NEGATIVE PRESSURE
WOUND THERAPY DEVICE

Instructions for Use

MODEL #: OCMPP-100 — Rev 09/06/2025

Table of Contents

The Nisus ONE Instructions for Use provides information regarding safe and effective operation of the Nisus ONE Negative Pressure Wound Therapy System. This manual may be used in training of personnel and reference for the caregiver/beneficiary. Disregarding the information on safety and use of this device is considered abnormal use.

Warnings

DO NOT OPERATE THIS EQUIPMENT WITHOUT FIRST READING AND UNDERSTANDING THIS MANUAL. IF YOU ARE UNABLE TO UNDERSTAND THE WARNINGS, CAUTIONS, AND INSTRUCTIONS, CONTACT THE MANUFACTURER IF APPLICABLE BEFORE ATTEMPTING TO USE THIS EQUIPMENT. OTHERWISE, INJURY OR DAMAGE MAY RESULT

REFER SERVICING TO CORK MEDICAL

DO NOT POWER UNIT IN THE PRESENCE OF FLAMMABLE GASES

RX REQUIRED

DO NOT USE IN PRESENCE OF AN MRI

WARNING/CAUTION NOTICES APPLY TO HAZARDS OR UNSAFE PRACTICES WHICH COULD RESULT IN PERSONAL INJURY OR PROPERTY DAMAGE

Use of Device: Introduction

Read all instructions prior to use. When using an electrical medical device, basic safety precautions should always be followed. To reduce the risk of burns, electrocution, fire, and/ or injury to persons using this device:

- ALWAYS unplug the device immediately after using it or once charging is complete.
- Do not use it while bathing or store products where it can fall into a tub or sink.
- Do not place or drop it into water or other liquid.
- Do not retrieve the device in the event is has fallen into water. Unplug from the wall immediately.
- The device should not be left unattended when plugged in.
- Supervision is recommended when this product is used near infants and children.
- The device should only be used for its intended use as described in this manual.
- Do not use accessories and components unless recommended by Cork Medical.
- Do not operate this device if it has been dropped, damaged, or submerged into water.
- Do not use the battery charger if the cord and/or plug is damaged.
- Keep the battery charger cord away from heated surfaces.
- Do not operate the device if drowsy or impaired.
- Unplug the battery charger from the outlet when not in use.
- When not in use, store the device and accessories in a cool, dry place.
- Do not attempt to service or repair the device. Contact your dealer or Cork Medical in these circumstances.
- If bright red blood is visible in the drainage tubing or canister, turn off NPWT, leaving dressing intact, hold pressure on dressing, and contact EMS immediately and your healthcare provider.

The use of battery charger and accessories other than those identified, provided, and specified by Cork Medical may result in increased electromagnetic emissions or decrease the immunity of the NPWT pump.

Use of this device adjacent or stacked next to equipment should be avoided because of possible improper operation. If such a scenario is required, observation of equipment is needed to verify normal operation.

When Cork Medical accessories and NPWT products (Type BF applied part) are used, patient leakage current will not exceed limits set for this device.

The Nisus ONE NPWT pump has been tested and complies with IEC 60601-1 (Edition 3.0) Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance.

Patient Safety Precautions

Magnetic Resonance Imaging (MRI): MRI Unsafe - keep away from magnetic resonance imaging (MRI) equipment. Do not take the Nisus ONE NPWT System into the MRI environment. The dressing can typically remain on the patient with minimal risk in an MRI environment.

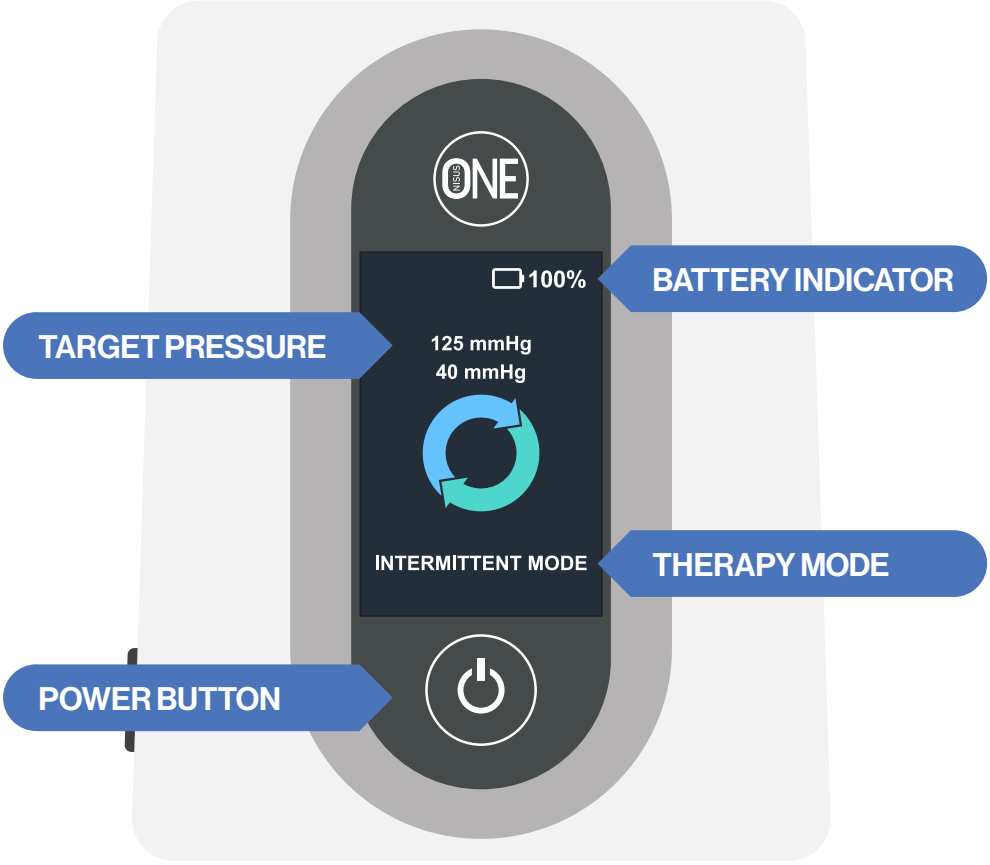
Hyperbaric Oxygen Therapy (HBO): The Nisus ONE NPWT System is not designed for the HBO environment and should be considered a fire hazard. Disconnect the Nisus ONE NPWT System and replace the wound dressing with another HBO compatible material during the hyper- baric treatment. If dressing is left in place, cover the luer lock end with gauze and leave port unclamped. If treatment is longer than 2 hours, wound dressing must be changed.

Nisus ONE NPWT System Components

Nisus ONE NPWT System Accessories

- Cork Medical NPWT Wound Dressing Kits
- Cork Medical Canisters
- Cork Medical NPWT Wound Dressing Accessories

Nisus ONE NPWT Pump



Use of Device: Battery

The Nisus ONE NPWT System is designed to run on a lithium-ion rechargeable battery. The pump can also operate with the provided battery charger plugged in.

The battery is recharged via a battery charger. Average recharge time of the battery is 2.4 hours. The average run time on a fully charged battery is 8 hours.

Specifications: 14.8volt nominal 1900mah, Lithium Polymer pack with safety circuit.

Battery Charger

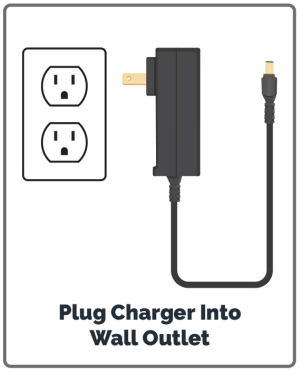
ONLY USE THE BATTERY CHARGER PROVIDED BY CORK MEDICAL.

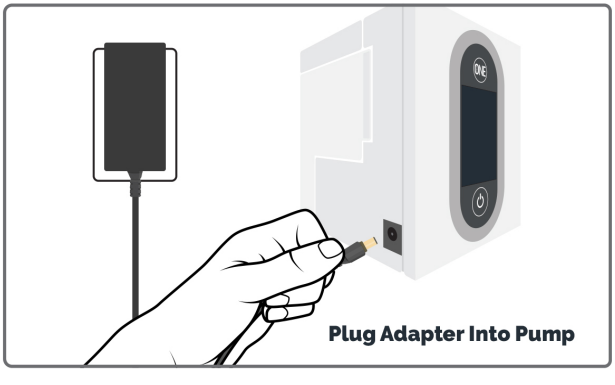
Once the charger is attached to a Nisus ONE NPWT System the charging process will begin.

When the battery life is less than 20%, a critical battery alarm will trigger, and a notification shall display that the user needs to plug in the battery charger to recharge the battery. If the battery charger is not plugged in at this time, a critical battery alarm will sound until the user connects the battery charger or the pump, will power down.

Charging the Pump

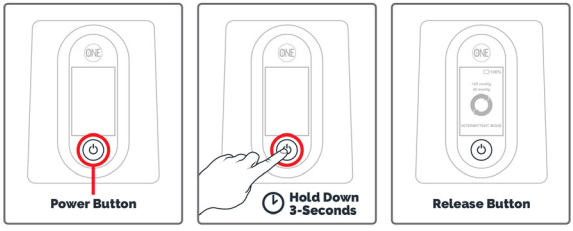
1. Plug charger into a non-switched wall outlet.
2. Plug in the charger into the charger port on the pump.
3. The power button on the Nisus ONE NPWT System will illuminate in a blue color to indicate charging, when the pump is powered on.
4. When the pump is on the battery status and percentage of life are displayed on the pump LCD in the upper right-hand corner of the display.



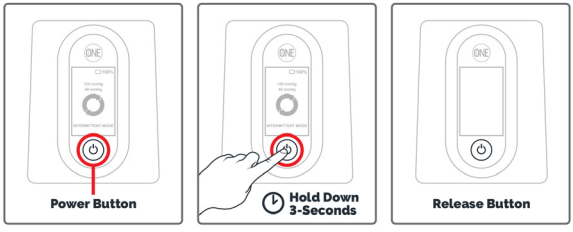


Use of Device: Powering On/Off

1. Power on the Nisus One NPWT System by pressing the POWER button and hold for 3 seconds and release.



2. To power off the pump, press and hold the power button for 3 seconds, release power button and countdown will occur from 3 when the powering down sequence begins.

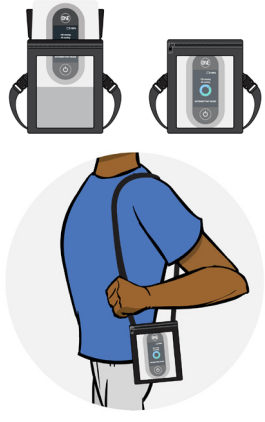


3. The pump will revert to previous settings set by your medical provider.
4. If any alarms occur see troubleshooting setting in IFU.

Carrying bag

The Nisus One NPWT System Bag should always be utilized. The Nisus One NPWT System should remain in the carrying bag unless a canister or battery change is necessary. **Steps:**

1. Unzip the top of the bag.
2. Place Nisus One NPWT System in bag. The top of the pump should be at the top of the zipper area on the bag.
3. Zip the bag once the pump is inserted into the bag.
4. Double check correct orientation of pump in bag. The button of the Nisus One NPWT System should be at the bottom of the bag.
5. Close front flap on bag



Device Operations: Correct Orientation

Nisus ONE NPWT System – Orientation of Pump

The Nisus ONE NPWT System must be used only in the upright position.

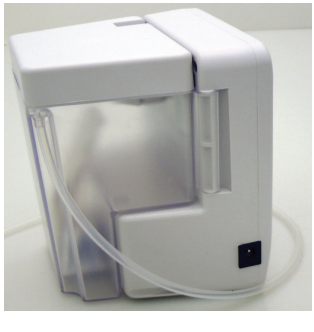
Correct Orientation:

Incorrect Orientation:

Device Operations: Attaching the Drainage Canister to Pump

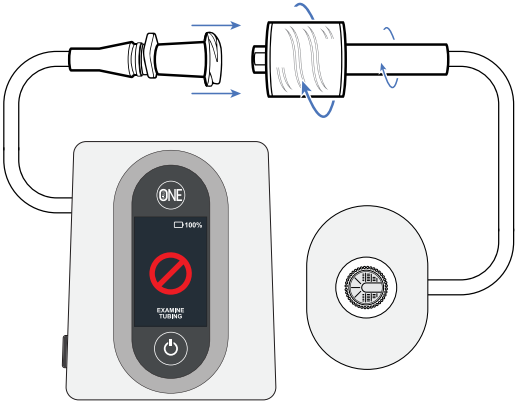
Use only Cork Medical NPWT Canisters with Nisus ONE NPWT System.

1. Clinician may instruct patient on canister change, if necessary and deemed appropriate by the clinician
2. Canisters are available in two sizes, 250-mL or 500-mL, use only Cork Medical's canisters. Attach the canister to the back of the Nisus ONE NPWT System by hooking the canister onto the pump hinge post then rotating to lock the canister into place.
3. The drainage canister is snapped into place and will be secure once properly attached by the user. Gently tug on the canister to ensure it is secured.
4. The canister includes drainage tubing with a luer fitting. Attach the drainage tubing from the canister to the drainage tubing from the wound dressing kit.
5. Once the canister is in place and the drainage tubing is connected to the wound dressing kit, the Nisus ONE NPWT System may then be powered on.
6. Change canister once the canister full alarm triggers or minimally once a week. When the canister is full, an alarm will sound – discard full canister and replace with a new, unused canister.



System Disconnection/Reconnection

1. Clamp canister tubing.
2. Clamp port pad tubing, the tubing that is connected to the wound.
3. Locate the connection port between the canister tubing and the port pad tubing
4. Unscrew counterclockwise.
5. Cover the end of port pad tubing and canister tubing with a medical glove.
6. Perform activities needed.
7. To reconnect, connect the port pad tubing to the canister tubing, and turn Leur lock clockwise (Don't Overtighten)
8. Unclamp port pad tubing.
9. Unclamp canister tubing.
10. Ensure the dressing is pulled down, will have a raisin like appearance.



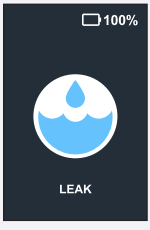
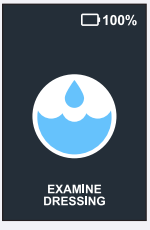
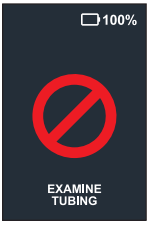
What Happens When Device Alarms

The Nisus ONE NPWT pump device provides audible and visual alarms to patients regarding critical battery, pressure leakage, system blockage, and when a collection canister is full. When an alarm condition occurs, a window shall display the specific alarm and alarm icon. The leak, blockage, and canister full alarms allow the patient or healthcare professional the option to mute the alarm temporarily.

When battery life is critically low (less than 20%), the pump will emit an audible alarm that cannot be muted, and the critical battery icon will display to alert the user the unit will power down if not connected to the battery charger.

What Happens When Device Alarms Clinician and Patient

The table below describes all the error messages and alarms of the Nisus ONE device. Troubleshooting for each alarm type is described below:

ALARM	ALARM DISPLAY	TROUBLESHOOTING DISPLAY	NOTIFICATION	TROUBLESHOOTING
Critical Battery Alarm			Visual message displayed along with audible alarm. If alarm not corrected, continuous audible alarm.	IMMEDIATELY CONNECT TO BATTERY CHARGER AND PLUG IN TO PREVENT DEVICE FROM SHUTTING DOWN.
Leak Alarm			Visual message displayed along with audible alarm. If alarm not corrected, continuous audible alarm. Alarm can be muted temporarily.	Drainage tubing not connected. Wound dressing not completely sealed. Canister not latched.
Blockage Alarm			Visual message displayed along with audible alarm. If alarm not corrected, continuous audible alarm. Alarm can be muted temporarily.	Pinch clamps activated. Drainage tubing kinked.
Canister Full Alarm			Visual message displayed along with audible alarm. If alarm not corrected, continuous audible alarm. Alarm can be muted temporarily.	Collection canister full. CHANGE CANISTER IMMEDIATELY TO RESOLVE ALARM.

What Happens When Device Alarms

Critical Battery Alarm Troubleshooting:

1. Plug pump into power outlet using charger that was provided.
2. Do not use a switched outlet.
3. Ensure that pump is charging. The power button will be illuminated.

Leakage Alarm Troubleshooting:

1. Inspect drainage canister to ensure that is has no visible cracks in it.
2. Ensure that port pad tubing is connected to canister tubing at luer lock connection.
3. Listen for air leak in and around wound dressing and if heard, use transparent film to seal leak.
4. Contact medical provider if the previous interventions do not resolve alarm.

Blockage Alarm Troubleshooting:

1. Ensure that both clamps are unclamped.
2. Inspect tubing to ensure that there are no kinks in tubing.
3. Ensure that the port pad does not have pressure applied directly on the dome.
4. Contact medical provider if the previous interventions do not resolve alarm.

Canister Full Alarm Troubleshooting:

1. Clamp both clamps and turn the pump off.
2. Disconnect canister tubing from port pad tubing at luer lock by turning luer lock counterclockwise.
3. Disposal of used canisters should follow facility policies or local ordinances relating to the handling of potentially infected or bio-hazardous materials.
4. Connect the new canister tubing to port pad tubing at luer lock by turning clockwise.
5. Unclamp all tubing.
6. Turn pump on – ensure that suction is being applied by watching if the foam in the dressing is compressing into a raisin like appearance.
7. Contact medical provider if the previous interventions do not resolve the alarm.

Troubleshooting Malfunction at Pump:

The Nisus ONE NPWT System should begin running after pressing the POWER button. In the event the pump does not power on, press, and hold the POWER button for at least 3 seconds and release the power button to begin the power down process. Attempt to power on again. If the unit still does not power on, it is possible that the battery needs to be recharged.

Connect the provided battery charger to the device and wait at least 30 minutes. Attempt to power on the unit again with the battery charger still plugged in. If the unit powers on, continue running with the battery charger connected to fully recharge the battery. If the unit still does not power on, contact Cork Medical.

Maintenance

General Information:

Before each usage and cleaning inspect the device for visible signs of damage. Please contact your distributor if visible signs of abuse and damage have been observed.

Cleaning:

Take precautions to keep Nisus ONE NPWT System components free of dirt, dust, lint, and debris. Maintain cleanliness of the system.

The Nisus ONE NPWT System should be cleaned immediately if you see any dirt, dust, lint, and/or debris. present. The pump needs to be cleaned minimally on a weekly basis and between each patient use. During the cleaning process a visible inspection of the device should be completed at this time. Perform a visible inspection post cleaning and if any dirt, dust, lint and/or debris is present, repeat the cleaning process.

Steps for cleaning the pump: 1. Cork Medical recommends using bacteriostatic cleaning wipes (e.g., Clorox Wipes) 2. Turn the pump off prior to cleaning the device 3. Ensure the device is not plugged into the wall charger during the cleaning process. 4. Wipe all external surfaces of the pump with the bacteriostatic cleaning wipe. 5. Perform a visible inspection post cleaning and if any dirt, dust, lint and/or debris is present, repeat the cleaning process 6. If any damage is noted, please contact your distributor or medical provider.

Do not submerge the device in any liquid and allow no solution to enter the internal portion of the pump. If any liquid penetrates the internal portion of device, return to your distributor for service.

Returning the Device:

Prior to returning the device, the product must be cleaned in line with the steps defined within this manual.
All used canisters shall be disposed of. Disposal of used canisters should follow facility policies or local ordinances relating to the handling of potentially infected or bio-hazardous materials.

The device should be returned in the original packaging and include the provided battery charger.

Disposal of Device: Disposal for Li-Ion Battery Pack:

The Nisus ONE NPWT System contains a battery pack. Do not dispose of the device by placing it in the trash. Return the device to Cork Medical.

Disposal for Li-Ion Battery Pack:

The rechargeable battery contains the following components that must be disposed of in accordance with local regulations: Lithium-Ion cells.

Caution: When the battery is worn out, insulate the connector terminals with adhesive tape or similar material before disposal.

Misuse or improper disposal of the battery pack may cause the battery to become very hot, ignite, or explode. When disposing of a battery pack, contact your local waste disposal service provider regarding local restrictions on the disposal and recycling of batteries.

The Healthcare provider will need to review the "Instructions for Use" with the patient/" Home User" before use.

Nisus ONE NPWT System – Therapy Mode Settings:

1. Power on the Nisus ONE NPWT System by pressing the power button on the keypad. Upon powering on, the pump will operate on the default settings, which is Continuous Mode at the pressure of 125-mmHg.

1. To adjust therapy mode, press and hold the power button for 10 or more seconds. This will switch the mode to Variable Intermittent Mode. (Performed by clinician)

Continuous Mode

1. The pump will operate at a pressure of 125-mmHg.

   NOTE: The pressure settings are not able to be manipulated by the user.
2. The target pressure of the pump, 125-mmHg, is displayed in the middle of the screen next to "Current[mmHg]." In the footer of the screen "Continuous Mode" will be displayed

Device Operations

Variable Intermittent Mode

1. The pump will operate at an up pressure of 125-mmHg with the up time of 10 minutes and the down pressure of 40-mmHg with the down time of 4 minutes. NOTE: The pressure settings are not able to be manipulated by the user.
2. The target pressure of the pump is displayed in the middle of the screen. In the footer of the screen, "Intermittent Mode" will be displayed.

Applying NPWT Wound Dressing:

Use only Cork Medical NPWT Wound Dressing Kits with the Nisus ONE NPWT System. Follow instructions for use when applying the wound dressing provided with the kits. Dressing applications are only performed by a healthcare professional.

Symbols

	Class II, Internally Powered
	Applied Part, Type BF
	Read instructions as a mandatory action
	Do not dispose
IP22	Ingress protection - protected against insertion of fingers and will not be damaged or become unsafe during a specified test in which it is exposed to vertically or nearly vertically dripping water
	Intertek registered certification mark of nationally recognized testing laboratory (NRTL)
	Used canisters are considered biohazardous and should be disposed of accordingly. Disposal of used canisters should follow facility policies or local ordinances relating to the handling of potentially infected or bio-hazardous materials.
Rx only	Caution: Federal Law (USA) restricts this device to sale by or on the order of a licensed physician.
	MRI Unsafe - keep away from magnetic resonance imaging (MRI) equipment

Clinical Safety and Precautions

- The following types of patients are at an increased risk of bleeding, which if not controlled could be potentially fatal:
- Patients who would have weakened or friable blood vessels or organs in or around the wound because of, but limited to suturing of blood vises, infection, trauma, and radiation.
- Patients without adequate wound hemostasis
- Patients who have been administered anticoagulants or platelet aggregation inhibitors.
- Patients who do not have adequate tissue coverage over vascular structures.

If active bleeding develops suddenly or large amounts of frank (bright red) blood is seen in the tubing or canister, immediately stop therapy, leave dressing in place, take measures to stop the bleeding, and seek immediate medical assistance. The Nisus ONE NPWT System should not be used to prevent, minimize, or stop vascular bleeding.

Protect Vessels and Organs: All exposed or superficial vessels and organs in or around the wound must be completely covered and protected prior to the administration of the Nisus ONE NPWT.

Large Wounds: Caution should be taken when treating large wounds that may contain hidden vessels which may not be readily apparent. The patient should be closely monitored for bleeding in a setting deemed appropriate by the treating physician.

Infected Blood Vessels: Infection may erode blood vessels and weaken the vascular wall which may increase susceptibility to vessel damage through abrasion or manipulation. The patient should be closely monitored for bleeding in a care setting deemed appropriate by the treating physician.

Hemostasis, Anticoagulants, and Platelet Aggregation Inhibitors: Due to the increased risk for bleeding, consideration should be given to the negative pressure setting and therapy mode used when initiating therapy. These patients should be treated and monitored in a care setting deemed appropriate by the treating physician.

Hemostatic Agents Applied at the Wound Site: if disrupted, may increase the risk of bleeding which, if uncontrolled, could be potentially fatal. Consideration should be given to the negative pressure setting and therapy mode used when initiating therapy.

Clinical Safety and Precautions

Sharp Edges or bone fragments must be covered or eliminated from the wound area to prevent them from puncturing blood vessels or organs prior to the application of the Nisus ONE NPWT System. Use caution when removing dressing components from the wound so that the wound tissue is not damaged by unprotected sharp edges.

Vascular Surgical Wounds of the Lower Extremities: Regardless of the treatment, wound complications from peripheral vascular surgery, especially those situated in the groin, are not uncommon and have the potential for severe consequences including significant blood loss.

Infected Wounds: Wound infections should be closely monitored and may require more frequent dressing changes. If there are any signs of the onset of systemic infection or advancing infection at the wound site, contact the treating healthcare physician immediately to determine if the Nisus ONE NPWT Pump should be discontinued.

Osteomyelitis: Nisus ONE NPWT should not be initiated on a wound with untreated osteomyelitis.

Tendons, Ligaments and Nerves: Protect exposed tendons, ligaments, and nerves with natural tissue, meshed non-adherent material or bio-engineered tissue to help minimize risk.

Foam Placement: Always use dressings from sterile packages that have not been opened or damaged. Do not place foam dressing into blind/unexplored tunnels. Always count the total number of pieces of foam used in the wound and document on the patient chart.

Foam Removal: Always count the total number of pieces of foam removed from the wound and ensure the same number of foam pieces are removed as were placed, as the dressings are not bioabsorbable. Regardless of treatment, disruption of the new granulation tissue during any dressing change may result in bleeding at the wound site.

Keep Nisus ONE NPWT System turned on: Never leave the foam dressing in place without the Nisus ONE NPWT System for more than 2 hours if therapy is turned off. If the therapy is off for more than 2 hours, remove the wound dressing and irrigate the wound; either apply a new Cork Medical NPWT wound dressing and restart the unit, or apply alternative dressing at the direction of the physician.

Clinical Safety and Precautions

Defibrillation: If defibrillation is required in the area of dressing placement, remove the dressing immediately, as failure to remove may inhibit transmission of electrical energy and/or patient resuscitation.

Precautions should be taken for patients who are or may be: Receiving anticoagulant therapy, patients with known hemolytic disease, untreated for malnutrition, and who are non-compliant or combative.

Universal Precautions: Hand washing must be performed prior to starting any procedure. Gloves must be donned prior to any direct patient contact. In addition to gloves, use a gown and goggles if exposure to body fluid is likely. Always follow your institutional guidelines on infection control practices.

Patient Size and Weight: The size and weight of the patient should be considered when prescribing negative pressure wound therapy. Infants, children, certain small adults, and elderly patients should be closely monitored for fluid loss and dehydration. Also, patients with highly exudating wounds or large wounds in relation to the patient size and weight should be closely monitored, as they may have a risk of excessive fluid loss and dehydration. When monitoring fluid output, consider the volume of fluid in both the tubing and canister.

Spinal Cord Injury: In the event a patient experiences autonomic hyperreflexia (sudden elevation in blood pressure or heart rate in response to stimulation of the sympathetic nervous system), discontinue therapy immediately and seek immediate medical assistance.

Bradycardia: The dressing should not be placed near the vagus nerve as this may cause bradycardia.

Enteric Fistulas: Nisus ONE NPWT System is not intended for containment of drainage of enteric fistulas. Nisus ONE may be used with enteric fistulas in the aid of promoting wound healing and not the sole purpose of containment of drainage. The physicians ordering the Nisus ONE for enteric fistulas need to closely monitor the patient for any complications that may occur.

Operating Precautions:

When operating, transporting, repairing, or disposing of Cork NPWT devices and accessories, the risk of infectious liquid being aspirated, or contamination of the device assembly through incorrect use, cannot be eliminated. Universal precautions should be observed when working with potentially contaminated parts or equipment.

Clinical Safety and Precautions

In the event materials of the Nisus ONE NPWT System cause skin irritation or an allergic reaction, cease use immediately and contact a physician.

Use of the Nisus ONE NPWT System must be prescribed by a physician per the stated indications for use. As a condition of use, the Nisus ONE NPWT System should only be used by qualified and authorized personnel. The user must have the necessary knowledge of the specific medical application for which negative pressure wound therapy is being used.

The Nisus ONE NPWT System should remain on and in use for the duration of the prescribed treatment. If the patient must disconnect the pump from the NPWT wound dressing, the ends of the tubing should be clamped prior to disconnecting. The length of time a patient may be disconnected from the Nisus ONE device is a clinical decision based on individual characteristics of the patient and the wound. Factors to consider include the location of the wound, the volume of drainage, the integrity of the NPWT wound dressing seal, the assessed bacterial burden, and the patient's risk of infection.

There is an increased risk of fall or trip hazard when using Nisus ONE NPWT pump during transport or ambulatory use. In the event a patient using the Nisus ONE NPWT system needs to be transported or ambulatory, it is recommended that the ends of the tubing should be clamped and disconnected from the NPWT wound dressing.

Ensure all components of the Cork NPWT Wound Dressing Kit are installed correctly and that the port pad assembly tubing is not kinked to avoid leakage and blockage during NPWT therapy. Position the Nisus ONE NPWT System and drainage tubing appropriately to avoid the risk of causing a trip hazard. When possible, position the pump device and drainage tubing at or below the level of the wound.

Tubing from the Cork NPWT Wound Dressing Kit and wound drainage canisters are long and represent a possible strangulation hazard. The battery charger cable also represents a possible strangulation hazard. Position the Nisus ONE NPWT System, its tubing, and cables appropriately to avoid the risk of strangulation.

Ensure the environment where Nisus ONE NPWT System is to be used is clean and free of excessive dirt, lint, dust, and debris. Avoid using or storing Nisus ONE NPWT System in an unclean environment. When not in use, store the device and accessories in a cool, dry place.

Clinical Safety and Precautions

Continuous Therapy Versus Variable Intermittent Therapy:

Continuous Therapy is recommended for unstable structures, such as an unstable chest wall or non-intact fascia. Continuous Therapy is also generally recommended for patients at risk of bleeding, highly exudating wounds, fresh flaps and grafts, and wounds with acute enteric fistulae.

Protect Periwound Skin:

Consider the use of a skin preparation product to protect periwound skin. Do not allow wound filler to overlap onto intact skin. Protect fragile/friable periwound skin with additional hydrocolloid or other transparent film.

- Multiple layers of the transparent film dressing may decrease the moisture vapor transmission rate, which may increase the risk of maceration.
- If any signs of irritation or sensitivity to the film dressing, wound filler or tubing assembly appear, discontinue use and consult a physician.
- To avoid trauma to the periwound skin, do not pull or stretch the transparent film over the wound filler dressing during film application.
- Extra caution should be used for patients with neuropathic etiologies or circulatory compromise.

Circumferential Dressing Application:

Avoid use of circumferential dressings except in the presence of anasarca or excessively weeping extremities, where a circumferential film technique may be necessary to establish and maintain a seal. Consider using multiple small pieces of transparent film rather than one continuous piece to minimize the risk of decreased distal circulation. Extreme care should be taken not to stretch or pull the film when securing it, but let it attach loosely and stabilize edges with an elastic wrap if necessary.

When using circumferential film techniques, it is crucial to systematically and recurrently palpate distal pulses and assess distal circulatory status. If circulatory compromise is suspected, discontinue therapy, remove dressing, and contact a physician.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a licensed physician.

Use of the Nisus ONE NPWT System must be prescribed by a physician per the stated indications for use. As a condition of use, the Nisus ONE NPWT System should only be used by qualified and authorized personnel. The user must have the necessary knowledge of the specific medical application for which negative pressure wound therapy is being used.

Prior to placement of the Nisus ONE NPWT System, the medical professional treating the patient must assess how to best use the system for an individual wound. It is important to carefully assess the wound and patient to ensure clinical indications for negative pressure wound therapy are met.

All orders should include:

- Wound location, size, and type
- Dressing kit type
- Negative pressure settings
- Frequency of dressing changes
- Secondary dressings

The Nisus ONE NPWT System is designed for use by healthcare professionals and limited use by patients as indicated in this IFU. Pressure setting and mode of operation is prescribed by ordering provider and the healthcare professional will only change these modes of operation. Use caution when using 500 ml canisters in the home care setting. Patients should be monitored for fluid loss and/or bleeding.

Indications for Use

The Nisus ONE Negative Pressure Wound Therapy System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device allows wound management.

The Nisus ONE Negative Pressure Wound Therapy System is only intended to be used with the Cork NPWT Wound Dressing Kit (K132004).

The Nisus ONE Negative Pressure Wound Therapy System is suitable for use in both a professional healthcare facility and home use environment.

Contraindications

The Nisus ONE NPWT System is contraindicated for patients with:

- Malignancy in the wound
- Untreated osteomyelitis
- Non-enteric and unexplored fistulas
- Necrotic tissue with eschar present (NOTE: After debridement of necrotic tissue and complete removal of eschar, Nisus ONE NPWT system may be used).

Caution, do not place dressing directly in contact with:

- Exposed blood vessels
- Anastomotic sites
- Organs
- Nerves

Technical Specifications

Nisus NPWT Canister

Shelf Life: 1 year from date of manufacture Provided Non-Sterile

Nisus NPWT Wound Dressing Kit

Expiration: 2 years from date of sterilization Sterilized via Ethylene Oxide and Gamma

Nisus ONE NPWT Pump

Use life: Pump life is 5 years, Battery life is 1 year, both from date of manufacture

Serviced annually by Cork Medical

Minimum operating negative pressure -40 mm/Hg+/-10 mm/Hg Maximum operating negative pressure -125 mm/Hg +/-10 mm/Hg Suction capacity of ~7 lpm

Pressure settings are a set continuous mode of operation at 125 mm/Hg or a variable intermittent mode with high pressure of 125 mm/Hg for 10 minutes and with a low pressure of 40 mm/Hg for 4 minutes.

***WARNING:* REFER SERVICING TO QUALIFIED PERSONNEL ONLY. THE DEVICE SHALL NOT BE MODIFIED IN ANY WAY.**

Dimensions / Weight

Dimensions: 6" (H) x 4.25" (W) x 3" (D) Weight: 2 lbs. with canister

Environmental Conditions

Operating Temperature: 18ºC to 34ºC (65ºF to 94ºF)

Operating Relative Humidity: 10% - 93% non-condensing

Operating Pressure: 700-hPA – 1060-hPA (10.15-atm – 15.37- atm) atmospheric pressure

Storage & Shipping Conditions

Storage Temperature: -30°C (-22°F) without relative humidity control to 60°C (158°F) up to 90% relative humidity (non-condensing). The storage and shipping conditions apply to the Nisus One NPWT between use

Patient Protection

Type BF

Limited Warranty

The Nisus ONE NPWT System Pump and Nisus Battery Charger have two-year limited warranties. The Nisus ONE NPWT System battery has a one-year warranty from the date of manufacturing.

Electromagnetic Compatibility

The Essential Performance Requirements of the Nisus ONE NPWT System, Model OCMPP-100, are to maintain 40 –125-mmHg +/- 10mmHg (60 second average) vacuum pressure with no false alarms.

Portable and mobile RF communications equipment can affect medical electrical equipment.

The following tables document compliance levels and guidance from the IEC 60601-1-2:2014+AMD1:2020S Standard for the electromagnetic environment in which the Nisus ONE NPWT Pump should be used in a clinical environment. The Nisus ONE NPWT Pump also meets the criteria for Electromagnetic Compatibility related to use in the home care environment, as established in IEC EC 60601-1-2 ed 4.0.

Contact Information

Cork Medical
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Indianapolis, IN 46250

Toll Free: 866.405.6138

Fax: 866.429.5524

Electromagnetic Compatibility

PRODUCT FAMILY	**APPLICATION**				
IEC 60601-1-2:2014+AMD1:2020	Electromagnetic compatibility requirements and test for Medical Electrical Equipment, which calls out CISPR and IEC required tests below.				
Emissions Test	**Test Descriptions**	**Port**	**Compliance Level**	**IEC 60601 Test Level**	**Results**
CISPR11 ed5.0 (with A1:2010)	Radiated Emissions	AC Port / Input power: 230VAC, 50Hz (charging)	Any	Class B Group 1	Complies
	AC Mains Conducted Emissions	Enclosure / Input power: 230VAC, 50Hz (charging) Input power: Battery	Any	Class B Group 1	Complies
IEC 61000-3-2 ed3.2 (with A1:2008 + A2:2009)	Harmonics	AC Port / Input power: 230VAC, 50Hz (charging)	Rated single voltage or 230V for single- phase; 400V for 3-phase, 50 or 60Hz	Class A	Complies
IEC 61000-3-3 ed3.0 (2013-05)	Flicker	AC Port / Input power: 230VAC, 50Hz (charging)	Rated single voltage or 230V for single- phase; 400V for 3-phase, 50 or 60Hz	All parameters, Dmax <4%	Complies
Immunity Test	**Test Descrip-tions**	**Port**	**Compliance Level**	**IEC 60601 Test Level**	**Results**
IEC 61000-4-2 ed2.0 (2008-12)	Electro-Static Discharge Immunity Test	Enclosure / Input power: 230VAC, 50Hz (charging) Input power: Battery	±2, 4, 8 kV ±2, 4, 8, 15 kV	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Complies
IEC 61000-4-3 ed3.0 (with A1:2007 + A2:2010)	Radiated, Ra-dio-Frequency, Electromag-netic Immunity	Enclosure / Input power: 230VAC, 50Hz (charging) Input power: Battery	3 V/m, Home: 10 V/m 80% AM AT 1 kHz or risk frequency 80 - 2700 MHz	10V/m, 80-2700MHz 80 % AM at 1 kHz See Table 9	Complies

IEC 61000-4-4 ed3.0 (2012-04)	Electrical Fast Transient/ Burst Immunity Test	AC Port / Input power: 230VAC, 50Hz (charging) DC Port / Input power: 230VAC, 50Hz (charging)	±2 kV, 100kHz PRF	± 2 kV	Complies
			±1 kV, 100 kHz PRF	100 kHz repetition frequency	
IEC 61000-4-5 ed2.0 (2005-11)	Immunity to Surges	AC Port / Input power: 230VAC, 50Hz (charging)	Any	Line-to-line: ± 0,5 kV, ± 1 kV Line-to-ground: ± 0,5 kV, ± 1 kV, ± 2 kV	Complies
IEC 61000-4-6 ed4.0 (2013:10)	Conducted, Radio-Frequency, Electromagnetic Immunity Test	AC Port / Input power: 230VAC, 50Hz (charging) DC Port / Input power: 230VAC, 50Hz (charging)	3V with 6V ISM,home: 6V amateur 80% AM at 1 kHz or risk frequency 150 kHz –80MHz	3 V, 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	Complies
			3V with 6V ISM,home: 6V amateur 80% AM at 1 kHz or risk frequency 150 kHz –80MHz	80 % AM at 1 kHz	Complies
IEC 61000-4-8 ed2.0 (2009-09)	Power Frequency Magnetic Field Immunity Test	Enclosure / Input power: 230VAC, 50Hz (charging) Input power: Battery	30A/m,50 or 60Hz	30 A/m, 50 Hz (charging) 30 A/m, 50 Hz and 60Hz (Battery)	Complies
IEC 61000-4-11 ed2.0 (2004-03)	Voltage Dips/ Interruptions Immunity Test	AC Port / Input power: 230VAC, 50Hz (charging)	100% drop,0.5 periods, 0º, 45º, 90º, 135º, 180º, 225º, 270º, 315º 100%dip, 1 period 30% dip, 25/30 periods	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle Single phase: at 0° 70 % UT; 25 cycles Single phase: at 0° 0 % UT; 250 cycles	Complies

Proximity magnetic fields IEC 61000-4-39	Testing and measurement techniques - Radiated fields in close proximity - Immunity test	Enclosure / Input power: 230VAC, 50Hz (charging) Input power: Battery	8 A/m (30 kHz) 65 A/m (134.2 kHz) 7.5 A/m (13.56 MHz)	8 A/m (30 kHz) 65 A/m (134.2 kHz) 7.5 A/m (13.56 MHz)	Complies

1EUT contains no signal cables.

Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The Nisus ONE NPWT System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Recommended separation distances between portable and mobile RF communications equipment and the Nisus ONE NPWT System.

The Nisus ONE NPWT System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Nisus ONE NPWT System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Nisus ONE NPWT System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter in meters		
W	**150 kHz to 80 MHz** **$d = 1.2\sqrt{P}$**	**80 MHz to 800 MHz** **$d = 1.2\sqrt{P}$**	**800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.74
1	1.2	1.2	2.3
10	3.8	3.8	7.4
100	12	12	23

for transmitters rated at a maximum output power not listed above, the recommended separate distanced in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: at 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: Guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from surfaces, objects, and people.
WARNING: This equipment has been tested for radiated RF immunity only at selected frequencies, and use of nearby emitters
At other frequencies could result in improper operation.

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Nisus ONE NPWT Pump, including cables, than the recommended separation distance calculated from the equation application to the frequency of the transmitter. Recommended Separation Distance Battery Operated Device d = 1.2√P d = 1.2√P 80 MHz to 800 MHz d = 2.3√P 800 MHz to 2.5 GHz Where P is the maximum output power rating of
Conducted RF IEC 61000-4-6	3Vms 150K–80 MHz	3V with 6V ISM, home: 6V amateur 80% AM at 1 kHz or risk frequency 150 kHz –80MHz	the transmitter in watts (W) according to the transmitter manufacturer and is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic sit survey (1), should be less than the compliance level in each frequency range (2).
Radiated RF IEC 61000-4-3	3V/meter 80 MHz – 2.5 GHz	3 V/m, Home: 10 V/m 80% AM AT 1 kHz or risk frequency. 80 - 2700 MHz"	Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: at 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: Guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from surfaces, objects, and people.

(1) 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 sit survey should be considered. If the measured field strength in the location in which the Nisus ONE NPWT Pump is used exceeds the applicable RF compliance level above, the Nisus ONE NPWT Pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-ordering the Nisus ONE NPWT Pump.
(2) Over the frequency range 150kHz, field strengths should be less than 3V/m.

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