KCI™
AN ACELITY COMPANY

PREVENA RESTOR™ INCISION MANAGEMENT SYSTEM

PREVENA RESTOR™ DRESSINGS

WITH SENSAT.R.A.C.™ TECHNOLOGY
FOR USE WITH PREVENA PLUS™ 125 THERAPY UNIT AND KCI V.A.C.® THERAPY UNITS

INSTRUCTIONS FOR USE

FOR CLINICIANS ONLY

Rx Only

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INSTRUCTIONS FOR USE
PREVENA RESTOR™ INCISION MANAGEMENT SYSTEM

KCI CUSTOMER CONTACT INFORMATION IS LOCATED IN THE BACK OF THIS GUIDE.

PRODUCT DESCRIPTION AND INDICATION FOR USE

The PREVENA RESTOR™ 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.

The system consists of:
A PREVENA RESTOR™ Dressing or Dressings and a source of negative pressure, which may be one of the following KCI therapy units:

- PREVENA PLUS™ 125 Therapy Unit (7 or 14 Day)
- ACTIV.A.C.™ Therapy Unit
- V.A.C.ULTA™ Therapy Unit
- V.A.C.RX4™ Therapy Unit

Clinical studies have been conducted on KCI Negative Pressure Incision Management Systems. Refer to the **Bibliography of Published Studies** in the back of this guide.

IMPORTANT INFORMATION FOR USERS

WARNING: DO NOT use with V.A.C. VERAFLO™ Therapy (Instillation) provided by the V.A.C.ULTA™ Therapy Unit. Instillation into the incision site may result in pooling of fluid which may result in maceration.

WARNING: The V.A.C.ULTA™ and V.A.C.RX4™ Therapy Units are only indicated for use in acute care settings. Before transitioning the patient to home care, this therapy unit must be replaced with one for home use, such as the PREVENA PLUS™ 125 or ACTIV.A.C.™ Therapy Unit.

For pressure settings and connection information for use of the PREVENA™ Dressings with the V.A.C.® Therapy Units listed above, see the **Using the PREVENA™ Dressing with KCI V.A.C.® Therapy Units** section.

CAUTION: The PREVENA RESTOR™ Incision Management System should be applied and removed only by qualified physicians or nurses.

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.

The PREVENA RESTOR™ Incision Management System dressings and therapy unit canisters are disposable and are for single use only. Re-use of disposable components may result in wound contamination, infection and/or failure of the wound to heal.

The V.A.C.® Y-Connector is used to connect two PREVENA RESTOR™ Dressings to a single KCI therapy unit.

OPTIMUM USE CONDITIONS

For maximum benefit the PREVENA RESTOR™ Incision Management System should be applied immediately post surgery to clean surgically closed wounds. It is to be continuously applied for up to a maximum of 7 days. It can transition home with the patient.

The PREVENA RESTOR™ Incision Management System will not be effective in addressing complications associated with:

- ischemia to the incision or incision area
- untreated or inadequately treated infection
- inadequate hemostasis of the incision
- cellulitis of the incision area

The PREVENA RESTOR™ Incision Management System should not be used to treat open or dehisced surgical wounds. V.A.C.® Therapy should be considered for treatment of these wounds.

Consider using the smallest available canister for the selected V.A.C.® Therapy Unit.

The PREVENA RESTOR™ 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™ 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

The PREVENA RESTOR™ Incision Management System is not intended to manage open or dehisced wounds.

DO NOT use with V.A.C. VERAFLO™ Therapy (Instillation) provided by the V.A.C.ULTA™ Therapy Unit. Instillation into the incision site may result in pooling of fluid which may result in maceration.

Bleeding: Before applying the PREVENA RESTOR™ 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™ Dressing in place, turn off the 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, purulent 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). **If infection develops, PREVENA RESTOR™ Therapy should be discontinued until the infection is treated.**

Allergic Response: The PREVENA™ Dressing has an acrylic adhesive coating, hydrocolloid adhesive 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, hydrocolloid adhesive or silver. If a patient has a known allergy or hypersensitivity to these materials, do not use PREVENA™ Dressings. 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™ 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): All KCI Therapy Units, including the PREVENA PLUS™ 125 Therapy Unit, are MR unsafe. Do not take therapy units into the MR environment. The PREVENA™ Dressings can typically remain on the patient with minimal risk in an MR environment. Interruption of PREVENA RESTOR™ Therapy during MRI may reduce the effectiveness of the PREVENA RESTOR™ Incision Management System. The PREVENA™ Dressings 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™ Dressing contains metallic silver that may impair visualization with certain imaging modalities.

Hyperbaric Oxygen Therapy (HBO): Do not take therapy units or PREVENA™ Dressings into a hyperbaric oxygen chamber. They are not designed for this environment and **should be considered a fire hazard**. If PREVENA RESTOR™ 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 RESTOR™ Incision Management System the canister becomes full of fluid, indicated by a therapy unit alert or visual inspection, the patient should turn off the therapy unit and contact the treating physician for additional instruction.

Standard Operation: Do not use accessories or materials not provided with the PREVENA RESTOR™ Incision Management System. For a list of acceptable therapy units with which PREVENA™ Dressings may be used, see the **Product Description and Indication for Use** section.

ADDITIONAL WARNINGS FOR V.A.C.® Y-CONNECTOR

- When multiple sites are being treated, SENSAT.R.A.C.™ Technology senses only one wound site, the side connected to the Y-Connector arm with the post (male port). See the illustration in the **Dressing Application** section.
- Diligent pressure monitoring should be considered when treating multiple flaps.
- A blockage or leak on the non-post side will not be detected by the unit.
- Do not connect wounds with different etiologies in which cross contamination may occur.
- It is not recommended to use more than one Y-Connector per V.A.C.® Therapy or PREVENA PLUS™ 125 Therapy Unit.

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.

Circumferential Dressing Application: Avoid applying the PREVENA™ Dressing circumferentially. In cases where the clinician determines that the benefits of applying the PREVENA™ Dressing circumferentially outweigh 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™ 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™ 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 dressing components and canisters of the PREVENA RESTOR™ 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.
- To **avoid tension or irritation** on intact skin, use PREVENA™ Patch Strips under the PREVENA™ Dressing for protection.

Compressive Garments or Dressings: Avoid tight compressive garments or dressings (such as surgical bras, elastic bandage wraps or abdominal binders) to prevent forcibly pressing the PREVENA™ Dressing into soft tissue.

PREVENA RESTOR™ INCISION MANAGEMENT SYSTEM SITE PREPARATION

1. Prior to surgery, shave or clip 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
   - all components of the PREVENA RESTOR™ Incision Management System (dressing and therapy unit)
3. After 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.
5. To **avoid tension or irritation** on intact skin, use PREVENA™ Patch Strips under the PREVENA™ Dressing for protection.

NOTE: Avoid placing PREVENA™ Patch Strips directly on the closed wound or incision.

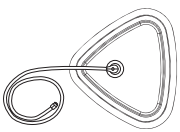
DRAIN TUBES AND PAIN MANAGEMENT CONTROL DEVICES

The PREVENA RESTOR™ 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 RESTOR™ Incision Management System.

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

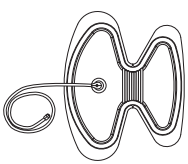
PREVENA RESTOR™ INCISION MANAGEMENT SYSTEM WITH DRESSING COMPONENTS

The sterile PREVENA RESTOR™ Incision Management System contains the following single use, disposable components.



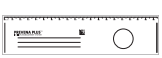
PREVENA™ Dressing of one of two configurations (A or B) - a specially designed dressing for application to the surgical area

A. PREVENA RESTOR BELLA•FORM™ Dressing - available in 21cm x 19cm, 24cm x 22cm or 29cm x 27cm



B. PREVENA RESTOR ARTHRO•FORM™ Dressing - available in 33cm x 30cm and 46cm x 30cm

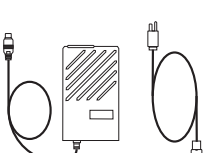
V.A.C.® Y-Connector - used to connect two PREVENA™ Dressings to the PREVENA PLUS™ 125 Therapy Unit or an approved KCI V.A.C.® Therapy Unit (as applicable)



Ruler - the removable label may be used as needed to record the date of dressing application or removal

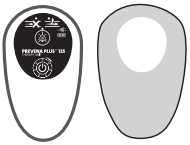
PREVENA™ Patch Strips - used to help seal leaks around dressing

PREVENA PLUS™ Connector - used to connect the PREVENA PLUS™ Canister to the PREVENA™ Therapy V.A.C.® Connector.



PREVENA PLUS™ 125 Therapy Unit Power Supply and Power Cord - a charging system provided with the PREVENA PLUS™ 125 Therapy Unit to charge the internal battery.

PREVENA PLUS™ 150 ml Canister - a sterile reservoir for collection of wound fluids



PREVENA PLUS™ 125 Therapy Unit - delivers negative pressure to the surgical area. The unit is battery and electrically powered. The non-sterile PREVENA PLUS™ 125 Therapy Unit Carrying Case is provided to facilitate patient mobility.

DRESSING APPLICATION

(Illustrations in the steps in this section show PREVENA RESTOR ARTHRO•FORM™ Dressing - 33cm x 30cm)

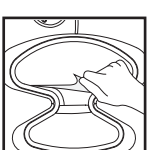
CAUTION: If the dressing covers the umbilicus, the umbilicus must first be fully filled with an anti-microbial petroleum gauze prior to dressing application.

WARNING: DO NOT use with V.A.C. VERAFLO™ Therapy (Instillation) provided by the V.A.C.ULTA™ Therapy Unit. Instillation into the incision site may result in pooling of fluid which may result in maceration.

1. Select the PREVENA RESTOR™ Incision Management System Kit based on the desired coverage area. Choose from:

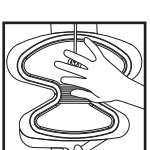
   A. PREVENA RESTOR BELLA•FORM™ Dressing - 21cm x 19cm, 24cm x 22cm or 29cm x 27cm
   B. PREVENA RESTOR ARTHRO•FORM™ Dressing - 33cm x 30cm and 46cm x 30cm

2. 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.

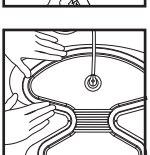


3. Gently peel back one release liner on the back of the dressing exposing the adhesive.

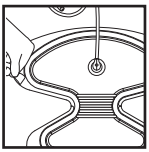
4. Center and apply the dressing over the closed wound or incision ensuring that the adhesive will not contact or cover the surgical closure. Orient the dressing on the patient to eliminate sharp bends or kinks in the tubing.



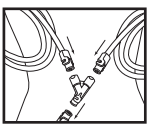
5. Remove the remaining release liner by grasping the bottom tab and gently pulling.



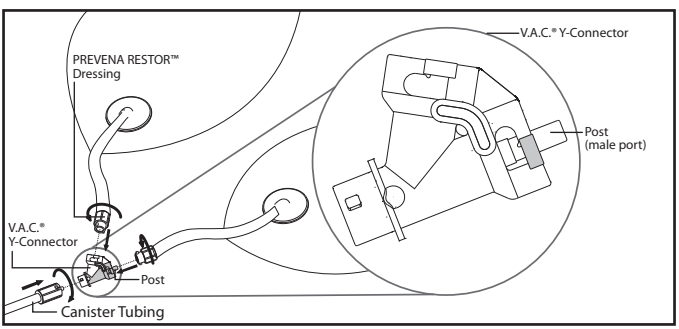
6. Firmly press around the dressing to ensure a good seal where the adhesive contacts the skin.



7. Remove top stabilization layers.



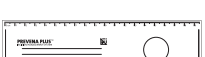
8. Optional step for multiple dressings: Connect the tubing from each PREVENA™ Dressing to the V.A.C.® Y-Connector.
   - Push the connectors together
   - Twist the connectors to lock



NOTE: When multiple sites are being treated, SENSAT.R.A.C.™ Technology senses only one wound site, the side connected to the Y-Connector arm with the post (male port).

9. Connect to the therapy unit. For connection to the PREVENA PLUS™ 125 Therapy Unit, see the **Connecting the Dressing to PREVENA PLUS™ 125 Therapy Unit** section. For connection to other KCI V.A.C.® Therapy Units, see the **Connecting the PREVENA RESTOR™ Dressing to V.A.C.® Therapy Units** section.

   For dressing removal, see the Dressing Removal section.



NOTE: The removable label on the supplied ruler may be used as needed to record date of dressing application or removal.

NOTE: If the wound is over a bony prominence or in areas where weight bearing may exert additional pressure or stress to the underlying tissues, a pressure redistribution (pressure relief) surface or device should be used to optimize patient offloading.

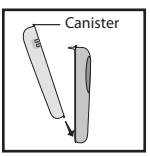
PREVENA PLUS™ CANISTER INSTALLATION

The canister used with the PREVENA PLUS™ 125 Therapy Unit is a single-use, sterile, 150ml container with graduated markings of approximately 50 cc/ml increments.

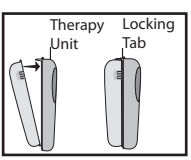
NOTE: If the canister is not fully engaged, the PREVENA PLUS™ 125 Therapy Unit will alert.

NOTE: Only use the recommended PREVENA PLUS™ 125 Therapy Unit Canister with this product.

NOTE: Never reuse a canister.



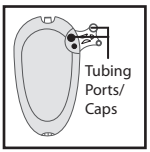
1. Remove the canister from the sterile package.
2. Hold therapy unit and canister, vertically or horizontally, one in each hand, and slide bottom of canister into slot on bottom of therapy unit.



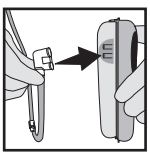
3. Close canister against therapy unit. The upper locking tab will click when canister is secured.

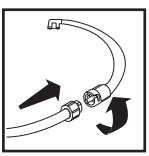
CONNECTING THE DRESSING TO THE PREVENA PLUS™ 125 THERAPY UNIT

For connecting to other KCI V.A.C.® Therapy Units, see the **Using the PREVENA™ Dressing with KCI V.A.C.® Therapy Units** section.

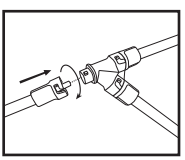


1. Connect the PREVENA PLUS™ Connector to the canister by aligning and plugging connector at end of tubing onto tubing ports on side of canister. Push together firmly.





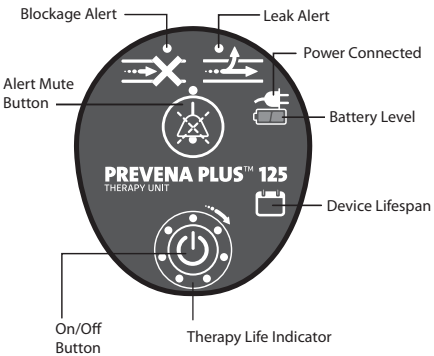
2. For a single dressing, connect the dressing tubing to the PREVENA PLUS™ Connector:
   - Push the connectors together
   - Twist the connectors to lock



3. For multiple dressings, connect the V.A.C.® Y-Connector to the PREVENA PLUS™ Connector
   - Push the connectors together
   - Twist the connectors to lock

4. Begin therapy.

BEGINNING THERAPY

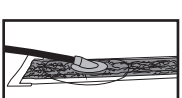


1. Ensure the PREVENA™ Dressing has been applied as described in the **PREVENA RESTOR™ Application** section.

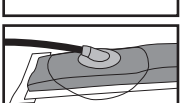
2. To begin therapy, press and hold center of the **On/Off** button for three seconds. The PREVENA PLUS™ 125 Therapy Unit, while in operation, may have a moderate sound emanating from the unit. All seven Therapy Life Indicators will illuminate with a green LED, indicating therapy is running.

NOTE: To interrupt therapy or turn unit off, press and hold center of the On/Off button for three seconds.
Once therapy is on for one hour non-stop, the lifespan begins and continues even if unit is turned off.

3. With therapy on, assess dressing to ensure integrity of seal.

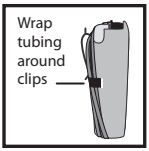


- The dressing should have a wrinkled appearance and the foam bolster should be compressed.



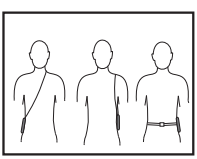
- If the foam bolster is not compressed or the therapy unit alerts, see the **Alerts** section.

4. If there is any evidence of a leak, check the dressing seals, tubing connectors and canister connection. Refer to the **Correcting a Leak Condition** section for more information.



5. Secure excess tubing to prevent interference with patient mobility.

6. If desired, place the therapy unit into the carrying case. Ensure display is visible through the opening in the carrying case.
7. The carrying case comes with both an adjustable strap and belt clip for carrying. The belt clip and additional clips on each side and at the bottom of the carrying case provide a place where excess tubing may be wrapped and stored to help prevent/minimize tripping and strangulation.

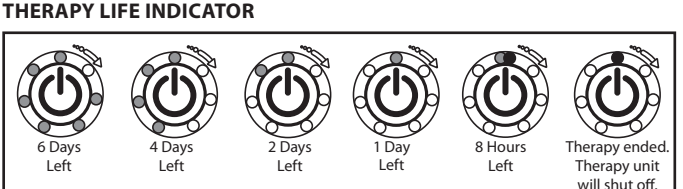


CAUTION: Do not wear or wrap strap around neck. Do not wrap tubing around neck.

UNIT TROUBLESHOOTING

If the PREVENA PLUS™ 125 Therapy Unit will not power on, make sure batteries are charged (see **Battery Charging** section). If the therapy unit still will not turn on, contact KCI.

THERAPY LIFE INDICATOR



NOTE: Grey represents green indicators and black represents yellow indicators.

The therapy life indicators provide a visual display of the therapy life cycle. When therapy begins all seven green LEDs are illuminated. During the last six days of therapy, after each 24-hour period an indicator will turn off. When eight hours of therapy time remains, the last indicator will illuminate with both a green and yellow LED simultaneously. When therapy time is about to expire, the last indicator will illuminate with a yellow LED and an alert will sound for approximately two minutes, then the therapy unit will shut off.

At the end of therapy, the therapy unit must be replaced with a new unit or alternative therapy must be used. Patients should be instructed to contact the treating physician or caregiver if therapy unit turns off and cannot be restarted before therapy is scheduled to end.

NOTE: Once therapy is on for one hour non-stop, the lifespan begins and continues even if the unit is turned off.

DURATION OF PREVENA PLUS™ THERAPY

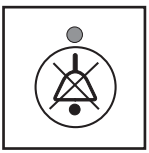
- Therapy should be continuous for a maximum of seven days per dressing.

  NOTE: The PREVENA PLUS™ 125 Therapy Unit will automatically time-out after fixed lifespan of the device. Once therapy is on for one hour without stopping, the lifespan begins and continues even if the unit is turned off.

- Patients should be instructed to contact their treating physician and not to turn therapy off unless:
  - advised by the treating physician
  - bleeding develops suddenly or in large amounts during therapy
  - there are signs of allergic reaction or infection
  - the canister is full of fluid
  - system alerts must be addressed
- Patient should be instructed to contact the treating physician if therapy unit turns off and cannot be restarted before therapy is scheduled to end, or if canister becomes full of fluid.
- At end of therapy, patient should return to treating physician for dressing removal.

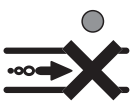
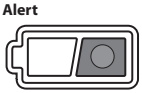
ALERTS

Audible Alerts - All audible alerts will sound two beeps, escalating and repeating every 15 seconds, which will increase in volume through four cycles. The fourth cycle will produce the loudest audible beep and will repeat until the alert condition is corrected.



Alert Mute Button - Press and hold center of the **Alert Mute** button for three seconds during an alert condition to silence the audible alert for two minutes. When pressed, the **Alert Mute** button will illuminate to indicate mute has been selected. The alert will re-occur after two minutes unless the alert condition has been corrected.

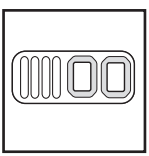
The therapy unit will sound audible and display visual alerts as follows:

Alert Type	ID and Resolution
Blockage Alert 	A solid yellow LED above the blockage symbol will turn on. Audible blockage alert will sound two beeps repeating every 15 seconds. When the blockage condition is resolved, audible and visual alerts will turn off. **To Correct Alert** Check for a full canister. Check for kinked tubing.
Leak Alert 	A solid yellow LED above the leak symbol will turn on. Leak alert will sound two beeps repeating every 15 seconds. When the leak condition is corrected, audible and visual alerts will turn off. **To Correct Alert** See the **Correcting a Leak Condition** section in this guide.
Low Battery Level Alert 	• A solid yellow LED on the battery level indicator will turn on. • Alert will sound two beeps repeating every four minutes. • A low battery alert indicates approximately two hours of therapy remain; charge batteries IMMEDIATELY to prevent disruption of therapy. • When battery is charged, audible and visual alerts will turn off. **To Correct Alert** Charge battery; see the **Battery Charging** section in this guide.
Therapy Ended 	• A solid yellow LED at the top of the Therapy Life Indicator will turn on. • The therapy unit will sound eight beeps, followed by a continuous beep for five seconds, then the therapy unit will turn off. • Notify the treating physician or caregiver: If the therapy unit has completed therapy and has timed out, and an attempt is made to turn the therapy unit on, the therapy unit will sound an alert for three seconds then shut off.
System Fault Alert  	• All LEDs will turn on and flash. • Two beeps sound, repeating every 15 seconds. **To Correct Alert** Power the therapy unit off and then on again. If alert continues contact the treating physician or caregiver.

CORRECTING A LEAK CONDITION

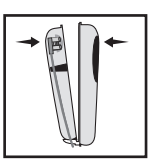
When the therapy unit detects a significant leak, a visual and audible leak alert will activate (see **Alerts** section).

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

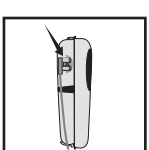


2. If a leak is identified, use PREVENA™ Patch Strips (located in dressing package) to help seal leaks around dressing. If large wrinkles are present, place patch strips so they run in line along the length of the wrinkle and not across the wrinkle.

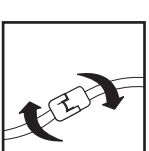
CHECK CANISTER TUBING CONNECTION



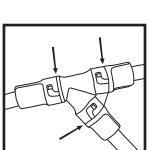
1. Ensure canister is securely locked onto the therapy unit. When canister is installed, a distinct click will be heard indicating it has been properly installed.



2. Check dressing tubing connector at canister.



3. Check tubing connectors to ensure they are fully engaged and locked.

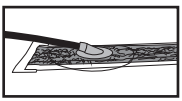


INDICATIONS THAT A LEAK CONDITION HAS BEEN CORRECTED

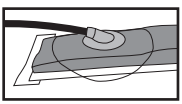
NOTE: Upon correcting a leak condition, a small delay will occur before the therapy unit senses the correction and silences the alerts.

The therapy unit will continue the alert until condition is corrected. When leak condition has been corrected, audible alerts will stop, and visual alerts will turn off.

The PREVENA™ Dressing will be compressed.



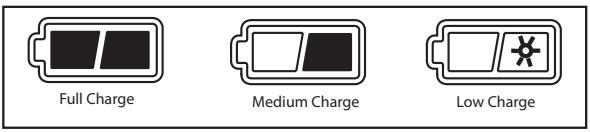
- Dressing compressed - system pressure acceptable.



- Dressing not compressed - system pressure not acceptable. Return to the **Correcting a Leak Condition** section to continue pressure correction steps

BATTERY CHARGING

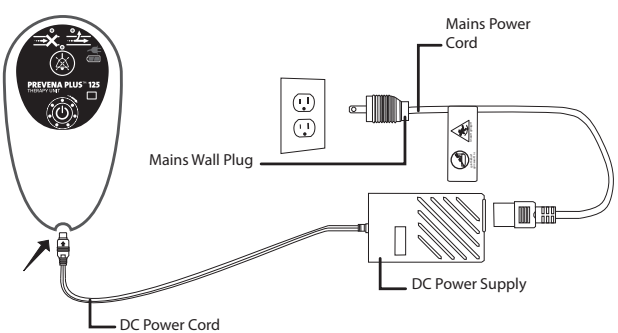
The PREVENA PLUS™ 125 Therapy Unit is battery-operated to facilitate patient mobility. The battery charge indicator on the user interface will display three levels of charge.



- Full charge (approximately nine hours remain)
- Medium charge (approximately two - seven hours remaining)
- Low charge. When low charge is indicated approximately two hours of therapy remain. Charge unit immediately to avoid disruption of therapy.

When the PREVENA PLUS™ 125 Therapy Unit is plugged into a power supply, the Power Connected icon turns yellow, indicating power is connected and system is charging. The icon will turn green when fully charged.

NOTE: Upon receipt, the PREVENA PLUS™ 125 Therapy Unit battery may not be fully charged.



NOTE: The rechargeable battery used in the PREVENA PLUS™ 125 Therapy Unit is not user accessible or replaceable.

1. Plug the mains power cord into a wall outlet.
2. Plug the other end of the mains power cord into the DC power supply.
3. Plug the DC power cord into the bottom of the therapy unit.
4. A fully discharged battery will recharge in approximately six hours.

CAUTION: Use only the charging system provided with the PREVENA PLUS™ 125 Therapy Unit. Using any other charging system may damage the therapy unit.

CAUTION: Power cords may present a tripping hazard. Ensure that power cords are out of areas where people walk.

NOTE: Power cords may have different wall plug configurations depending on country requirements.

CANISTER REMOVAL AND REPLACEMENT

1. Turn therapy off.
2. Unplug tubing from canister tubing ports.
3. Remove therapy unit from carrying case, if in use.
4. Press tab on canister to remove used canister from therapy unit.
5. Install new canister (see the **PREVENA PLUS™ Canister Installation** section).
6. Return therapy unit to carrying case if desired.
7. Reattach dressing tubing to canister tubing ports.
8. Turn therapy on.

NOTE: Dispose of used canister according to institution and local environmental regulations.

USING THE PREVENA RESTOR™ DRESSING WITH KCI V.A.C.® THERAPY UNITS

When directed by the treating physician, PREVENA™ Dressings can be used with negative pressure wound therapy provided by ACTIV.A.C.™, V.A.C.RX4™ and V.A.C.ULTA™ Therapy Units.

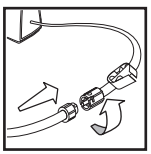
WARNING: Refer to the therapy unit's user manual for complete instructions for use and safety information before initiating therapy.

WARNING: DO NOT use with V.A.C. VERAFLO™ Therapy (Instillation) provided by the V.A.C.ULTA™ Therapy Unit. Instillation into the incision site may result in pooling of fluid which may result in maceration.

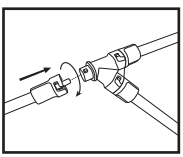
WARNING: The V.A.C.ULTA™ and V.A.C.RX4™ Therapy Units are only indicated for use in acute care settings. Before transitioning the patient to home care, the therapy unit must be replaced with one for home use, such as the PREVENA PLUS™ 125 or ACTIV.A.C.™ Therapy Unit.

NOTE: Consider using the smallest available canister for the selected V.A.C.® Therapy Unit.

CONNECTING THE PREVENA RESTOR™ DRESSING TO V.A.C.® THERAPY UNITS



1. For a single dressing, connect the PREVENA RESTOR™ Dressing tubing to the V.A.C.® Therapy Unit canister tubing:
   - Push the connectors together
   - Twist the connectors to lock



2. For multiple dressings, connect the V.A.C.® Y-Connector to the V.A.C.® Therapy Unit canister tubing:
   - Push the connectors together
   - Twist the connectors to lock
3. Ensure clamp on canister tubing is open.

SETTING NEGATIVE PRESSURE ON THE V.A.C.® THERAPY UNITS

Set and activate V.A.C.® Therapy at -125mmHg continuous. Do not choose any other negative pressure setting or intermittent or DYNAMIC PRESSURE CONTROL™ Therapy modes of negative pressure.

For V.A.C.ULTA™ Therapy Units:

- Select V.A.C.® Therapy or when available, PREVENA™ Therapy.
- Do NOT select V.A.C. VERAFLO™ Therapy (see the **WARNING** under **Using the PREVENA™ Dressings with KCI V.A.C.® Therapy Units**).
- See the **Choose Therapy** section of the V.A.C.ULTA™ Therapy User Manual for more information.

ALARM RESOLUTIONS

KCI V.A.C.® Therapy Unit alarms should be addressed in a timely manner. Refer to the appropriate therapy unit user manual for complete information on alarm resolutions. Refer to the **Correcting a Leak Condition** section for correcting a leak in the dressing.

PREVENA PLUS™ 125 THERAPY UNIT DISPOSAL

At the end of therapy, the patient should return the PREVENA PLUS™ 125 Therapy Unit to the physician for disposal. Dispose of all waste according to local requirements. Improper disposal may run the risk of regulatory non-compliance.

INSTRUCTIONS FOR PATIENTS

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

WARNING: The V.A.C.ULTA™ and V.A.C.RX4™ Therapy Units are only indicated for use in acute care settings. Before transitioning to home care, these therapy units must be replaced with one for home use, such as the PREVENA PLUS™ 125 or ACTIV.A.C.™ Therapy Unit.

DAILY USE

The PREVENA PLUS™ 125 and ACTIV.A.C.™ Therapy Units are portable and small enough that they may be worn beneath clothing during normal patient activities as approved by the treating physician.

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.

CAUTION: The PREVENA PLUS™ Incision Management System is a medical device not a toy. Keep away from children, pets and pests as they can damage the dressing and therapy unit and affect performance. Keep therapy unit free of dust and lint.

SLEEPING

Instruct patient 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

- Do not use the PREVENA PLUS™ 125 Therapy Unit while bathing/showering or where it can fall or be pulled into a tub, shower or sink.
- Do not reach for a product that has fallen into water. Unplug the unit immediately if plugged into an electrical source. Disconnect unit from dressing and contact treating physician or caregiver.
- Light showering is permissible, bathing is not. Before showering disconnect the dressing from the therapy unit.
- 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 the 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 PLUS™ Incision Management System.

CLEANING

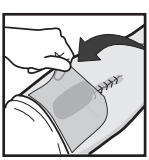
Advise patient that the therapy unit and carrying case can be wiped with a damp cloth using a mild household soap solution that does not contain bleach.

DRESSING REMOVAL

NOTE: If dressing is lifted to observe incision, 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.

1. Turn the therapy unit off by pressing and holding the On/Off button.



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.
3. Clean any residual adhesive.

NOTE: If used, dispose of the V.A.C.® Y-Connector according to institution and local environmental regulations.

If a new dressing is to be applied:

1. Ensure the incision area is clean by using an alcohol swab or an antiseptic wipe.
2. Allow skin to dry completely.
3. Follow the **Dressing Applications** instructions.

WARNINGS AND IMPORTANT INFORMATION FOR USERS - PREVENA PLUS™ 125 THERAPY UNIT

In order for KCI products to perform properly, KCI recommends the following conditions. Failure to comply with these conditions will void any applicable warranties.

- Use this product only in accordance with these instructions and applicable product labeling.
- Assembly, operations, extensions, re-adjustments, modifications, technical maintenance or repairs must be performed by qualified personnel authorized by KCI.
- Ensure the electrical installation of the room complies with the appropriate national electrical wiring standards. To avoid the risk of electrical shock, this product must be connected to a grounded power receptacle.
- Cell phones or similar products could affect the therapy unit. Move the therapy unit away from these devices if interference is suspected.
- 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.
- Do not drop or insert any object into any opening or tubing of this product.
- Do not connect this product or its components to devices not recommended by KCI.
- Do not modify the therapy unit or dressing. Do not connect the therapy unit or dressing to other devices being used.
- Use only PREVENA™ Dressings with this product.
- Keep this product away from heated surfaces.
- Equipment not suitable for use in presence of flammable anesthetic mixture with air, oxygen or nitrous oxide or in an environment in which the concentration of oxygen is: a) greater than 25% for ambient pressures up to 110 kPa; or b) the partial pressure of oxygen is greater than 27.5 kPa at ambient pressures exceeding 110 k.
- Avoid spilling fluids on any part of this product.
- Do not make any changes to the settings on the therapy unit without instructions from the treating physician.
- Small Parts - Choking Hazard
- The PREVENA PLUS™ Incision Management System is a medical device, 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 damage the dressing and therapy unit and affect performance.

WARNING: The PREVENA PLUS™ 125 Therapy Unit has no serviceable parts and should not be opened, disassembled or otherwise modified by the user, and should be replaced as a unit. All assembly, operations, adjustments, modifications, maintenance and repairs must be carried out by qualified personnel authorized by KCI.

Electric Shock Hazard - Do not open any electrical cover on the therapy unit. There are no serviceable parts. Refer to qualified KCI service personnel.

Fluids remaining on the electronic controls can cause corrosion that may cause the electronic components to fail. Component failures may cause the unit to operate erratically, possibly producing potential hazards to patient and staff. If spills do occur, unplug the unit immediately and clean with an absorbent cloth. Ensure there is no moisture in or near the power connection and power supply components before reconnecting power. If the product does not work properly, contact KCI.

PREVENA PLUS™ 125 THERAPY UNIT ELECTROMAGNETIC COMPATIBILITY

The following are guidance and manufacturer's declarations regarding EMC for the PREVENA PLUS™ 125 Therapy Unit.

- The PREVENA PLUS™ 125 Therapy Unit needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following pages.

WARNING: This equipment is intended for use by healthcare professionals only. As with all electrical medical equipment, this equipment 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, RFID readers, electronic article surveillance (anti-theft) equipment and metal detectors can affect the performance of the PREVENA PLUS™ 125 Therapy Unit. Please use the guidelines and recommendations specified in Tables 204 and 206.
- 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 cables, external power supplies and accessories listed or referenced in this manual have been shown to comply with the test requirements listed in the following tables. Care should be taken to use only manufacturer-recommended cables, power supplies and accessories with the PREVENA PLUS™ 125 Therapy Unit. If a third-party supplier offers cables, external power supplies and electrical accessories for use with the PREVENA PLUS™ 125 Therapy Unit and they are not listed or referenced in this manual, it is the responsibility of that third-party supplier to determine compliance with the standards and tests in the following tables.
- The use of electrical cables and accessories other than those specified in this manual or referenced documents may result in increased electromagnetic emissions from the PREVENA PLUS™ 125 Therapy Unit or decreased electromagnetic immunity of 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 cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. More precisely, the minimum recommended separation distance should be calculated from the equation applicable to the frequency of the transmitter, as noted in the guidance below.
- 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.

Table 201

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The PREVENA PLUS™ 125 Therapy Unit is intended for use in the electromagnetic environment specified below. The customer or the end user of the PREVENA PLUS™ 125 Therapy Unit should assure that it is used in such an environment.		
Emission Test	Compliance	Electromagnetic Environment - Guidance
RF emissions - CISPR 11 (Radiated & Conducted)	Group 1	The PREVENA PLUS™ 125 Therapy Unit uses RF energy only for its 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 (Radiated & Conducted)	Class B	The PREVENA PLUS™ 125 Therapy Unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 202

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The PREVENA PLUS™ 125 Therapy Unit is intended for use in the electromagnetic environment specified below. The customer or the end user of the unit should assure it is used only in such an environment.			
Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Intended Electromagnetic Environment
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If 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	±2 kV for power supply lines 100 kHz repetition frequency ±1 kV for input/ output lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or home healthcare environment.
Surge IEC 61000-4-5	±1 kV differential mode (line - line) ±2 kV common mode (line - earth)	±1 kV differential mode (line - line) ±2 kV common mode (line - earth)	Mains power quality should be that of a typical commercial or home healthcare environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 seconds	Dips: 0% Ut for 1 cycle 70% Ut for 25 cycles at 50 Hz or 30 cycles at 60 Hz Single phase: at 0˚ Interruptions: 0% Ut for 250 cycles at 50 Hz or 300 cycles at 60 Hz	Product has internal battery backup. If the user of the PREVENA PLUS™ 125 Therapy Unit requires continued operation during power mains interruptions, it is recommended that the unit be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or home healthcare environment.
NOTE: Ut is the A.C. mains voltage prior to application of the test level.			

Table 204

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The PREVENA PLUS™ 125 Therapy Unit is intended for use in the electromagnetic environment specified below. The customer or the end user of the unit should assure it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3Vrms 150kHz to 80 MHz 6Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz 80% AM at 1kHz 10 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the PREVENA PLUS™ 125 Therapy Unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 0.35\sqrt{P}$ 80MHz to 800 MHz $d = 0.7\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended minimum separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80MHz and 800MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from objects, structures and people.			
[a] 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 assess 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 PREVENA PLUS™ 125 Therapy Unit is used exceeds the applicable RF compliance level above, the unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PREVENA PLUS™ 125 Therapy Unit.			

Table 205

Guidance and Manufacturer's Declaration - Electromagnetic Immunity						
The PREVENA PLUS™ 125 Therapy Unit is intended for use in the electromagnetic environment specified below. The customer or the end user of the unit should assure it is used only in such an environment.						
Test Frequency (MHz)	Band[a] (MHz)	Service[a]	Modulation[b]	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 - 390	TETRA 400	Pulse modulation[b] 18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM[c] ±5 kHz deviation 1 kHz sine	2	0,3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation[b] 217 Hz	0,2	0,3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 - 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3 4, 25; UMTS	Pulse modulation[b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 - 2 570	Bluetooth WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b] 217 Hz	2	0,3	28
5 240	5 100 - 5 800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0,2	0,3	9
5 500						
5 785						
NOTE: If necessary to achieve the Immunity Test Level, the distance between the transmitting antenna and the ME Equipment or ME System may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.						
[a] For some services, only the uplink frequencies are included.						
[b] The carrier shall be modulated using a 50% duty cycle square wave signal.						
[c] As an alternative to FM modulation, a 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

Table 206

Recommended separation distances between portable and mobile RF communications equipment and the PREVENA PLUS™ 125 Therapy Unit			
The PREVENA PLUS™ 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 PLUS™ 125 Therapy Unit can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communications equipment (transmitters) and the unit as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum ouput power of transmitter in watts (W)	Separation distance according to frequency of transmitter in meters (m)		
	150 kHz to 80 MHz d = 1.2 √P	80 MHz to 800 MHz d = 0.35 √P	800 MHz to 2.5 GHz d = 0.7 √P
0.01	.12	.04	.07
0.1	.38	.11	.22
1	1.2	.35	.7
10	3.8	1.1	2.2
100	12	3.5	7
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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 structures, objects and people.			

INCLUDED POWER SUPPLIES

Part Number	Description	Manufacturer	Max Length
44001674	Power Supply, 5V, 10W	Inventus Power	1.03 m
413628	Cord, V.A.C.® Power, US	Consolidated Wire	2.08 m

The use of electrical cables and accessories other than those specified in the supplied instructions for use or referenced documents may result in increased electromagnetic emissions from the PREVENA PLUS™ 125 Therapy Unit or decreased electromagnetic immunity of the PREVENA PLUS™ 125 Therapy Unit.

CUSTOMER 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.acelity.com

Outside the US visit www.kci-medical.com

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

PREVENA PLUS™ 125 THERAPY UNIT SPECIFICATIONS

Dimensions: 3.5″W x 6.4″H x 2.16″D (8.9 x 16.3 x 5.49 cm)

Weight (with empty canister attached): ~.64 lbs (~.29 kg)

Pressure: 125 mmHg (16.7 kPa)

Canister Volume: 150 mL

Electrical:

Battery Run Life: ~8.5 hours

Battery Charge Time: ~6 hours from a fully discharged state

External Power Supply Input: 100-240VAC 0.5A-0.3A 50 - 60 Hz

External Power Supply Output: 5V, 2.0 A

Patient and Enclosure Leakage Current: <100 Microamps

Environmental Conditions:

Storage/Transport Conditions

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

Relative Humidity Range: 0-95% non-condensing

Operating Conditions

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

Relative Humidity Range: 15 - 93% non-condensing

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

Expected Service Life (7 Day device) 7.5 days

Expected Service Life (14 Day device) 14.5 days

IEC Classification

Medical Equipment

Type BF, Applied Part

Class II

IP22 - Protection against solid objects greater than 12.5 mm and against liquid water falling for short periods of time.

The dressing components of the PREVENA RESTOR™ Incision Management System are considered Applied Parts under IEC 60601-1.

Conforms to AAMI ES60601-1:2005 +A1:2012, IEC 60601-1-6 Ed.3.1:2013, IEC 60601-1-8 Ed.2.1:2012, IEC 60601-1-11 Ed.2.0:2015, CSA C22.2#60601-1:2014 Ed.3

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EN - SYMBOLS USED

	**EN** - Refer to Clinician Guide		**EN** - Consult Instructions for Use
IP22	**EN** - Ingress Protection		**EN** - Type BF applied part
STERILE R	**EN** - Sterile using radiation	LOT	**EN** - Lot Number
	**EN** - Date of Manufacture		**EN** - Manufacturer
	**EN** - No Bathing or Showering		**EN** - Use By
	**EN** - Fragile	REF	**EN** - Catalog Number
	**EN** - Keep Dry		**EN** - Single Use Only
	**EN** - MR Unsafe		**EN** - Tripping Hazard
	**EN** - Do Not Resterilize		**EN** - Class II Device
	**EN** - Content Information		**EN** - Temperature Limit
	**EN** - Do not use if package is damaged or open		**EN** - Single Patient Use Only

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

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

EN - Expected Service Life of Device in Days

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