

FIRST ACCUCINCH® ENROLLMENT AT MHIF

Minneapolis Heart Institute Foundation[®] Treats First Patient in AccuCinch[®] Study for Mitral Regurgitation and Heart Failure



Minneapolis, MN – March 16, 2018 – Research physicians at the Minneapolis Heart Institute Foundation[®] completed their first treatment with the AccuCinch[®] System, an investigational device, in a patient at Abbott Northwestern Hospital in late January.

The 35-year-old woman, who had massive dilation of the left ventricle and severe mitral valve regurgitation, became the 19th patient in the world approved to undergo the minimally invasive investigational procedure.

"The procedure is a ground-breaking approach that is designed to target both functional mitral regurgitation (FMR) and heart failure," said Dr. Paul Sorajja, Roger L. and Lynn C. Headrick Family Chair for Valve Science Research at the MHIF Valve Science Center.

<u>Stephanie Rawson</u>, the first patient enrolled at the Minneapolis Heart Institute Foundation, developed idiopathic heart failure in March 2011, shortly after giving birth to her daughter. Stephanie's quality of life was significantly diminished as a result of heart failure and FMR. While early in recovery, she is cautiously optimistic about her ability to live a more normal life. She lives on the third floor of her building, which has 24 stairs between the parking lot and her front door. In the past, she needed to stop to catch her breath, but after the AccuCinch procedure, she can walk up the steps without stopping.

"I feel like I'm doing something good for other people, not just myself, and if participating in research has the potential to help, it's worth it," said Stephanie. "I want to be able to do more things with my daughter and be the mom I want to be."

"In the U.S., there are approximately three million patients¹ who may benefit from this therapy but are currently not being treated. This therapy may prove to be invaluable to these undertreated patients," continued Sorajja.

Dr. Paul Sorajja is the principal investigator of the study and performed the procedure along with Dr. Mario Gössl and Dr. Richard Bae, researchers at MHIF Valve Science Center. Dr. Karol Mudy and Dr. Peter Eckman, both co-investigators on the study, supported the team in screening to determine eligibility for this patient.

Heart failure is a condition in which the heart's muscles weaken, leaving the heart unable to pump enough oxygen-rich blood to the rest of the body. FMR occurs when the left ventricle of the heart is distorted or enlarged and displaces the muscles supporting the mitral valve leaflets. The leaflets can no longer close completely, allowing blood to flow back into the atrium. The transcatheter AccuCinch procedure is the first of a new a class of therapies intended to repair the left ventricle. The therapy is designed to reshape the enlarged left ventricle to allow improved left ventricular function, reduce FMR, help reduce symptoms of heart failure and potentially lead to enhanced quality of life for patients.

During the procedure, a catheter is guided through the aortic valve to reach the left ventricle. A series of anchors are implanted in the left ventricle heart wall below the mitral valve. A cable connects the anchors and is cinched in place. Once cinched, the left ventricular size is reduced, the heart wall is strengthened, and symptoms of heart failure and FMR are reduced. Ancora Heart developed AccuCinch as an innovative treatment option for the millions of heart failure and FMR patients who are unlikely to survive the risks of open-heart surgery. Minneapolis Heart Institute Foundation and other leading cardiovascular research centers are studying AccuCinch's ability to repair and reshape the enlarged left ventricle. AccuCinch has the potential to be the first therapy to target the primary cause of FMR and heart failure and enable patients to feel better. More information can be found at <u>www.ancoraheart.com</u>.

About the Minneapolis Heart Institute Foundation® Valve Science Center

Established in 2016, the mission of the MHIF Valve Science Center is to eliminate the morbidity and mortality of valvular heart disease. Through its commitment to leading research and education, in partnership with physicians at the Minneapolis Heart Institute[®], the Center is addressing the root causes of currently poor outcomes by studying barriers to care, advancing public education and disease state awareness, accelerating innovation in medical technology, and introducing novel patient care pathways to improve outcomes. MHIF actively participates in major clinical trials and conducts many investigator-initiated research studies focused on disease mechanisms, clinical care effectiveness and applying new treatment, diagnosis or monitoring methods. MHIF's valve team has authored hundreds of papers and presents frequently at national conferences, such as American Heart Association, Transcatheter Cardiovascular Therapeutics and American College of Cardiology. More information can be found at http://www.mplsheart.org/valvesciencecenter

About the Minneapolis Heart Institute Foundation®

The Minneapolis Heart Institute Foundation (MHIF) strives to create a world without heart and vascular disease. To achieve this bold vision, it is dedicated to improving the cardiovascular health of individuals and communities through innovative research and education.

- Scientific Innovation and Research MHIF is a recognized research leader in the broadest range of cardiovascular medicine and population health initiatives. Each year MHIF leads more than 175 active research projects and publishes more than 175 peerreviewed abstracts. Cardiologists, hospitals and communities around the world adopt MHIF protocols to save lives, improve care and create healthier living opportunities.
- Education and Outreach MHIF provides more than 10,000 hours of education each year putting its research into practice to improve outcomes. And, MHIF leads cuttingedge, transformative population health research to connect, engage, inform and empower individuals and communities to improve their health.

The Minneapolis Heart Institute Foundation's work is funded by generous donors and sponsors and supports research initiatives of Minneapolis Heart Institute[®] at Abbott Northwestern Hospital. Minneapolis Heart Institute[®] physicians provide care for patients at Abbott Northwestern Hospital in Minneapolis and at 38 community sites across Minnesota and western Wisconsin. More information can be found at <u>http://www.mplsheart.org</u>

References

¹ Nkomo, VT (2006). Burden of valvular heart diseases: a population-based study. https://www.ncbi.nlm.nih.gov/pubmed/16980116