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## **CVI Cardiologist First in Florida and Among First Nationwide to Use New Technology to Treat Coronary Artery Disease Procedures Performed at North Florida Regional Medical Center**

*December 18, 2013, Gainesville, FL* – The Cardiac & Vascular Institute and The Heart & Vascular Center of North Florida Regional Healthcare announced that Interventional Cardiologist Arthur Lee, MD, is the first physician in the state of Florida to treat severely calcified coronary lesions using the revolutionary, new Diamondback 360(R) Coronary Orbital Atherectomy System (OAS). Dr. Lee performed two OAS procedures in the catheterization laboratories of North Florida Regional Medical Center on November 1, 2013. They were not only the first in the state of Florida; they were also the third and fourth cases performed in the entire nation.

The Diamondback 360 Coronary OAS uses a patented combination of differential sanding and centrifugal force to reduce arterial calcium that can cause complications when treating coronary artery disease (CAD). The system gained U.S. Food and Drug Administration (FDA) approval on October 21, 2013, and it is the first and only technology approved for the treatment of severely calcified coronary lesions.

"Calcification in the coronary arteries is a sign of advanced disease and has long been the nemesis to the interventional cardiologist," Dr. Lee says. "Calcification has historically translated into higher risk stent procedures and, in some circumstances even necessitated open heart surgery to remedy. The Diamondback Coronary OAS gives us the ability to treat these high risk patients safely and effectively. I fully expect the simplicity of the system will allow widespread uptake of this technology across the country so that all patients will eventually have access to this long awaited therapy."

The Diamondback 360 Coronary OAS is an eccentrically mounted 1.25-millimeter diamond-coated crown that sands away calcium in coronary arteries, enabling stent deployment. As the crown rotates and orbit increases, centrifugal force presses the crown against the lesion, reducing arterial calcium.

(more)

Thirty-day data from CSI's ORBIT II clinical study demonstrated that the Diamondback 360 Coronary OAS technology produced clinical outcomes that exceeded the trial's two primary endpoints (safety and efficacy) by a significant margin. The 30-day freedom from major adverse cardiac events (MACE) rate was 89.6 percent and the primary effectiveness was 88.9 percent, including MACE. Furthermore, 97.7 percent of stents were successfully delivered, and core lab assessed final procedure residual stenosis was 4.7 percent. The study included 443 patients at 49 U.S. medical centers and supported CSI's Premarket Application (PMA) submission. ORBIT II was the first Investigational Device Exemption (IDE) study in history to support approval for treating severely calcified coronary lesions. The technology was already in use for peripheral lesions.

Approximately 16.3 million Americans suffer from Coronary Artery Disease (CAD). Arterial calcium is a common occurrence and can lead to significant complications. According to estimates, significant arterial calcium is present in nearly 40 percent of patients undergoing a percutaneous coronary intervention.

"I have not been this excited by new technology in a long time, and I believe it is extremely promising," Dr. Lee says. "It is truly revolutionary and changes the outlook entirely for so many patients with coronary artery disease whose calcified lesions once made it more difficult to treat them and deliver the best outcomes for them. Thanks to Diamondback 360 Coronary OAD, that has changed in a big way."

**Note to Media:** Interviews, photographs and videography are available by contacting marketing representatives at either The Cardiac & Vascular Institute or North Florida Regional Medical Center.

**About Arthur Lee, MD, FACC:** Dr. Arthur Lee is a member of The Cardiac & Vascular Institute and is board certified in Interventional Cardiology, Nuclear Cardiology, Echocardiography, Cardiovascular Diseases and Internal Medicine. He completed his residency at Mount Sinai Medical Center and fellowship at Beth Israel Medical Center after medical training at Mount Sinai School of Medicine and undergraduate school at the University of Pennsylvania.

**About North Florida Regional Healthcare:** North Florida Regional Healthcare is an organization centered around the community hospital in Gainesville, Florida -- North Florida Regional Medical Center (NFRMC). NFRMC is a 445-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. A proven leader, NFRMC is fully accredited, is certified as a Primary Stroke Center and a Quality Top Performer by The Joint Commission in 2010, 2011 and 2012, is an accredited Chest Pain Center, is designated as a Blue Distinction™ Center for Knee and Hip Replacement, Spine Surgery and Bariatric Surgery and recognized by U.S. News & World Report for its High-Performing Gynecology Program in 2010. North Florida Regional Medical Center is a member of Hospital Corporation of America (HCA). Based in Nashville, Tennessee, HCA is the nation's leading provider of healthcare services, a company comprised of locally managed facilities that includes about 163 hospitals and 109 freestanding surgery centers in 20 states and Great Britain.

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