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## Medtronic Gains CE Mark for New Oxygenation System for Adult Cardiac Surgery



# Medtronic

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Medtronic, Inc. announced on September 24th, Conformité Européenne (CE) Mark for its new Affinity Fusion® oxygenation system in Europe. This system, which is designed to serve as a patient's lungs by oxygenating and removing carbon dioxide from blood during various open-heart surgical procedures, incorporates numerous innovations for patient safety and ease of use. Notably, system enhancements are designed to prevent and remove air bubbles that can enter the blood during the procedure, which may reduce the risk of stroke.

The Affinity Fusion oxygenation system's new design enhancements include:

- A proprietary fiber winding process with an interlaced pattern that efficiently filters the blood and removes particles and air while at the same time oxygenating the blood;
- Smooth tubular pathways for blood to pass through and a first-of-its-kind curved venous inlet tube, both of which reduce blood turbulence during the surgical procedure;
- Enhanced setup and customization capabilities, including a new oxygenator system holder, which gives perfusionists improved flexibility and ease of use in various operating rooms, including those with limited space.

"The new Affinity Fusion oxygenator is designed to provide perfusionists with the most innovative and enhanced product of its kind," said cardiac surgeon Dr. John Liddicoat, senior vice president and president of Medtronic's Structural Heart division. "With so many patients who undergo cardiac surgery each year, Affinity Fusion provides patients with a reliable oxygenation system they can count on."

The Fusion oxygenation system is used by perfusionists during open-heart surgical procedures that require a bloodless, motionless surgical field, such as lifesaving cardiopulmonary bypass surgery. As temporary "lungs," the system adds oxygen and removes carbon dioxide from the blood. This year, cardiopulmonary bypass will occur in roughly 1 million patients worldwide<sup>1</sup>. The development process of the Fusion oxygenator included extensive collaboration between Medtronic engineers and more than 500 perfusionists worldwide.

"During cardiopulmonary bypass, it is imperative that the equipment is designed to maximize patient safety, yet is also sophisticated, versatile and simple to use," said Simon Phillips, chief clinical perfusionist at St George's Hospital in London. "Being part of the collaboration process during the Affinity Fusion oxygenation system development, I am confident that this new technology will benefit patients who undergo these lifesaving procedures and the surgical teams that use it."

The Affinity Fusion oxygenator is not available in the United States, but Medtronic plans to submit an application for U.S. clearance.

In collaboration with leading clinicians, researchers and scientists, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers worldwide.

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