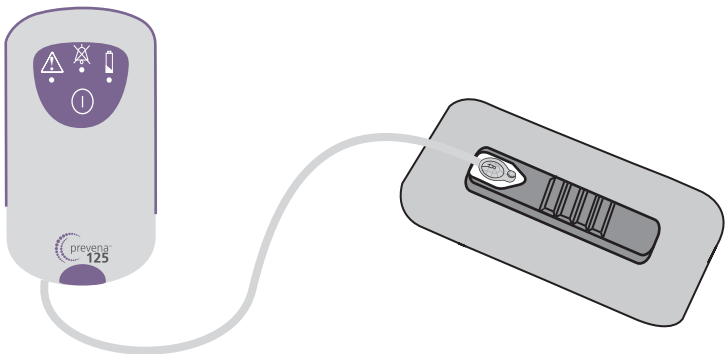
prevena™

Prevena™ Incision Management System

CLINICIAN GUIDE



Instructions For Use

KCI®

CLINICIAN GUIDE
PREVENA™ INCISION MANAGEMENT SYSTEM

KCI CONTACT INFORMATION IS LOCATED IN THE BACK OF THIS GUIDE

IMPORTANT

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.

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.

INDICATION FOR USE

The Prevena™ Incision Management System is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy.

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.

OPTIMUM USE CONDITIONS

For maximum benefit the Prevena™ Incision Management System should be applied immediately post surgery to clean surgically closed wounds. It is to be continuously applied for a minimum of 2 days up to a maximum of 7 days. It can transition home with the patient; however, all Prevena™ Incision Dressing changes should be performed under direct medical supervision.

The Prevena™ Incision Management System will not be effective in addressing complications associated with the following:

- Ischemia to the incision or incision area
- Untreated or inadequately treated infection
- Inadequate hemostasis of the incision
- Cellulitis of the incision area

The Prevena™ Incision Management System should not be used to treat open or dehisced surgical wounds or on patients who have excessive amounts of exudate from the incision area which may exceed the Prevena™ 45mL Canister. The V.A.C.® Therapy system should be considered for treatment of these wounds.

The Prevena™ Incision Management System should be used with caution in the following patients:

- Patients with fragile skin surrounding the incision as they may experience skin or tissue damage upon removal of the Prevena™ Incision Dressing
- Patients who are at an increased risk of bleeding from the incision associated with the use of anticoagulants and/or platelet aggregation inhibitors

CONTRAINDICATION:

- Sensitivity to silver.

WARNINGS

- **Bleeding:** Before applying the Prevena™ Incision Management System to patients who are at risk of bleeding complications due to the operative procedure or concomitant therapies and / or co-morbidities, ensure that hemostasis has been achieved and all tissue planes have been approximated. If active bleeding develops suddenly or in large amounts during therapy, or if frank blood is seen in the tubing or in the canister, the patient should leave the Prevena™ Incision Dressing in place, turn off Prevena™ 125 Therapy Unit and seek immediate emergency medical assistance.
- **Infected Wounds:** As with any wound treatment, clinicians and patients / caregivers should frequently monitor the patient's wound, periwound tissue and exudate for signs of infection, or other complications. Some signs of infection are fever, tenderness, redness, swelling, itching, rash, increased warmth in the wound or periwound area, prulent discharge, or strong odor. Infection can be serious, and can lead to complications such as pain, discomfort, fever, gangrene, toxic shock, septic shock and / or fatal injury. Some signs or complications of systemic infection are nausea, vomiting, diarrhea, headache, dizziness, fainting, sore throat with swelling of the mucus membranes, disorientation, high fever, refractory and / or orthostatic hypotension, or erythroderma (a sunburn-like rash). Silver in the interface layer of the Prevena™ Incision Dressing is not intended to treat infection, but to reduce bacterial colonization in the fabric. **If infection develops, Prevena™ Therapy should be discontinued until the infection is treated.**
- **Allergic Response:** 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 therapy unit and seek immediate emergency medical assistance.
- **Defibrillation:** Remove the Prevena™ Incision Dressing if defibrillation is required in the area of dressing placement. Failure to remove the dressing may inhibit transmission of electrical energy and / or patient resuscitation.
- **Magnetic Resonance Imaging (MRI):** The Prevena™ 125 Therapy Unit is **MR Unsafe**. Do not take the Prevena™ 125 Therapy Unit into the MR environment. The Prevena™ Incision Dressing can typically remain on the patient with minimal risk in an MR environment. Interruption of Prevena™ Therapy during MRI may reduce the effectiveness of Prevena™ Therapy. The Prevena™ Incision Dressing should pose no known hazards in an MR environment with the following conditions of use: static magnetic field of 3 Tesla or less, spatial gradient field of 720 Gauss/cm or less, and maximum whole-body-averaged specific absorption rate (SAR) of 3W/kg for 15 minutes of scanning.
- **Diagnostic Imaging:** The Prevena™ Incision Dressing contains metallic silver that may impair visualization with certain imaging modalities.
- **Hyperbaric Oxygen Therapy (HBO):** Do not take the Prevena™ 125 Therapy Unit or Prevena™ Incision Dressing into a hyperbaric oxygen chamber; it is not designed for this environment, and **should be considered a fire hazard**. If Prevena™ Therapy is reinitiated after HBO treatment, do not readhere the same dressing, a new dressing must be applied.
- **Canister Full:** If at any time while using the Prevena™ Incision Management System, the canister becomes full of fluid other than blood, indicated by a Maximum Capacity Alert or visual inspection, the patient should turn therapy unit off and contact the treating physician.

PRECAUTIONS

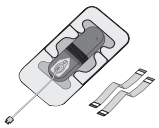
- **Standard Precautions:** To reduce the risk of transmission of bloodborne pathogens, apply standard precautions for infection control with all patients, per institutional protocol, regardless of their diagnosis or presumed infection status. In addition to gloves, use gown and goggles if exposure to body fluid is likely.

- **Circumferential Dressing Application:** Avoid applying the Prevena™ Incision Dressing circumferentially. In cases where the clinician determines that the benefits of applying the Prevena™ Incision Dressing circumferentially outweighs the risk of circulatory compromise, extreme care should be taken not to stretch or pull the dressing when securing it. Attach the dressing loosely and stabilize edges with an elastic wrap if necessary. It is crucial to systematically and recurrently palpate distal pulses and assess distal circulatory status. If circulatory compromise is suspected, discontinue therapy and remove dressing.
- **Electrodes or Conductive Gel:** Do not allow the Prevena™ Incision Dressing to come in contact with EKG or other electrodes or conductive gels during electronic monitoring or when taking electronic measurements.
- **Dressing Components:** The Prevena™ Incision Dressing contains ionic silver (0.019%). Application of products containing silver may cause temporary tissue discoloration.
  - ¤ Always use Prevena™ dressings and canisters from sterile packages that have not been opened or damaged.
  - ¤ All components of the Prevena™ Incision Management System are for single use only. Do not re-use any component of this system.
  - ¤ To avoid trauma to the skin, do not pull or stretch the adhesive border of the dressing during application.

PREVENA™ INCISION MANAGEMENT SYSTEM DESCRIPTION

The Prevena™ Incision Management System contains the following single use, disposable components (Fig. 1).
All patient contact materials are free of latex and DEHP [Di(2-ethylhexyl)phthalate].

Fig. 1 Prevena™ Incision Management System



Prevena™ Incision Dressing with Pressure Indicator and Prevena™ Patch Strips (sterile)

Prevena™ 45mL Canister (sterile)

Prevena™ 125 Therapy Unit and Prevena™ Carrying Case (non-sterile)

- Prevena™ Incision Dressing with Pressure Indicator - Specially designed dressing for application to the surgical area.
  - ¤ The dressing contains a skin interface layer that includes 0.019% ionic silver. *In vitro* log reduction tests, conducted without application of negative pressure, exposed samples of the skin interface layer to a six log challenge of each of the microorganisms listed below. Following inoculation, samples were tested for microbial counts immediately (day 0) and after incubation at 32° C in diluted nutrient broth for 1, 3, 5 and 7 days. The log reductions from the day 0 values are provided in the table below.

Challenge Organism	Mean Log Reduction from Day 0			
	Day 1	Day 3	Day 5	Day 7
Escherichia coli (ATCC 8739)	2.2	4.0	3.9	4.5
Pseudomonas aeruginosa (ATCC 09027)	2.0	3.9	3.5	3.7
Staphylococcus aureus (ATCC 6538)	1.6	3.6	3.6	3.5
Klebsiella pneumonia (ATCC 4352)	1.4	1.8	2.7	3.5
Candida albicans (ATCC 10231)	2.5	3.1	3.2	3.2
Aspergillus niger (ATCC 16404)	2.2	4.1	4.0	3.6

- Prevena™ Patch Strips - Used to help seal leaks around dressing.
- Prevena™ 45mL Canister - A sterile reservoir for collection of wound fluids.
- Prevena™ 125 Therapy Unit - Delivers negative pressure to the surgical area. The unit is battery powered. The Prevena™ Carrying Case is provided to facilitate patient mobility.

DRESSING APPLICATION

Site Preparation:

1. Prior to surgery, shave the surgical area where the dressing will be applied to improve dressing adhesion and seal integrity.
2. Gather all items needed for application:
   - Sterile wound cleaning solution, e.g. water, saline or alcohol.
   - Sterile gauze or other material to clean application site.
   - Prevena™ Incision Management System (Check expiration date on box).
3. Immediately post surgery, cleanse the application site with sterile gauze and sterile wound cleaning solution using a circular motion beginning at the center of the surgical area and extending outward to ensure that the site is free of foreign material.
4. Pat the application site dry with sterile gauze. To ensure proper adhesion, the application site must be completely dry before dressing is applied.

Drain Tubes and Pain Management Control Devices:

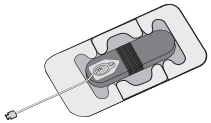
The Prevena™ Incision Management System can be used with both drain tubes and pain devices, provided the dressing is not placed over tubing where it exits the skin. Surgical drains must be routed under the skin beyond the boundary of the dressing and function independently of the Prevena™ Incision Management System.

NOTE: *While the concomitant use of surgical drains is allowable with the Prevena™ Incision Management System, the system must not be used as an outlet or reservoir for the drain.*

Prevena™ Incision Management System Application:

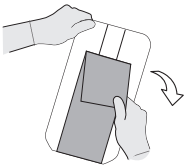
1. Open the sterile dressing package and remove dressing and patch strips using aseptic technique. Do not use if package has been torn or the sterile seal has been compromised.

Fig. 2 Top View of Dressing



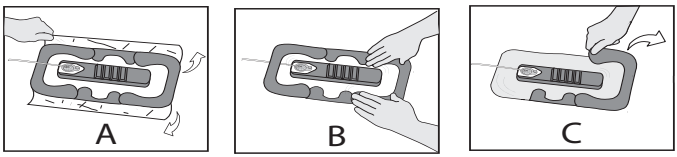
2. Gently peel back the center strip on the back of the dressing exposing the pull tabs and adhesive (Fig. 3).

Fig. 3 Bottom View of Dressing



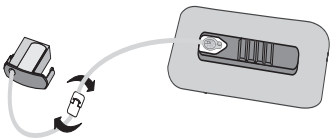
3. Center and apply the dressing over the closed wound or incision ensuring that the adhesive will not contact or cover the surgical closure. Orient the dressing on the patient to eliminate sharp bends/kinks in the tubing. Remove the remaining bottom adhesive covers by grasping the bottom tabs and gently pulling (Fig. 4A). Firmly press around the dressing to ensure a good seal where the adhesive contacts the skin (Fig. 4B). Remove top stabilization layers (Fig. 4C).

Fig. 4 Dressing Application



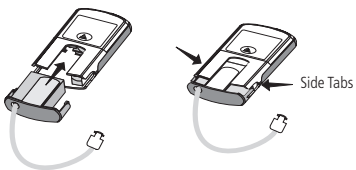
4. Remove the Prevena™ 45mL Canister from the sterile package. Do not use if package has been torn or the sterile seal has been compromised. Connect the dressing tubing to the canister tubing by twisting the connectors until they lock. (Fig. 5).

Fig. 5 Connecting Tubing



5. Insert the canister into the Prevena™ 125 Therapy Unit, and slide inward until canister clicks. Canister is fully inserted when the side tabs are flush with the body of the therapy unit (Fig. 6). Therapy can now begin, see **Beginning Therapy** section below.

Fig. 6 Canister Installation

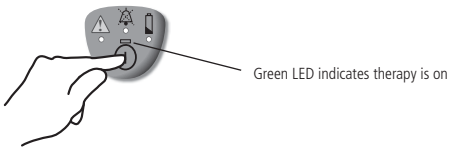


BEGINNING THERAPY

1. To begin therapy, press and hold the ON / OFF button for **2 seconds**; an audible beep will confirm that therapy is on. A green LED on the front of the unit indicates that therapy is on (Fig. 7).

NOTE: *Pressing the ON / OFF button begins the 192 hour (8 day) life cycle of the therapy unit. Turning the therapy unit off stops the life cycle counter. Turning the therapy unit on for purposes other than delivering therapy reduces the life cycle of the therapy unit. It is not recommended to press the On/Off button until therapy is ready to begin.*

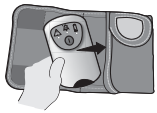
Fig. 7 Turning Therapy On



NOTE: *To turn therapy unit off - press and hold ON / OFF button for* **5 seconds**.

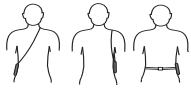
2. With therapy on, assess dressing to ensure integrity of seal.
   - The dressing should have a wrinkled appearance and the foam bolster should be compressed.
   - The Pressure Indicator on the dressing should be in the collapsed position (Fig. 13).
   - If there is any evidence of a leak, refer to the **LEAKS** section, page 5.
3. Place the therapy unit into the Prevena™ Carrying Case (Fig. 8). Make sure that the display is visible through the opening in the carrying case when the front flap is lifted.

Fig. 8 Placing Prevena™ 125 Therapy Unit Into Carrying Case



4. The Prevena™ Carrying Case has an integrated belt loop and a separate adjustable strap to allow for versatile positioning. (Fig. 9)
   CAUTION: *Do not wear strap around neck.*

Fig. 9 Prevena™ Carrying Case Options



DURATION OF THERAPY

- Therapy should be continuous for a minimum of 2 days up to a maximum of 7 days.
- Therapy unit will automatically time-out after 192 hours (8 days) of cumulative run time.
- Patients should be instructed not to turn therapy off unless:
  - Advised by the treating physician
  - Bleeding develops suddenly or in large amounts during therapy
  - There are serious signs of allergic reaction or infection
  - The canister is full of fluid
  - Batteries need to be changed
  - System alerts must be addressed
- Patient should be instructed to contact the treating physician if:
  - Bleeding develops
  - Signs of infection are present
  - Therapy unit turns off and cannot be restarted before therapy is scheduled to end
  - Canister becomes full of fluid
- At end of therapy, patient should return to treating physician for dressing removal.

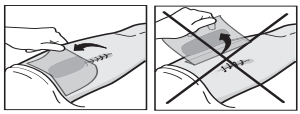
DRESSING REMOVAL

NOTE: *If dressing is lifted to observe wound, do not re-adhere the same dressing, a new dressing must be applied.*

WARNING: Dressings should always be removed in-line with the sutures and NEVER across the sutures. (Fig. 10)

1. Turn Prevena™ Therapy Unit off by pressing and holding the ON / OFF button for 5 seconds.
2. Gently stretch the drape/dressing horizontally to release the adhesive from the skin. Do not peel vertically. Remove the drape / dressing in-line with the sutures NEVER across the sutures.

Fig. 10 Dressing Removal



3. Clean any residual adhesive with alcohol swab.

If a new dressing is to be applied:

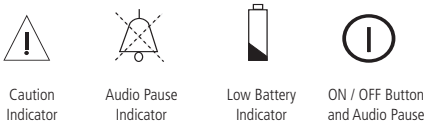
1. Ensure that area is clean, using an alcohol swab or antiseptic wipe.
2. Allow skin to completely dry before applying.
3. Follow Dressing Application instructions, page 2.

INDICATORS AND ALERTS

Visual Alerts - Flashing LEDs cannot be turned off or paused by the user. Visual alerts will only stop when the alert condition has been corrected.

Audible Alerts - Repeated beeps (which in some cases will increase in volume) can be temporarily muted (paused) by pressing the ON / OFF button once. The audible alert will re-occur after 60 minutes unless the alert condition has been corrected.

Fig. 11 Indicator and Alerts Symbols



The therapy unit will provide audible and visual alerts as shown below. If alert conditions cannot be corrected, patient should contact treating physician. For further product support see **CONTACT INFORMATION** in the back of this guide.

Leak Alert:
An audible alert sounding 1 beep, increasing in volume, visually indicated by 1 single flashing yellow LED.

See **Correcting a Leak Condition,** page 6.
When leak condition is corrected the therapy unit will cancel alert. There may be a brief delay between when the leak is corrected and the alert is discontinued**.**

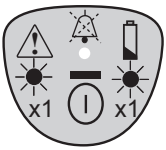
Low Battery Alert:
An audible alert sounding 1 beep, increasing in volume, visually indicated by 1 single flashing yellow LED. Change batteries within 6 hours.
An audible alert sounding 1 beep, repeating rapidly, increasing in volume, visually indicated by 1 **rapidly** flashing yellow LED. **Change batteries Immediately**.

Battery replacement cancels the low battery alert.
See **Battery Replacement** Section page 6.

Maximum Capacity Alert:

An audible alert sounding 2 beeps, increasing in volume, visually indicated by 1 double flashing yellow LED.

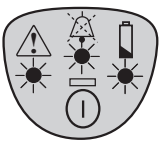
Visually inspect canister. If full or near full, turn therapy unit off and call the treating physician immediately.



System Error Alert:

An audible alert sounding 1 beep, visually indicated by 2 single flashing yellow LEDs.

Power the unit off and then on again. If alert continues notify the treating physician.



Device Lifecycle Expired:

Indicated by 3 solid yellow LEDs. If the lifecycle expires while therapy unit is on, an audible alert will sound for 15 seconds and then automatically shut off.

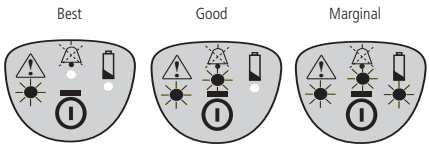
If the therapy unit is off, and has exceeded the run-time and an attempt is made to turn the therapy unit on, the therapy unit will alert for 3 seconds and automatically shut off.

LEAKS

VisiCheck™ Feature:

To ensure proper application of the Prevena™ Incision Management System, the Prevena™ 125 Therapy Unit provides a VisiCheck™ feature. By double pressing the ON / OFF button, the unit will display the leak rate of the system for 3 seconds. To prevent nuisance leak alarms, the leak rate status should be **Best** (1 LED illuminated) or **Good** (2 LEDs illuminated) (Fig. 12).

Fig. 12 VisiCheck™ Feature



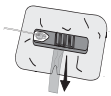
If the VisiCheck™ feature indicates a **Marginal** (3 LEDs illuminated) leak rate condition, refer to the following **Correcting a Leak Condition** section for methods of reducing the leak rate of the system. The system leak rate is calculated every 7 seconds. If a corrective action is taken to reduce a leak rate, use the VisiCheck™ feature afterward to verify the leak rate condition was corrected.

When the therapy unit detects a leak:

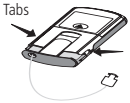
- A visual and audible Leak Alert will activate, see **Indicators and Alerts** Section page 4.
- Therapy unit will turn on more frequently.
- Pressure Indicator on the dressing may be in the up position (Fig. 13).

Correcting a Leak Condition:

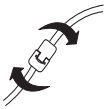
1. With therapy unit on, slowly press firmly around dressing edge, to ensure good contact between adhesive and skin.



2. If leak is identified, use Prevena™ Patch Strips (located in dressing package) to help seal leaks around dressing. If large wrinkles are present place patch strips so they run in line along the length of the wrinkle, and not across the wrinkle.



3. Ensure canister is securely locked in the therapy unit. When canister is installed, a distinct click will be heard indicating it has been properly installed. Side tabs on canister should be flush with unit.



4. Check tubing connectors to ensure they are fully engaged.

PREVENA™ INCISION DRESSING PRESSURE INDICATOR:

Each dressing is equipped with a pressure indicator that shows when system pressure is at an acceptable level (Fig. 13).

Fig. 13 Prevena™ Incision Dressing Pressure Indicator

Indicator Collapsed
System pressure acceptable

Indicator Up
System pressure not acceptable

INDICATIONS THAT A LEAK CONDITION HAS BEEN CORRECTED

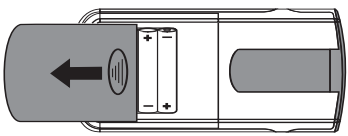
- Therapy unit will become quiet, running only intermittently.
- Audible leak alert will stop; visual alert will turn off. There may be a brief delay between when the leak is corrected and the alert is discontinued.
- Pressure indicator on the dressing will return to the collapsed position.

BATTERY REPLACEMENT

Battery replacement should be done as quickly as possible after a low battery alert to prevent therapy down-time.

1. Turn therapy unit off (Press and hold ON / OFF button for 5 seconds).
2. Remove therapy unit from carrying case.
3. Turn the therapy unit over to expose the back side of the unit. Locate the battery door and push to slide open (Fig. 14). Install (3) AA batteries (lithium batteries are recommended for optimal performance) into the battery compartment.
   NOTE: *Always replace with new batteries. Do not mix new batteries with used batteries.*
   NOTE: *The inside of the battery compartment is stenciled with (+) positive and (-) negative to aid in proper battery installation.*
4. Close battery door.
5. Return therapy unit to carrying case.
6. Turn therapy unit on to resume therapy (Press and hold ON / OFF button for 2 seconds).

Fig. 14 Battery Replacement



INSTRUCTIONS FOR PATIENT

The following information must be reviewed with the patient prior to patient discharge. This information is summarized in the Prevena™ Incision Management System Patient Guide which must be provided to the patient at discharge.

Daily Use

The Prevena™ Incision Management System is portable and small enough that it may be worn beneath clothing during normal patient activities as approved by the treating physician.

Sleeping:

Patients should be instructed to:

- Place the therapy unit in a position where tubing will not become kinked or pinched.
- Ensure therapy unit will not be pulled off a table or fall to the floor during sleep.

Showering and Bathing:

CAUTION: Advise patient to NOT SUBMERGE therapy unit or dressing in liquid and to ensure therapy unit is not pulled into a tub or sink where it may become submerged.

Fig. 15 Showering and Bathing

Patients should be advised of the following recommendations:

- Light showering is permissible, bathing is not.
- While showering, the device and dressing should be protected from prolonged direct spray and / or being submerged.
  - Hanging the therapy unit from a soap / shampoo holder or shower head may be acceptable if protected from prolonged direct spray.
  - Dressing may be exposed to common shower soaps and rinsed with indirect shower stream. Do not submerge dressing. Do not remove dressing.
- When towel drying, avoid disturbing or damaging dressing.

Strenuous Activity

Advise patient as to when and at what level physical activities may be resumed. It is recommended that patients avoid strenuous activity while using the Prevena™ Incision Management System.

Cleaning

Patient should be advised that the Prevena™ 125 Therapy Unit and Prevena™ Carrying Case can be wiped with a damp cloth using a mild household soap solution that does not contain bleach.

DEVICE DISPOSAL

At the end of therapy, the patient should return therapy unit to physician for disposal. Follow local institutional protocols for infection control and waste disposal procedures. Local protocols should be based on the applicable federal, state and / or local government environmental regulations. For additional information refer to the **CONTACT INFORMATION** section in the back of this guide.

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.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information in the following tables.

Electromagnetic Compatibility Cont.

The following tables document compliance levels and guidance from the IEC 60601-1-2 2007 Standard, for the Electromagnetic Environment in which the Prevena™ 125 Therapy Unit should be used in a Clinical Environment. The Prevena™ 125 Therapy Unit also meets the intent of the draft guidance for Electromagnetic Compatibility related to use in the Home Care environment (IEC 60601-1-11 2007-11-30 draft).

Guidance and manufacturer's declaration - electromagnetic emissions		
The Prevena™ 125 Therapy Unit is intended for use in the electromagnetic environment specified below. The customer or user of the Prevena™ 125 Therapy Unit should assure that it is used in such an environment.		
Emission Test	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	The Prevena™ 125 Therapy Unit uses RF energy only for internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Battery operated device
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Prevena™ 125 Therapy Unit is intended for use in the electromagnetic environment specified below. The customer or user of the Prevena™ 125 Therapy Unit should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	In accordance with IEC 60601-1-2: 2007, floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not Applicable	Battery operated device
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not Applicable	Battery operated device
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_r (>95 % dip in U_r) for 0.5 cycle 40 % U_r (60 % dip in U_r) for 5 cycles 70 % U_r (30 % dip in U_r) for 25 cycles <5 % U_r (>95 % dip in U_r) for 5 cycles	Not Applicable	Battery operated device
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_r is the a.c. mains voltage prior to application of the test level.			

Recommended separation distances between portable and mobile RF communications equipment and the Prevena™ 125 Therapy Unit

The Prevena™ 125 Therapy Unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Prevena™ 125 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Prevena™ 125 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 m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
W	not applicable	$d = [1.2] \sqrt{P}$	$d = [2.3] \sqrt{P}$
0.01	not applicable	0.12	0.23
0.1	not applicable	0.37	0.74
1	not applicable	1.17	2.33
10	not applicable	3.69	7.38
100	not applicable	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separate distance d in metres (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, These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from surfaces, objects and people.

Guidance and manufacturer's declaration - electromagnetic immunity

The Prevena™ 125 is intended for use in an electromagnetic environment specified below. The customer or user of the Prevena™ 125 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not Applicable	Portable and mobile RF communications equipment should be used no closer to any part of the Prevena™ 125, including cables, than the recommended separation distance calculated from the equation application to the frequency of the transmitter. Recommended separation distance Battery Operated Device
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = [1.2] \sqrt{P}$ 80 MHz to 800 MHz $d = [2.3] \sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[1], should be less than the compliance level in each frequency range.[2] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1, At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2, These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, 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 asses the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [ME EQUIPMENT OR ME SYSTEM] is used exceeds the applicable RF compliance level above, the [ME EQUIPMENT OR ME SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [ME EQUIPMENT OR ME SYSTEM].
[2] Over the frequency range 150kHz, field strengths should be less than [V1] V/m.

SYMBOLS USED


Do not use if package is damaged or open


Single Use Only


Keep Dry

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


Fragile

Non Sterile


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

Sterile using radiation


Manufacturer


Class II Device


Date of Manufacture


Expiration Date

Latex Free

Authorized Representative in the European Community


Type B applied part


Consult Instructions for Use


Refer to Clinician Guide

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

MANUFACTURER INFORMATION

KCI USA, Inc.
San Antonio, TX 78219 USA

CONTACT INFORMATION

For questions regarding this product, supplies, maintenance or additional 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.kci1.com