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DMC Cardiovascular Institute becomes first in Michigan to participate in CoreValve® Clinical Trial

Two patients who had severe aortic stenosis are “recovering well” – only days after the minimally invasive procedure

DETROIT – The Detroit Medical Center (DMC) Cardiovascular Institute (CVI) has completed the first two Medtronic CoreValve® transcatheter aortic valve implants (TAVI) ever achieved in Michigan. The procedures are a part of CVI’s participation in the Medtronic CoreValve U.S. Clinical Trial. This multi-state trial will evaluate a new, non-surgical alternative to open-heart surgery for patients with severe aortic stenosis.

The multidisciplinary team of DMC physicians, nurses, and technologists who completed the procedure – using the Medtronic CoreValve System, a device expressly designed for transcatheter aortic valve implantation – was led by Dr. Theodore L. Schreiber, president of the CVI, and Dr. Ali Kafi, chief of clinical cardio-thoracic surgery at DMC Harper University Hospital.

“The two non-surgical valve replacements that took place at the DMC late last week represent a major step forward in Michigan heart care,” said Dr. Schreiber. “The two transcatheter procedures were performed percutaneously, or through a small hole in the skin, and the patients involved were back on their feet and doing well within a day or two. That brief recovery period compares favorably with the more than one week that would typically be required to recover from open-heart aortic valve replacement.

DMC President and CEO Michael Duggan said he was “especially encouraged” by the fact that the clinical trial made its Michigan debut at the Detroit Medical Center.

“Once again, the DMC’s strong focus on helping heart patients has resulted in a major treatment breakthrough for patients in Michigan and the Midwest,” said Duggan. “Dr. Schreiber has been a national pioneer in developing new procedures to repair heart valves without invasive surgery, and as the president of the DMC Cardiovascular Institute, he’s ideally suited to participate in this investigational therapy.

“DMC Harper University Hospital was the site of the world’s first open-heart, pump-assisted surgery to repair a damaged valve, back in the 1950s . . . so I think it’s fitting that the DMC Cardiovascular Institute is now pioneering the latest heart-valve procedure, in this clinical trial, for patients all across Michigan and beyond.”

The two new patient procedures are part of a national clinical trial in which the Medtronic CoreValve System is being evaluated at 40 U.S. clinical sites. The high-tech valve-replacement therapy is already approved in Europe (the *Conformité Européenne* Mark, in 2007), and is now being used regularly in more than 40 countries around the world.

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The two patients who received the new aortic valves are among more than 300,000 people worldwide (100,000 in the U.S.) now struggling with severe aortic stenosis. That often-disabling condition, usually caused by narrowing of the valve and resulting in restricted of blood flow from the heart to the body, typically develops by age 50-70 and progresses with advancing age.

For U.S. patients with severe aortic stenosis, open-heart surgery is currently the only approved therapy with significant clinical effect. Approximately one-third of these patients are deemed to be ineligible for open-heart surgery. The CoreValve System could provide an alternative minimally invasive, non-surgical treatment option for these patients.

One of the two patients who received the implanted heart valves last week was Ms. Shirlene Stephens, 72, a grandmother of two who lives in Macomb County. A retired heavy-equipment worker, Ms. Stephens could not undergo surgery because of her severe emphysema. She underwent the TAVI replacement procedure on Friday and was up and moving less than 24 hours later. Because of her rapid recovery time, she will soon be returning home.

The clinical trial will allow a multidisciplinary team of interventional cardiologists and cardiac surgeons to replace a diseased or damaged heart valve. The new replacement valve typically is delivered through the femoral artery, then threaded through arteries and delivered in the native aortic valve. Once in place, the CoreValve is deployed to take over the native valve's function and ensure that oxygen-rich blood flows into the aorta and circulates throughout the body.

Dr. Schreiber, who was a pioneer in developing the stent procedure for relieving blocked carotid arteries, described the clinical trial as "another good example of why the DMC Cardiovascular Institute is now the acknowledged leader in Michigan and the Midwest in the treatment of structural heart defects."

Added Dr. Schreiber, who currently performs about 1,500 heart and vascular procedures per year at the DMC: "We're now training more physicians in structural and valve disease-related therapies than anybody else in Michigan – thanks to our continuing leadership in this vitally important area of heart care."

DMC Cardiovascular Institute is currently enrolling patients in the trial. For more information about participating in this clinical trial, call 1-(855) VALVEMD or 1-(855) 825-8363.

Physicians are available for interviews.

For broadcast quality animation, photos and bios, visit www.DMCCVI.org/aortic.

About Detroit Medical Center www.dmc.org

The Detroit Medical Center operates nine hospitals and institutes, including Children's Hospital of Michigan, Detroit Receiving Hospital, Harper University Hospital, Huron Valley-Sinai Hospital, Hutzel Women's Hospital, Rehabilitation Institute of Michigan, Sinai-Grace Hospital, DMC Surgery Hospital, and DMC Cardiovascular Institute. The Detroit Medical Center is a leading regional healthcare system with a mission of excellence in clinical care, research and medical education.

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