



CentriMag™ and PediMag™ Blood Pumps

PRODUCT HIGHLIGHTS

The only acute blood pumps driven by Full MagLev™ Flow Technology for excellent hemocompatibility across the widest range of patient applications

- Both blood pumps are compatible with the same hardware — no extra equipment required
- The pumps' rotors are fully magnetically levitated — no bearings or seals for a contact-free blood chamber, leading to minimized blood stagnation, friction and shear stress^{1,2}

PRODUCT SPECIFICATIONS

	CENTRIMAG™ BLOOD PUMP	PEDIMAG™ BLOOD PUMP*
Material, blood-contacting surfaces	Polycarbonate	Polycarbonate
Priming volume	31 mL	14 mL
Maximum flow rate	10 liters per minute	1.5 liters per minute
Connectors	3/8" barbed inflow and outflow ports	1/4" barbed inflow and outflow ports
Maximum operating pressure	600 mmHg	540 mmHg

PRODUCT LIST

PART NUMBER	DESCRIPTION
102953	CentriMag™ Blood Pump
201-90052	PediMag™ Blood Pump*



CentriMag™ Blood Pump



PediMag™ Blood Pump

***PMA approval for 30-day use of CentriMag™ System components include:** CentriMag™ Pump, CentriMag™ Console, CentriMag™ Motor, Mag Monitor, Flow Probe, and CentriMag™ Drainage Cannula and CentriMag™ Return Cannula.

Optional accessories include: CentriMag™ System Cart, CentriMag™ System Transporter and Pressure Transducer.

PMA approval for 30-day use of CentriMag™ System excludes: PediMag™ Blood Pump and any other pediatric components or accessories.

1. Aziz TA, Singh G, Popjes E, Stephenson E, Mulvey S, Pae W, El-Banayosa A. Initial experience with CentriMag extracorporeal membrane oxygenation for support of critically ill patients with refractory cardiogenic shock. *J Heart Lung Transplant.* 2010;29(1):66-71.
2. Bhama JK, Kormos RL, Toyoda Y, Teuteberg JJ, McCurry KR, Siegenthaler MP. Clinical experience using the Levitronix CentriMag system for temporary right ventricular mechanical circulatory support. *J Heart Lung Transplant.* 2009;28(9):971-976.

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Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

CentriMag™ Circulatory Support System Indications [PMA Approval; 30-day use]: Temporary circulatory support for up to 30 days for one or both sides of the heart to treat post-cardiotomy patients who fail to wean from cardiopulmonary bypass, providing 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.

CentriMag™ Circulatory Support System Contraindications [PMA Approval; 30-day use]: The CentriMag™ Circulatory Support System is contraindicated for use as a cardiomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

CentriMag™ Circulatory Support System Adverse Events [PMA Approval; 30-day use]: Adverse events that may be associated with mechanical circulatory support can include, but are not limited to, the following: bleeding on device support, hemolysis, infection, renal failure/dysfunction/complication, respiratory dysfunction, hepatic dysfunction, cardiac arrhythmias (atrial or ventricular), thromboembolism (venous and arterial non-CNS), hypotension, hypertension, device malfunction or failure, psychiatric events, right heart failure, and death.

Humanitarian Device Statement: Caution: Humanitarian Device. The CentriMag Circulatory Support System is authorized by Federal Law for temporary circulatory support for up to 30 days for patients in cardiogenic shock due to right ventricular failure. The effectiveness of this device for this use has not been demonstrated.

CentriMag™ RVAS Indications [Humanitarian Exemption Device (HDE) Approval; 30-day use]: The CentriMag Circulatory Support System is intended to provide temporary circulatory support for up to 30 days for patients in cardiogenic shock due to acute right ventricular failure.

CentriMag™ RVAS Contraindications [Humanitarian Exemption Device (HDE) Approval; 30-day use]: The CentriMag Circulatory Support System is contraindicated for use as a cardiomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

CentriMag™ Acute Circulatory Support System Temporary Expanded Indication: The FDA issued an enforcement policy guidance document in April 2020 allowing for FDA-cleared or approved cardiopulmonary bypass devices to be used in an ECMO circuit to treat patients who are experiencing acute respiratory failure and/or acute cardiopulmonary failure during the COVID-19 public health emergency. The CentriMag™ System including the CentriMag™ Blood Pump and PediMag™ Blood Pump are indicated for use as part of an ECMO circuit for longer than 6 hours to treat patients with acute respiratory failure and/or acute cardiopulmonary failure.

CentriMag™ Blood Pump Indications [510(k) Clearance; 6-hour use]: The CentriMag™ Circulatory Support System is indicated to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g. valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc.).

CentriMag™ Blood Pump Contraindications [510(k) Clearance; 6-hour use]: The CentriMag Circulatory Support System is contraindicated for use as a cardiomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

PediMag™ Blood Pump Indications for Use [510(k) Clearance; 6-hour use]: The PediMag™ Blood Pump is indicated for use with the CentriMag Circulatory Support System console and motor to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours) for surgical procedures such as mitral valve reoperation. It is also indicated for use in extracorporeal support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g. valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc.).

PediMag™ Blood Pump Contraindications [510(k) Clearance; 6-hour use]: The PediMag Blood Pump is contraindicated for use as a cardiomy suction device. The CentriMag Circulatory Support System is contraindicated for use as a cardiomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

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