Abbott

CentriMag™ Acute Circulatory Support System

THE **MOST VERSATILE** SYSTEM AVAILABLE

LVAD, RVAD, BiVAD AND ECMO* CAPABILITY ALLOWS **ESCALATION** AND **DE-ESCALATION** OF THERAPY

*ECMO for >6 hours use is authorized under FDAs enforcement policy guidance during the COVID-19 public health emergency.

PROVEN VERSATILITY DATA

ESCALATION OF THERAPY

WORKU[1] STUDY

VAD ● ● ● ● ● ● ● ● ● ● ● ● **ECMO***

22% of patients required **escalation** of therapy by adding an **oxygenator to the RVAD circuit**

In this study, **22% of patients** required escalation of therapy easily managed with the CentriMag™ Blood Pump by adding an oxygenator to the RVAD circuit.

A retrospective analysis of **27 patients** who received support with the CentriMag Blood Pump due to failure of medical management. **A 74% survival to hospital discharge was achieved.**

Age: **47 years old**

Length of support: **15.9 days**

INTERMACS‡ 1: **67%**

Configurations: **96% BiVAD | 4% LVAD**

SIGNIFICANT IMPROVEMENT IN HEPATIC AND RENAL FUNCTION DURING SUPPORT

Percutaneous devices allow for stabilization and decision-making, but are somewhat limited in flow rates and versatility, which may require conversion.[1]

DE-ESCALATION OF THERAPY

TAKAYAMA[2] STUDY

ECMO* ● ● ● ● ● ● ● ● ● ● ● **VAD**

30% of patients were **de-escalated from ECMO to VAD**

Age: **52 years old**

Length of support: **14 days**

INTERMACS‡ 1: **71%**

A retrospective analysis of **143 patients** who underwent support as bridge-to-decision using the CentriMag™ System.

Using a multistep weaning protocol easily managed with the CentriMag Blood Pump, an overall **30-day survival rate of 69%** was achieved.

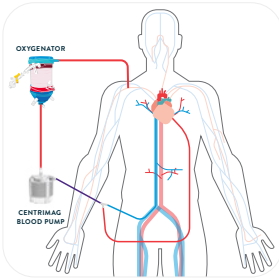
SIGNIFICANT HEMODYNAMIC IMPROVEMENT AND IMPROVED LACTIC ACIDOSIS AFTER SUPPORT

DE-ESCALATION OF THERAPY

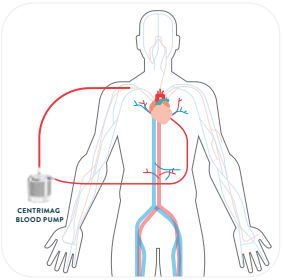
TAKEDA[3] STUDY

ECMO* ● ● ● ● ● ● ● ● ● ● ● **VAD**

A retrospective analysis of **112 patients** who underwent support with the CentriMag™ Blood Pump, as part of an ECMO circuit, comparing cannulation via conventional sternotomy and a minimally invasive technique.



Ec-VAD ECMO
LV apex inflow; RV unloading with femoral cannula; right axillary artery outflow return



APICO-AXILLARY LVAD
After removal of femoral cannula and oxygenator

EC-VAD

86% 30-DAY SURVIVAL

32% ($p < 0.01$) SIGNIFICANTLY LESS BLEEDING

With the versatility of the CentriMag™ System, Ec-VAD patients were able to be de-escalated from ECMO to apico-axillary LVAD, enabling ambulation and rehabilitation during recovery.

CONTACT YOUR ABBOTT REPRESENTATIVE TO LEARN MORE ABOUT THE **CENTRIMAG™ ACUTE CIRCULATORY SUPPORT SYSTEM**.

BiVAD = biventricular assist device
ECMO = extracorporeal membrane oxygenation
Ec-VAD = extracorporeal membrane oxygenation and CentriMag ventricular assist device
LV = left ventricular
LVAD = left ventricular assist device
RV = right ventricular
RVAD = right ventricular assist device
VAD = ventricular assist device

1. Worku B, Pak S, van Patten D, et al. The CentriMag ventricular assist device in acute heart failure refractory to medical management. *J Heart Lung Transplant*. June 2012;6;611-617.

2. 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 causes. *Circulation: Heart Failure*. September 2014;7(5):799-806.

3. 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. *European Journal of Cardio-Thoracic Surgery*. December 1, 2017;52(6):1055-1061.

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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™ 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 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.

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.

MAT-2104041 v1.0 | Item approved for U.S. use only.

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