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
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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. VERAFLÓ™ 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 in the Product Description and Indication for Use section 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 and could result in the failure of the wound to heal.

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 or infection.

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. VERAFLÒ™ 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, remove the dressing 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 ionic 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.

**Pediatric Use:** The PREVENA R ESTOR™ Incision Management System has not been studied in patients under 22 years of age.

**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 (one of several configurations) - 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

C. PREVENA RESTOR AXIO•FORM™ Dressing - available in 29cm x 28cm

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
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. VERA FLO™ 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
   C. PREVENA RESTOR AXIO-FORM™ Dressing - 29cm x 28cm

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.
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.
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.
CORRECTING A LEAK CONDITION

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

See the therapy unit clinician guide for additional information.

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.

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.
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.

SHOWERING AND BATHING
- Light showering with the dressing 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.
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

SPECIFICATIONS
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)
BIBLIOGRAPHY OF PUBLISHED STUDIES


EN - SYMBOLS USED

- Refer to Clinician Guide
- Consult Instructions for Use

- Ingress Protection
- Type BF applied part

- Sterile using radiation
- Lot Number

- Date of Manufacture
- Manufacturer

- No Bathing or Showering
- Use By

- Fragile
- Catalog Number

- Fragile
- Single Use Only

- Keep Dry
- Tripping Hazard

- MR Unsafe
- Class II Device

- Do Not Resterilize
- Temperature Limit

- Content Information
- Single Patient Use Only

- Do not use if package is damaged or open
- Caution

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

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

- Expected Service Life of Device in Days