Prevena™ Incision Management System

Instructions for Use for Clinicians

Featuring

Peel & Place™ Dressing

and

Customizable™ Dressing
# Table of Contents

- Important Information for Users ................................................................. 5
- Indication for Use .................................................................................. 5
- Optimum Use Conditions ...................................................................... 5
- Contraindication .................................................................................... 5
- Warnings ............................................................................................... 6
- Precautions ............................................................................................ 7
- Prevena™ Incision Management System (IMS) Site Preparation .......... 8
  - Drain Tubes and Pain Management Control Devices ....................... 8
- Prevena™ Incision Management System Dressings ......................... 8
- Prevena™ Peel & Place™ Dressing Application Instructions .............. 9
  - Peel & Place™ Dressing Components ............................................... 9
  - Prevena™ Peel & Place™ Dressing Application ................................ 10
- Prevena™ Customizable™ Dressing Application Instructions ............ 11
  - Customizable™ Dressing Components ............................................. 11
  - Prevena™ Customizable™ Dressing Applications ........................... 12
  - Drape Application ........................................................................... 18
  - Interface Pad Application ................................................................ 20
- Prevena™ Canister Install and Connect .................................................. 21
- Beginning Prevena™ Therapy ................................................................. 21
  - Duration of Therapy ......................................................................... 22
  - Dressing Removal ........................................................................... 22
  - New Dressing Application ................................................................ 22
- Indicators and Alerts ............................................................................ 23
- Leaks ..................................................................................................... 24
  - VisiCheck™ Feature ........................................................................ 24
- Correcting a Leak Condition ................................................................. 24
  - Prevena™ Peel & Place™ Dressing .................................................. 24
  - Prevena™ Customizable™ Dressing ............................................... 25
  - Check Canister and Tubing Connection .......................................... 25
- Indications That a Leak Condition Has Been Corrected .................... 25
Prevena™ Dressing Pressure Indicator ................................................................. 26
Battery Replacement .......................................................................................... 26
Instructions For Patient ..................................................................................... 27
  Daily Use ............................................................................................................. 27
  Sleeping .............................................................................................................. 27
  Showering and Bathing ....................................................................................... 27
  Strenuous Activity ............................................................................................. 27
  Cleaning .............................................................................................................. 28
Device Disposal .................................................................................................. 28
Using the Prevena™ Dressing with KCI V.A.C.® Therapy Units ................. 28
  Alarm Resolutions ............................................................................................. 28
Specifications ..................................................................................................... 29
Electromagnetic Compatibility ......................................................................... 29
Symbols Used ....................................................................................................... 33
Customer Contact Information ......................................................................... 33
INSTRUCTIONS FOR USE
PREVENA™ INCISION MANAGEMENT SYSTEM
KCI customer contact information is located in the back of this guide.

Important Information for Users
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 of the Prevena™ Incision Management System (IMS) components 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.

CAUTION: The Prevena™ IMS should be applied and removed only by qualified physicians, nurses or caregivers.

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.

Optimum Use Conditions
For maximum benefit the Prevena™ IMS should be applied immediately post surgery to clean surgically closed wounds. It is to be continuously applied for a minimum of two days up to a maximum of seven days. It can transition home with the patient; however, all Prevena™ Dressing changes should be performed under direct medical supervision.

The Prevena™ IMS 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™ IMS 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™ 45 mL Canister. The V.A.C.® Therapy System should be considered for treatment of these wounds.

The Prevena™ IMS 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

**Bleeding:** Before applying the Prevena™ IMS 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 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, 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). Silver in the interface layer of the Prevena™ 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™ 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™ IMS. 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):** The Prevena™ 125 Therapy Unit is MR unsafe. Do not take the Prevena™ 125 Therapy Unit into the MR environment. The Prevena™ Dressings 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.

**Diagnostic Imaging:** The Prevena™ 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™ Dressings into a hyperbaric oxygen chamber. They are not designed for this environment and should be considered a fire hazard. If Prevena™ Therapy is reinitiated after HBO treatment, do not reapply the same dressing; a new dressing must be applied.

**Canister Full:** If at any time while using the Prevena™ IMS the canister becomes full of fluid other than blood, indicated by a Maximum Capacity Alert or visual inspection, the patient should turn off the therapy unit and contact the treating physician.

**Standard Operation:** Do not use accessories or materials not provided with the Prevena™ IMS. For a list of acceptable therapy units with which Prevena™ Dressings may be used, see the Using the Prevena™ Dressing with KCI V.A.C.* Therapy Units section on page 28.
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 components of the Prevena™ IMS 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 (IMS) 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
   • Prevena™ IMS (Check expiration date on box)

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.

Drain Tubes and Pain Management Control Devices

The Prevena™ IMS 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™ IMS.

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

Prevena™ Incision Management System Dressings

The Prevena™ IMS features Peel & Place™ Dressing and Customizable™ Dressing. These dressings contain 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 90˚F (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.

<table>
<thead>
<tr>
<th>Challenge Organism</th>
<th>Mean Log Reduction from Day 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Day 1</td>
</tr>
<tr>
<td><em>Escherichia coli</em> (ATCC 8739)</td>
<td>2.2</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em> (ATCC 09027)</td>
<td>2.0</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em> (ATCC 6538)</td>
<td>1.6</td>
</tr>
<tr>
<td><em>Klebsiella pneumonia</em> (ATCC 4352)</td>
<td>1.4</td>
</tr>
<tr>
<td><em>Candida albicans</em> (ATCC 10231)</td>
<td>2.5</td>
</tr>
<tr>
<td><em>Aspergillus niger</em> (ATCC 16404)</td>
<td>2.2</td>
</tr>
</tbody>
</table>
Prevena™ Peel & Place™ Dressing Application Instructions

Peel & Place™ Dressing Components
The sterile Peel & Place™ Dressing system contains the following single use, disposable components.

- **Prevena™ Dressing with Pressure Indicator** - a specially designed dressing for application to the surgical area

- **Prevena™ Patch Strips™** - used to help seal leaks around dressing

- **Prevena™ 45 mL 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 non-sterile Prevena™ Carrying Case is provided to facilitate patient mobility.

- **V.A.C.® Connector** - used to connect the Prevena™ Dressing to a KCI V.A.C.® Therapy Unit
Prevena™ Peel & Place™ Dressing Application

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

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

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 or kinks in the tubing.

4. Remove the remaining bottom adhesive covers by grasping the bottom tabs and gently pulling.

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

6. Remove top stabilization layers.
Prevena™ Customizable™ Dressing Application Instructions

Customizable™ Dressing Components
The sterile Customizable™ Dressing system can be used for linear / non-linear incision applications and contains the following single use, disposable components.

Prevena™ Customizable™ Dressing (folded) - a specially designed dressing for application to the surgical area

Sealing Strips - used to create a continuous adhesive seal around the Prevena™ Customizable™ Dressing

KCI Drapes - used to cover dressing and provide a seal for negative pressure

Ruler - used to measure incision before cutting. The removeable label may be used as needed to record date of dressing application or removal. The oval cutout on the ruler is to be used as a template for cutting a hole in the drape for the interface pad.

Interface Pad - used to connect the Customizable™ Dressing to therapy unit

Prevena™ 45 mL Canister - a sterile reservoir used to collect wound fluids

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

V.A.C.® Connector - used to connect the Prevena™ Dressing to a KCI V.A.C.® Therapy Unit
Prevena™ Customizable™ Dressing Applications

The Prevena Customizable™ Dressing can be used for the following wound types:

- linear incisions
- non-linear incisions
- intersecting incisions

The following figures show completed dressing applications using the Customizable™ Dressing, KCI Drape and interface pad.

**Dressing Application for Linear Incisions**

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

1. Open the sterile dressing package, remove and unfold foam dressing using aseptic technique. Do not use if package has been torn or the sterile seal has been compromised.
2. Use the enclosed ruler to measure incision before cutting.
3. Cut foam dressing to the length necessary to cover the incision.

**CAUTION:** Do not cut the foam over the wound, as fragments may fall into the wound. Away from wound site, rub foam edges to remove any fragments or loose particles that may fall into or be left in the wound upon dressing removal.
4. Remove bottom release liner 1 on the foam dressing to expose adhesive seal and white fabric located on the bottom of the foam dressing. The white fabric covers the incision.

5. Add sealing strips to the ends of the foam dressing.

   NOTE: Use the Prevena™ Customizable™ Dressing to size the sealing strip as needed to fit the width of the dressing, approximately 3 in (8 cm).

   • Liner 1 **must be removed from the dressing** before applying sealing strips.

   • For sealing strips that have white liners: remove either top or bottom liner from the sealing strip. Sealing strips are tacky on both sides.

   • For sealing strips that have liners marked 1 and 2: remove liner 1 from the sealing strip.

   • Place sealing strip on end of foam dressing (creating a continuous seal). The strip should be placed half on dressing and half off dressing and overlap the adhesive seal on each side of the dressing. This ensures a seal all around the edge of the dressing.

   • Remove either the remaining white liner or liner 2 from the sealing strip. Repeat strip application on other end of foam dressing.

6. With sealing strips applied, position the foam dressing until the **adhesive seal and white fabric are facing down**.

7. Center the foam dressing over the incision / surgical closure. Ensure the **adhesive seal and white fabric are facing down**.
8. Press down around the length of the adhesive seal to ensure adhesion to the skin.

9. Peel off release liner 2 from the top of the adhesive seals.

10. Once the foam dressing has been applied to the incision, continue with the drape application (see the Drape Application section on page 18).
Dressing Application for Non-linear Incisions

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

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

2. Use enclosed ruler to measure incision before cutting.

3. Cut foam dressing to the length and shape necessary to cover the incision.

   CAUTION: Do not cut the foam over the wound, as fragments may fall into the wound. Away from wound site, rub foam edges to remove any fragments or loose particles that may fall into or be left in the wound upon dressing removal.

4. Make straight cuts at the desired angles to ensure the foam dressing pieces and seals make a flush / even connection with no gaps.

   CAUTION: Gaps at foam junctions may potentially cause erythema due to pinching of the skin when negative pressure is applied.

5. Use a sealing strip to bridge where the foam dressing pieces meet. Sealing strip should have equal overlap on both foam dressing pieces.

   NOTE: Use the Prevena™ Customizable™ Dressing to size the sealing strip as needed to fit the width of the dressing, approximately 3 in (8 cm).

   • Liner 1 must be removed from the dressing before applying sealing strips.
• Place sealing strip on end of foam dressing (creating a continuous seal). The strip should be placed half on dressing and half off dressing and overlap the adhesive seal on each side of the dressing. This ensures a seal all around the edge of the dressing.

NOTE: Having exposed adhesive material around all edges of the dressing provides a greater seal when the drape is applied.

• Remove the remaining liner from the sealing strip. Repeat strip application on other end of foam dressing.

6. With sealing strips applied, position the foam dressing until the adhesive seal and white fabric are facing down.

7. Place the foam dressing over the incision / surgical closure. Ensure the adhesive seal and white fabric are facing down.

8. After foam dressing placement is completed, ensure all liners are removed before continuing with the drape application (see the Drape Application section on page 18).
Dressing Application for Intersecting Incisions

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

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

2. Use enclosed ruler to measure incision before cutting.

3. Cut dressing as needed to fit incision. Ensure the foam dressings and seals meet with no gaps.

   CAUTION: Do not cut the foam over the wound, as fragments may fall into the wound. Away from wound site, rub foam edges to remove any fragments or loose particles that may fall into or be left in the wound upon dressing removal.

   CAUTION: Gaps at foam junctions may potentially cause erythema due to pinching of the skin when negative pressure is applied.

   CAUTION: Do not overlap foam dressing pieces on top of each other.

4. Use sealing strips at the ends of the foam dressing to create a continuous seal. Sealing strip should have equal overlap on both foam dressing pieces.

   NOTE: Use the Prevena™ Customizable™ Dressing to size the sealing strip as needed to fit the width of the dressing, approximately 3 in (8 cm).

   • Liner 1 must be removed from the dressing before applying sealing strips.

5. With sealing strips applied, position the foam dressing until the adhesive seal and white fabric are facing down.

   NOTE: It is acceptable if sealing strips cover the incision line.

6. Place the foam dressing over the incision / surgical closure. Ensure the adhesive seal and white fabric are facing down.

7. After foam dressing placement is completed, ensure all liners are removed before continuing with the drape application (see the Drape Application section on page 18).
Drape Application

CAUTION: Do not cover the umbilicus with drape. Before or after placement, ensure a small hole is cut in the drape in relation to the umbilicus.

Multiple pieces of drape may be needed when using Customizable™ Dressings depending on incision size. Drapes should always overlap each other by at least 1.2 in (3 cm). All dressing liners must be removed before any drape is used.

1. Trim KCI Drape as necessary. Ensure a minimum overlap of 1.2 in (3 cm) when using multiple pieces of KCI Drape. There is no drape under the blue handling bars.

2. Carefully remove the middle section of layer 1 from KCI Drape to expose adhesive. Leave the two end sections of layer 1 intact to maintain drape stability during application. The KCI Drape should be held by the blue handling bars.

3. With adhesive side down, apply KCI Drape over foam and onto intact skin. Ensure KCI Drape covers a minimum of 1.2 in (3 cm) of intact periwound tissue.

4. Lift the drape at both ends and remove the two remaining end sections of layer 1. Smooth out any wrinkles in the KCI Drape.

   CAUTION: Do not press blue handling bars down onto the sealing material.

5. Carefully remove striped layer 2 from KCI Drape.

6. Remove the two blue handling bars.
7. Add additional drape as needed to cover foam dressings in various configurations, as shown.
   - Smooth KCI Drape to remove creases and seal joints ensuring an occlusive seal.
   - All liners must be removed before additional drape is used.

   - Press drape down around the length of the adhesive seal to ensure adhesion to the skin.

   - Press down to seal all drapes.

   - Minimize any creases / wrinkles in drape.
   - Excess KCI Drape can be used to seal leaks.
Interface Pad Application

CAUTION: Do not place the interface pad directly over the umbilicus.

1. Use the oval cutout on the enclosed ruler as a template for hole size when cutting a hole in the drape for the interface pad. The removable label may be used as needed to record date of dressing application or removal.

2. Near center of foam dressing, carefully cut a hole in KCI Drape using a scalpel or scissors. It is not necessary to cut into the foam but if a small amount of foam is removed it will not inhibit performance.

3. Remove the cut section of drape.

4. Remove both backing layers 1 and 2 from pad to expose adhesive.

5. Place the pad opening in the central disc directly over hole in KCI Drape. Apply gentle pressure on the central disc and outer skirt to ensure complete adhesion of the pad.

6. Pull back on blue tab to remove pad stabilization layer. Interface pad application is complete.
Prevena™ Canister Install and Connect

1. Remove the Prevena™ 45 mL Canister from the sterile package. Do not use if package has been torn or the sterile seal has been compromised.

2. 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.

3. Connect the dressing tubing to the canister tubing by twisting the connectors until they lock. Peel & Place™ Dressing view is provided as representative example.

4. Begin therapy.

Beginning Prevena™ Therapy

1. Press and hold the On / Off button for two seconds; an audible beep will confirm that therapy is on. A green light on the front of the unit indicates that therapy is on.

   **NOTE:** Pressing the On / Off button begins the 192 hour (eight day expected service life) 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.

   **NOTE:** To turn therapy unit off, press and hold the On / Off button for five 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.
   - If there is any evidence of a leak, refer to the Leaks section on page 24.

3. Place the therapy unit into the Prevena™ Carrying Case. Make sure the display is visible through the opening in the carrying case when the front flap is lifted.
4. The Prevena™ Carrying Case has an integrated belt loop and a separate adjustable strap to allow for versatile positioning.

CAUTION: Do not wrap carrying case strap or dressing tubing around neck.

Duration of Therapy
- Therapy should be continuous for a minimum of two days up to a maximum of seven days.
- Therapy unit will automatically time-out after 192 hours (eight days) of cumulative run time.
- 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
  - batteries need to be changed
  - 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.

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.

1. Turn Prevena™ Therapy Unit off by pressing and holding the On / Off button for five 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.
3. Clean any residual adhesive with an alcohol swab.

New Dressing Application
1. Ensure the incision area is clean by using an alcohol swap or an antiseptic wipe.
2. Allow skin to dry completely before applying a new drape.
3. Follow either the Prevena™ Peel & Place™ Dressing Application instructions on page 10 or the Prevena™ Customizable™ Dressing Applications instructions on page 12.
Indicators and Alerts

Visual Alerts - Solid LEDs cannot be turned off 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.

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 Customer Contact Information section on page 33.

Leak Alert
One beep, one solid yellow light.
See Correcting a Leak Condition section on page 24.
When a leak condition is corrected the therapy unit will cancel alert. There may be a delay between when the leak is corrected and when the alert is discontinued.

Canister Full Alert
Two beeps, one solid yellow light.
Visually inspect canister. If full or near full, turn therapy unit off and call the treating physician immediately.

Low Battery Alerts
One slow beep, one solid yellow light. Change batteries within six hours.
One beep, repeating rapidly, increasing in volume, one solid yellow light. Change batteries immediately.
Battery replacement will cancel the alert.
See Battery Replacement section on page 26.

System Error Alert
One beep, repeating rapidly, increasing in volume, two solid yellow lights. Turn the unit off and then on again.
If alert continues, notify the treating physician.

Device Lifecycle Expired
Three solid yellow lights. If the lifecycle expires while therapy unit is on, a beep will sound for 15 seconds and then automatically shut off.
If the therapy unit is off, has exceeded the run time, and an attempt is made to turn the therapy unit on, the therapy unit will alert for three seconds and automatically shut off. Call the treating physician.
Leaks

VisiCheck™ Feature

To ensure proper application of the Prevena™ IMS, 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 three seconds.

To prevent nuisance leak alarms, the leak rate status should be “Best” (one light illuminated) or “Good” (two lights illuminated).

If the VisiCheck™ feature indicates a “Marginal” (three lights illuminated) leak rate condition, refer to the following Correcting a Leak Condition section below for methods of reducing the leak rate of the system. The system leak rate is calculated every seven 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 on page 23.
- Therapy unit will turn on more frequently.

Correcting a Leak Condition

Prevena™ Peel & Place™ Dressing

1. With therapy unit on, slowly press firmly around 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.
Prevena™ Customizable™ Dressing

1. Press down through drape onto the adhesive seal all the way around to ensure seal.

2. Use fingers to smooth out any creases or wrinkles.

3. Use excess KCl drape along the outer edge of drape to seal leaks.

Check Canister and Tubing Connection

1. 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.

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

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.
Prevena™ Dressing Pressure Indicator

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

- Indicator up - system pressure not acceptable.
- Indicator down - system pressure acceptable.

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 five seconds).
2. Remove therapy unit from carrying case. Turn the therapy unit over to expose the back side of the unit.
3. Locate the battery door and push to slide open. Install three 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 two seconds).

**Instructions For Patient**

Review the following information with the patient prior to discharge. This information is summarized in the Prevena™ IMS Patient Guide which must be provided to the patient at discharge.

**Daily Use**

The Prevena™ IMS is portable and small enough that it 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™ IMS 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**

Advise patient 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™ IMS.
Cleaning
Advise patient 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. Dispose of all waste according to local requirements. Improper disposal may run the risk of regulatory non-compliance.

Using the Prevena™ Dressing with KCI V.A.C.® Therapy Units
In certain cases as directed by the treating physician, Prevena™ Dressings can be used with a KCI V.A.C.® Therapy Unit.

Only the ActiV.A.C.®, InfoV.A.C.®, V.A.C.ATS® and V.A.C. Freedom® Therapy Units may be used on closed surgical incisions. Refer to the therapy unit’s user manual for complete instructions for use.

WARNING: Review all negative pressure wound therapy system safety information before initiating therapy.

NOTE: When Prevena™ Dressings are used with V.A.C.® Therapy, the SensaT.R.A.C.™ wound pressure sensing function on the therapy unit will be disabled. Instead, the Prevena™ Dressing Pressure Indicator (page 26) should be used to verify that incision site pressure is acceptable.

A KCI tubing connector will be needed to connect the Prevena™ Dressing to a KCI V.A.C.® Therapy Unit. This connector must be used for negative pressure wound therapy to work effectively and accurately. No other method for connecting the dressing to the therapy unit should be attempted.

1. Connect the Prevena™ Dressing tubing to the V.A.C.® Therapy Unit canister tubing:
   - Push the connectors together
   - Twist the connectors to lock

2. Ensure clamp on canister tubing is open.

3. Activate V.A.C.® Therapy at -125mmHg continuous.

Alarm Resolutions
KCI V.A.C.® Therapy Unit alarms should be addressed in a timely manner. Refer to the therapy unit user manual and the Leaks section on page 24 for complete information on alarm resolutions.
Specifications

Storage Conditions
Temperature Range: -4°F (-20°C) to 140°F (60°C)
Relative Humidity Range: 15% - 95%, non-condensing

Operating Conditions
Temperature Range: 41°F (5°C) to 104°F (40°C)
Atmospheric Pressure Range: 1060 hpa (-1253 ft / -381.9 m) (for Optimum Performance) to 700 hpa (9878 ft / 3010 m)

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

The Prevena™ IMS is classified as a Type BF applied part under IEC 60601-1:2005 (3rd Edition).

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

All alerts are classified as low priority according to IEC 60601-1-8:2006.

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 affect 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.

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. The Prevena™ 125 Therapy Unit also meets the standard for electromagnetic compatibility related to use in the home care environment (IEC 60601-1-11:2010).

<table>
<thead>
<tr>
<th>Guidance and manufacturer’s declaration - electromagnetic emissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Emission Test</th>
<th>Compliance</th>
<th>Electromagnetic environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>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.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td>Battery operated device</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations / flicker emissions IEC 61000-3-3</td>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>
**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.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>± 6 kV contact ± 8 kV air</td>
<td>± 6 kV contact ± 8 kV air</td>
<td>In accordance with IEC 60601-1-2: 2007, floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical fast transient / burst</td>
<td>± 2 kV for power supply lines ± 1 kV for input / output lines</td>
<td>Not Applicable</td>
<td>Battery operated device</td>
</tr>
<tr>
<td>Surge</td>
<td>± 1 kV line(s) to line(s) ± 2 kV line(s) to earth</td>
<td>Not Applicable</td>
<td>Battery operated device</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines</td>
<td>&lt;5 % $U_i$, (&gt;95 % dip in $U_i$) for 0.5 cycle 40 % $U_i$, (60 % dip in $U_i$) for 5 cycles 70 % $U_i$, (30 % dip in $U_i$) for 25 cycles &lt;5 % $U_i$, (&gt;95 % dip in $U_i$) for 5 cycles</td>
<td>Not Applicable</td>
<td>Battery operated device</td>
</tr>
<tr>
<td>Power frequency (50Hz / 60Hz) magnetic field</td>
<td>3 A / m</td>
<td>3 A / m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

NOTE: $U_i$ 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 Therapy Unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Prevena™ 125 Therapy Unit as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>Separation distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 80 MHz</td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td>not applicable</td>
<td>$d = \left[ \frac{3.5}{E1} \right] \sqrt{P}$</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>not applicable</td>
</tr>
<tr>
<td>1</td>
<td>not applicable</td>
</tr>
<tr>
<td>10</td>
<td>not applicable</td>
</tr>
<tr>
<td>100</td>
<td>not applicable</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>IEC 61000-4-6</td>
<td>3 Vrms 150 kHz to 80 MHz Not Applicable</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the Prevena™ 125 Therapy Unit, including cables, than the recommended separation distance calculated from the equation application to the frequency of the transmitter.</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>IEC 61000-4-3</td>
<td>3 V / m 80 MHz to 2.5 GHz</td>
<td>Recommended separation distance Battery Operated Device</td>
</tr>
</tbody>
</table>

**Battery Operated Device**

\[
d = \left[ \frac{3.5}{E_1^1} \right] \sqrt{P} \quad \text{80 MHz to 800 MHz}
\]

\[
d = \left[ \frac{7}{E_1^1} \right] \sqrt{P} \quad \text{800 MHz to 2.5 GHz}
\]

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: \(\odot\)

---

**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 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™ 125 Therapy Unit is used exceeds the applicable RF compliance level above, the Prevena™ 125 Therapy 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™ 125 Therapy Unit.

\(^2\) Over the frequency range 150kHz, field strengths should be less than \([V_1]\) V / m.
Symbols Used

Do not use if package is damaged or open

Rx only

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

IP24 Ingress Protection

Consult Instructions for Use

Type BF applied part

Refer to Clinician Guide

STERILE R Sterile using radiation

Single Use Only

Date of Manufacture

Latex Free

Manufacturer

Non Sterile

Fragile

Use By

Keep Dry

Catalog Number

Content Information

Lot Number

DEHP Free

Do Not Resterilize

Temperature Limits

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


Authorized Representative in the European Community

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.kci1.com

KCI USA, Inc. 12930 IH10 West, San Antonio, TX 78249