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Medtronic Evolut TAVI systems receive expanded redo TAVI indication in Europe

The Medtronic TAVI indication builds upon commitment to provide best in class patient outcomes today and enabling lifetime management solutions for the future

Medtronic plc, a global leader in healthcare technology, today announced it has received CE (Conformité Européenne) Mark for the expanded redo TAVI indication of the Evolut™ PRO+ and FX transcatheter aortic valve implantation (TAVI) systems. This approval allows for the implantation of a new Evolut transcatheter aortic valve (TAV) inside any failed previously implanted TAV.

The redo TAVI procedure is indicated for patients suffering from severe aortic stenosis with the failure of any TAV, regardless of the manufacturer, and for those at high-risk for open-heart surgery.

"The CE Mark approval for the Evolut TAVI system's redo TAVI procedure is great news for physicians working in this field, but most importantly for patients with failing transcatheter heart valves, who now have a crucial new treatment option" said Professor Dan Blackman, consultant interventional cardiologist, Leeds Teaching Hospitals NHS Trust, United Kingdom. "This minimally invasive procedure not only offers an alternative for patients at high risk for surgery but also underscores the commitment to improving outcomes and extending the benefits of TAVI therapy."

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]

“Redo TAVI indication builds upon the Evolut platform’s proven valve performance and durability to offer safe and reliable lifetime management options, providing physicians exceptional patient outcomes today, while maintaining important options for the future,” said Jorie Soskin, vice president and general manager, Structural Heart, which is part of the Cardiovascular Portfolio at Medtronic. “This approval is a testament to Medtronic’s ongoing commitment to advance patient care and expand treatment options and access around the globe.”

In native (i.e., non-prosthetic) aortic valves, Evolut TAVI systems are currently indicated for implantation in symptomatic severe aortic stenosis patients across all risk categories (extreme, high, intermediate, and low) in 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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