

NEWS RELEASE

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**AGA Medical Corporation Launches Clinical Study Comparing
AMPLATZER® PFO Occluder and Standard Drug Treatment
for Preventing Recurrent Stroke in PFO Patients**

MINNEAPOLIS, MN - June 30, 2003 — AGA Medical Corporation today announced the start of enrollment for a major clinical trial to evaluate whether transcatheter closure of a common heart defect, patent foramen ovale (PFO), using the implantable AMPLATZER® PFO Occluder is superior to standard of care medical treatment in preventing recurrent stroke or transient ischemic attack (TIA) in patients with PFO.

The RESPECT Clinical Trial (**Randomized Evaluation of Recurrent Stroke comparing PFo Closure to Established Current Standard of Care Treatment**) is the first of its kind unconditionally approved by the U.S. Food and Drug Administration (FDA). The trial will include a maximum of 45 medical institutions and 500 patients. Patients will be randomized so that half are implanted with the AMPLATZER PFO Occluder device and half receive one of four standard medical therapy regimens, typically anticoagulation or antiplatelet drugs (either alone or in combination with aspirin).

Enrollment in the RESPECT Clinical Trial is expected to close within 18 months. Follow-up time for each patient will be two years. Efficacy will be determined based on the number of patients who do not experience serious adverse events, including recurrent symptomatic stroke, fatal stroke, or death within 30 days from any cause. Although the trial could span as long as 48 months, “decision rules” built into the study’s design will enable an earlier outcome if and when the number of serious adverse events in either patient group exceeds certain statistically valid thresholds.

“The RESPECT Clinical Trial marks a true milestone in the investigation and treatment of PFO,” Franck Gougeon, AGA Medical’s chief executive officer. “If the AMPLATZER PFO Occluder proves superior to traditional medical treatment in preventing recurrence, stroke survivors who have a PFO will value knowing they have a safe, proven, highly effective alternative to a life-long regimen of drug therapy. AGA Medical is pleased to be conducting this ambitious study. And we appreciate greatly the involvement of the participating institutions and medical professionals.”

Patient Selection

Inclusion criteria for the RESPECT Clinical Trial include patients between the ages of 18 and 55, with PFO, who have had a cryptogenic stroke (defined as acute focal neurological deficit) within the last 90 days, presumed due to focal ischemia and either:

- Persisting more than 24 hours
- Persisting less than 24 hours, but associated with MR or CT findings

A number of exclusion criteria also have been established for the trial. Physicians who wish to learn more, enroll a patient, or find a participating medical center, can visit AGA Medical on the Web at [ww.amplatzer.com](http://www.amplatzer.com), or call toll-free 800-899-3925.

Background

The AMPLATZER PFO Occluder has been implanted internationally since 1997. In 2002 the FDA approved the device under Humanitarian Device Exemption (HDE) regulations, meaning it can be implanted in PFO patients only when conventional drug therapy fails to prevent recurrent stroke. AGA Medical expects to apply for full market approval of the device pending successful completion of the RESPECT Clinical Trial.

The foramen ovale is a gap in two overlapping sections of the septum, or wall, that divides the heart's upper chambers. This gap occurs normally in fetuses, but usually fuses shut soon after birth. When it remains open, or "patent," moderate to life-threatening circulatory disorders can occur, such as blood clots that pass through the PFO, triggering TIA (temporary blockage of blood supply to the brain) or stroke (prolonged interruption of blood supply to the brain).

Patients who experience a stroke or TIA, and who have been diagnosed with PFO, are typically treated with anticoagulant or antiplatelet drugs to prevent or minimize blood clotting. Despite drug therapy, many PFO patients suffer recurrent TIA or stroke. When a PFO patient's recurrent TIA or stroke cannot be traced to another source, the need for closure of the PFO is indicated.

The AMPLATZER PFO Occluder offers patients and their physicians a less-invasive alternative to open-heart surgery for closing PFO, a heart defect found in about 25 percent of adults. The device is implanted via a catheter inserted in the patient's groin. Its two Nitinol-wire mesh discs, filled with polyester fabric, "clasp" the septum shut. Typical implantation is a 1- to 2-hour procedure. Most recipients leave the hospital within 24 hours.

In the United States, it is estimated that more than 100,000 PFO patients suffer stroke or TIA each year. It is these patients who would be candidates to decline conventional drug treatment and opt instead for PFO closure with the AMPLATZER PFO Occluder, if the device proves superior to drug treatment in the RESPECT trial.

AGA Medical Corporation, a Minneapolis-based company, is the world's leading manufacturer of transcatheter occlusion devices that empower minimally invasive treatment of congenital heart defects. For more information, visit www.amplatzer.com.

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