CLINICIAN AND PATIENT USER MANUAL

PROSPERA™ FLEX

Negative Pressure Wound Therapy
7 Day Single-Use System

DeRoyal®

ORGANIZATION OF THE MANUAL

The Prospera Flex™ Single-Use Negative Pressure Wound Therapy System is a prescription medical device for use under the instruction of a licensed and trained clinician.

THIS USER MANUAL CONTAINS

- Intended use, contraindications, and warnings
- Listing of all symbols and icons with definitions
- Directions for device use, including accessories
- Travel, storage, and disposal
- Cleaning
- Warranty and service program
- Detailed technical data

TABLE OF CONTENTS

TABLE OF CONTENTS, CONT.

IMPORTANT SAFETY INFORMATION

The Prospera Flex™ Single-Use Negative Pressure Wound Therapy System is a prescription medical device for use under the instruction of a licensed and trained clinician. Carefully read and completely understand all contraindications, warnings, cautions, and instructions before use. This user manual is not intended as a training document. All licensed and trained clinicians should receive adequate negative pressure wound therapy (NPWT) training before operating the device. Failure to do so may result in serious injury to the patient.

Read and understand all safety instructions to ensure proper use and to minimize risk of injury.

- This User Manual is a component of the Prospera Flex System.
- Keep this User Manual in an accessible location.
- Include this User Manual when transferring the device to third parties.
- Include the Quick Reference Guide when transferring the device to third parties.
- Read and understand all safety instructions and directions for use included with all NPWT wound dressing kits, canisters, and accessories.

Local wound care by Prospera Flex Single-Use Negative Pressure Wound Therapy System cannot overcome the deficits of unrelieved malnutrition, pressure, trauma, or compromised blood flow.

To comply with service documentation specified by the manufacturer, and to comply with technical and hygienic precautionary measures, opening of the device and service and/or repairs must be performed only by DeRoyal or by DeRoyal-authorized professionals.

In case of an emergency, contact your local emergency service immediately. Dial 911 within the US.

For additional copies of any Prospera Flex literature, please contact DeRoyal Customer Service. US: 1.800.251.9864

Prospera Flex literature may be downloaded from the DeRoyal website at deroyal.com

INTRODUCTION

The **Prospera Flex™ NPWT Single-Use System** subsequently named "Prospera Flex", disposable Single-Use system for patients who have hard-to-heal wounds. Therapy is accomplished by the electronically controlled pump unit delivering a continuous negative pressure at -80 mmHg to the wound surface, which draws the exudate into a flexible exudate canister, creating an environment that promotes wound healing via the removal of low to moderate amounts (<37.5ml/day) of exudate and infectious materials from the wound. When the canister is full it can be replaced without disturbing the wound bed or the wound dressing. **This device is programmed to run for 7 days following battery tab removal after which the device will not operate and will need to be replaced.**

The system includes:

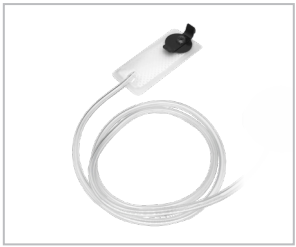
- Prospera Flex NPWT Single-Use System
- Carrying Bag
- 45cc Canister
- Prospera Propel™ FX Dome
- Two AA Lithium Batteries
- Clinician and Patient Quick Reference Guides

Dressings are not provided as part of the system. The system must be used with a commercially available wound dressing selected by a licensed and trained clinician, or a physician's prescription. Read and understand all safety instructions and directions for use included with all NPWT wound dressings, canisters and accessories.

THE PROSPERA FLEX™ SINGLE-USE NPWT SYSTEM INCLUDES

PROSPERA FLEX™ NPWT SINGLE-USE SYSTEM

CARRYING BAG



45CC CANISTER WITH TUBING

PROSPERA PROPEL™ FX DOME

TWO (2) AA LITHIUM BATTERIES


PROSPERA
DeRoyal
QUICK REFERENCE GUIDE
Please refer to the User Manual for full instructions.
ACTIVATE THE DEVICE - CLINICIAN ONLY
DO NOT remove the pull-tab until ready to deliver therapy. Locate the red pull-tab at the base of the battery cover.
Grip the pull tab firmly.
Pull the tab to remove it and begin the 7-day timer with the pump.
USING THE DEVICE
Confirm pump is connected to canister. To connect the pump to the canister, align the tabs on the pump and insert canister face down.
Confirm canister is connected to dome. To connect the canister to the dome, push the connectors together and twist clockwise.

QUICK REFERENCE GUIDE

SYMBOLS

 Leak Status

OK Pump Status

 Battery Life Status

 Pump **ON/OFF** Button

 Caution

 Single-Use. Do not re-use

 Manufacturer

 Date of Manufacture

 Sterilized by Ethylene Oxide

 Lot Number

 Serial Number

 Use by Date

 Replacement Battery Type and Direction

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

 Read Instructions Before Using

 Humidity Limitation for Operation, Transport and Storage

 Type BF Applied Part 1

 Keep Dry

 Temperature Limitation for Operation, Transport and Storage

 Part Number

 MR Unsafe

For a list of symbols used in this manual, visit **deroyal.com/symbols**

INDICATIONS FOR USE

The Prospera Flex™ system is indicated for patients who would benefit from Negative Pressure Wound Therapy as it may promote wound healing by removing low to moderate levels (< 37.5 ml/day) of exudate and infectious materials.

Appropriate wound types include:

- Closed incision sites
- Chronic wounds
- Acute, sub-acute and descended wounds
- Traumatic wounds
- Partial thickness burns
- Pressure or venous insufficiency ulcers
- Diabetic ulcers
- Flaps and grafts

INTENDED USER

The Prospera Flex system is intended to be set up on a patient and monitored regularly by licensed and trained clinicians; however, patients and caregivers may be required to monitor the therapy at home on a day-to-day basis following these Instructions for Use.

⚠ CAUTION
US Federal Law restricts this device to sale by or on the order of a physician.

The therapy is to be used 24 hours a day, or as directed by a clinician.

INTENDED PATIENT POPULATION

The Prospera Flex system is intended to be used on adult patients exhibiting conditions as described in the Indications for Use. The device can be used of any nationality who are alert and mentally competent and who are able to live a normal life but have a wound that requires NPWT.

The patient or caregiver must have the visual and hearing acuity necessary to appropriately respond to notifications from the system and have the sensory and cognitive ability to understand this user manual as well as directions from a licensed and trained clinician pertaining to the proper use of the system. This portable, body-worn device can be used both indoors and outdoors, in a hospital, long term care facility and home healthcare setting.

CONTRAINDICATIONS

The Prospera Flex™ system should **NOT** be used in the following conditions:

- Patients with malignancy in the wound bed or margins of the wound
- Previously confirmed and untreated osteomyelitis
- Non-enteric and unexplored fistulas
- Necrotic tissue with eschar
- Exposed arteries, veins, nerves or organs
- Anastomotic sites
- Emergency airway aspiration
- Pleural, mediastinal or chest tube drainage
- Surgical suction
- Patients with high (> 37.5 ml/day) exudate flow rates
- On neonates, infants, or children

If unsure, refer to the prescribing physician before using the device.

WOUND SUITABILITY FOR PROSPERA FLEX THERAPY

The Prospera Flex system should be used on wounds with low to medium exudate flow rates that:

Are difficult to heal.
Are less than 1 inch deep.
Have a surface area less than 12 square inches.
Are on patients with some degree of mobility, who wish for a discrete therapy which will not interfere with their daily activities.
Do not need daily monitoring by a licensed and trained clinician.
Are expected to show significant improvement using NPWT within 28 days.

WARNINGS AND CAUTIONS

Use system in accordance with all Instructions for Use. Please read and observe all warnings and cautions before using the device. This User Manual must be kept with the device. These Instructions for Use are a general guide for the use of the device. Unique medical situations must be addressed by a physician.

- Follow your facility's protocol for wound site preparation, debridement, dressing technique and proper placement of device when in use. Discard materials according to facility protocol, federal, state, and local law.
- Before use, thoroughly inspect device, including its accessories and tubing, for breaks, cracks, damage, or defects.
- The Prospera Flex™ device must be connected only to a Prospera Flex disposable exudate canister and suitable negative pressure wound dressing to enable its continuous and safe operation. Read and understand all safety instructions and directions for use included with suitable dressing kits and all DeRoyal NPWT canisters and accessories.
- Avoid exposure of device, dressings, canisters or accessories to direct sunlight, extreme heat or cold.

⚠ WARNINGS

1. Certain patients are at high risk of bleeding complications, which if uncontrolled could potentially be fatal. Patients must be closely monitored for bleeding. If sudden or increased bleeding is observed, immediately discontinue therapy, leave dressing in place, take appropriate measures to stop the bleeding and seek immediate medical assistance.
2. The use of anticoagulants does not deem a patient inappropriate for treatment with the Prospera Flex™ device; however, hemostasis must be achieved before applying the dressing. Patients suffering from difficult hemostasis or who are receiving anticoagulant therapy have an increased risk of bleeding. Avoid using hemostatic products that may increase the risk of bleeding if therapy is disrupted. Frequent assessment must be maintained and considered throughout the therapy.
3. Take care at all times to ensure the pump, canister, tubing and carrying bag does not:
    - Lie in a position where it could cause pressure injury to the patient.
    - Lie in a position where it could present a trip hazard, become entangled with the patient or become contaminated.
    - Present a risk of strangulation or a tourniquet to patients.
    - Become close to a source of heat.
    - Become twisted or trapped under clothing or bandages so that the negative pressure is blocked.
4. Serious or fatal injury can result from sharp edges or bone fragments in a wound under negative pressure, as organs may be punctured. Remove or cover such items prior to using the Prospera Flex system.
5. In the event that defibrillation is required disconnect the pump from the canister before the patient is defibrillated.
6. **MR Unsafe.** The Prospera Flex pump is not MRI compatible. Do not take the Prospera Flex pump into the MRI suite or near MRI equipment.

⚠ WARNINGS, CONT.

7. The Prospera Flex™ system has not been studied on pediatric patients. Patient size and weight should be considered when prescribing therapy. Weight Range for therapy is 30-150kg (70-330lbs).
8. The Prospera Flex system is unsuitable for use in areas where there is a danger of explosion (e.g. hyperbaric oxygen or nitrous oxide) or in the presence of a flammable anesthetic mixture or with oxygen or nitrous oxide.
9. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and other equipment should be observed to verify that they are operating normally.
10. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the Prospera Flex device. Otherwise, degradation of the performance of this equipment could result.
11. **DO NOT** modify, open or attempt to perform internal maintenance on the Prospera Flex device without authorization of DeRoyal.
12. Always place the pump inside the carrying bag when wearing the device.
13. Check the system, including wound dressings, canisters and device settings (pressure, alarms, battery life, etc.) at shift change or every eight (8) hours. Look for a compressed appearance at dressing surface. A compressed appearance means the dressing is properly adhered to skin, the dome is properly adhered to the dressing, and negative pressure is active.

⚠ CAUTIONS

1. Dressing should only be applied or changed by licensed and trained clinicians.
2. Due to high risk of bleeding complications, precautions should be taken in patients who are:
   - Receiving anticoagulant therapy or platelet aggregation inhibitors or actively bleeding.
   - Having weakened or friable blood vessels or organs in or around the wound as a result of, but not limited to, anastomoses, infection, trauma or radiation.
   - Suffering from difficult wound homeostasis.
   - Untreated for malnutrition.
   - Non-compliant or combative.
   - Suffering from wounds in close proximity to blood vessels or delicate fascia.
3. When the Prospera Flex™ system is used on infected wounds, more frequent dressing changes may be required. Regular monitoring of the wound should be conducted to check for signs of infection. If the infection worsens, the patient/caregiver should contact their physician.
4. The pump should be carried in a manner that provides a patient or clinician access to regularly check the status of the pump.
5. When the Prospera Flex system is used on patients with fragile skin, a skin protectant should be used.
6. If reddening or sensitization occurs, discontinue use and contact the patient's licensed and trained clinician.
7. Do not use the Prospera Flex system with oil-based products such as skin cream or petroleum-based ointment as it may compromise establishing an effective seal.

⚠ CAUTIONS, CONT.

8. The use of negative pressure presents a risk of tissue ingrowth into foam when foam is used as a wound filler. When using foam as a filler with the Prospera Flex™ system, tissue ingrowth may be reduced by using a wound contact layer, wrapping the foam in gauze, or increasing the frequency of dressing changes.
9. When replacing a wound dressing or removing the system, check all undermining and/or tunneling wounds for excess wound fillers (foam, gauze, etc.). Ensure all previous wound fillers are removed and take care to ensure wound fillers **DO NOT** rip or tear during removal.
10. The Prospera Flex system may be used in conjunction with surgical drains provided the dressing is not placed over tubing where it exits the skin. Any surgical drain should be routed under the skin away from the edge of the dressing and function independently of the Prospera Flex system.
11. When showering, the Prospera Flex pump and canister should be disconnected from the Prospera Propel™ FX Dome and placed in a safe and dry place.
12. This device is single use only. Use of any part of this system on more than one patient may result in cross contamination that may lead to infection.
13. During transport, there is a potential for radio frequency interference that could affect the Prospera Flex system performance. If the device malfunctions, remove and then replace batteries. If this is not successful replace with new batteries. If not corrected, contact your licensed and trained clinician to replace the device.
14. The Prospera Flex system is not intended for use aboard an aircraft, the batteries should be removed during air travel.
15. The potential for electromagnetic interference in all environments cannot be eliminated. Use caution if the Prospera Flex system is near electronic equipment such as RFID (Radio Frequency identification) readers, anti-theft equipment or metal detectors.

⚠ CAUTIONS

16. The Prospera Flex™ device must be connected only to a Prospera Flex disposable exudate canister and suitable negative pressure wound dressing to enable its continuous and safe operation. Read and understand all safety instructions and directions for use included with all NPWT wound dressing kits, canisters and accessories.
17. When in use, regularly check the system for pump operation, canister fill status and negative pressure at the wound dressing. Keep the pump away from sources of liquids and do not immerse in water.
18. Be advised there may be an odor associated with the exudate. Position accordingly for odor control.
19. Avoid placement of the Prospera Flex dressing next to the vagus nerve to minimize the risk of bradycardia.

ADVERSE REACTIONS

Excessive bleeding is a serious risk associated with the application of negative pressure to wounds which may result in death or serious injury. Careful patient selection in view of the above stated indications, warnings and cautions is essential. Monitor the wound, dressing and canister for any evidence of excessive blood loss. Notify the licensed and trained clinician of any sudden changes in volume or color of the exudate.

Notify the manufacturer of any adverse events using the contact details at the back of this manual.

LICENSED AND TRAINED CLINICIAN TASKS

INITIAL VISIT: SET-UP THE DEVICE

CHANGE THE DRESSING

LICENSED AND TRAINED CLINICIAN TASKS

CHANGE THE CANISTER

END OF THERAPY - REMOVE THE DEVICE

PATIENT AND CAREGIVER TASKS

ROUTINE MONITORING

SHOWERING

DAILY ACTIVITIES

PATIENT AND CAREGIVER TASKS

CLEANING

CHANGE THE CANISTER

CHANGE BATTERY

THE PROSPERA FLEX™ SYSTEM COMPONENTS

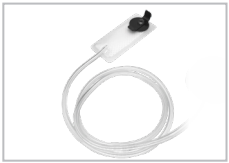
The Prospera Flex™ NPWT System is comprised of a Prospera Flex unit, batteries, dome, canister, and component accessories provided by DeRoyal. The following figures have been provided as graphical representation of the entirety of the Prospera Flex system and component accessories.

- Check the package containing the Prospera Flex system for completeness and general condition upon delivery.
- Inspect all packaging for damage or defects. Replace the entire kit and/or components if the packaging is damaged.
- Contact your provider immediately if any items are missing or damaged.
- The Prospera Flex system is for single patient use only.

AVAILABLE ACCESSORIES

PROSPERA FLEX™ NPWT SINGLE-USE SYSTEM

CARRYING BAG



45CC CANISTER AND TUBING

PROSPERA PROPEL™ FX DOME

TWO (2) AA LITHIUM BATTERIES

QUICK REFERENCE GUIDE

DEVICE CONTROLS AND STATUS INDICATORS

	Pump **ON/OFF** Button
	Leak Status
OK	Pump Status
	Battery Life Status

SELECT THE WOUND DRESSING

The Prospera Flex™ device is designed to operate safely and effectively using a suitable negative pressure wound therapy dressing as determined by a licensed and trained clinician.

> ⚠ **CAUTION**
> **Do not use any dressing or wound filler components if the sterile packaging is damaged or the item is beyond its sterility date.**

Dressing changes should be performed by licensed and trained clinicians, following physicians' prescribed treatment. This user manual and instructions for use are not intended to be training documents. All licensed and trained clinicians must receive adequate training before operating the device or attempting to change wound dressings. Improper use or inadequate training may result in serious injury to the patient.

A licensed and trained clinician will select the appropriate dressings and wound fillers to use based on:

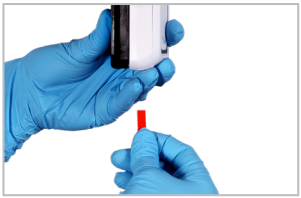
- Nutrition, Medication, Blood Pressure and Mobility of the Patient
- Physician's order
- Size, position and type of wound
- Wound infection

ACTIVATE THE DEVICE

- The therapy clock starts running as soon as the batteries are activated and lasts for 7 days, after which the pump must be replaced by a new one.
- The pump is delivered preset at 80mmHg and cannot be modified.
- One set of batteries should last for approximately 7 days depending on storage, usage and air leakage. It is advisable to have a spare set of lithium batteries available for use.
- When the low battery light is on, replace the batteries as soon as possible to maintain therapy.

1. **DO NOT** remove the pull tab until ready to deliver therapy. Locate the red pull tab at the base of the battery cover.

2. Grip the pull tab firmly.



3. Pull the tab to remove it. This will begin the 7-day timer within the pump.

USING THE DEVICE

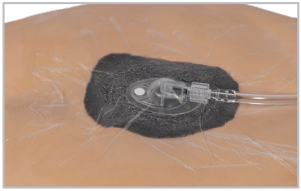
PREPARING THE DEVICE

Before starting therapy, follow these important steps:

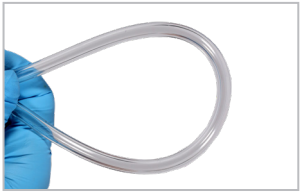
1. Confirm pump is connected to canister. To connect the pump to the canister, open the back of the pump and insert canister face-down. ***See Changing the Canister on pg 32.***

2. Confirm canister is connected to dome. To connect the canister to the dome, push the connectors together and twist clockwise.

PREPARING THE DEVICE, CONT.



3. Confirm wound dressing is applied properly and is securely connected to the canister and the Prospera Flex™ device.



4. Confirm all tubing, and tubing connections are open and free from kinks or other blockages.
   - Ensure patient is not lying on tubing.

5. Ensure device is operating in a safe environment, on a stable surface, and free from hazards.

6. Ensure device is secured to avoid accidental damage during therapy.

USING THE DEVICE

TURNING THE PUMP ON

Press the **ON/OFF** button firmly for approximately 2 seconds.

All lights flash and buzzer **BEEPS** indicating Therapy Day. ***See Therapy Day Indicator table on Page 43.***

Followed by: Green light flashes indicating normal operational state.

TURNING THE PUMP OFF

Press the **ON/OFF** button firmly for approximately 2 seconds.

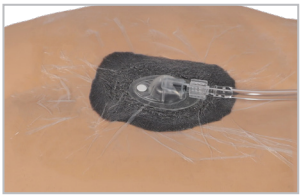
All lights go **OFF** and pump stops running. Therapy will not be maintained when the pump is **OFF.**

The Therapy Day will remain the same if device is powered off. It will not reset to zero.

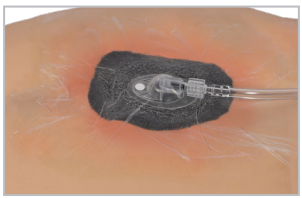
MONITORING THE SYSTEM OPERATION

1. Check the pump regularly. The pump is running when the green **OK** light is flashing. ***See Notifications and Troubleshooting on page 44*** for other pump alerts.

2. Check the dressing regularly.



- When the system is running normally, look for a compressed appearance at the dressing surface. A compressed appearance means the transparent wound dressing is properly adhered to skin, the Prospera Propel™ FX dome is properly adhered to the transparent wound dressing, and negative pressure is active.
- If the exudate tube is blocked, the dressing may appear loose on the wound (ex: exudate flow obstructed, clamp depressed, tubing is kinked, or stenosis in tubing). Check that the tube clamp is open, and the canister is not full, ***see Notifications and Troubleshooting.***
- If there is a leak in the system, there will be an alert on the pump, ***see Notifications and Troubleshooting.***



3. Monitor skin for redness and irritation.
   - Contact your clinician if skin condition deteriorates when the dressing is in use.

MONITORING THE SYSTEM OPERATION

4. The canister should be changed as soon as it is full. ***See Changing the Canister on page 32.***
   - The canister is full when there is loose exudate fluid seen within the canister not being absorbed.
   - Contact your clinician if canister fills up in less than 3 days, as the wound may have a higher-than-expected exudate flow rate.

CHANGING THE CANISTER

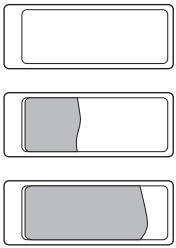
The Prospera Flex™ device can be connected only to canisters provided by DeRoyal and used only with suitable negative pressure wound dressings to enable continuous and safe operation. Read and understand all safety instructions for use included with all DeRoyal NPWT devices and accessories.

Confirm canisters and accessories are within reach before beginning any canister change procedure. Inspect canister and canister packaging for damage or defects, replace the canister if it is damaged. Turn device off before initiating any canister changes.

Contact your clinician if canister fills up in less than 1 day, as the wound may have a higher-than-expected exudate flow rate.

Monitor wound exudate in canister for signs of excess blood loss or other complications. If active bleeding occurs, disconnect the device from the dome, apply pressure to the wound, and call health provider immediately.

CHANGING THE CANISTER, CONT.



EMPTY

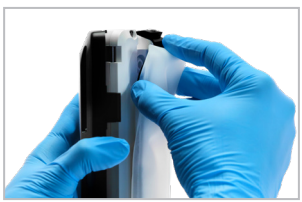
PARTIALLY FULL

FULL

1. Check the canister fill status.
   - The canister is full when there is loose fluid seen within the canister that is not being absorbed.
   - The canister can be changed without disturbing the wound dressing.

2. Disconnect the canister from the dome. Twist the connector counter-clockwise.

3. Turn the pump **OFF.**



4. Disconnect the canister from the pump by depressing the top tab and pushing away from device front face. Then remove bottom tab from holder.

CHANGING THE CANISTER

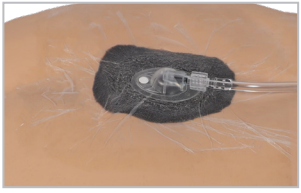
5. Appropriately dispose of canister, including black clip and tubing. ***See Removal and Disposal on page 49.***

6. Replace the canister by inserting the bottom tab and rocking the clip of the new canister into the housing until it clicks. Close canister door.

7. Reconnect the canister to the dome. Push and twist the connector clockwise.

8. Turn the pump **ON.**

CHANGING THE CANISTER, CONT.

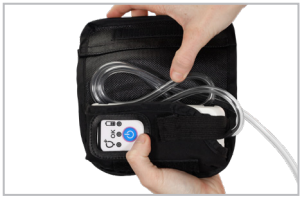


9. Check the pump.
   - The pump is running normally when the **OK** light is flashing.
   - ***See Notifications and Troubleshooting on page 44 for other pump alerts.***

10. Check the dressing.
    - When the system is running normally, look for a compressed appearance at dressing surface. A compressed appearance means the transparent wound dressing is properly adhered to skin, the Prosper Propel™ Flex dressing dome is properly adhered to the transparent wound dressing, and negative pressure is active.
    - If the exudate tube is blocked (exudate flow obstructed, clamp depressed, tubing is kinked, or stenosis in tubing) the dressing may appear loose on the wound. Check that the canister is not full, ***See Notifications and Troubleshooting on page 44***.
    - If there is a leak in the system, there will be an alert on the pump, see ***Notifications and Troubleshooting.***

SETTING UP THE CARRYING BAG

1. Place device inside case by sliding in top-first with device facing out to allow access to power button and alarm indicators.

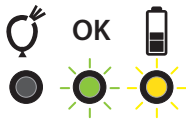


2. Secure over case with tubing protected wrap any excess tubing in elastic holder.

3. Close case by lowering flap and securing velcro.

4. Adjustable strap allows for wear around the neck or across chest. Back loop allows for wear on the belt. **DO NOT** allow tubing to wrap around the neck.

BATTERY STATUS

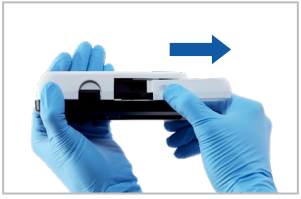
Battery Status	Display Status	Description and Troubleshooting
Low Battery		Green **OK** light and yellow **LOW BATTERY** light flashes. Therapy still working. Replace with lithium batteries as soon as possible.
Dead Battery		All lights **OFF.** Pump does not work when **ON/OFF** button pressed. Therapy not working. Replace batteries immediately.

See Battery Replacement on page 38 for replacement instructions.

BATTERY REPLACEMENT

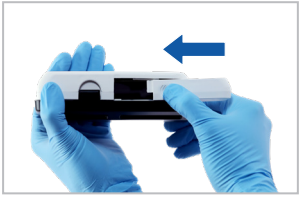
Replace with 2 x AA/L91 lithium batteries (Energizer Ultimate Lithium are recommended.)

- Other types of AA batteries such as alkaline batteries can be used in an emergency but will have a shorter life and may run out unexpectedly.



1. Slide the pump battery cover open.
   - To replace the batteries, turn the pump **OFF**, slide open the battery door and remove the batteries.

2. Insert the batteries according to the indications in the battery compartment.
   - The Therapy Day will remain the same when the batteries are replaced. It will not reset to zero.



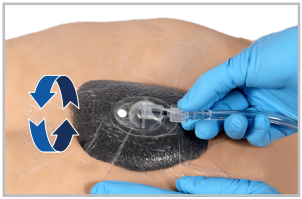
3. Slide the pump battery cover closed until it snaps into place.

4. Check the pump.
   - The pump is running normally when the green OK light is flashing.
   - ***See Notifications and Troubleshooting on page 44 for other pump alerts.***

BEFORE SHOWERING

DO NOT use the device while showering or bathing. Patients and caregivers should consult your licensed and trained clinician for detailed instructions on proper personal care while receiving therapy.

1. Turn the pump **OFF.**

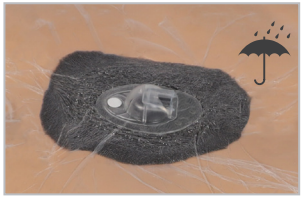


2. Disconnect the canister from the dome. Twist counter-clockwise.

3. Remove the carrying bag holding the pump and canister.

4. Place the unit on a secure surface, avoiding areas where unit is prone to falling, getting wet, or being damaged.

BEFORE SHOWERING

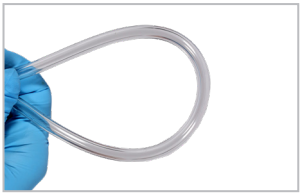


5. Protect the wound from direct spray from the shower and do not submerge in water.

AFTER SHOWERING

1. Put on the carrying bag holding the canister and pump.

2. Reconnect the canister to the dome. Push and twist the connector clockwise.

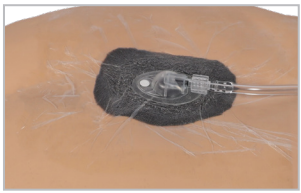


3. Route and fasten the tubing and straps to ensure they do not become kinked or entangled.

AFTER SHOWERING, CONT.

4. Turn the pump **ON**.

5. Check the pump.
   - The pump is running normally when the green **OK** light is flashing.
   - ***See Notifications and Troubleshooting on page 44 for other pump alerts.***



6. Check the dressing.
   - When the system is running normally, look for a compressed appearance at dressing surface. A compressed appearance means the transparent wound dressing is properly adhered to skin, the Prospera Flex™ dressing dome is properly adhered to the transparent wound dressing, and negative pressure is active.

     If the exudate tube is blocked the dressing may appear loose on the wound. Check that the flow is not obstructed and that the canister is not full. If there is a leak in the system, there will be an alert on the pump, see Notifications and Troubleshooting. ***See Notifications and Troubleshooting on page 44.***

DAILY ACTIVITIES

The unit may be worn while performing daily activities, like sitting, walking, driving, and sleeping. Patients and caregivers should consult your licensed and trained clinicians for detailed instructions on appropriate personal activities while receiving therapy.

⚠ WARNING
If therapy is discontinued or disrupted for more than 2 hours, seek emergency medical attention.

Route and fasten the tubing and straps to avoid kinking or trapping.

- Place the tubes inside clothing whenever possible to avoid pulling or snagging during patient movement.
- When sitting at home or in the car, avoid sitting on the pump, canister, or tubes.
- When sleeping, avoid laying on the pump, canister, or tubes.

THERAPY DAY INDICATOR

Check the current Therapy Day at any time by turning the pump **OFF** and then **ON** again.

1. The Therapy Day is shown before normal operation starts.
2. For Therapy Day 1, all the lights flash and the buzzer **BEEPS** once.
3. For Therapy Day 7, all the lights flash and the buzzer **BEEPS** 7 times.
4. The intervening days follow this pattern.

If the batteries are in the pump, the clock continues to count the therapy time whether the pump is **ON** or **OFF**. Removing the batteries stops the count but does not reset the Therapy Day.

Be prepared to replace the device or discontinue therapy when Therapy Day 7 is indicated.

THERAPY TIME COMPLETE

When the 7 days of therapy has come to an end, the pump will indicate therapy time is complete and turn **OFF** automatically. Attempting to restart the pump will only indicate the therapy time is complete and the pump will not operate.

Display Status	Light/Audible Status
 Therapy Time Complete	All lights are **ON**, and buzzer sounds continuously for 10 seconds. Followed by: All lights **OFF**, buzzer **OFF**, and pump powers **OFF.**

NOTIFICATIONS AND TROUBLESHOOTING

If machine will not operate, ensure batteries are inserted correctly. Contact your clinician if a problem cannot be resolved.

⚠ WARNING
If therapy is discontinued or disrupted for more than 2 hours, seek emergency medical attention.

Display Status	Light/Audible Status	Possible Causes	Troubleshooting
 Low Battery Alert	Green **OK** light and yellow **LOW BATTERY** light flashes.	Low battery. System on and functioning properly but battery power is low.	Replace with new batteries. Therapy will be maintained until batteries are exhausted. *See Battery Status and Replacement on page 37.*
	Yellow **LEAK** light flashes. Buzzer **BEEPS.** Pump running.	Leak in system. Air leak detected possibly due to a creased dressing or disconnected tube.	Check connections between canister-device and canister-tubing. Check dressing seal for leaks or creases. Add additional transparent wound dressing if needed.

NOTIFICATIONS AND TROUBLESHOOTING, CONT.

Display Status	Light/Audible Status	Possible Causes	Troubleshooting
	Yellow **LEAK** light and yellow **LOW BATTERY** light flashes. Buzzer **BEEPS**. Pump running.	Leak and low battery. Air leak detected possibly due to a creased dressing.	Replace with new batteries as soon as possible. Check connections between canister-device and canister-tubing. Check dressing seal for leaks or creases. Add additional transparent wound dressing if needed.
 Battery Depleted	All light **OFF.** Buzzer **OFF.** Pump will not run.	Depleted battery.	Replace batteries immediately. Therapy is not being maintained. ***See Battery Status and Replacement on page 37.***

NOTIFICATIONS AND TROUBLESHOOTING

Display Status	Light/Audible Status	Possible Causes	Troubleshooting
 Therapy Complete Alert	All lights **ON**, and buzzer sounds continuously for 10 seconds. Followed by: All lights **OFF**, buzzer **OFF**, and pump powers **OFF.**	Therapy Time Complete.	Contact a licensed and trained clinician to assess the wound and replace the system if required. ***See Therapy Time Complete on page 43.***
 System Error Alert	All lights **ON** continuously. Buzzer **OFF.**	Device Error. System is not usable, therapy not being given.	Replace the system.

NOTIFICATIONS AND TROUBLESHOOTING, CONT.

Display Status	Light/ Audible Status	Possible Causes	Troubleshooting
 Therapy Pressure out of Range	Yellow **LEAK** light **ON** continuously, buzzer **ON** continuously.	Vacuum level is greater than normal therapy range. Possible closed/ blocked system.	1. Turn pump **OFF.** 2. Check clamps, all tubing, and tubing connections for blocks or kinks. 3. Disconnect the canister from device to relieve pressure. 4. Reconnect the canister and turn the pump ON. The pump should restart. 5. If the alert does not clear, remove and replace the canister. If the alert does not clear, contact your licensed and trained clinician for potential troubleshooting. **NOTE:** Clinician should check and replace as necessary the canister, drape, and/or unit, in that order. If the alert does not clear, remove device and replace system.

CLEANING

Occasional cleaning of the system may be necessary. Dressings should be replaced by a licensed and trained clinician. Follow your facility's protocol, and these steps:

1. The unit can be wiped clean with a damp cloth using soapy water or a disinfectant wipe.
2. The canister can also be wiped clean with a damp cloth using soapy water or a disinfectant wipe.

Device can be damaged by use of improper cleaning agents. Follow instructions for use provided by the manufacturers of disinfectants, particularly with respect to material and surface compatibility. **DO NOT** use disinfectants that contain acetone, as these may damage or deform housing components and accessories. DeRoyal recommends with a damp cloth using soapy water or a disinfectant wipe. **DO NOT** submerge or spray liquids directly on the device. If you have questions or concerns, contact your durable medical equipment provider or DeRoyal customer service at the numbers listed in the back of this manual.

The Prospera Flex™ system, including unit, dome, and canisters are single use devices. **DO NOT** reprocess or re-sterilize any part of the system. Reuse, reprocessing, or re-sterilization may damage part or all of the system components.

MAINTENANCE

The Prospera Flex unit is maintenance free and will not require service. The batteries may be replaced if required. See Battery Status and Replacement on page 30. If the pump fails due to a manufacturing defect, follow directions found in the ***Warranty section on page 50.***

REMOVAL AND DISPOSAL

1. When replacing a wound dressing or removing the system, remove all wound filler material and particles from the wound bed, taking extra care if foam is being used.
2. Follow local regulations for infection control and waste disposal procedures for used dressings, and canisters.
3. At the end of therapy or when replacing batteries, remove and dispose of the batteries in accordance with local regulations.
4. Local protocols for disposal of the Prospera Flex™ pump should be based on the applicable federal, state and/or local government environment regulations for recycling electronic devices.

HANDLING AND STORAGE

DeRoyal recommends using original packaging and shipping boxes whenever shipping or transporting device between locations. New or additional shipping boxes can be purchased through DeRoyal Customer Service within the US at 1.800.251.9864.

Note environmental factors and restrictions when shipping device to ensure safe, dry, and temperature-controlled conditions. **DO NOT** expose the NPWT unit, dressings, canister or accessories to extreme heat or cold. The DeRoyal's Prospera™ Flex system and accessories should be stored in a dry, temperature-controlled environment. Avoid exposing unit or any accessories to extreme temperatures.

	Environmental Operating Conditions	**Environmental Storage and Shipping Conditions**
Temperature Range	+41ºF to +104ºF (+5ºC to +40ºC)	13ºF to +158ºF (-25ºC to +70ºC)
Relative Humidity	15% to 93% (Non-Condensing)	0% to 93% (Non-Condensing)
Atmospheric Pressure	0.69atm to 1.05atm	0.69atm to 1.05atm

PROSPERA FLEX™ 7 DAY NEGATIVE PRESSURE WOUND THERAPY DEVICE WARRANTY

DeRoyal's Prospera Flex Disposable Negative Pressure Wound Therapy unit is warranted to be free of defects in material and workmanship for seven (7) days from initial use or until expiration, whichever comes first. All operational aspects (mechanical and electrical) are covered by this warranty. This warranty does not cover accessories, spare parts, and consumables (including batteries).

To the extent allowed by law DeRoyal's written warranties are given in lieu of any implied warranties, including warranties of merchantability or fitness for a particular purpose.

PROSPERA FLEX DISPOSABLE NEGATIVE PRESSURE WOUND THERAPY ACCESSORIES, SPARE PARTS AND CONSUMABLES WARRANTY

DeRoyal-provided accessories, spare parts, and consumables are warranted for ninety (90) days from the date of shipment from DeRoyal as to product quality and workmanship. DeRoyal's written warranties are given in lieu of any implied warranties including warranties of merchantability or fitness for a particular purpose.

⚠ CAUTION

Warranty claims will not be accepted if (1) the unit has been modified or tampered with by unauthorized individuals; (2) the unit has not been used in accordance with the proper guidelines provided in the unit's user manual and/or instructions for use (this includes using any non-DeRoyal provided domes and canisters with the unit); (3) the unit has been rendered inoperable due to physical damage (inclusive of drops or falls of the unit) or (4) the unit has been used beyond the maximum allowable service life (7 days).

SPECIFICATIONS

Item	Specifications	
Item Number	Pump Canister Dome Carrying Bag	NP-8007D NP-8045C NP-190F NP-8007B
Electrical Classification	Type BF	
Applied Parts	The dressing component and Dome are considered applied parts under IEC 60601-1.	
Mode of Operation	Continuous, Internally powered, portable.	
Operating Time	7 Days	
Battery Type	Lithium AA Primary (L91)	
Power (Battery)	3V DC	
Negative Pressure Range	-80mmHg nominal	
Essential Performance	The unit should not deliver a Negative Pressure to the wound exceeding -225mmHg	
Pump Dimensions	5.3" x 2.2" x 1.5" (13.5cm x 5.6cm x 3.6)	
Pump Weight	Pump <0.5 lb (<225 g)	
Environment Requirements	Temperature: Operation +5ºC to +40ºC (+41ºF to +104ºF) Storage -25ºC to +70ºC (-13ºF to +158ºF) Humidity: Operation 15% to 93% non-condensing Storage 0% to 93% non-condensing Pressure: 0.69atm to 1.05atm	
Expected Service Life	Approximately 7 days	
Canister	45cc exudate capacity Canister made from Polyurethane. Single Patient Use only	
Safety Compliance	IEC 60601-1 ed 3.1 and IEC 60601-1-11 ed 2.0 IEC 60601-1-2 ed 4.0	

SAFETY AND EMC

When used in accordance with the manufacturer's instructions, the Prospera Flex™ system complies with the general requirements for safety of electrical medical equipment IEC 60601-1 ed 3.1 and the electromagnetic safety requirements of electrical medical equipment IEC 60601-1-2 ed 4.0 Class B.

ELECTROMAGNETIC COMPATIBILITY

The Prospera Flex system complies with the electromagnetic safety requirements of electrical medical equipment IEC 60601-1-2 ed 4.0, CISPR11 Group 1, Class B for use in the home healthcare and professional healthcare environment. The immunity test levels per home healthcare environment were applied. No deviations or allowances were used from this standard.

The limits in the standard are designed to provide reasonable protection against electromagnetic interference typical of home healthcare and professional healthcare environments, including public places and transport by car, but not transport by aircraft. The Prospera Flex unit should not be used near high frequency (HF) surgical equipment of near MRI equipment or rooms.

The "Essential Performance" of the Prospera Flex unit is that it should not deliver a Negative Pressure to the wound exceeding -225mmHg. This performance is protected from degradation by EMC by a mechanical pressure relief valve.

⚠ WARNING
Portable radio frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the Prospera Flex unit. Otherwise, degradation of the performance of this equipment could result.

DeRoyal Industries, Inc.
200 DeBusk Lane
Powell, TN 37849

Telephone | 800.251.9864
Fax | 800.543.2182
Website | deroyal.com/npwt

Part #: 0-1962
REV: 10/2023