

First in US aortic valve prosthesis implant to treat severe aortic stenosis

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David H. Adams, MD, Marie-Josée and Henry R. Kravis Professor and Chairman of the Department of Cardiothoracic Surgery, Samin K. Sharma, MD, the Zena and Michael A. Weiner Professor and Director of the Cardiac Catheterization Laboratory, and Annapoorna S. Kini, MD, Associate Professor and Associate Director of the Cardiac Catheterization Laboratory at The Mount Sinai Medical Center, have performed the first implantation of the Medtronic CoreValve® Transcatheter Aortic Valve Prosthesis in the United States. The CoreValve System is a new device that treats severe aortic stenosis, which affects about 300,000 people worldwide. Designed to replace a diseased aortic heart valve percutaneously via a catheter, CoreValve potentially provides a safe and less invasive alternative to open heart surgery.

The normal aortic valve opens and closes each time the [heart](#) beats to allow blood to leave the pumping chamber of the heart. In many patients of advanced aged, the leaflets of the valve become calcified, leading to a narrowing or stenosis of the valve and symptoms which include shortness of breath on activity. Severe aortic stenosis mostly affects patients older than 70 years of age, and the standard-of-care is open heart surgery to replace the diseased valve. It is estimated over one-third of patients with severe aortic stenosis are ineligible for conventional surgery, and many more are at high risk by undergoing it. Left untreated, about half of patients with symptomatic severe aortic stenosis will die within one year.

"There is an enormous unmet need in this patient population for a safe

and effective treatment," said Dr. Adams, who is also the National Co-Principal Investigator for the Medtronic CoreValve U.S. FDA Pivotal Trial, along with Dr. Jeff Popma, of the Beth Israel Deaconess Medical Center and Harvard Medical School. "CoreValve provides an exciting new option for these patients without the invasiveness of open heart surgery. We hope this FDA trial will help establish this treatment as an effective option for selected patients with severe aortic stenosis."

"In the past, high risk patients suffering from the most severe forms of aortic stenosis were often treated by balloon aortic valvuloplasty, which is effective for approximately six months. CoreValve at Mount Sinai gives us another tool to continue to treat the sickest of patients and provide long-lasting relief," said Dr. Sharma.

Aortic stenosis is a heart condition that occurs when the aortic valve narrows, preventing it from properly opening and closing, and diminishing blood flow between the heart and the rest of the body. The reduced blood flow increases pressure within the heart, causing the heart to weaken and function poorly. When aortic stenosis becomes severe and symptoms develop, it is life-threatening.

The first recipient of the Transcatheter CoreValve in U.S. is a 88-year-old male with recurrent heart failure due to severe aortic stenosis, whose symptoms recurred despite undergoing balloon aortic valvuloplasty three months earlier. His aorta was highly calcified, precluding traditional surgical aortic valve replacement. CoreValve implantation was deemed the only option for him to prolong his life span, and he underwent the procedure on December 17.

The Medtronic CoreValve System is a new technology designed to replace a diseased aortic heart valve without [open heart surgery](#) and without surgical removal of the diseased valve. In the Medtronic CoreValve U.S. Clinical Trial, the replacement valve is delivered

primarily through a small opening in the femoral artery, threaded through arteries and across the aorta, and deployed in the native [aortic valve](#). Once in place, the CoreValve is designed to take over the native valve's function and ensure that oxygen-rich blood flows into the aorta and circulates throughout the body.

"As the first center in the United States to implant this device Mount Sinai is once again demonstrating our commitment to providing innovative, treatments for our patients," said Wayne Keathley, President & Chief Operating Officer, The Mount Sinai Hospital. "Dr. Adams is a leader in this field and his work with our world-class interventional cardiology team led by Dr. Samin Sharma clearly demonstrates the strength and breadth of clinical talent at Mount Sinai."

Provided by The Mount Sinai Hospital

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