V.A.C.Via™
NEGATIVE PRESSURE WOUND THERAPY SYSTEM

V.A.C.Via™ UNTERDRUCKWUNDTHERAPIE-SYSTEM
V.A.C.Via™ NEGATIVE PRESSURE WOUND THERAPY SYSTEM
V.A.C.Via™ SYSTÈME DE THÉRAPIE PAR PRESSION NÉGATIVE
V.A.C.Via™ SISTEMA TERAPEUTICO A PRESSIONE NEGATIVA
V.A.C.Via™ SISTEMA DE TERAPIA DE PRESIÓN NEGATIVA PARA EL TRATAMIENTO DE HERDAS / V.A.C.Via™ NEGATIVE PRESSURE WOUND THERAPY SYSTEM
V.A.C.Via™ SÅRBEHANDLINGSSYSTEM MED NEGATIVT TRYCK
V.A.C.Via™ SISTEMA DE TERAPIA DE LESÕES COM PRESSÃO NEGATIVA
V.A.C.Via™ NEGATİF BASINÇ YARA TEDAVİ SİSTEMİ
V.A.C.Via™ ΘΕΡΑΠΕΙΑ ΕΠΟΥΛΩΣΗΣ ΤΡΑΥΜΑΤΩΝ ΜΕ ΕΦΑΡΜΟΓΗ ΑΡΝΗΤΙΚΗΣ ΠΙΕΣΗΣ
V.A.C.Via™-ALIPAINEIMUHOITOJÄRJESTELMÄ
V.A.C.Via™-SÅRBEHANDLINGSSYSTEM MED UNDERTRYKK

INSTRUCTIONS FOR USE

GEBRAUCHSANWEISUNG / GEBRUIKSAANWIJZING / MODE D'EMPLOI ISTRUZIONI PER L'USO / INSTRUCCIONES DE USO / BRUGERVEJLEDNING BRUKSANVISNING / INSTRUÇÕES DE USO / KULLANIM TALİMATLARI ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ / KÄYTTÖOHJEET / BRUKSANVISNING

English

Deutsch

Nederlands

Français

Italiano

Español

Dansk

Svenska

Português

Türkçe

Ελληνικά

Suomi

Norsk

English

V.A.C.Via™
NEGATIVE PRESSURE WOUND THERAPY SYSTEM

(7-Day V.A.C.® THERAPY SYSTEM)

INSTRUCTIONS FOR USE

Keep Instructions for Use with Device

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The V.A.C.Via™ Therapy Unit is a single use, disposable V.A.C.® Therapy device designed for moderate to low severity wounds. The V.A.C.Via™ Therapy Unit has a seven day lifespan and a rechargeable battery. This unit provides negative pressure at either 75 mmHg or 125 mmHg, and offers selection of Continuous therapy or Dynamic Pressure Control™ therapy. The V.A.C.Via™ Starter Kits include one therapy unit, one carrying case, one AC power cord, one 250 cc / mL canister and one Medium Spiral Granufoam Dressing. Dressing kits and canisters for the V.A.C.Via™ are also provided separately.

V.A.C.® THERAPY SAFETY INFORMATION

Disposable components of the V.A.C.® (Vacuum Assisted Closure®) Therapy System, including the foam dressing (i.e., V.A.C.® GranuFoam™, V.A.C. GranuFoam Silver®, or V.A.C.® WhiteFoam Dressing), tubing and drape are packaged sterile and are latex-free. V.A.C.® Therapy Unit canisters are packaged sterile or fluid path sterile and are latex-free. To help ensure safe and effective use, the V.A.C.® GranuFoam™ Dressings are to be used only with V.A.C.® Therapy Units.

All disposable components of the V.A.C.® Therapy System are for single use only. Re-use of disposable components may result in wound contamination, infection and / or failure of the wound to heal.

The decision to use clean versus sterile / aseptic technique is dependent upon wound pathophysiology, physician / clinician preference and institutional protocol.

IMPORTANT: As with any prescription medical device, failure to consult a physician and carefully read and follow all therapy unit and dressing instructions and safety information prior to each 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.

The V.A.C.Via™ Negative Pressure Wound Therapy System is intended to be operated by qualified clinical caregivers in acute, extended or home-care settings. In-service and training programs for use of V.A.C.® Therapy are available. Patients may monitor therapy unit information signals under the direction or supervision of the clinical caregiver. Patients are not expected to apply or change V.A.C. Via™ Dressings or adjust therapy unit settings. For further information refer to **Considerations for Transitioning V.A.C.® Therapy into Homecare**, page four of this guide.

INDICATIONS FOR USE

The V.A.C.Via™ Negative Pressure Wound Therapy System is an integrated wound management system for use in acute, extended and home care settings. It 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 exudates and infectious material. It is indicated for patients with chronic, acute, traumatic, sub acute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency) flaps and grafts.

CONTRAINDICATIONS

- Do not place foam dressings of the V.A.C.® Therapy System 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 is 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.

WARNINGS

Bleeding: With or without using V.A.C.® 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 anastamoses 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.® 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.® Therapy, or if frank (bright red) blood is seen in the tubing or in the canister, immediately stop V.A.C.® Therapy, leave dressing in place, take measures to stop the bleeding, and seek immediate medical assistance. The V.A.C.® Therapy Units and dressings 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.

  Always ensure that V.A.C.® 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, or bio-engineered tissue may be considered as an alternative, if deemed necessary 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 is applied in close proximity to infected or potentially infected blood vessels. (Refer to **Protect Vessels and Organs** section above.)

- **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.

- **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. 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.

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 and treatment goals. Refer to dressing application instructions (page six of this guide) 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 should be discontinued. For wound infections relating to blood vessels, please also refer to the section titled Infected Blood Vessels.

Osteomyelitis: The V.A.C.® System 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. These structures may be covered with natural tissue, meshed non-adherent material, or bio-engineered tissue to help minimize risk of desiccation or injury.

Foam Placement: Always use V.A.C.® 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. 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 document that number on the foam quantity label and in the patient's chart. Document the dressing change date on the foam quantity label.

Foam Removal: V.A.C.® Foam Dressings are not bioabsorbable. Always count the total number of foam pieces removed from the wound and ensure the same number of foam pieces was removed as was 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.® 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 System until adequate hemostasis has been achieved, and the patient is not at risk for continued bleeding.

Keep V.A.C.® Therapy On: Never leave a V.A.C.® Dressing in place without active V.A.C.® 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 from an unopened sterile package and restart V.A.C.® Therapy; or apply an alternative dressing at the direction of the treating clinician.

Acrylic Adhesive: The V.A.C.® Advanced Drape has 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.® 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 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.

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

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

Hyperbaric Oxygen Therapy (HBO): Do not take the V.A.C.® Therapy Unit into a hyperbaric oxygen chamber. V.A.C.® Therapy Unit are not designed for this environment, and should be considered a fire hazard. After disconnecting the V.A.C.® Therapy Unit, either (i) replace the V.A.C.® Dressing with another HBO compatible material during the hyperbaric treatment, or (ii) cover the unclamped end of the V.A.C.® Tubing with moist cotton gauze. For HBO therapy, the V.A.C.® 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 above.

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 Dynamic Pressure Control™ (DPC) V.A.C.® Therapy: Continuous, rather than Dynamic Pressure Control, 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, highly exudating wounds, fresh flaps and grafts, and wounds with acute enteric fistulae.

Patient Size and Weight: The size and weight of the patient should be considered when prescribing V.A.C.® 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: In the event a 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 to help minimize sensory stimulation and seek immediate medical assistance.

Bradycardia: To minimize the risk of bradycardia, V.A.C.® 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.

Protect Periwound Skin: Consider use of 3M™ Cavilon™ No Sting Barrier Film 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, 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 a 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 a physician.

CONSIDERATIONS FOR TRANSITIONING V.A.C.® THERAPY INTO HOMECARE

WARNING: Patients having an increased risk of bleeding complications should be treated and monitored in a care setting deemed appropriate by the treating physician.

In addition to the contraindications, warnings and precautions for use of V.A.C.® Therapy, consider the following before prescribing V.A.C.® Therapy for use in the home care setting.

The Patient's Situation:

- Clinical condition (adequate hemostasis, and a low risk of active and / or large amounts of bleeding at the wound site)
- Home environment (patient or family member / caregiver able to read and understand safety labeling, able to respond to alarms, able to follow instructions for use).

The Patient's Wound:

- Must be assessed for exposed vessels, anastomotic sites, organs, and nerves. Adequate protection must be present without the need for a protective, non-adherent layer placed between the V.A.C.® Dressing and the exposed structure for the sole purpose of protection of these structures (Refer to **Protect Vessels and Organs** in the **Warnings** section).

Labeling:

- The prescribing physician and health care clinician should be familiar with and send the V.A.C.® Therapy labeling materials that accompany the therapy unit and dressing cartons into the home.
- Additional homecare patient information is available from your KCI representative and on the KCI web site www.kci1.com or vactherapy.com. The prescribing physician and / or healthcare clinician should obtain these materials and carefully review them with the patient.
- KCI offers in-service and training programs for use of V.A.C.® Therapy. Contact your local KCI representative. In the U.S., call 1-800-275-4524 for scheduling. In other countries, contact your local KCI representative or KCI-medical.com or vactherapy.com.

For 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 clinical representative. For additional and most current information, please see KCI's web site at www.kci1.com, www.kci-medical.com or vactherapy.com.

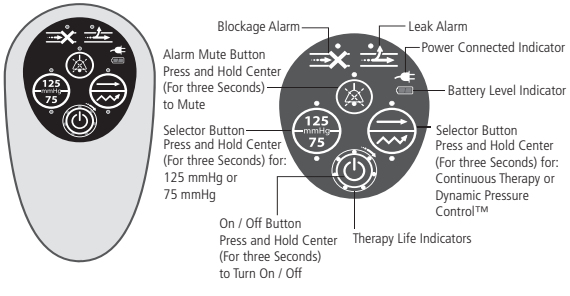
V.A.C.Via™ THERAPY UNIT

The V.A.C.Via™ Therapy Unit is a single use, disposable V.A.C.® Therapy Unit designed for moderate to low severity wounds. The V.A.C.Via™ Unit has a seven day lifespan and a rechargeable battery. The therapy unit features an interface panel which provides alarm and information signals and selectable therapy options. This unit provides negative pressure at either 75 mmHg or 125 mmHg, and offers selection of Continuous therapy or Dynamic Pressure Control™ therapy. As a safety feature, all selector buttons need to be pressed and held for three seconds for operation. The V.A.C.Via™ Starter Kits include one therapy unit, one carrying case, one AC power cord, one 250 cc / mL canister and one Medium Spiral Granufoam Dressing. Dressing kits and canisters for the V.A.C.Via™ are also provided separately.

CAUTION: Once therapy is on for one continuous hour, the seven day lifespan begins (one light for each day of therapy remaining) and continues even if unit is turned off.

WARNING: The V.A.C.Via™ Therapy Unit has no serviceable parts and should not be opened, disassembled or otherwise modified by the user, and should be replaced as a unit. All assembly, operations, adjustments, modifications, maintenance and repairs must be carried out by qualified personnel authorized by KCI.

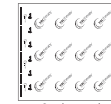
Electric Shock Hazard - Do not open any electrical cover on the therapy unit. There are no serviceable parts. Refer to qualified KCI service personnel.



V.A.C.Via™ DRESSING APPLICATION INSTRUCTIONS

V.A.C.® Spiral GranuFoam™ Dressing - Medium (Two per kit)

V.A.C.® Spiral GranuFoam™ Dressing - Small (Two per kit)



V.A.C.® Advanced Drape
Three with medium dressing
Two with small dressing

SensaT.R.A.C.® Pad with Foam Quantity Label

V.A.C.® Ruler

DRESSING CHANGES

Wounds being treated with a V.A.C.Via™ Therapy System should be monitored on a regular basis. In a monitored, non-infected wound, V.A.C.Via™ Dressings should be changed every 48 to 72 hours, but no less than three times per week, with frequency adjusted by the clinician as appropriate. Infected wounds must be monitored often and very closely. For these wounds, dressings may need to be changed more often than 48 to 72 hours; the dressing change intervals should be based on a continuing evaluation of wound condition and the patient's clinical presentation, rather than a fixed schedule.

For more information refer to the V.A.C.® Therapy Clinical Guidelines available at www.kci1.com, www.kci-medical.com, vactherapy.com or contact your local KCI representative for a printed copy.

WOUND PREPARATION

WARNING: Review all V.A.C.® Safety Information (located in the front of this guide) before beginning wound preparation.

1. Remove and discard previous dressing per institution protocol. Thoroughly inspect wound to ensure all pieces of dressing components have been removed.

   WARNING: Refer to **Foam Removal** section under **Warnings**.

   NOTE: If dressing adheres to wound, consider introducing sterile water or normal saline into the dressing, waiting 15-30 minutes, then gently removing the dressing from the wound. Consider placing a single layer, wide-meshed, non-adherent material prior to application of subsequent V.A.C.Via™ Dressings.
   If patient complains of or exhibits signs of discomfort during the dressing change, consider use of a non-adherent material prior to subsequent foam dressing placement, pre-medication, or introduction of a topical anesthetic agent into the dressing as prescribed by physician 15-20 minutes prior to dressing removal. Refer to V.A.C.® Therapy Clinical Guidelines for specific recommendations.
2. Debride all necrotic, non-viable tissue, including bone, eschar, or hardened slough, as prescribed by physician.
3. Perform thorough wound and periwound area cleaning per physician order or institution protocol prior to each dressing application.
4. Ensure adequate hemostasis has been achieved (refer to **Warnings** section, **Bleeding**, **Hemostasis**, **Anticoagulants and Platelet Aggregation Inhibitors**).
5. Protect vessels and organs (refer to **Warnings** section**, Bleeding**, **Protect Vessels and Organs**).
6. Sharp edges or bone fragments must be eliminated from wound area or covered (refer to **Warnings** section**, Bleeding**, **Sharp Edges**).
7. Clean and dry periwound tissue. The use of 3M™ Cavilon™ No Sting Barrier Film is suggested and may be provided with V.A.C.Via™ dressings in some but not all countries, to protect and prepare periwound skin (Fig. 2). Refer to 3M™ Cavilon™ No Sting Barrier Film product instructions for use, located on page eight of this guide. Do not allow foam to overlap onto intact skin. Protect fragile / friable periwound skin with additional V.A.C.® Advanced Drape, hydrocolloid, or other transparent film.

V.A.C.® SPIRAL GRANUFOAM™ APPLICATION

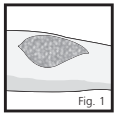


Fig. 1


Fig. 2


Fig. 3


Fig. 4


Fig. 5

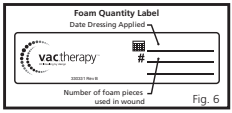


Fig. 6

Refer to V.A.C.® Therapy Clinical Guidelines for detailed instructions for treating different wound types and for multiple wound applications.

1. Assess wound dimensions and pathology, including the presence of undermining or tunnels (Fig. 1). Use V.A.C.® WhiteFoam Dressing with explored tunnels. Do not place any foam dressing into blind / unexplored tunnels. V.A.C.® Dressings may be used for wounds with shallow undermining or tunnel areas where the distal aspect is visible.

   NOTE: If adjunct materials are utilized under the V.A.C.® Dressing, they must be meshed or fenestrated to allow for effective delivery of negative pressure and exudate removal.

2. Carefully tear the V.A.C.® Spiral GranuFoam™ Dressing along the perforation to a size that will allow the foam to be placed gently into the wound without overlaping intact skin (Fig. 3).

   CAUTION: Do not cut or tear the foam over the wound, as fragments may fall into the wound (Fig. 4). Away from wound site, rub foam edges to remove any fragments or loose particles that may fall into or be left in the wound.

3. Gently place foam into wound cavity, ensuring contact with all wound surfaces (Fig. 3). Do not force the V.A.C.® Spiral GranuFoam™ Dressing into any areas of the wound.

   NOTE: Ensure foam-to-foam contact between adjacent pieces of foam for even distribution of negative pressure.

   NOTE: Always note the total number of pieces of foam used in the wound and document on the supplied foam quantity label (attached to the SensaT.R.A.C. ® pad tubing) (Fig. 6) and in the patient's chart.

   NOTE: Superficial or retention sutures should be covered with a single layer of non-adherent material placed between the sutures and the V.A.C.® Advanced Drape.

V.A.C.® ADVANCED DRAPE APPLICATION


Fig. 7

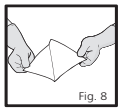


Fig. 8

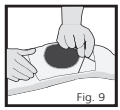
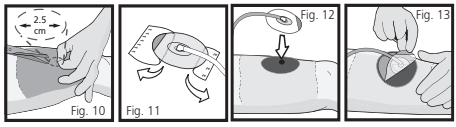


Fig. 9

CAUTION: Patient's skin condition should be carefully monitored (refer to **Precaution**, **Protect Periwound Skin** section (located in the front of this guide).

1. Trim the V.A.C.® Advanced Drape to cover the V.A.C.® Spiral GranuFoam™ Dressing and **an additional 3-5 cm border** of intact periwound tissue (Fig. 7). The V.A.C.® Advanced Drape may be cut into multiple pieces for easier handling. Excess V.A.C.® Advanced Drape may be kept to seal difficult areas, if needed.
2. Carefully remove layer 1 to expose adhesive (Fig. 8). The V.A.C.® Advanced Drape should be held by the ruler / handling bars.
3. Place the adhesive side down over foam and apply V.A.C.® Advanced Drape to cover foam and intact skin, ensuring V.A.C.® Advanced Drape covers **at least a 3-5 cm border** of intact periwound tissue. Smooth any wrinkles in drape to prevent leaks.
4. Remove layer 2 and handling bars and pat V.A.C.® Advanced Drape to ensure an occlusive seal (Fig. 9).

SensaT.R.A.C.® PAD APPLICATION



NOTE: Do not cut off the pad or insert the tubing into the foam dressing. This may occlude the tubing and cause the V.A.C.® Therapy Unit to alarm.

1. Choose pad application site. Give particular consideration to fluid flow and tubing positioning to allow for optimal flow, and avoid placement over bony prominences or within creases in the tissue.
2. Pinch V.A.C.® Advanced Drape and carefully cut an **approximately 2.5 cm hole** through the V.A.C.® Advanced Drape (Fig. 10). The hole should be large enough to allow for removal of fluid and / or exudate. It is not necessary to cut into the foam.

   NOTE: Cut a hole rather than a slit, as a slit may self-seal during therapy.
3. Apply pad, which has a central disc and a surrounding outer adhesive skirt.
   A. Remove both backing layers 1 and 2 to expose adhesive (Fig. 11).

   B. Place pad opening in central disc directly over hole in V.A.C.® Advanced Drape (Fig. 12).

   C. Apply gentle pressure on the central disc and outer skirt to ensure complete adhesion of the pad.

   D. Pull back on blue tab to remove pad stabilization layer (Fig. 13).

   E. If canister is on therapy unit connect dressing tubing to canister. If canister is not on therapy unit, see **V.A.C.Via™ Canister Installation** section of this guide.

   NOTE: To prevent periwound maceration and skin irritation with wounds that are smaller than the central disc of the pad, it is very important to frame the wound with drape to protect intact skin from direct foam contact and that the central disc lay on top of a piece of foam **at least 6.35 cm in diameter**. It may be necessary to augment the V.A.C.® Dressing with the larger end of the V.A.C.® Spiral GranuFoam™ Dressing. For additional dressing application techniques, refer to the V.A.C.® Therapy Clinical Guidelines available at www.kci1.com, www.kci-medical.com, vactherapy.com or contact your local KCI representative for a printed copy.

3M™ CAVILON™ NO STING BARRIER FILM

(information provided by 3M™ Company)

PRODUCT DESCRIPTION:

3M™ Cavilon™ No Sting barrier Film (Barrier Film) is a polymeric solution which forms a uniform film when applied to the skin. The product is dispersed in a unique non-cytotoxic, non-stinging solvent, which dries rapidly. Barrier Film helps to protect intact or damaged skin from irritation caused by urine and / or fecal incontinence, digestive juices, wound drainage, adhesives, and friction. The film is colorless, transparent, and possesses good oxygen and moisture vapor permeability.

INTENDED USE:

3M™ Cavilon™ No Sting Barrier Film is a liquid intended for use as a film- forming product, that upon application to intact or damaged skin forms a long lasting waterproof barrier, which acts as a protective interface between the skin and bodily waste, fluids, adhesive products and friction. It is intended as a primary barrier against irritation from body fluids. The product may be used on adults, children, and infants over one month of age.

INGREDIENTS:

Hexamethyldisiloxane, isooctane, acrylate terpolymer, polyphenylmethylsiloxane.

CONTRAINDICATIONS:

Barrier Film is NOT to be used:

1. As the only covering in situations that require dressing protection from bacterial contamination / penetration, e.g. intravenous therapy catheter sites and full or partial thickness wounds.
2. On infected areas of the skin.
   WARNING: Barrier Film, in liquid form, is flammable; use in well ventilated area. Avoid using around flames and sources of ignition. Keep out of reach of children.

PRECAUTIONS:

1. Should redness or other signs of irritation appear, or if redness or signs of irritation persist, consult a physician.
2. Use of other barrier products, ointments, creams or lotions may significantly reduce its effectiveness.

DIRECTION FOR USE:

1. Skin should be clean and dry prior to application of Barrier Film.
2. Apply a uniform coating of film over entire area of concern.
3. If an area is missed, reapply to that area only after first application of Barrier Film (approximately 30 seconds).
4. If Barrier Film is applied to area with skin folds or other skin-to-skin contact, make sure that skin-contact areas are separated to allow the film to thoroughly dry before returning to normal position.
5. When used under adhesive tapes, dressings, or devices:
   (a) allow Barrier Film to thoroughly dry before covering with dressings or adhesive products.
   (b) reapplication of Barrier Film is necessary each time dressing and / or adhesive products are changed; the barrier film is removed by the adhesive.
6. When used as a protectant against body fluids, feces, or urine etc., and no adhesive products are applied to skin:
   (a) reapplication of Barrier Film is recommended every 24-72 hours, depending on frequency of cleansing.
   (b) in extreme cases (e.g. constant diarrheal stooling) with very frequent cleansing, more frequent applications MAY be necessary (i.e. every 12-24 hours).
7. If desired, the film can be removed by using most medical adhesives removers as directed. Clean and dry the involved area and reapply Barrier Film.

HOW SUPPLIED:

Individually packaged for single use only. Sterile unless package is damaged or open.

STORAGE INFORMATION:

For best results, this product should be stored at room temperature. For shelf life, refer to the expiration date on each package.

V.A.C.Via™ CANISTER INSTALLATION

The canister used with the V.A.C.Via™ Therapy Unit is a single-use, latex free, sterile, 250 cc / mL container with graduated markings of approximately 50 cc / mL increments.

NOTE: If the canister is not fully engaged, the V.A.C.Via™ Therapy Unit will alarm.

NOTE: Never reuse a canister.

1. Remove the canister from the sterile package.
2. Hold therapy unit and canister, vertically or horizontally, one in each hand, and slide bottom of canister into slot on bottom of therapy unit (Fig. 14 Step 1).
3. Close canister against therapy unit (Fig. 14 Step 2). The upper locking tab will click when canister is secured (Fig. 14 Step 3).

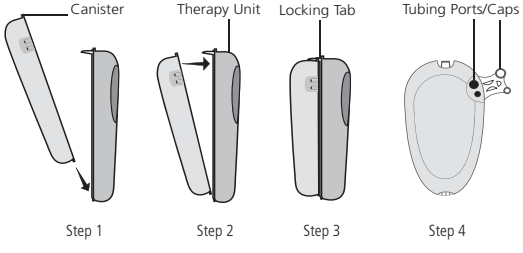


Fig. 14

4. Connect interface pad tubing to canister by aligning and plugging connector at end of tubing onto tubing ports on side of canister (Fig. 15). Push together firmly. Ensure clamp on tube is open. Position clamp away from patient.

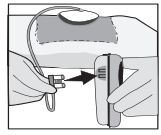


Fig. 15

BEGINNING THERAPY

WARNING: Review all **V.A.C.® Therapy System Safety Information**, located in the front of this guide, before initiating therapy.

1. Ensure the the V.A.C.Via™ Dressing has been applied as described in the **Dressing Application** section of this guide.
2. To begin therapy, press and hold center of the On / Off button for three seconds (Fig. 16). The V.A.C.Via™ Therapy Unit, while in operation, is virtually silent. All seven Therapy Life Indicators will illuminate with a green LED, indicating therapy is running.

   NOTE: On initial start up the green LED above the 125 mmHg selector button (default setting) or below the 75 mmHg selector button will flash until selected pressure is reached. When pressure is reached, LED will stop flashing and remain solid.

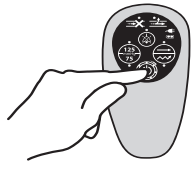


Fig. 16

   NOTE: To interrupt therapy or turn unit off, press and hold center of the On / Off button for three seconds.

   Once therapy is on for one continuous hour, the seven day lifespan begins and continues even if unit is turned off.

3. Select therapy pressure of **75 mmHg or 125 mmHg** (press and hold center for three seconds).
   - The green LED next to the button will indicate the selected pressure.
   - If a pressure setting is not selected, therapy unit will default to 125 mmHg.
4. Select Continuous or Dynamic Pressure Control™ (DPC) Therapy:
   - Continuous therapy (——►) maintains the selected therapy at a constant pressure.
   - Dynamic Pressure Control™ therapy (⌇⌇►) cycles the selected therapy as follows:
   - 75 mmHg - Pressure will cycle between 25 mmHg and 75 mmHg every three minutes.
   - 125 mmHg - Pressure will cycle between 25 mmHg and 125 mmHg every three minutes.
5. Assess dressing to ensure seal integrity. The dressing should be collapsed and should have a wrinkled appearance. There should be no hissing sounds.
6. If there is any evidence of non-integrity, check interface pad and the V.A.C.Via™ Dressing seals, tubing connectors, and canister connection, and ensure clamp is open.
7. If there is any evidence of a leak, refer to the **LEAKS** section of this guide.
8. Secure excess tubing to prevent interference with patient mobility (Fig 18).

   NOTE: If the wound is over a bony prominence or in areas where weight bearing may exert additional pressure or stress to the underlying tissues, a pressure-relief surface or device should be used to optimize patient offloading.

9. If desired, place the therapy unit into the carrying case (Fig. 17). Ensure display is visible through the opening in the carrying case.

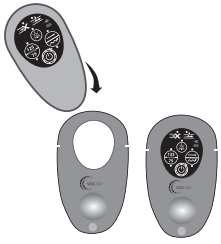


Fig. 17

10. The carrying case comes with both an adjustable strap and belt clip for carrying (Fig. 18). The belt clip and additional clips on each side and at the bottom of the carrying case provide a place where excess tubing may be wrapped and stored to help prevent / minimize tripping (Fig. 18).

    CAUTION: Do not wear strap around neck.

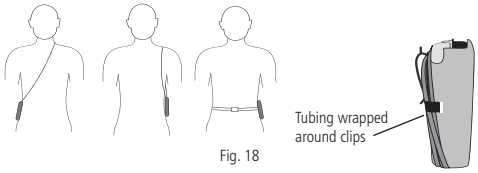


Fig. 18

DURATION OF THERAPY

Therapy Life Indicators

The therapy life indicators provide a visual indication of the seven day therapy life cycle and the therapy life remaining (Fig. 19). When therapy begins all seven green LEDs are illuminated. During therapy, after each 24-hour period an indicator will turn off. When eight hours of therapy time remains, the last indicator will illuminate with both a green and yellow LED simultaneously (**NOTE:** in Fig. 19 below, black represents green indicators and grey represents yellow indicators). When therapy time is about to expire, the last indicator will illuminate with a yellow LED and an alarm will sound for approximately two minutes, then the therapy unit will shut off.

At the end of therapy, the therapy unit must be replaced with a new therapy unit or alternative therapy must be used. Patients should be instructed to contact the treating physician or caregiver if therapy unit turns off and cannot be restarted before therapy is scheduled to end.

Begin Therapy | 4 Days Left | 2 Days Left | 1 Day Left | 8 Hours Left | Therapy Ended

Fig. 19

NOTE: Once therapy is on for one continuous hour, the seven day lifespan begins and continues even if unit is turned off.

WARNING: Never leave a V.A.C.® Dressing in place without active V.A.C.® 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 from an unopened sterile package and restart V.A.C.® Therapy; or apply an alternative dressing at the direction of the treating physician or caregiver.

DRESSING REMOVAL

NOTE: If dressing is lifted to observe wound, do not re-adhere the same dressing, a new dressing must be applied.

1. Turn therapy unit off by pressing and holding the On / Off button for three seconds.
2. Gently stretch the drape horizontally to release the adhesive from the skin.
3. Do not peel vertically. Gently remove the drape from the wound.
4. Clean any residual adhesive with alcohol swab.

If a new dressing is to be applied:

1. Ensure that area is clean, using an alcohol swab or antiseptic wipe.
2. Allow skin to completely dry before applying.
3. Follow Dressing Application instructions, page six.

CANISTER REMOVAL AND REPLACEMENT

1. Turn therapy off.
2. Slide dressing tubing clamp close to where tubing plugs into canister. Close clamp.
3. Unplug tubing from canister tubing ports.
4. Remove therapy unit from carrying case, if in use.
5. Depress tab on canister to remove used canister from therapy unit (Fig. 14).
6. Install new canister (see **Canister Installation** section in this guide).
7. Return therapy unit to carrying case if desired.
8. Reattach dressing tubing to canister tubing ports.
9. Release tubing clamp.
10. Turn therapy on.

NOTE: Dispose of used canister according to institution and local environmental regulations.

LEAKS

When the therapy unit detects a significant leak, a visual and audible leak alarm will activate (See **Alarms** section of this guide). When 125 mmHg is selected, the leak alarm will activate at pressures of 75 mmHg or less. When 75 mmHg is selected, the leak alarm will activate at pressures of 50 mmHg or less.

1. During a leak condition, a solid yellow LED above the leak symbol will turn on. The system will sound two beeps repeating every 15 seconds. The therapy unit will continue the alarm until condition is corrected.

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

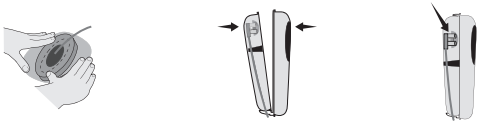
2. When leak condition has been corrected, audible alarms will stop, and visual alarms will turn off.

   NOTE: The green LED next to the therapy pressure selector button, 75 mmHg or 125 mmHg, will remain on while the therapy system cycles through the steps above.

   NOTE: When 75 mmHg is selected, the operating range is 50 mmHg to 75 mmHg. When 125 mmHg is selected, the operating range is 75 mmHg to 125 mmHg.

Correcting a Leak Condition:

1. With therapy on, slowly run hand and fingers around edge of dressing pressing down firmly to ensure good contact between adhesive and skin to verify a good seal (Fig. 20 A). If a leak source is identified, patch with additional V.A.C.® Advanced Drape to ensure seal integrity.
2. Ensure canister is securely locked onto the therapy unit. When canister is installed, a distinct click will be heard indicating it has been properly installed. (Fig. 20 B).
3. Check dressing tubing connector at canister (Fig. 20 C).



A B C

Fig. 20

4. When leak condition has been corrected, audible alarms will stop, and visual alarms will turn off.

   NOTE: Upon correcting a leak condition, a small delay will occur before the therapy unit senses the correction and silences the alarms.

ALARMS

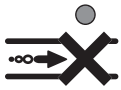
Audible Alarms - All audible alarms will sound two beeps, escalating and repeating every 15 seconds, which will increase in volume through four cycles. The fourth cycle will produce the loudest audible beep and will repeat until the alarm condition is corrected.

Alarm Mute Button - Press and hold center of the Alarm Mute Button for three seconds (Fig. 21) during an alarm condition to silence the audible alarm for two minutes. When pressed, the Alarm Mute Button will illuminate to indicate mute has been selected. The alarm will re-occur after two minutes unless the alarm condition has been corrected.

Alarm Mute Button
(**Press and hold center for three seconds**)

Fig. 21

The therapy unit will sound audible and display visual alarms as follows:



BLOCKAGE ALARM

- A solid yellow LED above the blockage symbol will turn on.
- Audible blockage alarm will sound two beeps repeating every 15 seconds.
- When the blockage condition is resolved, audible and visual alarms will turn off.

To Correct Alarm

Check for a full canister.

Check for kinked tubing.

Ensure tubing clamp is open.

LEAK ALARM

- A solid yellow LED above the leak symbol will turn on.
- Leak alarm will sound two beeps repeating every 15 seconds.
- When the leak condition is corrected, audible and visual alarms will turn off.

To Correct Alarm

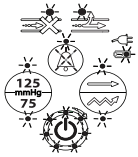
See **Leaks** section in this guide.

LOW BATTERY LEVEL ALARM

- A solid yellow LED on the battery level indicator will turn on.
- Alarm will sound two beeps repeating every four minutes
- A low battery alarm indicates approximately two hours of therapy remain; charge batteries IMMEDIATELY to prevent disruption of therapy.
- When battery is charged, audible and visual alarms will turn off.

To Correct Alarm

Charge battery; see **Battery Charging** section in this guide.



SYSTEM FAULT ALARM

- All LEDs will turn on and flash.
- Two beeps sound, repeating every 15 seconds.

To Correct Alarm

Power the therapy unit off and then on again. If alarm continues contact the treating physician or caregiver.

THERAPY ENDED

- A solid yellow LED at the top of the Therapy Life Indicator will turn on.
- The therapy unit will sound eight beeps, followed by a continuous beep for five seconds, then the therapy unit will turn off.
- Notify the treating physician or caregiver.

If the therapy unit has completed the seven day therapy and has timed out, and an attempt is made to turn the therapy unit on, the therapy unit will sound an alarm for three seconds then shut off.

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

BATTERY

The V.A.C.Via™ Therapy Unit is battery-operated to facilitate patient mobility.

The battery charge indicator on the user interface will display three levels of charge (Fig. 22).

- Full charge (approximately nine hours remain)
- Medium charge (approximately two - seven hours remaining)
- Low charge. When low charge is indicated approximately two hours of therapy remain. Charge unit immediately to avoid disruption of therapy. See charging instructions below.

Fig. 22

When the V.A.C.Via™ Therapy Unit is plugged into a power supply, the icon below turns yellow, indicating power is connected and system is charging. The icon will turn green when fully charged (Fig. 23).

Fig. 23

NOTE: Upon receipt, the V.A.C.Via™ Therapy Unit battery may not be fully charged.

Battery Charging

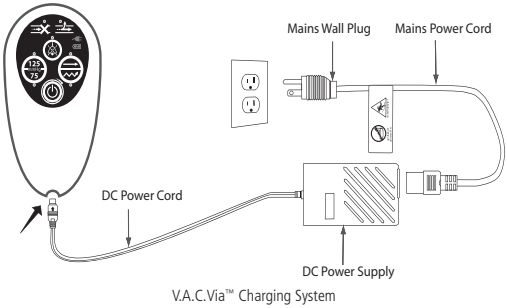
CAUTION: Use only the charging system provided with the V.A.C.Via™ Therapy Unit. Using any other charging system may damage the therapy unit.

CAUTION: Power cords may present a tripping hazard. Ensure that power cords are out of areas where people walk.

NOTE: Power cords may have different wall plug configurations depending on country requirements.

The rechargeable battery used in the V.A.C.Via™ Therapy Unit is not user accessible or replaceable.

1. Plug the mains power cord into a wall outlet.
2. Plug the other end of the mains power cord into the DC power supply.
3. Plug the DC power cord into the bottom of the therapy unit.
4. A fully discharged battery will recharge in approximately six hours.



V.A.C.Via™ Charging System

Fig. 24

IMPORTANT INFORMATION TO DISCUSS WITH PATIENTS

Review the V.A.C.Via™ Therapy Safety Information, including Considerations for Transitioning V.A.C. ® Therapy into Homecare (located at the front of this Guide) with your patient at time of initial placement.

The following information must be reviewed with the patient prior to patient discharge with the V.A.C.Via™ Therapy System. This information is summarized in the V.A.C.Via™ Quick Reference Guide which must be provided to the patient at discharge.

Instruct patient that If unable to correct an alarm condition, they should contact their treating physician or healthcare provider immediately. In case of an emergency the patient should be instructed to contact local emergency medical assistance.

DAILY USE

The V.A.C.Via™ Therapy Unit is portable and small enough that it may be worn beneath clothing during normal patient activities as approved by the treating physician.

Sleeping:

- Position the therapy unit so that tubing will not become kinked or pinched.
- Ensure therapy unit will not be pulled off a table or fall to the floor during sleep.
- It is recommended to keep therapy unit plugged in and charging while sleeping.

Showering and Bathing:

- Do not use the V.A.C.Via™ Therapy Unit while bathing / showering or where it can fall or be pulled into a tub, shower or sink.
- Do not reach for a product that has fallen into water. Unplug the unit immediately if plugged into an electrical source. Disconnect unit from dressing and contact treating Physician or Caregiver.
- The clear drape is waterproof; patient may wash or shower with dressing in place and the tube clamped and disconnected from the therapy unit.
- When towel drying, avoid disturbing or damaging the dressing.

Cleaning:

- The V.A.C.Via™ Therapy Unit and Carrying Case can be wiped as necessary with a damp cloth using a mild household cleaner.

DEVICE DISPOSAL

At the end of therapy, follow local institutional protocols for infection control and waste disposal procedures for dressings and canisters. Local protocols for the disposal of the V.A.C.Via™ Unit should be based on the applicable federal, state and / or local government environmental regulations for recycling electronic devices. For additional information from KCI refer to the Contact Information in the back of this guide.

Electromagnetic Compatibility:

Electromagnetic Interference - Although this equipment conforms with the intent of the directive 89 / 336 / EEC in relation to Electromagnetic Compatibility (EMC), all electrical equipment may produce interference. If interference is suspected, move equipment away from sensitive devices or contact the manufacturer.

The Essential Performance requirements of the Model 60300 are to maintain 125mmHg + / - 15 mmHg (30 second average) vacuum pressure with no false alarms.

Portable and mobile RF communications equipment can effect medical electrical equipment.

Radios, cell phones and similar devices may affect this equipment and should be kept at least 6.5 feet (2 meters) away from the equipment.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information in the following tables.

The following tables document compliance levels and guidance from the IEC 60601-1-2 2007 Standard, for the electromagnetic environment in which the V.A.C.Via™ Therapy Unit should be used in a clinical environment. The V.A.C.Via™ Therapy Unit also meets the intent of the draft guidance for Electromagnetic Compatibility related to use in the home care environment (IEC 60601-1-11 2007-11-30 draft).

The V.A.C.Via™ Therapy Unit was tested under model 60300 for EMC.

Guidance and manufacturer's declaration - electromagnetic emissions		
The V.A.C.Via™ Therapy Unit is intended for use in the electromagnetic environment specified below. The customer or user of the V.A.C.Via™ Therapy Unit should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment
RF emissions CISPR 11	Group 1	The V.A.C.Via™ Therapy Unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations / flicker emissions IEC 61000-3-3	complies	

The VACVIA™ is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration - electromagnetic immunity			
The V.A.C.Via™ Therapy Unit is intended for use in the electromagnetic environment specified below. The customer or user of the V.A.C.Via™ Therapy Unit should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV Contact ±8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% X* for .5 cycle < 40% X* for 5 cycle < 70% X* for 25 cycle < 5% X* for 5 seconds	< 5% X* for .5 cycle < 40% X* for 5 cycle < 70% X* for 25 cycle < 5% X* for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the V.A.C.Via™ Therapy Unit requires continued operation during power mains interruptions, it is recommended that the V.A.C.Via™ Therapy Unit be powered from an uninterruptible power supply or battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: X* is the a.c. mains voltage prior to application of the test level.			

Accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the medical electrical equipment as replacement parts for internal components, may result in increased emissions or decreased immunity of the medical equipment and model or part number.

The V.A.C.Via™ Therapy Unit should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the V.A.C.Via™ Therapy Unit should be observed to verify normal operation in the configuration in which it will be used.

Recommended separation distances between portable and mobile RF communications equipment and the V.A.C.Via™ Therapy Unit

The V.A.C.Via™ Therapy Unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of theV.A.C.Via™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the V.A.C.Via™ Therapy Unit as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
W	d=1.17 x sqrt (p)	d=1.17 x sqrt (p)	d=2.34 x sqrt (p)
0.01	0.1	0.1	0.2
0.1	0.4	0.4	0.7
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.4

For transmitters rated at a maximum output power not listed above, the recommended separate distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1, At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2, These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from surfaces, objects and people.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The V.A.C.Via™ Therapy Unit is intended for use in an electromagnetic environment specified below. The customer or user of the V.A.C.Via™ should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3Vrms 150K - 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the V.A.C.Via™ Therapy Unit, including cables, than the recommended separation distance calculated from the equation application to the frequency of the transmitter. **Recommended Separation Distance** d = (1.17) x sqrt(p) d = (1.17) x sqrt(p) 80 MHz to 800 MHz d = (2.34) x sqrt(p) 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 v/m 80 MHz - 2.5 GHz	3 V/m	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (see note a) should be less than the compliance level in each frequency range (see note b). Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1, At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2, These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To asses the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [ME EQUIPMENT OR ME SYSTEM] is used exceeds the applicable RF compliance level above, the V.A.C.Via™ Therapy Unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the V.A.C.Via™ Therapy Unit.
b) Over the frequency range 150kHz to 80 MHz,, field strengths should be less than 3 V/m.

SYMBOLS USED

CE 0473 — Conforms with the Medical Device Directive (93 / 42 / EEC) and has been subject to the conformity procedures laid down in the council directive

Do not use if package is damaged or open

ETL 3182664 — ETL Listed, Conforms to UL Std. 60601-1 certified to CAN / CSA C22.2 Std. No. 601.1.

Fragile

This product is designated for separate collection at an appropriate collection point. Do not dispose of as household waste.

Keep Dry

Class II Device

Date of Manufacture

Manufacturer

Use By

Latex Free

Type BF Applied Part

Single Use Only

Do not Resterilize

Non Sterile

STERILE R — Sterile using Radiation

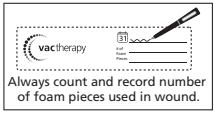
EC REP — Authorized Representative in the European Community

Consult Instructions for Use

Refer to Instruction Manual

REF Catalog Number

Each — Content Information



Always count and record number of foam pieces used in wound

Rx only Federal (US) law restricts this device to sale or rental by or on the order of a physician.

SPECIFICATIONS

Environmental Conditions:

Transport and Storage Conditions:

Temperature Range: -20.2º F (-29º C) to 140ºF (60º C)

Storage Humidity: 0-95%, non-condensing

Operating Conditions:

Temperature Range: 41º F (5º C) to 104º F (40º C)

Relative Humidity Range: 15 -95%, non-condensing

Altitude Range:

Optimum Performance: 0 to 8,000 ft (0 m to 2438 m)

Equipment not suitable for use in presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.

IP22 - Protection level against ingress of solid foreign objects and liquids.

MANUFACTURER INFORMATION

Manufactured for:
KCI USA, Inc.
San Antonio Texas, 78219

EC REP

KCI Medical Products (UK) Ltd.
Wimborne, Dorset, BH21 7SH
United Kingdom

CONTACT INFORMATION

For questions regarding this product, supplies, maintenance or additional information about KCI products and services, please contact KCI or a KCI authorized representative, or:

In the US, call 1-800-275-4524 or visit www.kci1.com or www.vacvia.com

Outside the US, visit www.kci-medical.com

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Rx only

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