

## TECHNICAL MANUAL

### Models 7910, 7910R, 7910RL and 7910LF AUTOVAC® Autotransfusion Systems for Orthopedic Wound Drainage

**CAUTION:** Federal law restricts this device to sale by or on the order of a physician. Please read these instructions carefully.

#### **PRODUCT DESCRIPTION**

The 7910 series AUTOVAC® is a disposable, single use, sterile device. It consists of a universal 'Y' connector attached to a canister that provides continuous and closed wound catheter collection before, during and after autotransfusion. The collection canister contains an integral standard blood bag, integral regulator (R models) clot filter and fat absorber (L models).

#### **INDICATIONS**

The 7910 series AUTOVAC® is indicated for the collection and infusion of wound drainage from orthopedic surgical procedures, such as total knee and hip replacement and spinal fusion.

#### **CONTRAINDICATIONS FOR USE**

Do not infuse blood suspected of containing amniotic fluid, bacteria, bile, gastric fluid, urine, foreign matter, hemostatic agents such as Avitene®, Gelfoam®, thrombin, or uncured bone cements.

Autotransfusion is contraindicated in the presence of suspected systemic infections, coagulopathies, malignant tumors, or impaired renal function.

Use of the Boehringer AUTOVAC® 7910 series is contraindicated during intraoperative orthopedic procedures. In these procedures, high hemolysis (caused by "skimming" type collection with a wand), irrigants, pharmaceuticals, and surgical debris may cause such collected blood to require cell-processing techniques prior to infusion.

#### **WARNINGS**

- Blood should be infused by gravity. Use of an infusion pump or an external inflating cuff is not recommended.
- Infusion of air resulting in an air embolism is a major concern. Follow these steps to minimize this risk.
  - Always use a 20-40 micron microemboli blood filter for infusion (Pall SQ40 or equivalent).
  - Purge all air from bag, infusion line and filter prior to infusion.
  - Monitor blood filter for air or emboli and replace as needed.

#### **PRECAUTIONS**

- Follow the AABB Standards and hospital procedures for autologous infusion, including fluid balance and recommended monitoring before, during and after infusion.
- The risk of dilutional coagulopathy increases as the volume of transfused blood products increases. The Physician is responsible for assessing the overall clinical condition of the Patient and administering blood products accordingly. Exercise care when administering autologous whole blood volumes that exceed a significant portion of total blood volume (i.e. 2000 ml. in a normal, otherwise healthy adult).
- Anticoagulant is recommended at the discretion of a physician.
- Infusion of blood treated with anticoagulant ACD-A into a central line is not recommended because of the risk of citrate toxicity. See note on Citrate Toxicity below under "Adverse Reactions Relating to Infusion".
- Do not mix autologous blood with any medication or "piggyback" the medication into a flowing blood path.

#### **ADVERSE REACTIONS RELATING TO INFUSION**

- **Air Embolism:** Infusion of air, which could result in an air embolism, is an important concern. Please see the 'WARNINGS' section of these instructions.
- **Citrate Toxicity:** Citrate Toxicity indicated by perioral paresthesia may occur in cases where excess anticoagulant is present and rapid infusion is employed into central lines. This is a main reason for prohibiting infusion into a central line. Partial withdrawal of catheters has been shown to reduce this effect. It may be necessary to increase the supply of serum calcium by slowing the infusion or through the ingestion of an antacid pill. One antacid pill contains approximately 500 mg. calcium.
- **Coagulopathy:** A coagulopathy may result when autologous blood is infused which contains bile, gastric fluid, foreign matter, hemostatic agents, or uncured bone cements. Do not infuse blood that is suspected of containing these substances.
- **Infection:** An infection may result when autologous blood is infused which contains bacteria, gastric fluid, bile, or foreign matter. Do not infuse blood that is suspected of containing these substances.
- **Dissemination of Tumor Cells:** The dissemination of tumor cells may result when infusing autologous blood, which contains malignant neoplasms. Do not infuse blood suspected of containing these cells.
- **Febrile Reactions:** Reactions may occur upon infusion. Infusion should be discontinued until appropriate action can be taken.

## **DIRECTIONS FOR USE**

### **ADDITIONAL ITEMS REQUIRED:**

- COLLECTION: ACD-A anticoagulant (Boehringer p/n 7940), wall suction per JCAHO standards.
- INFUSION: Infusion set, 20-40 micron infusion filter and any other miscellaneous supplies recommended by the infusion set and/or filter manufacturer.

### **SET UP FOR COLLECTION**

1. Using sterile technique, remove the AUTOVAC® from its package and pass to scrub nurse.
2. If anticoagulant is indicated, pour 40 ml. of ACD-A into a sterile specimen cup. Place the cut end of the 'Y' connector into the ACD-A. Attach suction and aspirate the ACD-A into the canister through the 'Y' connector. Shut off suction.
3. Attach wound drain(s) to universal "Y" connector.
4. Depending on the Model used, attach vacuum to the suction fitting on the canister as follows:
  - 7910, 7910LF : Regulated Suction set to 100 mmHg maximum with the patient line occluded.
  - 7910R, 7910RL:Unregulated Wall Suction – the integral regulator will regulate down to safe levels

**CAUTION:** Collection will begin when active vacuum is attached to the canister.

5. Record patient data and collection start time on identification label on the canister.
6. The system will maintain a vacuum when suction needs to be disconnected for transport of the patient. Hang system and reconnect to suction source as soon as possible after transport.

**CAUTION:** In accordance with AABB Standards and the hospital's transfusion protocol, infusion may begin as indicated by blood loss and patient status. If 40 ml of ACD-A has been injected into the canister, do not infuse with less than 240 ml of indicated fluid volume. This ensures a minimum of a 5:1 ratio of blood to ACD-A. Adjust infusion volumes appropriately for less than 40 ml ACD-A.

### **SETUP FOR INFUSION:**

1. Clamp the inlet line entering the AUTOVAC® canister. Clamp the drain line above the patient connection.
2. Disconnect the AUTOVAC® canister from the suction and drain lines.
  - To continue collection for transfusion, insert another AUTOVAC® canister or a passive collection device if drainage quantity is insufficient for salvage.
  - To continue drainage NOT for transfusion, remove the adaptor from the peel pouch and attach to your drainage device. Remove the red cap and attach the patient drain line to the adaptor. Attach suction to your drainage device and unclamp the drain line.
3. Record infusion start time on canister label. Transfer label to patient record as required.
4. Remove the blood bag from the canister by removing the white safety tape and popping the lid from the canister.
5. Purge residual air through the suction port by gently squeezing the bag. The bacterial filter protects the sterility of the system. The filter will shut off flow when air has been removed. Monitor bag for complete air removal.
6. Using metal hook on canister top, hang bag from IV pole.
7. The bag incorporates a conventional spike port for use with a standard filtered infusion set. Spike the bag with a 20-40 micron filtered infusion set. Prime the infusion set in accordance with manufacturer's instructions.
8. Infuse blood product in accordance with AABB Standards and the hospital's transfusion protocol. Infuse shed blood via gravity only. **WARNING: Pressure infusion is not recommended.**
9. Monitor patient for adverse and/or site reactions, and rate of infusion checks per hospital protocol.

## **CONFORMANCE TO STANDARDS**

Boehringer Laboratories warrants that the 7910 series AUTOVAC® is in compliance with the Standards and Guidelines applicable to autologous whole blood collected perioperatively as defined in:

- Standards for Blood Banks and Transfusion Services, 20<sup>th</sup> edition, American Association of Blood Banks
- Circular of Information for the Use of Human Blood and Blood Components (AABB OP 1594 ARC 1751), American Association of Blood Banks, American Red Cross, Council of Community Blood Centers, March 1994

Shed blood may be collected for transfusion for up to six hours. After six hours, the 7910 series AUTOVAC® should be disconnected from the patient. If clinically indicated, begin infusion. The infusion should be at a rate as fast as clinically necessary but should not exceed 4 hours.

## **AUTOTRANSFUSION REFERENCES**

1. Eisenstaedt, Richard S., Operative Red Cell Salvage and Auto-transfusion (Transfusion Science 1989, 10:185-198).
2. Berman, A.T., Levenberg, R.J., Tropiano, M.T., Parks, Brent, Bosacco, S.J., Postoperative Autotransfusion After Total Knee Arthroplasty (Hahnemann University, Department of Orthopedic Surgery)
3. Ayers, D.C., Murray, D.G., Postoperative Blood Salvage Following Total Joint Arthroplasty (AAHKS 1993, #34)
4. Gregoretti, S., Suction-Induced Hemolysis at Various Vacuum Pressures: Implications for Intraoperative Blood Salvage (Transfusion, 1996 Jan; 36(1): 57-60)
5. AABB Technical Manual, 13<sup>th</sup> Edition, American Association of Blood Banks

## **PRODUCT SPECIFICATIONS**

- "Y" connector fits 1/4", 3/16", 1/8" and 3/32" drains
- AUTOVAC® Canister Capacity: 1000 ml: 7910, 7910R  
800 ml: 7910LF, 7910RL
- Microaggregate Filter: 170 micron
- Transport: 0°F to 115°F
- Storage: 50°F to 100°F
- Sterile, non-pyrogenic and non-toxic
- Single use, disposable



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