CLEARCHOICE
THERAPEUTICS

Innovating, Developing and Advancing Care

REF UNBAR1013, UNBAR2013, UNBAR2025,
UNPRE1013, UNPRE2013, UNPRE2025

℞ only

Symbols Glossary

STERILE EO — Sterilization with Ethylene Oxide gas

REF — Catalogue number

Consult instructions for use

LOT — Batch code

Use-by date

Manufactured by
Clear Choice Therapeutics, Inc.
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WARNING

- Bleeding: Some patients have a high risk of bleeding complications (with or without NPWT). Bleeding continues to be the cause of the most serious adverse events reported to the Food and Drug Administration. Bleeding occurs in patients who have blood vessel grafts, wound infection, receiving medication for blood clots, and during removal of dressing attached to the tissues.

  Bleeding contributes to shock, low blood pressure, and swelling containing blood (hematoma) and can lead to additional surgery to stop the bleeding and to blood transfusions.

- Immediately **DISCONTINUE/STOP NPWT** therapy if active bleeding or frank bright red blood is present in the tubing, canister, or for any copious amount of blood noted.
  Do not remove the dressing, but immediately seek medical assistance while taking immediate measure to stop the bleeding.

STORAGE

Store CCT PREVENT Kits in normal warehouse conditions. Keep dry. Avoid excess heat or humidity.

CLEAR CHOICE THERAPEUTICS

NPWT Wound PREVENT™ Kit Instructions

Caution Federal law restricts this device to sale by or on the order of a physician. See instructions for use.

INDICATIONS FOR USE

The PREVENT™ Kit is intended to be used as an alternative to foam and other negative pressure wound therapy fillers when used in conjunction with the CCT1 and CCT Mini Negative Pressure Wound Drainage Pumps (K082311) for the application of negative pressure wound therapy to the wound. When used in conjunction with the CCT1 or CCT Mini Negative Pressure Wound Drainage Pumps, the PREVENT Kit is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by removal of excess exudate, infectious material and tissue debris.

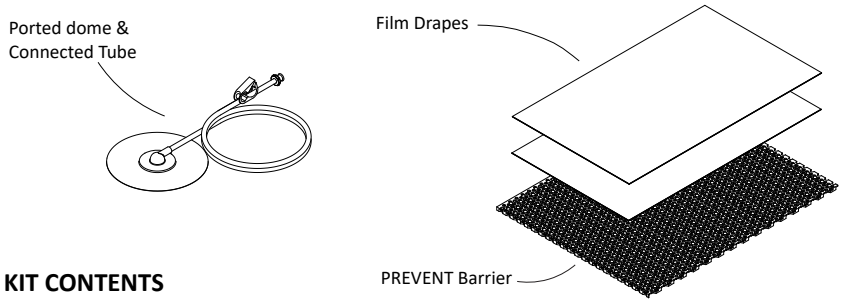
The PREVENT Kit is appropriate for use on the following wounds:

- Pressure Ulcers
- Diabetic/Neuropathic Ulcers
- Venous Insufficiency Ulcers
- Traumatic Wounds
- Post-Operative and Dehisced Surgical Wounds
- Skin Flap and Grafts

The system is for prescription use only.

PRODUCT DESCRIPTION

The NPWT PREVENT Kit is used with the CCT1 and CCT Mini Negative Pressure Wound Drainage Pumps for negative pressure wound therapy (NPWT). NPWT uses a closed drainage system to apply controlled suction (vacuum) to a wound bed. Instead of foam or other wound filler the wound is filled with a SINGLE LAYER of a NPWT PREVENT barrier dressing which acts like a wound filler to allow pressure to be distributed evenly to the wound bed. The wound is then sealed with an adhesive film drape. A dome drainage tube is connected to the dressing through an opening of the film drape. The drainage tube is connected to a canister on the side of the vacuum pump. The vacuum may be applied continuously or intermittently, depending on the type of wound being treated and the clinical objectives.



KIT CONTENTS

REF	Drapes[1]	Dome assembly[2]	PREVENT Barrier
UNPRE2025	QTY 2	QTY 1	QTY 1, 20 cm x 25 cm
UNBAR2025	None	None	QTY 1, 20 cm x 25 cm
UNPRE2013	QTY 2	QTY 1	QTY 1, 20 cm x 12.5 cm
UNBAR2013	None	None	QTY 1, 20 cm x 12.5 cm
UNPRE1013	QTY 1	QTY 1	QTY 1, 10 cm x 12.5 cm
UNBAR1013	None	None	QTY 1, 10 cm x 12.5 cm

[1]10x12 in. transparent film drapes.
[2]Consists of ported dome with skirt, and connecting tubing including clamp and luer lock connection.
The CCT1 and CCT Mini Negative Pressure Wound Drainage Pumps are not included in the PREVENT Kits. Please refer to the CCT1 and CCT Mini Negative Pressure Wound Drainage Pumps User's Manual and follow the recommendations for use.

LBL 11809-370-04 Rev06

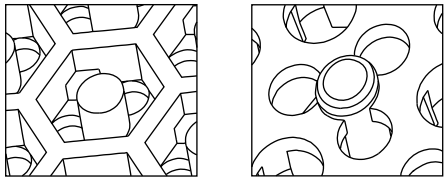
INSTRUCTIONS FOR USE

Before use, inspect the NPWT PREVENT Kit for completeness and verify physician's orders and read instructions. Follow institution's protocol, policy, and procedures. Always assess that the wound is appropriate for NPWT at the start of therapy and with each dressing change.

STEP 1: Debride any necrotic tissue and cleanse the wound and peri-wound area according to the institution guidelines and physician's orders.

Step 2 : Cut the PREVENT barrier to the shape of the wound and place a SINGLE LAYER of the PREVENT barrier inside the wound (always cut the PREVENT barrier away from the wound to prevent any unwanted debris from falling into the wound bed). Ensure that the barrier is honeycomb side up with flat side down toward the wound bed. Refer to diagram on package label.

IMPORTANT: Use a SINGLE LAYER of the PREVENT barrier to fill wound bed. Do not place pieces of barrier in tunneled or undermined areas. (Use standard clinical practices for tunneled or undermined areas).



HONEYCOMB SIDE UP **FLAT SIDE DOWN**

Step 3: Size and trim the transparent drape to cover the PREVENT barrier.

Step 4: Peel off tab #1 first. Gently press down the exposed adhesive to the skin.

Peel off tab #2 and gently press the drape around the peri-wound. Apply gentle pressure inside the drape and work outside the area.

Make sure to form a proper seal before peeling off tab #3.

Step 5: Gently lift the drape with your thumb and forefinger and cut a 2 cm round hole in the drape.

Important - Do not cut a slit in the drape. When NPWT is applied the slit may collapse and block the pressure.

Step 6: Make sure to properly align the Dome Pad opening to the cut hole on the drape. After properly aligning the holes, peel off the bottom liner and attach the dome pad to the drape.

Once finished, peel off the top liner and the side tabs.

Step 7: Make sure to pat around the dome pad to ensure the dome is securely placed on the wound. Connect the tube end of the dome pad to the tube end of the canister by firmly twisting the two connectors together before starting the NPWT pump.

Step 8: Count and document all pieces of barrier, gauze, or adjunctive materials on the outer dressing in the medical record, to help prevent retention of materials in the wound.

DRESSING CHANGE

- Follow hospital protocol, policy, and procedure for using NPWT dressings and pumps.
- With a heavily colonized or infected wound, consider changing the dressing every 12 to 24 hours. Regular monitoring of the wound must be maintained to check for signs of infection.
- The clamp is designed for on/off control of fluid or air. The purpose of the clamp is to close the dressing tubing to reduce the risk of contamination during dressing changes and bathing.
- Monitor the patient frequently for signs and symptoms of complications.
- Moisten and irrigate wound with normal saline if dressing is adhered to wound bed, before removing it.
- Disposal of the NPWT dressing, dome tubing, drape and canister should follow facility protocols or local ordinances relating to the handling of potentially infected bio-hazardous materials.

CONTRAINDICATIONS

The following contraindications identify the types of wounds for which NPWT are contraindicated:

- Necrotic tissue with eschar present
- Untreated osteomyelitis
- Non-enteric and unexplored fistulas
- Malignancy in the wound
- Exposed vasculature
- Exposed nerves
- Exposed anastomotic site
- Exposed bone or tendons
- Not for use on children

PRECAUTIONS

Physician should be alerted before beginning treatment if the patient has one of the following precautions:

- To reduce the risk of transmission of bloodborne pathogens, apply standard precautions for infection control with all patients, per institutional protocol, regardless of their diagnosis or presumed infection status. In addition to gloves, use gown and goggles if exposure to body fluid is likely.
- Do not use on children
- Do not use if individual pouch is damaged/opened
- Do not re-use
- Do not re-sterilize

PATIENT RISK FACTOR/CHARACTERISTICS TO CONSIDER BEFORE NPWT USE

- Patients at high risk for bleeding and hemorrhage
- Patients on anticoagulants or platelet aggregation inhibitors
- Patients with:
  - Friable vessels and infected blood vessels
  - Vascular anastomosis
  - Infected wounds
  - Osteomyelitis
  - Exposed organs, vessels, nerves, tendons, and ligaments
  - Sharp edges in the wound (i.e. bone fragments)
  - Spinal cord injury (stimulation of sympathetic nervous system)
  - Enteric fistulas
- Dressing material may interfere with MRI, defibrillation, and hyperbaric chamber use
- Patient size and weight
- Use near vagus nerve (bradycardia)
- Circumferential dressing application
- Mode of therapy - intermittent versus continuous negative pressure