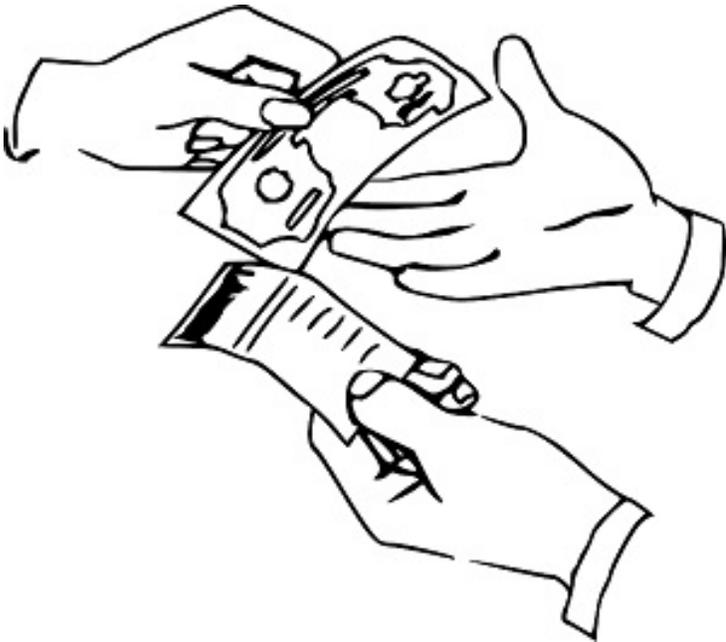


Medtronic gets FDA approval for New Recaptureable TAVR System

27 October 2016 | News | By BioSpectrum Bureau

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Medtronic plc has announced the US Food and Drug Administration (FDA) approval and U.S. launch of the CoreValve(TM) Evolut(TM) R 34 mm valve—the largest sized transcatheter aortic valve replacement (TAVR) system available in the US. The new Evolut R 34 mm valve is approved for severe aortic stenosis patients who are at high or extreme risk for surgery with an annulus size ranging from 26-30 mm. This large valve segment is estimated to account for approximately 25-30 percent of the eligible global TAVR patient population. Previously, some of these patients were unable to receive a TAVR due to the larger size of their native diseased aortic valve.

The Evolut R 34mm valve is delivered through the EnVeo(TM) R Delivery Catheter System, which features an InLine Sheath. The system delivers the lowest, true delivery profile currently on the market (16 Fr equivalent, approximately 1/5 inch), which provides a greater opportunity to treat patients with smaller vessels through the preferred transfemoral access route. The Evolut R System, with its self-expanding nitinol frame, is designed to fit within the native aortic valve, using its supra-annular valve position to help achieve excellent hemodynamic performance.

"Heart teams can now use the Evolut R platform to treat the broadest annulus range in the U.S. market. The approval of the 34mm valve expands the patient population that can now receive this minimally invasive treatment alternative to open heart surgery," said Rhonda Robb, vice president and general manager of the Heart Valve Therapies business, a part of Medtronic's Cardiac and Vascular Group. "We look forward to working with physicians and heart teams across the U.S. to provide this valve to the many patients who need it."

The CoreValve Evolut R 34 mm valve is only approved in the United States and not approved in Europe and other countries.

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.