CentriMag® Ventricular Assist System (VAS): Patient & Device Management Guidelines

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CAUTION: The CentriMag VAS is an Investigational Device in the United States (USA) and limited by USA Federal law to investigational use only.

CAUTION: The CentriMag RVAS is a Humanitarian Device in the USA. The Levitronix CentriMag RVAS is authorized by USA Federal law to provide temporary circulatory support for up to 30 days for patients in cardiogenic shock due to acute right ventricular failure. The effectiveness of this device for this use has not been demonstrated. Distribution of this device is restricted to use by or on the order of a physician.
The CentriMag VAS (Ventricular Assist System) may be used in the United States for up to 30 days of circulatory support in the following situations:

1. The CentriMag RVAS is FDA approved for use under a humanitarian device designation (HDE). The CentriMag VAS may be used as a right heart assist device (RVAD) for patients requiring mechanical right ventricular support.

2. The CentriMag VAS is FDA approved for use under an investigational device exemption (IDE). The CentriMag VAS may be used for right, left or biventricular support for patients who cannot be weaned from cardiopulmonary bypass (failure to wean), and who are enrolled in the FDA-approved pivotal trial.

This document is a training aid intended to accompany CentriMag VAS educational material. It provides technical information concerning the CentriMag VAS and clinical guidelines for managing the CentriMag VAS system and patients.

The clinical information in this document is intended for guidance only. Each medical professional must determine the appropriate course of therapy and suitability of these guidelines based on the needs of each individual patient.

This document is not intended to replace the CentriMag Blood Pump Instructions for Use (IFU) or the CentriMag Console Operating Manual. For the CentriMag Pivotal Trial, the study protocol supersedes this document and must be followed.

For a complete list of warnings and cautions refer to the CentriMag Blood Pump Instructions for Use and the CentriMag Console Operating Manual.

Warning: Carefully read all Warnings, Precautions, Manuals, and Instructions for Use for the CentriMag VAS and HDE RVAS prior to use of either system. Failure to read and follow all instructions for use, or failure to observe all stated warnings, could cause serious injury or death to the patient.

Warning: The Guidelines in this document only apply to, the Levitronix CentriMag VAS currently under evaluation in a U.S. pivotal clinical trial and, to the CentriMag RVAS approved for Humanitarian Use (HDE). These Guidelines do not apply to any other Levitronix extracorporeal circulatory support or cardiopulmonary bypass products.

The information contained in this document is subject to change without notice.

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1 LEARNING OBJECTIVES

After reading this document along with the CentriMag Console Operating Manual, the reader will be able to:

- Describe the main characteristics and components of the CentriMag System.
- List the key design features of the CentriMag VAS.
- Describe how the CentriMag blood pump works.
- Discuss the clinical applications of the CentriMag VAS.
- Describe the cannulation procedures for RVAS and LVAS support.
- Describe the essential pre- and post-VAS medical management considerations including methods for hemodynamic assessment and anticoagulation therapy.
- List equipment and supplies needed to implement CentriMag support.
- Describe how to assemble the CentriMag VAS Equipment and Circuit.
- Describe startup and initiation of support procedures for the CentriMag VAS.
- Describe management of the CentriMag VAS during transport.
- Describe potential complications, troubleshooting and their treatment.
- Describe potential CentriMag console troubleshooting procedures.
2 INTRODUCTION

The CentriMag ventricular assist system (VAS) is designed to provide a reliable, versatile, and efficient means for implementing mechanical circulatory support in a variety of clinical scenarios. The CentriMag VAS has the potential to improve outcomes in patients with acute heart failure by decreasing ventricular workload, stabilizing hemodynamic conditions, and providing optimal conditions for facilitating myocardial recovery.1-5 Patients in acute cardiac failure are at risk of developing multisystem organ failure which can threaten long-term survival. For these patients, short-term circulatory support can provide optimal conditions for recovery of ventricular function or provide a means to hemodynamically stabilize the patient until an alternative, longer-term therapy can be implemented.

The CentriMag design characteristics are intended to minimize trauma to blood cells, and to allow left, right or biventricular circulatory support for up to 30 days.

![CentriMag Blood Pump](image)

**Figure 1:** The CentriMag Blood Pump (left) is controlled electromagnetically. This unique design eliminates the need for bearings, seals or shafts, as seen in the schematic (right).

The primary design features of the CentriMag VAS are described in Table 1.

<table>
<thead>
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<th>Table 1. Design Features of the CentriMag VAS</th>
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<tr>
<td>Magnetically levitated impeller</td>
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<tr>
<td>No bearings, shafts, valves, or seals within blood pump</td>
</tr>
<tr>
<td>Low priming volume (31 cc) designed for ease of priming</td>
</tr>
<tr>
<td>Designed to minimize the risk of blood stasis and hemolysis</td>
</tr>
<tr>
<td>Easy to implant, implement support, adjust flow, and manage system</td>
</tr>
<tr>
<td>Disposable (polycarbonate) blood pump with standard 3/8&quot; connectors</td>
</tr>
<tr>
<td>Reusable motor, console, non-invasive flow probe and accessories</td>
</tr>
<tr>
<td>Versatile: Capable of being used as an LVAD, RVAD, or BiVAD</td>
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3 SYSTEM DESCRIPTION

The core components of the CentriMag VAS consist of a continuous flow centrifugal blood pump, a primary console and motor, a flow probe, a backup console and motor, tubing, and cannulae (Figure 2). The pump, which has a priming volume of 31 mL, can be operated up to a maximum speed of 5500 rpm while generating up to 9.9 L/min flow. When the pump is inserted into the motor and activated the internal impeller is electromagnetically levitated and centered, eliminating the need for shafts, seals, and bearings in the pump. Shafts, seals, and bearings are the sites typically responsible for hemolysis, thrombus and particle formation. Large gaps between the impeller and pump housing are designed to minimize potential shear forces on blood cells, thereby allowing high blood flow rate with minimal hemolysis. Utilizing magnetic levitation to suspend and spin the impeller reduces friction in the pump and eliminates the point source of friction (bearing) resulting in minimal heat and wear of the pump components.

During patient support a CentriMag Primary Console is used to control pump speed, the resultant blood flow, and monitor the safe operation of the system. A cable connects the console to the motor allowing the blood pump and motor to be positioned near the patient. When needed, a battery in the Primary Console will power the system for approximately one hour. A portable CentriMag Back-Up console and motor are available for emergency replacement. The CentriMag Back-Up console may be operated from battery power and additional, easy to replace, batteries are available for the CentriMag Back-Up Console.

![Figure 2](image.png)  
*Figure 2. The core components of the CentriMag VAS includes a centrifugal blood pump, a motor, primary console, flow probe, a backup console, backup motor, cannulae, and tubing.*
The specifications for the CentriMag System are provided in Table 2. Additional details on the system can be obtained from the CentriMag Console Operating Manual and the System Instructions for Use.

The system components required for patient support include:

- CentriMag console, motor, and flow probe
- Emergency backup components to be with the patient at all times must include a second Primary or Back-Up Console and a second motor.
- Additional batteries are available for the CentriMag Back-Up Console.

<table>
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<th>Table 2. Specifications of the CentriMag VAS</th>
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<td><strong>Console</strong></td>
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<td>Power: 100–240 VAC at 50/60 Hz, 120 W</td>
</tr>
<tr>
<td>Height: 21.21 cm (8.35 in)</td>
</tr>
<tr>
<td>Width: 25.98 cm (10.23 in)</td>
</tr>
<tr>
<td>Depth: 31.95 cm (12.58 in)</td>
</tr>
<tr>
<td>Weight: 6.6 kg (15 lb)</td>
</tr>
<tr>
<td><strong>Pump</strong></td>
</tr>
<tr>
<td>Priming volume: 31 mL</td>
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<tr>
<td>Flow: Up to 9.9 L/min flow</td>
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<tr>
<td>Maximum pump speed: 5,500 rpm</td>
</tr>
<tr>
<td>Maximum operating pressure: 600 mm Hg</td>
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<tr>
<td>Connectors: 3/8-in barbed inlet/outlet ports</td>
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<tr>
<td>Material: single-use, medical-grade polycarbonate</td>
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<tr>
<td><strong>Motor</strong></td>
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<tr>
<td>Height: 82 cm (3.23 in)</td>
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<tr>
<td>Outer diameter: 100 cm (3.94 in)</td>
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<td>Weight: 1.7 kg (3.75 lb)</td>
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The CentriMag pump is a continuous flow centrifugal pump. The Pump contains inflow and outflow ports that are at right angles to one another, and a vaned impeller (Figure 3). When the impeller is rotated, a pressure gradient develops between the center and outside edge of the pump, causing blood to flow from the inflow to the outflow port of the pump. The rotation of the impeller, as well as the resulting blood flow, is not sensitive to the pump height or position. The amount of flow through the pump depends on the speed of the impeller, and the difference between the inlet and outlet pressures. In the clinical setting, flow is affected by the pump speed, as well as the preload (atrial or ventricular) pressure, afterload (arterial) pressure, inflow cannula resistance, outflow cannula resistance, and tubing length.
Figure 3. CentriMag Blood Pump; the inflow port is located on top and the outflow port is located on the side.

When the pump is placed in the motor mount and activated, the impeller is levitated and centered by an applied electromagnetic force. Using magnetic levitation to center the impeller allows it to be suspended without contact with any surfaces. A large gap exists between the impeller and the outer housing when the system is operated, and shear forces within the pump are reduced when the impeller is spinning.

Flow is generated by the rotation of the CentriMag pump impeller. The blood flow is measured by a clamp-on, non-invasive flow probe and displayed on the console screen. The rotational speed of the impeller must be sufficient to create enough pressure to overcome the resistance (afterload) pressure to allow forward flow of blood. With adequate volume available for the desired flow, increasing the RPM will increase the flow of blood through the pump. If the drainage or outflow cannula is placed directly in the heart (left or right atria or ventricles) then the removal of blood from the heart will unload the heart and reduce the amount of blood flowing through the ventricular outflow (pulmonary or aortic) valves.
4 CLINICAL USE OF THE CENTRIMAG VAS

4.1 General Principles

The CentriMag VAS is capable of providing circulatory assistance for patients with acute heart failure associated with multiple etiologies, as outlined below. Patients in acute hemodynamic compromise requiring CentriMag support represent a moribund population whose treatment options are limited. The CentriMag has been approved or is in clinical trials for the indications below.

At present, Institutional Review Board (IRB) approval is required before implanting the CentriMag VAD or RVAD in accordance with the requirements of the FDA approved IDE and HDE clearances.

4.2 Indications for Use in the United States

The CentriMag RVAS received HDE (humanitarian device exemption) approval for right ventricular support in October 2008. Under the HDE approval the indications for use are: The Levitronix CentriMag RVAS is intended to provide temporary circulatory support for up to 30 days for patients in cardiogenic shock due to acute right ventricular failure.

The CentriMag VAS is also being studied in a U.S. pivotal clinical trial for use as a bridge to decision for support of the left, right, or both ventricles for the indication of failure-to-wean from cardiopulmonary bypass. In this pivotal trial the proposed indications for use are: The CentriMag VAS may be used for use for up to 30 days to support one or both sides of the heart, as a bridge to decision. As a bridge-to-decision it is often unclear whether the patient’s heart will recover or whether the patient will need alternative, longer-term therapy. The device is specifically indicated in the trial to treat patients that are hemodynamically unstable, fail to wean from cardiopulmonary bypass, and cannot be moved from the operating room without mechanical circulatory support.

The Levitronix CentriMag VAS is contraindicated for patients who are unable or unwilling to be treated with heparin or an appropriate alternative anticoagulation.

4.3 CentriMag VAS Clinical trial Enrollment Criteria

As stated in the Study Protocol (IDE G030052), the inclusion and exclusion criteria for patient enrollment are as follows:

4.3.1 Inclusion Criteria

The Inclusion Criteria for use of the CentriMag VAS within the clinical trial is as follows:

- At least 18 years of age.
- Cardiac dysfunction due to failure-to-wean from cardiopulmonary bypass.
• Subjects who are on IABP, CPB, ECMO or CPS support prior to evaluation should have the device turned off, if possible, for the purpose of measuring inclusion hemodynamics. However, these devices should not be turned off in patients who would be harmed by interruption of support.

• At the time of enrollment all potential subjects must meet the hemodynamic indications of heart failure outlined in the study protocol or be determined to be too unstable to be evaluated.

• Enrollment without hemodynamic measurements due to frequent or unpredictable dysrhythmias, unacceptable cardiac function, or hemodynamic instability is allowed.

• Placement of an intra-aortic balloon pump has been attempted unless contraindicated.

• All possible 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 using pharmacologic agents, and epicardial pacing (if appropriate and possible) has been attempted.

• Written, signed, and dated informed consent.

4.3.2 Exclusion Criteria
The Exclusion Criteria for use of the CentriMag VAS within the clinical trial is as follows:

• BUN > 100 mg/dl. (Based on lab data from the 24 hours prior to enrollment).

• Creatinine > 5 mg/dl (Based on lab data from the 24 hours prior to enrollment).

• Presence of any investigational mechanical circulatory support device.

• Known history of liver cirrhosis or portal hypertension.

• Pulmonary infarction. Pulmonary angiograms with evidence of significant embolism within two weeks prior to consideration. A significant embolism is one that causes lung infarction in more than one lung segment proven by a V/Q scan or pulmonary angiogram.

• Stroke, TIA or history of either condition within the last six months and/or any confirmed, existing neurologic deficits.

• Active systemic infection defined as positive blood cultures, core temperature >100.5°F, white blood count > 12,500, and treatment with antimicrobials.
• Participation in a clinical trial with any experimental treatment within 30 days prior to screening or previous participation in the present study.

• Other serious disease(s) limiting life expectancy.

4.4 Limitations of CentriMag Use

If the patient cannot be weaned from CentriMag VAD support within the intended duration of support, as described in the CentriMag Pump Instructions for Use (IFU), it is the responsibility of the physician to evaluate the risks and benefits of continuing CentriMag support or of treating the patient with other therapies.

CentriMag VAS support is currently initiated in the operating room as a surgical procedure in accordance with the procedures outlined in the Instructions for Use (IFU) and the investigational protocol.

4.5 Bridge to Decision

Patients presenting with acute cardiogenic shock and hypotension have a poor prognosis and are at increased risk of developing multiple organ failure (MOF). Neurologic, pulmonary, renal, and hepatic failure may become irreversible if adequate levels of circulation are not promptly restored. The time until irreversible failure varies by organ and patient, but it is well understood that the extent and time of ischemia will determine the outcome. Unfortunately, in most cases, it is not possible to accurately assess the reversibility of MOF and the viability of the patient during the initial presentation.

Temporary circulatory support with the CentriMag VAS can restore hemodynamic stability, reduce the risk of further end-organ damage, and provide conditions under which organ function can recover. By stabilizing the hemodynamics and optimizing the patient’s condition, a detailed assessment of all organ systems can be completed, which will then determine the clinical course for the patient (Figure 4).2-4

In many cases myocardial and end organ recovery will be sufficient to allow removal of VAS support. Other patients may need long-term support with an implantable LVAD as a bridge to transplant or for destination therapy. However, the extent of myocardial damage, neurological deficit, and end organ failure may be so severe that the patient may not recover regardless of the adequacy of circulator support, and will expire while on support. Under this scenario, implantation of a more expensive long-term ventricular assist system may be avoided and /or the use of a scarce donor heart may be spared.
Patients suffering from right heart failure and cardiogenic shock following an acute myocardial infarction (AMI) may present in emergency centers or be transferred from other institutions. These transfer cases present a great challenge because of the lack of a reliable history regarding the duration of shock and cardiac resuscitation the patient may have experienced. Timely initiation of CentriMag RVAS support for this population can provide restoration of blood circulation and improve the likelihood of survival.

Patients undergoing cardiac surgery who fail to be weaned from CPB bypass due to poor cardiac function or high risk of dysrhythmias may benefit from continued circulatory support with a ventricular assist device.\textsuperscript{5-7} In the postcardiotomy scenario, CentriMag support can be initiated within a short period of time without significant additional resources. Patients can then be transferred to a recovery area or intensive care unit in a hemodynamically stable condition. Further patient assessment and treatment options can then be considered.

Other acute heart failure scenarios where the CentriMag RVAS has been used to successfully support critically ill patients include: myocarditis, post-partum cardiomyopathy, acute graft failure following heart transplant, and decompensated heart failure.\textsuperscript{10}

\textbf{Figure 4.} Management of acute refractory cardiogenic shock. Adapted from John et. al.\textsuperscript{2}
4.6 Types of Support

4.6.1 Isolated LVAD

Left ventricular support is the most commonly used form of VAD support for patients unable to be weaned from CPB because the left heart performs the most work and as a result is more prone to failure. If pre-operative assessments (cardiac echo, measurement of right heart preload/CVP, pulmonary pressures / PAP, and pulmonary vascular resistance/PVR) suggest the right ventricle is functioning adequately, an LVAD may be all that is required to provide adequate support. Cannulation options include placement of a drainage cannula in the left atrium or left ventricle with a return cannula placed or attached to the ascending aorta. The IDE approved CentriMag VAD may be used for isolated LVAD support.

4.6.2 Isolated RVAD

Isolated RVAD support is indicated in approximately 15% of cases in which short term circulatory support is required. The most frequent conditions requiring an isolated RVAD include severe pulmonary hypertension, right ventricular failure post cardiac transplantation, postcardiomyopathy cardiac failure, and a right ventricular myocardial infarction. Patient history and pre-implant assessment of the heart using cardiac echocardiography and a determination of PVR should help to identify patients who will be adequately supported with univentricular, RVAD support. Cannulation options are placement of a drainage cannula in the right atrium or right ventricle with a return cannula to the pulmonary artery. Both the HDE and IDE CentriMag VADs may be used for isolated right heart support.

4.6.3 RVAD support following LVAD implantation

RVAD support may be required following implantation of a long-term LVAD device. Initiating LVAD support can cause an acute decrease in left ventricular pressure that can change the position of the intra-ventricular septum, lead to distention of the right ventricle, and an increase in right atrial pressure. Under these conditions, right atrial pressures above 15-20 mmHg are suggestive of right dysfunction. Such a condition is often associated with a decrease in right ventricular contractility and tricuspid insufficiency. If adequate LVAS device flow cannot be achieved, and there are signs of right heart failure, it may be necessary to assess the level of inotropic support, use
nitric oxide therapy and, if conventional therapy fails to consider temporary support
the right ventricle with a RVAD. Diagnostic assessments include cardiac
echocardiography, measurement of right heart pressures, and if possible, direct
visualization of the functioning of the right ventricle. Both the HDE and IDE approved
devices may be used for isolated right heart support following implantation of a long-
term LVAD device. The IDE device may be used for this indication if the patient
meets the study enrollment criteria outlined in the failure to wean from
cardiopulmonary bypass protocol.

4.6.4 Biventricular support

Biventricular support may be necessary in instances where the entire heart is
functioning poorly following surgery requiring cardiopulmonary bypass. Diagnostic
assessments include cardiac echo, ECG, and measurement of right sided pressures.
The final requirement for biventricular support may only be possible to assess after
placement of an LVAD or RVAD. The most common scenario is initiation of left heart
support followed by the diagnosis of right heart dysfunction by the inadequate blood
flow through the lungs. If pharmacologic reduction of pulmonary vascular resistance
does not adequately improve LVAD flow, then the addition of RVAD support is
indicated. Only the IDE approved study devices may be used for biventricular
support for the indication of failure to wean from cardiopulmonary bypass.
5 PREPARING FOR CENTRIMAG USE

The CentriMag System components and supplies are often stored in the operating room area to be immediately available when needed. The Primary and Back-Up Consoles must be stored connected to AC power to ensure that the batteries are always fully charged. A Primary and Back-Up system (consoles and motors) must always be in close proximity to the patient in the event it becomes necessary to switch from the Primary system to a Back-Up system.

5.1 Ventricular Assist System Setup

VAS setup and initiation of support is often performed under emergent conditions. The procedure for setting up the CentriMag for VAS support, as described in the Instructions for Use and Clinical Study Protocol, may be tailored to meet the anatomical and clinical conditions of individual patients. Different methods for priming the pump and circuit are discussed below.

5.2 Alternatives for Pump Priming and De-airing

Priming may be performed using either a preassembled priming pack or a circuit submersion technique. In each instance aseptic techniques for preparation of an implantable or similar VAD (clean room, gown covering scrubs, sterile gloves, cap, mask, etc.) are required. Procedures for preparation of a circuit are identical for a CentriMag RVAD and a CentriMag LVAD. Both techniques are effective means of priming and de-airing of the VAD circuits.

5.3 Preassembled Priming Pack

The following is a suggested list of equipment and supplies that may be used with a pre-assembled circuit or priming pack.

- CentriMag blood pumps (Two pumps for univentricular support of the left or right ventricle; Three pumps for biventricular support)
- CentriMag Primary Console with motor and flow probe attached
- CentriMag Back-Up Console and Motor in the immediate vicinity
- Preassembled (Medtronic) VAD circuit and priming pack
- One inlet (venous) cannula
- One outlet (arterial) cannula
- Two 3/8” straight connectors
- Sterile tubing clamps and scissors
- One liter of a warm balanced electrolyte solution for priming
- Small nylon bands (~ 3” in length)
5.4 Preassembled Pack Priming Procedures

1. Open the pack using aseptic techniques. Open the CentriMag pump package. Attach the blue inflow tubing and red outflow tubing to the appropriate barbed ports of the pump. Suspend the bag from an IV pole.

2. When possible, flush the recirculation bag and circuit with CO₂ to remove air. Clamp the outlet lines from the reservoir bag. Fill the reservoir bag with one liter of a balanced electrolyte solution. Open the circuit arterial limb vent line.

3. Raise the pump up to the level of the bag. Remove the clamp from the venous (blue) port of the bag. Slowly fill the circuit with fluid by “walking” the fluid through the circuit, while venting the air through the vent line.

4. Place the pump in the motor mount and recirculate the fluid at a low flow.

---

**Figure 6.** Preassembled (Medtronic) “Quick-Prime” VAD Circuit

Legend:
- Robert’s Clamp
- 3 way Luer Lock Connector
- Priming Spike
- 10 cc syringe
- Pump
- 3/8” tubing covered with “snake-wrap”
- ETO caps, minimum 1” tear tab
- Fenestrated tip
- Color-Coded Tubing Caps
- Tape Markers at bag exit

Notes:
- Drawing not to scale
- No Luer Lock ports or any tubing adapter
- “Snake-wraps” are narrow variety to reduce possibility of pinching tubing at connections
- Directional arrows preferred on ETO past tape points
- Preassemble both inlet and outlet tubing to bag if ETO sterilization will allow. If not leave red line separated and mark both sides of connection with colored tape.
5.5 Equipment and Supplies Needed for “Submersion” Priming Technique

- CentriMag blood pumps (Two pumps for univentricular support of the left or right ventricle; Three pumps for biventricular support)
- CentriMag Primary Console with motor and flow probe attached
- CentriMag Back-Up Console and Motor in the immediate vicinity at all times
- Standard 3/8” ID x 3/32” wall tubing, 8’ length (two 4’ lengths)
- One inlet (venous) cannula
- One outlet (arterial) cannula
- Two 3/8” straight connectors
- Sterile tubing clamps and scissors
- Three litres of warm balanced electrolyte solution
- Bulb syringe and scissors
- Small nylon bands (~ 3” length)

5.6 Submersion Technique

1. All steps are performed within a sterile field using aseptic techniques.
2. Fill a large sterile basin with three liters of a warm balanced electrolyte solution.
3. Slowly submerge one end of the 4-foot tubing and gradually submerge the entire piece, allowing the tubing to fill completely from one end to the other. Clamp both ends of the tubing. Repeat for second piece of 4-foot tubing.
4. Open the CentriMag pump package. Submerge the pump in the saline, rotating from side to side to ensure complete removal of air. Connect to tubing.
5. With pump and both pieces of tubing completely submerged, release a clamp from the inflow tubing and attach it to the appropriate barbed port. Repeat with the outflow tubing and port.
Figure 7. Submersion priming technique. Slowly submerge one end of the 4-foot tubing and gradually submerge the entire tube, allowing the tubing to completely fill.

Figure 8. Submersion priming technique. Submerge the pump in the priming solution, rotating from side to side to ensure complete removal of air. Connect to tubing.
5.7 Inserting the blood pump into the motor housing

Once the pump and tubing are primed and deaired, insert the pump into the motor per the CentriMag Pump Instructions for Use. Match the grooves on the pump with those on the motor mounting plate. Rotate counterclockwise until the pump locks into place. Thread the retaining screw clockwise into one of the grooves to secure the pump in place. Increase the speed of the pump (RPM) and re-circulate the priming solution through a reservoir to aid in removing any remaining air. The preassembled circuit tubing can be unsheathed for transfer to the sterile field as the case proceeds.

![Correctly Mounted Pump](image1)
![Incorrectly Mounted Pump](image2)

Figure 9. Rotate the pump counterclockwise and secure with the retaining screw. On the left is a correctly mounted pump and on the right is an incorrectly mounted pump.

5.8 Cannulae

A 32 Fr drainage cannula and a 24 Fr return cannula are provided in the CentriMag VAD Kit. These cannulae are wire-reinforced to resist kinking. The drainage (venous) cannula is malleable, and therefore, will hold its shape after introducing a bend. For ventricular cannulation, the venous cannula may not need to be bent. Placing approximately a 90° bend in the cannula may help with atrial cannulation.

<table>
<thead>
<tr>
<th>Drainage Cannula</th>
<th>Return Cannula</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edwards TFM032L</td>
<td>Medtronic EOPA 77722</td>
</tr>
<tr>
<td>(Edwards Lifesciences, LLC, Irvine, CA)</td>
<td>(Medtronic, Inc., Minneapolis, MN)</td>
</tr>
<tr>
<td>32 Fr (10.7 mm)</td>
<td>22 Fr (7.3 mm)</td>
</tr>
<tr>
<td>40 cm (16&quot;)</td>
<td>30.5 cm (12&quot;)</td>
</tr>
<tr>
<td>Single stage malleable venous cannula</td>
<td>EOPA arterial cannula, blunt tip introducer without guide wire</td>
</tr>
</tbody>
</table>
6 SURGICAL TECHNIQUE FOR IMPLANTATION

6.1 Overview

Standard surgical techniques will be used for implantation of the CentriMag Ventricular Assist Device (VAD, LVAD, RVAD) or Devices (BVAD). The ventricular assist device, circuit, and cannulae will be similar for all patients, although the surgical procedures may vary according to the patient’s anatomy, circumstances of support initiation and local standard. In general the procedures are as follows: the cannulae are tunneled and positioned for left, right, or biventricular support. The extracorporeal VAD circuit (or circuits) is prepared, primed, connected to the cannulae, subjected to a final inspection of the circuit, and support is initiated.

The surgical approach for implantation will usually be through a median sternotomy. Typically the implantation surgery is done while the patient is fully supported on cardiopulmonary bypass (CPB). If the condition and stability of the patient permit all cannulae should be tunneled and brought through the skin of the anterior abdominal wall in the subcostal region prior to cannulation of the heart and major vessels. For left heart LVAD support the inflow cannula will be placed in the apex of the left ventricle or atria and return cannula will usually be placed in the ascending or arch region of the aorta. If an RVAD for right heart support is needed the inflow cannula will usually be placed in the right atrium and the outflow cannula will be placed in the proximal portion of the main pulmonary artery. All cannulae are usually placed through stab wounds and secured with two concentric 4-0 pledged purse string sutures. The sutures are passed through Rumel tourniquets, secured with clips, and secured to the cannulae with braided suture.

The blood pump and extracorporeal circuit are primed with a balanced electrolyte solution, deaired, and inspected. Connection of the circuit to the cannula connector is made while adding fluid to the connection to exclude air. The tubing and cannulae are secured to the skin with sutures and the blood pump is passed to the console operator. The blood pump is positioned on the motor and the console is prepared for support. The status of the heart is monitored with echocardiography, hemodynamics, palpation, and direct visualization, to insure adequate intravascular volume. CPB flow is reduced while VAD support is initiated. The sternum and skin are closed using standard surgical techniques. If unable to close the sternum due to mediastinal bleeding, or if edema causes compromised flow, the sternum may be splinted open and the wound covered with an occlusive sterile dressing.

6.1 Monitoring

Hemodynamic assessment before and during CentriMag support should include standard cardiac surgery monitoring including an arterial line and a pulmonary artery catheter. Transesophageal echocardiogram (TEE) should be performed to rule out: a patent foramen ovale (PFO), intra-atrial and intra-ventricular thrombus, aortic valve insufficiency, and valvular dysfunction before initiating CPB bypass and placement of the CentriMag VAD cannulae. TEE should be used to visualize the heart chambers and to ensure that the heart is completely deaired before VAS startup. TEE may also be used to assess: cannulae tip position, ventricular volume, ventricular size, optimal neutral position of the ventricular septum, and the amount of unloading by the heart chambers.
If CPB is used for the VAS implant, anticoagulation appropriate for CPB must be administered before CPB. If the implant is to be performed without CPB, heparin should be administered prior to cannulation to target an activated coagulation time (ACT) between 200 and 250 seconds. Cannulation is typically performed through a median sternotomy approach. A thoracotomy (right or left) may be an appropriate approach for some patients; however, for patients with the potential for biventricular support, a sternotomy is the preferred approach.

In most cases, the initial intent is to provide isolated LVAS support, but the subsequent addition of an RVAS may be required. Patients at risk of right heart failure are those with an elevated PVR, worsening right ventricular function, a dilated or distended right ventricle, and/or with a history of coagulopathy. These patients may also have a potential need for the addition of an oxygenator to the circuit, and may require prolonged mechanical ventilation. The need for an RVAS is not always immediately obvious, and may only become apparent after worsening symptoms occurring hours or days after LVAS support is initiated. In the post-operative period the symptoms of right ventricular failure may be subtle, precipitating low LVAD output syndrome and multi organ failure.

6.2 Tunneling

Cannulae should be tunneled obliquely through the abdominal or chest wall using a standard stab technique. It is recommended that tunneling be performed prior to cannulation so that the cannula can be positioned without bends or kinks. At the end of the case, the cannulae should be securely sutured to both fascia and skin, with minimal tension.

6.3 Cannula site selection and cannulation

The standard cannulation for biventricular support with the CentriMag is shown in Figures 10 and 11. The cannulation for univentricular support is similar. For LVAS support, the inflow cannula is usually placed directly into the left ventricle or into the left atrium. Left ventricular cannulation is preferred because the unloading is more complete, the risk of intra-ventricular thrombus is much lower, and collapse of the chamber is less likely. If RVAS support is needed, cannulation of the right atrium or ventricle is performed with the return cannula placed in the pulmonary artery.
Figures 10 and 11. Standard cannulation for biventricular VAS support.
On the left the left ventricle is cannulated via the left ventricular apex and on the right via the left atrium.

For LVAS support, the 32-Fr inflow cannula is inserted into the apex of the left ventricle or into the left atrium at the level of the junction between the superior and inferior pulmonary veins. For return blood flow the 22-Fr outflow cannula is inserted into the ascending aorta. All cannulae are secured with dual pledgeted purse string sutures.

When biventricular (BiVAS) support is required, two CentriMag circuits can be used. Left heart cannulation is performed first as previously described. For right heart cannulation, the 32-Fr inflow cannula (usually labeled blue) is placed in the right atrium, and the 22-Fr outflow cannula (usually labeled red) is placed in main pulmonary artery.
7 INTRAOPERATIVE DEVICE MANAGEMENT

After the cannulae are placed and secured, the VAD circuit (or circuits) is connected to the cannulae. It is critical to avoid the introduction of air into the circuit during connection of the tubing to the cannula. After all cannula-to-tubing connections are completed, and the CentriMag system is ready to support the patient, CPB flow should be gradually decreased (~1-2 L/min.) to allow filling of the heart. For LVAD support, left atrial pressure should be maintained between 10 and 15 mmHg in order to avoid suction within the left ventricle and inflow obstruction, which can lead to air entrainment. For RVAD support, right atrial pressure is also maintained between 10 and 15 mm Hg. A clamp is placed on the outflow tubing of each pump, while all other clamps are removed from the circuit. Before the outflow clamp is released, the pump speed (RPM) is increased to at least 1,000 rpm in order to prevent regurgitant flow through the system. The RPM is then gradually increased to reach the desired flow rate. Once the VAS is ON and the pump RPM is gradually increased, CPB support can be simultaneously decreased and then terminated. During weaning from CPB and initiation of VAD support the patient must be carefully monitored with hemodynamic monitoring (usually CVP, PAP and ABP), echocardiography, manual palpation and visual inspection of the heart to insure that adequate blood volume is available for the desired VAD flow and to reduce the risk of a suction event.

The desired flow rate can be predetermined by calculating the flow needed to achieve a cardiac index of approximately 2.0-2.2 l/min/m². As the flow is increased, the atria and/or ventricles are monitored for adequate pressure and blood volume for the desired pump flow. The console operator continuously monitors the pump flow, RPM, and blood pressure for signs of suction within the circuit. Suction is most likely when filling pressures are <10 mmHg and is accompanied by fluctuations in VAD flow. When suction is detected the speed of the pump (rpm) must be immediately decreased until filling pressure and volume are adequate to increase flow. The system should be monitored frequently in the operating room when the patient’s chest is open as this is the period of highest risk for suction and air entrainment.

The central venous pressure (CVP), VAS flow rate, total cardiac output, pulmonary capillary wedge pressure, left atrial pressure (LAP - valuable, but not essential) and arterial blood pressure (ABP) should be monitored frequently as hemodynamic conditions change rapidly during surgery. LAP may be estimated from PCWP or PADP, or by placement of a LAP monitoring catheter directly into the left atrium, usually through the left atrial appendage. Communication of hemodynamic parameters between the surgeon, perfusionist, anesthesiologist, and VAS operator is vital to safe support.

Initially, Trans Esophageal Echocardiography (TEE), hemodynamic monitoring, palpation, and direct visualization of the heart will help to determine the volume of blood available for the VAD and the optimal level of flow. After the chest is closed, the patient can be monitored with conventional hemodynamic parameters (CVP, PCWP, LAP, PADP) and TEE to ensure adequate ventricular unloading, and to permit a gradual increase to a target Cardiac Index between 2.0 and 2.5 l/min/m², consistent with the patient’s physiologic needs.

TEE should also be used to rule out the presence of a patent foramen ovale (PFO) after left ventricular decompression. A previously undetected PFO may develop when the pump begins to decompress the left heart. If present, a significant defect should be repaired to prevent right-to-left shunting and the resulting hypoxemia. Unloading of the ventricle(s) during VAS support may also cause atrial or ventricular collapse, which may be able to be observed or assessed with manual palpation by the surgeon. During closure of the chest, VAD flow and the patient’s hemodynamics must be monitored as cannula position can change altering flow through the pump.
8 POSTOPERATIVE DEVICE MANAGEMENT

Postoperative care with the CentriMag blood pump is similar to other types of circulatory support. Key principles of care include hemodynamic stabilization, adequate anticoagulation, and prevention of wound infection. The intravascular volume must be carefully assessed and controlled. Management of bleeding, and prompt blood product replacement, is essential to stabilization and recovery. Frequent laboratory assessment of hematology, coagulation, hepatic enzymes, and blood chemistry must be used to evaluate end organ function and to guide therapy.

8.1 CentriMag System Assessment and Adjustments

Pump speed and alarm settings must be assessed frequently and manually adjusted when necessary. Speed changes should be gradual while monitoring the changes in available volume and the resultant hemodynamic effects. For biventricular support the hemodynamic conditions of the pulmonary and systemic circulations must be balanced. This may be accomplished by balancing the left and right atrial or ventricular pressures rather than flows (see Table 4). Increase or decrease RPM gradually, in 50-100 RPM increments every few seconds, allowing the patient’s vascular system to adjust between each RPM change. The pump speed should be gradually increased to the desired flow. If VAD flow drops or tubing chatter is observed the speed should be immediately reduced 100-200 RPM.

Table 4. Normal CentriMag Operating Conditions

<table>
<thead>
<tr>
<th>Description</th>
<th>Conditions</th>
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<tbody>
<tr>
<td>Pump flow</td>
<td>4–5 LPM with Pump speed: 3000–4000 RPM</td>
</tr>
<tr>
<td>RAP and LAP</td>
<td>10–15 mmHg [8-12 mmHg after several stable days of support]</td>
</tr>
<tr>
<td>RAP–LAP balance</td>
<td>RAP and LAP should be approximately equal, which may be confirmed by visualization of the ventricular septum with TEE</td>
</tr>
<tr>
<td>Systemic arterial pressure</td>
<td>Approximately 90/70 with a mean of 70-80 mmHg</td>
</tr>
<tr>
<td>Target ACT</td>
<td>160–180 mmHg after bleeding has subsided</td>
</tr>
<tr>
<td><strong>Abbreviations:</strong> RAP, right atrial pressure; LAP, left atrial pressure; ACT, activated coagulation time; RPM revolutions per minute; LPM liters per minute; TEE, transesophageal echocardiography</td>
<td></td>
</tr>
</tbody>
</table>

It is useful to periodically turn the speed of the pump down 1,000 to 1,500 rpm for 10 to 15 seconds to assess ventricular function, to allow more complete filling, and to permit washing of the ventricles. This maneuver will help to fill and empty the ventricle more completely, causing a washout effect to help prevent atrial and ventricular thrombosis. This procedure may not be necessary if there is sufficient ventricular ejection or valve leakage to prevent stasis of blood in the ventricles. The frequency of this procedure will depend on ventricular wall motion, ejection, valve competence, anticoagulation and similar factors which contribute to the risk of
intraventricular stasis and thrombosis. The pump should never be turned OFF (0 RPM) because blood flow through the VAD circuit will reverse. This is due to the outlet pressure being greater than inlet pressure, except at peak systole. Pump flow (LPM) and speed (RPM) should be recorded with vital signs on the patient’s chart to trend hemodynamic change with the CentriMag pump parameters.

The CentriMag pump speed settings during biventricular assist require attention to the proper balance of flow from each pump. Normally the natural left heart output is slightly greater than the right heart due to the contributions of bronchial and coronary blood flow. When providing maximal support, the right and left pump flows should be nearly equal but may vary as much as 0.5 L/min to 1.0 L/min. The factors that affect this difference are the variance in the flow probe measurements, valvular incompetence, and ventricular ejection through the pulmonic or aortic valves, that is not reflected in the VAS flow. Generally, the right flow should not greatly exceed the left flow, left and right atrial pressures should be approximately equal, with the intraventricular septum in a neutral position. High RVAS pulmonary flow without a corresponding high LVAS systemic flow may result in pulmonary edema.

The position of the flow probe should be such that it does not cause kinking of the tubing. If positioned close to the pump, the weight of the flow probe may cause a kink in the tubing near the inlet or outlet of the pump. Moving the probe further away from the pump will usually resolve this. Daily or more frequent checks should be performed to ensure that tubing is secured to the patient and is free of sharp bends or kinks, the console is on AC power, the battery is fully charged, the Back-Up Console is ready for use, and the consoles are plugged into the hospital’s emergency, uninterruptable power outlets. The low flow alarm should be set at approximately 75% of the desired clinical flow and checked periodically. At all times, there should be air circulation around the motor and console, and two tubing clamps must be near each pump. Staff should review the “Emergency Switch to Backup” reference card and periodically rehearse switching to the backup motor and console using a training console, motor, pump and circuit.

8.2 Hemodynamic Assessment and Support

Hemodynamic monitoring during support with the CentriMag VAS has some special considerations. During LVAS support, the arterial pressure waveform will normally show a significantly reduced pulse pressure (Systolic-Diastolic) when the left ventricle is completely unloaded. (Figure 12). An increase in the pulse pressure will be observed as the ventricle recovers, when the pump flow is decreased, or if the volume status of the patient is increased. (Figure 13). A similar change will be seen on the pulmonary artery waveform during RVAD support.
Figure 12. Arterial pressure tracing with complete unloading of the left ventricle resulting in a flat arterial pressure waveform.

Figure 13. Arterial pressure tracing with increasing contractility, recovery, or volume loading of the ventricle may cause an increase in the pulse pressure.

Pulmonary artery catheters may prove useful for monitoring during VAS support, but there are some important considerations during RVAD support. First, because the pulmonary artery catheter is inserted and maintained in position with the aid of blood flow through the right heart, insertion of a catheter during RVAD support usually is not possible. Pulmonary artery catheters that are in place before RVAD implant may be used for pressure monitoring and mixed venous oxygen saturation only, but often can migrate out of the pulmonary artery. Thermodilution or continuous cardiac output determinations are inaccurate during RVAD support. Since the inflow and outflow cannulae are placed in the right atrium and pulmonary artery, the majority of the circulating blood travels through the pump circuit, rendering the pulmonary artery flow measured by the catheter incorrect. The RVAD flow bypasses the thermistors that measure the temperature changes needed for the cardiac output measurement. However, in most cases the mixed venous oxygen saturation may be used to estimate changes in total cardiac output based on the Fick principle. Users should be cautioned that the usual thermodilution methods for measuring total cardiac output may be inaccurate, and pump flow may not represent total cardiac output. Although the VAS may capture the majority of blood flow, some ventricular output may be through the aortic or pulmonic valve. VAS flow may also be elevated due to shunts or incompetent valves.

Adequate volume is essential for pump operation. Fluid balance should be routinely monitored using patient weight, central venous pressure (CVP), left atrial pressure (LAP), and/or pulmonary capillary wedge pressure (PCWP), with careful attention to intake and output. Bleeding is a common complication following VAS placement and should, therefore, be carefully monitored. Excessive or life threatening bleeding that does not decrease may require temporary reduction or discontinuation of anticoagulation, or a surgical re-exploration to correct. Constant attention must be given to maintaining a normal hemoglobin concentration. Inotropic support is often used to support ventricular function, maintain wall motion, and reduce the risk of intra-ventricular thrombosis, but should be used conservatively during VAS support. High doses or prolonged use of inotropes may deplete myocardial energy stores, making weaning and complete recovery more difficult. Milrinone is a usual drug of
choice because of its positive inotropic and vasodilatation effects. Inotropic support should be avoided during the initial weaning, and assessments of recovery, but gradually increased during the VAS explant.

The pulmonary vascular resistance (PVR) should be carefully monitored and treated when necessary. Because the PVR is not continuously monitored, acute changes may not be observed. A sudden decrease in the LVAD flow is often caused by inadequate intra-ventricular volume but may also be an indication of an elevated PVR due to administration of blood products, a response to an infusion, or other cause. Pulmonary vasodilators are commonly used in the immediate postoperative period, with inhaled nitric oxide being the most effective and safe. Patients with significant bleeding that require transfusions may be expected to have an increase in PVR. Many VAS users apply prophylactic nitric oxide and use intravenous vasodilators as a last resort.

An intra aortic balloon pump (IABP) may provide pulsatility during CentriMag support, but its usefulness has not been demonstrated. If used with LVAD support the augmentation or balloon volume should be decreased so that complete occlusion of the aorta does not occur. Consider pulling back the sheath to improve distal perfusion, which should be assessed at least hourly. The IABP may be removed in the critical care unit after coagulation parameters have normalized. If weaning is anticipated within 48 to 72 hours, leaving the IABP in place may be appropriate.

8.3 Anticoagulation

Generally, no anticoagulation therapy is used in the first 6 to 12 hours after initiation of support due to usual postoperative bleeding. In cases where CPB was not used prior to initiation of support, and bleeding is minimal, low dose anticoagulation with heparin should be started sooner. Pump thrombosis may be minimized by maintaining VAS flow of at least 4.0 LPM. Intravenous heparin is usually started after the chest tube drainage is less than 50 ml/hour for the 2 to 3 hours. The initial target for ACT is 160-180 sec (Hemochron Celite ACT), or the target PTT is 1.3-1.6 (e.g. 39 - 48) times the laboratory normal. The target ACT and PTT are increased approximately 5% each day with improvement in end organ function and hemostasis. By the 4th postoperative day the target ACT is 190-210 seconds, and the target PTT is 1.5-1.8 times normal. Low dose antiplatelet therapy with 81-325 mg aspirin per day should be started when indicated by improved platelet function (e.g. with TEG) or for an expectation of longer periods of support. The level of platelet inhibition will be dependent on the expected course of support, history of bleeding, and level of VAD flow. Higher levels of inhibition are indicated for patients with low risk of bleeding, expected longer durations of support, and/or lower levels of VAD flow.

Thromboelastography (TEG) can be useful and reliable in the management of anticoagulation. Not all centers have TEG systems, and its use for VAD patients is not universally accepted, but some centers with experienced personnel and dedicated approaches have found it useful and reliable. Teams should be trained to ensure consistent results. The TEG is initially reviewed carefully every day to assess antiplatelet needs until stable and satisfactory levels are achieved. Anticoagulation needs vary by patient, and should be adjusted based on clinical judgment.

Heparin-induced thrombocytopenia (HIT) is a complication of heparin therapy that presents with bleeding and consumption of platelets. Treatment for HIT consists of withholding or reversing heparin. Aspirin, bivalirudin, warfarin, and a variety of other
anticoagulants may be considered as alternatives to heparin, depending on clinical objectives, experience at the individual center, and hepatic and/or renal function.\textsuperscript{10,11} Existing institutional protocols for managing HIT should be implemented as appropriate. A hematology consult can also be valuable in the management of these patients.

8.4 Wound Care

Postoperative wound care should be consistent with the protocol that surgeons and staff are most comfortable using. A standard occlusive dressing should be used at the surgical sites to minimize the risk of air entrainment.

Aseptic technique should be used by all staff when handling the surgical sites during dressing changes and other wound care. The importance of consistent hand washing practices by staff and caretakers cannot be overemphasized. Wound sites should be carefully inspected for signs of tissue breakdown or excessive drainage. Undue pressure or torque to the surgical site should be avoided in order to minimize trauma.

8.5 Nutrition

Enteral or parenteral feeding should be implemented when feasible during support. It is important that patients who achieve explantation receive proper nutritional education from the hospital nutritionist to optimize recovery.

8.6 Physical Therapy

When feasible, the patient should receive passive and active range of motion physical therapy as tolerated, but restricted to their ICU bed. Although it is not common, some patients have been able to ambulate during CentriMag support. Patient ambulation is not recommended since the risk of cannula dislodgement and tubing disconnects are high during ambulation. Bedside range of motion or other light exercise is possible with extreme care and useful for patients on VAS support for many weeks.
9 WEANING AND EXPLANTATION

The amount of time needed to achieve recovery sufficient for VAS removal is not known. Depending on the extent of myocardial injury, some patients may recover sufficiently to be weaned within 48 to 72 hours, while others may require support for up to 30 days. Improvement in ventricular function is usually first noted with increased contractility and ventricular ejection apparent on the arterial pressure waveform, decrease VAD flow, and a decreased dependence on inotropic support. Initial assessments of ventricular function should be made without increasing inotropic support, IABP support, or without volume loading of the ventricles. Echocardiography is useful to assess improvement in ventricular size, wall motion and ejection fraction. When possible, a pulmonary artery catheter will provide useful information on recovery. Recovery is based on the patient’s ability to maintain hemodynamic status, perfusion and end organ function during an extended period of low pump flow without additional pharmacological or mechanical support.

A trial period of CentriMag weaning over three hours may be attempted after the following criteria are met:

- Hemodynamic evidence of ventricular function improvement based on increased cardiac output (> 0.5 LPM)
- Increase in mean arterial blood pressure (> 10%)
- Documented pressure or TEE evidence of ventricular ejection with little or no inotropic support

Initial attempts at weaning should be of short duration with an appropriate increase in anticoagulation and gradual reduction in pump flow to 1.5 to 2.0 liters per minute. If the ventricles become visibly dilated on TEE, mixed venous oxygen saturation is compromised, or the patient's hemodynamic parameters deteriorate, the weaning attempt should be discontinued.

9.1 Weaning Protocol

The most appropriate timing for weaning CentriMag support has not been determined and there are no specific criteria. However, key parameters to assess for weaning are ventricular contractility and ejection. As the heart recovers function the pulse pressure on the arterial pressure tracing will increase. Serial echocardiography to assess contractility and ejection fraction provides a good indication of ventricular recovery. Decreased dependence on inotropic drugs is an important indicator of recovery. The following is a guide for weaning a patient from and termination of CentriMag support while in an operating room prepared to explant.

1. Final weaning and termination is preferentially done in an operating room.
2. Transesophageal echocardiography should be used continuously to assess ventricular function. Observe for ventricular dilation, septal shift, ejection fraction, and changes in inotropic drug requirements.
3. Decrease the flow rate by 0.5 L/Min every 15 minutes until 2.0 L/Min is reached.
4. Increase anticoagulation by administering 100 units per kilogram intravenously. Verify adequacy of anticoagulation with an ACT > 300 sec.
5. Continue weaning as above until flow rate is 0.5 L/Min.
6. Clamp the out flow tubing to terminate support, decrease the RPM to zero, and continue to carefully monitor the patient’s hemodynamics and perfusion.
7. If the patient remains stable on low dose inotropic support, decannulate.
8. Consider using an IABP and/or leaving the sternum unwired (skin closure only) for patients with marginal function following decannulation.

9.2 Device Exchange

CentriMag pump exchange may be necessary if hemolysis is believed to be caused by the pump, if the pump is damaged or if there are indications of thrombosis at a connector or in the pump. During the period that support is interrupted for a pump or circuit component exchange anticoagulation should be increased. If heparin is used, an appropriate bolus of heparin to achieve an ACT>300 during the period of the pump exchange is recommended.

A pump may be exchanged using the following procedures:

1. Using a sterile field and aseptic technique, a new pump and circuit are prepared as described above. Tubing connectors are placed at the patient ends of the tubing. Fill the pump and tubing with a warm balanced electrolyte solution or other suitable priming solution.
2. Four tubing clamps are used to clamp the patient’s cannulae and the inflow/outflow tubing.
3. After the clamps are placed the pump speed setting on the console is turned to zero.
4. The existing tubing is cut at least 4-5 cm from the cannula-connector end.
5. The new tubing-connectors are attached using a wet-wet connection while taking care to eliminate air at the junction as well as in the circuit.
6. The new pump is placed in the motor mount housing.
7. The clamps are removed and the pump is turned back on.

9.3 Explantation

Before device removal, ensure adequate volume and anticoagulation levels, particularly if the pump is going to be run with low flow (under 2 liters per minute) for any length of time. As a general rule for flow less than 2 LPM, anticoagulation should be adjusted to maintain an ACT of >200 sec. This is a general rule and dependent on many factors including the risk of bleeding, duration of low flow, position of cannulae, and other considerations. Use TEE to check for blood flow through the ventricles, and the presence of thrombi in the atria, ventricles, and at the cannulation sites prior to weaning and device removal.

Explantation generally requires a repeat sternotomy. During decannulation the surgeon should allow retrograde bleeding from the cannulation site to remove any thrombus that may have formed at the cannula site. During periods when the heart is being manipulated, the pump RPM should be reduced. If VAD flow is compromised by manipulation of the heart, immediately reduce the pump RPM or clamp the pump outflow line as necessary to prevent inflow obstruction and air entrainment.
10 PATIENT TRANSPORT

In some cases, a patient on CentriMag support may need to be transported to another location within the hospital or to another medical center (Figure 14). The CentriMag system has been designed for portability in acute and critical care situations.

When transporting a patient within the hospital care must be given to avoid dislodgement or disconnection of the cannula. The pump and motor unit should be on a stable cart or placed in the bed with the patient and secured. The cable length from the console to the motor is usually sufficient to transport the console on its cart alongside of the patient bed. If necessary, the console can be detached from its cart and placed in the bed. Because of the weight of the motor and the console, these items should not be placed on top of the patient. The motor, when operating, is warm to touch. Blankets beneath the motor can be used to ensure that heat from the motor does not come in contact with the patient’s skin; however, DO NOT cover the motor with blankets to avoid overheating of the motor.

In the event the patient is being transported to another medical center, the transport process involves three teams: the transferring (spoke) center team; air or ground transport team; and the receiving (hub) center team. Key priorities include pre-transport coordination, maintaining hemodynamic support, continuously monitoring of blood pressures and VAD flows, and ensuring adequate power. A Back-Up Console and Motor must be available in the immediate vicinity of the patient at all times.

Figure 14. The CentriMag system meets international standards for air and ground transport and is designed for ease of use during transport between medical centers.12
10.1 Transport Protocols

Existing institutional protocols for IABP, cardiopulmonary support, or ventilator-dependent patient transport may serve as useful templates for institutional CentriMag transport protocols. Transport protocols should include:

- Equipment and supplies needed
- Individuals and responsibilities
- Primary and backup power sources
- Securing of equipment during transport
- Response to most likely complications

Table 5. Transporting a Patient on CentriMag Support Requires a Team Approach for the Best Results

<table>
<thead>
<tr>
<th>Priorities in CentriMag Transport</th>
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</thead>
<tbody>
<tr>
<td>Identify and communicate with the receiving or hub hospital in advance.</td>
</tr>
<tr>
<td>Assign one individual to monitor the circuit, consoles and blood pumps.</td>
</tr>
<tr>
<td>Preposition equipment and supplies. Load all backup equipment and supplies into the transport vehicle before loading the patient.</td>
</tr>
<tr>
<td>Secure the CentriMag console or CentriMag cart with console to the gurney or stretcher for both intra- and inter-hospital transport.</td>
</tr>
<tr>
<td>Ensure that pumps are not covered, and that a Back-Up Console, motor and tubing clamps are always with the patient.</td>
</tr>
<tr>
<td>The console should be secured to the gurney, stretcher or transport vehicle with appropriate straps or fixtures to prevent movement during transport.</td>
</tr>
<tr>
<td>The Primary Console has approximately one hour of battery power and the Back-Up Console has two hours of battery power. If additional power is required, additional backup batteries or an approved uninterruptable power supply can be used.</td>
</tr>
<tr>
<td>Prior to shutting OFF the power supply and removal of the patient from the transport vehicle briefly unplug the console’s power cord to confirm adequate battery charge and console operation.</td>
</tr>
</tbody>
</table>

Additional equipment to consider includes the following:

- CentriMag power conditioning unit for reduced EMI during air transport.
- Power strips for extra outlets (for use with equipment other than the CentriMag)
- Portable monitors, ventilator, and IABP console
- Straps to secure consoles, other equipment and supplies
- Additional sterile supplies, such as an extra blood pump, tubing, prime solution, sterile scissors, tubing clamps, connectors, oxygenator, or other component of the extracorporeal circuit that may be needed or replaced during transport
• Uninterruptible power supply (UPS). Detailed information on qualified models is given in the CentriMag primary console operating manual.

10.2 FAA and Other Standards for Transport

The CentriMag System has been successfully tested against applicable international standards for air and ground transport. The System met all applicable requirements for the following standards:

• IEC 68-2-6: Environmental Testing: Vibration
• RTCA DO-160F: Environmental Conditions for Airborne Equipment
• RTCA DO-160F: Test Procedures for Airborne Equipment

Note: When transporting a patient on AC power in an aircraft, the CentriMag Console must be plugged into a CentriMag Power Conditioning Unit (PCU) and not directly into the airplanes power bus for the CentriMag system to meet the above standards.
11 POTENTIAL COMPLICATIONS

Potential complications are similar to those seen with the use of other extracorporeal ventricular assist devices and include but are not limited to:

- Death
- Stroke
- Bleeding
- Reoperation
- Hemolysis
- Infection (all cause)
- Renal failure or dysfunction
- Respiratory dysfunction
- Hepatic Dysfunction
- Cardiac arrhythmias (atrial or ventricular)
- Limb ischemia or loss of limb
- Myocardial Infarction
- Neurological dysfunction
- Thromboembolism
- Mechanical or electrical malfunction or possible failure
- Psychiatric events
- Hypotension
- Hypertension

Table 6 (below) provides guidelines for prevention and management of possible complications. Flow disruption is the most common complication and can result from hypovolemia, obstruction or malposition of cannulae, right ventricular failure, cardiac tamponade, and/or arrhythmia. In these cases, increasing the RPM may result in an exasperation of the complication, or accelerated decrease in VAD flow. This should alert the operator to immediately reduce the RPM, diagnose, and address the underlying condition causing the complication. Patients should be carefully and frequently assessed for the following.

<table>
<thead>
<tr>
<th>Complication</th>
<th>Prevention and management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low flow or inflow obstruction</td>
<td>Decrease RPM. Monitor pressures and flow. Rule out and correct hypovolemia, tamponade, and/or obstruction or malposition of cannula.</td>
</tr>
<tr>
<td>Right ventricular dysfunction</td>
<td>Rule out and, if possible, adjust VAD flows, vasodilators, and/or inotropes to correct an intra-ventricular septal shift toward the left ventricle. Consider pulmonary vasodilators or mechanical right ventricular (RVAD) support.</td>
</tr>
<tr>
<td>Increased pulmonary vascular</td>
<td>Minimize fluids and transfusions as feasible. Hyperventilate. Consider pulmonary vasodilators.</td>
</tr>
<tr>
<td>resistance</td>
<td></td>
</tr>
</tbody>
</table>
### Table 6. Prevention and Management of Potential Complications

<table>
<thead>
<tr>
<th>Condition</th>
<th>Prevention and Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patent foramen ovale with shunting</td>
<td>Repair defect if feasible. If not feasible, reduce or eliminate shunting by adjusting VAD flow and pharmacological support to maintain LAP &gt; RAP.</td>
</tr>
<tr>
<td>Thrombus formation within the heart, circuit or system components</td>
<td>Assess thrombi with TEE for stability; and remove during surgery or address with appropriate anticoagulation. Consider replacing affected components of the VAD circuit for the presence of unstable thrombus. Delay weaning, if necessary, until resolved. Avoid conditions which can cause suction, interruption of flow or line chatter. Avoid flexing the tubing, particularly near the connectors, which can dislodge fibrin or deposits.</td>
</tr>
<tr>
<td>Hemolysis (rare)</td>
<td>Troubleshoot to identify cause: cannulae position, cannulae selection, CVVH, oxygenator, kinked tubing, another device, high RPM/flow. Consider pump change if suspect as a final option.</td>
</tr>
<tr>
<td>Pump not inserted correctly</td>
<td>Mount the pump correctly. Change pump if incorrect mount is accompanied by platelet consumption &amp;/or hemolysis.</td>
</tr>
<tr>
<td>Console or motor malfunction</td>
<td>Switch blood pump to backup Console and motor. Document, replace &amp; report.</td>
</tr>
<tr>
<td>Decannulation</td>
<td>Prevent. Secure the cannulae to the tissue at multiple sites following cannulation. Minimize postoperative patient and circuit movement. Use extreme care when moving the patient.</td>
</tr>
<tr>
<td>Air entrainment and embolism</td>
<td>Immediately clamp pump outlet tubing. Stop pump. Depending on circumstances and anticoagulation consider splicing in a connector, deairing, and/or pump exchange. (See additional guidance below)</td>
</tr>
</tbody>
</table>

### 11.1 Switching to a Back-Up Console

Should the Primary Console or Motor cease to function, it will be necessary to remove the Blood Pump from the Primary Motor and Console and switch to a Back-up Motor and Console. The following outline describes the steps to be followed.

Note: Refer to the CentriMag Primary and Back-Up Console Manuals for a more detailed description and additional guidance on performance of this procedure.
1. Clamp the pump outflow tubing to prevent retrograde flow.

2. Reduce the Primary Console RPM to zero to stop the pump. If necessary, power OFF the Primary Console to insure that the pump is stopped prior to removing the blood pump from the motor mount.

3. If not already powered ON, turn the Back-Up Console ON.

4. Remove the Pump from the Motor receptacle, by turning the retaining screw counterclockwise until the screw tip is clear of the locking groove on the pump.

5. Rotate the Blood Pump body clockwise until the grooves in the Blood Pump match the Motor and lift the Blood Pump from the receptacle.

6. Now place the Blood Pump in the back-up Motor receptacle (the Blood Pump will drop into place in one of 3 orientations), rotate it counterclockwise until it stops.

7. Thread the Blood Pump retaining screw to secure the Blood Pump in place by turning the screw clockwise until it stops.

8. Be sure to reset all options and alarms to match those in use on the Primary Console prior to Console exchange. It is important to note that the Back-Up Console DOES NOT display pump flow and flow alarms may not be an option.

9. Slowly increase the speed of the Back-Up Console and unclamp the outflow cannula to achieve forward flow.

Note: To be ready for use, the Back-Up Console must always be connected to a motor, be in the immediate vicinity of the patient, plugged into a hospital emergency, noninterruptable power outlet, and the power switch set in the ON position.

In some instances when the Blood Pump has been OFF for more than five minutes without adequate anticoagulation, or if there has been a Motor Overheating condition, it will be necessary to also replace the Blood Pump. To do so, disconnect the Blood Pump and any affected tubing. Attach the Blood Pump per the standard procedure, prime, and debubble.

**IF THE PUMP HAS BEEN OFF FOR MORE THAN 5 MINUTES WITHOUT ADEQUATE ANTICOAGULATION CHANGE ALL CIRCUIT COMPONENTS (Cannulae, connectors, tubing, and pump) PRIOR TO RESUMING SUPPORT.**

11.2 Prevention of Air Entrainment

Massive entry of air into the system will cause blood flow to stop by creating an air lock in the pump. Smaller amounts of air can cause air embolism with resultant injury and organ damage. This risk can be reduced by using the following guidelines.

11.2.1 When Initiating Support

- Maintain atrial pressures between 10 and 15 mmHg during surgery.
- Partially inflate the lungs prior to separation from CPB.
- Place the patient in Trendelenburg position.
- Check the heart and aorta for air with TEE.
- Fill the chest with warm normal saline or CO₂.
- Increase RPM very slowly while initiating support.
- Insure adequate volume in heart chamber when coming off CPB bypass.
- Watch the circuit, flow, CVP, and LAP (if monitored) continuously and be prepared to immediately clamp the outflow tubing if air is observed.
- Under perfuse circulation while the chest is open or patient is being moved. The level of under perfusion is dependent on patient tolerance, but often in the range of 10-20 % below the target level of perfusion.

11.2.2 During Support

- Monitor volume with TEE and pressures.
- Reduce VAD flow rate while the chest is open.
- Reduce RPM for any indication of inadequate volume, during manipulation of the heart, or prior to moving the patient.
- Monitor the tubing for chatter and be prepared to respond.
- As soon as practical, set the low-flow alarm at 75% of the target flow.
- Train staff that air can be drawn into the vasculature by the flow characteristics of circulatory support through any open stopcock, IV or infusion line.
- Avoid conditions that may result in suction, line chatter, or shaking.
12 ALARMS/ ALERTS AND TROUBLESHOOTING

Refer to the Alarm/Alert table provided in the CentriMag Primary and Back-Up Console Operating Manuals.
13 PROFICIENCY ASSESSMENTS/POST-TEST

1. What is the maximum flow rate of the CentriMag?
   a. 12 L/Min
   b. 6.5 L/Min
   c. 8.5 L/Min
   d. 9.9 L/Min

2. The battery in the CentriMag Primary Console will power the system for approximately how long?
   a. 20 min
   b. 5 hours
   c. 60 min
   d. 15 min

3. What is the rpm speed setting range for the CentriMag system?
   a. 0 – 10,000 rpm
   b. 0 – 8,000 rpm
   c. 0 – 5,500 rpm
   d. 8,000 – 12,000 rpm

4. Weaning has started on a patient and the flow rate was decreased from 4.0 L/min to 2.0 L/min. During weaning and reduction in VAD flow what is the most important consideration for safe support?
   a. Antibiotic Therapy
   b. Proper Sedation
   c. Increase Anticoagulation
   d. Assess hepatic Function

5. At the time of initiation of support in an O.R. a CentriMag console is on at 800 rpm, all tubing clamps are off, the tubing/cannula connections appear normal and the flow rate reading is “----”. What is the most likely problem?
   a. The heart rate is 0 and the patient has no BP
   b. Speed is not high enough and there is retrograde flow
   c. The speed setting is not correct and the pump is off
   d. This is normal and will resolve with time

6. Just after initiation of CentriMag support air is seen in the tubing and pump. What should be done immediately?
   a. Increase the RPM to force the air out
   b. Wait for the surgeon to tell you what to do
   c. Clamp the outflow tubing and turn the speed control to 0
   d. Do nothing, this is normal and will resolve with time
7. Which of the following item(s) are not supplied by the manufacturer and must be obtained from the hospital supply prior to a CentriMag implant?

   a. Tubing clamps  
   b. Inflow Cannula  
   c. Outflow Cannula  
   d. Connecting tubing and adapters  
   e. All of the above

8. The back-Up CentriMag Console DOES NOT have which of the following functions?

   a. Flow rate display  
   b. Battery power  
   c. Speed control  
   d. Audio/visual alarm

9. How do you stop the CentriMag pump rapidly in an emergency?

   a. Unplug the power cord from the wall  
   b. Push the stop button once briefly  
   c. Push and hold the stop button for at least 2 seconds  
   d. Detach the flow meter

10. At startup of the CentriMag, after placing the pump in the motor housing, you increase the rpm to 1,000 and the alarm display reads “PUMP NOT INSERTED”. What should be done?

    a. Reposition the pump in the motor housing  
    b. Replace the console  
    c. Replace the CentriMag pump  
    d. Increase the speed to 6,000 rpm

11. What should be done when the CentriMag console displays “SYSTEM FAULT (Run-Time System Failure)”?

    a. Switch to a backup console and motor  
    b. Ask the anesthesiologist to rezero the CVP transducer  
    c. Turn the console off and on to “Reboot”  
    d. Change the pump, tubing, and connectors

12. Just after startup of the CentriMag system, the speed is 5,200 rpm, the flow rate is 1.1 L/min, and the tubing is bouncing/chattering. What should you do?

    a. Immediately decrease the rpm  
    b. Switch to the backup console and motor  
    c. Inform the surgeon and anesthesiologist  
    d. Increase the speed to 6,000 rpm
14 REFERENCES


12. Picture reprinted with permission of the German Pediatric Heart Center, Cardiopulmonary Support Department, Sankt Augustin Germany; 2009.