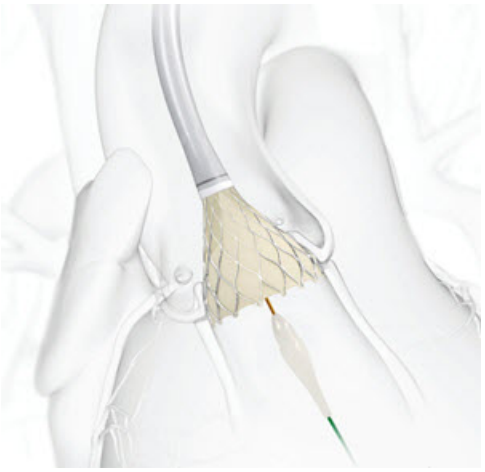
Medtronic Canada Newsroom

Medtronic Announces Health Canada Licence for New Tavi System, Introduces First and Only Recapturable Transcatheter Heart Valve in Canada

CoreValve™ Evolut™ R Recapturable and Repositionable Heart Valve Improves Positioning Accuracy and Control During Deployment



BRAMPTON, Canada – Oct. 22, 2016 – Medtronic Canada, a subsidiary of Medtronic plc (NYSE: MDT), today announced Health Canada licence of the new recapturable, self-expanding CoreValve™ Evolut™ R System. The first and only recapturable and repositionable device available in Canada, the CoreValve Evolut R System is licenced for transcatheter aortic valve implantation (TAVI) 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.

“Obtaining a Health Canada licence for Evolut R marks a significant milestone for Medtronic and TAVI, and ushers in a new era in transcatheter aortic valves with advanced, recapturable capabilities,” said Michael Blackwell, senior director of the CardioVascular Group at Medtronic Canada. “This licence 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 licencing of Evolut R as the first self-expanding, recapturable transcatheter heart valve available in Canada follows other significant milestones reached over the past 18 months showcasing the company’s leadership in the TAVI market. Last year, the CoreValve System was the first TAVI system to be licenced in Canada for valve-in-valve (VIV) procedures in patients whose surgical aortic heart valves have failed. Also in March 2015, the highly anticipated two-year data from the High Risk Study of the CoreValve U.S. Pivotal Trial was presented at the American College of Cardiology 2015, which showed superior survival benefit at two years for TAVI with the CoreValve System compared to patients who underwent surgical aortic valve replacement (SAVR).

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers one of the broadest ranges 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.

About Medtronic

Medtronic Canada (www.medtronic.ca), headquartered in Brampton, Ontario is a subsidiary of Medtronic plc, which is among the world's largest medical technology, services and solutions companies — alleviating pain, restoring health and extending life for millions of people around the world. Medtronic is proud to employ over 1,600 people in Canada, serving physicians, hospitals and patients across the country. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as thosedescribed 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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