XLR8

Patient Handbook

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Introduction

XLR8 is an advance wound healing therapy that can be readily integrated into the clinicians wound healing practice to optimize patient care. XLR8 may be used in hospital, Long Term Care and at home settings.

The XLR8 NPWT system is for use in patients who would benefit from NPWT particularly as the device may promote wound healing by the removal of excess exudates, infections 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 alarm settings within the XLR8: leakage (target timeout), blockage, 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 30 seconds, this means that in the event of a leakage, it will have to last for at least 30 seconds continuously before the system starts alarming. This avoids false alarms due to dressing shifts caused by patient movement.

Points to remember: Follow standard infection control precautions

1. Ensure that the wound is suitable for the XLR8 Negative Pressure Wound Therapy
2. Read and follow all user instructions and safety information that accompany the XLR8
3. Do not place XLR8 dressings directly over exposed organs, blood vessels and/or nerves
4. Complete proper debridement prior to application of XLR8
5. Do not over pack dressings into the wound
   Always count the pieces of foam used and record the number in the patient chart. When dressing is removed, confirm the number of pieces and correlate that number to the original count in the chart to verify that all pieces have been removed
   Do not leave the XLR8 in place if therapy is switched off for more than 2 hours
   If no improvement occurs in the wound within 2 weeks, reassess the treatment plan

XLR8 Safety Information

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

The decision to use clean vs. 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 use may lead to improper product performance and potential serious or fatal injury.

INDICATIONS FOR USE

The Genadyne XLR8 is indicated for use in acute, extended 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.

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
- More than 20% slough/necrotic tissue present, if slough/necrotic tissue is greater than 20%, debridement is necessary prior to initiating NPWT
- NPWT should not be applied to eschar tissue

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:
    - Suturing of blood vises
    - 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 active bleeding develops suddenly or large around of frank (bright red) blood is seen in the tubing or canister, immediately stop therapy, leave dressing in place, take measures to stop the bleeding and seek immediate medical assistance. The XLR8 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.

  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. The patient should be closely monitored for bleeding in a care setting deemed appropriate by the treating physician.
- Hemostasis, Anticoagulants and Platelet Aggregation Inhibitors. Due 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 could be potentially fatal. Consideration should be given to the negative pressure setting and therapy mode used when initiating therapy.
- Shape Edges. 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. 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 should be discontinued.

Osteomyelitis; XLR8 should not be initiated on a wound with untreated osteomyelitis.

Protect 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 foam pieces are removed as were placed as they dressings are not bio absorbable. Regardless of treatment, disruption of the new granulation tissue during any dressing change may result in bleeding at the wound site.

Keep XLR8 turned on; Never leave the foam dressing in place without the XLR8 for more than 2 hours if therapy is turned off. If the 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 in to the MRI environment. The dressing can typically remain on the patient with minimal risk in an MRI environment.

Hyperbaric Oxygen Therapy (HBO); The XLR8 unit is not designed for the HBO environment and should be considered a fire hazard. Disconnect the XLR8 and replace the dressing with another HBO compatible material during the hyperbaric treatment

PRECAUTIONS

Standard Precautions; Apply standard precautions for infection control with all patients as per institutional protocol to reduce the risk of transmission of bloodborne 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, highly exudating wounds, 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 patients with highly exudating wounds or large wounds in relation to the patient size and weight should be closely monitored.

Bradycardia; To minimize the risk of bradycardia the XLR8 is not to be placed near the vagus nerve.

Enteric Fistulas; Require special precautions to optimize XLR8. Use is not recommended if the effluent management of containment is the sole goal of the use of the XLR8.

Circumferential Dressing Application; Avoid the use of circumferential dressings. Where a circumferential application may be necessary consider using multiple small pieces of XLR8 Drape to minimize the risk of decreased distal circulation and extreme care should be taken not to stretch or pull the XLR8 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 if the patient has a known sensitivity to Silver or metal. Do not allow the Silver foam to come into contact with electrodes or conductive gels.

PATIENT INFORMATION GUIDE

Daily Use
The XLR8 is portable and small enough that it may be worn during normal patient activities as approved by the treating physician.

Sleeping

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

Showering and Bathing

- Do not use XLR8 where it can fall or be pulled into a tub, shower or sink.
- Do not reach for a product that has fallen into water. Unplug the unit immediately if plugged into electrical source. Clamp tubing, disconnect therapy unit from dressing and contact Genadyne.
- To shower, clamp tubing and disconnect from therapy unit
- The clear drape is waterproof; patient may wash or shower with dressing in place and the tube clamped and disconnected from the therapy unit.
- When towel drying avoid disturbing or damaging the dressing

Cleaning

- The XLR8 and carrying case can be wiped with a damp cloth using a mild household cleaner.

KEY PAD FEATURES

Keypad Feature	
	**Power Button** Turns the device on and off.
	**Up Button** Increase suction pressure. Enable user to scroll up in a menu.
	**Down Button** Decrease suction pressure. Enable user to scroll down in a menu.
	**Lock / Unlock** Lock and unlock keypad.
	**Menu / Select** Brings up the system menu. Enable user to select the desired function.
	**Exit / Cancel** Exit from the system menu. Enable user to cancel from current and selected function.

BATTERY INFORMATION

	Battery life is between 2% to 25%
	Battery life is between 25% to 50%
	Battery life is between 50% to 75%
	Battery life is between 75% to 100%
	Battery life is between 0% to 2% (Alarm notification will occur, user needs to plug in the power adapter to recharge the battery)
	Battery is charging
	Battery is fully charged and system is running on while the power adapter is plugged in

ALARM TROUBLESHOOTING GUIDE

System Alarm	Alarm Condition	Action	User Tips
Leak Alarm	XLR8 has detected the negative pressure is less than what the target pressure is	• Check the dressing for leaks • Check the Canister is secured properly	• Feel around the dressing edge, when 4 green bars and a checkmark are seen patch where the leak is with extra drape • Re-fit the canister by pulling it out and placing it back
Canister Full Alarm	XLR8 has detected the canister is full even though there may be little exudate in it	• Change the XLR8 canister	• Ensure the XLR8 is in the upright position • Ensure to power the unit down before changing the canister
Blockage Alarm	XLR8 system has detected there is a blockage somewhere in the system	• Check tubing for closed clamps, kinks or blockages • Check that the hole in the covering drape is at least the size of a quarter • Check the dome of the Port pad to make sure it is not collapsed	• Ensure a quarter size hole is cut in the drape prior to placement of the Port pad • Ensure the Port pad is off loaded from any pressure point and the tubing is not placed in a way that may cause it to kink or block
Low Battery Alarm	XLR8 has detected the battery is less than 20% charge remaining	• Plug in the unit to a working outlet	• Ensure the each piece of the charger is securely fastened • **ONLY** use the power adapter supplied by Genadyne. Using power adapters that are not supplied by Genadyne might damage the system
Critical Battery Alarm	XLR8 has detected less than 2% of battery life remaining	• "Please Recharge" sign will appear and machine will stop working and shut down • Charge the unit right away to enable the system to resume therapy	• Ensure the each piece of the charger is securely fastened • "Please Recharge" sign will disappear after the unit is plugged in • Check to see if the keypad is locked to power the unit ON if it did not turn on automatically

For further information please contact your Genadyne representative.