Abbott's Life Support System Receives New FDA Clearances To Help Doctors Treat More Critically Ill Patients

- Abbott's CentriMag™ Blood Pump, previously cleared for use up to six hours, now can be used to provide longer-term life support to critically ill patients, providing doctors more time to make critical care decisions
- Abbott's CentriMag™ Pre-connected Pack, which combines a blood pump and oxygenator to form a life support circuit, also received FDA clearance for life support lasting less than six hours, helping physicians provide urgent critical care more efficiently and in fewer steps

ABBOTT PARK, Ill., April 25, 2023 /PRNewswire/ -- Abbott (NYSE: ABT) today announced two new clearances from the U.S. Food and Drug Administration (FDA) for the company's industry-leading life support system. With the new indication, the CentriMag Blood Pump for use with the CentriMag™ System, is now cleared for longer-term use in adults when extracorporeal membrane oxygenation (ECMO) – a type of life support for people whose heart and lungs are not working – is critical to saving their life. Now, the clearance for longer-term support allows physicians more time to assess next steps and make critical care decisions for their patients.

Abbott also received FDA clearance for its newCentriMag Pre-connected Pack – a packaged system with several pre-connected components of the CentriMag system that can accelerate the deployment of the life support system. Combined, the dual clearances further build out Abbott's ability to offer leading life support systems to hospitals and physicians managing critically ill patients.

New Indication Provides More Time on Life Support

The CentriMag pump was previously cleared for providing life support for up to six hours – often referred to as "short-term support" – which limited the flexibility for doctors to make care decisions for patients battling critical conditions or for those whose heart can't pump enough blood to meet their body's needs. By providing prolonged life support for more than six hours through ECMO – which physicians often call "long-term support" – Abbott's CentriMag pump temporarily replaces the function of the heart.

The life support system pumps blood outside of the body and into a series of devices that add oxygen, where a machine then pumps the oxygenated blood back into the body[i]. Used in intensive care units, the support became a life-saving resource for many people during the COVID-19 pandemic.

"Life support technology is a critical tool for physicians as we assess next steps for our sickest patients. The need for long-term support from systems like the Abbott CentriMag pump was vital during the COVID-19 pandemic," said Antone Tatooles, M.D., a cardiothoracic surgeon at Advocate Christ Hospital and Medical Center in Oak Lawn, Ill.

Aside from treating patients with conditions such as COVID-19, the new longer-term indication for Abbott's CentriMag pump also provides physicians with more options for treating patients who have undergone open heart surgery and require further ECMO support.

Second FDA Clearance Strives to Give Physicians More Time

In addition to a longer-term indication for the CentriMag pump for use with the CentriMag system, Abbott also received FDA clearance for its CentriMag Pre-connected Pack for urgent cardiopulmonary support lasting less than six hours. The Pre-connected Pack combines several system components including the blood pump and oxygenator, allowing physicians to provide full support in fewer steps in the most urgent of critical care settings. Previous to this clearance, the system needed to be put together from separate components, which could lead to delays in urgent care.

"With CentriMag, our mission has always been to transform the treatment of advanced cardiac and respiratory conditions to improve clinicians' ability to most effectively manage their sickest patients," said Robert L. Kormos, M.D., divisional vice president, global medical affairs, Abbott's heart failure business. "With the two new FDA clearances, physicians can deploy support in fewer steps and are provided more time to get their patients the necessary treatment during a critical window."

Indications and Important Safety Information:

For U.S. important safety information for the CentriMag System and Pre-connected Pack, visit:Indications, Safety and Warnings for the CentriMag System | Abbott (cardiovascular.abbott)

About Abbott

Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 115,000 colleagues serve people in more than 160 countries.

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[i] Cleveland Clinic. *ECMO.* What Is ECMO? (clevelandclinic.org). Accessed April 7, 2023.

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