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Roper St. Francis First in South Carolina to Implant AMPLATZER Cardiac Plug in Stroke Prevention Study

New clinical research study offers hope for patients with atrial fibrillation

CHARLESTON, S.C. (Current Date) – Two doctors at Roper St. Francis recently performed a groundbreaking heart procedure that may prevent blood clots from escaping the heart and causing a stroke.

Doctors conducted the procedure Aug. 13 at Roper Hospital, marking the first time in South Carolina that a physician inserted the AMPLATZER™ Cardiac Plug. Considered an investigational device in the U.S., the device prevents blood clots from migrating out of an area of the heart called the left atrial appendage (LAA) and potentially causing a stroke in patients with non-valvular atrial fibrillation (AF). Defined as a quivering or irregular heartbeat (arrhythmia), AF can lead to blood clots, stroke and heart failure.

The procedure is part of a new clinical trial which is being conducted by PMG Research of Charleston and is sponsored by St. Jude Medical, who developed the device. Currently, RSF is the only approved hospital participating in the study in South Carolina. Brett Baker, MD, of Carolina Arrhythmia Consultants and Matthew O'Steen, MD, of Coastal Cardiology, both RSF affiliates, are the principal investigators for this new clinical study at Roper Hospital.

O'Steen called the plug a possible "blockbuster" for stroke prevention which could be used as an alternative to clot-reducing drugs should the device be proved safe and effective. Baker, his clinical trial colleague, could not agree more.

"Strokes from atrial fibrillation are one of the most devastating events a person can experience," Baker said. "And this device is the most exciting development in stroke prevention to come along in the past 25 years."

The purpose of the clinical trial is to test the safety and effectiveness of the AMPLATZER Cardiac Plug to traditional medical treatment where patients with AF take long-term, blood-thinning medication. Delivered via a catheter that is inserted in a patient's leg, the device is designed to completely seal off the LAA at its opening, and minimize blood clots from forming and migrating into the bloodstream.

The LAA is a small finger-shaped pouch located on the upper left atrium of the heart. Blood can pool in the LAA and over time, form clots that can escape from the heart, travel to the brain and potentially lead to a stroke. Clots may also travel to other parts of the body and cause serious health problems.

According to the American Heart Association, an estimated 2.7 million Americans have atrial fibrillation and the likelihood of developing it increases with age. The new tool could help cardiovascular physicians serve people who suffer from AF, a condition caused when the heart's upper chambers beat too fast and irregularly, reducing the atrium's ability to pump blood.

"A trial with a similar device has been shown to decrease mortality at four years after implantation in patients who had their left atrial appendage plugged rather than stay on anticoagulation medications," O'Steen said.

That is promising news, as research shows two-thirds of strokes in AF are either fatal or severely debilitating and more than 90 percent of strokes in AF patients originate in the LAA.

For more information about this trial, contact PMG Research of Charleston at (843) 849-1880 or www.PMGofCharleston.com

About PMG Research, Inc.

PMG Research, Inc. is an Integrated Site Network (ISN) of clinical research facilities in the southeast region of the United States. We have extensive experience conducting all phases of trials across a comprehensive list of conditions. Since 1979, PMG has conducted over 6,000 research studies for more than 100 pharmaceutical sponsors and CROs. Our progressive organization is comprised of a team of highly effective professionals and a network of specially designed sites. Our mission as an ISN is to provide unparalleled service to our clinical trial partners. We commit to progress, integrity and excellence. For more information about PMG Research, please visit www.pmg-research.com.

About Roper St. Francis

Roper St. Francis is the Lowcountry's only private, not-for-profit healthcare provider. The 657-bed system comprises more than 90 facilities and services in seven South Carolina counties. Learn more at rsfh.com.