



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[®] and PediMag[®] Blood Pump Fact Sheet

Products: The CentriMag and PediMag (called the PediVAS[®] outside the U.S.) blood pumps are a family of extracorporeal circulatory support devices that provide hemodynamic stabilization in both adult and pediatric patients in need of cardiopulmonary support. The CentriMag can provide flows up to 9.9 lpm and is appropriate for patients larger than 20kg. The PediMag can provide flows up to 1.5 lpm and is optimized for pediatric patients up to ~ 20kg.

Current Indications:

- Cleared in the U.S. for clinical use up to six hours, CentriMag and PediMag can be used as a short-term solution to support the circulation while longer-term options are considered.
- Additionally, 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 VAS* 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 and PediMag offer a range of features and benefits:

- **Simplicity/Ease-of-Use.** The CentriMag and PediMag blood pumps are simple to implant and manage.
- **Minimize Blood-Related Complications.** The CentriMag and PediMag have 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.
- **Common hardware platform.** Both the CentriMag and PediMag operate on an identical hardware platform, eliminating the need to invest in separate systems to support adult and pediatric patients.

How it works: The CentriMag and PediMag Systems comprise a single-use centrifugal pump, a motor and a primary drive console. They are designed to operate without mechanical bearings or seals, as the motor magnetically levitates the impeller, achieving rotation with no friction or wearⁱ.

The CentriMag and PediMag can be used for perioperative or postcardiotomy circulatory support of the failing heart. Each 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.

DEVICE	DURATION	INDICATION	STATUS
Thoratec CentriMag and PediMag Blood Pumps	• 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	• Clinical trial underway in the U.S. • Received Conformité Européene (CE) Mark

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† Humanitarian Use Device. The 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 VAS use as a VAD for support for up to 30 days.

* CAUTION: The CentriMag VAS is an Investigational Device limited by Federal (U.S.A.) law to investigational use.

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