

HEARTMATE® XVE LVAS

EXtended Lead Vented Electric
Left Ventricular Assist System

INSTRUCTIONS FOR USE



T H O R A T E C[®]
C O R P O R A T I O N

6035 Stoneridge Drive
Pleasanton, CA 94588
USA
Tel: 925/847-8600
Fax: 925/847-8574
www.thoratec.com

Emergency HeartLine™ USA: (800) 456-1477

CAUTION !

Federal (USA) law restricts this device to sale by or on the order of a physician.



Document # 29128
Rev F
01/2006

Table of Contents

SECTION 1

1.0	Device Description	1
2.0	Indications for Use	2
3.0	Contraindication	2
4.0	Warnings & Precautions	3
5.0	Clinical Studies	9
5.1	Bridge-to-Transplant Study	9
5.2	Study for Non-Transplant Candidates	19
	Reliability Evaluation	33
	Factors that May Affect Pump Life	34
	Types and Timing of Device Events	35
6.0	LVAS Components	36
6.1	Equipment & Supplies Required for Implant	37

SECTION 2

7.0	Implant Procedure	39
7.1	Setting Up & Initializing the System	39
7.2	Initializing the XVE System Controller	40
7.3	Pre-Clotting	43
7.3A	Pre-Clotting the Outflow Graft	43
7.3B	Pre-Clotting the New Inflow Valve Conduit	44
7.3C	Pre-Clotting the Outflow Valve Conduit	46
7.4	Priming the LVAD	48
7.5	Implantation	50
7.5A	Surgical Technique for Preperitoneal Placement	51
7.5B	Surgical Technique for Intra-Abdominal Placement	52
7.6	Selecting & Creating a Percutaneous Tube Exit Site	52
7.7	Preparing the Ventricular Apex Conduit Site	53
7.8	Orientation of the Inflow Valve Conduit	54
7.9	Attaching the Outflow Graft	57
7.10	De-Airing the XVE LVAD	59
7.11	Startup & Weaning from Cardiopulmonary Bypass	64
7.12	Anchoring the Pump	67
7.13	Transferring the Patient Out of the Operating Room	68

SECTION 3

8.0	Patient Management	71
8.1	Treating the Percutaneous Tube Exit Site	72
8.2	Anticoagulation Therapy	73
8.3	Diagnosing a Blood Leak	74
8.4	Right Heart Failure	74
8.5	Avoiding Static Discharge	75
8.6	Infection Control	75
8.7	Anticipating End of Pump Life	75
8.8	Managing Physiologic Conditions that May Affect Pump Life	76
8.9	Discharge Planning	78
9.0	Patient Discharge	77

Table of Contents continued

SECTION 4

10.0	Exchanging a New Inflow Valve Conduit	78
10.1	Valve Preparation & Pre-Clotting	79
10.2	Exchanging Inflow Valve c/n 2033 for 2033	81
10.3	Exchanging Inflow Valve c/n 1033 for 2033	84
11.0	Explanting the XVE LVAD	87
12.0	Device Tracking & Reporting Requirements	88
13.0	Service	89
14.0	Testing & Classification	90
15.0	Authorized European (EU) Representative	96

1.0 Device Description

The HeartMate EXtended Lead Vented Electric Left Ventricular Assist System (XVE LVAS) consists of an implanted blood pump, external XVE System Controller, and external power supply components. The blood pump, or Left Ventricular Assist Device (LVAD), is a pusher-plate type device that is capable of producing a stroke volume of 83ml, generating approximately 10 liters of blood flow per minute, and a beat rate up to 120 beats per minute (bpm).

The pump consists of a rigid titanium housing divided in half by a flexible diaphragm. One half functions as the blood chamber, while the opposite half serves as a chamber for the electric motor. This motor chamber is connected to the external control and power components via a percutaneous tube. Displacement of the diaphragm by rotation of the electric motor results in pumping of the blood.

The XVE System Controller is a microprocessor-based unit that initiates motor actuation, monitors and reports on system function, and serves as the primary interface with the system. The XVE System Controller provides 2 modes of operation, either Fixed Rate or Auto Rate. The Auto Rate is programmed with OptiFill™ Software, which varies in response to physiologic demand.

LVAD function is adjusted by a switch panel located on the top of the XVE System Controller, or via a separate System Monitor. The XVE System Controller's audio and visual alarms alert users of potentially dangerous conditions. Alarms are sounded primarily if there are either low flow or low stroke conditions, or if battery charge levels are low (see *HeartMate XVE LVAS Operating Manual* for full discussion of alarms).

The XVE LVAS is routinely powered through the XVE System Controller by either a pair of wearable, rechargeable batteries, or via connection to a dedicated power supply device called a Power Base Unit (PBU). An additional portable, back-up power source - the Emergency Power Pack (EPP) - can be used in periods of extended power outage (eg, during storms that down power lines). In the event that electric motor actuation is disrupted, the XVE LVAD also may be actuated by delivery of a pneumatic pulse through the percutaneous tube. This pulse can be provided by either the hand pump or a standard HeartMate Implantable Pneumatic Drive Console.

2.0 Indications for Use

The HeartMate XVE LVAS is intended for use as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from non-reversible left ventricular failure. The HeartMate XVE LVAS is also indicated for use in patients with NYHA class IV end-stage left ventricular failure who have received optimal medical therapy for at least 60 of the last 90 days, who have life expectancy of less than 2 years, and who are not candidates for cardiac transplantation. The HeartMate XVE LVAS is intended for use both inside and outside the hospital.

3.0 Contraindication

The HeartMate XVE LVAS is contraindicated for patients whose body surface area is less than 1.5m².

4.0 Warnings and Precautions

4.1 Warnings

General Warnings

- A thorough understanding of the technical principles, clinical applications, and risks associated with left ventricular support is necessary before using this product. Read this entire *Instructions for Use* and the *HeartMate XVE LVAS Operating Manual* before attempting implantation. Completion of the Thoratec user-training program, including animal implantation and device operation, also is required prior to use of the HeartMate Extended Lead Vented Electric Left Ventricular Assist System (XVE LVAS).
- While *most* VE and XVE components are interchangeable (eg, PBU, System Monitor, Display Module), **the XVE System Controller and XVE Vent Adapter are NOT interchangeable with VE system components.** Therefore, the XVE LVAD should be used only with the XVE System Controller, System Controller Battery Module, and XVE Vent Adapter.
- Do NOT use the Power Base Unit (PBU) in the presence of flammable anesthetic agents, or an explosion could occur.
- Connect the PBU (and any peripheral devices) only to properly tested, grounded, and dedicated alternating current (AC) outlets. Do NOT use an adapter for ungrounded wall outlets or multiple portable socket outlets (power strips), or the risk of electrocution increases.
- Do NOT connect the PBU to an outlet controlled by a wall switch, or the PBU may be left inoperable.
- There may be risks associated with the use of an LVAD in pregnant women or in any woman likely to become pregnant during her period of LVAS support. A growing fetus may dislodge the pump, which may result in device failure or fatal hemorrhage. The effect of an LVAD on a growing fetus is unknown.
- Do NOT subject patients implanted with the HeartMate XVE LVAS to Magnetic Resonance Imaging (MRI), as the LVAD contains ferro-magnetic components, and MRI exposure could cause device failure or patient injury.
- Post implant, patients should avoid strong static discharges (eg, television or computer screens), as contact with strong static discharges can damage the electrical parts of the system and cause the LVAD to stop.
- Keep the PBU away from water. If the PBU has contact with water, shower spray, or wet surfaces, the XVE LVAD may stop, or the patient may receive a serious electric shock.

continued


4.0 Warnings and Precautions continued

4.1 Warnings

General Warnings cont.

- Never store the hand pump with the bulb in the collapsed position, or the bulb may not work properly when the hand pump is needed.
- Therapeutic ionizing radiation may damage the device, which may not be immediately detectable.
- Implanted components should NOT be exposed to therapeutic levels of ultrasound energy, as the device may inadvertently concentrate the ultrasound field and cause harm.
- The patient should be carefully monitored during any medical treatment in which high frequency current (eg, diathermy) is passed through the patient's body.
- If the patient is given any medical treatment in which an electrical current is passed through their body from an external source, care should be taken to monitor the functioning of the LVAD during the initial stages of treatment.

Warnings Specific to Implantation


- During the implant process, a complete back-up XVE LVAS system (XVE LVAD Implant Kit and external components) must be available on-site and in close proximity to the patient for use in an emergency.
- Prior to advancing the Inflow Valve Conduit into the Left Ventricle (LV) through the Apical Sewing Ring, remove glove tip from the Inflow Valve Conduit and remove the Centering Device from the Apical Sewing Ring.
- Prior to advancing the Inflow Valve Conduit into the LV through the Apical Sewing Ring, inspect the ventricle and remove any previously formed clots, or a catastrophic embolism may occur.
- Insure that the Thread Protectors have been removed from the Outflow Valve Conduits in order to minimize the risk of air embolus.
- Initial weaning of cardiopulmonary bypass should insure a minimum of 2 liters per minute of blood flow to the XVE LVAD in order to prevent air embolism.
 **Note:** Prolonged deaeration may be due to inadequate blood supply to the XVE LVAD.
- Failure to adequately secure the Outflow Valve and Outflow Graft Screw Rings may allow these connection points to loosen, and result in potentially fatal hemorrhage.

4.0 Warnings and Precautions continued

4.1 Warnings

Warnings Specific to Implantation cont.

- Do NOT autoclave valve conduits. Doing so will damage the xenograft porcine valves inside.
- A minimum of 2 fully charged batteries are required at the time of implantation to power the LVAS when transporting the patient out of the operating room.
- Never allow fluids to enter the percutaneous tube through the Vent Port or Vent Filter, or the pump may stop.
- Remove connection between percutaneous tube and XVE System Controller before using a defibrillator or the XVE LVAS could be permanently damaged.

 **Note:** Before connecting or disconnecting the XVE System Controller from the XVE LVAD, remove all power sources.

Warnings Specific to System Management

- In the event that the XVE LVAS stops operating, all attempts must be made to restore pump function immediately using electric or pneumatic activation. In the event that the XVE LVAS stops operating and blood is stagnant in the pump for more than a few minutes (depending on the coagulation status of the patient) there is a risk of stroke or thromboembolism if, or when, the device is restarted.
- Loss of power will cause the XVE LVAS to stop and blood pumping to cease. Power must be restored immediately. If power cannot be restored, use the hand pump to perform pneumatic pump activation.
- When the XVE System Controller is disconnected from the percutaneous tube, pump function will stop. The XVE System Controller and power must be reconnected as quickly as possible to resume pump function.
- There is a risk of embolism at device explant or reoperation if manipulation of the device or cannulae is performed prior to initiation of cardiopulmonary bypass and stoppage of XVE LVAD pumping.
- Do NOT allow the percutaneous tube to become contaminated or its inner lumen to become wet, or the pump may stop.

4.0 Warnings and Precautions continued

4.1 Warnings

Warnings Specific to Patient Management

- There may be risks associated with performing external chest compression, in the event of cardiac arrest, due to the location of the Outflow Graft Conduit and the presence of ventricular apical anastomosis. Performing external chest compression may result in damage to the Outflow Graft Conduit or the dislodgement of the LVAD inflow tract.
- Cardiac massage under direct vision, performed by a skilled surgeon, may be effective in patients who have had recent device implant (prior to mediastinal healing).

4.2 Precautions

General Precautions

- These *Instructions for Use* address XVE LVAD handling, preparation, and other perioperative issues. The *HeartMate XVE LVAS Operating Manual* must be used in connection with these directions for other important guidelines. These manuals are not intended to replace comprehensive laboratory or educational programs, nor to supersede appropriate medical judgment.
- Sterile components of the HeartMate XVE LVAS are intended for single use only. Do NOT reuse sterile device components.
- Store the HeartMate LVAS Inflow and Outflow Valves at 5°C -- 25°C.
- Patients with mitral or aortic mechanical valves may be at added risk of thrombus accumulation on valves when supported with left ventricular assist devices.
- Use only the Thoratec supplied Power Base Unit (PBU) to charge Batteries. Other battery chargers may damage the batteries.
- The power entry module on the rear panel of the PBU has been equipped with the proper fuse and set to the appropriate electric mains voltage for your location. Fuse replacement should be performed only by qualified, Thoratec-trained service personnel.
- XVE System Controller connectors should be kept clean and dry. Do NOT expose connectors to water when making or breaking connections.
- Never use tools to tighten connections. Hand tighten only. Using tools may damage the connectors and cause the pump to stop.

4.0 Warnings and Precautions continued

4.2 Precautions

Precautions Specific to Implantation

- Care must be taken to prevent blood from entering and collecting in the lumen of valve conduits. Blood on the inner lumen may increase the risk of thromboembolism due to coagulum breaking free in the circulatory system. The inner lumen must, therefore, be rinsed thoroughly prior to attachment to the XVE LVAD.
- Do NOT over tighten Thread Protectors.
- Do NOT allow Coring Knife to involve ventricular septum while performing the core.
- If you encounter problems using the coring knife while preparing the ventricular apex conduit site, use conventional surgical tools and techniques in place of the coring knife.
- Do NOT remove the Centering Device from Apical Sewing Ring until ready to insert the Inflow Valve Conduit into the Left Ventricular (LV) apex.
- Do NOT kink the Outflow Graft or position it where it could abrade against a pump component or body structure.
- Do NOT clamp the Outflow Graft Bend Relief or a kink may occur. This kink could lead to abrasion and blood loss through the graft
- Do NOT trim or cut the Outflow Graft Bend Relief or a sharp edge may result. This sharp edge could damage the underlying graft material and cause blood loss.
- Do NOT clamp any portion of the percutaneous tube during implant. Clamping may damage the tubing or the electrical leads located inside.
- Once the XVE LVAD is activated, rapidly reduce cardiopulmonary bypass flow to provide ample blood flow to the XVE LVAD. A stroke volume of 70 to 80ml should be achieved and maintained.
- A persistent stroke volume of <30ml may require anticoagulation to prevent possible thrombus accumulation.

Precautions Specific to Patient or System Management

- Diligent care throughout the course of patient LVAS support must be exercised to prevent infection and sepsis. Systemic infections and localized infection of the percutaneous tube exit site may occur with use of this device. Infection may contribute to patient morbidity and death.
- Right heart failure can occur following implantation of the device. Right ventricular dysfunction, especially when combined with elevated pulmonary vascular resistance, may limit XVE LVAS effectiveness due to reduced filling of the XVE LVAD.

4.0 Warnings and Precautions continued

4.2 Precautions

Precautions Specific to Patient or System Management cont.

- Persistent hypercalcemia in the presence of fungal infection may increase the risk of granular calcium deposition abrading the diaphragm.
- An electro cardiogram (ECG) may be indicated to rule out fibrillation if a patient complains of feeling “different.”
- Reports of a change in sounds and/or motion of the system by the patient should initiate evaluation for cause, including the possibility of device malfunction.
- Physiological factors that affect filling of the pump, such as hypovolemia or postural hypotension, will result in reduced pump flows as long as the condition persists. Pump flows will not be restored to normal unless such conditions are resolved.
- The percutaneous tube at explant is not sterile; and, thus, care must be taken to avoid contamination of the sterile field. The tips of sterile, non-powdered gloves may be placed on the ends of the lead once the lead is cut to minimize the risk of the tube contacting and contaminating the sterile field.
- When connecting cables, do not force together connectors without proper alignment. Forcing together misaligned connectors may damage connections.
- Before connecting or disconnecting the XVE System Controller from the XVE LVAD, remove all power sources.
- A back-up XVE System Controller, spare Batteries, and the hand pump must be with the patient at all times for use in an emergency.
- Use of expired or defective Batteries may result in reduced operating time or in abrupt loss of XVE LVAD function.
- To prevent deterioration or damage to Batteries:
 - Do NOT drop or subject Batteries to strong physical shock. Dropped Batteries should be replaced.
 - Do NOT use Batteries in temperatures that are below 15° F (-10° C) or above 105° F (+40° C), or the Batteries may fail suddenly.
 - Do NOT leave or store Batteries in extreme temperatures (eg, in cars or car trunks), or battery life will be shortened.
 - Do NOT directly connect negative and positive battery terminals.
Recharge used Batteries within 12 hours, or battery life will be shortened.

5.0 Clinical Studies

Two clinical studies have been performed with the HeartMate VE LVAS. One study included patients who were transplant candidates; the other included non-transplant candidates. The results of these studies are presented below.

5.1 *Bridge-to-Transplant Study*

Study Overview

The clinical study for bridge-to-transplantation was designed to answer 2 questions:

- 1) Is the HeartMate VE LVAS a suitable alternative for the HeartMate Implantable Pneumatic (IP) LVAS as a bridge to cardiac transplantation?
- 2) Is the HeartMate VE LVAS safe for use outside of the hospital?

The primary study endpoints were device flow (pump index) and adverse events. Survival data also were collected.

Enrollment criteria for cardiac transplant candidates to enter the trial:

- Approved cardiac transplant candidate
- On inotropes
- On an intra-aortic balloon pump (if possible)
- With left arterial pressure or pulmonary capillary wedge pressure ≥ 20 mmHg with either:
 - Systolic blood pressure ≤ 80 mmHg, or
 - Cardiac index of ≤ 2.0 l/min/m²
- With reversible end organ dysfunction

5.0 Clinical Studies continued

5.1 *Bridge-to-Transplant Study*

Study Overview cont.

The study group consisted of 2 phases. **Phase I** included all patients implanted with the device. **Phase II** included those patients eligible to leave the hospital during their wait for a transplant. To enroll into Phase II, patients were at least 14 days post implant and had recovered to New York Heart Association (NYHA) functional class I or II. Patients also were required, upon leaving the hospital, to have a trained companion in the immediate vicinity at all times.

Twenty-four (24) participating US sites contributed 280 patients. Patients (N=69) who were subsequently found to not meet 1 or more enrollment criteria were included in the analyses of adverse events. The 211 patients who met all criteria (Phase I Core patients) were included in the survival analysis and a subset (N=203) provided the pump flow data. **Figure A** shows the outcomes of all patients entered into the trial. In the 211 Core patients, LVAS support duration ranged from 0 to 685 days, with a mean of 96 days.

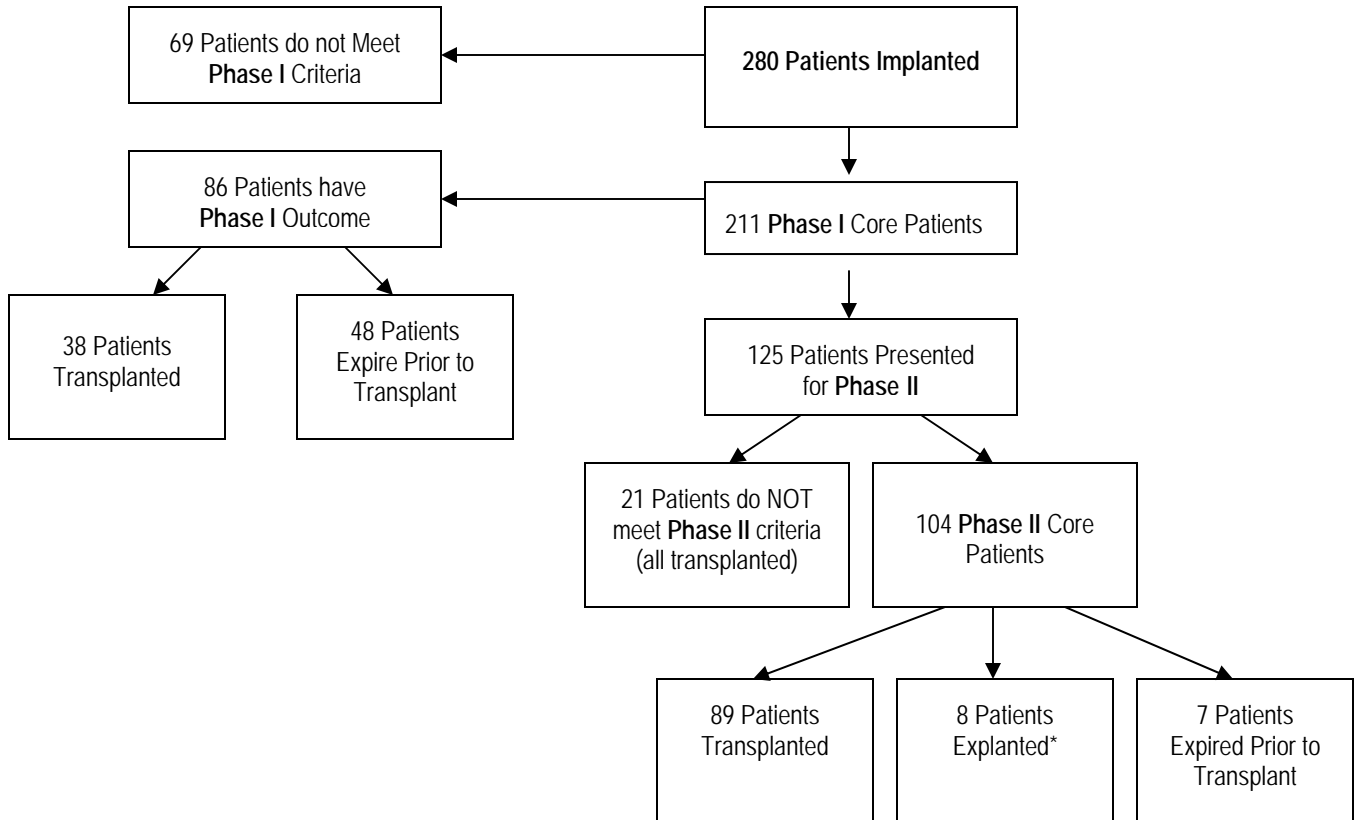
Pump flow was measured using the average pump index. The average pump index was $\geq 2\text{L/min/m}^2$ throughout the trial for 198 of 203 (98%) of the Core patients in Phase I and all 125 of the Core patients in Phase II. For Core patients, the average pump index was 2.77 L/min/m² in Phase I, and was 3.04 L/min/m² for core patients in Phase II. The average pump index in the IP study was 2.86 L/min/m². Data comparing the IP and VE results are presented graphically in **Figure B**.

5.0 Clinical Studies continued

5.1 Bridge-to-Transplant Study

Study Overview cont.

Figure A VE LVAS BRIDGE TO TRANSPLANT CLINICAL TRIAL



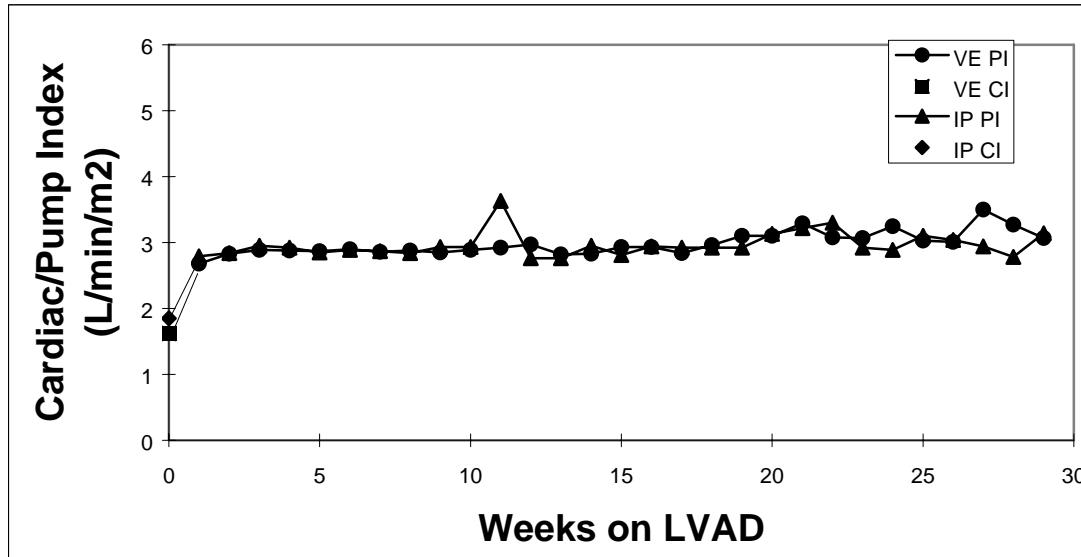
*LVAD removed and NOT replaced due to physician's judgment of myocardial recovery.

5.0 Clinical Studies continued

5.1 Bridge-to-Transplant Study

Study Overview cont.

Figure B Average Pump Index and baseline Cardiac Index values versus time for LVAD patients. Pump index throughout support was significantly greater than Cardiac Index. All values are L/min/m².



WEEKS ON IP LVAD											
	Cardiac Index	Pump Index									
	0 ¹	1	2	3	4	8	12	16	20	24	28
N	131	110	101	97	91	70	41	24	19	11	6
Median	1.71	2.73	2.77	2.97	2.93	2.79	2.77	2.93	3.09	2.68	2.76
Mean	1.85	2.79	2.84	2.95	2.92	2.84	2.76	2.94	3.13	2.89	2.78
STD	0.56	0.49	0.61	0.59	0.56	0.54	0.58	0.53	0.65	0.89	0.51
SEM	0.05	0.05	0.06	0.06	0.06	0.06	0.09	0.12	0.15	0.27	0.21
WEEKS ON VE LVAD											
	Cardiac Index	Pump Index									
	0 ¹	1	2	3	4	8	12	16	20	24	28
N	149	183	174	117	107	55	34	27	18	9	8
Median	1.70	2.60	2.81	2.83	2.87	2.83	3.00	2.78	2.99	3.40	3.31
Mean	1.62	2.68	2.83	2.89	2.88	2.88	2.97	2.93	3.10	3.25	3.27
STD	0.32	0.53	0.51	0.58	0.52	0.58	0.66	0.57	0.68	0.62	0.65
SEM	0.03	0.04	0.04	0.05	0.05	0.08	0.11	0.11	0.16	0.21	0.23

¹ Values measured within 24 hours prior to implantation of LVAD.

5.0 Clinical Studies continued

5.1 *Bridge-to-Transplant Study*

Study Overview cont.

Hemodynamic, hematologic, biochemical data, and adverse event data were collected throughout the study. **Table 1** (following page) provides the numbers of adverse events and rates for the VE study and the IP study. **Table 2** provides the adverse event reports for device-related adverse events.

Tables 3 and **4** give similar reports by study phase (i.e., Phase I and II). There were 3 LVAS failures during the study. The 148 Core patients transplanted included 38 Phase I, 89 Phase II and 21 patients who entered Phase II who did not meet the Phase II criteria. The transplant rate for Core patients is 141/211 (70%). The VE results of survival to transplant are compared to the IP results in **Table 5**. One year post implant, the survival status of VE patients was assessed. **Table 6** compares the 1-year post-transplant results for Core IP and Core VE patients who survived to transplant.

5.0 Clinical Studies continued

5.1 Bridge-to-Transplant Study

Study Overview cont.


Table 1 COMPARISON OF ADVERSE EVENTS IN IP & VE STUDIES

(Adverse Events Independent of Cause)

Adverse Event	IP LVAS N = 223 Pt. Years = 42.4			VE LVAS N = 280 Pt. Years = 86.2		
	Patients	Percent	Events	Patients	Percent	Event
Bleeding	103	46%	145	133	48%	195
Hemolysis	10	4%	10	0	0%	0
Infection Events	105	47%	360	125	45%	290
Thromboembolic Events	8	4%	8	34	12%	44
Right Heart Failure	39	17%	39	31	11%	32
Reoperations	127	57%	285	165	59%	337
Renal Dysfunction*	135	61%	135	158	56%	158
Hepatic Dysfunction*	217	97%	217	263	94%	264
Neural Dysfunction	46	21%	46	75	27%	93
Pulmonary Dysfunction	18	8%	18	5	2%	5
Device Failures	1	<1%	1	3	1%	3
Deaths	75	34%	75	82	29%	82

Table 1 presents the number of patients, percent of patients, and the total number of events for each adverse event, comparing events that occurred in the IP Study versus events that occurred in the VE Study.

* Includes patients who entered trial with hepatic and renal dysfunction.

 **Note:** The need for reoperation may result from bleeding, infection, gastrointestinal complications (such as adhesions, perforations, tissue erosion and herniation), or to treat arrhythmias with implantation of a pacemaker.

Neurological dysfunction may result from air emboli, stroke, cerebral vascular accident, temporary ischemic attack, or hypoperfusion. In addition, there is the risk of myocardial or other organ infarction, loss of limb(s), or other vascular obstruction due to embolism. What's more, it is possible that the LVAS will produce *no* significant hemodynamic improvement, and the patient will have been exposed to the risks of cardiothoracic procedure without the benefit of hemodynamic improvement.

5.0 Clinical Studies continued

5.1 Bridge-to-Transplant Study

Study Overview cont.

Table 2 COMPARISON OF ADVERSE EVENTS IN IP AND VE STUDIES
 (Device-Related Adverse Events)

Adverse Event	IP LVAS N = 223 Pt. Years = 42.4			VE LVAS N = 280 Pt. Years = 86.2		
	Patients	Percent	Events	Patients	Percent	Event
Bleeding	22	10%	26	31	11%	36
Hemolysis	6	3%	6	0	0%	0
Infection Events	91	41%	286	113	40%	159*
Thromboembolic Events	6	3%	6	17	6%	21
Right Heart Failure	0	0%	0	0	0%	0
Reoperations	28	13%	52	47	17%	71
Renal Dysfunction	0	0%	0	0	0%	0
Hepatic Dysfunction	0	0%	0	0	0%	0
Neural Dysfunction	11	5%	11	14	5%	17
Pulmonary Dysfunction	0	0%	0	0	0%	50
Device Failures	1	<1%	1	3	1%	3
Deaths	1	<1%	1	3	1%	3

Table 2 presents the number of patients, percent of patients, and total number of events for each device-related adverse event, comparing events that occurred in the IP study versus events that occurred in the VE study.

*Number of positive cultures. One infection event may include a number of positive cultures collected to monitor the effectiveness of therapy.

5.0 Clinical Studies continued

5.1 Bridge-to-Transplant Study

Study Overview cont.

Table 3 COMPARISON OF ADVERSE EVENTS IN PHASE I AND PHASE II
 (Adverse Events Independent of Cause)

Adverse Event	VE LVAS PHASE I N = 280; Pt. Years = 33.2			VE LVAS PHASE II N = 160; Pt. Years = 52.9		
	Patients	Percent	Events	Patients	Percent	Event
Bleeding	121	43%	166	20	13%	29
Hemolysis	0	0%	0	0	0%	0
Infection Events	117	42%	230	46	29%	60*
Thromboembolic Events	25	9%	30	11	7%	14
Right Heart Failure	30	11%	31	1	1%	1
Reoperations	146	52%	226	37	23%	71
Renal Dysfunction	149	53%	149	9	6%	9
Hepatic Dysfunction	254	91%	254	10	6%	10
Neural Dysfunction	69	25%	77	12	8%	16
Pulmonary Dysfunction	4	1%	4	1	1%	1
Device Failures	2	1%	2	1	1%	1
Deaths	70	25%	70	12	8%	12

Table 3 presents the number of patients, percent of patients, and total number of events for each listed adverse event, comparing events that occurred exclusively in Phase I versus events occurring exclusively in Phase II.

The substantial difference seen between rates of occurrence of some events in Phase I versus Phase II is due to the increased likelihood of an event occurring in the immediate post-operative period.

5.0 Clinical Studies continued

5.1 Bridge-to-Transplant Study

Study Overview cont.

Table 4 COMPARISON OF ADVERSE EVENTS IN PHASE I & PHASE II
 (Device-Related Events)

Adverse Event	VE LVAS PHASE I			VE LVAS PHASE II		
	(N=280; Patient Years = 33.2)			(N=160; Patient Years = 52.9)		
	Patients	Percent	Events	Patients	Percent	Events
Bleeding	20	7%	21	12	8%	15
Hemolysis	0	0%	0	0	0%	0
Infection Events	75	27%	105	45	28%	54
Thromboembolic Events	11	4%	11	7	4%	10
Right Heart Failure	0	0%	0	0	0	0
Reoperations	33	12%	43	17	11%	28
Renal Dysfunction	0	0%	0	0	0%	0
Hepatic Dysfunction	0	0%	0	0	0%	0
Neural Dysfunction	11	4%	13	4	3%	4
Pulmonary Dysfunction	0	0%	0	0	0%	0
Device Failures	2	1%	2	1	1%	1
Deaths	2	1%	2	1	1%	1

Table 4 presents the number, percent of patients, and total number of events for each listed adverse event, comparing events that occurred exclusively in Phase I versus events occurring exclusively in Phase II.

5.0 Clinical Studies continued

5.1 Bridge-to-Transplant Study

Study Overview cont.

Table 5 SURVIVAL TO TRANSPLANT COMPARISON IN IP AND VE STUDIES

(Includes Percent Survival Difference with 95% Confidence Intervals)

	VE LVAS Core Patients N = 211	IP LVAS Core Patients N = 134	Difference (95% CI)
Percent Survival to Transplant	70% (148/211)	71% (95/134)	-0.8% (-10.6%, 9.1%)

Table 6 PERCENT SURVIVAL POST TRANSPLANT (COMPARISON 1 YEAR
 POST TRANSPLANT IN IP & VE STUDIES)

(Includes Percent Survival Difference with 95% Confidence Intervals)

	VE LVAS Core Patients N = 143	IP LVAS Core Patients N = 95	Difference (95% CI)
Percent Survival to Transplant	80% (115/143)	81% (77/95)	-0.6% (-10.9%, 9.6%)

For VE: the number of patients who met Phase I inclusion/exclusion criteria and were transplanted prior to April 11, 1999.

5.0 Clinical Studies continued

5.2 Study for Non-Transplant Candidates

Study Overview

The study that was performed in non-transplant candidates was called Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart failure (REMATCH). This study was conducted by a cooperative agreement between Thoratec Corporation, the National Institutes of Health (NIH), and Columbia University.

The primary objective of the study was to determine the effect of the VE LVAD on all-cause mortality in patients with end-stage chronic heart failure who were on Optimal Medical Management (OMM) and were not candidates for cardiac transplantation. The safety of the VE LVAS was documented by the incidence of adverse events and the incidence of device malfunction and failure.

In addition, a number of secondary objectives were evaluated during the REMATCH study, including a comparison of the functional status, quality of life, days alive and out-of hospital, and the incidence of cardiovascular mortality between the 2 groups.

Two configurations of the device were used during the study, the original VE LVAS and the VE-SNAP LVAS. The XVE LVAS incorporates incremental changes designed to enhance the durability and reliability of the device.

Study Design

The study was a multi-center, non-blinded, randomized study in which eligible patients were randomized to treatment with the HeartMate SNAP-VE LVAS or to OMM in a 1:1 ratio. The randomization was stratified by center and blocked to ensure approximately equal numbers of patients per arm at each center over time. The block sizes were selected at random to prevent centers from manipulating the treatment assignment. The goal was to enroll up to 140 patients in the study until the study endpoint of the 92nd death was reached. Three interim analyses were performed (every 23 deaths) and the results were reviewed by the Data Safety and Monitoring Board (DSMB).

All patients are to be followed for 2 years or until death or withdrawal from the study, whichever occurs first. For those patients in either group who survive after 2 years only mortality and explant data are planned to be collected, including autopsy and adverse events identified at explant / autopsy.

5.0 Clinical Studies continued

5.2 Study for Non-Transplant Candidates continued

Patient Population

A total of 129 patients were enrolled into the study at 21 investigational centers in the United States between May 15, 1998 and June 28, 2001. Of the 129 patients enrolled, 68 patients were randomized to the LVAD and 61 patients were randomized to Optimal Medical Management (OMM). See **Figure C** on following page (*Enrollment and Follow Up of 129 Randomized Patients*) for a summary of patient enrollment and outcomes.

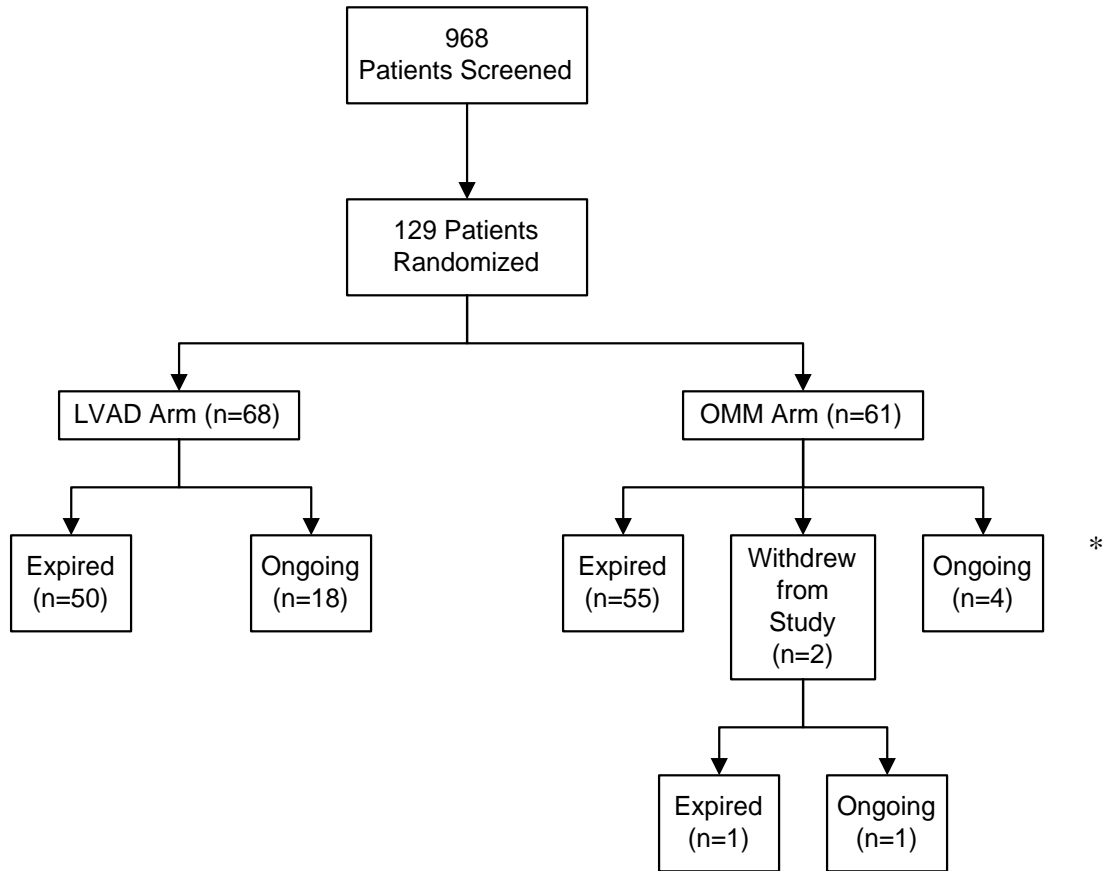
The REMATCH patient population included patients who were in end-stage heart failure (NYHA class IV, or class III on IABP or inotropes) and were treated with optimal medical therapy (i.e., digoxin, ACE inhibitors, and diuretics) for at least 60 of the last 90 days, who were older than 18 years, and who were not pregnant. The patients were non-transplant candidates due to their age (greater than 65 years), presence of insulin dependent diabetes mellitus with end-organ damage, chronic renal failure, or any major co-morbidity that would make the patient ineligible for cardiac transplantation.

The patients enrolled into the study were older than patients in previous bridge to transplant studies, with a median age of 69 years (range 34 to 84 years); 80% were male and 20% female; 90% were Caucasian. The majority of patients (74%) had ischemic etiology of heart failure. The majority of patients were in NYHA class IV (98%), and 70% were receiving IV inotropic support at baseline. Other heart failure medications at baseline included: digoxin (86%), ACE Inhibitors (57%) and diuretics (96%). The median baseline LVEF was 18% (range 4 to 25%) and VO₂max was 9.5 ml/kg/min (range 3.9 to 13.9). In almost half of the patients the cardiopulmonary exercise test could not be performed due to the patient being dependent on inotropes.

5.0 Clinical Studies continued

5.2 Study for Non-Transplant Candidates cont.

Figure C Enrollment and Follow Up of 129 Randomized Non-Transplant Patients as of April 15, 2002



* Three (3) patients crossed over to LVAD after enrollment was stopped.

5.0 Clinical Studies_{continued}

5.2 Study for Non-Transplant Candidates_{cont.}

Effectiveness: Survival Advantage of LVADs

Survival data was analyzed using the product – limit method of Kaplan and Meier. The data presented below is based on REMATCH Clinical Trial results, as of April 2002. At the time of the April 2002 analysis, 18 LVAD and 5 OMM patients remained alive and ongoing in the trial. These patients were censored in the analysis at the study duration they had achieved at the time of the analysis. Differences in survival distribution between the LVAD and OMM arms were analyzed using a logrank test.

Patients enrolled into the REMATCH trial were much sicker and had a substantially higher mortality rate than predicted during the design of the study. However, patients were randomly assigned into a treatment group, which provided an appropriate comparison group to detect a clinically meaningful treatment effect (33% reduction in mortality at 2 years with the use of the LVAS). The Kaplan-Meier analysis (see **Figure D** and **Table 7** on the following page) shows significantly reduced mortality in the LVAD group ($P=0.0012$). The probability of surviving 1 year (\pm standard error) was $51.4 \pm 6.1\%$ for the LVAD arm and $27.9 \pm 5.7\%$ for OMM patients. Predicted 2 year survival was $26.5 \pm 6.5\%$ for LVAD patients and $10.0 \pm 4.31\%$ for OMM patients. Median survival is 408 days for LVAD patients and 150 days for OMM patients.

The Kaplan-Meier analysis conclusively proves the efficacy of the HeartMate VE LVAD in reducing all-cause mortality in patients with end-stage chronic heart failure who are receiving optimal medical management and are not candidates for cardiac transplantation.

5.0 Clinical Studies continued

5.2 Study for Non-Transplant Candidates cont.

Figure D Kaplan-Meier Plot illustrating the Probability of Survival of VE LVAD versus Optimal Medical Management. April 2002. Logrank analysis: P = 0.0012 (Intent to Treat Analysis).

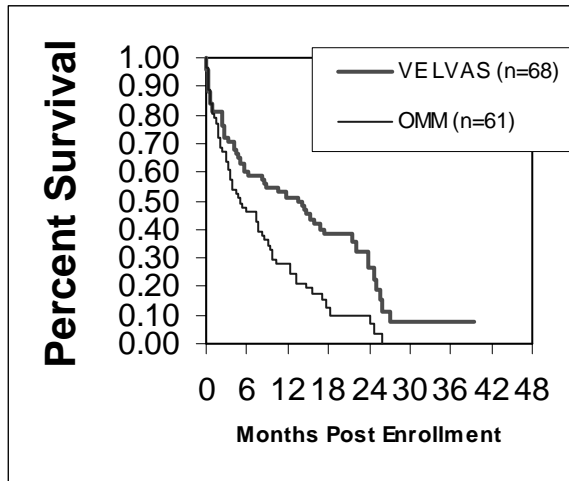


Table 7 Kaplan-Meier for ALL Cause Mortality.

VE LVAS						
	Time Interval (Months)					
	0 - 1	1 - 3	3 - 6	6 - 12	12 - 18	18 - 24
Number of patients starting interval	68	55	49	41	34	20
Number of patients who had event this interval	13	6	8	6	8	4
Number of cumulative patient events	13	19	27	33	41	45
Number of patients censored in interval	0	0	0	1	6	7
Number of cumulative censored patients	0	0	0	1	7	14
Probability of surviving interval event free	0.809	0.721	0.603	0.514	0.383	0.265
+/- 95% Confidence Limit at end of interval	0.09	0.11	0.12	0.12	0.13	0.15
Optimal Medical Management						
	Time Interval (Months)					
	0 - 1	1 - 3	3 - 6	6 - 12	12 - 18	18 - 24
Number of patients starting interval	61	49	39	28	17	5
Number of patients who had event this interval	12	10	11	11	8	1
Number of cumulative patient events	12	22	33	44	52	53
Number of patients censored in interval	0	0	0	0	4	1
Number of cumulative censored patients	0	0	0	0	4	5
Probability of surviving interval event free	0.803	0.639	0.459	0.279	0.126	0.100
+/- 95% Confidence Limit at end of interval	0.10	0.12	0.13	0.11	0.10	0.11

Nine (9) LVAD patients survived beyond 24 months (4 ongoing at 24.2, 24.6, 29.6, and 39.6 months), 5 expired at 24.7, 25.0, 25.7, 25.9, and 27. Three (3) optimally medically managed (OMM) patients survived beyond 24 months (all expired at 24.0, 24.8 and 26.0 months).

5.0 Clinical Studies_{continued}

5.2 Study for Non-Transplant Candidates_{cont.}

Safety: Adverse Events

The Tables on the following pages (see **Tables 8 – 11** and **Figure E**) present the number of patients, percent of patients and the total number of events for each anticipated adverse event in the REMATCH study. There were no unanticipated adverse events. The adverse events are presented as events regardless of severity; and, as serious adverse events if they resulted in a fatality, were life threatening, resulted in permanent disability, required hospitalization or prolonged a hospital stay. Due to the differences in survival between the 2 patient groups, the adverse events are also presented as rates per patient year.

- Overall, the incidence of serious adverse events was 2.27 times as likely to occur to LVAD patients as OMM patients. Serious adverse events occurred in 98% (67/68) of LVAS patients and in 67% (41/61) of OMM patients.
- Confirmed device malfunctions (i.e., any component of the system that fails intended function) occurred at a rate of 0.62 events / patient year and LVAD failures (i.e., inability of device to maintain adequate circulatory support) occurred at a rate of 0.04 events / patient year. Three LVAS patients who experienced LVAS failures could not be supported by back-up systems; these patients died.
- 35% (24/68) of LVAS patients underwent surgery to replace implanted device system components that malfunctioned. The estimated probability of requiring an operation to repair or replace an implanted LVAS component is 7% within the first 6 months, 30% between 6 and 12 months, and 78% between 1 and 2 years. The operative mortality from replacement of an implanted component was 29% (7/24).
- 22% (15/68) of LVAS patients (or their families) chose to have the LVAS turned off or did not agree to surgical replacement of malfunctioning system components. 21% (13/61) of the OMM patients opted for palliative care only.
- Additional operations (of all types, including abdominal/mediastinal explorations, tracheostomy, wound debridement, catheter placement, hernia repair etc.; subsequent to device placement or enrollment in the study) were required in 68% (46/68) of LVAS patients and in 28% (17/61) of OMM patients.

5.0 Clinical Studies continued

5.2 Study for Non-Transplant Candidates cont.

Safety: Adverse Events continued

Table 8. Summary of adverse events regardless of severity April 2002

	LVAD (n=68)					OMM (n=61)				
	# pts	% pts	UCL	LCL	Events	# pts	% pts	UCL	LCL	Events
Neurologic Dysfunction ¹	33	49%	57%	40%	45	4	7%	11%	2%	4
Bleeding	27	40%	48%	31%	57	3	5%	9%	1%	3
Local Infection	47	69%	77%	61%	106	26	43%	51%	34%	37
Sepsis	36	53%	61%	44%	51	9	15%	21%	8%	11
Thromboembolic Event (peripheral)	12	18%	24%	11%	15	4	7%	11%	2%	4
Cardiac Arrest requiring defibrillation	3	4%	8%	1%	6	4	7%	11%	2%	7
Sustained ventricular arrhythmia	20	29%	37%	22%	25	15	25%	32%	17%	23
Supraventricular arrhythmia	20	29%	37%	22%	27	4	7%	11%	2%	5
Syncope	5	7%	12%	3%	7	4	7%	11%	2%	4
Perioperative Myocardial Infarction	0	0%	0%	0%	0	0	0%	0%	0%	0
Non-periop Myocardial Infarction	2	3%	6%	0%	2	1	2%	4%	0%	1
Renal Failure	23	34%	42%	26%	25	7	11%	17%	6%	7
Chronic Renal Dysfunction	0	0%	0%	0%	0	0	0%	0%	0%	0
Hepatic Dysfunction	5	7%	12%	3%	5	0	0%	0%	0%	0
Psychiatric Episode	17	25%	32%	18%	20	2	3%	6%	0%	2
LVAD Related Adverse Events										
LVAD Related Right Heart Failure	13	19%	26%	12%	14					
Perioperative Bleeding	30	44%	53%	36%	35					
Percutaneous or Pocket Infection	34	50%	58%	42%	51					
Pump housing, Inflow , or Outflow Infection	17	25%	32%	18%	20					
Device Thrombosis	9	13%	19%	7%	9					
Confirmed Device Malfunctions	42	62%	70%	54%	114					
LVAS Failure	3	4%	8%	1%	3					

Pts = number of patients who experience event

UCL = Upper 95% Confidence Limit

LCL = Lower 95% Confidence Limit

Events = total number of events reported

5.0 Clinical Studies continued

5.2 Study for Non-Transplant Candidates cont.

Safety: Adverse Events continued

Serious adverse events are defined as those that result in a fatality, are life-threatening, result in permanent disability, require hospitalization or that prolong a hospital stay. **Table 9** summarizes the number and percent of patients who experienced a serious adverse event and the number of events recorded for both the LVAD and OMM groups. Due to survival differences between the LVAD and OMM groups, adverse events are better compared as event rates. **Figure A** and **Table 10A** depict the rate of death and serious adverse events per patient year for both study cohorts. **Table 10B** presents serious adverse events per 30-day patient interval.

Table 9. Summary of Serious Adverse Events - April 2002 Dataset

	LVAD (n=68)					OMM (n=61)				
	# pts	% pts	UCL	LCL	Events	# pts	% pts	UCL	LCL	Events
Neurologic Dysfunction ¹	22	32%	40%	24%	27	4	7%	11%	2%	4
Bleeding	22	32%	40%	24%	40	3	5%	9%	1%	3
Local Infection	15	22%	29%	15%	24	5	8%	13%	3%	8
Sepsis	28	41%	50%	33%	35	8	13%	19%	7%	10
Thromboembolic Event (peripheral)	7	10%	15%	5%	7	3	5%	9%	1%	3
Cardiac Arrest requiring defibrillation	3	4%	8%	1%	5	4	7%	11%	2%	6
Sustained ventricular arrhythmia	11	16%	22%	10%	15	10	16%	23%	10%	14
Supraventricular arrhythmia	6	9%	14%	4%	7	2	3%	6%	0%	3
Syncope	4	6%	10%	2%	5	0	0%	0%	0%	0
Perioperative Myocardial Infarction	0	0%	0%	0%	0	0	0%	0%	0%	0
Non-periop Myocardial Infarction	1	1%	4%	0%	1	0	0%	0%	0%	0
Renal Failure	12	18%	24%	11%	12	5	8%	13%	3%	5
Chronic Renal Dysfunction	0	0%	0%	0%	0	0	0%	0%	0%	0
Hepatic Dysfunction	2	3%	6%	0%	2	0	0%	0%	0%	0
Psychiatric Episode	3	4%	8%	1%	3	0	0%	0%	0%	0
LVAD Related Adverse Events										
LVAD Related Right Heart Failure	10	15%	21%	9%	11					
Perioperative Bleeding	26	38%	46%	30%	28					
Percutaneous or Pocket Infection	19	28%	36%	20%	24					
Pump housing, Inflow, or Outflow Infection	11	16%	22%	10%	13					
Device Thrombosis	3	4%	8%	1%	3					
Confirmed Device Malfunctions	26	38%	46%	30%	41					
LVAS Failure	3	4%	8%	1%	3					

Pts = number of patients who experience event

UCL = Upper 95% Confidence Limit

Events = total number of events reported

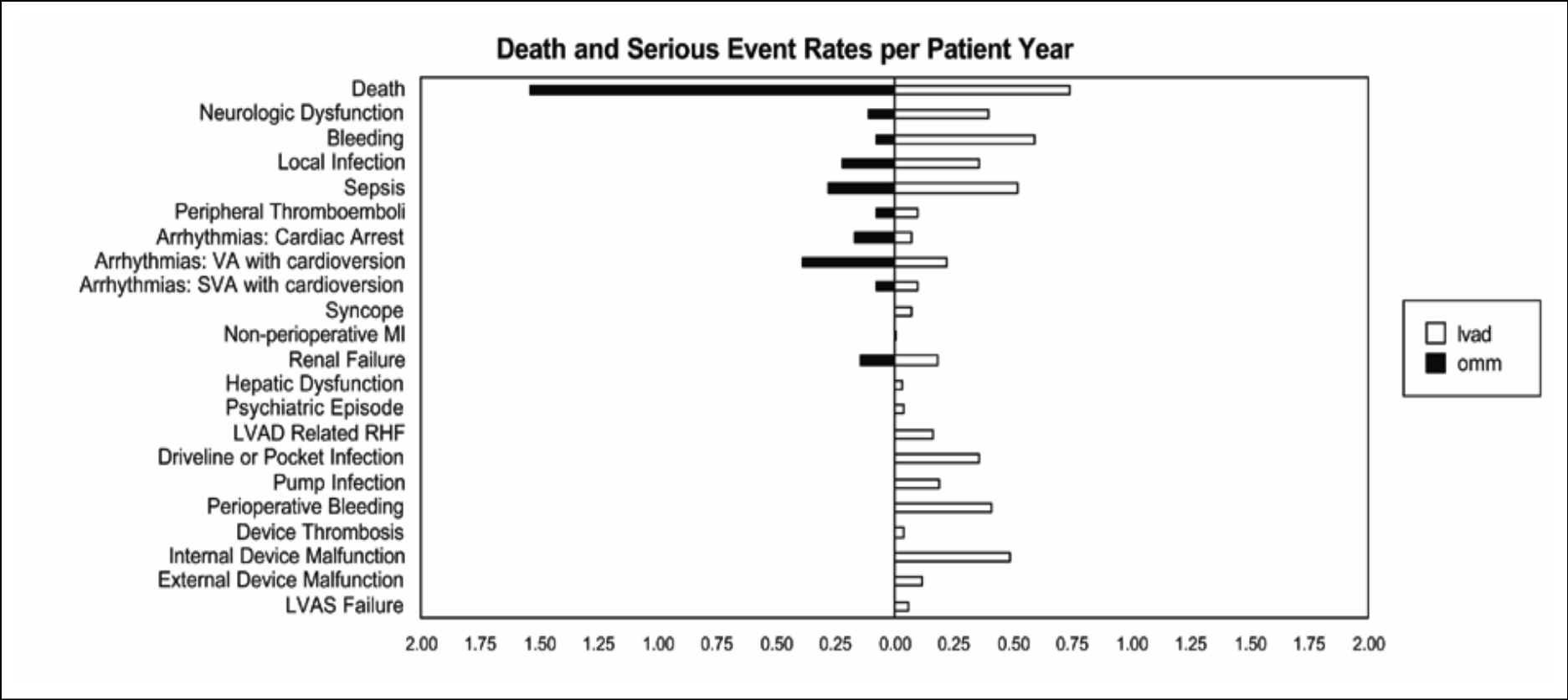
LCL = Lower 95% Confidence Limit

5.0 Clinical Studies continued

5.2 Study for Non-Transplant Candidates cont.

Safety: Adverse Events continued

Figure E



5.0 Clinical Studies continued

5.2 Study for Non-Transplant Candidates cont.

Safety: Adverse Events continued

Table 10A Serious¹ Adverse Event Rates Per Patient Years

Event	LVAD (n=68) Events / pt years	OMM (N=61) Events / pt years	Risk Ratio (95% Confidence Limits)	P ^a
Total Follow Up (years)	67.5	36.4	---	---
All Serious Adverse Events	5.87	2.59	2.27 (1.81 - 2.84)	< 0.0001
Neurologic Dysfunction ²	0.40	0.11	3.64 (1.27 - 10.39)	0.0080
Bleeding	0.59	0.08	7.18 (2.22 - 23.22)	<0.0001
Localized Infection	0.36	0.22	1.62 (0.73 - 3.60)	0.2702
Sepsis	0.52	0.28	1.89 (0.93 - 3.81)	0.0849
Thromboembolic Event (peripheral)	0.10	0.08	1.26 (0.33 - 4.86)	1.0000
Cardiac Arrest requiring Defibrillation	0.07	0.17	0.45 (0.14 - 1.47)	0.2093
Sustained ventricular arrhythmia requiring cardioversion	0.22	0.39	0.58 (0.28 - 1.20)	0.1715
Sustained supraventricular arrhythmia requiring pharmacologic treatment or cardioversion	0.10	0.08	1.26 (0.33 - 4.86)	1.0000
Syncope	0.07	0.00	----	0.17
Perioperative Myocardial Infarction	0.00	0.00	----	----
Non-perioperative myocardial infarction	0.01	0.00	----	1.0000
Renal Failure	0.18	0.14	1.29 (0.46 - 3.67)	0.8009
Chronic Renal Dysfunction	0.00	0.00	----	----
Hepatic Dysfunction	0.03	0.00	----	0.5449
Psychiatric Episode	0.04	0.00	----	0.5564
Other Serious Adverse Events	1.32	1.05	1.26 (0.86 - 1.85)	0.2635
LVAS EVENTS				
LVAS Related Right Heart Failure	0.16			
Perioperative Bleeding	0.41			
Percutaneous site or pocket infection	0.36			
Pump housing, inflow or outflow tract infection	0.19			
Device Thrombosis	0.04			
Confirmed Device Malfunction	0.62			
LVAS System Failure	0.04			

^a Fisher Exact Test (2-tailed)

¹ Serious adverse events were defined as those that result in a fatality, are life-threatening, result in permanent disability, require hospitalization, or prolong a hospital stay. Worsening heart failure resulting in death was not counted as an adverse event.

² Neurological dysfunction includes CVAs, TIAs, encephalopathy and other neurologic events. Ischemic stroke occurred in 7 (10%) of the LVAS patients at a rate of 0.10 events per patient year.

5.0 Clinical Studies continued

5.2 Study for Non-Transplant Candidates

Safety: Adverse Events cont.

Table 10B Serious¹ Adverse Event Rates Per 30 Patient Days
 By Time Interval – April 2002

Event	0 - 30 days		31 - 90 days		91 - 180 days		181 - 360 days		> 360 days	
	LVAD	OMM	LVAD	OMM	LVAD	OMM	LVAD	OMM	LVAD	OMM
Neurologic Dysfunction ¹	0.10	0.00	0.03	0.02	0.04	0.01	0.01	0.00	0.03	0.01
Bleeding	0.10	0.00	0.04	0.01	0.08	0.01	0.05	0.00	0.02	0.01
Localized Infection	0.13	0.00	0.05	0.01	0.03	0.04	0.02	0.02	0.01	0.00
Sepsis	0.17	0.06	0.08	0.02	0.02	0.01	0.02	0.03	0.03	0.00
Thromboembolic Event	0.05	0.00	0.00	0.01	0.01	0.00	0.01	0.01	0.00	0.01
Cardiac Arrest requiring Defibrillation	0.02	0.04	0.01	0.03	0.01	0.00	0.01	0.01	0.00	0.00
Sustained ventricular arrhythmia	0.08	0.09	0.01	0.03	0.01	0.01	0.01	0.02	0.01	0.02
Sustained supraventricular arrhythmia	0.03	0.04	0.00	0.01	0.01	0.00	0.00	0.00	0.01	0.00
Syncope	0.00	0.00	0.01	0.00	0.00	0.00	0.00	0.00	0.01	0.00
Perioperative Myocardial Infarction	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Non-perioperative myocardial infarction	0.02	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Renal Failure	0.07	0.02	0.00	0.01	0.01	0.01	0.00	0.02	0.02	0.00
Chronic Renal Dysfunction	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Hepatic Dysfunction	0.02	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Psychiatric Episode	0.03	0.00	0.00	0.00	0.01	0.00	0.00	0.00	0.00	0.00
LVAD EVENTS										
LVAD Related Right Heart Failure	0.12		0.01		0.00		0.00		0.01	
Perioperative Bleeding	0.30		0.02		0.01		0.01		0.02	
Percutaneous site or pocket infection	0.07		0.08		0.04		0.01		0.01	
Pump housing , inflow or outflow tract infection	0.02		0.03		0.04		0.00		0.01	
Device Thrombosis	0.00		0.00		0.00		0.00		0.01	
LVAD Failure	0.00		0.00		0.00		0.00		0.01	

5.0 Clinical Studies continued

5.2 Study for Non-Transplant Candidates

Secondary Objectives

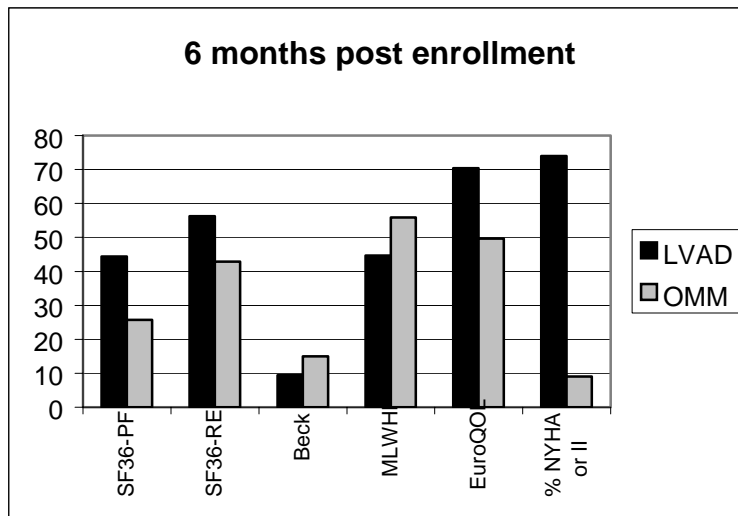
The secondary objectives that were studied in both treatment groups included a comparison of the NYHA Class (as determined by the site investigators), quality of life (as determined by questionnaires), functional status (by 6-minute hall walk and by measurement of MVO₂), and days alive and out-of-hospital. These data were compared between the LVAS and OMM groups.

Quality of Life

Quality of Life 6 months post enrollment (Table 11A): 42 LVAS and 28 OMM patients alive at start of interval. LVAS patients had significantly better quality of life (QoL) when compared to OMM patients using analysis of covariance for the following indices:

- NYHA Functional Class
- SF36 – PF
- Beck Depression Inventory
- MLWHF
- EuroQoL

Table 11A



- | | | |
|---------|---|---|
| SF36-PF | = | SF36 Physical Functioning – higher score indicates better QOL |
| SF36-RE | = | SF36 Role –Emotional - higher score indicates better QOL |
| Beck | = | Beck Depression Inventory – lower score indicates better QOL |
| MLWHF | = | Minnesota Living w/ Heart Failure – lower score indicates better QOL |
| EuroQOL | = | EuroQOL Self Assessment of State of Health – higher score indicates better QOL |
| NYHA I | = | Patients have cardiac disease but <i>without</i> the resulting <i>limitations</i> of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain. |
| NYHA II | = | Patients have cardiac disease resulting in <i>slight limitation</i> of physical activity results in fatigue, palpitation, dyspnea, or anginal pain. |

5.0 Clinical Studies continued

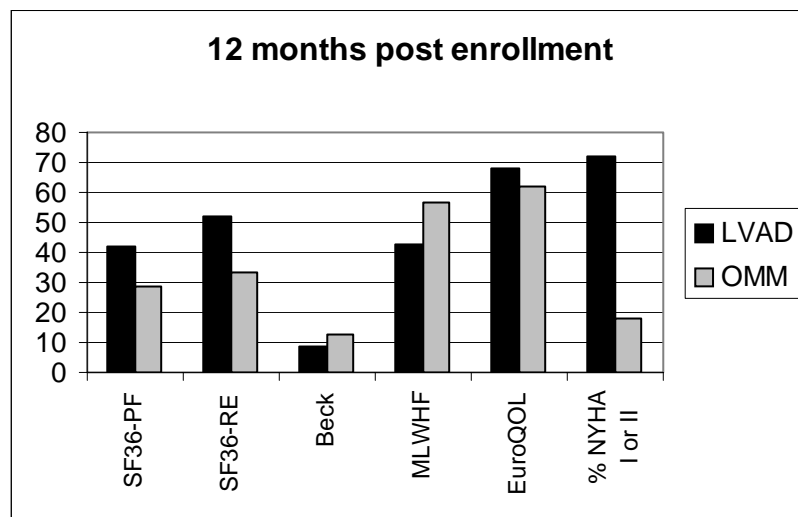
5.2 Study for Non-Transplant Candidates

Quality of Life cont.

Quality of life 12 months post enrollment (Table 11B): 35 LVAS and 16 OMM patients alive at start of interval. LVAS patients had significantly better QoL when compared to OMM patients using analysis of covariance for the following indices:

- NYHA Functional Class
- Beck Depression Inventory

Table 11B



SF36-PF	=	SF36 Physical Functioning – higher score indicates better QoL
SF36-RE	=	SF36 Role –Emotional - higher score indicates better QoL
Beck	=	Beck Depression Inventory – lower score indicates better QoL
MLWHF	=	Minnesota Living w/ Heart Failure – lower score indicates better QoL
EuroQoL	=	EuroQoL Self Assessment of State of Health – higher score indicates better QoL
NYHA I	=	Patients have cardiac disease but <i>without</i> the resulting <i>limitations</i> of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.
NYHA II	=	Patients have cardiac disease resulting in <i>slight limitation</i> of physical activity results in fatigue, palpitation, dyspnea, or anginal pain.
%NYHA I or II	=	Percent of patients with NYHA Functional Class I or II

5.0 Clinical Studies continued

5.2 Study for Non-Transplant Candidates

Quality of Life cont.

Although both the LVAS and OMM arms experienced improvements in quality of life when compared to baseline scores, the LVAS group showed significant improvement in physical functioning, perceptions of general health, and depression scores when compared to the OMM group. At **1 month post enrollment**, while the LVAS patients were recovering from implant surgery, the OMM group showed significantly better quality of life scores that measure body pain and physical functioning during this interval. **However, despite this**, the LVAS group showed significantly improved perceptions of general health and less depression even in this early interval. From Month 3 through Month 6, the LVAS group showed significant improvement over the OMM group in physical function (SF-36), perception of general health (SF-36, EuroQOL), depression (Becks), and the effect of heart failure on normal activities (Minnesota Living with Heart Failure, SF-36). There were too few OMM patients available for valid statistical comparison from Visit 12 on.

In summary, the results of the additional secondary objectives are as follows:

- **The quality of life was significantly improved in LVAS patients** as evidenced by the Minnesota Living with Heart Failure score, the Beck Depression Inventory, and the SF36 physical function scores 6 months after enrollment. LVAS patients, despite major heart surgery and increased adverse events, demonstrated improved quality of life as compared to baseline scores and continued to achieve significantly improved quality of life when compared to OMM patients in domains that measure general health and physical functioning through month 9, and depression through month 12. By month 12 the sample sizes were too small, mostly due to high mortality in the OMM arm, to allow for meaningful analysis. 100% (68/68) of the LVAS patients and 100% (61/61) of the OMM patients were tested at baseline; 91% (32/35) of LVAS patients and 56% (9/16) of OMM patients were tested at 1 year; 64% (7 /11) of LVAS patients and 100% (3/3) OMM patients were tested at 2 years.
- The **NYHA class** (as determined by the site investigators) **was significantly improved in the LVAS patients** as compared to the OMM patients. Within 1 month, the LVAD patients had statistically improved NYHA class functional status, which was maintained at follow-ups at 3, 6, 9, and 12 months. After month 12 the sample sizes were too small for calculation. Ninety-four percent (94%) (33/35) of LVAS patients and 69% (11/16) of OMM patients were tested at 1 year; 100% of LVAS (11/11) and 100% (3/3) of OMM patients were tested at 2 years.

5.0 Clinical Studies continued

5.2 Study for Non-Transplant Candidates

Quality of Life cont.

- **Exercise ability** as assessed by the 6-minute hall walk test and by MVO₂ tests **did not show any difference** between LVAS and OMM patients at either 1 or 2 years. Only 71% (25/35, 6 minute walk) and 63% (22/35, MVO₂) of LVAS and 25% (4/16, 6 minute walk) and 31% (5/16, MVO₂) of OMM patients were tested at 1 year. At 2 years the percentages of patients tested were 54% (6/11) and 36% (4/11) for LVAS patients and 100% (3/3) and 33% (1/3) for OMM patients.
- **LVAD patients lived longer and had more days out-of-hospital** than the OMM patients. However, the LVAS patients spent a higher percentage of the remainder of their life in the hospital (22% for LVAS vs. 15% for OMM patients).

5.3 Reliability Evaluation

It is incumbent upon the attending physician to be prepared for eventual device failure and to anticipate the need for device replacement should patients require VAD support for extended periods of time. Be advised, the mean time to pump failure data provided below is based on in vitro test data and may not reflect actual clinical reliability. Clinical experience indicates that variations in implant technique, as well as differences in patient physiology and patient management may result in diminished mean time to pump failure. For information on managing factors that may affect pump life, see section 6.4, *Factors that May Affect Pump Life*, in the Clinical Studies portion of this manual.

The purpose of reliability testing is to obtain a reasonable estimate of how long a given device will perform as intended without failure. *In-vitro* reliability testing of 15 VE systems began in July 1997 (range 1 - 5.5 years). Cumulative test time: 54.5 years.

Based on *in vitro* testing to a confidence interval of 90%, there is 99.8% chance that this device will be free of critical failures at 2 months of use; an 93% chance that this device will be free of critical failures at 1 year of use; and a 77% chance that this device will be free of critical failures at 2 years of use. The mean-time-to-failure (MTTF) for the device is estimated to be 3.6 years at the 90% confidence interval. However, the reliability and time-to-failure predictions derived from the bench testing were not an adequate predictor of actual device reliability observed during the clinical trial.

Three (3) device failures occurred during the clinical trial, at times ranging from 15 to 17 months; significantly less than the mean time to failure

5.0 Clinical Studies_{continued}

5.3 *Reliability Evaluation*_{cont.}

predicted by the reliability model. Multiple device malfunctions, 27 of which required surgical intervention occurred during the clinical trial, the most prevalent of these being 12 occurrences of inflow valve incompetence. There is as yet insufficient information to definitely show that steps taken to reduce these device malfunctions are effective.

5.4 *Factors that May Affect Pump Life*

Clinical experience indicates that variations in implant technique, as well as differences in patient physiology, may influence pump chamber pressure, which can result in diminished mean time to pump failure (see Section 6.3, *Reliability Evaluation*). For example, pump migration can cause Outflow Graft Conduit kinking and hypertension, or a poor anastomosis (or anatomic changes at the anastomosis site) may contribute to increased pump chamber pressure. Using a smaller than recommended graft can contribute to increased pump chamber pressure as well.

Reducing elevated pump chamber pressures and operating the VAD at the lowest possible pump chamber pressure can effectively reduce the complications mentioned above. Specific suggestions for managing pressure-related factors appear below:

- **Maintain Low Patient Arterial Pressure.** Care must be taken to reduce patient arterial pressure whenever possible. High pressures put undue stress on the Inflow Valves.
- **Remove Tissue from the Aortic Anastomotic Site.** Remove tissue from the aortic anastomotic site in order to produce an elliptical or round opening, as opposed to a slit (slits can only open under pressure).
- **Use Outflow Grafts Provided by Thoratec with LVAS.** Smaller diameter grafts may contribute to elevated pump chamber pressure.
- **Use Outflow Graft Bend Reliefs.** To reduce graft kinks, a Thoratec-supplied Outflow Graft Bend Relief should be used over the Outflow Graft Conduit where it attaches to the Outflow Valve Housing (see section 7.9, *Attaching the Outflow Graft Conduit*). Only Thoratec-supplied Bend Reliefs should be used to insure proper functioning.
- **Avoid twisting the Inflow Valve Conduits.** Inserting the inflow cannula into the ventricular apex can become difficult for a variety of reasons, thereby necessitating twisting and pushing of the Inflow Conduit assembly. Twisting this assembly can result in abnormal valve function. Avoid inflow assembly damage by holding the assembly at the bell housing and pushing the assembly without twisting. Proper alignment of the conduit will lead to longer valve life. Therefore, take care to not twist the Inflow Valve

5.0 Clinical Studies continued

5.4 *Factors that May Affect Pump Life* cont.

assembly once the pump is in its final position. (see section 7.8, *Orientation of the Inflow Valve Conduit*).

- **Operate the System at a Lower Fixed Rate.** Whenever possible (eg, when the patient is resting or sleeping), operate the pump in the full-stroke ($\geq 80\text{ml}$) fixed rate mode to eliminate the impact of the rotor hitting the diaphragm pusher plate. This precaution can lessen the incidence of valve incompetence that may be induced by continuously high pump rates and elevated pressure pulses.

5.5 *Types and Timing of Device Events*


Table 12 Probability of Reoperation to Repair or Replace the LVAD

At 0-6 Months	At 6-12 Months	At 12-24 Months
7.2%	29.8%	77.6%

6.0 LVAS Components continued


The following are components of the HeartMate XVE LVAS:

Component Name/Description	Catalog Name/Number
HeartMate XVE LVAS Implant Kit	1270
<i>HeartMate XVE LVAS Operating Manual</i>	28080 (document no.)
Power Base Unit (PBU) with Cable	1240
XVE System Controller	1275
Battery Module for XVE System Controller	1264
Rechargeable Battery Set	2025
Battery Holster	1236
Battery Clip Set	1237
VE Display Module	1280N
VE System Monitor	1286
Stroke Volume Limiter	1295
Hand Pump	1290
Vent Filter Set	1255
Vent Adapter	1238
Emergency Power Pak (EPP)	2020 VE
Travel Case	1260
Shower Kit	1224
Night Belt	1233
Pocket Pak	1235

 **Note:** Components must be stored in a cool, dry location.

Refurbishment and reuse of XVE LVAD blood-contacting titanium components of up to 5 times is a standard manufacturing process of the XVE LVAD. Accordingly, all HeartMate LVADs may contain refurbished titanium components.

For additional product information and specifications, consult the *HeartMate XVE LVAS Operating Manual*, or contact Thoratec Corporation.

 **Note:** Thoratec reserves the right to change specifications without notice.

CAUTION !

Sterile components of the HeartMate XVE LVAS are intended for single-use only. Do NOT reuse sterile device components.

6.0 LVAS Components continued

6.1 *Equipment and Supplies Required for Implant*

In the operating room, before initiating the implant procedure, open the XVE LVAS Implant Kit and ensure that the following components of the system are present:

- XVE LVAD (blood pump) Assembly
- XVE System Controller with Battery Module
- Outflow Graft Conduit with Bend Relief
- Apical Sewing Ring
- Inflow Valve Conduit
- Outflow Valve Conduit
- Vent Filter
- Vent Adapter
- Thread Protectors (1 set)
- Coring Knife
- Tunneling shroud
- Protective “bullet”

In addition to these *Instructions for Use*, the *HeartMate XVE LVAS Operating Manual*, which is provided with the System Monitor, also should be present during the implant procedure.

The following equipment, also necessary for the implant procedure, should be ordered from Thoratec Corporation.

Component Name/Description	Catalog Number
• VE System Monitor	1286
• Power Base Unit (PBU) with Cable	1240
• Rechargeable Battery Set (fully charged)	2025
• Hand Pump	1290
• Tunneler with Guide(s)	1035
• Battery Clip Set	1237
• HeartMate VE Sizer	2643

6.0 LVAS Components continued

6.1 *Equipment and Supplies Required for Implant* cont.

The following equipment, also necessary for the implant procedure, is supplied by the hospital:

Hospital-Supplied Equipment

- 20cc syringe (no needle) with non-heparinized autologous whole blood
- 60cc syringe (no needle) with 1cc of Heparin
- Small drip basin
- 4 Small bowls of sterile normal saline
- 1 Large basin
- 4 Sterile centrifuge tubes
- 2 Emesis basins
- Vent needle
- Autologous serum/un-anticoagulated whole blood
- CV Major Surgical Set
- Heavy non-absorbable ligature
- Catheter-tipped syringe with sterile normal saline

WARNING !

As a precaution against system malfunction, which cannot be readily corrected by reference to these *Instructions for Use* or the *HeartMate XVE LVAS Operating Manual*, a complete back-up system [Extended Lead Left Ventricular Assist Device (XVE LVAD) and external components] must be available on-site and in close proximity for use in an emergency.

End of Section I

7.0 Implant Procedure

Prior to Implantation

The patient is transported to a cardiovascular operating room, prepped, and anesthetized according to standard procedures. A sternotomy with extended midline abdominal incision is then made and cardiopulmonary bypass instituted.


WARNING !

- A minimum of 2 fully-charged Batteries are required at time of implant to power the LVAS when transporting the patient out of the operating room.
- Do NOT use the Power Base Unit (PBU) in the presence of flammable anesthetic agents, or an explosion could occur.
- Keep the PBU away from water. If the PBU has contact with water, shower spray, or wet surfaces, the XVE LVAD may stop or the patient may receive a serious electric shock.

7.1 Setting Up and Initializing the System

The HeartMate XVE LVAS can be configured to operate through the Power Base Unit (PBU) (as shown in **Figure 1**), or with Batteries (as shown in **Figure 2**).

To Set Up and Initialize the System:




- 1 Plug the PBU into the AC mains (electric outlet), then turn on the PBU.
- 2 Connect the System Monitor to the PBU “Display” socket (back panel), then turn on the System Monitor.
 **Note:** When initialization is complete, the “NOT RECEIVING DATA” message will appear at the bottom of the monitor screen (indicating that the System Monitor is not yet linked to the XVE System Controller).
- 3 Insert a minimum of 4 Batteries into the Power Base Unit (PBU) charging slots.
- 4 Ascertain that at least 2 Batteries are fully charged (indicated by green light) so they will be available for patient transport out of the operating room.

CAUTION !

- Only use the Thoratec Power Base Unit (PBU) to charge Batteries. Other chargers may damage Batteries.
- The power entry module on the rear panel of the PBU has been equipped with the proper fuse and set to the appropriate AC mains voltage for your location. Only qualified, Thoratec-trained service personnel should perform fuse replacement.

7.0 Implant Procedure continued

7.2 *Initializing the XVE System Controller*

- 1 Remove XVE System Controller from its sterile package.
 **Note:** An XVE System Controller Battery Module (to be installed in the XVE System Controller at a later time) is included in the sterile package.
- 2 Set aside XVE System Controller in a safe location to await later use.
- 3 Plug the large circular connector-end of the PBU Cable into the “Patient” connector located in rear of the PBU.
- 4 Pass the parallel XVE System Controller Cable ends out of the sterile field and connect them to the bifurcated ends of the PBU Cable (**Figure 1**).
 **Note:** Both the PBU and the XVE System Controller will indicate a Hazard Alarm condition (signifying that the XVE System Controller is powered but not connected to the XVE LVAD). The XVE System Controller will display a RED HEART and a YELLOW WRENCH symbol while emitting a CONTINUOUS AUDIO TONE; at the same time, the System Monitor will display the message LOW RATE (with timer). Reset these alarms by pressing the XVE System Controller Alarm Reset Switch.
- 5 Ascertain that the System Monitor indicates that the system is in Fixed Rate Mode of 50 beats per minute. If necessary, decrease the rate by touching the on-screen arrow keys.
- 6 Disconnect both connectors of the PBU Cable from the XVE System Controller.
 **Note:** Maintain sterility of XVE System Controller throughout the XVE LVAD implant.

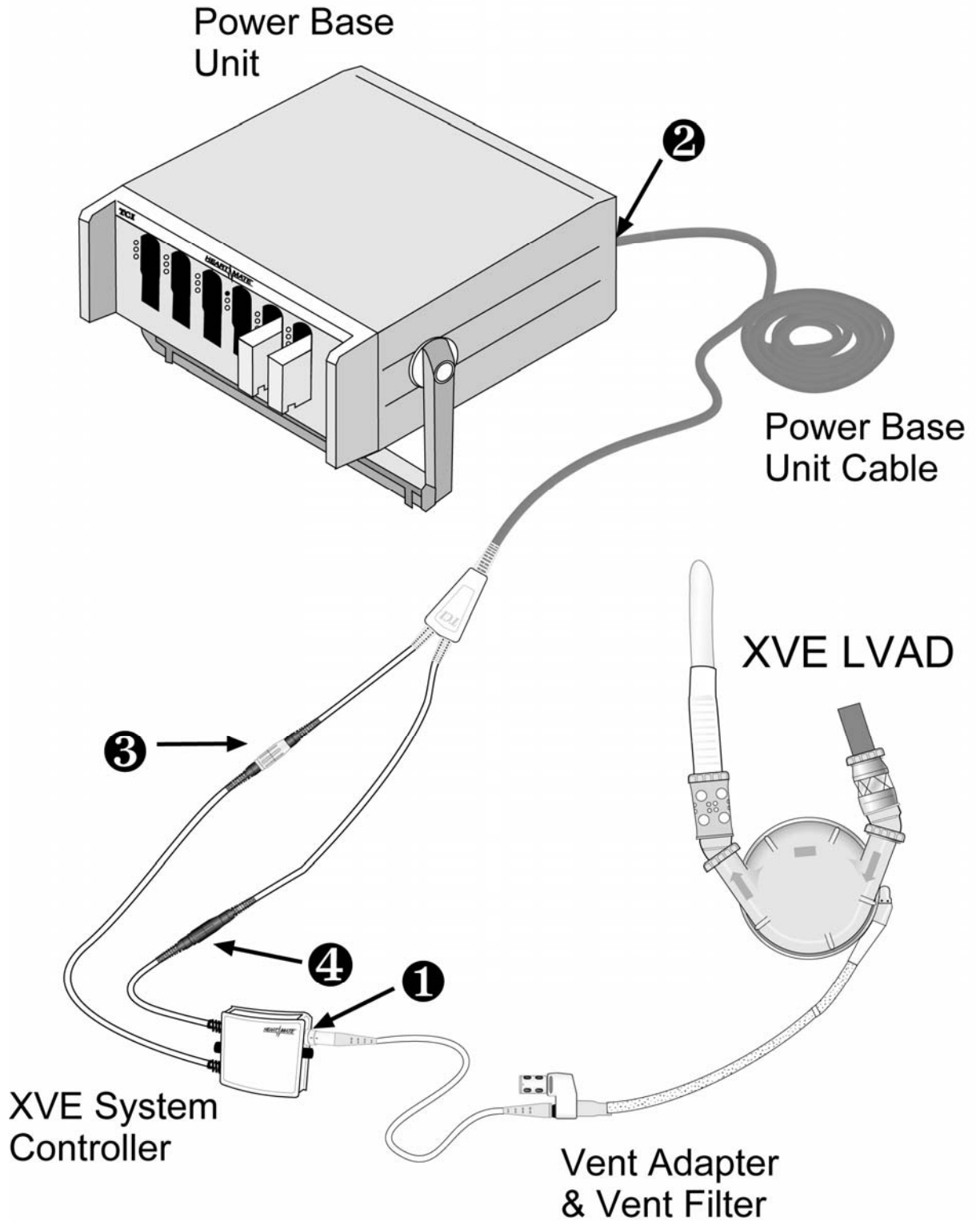
CAUTION !

- Connectors of the XVE System Controller that are extended beyond the sterile field should remain outside the sterile field.
- When connecting cables, do NOT force together connectors without proper alignment. Forcing together misaligned connectors may damage connectors.
- Connectors should be kept clean and dry. Do NOT expose connectors to water when making or breaking connections.
- Never use tools to tighten connections. Hand tighten only. Using tools may damage the connectors and cause the pump to stop.

7.0 Implant Procedure continued

7.2 *Initializing the XVE System Controller* cont.

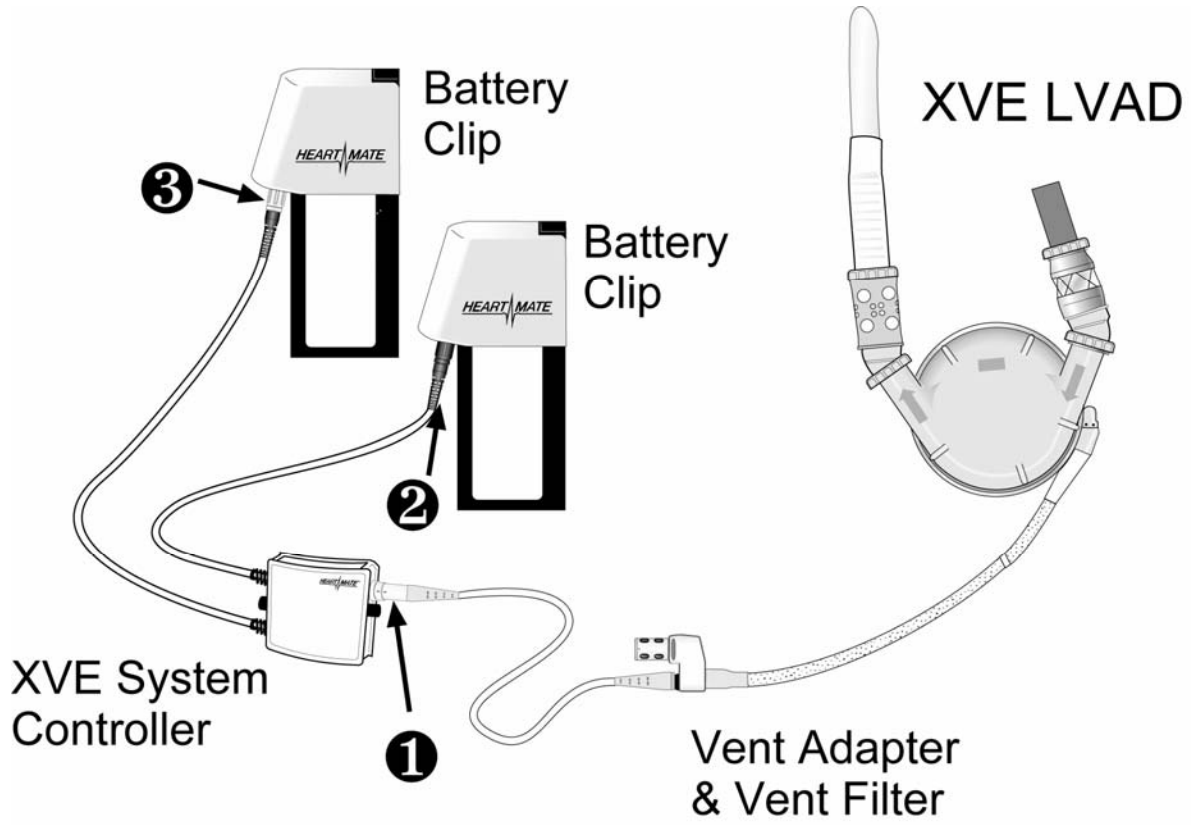
Figure 1 XVE System Controller using the Power Base Unit (PBU). Connections are made in numeric order.



7.0 Implant Procedure continued

7.2 *Initializing the XVE System Controller* cont.

Figure 2 System connections using rechargeable Batteries. Connections are made in numeric order.



7.0 Implant Procedure continued



7.3 Pre-Clotting

The Inflow and Outflow Valve Conduits, as well as the Outflow Graft, must be pre-clotted before use in order to facilitate homeostasis. The next procedures describe the steps to follow for pre-clotting each component. Care must be taken to ensure that pre-clotting occurs as indicated.

CAUTION !

Coat ONLY the EXTERNAL surface of graft material.

7.3A Pre-Clotting the Outflow Graft

- 1 Using strict aseptic technique, remove the Bend Relief from the Outflow Graft; reserve Bend Relief for use after pre-clotting procedure.
 **Note:** Ensure the white washer remains inside the Screw Ring.
- 2 In an emesis basin, evenly coat the external surface of the graft with whole blood or other standard approved pre-clotting agent(s).
- 3 Drain graft; place it into a dry basin.
- 4 Heat graft in an autoclave to coagulate the pre-clotting agent(s), if necessary (not all pre-clotting agents require heat).
- 5 Allow heated graft to cool.
- 6 Inspect the interior of the graft; remove any debris or clots.
- 7 Examine Screw Ring to ensure that white washer is inside and properly positioned.
- 8 Replace Screw Ring (with attached Bend Relief) onto graft connector.
 **Note:** Orient Screw Ring and Bend Relief so that the Screw Ring covers the proximal metal end of the graft conduit.
- 9 Place Thread Protector onto Screw Ring to prevent contamination of conduit threads.

CAUTION !

Do NOT over tighten Thread Protector.

7.0 Implant Procedure continued

7.3B Pre-Clotting the New Inflow Valve Conduit

WARNING !

Prior to use, insure that the Screw Ring on the New Inflow Valve Conduit is attached tightly. To verify tightness, turn the Screw Ring *clockwise* by hand. A clicking sound indicates that the connection is too loose; continue turning clockwise by hand until connection is tight. Hand tighten only; do NOT use tools.

WARNING !

Prior to use, the external surfaces of the New Inflow Valve Conduit must be pre-clotted to reduce the possibility of air entering the patient's circulatory system and of bleeding from the XVE LVAD during startup. During pre-clotting, coat only the EXTERNAL surface of New Inflow Valve Conduit graft material.

WARNING !

Do NOT autoclave the New Inflow Valve Conduit. Doing so will damage the porcine xenograft valves inside.

- 1 Fill 3 emesis basins with sterile normal saline.
- 2 Actively rinse the New Inflow Valve Conduit in sterile normal saline for 10 minutes in basin one; for 3 minutes in basin two; and for 3 minutes in basin three.
- 3 Hold the valve conduit in a horizontal position over a drip basin and slowly expel non-heparinized blood, or other approved preclotting agent, from a syringe through the clotting access slots (**Figure 3**) of the valve conduit onto the **EXTERIOR** only of the valve conduit graft material.

Clotting Access Slot

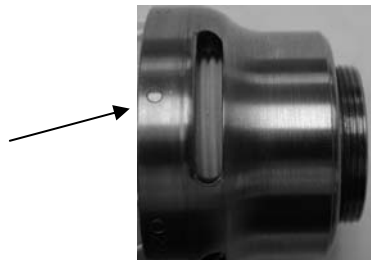




Figure 3 Clotting access slots of the New Inflow Valve Conduit.

7.0 Implant Procedure continued

7.3B Pre-Clotting the New Inflow Valve Conduit cont.

WARNING !

Prior to use, insure that the Screw Ring on the New Inflow Valve Conduit is attached tightly. To verify tightness, turn the Screw Ring *clockwise* by hand. A clicking sound indicates that the connection is too loose; continue turning clockwise by hand until connection is tight. Hand tighten only; do NOT use tools.

- 4 Rotate the conduit and continue coating the graft material through each clotting access slot while allowing the blood to clot.
 **Note:** When using blood, it may take as long as 30 to 40 minutes for an acceptable clot to form in cases of coagulopathy.
- 5 Repeat Steps 2 and 3 until all visible graft material is covered and clotting is complete.
 **Note:** Every 3 to 5 minutes, moisten the porcine xenograft tissue valve by gently dripping (over a separate basin) sterile normal saline into both ends of the valve conduit. This prevents the porcine xenograft tissue valve from drying out until implanted.
- 6 Place pre-clotted valve conduit in basin of sterile saline and cover with sterile towel until needed.

7.0 Implant Procedure continued



7.3C Pre-Clotting the Outflow Valve Conduit

WARNING !

Prior to use, the external surfaces of the New Inflow Valve Conduit must be pre-clotted to reduce the possibility of air entering the patient's circulatory system and of bleeding from the XVE LVAD during startup. During pre-clotting, coat only the EXTERNAL surface of Outflow Valve Conduit graft material.

WARNING !

Do NOT autoclave valve conduits. Doing so will damage the porcine xenograft valves inside.

- 1 Fill 3 emesis basins with sterile normal saline.
- 2 Actively rinse the Outflow Valve Conduit in sterile normal saline for 10 minutes in basin one; for 3 minutes in basin two; and for 3 minutes in basin three.
- 3 Hold the Outflow Valve Conduit in a horizontal position over dry basin and slowly expel non-heparinized blood (or other standard pre-clotting agents) from the syringe onto the *exterior* of the valve conduit graft material. Allow blood to drip into the small basin so that it may be redrawn into the syringe for repeated use.
- 4 Rotate the Outflow Valve Conduit and coat the graft material while allowing the blood to clot.
 **Note:** It may take as long as 30 to 40 minutes for an acceptable clot to form in cases of coagulopathy.
- 5 Repeat steps 2 - 3 until all visible graft material is covered and coating is complete.
 **Note:** Every 3 to 5 minutes, moisten the porcine xenograft valves by gently dripping (over a separate basin) sterile normal saline into both ends of the valve conduit. This prevents the porcine xenograft valves from drying.
- 6 Inspect the Outflow Valve Conduit for complete coating. Repeat coating procedure as necessary to ensure complete coverage.

WARNING !

Coat ONLY the EXTERNAL surface of graft material.

7.0 Implant Procedure continued

7.3C *Pre-Clotting the Outflow Valve Conduit* cont.

- 7 Immediately after the exterior of the Outflow Valve Conduit has been completely coated, moisten the porcine xenograft valve with sterile normal saline; then proceed with pump assembly and priming (see 7.4 *Priming the XVE LVAD* next page).

WARNING !

Care must be taken to prevent blood from entering and collecting in the lumen of the valve conduits. Blood on the inner lumen may increase the risk of thromboembolism due to coagulum breaking free in the circulatory system. The inner lumen of the valve conduits must, therefore, be rinsed thoroughly prior to attachment to the XVE LVAD.

7.0 Implant Procedure continued

7.4 Priming the XVE LVAD


Using strict aseptic technique:

- 1 Attach the pre-clotted Inflow and Outflow Valve Conduits to the XVE LVAD.

WARNING !

Failure to adequately secure the Inflow and Outflow Valve Conduits may allow these connection points to loosen and result in potentially fatal hemorrhage.

- 2 Turn the Screw Ring (on the outflow side) clockwise until a clicking sound is heard, and then continue turning until connection is tight.

 **Note:** Arrows on the XVE LVAD housing indicate correct orientation of the Inflow versus the Outflow Valve Conduits.

- 3 Insure that the XVE LVAD is correctly assembled and that all connections (including Inflow and Outflow Conduit connections) are tight.

- 4 Slide the tunneling shroud over the vent holes (**Figure 4**) and insure that the shroud is securely in place (covering the vent holes on the percutaneous tube)


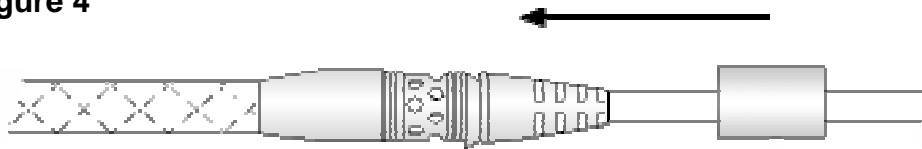
 **Note:** The tunneling shroud is designed to prevent material from entering the vent holes during the tunneling process; it will be removed later (see 7.10, *De-Airing the XVE LVAD*).

Figure 4



- 5 Insure that the protective “bullet” on the percutaneous tube is screwed securely to the connector-end of the tube.
- 6 Place the XVE LVAD in a large basin to help prevent contamination.
- 7 Hold the XVE LVAD in a vertical position.

7.0 Implant Procedure continued

7.4 Priming the XVE LVAD cont.

- 8 Pour sterile normal saline into the Inflow Valve Conduit until the XVE LVAD appears full.


WARNING !

Do NOT allow the Percutaneous tube connector to become contaminated or its inner lumen to become wet, or the pump may stop.

- 9 Gently tap the XVE LVAD to dislodge any air bubbles, and rotate the XVE LVAD body to allow all entrapped air to escape through the Outflow Valve Conduit.
- 10 Hold the XVE LVAD so that the Outflow Valve Conduit is at the highest level, and continue filling the XVE LVAD through the Inflow Valve Conduit.

WARNING !

All entrapped air must be removed from the XVE LVAD blood pumping chamber and conduits in order to minimize the risk of air embolus.

- 11 Once the XVE LVAD is filled completely, place the cut-off fingertip of a sterile, non-powdered glove over the Inflow Valve Conduit.
- 12 Place the solid Thread Protector on the Outflow Valve Conduit to prevent gross loss of priming fluid and tissue contamination of the conduit threads.
 **Note:** Some fluid leakage will occur through the conduit and connections.

CAUTION !

Do NOT over tighten Thread Protector.

7.0 Implant Procedure continued

7.5 Implantation

The proper orientation of the implanted components may be seen in **Figure 5a**. The Inflow Valve Conduit is placed using apical cannulation, and the pump is positioned inferior to the diaphragm.

CAUTION !

Do NOT clamp any portion of the Percutaneous tube during implant. Clamping may damage the tubing or electrical leads located inside.

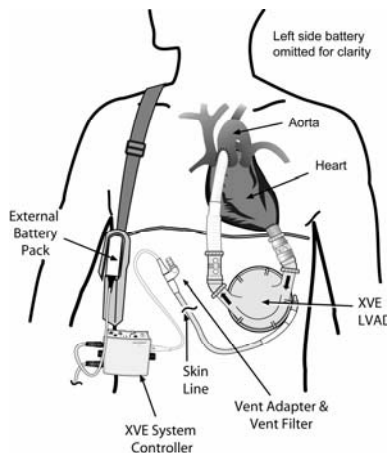
Preperitoneal Pump Placement vs. Intra-Abdominal Pump Placement

The HeartMate XVE LVAD may be surgically implanted *either* pre-peritoneally or intra-abdominally. As described below, the **preperitoneal technique** requires creating a “pocket” for the pump under the posterior rectus sheath and transversalis fascia, and above the rectus abdominis and internal oblique muscles. With the **intra-abdominal technique**, the pump is inserted intra-abdominally into the left upper abdominal quadrant. Both techniques have been employed successfully, and may be used based on the preference of the implanting surgeon. *Potential advantages and disadvantages of each technique are outlined below.*

Preperitoneal Placement

Preperitoneal placement appears preferable for patients who have undergone previous abdominal surgery, or patients with a short torso. One advantage of the preperitoneal approach is that the device is placed outside the abdominal viscera where bowel adhesions are unlikely. Potential disadvantages of using the preperitoneal approach include the risk of pocket hematoma, pocket and exit site infection, wound dehiscence, and erosion of the skin overlying the implanted device.

Figure 5a Implanted and worn components of HeartMate XVE LVAS.





7.0 Implant Procedure continued

7.5 *Implantation* cont.

Intra-Abdominal Placement


Intra-Abdominal placement may be preferable for thin patients in whom the risk of erosion of the pump through the skin is a concern. Also, thin patients may not accommodate adequate “tunneling” of the percutaneous tube to allow sufficient ingrowth as a barrier to infection. The intra-abdominal location may be preferable for patients who have been previously treated with an Automatic Implantable Cardiovert Defibrillator (AICD), as the ability to create an intra-abdominal pocket may be hampered by the placement of the AICD. Potential disadvantages of intra-abdominal placement include diaphragmatic herniation into the pericardial space, wound dehiscence, abdominal (bowel) adhesions, bowel obstruction, bowel perforation, and erosion of the stomach, colon, liver, and abdominal viscera.

7.5A *Surgical Technique for PREPERITONEAL Placement*



- 1 Once the sternum is divided, open the left anterior rectus sheath medially and use electrocautery to create a pocket behind the rectus muscle.
- 2 Extend the dissection laterally.
- 3 Form a pocket between the posterior rectus sheath and transversalis fascia underneath, and the rectus abdominis and the internal oblique muscles above.
- 4 Open the pericardium and reflect it laterally to allow exposure of the left ventricular (LV) apex.
- 5 Dissect the peritoneum away from the diaphragm.
- 6 Perform further dissection as necessary to facilitate insertion of the Inflow Valve Conduit into the LV apex.
- 7 Once cardiopulmonary bypass is established and the LV apex is prepared for insertion of the Inflow Valve Conduit, pass the percutaneous tube from the inferior aspect of the pocket through the subcutaneous tissue to the medial side of the iliac crest. Adjust the pump in the pocket as necessary.
- 8 Insert the Inflow Valve Conduit into the LV apex and secure it.
 **Note:** A small preperitoneal pocket also is made behind the right rectus muscle to allow for the Outflow Valve Conduit and Graft. Outflow is directed to the ascending aorta.
- 9 Anastomose the graft to the ascending aorta in an end-to-side fashion.
 **Note:** The anastomosis should be non-restrictive, and the suture line should be secure without evidence of blood loss.
- 10 Externalize the percutaneous tube through the right upper quadrant.

7.0 Implant Procedure continued

7.5B Surgical Technique for *INTRA-ABDOMINAL* Placement

- 1 Make a midline chest incision, extended to the umbilicus.
- 2 Once cardiopulmonary bypass is instituted and the aorta is clamped, prepare the left ventricle (LV) apex for insertion of the Inflow Valve Conduit.
- 3 Place the pump intraperitoneally into the left upper quadrant.
- 4 Pass the Inflow Valve Conduit through the anterior portion of the left hemi diaphragm to allow insertion of the Inflow Valve Conduit into the LV apex.
- 5 Place the Outflow Graft over the diaphragm and anastomose the graft to the ascending aorta in an end-to-side fashion.
 **Note:** The anastomosis should be non-restrictive, and the suture line should be secure without evidence of blood loss.
- 6 Externalize the percutaneous tube through the right upper quadrant.

7.6 *Selecting and Creating a Percutaneous Tube Exit Site*

- 1 Insure that the selected exit site location will not interfere with the patient's clothing (eg, belts, waistbands).
- 2 Insure that *at least* 1.0 inch (2.5 cm) of the *smaller diameter* polyester velour covering of the percutaneous tube remains *within* the subcutaneous tunnel, before exiting the skin.
 **Note:** Adherence of tissue to the polyester velour is essential in minimizing the risk of exit site infection.
- 3 At the selected exit site, make a circular incision of 0.50 inch (1.0 – 1.2cm) diameter.
- 4 Form a blunt dissection tunnel from the circular incision site to the pump cavity location.
- 5 Externalize the percutaneous tube through the exit site tunnel.
 **Note:** The “bullet” on the end of the percutaneous tube contains a suture tape that can be used to pull the lead through the tunnel. In addition, the bullet tip is threaded and may be attached to tunneling tools of corresponding size.

CAUTION !

Do NOT clamp any portion of the percutaneous tube during implant. Clamping may damage the tubing or electrical leads located inside.

7.0 Implant Procedure continued


7.7 Preparing the Ventricular Apex Conduit Site

The following steps are required to insure proper Apical Sewing Ring placement and attachment (see **Figures 6A-5C**).

- 1 Cut the ligature securing the Coring Knife and remove the plastic plugs from each end.
- 2 Put the handle through the hole in the Coring Knife cylinder to make a “T” handle.
- 3 **Choose coring location:** Ideally located slightly anterior to the apex, a few centimeters lateral to the left anterior descending coronary artery.
- 4 Perform the core with the Coring Knife oriented toward the mitral valve inflow (see **Figure 6A**).

CAUTION !

Do NOT allow the Coring Knife to involve the ventricular septum while performing the core.

- 5 Apply cutting edge of knife to the epicardium and maintain pressure while rotating the Coring Knife back and forth, until the ventricular cavity is entered.
 **Note:** If you encounter problems using the coring knife while preparing the ventricular apex conduit site, use conventional surgical tools and techniques in place of the coring knife.
- 6 Remove the core and inspect the ventricle for thrombus.
- 7 Remove the Apical Sewing Ring from the package and loosen the green ligature.
- 8 Have an assistant hold the centering portion of the Sewing Ring assembly so that the felt portion is directed toward the heart and the silicone, tubular portion is facing outward (**Figure 6B**).
- 9 Moisten Sewing Ring with sterile normal saline prior to positioning in core for easier removal of the centering fixture.
- 10 Use at least 12 pledgeted sutures to attach the cuff of the Sewing Ring to the apex (see **Figure 6C**).

CAUTION !

Do NOT remove the Centering Device from the Sewing Ring until ready to insert the Inflow Valve Conduit.

7.0 Implant Procedure continued

7.8 Orientation of the Inflow Valve Conduit

Before implantation, ensure that:

- Outflow Graft is pre-clotted on the external surface with serum or other standard pre-clotting agent.
- Inflow and Outflow Valve Conduits are pre-clotted on their external surfaces.
- XVE LVAD is correctly assembled and all joints, including the Inflow and Outflow Valve Conduit connections, are tight.
- XVE LVAD is completely primed with sterile normal saline.
- Outflow Valve Conduit connection is topped-off with sterile normal saline.


Selecting Optimal Orientation

Selection of the optimal Inflow Valve Conduit orientation at the ventricular apex is important. Care must be taken to avoid excessive angulations of the Inflow Valve Conduit once the XVE LVAD is *in-situ*. The ideal orientation will allow a straight path from the Inflow Valve Conduit to the XVE LVAD chamber (**Figure 5b**).

Inserting the inflow cannula into the ventricular apex can become difficult for a variety of reasons, thereby necessitating twisting and pushing of the Inflow Conduit assembly. Twisting this assembly can result in abnormal valve function. Avoid inflow assembly damage by holding the assembly at the bell housing and pushing the assembly *without twisting*. Proper alignment of the conduit will lead to longer valve life. Therefore, take care to NOT twist the Inflow Valve assembly once the pump is in its final position.

When positioning the inflow cannula, consider the likelihood that the dilated Left Ventricle may shrink in size as the XVE LVAD assumes its workload.

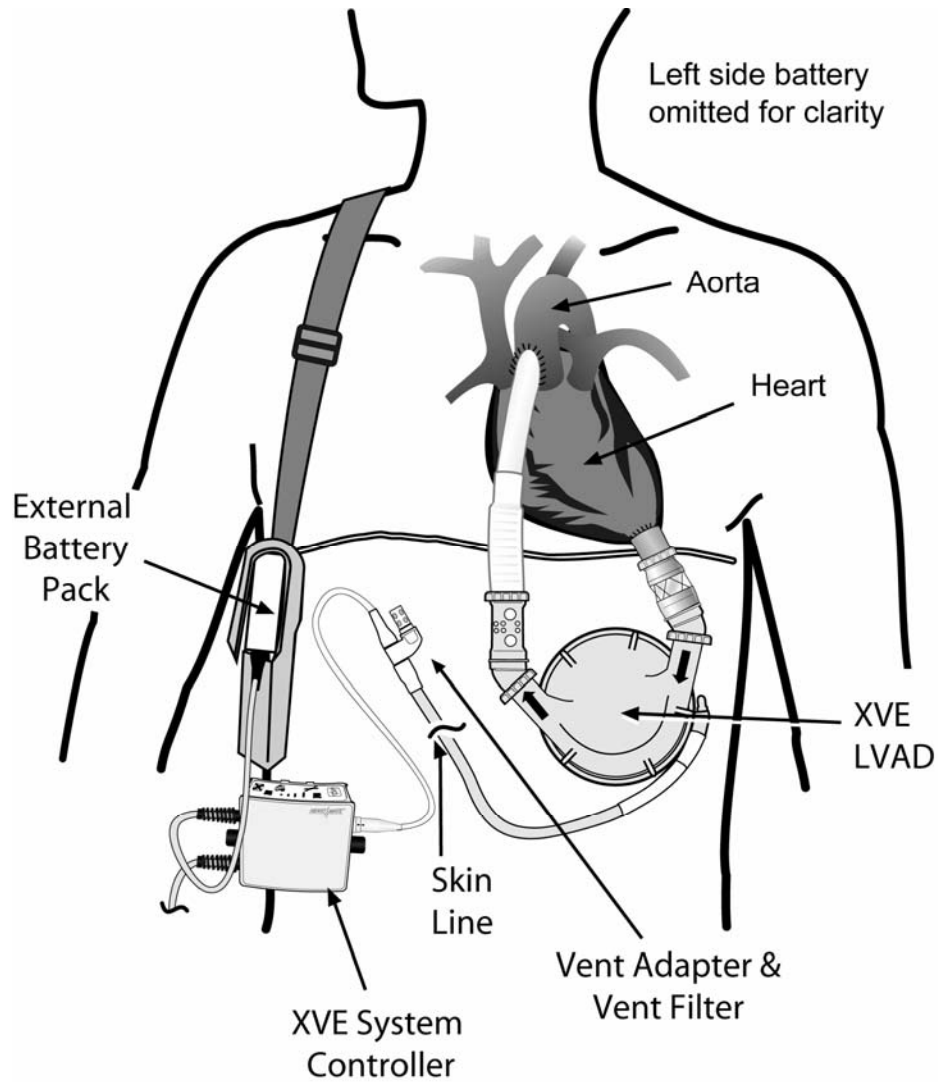
Once alignment is satisfactory, firmly secure the Apical Sewing Ring with the attached green non-absorbable suture.

 **Note:** Additional heavy ligature may be employed to insure that this connection is secure and leak-resistant.

7.0 Implant Procedure continued

7.8 Orientation of the Inflow Valve Conduit cont.

Figure 5b Implanted and worn components of HeartMate XVE LVAS.



7.0 Implant Procedure continued

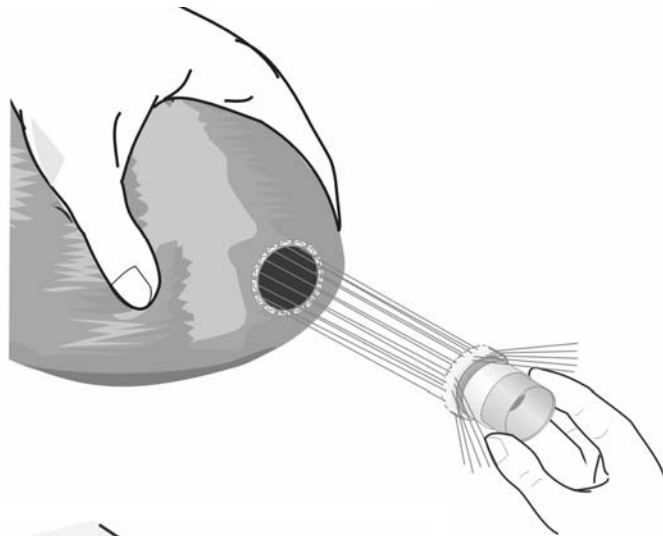
7.8 *Orientation of the Inflow Valve Conduit* cont.

Figures 6A-C Preparing the Ventricular Apex Conduit site.

A



B



C



7.0 Implant Procedure continued

7.8 *Orientation of the Inflow Valve Conduit* cont.


WARNING !

- Prior to advancing the Inflow Valve Conduit into the Left Ventricle (LV) through the Apical Sewing Ring, remove the glove tip from the Inflow Valve Conduit and remove the Centering Device from the Apical Sewing Ring.
- Inspect the ventricle and remove any previously formed clots or a catastrophic embolism may occur.

CAUTION !

Do NOT twist or pull on the Inflow Valve Conduit assembly. The Inflow Valve Conduit and the valve leaflets could be distorted and valve function compromised. Hold the conduit by the frame only.

7.9 *Attaching the Outflow Graft*

- 1 Measure and cut the graft to the appropriate length.
- 2 Anastomose the Outflow Graft to ascending aorta in an end-to-side fashion.
 -  **Note:** Remove tissue from the anastomosis site in order to produce an elliptical or round opening, as opposed to a slit (slits can only open under pressure). In addition, the anastomosis should be non-restrictive and the suture line should be secure with no evidence of blood loss.

CAUTION !

Do NOT trim or cut the Outflow Graft Bend Relief or a sharp edge could result. This sharp edge could damage the underlying graft material and cause blood loss.

7.0 Implant Procedure continued

7.9 *Attaching the Outflow Graft* cont.

- 3 Cross-clamp the graft and remove the Thread Protectors.

CAUTION !


Do NOT clamp Outflow Graft Bend Relief or a kink may occur. This kink could lead to abrasion and blood loss through the graft.

- 4 Using the Screw Ring, attach the proximal end to Outflow Valve Conduit.

WARNING !

Insure that the Thread Protectors have been removed from the Outflow Valve Conduit and Graft before attempting connection, or connection will not be possible.

- 5 Turn the Screw Ring until a clicking sound is heard, and then continue turning until the connection is tight.

 **Note:** Hand tighten only; do NOT use tools.

- 6 Insure that the connection is tight.

- 7 Allow the graft to back-fill with blood from the aorta before de-airing the LVAD (see 7.10 *De-Airing the XVE LVAD*).

WARNING !

Failure to adequately secure the Outflow Graft Screw Ring may allow this connection point to loosen and result in potentially fatal hemorrhage.

7.0 Implant Procedure continued

7.10 De-Airing the XVE LVAD

Once the XVE LVAD is in place and Outflow Graft anastomosis is complete, completely evacuate any residual air from the XVE LVAD pumping chamber.


 **Note:** This must be done before electric LVAD activation. Intraoperative transesophageal echocardiography may be used to monitor the presence of air in the aorta. It is advisable to monitor the left atrial pressure, which should be maintained at greater than 10 mmHg.

Figure 7 Removing the “Bullet.”



De-Airing is performed using the Hand Pump.


To connect the Hand Pump:

- 1 Remove “bullet” from the pump’s percutaneous tube, after the tube has been exteriorized (see **Figure 7**).
- 2 Remove tunneling shroud (covering the vent holes) by sliding the shroud over the percutaneous tube (see **Figure 8**).

Figure 8



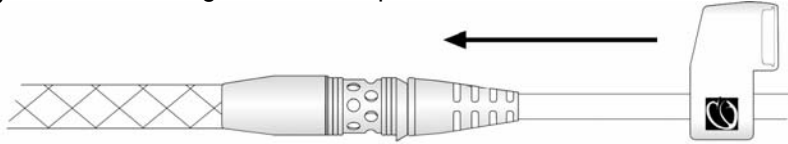
- 3 Slide the Vent Adapter over the percutaneous tube (**Figure 8**) until the Vent Adapter completely covers the blue O-rings *and* the black ring locks into place (ie, becomes completely visible and is slightly offset).

 **Note:** The Vent Adapter is fully functional when attached in either orientation (ie, facing the patient or away from the patient); however, for ease of access, consider orienting Vent Adapter with the opening facing *away from* the patient (see **Figure 8** for suggested orientation).

7.0 Implant Procedure continued

7.10 De-Airing the XVE LVAD cont.

Figure 9 Attaching the Vent Adapter.




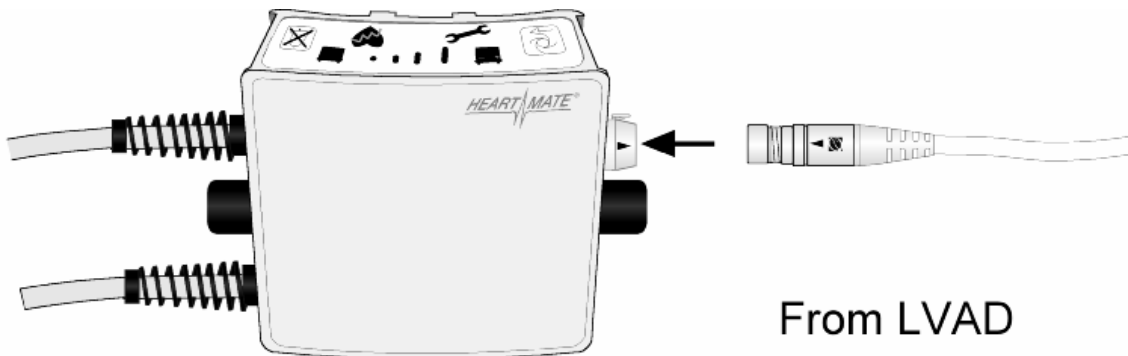
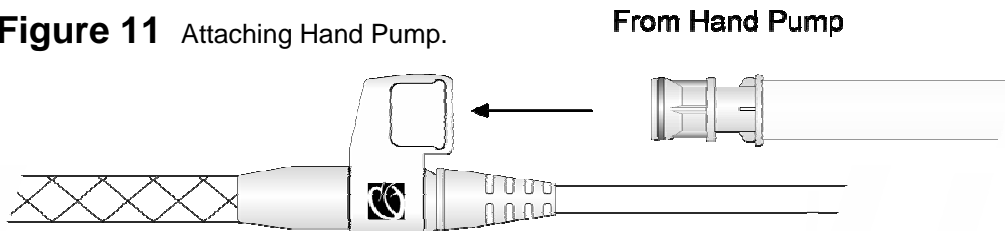
- 4 Insure that power leads from the PBU Cable to the XVE System Controller are NOT connected.
- 5 Connect the XVE LVAD to the XVE System Controller by aligning the arrow on the percutaneous tube connector with the arrow on the white System Controller socket (**Figure 10**); press together until fully engaged.
 **Note:** Insure that connection is fully engaged by gently pulling on percutaneous tube connector.

Figure 10 Connecting the percutaneous tube to XVE System Controller.



- 6 Attach the hand pump by inserting the connector from the hand pump into the Vent Port on the Vent Adapter until a click is heard (**Figure 11**).

Figure 11 Attaching Hand Pump.



7.0 Implant Procedure continued

7.10 De-Airing the XVE LVAD cont.

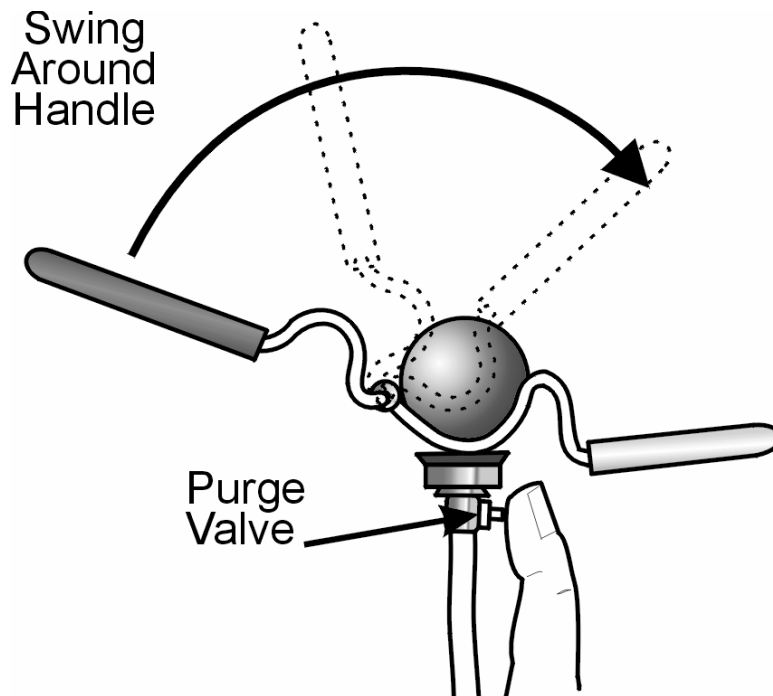
- 7 Cross-clamp the Outflow Graft at the distal end.

CAUTION !

Do NOT clamp the Outflow Graft Bend Relief or a kink may occur. This kink could lead to abrasion and blood loss through the graft.

- 8 Position the Outflow Graft in a vertical position, such that an arch forms the highest point.
- 9 Insert a vent needle into the Outflow Graft at the highest point in the lumen, between the clamp and the Outflow Conduit connection (anterior side), to optimized air removal.
Note: Position vent needle distal to the end of the Bend Relief to allow easy access for later sealing when de-airing is complete.
- 10 With the cross clamp on the Outflow Graft and the graft vent in place, depress the purge valve on the hand pump and collapse the bulb (**Figure 12**).


Figure 12 Depressing Purge Valve and collapsing bulb.



7.0 Implant Procedure continued


7.10 De-Airing the XVE LVAD cont.

- 11 Release the purge valve and then release the bulb.

 **Note:** The bulb should remain slightly collapsed. The vacuum that the bulb creates causes the diaphragm in the XVE LVAD to be pulled into its “fill” position.

- 12 Wait 10 seconds, then press the purge valve. When the bulb is fully expanded, release the purge valve.

- 13 Reduce cardiopulmonary bypass flow to allow filling of the left ventricle (LV) and XVE LVAD by diverting at least 2 liters per minute of blood to the ventricle.


 **Note:** A vent needle may be placed into the ventricular wall to further remove entrapped air. Remove the needle once the air is evacuated to eliminate an access point for air entry once LVAD operation is initiated. In addition, the surgical field may be optionally flooded with sterile normal saline to further minimize the risk of air entry and possible embolism.

CAUTION !

Remove all vent needles on the inflow side of the XVE LVAD, including needles in the pulmonary vein, left atrium, and the Left Ventricle before initiation of pumping.

- 14 Lower patient’s head to a Trendelenburg position.

- 15 Slowly begin actuating XVE LVAD with the hand pump.

 **Note:** If the bulb does not inflate fully between hand pump compression cycles, poor filling of the XVE LVAD from the ventricle may be the cause. If this occurs, additional flow may need to be delivered to fill the LV. Also check positioning of the Inflow Valve Conduit to ensure that an occlusion is not preventing pump filling.


WARNING !

- All entrapped air must be removed from the XVE LVAD blood pumping chamber and conduits in order to minimize the risk of an air embolus.
- Remove connection between Percutaneous tube and XVE System Controller prior to use of defibrillator or the XVE system could be permanently damaged.
- Before connecting or disconnecting the XVE System Controller from the XVE LVAD, remove all power sources.

7.0 Implant Procedure continued

7.10 De-Airing the XVE LVAD cont.

- 16 When adequate filling of the LVAD is assured, partially remove the Outflow Graft cross-clamp while continuing to manually hand pump the XVE LVAS.


 **Note:** Blood volume should be shifted from cardiopulmonary bypass to the patient to allow for adequate XVE LVAD filling.

- 17 Continue hand pumping slowly to evacuate all air from the system and to allow the XVE LVAD to fill completely.

WARNING !

Initial weaning of cardiopulmonary bypass should insure a minimum of two (2) liters per minute of blood for flow to the XVE LVAD in order to prevent air embolism. Prolonged deaeration may be due to inadequate blood volume in the pump.

- 18 Remove the vent needle from the Outflow Graft only when air can no longer be observed exiting through the needle.

 **Note:** If air persists in the pump Outflow Graft for a prolonged period (more than 5 – 10 minutes), rule out leaks at the Inflow Valve Conduit and pump connection.

- 19 Once air is evacuated from Outflow Graft, suture vent hole to eliminate access point for air re-entry when LVAD operation is initiated.

- 20 When all air has been removed from the LVAD and the vent hole has been sealed, initiate electric actuation of the LVAD (see 7.11 *Startup and Weaning from Cardiopulmonary Bypass*).

WARNING !

All entrapped air must be removed from the XVE LVAD blood pumping chamber and conduits in order to minimize the risk of air embolus.

7.0 Implant Procedure continued

7.11 Startup and Weaning from Cardiopulmonary Bypass

After slow manual pumping has succeeded in evacuating all air from the system and the XVE LVAD is filling completely, Fixed Rate pumping may begin at 50 beats per minute (bpm).

To begin electric actuation of the LVAD

- 1 Disconnect the hand pump from the Vent Adapter (**Figure 13**).
- 2 Attach sterile Vent Filter (supplied with the pump) to the Vent Adapter by inserting it into the Vent Port until it snaps into place securely (**Figure 14**).

WARNING !

Never allow any fluids to enter the Percutaneous tube through the Vent Port or Vent Filter, or the pump may stop.

Figure 13 Disconnecting the Hand Pump.

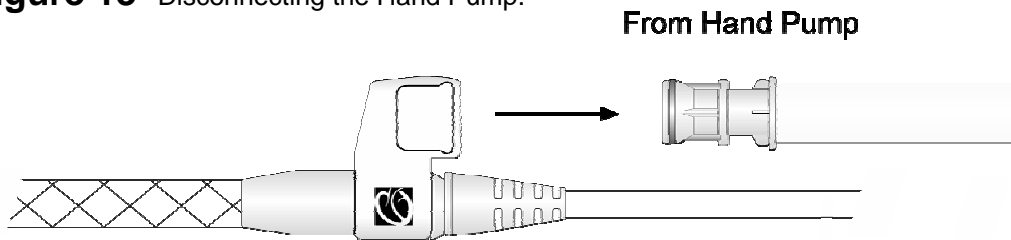
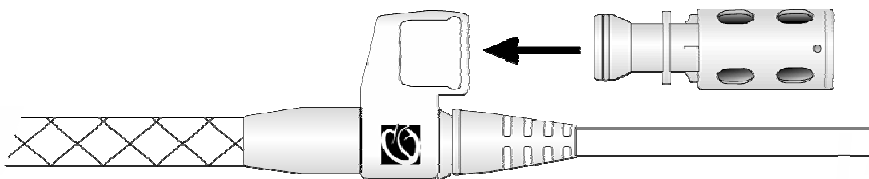


Figure 14 Attaching Vent Filter to the Vent Adapter.



7.0 Implant Procedure continued

7.11 Startup and Weaning from Cardiopulmonary Bypass cont.

To begin electric actuation of the LVAD


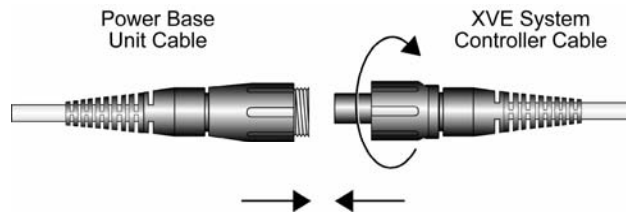


- 3 Connect the **white** connector of the Power Base Unit (PBU) Cable to the **white** connector of the XVE System Controller Cable by aligning the connectors and tightening the fitting (**Figure 15**).
 **Note:** The XVE LVAD will immediately begin operation at 50 beats per minute (bpm) and the System Monitor will show XVE LVAD rate, flow and stroke volume while indicating the Fixed Rate Mode and the 50 bpm set point.

Figure 15 Connecting XVE System Controller to PBU Cable (white leads first).



- 4 Connect the **black** connectors in the same fashion as the white connections (as in Step 3).
 **Note:** A flashing YELLOW BATTERY will illuminate and the PBU alarm will sound until the XVE System Controller Battery Module is installed in the XVE System Controller.
- 5 Reset alarms/advisories using the Alarm Reset Switch on the XVE System Controller.
- 6 Reduce cardiopulmonary bypass to provide ample blood flow to the XVE LVAD.
 **Note:** The goal at this time is to achieve and maintain a stroke volume of 70-80ml.

CAUTION !

Once XVE LVAD is activated, rapidly reduce cardiopulmonary bypass flow to provide ample blood flow to the XVE LVAD. A stroke volume of 70-80ml should be achieved and maintained.

7.0 Implant Procedure continued

7.11 Startup and Weaning from Cardiopulmonary Bypass cont.

To begin electric actuation of the LVAD

- 7 To eliminate XVE System Controller alarm, insert the Battery Module into the XVE System Controller body and screw it down until it is finger-tight (**Figure 16**). Do NOT use tools, a coin, or other similar flat object to insert or tighten the Battery Module. Do NOT over tighten – HAND TIGHTEN ONLY.


 **Note:** The Battery Module enables the XVE System Controller alarm to sound a steady tone if the XVE System Controller loses power while connected to the patient. At this point, no further alarms/advisories should occur.

Figure 16 Inserting the XVE System Controller Battery Module.



- 8 Complete weaning from cardiopulmonary bypass as XVE LVAD rate and flow are increased.

7.0 Implant Procedure continued

7.12 Anchoring the Pump

Eyelets on the XVE LVAD housing serve as attachment points for immobilizing the XVE LVAD *in-situ*. Once the XVE LVAD has been inserted and de-aired, it must be sutured to the abdominal wall or surrounding fascia using hospital-supplied non-absorbable sutures.

Failure to suture the XVE LVAD into place may lead to its movement or migration in the body. This displacement may damage the Inflow Valve(s), percutaneous tube, or Outflow Graft, or traumatize the anastomosis site, resulting in their failure and patient injury or death.

WARNING !

The XVE LVAD must be sutured securely into position to prevent pump displacement and possible serious injury to the patient.

CAUTION !



The Outflow Graft must NOT be kinked or positioned where it could abrade against a pump component or body structure.

Once the pump is immobilized, close incisions in standard fashion.

7.0 Implant Procedure continued

7.13 Transferring the Patient Out of the Operating Room


When it is time to transfer the patient out of the operating room, the XVE LVAS should be switched from Power Base Unit (PBU) to battery power.

- 1 Insert a battery into each of the 2 battery clips.
- 2 Unplug either one of the XVE System Controller connectors from the PBU Cable and connect it to one of the Battery Clips.
 **Note:** The alarm indicating PBU disconnection will sound.
- 3 When the disconnect alarm ceases, unplug the remaining XVE System Controller connector from the PBU Cable and transfer it to the second Battery Clip.
 **Note:** The disconnect alarm should again cease.
- 4 Tuck Batteries safely beside the patient so that the XVE System Controller leads are not under strain.

CAUTION !

Use of expired or defective Batteries may result in reduced operating time or abrupt loss of XVE LVAD function. To prevent deterioration or damage to Batteries:

- Do NOT drop or subject Batteries to strong physical shock. Dropped Batteries should be replaced.
- Do NOT use Batteries in temperatures that are below 15° F (-10°C) or above 105° F (+40° C), or the Batteries may fail suddenly.
- Do NOT leave or store Batteries in extreme temperatures (eg, in cars or car trunks), or Battery life will be shortened.
- Do NOT directly connect negative and positive Battery terminals.
- Recharge used Batteries within 12 hours, or battery life will be shortened.

 **Note:** Because the ability to receive stroke volume and flow data is lost during transport (when the XVE System Controller is no longer attached to the PBU), a portable pressure monitor is usually used during patient transport to gauge effectiveness of the HeartMate XVE LVAS. A cart bearing the PBU and the System Monitor typically follows the patient to his or her room, where the LVAS is re-attached (white leads first) to the PBU and System Monitor.

7.0 Implant Procedure continued

Miscellaneous Warnings

WARNING !

- There may be risks associated with the use of an LVAD in pregnant women or in any woman likely to become pregnant during her period of LVAS support. A growing fetus may dislodge the pump, which may result in device failure or fatal hemorrhage. The effect of an LVAD on a growing fetus is unknown.
- Do NOT subject patients implanted with the HeartMate XVE LVAS to Magnetic Resonance Imaging (MRI), as the LVAD contains ferro-magnetic components and MRI could cause device failure or patient injury.
- Remove connection between Percutaneous tube and XVE System Controller prior to use of defibrillator, or the XVE LVAS could be permanently damaged.
- Before connecting or disconnecting the XVE System Controller from the XVE LVAD, remove all power sources.

End of Section 2

This page intentionally blank.

8.0 Patient Management

Support of a HeartMate XVE LVAS patient in the hospital requires the following equipment on hand and readily available.

Equipment	Primary (required)	Back-Up (required)	Optional
Implanted XVE LVAD	X	--	--
XVE System Controller	X	X	--
Rechargeable Batteries (2 sets)	X (2 sets)	X	X
Battery Clips	X	--	X
HeartWear Accessories*	X	--	X
Power Base Unit (PBU)	X	X	--
Pneumatic Drive Console	--	X	--
Stroke Volume Limiter	--	X	--
Display Module or System Monitor	X	--	--
Controller Battery Module	--	X	--
Vent Adapter	--	--	X
Vent Filter	-	X	--
Hand Pump	X	X	--
System Monitor	--	--	X

*HeartWear accessories include the Battery Holster, Shower Kit, Night Belt, Travel Case and Pocket Pak.


Proper care of patients supported by a HeartMate XVE LVAS requires a thorough understanding of LVAS operation and patient condition. Physician judgment and experience may vary; however, important post-implant care and management issues (outlined on the following pages) must be considered by all caregivers.

8.0 Patient Management continued

8.1 *Treating the Percutaneous Tube Exit Site*

The following points must be considered when caring for a patient supported by the HeartMate XVE LVAS:

- Adhere to aseptic technique any time the exit site is inspected, dressed, or otherwise handled.
- Establish and follow daily exit site care using a persistent antiseptic cleaning agent, such as chlorhexidine-containing scrub solutions.
- After cleansing, dry the exit site to avoid tissue maceration.
- The exit site must be kept clean and dry. Prophylactic topical agents, such as silver sulfadiazine or polymixin-neomycin-bacitracin must NOT be used, as these agents applied to the exit site may macerate the tissue.
- Apply a sterile bandage to the exit site at least daily.
- Immobilize the percutaneous tube with abdominal wraps or binders to reduce trauma to the exit site, especially when the patient is ambulatory, because trauma to the exit site will increase the risk of infection.
- Withdraw all intravascular lines as soon as practical to reduce the risk of systemic infection.
- Use parenteral treatment with antibiotics or surgical drainage, as indicated, in patients with evidence of pump pocket infection.

 **Note:** Fungal infection resulting from organisms such as *Candida albicans*, may be associated with vegetative growth on the device. Persistent system fungal infection (refractory to antimicrobial treatment) may necessitate LVAD replacement.

8.0 Patient Management continued

8.2 *Anticoagulation Therapy*

Heparin is administered in standard fashion during cardiopulmonary bypass to minimize the risk of intraoperative thrombus formation. Once the device is successfully implanted, and the stroke volume generated by the device is adequate, Protamine is administered to reverse the effects of heparin.

Heparin is not routinely used after device implantation, unless low flow conditions (stroke volume <30ml) persist, or if medically indicated. Following reversal of the heparin intraoperatively, 10% low molecular weight Dextran is indicated until the patient can accept oral medication. Inhibition of platelet activity throughout the remainder of implant is maintained by administering 75mg of dipyridamole 3 times daily (t.i.d.) and 80mg of aspirin once daily (q.d.), if not contraindicated.

CAUTION !

A persistent stroke volume of <30ml may require anticoagulation to prevent possible thrombus accumulation.

WARNING !

In the event that the XVE LVAD stops operating, all attempts must be made to restore pump function immediately using electric or pneumatic activation. In the event that the XVE LVAD stops operating and blood is stagnant in the pump for more than few minutes (depending on the coagulation status of the patient) there is a risk of stroke or thromboembolism if, or when, the device is restarted.

WARNING !


- There may be risks associated with performing external chest compressions, in the event of cardiac arrest, due to the location of the Outflow Graft Conduit and the presence of the ventricular apical anastomosis. Performing external chest compressions may result in damage to the Outflow Graft Conduit or the dislodgement of the LVAD inflow tract.
- Cardiac massage under direct vision, performed by a skilled surgeon, may be effective in patients who have had recent device implantation (prior to mediastinal healing).

8.0 Patient Management continued

8.3 *Diagnosing a Blood Leak*

A blood leak from any implanted component of the XVE LVAS is typically identified through the presence of 1 or more of the following symptoms:

- Unexplained internal bleeding (beyond the perioperative period following implant), possibly with painful distention of the abdomen.
- Blood draining from the percutaneous tube exit site, external to the tubing.
- Evidence of decreased hemoglobin/hematocrit.

 **Note:** These symptoms may also occur due to bleeding from native tissue.

WARNING !

There is a risk of embolism at device explant or reoperation if manipulation of the device or cannulae is performed before initiation of cardiopulmonary bypass and stoppage of XVE LVAD pumping.

8.4 *Right Heart Failure*

Some patients suddenly develop Right Ventricular (RV) failure during, or shortly after, device implantation. The onset of RV dysfunction in these patients is often accompanied by the inability of the XVE LVAD to fill and by drastically reduced flow rates. Limited filling is further exacerbated in the presence of right heart failure with an elevated trans-pulmonary pressure gradient or high pulmonary vascular resistance.

CAUTION !

Right heart failure can occur following implantation of the device. Right ventricular dysfunction, especially when combined with elevated pulmonary vascular resistance, may limit XVE LVAS effectiveness due to reduced filling of the XVE LVAD.

Treatment for patients in right heart failure typically consists of the use of inotropes to augment RV contractility, fluid management, hyperventilation, and pharmacological modulation of pulmonary vascular resistance (ie, nitric oxide). As a last resort, a right ventricular assist device may be employed.

8.0 Patient Management continued

8.5 *Avoiding Static Electric Discharge*

WARNING !

Following implant, patients should avoid strong static discharges (eg, television or computer screens) as exposure to strong static discharges can damage the electrical parts of the system and cause the XVE LVAD to stop.

8.6 *Infection Control*

Infection among implantable-LVAD patients is common, especially in patients with multi-system organ failure who require prolonged stays in the ICU. Infection rates can be minimized, however, by applying the following approaches to patient management:

- Strict adherence to aseptic technique during exit site dressing (as outlined above).
- Withdraw all intravascular lines as soon as practical to reduce the risk of systemic infection.
- Administer parenteral treatment with antibiotics or surgical drainage, as indicated, in patients with evidence of pump pocket infection.

Refer to *Infection Control Guidelines* (document number H017-0702) for more information about approaches to successful infection control used by experienced LVAD implant centers with low rates of infection.

8.7 *Anticipating End of Pump Life*

The XVE LVAS may eventually need to be replaced. Although symptoms are not universal, it has been observed that VADs nearing their end of life often exhibit the following tendencies:

- More frequent alarms, particularly Yellow Wrench alarms (for Power Limit Advisories) and Red Heart alarms (for Lo Beat Rate).
- Significant increase or decrease in flow rates.
- New or unusual noises, such as grinding or screeching.
- New or unusual sensations when beating.
- Requiring vent filter changes several times per week.

VADs exhibiting sudden or significant operating changes, or new or different sounds or sensations, should trigger prompt evaluation for cause.

8.0 Patient Management continued

8.8 *Managing Physiologic Conditions that May Affect Pump Life*

Clinical experience indicates that high arterial pressure can put undue stress on the Inflow Valves, which can lead to valve incompetence that may result in diminished mean time to pump failure. Care must be taken, therefore, to reduce patient arterial pressure whenever possible (eg, during rest or sleep).

8.9 *Discharge Planning*

Adequate discharge planning contributes to successful outcomes. A variety of tools and documents are offered by Thoratec to support discharge-planning activities, including the *HeartMate Community Living Manual* (document number 28963). Also see *Patient Discharge*, Section 9.0 of this manual.

9.0 Patient Discharge

Patients discharged to a lower care facility, or to home, must be trained in device use, maintenance, and trouble-shooting as described in the *HeartMate XVE LVAS Operating Manual*. In addition, device malfunction may necessitate emergency treatment; therefore, patients should not be more than 2 hours from a XVE LVAS healthcare facility with trained personnel.

The following equipment is required for patients who reside outside a hospital setting:

Equipment	Primary (required)	Back-Up (required)	Optional
Implanted XVE LVAD	X	--	--
XVE System Controller	X	X	--
Rechargeable Batteries (2 sets)	X (2 sets)	--	X
Emergency Power Pak (EPP)	--	--	X
HeartWear Accessories*	X	--	X
Power Base Unit (PBU)	X	--	--
Battery Clips	X	--	--
Display Module	--	--	X
Vent Adapter	--	--	X
Vent Filter	--	X	--
Battery Module	--	X	--
Hand Pump	X	--	X
XVE Patient Handbook	X	--	--

*HeartWear accessories include the Battery Holster, Shower Kit, Night Belt, Travel Case and Pocket Pak.

CAUTION !

A back-up XVE System Controller, spare Batteries, and the hand pump must be with the patients AT ALL TIMES for use in an emergency.

End of Section 3

10.0 Exchanging a New Inflow Valve Conduit

Prior to a New Inflow Valve Conduit exchange procedure, transport the patient to a cardiovascular operating room. Prep and anesthetize the patient according to standard procedures and then initiate cardiopulmonary bypass. Once bypass has been established, stop the LVAD from pumping by disconnecting power from the XVE System Controller, and then disconnecting the XVE System Controller from the percutaneous tube. Perform a sternotomy with extended midline abdominal incision, or other appropriate surgical approach, to expose the existing Inflow Valve Conduit and Outflow Graft by dissecting scar tissue.

CAUTION !

The percutaneous tube and XVE System Controller on an implanted patient is non-sterile. Take proper precautions to avoid contamination of the sterile field.

CAUTION !

Do NOT clamp the Outflow Graft Bend Relief or a kink may occur. This kink could lead to abrasion and blood loss through the graft.

WARNING !

There is a risk of air embolism at reoperation if manipulation of the device or cannulae is performed prior to initiating cardiopulmonary bypass and stopping the pump.

WARNING !

The New Inflow Valve Conduit (c/n 2033) is supplied sterile for single-use only. Use sterile technique to remove the New Inflow Valve Conduit from its jar.

WARNING !

Prior to performing a valve exchange procedure, the New Inflow Valve Conduit must be rinsed and pre-clotted and the Exchange Tools must be sterilized.

10.0 Exchanging a New Inflow Valve Conduit continued

10.1 Valve Preparation and Preclotting

WARNING !

The New Inflow Valve Conduit (c/n 2033) is supplied sterile for single-use only. Use sterile technique to remove the New Inflow Valve Conduit from its jar.

WARNING !

Prior to performing the valve exchange procedure, the New Inflow Valve Conduit must be rinsed and pre-clotted and the Exchange Tools must be sterilized.

10.1.1 Prior to Exchange

- 1 Use sterile technique to remove the New Inflow Valve Conduit from jar.
- 2 Confirm that the serial number on the jar matches the number on the tag attached to the valve and printed on the device tracking labels.
- 3 Attach 1 device tracking label to the device tracking form and place other into the patient's medical record.
- 4 Remove and discard the white serial number tag on the valve conduit.

10.1.2 Pre-Clotting

See Section 7.3B, *Pre-clotting the New Inflow Valve Conduit*, for instructions on pre-clotting the external surfaces of the New Inflow Valve Conduit.

WARNING !


Prior to use, the external surfaces of the New Inflow Valve Conduit must be pre-clotted to facilitate hemostasis to prevent the possibility of air entering the patient's circulatory system and to prevent bleeding from the XVE LVAD once the system is re-actuated.

10.0 Exchanging a New Inflow Valve Conduit continued

10.1 *Valve Preparation and Pre-clotting* cont.

10.1.3 Preparing the New Inflow Valve Conduit for Exchange

- 1 Once the New Inflow Valve Conduit is pre-clotted per procedure 10.1.2, prepare the valve conduit for exchange.
- 2 If exchanging an Inflow Valve Conduit (housing-portion only) in a patient who is already implanted with a New Inflow Valve Conduit (2-piece design), separate the inlet cannula from the valve assembly by following steps 2a and 2b below.

 **Note:** For this procedure the inlet cannula on the new valve assembly is not used, as the previously-implanted 1 will be retained.

- a Hold the bell graft nut in one hand.
- b Using your other hand, unscrew the screw ring by turning it *counter-clockwise* until it detaches from the valve assembly.

CAUTION !

Do NOT separate the inlet cannula from the valve assembly if replacing the valve conduit in a patient who has previously been implanted with a 1-piece Inflow Valve Conduit.

OR

- 2 If exchanging a 1-piece Inflow Valve (c/n 1033) for a new 2-piece designed Inflow Valve Conduit (c/n 2033), the inlet cannula should remain attached to the new assembly.

10.0 Exchanging a New Inflow Valve Conduit continued


10.2 Exchanging Inflow c/n 2033 for 2033 - housing-portion only (2-piece model to 2-piece model)


WARNING !

There is a risk of air embolism:

- If the device or cannulae are manipulated prior to initiation of cardiopulmonary bypass and pump stoppage.
- If proper de-airing is not performed prior to pump actuation.

- 1 To exchange the Inflow Valve (housing-portion only) **on a patient who is already implanted** with a New Inflow Valve Conduit (2-piece design), separate the inlet cannula from the valve housing by detaching the screw ring (as outlined in steps 1a and 2b below and illustrated in **Figure 17**).
 - a Secure the bell graft nut using the Inflow Valve Bell Nut Tool (p/n 100401).

 **Note:** Use the clotting slots for anti-rotation.
 - b Unthread the screw ring using the Inflow Valve Screw Ring Tool by turning the screw ring *counter-clockwise* until it detaches.

 **Note:** The previously implanted inlet cannula will remain connected to the apical sewing ring.
- 2 Unscrew the valve housing from the inlet elbow of the LVAD (**Figure 17**). Use the Bell Nut Tool to disconnect the valve housing from the LVAD by placing it on the belt nut portion of the valve housing.

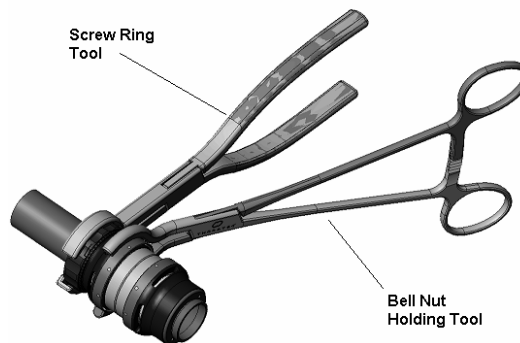


Figure 17 Unscrewing the Screw Ring using the surgical tools.

10.0 Exchanging a New Inflow Valve Conduit continued

10.2 *Exchanging Inflow Valve Catalog Number 2033 for 2033 - housing-portion only (2-piece model to 2-piece model)* cont.


- 3 Place explanted Inflow Valve Conduit in a basin of sterile normal saline solution.
 **Note:** After the exchange procedure is complete, call Thoratec Corporation (800-456-1477 in the US; 925-847-8600 outside the US) for a Returned Materials Authorization (RMA) number and return the explanted Inflow Valve Conduit to Thoratec Corporation.
- 4 Attach the valve housing base of the New Inflow Valve Conduit (outlet 25mm graft attachment portion) to the inflow side of the LVAD by grasping the outlet bell graft nut and screwing it onto the inlet elbow (**Figure 18**).



Figure 18 Attaching the New Inflow Valve Conduit to the inflow side of the LVAD by grasping the outlet bell graft nut and screwing it onto the Inlet Elbow.

WARNING !

Failure to adequately secure the New Inflow Valve Conduit may allow these connection points to loosen and result in potentially fatal hemorrhage.

- 5 Insert the inlet cannula into the New Inflow Valve assembly by aligning the valve.

CAUTION !

Do NOT twist or pull on the New Inflow Valve Conduit. The New Inflow Valve Conduit and valve leaflets could be distorted and valve function compromised.

10.0 Exchanging a New Inflow Valve Conduit continued

10.2 *Exchanging Inflow Valve c/n 2033 for 2033 - housing-portion only (2-piece model to 2-piece model)* cont.

- 6 Hand tighten the screw ring by turning it *clockwise* until you hear a clicking sound, and then continue turning until the connection is tight.

CAUTION !

All connections should be hand-tightened only. Do NOT use tools or other instruments to tighten any of the connection on the HeartMate device. Tools are provided only to aid *removal* of the Screw Ring.

- 7 Insure that all connections are tight.
- 8 See section 7.10 of this manual for instructions on:
 - De-airing of the left ventricle and the LVAD,
 - Electrical actuation of the device, and
 - Weaning the patient off bypass.

10.0 Exchanging a New Inflow Valve Conduit continued

10.3 *Exchanging Inflow Valve c/n 1033 for 2033 - full assembly (1-piece model to 2-piece model)*

WARNING !

There is a risk of air embolism:


- If the device or cannulae are manipulated prior to initiation of cardiopulmonary bypass and pump stoppage.
- If proper de-airing is not performed prior to pump actuation.

- 1 Carefully cut the sutures securing the inlet cannula into the apical sewing ring to avoid damaging the apical sewing ring.
- 2 Remove the entire Inflow Valve Conduit, including the inlet cannula, from the apical sewing ring with a gentle twisting motion.

CAUTION !

A 1-piece Inflow Valve Conduit must be replaced by removing the entire Inflow Valve Conduit, including the implanted inlet cannula, from the Apical Sewing Ring.

- 3 Unscrew the valve housing from the inlet elbow of the LVAD by hand.
- 4 Place explanted 1-piece Inflow Valve in a basin of sterile normal saline solution.

 **Note:** After exchange procedure is complete, call Thoratec Corporation (800-456-1477 in the US; 925-847-8600 outside the US) for an RMA number and return the explanted Inflow Valve Conduit to Thoratec Corporation.

10.0 Exchanging a New Inflow Valve Conduit continued

10.3 *Exchanging Inflow Valve c/n 1033 for 2033 - full assembly (1-piece model to 2-piece model)* cont.

- 5 Attach the valve housing base of the New Inflow Valve Conduit (Outlet 25mm graft attachment portion) to the inflow side of the LVAD by grasping the outlet bell graft nut and screwing it onto the inlet elbow (**Figure 19**).



Figure 19 Attaching the New Inflow Valve Conduit to the inflow side of the LVAD by grasping the outlet bell graft nut and screwing it onto the Inlet Elbow.

WARNING !

Failure to adequately secure the New Inflow Valve Conduit may allow these connection points to loosen and result in potentially fatal hemorrhage.

- 6 Insert the inlet cannula of the new Inflow Valve Assembly through the diaphragm and into the existing silicone sleeve of the apical sewing ring until the sintered titanium surface is fully seated against the edge of the cuff.
- 7 Secure the inlet cannula to the silicone sleeve of the apical sewing ring with heavy non-absorbable ligature. Ensure this connection is secure and leak resistant.

CAUTION !

Do NOT twist or pull on the New Inflow Valve Conduit. The New Inflow Valve Conduit and the valve leaflets could be distorted and valve function compromised.

10.0 Exchanging a New Inflow Valve Conduit continued

10.3 Exchanging Inflow Valve c/n 1033 for 2033 - full assembly (1-piece model to 2-piece model) cont.

WARNING !

The junction between the Apical Sewing Ring and the inlet cannula must be secure to prevent catastrophic separation or air entrapment with resulting embolization.

CAUTION !

All connections should be hand-tightened only. Do NOT use tools or other instruments to tighten any of the connections on the HeartMate device. Tools are provided only to aid *removal* of the Screw Ring.

- 8 Insure that all connections are tight.
- 9 See Section 7.10, *De-Airing the XVE LVAD*, for instructions on:
 - De-airing the left ventricle and the LVAD,
 - Electrical actuation of the device, and
 - Weaning the patient off bypass.

11.0 Explanting the XVE LVAD

- 1 Place patient on cardiopulmonary bypass and establish flow.
- 2 Disconnect power from the XVE System Controller, and then disconnect the XVE System Controller from the percutaneous tube to stop pumping.
- 3 Expose the HeartMate XVE LVAD and carefully dissect it free.
- 4 Cut out eyelet sutures connecting the XVE LVAD to the abdominal wall or fascia.

WARNING !


There is a risk of embolism at device explant or reoperation if manipulation of the device or cannulae is performed before initiation of cardiopulmonary bypass and stoppage of XVE LVAD pumping.

- 5 Cross-clamp the Outflow Graft just distal to the Outflow Valve Conduit and divide the graft.
- 6 Divide the ligatures securing the Apical Sewing Ring to the Inflow Valve Conduit, and remove the Inflow Valve Conduit from the ventricle.
- 7 Dissect the percutaneous tube between the XVE LVAD body and the abdominal wall.
- 7 Cut the percutaneous tube and remove the externalized portion.

CAUTION !

The Percutaneous tube at explant is not sterile and care must be taken to avoid contamination of the sterile field. The cut off fingertips of a sterile, non-powdered glove may be placed on the ends of the tube once it is cut to minimize the risk of the tube contacting and contaminating the sterile field.

- 9 Remove XVE LVAD from the abdomen or preperitoneal pocket and remove the remaining portion of the percutaneous tube, from-the-inside-out, by careful dissection.
- 10 Close percutaneous tube exit site in standard fashion.
- 11 Remove Outflow Graft remnant from the aorta and repair the anastomosis site.

 **Note:** Once explanted, the HeartMate XVE LVAS should be returned to Thoratec Corporation in the Thoratec-supplied Explant Kit. Directions for proper handling and return are included in the kit.

12.0 Device Tracking and Reporting Requirements

The LVAS is considered a life-sustaining medical device and must be tracked per US Food and Drug Administration (FDA), Health Canada, and other foreign regulatory agency regulations. Compliance is mandatory. Accordingly, all device-tracking paperwork shipped with the device must be completed and promptly returned to Thoratec. In addition, any device malfunctions must be reported to Thoratec by the implanting center.

13.0 Service

Thoratec Corporation employs highly trained representatives, technicians, and engineers throughout the world to serve you; and, at your request, to provide additional training in the use of Thoratec products and related procedures. In addition, Thoratec maintains a professional staff to provide technical and medical consultation to product users on a routine and emergency basis.

For supplemental information regarding Thoratec's client support services, contact your local Thoratec representative or contact Thoratec directly.

14.0 Testing and Classification

The HeartMate XVE LVAS has been thoroughly tested and classified by Underwriters Laboratories (UL) to fire, casualty, and electric shock hazard requirements of UL 2601-1. In addition, the HeartMate XVE LVAS meets the following European EN safety standards: EN 60601-1: 1987, Amendment 1:1993, and Amendment 2:1995. These standards require making the following declarations and stating the type and degree of protection for listed hazards.

Declaration Concerning General Safety Standards

Type	Degree of Protection
Mode of Operation	Continuous
Method of Sterilization	100% EtO for blood pump and all sterile accessories
Type of protection against electrical shock	Class I (grounded) and internally powered
Degree of protection against electric shock	Type CF (Cardio Floating)
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
Degree of protection against harmful ingress of water	System Driver - IPX3 PBU - IPX0 System Monitor (s/n <2000 - IPX0) System Monitor (s/n >2000 - IPX1)



Medical Electric Equipment
 with respect to shock, fire,
 mechanical and other specified
 hazards only in accordance with
 UL 2601-1 and CAN/CSA C22.2
 No.601-1 7D72

Declaration and Guidance Concerning Electromagnetic Emissions

The HeartMate XVE LVAS is intended for use in the electromagnetic environment specified below. The customer or the user of the HeartMate XVE LVAS should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment—Guidance
RF emissions CISPR 11 EN 55011	Group 1	The HeartMate XVE LVAS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11 EN 55011	Class B	The HeartMate XVE LVAS is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2 EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3 EN 61000-3-3	Complies	
Radiated emissions, magnetic field MIL-STD-461E	RE101	The HeartMate XVE LVAS generates magnetic fields due to the presences of RF energy created by its internal function. Therefore, its magnetic field emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Declaration and Guidance Concerning Electromagnetic Immunity for all HeartMate XVE LVAS equipment, including the PBU & System Monitor

The HeartMate XVE LVAS is intended for use in the electromagnetic environment specified below. The customer or the user of the HeartMate XVE LVAS should assure that it is used in such an environment.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2 EN 61000-4-2	min. ±6 kV contact min. ±8 kV air	Power Base Unit and System Monitor (s/n below 2000) [±6] kV contact [±8] kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic discharge (ESD) IEC 61000-4-2 EN 61000-4-2	min. ±6 kV contact min. ±8 kV air	System Monitor (s/n above 2000), LVAD, and System Driver [±8] kV contact [±15] kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4 EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5 EN 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 EN 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s where $U_T = 100 \text{ VAC}, 120 \text{ VAC}, 230 \text{ VAC}, \text{ or } 240 \text{ VAC},$	Mains power quality should be that of a typical commercial or hospital environment. The Power Base Unit contains an internal battery, which will provide uninterruptible power for a minimum of ½ hr. NOTE: U_T is the A.C. mains voltage prior to application of the test level.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 EN 61000-4-8	3 A/m	3 A/m	If disturbance occurs, it may be necessary to position the HeartMate XVE LVAS further from sources of power frequency magnetic fields or install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

Declaration and Guidance Concerning Electromagnetic Immunity for Life-Sustaining HeartMate XVE LVAS Equipment, including LVAD, System Controller & Batteries

The HeartMate XVE left ventricular assist device (LVAD), System Controller, and batteries are intended for use in the electromagnetic environment specified below. The customer or the user of the *HeartMate XVE LVAD, System Controller, and batteries* should assure that they are used in such an electromagnetic environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the HeartMate XVE LVAD, System Controller, and batteries (including cables), than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended Separation Distances			
Conducted RF IEC 61000-4-6 EN 61000-4-6	Min. 3 Vrms 150 kHz to 80 MHz outside ISM bands ^a	[3] Vrms	$d = \left[\frac{3.5}{3} \right] / P$
	Min. 10 Vrms 150 kHz to 80 MHz in ISM bands ^a	[10] Vrms	$d = \left[\frac{12}{10} \right] / P$
Radiated RF IEC 61000-4-3 EN 61000-4-3	Min. 10 V/m 80 MHz to 2.5 GHz	[10] V/m	$d = \left[\frac{12}{10} \right] / P$ 80 MHz to 800 MHz $d = \left[\frac{23}{10} \right] / P$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). ^b
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^c should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment that is marked with the IEC symbol for non-ionizing radiation.



continued

Declaration and Guidance Concerning Electromagnetic Immunity for Life-Sustaining HeartMate XVE LVAS Equipment, including LVAD, System Controller & Batteries (continued)


NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies

NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

- ^a The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.95 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.77 MHz.
- ^b Compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into the patient areas. For this reason, an additional factor of (*min. 10/3*) is used in calculating the recommended separation distance for transmitters in these frequency ranges.
- ^c Field strengths from fixed transmitters, such as base stations for radios (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HeartMate XVE LVAS is used exceeds the applicable RF compliance level above, HeartMate XVE LVAS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HeartMate XVE LVAS.

The HeartMate XVE LVAS has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2001 Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The HeartMate XVE LVAS generates, uses, and can radiate radio frequency energy; and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult Thoratec Corporation for help.

 **Note:** Special precautions are required for installing and using the HeartMate XVE LVAS within portable and RF communication environments.

WARNING !

Use of equipment and supplies other than those specified in this manual or sold by Thoratec for replacement parts may result in increased emissions or decreased immunity of the HeartMate XVE LVAS.

WARNING !

The HeartMate XVE LVAS should not be used adjacent to other equipment or in a stacked configuration with other equipment. The normal operation of the HeartMate XVE LVAS must be verified when used in these configurations.

15.0 Authorized European Union (EU) Representative

Thoratec Europe, Ltd.
5 Brunel Court, Burrell Road
St. Ives, Cambridgeshire PE27 3LW United Kingdom

End of Section 4