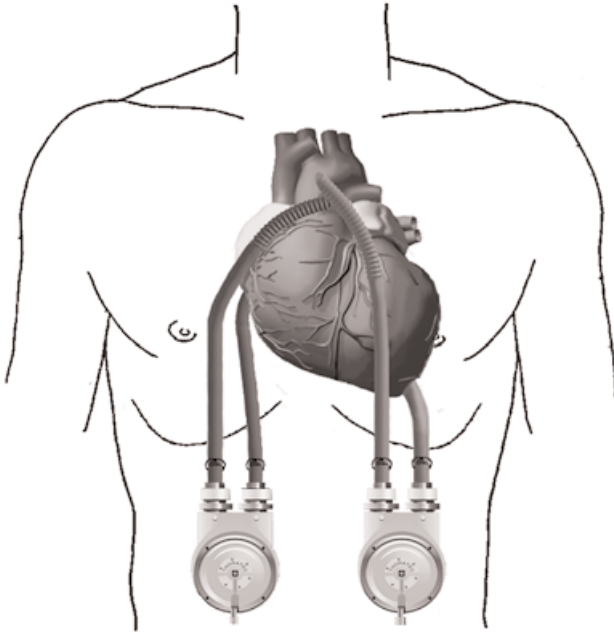


---

# Thoratec® Ventricular Assist Device (VAD) System Instructions for Use



**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.  
15003.J 3/06



**THORATEC®**  
CORPORATION

---

## Table of Contents

1.0 Device Description.....	1
2.0 Indications for Use.....	1
3.0 Contraindications.....	1
4.0 Warnings.....	2
4.1 Patient Population: General.....	2
4.2 Patient Population: Bridge-to-Transplant.....	2
4.3 Patient Population: Postcardiotomy Recovery.....	3
4.4 Procedural Techniques: All Indications for Use.....	3
5.0 Precautions.....	3
5.1 Training of Personnel.....	3
5.2 Technique of VAD Placement.....	3
5.3 External Alarms: Dual Drive Console Only.....	4
5.4 Required System Backup.....	4
5.5 Steps to Minimize the Risk of Thrombosis.....	5
5.6 Interaction with Magnetic Resonance Imaging.....	5
6.0 Adverse Events.....	5
7.0 Clinical Background and Concerns: Bridge-to-Transplant.....	8
8.0 Clinical Background and Concerns: Postcardiotomy Recovery.....	9
9.0 Criteria for BiVAD Placement.....	11
10.0 Thoratec VAD System Components.....	12
10.1 Thoratec VAD Blood Pump.....	12
10.2 Cannulae.....	12
10.3 Pneumatic and Electrical Leads.....	14
10.4 Surgical Implant Accessory Kit.....	14
10.5 Thoratec Cannula Tunneler.....	15
10.6 Thoratec Dual Drive Console.....	15
10.7 TLC-II Portable Driver.....	16
11.0 Reliability Evaluation.....	16
12.0 Clinical Procedures.....	17
12.1 Preparation of the VAD.....	17
12.2 Preparation for Cannulation.....	18
12.3 LVAD Inflow Cannulation.....	20
12.3.1 Cannulation of Left Ventricular Apex.....	20
12.3.2 Cannulation of Left Atrial Appendage.....	22
12.3.3 Cannulation of Left Atrium Via the Interatrial Groove.....	23
12.4 VAD Outflow Arterial Cannulation.....	24
12.4.1 Preparation of Arterial Graft.....	24
12.4.2 Preclot Arterial Graft.....	25
12.4.2.1 Method A.....	25
12.4.2.2 Method B.....	25
12.4.3 Aortic Anastomosis.....	25

---

12.5	Connect Cannulae to VAD and Eliminate Air.....	27
12.5.1	Method A: Using VAD Accessory Kit.....	27
12.5.2	Method B: Using De-airing Catheter.....	28
12.6	Installation of RVAD.....	30
12.7	Initiation of Pumping and Completion of Procedure.....	30
12.8	Weaning the Patient from VAD Support: Recommended Procedure.....	31
12.9	Explantation of LVAD and RVAD.....	32
12.10	VAD Replacement Procedure.....	32
13.0	Patient Management.....	34
13.1	Fluids, Inotropic and Vasoactive Drugs.....	34
13.2	Infection Control.....	34
13.3	Control of Bleeding.....	35
13.4	Recommended Anticoagulation Regimen.....	35
14.0	References.....	36
	Appendix A.....	39



# 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, the *Dual Drive Console Instructions for Use*, and the *TLC-II Instructions 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 pneumatic driver. See Section 10.0 for a more detailed description of the system components.

## 2.0 Indications for Use

The Thoratec Ventricular Assist Device is indicated for:

- Bridge-to-transplant patients who meet all of the following criteria:
  - Candidate for cardiac transplantation.
  - Imminent risk of dying before donor heart procurement.
  - 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.

Sealed arterial cannulae should not be implanted in patients who exhibit sensitivity to materials of bovine origin.

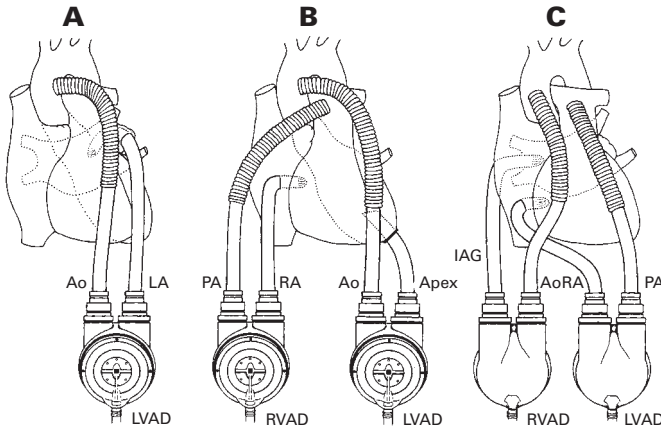


Figure 1. Thoratec Ventricular Assist Device (VAD) and three cannulation approaches for univentricular left heart support (Panel A) and biventricular support (Panels B and C). Ao=aorta, LA=left atrial appendage, PA=pulmonary artery, RA=right atrium, Apex=left ventricular apex, IAG=cannula inserted via 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).

## 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 and cannulae are provided sterile; caution must be taken in opening the packages. Do not resterilize. Do not use if packages are damaged. Store at 20–30°C.

The sealed arterial cannula packaging includes an outer foil pouch that encases the cannula tray set and preserves optimal prosthesis characteristics of the sealed graft. A sachet containing molecular sieves is included to further aid this purpose. The pouch and the outer tray of the cannula are NOT sterile; only the innermost tray may be introduced into the sterile field. Once the cannula tray set has been removed from the foil pouch, the sealed arterial cannula must be implanted within one month.

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, ethyl acetate, 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) may be used.

## 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.

Unless a sealed arterial cannula is used, the graft section of the arterial cannula must be preclotted before use. Do not preclot sealed arterial cannulae.

The distal end of the arterial, ventricular, and beveled tip atrial 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, heart and cannulae have 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: Dual Drive Console Only

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 in 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 Dual Drive Console contains two independent drive modules, and therefore contains adequate built-in back-up capability for uni-ventricular support. For patients using the TLC-II or receiving bi-ventricular support on the Dual Drive Console driver, an additional TLC-II or Dual Drive Console must be available as a back-up to be used in the event of a failure of the primary driver.

Personnel should be trained how to hand pump a VAD in the event of a Dual Drive Console or TLC-II failure. If for any reason there is a driver failure, blood flow can be maintained to the patient and stasis prevented in the blood pump by disconnecting the VAD pneumatic lead from the driver and connecting it to the hand pump for the short period of time necessary to connect the back-up driver. Squeeze the hand pump about once per second to empty and fill the blood pump. Alternatively place hand pump on floor and use your foot to compress the hand pump (again, once per second). Connect the back-up Dual Drive Console or TLC-II as soon as possible.

ble. The hand pumping 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 (auto mode on TLC-II). 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 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.

A variety of other adverse 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

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

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

free hemoglobin after 2 weeks of pumping averaging  $18 \pm 9$  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/m<sup>2</sup> or systolic pressure
- 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 ( $1.4 \pm 0.7$  L/min/m<sup>2</sup>) improved following VAD placement to an LVAD flow index of  $2.5 \pm 0.5$  L/min/m<sup>2</sup> 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  $2.8 \pm 0.5$  L/min/m<sup>2</sup>) 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 ( $1.5 \pm 0.5$  L/min/m<sup>2</sup>) improved following VAD placement to a VAD flow index of  $2.2 \pm 0.3$  L/min/m<sup>2</sup> 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

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

Category	Primary Data Cohort (n=29)			Other Data (n=31)			
	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

(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.

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/m<sup>2</sup> 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, sterilized with ethylene oxide (EO). 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 driver 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, sterilized with ethylene oxide (EO). Do not reuse or resterilize.

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

Table 4. Cannula Configurations

Cannula Type	Cannula Type		Tip		Cannula Shape
	Length	I.D.	Length	I.D.	
Beveled tip atrial inflow	25-30 cm	11 mm	2 cm	11 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
Sealed arterial outflow	15-20 cm	16 mm	30 cm polyester graft	14-18 mm	straight or curved

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.

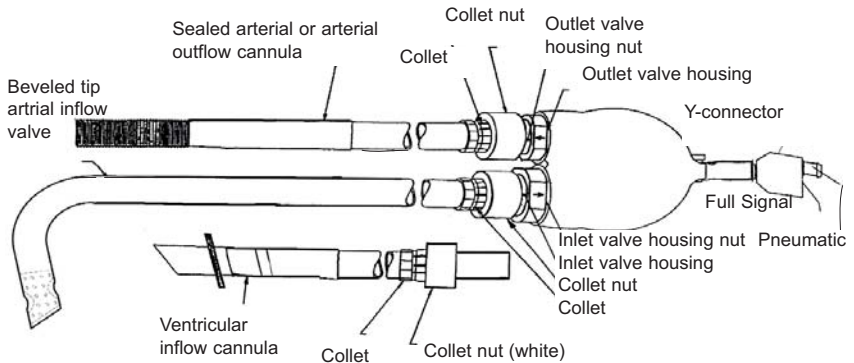


Figure 2. VAD and connections to inflow and outflow cannulae. Atrial cannulation is performed using the beveled tip atrial cannula, whereas apex cannulation utilizes the ventricular cannula. All other cannulae (beveled tip atrial, ventricular, arterial, and sealed arterial) are connected to the pump using a white collet nut and collet.

### 10.3 Pneumatic and Electrical Leads





The pneumatic and electrical leads are provided sterile for single-use only, sterilized with ethylene oxide (EO). Do not reuse or resterilize.

The blood pump is connected to the Dual Drive Console or TLC-II Portable Driver 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.

### 10.4 Surgical Implant Accessory Kit

The surgical implant accessory kit is provided sterile for single-use only, sterilized with gamma radiation (R).

The surgical implant accessory kit is intended to facilitate the preparation and implantation of the Thoratec VAD System. The kit consists of:

- |         |                                       |   |
|---------|---------------------------------------|---|
| One (1) | Ventricular cannula venting connector |    |
| Two (2) | Valve housing caps                    |    |
| Two (2) | Cannula plugs                         |   |
| One (1) | Dual lead connector cap               |  |

## 10.5 Thoratec Cannula Tunneler

Note: refer to the *Thoratec VAD System Cannula Tunneler Instructions for Use* for more information.

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



Figure 3. VAD Cannula Tunneler

## 10.6 Thoratec Dual Drive Console

Note: refer to the *Dual Drive Console Instructions for Use* for more information.

The Dual 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.



### CAUTION:

**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.

## 10.7 TLC-II Portable Driver

Note: refer to the *TLC-II Instructions for Use* for more information.

The TLC-II is a small portable VAD driver for patients with univentricular or biventricular support. The TLC-II can be used interchangeably with the Dual Drive Console, and operates under similar principles. The TLC-II 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.



### CAUTION:

**A TLC-II or Dual Drive Console must be available as a backup to be used in the event of a failure of the primary TLC-II.**

The TLC-II can be controlled in two different modes: A) fixed rate, when a particular rate and ejection time are set by the user and the TLC-II maintains those conditions indefinitely (same as asynchronous mode on the Dual Drive Console); and b) auto Rate mode, when ejection begins after the VAD is completely full with blood (same as volume mode on the Dual Drive Console). The auto Rate 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 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 12.10 for VAD Replacement Procedures.

Based on 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) VAD Surgical Implantation Procedure videotape, b) VAD Dual Drive Console videotape, c) *Dual Drive Console Instructions for Use*, d) *TLC-II Instructions for Use* and videotape, and e) Patient Management Manual.

#### 12.1 Preparation of the VAD

1. Review VAD components and accessories to ensure that all components needed for the procedure are present.
2. Place the dual lead connector cap (See figures in Section 10.4) over the dual lead connector in order to keep blood or other fluids from the driver connection lines. (Figure 4)
3. Remove the collet and collet nut pairs from the VAD.



**CAUTION:**

**Ensure that the collets stay with their associated collet nuts at all times. If the VAD pump has a black/white combination, discard the black collet and collet nut.**

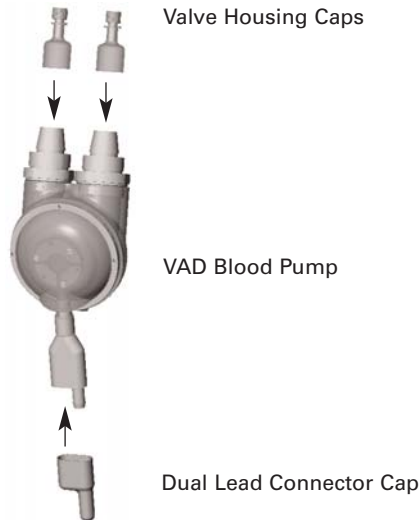


Figure 4. VAD valve housing and dual lead connector caps

4. 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.
5. Wet the valve housing caps (see figures in Section 10.4) and the valve housings with saline for lubrication. Then, place the caps on the VAD valve housing orifices to prevent any fluid from leaking out (Figure 4).
6. Position the VAD so that the valve housings are pointing upward.

The solution should be left in the VAD for 15 minutes prior to implantation (provides a passive protein coat on the blood contacting surfaces).

## 12.2 Preparation for Cannulation

1. Decide on the 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 arterial graft on the VAD outflow cannula can be sutured to the right lateral border of the ascending aorta.
2. Place the VAD in a paracorporeal position as illustrated in Figure 5 (See also Figure 1).

The percutaneous cannula sites will be approximately 4 cm apart below the costal margin. When LVAD inflow cannulation is from the left atrial 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. 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.

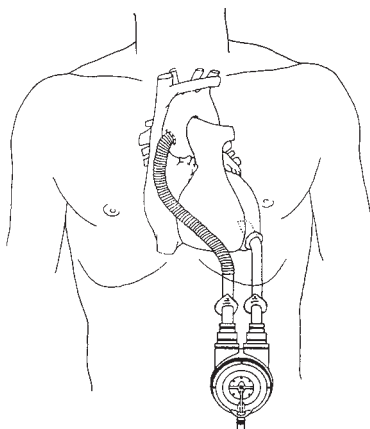


Figure 5. LVAD in a paracorporeal position, with cannulation from the left ventricular apex to ascending aorta

3. Make circular skin and short fascial incisions to facilitate subsequent passage of the inflow and outflow cannulae (Figure 5).

The 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. The cannula tunneler can facilitate the creation of the sub-costal tunnels (See Section 10.5).

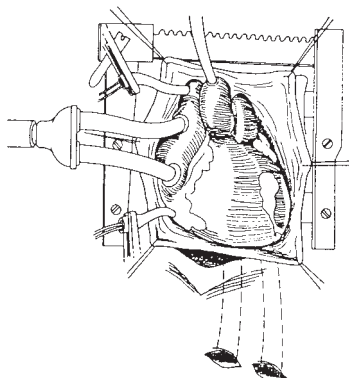


Figure 6. Percutaneous cannula exit sites below the left costal margin and to the left of the midline

## 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.

### 12.3.1 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.**

**Note:** 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 sites are not desirable because of cannula kinking and awkward VAD placement outside the body.

1. Preplace six to twelve pledgeted double-armed 4-0 sutures around the apex.

The sutures should form a circle approximately 3-4 cm in diameter.

2. Core the ventricle.

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 12 mm diameter; or c) a commercial instrument such as that designed for placement of LV outflow conduits.

3. Once the apex is cored, inspect the ventricular chamber and remove any mural thrombus.
4. Insert the ventricular cannula into the ventricle.

Position cannula tips with beveled ends so that the long lip is against the ventricular septum.

5. When properly seated, pass each arm of the suture through the felt sewing cuff and tie it against the myocardium.
6. Following insertion of the ventricular cannula into the ventricular apex, place the cannula tunneler in the lateral of the two tunnels.
7. Pass the non-valve end of the ventricular cannula venting connector through the tunneler and into the chest (See Section 10.4).
8. Using saline to lubricate, insert the non-valve end of the ventricular cannula venting connector into the distal end of the ventricular cannula (Figure 7).
9. Set the suction valve to its lowest setting and then connect this end of the ventricular cannula venting connector to the cardiopulmonary bypass circuit suction line.

10. Adjust the valve to the desired suction level.
11. Position the patient to facilitate de-airing, and then use the ventricular cannula venting connector to de-air the ventricle and the ventricular cannula.
12. Without disconnecting the ventricular cannula venting connector, pass the ventricular cannula out of the chest through the cannula tunneler.
13. Use smooth-jawed tubing clamps to cross clamp the ventricular cannula at its distal, non-reinforced end and then remove the ventricular cannula venting connector.

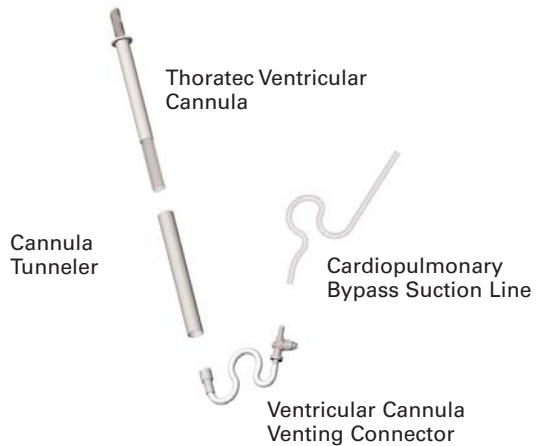


Figure 7. Ventricular Cannula and ventricle de-airing set up

### 12.3.2 Cannulation of Left Atrial Appendage



CAUTION:

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



CAUTION:

1. Retract the heart to the patient's right side, exposing the left atrial appendage (Figure 8).
2. Place two 2-0 or 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.
3. FOR THE BEVELED TIP ATRIAL CANNULA: Following cannulation using a beveled tip atrial cannula, it should be passed end first through the chest. Insert a cannula plug into the end (Figure I0B) and pass the cannula through the lateral of the two sub-costal tunnels. The cannula tunneler can facilitate its passage.
4. Incise the left atrium and gradually dilate the opening with Hegar dilators.
5. Insert the atrial cannula approximately 4 cm from the end of the tip. The single and double line markers are 5 and 6 cm from the tip, respectively.
6. Tighten the rubber keepers and tie them over buttons.
7. Secure the cannula by tying a tape ligature around each keeper and the cannula.

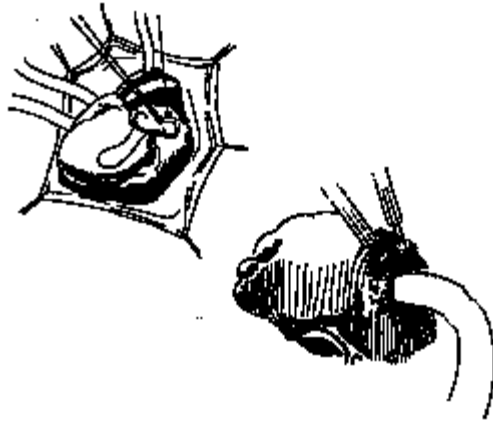


Figure 8. Cannulation of the left atrial appendage

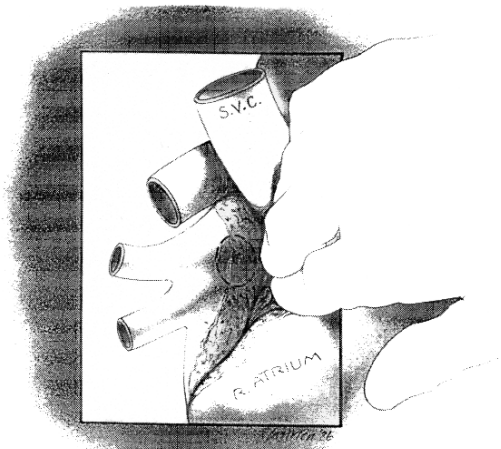


Figure 9. Cannulation site for the left atrium via the interatrial groove

### 12.3.3 Cannulation of Left Atrium Via the Interatrial Groove

**Note:** If the patient has a moderate to large left atrium with a friable or obliterated left atrial appendage, an alternate cannulation technique via the interatrial groove can be used (Figure 9). 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.

1. FOR THE BEVELED TIP ATRIAL CANNULA: Following cannulation using a beveled tip atrial cannula, it should be passed end first through the chest. Insert a cannula plug into the end (Figure 10B) and pass the cannula through the lateral of the two sub-costal tunnels. The cannula tunneler can facilitate its passage.
2. Insert the atrial cannula into the left atrium along the interatrial groove between the right superior and inferior pulmonary veins (Figure 9).
3. Use purse-string sutures with keepers to secure the cannula in a similar fashion to that used for the left atrial appendage.

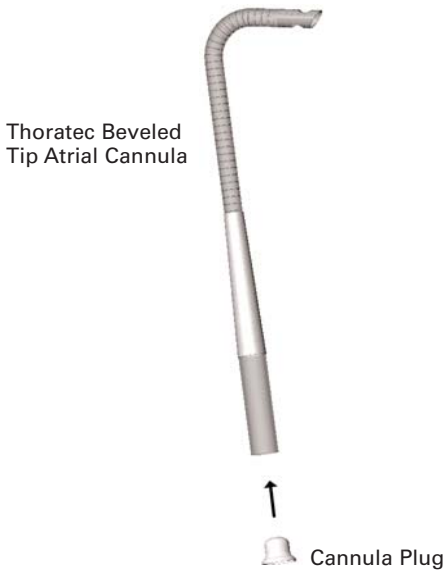


Figure 10. Beveled tip atrial cannula with plug

## 12.4 VAD Outflow Arterial Cannulation

### 12.4.1 Preparation of Arterial Graft

Tightly stretch the arterial graft portion of the outflow cannula and cut to length.

If a sealed arterial cannula is used, rinse the graft in sterile saline for at least one minute to improve its handling qualities and remove any extraneous gelatin particles.

## 12.4.2 Preclot Arterial Graft



### CAUTION:

**If the sealed arterial cannula is used, do not preclot the arterial graft. Skip the following steps and proceed to Section 12.4.3.**

Unless a sealed arterial cannula is used, preclot the graft using one of the following two procedures.

### 12.4.2.1 Method A

1. Immerse the graft in 2 units (50 cc/unit) of cryoprecipitate and massage it for 5 minutes.
2. Remove the graft from the cryoprecipitate and place it in a basin of 50 ml of thrombin (1000 units/cc).
3. Massage the thrombin into the graft for 3-4 minutes.  
A gel should form on the graft. If not, repeat the process.
4. Flush the graft out carefully with saline to remove any remaining thrombin.

Carefully inspect the graft interior and remove all clumps of gel.

### 12.4.2.2 Method B

1. Immerse the graft in non-heparinized blood (about 100 ml) mixed with 5 mg protamine and one ampule (5000 units) of topical thrombin.
2. Massage the graft meticulously for 5 minutes. Carefully inspect the graft interior and remove any clumps of gel.  
A gel should form on the graft. If not, add more thrombin and protamine, and massage for 5 more minutes.
3. Flush the graft out carefully with saline to remove any clots. Carefully inspect the graft interior and remove any clots.

## 12.4.3 Aortic Anastomosis

1. Make sure the arterial graft portion of the cannula is cut (tightly stretched) to length. Unless a sealed arterial cannula is used, confirm that the graft is preclotted.  
Do not preclot sealed arterial cannulae.
2. Apply an arterial tangential clamp to the right lateral border of the ascending aorta.
3. Open the aorta and anastomose the graft using double-armed 4-0 polypropylene sutures (Figure 11).
4. After completing the anastomosis, release the tangential clamp and de-air the cannula.
5. Apply a tubing clamp to the graft portion of the cannula.
6. Insert a cannula plug (refer to figures in Section 10.4) into the end and pass the cannula through the medial subcostal tunnel

using the cannula tunneler.

7. Cut the cannula to length.

If a ventricular inflow cannula or beveled tip atrial inflow cannula is in place, trim the inflow and outflow cannulae as short as possible, but leave at least 4 cm of non-reinforced polyurethane cannula for proper attachment to the VAD.

## 12.5 Connect Cannulae to VAD and Eliminate Air

### 12.5.1 Method A: Using VAD Accessory Kit

Note: The beveled tip atrial, ventricular, arterial, and sealed arterial) cannulae utilize the smaller flared clamping ring collets and the white collet nuts.

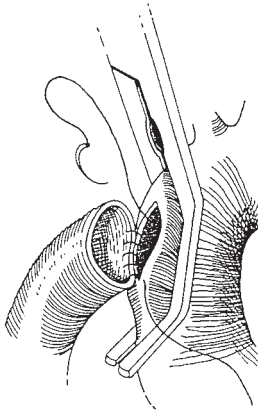


Figure 11. Aortic Anastomosis



**WARNING:**

**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. Use ONLY a White collet and White collet Nut.**

1. Remove the VAD valve housing caps and slowly pour the albumin solution out of the blood pump.
2. Completely fill the VAD with sterile saline and replace the valve housing caps back over the metal housings. The valve housing caps and the valve housings should both be wet with saline when placing the caps on the VAD.
3. Use the valve housing cap fittings and a saline filled syringe with luer fitting to completely de-air the VAD blood pump and caps.  
While de-airing, the VAD should be manipulated to ensure that air bubbles are not trapped anywhere within the pump or caps.
4. Slide the correct collet and nut over the end of the inflow cannula that is to be connected to the VAD.
5. With the VAD upright, remove the inflow valve housing cap, leaving the outflow valve housing cap in place.  
The open valve housing should be maintained at a higher level than the rest of the VAD, thus eliminating any residual air from the system.
6. Partially engage the inflow cannula on the valve housing.



**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.**

7. While an assistant uses a bulb syringe to squirt saline on the connection to prevent the introduction of air force the cannula all the way onto the valve housing (Figure 12). Keep the open junction at the highest elevation throughout the attachment process to avoid introducing air into the system.
8. Slide the outlet collet and white nut over the end of the outflow arterial cannula.
9. Again, without the introduction of air, connect the arterial cannula to the pump in the same manner that the inflow cannula was connected.



**CAUTION:**

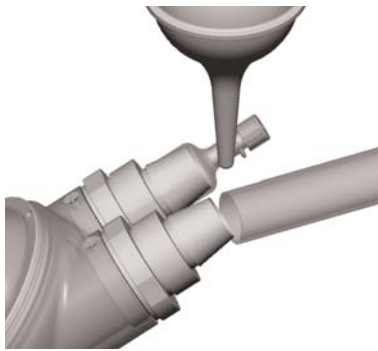
**The system should be carefully inspected for air. If any air bubbles are present, the cannula must be removed and the previous steps repeated until the VAD blood pump is completely devoid of air.**

10. Slide the collets into place as far as possible and tighten the

nuts firmly by hand.

### 12.5.2 Method B: Using De-airing Catheter

The instructions described above are designed to allow de-airing of the VAD without the use of a de-airing catheter. If preferred, a de-airing catheter can facilitate the removal of air in the VAD, which must be inserted prior to connecting an 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 4-0 or 5-0 felt backed purse-string stitch at the graft nick and secure it with a tourniquet. Advance the



**Figure 12. Use of Bulb Syringe for Cannula Connection**

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. 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 the collet 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 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 patient in Trendelenburg's position.

Place the de-airing 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 purse-string suture.

## 12.6 Installation of RVAD

Use techniques similar to that for inserting the LVAD with atrial cannulation. Place the percutaneous cannula sites to the right of mid-line below the right costal margin. In those cases where the LVAD inflow is cannulated from the inter-atrial groove, the RVAD will be positioned to the left of midline. Use a 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 if not using a sealed arterial cannula, preclot as described for the

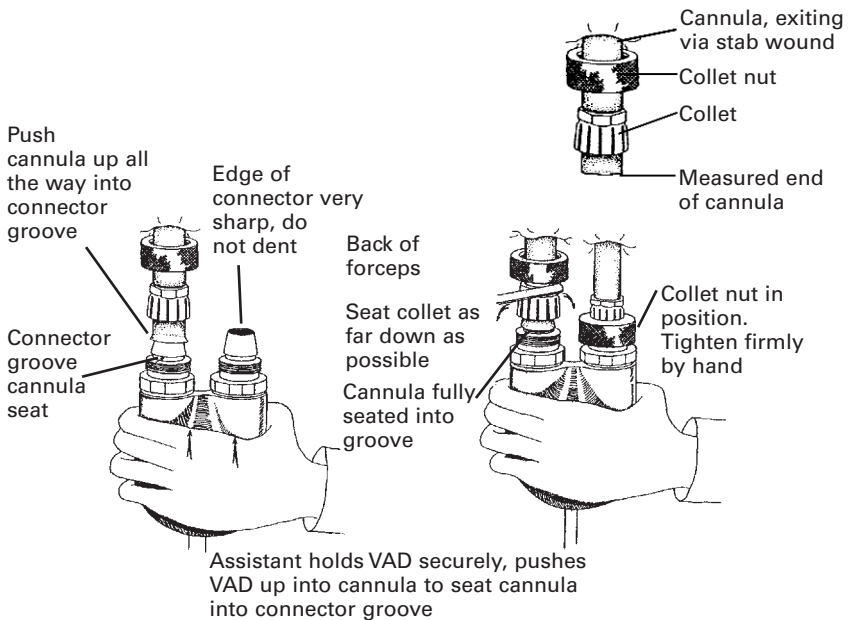


Figure 13. Cannula Connections to VAD

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 de-air as described for the LVAD.

## 12.7 Initiation of Pumping and Completion of Procedure

**Note:** Refer to the Dual Drive Console or *TLC-II Instructions for Use* for more detailed procedures.

1. 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 driver technician.
2. For the Dual Drive Console, make sure the module selector valve on the inside of the console back door is correctly positioned in the middle position.
3. Initiate VAD pumping.

Dual Drive Console:

Drive the VAD initially at a slow fixed rate (asynchronous 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 VAD for leaks at this time. Gradually increase eject pressure to over 225 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:**

**When using the Dual Drive Console, do not lower the LVAD drive pressure below 225 mmHg or the RVAD drive pressure below 135 mmHg. Lower drive pressure may result in incomplete VAD ejection, which can lead to blood stasis and possible thromboembolism.**

TLC-II:

When initiating pumping with the TLC-II, start with a slow fixed rate of 40 beats per minute and an eject time of 300 msec. The accumulator pressure should initially be set to 200 mmHg with the vacuum regulator set to its minimum value. Check VAD for leaks at this time. To attain full ejection and filling, accumulator pressure should be gradually increased to about 250 mmHg and the level of vacuum increased to moderate levels. The TLC-II RVAD drive pressure is not adjustable. Adjustments to attain full ejection of the RVAD must be done by increasing eject time. When the VAD is filling and emptying regularly, the TLC-II auto 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.

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

## 12.8 Weaning the Patient from VAD Support: Recommended Procedure

Note: It is preferable that the patient not need or be receiving inotropic agents before VAD removal.

1. 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 mmHg or less (via pulmonary artery catheter or direct atrial line), and a systolic arterial pressure of 100 mmHg or more, then take at least two measurements of cardiac index.

2. When two consecutive measurements of cardiac index exceed 2.0 L/min/m<sup>2</sup> 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/Fixed Rate mode (rather than the volume/auto 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.



### CAUTION:

**Anticoagulation should be carefully monitored and maintained during weaning because lower flow could result in thrombus formation within the VAD (See Section 13.4).**

3. 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

1. Administer intravenous antibiotics 1 hour before VAD removal.
2. Continue VAD pumping while the patient is moved from the intensive care unit to the operating room.
3. After induction of anesthesia, thoroughly prep chest, abdomen, VAD, and groin areas.
4. 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.
5. 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.**

6. If proceeding to heart transplantation, establish cardiopulmonary bypass and stop VAD pumping.
7. Clamp the inlet and outlet cannulae inside the chest and cut the cannulae near the inside chest wall.
8. Pull the VAD and attached cannulae through the chest wall as a single unit.
9. Remove remaining cannula sections from the heart and proceed with cardiac transplantation in the usual manner.
10. Continue thereafter with conventional patient management.

## 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 1992; 54: 1226-1227).

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.
11. Slowly unclamp the cannula to allow the blood pump to fill with blood, then reclamp the cannula.
12. When the blood sac is nearly full of blood, partially connect the VAD to the outflow cannula.
13. Using a bulb syringe, squirt heparinized saline on the connectors while connecting the outflow cannula and VAD.
14. Check the system for air.  
If any air is present, the cannula must be removed and the step repeated until no air is in the VAD blood pump.
15. 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/m<sup>2</sup> 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 is 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); Chlorohexadone or 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 Recommended Anticoagulation Regimen

Anticoagulation strategy is similar to that for patients with mechani-

cal 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), anti-coagulants 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.

## 14.0 References

1. Hill, J.D., et al. *Use of a Prosthetic Ventricle as a Bridge to Cardiac Transplantation for Postinfarction Cardiogenic Shock*. N Engl J Med 1986; 314: 626-628.
2. Carpentier, A., et al. *Heterotopic Artificial Heart as a Bridge to Transplantation*. Lancet 1986; 2(8498): 97-98.
3. Hill, J.D., et al. *Bridge to Cardiac Transplantation: Successful Use of Prosthetic Biventricular Support in a Patient Awaiting a Donor Heart*. Trans Am Soc Intern Organs 1986; 32: 233-237.
4. Farrar, D.J., et al. *Heterotopic Prosthetic Ventricles as a Bridge to Cardiac Transplantation: A Multicenter Study in 29 Patients*. N Engl J Med 1988; 318: 333-340.
5. Farrar, D.J., et al. *In Vivo Evaluations of a New Thrombo-Resistant Polyurethane for Artificial Heart Blood Pumps*. J Thorac Cardiovasc Surg 1988; 95: 191-200.
6. Termuhlen, D.F., et al. *Predictors for Weaning Patients from Ventricular Assist Devices*. ASAIO Transactions 1988; 34: 131-139.
7. Brugger, J.P., et al. *SWAT team approach to ventricular assistance*. Ann Thorac Surg 1989; 47: 136-141.
8. Farrar, D.J., et al. *Successful Biventricular Circulatory Support as a Bridge to Cardiac Transplantation During Prolonged Ventricular Fibrillation and Asystole*. Circulation 1989; 80: III 147-151.
9. Gray, L.A., et al. *The Pierce-Donachy Ventricular Assist Device as a Bridge to Cardiac Transplantation*. Ann Thorac Surg 1989; 48: 222-227.
10. Hill, J.D. *Bridging to Cardiac Transplantation*. Ann Thorac Surg 1989; 47: 167-171.
11. Farrar, D.J., et al. *Thoratec VAD System as a Bridge to Heart Transplantation*. J Heart Transplant 1990; 9: 415-423.
12. Pennington, D.G. and Reedy, J.E. *Bridging to Cardiac Transplantation with Pulsatile Ventricular Assist Devices*. Transplantation Science 1992; 2: 43-45.
13. Seifert, P.E., Auer, J.E., and Hazelrigg, S.R. *Successful Double Bridge to Transplantation with the Thoratec Ventricular Assist Device*. J Heart Lung Transplant 1992; 11: 812-814.
14. Reedy, J., et al. *The Importance of Patient Mobility with Ventricular Assist Device Support*. ASAIO J 1992; 38(3): M151-153.
15. Farrar, D.J., and Hill, J.D. *Univentricular and Biventricular Thoratec VAD Support as a Bridge to Transplantation*. Ann Thorac Surg 1993; 55: 276-282.
16. Hill, J.D., Farrar, D.J., and Topic, N. *The Thoratec Experience in Bridge to Cardiac Transplantation*. In: Ott RA, Gutfinger DE, Gazzaniga AB: *Mechanical Cardiac Assist*. Hanley and Belfus. Philadelphia 1993.
17. Buckland, M.R., Bergin, .P, and Esmore, D. *Transoesophageal Echocardiography Aids Insertion and Management of the "Thoratec" Ventricular Assist Device*. Anaesthesia and Intensive Care 1993; 21: 346-349.

18. Holman, W.L., et al. *Influence of Left Ventricular Assist on Valvular Regurgitation*. Circulation, 1993; 88 (part 2): 309-318.
19. Pennington, D.G., et al. *Eight Years' Experience with Bridging to Cardiac Transplantation*. J. Thorac Cardiovasc Surg 1994; 107: 472-481.
20. Farrar, D.J. *Preoperative Predictors of Survival in Patients with Thoratec Ventricular Assist Devices as a Bridge to Heart Transplantation*. J Heart Lung Transplant 1994; 13: 93-100.
21. McBride, L.R. *Bridging to Cardiac Transplantation with External Ventricular Assist Devices*. Seminars Thor Cardiovas Surg 1994; 6: 169-173.
22. Farrar, D.J., Hill, J.D., and Thoratec VAD Principal Investigators. *Recovery of Major Organ Function in Patients Awaiting Heart Transplantation with Thoratec Ventricular Assist Devices*. J Heart Lung Transplant 1994; 13: 1125-1132.
23. Salamonsen, R.F., Kaye, D., and Esmore, D.S. *Inhalation of Nitric Oxide Provides Selective Pulmonary Vasodilatation, Aiding Mechanical Cardiac Assist with Thoratec Left Ventricular Assist Device*. Anaesthesia and Intensive Care 1994; 22(2): 209-210.
24. Holman, W.L., et al. *Left Atrial or Ventricular Cannulation Beyond 30 Days for a Thoratec Ventricular Assist Device*. ASAIO J 1995; 41(3): M517-M522.
25. Holman, W.L., et al. *Circulatory Support for Myocardial Infarction With Ventricular Arrhythmias*. Ann Thorac Surg 1995; 59: 1230-1.
27. Pennington, D.G., et al. *Experience with the Pierce-Donachy Ventricular Assist Device in Postcardiotomy Patients with Cardiogenic Shock*. World J Surg 1985; 9: 37-46.
28. Swartz, M.T. and Pennington, D.G. *Use of a Ventricular Assist Device in Postcardiotomy Shock*. J Clin Engin 1985; 10: 241-249.
29. Farrar, D.J., et al. *Control modes of a Clinical Ventricular Assist Device*. IEEE Engin in Med and Biol 1986; March 19-25.
30. Glenville, B. and Ross, D. *Ventricular Assist Devices*. Brit Med J 1986; 292: 361-362.
31. Ruzevich, S.A., et al. *Long-Term Follow-Up Study of Survivors of Postcardiotomy Circulatory Support*. Trans Am Soc Artif Int Organs 1988; 34: 116-124.
32. Termuhlen, D.F., et al. *Predictors for Weaning Patients from Ventricular Assist Devices*. ASAIO Transactions 1988; 34: 131-139.
33. Ganzel, B.L., et al. *Surgical Techniques for the Implantation of Heterotopic Prosthetic Ventricles*. Ann Thorac Surg 1989; 47: 113-120.
34. Lawson, J.H. and Cederwall, G. *Clinical Experience with the Thoratec Ventricular Assist Device*. Assisted Circulation 3, F. Unger (Ed.) Springer-Verlag, Berlin Heidelberg, 1989.
35. Pennington, D.G., et al. *Seven Years' Experience with the Pierce-Donachy Ventricular Assist Device*. Ann Thorac Surg 1989; 96: 901-911.

36. Pennington, D.G., et al. *Use of the Pierce-Donachy Ventricular Assist Device in Patients with Cardiogenic Shock after Cardiac Operations*. *Ann Thorac Surg* 1989; 47: 130-135.
37. Pennington, D.G., et al. *Univentricular Versus Biventricular Assist Device Support*. *J Heart Lung Transplant* 1991; 10: 258-63.
38. Ley, S.J. *The Thoratec Ventricular Assist Device: Nursing Guidelines*. *AACN Clinical Issues in Critical Care Nursing*, 1991; 2: 529-544.
39. Holman, W.L., Bourge, R.C., and Kirklin, J.K. *Case Report: Circulatory Support for Seventy Days with Resolution of Acute Heart Failure*. *J Thorac Cardiovasc Surg* 1991; 102: 932-934.
40. Smith, J.A., et al. *Initial Australian Experience with the Thoratec Ventricular Assist Device*. *Australian J Cardiac Thorac Surg* 1992; 1: 37-43.
41. Ley, S.J. and Hill, J.D. *Thoratec Ventricular Assist Device*. chap 6. In Quall S, ed: *Cardiac Mechanical Assistance Beyond Balloon Pumping*. Mosby-Year Book St. Louis 1993.
42. Pennington, D.G., et al. *Eleven Years' Experience with the Pierce Donachy Ventricular Assist Device*. *J Heart Lung Transplant* 1994; 13: 803-10.
43. Holman, W.L., et al. *Ventricular Assist: Experience with a Pulsatile Heterotopic Device*. *Seminars Thor Cardiovas Surg* 1994; 6: 147-153.
44. Körfer, R., et al. *Mechanical Circulatory Support: The Bad Oeynhausen Experience*. *Ann Thorac Surg* 1995; 59: S56-63.

**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
Dual Drive Console	model 2601, 220-240V/50-60 Hz	10025-2601-007
TLC-II	Complete Portable VAD System	10025-2601-007
TLC-II	Driver Package	20010-2805-000
Arterial Outflow Cannulae	Arterial Cannula, short, straight 15 cm long straight tube + 30 cm long graft (14 mm ID)	14125-2559-000
	Arterial Cannula, long, straight 18 cm long straight tube + 30 cm long graft (14 mm ID)	14126-2558-000
	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
Sealed Arteria Outflow Cannulae	Sealed arterial cannula, short, straight 15 cm long straight tube + 30 cm long graft (14 mm ID)	100118
	Sealed arterial cannula, long, straight 18 cm long straight tube + 30 cm long graft (14 mm ID)	100121
	Sealed arterial cannula, long, straight, 18 mm graft 18 cm long straight tube + 30 cm long graft (18 mm ID)	100129
	Sealed arterial cannula, ex long, straight, 18 mm graft 20 cm long straight tube + 30 cm long graft (18 mm ID)	100166
Beveled Tip Atrial Inflow Cannulae	Beveled tip atrial cannula, short 25 cm long with right angle bend and 11 cm velour cuff	10075-2574-001
	Beveled tip atrial cannula, long 30 cm long with right angle bend and 11 cm velour cuff	10075-2573-001

**Appendix A**  
**Thoratec VAD System**  
**Components and Accessories**

	Description	Catalog No.
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
	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
Dual Drive Console Accessories	Pneumatic Lead 8': Eight foot (2.4 m) 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 12': Twelve foot (3.5 m) long fill switch cable	14823-2578-000
	External Pressure/Vacuum Connector set	10025-2585-000
	External Alarm Cable	20002-0000-081
	Videotape: VAD Dual Drive Console	14805
TLC-II Accessories	Docking Station with HeartTouch Computer	20010-2810-000
	Battery Charger (1)	20010-2820-000
	TLC-II Battery (1)	20010-2815-000
	Mobility Cart	20010-0000-095
	LVAD Sterile Pneumatic Lead 5 ft (1.5 m)	20010-0000-108
	RVAD Sterile Pneumatic Lead 5 ft (1.5 m)	20010-0000-109
	LVAD Sterile Electrical Lead 5 ft (1.5 m)	20010-0000-110
	RVAD Sterile Electrical Lead 5 ft (1.5 m)	20010-0000-111
	Seven foot (2 m) LVAD Electrical Extension Lead (non-sterile)	20010-0000-089
	Seven foot (2 m) RVAD Electrical Extension Lead (non-sterile)	20010-0000-090
Seven foot (2 m) LVAD Pneumatic Extension Lead (non-sterile)	20010-0000-091	

**Appendix A**  
**Thoratec VAD System**  
**Components and Accessories**

	Description	Catalog No.
TLC-II Accessories (cont.)	Seven foot (2 m) RVAD Pneumatic Extension Lead (non-sterile)	20010-0000-092
	Set-Up Plugs	20010-0000-139
	Extension Lead Junction Box	20010-0000-093
	Computer Cable 15 ft (4.5 m)	20010-0000-102
Accessories	Cannula Trocar	14451-2583-000
	VAD Surgical Implant Accessory Kit	20002-2615-001
	Hand Pump	14148-2588-000
	Hand Pump with Quick Connects	14787-2589-000
Training	Clinical VAD Training Program	TRAIN-2599-VAD
	Dual Drive Console Instructions for Use	14025
	Thoratec VAD Console Operation with Illustrations	14803
	Dual Drive Console Quick Reference Guide	14831
	Patient Management Manual	14577
	Videotape: VAD Surgical Implantation Procedure	C049-0100
	Videotape: VAD Dual Drive Console	14805
Videotape: TLC-II	C079-0701	

Manufactured by:  
Thoratec Corporation  
6035 Stoneridge Drive  
Pleasanton, CA 94588  
USA  
Tel: 925-847-8600  
Fax: 925-847-8574  
Internet: [www.thoratec.com](http://www.thoratec.com)

Authorized European Representative:  
Thoratec Europe Limited  
5 Brunel Court  
Burrel Road  
St. Ives  
Cambridgeshire  
PE27 3LW  
United Kingdom  
Tel: +44(0) 1480 409070  
24-hour Tel: +44(0) 7659 877901  
Fax: +44(0) 1480 461877

