



FIRST IN FLORIDA- THE FLORIDA STRUCTURAL HEART DISEASE CENTER TOGETHER WITH THE CARDIAC & VASCULAR INSTITUTE RESEARCH FOUNDATION IMPLANT PASCAL TRANSCATHETER MITRAL VALVE REPAIR DEVICE AS PART OF THE CLASP IID/IIF PIVOTAL TRIAL

GAINESVILLE, FLORIDA August 25, 2020 - The Florida Structural Heart Disease Center at North Florida Regional Medical Center (NFRMC) together with The Florida Heart & Lung Institute (FHLI) and The Cardiac & Vascular Institute Research Foundation (TCVIRF), have announced that they are the first in the state of Florida to implant the Edwards Lifesciences PASCAL CLASP IID/IIF device as a part of the Edwards Lifesciences PASCAL CLASP IID/IIF Pivotal Clinical Trial. This clinical trial will evaluate the Edwards PASCAL transcatheter valve repair system for the management of patients with mitral regurgitation who have been determined to be at prohibitive risk for mitral valve surgery by the Structural Heart Team; there is a separate cohort class (IIF) studying patients with functional mitral regurgitation (FMR).

Mitral valve regurgitation is a condition in which the mitral valve does not close completely, causing blood to leak back into the left atrium of the heart. This increases the workload on the heart and if left untreated, can increase the risk of heart failure. Open heart surgery is an effective treatment for patients with mitral valve regurgitation, however, not everyone is a candidate for surgery. Transcatheter Mitral Valve Repair (TMVR) provides a minimally invasive, catheter-based procedure treatment option for those with mitral problems unable to undergo surgery.

The Structural Heart Program, co-led by Florida Heart & Lung Institute's Cardiothoracic Surgeon Charles Klodell, M.D. and The Cardiac & Vascular Institute's Interventional Cardiologist Ilie Barb, M.D., has been instrumental in bringing this ground breaking Transcatheter Mitral Valve Repair technology to North Central Florida.

"We are happy to offer the new PASCAL transcatheter mitral valve repair system as it is a promising tool that increases our arsenal to treat the mitral valve. On June 23rd, we treated our first patient in the trial and they were overwhelmingly excited to be the first patient enrolled and to receive the device in Florida," says Charles Klodell, M.D., co-principle investigator in the clinical trial.

"We are proud of the top tier Structural Heart Program that we have collaboratively built here in Gainesville which positioned us to become a site for PASCAL CLASP IID/IIF clinical trial and the first site to implant the PASCAL CLASP IID/IIF device in the state of Florida," says Ilie Barb, M.D., co-principle investigator in the clinical trial.

This is just one of the many clinical trials that are offered to patients at the Florida Structural Heart Disease Center together with The Cardiac & Vascular Institute Research Foundation at North Florida Regional Medical Center. There are multiple clinical trials offered for structural heart disease in addition to various other cardiac and vascular clinical trials. To learn more, patients can contact The Cardiac & Vascular Institute Research Foundation, Florida Heart & Lung Institute and North Florida Regional Medical Center.

About North Florida Regional Medical Center & The Florida Heart and Lung Institute

NFRMC is a 432 bed, full-service medical and surgical acute care center serving North Central Florida for over 45 years. NFRMC offers comprehensive cardiovascular care, oncology, orthopedics, neurosciences, minimally-invasive laparoscopic and robotic surgery, weight loss surgery and treatment, women's health and wound therapy, among other services. NFRMC is fully accredited by the Joint Commission, is certified as a Comprehensive Stroke Center, an Accredited Chest Pain Center by ACC (American College of Cardiology), and is designated as a Blue Distinction Center for Spine Surgery and Bariatric Surgery. NFRMC has also received the highest scores available recognizing their commitment to patient safety and quality of care. For more information, please visit www.NFRMC.com.

The Florida Heart and Lung Institute (FHLI) is a group of our cardiothoracic surgeons offering a comprehensive range of services and specializing in heart and lung surgery. Dr. Charles T. Klodell and Dr. Thomas Zeyl specialize in heart and lung surgical procedures including minimally invasive aortic and mitral valve repair or replacement, aortic aneurysm repair, treatment of hyperhidrosis, TAVR, less invasive mitral regurgitation procedures and open heart surgery. FHLI provides specialized care to the North Central Florida area including: Gainesville, Newberry, Alachua, Waldo, Hawthorne, and Micanopy with satellite offices in Ocala, Kissimmee, Sanford, Tallahassee and the Panhandle. For more information on the practice, please visit www.flheartandlung.com.

About The Cardiac & Vascular Institute and Research Foundation

The Cardiac & Vascular Institute (TCAVI) provides specialized cardiology and vascular care to North Central Florida with offices located in both Gainesville and Lake City, Florida. TCAVI is committed to providing the highest quality state-of-the-art health services to our patients. With 18 cardiologists, two electrophysiologists, and two vascular surgeons providing diagnostic, therapeutic and preventive cardiac services, TCAVI specializes in areas including atrial fibrillation, hypertension management, heart failure management, minimally invasive valve repair or replacement, peripheral vascular disease, and critical limb ischemia. For more information visit www.TCAVI.com.

Since its establishment in 2010, The Cardiac & Vascular Institute Research Foundation (TCAVIRF) has been at the forefront of cardiovascular research participating in both cardiac and vascular disease clinical trials. TCAVIRF is comprised of board-certified physicians from The Cardiac & Vascular Institute and The Florida Heart & Lung Institute. Together these physicians are also part of the Florida Structural Heart Disease Center at North Florida Regional Medical Center. The Florida Structural Heart Disease Center is accredited by the American College of Cardiology with its Transcatheter Valve Certification making it the first accredited transcatheter valve center in the state of Florida and the 7th in the United

IRB Approved at the
Study Level

Aug 17, 2020

States. For more information on The Cardiac & Vascular Institute Research Foundation please visit
www.TCAVI.com/researchfoundation.

###

Media Contact: Lauren Lettelier
North Florida Regional Medical Center
Director, Public Relations and Communications
Lauren.Lettelier@hcahealthcare.com
P: 352.333.4949, C: 352.672.3569

Media Contact: Jennifer Massenburg
The Cardiac & Vascular Institute and Research Foundation
Director, Marketing and Communications
jmassenburg@tcavi.com
P: 352.375.1212