Abbott

FEWER STEPS TO FULL SUPPORT

CentriMag™ Acute Circulatory Support System with Full MagLev™ Flow Technology

The ONLY device approved for 30-day LVAD, RVAD and BiVAD*

CENTRIMAG™ ACUTE CIRCULATORY SUPPORT SYSTEM

WITH FULL MAGLEV™ FLOW TECHNOLOGY

The CentriMag™ Acute Circulatory Support System with Full MagLev™ Flow Technology is designed to deliver excellent hemocompatibility across the widest range of patient applications.[1,2]

BACKED BY AN UNMATCHED LEGACY OF EXPERIENCE

LOW

Device failure rate for consistent, trusted performance[1-4]

440+

Published articles[5]

70,000+

CentriMag™ Pumps sold since 2006

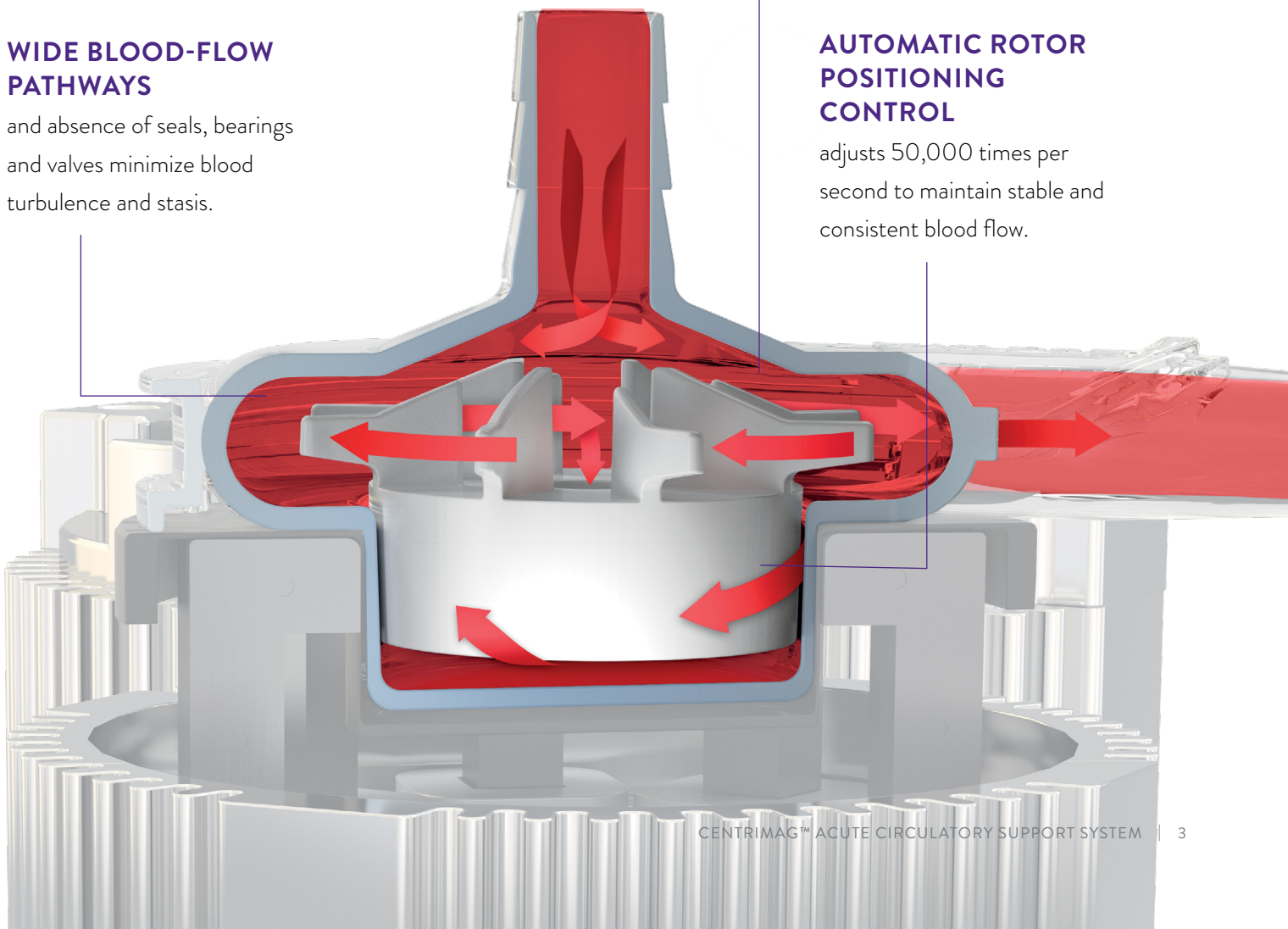
"IF IT WASN'T FOR MY INCREDIBLE CARE TEAM, AND THIS TRULY AMAZING TECHNOLOGY, I DON'T BELIEVE I WOULD BE HERE TO COACH MY SON'S BASEBALL GAMES."
— MIKE S.

FULL MAGLEV™ FLOW TECHNOLOGY PROMOTES GENTLE BLOOD HANDLING[1-3]

WIDE BLOOD-FLOW PATHWAYS
and absence of seals, bearings and valves minimize blood turbulence and stasis.

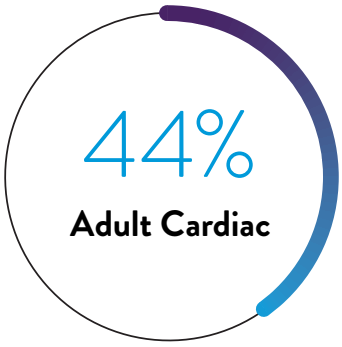
FREE-FLOATING MAGNETICALLY LEVITATED ROTOR
prevents surface-to-surface contact that could cause blood trauma.

AUTOMATIC ROTOR POSITIONING CONTROL
adjusts 50,000 times per second to maintain stable and consistent blood flow.



EXCELLENT SURVIVAL OUTCOMES AT DISCHARGE

ELSO INTERNATIONAL SUMMARY:
SURVIVAL TO DISCHARGE[6]



CENTRIMAG™ BLOOD PUMP:
SURVIVAL TO DISCHARGE[7]

Survival to discharge for other adult support indications includes 54% overall, 30% ECPR and 59% pulmonary.

PUMP DESIGNED FOR OPTIMAL HEMOCOMPATIBILITY[1,2,8]

FULL MAGLEV™ FLOW TECHNOLOGY ENABLES EXCELLENT HEMODYNAMICS[3,4,8]

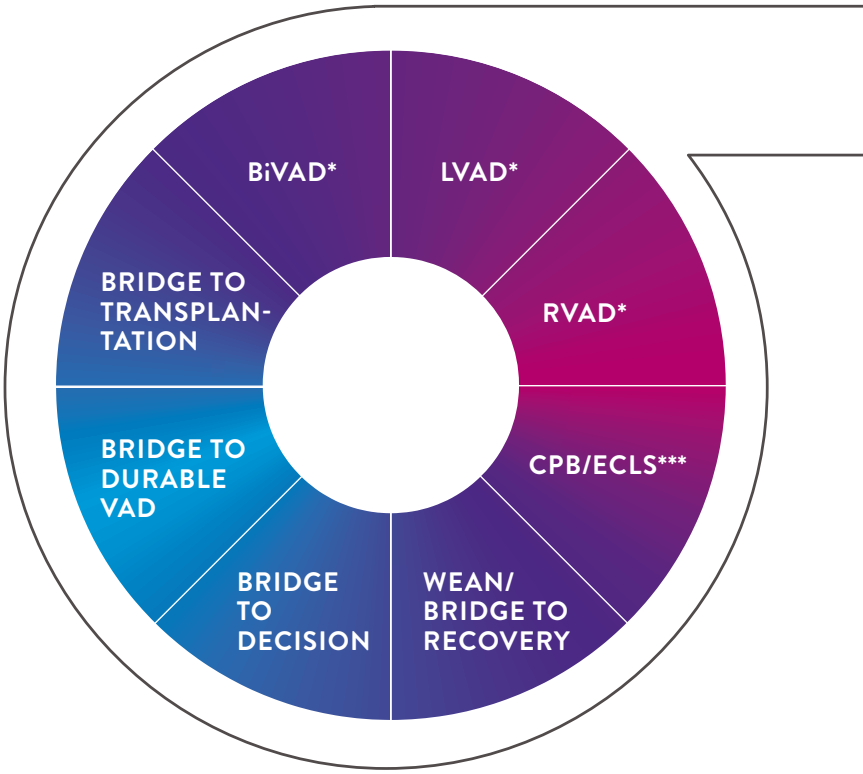
LOW DEVICE-RELATED THROMBOSIS[1]
2.5%

LOW HEMOLYSIS[1]
5%

MINIMIZED BLOOD STAGNATION, FRICTION AND SHEAR STRESS[2,3,8]

MOST VERSATILE SYSTEM FOR ESCALATION AND DE-ESCALATION OF THERAPY[9-11]

The CentriMag™ System is the most versatile platform available, addressing the broadest spectrum of clinical challenges, eliminating the need to train on multiple platforms, and reducing the burden on center resources.



TRUSTED FOR A WIDE RANGE OF PATIENT TYPES AND SIZES

CentriMag System hardware (console, motor and monitor) is shared between the adult and pediatric pump options.

PRODUCES FLOWS OF UP TO 10 LPM WITH FEWER ROTATIONS PER MINUTE[3]

Adult and pediatric pump options are available.*

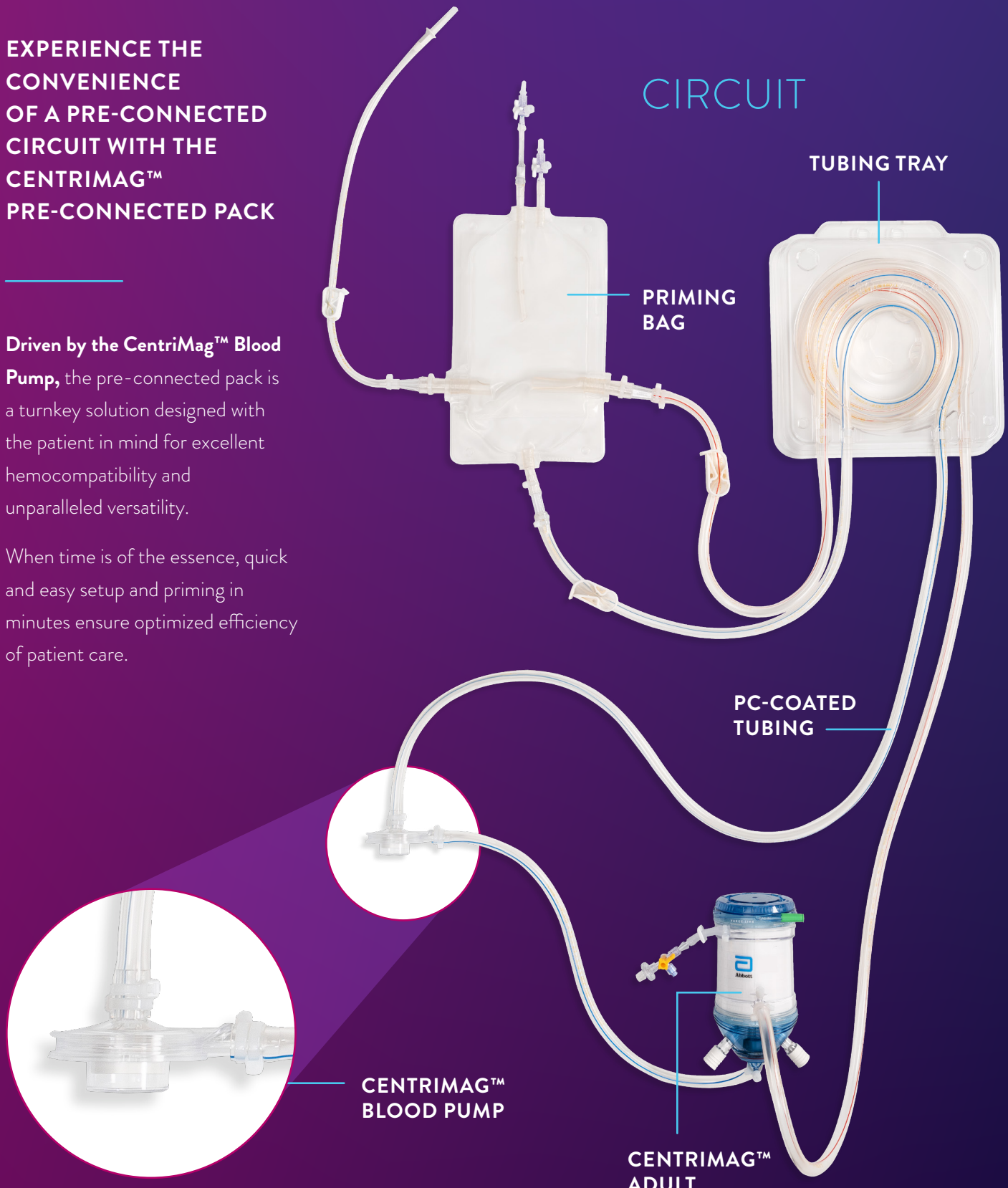
CENTRIMAG™ PRE-CONNECTED PACK

FEWER STEPS TO **FULL SUPPORT**

EXPERIENCE THE CONVENIENCE OF A PRE-CONNECTED CIRCUIT WITH THE CENTRIMAG™ PRE-CONNECTED PACK

Driven by the CentriMag™ Blood Pump, the pre-connected pack is a turnkey solution designed with the patient in mind for excellent hemocompatibility and unparalleled versatility.

When time is of the essence, quick and easy setup and priming in minutes ensure optimized efficiency of patient care.



ACCESSORIES

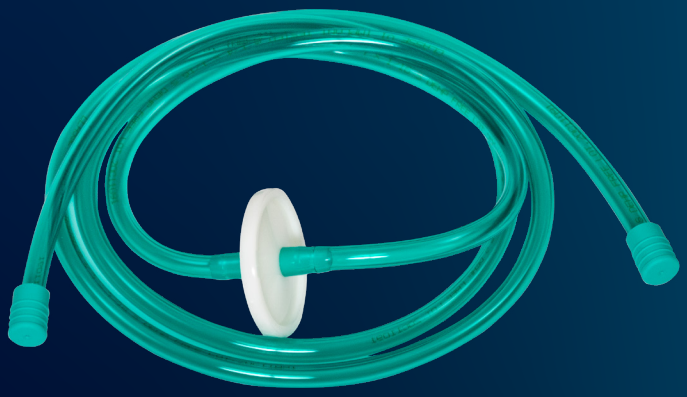
CUTTER (1)

HIGH-FLOW PIGTAILS WITH THREE-WAY STOPCOCK (4)

3/8-INCH CONNECTORS WITH LUER (2)

TUBING CLAMPS (5)

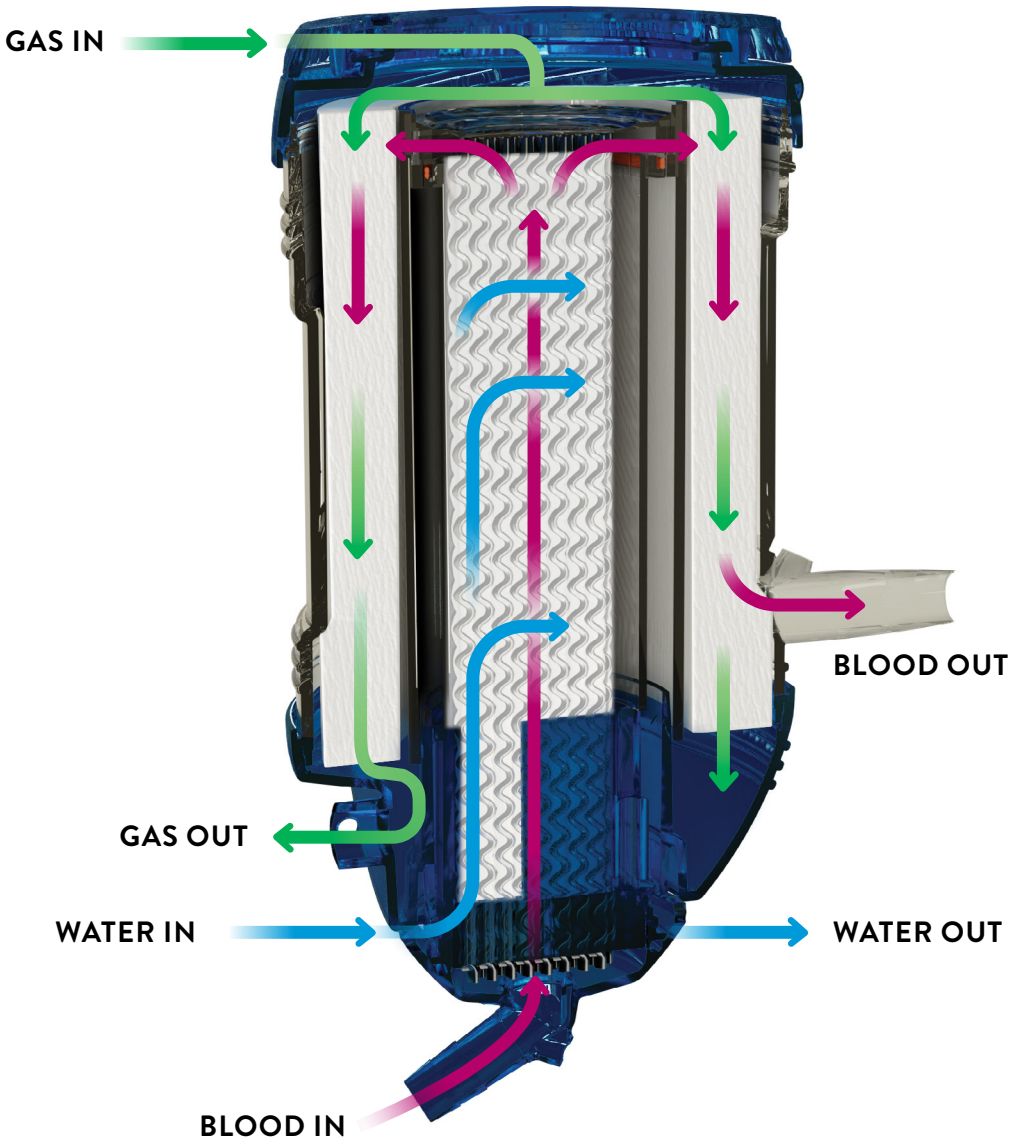
TIE BANDS (8)



GAS LINE (1)

AMG PMP OXYGENATORS

When paired with the Full MagLev™ Flow Technology of the CentriMag™ and PediMag™ Blood Pumps, our portfolio of AMG PMP Oxygenators provides a comprehensive solution for a wide variety of patients.



AMG PMP OXYGENATOR BENEFITS AND FEATURES

- PMP fibers ensure reliable gas-exchange performance over the duration of use.
- PC coating minimizes inflammation[1] and thrombosis.[2]
- Stainless steel heat exchanger helps eliminate risk of potential contamination.
- Shape, fiber orientation and blood-flow path are designed for low shear stress.

CentriMag™ Adult Oxygenator

AMG PMP OXYGENATORS

AMG PMP Adult Oxygenator

AMG PMP Pediatric Oxygenator

AMG PMP Infant Oxygenator

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

CENTRIMAG™ SYSTEM TRANSPORTER GETS PATIENTS WHERE THEY NEED TO BE

A COMPACT MODULAR SOLUTION FOR IN-HOSPITAL OR OUT-OF-HOSPITAL TRANSPORTATION

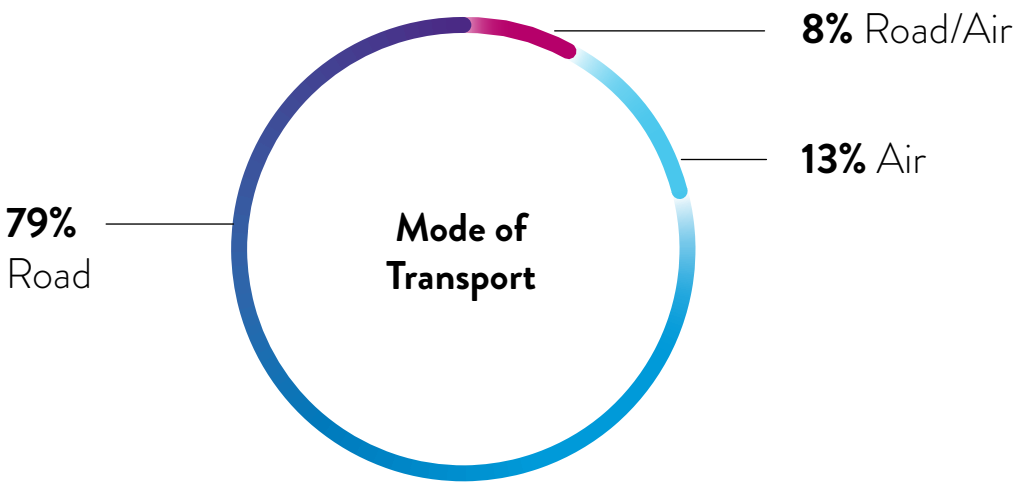
Get patients where they need to be with the next-generation CentriMag™ System Transporter. The CentriMag™ System Transporter is an optional accessory to the CentriMag™ Acute Circulatory Support System to facilitate patient transport by ground vehicle or aircraft as well as operation in the EMS environment.

TRANSPORT SUCCESS
DEMONSTRATED BY EXCELLENT REAL-WORLD EXPERIENCE[12]

BUILDING ON 10 YEARS OF TRANSPORT DATA WITH THE CENTRIMAG™ ACUTE CIRCULATORY SUPPORT SYSTEM[1]

Mobile ECMO Transports Demographic Breakdown

51% Adult **32%** Pediatric **17%** Neonate



MOBILE ECMO IS SAFE AND RELIABLE TO TRANSFER THE SICKEST OF PATIENTS

5.5 hours
average transport duration

No major complications
or deaths during transport

> 84% survival
to hospital discharge after transport

FOR MORE INFORMATION on the CentriMag™ Acute Circulatory Support System or how to order the different system components, contact your Abbott representative.

EMPOWERING THE TRANSFORMATION OF HEART FAILURE

From treatment to ongoing patient management, Abbott is committed to working with you to transform heart failure and improve more patient lives.

BiVAD = biventricular assist device; CPB = cardiopulmonary bypass; ECLS = extracorporeal life support; ECMO = extracorporeal membrane oxygenation; ECPR = extracorporeal cardiopulmonary resuscitation; ELSO = Extracorporeal Life Support Organization; EMS = emergency medical services; LVAD = left ventricular assist device; PC = phosphorylcholine; PMA = pre-market approval; PMP = polymethylpentene; RVAD = right ventricular assist device; VA-ECMO = veno-arterial extracorporeal membrane oxygenation; VAD = ventricular assist device

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

**As part of a VA-ECMO circuit.

***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.

1. John R, Massey HT, Griffith BP, et al. Outcomes of a multicenter trial of the Levitronix CentriMag ventricular assist system for short-term circulatory support. *J Thoracic Cardiovasc Surg*. 2011;141:932-939.
2. John R, Liao K, Lietz K, et al. Experience with the Levitronix CentriMag circulatory support system as a bridge to decision in patients with refractory acute cardiogenic shock and multisystem organ failure. *J Thorac Cardiovasc Surg*. 2007;134:351-358.
3. Aziz TA, Singh G, Popjes E, et al. Initial experience with CentriMag extracorporeal membrane oxygenation for support of critically ill patients with refractory cardiogenic shock. *J Heart Lung Transplant*. 2010;29:66-71.
4. Bhama JK, Kormos RL, Toyoda Y, et al. Clinical experience using the Levitronix CentriMag system for temporary right ventricular mechanical circulatory support. *J Heart Lung Transplant*. 2009;28:971-976.
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8. Zhang J, Gellman B, Koert A, et al. Computational and experimental evaluation of the fluid dynamics and hemocompatibility of the CentriMag blood pump. *Artificial Organs*. 2006;30:168-177.
9. Takeda K, Garan AR, Ando M, et al. Minimally invasive CentriMag ventricular assist device support integrated with extracorporeal membrane oxygenation in cardiogenic shock patients: a comparison with conventional CentriMag biventricular support configuration. *Euro J of Cardio-Thoracic Surgery*. 2017;52:1055-1061.
10. Takayama H, Soni L, Kalesan B, et al. Bridge-to-decision therapy with a continuous-flow external ventricular assist device in refractory cardiogenic shock of various cases. *Circ Heart Failure*. 2014;7:799-806.
11. Worku B, Pak S, Patten D, et al. The CentriMag ventricular assist device in acute heart failure refractory to medical management. *J of Heart & Lung Transplantation*. 2012;31:611-617.
12. Corno A, Faulkner G, Harvey C. Mobile extracorporeal membrane oxygenation. *ASAIO Journal*. 2020. doi:10.1097/MAT.0000000000012786

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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™ Adult Pre-connected Pack Indications for Use [510(k) Clearance; 6-hour use]: The CentriMag™ Adult Pre-connected Pack is indicated for use with the CentriMag™ Acute Circulatory Support System to provide physiologic gas exchange of the blood and to pump a patient's blood through an extracorporeal circuit for periods lasting less than six (6) hours for the purpose of providing either: (i) Full or partial cardiopulmonary bypass 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 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™ 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 Indication [ECMO, 510(k) Clearance; >6-hour use]: The CentriMag™ Blood Pump for use with the 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.

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.

MAT-1901664 v2.0 | Item approved for U.S. use only.

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