

GENADYNE



XLR8

Clinical Guidelines

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Introduction

The Genadyne XLR8 is an advanced wound healing therapy that can be readily integrated into the clinicians wound healing practice to optimize patient care. The XLR8 is suitable for use in hospital, Long Term Care and in 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 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 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 Negative Pressure Wound Therapy
3. Read and follow all user instructions and safety information that accompany the XLR8
4. Do not place XLR8 dressings directly over exposed organs, blood vessels and/or nerves
5. Complete proper debridement prior to application of XLR8
6. Do not pack dressings into the wound

7. Always count the number of pieces of foam used and record in the patient chart and when dressing is removed, count the number of pieces and correlate that number to the number of pieces removed to verify removal of all foam pieces.
8. Do not leave the XLR8 in place if therapy is switched off for more than 2 hours
9. If no improvement 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 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 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
- Necrotic tissue with eschar present

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 vessels
 - 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 amount 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 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 could 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. 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.

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 foam pieces are removed as were placed, as the 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. Silver Foam must be removed.

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. If dressing is left in place, cover the luer lock end with gauze and leave Port unclamped. If treatment is longer than 2 hours dressing must be changed.

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, 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: Requires 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.

CONSIDERATIONS FOR TRANSITIONING PATIENT INTO HOME CARE WITH AN XLR8

- Patients Situation
 - Clinical condition – adequate hemostasis and a low risk of active and/or large amounts of bleeding at the wound

- 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 please refer to the detailed guidelines within this document or contact your local Genadyne representative.

XLR8 SYSTEM

XLR8 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 an expert clinician's guidance.

The default setting is 125 mmHg but the setting can be individualized to the patient needs.

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

- Excessive drainage
- Large wound volume

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	✓	
Highly exudating	✓	
Grafts	✓	
Painful wounds	✓	✓
Tunnels or undermining	✓	✓
Unstable structures	✓	
Minimally exudating	✓	✓
Large wounds	✓	✓
Small wounds	✓	✓
Stalled progress	✓	✓

XLR8 DRESSING KITS, CANISTERS and DISPOSABLES

Each XLR8 Green Foam kit contains the following:

- Silicone Portpad
- XLR8 Green Foam
- XLR8 Drape
- Oil Emulsion Dressing
- Ostomy Paste
- Barrier Wipe
- Cotton Tip Applicator

The XLR8 offers 3 foams for use:

XLR8 Green Foam



XLR8 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 granulations. In addition, fraying is reduced, preventing stray pieces from being left in the wound bed. The Duo-decahedron structure gives the cells a three-dimensional skeletal strand. This provides special filtering qualities. The combination of cell structure and composition gives the foam a non-adherent property, easing the removal during dressing changes and almost eliminating pain.

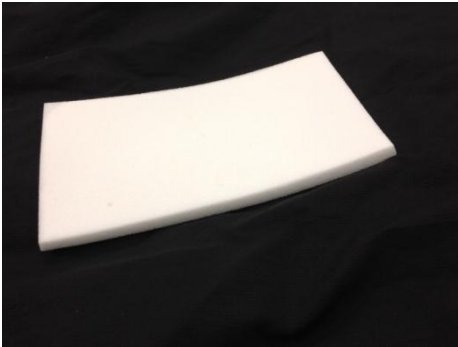
XLR8 Silver Foam



The XLR8 Silver Foam is fully reticulated polyurethane foam made with polyether resin that has been mircobonded with metallic silver.

The exposure of the dressing to the wound fluid results in oxidation of the metallic silver to ionic silver thus, allowing the continuous and sustained release of silver ions that act as an effective barrier to bacterial penetration.

XLR8 White Foam



The Molecular structure of the foam is a cross-linked polyvinyl alcohol, for use in tunnels, undermined areas, painful wounds and shallow wounds. XLR8 white foam comes pre-moistened in sterile water, has a greater density and tensile strength than the Green foam.

MULTI CANISTER SYSTEM



The multi canister system allows the clinician to choose the right size dependent on wound drainage and patient mobility. Canisters for the XLR8 are offered in 200cc, 400cc, 600cc and 800cc.

XLR8 GENERAL DRESSING APPLICATION GUIDELINES

All disposable components of the XLR8 dressing kit are packaged sterile and are latex free. All XLR8 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 and the dressing in non-infected wound should be changed 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.

WOUND PREPARATION

1. Remove and discard previous dressing per institutional protocol. Thoroughly inspect wound to ensure all pieces of dressing components have been removed. If removing the XLR8 dressing please follow these steps:
 - a. Raise the tubing above the level of the therapy unit
 - b. Clamp close the dressing tubing
 - c. Disconnect the canister from the unit by disconnecting the luer lock.
 - d. Turn off the XLR8 unit and wait for the foam to decompress
 - e. Remove XLR8 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. Perform thorough wound and periwound area cleaning
4. Ensure adequate hemostasis has been achieved
5. Prior to foam placement, protect vessels and organs
6. Sharp edges or bone fragments must be eliminated from wound area or covered
7. Use a skin preparation product on the periwound skin

XLR8 Foam Application for Single Wound



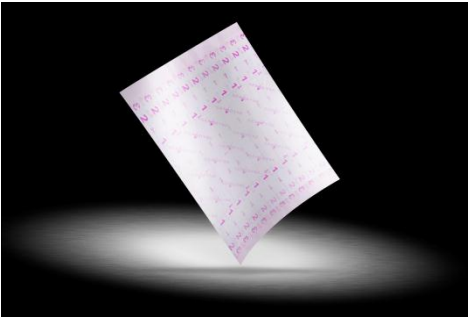
1. Assess wound dimensions and pathology, including the presence of undermining or tunnels. XLR8 Green Foam and XLR8 Silver Foam may be used for wounds with shallow undermining or tunneled areas where the distal aspect is visible.
2. Cut XLR8 Foam to the dimensions that would allow the foam to be placed gently into the wound without overlapping onto skin.
Note: Do not cut the foam over the wound as fragments may fall into the wound.
3. Gently place foam into wound cavity 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

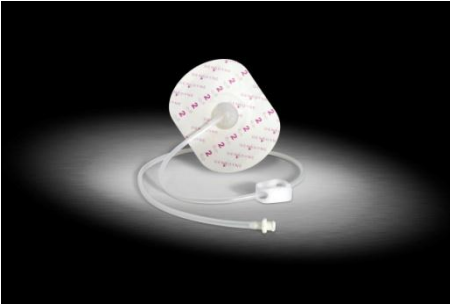
Note: Superficial or retention sutures should be covered with a single layer of non-adherent material placed between the sutures and the XLR8 Drape.

XLR8 Drape Application



1. Trim the drape to cover the foam dressing with an additional 3 – 5 cm (1 -2 Inches) boarder of intact periwound tissue. XLR8 Drape may be cut into multiple pieces for easier handling. Use excess drape to seal difficult areas.
2. Pull back on side labeled 1 to expose adhesive
3. Place the adhesive face down over foam and apply drape to cover foam and intact skin with a 3-5 cm (1-2 inch) boarder around the wound
4. Remove remaining side labeled 1 and pat down to ensure an occlusive seal
5. Remove the backing side labeled 2
6. Remove the backing labeled 3
7. Remove the purple perforated handling tab

XLR8 Silicone Port Pad Application



1. Choose a application site with consideration to fluid flow, tubing positioning and avoid placement over bony prominences or within creases in the tissue
2. Pinch XLR8 drape and cut a 2.5cm (1inch) hole through the drape. Do not cut into the foam.
3. Remove backing layer on the XLR8 Silicone Port Pad and apply pad directly over the hold in the drape and apply gentle pressure on the disc and outer skirt of the pad to ensure adhesion

XLR8 Canister Application and Initiating the XLR8 Therapy



1. Remove XLR8 Canister from packaging and insert into the XLR8 Therapy Unit until it locks into place
2. Connect XLR8 Port Pad tubing to the canister tubing via the luer lock and ensure clamp is open
3. Turn on the XLR8 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
- Look for air leaks by moving your hand around the edges of the dressing while applying light pressure
 - 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

Maintaining a Seal

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

- Dry the periwound area thoroughly after cleaning. A protective skin barrier preparation may be used to prepare the skin
 - For delicate periwound tissue or in areas that are difficult to dress, apply protective skin preparation and frame the wound with transparent film or hydrocolloid dressing or other appropriate barrier
- Ensure XLR8 Green Foam is appropriate for the depth of the wound by either cutting or use thinner dressing where indicated

- Position the Silicone Port tubing on flat surfaces and away from the perineal area, bony prominences or pressure areas
 - 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 Canister should be changed when full or at least once per week to control odor:

1. Follow standard 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
4. Remove the canister from the unit
5. Dispose of the canister according to specified institution protocol
6. Install a new canister as described above
7. Connect the new canister to the dressing tubing and initiate therapy as ordered.

XLR8 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 unit.

- It is recommended to not 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 required

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

- Protect the peri-wound skin as well as the area between the wounds where the bridge is going to be as to avoid the foam coming in contact with good skin
- Place the 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.

XLR8 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 the XLR8 White Foam slightly smaller than the width of the tunnel, ensure the end going into the tunnel is cut in a v shape to allow for easier placement into the tunnel
- The first application gets inserted into the tunnel until it touches the end of the tunnel, ensure to leave part of the white foam sticking out into the wound bed for complete contact with the rest of the foam
- Subsequent dressing change, place the foam into the tunnel to the end than pull back a few cm's with each change
- Repeat this procedure until the tunnel is closed

Application for Undermining.

- Measure the undermined area
- Cut the White foam to sit nicely into the undermined area starting at the distal end, avoid packing the undermined area to tightly
- Pull the foam out about 1-2 cm's leaving part of the foam in the wound bed to ensure good contact with the foam in the rest of the wound
- Each subsequent change will be the same procedure as above ensuring the distal end of the undermined area is clear of foam so the negative pressure can allow the free area to collapse them together

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

- Protect the peri wound area with the transparent film ensuring the film is larger than the Port pad
- Cut the foam to fit inside the wound
- Cut a second piece of foam larger than the size of the Port Pad and place it on top of the foam in the wound
- Seal the dressing and place the Port Pad as in previous dressing applications

NOTE: IF THE WOUND IS LOCATED IN ANY PRESSURE POINT OR PRESSURE SENSATIVE AREA, THE PORT PAD SHOULD BE OFFLOADED AWAY FROM THAT AREA.

- Protect the offloaded area with the transparent film as to avoid the foam coming into contact with the good skin.
- Dress the wound as described in the previous section
- Cut a piece of foam to bridge from the wound 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 Wound Monitoring, while the patient is receiving treatment with the XLR8, they should be monitored and assessed by the clinician and or physician on a regular basis. The indicators the XLR8 therapy is effective; wound measurements should be getting smaller over time, the wound should have 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 to ensure the unit has been on for the recommended amount of time and the unit is functioning as it should. If you suspect there is an issue, contact your representative to replace the unit.

Pain Management, if the patient is experiencing pain during treatment and or 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. 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 investigated by a medical professional.

XLR8 Specific Wound Applications

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

The XLR8 can be used to treat all wound types listed. The following recommended settings are a guideline 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, vital structures must be completely covered and protected prior to the initiation of the XLR8 therapy.
- The XLR8 green foam may be placed directly over absorbable and non-absorbable mesh, or intact fascia.
- The XLR8 should not be initiated in a wound with untreated osteomyelitis. Once treatment has commenced for the osteomyelitis then treatment with the XLR8 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 treatment in groin wounds with pseudoaneurysm, gross infection, lack of wound hemostasis, unprotected vascular anastomosis, weakened or irradiated blood vessels is not recommended. Once hemostasis of the wound is achieved, the infection has been treated the XLR8 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 therapy should be stopped immediately if sudden, active or large amounts of bleeding occur if frank red blood is seen in the tubing or canister:**
 - The therapy should be stopped immediately
 - Leave the dressing in place until the wound can be assessed by the physician
 - Take measures to stop the bleeding
 - 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 Green Foam the same size as the non-adherent dressing, place the foam over the non-adherent layer, be careful to not have the foam touch good skin
- Cover the foam with the XLR8 Drape and place Port Pad, connect to the unit, set the desired pressure
- Setting should be on continuous to maintain the constant bolster
- The dressing stays in place for 4-5 days
- You should see the amount of exudate taper off 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 exudating	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 1-888-787-2811