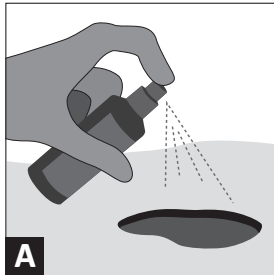
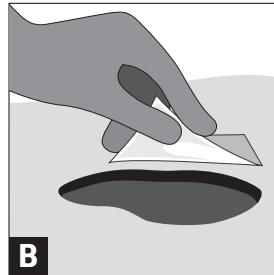


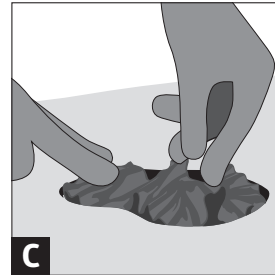
THE NewEra® DOME KIT



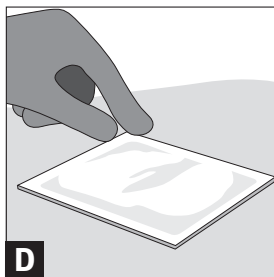
A
Cleanse the wound with PhaseOne™ wound cleanser.



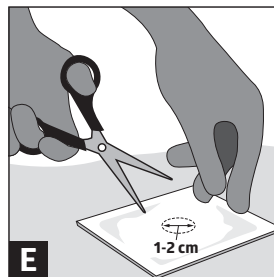
B
Apply SkinTac™ to the peri-wound area.



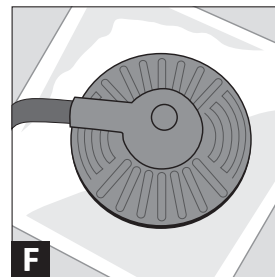
C
Fluff and fill™ the wound with Cutimed® Sorbact® appropriately.



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



E
Pinch the drape and cut a 1-2 cm circular hole in it.



F
Remove adhesive cover and secure the dome to the drape.

STEP 1 ▶ Inspect the integrity of the packaging and the contents within the NewEra® Dome Kit.

STEP 2 ▶ **[A]** Open the bottle of PhaseOne™ by twisting the lid to break the perforation. DO NOT remove the shrink-wrap around the bottle—it is there in case the bottle breaks. PhaseOne may be poured or sprayed. 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. This is done to clean the skin and remove skin oils in order to achieve better adhesion with the IHT Drape. Apply to a 2-inch surrounding surface area (peri-wound). Allow skin barrier to dry. SkinTac™ is included in the kit.

STEP 4 ▶ **[C]** Remove the Cutimed® Sorbact® dressing from the NewEra Dome Kit. Fluff the dressing to (loosely) fill the wound cavity. Do not overpack the wound. 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.

STEP 5 ▶ Place Cutimed Sorbact dressing in the wound bed. If more than one piece is used, document the number of pieces of Cutimed Sorbact that were placed in the wound.

STEP 6 ▶ Remove the clear drape from the NewEra Dome 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 7 ▶ **[D]** 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.

STEP 8 ▶ **[E]** Pinch the drape over the Cutimed Sorbact dressing and cut a round hole to expose the Cutimed Sorbact. The hole should be about 1-2 cm in diameter.

STEP 9 ▶ Remove the IHT Dome from the NewEra Dome Kit. Peel the dome skirt backing from the IHT Dome. This backing is labeled with the words “Peel Off”.

STEP 10 ▶ **[F]** Place the IHT Dome over the hole that was cut over the Cutimed Sorbact dressing. Press firmly and secure the IHT Dome in place. Remove the side tabs by pressing and holding the IHT Dome in place and pulling the side tabs. Press the dressing down to ensure a proper seal.

Check for leaks. Consult NewEra I or II pump instructions and labeling before use and as appropriate. 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.

COMPONENT MATERIALS: IHT Dome—Thermoplastic Elastomer; IHT Drape—Polyurethane film; PhaseOne—0.025% Hypochlorous acid in Saline; Cutimed Sorbact—Acetate mesh with DACC coating; SkinTac—Isopropyl Alcohol, Rosin; Ruler—Paper

THE *NewEra*[®] DOME KIT

INDICATIONS

The NewEra Dome Kit is intended to be used with the NewEra I and II pumps. The system is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formations and perfusion, and by removing exudate and infectious material.

NPWT is appropriate for use on the following wounds:

- ▶ Pressure Ulcers
- ▶ Diabetic/neuropathic ulcers
- ▶ Venous insufficiency ulcers
- ▶ Chronic, Acute, Traumatic, and Subacute wounds
- ▶ Post-operative and dehisced surgical wounds
- ▶ Explored fistulas
- ▶ Skin flaps and grafts

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 application 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 Dome Kit.
- ▶ If active bleeding develops suddenly or in large amounts during therapy, or if frank (bright red) blood is seen in the tubing or in the canister, immediately stop therapy, leave dressing in place, take measures to stop the bleeding and seek im-

mediate medical assistance. The NewEra I/II and NewEra Dome Kit dressings should not be used to prevent, minimize or stop vascular bleeding.

- ▶ **Sharp Edges:** Bone fragments or sharp edges could puncture protective barriers, vessels, or organs, causing injury. Any injury could cause bleeding, which, if uncontrolled, could be potentially fatal. Beware of possible shifting in the relative position of tissues, vessels or organs within the wound that might increase the possibility of contact with sharp edges. Sharp edges or bone fragments must be covered or eliminated from the wound area to prevent them from puncturing blood vessels or organs before the application of NPWT. Where possible, completely smooth and cover any residual edges to decrease the risk of serious or fatal injury, should shifting of structures occur. Use caution when removing dressing components from the wound so that wound tissue is not damaged by unprotected sharp edges.
- ▶ Do not use an excessive amount of Cutimed Sorbact, force Cutimed Sorbact into any area of the wound, or pack too tightly the Cutimed Sorbact, as this may damage tissue, alter the delivery of negative pressure or hinder exudate and Cutimed Sorbact removal. Be sure to document the number of pieces of Cutimed Sorbact placed in the wound.
- ▶ If any signs of allergic reaction or hypersensitivity develop, such as redness, swelling, rash, urticaria or significant pruritus, discontinue use and consult a physician immediately.
- ▶ The NewEra Dome Kit should not be used by anyone not professionally trained in the use of NPWT devices.
- ▶ All arteries, veins, tendons, ligaments, nerves, and other organs have to be covered completely prior to application of the NewEra Dome 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.
- ▶ If Cutimed Sorbact adheres to wound, or in the case of tissue ingrowth, consider introducing sterile water or normal saline into the gauze, waiting 15–30 minutes, then gently removing the Cutimed Sorbact from the wound. Regardless of treatment modality, disruption of the new granulation tissue during any dressing change may result in bleeding at the wound site. Minor bleeding may be observed and considered expected. However, patients with increased risk of bleeding, as described before, have a potential for more serious bleeding from the wound site. If significant bleeding develops, immediately discontinue the

use of NPWT, take measures to stop the bleeding and do not remove the NewEra Dome Kit until the treating physician or surgeon is consulted. Do not resume the use of NPWT until adequate hemostasis has been achieved, and the patient is not at risk for continued 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 Dome Kit has not been studied on pediatric patients.
- ▶ Always use NewEra Dome Kit Components from sterile packages that have not been opened or damaged.
- ▶ Disconnecting the NewEra Dome Kit from the pump:

In the event that the patient needs to be disconnected from the pump (eg, rehabilitation, ambulation, etc) and exudate is controlled, follow the steps below:

- ◆ Close the clamp on the IHT Dome
- ◆ Separate the canister tubing from the IHT Dome by disconnecting them at the connector
- ◆ Allow the pump to pull the exudate in the canister tubing into the canister and then close the clamp on the canister tubing.
- ◆ Switch the vacuum off on the pump (see pump instructions for any questions regarding use).
- ▶ Dressing Changes:
 - ◆ Gently stretch the IHT drape horizontally and slowly remove from the skin. Do not peel.
 - ◆ Gently remove the Cutimed Sorbact from the wound.
 - ◆ Consider simultaneous saline irrigation if required.
 - ◆ Discard disposables in accordance with local guidelines.
- ▶ Wounds treated with the NewEra Dome Kit should be monitored on a regular basis by your doctor or nurse who is responsible for treatment.
- ▶ For a non-infected wound: IHT recommends the NewEra Dome Kit be changed every 48 to 72 hours, but no less than 3 times per week.
- ▶ For infected wounds: These wounds must be monitored often and very closely. Infected wounds dressing changes may need to be changed more often than 48 to 72 hours. Dressing change intervals should be based on continuing evaluation of your wound condition by your doctor or nurse.

NEWERA DOME KIT COMPLIANCE

Patient compliance with the NewEra Dome Kit is important for proper healing. Your doctor will determine the negative pressure therapy for you. Please do not remove the dressing unless told to do so by your doctor or nurse.



Integrated Healing Technologies