HeartMate® VE LVAS

Vented Electric
Left Ventricular Assist System

DIRECTIONS FOR USE

CAUTION

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

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1.0 Device Description

The HeartMate Vented Electric Left Ventricular Assist System (VE LVAS) consists of an implanted blood pump, external System Controller, and external power supply components. The blood pump (Left Ventricular Assist Device or LVAD) is a pusher-plate type device that is capable of producing a stroke volume of 83 ml, generating approximately 10 liters of blood flow per minute, and a beat rate up to 120 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 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 System Controller provides two modes of operation, either a fixed beat rate mode or a variable beat rate mode that responds to physiologic demand.

LVAD function is adjusted by a switch-panel located on the top of the System Controller, or via a separate system monitor. The System Controller audible and visual alarms alert the user of a potentially dangerous condition. Alarms are sounded primarily if there are either low flow/stroke conditions or if the batteries are low (see Operating Manual for full discussion of alarms).

The VE LVAS is routinely powered through the System Controller by either a pair of wearable, rechargeable batteries, or through connection to a dedicated power supply device. An additional back-up portable power supply that can be used in periods of extended power outage is the emergency power pack, or EPP. In the event that electric motor actuation is disrupted, the VE LVAD may also 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 VE LVAS is intended for use as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from nonreversible left ventricular failure. The HeartMate VE LVAS is also indicated for use both inside and outside the hospital.

3.0 CONTRAINDICATION

Body surface area less than 1.5 m^2.

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4.0 WARNINGS AND PRECAUTIONS

4.1 Warnings

Global Items

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 booklet and the HeartMate VE LVAS Operating Manual prior to attempting implantation. Completion of the TCI user training program, including animal implantation and device operation, is required prior to use of the HeartMate Vented Electric Left Ventricular Assist System (VE LVAS).

Do not use the Power Base Unit (PBU) in the presence of Flammable Anesthetic Agents or an explosion could occur.

Connect Power Base Unit and any peripheral devices only to properly tested, grounded and dedicated AC outlets. Do not use an adapter for ungrounded wall outlets or there is an increased risk of electrocution.

Do not connect the Power Base Unit to an outlet controlled by a wall switch or it may be left inoperable.

Do not use this device in pregnant women or any woman likely to get pregnant during their period of LVAS support. A growing fetus will dislodge the pump which may result in device failure or fatal hemorrhage.

Do not subject patients implanted with the HeartMate VE LVAS to Magnetic Resonance Imaging (MRI) as the LVAD contains ferro-magnetic components, and MRI could cause device failure or patient injury.

Avoid strong static discharges (e.g. television or computer monitor screens) as this can damage the electrical parts of the system and cause the VE LVAD to stop.

Keep the Power Base Unit (PBU) away from water. If the PBU has contact with water, shower spray or wet surfaces, the VE LVAD may stop, or users may receive a serious electric shock.

Never store the Hand Pump with the bulb in the collapsed position or it may not work properly when needed.

Specific Implantation Issues

During the implant process, a complete back-up system (VE LVAD implant kit and external components) must be available on-site and in close proximity for use in emergency.

Prior to advancing the inflow valve conduit into the left ventricle through the apical sewing ring, remove glove tip from the inflow valve conduit and the centering tool from the 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 conduit and graft prior to attempting connection or connection will not be possible.

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

Initial weaning of cardiopulmonary bypass should insure a minimum of two liters per minute of blood flow to the VE LVAD in order to prevent air embolism. Prolonged deaeration may be due to inadequate blood supply to the VE LVAD.

Failure to adequately secure the standard outflow graft screw ring suture may allow this connection point to loosen, and result in potentially fatal hemorrhage.

Do not autoclave valve conduits. Doing so will cause damage to the porcine xenograft valves.

Failure to apply the additional retaining suture may result in catastrophic disconnection and potentially fatal hemorrhage.

A minimum of two fully charged Batteries are required at the time of implantation in order to power the system when transporting the patient out of the operating room.

Never allow any fluids to enter the percutaneous lead through the vent port or filter or the pump may stop.

Remove connection between percutaneous cable and System Controller prior to use of defibrillator or the VE system could be permanently damaged.

Patient/System Management Issues

In the event that the VE LVAD stops operating, all attempts must be made to restore pump function immediately, using electric or pneumatic activation. In the event that the VE LVAD 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 should the device be restarted.

Loss of power will cause the VE LVAD to stop and blood pumping to cease. Power must be restored immediately. If power cannot be restored, use the HeartMate Hand Pump to perform pneumatic pump activation.

When the System Controller is disconnected from the percutaneous lead, pump function will stop. The System Controller and power must be reconnected as quickly as possible to resume pump function.

One System Controller lead must be connected to a Battery or the Power Base Unit at all times. Disconnecting both System Controller leads at the same time will result in loss of pump function.

There is a risk of embolism at device explant or reoperation if manipulation of the device or canulae is performed prior to initiation of cardiopulmonary bypass and stoppage of VE LVAD pumping.

Remove connection between percutaneous cable and System Controller prior to use of defibrillator or the VE system could be permanently damaged.

Do not allow the percutaneous lead to become contaminated, or its' inner lumen to become wet or the pump may stop.

4.2 Precautions

Global Items

These Directions for Use address VE LVAD handling, preparation and other perioperative issues. The HeartMate VE LVAS Operating Manual must be used in conjunction with these directions for other important guidelines. These manuals are not intended to replace comprehensive laboratory or educational programs, or to supersede appropriate medical judgment.

Sterile components of the HeartMate VE LVAS are intended for single use only. Do not reuse sterile device components.

Patients with mitral or aortic mechanical valves may be at added risk of accumulating thrombus on the valve when supported with left ventricular assist devices.

Only use the TCI Power Base Unit (PBU) to charge Batteries. Other Battery chargers may damage the Batteries.

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The power entry module on the rear panel (PBU) has been equipped with the proper fuse and set to the appropriate AC mains voltage for your location. Replacement of the fuse should be performed only by qualified service personnel.

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.

Specific Implantation Issues

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 must therefore be rinsed thoroughly prior to attachment to the VE LVAD.

Do not over tighten thread protectors.

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

Do not remove the centering tool until ready to insert the inflow conduit.

Outflow graft must not be kinked or positioned where it could abrade against a pump component or body structure.

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

Patient/System Management Issues

Diligent care throughout the course of support must be exercised to prevent infection and sepsis. Systemic infections and localized infection of the drive-line exist 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 VE LVAS effectiveness due to reduced filling of the VE LVAD.

A persistent stroke volume of ≤ 30 mL may require anticoagulation to prevent possible thrombus accumulation.

Persistent hypercalcemia in the presence of fungal infection may increase the risk of a granular calcium deposition abrading the diaphragm.

An 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 prompt 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 treated.

The percutaneous lead at explant is not sterile, and care must be taken to avoid contamination of the sterile field. Sterile glove fingertips can be attached to the ends of lead once cut to minimize the risk of contact with the sterile field.

When mating cables, do not force connectors together without proper alignment. Forcing connectors together may cause damage to the connectors.

Before connecting or disconnecting the System Controller from the VE LVAD remove all power sources.

A back-up 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 abrupt loss of VE LVAD function.

To prevent deterioration or damage to the Battery:

- Do not drop or subject to strong physical shock. Dropped Batteries should be replaced.
- Do not use below 15°F (-10°C) or above 105°F (+40°C), or they may fail suddenly.
- Do not leave or store Batteries in hot areas (car trunks, etc.) or Battery life will be shortened.
- Do not directly connect the negative and positive Battery terminals.
- Recharge used batteries within 12 hours or Battery life will be shortened.

5.0 ADVERSE EVENTS

Based on the clinical study of 86 patients (see section 7), the risks associated with the use of the HeartMate VE LVAS include the events listed below that occurred in greater than 1% of patients (note, mechanical or electrical equipment failure did not occur). The most frequently occurring event was Hepatic Dysfunction.

- Hepatic Dysfunction (78%)
- Renal Dysfunction (49%)
- Bleeding (44%)
- Neurological Dysfunction (23%)
- Thromboembolism (6%)
- Need for Reoperation (52%)
- Infection (48%)
- Death (24%)
- Right Heart Failure (7%)
- Pulmonary Dysfunction (2%)

Note: The need for reoperation may result from bleeding, infarction, gastrointestinal complications including 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, hypoperfusion, or other mental impairment.

Embolism may result in myocardial or other organ infarction, loss of limb(s), or other vascular obstruction. In addition, it is possible that the LVAS will produce no significant hemodynamic improvement and the patient will have been exposed to the risks of a cardiothoracic procedure.

6.0 RELIABILITY EVALUATION

The purpose of reliability testing is to obtain a reasonable estimate of how long a given device will perform, as intended, without failure. It is incumbent upon the attending physician, therefore, to be prepared for eventual device failures, and to anticipate the need for device replacement should patients require treatment for extended periods of time.

In-vitro reliability testing of 15 VE systems began in July, 1997 (range 318-448 days). Cumulative test time of nearly 17 years (6153 days) produced no critical failures. All 15 complete systems continue on test in September, 1998, without failure.

Based on this *in-vitro* testing to a confidence interval of 90%, there is a 98% chance that this device will be free of critical failures at two months of use, and an 87% chance that this device will be free of critical failures at one year of use.

7.0 Clinical Studies

The intent of the clinical study was to answer two questions: 1) is the HeartMate VE LVAS a suitable alternative for HeartMate Implantable Pneumatic (IP) LVAS as a bridge to cardiac transplantation; and 2) is it safe for use outside of the hospital? The primary study endpoints were device flow (pump index) and adverse events. Survival data were also collected. Enrollment criteria for cardiac transplant candidates to enter the trial were:

1. Approved cardiac transplant candidate.
2. On inotropes.
3. On an intra-aortic balloon pump (if possible).
4. Left atrial pressure or pulmonary capillary wedge pressure $\geq$ 20 mmHg with either:
    a. Systolic blood pressure $\leq$ 80 mmHg, or
    b. Cardiac index of $\leq$ 2.0 l/min/m^2.

with reversible end organ dysfunction.

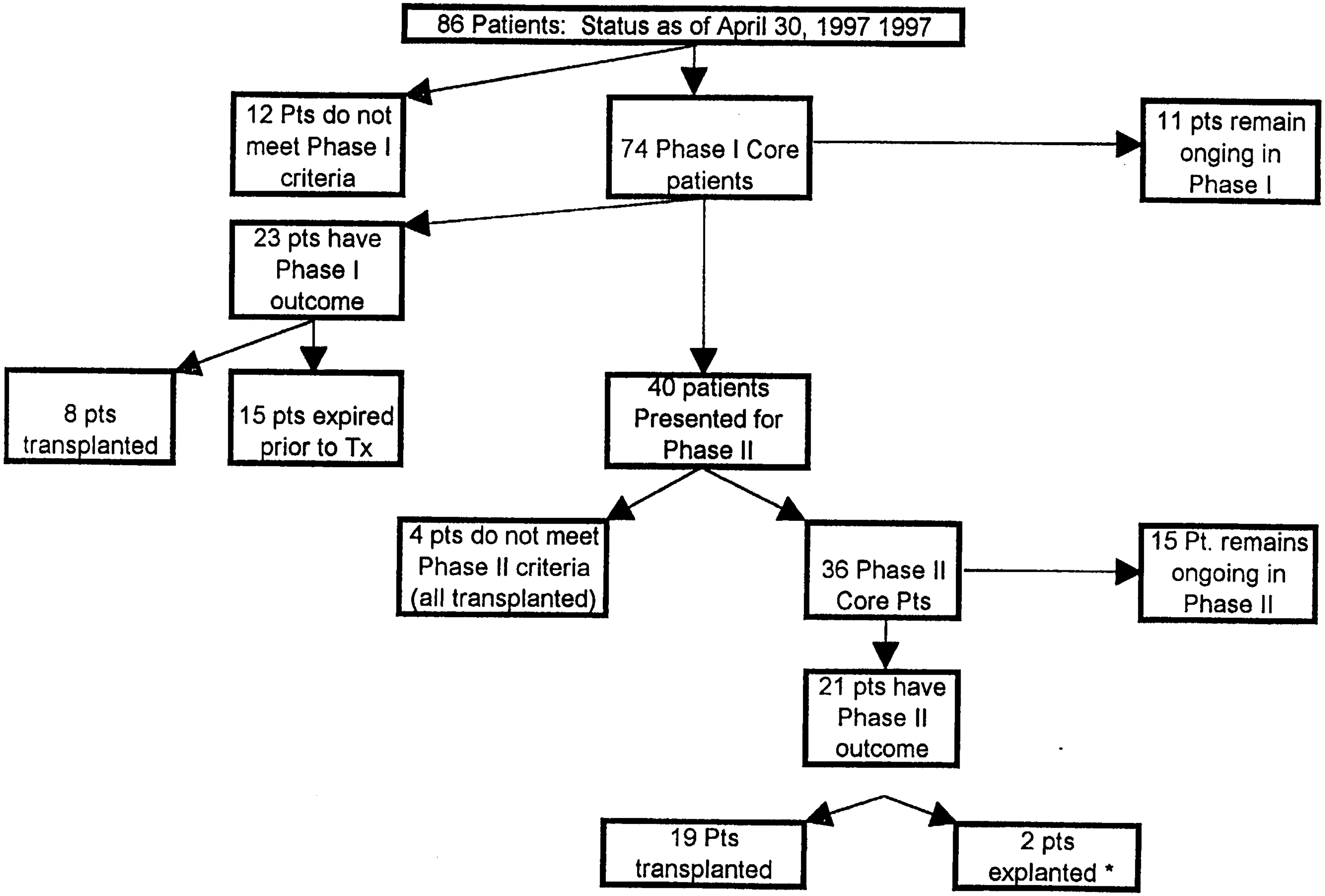
The study group consisted of two phases. Phase I included all patients implanted with the device. Those patients eligible to leave the hospital during their wait for a transplant were entered into Phase II of the study. To enroll into Phase II, patients were at least 14 days post implant and had recovered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

The 18 participating US sites contributed 86 patients as of April 30, 1997. Patients (N=12) who were subsequently found to not meet one or more of enrollment criteria were included in the analyses of adverse events. The 74 patients who met all criteria (Phase I Core patients) were included in the survival analysis and a subset (N=43) provided the pump flow data. Figure 1 details the outcomes of all patients entered into the trial.

In the 74 core patients, the average and range of LVAS support duration ranged from 2 to 316 days with a mean of 96 days. None of the 36 Phase II out-patient core patients died while participating in the program. All of these patients maintained a NYHA functional class of I or II.

Pump flow was measured using the average pump index. The average pump index was > 2 L/min/m^2 throughout the trial for 70 of 74 (95%) of the core patients in Phase I and all 36 of the core patients in Phase II. For core patients, the average pump index was 2.70 L/min/m^2 in Phase I, and was 3.05 L/min/m^2 for core patients in Phase II. The average pump index in the IP study was 2.77 L/min/m^2. These data comparing the IP and VE results are presented graphically in Figure 2.

Figure 1
VE LVAS Bridge to Transplant Clinical Trial



* LVAD removed and not replaced due to physician's judgement of myocardial recovery

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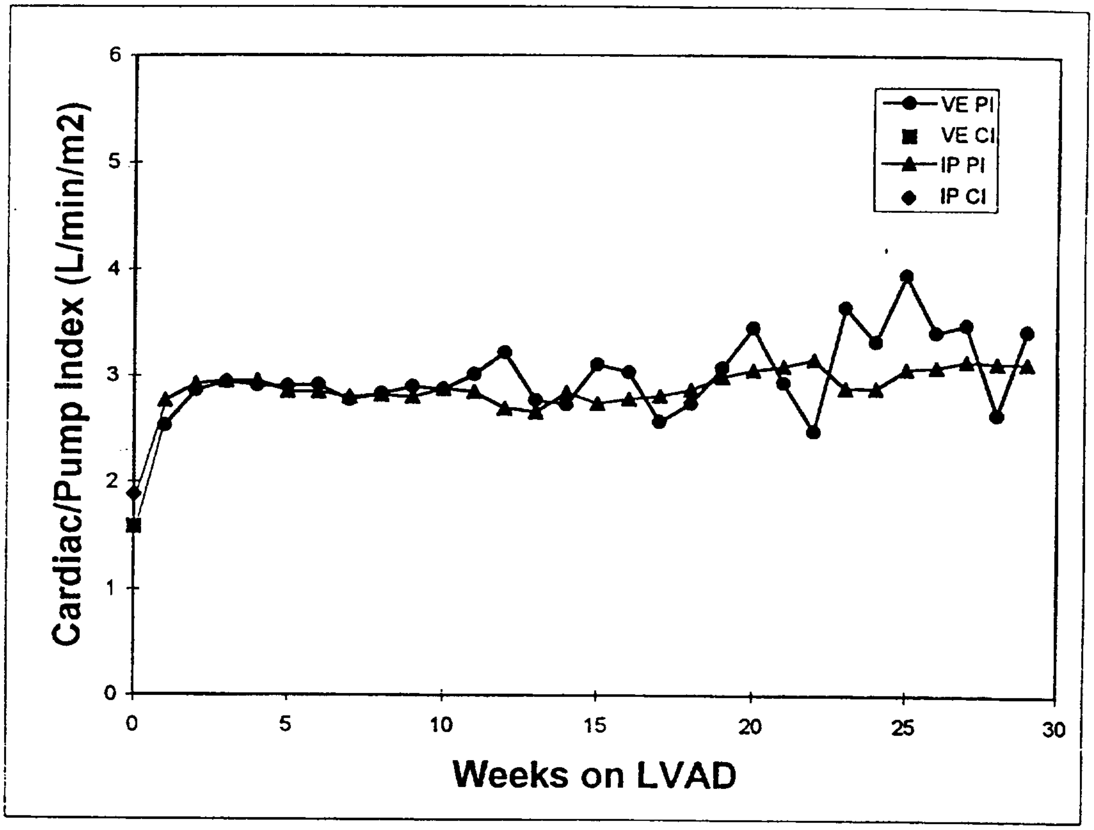
Figure 2

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/m^2.



	WEEKS ON IP LVAD										
	Cardiac Index	Pump Index									
	0[1]	1	2	3	4	8	12	16	20	24	28
N[2]	99	83	75	71	61	46	28	17	11	10	6
Median	1.80	2.78	2.84	2.91	2.99	2.81	2.63	2.66	3.10	2.47	2.92
Mean	1.88	2.77	2.92	2.95	2.96	2.82	2.70	2.79	3.06	2.89	3.13
STD[3]	0.54	0.48	0.58	0.56	0.54	0.55	0.52	0.52	0.79	0.91	0.87
SEM	0.05	0.05	0.07	0.07	0.07	0.08	0.10	0.13	0.24	0.29	0.36

	WEEKS ON VE LVAD										
	Cardiac Index	Pump Index									
	0[1]	1	2	3	4	8	12	16	20	24	28
N[2]	35	43	43	40	38	29	19	7	3	1	1
Median	1.67	2.53	2.84	2.83	2.97	2.77	3.06	3.16	3.19	3.33	2.65
Mean	1.58	2.53	2.86	2.94	2.91	2.84	3.22	3.04	3.46	3.33	2.65
STD[3]	0.35	0.51	0.53	0.58	0.47	0.61	0.60	0.60	0.80	-	-
SEM	0.06	0.08	0.08	0.09	0.08	0.11	0.14	0.23	0.46	-	-

Hemodynamic, hematologic, biochemical data, and adverse event data were collected throughout the study. Table 1 gives the numbers of adverse events and rates for the VE study and the IP study. Table 2 gives the adverse event reports for device related adverse events. Tables 3 and 4 give similar reports by study phase (Phase I and Phase II).

There were no device system failures during the study.

The 31 core patients transplanted included 8 Phase I, 19 Phase II, and 4 patients who entered Phase II that had not met the Phase II criteria, and 26 patients continued on LVAS support. Accounting for the 26 on-going patients gives a transplant rate of 65% (31 of 48). These results of survival to transplant are compared to the IP results in Table 5. The survival status of the 31 transplanted patients one year following transplant was evaluated in April, 1998. Table 6 compares the one year post-transplant results for core IP and core VE patients who survived to transplant.

HeartMate VE LVAS Clinical Study - Table 1
Comparison of Adverse Events in IP and VE Studies
Adverse Events Independent of Cause

Adverse Event	IP LVAS N=116, pt. years=20.1			VE LVAS N=86, pt. years=21.8		
	Patients	Percent	Events	Patients	Percent	Events
Bleeding	52	45%	66	38	44%	41
Hemolysis	7	6%	7	0	0%	0
Infection Events	53	46%	181	38	44%	95
Thromboemobolic Events	5	4%	5	5	6%	5
Right Heart Failure	22	19%	22	6	7%	6
Reoperations	59	51%	111	40	47%	61
Renal Dysfunction	67	58%	67	41	48%	41
Hepatic Dysfunction	112	97%	112	66	77%	66
Neural Dysfunction	24	21%	24	20	23%	23
Pulmonary	5	4%	5	2	2%	2
Device Failure	1	0.9%	1	0	0%	0
Hepatic Dysfunction	112	97%	112	66	77%	66
Neural Dysfunction	24	21%	24	20	23%	23
Pulmonary	5	4%	5	2	2%	2
Device Failure	1	0.9%	1	0	0%	0
Hepatic Dysfunction	112	97%	112	66	77%	66
Neural Dysfunction	24	21%	24	20	23%	23
Pulmonary	5	4%	5	2	2%	2
Device Failure	1	0.9%	1	0	0%	0
Hepatic Dysfunction	112	97%	112	66	77%	66
Neural Dysfunction	24	21%	24	20	23%	23
Pulmonary	5	4%	5	2	2%	2
Device Failure	1	0.9%	1	0	0%	0

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Right Heart Failure	22	19%	22	6	7%	6
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Renal Dysfunction	67	58%	67	41	48%	41
Hepatic Dysfunction	112	97%	112	66	77%	66
Neural Dysfunction	24	21%	24	20	23%	23
Pulmonary	5	4%	5	2	2%	2
Device Failure	1	0.9%	1	0	0%	0
Deaths	45	39%	45	20	23%	20

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

HeartMate VE LVAS Clinical Study - Table 2

Comparison of Adverse Events in IP and VE Studies

Device Related Adverse Events

Adverse Event	IP LVAS N=116, pt. years=20.1			VE LVAS N=86, pt. years=21.8		
	Patients	Percent	Events	Patients	Percent	Events
Bleeding	11	9%	13	8	9%	9
Hemolysis	5	4%	5	0	0%	0
Infection Events	37	32%	104	28	33%	51
Thromboemobolic Events	4	3%	4	5	6%	5
Right Heart Failure	0	0%	0	0	0%	0
Reoperations	15	13%	25	12	14%	16
Renal Dysfunction	0	0%	0	0	0%	0
Hepatic Dysfunction	0	0%	0	0	0%	0
Neural Dysfunction	9	8%	9	7	8%	7
Pulmonary Dysfunction	0	0%	0	0	0%	0
Device Failure	1	0.9%	1	0	0%	0
Deaths (device related)	1	0.9%	1	0	0%	0

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

HeartMate VE LVAS Clinical Study - Table 3

Comparison of Adverse Events in Phase I and Phase II

Adverse Events Independent of Cause

Adverse Event	VE LVAS Phase I N=86, pt. years=11.5			VE LVAS Phase II N=46, pt. years=10.3		
	Patients	Percent	Events	Patients	Percent	Events
Bleeding	38	44%	41	2	4%	2
Hemolysis	0	0%	0	0	0%	0
Infection Events	38	44%	95	7	16%	17
Thromboembolic Events	5	6%	5	0	0%	0
Right Heart Failure	6	7%	6	0	0%	0
Reoperations	40	47%	61	8	18%	14
Renal Dysfunction	41	48%	41	1	2%	1
Hepatic Dysfunction	66	77%	66	1	2%	1
Neural Dysfunction	20	23%	23	0	0%	0
Pulmonary Dysfunction	2	2%	2	0	0%	0
Device Failures	0	0%	0	0	0%	0
Deaths	20	23%	20	1	2%	1

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.

HeartMate VE LVAS Clinical Study - Table 4

Comparison of Adverse Events in Phase I and Phase II

Device Related Adverse Events

Adverse Event	VE LVAS Phase I N=86, pt. years=11.5			VE LVAS Phase II N=46, pt. years=10.3		
	Patients	Percent	Events	Patients	Percent	Events
Bleeding	8	9%	9	0	0%	0
Hemolysis	0	0%	0	0	0%	0
Infection Events	24	28%	34	7	15%	17
Thromboembolic Events	5	6%	5	0	0%	0
Right Heart Failure	0	0%	0	0	0%	0
Reoperations	11	13%	14	2	4%	2
Renal Dysfunction	0	0%	0	0	0%	0
Hepatic Dysfunction	0	0%	0	0	0%	0
Neural Dysfunction	7	8%	7	0	0%	0
Pulmonary Dysfunction	0	0%	0	0	0%	0
Device Failures	0	0%	0	0	0%	0
Deaths (device related)	0	0%	0	0	0%	0

Table 4 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.

HeartMate VE LVAS Clinical Study - Table 5
Survival to Transplant Comparison in IP and VE Studies
Includes Percent Survival and Difference at 95% Confidence Intervals

	VE LVAS Core Patients N=74	IP LVAS Core Patients N=75	Difference [95% CI]
Percent Survival to Transplant	65% (31/48*)	77% (58/75)	-12.7% [-29.3%, 3.8%]

* Excludes VE patients continuing on LVAS support.

HeartMate VE LVAS Clinical Study - Table 6
Survival Comparison One Year Post Transplant in IP and VE Studies
Includes Percent Survival and Difference at 95% Confidence Intervals

	VE LVAS Core Patients N=31*	IP LVAS Core Patients N=58	Difference [95% CI]
Percent Survival One Year Post Transplant	74% (23/31)	86% (50/58)	-12.0% [-29.8%, 5.8%]

* For VE, number of patients who meet Phase I inclusion/exclusion criteria.

8.0 HOW SUPPLIED

Following is a list of the major components supplied with the HeartMate VE LVAS. These components must be stored in a cool, dry place. Also provided is the catalog number of each item.

Refurbishment and reuse of the VE LVAD blood contacting titanium components up to five times is a standard feature of the manufacturing process. Therefore, all HeartMate VE LVADs may contain some or no refurbished titanium components.

Major System Components:

Catalog #	Description
1212	HeartMate VE LVAS Implant Kit
1240	Power Base Unit with Cable
1215	System Controller
2025	Rechargeable Battery Set
1280N	VE Display Module
1286	VE System Monitor
1290	HeartMate Hand Pump
1255	Vent Filter Set
2020	Emergency Power Pack
1237	Battery Clip Set
2653	HeartMate VE LVAS Operating Manual
1218	Y-Connector
1242	Battery Cell for System Controller
1295	Stroke Volume Limiter
1236	Battery Holster
1260	Travel Case
1224	Shower Kit
1233	Night Belt
1235	Pocket Pak™

For additional product information and specifications, consult the HeartMate VE LVAS Operating Manual or contact TCI. We reserve the right to change specifications without notice.

Caution:
Sterile components of the HeartMate VE LVAS are intended for single use only. Do not reuse sterile device components.

8.1 Equipment and supplies required for implant

Ensure that each of the components of the HeartMate VE LVAS are available in the operating room prior to initiating the implant procedure. Open the VE LVAS Implant Kit and ensure that the following components of the system are present:

VE LVAD (Blood Pump) Assembly
System Controller with Integral Battery Cell
Outflow Graft Conduit
Apical Sewing Ring
Inflow Valve Conduit
Outflow Valve Conduit
Y-Connector
Vent Filter
Nonabsorbable Suture
Thread Protectors (1 set)
Coring Knife
Explant Kit with Motor Cap and Handling Instructions

Note: Save the Explant Kit, motor cap and instructions for return of the explanted pump to TCI.

In addition to these directions for use, the system Operating Manual should be present. Addition equipment required is listed below:

TCI-Supplied:

Catalog #	Description
1280N	VE Display Module
1286	VE System Monitor
1240	Power Base Unit with VE Cable
2025	Fully Charged Rechargeable Battery Set
1290	HeartMate Hand Pump
1035	Tunneler with Guides

Hospital-Supplied:

20cc Non-heparinized Autologous Whole Blood in a Syringe (no needle)
60cc Syringe with 1cc Heparin (no needle)
Small Drip Basin
4 Small Bowls of Sterile Normal Saline
Large Basin

4 Sterile Centrifuge Tubes
2 Emesis Basins
Vent Needle
Autologous Serum/Unanticoagulated Whole Blood
CV Major Surgical Set
Heavy Nonabsorbable Ligature
Catheter Tipped Syringe with Sterile Normal Saline

CAUTION:
As a precaution against system malfunction which cannot be readily corrected by reference to these Directions for Use and the Operating Manual, a complete back-up system (Left Ventricular Assist Device (VE LVAD) and external components) must be available on-site and in close proximity for use in emergency.

9.0 IMPLANT PROCEDURE

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

WARNING:
A minimum of two fully charged Batteries are required at the time of implantation in order to power the system when transporting the patient out of the operating room.

WARNING:
Do not use the Power Base Unit (PBU) in the presence of Flammable Anesthetic Agents or an explosion could occur.

WARNING:
Keep the Power Base Unit (PBU) away from water. If the PBU has contact with water, shower spray or wet surfaces, the VE LVAD may stop, or the patient may receive a serious electric shock.

9.1 Setting up And Initializing The System

The HeartMate VE LVAS can be configured to operate through the Power Base Unit as shown in Figure 3, or with individual Batteries as shown in Figure 4.

Plug the Power Base Unit (PBU) into the AC mains and turn it on. Connect the VE System Monitor to the PBU back panel "Display" connector, and turn it on also. When initialization is complete, the "NOT RECEIVING DATA" message will appear at the bottom of the screen, indicating that the System Monitor is not yet linked to the System Controller.

Insert a minimum of four Batteries into the PBU charging slots. Ascertain that at least two Batteries are fully charged (green light) so that they will be available for patient transport out of the Operating Room.

CAUTION:
Only use the TCI Power Base Unit (PBU) to charge Batteries. Other Battery chargers may damage the Batteries.

CAUTION:
The power entry module on the rear panel (PBU) has been equipped with the proper fuse and set to the appropriate AC mains voltage for your location. Replacement of the fuse should be performed only by qualified service personnel.

9.2 Initializing The System Controller

a. Have the System Controller removed from its sterile package. A Controller Cell, to be installed in the System Controller at a later time, is included in the sterile package. See that this Controller Cell is set aside in a safe place.

b. Plug the large circular connector end of the PBU Cable into the rear of the PBU.

c. Pass the two parallel System Controller cable ends out of the sterile field and connect them to the bifurcated ends of the Power Base Unit (PBU) Cable (see Figure 1). Both the PBU and the System Controller will indicate a Hazard Alarm condition (signifying that the System Controller is powered but not connected to the VE LVAD). The System Controller display will show the "RED Heart" and "Yellow Wrench" symbol while emitting a steady audio tone and the System Monitor will display the message: "LOW RATE"(with timer). Reset these alarms with the System Controller alarm reset switche.

d. The System Monitor display will indicate FIXED MODE. Ensure the System Controller is set in Fixed Rate mode at 50 bpm. Modify with the System Monitor touch screen arrow keys.

e. Disconnect both connectors of the PBU cable from the System Controller. Maintain sterility of System Controller throughout VE LVAD implantation.

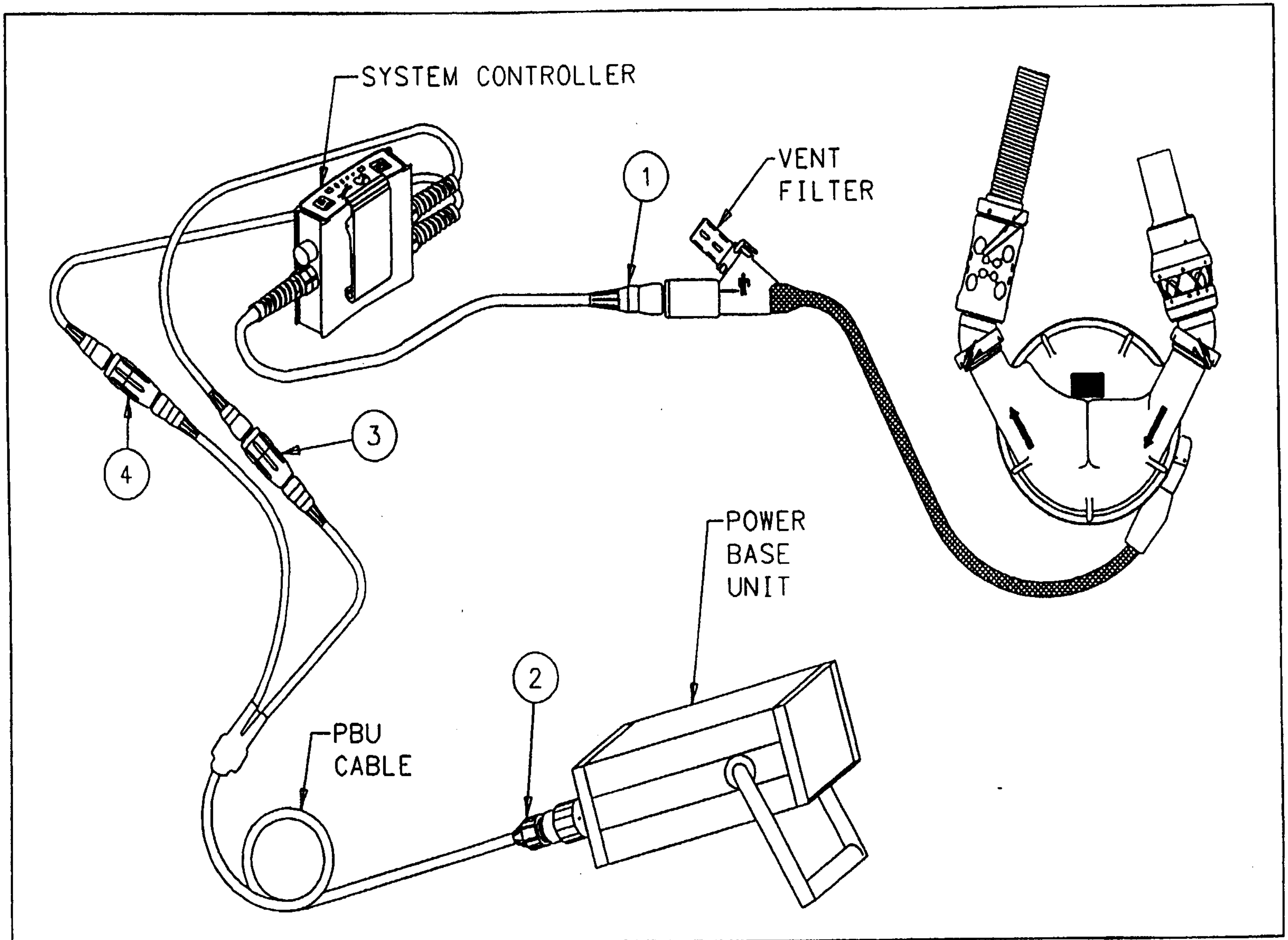

Figure 3: System Connections using the Power Base Unit. Connections are made in numeric order.

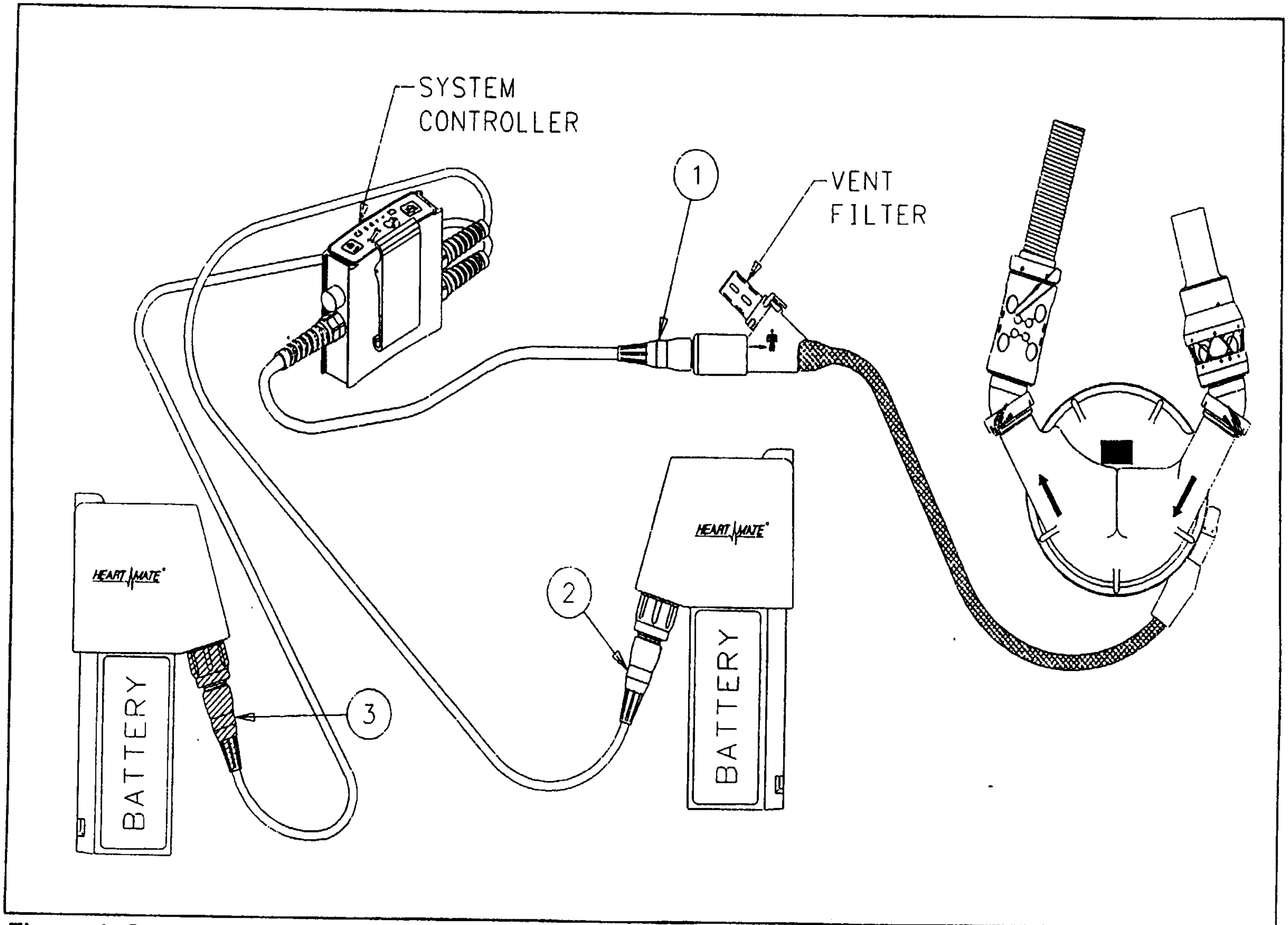

Figure 4: System connections using rechargeable Batteries. Connections are made in numeric order.

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CAUTION:
The connectors of the System Controller that were extended beyond the sterile field should remain outside the sterile field.

CAUTION:
When mating cables, do not force connectors together without proper alignment. Forcing connectors together may cause damage to the connectors.

CAUTION:
Connectors should be kept clean and dry. Do not expose connectors to water when making or breaking connections.

CAUTION:
Never use tools to tighten connections. Hand tighten only. Using tools may damage the connectors and cause the pump to stop.

9.3 Pre-clotting

The inflow and outflow valve conduits, as well as the outflow graft, must be pre-clotted prior to use in order to facilitate hemostasis. The next two sections of these directions describe the steps to follow for each pre-clotted component. Care must be taken to insure that proper pre-clotting occurs as indicated.

A) Outflow Graft

Pre-clot the external surface of the outflow graft with serum or other standard preclotting agent(s) as follows:

- Using strict aseptic technique, remove metal ring connector from graft and reserve for use after pre-clotting procedure (insure washer remains in place).
- Coat the graft evenly with serum or other preclotting agent(s) in an emesis basin, drain and place in a dry basin.
- Flash sterilize the graft in an autoclave, if applicable. Allow graft to cool after autoclaving.
- Replace metal ring, lip facing downward on the graft connector (insure washer is properly positioned).

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- Attach the thread protector to the metal ring on the outflow conduit.

CAUTION:
Do not over tighten thread protectors.

B) Inflow And Outflow Valve Conduits

To reduce the possibility of entry of air into the patient's circulatory system and bleeding from the VE LVAD during start-up, the **external surface of the inflow and outflow valve conduits** must be pre-clotted.

- Rinse both valve conduits in accordance with standard tissue valve rinse protocol (3 basin rinse).

WARNING:
Do not autoclave valve conduits. Doing so will cause damage to the porcine xenograft valves.

- Hold the conduits in a horizontal position over a dry sterile basin and slowly expel the non-heparinized blood from the syringe onto the **exterior** of the inflow and outflow valve conduit graft material. Allow the blood to drip into the small basin so that it can be redrawn into the syringe for repeated use.

- Rotate the conduits and coat the graft material while allowing the blood to clot. It may take as long as 30 to 40 minutes for an acceptable clot to form in cases of coagulopathy.

- Frequently (every 3 to 5 minutes) wet the valves by gently dripping normal saline into both ends of the valve conduit over a separate basin. This prevents drying of the porcine valves.

- Continue procedure, covering all visible graft material.

- Inspect the conduits for complete coating. Continue procedure, if necessary, to complete pre-clotting process.

CAUTION:
All graft material must be coated on the external surface.

- Immediately after the exterior of the conduits have been completely coated, wet the porcine valves again with normal saline and proceed with pump assembly and priming.

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CAUTION:
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 VE LVAD.

9.4 Priming the VE LVAD

Using strict aseptic technique:

- Attach the pre-clotted inflow and outflow valve conduits to the VE LVAD. Arrows on the VE LVAD housing indicated correct orientation of the inflow versus outflow valve conduits.

- Insure that the VE LVAD is correctly assembled and all connections including the inflow and outflow conduit connections are tight.

- Insure that the percutaneous lead protective "bullet" is completely screwed down tight onto the connector end of this lead.

- To help prevent contamination, place the VE LVAD and percutaneous lead in a large basin.

- Hold the VE LVAD in a vertical position. Fill the chamber with sterile normal saline through the inflow valve conduit until it appears that the VE LVAD is full.

WARNING:
Do not allow the percutaneous lead to become contaminated, or it's inner lumen to become wet or the pump may stop.

- Gently tap the VE LVAD to dislodge any air bubbles and rotate the VE LVAD body to allow all entrapped air to escape through the outflow valve conduit. Hold the VE LVAD so that the outflow valve conduit is at the highest level, and continue filling the VE LVAD through the inflow conduit.

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

- Once the VE LVAD is filled completely, attach a non-powdered sterile glove fingertip over the inflow valve conduit. Place the solid thread protector on the outflow valve conduit to prevent gross loss of priming fluid and tissue contamination of the conduit threads.

CAUTION:
Do not over tighten thread protectors.

Note: Some fluid leakage will occur through the conduit and connections.

9.5 Implantation

The proper orientation of the implanted components may be seen in Figure 5. The inlet conduit is placed utilizing apical cannulation, and the pump is positioned inferior to the diaphragm.

A) Intra-abdominal Versus Preperitoneal

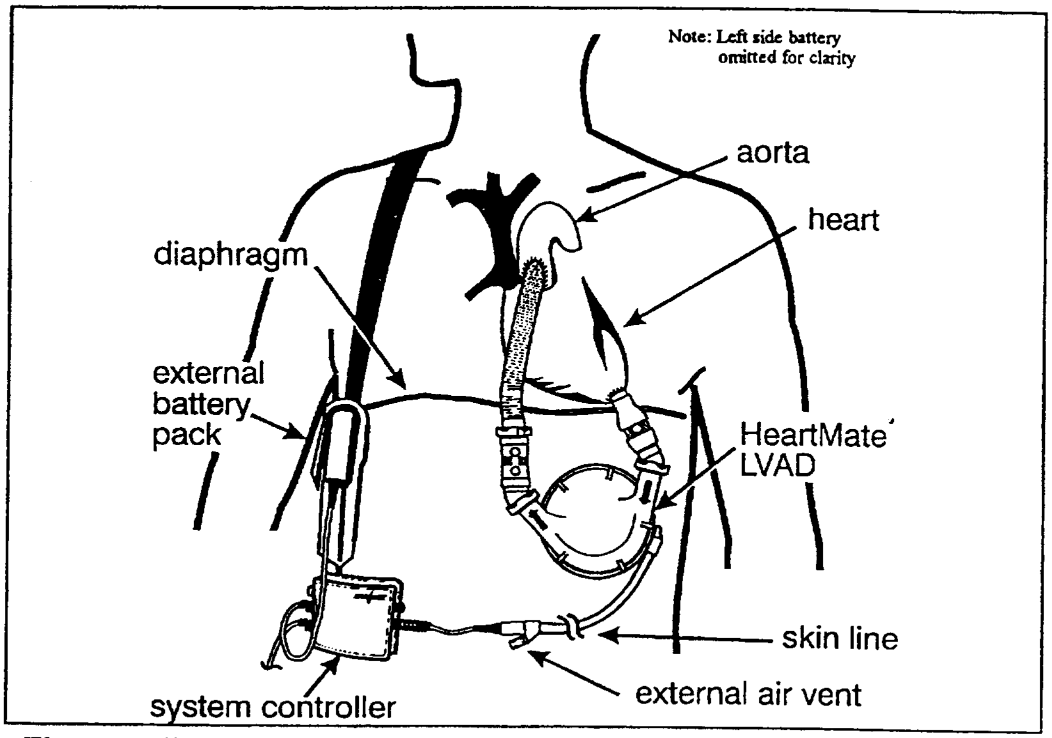

Figure 5 : Implanted and Worn Components of the HeartMate VE LVAS

The HeartMate VE LVAD may be surgically implanted in either the preperitoneal or intra-abdominal locations. 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

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abdominis and internal oblique muscles. For intra-abdominal placement, the pump is inserted intraperitoneally in 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 approach are discussed below.

Preperitoneal placement appears preferable for patients that have undergone previous abdominal surgery, or patients with a short torso. Another aspect 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.

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 permit adequate "tunneling" of the percutaneous lines to allow sufficient ingrowth as a barrier to infection. The intra-abdominal location may also be preferable for patients that have been previously treated with an Automatic Implantable Cardioverter Defibrillator (AICD). The ability to create a preperitoneal pocket may be hampered by the placement of the AICD. Risks 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.

Surgical Technique for Preperitoneal Placement

Once the sternum is divided, the left anterior rectus sheath is opened medially, and electrocautery is used to create a pocket behind the rectus muscle. The dissection is extended laterally, and a pocket is formed between the posterior rectus sheath and transversalis fascia underneath, and the rectus abdominis and internal oblique muscles above. The pericardium is opened and reflected laterally to allow exposure of the LV apex. The peritoneum is dissected away from the diaphragm. Further dissection is performed to facilitate insertion of the inflow conduit into the LV apex.

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Once cardiopulmonary bypass is established, and the LV apex prepared for insertion of the inflow cannula, the percutaneous tube is passed from the inferior aspect of the pocket through the subcutaneous tissue to the medial side of the iliac crest. The pump is adjusted in the pocket, and the inflow conduit inserted into the LV apex and secured. A small preperitoneal pocket is also made behind the right rectus muscle to allow for the outflow conduit and graft. The outflow is directed to the ascending aorta.

Surgical Technique for Intra-abdominal Placement

A midline chest incision is made and extended to the umbilicus. Once cardiopulmonary bypass is instituted, and the aorta cross clamped, the LV apex is prepared for insertion of the inflow conduit. The pump is placed intraperitoneally in the left upper quadrant, and the inflow conduit is passed through the anterior portion of the left hemidiaphragm to allow insertion of the inflow conduit into the LV apex. The outlet graft is placed over the diaphragm and inserted into the ascending aorta. The percutaneous line exits the body through the left lower quadrant.

9.6 Creating Percutaneous Lead Exit Site

Following are the steps for exit site selection and creation:

a. Insure that the exit site location does not interfere with clothing (belts, waistband).

b. Care must be taken to ensure that at least 1.0 inch (2.5 cm) of the polyester velour covering the percutaneous lead remains in the subcutaneous tunnel prior to exiting the skin. The adherence of the skin to the polyester is essential to minimize the risk of exit site infection.

c. At the desired exit site, make a circular incision of 0.50 inch diameter (1.3 cm).

d. Form a blunt dissection tunnel from the circular incision site to the pump cavity location.

e. Carefully externalize the percutaneous lead through the exit site tunnel created.

Note: The bullet on the end of the percutaneous lead contains a suture tape that can be used to pull the lead through the tunnel. Also, the bullet tip is threaded and can be attached to appropriately sized tunneling tools.

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9.7 Preparing The Ventricular Apex Conduit Site

Following are the steps required to insure proper apical sewing ring placement and attachment (also illustrated in Figure 6).

- Cut the ligature securing the coring knife and remove the plastic plugs from each end. Put the handle through the hole in the Coring Knife cylinder to make a "T" handle.

- Choose the coring location slightly anterior to the apex, a few centimeters lateral to the left anterior descending coronary artery. Core with the orientation of the coring knife toward the mitral valve inflow (Fig. 6.A).

CAUTION:
Do not allow the Coring Knife to involve the ventricular septum while performing the core.

- Apply cutting edge to the epicardium and maintain pressure while rotating the Coring Knife back and forth until the ventricular cavity is entered. Remove the core and inspect the ventricle for thrombus.

- Remove the sewing ring from the package and loosen the green ligature.

- Have an assistant hold the centering portion of the sewing ring assembly so that the felt portion will be directed towards the heart and the silicone tubular portion of the sewing ring is facing outward (Fig. 6.B).

- Use at least 12 pledgeted sutures in attaching the cuff of the sewing ring (Fig. 6.C).

- Wet sewing ring with saline prior to positioning in core for easier removal of the centering fixture.

CAUTION:
Do not remove the centering tool until ready to insert the inflow conduit.

9.8 Orientation of The Inflow Valve Conduit

Prior to implantation, ensure that the:

- Outflow graft is pre-clotted on the external surface with serum or other standard preclotting agent.

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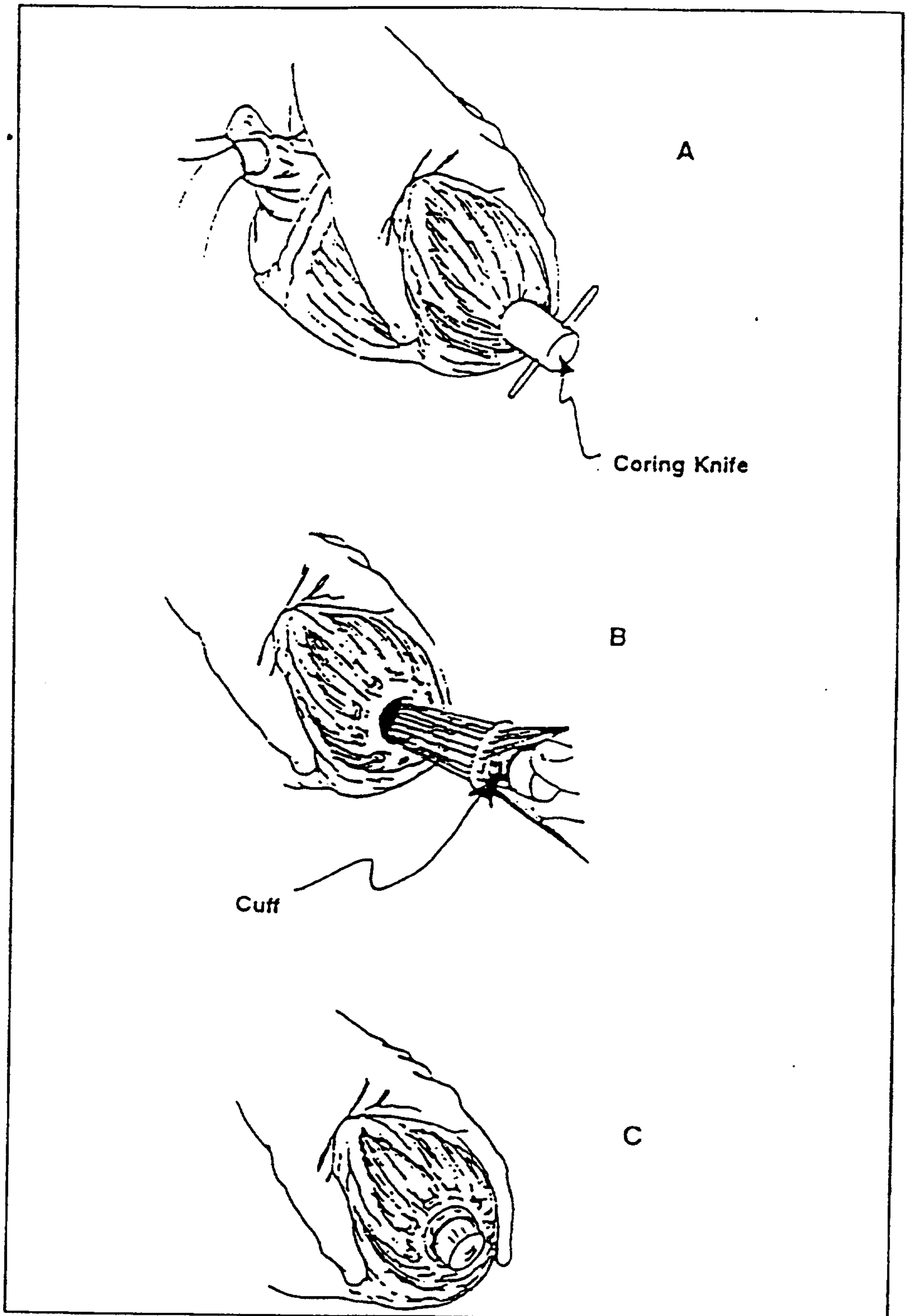

Figure 6 : Preparing the Ventricular Apex Conduit site

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- Inflow and outflow valve conduits are pre-clotted on the **external** surface.
- VE LVAD is correctly assembled and all joints including the inflow and outflow valve conduit connections are tight.
- VE LVAD is completely primed with sterile normal saline.
- Outflow valve conduit connection is topped off with saline.

Selection of the optimal inflow valve conduit orientation at the ventricular apex is important. Care must be taken to avoid excessive angulation of the inflow valve conduit once the VE LVAD is *in-situ*. The ideal orientation will allow the path from the inflow valve conduit to the VE LVAD chamber to be a straight line. When positioning the inflow cannula, one must also consider the likelihood that a dilated left ventricle may shrink in size as it's work load is assumed by the VE LVAD. Once the alignment is satisfactory, the inflow valve conduit must be firmly secured to the Apical Sewing Ring with the attached green non-absorbable suture. Additional banding may be employed to insure that this connection is secure and leak-tight.

WARNING:
Prior to advancing the inflow valve conduit into the left ventricle through the apical sewing ring, remove glove tip from the inflow valve conduit and the centering tool 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 assembly. The valve conduit and the valve leaflets could be accidentally distorted and valve function compromised. Hold the conduit by the frame only.

9.9 Attachment of the Outflow Graft

Anastomose the outflow graft to the ascending aorta in an end to side fashion by measuring and cutting the graft to an appropriate length. Insure that the suture line is secure with no blood loss.

Cross-clamp the graft and attach the proximal end to the outflow valve conduit using the threaded coupling.

WARNING:
Insure that the thread protectors have been removed from the outflow valve conduit and graft prior to attempting connection or connection will not be possible.

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Insure that the connection is tight, and allow the graft to back-fill with blood from the aorta prior to deaeration.

9.10 De-Airing the VE LVAD

Once the VE LVAD is in place and the outflow graft anastomosis is completed, residual air must be completely evacuated from the VE LVAD pumping chamber prior to initiating electric LVAD activation. Intraoperative transesophageal echocardiography may be utilized to monitor the presence of air in the aorta. It is advisable to monitor the left atrial pressures, which should be maintained at greater than 10 mmHg.

De-airing is performed by using the HeartMate Hand Pump. To connect the hand pump:

1. Remove the bullet from the pump's percutaneous lead after the lead has been exteriorized (Figure 7).

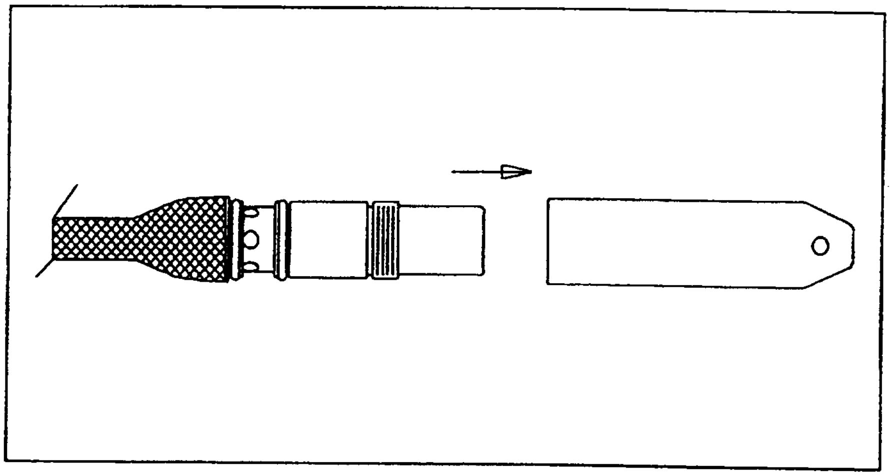

Figure 7 : Remove Bullet

2. Attach the Y-Connector by sliding the fitting completely over the percutaneous lead until snug. The O-rings on the percutaneous lead should be fully engaged into the Y-Connector (Figure 8). Insure proper orientation of the Y-Connector.

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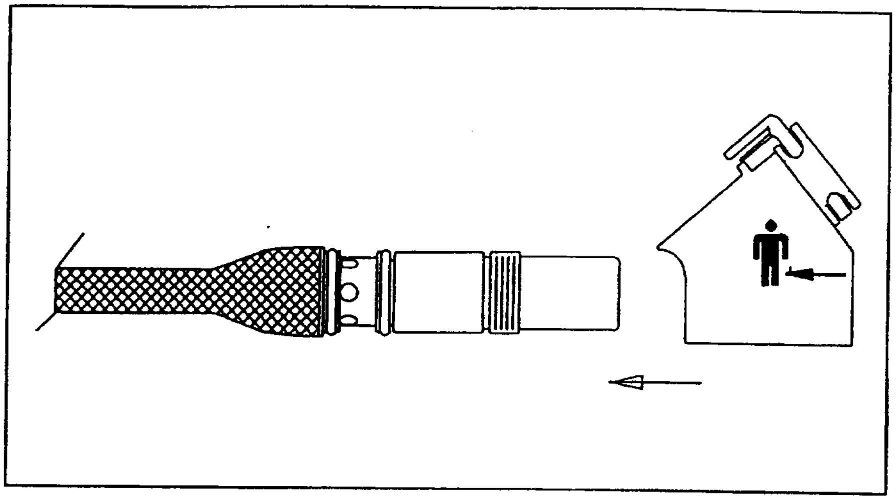

Figure 8 : Attach Y-Connector

3. Ensuring that the power leads from the PBU cable to the System Controller are not connected, attach the single percutaneous connector from the System Controller to the pump lead by aligning the connectors and

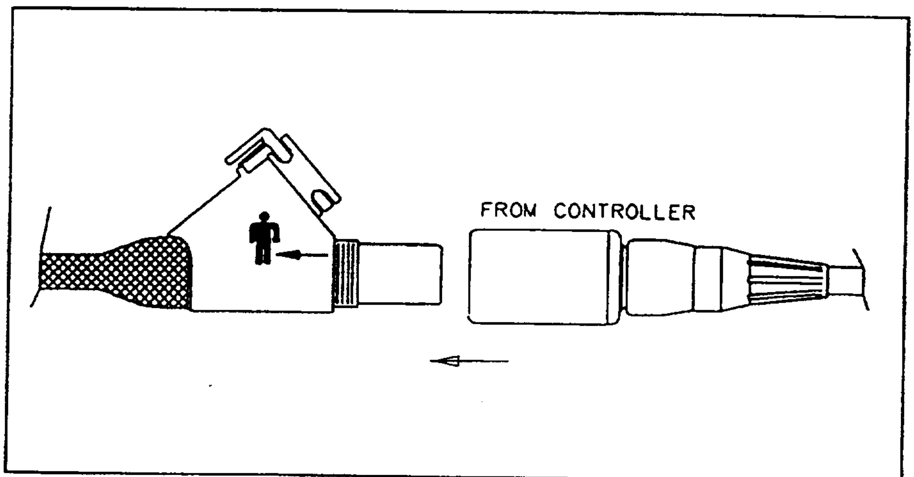

Figure 9 : Connect Percutaneous Lead to System Controller

tightening the barrel fitting (Figure 9).

4. Attach the HeartMate Hand Pump by inserting the connector from the Hand Pump into the vent port on the Y-Connector until a click is heard (Figure 10).

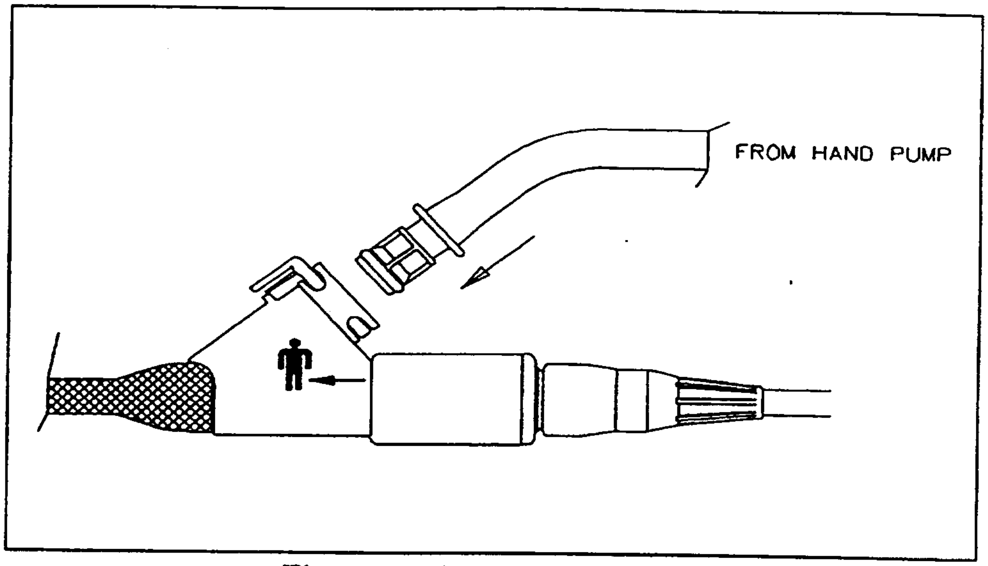

Figure 10: Attach Hand Pump

5. With the cross clamp on the outflow graft and the graft vent in place, depress the vent button on the hand pump and collapse the bulb (Figure 11).

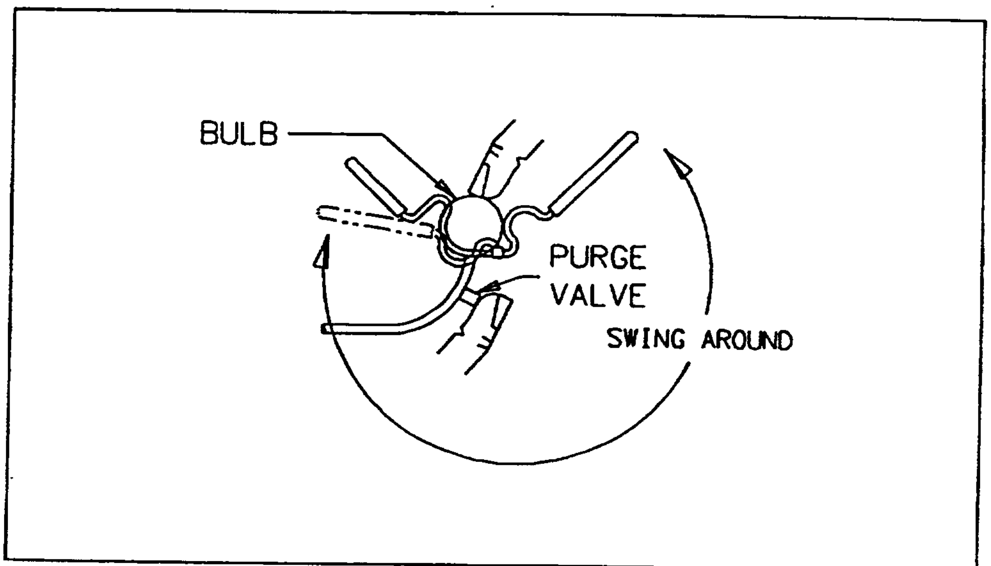

Figure 11: Depress Vent Button and Collapse the Bulb

6. Release the vent button and then release the bulb. The bulb should remain slightly collapsed. The vacuum that the bulb will create ensures the diaphragm in the VE LVAD will be pulled to its fill position.

7. Wait a few seconds, then press the vent button. When the bulb is fully expanded, release the vent button.

8. Cross-clamp the outflow graft at the distal end.

9. Position the outflow graft in a vertical position, such that an arch forms the highest point.

10. Insert a vent needle in the outflow graft at the highest point in the lumen between the clamp and the outflow conduit connection (anterior side) to optimize air removal.

11. Reduce cardiopulmonary bypass flow to allow filling of the left ventricle and VE LVAD by diverting at least two liters per minute of blood to the ventricle.

Note: A needle vent can be placed in 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.

CAUTION:
Remove all vents on the inflow side of the VE LVAD, including needles in the pulmonary vein, left atrium and the left ventricle prior to initiation of pumping.

Note: The surgical field may be optionally flooded with sterile saline to further minimize the risk of air entry and possible embolization.

12. Lower the patient's head to a Trendelenburg position.

13. Begin slowly actuating the VE LVAD with the hand pump. If the bulb does not inflate fully between hand pump compression cycles, poor filling of the VE LVAD from the left ventricle may be the cause.

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

WARNING:
Remove connection between percutaneous cable and System Controller prior to use of defibrillator or the VE system could be permanently damaged.

14. When appropriate, partially remove the outflow graft cross-clamp while continuing to manually hand pump the VE LVAD. Blood volume should be shifted from cardiopulmonary bypass to the patient to allow for adequate VE LVAD filling.

15. Continue hand pumping slowly to evacuate all air from the system and to allow the VE LVAD to fill completely.

WARNING:
Initial weaning of cardiopulmonary bypass should insure a minimum of two liters per minute of blood for flow to the VE LVAD in order to prevent air embolism. Prolonged deaerating may be due to inadequate blood volume in the pump.

16. Remove the vent needle from the outflow graft only when air can no longer be observed exiting through the needle. If air persists in the pump outflow graft for a prolonged period (> 5 - 10 minutes), rule out leaks at the inflow conduit/pump connection.

17. When all air has been removed from the VE LVAD, it is safe to initiate electric actuation.

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

9.11 Startup And Weaning From Cardiopulmonary Bypass

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

To begin electric operation of the pump:

1. Disconnect the HeartMate Hand Pump from the vent port by depressing the plastic tab and removing the connector (Figure 12).

2. Attach the sterile vent filter supplied with the pump to the Y-Connector by inserting it into the vent port until it snaps in place securely (Figure 13).

WARNING:
Never allow any fluids to enter the percutaneous lead through the vent port or filter or the pump may stop.

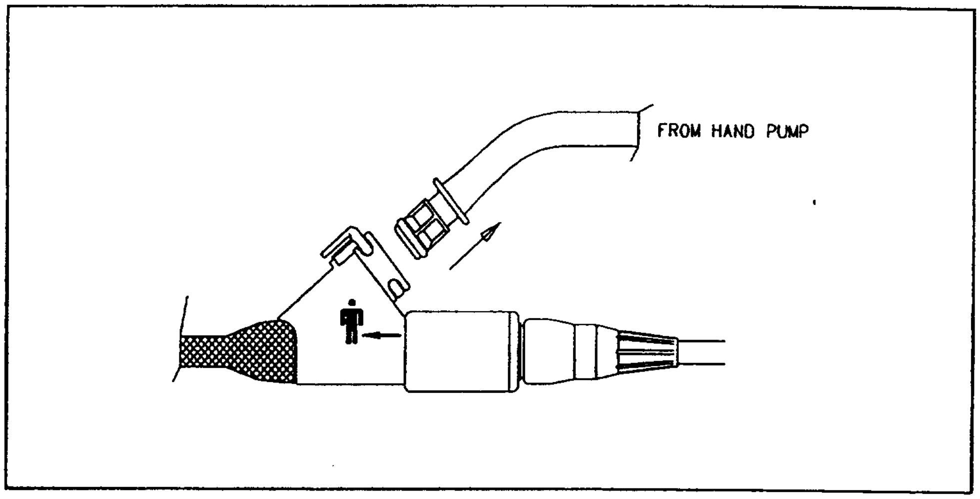

Figure 12: Disconnect the Hand Pump

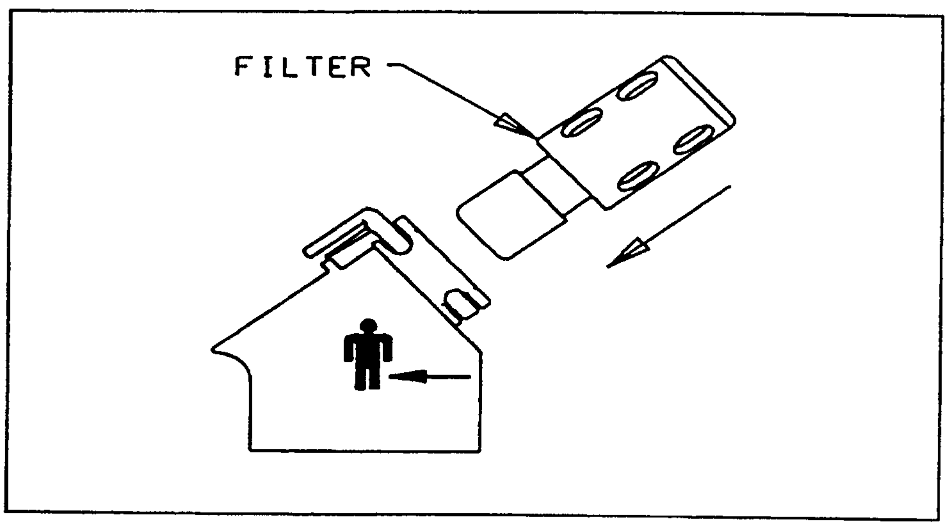

Figure 13: Attach Sterile Vent Filter

3. To begin electric actuation, connect the white connector of the Power Base Unit cable to the white connector of the System Controller by aligning the connectors and tightening the fitting (Figure 14). The VE LVAD will immediately begin operation at 50 beats per minute, and the System Monitor will show VE LVAD rate, flow and stroke volume information, while indicating the "FIXED" mode and the 50 bpm set point. Connect the black connectors in the same fashion. The "Yellow Wrench" light and once-per-second audio beep will activate (as will the PBU alarm) until the Controller Cell is installed in the System Controller. Reset these advisories using the Alarm Reset key on the System Controller.

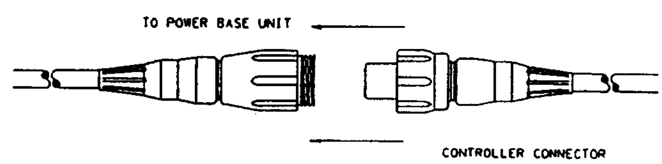

Figure 14: Connect System Controller to PBU Cable (white leads first)

4. Cardiopulmonary bypass should now be reduced to provide ample blood flow to the VE LVAD. The goal at this time is to achieve and maintain a stroke volume of 70-80 mL.

CAUTION:
Once the VE LVAD is activated, reduce cardiopulmonary bypass flow rapidly to provide ample blood flow to the VE LVAD. A stroke volume of 70 to 80 mL should be achieved and maintained.

5. When convenient, insert the Controller Cell into the System Controller body and screw it down until it is finger tight (Figure 15). This Controller Cell enables the System Controller beeper to sound a steady tone if the System Controller loses power while connected to a patient. At this point, no further hazards/advisories should occur. Weaning from cardiopulmonary bypass will be completed as VE LVAD rate and flow are increased.

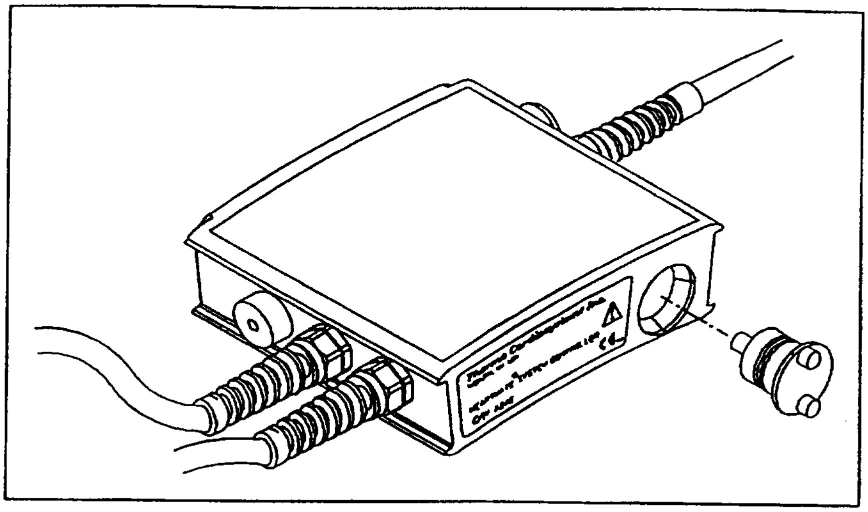

Figure 15: Insert Battery Cell

9.12 Securing The Outflow Connection And Anchoring The Pump

Once electric function is initiated and flow through the VE LVAD is satisfactory, secure the outflow valve conduit to the outflow graft using TCI-supplied nonabsorbable suture. Apply a suture (standard suture - Figure 16) from the outflow graft screw ring to a conduit strut in a clockwise direction to prevent inadvertent counterclockwise loosening of the connection.

WARNING:
Failure to adequately secure the standard outflow graft screw ring suture may allow this connection point to loosen, and result in potentially fatal hemorrhage.

WARNING:
Do not cut or damage underlying valve conduit material.

CAUTION:
Outflow graft must not be kinked or positioned where it could abrade against a pump component or body structure.

Following standard suture placement on the Outflow Graft Screw Ring, add an additional retaining suture (No. 2 Tevdek II 7-776 or larger) by placing it from the Outflow Graft Screw Ring to the Outflow Elbow Screw Ring to prevent assembly rotation or disconnection (Figure 16). Place the suture after the pump is in place and functioning, assuring that it is laterally positioned to avoid suture abrasion by the sternum.

WARNING:
Failure to apply the additional retaining suture may result in catastrophic disconnection and potentially fatal hemorrhage.

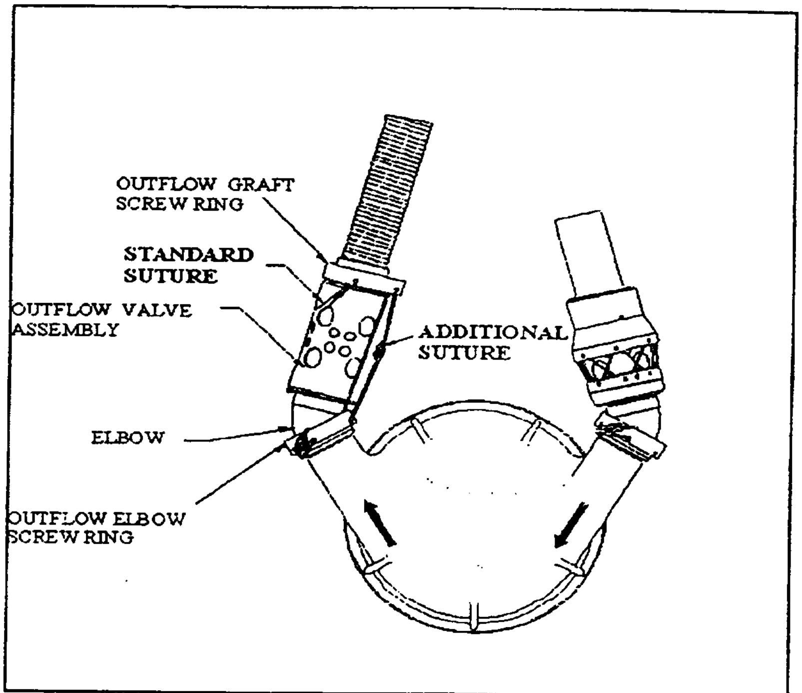

Figure 16: Position of Standard and Additional Sutures

Eyelets on the VE LVAD housing serve as attachment points for immobilizing the VE LVAD *in situ*. Once the VE LVAD has been inserted and deaerated, it must be sutured to the abdominal wall or surrounding fascia using hospital-supplied nonabsorbable suture. Failure to suture the VE LVAD in place may lead to its movement or migration in the body. This displacement may damage the valve(s) or the percutaneous tube, resulting in their failure and patient injury or death.

WARNING:
The VE LVAD must be sutured securely in position to prevent pump displacement and possible serious injury to the patient.

The incisions may now be closed in the standard fashion.

9.13 Transferring out of the Operating Room

When it is time to transfer the patient out of the Operating Room, the HeartMate VE system must be transferred from the PBU to Battery power. To effect the transfer, insert a Battery into each of the two Battery Clips. Unplug either of the System Controller connectors from the PBU cable and connect it to one of the Battery Clips. When the disconnect alarm ceases, unplug the remaining System Controller connector from the PBU cable and transfer it to the second Battery Clip. The disconnect alarm should again cease. Tuck the Batteries safely beside the patient so that the System Controller leads are not under strain.

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

> **Do not drop or subject to strong physical shock. Dropped Batteries should be replaced.**
> **Do not use below 15°F (-10°C) or above 105°F (+40°C), or they may fail suddenly.**
> **Do not leave or store Batteries in hot areas (car trunks, etc.) or Battery life will be shortened.**
> **Do not directly connect the 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, a portable pressure monitor is usually employed during this period to gauge the effectiveness of the HeartMate VE system.

A cart containing the PBU and the System Monitor can closely follow the patient, to be re-attached, one System Controller lead at a time, when the patient arrives at his or her destination.

9.14 Other Patient Considerations

WARNING:
Do not use this device in pregnant women or any woman likely to get pregnant during their period of LVAS support. A growing fetus will dislodge the pump which may result in device failure or fatal hemorrhage.

WARNING:
Do not subject patients implanted with the HeartMate VE LVAS to Magnetic Resonance Imaging (MRI) as the LVAD contains ferro-magnetic components, and MRI could cause device failure or patient injury.

WARNING:
Remove connection between percutaneous cable and System Controller prior to use of defibrillator or the VE system could be permanently damaged.

10.0 PATIENT MANAGEMENT

Support of a HeartMate VE LVAS patient in the hospital requires that the following equipment be on hand and readily available:

COMPONENT	Primary (Required)	Back-Up (Required)	Optional
The Implanted VE LVAD	X	--	--
System Controller	X	X	--
Rechargeable Batteries	X (2 sets)	--	X
Battery Clips	X	--	X
HeartWear Accessories*	X	--	X
Power Base Unit	X	X	--
Pneumatic Drive Console	--	X	--
Stroke Volume Limiter	--	X	--
Display Module	X	--	--
Controller Battery Cell	--	X	--
Y-connector	--	--	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.

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Proper care of a patient supported by the HeartMate VE LVAS requires thorough understanding of the system operation and patient condition. Physician judgment and experience may vary; however, the following points should be considered:

10.1 Treatment of the Exit Site

The following points were considered during the study in treating the exit site:

Daily exit site care was performed using a persistent antiseptic cleansing agent such as chlorhexidine containing scrub solutions. Following aseptic cleansing, the site was dried to avoid tissue maceration. Aseptic technique was adhered to whenever the exit site was inspected, dressed or otherwise handled.

The exit site was kept clean and dry. Prophylactic topical agents such as silver sulfadiazine or polymixin-neomycin-bacitracin were not used as these ointments applied to the exit site could have macerated the tissues. A sterile bandage was applied daily;

The percutaneous tube was Immobilized with abdominal wraps or binders to reduce trauma to the exit site, especially when the patient was ambulatory because trauma to the wound could increase the risk of infection.

All intravascular lines were withdrawn as soon as is practical to reduce the risk of systemic infection.

Parenteral treatment with antibiotics and surgical drainage were used in patients with evidence of pump pocket infection.

Fungal infection resulting from organisms such as *Candida albicans*, may have been associated with vegetative growth on the device. Persistent systemic fungal infection, refractory to antimicrobial treatment, resulted in LVAD replacement.

10.2 Anticoagulation Therapy

During the study, Heparin was administrated in standard fashion during cardiopulmonary bypass to minimize the risk of intraoperative thrombus formation. Once the device was successfully implanted, and the stroke volume generated by the device was adequate, Protamine was administered to reverse the effects of heparin. Heparin was not routinely used after device implantation unless low flow conditions (stroke volume $\leq$ 30 mL) persisted, or if medically indicated. Following reversal of the heparin intraoperatively, 10% low molecular weight dextran was indicated until the patient could accept oral medications. Inhibition of platelet activity throughout the remainder of the implant was maintained by administering 75 mg of dipyridamole three times daily, and one 80 mg aspirin per day, if not contraindicated.

CAUTION:
A persistent stroke volume of ≤ 30 mL may require anticoagulation to prevent possible thrombus accumulation.

WARNING:
In the event that the VE LVAD stops operating, all attempts must be made to restore pump function immediately, using electric or pneumatic activation. In the event that the VE LVAD 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 should the device be restarted.

10.3 Diagnosing Blood Leak

A blood leak from any implanted component of the VE system is typically identified through presence of one of the following symptoms:

- Unexplained internal bleeding (beyond the perioperative period following implant), possibly with painful distension 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 canulae is performed prior to initiation of cardiopulmonary bypass and stoppage of VE LVAD pumping.

10.4 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 VE LVAD to fill and drastically reduced flow rates. Limited filling is further exacerbated in the presence of right heart failure with

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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 VE LVAS effectiveness due to reduced filling of the VE LVAD.

Treatment for patients in right heart failure has consisted of use of inotropes to augment RV contractility, fluid management, hyperventilation, and pharmacologic modulation of pulmonary vascular resistance. As a last resort, a right ventricular assist device may be employed.

10.5 Avoiding Static Electric Discharge

WARNING:
Avoid strong static discharges (e.g. television or computer monitor screens) as this can damage the electrical parts of the system and cause the VE LVAD to stop.

11.0 PATIENT DISCHARGE

For patients discharged to a lower care facility, they must be trained as described in the Operating Manual, and a trained companion is recommended. A device malfunction may necessitate emergency treatment, therefore patients should not be more than two hours from a trained HeartMate VE LVAS health care facility. Following is a list of equipment required outside the hospital setting:

COMPONENT	Primary (Required)	Back-Up (Required)	Optional
The Implanted VE LVAD	X	--	--
System Controller	X	X	--
Rechargeable Batteries	X (2 sets)	--	X
Emergency Power Pack	--	--	X
HeartWear Accessories*	X	--	X
Power Base Unit	X	--	--
Battery Clips	X	--	--

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Display Module	--	--	X
Y-connector	--	--	X
Vent Filter	--	X	--
Controller Battery Cell	--	X	--
Hand Pump	X	--	X
Patient Handbook	X	--	--

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

CAUTION:
A back-up System Controller, spare batteries, and the Hand Pump must be with the patient at all times for use in an emergency.

12.0 EXPLANTING THE VE LVAD

The HeartMate VE LVAD may be removed by following these steps:

WARNING:
There is a risk of embolism at device explant or reoperation if manipulation of the device or canulae is performed prior to initiation of cardiopulmonary bypass and stoppage of VE LVAD pumping.

- Expose the HeartMate VE LVAD and carefully dissect it free. The eyelet sutures connecting the VE LVAD body to the abdominal wall or fascia are then cut.

- Place the patient on cardiopulmonary bypass and establish flow. Then disconnect the System Controller from the percutaneous lead to stop pumping.

- Cross-clamp the outflow graft just distal to the outflow valve conduit and divide the graft.

- Divide the ligatures securing the apical suture ring to the inflow valve conduit, and remove the inflow valve conduit from the ventricle.

- Dissect the percutaneous lead between the VE LVAD body and the abdominal wall. Cut the Percutaneous Tube and remove the externalized

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