

PREVENA™

INCISION MANAGEMENT SYSTEM

PATIENT GUIDE



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



PREVENA™ 125 Therapy Unit

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™ 125 Incision Management System and important information including safety information, cautions and warnings, consult with your physician.

PREVENA™ 125 and PREVENA PLUS™ 125 Therapy Units Indication for Use and Limitations

PREVENA™ 125 and PREVENA PLUS™ 125 Therapy Units manage the environment of closed surgical incisions and remove fluid away from the surgical incision via the application of -125mmHg continuous negative pressure. When used with legally marketed compatible dressings, PREVENA™ 125 and PREVENA PLUS™ 125 Therapy Units are intended to aid in reducing the incidence of seroma and, in patients at high risk for post-operative infections, aid in reducing the incidence of superficial surgical site infection in Class I and Class II wounds.

- The device has not been demonstrated to be effective in preventing surgical site infection and seroma from happening in all patient populations.
- The device is not intended to treat existing surgical site infection or seroma.
- Safety and effectiveness in pediatric population (<22 years old) have not been evaluated.
- Safety and effectiveness in contaminated, dirty or infected wounds have not been demonstrated.
- The device should only be used on sutured or stapled surgical incisions.

You have been prescribed a PREVENA™ 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™ Dressing or therapy unit.**

Do not re-use any part of the PREVENA™ 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™ 125 Therapy Unit is a single use, disposable therapy device. This unit provides negative pressure continuously at 125 mmHg. The PREVENA™ 125 Therapy Unit has a fixed lifespan of 7 days.

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 (if provided) 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.

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.

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.

Do not drop or insert any object into an opening or tubing on the therapy unit.

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 (other than blood) 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 is infected. Call your doctor right away if you:

- have swelling at the dressing
- feel 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. Call your local emergency service (i.e. 911) right away and turn off the therapy unit and remove the dressing.

Instructions for Use

Check the appearance of the dressing regularly. See the **PREVENA™ Incision Dressing Pressure Check** section for more details. Do not turn off the therapy unit unless:



- your doctor instructs you
- you experience bleeding
- you have an allergic reaction

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

The dressing should only be applied or removed by your doctor.

Do not modify the therapy unit or dressing. Do not connect 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.

Cleaning



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

Bathing



• Bathing in tub is not recommended.



• Do not submerge the therapy unit or dressing.

Showering



- Quick showering is permitted if cleared with your doctor. Protect the therapy unit from direct spray of water. Avoid prolonged water contact with the therapy unit and dressing.
- When towel drying, be careful not to disrupt or damage the dressing.

Sleeping



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

Strenuous Activity

Stay away from strenuous activity when using the therapy unit. Ask your doctor:



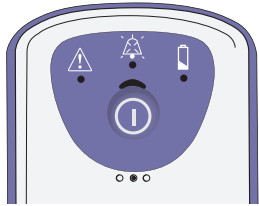
- how active you can be
- when you can resume your daily routine

PREVENA™ 125 Therapy System

If the therapy unit beeps, see the **Indicators and Alerts** section of this guide for more information.

Do not re-use any part of the PREVENA™ System. The therapy unit, canister and dressing are for single use only. Re-use of any part could cause wound contamination, infection or failure to heal.

PREVENA™ 125 Therapy Unit



Caution Light



Audio Pause Light



Low Battery Light

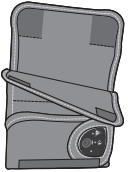


On/Off and Audio Pause Button: Press once to mute audible alerts for 60 minutes.



Press the On/Off button to start the 192 hour (eight day) life cycle of the therapy unit.

PREVENA™ 125 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. Do not wrap the carrying case strap or dressing tubing around neck.

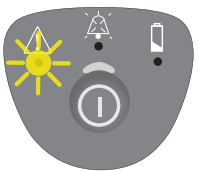
Audio Pause/Mute Feature

See the **Indicators and Alerts** section for more details.

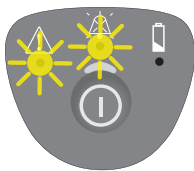


On/Off and Audio Pause Button: Push once to mute audible alerts.

LEAK ALERT



ALERT PAUSED

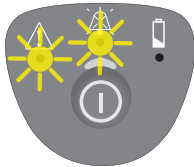


Mutes audible alert for **eight hours**. Check the **PREVENA™ Incision Dressing** section to see if therapy is being applied or not.

CANISTER FULL ALERT

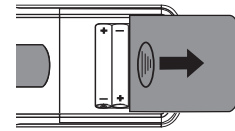


ALERT PAUSED



Mutes audible alert for **one hour**.

Battery Replacement

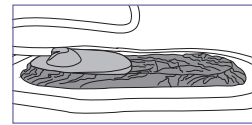


Push here to slide open the battery cover.



Replace with AA size batteries. Lithium batteries will last longer than regular batteries.

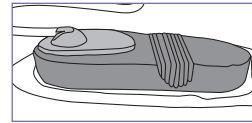
PREVENA™ Incision Dressing Pressure Check



Dressing Compressed



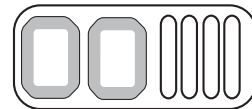
When the dressing is compressed, therapy is being applied to the dressing.



Dressing Not Compressed



When the dressing is not compressed, therapy is not at the proper pressure. See the **Indicators and Alerts** section for pressure check information.



To seal leaks:

- Use PREVENA™ Patch Strips (shown) for PEEL & PLACE™ Dressing
- Use excess KCI Drape (not shown) for CUSTOMIZABLE™ Dressing

LOW BATTERY ALERT

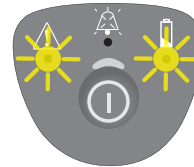


ALERT PAUSED

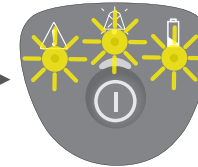


Mutes audible alert for **one hour**.

SYSTEM ERROR ALERT



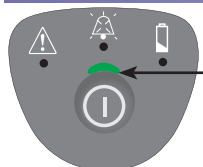
ALERT PAUSED



Mutes audible alert for **one hour**.

Indicators and Alerts

Therapy On / Off

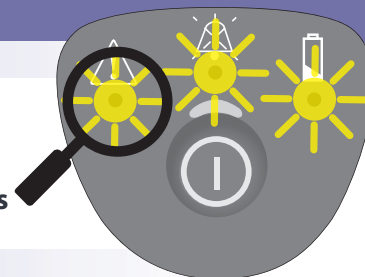


Green light shows therapy is on.

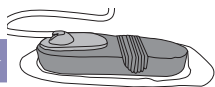
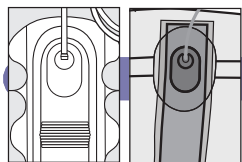


ON / OFF AND AUDIO PAUSE BUTTON
TURN ON - Hold two seconds
TURN OFF - Hold five seconds
AUDIO PAUSE/MUTE - Press once to mute alerts
 (See the Audio Pause / Mute Feature section.)

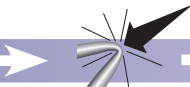
Alert Lights



PREVENA™ Incision Dressing Pressure Check



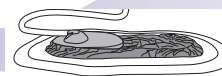
Dressing Not Compressed?



Check for kinked or pinched tubing.

Check for leaks.

See Leak Alert section below.



Dressing Compressed?

YES

Continue therapy. If alarming for leak, see the Leak Alert section below.

NO

See Leak Alert section below.

Leak Alert



one beep, one solid light

Check all connectors for leaks.

Make sure canister is securely locked and side tabs are flush with unit.

Press firmly around dressing edge.

Use PREVENA™ Patch Strips or excess KCI Drape to seal leak.

Leak Alert fixed?

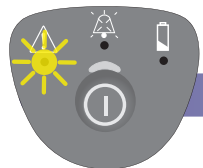
YES

Continue therapy.

NO

Use Audio Pause; call KCI at 1-800-275-4524

Canister Full Alert



two beeps, one solid light

Check fluid level in canister.

Full or near full?

NO

Check for kinked or pinched tubing.

YES

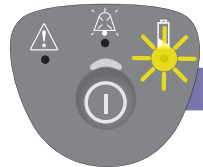
Turn unit off. See Therapy On/Off above.



Call KCI at 1-800-275-4524.

See Warnings section.

Low Battery Alert



LOW - A slow beep and one solid light - Be prepared to change batteries.
CRITICAL - A rapid beep and one solid light - Change batteries right away.

Hold five seconds to **TURN OFF**.

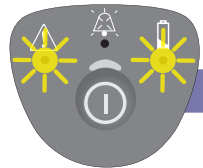
Press and push to open panel.

Three AA batteries required. Lithium batteries recommended.

Press and push to close panel.

Hold two seconds to **TURN ON**.

System Error Alert



A repeated beep increasing in volume, and two solid lights

Hold five seconds to **TURN OFF**.

Hold two seconds to **TURN BACK ON**.

Therapy running?

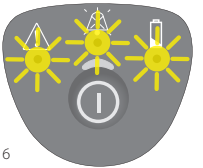
YES

Continue therapy.

NO

Call KCI at 1-800-275-4524.

Device Life Cycle Expired



Three lights show life cycle is up. There will be a repeated beep for 15 seconds and then the unit will shut off.
 Life cycle = 192 hours (eight days)



Call KCI at 1-800-275-4524.

Symbols Used



Refer to Clinician Guide



Fragile



Do Not Resterilize

IP24

Ingress Protection



Date of Manufacture



MR Unsafe



Single Use Only



Type BF Applied Part



Consult Instructions for Use



Keep Dry



Do not use if package is damaged or open



Sterile Using Radiation



Use By



Temperature Limit



Manufacturer



Content Information

LOT

Lot Number

REF

Catalog Number



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

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

Specifications

Environmental and Storage Conditions

Temperature Range:-4°F (-20°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)

Atmospheric Pressure Range:..... 1060 hpa (-1253 ft/-381.9 m)
(for optimum performance) to 700 hpa (9878 ft/3010 m)

Equipment not suitable for use in presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.

The PREVENA™ 125 Therapy Unit is classified as a Type BF applied part under IEC 60601-1.

IP24 - Protection against solid objects greater than 12.5mm and against liquid water sprays for short periods of time.

All alerts are classified as low priority according to IEC 60601-1-8.

Conforms to IEC 60601-1, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-11.

Disposal

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

Electrical Equipment Interference

Cell phones or similar products could affect the therapy unit. Move the therapy unit away from these devices if interference is suspected.

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

KCI USA, Inc. 12930 IH 10 West, San Antonio, Texas, 78249

Outside the US visit www.kci-medical.com

Treating Physician: _____

Phone: _____

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