Prevena™ Incision Management System

Patient Guide

Device Description

This guide provides important information including a contraindication, cautions and warnings that you should read and review. You have been prescribed the Prevena™ Incision Management System. Do not remove the dressing or turn off the unit, unless directed by your treating physician or this guide. If an alert sounds, an action is required on your part; refer to **Indicators** and **Alerts**. For questions or concerns regarding this therapy, contact KCI at 1-800-275-4524.

All disposable components of the Prevena™ Incision Management System are for single use only. Re-use of disposable components may result in wound contamination, infection and / or failure of the wound to heal.

Prevena™ 125 Therapy Unit

Prevena™ 125 Carrying Case

Prevena™ Carrying Case can be worn on a belt, over the shoulder or diagonally across the chest (not around the neck) with adjustable strap (provided).

Indicators

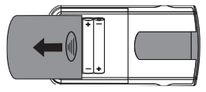
On / Off Button and Audio Pause (Push once to pause audible alerts for 60 minutes).

Caution Indicator

Audio Pause Indicator

Low Battery Indicator

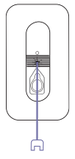
Battery Replacement



Push here to slide open battery cover.

Replace with "AA" batteries. Lithium batteries recommended for optimal performance.

Prevena™ Incision Dressing with Pressure Indicator



Use Prevena™ Patch Strips to seal leaks.

Dressing Pressure Indicator in down position indicates therapy at acceptable pressure.

Dressing Pressure Indicator in up position indicates therapy is not at the acceptable pressure. (Refer to **Indicators** and **Alerts**)

Instructions for Use

IMPORTANT: Monitor the pressure indicator on the dressing regularly. Refer to the **Indicators** and **Alerts** section of this guide for more details.

IMPORTANT: Do not turn therapy unit off unless advised by the treating physician or there is bleeding, signs of infection or signs of an allergic response; see **WARNINGS** below.

CAUTION: Dressing should only be removed by or on the advice of the treating physician.

Bathing
- Bathing in tub is not recommended.
- Do not submerge therapy unit or dressing.

Showering
- Light showering is permissible. Protect therapy unit from direct spray. Avoid prolonged water contact with therapy unit and dressing.
- When towel drying avoid disrupting or damaging the dressing.

Cleaning

The therapy unit and carrying case can be wiped with a damp cloth using a mild household soap solution that does not contain bleach.

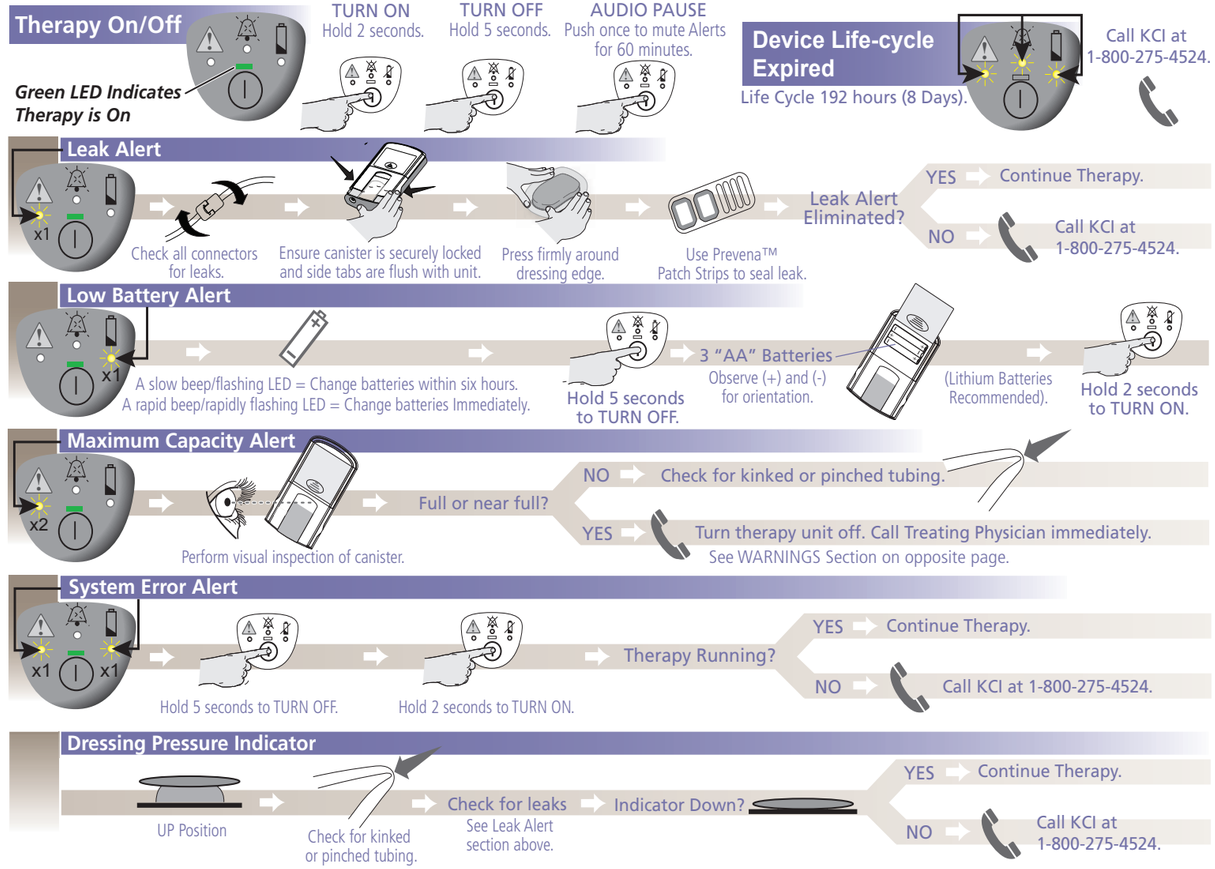
Strenuous Activity
- Refer to treating physician for when and what level physical activities may be resumed.
- Avoid strenuous activities when using the Prevena™ Incision Management System.

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

Contraindication and Warnings

- **Contraindication:** Sensitivity to silver.
- As with any prescription medical device, failure to carefully read and follow all instructions and safety information prior to use may lead to improper product performance.
- Bleeding: With or without using the Prevena™ Incision Management System, certain patients are at risk of bleeding complications due to the operative procedure or concomitant therapies and/or comorbidities. If bleeding develops suddenly or in large amounts during therapy, leave Prevena™ Incision Dressing in place, turn off Prevena™ Therapy Unit and **seek immediate emergency medical assistance**.
- If you experience any of the following, you should call your treating physician right away as your incision may have become infected: you become feverish and / or there is an increase in soreness, redness, swelling, itching, warmth, or if there is pus or a bad odor. Your physician will advise you as to whether Prevena™ Therapy should be discontinued.
- Magnetic Resonance Imaging (MRI): Do not take the Prevena™125 Therapy Unit into the MR environment. The Prevena™ Incision Dressing can typically remain with minimal risk in an MR environment.
- Hyperbaric Oxygen Therapy (HBO): Do not take the Prevena™ 125 Therapy Unit or Prevena™ Incision Dressing into the hyperbaric oxygen chamber, it is not designed for this environment and **should be considered a fire hazard**.
- If defibrillation is required in the area of Prevena™ Incision Dressing placement, the dressing should be removed before defibrillation, follow clinician's instructions.
- If at any time while using Prevena™ Incision Management System, the canister becomes full of fluid other than blood, indicated by a "Maximum Capacity" alert or visual inspection, turn therapy unit off and contact the treating physician.
- The Prevena™ Incision Dressing has an acrylic adhesive coating and a skin interface layer with silver, which may present a risk of an adverse reaction in patients who are allergic or hypersensitive to acrylic adhesives or silver. If a patient has a known allergy or hypersensitivity to these materials, do not use the Prevena™ Incision Management System. If any signs of allergic reaction, irritation or hypersensitivity develop, such as redness, swelling, rash, urticaria, or significant pruritus, patient should consult a physician immediately. If bronchospasm or more serious signs of allergic reaction appear, the patient should turn off the Prevena™ Therapy Unit and **seek immediate emergency medical assistance**.

Indicators and Alerts



Symbols Used

ETL Listed, Conforms to UL Std. 60601-1 certified to CAN / CSA C22.2 Std. No. 601.1.
3182664

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

Consult Instructions for Use

Latex Free

Non Sterile

Sterile using Radiation

Date of Manufacture

Class II Device

Refer to Clinician Guide

Fragile

Single Use Only

Do not Resterilize

Do not use if package is damaged or open

Type B Applied Part

Expiration Date

Keep Dry

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

Specifications

Environmental Conditions:

Storage Conditions:		Operating Conditions:	
Temperature Range:	-4°F (-20°C) to 140°F (60°C)	Temperature Range:	41°F (5°C) to 122°F (50°C)
Relative Humidity Range:	0-95%, non-condensing	Altitude Range for Optimum Performance:	-50 to 8000 feet (-15.24 m to 2438 m)

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

IPX4 - Ingress Protection Level

Electromagnetic Compatibility:

Electromagnetic Interference - Although this equipment conforms with the intent of the directive 89 / 336 / EEC in relation to Electromagnetic Compatibility (EMC), all electrical equipment may produce interference. If interference is suspected, move equipment away from sensitive devices or contact the manufacturer.
Portable and mobile RF communications equipment can effect medical electrical equipment.

Refer to the Prevena™ Clinician Guide for additional information.

Manufacturer Information

KCI USA, Inc.
San Antonio, TX
78219 USA

Contact Information

For additional information concerning the Prevena™ Incision Management System, contact your local KCI representative.

KCI

Treating Physician_____ Phone: _____