Medtronic News

Medtronic Announces CE Mark for Recapturable CoreValve Evolut R System

Next-Generation TAVI System Offers Ability to Recapture and Reposition During Deployment

MINNEAPOLIS - Sept. 3, 2014 - Medtronic, Inc. (NYSE: MDT) today announced CE (*Conformité Européene*) Mark for the 23 mm CoreValve® Evolut(TM) R System for transcatheter aortic valve implantation (TAVI). The novel, self-expanding valve and 14FR equivalent delivery system offers new capabilities that advance valve performance and deliverability during the procedure, while providing the option to recapture (re-sheath the valve back into the catheter) and reposition (move the valve to a new position either above or below its current placement) the valve during deployment phase, if needed.

"The CoreValve Evolut R System offers improvements to a proven TAVI technology platform," said Eberhard Grube, M.D., head, Center of Innovative Interventions in Cardiology (CIIC), University Hospital Bonn, Germany. "The system's new recapture-enabled capabilities and advancements in valve delivery provide physicians with added procedural confidence. It's a significant advance to know there is the option to redeploy the valve in the ideal position if necessary."

The novel system consisting of the CoreValve Evolut R transcatheter aortic valve and the EnVeo(TM) R Delivery Catheter System is designed for first-time positioning accuracy and also offers a new InLine(TM) Sheath that significantly reduces the profile to the lowest on the market (14 Fr equivalent, less than 1/5 inch); a smaller profile size is believed to minimize the risk of major vascular complications. The new valve is anatomically designed to increase conformability at the annulus for optimal annular fit and sealing, while maintaining supra-annular valve position for improved hemodynamic performance.

"Built on the proven foundation and procedural success of the CoreValve System with more than 65,000 implants worldwide, the CoreValve Evolut R System is the future of transcatheter aortic valve replacement," said Rhonda Robb, vice president and general manager, Heart-Valve Therapies, Medtronic. "A truly next-generation device, CoreValve Evolut R provides heart teams with meaningful advancements that will increase the potential for optimal device placement."

The 23 mm CoreValve Evolut R transcatheter valve and the CoreValve EnVeo R Delivery Catheter System are now available in Europe and other countries that recognize the CE mark. It is not approved for commercial use in the United States, where it is currently undergoing clinical trials.

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.

ABOUT MEDTRONIC

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

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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