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THORATEC™
LABORATORIES

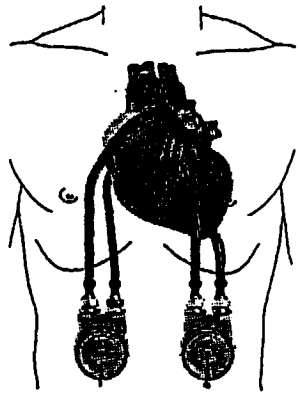
CE 0197

Thoratec Laboratories Corporation 6035 Stoneridge Drive Pleasanton, CA 94588 Tel: 925-847-8600 Toll Free: 800-528-2577 Fax: 925-847-8574 www.thoratec.com Thoratec Laboratories is ISO 9001 quality systems certified. The Thoratec VAD System has the CE mark. Figures current as of 6/98. 15003.A Printed in the U.S.A. References on file.

Thoratec® Ventricular Assist Device (VAD) System

DIRECTIONS FOR USE

15003.A. 6/98



Caution: Federal (USA) law restricts this device to sale by or on the order of a Physician

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APPENDIX A THORATEC VAD SYSTEM COMPONENTS AND ACCESSORIES A-1

THORATEC® VENTRICULAR ASSIST DEVICE (VAD) SYSTEM

Directions for Use

SECTION I GENERAL INFORMATION

WARNING:

A thorough understanding of the technical principles, clinical applications, and risks associated with ventricular support is necessary before using this product. Read this entire booklet, and the Dual Drive Console Directions for Use prior to attempting implantation. Completion of the Thoratec VAD Training program is required prior to use of the Thoratec Ventricular Assist Device (VAD) System.

1.0 DEVICE DESCRIPTION

The Thoratec VAD System includes a ventricular assist device designed to support the circulation of blood in the pulmonary and/or systemic circulation when the natural heart, with the help of standard drug therapy and intraaortic balloon counterpulsation, is unable to maintain normal blood flows and pressures in those vascular beds. To accomplish this support, blood is shunted from the natural heart to the VAD, which then pumps pulsatile blood flow back to the body at normal arterial pressures.

The VAD System can be used in several configurations to provide for the circulation of blood in either or both the pulmonary or systemic vascular beds at physiological pressures and flows (see Figure 1). The system consists of three major components: a blood pump, cannulae, and a drive console. See Section 10.0 for a more detailed description of the system components.

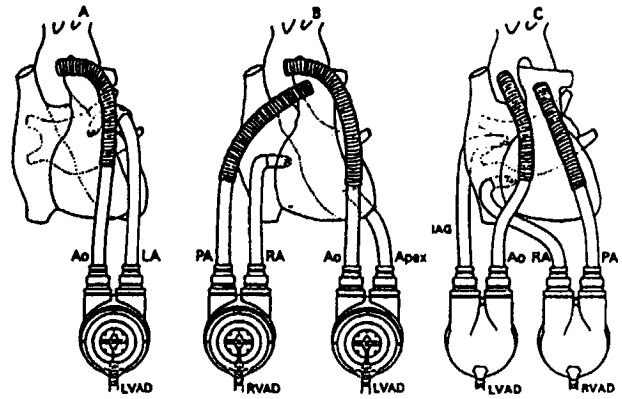

Figure 1. Thoratec Ventricular Assist Device (VAD) and three cannulation approaches for univentricular left heart support (Panel A) and biventricular support (Panels B and C). Ao=aorta, LA=left atrial appendage, PA=pulmonary artery, RA=right atrium, Apex=left ventricular apex, IAG=cannula inserted via the interatrial groove and directed towards LA roof. Note that the VADs in Panel C are turned over and are on the sides of the chest that are opposite of those in Panel B. (Modified from Farrar DJ et al. New England Journal of Medicine 1988; 318:333-340. Copyright 1988, Massachusetts Medical Society).

2.0 INDICATIONS FOR USE

The Thoratec Ventricular Assist Device is indicated for:

Bridge to transplant patients who meet all of the following criteria:

1. Candidate for cardiac transplantation.
2. Imminent risk of dying before donor heart procurement.
3. Dependence on, or incomplete response to, continued vasopressor support.

Postcardiotomy recovery patients who are unable to be weaned from cardiopulmonary bypass.

3.0 CONTRAINDICATIONS

Uncontrolled hemorrhage.

Central nervous system damage resulting in fixed and dilated pupils.

Contraindications to cardiac transplantation contraindicate use of the device for bridge to transplant.

4.0 WARNINGS

4.1 Patient Population - General

VAD patients with prosthetic aortic valves may have increased risk of thromboembolism due to blood flow shunted away from the valve.

Patients with greater than 1.5+ aortic insufficiency should either not be considered a candidate for VAD support, or should be considered only after repair or replacement of the aortic valve.

Significant right-to-left shunting can occur in patients with a patent foramen ovale. Patency of the foramen ovale should be considered and corrected if necessary, prior to insertion of VADs.

Cannulae may be difficult to insert in patients with small hearts, in patients with congenital abnormalities, or in patients with previous cardiac reconstructive surgery. There are no detailed data available at this time regarding this issue.

4.2 Patient Population - Bridge to Transplant

Patients with hepatic and/or renal dysfunction may require 2 to 3 weeks of VAD support for major organ function to recover.

Patients with elevated levels in the panel of reactive antibodies (PRA) may require extensive duration of VAD support in order to locate a donor heart. Patients should be excluded if the expectation of finding a donor heart is not reasonable.

4.3 Patient Population - Postcardiotomy Recovery

There are no additional warnings other than those listed in Section 4.1 specific to the use of the device pending postcardiotomy myocardial recovery.

4.4 Procedural Techniques - All Indications for Use

The VAD is provided sterile; caution must be taken in opening the package. Do not resterilize. Do not use if package is damaged.

Do not disassemble the VAD. Collet nuts and collets must be removed to attach cannulae to the VAD, and this can be performed by hand. Disassembly or attempts to loosen the cap ring, valve housing nuts, or any other component of the VAD may affect VAD function.

Do not use polar organic solvents, such as ketones, chlorinated hydrocarbons, and aromatic hydrocarbons, anywhere near the VAD. Such use has caused stress-cracking of the polysulfone and other damage to the VAD housing. These solvents include, but are not limited to, acetone, methyl ethyl ketone (MEK), methylene chloride, chloroform, trichloroethane, and benzene and its derivatives.

Do not use povidone-iodine (e.g., betadine) ointments, or other polyethylene glycol-based ointments in contact with the cannula for prophylactic care of the transdermal skin site. Such use over several months has caused cannula degradation at the end of the wire reinforced region. Povidone-iodine solution (not containing polyethylene glycol) is recommended.

5.0 PRECAUTIONS

5.1 Training of Personnel

Surgical, nursing, and perfusion staff responsible for the VAD program at each hospital should complete the Thoratec VAD Training program.

5.2 Technique of VAD Placement

Use strict aseptic techniques during implantation and extreme care throughout VAD support to prevent infection.

The arterial graft on the arterial cannula must be preclotted before use.

Do not cut the tapered end of the atrial cannula.

The distal end of the arterial and ventricular cannulae can be trimmed, but at least 4 cm of nonwire reinforced polyurethane cannula are required for proper attachment to the VAD.

Do not allow tissue fluid or particulate matter to contaminate the inside of the cannulae, especially when passing the cannulae through the percutaneous exit tunnels.

The VAD valve housing has a very sharp edge designed to minimize seam thrombus. Do not dent or scratch the sharp edge, and be careful to avoid cutting yourself.

Do not allow blood or other fluids to contact the electrical fill switch connector on the VAD.

Do not initiate VAD pumping until the blood pump has been completely de-aired after connecting the cannulae.

If VAD cannulae are not properly inserted, suboptimal VAD blood flows may occur.

5.3 External Alarms

The VOLUME mode is the recommended control mode for most patients. This is the only mode where both audible and visual alarms on the Dual Drive Console (triggering on the absence of the VAD fill signal) are present if the VAD were to cease to operate due to adverse scenarios such as blockage of the pneumatic drive or cannulae. Any patient supported with the VAD drive console in the ASYNC or EXT SYNC modes must have the external alarm output on the drive console connected to the hospital nurse call system, or other similar external alarm system. This alarm output will trigger the external independent alarm after an 8 second absence of the VAD fill signal, thus alerting the user to check the VAD and drive console to determine that they are operating properly. This alarm is available in all control modes, but is redundant when using VOLUME mode since internal audible alarms are present in that mode.

5.4 Required System Backup

Each console contains two independent drive modules, and therefore contains adequate built-in back-up capability for univentricular support. For patients receiving biventricular support, a complete dual drive console must be available as a back-up to be used in the event of a failure of the primary console.

Personnel should be trained how to hand pump a VAD in the event of a drive console failure. If for any reason there is a drive console failure, blood flow can be maintained to the patient and stasis prevented in the blood pump by disconnecting the VAD airline tube from the drive console and connecting it to the hand bulb for the short period of time necessary to connect the back-up drive console. Squeeze the hand bulb about once per second to empty and fill the blood pump. Connect the back-up drive console as soon as possible. This procedure is for emergency use only.

5.5 Steps to Minimize the Risk of Thrombosis

At low beat rates there is an increased risk of thrombus formation in the VAD. Therefore it is recommended that the device be operated at rates above 40 bpm and with complete filling and ejection of the VAD blood pump in the VOLUME mode. Pneumatic drive ejection pressures of at least 100 mmHg above the patient's systolic blood pressure are recommended for complete ejection. Complete VAD emptying can be verified by using a flashlight (see Section 12.7 for details). During weaning the patient from the VAD, and or during other conditions that result in low flow or beat rates below 40 bpm, continuous infusion of heparin for anticoagulation to achieve a partial thromboplastin time of 1.5 times control is recommended. See Section 13.4 for anticoagulation regimen.

5.6 Interaction with Magnetic Resonance Imaging

This device contains ferro-magnetic metal components. Do not perform MRI imaging procedures on patients with the Thoratec VAD.

6.0 ADVERSE EVENTS

Adverse events were collected for all patients enrolled in the clinical studies of the device. The bridge to transplant study included 71 patients at 20 medical centers. The postcardiotomy myocardial recovery study included 29 patients at 12 medical centers. The frequency of nine critical adverse events that occurred during the period of VAD support in the clinical trials is presented in Table 1. In the postcardiotomy myocardial recovery study the type and frequency of adverse events was similar between the primary data cohort presented in Table 1 and the other supporting data excluded from the primary data analyses. In the bridge to transplant study, the frequency of these adverse events was higher in the other data cohort (ranging from 9% higher for cardiovascular dysfunction to 37% higher for death) as compared to the primary data cohort presented in Table 1, due to the greater severity of illness in these patients at the time of VAD implant.

Table 1. Critical adverse events by category while on VAD support

	Bridge to Transplant (n = 71)			Postcardiotomy Recovery (n = 29)		
EVENT CATEGORY	# Events	# Pts	% Pts	# Events	# Pts	% Pts
Death	22	22	31%	15	15	52%
Cardiovascular dysfunction (e.g. any single event of hypo- or hypertension, arrhythmias, RV failure)	90	55	77%	28	21	72%
Hepatic dysfunction (e.g., any single total bilirubin >3x high normal, cholecystitis)	40	40	56%	17	17	59%
Renal dysfunction (e.g., dialysis, any single creatinine >1.5x high normal)	38	38	54%	18	18	62%
Bleeding (e.g., excessive CT drainage, DIC, tamponade, hematuria)	54	36	51%	25	18	62%
Hemolysis (e.g., any single plasma free hemoglobin >3x high normal after 24 hr)	36	36	51%	9	9	31%
Infection (e.g., any positive culture, purulent discharge)	50	35	49%	18	13	45%
Reoperation (for any cause - e.g., hemostasis, cannula reposition, tracheostomy, cholecystectomy)	51	32	45%	27	16	55%
Thromboembolism (e.g., all autopsy evidence of any organ infarction, stroke, TIA)	27	20	28%	14	11	38%

A variety of ot.. .dverse events were noted during the studies including:

- Mechanical dysfunction
- Thrombocytopenia
- Neurological dysfunction
- Respiratory dysfunction
- Pleural effusions
- Pancreatitis

Note:

Bleeding can be due to surgical- and device-related reasons at the cannulation sites or arterial anastomoses, or it can occur due to coagulopathy.

The need for reoperation may result from excessive bleeding, right ventricular failure requiring RVAD insertion, VAD inflow problems requiring cannula repositioning, etc.

There was evidence that the VAD produces some hemolysis, with plasma free hemoglobin after 2 weeks of pumping averaging 18 ± 9 mg/dL. Blood transfusions may be required for patients who have excessive bleeding or hemolysis.

Infection can also occur at the cannulation sites, around the monitoring lines, or in the blood, urinary tract, or respiratory tract. There was no apparent pattern of organisms or source.

Neurological dysfunction may result from pre-existing hypoxic brain injury (for example, from pre-VAD cardiac arrest or hypotension), or events during the VAD period such as cerebral hemorrhage, drug-related side effects, and cerebral hypoperfusion.

Thromboembolism can also occur from the VAD, cannulae, natural heart chambers, or arteries. Embolism may result in stroke, pulmonary or other non-cerebral organ infarction, leg ischemia, or other vascular obstruction. Continuous anticoagulation with heparin or warfarin is recommended. See Section 13.4 for anticoagulation regimen.

In addition, it is possible that the VAD will produce no significant hemodynamic improvement.

SECTION II CLINICAL EVALUATION

7.0 CLINICAL BACKGROUND AND CONCERNS - BRIDGE TO TRANSPLANT

Clinical Study Experience

Clinical study experience demonstrated that the Thoratec VAD System (VAD): 1) provided sustained improvement in hemodynamics and served as an effective bridge to transplantation; 2) did not negatively impact post-transplant survival rates.

The purpose of the study was to evaluate patients who had VADs placed prior to heart transplantation to maintain patient viability while waiting for a donor heart. Patients (ages 15-60 years) were selected who were awaiting heart transplantation and at imminent risk of death before a donor heart could be obtained. Qualifying patients [i.e., patients who met all of the study entrance criteria (Cohort 1A)] had received maximal conventional therapy, had pulmonary capillary wedge pressure ≥

20 mmHg and either a cardiac index ≤ 1.8 L/min/m² or systolic .e ≤ 90 mmHg or mean pressure ≤ 70 mmHg. Patients were excluded for total bilirubin ≥ 5 mg/dl or creatinine ≥ 4 mg/dl or irreversible end organ dysfunction. Seventy-one patients (54 males, 17 females) met all inclusion/exclusion criteria. The gender distribution (24% female) was consistent with the UNOS registry of patients awaiting cardiac transplantation (17.5% female). A retrospective control group (9 males, 1 female) met all the inclusion/exclusion criteria but were not treated with the ventricular assist system.

Results: Forty-nine of the 71 (69%) patients received biventricular (BiVAD) support; 22 (31%) received only left ventricular (LVAD) support. Thirty-two patients required a total of 51 reoperations; 35 for bleeding; 16 for other reasons. Preoperative cardiac index (1.4 ± 0.7 L/min/m²) improved following VAD placement to an LVAD flow index of 2.5 ± 0.5 L/min/m² on post-VAD day 1 ($p < 0.001$) and remained within a clinically normal range thereafter. (At two weeks of VAD support, LVAD flow index averaged 2.8±0.5 L/min/m².) Median VAD support period was 16 days (mean: 35 days, maximum: 247 days). The median survival time from implant to follow-up cut-off date (June 1, 1994) was 223 days (mean: 503 days), with 38 current survivors. Median survival time was 10 days (mean: 14 days) in 10 control patients with 0 survivors. Of the 71 patients implanted with the device, 49 (69%) survived to receive a transplant compared to 0 of 10 control patients. Twenty-six of 55 (47%) patients implanted with the device survived at least 1 year post transplantation, and the other sixteen patients remained alive but had not yet reached the one-year period as of the study cut-off date (June 1, 1994). The Kaplan-Meier estimate of survival for the 49 transplanted patients was 84% at 1 year. Multivariate analysis identified two correlates of successful bridge to transplantation: low preoperative total bilirubin levels and absence of previous cardiac operations.

Adverse events were collected for all 71 Cohort 1A patients enrolled in the study. The major risks associated with the use of ventricular assist devices are bleeding, infection, renal and hepatic dysfunction, hemolysis, thromboembolism, and reoperation. See Table 1, Section 6.0 Adverse Events, for a summary of adverse event frequency. Reoperations to control bleeding were required in 31% of the patients, mostly in the first two post-operative days. Infections (documented by at least one positive culture of blood, urine, sputum, or wound) occurred in 49% of patients, and sepsis was a cause of death in 7% of patients implanted with VADs. In some patients, 2 to 4 weeks of VAD support were required for recovery of renal and/or hepatic function. Hemodialysis was required in 15% of VAD patients. Embolic stroke occurred in 6 VAD patients (8% of the total).

8.0 CLINICAL BACKGROUND AND CONCERNS - POSTCARDIOTOMY RECOVERY

Clinical Study Experience

Clinical study experience demonstrated that the Thoratec VAD: 1) provided sustained improvement in hemodynamics, 2) allowed for myocardial recovery 3) allowed for survival to discharge, 4) permitted survival to one year post-explant in some patients, and 5) had a high but acceptable complication rate for this patient population.

The purpose of the study was to demonstrate that the Thoratec VAD provided adequate hemodynamic support to permit myocardial recovery with survival in patients who were unable to be weaned from cardiopulmonary bypass.

The device in its final configuration was implanted in 66 patients (ages 12-73 years). Sixty (60) patients had undergone an open heart operation, but could not be weaned from cardiopulmonary bypass (n=49), or had persistent cardiac failure after weaning from bypass (n=11). All patients had received maximal conventional therapy. Twenty-nine patients (23 males, 6 females) who could not be weaned from cardiopulmonary bypass and met all study inclusion/exclusion criteria form the Primary Data Cohort.

The other thirty-one (31) postcardiotomy patients include sixteen (16) patients with failed cardiac transplants, eight (8) patients who were initially weaned from cardiopulmonary bypass, but who required VAD support after leaving the operating room, four (4) patients who did not meet all study entry criteria, and three (3) patients who were not effectively placed on VAD support. An additional six (6) patients received VADs pending myocardial recovery from cardiomyopathies without having undergone a prior open heart operation.

Results: Preoperative cardiac index (1.5 ± 0.5 L/min/m²) improved following VAD placement to a VAD flow index of 2.2 ± 0.3 L/min/m² on post-VAD day 1 ($p < 0.001$) and remained within a clinically normal range thereafter. Sixteen patients required a total of 27 reoperations; 18 for bleeding, 9 for other reasons. Median VAD support period was 6 days (mean: 12 days, maximum: 80 days). The median survival time after weaning from VAD support is 534 days (mean: 847 days). See Table 1, Section 6.0 Adverse Events, for a summary of the incidence of adverse events during the period of VAD support.

Of the 29 Primary Data Cohort patients, 10 (34%, 95% confidence interval: 17-52%) survived to discharge and 8 (28%, 95% confidence interval: 11- 44%) survived at least one year after weaning from VAD support. Multivariate analysis including both pre-implant and post-implant measures found none of the pre-implant measures to be predictive of survival to discharge. Only reoperation during VAD support was negatively associated with survival to weaning and survival to discharge.

Table 2. Principal Effectiveness Outcomes, Postcardiotomy Myocardial Recovery Support

	Primary Data Cohort (n=29)		Other Data (n=31)	
	No. of Patients	% [95% CI]	No. of Patients	% [95% CI]
Hemodynamic Function Restored	22	76% [60 - 91%]	18	58% [41 - 75%]
Survival to Weaning	14	48% [30 -67%]	12	39% [22 - 56%]
Survival to Discharge	10	34% [17 -52%]	5	16% [3 - 29%]
Survival to One Year	8	28% [11 - 44%]	5	16% [3 - 29%]

Table 3. Causes of Death While on VAD Support Pending Postcardiotomy Myocardial Recovery

	Primary Data Cohort (n=29)			Other Data (n=31)			
Category	BiVAD	LVAD	Total	BiVAD	LVAD	RVAD	Total
Multi-organ Failure	2	2	4	5	1	3	9
Neurological	2	3	5	3	0	1	4
Sepsis	4	0	4	0	1	0	1
Bleeding	0	2	2	1	1	0	2
Respiratory	0	0	0	2	0	1	3
All causes	8	7	15	11	3	5	19

Survival was also analyzed for three groups excluded from the Primary Data Cohort of 29 patients. Five of six (83%) non-postcardiotomy cardiomyopathy patients survived to discharge, with four of six (67%) surviving to at least one year after weaning from VAD support. Four of 12 (33%) patients with post-cardiac transplant graft failure were discharged alive and survived to at least one year. Only one of 11 patients (9%) who were initially weaned from cardiopulmonary bypass, but had to be returned to the operating room for VAD support, survived to discharge.

9.0 CRITERIA FOR BIVAD PLACEMENT

Adequate right ventricular function is essential for the successful utilization of left ventricular assist devices, to provide sufficient blood flow through the pulmonary circulation to the left side of the heart. In situations where there are no accurate physiologic markers of right heart failure, an LVAD can be implanted first. Then a right ventricular assist device is used in addition to a left ventricular assist device (biventricular assist) when right heart failure prevents adequate function of the LVAD, generally when the blood flow index is less than 2.0 L/min/m² with a central venous pressure greater than 20 mmHg. Biventricular support is also indicated in patients with potentially lethal arrhythmias, or severe right ventricular infarction which could result in death during univentricular support. An RVAD may be considered at the time of LVAD implantation to obviate the need for a reoperation to implant the RVAD.

An isolated right ventricular assist device may also be suitable for patients with isolated right heart failure.

SECTION III HOW SUPPLIED

10.0 THORATEC VAD SYSTEM COMPONENTS

10.1 Thoratec VAD Blood Pump

The VAD blood pump is supplied sterile and non-pyrogenic for single-use only. Do not reuse or resterilize.

The central part of the system is the blood pump, which can be used as a left (LVAD), right (RVAD), or biventricular (BiVAD) assist device. It has a rigid plastic case containing an elastomeric blood pumping sac, composed of Thoratec's Thoralon™, a proprietary polyurethane multi-polymer. The blood sac is compressed by air from a pneumatic drive console to eject blood from the sac. Mechanical valves, mounted in the inflow and outflow ports of the blood pump, control the direction of blood flow. The blood pump has an effective stroke volume of 65 ml and, depending on various conditions, will pump up to 6.5 L/min at a rate of 100 beats per minute.

10.2 Cannulae

The VAD cannulae are supplied sterile and non-pyrogenic for single-use only. Do not reuse or resterilize.

Each VAD blood pump is connected to the patient's heart and great vessels with cannulae. Cannulae can be inserted in the left or right atrium or placed in the left ventricular apex to provide inflow to the VAD blood pump. Blood is returned to the patient with an arterial cannula in the aorta or the pulmonary artery depending on whether the left or right ventricle is being assisted.

The VAD and connections to inflow and outflow cannulae are shown in Figure 2.

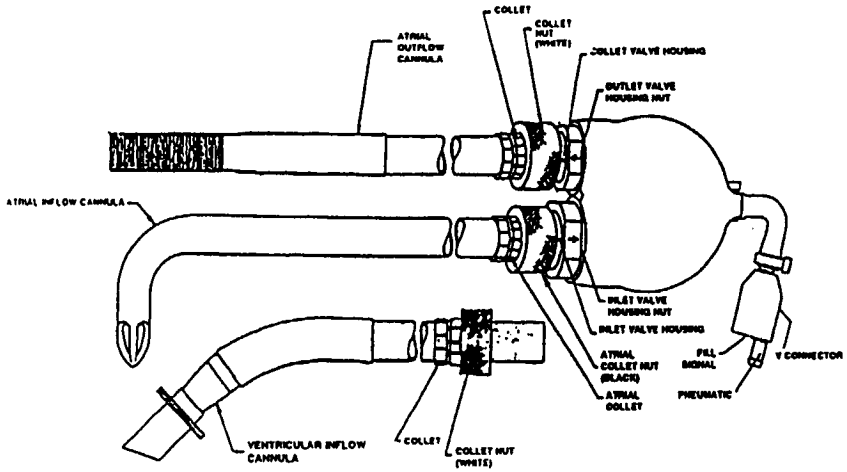

Figure 2. Thoratec VAD shown connected to arterial and atrial cannulae. For apex cannulation, the ventricular inflow cannula and its collet and white collet nut are used in place of the atrial cannula and its collet and black collet nut.

Cannulae are provided in the following configurations (see also Appendix A):

Cannula Type	Cannula Tube		Tip		Cannula Shape
	Length	I.D.	Length	I.D.	
Atrial Inflow	25-30 cm	13 mm	2 cm cage	10 mm	90° bend
Ventricular Inflow	19-32 cm	16 mm	2-5 cm	12-15 mm	straight or curved
Arterial Outflow	15-20 cm	16 mm	30 cm polyester graft	14-18 mm	straight or curved

10.3 Pneumatic and Electrical Leads and Cannula Trocar

The pneumatic and electrical leads are provided sterile for single-use only. Do not reuse or resterilize.

The blood pump is connected to the drive console by flexible plastic pneumatic tubing for drive pressure and vacuum, and by an electrical cable for transmission of the signal from the fill switch from the pump to the driver.

The cannula trocar is provided non-sterile as a reusable instrument. It must be sterilized by steam autoclave before use.

10.4 Thoratec Dual Drive Console

Note: Refer to the Dual Drive Console Directions for Use for more information.

The drive console has two independent control modules and internal compressors to provide pressure and vacuum. The driver supplies pulses of pneumatic pressure to the blood pump to eject blood into the body. Each ejection period alternates with a filling period when blood, assisted by a slight vacuum, fills the VAD.

PRECAUTION:

Each console contains two independent drive modules, and therefore contains adequate built-in back-up capability for univentricular support. For patients receiving biventricular support, a complete dual drive console must be available as a back-up to be used in the event of a failure of the primary console.

Air pulses provided by the pneumatic driver can be controlled in three different modes: an asynchronous mode when a particular rate and percent systole is set by the user and the driver maintains those conditions indefinitely (fixed rate, variable

stroke volume); a volume mode when ejection begins the instant complete filling occurs (variable rate, fixed stroke volume); and a synchronous mode when the driver, similar to an intraaortic balloon pump, provides counterpulsation using the patient's R-wave to end ejection (variable rate, variable stroke volume). The volume mode is used in most patients because the VAD flow responds automatically to changes in physiological conditions.

See Appendix A for a complete list of components and accessories with catalog order numbers.

11.0 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. See Section 11.9 for VAD replacement procedures.

Based on the in-vitro overall system reliability testing (through the study cut-off date), there is a 94% chance (using the lower 90% confidence intervals) that this device will be free of critical failures through 50 days of use, and a 65% chance that this device will be free of critical failures through one year of use.

SECTION IV IMPLANTATION PROCEDURE

12.0 CLINICAL PROCEDURES

Note: Refer to the following documents and videotapes for more information: a) Surgical Implantation Procedures videotape, b) the VAD Dual Drive Console videotape, c) the Dual Drive Console Directions for Use, and d) the Patient Management Manual.

12.1 Preparation of the VAD

Review VAD components and accessories to ensure that all components needed for the procedure are present.

Air from the VAD case chamber behind the blood pumping sac has already been evacuated during manufacturing, and normally no further action is required of the user. However, if necessary, more air can be removed with a 20 cc syringe and 22 gauge needle inserted through the small hole in the deairing port of the VAD case. Tilt the VAD to allow air to displace into the syringe and withdraw as much air as possible. Remove the syringe needle from the deairing port and from the sterile field.

Fill the VAD with a sterile heparinized albumin solution, 100 units of sodium heparin USP per 250 ml 5% albumin; typically 130 ml are needed to fill the VAD. Leave this solution in the VAD for 15 minutes before implantation (provides a passive protein coat on blood contacting surfaces). Use care to keep blood and other fluids from the electrical fill switch connector.

12.2 Preparation for Cannulation

Decide on length and type of inlet and outlet cannulae.

a. For most patients, the left ventricular apex is the preferred cannulation site for bridge to cardiac transplantation. Clinical experience has shown that higher blood flow levels can be achieved with this approach compared to atrial cannulation. Ventricular apex cannulation may also reduce the possibility of thrombosis in the natural left ventricle.

b. If left atrial cannulation is desired, the left atrial cannula can be inserted into either the left atrial appendage or via the interatrial groove. For the majority of patients, use the long atrial cannula (30 cm) for the left atrium and the short atrial cannula (25 cm) for the right atrium.

c. Position the cardiopulmonary bypass aortic perfusion cannula site so the 14 mm arterial graft on the VAD outflow cannula can be sutured to the right lateral border of the ascending aorta.

The LVAD is placed in a paracorporeal position as illustrated in Figure 3 (also see Figure 1). The percutaneous cannula sites will be approximately 4 cm apart below the costal margin. When LVAD inflow cannulation is from the LA appendage or the LV apex, the LVAD goes on the anterior abdominal wall to the left of the midline and the RVAD goes to the right of the midline, below the costal margin. If LVAD inflow cannulation is from the interatrial groove, then the LVAD is on the right and the RVAD is on the left of the midline. For LVAD placement, position both cannula exit incisions to the left of the midline to save space in the event a RVAD is needed.

Make short skin and fascial incisions to facilitate subsequent passage of the inflow and outflow cannulae (Figure 4). These openings must permit easy passage of the cannulae from the pericardial sac to the skin after the cannulae are attached to the heart and great vessels. Cannula tunnels should not be much larger than the outside diameter of the cannulae as this will allow fluid to collect and delay tissue adhesion to the velour cuff.

Plan for a length of 5 to 6 cm of cannula including 1 cm of velour cuff to be exposed on the patients abdomen for each cannula. For the arterial cannula, the entire polyester graft will remain in the chest. Cannula length determines the position of the VAD on the abdomen.

12.3 LVAD Inflow Cannulation

Blood flow to the LVAD can be provided by a ventricular inflow cannula in the left ventricular apex, or an atrial cannula in the left atrial appendage or the left atrium via the interatrial groove (Figure 1.). Cannulae can be crossclamped with smooth-jawed tubing clamps in the non-reinforced sections.

Cannulation of left ventricular apex

CAUTION:

Use caution in attempting apical cannulation if the patient has sustained a recent infarct of this area of the heart.

Preplace six to twelve pledgeted double-armed 4-0 sutures around the apex. These should form a circle approximately 3-4 cm in diameter.

Coring of the ventricle can be accomplished by one of three methods: a) direct incision and cutting of the myocardium with scissors; b) use of a sharpened circular cutting tool, approximately 14 mm diameter, such as a cork borer; or 3) a commercial instrument such as that designed for placement of LV outflow conduits.

Once the apex is cored, inspect the ventricular chamber and remove any mural thrombus. Position cannula tips with beveled ends so that the long lip is against the ventricular septum.

When properly seated, pass each arm of the suture through the felt sewing cuff and tie it against the myocardium.

The free end is then brought out through the chest wall through the lateral of the two tunnels. This can be facilitated with the cannula trocar. It is suggested that the ventricular cannula be positioned in the heart before making the skin incisions. The exit site should be in a subcostal position so that the VAD will lie on the abdomen in the left upper quadrant. Intercostal lateral exit sites are not desirable because of cannula kinking and awkward VAD placement outside the body.

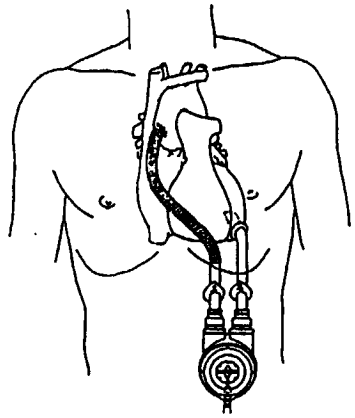

Figure 3. LVAD in a paracorporeal position, with cannulation from the left ventricular apex to ascending aorta.

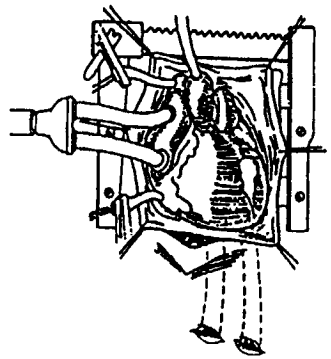

Figure 4. Percutaneous cannula exit sites below the left costal margin and to the left of the midline.

Cannulation of left atrial appendage

CAUTION:

Suboptimal flow may occur if the cannula tip is obstructed in the atrium.

CAUTION:

Do not trim the tapered end of the atrial cannula.

For atrial cannulation, it may be easier to pass the cannula through the lateral of the two subcostal tunnels before inserting it into the atrium. Retract the heart to the patient's right side, exposing the left atrial appendage (Figure 5). Place two 3-0 polypropylene purse string sutures at the base of the appendage. Begin and end each suture by passing it through a felt pledget. Leave the sutures long and pass them through 15 cm long rubber tube keepers.

Incise the left atrium and gradually dilate the opening with Hegar dilators. Insert the atrial cannula approximately 4 cm from the end of the tip (note: the single and double line markers are 5 and 6 cm from the tip, respectively). Tighten the rubber keepers and tie them over buttons. Secure the cannula by tying a tape ligature around each keeper and the cannula. Pass the cannula through the subcostal tunnel if this has not been done. The cannula trocar can facilitate this passage.

Cannulation of the left atrium via the interatrial groove

An alternate cannulation technique of the left atrium is via the interatrial groove. If the patient has a moderate to large left atrium with a friable or obliterated left atrial appendage, insert the inflow cannula into the left atrium along the interatrial groove between the right superior and inferior pulmonary veins (Figure 6). Do not insert the cannula directly into a pulmonary vein because of potential stasis thrombosis in the vein.

Use pursestring sutures with keepers to suture the cannula in a similar fashion to that used for the left atrial appendage. With this cannula placement, the VAD will be positioned to the right of the midline and upside down with the fill switch side of the VAD against the abdomen as shown in Figure 1C.

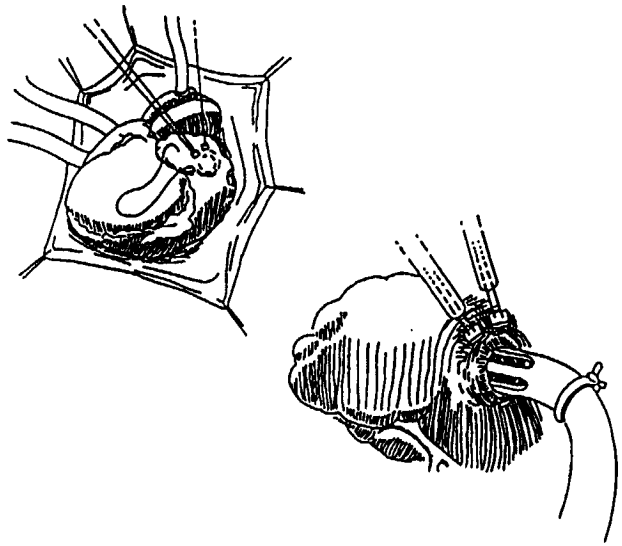

Figure 5. Cannulation of the left atrial appendage.

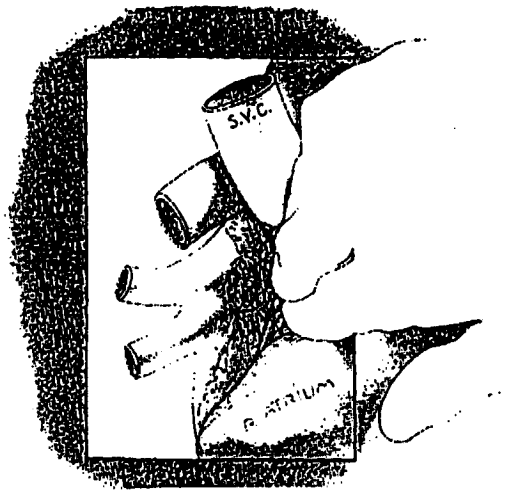

Figure 6. Cannulation site for the left atrium via the interatrial groove.

12.4 VAD arterial outflow cannulation

Preclot arterial graft

Cut the tightly stretched graft to length.

Method A: Immerse it in blood (about 100 ml) mixed with 5 mg protamine and one ampule (5000 units) of topical thrombin. Massage into graft for 5 minutes until graft is sealed.

Method B:

a. Put 2 units (50 cc/unit) of cryoprecipitate in a kidney basin and massage into graft for 5 minutes.

b. Put 50 cc of thrombin (Parke-Davis, 1000 units/cc) in another kidney basin. Remove graft from cryoprecipitate and place in basin of thrombin and massage thrombin into graft for 3-4 minutes. A gel will form on the graft.

c. Flush out graft carefully with saline to remove any remaining thrombin. Carefully inspect interior of graft and remove all clumps of gel.

Aortic Anastomosis

Make sure the arterial graft is preclotted and cut (tightly stretched) to length. Apply an arterial tangential clamp (Beck) to the right lateral border of the ascending aorta, open the aorta, and anastomose the graft using double-armed 4-0 polypropylene suture (Figure 7). After completing the anastomosis, release the tangential clamp and deair the cannula. Apply a tubing clamp to the non wire-wound portion of the cannula. Cover the end with a rubber finger cut from a glove and pass the tube through the medial subcostal cannula tunnel. The cannula trocar can facilitate this passage.

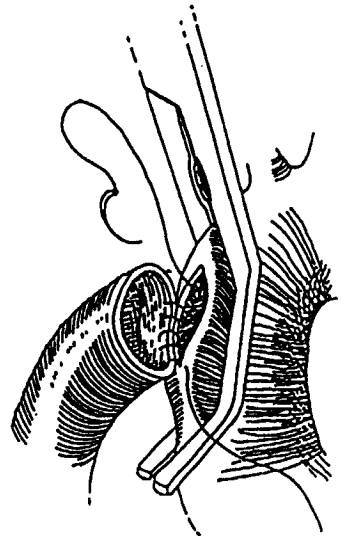

Figure 7. Aortic anastomosis.

If an .. .. inflow cannula is in place, cut the distal polyurethane end of the arterial cannula to match the length of the flared atrial cannula. Do not cut the tapered end of the atrial cannula. If a ventricular inflow cannula is in place, trim the ventricular cannula and the arterial cannula as short as possible, but leave at least 4 cm of non wire-reinforced cannula for proper attachment to the VAD.

12.5 Connect Cannulae to VAD and Eliminate Air

There are two sizes of cannula connectors. The smaller of the flared clamping ring collets and the white collet nuts are used for the arterial and ventricular cannulae. The atrial cannula requires the larger collet and the black collet nut. The standard VAD configuration is shipped with an arterial collet and white nut on the outflow port and with an atrial collet and black nut on the inflow port. If left ventricular cannulation is to be performed, remove the atrial collet and black nut and replace with the ventricular collet and white nut packaged with each ventricular cannula.

WARNING:

Use the ventricular collet and WHITE collet nut provided with the ventricular cannula to attach the cannula to the VAD blood pump. DO NOT use the atrial collet and BLACK collet nut shipped with the VAD to attach a ventricular cannula. Remove the atrial collet and black collet nut from the surgical field. Failure to use the correct collet and collet nut may result in insecure cannula engagement leading to the possibility of serious injury or patient death.

Keep both inflow and outflow cannulae clamped while securing cannulae on the VAD. Clamp the arterial graft near the aortic anastomosis. Carefully (to reduce bubbles) pour the heparinized albumin out of the VAD and refill with sterile saline. Remove the white arterial collet nut and the collet from the VAD and slide over the end of the VAD outflow cannula.

A deairing catheter can facilitate the removal of air in the VAD, which must be inserted prior to connecting the VAD arterial outflow cannula to the VAD. Nick the graft and insert a 5-7 F right angle angiography catheter filled with saline and connected to a 50 ml syringe and a three way stopcock. Place a 3-0 felt backed pursestring stitch at the graft nick and secure it with a tourniquet. Advance the catheter toward the VAD and out of the cannula and then through the outflow valve and into the VAD.

Position the arterial cannula on the VAD outflow port (Figure 8). Direction of blood flow is indicated by arrows on the valve housing nuts. Use gauze, if necessary, to work the cannula tip up the cone-shaped valve housing until the cannula edge is all the way into the connector groove.

CAUTION:

The valve housing has a very sharp edge designed to minimize seam thrombus. Do not dent or scratch this sharp edge and be careful to avoid cutting yourself.

When the cannula tube is fully seated on the valve housing, force .. .ollet over the tube as far onto the VAD as possible. Using the back of a pair of forceps facilitates this process. Then tighten the nut firmly by hand.

Now attach the inflow cannula. Slide the correct inflow cannula collet and collet nut (black for atrial and white for ventricular apex) onto the inflow cannula. Hold the inflow cannula against the inlet connector of the VAD. Unclamp the arterial cannula and tilt the VAD so the uppermost portion of the inflow connector is high, thus eliminating air from the VAD. Then force the inflow cannula on the VAD cone shaped valve housing, again working it all the way into the connector groove. Slide the collet into place as far as possible and tighten the nut by hand.

Place the deairing catheter tip at the apex of the VAD. Then unclamp the arterial cannula and withdraw air through the catheter. Make sure all air has been removed before withdrawing the catheter. Allow the small opening in the graft to bleed for the first few minutes of VAD pumping to evacuate any remaining bubbles, then seal by tying the previously placed pursestring suture.

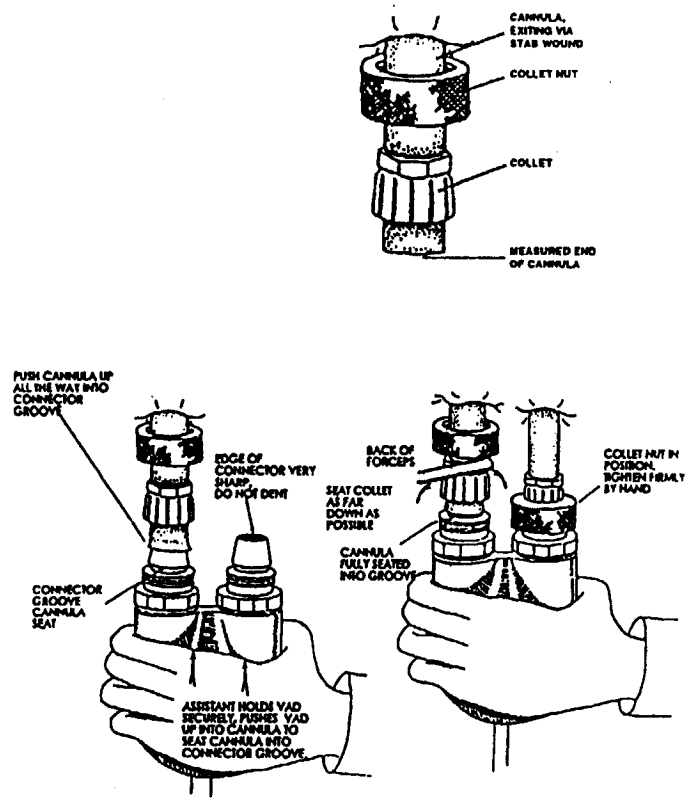

Figure 8. Cannula connections to VAD.

12.6 Insta...n of RVAD

Use techniques similar to that for inserting the LVAD with atrial cannulation. Place the percutaneous cannula sites to the right of midline below the right costal margin. In those cases where the LVAD inflow is cannulated from the interatrial groove, the RVAD will be positioned to the left of midline. Use the short atrial cannula for most patients and place the atrial cannula in the body of the right atrium opposite the tricuspid valve rather than near the appendage. For the pulmonary arterial cannula, cut the arterial graft to length and preclot as for the LVAD. Cross the pulmonary arterial cannula over the aortic cannula before anastomosis to the upper surface of the main pulmonary artery. Connect the RVAD and deair as described for the LVAD.

12.7 Initiation of Pumping and Completion of Procedure

Refer to Dual Drive Console Directions for Use for more detailed procedures.

Connect the VAD pneumatic drive tube and electrical lead (align red dots on both halves of electrical connectors) to the VAD and pass the drive unit ends off the sterile field to the drive console technician.

Make sure the module selector valve on the inside of the console back door is correctly positioned in the middle position. Drive the VAD initially at a slow fixed rate (asynchronous fixed rate mode; 40 beats per minute, 20% systole), with a drive pressure initially set to about 100 to 110 mmHg and with vacuum at 0 to -4 mmHg. Check for VAD leaks at this time. Gradually increase eject pressure to over 200 mmHg with moderate levels of vacuum (i.e. -10 to -25 mmHg). When the VAD is filling and emptying regularly, the volume mode can be used.

CAUTION:

Applying excess vacuum with the chest open increases the risk of air embolism. If an atrial vent is to be removed or a direct left atrial pressure monitoring line is inserted, clamp the left atrial cannula before removing the vent or inserting the catheter, and keep the clamp in place until after the left atrial opening is sealed.

When the chest is closed, full vacuum (-25 to -40 mmHg) can be applied. It is recommended that the pneumatic drive pressure be set at least 100 mmHg above the systolic blood pressure (LVAD: 230 to 245 mmHg; RVAD: 140 to 160 mmHg) to completely empty the VAD with a systolic ejection time of 300 msec.

Complete VAD emptying can be verified by shining a flashlight through the fill switch side of the pump housing and looking on the other side for a flash of light. Inadequate filling in the absence of cannula obstruction can often be treated with volume infusion.

After satisfactorily weaning the patient from cardiopulmonary bypass, administer the usual doses of protamine. Hold the sternum closed and check for adequate VAD filling and cannula positioning. Then completely close the sternum and skin with standard techniques.

12.8 Weaning the Patient from VAD Support - Recommended Proce

Briefly discontinue VAD use each day for no more than 60 seconds at a time and evaluate the patient's own ventricular function. If the patient maintains an atrial pressure of 20 mm Hg or less (via pulmonary artery catheter or direct atrial line) and a systolic arterial pressure of 100 mmHg or more, then make at least two measurements of cardiac index.

When two consecutive measurements of cardiac index exceed 2.0 L/min/m² without the VAD, decrease VAD output in steps at 6 hour intervals to gradually permit the patient's ventricle to resume full circulatory support.

To decrease VAD output, use the asynchronous mode (rather than the volume mode) and decrease VAD rate 5 beats per minute every 6 hours, while maintaining complete VAD filling and emptying. The goal is to achieve adequate hemodynamics as documented by atrial pressure, arterial pressure, and cardiac index throughout the weaning period, while reducing the VAD beat rate to a minimum of 30 beats per minute. Anticoagulation should be carefully monitored and maintained during weaning because lower flow could result in thrombus formation within the VAD (See Section 13.4).

Adequate ventricular function, as documented by atrial pressure, arterial pressure, and cardiac indices during 60 seconds without VAD pumping, should be demonstrated at least four times during 24 hours before VAD removal.

Preferably, the patient should not need or be receiving inotropic agents before VAD removal.

12.9 Explantation of LVAD and RVAD

Administer intravenous antibiotics 1 hour before VAD removal.

Continue VAD pumping while the patient is moved from the intensive care unit to the operating room.

After induction of anesthesia, thoroughly prep chest, abdomen, VAD, and groin areas.

Wrap the external portion of the VAD and cannulae with sterile wraps, all of which will be passed as one package from the sterile field after removal.

Drape the patient and reopen the sternal incision.

CAUTION:

Use care to avoid cutting into the VAD cannulae and arterial grafts. Carefully remove any mediastinal clot and expose the cannulae.

If proceeding to heart transplantation, establish cardiopulmonary bypass and stop VAD pumping.

Clamp the inlet and outlet cannulae inside the chest and cut the cannulae near the inside chest wall.

Pull the VAD and attached cannulae through the chest wall as a single unit.

Ren.. remaining cannula sections from the heart and proceed with cardiac transplantation in the usual manner.

Patient management is conventional thereafter.

12.10 VAD Replacement Procedure

If for any reason a VAD requires replacement, the following procedure may be used (based on Lohmann DP, et al: Replacement of paracorporeal ventricular assist devices. Ann Thorac Surg 54:1226-1227, 1992). The cannulae are clamped and the VAD is removed from the cannula ends and a new VAD is attached.

1. Anesthetize, prep, and drape the patient in a sterile field.
2. Insert monitoring lines (arterial and Swan-Ganz) and make standby peripheral bypass available.
3. Anticoagulate the patient with heparin (1 mg/kg).
4. Apply povidone-iodine solution to all VAD surfaces, wipe dry with sterile towels, and respray with povidone-iodine. All surfaces should still be considered contaminated.
5. Insert lines for infusion of inotropic agents if required to provide some support during the period of VAD changeout.
6. Terminate VAD pumping. If the systolic blood pressure drops below 80 mmHg for more than 5 minutes, reinstitute VAD pumping and initiate cardiopulmonary bypass through groin vessels.
7. Clamp the VAD cannulae.
8. Remove the cannula connectors from the VAD and carefully remove the cannulae from the valve housing, taking care not to damage the ends that will be used on the replacement VAD.
9. Prepare a new VAD as in Section 12.1.
10. Connect the VAD to the inflow cannula. Slowly unclamp the cannula to allow the blood pump to fill with blood, then reclamp the cannula.
11. When the blood sac is nearly full of blood, partially connect the VAD to the outflow cannula.
12. Using a bulb syringe, squirt heparinized saline on the connectors while connecting the outflow cannula and VAD. If any air is present, the cannula must be removed and the step repeated until no air is in the VAD blood pump.
13. Once all air is eliminated from the system, VAD pumping can be initiated, and the patient can be weaned from inotropic support and/or cardiopulmonary bypass can be terminated.

SECTION V OTHER CONSIDERATIONS

13.0 PATIENT MANAGEMENT

13.1 Fluids, Inotropic and Vasoactive Drugs

After implantation, the patient is returned to the cardiovascular intensive care unit. Fluids are given to maintain LVAD flow index at greater than 2.0 L/min/m² with central venous pressure and left atrial pressure less than 20 mmHg. Some vasopressor and/or vasodilatory pharmacologic assistance can be used as required to adjust vasomotor tone. Patients with isolated LVAD support may require inotropic assistance of right ventricular function.

13.2 Infection Control

For prevention of infection, a broad spectrum cephalosporin should be used for antibiotic prophylaxis for the first 24 to 48 hours at a dosage of 1 to 3 gm/day, similar to that of other open-heart procedures. After this, organism-specific antibiotics are resumed as needed based on positive culture results. Early extubation and removal of monitoring lines and patient ambulation are to be encouraged. Rapid restoration of oral nutrition is attempted using tube feeding if necessary. Physical therapy and range of motion can begin after 24 hours. The patient can be moved to a chair and can use an exercise bicycle as soon as possible. Nursing measures to decrease infection include frequent hand washing, and strict aseptic technique during contact with invasive lines or during VAD cannula site dressing changes. Dressings around cannulae are changed twice daily for the first two days and then daily.

WARNING:

Do not use Povidone-iodine ointment because of possible damage to cannulae (see Section 4.4); Povidone-iodine solution is recommended.

13.3 Control of Bleeding

Bleeding is one of the more frequent adverse events in VAD patients. The chest tube output should be monitored every 30 to 60 minutes, and laboratory measurements of partial thromboplastin time, prothrombin time, fibrinogen and platelet count should be measured routinely. If bleeding is excessive, platelets can be given, and packed red blood cells and fresh frozen plasma are administered to correct for abnormalities in hematologic measurements. Re-exploration should be considered if chest tube output exceeds 200 ml/hour for 2 consecutive hours after clotting factors have been restored.

13.4 Rec. ..nded Anticoagulation Regimen

Anticoagulation strategy is similar to that for patients with mechanical heart valves. Taking into consideration the patient's coagulation parameters, once the chest tube drainage falls to about 50 ml/hr for 2 to 3 hours (usually in the first or second postoperative day), anticoagulants should be considered to minimize the risk of thromboembolism. Two primary anticoagulation agents have been used in VAD patients: heparin and warfarin. Patients have been started on intravenous heparin on the first or second postoperative day at a dosage of approximately 10 units/kg/hr, gradually increasing to maintain the partial thromboplastin time at approximately 1.5 times control. As patients tolerate oral medication, they have been switched to oral warfarin in order to eliminate the intravenous line required for heparin. Warfarin has been administered similar to that for patients with mechanical heart valves to keep the International Normalized Ratio (INR) at 2.5 to 3.5. Low molecular weight dextran, aspirin, and persantine have also been used.

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Appendix A
THORATEC® VAD SYSTEM
COMPONENTS AND ACCESSORIES

	Description	Catalog No.
Clinical VAD	Ventricular Assist Device Blood Pump	14086-2550-000
Dual Drive Console	Model 2600, 110-120V/50-60 Hz	10025-2600-005
Clinical Arterial Outflow Cannulae	Arterial Cannula, short, straight 15 cm long straight tube + 30 cm long graft (14mm ID)	14125-2559-000
	Arterial Cannula, short, curved 15 cm long curved tube + 30 cm long graft (14 mm ID)	14124-2561-000
	Arterial Cannula, long, straight 18 cm long straight tube + 30 cm long graft (14 mm ID)	14126-2558-000
	Arterial Cannula, long, curved 18 cm long curved tube + 30 cm long graft (14 mm ID)	14127-2560-000
	Arterial Cannula, long straight, 18 mm graft 18 cm long straight tube + 30 cm long graft (18 mm ID)	14812-2556-000
	Arterial Cannula, ex long, straight, 18 mm graft 20 cm long straight tube + 30 cm long graft (18 mm ID)	14813-2557-000
Clinical Atrial Inflow Cannulae	Atrial Cannula, short 25 cm long with right angle bend and 10 cm velour cuff	14120-2563-000
	Atrial Cannula, long 30 cm long with right angle bend and 10 cm velour cuff	14121-2562-000
	Atrial Cannula, long, with extra long velour 30 cm long with right angle bend and 13 cm velour cuff	14814-2575-000
Clinical Ventricular Inflow Cannulae	Ventricular Cannula with two side-holes 20 cm long straight tube + 5 cm long, 16 mm OD smooth tip (beveled, with 2 side-holes)	14111-2571-000
	Ventricular Cannula, extra long, with two side-holes 25 cm long straight tube + 5 cm long, 16 mm OD smooth tip (beveled, with 2 side-holes)	14815-2568-000
	Ventricular Cannula, blunt tip 27 cm long straight tube + 2.5 cm long, 16 mm OD velour-covered tip (blunt, no side-holes)	14114-2572-000
	Ventricular Cannula, extra long, blunt tip 29 cm long straight tube + 2.5 cm long, 16 mm OD velour-covered tip (blunt, no side-holes)	14816-2569-000

Appendix A
THORATEC® VAD SYSTEM
COMPONENTS AND ACCESSORIES

	Description	Catalog No.
Clinical Ventricular Inflow Cannulae (cont.)	Ventricular Cannula, short, curved 16 cm long curved tube + 3 cm long, 16 mm OD velour-covered tip (beveled, no side-holes)	14115-2565-000
	Ventricular Cannula, long, curved 21 cm long curved tube + 3 cm long, 16 mm OD velour-covered tip (beveled, no side-holes)	14116-2564-000
	Ventricular Cannula, long, large tip 28 cm long straight tube + 4 cm long, 19 mm OD smooth tip (beveled, no side-holes)	14819-2570-000
Accessories	Pneumatic Lead 8': Eight foot (2.4m) long pneumatic tube	14133-2580-000
	Pneumatic Lead 12': Twelve foot (3.5 m) long reinforced pneumatic tube, quick connects	14822-2579-000
	Electrical Lead 8': Eight foot (2.4 m) long fill switch cable	14144-2581-000
	Electrical Lead 12': Twelve foot (3.5 m) long fill switch cable	14823-2578-000
	Cannula Trocar	14451-2583-000
	External Alarm cable	14820-2584-000
	Hand Pumping Bulb	14148-2588-000
	Hand Pumping Bulb with Quick Connects	14787-2589-000
	External Pressure/Vacuum Connector set	10025-2585-000
Training	Clinical VAD Training Program	TRAIN-2599-VAD
	Dual Drive Console Directions for Use	14025
	Thoratec VAD Console Operation with Illustrations	14803
	Dual Drive Console Quick Reference Card	14831
	Patient Management Manual	14577
	Videotape: Surgical Implantation Procedures	14804
	Videotape: VAD Dual Drive Console	14805
Training Devices	Animal VAD	14058-2552-000
	Animal Arterial Cannula 18 cm long straight tube + 15 cm long graft (18 mm ID)	13891-2590-000
	Animal Ventricular Cannula 31 cm long double bend tube + 4 cm long smooth tip (19 mm OD, beveled, no side-holes)	13910-2591-000
	Animal Atrial Cannula 30 cm long with right angle bend and 10 cm velour cuff	14049-2592-000