



**CARDIOVASCULAR SYSTEMS PRESENTS NEW ACUTE AND LONG-TERM DATA FROM THREE PERIPHERAL CLINICAL STUDIES**

**CALCIUM 360° Study Shows Improved Six-Month Results with Diamondback 360° Versus Balloon Angioplasty Alone in Patients with Critical Limb Ischemia**

**Predator 360° Study Shows Durable Long-Term Results**

**Single-Center Data from CONFIRM II Predator Registry Demonstrate Excellent Safety and Efficacy Results in Challenging, Real-World Population**

**St. Paul, Minn. and New Orleans – June 6, 2011** – Cardiovascular Systems, Inc. (CSI) (Nasdaq: CSII), announced data highlighting the advantages of its Diamondback and Predator 360° PAD Systems at the New Cardiovascular Horizons (NCVH) meeting in New Orleans. Both systems, developed by CSI, are minimally invasive catheter systems that remove hardened plaque to restore blood flow in peripheral arteries. Three different studies representing four e-abstracts confirm the safety and effectiveness, as well as long-term effectiveness of plaque modification with orbital technology in arteries above and below the knee. These studies contribute to a large and growing body of clinical evidence demonstrating that CSI’s orbital PAD systems can predictably treat peripheral arterial disease (PAD) in routine and complex cases.

“The data presented at NCVH reinforce the advantages of our orbital technology, including improved results versus balloon angioplasty, which was once considered the gold standard,” said David L. Martin, president and chief executive officer of CSI. “We now have data from nearly 3,000 patients—more than any other device of its kind—and we are committed to ongoing clinical and scientific investigation to support physicians in making treatment decisions and achieving optimal patient outcomes.”

**Six-Month Results of CALCIUM 360° Study Show Improved Outcomes Over the Current Standard of Care**

Dr. Russell Lam, Presbyterian Hospital, Dallas, reported on the newly released six-month results of the prospective CALCIUM 360° study. The study randomized 50 patients to either orbital treatment or balloon angioplasty in patients with Critical Limb Ischemia (CLI). The key finding was that the Diamondback 360° did not increase procedural costs, but ischemic burden of the limb was reduced. Orbital treatment outperformed balloon angioplasty on the primary endpoint of device success ( $\leq 30$  percent residual stenosis with no dissection C-F) with 92.6 percent in the orbital arm versus 78.8 percent in the balloon arm meeting the endpoint. In addition, durability at six months shows potential for improved long term outcomes.

<b>Six-Month CALCIUM 360° Results</b>		
	Orbital Arm	Balloon Arm
Death	0	16%
Freedom from amputation	92%	88%
Re-intervention	0	4%
ABI (Baseline / 6 months)	.81 / .97	.70 / 1.00

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“Endovascular treatment with the Diamondback 360° should be viewed as a new standard of care in treating patients who are at risk of losing their limbs,” said Dr. Lam. “By modifying calcified lesions first, the Diamondback 360° allows use of a lower pressure adjunctive balloon therapy, and reduces the need for bailout stenting with improved longer-term patient outcomes.”

### **Single-Center Results of CALCIUM 360° Study Provide Insight into Treating CLI Patients**

Single-center results from the CALCIUM 360° Study were presented by Dr. Mustapha, Metro Health Hospital, Grand Rapids, Mich. The data included 15 patients with 18 lesions with moderately or severely calcified below-the-knee lesions. Results revealed the final residual stenosis was less for the Diamondback 360° system, at 9 percent, than for balloon angioplasty, at 36 percent; a lower rate of intraprocedural events and bail-out stenting; and six-month results consistent with the overall study population.

### **Diamondback 360° Predator Study Delivers Durable 12-Month Results**

Dr. Prakash Makam, Community Hospital, Munster, Ind., evaluated the long-term durability of plaque modification with the Predator 360° on 46 patients with 57 lesions. Only five patients (8.8 percent) returned for retreatment of the target lesion within 12 months, which is consistent with the OASIS Long-Term Study 12-month results of 8.9 percent. In addition, this single-center study showed that the Predator 360° effectively modified lesion compliance in resistant plaques, demonstrated by the need for only a low pressure adjunctive balloon (5.3 atmospheres of pressure for an average of 2.3 minutes). Bail-out stenting was not needed in this challenging patient population, and only one dissection was reported.

### **Single-Center Results of CONFIRM II Predator Registry Yield Excellent Acute Outcomes**

Dr. Gaurav Aggarwala, Utah Cardiology, Layton, Utah, reported on his single-center results of 35 patients with 65 lesions from the recently completed CONFIRM II Predator Study, which enrolled a total of 1,127 patients from 122 centers. Intraprocedural events included one minor dissection due to balloon angioplasty (1.5 percent), and no occurrences of perforation, slow flow, abrupt closure or distal embolization. Bail-out stenting due to dissection occurred in only 1.5 percent of lesions. Patients had lesions throughout the entire leg (superficial femoral and other proximal vessels 51 percent, popliteal 38 percent, and tibials 11 percent). Results included a reduction in stenosis from 89 percent pre-procedure, to 31 percent post orbital treatment and 7 percent post adjunctive therapy. Device run time averaged 71 seconds per patient and was followed by low-pressure balloon angioplasty (mean 2.61 atmospheres of pressure) in 92 percent of patients.

“This data validates that the Predator 360° can safely remove moderately to severely calcified plaque throughout the entire leg,” said Dr. Aggarwala. “In my experience, this method of plaque removal, followed by low-pressure balloon angioplasty, provides predictable, repeatable results.”

### **About Peripheral Arterial Disease**

As many as 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 the Stealth 360° and Diamondback 360°, minimally invasive catheter systems developed and manufactured by CSI. These systems use a diamond-coated crown, attached to a guide wire to sand away plaque while preserving healthy vessel tissue, or medial integrity — 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 Stealth 360°™, Diamondback 360°® and Diamondback Predator 360°® Orbital PAD Systems treat calcified and fibrotic plaque in arterial vessels throughout the leg 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° in August 2007 and for the Stealth 360° in March 2011. To date, more than 46,000 PAD procedures have been performed using the Diamondback 360° in leading institutions across the United States.

CSI has also commenced its ORBIT II Investigational Device Exemption clinical trial to evaluate the safety and effectiveness of its Diamondback 360° System in treating coronary arteries. The coronary system is under clinical investigation and is currently not commercially available in the United States.

For more information, visit the company's website at [www.csi360.com](http://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 CSI's ongoing and future clinical trials and the future benefits of CSI's orbital PAD systems 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 the potential for unanticipated delays in enrolling medical centers and patients for clinical trials; the performance of the Diamondback Systems; 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**

The Diamondback 360°® PAD System, Diamondback Predator 360°™ PAD System and Stealth 360° Orbital PAD System 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 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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