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Medtronic has announced the US Food and Drug Administration (US FDA) approval and the US launch of the new recapturable, self-expanding CoreValve Evolut R System. It is said to be the first-and-only recapturable and repositionable device available in the US, the Evolut R System is approved for transcatheter aortic valve replacement (TAVR) in severe aortic stenosis patients who are at high or extreme risk for surgery. Untreated, aortic valve stenosis can lead to serious heart problems including heart failure and even death.

Designed to treat patients with aortic stenosis, a condition where the aortic valve narrows thereby limiting blood flow from the aorta to the rest of the body, the CoreValve Evolut R System is built on the proven foundation and procedural success of the CoreValve System, which has been implanted in more than 75,000 patients in 60 countries.

The new system consists of the CoreValve Evolut R transcatheter valve and the EnVeo R Delivery System, which features an InLine Sheath that significantly reduces the profile to the lowest on the market (14 Fr equivalent, less than 1/5 inch). A smaller profile size provides a greater opportunity to treat an expanded patient population with smaller vessels (down to 5.0 mm), through the preferred transfemoral access route, which may minimize the risk of major vascular complications in some patients.

Based on the knowledge gained through the extensive experience with the CoreValve System, the Evolut R is optimized to increase conformability and sealing at the annulus, while maintaining supra-annular valve positioning for improved blood flow and hemodynamic performance. An extended sealing skirt on the 26mm and 29mm valve sizes is intended to further promote valve sealing at the annulus.

"The FDA approval of Evolut R marks a significant milestone for Medtronic and TAVR, and ushers in a new era in transcatheter aortic valves with advanced, recapturable capabilities," said Ms Rhonda Robb, vice-president and general manager, Heart Valve Therapies, Medtronic. She added, "This approval is an outcome of our commitment to building a market-leading innovation pipeline in the transcatheter space, and we look forward to supporting heart teams as they look to next-generation technologies that optimize valve performance for a broad range of patients."

The 23 mm, 26 mm and 29 mm sizes of the CoreValve Evolut R transcatheter valve and the CoreValve EnVeo R Delivery Catheter System are available for use in the United States. The device is also available in Europe and other countries that recognize the CE (ConformitÃ© EuropÃ©ene) mark.