Medtronic News

Medtronic Announces FDA Approval of Next-Gen TAVR System for Treatment of Symptomatic Severe Aortic Stenosis

Evolut™ FX TAVR System Adds Innovative Features to Enhance Ease-of-Use and Predictable Valve Deployment

DUBLIN, Aug. 24, 2021 /PRNewswire/ -- Medtronic plc (NYSE: MDT), the global leader in medical technology, today announced U.S. Food and Drug Administration (FDA) approval of its newest-generation, self-expanding transcatheter aortic valve replacement (TAVR) system, the Evolut™ FX TAVR system. Designed to enhance ease-of-use and provide greater precision and control throughout the procedure, the Evolut FX system maintains the industry-leading hemodynamic (blood flow) and durability benefits of the Evolut platform, while bringing product and procedure innovation for patients with symptomatic severe aortic stenosis.

The Evolut FX system incorporates the same supra-annular valve design that has shown hemodynamic performance superior to surgical aortic valve replacement (SAVR) across large-scale, randomized clinical trials. The fourth-generation Evolut technology is equipped with gold markers built into the frame to provide implanters with direct visualization of depth and valve leaflet location during implant. In addition, the Evolut FX system incorporates a redesigned catheter tip for a smoother insertion profile, a more flexible delivery system that allows for 360-degree freedom of motion, with a stable, predictable deployment. Like its predecessor (Evolut PRO+), the newest system includes four valve sizes for the largest indicated patient treatment range and the lowest delivery profile currently on the market.

"The self-expanding, supra-annular Evolut platform has evolved considerably over time and has brought heart teams innovative features like recapturability, an expanded size matrix, and advanced valve sealing to help minimize paravalvular leak. Today, the Evolut FX system further refines a trusted platform with key product and procedural enhancements that make the self-expanding system easier to use with enhanced visualization capabilities for orientation and depth," said Jeffrey Popma, M.D., vice president and chief medical officer for the Coronary & Renal Denervation business and the Structural Heart & Aortic business, which are part of the Cardiovascular Portfolio at Medtronic.

Severe aortic stenosis occurs when the aortic valve leaflets become stiff and thickened and have difficulty opening and closing, making the heart work harder to pump blood to the rest of the body. Severe aortic stenosis often reduces a patient's quality of life and limits their daily activities. If left untreated, patients with symptomatic severe aortic stenosis can die from heart failure in as little as two years.

The Evolut TAVR platform (including the Evolut™ R, Evolut™ PRO, Evolut PRO+, and Evolut FX) is indicated for symptomatic severe aortic stenosis patients across all risk categories (extreme, high, intermediate and low) in the U.S. Limited commercial release is planned for the fall with a full launch anticipated in early 2022.

In collaboration with leading clinicians, researchers and scientists worldwide, 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 around the world.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies – alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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.

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