



FOR IMMEDIATE RELEASE

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The Cardiac & Vascular Institute and North Florida Regional Medical Center join together in a clinical trial to test an innovative artificial intelligence (AI) device to improve patient safety.

Gainesville, FL January 8, 2019 – The Cardiac & Vascular Institute (TCAVI) and North Florida Regional Medical Center (NFRMC) collaborated this week to test an artificial intelligence (AI) device designed to alert clinicians to bleeding episodes during endovascular procedures.

According to a press release, the AI device, (named Early Bird™ Bleed Monitoring System by Houston-based company Saranas™), uses a sheath embedded with an array of electrodes used to detect when the electrical resistance changes across blood vessels. By sensing a change in the vessel's electrical resistance, the device is designed to detect, monitor and signal blood pooling outside of vessels, triggering audible and visual notifications that alert the care team to a possible bleed.

“Severe, life threatening bleeding remains a significant problem, which limits our ability to safely complete our large bore transcatheter procedures,” says Interventional Cardiologist Mark Tulli, M.D. of The Cardiac & Vascular Institute. “These procedures are life saving for the most complex and very sickest of patients, who have few options to help make them better. Even the smallest of bleed, in these sick patients, is not tolerated well. Our hope is that the Early Bird™ Bleeding Monitoring Device will help detect bleeding before it is clinically evident, helping us treat these complex patients and achieving the best outcomes.”

“With the expanding indications for transcatheter aortic valve replacement and other similar large bore arterial access procedures, the overall benefit to patients is immeasurable. However, the Achilles' heel remains careful monitoring for arterial access site complications,” according to Charles Klodell, M.D., Cardiothoracic Surgeon at North Florida Regional Medical Center and Principle Investigator on this clinical trial. “The Early Bird Device has the potential to help us recognize any abnormalities early and quickly develop mitigating strategies to mitigate any of the adverse consequences that may occur. This device will play a key role in allowing us to monitor for bleeding in real-time making these procedures safer in the future.”



With vascular access procedures on the rise, the Early Bird Bleed Monitoring System is designed to protect, and in some cases, save the lives of patients undergoing an endovascular procedure by using embedded sensors designed to detect and monitor bleeding from a blood vessel accidentally injured during endovascular procedures. If detected early, bleeds can be stopped or even prevented, which can help to decrease procedural complications, healthcare costs and the length of stay in the hospital after a procedure.

Sheaths are currently used in cardiac and vascular procedures to keep vessels open, which means that this device will be applicable to existing operations. The Early Bird Bleed Monitoring System is not yet cleared by the U.S. Food and Drug Administration and is currently available for investigational use only.

About The Cardiac & Vascular Institute

The Cardiac & Vascular Institute (TCAVI) has offices in both Gainesville and Lake City, Florida. TCAVI is committed to providing the highest quality health services to our patients. The physicians of TCAVI are board certified in every aspect of cardiology providing state of the art diagnostic, therapeutic and preventive cardiac services by utilizing the best in both the technology and the art of medicine. TCAVI's focus is understanding and resolving patients' health care needs. The Cardiac & Vascular Institute is dedicated to providing the highest quality medical care to our patients. For more information on the practice or to schedule an appointment with The Cardiac & Vascular Institute, please contact (352)375-1212 or visit www.TCAVI.com.

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 and offering 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 a member of Hospital Corporation of America (HCA). Based in Nashville, Tennessee, HCA Healthcare is one of the nation's leading providers of healthcare services, comprising 178 hospitals and approximately 1,800 sites of care, including surgery centers, freestanding ERs, urgent care centers and physician clinics, in 20 states and the United Kingdom.

At The Florida Heart and Lung Institute (FHLI) our cardiothoracic surgeons offer a comprehensive range of services and specialize 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, MitraClip and open heart surgery. We provide specialized care to the North Central Florida area including: Gainesville, Newberry, Alachua, Waldo, Hawthorne, Micanopy additionally with satellite offices in Sanford, Tallahassee and the Panhandle. Their mission is to deliver the highest quality, expert care with compassion and consideration.



For more information on the practice or to schedule an appointment with The Florida Heart & Lung Institute, please contact (352) 333-5610 or visit www.flheartandlung.com

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