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Medtronic receives CE Mark for Evolut™ FX+ TAVI system for treatment of symptomatic severe aortic stenosis

Newest-generation Evolut TAVI system builds on its market leading valve performance and durability with enhanced coronary access

Medtronic plc, a global leader in healthcare technology, today announced it has received CE (Conformité Européenne) Mark for the Evolut™ FX+ transcatheter aortic valve implantation (TAVI) system, the company's latest Evolut TAVI system for the treatment of symptomatic severe aortic stenosis. This follows the recent United States Food and Drug Administration (FDA) approval of the system in March 2024.

The latest Evolut FX+ TAVI system offers three larger coronary access windows through a modified diamond-shaped frame design, which are four times larger than regular cells of the Evolut TAVI system. Evolut FX+ provides increased space for catheter maneuverability to facilitate access to coronary arteries of varying patient anatomies. Importantly, the new design builds on the leading valve performance, excellent durability, and excellent outcomes that clinicians expect from the Evolut platform.[1]

"We are excited to complete this momentous milestone and expand our solutions for severe aortic stenosis across Europe," said Jorie Soskin, vice president and general manager, Structural Heart within the Structural Heart & Aortic business, which is part of the Cardiovascular Portfolio at Medtronic. "Through our promise of continued innovation for the Evolut TAVI platform, we have delivered a more advanced and minimally invasive treatment option with proven valve performance and durability to physicians and patients across the globe."

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, 50% of patients with symptomatic severe aortic stenosis can die from heart failure in as little as two years.[2]

"The Medtronic Evolut FX+ system represents a significant step forward in the evolution of heart valve disease care," said Didier Tchetche, M.D., interventional cardiologist and director of the Structural Heart Disease Department at Clinique Pasteur in Toulouse, France. "This advanced technology enables coronary access across multiple patient anatomies and offers clinicians a contemporary tool to improve outcomes without compromising

an established valve performance. We are excited to see this innovative solution approved in European regions and look forward to using it for the benefit of patients."

The Evolut FX+ TAVI system is indicated for symptomatic severe aortic stenosis adult patients across all risk categories (extreme, high, intermediate, and low) in the European Union and is also indicated for symptomatic severe aortic stenosis patients across all risk categories in the U.S. The Evolut FX+ system is expected to be commercially available across Europe in the coming weeks as teams and physicians are trained on this new technology.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic, visit www.Medtronic.com, and follow Medtronic on LinkedIn.

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.

[1] Medtronic data on file compared to the Evolut platform. Bench top model may not be indicative of clinical performance.

[2] Ross J Jr, Braunwald E. Aortic stenosis. Circulation. July 1968; 38(1 Suppl):61-67.

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