Instructions For Use

Chest Drain Autotransfusion

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 intravascular and postoperative conditions:

- Coagulopathy or D.I.C.
- Peripheral, myocardial, or systemic infections.
- Pulmonary and respiratory infection or infestation.
- Presence of malignant neoplasms.
- Enteric contaminated thoraco-abdominal cavities.
- Intermittent thoracic or mediastinal outflow of topical thrombin, microfibrillar hemostatic agents or povidone-iodine antiseptic gels or solutions.

Warnings
1. Chest drain autologous blood should not remain in the chest drain or ATS bag collected 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 chest drain handling, anticoagulation, storage conditions, and maximum storage times.
2. Patient tube clamp must remain open during chest drainage operation.
3. Prior to IV circuit patient connection, it is important to purge all air from the IV filter and IV administration set. Failure to purge all air from the complete IV circuit prior to patient connection can result in air emboli.
4. Do not reenter ends ATS blood bag contents completely through microemboli blood filter and IV set, as an air embolus can result.
5. Rapid infusion of citrated autotransfused 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 re-sterilize. 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 chest 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 prior to reconnection to the drain.
4. Do not hang or hand carry ATS bag to be hanging set; use gerson holder.
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 re-enter this device.
8. Do not pressure 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 drug administration 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, IV blood administration sets, blood compatible infusion pumps and pressure infusion devices prior to use with the ATS bag. All hospital protocols for blood handling, anti-coagulant administration, autotransfusion, pressure infusion of blood, disposal handling and infection control should be followed carefully.
13. 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.

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

- Presence of malignant neoplasms.
- Pulmonary and respiratory infection or infestation.
- Pericardial, mediastinal, or systemic infections.
- Coagulopathy or D.I.C. in patients with severe blood loss, shock, sepsis or in postoperative and trauma blood loss management.

1. Close chest drain ATS access line clamps prior to remove spike port cap. Insert ATS bag spike into access line. Position ATS bag below line of chest drain.
2. Replace cap on top of head drain, bend ATS bag upward where indicated by access line clamps. Remove spike port cap from ATS access line and insert into ATS bag spike port. Place ATS access line spike port and access line access in the header located on top of ATS bag. Keep ATS clamp fully closed at all times when not in use.

Setup For In-Line ATS Blood Bag
1. Place into chest drain, close both bag clamps prior to cap removal.
2. Connect chest drain to chest drain.
3. Open clamps to begin blood collection.
4. Turn may result in patient injury, illness or death.
5. Connect patient line to drain: connect male and female bag connectors and unclamp patient line.

ATS Bag Reinfusion Setup
1. Close chest drain ATS access line clamps and remove spike port cap. Insert ATS bag spike port point upward and remove cap using sterile technique. Insert spike filter spike into ATS bag spike port. Return bag to upright position and place on standard height IV pole.
2. Hemostatic and non-hemostatic clamps to complete priming. Air within the IV circuit must be evacuated prior to patient connection. Close IV clamp when primed. IV is now ready for connection.
3. Attach primed IV set to patient and open clamp.