extriCARE®

extriCARE® NPWT Foam Kit

Instruction for Use

ALLEVA MEDICAL

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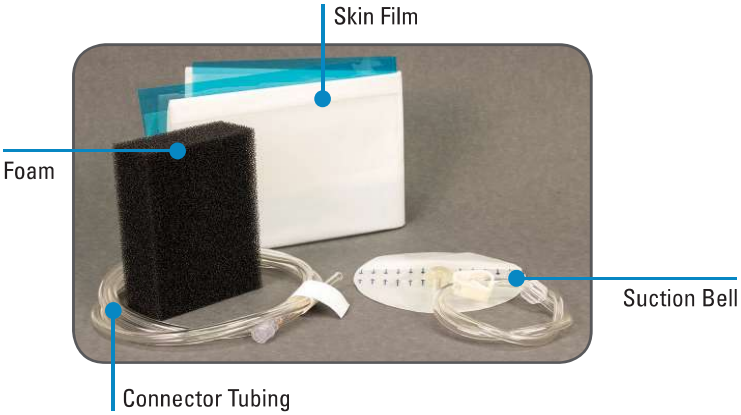
℞

IFU-ST396-001.001

Symbols

	**Warning/Caution:** See instructions for use
	Single Use Only
	Date Of Manufacture
	Use By
	Keep Dry
STERILE EO	Sterilized Using Ethylene Oxide
LOT	Manufacture Lot Number
EC REP	Authorized Representative in the European Community
	Manufacturer



Intended Use

The **extriCARE®** NPWT foam kit is intended to be used in conjunction with the **extriCARE®** NPWT pump. The **extriCARE® Negative Pressure Wound Therapy System** is indicated for wound management via the application of negative pressure to the wound by the removal of wound exudate, infectious materials, and tissue debris from the wound bed. The **extriCARE® Negative Pressure Wound Therapy System** 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: Federal law restricts this device to be sale by or on the order of a licenced healthcare practioner.

Product Description

The **extriCARE®** Foam Dressing Kit is intended to be used in conjunction with the **extriCARE® Negative Pressure Wound Therapy Pump**. For direction to use the pump, please refer to the **extriCARE® Negative Pressure Wound Therapy Pump** Instruction for Use.

The **extriCARE® Negative Pressure Wound Therapy Foam Dressing** is intended to be changed at a minimum of every 72 hours.

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-E	10cm x 7.5cm x 3cm
Large	EC-Foam-L -E	25cm x 16cm x 3cm

Contraindications

The **extriCARE® Negative Pressure Wound Therapy System** should **NOT** be used in the following conditions:

- Exposed vessels, organs, or nerves.
- Anastomotic sites.
- Exposed arteries or veins in a wound.
- 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.

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:** The **extriCARE®** system should not be used in an magnetic resonance imaging (MRI) environment, in hyperbaric chamber environment (HBO), nor with defibrillation. Please disconnect device and/or remove dressings as instructed by your physician if these situations arise.
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.

Precautions: Be aware for any of the following conditions:

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® Negative Pressure Wound Therapy Dressings** next to the vagus nerve to minimize the risk of bradycardia.

11. **PERIWOUND SKIN:** Protect periwound skin with additional hydrocolloid, other transparent film, or other skin prep methods. Monitor skin for any signs of irritation or irregularity. If this occurs, stop treatment and consult physician.

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

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.

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.
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 female luer lock on the suction bell tubing to the male luer lock on the canister tubing.
9. Set the **extriCARE® NPWT System** to the physician prescribed therapy settings and initiate therapy.

Note: **extriCARE®** bandage dressing is a single use only product. If the user does not intend to change the dressing but need to pause the treatment, please do not remove the dressing. Use the clamp on the tubing to seal the tubing and disconnect the luer lock to pause the treatment. When treatment needs to be continued, simply connect the tubing again and release the clamp.

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.