ConvaTec

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Avelle™

Negative Pressure Wound Therapy System

INSTRUCTIONS FOR USE

1. PRODUCT DESCRIPTION

The Avelle™ Negative Pressure Wound Therapy (NPWT) System consists of a non- sterile pump, a sterile wound dressing, extension tube set, fixation strips and two sets of three batteries.

A negative pressure of 80mmHg ±20mmHg 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.

The Avelle™ NPWT System is intended for use in wounds which are considered to be low to moderately exuding up to a depth of 2cm (0.8 in.) For low to moderately exuding wounds, the wound area should be no more than 25% of the pad area of the dressing. Place the dressing port over intact skin and not over the wound.

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. Wear time of the dressing may be less than indicated if clinical practice or other factors result in more frequent dressing changes. The dressing changes should be performed by an appropriately qualified Health Care Professional.

2. INDICATIONS

The Avelle™ NPWT System is indicated for use on patients that would benefit from a NPWT device as it may promote wound healing via removal of exudate and infectious materials from low to moderately exuding wounds, such as:

- Chronic wounds e.g. leg ulcers
- Acute wounds
- Subacute and dehisced wounds
- Traumatic wounds
- Flaps & grafts
- Surgically closed incision sites

Avelle™ NPWT System is suitable for use in a hospital, post-acute and home health environment.

2.1 Patient Selection

Health Care 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 7 and 8 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

3. 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.
- Anastomosis sites.
- For emergency airway aspiration.
- Pleural, mediastinal or chest tube drainage.
- Surgical suction.
- Burns including partial thickness burns.

4. ⚠ PRECAUTIONS/WARNINGS

FOR USE UNDER THE DIRECTION OF A HEALTH CARE PROFESSIONAL

4.1 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.

4.2 The dressing change frequency must be determined and performed by a suitably qualified Health Care Professional.

4.3 The pump is intended for single patient use only. Re-use may lead to increased risk of infection or cross-contamination.

4.4 Dressing sterility is guaranteed unless the dressing pouch is damaged or opened prior to use. **Do not** re-sterilise.

4.5 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 12.

4.6 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 they could be a trip or strangulation hazard.

4.7 Wounds with exposed sensitive structures such as, but not limited to, blood vessels, nerves, organs and tendons should be protected from direct contact with the NPWT dressing according to current clinical practice guidelines.

4.8 Wounds with exposed bones or fragments must be protected by a suitable dressing, according to current clinical practice guidelines, prior to using the Avelle™ NPWT Dressing.

4.9 A risk linked to the use of NPWT is bleeding which may be minor or excessive and could lead to serious injury or death. The Avelle™ NPWT Dressing and wound should be carefully monitored for any signs in blood loss. In the event of bleeding the dressing color would change and the bleeding would be visible to the clinician allowing for a clinical intervention.

4.10 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.

4.11 If a surgical drain is being used, it should operate independently of the Avelle™ NPWT System and be positioned away from the dressing edge.

4.12 Care should be taken that circulation is not lost through use of a circumferential dressing or NPWT on ischaemic limbs.

4.13 In the event of defibrillation, ensure the Avelle™ NPWT Pump has been disconnected. Remove the Avelle™ NPWT Dressing if placed where defibrillation is required so not to prevent electrical transmission and patient resuscitation.

4.14 ⚠ The Avelle™ NPWT Pump should be considered a fire hazard in oxygen rich environments. Avelle™ is unsuitable for use in areas where there is danger of explosion (e.g. hyperbaric oxygen chamber).

4.15 The Avelle™ NPWT Pump is **MRI Unsafe**; the pump must be disconnected from the Avelle™ NPWT Dressing prior to entry into the MRI suite.

4.16 The Avelle™ NPWT Pump could affect or be affected by CT scanning/X-ray equipment. The Avelle™ NPWT Pump must be removed prior to entry into the scanner/X-ray suite. The dressing may remain in place. The Avelle™ NPWT System should be used with caution when in the vicinity of electronic equipment such as metal detectors, Radio Frequency Identification Readers or anti-theft equipment, as the potential of EMC interference in all settings cannot be eliminated. Check to ensure the pump is functioning correctly as explained in Section 8.1.

4.17 Patients must be closely monitored for bleeding as some patients are at a high risk of bleeding complications. If significant bleeding is observed, the therapy should be interrupted and appropriate medical personnel should be contacted immediately. Precautions should be taken in the following situations due to a high risk of bleeding complications:

- Patients with difficult haemostasis.
- Patients receiving anti-coagulants 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.

4.18 The Avelle™ NPWT System can be used on patients receiving anticoagulants; however, haemostasis must be achieved prior to application. Ensure haemostasis is maintained throughout NPWT. Assess frequently throughout therapy as patients receiving anticoagulants have an increased risk of bleeding during therapy.

4.19 The wound should be inspected during dressing changes for signs of infection, increased pain, bleeding, warmth, redness of surrounding tissue, and any other unexpected symptoms that occur.

4.20 Care should be taken in the following circumstances:

- Where wounds are near an anastomosis site or near weakened or friable blood vessels or organs or in the presence of wound infection, trauma or radiation.

4.21 **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.

4.22 **Do not** disassemble or modify the pump.

4.23 The pump unit does not contain any serviceable parts and does not require calibration prior to use.

4.24 **Do not** cut the dressing or tubing or pull on the tubing.

4.25 **Do not** place occlusive dressings over the Avelle™ NPWT Dressing as this may prevent inspection and moisture evaporation.

4.26 **Do not** use the pump if the battery compartment cover is missing.

4.27 **Do not** expose any elements of the System to prolonged direct heat or sunlight.

4.28 **Do not** secure the pump against the skin.

4.29 **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.

4.30 Replace the pump and tubing at the same time.

4.31 The Avelle™ NPWT System has not been demonstrated for use in paediatrics or neonates.

4.32 Use only with the Instructions for Use (IFU) supplied with this device.

4.33 Avoid exposure of the Avelle™ NPWT Pump to sources of liquid. If fluid ingress is observed, discontinue use of the device.

4.34 Avelle™ NPWT System is not intended for use on aircraft; batteries should be removed. Follow airline company policy on lithium battery storage and transportation.

The Health Care Professional must advise the patient of the following:

- To inform their Health Care 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/or the extension tube set (if fitted) and **do not** directly spray the dressing or submerge in water.
- The Avelle™ NPWT System does not emit an audible alarm and that the Avelle™ NPWT Pump should be accessible so that status can be monitored regularly.
- Check that the system is functioning correctly immediately prior to sleeping and on awakening.
- On careful placement of the pump and tubing during home use.

4.35 KEEP OUT OF REACH OF CHILDREN. Swallowing can lead to chemical burns, perforation of soft tissue, and death. Severe burns can occur within 2 hours of ingestion. Seek medical attention immediately.

4.36 Incorrect replacement of batteries could result in a hazardous situation such as excessive temperatures, fire or explosion.

4.37 **Do not** allow children to replace batteries.

4.38 Always insert batteries correctly with regard to polarity (+ and –) marked on the battery. Warning, replacement of batteries by inadequately trained personnel could result in a hazard.

4.39 **Do not** force discharge batteries.

4.40 Exhausted batteries should be immediately removed from equipment and properly disposed of.

4.41 **Do not** weld or solder directly to batteries.

4.42 A lithium battery with a damaged container should not be exposed to water.

4.43 **Do not** encapsulate and/or modify batteries.

4.44 Store unused batteries in their original packaging away from metal objects. If already unpacked, **do not** mix or jumble batteries.

5. OBSERVATIONS

5.1 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.

5.2 If the wound becomes infected, dressings should be checked more frequently and may require changing more often. NPWT is not intended to treat infection. If there are any signs of systemic or advancing infection at the wound area the treating Health Care Professional should be contacted immediately.

5.3 When the Avelle™ NPWT Dressing is repeatedly used or 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 to avoid skin stripping.

5.4 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.

5.5 Careful patient selection is essential; the stated contraindications and precautions should be taken into account.

5.6 Based on *in vitro* performance testing, the Avelle™ NPWT Dressing is an effective barrier to viruses larger than 27nm.

6. DIRECTIONS FOR USE – For the Health Care Professional Only

6.1 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 low to moderately exuding wounds, the wound area should be no more than 25% of the pad area, ensuring there is at least a 1cm (0.4 in.) overlap of the pad onto the peri-wound skin.
- Wounds greater than 0.5cm (0.2 in.) in depth may need to be used in conjunction with AQUACEL™ Ag Advantage, AQUACEL™ Ag+ Extra™, AQUACEL™ Ag, AQUACEL™ Ag Extra™, AQUACEL™ Ag WSF, AQUACEL™ Extra™ or AQUACEL™ dressings, or, if not available, standard gauze. See Section 6.6.

6.2 System Application

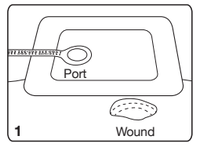
6.2.1 The application and setup of the System is to be performed by a Health Care Professional trained in the application of NPWT devices.

6.2.2 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.

6.2.3 Irrigate the wound with sterile saline as required and ensure the peri-wound skin is dry prior to dressing application.

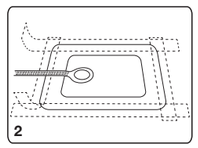
6.2.4 Use an aseptic technique to apply the dressing to the wound:

- 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 to minimise the risk of fluid collecting around the port and potentially reducing the application of negative pressure.

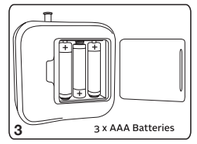


Gently smooth down the dressing border securing it in place while avoiding creasing. Reposition if required to avoid creasing.

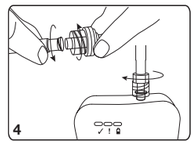
- If Sensi-Care™ Sting Free Skin Barrier is used to protect surrounding skin from use of fixation strips, use in accordance with its Instructions For Use (IFU) and allow skin to completely dry.
- Apply the fixation strips with a 1cm (0.4 in.) overlap to all sides of the dressing in order to maintain a seal during the wear time of the dressing (image 2). Take care not to trap the tubing and ensure all release liners are removed. Fixation strips and dressing should be replaced simultaneously if either one is removed.

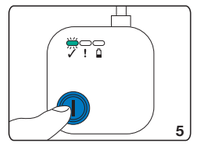


6.2.5 **Insert the batteries into the back of the pump by removing the battery compartment cover and insert 3x AAA (only recommended batteries should be used, see Section 12)** in the correct orientation as indicated in the compartment (image 3). Ensure all batteries are undamaged and terminals are secure and intact. All indicator lights will immediately flash once simultaneously signifying the batteries have been inserted correctly and the pump is ready to use. Secure the battery compartment cover.



6.2.6 Twist together the luer lock connectors in a clockwise direction to securely connect the dressing, pump and pump extension tubing if required (image 4). **Do not** over tighten. The dressing tubing can either be connected directly to the pump if a shorter connection is preferred or connected to the extension tube set if a longer 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 (image 5) and it will take up to 30 seconds to establish negative pressure; the pump can be heard functioning during this time. If negative pressure is not established, the Yellow '!' indicator light will flash after 20 seconds, for a further 10 seconds, then stop. Refer to Section 8 for general troubleshooting.





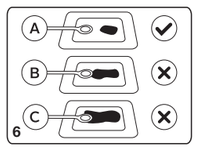
6.2.7 On initiation of therapy it is expected that the operator will be situated directly in front of the pump unit.

6.2.8 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.

6.2.9 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.

6.3 Dressing Change – to be performed by the Health Care Professional

6.3.1 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 4.17, 4.18, 4.19 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. The dressing needs to be changed as soon as possible as it has reached its absorption capacity and the port may become blocked with exudate (image 6).

6.3.2 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.

6.3.3 If NPWT is to be continued, apply a new Avelle™ NPWT Dressing repeating the steps in sections 6.2.4 and 6.2.5, 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.

6.4 Pump Change

- The pump is designed to operate for 30 days from start of negative pressure therapy.
- The pump is supplied with two sets of batteries, which should provide power to the pump for 30 days.
- The yellow indicator light will illuminate and flash when battery power is low. Refer to Section 8.2.
- After 30 days all indicator lights will stop illuminating. Refer to Section 8.1.
- 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 6.2

6.5 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. Pump units, extension tubes and dressings should be disposed of as clinical waste in accordance with local clinical guidelines. Recycling of batteries should be in accordance with local recycling regulations where applicable, for additional guidance the patient or carer should visit www.convatec.com or contact ConvaTec.

6.6 Wound Fillers and Contact Layers

- For shallow wounds (up to 0.5cm (0.2 in.) in depth) the Avelle™ NPWT System does not need to be used with a filler dressing. For deeper wounds up to 2cm (0.8 in.) a filler may be used such as AQUACEL™ Ag Advantage, AQUACEL™ Ag+ Extra™, AQUACEL™ Ag, AQUACEL™ Ag Extra™, AQUACEL™ Ag WSF, AQUACEL™ Extra™ or AQUACEL™ dressings. If unavailable, standard gauze may be used. Avoid over packing. Fillers should be changed along with the Avelle™ NPWT Dressing.

7. GENERAL/DAILY USE

Intended operators are Health Care Professionals or patient/ carer in a home healthcare environment.

7.1 On/Off

The Avelle™ NPWT Pump unit is fitted with a single button. Press the blue button for 3 seconds to turn the pump ON or OFF.

7.2 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 connector should point downwards away from the flow of water to reduce water entry into the dressing tube. Note: The dressing connector contains a one way valve which is designed to maintain negative pressure at the wound bed during short periods of disconnection from the pump.
- After showering re-connect dressing to the pump unit in accordance with Section 6.2.7 (image 4) and press the blue button for 3 seconds to re-instate therapy (image 5). Check pump and dressing are functioning correctly (Section 8). If therapy cannot be re-established, the patient or carer should contact the Health Care Professional.

7.3 Battery Replacement

- Turn the pump OFF and change the batteries in accordance with Section 6.2.6. 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.

7.4 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.

7.5 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 8. If therapy cannot be established for any reason, the patient or carer should contact their Health Care Professional or ConvaTec.
- Ensure all tubing is free from kinks where possible as not to block the flow of negative pressure.
- Check the pump regularly to ensure it is functioning and follow the IFU for guidance.

7.6 ⚠ Precautions/Warnings

Patients should be advised of the following:

- Do not perform any maintenance while 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 (0.5 in.) 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 7.4.
  - 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 Health Care Professional.
- For additional precautions/warnings refer to Section 4.

8. PUMP INDICATION, OPERATING AND TROUBLESHOOTING GUIDE

8.1 Normal Operation

Visual Indicator(s) Display and Status	Possible Cause(s)	Corrective Action/Comments
✓ !	No indicator lights illuminated.	The pump unit is turned OFF. Check the batteries have been inserted in the correct orientation and correct if necessary.	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.
✓ !	All indicator lights flash once.	This indicates the batteries have been fitted correctly and the pump unit is ready for use.	Pump unit functioning correctly.
✓ !	Green ✓ indicator light flashes.	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. Creases in the dressing's adhesive border may cause the pump to run more frequently; smoothing creases out may reduce pump run frequency.

8.2 Alerts and Faults

Visual Indicator(s) Display and Status	Possible Cause(s)	Corrective Action/Comments
✓ !	Yellow ! indicator light flashes.	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 dressing's 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 the blue button for 3 seconds. If therapy cannot be established the patient or carer should contact the Health Care Professional.
✓ !	Green ✓ indicator light flashes. Yellow indicator light flashes.	The pump unit is signifying it is operating correctly. Battery power is low.	Change all batteries within 24 hours. Press the 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 reinitiate therapy.
✓ !	Yellow ! indicator light flashes Yellow indicator light flashes	Air leak in the device. Battery power is low.	Address air leak as previously indicated above. Change all batteries within 24 hours as previously indicated above.
✓ !	Yellow ! and indicator lights to flash alternately	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.

9. AVELLE™ NPWT PUMP UNIT SPECIFICATIONS (MODEL CR4395)

Pump Unit Specifications	
Dimensions (maximum)	72mm x 78mm x 25mm / 3 in. x 3 in. x 1 in.
Weight (excluding batteries)	78g
Lifespan (pump unit) once batteries installed	30 days
Supply Voltage	4.5V DC/Battery (1.5V DC/Battery)
Battery type/Quantity	3x AAA Philips™ Lithium Ultra FR03 batteries
Mode of Operation	Continuous
Nominal vacuum	80mmHg
Maximum vacuum	144mmHg
Equipment Classification	Internally Powered
Degree of Protection Against Electrical Shock	Type BF. Applied parts include Avelle™ NPWT Dressing.
Ingress protection	IP22
Storage/Transport	-25 to +70°C (-13 - 158°F), 90% RH. 700 to 1060 mbar atmospheric pressure
Operation environment	5-40°C (41 - 104°F), 15-90% RH 700 to 1060 mbar atmospheric pressure
Compliance	21 CFR 807, subpart E. Class II
	IEC 60601-1:2005+AMD1:2012, BS EN 60601-1:2006+A12:2014, ANSI/AAMI ES60601-1:2005/(R)2012, CAN/CSA-C22.2 No. 60601-1:14
	IEC 60601-1-2:2014
	IEC 60601-1-11:2015
Sterility	non sterile
Programmable Electronic Medical Systems (PEMS) identifier	SNPC1
Materials of Construction (patient contact)	Pump (moulded parts) - Polycarbonate/ABS Tubing – PVC (DEHP free)

10. ELECTROMAGNETIC COMPATIBILITY

Having been tested, this device is compliant with the limits for medical devices in accordance with IEC 60601-1-2:2014 (4th Ed). 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.

The Avelle™ Negative Pressure Wound Therapy (NPWT) System complies with Essential Performance requirements of IEC 60601-1:2005+AMD1:2012 Clause 4.3. Essential Performance of the Avelle™ NPWT System, to achieve its intended use, is to maintain a nominal Negative Pressure of 80 mmHg.

If damage to the Avelle™ Negative Pressure Wound Therapy System occurs, please contact your Health Care Professional as soon as possible.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Avelle™ NPWT System is intended for use in the electromagnetic environment specified below. The customer or the user of the Avelle™ NPWT System should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Avelle™ NPWT System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The RF emissions characteristics of Avelle™ NPWT System make it suitable for use in hospitals, transport and home use environments.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/flicker Emissions IEC 61000-3-3	Not Applicable	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Avelle™ NPWT System is intended for use in the electromagnetic environment specified below. The customer or the user of the Avelle™ NPWT System should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not Applicable	Not Applicable
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not Applicable	Not Applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 cycles	Not Applicable	Not Applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The Avelle™ NPWT System is intended for use in the electromagnetic environment specified below. The customer or the user of the Avelle™ NPWT System should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	10 Vrms 150kHz to 80MHz	Not Applicable	Not Applicable
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz 9 V/m to 28 V/m 385 MHz to 5785 MHz	10 V/m 80 MHz to 2,7 GHz 9 V/m to 28 V/m 385 MHz to 5785 MHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Avelle™ NPWT System is used exceeds the applicable RF compliance level above, the Avelle™ NPWT System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Avelle™ NPWT System

Portable RF communications equipment should be used no closer than 30cm (12 in.) to the Avelle™ NPWT Pump unit.

11. 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 labeling.

12. REQUIRED COMPONENTS TO OPERATE THE AVELLE™ NPWT SYSTEM EFFECTIVELY

- Avelle™ NPWT sterile dressing (sterilisation via Ethylene Oxide)
- Adhesive fixation sterile strips (supplied with dressing and sterilisation via Ethylene Oxide)
- Avelle™ NPWT pump unit (CR4395)
- 3x AAA Philips™ Lithium Ultra FR03 Lithium batteries (six batteries supplied with pump unit and three to be in use at any one time)
- Extension tubing with luer connectors (supplied with pump unit)
- Instructions for use (supplied with dressing and pump unit)

13. DEFINITION OF SYMBOLS

Symbol	Definition	Symbol	Definition
LOT	Batch Code		Temperature limit 5°C /41°F - 25°C /77°F
STERILE EO	Sterilized Using Ethylene Oxide		Atmospheric Pressure Limits
	Humidity Limits		Follow Instrucions for Use
NON STERILE	Non Sterile		ON/OFF
SN	Serial Number		Low Power Indicator
REF	Catalogue Number	✓	Device is Operating Correctly
	Manufacturer (EU)	!	Device is Not Operating Correctly
	Date of Manufacture	"AAA" x3	Pump Unit Battery Type/Quantity
CE 2797	CE Mark (EU)		Keep Away from Sunlight
	Do Not Reuse		Opening End
	Keep Dry		
	EU: Not for General Waste		Consult Instructions for Use
	Equipment Classification Isolation Type BF	2 STERILE	Do Not Re-sterilise
LATEX	Latex Free	4.5V	Voltage
	Caution		Fragile - Handle with Care
	Do Not Use if Pack is Damaged		Expiry Date
	Risk of Explosion	IP22	Protection of fingers against access to hazardous parts, and protection of equipment against objects larger than 12.5mm (0.5 in.). Protection against drops of water falling vertically when the object is tilted up to 15 degrees from its normal position (in any direction).
MR	MR Unsafe - keep away from magnetic resonance imaging (MRI) equipment		
Rx ONLY	Federal (U.S.A.) law restricts this device to sale by or on the order of a physician		
	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 Circut
			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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