

DIRECTIONS FOR USE

The DeBakey VAD[®] *Child* **For Humanitarian Use in Pediatrics**

The DeBakey VAD^(r) Child is Authorized by Federal law for use in providing temporary left side mechanical circulatory support as a bridge to cardiac transplantation for pediatric patients (5-16 years old, with BSA $\geq 0.7 \text{ m}^2$ and $< 1.5 \text{ m}^2$) who are in NYHA Class IV end stage heart failure, are refractory to medical therapy and who are (listed) candidates for cardiac transplantation. The effectiveness of this device for this use has not been demonstrated.

MicroMed Technology, Inc.

8965 Interchange Drive
Houston, Texas
Tel: (1) 713-838-9210
Fax: (1) 713-838-9214

Emergency Technical and Clinical Support: (1) 713-428-6194

CAUTION

Distribution of this device is restricted to use by or on the order of a physician.

31

The DeBakey VAD *Child* Directions for Use

TABLE OF CONTENTS

1.0	INTRODUCTION	3
2.0	INDICATIONS AND CONTRAINDICATIONS FOR USE.....	3
3.0	POTENTIAL COMPLICATIONS	3
4.0	MAJOR SYSTEM COMPONENTS	4
5.0	HOW SUPPLIED	4
6.0	STORAGE	4
7.0	EQUIPMENT AND SUPPLIES REQUIRED FOR IMPLANT	4
8.0	WARNINGS	5
9.0	CAUTIONS	6
10.0	RELIABILITY	7
11.0	TRAINING.....	7
12.0	DEVICE PREPARATION	8
13.0	SURGICAL IMPLANTATION.....	8
14.0	PATIENT MANAGEMENT	11
15.0	FLUIDS, INOTROPES AND VASOACTIVE MEDICATIONS	12
16.0	INFECTION CONTROL.....	12
17.0	TREATMENT OF THE EXIT SITE	14
18.0	CONTROL OF BLEEDING.....	14
19.0	ANTICOAGULATION THERAPY	14
20.0	PUMP STOP.....	14
21.0	REGURGITANT FLOW	15
22.0	RIGHT HEART FAILURE.....	15
23.0	DIAGNOSING VENTRICULAR COLLAPSE	15
24.0	AMBULATION.....	15
25.0	SLEEPING.....	15
26.0	BATHING.....	16
27.0	AVOIDING STATIC ELECTRIC DISCHARGE	16
28.0	PATIENT DISCHARGE	16
29.0	EXPLANTING THE LVAD.....	16
30.0	SERVICE	16

32

The DeBakey VAD *Child* Directions for Use

GENERAL INFORMATION

WARNING

A thorough understanding of the technical principles, clinical applications, and risks associated with ventricular support is necessary before using this product. Read this entire booklet and the Operator's Manual prior to attempting implantation.

1.0 INTRODUCTION

The DeBakey VAD *Child* system consists of four subsystems: an implantable pump system, an external controller system, an external Clinical Data Acquisition System (CDAS) and an external Patient Home Support System (PHSS). The blood pump, intended to provide mechanical assistance to the failing left ventricle, is a miniaturized, implantable, titanium, electromagnetically actuated axial flow pump. The pump is 1.2 inches (30.5 mm) in diameter, 3.0 inches (76.2 mm) in length and weighs 95 grams. A titanium inflow cannula connects the pump to the ventricular apex and a Vascutek Gelweave™ vascular graft (outflow conduit) connects the pump to the aorta. Blood flow from the pump is measured by an ultrasonic flow probe placed around the outflow conduit. The flow probe's wiring is bundled with the pump motor's wiring in a polymer-coated assembly. The cable assembly exits the skin superior to the iliac crest on the right frontal portion of the body and attaches to the VAD's external controller system. The controller provides energy to the device causing the impeller to rotate and pump blood. The controller system is always connected to the batteries and may be connected to the CDAS or PHSS. An ergonomic, wearable pouch called the VADPAK carries the controller and batteries for the patient. The CDAS receives pump speed, flow, power and current signals from the controller and displays that information so the physician can, if needed, adjust pump operation. The CDAS is intended for use only by the clinician. The Patient Home Support System (PHSS) is a small unit that serves as a battery charger and provides wall power to the controller. The PHSS is intended for use inside or outside the hospital setting.

2.0 INDICATIONS AND CONTRAINDICATIONS FOR USE

The DeBakey VAD *Child* is authorized by Federal (USA) law as a Humanitarian Use Device for use in providing temporary left side mechanical circulatory support as a bridge to cardiac transplantation for pediatric patients (5-16 years old, with BSA $\geq 0.7 \text{ m}^2$ and $< 1.5 \text{ m}^2$) who are in NYHA Class IV end stage heart failure, are refractory to medical therapy and who are (listed) candidates for cardiac transplantation. The DeBakey VAD *Child* is indicated for use both inside and outside the hospital setting.

The DeBakey VAD *Child* is contraindicated in:

- Patients under 5 years old
- Patients with BSA less than 0.7 m^2
- Patients suffering from right ventricular failure unresolved by medical therapy
- Patients with a primary coagulopathy or platelet disorders
- Prior surgery where apical cannulation, pump replacement or graft anastomosis is not feasible

3.0 POTENTIAL COMPLICATIONS

Based on the clinical trial of the MicroMed DeBakey VAD®, the medical risks associated with the use of the system include the following adverse events:

- Bleeding
- Reoperation
- Hemolysis
- Infection (all causes)
- Renal dysfunction
- Hepatic dysfunction
- Right ventricular dysfunction
- Neural dysfunction
- Thromboembolism
- Mechanical or electrical failure

Adverse events may also occur from any of the risks usually associated with cardiac surgery.

The DeBakey VAD *Child* Directions for Use

Death may result from any of the risks associated with VAD implant.

Notes:

- The need for reoperation may be a result of bleeding, right ventricular failure requiring placement of an RVAD, or need for inflow cannula repositioning.
- Neurologic dysfunction may result from pre-existing hypoxic injury or hypoxic events during VAD implantation including cerebral hypoperfusion, hemorrhage or drug related side effects.
- Embolism may result in stroke, pulmonary or other non-cerebral organ infarction including limb ischemia or other vascular obstruction.
- It is possible that implantation of the DeBakey VAD *Child* will produce no significant improvement in patient hemodynamic status.

4.0 MAJOR SYSTEM COMPONENTS

- The DeBakey VAD *Child* PUMP
- MICROMED DEBAKEY VAD® CONTROLLER (INCLUDING BATTERIES)
- MICROMED DEBAKEY VAD® CLINICAL DATA ACQUISITION SYSTEM (CDAS)
- MICROMED DEBAKEY VAD® VADPAK
- MICROMED DEBAKEY VAD® PATIENT HOME SUPPORT SYSTEM (PHSS)
- MICROMED DEBAKEY VAD® SURGICAL TOOLS
- MICROMED DEBAKEY VAD® SURGICAL KIT
- FAIL-SAFE DONGLE
- MICROMED DEBAKEY VAD® SHOWER BAG (MOBILITY KIT)

5.0 HOW SUPPLIED

The DeBakey VAD *Child* pump, surgical kit and test cable are supplied STERILE and are for SINGLE USE ONLY. Surgical tools are supplied NON-STERILE and should be sterilized by autoclave prior to implant; the surgical tools may be reused. The controller, CDAS, VADPAK and PHSS are used outside the body and are supplied NON-STERILE.

6.0 STORAGE

The DeBakey VAD *Child* and components should be stored in a cool, dry place, away from strong electro-magnetic fields. The system storage environment must be greater than -20°C and not higher than 55°C.

7.0 EQUIPMENT AND SUPPLIES REQUIRED FOR IMPLANT

7.1 SUPPLIED EQUIPMENT

The DeBakey VAD *Child* Assembly (2), which includes:

- Pump and Accessories (1)
- ISS-1 Shipper Assembly (1)
- Outflow graft (1)
- Controller and Accessories (1)
- 12V Battery Assembly (1)
- VADPAK Assembly (1)
- CDAS (1)
- PHSS (1)

For additional product information or information regarding component specifications, consult the MicroMed deBakey VAD® Operator's Manual or contact MicroMed Technology, Inc. We reserve the right to change specifications.

CAUTION: Components supplied sterile are intended for single use only. Do not reuse sterile device components.

The DeBakey VAD *Child* Directions for Use

7.2 HOSPITAL SUPPLIED EQUIPMENT

Large basin
3 liters of 5% dextrose in water (D5W)
Vent needle (18 gauge)
Major cardiovascular surgical kit
Suture (2.0, 4.0 and 5.0 Polypropylene)
Transesophageal Echocardiography (TEE)

In addition to this equipment, the MicroMed DeBakey VAD® Operator's Manual should be readily available in the Operating Theatre.

CAUTION: In case of emergency, a complete system (VAD pump and all components and CDAS/PHSS) must be available as a backup on site and in close proximity to the operating theatre in the event that a system malfunction occurs which cannot be resolved by reference to the Directions for Use or the Operator's Manual.

8.0 WARNINGS

8.1 GENERAL

Surgeons and participating staff members must complete the Manufacturer's prescribed training course before implanting the device or managing device patients.

8.2 IMPLANT PROCEDURE

Entrapped air must be removed from the VAD and conduits prior to releasing the outflow graft cross-clamp in order to reduce the risk of air embolus.

8.3 SYSTEM OPERATION

- Do not expose the patient to MRI. Strong magnetic fields may affect the device causing injury to the patient.
- Do not expose the patient to therapeutic levels of ultrasound energy as the VAD may inadvertently concentrate the ultrasound field and cause harm.
- If the patient is exposed to diathermy, care should be taken to monitor pump performance closely during the initial stages of treatment.
- A spare controller and power source or batteries with battery pocket must be immediately accessible to the patient at all times.
- Use only power cables supplied by MicroMed Technology, Inc.
- Do not service this equipment. Only qualified personnel can service this equipment. If service is required, contact MicroMed Technology, Inc.
- Do not disconnect both batteries at the same time - the pump will stop.
- Use only batteries supplied by MicroMed Technology, Inc.
- Do not disconnect the VAD connector from the controller - the pump will stop.
- Disconnect the controller from the CDAS or PHSS before unplugging the CDAS or PHSS from its power source.
- ~~Make~~ Make sure that only fuses with the required current rating and of the specified type as listed on the rear panel of the CDAS are used for replacement. The use of makeshift fuses or short-circuiting of the fuse holder is prohibited.
- Any interruption of the protective conductor inside or outside the CDAS while the mains are connected is likely to make the device dangerous. Intentional interruption of the protective conductor is prohibited while the mains are connected.
- Use only fuses supplied by MicroMed Technology, Inc. for the PHSS.
- Disconnect the power cord from the power source before changing fuses with the PHSS.
- Do not open the back cover of the PHSS.
- The PHSS should not be used in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.
- Do not operate the Controller where temperatures are less than -10° C or greater than 40°C.
- Do not operate the CDAS or PHSS where temperatures are less than 10°C or greater than 40°C.

The DeBakey VAD *Child* Directions for Use

8.4 PATIENT MANAGEMENT

- The DeBakey VAD *Child* is a continuous flow device and will operate until all power sources are removed. Care should be taken to ensure adequate left ventricular filling to prevent ventricular collapse.
- The PHSS must be disconnected from the patient and the patient should be receiving power from the two batteries in the VADPAK before external defibrillation. Defibrillation may be performed while the patient is connected to the CDAS.
- Before allowing the patient to leave the hospital, ensure that the backup Controller has been preprogrammed to same speed as the main controller.

9.0 CAUTIONS

9.1 PATIENT SELECTION

- Female patients of childbearing age should be assessed for pregnancy prior to implant and counseling regarding birth control provided as long as the patient is anticoagulated for the DeBakey VAD *Child* implant.
- Patients should be carefully evaluated for the presence of intraventricular thrombus; when intraventricular thrombus is identified, the ventricle should be thoroughly cleaned prior to implant of the DeBakey VAD *Child*.
- Patients with previous sternotomy or who are receiving immunosuppressive therapy may have an increased risk of perioperative complications when implanting the DeBakey VAD *Child*.
- The DeBakey VAD *Child* implantation in patients with vascular impairment of major organ systems may increase technical difficulty of the procedure and adversely affect post-implant outcomes.
- The DeBakey VAD *Child* implantation in patients with end-stage renal disease may increase perioperative risks and adversely affect outcome.
- The need for aneurysmectomy and removal of intraventricular thrombus should be assessed prior to implant in patients with severe left ventricular dilatation (LVID > 85 mm).
- Patients with prosthetic aortic valves may have an increased risk of thromboembolism due to blood flow shunted away from the valve and decreased washing of valve leaflets. Patients with 1.5+ aortic regurgitation or with mechanical prosthetic valves should be considered for valve replacement or repair with a tissue valve prior to VAD implant.
- The Physician should also consider the following:
 - Cannula fits into ventricle
 - Pump fits into chest (cannula angle is appropriate)
 - Graft can be attached to the aorta

9.2 IMPLANT PROCEDURE

- Implantable parts of this system should not be reused.
- Inspect sterile packages before opening. If seal is broken, contents may not be sterile and may lead to infection.
- Rechargeable batteries should be fully charged prior to beginning the implantation procedure to allow patient transfer out of the operating room following the procedure.
- ~~•~~ Maintain left atrial pressure at a level greater than 10 mm Hg in order to reduce the potential for entrained air.
- When beginning to wean from cardiopulmonary bypass, initially allow a minimum blood flow to pass through the ventricle and the pump in order to eliminate the possibility of entraining air.

9.3 SYSTEM OPERATION

- If unexpected changes are experienced in any device component function, evaluate the environment for the possibility of other sources of electrical or electromagnetic interference.
- Plug equipment into hospital grade or grounded outlets only.
- Do not expose the batteries to moisture or to heat.
- Damage can occur to the battery pocket or battery plug cable if the connector is forced without proper alignment.
- Do not submerge batteries in liquid or expose to heat. Submerging the batteries or exposure to heat may cause them to malfunction.
- Batteries not in use with the VADPAK should be recharging in the PHSS or other MicroMed charging system (i.e., the ChargePAK) at all times.

The DeBakey VAD *Child* Directions for Use

- Do not submerge the Controller in liquid because it may damage internal components causing the device to malfunction.
- The controller must always be placed in the surgery pouch (with a battery) or the VADPAK to allow proper cooling of the controller and eliminate potential harm to the patient.
- The tether cable from the patient Controller should be handled with care to prevent damage.
- All connectors should be handled with care and kept free of liquid, dust or debris.
- Do not disconnect the VAD pump cable or the VADPAK/battery box cables when replacing the internal battery.
- Do not disconnect the VAD pump cable or both batteries when inserting the fail-safe dongle.
- Fail-safe dongle must be kept in VADPAK.
- Do not expose the CDAS to moisture.
- The operator should not attempt to make any changes to system software or use the CDAS as a personal computer. Any modification of, or attempt to modify the operating system software could result in rendering this device non-functional for its intended use.
- Device placement will vary across environments. Operators and persons in the vicinity of the CDAS should be instructed to take care not to trip over the power cord.
- The CDAS may be cleaned by wiping it down with a damp cloth followed by a wipe down with isopropanol to remove contaminants.
- Do not drop the PHSS or the controller on any hard surface. Dropping it may damage internal components causing the device to malfunction.
- The PHSS should not be used near water or while bathing/showering due to the risk of electrical shock.
- Do not obstruct the fans on the side of the PHSS. Keep this area clear so that air can circulate. Overheating of the PHSS could cause the batteries to take longer to recharge.
- Do not invert the cabinet of the PHSS while installing batteries.
- The PHSS may radiate radio frequency energy that may cause harmful interference with other medical devices in the vicinity if it is not installed and /or used according to instructions herein.
- When the PHSS is not plugged into power, the batteries should be removed.

9.4 PATIENT MANAGEMENT

- Do not bathe or shower with the VADPAK without it being encased in the shower bag provided in the mobility kit.
- Patients may develop hemolysis while on the DeBakey VAD *Child* support. Laboratory parameters including hemoglobin, reticulocyte count, plasma free hemoglobin and/or serum haptoglobin should be monitored. In order to minimize the potential for hemolysis, conditions favoring ventricular collapse should be avoided and the pump should be run at the lowest speed that produces the desired hemodynamic result.
- Currently, no validated method for assessing the effects of continuous flow on regional renal blood flow in animals or patients with advanced heart failure is available. Although the renal failure rate in the clinical study did not exceed the current standard of renal failure with VAD devices, patients should be closely monitored for potential renal dysfunction and/or renal infarction throughout device support.

10.0 RELIABILITY

The purpose of reliability testing is to obtain a reasonable estimate of how long a given device will perform as intended without failure. Reliability of the MicroMed DeBakey VAD[®] was evaluated employing the MicroMed Pulsatile Loop, a mock loop system designed to reproduce physiologic conditions. Twelve pumps were tested under conditions representing profound heart failure (i.e., speed 11,300 RPM, average flow 7.1 L/min and outlet pressure of 111 mm Hg). Five days per week, the pump speed was reduced to the fail-safe speed of 8,500 RPM and operated at that speed for four hours each day. Based on this data, there is an 80% probability that the DeBakey VAD *Child* will be free of critical failure at 12 months (confidence level 70%). It is incumbent upon physicians to prepare for possible device failure and anticipate the potential need for device replacement when patients require treatment for extended periods of time.

11.0 TRAINING

All surgeons and staff will complete the DeBakey VAD *Child* training course prior to device implant.

37

The DeBakey VAD *Child* Directions for Use

12.0 DEVICE PREPARATION

- Prior to the day of surgery, verify the contents of the suitcase.
- Download language to controller, run controller tests and preset the pump speed to 7,500 RPM.
- Stop pump from the CDAS, verify alarms and install the internal battery.
- Connect one battery pocket to the primary controller and install one fully charged battery. Place the controller and battery pocket with battery in the surgical pouch and hang the surgical pouch on the side of the operating table.
- Position the CDAS to the right of the operating table.
- Connect pressure probe with patient arterial line and zero pressure.
- The pump is shipped within a protective foil pouch. This foil pouch is not sterile. The inner package is sterile while the outer package is not. The foil pouch should be opened before entering the OR and the pouch and desiccant bag disposed of properly.
- After removing contents from sterile package attach the outflow graft to the pump. Tighten the wedge nut with the wrench.
- Slide on the graft protector and ensure it snaps over the wedge nut.
- Slide on the flow probe.

CAUTION: The flow probe wire points in the direction of the pump and should be parallel with the pump motor wires.

- Using the extension cable provided, test the pump with 5% dextrose in water. Approximately, 3 liters of D5W are required to submerge the pump for testing.

CAUTION: When test-starting the pump, be sure to cover 80% of the pump inlet with a thumb to partially occlude the inflow. The inlet should be covered whenever starting the pump outside of the body and whenever the pump is running in 5% dextrose in water.

- Place the protective cap on the VAD cable to protect the connector.

13.0 SURGICAL IMPLANTATION

13.1 PREPARING THE PUMP POCKET

- Make a median sternotomy incision extended to the xiphoid process.
- Form a pocket in the rectus sheath beneath the rectus muscle.
- Using the dummy pump provided, size the pocket making it large enough to accommodate the pump. Take care not to make the pocket too large in order to minimize the potential for bleeding and / or infection.
- Open the pericardium to access the LV apex.
- Divide the diaphragmatic attachment to the costal margin and extend both laterally beyond the apex.
- Prior to placing the patient on cardiopulmonary bypass assess the patient for the presence of a patent foramen ovale using transesophageal echocardiography. If a PFO is present, correct the defect before proceeding with VAD implant.

13.2 APPLY APICAL FIXATION RING

- Elevate the LV apex.
- Select the insertion site for the inflow cannula.
- The coring site selected should be slightly anterior to the apex and 2-3 cm left of the anterior descending coronary artery.
- Sew the apical fixation ring in place with 8-12 interrupted double-armed 2-0 polypropylene mattress sutures with large Teflon pledgets.
- Use caution when applying the apical fixation ring or coring the ventricle in a patient who has sustained a recent myocardial infarction in this area of the heart.

13.3 MAKE SURE THE PUMP HAS THE GRAFT PROPERLY ATTACHED AND HAS BEEN TESTED PRIOR TO IMPLANT.

The DeBakey VAD *Child* Directions for Use

13.4 TUNNEL THE DRIVELINE

- Attach the trocar to the driveline.
- Tunnel the driveline from the abdominal wall pocket across the midline to exit through the skin in a convenient position above the right iliac crest.
- Ensure that the bend radius as the cable leaves the pump housing is not sharp. Provide a larger bend radius to prevent damage to the cable or wires.
- Remove the trocar.
- Pass the driveline off the table to the assistant and attach the driveline to the controller (if not immediately attached to the controller attach the cap protector).

13.5 INSERT THE INFLOW CANNULA

- Elevate the LV apex (the heart may be beating, fibrillating or arrested).
- Using an 11-blade make a full thickness cruciate incision inside the apical ring.
- Manually compress the ventricular apex to prevent bleeding.
- Insert the coring device into the left ventricle and extract a core of the apex.
 - Core with the coring knife's orientation between the mitral valve and aortic valve inflows.
 - Apply the cutting edge of the coring knife to the epicardium and maintain pressure while rotating the knife until the ventricular cavity is entered.
- To confirm precise coring examine apical tissue removed from the coring device.
- Perform digital exploration to evaluate core position and ensure the absence of potential obstruction to the inflow inside the ventricle (e.g., thrombus, muscle remnant).
- Clamp the outflow graft.
- Insert the inflow cannula into the ventricle.
- Ensure correct position of the inflow cannula by evaluating with transesophageal echocardiography.
- Using the previously placed polypropylene sutures, sew the suture ring (hat) on the inflow cannula to apical fixation ring.
- Tighten the two sets of purse strings on the apical sewing ring.
- The apical sewing ring and hat on the inflow cannula must be tightly sewed together to prevent blood or air leakage. Additional Teflon strips may be applied to prevent any leakage.

13.6 DE-AIRING THE PUMP

- Fill the ventricle completely from the bypass pump.
- Elevate the DeBakey pump and outflow graft.
- Allow the pump and outflow graft to fill with blood from the ventricle by releasing then reapply the clamp on the outflow graft.
- Check the apical insertion site for bleeding - add reinforcing pledgeted sutures as needed (continuous 2-0 polypropylene suture with felt strip).

13.7 ATTACH THE OUTFLOW GRAFT TO THE AORTA

- Place pump in the abdominal pocket and measure the length of the outflow graft.
- Trim as needed to ensure the graft lies under the right sternal border without kinking or overstretching. If the graft is not accurately trimmed the backup graft in the backup suitcase may be utilized. If the graft is too long or too short, the graft may kink or stenose.
- Proper placement of the pump pocket and ensuring that the graft length is not too short is essential to prevent kinking of the outflow graft protector.
- A portion of the right diaphragmatic costal margin may need to be released to place the graft correctly without kinking.
- Make sure the flow probe is secured to the distal outflow graft protector.
- Place partial occlusion clamp on the ascending aorta.
- Make a longitudinal arteriotomy and sew the graft to lateral ascending aorta with 5-0 polypropylene suture.
- Any damage to the graft such as a needle hole or tear may be repaired by suturing.

The DeBakey VAD *Child* Directions for Use

13.8 DE-AIRING II

- Place an 18-gauge needle in the outflow graft between the aortic anastomosis and graft clamp.
- Temporarily release the aortic partial occlusion clamp, this will fill the distal aortic graft with blood and trapped air will escape through the needle.
- Re-clamp the aorta then unclamp the outflow graft and intermittently start and stop the pump.
- After all air is released, remove the 18-gauge needle and oversee the needle hole with a pledgeted 4-0 polypropylene suture.

WARNING: All entrapped air must be removed from the DeBakey VAD *Child* blood pumping chamber and conduits in order to reduce the risk of air embolus.

NOTE: The needle vent should be placed in the outflow graft in the highest point in the lumen (anterior side to optimize air removal).

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

13.9 POST-IMPLANT

- As the patient is being weaned from bypass, adjust flow to optimize cardiac index while being careful not to overload the right ventricle.
- Maintain inotropic support for the right ventricle as indicated.
- Ensure adequate preload to prevent ventricular collapse.
- Use transthoracic echocardiography to assess the inflow cannula position and verify the position is acceptable.
- Reverse heparin with protamine if indicated.
- Re-evaluate pump flow and cannula position with chest closed before placing sutures.
- Cover the outflow graft and pump/ventricular apex with Gortex to facilitate re-entry upon transplant.
- Place drains in the pump pocket and mediastinum.
- Secure the driveline in place with a single suture.

13.10 TRANSFERRING OUT OF THE OPERATING ROOM

When ready to transport the patient from the operating theatre to the intensive care unit, the DeBakey VAD® system must be transferred from wall power via the CDAS to battery power. A fully charged battery is already in the surgery pouch attached to the controller. The CDAS should be removed from the controller port for transfer and then the CDAS reconnected once the patient is settled in the intensive care unit. At the bedside, the surgical pouch with controller and battery may be hung from an intravenous IV pole or secured to the bed itself with towel clamps.

CAUTION: Do not attach the surgical pouch to the bed rail. Movement with lowering and elevating the bed rail may damage cables.

CAUTION: Do not place the surgical pouch beneath blankets, sheets or the patient's body. The controller must be kept uncovered to allow proper cooling.

CAUTION: The controller must always be kept in either the surgical pouch or the VADPAK to prevent thermal injury.

NOTE: Because pump outputs strongly affected by increases in afterload and decreases in preload, a portable blood pressure monitor may be used to gauge the effectiveness of support during transport. The CDAS and arterial pressure lines may be quickly re-attached upon reaching the ICU.

40

The DeBakey VAD *Child* Directions for Use

14.0 PATIENT MANAGEMENT

14.1 SUPPORT IN THE HOSPITAL requires that the following equipment be on hand and readily available:

Component	Primary (Required)	Backup (Required)	Optional
Implanted VAD	X	X	
Controller	X	X	
Rechargeable batteries	X (4 batteries)		X (2 additional if discharged)
CDAS	X	X	
PHSS	X	X	
VADPAK	X		X
CDAS to Controller Cable	X	X	
Fail-safe dongle	X		X
Shower bag			X
Battery Pocket		X	

It is the policy of MicroMed Technology, Inc. that each active site maintains one backup VAD for every three patients on DeBakey VAD support. Every patient must have a backup controller, backup battery pocket and backup CDAS to controller cable immediately available. There must be at least one CDAS available at each active site for every three patients on device. Adequate PHSS must be available to charge batteries and provide wall support. The number of PHSS will vary with respect to the number of patients on device, whether or not they are in an intensive care unit and whether or not they are taking out of hospital excursions. For implant, a hospital must have at least two PHSS to allow for charging of the batteries to transport the patient from the operating room.

14.2 PUMP OPERATION once the patient has been stabilized should be adjusted to a level that provides the desired forward flow without signs of regurgitant flow or ventricular collapse. This level should then be maintained. It is useful to employ mixed venous oxygen saturation to adjust pump speed/flow maintaining mixed venous oxygen saturation between 60 and 70%.

14.3 BATTERY MANAGEMENT should initially be supervised by hospital staff and then as appropriate transferred to the patient. Batteries will last 2 ½ to 4 hours depending on pump speed and flow sensor board status. Once the second battery alarm indicates it has discharged to 25%, the batteries must be changed immediately. However, it is recommended that the first battery be changed immediately after it alarms at 25% discharge.

14.4 GENERAL TREATMENT ISSUES

Flow across the DeBakey VAD *Child* is, in large part is influenced by the pressure gradient across the pump (from outflow to inflow). Therefore, pump output is dependent upon changes in left ventricular filling (preload) and systemic vascular resistance (afterload).

Physician judgment and experience may vary; therefore proper care of a patient supported by the DeBakey VAD *Child* requires thorough understanding of system operation, the patient's condition and the unique physiologic support provided by axial flow rotary devices.

The following treatment issues are considered critical to the achievement of the best outcomes in patients supported by the DeBakey VAD *Child*:

- Close surveillance for physiologic, pathophysiologic or iatrogenic changes in left ventricular filling (preload) and systemic vascular resistance (afterload) is required following implantation. Small increases in afterload or small decreases in preload may result in diminished pump flow, a reduction that may manifest in a clinically relevant decrease in perfusion. In the case of inadequate ventricular filling, increasing pump speed will not increase flow.

41

The DeBakey VAD *Child* Directions for Use

- Standard methods for adequate perfusion may not be helpful under all physiologic conditions. As described above, changes in preload or afterload should prompt an immediate patient assessment that includes physical examination to confirm the adequacy of peripheral perfusion. In shock states, physical examination may not provide adequate evidence of perfusion restoration. The use of right heart catheterization under conditions of hemodynamic instability is highly recommended. Mixed venous oxygen saturation measured intermittently or continuously will provide the most sensitive guide to perfusion in post-implantation shock states. If right heart catheterization is not possible, a mixed-venous O₂ saturation from a right atrial catheter may be substituted.
- Under stable physiologic conditions, the use of automated blood pressure monitoring devices (oscillatory blood pressure) may not yield accurate blood pressure data. Manual auscultation of an extremity blood pressure is recommended. Nevertheless, in circumstances where the flow has minimal pulsatility (vasodilatory states) manual blood pressures may be difficult to obtain. Doppler stethoscope technologies have been effectively employed to obtain manual blood pressures when pulseless flow prevents palpation of pulses.
- Maintain inotropes during the immediate post-operative period at pre-operative levels to protect right heart function.
- Right heart failure may occur at any time following implantation. Follow-up closely and intervene with nitric oxide, vasodilators, diuretics, inotropic drugs or right ventricular assist as indicated.
- Early ambulation and resumption of dietary intake are encouraged.
- Social and family support during rehabilitation is encouraged. Exercise physiotherapy is recommended post-implantation.

15.0 FLUIDS, INOTROPES AND VASOACTIVE MEDICATIONS

- 15.1 Fluids should be administered to optimize VAD flow while avoiding right heart failure.
- 15.2 All measures should be taken to maintain left ventricular filling. These include aggressive replacement of volume lost and close vigilance of right heart function and pulmonary vascular resistance.
- 15.3 Sudden decreases in pump flow may be initially treated with restoration of volume, if volume replacement does not augment flow, potential sources of bleeding should be ruled out. When these measures do not restore adequate flow, right heart function should be evaluated and inotropic support instituted as indicated.
- 15.4 Complaints of dizziness should prompt immediate evaluation of the patient and system.
- 15.5 Post-implantation hypertension should be treated at the discretion of the attending physician. Although ACE inhibitors are recommended, any therapy that consistently maintains systolic blood pressure appropriate to the patient's body surface, age and clinical condition should be considered adequate.

16.0 INFECTION CONTROL

To prevent infection, a broad spectrum antibiotic should be administered during the first 48 hours following implant in a manner similar to procedures for any open heart surgery. Then, organism specific antibiotics may be administered as needed based upon positive culture results. Early extubation and removal of patient monitoring lines will help prevent infection, as will early ambulation. Nursing measures to reduce the potential for infection should include frequent hand washing and aseptic technique should be employed whenever invasive lines are contacted and when the exit site dressing is changed. Parenteral treatment with antibiotics and surgical drainage is used if evidence of pump pocket infection exists. Fungal infection resulting from organisms such as *Candida* species, have been associated with vegetative growth on other VADs. Persistent systemic fungal infection, refractory to antimicrobial treatment may require VAD replacement. A recommended Infection Control Protocol follows.

The protocol below is reproduced here with permission of James Long, M.D. LDS Hospital, Salt Lake City, UT; Walter Dembitsky, M.D. Sharp Memorial Hospital, San Diego, CA; and Soon Park, M.D. University of Minnesota Hospital, Minneapolis, MN, on behalf of the REMATCH Trial Surgical Working Group.

The protocol is adapted from the protocol developed during the REMATCH trial of the HeartMate® VE (used by permission as above).

The DeBakey VAD *Child* Directions for Use

PRE-OPERATIVE:

1. Consider patient selection issues to reduce infectious risk (e.g. afebrile, stable white cell count)
2. Remove all unnecessary intravenous catheters and replace all others 12-24 hrs pre-operatively.
3. Antimicrobial prophylaxis.

The choice of antibiotics should be based on the hospital's nosocomial and microbial sensitivity profile with sufficient coverage for staph aureus, staph epidermidis and enterococcus considered. Recommended regimen is:

- Vancomycin 15 mg/kg IV 1 hr pre-op, then q 12 hrs x 48 hrs.
 - Levofloxacin 500 mg IV 1 hr pre-op, then q 24 hrs x 48 hrs.
 - OR Trovafloxacin 400 mg IV 1 hr pre-op, then q 24 hrs x 48 hrs
 - Rifampin 600 mg PO 1-2 hrs pre-op and QD x 48 hrs
 - Fluconazole 200 mg IV pre-op, then q 24 hrs x 48hrs
 - Consider nasal Bactroban application the evening prior to surgery
4. Preoperative scrub (night and morning before when possible) with chlorhexidine (or equivalent) and clip body hair shortly before the procedure begins.
 5. Operating Room (OR) precautions:
 - All staff must wear fresh scrubs, booties and headwear that covers all hair.
 - Restrict traffic through OR and near pump assembly table.
 - Sterile field out-of-reach rule with barriers to protect field.

INTRA-OPERATIVE:

1. Prior to the procedure review plans for driveline and exit site positions to minimize manipulation of the aseptic site during surgery.
2. Prepare with antiseptic scrub, alcohol and Betadine gel (or equivalent) and drape with steri-drapes (e.g. Ioban)
3. Minimize exposure of LVAD by:
 - Not opening device too early and eliminating unnecessary traffic.
 - Using fit model for device positioning not the actual device.
 - Covering the bowl containing device after it has been tested prior to implant for the DeBakey VAD®
4. Percutaneous lead management:
Tunnel percutaneous lead to the right upper quadrant, sub-costal region exiting in the mid-clavicular line 4-6 cm below costal margin (with the percutaneous lead passing through a long intramuscular tunnel); orient the exteriorized percutaneous lead towards anterior axillary fold. Adjust this procedure as needed to fit body habitus.
5. Secure meticulous hemostasis
6. Irrigate all surfaces with antibiotic solution prior to closing (Vancomycin 2 gms/liter and Gentamycin 160 mg/liter in NS)
7. Place thoracic and consider LVAD pocket drains.
8. Immobilize percutaneous lead (consider retaining suture) with exit site dressing.

Post-Operative:

1. Systemic antimicrobials: continue anti microbial prophylaxis for 48-hours or modify regimen as clinically indicated.
2. All indwelling catheters require aseptic precautions and early removal or frequent rotations
3. Drains / Securing Suture:
Remove thoracic tubes per institutional protocol followed by LVAD pocket drains, if inserted, when drainage < 30-50 cc/day (usually 3-7 days)
Remove percutaneous lead securing suture when good tissue ingrowth is seen.
4. Exit Site Dressing Changes and Exit Site Monitoring:
 - Always employ aseptic techniques.
 - Dressing change protocol as per institutional guidelines

The DeBakey VAD *Child* Directions for Use

- Dressing change frequency depends on length of time post op, degree of tissue ingrowth and freedom from exit site problems like drainage, infection or recent trauma (QD, BID or >BID as clinically indicated).
 - Routine monitoring is essential to evaluate exit site healing, rule out infection and assure proper positioning and immobilization to avoid tissue -driveline separation.
5. Percutaneous lead immobilization:
- In the DeBakey VAD® experience, the percutaneous lead has not needed specific immobilization because of its small diameter and flexibility. The percutaneous lead should be immobilized for at least the first two weeks following the implant with tape, gauze or other suitable means.

BATHING:

1. First 30 days post op, until exit site has healed well with good tissue - percutaneous lead ingrowth: Sponge baths while protecting wound from contamination and moisture.
2. After 30 days post op and exit site is healed: Shower per instructions in the Operator's Manual or Patient User's Manual while covering exit site with gauze pad and plastic wrap.

GENERAL MEDICAL ISSUES:

- Maintain nutritional needs especially during the immediate post-operative period and ensure good control of diabetes mellitus and avoid immuno-suppression whenever possible.

17.0 TREATMENT OF THE EXIT SITE

- 17.1 Daily exit site care is performed using a persistent antiseptic cleansing agent such as chlorhexidine containing scrub solutions. Following aseptic cleansing, the site should be dried to avoid tissue maceration. Aseptic technique should be adhered to whenever the exit site is inspected, dressed or otherwise handled.
- 17.2 The exit site should be kept clean and dry. Prophylactic topical agents, such as silver sulfadiazine or polymixin-neomycin-bacitracin, are not typically used, as these ointments applied to the exit site, can macerate the tissues or degrade the exterior cable coating. A sterile bandage is applied daily.
- 17.3 Movement of the percutaneous cable should be minimized. Specific immobilization techniques or strain relief have not been necessary with the DeBakey VAD *Child* due to the small external diameter and flexibility of the percutaneous cable.

18.0 CONTROL OF BLEEDING

Bleeding is a common complication of VAD implantations in general. Chest tube output should be carefully monitored. Routine measurement of the patient's anticoagulation system should be performed. Blood products should be administered as needed to correct hematologic abnormalities. Surgical re-exploration should be considered if chest tube bleeding exceeds 100 ml/hour after coagulation factors have been restored.

19.0 ANTICOAGULATION THERAPY

Anticoagulation should be initiated in the DeBakey VAD *Child* patients once chest tube bleeding has diminished sufficiently. Heparin may be started at this time and continued until oral anticoagulation reaches therapeutic levels. Oral anticoagulation may include warfarin and anti-platelet agents such as aspirin and/or clopidogrel (Plavix). Monitoring anticoagulation and antiplatelet medications may be helpful for adjusting the dosages. Recommended target INR is 2.0-3.0, with the understanding that this target recommendation is based upon the adult experience with the DeBakey VAD® and caution should be used when applying it to children. Monitoring anticoagulation and antiplatelet medications may be helpful for adjusting the dosages of medications used as anticoagulant and anti-platelet therapy.

20.0 PUMP STOP

The cause of pump stop should be identified and corrected as soon as possible. Mechanical or electrical causes of pump stop may be rectified by applying the backup controller or fail-safe dongle. All attempts to restart the pump must be made immediately. Pump stops, which are a result of pump thrombus, may be heralded by increases in current and power as well as decreases in flow.

44

The DeBakey VAD *Child* Directions for Use

21.0 REGURGITANT FLOW

Regurgitant (mean) flow may occur if the pump stops. If regurgitant flow associated with a pump stop results in exacerbation of heart failure, the pump may need to be exchanged. The pump may also be removed completely or left in place if the physician ligates the outflow graft.

WARNING: In the event that the DeBakey VAD *Child* stops operating, the patient should seek immediate medical attention to treat the potential physiologic consequences of regurgitant flow. Treatment measures may include heparinization, standard interventions for acutely decompensated congestive heart failure or surgical exploration.

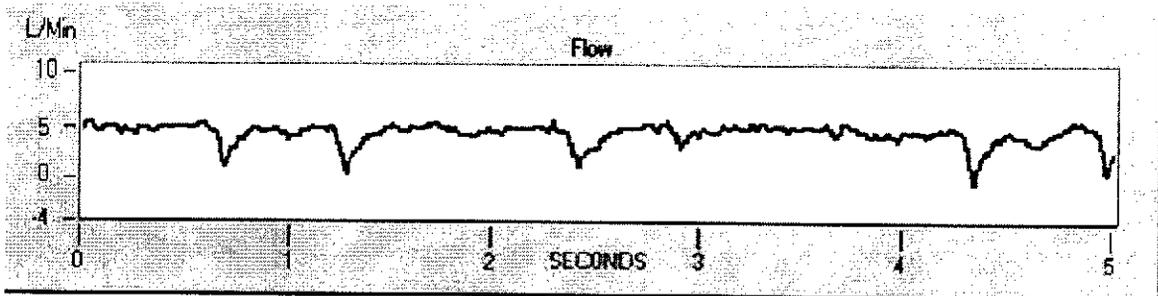
22.0 RIGHT HEART FAILURE

Patients can suddenly develop right ventricular (RV) failure during or after device implantation. The onset of RV dysfunction in these patients is often accompanied by the inability of the left ventricle to fill and drastically reduced flows across the DeBakey VAD *Child*. Limited filling is further exacerbated in the presence of right heart failure with an elevated trans-pulmonary pressure gradient or high pulmonary vascular resistance.

Treatment for patients in right heart failure includes the administration of inotropes to augment RV contractility, fluid management, hyperventilation, and pharmacologic modulation of pulmonary vascular resistance. If these measures are not effective, a right ventricular assist device may be employed.

23.0 DIAGNOSING VENTRICULAR COLLAPSE

When left ventricular filling is compromised by right ventricular failure, bleeding or hypovolemia, the ventricular chamber may collapse around the inflow cannula of the DeBakey VAD *Child* further limiting flow. Ventricular collapse can be recognized by sudden flow reductions in the presence of any of the above conditions. Ventricular collapse can also be recognized from the flow waveform displayed on the CDAS. The Figure below illustrates the characteristics of the flow waveform during ventricular collapse.



Ventricular collapse is best treated by correcting the cause of reduced left ventricular filling. In rare cases, ventricular collapse may be a result of inflow cannula position. If the inflow cannula is positioned too close to either the septum or the left ventricular free wall, the negative pressure created by the device may result in obstruction of the inflow cannula by surrounding myocardium.

24.0 AMBULATION

Once recovered from surgery, patients should be ambulated as much as possible. Patients should be instructed how to wear the VADPAK with controller and batteries correctly. VADPAK wear instructions are conveyed to the patient in the hospital. Whenever ambulating away from the hospital room or home, the patient should carry a backup controller and at least 2 extra batteries and a spare battery pocket. Once recovered, patients should be able to perform exercise although contact sports and swimming must be avoided.

25.0 SLEEPING

Because patients may sleep through a battery alarm, patients should sleep tethered to the CDAS or PHSS. Pump operation should not be adjusted to accommodate for normal physiologic changes that occur with sleeping. It is

The DeBakey VAD *Child* Directions for Use

possible that decreases in flow and waveform patterns indicative of sucking (ventricular collapse) may occur overnight or during the early morning if the patient becomes hypovolemic.

26.0 BATHING

The controller, batteries and cables must be enclosed properly in the VADPAK while showering. The VADPAK must then be encased in the shower bag. Only showering is allowed. The VADPAK should be removed from the shower bag as soon as possible to promote proper cooling. The controller, VADPAK and percutaneous lead should never be fully submerged in any liquid.

27.0 AVOIDING STATIC ELECTRIC DISCHARGE

CAUTION: Avoid direct contact with devices with high voltage such as television or computer screens since direct contact may damage the electrical components of the system and may cause the DeBakey VAD *Child* to stop.

28.0 PATIENT DISCHARGE

Patients discharged to home or a lower care facility must master concepts presented herein and at the hospital. A trained companion is recommended for pediatric patients going home with the DeBakey VAD *Child*. A device malfunction or other complication may necessitate emergency treatment; therefore, arrangements with local physicians and emergency systems should be established prior to patient release. Additionally, patients who live at distances away from the implanting hospital that might prevent timely return for surgical intervention when necessary may not be suitable for discharge.

29.0 EXPLANTING THE LVAD

The DeBakey VAD *Child* may be removed by following these steps:

- Expose the DeBakey VAD *Child* and dissect it free.
- Place the patient on cardiopulmonary bypass and establish flow.
- Stop the DeBakey VAD *Child*.
- Dissect the percutaneous cable free and cut the cable close to the exit site. Pull the exterior portion of the percutaneous cable through the exit site. Culture the cable as indicated and place in the container for return to the manufacturer.
- Cut the sutures between the sewing rings and remove the inflow cannula from the ventricle.
- Remove a small portion of the aorta where the aortic anastomosis has been made.
- Remove the entire device and cannula as a unit.
- Culture pump as indicated.
- Place the entire device in 10% formalin in jar provided in the suitcase.
- After 24 hours, replace the formalin with saline and ship the device back to MicroMed Technology, Inc. at the address indicated on the front cover of this document.

NOTE: It is a violation of law to ship formalin or formalin containing jars. Please ensure that formalin is removed prior to shipment.

30.0 SERVICE

There are no user serviceable parts associated with the DeBakey VAD *Child* system. Any component that requires repair should be returned to MicroMed Technology, Inc. at the address indicated on the front cover of this document.