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Medtronic Evolut TAVR systems receive FDA approval for expanded Redo TAVR indication

Indication demonstrates Medtronic's commitment to innovative patient-centered solutions shaping the future of TAVR

Medtronic plc, a global leader in healthcare technology, today announced it received U.S. Food and Drug Administration (FDA) approval for the expanded Redo-TAVR indication of the Evolut™ transcatheter aortic valve replacement (TAVR) system. This approval allows for the implantation of a new Evolut transcatheter aortic valve (TAV) inside any failed previously implanted TAV and follows CE (Conformité Européenne) Mark for Evolut PRO+, FX and FX+ systems.

The Redo-TAVR procedure is indicated for patients experiencing failure of any TAV, including but not limited to severe aortic stenosis, who are at high-risk for open-heart surgery.

"FDA approval for Redo-TAVR with the Evolut system marks a significant milestone in patient care, empowering physicians across the United States to offer a critical treatment option for patients with failing transcatheter heart valves who are at high surgical risk," said Dr. Michael Caskey, MD, attending cardiothoracic surgeon at Abrazo Arizona Heart Hospital in Phoenix. "This advancement also benefits patients considering a new TAVR procedure today, giving patients options for future intervention and has the potential to profoundly improve their long-term outcomes and quality of life."

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.[1]

"The Redo-TAVR indication marks an important milestone for our Evolut TAVR systems, reinforcing our commitment to provide physicians with patient-specific solutions today, and for the future of TAVR," said Jorie Soskin, vice president and general manager of the Structural Heart business within the Cardiovascular Portfolio at Medtronic. "With a broader indication than other available options, this expansion, together with the launch of our RESTORE study build on our differentiated design and unparalleled evidence to advance solutions and elevate care options for heart teams and patients worldwide."

RESTORE Study to further evaluate Redo-TAVR procedure

In addition to the FDA approval, Medtronic has launched the RESTORE study to evaluate the outcomes of Redo transcatheter aortic valve replacement (TAVR) in patients experiencing symptomatic bioprosthetic valve failure. This pivotal study will enroll 225 participants and follow them for up to five years, focusing on both immediate and long-term clinical outcomes. The study aims to assess 30-day procedural success rates, one-year freedom from mortality and stroke, and additional measures of safety, technical success, and quality of life. By advancing insights into the effectiveness of redo TAVR, the RESTORE study underscores Medtronic's commitment to improving solutions for complex cardiovascular conditions.

In native (i.e., non-prosthetic) aortic valves, Evolut TAVR systems are currently indicated for implantation in symptomatic severe aortic stenosis patients across all risk categories (extreme, high, intermediate, and low) in more than 120 countries in the world, including the European Union and the United States.

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 more than 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.

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

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