

## **V.A.C.® THERAPY SAFETY INFORMATION**

Disposable components of the V.A.C.® Therapy System are provided as indicated on the associated product labeling. V.A.C.® Therapy Unit canisters are packaged sterile or fluid path sterile and are latex-free. All disposable components of the V.A.C.® Therapy System are for single use only. To help ensure safe and effective use, the V.A.C.® GranuFoam™ Dressing, V.A.C. GranuFoam Silver® Dressing and V.A.C.® WhiteFoam 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 treating physician.

### **Indications for Use**

The ActiV.A.C.®, InfoV.A.C.®, V.A.C. ATS® and V.A.C. Freedom® Therapy Systems are integrated wound management systems for use in acute, extended and home care settings. They are 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. They are indicated for patients with chronic, acute, traumatic, subacute and dehiscent wounds, partial thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts.

The V.A.C. GranuFoam Silver® Dressing is an effective barrier to bacterial penetration and may help reduce infection in the above wound types.

### **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.

- Sensitivity to silver (V.A.C. GranuFoam Silver® Dressing only)

## **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 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.® 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.® 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 or bio-engineered tissue may be

considered as an alternative, if deemed by the treating physician to provide a complete protective barrier. If using non-adherent materials, ensure they are secured in a manner that will 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). The patient should be closely monitored for bleeding in a care setting deemed appropriate by the treating physician.
- **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 covered or eliminated from the wound area, 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.

**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.

**Vascular Surgical Wounds of the Lower Extremities:** Regardless of treatment modality, wound complications from peripheral vascular surgery, especially those situated in the groin, are not uncommon, and have the potential for severe consequences, including significant blood loss from vessel rupture.

Groin wound infections can be increasingly difficult to treat because of the multiple comorbidities of patients undergoing vascular surgery and the wide array of resistant bacterial organisms in health care institutions. The skin in the groin is a major reservoir of bacteria. Surgical site infections are common in the groin area. Vascular graft infections are a serious concern and demand close attention because of the potential for complications. V.A.C.® Therapy can be used as an adjunct to the management of vascular groin infections and dehiscence, after surgical exploration, irrigation and debridement and targeted antibiotic therapy.

The patient should be closely monitored for bleeding in a care setting deemed appropriate by the treating physician.

Please refer to the V.A.C.® Therapy Clinical Guidelines for more information on managing Vascular Surgical Wounds of the Lower Extremities.

**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 instillation therapy parameters (for the V.A.C. Instill® Therapy System). Refer to dressing application instructions (found in V.A.C.® 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 the treating 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**.

**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.

**Osteomyelitis:** V.A.C.® 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 intact bone with a single layer of non-adherent material.

**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. Document the foam quantity and dressing change date on the drape or Foam Quantity Label if available, and in the patient's chart.

**V.A.C.® Foam Dressings are radiolucent, not detectable on X-Ray.**

**Foam Removal:** V.A.C.® 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 are removed as were 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 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. Regardless of treatment modality, disruption of the new granulation tissue during any dressing change may result in bleeding at the wound site. Minor bleeding may be observed and considered expected. However, patients with increased risk of bleeding, as described on pg. 4, have a potential for more serious bleeding from the wound site. As a precautionary step, consider using V.A.C.® WhiteFoam or wide-mesh non-adherent material underneath the V.A.C.® GranuFoam™ Dressing to help minimize the potential for bleeding at dressing removal in these patients. 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 physician.

**Acrylic Adhesive:** The V.A.C.® 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) - V.A.C.® Therapy Unit:** The V.A.C.® Therapy Unit is MR unsafe. Do not take the V.A.C.® Therapy 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** section).

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
- 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.® Therapy Unit into a hyperbaric oxygen chamber. The V.A.C.® Therapy Unit is 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 and completely cover the V.A.C.® Dressing (including tubing) with a moist towel throughout the treatment in the chamber.

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 (refer to **Keep V.A.C.® Therapy On** section).

**NOTE:** *The V.A.C.® GranuFoam™ Bridge Dressing contains additional synthetic materials which may pose a risk during HBO Therapy.*

### **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 Intermittent V.A.C.® Therapy:** Continuous rather than intermittent 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 these patients 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. 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 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.® Drape, hydrocolloid or other transparent film.

- Multiple layers of V.A.C.® 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.® 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 treating physician.

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



