PREVENA PLUS™

INCISION MANAGEMENT SYSTEM

WITH PREVENA PLUS™ 125 THERAPY UNIT (14 DAY)

PATIENT GUIDE

KCI™
AN ACELITY COMPANY

Rx Only

PREVENA PLUS™ 125 Therapy Unit for Use at Home with PREVENA PLUS™ Dressings

PREVENA PLUS™ 125 Therapy Unit (14 Day)

IMPORTANT: As with any prescription medical device, failure to consult a physician and carefully read and follow all therapy unit and dressing instructions prior to each use may lead to improper product performance and the potential for serious or fatal injury. Do not adjust therapy unit settings or perform therapy application without directions from/supervision by the treating physician.

This guide is not intended as a comprehensive resource. For additional information concerning proper use of the PREVENA PLUS™ Incision Management System and important information including safety information, cautions and warnings, consult with your physician.

PREVENA PLUS™ Incision Management System Patient Guide

You have been prescribed a PREVENA PLUS™ Dressing and a therapy unit to manage your incision. Please read this guide to learn more about these items and how to use them. This guide also includes important warnings for your safety. **Call your doctor or KCI at 1-800-275-4524 if you have any questions about the PREVENA PLUS™ Dressing or therapy unit.**

Do not re-use any part of the PREVENA PLUS™ Dressing or canisters. These items are for single use only. Re-use of these items could cause wound contamination, infection or failure to heal.

The PREVENA PLUS™ 125 Therapy Unit is a single use, disposable therapy device. This unit provides negative pressure continuously at 125 mmHg. The PREVENA PLUS™ 125 Therapy Unit has a fixed lifespan and a rechargeable battery. Upon receipt of the therapy unit, the battery may not be fully charged.

Contraindication and Warnings

Contraindication

The dressing contains silver. If you are sensitive or allergic to silver, call your doctor right away.

Warnings

- Do not wrap carrying case strap or dressing tubing around neck.
- Small Parts - Choking Hazard
- The therapy unit is a prescription medical device. Please read and follow all the instructions in this guide so the product can perform properly while in use.
- Do not operate this product if it has a damaged power cord, power supply or plug.

If you need:

- Magnetic Resonance Imaging (MRI), your doctor or nurse must remove the therapy unit. The dressing can remain in place.
- Hyperbaric Oxygen Therapy (HBO), your doctor or nurse must remove the therapy unit **and** dressing.

If defibrillation is required, a doctor or nurse will decide if the dressing should be removed.

Bleeding

Some patients may be at risk of heavy bleeding, with or without using the prescribed therapy system. This bleeding can be caused by the type of surgical procedure or by certain patient conditions.

If you see a large amount of blood near your incision or in the tubing or canister, leave the dressing in place. Turn off the therapy unit. Call your local emergency service (i.e. 911) right away.

Full Canister

The canister may fill up with fluid before your therapy is done. If you see a large amount of fluid in the canister, turn off the therapy unit. Call your doctor right away. The therapy unit will let you know when the canister is full.

Infection

The following symptoms may mean that your incision in infected. Call your doctor right away if you:

- have swelling at the dressing
- feel an increase in soreness at the dressing
- have redness around the dressing
- feel feverish
- feel itching at the dressing
- feel warmth at the dressing
- have pus at the dressing
- have a bad odor at the dressing

Allergic Reaction

The dressing may cause an allergic reaction if you are sensitive to acrylic adhesives or to silver. The following symptoms may mean you are having an allergic reaction. Call your doctor right away if you:

- notice redness
- notice swelling
- develop a rash
- develop hives
- develop itching

If you feel short of breath, your allergic reaction may be more serious. Immediately call your local emergency service (i.e. 911). Turn off the therapy unit and remove the dressing.

Contraindication and Warnings (continued)

- The dressing should only be applied or removed by your doctor.
- Do not modify, open or disassemble the therapy unit or dressing. Do not connect the therapy unit or dressing to other devices that you might be using.
- The therapy unit is a medical device that monitors pressure and is not a toy. Keep away from children, pets and pests as they can damage the dressing and therapy unit and affect performance. Keep the therapy unit free of dust and lint as they can also cause damage and affect performance.
- To avoid damage to the therapy unit, use only the power supply and cord that comes with the unit.
- Keep the therapy unit away from heated surfaces.
- Do not use the therapy unit in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide or in an oxygen-rich environment.
- When you receive the therapy unit, the battery may not be fully charged.
- Do not drop or insert any object into an opening or tubing on the therapy unit.

Instructions for Use

Check the appearance of the dressing regularly. Do not turn off the therapy unit unless:

- your doctor instructs you
- you experience bleeding
- you have an allergic reaction
- you need to disconnect the unit to shower

- See the **Warnings** section of this guide for more details.

Daily Activity

The therapy unit is small and portable. It can be worn beneath your clothing. Stay away from strenuous activity when using the therapy unit. Ask your doctor the following before wearing the device during daily activities.

- How active you can be.
- When you can resume your daily routine.

Sleeping

- Place the therapy unit in a position where the tubing will not become kinked or pinched.
- Ensure the therapy unit cannot be pulled off the table or dropped on the floor.

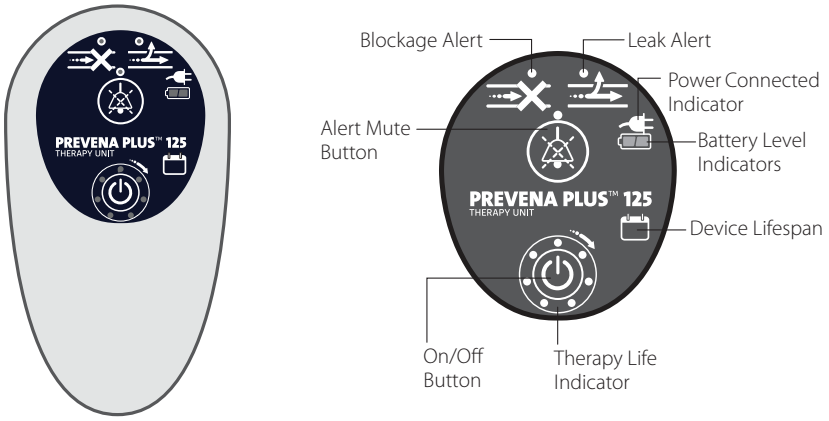
Showering and Bathing

- Do not use the therapy unit in the bathtub or shower.
- Do not spill fluids on any part of the therapy unit. If spills do occur, unplug the unit immediately if plugged in. Clean the fluid from the therapy unit. Ensure there is no moisture on the unit and power supply components before plugging in. If the unit does not work, call KCI.
- Do not place the therapy unit where it can fall or be pulled into a tub, shower or sink.
- Do not reach for a therapy unit that has fallen into water. Unplug the unit immediately if plugged in. Disconnect the unit from the dressing and call KCI.
- Before showering press the On/Off button to stop therapy. Close the tubing clamp and disconnect the tubing from the therapy unit.
- The clear drape is waterproof. You may wash or shower with the dressing in place. Avoid prolonged water contact with the dressing.
- When towel drying, be careful not to disrupt or damage the dressing.

Cleaning

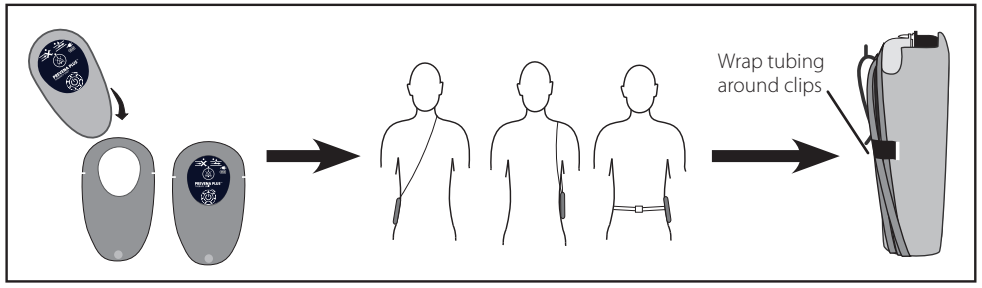
If needed, clean the therapy unit and carrying case with a damp cloth and mild soap and water solution. Do not use bleach.

The PREVENA PLUS™ 125 Therapy Unit



Therapy Unit Carrying Case

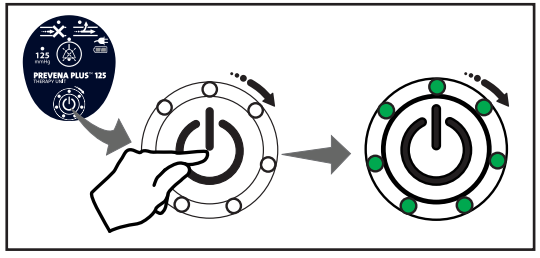
Use the adjustable strap to wear the carrying case over your shoulder or across your chest. You can also wear the carrying case on your belt. Secure any excess tubing with the clips on the carrying case.



CAUTION: Do not wrap the carrying case strap, power cord or dressing tubing around your neck.

Turn Therapy On

Press and hold the On/Off button for three seconds.



Therapy Life Indicators

The therapy unit has a fixed lifespan.

CAUTION: This lifespan will start after the unit has run for one hour, non-stop. The lifespan will continue to count down even if the unit is turned off. The LEDs around the On/Off button show how many days are left in the lifespan.

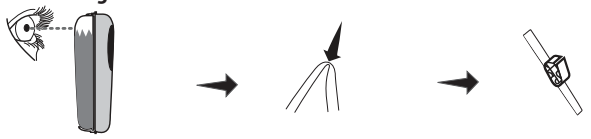
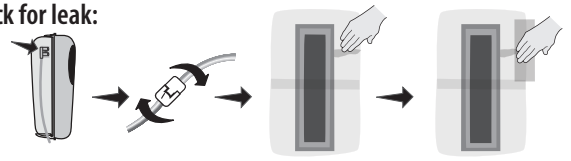
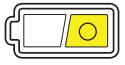
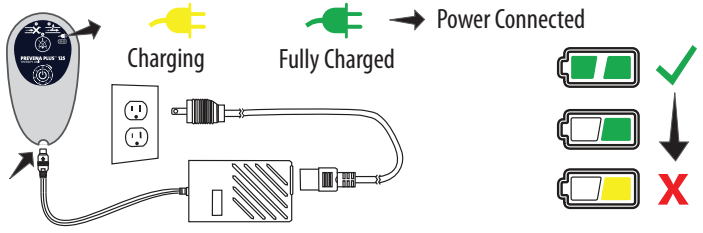
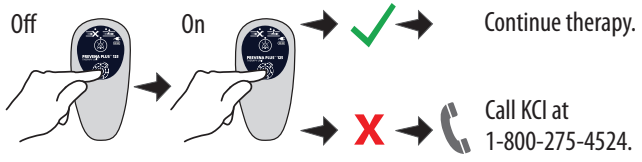
Alerts

Alerts are indicated by LEDs and two beeps. The beeps may become louder, depending on the type of alert.

Alert Mute: Press the Mute Button to silence the alert beeps. The alert beeps will come back on in two minutes if the alert condition has not been fixed.

- Refer to the Alert Table for instructions to fix the alert condition.
- LEDs cannot be turned off or muted (paused) by the user. Visual Alerts will only stop when the alert condition has been corrected.
- If the alert condition cannot be fixed, contact KCI at 1-800-275-4524.

Alert Table

Alert Type	How to fix
Blockage Alert 	**Check for blockage:** 
Leak Alert 	**Check for leak:** 
Low Battery Alert 	
System Error Alert  All LEDs flashing and two beeps every 15 seconds	**Turn therapy unit off then on.** 

Therapy Complete

After the fixed lifespan of the unit is complete, the PREVENA PLUS™ 125 Therapy Unit will shut off.

Disposal

The therapy unit, power supply, accessories and dressing should be removed by your doctor or nurse. Do not discard these items with household trash. This could violate local laws regarding hazardous waste.

Specifications

Transport and Storage Conditions:

Temperature Range: ..... 0˚F (-18˚C) to 140˚F (60˚C)

Relative Humidity Range: ..... 15 - 95%, non-condensing

Operating Conditions:

Temperature Range: ..... 41˚F (5˚C) to 104˚F (40˚C)

Relative Humidity Range: ..... 15 - 93%, non-condensing

Atmospheric Pressure Range for Optimum Performance: .....
1060 hpa (-1253 ft/-381. 9 m) to 700 hpa (9878 ft/3010 m)

Electrical Equipment Interference

Refer to the **Electrical Safety/Electromagnetic Compatibility Information** section for information on electrical equipment interference.

Explanation of Symbols Used


Do not use if package is damaged or open

IP22 Ingress Protection


Type BF applied part

Sterile using radiation


Date of Manufacture


Manufacturer


Fragile


Keep Dry

Content Information


Class II Device


Temperature Limit

MR Unsafe

Rx only CAUTION: Federal (US) law restricts this device to sale by or on the order of a physician.


Consult Instructions for Use


Refer to Clinician Guide


Single Use Only

Contains Phthalates (SENSAT.R.A.C.™ Pad Tubing)


Tripping Hazard


Use By

Catalog Number

Lot Number

Do Not Resterilize


This product is designated for separate collection at an appropriate collection point. Do not dispose of as household waste.


No Bathing or Showering

Electrical Safety/Electromagnetic Compatibility Information

Electrical Safety

- Do not operate this product if it has a damaged power cord, power supply or plug. If these components are worn or damaged, contact KCI.
- The PREVENA PLUS™ Incision Management System is classified as a Type BF applied part under IEC 60601-1.
- It provides IP22-Protection level against ingress of solid foreign objects and liquids.
- All alerts are classified as low priority according to IEC 60601-1.
- Conforms to: IEC 60601-1, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-1-8.

Electromagnetic Compatibility

The PREVENA PLUS™ 125 Therapy Unit needs special precautions regarding EMC.

WARNING: As with all electrical medical equipment, the therapy unit may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as re-orienting or relocating the PREVENA PLUS™ 125 Therapy Unit or shielding the location.

- Portable and Mobile RF communications equipment including cell phones and similar devices, RFID readers, electronic article surveillance (anti-theft) equipment and metal detectors can affect the performance of the PREVENA PLUS™ 125 Therapy Unit.
- Other medical equipment or systems can produce electromagnetic emissions and therefore can interfere with the functionality of the PREVENA PLUS™ 125 Therapy Unit. Care should be used when operating the PREVENA PLUS™ 125 Therapy Unit adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the PREVENA PLUS™ 125 Therapy Unit and the other equipment should initially be observed to verify normal operation in the configuration in which it will be used.
- The electrical cable, external power supply and accessories provided by the manufacturer have been shown to comply with the test requirements. Use only the manufacturer-supplied electrical cable, power supply and accessories with the PREVENA PLUS™ 125 Therapy Unit.
- Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the PREVENA PLUS™ 125 Therapy Unit including power cord and power supply provided by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- NOTE: This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2: 2014 4th edition. These limits and test levels are intended to provide reasonable safety with regard to electromagnetic disturbances when the device is used in a typical medical installation.

Contact Information

For questions about this product, supplies, maintenance or more information about KCI products and services, please contact KCI or a KCI authorized representative, or:

In the US call 1-800-275-4524 or visit www.acelity.com

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Outside the US visit www.kci-medical.com

Treating Physician: _____

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