University Hospitals completes first Evolut™ PRO+ case in the world

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Physicians at University Hospitals Cleveland Medical Center completed the first procedure in the world using Medtronic's new Evolut PRO+ TAVR System.

Guilherme Attizzani, MD, Director, Valve and Structural Heart Disease Center, and Cristian Baeza, MD, cardiac surgeon, both with the UH Harrington Heart & Vascular Institute, performed the procedure on Oct. 1.

"It was pristine. It went great," said Dr. Attizzani. "It's a smaller device that can minimize the risk of vascular complications."

Medtronic, a worldwide leader in heart valve therapies, announced U.S. Food and Drug Administration (FDA) approval and U.S. launch of the Evolut PRO+ TAVR System on Sept. 23. The Evolut PRO+ is a new-generation Medtronic TAVR (transcatheter aortic valve replacement) system that builds off the self-expanding, supra-annular Evolut TAVR platform. The new system includes four valve sizes with an external pericardial tissue wrap that provides advanced sealing for the largest indicated patient treatment range and the lowest delivery profile.

The patient, 84-year-old Russell Beck of Avon Lake, Ohio, is doing well post-procedure.

"I was surprised they did it so quickly," said Beck about the procedure which lasted about 60 minutes. "I was impressed with the team that

worked on me."

Aortic stenosis is a condition where the aortic valve that leads blood from the heart to the rest of the body becomes obstructed. This makes the heart work harder to pump blood to the rest of the body and impacts a person's daily activities with symptoms such as chest pains and shortness of breath. If left untreated, patients with symptomatic severe aortic stenosis can die from heart failure in as little as two years.

The launch of this new system comes on the heels of the FDA's recent indication expansion for treating patients with symptomatic severe aortic stenosis at a low risk of surgical mortality, the final surgical risk category to be approved for TAVR. Tens of thousands of more patients a year are now eligible for TAVR, in addition to the nearly 60,000 intermediate- and high-risk patients who previously underwent the procedure.

The Evolut TAVR platform, including the Evolut R, Evolut PRO and Evolut PRO+ TAVR Systems, is indicated for symptomatic severe aortic stenosis patients across all risk categories (extreme, high, intermediate and low) in the U.S.

"This is a demonstration of our leadership in the field," said Dr. Attizzani of being the first to use the Evolut PRO+ system. "This is how we utilize the trust that we get from professionals in this field."

Provided by University Hospitals Cleveland Medical Center