

Professional LABELING

CentriMag[®] RVAD (Blood Pump)

Instructions For Use (IFU)

CAUTION

Humanitarian Device: The Levitronix CentriMag RVAS is authorized by Federal law to provide temporary circulatory support for up to 14 days for patients in cardiogenic shock due to acute right ventricular failure. The effectiveness of this device for this use has not been demonstrated.

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

Levitronix Clinical & Technical Support Phone numbers

| | |
|------------------------------------|----------------|
| U.S. Clinical Support (Pager) | (800) 372-4698 |
| U.S. Technical Support (Toll Free) | (866) 487-2837 |
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READ ENTIRE CONTENTS PRIOR TO USING THIS DEVICE



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PL-0085, Rev. 04
October 2008
DCO No. 08-174

R_x Only

SUPPLIED STERILE AND READY FOR USE – DO NOT USE IF PACKAGING IS DAMAGED OR ANY STERILE SEALS ARE BROKEN.

WARNING (Definition)
Warnings are used if there is a potential for a serious hazard with misuse of the device, when special attention is required for safety of the patient, or when special care should be exercised to prevent improper operation of the device that may cause damage.

CAUTION (Definition)
Cautions are used to alert the user to exercise special care for the safe use of the device.

DESCRIPTION

The CentriMag RVAD (“Blood Pump”) has a spinning impeller that imparts rotary motion to the incoming blood, directing it through the outlet port. When used as a right ventricular support system, blood from the failing right heart is directed from the right ventricle or atrium to the inlet of the pump via an inlet cannula. Blood exits through the outlet of the pump, through the outlet cannula, and ultimately to the pulmonary circulation.

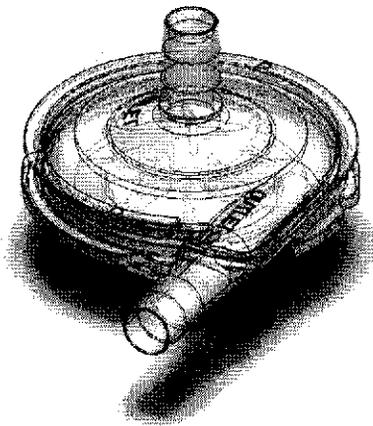


Figure 1 – CentriMag® RVAD

The CentriMag Blood Pump couples to a magnetic drive motor which is connected to a console. The CentriMag Blood Pump, magnetic drive motor and console comprise the Levitronix CentriMag Right Ventricular Assist System (RVAS).

ADVERSE EVENTS

Based on a review of the published literature on other ventricular assist devices, the risks usually associated with use of these devices and from a review of the data obtained from the CentriMag VAD worldwide experience, potential medical risks associated with use of the CentriMag VAD include:

- Death
- Stroke
- Bleeding
- Reoperation
- Hemolysis
- Infection (all cause)
- Renal failure or dysfunction
- Respiratory dysfunction
- Hepatic Dysfunction
- Cardiac arrhythmias (atrial or ventricular)
- Limb ischemia or loss of limb
- Myocardial Infarction
- Neurological dysfunction
- Thromboembolism
- Mechanical or electrical malfunction or possible failure
- Psychiatric events
- Hypotension
- Hypertension

In addition, risks due to the implantation procedure or anesthesia may also occur.

HOW SUPPLIED

Each CentriMag RVAD Kit contains the following sterile components:

| Contents of the CentriMag RVAD Kit | |
|---|-----------------|
| DESCRIPTION | QUANTITY |
| CentriMag Blood Pump | 1 |
| CentriMag Inlet Cannula | 1 |
| CentriMag Outlet Cannula | 1 |
| Tubing Set | 2 |
| 3/8" Straight Connector | 2 |

CLINICAL SUMMARY

Patients that received a CentriMag RVAD suffered right ventricular failure after placement of either a commercially available left ventricular assist device (LVAD) or after placement of a CentriMag LVAD. These patients were enrolled either intraoperatively or postoperatively. The CentriMag RVAD was used for short-term support until recovery, transplantation or implantation with a long term device. A total of 24 patients were implanted with a CentriMag RVAD in U.S. clinical studies. Ten patients received a CentriMag RVAD after placement of a commercially available LVAD. Fourteen patients received biventricular CentriMag devices. Average duration of support for these 24 patients was 14.3 days (range: 1 – 60 days). Twelve patients (50%) were alive at 30 days. In general, the survival outcome for males and females appeared comparable, though it is difficult to draw conclusions regarding sex-specific outcomes due to the limited clinical experience with the CentriMag RVAS.

Pump flow remained stable at ranges of approximately 4.5 – 6.0 LPM. In general, central venous pressure decreased over time while on support while mean arterial pressure remained stable. Indicators of end-organ function demonstrated stable renal and hepatic function in survivors. Non-survivors demonstrated signs of deteriorating end-organ function over time as evidenced by worsening renal and hepatic laboratory measurements (increasing BUN and total bilirubin levels, respectively), although some laboratory indicators of renal function (creatinine levels) remained stable over time. Previous studies of short-term ventricular assist devices have shown increases in BUN with stable creatinine, citing cardiogenic shock as a possible precursor to mild renal dysfunction.

The studies were not powered for a specific analysis of adverse event rates. All adverse events were reported by the clinical centers, regardless of the relationship to the device. Investigators were required to classify the cause of each event as being device-related, patient-related, management-related or other-related. There were no new types of adverse events observed. Rates of adverse events were within the expected range for patients with RV failure supported by a mechanical circulatory support device. As expected in this patient population, the rate of bleeding (84%), infection (53%) and respiratory failure (66%) was high, although the number of these events which were directly attributable to the device was relatively low. In many instances, the patients' chests were not closed after the initial surgery, requiring a planned reoperation. In the case of infection, all infections diagnosed during the period of VAD support were classified as "device related", unless the infection had been diagnosed and the organism(s) cultured prior to initiation of VAD support. There were no instances of device failure.

In a review of adverse events by gender, there was a potential trend toward higher rates of bleeding and limb ischemia in males, and a potential trend toward higher rates of infection, arrhythmias, and neurologic dysfunction in females. None of these potential trends were statistically significant. The small sample size and variability of patient population (as evidenced in baseline characteristics) makes it difficult to draw any conclusions. Risks associated with the CentriMag RVAS are consistent with those associated with commercially approved devices and alternative treatment options.

The positive outcome data combined with the low incidence of device related adverse events suggest the benefits associated with use of the CentriMag RVAS VAD outweigh the risks. This risk-benefit ratio is highlighted when taking into account the risks and benefits associated from alternative methods of treatment, and from the morbidity and mortality associated with cardiogenic shock if left untreated.

RECOMMENDED ANTICOAGULATION GUIDELINES

It is intended that systemic anticoagulation be utilized while the CentriMag System is in use. Anticoagulation levels should be determined by the physician based on risks and benefits to the patient. In general, the following anticoagulation guidelines should be considered.

- For patients that were on cardiopulmonary bypass:
 - No anticoagulation for 6-12 hours after device placement
 - Start heparin infusion if chest tube output is < 50 cc/hr for 2-3 hrs
 - Target ACT 160-180 sec (e.g. Hemochron Celite ACT)
 - Target PTT 1.3-1.6 (e.g. 39-48) times laboratory normal for patient
 - Add platelet anti-aggregant (e.g. 81-325 mg aspirin per day) by the 4th post-op day
 - Target ACT 250-300 sec for weaning or for persistent low flow conditions
- For patients that did not undergo cardiopulmonary bypass:
 - Start heparin infusion if chest tube output is < 50 cc/hr for 2-3 hrs
 - Target ACT 160-180 sec (e.g. Hemochron Celite ACT)
 - Target PTT 1.3-1.6 (e.g. 39-48) times laboratory normal for patient
 - Add platelet anti-aggregant (e.g. 81-325 mg aspirin per day) by the 4th post-op day
 - Target ACT 250-300 sec for weaning or for persistent low flow conditions

INDICATIONS FOR USE

The Levitronix CentriMag RVAS is intended to provide temporary circulatory support for up to 14 days for patients in cardiogenic shock due to acute right ventricular failure.

CONTRAINDICATIONS

This CentriMag RVAS is contraindicated for use as a cardiotomy suction device. It is also contraindicated for patients who are unable or unwilling to be treated with heparin or an appropriate alternative anticoagulation.

INSPECTION PRIOR TO USE

1. The packages containing the blood pump, cannulae, tubing and connectors should be inspected prior to use for any damage to the sterile barriers. The package seals should be intact to insure sterility. Do not use the Blood Pump, or any of sterile accessory (cannulae, tubing or connector) if the associated package is damaged. Contact Levitronix regarding return of any damaged product.
2. The Blood Pump should be inspected prior to use for any damage or particulate matter contamination. Do not use the Blood Pump if damaged or if any particulate matter is found on or inside the Blood Pump. Contact Levitronix regarding return of any suspect Blood Pump.

WARNINGS

1. Carefully read all Warnings, Precautions, Manuals, and Instructions for Use for this and all related Levitronix extracorporeal devices prior to use. Failure to read and follow all instruction, or failure to observe all stated warnings, could cause serious injury or death to the patient.
2. Possible side effects include, but are not limited to: Infection, mechanical failure, hemolysis, end organ dysfunction, neurologic dysfunction, bleeding, and embolic phenomena. These are potential side effects with all mechanical circulatory support systems.
3. The CentriMag RVAS is intended for use in patients with a body surface area 1.4 m² or greater.
4. Ensure that the CentriMag Blood Pump and circuit have been debubbled and primed properly prior to use to minimize the risk of air entry to the patient.
5. Ingress of air into the pump that causes total displacement of the fluid will result in depriming of the Blood Pump and blood flow will stop.

Clamp the outlet tubing and stop the Blood Pump and remove air prior to resuming circulation.

6. Do not expose the CentriMag Blood Pump to chemical agents as they may affect the integrity of this device. Anesthesia solutions such as forane are known to degrade polycarbonate plastics.
7. To prevent backflow of the patient's blood when the Blood Pump outlet tubing is open, establish and maintain a minimum pump speed that overcomes line and patient resistance. Failure to do this could allow retrograde flow and limit arterial pressure. Retrograde flow may be diagnosed by observing dashes ("---") on the Primary Console flow display.
8. A Blood Pump stoppage will create a reverse flow shunt through the Blood Pump, as well as limit the body's ability to maintain adequate arterial pressure. If the Blood Pump is stopped, clamp the outlet tubing from the Blood Pump to prevent a low flow, low pressure, and reverse flow condition. The tubing clamp must be removed before returning to normal pumping activity.
9. It is intended that systemic anticoagulation be utilized while this device is in use. Anticoagulation levels should be determined by the physician based on risks and benefits to the patient.
10. The CentriMag Blood Pump is designed to be operated only with the CentriMag drive console. There are no safety or performance data known to Levitronix which establishes compatibility of any other manufacturer's devices or components to the CentriMag RVAS.
11. Potential risk to the patient should be evaluated prior to changing a CentriMag Blood Pump.
12. Frequent patient and device monitoring is recommended.
13. Do not use the CentriMag Blood Pump if the "Use Before" Date on the package has past or expired.
14. Do not operate the CentriMag Blood Pump in the absence of forward flow. The temperature within the Blood Pump will rise and increased cellular damage and clotting may result.
15. The CentriMag Blood Pump must be handled in an aseptic manner until primed and connected to a closed tubing circuit.
16. Do not operate the CentriMag Blood Pump with its inlet tubing clamped as a negative pressure

will be generated in the Blood Pump and air bubbles may formed in the priming fluid or blood.

17. Monitor patient's hemodynamics and the Console Flow display to insure adequate blood volume for the inlet cannula position, Blood Pump RPM, and desired flow. Increase Blood Pump RPM in small increments to minimize the risk of exceeding the available blood volume and causing inlet cannula obstruction, suction, outgassing, and/or cavitation.
18. As with all continuous flow pumps, operating at too high a speed can result in negative pressure at the inlet which can lead to collapse of the ventricle or blood vessels, inlet cannula obstruction, inspiration of air, outgassing, cavitation and increased risk of embolism. Transient negative pressure conditions can be detected either by observing "line chatter" on the inlet side of the pump, or with audio/visual low flow alerts. Should "line chatter" or low flow alerts occur, reduce pump speed until the negative pressure condition resolves. Always operate the system at the lowest speed consistent with the volume of blood available to be pumped and clinically acceptable circulatory support.
19. The CentriMag Blood Pump contains a magnet. To avoid injury, keep all sharp metal objects and instruments at least six inches away for the Blood Pump. Do not remove the CentriMag Blood Pump from its inner tray until ready to assemble RVAD circuit and insert pump into the motor receptacle.
20. If CentriMag Blood Pump operation is ever halted or flow reduced, consideration should be given to monitoring and adjustment of the patient's anticoagulation status.
21. Do not restart the CentriMag Blood Pump if the Blood Pump has been stopped for more than 5 minutes without adequate anticoagulation, as the risk of thromboembolism is increased after blood has remained stagnant in the Blood Pump, extracorporeal circuit, connectors, and cannulae.
22. Monitor the pump and tubing for air because the CentriMag Blood Pump, similar to other centrifugal pumps, will pump air. Immediately clamp Pump outlet tubing if air enters the CentriMag Blood Pump as gaseous emboli may be introduced into the patient, with attendant risk of death or severe bodily injury. Ingress of air into the pump that causes total displacement of the fluid will result in depriming of the Blood Pump and blood flow will stop.
23. Use of the CentriMag Blood Pump for periods longer than 14 days may result in blood pump failure, reduced pumping capacity, excessive blood trauma, and/or degradation of blood

contact materials with possibility of particles passing through the cannulae to the patient, leaks, and increased potential for gaseous emboli.

CAUTIONS

1. Distribution of this device is restricted to use by or on the order of a physician.
2. This device should only be used by persons thoroughly trained in extracorporeal circulation procedures.
3. Do not hit or strike the CentriMag Blood Pump with hands, objects, or instruments. Do not strike the CentriMag Blood Pump against any surface or object. Shock may cause damage to the device, which may cause device malfunction.
4. The CentriMag Blood Pump is provided sterile in an unopened and undamaged unit package. Inspect device and package carefully prior to use. Do not use if the unit package or the product has been dropped, damaged or soiled.
5. Each CentriMag Blood Pump is intended for single use only. Do not resterilize. Resterilization by any means may cause severe damage to the device or its components. Dispose of safely after single use to avoid risk of infection.
6. Attach tubing to the Blood Pump in such a manner as to prevent kinks or restrictions that may alter flow or cause regions of stasis or turbulence. Attach in a manner that does not bend or fracture the tubing connectors or ports. Advance tubing beyond the second barb point of the Blood Pump connectors.
7. The inlet and outlet tubing and cannulae connections must be secured with two small (approximately 10 cm length) cable-ties or tie bands on each connector. The locking mechanisms of the two ties should be oriented 180 degrees from each other to insure a tight seal of the tubing to the connector.
8. Ensure the CentriMag Blood Pump is properly locked into the CentriMag Motor per the Directions for Use supplied with the Motor.
9. Monitor carefully for any signs of occlusion throughout the circuit.
10. Do not operate the CentriMag Blood Pump when unprimed as it may damage the Blood Pump impeller.
11. Run the CentriMag Blood Pump only on a properly maintained CentriMag drive Console and Motor.

12. Do not use the CentriMag Blood Pump if it has been dropped. Dropping or other severe shock may cause damage which could lead to device malfunction.
13. Do not use excessive force to install tubing on the CentriMag Blood Pump as damage to the Blood Pump and 3/8" pump ports may occur.
14. Take care to prevent damage to CentriMag Blood Pump connectors when setting-up and de-airing the Blood Pump.
15. Always have a spare CentriMag Blood Pump, Back-Up Console, motor, and accessories available for change out.
16. Do not place CentriMag Blood Pump near items adversely affected by magnetic fields.
17. Use only the Edwards Lifesciences #TFM032L, 32 FR Thin-Flex Single Stage Malleable Venous Drainage Cannula for Inlet cannulation. Inlet cannulation with cannulae other than the one specified may subject patients to unknown risks.
18. Use only the Medtronic EOPA™ #77722, 22 FR arterial cannula for Outlet cannulation. Outlet cannulation with cannulae other than the one specified may subject patients to unknown risks.
19. The CentriMag RVAS has been qualified for use with the Transonic H9XLA-series flow probe. Do not use any other flow probe as their performance has not been qualified for use with the CentriMag RVAS.

PRE-PUMPING CHECKLIST

1. Connect the CentriMag Motor to the CentriMag Console.
2. Check that all electrical connections are secure including flow probe and AC power cord.
3. Test the CentriMag Console by powering it up; verify that there are no self-test errors on boot-up.
4. Check the date and integrity of sterile CentriMag Blood Pump package, sterile cannulae, sterile tubing and connectors.
5. Check that a Transonic H9XLA flow probe is included with the CentriMag Primary Console and is clean and ready for use. CentriMag Back-Up Console does not have flow measurement capability hence a flow probe is not included with the Back-Up Console.

BLOOD PUMP SETUP AND OPERATION

Follow the system preparation directions in the Operating Manual for the CentriMag Primary Console. Inspect the complete system; do not use a malfunctioning or damaged system.

1. Remove from the CentriMag VAD Kit the following five components:
 - One CentriMag Blood Pump,
 - One inlet cannula,
 - One outlet cannula,
 - Two Tubing Sets, and
 - Two Sterile Straight Barbed Connectors without Luer Lock ports.
2. To mount the CentriMag Blood Pump on the CentriMag Motor, remove the Blood Pump from the inner tray and insert the Blood Pump into the motor receptacle. Place the bottom of the Blood Pump into the motor receptacle with the outlet port positioned in the large groove. Match the grooves on the periphery of the Blood Pump with the fittings on the motor receptacle. **ROTATE BLOOD PUMP COUNTERCLOCKWISE** until the Blood Pump locks securely into place. Thread the retaining screw clockwise to secure in place. The CentriMag Blood Pump must be fully seated into the receptacle to function properly.

Note: If the CentriMag Blood Pump is not properly seated an alarm "Pump Not Inserted" will be displayed on the CentriMag Console display.

3. To remove the CentriMag Blood Pump from the CentriMag Motor, unthread the retaining screw counterclockwise, and then rotate the Blood Pump clockwise until the grooves are matched. Lift and remove the Blood Pump.
4. Fill a sterile basin with sterile heparinized saline. Use 10,000 units of heparin per liter saline. Remove from packaging and submerge into the heparinized saline the following four components:
 - Two Medtronic Intersept® 3/8 X 3/32 inch (9.5 X 2.4 mm) (4') sterile tubing sets (Model 3504),
 - One inlet cannula (Edwards Lifesciences #TFM032L, 32 FR Thin-Flex Single Stage Malleable Venous Drainage Cannula),
 - One outlet cannula (Medtronic EOPA™ #77722, 22 FR arterial cannula), and
 - One tubing interconnector (Medtronic Intersept® 3/8 X 3/8 inch (9.5 X 9.5 mm) Sterile Straight Barbed Connector without Luer Lock (Model 6023).

5. Insert the outlet cannula into the pulmonary artery by standard technique with the supplied introducer and Trocar from the outlet cannula kit. Clamp the outlet cannula approximately 25 mm from 3/8" adapter as Trocar is removed to prevent blood loss. Secure the outlet cannula in place with double purse string suture. Carefully bleed the outlet cannula by gently unclamping restriction and letting any air bubbles out.

WARNING

Do not over tighten sutures when securing cannulae to tissues and vessels. Over tightened sutures may result in obstruction and interruption of blood flow through the cannulae. Suturing used to secure cannula must be made with sufficient tension to hold the cannula in place over the full range of patient activity. Failure to effectively secure cannulae in place poses risk of decannulation, bleeding, or air embolus.

6. After the outlet cannula has been surgically inserted and externalized, connect one of the pre-wetted, filled and debubbled extension tubes to the barbed connector of the outlet cannula. Debubble and clamp the tubing at a length beyond the anticipated final tubing length.
7. Fill the inlet cannula with sterile heparinized saline. Clamp at approximately 25 mm from the distal end of the inlet cannula where there is no reinforcing spring. Place the inlet cannula directly into the right ventricle (or right atrium) by means of a surgical incision, and then secure it in place with a pledgeted purse-string suture to the ventricular apex. Ensure that the cannula tip does not compromise the valves of the ventricle.
8. Allow blood to displace any air within the inlet cannula by holding the distal end vertically, and partially unclamp to gently let any air escape.
9. After the inlet cannula has been surgically inserted and externalized, take the pre-wetted Medtronic Intersept[®] 3/8 X 3/8 inch (9.5 X 9.5 mm) barbed connector and insert into the inlet cannula.
10. Take the remaining pre-wetted, filled and debubbled extension tubing set and connect to the barbed connector on the inlet cannula. Debubble and clamp at a length beyond the expected final tubing length.
11. Prime and debubble the CentriMag Blood Pump by flushing through the outlet port while debubbling through the inlet port. Eliminate air

from the device by "walking" the air out of the inlet.

12. Cut the outlet extension tubing to length based on the desired final location of the CentriMag Blood Pump.
13. Connect the outlet tubing to the outlet port of the CentriMag Blood Pump taking care to clear the flow path of bubbles. This can be accomplished by continuously irrigating the connection with sterile heparinized saline solution while mating.
14. Position the inlet tubing immediately adjacent to the inlet of the CentriMag Blood Pump and determine the correct length for the extension tubing. Clamp the extension tubing between the cannula and the CentriMag Blood Pump inlet port. Cut the extension tubing to length. Fully fill both the inlet tubing and Blood Pump with the sterile heparinized saline solution. While continuously irrigating, make the connection.
15. With the inlet tubing unclamped, and the outlet tubing clamped, turn the CentriMag Console ON.
16. Connect the Transonic H9XLA-series flow probe to the outlet tubing according to the instructions provided in the CentriMag Console Operating Manual.

WARNING

Do not reverse the inlet and outlet cannulae connections. Reversal of inlet and outlet cannulae will limit circulatory support. Always use care in determining the direction of flow when connecting the CentriMag Blood Pump to the cannulae to avoid physical harm to the patient.

CAUTION

Do not hit or strike the CentriMag Blood Pump with hands, objects, or instruments. Do not strike the CentriMag Blood Pump against any surface or object. Shock may cause damage to the device, which may cause device malfunction.

WARNING

Ensure that the CentriMag VAD and circuit have been debubbled and primed properly to minimize the risk of air reaching the patient.

WARNING

Ingress of air into the pump that causes total displacement of the fluid will result in depriving of the Blood Pump and blood flow will stop. Clamp the outlet tubing, stop the Blood Pump, and remove air prior to resuming circulation.

WARNING

Do not operate the Blood Pump in the absence of forward flow. The temperature within the Blood Pump may rise and increased cellular damage may result.

WARNING

Do not operate the Blood Pump with the inlet tubing or cannula clamped as a negative pressure will be generated in the Blood Pump and bubbles may form in the Pump.

17. Remove all remaining tubing clamps, bring the CentriMag Blood Pump's RPM up to a sufficient speed to achieve a positive flow, inspect the integrity of the Blood Pump, the tubing, and the connections, if any anomalies are noted, immediately stop the Blood Pump, clamp the outlet tubing and correct the anomaly before unclamping and restarting.

CAUTION

Placing a tubing clamp on the tubing near a tubing connection point can damage the connector, resulting in thrombus formation at the area of the damage.

WARNING

If leaks or other anomalies are found on the CentriMag VAD, remove the Blood Pump and replace with a new, sterile Blood Pump, repeating the above steps to prime.

18. Increase RPM to produce desired flow.
19. Set the Console's low flow alarm to the desired minimum flow point.
20. Secure the motor in order to maintain its location in relation to the patient.

WARNING

Motor must be immobilized near the patient. Failure to immobilize the CentriMag Motor could lead to unanticipated movement of the Motor resulting in stress on the cannulae.

WARNING

As with any continuous flow pump, operating at too high a speed can result in negative pressure at the inlet which can lead to collapse of the ventricle or blood vessels, inlet cannula obstruction, inspiration of air, out gassing, cavitation and increased risk of embolism. Transient negative pressure conditions can be detected either by observing "line chatter" on the inlet side of the pump, or with audio/visual low flow alerts. Should "line chatter" or low flow alerts occur, reduce pump speed until the negative pressure condition resolves. Always operate the system at the lowest speed consistent with the volume of blood available to be pumped, cannulae placement, and clinically acceptable circulatory support.

CAUTION

Any time the CentriMag Blood Pump is stopped the pump outlet should be clamped to prevent retrograde flow. The clamp used should be a smooth jawed tubing clamp.

WARNING

Do not use Valleylab SSE2L or Valleylab Force FX series ESUs on a patient supported with the CentriMag Blood Pumping System. Use of these ESUs may result in stoppage of the pump and potentially cause serious injury or death.

Should pump stoppage occur, clamp the Pump outflow line, turn the CentriMag Console OFF then ON and verify that the system is operating. If the CentriMag Console fails to operate properly, switch to the CentriMag Back-Up Console and Motor. Once the CentriMag System is operational, unclamp the outlet tubing and resume support.

However, be aware that stoppage of the pump may reoccur unless an alternative electrosurgical unit or blood pump is used.

EMERGENCY BACK-UP EQUIPMENT

1. A CentriMag Back-Up Console must be plugged in with motor and flow probe connected (if designed to accommodate a flow probe), and kept near the patient ready for use.
2. Back-up sterile CentriMag Blood Pump and supplies to prime available.
3. Back-up power available.
4. Two smooth jawed tubing clamps.

CLEANUP AFTER USE

1. Turn OFF power to the Primary and Back-up CentriMag Consoles.
2. Properly discard disposable components according to hospital procedure for contaminated materials.
3. Clean CentriMag Console and Motor according to established hospital procedure.
4. Clean flow probe according to established hospital procedure.
5. Reconnect CentriMag Consoles to AC power to maintain charge on batteries.

EMERGENCY PUMP REPLACEMENT

In some instances when the CentriMag Blood Pump has been OFF for more than five minutes, or if there

has been a Motor overheating condition, it will be necessary to either terminate pumping OR replace the Blood Pump.

To replace the CentriMag Blood Pump, disconnect the Blood Pump from the Motor and any affected tubing. Attach the replacement Blood Pump per the standard procedures described above, prime and debubble. Operate the Console as described in the CentriMag Console Operating Manual.

BLOOD PUMP SPECIFICATIONS

Blood contact materials: Polycarbonate
Pump priming volume: 31 ml
Pump rotational range: 0-5,500 RPM
Outflow capacity: (see graph) 0-9.9 L/min
Outflow pressure: (see graph) 0-600 mmHg
Connects to 3/8 inch (9,5mm) I.D. tubing

STORAGE CONDITIONS

Temperature: 0 - 40 °C (32 - 104 °F);
Relative Humidity: 15% - 85%

OPERATING CONDITIONS

Temperature: 15 - 30 °C (59 - 86 °F);
Relative Humidity: 30% - 75%

PRODUCT RETURNS

Prior to returning any product, contact your Levitronix Customer Service Representative for a return authorization and instructions.

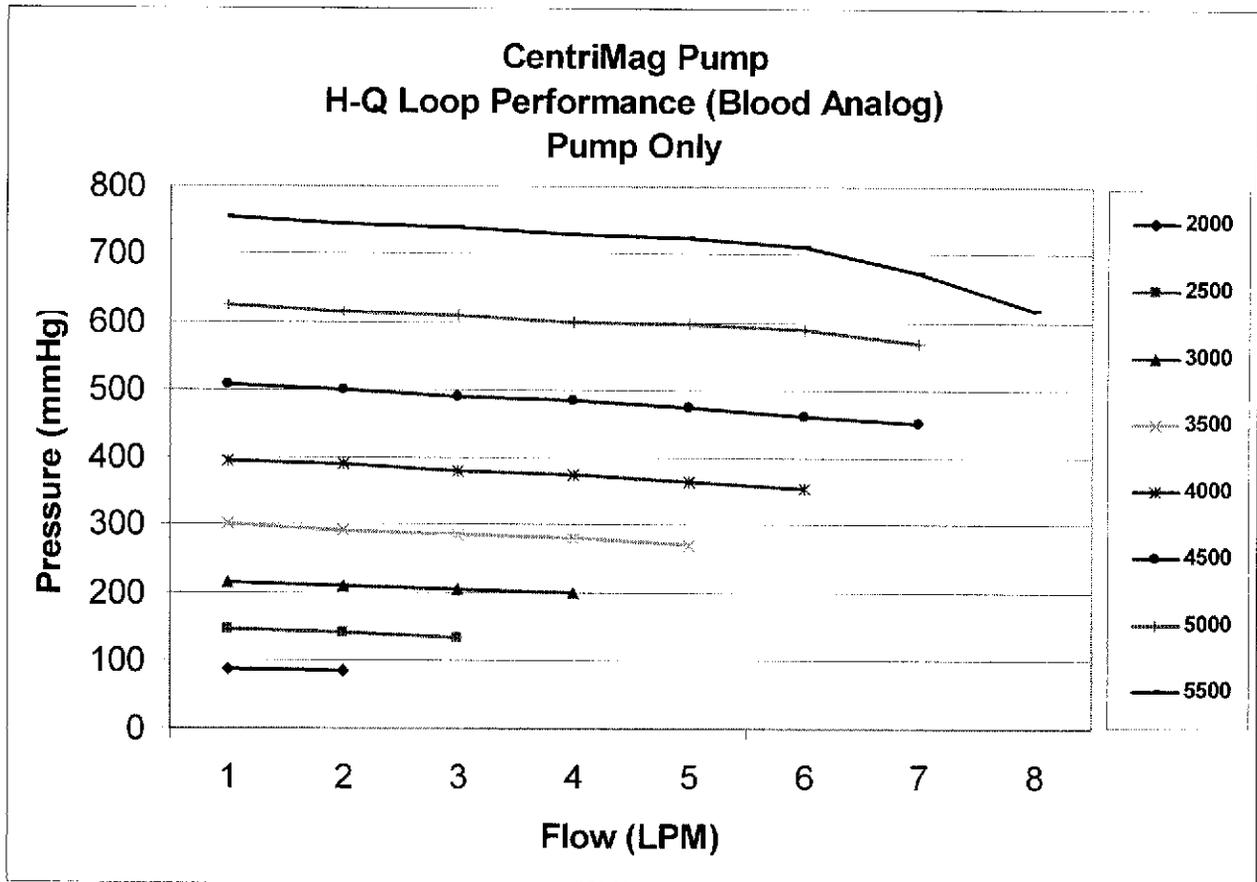
SYMBOLS ON THE PRODUCT PACKAGE

The following table describes the symbols used on CentriMag Blood Pump package:

| Symbol | Description |
|--|--|
| REF. | Catalog Number |
|  | Lot Number |
|  | Use Before |
|  | For single use only. Do not reuse. |
|  | Sterilized with ethylene oxide gas |
|  | See Instructions for Use. |
|  | The blood path by means of a validated method proven to be PYROGEN free. |
|  | Single Use Device. Do Not Resterilize. |
|  | Federal (USA) law restricts this device to sale, distribution and use by or on the order of a physician. |

PRESSURE VS FLOW GRAPH

The CentriMag Blood Pump output is pressure responsive. In the graph below, the Pump flow rate (L/min) versus the outlet pressure (mmHg) is plotted at a variety of pump speeds. This graph is for informational purposes only and does not necessarily reflect the rates to be achieved under clinical conditions.



Note: Actual obtainable flow is dependent on the difference between the preload and afterload of the Blood Pump (pump pressure differential), the resistance to flow through the extracorporeal circuit components (Cannulae, tubing, etc.) and the patient hemodynamics (intravascular pressures, cardiac output, and available volume).

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Patient LABELING

Patient Information Guide for the Levitronix[®] CentriMag[®] Right Ventricular Assist System (RVAS)

CAUTION

Humanitarian Device: The Levitronix CentriMag RVAS is authorized by Federal law to provide temporary circulatory support for up to 14 days for patients in cardiogenic shock due to acute right ventricular failure. The effectiveness of this device for this use has not been demonstrated.

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

Please address any questions you have about the CentriMag to your doctor.



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R_x Only

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I. WHAT IS THE LEVITRONIX CENTRIMAG RVAS?

Your heart is a pump which contains four chambers. There are two chambers on the left side and two on the right side of your heart.

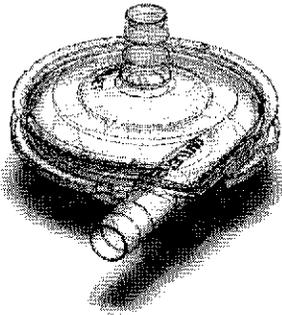
The right side of your heart is made up of upper and lower chambers. The lower chamber (the right ventricle) is the stronger of the two chambers. The right ventricle pumps oxygen-poor blood to your lungs. From the lungs, the blood is pumped to the left side of your heart. The lower chamber on the left side of your heart (the left ventricle) pumps oxygen-rich blood to the rest of your body. When your heart muscle isn't strong enough to pump blood on its own, a device such as the CentriMag can be used to help pump the blood.

Your doctor has found that the right side of your heart (the right ventricle) is not strong enough to pump enough blood flow to your lungs on its own. The CentriMag Right Ventricular Assist System is designed to help your right ventricle pump blood to your lungs. The CentriMag Right Ventricular Assist System is also called an RVAS. The CentriMag RVAS is made of eight major parts:

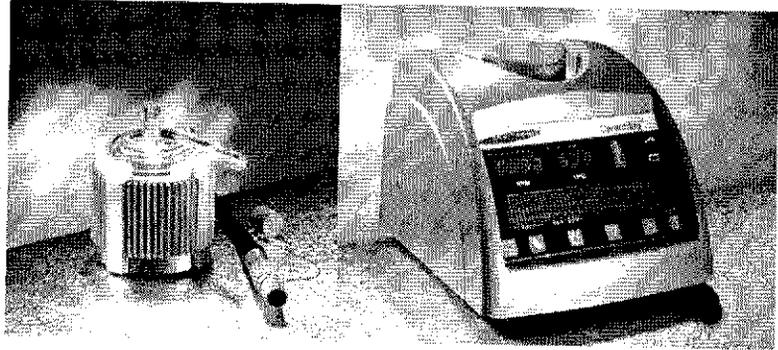
- a) A **Blood Pump** to help pump your blood,
- b) A **Motor** which runs the Blood Pump,
- c) A **Control Unit** (Primary Console) which is used to program settings for the pump and motor. This control unit also has alarms which alert your caregiver(s) to potential problems.
- d) A **back-up Motor** to be used if the primary Motor is not working properly,
- e) A **back-up Control Unit** (Back-Up Console) to be used if the primary control unit is not working properly,
- f) A flow probe which clips onto the pump tubing to measure blood flow,
- g) Tubing (**Inlet Cannula and Outlet Cannula**) that attaches directly to your heart, and
- h) **Extension Tubing** that attaches the tubing from your heart to the blood pump.

Photographs of each of the different parts of the system are shown below in Figure 1.

Figure 1

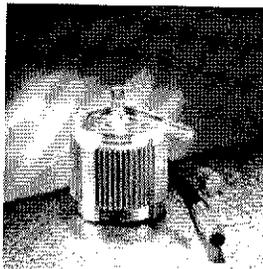


a) Blood Pump

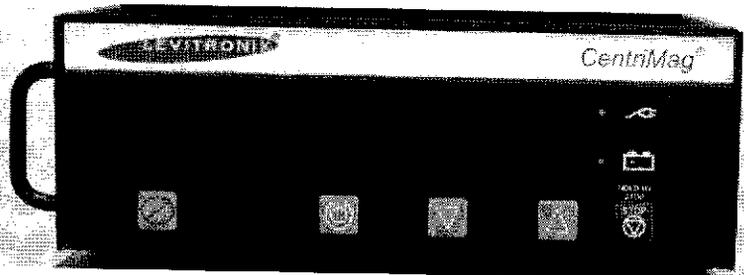


b) Motor

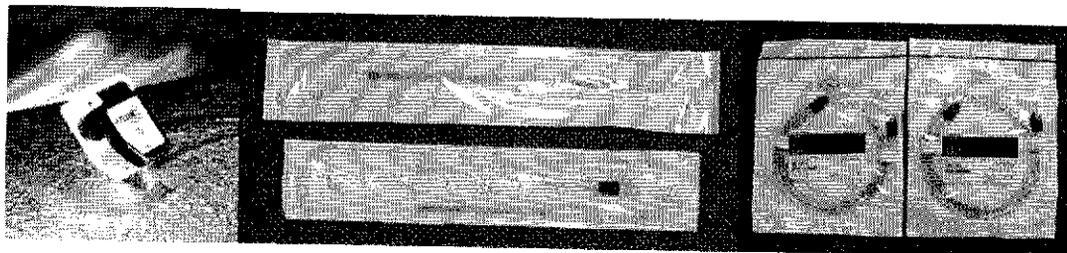
c) Control Unit



d) Back-Up Motor



e) Back-Up Control Unit



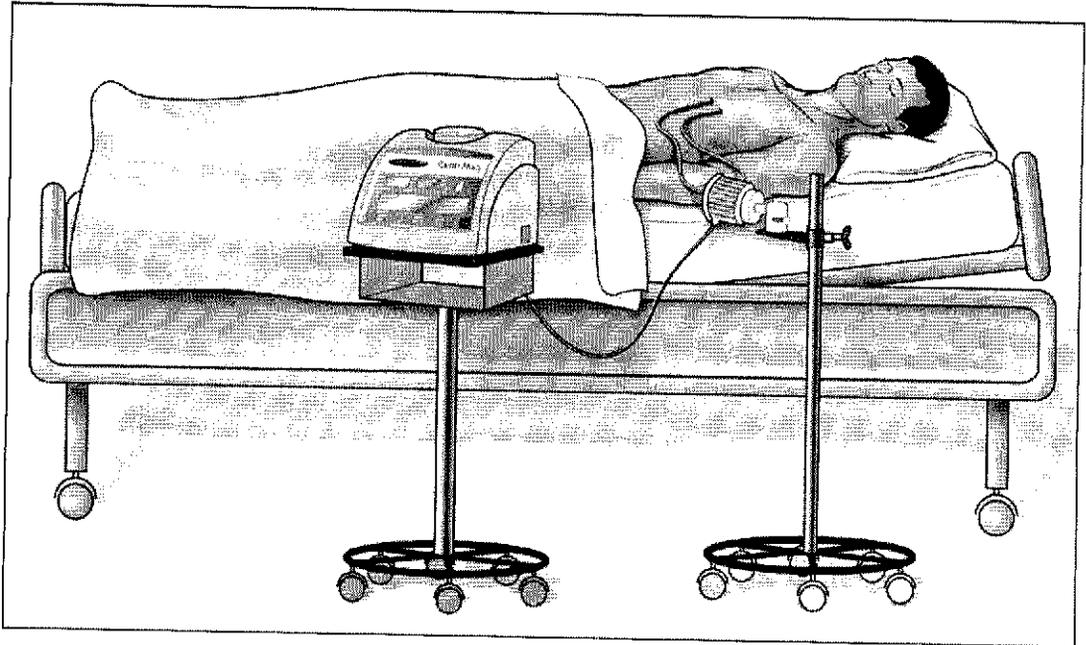
f) Flow Probe

g) Inlet and Outlet Cannula

h) Extension Tubing

Figure 2 below shows what the system looks like when attached to a patient. The tubing (inlet and outlet cannula) attached directly to the heart is coming out through the chest. The extension tubing is connected to the cannula. Finally, the extension tubing is connected to a motor and the motor is connected to the control unit.

Figure 2



II. WHY DO YOU NEED THE CENTRIMAG RVAS?

The CentriMag RVAS is designed to keep you alive until the right side of your heart recovers. Once your right heart recovers, the CentriMag RVAS is removed. If your heart does not recover enough to allow the CentriMag RVAS to be removed then other options must be considered. If your heart does not recover you may need another RVAS, have a heart transplant, or have the CentriMag RVAS removed and be treated with standard heart failure medicines or you may need to be implanted with a heart pump that can be used for long-term support.

Even though the CentriMag RVAS may improve your chances for survival, your heart disease may be so severe that the CentriMag RVAS might not help you. Other options available to you, instead of a CentriMag RVAS, include continuing treatment on heart failure medicines, an intra-aortic balloon pump (another type of pump made by another company) or an alternative RVAS made by another company.

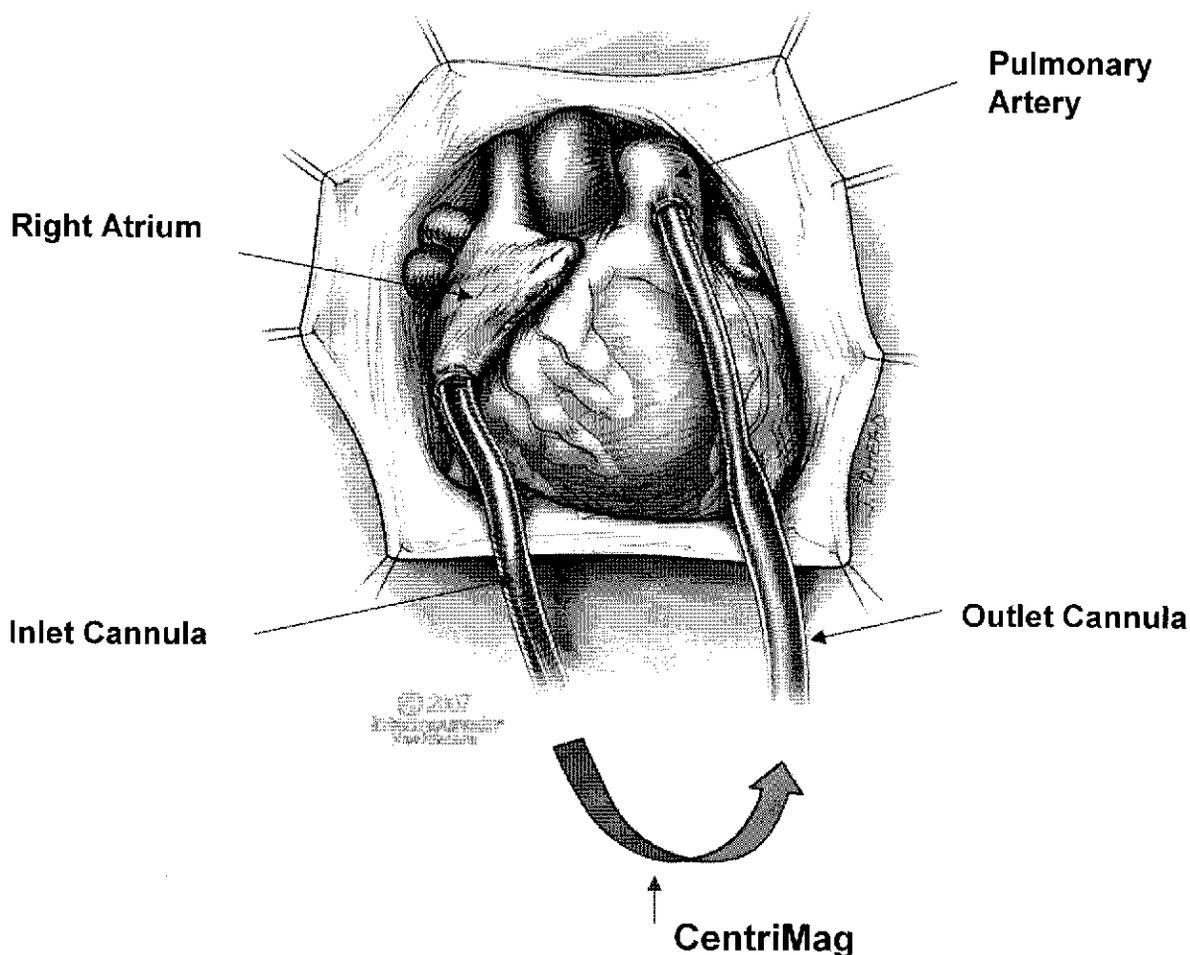
III. HOW IS THE CENTRIMAG RVAS PLACED?

- You will need an operation to have the CentriMag placed. You will be under general anesthesia during the operation. The surgery needed to attach the

CentriMag Blood Pump to your heart requires placing a tube (cannula) into the upper chamber of your right heart, which is called the right atrium.

- A second tube (cannula) is placed into one of your main blood vessels (pulmonary artery). The pulmonary artery carries blood from the right ventricle to the lungs. The blood picks up oxygen at the lungs to be used by the rest of your body.
- The other ends of both these tubes are passed from your heart through the skin, connected to extension tubing and then connected to the CentriMag. Blood will then flow from the right side of your heart, through the CentriMag blood pump to your lungs. The connection of the tubing (inlet and outlet cannula and extension tubing) is illustrated in the picture below (Figure 3).

Figure 3



- The CentriMag may be used either until your heart recovers, or until a decision is made to treat you with another heart failure therapy. Generally, the CentriMag is used for up to 14 days. Use of the CentriMag may be longer if your heart does not recover, but it is unknown whether the device is capable of pumping as needed if it is used for more than 14 days.
- If it is not possible to stop use of the CentriMag because your heart is too damaged, other options include removing the CentriMag device, replacing it with a long-term device, treating you with heart failure medicines, continuing support with the CentriMag, or having a heart transplant. You may not be eligible for all of these options.

IV. PROBABLE BENEFIT

Temporary use of the CentriMag may assist your right heart in providing blood flow to your lungs to pick up oxygen, which may allow your right heart to recover. The average waiting time for your heart to recover is unpredictable.

A total of 32 patients were enrolled into clinical studies in the United States and treated with a CentriMag. All 32 patients were studied to assess whether the probable benefit from treatment with the CentriMag outweighs the risks of using the device. In many patients, the CentriMag RVAS was shown to improve heart function with a low rate of device problems. The CentriMag did not help all patients in these studies.

While the effectiveness of this device for this particular use has not been demonstrated, the probable benefits associated with the CentriMag included: 1) allowing the patient's right ventricle to rest, 2) improved heart function, 3) reliable device function, 4) a low rate of device-related complications, and 5) potential for recovery after the CentriMag was removed. Some of the patients needed additional treatment after the CentriMag was removed including heart transplantation or treatment with a long-term device.

V. RISKS AND DISCOMFORTS

Risks associated with the CentriMag are consistent with other devices similar to the CentriMag and other types of heart treatment. The potential complications that can occur with the use of the CentriMag include those that can happen with any heart surgery done under general anesthesia. The most serious risks associated with use of the CentriMag are believed to be, but not necessarily limited to:

- Death
- Stroke (for example, caused by bleeding in the brain)
- Major bleeding (for example, due to surgery or from the device)
- Formation of blood clots that can dislodge (thromboembolism) and travel to the lungs
- Right heart failure (after the CentriMag is removed the right side of the heart may fail again)
- Infection (for example, due to the tubes that run through the skin)
- Kidney failure (for example, due to blood clots that can lodge in the kidney or due to prolonged low blood flow either before or during CentriMag support)
- Liver failure (for example, due to blood clots that can lodge in the liver or due to prolonged low blood flow either before or during CentriMag support)
- Destruction of red blood cells (for example, due to drug reaction or direct damage from the device)
- Device failure (for example, the CentriMag or one of its parts might break or fail to operate)

Any of these complications may cause serious injury or death.

You may have discomfort after your operation, some of it due to the CentriMag. You will possibly hear and feel the effects of the pump assisting your heart. You may have pain where the tubes enter your body through the skin.

The CentriMag cannot be used for long-term support of the heart (for more than 14 days). If the CentriMag fails it will need to be removed as soon as possible or replaced with another device.

You will need to stay in bed while you have the CentriMag in place. Your doctor may allow you to sit in a chair. You must stay in an intensive care unit while you are treated with the CentriMag. Since the CentriMag is not for long-term use, you cannot be discharged from the hospital with a CentriMag in place.

Any of these complications or others that have been explained to you may extend your time in the hospital.

You may have other questions. Please address any questions you have about the CentriMag to your doctor.

VI. NATURE AND USE OF DEVICE

The CentriMag is intended to provide temporary circulatory support for up to 14 days for patients in cardiogenic shock due to acute right ventricular failure.

This means that the CentriMag is designed to provide short-term support of the failing right side of the heart for a period up to 14 days. The device will be connected via tubes from outside your body to the heart and pulmonary artery. The pump will be driven by a motor that is controlled by an external control unit.

Placement of the CentriMag requires surgery to your chest, and because it is temporary, a second operation under general anesthesia will be necessary for removal of the CentriMag.

VII. CONTRAINDICATIONS

The CentriMag cannot be used in patients who are unable or unwilling to be treated with blood thinning drugs.