Medtronic News

Medtronic Announces FDA Clearance and First Uses of New Oxygenation System for Adult Cardiac Surgery

New System Designed for Patient Safety, Ease of Use During Open-Heart Procedures

MINNEAPOLIS - April 2, 2013 - Medtronic, Inc. (NYSE: MDT) today announced U.S. Food and Drug Administration (FDA) 510(k) clearance and the first U.S. clinical uses of its new Affinity Fusion® oxygenation system. 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 potentially 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 can 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 undergoing cardiac surgery each year, Affinity Fusion provides patients with a reliable oxygenation system that is designed to proactively manage air and gently handle blood. This is an important consideration for hospitals that are focused on implementing patient blood management programs and other initiatives that can impact costs associated with transfusions and post-operative complications."

The Fusion oxygenation system was used in the U.S. for the first time at Cleveland Clinic by perfusionist Patrick Grady, director of Perfusion Services and a paid member of the expert advisory board for the Fusion, during an open-heart surgery in which a patient underwent a right mini-thoracotomy and mitral valve repair procedure. The surgery was performed by Joseph Sabik, M.D., chair of the Department of Thoracic and Cardiovascular Surgery at Cleveland Clinic and a paid member of Medtronic's valve scientific advisory board. Additionally, the Fusion system was used in mitral valve repair cases at The Heart Hospital Baylor Plano, in Plano, Texas by cardiovascular surgeons Will Ryan, M.D., and Robert Smith, M.D., with chief perfusionist Al Lione.

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[1]. The development process of the Fusion oxygenator included extensive collaboration between Medtronic engineers and more than 500 perfusionists worldwide.

The Affinity Fusion oxygenator received CE Mark in September 2012.

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.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating

pain, restoring health, and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

- end -

---

[1] 2008 HRI report

Contacts:

Joey Lomicky
Public Relations
+1-763-526-2494

Jeff Warren
Investor Relations
+1-763-505-2696

---

https://news.medtronic.com/2013-04-02-Medtronic-Announces-FDA-Clearance-and-First-Uses-of-New-Oxygenation-System-for-Adult-Cardiac-Surgery