with instillation therapy reduced the need for repeated surgical interventions compared to the present standard approach.

Instillation therapy and chronic osteomyelitis - preliminary results with the V.A.C. Instill® Therapy

Pilot Study
- 6 patients treated with chronic osteomyelitis treated with NPWTi and Lavasept, an antiseptic solution
- 2-4 instillations with NPWT were completed (mean instillation time of 20 seconds followed by a 20 minute solution dwell time)
- Negative pressure cycle lasted 3-6 hours based on wound status

Results
- After initiation of NPWTi, all bacterial cultures were sterile

Conclusions
- NPWTi could be easily and safely used in conjunction with debridement, surgical reconstruction and appropriate antibiotic therapy for the treatment of osteomyelitis

Negative pressure wound therapy with instillation: a pilot study describing a new method for treating infected wounds

Retrospective with historical control
- NPWTi with silver nitrate solution vs. Moist gauze wound care
- 15 patients with complex, infected wounds treated with NPWTi compared to a retrospective historical control of 15 patients treated with moist gauze wound care
- 30 second instillation time with silver nitrate with a 1-second hold time followed by 2 hours of NPWT at -125mmHg continuously

Results
- Compared to the control group, the NPWTi group:
  - Required fewer days of treatment (p<0.001),
  - Cleared the infection earlier (p<0.001),
  - Had a shorter length of stay (p<0.001).

Conclusions
- “Outcomes from this study analysis suggest that the use of NPWTi may reduce cost and decreases inpatient care requirements for these complex infected wounds.”

Combination of subatmospheric pressure dressing and gravity feed antibiotic instillation in the treatment of post-surgical diabetic foot wounds: A case series. Bernstein et al, 2005

Case Series
- 5 post-surgical diabetic patients whose foot wounds were treated with NPWTi
- 6 hours of NPWT at -125mmHg followed by instillation of a solution composed of saline, polymyxin B, and bacitracin*
- 90 second instillation followed by 5 minute dwell time
  * Solutions have not been tested or approved for use

Results
- 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

The impact of V.A.C. Instill in severe soft tissue infections and necrotizing fasciitis. Schintler et al, 2009

Case Series
- 15 patients with skin and soft tissue infection using NPWTi
  - Instillation solution used was polyhexanide
  - Instillation time was dependent of wound size; dwell time was 20 minutes in all cases
  - Therapy duration ranged from 4-18 days with dressing changes every 2-4 days

Results
- Infection was controlled and complete healing was achieved in all patients

Conclusions
- Authors concluded that NPWTi may be a viable option for infection control in complicated anatomical regions

Vacuum-assisted closure instill as a method of sterilizing massive venous stasis wounds prior to split thickness skin graft placement. Raad et al, 2010

Retrospective review of a prospective wound care data over 2 years
- 5 patients with venous ulcer sizes (>200cm²) and colonization greater than 10^5 bacteria
- Patients were initially debrided and then treated with NPWTi for 10 days with 0.125% Dakin’s solution instilled for 10 minutes every hour
- Following NPWTi treatment, patients received STSGs and standard NPWT was applied for 4 days

Results
- 100% graft take at 1 month follow up

Conclusions
- NPWTi provided an effective therapy for managing patients with infected chronic venous stasis ulcers
Case Studies

The following slides are case studies and/or clinical reports based on clinical experience and research. 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.

V.A.C. VeraFlo™ Therapy Case Study: Ileostomy Site Wound

Open postoperative contaminated wound at a previous ileostomy site on an 83-year-old male.
A) Immediate postoperative, right lower quadrant wound. B) Application of V.A.C. VeraFlo™ Therapy with instillation of Microcyn. C) Day 10 of V.A.C. VeraFlo™ Therapy at 4th dressing change. D) Follow-up postoperative Day 34.

Photos courtesy of Dr. Tom Wolvos, Scottsdale, AZ

11/5/2012
V.A.C.VeraFlo™ Therapy Case Study: Postoperative Midline Wound


V.A.C.VeraFlo™ Therapy Case Study: Radiated Chest Wound


V.A.C.VeraFlo™ Therapy Case Study: Left Foot Abscess

Left foot abscess on an 86-year-old diabetic female patient. 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.
Clinical Considerations

- Anatomical location
- Patient positioning
- Relation to gravity
- Complexity
  - Tunnel
  - Undermining
- Infection
- Hardware
  - Size
  - Area
- Volume
- Others

Sacral Pressure Ulcer Challenges

- Anatomical position
  - Maintaining seal
- Patient position
  - Supine or prone?
  - Volume or weight?
  - Dressing support?
- Relation to gravity
  - Dependent areas
  - Independent areas
3M™ Cavilon™ Skin Prep

- A fast-drying, non-sticky, alcohol-free liquid barrier film that forms a breathable, transparent coating on the skin.
- Protects damaged or intact skin from body fluids, adhesive trauma, friction, and incontinence.
- The film is hypoallergenic and non-cytotoxic.

V.A.C. VeraT.R.A.C. Duo™ Pad Positioning

Allow for fluid to flow from the most independent area to the most dependent area of the wound.

- Instillation Pad
- Vacuum Pad
- Flow Direction

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 (e.g., Hypochlorite and Sodium Hypochlorite)</td>
<td>Dakin’s Solution (quarter-strength), Zinnaq® Micropak®</td>
<td>Dakin’s Solution should not be used in concentrations greater than 0.125% (quarter-strength). Consider using the lowest irritation cycle and minimizing hold times in the lower quadrant, which is usually relevant.</td>
</tr>
<tr>
<td>Silver nitrate (5%)</td>
<td>Viscous</td>
<td>Silver nitrate is a light sensitive, frozen V.A.C. VeraFlo™ Instillation Tubing from light, used with silver nitrate.</td>
</tr>
<tr>
<td>Silver-based solutions (Silveramino)</td>
<td>Meltex silver, Silveram®</td>
<td>Refer to manufacturer’s labeling for solution-specific considerations. No documented considerations for use with V.A.C. VeraFlo™ Therapy.</td>
</tr>
<tr>
<td>Peracetic acid (Depa-azide)</td>
<td>Proline®</td>
<td>May need to be transferred to a container that can be aerosolized at time.</td>
</tr>
<tr>
<td>Calcium solutions (Dextran, Bacterial-lymphocytic Cholesterol)</td>
<td>DynoPak®, ZephaPak®</td>
<td>Refer to manufacturer’s labeling for solution-specific considerations. No documented considerations for use with V.A.C. VeraFlo™ Therapy.</td>
</tr>
<tr>
<td>Amino Solutions</td>
<td>Normal saline solution, Lactated Ringer’s solution</td>
<td>Refer to manufacturer’s labeling for solution-specific considerations. No documented considerations for use with V.A.C. VeraFlo™ Therapy.</td>
</tr>
</tbody>
</table>
Safety Slides

V.A.C.® Therapy is indicated for patients with:

- Chronic Wounds
- Acute Wounds
- Traumatic Wounds
- Sub-acute Wounds
- Partial-thickness burns
- Dehisced wounds
- Clean, closed surgical incisions
- Ulcers such as:
  - Diabetic
  - Venous Insufficiency
  - Pressure
  - Flaps
  - Grafts

V.A.C.® Therapy Contraindications

- Do not place any V.A.C.® Foam Dressings (V.A.C.® GranuFoam™, V.A.C. GranuFoam Silver®, V.A.C. WhiteFoam, V.A.C. VeraFoam™, and V.A.C. VeraFoam Cleansing™ Dressings) in direct contact with exposed blood vessels, anastomotic sites, organs or nerves.
- Do not use V.A.C.® Therapy:
  - when there is malignancy in the wound
  - with untreated osteomyelitis
  - with necrotic tissue with eschar present
- Do not use the V.A.C. GranuFoam Silver® Dressing on a patient with a known sensitivity to silver.
- Do not use V.A.C.® VeraFoam™ Dressings with Octenisept™, hydrogen peroxide or solutions that are alcohol-based or contain alcohol.
- Do not deliver fluids to the thoracic cavity or abdominal cavity due to the potential risk to alter core body temperature and the potential for fluid retention within the thoracic cavity.
- Do not use use V.A.C.® VeraFoam™ Therapy unless the wound has been thoroughly explored due to the potential for inadvertent instillation of topical wound solutions to adjacent body cavities.

Note: Octenisept™ is not available in the United States.
V.A.C.® Therapy Warning Categories

- Canister Size
- Allergy
- Resuscitation
- Use in Altered Environment

- V.A.C.® Therapy Units should not be taken into a Magnetic Resonance Imaging (MRI) environment as they are MRI unsafe.
- Foam may interfere with quality of image.
- V.A.C.® Therapy Units should not be taken into a Hyperbaric Oxygen Therapy (HBO) chamber as they are HBO unsafe.
- V.A.C.® GranuFoam™ and V.A.C.® WhiteFoam Dressings have been used safely in the HBO chamber.
- Ensure dressing tubing is not clamped during HBO therapy.
- The V.A.C.® GranuFoam™ Bridge Dressing contains additional synthetic materials which may pose a risk during HBO Therapy.
- Patients with a known allergy to acrylic adhesives may react adversely to the V.A.C.® Drape.
- Seek medical attention if patient experiences a severe reaction.
- The foam dressing, if in the thoracic area, may interfere with defibrillation efforts.
- Joules may need to be adjusted to compensate or the dressing may need to be removed.
- Patients at high risk of bleeding or unable to tolerate a large loss of fluid volume should not use the therapy.
- V.A.C.® Therapy Units are MRI unsafe and should not be taken into an MRI environment.
- Foam may interfere with quality of image.
- V.A.C.® Therapy Units are HBO unsafe and should not be taken into a HBO chamber.
- V.A.C.® GranuFoam™ and V.A.C.® WhiteFoam Dressings have been used safely in the HBO chamber.
- Ensure dressing tubing is not clamped during HBO therapy.
- The V.A.C.® GranuFoam™ Bridge Dressing contains additional synthetic materials which may pose a risk during HBO Therapy.
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- Seek medical attention if patient experiences a severe reaction.
- The foam dressing, if in the thoracic area, may interfere with defibrillation efforts.
- Joules may need to be adjusted to compensate or the dressing may need to be removed.

V.A.C.® Therapy Precaution Categories

- Standard precautions reduce the risk of transmission of blood borne pathogens.
- Continuous therapy setting is recommended for:
  - First 48 hours of V.A.C.® Therapy
  - Skin and skin substitute grafts
  - High-output wounds
  - Tunnels and undermined areas
  - Difficult dressing applications
  - Painful wounds
  - Intermittent or Dynamic Pressure Control™ should not be used in the situations recommended for continuous therapy.
  - Patient Size and Weight may influence response to fluid loss and dehydration.
  - Spinal Cord Injury Patients may experience sudden changes in heart rate or blood pressure due to autonomic dysreflexia, which requires removal from V.A.C.® Therapy.
  - Bradycardia may occur if foam dressing is placed close to the vagus nerve.
  - Wounds with enteroatmospheric (entero-atmospheric) fistulae require special dressing application techniques. Refer to V.A.C.® Therapy Clinical Guidelines.
  - Protect periwound skin from foam contact.
  - Circumferential dressings should be applied loosely – do not tightly stretch drape as this may impair blood flow.
  - Check circulation distal to dressing frequently.
  - V.A.C.® Therapy Unit Pressure Excursions
    - May occur if therapy unit senses blockage.
    - Therapy unit may briefly go to -250mmHg or higher.

* Dynamic Pressure Control ™ provided on V.A.C.Via™ and V.A.C.Ultra™ Therapy Systems.
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Questions?