

Avelle™

CR4395 Negative Pressure Wound Therapy System

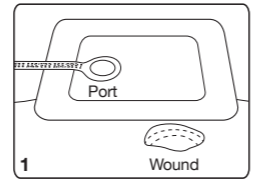
INSTRUCTIONS FOR USE

- PRODUCT DESCRIPTION**
The Avelle™ Negative Pressure Wound Therapy (NPWT) System consists of a non-sterile pump, a sterile wound dressing, fixation strips and batteries. The pump is a disposable unit that may be used for up to 30 days as a single patient use device. The dressing may be left in place for up to 7 days. A nominal negative pressure of 80mmHg is maintained at the wound surface by the Avelle™ NPWT Pump. Wound exudate is managed by the dressing through the absorption and gelling capability of Hydrofiber™ Technology and via moisture evaporation at the dressing outer surface.
- INDICATIONS**
The Avelle™ NPWT System is indicated for use on patients that would benefit from a NPWT device and with a low to moderately exuding wound, such as:
 - Chronic Wounds e.g. Leg ulcers
 - Acute Wounds
 - Subacute and dehisced wounds
 - Traumatic wounds
 - Flaps & Grafts
 - Surgically closed incision sites
- PATIENT SELECTION**
Healthcare Professionals (HCP) trained in the use of the Avelle™ NPWT system should assess patient suitability for in home use. Selection should take into account the indications, contraindications, observations and warnings. The HCP should ensure that users are educated in the use of the Avelle™ NPWT system alerting them to Section 8 and 9 of this information leaflet. Patient selection for home use should be based upon:
 - Wound location
 - Patient/carer understanding of the device and its use
 - Physical ability of the patient/carer to operate the system on a daily basis
- CONTRAINDICATIONS**
The Avelle™ NPWT System should NOT be used in the following situations:
 - Patients who are sensitive to, or have known allergies to, silicone/acrylic adhesives, sodium carboxymethylcellulose or nylon.
 - Malignant wounds (wound bed and/or wound margins) (except in palliative care to enhance quality of life).
 - Wounds with confirmed and untreated osteomyelitis.
 - Non-enteric and unexplored fistulas.
 - Necrotic wounds or wounds with eschar present.
 - Wounds with exposed arteries, veins, nerves or organs.
 - Anastomosis sites.
 - For emergency airway aspiration.
 - Pleural, mediastinal or chest tube drainage.
 - Surgical suction.
 - Burns including partial thickness burns.
- PRECAUTIONS/WARNINGS**
FOR USE UNDER THE DIRECTION OF A HEALTHCARE PROFESSIONAL
The Avelle™ NPWT Dressing is single use and should not be re-used. Re-use may lead to increased risk of infection or cross contamination.
 - The pump is intended for single patient use only. Re-use may lead to increased risk of infection or cross-contamination.
 - Dressing sterility is guaranteed unless the dressing pouch is damaged or opened prior to use. Do not re-sterilise.
 - The Avelle™ NPWT Dressing should not be used with alternative NPWT devices. The Avelle™ NPWT Pump should not be used with any other NPWT accessories other than those stated in Section 13.
 - Care should be taken at all times to ensure the tubing and the connections to the pump are not kinked, and the tubing and pump are not trapped in clothing/bedding/bandages, in a position where they could cause pressure damage to the patient or placed where there could be a trip or strangulation hazard.
 - Wounds with protruding sharp bones or fragments must be protected by a suitable dressing, or they must be removed prior to using the Avelle™ NPWT System due to a risk of puncturing organs or blood vessels whilst under negative pressure.
 - The Avelle™ NPWT System may be used alongside surgical drains, but the dressing must not be placed over the tubing where it exits the skin as this may compromise the dressing seal and effective performance of the drain.
 - If a surgical drain is being used, it should operate independently of the Avelle™ NPWT System and be positioned away from the dressing edge.
 - Care should be taken that circulation is not lost through use of a circumferential dressing or NPWT on ischaemic limbs.
 - In the event of defibrillation, ensure the Avelle™ NPWT Pump has been disconnected. Remove Avelle™ Dressing if placed where defibrillation is required so

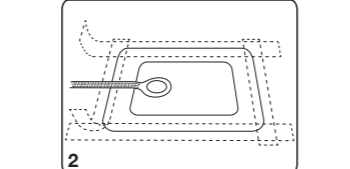
- During the body's normal healing process, non-viable tissue is removed from the wound (autolytic debridement), which could initially make the wound appear larger. If the wound becomes infected, dressings should be checked more frequently and may require changing more often.
- When the Avelle™ NPWT Dressing is used on friable skin, a skin protector, such as Sensi-Care™ Sting Free Skin Barrier, should be used prior to the application of the fixation strips.
- If the Avelle™ NPWT System is used to bolster skin grafts, inspect the wound regularly, especially in the first week, to ensure negative pressure is continually applied and a seal is maintained.
- If the wound contact pad is adhered to the wound, soak with sterile saline or sterile water prior to removal. The adhesive border requires lifting prior to pre-soaking. Careful patient selection is essential; the stated contraindications and precautions should be taken into account.
- ADVERSE REACTIONS**
A serious risk linked to the use of suction on wounds is excessive bleeding which may lead to serious injury or death. The wound and wound dressings should be regularly inspected for any sign of a change in the patient's blood loss status.

- DIRECTIONS FOR USE**
Dressing Selection
When selecting the appropriate dressing the following should be considered:
 - The wound should fit comfortably within the pad area allowing for the port to be positioned over intact skin.
 - For a moderately exuding wound, the wound area should be no more than 25% of the pad area, ensuring there is a least a 1cm overlap of the pad onto the peri-wound skin.
 - Wounds greater than 0.5cm in depth may need to be used in conjunction with AQUACEL® Extra or AQUACEL® dressings, or, if not available, standard gauze. See Section 7.6.
- System Application**
7.2.1 Initial application and setup of the system is to be performed by a Healthcare Professional trained in the application of NPWT devices.
 - Patients with difficult haemostasis.
 - Patients actively bleeding, receiving anticoagulants or platelet-aggregation inhibitors.
 - Patients with wounds in close proximity to delicate fascia or blood vessels.
 - Patients having weakened or friable blood vessels, or organs in or around the wound because of, but not restricted to, infection, trauma, anastomosis, or radiation.

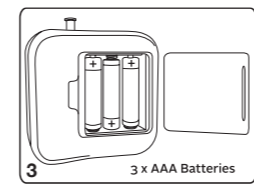
- 7.2.2 If the pump unit has been transported or stored outside the recommended operational temperature range of 5-40°C, allow the pump unit to acclimatise e.g. warm up or cool down at room temperature for at least 10 minutes.
- 7.2.3 If required, remove any excess hair from the peri-wound skin in order to ensure good contact between the peri-wound skin and the adhesive of both the dressing adhesive border and fixation strips.
- 7.2.4 Irrigate the wound with sterile saline as required and ensure the peri-wound skin is dry prior to dressing application.
- 7.2.5 Use an aseptic technique to apply the dressing to the wound:
 - Remove the release liners.
 - Apply the dressing centrally and flat to the wound and surrounding skin (image 1). Ensure that the port is positioned away from the wound uppermost over intact skin.



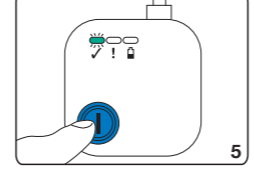
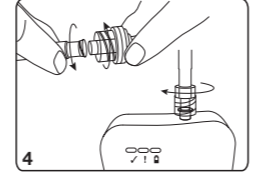
- 7.2.6 Do not use with creams/oil based products, as the dressing and strips may not form an effective seal. The Avelle™ NPWT Dressing is not compatible with oil-based products, such as petrolatum.
- 7.2.7 Do not disassemble or modify the pump. The pump unit does not contain any serviceable parts and does not require calibration prior to use.
- 7.2.8 Do not cut the dressing or tubing.
- 7.2.9 Do not place occlusive dressings over the Avelle™ NPWT Dressing.
- 7.2.10 Do not use pump if battery compartment cover is missing.
- 7.2.11 Do not expose any elements of the system to direct heat or sunlight.
- 7.2.12 Do not secure the pump against the skin.
- 7.2.13 Do not allow small children to play with the Avelle™ NPWT Pump, as the batteries/battery door could pose a choking hazard. Keep out of reach of children.
- 7.2.14 Replace pump and tubing at the same time. Hot and humid environments may affect the adherence of the dressing.
- 7.2.15 The Avelle™ NPWT System has not been demonstrated for use in paediatrics or neonates.
- 7.2.16 Use only with the instructions supplied with this device.
The health care professional should advise the patient of the following:
 - To inform their healthcare professional should they experience symptoms of irritation, increased pain, leakage of wound exudate, or evidence of bleeding.
 - If bleeding is evident, patients should be instructed to disconnect the pump, leave the dressing in place and seek medical assistance.
 - Not to change the Avelle™ NPWT Dressing.
 - When showering, disconnect the Avelle™ NPWT Pump from the dressing and do not directly spray the dressing or submerge in water.



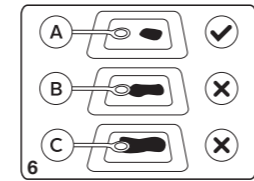
- OBSERVATIONS**
Note: Because Hydrofiber™ Technology is known to support the growth of new blood vessels, the delicate newly formed blood vessels may occasionally produce blood-stained wound fluid.



- 7.2.7 Twist together the connectors to securely connect the dressing, pump and pump tubing (image 4). Do not over tighten. The dressing tubing can be connected directly to the pump if a shorter connection is preferred. Press the blue button on the front of the pump for 3 seconds to start. The green ✓ indicator light will start to flash to confirm the pump is working and it will take up to 30 seconds to establish negative pressure; the pump can be heard functioning during this time (image 5). If negative pressure is not established, the Yellow ! indicator light will illuminate. Refer to Section 9 for general troubleshooting.



- 7.2.8 On initiation of therapy it is expected that the operator will be situated directly in front of the pump unit.
- 7.2.9 As the pump is designed to be portable/hand held its location during use will be dependent upon the patient's status and wound location. The pump should not be placed in direct contact with skin for prolonged periods of time and should be positioned adjacent to the patient e.g. within their outer garments or in a bag carried by the patient.
- 7.2.10 Contact ConvaTec if you require assistance in setting up, using or maintaining the Avelle™ NPWT System, or if any unexpected alerts, faults or events are noted with the system.
- Dressing Change**
7.3.1 The dressing should be changed in accordance with these instructions or as clinically indicated. A typical wear time is 3-4 days up to a maximum wear time of 7 days. Depending on wound exudate level or other clinical indicators, a more frequent dressing change may be required – refer to Sections 4.15, 4.17 and 5.2. The dressing should also be changed if there are signs of leakage, pooling around the port, or loss of adhesion.



- A. Dressing is positioned correctly and can remain in place (image 6).
- B. Dressing needs to be changed as port may become blocked with exudate (image 6).
- C. Dressing needs to be changed as dressing has reached its absorption capacity and port may become blocked with exudate (image 6).
- 7.3.2 Regularly check the dressing. Before changing the dressing:
 - Turn off the pump by pressing the blue button for 3 seconds and disconnect the tubing to separate the pump from the dressing.
 - To remove the dressing, carefully stretch the fixation strips away from the skin and lift and remove the dressing. Use an adhesive releaser to help with removal, e.g. Sensi-Care™ Sting Free Adhesive Releaser Spray.
- 7.3.3 If NPWT is to be continued, apply a new Avelle™ NPWT dressing repeating the steps in Section 7.2, reconnect the dressing to the Avelle™ NPWT pump and press the blue button for 3 seconds to restart NPWT. The green ✓ indicator light will flash to show the system is working correctly

- Pump Change**
 - The pump is designed to operate for 30 days from start of negative pressure therapy.
 - The pump is supplied with one set of batteries which should power the pump for a period in excess of 7 days but may require replacement within the 30 days.
 - The yellow ! indicator light will illuminate when battery power is low. Refer to Section 9.2.

- After 30 days all indicator lights will stop illuminating. Refer to Section 9.1.
- To change the pump, disconnect the tubing from the dressing by untwisting the connectors and connect the new pump and new tubing – refer to Section 7.2.7.
- Disposal**
 - Used dressings should be disposed of as clinical waste in accordance with local clinical protocols.
 - Used pump units should have batteries removed and batteries recycled. Where possible pump units should be decontaminated and recycled. If contaminated with bodily fluids, wipe with a non-flammable antimicrobial wash, for additional guidance the patient or carer should visit www.convatec.com or contact ConvaTec. If decontamination is not possible pumps should be disposed of as clinical waste in accordance with local clinical guidelines. Recycling of batteries and pump units should be in accordance with local recycling regulations and the Waste Electrical and Electronic Equipment (WEEE) directive where applicable.
- Wound fillers, contact layers, and compression**
 - For shallow wounds (up to 0.5cm in depth) the Avelle™ NPWT System does not need to be used with a filler dressing. For deeper wounds up to 2.0cm a filler may be used such as AQUACEL® Extra™ or AQUACEL® dressings. If unavailable, standard gauze may be used. Fillers should be changed along with the Avelle™ NPWT Dressing.
 - The Avelle™ NPWT System can be used in conjunction with compression therapy if required. Care should be taken to ensure that the tubing is routed outside the bandage.

- GENERAL/DAILY USE**
Intended operators are healthcare professional or patient/carer in a home healthcare environment.
- ON/OFF**
The Avelle™ pump unit is fitted with a single button. Press the blue button for 3 seconds to turn the pump ON or OFF.
- Showering and bathing**
 - A light shower is possible, but the dressing should not be directly sprayed or submerged in water.
 - Prior to showering, turn off the pump by pressing the blue button for 3 seconds and disconnect the tubing to separate the pump from the dressing (image 4), and place in a safe, dry place.
 - The dressing will maintain vacuum for approximately 60 minutes upon disconnection from the pump.
 - After showering re connect dressing to the pump unit in accordance with Section 7.2.7 (image 4) and press the blue button for 3 seconds to re instate therapy (image 5). Check pump and dressing are functioning correctly (Section 9). If therapy cannot be re-established, the patient or carer should contact the Healthcare Professional.
- Battery replacement**
 - Turn the pump OFF and change the batteries in accordance with Section 7.2.6. If batteries are not changed within the suggested time period the pump will automatically turn OFF ceasing therapy and the yellow ! indicator light will flash when the blue ON/OFF button is pressed.
- Cleaning**
 - To clean the pump unit's outer surfaces, wipe with a soft, lint free cloth dampened with mild soapy water. If contaminated with bodily fluids, wipe with a soft lint free cloth dampened with a non-flammable antimicrobial wash. Do not immerse in fluids.
- Routine operation**
 - The Avelle™ NPWT Pump unit is fitted with visual indicators to show the pump is functioning accurately. The Avelle™ NPWT Pump unit is not fitted with audible alarms. During use, users should regularly check the pump is functioning accurately. For definitions of the pump units operating indicators consult Section 9. If therapy cannot be established for any reason the patient or carer should contact their Healthcare Professional or ConvaTec.
 - Ensure all tubing is free from kinks where possible as not to block the flow of negative pressure.
- Precautions/Warnings** **Patients should be advised of the following:**
 - Do not perform any maintenance whilst the pump is in use, i.e. cleaning or changing of batteries.
 - Keep pump unit out of direct sunlight and away from direct heat.
 - Do not secure pump against the skin.
 - When showering, disconnect the Avelle™ NPWT Pump from the dressing and do not directly spray the dressing or submerge in water. The pump unit has been tested and rated to IP22 as to not be damaged or become unsafe if accidentally exposed to vertically or nearly vertically dripping water and is protected against solid objects >12.5mm e.g. a finger.
 - Keep pump unit free from dust and lint and out of reach of children, pets or pests. During use the pump unit and tubing should be routinely inspected for the following:
 - Dust and lint on the pump unit: refer to cleaning Section 8.4.
 - Damage to the pump unit or tubing by pest, pets or children: if there is evidence of damage the patient or carer should contact their Healthcare Professional.
 - For additional precautions/warnings refer to Section 4.

9. PUMP INDICATION, OPERATING AND TROUBLESHOOTING GUIDE

9.1 Normal Operation

Visual Indicator(s) Display and Status	Possible Cause(s)	Corrective Action/Comments
	The pump unit is turned OFF.	Therapy is not being applied. Press the blue button for 3 seconds to initiate therapy, green ✓ indicator light will flash periodically.
	The pump unit is turned OFF.	If the pump unit has been in use for less than its 30 day life span, battery power may be depleted and batteries should be replaced.
	The pump unit has exceeded its lifespan.	The pump unit has a maximum lifespan of 30 days, upon which the pump unit will stop operating and therapy will cease. Pressing the blue button for 3 seconds will cause both yellow indicator lights to flash alternately, but the pump unit will not start.
	This indicates the batteries have been fitted correctly and the pump unit is ready for use.	Pump unit functioning correctly.
	When attached to an affixed dressing and turned ON, the pump unit is signifying it is operating correctly.	During regular use the pump unit should run intermittently (several times per hour) ensuring a negative pressure within the device is maintained. Increases in the dressing's adhesive border may cause the pump to run more frequently; smoothing creases out may reduce pump run frequency.

9.2 Alerts and Faults

Visual Indicator(s) Display and Status	Possible Cause(s)	Corrective Action/Comments
	Negative pressure therapy is not being established due to an air leak in the system.	The pump unit will turn OFF after 10 seconds if the target negative pressure has not been established. Check dressing/tubing/pump connections are secure. Check for possible air leaks and smooth out any creases in the dressings adhesive border. Note that kinks in the tubing will not cause the Yellow ! indicator light to flash. Press the Blue button for 3 seconds to initiate therapy, the Green ✓ indicator light will flash as pressure is established. If the air leak persists the Yellow ! indicator will flash and the pump will again turn OFF. Continue checking the dressing for creases and all connectors for leaks and press blue button for 3 seconds. If therapy cannot be established the patient or carer should contact the Healthcare Professional.
	The pump unit is signifying it is operating correctly.	Change all batteries within 24 hours.
	Battery power is low.	Press blue button for 3 seconds to turn off the pump unit. Open the battery compartment door located at the back of the unit and remove and replace all 3 AAA batteries and secure compartment door. Press the blue button for 3 seconds to re initiate therapy. Dressing connector is fitted with a one way valve to reduce pressure loss and to assist with the maintenance of therapy when the pump unit is disconnected for short periods of time.
	Air leak in the device	Address air leak as previously indicated above.
	Battery power is low	Change all batteries within 24 hours as previously indicated above.

10. Avelle™ Pump Unit Specifications (model CR4395)

Pump Unit Specifications		Pump Unit Specifications	
Dimensions (maximum)	72mm x 78mm x 25mm	Ingress protection	IP22
Weight (excluding batteries)	78g	Storage/Transport	5-25°C (41-77°F) 15-85%RH 700 to 1060 mbar atmospheric pressure
Lifespan (pump unit) once batteries installed	30 days	Operation environment	5-40°C (41-104°F) 700 to 1060 mbar atmospheric pressure
Power/Type	4.5V DC/Battery	Compliance	Directive 93/42/EEC; IIA IEC EN60601-1 IEC EN60601-1-2
Battery type/Quantity	3x AAA Philips™ Lithium Ultra FR03 batteries	Sterility	non sterile
Mode of Operation	Continuous	Programmable Electronic Medical Systems (PEMS) identifier	SNPC1
Nominal vacuum	80mmHg	Materials of Construction (patient contact)	Pump (moulded parts) - Polycarbonate/ABS Tubing - PVC (DEHP free)
Maximum vacuum	140mmHg		
Equipment Classification	Internally Powered		
Degree of Protection Against Electrical Shock	Type BF Applied parts include Avelle™ pump, extension tubing and Avelle™ dressing.		

- Electromagnetic Compatibility**
Having been tested, this device is compliant with the limits for medical devices in accordance with EN60601-1-2:2014. These limits are designed to provide reasonable protection to assure the safety of medical devices from interference from other electrical equipment and devices. This equipment can be affected by radio frequency energy and, if not installed and used in accordance with the instructions, may cause interference to other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation. If further information or guidance on electromagnetic immunity and emissions is needed, please contact ConvaTec or visit us online at www.convatec.com.
- Cautions**
These instructions for use are not intended as a guarantee or warranty. They are only intended as a guide. For medical questions, please consult a physician. This product must be used in accordance with these instructions for use and related labelling.
- Required Components to Operate the Avelle™ NPWT System Effectively**
 - Avelle™ NPWT sterile dressing (sterilisation via Ethylene Oxide)
 - 6x Adhesive fixation sterile strips (supplied with dressing and sterilisation via Ethylene Oxide)
 - Avelle™ NPWT pump unit (CR4395)
 - 3x AAA Philips™ Lithium Ultra FR03 batteries (supplied with pump unit and recommended)
 - Extension tubing with luer connectors (supplied with pump unit)
 - Instructions for use (supplied with dressing and pump unit)

14. Definition of Symbols

Symbol	Definition	Symbol	Definition
	Lot Number		Temperature limits
	Ethylene Oxide Sterilised		Atmospheric Pressure Limits
	Humidity Limits		Consult Instruction for Use (pump only)
	Non Sterile		ON/OFF
	Serial Number		Low Power Indicator
	Order Number		Device is Operating Correctly
	Manufacturer (EU)		Device is Not Operating Correctly
	Date of Manufacture		Battery/Type Powered
	CE mark		Keep Away from Sunlight
	Do Not Reuse		Opening End
	Keep Dry		Consult Instructions for Use
	EU: Not for General Waste		Do Not Re-sterilise
	Equipment Classification Isolation Type BF		Voltage
	Latex Free		Fragile - Handle with Care
	Caution		Expiry Date
	Do Not Use if Pack is Damaged		Enclosure Rating
	Risk of Explosion		MIR Unsafe - keep away from magnetic resonance imaging (MRI) equipment
	Do Not Charge		Do Not Mix Different Types of Brands
	Do Not Deform or Damage		Do Not Mix New and Used
	Do Not Dispose of in Fire		Do Not Open or Dismantle
	Do Not Insert Incorrectly		Do Not Short Circuit
	Keep Out of Reach of Children		

The Avelle™ NPWT System is manufactured and packaged in the UK; origin of batteries is as labelled.

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