
St. Jude Medical Announces First Patient Implant with AMPLATZER Cardiac Plug



The AMPLATZER™ Cardiac Plug (Image Credit: St. Jude Medical, Inc.)

St. Jude Medical, Inc., a global medical device company, today announced the first patient implant in a new pivotal trial evaluating the company's AMPLATZER™ Cardiac Plug (ACP) for the prevention of stroke. The AMPLATZER™ Cardiac Plug Clinical Trial (ACP Trial) is designed to determine if the ACP device is safe and effective in preventing thrombus (blood clots) from migrating out of the left atrial appendage (LAA) in patients with non-valvular atrial fibrillation (AF) who have a high risk for stroke.

The ACP Trial is a prospective, randomized, multi-center clinical study with an adaptive trial design that will enroll no fewer than 400 and no more than 3,000 patients at up to 90 sites in the U.S. and Canada. The trial compares the safety and efficacy of the ACP device to traditional medical treatment using long-term, blood-thinning medication.

Dr. Christian Machado, director of electrophysiology at the Providence Hospital Heart Institute, Southfield, Mich., and investigator in the study, performed the first AMPLATZER Cardiac Plug implant in the pivotal phase of the trial. The procedure was assisted by Dr. Thomas Forbes, a pediatric interventional cardiologist who is also an investigator in the study.

"Patients with untreated atrial fibrillation are four to five times more likely to have a stroke, which greatly increases their risk of disability or death. Dr. Forbes and I consider the ACP Trial an important study as we look for ways to reduce this risk," said Dr. Machado. "We are excited to contribute research that may help expand treatment options for patients."

The AMPLATZER™ device has been the market leader for LAA occlusion since its introduction in 2008. A self-expanding occlusion device constructed from nitinol mesh, and delivered via catheter, the ACP device is designed to completely seal the LAA (a tubular-shaped, muscular appendage connected to the left atrium of the heart) at its opening, and minimize blood clots from forming in the LAA and migrating into the bloodstream.

According to the American Heart Association, an estimated 2.7 million Americans have AF and the likelihood of developing it increases with age. Defined as a quivering or irregular heartbeat (arrhythmia), AF can lead to blood clots, stroke, heart failure and other heart-related complications. AF is the most common heart rhythm abnormality in people over the age of 65.

During episodes of AF, the heart contracts at rapid and irregular intervals, which can increase the likelihood of clot formation in the LAA. If a clot is released from the LAA, it can enter the blood stream and potentially travel to the brain, resulting in a stroke.

Each ACP Trial study site will have physicians who specialize in electrophysiology (doctors trained to diagnose and treat abnormal heart rhythms) and interventional cardiology (doctors who perform minimally invasive, catheter-based procedures for the heart) forming a collaboration between the two specialties.

"The current standard of care for the prevention of stroke is warfarin or other oral blood-thinning medications that can be difficult for some people to tolerate, and may carry a risk of serious complications, such as bleeding," said Dr. James Hermiller, an interventional cardiologist from St. Vincent Hospital in Indianapolis and ACP Trial investigator. "As physicians, we are always looking for new ways to best treat our patients. We hope the ACP Trial will prove that we can reduce the risk of stroke in patients with atrial fibrillation through this minimally-invasive procedure."

According to the World Health Organization (WHO), an estimated 15 million strokes occur worldwide each year. In 2010, stroke cost the U.S. an estimated \$53.9 billion in health care services, medications and missed days of work. Approximately 87 percent of all strokes are ischemic, which occur when blood clots block the blood vessels to the brain. AF is responsible for approximately 20 percent of ischemic strokes, and about one-third of AF patients will have a stroke in their lifetime if not treated appropriately.

"The AMPLATZER Cardiac Plug has shown great promise in international markets and we look forward to establishing the evidence required to make it available in the U.S.," said Frank J. Callaghan, president of the St. Jude Medical Cardiovascular and Ablation Technologies Division. "The ACP Trial is another example of significant investment by St. Jude Medical to develop landmark clinical evidence. This trial will help us understand the long-term benefits of LAA occlusion therapy for lowering the risk of stroke in atrial fibrillation patients and potentially improve their quality of life."

Earlier this year, St. Jude Medical received CE Mark approval and launched the AMPLATZER™ Amulet™ Left Atrial Appendage Occluder. Considered a next-generation occlusion device, the AMPLATZER Amulet design was driven by feedback from physicians who have been

implanting the AMPLATZER Cardiac Plug in Europe since 2008. The Amulet occluder is built with a longer lobe and waist than previous versions to allow for easier placement. The end screw is flush with the disc to create a smooth surface within the left atrium, and the larger disc diameter offers increased orifice coverage. The AMPLATZER Amulet device is offered in eight sizes to accommodate varying anatomies. Additionally, the device is pre-loaded into the delivery catheter, which simplifies device preparation and ultimately streamlines the entire procedure for the physician.

The AMPLATZER Cardiac Plug device is currently not approved for use in the U.S. The ACP Trial is conducted under an Investigational Device Exemption (IDE) from the U.S. Food and Drug Administration (FDA).

Source: [St. Jude Medical](#)

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