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HeartMate® II LVAS: Patient Management Guidelines

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I. Introduction

KEY POINTS
The HeartMate® II is a new-generation left ventricular assist system with a number of major advantages over current technology: • Use of an axial flow pump allows for a lighter, smaller system suitable for implantation in patients with smaller body size. • The pump has a simple design that includes only one internal moving part: the rotor. • The axial flow pump eliminates the need for a blood pumping chamber and volume compensation. Thus the need for venting is eliminated and driveline diameter can be reduced. • The potential benefits of the smaller driveline include a reduced risk of infections and greater patient comfort and quality of life. • The simplicity of design (single moving part and no internal valves) may provide increased long-term durability of the device.

The HeartMate® II left ventricular assist system (LVAS) is a new generation of rotary pump with axial flow design. The system consists of an internal blood pump with a percutaneous lead that connects the pump to an external system controller (computer controller) and power source (batteries or power base unit/battery charger).

The major advantage of the HeartMate II LVAS is its axial flow design, which significantly reduces its size and weight compared to the current generation of implantable pulsatile

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pumps. The axial flow design eliminates the need for the blood pumping chamber and volume compensation necessary for volume-displacement left ventricular assist device (LVAD) systems. This feature of the HeartMate II LVAS makes the device more suitable for implantation in patients with smaller body size.

These features have theoretical benefits over current technology: (1) a reduced risk of infections, (2) greater patient comfort and quality of life (smaller driveline), and (3) greater durability (provided by the single internal moving part, the pump rotor, and the elimination of internal valves). These design features—particularly the absence of a compliance chamber—also may facilitate future conversion to a completely implantable system utilizing transcutaneous energy-transmission technology.

The HeartMate II LVAS represents the next generation of an implantable LVAS designed to meet the need for a smaller, more reliable device suitable for long-term outpatient circulatory support.

It is highly recommended that readers review *Advanced Practice Guidelines for HeartMate Destination Therapy*[1, 2] (Thoratec Corporation), volumes 1 and 2, which although written for the HeartMate XVE are also relevant for all indications and the HeartMate II LVAS. These guidelines cover important topics for successful LVAD programs, including candidate selection, team organization, nutrition management, infection prevention and management, intra- and perioperative management, and discharge planning.

Published versions of the advanced practice guidelines are also recommended on infection management[3] (Chinn et al, 2005), nutrition management[4] (Holdy et al, 2005), and patient selection[5] (Miller and Lietz, 2006). The article by Chinn et al on infection management

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emphasizes that “adherence to evidence-based infection control and prevention guidelines, meticulous surgical technique, and optimal postoperative surgical site care form the foundation for LVAD-associated infection prevention.” The article by Holdy and colleagues on nutrition management stresses that “comprehensive preoperative evaluation of the LVAD patient should include a nutrition assessment and formalized plan to initiate and advance nutrition support while addressing the metabolic imbalances associated with heart failure.” The patient selection article by Miller and Lietz indicates that well-selected candidates may have a 2-year survival rate equal to or greater than that reported for heart transplantation in an older population.

This current guideline addresses topics specific to the HeartMate II system in the areas of patient selection and preoperative considerations, intraoperative issues, and postoperative patient and device management. ***For use within any clinical trial of the HeartMate II, study protocol supercedes this document and should be followed.***

II. Patient Selection and Preoperative Considerations

KEY POINTS
• The use of mechanical circulatory support for long-term therapy in selected patients is the standard of care at many medical centers. • Patient selection is the major determinant of success. • Key selection criteria involve the patient’s degree of illness and ability to undergo the procedure, and the availability of postoperative care and support. • Emerging survival data are favorable for LVAD compared with

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inotropic therapy. The trend at many centers is toward earlier use of an LVAD. Earlier use of an LVAD may avoid the progressive damage that can occur during inotropic therapy, which in turn can undermine the benefits of LVAD therapy.

The use of mechanical circulatory support as long-term therapy in selected patients with advanced heart failure is the standard of care at many medical centers. Various strategies have been developed to minimize morbidity and mortality in this high-risk population.

Patient selection and the timing of implantation remain the primary determinants of success for permanent ventricular assist device (VAD) therapy. Patients are assessed for (1) appropriateness for LVAD support based on degree of illness; (2) ability to undergo the operative procedure with acceptable operating room (OR), intensive care unit (ICU), and overall hospital morbidity; and (3) ability to be discharged to home with adequate support for short-term and long- term success.

II.A. Patient appropriateness for LVAD support based on degree of illness

The indications for a HeartMate II LVAS in bridge-to-transplantation (BTT) therapy are similar to the indications for placement of any LVAD (Table 1). Compared with the HeartMate XVE, the HeartMate II can be implanted in smaller patients: ie, those with a body surface area (BSA) $\geq$1.2 m^2 versus $\geq$1.5 m^2. This formula is used to calculate BSA:

$$\text{BSA} = \sqrt{\frac{\text{weight (kg)} \times \text{height (cm)}}{3600}}$$

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Experienced centers are leaning toward earlier use of mechanical support devices—before patients on inotropes deteriorate too far to benefit from LVAD support. A recent subset analysis of the REMATCH randomized clinical trial showed improved survival of patients with an LVAD compared with those on inotropic therapy.[6]

The HeartMate II is designed for long-term support in patients with chronic advanced heart failure. There is insufficient data to determine if pulsatile first-generation devices may be more appropriate if the patient (1) presents with cardiogenic shock and modest to high inotrope requirement; or (2) is post-cardiotomy and has accompanying shock. There is also limited experience with long-term VAD therapy in the presence of restrictive cardiomyopathy; such reports are anecdotal and center-specific at this time.

Many issues affecting successful outcomes after LVAD implantation are not specific to the HeartMate II system but are related to selecting and implanting patients before irreversible loss in end-organ function has occurred. Patients with multiple comorbidities that will decrease their quality or quantity of life should not be considered candidates. Both the Heart Failure Survival Score[7] and the Seattle Heart Failure Model[8] are used to estimate a patient's survival over the next 1 to 2 years. Table 1 lists risk factors associated with poor outcomes in patients receiving an LVAD.[1, 9-12]

Table 1. Risk factors associated with poor outcomes in LVAD patients[1, 9-12]
• Severe chronic malnutrition, cardiac cachexia • Extreme obesity • Severe liver disease • Severe renal dysfunction

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- Severe chronic obstructive pulmonary disease
- History of noncompliance

Obesity is common in patients with heart failure. In the HeartMate II BTT and destination therapy (DT) trial, a body mass index (BMI) >40 kg/m^2 was an exclusion criterion for study purposes, but a recent publication did not show any deleterious effects of obesity on outcome in LVAD patients.[13] There is no contraindication to using the HeartMate II system in patients with a high BSA, as the system can provide flows of up to 10 L/min. Good outcomes in obese patients likely will depend on the capability of a VAD system to create and maintain an appropriate hemodynamic state.

II.B. Patient ability to undergo surgery

An analysis of data from the HeartMate XVE Destination Therapy Registry revealed that the risk of early mortality in patients receiving an implant as DT increased concurrently with worsening of nutritional status and end-organ and right-heart function (factors also relevant to BTT). These preoperative clinical characteristics identified patients who were at high risk for surviving surgery. Preoperative risk factors associated with the highest risk of mortality were severe functional impairment, markers of global cardiac dysfunction, end-organ damage, and malnutrition.[11]

The timing of the operation is very important. In general, with each admission patients become more malnourished, develop worse renal and hepatic function, and therefore have increased operative risks, slower recoveries, and poorer outcomes. Patients with evidence of end-organ dysfunction, poor nutrition, and right-heart failure had poor postoperative results and accounted for most of the early mortality of patients undergoing implantation of an LVAD.[11]

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Once a patient is deemed a suitable candidate for an LVAD, early implantation—that is, implantation before the patient experiences end-organ dysfunction—is a key to better outcomes.

LVAD implantation before end-organ deterioration or inotrope therapy maximizes outcomes. Patients who are inotrope-dependent have shown a survival benefit with implantation of an LVAD.[6] This is important to consider when transplant waiting times are expected to be longer than 6 months at status 1b for particular blood types and BMI. LVAD therapy should be strongly considered before hospice care with continuous infusion therapy.

The above factors are pertinent when deciding whether to proceed with LVAD implantation. Considerations related specifically to the HeartMate II LVAS are discussed below.

II.B.1. Intracardiac considerations

As LVAD implantation is associated with multiple effects on the right ventricle (RV), RV function is an important consideration for both volume displacement and axial flow LVADs. Since the left ventricle (LV) is unloaded with the LVAD, there should be beneficial effects of decreased RV afterload attributed to a reduction in pulmonary artery pressure (PAP) and improved RV diastolic compliance due to the septum shifting to the left.[14] However, possible detrimental effects include increased venous return that can stress the RV, and a decreased contribution from the interventricular septum to RV contractility when the LV is fully unloaded [14]. Acute stress on the RV can result in poor early outcomes if the RV cannot adequately handle the stress.

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In an analysis of 69 patients implanted with an LVAD, Kavarana et al found that 30% of patients had RV dysfunction.[15] This was associated with postoperative complications including an increased incidence of continuous venovenous hemofiltration dialysis (73% vs 23%) and transfusion of red blood cells and platelets, longer ICU stays (34 vs 9 days), and higher mortality (43% vs 15%).

Factors that appeared to predict RV failure included a lower right ventricle stroke work index (RVSWI) and signs of RV failure such as higher total bilirubin and aspartate aminotransferase (AST) levels. The RVSWI is calculated using this formula:

$$\text{RVSWI (mmHg * mL/m}^2\text{)} = \frac{(\text{mean PAP [mmHg]} - \text{mean CVP [mmHg]}) \times \text{SV (mL)}}{\text{BSA (m}^2\text{)}}$$

Abbreviations: BSA, body surface area; CVP, central venous pressure; PAP, pulmonary artery pressure; SV, stroke volume.

Of note, there was no difference in right atrial pressure (RAP), mean PAP, or pulmonary capillary wedge pressure between the two groups. The authors found that the group with early RV failure had a preoperative RVSWI significantly lower than those without RV failure. Other investigators[16] have found low preoperative RVSWI correlated with prolonged inotropic use after LVAD implantation, supporting the role of RVSWI as a predictor of RV dysfunction (Figure 1). Most of these data are from patients implanted with volume displacement pumps; analysis of data specific to HeartMate II patients is ongoing.

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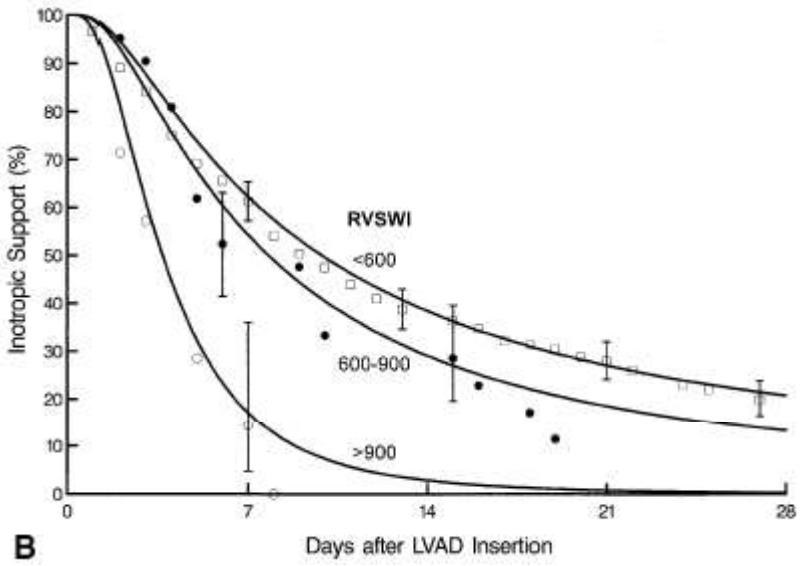

Figure 1: Right ventricle stroke work index (RVSWI) correlates highly with postoperative use of inotropic therapy. Of patients with an RVSWI of 600 mmHg × mL/m^2 or less, 38% were on inotropes on day 14 compared with 29% of patients having RVSWI levels between 600 and 900 mmHg × mL/m^2 and only 3% of patients having RVSWI greater than 900 mmHg × mL/m^2. (Adapted from Schenk et al.[16])

Other signs of poor RV function can be found on echocardiography. Close attention should be paid to RV size, with particular caution extended to patients who have a dilated, poorly contracting RV. Severe tricuspid regurgitation (TR) also can be associated with early postoperative RV failure. It should be noted that, in patients with RV dysfunction, setting pump speed to achieve appropriate flow may be more challenging with axial flow devices than with volume displacement pumps.

Conditions that may contribute to RV dysfunction—and the initiation of steps to correct these conditions—are important preoperative considerations. Among these conditions are pulmonary hypertension, right ventricular infarction, and right ventricular ischemia from CAD.[14] Therapy with medications that can lower pulmonary vascular resistance (PVR) and improve

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cardiac index (CI) prior to implantation of the LVAD may be beneficial in reducing the incidence of RV failure post-implantation.[17, 18]

Various therapies that have been shown to reduce PVR include angiotensin-converting enzyme inhibitors, nitroglycerin, and inotropes (milrinone > dobutamine). Although absolute pulmonary pressures have not been shown to predict RV dysfunction, reducing PVR is usually beneficial. However, patients with high preoperative pulmonary pressures (and thus high RVSWI) are actually at lower risk of postoperative RV failure, since this finding demonstrates that the RV is capable of generating pressure.

Considerations for evaluating right-heart function are listed in Table 2. Issues related to the presence of valvular heart disease are discussed in section **III**. The management of RV dysfunction is described in section **III.G**. RV function and volumes related to postoperative device management are outlined in section **IV.A**.

Table 2. Evaluating right-heart function

Parameter	Desirable value
RVSWI	> 600 mmHg × mL/m^2
CVP	<16 mmHg; 5 mmHg <PCWP
Presence of tricuspid regurgitation	Minimal to moderate
PVR and TPG	PVR <4 Woods Units and TPG <15 mmHg
RV size	RVEDV <200 mL and RVESV <177 mL

Abbreviations: CVP, central venous pressure; PCWP, pulmonary capillary wedge pressure; PVR, pulmonary vascular resistance; RV, right ventricle; RVEDV, right ventricular end-diastolic volume; RVESV, right ventricular end-systolic volume; TPG, transpulmonary gradient.

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II.B.2. Extracardiac considerations

As with any candidate for LVAD therapy, attention must be paid to the patient's nutritional status, which should be optimized prior to implantation. Malnutrition increases the risk of infection and is associated with generally poor outcomes. Attention to infection prophylaxis is similarly of critical importance. Although the HeartMate II driveline is smaller in diameter than that of the HeartMate XVE, potentially reducing the risk of exit wound and driveline infections, appropriate infection prophylaxis always should be observed. (See sections **IV.D.1**, **IV.D.2**, and **VI** for more information on infection risks and management.)

Renal: In general, renal function improves after implantation of an LVAD if decreased glomerular flow rate is due to low cardiac output. Even with increased renal blood flow, however, renal function may not improve in patients who have sustained renal damage due to poor perfusion or, more commonly, in patients with diabetes and evidence of diabetic nephropathy. A presentation at the 2006 International Society of Heart and Lung Transplantation meeting, based on the HeartMate II pilot study, showed that blood urea nitrogen levels improved from 31 to 12 mg/dL by the third month post-implantation.[19] Evidence of renal dysfunction is not an absolute contraindication to use of the HeartMate II LVAS.

Gastrointestinal: Since the HeartMate II requires systemic anticoagulation, its use in patients with a history of gastrointestinal (GI) bleeding should be carefully considered. For this type of patient, the HeartMate XVE, which typically requires only aspirin therapy, may be the preferred option.

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There are no guidelines to determine when it is safe to anticoagulate patients with a history of GI bleeding, and clinical common sense should be applied. If a patient has an active GI bleed, the problem should be managed prior to proceeding with LVAD placement. Conversely, if the patient has a history of peptic or duodenal ulcer but has not had any recent GI issues, for example in the previous 30 days, the HeartMate II may be considered.

Hepatic: As with renal function, there is some evidence that hepatic function improves after implantation of a HeartMate II. In patients receiving the HeartMate II in the pilot clinical study, both ALT and total bilirubin values improved to normal.[19] Caution should be taken in patients with evidence of poor hepatic synthetic function (abnormal prothrombin time [PT]/partial thromboplastin time [PTT] and international normalized ratio [INR]) and steps should be taken to try to improve hepatic function as much as possible preoperatively by boosting forward flow and reducing hepatic congestion. Consideration of an intraaortic balloon pump or a temporary percutaneous assist device to improve cardiac function is warranted.

Hepatic cirrhosis is associated with very poor outcomes. Evidence of hepatic dysfunction is a predictor of biventricular failure and potentially greater need for support by means of a right ventricular assist device (RVAD).

Hematologic: Similar to the assessment of any patient undergoing a major surgical procedure, attempts should be made to correct or improve clotting factor abnormalities preoperatively. This may be more important in HeartMate II patients than in those receiving the HeartMate XVE, as systemic anticoagulation is used in conjunction with the HeartMate II system. At a minimum, one should check PT/PTT, INR, platelet count, and for the presence of antibodies to heparin.

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Peripheral vascular disease: In the HeartMate II clinical trial, patients with significant peripheral vascular disease were excluded. There have been anecdotal reports that have shown that even moderate to severe peripheral vascular disease is not a contraindication to a VAD. An abdominal ultrasound and determination of the ankle-brachial index may be warranted to fully evaluate the degree of disease burden in a particular patient.

II.C. General preoperative assessment

Table 3 outlines various tests and assessments that should be done in all patients prior to LVAD implantation. Table 4 lists preoperative goals in terms of relevant metabolic markers.

Table 3. General preoperative assessment

Labs*	Studies	Other
• CBC with differential • Electrolyte panel, Mg • Liver function panel • Uric acid • Plasma-free hemoglobin • LDH • PT/PTT, INR • Type and cross (12 units PRBCs, 12 units FFP) • PRA (if potential transplant	• Chest x-ray (PA and lateral) • Carotid Doppler if history of CAD or >50 years old • Chest/abdominal CT if previous chest or abdominal surgery • ABI if claudication history • Abdominal US for AAA screen	• Dental evaluation with Panorex® films

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candidate) • Pregnancy test (if female) • Iron, transferrin, ferritin • Glycosylated hemoglobin • Heparin antibody • Seratonin release assay (if heparin antibody positive) • Copper, selenium, zinc • Albumin, prealbumin • Blood cultures × 2 (including a peripheral site) • Urinalysis, culture, and sensitivity • Nasal swabs for staph • Rectal swab for VRE • TSH, T3, T4	• EGD/colonoscopy within past 2 years	

* In addition to tests shown, some centers check protein C, protein S, and anticardiolipin antibodies to identify coagulation abnormalities that may be used to guide postoperative management.

Abbreviations: AAA, abdominal aortic aneurysm; ABI, ankle-brachial index; CAD, coronary artery disease; CBC, complete blood count; CT, computed tomography; EGD, esophagogastroduodenoscopy; FFP, fresh frozen plasma; INR, international normalized ratio; LDH, lactate dehydrogenase test; Mg, magnesium; PA, postero-anterior; PRA. plasma renin activity; PRBC, packed red blood cells; PT, prothrombin time; PTT, partial thromboplastin time; TSH, thyroid-stimulating hormone; US, ultrasonography; VRE, vancomycin-resistant enterovirus.

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Table 4. Minimal pre-implantation goals	
Parameter	**Desired value**
Renal	BUN <50 mg/dL SCr <2.5 mg/dL
Hematologic	INR <1.2 Hb >10g/dL PLT >150,000/mm
Nutritional	Albumin >3 g/dL Pre-albumin >15 mg/dL Transferrin >250 mg/dL
Hepatic	TB <2.5 mg/dL ALT, AST <2 times normal
Hemodynamic	RAP <15 mmHg PCWP <24 mmHg

Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase; BUN, blood urea nitrogen; Hb, hemoglobin; INR, international normalized ratio; PCWP, pulmonary capillary wedge pressure; PLT, platelets; RAP, right atrial pressure; SCr, serum creatinine; TB, total bilirubin.

III. Intraoperative Considerations

KEY POINTS
• Moderate to severe aortic insufficiency and mitral stenosis must be corrected during the same operation before pump placement. • Both the inflow segment and outflow graft need to be meticulously

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preclotted. If a react-in-place sealant is used, special care must be taken to deliver the sealant into place before reaction is complete. Hemostatic matrix materials should not be used.

- The HeartMate II LVAD is designed for preperitoneal placement.
- The inflow cannula of the HeartMate II must point posteriorly toward the mitral valve. Obstruction may result if the cannula is pointing or angled toward the septum or free wall.
- The driveline is positioned in a gentle loop, leaving some internal slack for accidental tugs in the perioperative period. The distance between the pump pocket and exit site is maximized.
- Certain steps in LVAD implantation can be taken while the patient is stable prior to cardiopulmonary bypass (CPB) in order to minimize exposure. Although a few patients have been implanted with the HeartMate II using off-pump techniques, these approaches are considered experimental and are not recommended at this time.
- Prior to coming off bypass, de-airing should be conducted at low VAD speeds (usually ~6000 rpm). Before higher speeds are initiated, the patient should be weaned off CPB and the LV should be completely full (>10 mmHg) to avoid sucking in air.
- Care should be taken not to overstress the RV and to preserve RV function. If RV failure occurs and the LVAD is not filling, temporary right-heart bypass can be performed to provide blood flow to the LVAD while transitioning from bypass.
- Intraoperative echocardiography can help locate intracardiac

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thrombi, which should be removed. Intraoperative echocardiography and assessment of LV chamber size and aortic valve opening also play a critical role in determining optimal pump speed.

Standard procedures for infection control and prophylaxis have been well described in the literature[1-3, 20] and should be followed. This section addresses some general intraoperative considerations and a number of recommendations specific to the HeartMate II LVAS. For more detailed instructions on implantation, refer to the HeartMate II Instructions for Use.

III.A. Valvular heart disease

Table 5 lists valvular conditions that should be considered and, where appropriate, potential intraoperative approaches. Aortic, mitral, and tricuspid valve issues are described in greater detail below.

Table 5. Valve issues

Issue	Possible Solution and Comments
Aortic insufficiency	AI of 2+ or greater *must* be corrected. The aortic valve leaflets can be partially oversewn or the valve can be replaced with a bioprosthetic valve.
Mitral regurgitation	Generally does not require repair
Mitral stenosis	*Must* be corrected with MV replacement with a bioprosthetic valve
Tricuspid insufficiency	For 3+ to 4+ TR, consider annuloplasty repair (ring or modified De Vega reinforced with multiple pledgets)

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Mechanical prosthetic valves	Aortic valve: consider replacement with a bioprosthetic valve. Mitral valve: generally does not require replacement; consider greater anticoagulation

Abbreviations: AI, aortic insufficiency; AVR, aortic valve replacement; LV, left ventricle; MV, mitral valve; MVR, mitral valve replacement; TR, tricuspid regurgitation.

III.A.1. Aortic valve pathology

Aortic stenosis: Existing stenosis of the aortic valve usually does not require correction prior to implanting the LVAD. The LVAD will decompress the LV and provide the majority of the cardiac output. Therefore, aortic stenosis is generally hemodynamically insignificant with regard to pump performance.

Aortic insufficiency: With continuous-flow devices, the patient usually has minimal to no pulse pressure. The native LV, although contracting, may not generate enough pressure to open the aortic valve. An aortic insufficiency (AI) jet therefore may be present in both diastole and systole, resulting in rapid ventricular filling and high pump flows. Thus, AI tends to have a significant effect on pump performance and the assessment of flow rates.

The importance of AI also relates to the duration of anticipated VAD support. For example, for very-long-term VAD support, the presence of AI may represent a more significant lesion, as AI is likely to progress over time. On the other hand, for patients on BTT therapy with VAD support for a couple of months, AI may be a less significant problem. Most surgeons recommend leaving mild AI alone.

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Moderate to severe AI warrants surgical repair or replacement.

- **Partial oversewing of the aortic valve**: Some surgeons sew the leading edges of the cusps together (the "Park stitch") to eliminate the majority of the insufficiency.[21]
- **Complete oversewing of the outflow tract[22, 23]:** There are several approaches to oversewing the outflow tract. ***It should be recognized that a patient with an oversewn aortic valve is completely dependent on the LVAD and even short-term disruption of device function could be fatal***. One approach is to remove the leaflets, size the opening with an aortic valve sizer, and put in a Hemashield® (Boston Scientific) circular patch using standard aortic valve suturing techniques. Care should be taken to make sure that the edges of the patch are below the coronary ostia. If a mechanical valve is in place, it is also quick and easy to sew a bovine pericardial patch to the sewing cuff of the mechanical valve, thereby covering it and excluding it from the blood flow.
- **Valve replacement**: If aortic valve replacement must be done, use of a mechanical valve is not recommended because of the potential for thromboembolic complications. Thrombus may form under the leaflets due to infrequent opening and stasis. Therefore, tissue valves are preferred. Pump speed may need to be reduced to allow intermittent opening of the valve as long as adequate support can be provided. There have been several reports of patients who have both a continuous-flow LVAD and a bioprosthetic aortic valve in whom the development of fibrosis or endothelialization of the bioprosthetic valve resulted in its functional closure.[24]

Preexisting aortic mechanical valve: Although these patients were excluded from the clinical trial if they were not converted to a bioprosthetic valve, a preexisting aortic mechanical valve is not considered an absolute contraindication to LVAD implantation. There is ongoing debate whether to leave the mechanical valve in place or replace it with a tissue valve. The individual patient's indications for LVAD support may dictate the course of action.

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If the patient is receiving the pump for long-term support, then a mechanical valve should be replaced with a tissue valve or the outflow tract oversewn as previously described, since there may be a greater chance for thromboembolic events over an extended period of time.

For all clinical scenarios, these recommendations are based on past experience with other LVADs[25] and experience to date with the HeartMate II LVAS. As additional experience is gained with the HeartMate II and other continuous-flow pumps, these recommendations may change.

III.A.2. Mitral valve pathology

Mitral valve stenosis: Mitral stenosis needs to be corrected at time of implant to maximize ventricular and LVAD filling. Unlike aortic valve stenosis, mitral stenosis will limit pump flow while maintaining a high left atrial pressure (LAP). Elevated LAP could cause persistent pulmonary hypertension and RV dysfunction. Currently, valve replacement with a tissue valve would be most appropriate. However, there may be specific situations where a mitral valvuloplasty may be indicated.

Mitral insufficiency: There is no general consensus on whether mitral insufficiency is a lesion that requires repair in continuous-flow LVAD patients. The majority of mitral insufficiency in end-stage heart failure is from annular dilation and LV dysfunction. Once the LV is decompressed with the LVAD, the mitral regurgitation (MR) may improve. Although some have suggested that mitral valve repair can improve postoperative LVAD and LV function, usually no surgical procedure is required for MR in patients being implantation with an LVAD. Also, MR can be reduced by increasing the speed of the pump when appropriate, which will improve unloading

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the ventricle. In cases where the pump is removed after myocardial recovery, significant residual mitral insufficiency should be repaired.

Existing prosthetic valves: There is general agreement that a functioning bioprosthetic or mechanical mitral prostheses does not require removal or replacement, although greater anticoagulation should be considered to avoid thromboembolic risk.

III.A.3. Tricuspid valve pathology

Tricuspid insufficiency: Because of the importance of improving early right-heart function, there is general consensus that severe tricuspid insufficiency should either be repaired or treated with valvular replacement, which would have an early beneficial effect. Mild to moderate TR and a functional valve would probably improve with RV afterload reduction.

III.B. Preclotting options

Both the inflow segment and outflow graft need to be preclotted correctly and meticulously (Figure 2). Care must be taken to ensure that preclotting material is inserted along the graft down into the space between the graft and the metal junction of the connector to the LVAD. Inserting material into this space may be accomplished more easily if the material remains fluid for a period of time after application (eg, albumin solution followed by autoclaving, or cryoprecipitate followed by thrombin). If a react-in-place sealant such as Tisseel® (Baxter Healthcare Corp) or CoSeal® (Baxter Healthcare Corp) is used, special care must be taken to deliver the sealant into these spaces before reaction is complete.

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Hemostatic matrix materials such as Surgiflo® (Ethicon) or FloSeal® (Fusion Medical Technologies) should not be used, as the material does not produce a layer with sufficient strength to ensure that the graft is sealed.

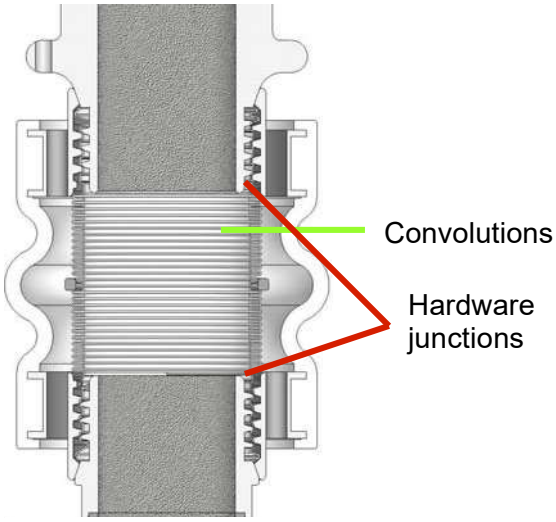

Figure 2A: Inflow cannula preclotting must ensure coating between convolutions and at junction of hardware and graft.

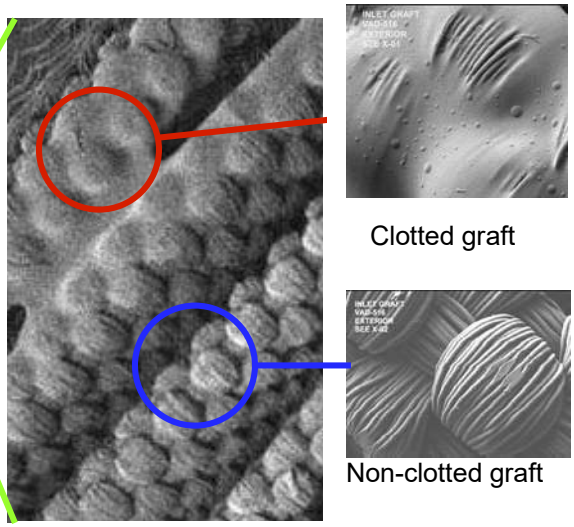

Figure 2B: Scanning electron microscopy after explantation shows preclotting material not completely covering graft.

III.C. Pump placement

The HeartMate II LVAD was designed for preperitoneal placement—ie, below the left rectus muscle, above the posterior rectus sheath (Figure 3). Keys to proper placement include:

- Inflow cannula must point posteriorly toward the mitral valve. The cannula should not be pointing or angled toward the septum or free wall because it may cause partial occlusion of the inflow cannula, leading to poor filling of the LVAD and possible thromboembolic complications.
- Outflow graft should be attached to the ascending aorta in an end-to-side fashion.

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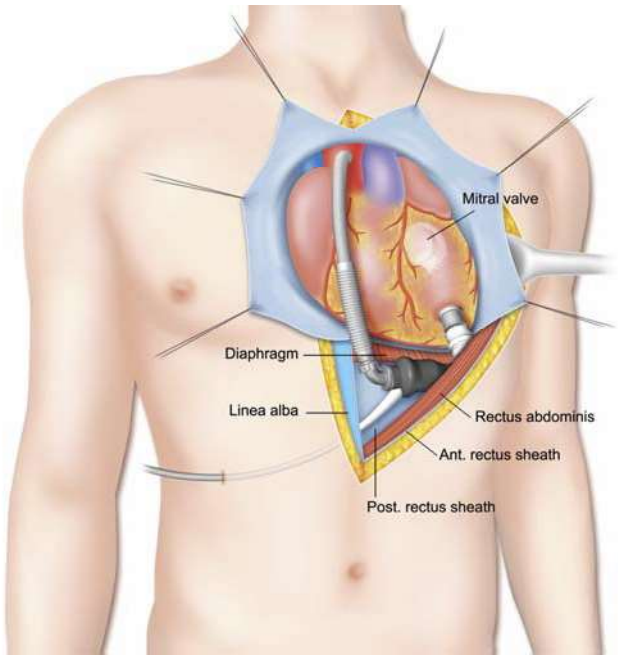

Figure 3: Preperitoneal placement of the HeartMate II pump (below the left rectus muscle and above the posterior rectus sheath).

The sequence of surgical steps includes:

1. Create sternotomy with 4- to 6-cm extension in the upper midline.
2. Incise the left anterior rectus fascia.
3. Elevate the left rectus muscle.
4. With the heart beating, select the location on the dome of the diaphragm for the inflow cannula.
5. Set the pump below the left rectus muscle, anterior to the posterior rectus sheath. No opening is made in the diaphragm.

As with preperitoneal placement of the HeartMate XVE device, preperitoneal placement of the HeartMate II requires the dissection of a pocket. However, the pocket dissection is smaller with the HeartMate II, requiring less time and potentially introducing less risk of infection. Most

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patients in the clinical trial were implanted in the preperitoneal position although intraabdominal placement can also be used. The relative advantages and disadvantages of preperitoneal versus intraabdominal placement are shown in Table 6.

Table 6. Preperitoneal vs intraabdominal placement

Pocket Position	Advantages	Disadvantages

Preperitoneal	• Isolation from abdominal contents
	• Easier reoperation for explant or replacement
	• Less posterior compression on stomach
		• Time to create pocket
		  ○ Less with HeartMate II vs XVE
		• Potential for prolonged pocket drainage and increased risk of infection
		  ○ Potentially less with HeartMate II vs XVE

Intraabdominal	• No pocket dissection/hematoma • Omental wrap of housing and percutaneous lead • Potential for less infection	• Visceral contact/erosion • More complex re-exposure at replacement • Visceral compression and early satiety

III.D. Driveline Placement

Techniques for driveline placement (Figure 4) vary with surgeon comfort and experience. In general, the distance between the pocket and exit site is maximized. Some surgeons bend the tunneler instrument into a tight U and guide it from near the apex across to the right subcostal

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area. The driveline is test-measured first to assure that the entry site allows the driveline to exit at the desired point with 1 to 2 cm of velour exteriorized. The driveline is typically positioned in a gentle loop, leaving some internal slack for accidental tugs in the perioperative period, and providing a long segment for incorporation prior to the pump pocket. This placement can also help prevent driveline damage at resternotomy for transplant. The exit site is prepared with a punch or slit through muscle, not just subcutaneous tissue, and stabilized with a suture.

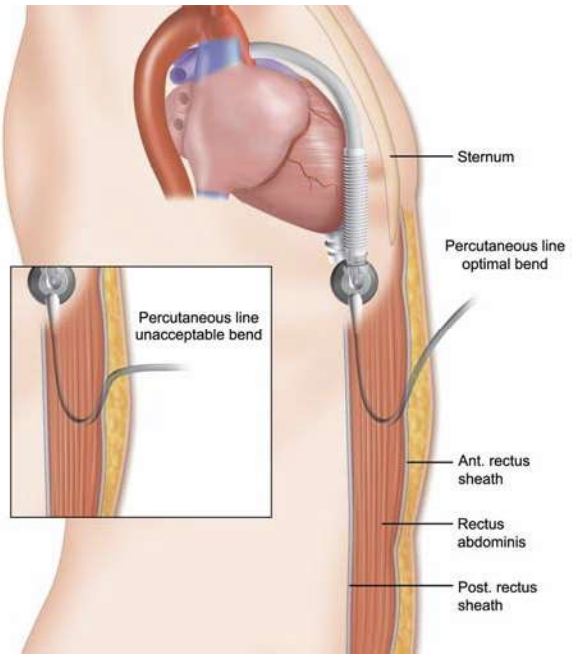

Figure 4: The driveline is positioned in a gentle loop, leaving some internal slack for accidental tugs in the perioperative period.

III.E. Cardiopulmonary bypass

Issues surrounding cardiopulmonary bypass (CPB) during LVAD implantation, for any indication, are covered in detail in volume 1 of *Advanced Practice Guidelines for HeartMate Destination Therapy*.[1] Additionally, information related to the transition from CPB to HeartMate II implantation is contained in section **III.F** below.

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In general, adjusting inotropic and afterload-reducing drugs prior to CPB can help maximize RV function and reduce PVR while optimizing systemic perfusion pressure. As prolonged CPB can have deleterious effects—particularly coagulopathy and inflammatory responses contributing to systemic hypotension, pulmonary hypertension, and resultant right-sided circulatory failure[26]—steps should be taken to minimize CPB exposure. For example, tunneling, outflow graft connection, and pump placement can be done prior to CPB provided that the patient is stable.

Although a few patients have been implanted with the HeartMate II using off-pump techniques, these approaches are considered experimental and are not recommended until special coring tools can be developed and safe techniques validated. Off-pump strategies compromise the usual principles associated with placement of the LVAD. One of the most important concerns is that off-pump implantation does not allow for the visualization and removal of LV thrombus or obstructing trabeculae. In addition, the duration of CPB required for implantation of the device is relatively short (less than 1 hour), and the possible deleterious effects of such a short period of CPB are considered minor in comparison to unknown risks associated with off-pump techniques.

III.F. De-airing and transitioning from cardiopulmonary bypass

Prior to coming off bypass, de-airing should be conducted at low VAD speeds (usually ~6000 rpm). A temporary flow probe may be helpful in determining the magnitude of forward VAD flow at the lower speed. Most surgeons do not utilize a left ventricular vent, and will vent via the outflow graft instead.

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Before higher speeds are initiated, the patient should be weaned off CPB and the LV should be completely full (>10 mmHg) to avoid sucking air. Elevating the LV apex can aid in the removal of air from the heart. The use of higher speeds (eg, ~8000 rpm) prior to completely filling the LV and coming off CPB is not recommended as it can lead to entrainment of air and difficulty with further de-airing. Flooding the field with CO_2 during de-airing has been used successfully. Transesophageal echocardiography is routinely used to view the LV chamber and septal position for determining initial pump speeds. In select cases, CPB can be completely discontinued to allow thorough de-airing before actuation of the device.

Some centers have found that direct measurements of LAP are useful in setting pump speeds and assuring that there is adequate RV output. Only centers with routine experience in placing and using direct left atrial (LA) monitoring lines should attempt this. If an LA line is placed, use extreme caution to avoid sucking air into the LA through the insertion site, and to avoid flushing air into the LA directly through the LA catheter.

A straightforward method for de-airing is:

- Flush the outflow graft.
- Insert a needle in the outflow graft.
- Let the heart beat for a few moments (after ensuring heart is full).
- Look for air on the echocardiogram.
- If no air is observed, remove the clamp from the outflow graft (de-air through outflow graft).

It is important to make sure that the inflow graft is completely preclotted and the pump is sealed properly to avoid drawing in air through the inflow sleeve.

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III.G. Management of right ventricular dysfunction

Management of RV dysfunction should focus on prevention rather than treatment. The tricuspid valve should be evaluated and repaired, if necessary. Care should be taken to avoid RV volume overload and to maintain central venous pressure (CVP) below 16 to 18 mmHg. If CVP is ≤10 mmHg, some volume may be given to improve flow. With moderate RV dysfunction, milrinone, epinephrine, or vasopressin can be used. Inhaled nitric oxide can reduce PVR, and some centers have found that inhaled Flolan® (GlaxoSmithKline) is effective and less expensive than nitric oxide. Pacing can be used if the heart rate is not optimal.[27-29] High LVAD pump speeds that cause leftward septal shift should be avoided. Leaving the sternum open for 24 hours has been reported to help reduce CVP in patients with CVP >16 mmHg. If in spite of these interventions the CI is less than 2.0 L/min/m^2 and the CVP >16 mmHg, a temporary RVAD should be considered. With temporary RVADs, excessively high flow rates should be avoided.

If RV failure occurs and the LVAD is not filling, temporary right-heart bypass can be established to deliver oxygenated blood to the LVAD.[30] This can be done by returning part of the blood from the CPB circuit through a cannula inserted in either the pulmonary artery or LA via the right superior pulmonary vein. A bypass of this type allows adequate filling of the LVAD without requiring excessive right-heart work.

III.H. Intraoperative echocardiography

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Intraoperative echocardiography can help locate intracardiac thrombi, which should be removed. Intraoperative echocardiography also plays a critical role in determining optimal pump speed. This process is described in sections **IV.A** and **V.A.3** below.

Due to a significant incidence of false-negatives in exams (including bubble studies) conducted in the pre-bypass period,[31] some centers visually inspect the interatrial septum to rule out PFO. If direct inspection is not undertaken, it may be necessary to repeat the bubble study after LVAD implant and weaning from CPB. With the left heart decompressed and the right heart working and loaded, a previously undetected PFO may be unmasked and significant shunting may be seen by color-flow Doppler and bubble study (Figure 5). It is important to repair a PFO to prevent right-to-left shunting and potentially hypoxemia post-implantation.[1]

Figure 6: This transesophageal echocardiogram shows significant flow by color Doppler across a patent foramen ovale (PFO) after the left ventricle was decompressed by LVAD support. The PFO was not apparent in the pre-bypass period due to the previously high left atrial pressure.

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III.I. Replacement of the HeartMate XVE with the HeartMate II LVAD

At its end of pump life, the HeartMate XVE LVAD can be replaced with a HeartMate II LVAD. For this procedure:

- A redo sternotomy approach is recommended.
- The patient is placed on CPB.
- The apical sewing cuff from the HeartMate XVE is usually retained.
- The old apical cannula is removed.
- The inflow cannula from the HeartMate II LVAD is placed through the old apical sewing cuff.

The outflow graft on the HeartMate II device is smaller than the existing HeartMate XVE aortic graft, but they can be sewn together easily end-to-end. The HeartMate II grafts should be beveled in order to accommodate the larger HeartMate XVE graft. De-airing issues are similar to those described in section **III.F**.

IV. Postoperative Patient Management

KEY POINTS
• A patient's RV function is greatly affected by pump speed. It is important to avoid setting the pump speed so high that it causes a significant leftward septal shift and abnormal RV geometry, which can adversely affect RV function. • Anticoagulation should be completely reversed following CPB. Patients are usually anticoagulated with warfarin and antiplatelet

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agents (aspirin and dipyridamole).

- In the early postoperative period, an arterial line is used to follow blood pressure, with the goal being to maintain a mean pressure of 70 to 80 mmHg and a maximum pressure below 90 mmHg.
- As with any LVAD, patient education related to the HeartMate II requires the collaboration of a well-trained team. Self-care should stress aseptic maintenance of the exit site and continuous immobilization of the LVAS controller.

The postoperative management of HeartMate II patients in most instances is quite similar to the management of all patients after major cardiac surgery.[2] HeartMate II patients have special considerations related to RV function and volumes, anticoagulation and bleeding, blood pressure monitoring and management, and patient education, which are described in this section.

IV.A. Right ventricular function and volumes

There are a few general considerations when evaluating and managing RV function and setting the HeartMate II pump speed in the postoperative setting:

- It is important to avoid setting the pump speed so high that it causes a significant leftward septal shift and abnormal RV geometry, which can adversely affect RV function. High pump speeds also can collapse the LV and obstruct flow through the LVAD inlet cannula draining the LV. (Optimum speed selection is covered in section **V.A.3**.)

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- Because there is potential for large volume shifts in the early postoperative period, echocardiography should be performed fairly routinely, since these volume changes alone may cause changes in RV and LV function.
- There is debate as to how often the aortic valve needs to open. One practice when adjusting pump speed is that the aortic valve should open every second or third beat. This provides a pump speed setting that reduces the risk of aortic valve thrombosis and at the same time assures that the LV is reasonably loaded and not near collapse. In some patients, however, even at low pump speed the aortic valve will not open due to poor LV function. There are insufficient data to make firm conclusions about the long-term effects of this phenomenon. Although there are reports of chronic mechanical circulatory support with the aortic valve remaining closed without apparent negative clinical effect, there has been at least one anecdotal report of aortic valve thrombus developing on the noncoronary cusp.
- If a patient is clinically decompensating (signs of poor forward flow or right-heart failure), consider a repeat echocardiogram and reevaluate pump speed.
- When setting pump speed, the RV should be assessed to see if it becomes dilated and hypocontractile at either high or low speeds.
- A sign of poor LV unloading in some patients is the amount of MR. If the patient has severe MR, consider increasing the pump speed.

IV.B. Anticoagulation

The use of axial flow devices requires anticoagulation and/or platelet modifiers post-implantation, although the appropriate levels are the subject of much discussion. Most centers start with heparin (see section **IV.B.1** and the footnote [†] to Table 7) and subsequently use a

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combination of antiplatelet and anticoagulation agents long-term, mostly relying on warfarin and aspirin (Table 7).

Table 7. Postoperative anticoagulation guidelines

Timing	Action
Prior to leaving OR	Completely reverse the anticoagulation
Immediate postoperative period	Generally, no action*
Day 1 (or when chest tube drainage is <50 mL/hr)	Begin IV heparin if appropriate†: • Initially titrate to a PTT of 45 to 50 for 24 hours (1.2 to 1.4 times control) • After 24 hours, increase heparin and titrate to PTT 50 to 60 (1.4 to 1.7 times control) • After another 24 hours, increase heparin and titrate to PTT 55 to 65 (1.5 to 1.8 times control)
Day 2 and 3	Initiate: • Aspirin 81 to 100 mg daily • Dipyridamole 75 mg three times daily
Day 3 to 5	• Once there is no evidence of bleeding and the chest tubes have been removed, begin warfarin (overlapping with heparin) • Discontinue heparin after obtaining an acceptable, stable INR (2.0 to 3.0)
Duration of support	Maintain on aspirin, dipyridamole, and warfarin

Source: Adapted from HeartMate II protocol (3/31/05).

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*Trial protocol allowed the use of 10% low-molecular-weight dextran at 25 mL/hr. This practice is considered optional until its benefits can be further delineated.

†Some centers have eliminated the use of heparin to lower the risk of postoperative bleeding.

Abbreviations: INR, international normalized ratio; IV, intravenous; OR, operating room; PTT, partial thromboplastin time.

IV.B.1. Titrating anticoagulation

One common mistake is starting anticoagulation too early; therefore, make sure you have adequate hemostasis prior to initiating anticoagulation. Modification of the anticoagulation regimen may be required in the face of changing clinical targets and situations. If pump flow remains low (<3.0 L/min), consider increasing anticoagulation to the upper limits of the suggested range. If there is a risk of bleeding, consider decreasing heparin/warfarin but potentially increasing or maintaining antiplatelet medications. Antiplatelet effect should be confirmed with lab studies.

Because of the incidence of bleeding in the initial clinical trial patients, some centers have been reducing the levels of anticoagulation. The use of heparin postoperatively is controversial, as it is implicated in hematomas, tamponade, and other bleeding adverse events requiring reoperation or transfusion. Some centers have eliminated the use of postoperative heparin and have initiated warfarin as soon as possible. There have been anecdotal trends toward reduced postoperative bleeding with this strategy, but the long-term effect on the incidence of thromboembolism is not known. The INR levels for those patients maintained on warfarin average 2.3 standard deviation of 0.9 (133 BTT PMA data). [32]

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Patients on stable doses of anticoagulation and antiplatelet therapy may benefit from close monitoring at time of concurrent illness. Stable patients who develop fever or an extrathoracic site of infection should be monitored closely, as this is frequently a prelude to a period of relative hypercoagulability.[33]

IV.B.2. Use of thromboelastography

Some centers are utilizing thromboelastography (TEG) to manage and adjust anticoagulation therapy. Not all centers have TEG systems, and its use for LVAD patients is not universally accepted, but some centers with experienced personnel and dedicated approaches have found it useful and reliable. Teams should be well trained to ensure consistent results. The TEG is initially reviewed carefully every day to assess antiplatelet needs until stable and satisfactory levels are achieved.

One centers protocol is presented here as an example. For the assessment of platelet function, the maximal amplitude (MA) of the TEG is the most useful parameter to help tailor therapy to the individual patient. In general, an MA in the 56 to 75 range has been used as an appropriate target range for platelet activity in HeartMate II patients with good results. An MA of less than 55 indicates a hypocoagulable state and is cause for concern for inadequate platelet activity, whereas an MA exceeding 75 (especially >80), indicates a hypercoagulable state, and more aggressive antiplatelet therapy should be instituted.

The general escalation of antiplatelet therapy has been initiation of aspirin at 81 mg, then the next stepwise addition of Persantine® (dipyridamole) 75 mg either twice or three times daily, depending on the MA. Dosage may be incrementally increased up to a maximal dose

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of about 1 g/day, with an increasing risk of GI side effects at higher doses. The aspirin dosage can be increased as well (to adult strength) if the heightened platelet activity remains refractory. In the extremely rare patient who remains hypercoagulable (MA >75) by TEG and also by PFA-100® verification, Plavix® (clopidogrel) either 75 mg every other day or 75 mg daily can be used temporarily to reduce MA to an acceptable level.

The TEG R-time value has also been useful in correlating with the enzymatic anticoagulation by PTT. Frequently prior to discontinuing heparin, a TEG with heparinase may better elucidate the true anticoagulation status. Some centers also report the use of the TEG lysis 30 time as an early marker of increased blood component breakdown.

IV.C. Blood pressure monitoring and management

Due to the continuous-flow nature of the HeartMate II, it is often difficult to find a heart rate and measure blood pressure by the usual physical examination techniques. In the early postoperative period, an arterial line is used to follow blood pressure, with the goal being to maintain a mean pressure of 70 to 80 mmHg with a maximum pressure below 90 mmHg.

After the patient transitions from the ICU to the floor, the staff needs to be carefully instructed on methods to obtain accurate blood pressure readings. Automatic blood pressure cuffs may not detect a blood pressure; if they do, however, the measurement is usually reliable. When listening with a manual blood pressure cuff, the start of Korotkoff sounds is assumed to represent mean blood pressure. Doppler ultrasound is often preferred to measure blood pressure and is often made available in both inpatient and outpatient settings. It is unclear if Doppler flow or Korotkoff sounds reflect systolic blood pressure or mean blood pressure in

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these patients. However, a narrow pulse pressure is not uncommon in these patients and the two pressures are often quite similar.

Monitoring patients undergoing unconscious sedation can be challenging. Doppler is usually required to monitor blood pressure. Pulse oximetry, if obtainable, may be unreliable due to the diminished pulse pressure. Instead, some centers have found cerebral oximetry useful in assessing the hemodynamic condition of patients during unconscious sedation or in situations when more invasive monitoring is not available.

IV.D. Patient education

The patient education process related to LVAD implantation can be complex, requiring a collaboration of multiple team members and extending not only to patients but to patients' companions in care. The fundamental features of an effective patient education program are described in *Advanced Practice Guidelines for HeartMate Destination Therapy,*[2] (vol 2).

IV.D.1 System operation

A thorough understanding of the LVAD and system components by the patient and companion is necessary to ensure patient safety in the outpatient setting. The patient and companion should be able to identify and respond appropriately to alarm symbols and audible tones. Of particular importance, the device must have an adequate power supply at all times, either through the power base unit or battery pack, and patient training should focus on the proper procedure for switching between power sources and estimating battery charge levels. Loss of power will result in the pump stopping, which may have serious consequences especially in those patients who are device-dependent

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or in whom the outflow tract has been oversewn (troubleshooting pump stop is covered in greater detail in section **V.B.2**).

IV.D.2 Self-care infection prophylaxis

The system controller of the HeartMate II is heavier than the controller of the HeartMate XVE. Because of this, patients are sometimes less comfortable wearing it on a belt and often want to place it on a table. This is not advisable, as incidents have been reported where patients forget about their controller and attempt to walk away, pulling the controller off the table. Obviously, this highlights the need to train patients as to the importance of immobilizing the driveline at all times.

In terms of patient education, immobilization of the driveline and aseptic maintenance of the exit site are critical self-care lessons that may have a direct impact on the risk of infections.[3] Despite the smaller-diameter driveline and smaller exit site of the HeartMate II compared with the XVE, there is no reason to believe that maintenance of an aseptic exit site is any more or less important with one device versus the other, or that any difference in technique is warranted.

IV.D.3. Driveline immobilization

Experience has shown that immobilizing the driveline is a critical component of infection prevention.[3] The driveline should be immobilized in the OR using a stabilization belt or restraint device, which should be worn continuously. Patients' ability to accomplish this goal in day-to-day life can greatly depend on the effectiveness of the patient education program to which they have access.

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Infection leads to increased morbidity and mortality. Serious infections may negate the benefits of LVAD implantation, resulting in generally poor outcomes with increased costs and reduced quality of life. Preventing infection post-implantation is crucial to the cost-effective use of mechanical circulatory support devices.[3] (For additional information on infection prevention and management, see Table 11 in section **VI** and articles by Chinn et al[3] and Holman et al.[20])

IV.D.4. Maintaining volume status/hydration

Patients should be taught how to maintain their volume status and cautioned that their pre-LVAD routines may actually lead to dehydration post-LVAD. It is not uncommon for patients to become dehydrated because they continue to limit their oral intake and maintain a salt-restricted diet.

General patient self-care recommendations should include weighing themselves daily and paying attention to symptoms such as orthostatic hypotension. Patients should be prompted to call if they have greater than 3-lb fluctuations in weight over a 24-hour period. Once the patient is determined to be wet, dry, or euvolemic, normal procedures may be followed. Consider repeating an echocardiogram at that time to determine if the patient's pump is set at the proper speed.

V. Postoperative Device Management

KEY POINTS

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- The HeartMate II does not contain valves and depending on the patient, pump stop can have severe consequences. Special attention must be provided to avoid power interruption or inadvertent power lead disconnects that would lead to loss of support.
- The HeartMate II pump can generate large negative pressures at the pump inlet, which may result in septal shift or ventricular collapse. Pump-speed optimization and device monitoring therefore present unique challenges compared with pulsatile devices.
- Avoid setting the pump speed too high, which can result in ventricular suction and collapse and initiate arrhythmias.
- The system-provided parameters of speed, power, pulsatility index and flow in conjunction with echocardiography serve as the primary indicators of device function. No single parameter is a surrogate for monitoring the clinical status of the patient and the changes in all parameters should be considered when assessing a situation.
- The range of safe operating speeds is determined by means of a ramped speed study under echocardiography, observing changes in ventricular shape and function and the patient's physiological response to changing pump speeds. A fixed speed is set within this range based on clinical judgment.

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The unique axial-flow design of the HeartMate II LVAS presents equally unique challenges in monitoring and optimizing device performance. This section describes how the system-provided parameters of speed, power, pulsatility index (PI), and estimated flow are used to this end, and concludes with troubleshooting tips. (Note—The formal term *pulsatility index* is shortened to **Pulse Index** for display on the HeartMate II system monitor.)

V.A. Monitoring device function

Unlike pulsatile blood pumps, the output of the HeartMate II pump at a given speed depends on the prevailing afterload and can become retrograde in the presence of high pressures and low speeds. Another distinctive feature of the HeartMate II is its ability to generate large negative pressures at the pump inlet, which may result in septal shift or ventricular collapse. Consequently, speed optimization and device monitoring present some unique challenges compared with pulsatile devices.

The system-provided parameters of speed, power, PI and estimated flow in conjunction with echocardiography serve as the primary indicators of device function. It is important to view each of these device parameters in the larger context of overall patient condition. Once baseline values representing a satisfactory level of patient support are established, the degree of change in a parameter usually has more clinical significance than its absolute value. The use of these parameters in troubleshooting is described in section **V.B** and Table 9 below.

V.A.1. Flow/power

These two parameters (flow and power) are closely related by virtue of the fact that, at a given speed, there is generally a linear relationship between them. However, the power

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is directly measured by the system controller while the reported flow is an estimated value based on power. This means that any increase in power not related to increased flow, such as a thrombus rubbing on the rotor, will cause an erroneously high flow reading. Power values greater than 10 to 12 W depending on the speed may indicate the presence of thrombus. Conversely, an occlusion of the flow path will decrease flow and cause a corresponding decrease in power. In either situation, an independent assessment of pump output should be performed.

V.A.2. Pulsatility index

When the left ventricle contracts, the increase in ventricular pressure causes an increase in pump flow during cardiac systole. The magnitude of these flow pulses is measured and averaged over a 15-second interval to produce the displayed PI value (appears as **Pulse Index** on monitor). In general, the magnitude of the PI value is related to the amount of assistance provided by the blood pump. As the level of pump support increases, there is less ventricular filling and a corresponding decrease in measured PI. Under otherwise stable conditions, a significant drop in PI may indicate a decrease in circulating blood volume.

V.A.3. Optimum speed selection

A ramped speed study using echocardiography provides the most direct method for a physician to ascertain what speed provides the desired level of cardiac support for each patient. Throughout the procedure, LV size, position of the septum, and aortic valve opening should be monitored to determine the appropriate combination of factors that define the optimum operating point. The final decision for selecting the operating point is ultimately dependent on the physician's clinical judgment and will vary from patient to patient and center to center.

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To set the pump speed in patients who are stable and euvolemic, the following protocol can be used:

- The range of safe operating speeds is determined by means of a ramped speed study under echocardiography, observing changes in ventricular shape and function and the patient's physiological response to changing pump speeds. A fixed speed is set within this range based on clinical judgment, taking into consideration the desire for periodic aortic valve opening and a palpable pulse.
    1. Have the patient sitting or lying in a comfortable position, with echocardiography available.
    2. Determine minimum speed: Starting from the current fixed speed, lower the speed gradually to a speed as low as possible without the patient experiencing signs of worsening heart failure (eg, shortness of breath, lightheadedness, etc). Allow the patient to stabilize at each speed setting. *Do not allow the fixed speed to decrease below 8000 rpm*. Reduce the speed until the aortic valve opens with each beat or the patient starts to become symptomatic.
    3. Determine maximum speed: Starting from the minimum fixed speed as determined above, increase the pump speed gradually until the parasternal short-axis echocardiography view shows flattening of the interventricular septum (or is clinically acceptable based on the echocardiographic evaluation) (Figure 7).
- An appropriate fixed speed setting usually will fall midway between the minimum and maximum speeds. The selected speed may be adjusted from the midpoint based on clinical judgment, taking into consideration the desire for periodic aortic valve opening and a palpable pulse. To accommodate normal shifts in volume and hemodynamic status, the fixed speed should generally be set at least 400 rpm below the maximum speed as determined above. If premature ventricular contractions or arrhythmia

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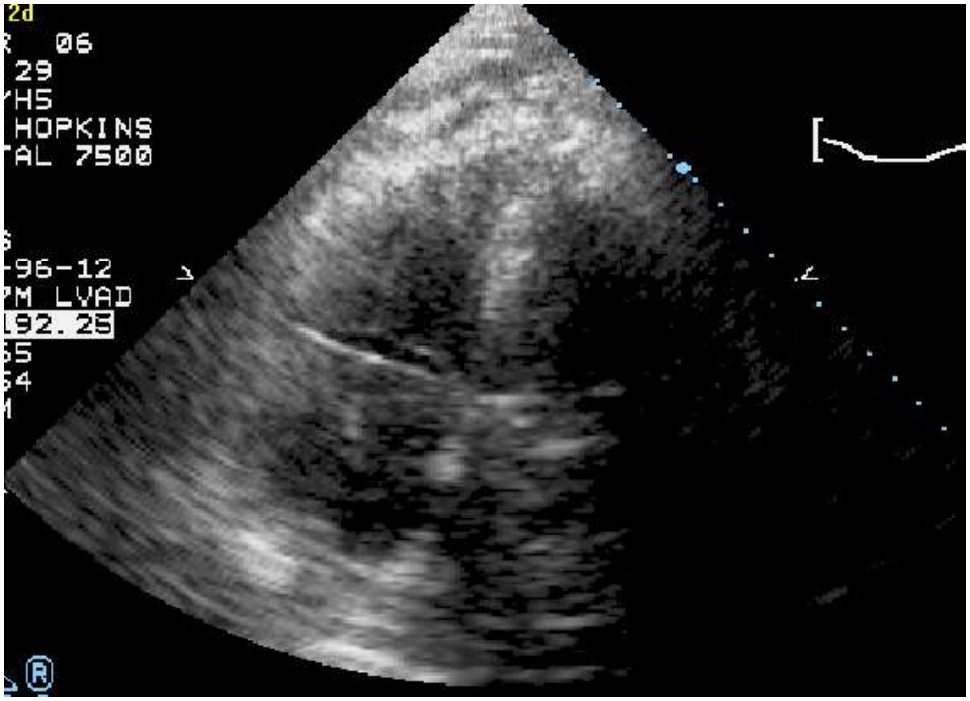
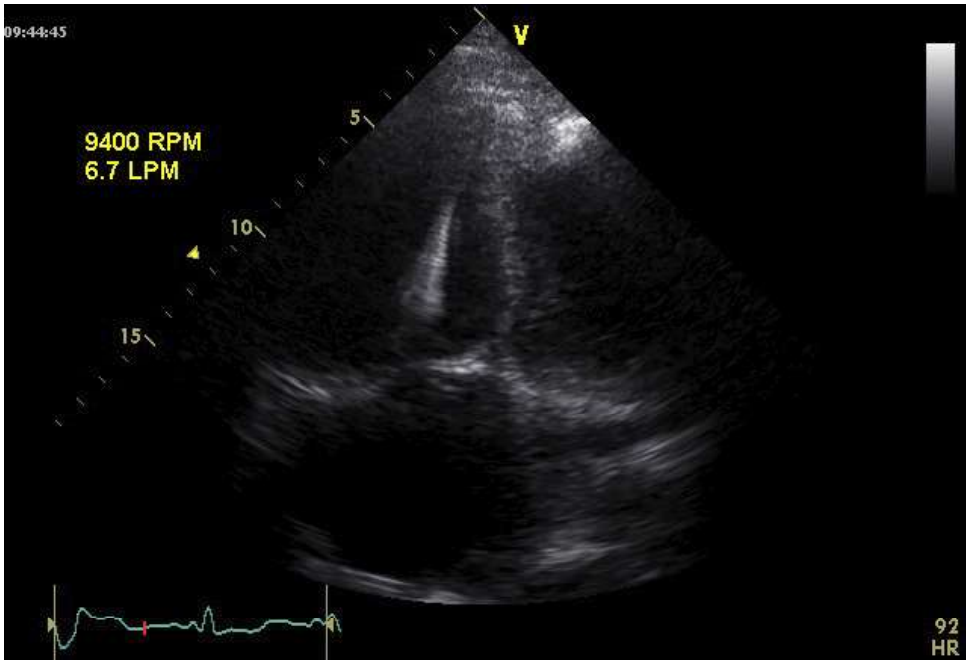
(ventricular tachycardia) occur with increased pump speed, the speed is too high and should be reduced.



A.



B.

Figure 7: Echocardiography at 9000 rpm (A) and 9400 rpm (B). Septal shifting is evident at 9400 rpm.

V.B. Troubleshooting

As described above, the HeartMate II system provides a number of parameters that can be used to assist in monitoring patient and pump conditions. These parameters and their significance in troubleshooting are listed in Table 8.

Table 8. Significance of displayed pump parameters

Parameter	How parameter is generated	Significance of changes

Pump rotor speed	Direct measurement through motor coil	• System operates at fixed speed that matches displayed setting ±~100 rpm under normal conditions
		• Large speed changes with system in fixed speed mode indicate an abnormal condition
		  ○ Suction event will precipitate decrease in speed to low speed limit (default: 9000 rpm)
		  ○ At end of suction event, speed gradually increases to fixed speed setting
		• Failure of the system to maintain fixed speed setting in absence of suction event indicates other pump or controller issue

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Power	Direct measure of current and voltage applied to motor	• Varies directly with pump speed and flow under normal conditions
		  ○ Flow obstruction results in reduced power
		  ○ Changes in physiologic demand can affect power
		• Abrupt changes should not occur and should be evaluated
		  ○ Note that abrupt power changes up to 2 Watts have been reported in the clinical trial with no adverse clinical sequelae
		  ○ Contact Thoratec technical support
		• Gradual power increase (over hours or days) may signal deposition or thrombus on the bearings or rotor (see section **V.B.1**)

Pulsatility index	Calculated from pump power normalized by mean power	• Corresponds to magnitude of flow pulse through the pump ○ PI fluctuates with changes in physiologic demand, volume status, the natural heart's contractility, and RV function • Under normal conditions, PI increases with increased pressure developed by the natural heart, which can result from increased LV preload or contractility • PI decreases

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		○ Abnormal power elevation (eg, from deposition or thrombus on the rotor or bearings) ○ Inflow/outflow obstruction, which reduces relative magnitude of the flow pulse and consequently the power pulse
Flow	Estimation based on pump speed and power	• Estimation assumes normal pump operation ○ Imprecise at flow rates less than ~3 L/min • Under normal conditions, reflects actual pump flow changes due to patient conditions or device operation • Increases with decreased pressure differential across the pump and with increased pump speed • Abnormal power elevation (eg, from deposition or thrombus on rotor or bearings) can result in overestimation of flow ○ May introduce a false-negative when using flow estimate to rule out low-flow conditions ○ Even in abnormal situations, flow estimate is unlikely to underpredict actual flow

Abbreviations: LV, left ventricle; PI, pulsatility index; RV, right ventricle.

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No single parameter is a surrogate for monitoring the clinical status of the patient and the changes in all parameters should be considered when assessing a situation. Due to the inherent variability between patients, the absolute values of the system parameters are usually less valuable than the trends observed. Abrupt changes in the parameters, not associated with normal physiologic changes, can be used to identify conditions that warrant further evaluation.

The use of these parameters in troubleshooting several selected complications is presented below and in Table 9. Typical methods for assessing situations are given, along with the corresponding device behavior. It is important to monitor pump readings and interpret changes as they may relate to patient complications.

Table 9. Potential device complications

Problem	Assessment	Management
Inflow obstruction	• HF symptoms, potential hemolysis, echocardiography (inflow position, ramped speed study, Doppler), angiography • Low pump power, LV not unloading with increasing speed; suction events; decreased PI; low flow	Ensure patient is hydrated, adjust pump speed, evaluate right heart function. Reexplore chest cavity, anchor pump
Outflow obstruction	• HF symptoms, potential hemolysis, echocardiography (outflow position, ramped speed study, Doppler),	Consider reexploring chest cavity

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	angiography • Low pump power; LV not unloading with increasing speed; decreased PI: low flow	

LV suck down or suction event	• Echocardiography (inflow position, LV size)
	• Arrhythmias
	• Suction events
	  ○ Displayed pump speed drops below fixed speed setting
	  ○ Decreased pump flow
		Ensure patient is hydrated, adjust pump speed, evaluate RV function

Percutaneous lead or motor failure	• HF symptoms, hypotensive • Pump runs rough/vibrates; not maintaining set pump speed; damaged controllers	Replace pump
Thrombus in pump	• HF symptoms, hypotensive, potential hemolysis, angiography • Low flow (echo Doppler); high power and estimated flow; decreased PI; LV does not unload with increasing speed	Replace pump
Bearing failure	• HF symptoms, hypotensive, potential hemolysis • Low flow (echo Doppler); high power and estimated flow	Replace pump

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Abbreviations: HF, heart failure; LV, left ventricle; PI, pulsatility index.

V.B.1. Pump thrombus

Clinically relevant pump thrombus was rare during the HeartMate II clinical trial, occurring as of August 2006 in 3 out of the first 300 BTT and DT implants, all 3 requiring pump replacement. The source of the thrombus may have been related to ingestion of tissue or emboli from upstream of the pump. Thrombus can also conceivably grow from smaller depositions within the pump.

Thrombus can affect all four parameters of the HeartMate II LVAS: speed, power, flow, and PI. If the thrombus is sufficiently large, it can obstruct the flow through the pump. If a large thrombus is in contact with the rotor or bearings, it can increase the drag on the rotor and increase the power requirement. Such increases in power have been relatively gradual, taking hours or days as opposed to abrupt changes. With the increased power, the PI is reduced because the pulsatile component of power becomes relatively small compared with the steady component of power required to overcome the drag. In addition, if the flow obstruction is substantial, the pressure difference across the pump will be dominated by the obstruction, so the relative influence of the pressure pulse and consequently the PI is diminished. In such situations the pump flow is also limited; the normal unloading of the LV with increasing pump speed, therefore, is not observed. Thus the combination of decreased PI and increased arterial pulse pressure from the increased preload can be an indication of a pump blockage.

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In an extreme case, although rare, the drag on the rotor can become high enough that the motor can no longer maintain the pump speed and the speed will fall below the fixed speed setting. It is important to note that in cases where thrombus increases pump power, the flow will be overestimated and displayed flow could appear in the normal range even though the pump flow is very low.

V.B.2. Pump stop

Because all pump stops are not associated with a hardware malfunction, it is important to understand why it occurs and how to identify it. A pump stop condition can be created if the pump stop command is entered on the system monitor. Loss of power to the pump (both power leads) will, of course, result in the pump stopping, as will disconnection of the percutaneous lead from the controller.

Unlike a positive-displacement LVAD that contains valves, if the HeartMate II pump stops, there will be regurgitant flow from the aorta to the LV. Under normal physiological pressures, this regurgitant flow will be approximately 1 to 2 L/min. Just as the pump in the stopped condition will limit the backflow, the pump provides substantial resistance to forward flow. As a result, if the pump is stopped and the LV outflow tract is compromised or absent, the hemodynamic support of the patient will be very limited.

If the pump stops, an audible alarm will sound. If the stop is a result of complete loss of power, there will be a continuous audible alarm and no indicator light will illuminate on the controller. If the controller is still powered, the pump stop will be associated with an audible alarm and a red heart alarm will illuminate on the controller. The pump stop condition will also be indicated on the system monitor. The pump speed and flow will not

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be displayed and the power will be zero. If a pump is stopped and all connections to the controller are intact, pressing the **Test Select** button or **Alarm Reset** switch will restart the pump.

When the system monitor is connected, both an operating pump and a stopped pump are obvious based on the pump speed and power displays. If the monitor is not connected, confirming the pump is running can be done by inference on the controller. If the pump is running, the green power symbol on the controller will be illuminated and there will be no visual or audible alarms. If the pump is not running, the red heart symbol will be illuminated and a continuous audible alarm will sound. If all power to the controller has been disconnected, no lights will be illuminated and a continuous audible alarm will sound. An alternative approach for confirming that the pump is running is to place a stethoscope over the pump location and listen.

V.B.3. Suction event

The system parameters can also be used to troubleshoot suction events. Suction events occur when the pump speed is high for the physiologic conditions. Such events are typically precipitated by the patient becoming hypovolemic, but can also be caused by anything that reduces the return of blood to the LV, such as RV failure. Poor cannula positioning can also increase the propensity for a suction event; ie, the inflow cannula becomes obstructed by the LV wall or the septum.

When the system detects a suction event, the pump speed is automatically reduced below the fixed speed setting to the low speed limit setting in the controller. Once suction events are no longer detected, the speed gradually increases (at a rate of 100 rpm per

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second) back to the original speed setting. This drop in speed is also associated with a reduction in pump flow and is reflected in the displayed flow estimate.

V.B.4. Obstruction

Flow path obstruction can occur if the inflow or outflow cannula is blocked or kinked. A kink in the grafts or a blockage of the inflow cannula results in a higher pressure difference across the pump and consequently lower pump flow. Because such flow restrictions do not influence the action of the pump rotor or hydraulic components, the flow estimator will reflect the reduction in flow. If the flow is reduced beyond the lower limit of the display range (~3 L/min), the flow display will be blanked.

With decrease in flow there is also a decrease in pump power. In addition, the added pressure difference across the pump will reduce the relative pressure pulse magnitude across the pump and consequently the PI will be diminished. A flow obstruction will limit the pump flow, so the normal unloading of the LV associated with increasing pump speed will be diminished or absent.

The location of a flow obstruction cannot be determined from the pump parameters, as the pump only responds to the differential pressure across the pump and changes upstream or downstream of the pump have identical effects.

VI. Diagnosing and Managing Postoperative Complications

Clinical common sense should be applied to the diagnosis and management of postoperative complications. Occasionally, catheterization or computed tomography

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(CT) may be helpful. It is possible to perform angiography of the VAD to look for both inflow and outflow obstruction. A pigtail catheter can be placed in the LV in the same manner as for a left ventriculogram. Panning over the inflow followed by the outflow cannulae permits visual assessment for graft kinking as well as for flow obstruction. Alternatively, CT scan has been use by some centers to non-invasively assess the outflow graft and inflow cannula.

- **Left-heart catheterization**: Some patients may have progression of their CAD and have either acute or subacute coronary syndromes while on the VAD. It is appropriate to treat these patients in the normal manner—ie, the same as non-VAD patients—and it is safe to perform coronary arteriograms. One caution: the outflow cannula is attached to the ascending aorta and catheters could potentially enter them.

- **Right-heart catheterization**: The flow shown on the HeartMate II power base unit is based on pump speed and power, and is an estimate of actual flow through the LVAD. This value does not necessarily reflect the correct cardiac output. For a more precise estimate of right- and left-heart function, a right-heart catheterization can be performed. This may be done on therapeutic levels of warfarin instead of bridging the anticoagulation with heparin.
- **Computed tomography:** CT can be used to assess the outflow and inflow graft for kinking, twisting, or thrombus. It does not allow visualization of the titanium portions of the pump or inlet cannula.

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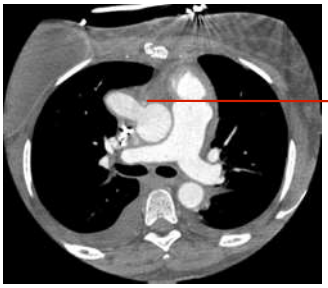
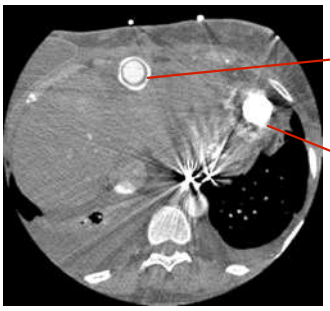
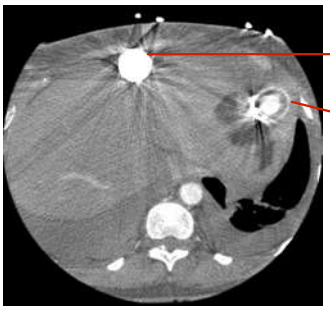


Anastomosis of outflow graft to ascending aorta



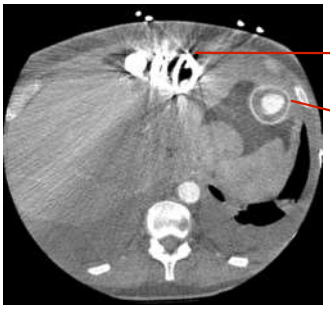
Outflow graft with surrounding bend relief. Contrast fills entire graft with no evidence of kinking.

Inlet portion of the inflow cannula at LV apex



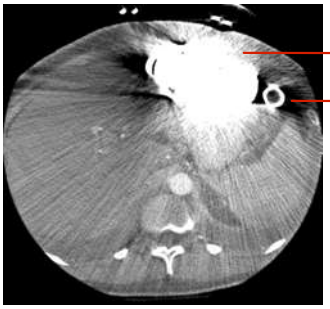
Outflow cannula

Flexible portion of the inflow graft with surrounding silastic sleeve. Contrast fills entire graft with no evidence of kinking.



Pump

Flexible portion of inflow graft with surrounding silastic sleeve



Pump

Rigid portion of inflow cannula

Figure 8: CT scan with contrast to assess inflow and outflow grafts

Table 10 lists potential complications and suggested management approaches related to HeartMate II LVAS implantation.

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Table 10. Potential complications specific to HeartMate II LVAD patients		
Potential Problem	**Assessment**	**Management**
Bleeding	• Hct, PT/PTT, INR, TEG, PFA-100	• Consider reducing or eliminating heparin, or lowering the INR therapeutic goal. • Consider the pump as the source of the bleed (leaky connection) *See anticoagulation section.*
Hematoma with falls	• Hct, PT/PTT, INR, TEG, PFA-100	• Consider adjusting anticoagulation
Nosebleeds	• Hct, PT/PTT, INR, TEG, PFA-100	• Consider adjusting anticoagulation
TIA/stroke	CT, Hct, PT/PTT, INR, TEG, PFA-100	• Do not aggressively anticoagulate a patient who experiences a TIA or potentially reversible ischemic stroke in order to avoid the more serious complications of hemorrhagic stroke
GI bleed	• Hct, PT/PTT, INR, TEG, PFA-100	• Consider reducing anticoagulation • Some centers believe that GI bleed can occur with AV malformation due to diminished pulsatility and therefore reduce

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		pump speed to achieve greater pulsatility
Cardiac		
Volume overload	• Physical exam (JVP, edema), echocardiography • RHC • Increased PI, flow, power	• Diuretics • Consider increasing pump speed under echocardiography
Dehydration	• Physical exam (JVP, edema), echocardiography • RHC • Suction events and arrhythmias • Decrease in PI	• Hydration (adjust diuretics) • Consider decreasing pump speed
Arrhythmias	• ECG, symptoms • Potential suction events • Decrease in flow , power, PI	• Antiarrhythmic medications • Evaluate pump speed under echocardiography for excessive unloading or for contact between the inflow cannula and LV wall • Carefully assess RV function and the necessity of RV function for pump flow. Some patients can tolerate ventricular tachycardia and fibrillation in the short term,

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		but would still consider cardioversion • Consider ICD
RV failure	• Exam, echocardiography (RV size, TR) • Suction events • Displayed pump speed drops below fixed speed setting • Decreased pump flow	• Consider inotropes • Change pump speed under echocardiography • RVAD
Tamponade	• Exam, symptoms, echocardiography • Suction events • Decreased pump flow	• Return to OR for reexploration
Hypotension	• Symptoms, BP monitoring • Increase in pump flow and power • Decrease in PI	• Adjust vasoactive medications • Consider volume expansion
Hypertension	• BP monitoring • Decrease in pump flow and power • Increase in PI	• Decrease afterload with medications
Recurrence of heart failure	• Symptoms • Decrease in pump flow and PI	• Evaluate pump speed settings • Evaluate RV function

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Aortic insufficiency	• Decreased perfusion • Dilated LV with high pump flow	• Repair/replace (see section **III.A**)
Infection		
Driveline	• Exam	• Antibiotics • Improve driveline care and immobilization

Pocket	• Exam	• Antibiotics
		• Pocket exploration[20] and drainage of abscess fluid[3]
		  ○ Cultures are taken
		  ○ PMMA beads (typically containing vancomycin and tobramycin) are placed in pouch
		  ○ Pocket revision through a new access may be required

Other		
Driveline site tearing	• Exam	• Patient training. Warn the patient to avoid tugging or twisting percutaneous lead or allowing controller to fall/drop • Driver immobilization with use of stabilization belt
Driveline	• Visual exam	• Patient training.

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insulation tearing		• Contact Thoratec
Hemolysis	• LDH • PFHb • Consider decreasing speed	• Evaluate potential sources: inflow/outflow occlusions, pump issues, etc (see section **V**) • Consider temporarily reducing pump speed (most cases are transient)

Abbreviations: AV, arteriovenous; BP, blood pressure; CT, computed tomography; ECG, electrocardiogram; GI, gastrointestinal; Hct, hematocrit; INR, international normalized ratio; JVP, jugular venous pressure; LDH, lactate dehydrogenase test; LV, left ventricle; OR, operating room; PI, pulsatility index; PFA-100, Platelet Function Analyzer (PFA)-100®; PFHb, plasma free hemoglobin; PMMA, polymethylmethacrylate; PT, prothrombin time; PTT, partial thromboplastin time; RHC, right-heart catheterization; RV, right ventricle; RVAD, right ventricular assist device; TEG, thromboelastograms; TIA, transient ischemic attack; TR, tricuspid regurgitation.

VI.A. Arrhythmias

Patient populations with indications for the HeartMate II LVAD are at high risk for potentially lethal arrhythmias. Approximately 75% of patients implanted with the HeartMate II already have an implantable cardioverter defibrillator (ICD) in place. This is consistent with guidelines for advanced heart failure patient populations developed by the American College of Cardiology and American Heart Association.[34]

Ventricular arrhythmias can be exacerbated by the HeartMate II LVAD, either by mechanical irritation at the LV apex, the apical tube touching the septum or free wall, or by ventricular suction or collapse caused by the pump speed set too high, resulting in the LVAD

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attempting to pump more flow than the RV can provide to the LVAD. In setting the pump speed, the patient's anticipated volume status fluctuations should be considered so as to avoid a pump speed setting that is too high or too low.

Ventricular arrhythmias are tolerated in some patients, but suction-induced arrhythmias appear to be more apparent with rotary pumps than with pulsatile LVADs or biventricular assist devices, which are quite tolerant of arrhythmias. A study at one center suggested an increased incidence of ventricular tachycardia in HeartMate II patients compared with HeartMate XVE patients,[35] whereas a multicenter analysis[36] suggested that there was no significant difference. Strong consideration for placing an ICD should be given for patients who meet standard requirements for ICD prior to discharge. If an ICD is to be implanted, its compatibility with the LVAD should be assessed. External cardioversion, defibrillation or ICD firing should not affect the pump or components; therefore disconnection from power or the system controller is not required during these procedures.

VII. Conclusion and Summary

VII.A. Unique features of the HeartMate II LVAS

The HeartMate II LVAS incorporates design features aimed at meeting the need for a smaller, more reliable device suitable for long-term outpatient circulatory support. The major feature of the system, which defines it as a new-generation device, is the axial flow pump, which significantly reduces LVAD size and weight compared with the current generation of

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implantable pulsatile pumps. Surgeons with experience implanting pulsatile-pump LVADs such as the HeartMate XVE should familiarize themselves with the features of the axial flow system, which are described in this guideline and summarized in Table 11.

Table 11. Summary of considerations for successful application of the HeartMate II

Preoperative considerations	
HeartMate II feature	**Ramification**
Smaller size	• Can be implanted in smaller patients (BSA ≥1.2 m^2) • Reduced magnitude of surgical intervention • Improved anatomical fit
Use of systemic anticoagulation	• Caution in patients with history of GI bleeding • Patients with history of peptic or duodenal ulcer but no GI issues in previous 30 days may be considered
Axial flow pump	• Flow rate up to 10 L/min can accommodate patients with high BSA • Pulsatile-pump device may be more appropriate in some patients ○ Post-cardiotomy patients who have accompanying shock
Potential for greater durability	• Simplicity of design (one internal moving part, no valves) may lend itself to longer use
Intraoperative considerations	
HeartMate II Feature	**Ramification**
Smaller size	• Designed for preperitoneal placement

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	• Smaller pocket dissection
	  ○ Less time
	  ○ Reduced intervention
	  ○ Possible lower infection risk

Smaller-diameter driveline	• Smaller-diameter tunnel
	  ○ Less time
	  ○ Reduced intervention
	  ○ Possible lower infection risk
	• Driveline positioned in gentle loop
	  ○ Distance between the pump pocket and exit site maximized

Axial flow pump	• Moderate to severe aortic insufficiency and mitral stenosis must be corrected prior to pump placement
	• De-airing conducted at low VAD speeds (usually 6000 rpm)
	  ○ Before higher speeds are initiated, the patient should be weaned off CPB and the LV should be completely full (>10 mmHg) to avoid sucking in air
	• Inflow cannula should point posteriorly toward the mitral valve
	  ○ Obstruction may result if cannula is pointing toward septum or free wall
	• Large negative pressures generated at pump inlet
	  ○ May result in septal shift or ventricular collapse
	  ○ Speed optimization and device monitoring more

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	challenging than techniques used with pulsatile-pump devices • Care should be taken not to overstress the RV and to preserve RV function ○ If RV failure occurs and the LVAD is not filling during implantation, temporary right-heart bypass may be needed
Postoperative considerations	
HeartMate II Feature	**Ramification**
Smaller size	• Possible lower infection risk • Possible increased patient comfort

Smaller-diameter driveline	• Smaller exit site
	  ○ Possible easier, more aseptic maintenance
	  ○ Possible lower infection risk

Larger and heavier battery pack/controller	• Increased need for patient education on importance of driveline immobilization

Axial pump	• Need to establish and follow anticoagulation protocol
	• Flow, power, and PI with echocardiography are primary indicators of device function
	  ○ Speed adjustments made with ramped speed test under echocardiography
	  ○ No single parameter is a substitute for monitoring clinical status of patients
	• BP monitoring by usual techniques may be problematic
	  ○ Arterial line is used in early postoperative period with

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	the goal of maintaining a mean pressure of 70 to 80 mmHg and a maximum pressure below 90 mmHg ○ After patient transitions to the floor, staff needs to be instructed on methods to obtain accurate BP readings • Surgeons should become familiar with use of pump parameters to identify and manage postoperative complications such as pump thrombus, pump stop, suction events, and flow obstructions
Potential for greater durability	• Simplicity of design (one internal moving part, no valves) may lead to greater dependability and longer system life ○ Possible improved QOL ○ Possible reduction in morbidity and mortality

Abbreviations: BP, blood pressure; BSA, body surface area; BTT, bridge to therapy; CPB, cardiopulmonary bypass; DT, destination therapy; LV, left ventricle; PI, pulsatility index; QOL, quality of life; RV, right ventricle; VAD, ventricular assist device.

VII.B. Looking ahead: emerging data

The HeartMate II LVAS is under study in two important clinical trials, one on BTT and the other on DT (Table 12). Future reports from these studies will provide valuable information on efficacy, morbidity, and mortality outcomes related to the HeartMate II system.

Table 12. HeartMate II LVAS clinical studies

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Bridge-to-transplant study	
Current status	Completed
Number of centers	40
Number of patients	133
Study design	Nonrandomized clinical trial
Patient selection criteria	– Listed for transplant – NYHA Class IV – On Inotropes – Either 1A or 1B meeting hemodynamic criteria
Primary endpoint	Survival to transplant or 180 days of LVAD support
Secondary endpoints	– Adverse events – Clinical reliability – Quality of life – Functional status – Re-operations – 30 day and 1 year post-transplant follow up
Destination therapy study	
Current status	Patient enrollment ongoing
Number of centers	40
Number of patients	200
Study design	Randomized clinical trial HM II vs HM XVE
Patient selection criteria	– Not a transplant candidate – NYHA Class IIIB or IV – Optimum medical management for 45 out of 60 days

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	or intolerant to beta blockers or ACE inhibitors ***or*** dependent on IABP for 7 days ***or*** inotropes for 14 days – EF < 25% – VO2 max < 14 ml/kg/min
Primary endpoint	Composite endpoint including survival to 2 years
Secondary endpoints	– Adverse events – Clinical reliability – Quality of life – Functional status – Reoperations

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