MasVidaHealth™ CARE SOLUTIONS

GENADYNE

Clinical Guidelines

XLR8/XLR8 Plus

110122

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1. INTRODUCTION

The Genadyne XLR8/XLR Plus is an advanced wound healing therapy that can be readily integrated into the clinician's wound healing practice to optimize patient care. The XLR8/XLR8 Plus is suitable for use in acute, long-term care, and home settings.

The XLR8 NPWT system is for use in patients who would benefit from Negative Pressure Wound Therapy (NPWT) particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, pressure ulcers, diabetic ulcers and venous ulcers, flaps and grafts.

There are five alert settings within the XLR8/ XLR8 Plus: leakage (target timeout), blockage, a canister full, low battery, and critical battery. Each of these alarms can be disabled at any time as determined by the caregiver. In addition, the leakage (Target time out) can be adjusted. For example, if the target time out is set at 60 30 seconds, this means that in the event of leakage it will have to last for at least 60 seconds continuously before the system starts alarming. This avoids false alarms due to dressing shifts as a result of patient movement.

Points to remember:

1. Follow standard infection control precautions.
2. Ensure that the wound is suitable for the XLR8/XLR8 Plus Negative Pressure Wound Therapy.
3. Read and follow all user instructions and safety information that accompany the XLR8/XLR8 Plus.
4. Do not place XLR8/XLR8 Plus dressings directly over exposed organs, blood vessels and/or nerves.
5. Complete proper debridement before application of XLR8 Plus.
6. Do not over-pack dressings into the wound.
7. Always count and record the pieces of foam used in the wound bed. Confirm the number of pieces initially recorded, match at dressing change,
8. Do not leave the XLR8/XLR8 Plus dressing in place if therapy

is switched off for more than 2 hours; if this occurs, remove dressing and replace with a new NPWT dressing or alternative dressing as ordered.

9. If no improvement in the wound within 2 weeks reassess the treatment plan

XLR8 Safety Information

All disposable components of the XLR8/XLR8 Plus are for single use only. All contents within the XLR8 foam kits are sterile and latex free. The XLR8/ XLR8 Plus foam kits are only for use with the Genadyne XLR8/XLR8 Plus.

The decision to use a clean 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 potentially serious or fatal injury.

2. INDICATIONS FOR USE

The Genadyne XLR8/XLR8 Plus is indicated for use in acute, long term care and home care settings. It 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. It is indicated for patients with chronic, acute, traumatic, subacute, and dehisced wounds, partial-thickness burns, pressure ulcers, diabetic ulcers, venous ulcers, flaps, and grafts.

3. CONTRAINDICATIONS

- Do not place XLR8 foam dressings directly in contact with exposed blood vessels, anastomotic sites, organs, or nerves
- Malignancy in the wound
- Untreated osteomyelitis

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

4. WARNINGS

Bleeding: The following types of patients are at increased risk of bleeding, which, if uncontrolled, could be potentially fatal:

- Patients who would have weakened or friable blood vessels or organs in or around the wound as a result of, but limited to:
  - o Suturing of blood vessel
  - o Infection
  - o Trauma
  - o 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 active bleeding develops suddenly or a large amount of frank (bright red) blood is seen in the tubing or canister, immediately stop therapy, leave the dressing in place, take measures to stop the bleeding, and seek immediate medical assistance. The XLR8/ XLR8 Plus 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 the XLR8/XLR8 Plus.
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 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. The patient should be closely monitored

for bleeding in a care setting deemed appropriate by the treating physician.

- **Hemostasis, Anticoagulants and Platelet Aggregation Inhibitors.** Do to the increase risk for bleeding consideration should be given to the negative pressure setting and therapy mode used when initiating therapy. These patients should be treated and monitored in a care setting deemed appropriate by the treating physician.

- **Hemostatic Agents Applied at the Wound Site** may, if disrupted, increase the risk of bleeding which, if uncontrolled, and may be potentially fatal. Consideration should be given to the negative pressure setting and therapy mode used when initiating therapy.

- **Shape Edges** or bone fragments must be covered or eliminated from the wound area to prevent them from puncturing blood vessel or organs before the application of the XLR8/XLR8 Plus. Use caution when removing dressing components from the wound so that the wound tissue is not damaged by unprotected sharp edges.

Vascular Surgical Wounds of the Lower Extremities: Regardless of the treatment, 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. Please refer to the information on managing Vascular Surgical Wounds of the Lower Extremities.

Infected Wounds: Should be closely monitored and may require more frequent dressing changes. 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 the XLR8/XLR8 Plus should be discontinued.

Osteomyelitis: XLR8/XLR8 Plus should not be initiated on a wound with untreated osteomyelitis.

Tendons, Ligaments and Nerves: Protect exposed tendons, ligaments and nerves with natural tissue, meshed non-adherent material or bio-engineered tissue to help minimize risk.

Foam Placement: Always use dressings from sterile packages that have not been opened or damaged. Do not place any foam dressing into blind/ unexplored tunnels. Always count the total number of pieces of foam used in the wound and document on the patient chart.

Foam Removal: Always count the total number of pieces of foam removed from the wound and ensure the same number of of foam pieces are removed as were placed, as the dressings are not bioabsorbable. Regardless of treatment, disruption of the new granulation tissue during any dressing change may result in bleeding at the wound site.

Keep XLR8/XLR8 Plus turned on: Never leave the foam dressing in place with the XLR8/ XLR8 Plus off for more than 2 hours. If therapy is off for more than 2 hours remove the XLR8 dressing and irrigate the wound; either apply a new XLR8 dressing and restart the unit or apply alternative dressing at the direction of the physician.

Defibrillation: If defibrillation is required in the area of dressing placement, remove the dressing as failure to remove may inhibit transmission of electrical energy and/or patient resuscitation.

Magnetic Resonance Imaging (MRI): Do not take the XLR8 /XLR8 Plus in to the MRI environment. The dressing can typically remain on the patient with minimal risk in an MRI environment. Silver Foam be removed. If MRI is longer than 2 hours dressing must be changed.

Hyperbaric Oxygen Therapy (HBO): The XLR8/XLR8 Plus unit is not designed for the HBO environment and should be considered a fire hazard. Disconnect the XLR8/ XLR8 Plus unit. If dressing is left in place, cover the luer lock end with gauze and leave port tubing unclamped. If treatment is longer than 2 hours dressing must be changed.

5. PRECAUTIONS

Standard Precautions: Apply standard precautions for infection control with all patients as per institutional protocol to reduce the risk of transmission of blood borne pathogens.

Continuous vs. Variable Intermittent Therapy: Continuous is recommended over unstable structures in order to help minimize movement and stabilize the wound bed. Continuous is generally recommended for patients at increased risk of bleeding, wounds with heavy exudate, fresh flaps and grafts, and wounds with acute enteric fistulae.

Patient Size and Weight: Infants, children, certain small adults and elderly patients should be closely monitored for fluid loss and dehydration. Also wounds with heavy exudate or large wounds in relation to the patient size and weight should be closely monitored.

Bradycardia: To minimize the risk of bradycardia the XLR8 /XLR8 Plus is not to be placed near the vague nerve.

Enteric Fistulas: Requires special precautions to optimize XLR8/XLR8 Plus. Use is not recommended if the effluent management of containment is the sole goal of the use of the XLR8/XLR8 Plus.

Circumferential Dressing Application: Avoid the use of circumferential dressings. Where a circumferential application may be necessary, consider using multiple small pieces of XLR8/XLR8 Plus drape to minimize the risk of decreased distal circulation. Extreme care should be taken not to stretch or pull the XLR8/XLR8 Plus drape when securing it. It is crucial to palpate distal pulses and assess distal circulatory status on a regular basis.

Additional Information for Genadyne Silver Dressings: When utilizing the silver foam, avoid using any topical solutions or agents that may cause an adverse reaction with the silver. Avoid use of silver foam/silver contact layer if the patient has a known sensitivity to silver or metal. Do not allow the silver foam/silver contact layer to come into contact with electrodes or conductive gels.

CONSIDERATIONS FOR TRANSITIONING PATIENT INTO HOME CARE WITH AN XLR8/XLR8 Plus:

- o Patient's situation
- o Clinical condition – adequate hemostasis and a low risk of active and/

or large amounts of bleeding at the wound.

o Home Environment – is the patient or family member/caregiver able to read and understand all labeling, follow instructions for use and respond to alarms.

- The Patients Wound
  - Assess the wound for exposed vessels, organs and nerves. Adequate protection must be present without the need for protective, non-adherent layer placed between the dressing and the exposed structure.

If there are any questions regarding the proper placement or usage of the XLR8/ XLR8 Plus please refer to the detailed guidelines within this document or contact your local Genadyne representative.

6. XLR8/ XLR8 Plus PRESSURE SETTINGS

The settings in this guideline are general recommendations. Adjustments to the pressure settings may vary depending on the individual patient need, physician orders, or clinician guidance.

The standard setting is 125 mmHg; however, the setting may be individualized to the patient needs.

Consider changing the pressure setting up by 25 mmHg for the following conditions:

- Excessive drainage
- Large wound volume
- Use of white PVA foam (denser foam)

Consider changing the pressure down by 25mmHg for the following conditions:

- Extremes of age
- Compromised nutrition
- Risk of excessive bleeding
- Circulatory compromise
- Pain or discomfort not relieved by appropriate analgesia
- Periwound or wound bed ecchymosis

Recommended Therapy Settings

Wound Characteristics	Continuous	Variable Intermittent
Difficult dressing application	√	√
Flaps	√	
Heavy exudate	√	
Grafts	√	
Painful wounds	√	√
Tunnels or undermining	√	√
Unstable structures	√	
Minimal exudate	√	√
Large wounds	√	√
Small wounds	√	√
Stalled progress	√	√

The XLR8 Plus unit offers an Intensity setting option. The standard intensity is set at 1. Consider increasing the intensity setting to 2 or 3 for wounds containing a large surface area. Increasing the intensity setting allows the compressor on the XLR8 Plus unit to stabilize target pressure, facilitating the movement of drainage. Initially increase Intensity to 2 and assess if the desired outcome is achieved; if not, increase Intensity to the highest setting, 3. *Note: an increase in intensity may be associated with an increase in discomfort. Assess patient tolerance to an increase in intensity and adjust accordingly.

XLR8/XLR8 Plus DRESSING KITS, CANISTERS, and DISPOSABLES

Each XLR8/XLR8 Plus Green Foam kit contain the following:

- Silicone Portpad
- XLR8/XLR8 Plus Green Foam
- XLR8/XLR8 Plus Drape

The XLR8/ XLR8 Plus offers 3 foam dimensions and depths for use:

XLR8 /XLR8 Plus Green Foam

XLR8/ XLR8 Plus Green Foam is a reticulated polyurethane foam made with polyether resin to allow better hydrolytic stability. While under pressure, this design allows increased performance in moist environments. The Foam promotes perfusion and assists in tissue granulation formation. In addition, fraying is reduced, preventing stray pieces from being left behind in the wound bed. The Duodecahedron structure gives the cells a three-dimensional skeletal strand, providing exceptional filtering properties. The cell structure and composite of the foam, aides in foam removal, decreasing patient discomfort during dressing change.

MULTI CANISTER SYSTEM

The multi canister system allows the clinician to choose the appropriate size, dependent on wound drainage. XLR8/XLR8 Plus canisters are offered in 200ml, 400ml, 600ml, 800ml and 1100ml.

7. XLR8/ XLR8 Plus GENERAL DRESSING APPLICATION GUIDELINES

All disposable components of the XLR8/ XLR8 Plus dressing kits are packaged sterile and are latex free. All XLR8/ XLR8 Plus canisters are packaged sterile and are latex-free. All disposable components are for single use only.
The decision to use clean vs. sterile/aseptic technique is dependent on institutional protocol and physician/clinician preference.

DRESSING CHANGES

Wounds should be monitored on a regular basis. Infected wound dressing change is recommended every 48 to 72 hours but no less than 3 times per week. Infected wounds must be monitored often and closely and the dressings may need to be changed more often than 48 to 72 hours.

The NPWT dressing may be left in place up to 5 days for noninfected skin grafts to avoid disruption to the skin graft.

The NPWT dressing may be left in place up to 5 days for noninfected incisional management.

WOUND PREPARATION

1. Remove and discard used dressing per institutional protocol. Thoroughly inspect wound to ensure all pieces of dressing components have been removed. When removing the XLR8/ XLR8 Plus dressing, follow these steps:
    a. Raise tubing above the level of the therapy unit.
    b. Clamp Port dressing and canister tubing.
    c. Turn off the XLR8/ XLR8 Plus unit.
    d. Disconnect the canister tubing from the dressing tubing by twisting and separating the purple luer lock.
    e. Remove XLR8/XLR8 Plus drape from the skin, gently stretch the. drape horizontally to release the adhesive from the skin.
    f. Gently remove foam from the wound.
    g. Discard disposables according to institutional protocols.

2. Debride all necrotic, non-viable tissue, including bone, eschar or hardened slough.
3. Clean wound and periwound as ordered, or per facility protocol.
4. Ensure adequate hemostasis has been achieved.
5. Prior to foam placement, protect vessels and organs with appropriate contact layer.
6. Sharp edges or bone fragments must be eliminated from wound area or covered with an appropriate contact layer.
7. Use a skin preparation product on the periwound skin as well as the surrounding intact skin that will be in contact with drape.

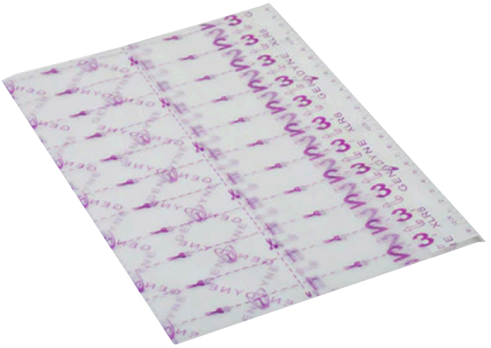
XLR8 / XLR8 Plus Foam Application for Single Wound

1. Assess wound dimensions and pathology, including the presence of undermining or tunnels. XLR8/XLR8 Plus Green Foam and XLR8 /XLR8 Plus Silver Foam/ Silver Contact Layer may be used for wounds with shallow undermining or tunneled areas where the distal aspect is visible.
2. Cut XLR8/XLR8 Plus Foam to dimensions that allow the foam to be placed gently into the wound without overlapping foam onto skin.
   Note: Do not cut foam over the wound as fragments may fall into the wound bed. Consider framing the periwound edges with 3-5 cm of drape to protect wound edges from unintentional foam exposure.
3. Gently place foam into wound bed ensuring contact with all wound surfaces. Do not force the foam into any area of the wound.
   Note: Ensure foam-to-foam contact between adjacent pieces for even distribution of pressure.

Note: Always count the number of pieces of foam used in the wound and document in the patient chart.

Note: Superficial or retention sutures should be covered with a single layer of non-adherent material place between the sutures and the XLR8/ XLR8 Plus drape.

XLR8/XLR8 Plus Drape Application



1. Trim the drape to cover and seal the foam dressing with an additional 3 – 5 cm (1 -2 Inches) border extending past the peri-wound tissue. XLR8/ XLR8 Plus drape may be cut into multiple pieces for easier handling. Use excess drape, as needed, to ensure a seal to difficult areas.
2. Pull back on tab side the labeled 1 to expose drape adhesive.
3. Place the adhesive side of the drape face down over foam and cover foam and intact skin with a 3-5 cm (1-2 inch) border around the wound.
4. Remove the remaining tab labeled 1 and smooth down to ensure an occlusive seal.
5. Remove the backing tab labeled 2 and smooth down to ensure an occlusive seal.
6. Remove the backing tab labeled 3 from the top of the drape.
7. Remove the white perforated handling tab.

XLR8/XLR8 Plus Silicone Port Pad Application

1. Choose an application site over the foam with consideration to drainage flow and tubing positioning. Avoid placement over pressure areas, bony prominences, or within creases in the tissue.
2. XLR8/XLR8 Plus drape.
3. Remove the backing layer, labeled 1, from the XLR8/XLR8 Plus Silicone Port Pad and apply directly over the opening created in the e hold in the drape. Remove backing labeled 2. Flip white paper handlers on the sides and remove them. Apply gentle pressure around the edges of the Port Pad disc and beyond to ensure adhesion.

XLR8/XLR8 Plus Canister Application and Initiating Therapy

1. Remove XLR8/XLR8 Plus Canister from packaging and insert securely to back of the unit.
2. Connect XLR8/XLR8 Plus Port Pad tubing to the canister tubing via the purple luer lock. Ensure both Canister and Port Pad Tubing are open.
3. Turn on the XLR8/XLR8 Plus Therapy Unit. Assess dressing to ensure

seal integrity. The dressing should be collapsed and there should be no hissing sounds. If there is a leak, place extra drape over the area to ensure seal integrity.

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

Ensuring Dressing Integrity

It is recommended that the dressing is checked every couple of hours to ensure that the foam is firm and collapsed in the wound bed while therapy is active, if not:

- Make sure the therapy is ON. If not, press the ON button.
- Confirm the clamps are open and the tubing is not kinked.
- Check for air leaks by moving you hand around the edges of the drape and dressing while applying light pressure.
    - o If seal is broken and/or drape is loose, trim away loose edges, ensure the skin is dry and apply new drape over the area.

Caution: Multiple layers of drape may cause decreased moisture vapor transmission rate, which may increase the risk of maceration and moisture build up under the drape.

Maintaining a Seal

Maintaining a seal around the dressing is key to successful XLR8/XLR8 Plus Therapy. The following is recommended to maintain seal integrity:

- Dry the periwound area thoroughly after cleaning. A protective skin barrier preparation may be used to prepare the skin.
    - o For delicate periwound tissue or in areas where it is difficult to dress, apply protective skin preparation and frame the wound, with drape or hydrocolloid dressing or other appropriate barrier.
- Ensure XLR8/XLR8 Plus Green Foam is appropriate for the depth of the wound. Cut depth of foam dressing for shallow wounds. For deep wounds add a layer of foam, as needed, to ensure wound bed and all sides are receiving therapy.
- Position the Silicone Port tubing on flat surfaces and away from the perineal area, bony prominences or pressure areas
    - o Secure or anchor the tubing several centimeters away from the dressing or wound. If secured directly to the dressing, tension on the tubing may interrupt the dressing seal.

Changing the Canister

The XLR8/XLR8 Plus Canister should be changed when full or at least once per week to control odor:

1. Follow standard universal precautions as the system may contain body fluids.
2. Close the clamps on both the canister and dressing tubing.
3. Disconnect the canister tubing from the dressing tubing by twisting and separating the purple luer lock.
4. Remove the canister from the unit.
5. Dispose of the canister according to specified institution protocol.
6. Insert a new canister as described previously.
7. Connect the new canister tubing to the dressing tubing and initiate therapy as ordered.

8. XLR8/XLR8 PLUS APPLICATION FOR DRESSING MULTIPLE WOUNDS

Y Connectors: Can be utilized when multiple wounds are present. Each wound must be dressed separately and checked for seal integrity before being joined by the Y-connector. This application allows multiple wounds to be treated with 1 XLR8/XLR8 Plus unit.

- It is not recommended to Y Connect flaps or grafts.
- Avoid using a Y connector in wounds that do not have the same etiology.
- It is recommended to change the Y connector weekly or as often as needed.

Bridging: Can be utilized with wounds of the same etiology and are in close proximity to each other.

- Use drape to protect the peri-wound skin as well as the skin beneath the bridge foam.
- Foam should NEVER be in direct contact with intact skin; always place drape under foam when creating a bridge as a protective barrier.
- Precisely place foam in each wound as described in the dressing application section.
- Connect the 2 wounds with another piece of foam creating a bridge, ensure all the foam pieces are in contact with each other.
- Cover all the foam with the transparent film as described in the dressing

application section

- Place the Port Pad in the center of the bridge to avoid drawing exudate from one wound to the other.

9. XLR8/XLR8 PLUS APPLICATION FOR TUNNELS AND UNDERMINING

Application for Tunnels: Do not place foam into an unexplored tunnel or sinus tract.

- Measure the length of the tunnel.
- Cut a piece of PVA white foam slightly smaller than the width of the tunnel, and ensure the end going into the tunnel is cut in a v shape to allow for easier placement into the tunnel.
- Use a sterile/aseptic cotton applicator to gently Insert the PVA white foam into the tunnel; advance forward until it reaches the end of the tunnel then pull back 1-2 cm. Leave out a piece of PVA white foam into the wound bed to ensure contact with foam in the wound bed.
- Repeat this procedure until the tunnel is closed.

Application for Undermining:

- Measure the undermined area.
- Cut PVA white foam to fit into the undermined area starting at the distal end, avoid packing the undermined area too tightly.
- Pull the foam out about 1-2 cm, leaving part of the foam in the wound bed to ensure good contact with the foam in the rest of the wound.

XLR8 /XLR8 Plus Application for wounds smaller than the Port Pad – Mushroom Effect

- Protect the peri-wound area and intact skin with a drape. Ensure the drape is large enough to protect the skin beneath the foam being placed.
- Cut the foam to fit inside the wound.
- Cut a second piece of foam large enough to accommodate the Port Pad (this will prevent the Port Pad from creating a pressure area directly on the skin) and place it on top of the foam in the wound bed.
- Seal the foam dressing with a drape and place the Port Pad, as in previous dressing applications, over the opening in the drape that has been created.

NOTE: IF THE WOUND IS LOCATED ON ANY PRESSURE POINT, CREASE IN THE BODY, OR PRESSURE SENSITIVE AREA, THE PORT PAD SHOULD BE OFFLOADED/BRIDGED AWAY FROM THAT AREA.

- Protect the offloaded/bridged area with drape to avoid foam coming into direct contact with intact skin.
- Dress the wound as described in the previous section.
- Cut a piece of foam to bridge from the foam in the wound bed to the offloaded position.
- Place the Port Pad at the end away from the wound, this will ensure there is no added pressure on the wound.

XLR8/XLR8 Plus Wound Monitoring while the patient is receiving treatment with the XLR8/XLR8 PLUS, they should be monitored and assessed by the clinician and or physician on a regular basis. Indication the XLR8/XLR8 PLUS therapy is effective; would show wound measurements getting smaller over time, the wound should appear a dark red color as perfusion to the wound bed increases, exudate should be decreasing in amount. New granulation tissue should be evident in the wound bed.

Ensure wound assessments are being completed on a regular basis. If there appears to be maceration around the wound, check the treatment time, located on the home screen of the XLR8/XLR8 Plus, to ensure the XLR8/XLR8 Plus unit has remained ON for the duration of the recommended treatment and the unit is functioning properly.

The user may also press the Menu/Select button to check the Alert Log and view any Leak, Blockage, Full Canister, or Low Battery Alerts that may have occurred.

If you suspect there is an issue, contact your representative to replace the XLR8/XLR8 Plus unit.

Pain Management: if the patient is experiencing pain during NPWT treatment and/or during the removal of the dressing, refer to your institutional guidelines on pain management. The unit can be turned off 30 minutes prior

to dressing removal to lessen the adherence of the foam and moistened with normal saline or sterile water to assist in foam removal. An interface may be used if the patient complains of excess pain during treatment. If there is a sudden increase or change in the pain being reported by the patient it should be assessed by a medical professional.

10. XLR8/XLR8 PLUS SPECIFIC WOUND APPLICATIONS

Acute/Traumatic/Chronic wounds/ Partial Thickness Burns/ Dehisced Wounds

The XLR8/XLR8 Plus can be used to treat all wound types listed above. The following recommended settings are a guidelines only. Pressure settings are determined by the treating clinician and or physician. Consult treating Clinician or Physician to verify desired pressure settings for each patient.

- Tendons, ligaments, bone, blood vessels, organs, nerves, and vital structures must be completely covered and protected prior to the initiation of the XLR8 therapy.
- The XLR8/XLR8 Plus Green Foam may be placed directly over the absorbable and non-absorbable mesh, or intact fascia.
- The XLR8/XLR8 Plus should not be initiated in a wound with untreated osteomyelitis. Once treatment has commenced for the osteomyelitis then treatment with the XLR8/XLR8 Plus can be initiated.
- Dressing application is completed as set forth in General Application Guidelines.

Lower Extremities Vascular Surgical Wounds

- Regardless of the treatment, 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.
- The use of the XLR8/XLR8 Plus treatment in groin wounds with pseudo aneurysm, gross infection, lack of wound hemostasis, unprotected vascular anastomosis, and weakened or irradiated blood vessels is not recommended. Once hemostasis of the wound is achieved, the infection has been treated the XLR8/XLR8 Plus therapy can be initiated.
- Grafts should be covered with well-vascularized tissue; the foam should

not be placed directly over a graft, exposed vessel or anastomotic site.

- **XLR8 /XLR8 Plus therapy should be stopped immediately if sudden, active or large amounts of bleeding occur, or if frank red blood is visualized in the tubing or canister:**
    - o Therapy should be stopped immediately.
    - o Leave the dressing in place until the wound can be assessed by the physician.
    - o Take measures to stop the bleeding.
    - o Provide immediate medical assistance if required.
- If wound deterioration is suspected the lead clinician should be notified and the wound should be assessed.

Meshed Grafts /Flaps

- Place a single layer of a non-adherent dressing over the graft site plus a 1-2 cm border.
- Cut the XLR8/XLR8 Plus Green Foam the same size as the non-adherent dressing, and place the foam over the nonadherent layer. Do NOT allow foam contact on intact skin.
- Cover the foam with the XLR8/XLR8 Plus Drape and place Port Pad, connect to the unit, set the desired pressure
- Setting should be continuous to maintain the constant bolster
- The dressing stays in place for 4-5 days
- You should notice the amount of exudate decrease after the first 24 hours, if exudate increases or there are signs of infection, the dressing should be taken off and the wound assessed by a clinician.

Wound Characteristics	Recommended Target Pressure	Dressing Change Interval	C	V/IT
Acute/Traumatic / Chronic Wounds/Partial Thickness Burns/ Dehisced Wounds	125	48-72 hrs	✓	✓
Flaps	125	Remove dressing after 72 hours post operatively	✓	
Highly exudation	125-175	48-72hrs	✓	
Grafts	125	Remove dressing after 4-5 days	✓	
Painful wounds	100	48-72 hrs	✓	✓
Tunnels or undermining	125	48-72 hrs	✓	✓
Unstable structures	100-125	48-72 hrs	✓	
Minimally exudation	100-125	48-72 hrs	✓	✓
Large wounds	100-125	48-72 hrs	✓	✓
Small wounds	100-125	48-72 hrs	✓	✓

C = Continuous V/IT = Variable/ Intermittent

For further information please contact your local Genadyne Representative at 1-516-487-8787.

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