

STERILE EO



PLEUR-EVAC SAHARA 
CONTINUOUS REINFUSION AUTOTRANSFUSION SYSTEM

S-1150-08

Instructions for Use

PLEUR-EVAC SAHARA® Plus

Continuous Reinfusion Autotransfusion System

Instruções de Utilização

PLEUR-EVAC SAHARA® Plus

Sistema de Auto-transusão com Reinfusão Contínua

Mode d'emploi

PLEUR-EVAC SAHARA® Plus

Système d'autotransfusion à réinjection continue

Οδηγίες Χρήσης

PLEUR-EVAC SAHARA® Plus

Σύστημα Αυτομάτης Συνχούς Επανάγχυσης

Gebrauchsanleitung

PLEUR-EVAC SAHARA® Plus

Autotransfusionssystem zur kontinuierlichen Reinfusion

Bruksanvisning

PLEUR-EVAC SAHARA® Plus

Autotransfusionssystem för kontinuerlig reinfusion

Istruzioni per l'uso

PLEUR-EVAC SAHARA® Plus

Sistema per autotrasfusione a reinfusione continua

Käyttöohjeet

PLEUR-EVAC SAHARA® Plus

Jatkuva reinfuusio-autotransfusiojärjestelmä

Instrucciones de uso

PLEUR-EVAC SAHARA® Plus

Sistema de autotransfusión de reinfusión continua

Bruksveiledning

PLEUR-EVAC SAHARA® Plus

Kontinuerlig reinfusjon/autotransfusjonssystem

Gebruiksaanwijzing

PLEUR-EVAC SAHARA® Plus

Doorlopende herinfusie-autotransfusiesysteem

Brugsanvisning

PLEUR-EVAC SAHARA® Plus

Autotransfusionssystem til kontinuerlig reinfusion



Teleflex
MEDICAL

SINGLE USE ONLY DO NOT RESTERILIZE Rx ONLY
STERILE: Contents sterile unless package has been opened or damaged.

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PRODUCT DESCRIPTION

The PLEUR-EVAC SAHARA Plus Continuous Reinfusion Autotransfusion System is provided as a sterile, non-pyrogenic unit intended for single patient use. The PLEUR-EVAC SAHARA Plus System is used for the collection and continuous reinfusion of autologous blood. By attaching the PLEUR-EVAC SAHARA Autotransfusion Bag, the PLEUR-EVAC SAHARA Plus System serves as a bag reinfusion system. When autotransfusion is completed, the PLEUR-EVAC SAHARA Plus System can serve as a chest drainage collection unit. These instructions will address the set up and operation of the PLEUR-EVAC SAHARA Plus Continuous Reinfusion Autotransfusion System. Refer to manufacturer's directions for use, warnings, and cautions for microaggregate filters, I.V. blood administration sets, and blood compatible infusion pumps prior to use with this autotransfusion system.

INDICATIONS FOR USE

The PLEUR-EVAC SAHARA Plus System is indicated:

- ◆ For the collection of autologous blood from the patient's pleural cavity or mediastinal area for reinfusion purposes in trauma and post operative situations
- ◆ 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 SAHARA Plus System should be handled and disposed of in accordance with all applicable regulations including, without limitation, those pertaining to human health and safety and the environment.

WARNINGS

1. Do not perform continuous reinfusion unless a minimum of 50 ml of blood remains in the collection chamber after the reinfusion system, including microaggregate filter, has been primed with blood or sterile saline. Continuously monitor the fluid level in the collection chamber.
2. A microaggregate filter must be used during reinfusion.
3. If all air is not removed from the system prior to reinfusion, air embolism may result.
4. Negativity during autotransfusion should not exceed -60 cm of water.
5. Stripping of the patient tube in addition to the on-going mechanical action of the infusion pump can cause excessive negativity.
6. Chest tubes should not be clamped except when changing the PLEUR-EVAC SAHARA Plus System. In the event of an air leak, clamping chest tubes could lead to a tension pneumothorax.
7. 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.
8. A blood compatible I.V. infusion pump with air/bubble detector must be used for continuous reinfusion. Follow manufacturer's instructions for use to ensure proper priming and complete removal of air from the blood administration set prior to connection to the patient.

CONTRAINDICATIONS FOR AUTOTRANSFUSION

- ◆ Pericardial, mediastinal, or systemic infections
- ◆ Pulmonary and respiratory infection or infestation
- ◆ Presence of malignant neoplasms
- ◆ Coagulopathies
- ◆ Suspected thoraco-abdominal injuries with possible enteric contamination
- ◆ Impaired renal function
- ◆ Intraoperative thoracic or mediastinal cavity use of topical thrombin, microfibrillar hemostatic agents or povidone-iodine antiseptic gels or solutions and non I.V. compatible antibiotics

CAUTIONS

1. Collected autologous shed blood should be reinfused within six hours from the initiation of collection.
2. Keep the PLEUR-EVAC SAHARA Plus System below the patient's chest level at all times.
3. Avoid loops in the patient tube.
4. Be sure the clamp on the exit port tube is in the closed position and the tethered cap in place after discontinuing continuous reinfusion.
5. Caution should be used when the possibility exists for exposure to blood or body fluids. Follow hospital policy regarding the use of protective wear.
6. The clamp on the patient tube should be placed away from the patient to avoid accidental closure.
7. Use only a standard luer slip tip syringe to fill the Air Leak Meter. **NO NEEDLE IS REQUIRED.**
8. Monitor the Pleur-Evac collection chamber. To avoid overflow replace the unit before exceeding the fill capacity of 1700ml indicated by the volume graduation printed on collection chamber.

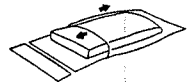
ADVERSE REACTIONS

The following complications have been known to occur during autotransfusion:

- ◆ Blood trauma
- ◆ Coagulopathies
- ◆ Particulate or air embolism

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.



SET UP INSTRUCTIONS

If suction is prescribed, follow steps 1 through 5. If suction is not required, follow steps 1 and 2 only.

1. CONNECT TO THE PATIENT THORACIC CATHETER

Connect the patient tube, which is the long tube from the collection chamber, to the patient's thoracic catheter. One way seal is now established for patient protection (Figure 1).

NOTE: A connector is provided at the end of the patient tube for easy connection to the thoracic catheter. This connector is capped to maintain aseptic technique during set up. **DISCARD** cap on patient tube after removing.

2. FOR AIR LEAK DIAGNOSTICS

- A syringe of sterile water, not for injection is provided to facilitate filling.
- Use with Pleur-Evac chest drainage units only. To open, remove cap from tip.
- Attach the exposed tip into the Needleless Injection Site on the top of the unit (Figure 1)
- Depress the plunger on the syringe. The syringe contains enough water to fill the Air Leak Meter.
- Fill to the "fill" line (Figure 1)
- Avoid overfilling
- Once filled. The water will turn blue.

CAUTION: If additional water is required, use only a standard luer slip tip syringe to fill the AIR Leak Meter. **NO NEEDLE IS REQUIRED.**

3. CONNECT TO SUCTION SOURCE

Connect the suction source to the suction port (Figure 1).

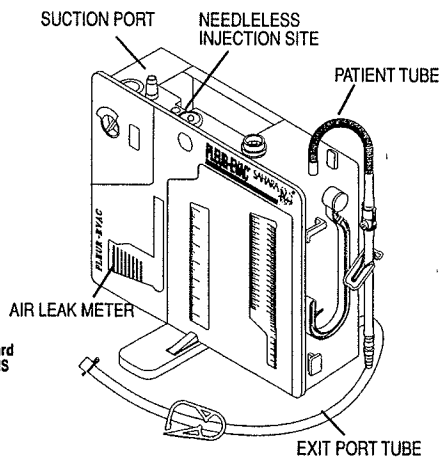


FIGURE 1

4. SUCTION CONTROL

A dial to set the suction is located on the upper left side of the unit. **NO WATER IS NEEDED IN THE SUCTION CONTROL CHAMBER.** To adjust the suction setting, rotate the dial until the red stripe in the semi-circular window aligns with the prescribed suction level and clicks into place. Suction can be set at -10, -15, -20, -30 and -40 cm of water. Figure 2 shows the suction control dial set at -20 cm of water. The unit is set at -20 cm of water when opened.

5. SUCTION SOURCE

Increase source suction until the orange float appears in the suction indicator window. The position of the suction dial determines the approximate amount of suction imposed regardless of the amount of source suction—as long as the orange float appears in the indicator window. Figure 3 shows the suction control dial set at -40 cm of water and the float in the indicator window.

NOTE: Source suction must be capable of delivering a minimum of 16 liters per minute (LPM) air flow.

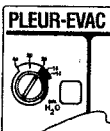


FIGURE 2

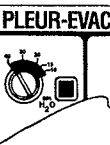


FIGURE 3

A. SUCTION CONTROL CHAMBER

A-1 SUCTION DIAL

The suction level is determined by the position of the edge of the red stripe in the semi-circular window above the suction dial. Rotate the dial to position the edge of the stripe at the desired suction setting. The dial will click into position at each of the indicated settings.

A-2 SUCTION INDICATOR

When the orange float appears in the suction indicator window, the suction imposed is determined by the dial setting (red stripe). As long as the float appears in the window, the unit is operating at the indicated suction ± 4 cm of water.

NOTE: In the presence of a large air leak, air flow through the PLEUR-EVAC 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 System.

Check the unit periodically to ensure that adequate suction is being applied to the unit and that the orange float remains in the suction indicator window.

NOTE: If suction setting is changed 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).

A-3 SUCTION PORT

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.

A-4 NEGATIVE PRESSURE INDICATOR

Negative pressure exists in the collection chamber when "YES" can be seen in the indicator window. During gravity drainage, the indicator may intermittently indicate a negative pressure in the collection chamber with patient respiration. During suction drainage, the pressure indicator should indicate a negative pressure continuously.

CAUTION: If the "YES" is not visible in the negative pressure indicator window as described, 1) check patient connections for leaks, 2) check tubing connections on the unit. If all connections are secure and the "YES" does not appear, replace the unit. The negative pressure indicator does not confirm drainage tube patency. Routinely check the drainage tube patency.

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 PATIENT AIR LEAK METER

If air leak diagnostics are desired, the Patient Air Leak Meter must be filled with water to the fill range. 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.

B-2 NEEDLELESS INJECTION SITE

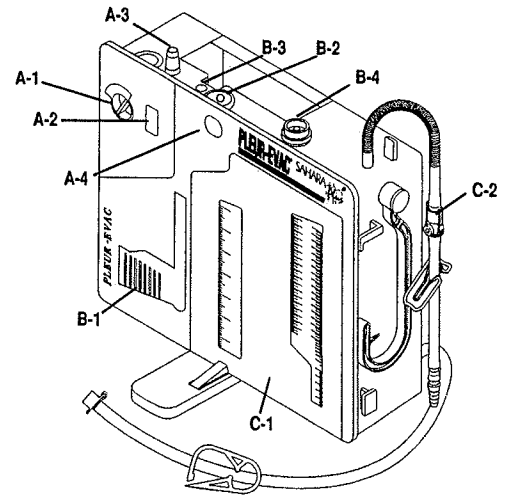
Sterile water or saline can be injected into the Air Leak Meter through the NEEDLELESS INJECTION SITE using a standard luer slip tip syringe.

CAUTION: Use only a standard luer slip tip syringe to fill the Air Leak Meter. NO NEEDLE IS REQUIRED.

B-3 POSITIVE PRESSURE RELIEF VALVE

The Positive Pressure Relief Valve opens with increases 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 the button to relieve negativity. Filtered air will enter the unit.

WARNING: Stripping or milking of the patient drainage tube 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 SAHARA Plus System has an automatic high negative pressure relief valve to limit the negative pressure to approximately -50 cm of water.

C. COLLECTION CHAMBER

C-1 The Collection Chamber/Reinflation Chamber has a capacity of 1700 ml ($\pm 10\%$). The Collection Chamber is calibrated in 10 ml increments up to 50 ml and 50 ml increments up to 1700 ml. In the event fluid collected in the reinflation compartment is greater than 1050 ml, then the fluid will spill over into the 2nd collection compartment.

CAUTION: Only blood collected in the 1st collection chamber compartment is available for reinflation. Blood collected in the 2nd compartment cannot be easily reinfused.

When reading the collection chamber calibrations, note that there may be a decrease in original volume of the first compartment after fluids spill over into the next. (This may be attributed to surface tension "build-up".) The actual volume of the previous compartment(s) should therefore be checked if accuracy of the total reading is critical. "Spillover" from one compartment to the next should also be noted after the PLEUR-EVAC unit has been moved or handled.

When drainage reaches 1700 ml, 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.

C-2 SAMPLING

A self-sealing sampling port is provided in the Autotransfusion Connectors for taking samples of patient drainage. Use an 18 gauge (1.24 mm) or smaller needle, attached to a syringe, for withdrawing samples.

D. OTHER FEATURES

An attached floorstand swings out to stabilize the PLEUR-EVAC 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. A carrying handle is provided for ease of patient ambulation or transport of the unit.

Marking surfaces are for making notations. Use pen or pencil.

Two hangers are provided to hang the PLEUR-EVAC unit from a bed, O.R. stand or stretcher.

Autotransfusion Connectors (C-2, red and blue) are provided in the patient tube. Refer to the PLEUR-EVAC SAHARA Autotransfusion Bag Instructions for Use for attachment of the autotransfusion bag and use of these connectors.

E. AUTOTRANSFUSION OPTIONS

Autotransfusion can be accomplished by one of the following methods:

1. Continuous Reinfusion as described elsewhere on this page.
2. PLEUR-EVAC SAHARA Autotransfusion Bag Collection. Consult your Genzyme Representative and the instructions for use which accompany the PLEUR-EVAC SAHARA Autotransfusion Bag.
3. Genzyme Rapid Transfer Blood Bag for batch reinfusion. Consult your Genzyme Representative and the instructions for use which accompany the Genzyme Rapid Transfer Blood Bag.

CONTINUOUS REINFLUSION SET UP INSTRUCTIONS

A. COLLECTION AND CONTINUOUS REINFLUSION

1. Set up a blood compatible I.V. pump.
2. Obtain a microaggregate filter and administration set for use with that pump.
3. If the infusion pump being used requires prepriming with sterile saline:
 - a. Prime the microaggregate filter and administration set with sterile normal saline.
 - b. Assure the clamp on the exit port tube is open.
- c. Holding the tube below the bottom of the PLEUR-EVAC unit, gently milk the tube until it is primed with blood and free of air.
- d. Close the clamp on the exit port tube.
- e. Remove the tethered cap from the exit port tube, and spike the tube with saline primed microaggregate filter and administration set.
- f. Open the clamp.
4. If the infusion pump being used does not require pre-priming with saline:
 - a. Assure the clamp on the exit port tube is open.

- b. Holding the tube below the bottom of the PLEUR-EVAC unit, gently milk tube until it is primed with blood and free of air.
 - c. Close the clamp on the exit port tube.
 - d. Remove the tethered cap from the exit port tube and spike the tube with the microaggregate filter and administration set.
 - e. Position the microaggregate filter and the administration set in a spike up orientation for priming.
 - f. Open the clamp.
 - g. Use the I.V. pump or a 60 ml syringe and stopcock to prime the microaggregate filter and administration set with blood.
5. Position the exit port tube to maintain the filter and drip chamber in an upright position. Use the retainer post located on the top of the unit behind the patient port to secure the exit port tube.
 6. If needed, depress the High Negativity Relief Valve on the top of the PLEUR-EVAC unit to relieve excessive negativity.
 7. Make sure infusion line is filled with blood and contains no air. Attach the infusion line to the patient's I.V. catheter. Make sure all connections are secure.
 8. Set infusion rate as ordered by the physician.

B. DISCONTINUING CONTINUOUS REINFLUSION

At the conclusion of continuous reinfusion therapy, a decision is made to:

1. Discontinue reinfusion and use the PLEUR-EVAC SAHARA Plus System as a simple chest drainage collection unit. Keep the exit port tube in the upward position.
2. Begin autotransfusion bag collection for reinfusion. Refer to the SAHARA Autotransfusion Bag Set up Instructions.

CAUTION: Be sure the clamp on the exit port tube is in the closed position and the tethered cap is in place after discontinuing continuous reinfusion.

ANTICOAGULANTS

Anticoagulants may be used at the discretion of the physician. Add anticoagulant using an 18 gauge (1.24 mm) or smaller needle through the self-sealing injection site in the autotransfusion connector.