

# PLEUR-EVAC<sup>®</sup>

## AUTOTRANSFUSION BAG



**SINGLE USE ONLY DO NOT RESTERILIZE**

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

**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

**STERILE EO** ②

### INDICATIONS FOR USE

The PLEUR-EVAC<sup>®</sup> 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 Chest Drainage Unit.

### PRODUCT DESCRIPTION

The PLEUR-EVAC 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 Unit.

This bag may be used as the initial collection bag by attaching it to a PLEUR-EVAC Unit that contains connectors for this purpose. It may also be used as a bag after a bag is removed from a PLEUR-EVAC Unit. Increments for measuring the amount of drainage collected are printed on the Autotransfusion Bag. These increments are calibrated for use with gravity drainage and at -20 cm of water suction. Capacity of the Autotransfusion Bag is approximately 1400 ml (ml  $\pm$  10%) gravity and 800 ml at -20 cm of water. All collection volume measurements must be made with the Autotransfusion Bag on the support frame. A conversion chart for -30 cm of water and -40 cm 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 -30 cm of water or -40 cm of water. This will be the drainage volume at these other operating pressures.

### 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 Unit 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 50 ml 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 patient tube can cause excessive negativity. Use the High Negativity Relief Valve on the PLEUR-EVAC Unit to restore negativity to prescribed levels.
8. Stripping of the patient tube must be done with the tubing clamp 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 150 mmHg.
2. Blood collected in the Autotransfusion Bag must be reinfused within 6 hours of the beginning of collection.
3. Monitor the PLEUR-EVAC collection chamber to avoid overflow. Replace the unit before exceeding the fill capacity of PLEUR-EVAC indicated by the volume graduation printed on the collection chamber.

### ANTICOAGULANTS

Anticoagulants may be used at the discretion of the physician.

Add anticoagulant using a standard needless luer lock syringe through the self-sealing injection site in the ATS connector. Either CPD or heparin may be used.

### DISPOSAL

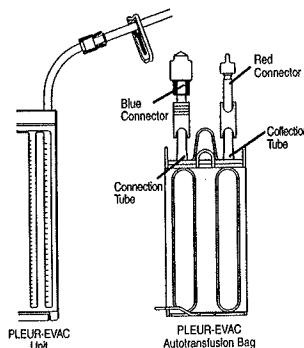
The PLEUR-EVAC Chest Drainage Unit and Autotransfusion Bag should be handled and disposed of in accordance with all applicable regulations including, without limitation, those pertaining to human health and safety and the environment. Caution should be used when the possibility exists for exposure to 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 Autotransfusion Bag.
2. Close the two clamps on the top of the Autotransfusion Bag.
3. Close the clamp on the PLEUR-EVAC patient tube and milk blood from the patient tube into the PLEUR-EVAC Unit.
4. Separate the red and blue connectors on the patient tube.
5. Remove the red protective cap from the collection tube on the Autotransfusion Bag. Connect this tube, using the red connectors, to the PLEUR-EVAC patient tube.
6. 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 tube.
7. **OPEN ALL CLAMPS.** Make sure all connections are secure. The autotransfusion system is now operational.
8. Attach the Autotransfusion Bag to the PLEUR-EVAC

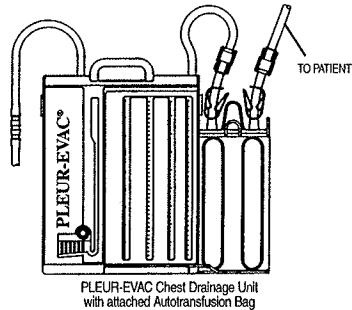
9. If prescribed, anticoagulants may be added, as directed by the physician (see ANTICOAGULANTS).



## 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 Chest Drainage Unit; or,
- ◆ Add another Autotransfusion Bag and continue autotransfusion collection; or,
- ◆ Leave the Autotransfusion Bag attached and perform continuous reinfusion.



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

## TO DISCONTINUE AUTOTRANSFUSION COLLECTION AND RESUME DRAINAGE IN THE PLEUR-EVAC

1. Use the High Negativity Relief Valve on the PLEUR-EVAC Unit 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 tube (blue connector).
6. Open clamp on patient tube.
7. Patient drainage will now be collected in the PLEUR-EVAC Chest Drainage Unit.
8. Remove the Autotransfusion Bag from PLEUR-EVAC Unit by removing autotransfusion bag frame from the hanger on side of unit. Disconnect the foot hook from the PLEUR-EVAC Unit.
9. Prepare the Autotransfusion Bag for reinfusion.

## TO CHANGE AUTOTRANSFUSION BAG

1. Use the High Negativity Relief Valve on the PLEUR-EVAC Unit to reduce excessive negativity.
2. Obtain and unwrap the new 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 PLEUR-EVAC 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 tube.
8. Remove the existing Autotransfusion Bag from the PLEUR-EVAC Unit by removing autotransfusion bag frame from hanger on side of unit. Disconnect the foot hook from the PLEUR-EVAC Unit.
9. Attach the new bag to the PLEUR-EVAC Unit using the foot hook and autotransfusion hanger on side of unit.
10. OPEN ALL CLAMPS.

## PREPARING FOR GRAVITY OR PRESSURE CUFF REINFUSION

1. 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.
2. Invert the bag so the spike port points upwards. Remove the protective cap.
3. Insert a microaggregate filter into the spike port using a constant twisting motion. Attach infusion set. Follow manufacturer's direction for attaching.
4. 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.
5. 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.
6. Invert the Autotransfusion Bag and suspend from an I.V. pole using the plastic strap.
7. 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 Unit 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 Chest Drainage Unit 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.

