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**Piedmont Heart Institute Enrolling Patients in Clinical Trial**  
*Replacing Heart Valves Without Surgery*

**Atlanta, Ga.** (August 4, 2011)—Piedmont Heart Institute Physicians are currently accepting patients for the Medtronic CoreValve® U.S. Clinical Trial. Piedmont Hospital is one of 40 hospitals across the United States to participate in the trial to evaluate a revolutionary non-surgical, less-invasive procedure as a treatment alternative to open-heart surgery for patients with severe aortic stenosis.

Patients who have severe aortic stenosis as well as a predicted high risk of requiring aortic valve surgery may be eligible to participate in the clinical trial. For more information about the CoreValve trial and eligibility, visit [clinicaltrials.gov](http://clinicaltrials.gov) and search for the CoreValve trial.

“With an estimated 5 percent of those over the age of 65 experiencing some form of aortic stenosis, there is significant need for new treatment options that do not involve invasive surgery,” said Piedmont principal investigator Vivek Rajagopal, M.D., an interventional cardiologist with Piedmont Heart Institute Physicians. “As the population ages, the need for this procedure will continue to grow.”

According to an abstract published in the *European Heart Journal* in 2003, worldwide, approximately 300,000 people have been diagnosed with this condition (100,000 in the United States), and approximately one-third of these patients are deemed high risk for open-heart surgery, the only therapy with significant clinical effect that is currently available in the United States.

For trial participants randomly selected to receive the CoreValve System, physicians channel a catheter (thin tube) with a porcine, prosthetic valve through a small opening in the patient’s femoral artery to reach the heart. The physician guides the CoreValve System to the aortic valve, where it self-expands to replace the diseased aortic valve; the procedure is completed without open-heart surgery or surgical removal of the native valve.

In the United States, the CoreValve System will not be commercially available until the successful completion of this clinical trial and approval by the U.S. Food and Drug Administration (FDA). The CoreValve System received CE (Conformité Européenne) Mark in Europe in 2007.

For more information or to be considered as a participant in the trial, contact the Piedmont Heart Institute at 404-605-5003 or email [phri@piedmont.org](mailto:phri@piedmont.org).

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#### **About Aortic Stenosis**

Aortic stenosis, which is most prevalent in the elderly population, inhibits blood flow between the heart and the body and causes symptoms such as shortness of breath, chest pain, fatigue and heart palpitations. While the heart initially compensates for stenosis by thickening its walls to help push blood through the valve, eventually this extra work weakens the heart and leads to an insufficient supply of oxygen-rich blood and sometimes causes a back-up of blood into the lungs. Untreated, aortic valve stenosis can lead to serious heart problems including heart failure and even death. Other than surgery, patients with this condition have had few, if any, successful treatment options.

#### **About Piedmont Heart Institute**

*Piedmont Heart Institute (PHI) is the first integrated cardiovascular healthcare delivery program affiliated with a community health system in greater Atlanta and is headquartered on the campus of Piedmont Hospital, a 481-bed tertiary care facility offering all major medical, surgical and diagnostic services. Offering a continuum of patient care, including primary and secondary prevention, outpatient and inpatient cardiovascular care, and appropriate quality measures and metrics to demonstrate enhanced outcomes, Piedmont Heart Institute combines more than 100 affiliated cardiovascular specialists in Piedmont Heart Institute Physicians with over 30 locations to propel new programs in cardiovascular research, education and excellence in prevention, arrhythmias, coronary and vascular intervention, stroke and cardiac imaging. Locations span from south of Atlanta in Fayette and Coweta counties to north of Blairsville in Murphy, N.C. South of Atlanta, Piedmont Heart Institute Physicians practice at both Piedmont Fayette Hospital and Piedmont Newnan Hospital. Piedmont Heart Institute is part of Piedmont Healthcare (PHC), a not-for-profit organization that also includes Piedmont Fayette Hospital, a 143-bed, acute-care community hospital in Fayetteville and one of the 100 Top Hospitals® in the nation; Piedmont Mountainside Hospital, a 42-bed community hospital in Jasper; and Piedmont Newnan Hospital, a 143-bed, acute-care community hospital in Newnan. Piedmont Healthcare also is the parent company of the Piedmont Physicians Group, with more than 100 primary care physicians in over 30 offices throughout metro Atlanta; the Piedmont Clinic, a 600-member physician network; and Piedmont Philanthropy, the philanthropic entity for private fundraising initiatives. For more information, visit [piedmonthheart.org](http://piedmonthheart.org).*