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**EXOSEAL VASCULAR PLUG GETS GOOD REVIEWS IN ECLIPSE STUDY**  
*Bleeding stops sooner, patients walk earlier with bioabsorbable plug*

**CHICAGO, Ill. (April 1, 2008)** — A new bioabsorbable plug that seals the arterial puncture site used for threading catheters into the body during diagnostic angiography and interventional procedures significantly shortens bleeding time and enables patients to get up and walk around far sooner than when manual compression is applied to the groin. In addition, there were no access site complications at 30 days in the ECLIPSE Trial, a multicenter randomized study that is testing the safety and effectiveness of the investigational ExoSeal vascular closure device.

The study will be reported today in a Late-Breaking Clinical Trials session at the SCAI Annual Scientific Sessions in Partnership with ACC i2 Summit (SCAI-ACCi2) in Chicago. SCAI-ACCi2 is a scientific meeting for practicing cardiovascular interventionalists sponsored by the Society for Cardiovascular Angiography and Interventions (SCAI) in partnership with the American College of Cardiology (ACC).

“We demonstrated that the ExoSeal device is a great alternative to manual compression following diagnostic and interventional procedures,” said Shing-Chiu Wong, MD, a professor of medicine at Weill Medical College of Cornell University and director of the cardiac catheterization laboratories at New York Presbyterian Hospital/Weill Cornell Medical Center, New York City. “It enables early ambulation and, potentially, early discharge from the hospital following the procedure.”

The ExoSeal™ Vascular Closure Device consists of a felt-like plug made of polyglycolic acid. It is anchored in place on top of the puncture in the femoral artery, after the catheter is removed. Because none of the plug is inserted into the artery itself, it does not interfere with blood flow. Over about three months, it completely dissolves. By comparison, manual compression involves exerting pressure on the femoral artery by hand or through use of a weight or clamp. This process can be uncomfortable for patients. It can take up to roughly 20 minutes for the bleeding to stop and several hours before the patient can get up from lying flat in bed.

For the study, Dr. Wong and his colleagues recruited 488 patients from 17 medical centers, half of whom were undergoing diagnostic angiography and half, an interventional procedure. Some 90 percent were being examined or treated for coronary disease, the remaining 10 percent for peripheral disease. Patients were randomly assigned to treatment with the ExoSeal or to manual compression.

The ExoSeal device was put into place in an average of just one minute and was used successfully in 89.1 percent of patients. There was no difference in procedural success between the ExoSeal and manual compression groups (91.8 percent and 91.0 percent, respectively). However, the average time to cessation of bleeding was significantly shorter in patients treated with the ExoSeal (4.38 minutes vs. 20.05 minutes,  $p < 0.0001$ ). Similarly, patients treated with the vascular closure device were able to get out of bed and walk around far sooner, within 2.54 hours, on average, with the ExoSeal, as compared with 6.24 hours with manual compression ( $p = 0.028$ ).

The next research step will be to put the ExoSeal to tougher challenges. "Further investigation is needed to delineate the device's applicability in patients with access puncture sites at or below the branchpoint of the femoral and iliac arteries and in patients with mild or moderate peripheral vascular disease," he said. "Comparative studies of efficacy and patient comfort with the ExoSeal and other vascular closure devices will also be intriguing."

*Dr. Wong will present the results of the "Ensure's Vascular Closure Device Speeds Hemostasis" (ECLIPSE) study on Tuesday, April 1 at 11:00 a.m. CDT in the Grand Ballroom, S100.*

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### **About SCAI**

Headquartered in Washington, DC, the Society for Cardiovascular Angiography and Interventions is a 4,000-member professional organization representing invasive and interventional cardiologists in over 60 nations. SCAI's mission is to promote excellence in invasive and interventional cardiovascular medicine through physician education and representation, and advancement of quality standards to enhance patient care. SCAI's annual meeting has become the leading venue for education, discussion, and debate about the latest developments in this dynamic medical specialty.

### **About ACC**

The American College of Cardiology is leading the way to optimal cardiovascular care and disease prevention. The College is a 34,000-member nonprofit medical society and bestows the credential Fellow of the American College of Cardiology upon physicians who meet its stringent qualifications. The College is a leader in the formulation of health policy, standards and guidelines, and is a staunch supporter of cardiovascular research. The ACC provides professional education and operates national registries for the measurement and improvement of quality care.