

NEWS RELEASE

CONTACT: Katie Welch Peterson
952-294-9814

**AGA Medical Announces U.S. Launch Of Amplatzer® Septal Occluder,
Marking Breakthrough In Treatment Of Common Congenital Heart Defect**

MINNEAPOLIS, MN— AGA Medical Corporation, a global leader in minimally invasive occlusion technologies for treating congenital heart defects, announced U.S. market release of its AMPLATZER® Septal Occluder, a dramatically less-invasive alternative to cardiac surgery for patients with atrial septal defect (ASD), a common and potentially fatal congenital heart abnormality.

Since 1996 the AMPLATZER Septal Occluder has been implanted in more than 10,000 patients worldwide. It is the first device of its kind approved by the Food and Drug Administration for treatment of ASD. The FDA granted approval after reviewing results of a clinical trial involving 442 patients.

The American Heart Association estimates that annually 40,000 people are born with heart defects. Of that number, an estimated 10 percent have an ASD — an opening in the septum, or wall, dividing the heart’s upper chambers. AGA Medical projects that each year between 2,500 and 5,000 U.S. patients will be candidates for AMPLATZER Septal Occluder implantation.

“This most recent successful trial, plus years of clinical experience internationally, demonstrate that the AMPLATZER Septal Occluder is an extremely safe and effective treatment for closure of ASD,” said Franck Gougeon, AGA Medical executive vice president.

“Because the device and the procedure are so minimally invasive, we believe U.S. cardiac surgeons and their patients will find the AMPLATZER Septal Occluder a welcome alternative to the rigors and recovery time associated with cardiac surgery.”

Most commonly diagnosed in infants and children, ASD allows increased blood flow into the heart’s right side, forcing it to work harder than normal. In certain cases the defect is relatively small and closes naturally. When the defect is larger or fails to close, patients can become easily fatigued, have difficulty breathing, fail to grow normally, and be susceptible to colds, pneumonia and other infectious diseases. Left untreated, ASD can lead to heart arrhythmias, heart failure, high blood pressure, stroke, even death.

Traditionally, the only treatment for ASD has been open-heart surgery, requiring incisions through the breastbone and the heart muscle, followed by sewing of a patch over larger defects or a stitching together of the septum in smaller defects. Open-heart procedures average 3 hours in duration, sometimes longer. The patient typically spends 3 to 5 days hospitalized and faces considerable post-operative recovery.

The AMPLATZER Septal Occluder is a self-expanding device designed to occlude, or close, ASD. Featuring two Nitinol-wire mesh discs, connected by a “waist” that corresponds to the size of the defect, the device is implanted via a catheter inserted in the patient’s groin.

Typical implantation is a 1- to 2-hour procedure. Most patients leave the hospital within 24 hours and resume normal activity soon thereafter.

Besides approving the AMPLATZER Septal Occluder for treatment of ASD in the secundum (mid-section) of the atrial septum, the FDA also approved its use for closing a small hole, called a fenestration, made by cardiac surgeons when performing a “Fontan” procedure to improve blood circulation in patients.

AGA Medical Corporation is a Minneapolis-based company that pioneers development and manufacture of occlusion technologies that empower minimally invasive treatment of congenital heart defects. More information about AGA Medical can be found on the Web at www.amplatzer.com.

###