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2nd Generation CentriMag™ Acute Circulatory Support System

PRODUCT HIGHLIGHTS

2nd 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 2 hours of power at typical operating parameters.
- Live data transfer of system parameters is capable through the optional CentriMag™ RS Data Cable.
- Consoles are designed to be stacked and can be affixed to a cart using included hardware.

Note: Use appropriate Abbott-provided hardware only.

PRODUCT SPECIFICATIONS

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

2nd Generation CentriMag™
Acute Circulatory Support System

ECMO = extracorporeal membrane oxygenation
VAD = ventricular assist device

*ECMO clearance for > 6-hour use is indicated for the CentriMag™ Blood Pump to be used with: CentriMag™ Console, CentriMag™ Motor, Mag Monitor and Flow Probe. ECMO clearance for the CentriMag™ Blood Pump is for adult use only and excludes CentriMag™ Drainage Cannula and CentriMag™ Return Cannula.

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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6101 Stoneridge Dr., Pleasanton, CA 94588 USA, Tel: 1 925 847 8600
Cardiovascular.Abbott/CentriMag

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 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™ 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, cardia 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 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™ Circulatory Support System Indications [510(k) Clearance; 6-hour use]: The CentriMag Extracorporeal Blood Pumping System is a non-roller-type cardiopulmonary and circulatory bypass blood pump used to pump a patient's blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either:
i. Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels: or
ii. Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava

CentriMag™ Circulatory Support System 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™ Console and Motor. It is a non-roller-type cardiopulmonary and circulatory bypass blood pump used to pump a patient's blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either:
1. Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels: or
2. Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava

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.

CentriMag™ Blood Pump Indication [ECMO, 510(k) Clearance; >6-hour use]: The CentriMag™ Blood Pump for use with CentriMag™ Acute Circulatory Support System (Motor, Monitor, Console, and Flow Probes) is indicated for controlling blood flow as part of an extracorporeal membrane oxygenation (ECMO) circuit. ECMO is intended to provide assisted extracorporeal circulation and physiologic gas exchange of the patients' blood for adult patients with acute respiratory failure and/or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent.

CentriMag™ Blood Pump Contraindications [ECMO, 510(k) Clearance; >6-hour use]: The CentriMag™ 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 Adverse Events [ECMO, 510(k) Clearance; >6-hour use]: Potential adverse events associated with the use of extracorporeal membrane oxygenation include, but are not limited to the following: Death, Mechanical Failures/Dysfunction, Bleeding (including Cardiac Tamponade), Hemolysis (including Hemoglobinuria, Anemia, Hyperbilirubinemia), Neurologic Dysfunction (including Stroke, Seizures), Cardiac Dysfunction (including Myocardial Infarction, Arrythmias, Right/Left Heart Failure), Hypertension, Hypotension, Vascular (including Air Embolism, Thromboembolism (venous/arterial), Limb Ischemia, Vascular Damage) Pulmonary Dysfunction (including Pulmonary Embolism, Respiratory Failure), Renal Dysfunction, Cardiogenic Shock, Hypovolemia, Hypervolemia, Hepatic Dysfunction, Coagulation Disorders (including Thrombocytopenia, DIC), Infection (including Wound Dehiscence), Metabolic/Respiratory Acidosis, Psychiatric Disorder.

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