

LIGHTSTONE

— MEDICAL —



Tzoar NPWT One Piece Dressing

INSTRUCTIONS FOR USE

Tzoar NPWT System

Table of Contents

- 2. Symbol List
- 4. Intended Use
- 5. Product Description
- 6. Contraindications for Use
- 7. Precautions
- 11. 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.		

Figure 1. One Piece Dressing

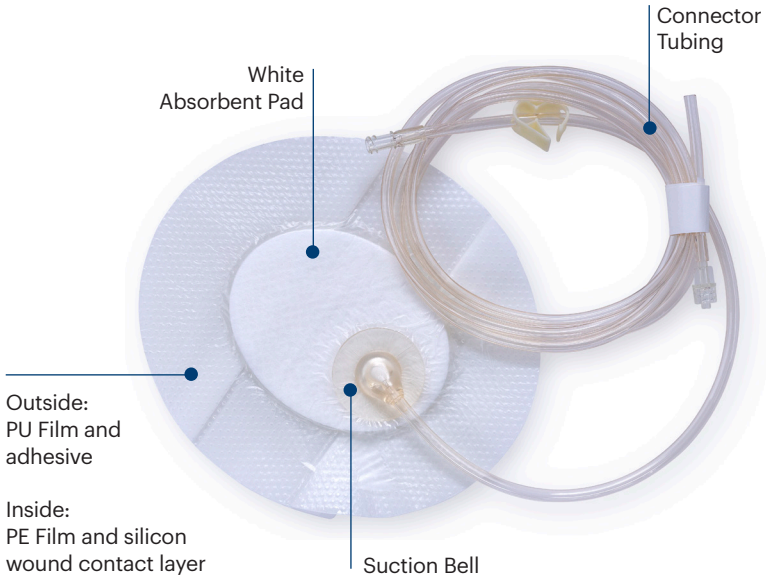


Figure 2. Transparent Dressing Strips



5 pieces of transparent
dressing strips are included.
Each is
335 x 50 mm



CAUTION!

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

The Tzoar NPWT One Piece Dressing is intended to be used in conjunction with the Tzoar 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 One Piece Dressing is intended to be used in conjunction with the Tzoar 207 Negative Pressure Wound Therapy Pump. For direction to use the pump, please refer to the Tzoar 207 Negative Pressure Wound Therapy Pump Instruction for Use.

The Tzoar Negative Pressure Wound Therapy One Piece Dressing is intended to be changed at a minimum of every 72 hours.

The Tzoar Negative Pressure Wound Therapy One Piece Dressing consists of PU film with adhesive, silicon wound contact layer, PE film, white absorbent pad, connector tubing, suction bell, and 5 strips of transparent dressings.

Choice of dressing size is dependent on the size of the wound. The dressing pad must cover the entire wound. The One Piece Dressing is available in the following sizes:

SKU#	Product Type	Size	Pad Size
LSM-IN-2207	Tzoar NPWT One Piece Dressing - Rectangular 2207	27 x 12.5cm	22cm x 7.5cm
LSM-LO-1410	Tzoar NPWT One Piece Dressing - Large Oval 1410	22.5 x 18cm	14.5cm x 10cm
LSM-SO-1008	Tzoar NPWT One Piece Dressing - Small Oval 1008	8cm x 16cm	10cm x 8cm
LSM-SQ-1515	Tzoar NPWT One Piece Dressing - Square 1515	20cm x 20cm	15cm x 15cm
LSM-SC-1312	Tzoar NPWT One Piece Dressing - Sacrum 1312	18.2cm x 17.3cm	13cm x 11.8cm
LSM-SQ-2020	Tzoar NPWT One Piece Dressing - Square 2020	25cm x 25cm	20cm x 20cm
LSM-SQ-1010	Tzoar NPWT One Piece Dressing - Square 1010	15cm x 15cm	10cm x 10cm

Contraindications for Use

The Tzoar 207 Negative Pressure Wound Therapy System should NOT be used in the

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 Wound Dressing 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 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 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.

Precautions

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 NPWT Pump into a hyperbaric oxygen chamber. Tzoar NPWT Pumps are not designed for this environment and should be considered a fire hazard in such an environment.

After disconnecting the Tzoar 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.

G MODE

The Tzoar NPWT One Piece Dressing is intended for Continuous therapy. The prescriber should consider the Tzoar NPWT Foam Kit as an alternative, if Intermittent therapy is desired.

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.

Precautions

- Periound 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 periound 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 periound 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 One Piece Dressing is intended for single use only. Do not use the Tzoar One Piece Dressing if the packaging is opened or damaged as sterility may be compromised.

Dressing Application:

The Tzoar One Piece Dressing is intended for wounds with 0.5mm or less depth. If the depth of the wound exceeds 0.5mm, the clinician may loosely place non-occlusive dressing material into areas of depth, undermining, and tunneling. The decision on material used to fill additional depth is determined by prescribing physician.

Choice of dressing size is dependent on the size of the wound. The dressing pad must cover the entire wound.

The procedures are as follows:

- 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.
- 3** Optional: You may treat the edges of the wound with hydrocolloids, ostomy putty or a border of transparent dressing for a better seal.
- 4** Remove the release paper from the One Piece Dressing.
- 5** Holding the two finger tabs on the dressing and place it over the wound bed, making sure the pad is covering the entire wound, remove the finger tabs.
- 6** Press down firmly around the silicone skirt and dressing pad to help ensure a good seal. Avoid pleating the dressing. Transparent dressing strips are included in the dressing kit and may be optionally used to help obtain a seal and secure the dressing. The transparent dressing strips may be placed around the border of the dressing, overlapping the dressing and surrounding skin.

Instructions for Use

- 7 Connect the connection tubing to the dressing tubing.
- 8 Attach the connection tubing to the **Tzoar NPWT Canister**.
- 9 Set the **Tzoar 207 NPWT System** to the physician prescribed therapy settings and initiate therapy.

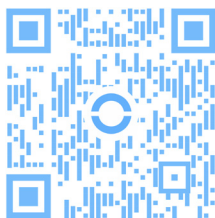




(201) 801-1300

info@lightstonemed.com

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