

## **News Release**

# Physician Demand Continues to Build for Cardiovascular Systems' New Coronary Artery Disease Treatment Technology

- Additional first cases treated at:
  - Chandler Regional Medical Center, Chandler, Ariz.
  - Deborah Heart and Lung Center, Brown Mills, N.J.
  - Florida Hospital, Orlando, Fla.

ST. PAUL, Minn.--(BUSINESS WIRE)--Jan. 23, 2014-- Cardiovascular Systems, Inc. (CSI) (NASDAQ: CSII), today announced that physician demand continues to build throughout the United States for its recently approved Diamondback 360® Coronary Orbital Atherectomy System (OAS). The system is the first and only technology approved for the treatment of severely calcified coronary lesions, and the only new FDA-approved coronary atherectomy device in more than two decades.

Said Dr. Rohit Bhatheja, Interventional Cardiologist, Florida Hospital, Orlando, Fla., a physician who recently treated his first case with the Diamondback 360 Coronary OAS: "Calcium in coronary arteries often goes undetected and even more, is left untreated because of its complexity. CSI's OAS enables physicians to easily treat severely calcified vessels, and allows for successful stent deployment."

Significant arterial calcium is present in nearly 40 percent of patients undergoing a percutaneous coronary intervention, and contributes to poor outcomes and higher treatment costs in coronary interventions when traditional therapies are used—including a substantially higher occurrence of death and major adverse cardiac events.

Commented Dr. Georges Nseir, Invasive Cardiologist, Chandler Regional Medical Center, Chandler, Ariz., "I am pleased there is a new technology available to treat the challenges of severely calcified coronary lesions. Clinical data shows that the Diamondback 360 device can help patients with severe coronary calcium, a tough-to-treat patient population. I appreciate having a proven and easy-to-use new technology."

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). It has 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.

According to Dr. Richard Kovach, Interventional Cardiologist, Deborah Heart and Lung Center, Brown Mills, N.J.: "CSI's new Diamondback 360 device offers my colleagues and me the ability to

more appropriately treat severe calcium in coronary arteries. The device has the ability to facilitate stent deployment by reducing the calcium in the vessel."

CSI continues its targeted coronary market launch, and plans to announce critical one-year data at the ACC conference in March 2014.

### **About Coronary Arterial Disease**

Coronary Artery Disease (CAD) is a life-threatening condition and leading cause of death in men and women in the United States. CAD occurs when a fatty material called plaque builds up on the walls of arteries that supply blood to the heart. The plaque buildup causes the arteries to harden and narrow (atherosclerosis), reducing blood flow. The risk of CAD increases if a person has one or more of the following: high blood pressure, abnormal cholesterol levels, diabetes, or family history of early heart disease. CAD affects an estimated 16.3 million people in the United States and is the most common form of heart disease. Heart disease claims more than 600,000 lives, or 1 in 4 Americans, in the United States each year. According to estimates, significant arterial calcium is present in nearly 40 percent of patients undergoing a percutaneous coronary intervention (PCI). Significant calcium contributes to poor outcomes and higher treatment costs in coronary interventions when traditional therapies are used, including a significantly higher occurrence of death and major adverse cardiac events (MACE).

#### About Cardiovascular Systems, Inc.

Cardiovascular Systems, Inc., based in St. Paul, Minn., is a medical device company focused on developing and commercializing innovative solutions for treating vascular and coronary disease. The company's Orbital Atherectomy Systems treat calcified plaque in arterial vessels throughout the leg and heart in a few minutes of treatment time, and address many of the limitations associated with existing surgical, catheter and pharmacological treatment alternatives. The U.S. FDA granted 510(k) clearance for the use of the Diamondback 360 Orbital Atherectomy System in August 2007. To date, more than 125,000 of CSI's devices have been sold to leading institutions across the United States. In October 2013, the company received FDA approval for the use of the Diamondback 360 Coronary Orbital Atherectomy System in coronary arteries. For more information, visit the company's website at www.csi360.com.

#### Safe Harbor

Certain statements in this news release are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and are provided under the protection of the safe harbor for forward-looking statements provided by that Act. For example, statements in this press release regarding (i) CSI's targeted coronary market launch, and (ii) CSI's plan to announce critical one-year data at the ACC conference in March 2014, are forward-looking statements.

These statements involve risks and uncertainties which could cause results to differ materially from those projected, including but not limited to dependence on market growth; the reluctance of physicians to accept new products; the effectiveness of the Diamondback 360 Coronary OAS; actual clinical trial and study results; the impact of competitive products and pricing; approval of products for reimbursement and the level of reimbursement; general economic conditions and other factors detailed from time to time in CSI's SEC reports, including its most recent annual report on Form 10-K

and subsequent quarterly reports on Form 10-Q. CSI encourages you to consider all of these risks, uncertainties and other factors carefully in evaluating the forward-looking statements contained in this release. As a result of these matters, changes in facts, assumptions not being realized or other circumstances, CSI's actual results may differ materially from the expected results discussed in the forward-looking statements contained in this release. The forward-looking statements made in this release are made only as of the date of this release, and CSI undertakes no obligation to update them to reflect subsequent events or circumstances.

#### **Product Disclosure**

**Indications:** The Diamondback 360° Coronary Orbital Atherectomy System (OAS) is a percutaneous orbital atherectomy system indicated to facilitate stent delivery in patients with coronary artery disease (CAD) who are acceptable candidates for PTCA or stenting due to *de novo*, severely calcified coronary artery lesions.

**Contraindications:** The OAS is contraindicated when the VIPERWIRE guide wire cannot pass across the coronary lesion or the target lesion is within a bypass graft or stent. The OAS is contraindicated when the patient is not an appropriate candidate for bypass surgery, angioplasty, or atherectomy therapy, or has angiographic evidence of thrombus, or has only one open vessel, or has angiographic evidence of significant dissection at the treatment site and for women who are pregnant or children.

**Warnings/Precautions:** Performing treatment in excessively tortuous vessels or bifurcations may result in vessel damage; The OAS was only evaluated in severely calcified lesions, A temporary pacing lead may be necessary when treating lesions in the right coronary and circumflex arteries; On-site surgical back-up should be included as a clinical consideration; Use in patients with an ejection fraction (EF) of less than 25 percent has not been evaluated.

See the instructions for use before performing DIAMONDBACK 360 coronary orbital atherectomy procedures for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information call CSI at 1-877-274-0901 and/or consult CSI's website at www.csi360.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Source: Cardiovascular Systems, Inc.

#### Cardiovascular Systems, Inc.

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