

TECHNICAL MANUAL**Models 7904 and 7904R AUTOVAC®
Intraoperative Autotransfusion System**

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

PRODUCT DESCRIPTION

The 7904 series AUTOVAC® is a disposable, single use, sterile device. It consists of a Yankauer suction wand attached to a collection canister. The collection canister contains an integral standard blood bag, integral regulator (R model) and clot filter.

INDICATIONS FOR USE

The 7904 series AUTOVAC® is indicated for the collection and infusion of whole blood shed during a surgical procedure in which blood can be collected from the surgical field during periods of significant hemorrhage, blood components are routinely ordered and transfusion is indicated.

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® 7904 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. **If pressure infusion is necessary, use an external cuff on the bag.**
- 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. See chart on the next page of these instructions.
- 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 a major 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), waste receptacle, 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. Retain the suction wand in the sterile field and pass out the collection canister.
3. Using the removable tie wrap, secure the canister at or below the level of the collection field. Keep canister vertical and minimize sharp bends in the hose. Do not kink the hose.
4. Depending on the AUTOVAC® Model used, attach vacuum to the suction fitting on the canister as follows:
 - **7904:** Attach the 7904 to Regulated Wall Suction set to 100 mmHg maximum with the patient line occluded.
CAUTION: Use of unregulated vacuum with Model 7904 may cause hemolysis.
 - **7904R:** Attach the 7904R to Unregulated Wall Suction – the integral regulator will regulate down to safe levels
CAUTION: Use of regulated vacuum with Model 7904R may cause low suction at the wand tip.

SET UP FOR COLLECTION (cont.)

5. Anticoagulate the canister by aspirating ACD-A through the suction wand. Aspirate anticoagulant into the canister per the following guidelines. These guidelines maintain the ratio of blood to ACD-A in the AABB required range of 5:1 to 10:1 for effective anticoagulation.

ACD-A Volume to Add	For Non-Heparinized Patient, Add ACD-A	For Heparinized Patient, Add ACD-A
1st 40 ml	Start of procedure (before collection)	Start of procedure (before collection)
2nd 40 ml	When 440 ml fluid is in the canister	When 500 ml fluid is in the canister
3rd 40 ml	When 680 ml fluid is in the canister	not required

6. Begin collection of blood. Minimize skimming and air/blood mixing during collection to minimize hemolysis.
7. Gently agitate the canister to mix the anticoagulant and blood.

CAUTION: DO NOT shake or invert the canister while connected to active vacuum. This may clog the shut-off mechanism and prevent continued collection.

8. Record patient data and collection start time on identification label on the canister.

CAUTION: In accordance with AABB Standards and the hospital's transfusion protocol, infusion may begin as indicated by blood loss and patient status. To ensure the AABB minimum 5:1 ratio of blood to ACD-A and reduce the risk of citrate toxicity, refer to the following chart for minimum infusion volumes. Adjust minimum infusion volumes appropriately for different ACD-A volumes.

Total ACD-A added to the Canister	Minimum Canister Volume for Infusion
40 ml	240 ml
80 ml	480 ml
120 ml	720 ml

SETUP FOR INFUSION:

1. Clamp the inlet line entering the AUTOVAC® canister.
2. Disconnect the AUTOVAC® canister from the suction and collection lines. Remove red cap from peel pouch and place on exposed inlet port of collection canister. To continue collection, connect another AUTOVAC® canister.
3. Record collection information 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 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. If pressure infusion is necessary, use an external cuff on the bag.
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 7904 series AUTOVAC® is in compliance with the Standards and Guidelines applicable to autologous whole blood collected perioperatively as defined in:

- Standards for Perioperative Autologous Blood Collection and Administration, 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, July 1998

Shed blood may be collected for transfusion in accordance with AABB Standards and hospital procedures for autologous collection. Refer to the current AABB standards for handling, storage and expiration.

Should there exist a clinical need to continue collection for infusion beyond the designated expiration time, i.e. significant drainage volume over a short period of time, the primary physician should be informed. There may be other factors that require the attention of the physician. At this point the AUTOVAC® is a closed and sterile system that can continue to collect and infuse for as long as clinically necessary as directed by the primary physician.

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, 13th Edition, American Association of Blood Banks

PRODUCT SPECIFICATIONS

- Yankauer Suction Wand
- AUTOVAC® Canister Capacity: 1000 ml
- 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



©1996, 2001, 2007 Boehringer Laboratories, Inc.

Boehringer products are designed and manufactured in the U.S.A. The AUTOVAC® product line is patented. Additional information is available through your representative or directly from the manufacturer:

Boehringer Laboratories, LLC • 500 East Washington Street • Norristown, PA 19401 • 800-642-4945

www.boehringerlabs.com or www.autovac.com

Avitene® is a registered trademark of Alcon, Inc. (Puerto Rico), Gelfoam® is a registered trademark of The Upjohn Company