

LIGHTSTONE

— MEDICAL —



Tzoar NPWT Foam Kit

INSTRUCTIONS FOR USE

Tzoar NPWT System



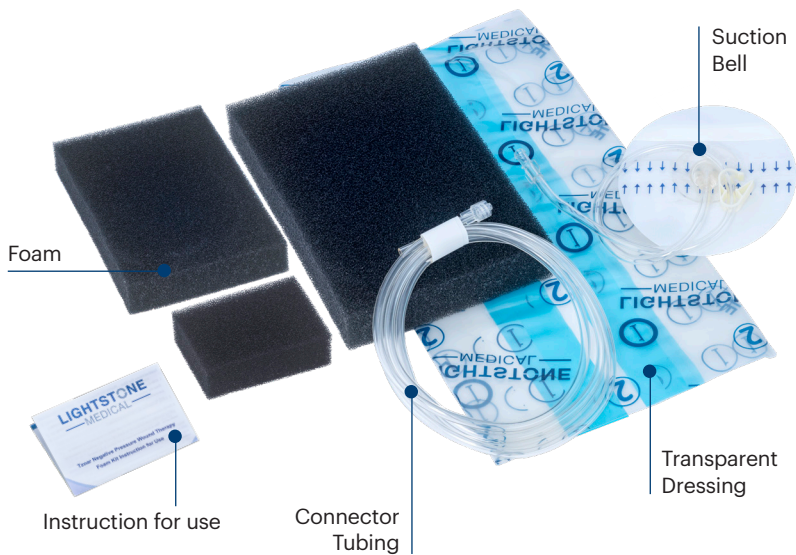
Table of Contents

- 2. Symbol List
- 3. Intended Use
- 4. Product Description
- 5. Contraindications for Use
- 6. Precautions
- 10. Instructions for Use



Symbol list

	Warning/Caution		Manufacture Lot Number
	Single Use Only		Use by
	Date of Manufacture		Manufacturer
	Keep Dry		Sterilized Using Ethylene Oxide
	Caution: Federal Law (USA) restricts this device to sale by or on the order of a licensed physician.		



Intended use



CAUTION!

Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

The Tzoar NPWT Foam Kit is intended to be used in conjunction with the Tzoar 207 NPWT pump.

The Tzoar 207 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 Tzoar 207 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.



Model# Tzoar 207

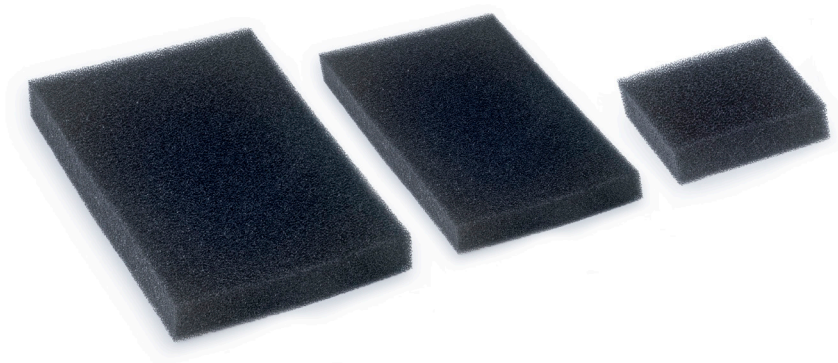
Product Description

The Tzoar NPWT Foam Kit is intended to be used in conjunction with the Tzoar 207 Negative Pressure Wound Therapy Pump. For pump operating instructions, please refer to the Tzoar 207 Negative Pressure Wound Therapy Pump Instruction for Use.

The Tzoar Negative Pressure Wound Therapy Foam Kit is intended to be changed at a minimum of every 72 hours.

The Tzoar Negative Pressure Wound Therapy Foam Kit consists of black foam, transparent dressing, drainage tubing set, suction bell, and a paper ruler. The foam kit is available in the following sizes:

SKU#	Product Type	FOAM Size
LSM-KL	Tzoar NPWT Foam Kit - Large	25cm x 16cm x 3cm
LSM-KM	Tzoar NPWT Foam Kit - Medium	18cm x 12.5cm x 3cm
LSM-KS	Tzoar NPWT Foam Kit - Small	10cm x 7.5cm x 3cm



Contraindications for Use



The Tzoar 207 NPWT 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.

Caution should be taken when treating wounds that may contain hidden vessels which may not be readily apparent. The patient should be closely monitored for bleeding in a setting deemed appropriate by the treating physician.

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:



Never leave a Tzoar NPWT Foam Kits in place on or in a wound without active Negative Pressure Wound Therapy for more than two hours.

There are additional conditions to take into account before using Tzoar 207 Negative Pressure Wound Therapy, such as:

A BLEEDING

There is a risk of bleeding/hemorrhaging with negative pressure wound therapy. Patients with weakened or friable blood vessels or infected vascular anastomosis, organs in or around the wound as a result of, but not limited to suturing of blood vessels, infection, trauma, and radiation may have an increased risk for bleeding. If hemostasis cannot be achieved, if the patient is on anticoagulants or platelet aggregation factors, does not have adequate tissue coverage over vascular structures, 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 large amounts of frank (bright red) blood is seen in the tubing or canister, immediately stop therapy, leave dressing in place, take measures to stop the bleeding, and seek immediate medical assistance. The Tzoar 207 NPWT System should not be used to prevent, minimize or stop vascular bleeding.

B 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.

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.

C ENVIRONMENT

Do not take the Tzoar 207 NPWT Pump into a hyperbaric oxygen chamber. Tzoar 207 NPWT Pumps are not designed for this environment and should be considered a fire hazard in such an environment. After disconnecting the Tzoar 207 NPWT Pump, either

- replace the Tzoar Wound Dressing with another HBO compatible material during the hyperbaric treatment, or
- cover the unclamped end of the Tzoar tubing. For HBO therapy, the Tzoar tubing must not be clamped.

D INFECTION

Wound infections that require frequent monitoring may require more frequent dressing changes. If there are any signs of the onset of systemic infection or advancing infection at the wound site, contact the treating prescriber immediately to determine if NPWT Pump should be discontinued.

Osteomyelitis: Tzoar 207 NPWT System should not be initiated on a wound with untreated osteomyelitis.

E PATIENT SIZE AND WEIGHT

Wounds heavily draining or large wounds in relation to the patient size and weight should be closely monitored, as they may have a risk of excessive fluid loss and dehydration. When monitoring fluid output, consider the volume of fluid in both the tubing and canister.

F SPINAL CORD INJURY

If a patient experiences autonomic dysreflexia (sudden changes in blood pressure or heart rate because of sympathetic nervous system stimulation), discontinue Tzoar 207 NPWT System therapy to minimize sensory stimulation and seek immediate medical assistance.

Precautions

G 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.

H 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, the Tzoar 207 NPWT system is not recommended.

I CIRCUMFERENTIAL DRESSING

Do not use circumferential dressings.

J BRADYCARDIA

Avoid placement of the Tzoar NPWT Wound Dressings next to the vagus nerve to minimize the risk of bradycardia.

K DEFIBRILLATION

If defibrillation is required in the area of dressing placement, remove the dressing immediately, as failure to remove may inhibit transmission of electrical energy and/or patient resuscitation.

L 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 air dry. The use of a skin preparation wipe is also recommended.
- Do not allow wound filler to overlap wound borders onto intact skin.

- Periwound skin may be protected with hydrocolloid, silicone strips, transparent film, or other skin prep methods such as ostomy putty or paste. Transparent film may be used to protect periwound skin, however multiple layers of the transparent film dressing may decrease the moisture vapor transmission rate, which may increase the risk of maceration.
- To avoid trauma to the periwound skin, do not pull or stretch the transparent film over the wound filler dressing during film application.
- 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 domestic distributor before using the device.



PLEASE NOTE:

The Tzoar NPWT Foam Kit is intended for single use only. Do not use the Tzoar NPWT 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 and type.
- 2 Apply skin sealant to the area surrounding the wound bed. If used on anatomically challenging areas or where adhesion is a problem, a hydrocolloid or a thin layer of ostomy paste or putty may be applied as an aid to create /maintain a seal.
- 3 Cut the foam to wound size and 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 peeled off and applied to the transparent dressing over the body after the application is completed.



Date:	# of pieces used:

- 5 Trim Transparent Dressing to cover area of wound bed with an extra circumference of at least 5cm.
Peel back one side of Layer 1 and place adhesive side over foam. Remove the remaining side of Layer 1 along with Layer 2 and the blue handling tab(s). Place the transparent dressing to create a smooth, wrinkle free layer over the foam and skin.
- 6 Once applied, pinch the Transparent Dressing 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 and place the suction bell opening directly over the hole in the Transparent Dressing 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 **Tzoar 207 NPWT System** to the physician prescribed therapy settings and initiate therapy.

NOTE



Tzoar NPWT Foam Kits 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 **Tzoar 207 NPWT Pump** still running, disconnect the tubing at the luer lock. Once the tubing is clear of fluid, turn off the **Tzoar 207 NPWT Pump**. If necessary, pre-medicate the patient for pain.
- 2 Gently remove the Transparent Dressing 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 Dispose of Transparent Dressing and Foam according to policy. All dressing 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, as directed by physician.

Note: Any dressing change can disrupt fragile blood vessels, so minor bleeding may occur. If patient develops significant bleeding at the wound site, leave dressing in place, turn off the Tzoar 207 NPWT System, and seek medical care immediately.



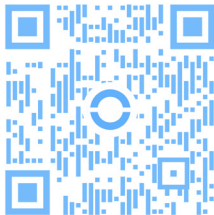


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