AB5000™
Ventricle
Training Guide

ABIOMED®

Circulatory Support System
IMPORTANT NOTICE: Read the entire AB5000™ Ventricle Instructions for Use (0055-9001) before using the Ventricle. The Ventricle is to be used only in accordance with the Instructions for Use. Rx Only.

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Contents

Chapter 1  Introduction ............................................................................................. 1
  Description ............................................................................................................... 1
  Accessories ............................................................................................................. 2

Chapter 2  Indications and Contraindications .................................................... 3
  Indications for Use .................................................................................................. 3
  Contraindications for Use ...................................................................................... 4

Chapter 3  Warnings and Cautions ................................................................. 5
  Warnings .................................................................................................................. 5
  Cautions ................................................................................................................... 8

Chapter 4  AB5000™ Ventricle Operation .................................................. 9
  Description .............................................................................................................. 9
  Ventricle Cycles .................................................................................................... 9
    Diastole ............................................................................................................. 9
    Systole .............................................................................................................. 10
  Effects of Change in Preload ................................................................................ 10
  Effects of Change in Afterload ............................................................................. 10
    Systemic Vascular Resistance (SVR) ............................................................ 10
    Pulmonary Vascular Resistance (PVR) ......................................................... 10
  Optimizing Filling and Flow .............................................................................. 11
  Causes of Inadequate Filling of Bladder .............................................................. 11
    Physiological .................................................................................................. 11
    Mechanical ..................................................................................................... 13
  Causes of Inadequate Emptying of Bladder ...................................................... 13
    Physiological .................................................................................................. 13
    Mechanical ..................................................................................................... 13
  Biventricular Flow .............................................................................................. 13
  Flow Imbalance .................................................................................................. 14
  Options for Balancing Flows ............................................................................ 14
Chapter 5  Implanting the Circulatory Support System (CSS)....15

Priming ...................................................................................................................... 15
Materials............................................................................................................. 15
Procedure ............................................................................................................ 16
Cannulation ........................................................................................................... 20
Connecting the Cannulae to the Ventricle ................................................................. 25
Initiating Support ................................................................................................... 31
Univentricular Support ......................................................................................... 31
Biventricular Support ......................................................................................... 33

Chapter 6  Patient Management .................................................................35

Achieving Hemostasis ............................................................................................... 35
Excessive / Uncontrolled Bleeding ........................................................................... 36
Hemodynamic Management ....................................................................................... 37
Pharmacologic Therapy ............................................................................................. 38
Inotropes ............................................................................................................. 39
Sedation .............................................................................................................. 39
Pain Management ............................................................................................... 39
Antibiotics .......................................................................................................... 39
Anticoagulation Management ................................................................................... 40
ACT Monitoring .................................................................................................... 40
PTT Monitoring .................................................................................................. 41
Anti-Thrombin III .................................................................................................. 41
Decreasing the Risk of Thrombus Formation ........................................................... 41
Renal Management ................................................................................................. 42
Pulmonary Management ........................................................................................ 43
Arrhythmia Management ......................................................................................... 43
Ventricular Fibrillation and Ventricular Tachycardia ........................................ 43
Atrial Fibrillation ................................................................................................ 44
Bradycardia or Asystole ....................................................................................... 44
Intra-Aortic Balloon Pump (IABP) ........................................................................... 45
List of Figures

Figure 1: AB5000™ Ventricle ................................................................. 1
Figure 2: Removing the Clamped Tubes .................................................. 16
Figure 3: Submerging the Ventricle ......................................................... 17
Figure 4: Pointing the Arterial and Atrial Connectors Downward .......... 17
Figure 5: Rotating the Ventricle to Remove Trapped Air ..................... 18
Figure 6: Identifying the Atrial Connector ............................................. 26
Figure 7: Irrigating the Junction with Fluid ......................................... 27
Figure 8: Connecting the Atrial Cannula ............................................... 28
Figure 9: Identifying the Arterial Connector ......................................... 29
Figure 10: Connecting the Arterial Cannula ......................................... 30
Figure 11: Connecting to the AB5000™ Console ............................... 32
Figure 12: CSS Support During Ventricular Fibrillation ...................... 44
Figure 13: Synchronous Native Ejections ............................................. 47
Figure 14: Native Ejections During Weaning ........................................ 48

List of Tables

Table 1: Recommended Target Hemodynamics ..................................... 37
Table 2: Vasoactive Medications ......................................................... 38
About This Guide

The AB5000™ Ventricle Training Guide is one of a series of manuals for the AB5000™ Circulatory Support System (CSS). This 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.
Chapter 1
Introduction

Description

The AB5000™ Ventricle (or “Ventricle”), a major component of the AB5000™ Circulatory Support System (CSS), is a pneumatically driven blood pump (Figure 1) that provides pulsatile, hemodynamic support. The sterile, disposable Ventricle provides circulatory support in the presence of left-, right-, or both-sided heart failure. The Ventricle is:

- Located external to the patient
- Capable of operating horizontally or vertically
- Designed to be used only with the AB5000™ Console (“Console”)
- Provided with attached driveline and cannula connectors

Figure 1: AB5000™ Ventricle
The Console’s mechanical system drive medium is compressed room air. Return air is allowed to vent briefly to atmosphere before vacuum is applied.

The Console uses vacuum assist technology to allow the Ventricle to operate horizontally or vertically. It is important to remember that Ventricle filling is affected by gravity; slightly higher flow may be achieved by placing the Ventricle level with or below the patient’s atrium.

**NOTE:** Be sure to use sterile technique when unpacking the Ventricle and all accessories. Slide off the Ventricle’s packing sleeve in the direction indicated on the sleeve.

### Accessories

- One atrial cannula
- One arterial cannula
- Tunneling bullets
- Cannula restraints
- Sterile lubricant
- One Tubing adapter

**NOTE:** 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.
Indications for Use

ABIOMED® AB5000™ Circulatory Support System (CSS) therapy is intended to treat patients suffering from reversible ventricular dysfunction. Typical patients have undergone successful cardiac surgery and subsequently developed low cardiac output, or have suffered from acute cardiac disorders leading to hemodynamic instability.

The intent of the 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 (CPB) following heart surgery.
- Failed transplant patients who require ventricular assist following heart transplantation.
- Patients who require right ventricular assist device (RVAD) support while on implantable left ventricular assist device (LVAD) support.
- 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:

- Patient has a body surface area > 1.3 m² and is ≤ 75 years of age.
- Patient is in relatively good health other than the cardiovascular problem for which surgery was undertaken.
- 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.
- Cardiac resuscitation employing pharmacologic agents has been attempted. While the use of an 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).
- Patient is unable to be weaned from CPB 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.

### Contraindications for Use

- 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.
- Central nervous system damage resulting in fixed and dilated pupils.
Chapter 3
Warnings and Cautions

Warnings

- Prior to use, refer to the AB5000™ Circulatory Support System Operator's Manual (0015-9000), Cannulae Instructions for Use (0506-9110), and AB5000™ Ventricle Instructions for Use (0055-9001) for important instructions. Clinical warnings are not included in this Warnings section. Refer to the above documents for clinical warnings.

- Do NOT resterilize or reuse the Ventricle. It is a disposable device and is intended for single use only.

- Do NOT allow the following agents (and similar agents such as those listed here) to come in contact with the 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.

- Do NOT use the Ventricle with any console or drive mechanism other than the AB5000™ Console.

- The temperature of the Ventricle priming solution must NOT exceed 55 °C (131 °F).

- Do NOT use the Ventricle with any cannulae other than those provided by ABIOMED. These cannulae have been designed to form a smooth junction when joined with the Ventricle. This minimizes the risk of thrombus formation.
Warnings (continued)

- Only use white, threaded cannula restraints provided with the Ventricle. Use of nonthreaded or any other type of cannula restraints may result in: (1) cannulae becoming disconnected from the Ventricle, and (2) thrombus formation.

- 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.

- Make sure the cannulae are connected to the correct Ventricle connectors. The atrial cannula connects to the atrial (blue arrow) connector of the Ventricle. The arterial cannula connects to the arterial (red arrow) connector of the Ventricle. Reversed connections may result in serious injury or death.

- Air embolism is possible if the atrial cannula is not properly secured. To minimize this risk, be sure to follow these steps during cannulation:
  - Secure the atrial cannula using pledgets.
  - Fasten purse-string tourniquets directly to the atrial cannula using heavy sutures.

- 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.

- Air embolism is possible if air is present in the Ventricle. Be sure that all air has been removed from the Ventricle.

- 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.

- Air embolism is possible if air enters the Ventricle through the atrial cannulation sites during the procedure described in Initiating Support. To minimize this risk, be sure to carefully follow all steps in this procedure.
Warnings (continued)

- Chest compressions and/or precordial thump must *NOT* be performed on a CSS patient.

- To reduce the risk of hypercoagulation, do *NOT* apply heat externally to the Ventricle or cannulae. Consider traditional warming methods for patients encountering hypothermic episodes following open-heart surgery.

- During support, maintain continuous flow in the Ventricle. Interrupted use may cause thromboembolism upon restart.

- Use may result in the following:
  - Bleeding
  - Ventricle dependence
  - Impairment or loss of organ function
  - Infection
  - Hemolysis
  - Thromboembolism
  - Death
Cautions

- The arterial cannula contains a precoated graft that eliminates the need for preclotting. Do **NOT** preclot the arterial cannula graft.

- Handle the cannula connectors carefully to prevent damage to their edges.

- To prevent damage to the inflow valve (located behind the atrial connector) and outflow valve (located behind the arterial connector), do **NOT** touch the valves with the bulb syringe.

- Position the Ventricle to minimize stress at the cannula/skin exit sites and to prevent kinking of cannulae and driveline tubing. Avoid any actions that would result in tugging against a cannula. Also avoid any actions that would result in a cannula being bent in the area where it exits the skin and along its length.

- Measures should be taken to prevent infection or sepsis, especially at the cannula/skin exit sites.

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**Definition**

_A caution indicates a situation in which equipment may malfunction or be damaged._
Chapter 4
AB5000™ Ventricle Operation

Description

Assisted by vacuum, blood flows from the native heart into the AB5000™ Ventricle bladder. The bladder, which holds about 100 cc of blood, fills during diastole and empties during systole.

As the bladder fills, the air that surrounds the bladder is displaced through the driveline to the Console. A sensor in the Console detects when this airflow stops, indicating that the bladder is full.

When the bladder is full, the Console returns a bolus of air through the driveline. This compresses the bladder and delivers about 95 cc of blood to the patient.

Ventricle Cycles

Diastole

- Duration is the period of time necessary to fill the bladder.
- Ventricle adjusts to changes in volume or preload.
- Diastole shortens with increasing preload.

Example

Hypovolemia

Time to fill bladder increases, diastole lengthens, Ventricle rate decreases, Ventricle flow decreases.
Systole

- Duration is the period of time necessary to eject about 95 cc.
- Ventricle adjusts to changes in afterload.
- Systole lengthens with increasing afterload.

**Example**

**Hypertension**

Systemic Vascular Resistance (SVR) increases, time to empty bladder is prolonged, systole lengthens, Ventricle rate decreases, Ventricle flow decreases.

**Effects of Change in Preload**

\[\text{↑ Preload results in: ↑ Beat Rate and ↑ Cardiac Output}\]

\[\text{↓ Preload results in: ↓ Beat Rate and ↓ Cardiac Output}\]

**Effects of Change in Afterload**

**Systemic Vascular Resistance (SVR)**

\[\text{↑ SVR results in: ↓ Beat Rate and ↓ Cardiac Output}\]

**Pulmonary Vascular Resistance (PVR)**

\[\text{↑ PVR results in: ↓ Beat Rate and ↓ Cardiac Output}\]
Optimizing Filling and Flow

The Console uses vacuum assist technology to allow the Ventricle to operate vertically or horizontally. However, it is important to remember that Ventricle filling is affected by gravity. Slightly higher flow may be achieved by placing the Ventricle level with or below the patient’s atrium.

- Is preload sensitive.
- Works in a fill-to-empty mode.

Causes of Inadequate Filling of Bladder

Physiological

**Inadequate Volume**

**Tamponade**

Postoperative bleeding is the most common complication in CSS patients. When an accumulation of clot or pooled blood compresses the heart, Ventricle filling is affected and flow decreases. This can occur in the immediate postoperative period or at any time during the CSS therapy. Maintaining patency of the chest tubes can prevent or delay tamponade.

Symptoms of tamponade in CSS patients are similar to those of other postcardiotomy patients. (In late tamponade, these symptoms may not be readily apparent.):

- Cessation of previously rapid bleeding
- Elevation of filling pressures
- Poor filling and decreased Ventricle flow
- Hypotension
- Minimal response to volume
- General signs and symptoms of low output
Diagnosis and intervention should be swift. Until the patient can be re-explored, system and organ perfusion must be maintained with volume and pharmacologic therapy.

**Failure of the Unassisted Native Ventricle**

If only one side of the heart is supported, the unsupported side may be more vulnerable to failure. For example, heavy bleeding and the resulting requirement for blood product administration can exacerbate right heart failure in the LVAD patient. This leads to hepatic congestion, hepatomegaly, and increased coagulopathy. Pulmonary edema in an RVAD patient may indicate left-side failure.

Failure of the unassisted native ventricle can be precipitous and should be treated aggressively. Inotropes and vasoactive drugs will be needed to assist the failing native ventricle and support end-organ perfusion. Increasing preload usually leads to worsening of the hemodynamic picture. If the patient does not improve sufficiently with nonsurgical interventions, plans should be made to return to surgery for BiVAD support.

Symptoms of failure of the unassisted native ventricle are:

- Increasing filling pressures on the unassisted side
- Normal-to-low filling pressures on the assisted side
- Poor filling and decreased Ventricle flow
- Signs and symptoms of low output
Mechanical

Kink in Atrial Cannula

Cannula Placement

- Poor drainage
- Vena cava compression

Causes of Inadequate Emptying of Bladder

Physiological

Increased Afterload

- Elevated SVR with left-side support
- Elevated PVR with right-side support

Mechanical

Kink in Arterial Cannula

Ventricle Positioned above Patient’s Atrium

Biventricular Flow

During biventricular support, Ventricles operate independent of each other. Because each Ventricle responds to its own preload and afterload, right and left flows may not be equal. This difference is usually within 0.5 liter per minute (L/min) and is not a cause for concern. If the flow differential is > 0.5 L/min, determine the cause of the imbalance before intervening.
Flow Imbalance

- If right-side flow exceeds left-side flow, and the pulmonary and hemodynamic status is stable, balancing flows is not necessary. (Flow imbalance may be caused by native heart ejections that are contributing to the total cardiac output. Observe the arterial waveform for ejection spikes that indicate native left ventricular recovery. These ejection spikes correlate with the patient’s R-wave on the EKG.)

- If right-side flow exceeds left-side flow, and the pulmonary and hemodynamic status is unstable, this may be due to elevated SVR.

- Systemic vascular resistance (SVR) will increase with hypertension, decreasing left-side flow.

- High pulmonary vascular resistance (PVR) impedes blood flow across the lungs, decreasing right-side flow.

- Right-side flow exceeding left-side flow could contribute to pulmonary edema.

- Decreasing right-side flow to less than left-side flow has been employed to help resolve pulmonary edema.

Options for Balancing Flows

- Optimize preload by giving volume or diuretics.

- Medically optimize afterload by giving vasoactive drugs.

- Use the weaning control to maintain balanced flows (± 0.5 L/min).

- Allow the Console at least 2 minutes between weaning reductions to adjust flow.
Chapter 5
Implanting the CSS

IMPORTANT GUIDELINE: The TIMING of the implant is critically important to the SUCCESS of the implant.

See the AB5000™ Ventricle Instructions for Use (0055-9001) provided with each Ventricle.

This chapter describes the procedures for implanting the CSS and initiating univentricular or biventricular support:

- Priming
- Cannulation
- Connecting the Cannulae to the Ventricle
- Initiating Support

Priming

Materials

- Deep basin
- Warmed priming solution (such as Normasol, Lactated Ringers, Plasmalyte, or normal saline for intravenous infusion)

WARNING: The temperature of the priming solution must NOT exceed 55 ºC (131 ºF).

- Large bulb syringe
- AB5000™ hand pump
Procedure

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

   **NOTE:** The use of warmed priming solution may help prevent the formation of air bubbles.

2. Remove the clamped tubes (with open clamps) from the arterial and atrial connectors of the Ventricle (Figure 2). Set these lengths of tubing aside to be used as connector caps after priming.

   **NOTE:** Arrows indicate direction of flow.

   ![Figure 2: Removing the Clamped Tubes](image)

3. Pass the end of the driveline of the Ventricle out of the sterile field. Secure the sterile portion of the driveline to the sterile drape.

4. Connect the AB5000™ hand pump to the driveline.

5. Use the hand pump to evaluate the expansion and contraction of the Ventricle bladder. Leave the bladder fully expanded.
CAUTION: To prevent damage to the inflow valve (located behind the atrial connector) and outflow valve (located behind the arterial connector) during the following step, do NOT touch the valves with the bulb syringe.

6 Fill the Ventricle, using the bulb syringe, by slowly pouring priming solution into the atrial connector, which is marked with a blue arrow.

7 With the arterial and atrial connectors facing upward, submerge the Ventricle in the basin (Figure 3).

![Figure 3: Submerging the Ventricle](image)

(Driveline is not shown.)

8 Point the arterial and atrial connectors downward. Tap the Ventricle several times to move trapped air to the back of the housing (Figure 4).

![Figure 4: Pointing the Arterial and Atrial Connectors Downward](image)
9 Rotate the Ventricle so that the arterial and atrial connectors are again pointed upward. Roll the housing as necessary to move trapped air toward the arterial connector (Figure 5).

![Location of trapped air](image)

**Figure 5: Rotating the Ventricle to Remove Trapped Air**

10 Using the AB5000™ hand pump, begin pumping at about 40 to 60 strokes per minute to remove any trapped air. The last stroke should leave the Ventricle bladder fully expanded.

11 Inspect the Ventricle for air while it is still submerged in the priming solution. If air is found, repeat steps 8–10.

---

**NOTE:** The Ventricle housing material may contain small, trapped bubbles. These are normal and can be ignored.

12 Submerge the two lengths of clamped tubing in the priming solution. Make sure all air has been removed from the tubing and then tighten the clamps.

13 Push the clamped tubing onto the arterial and atrial connectors. This will prevent air from entering the Ventricle when it is removed from the priming solution.

14 Remove the Ventricle from the priming solution. Inspect the Ventricle for air.
**WARNING:** Air embolism is possible if air is present in the Ventricle. Before proceeding, be sure that all air has been removed from the Ventricle.

The Ventricle is now primed and ready for connection to the arterial and atrial cannulae.
Cannulation

Percutaneous cannula exit sites should be 5 cm apart as measured from the center of each cannula. The cannulae should exit at an angle that reduces the chances of kinking when the Ventricle is placed directly below the cannula exit sites.

CAUTION: Position the Ventricle to minimize stress at the cannula/skin exit sites and to prevent kinking of cannulae and driveline tubing. Avoid any actions that would result in tugging against a cannula. Also avoid any actions that would result in a cannula being bent in the area where it exits the skin and along its length.

See the Cannulae Instructions for Use (0506-9110) provided with each cannula.

Ventricle flow is dependent on cannula size. It is recommended that the following cannulae be used with Ventricles.

- 32 Fr. atrial – flow > 4.0 L/min.
- 42 Fr. atrial – flow > 4.8 L/min.

WARNING: Air embolism is possible if the atrial cannula is not properly secured. To minimize this risk, be sure to follow these steps during cannulation:
- Secure the atrial cannula using pledgets.
- Fasten purse-string tourniquets directly to the atrial cannula using heavy sutures.

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.
Atrial (Venous) Cannulation Sites

Right

Mid-Free Wall

Most commonly used site

Appendage

Usually used for venous CPB cannulation, making accessibility difficult for CSS cannulation

Left

Inter-Atrial Groove

- Requires more manipulation of the heart than other sites
- Following implant, this site should be closely observed for impaired filling of the Ventricle secondary to:
  - Compression of the vena cava
  - Cannula pushing on the septum, causing it to bow into the right atrium and obstruct flow

Superior Pulmonary Vein

Consider use of 32 Fr. cannula

Appendage

- Usually small and inaccessible in most noncardiomyopathy patients
- May be difficult to obtain good drainage
- Tissue may be more fragile than other sites, making implant more difficult
Chapter 5 Implanting the CSS

Cannulation

**Dome**
- Consider for small hearts and small patients
- Located posteriorly, between the superior vena cava and the aorta
- Requires less manipulation of the heart during explantation than other sites

**Ventricular Cannulation**

**LV Apex**
- Affords more complete decompression of the LV, eliminating stasis
- Recommended approach for patients with prosthetic mitral valve, because it maintains flow across the mitral valve to inhibit stasis and thrombus
- Involves the use of concentric, pledgeted purse-string sutures placed on the anterior aspect of the LV apex
- Bevel to be positioned away from the septal wall when using 36 Fr. atrial cannula
- TEE to be considered to verify cannula position below cordae and valve apparatus

**Atrial Cannulation Techniques**

1. The tunneling bullet is inserted into the distal end of the cannula for externalization. The surgeon then tunnels the cannula from the pericardial space out through the skin below the ribs.

   **NOTE:** *The location of the exit site is determined by the orientation of the atrial cannula.*

2. After the cannula is externalized, the tunneling bullet is removed. The cannula restraint is attached with the notched end away from the heart.
3 It is recommended that 2-0 or 3-0 polypropylene sutures be used to perform double concentric purse strings with pledgets at the cannulation site. Bovine pericardium, pericardial patches, or pledgets may be used to seal the purse-string suture sites.

4 The CPB flow should be reduced to allow the atrium to fill.

5 A stab incision is made inside the double concentric purse string. If necessary, the site is dilated.

6 The surgeon inserts the atrial cannula into the incision to at least the 2-cm depth marker.

7 The purse strings are tightened and the tourniquet is secured. The purse strings can be wrapped around the tourniquet and secured to keep them from loosening or knotting. Metal clips can also be used.

8 The tourniquets are secured onto themselves and then onto the cannula with heavy suture to stabilize the cannula and help prevent loosening of the purse-string sutures.

9 The Valsalva maneuver is performed to fill the atrial cannula.

Arterial Cannulation Sites

Right

Main Pulmonary Artery

Left

Ascending Aorta
Arterial Cannulation (Grafting) Techniques

General Guidelines

- Consider the use of 4-0 or 5-0 polypropylene sutures.
- Consider heel-and-toe pledgets or a pericardial collar at the anastomosis site. Surgical glue may also be used.
- If at all feasible, consider the placement of the proximal anastomoses of the bypass grafts to allow room for the potential need for the placement of the Ventricle arterial graft. The anterolateral wall of the aorta is the common anastomotic site for left arterial grafting. However, the posterior wall of the aorta has been used when bypass grafts crowd the anterolateral wall.
- Care must be taken to place the right arterial graft high enough on the main distal pulmonary trunk. Placing the right arterial graft too close to the pulmonic valve could deform the valve, causing valvular insufficiency and retrograde flow.

Placing the Arterial Cannula (Graft)

1. The excess graft is trimmed and then beveled at a 30° angle to prevent tension on the end-to-side anastomosis site.

2. The graft does not require preclotting. The graft is tapped or massaged to release trapped air.

3. The surgeon externalizes the cannula using the tunneling bullet. (Some surgeons prefer to externalize the arterial graft after it has been anastomosed to the great vessel; this allows the heel of the suture site to be checked for oozing while the graft is backflushed.)
Connecting the Cannulae to the Ventricle

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

**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. The cannulae exiting the patient must be of equal length. If necessary, cut the longer of the two cannulae. To allow a secure connection to the Ventricle, leave a minimum of 5 cm of tubing without wire reinforcement.

2. Apply sterile lubricant (provided) to the inner diameter and threads of the atrial and arterial cannula restraints. Slide the atrial cannula restraint onto the atrial cannula. Repeat this process for the arterial cannula.

**NOTE:** If the cannulae are of equal length, proceed to step 6. If the cannulae are not of equal length and cannot be cut, use the tubing adapter (provided) by performing the following steps, beginning with step 3.

3. Push the barbed connector of the tubing adapter fully into the shorter cannula. Slide the cannula restraint towards the connector until it is snug against the fitting.

4. Hold the adapter connector and finger tighten the cannula restraint. Make sure the restraint is not cross threaded.
Chapter 5 Implanting the CSS
Connecting the Cannulae to the Ventricle

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

5 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.

6 Remove all air from the atrial cannula by backfilling with blood or filling the atrial cannula with saline irrigation fluid. Clamp the atrial cannula close to, but not over, the reinforcing wire.

7 Using care to prevent air from entering the Ventricle, remove the clamped tubing from the atrial connector.

WARNING: In the following step, make sure the atrial cannula and atrial connector are correctly identified (Figure 6). The atrial connector is marked with a blue arrow. Reversed connections may result in serious injury or death.

![Figure 6: Identifying the Atrial Connector](image)
Chapter 5  Implanting the CSS

Connecting the Cannulae to the Ventricle

8  Hold the atrial cannula against the atrial connector (Figure 7). *Irrigate the junction with fluid* and push the cannula onto the connector.

![Figure 7: Irrigating the Junction with Fluid](image)

9  Inspect the junction for air.

---

**WARNING:**  Air embolism is possible if air is present in the Ventricle. Before proceeding, be sure that all air has been removed from the Ventricle.

---

10  Slide the cannula restraint toward the connector until it is snug against the fitting.
11 Finger tighten the cannula restraint (Figure 8). Make sure the restraint is *properly threaded* (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.

12 Remove all air from the arterial cannula by backfilling with blood or filling the arterial cannula with saline irrigation fluid. Clamp the arterial cannula close to, but not over, the reinforcing wire.

13 Using care to prevent air from entering the Ventricle, remove the clamped tubing from the arterial connector.
**WARNING:** In the following step, make sure the arterial cannula and arterial connector are correctly identified (Figure 9). The arterial connector is marked with a red arrow. Reversed connections may result in serious injury or death.

**Figure 9: Identifying the Arterial Connector**

14 Hold the arterial cannula against the arterial connector. Irrigate the junction with fluid and push the cannula onto the connector.

15 Inspect the junction for air.

**WARNING:** Air embolism is possible if air is present in the Ventricle. Before proceeding, be sure that all air has been removed from the Ventricle.

16 Slide the cannula restraint toward the connector until it is snug against the fitting.
17 Finger tighten the cannula restraint (Figure 10). Make sure the restraint is *properly threaded* (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.

---

*Figure 10: Connecting the Arterial Cannula*

Both cannulae will be unclamped prior to initiating support.
Initiating Support

**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.

Univentricular Support

1. As described in the *AB5000™ Circulatory Support System Operator's Manual (0015-9000)*, turn on the Console and allow the complete self-test to run.

2. Place the patient in the Trendelenberg position.

**WARNING:** Air embolism is possible if air enters the Ventricle through the atrial cannulation sites during this procedure. To minimize this risk, be sure to carefully follow all steps in this procedure.

**NOTE:** Some possible causes of air intrusion are:
- Purse-string sutures not tight enough.
- Atrium not filled prior to initiation of support.
- Atrial cannula not positioned deeply enough.
- Atrial wall torn.

3. Reduce or stop CPB to allow the patient’s atria to fill with blood.

4. Use saline or blood to **submerge** the atrial cannulation sites.

5. To aid in inspection for air, position the Ventricle above the patient’s atria.
6 Release both cannula clamps. Leave the clamps close to, but not over, the reinforcing wire.

7 Slowly press the AB5000™ hand pump (or activate the single stroke feature).

8 Inspect the Ventricle for air. If air is present, stop pumping and remove the air by performing the following steps:
   a. Discontinue the use of the hand pump (or the single stroke feature).
   b. Clamp both cannulae and disconnect them from the Ventricle. Work the air towards and out of the junctions.
   c. While using continuous saline irrigation to prevent air from entering the system, reconnect the cannulae to the Ventricle.
   d. Inspect the junctions for air.
   e. Slowly press the hand pump (or activate the single stroke feature) and carefully check the system for air.

9 Connect the driveline connector to the AB5000™ Console (Figure 11).

![Driveline Connector](image)

**Figure 11: Connecting to the AB5000™ Console**

**NOTE:** For proper system operation, the driveline connector must be attached to the Console before the ON button is pressed. An alarm will be generated if the driveline connector is attached after the ON button is pressed.
10 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 by performing the procedure described in step 8 of this section. Unclamp the driveline tubing and press the Console’s ON button.

**WARNING:** During support, maintain continuous flow in the Ventricle. Interrupted use may cause thromboembolism upon restart.

11 Observe the beat rate. An unstable beat rate may indicate a problem with cannula positioning.

**NOTE:** A slight change in beat rate is normal, especially during the first 2 minutes while the Console adjusts to the optimal beat rate. A brief extension of 1 beat every 15 minutes is normal as the Console recalibrates.

12 After the pumping has reached a steady state, observe the filling and emptying of the Ventricle to determine preload and afterload status.

13 Consider volume replacement.

14 Adjust the position of the Ventricle as filling indicates. Allow the system to stabilize for 2 minutes after each adjustment.

**Biventricular Support**

Consider biventricular support if the unassisted side of the heart cannot effectively pump because of the increased flow from the assisted side. Biventricular support is initiated by performing the following steps:

1 If necessary, place the patient back on full CPB. If the patient is placed on CPB, CSS therapy must be discontinued.
2 To prevent stasis, intermittently move blood through the cannulated side of the heart and through the Ventricle using the hand pump (or the single stroke feature) as described below:
   a. Reduce bypass flow and allow the atrium to fill.
   b. Press the hand pump (or activate the single stroke feature) 2 or 3 times every 2 to 5 minutes.
   c. Resume full CPB.

3 Prime the second Ventricle.

4 Perform cannulation, make connections, and initiate support (including removal of air) as previously described. Left-side support should be initiated before right-side support.
This chapter 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.

**Achieving Hemostasis**

The most important consideration in the postoperative management of CSS patients is achieving hemostasis. Because postoperative bleeding can be caused by many factors, it is important to be systematic when determining the source of the blood loss.

The approach to achieving hemostasis *begins in the OR*. Recommended guidelines are as follows:

1. Reverse heparin in the OR to achieve a preoperative baseline ACT.

2. Reverse postbypass coagulopathy as follows:
   - Rewarm the patient to a normothermic state.
   - Administer blood products and clotting factors. These blood products include, but are not limited to: packed red blood cells, platelets, FFP, and cryoprecipitate.

3. Closely monitor chest tube drainage.
Chapter 6: Patient Management

Excessive / Uncontrolled Bleeding

**WARNING:** To reduce the risk of hypercoagulation, do **NOT** apply heat externally to the Ventricle or cannulae. Consider traditional warming methods for patients encountering hypothermic episodes following open-heart surgery.

4. Achieve and maintain normothermia (> 36 °C).
   - Use a warming blanket.
   - Administer warmed blood products.

5. Replace blood components as needed. Recommended target values are:
   - Hemoglobin > 10 gm/dL
   - Hematocrit > 30%
   - Platelets > 100,000/mm$^3$

6. Consider leukocyte filtration in order to prevent potential elevation of panel reactive antibody. Leukocyte filtration may also reduce CPB-induced inflammatory response.

**Excessive / Uncontrolled Bleeding**

- Rule out surgical bleeding vs. coagulopathy.
- Consider the use of:
  - Cryoprecipitate
  - Amicar®
  - DDAVP
  - Aprotinin
- Consider RVAD implantation. Extensive blood-product transfusions can cause a weakened RV to fail. This leads to liver congestion, reduction of clotting factor synthesis, and increased venous bleeding.
Hemodynamic Management

Volume administration, vasoactive pharmacologic support, and efficient removal of fluid overload are important factors in successful patient management. Optimization of hemodynamic parameters is key in achieving maximum Ventricles flows and systemic perfusion.

To properly assess right- and left-sided pressure values, a Swan-Ganz® catheter is recommended for at least 48 to 72 hours.

Table 1: Recommended Target Hemodynamics

<table>
<thead>
<tr>
<th>Recommended Target Hemodynamics</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAP</td>
</tr>
<tr>
<td>CVP</td>
</tr>
<tr>
<td>LA / PCWP</td>
</tr>
<tr>
<td>SVR</td>
</tr>
<tr>
<td>PVR</td>
</tr>
<tr>
<td>CI</td>
</tr>
</tbody>
</table>

NOTE: Volume replacement with blood, blood products, and albumin (rather than crystalloid) is recommended to promote increased colloidal osmotic pressure. This helps limit interstitial edema. Due to the potential for inducing or worsening a proinflammatory and coagulopathic state, autotransfusion should be avoided.
NOTE: In the presence of an RVAD, thermodilution cardiac outputs would be inaccurate due to the altered path of injectate through the right Ventricle. The following formulas are used to calculate SVR and PVR:

\[
SVR \text{ (in dynes x sec / cm}^5\text{)} = \left(\frac{MAP-CVP}{LVAD \text{ flow}}\right) \times 80
\]

\[
PVR \text{ (in dynes x sec / cm}^5\text{)} = \left(\frac{MPAP-PCWP}{RVAD \text{ flow}}\right) \times 80
\]

Pharmacologic Therapy

Vasoactive medications may be required to achieve and maintain the target hemodynamics. However, inotropic support should not be needed in the BiVAD-supported patient.

Table 2: Vasoactive Medications

<table>
<thead>
<tr>
<th>Vasoconstrictors (to maintain vascular tone and normal peripheral resistance)</th>
<th>Vasodilators (to reduce afterload)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vasopressin (physiologic dose: 0.04 – 0.1 units/min or 2.4 – 6 units/hr) (Physiologic replacement doses of the hormone L-arginine vasopressin have been shown to restore vascular tone, increase mean arterial pressure, and rapidly reduce catecholamine requirements.)</td>
<td>For SVR: Nitroprusside</td>
</tr>
<tr>
<td>For PVR: Milrinone, Prostoglandin E1, Nitric Oxide</td>
<td></td>
</tr>
<tr>
<td>Norepinephrine</td>
<td>---</td>
</tr>
<tr>
<td>Epinephrine</td>
<td>---</td>
</tr>
<tr>
<td>Neo-Synephrine®</td>
<td>---</td>
</tr>
</tbody>
</table>
Inotropes

If only the left side of the heart is supported, there may be a need to pharmacologically assist the unsupported ventricle, thus helping to provide the preload for the assisted side of the heart.

Sedation

Unless the patient’s condition dictates otherwise, chemical paralysis is not necessary. Sedation levels appropriate to ventilator management and anxiety relief are advised.

During CSS therapy, initial and periodic neurologic assessments must be performed.

Pain Management

In addition to sedation, pain management should be addressed.

Antibiotics

A broad-spectrum antibiotic is recommended. Organism-specific coverage should be prescribed as needed.
Anticoagulation Management

The approach to anticoagulation begins in the OR and is based on achieving surgical hemostasis and a stable coagulation profile.

Recommended guidelines for initiating anticoagulation therapy are as follows:

- Mediastinal drainage < 50 to 75 cc/hr for 3 consecutive hours
- Normothermia achieved (> 36 ºC)
- Hemoglobin > 10 gm/dL
- Hematocrit > 30%
- Platelets > 100,000/mm³

It is recommended that anticoagulation be attained by using heparin, with an initial infusion of 10 to 15 units/kg/hr. To maintain anticoagulation parameters within the targeted range, adjustments to the heparin drip are necessary. Heparin bolus is not recommended.

Antiplatelet agents such as aspirin, Persantine®, or low-molecular-weight dextran can also be used, at the clinician’s discretion. As the patient becomes ambulatory, the administration of Coumadin® is considered.

ACT Monitoring

ACTs should be monitored hourly until the therapeutic level of 180 to 200 seconds is achieved (values close to 200 are recommended). When a therapeutic level has been reached and maintained, testing frequency can be extended to every 2 hours.

ACT levels should be increased to 250 to 300 seconds for unresolved atrial or ventricular fibrillatory rhythms, as well as for low-flow states (< 3.0 L/min).
PTT Monitoring

If PTT values are used to manage anticoagulation, values should be assessed every hour until the target range of 2 to 2.5 times the lab control’s normal value is achieved. When a therapeutic level has been reached and maintained, testing frequency can be extended to every 2 hours.

PTTs should be increased to 2.5 to 3 times the lab control’s normal value for unresolved atrial or ventricular fibrillatory rhythms, weaning, and low-flow states (< 3.0 L/min).

Some surgical teams monitor platelet aggregation values or use thromboelastograph to guide anticoagulation, antiplatelet management, and factor replacement decisions.

Anti-Thrombin III

Anti-Thrombin III (AT III) deficiencies are common in patients receiving a continuous heparin infusion. This condition can manifest as an inability to sustain a therapeutic level of anticoagulation without significant increases in the drug. Most clinicians treat this condition with the administration of one or two units of FFP because AT III is found in plasma at about 1 unit/ml.

Decreasing the Risk of Thrombus Formation

Maintaining flow > 4.0 L/min will minimize stasis in the Ventricle and ensure proper washing of the inflow and outflow valves.

If flows are < 3.0 L/min, ACTs should be increased to 250 to 300 seconds (or PTTs to 2.5 to 3 times the lab control’s normal value). Flows < 2.0 L/min should be avoided.
Care must be taken when cannulating in a patient with a prosthetic heart valve. Isolation of the native ventricle can occur when a cannula is implanted in the atria, diverting blood from the atria to the AB5000™ Ventricle. The flow of blood across the prosthetic heart valve may be insufficient and cause the valve to remain closed. This diminished flow may lead to valvular thrombus formation.

For patients with prosthetic mitral valves, cannulation of the LV apex allows for flow across the valve while providing maximal ventricular decompression.

With a prosthetic aortic valve, there is no alternate cannulation choice. The use of inotropic support, which enhances LV ejection, has been used by some clinicians to achieve flow across the aortic valve. Others have used the CSS weaning mode; this allows partial flow into the LV and across the aortic valve. Prophylactically increasing the anticoagulation level should also be considered.

Renal Management

Diuretics administered in a continuous infusion (rather than bolus) are recommended to offer protection from sudden decreases in Ventricle preload and flow.

Some clinicians recommend titration of the infusion to yield a urine output of 100 to 200 cc greater than input each hour. Short-term hemodialysis is not usually a viable option due to rapid shifts in intravascular volume.

The use of CVVH(D) is recommended in patients with compromised renal function. Many of the proinflammatory biological mediators are also filtered out during this process, potentially reducing the inflammatory cascade.
Pulmonary Management

In the immediate postoperative period, CSS patients will require mechanical ventilation. Patients can be weaned from the ventilator and extubated while on CSS therapy.

Monitoring the patient’s pulmonary status helps prevent hypoxia, which can lead to pulmonary vasoconstriction that will impede Ventricle ejection.

Aggressive pulmonary toilet and turning the patient side-to-side should be considered. Many institutions provide pulmonary therapy beds for their CSS patients.

Arrhythmia Management

Because the CSS System works asynchronously to the native heart, the BiVAD-supported patient will remain hemodynamically stable during episodes of malignant arrhythmia. However, prompt intervention may be necessary to preserve myocardium.

Ventricular Fibrillation and Ventricular Tachycardia

WARNING: Chest compressions and/or precordial thump must NOT be performed on a CSS patient.

- The heart should be defibrillated. It is not necessary to turn off CSS therapy prior to defibrillation. Pharmacologic support is recommended.

- If sustained, the following recommendations apply:
  - ACTs should be increased to 250 to 300 seconds.
  - PTTs should be increased to 2.5 to 3 times the lab control’s normal level.
Atrial Fibrillation

- Electrical cardioversion is recommended. It is not necessary to turn off CSS therapy prior to cardioversion. Pharmacologic support is also recommended.

- If chronic, the following recommendations apply:
  - ACTs should be increased to 250 to 300 seconds.
  - PTTs should be increased to 2.5 to 3 times the lab control’s normal level.

Bradycardia or Asystole

**WARNING:** Chest compressions and/or precordial thump must **NOT** be performed on a CSS patient.

- Consider the use of a temporary pacemaker to support electrical conduction.
- Pharmacologic support is recommended.
Intra-Aortic Balloon Pump (IABP)

With a functioning LVAD in place, the need for an IABP is eliminated. Discontinuing IABP therapy while still in surgery allows more effective hemodynamic management and a less cumbersome patient transport to the ICU. Otherwise, the IABP should be discontinued in the initial postoperative period after hemostasis is achieved and prior to the start of anticoagulation therapy.

Because the CSS System works asynchronously to the native heart, timing the IABP to the EKG trigger may compromise VAD flow if balloon inflation occurs during VAD ejection. It is recommended that the IABP be timed using the arterial pressure trigger that synchronizes the IABP to the VAD cycle.

An IABP may be used in conjunction with an RVAD. In this instance, the IABP can be timed to the EKG because the left side of the heart will be synchronous with normal conduction activity.

Nutrition

Nutritional support should be started as soon as possible. Patients requiring ventricular assist may have an increased need for protein. Tube feeding or TPN can be initiated while the patient is still intubated.

Cannulation Site Care

Cannulation sites should be cleansed daily and as needed using standard sterile dressing change technique.
Patient Activity

After hemodynamics have stabilized and the chest is closed, progressive activity is encouraged as tolerated. The head of the bed may be raised, using caution to prevent kinking of the Ventricle tubing.

Patients should be turned frequently to prevent pulmonary complications and skin breakdown. Patients can be assisted to sit at the side of the bed or in a cardiac chair.

**NOTE:** *Ventricle position may need to be adjusted after the patient is moved.*

Turning the patient may alter Ventricle filling because of caval compression. It is advised to assess Ventricle filling before and after turning the patient. The patient should be repositioned as necessary.

Physical therapy should be initiated as soon as possible. Isometric exercises should be included if the patient’s condition permits.

Patient Transport Within the Hospital

Whenever the patient is being transported, care **must** be taken to prevent damage to the Ventricles and drivelines. Drivelines and driveline/drive port connections should be protected from tension during transport.

Vacuum assist technology allows horizontal or vertical orientation of the Ventricle. The Ventricle(s) operate horizontally beside the patient while the patient is supine and vertically when the patient is upright.
Chapter 7  
Weaning from Support

The arterial waveform is checked for native ejections to evaluate LV recovery. The pulmonary artery waveform is checked for native ejections to evaluate RV recovery. In most cases, some evidence of myocardial recovery is seen between 48 and 96 hours after CSS therapy is initiated.

![Figure 13: Synchronous Native Ejections](image)

Weaning should be attempted only after native heart recovery has been confirmed by TEE. The first postoperative TEE is often performed on the second or third day of CSS therapy. TEE should demonstrate improved wall motion and increased ejection fraction in a volume-loaded heart. Reasonable hemodynamic stability should be sustained during the process as further evidence of ventricular recovery.

Following a successful weaning process, minimal inotropic support may be required prior to explantation. In some cases, an IABP has been used after explantation to provide ventricular support.
Procedure

1. The TEE probe is advanced into position. Baseline hemodynamics are observed.

2. Flow is reduced by 0.5 L/min every 5 minutes using the weaning controls.

3. Flow should not be reduced below 3.0 L/min without increasing ACT to 250 to 300 seconds (or PTT to 2.5 to 3 times the lab control’s normal value). (The AB5000™ Console will not reduce flow below 2.0 L/min.)

4. The ventricular response to the increased workload is evaluated.

5. If normal hemodynamics are maintained for a brief period of time, explantation should be considered. If hemodynamics are not satisfactory, the patient should be returned to full CSS therapy.

Assessing Recovery

As flow is decreased, native ejections should become more prominent on the arterial waveform.

*Figure 14: Native Ejections During Weaning*
Chapter 8
Explantation

Preparation

Recommended guidelines for the period prior to explantation are as follows:

• The patient should be fully anticoagulated until explantation.
• Low-dose inotropic support should be considered.

Procedure

NOTE: Explantation can be performed with or without CPB.

1 If only one side has recovered, the recovered side is explanted, and support is maintained for the nonrecovered side. (If both sides have recovered, the right side is explanted first.)

NOTE: The Console’s OFF button must be pressed twice to stop pumping. (A single press is ignored after 13 seconds.) This is a safety feature to prevent accidental cessation of pumping.

2 After the atrial cannula is removed, about 100 cc of back-bleeding is allowed to expel any pannus formation at the cannula tip and/or in the atrium or native ventricle.

3 An arterial side-biting clamp is used. The arterial graft is cut and removed; it is then oversewn or stapled.
4 When explanting the LV Apical cannula, consider having CPB on standby.

5 The arterial graft is entirely removed if the patient is infected or receiving a transplant.

6 All cannulae and grafts are removed from the thoracic cavity.

7 A small ellipse of tissue is excised around each skin exit site. Sites are then closed primarily.
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