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CEREBRAL EMBOLIC PROTECTION AND CAROTID STENT SYSTEMS HELP HIGH-RISK SURGICAL PATIENTS

NEW ORLEANS, La. (March 26, 2007) — High-risk surgical patients in community hospital settings can safely benefit from the use of new embolus-removing and stent-inserting systems, according to a study presented today at the American College of Cardiology's *Innovation in Intervention: i2 Summit* in New Orleans, La. The use of these systems to treat carotid artery blockage has only been studied in limited clinical trials, prior to FDA approval, in the pivotal SECuRITY (Registry Study to Evaluate the Neuroshield Bare Wire Cerebral Protection System and X-Act Stent in Patients at High Risk for Carotid Endarterectomy, 2004) study. *Innovation in Intervention: i2 Summit* is an annual meeting for practicing cardiovascular interventionalists sponsored by the American College of Cardiology in partnership with the Society for Cardiovascular Angiography and Interventions.

During carotid artery stenting, a small catheter tube is threaded into the artery and a stent is inserted and expanded inside the artery to increase blood flow in areas blocked by arterial build-up. While the stent is being placed, either arterial plaque or a blood clot could dislodge and cause serious complications. Embolic protection devices help capture and remove the debris created during arterial procedures through the use of a filter trap.

The current study, known as the EXACT study (Emboshield™ and Xact® Post Approval Carotid Stent Trial), tracked the progress of 1,500 patients in community hospitals who received

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carotid stent and/or embolic protection device treatments over the course of 30 days. Arterial pre-dialation (enlargement/widening of the arteries prior to stenting), symptomatic status and age acted as independent factors for death, stroke or peri-procedural complications, but only 4.5 percent of patients in the EXACT study suffered from peri-procedural complications, compared to 7.5 percent in the SECuRITY study.

"The EXACT results demonstrate that community hospital physicians with appropriate experience levels and device training can provide exemplary outcomes for patients in need of carotid stenting, and that results of stenting appear to be improving with greater experience," said William Gray, M.D., Director of Endovascular Services, Associate Professor of Medicine, Columbia University and lead author of the study. "Post-approval studies like EXACT are very important because they provide an opportunity to assess how technology can transfer to a new group of physicians, identify unforeseen equipment issues, and evaluate treatment outcomes not identified in restricted clinical trial settings."

Dr. Gray will present the results of the "EXACT 1500 Registry: Report of U.S. Multi Center Experience in Carotid Stenting in High Surgical Risk Patients" study on Monday, March 26 at 11:15 a.m. in room La Nouvelle Orleans C.

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