

# First Patient Enrolled in COMPLIANCE 360° Clinical Trial

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## Prospective, Randomized Trial Evaluating the Clinical Benefits of Treating Above-the-Knee Peripheral Arterial Disease with the Diamondback® 360 PAD System

St. Paul, Minn., July 13, 2009 – Cardiovascular Systems, Inc. (CSI; Nasdaq: CSII), a medical device company developing and commercializing innovative interventional treatment systems for vascular disease, announced today that the first patient has been enrolled in the COMPLIANCE 360° clinical trial. This prospective, randomized study will generate additional data on patient outcomes achieved in treating lesions above the knee with CSI's Diamondback 360® System, a minimally invasive catheter for treating peripheral arterial disease (PAD).

COMPLIANCE 360° will compare the benefits of first modifying calcified plaque with the Diamondback 360° system followed by low-pressure balloon inflation if needed, versus the use of high-pressure balloon angioplasty alone in calcified lesions above the knee. Treatment with only high-pressure balloon angioplasty often damages large diseased vessels above the knee. Initial treatment with the Diamondback 360° could reduce the level of balloon pressure required to finish opening the vessel. The COMPLIANCE 360° study calls for enrolling 50 patients at five U.S. medical centers. Patients will be followed for 12 months, and an independent angiography core lab will verify results.

"CSI is devoted to clinical research that leads to innovative solutions to conquer PAD and keep patients walking without pain," said David L. Martin, CSI president and chief executive officer. "The physical, emotional and financial toll of more than 100,000 amputations annually in the United States is unacceptable. Our tool in doctors' hands has successfully treated more than 15,000 patients in less than two years since our FDA clearance. We are confident that the Diamondback 360° offers an effective solution to address PAD, giving patients and their loved ones new hope. COMPLIANCE 360° is the first of several post-market studies CSI is sponsoring to provide physicians with the clinical data they need. We plan to launch CALCIUM 360°, a study evaluating treatment with the Diamondback 360° in calcified lesions below the knee, in the coming months."

CSI received FDA 510(k) marketing clearance for the Diamondback 360° as a PAD therapy in August 2007 on the basis of data from the OASIS study, a prospective study which enrolled 124 patients at 20 medical centers. Since then, nearly 500 hospitals have adopted the Diamondback 360° system.

Dr. Ravish Sachar, an interventional cardiologist at WakeMed Health and Hospital in Raleigh, N.C., who enrolled the first patient in the COMPLIANCE 360° trial, commented, "The Diamondback 360° represents a viable treatment option for patients who previously have had limited options. Treating this disease can be very challenging due to the frequency of non-compliant, calcified plaque resulting from diabetes, smoking or renal failure. It has long been understood that high-pressure balloon angioplasty alone in these types of lesions can lead to vessel damage, and this study will help provide insight into the benefits of plaque modification prior to angioplasty."

Dr. Ray Dattilo, COMPLIANCE 360° principal investigator and director of peripheral interventions at St. Francis Hospital, Topeka, Kan., added, "In this difficult healthcare environment, with increasing costs and not enough dollars to go around, it is especially important to demonstrate that a new technology is better than the current standard of care. CSI understands that spending scarce healthcare dollars wisely is a necessity, and the company is willing to devote resources to a randomized trial. The Diamondback system, supported by sound clinical data, could create a paradigm shift in the treatment of PAD."

### About Cardiovascular Systems, Inc.

Cardiovascular Systems, Inc. is a medical device company focused on developing and commercializing interventional treatment systems for vascular disease. Between 8 and 12 million Americans suffer from peripheral arterial disease (PAD), which is caused by the accumulation of plaque in leg or foot arteries, reducing blood flow and leading to leg pain, and eventually tissue loss and amputation. The company's Diamondback 360° Peripheral Arterial System is capable of treating a broad range of plaque types both above and below the knee, and addresses many of the limitations associated with existing treatment alternatives. In August 2007, the U.S. FDA granted 510(k) clearance for the use of the Diamondback 360° as a therapy for PAD (peripheral arterial disease), and CSI commenced a U.S. product launch in September 2007. The company provides a comprehensive system for treating PAD through its Viper line of supplemental products and by offering Invatec balloon catheters. The Diamondback 360° system has been adopted by nearly 500 hospitals across the United States. For more information visit the company's Web site 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 intended to enjoy the protection of the safe harbor for forward-looking statements provided by that Act. For example, statements in this press release regarding (i) the data to be generated by the COMPLIANCE 360° study; (ii) the anticipated benefits of initial treatment with the Diamondback 360°; (iii) the number of patients to be enrolled and expected follow up; and (iv) our plans to launch the CALCIUM 360° study, 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 studies; new data or events that may disrupt plans for these studies; and other factors detailed from time to time in CSI's SEC reports, including its registration statement on Form S-4 declared effective by the SEC on January 26, 2009. 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.