

**Model 7926 AUTOVAC®
Autotransfusion System 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. Use of the AUTOVAC® system is restricted to individuals that have been properly trained in the techniques of collection, handling and infusion of autologous blood products.

PRODUCT DESCRIPTION

The 7926 AUTOVAC® is a disposable, single use, sterile device. It consists of a collection bulb and universal 'Y' connector that provides continuous and closed wound catheter collection before, during and after autotransfusion. Attached to the bulb is a standard blood bag with an integral clot filter, fat absorber and anti-air embolism valve.

INDICATIONS

The 7926 AUTOVAC® system is indicated for the continuous collection and infusion of wound drainage from orthopedic procedures such as Total Knee Replacement, Total Hip Replacement and Spinal Fusion. The blood is to be collected via a surgical drain tube placed in the operative site.

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 any Boehringer AUTOVAC® System employing wand collection 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.
 - Clamp infusion line when squeezing the collection bulb.

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:** A special anti-air embolism valve has been built into the AUTOVAC®. Infusion of air, which could result in an air embolism, is still an important concern. Please see the 'WARNINGS' section of this technical manual.
- **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.
- **Febriile Reactions:** Reactions may occur upon infusion. Infusion should be discontinued until appropriate action can be taken.
- **Hemoglobinuria:** Excess hemolysis due to improper collection technique and wand salvage during orthopedic procedures may occur resulting in elevated levels of hemoglobin in the urine of the patient. Follow the directions for setup and use and pay special attention to collection technique and vacuum level used for collection.

DIRECTIONS FOR USE**ADDITIONAL ITEMS REQUIRED:**

- COLLECTION: ACD-A anticoagulant (Boehringer p/n 7940).
- 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® in its protective bag from the sterile package and pass to scrub nurse. Do not remove the protective bag at this time. Expose the "Y" connector, but leave the rest of the Autovac system in the protective bag.
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. Squeeze and release bulb to aspirate ACD-A into the bulb.
3. Attach wound drain(s) to universal "Y" connector.
4. To start the collection, fully squeeze the bulb. The unit can be laid on its side for transport.

WARNING: If a significant air leak is detected in the drain line, System sterility may be compromised. Infusion of blood is at the discretion of the physician.

SET UP FOR INFUSION

1. The setup for infusion can be initiated any time after the drains are placed.

2. Remove the Autovac from the protective bag. Using the metal hook on top of bag, hang bag from IV pole. As the bulb fills, squeeze the bulb to empty contents into the infusion bag.
3. Infusion may begin as soon as blood is present in the infusion bag or as indicated. Record patient data (start times and fluid volumes) as necessary.

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 drawn into the AUTOVAC®, do not infuse with less than 240 ml of total 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. There is no minimum requirement if no ACD-A is used, but the benefit of infusion of small volumes of blood must be weighed against the risks associated with any infusion.

4. Purge residual air in the bag by holding the bag vertical and gently squeezing. 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.
5. 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.
6. 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 because of the risk of air embolism.

7. Monitor patient for adverse and/or site reactions, and rate of infusion checks per hospital protocol.
8. Each time the bulb fills, additional blood can be transferred to the infusion bag as follows:
 - a. Apply clamp on infusion line (i.e. the line from the bag to the patient).
 - b. Hold bulb vertical to indicate volume. Record volume.
 - c. Squeeze bulb to transfer contents.
 - d. Express residual air from bag, if required.
 - e. Open clamp on infusion line.

SET UP FOR CLOSED WOUND DRAINAGE

1. To convert to closed wound drainage, clamp off the IV line between the patient and the infusion bag, remove the IV access from the patient. Cut off the needle portion of the IV line to prevent inadvertent infusion. Use the infusion bag as a waste receptacle until the drains are removed.
2. Alternatively; if desired, the infusion bag may be removed from the bulb. Remove the heat shrink seal from the fittings and disconnect the bulb and cap the open ports. The infusion bag may be disposed of after completion of infusion. Additional drainage may be expressed into a waste bag or graduated cup, if required. Dispose of additional drainage as medical waste in accordance with hospital procedures.

CONFORMANCE TO STANDARDS

Boehringer Laboratories warrants that this model 7926 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

- Bulb Capacity: 250 ml.
- Bulb Vacuum: Full Squeeze: 100 mmHg
- "Y" connector fits 1/4", 3/16", 1/8" and 3/32" drains
- Microaggregate Filter: 170 micron
- AUTOVAC® Bag Capacity: 800 ml
- 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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