Wound Healing Technologies

extriCARE® 3600 Negative Pressure Wound Therapy (NPWT) System

Indications for Use

The **extriCARE® 3600 Negative Pressure Wound Therapy Pump Systems** are indicated for wound management via the application of negative pressure to the wound by removal of wound exudate, infectious materials, and tissue debris from the wound bed. The **extriCARE® 3600 Negative Pressure Wound Therapy Pump Systems** is indicated for the following wound types: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

CAUTION: In the USA, Federal Law restricts this device to sale, by or on the order of a physician.

Contraindications for Use

The **extriCARE® NPWT Systems** should **NOT** be used in the following conditions:

- Exposed vessels, organs, or nerves.
- Anastomotic sites.
- Exposed arteries or veins in a wound. All exposed vessels and organs in and around the wound must be completely covered prior to initiation of NPWT. **Note:** A thick layer of natural tissue is preferred. Several layers of fine meshed non-adherent material or bio-engineered tissue may be an alternative. Ensure that protective materials will maintain their position throughout therapy.
- Fistulas, unexplored or non-enteric.
- Untreated osteomyelitis.
- Malignancy in the wound.
- Excess amount of necrotic tissue with eschar.
- Wounds which are too large or too deep to be accommodated by the dressing.
- Inability to be followed by a medical professional or to keep scheduled appointments.
- Allergy to urethane dressings and adhesives.
- Use of topical products which must be applied more frequently than the dressing change schedule allows.

Prior to Therapy

- Patient should be assessed and measures should be taken to optimize and stabilize their medical condition. Nutrition, medication, blood glucose, blood pressure, and circulation as well as other medical issues should be addressed.
- The wound should be recently debrided by whatever measure is appropriate and the amount of necrotic tissue should be minimized.
- Issues of infection should be addressed.

Periwound Skin

- Ensure that the skin that will be under the dressing is clean, dry, free of surfactants and oil. Any hair should be clipped.
- The periwound area should be cleaned and allowed to dry. The use of a skin preparation wipe is also recommended.
- A thin film dressing or hydrocolloid may be used as additional protection.
- Monitor skin for signs of irritation or breakdown. Treatment may be discontinued if this occurs and cannot be managed.

Warnings

- Review the user manual prior to using the **extriCARE® 2400 or 3600 Negative Pressure Wound Therapy Pump Systems**.
- Do not use the **extriCARE® Negative Pressure Wound Therapy Pump** around explosive or flammable material. Do not use the pump in an MRI environment or hyperbaric chamber. Disconnect prior to defibrillation.
- This pump should be used only under the direction of a trained professional, such as a doctor or nurse.
- The 400cc canister should only be used in a facility where drainage can be closely monitored. This is due to the increased risk of injury due to bleeding and excess drainage.
- Negative Pressure Wound Therapy has not been cleared for use on children.
- Use a properly rated charger to charge the lithium battery. Incorrect voltage and/or current can cause fire.
- Do not place this pump at temperatures greater than 170°F for more than 2 hours, as it may cause a battery fire.
- If battery swells, gets hot, or smokes while charging, disconnect the charger immediately. This may cause the battery to leak, and the reaction with air may cause the chemicals to ignite, resulting in fire.

Dressing Management

Clean and debride the wound as necessary. Any bleeding should be controlled. Follow facility protocol for wound prep and infection control. The type of **extriCARE®** wound dressings chosen for use is dependent on the wound type, size, and location. **extriCARE®** wound dressings size and type is labeled on each package.

The **extriCARE®** one piece dressing is an all inclusive dressing. In the event that this dressing comes apart, all **extriCARE®** wound dressing materials must be removed from the wound prior to further treatment.

If a foam dressing is chosen, use pieces of foam large enough for easy removal. The total numbers of foam pieces must be documented on dressing label. All materials must be removed with each dressing change.

- Care should be taken to avoid stretching of the dressing.
- Minimize pleating the **extriCARE®** wound dressings. Additional tape and urethane may be applied to secure the **extriCARE®** dressing in place.
- Do not use as a circumferential dressing.
- Additional wrap dressing may be applied over the **extriCARE®** wound dressings to further secure the **extriCARE®** wound dressings and provide additional support.
- If used on anatomically challenging areas or where adhesion is a problem, a thin layer of ostomy paste may be applied. Refer to instructions for specific information regarding each **extriCARE®** wound dressings.

Precautions

Be aware for any of the following conditions:

There are additional conditions to take into account before using **Negative Pressure Wound Therapy**, such as:

1. **BLEEDING:** There is a risk of bleeding/hemorrhaging with negative pressure wound therapy. If hemostasis cannot be achieved, if the patient is on anticoagulants or platelet aggregation factors, or if the patient has friable blood vessels or infected vascular anastomosis, he or she may have an increased risk of bleeding; accordingly these patients should be treated in an inpatient care facility per their treating physician. If active bleeding develops suddenly or in large amounts during therapy, immediately disconnect the pump, leave the **extriCARE**® wound dressings in place, and take measures to stop bleeding. Seek medical attention immediately.

2. **VESSEL AND BONE PROTECTION:** Precautionary measures should be taken if any bones, vessels, ligaments or tendons are exposed. Additionally, sharp edges (due to bone fragments) require special attention; these areas should be covered and smoothed wherever possible. These conditions should be factored into the therapy prescription as the attending clinician sees fit.

3. **ENVIRONMENT:**

a. Defibrillation: Remove the **extriCARE**® dressing if defibrillation is required in the area of dressing placement. Failure to remove the **extriCARE**® wound dressings may inhibit transmission of electrical energy and/or patient resuscitation.

b. Magnetic Resonance Imaging (MRI): The **extriCARE**® pump is unsafe in the MR environment. Do not take the **extriCARE**® pump into the MR environment. **extriCARE**® dressings however can typically stay on the patient with minimal risk in an MR environment, assuming that the use of the **extriCARE® Negative Pressure Wound Therapy System** is not interrupted for more than two hours.

c. Hyperbaric Oxygen Therapy (HBO): Do not take the **extriCARE**® pump into a hyperbaric oxygen chamber. **extriCARE**® pumps are not designed for this environment, and should be considered a fire hazard in such an environment. After disconnecting the **extriCARE**® pump, either (i) replace the **extriCARE**® dressing with another HBO compatible material during the hyperbaric treatment, or (ii) cover the unclamped end of the **extriCARE**® tubing. For HBO therapy, the **extriCARE**® tubing must not be clamped. Never leave an **extriCARE**® dressing in place without active **extriCARE® Negative Pressure Wound Therapy** for more than two hours.

Precautions

Be aware for any of the following conditions:

4. **INFECTION:** Infected wounds and osteomyelitis pose significant risks for **Negative Pressure Wound Therapy**. If untreated osteomyelitis is present, therapy should not be initiated. **Negative Pressure Wound Therapy** should not be used to treat infections, and all infections should be treated and addressed prior to using the **extriCARE® Negative Pressure Wound Therapy System**.

5. **PATIENT SIZE AND WEIGHT:** Patient size and weight should be taken into account when prescribing therapy. In addition, small adults, young adults or elderly patients should be closely monitored.

6. **SPINAL CORD INJURY:** If a patient experiences autonomic dysreflexia (sudden changes in blood pressure or heart rate because of sympathetic nervous system stimulation) discontinue **extriCARE®** therapy to minimize sensory stimulation and give immediate medical assistance.

7. **MODE:** In unstable anatomical structures, continuous rather than intermittent therapy is recommended to help minimize movement and instability. Continuous therapy is also recommended in patients with an increased bleeding risk, profusely exudating wounds, fresh grafts and/or flaps, and wounds with acute enteric fistulae.

8. **ENTERIC FISTULAS:** Wounds with enteric fistulas require special consideration to be effective in negative pressure wound therapy. If enteric fistula effluent management or containment is the only goal of such therapy, **extriCARE®** is not recommended.

9. **CIRCUMFERENTIAL DRESSING:** Do not use circumferential dressings.

10. **BRADYCARDIA:** Avoid placement of the **extriCARE® 2400 Negative Pressure Wound Therapy Dressings** next to the vagus nerve to minimize the risk of bradycardia.

NOTE: If any of this information is not understood, contact the manufacturer before using the device.