



TANDEMHEART CLEARED FOR USE WITH OXYGENATOR

Oxygenator technology now an FDA-cleared optional accessory to the TandemHeart extracorporeal blood circuit

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The TandemHeart circulatory support system has been cleared by the FDA for use with an oxygenator, which is a medical device that exchanges oxygen for carbon dioxide in the blood of a patient with compromised lung function. The TandemHeart system is now the only FDA-cleared temporary circulatory support device providing the transeptal advantage of direct left ventricular unloading together with blood oxygenation in both percutaneous and surgical configurations.

“We truly appreciate the FDA decision to include oxygenator technology as an optional component of the TandemHeart system,” said Kraig McEwen, President and CEO of CardiacAssist, Inc. “In the past several years, we have seen a dramatic increase in the prevalence of oxygenator integration with the TandemHeart circuit as physicians have gained confidence with this resurgent approach. This labeling change will enable us to better care for our physician customers and their patients with the most knowledgeable clinical education and support team in the industry.”

The TandemHeart system is designed to provide a high degree of direct left ventricular unloading through a percutaneous transeptal approach, allowing damaged heart muscle to rest while augmenting the flow of blood to the patient’s vital organs and the rest of the body. However, many patients with decreased cardiac function are further challenged by a deterioration of the lungs’ ability to properly oxygenate the blood. The addition of oxygenator technology to the powerful support capability of the TandemHeart provides a unique tool for physicians and opens new treatment options to patients in need of cardiopulmonary support.

About TandemHeart

The FDA-cleared TandemHeart system has been used by physicians to provide critical heart support to over 2,500 patients at more than 170 of the top cardiac centers in the United States. With flow rates up to 5.0 liters per minute, the TandemHeart delivers up to 5 times more hemodynamic support than the intra-aortic balloon pump and twice the support of any other available percutaneous technology.

About CardiacAssist

Headquartered in Pittsburgh, PA, privately held CardiacAssist is a growing medical technology company that develops, manufactures and markets cardiac assist devices. The company developed the TandemHeart system, the world’s first FDA-cleared and CE-marked short-term extracorporeal circulatory support system for both cardiologists and cardiac surgeons.

SOURCE: CardiacAssist, Inc.

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