

CentriMag[™] System Transporter



CentriMag[™] System Transporter

PRODUCT HIGHLIGHTS

Get patients where they need to be with a modular transportation solution. The CentriMag[™] System Transporter provides the durability and protection needed to safely transport patients inside or outside the hospital, including via ground or air ambulance.

Key Features

- Space for core system components, including console, pump/motor, oxygenator and oxygen tank
- No ground plate required; CentriMag[™] Pump impeller maintains its orientation automatically through Full MagLev[™] Flow Technology
- Brackets available for most commercially available oxygenators, including the Eurosets AMG PMP Adult Oxygenator, available only from Abbott
- Complies with standards for air and ground transportation, including RTCA/DO-160G, IEC 60068-2-27 and IEC 60068-2-6
- Collapsible hooks on back of transporter allow frame to mount onto rail
- Allows for detachment of side compartments for greater transport flexibility

PRODUCT SPECIFICATIONS

SPECIFICATIONS	
Height	557 mm
Width	766 mm
Depth	186 mm
Weight	9.2 kg

HARDWARE SPECIFICATIONS

PART NUMBER	DESCRIPTION	DIAMETER
201-50140	CentriMag™ System Transporter (Oxygenator Bracket Not Included)	NA
201-50141	Small Circular Oxygenator Bracket	55 mm
201-50142	Medium Circular Oxygenator Bracket	67 mm
201-50143	Large Circular Oxygenator Bracket	90 mm
201-50144	Square Oxygen Bracket	NA



CentriMag System Transporter with sides detached for flexibility during transport

AMG PMP Oxygenators and Oxygenator Holder are manufactured by Eurosets s.r.l. and distributed by Abbott.

*PMA approval for 30-day use of CentriMagTM System components include: CentriMagTM Pump, CentriMagTM Console, CentriMagTM 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. Abbott

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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 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 TM 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™ 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 CentriMagTM Blood Pump and PediMagTM 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 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 yena caya 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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