A. Introduction

Thank you for your selection of Carilex VT device and Carilex VT Dressing Kits for use in negative pressure wound therapy (NPWT). Carilex VT Dressing Kits is intended to transfer negative pressure from Carilex VT device to the wound site to promote active fluid removal. **PLEASE READ THESE INSTRUCTIONS FOR USE CAREFULLY BEFORE USING THIS DEVICE.**

B. Intended Purpose

Carilex ”Negative Pressure Wound Therapy System” (NPWT) is indicated for patients who would benefit from wound management via the application of negative pressure for removal of fluids and excess exudates, irrigation fluids, infectious material, and tissue debris which may promote wound healing. To help provide safe and effective use, Carilex dressing kits is to be used only with the Carilex components: canister and pump.

Intended users: Medical practitioner (Clinician use only)
Intended patient populations: No restriction in patient population.
Use environment: Carilex ”NPWT” is intended to be used in hospitals, clinics, nursing home, elderly homes.

Indications:

- Traumatic
- Dehisced wounds
- Partial thickness burns
- Chronic wounds such as pressure ulcers, diabetic foot ulcers, venous leg ulcers
- Acute wounds
- Flaps and grafts

Contraindications:

Patients with the following conditions:

- Presence of necrotic tissue
- Malignancy (except for quality of life reason for terminal patients)
- Exposed arteries, veins, nerves, organs or vascular graft
- Use over anastomotic sites
- Untreated osteomyelitis
- Unexplored or non-enteric fistulas

Relative Contraindications

- Ischemic wounds
- Ongoing infection
- Fragile skin
- Adhesive allergy

Clinical benefits:

NPWT benefits include rapid wound healing, reduction of dressing changes, reduced infection risk, reduced treatment costs, control of exudate, reduction of oedema and provision of a closed moist wound healing environment, concurrent rehabilitation, and better patient comfort and tolerance.

C. Precautions

Precautions should be taken for patients with the following conditions:

- Difficult wound hemostasis, or who are on anticoagulants. Patients on anticoagulation medicine or who have active bleeding or who have difficult wound hemostasis should be treated with caution. These patients are at an increased risk for bleeding and bleeding complications and should be treated and monitored by properly trained medical caregivers in a controlled setting.
- Exposed tendon, nerves or blood vessels should be protected. Close proximity of blood vessels, organs, muscle, and fascia. All blood vessels, organs, muscles, and fascia that are in close proximity to the wound site and/or are exposed and /or are near the skin surface should be properly protected prior to initiating NPWT. Patients with infections in the wound and or other parts of the body have to receive proper systemic treatment.
- Weakened, irradiated or sutured blood vessels or organs. These patients are at an increased risk for bleeding and bleeding complications and should be treated and monitored by properly trained medical caregivers in a controlled setting.
- Bone fragments or sharp edges. Sharp edges from bony fragment may puncture blood vessels, organs, muscles, and fascia and may lead to bleeding. Proper care should be taken to cover the bony fragments and protect the wound area and other areas from bleeding.
- Infected wound. Patient with infections in the wound and or other parts of the body have to receive proper systemic treatment. Infected wounds may need more frequent dressing changes, up to twice a day, and the patient and wound must be inspected regularly for signs of increased infection or sepsis.
- For patients a known history of autonomic dysreflexia, please increase number of monitoring during the treatment as well as inspection for displacement of dressings.
- Do not use NPWT if person experiences autonomic dysreflexia.

D. General Precautions for all indication for use

It is important that a physician or other qualified healthcare provider evaluates the patient to ensure that the use of the Carilex VT is an appropriate therapy.
To reduce the risk of transmission of blood-borne pathogens, regardless of their diagnosis or presumed infection status, all patients should take medical standard operating procedure precautions against infection control. In addition, a healthcare provider should wear gloves, a gown, and goggles if there is the possibility of contact with the patient's body fluids.

NOTE: Before using, please inspect the dressing kits to make sure there is no damage to the packaging, which may comprise the sterility of the contents.

CAUTION: Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged.

CAUTION: For single use only. Do not reuse or resterilize. Reuse or resterilization may create a risk of contamination of the device and/or cause patient infection.

NOTE: User shall protect the periwound skin during dressing application, and to avoid circumferential dressing application.

CAUTION: Unapproved stop the therapy risks to patients because they have not been evaluated by the physician for wound assessment. Without physician evaluate, there is no way to know if the wound is healthy, whether the wound is infection or worsened. Do not stop the therapy by yourself, or, contact your caregiver if any problem.

NOTE: After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

E. Warnings

The following Warning statements describe the potential for serious consequences to the patient such as death, injury, or adverse reactions Failure to read and follow all instructions in this manual prior to use may result in death or injury of the patient.

- Physician should consider the patients' size and weight when prescribing this device. Infants, children, certain small adults and elderly patients should be closely monitored for fluid loss and dehydration.
- Patients with spinal cord injury (stimulation of sympathetic nervous system) and use near vagus nerve (bradycardia) shall be treated with care.
- The device is not safe for use with an MRI or PET scan and must be disconnected from the patient prior to MRI or PET scan.
- Do not use the suction pump in a Hyperbaric Chamber or in the presence of flammable gases. Patient dressing may remain in place when disconnected from the unit.
- The device may be used in the event that defibrillation is needed, provided there is no electrical connection between the patient and the device. In such case, the device must be completely disconnected from the patient. Be especially vigilant about removing wound 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.
- Residues of gauze/foam that may increase the risk associated with wound infection and bleeding. To prevent unintentional gauze/foam retention, all dressings should be carefully removed from the wound and the entire wound bed. Upon removal of the dressings, the wound bed should be cleaned in accordance with standard wound care practices (or facility guidelines), prior to the application of new sterile dressing.
- If necessary, all wounds should be debrided prior to application of the therapy and/or dressings.
- Ensure that there are no pockets left in the wound after application of the dressings.
- Infected wounds may need more frequent dressing changes, up to twice a day, and the patient and the wound must be inspected regularly for signs of increased infection or sepsis.
- Wound infection that may increase the risk associated with wound worsen, sepsis or osteomyelitis. Please be careful to seal the dressing, or, contact your caregiver when the dressing come off from the skin.
- A delay in the patient's care that may increase the risk associated with wound infection and bleeding. Please contact your caregiver when the dressing apply on the wound more than 48-72 hours.
- Patients who do not have adequate hemostasis, and on whom anticoagulation or platelet aggregation inhibitors are being used, have an increased risk of bleeding with or without the Carilex VT Dressing Kits.

- All arteries, veins, tendons, ligaments, nerves, and organs must be covered completely prior to application of the Carilex VT Dressing Kits.
- Patients with increased risks of bleeding due to having weakened or friable blood vessels or organs, such as suture of the blood vessel (native anastomoses or grafts) / organs, infection, trauma, and radiation, which, if not controlled well, could be potentially fatal.
- Infected tissue such as blood vessels may have a weakened structure and have to be treated with care. Infected blood vessels may bleed more readily than normal blood vessels.
- To prevent leak, lockable connector should be properly tight.
- Patient tripped over the tube that may increase the risk associated with wound bleeding. Please fasten the tube appropriately, to avoid the unexpected severe injury.
- Forcibly removed dressing from the tissue that may causing skin Injury or blister with patient. Therefore, caregiver shall follow the IFU to remove the dressing.

F. Dressing Changes

- It is recommended dressings changing every 48 – 72 hours based upon clinical evaluation of the wound condition.
- Each dressing should be changed at least 3 times per week but this is dependent upon the amount of wound exudate. Heavy exuding wounds should have more regular dressing changes.
- Each dressing change should be performed with thorough wound cleaning as described in section G.
- Remove dressing slowly keeping dressing horizontal and close to skin.
- Remove in the direction of hair growth.
- Support exposed skin at the peel line as dressing is removed.

G. Cleaning the wound

- Prior to dressing application, thoroughly clean the wound with aseptic techniques in accordance with your institutions protocols.
- Debride any necrotic or devitalized tissue.
- Clean and dry the skin to remove soil and residue.

H. Use of Foam

- Cut foam to fit loosely into the wound bed. Do not force the foam into the wound. Do not place foam into unexplored tunnels. Cut foam away from the wound site to prevent fragments from falling into the wound.

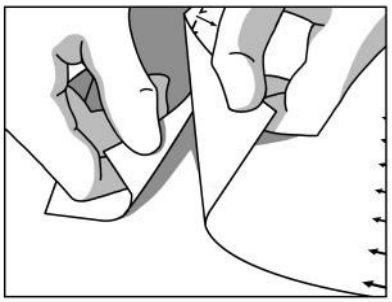
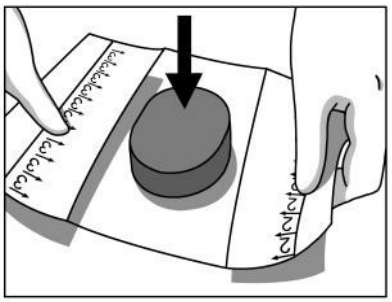
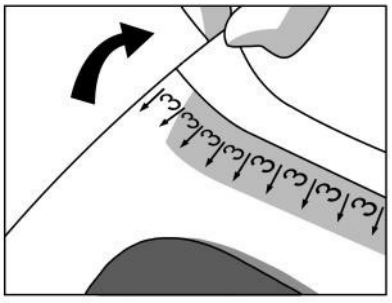
I. Disposal of Foam

- The used dressing should be disposed according to the local or facility guidelines for handling infected or bio-hazardous materials.

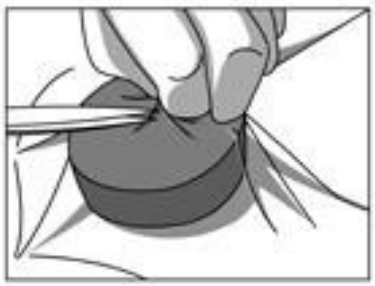
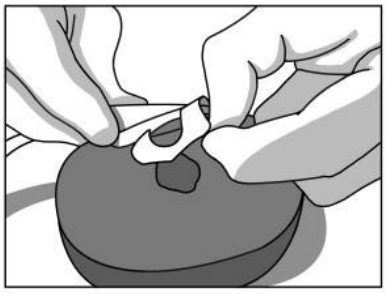
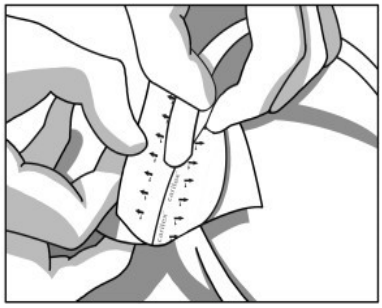
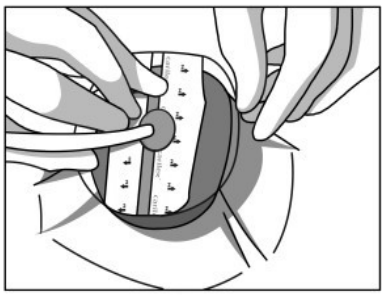
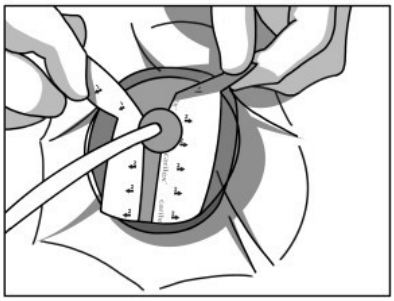
J. Foam Application

• Wear gloves. • Cut the supplied foam to fit the wound. • Do not over-pack the wound or allow foam to contact the peri-wound area. • Deep wounds may require foam to be stacked. If this is necessary, record the number of foam elements used to ensure none is left in the wound after dressing removal. • Place the foam into the wound.	

K. Seal the wound

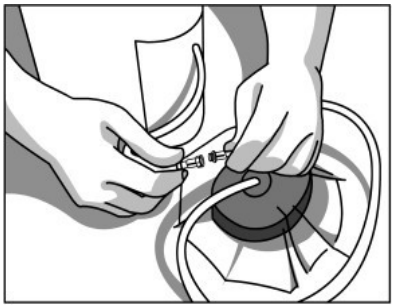
• Take the supplied drape and remove layers 1 and 2 to expose the adhesive.	
• Apply the drape over the foam allowing at least 5cm margin to the wound edge. Push the drape to seal against the patient's skin. • Apply dressing without stretch or tension. • Apply dressing pressure after application, stroking the tape in place.	
• Remove the backing layer 3 from the drape and check seal of drape to the patient's skin once more.	

L. Apply the Port

• Pull a small amount of drape up from the center of the wound location and cut with scissors to leave a hole in the drape of approximately 2cm.	
• Peel off the liner from the underside of the Port and apply the Port over the hole. Gently push down to ensure it is sealed	
• Remove layer 1 from the Circle Drape, which is attached to the tubing, to expose the adhesive.	
• Apply to the Port and seal to the drape.	
• Once sealed, remove the backing layer 2.	

M. Connect the Therapy Unit

- Connect the VT Dressing tubing to the VT therapy unit Canister tubing.
- Check tubing connectors to ensure they are fully engaged and locked.
- Ensure the white Tube Clamps are released from the tubing.
- Refer to the Instructions for Use of the Carilex VT Therapy unit before activate the device.
- Check the seal of the dressing once therapy is activated.
- Larger dressings will take longer to evacuate.

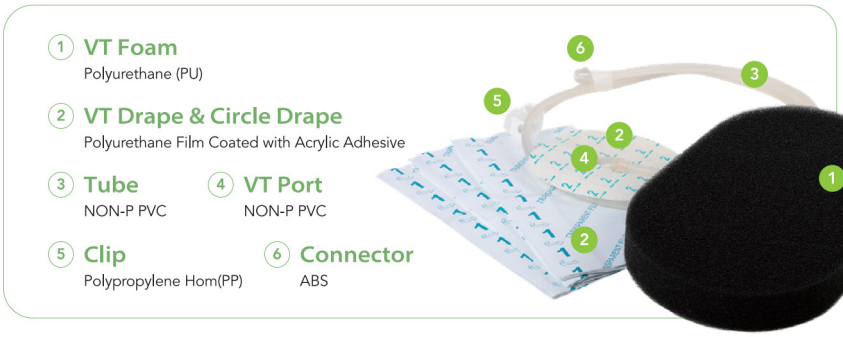


N. Additional Symbols to the Safety Information

	Consult instruction for use		Quantity per pack	LOT	Batch code
	Single use only	TW	Country and date of manufacture		Do not use if package is damaged or open
STERILIZE	Do not re-sterilize		Manufacturer		Use-by date
STERILE EO	Sterilized using ethylene oxide	Rx only	USA Federal law restricts this device to sale by or on the order of a physician	REF	Catalogue Number
EC REP	Authorized Representative in the European Community		Temperature limit	CE 2460	Declaration of Conformity to MDD 93/42/EEC
UDI	Unique Device Identifier	MD	Medical Device	#	Model Number

O. VT Dressing Kit

S1001-2040	VT Dressing Kit S Carilex
S1001-2050	VT Dressing Kit M Carilex
S1001-2060	VT Dressing Kit L Carilex
S1001-2100	VT Spiral Dressing Kit Black Lock
S1001-2120	VT Dressing Kit XL Carilex
S1001-2200	VT Dressing Kit TS S Carilex
S1001-2210	VT Dressing Kit TS M Carilex
S1001-2220	VT Dressing Kit TS L Carilex



USA Federal law restricts this device to sale by or on the order of a physician.

Warnings
Use a none genuine Carilex Medical dressing kits may contain plasticizer or irritants that may increase the risk associated with allergic contact dermatitis.

If the user or/and patient occur any serious incident in relation to the device should be reported to Carilex and European Authorized Representative immediately.

Recommended environmental conditions:

- For Operating Conditions
  Temperature range: 20°C (68°F) to 30°C (95°F)
  Relative Humidity range: 15% to 90%
- For Storage Conditions
  Temperature range: 15°C (59°F) to 25°C (77°F)
  Relative Humidity range: 0% to 90%
- For Transport Conditions
  Temperature range: -25°C (-13°F) to 70°C (158°F)
  Relative Humidity range: 0% to 90%

CE 2460

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