

Chest Drain Autotransfusion

GB **Instructions For Use**

Instructions For Use

USA

GB

Chest Drain Autotransfusion

Drainage thoracique d'autotransfusion

Autotransfusionssystem für Thorax-Drainage

Sistema de autotransfusión para drenaje torácico

Autotrasfusione per drenaggio toracico

Transfusão automática para drenagem torácica

Thoraxdrain met een ATS-autotransfusiesysteem

Brystdræn med autotransfusionssystem

Autotransfusionsanordning för thoraxdränageslang

Autotransfusiolaite pleuraimua varten

Autotransfusionsanordning för thoraxdränageslang

Thoraxdrenasje med et autotransfusjonssystem

Αυτομεγγύαση για Παροχέτευση

Dren piersiowy do autotransfuzji

胸腔ドレナージ自家輸血

ATRIUM

ATRIUM MEDICAL CORPORATION
5 Wentworth Drive
Hudson, New Hampshire 03051 U.S.A.
☎ 603-880-1433 📠 603-880-6718

ATRIUM EUROPE B.V.
Rendementsweg 20B
3641 SL Mijdrecht, The Netherlands
☎ +31-297-230-420 📠 +31-297-282-653

EC REP

ATRIUM AUSTRALIA-PACIFIC RIM PTY. LTD.
Level 6, 579 Harris Street
Ultimo NSW 2007 Australia
☎ +61-2-8272-3100 📠 +61-2-8272-3199

©2010
Atrium is a trademark
of Atrium Medical Corporation
Rev. 2010/04

CE 0086

001813

www.atriummed.com

Indications For Use

Collection of autologous blood from the patient's pleural cavity or mediastinal area for reinfusion purposes in postoperative and trauma blood loss management.

Contraindications For Autotransfusion

Reinfusion of autologous blood is contraindicated in the presence of one or more of the following intraoperative and postoperative conditions:

- Coagulopathy or D.I.C.
- Pericardial, mediastinal, or systemic infections.
- Pulmonary and respiratory infection or infestation.
- Presence of malignant neoplasm.
- Enteric contaminated thoraco-abdominal cavities.
- Intraoperative thoracic or mediastinal cavity use of topical thrombin, microfibrillar hemostatic agents or povidone-iodine antiseptic gels or solutions.

Warnings

1. Collected autologous blood should not remain in the chest drain or ATS bag collectively for more than 6 hours prior to autotransfusion. Atrium recommends that the most recently published standards from the American Association of Blood Banks be referenced for specific information regarding blood handling, anticoagulants, storage conditions, and maximum storage times.
2. Patient tube clamp must remain open during chest drainage operation.
3. Prior to I.V. circuit patient connection, it is important to purge all air from the blood filter and I.V. administration set. Failure to purge all air from the complete I.V. circuit prior to patient connection can result in air emboli.
4. Do not reinfuse entire ATS blood bag contents completely through microemboli blood filter and I.V. set, as air emboli can result.
5. Rapid infusion of citrate anticoagulated blood may cause citrate toxicity and myocardial depression. Indications are tingling sensations around the mouth, followed by stomach cramps and possible arrhythmia.
6. For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.

Precautions

1. Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
2. For any procedure requiring direct reinfusion of shed autologous blood, a microemboli blood filter suitable for autotransfusion must be used.
3. In-line ATS bag clamps must remain firmly clamped at all times after disconnection from the chest drain, during patient infusion and for unit disposal.
4. Do not hang or hand carry ATS bag by its tubing; use hanger provided.
5. Replace spike port cap immediately following blood filter removal from ATS access line.
6. This product is for single patient use and for one time patient connection only.
7. Do not resterilize this device.
8. Do not pressure infuse ATS bag with air vent open.
9. Air vent must remain closed at all times when not in use.
10. Maximum infusion pressure: 150mmHg.
11. Anticoagulant therapy and dosage recommendations are at the discretion of a physician, and should be monitored carefully during and after patient reinfusion.
12. Please refer to all manufacturer's directions for use, warnings and cautions for anticoagulant medications, microemboli filters, I.V. blood administration sets, blood compatible infusion pumps and pressure infuser devices prior to use with this ATS bag.
13. All hospital protocols for blood handling, anti-coagulant administration, autotransfusion, pressure infusion of blood, disposal handling and infection control should be carefully followed.
14. A new microemboli blood filter must be used for each ATS bag.

Adverse Reactions

Adverse reactions such as coagulopathy, D.I.C., blood trauma and particulate embolism have been reported to occur during and after autotransfusion of shed mediastinal/pleural blood from surgery and chest trauma.

Setup For Continuous ATS

For direct reinfusion of shed autologous blood via a blood compatible infusion pump, a microemboli blood filter and non-vented, blood compatible I.V. administration set must be used. **Please refer to all pump manufacturer's Directions for Use and Warnings and Cautions prior to use.**

Infusion Pump Setup

Non self-priming infusion pumps, filter and I.V. set can be primed by aspirating air out of the I.V. circuit with a three-way stopcock and syringe or pre-primed with saline prior to attachment to the blood filter.

1. Clamp ATS access line
2. Place ATS access line around hanger or patient line before spiking filter
3. Remove spike port cap and insert blood filter
4. Spike blood set into filter
5. Attach 3-way stopcock to patient end of IV set
6. Connect 60cc luer lock syringe to side port of stopcock
7. Open free flow setting on pump & cassette
8. Turn filter in "spike down" position
9. Unclamp ATS access line and IV tubing
10. Use 60cc syringe to aspirate blood
11. When drip chamber is 1/2 full, turn spike up and continue purging air from line
12. When completed, insert IV cassette into pump
13. Purge all air prior to patient connection
14. Set pump to desired "volume to be infused" and "ml per hour"

Setup For Self-Filling ATS Blood Bag

1. Close chest drain ATS access line clamp and remove spike port cap. Insert ATS bag spike into access line. Position ATS bag below the base of the chest drain.
2. Open both clamps. Holding ATS bag below base of chest drain, bend ATS bag upward where indicated. Do not activate ATS bag prior to connecting chest drain.
3. If necessary, squeeze ATS bag to allow more blood volume into bag.
4. Close ATS access line and ATS blood bag clamps. Remove spike from ATS access line and insert into spike holder. Recap ATS access line spike port and position access line in the holder located on top of the chest drain. Keep ATS clamp fully closed at all times when not in use.

Setup For In-Line ATS Blood Bag

1. Place onto chest drain, close both bag clamps prior to cap removal
2. Connect ATS Bag to chest drain
3. Open clamps to begin blood collection
4. To disconnect bag from chest drain, close patient tube clamp and ATS bag clamps. Disconnect from drain first then from patient side.
5. Reconnect patient line to drain, connect male and female bag connectors and unclamp patient line.

ATS Bag Reinfusion Setup

1. Prime I.V. blood administration and microemboli blood filter with sterile saline.
2. Invert ATS bag with spike port pointing upward and remove cap using sterile technique. Insert saline filter spike into ATS bag spike port. Return bag to upright position and place on standard height I.V. pole.
3. Open air vent and I.V. clamp to complete priming. All air within the I.V. circuit must be evacuated prior to patient connection. Close I.V. clamp when primed. I.V. is now ready for connection.
4. Attach primed I.V. set to patient and open clamp.

SYMBOLS USED ON PRODUCT LABELS

REF CODE NUMBER LOT LOT NUMBER

STERILE EO STERILE. STERILIZED BY ETHYLENE OXIDE.

STERILE R STERILE. STERILIZED BY GAMMA RADIATION.

SEE PACKAGE INSERT SINGLE USE ONLY EXPIRATION DATE

ATS Bag Compatible ATS Chamber Rx Only Prescription Only

This device is covered under one or more of the following U.S. patents:
4,988,342; 5,114,416; 5,154,712; 5,286,262.

Other patents pending.
Atrium is a trademark of Atrium Medical Corporation.
©2010 All Rights Reserved.

ATRIUM

CE 0086

ATRIUM MEDICAL CORPORATION
5 Wentworth Drive, Hudson, New Hampshire 03051 U.S.A.
☎ 603-880-1433 📠 603-880-6718

ATRIUM EUROPE B.V.
Rendementsweg 20 B, 3641 SL Mijdrecht,
The Netherlands
☎ +31-297-230-420 📠 +31-297-282-653