Thoratec Paracorporeal Pneumatic Ventricular Assist Device

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The use of mechanical circulatory support is considered standard care for postcardiotomy cardiogenic shock that is both drug and intra-aortic balloon pump refractory, as well as in the bridge-to-transplant, application.[1] In the postcardiotomy application, the patient can be supported with either a right (RVAD) or left ventricular assist device (LVAD), or with two devices in the case of severe biventricular failure. The goals are to provide adequate systemic and/or pulmonary blood flow while unloading the failing ventricle until myocardial recovery occurs, at which time the device(s) is explanted. In the rare instance of device dependency and the absence of contraindications to orthotopic heart transplant, bridge-to-transplantation may be a further option. In the bridge-to-transplant application, a potential cardiac transplant recipient who deteriorates hemodynamically before the availability of a donor organ can be likewise supported until such becomes available. Obviously, the goals are somewhat different. The device(s) allows for support of the circulation with rehabilitation potential; however, cardiac function is not expected to return.

Overview of the System

The Thoratec VAD (Thoratec, Pleasanton, CA) represents the only system currently approved in the United States for both of the previously mentioned applications. This paracorporeal device has a great deal of flexibility in that it can be configured for univentricular, right- or left-sided, or biventricular support (Fig IA-D).[1,2] Furthermore, inflow cannulation can be via the atria or ventricle using the appropriate cannulae (Fig II). The paracorporeal location allows for use in the small patient (0.7 m^2 body surface area). The prosthetic ventricle consists of a machined polycarbonate housing of an angle port design containing a seam-free proprietary segmented polyurethane sac (Fig III). The pumping chamber is separated from the air chamber by a polyurethane diaphragm, which serves both as a volume limiter and a safety chamber. The VAD uses monostrut inlet and outlet valves to provide unidirectional flow (Fig IV). Systemic anticoagulation is therefore necessary. Alternating pulses of pressure and vacuum, delivered by a dual-drive console via an 8- or 12-foot pneumatic lead, empty and fill the blood sac. The stroke volume is approximately 65 mL. A Hall effect switch built into the polycarbonate case indicates complete filling of the device. The dual-drive console has two independent drive modules, each of which is designed to drive one ventricle or provide backup safety in the case of univentricular support (Fig V). Recently, Thoratec has developed the TLC-II (Pleasanton, CA), a compact and lightweight (9-kg) portable drive unit designed to promote management with either uni- or biventricular support (Fig V). Regardless, these drive units can be operated in a fixed asynchronous mode chosen by the operator or in a volume, or automatic mode, where changes in flow output occur in response to changes in physiological conditions. This mode is a variable-rate fixed-stroke volume, or full-to-empty pattern, where the instant the blood pump is full, the fill switch signals the driver to eject. The rate varies with the preload (ie, atrial or ventricular inlet pressure) and allows for a full-to-empty operation from 20 to 110 beats per minute or outputs ranging from approximately 1.3 to 7.1 L/min.

Next is described the techniques for cannulation and implantation of the Thoratec system, which was initially developed at our institution as the Pierce-Donachy VAD and was first clinically used in 1976.[3]

Preparing for Cardiopulmonary Bypass and General Considerations for Insertion of Thoratec VAD

For LV support, inflow cannulation can be via the left atrial appendage, intra-atrial groove, left atrial roof, or ventricular apex. Generally, atrial inflow cannulation is preferred in the recovery situation postcardiotomy because insertion avoids further myocardial damage and removal does not require cardiopulmonary bypass (CPB). In fact, under certain circumstances, the device may even be inserted without CPB. However, the thromboembolic rate is likely higher, and this mode should be avoided with prosthetic mitral valves to prevent ventricular thrombosis. Currently, the atrial inflow cannula is a 51F right-angled venous return cannula coated with proprietary segmented polyurethane. LV apical inflow is the method of choice in the bridge-to-transplant application because maximal reduction in wedge pressures and, therefore, pulmonary artery pressures and pulmonary vascular resistance, occurs. The additional LV damage is inconsequential because recovery is not expected. Thromboembolic rates are lower.

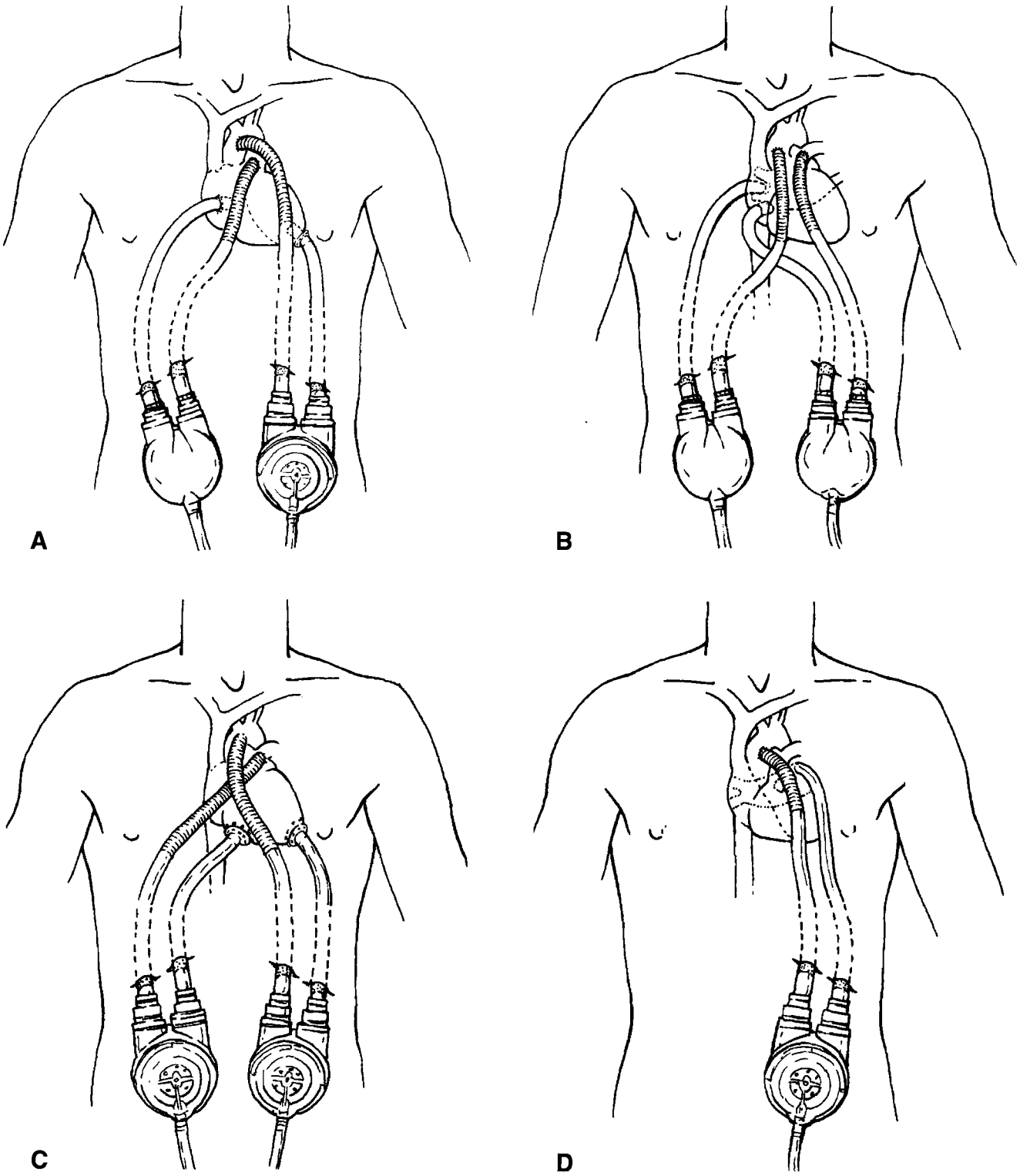


Fig I. The various and most commonly used approaches for the Thoratec VAD. (A) Biventricular support using apical ventricular and right atrial inflow cannulation. This is a popular and useful method for bridge-to-transplantation, although, recently, we have favored RV inflow cannulation. (B) Biventricular support using biatrial inflow cannulation. This is commonly used in the postcardiotomy application. A curved right atrial inflow cannula facilitates this configuration. (C) Biventricular support using biventricular inflow. This offers the advantage of higher flows in our experience. (D) Univentricular configuration using inflow cannulation via the base of the left atrial appendage. Note that it is possible at times to perform insertion without CPB when using atrial inflow cannulation via the interatrial groove.

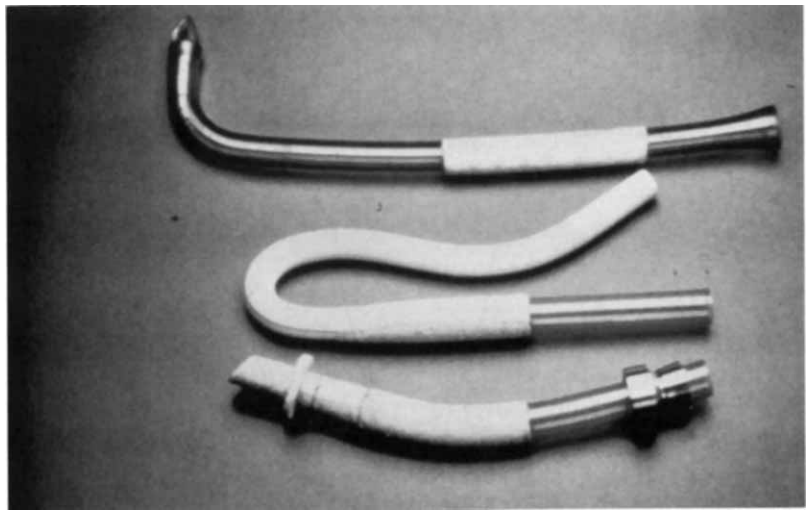


Fig II. The Thoratec cannulae that we commonly use are depicted. At the top, the long right-angled atrial inflow cannula. Pictured in the middle is the composite polyurethane and Dacron graft outflow cannula that is anastomosed to the aorta or pulmonary artery. At the bottom is the ventricular inlet cannula (bevel-tipped model). We generally prefer the blunt-ended type, with the intraventricular portion covered with velour.

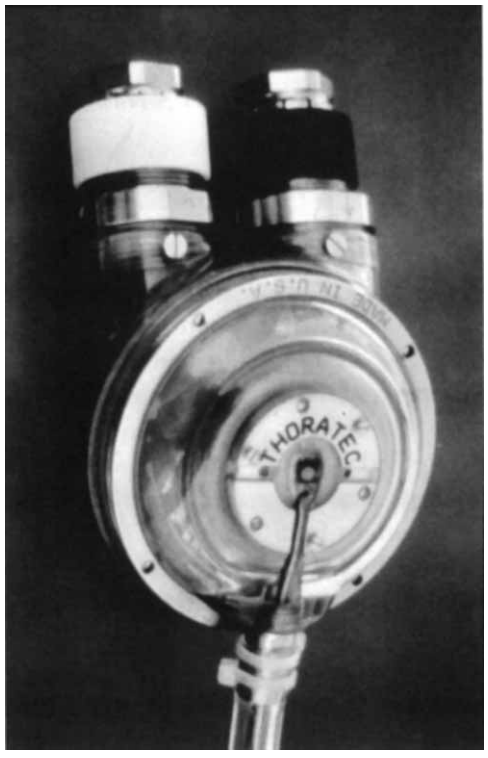


Fig III. The prosthetic ventricle is shown with the black colletnut on inflow housing and white colletnut on outflow housing. The fill switch can been seen in the middle of the housing of the ventricle and the electrical and pneumatic connection at the bottom.

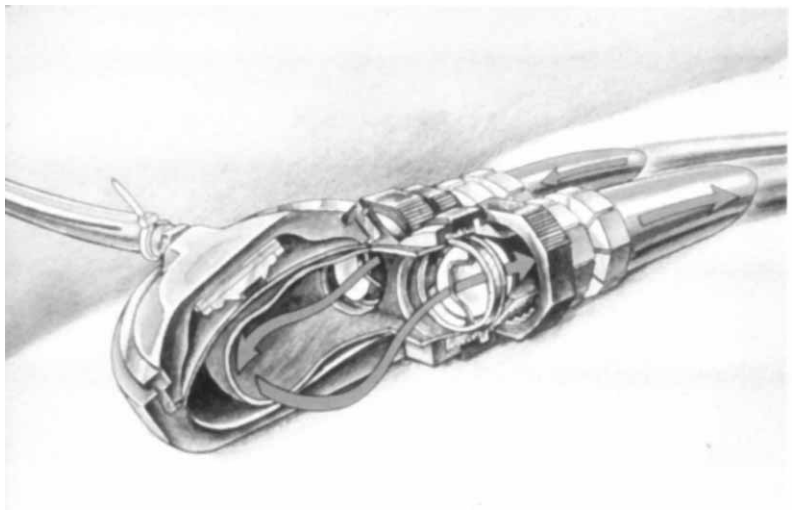


Fig IV. Artist's rendition of a cut-a-way of the prosthetic ventricle with a rigid polycarbonate housing enclosing a seam-free proprietary segmented polyurethane sac. Monostrut inlet and outlet valves provide unidirectional flow when pulses of air are delivered between the outer case and the stroke-limiting diaphragm.

Fig V. To the right of the patient is the dual-drive console contrasting, with the portable TLC-II (Thoratec) slung from the patient's left shoulder. The portable driver has biventricular pumping capabilities and provides for improved patient mobility.

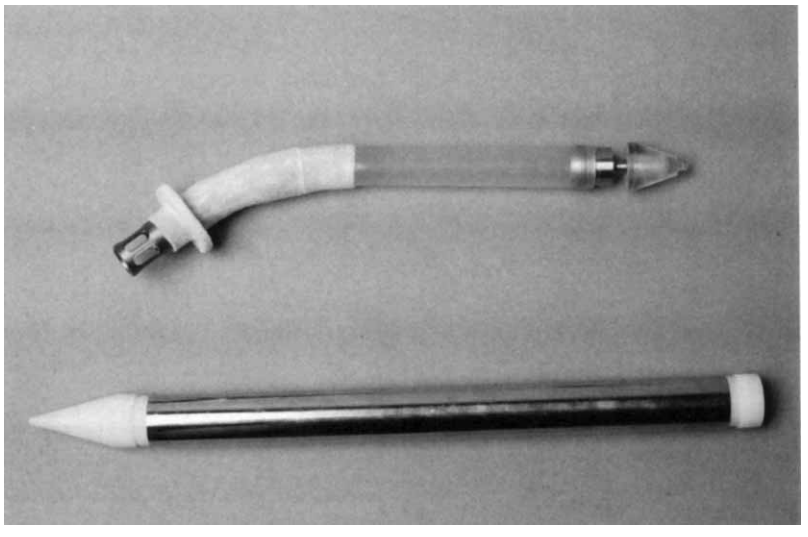


Fig VI. The ventricular cannula with the combination cannula plug/suction connector. When the screw-on cap of the combination cannula plug/suction connector is removed, connection is made to cardiotomy suction, allowing for venting of the heart and deairing via the inflow cannula. Below is the tunneler, which facilitates bringing the cannula from its pericardial target site out through the skin with minimal dissection, thus, keeping the surrounding tissue in tight approximation to minimize dead space and allowing for tissue ingrowth. The bullet tip and end-cap are removable.

For RV support, inflow uses the same cannulae as for left-sided applications and can be via the right atrium or RV with the latter providing higher flows.

The outflow cannula, regardless of the application, is a composite proprietary segmented polyurethane conduit with an attached 14-mm woven Dacron (Dupont, Wilmington, DE) graft. Inflow and outflow cannulae are partially velour-covered, and accurate adjustment at the exit sites to allow for tissue ingrowth, which decreases the potential for ascending infection of the mediastinum, is important.

The patient is prepared and draped in a standard fashion for CPB. The groin is prepared for femoral vascular access in patients with previous open heart surgery. One outflow graft is prepared when univentricular support is planned, and two are prepared if biventricular support is anticipated. We soak the Dacron portion of the outflow cannulae in 25% albumin and autoclave for 3 to 4 minutes at 83°C. Another approach is to preclot the outflow graft in 100 mL of nonheparinized blood mixed with 5 mg protamine and 5,000 U of topical thrombin. Regardless, care is taken not to get material inside the graft. The VAD is filled with 5% albumin with 100 U heparin/250 mL, which passivates the surface and enhances removal of air later. The electrical connector on the driveline is covered with a finger cut from a sterile glove to protect it from fluids, and the inlet and outlet ports are plugged with silicone rubber stoppers.

Transesophageal echocardiography (TEE) is used continuously to search for a patent foramen ovale (PFO) (which must be closed to prevent right-to-left shunting/hypoxia/cyanosis), aortic insufficiency, air, cannula position, RV function, and LV or atrial thrombus. Significant aortic insufficiency must be corrected and sought for just as a PFO after the LV end-diastolic pressure has been lowered by assist pumping.

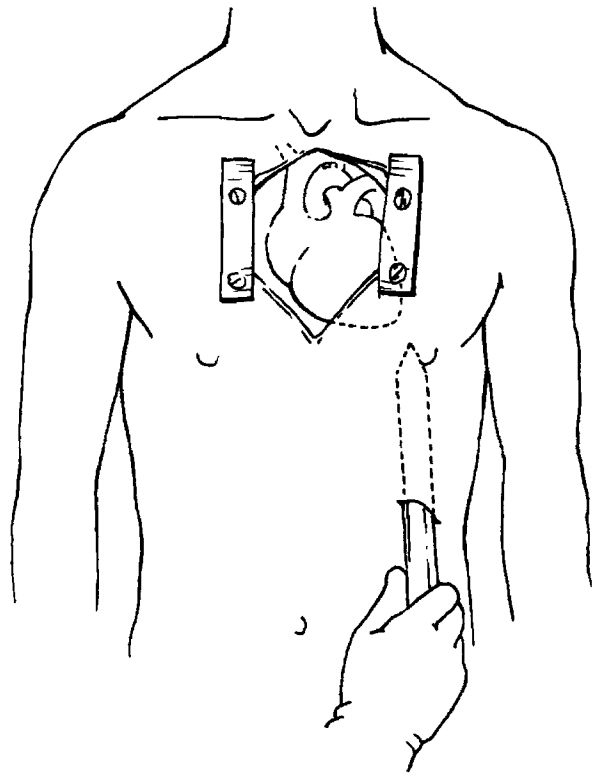
Aortic cannulation sutures are made in a standard fashion as high as possible on the inner curvature of the ascending aorta or transverse arch. A standard two-staged venous cannula through the right atrial appendage is used for venous return. Full CPB without active cooling is instituted. The aorta is not cross-clamped. Standard full-dose aprotinin is used to decrease bleeding, blood, and blood product usage and subsequent RV failure.

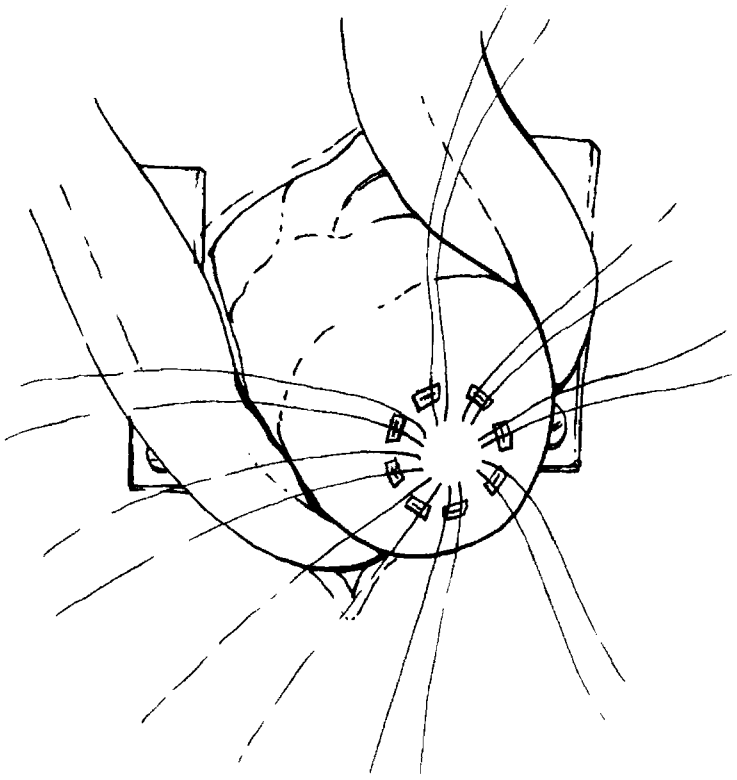
The VAD comes with a black collet and colletnut on the valve housing of the inflow VAD. This black collet and colletnut should always be used with the inflow atrial cannulae. Although the ventricular inlet cannulae can be cut to length, do not cut the atrial cannulae. When LV or RV cannulation is planned, remove the black colletnut and collet from VAD inflow housing. Only the white colletnut and collet packaged with the

ventricular inlet cannula can be used for coupling to the inflow valve housing. The different collets and collet-nuts are necessary because of the wall thickness of the respective cannulae. Using the wrong collets and collet-nuts can result in the disasterous complication of pump disconnect! Proper selection of the percutaneous exit site is critical to allow the heart to lie in its anatomical position and to prevent kinking of the cannulae, as well as discomfort to the patient. The lateral of the skin incisions should generally be in the mid-clavicular line 2 to 3 cm below the subcostal margin on the right or left side, depending on the planned procedure. The medial incision should be approximately 4 cm from, and parallel to, the lateral incision. The skin incisions for inflow grafts should correspond well with cannulation sites on the heart in the pericardial well. The skin incisions should be as tight as possible to allow tissue ingrowth. Generally, there should be about 6 to 7 cm of cannula above skin level, including 2 cm of velour. If shorter than this, it is difficult to connect to the VAD, and if longer than this, kinking and discomfort can be a problem. The cannulae should be affixed to the skin with heavy nonabsorbable suture, which are left in place for 2 weeks, postoperatively. This limits motion and allows for tissue ingrowth. We have developed several instruments to facilitate operative insertion (Fig VI). These will soon be available in a commercial form from Thoratec (Pleasanton, CA).

SURGICAL TECHNIQUE: LVAD-VENTRICULAR CANNULATION

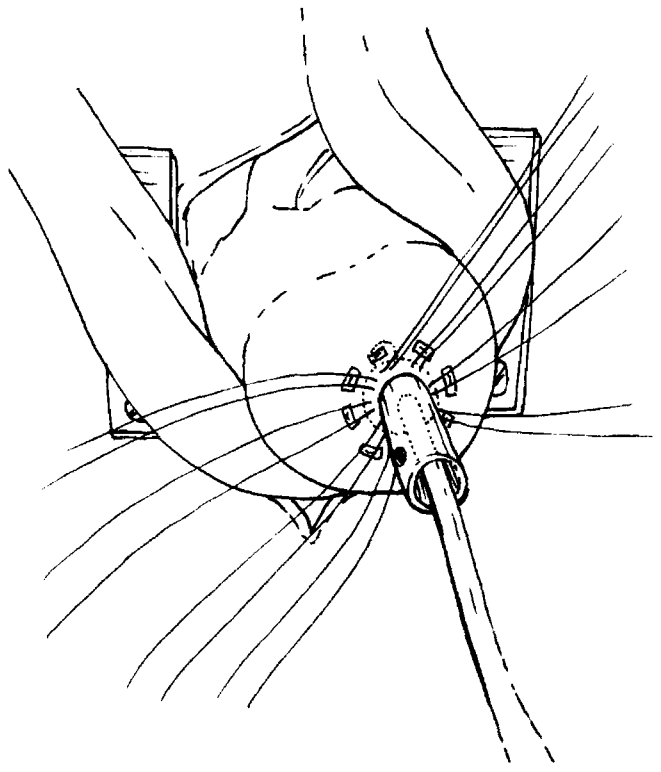
1-1 **Exit site and tunneling for LV cannulae.** Perform median sternotomy. Prepare for CPB and VAD insertion according to previous section. Make a skin incision (button, 1.5 cm wide) approximately in the left mid-clavicular line 2 to 3 cm below the left subcostal margin, which should correspond with the LV apex in the pericardial well. The electrocautery is used to divide the subcutaneous tissue, upper fascia, and rectus muscle. Stop when the lower fascia is reached. Bring tunneler through the incision within the rectus sheath beneath the costal margin into the diaphragmatic pericardium. The tunneler is brought into the pericardium after an incision is made with the electrocautery.

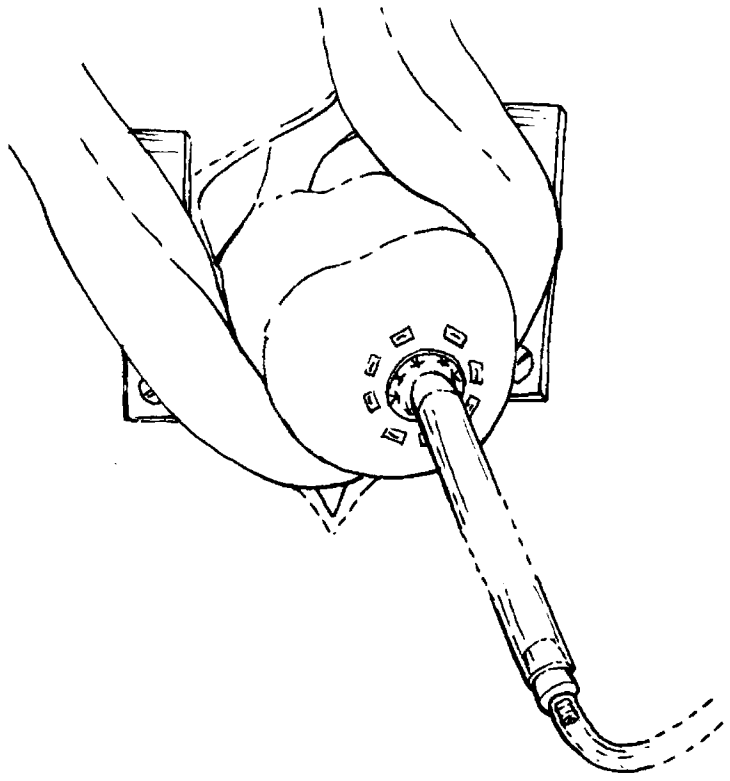




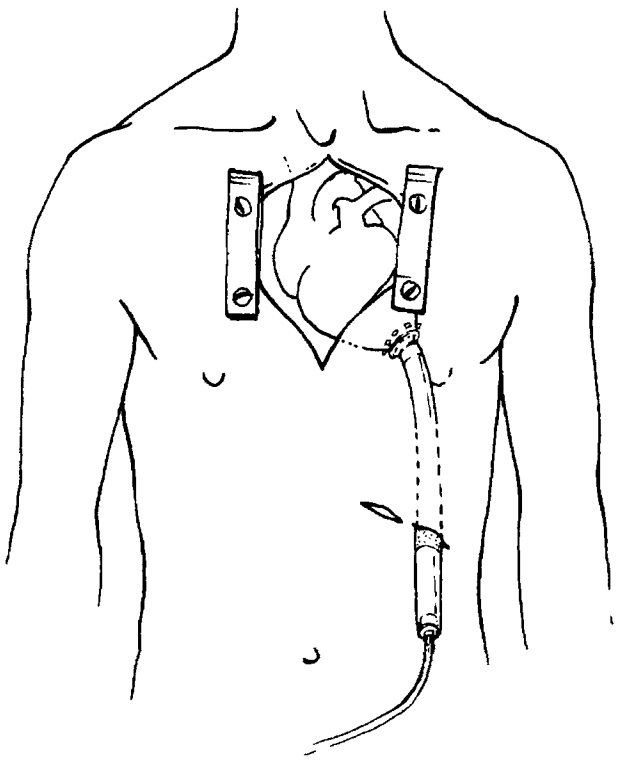
1-2 Placement of apical ventricular sutures. Expose the apex by placing two to three laparatomy pads underneath and lateral to the apex. A sling can be made from a laparatomy pad and passed under the LV and pulled and fixated to facilitate exposure further. Palpate the apical dimple about 2 *cm* lateral to the left anterior descending. Eight to 12 2-0 nonabsorbable sutures buttressed with felt are passed radially full-thickness through the apical LV muscle around the apical dimple. Once the first two to four sutures are in place, they can be used for bringing the ventricular apex up further in the field for exposure.

1-3 Coring of the apex. The patient is placed in the Trendelenburg position; a stab incision is made in the center of the circle created by the suture placement. A large Foley catheter, with a 30-mL balloon, is passed through the lumen of a sharpened cork borer (12 to 14 mm); the Foley catheter is inserted into the stab incision and the balloon inflated with saline. The sharpened cork borer is lowered into position. The Foley balloon is used as an anvil. A core of myocardial apex is excised. The Foley catheter is deflated and removed, and the inside of the LV cavity is inspected for thrombus or large trabeculae that need to be removed.

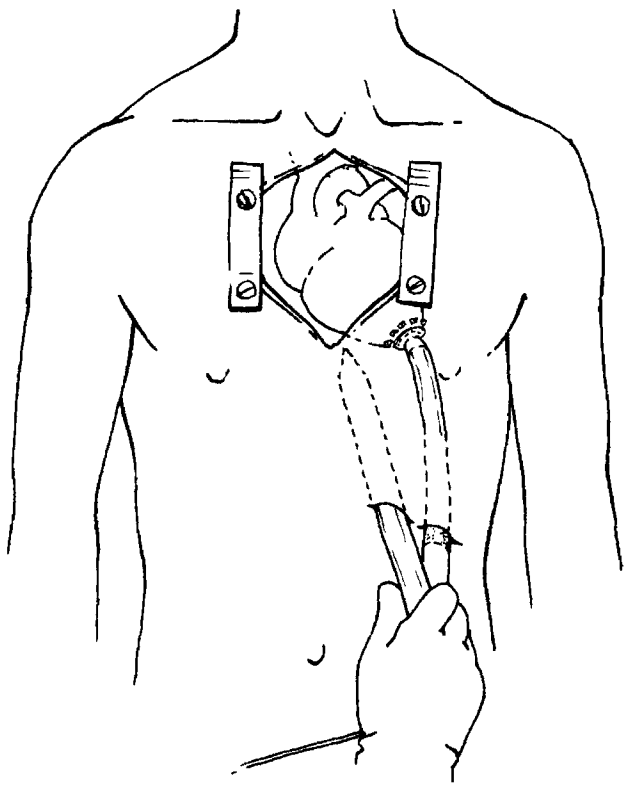




1-4 **Cannula insertion and fixation.** The ventricular cannula is inserted. The combination cannula plug/suction connector is inserted into the distal end of the cannula and is affixed to cardiotomy suction. This ventilates the LV while sutures are passed through the sewing ring and tied. We prefer the blunt-tip velour-covered cannula. The inflow cannulation site must be absolutely hemostatic, and care must be taken during suture placement and tying, particularly in the face of recent myocardial infarction.

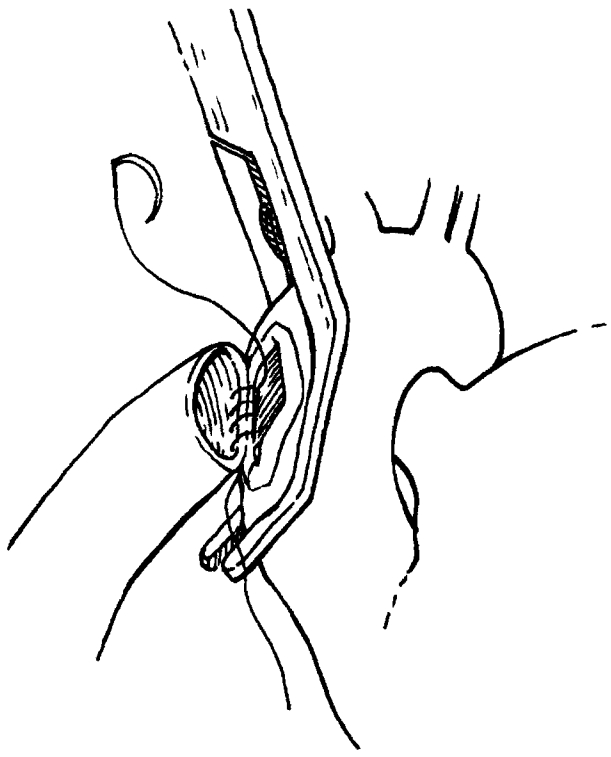


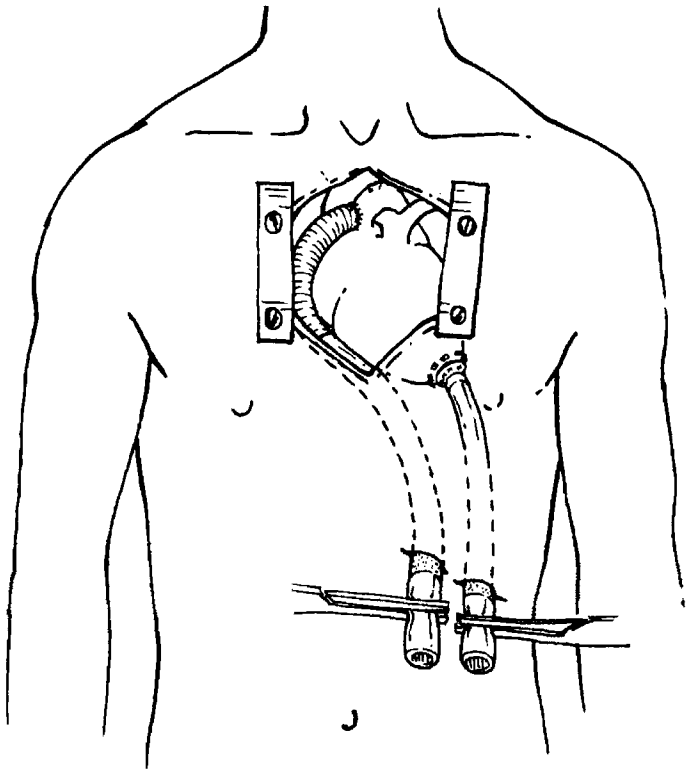
1-5 **Inflow tunneling to the exit site.** The end of the inflow cannula is plugged with the cap of the combination cannula plug/suction connector, making sure that air is absent, and the cannula is then passed out through the tunneler. The tunneler is removed. A cardiotomy suction line is once again connected to the combination cannula plug/suction connector after removing the screw-on cap for continued venting and deairing.



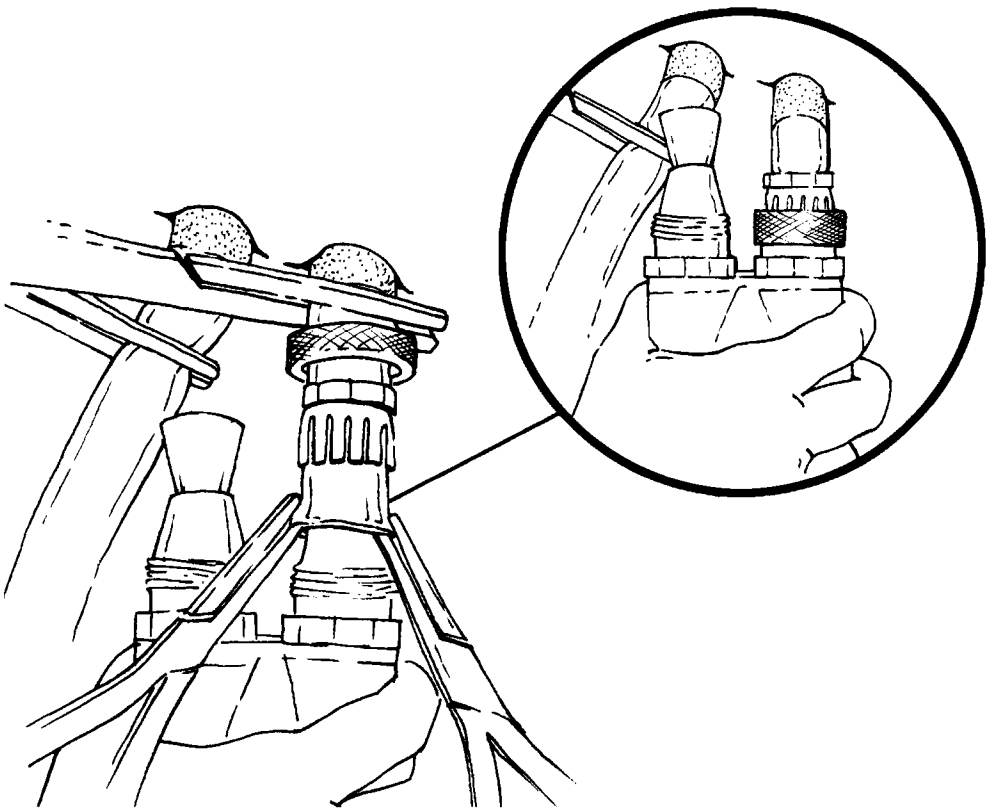
1-6 Exit site and tunnel for outflow graft. The outflow graft is measured to the appropriate length, and the Dacron graft is cut, beveled, and trimmed. The graft should be long enough to be able to be directed under the right half of the sternum in order to be protected when re-entering the chest but should be short enough to prevent kinking. A second skin button is made 4 cm toward the midline, parallel to the inflow cannula incision. The tunneler is brought through the incision as before to the diaphragmatic pericardial surface and is left in place.

1-7 Outflow graft aortic anastomosis. The outflow cannulation site for patients being considered for bridge-to-transplantation is along the greater curvature of the ascending aorta as low as safely possible to allow for removal of the graft site at the time of recipient cardioectomy. The cannulation site for the postcardiotomy group of patients is dictated by the presence of proximal vein-graft anastomoses. A partial occluding clamp is placed on the ascending aorta, and a longitudinal aortotomy is made. The graft is sewn in an end-to-side fashion using a running 4-0 polypropylene suture that is reinforced with a strip of felt or pericardium. The partial clamp is removed from the aorta, and the Dacron graft is clamped with a soft vascular clamp close to the aortic anastomosis. Check for hemostasis and a need for additional sutures.



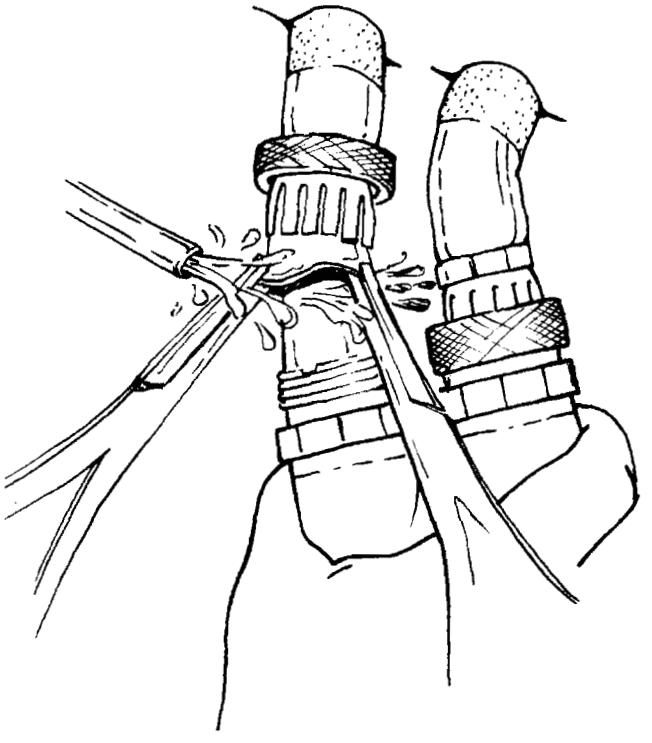


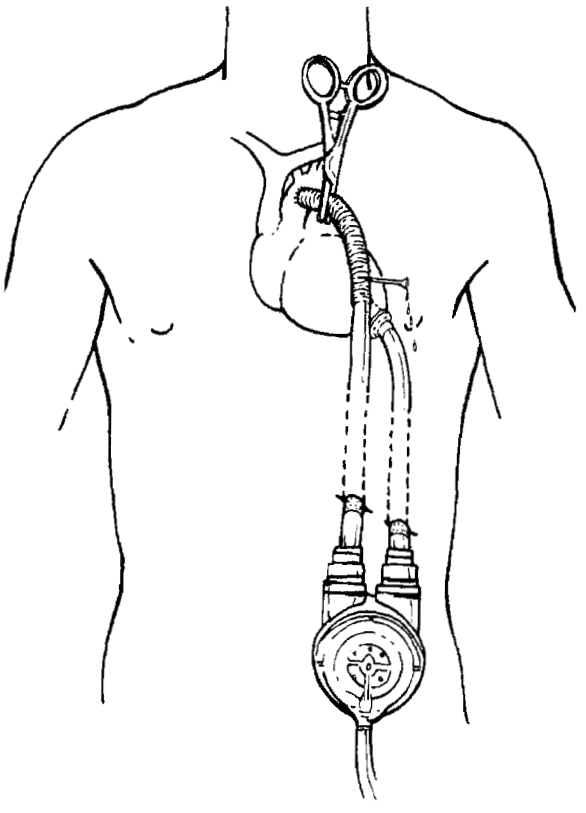
1-8 Final preparation for connection. The outflow graft is brought through the tunneler and the tunneler is removed. There should now be about 6 cm of out- and inflow cannula above skin level including 1 to 2 cm of velour. If any of the cannulae are too long, they can now be cut. The soft clamp is removed from the outflow graft, is allowed to fill with blood, and is deaired, and a tubing clamp is applied distal to the velour. The combination cannula plug/suction connector is removed from the inflow graft and is clamped distal to the velour.



1-9 **Connection of inflow graft to VAD.** The silicone stopper is removed from inflow VAD housing. Verify proper VAD pump alignment with arrows on inlet and outlet valve housing. Advance the apical cannula along the cone-shaped valve housing until the cannula edge is all the way into the connector groove. This can be done carefully with two small hemostats and a "peanut." Slide the collet and colletnut over the inflow cannula as far as possible and then hand tighten the colletnut.

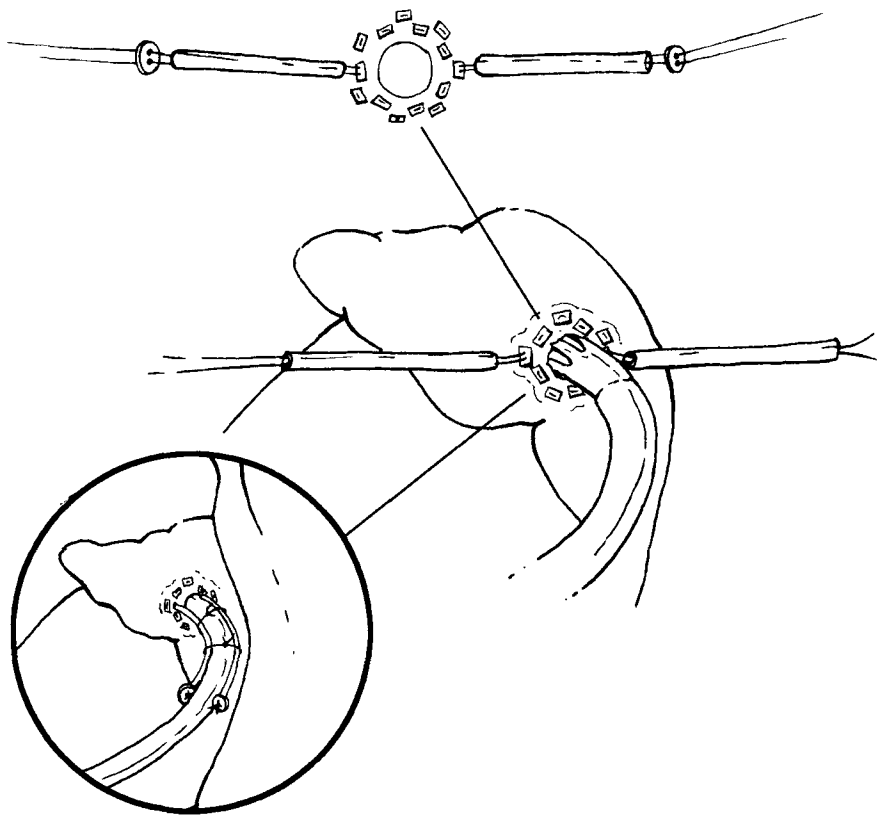
1-10 **Connection of the outflow graft to the VAD and initial deairing.** Remove the tubing clamp from the inflow graft and allow the heart to fill with blood. Rotate the table toward the patient's left side and tilt the VAD toward the left so that the remaining air can be flushed out through the VAD outflow port after removal of the silicone stopper. Put a soft jaw vascular clamp on the Dacron portion of the outflow graft near the aortic anastomosis and remove the tubing clamp; slow backbleeding will occur. Shake the VAD to deair, noting that many times, there is air trapped below the outflow valve. Place the patient in the reverse Trendelenburg position. Connect the outflow cannula to the VAD as described previously while flooding the connection with heparinized saline.





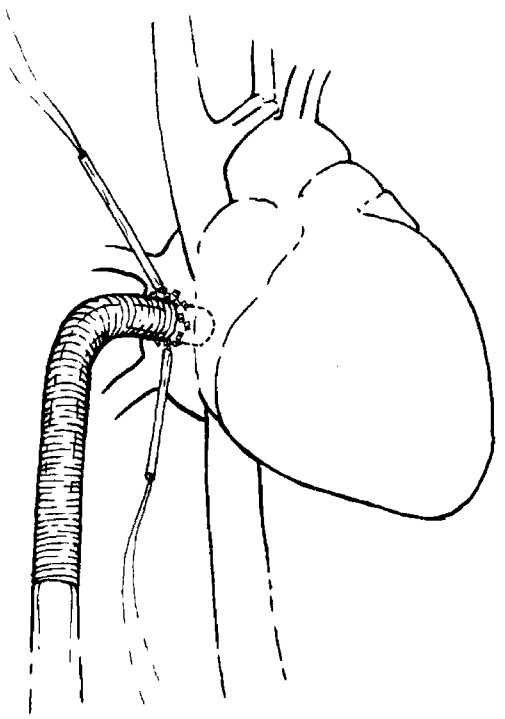
1-11 **Final deairing and VAD initiation.** Place a needle into the Dacron graft in a high spot, and, optionally, the ascending aorta may be vented as well. Remove the glove protector from the Y-pneumatic driveline/electrical connector and attach the pneumatic and electrical lead. Place the patient in the Trendelenburg position, start handpumping the VAD slowly, and check for air in the VAD housing and inlet and outlet cannulae and for hemostatic properties of suture lines. Check for residual air in the aorta or left heart with TEE. Remove the soft jaw clamp from the outflow graft and hand pump again. Connect lead to console and begin console operation. Gradually increase the VAD rate as CPB is discontinued. Provide the usual management of right heart dysfunction including inotropes, nitric oxide, volume, and pacing. Satisfactory pumping is cardiac index (CI) > 2.2 L/min/m, left atrial pressure (LA) < 15 mm Hg, and central venous pressure (CVP) < 15 mm Hg. Do not apply pump vacuum until the chest is closed. Careful measurement of filling pressures, cardiac output, and TEE will confirm satisfactory operation or indicate inlet cannula obstruction requiring repositioning or right heart failure requiring a second device.

LVAD–ATRIAL CANNULATION



2-1 **Left atrial appendage.** This is not an optimal inflow cannulation site when circumflex vein grafts are present because of the risk of vein-graft compression. Determine if a long or short atrial inflow cannula is to be used (in most patients the long right-angled one is best fitted). Appropriate measurement is important because the inflow cannula cannot be trimmed to length. The black colletnut and collet are used. The VAD rests on the anterior abdominal wall to the left as in LV apical cannulation, and the exit sites and skin buttons are made in the same fashion (see **1-4**). Make the lateral skin button and incision and tunnel the atrial inflow cannula to its target site in the pericardium near the left atrial appendage. This is a fixed position. Prepare the outflow graft by measuring it, then cut and bevel the Dacron part. Make the exit site for the site for the outflow graft and leave the tunneler in place.

Retract the heart to the patient's right side, exposing the left atrial appendage. Place two 3-0 polypropylene purse-string sutures at the base of the appendage. Each bite of suture on the appendage surface is brought in and out of small felt pledgets. Leave sutures long and pass them through rubber tube keepers. This facilitates removal later. Incise the appendage in the center of purse string and dilate the opening. Make sure the atrial cannula is clamped and insert it approximately 4 cm from the end of the tip. Single- and double-line markers are 5 and 6 cm from the tip. Tighten the rubber keepers and tie them over polypropylene buttons. Secure the cannula by tying a tape ligature around each keeper and the cannula. The distal end of the cannula is plugged with a combination cannula plug/suction connector, which is then connected to cardiotomy suction. Proceed with aortic anastomosis, inflow connection, outflow connection, and deairing as in LV apical cannulation. Confirm position with TEE.

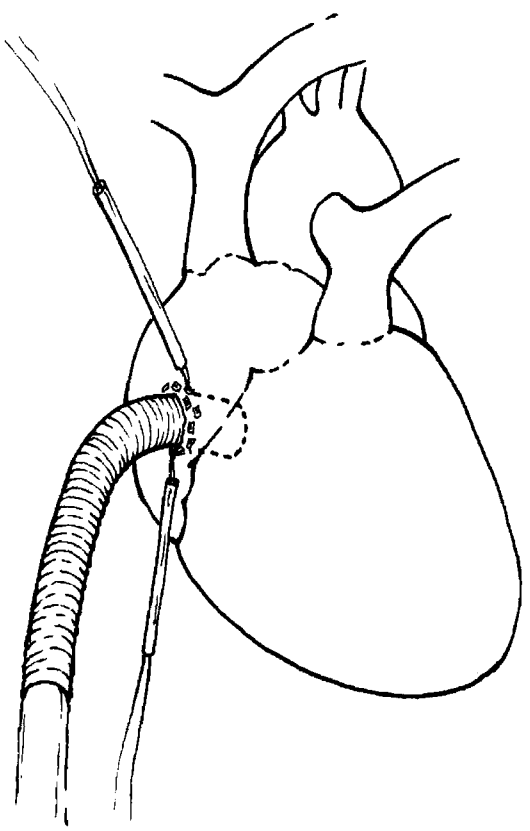


2-2 **Interatrial groove.** Determine which atrial inflow cannula is to be used; for most patients, the long one is most appropriate. Measurement is important because, once again, the cannula cannot be trimmed to length. The black colletnut and collet are used. With this inflow cannula placement, the VAD will be to the right of the midline and upside down, with the fill switch side against the abdomen as shown in **1-2.**

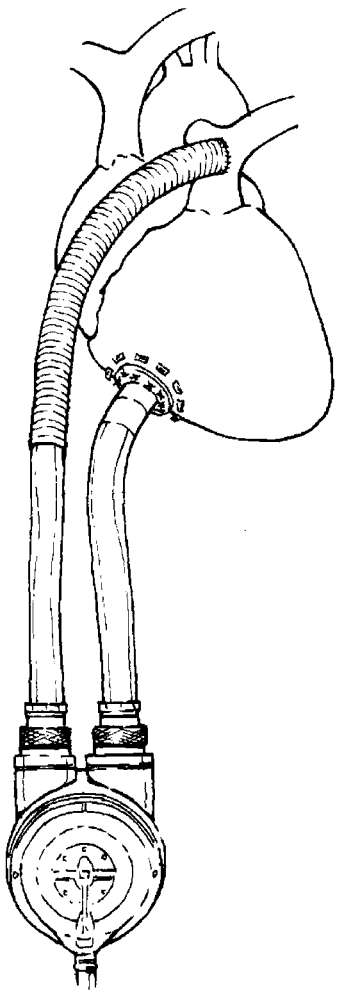
Make the lateral skin button and incision and tunnel the atrial inflow cannula to its target site by the interatrial groove. This is a fixed position. Prepare the outflow graft by measuring it, then cut and bevel the Dacron part. Make the exit site for the outflow graft and leave the tunneler in place.

Retract the heart to the left side. Place two 3-0 polypropylene purse-string sutures along the interatrial groove between the right superior and inferior pulmonary vein. Each bite of the suture on the epicardial surface is brought in and out of small felt pledgets. Leave sutures long and pass them through rubber tube keepers. The cannula should never be inserted directly into a pulmonary vein because of potential stasis and thrombosis. Incise in the center of purse string and dilate. Make sure the atrial cannula is clamped and insert it 4 cm pointing toward the mitral valve. Secure and tighten as described for left atrial appendage cannulation. Proceed with the rest as described for LV apical and appendage cannulation. Confirm position with TEE.

RVAD



3-1 Right atrial cannulation. The RVAD placement and orientation is determined by the mode of support (uni- or biventricular) and the LVAD inflow cannulation site (see **1-1**, **1-2**, and **1-3**). Determine which atrial cannula is to be used (usually the short one in the bridge-to-transplant application). Once again, measurement is important because atrial inflow cannulae cannot be trimmed to length. The black collet and colletnut are used. Place the curved portion of the atrial cannula next to the right atrial appendage and approximate the skin exit. Make a skin button and incision; tunnel the atrial inflow cannula to its target site by the right atrium. Prepare the outflow graft by measuring it to pass over the RV to the pulmonary artery, then cut and bevel the Dacron part. Make the exit site for the outflow graft and leave the tunneler in place. Place two 3-0 polypropylene purse-string sutures with felt (as described for the left atrial cannulation) in the body of the right atrium opposite the tricuspid valve. Make a stab wound in the center of the purse string and dilate. Insert the atrial cannula 4 cm toward the tricuspid valve. Tighten keepers and secure as described for left atrial cannulation. The pulmonary artery is gently elevated, and a partial occluding clamp is applied above the level of the valve. When on CPB, the anastomosis can be performed without a partial-occluding clamp. A longitudinal arteriotomy is made in the pulmonary artery. A running end-to-side anastomosis with 4-0 polypropylene is made and optionally reinforced with felt or pericardium. The Dacron graft is clamped with a soft vascular clamp 5 to 10 cm above the anastomosis, and the partial-occluding clamp on the pulmonary artery is removed. The graft is brought out through the tunneler. Proceed as described for LV cannulation after the aortic anastomosis is performed. Confirm position with TEE.



3-2 **RV cannulation.** The RVAD is placed to the right of the midline, and the ventricular inflow cannula will be the medial of the skin exits (see **1-3**). The inflow cannula (same as used for the LV apical cannulation) enters the RV through the diaphragmatic wall, superior to the posterior descending artery. TEE can be helpful in determining the best location for placement of the cannula. The tip of the ventricular cannula is directed toward the tricuspid valve to optimize inflow into the RVAD. We prefer this method in the bridge-to-transplant application, because flows seem to be higher.

Place the apical cannula tip next to the chosen cannulation site and estimate the skin exit site. Make the skin button and incision. Bring the tunneler through to the pericardial space and leave it in place. Expose the cannulation site by using laparotomy pads as described for the LV apical cannulation. Place 8 to 12 pledgeted 2-0 sutures on the diaphragmatic surface of the right ventricle. A purse-string suture can be placed through the pledgets to provide additional hemostasis (the RV wall is thin in this location). The remainder of the insertion is as described for the LV apical cannulation except that the outflow graft is attached to the pulmonary artery and the skin exit site is the lateral of the two.

CONCLUSION

After nearly 25 years of experience with this device, we feel that the key to successful outcomes is based primarily on patient selection combined with early implantation. Operative strategy has been standardized. According to the Thoratec voluntary registry, over 1,000 patients have been implanted with this device. Nearly 35% of the patients received biventricular support in the recovery application, postcardiotomy, and 62% received support in the bridge-to-transplant group. Postcardiotomy results have always been somewhat disappointing but expected, with 38% to 48% of patients being weaned from support and about one half of those weaned being discharged from the hospital. Our own individual institutional results, as well as those reported from a wider voluntary registry, are very similar.[4,5] In the bridge-to-transplant application, Thoratec registry results report a transplant rate, overall, of 61%, with 83% of the biventricular support patients discharged after transplant and 93% of the LVAD patients discharged after transplant. Major adverse events include reoperation for bleeding (10% LVADs, 32% biventricular [VADs], device-related infection (13%), and embolic stroke (5%). Institutional reports, as well as voluntary registry reports, indicate comparable results.[6-11] We recently reviewed our last 86 consecutive patients who received circulatory support with the intent to bridge-to-transplantation.[12] Thirty-three patients received this Pierce-Donachy–type device from 40 to 150 days while awaiting transplantation. Bleeding that required reoperation was seen in 21% of these 33. Device-related infection was seen in 3% of these, and 8 of the patients (24%) had neurological events. One half of these events were nonfatal and left no neurological residua. Thromboembolic events occurred more frequently in patients with recent acute myocardial infarction and in patients with left atrial inflow cannulation. These likely account for the difference between our series and that reported by Thoratec. Seventy percent of our patients underwent orthotopic cardiac transplantation, and 91% of those transplanted were discharged and are still doing well.

We firmly believe that a variety of devices should be available to accommodate the patient, not the converse. The Thoratec device provides a versatile system for multimodal inlet cannulation, biventricular support, and use in the small patient. It also provides a cost advantage, with a minimal change in the quality of life when used with the portable driving system patients who are expected to have short waits for donor organs in the bridge-to-transplant application. Postcardiotomy, there is no need for immediate intense anticoagulation. Furthermore, the device can be used for extended periods of time. Device changeover in the event of nonrecovery and transplant candidacy is unnecessary. Overall reliability has been excellent, and clinical results have been quite commendable and comparable to other available pump designs.

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