



Acelity™

**V.A.C.ULTA™ NEGATIVE  
PRESSURE WOUND THERAPY  
SYSTEM  
(V.A.C.ULTA™ THERAPY  
SYSTEM)  
SAFETY INFORMATION**

ONLY FOR USE WITH THE KCI V.A.C.ULTA™ THERAPY SYSTEM

Rx Only



## TABLE OF CONTENTS

Important Information for Users.....	4
Dressing Systems for Use with V.A.C.ULTA™ Therapy Unit.....	4
Products not Intended for Use with V.A.C. VERAFLOR™ Therapy (Instillation).....	5
Indications for Use.....	5
Transitioning V.A.C.® Therapy Into Home Care.....	6
V.A.C.ULTA™ Therapy System Contraindications.....	6
Additional Contraindications Specific to V.A.C. VERAFLOR™ Therapy.....	7
V.A.C.ULTA™ Therapy System Warnings.....	7
Additional Warnings for V.A.C. VERAFLOR™ Therapy.....	11
V.A.C.ULTA™ Therapy System Precautions.....	12
Additional Precautions for V.A.C. VERAFLOR™ Therapy.....	13
Additional Precautions for the PREVENA™ Incision Management Dressing.....	14
Additional Precautions for the ABTHERA™ SENSATR.A.C.™ Open Abdomen Dressing.....	14
Additional Precautions for V.A.C.® GRANUFOAM SILVER™ Dressing.....	15
Additional Precautions for the KCI™ Negative Pressure Wound Therapy Gauze Dressing.....	15

## IMPORTANT INFORMATION FOR USERS

The V.A.C.ULTA™ Negative Pressure Wound Therapy System (V.A.C.ULTA™ Therapy System) is an integrated wound therapy system that can be used for:



- **V.A.C. VERAFLU™ Therapy** (Instillation), which consists of negative pressure wound therapy (**V.A.C.® Therapy**) coupled with controlled delivery and drainage of topical wound irrigation treatment solutions and suspensions over the wound bed.

**OR**

- **V.A.C.® Therapy**, which consists of negative pressure wound therapy alone.



When using V.A.C. VERAFLU™ Therapy (Instillation), there are important **Contraindications, Warnings, and Precautions** that should be considered in addition to the **Contraindications, Warnings** and **Precautions** for V.A.C.® Therapy. **Contraindications, Warnings** and **Precautions** specific to V.A.C. VERAFLU™ Therapy are highlighted in grey throughout the document and are identified by the V.A.C. VERAFLU™ Therapy symbol to the left of the text. When using V.A.C.® Therapy alone, the V.A.C. VERAFLU™ Therapy **Contraindications, Warnings** and **Precautions** are not applicable.

**IMPORTANT:** As with any prescription medical device, failure to consult a physician and carefully read and follow all safety information and application instructions provided with the therapy unit and dressing cartons prior to use may lead to improper product performance and the potential for serious or fatal injury. Do not adjust therapy unit settings or perform therapy application without directions from / or supervision by the clinical caregiver.

## DRESSING SYSTEMS FOR USE WITH V.A.C.ULTA™ THERAPY UNIT

V.A.C.® Therapy can be used with any of the following dressings:

- V.A.C.® GRANUFOAM™ Dressings
- V.A.C.® GRANUFOAM SILVER™ Dressings
- V.A.C. WHITEFOAM™ Dressings
- PREVENA™ Incision Management Dressings
- ABTHERA™ SENSAT.R.A.C.™ Open Abdomen Dressings
- KCI™ Negative Pressure Wound Therapy Gauze Dressing



V.A.C. VERAFLU™ Therapy should be delivered with V.A.C. VERAFLU™ or V.A.C. VERAFLU CLEANSE™ Dressings.

## **PRODUCTS NOT INTENDED FOR USE WITH V.A.C. VERAFLU™ THERAPY (INSTILLATION)**

- Cellular or acellular bioengineered tissues.
- V.A.C.® GRANUFOAM SILVER™ Dressings
- PREVENA™ Incision Management Dressings
- The ABTHERA™ SENSAT.R.A.C.™ Open Abdomen Dressing
- KCI™ Negative Pressure Wound Therapy Gauze Dressing

Refer to the additional warnings and precautions for V.A.C. VERAFLU™ Therapy.

## **INDICATIONS FOR USE**

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

- Negative Pressure Wound Therapy in the absence of instillation is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material.
- The instillation option is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed.

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

- Negative Pressure Wound Therapy in the absence of instillation may also be used for:
  - The temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary and for open abdominal wounds with exposed viscera including, but not limited to, abdominal compartment syndrome. The intended care setting is a closely monitored area within the acute care hospital, such as the ICU. The abdominal dressing will most often be applied in the operating theater.
  - The management of the environment of closed surgical incisions and surrounding intact skin in patients at risk for developing post-operative complications, such as infection, by maintaining a closed environment via the application of a negative pressure wound therapy system to the incision. The PREVENA™ Incision Dressing skin interface layer with silver reduces microbial colonization in the fabric.

## TRANSITIONING V.A.C.® THERAPY INTO HOME CARE

- The V.A.C.ULTA™ Therapy System is not intended for home use\*.
- If there is a need to continue V.A.C.® Therapy when a patient transitions home, consider using one of the KCI Therapy Systems approved for the post-acute environment, such as:
  - PREVENA™ 125 Therapy Unit
  - PREVENA PLUS™ 125 Therapy Unit
  - ACTIV.A.C.™ Therapy Unit
  - V.A.C. FREEDOM™ Therapy Unit
  - V.A.C. SIMPLICITY™ Unit
  - V.A.C.VIA™ Therapy System

Refer to the safety information included with those devices for important information.

## V.A.C.ULTA™ THERAPY SYSTEM CONTRAINDICATIONS

- Do not place foam dressings of the V.A.C.ULTA™ Therapy System (including both V.A.C.® Therapy and V.A.C. VERAFLOR™ Therapy Dressings) 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. VERAFLOR™ Therapy are contraindicated for patients with:

- Malignancy in the wound
- Untreated osteomyelitis

**NOTE:** Refer to **Warnings** section for Osteomyelitis information.

- Non-enteric and unexplored fistulas
- Necrotic tissue with eschar present

**NOTE:** After debridement of necrotic tissue and complete removal of eschar, V.A.C.® Therapy may be used.

- Sensitivity to silver (V.A.C.® GRANUFOAM SILVER™ Dressing and PREVENA™ Incision Management Dressings only)

\* In France, the V.A.C.ULTA™ Therapy System (P/N HCULTDEV01/FR) may be used in the HAD Healthcare System.



## ADDITIONAL CONTRAINDICATIONS SPECIFIC TO V.A.C. VERAFLOR<sup>TM</sup> THERAPY

- Do not use V.A.C.<sup>®</sup> Dressings with Octenisept<sup>\*\*</sup>, hydrogen peroxide or solutions that are alcohol-based or contain alcohol.
- 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. VERAFLOR<sup>TM</sup> Therapy unless the wound has been thoroughly explored due to the potential for inadvertent instillation of topical wound solutions to adjacent body cavities.

\*Not available in the United States. Brand name referenced is not a trademark of KCI, its affiliates and / or licensors.

## V.A.C.ULTA<sup>TM</sup> THERAPY SYSTEM WARNINGS

**Bleeding:** With or without using V.A.C.<sup>®</sup> Therapy or V.A.C. VERAFLOR<sup>TM</sup> Therapy, certain patients are at high risk of bleeding complications. The following types of patients are at increased risk of bleeding, which, if uncontrolled, could be potentially fatal.

- Patients who have weakened or friable blood vessels or organs in or around the wound as a result of, but not limited to:
  - Suturing of the blood vessel (native anastomoses or grafts) / organ
  - Infection
  - Trauma
  - Radiation
- Patients without adequate wound hemostasis
- Patients who have been administered anticoagulants or platelet aggregation inhibitors
- Patients who do not have adequate tissue coverage over vascular structures.

**If V.A.C.<sup>®</sup> Therapy or V.A.C. VERAFLOR<sup>TM</sup> Therapy is prescribed for patients who have an increased risk of bleeding complications, they should be treated and monitored in a care setting deemed appropriate by the treating physician.**

**If active bleeding develops suddenly or in large amounts during V.A.C.<sup>®</sup> Therapy or V.A.C. VERAFLOR<sup>TM</sup> Therapy, or if frank (bright red) blood is seen in the tubing or in the canister, immediately stop therapy, leave dressing in place, take measures to stop the bleeding, and seek immediate medical assistance. The V.A.C.ULTA<sup>TM</sup> Therapy Unit and dressings (both V.A.C.<sup>®</sup> Therapy and V.A.C. VERAFLOR<sup>TM</sup> Therapy) should not be used to prevent, minimize or stop vascular bleeding.**

- **Protect Vessels and Organs:** All exposed or superficial vessels and organs in or around the wound must be completely covered and protected prior to the administration of V.A.C.® Therapy or V.A.C. VERAFLOR™ Therapy.

Always ensure that V.A.C.® Foam Dressings and V.A.C. VERAFLOR™ Foam Dressings do not come in direct contact with vessels or organs. Use of a thick layer of natural tissue should provide the most effective protection. If a thick layer of natural tissue is not available or is not surgically possible, multiple layers of fine-meshed, non-adherent material may be considered as an alternative, if deemed by the treating physician to provide a complete protective barrier. If using non-adherent materials, ensure that they are secured in a manner as to maintain their protective position throughout therapy.

Consideration should also be given to the negative pressure setting and therapy mode used when initiating therapy.

Caution should be taken when treating large wounds that may contain hidden vessels, which may not be readily apparent. The patient should be closely monitored for bleeding in a care setting deemed appropriate by the treating physician.

- **Infected Blood Vessels:** Infection may erode blood vessels and weaken the vascular wall which may increase susceptibility to vessel damage through abrasion or manipulation. **Infected blood vessels are at risk of complications, including bleeding, which, if uncontrolled, could be potentially fatal. Extreme caution should be used when V.A.C.® Therapy or V.A.C. VERAFLOR™ Therapy is applied in close proximity to infected or potentially infected blood vessels.** (Refer to **Protect Vessels and Organs** section.)
- **Hemostasis, Anticoagulants and Platelet Aggregation Inhibitors:** Patients without adequate wound hemostasis have an increased risk of bleeding, which, if uncontrolled, could be potentially fatal. These patients should be treated and monitored in a care setting deemed appropriate by the treating physician.

Caution should be used in treating patients on doses of anticoagulants or platelet aggregation inhibitors thought to increase their risk for bleeding (relative to the type and complexity of the wound). Consideration should be given to the negative pressure setting and therapy mode used when initiating therapy.

- **Hemostatic Agents Applied at the Wound Site:** Non-sutured hemostatic agents (for example, bone wax, absorbable gelatin sponge or spray wound sealant) may, if disrupted, increase the risk of bleeding, which, if uncontrolled, could be potentially fatal. Protect against dislodging such agents. Consideration should be given to the negative pressure setting and therapy mode used when initiating therapy. (Refer to **Additional Warnings for V.A.C. VERAFLOR™ Therapy** section).
- **Sharp Edges:** Bone fragments or sharp edges could puncture protective barriers, vessels or organs causing injury. Any injury could cause bleeding, which, if uncontrolled, could be potentially fatal. Beware of possible shifting in the relative position of tissues, vessels or organs within the wound that might increase the possibility of contact with sharp edges. Sharp edges or bone fragments must be eliminated from the wound area or covered to prevent them from puncturing blood vessels or organs before the application of V.A.C.® Therapy or V.A.C. VERAFLOR™ Therapy. Where possible, completely smooth and cover any residual edges to decrease the risk of serious or fatal injury, should shifting of structures occur. Use caution when removing dressing components from the wound so that wound tissue is not damaged by unprotected sharp edges.



**1000 mL Canister:** **DO NOT USE the 1000 mL canister on patients with a high risk of bleeding or on patients unable to tolerate a large loss of fluid volume, including children and the elderly.**

Consider the size and weight of the patient, patient condition, wound type, monitoring capability and care setting when using this canister. This canister is recommended for acute care (hospital) use only.

**Infected Wounds:** Infected wounds should be monitored closely and may require more frequent dressing changes than non-infected wounds, dependent upon factors such as wound conditions, treatment goals and V.A.C. VERAFLOR™ Therapy parameters (for the V.A.C.ULTA™ Therapy System). Refer to dressing application instructions (found in V.A.C.® Dressing and V.A.C. VERAFLOR™ Dressing cartons) for details regarding dressing change frequency. As with any wound treatment, clinicians and patients / caregivers should frequently monitor the patient's wound, periwound tissue and exudate for signs of infection, worsening infection or other complications. Some signs of infection are fever, tenderness, redness, swelling, itching, rash, increased warmth in the wound or periwound area, purulent discharge or strong odor. Infection can be serious, and can lead to complications such as pain, discomfort, fever, gangrene, toxic shock, septic shock and / or fatal injury. Some signs or complications of systemic infection are nausea, vomiting, diarrhea, headache, dizziness, fainting, sore throat with swelling of the mucus membranes, disorientation, high fever, refractory and / or orthostatic hypotension, or erythroderma (a sunburn-like rash). **If there are any signs of the onset of systemic infection or advancing infection at the wound site, contact a physician immediately to determine if V.A.C.® Therapy or V.A.C. VERAFLOR™ Therapy should be discontinued.** For wound infections relating to blood vessels, please also refer to the section titled **Infected Blood Vessels**.

**Infected Wounds with V.A.C.® GRANUFOAM SILVER™ Dressing:** In the event of clinical infection, V.A.C.® GRANUFOAM SILVER™ Dressing is not intended to replace the use of systemic therapy or other infection treatment regimens. V.A.C.® GRANUFOAM SILVER™ Dressing may be used to provide a barrier to bacterial penetration. Refer to the section titled **Additional Precautions for V.A.C.® GRANUFOAM SILVER™ Dressing**.

**Osteomyelitis:** V.A.C.® Therapy and V.A.C. VERAFLOR™ Therapy should NOT be initiated on a wound with untreated osteomyelitis. Consideration should be given to thorough debridement of all necrotic, non-viable tissue, including infected bone (if necessary), and appropriate antibiotic therapy.

**Protect Tendons, Ligaments and Nerves:** Tendons, ligaments and nerves should be protected to avoid direct contact with V.A.C.® Foam Dressings or V.A.C. VERAFLOR™ Therapy Foam Dressings. These structures may be covered with natural tissue or meshed non-adherent material to help minimize risk of desiccation or injury.

**Foam Placement:** Always use V.A.C.® Dressings or V.A.C. VERAFLOR™ Therapy Dressings from sterile packages that have not been opened or damaged. Do not place any foam dressing into blind / unexplored tunnels. The V.A.C. WHITEFOAM™ Dressing may be more appropriate for use with explored tunnels. The V.A.C. VERAFLOR CLEANSE™ Dressing System may be more appropriate for use with explored tunnels when using V.A.C. VERAFLOR™ Therapy where robust granulation tissue formation is not desired. Do not force foam dressings into any area of the wound, as this may damage tissue, alter the delivery of negative pressure, or hinder exudate and foam removal. Always count the total number of pieces of foam used in the wound and the dressing change date and document that number on the drape, in the patient's chart and on the foam quantity label attached to the pad tubing (if provided).

**Foam Removal:** V.A.C.® Foam Dressings and V.A.C. VERAFLOR™ Therapy Foam Dressings are not bioabsorbable. **Always count the total number of pieces of foam removed from the wound and ensure the same number of foam pieces was removed as placed.** Foam left in the wound for greater than the recommended time period may foster ingrowth of tissue into the foam, create difficulty in removing foam from the wound, or lead to infection or other adverse events. **If significant bleeding develops, immediately discontinue the use of the V.A.C.ULTA™ Therapy System, take measures to stop the bleeding, and do not remove the foam dressing until the treating physician or surgeon is consulted. Do not resume the use of the V.A.C.® Therapy or V.A.C. VERAFLOR™ Therapy until adequate hemostasis has been achieved and the patient is not at risk for continued bleeding.**

**Keep V.A.C.® Therapy and V.A.C. VERAFLOR™ Therapy On:** Never leave a V.A.C.® Dressing or V.A.C. VERAFLOR™ Therapy Dressing in place without active V.A.C.® Therapy or V.A.C. VERAFLOR™ Therapy for more than two hours. If therapy is off for more than two hours, remove the old dressing and irrigate the wound. Either apply a new V.A.C.® Dressing or V.A.C. VERAFLOR™ Therapy Dressing from an unopened sterile package and restart therapy; or apply an alternative dressing at the direction of the treating clinician.

**Acrylic Adhesive:** The V.A.C.® Drape (supplied with V.A.C.® Dressings) and the V.A.C.® Advanced Drape (supplied with V.A.C. VERAFLOR™ Therapy Dressings) have an acrylic adhesive coating, which may present a risk of an adverse reaction in patients who are allergic or hypersensitive to acrylic adhesives. If a patient has a known allergy or hypersensitivity to such adhesives, do not use the V.A.C.ULTA™ Therapy System. If any signs of allergic reaction or hypersensitivity develop, such as redness, swelling, rash, urticaria or significant pruritus, discontinue use and consult a physician immediately. If bronchospasm or more serious signs of allergic reaction appear, seek immediate medical assistance.

**Defibrillation:** Remove the V.A.C.® Dressing or V.A.C. VERAFLOR™ Therapy Dressing if defibrillation is required in the area of dressing placement. Failure to remove the dressing may inhibit transmission of electrical energy and / or patient resuscitation.

**Flammable Environment:** Equipment not suitable for use in the presence of a flammable anesthetic mixture of air, oxygen, or nitrous oxide, or in an oxygen enriched environment.

**Magnetic Resonance Imaging (MRI) – Therapy Unit:** The V.A.C.ULTA™ Therapy Unit is **MR Unsafe.** Do not take the V.A.C.ULTA™ Therapy Unit into the MR environment.

**Magnetic Resonance Imaging (MRI) – V.A.C.® Dressings:** V.A.C.® Dressings and V.A.C. VERAFLOR™ Therapy Dressings can typically remain on the patient with minimal risk in an MR environment, assuming that use of the V.A.C.ULTA™ Therapy System is not interrupted for more than two hours (refer to **Keep V.A.C.® Therapy and V.A.C. VERAFLOR™ Therapy On** above).



**NOTE:** *If using V.A.C. VERAFLOR™ Therapy ensure that irrigation fluid or treatment solutions are fully removed from the dressing prior to stopping negative pressure wound therapy.*

The V.A.C.® GRANUFOAM SILVER™ Dressing has been shown to pose no known hazards in an MR environment with the following conditions of use:

- Static magnetic field of 3 Tesla or less,
- Spatial gradient field of 720 Gauss / cm or less, and
- Maximum whole-body-averaged specific absorption rate (SAR) of 3 W / kg for 15 minutes of scanning

Non-clinical testing under these same conditions produced a temperature rise of <0.4°C. MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the V.A.C.® GRANUFOAM SILVER™ Dressing.

**Hyperbaric Oxygen Therapy (HBO):** Do not take the V.A.C.ULTA™ Therapy Unit into a hyperbaric oxygen chamber. The V.A.C.ULTA™ Therapy Unit is not designed for this environment and should be considered a fire hazard. After disconnecting the V.A.C.ULTA™ Therapy Unit, either (i) replace the V.A.C.® Dressing or V.A.C. VERAFLU™ Therapy Dressing with another HBO compatible material during the hyperbaric treatment, or (ii) cover the unclamped end of the V.A.C.® Tubing with dry gauze. For HBO therapy, the V.A.C.® Tubing or V.A.C. VERAFLU™ Therapy Tubing must not be clamped. Never leave a V.A.C.® Dressing in place without active V.A.C.® Therapy for more than two hours; please refer to the **Keep V.A.C.® Therapy On** section.



**NOTE:** *If using V.A.C. VERAFLU™ Therapy ensure that irrigation fluid or treatment solutions are fully removed from the dressing prior to stopping negative pressure wound therapy.*

## **ADDITIONAL WARNINGS FOR V.A.C. VERAFLU™ THERAPY**

**Topical Wound Solutions:** Topical wound solutions or suspensions may enter internal body cavities if the wound is open to such cavities. They should not be infused into wounds with unexplored tunnels or unexplored undermining as they may enter into unintended cavities.

**Pauses in Negative Pressure:** Application of V.A.C. VERAFLU™ Therapy will result in pauses of negative pressure wound therapy, which is not recommended on wounds requiring continuous V.A.C.® Therapy. Do not use V.A.C. VERAFLU™ Therapy over unstable structures, such as unstable chest wall or non-intact fascia, on patients at increased risk of bleeding, on flaps, grafts or wounds with acute enteric fistulae.

**Bioengineered Tissue:** V.A.C. VERAFLU™ Therapy is not intended for use with cellular or acellular bioengineered tissues.

**Hemostasis:** Patients with difficult or fragile wound hemostasis are at increased risk of bleeding associated with V.A.C. VERAFLU™ Therapy due to the potential for disruption of clots or dilution of clotting factors. Do not use V.A.C. VERAFLU™ Therapy where hemostatic agents have been used in the wound bed.

**Closed Surgical Incisions:** DO NOT use V.A.C. VERAFLU™ Therapy with PREVENA™ Dressings over closed surgical incisions. Instillation may result in pooling of fluid which may result in maceration.

**Open Abdomen:** DO NOT use V.A.C. VERAFLU™ Therapy with the ABTHERA™ SENSAT.R.A.C.™ Open Abdomen Dressing over an open abdomen. Potential risks of instillation into the open abdomen include:

- Instillation of fluid in the abdomen without sufficient fluid recovery may lead to abdominal compartment syndrome.
- Instillation of fluids in the abdomen that are untested for safety and efficacy with this application could lead to severe hollow viscus and solid organ damage.
- Instillation of unwarmed fluid in large quantities may lead to hypothermia.

## V.A.C.ULTA™ THERAPY SYSTEM PRECAUTIONS

**Standard Precautions:** To reduce the risk of transmission of bloodborne pathogens, apply standard precautions for infection control with all patients, per institutional protocol, regardless of their diagnosis or presumed infection status. In addition to gloves, use gown and goggles if exposure to body fluids is likely.

**Continuous Versus DPC (Dynamic Pressure Control) V.A.C.® Therapy:** Continuous V.A.C.® Therapy is recommended over unstable structures, such as an unstable chest wall or non-intact fascia, in order to help minimize movement and stabilize the wound bed. Continuous therapy is also generally recommended for patients at increased risk of bleeding, fresh flaps and grafts, and wounds with acute enteric fistulae.



**NOTE:** V.A.C. VERAFLU™ Therapy, due to the controlled delivery of wound irrigation and treatment solutions, provides intermittent V.A.C.® Therapy and is not recommended in the above wound types or conditions.

**Patient Size and Weight:** The size and weight of the patient should be considered when prescribing V.A.C.® Therapy or V.A.C. VERAFLU™ Therapy. Infants, children, certain small adults and elderly patients should be closely monitored for fluid loss and dehydration. Also, patients with highly exudating wounds or large wounds in relation to the patient size and weight should be closely monitored, as they have a risk of excessive fluid loss and dehydration. When monitoring fluid output, consider the volume of fluid in both the tubing and canister.

**Spinal Cord Injury (SCI):** In the event an SCI patient experiences autonomic dysreflexia (sudden changes in blood pressure or heart rate in response to stimulation of the sympathetic nervous system), discontinue V.A.C.® Therapy or V.A.C. VERAFLU™ Therapy to help minimize sensory stimulation and seek immediate medical assistance.

**Bradycardia:** To minimize the risk of bradycardia, V.A.C.® Therapy and V.A.C. VERAFLU™ Therapy must not be placed in proximity to the vagus nerve.

**Enteric Fistulas:** Wounds with enteric fistulas require special precautions to optimize V.A.C.® Therapy. Refer to V.A.C.® Therapy Clinical Guidelines for more detail. V.A.C.® Therapy is not recommended if enteric fistula effluent management or containment is the sole goal of therapy.



**NOTE:** V.A.C. VERAFLU™ Therapy should not be used in the presence of enteric fistula to prevent wound contamination.

**Protect Periwound Skin:** Consider use of a skin preparation product to protect periwound skin. Do not allow foam to overlap onto intact skin. Protect fragile / friable periwound skin with additional V.A.C.® Advanced Drape, skin protectant, hydrocolloid or other transparent film. Multiple layers of the V.A.C.® Advanced Drape may decrease the moisture vapor transmission rate, which may increase the risk of maceration. If any signs of irritation or sensitivity to the drape, foam or tubing assembly appear, discontinue use and consult treating physician. To avoid trauma to the periwound skin, do not pull or stretch the drape over the foam dressing during drape application. Extra caution should be used for patients with neuropathic etiologies or circulatory compromise.

**Circumferential Dressing Application:** Avoid use of circumferential dressings except in the presence of anasarca or excessively weeping extremities, where a circumferential drape technique may be necessary to establish and maintain a seal. Consider using multiple small pieces of V.A.C.® Advanced Drape rather than one continuous piece to minimize the risk of decreased distal circulation. Extreme care should be taken not to stretch or pull the drape when securing it, but let it attach loosely and stabilize the edges with an elastic wrap, if necessary. When using circumferential drape applications, it is crucial to systematically and recurrently palpate distal pulses, and assess distal circulatory status. If circulatory compromise is suspected, discontinue therapy, remove dressing and contact treating physician.

**Pressure Points:** Periodically assess and monitor the location of tubing connectors, caps, clamps or other rigid components to ensure they do not create inadvertent pressure points in relation to patient position.

**V.A.C.ULTA™ Therapy Unit Pressure Excursions:** In rare instances, tubing blockages with the V.A.C.ULTA™ Therapy Unit may result in brief vacuum excursions to more than 250 mmHg negative pressure. Resolve alarm conditions immediately. Refer to the V.A.C.ULTA™ Therapy System User Manual or contact your KCI representative for additional information.

## ADDITIONAL PRECAUTIONS FOR V.A.C. VERAFLOR™ THERAPY



**Suitable Solutions:** V.A.C. VERAFLOR™ Therapy is intended for use with V.A.C. VERAFLOR™ Therapy disposables and topical wound treatment solutions and suspensions. Only use solutions or suspensions that are:

- Indicated for topical wound treatment according to solution manufacturer's instructions for use. Some topical agents may not be intended for extended tissue contact. If in doubt about the appropriateness of using a particular solution for V.A.C. VERAFLOR™ Therapy, contact the solution's manufacturer about its suitability for saturated topical wound exposure.
- Compatible with V.A.C.® Dressings and disposable components. Contact your KCI representative for a list of solutions shown to be compatible with V.A.C.® Dressings and disposable components.

**NOTE:** *Hypochlorous acid solutions applied frequently at high concentrations can lead to significant material degradation. Consider utilizing concentrations and exposure durations as low as clinically relevant.*

**NOTE:** *The V.A.C.® GRANUFOAM SILVER™ Dressing is not intended to be used with V.A.C. VERAFLOR™ Therapy because instillation solutions may negatively impact the benefits of the V.A.C.® GRANUFOAM SILVER™ Dressing.*

**KCI™ Negative Pressure Wound Therapy Gauze Dressing:** The KCI™ Negative Pressure Wound Therapy Gauze Dressing is not intended for use with V.A.C. VERAFLOR™ Therapy.

**Canister Changes:** Monitor fluid level in canisters frequently during use of the V.A.C. VERAFLOR™ Therapy. Frequent canister changes may be necessary depending on volume of fluid instilled and wound exudates. At a minimum the canister should be changed weekly and disposed of according to institutional protocol.

## ADDITIONAL PRECAUTIONS FOR THE PREVENA™ INCISION MANAGEMENT DRESSING



**PREVENA™ Incision Management Dressing:** When using the V.A.C.ULTA™ Therapy Unit as the negative pressure source for the PREVENA™ Incision Management Dressings, **refer to the Instructions for Use provided with PREVENA™ Incision Management Dressing for complete safety information, dressing application instructions and the procedure for connection to the V.A.C.ULTA™ Therapy Unit.**

The PREVENA™ Incision Management System is intended to manage the environment of closed surgical incisions and surrounding intact skin in patients at risk for developing post-operative complications such as infection, by maintaining a closed environment via the application of a negative pressure wound therapy system to the incision. The PREVENA™ Incision Dressing skin interface layer with silver reduces microbial colonization in the fabric.

Before transitioning the patient to home care, the V.A.C.ULTA™ Therapy Unit must be replaced with one indicated for home care (refer to **Transitioning V.A.C.® Therapy Into Home Care**).

## ADDITIONAL PRECAUTIONS FOR THE ABTHERA™ SENSAT.R.A.C.™ OPEN ABDOMEN DRESSING



**ABTHERA™ SENSAT.R.A.C.™ Open Abdomen Dressing:** When using the V.A.C.ULTA™ Therapy Unit as the negative pressure source for the ABTHERA™ SENSAT.R.A.C.™ Open Abdomen Dressing, **refer to the Instructions for Use provided with the ABTHERA™ SENSAT.R.A.C.™ Open Abdomen Dressing for complete safety information, dressing application instructions and the procedure for connection to the V.A.C.ULTA™ Therapy Unit.**

The ABTHERA™ SENSAT.R.A.C.™ Open Abdomen Dressing is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary. The intended use of this dressing is in open abdominal wounds with exposed viscera including, but not limited to, abdominal compartment syndrome. The intended care setting is a closely monitored area within the acute care hospital, such as the ICU. The abdominal dressing will most often be applied in the operating theater.

## **ADDITIONAL PRECAUTIONS FOR V.A.C.® GRANUFOAM SILVER™ DRESSING**

When using the V.A.C.ULTA™ Therapy Unit as the negative pressure source for the V.A.C.® GRANUFOAM SILVER™ Dressing, **refer to the Instructions for Use provided with the V.A.C.® GRANUFOAM SILVER™ Dressing for complete safety information and dressing application instructions.**

V.A.C.® GRANUFOAM SILVER™ Dressing may be used in the acute care as well as home settings with a therapy unit indicated for home care (refer to **Transitioning V.A.C.® Therapy Into Home Care**).

## **ADDITIONAL PRECAUTIONS FOR THE KCI™ NEGATIVE PRESSURE WOUND THERAPY GAUZE DRESSING**

When using the V.A.C.ULTA™ Therapy Unit as the negative pressure source for the KCI™ NPWT Gauze Dressing, refer to the Instructions for Use provided with the KCI™ NPWT Gauze Dressing for complete safety information and dressing application instructions.

The KCI™ NPWT Gauze Dressing is not intended for use with V.A.C. VERAFLU™ Therapy.

Before transitioning the patient to home care, the V.A.C.ULTA™ Therapy Unit must be replaced with one indicated for home care (refer to **Transitioning V.A.C.® Therapy Into Home Care**).

Additional warnings and precautions apply to certain V.A.C.® specialty dressings and V.A.C.® Therapy Units. Please refer to the specific product instructions for use prior to use.

If there are any questions regarding the proper placement or usage of V.A.C.® Therapy, please refer to the V.A.C.® Therapy Clinical Guidelines for more detailed instructions or contact your local KCI representative. For additional and most current information, please see KCI's website at [www.acylity.com](http://www.acylity.com) (US) or [www.kci-medical.com](http://www.kci-medical.com) (OUS).



KCI Manufacturing Unlimited Company  
IDA Business & Technology Park  
Dublin Road, Athlone,  
Co. Westmeath, Ireland  
[www.kci-medical.com](http://www.kci-medical.com)



KCI USA, Inc.  
12930 IH 10 West  
San Antonio, TX 78249 USA  
1-800-275-4524  
[www.acelity.com](http://www.acelity.com)



An Acelity Company

All trademarks designated herein are proprietary to KCI Licensing, Inc., its affiliates and / or licensors.

Copyright 2017 KCI Licensing, Inc. All rights reserved. 417659 Rev A 7/2017