

SINGLE USE ONLY DO NOT RESTERILIZE Rx ONLY

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

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.

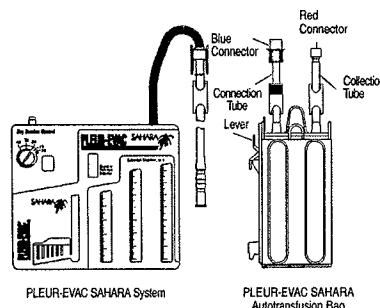
DISPOSAL

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.

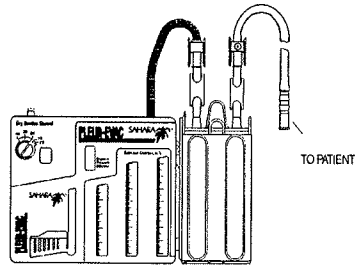
1. Unwrap the PLEUR-EVAC SAHARA Autotransfusion Bag.
2. Close the two clamps on the top of the Autotransfusion Bag.
3. Align the bottom leg and the lever of the adaptor with their mating receptacles on the PLEUR-EVAC SAHARA System. Insert with a downward motion until the lever "clicks" into position. 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).



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.

