

NEWS RELEASE

CONTACT: Katie Welch Peterson
952-294-9814

**AGA Medical Corporation Earns FDA Approval of
AMPLATZER[®] Duct Occluder for Treating Congenital Heart Defect**

MINNEAPOLIS, MN - May 17, 2003 — AGA Medical Corporation today received approval from the Food and Drug Administration for the AMPLATZER[®] Duct Occluder, a less-invasive alternative to cardiac surgery for closing patent ductus arteriosus (PDA), a common and potentially fatal congenital heart defect.

The AMPLATZER Duct Occluder is the first device of its kind approved by the FDA for treatment of PDA. Since 1998 the device has been implanted in thousands of patients worldwide. The FDA approved the device after reviewing results of a clinical trial involving 435 implanted patients at 24 U.S. hospitals and clinics. Based on one-year follow-ups of 227 patients who received the implant, the device was 100 percent effective in closing the PDA.

The American Heart Association estimates that 40,000 people are born each year with heart defects. Of those, approximately 3,000 to 4,000 have a PDA, a condition normally diagnosed in newborns and young children, but occasionally discovered in adults.

Because a child in the womb receives oxygen from its mother, its lungs require minimal blood flow. The ductus arteriosus is a small blood vessel that connects the heart's two large blood vessels (the pulmonary artery and the aorta), bypassing the child's lungs. After birth, as a newborn's heart

and lungs assume normal function, the ductus arteriosus normally closes. In some cases, however, it stays open, or “patent.” This adversely affects circulation, causing symptoms that can include fatigue, rapid or difficulty breathing, chronic respiratory infections, failure to grow normally, even heart failure and death.

Traditionally, among the two most common treatments for PDA has been open-chest heart surgery — requiring an incision through the breastbone, then surgical ligation (sewing shut) of the ductus. For patients, heart surgery can mean hours in the operating room, 3 to 5 days of hospitalization, considerable post-operative recovery, not to mention a substantial chest scar. Of the five primary types of PDA, two are difficult to close with surgical ligation.

To date the most common treatment for closure of PDA has been metal, spring-shaped coils. It has been reported in the literature that placement of coils has had limited success and placement can be difficult. In many cases, multiple coils or procedures are required for complete closure of the PDA. The AMPLATZER Duct occluder was designed to address ease of placement and higher rates of occlusion for all sizes and types of PDAs. Clinical results using the AMPLATZER Duct Occluder demonstrated low rates of dislodgment and extremely high occlusion rates with a single device and procedure.

The AMPLATZER Duct Occluder is a self-expanding, implantable device designed to occlude, or close, PDA. The device is made from super-elastic Nitinol wire mesh and features a retention skirt that secures positioning within the “mouth” of the ductus. The device is compressed inside a catheter, then introduced via a vein in the patient’s groin. Typical implantation time is 1- to 2-hours. Most patients leave the hospital within 24 hours and resume normal activity soon thereafter.

“I love this device,” said Dr. Thomas M. Zellers, a cardiologist at Children’s Medical Center of Dallas, who participated in the AMPLATZER Duct Occluder clinical trial. “It is applicable to all but the smallest PDA. It has had excellent total closure rates — 100 percent in our hands. It’s easy to load and deploy. And it represents a minimally invasive tool to use in patients that would otherwise require surgery to achieve the same results, or transcatheter closure with standard coils, with uncertainty as to the result.”

The AMPLATZER Duct Occluder is the third AGA Medical Corporation device to earn FDA approval in recent months:

- In December 2001 the FDA approved the AMPLATZER® Septal Occluder for treating atrial septal defects, present in about 10 percent of congenital heart defect patients.
- In April 2002 the FDA granted Humanitarian Device Exemption for the AMPLATZER® PFO Occluder in selected patients with PFO and recurrent cryptogenic stroke, designed to prevent life-threatening blood clots from passing through the patent foramen ovale, a heart defect found in about 25 percent of adults.

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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