



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

FOR USE ANYTIME

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Thoratec[®] CentriMag[®] Blood Pump Fact Sheet

Product: The CentriMag blood pump is an extracorporeal circulatory support device that provides hemodynamic stabilization in patients in need of cardiopulmonary support.

Current Indications:

- Cleared for clinical use up to six hours, CentriMag can be used as a short-term solution to support the circulation while longer-term options are considered.
- CentriMag is approved for use as a right ventricular assist device (RVAD) for periods of support up to 30 days for patients in cardiogenic shock due to acute right ventricular failure.[†]
- CentriMag is also being evaluated in the United States for use in Failure to Wean Patients as a bridge to recovery, transplant, or a short-term ventricular assist device (VAD) in patients unable to be weaned from cardiopulmonary bypass.^{††}

Benefits: CentriMag offers a range of features and benefits:

- **Simplicity/Ease-of-Use.** The CentriMag blood pump is simple to implant and manage.
- **Minimize Blood-Related Complications.** The CentriMag has a magnetically-levitated pump impeller that provides a contact-free environment to help minimize blood-related complications such as hemolysis.
- **High Blood Flows.** The CentriMag is capable of delivering high flows up to 9.9 LPM.
- **Portability.** Compact design is fully portable and facilitates patient transfer in emergency transport situations.

How it works: The CentriMag System comprises a single-use centrifugal pump, a motor and a primary drive console. It is designed to operate without mechanical bearings or seals, as the motor magnetically levitates the impeller, achieving rotation with no friction or wear [1].

The CentriMag can be used for perioperative or postcardiotomy circulatory support of the failing heart. The device resides at the patient's bedside, and the

cannulae are usually inserted through a midline sternotomy, with the inflow cannula in the left ventricle or right superior pulmonary vein and the outflow cannula in the aorta.

**CentriMag
VAS
Pivotal
Trial:**

The CentriMag VAS Pivotal Trial will evaluate the safety and effectiveness of the Levitronix CentriMag for support of patients with cardiac dysfunction and failure-to-wean from cardiopulmonary bypass. The device is specifically indicated to treat patients who are hemodynamically unstable and unable to be moved from the operating room without mechanical circulatory support. The device will be used for up to 30 days to support one or both sides of the heart as a bridge to decision, when it is unclear whether the patient's heart will recover or whether the patient will need alternative, longer-term therapy or transplantation. This prospective, non-randomized trial will enroll a total of 30 patients at up to 25 clinical centers. The CentriMag Pivotal Trial will be conducted jointly by Thoratec and Levitronix.

DEVICE	DURATION	INDICATION	STATUS
Thoratec CentriMag Blood Pump	• 6 hours	• Acute support	• U.S. FDA 510k clearance for use in patients requiring short-term extracorporeal (i.e. outside the body) circulatory support during cardiac surgery.
Thoratec CentriMag VAS*	• Days to weeks	• Acute support	• Levitronix clinical trial underway in the U.S. • Received Conformité Européene (CE) Mark

CentriMag is a registered trademark of and is manufactured by Levitronix, LLC.

† Humanitarian Use Device. The Levitronix CentriMag RVAS is authorized by Federal law to provide temporary circulatory support for up to 30 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.

†† A clinical trial is currently underway in the United States to investigate CentriMag use as a VAD for support for up to 30 days.

* CAUTION: When used for left or biventricular support for periods over six hours, the CentriMag VAS is an Investigational Device limited by Federal (U.S.A.) law to investigational use. To participate in the clinical trial, contact Mark Macedo, Director of Clinical Affairs at 781-622-5096, mmacedo@levitronix.com.

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ⁱ Source: <http://www.texasheart.org/Research/Devices/levitronix.cfm>