

PLEUR-EVAC®



MINI SAHARA Chest Drainage System

Système de drainage thoracique

Thoraxdrainagesystem

Sistema di drenaggio toracico

Sistema de drenaje del tórax

Sistema de drenagem torácica

Thoraxdrænsystem

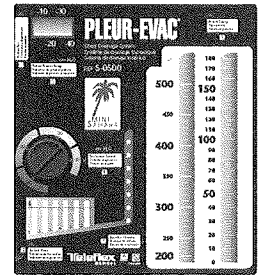
Longdrainagesysteem

Bröstkorgsdräneringssystem

Brystdrenasjesystem

Rintaontelon tyhjennysjärjestelmä

Σύστημα Θωρακικής Παροχέτευσης



Rx ONLY **STERILE** **EO**



CE **EC REP**
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Assembled in Mexico with US and Foreign components.
220002423 Rev 03



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Manufacturer. Fabricant. Hersteller. Produttore. Fabricante. Fabricante. Producent. Fabrikant. Tillverkare. Produsent. Valmistaja. Κατασκευαστής.



Pre-filled syringe to fill air leak meter through the injection site on the back of unit. Seringue préremplie pour remplir l'indicateur de fuite d'air par le site d'injection situé à l'arrière du dispositif. Vorgefüllte Spritze zum Füllen des Luftverlustmessers über die Injektionsöffnung auf der Rückseite des Geräts. Siringa pre-riempita per riempire il misuratore di tenuta attraverso il sito di iniezione sulla parte posteriore dell'unità. La jeringa prellenada debe llenar el medidor de fugas de aire a través del sitio de inyección que se encuentra en la parte posterior de la unidad. Seringa pré-cheia para encher o medidor de fuga de ar através do local da injeção na parte posterior da unidade. Forud-fyldt sprøjte til fyldning af luftlækemåler gennem injektionsstedet bag på enheden. Voorgevulde injectiespuit om de luchtlekkagemeter te vullen via de injectieplaats aan de achterzijde van de unit. Förfylld spruta för att fylla luftläckagemätaren via injektionsplatsen på enhetens baksida. Forhåndsfyldt sprøjte til å fylle luftlekkasje-måleren gjennom innsprøytningsstedet på baksiden av enheten. Esitäytetty ruisku ilmapuutomittarin täyttämiseen yksikön takana olevan injektiokohdasta kautta. Προγεμισμένη σύριγγα για την πλήρωση του μετρητή διαφυγής αέρος μέσω της τοποθεσίας έγχυσης στην πίσω όψη της μονάδας.



Do not fill suction port. Ne pas remplir le connecteur d'aspiration. Nicht über den Absauganschluss füllen. Non riempire dal port di aspirazione. Não llene la boca de succión. Não encher a porta de aspiração. Fyld ikke sugoporten. Vul de aanzuigpoort niet. Fyll inte insugningsporten. Fyll ikke i sugearningen. Älä täytä imuaukkoa. Μη γεμίζετε τη θύρα αναρρόφησης.



Do not use if package has been opened or damaged. Ne pas utiliser si l'emballage est ouvert ou endommagé. Nicht verwenden, wenn die Packung offen oder beschädigt ist. Non utilizzare se la confezione è stata aperta o danneggiata. No lo utilice si el envase está abierto o dañado. Não utilize caso a embalagem esteja aberta ou danificada. Må ikke anvendes, hvis pakningen er anbrudt eller beskadiget. Niet gebruiken indien de verpakking geopend of beschadigd is. Använd inte produkten, om förpackningen har öppnats eller skadats. Må ikke brukes hvis pakken har vært åpnet eller skadet. Ei saa käyttää, jos pakkaus on auki tai vaurioitunut. Μη χρησιμοποιείτε εάν η συσκευασία έχει ανοιχτεί ή υποστεί ζημιά.



Latex Free. Sans latex. Ohne Latex. Senza lattice. Sin latex. Não contém látex. Latex-fri. Latexvrij. Latex-fri. Latex fri. Lateksiton. Χωρίς Latex.

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PLEUR-EVAC[®]
**PLEUR-EVAC
MINI SAHARA**
Chest Drainage System

The PLEUR-EVAC MINI SAHARA Chest Drainage System is provided as a sterile, non-pyrogenic unit intended for single use. **STERILE: Contents sterile unless package has been opened or damaged.**

INDICATIONS FOR USE

The PLEUR-EVAC MINI SAHARA Chest Drainage System is indicated:

- To evacuate air and/or fluid from the chest cavity or mediastinum
- To help prevent air and/or fluid from reaccumulating in the chest cavity or mediastinum
- To help re-establish and maintain normal intrathoracic pressure gradients
- To facilitate complete lung re-expansion to restore normal breathing dynamics

DISPOSAL

The PLEUR-EVAC MINI SAHARA Chest Drainage System should be handled and disposed in accordance with all applicable local, state and federal regulations including, without limitation, those pertaining to human health and safety and the environment.

WARNINGS

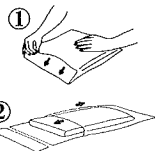
1. The collected contents of the PLEUR-EVAC MINI SAHARA System should not be used for reinfusion.
2. Chest tubes should not be clamped except when changing the PLEUR-EVAC MINI SAHARA system or adding additional patient tubing. In the event of an air leak, clamping chest tubes could lead to a tension pneumothorax.
3. Stripping of the patient tube must be done with the patient tube clamp open. Stripping with the clamps closed can result in the build up of excessive positive pressure.

CAUTIONS

1. Keep the PLEUR-EVAC MINI SAHARA System below the patient's chest level at all times.
2. Avoid loops in the patient tubing.
3. Caution should be used when the possibility exists for exposure to blood or body fluids. Follow hospital policy regarding the use of protective wear.
4. The clamp on the patient tube should be placed away from the patient, avoiding accidental closure.
5. Use only a standard luer slip tip syringe (enclosed with the unit) to fill the Air Leak Meter and a standard luer lock syringe to withdraw samples from the sampling port. **NO NEEDLE IS REQUIRED.**
6. Monitor the PLEUR-EVAC MINI SAHARA collection chamber to avoid overflow. Replace the unit before exceeding the fill capacity of 500cc indicated by the volume graduation printed on the collection chamber.

TO OPEN PACKAGE

1. Grasp the bottom edge of flap and pull up toward sterile opening.
2. Pull flap back pushing the wrapped unit out of bag OR completely remove the breather strip. Push the wrapped unit out of the bag using aseptic technique.



1

SET UP INSTRUCTIONS:

1. Patient tubing
2. Air leak meter
3. Suction port
4. Dry suction control dial
5. Patient pressure gauge
6. Collection chamber

Connect the patient tube [1] to the thoracic catheter. The one-way seal is now established for patient protection.

NOTE: A connector is provided at the end of the patient tube for easy connection to the thoracic catheter. The connector is capped to maintain good aseptic technique during set-up. Discard cap on patient tubing after set-up.

If patient is not mobile, additional tubing provided with the unit may be added to facilitate locating the unit on the floor or bedrail.

If air leak diagnostics are desired, add sterile water to the air leak meter [2] through the injection site on the back of the unit using the pre-filled syringe provided with the unit.

CAUTION: Do not use pre-filled syringe for any purpose other than the filling of the air leak meter. Not for human injection.

- To open, remove cap from tip of syringe. Attached the exposed tip into the needleless injection site at the back of the unit.
- Depress the plunger on the syringe. The syringe contains enough water to fill the air leak meter to the "fill" line.
- Avoid overfilling.
- Once filled, the water will turn blue.

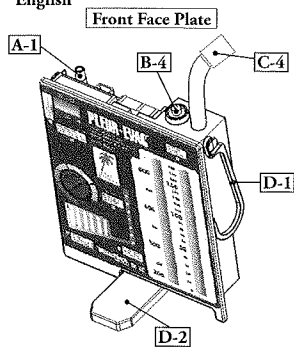
If suction is not required, go to [6].

If suction is required, confirm wall suction is off. Connect the suction source to the suction port [3]. NO water is needed in the suction control chamber.

Use the dry suction control dial [4] to set desired setting. Turn wall suction on and adjust wall suction setting until desired level appears in the patient pressure gauge window [5]. If patient pressure exceeds prescribed level, refer to section B-4.

Document patient drainage when prescribed at the collection chamber [6].

2



A SUCTION CONTROL

A-1 Suction Port

Use to attach to wall suction (if prescribed).

A-2 Dry Suction Control (Dial)

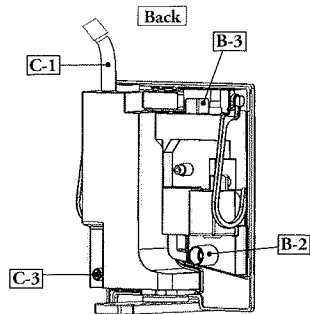
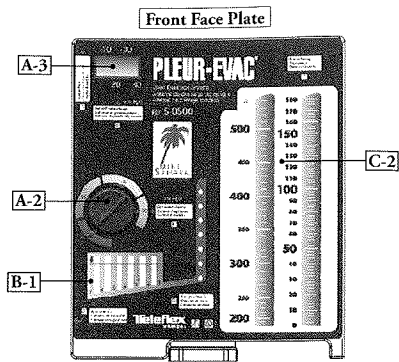
The suction level is determined by the position of the dial on the dry suction control and wall suction setting. Rotate the dry suction control dial to set to the desired suction level. The suction level is determined by the position of the gauge in the patient pressure gauge window.

A-3 Patient Pressure Gauge

After suction is applied, the gauge appears in the patient pressure gauge window. The suction imposed is determined by the dry suction control dial and source of air from the wall suction setting. Increase/decrease wall suction level until unit is operating at the prescribed suction setting as indicated in the patient pressure gauge window.

NOTES:

- In the presence of a large air leak, air flow through the PLEUR-EVAC MINI SAHARA system may be increased by increasing suction source WITHOUT increasing imposed negativity. It is not necessary to change the suction setting on the PLEUR-EVAC MINI SAHARA.
- When changing a suction setting from a higher level to a lower level, the patient negativity on the patient side of the seal may remain at the higher level unless the negativity is relieved. Use high negativity relief valve to reduce negativity to desired level. (See B-4)
- Check the unit periodically to ensure that adequate suction is being applied to the unit and that the indicator in the patient pressure gauge window is at the desired level.



GRAVITY DRAINAGE

If gravity drainage is prescribed, the suction port should remain UNCAPPED and free of OBSTRUCTIONS, to allow air to exit and minimize possibility of tension pneumothorax.

B ONE WAY SEAL

A check valve provides the one-way seal which allows air to exit from the pleural space while retarding the reverse flow of air. Water is not required to achieve this one-way seal.

NOTE: The fluid in the patient air leak meter is used for air leak detection and is NOT a water seal.

B-1 Air Leak Meter For Diagnostics

If air leak diagnostics are desired, the patient AIR LEAK METER must be filled with water to the fill level. Use the pre-filled syringe with 20cc of sterile water to fill the air leak meter (See B-2). DO NOT FILL through the Suction Port. (See A-1)

The patient air leak meter indicates the approximate degree of air leak from the chest cavity. Observe bubbling in the columns of the patient air leak meter. The meter is labeled from LOW (1) to HIGH (7). The higher the numbered column through which the bubbling occurs, the greater the degree of air leak.

The small arm of the patient air leak meter will display tidaling with patient respiration if there is a pleural chest tube placement. The markings on the column are for reference only and do not correspond to actual patient negativity.

B-2 Needleless Injection Site

Sterile water or saline can be injected into the Air Leak Meter through the needleless injection site located on the back of the unit.

CAUTION: Use only the supplied pre-filled luer slip tip syringe to fill the air leak meter. Do not use needle to prevent damage.

B-3 Positive Pressure Relief Valve

The positive pressure relief valve automatically opens with increase in positive pressure, preventing pressure accumulation.

WARNING: Do not obstruct the positive pressure relief valve.

B-4 Filtered High Negativity Relief Valve

The filtered high negativity relief valve is provided to vent excessive negativity. Depress button to relieve negativity; filtered air will enter the unit.

WARNING: Stripping or milking of the thoracic tubing can cause excessive negativity. Use the high negativity relief valve to restore negativity to prescribed levels.

CAUTION: If suction is not operative, or if operating on gravity drainage, depressing the high negativity relief valve can reduce negative pressure within the collection chamber to zero (atmosphere) with the resulting possibility of a pneumothorax. **CAUTION:** The PLEUR-EVAC MINI SAHARA system has an automatic high negative pressure relief valve to limit the negative pressure to approximately -50cm of water.

English

C COLLECTION CHAMBER

C-1 Patient Tubing

The patient tubing is connected to the thoracic catheter.

C-2 Collection Chamber

The collection chamber has a capacity of 500cc. The collection chamber has measurements in 2cc increments up to 180cc, and 10cc increments up to 500cc (+/- 10%). When drainage reaches 500cc, the unit is filled to capacity. Replace the unit. When changing the unit, maximum speed can be achieved by making ready a new unit and following the set-up and operating instructions. Marking surfaces on the collection chamber are for making notations. Use pen or pencil.

CAUTION: Check tubing periodically for obstruction of drainage flow.

CAUTION: Monitor the PLEUR-EVAC MINI SAHARA collection chamber to avoid overflow. Replace the unit before exceeding the fill capacity of 500cc indicated by the volume graduation printed on the collection chamber.

C-3 AND C-4 Needleless Sampling Ports (2 Sites)

Use ports for drainage collection samples.

D OTHER FEATURES

D-1 Hangers

Two hangers are provided to hang the PLEUR-EVAC MINI SAHARA from a bed, stand, or stretcher.

D-2 Floorstand

An attached floorstand swings out to stabilize the unit when it is set on the floor. The floorstand contains an automatic locking mechanism that locks the floorstand in the open position. To close, press the locking tab and rotate the floorstand.

EXTENDED TUBING

An extended tubing set is included for ease of unit location. Use when patient is not mobile to facilitate locating the unit on the floor or bedrail. To attach additional tubing, clamp off patient tubing using sterile technique and using connectors attached to the tubing.

CARRYING BAG

A carrying bag is provided for ease of patient ambulation or transport within professional healthcare supervision. Assistance from healthcare provider will be required for set up. The strap is included inside the clear carrying bag. Remove strap from carrying bag. Insert upright PLEUR-EVAC MINI SAHARA into bag with patient tubing wrapping around the back of the patient. For shoulder placement, slide the buckle through the slots provided on the side of the bag. For waist placement, slide the buckle through the slots provided on the back of the bag. Adjust to desired length.