CARDIOVASCULAR SYSTEMS CORONARY DATA HIGHLIGHTED IN LATE-BREAKING PRESENTATION AT EUROPCR CONFERENCE

- Key Data on Treating Coronary Patients with Impaired Renal Function Also Featured in Podium Presentation
- Tibiopedal Peripheral Procedure Highlighted in Interactive Case Study


Dr. Jeffrey Chambers of Metropolitan Heart and Vascular Institute, Minneapolis, presented the data that demonstrated freedom from major adverse cardiac events (MACE) of 84 percent and freedom from target lesion revascularization of 95 percent.

Additionally, Dr. Chambers highlighted key economic statistics revealing that patients treated with the Diamondback 360® Coronary Orbital Atherectomy System (OAS) have been associated with shorter lengths of hospital stay and lower readmission rates than those treated with other atherectomy devices or stenting alone, suggesting an estimated cost savings in excess of $4,000 per patient for the treating institutions. The economic statistics are derived from a medical resource utilization analysis for both the index procedure and related readmission within 30 days of discharge from the ORBIT II clinical trial, compared to Medicare data available at that time, MedPAR data with code 414.4 between October 1, 2011, and September 30, 2012.

David L. Martin, CSI president and chief executive officer, said, “One-year results from the ORBIT II study reaffirm that CSI's orbital atherectomy technology is a safe and effective treatment for severely calcified coronary arteries that also results in durable outcomes. This is critical information for physicians to know, so we’re pleased that EuroPCR selected our data for a late-breaking presentation.”

ORBIT II, CSI’s pivotal study, evaluated the safety and effectiveness of the company’s orbital atherectomy technology in coronary arteries. CSI completed ORBIT II enrollment of 443 patients at 49 U.S. medical centers in November 2012. On October 21, 2013, the company received PMA approval from the U.S. Food and Drug Administration (FDA) to market its Diamondback 360 Coronary OAS as a treatment for severely calcified coronary arteries.

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. The poor outcomes include a substantially higher occurrence of death and MACE.

Podium Presentation: Treating Severely Calcified Lesions in Patients with Impaired Renal Function

Dr. Chambers, Dr. Stevan I. Himmelstein, the Stern Cardiovascular Center, Memphis, Tenn., and Dr. Arthur Lee, the Cardiac and Vascular Institute, Gainesville, Fla., also presented new ORBIT II data at a EuroPCR podium presentation. The results detail 30-day outcomes in patients with impaired renal function who were treated with the Diamondback 360 Coronary OAS to prepare severely calcified coronary lesions prior to stent deployment. A key finding was that, despite being an older demographic with longer lengths of calcium, patients with impaired renal function who were pretreated with the OAS had similar rates of procedural success (successful stent delivery and less than 50 percent residual stenosis) compared with patients without impaired renal function.
Tibiopedal Interactive Case Study
In March 2014, the FDA cleared CSI’s new Diamondback 360® 60cm Peripheral OAS device for the treatment of peripheral arterial disease (PAD). The clearance expands treatment options for challenging lesions in the lower leg, often associated with Critical Limb Ischemia (CLI). If left untreated, CLI may result in lower limb amputation.

At EuroPCR, Dr. Arthur Lee presented an interactive case study featuring a 75-year old woman with severely calcified multilevel disease, facing possible amputation. He showed that:

- The Diamondback 360 60cm Peripheral OAS device is 4F compatible, allowing treatment of the entire leg from a 4F tibial access point.
- Use of small access sheaths can reduce procedure times, enable quicker patient recovery and have fewer procedural complications from bleeding, providing additional procedural benefits to patients and physicians.

CSI’s Martin said: “The use of smaller access sheaths also reduces radiation exposure for the patient, physician and staff. Tibiopedal access expands treatment options for the estimated 20 percent of below-the-knee occlusions that are unable to be treated from the traditional femoral artery access site.”

About Coronary Artery 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. According to the American Heart Association, 16.3 million people in the United States have been diagnosed with CAD, the most common form of heart disease. Heart disease claims more than 600,000 lives 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 Peripheral Arterial Disease
More than 12 million Americans, most over age 65, suffer from PAD, which is caused by the accumulation of plaque in peripheral arteries (commonly the pelvis or leg) reducing blood flow. Symptoms include leg pain when walking or at rest. Left untreated, PAD can lead to severe pain, immobility, non-healing wounds and eventually limb amputation. With risk factors such as diabetes and obesity on the rise, the prevalence of PAD is growing at double-digit rates.

Millions of patients with PAD may benefit from treatment with orbital atherectomy utilizing the Stealth 360 and Diamondback 360, minimally invasive catheter systems developed and manufactured by CSI. These systems use a diamond-coated crown, attached to an orbiting shaft, which sands away plaque while preserving healthy vessel tissue—a critical factor in preventing reoccurrences. Balloon angioplasty and stents have significant shortcomings in treating hard, calcified lesions. Stents are prone to fractures and high recurrence rates, and treatment of hard, calcified lesions often leads to vessel damage and suboptimal results.

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 and fibrotic 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 Orbital Atherectomy System in August 2007. To date, over 146,000 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 Orbital Atherectomy System in coronary arteries. For more information, visit the company’s website at www.csi360.com.

**Coronary 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.

**Peripheral Product Disclosure**

The Diamondback 360® Peripheral Orbital Atherectomy Systems are percutaneous orbital atherectomy systems indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and stenotic material from artificial arteriovenous dialysis fistulae. The peripheral systems are contraindicated for use in coronary arteries, bypass grafts, stents or where thrombus or dissections are present. Although the incidence of adverse events is rare, potential events that can occur with atherectomy include: pain, hypotension, CVA/TIA, death, dissection, perforation, distal embolization, thrombus formation, hematuria, abrupt or acute vessel closure, or arterial spasm.

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