



2nd Generation CentriMag™ Acute Circulatory Support System

PRODUCT HIGHLIGHTS

Second-generation CentriMag™ System hardware designed for simple, easy and safe operation of the CentriMag™ and PediMag™ Blood Pumps.

- All CentriMag System hardware is compatible with CentriMag and PediMag Blood Pumps.
- Monitor can be connected to one or two consoles to automatically display univentricular or biventricular data as appropriate.
- Internal rechargeable lithium-ion battery provides two hours of power at typical operating parameters.
- Monitor includes USB port for data export.
- Consoles are designed to be stacked, and can be affixed to a cart using included hardware.

PRODUCT SPECIFICATIONS

PART NUMBER	DESCRIPTION
201-90411	CentriMag 2nd Generation Console
201-90404	Monitor Kit (Includes: CentriMag Monitor, Monitor Arm Clamp, Monitor Arm)
102956	CentriMag Motor
201-30105	3/8" Flow Probe for CentriMag 2nd Generation Console
201-30107	1/4" Flow Probe for CentriMag 2nd Generation Console



2nd Generation CentriMag™ Acute Circulatory Support System

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.

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Rx Only

Important Safety Information

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 cardiotomy 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.

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 cardiotomy 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 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 cardiotomy 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 cardiotomy suction device. The CentriMag Circulatory Support System is contraindicated for use as a cardiotomy 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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