CLEARCHOICE THERAPEUTICS

Innovating, Developing and Advancing Care

REF WCL2025, WCL2013, WCL1013

℞ 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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www.clearchoicetherapeutics.com

WARNINGS

- Bleeding: Some patients have a high risk of bleeding complications. 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 use if active bleeding or frank bright blood is present, or for any copious amount of blood noted. Do not remove the barrier, but immediately seek medical assistance while taking immediate measure to stop bleeding.

STORAGE

Store PREVENT Barrier Wound Contact Layer in normal warehouse conditions. Keep dry. Avoid excess heat or humidity.

POUCH CONTENTS

(1) PREVENT Barrier provided sterile (EO) and latex-free.

NOTE: The following warnings, contraindications, and precautions are specific to use of the PREVENT Barrier as a wound contact layer. If the PREVENT Barrier is to be used with negative pressure wound therapy (NPWT), please refer to the Instructions for Use (IFU) for the NPWT system that you are going to use for that therapy, as there will be additional warnings, contraindications, and precautions that must be addressed before use.

CLEAR CHOICE THERAPEUTICS

PREVENT™ Barrier Wound Contact Layer Instructions for Use

INDICATIONS FOR USE

The PREVENT™ Barrier is a non-adhering, TPE-based barrier designed as a primary wound contact layer for use in the management of pressure ulcers, diabetic and neuropathic ulcers, venous insufficiency ulcers, traumatic wounds, post-operative and dehisced surgical wounds, skin flaps, and grafts.

The device is for prescription use only by trained healthcare practitioners.

PRODUCT DESCRIPTION

The PREVENT Barrier is a transparent, flexible wound contact layer designed to allow visibility to the wound bed. Each side of the device has a unique geometry to provide a comfortable, non-adherent layer that may help reduce adhesion (tissue in-growth). The product is available in 3 sizes to accommodate all wound sizes, and the device may be cut to best fit the wound.

CONTRAINDICATIONS

The following contraindications identify the types of wounds for which the PREVENT Barrier may be contraindicated. Physicians should be alerted before use if the patient has one of the following contraindications:

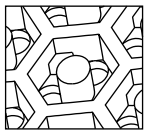
- Necrotic tissue with eschar present
- Untreated osteomyelitis
- Non-enteric and unexplored fistulas
- Malignancy in the wound
- Exposed vasculature
- Exposed nerves
- Exposed anastomotic site
- Exposed bone or tendons
- Not for use on children

PRECAUTIONS

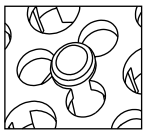
- To reduce risk of transmission of bloodborne pathogens, apply standard precautions for infection control with all patients, per institutional protocol, regardless of their diagnosis or presumed infection status. In addition to gloves, use gown and goggles if exposure to body fluid is likely.
- Do not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

INSTRUCTIONS FOR USE

Verify physician's orders and read all instructions.



HONEYCOMB SIDE UP



FLAT SIDE DOWN

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 the 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 above.

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

- Follow hospital protocol, policy, and procedure for wound treatment.
- With a heavily colonized or infected wound, consider changing the barrier every 12 to 24 hours. Regular monitoring of the wound must be maintained to check for signs of infection.
- Monitor the patient frequently for signs and symptoms of complications.
- Moisten and irrigate wound with normal saline if the barrier is adhered to wound bed before removing it.
- Disposal of the PREVENT Barrier should follow facility protocols or local ordinances relating to the handling of potentially infected bio-hazardous materials.

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