



Single Use **Rx ONLY**

STERILE EO

Sterile: Method of sterilization  
using ethylene oxide

**PLEUR-EVAC**

SAHARA®



CHEST DRAINAGE SYSTEM

**S-1100-08**

Instructions for Use

**PLEUR-EVAC SAHARA®**

Chest Drainage System

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0120

**Teleflex**  
MEDICAL

# PLEUR-EVAC



## CHEST DRAINAGE SYSTEM

SINGLE USE ONLY DO NOT RESTERILIZE

**STERILE:** Contents sterile unless package has been opened or damaged.

### PRODUCT DESCRIPTION

The PLEUR-EVAC SAHARA® Chest Drainage System is provided as a sterile, non-pyrogenic unit intended for single patient use. By attaching the PLEUR-EVAC SAHARA Autotransfusion Bag, the PLEUR-EVAC SAHARA Chest Drainage System serves as a collection/reinfusion system for autologous blood. These instructions will address the set-up and operation of the PLEUR-EVAC SAHARA Chest Drainage System. Refer to SAHARA Autotransfusion Bag instructions for use for attachment of the Autotransfusion Bag.

### INDICATIONS FOR USE

The PLEUR-EVAC 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

### WARNINGS

1. The collected contents of the PLEUR-EVAC SAHARA System should not be used for reinfusion.
2. Chest tubes should not be clamped except when changing PLEUR-EVAC SAHARA System. In the event of an air leak, clamping chest tubes could lead to a tension pneumothorax.
3. Stripping of the patient tubing 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 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 to fill the Air Leak Meter and a standard luer lock syringe to withdraw samples from the sampling port on the autotransfusion connector. **NO NEEDLE IS REQUIRED.**
6. Monitor the PLEUR-EVAC collection chamber. To avoid overflow, replace the unit before exceeding the fill capacity of 2000 ml indicated by the volume graduation printed on the collection chamber.

### DISPOSAL

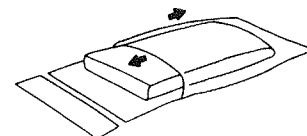
The PLEUR-EVAC SAHARA Chest Drainage System should be handled and disposed of in accordance with all applicable regulations including, without limitation, those pertaining to human health and safety and the environment.

### 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 good aseptic technique during set-up. DISCARD cap on patient tubing after set-up.

#### 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.

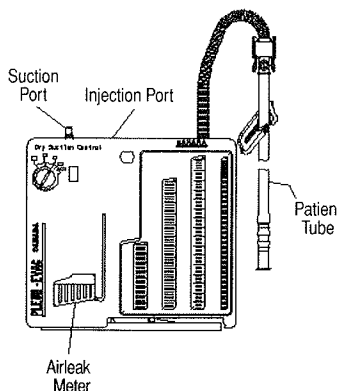


FIGURE 1

**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)

**4. SUCTION CONTROL** - A dial to set the suction control setting is located on the upper left side of the unit. **NO WATER IS NEEDED IN THE SUCTION CONTROL CHAMBER.** To set the suction control setting, rotate the dial until the red stripe appears in the semi-circular window at 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.

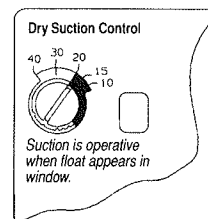


FIGURE 2

**5. SUCTION SOURCE** - Increase suction source until the orange float appears in the suction control indicator window. The setting of the suction control 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 -20 cm of water and the float in the indicator window.

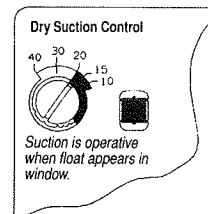


FIGURE 3

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

# PLEUR-EVAC SAHARA® CHEST DRAINAGE INSTRUCTIONS

## A. SUCTION CONTROL CHAMBER

### A-1 SUCTION DIAL

The suction level is determined by the position of the red stripe in the semi-circular suction control window. Rotate the dial to adjust the desired suction level.

### A-2 SUCTION INDICATOR

When suction is applied and 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 suction setting ( $\pm 4$  cm of water) that appears in the suction control window.

**NOTE:** In the presence of a large air leak air flow through the PLEUR-EVAC 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 SAHARA 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)

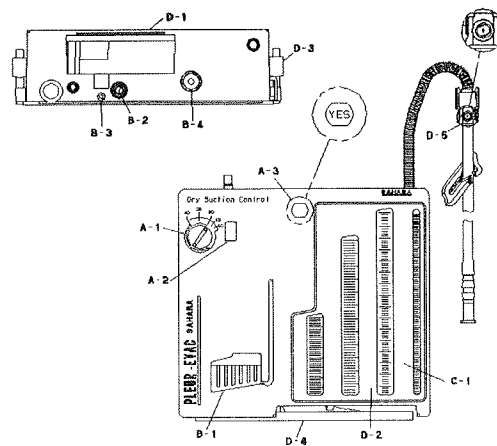
### GRAVITY DRAINAGE

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.

### A-3 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 AIR LEAK DIAGNOSTICS**—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.

The small arm of the patient air leak meter will display tideling 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 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** 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** 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 SAHARA 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** has a capacity of 2000 ml ( $\pm 10\%$ ). The collection chamber is calibrated in 2 ml increments up to 50 ml and 5 ml increments up to 500 ml. Over 500 ml, calibrations are in 10 ml increments. Fluids overflow from one compartment to the next. When reading the collection chamber calibrations, please 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.

When drainage reaches 2000 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.

## D. OTHER FEATURES

**D-1** A carrying handle is provided for ease of patient ambulation or transport of the unit.

**D-2** Marking surfaces are for making notations. Use pen or pencil.

**D-3** Two hangers are provided to hang the PLEUR-EVAC SAHARA from a bed, O.R. stand or stretcher.

**D-4** An attached floorstand swings out to stabilize the PLEUR-EVAC SAHARA unit when it is set on the floor. The floorstand contains an automatic locking mechanism that locks the floorstand into the open position. To close, press the locking tab and rotate the floorstand.

**D-5** Autotransfusion connectors (red and blue) are provided in the patient tube. A needleless sampling site is provided in the connector for taking samples of patient drainage. Use a standard luer lock syringe for withdrawing samples. The connector and syringe can be inverted to facilitate sample collection.

**CAUTION:** Use only a standard luer lock syringe to withdraw samples from the Autotransfusion connector. NO NEEDLE IS REQUIRED.

SINGLE USE ONLY DO NOT RESTERILIZE Rx ONLY

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STERILE EO

**INDICATIONS FOR USE**

The PLEUR-EVAC SAHARA® Autotransfusion Bag is a sterile, non-pyrogenic, single use device used for collection and reinfusion of autologous blood from the thoracic cavity when attached to a PLEUR-EVAC SAHARA System.

**PRODUCT DESCRIPTION**

The PLEUR-EVAC SAHARA Autotransfusion Bag contains a 200 micron filter for filtration of particulates from shed blood. Attached to the Autotransfusion Bag are two tubes, one for collecting the shed blood into the bag, the other for connection to the PLEUR-EVAC SAHARA System. This bag may be used as the initial collection bag by attaching it to a PLEUR-EVAC SAHARA System that contains connectors for this purpose. It may also be used as a replacement bag after a bag is removed from a PLEUR-EVAC SAHARA System.

Increments for measuring the amount of drainage collected are printed on the Autotransfusion Bag (ml±10%). These increments are calibrated for use with gravity drainage and at -20cm of water suction. A conversion chart for -30cm of water and -40cm of water suction appears on the bag. Capacity of the Autotransfusion Bag is approximately 1400ml gravity and 800ml at -20cm of water. All collection volume measurements must be made with the Autotransfusion Bag on the support frame.

A conversion chart for -30cm of water and -40cm of water suction appears on the bag. Record the drainage volume from the suction scale. Multiply the recorded volume by the number as noted in the conversion chart for either -30cm of water or -40cm of water. This will be the drainage volume at these other operating pressures. The PLEUR-EVAC SAHARA Autotransfusion Bag can be used with the PLEUR-EVAC SAHARA Chest Drainage System, or with the PLEUR-EVAC SAHARA Continuous Reinfusion System.

**CONTRAINDICATIONS**

- ◆ 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.

**ADVERSE REACTIONS**

The following complications have been known to occur during autotransfusion:

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

**WARNINGS**

1. A microaggregate filter must be used during reinfusion. A new microaggregate filter must be used with each new autotransfusion bag.
2. Only reinfuse blood that has been collected in the flexible Autotransfusion Bag.
3. Blood collected in the PLEUR-EVAC SAHARA System must not be reinfused.
4. Fully prime the blood administration set and 40 micron microaggregate filter. If all air is not removed from the system prior to reinfusion, air embolism may result.
5. Carefully monitor the patient line when pressure reinfusing to prevent the infusion of air. Clamp the line when the drip chamber empties.
6. Do not perform continuous reinfusion unless a minimum of 50ml of blood remains in the bag after the reinfusion system, including microaggregate filter, has been primed with blood or sterile saline.
7. Stripping of the thoracic tubing can cause excessive negativity. Use the high negativity relief valve on the PLEUR-EVAC SAHARA System to restore negativity to prescribed levels.
8. Stripping of the thoracic tubing must be done with the thoracic tubing open. Stripping with the clamps closed can result in the build-up of excessive positive pressure.

**CAUTIONS**

1. When pressure reinfusing, pressure cuff infusion pressure should not exceed 150mm Hg.
2. Blood collected in the Autotransfusion Bag must be reinfused within 6 hours of the beginning of collection.

**ANTICOAGULANTS**

Anticoagulants may be used at the discretion of the physician. Add anticoagulant using an 18 gauge (1,24mm) or smaller needle through the self-sealing injection site in the connector.

**DISPOSAL**

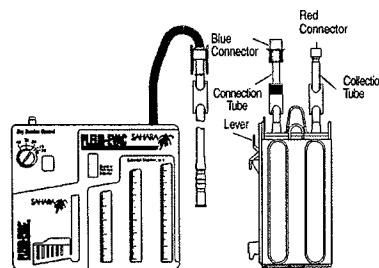
The PLEUR-EVAC SAHARA Systems and Autotransfusion Bags should be handled and disposed of in accordance with all applicable regulations including, without limitation, those pertaining to human health and safety and the environment. Caution should be used when the possibility exists for exposure to blood or body fluids. Follow hospital policy regarding use of protective wear.

**SET UP INSTRUCTIONS**

Careful attention to the instructions and the use of aseptic technique is necessary in order to maintain sterility.



1. Unwrap the PLEUR-EVAC SAHARA Autotransfusion Bag.
2. Close the two clamps on the top of the Autotransfusion Bag.
3. Align the bottom leg and the lever of the adaptor with their mating receptacles on the PLEUR-EVAC SAHARA System. Insert with a downward motion until the lever "clicks" into position. The Autotransfusion Bag should be firmly attached to the PLEUR-EVAC SAHARA System.
4. Close the clamp on the patient tube and milk blood from the tubing into the PLEUR-EVAC SAHARA System.
5. Separate the red and blue connectors on the patient tube.
6. Remove the red protective cap from the collection tube on the Autotransfusion Bag. Connect this tube, using the red connectors, to the patient tube.
7. Remove the blue protective cap from the connection tube on the Autotransfusion Bag. Connect this tube, using the blue connectors, to the short PLEUR-EVAC SAHARA tube.
8. OPEN ALL CLAMPS. Make sure all connections are secure. The autotransfusion system is now operational.
9. If prescribed, anticoagulants may be added as directed by the physician. (see ANTICOAGULANTS).



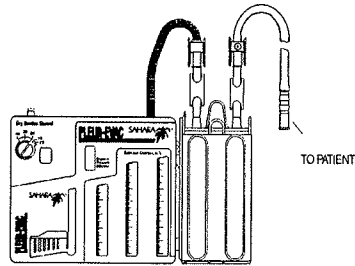
PLEUR-EVAC SAHARA System

PLEUR-EVAC SAHARA  
Autotransfusion Bag

## COLLECTION

Blood collected in the Autotransfusion Bag must be reinfused within 6 hours of the beginning of collection. For reinfusion of the collected blood, a decision is made to:

- ◆ Discontinue autotransfusion collection and prepare the bag for reinfusion. Complete chest drainage with the PLEUR-EVAC SAHARA System; or,
- ◆ Add another Autotransfusion Bag and continue autotransfusion collection; or,
- ◆ Leave the autotransfusion bag attached and perform continuous reinfusion.



PLEUR-EVAC SAHARA System  
with attached Autotransfusion Bag

## TO DISCONTINUE AUTOTRANSFUSION COLLECTION AND RESUME DRAINAGE IN SYSTEM

1. Use the high negativity relief valve on the PLEUR-EVAC SAHARA System to reduce excessive negativity.
2. Close the clamp on the patient tube and both clamps on the Autotransfusion Bag.
3. Separate the red connectors on the patient tube and the blue connectors on the connector tube.
4. Connect together the red and blue connectors on the Autotransfusion Bag.
5. Securely attach the red and blue connectors joining the patient tube (red connector) to the short PLEUR-EVAC SAHARA tube (blue connector).
6. Open the clamp on the patient tube.
7. Patient drainage will now be collected in the PLEUR-EVAC SAHARA System.
8. Remove the Autotransfusion Bag from PLEUR-EVAC SAHARA System by depressing the lever and lifting up the Autotransfusion Bag.
9. Prepare the Autotransfusion Bag for reinfusion.

## TO CHANGE AUTOTRANSFUSION BAG

1. Use the high negativity relief valve on the PLEUR-EVAC SAHARA System to reduce excessive negativity.
2. Obtain and unwrap the new PLEUR-EVAC SAHARA Autotransfusion Bag.
3. Close the two clamps on the top of the new Autotransfusion Bag.
4. Close the clamp on the patient tube and both clamps on the existing Autotransfusion Bag.
5. Separate the red connectors on the patient tube and the blue connectors on the connector tube.
6. Remove the red protective cap from the collection tube on the Autotransfusion Bag. Connect this tube, using the red connectors, to the patient tube.
7. Remove the blue protective cap from the connection tube on the Autotransfusion Bag. Connect this tube, using the blue connectors, to the short PLEUR-EVAC SAHARA Tube.
8. Remove the existing Autotransfusion Bag from the PLEUR-EVAC SAHARA System by pressing the lever and lift the Autotransfusion Bag up until it is free of the PLEUR-EVAC SAHARA System.
9. Attach the new Autotransfusion Bag to the PLEUR-EVAC SAHARA System. Align the bottom leg and the lever of the adaptor with their mating receptacles on the PLEUR-EVAC SAHARA System. Insert with a downward motion until the lever "clicks" into position. The Autotransfusion Bag should be firmly attached to the PLEUR-EVAC SAHARA System.
10. OPEN ALL CLAMPS.

## PREPARING FOR GRAVITY OR PRESSURE CUFF REINFUSION

1. Remove the adaptor bracket from the wire frame by twisting it slightly to disengage the bottom and then unhook the top.
2. Slide the Autotransfusion Bag off the wire support frame. Make sure the red and blue connectors on the top of the unit are secure. Ensure the clamps are closed.
3. Invert the bag so the spike port points upwards. Remove the protective cap.
4. Insert a microaggregate filter into the spike port using a constant twisting motion. Attach infusion set. Follow manufacturer's directions for attaching.
5. Evacuate residual air from the bag. Open the infusion set clamp, keeping the unit inverted, and carefully squeeze all the air from the bag through the filter and drip chamber assembly.
6. With infusion set clamps open and keeping the bag inverted, gently squeeze the Autotransfusion Bag, allowing blood to slowly prime the filter. Continue squeezing until the filter is saturated with blood and the drip chamber is half full. Close the clamp on the infusion line.
7. Invert the Autotransfusion Bag and suspend from an I.V. pole using the plastic strap.
8. Open the infusion set clamp and carefully flush the administration line to remove air.

## CONTINUOUS REINFUSION

1. Set up a blood compatible I.V. pump.
2. Obtain a microaggregate filter and administration set for use with that pump.
3. Prime the filter, drip chamber and administration set with normal saline. Remove the bag of normal saline.
4. Remove the blue protective cap from the Autotransfusion Bag, and spike the bag with the blood filter.
5. Use an I.V. pump to prime the filter, drip chamber and infusion line with blood.
6. If needed, depress the high negativity relief valve on the top of the PLEUR-EVAC SAHARA System to relieve excessive negativity.
7. Make sure the infusion line is filled with blood and contains no air. Attach to the patient's I.V. catheter. Make sure all connections are secure.
8. Set infusion rate as ordered by physician.
9. Attach the PLEUR-EVAC SAHARA System and Autotransfusion Bag to bed rail using hangers.

## REINFUSION

1. Attach the distal end of infusion set assembly to appropriate patient line.
2. Infuse blood according to approved hospital procedure, using gravity or pressure reinfusion.

