V.A.C.® THERAPY SYSTEM SAFETY INFORMATION AND V.A.C.® GRANUFOAM™ BRIDGE DRESSING AND V.A.C.® GRANUFOAM™ BRIDGE XG DRESSING APPLICATION INSTRUCTIONS

ONLY FOR USE WITH KCI V.A.C.® THERAPY SYSTEMS

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.

Refer to the V.A.C.® Therapy Clinical Guidelines available at www.kci1.com or contact your local KCI Representative for a printed copy.

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 dehisced 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 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.® 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 and treatment goals. 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 page 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. Refer to the 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 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.

ADDITIONAL PRECAUTIONS FOR V.A.C. GRANUFOAM SILVER® DRESSING

Topical Solutions or Agents: When using the V.A.C. GranuFoam Silver® Dressing, do not use topical solutions or agents that may have adverse interactions with silver. For example, saline solutions may compromise the effectiveness of the V.A.C. GranuFoam Silver® Dressing.

Protective Layer: For maximum effectiveness, the V.A.C. GranuFoam Silver® Dressing should be applied directly to the wound surface to enhance optimal contact of the tissue with the foam / silver interface. However, as with all V.A.C.® Foam Dressings, the V.A.C. GranuFoam Silver® Dressing should not be placed in direct contact with exposed blood vessels, anastomotic sites, organs or nerves (refer to section on **Protect Vessels and Organs**). Intervening non-adherent layers may be placed between the V.A.C. GranuFoam Silver® Dressing and the wound surface; however, these products may compromise the effectiveness of the V.A.C. GranuFoam Silver® Dressing in the area covered by the non-adherent layer.

Electrodes or Conductive Gel: Do not allow the V.A.C. GranuFoam Silver® Dressing to come in contact with EKG or other electrodes or conductive gels during electronic monitoring or when taking electronic measurements.

Diagnostic Imaging: The V.A.C. GranuFoam Silver® Dressing contains metallic silver that may impair visualization with certain imaging modalities.

Dressing Components: The V.A.C. GranuFoam Silver® Dressing contains elemental silver (10%) as a sustained release formulation. Application of products containing silver may cause temporary tissue discoloration.

In addition to these general warnings and precautions for V.A.C.® Therapy, 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 and labeling prior to application.

CONSIDERATIONS FOR TRANSITIONING V.A.C.® THERAPY INTO HOME CARE

WARNING: Patients with 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.

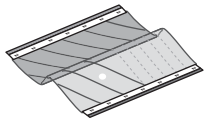
- **The Patient's Situation:**
  - Clinical condition (adequate hemostasis and a low risk of active and / or large amounts of bleeding at the wound site)
  - Home environment (patient or family member / caregiver able to read and understand safety labeling, able to respond to alarms, able to follow instructions 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).
- **The V.A.C.® Therapy System Canister Size:**
  - The 1000 mL canister is **NOT** intended for use in the home.
- **Labeling:**
  - The prescribing physician and health care clinician should be familiar with the V.A.C.® Therapy instructional materials that accompany the therapy unit and dressing cartons into the home.
  - An information folder is provided with the therapy unit. The prescribing physician and / or healthcare clinician should carefully review these materials with the patient and patient's caregiver.
  - KCI offers in-service and training programs for use of V.A.C.® Therapy. Contact your local KCI representative. In the US, call 1-800-275-4524 for scheduling.

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.kci1.com or www.kci-medical.com.

V.A.C.® GRANUFOAM™ BRIDGE DRESSING AND V.A.C.® GRANUFOAM™ BRIDGE XG APPLICATION INSTRUCTIONS

V.A.C.® GRANUFOAM™ BRIDGE DRESSING DISPOSABLE COMPONENT IDENTIFICATION

V.A.C.® GranuFoam™ Bridge
with pre-attached SensaT.R.A.C.™ Pad



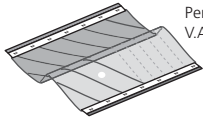
Perforated
V.A.C.® Drape

Pre-Cut
V.A.C.® GranuFoam™
Dressing

V.A.C.® Ruler
with two Foam
Quantity Labels

V.A.C.® GRANUFOAM™ BRIDGE XG DRESSING DISPOSABLE COMPONENT IDENTIFICATION

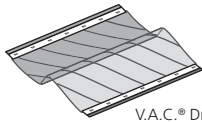
V.A.C.® GranuFoam™ Bridge
with pre-attached SensaT.R.A.C.™ Pad



Perforated
V.A.C.® Drape

V.A.C.® GranuFoam™
Spiral Dressing - Medium
(Quantity - 2)

V.A.C.® Ruler
with two Foam
Quantity Labels



V.A.C.® Drape

Disposable components of the V.A.C.® Therapy System including the foam dressing (V.A.C.® GranuFoam™ Dressing, V.A.C. GranuFoam Silver® Dressing, 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. 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.

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

Always consult a physician and review and follow V.A.C.® Therapy Safety Information, V.A.C.® Therapy Unit instructions and appropriate sections of the V.A.C.® Therapy Clinical Guidelines prior to use.

PRODUCT DESCRIPTION

The V.A.C.® GranuFoam™ Bridge / V.A.C.® GranuFoam™ Bridge XG Dressing is a component of the V.A.C.® Therapy System and provides for the application of negative pressure wound therapy to those wounds, which because of their anatomical location, require that the SensaT.R.A.C.™ Pad be placed at a remote location, such as with sacral wounds or wounds on the foot.

The V.A.C.® GranuFoam™ Bridge / V.A.C.® GranuFoam™ Bridge XG Dressing is not recommended for use with hydrocolloids due to increased risk of occluding the bridge component and causing a decrease in negative pressure at the wound site.

DRESSING CHANGES

Wounds being treated with the V.A.C.® Therapy System should be monitored on a regular basis. In a monitored, non-infected wound, V.A.C.® 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. Refer to the V.A.C.® Therapy Clinical Guidelines for more detail.

Refer to the V.A.C.® Therapy Clinical Guidelines available at www.kci1.com or contact your local KCI Representative for a printed copy.

VERTICAL BRIDGE PLACEMENT ON MODERATELY TO HIGHLY EXUDATING WOUNDS

PRECAUTION: When the V.A.C.® GranuFoam™ Bridge / V.A.C.® GranuFoam™ Bridge XG Dressing is applied vertically on moderately to highly exudating wounds, there is a potential for a decrease in negative pressure at the wound site (up to 50 mmHg). In order to provide adequate therapy and minimize the risk of maceration, do not use a prescribed negative pressure setting below 125 mmHg.

WOUND PREPARATION

WARNING: Review all V.A.C.® Therapy System Safety Information 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.

V.A.C.® DRESSING REMOVAL

2. Gently remove an existing V.A.C.® Dressing according to the following procedure:
   a. Raise the tubing connectors above the level of the therapy unit.
   b. Close clamp on the dressing tubing.
   c. Disconnect canister tubing from dressing tubing.
   d. Allow the therapy unit to pull the exudate in the canister tube into the canister, then close the clamp on the canister tubing.
   e. Press THERAPY ON / OFF to deactivate the V.A.C.® Therapy Unit. Wait 15 - 30 seconds to allow foam to decompress.

f. To remove the drape from the skin, gently stretch the drape horizontally to release adhesive from the skin. Do not peel vertically.

g. Gently remove foam from the wound.

WARNING: Refer to Foam Removal section under Warnings.

h. Discard disposables according to institutional or state regulations.

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 placement of the V.A.C.® Foam Dressing to potentially reduce future adherence, or consider more frequent dressing changes. For V.A.C. GranuFoam Silver® Dressing, refer to* ***Additional Precautions for V.A.C. GranuFoam Silver® Dressing****,* ***Protective Layer*** *section for more information.*

If the patient complains of discomfort during the dressing change*, consider premedication, the use of a non-adherent interposed layer before foam placement, using V.A.C.® WhiteFoam to dress the wound, or managing the discomfort as prescribed by the treating physician. Refer to the* ***Pain Management*** *section of the V.A.C.® Therapy Clinical Guidelines for specific recommendations.*

3. Debride all necrotic, non-viable tissue, including bone, eschar or hardened slough, as prescribed by physician.

4. Perform thorough wound and periwound area cleaning per physician order or institution protocol prior to each dressing application.

5. Ensure adequate hemostasis has been achieved (refer to **Warnings**, **Bleeding** section, **Hemostasis, Anticoagulants and Platelet Aggregation Inhibitors**).

6. Prior to foam placement, protect vessels and organs (refer to **Warnings**, **Bleeding** section, **Protect Vessels and Organs**).

7. Sharp edges or bone fragments must be eliminated from wound area or covered (refer to **Warnings**, **Bleeding** section, **Sharp Edges**).

8. Clean and dry periwound skin.

9. 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 or other transparent film.

V.A.C.® GRANUFOAM™ DRESSING APPLICATION

Perforated V.A.C.® Drape - Preparation

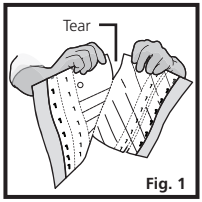


Fig. 1

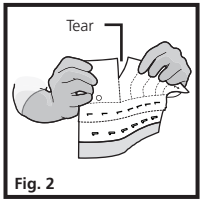


Fig. 2

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

1. Carefully tear the Perforated V.A.C.® Drape in half along perforation (**Fig. 1**).
2. Carefully tear off the Perforated V.A.C.® Drape section with pre-cut hole (**Fig. 2**).

Assess Wound Size

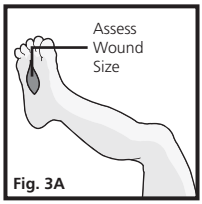


Fig. 3A

Fig. 3B

3. Assess wound dimensions and pathology, including the presence of undermining or tunnels (**Fig 3A** and **Fig. 3B**). Do not place any foam dressing into blind / unexplored tunnels. V.A.C.® GranuFoam™ Dressings may be used for wounds with shallow undermining or tunnel areas where the distal aspect is visible. For deeper or more extensive undermining or tunneling, where full visualization is not possible, V.A.C.® WhiteFoam can be used.

   NOTE: *If adjunct materials are utilized under the V.A.C.® GranuFoam™ Bridge / V.A.C.® GranuFoam™ Bridge XG Dressing, they must be meshed or fenestrated to allow for effective exudate removal. Document on the drape or Foam Quantity Label if available, and in the patient's chart to ensure removal with subsequent dressing changes.*

Pre-cut V.A.C.® GranuFoam Dressing Application - V.A.C.® GranuFoam™ Bridge Dressing


Fig. 4

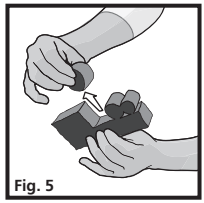


Fig. 5

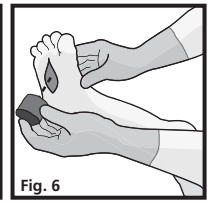


Fig. 6

4. Select an appropriately sized Pre-cut V.A.C.® GranuFoam™ Dressing and tear away from foam block (**Fig. 4**, **Fig. 5**).

   NOTE: *Pre-cut V.A.C.® GranuFoam™ Dressing may be further trimmed as necessary.*

   CAUTION: *Do not tear or trim the foam over the wound, as fragments may fall into the wound. Away from wound site, rub foam edges to remove any fragments or loose particles that may fall into or be left in the wound upon dressing removal.*

5. Gently place foam into wound cavity, ensuring contact with all wound surfaces (**Fig. 6**). Do not force the Pre-Cut V.A.C.® GranuFoam™ Dressing into any area of the wound.

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

   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.® Drape.*

V.A.C.® GranuFoam™ Spiral Dressing Application -
V.A.C.® GranuFoam™ Bridge XG Dressing

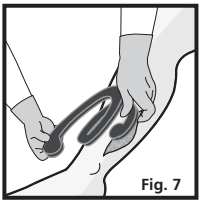


Fig. 7

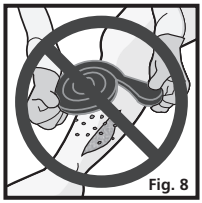


Fig. 8

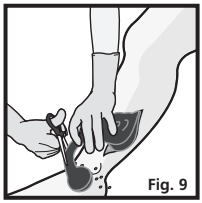


Fig. 9

6. Carefully tear the V.A.C.® GranuFoam™ Spiral Dressing along the perforation to a size that will allow the foam to be placed gently into the wound without overlapping onto intact skin (**Fig. 7**).

   NOTE: *V.A.C.® GranuFoam™ Spiral Dressing may be further trimmed as necessary.*

   CAUTION: ***Do not cut or tear the foam over the wound, as fragments may fall into the wound (Fig. 8). Away from wound site, rub foam edges to remove any fragments or loose particles that may fall into or be left in the wound upon dressing removal.***

7. Gently place foam into wound cavity, ensuring contact with all wound surfaces (**Fig. 9**). Do not force the V.A.C.® GranuFoam™ Spiral 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: *Superficial or retention sutures should be covered with a single layer of non-adherent material placed between the sutures and the V.A.C.® Drape.*

Foam Quantity Label Application

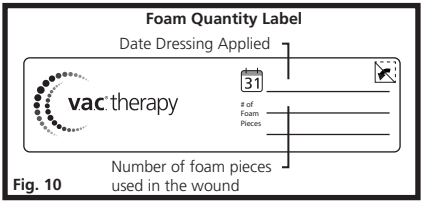


Fig. 10

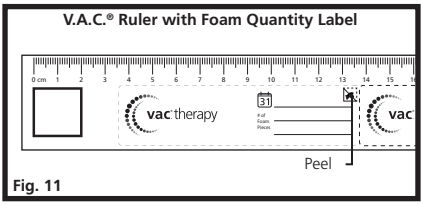
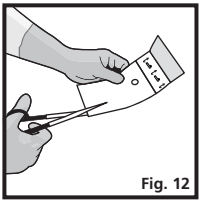
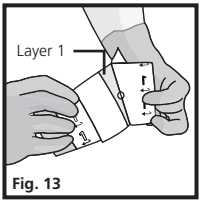


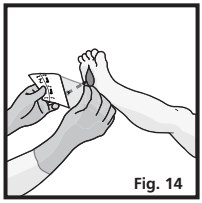
Fig. 11

8. Note the total number of pieces of foam used in the wound and document on the supplied Foam Quantity Label on the V.A.C.® Ruler (**Fig. 10**) and in the patient's chart. The Foam Quantity Label can be peeled off the V.A.C.® Ruler (**Fig. 11**) and should be placed in an area that can be seen by the next treating clinician (placed around the SensaT.R.A.C.™ tubing, on the V.A.C.® Drape, in the patient's chart, etc.).

PERFORATED V.A.C.® DRAPE APPLICATION







CAUTION: *Patient's skin condition should be carefully monitored (refer to* **Precautions**, **Protect Periwound Skin** *section).*

1. Trim as necessary (**Fig. 12**) and place the Perforated V.A.C.® Drape with pre-cut hole to cover the Pre-Cut V.A.C.® GranuFoam™ Dressing and an additional 3 - 5 cm border of intact periwound tissue. Additional Perforated V.A.C. ® Drape may be used to seal difficult areas, if needed.
2. Carefully remove Layer 1 to expose adhesive (**Fig. 13**). The Perforated V.A.C.® Drape may be held by the Blue Handling Bar.
3. Place the adhesive face down with pre-cut hole centered over foam and apply additional Perforated V.A.C.® Drape to cover foam and intact skin, ensuring drape covers at least a 3 - 5 cm border of intact periwound tissue (**Fig. 14**, V.A.C.® GranuFoam™ Bridge Dressing Application shown).
4. Remove second Layer 1 and Layer 2 and pat drape to ensure an occlusive seal.
5. Remove Blue Handling Bar.

V.A.C.® GRANUFOAM™ BRIDGE APPLICATION

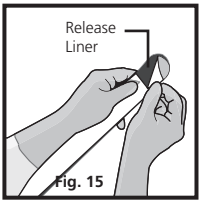


Fig. 15

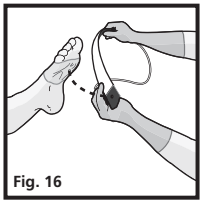


Fig. 16

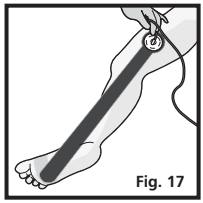


Fig. 17

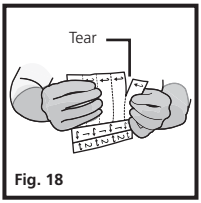


Fig. 18

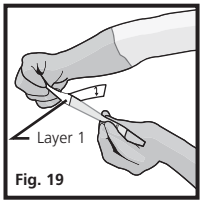


Fig. 19

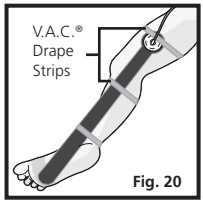


Fig. 20

1. Remove the release liner from the V.A.C.® GranuFoam™ Bridge (**Fig. 15**).
2. Align the pre-cut hole on the underside of the V.A.C.® GranuFoam™ Bridge with the pre-cut hole on the Perforated V.A.C.® Drape at the wound site (**Fig. 16**). Apply firm even pressure to adhesive end of V.A.C.® GranuFoam™ Bridge Dressing to ensure proper adhesion to wound site.
3. Route the V.A.C.® GranuFoam™ Bridge to a location away from bony prominences that will minimize pressure or stress to underlying tissue. Minimize wrinkles and creases when applying the V.A.C.® GranuFoam™ Bridge Dressing.

   NOTE: *If V.A.C.® GranuFoam™ Bridge / V.A.C.® GranuFoam™ Bridge XG Dressing is applied on the foot, route the bridge through the instep and up the leg (**Fig. 17**).*
4. Secure the V.A.C.® GranuFoam™ Bridge to the patient's skin.
   a. Carefully tear Perforated V.A.C.® Drape strips along perforations (**Fig. 18**).
   b. Pull back Layer 1 to expose adhesive (**Fig. 19**).
   c. Secure V.A.C.® GranuFoam™ Bridge (**Fig. 20**).

      NOTE: *Secure the bridge to ensure that range of motion of the foot is not limited.*
   d. Remove second Layer 1.
   e. Remove Layer 2 and pat drape to ensure an occlusive seal.
5. Remove Blue Handling Bar.
6. Repeat Step 4 as necessary to fully secure V.A.C.® GranuFoam™ Bridge to patient.

   NOTE: *Secure the V.A.C.® GranuFoam™ Bridge / V.A.C.® GranuFoam™ Bridge XG Dressing with additional V.A.C.® Drape strips (as required) to avoid migration of the bridge dressing and to minimize additional pressure points.*

V.A.C.® GRANUFOAM™ BRIDGE APPLICATION USING A Z FOLD

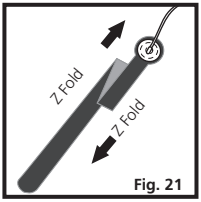


Fig. 21

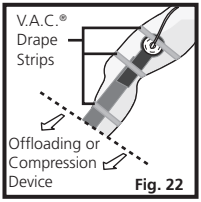


Fig. 22

If adjustment to the length of V.A.C.® GranuFoam™ Bridge is desired, a Z fold may be used.

1. Refer to the **V.A.C.® GranuFoam™ Bridge Application** section and apply as directed.

2. Fold V.A.C.® GranuFoam™ Bridge as shown in **Fig. 21** and secure to patient with additional V.A.C.® Drape strips (**Fig. 22**). Ensure the Z fold segment is outside the off-loading device or compression product (**Fig. 22**).

V.A.C.® THERAPY APPLICATION

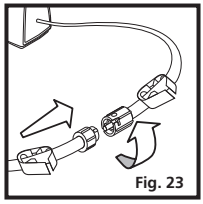


Fig. 23

WARNING: Review all V.A.C.® Therapy System Safety Information before initiating V.A.C.® Therapy.

1. Remove V.A.C.® Canister from packaging and insert into the V.A.C.® Therapy Unit until it locks into place.

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

2. Connect SensaT.R.A.C.™ Pad tubing to canister tubing and ensure clamp on each tube is open (**Fig. 23**). Position clamps away from patient.

3. Turn on power to the V.A.C.® Therapy Unit and select the prescribed therapy setting.

   PRECAUTION: When the V.A.C.® GranuFoam™ Bridge / V.A.C.® GranuFoam™ Bridge XG Dressing is applied vertically on moderately to highly exudating wounds, there is a potential for a decrease in negative pressure at the wound site (up to 50 mmHg). In order to provide adequate therapy and minimize the risk of maceration, do not use a prescribed negative pressure setting below 125 mmHg.

4. Initiate V.A.C.® Therapy. Assess dressing to ensure seal integrity. The dressing should be collapsed. The dressing should have a wrinkled appearance. There should be no hissing sounds. For ActiV.A.C.® and InfoV.A.C.® Therapy Systems use the SealCheck™ screen to verify that the rate of air leakage is below the alarm threshold. If there is any evidence of non-integrity, check SensaT.R.A.C.™ Pad and drape seals, tubing connections, canister insertion, and ensure clamps are open.

5. Secure excess tubing to prevent interference with patient mobility.

   NOTE: *Refer to unit specific user guide or manual and / or quick reference guide for information regarding alarms.*

   NOTE: *If a leak source is identified, patch with additional drape to ensure seal integrity.*

   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 redistribution (pressure relief) surface or device should be used to optimize patient offloading.*

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 such as wet to moist gauze, as approved during times of extreme need by treating clinician.

USE OF V.A.C.® GRANUFOAM™ BRIDGE / V.A.C.® GRANUFOAM™ BRIDGE XG DRESSING WITH OFFLOADING MODALITIES AND COMPRESSION DEVICES

If the patient will be concomitantly utilizing an offloading device with V.A.C.® Therapy, it must be used in accordance with clinician orders and manufacturer's instructions for use

- Allows combination of V.A.C.® Therapy with offloading or compression device.
- Allows the patient to ambulate and resume normal daily activities.

OFF-LOADING DEVICE APPLICATION

Apply off-loading device according to the manufacturer's instructions (**Fig. 24**).

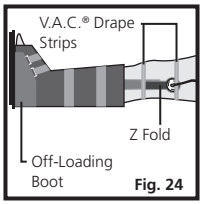


Fig. 24

NOTE: *Ensure the SensaT.R.A.C.™ Pad portion of the V.A.C.® GranuFoam™ Bridge is outside the off-loading device.*

NOTE: *If used, ensure the Z fold segment is outside the off-loading device or compression product.*

COMPRESSION PRODUCT APPLICATION

Apply compression product according to the manufacturer's instructions (**Fig. 25**).

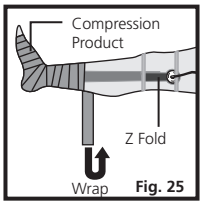


Fig. 25

If the wound is a Venous Insufficiency Ulcer, ensure the entire ulcer is covered by the compression product.

NOTE: *Ensure the SensaT.R.A.C.™ portion of the V.A.C.® GranuFoam™ Bridge is outside the compression product.*

NOTE: *If used, ensure the Z fold segment is outside the off-loading or compression product.*

GARMENT REMOVAL

Throughout the course of V.A.C.® Therapy, care should be taken when removing any garment in order to avoid removal of the V.A.C.® Drape or other components of the V.A.C.® GranuFoam™ Bridge / V.A.C.® GranuFoam™ Bridge XG Dressing.

EXPLANATION OF SYMBOLS USED

STERILE R — Method of Sterilization - Radiation

STERILE R — Fluid Path Sterile by Radiation

Do not use if package is damaged or open

Latex — Latex Free

Single Use Only

STERILIZE — Do Not Resterilize

Do Not Resterilize

Consult Instructions For Use

Rx Only — **CAUTION:** Federal (US) law restricts this device to sale / rental by or on the order of a physician

PHT DEHP — Contains PHTHALATES (T.R.A.C.™ / SensaT.R.A.C. Pad Tubing)

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

Keep Dry

Use By

Date of Manufacture

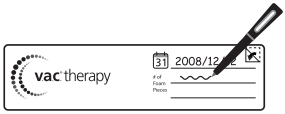
LOT — Lot Number

Manufacturer

EC REP — Authorized Representative in the European Community

n Each — Content Information

REF — Catalog Number



Always count and record number of foam pieces used in wound.

≥ 125 mmHg

CAUTION: For vertical bridge placement on moderately to highly exudating wounds, the V.A.C.® GranuFoam™ Bridge / V.A.C.® GranuFoam™ Bridge XG Dressing should not be used for prescribed pressure settings below 125 mmHg.

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Rx Only