extriCARE®

extriCARE® NPWT Foam Kit Instruction for Use

DEVON MEDICAL

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EC REP

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CE 0123

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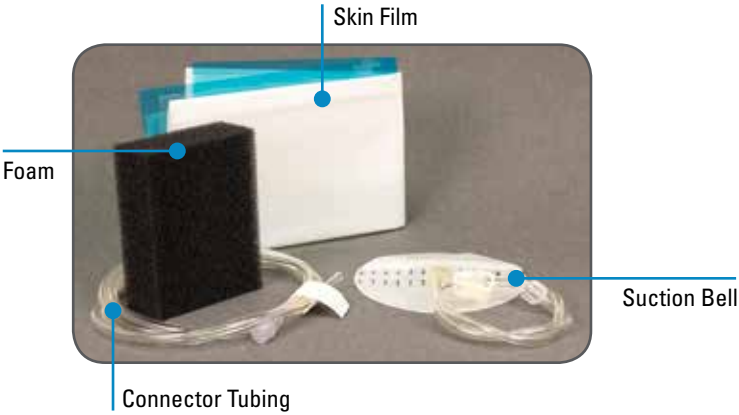
Symbols

	Warning/Caution: See instructions for use
	Single Use Only
	Date Of Manufacture
	Use By
	Keep Dry
STERILE EO	Sterilized Using Ethylene Oxide
	Prescription Use Only
LOT	Manufacture Lot Number
EC REP	Authorized Representative in the European Community
	Manufacturer
CE 0123	Conforms with the Medical Device Directive (93/42/EEC) and has been subject to the conformity procedures laid down in the council directive



Instructions for Use - Dressing Application:

1. Clean wound bed (according to facility protocol) with alcohol free prep and assess wound size & type.
2. Apply skin sealant to the area surrounding the wound bed.

   To enhance the sealing, skin sealant such as hydrogel or hydrocolloid strips may be applied contiguously around the wound bed prior to application of the skin film cover.
3. Cut the foam to wound size & shape.

   Cut Foam away from wound to prevent debris from falling into the wound bed.
4. Place the foam in the wound bed.

   Be careful not to over pack the wound bed.

   Record the date and number of foam pieces used on the chart on the ruler. The chart can be later peeled off and stick to the skin film over the body after the application is completed.

DATE	# of pieces used

5. Trim Skin Film to cover area of wound bed with an extra circumference of at least 5cm.

   Peel back one side of Layer 1 & place adhesive side over foam. Remove the remaining side of Layer 1 along with Layer 2 and the blue handling tab(s).
6. Once applied, pinch the Skin Film over the foam and cut a hole the size of a quarter at the desired location of the suction bell.
7. Remove the backing layers from the suction bell skirt & place the suction bell opening directly over the hole in the Skin Film with tubing at the desired angle.
8. Connect the suction bell tubing to the canister tubing.
9. Set the **extriCARE® NPWT System** to the physician prescribed therapy settings and initiate therapy.

Instructions for Use - Dressing Removal

1. With the **extriCARE® pump** still running, disconnect the tubing at the luer lock. Once the tubing is clear of fluid,turn off the **extriCARE® pump**. If necessary, pre-medicate the patient for pain.

2. Gently remove the Skin Film from the patient.

3. Gently remove the foam from the wound. Make sure to count the number of pieces removed from the wound, as it should match the number documented on application. This is to ensure no foam is left behind in the wound.

Note: Foam adherence to the wound may increase over time due to tissue ingrowth into the foam. Removal can be difficult and cause pain. If necessary, infuse foam with normal saline or sterile water and allow to sit for 15-30 minutes prior to removal.

4. Discard of Skin Film and Foam according to policy. All components are disposable. The reuse of any dressing components can result in increased growth of microbes and could lead to infection, delayed healing, and other problems detrimental to the patient and the wound.

5. If the dressing is left in place greater than 2 hours without connection to negative pressure, remove the dressing and cleanse the wound as directed. Replace with new foam dressing or alternative dressing.

Note: Any dressing change can disrupt fragile blood vessels, so minor bleeding is common. If patient develops significant bleeding at the wound site, leave dressing in place, turn off the extriCARE® system, and seek medical care immediately.

PLEASE NOTE:

The **extriCARE® Foam Kit** is intended for single use only. Do not use the **extriCARE® Foam Kit** if the packaging is opened or damaged as sterility may be compromised.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Intended Use

The extriCARE® Negative Pressure Wound Therapy Foam Kit is intended to be used in conjunction with Devon Medical, Inc. **extriCARE® Negative Pressure Wound Therapy (NPWT) Systems,** adding to the original integrated bandage. NPWT is intended to generate negative pressure or suction to remove wound exudates, infectious material, and tissue debris from the wound bed which may promote would healing.

Examples of appropriate wound types include: chronic, acute, traumatic, sub-acute and dehisced wounds, ulcers (pressure ulcer, diabetic ulcers, or venous insufficiency ulcers), partial-thickness burns, flaps and grafts.

Product Description

The **extriCARE® Negative Pressure Wound Therapy Foam Kit** consists of block foam, skin film, drainage tubing set, and a paper ruler. The foam kit is available in the following sizes:

Foam Kit Type	Model Number	Foam Size
Small	EC-Foam-S	10cm x 7.5cm x 3cm
Medium	EC-Foam-M	18cm x 12.5cm x 3cm
Large	EC-Foam-L	25cm x 16cm x 3cm

Contraindications

The extriCARE® Negative Pressure Wound therapy Foam Kit 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. The system may be used after excision of malignancy if all margins are clear.
- Wounds containing necrotic tissue with eschar present.
- 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.

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® device** is unsafe in the MR environment. Do not take the **extriCARE® device** 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® device** into a hyperbaric oxygen chamber. **extriCARE® devices** are not designed for this environment, and should be considered a fire hazard in such an environment. After disconnecting the **extriCARE® device**, 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.

4. **INFECTION:** Infected wounds and osteomyelitis pose significant risks for **Negative Pressure Wound Therapy.** If untreated osteomyelitis is present, therapy should not be initiated. If the wound is infected, it should be closely monitored and dressings should be change frequently. Additionally, to reduce the risk of transmission of infectious agents, standard precautions should be taken when handling or working with therapeutic parts or equipment.

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.