

A. Introduction

Thank you for your selection of Carilex VT Canister for use in negative pressure wound therapy (NPWT). Carilex NPWT 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 canister is to be used only with the Carilex components: dressing kits 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.

CAUTION: DO NOT use the contents of a damaged package; instead, dispose of properly.

CAUTION: DO NOT re-use the VT Canister to avoid the cross infection.

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

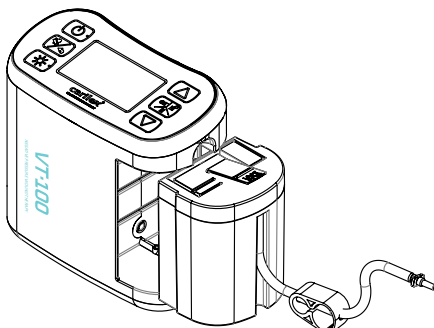
The following Warning statements describe the potential for serious consequences to the patient such as death, injury, or adverse reactions. Failure to read and follow all instructions in this manual prior to use may result in death or injury of the patient.

- 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.

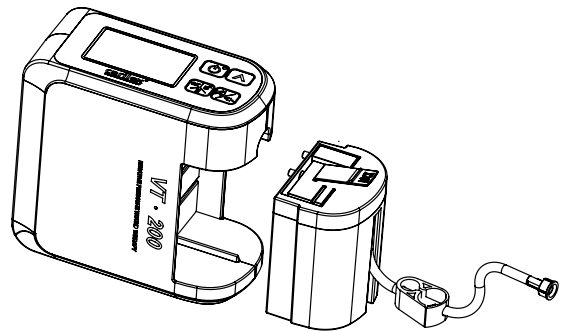
- Infected tissue such as blood vessels may have a weakened structure and have to be treated with care. Infected blood vessels may bleed more readily than normal blood vessels.
- To prevent leak, lockable connector should be properly tight.
- Patient tripped over the tube that may increase the risk associated 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. Install the Canister

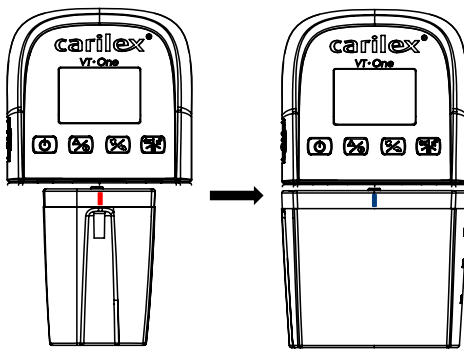
- Always make sure the canister is properly inserted and hear "click" for proper engagement.



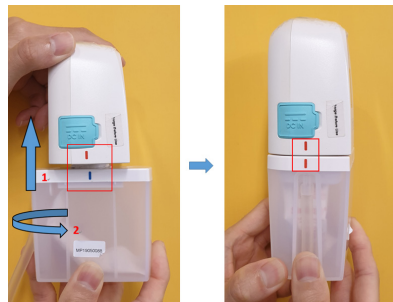
S1001 series



S1002 series



S1004 series



- Check tubing connectors to ensure they are fully engaged and locked.
- And must remain in an upright position during use.



S1001 & S1002 series



















S1004 series

G. Change the Canister

- The canister has to be changed on the basis of a visual check or according to the instructions on the display.
- When the liquid absorber reaches the canister full level, the audible and visual indicators will be triggered and the message indicator "canister full" will be displayed on the display panel.
- Do not pull the tubing of the canister horizontally to avoid the breaking of the suction inlet on the canister.
- The collection canister is to be properly discarded when full; it must be replaced after every patient use.
- The canister should also be inspected and replaced weekly or between patient uses or otherwise as needed

NOTE: DO NOT re-use the canister to avoid the cross infection.

H. Additional Symbols to the Safety Information

	Consult instruction for use		Quantity per pack		Batch code
	Single use only		Country and date of manufacture		Do not use if package is damaged or open
	Unique Device Identifier		Manufacturer		Use-by date
	Medical Device		USA Federal law restricts this device to sale by or on the order of a physician		Catalogue Number
	Authorized Representative in the European Community		Temperature limit		The CE mark indicates compliance with European harmonized legislation
	Model Number				

L. VT Caniseter

S1001-6020	Canister for VT · 100 - 500ml lock
S1001-6040	Canister for VT · 100 - 1000ml lock
S1001-6060	Canister for VT · 100 - 300ml lock
S1001-6100	Canister for VT · 100 - 300ml luer lock
S1001-6110	Canister for VT · 100 - 500ml luer lock
S1004-6010	Canister for VT · One - 150ml
S1004-6030	Canister for VT · One - 150ml Luer Lock



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

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

Recommended environmental conditions:

- For Operating Conditions
 - Temperature range: 5°C (41°F) to 40°C (104°F)
 - Relative Humidity range: 15% to 90%
- For Transport Conditions
 - Temperature range: -25°C (-13°F) to 70°C (158°F)
 - Relative Humidity range: 0% to 90%



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carilex[®]

產品用途

本產品是一種針對醫院、護理之家和家居照護而設計的負壓傷口治療產品，可在傷口內形成負壓環境，移除灌洗液和體液、傷口滲液及感染物質等液體，以促進傷口癒合。

A. 前言

感謝您選擇“暄達”負壓傷口治療系統應用於負壓傷口治療。負壓傷口治療是藉由真空動力式體液吸收器於傷口床形成負壓環境，達到移除傷口清洗溶液（如生理食鹽水）、傷口滲液、體液及感染物質等，以維持良好的治療環境並促進周遭血液微循環，從而達到促進傷口癒合的效果。

請於第一次使用“暄達”負壓傷口治療系統收集罐（以下簡稱本產品）前詳閱此使用手冊。

B. 適應症

本產品僅能搭配“暄達”負壓傷口治療機合併使用。

本產品適用於：

- 慢性傷口
- 急性傷口
- 外傷性傷口
- 糖尿病潰瘍
- 壓瘡
- 亞急性及開裂式傷口
- 部分皮層燒傷
- 皮瓣及網狀皮膚移植



本產品需經專業醫師評估傷口類型及情況，由醫師處方指示適用於負壓傷口治療



本產品僅限由受過專業醫療抽吸程序訓練之傷口護理、負壓傷口治療和居家照護等護理人員操作。

C. 禁忌症

有以下情況病患不建議使用負壓傷口治療：

- 存在痂皮的壞死組織
- 惡性腫瘤的傷口
- 未經治療的骨髓炎
- 暴露之血管、器官或神經、器官
- 非腸道性瘻管及未經檢查之瘻管
- 過度用於治療的血管或器官

D. 注意事項

- 已接受抗凝血劑或抗血栓藥物治療的病患。

未對傷口進行充分止血的病患將面臨出血風險，若不加控制，可能會致命，這些病患應在主治醫生認為適合的護理環境中接受治療和護理。開始治療前應考慮使用的負壓裝置及治療模式並注意接受抗凝血劑或抗血栓藥物治療的病患將面臨較大的出血風險（與傷口類型及複雜性有關）。

- 在使用本產品治療前，傷口內或周圍的所有暴露或淺表血管和器官必須完全覆蓋和受到保護，從頭到尾要確保敷料不直接接觸血管或器官。使用自體組織能提供最有效的保護，若不具備或無法從外科手術獲取此種自體組織，在主治醫生認為替代材料能提供完整的保護前提下，可考慮使用多層細孔防黏材料或生物組織替代。使用防黏材料時，確保其被固定在對應部位中整個治療過程中始終提供保護作用。
- 開始治療時應考慮使用的負壓設置及治療模式。
- 當治療可能含有不易發現的隱藏血管的大創面時，應特別謹慎。患者應在治療醫生認為合適的護理環境中密切監測出血情況。
- 存在銳邊風險

碎片或銳邊可能刺穿保護屏障、血管或器官，因而引起損傷。任何損傷都可能導致出血，若不加控制，可能致命。注意傷口內銳邊與組織、血管或器官相對位置可能發生改變而接觸。使用本產品進行治療前必須清除或覆蓋傷口部位的銳邊或骨頭碎片，來防止可能的刺穿血管或器官。盡可能完全磨平或覆蓋任何殘邊，以防止萬一發生移動時造成的損傷，來降低嚴重損傷或致命傷的風險。從傷口部位移除敷料時應盡可能謹慎，以防止創面組織被未經保護的銳邊劃傷。

- 為了降低血源性病原體傳播的風險，無論何種診斷結果或是否懷疑存在感染，所有病患均可按醫療機構標準作業程序來預防感染。對所有病患及醫療機構規定，無論診斷結果或懷疑有感染情況，均施行標準防護措施來控制感染。如果有接觸體液的可能性，除了戴手套，還應穿防護衣和護目鏡。

E. 警語

- 若本產品已停止運作 2 小時以上，請移除敷料
- 病患身高和體重

在為病患給予負壓傷口治療前應考慮病患的身高和體重，且要密切監控嬰兒、兒童、一些體形較小的成人和老年病患的體液流失和脫水情況。另外，密切監控傷口面嚴重滲液或相對身高和體重而言傷口面較大的病患，因為這些病患可能存在體液流失過多及脫水的危險。監控體液流失情況時，也應將引流管及廢液罐中的液體量考慮在內。

- 傷口感染

傷口感染應接受密切監控，綜合傷口情況、治療目標及設定治療參數等因素，其敷料更換頻率高於非感染傷口。任何傷口治療，臨床醫生及病患/護理人員應經常檢查病患的傷口、傷口周圍的組織及滲出液是否存在感染徵兆、感染是否惡化或出現其它的併發症。一些感染徵兆包括發燒、紅、腫、癢、痛、傷口內或傷口周圍組織體表溫度升高、膿液或強烈的氣味。嚴重的感染會導致疼痛、不適、發燒、壞疽、中毒性休克、感染性休克和/或死亡等併發症。全身感染的一些徵兆或併發症包括噁心、嘔吐、腹瀉、頭痛、暈眩、昏厥、心跳加快、高燒。如果出現任何全身或傷口部位的感染徵兆，立刻聯絡醫生，以確定是否需停止進行本產品治療。

- 保護肌腱、韌帶和神經

本產品治療期間應保護肌腱、韌帶和神經，避免其與海綿敷料直接接觸。這些接觸面可用自體組織、網狀防黏材料或生物工程組織覆蓋，以將乾燥或本產品使用說明損傷風險降至最低。

- 保護傷口面周圍的皮膚

不得將海綿敷料疊蓋在完整的皮膚上，另外可使用黏性密封薄膜、水膠體或其他透明薄膜保護傷口面周圍脆弱的皮膚。

- 磁共振造影 (MRI)

本產品進行負壓傷口治療在 MR 環境中構成危險，禁止將本產品帶入 MR 環境中。

• 高壓氧療法 (HBO)

禁止將本產品帶入高壓氧艙。本產品不適合在此環境中使用，並可能會有火災危害。在關閉負壓傷口治療機後，(1) 在高壓氧治療期間使用另一種與 HBO 相容的材料替換負壓傷口治療敷料；或者 (2) 在高壓氧艙內的整個治療過程中用濕紗布覆蓋引流管的開口端並用濕毛巾完全覆蓋敷料（包括引流管）若患者在高壓氧艙中預計會超過兩個小時，請移除敷料。

• 脊髓損傷

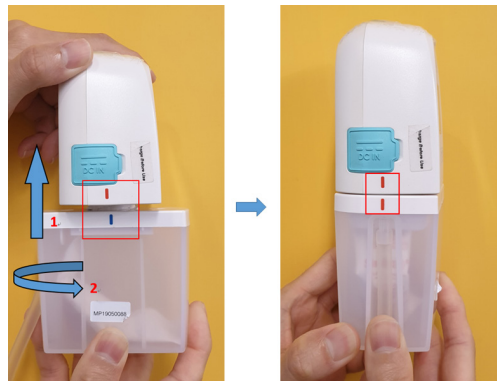
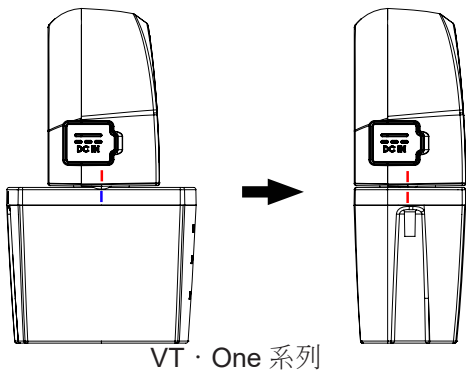
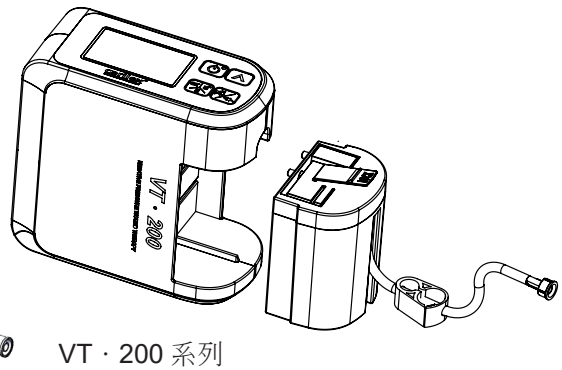
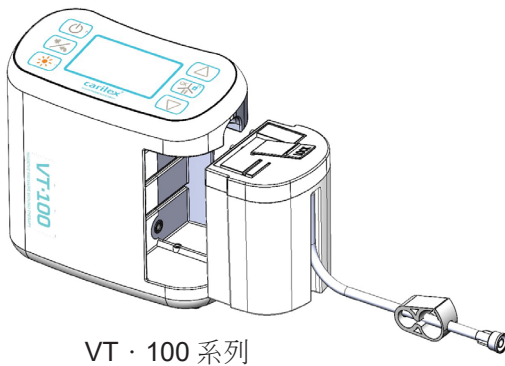
若病患出現自主反射亢進（受交感神經系統的刺激血壓或心率突然變化大），應立即停止負壓傷口治療，以將感覺刺激降至最低並立刻尋求醫療救助。

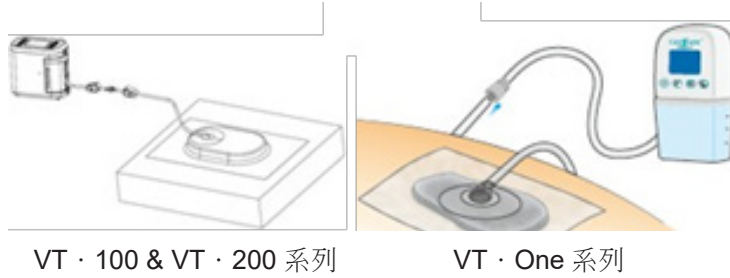
• 負壓傷口治療儀的壓力上升

極少數情況下，負壓傷口治療的引流管堵塞可能導致真空壓力短時間內上升至 -250mmHg 負壓以上，需要立刻解除造成警報的狀況，並聯絡製造業者。

F. 安裝收集罐

- VT·100、200 系列：安裝收集罐時必須聽到「喀」聲以確認收集罐安裝妥善。
- VT·One 系列：請將機器及罐身上的標示線對齊，並旋轉安裝。
- 將管路連接敷料並確實鎖上。
- 使用過程中機器及收集罐必須保持直立，避免橫放或倒置。





G. 更換收集罐

- 可目視收集罐中液體高度或依照顯示螢幕上的指示之時機更換收集罐
- 若收集罐集滿液體，即觸發聲音及視覺提示，螢幕上顯示「滿罐」
- 為避免破壞收集罐吸入口，請勿橫向拉扯管路
- 收集罐使用完畢或集滿後必須拋棄，不可重複使用收集罐
- 每位病人使用後必須更換收集罐以避免交叉感染
- 收集罐需每周檢查並更換，若有其他狀況需要也請更換收集罐



收集罐不得重複使用以避免交叉感染。

H. 相關符號

	使用前請詳閱使用手冊		包裝數量	LOT	產品批號
	禁止重複使用		製造地及製造日期		包裝破損請勿使用
	製造日期		醫療器材商及製造業者		有效日期
CE	歐盟認證	Rx only	醫療處方專用	REF	產品編號

I. 負壓傷口治療系統收集罐

S1001-6010	”暄達”負壓傷口治療系統 收集罐（未滅菌）300 cc/ml	衛部醫器製字第 005375 號
S1001-6020	”暄達”負壓傷口治療系統 可鎖式接頭 收集罐（未滅菌）500 cc/ml	衛部醫器製字第 005375 號
S1001-6030	”暄達”負壓傷口治療系統 收集罐（未滅菌）500 cc/ml	衛部醫器製字第 005375 號
S1001-6040	”暄達”負壓傷口治療系統 可鎖式接頭 收集罐（未滅菌）1000 cc/ml	衛部醫器製字第 005375 號
S1001-6050	”暄達”負壓傷口治療系統 收集罐（未滅菌）1000 cc/ml	衛部醫器製字第 005375 號
S1001-6060	”暄達”負壓傷口治療系統 可鎖式接頭 收集罐（未滅菌）300 cc/ml	衛部醫器製字第 005375 號
S1001-6100	”暄達”負壓傷口治療系統 魯爾接頭 收集罐（未滅菌）300 cc/ml	衛部醫器製字第 005375 號
S1001-6110	”暄達”負壓傷口治療系統 魯爾接頭 收集罐（未滅菌）500 cc/ml	衛部醫器製字第 005375 號
S1004-6010	”暄達”負壓傷口治療機 可鎖式接頭 收集罐（未滅菌）150 cc/ml	衛部醫器製字第 005719 號

醫療器材商 / 製造業者名稱：

暄達醫學科技股份有限公司

醫療器材商地址：桃園市龜山區科技一路 77 號

製造業者地址：桃園市龜山區科技一路 77 號 1、2、3 樓



carilex[®]

A. Introdução

Obrigado por escolher a utilização do Reservatório Carilex VT para o uso em Terapia de Feridas por Pressão Negativa (NPWT). Carilex NPWT destina-se a transferir a pressão negativa do dispositivo Carilex VT para o local da ferida proporcionando a remoção do fluido ativo. **POR FAVOR, LEIA ESTAS INSTRUÇÕES DE USO CUIDADOSAMENTE ANTES DE USAR ESTE DISPOSITIVO.**

B. Descrição

Reservatório coletor de fluido e exsudato translúcido, leve e ergonomicamente projetado. O sofisticado sistema de filtro de três camadas funciona como uma barreira para evitar contaminação cruzada e odor. Com um sachê de gel recíproco no reservatório para solidificar o fluido coletado, permitindo o descarte seguro e higiênico após o uso.

A trava de liberação do reservatório integrada para operação com uma mão e os marcadores de nível de fluido são fáceis de ler e foram projetados para que a operação seja sempre de forma fácil e eficaz.

Usuários previstos: Médicos e profissionais da saúde qualificados

Ambiente de uso: Carilex "NPWT" é destinado ao uso em hospitais, clínicas, asilos, lares de idosos, e home care.

Indicações:

Indicado em Terapia por Pressão Negativa

Benefícios clínicos:

Os benefícios da NPWT incluem rápida cicatrização de feridas, redução de trocas de curativos, redução do risco de infecção, redução dos custos de tratamento, controle do exsudato, redução de edema e fornecimento de um ambiente fechado e úmido para cicatrização da ferida, reabilitação concomitante e melhor conforto e tolerância do paciente.

C. Precauções

Sempre verifique se o reservatório está inserido corretamente e ouve um "clique" para o engate correto, e deve permanecer na posição vertical (estojo de transporte) durante uso. O reservatório Carilex foi projetado apenas para uso em um único paciente. **NÃO** reutilize o reservatório para evitar a infecção cruzada entre os pacientes

D. Precauções gerais para todas as indicações de uso

É importante que um médico ou outro profissional de saúde qualificado avalie o paciente para garantir que o uso da Carilex VT NPWT seja uma terapia apropriada.

Para reduzir o risco de transmissão de patógenos transmitidos pelo sangue, independentemente de seu diagnóstico ou estado de infecção presumido, todos os pacientes devem tomar precauções de procedimentos operacionais padrão médicos contra o controle de infecções. Além disso, o profissional de saúde deve usar luvas, avental e óculos de proteção (Se houver a possibilidade de contato com fluidos corporais do paciente).

E. Avisos

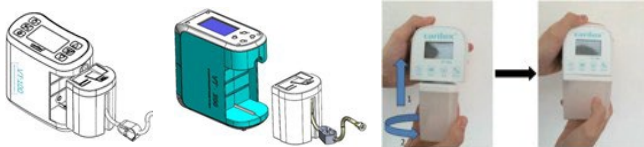
• Para evitar vazamentos, o conector deve estar bem apertado e travado.

NÃO utilize o reservatório se a embalagem estiver danificada; em vez disso, descarte adequadamente.

NÃO reutilize o reservatório para evitar a infecção cruzada.

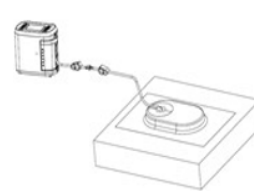
F. Instalação do reservatório

• Certifique-se sempre de que o reservatório esteja inserido corretamente até que se ouça um "clique" para o encaixe adequado.

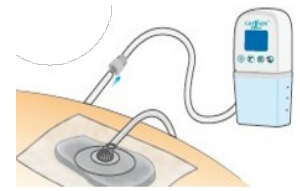


• Verifique os conectores da tubulação para garantir que estejam totalmente encaixados e travados.

• O equipamento deve permanecer na posição vertical durante o uso conforme exibido nas imagens abaixo.



Série S1001 & S1002



Série S1004

G. Troca do reservatório

• O recipiente deve ser trocado com base em uma verificação visual ou de acordo com as instruções no visor.

• Quando o absorvedor de líquido atingir o nível do reservatório cheio, os indicadores sonoros e visuais serão acionados e o indicador de mensagem "reservatório cheio" será exibido no painel do equipamento.

Não puxe a tubulação do reservatório na horizontal para evitar a quebra da entrada de sucção do reservatório.

• O reservatório deve ser descartado adequadamente quando estiver cheio; deve ser substituído após o uso no paciente.

• O recipiente também deve ser inspecionado e substituído semanalmente ou entre os usos do paciente ou conforme necessário.

NOTA: NÃO reutilize o recipiente para evitar a infecção cruzada.

H. Reservatório Carilex VT

S1001-6020	RESERVATORIO CARILEX - 500ml lock
S1001-6040	RESERVATORIO CARILEX - 1000ml lock
S1001-6060	RESERVATORIO CARILEX - 300ml lock
S1004-6010	RESERVATORIO VT ONE CARILEX - 150ml

Condições ambientais recomendadas:

• Para condições de operação:

Faixa de temperatura: de 5°C (41°F) a 40°C (104°F)

Faixa de umidade relativa: 15% a 90%

• Para condições de transporte e armazenamento:

Faixa de temperatura: -25°C (-13°F) a 70°C (158°F)

Faixa de umidade relativa: 0% a 90%

I. Símbolos Adicionais às Informações de Segurança

	Consulte as Instruções de uso		Quantidade por pacote		Código do Lote
	Não reutilizar		Pais e data de fabricação		Não utilize se a embalagem estiver danificada ou aberta
	Identificador de dispositivo exclusivo		Fabricante		Use-by date
	Equipamento Médico		A lei federal dos EUA restringe a venda deste dispositivo a médicos ou mediante prescrição médica		Número de catálogo
	Representante autorizado na Comunidade Europeia		Limite de Temperatura		Declaração de Conformidade com MDR 2017/745
	Número do Modelo				

Fabricante
Carilex Medical, Inc. (<https://www.carilexmedical.com/>)
No. 77, Keji 1st Rd., Guishan Dist., Taoyuan City, 333, Taiwan

Emgero Europe B.V.
Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands

