CLINICAL GUIDE

Genadyne A4
&
Genadyne A4 – XLR8
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**Indications for use**

The Genadyne A4-XLR8 Wound Vacuum System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.

**Contraindications**

- Do not place dressing directly in contact with:-
  - Exposed blood vessels
  - Anastomotic sites
  - Organs
  - Nerves

*NOTE: Refer to Warnings section for additional information concerning Bleeding.*

- Genadyne A4-XLR8 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, Genadyne A4-XLR8 Therapy may be used.*
Warnings

DO NOT OPERATE THIS EQUIPMENT WITHOUT FIRST READING AND UNDERSTANDING THIS MANUAL. IF YOU ARE UNABLE TO UNDERSTAND THE WARNINGS, CAUTIONS AND INSTRUCTIONS, CONTACT A HEALTHCARE PROFESSIONAL, DEALER OR TECHNICAL PERSONNEL IF APPLICABLE BEFORE ATTEMPTING TO USE THIS EQUIPMENT. OTHERWISE INJURY OR DAMAGE MAY RESULT.

Bleeding

With or without using Genadyne A4-XLR8 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 anastamosis 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 Genadyne A4-XLR8 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 Genadyne A4-XLR8 Therapy, or if frank (bright red) blood is seen in the tubing or in the canister, immediately stop Genadyne A4-XLR8 Therapy, leave dressing in place, take measures to stop the bleeding, and seek immediate medical assistance. The Genadyne A4-XLR8 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 Genadyne A4-XLR8 Therapy.

Always ensure that A4-XLR8 wound filler dressing 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 bioengineered 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 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 Genadyne A4-XLR8 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 Genadyne A4-XLR8 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.

**1000mL Canister Size:**

DO NOT USE the 1000mL canister on patients with a high risk of bleeding or on patients unable to tolerate a large loss of fluid volume, including children and the elderly. Consider the size and weight of the patient, patient condition, wound type, monitoring capability and care setting when using this canister. This canister is recommended for acute care (hospital) use only.

**Infected Wounds**

Infected wounds should be monitored closely and may require more frequent dressing changes than non-infected wounds, dependent upon factors such as wound condition and treatment goals. Dressing change frequency will be determined by the physician who prescribed the therapy to the patient. 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 Genadyne A4-XLR8 Therapy should be discontinued. For wound infections relating to blood vessels, please also refer to the section titled Infected Blood Vessels.

**Infected Wounds with Genadyne A4-XLR8 Antimicrobial Wound filler Dressing**

In the event of clinical infection, Genadyne A4-XLR8 Antimicrobial Wound filler dressing is not intended to replace the use of systemic therapy or other infection treatment regimens. Genadyne A4-XLR8 Antimicrobial Wound filler dressing may be used on infected wounds as an adjunct to the standard treatment regimen and to provide a barrier to bacterial penetration.

**Osteomyelitis**

The Genadyne A4-XLR8 System should NOT be initiated on a wound with untreated osteomyelitis. Consideration should be given to thorough debridement of all necrotic, nonviable 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 Genadyne A4-XLR8 wound filler dressing. These structures may be covered with natural tissue, meshed non-adherent material, or bioengineered tissue to help minimize risk of desiccation or injury.

**Wound filler Placement**

Always use Genadyne A4-XLR8 Wound filler Dressing from sterile packages that have not been opened or damaged. Do not place any wound filler dressing into blind/unexplored tunnels. Do not force wound filler dressings into any area of the wound, as this may damage tissue, alter the delivery of negative pressure, or hinder exudate and wound filler removal. **Always count the total number of pieces of wound filler used in the wound and document that number on the drape and in the patient’s chart. Also document the dressing change date on the drape.**

**Wound filler Removal**

Genadyne A4-XLR8 wound filler dressings are not bio absorbable. **Always count the total number of pieces of wound filler removed from the wound and ensure the same number of wound filler pieces was removed as placed.** Wound filler left in the wound for greater than the recommended time period may foster in growth of tissue into the wound filler, create difficulty in removing wound filler from the wound, or lead to infection or other adverse events. If significant bleeding develops, immediately discontinue the use of the Genadyne A4-XLR8 Therapy System, take measures to stop the bleeding, and do not remove the wound filler dressing until the treating physician or surgeon is consulted. Do not resume the use of the Genadyne A4-XLR8 Therapy System until adequate hemostasis has been achieved, and the patient is not at risk for continued bleeding.
Keep Genadyne A4-XLR8 Therapy On

Never leave an A4-XLR8 Dressing in place without active Genadyne A4-XLR8 Therapy for more than 2 hours (for foam dressing) or more than 12 hours (for Anti-microbial super sponge). If therapy is off for more than the allowable hours based on dressing type, remove the old dressing and irrigate the wound. Either apply a new A4-XLR8 Dressing from an unopened sterile package and restart Genadyne A4-XLR8 Therapy; or apply an alternative dressing at the direction of the treating clinician.

Defibrillation

Remove the wound filler 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 Genadyne A4-XLR8 Therapy Unit is MR Unsafe. Do not take the A4-XLR8 Therapy Unit into the MR environment.

Magnetic Resonance Imaging (MRI)—Wound filler Dressings

Wound filler Dressings can typically remain on the patient with minimal risk in an MR environment, assuming that use of the Genadyne A4-XLR8 Therapy System is not interrupted for more than 2 hours (refer to Keep Genadyne A4-XLR8 Therapy On). The wound filler 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 3W/kg for 15minutes 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 wound filler dressing.

Hyperbaric Oxygen Therapy (HBO)

Do not take the Genadyne A4-XLR8 Therapy Unit into a hyperbaric oxygen chamber. The Genadyne A4-XLR8 Therapy Unit is not designed for this environment, and should be considered a fire hazard. After disconnecting the Genadyne A4-XLR8 Therapy Unit, either

1. replace the wound filler dressing with another HBO compatible material during the hyperbaric treatment, or
2. cover the unclamped end of the negative pressure wound therapy tubing with moist cotton wound filler and completely cover the wound filler dressing (including tubing) with a moist towel throughout the treatment in the chamber. For HBO therapy, the negative pressure wound therapy tubing must not be clamped. Never leave wound filler dressing in place without active Genadyne A4-XLR8 Therapy for more than 2 hours; please refer to the Keep Genadyne A4-XLR8 Therapy On.
Precautions

Precautions should be taken for patients who are or may be: receiving anticoagulant therapy, suffering from difficult hemostasis, untreated for malnutrition and non-complaint or combative.

Standard Precautions

To reduce the risk of transmission of blood borne 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 fluid is likely.

Continuous versus Intermittent Therapy

Continuous, rather than intermittent, Genadyne A4-XLR8 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 Genadyne A4-XLR8 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 may 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 hyperreflexia (sudden elevation in blood pressure or heart rate in response to stimulation of the sympathetic nervous system), discontinue Genadyne A4-XLR8 Therapy to help minimize sensory stimulation and seek immediate medical assistance.

Bradycardia

To minimize the risk of bradycardia, the Genadyne A4-XLR8 Therapy dressing must not be placed in proximity to the vagus nerve.

Enteric Fistulas

Wounds with enteric fistulas require special precautions to optimize Genadyne A4-XLR8 Therapy. In certain circumstances, the Genadyne A4-XLR8 Therapy may help to promote healing in wounds with an enteric fistula. When the physician orders the Genadyne A4-XLR8 Therapy, it is recommended that
support from an expert clinician is sought. Genadyne A4-XLR8 Therapy is not recommended or designed for fistula effluent management or containment, but as an aid to wound healing. Genadyne A4-XLR8 Therapy is not recommended if enteric fistula effluent management or containment is the sole goal of this therapy.

Protect Periwound Skin

Consider use of a skin preparation product to protect periwound skin. Do not allow wound filler to overlap onto intact skin. Protect fragile/friable periwound skin with additional hydrocolloid or other transparent film.

- Multiple layers of the transparent film dressing may decrease the moisture vapor transmission rate, which may increase the risk of maceration.
- If any signs of irritation or sensitivity to the film dressing, wound filler or tubing assembly appear, discontinue use and consult a physician.
- To avoid trauma to the periwound skin, do not pull or stretch the transparent film over the wound filler dressing during film 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 film technique may be necessary to establish and maintain a seal. Consider using multiple small pieces of transparent film rather than one continuous piece to minimize the risk of decreased distal circulation. Extreme care should be taken not to stretch or pull the film when securing it, but let it attach loosely and stabilize edges with an elastic wrap if necessary. When using circumferential film techniques, 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.
**Contact info**

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