Latest

FDA Clears MC3 Cardiopulmonary Nautilus™ device for Extracorporeal Membrane Oxygenation (ECMO), Enabling Support of Patients with Respiratory and Cardiopulmonary Failure

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MC3 Cardiopulmonary (mc3corp.com), The ECMO Company™, announces FDA clearance for the Nautilus™ portfolio of products for use in ECMO.

MC3's Nautilus™ Smart ECMO Module used for extracorporeal life support procedures in patients requiring respiratory and/or cardiopulmonary support. The device oxygenates blood, removes carbon dioxide, regulates blood temperature and provides real-time hemodynamic data analytics. It's the first device that combines the capabilities of a long-term, plasma-tight Polymethylpentene (PMP) hollow fiber ECMO oxygenator and the integration of real time, at-a-glance-enabled hemodynamic monitoring into one disposable life-support device.

The Nautilus™ Module connects to most component-based blood pumps. Blood enters the device and passes through both the heat exchange membrane—where temperature is adjusted—and the gas transfer membrane—where oxygen is added, and carbon dioxide is removed. The device contains integrated sensors with an electronic touch screen display and a status bar that enables vital, at-a-glance monitoring of hemodynamic device health parameters.

"ECMO technology is advancing rapidly, and clinicians are finding clinical value in its capability to provide life support for select patients, deemed candidates, after traditional therapies such as mechanical ventilation have failed," said Scott Merz, CEO of MC3 Cardiopulmonary. "Due to the disposable nature of the Nautilus™ Smart ECMO Module, we can connect it with virtually any component-based blood pump used in ECMO to provide state-of-the-art support and data monitoring for a versatile user base."

The FDA clearance of the Nautilus™ portfolio of products, follow the CE Mark and launch of the Nautilus™ devices in Europe and the CE Mark and FDA clearance and launch of MC3's Crescent® Dual Lumen Catheter for VV ECMO and the Opus™ Vascular Access Kit. The Crescent® catheter was the first device cleared by the FDA for ECMO in the United States. MC3's portfolio of ECMO products are distributed by Medtronic.