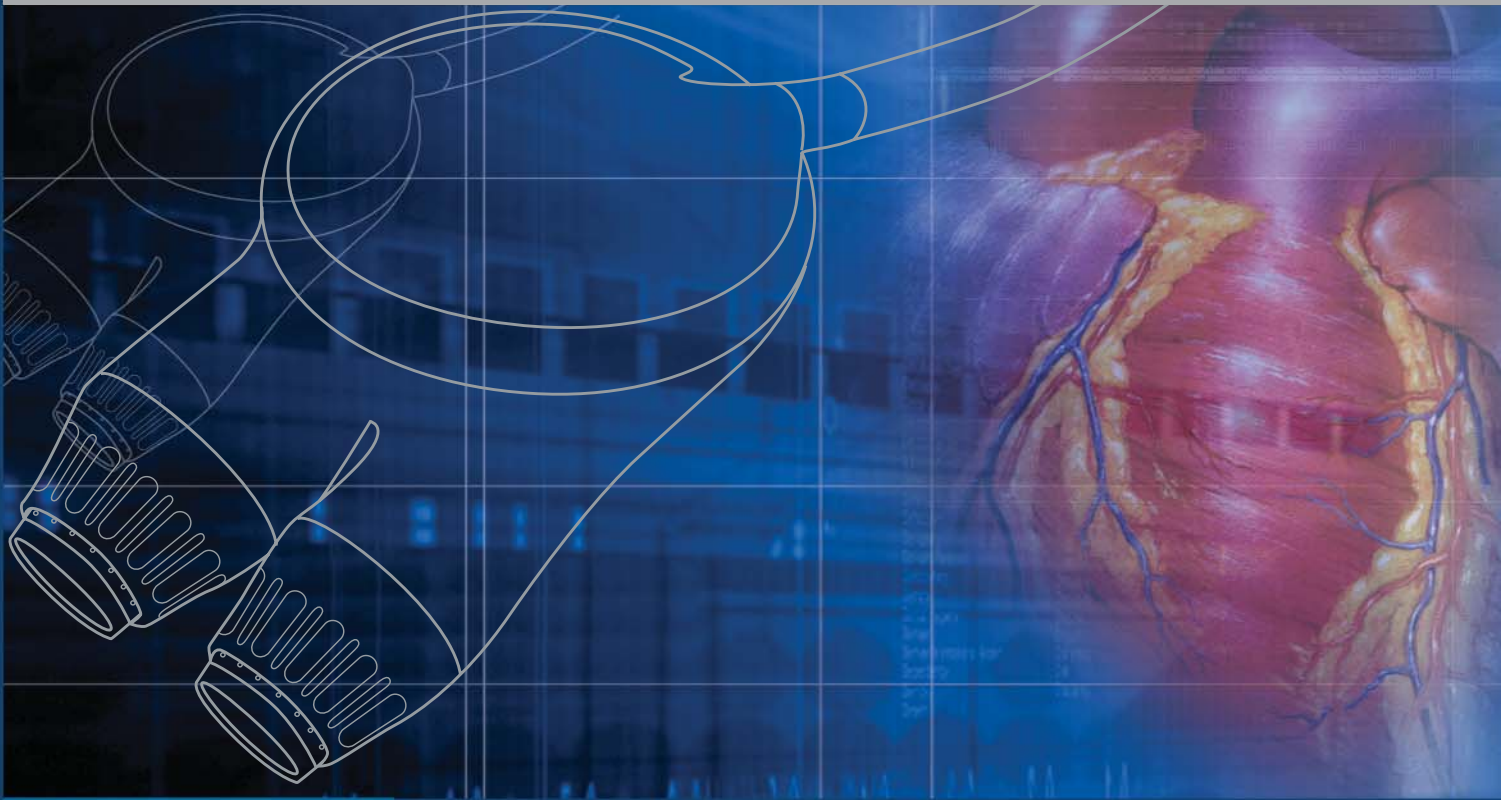


Thoratec® Implantable Ventricular Assist Device (IVAD™)

Instructions for Use



THORATEC®
CORPORATION



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

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CAUTION:

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

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**Thoratec IVAD
Instructions for Use**

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CAUTION:

A complete understanding of the technical principles, clinical applications, and risks associated with ventricular support is necessary before using the Implantable Ventricular Assist Device (IVAD) system. Read this entire booklet, as well as the *Dual Drive Console Instructions for Use* and *TLC-II Portable Driver Instructions for Use*, before proceeding with IVAD implantation. Completion of the Thoratec IVAD Training Program is required prior to using the Thoratec IVAD system.

1.0 System Description

The Thoratec Implantable Ventricular Assist Device (IVAD) system is designed to support pulmonary and/or systemic circulation of blood when the natural heart is unable to maintain adequate perfusion with conventional therapy. To accomplish support, the IVAD system shunts blood from the natural heart and then pumps blood to the arterial system in a pulsatile manner at normal arterial pressures.

The IVAD system consists of 3 major components: 1) Blood pump, 2) cannulae, and 3) driver. The **blood pump** provides the pulsatile ventricular support, the **cannulae** provide conduits for blood flow to and from the pump, and the **driver** controls and generates pneumatic power to drive the blood pump by way of interconnecting leads. See Section 6.0 for a more detailed description of system components.

2.0 Indications for Use

The Thoratec IVAD is indicated for:

1. Bridge-to-transplant (BTT) for patients who meet all of the following criteria:
 - Candidates for cardiac transplantation.
 - At imminent risk of dying before donor heart procurement.
 - Dependent on, or having incomplete response to, continued vasopressor support.
2. Postcardiotomy recovery for patients who are unable to be weaned from cardiopulmonary bypass.

3.0 Contraindications

The Thoratec IVAD is contraindicated for the following.

- Uncontrolled hemorrhage.

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- Central nervous system damage resulting in fixed and dilated pupils.
- BTT for patients who are contraindicated for cardiac transplantation.
- Patients who exhibit sensitivity to materials of bovine origin. **Note:** Only applicable for sealed arterial cannulae patients.

4.0 Warnings

4.1 Patient Population – General

- IVAD patients with prosthetic aortic valves may have increased risk of thromboembolism due to blood flow being shunted away from the valves.
- Significant right-to-left shunting can occur in patients with a patent foramen ovale or atrial septal defect (ASD). If necessary, patency of the foramen ovale or ASD must be corrected prior to implanting IVADs.
- Patients with greater than 1.5 aortic insufficiency should be considered a candidate for IVAD support *only after* repair or replacement of the aortic valve.
- Cannulae may be difficult to insert in patients with small hearts or congenital abnormalities, or in patients who have had previous cardiac reconstructive surgery.

4.2 Patient Population – Bridge to Transplant

- Patients with either hepatic or renal dysfunction may require 2-3 weeks, or more, of IVAD support before recovering major organ function.
- Patients with elevated levels of panel reactive antibodies (PRAs) may require extensive duration of IVAD support before a donor heart can be located. Patients should be excluded from IVAD support if the expectation of finding a donor heart is not reasonable.

4.3 Patient Population – Postcardiotomy Recovery

- Warnings related to patients pending postcardiotomy myocardial recovery are the same as those for the general patient population (Section 4.1).

4.4 Procedural Techniques – All Indications for Use

- Some components of the IVAD system are provided sterile. These components must be stored in their sealed packaging under the

storage conditions indicated on the packaging. Do NOT use these components if the packaging is damaged. Care must be taken in opening packaging so as to not contaminate or damage these components.

- The IVAD and cannulae are provided sterile. Use caution when opening the packaging. Do NOT re-sterilize. Do NOT use if packaging is damaged. Store at 20 to 30° C or 68 to 86° F.
- 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 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 1 month.
- Only the cannula connectors are intended to be manually unthreaded from the pump. Disassembling any other pump components may adversely affect device function.
- Do NOT use povidone-iodine ointment with the percutaneous line for the prophylactic care of the transdermal skin site; use povidone-iodine solution instead. Ointment can cause degradation of the line near its end.

5.0 Precautions

5.1 Training

- Surgical, medical, nursing, and perfusion staff who are responsible for, or participate in, the hospital's IVAD program should complete the Thoratec IVAD Training Program prior to the use of the Thoratec IVAD system.

5.2 Implantation

- The IVAD has NOT been used in patients smaller than 1.3 m² BSA and 42 kg. Evaluate patient size and body habitus prior to implantation to ensure an appropriate fit of the device.
- Use strict aseptic technique during implantation and extreme care throughout IVAD support to reduce the risk of infection.
- Pre-clot the polyester-graft arterial cannula before use, unless using a sealed arterial cannula.
- Insert, anastomose, and position cannulae carefully so as to not compromise blood flow.

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- Do NOT allow tissue or particulate matter to contaminate the inside of the pump or cannulae.
- Do NOT initiate IVAD pumping until the pump has been completely deaired after connecting the cannulae.

5.3 *Driver Alarms*

- If the pump “full” signal has been lost, audible and visual alarms occur in the DCC (VOLUME mode only) and the TLC-II (AUTO and FIXED modes). These alarms may indicate adverse events such as pneumatic lead or cannula kinking.
- There are NO audible or visual alarms for loss of the full signal on the DDC when supporting a patient in the ASYNC or EXT SYNC modes. Any patient supported in these modes must be connected to a hospital nurse call system or other similar external alarm system.
- Loss of full signal for the DDC causes the loss of empty indication on the IVAD signal processor; this does not imply that the pump is not emptying. The empty signal should return to normal function with the return of the full signal.

5.4 *Driver Back-Up*

- A back-up driver is used for replacing the primary driver in the event of primary driver malfunction. The back-up driver, DDC or TLC-II, must be available in all cases, except when a patient is receiving univentricular support with the DDC. The 2 independent drive modules within the DDC allow it to act as its own back-up when performing univentricular support.
- IVAD program personnel should be trained on how to hand pump the IVAD in the event of emergencies (e.g., driver malfunction or failure).
- Do NOT hand pump the RVAD faster than the LVAD, as this may result in pulmonary edema.
- Use the hand pump for emergencies only. Connect the IVAD to the back-up driver as soon as possible.

Note: To use the hand pump, disconnect the IVAD pneumatic lead from the driver and connect it to the hand pump. Squeeze the hand pump once per second (60 times per minute) to empty and fill the IVAD.

5.5 *Patient Management*

- The AUTO mode on the TLC-II and the VOLUME mode on the DDC are the preferred control modes for most patients because in these

modes IVAD flow responds automatically to changes in a patient's physiological conditions.

- At low IVAD pumping rates, there is an increased risk of thrombus formation within the pump. Therefore, it is recommended that the device be operated at rates above 40 beats per minute (bpm) and with complete filling and ejection of the pump in the VOLUME and AUTO Modes.
- Drive pressure of at least 100 mmHg above the patient's systolic blood pressure is recommended for complete ejection of blood from the pump. Complete emptying of the pump is important for washing the pump and minimizing the risk of thrombosis. The light on the IVAD signal processor indicates complete IVAD emptying.
- When weaning the patient from IVAD support or during other conditions that result in beat rates below 40 bpm, an anticoagulation regimen is recommended in which a continuous infusion of heparin achieves a partial thromboplastin time of 1.5 times control. See Section 11.4 for the anticoagulation regimen.

5.6 Interaction with Other Medical Treatments

- The IVAD system contains ferro-magnetic components. Do NOT perform MRI procedures on patients with the IVAD system.
- Effects of therapeutic ionizing radiation on the devices have not been determined. Radiation may damage the devices in a way that is not immediately detectable.
- Avoid medical treatments that involve applying high power electrical currents through the patient to prevent device heating or damage.
- Although the IVAD system has undergone considerable safety testing and should not be affected by external defibrillation, it has not undergone the specific defibrillation testing recognized by the international standard, IEC 60601, clause 17(h).

DEVICE INFORMATION

6.0 IVAD System Components

See the Appendix for a complete list of system components and catalog numbers.

6.1 *Thoratec IVAD Blood Pump*

The IVAD blood pump is supplied **sterile** and **non-pyrogenic** for single-use only. The pump is sterilized with ethylene oxide (EO).

CAUTION:

Do NOT sterilize the IVAD Pump for re-use.

The central part of the IVAD system is the blood pump, which can be used as a left, right, or biventricular assist device. The pump has a titanium alloy case containing an elastomeric, blood-pumping sac, which is composed of Thoralon™, Thoratec's proprietary polyurethane multi-polymer. During use, the blood sac is compressed by applying pressure from a pneumatic driver, thus ejecting blood from the sac. Similarly, the blood sac is expanded by applying vacuum from the driver, thus allowing the pre-load volumes to fill the sac with blood. 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 approximately 6.5 L/min at a rate of 100 bpm.

6.2 *Cannulae*

IVAD cannulae are supplied **sterile** and **non-pyrogenic** for single-use only. cannulae are sterilized with EO. **Table 1** lists the different cannula options.

CAUTION:

Do NOT sterilize the IVAD cannulae for re-use.

Table 1 Cannula options.

Cannula type	Cannula tube			Tip		Cannula Shape
	Running length (cm)	Height (cm)	ID (mm)	Length (cm)	ID (mm)	
Ventricular Inflow	Short (Blunt tip): 9 Short (Beveled tip): 9* Long: 13	Short (Blunt tip): 8 Short (Beveled tip): 8 Long: 11	16	3 5 3	13	Curved
Atrial Inflow	Short: 17 Long: 22	Short: 12 Long: 17	11 – 16 Tapered	2	11	90° Bend
Arterial Outflow	Short: 8 Short (curved): 8* Long: 11	Short: 8 Short (curved): 8 Long: 10	16	Graft: 30	14	Short: Straight Short: Curved Long: Curved
Sealed Arterial Outflow	Short: 8 Long: 11	Short: 8 Long: 10	16	30 (polyester graft)	14	Short: Straight Long: Curved

The IVAD is connected to the patient’s heart and great vessels with cannulae. A cannula is inserted into the atrium or ventricle to provide inflow to the IVAD. Blood is returned to the patient with an arterial cannula anastomosed onto the ascending aorta or the main pulmonary artery, depending on whether the left or right ventricle is being assisted.

6.3 Pneumatic and Electrical Leads

The 5-foot pneumatic lead and electrical leads are provided **sterile** for single-use only. Leads are sterilized by EO. The IVAD signal processor and 7-foot pneumatic extension leads are provided **non-sterile**.

CAUTION:
Do NOT sterilize the 5-foot pneumatic and electrical leads for re-use. The 5-foot electrical lead must be used during implant because the IVAD signal processor is provided **non-sterile** and should NOT be allowed onto the sterile field.

A **sterile** Y-connector is provided with the IVAD to connect the external electrical and pneumatic leads to the velour covered percutaneous lead that is tunneled through the skin. A **sterile** disposable cap for the velour-covered percutaneous line is also provided to protect the fitting during tunneling.

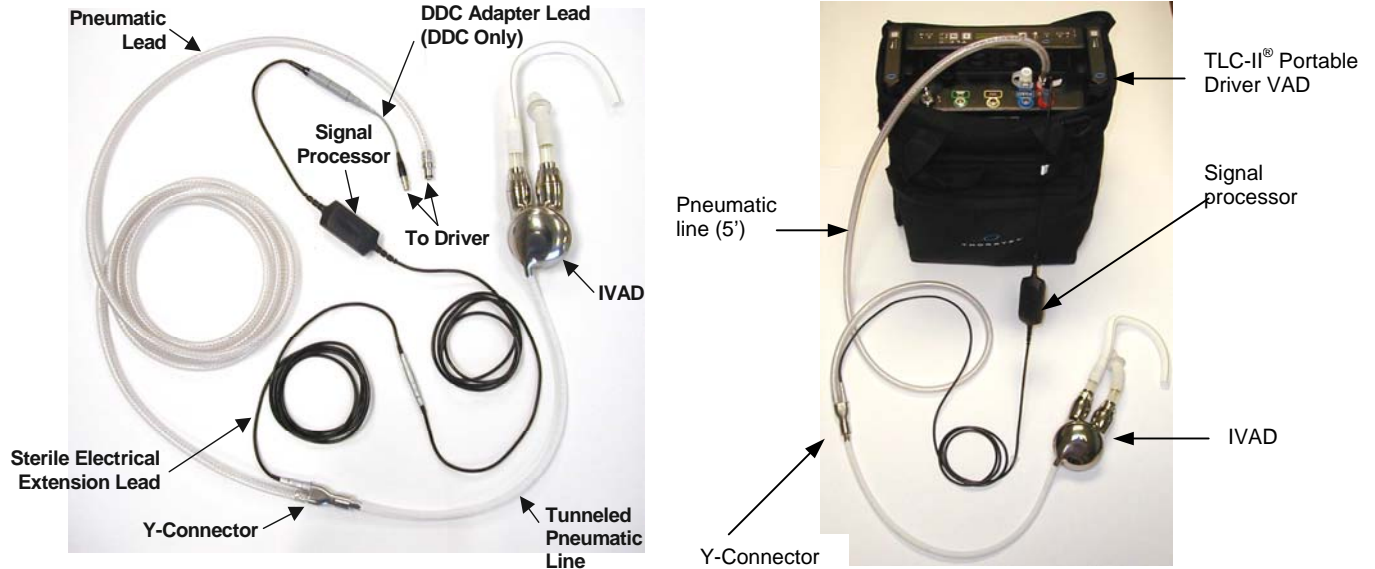
The 5-foot sterile electrical lead and the 5-foot sterile pneumatic lead are connected to the IVAD Y-connector during implant (**Figures 1**). The 5-foot pneumatic lead is connected directly to the TLC-II, or to the DDC via the 7-foot pneumatic extension lead. The sterile electrical lead connects to the signal processor, which plugs directly into the TLC-II or through an adaptor lead to the DDC. If a TLC-II is used, when the implant is complete and the

* For use in US only

DEVICE INFORMATION

sterile field broken, the electrical lead can be removed and the signal processor connected directly to the IVAD Y-connector.

Figures 1A & 1B IVAD pneumatic and electrical connections.

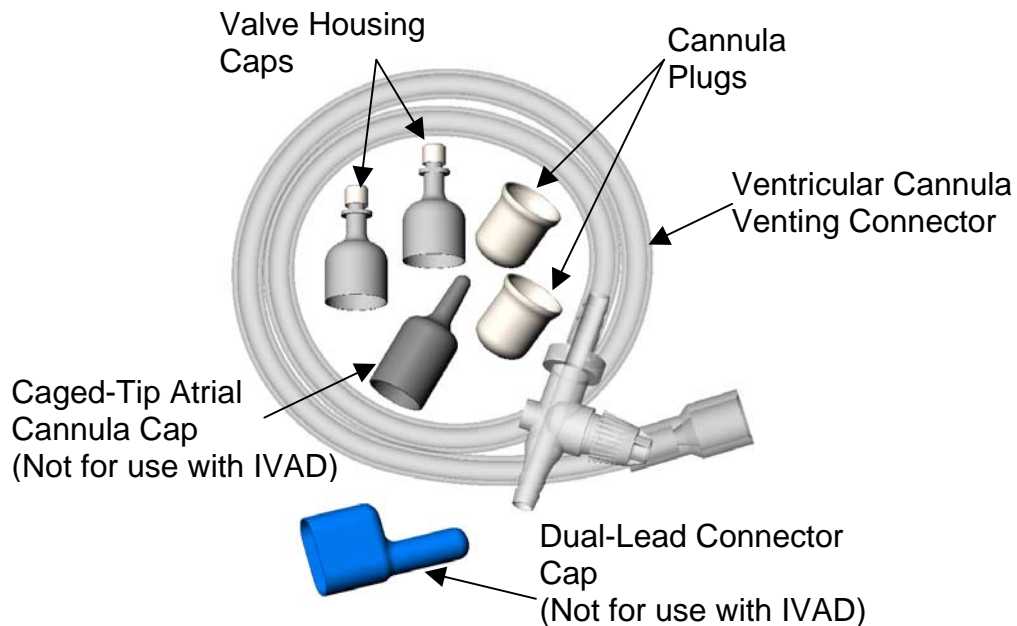


6.4 Surgical Tools

Several devices are available to facilitate IVAD implantation; they are listed below.

- The surgical implant accessory kit facilitates the preparation of the pump and cannulae for implantation. The kit (**Figure 2**) is provided **sterile** for single-use only and is sterilized using gamma radiation (R).

Figure 2 Surgical implant accessory kit.



- The IVAD sizer facilitates the creation of a pocket for the pump. The sizer is provided **non-sterile**. It is intended for multiple-uses and must be re-sterilized before each use (see *IVAD Sizer IFU*).
- The cannula attachment tool facilitates the installation of cannulae on the pump valve housings. The cannula attachment tool is provided **non-sterile**. It is intended for multiple-uses and must be re-sterilized before each use (see *Cannula Attachment Tool IFU*).
- The IVAD cannula connector wrench facilitates the installation of the cannula fittings. The connector wrench is provided **non-sterile**. It is intended for multiple-uses and must be re-sterilized before each use (see *IVAD Cannula Connector Wrench IFU*).
- The IVAD percutaneous line tunneler facilitates the creation of the tunnel for the percutaneous line. The tunneler is provided **non-sterile**. It is intended for multiple-uses and must be re-sterilized before each use (see *IVAD Percutaneous Line Tunneler IFU*).

6.5 Thoratec Dual Drive Console (DDC)

Note: Refer to the Dual Drive Console (DDC) Instructions for Use for more detailed information on using the DDC.

DEVICE INFORMATION

CAUTION:

When using a DDC for biventricular support, a separate DDC or TLC-II Driver must be available as a back up in the event of malfunction or failure of the primary DDC.

The DDC has 2 independent control modules and internal compressors to provide pressure (ejection) and vacuum (fill). The driver supplies pulses of pneumatic pressure to the blood pump to eject blood from the pump into the pulmonary artery (RVAD) or ascending aorta (LVAD). Each ejection period alternates with a filling period in which blood, assisted by vacuum, fills the IVAD.

Air pulses from the DDC can be controlled in 3 modes:

- **ASync** – A fixed-rate mode in which the rate and percent systole are set by the user.
- **VOLUME** – A variable-rate mode in which blood ejection begins the instant that complete filling occurs.
- **EXT SYNC** – A variable-rate mode in which the driver, similar to an intra-aortic balloon pump, provides counter-pulsation using the patient's R-wave to synchronize the end of blood ejection from the pump.

The VOLUME Mode is used primarily because pump flow responds automatically to changes in a patient's physiological conditions.

An external independent alarm is required on the DDC when in the ASync or EXT SYNC Modes. The alarm output will trigger the external independent alarm after an 8-second absence of the IVAD full signal, thus alerting the user to check the system and patient.

6.6 Thoratec TLC-II Driver

Note: Refer to the *TLC-II Instructions for Use* for more detailed information on using the TLC-II.

CAUTION:

A separate DDC or TLC-II driver must be available as a back up in the event of malfunction or failure of the primary TLC-II driver.

The TLC-II Driver delivers pulses of pneumatic pressure to the blood pump to eject blood into the body. Each ejection period alternates with a filling period in which blood, assisted by vacuum, fills the IVAD.

Air pulses provided by the pneumatic driver can be controlled in 2 modes:

- **FIXED** – A fixed-rate mode, in which the rate is set by the user and in which the driver maintains those conditions indefinitely

- **AUTO** – A variable-rate mode, in which ejection begins the instant complete filling occurs

The AUTO Mode is used primarily because the pump flow responds automatically to changes in a patient’s physiological conditions.

7.0 Reliability Evaluation

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

Based upon *in vitro* overall system reliability testing, there is a 98% chance (using the lower 60% confidence interval) that the system will be free of critical failures through 100 days of use, and a 94% chance that the system will be free of critical failures through one year of use.

Given that the complex electronics are located outside the IVAD pump, there are very few failure modes that would lead to pump replacement, namely breach of blood sac, breach of actuation diaphragm, and valve wear out. None of these failure modes are likely to cause catastrophic cessation of VAD pumping and each may be accompanied by signs that may alert you to the need for pump replacement, such as:

- **Breach of blood sac** – loss of full and/or empty indication; altered pneumatic drive pressure wave form; decreased perfusion; pump output alarms
- **Breach of diaphragm** – silicone oil observed in the pneumatic line near the y connector
- **Valve wear-out** – decreased perfusion; echocardiographic evidence

Loss of full and/or empty condition alone does not constitute a failure mode requiring pump replacement. Patients can be managed under these conditions, provided that full and empty are evident in the pressure waveform (reference IVAD IFU Section 9.9, figure 14).

8.0 Clinical Study Summary

8.1 Study Overview

A clinical study was performed to evaluate the safety and effectiveness of the Thoratec Implantable Ventricular Assist Device (IVAD). This study compared the IVAD to the results of previous clinical studies of the commercially available paracorporeal Thoratec Ventricular Assist Device (PVAD) system.

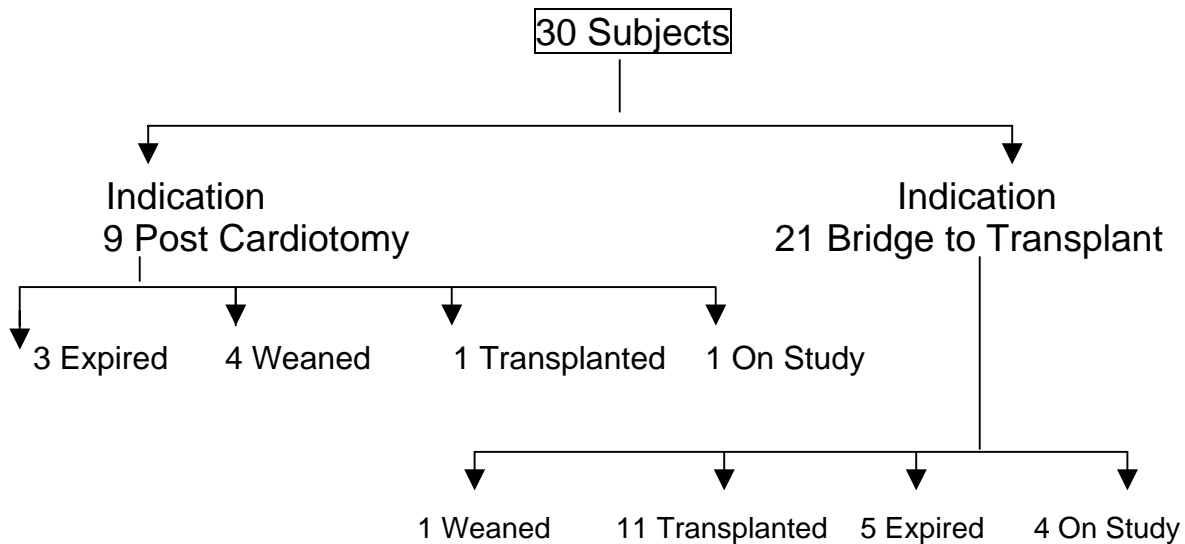
DEVICE INFORMATION

The IVAD was studied in a prospective, multicenter, clinical trial for use as a bridge to cardiac transplant or for postcardiotomy recovery patients who are unable to be weaned from cardiopulmonary bypass. The IVAD blood pump is an incremental change to the commercially available PVAD, facilitating the implantation of the pump. Patients in the study were followed until their outcome of transplantation, VAD explant (in the case of recovery), or death and hospital discharge after these events.

8.2 Patient Population

A total of 30 patients were enrolled in the IVAD Study from October 2001 to July 2003 at 11 investigational centers in the United States and Europe. A summary of patient enrollment and follow-up can be seen in the diagram in **Figure 3**. A total of 8 patients expired, 12 patients were transplanted, 5 patients were weaned, and 5 patients remained ongoing as of September 1, 2003.

Figure 3 Enrollment and Follow-up of 30 Enrolled Patients



The median age of the 30 IVAD patients was 47.5 years (range 16 to 66) with the majority of patients being male (73%). The median body surface area (BSA) was 1.94 sq. m (range 1.31 to 2.35 sq. m) with the majority of patients (63%) receiving a LVAD versus a BiVAD. In addition, the majority of patients (70%) were implanted for the Bridge-to-Transplant indication.

The PVAD study included 100 patients that were enrolled at 22 investigational centers in the United States between December 1987 and November 1995.

The baseline demographics for these patients were similar to the IVAD patient cohort.

8.3 **Effectiveness: IVAD Flow Index and Survival**

IVAD Flow Index

The IVAD is considered to be effective if the LVAD flow index is greater than 2.0 L/min/m². The overall LVAD flow index was greater than 2.0L/min/m²; a mean of 2.55 L/min/m² was achieved, with a flow index range of 1.85 to 3.08 L/min/m². The mean RVAD flow index was 2.15L/min/m². Twenty-nine (29) of the 30 IVAD patients had a flow index which averaged >2.0 L/min/m². One (1) patient had an average flow index of 1.85 L/min/m² due to pump positioning, however this patient was adequately perfused and supported as evidenced by the patient's end-organ function and survival to explant.

Survival

Another measure of effectiveness was survival of the IVAD patients to:

- Thirty (30) days post-implant survival, either on VAD support, transplant or recovery;
- Survival to 30 days post-VAD explant with intact neurological status;
- Survival to discharge post VAD explant.

Twenty-six (26) of the 30 patients (87%) were alive 30 days post-implant versus 66% (66/100) of the PVAD patients. This is a statistically significant difference, indicating that the survival 30 days post-implant has improved in the IVAD group. Twenty-five (25) remained on IVAD support, 1 patient was transplanted, and 4 patients had expired.

Twelve (12) of 16 patients (75%) survived 30 days post-VAD removal (transplant or weaned) versus 87% (52/60) of the PVAD patients. There is no statistical difference between the 2 groups. Of the 12 patients who survived, all except 1 patient, were intact neurologically.

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Of the 17 patients that were transplanted or weaned, 10 (59%) were discharged post IVAD explant, 2 (12%) remained hospitalized following IVAD explant, and 5 (29%) expired post explant.

8.4 Adverse Events

The following 2 tables present data on the rates and frequency of adverse events between the two groups. The first table presents the number of patients experiencing adverse events regardless of cause. **Table 3** and **Figure 4** present the data normalized per 30 patient days.

No new adverse events were observed in the IVAD Study that have not occurred in previous studies with the VAD system.

Table 2 Adverse Events Regardless of Cause

Event	IVAD Patients (n=30)					PVAD Patients (n=100)				
	Patients	% of Pts	LCL	UCL	Events	Patients	% of Pts	LCL	UCL	Events
Bleeding	11	36.7%	19.4%	53.9%	24	49	49.0%	39.2%	58.8%	63
Cardiac Tamponade	5	16.7%	3.3%	30.0%	5	5	5.0%	0.7%	9.3%	5
Hemolysis	1	3.3%	0.0%	9.8%	1	7	7.0%	2.0%	12.0%	7
Infection	17	56.7%	38.9%	74.4%	26	44	44.0%	34.3%	53.7%	58
Arrhythmias	5	16.7%	3.3%	30.0%	7	20	20.0%	12.2%	27.8%	22
Right Heart Failure	1	3.3%	0.0%	9.8%	1	9	9.0%	3.4%	14.6%	9
Thromboembolic Complication	2	6.7%	0.0%	15.6%	2	15	15.0%	8.0%	22.0%	15
Hepatic Dysfunction	13	43.3%	25.6%	61.1%	13	66	66.0%	56.7%	75.3%	66
Renal Failure	8	26.7%	10.8%	42.5%	8	20	20.0%	12.2%	27.8%	20
Neurological Dysfunction	10	33.3%	16.5%	50.2%	15	32	32.0%	22.9%	41.1%	41
Respiratory Failure	7	23.3%	8.2%	38.5%	7	12	12.0%	5.6%	18.4%	14
Pleural Effusion	5	16.7%	3.3%	30.0%	7	9	9.0%	3.4%	14.6%	10
Hypertension	1	3.3%	0.0%	9.8%	1	Not directly comparable				
Hypotension	5	16.7%	3.3%	30.0%	5	Not directly comparable				

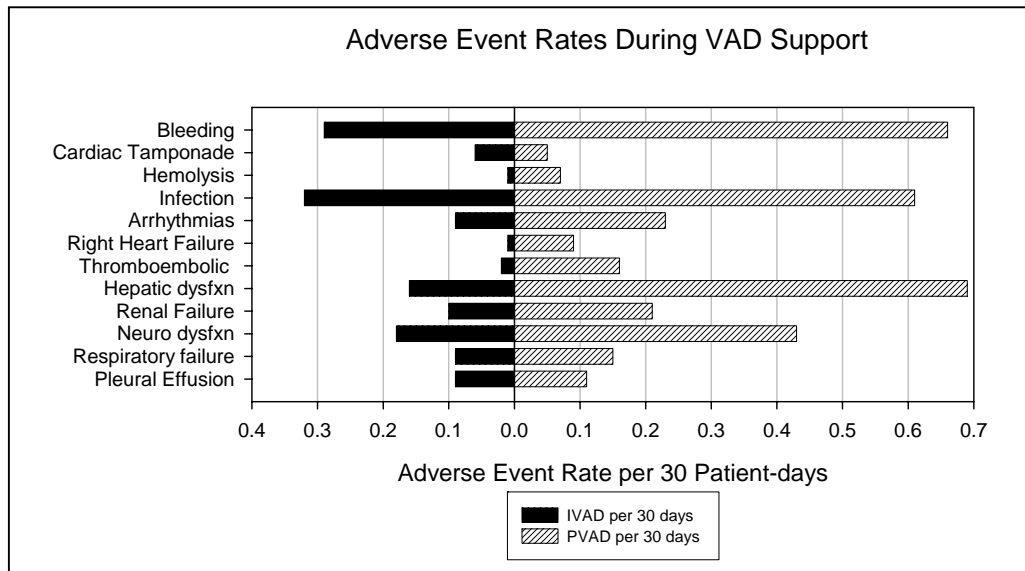
*LCL = Lower 95% confidence limit

*UCL = upper 95% confidence limit

Table 3 All Cause Adverse events per 30 patient days

	IVAD (n=30)	PVAD (n=100)	IVAD-to-PVAD Risk Ratio (95% Confidence Limits)
Days of support:	2462	2857	
	events / 30 pt days	events / 30 pt days	
Bleeding	0.29	0.66	0.44 (0.27 - 0.71)
Cardiac Tamponade	0.06	0.05	1.16 (0.34 - 4.01)
Hemolysis	0.01	0.07	0.17 (0.02 - 1.35)
Infection	0.32	0.61	0.52 (0.33 - 0.83)
Arrhythmias	0.09	0.23	0.37 (0.16 - 0.87)
Right Heart Failure	0.01	0.09	0.13 (0.02 - 1.02)
Thromboembolic Complication	0.02	0.16	0.15 (0.04 - 0.68)
Hepatic Dysfunction	0.16	0.69	0.23 (0.13 - 0.42)
Renal Failure	0.10	0.21	0.46 (0.20 - 1.06)
Neurological Dysfunction	0.18	0.43	0.42 (0.23 - 0.77)
Respiratory Failure	0.09	0.15	0.58 (0.23 - 1.44)
Pleural Effusion	0.09	0.11	0.81 (0.31 - 2.14)

Figure 4 Adverse Event Rates During VAD Support



IMPLANT PROCEDURES

9.0 Implant Procedures

Adequate right ventricular function is essential for successful use of a left ventricular assist device (LVAD) in order 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, if indicated, a right ventricular assist device (RVAD) can be used in addition to the LVAD. Biventricular (BiVAD) support may be required if right heart failure prevents adequate function of the LVAD, which is generally when the cardiac index is less than 2.0 L/min/m² and the central venous pressure is greater than 20 mmHg. Biventricular support also is indicated in patients with potentially lethal arrhythmias or severe right ventricular infarction that could result in death during exclusively univentricular support. An RVAD should be considered at the time of LVAD implantation to obviate the need for a re-operation to implant the RVAD.

An isolated RVAD also may be suitable for patients with isolated right heart failure.

Note: Refer to the following for more information:

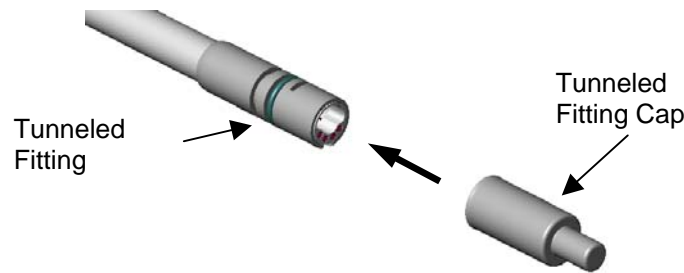
- DDC Instructions for Use
- DDC videotape
- TLC-II Instructions for Use
- TLC-II videotape
- Clinical Operations and Patient Management Guide

9.1 *Preparing the IVAD*

1. Review the IVAD components and accessories to ensure that all necessary components are present.
2. Place the tunneled fitting cap over the tunneled fitting at the end of the velour-covered percutaneous line in order to keep blood or other fluids from entering the line (**Figure 5**).

Note: Be sure that the cap is fully seated over the o-ring. The fitting cap is for protective use only. It is NOT intended for pulling the percutaneous line into position when tunneling.

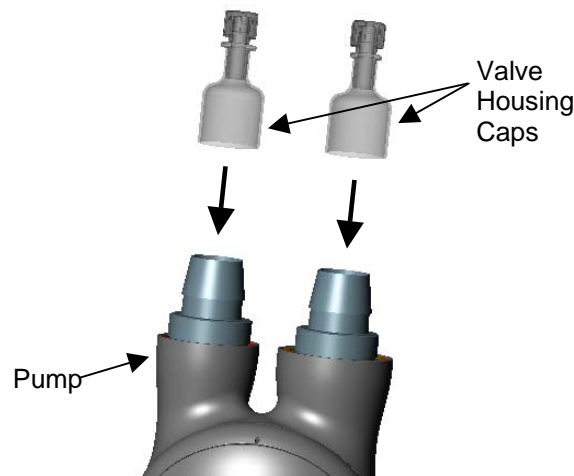
Figure 5 Tunneled Fitting Cap placement.



3. Remove the cannula connectors from the IVAD. The inflow and outflow cannula connectors are different sizes and should be used only on their respective ports. The larger cannula connector is intended for the inflow port; the smaller cannula connector is intended for the outflow port.
4. Fill the IVAD with approximately 120 ml of sterile heparinized albumin solution (100 units of sodium heparin USP per 250 ml 5% albumin).
5. Moisten the valve housing caps (**Figure 2**) and the valve housings with saline for lubrication. Then, place the Caps on the IVAD valve housings to prevent fluid from leaking out (**Figure 6**). Add additional albumin solution through the fittings on the caps to insure all surfaces are covered.
6. Leave the albumin solution in the IVAD for at least 15 minutes prior to implantation to provide a passive protein coat on the blood-contacting surfaces.

Note: Maintain the IVAD so that the valve housings are pointing upward. The IVAD can be held vertically within the plastic packing tray, which has a pre-formed shape for this purpose.

Figure 6 Valve Housing Cap placement.



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9.2 *Creating a Pocket and Preparing for Cannulation*

Note: Alternatively, intra-peritoneal placement of the IVAD may be utilized with similar positioning of the pump and cannulae.

Note: In the event the IVAD cannot be implanted, it can be placed in a paracorporeal position with the use of Thoratec paracorporeal cannulae. However, additional effort may be required for cannula connector installation due to more variability in wall thickness for paracorporeal cannulae.

CAUTION:

Do NOT use the IVAD with the thick-walled, caged tip atrial cannulae (catalog numbers 14120-2563-000, 14121-2562-000, and 14814-2575-000) because of incompatibility between the cannulae and the IVAD cannulae connectors.

CAUTION:

Do NOT use IVAD cannulae when placing IVAD in a paracorporeal position. Use VAD cannulae for this application.

CAUTION:

IVAD cannula connectors must always be used with IVAD.

1. Prepare a pre-peritoneal, sub-rectus pocket for an LVAD by following these steps.

Note: The steps for the implantation of an LVAD and an RVAD are nearly identical; differences for RVAD pocket preparation are presented in parentheses.

- a. Perform a median sternotomy extending the skin incision from the suprasternal notch to approximately 5 cm above the umbilicus.
- b. Identify the linea alba and the right and left anterior rectus fascia.
- c. Incise the left (right) anterior rectus sheath approximately 2 cm lateral to the linea alba, taking precautions not to rupture the linea alba, enter the peritoneal cavity, and increase the risk of ventral hernia formation.
- d. Develop a plane between the left (right) rectus abdominis muscle and the posterior rectus sheath for the creation of a pocket to house the IVAD. The pocket extends superiorly from the subcostal margin to the iliac crest inferiorly and the linea semilunaris laterally.
- e. Extend under the external oblique muscle in patients with small abdomens, if necessary.
- f. Insert the IVAD sizer into the pocket to ascertain proper sizing. Alternatively, insert the pump, provided that the valve housing

caps and percutaneous line fitting cap are in place. Position the sizer as superior as possible so that edge of the pump cap lies at or near the costal margin. See the *IVAD Sizer IFU* for more details.

2. After preparing the pump pocket enter the pericardial sac.
3. Initiate cardiopulmonary bypass using single 2-stage or bicaval cannulation for venous return, and arterial cannulation in the ascending aorta. Position the aortic perfusion cannula site so that the IVAD arterial graft can be anastomosed to the right lateral border of the ascending aorta.
4. Create a passage for the inflow and outflow cannula between the left ventricular (LV) apex and the preperitoneal pocket. Generally, the diaphragm can be locally dissected free from the chest wall for cannula passage.
5. Select the length and type of inflow and outflow cannulae.

Note: Clinical experience has shown that higher blood flow can be achieved with LV apex cannulation compared to atrial cannulation. Ventricular apex cannulation may also reduce the possibility of thrombosis in the natural left ventricle.

Note: The sizer can be used to help select the appropriate cannula size (see the *IVAD Sizer IFU*). The short inflow and outflow cannula can be used with most patients. In general, shorter cannulae allow the pump to be positioned superiorly with the cannula connectors under the costal margin, which is preferred. Do NOT trim the IVAD cannulae, as their ends are flared for ease of installation.

CAUTION:

Do NOT combine a short inflow cannula with a long outflow cannula. Size mismatch can lead to interference of the outflow cannula with the right ventricle (RV) or to kinking of the outflow graft.

9.3 LVAD Inflow Cannulation

CAUTION:

Use caution in attempting apical cannulation if the patient has sustained a recent infarct of this area of the heart. If necessary, atrial cannulation in the left atrial appendage may be used.

Blood flow to the LVAD is provided by a ventricular inflow cannula in the LV apex.

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1. Place 6-12 pledgeted, double-armed, 2-0 sutures circumferentially around the LV apex. The sutures should be equally spaced and form a circle of 3 to 4 cm in diameter.

CAUTION:

If sutures are placed after coring, the sutures are NOT to pass through the cored hole.

2. Core the ventricle. Coring of the ventricle can be accomplished by one of 3 methods:
 - Direct incision.
 - Use of a sharpened circular cutting tool, approximately 8 to 12 mm in diameter.
 - Use of a commercial instrument such as that designed for placement of LV outflow conduits.
3. Once the apex is cored, inspect the ventricular chamber, remove any mural thrombus and excise any excess trabeculae.
4. Insert the ventricular cannula into the ventricle.
If using the beveled-tip with side-holes ventricular cannula, 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. Pass the non-valve end of the ventricular cannula venting connector (**Figure 2**) through the lateral diaphragm passage and into the chest.
7. 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**).
8. Connect the valve of the ventricular cannula venting connector to the cardiopulmonary bypass circuit vent line (**Figure 7**) under low suction.
9. Position the patient to facilitate de-airing, and then de-air the ventricle and cannula using the ventricular cannula venting connector.
10. Adjust the circuit to the desired suction level.
11. Without disconnecting the ventricular cannula venting connector, pass the ventricular cannula out of the chest and into the device pocket.

* For use in US only

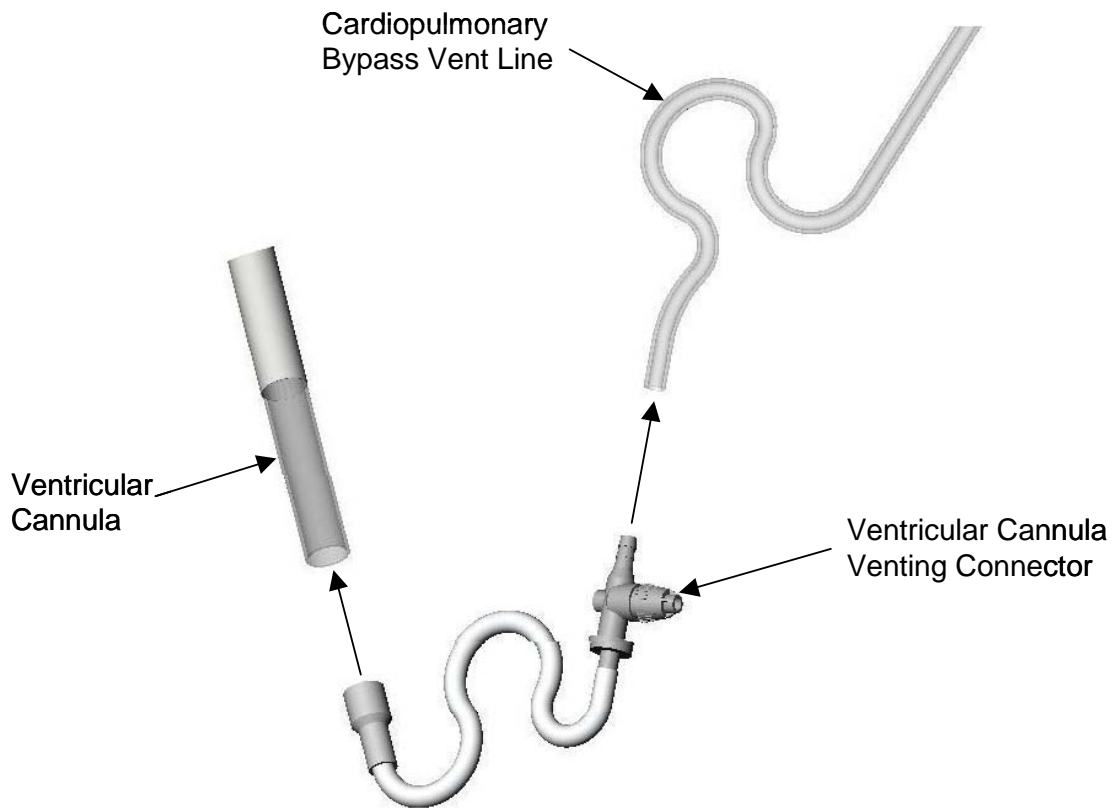
12. Use smooth-jawed tubing clamps to cross-clamp the ventricular cannula at its non-reinforced segment and remove the ventricular cannula venting connector.

Note: With the IVAD ventricular cannulae, the non-reinforced segment is directly adjacent to the sewing ring.

CAUTION:

Do NOT clamp the wire-reinforced regions of the cannula.

Figure 7 Set up for de-airing the ventricle by way of the ventricular cannula.



9.4 LVAD Outflow Cannulation

A. Preparing the Sealed Arterial Graft

CAUTION:

If a non-sealed arterial cannula is used, do NOT rinse the arterial graft of gelatin particles. Skip to Pre-Clotting the Non-Sealed Arterial Graft (see Step B).

1. If a sealed arterial cannula is used, rinse the graft in sterile normal saline for at least 1 minute to improve its handling qualities and to remove any extraneous gelatin particles.

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2. While stretching the graft tight, cut it to length.

B. Pre-Clotting the Non-sealed Arterial Graft

CAUTION:

If a sealed arterial cannula is used, do NOT pre-clot the arterial graft. Skip to aortic anastomosis (see Step C).

1. If a non-sealed arterial cannula is used, pre-clot the polyester-graft arterial cannula using one of the following 2 methods.

Method A

- a. Immerse the graft in 50 cc of cryoprecipitate and massage it for 5 minutes.
- b. Remove the graft from the cryoprecipitate and place it in a basin of 50 ml of thrombin (1000 units/cc).
- c. Massage the thrombin into the graft for 3-4 minutes. A gel should form on the graft; if not, repeat the process.
- d. Carefully flush out the graft with saline to remove any remaining thrombin.
- e. Carefully inspect the graft interior and remove all clumps of gel.

Method B:

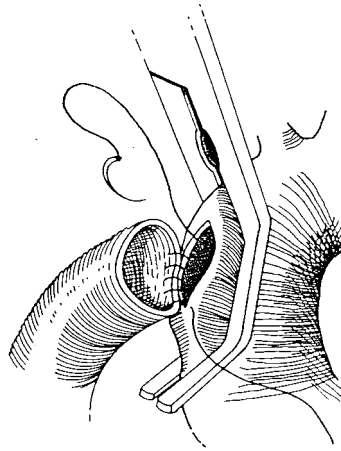
- a. Immerse the graft in non-heparinized blood (about 100 ml) mixed with 5 mg protamine and 5000 units of topical thrombin.
- b. Massage the graft meticulously for 5 minutes. A gel should form on the graft. If not, add more thrombin and protamine, and massage for 5 minutes more.
- c. Carefully inspect the graft interior and remove any clumps of gel.

2. While stretching the graft tight, cut it to length.

C. Aortic Anastomosis

1. Apply a side-biting clamp to the right lateral border of the ascending aorta.
2. Open the aorta and anastomose the graft using double-armed 4-0 polypropylene sutures (**Figure 8**).
3. After completing the anastomosis, release the tangential clamp and de-air the cannula. Placing the patient in Trendelenburg's position is recommended.
4. Apply a tubing or vascular clamp to the graft portion of the cannula.
5. Insert a cannula plug (**Figure 2**) into the end of the cannula and pass it into the pump pocket.

Figure 8 Aortic anastomosis.



9.5 De-Airing the Pump

1. Remove IVAD valve housing caps and slowly pour the albumin solution out of the IVAD.
2. Completely fill the IVAD with sterile saline.
3. Replace valve housing caps over the metal housings. Both the valve housing caps and the valve housings should be moistened with saline when placing the caps on the IVAD.
4. Use the valve housing cap fittings and a saline-filled, Luer-lock syringe to completely de-air the IVAD and caps.
5. While de-airing, manipulate the IVAD to ensure that air bubbles are not trapped anywhere within the IVAD or caps.
6. Place the IVAD into the plastic packing tray.

9.6 Cannula-to-Pump Connection and Final De-airing

There are 2 sizes of cannula connectors. Each contains a flared clamping ring (collet) trapped inside a collet nut. The collet cannot be removed from the nut. The larger diameter connector is used for the inflow cannula and port. Arrows on the IVAD identify the direction of flow.

Note: The maximum connector retention strength has been shown to exceed 34 pounds in laboratory testing.

1. Prior to connecting the IVAD to the cannulae, inspect the Housing caps for air. Rotate and manipulate the IVAD to release any air within the pump and extract the air through the Luer fitting on the Cap. A 20-cc

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syringe with 10 cc of saline connected to the luer fitting can be used to push in saline and aspirate out air.

2. Moisten the exterior of the inflow cannula with saline and slide the larger diameter cannula connector over the end of the inflow cannula. Fill the heart with blood and confirm that the inflow cannula is adequately de-aired.

Note: If an atrial cannula is used, back-bleed the cannula as necessary.

3. When connecting the pump to the cannulae, the IVAD may be positioned within the abdominal pocket with a surgical assistant retracting the abdominal wall.

OR

If the cannula length and abdominal wall positioning permit, the IVAD may be brought to the midline outside the pocket during connection of the cannulae.

4. Place the patient in Trendelenburg's position and rotate, as necessary, to insure the open ends of the cannula are elevated above the other portions of the cannula.
5. Check that there is no air visible within the housing caps. A de-aired syringe may be left on the Luer fitting of the outflow housing cap for repeat de-airing in subsequent steps.
6. With the IVAD as upright as possible, remove the inflow valve housing cap, leaving the outflow valve housing cap in place. The inflow valve housing should be maintained at a higher level than the rest of the IVAD.

CAUTION:

Keep the inflow valve housing at the highest elevation throughout the attachment process to avoid introducing air into the system.

7. Partially engage the inflow cannula on the valve housing.

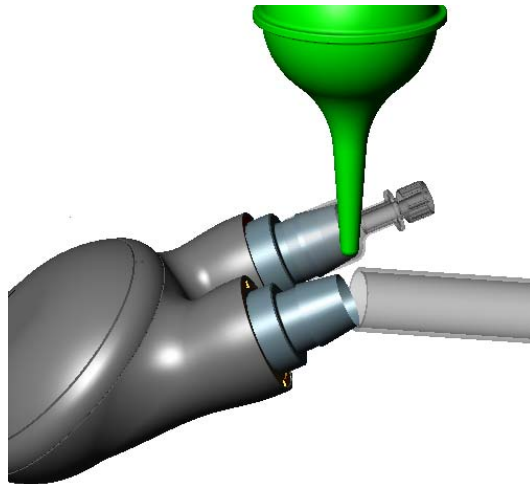
CAUTION:

The valve housing has a very sharp edge designed to minimize seam thrombus. Do NOT dent or scratch this sharp edge. Use care to avoid cutting yourself.

8. 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 9**).
9. Ensure the cannula is advanced fully over the barb-shaped valve housings.

Note: If necessary, use gauze or the cannula attachment tool to push the cannula end until it contacts the flat shoulder of the housing.

Figure 9 Use of Bulb Syringe for Cannula Connection.



10. Moisten the interior of the inflow cannula connector and the exterior of the cannulae with saline.
11. Slide the cannula connector forward until it engages the threads on the valve housing.
Note: When sliding the cannula connector, ensure that the collet does not push out the back end of the connector prior to engaging the thread. If this happens, push the collet back into the connector and continue sliding the connector.
12. Thread the inlet cannula connector to the pump until fully seated.
Note: The cannula connector wrench can be used to assist in applying torque to the connector (see *Cannula Connector IFU*). No gap should remain between the connector and the pump (**Figure 10**).
13. If necessary, use the syringe connected to the outflow valve housing cap to remove air introduced when attaching the inflow cannula. Manipulate the pump and remove any trapped air bubbles. In general, air found in the pump at this point requires repeat de-airing and a return to Section 9.5.
14. Moisten the exterior of the outflow cannula with saline as done previously for the inflow cannula and slide the smaller diameter cannula connector over the end of the outflow arterial cannula.
15. Clamp the inflow cannula on the non-reinforced region prior to removing the outflow valve housing cap.

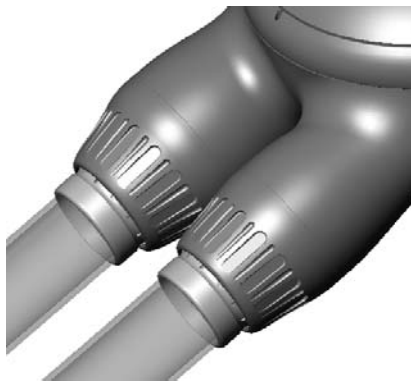
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16. Connect the arterial cannula to the pump in the same manner that the inflow cannula was connected, taking care to not introduce air.
17. Secure the outflow cannula connector in the same manner as the inflow connector.

CAUTION:

Carefully inspect the end of the cannulae for air and rotate the IVAD to release any trapped air. If any air bubbles are present, the cannula must be removed and the previous steps repeated until the blood pump is completely devoid of air.

Figure 10 Cannula connections to the pump.



9.7 RVAD Installation

The steps for RVAD installation are nearly identical to those for LVAD installation; differences are noted below.

1. Prepare the pump as detailed in Section 9.1.
2. Create a pocket as detailed in Section 9.2.
3. Cannulate the right atrium following these steps.

Note: The atrial cannula can be cross-clamped with smooth-jawed tubing clamps **only** in the non-reinforced, non-velour-covered section at the pump attachment end of the cannula.

- a. Place 2 polypropylene purse-string sutures in the body of the right atrium opposite the tricuspid valve. Begin and end each suture by passing it through a felt pledget. Leave the sutures long and pass them through 15-cm rubber tube keepers.
- b. Insert a cannula plug (**Figure 2**) into the end and pass the atrial cannula to the pump.
- c. Incise the atrium and gradually dilate the opening with Hegar dilators.

- d. Insert the atrial cannula approximately 4 cm from the end of the tip.
- e. Tighten the rubber keepers and tie them over buttons.
- f. Secure the cannula by tying a tape ligature around each keeper and the cannula.

CAUTION:

Sub-optimal flow may occur if the cannula tip is obstructed in the atrium.

- 4. Anastomose the pulmonary artery following these steps:
 - a. If using the sealed arterial cannula, prepare the graft as detailed in Section 9.4.
OR
If using the non-sealed arterial cannula, pre-clot the polyester-graft arterial cannula using method A or B as detailed in Section 9.4.
 - b. Place 2 silk sutures on the pulmonary artery, 1 at the pulmonary artery bifurcation and 1 at the level of the pulmonary valve.
 - c. Raise the pulmonary artery with the 2 tagged sutures and make a linear pulmonary arteriotomy.
 - d. Pass a Ferguson vent through the arterial graft into the pulmonary artery to prevent clamping of the pulmonary artery.
 - e. Cut the arterial graft to length and anastomose it to the main pulmonary artery using double armed 4-0 polypropylene suture.
 - f. Remove the vent and clamp the graft.
 - g. Cross the pulmonary arterial cannula over the aortic cannula before connecting the RVAD.
- 5. De-air the pump as detailed in Section 9.5.
- 6. Connect the pump and perform final de-airing as detailed in Section 9.6.

9.8 Percutaneous Line Tunneling

The velour-covered IVAD percutaneous line is tunneled subcutaneously exiting in either the right or left upper quadrant of the abdomen using the curved percutaneous line tunneler. Two (2) tunnelers, 1 shorter and with greater curvature, are available to accommodate patients with various sized abdomens.

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CAUTION:

A snug fit of the skin around the percutaneous exit site and immobilization of the percutaneous line may reduce risk of infection.

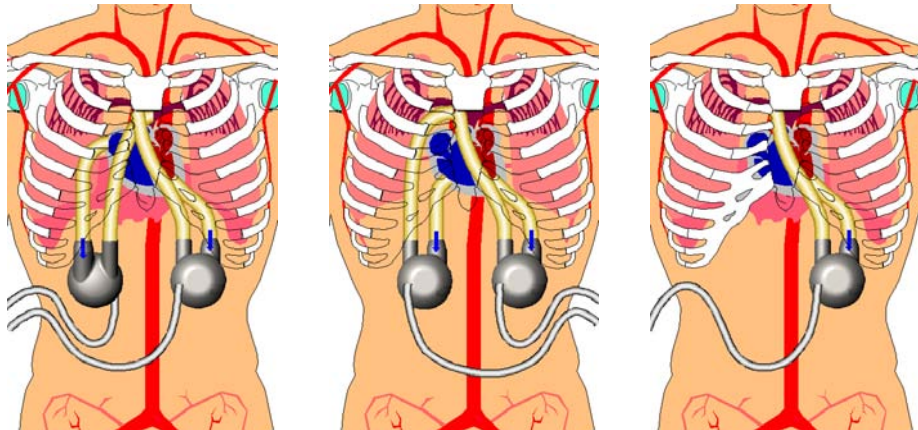
1. When implanting an RVAD with atrial cannulation, place the RVAD in the abdominal pocket, cap-side-down, so that the percutaneous line port is closer to the midline and the tunnel route can loop inferiorly before exiting in the right upper quadrant (**Figure 11**, left).

OR

When implanting an RVAD with ventricular cannulation, place the RVAD, cap-side-up with the percutaneous line port on the right lateral side, thus allowing the lines for both IVADs to exit in the upper left quadrant (**Figure 11**, middle).

Figure 11

Thoratec IVAD: Biventricular IVAD with left ventricular and right atrial cannulation (left), biventricular IVAD with left ventricular and right ventricular cannulation (middle), and left IVAD with left ventricular cannulation (right).

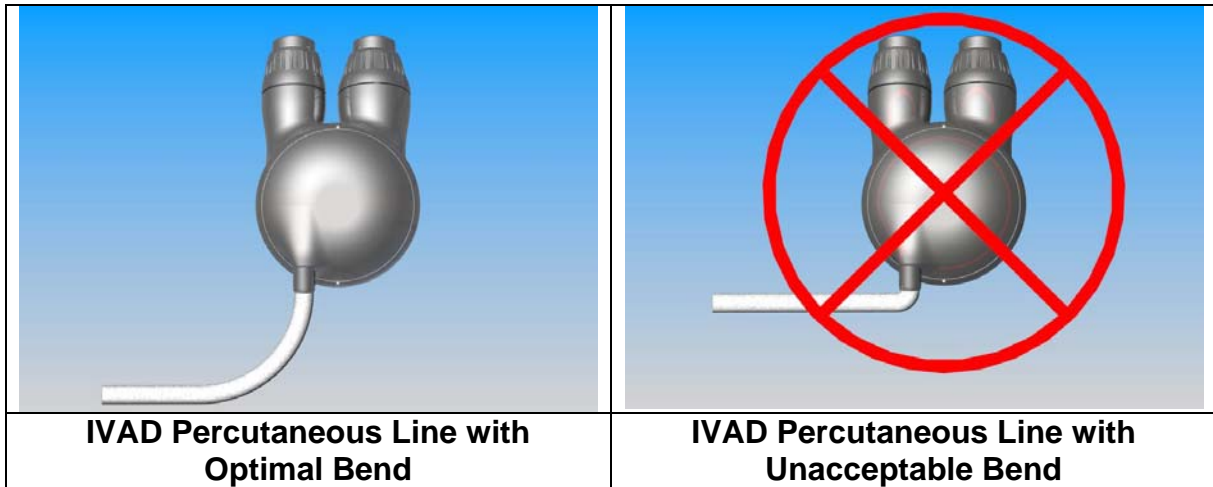


2. Create a tunnel route that loops inferiorly to form a long and gently curved tunnel, therefore increasing the length of the tissue ingrowth barrier to infection and minimizing the risk of line kinking. The tunnel should enter the pump pocket in the pocket's most inferior region to allow for desirable pump positioning and a smooth driveline-to-pump transition without sharp bends or kinks.

CAUTION:

Use care not to kink or sharply bend the tunneled driveline during placement either along its length or at its junction with the pump case.

Figure 12



CAUTION:

Check that the tunneled fitting cap is pushed past the o-ring on the percutaneous line before passing the line through the tunneler. Failure to do so can make it difficult to pass the line through the tunnel.

3. Position the exit site at the lateral border of the rectus muscle but not on the flank. The exit sites should be “above the belt line” to facilitate patient ambulation, wound care, and protect the site from irritation or injury. When tunneling for BiVAD support, the exit sites should be separated by a minimum of 2 cm.
4. Once the percutaneous line tunneler is in place and the exit site created, unscrew the tunneler tip and remove the tunneler handle.
5. Place the IVAD in the abdominal pocket and pass the percutaneous line through the tunneler.

CAUTION:

Use care not to kink the tunneled driveline during placement.

6. Once the IVAD is positioned in the pocket, the tunneler sheath can be removed, leaving the line in place.

9.9 Connecting to Driver, Initiating pumping, and Completing Implant

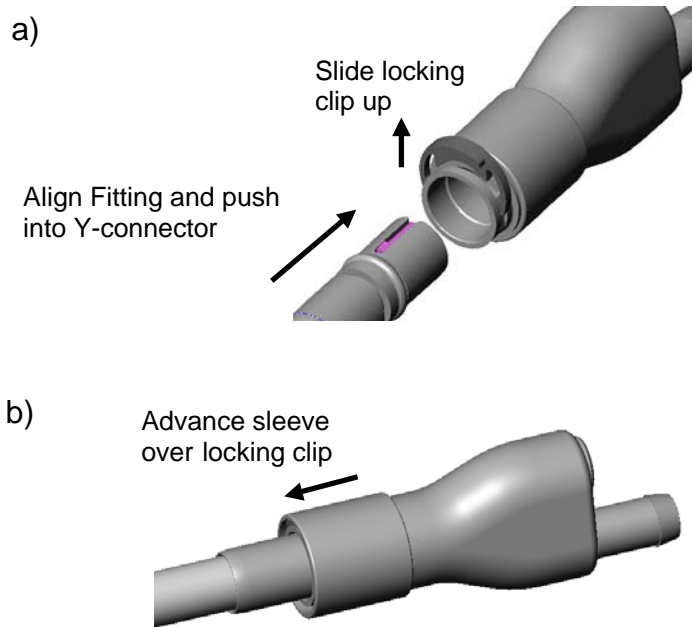
Note: Refer to the *TLC-II Instruction for Use* or the *Dual Drive Console Instruction for Use* for more detail using the drivers.

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1. Remove the protective cap from the fitting on the end of the velour-covered, tunneled percutaneous line.
2. Retract the locking sleeve of the Y-connector by rotating it clockwise as viewed from the single-port side.
3. Slide the locking clip on the Y-connector up to the open position and insert the tunneled fitting (**Figure 13**).

Note: The locking clip should not disconnect from the Y-connector.

Figure 13 Y-connector attachment: (a) open position and (b) locked position



4. Once the fitting is fully inserted, slide the clip down to the closed position and rotate the locking sleeve on the Y-connector until the locking clip is completely covered (**Figure 13**).
5. Connect the 5-foot sterile pneumatic lead to the Y-connector.
6. Connect the 5-foot sterile IVAD electrical lead to the pump by aligning the red dots on both halves of the electrical connector.
7. Pass the end of the leads off the sterile field.
8. Connect the sterile electrical lead to the non-sterile IVAD full/empty signal processor cable. Connections to the driver depend on the driver type, as indicated below.
 - If a TLC-II is used, the sterile pneumatic line and the non-sterile Signal processor are connected to the driver.

- If a DDC is used, the sterile pneumatic line is connected to a 7-foot non-sterile pneumatic extension, which is in turn connected to the console. Also, the signal processor is connected to an adaptor lead, which is in turn connected to the console.
9. Initiate IVAD pumping at a slow fixed rate (ASYNCR mode on the DDC or FIXED mode on the TLC-II) with a moderate level of vacuum and a low ejection pressure. Consult the *Driver IFU* for recommended settings.
 10. Check suture lines for leaks.
 11. Gradually increase ejection pressure and adjust vacuum until complete pump filling and emptying is achieved. Consult the *Driver IFU* for recommended settings.

CAUTION:

Applying excess vacuum with the chest open increases the risk of air embolism. It is after the chest is closed that full vacuum can be applied. Consult the *Driver IFU* for recommended settings.

12. Verify filling of the pump.
Note: Complete filling is indicated by the full signal light on the driver. Incomplete IVAD filling in the absence of cannula obstruction often can be treated with volume infusion and vasopressor support.
13. Verify emptying of the pump.
Note: Complete IVAD emptying is indicated by the green empty signal light on the IVAD signal processor.
14. Check the signal processor for an indication of empty as detailed below.
 - **Cyclic flashing** indicates emptying at a rate of once per flash. An occasionally missed flash is to be expected.
 - **Rapid flashing** at a rate of 7 times per second indicates the need to reset the signal processor. This is accomplished by disconnecting and reconnecting the processor from the driver. If resetting the processor does not correct the rapid flashing, replace the signal processor.
 - **No flashing** indicates a loss of empty signal. Increasing the ejection duration or pressure may be helpful in recapturing the empty signal.

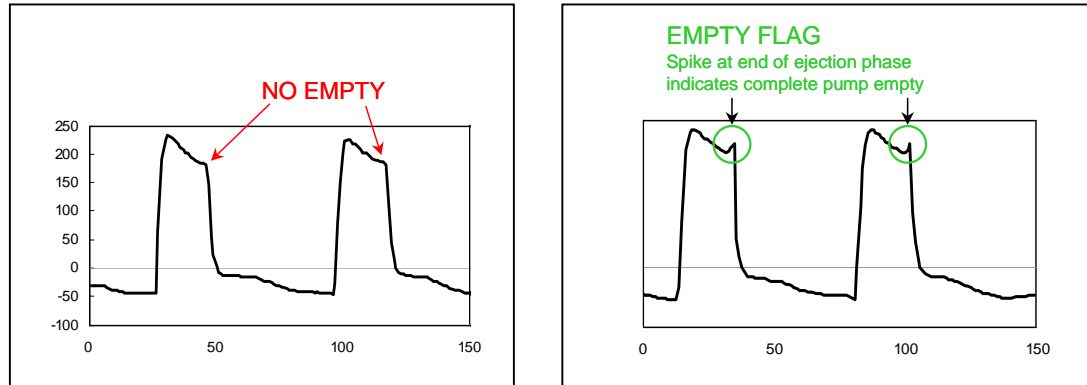
Note: When connected to the DDC, the loss of full signal will cause the loss of empty indication (**no-flashing condition**) on the signal

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processor automatically. This does not imply that the pump is not emptying.

15. If empty signal light is absent, check for empty flag on pressure tracing on the TLC-II docking station plots screen (**Figure 14**).

Figure 14 Empty flag on Plots Screen



16. When the IVAD is filling and emptying consistently, switch the driver to VOLUME or AUTO.

CAUTION:

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.

17. Wean the patient from cardiopulmonary bypass and administer the usual dose of protamine.
18. Hold the sternum closed and check for adequate IVAD filling, IVAD emptying, and cannula positioning.
19. Close the sternum and skin using standard techniques.

CAUTION:

In closing the chest and abdomen, precaution must be taken to not compress the cannulae. Consider the placement of 24 Fr Silastic drains in the device pocket(s) to a closed, water-sealed system at -20 cm H_2O .

20. Re-approximate the anterior rectus sheath to the linea alba with interrupted absorbable suture, the subcutaneous tissue with a running absorbable suture, and the skin with subcuticular sutures or skin staples. If both an LVAD and RVAD are placed, close the anterior rectus sheath on both sides separately to create 2 pockets.

10.0 Follow-Up or Re-Operative Procedures

10.1 Weaning the Patient from IVAD Support – Recommended Procedure

Note: Preferably, the patient should not need nor be receiving IV inotropic agents and should be clinically stable with normalized renal and hepatic function before IVAD removal.

1. Order diagnostic procedures to evaluate if the patient is ready to be weaned from the device or have it removed.

Note: At a minimum, this should include echocardiography and blood pressure monitoring. Record cardiac index, right atrial, and pulmonary capillary wedge pressure (PCWP) if a pulmonary artery catheter is in place. Additional procedures may be useful, such as cardiopulmonary exercise testing, dobutamine stress echocardiography, MUGA scan, and cardiac catheterization.

2. Record resting hemodynamics, echocardiography, and IVAD measurements with full IVAD support in the VOLUME/AUTO mode. Change to the ASYNC/FIXED mode of pumping at approximately the same beat rate as in the VOLUME/AUTO mode. Slowly decrease the IVAD rate 10 bpm every few minutes, while monitoring blood pressure, until reaching the lowest driver setting. Turn off the driver temporarily.

CAUTION:

If the blood pressure drops too low or the patient becomes symptomatic, the IVAD settings should be turned back to pre-procedure settings. For low driver rates or temporary driver shut off, the patient should be appropriately anticoagulated. For extended driver shut off, the patient should receive heparin and the patient's ACT should be greater than 300 seconds. If the IVAD remains off for more than 60 seconds, a single driver ejection/full cycle or hand pump should be used once every 60 seconds to prevent stasis in the blood pump.

3. After temporarily shutting off the pump (see previous step), return the IVAD rate to prior settings. If the ACT is >300, the effects of heparin can be reversed with protamine **or** the heparin can be allowed to metabolize. After the procedure, the patient should be confined to bed until the ACT normalizes.
4. Device weaning can begin when the patient achieves all of the following with the IVAD temporarily turned off (see next step).
 - LVEF is greater than or equal to 35%.
 - Ventricular chamber size remains normal or mildly dilated.
 - Systolic blood pressure is greater than or equal to 100 mmHg.

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- If a thermal dilution pulmonary artery catheter is in place, the cardiac index should be greater than or equal to 2.0 L/min/m² with a PCWP and right atrial pressure less than or equal to 20 mmHg.
5. For weaning the patient from IVAD support, decrease the IVAD output in steps at 6-hour intervals to gradually permit the patient's ventricle to resume full circulatory function. Use the ASYNC/FIXED mode and decrease IVAD rate 5 bpm every 6 hours, while maintaining complete VAD filling and emptying.

Note: The goal is to achieve adequate hemodynamics as documented by LVEF, ventricular chamber size, blood pressure, and cardiac index (if available), while reducing the IVAD rate to a minimum of 30 bpm.

CAUTION:

Anticoagulation should be carefully monitored and maintained during weaning because lower flow could result in thrombus formation within the IVAD. During device weaning intravenous heparin should be administered to prolong the PTT to 1.5 times normal value (see Section 11.4).

6. The VAD can be removed when adequate ventricular function is demonstrated at least 2 times during the prior 24 hours.

Note: Adequate ventricular function should be documented, at a minimum, by LVEF, ventricular chamber size, blood pressure, and cardiac index (if available) during 60 seconds without IVAD pumping.

10.2 Explanting the LVAD and RVAD

1. Administer intravenous antibiotics 1 hour before IVAD removal.
2. Continue IVAD pumping while the patient is moved from the intensive care unit to the operating room.
3. After induction of anesthesia, thoroughly prep chest, abdomen and groin areas.
4. Wrap the proximal external portion of the leads with sterile wraps.
5. Drape the patient and reopen the sternal and abdominal incisions.

CAUTION:

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

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

7. For a paracorporeal IVAD, clamp the inflow and outflow cannulae inside the chest and cut the cannulae near the inside chest wall. For an implantable IVAD, clamp the inflow and outflow cannulae in their graft/non-reinforced regions and cut the cannulae near the pump's cannula connectors.
8. Carefully dissect the tunneled percutaneous line along its length.
9. Dissect out the IVAD and pull the IVAD and cannulae, as a single unit, out of the abdominal pocket.

Note: To ease explantation, the percutaneous line can be dissected near the pump, provided that the cut ends of the line have been covered to prevent contamination of the sterile field.

CAUTION:

The inner lumen of the percutaneous line is **non-sterile**; care must be taken not to contaminate the surgical field.

10. Remove the remaining cannula sections from the heart and proceed with cardiac transplantation in the usual manner, if applicable.
11. Continue thereafter with conventional patient management.

10.3 IVAD Replacement

Note: If for any reason an IVAD requires replacement, the following procedure based on the Thoratec PVAD experience may be used (Lohmann et al, 1992).

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. Prepare a new IVAD as in Section 9.1.
4. Open the abdominal incision and dissect out the percutaneous line, pump and cannulae connections as described in Section 10.2.
5. Anticoagulate the patient with heparin (1 mg/kg).
6. Insert lines for infusion of inotropic agents if required to provide some support during the period of IVAD exchange.
7. Terminate IVAD pumping. If the systolic blood pressure drops below 80 mmHg for more than 5 minutes, reinstitute IVAD pumping and initiate cardiopulmonary bypass through groin vessels.

IMPLANT PROCEDURES

8. Clamp the IVAD cannulae on their non-reinforced sections.
9. Remove the cannula connectors from the IVAD and carefully remove the cannulae from the valve housings, taking care not to damage the ends that will be used on the replacement IVAD.
10. Connect the IVAD to the inflow cannula as in Section 9.6.
11. De-air the pump as in Section 9.5.
12. Connect the pump as in Section 9.6.
13. Tunnel the IVAD percutaneous line as in Section 9.8.
14. Connect pump to the driver and initiate pumping as in Section 9.9.
15. Wean the patient from inotropic support and/or terminate cardiopulmonary bypass.

11.0 Patient Management

11.1 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. IVAD filling is dependent on pre-load and a slightly elevated CVP should be maintained during the initial postoperative period. 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.

11.2 Infection Control

To reduce the risk of infection, use a broad-spectrum cephalosporin for antibiotic prophylaxis for the first 24-48 hours at a dosage of 1 to 3 gm/day, similar to that of other open-heart procedures. After this, resume organism-specific antibiotics as needed based upon positive culture results.

Nursing measures to decrease infection include frequent hand washing and strict aseptic techniques during contact with invasive lines and during dressing changes. Sterile dressing change to the IVAD driveline should be performed daily and as needed. The dressing should always be dry and occlusive. Antibacterial agents, saline or Betadine™ (solution or scrub) can be used to cleanse the exit site. An abdominal binder to stabilize the percutaneous line should be worn at all times to reduce movement of the line and disruption of the exit site.

WARNING:

Do NOT use povidone-iodine ointment with the percutaneous line for the prophylactic care of the transdermal skin site; use povidone-iodine solution instead. The ointment can cause degradation of the line near its ends.

CAUTION:

Prolonged exposure to hydrogen peroxide or bleach solutions may cause degradation of Thoralon®, the material comprising the percutaneous line.

Early extubation, removal of monitoring lines, and patient ambulation are encouraged. Rapid restoration of oral nutrition should be attempted using tube feeding if necessary. Turning the patient side-to-side can start once the patient is clinically stable. Physical therapy and active range of motion can begin on the first postoperative day. The patient can be moved to a chair and should use an exercise bicycle or treadmill as soon as possible.

PATIENT MANAGEMENT

11.3 *Control of Bleeding*

Bleeding is one of the more frequent adverse events in IVAD 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 administered to correct for abnormalities in hematologic measurements. Re-exploration should be considered if chest tube output exceeds 200 ml/hour for two consecutive hours after clotting factors and patient body temperature have normalized.

11.4 *Recommended Anticoagulation Regimen*

Anticoagulation strategy is similar to that for patients with mechanical heart valves. When the chest tube drainage falls to approximately 50 ml/hr for two to 3 hours, with stable hematocrit and hemoglobin levels without transfusion of blood products, and coagulation factors are approaching normal (usually in the first or second post-operative day), anticoagulants should be considered to minimize the risk of thromboembolism. Two (2) primary anticoagulation agents have been used in IVAD patients: 1) heparin and 2) warfarin.

Patients have been started on intravenous **heparin** on the first or second post-operative 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 should be started on 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. Once the INR reaches an acceptable level, discontinue the heparin. Low molecular weight **dextran**, **aspirin**, and **Persantine**[™] have also been used.

Significant drops in hematocrit (Hct) and hemoglobin (Hbg) levels, possibly requiring blood transfusions, or the inability to stabilize Hct and Hbg levels, may require modification of anticoagulation (i.e., lowering heparin or warfarin dosage or discontinuing aspirin administration).

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APPENDIX

THORATEC IVAD SYSTEM COMPONENTS AND ACCESSORIES

Description	Catalog No.
Pump and Cannulae	
Sterile Implantable Ventricular Assist Device (IVAD)	10012-2555-001
Sterile Ventricular Cannula – long, curved, blunt tip	10012-2520-001
Sterile Ventricular Cannula – short, curved, blunt tip	10012-2521-001
Sterile Ventricular Cannula – short, curved, beveled tip with side holes*	101614*
Sterile Arterial Cannula – long, curved, 14mm graft	10012-2524-001
Sterile Arterial Cannula - short, straight, 14mm graft	10012-2525-001
Sterile Arterial Cannula - short , curved, 14mm graft*	101613*
Sterile Atrial Cannula - long, beveled tip with side holes	10012-2528-001
Sterile Atrial Cannula - short, beveled tip with side holes	10012-2529-001
Sterile Sealed Arterial Cannula - long, curved, 14mm graft	100125
Sterile Sealed Arterial Cannula - short, straight, 14mm graft	100113
Electrical and Pneumatic Leads	
Sterile IVAD Signal Lead, 5 FT	10012-2510-001
Non-Sterile IVAD Signal Processor	10012-2515-001
Non-Sterile Dual Drive Console to IVAD Processor Adapter	10012-2511-001
Sterile TLC-II LVAD Pneumatic Lead, 5ft	20010-0000-108
Sterile TLC-II RVAD Pneumatic Lead, 5ft	20010-0000-109
Non-Sterile LVAD Pneumatic Extension Lead, 7ft	20010-0000-091
Non-Sterile RVAD Pneumatic Extension Lead, 7ft	20010-0000-092
Drivers	
Dual Drive Console: Model 2600, 110-120V/50-60Hz	10025-2600-005
Dual Drive Console: Model 2601, 220-240V/50-60Hz	10025-2601-007
TLC-II Portable IVAD Driver Package	20010-2806-000
Accessories	
IVAD Sizer	100394
IVAD Cannula Connector Wrench	10012-2537-001
Non-Sterile Percutaneous Line Tunnelers, 6" & 8" Curvature	10012-2534-001
Sterile Surgical Implant Accessory Kit	20002-2615-001
Non-Sterile VAD Cannula Attachment Tool	10099-2517-001
Training	
Dual Drive Console Instructions for Use	14025
Thoratec VAD Console Operation with Illustrations	14803
Dual Drive Console Quick Reference Card	14831

* For use in US only

TLC-II Portable Driver Instructions for Use Patient Management Manual	50010-0006-002 14577
Videotape: VAD Dual Drive Console	14805