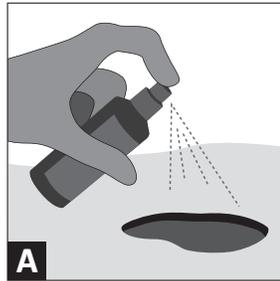
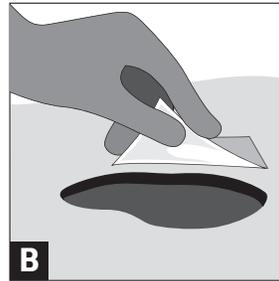


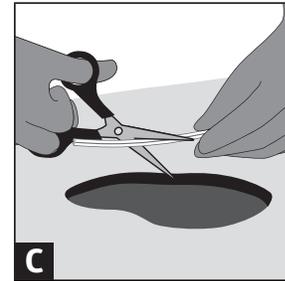
THE *NewEra™* DRAIN KIT



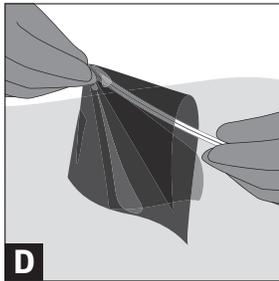
A Cleanse the wound with PhaseOne™ wound cleanser.



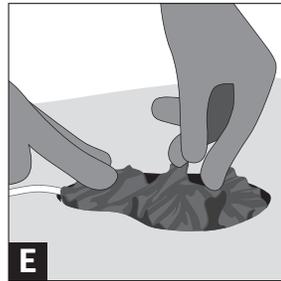
B Apply SkinTac™ to the peri-wound area.



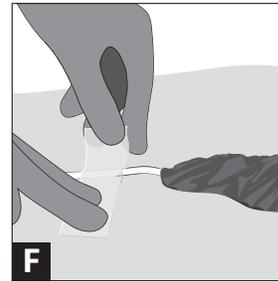
C Cut the round drain to a length appropriate for the wound.



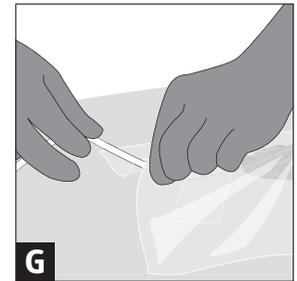
D Loosely wrap drain with Cutimed® Sorbact®



E Fluff and fill™ any additional space in the wound.



F Apply gel strips to secure drain tube in place.



G Cover with a drape. Follow instructions on the drape.

STEP 1 ▶ Inspect the integrity of the packaging and the contents within the NewEra™ Drain Kit.

STEP 2 ▶ **[A]** Prepare and cleanse the wound with PhaseOne™ according to facility protocol or physician orders. This includes measuring the wound size for documentation.

STEP 3 ▶ **[B]** Prepare the peri-wound area with a skin barrier. Apply to a 2-inch surrounding surface area (peri-wound). Allow skin barrier to dry. SkinTac™ is included in the kit.

STEP 4 ▶ **[C]** If required, cut flat/round drain to fit wound dimensions. Cut the drain approximately 1 inch shorter than the base or sides of the wound site.

STEP 5 ▶ **[D]** Remove the Cutimed® Sorbact® dressing from the NewEra Drain Kit. Loosely wrap the drain with Cutimed Sorbact and place in the wound bed. If necessary, use scissors to cut or trim the Cutimed

Sorbact to the correct size and shape of the wound. Do not cut the Cutimed Sorbact over the wound bed. Before placing the dressing in the wound bed, remove any loose particles that may be present on the dressing. If more than one piece is used, document the number of pieces of Cutimed Sorbact that were placed in the wound.

STEP 6 ▶ **[E]** Loosely fluff and fill any extra space with Cutimed Sorbact. Do not over-pack the wound.

STEP 7 ▶ **[F]** To ultimately prevent dressing leaks, secure the drain using a piece of gel strip beneath and on top of drain.

STEP 8 ▶ Remove the clear drape from the NewEra Drain Kit. Cut the drape to the size and shape that is needed to cover the wound and a 2-inch surrounding surface area (peri-wound).

STEP 9 ▶ **[G]** Apply the clear drape over the wound and Cutimed Sorbact dressing by

using the numbered tabs. Begin by removing the tab labeled with the number “1”. Secure the drape over the Cutimed Sorbact dressing and wound area by pressing firmly. You may then remove the tab labeled with the number “2”. Do this while pressing and holding the drape in place. Once the drape is in place, you may remove the upper tab labeled with the number “3”. Remove the side tabs by pressing and holding the clear drape in place and pulling the side tab. Remove adhesive cover and secure the dome to the drape.

STEP 10 ▶ Pinch the drape under the drain. Use gel strips or tape to secure drain tubing to prevent dislodging or entanglement.

Check for leaks. Begin therapy, according to physician’s orders for the NPWT settings, by powering on the pump. Proceed according to the pump manual to adjust settings.

Follow facility policy or physician’s orders for frequency of dressing changes.

THE *NewEra*[™] DRAIN KIT

INDICATIONS

The NewEra Drain Kit is indicated for patients who would benefit from the application of negative pressure to the area of a wound to promote wound healing by the drainage of fluids and infected materials from the wound and wound bed. The system is intended for acute, institutional, and long-term care use and only when prescribed by a physician. Product may be indicated for patient home-care, when carefully monitored by licensed home health-care providers, and only when prescribed by a physician.

CONTRAINDICATIONS

Negative Pressure Wound Therapy is contraindicated for the following reasons for wound treatment:

- ▶ Non-enteric and unexplored fistulas
- ▶ Exposed anastomotic site
- ▶ Presence of necrotic tissue
- ▶ Malignancy (except for quality of life reason for terminal patients)
- ▶ Untreated osteomyelitis
- ▶ Untreated malnutrition
- ▶ Use on exposed arteries, veins, or organs

WARNINGS

- ▶ Consult the Instructions for Use, indications for use, precautions, and contraindications for the Negative Pressure Wound Therapy device.
- ▶ To prevent unintentional gauze retention, all dressings are removed from the wound and wound bed.
- ▶ Upon removal of dressing(s), the wound bed should be cleaned in accordance with standard wound care practices, prior to the ap-

plication of new sterile dressing.

- ▶ If necessary, all wounds should be debrided prior to application of the therapy and/or dressings.
- ▶ Ensure there are no pockets left in the wound bed after application of the dressing.
- ▶ Infected wounds may need more frequent dressing changes, up to twice a day, and the patient and the wound must be inspected regularly for signs of increased infection or sepsis.
- ▶ Patients who do not have adequate hemostasis, and on whom anticoagulation or platelet aggregation inhibitors are being used, have an increased risk of bleeding with or without the NewEra Drain Kit.
- ▶ All arteries, veins, tendons, ligaments, nerves, and other organs have to be covered completely prior to application of the NewEra Drain Kit.
- ▶ Infected tissue, such as blood vessels, may have a weakened structure and have to be treated with care.
- ▶ Infected blood vessels may bleed more readily than normal blood vessels

PRECAUTIONS

- ▶ Patients on anticoagulants or with difficult hemostasis should be treated with caution and have to be controlled regularly for bleeding.
- ▶ Patients with infections in the wound and/or other parts of the body have to receive proper systemic treatment.
- ▶ Non-compliant patients
- ▶ The NewEra Drain Kit has not been studied on pediatric patients.



Integrated Healing Technologies