

STERILE EO

PLEUR-EVAC SAHARA®
RAPID TRANSFER BLOOD BAG
For Use With SAHARA Continuous Reinfusion
Autotransfusion Systems



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Instructions for Use
PLEUR-EVAC SAHARA® Rapid Transfer Blood Bag
For Use With SAHARA Continuous Reinfusion
Autotransfusion Systems

Instruções de utilização
Saco para sangue de transferência rápida
PLEUR-EVAC SAHARA®
Para utilização com os Sistemas de
autotransfusão de reinfusão contínua SAHARA

Mode d'emploi
Poche de sang pour transfusion rapide
PLEUR-EVAC SAHARA®
Pour usage avec les systèmes d'autotransfusion à
réinjection continue SAHARA

Οδηγίες Χρήσης
Σάκος ταχείας μεταφοράς αίματος
PLEUR-EVAC SAHARA®
Για χρήση με τα Συστήματα αυτομετάγγισης συνεχούς
επανεγγύσης SAHARA

Gebrauchsanleitung
PLEUR-EVAC SAHARA® Schnelltransfer-Blutbeutel
Zur Verwendung mit SAHARA Autotransfusions-
systemen zur kontinuierlichen Reinfusion

Bruksanvisning
PLEUR-EVAC SAHARA® snabbörföringspåse
för blod
För användning tillsammans med SAHARA
autotransfusionssystem för kontinuerlig reinfusion

Istruzioni per l'uso
Sacca ematica per trasferimento rapido
PLEUR-EVAC SAHARA®
Prevista per l'uso con i sistemi di
autotrasfusione a reinfusione continua SAHARA

Käyttöohjeet
PLEUR-EVAC SAHARA® Rapid Transfer -veripussi
Käytetään yhdessä SAHARA -jatkuvan reinfuusion-
autotransfuusionjärjestelmän kanssa

Instrucciones de uso
Bolsa de sangre de transferencia rápida
PLEUR-EVAC SAHARA®
Para uso con sistemas de autotransfusión
de reinfusión continua SAHARA

Bruksanvisning
PLEUR-EVAC SAHARA® blodpose for
hurtigoverføring
Brukes sammen med SAHARA kontinuerlig
reinfusion/autotransfusjonssystemer

Gebruiksaanwijzing
PLEUR-EVAC SAHARA® sneltransfer bloedzak
Te gebruiken met SAHARA
autotransfusiesystemen voor continue reïfusie

Brugsanvisning
PLEUR-EVAC SAHARA® blodpose til hurtig
blodoverførsel
Anvendes sammen med SAHARA
autotransfusionssystemer til kontinuerlig reinfusion



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PLEUR-EVAC SAHARA®
RAPID TRANSFER BLOOD BAG



Teleflex
 MEDICAL

700 ml Capacity (ml±10%)

STERILE EO



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CONTENTS: One (1) Unit

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.



PRODUCT DESCRIPTION

The PLEUR-EVAC SAHARA® Rapid Transfer Blood Bag is a blood evacuation device for use with Genzyme Surgical Products SAHARA Continuous Reinfusion Autotransfusion Systems (SAHARA models that have a reinfusion tube and spike port). The PLEUR-EVAC SAHARA Rapid Transfer Blood Bag provides for the rapid transfer of blood from SAHARA Continuous Reinfusion Autotransfusion Systems without disconnecting the patient from the chest drain.

INDICATIONS FOR USE

The PLEUR-EVAC SAHARA Rapid Transfer Blood Bag is a sterile, non-pyrogenic, single use device used for blood evacuation and reinfusion of shed mediastinal or pleural drainage when attached to a SAHARA Continuous Reinfusion Autotransfusion System.

ADVERSE REACTIONS

The following complications have been known to occur during autotransfusion:

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

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.

TO OPEN PACKAGE

1. Grasp the bottom edge of flap and pull up to open pouch.
2. Remove the wrapped Rapid Transfer Blood Bag from pouch and unwrap using aseptic technique.

SETUP and ACTIVATION INSTRUCTIONS

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

Attach the Rapid Transfer Blood Bag to the SAHARA Continuous Reinfusion Autotransfusion System

1. To optimize blood flow, reduce the suction setting to the 20 cm H₂O level or lower prior to connecting the Rapid Transfer Blood Bag to the SAHARA Continuous Reinfusion Autotransfusion System.
2. The SAHARA Continuous Reinfusion Autotransfusion System airleak meter injection site is configured with a needleless port injection site.
 - A. Attach the red relief valve provided with the Rapid Transfer Blood Bag by inserting firmly into the SAHARA Continuous Reinfusion Autotransfusion System needleless port injection site (reference Figure 1).
3. Close the clamp on the SAHARA Continuous Reinfusion Autotransfusion System reinfusion line.
4. Remove the clear spike port cap on the SAHARA Continuous Reinfusion Autotransfusion System reinfusion line.
5. Remove the white spike cap on the Rapid Transfer Blood Bag.
6. Insert the spike from the Rapid Transfer Blood Bag into the spike port on the SAHARA Continuous Reinfusion Autotransfusion System reinfusion line (reference Figure 2).
7. OPEN THE CLAMP on the SAHARA Continuous Reinfusion Autotransfusion System reinfusion line.
8. Position the Rapid Transfer Blood Bag below the level of the SAHARA Continuous Reinfusion Autotransfusion System to optimize transfer of blood.

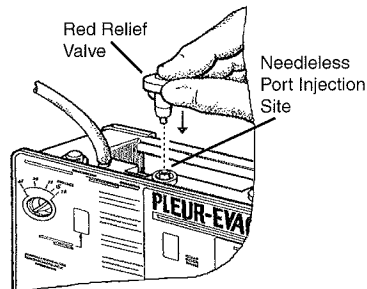


Figure 1

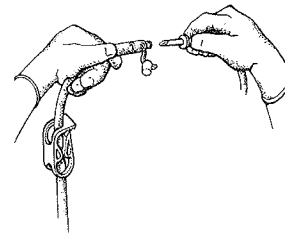


Figure 2

Activate the Rapid Transfer Blood Bag

1. After the Rapid Transfer Blood Bag is positioned below the SAHARA Continuous Reinfusion Autotransfusion System, ensure that the tubing clamps on the reinfusion line and the Rapid Transfer Blood Bag are OPEN.
2. Gently lift the actuator handle on the Rapid Transfer Blood Bag to the upright locking position to begin blood transfer. Maintain the Rapid Transfer Blood Bag below the level of the SAHARA Continuous Reinfusion Autotransfusion System (reference Figure 3).
3. When activated, the Rapid Transfer Blood Bag will begin to expand and will fill with blood as it is drawn from the SAHARA Continuous Reinfusion Autotransfusion System. End transfer prior to drawing air from the SAHARA Continuous Reinfusion Autotransfusion System by clamping the SAHARA Continuous Reinfusion Autotransfusion System reinfusion line.

CAUTION: Do not activate the Rapid Transfer Blood Bag prior to connecting to the SAHARA Continuous Reinfusion Autotransfusion System.

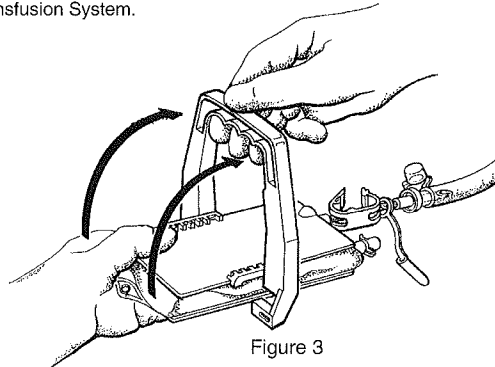


Figure 3

REINFUSION INSTRUCTIONS

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

Disconnecting the Rapid Transfer Blood Bag from the SAHARA Continuous Reinfusion Autotransfusion System

1. After the blood transfer is completed, close the clamps on the SAHARA Continuous Reinfusion Autotransfusion System reinfusion line and on the Rapid Transfer Blood Bag.
2. **REMOVE** the red relief valve and discard.
3. Move the actuator handle back toward the home position to disengage the handle from the bag. Discard the handle (reference Figure 4).
4. Volume can be determined from the graduations on the front panel before priming.
5. Remove the spike from the spike port and cap the spike with the red cap attached to the Rapid Transfer Blood Bag.
CAUTION: The clamp must remain closed on the Rapid Transfer Blood Bag inlet tube to prevent blood spillage.
6. Replace the clear cap on the spike port on the SAHARA Continuous Reinfusion Autotransfusion System reinfusion line.
CAUTION: The clamp must remain closed on the SAHARA Continuous Reinfusion Autotransfusion System reinfusion line to prevent blood spillage.

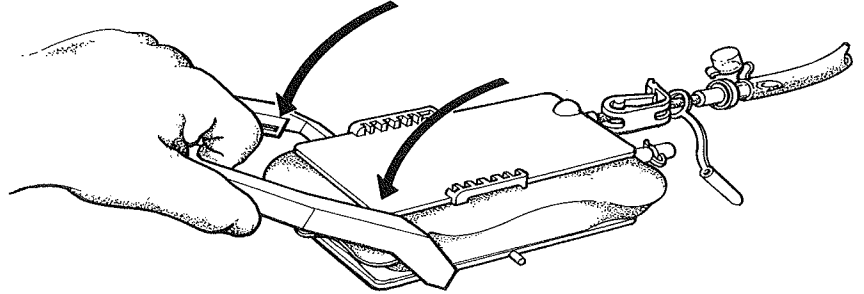


Figure 4

Reinfusion Setup

1. Position the Rapid Transfer Blood Bag so the spike port is pointing upwards. Remove the protective cap.
2. Insert a microaggregate filter into the spike port using a constant twisting motion. Attach the infusion set to the microaggregate filter. Follow manufacturer's directions for attaching.
3. Evacuate residual air from the Rapid Transfer Blood Bag. Prime the filter and blood administration set by gently squeezing the Rapid Transfer Blood Bag until the filter is saturated with blood and the drip chamber is half full. Close the clamp on the infusion line.
4. Invert the Rapid Transfer Blood Bag and suspend from an IV pole.
5. Open the infusion line clamp and carefully prime the remaining length of the infusion line to remove all air.
WARNING: 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.

Reinfusion

1. Attach the distal end of the primed infusion set to the appropriate patient line.
2. Infuse blood according to approved hospital policy, using either gravity reinfusion or pressure reinfusion.
WARNING: Pressure cuff infusion pressure must not exceed 150 mm Hg.
WARNING: Carefully monitor the patient line when pressure reinfusing to prevent the infusion of air. Clamp the line when the drip chamber empties.

WARNINGS

1. A new microaggregate filter must be used during reinfusion. A new microaggregate filter must be used with each new Rapid Transfer Blood Bag.
2. 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.
3. Carefully monitor the patient line when pressure reinfusing to prevent the infusion of air. Clamp the line when the drip chamber empties.
4. Chest tubes must not be clamped except when changing the SAHARA Continuous Reinfusion Autotransfusion System. In the event of a patient air leak, clamping the chest tube could lead to a tension pneumothorax.

CAUTIONS

1. When pressure reinfusing, pressure cuff infusion pressure must not exceed 150 mm Hg.
2. Collected autologous blood must be reinfused within six (6) hours of the beginning of collection.
3. Keep the SAHARA Continuous Reinfusion Autotransfusion System below the patient's chest level at all times.
4. Avoid loops in the patient drainage tube.
5. After discontinuing blood transfer, make sure the clamp on the SAHARA Continuous Reinfusion Autotransfusion System reinfusion line is closed and the tethered cap is securely in place.
6. After discontinuing blood transfer, make sure the clamp on the Rapid Transfer Blood Bag inlet tube is closed and the red cap is securely in place on the spike.
7. Remove the red relief valve from the SAHARA Continuous Reinfusion Autotransfusion System after blood transfer.

ANTICOAGULANTS

Anticoagulant (ACD-A, CPD) may be used at the discretion of the physician. The amount of anticoagulant used should be adjusted according to the patient's condition and type of procedure. Careful attention should be paid to the amount of anticoagulant used and to the amount of shed blood collected in order not to exceed the American Association of Blood Banks recommended anticoagulant/blood ratio of 1:5 to 1:10.

Anticoagulant may be added through the self-sealing injection site located on the SAHARA Continuous Reinfusion Autotransfusion System snap-lock connectors, when desired, and as specified by the physician. Add the anticoagulant by inserting an 18 gauge (1,24 mm) or smaller needle.

DISPOSAL

The SAHARA Rapid Transfer Blood 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.

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