

CentriMag™ System Cart



PRODUCT HIGHLIGHTS

Maximize convenience with a configurable cart solution built to safely secure your complete CentriMag $^{\text{\tiny TM}}$ System. The CentriMag System cart gives you the versatility you need to organize your system in any configuration.

Key Features

- Gas tank holder
- Four lockable wheels
- Two telescoping poles with IV hooks
- Locking bolt to secure up to two consoles per upper shelves
- Drawer for additional storage
- Middle shelf fully adjustable (18 in wide × 19.5 in deep)

PRODUCT SPECIFICATIONS

SPECIFICATIONS	METRIC
Height	53–86 in (depending on IV pole height)
Width	21 in
Depth	25.5 in
Weight	78 lb

HARDWARE LIST

PART NUMBER	DESCRIPTION
107533	System Cart

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 circulat 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 Blood Pump is contraindicated for use as a cardiotomy suction device. It is also contraindicated for patients who are unable or unwilling to be treated with Heparin or an appropriate alternative anti-coagulant.

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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