

**ABIOMED® AB5000™
CIRCULATORY SUPPORT SYSTEM**

AB5000™ VENTRICLE

Instructions for Use

Rx Only.

STERILE

(Ethylene Oxide Sterilization)

Contents sterile unless package has been opened or damaged.

Do not use if opened or damaged.

Single use only. Do not resterilize or reuse.

For use by personnel trained in accordance with the
ABIOMED Training Program only.

Read all warnings, cautions, and instructions carefully prior to use.

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ABIOMED® AB5000™
CIRCULATORY SUPPORT SYSTEM
VENTRICLE
CATALOG NO. 0055-3500

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I. DESCRIPTION

This manual, the AB5000™ Ventricle Instructions for Use, is one of a series of manuals for the AB5000™ Circulatory Support System (AB5000 System). The AB5000 System consists of a Console and multiple pump configurations.

This manual covers the use of the AB5000 Ventricle used in conjunction with the AB5000™ Console. It is important to note that the AB5000 Ventricle is designed to be used **only** with the AB5000 Console.

The AB5000 Ventricle is a pneumatically driven device that provides pulsatile hemodynamic support. Each sterile, disposable AB5000 Ventricle is intended to provide circulatory support in the presence of left-, right-, or both-sided heart failure.

The AB5000 Ventricle is an ambulatory version of the BVS® Blood Pump.

Each AB5000 Ventricle has drive tubing and cannula connectors permanently attached.

One atrial cannula and one arterial cannula; tunneling bullets (one per cannula); and white, threaded cannula restraints (one per cannula) are needed with each AB5000 Ventricle. **The term atrial cannula will be used throughout to describe the cannula used for providing inflow into the device. Inflow can be obtained either by placing the cannula in the patient's atrium or in the patient's ventricle.**

The cannulae are surgically placed transthoracically. The AB5000 Ventricle is located external to the patient. The only connections between the patient and the AB5000 Ventricle are the atrial and arterial cannula-tubing connections. The only connection between the AB5000 Ventricle and the AB5000 Console is the driveline.

II. INDICATIONS FOR USE

The AB5000 System is a mechanical support system for use in patients suffering from reversible ventricular dysfunction. These are patients who have undergone successful cardiac surgery and subsequently develop low cardiac output, or patients who suffer from acute cardiac disorders leading to hemodynamic instability. The intent of AB5000 System therapy is to provide circulatory support, restore normal hemodynamics, reduce ventricular work, and allow the heart time to recover adequate mechanical function. The AB5000 Ventricle is external to the patient and is intended for short-term use.

Appropriate patient groups include those that are likely to recover cardiac function after the myocardium is permitted to rest on ventricular support. Examples include, but are not limited to:

- Patients who fail to wean from cardiopulmonary bypass following heart surgery.
- Failed transplant patients who require ventricular assist following heart transplantation.
- Patients who require right heart assist (RVAD) support while on implantable left ventricular assist device (LVAD).
- Patients suffering from acute cardiac disorders such as viral myocarditis.

A patient **is a candidate** for mechanical assistance with the AB5000 System if she/he meets all of the following criteria:

- a) Patient has a body surface area $> 1.3 \text{ m}^2$ and is ≤ 75 years of age.

- b) Patient is in relatively good health other than the cardiovascular problem for which surgery was undertaken.
- c) All appropriate measures have been attempted to correct low arterial pH, arterial blood gas abnormalities, electrolytes, hypovolemia, hypervolemia, inadequate cardiac rate, dysrhythmias, and residual hypothermia.
- d) Cardiac resuscitation employing pharmacologic agents has been attempted. While the use of the Intra-Aortic Balloon Pump (IABP) is recommended prior to AB5000™ System assistance, its use may not always be appropriate (e.g., fibrillating heart, peripheral atherosclerosis).
- e) Patient is unable to be weaned from cardiopulmonary bypass or is unable to maintain acceptable hemodynamics in the immediate postoperative period (< 6 hours after the first attempt to wean from CPB) **or**
 Patient is unable to maintain acceptable hemodynamics following a significant cardiac event despite the measures cited above.

III. CONTRAINDICATIONS FOR USE

- 1) Major cardiac or extracardiac catastrophes occurring during operation or in the postoperative period that preclude survival such as uncontrolled hemorrhage, massive air embolization, interstitial pulmonary hemorrhage with inability to maintain adequate ventilation, pump oxygenator or perfusion difficulties, or massive transfusion reaction, hemolysis during bypass, or inadequate cannulation.
- 2) Central nervous system damage resulting in fixed and dilated pupils.

IV. WARNINGS

Note: A warning indicates a situation that could result in injury or death.

- 1) Prior to use, refer to the AB5000™ Circulatory Support System Operator's Manual 0015-9000 and the AB5000 Ventricle Training Guide 0055-9002 for important information.
- 2) Do **NOT** perform chest compressions and/or precordial thump on a patient implanted with an AB5000 Ventricle.
- 3) Make certain the proper connections are made: AB5000™ Ventricle atrial connector to **atrial (blue arrow)** cannula, and AB5000 Ventricle arterial connector to **arterial (red arrow)** cannula. Reversed connections may result in serious injury or death.
- 4) Caution should be taken when connecting the AB5000 Ventricle connector to its appropriate cannula. Maintain a purged and "air bubble free" junction when fitting the connector into the cannula.
- 5) Do **NOT** use the AB5000 Ventricle with any console or drive mechanism other than the AB5000 Console.
- 6) The temperature of the Ventricle priming solution must **NOT** exceed 55 °C (131 °F).

WARNINGS (continued)

- 7) Do **NOT** use the AB5000™ Ventricle with any cannulae other than those provided by ABIOMED. These cannulae have been designed to form a smooth junction when joined with the AB5000 Ventricle. This minimizes the risk of thrombus formation. Prior to use, refer to the Cannulae Instructions for Use 0506-9110 provided with each cannula.
- 8) Only use **white, threaded** cannula restraints with the AB5000 Ventricle. Use of nonthreaded cannula restraints may result in: (1) cannulae becoming disconnected from the Ventricle, and (2) thrombus formation.
- 9) Only use a **white, threaded** cannula restraint **marked with a red arrow** with a Hemashield® cannula. Use of any other type of cannula restraint may result in: (1) cannulae becoming disconnected from the Ventricle, and (2) thrombus formation.
- 10) Setup and operation of this device should only be undertaken by personnel trained in accordance with the ABIOMED Training Program. (See Appendix B for outline of Training Program.)
- 11) The AB5000 Ventricle is a disposable device and is intended for single use only; **do not resterilize or reuse.**
- 12) Sufficient data have not been collected to establish the level of preimplant renal/hepatic dysfunction, cerebrovascular disease, or neurological dysfunction that can be tolerated without affecting outcome.
- 13) Do **NOT** allow the following agents to come in contact with the AB5000 Ventricle because they may attack the plastic and cause damage to the device: alcohol and alcohol-related agents; halogenated hydrocarbon-based anesthetic agents; other halogenated hydrocarbons, such as chloroform; highly alkaline chemicals, such as sodium hydroxide; aromatic hydrocarbons, such as gasoline; and ketones, such as acetone.
- 14) There is a potential for air embolism during and after cannulation. Surgeons should take the following steps to minimize the possibility of air inadvertently entering the AB5000 Ventricle through the cannulation sites:
 - a) Use pledgeted, double purse string sutures to secure atrial cannulae.
 - b) Fasten purse string tourniquets directly to the cannula using heavy sutures.
 - c) Submerge atrial cannulation sites in saline or blood.
 - d) During hand pumping at startup, keep the AB5000 Ventricle above the patient's atria to aid in inspection for air bubbles.
 - e) Reduce cardiopulmonary bypass flow to fill the patient's atria prior to turning the AB5000 Ventricle on.
- 15) Do **NOT** adjust the inflow cannula position while the Ventricle is activated. Before adjusting the cannula position, stop the Console. Restart the Console only after the purse-string sutures are retightened.
- 16) Air embolism is possible if the cannula restraints are not properly tightened (are too loose). Be sure to **finger tighten** the cannula restraints when making connections.

WARNINGS (continued)

- 17) During normal operation of this device, the patient must be anticoagulated with heparin to maintain a minimum Activated Clotting Time (ACT) of approximately 180-200 seconds. During periods when the weaning mode is used, or during normal operation when AB5000 Ventricle flows are consistently 3.0 liters/minute or less, an ACT of approximately 300 seconds is recommended.
- 18) To reduce the risk of hypercoagulation, do **NOT** apply heat externally to the AB5000 Ventricle or cannulae. For patients encountering hypothermic episodes following open heart surgery, traditional methods of warming patients should be considered.
- 19) Maintain continuous flow in the AB5000 Ventricle after starting. Interrupted use may cause thromboembolism upon restart.
- 20) Data were not collected in the clinical study for patients with the following conditions:
 - a) Cancer with metastases.
 - b) Significant blood dyscrasia or hemorrhagic diathesis. This involves any of numerous syndromes demonstrating abnormal cellular elements or a tendency toward spontaneous hemorrhage from clotting deficits and/or weakness of blood vessels.
 - c) Severe emphysema and chronic obstructive pulmonary disease (COPD) as determined by one or more of the following: chest x-ray, auscultation, evidence of right ventricular hypertrophy secondary to COPD.
 - d) Concurrent uncontrolled sepsis determined by fever, elevated leukocyte count requiring treatment with antibiotics, and/or positive blood, urine, or sputum cultures.
 - e) Congenital heart disease with severe pulmonary vascular obstructive disease.
 - f) Chronic renal failure requiring dialysis or resulting in creatinine >5 mg/dl.
 - g) Prolonged (>1 hour) unsuccessful attempts to resuscitate the fibrillating or arrested heart using pharmacologic agents.
- 21) Use may result in the following complications:
 - a) Bleeding
 - b) AB5000™ Ventricle dependence
 - c) Impairment or loss of organ function
 - d) Infection: In an AB5000 supported, 45 Patient Post Approval Study, the AB5000 was found to have 1.8 times the infection rate (per patient-day) when compared with the BVS in clinical use.
 - e) Hemolysis
 - f) Thromboembolism
 - g) Death

V. CAUTIONS

Note: A caution indicates a situation in which equipment may malfunction or be damaged.

- 1) The arterial cannula contains a precoated graft that eliminates the need for preclotting. Do not preclot the arterial cannula graft.
- 2) Handle the cannulae connectors carefully to prevent damage to their edges.
- 3) Care should be taken to prevent damage to the AB5000 Ventricle valve when using a bulb syringe to fill the AB5000 Ventricle through the inflow port.
- 4) Care should be taken to position the AB5000 Ventricle to minimize stress at the cannula-skin exit sites, and to prevent kinking of the cannula and pneumatic tubing. Avoid any actions that would result in tugging against the cannula. Also avoid any actions that would result in the cannula being bent in the area where it exits the skin or along its length.
- 5) Measures should be taken to prevent infection or sepsis, especially at the cannula-skin exit sites.
- 6) Do not submerge the driveline connector during priming and take care to minimize exposure of this connector to fluids.

VI. SUMMARY OF CLINICAL EXPERIENCE

The FDA approved the AB5000™ Ventricle for use in patients with failing but potentially recoverable hearts on September 24, 2003 under PMA Supplement P900023/S038. It is the ambulatory version of the BVS® Blood Pump introduced into clinical use under PMA P900023 in 1992. The AB5000 Ventricle indications for use remain consistent with the BVS Blood Pump.

As of March 23, 2004, 60 patients were implanted with the AB5000 Ventricle in 20 centers. Forty-five of these cases were directly implanted with the Ventricle. The remaining 15 cases were transitions from the BVS Blood Pump due mostly to transfers from outlying centers. *

The mean age of patients was 56 years (± 13) with 67% being male. The average BSA was 2 (± 0.3).

Based on the results of this Post Approval Study, the survival rate for patients on the AB5000 Ventricle was 22%, survival being defined as patients that were explanted and alive 20 days post explant.

The absence of bleeding was directly associated with better outcomes, whereas hemolysis, infection, neuro-events, and re-operation did not correlate with survival.

The mean length of support was 13 days, with the longest single pump duration equal to 57 days. Several patients ambulated without complication and some were able to ambulate outside of the facility.

The initial clinical experience with the AB5000 Ventricle has demonstrated survival outcomes and adverse event rates similar to the BVS Blood Pump (for the same indications for use) while demonstrating patient ambulation and longer support duration.

*To date, the AB5000 Ventricle has been used on more than 150 patients in over 40 centers.

VII. RELIABILITY TESTING OF THE AB5000 VENTRICLE

In Vitro Testing of the AB5000 Ventricle demonstrated that it can function reliably for over one year of operation. The test results showed that at one year, the mechanical reliability is greater than 90% at a confidence level (CL) of 60% and that this reliability remains greater than or equal to 80% (CL=60%) at an operation duration of 440 days.

VIII. EXPERIENCE IN PATIENTS WHO DO NOT RECOVER NATIVE HEART FUNCTION

Acute heart failure patients, with potentially recoverable cardiac function when placed on support to promote heart recovery but later failed to wean from support but have recovered from or had no other organ dysfunctions, would be clinically considered for the next option in therapy. These options could be heart transplantation if eligible or destination therapy. This section describes the clinical experience of failure to wean patients supported on the AB5000 who are otherwise in need of the next step in the therapeutic armamentarium. Data were gleaned from the AB5000 Voluntary Registry.

Sixty-six patients placed on the AB5000 Ventricle for bridge to recovery subsequently failed to demonstrate heart recovery were listed for heart transplant. A multicenter retrospective data analysis of these patients, who were listed for transplant while on support with the AB5000 Ventricle, demonstrated

AB5000™ Circulatory Support System Ventricle Instructions for Use

survival rates to transplantation comparable to those reported in the literature.. (Data presented at ISHLT 2007, General Posters: Poster Session, Clinical Experience with the AB5000 as a Bridge-to-Transplant VAD: Successful Cross-Over for Extended Bridge-to-Recovery Patients, Elefteriades, M. Madani, A.J. Crumbley, D. Adams, M. Anderson.)

The 66 patients studied were implanted with the AB5000 Ventricle to stabilize acute shock conditions and allow their native hearts the opportunity to recover. The average age of the patients was 50 years old (range 13 to 71) and 62% were males.

Extended support did not lead to cardiac recovery for these patients and all were listed for transplant at 29 institutions in the U.S. between October 23, 2003 and December 31, 2006.

The patients were supported for a mean of 42±39 days. The longest support duration was 173 days. Of the 66 patients, six patients following listing had sufficient cardiac recovery to be weaned from VAD support and three patients were transitioned to other VADs. Of the 57 patients who remained on the device, 39 (68%) survived to transplantation.

IX. DIRECTIONS FOR USE

A. Preparation

Read all Instructions and Warnings, including the AB5000™ System Operator's Manual 0015-9000 and the Cannulae Instructions for Use 0506-9110, before use.

- 1) Shown below is a photo of the AB5000 Ventricle (see Figure 1).

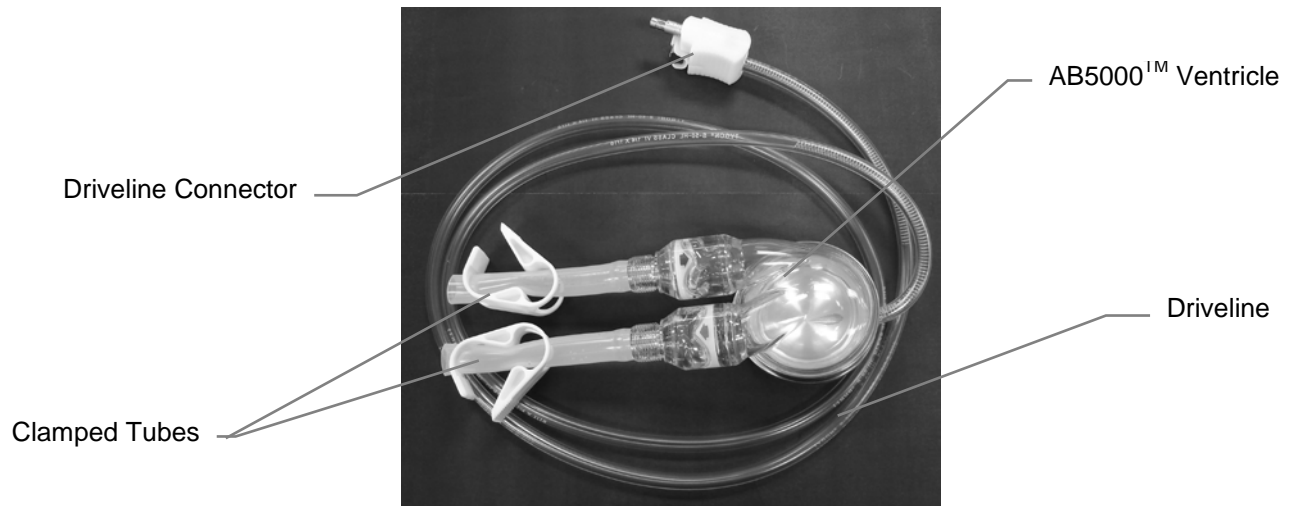


Figure 1 AB5000™ Ventricle

- 2) While the patient is being prepared, power up and test the AB5000™ Console according to the instructions in the AB5000™ System Operator's Manual 0015-9000.
- 3) Examine the AB5000 Ventricle package. It must be unopened and without any damage, including abrasion, delamination, or punctures.
- 4) Examine the cannulae in their sterile packages. These packages must be unopened and undamaged. Cannula bullets and cannula restraints must be available for each cannula.

Note: It is recommended that a backup AB5000 Ventricle and Console be available during AB5000 System implantation and support.

Important: Recommendations for Patient Management are included in Appendix A.

B. Unpacking the AB5000™ Ventricle

- 1) Remove the cover of the white box.



Figure 2 AB5000™ Ventricle Box

- 2) Open the accessories container (see Figure 3).



Figure 3 Opening the Accessories Container

- 3) Take the accessories out of the accessories container (see Figure 4).



Figure 4 Removing the Accessories

- 4) Remove the accessories container from the white box. The AB5000™ Ventricle will now be exposed (see Figure 5).



Figure 5 After Removing the Accessories Holder

- 5) Take the AB5000 Ventricle out of the box.
- 6) Using sterile technique, unpack the accessories and AB5000 Ventricle. All items are double-pouched (see Figure 6).



Figure 6 Unpacking the AB5000™ Ventricle

- 7) Slide the sleeve off the AB5000™ Ventricle (refer to the arrow shown in Figure 7).



Figure 7 Sliding the Sleeve off the AB5000™ Ventricle

- 8) The AB5000 Ventricle should be visually inspected for any possible damage. Particular attention should be given to the following areas:
- The clear shell that contains the pump bladder
 - The necks of the inflow and outflow ports

C. Priming the AB5000™ Ventricle

The recommended method of priming involves the use of a deep basin, a large bulb syringe, and an AB5000™ hand pump. Following are detailed instructions for priming the AB5000 Ventricle and removing all air bubbles.

- 1) Place the following sterile materials in a sterile field: AB5000 Ventricle, deep basin, priming solution (enough to fill basin), and large bulb syringe.

WARNING: The temperature of the priming solution must **NOT** exceed 55 °C (131 °F).

CAUTION: Do not submerge the driveline connector during priming and take care to minimize exposure of this connector to fluids.

- 2) Remove the two clamped tubes from the inflow and outflow of the AB5000 Ventricle (see Figure 8).

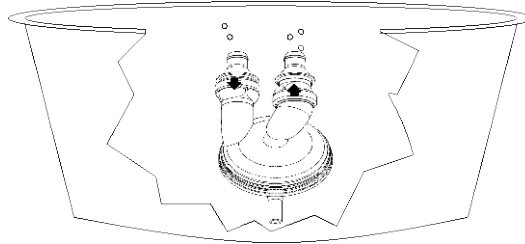


Figure 8 Removing the Clamped Tubes

- 3) Set the two clamped tubes aside; these will be used as caps for the inflow and outflow connectors. (The clamps are purposely left open to allow for proper sterilization.)
- 4) Pass the end of the driveline of the AB5000 Ventricle out of the sterile field. Secure the sterile portion of the driveline to the sterile drape.
- 5) Using an AB5000 hand pump, apply vacuum to the driveline. This will fully expand the AB5000 Ventricle bladder.
- 6) Using the large sterile bulb syringe, fill the AB5000 Ventricle by slowly pouring priming solution over the inflow valve. The valve can be identified by an arrow pointing toward the AB5000 Ventricle.

CAUTION: To prevent any possible damage to the inflow valve, care should be taken not to touch the valve with the syringe or any hard object.

- 7) With the inflow and outflow valves facing up, submerge the AB5000™ Ventricle in the basin (see Figure 9).



Note: Driveline is not shown.

Figure 9 Submerging the AB5000™ Ventricle

- 8) Point the inflow and outflow valves down. Tap the AB5000 Ventricle gently several times to get any air bubbles to move into the back of the pump (Figure 10). Warning: Tapping the Ventricle sharply around the valve housings or connectors with a metallic instrument could crack the necks.

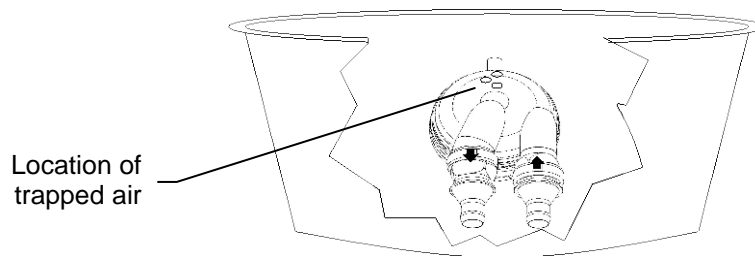


Figure 10 Pointing the Inflow and Outflow Valves Down

- 9) Roll the AB5000™ Ventricle so the inflow and outflow valves are again angled toward the surface of the priming solution. The pump should be rolled in a direction that moves the air bubbles toward the outflow valve (Figure 11).

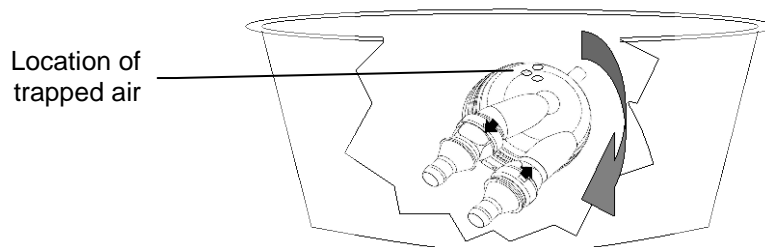


Figure 11 Rolling the AB5000™ Ventricle to Remove Air Bubbles

- 10) Using an AB5000™ hand pump, begin pumping at a moderate rate (40-60 beats per minute) to remove any remaining air bubbles. The last stroke should leave the AB5000 Ventricle bladder fully expanded.
 - 11) Inspect the AB5000 Ventricle for bubbles while it is still submerged in the priming solution. If bubbles are found, repeat steps 8–10.
- Note: The pump housing material may contain small trapped air bubbles. These are normal and can be ignored.
- 12) Submerge the clamped tubes in the priming solution. Make sure all air bubbles are removed from the tubing and then tighten the clamps.
 - 13) Push the clamped tubing onto the inflow and outflow connectors. This will prevent air from entering the pump when it is removed from the priming solution.
 - 14) Remove the AB5000 Ventricle from the priming solution. Inspect the pump for air bubbles.

D. Recommended Cannulation Method

To facilitate connection of the AB5000™ Ventricle, the percutaneous cannulation sites should be 5 cm apart as measured from the center of each cannula. In addition, the angle at which the cannulae exit should be planned to reduce the chance of kinking when the AB5000 Ventricle is placed directly below the cannulation sites.

See specific Cannulae Instructions for Use 0506-9110 provided with each cannula.

E. Interconnection Procedure

WARNING: Only use **white, threaded** cannula restraints with the AB5000 Ventricle. Use of nonthreaded cannula restraints may result in: (1) cannulae becoming disconnected from the Ventricle, and (2) thrombus formation.



Only use **white, threaded** cannula restraints marked "AB5000™ ONLY"

WARNING: Only use a **white, threaded** cannula restraint **marked with a red arrow** with a Hemashield® cannula. Use of any other type of cannula restraint may result in: (1) cannulae becoming disconnected from the Ventricle, and (2) thrombus formation.

- 1) Prior to connecting the AB5000 Ventricle, the cannulae exiting the patient must be of equal length. The preferred method to accomplish this is to cut the longer of the two cannulae.

Note: When cutting a cannula, make sure to leave a minimum of 5 cm of tubing without wire reinforcement so a proper connection to the AB5000 Ventricle can be made.

If the difference in cannulae length is too large, it will not be possible to cut the longer cannula without getting too close to the wire reinforcement. In this case a tubing adapter (provided) should be added, as described below, to the shorter cannula.

- 2) Apply sterile lubricant (provided) to the inner diameter and threads of the white, threaded cannula restraint. Slide the restraint onto the cannula.
- 3) **If a tubing adapter is not used, proceed to step 5.** If a tubing adapter is used, proceed to step 4.
- 4) Push the barbed connector of the tubing adapter fully into the cannula. Slide the cannula restraint towards the connector until it is snug against the fitting. Hold the adapter connector and finger tighten the cannula restraint. Make sure the restraint is not cross-threaded.

WARNING: Air embolism is possible if the cannula restraint is not properly tightened (is too loose). Be sure to **finger tighten** the cannula restraint.

Note: Apply sterile lubricant to the inner diameter and threads of the cannula restraint of the tubing adapter. Position the restraint to remain on the tubing and then cut the tubing to length. In the following steps, treat the adapter as the cannula.

- 5) Remove any air from the cannula and clamp it close to, but not over, the reinforcing wire.
- 6) Remove one of the caps from the primed AB5000 Ventricle, using care not to let any air enter the chamber of the pump.
- 7) Bring together the AB5000™ Ventricle and clamped end of the cannula. Make sure that the arrow on the AB5000 Ventricle connector indicates flow in the **proper direction**. Irrigate the junction with fluid and push the connector into the cannula (see Figure 12).



Figure 12 Irrigating the Junction with Fluid

- 8) Check the connection for air bubbles.
- 9) **Make sure the system is free of air.** Slide the cannula restraint toward the connector until it is snug against the fitting.
- 10) Finger tighten the cannula restraint. Make sure the restraint is **not cross threaded**.

WARNING: Air embolism is possible if the cannula restraint is not properly tightened (is too loose). Be sure to **finger tighten** the cannula restraint.

- 11) Repeat the procedure for the other cannula.
- 12) Unclamp both cannulae prior to initiation of pumping.

F. Prior to Initiating Pumping

- 1) Place the patient in the Trendelenberg position.
- 2) To minimize the risk of air entering the AB5000 Ventricles, reduce or stop cardiopulmonary bypass to allow the patient's atria to fill with blood.
- 3) Use saline to **submerge** atrial cannulation sites. This will minimize the possibility of air entry through the atrial cannulation sites.
- 4) Use the AB5000™ hand pump to start a slow, controlled pumping of blood.
- 5) Check the AB5000 Ventricle for air. If air is observed, stop the hand pump and **remove the air**.

G. To Initiate Pumping

WARNING: Do **NOT** adjust the inflow cannula position while the Ventricle is activated. Before adjusting the cannula position, stop the Console. Restart the Console only after the purse-string sutures are retightened.

- 1) **Make sure the system is free of air.** Connect the driveline connector (which includes an electronic key for pump identification) to the AB5000™ Console (see Figure 13). For proper system operation, the driveline connector must be attached to the Console before the pump ON button is pressed. An alarm will be generated if the driveline connector is attached after the ON button is pressed.

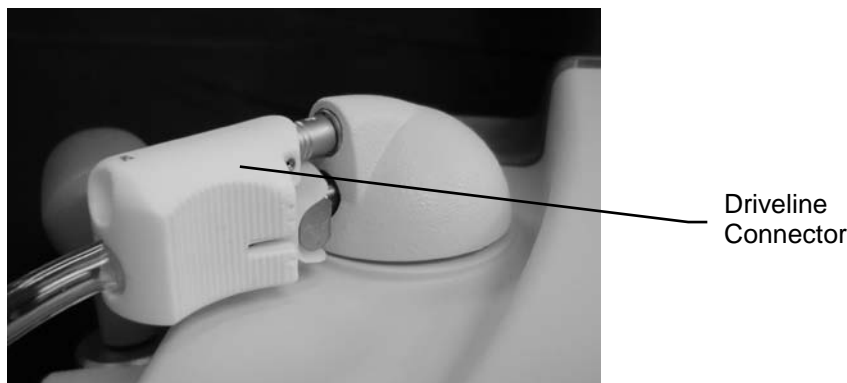


Figure 13 Connection to AB5000™ Console

- 2) Press the Console's ON button. **If air is observed after pumping is started, immediately clamp the Ventricle driveline tubing to stop pumping.** Then press the OFF button twice within 13 seconds. **Remove the air.** Unclamp the driveline tubing and press the ON button.

For biventricular support, initiate left-side pumping before right-side pumping.

- 3) Observe the beat rate. Any gross instability of beat rate indicates a possible problem with the cannula positioning.

A step change in rate is normal, especially during the first two minutes while the Console adjusts to the optimal pumping rate. A brief extension of one beat every 15 minutes is normal as the Console routinely recalibrates. For further operational instructions regarding the Console, refer to the AB5000™ System Operator's Manual 0015-9000.

H. To Stop Pumping

During biventricular support, first stop pumping on the right side by pressing the OFF button on the right side **twice within 13 seconds**. The button **must** be pressed twice to stop the AB5000 Ventricle; this is a safety feature to prevent accidental cessation of pumping. (A single press of the OFF button will be ignored after 13 seconds.) Then press the OFF button on the left side. In univentricular support, press the appropriate OFF button.

APPENDIX A

Recommendations for Patient Management

This appendix presents **suggested guidelines**. Each medical professional must determine the suitability of these guidelines based on the needs of the individual patient. These guidelines are not intended to be a substitute for the independent medical judgment of the medical professional.

1) Univentricular vs. Biventricular Support

In the majority of postcardiotomy patients, left heart support should be initiated first. It is recommended that right support be pursued after an adequate trial of the right ventricle has been made as described below:

- a) Establish left heart support and assess the performance of the right ventricle during approximately the first 30 minutes of assist. Administer pulmonary vasodilators during this period, if indicated.
- b) Right ventricular function should be assessed by direct visualization, maintenance of right atrial pressure below approximately 15 mmHg, maintenance of adequate flow through the left AB5000™ Ventricle, and maintenance of adequate arterial pressure. Transesophageal echocardiography (TEE) and measuring the right ventricular ejection fraction are alternative methods for evaluating right ventricular function. Right ventricular contractility and ejection fraction should increase with left heart support.
- c) If the right ventricle does not respond favorably during this period of left heart assist, biventricular support should be pursued.

The likelihood for eventual right heart failure should also be considered. Biventricular support may be indicated if the patient has a diseased right coronary artery, a septal or right ventricular wall infarction, or significantly elevated PA pressures.

2) Anticoagulation Therapy

The level of anticoagulation will vary depending on the patient's coagulation status. Initially, the patient may require heparin reversal to control bleeding. Heparin should not be administered until postoperative bleeding is under reasonable control, which typically occurs during the first postoperative day. Thereafter, the recommended anticoagulation will consist of heparin as needed to maintain an Activated Clotting Time (ACT) of between 180 - 200 seconds or an Activated Partial Thromboplastin Time (APTT) of 1.5 -2.0 times control. Low molecular weight dextran may also be used in conjunction with heparin as long as the ACT or PTT is maintained within the desired range.

When an AB5000™ System patient is being weaned from support with AB5000 Ventricle flows below 3 Liters per minute (L/min), it is recommended that the ACT be increased and maintained at greater than 300 seconds.

3) Fluid Therapy

Assessment of an AB5000 System patient's volume status should be performed as it would be for any postoperative patient. The operator should keep in mind that flow through the AB5000 Ventricle is influenced by preload, so maintenance of adequate atrial pressures is important.

4) Antibiotic Therapy and Wound Management

The sternotomy incision should be closed and dressed according to hospital protocol. Typically, cannula exteriorization site dressings should be changed every 24 hours. All wounds should be visually inspected and cultured if considered suspect for infection. The status of all insertion sites should be recorded after every dressing change.

Measures are recommended to prevent pressure-induced necrosis of skin underlying the AB5000™ Ventricle. A dressing placed under the pump is recommended to help protect the skin. The overall assessment and documentation of skin integrity should be performed according to existing protocols.

During the clinical study, prophylactic antibiotic coverage was maintained for a minimum of the first three days of support. The duration and type of such coverage is at the discretion of the physician.

5) Mobility

The AB5000 Ventricle, in conjunction with the AB5000™ Console, is designed to give the patient mobility. At the discretion of a physician, walking and light exercise are allowed.

Extra precautions should be considered to minimize stress at the cannula-skin exit sites during motion. These sites can be protected by limiting the displacement of the cannulae using an ACE® bandage or other restraining device.

The physical movement of the Ventricle can be limited using a telemetry monitoring unit pouch (ref. Reedy, et al., "Nursing Care of the Ambulatory Patient with a Mechanical Assist Device," J. of Heart Transplantation, V. 9, No. 2, pp. 97-105, 1990) or other such device.

During exercise, care should be taken to prevent kinking of cannulae and pneumatic tubing.

6) Weaning from Support

The decision to begin the weaning process involves multiple factors. The extent of the disease, completeness of revascularization, and preoperative ejection fraction must be part of the decision-making process. Evidence of ventricular ejection while the patient is on AB5000™ System support is a good indication that weaning from support may be possible.

TEE is a useful method for assessing ventricular function of an assisted heart. TEE should be performed with the patient on full AB5000 System support and also with the patient on reduced AB5000 System support (using the weaning mode). Evaluating ventricular contractility in this manner is helpful in assessing performance with an increased preload. Several BVS® clinical trial investigators turned the BVS® pumps off for brief periods and assessed ventricular function (i.e., ejection fraction) by TEE. This was typically done as a final prelude to BVS removal after pump flow had successfully been reduced to 2.0 L/min.

To initiate weaning, pump flow is reduced in 0.5 L/min decrements. Patient hemodynamics should be monitored for 1-2 hours after each reduction in pump flow unless the reduction is monitored by TEE. The use of TEE may allow for a more rapid reduction in pump flow. Each evaluation of ventricular function during weaning should be made with appropriate levels of inotropic support.

Note: If a patient is on right or biventricular support, the cardiac output can be measured by thermodilution by momentarily turning the right Ventricle off prior to injection. Right AB5000™ System support should then be returned to the original setting.

Appendix B

Outline of Training Program

Setup and operation of this device should only be undertaken by personnel trained in accordance with the ABIOMED Training Program. Training will include the following topics:

- 1) Indications and Contraindications
- 2) System Overview
- 3) Cannulation Techniques
- 4) AB5000™ Ventricle Priming Techniques
- 5) Connection of the AB5000™ Ventricle and Cannulae
- 6) Starting the AB5000 Ventricle
- 7) Hands-on Practice with the AB5000™ System
- 8) Patient Management During AB5000™ System Support
- 9) Weaning from AB5000 System Support
- 10) Summary of Clinical Study Results
- 11) Animal Procedure (Optional)

Contact ABIOMED for Training Program details.

Appendix C

Materials Matrix

The following information is provided to aid in evaluating the possibility of allergic reactions:

- | | |
|---|----------------------------|
| 1) AB5000™ Ventricle Assembly
and Cannula Connectors | USP Class VI Polycarbonate |
| 2) Pneumatic Driveline | USP Class VI PVC |
| 3) Valves and Bladder | Angioflex® Polyurethane |
| 4) Silicone Tubing
(used during priming) | Medical Grade Silicone |

