

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/43

Issued: 20<sup>th</sup> July 2006

For:

<b>IMMEDIATE ACTION</b>	✓
ACTION	
UPDATE	
INFORMATION	



**HEALTH ESTATES**

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	Section
<b>Medical Device/Equipment:</b> Cardiac atrial septal occluder – AMPLATZER <sup>®</sup> , AGA Medical.	▶ ①
<b>Problem:</b> Haemodynamic compromise associated with incorrectly sized occluder.	▶ ②
<b>Action by:</b> Interventional cardiologists.	▶ ③
<b>Action:</b> Follow the guidance in the manufacturer's technical note on patient selection, follow-up and education (see page 4 of the attached Appendix).	▶ ④
<b>Distributed by NIAIC to:</b> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers <b>For onward distribution see Section 5</b>	▶ ⑤
<b>Contacts</b> Details of manufacturer/supplier contacts and NIAIC contacts for clinical aspects.	▶ ⑥
<b>Feedback Requirements to NIAIC</b> None required	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

## 1. DEVICE/EQUIPMENT:

Cardiac atrial septal occluder – AMPLATZER®, AGA Medical.

## 2. PROBLEM:

On-going review by AGA Medical's panel of experts of incidents of haemodynamic compromise associated with the AMPLATZER® septal occluder identified a common trend of occluder oversizing.

Between February 1998 and December 2005 AGA Medical received 37 reports of haemodynamic compromise, an incidence of 0.11% or approximately 1 in 1,000. AGA Medical issued the attached technical note (see Appendix) to their customers earlier this year providing information to interventional cardiologists on minimising the risk of tissue erosion and haemodynamic compromise. It gives recommendations on the correct device sizing and patient follow-up/education. AGA Medical plan to modify the device instructions for use to include relevant information along with training material and updated guidance.

The review findings confirmed that for most patients the anterior/superior atrial free wall (right or left) is in close contact with the device edge(s), especially at the aortic/superior rim. If the device is oversized, the aorta compresses the waist of the device (not the discs) which stretches the atrial free wall over the device discs and the device edge may erode the free wall/aorta causing haemodynamic compromise. Tissue erosion is more likely to occur if the diameter of the device is greater than 1.5 times the diameter of the defect.

## 3. ACTION BY:

Interventional cardiologists.

## 4. ACTION:

When implanting this device:

- Measure the defect diameter using echocardiographic imaging prior to balloon sizing.
- Perform balloon sizing. Do not use the 'pull' technique. When using the 'stop flow' technique do not inflate the balloon beyond the cessation of the shunt. When using the 'stretch' technique do not inflate the balloon beyond the point where a small waist is visible. Never over inflate the balloon.
- Select a device which is equal to or one size larger than the defect (as determined by balloon sizing). Do not select a device greater than 1.5 times the defect diameter (as determined by echocardiography prior to balloon sizing).

In addition, follow the guidance in the manufacturer's technical note on patient selection, follow-up and education (see page 4 of the attached Appendix).

## 5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Cardiovascular Surgeons (For Information)
- Cathlab Managers
- Clinical Governance Leads
- Independent Health and Social Care Providers  
– Private Hospitals through RQIA
- Interventional Cardiologists
- Interventional Radiologists (For Information)
- Medical Directors
- Risk Managers
- Supplies Managers
- Theatre Managers

## 6. CONTACTS:

Enquiries to the manufacturer/supplier should be addressed to:

### Manufacturer

AGA Medical Corporation  
628 Mendelssohn Avenue  
Golden Valley  
Minnesota  
MN 55427  
USA

Tel: 001 763 513 9227  
Fax: 001 763 513 9226

E-mail: [jraus@amplatzer.com](mailto:jraus@amplatzer.com)

### Supplier

BVM Medical  
Trinity Lane  
Hinckley  
Leicestershire  
LE10 0BL

Tel: 01455 614555  
Fax: 01455 614546

E-mail: [hitesh@bvmmedical.com](mailto:hitesh@bvmmedical.com)

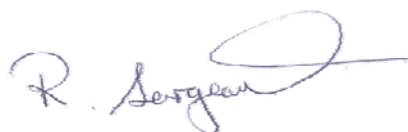
Enquires to NIAIC should quote reference number MDEA(NI)2006/43 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US

Tel: 028 9052 3868  
Fax: 028 9052 3900  
Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

## 7. FEEDBACK:

None required.



Robert Sergeant  
NIAIC Operational Manager

### HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety*



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## TECH NOTE

TO Physicians Implanting the AMPLATZER® Septal Occluder

FROM Franck Gougeon, President/CEO, AGA Medical Corporation

DATE 02 January 2006

SUBJECT Hemodynamic Compromise with the AMPLATZER® Septal Occluder  
Importance of proper balloon sizing techniques

The purpose of this Tech Note is to draw your attention to a very important issue. There have been reports of tissue erosion associated with the use of the AMPLATZER Septal Occluder (“ASO”). This Tech Note will present the facts and offer recommendations to mitigate the risk of this remote, but nonetheless very serious, complication.

### **Summary: Mechanism of Erosion**

- In the majority of patients suitable for ASO implantation, the anterior/superior atrial free wall (right or left) is in close contact with the device edge(s), especially with aortic/superior rim.
- If the ASO is not oversized compared with the native (static) diameter of the defect as determined by echocardiography, the device will re-adjust during normal cardiac function.
- If the device is oversized, the aorta compresses the waist (not the discs) which stretches the atrial free wall over the device discs, and the device edge may erode the free wall/aorta causing Hemodynamic Compromise.
- All adjudicated erosions occurred at the superior/anterior and aortic rim areas.

### **Summary: Mitigating Erosion**

- Erosion is unlikely to occur if the diameter of the ASO device implanted is  $\leq 1.5$  times the native (static) diameter of the defect.

## **Regulatory History**

The first adverse event was reported in 1998, three years after the introduction of the ASO. However, it was not until 2004 that a trend could be detected in the reports of Hemodynamic Compromise<sup>1</sup>.

AGA Medical voluntarily convened a Review Board<sup>2</sup> to analyze all reports of Hemodynamic Compromise. The Review Board met for the first time in September 2002, and has met at least annually thereafter. The Review Board was given access to AGA Medical's internal files as well as all information AGA Medical had received from the physicians reporting the complaint (e.g., pre-procedure, procedure and post-procedure echocardiograms, catheterization lab reports, and surgical reports). At the March 2004 meeting, the Review Board concluded that there were enough patients (28 - worldwide) to detect a trend in the cases; that trend was oversizing in the presence of patients with deficient aortic and superior rims. The Review Board published a paper with their findings; a copy of which is attached for your reference.

## **Incidence Rate**

To date, more than 97,000 ASO devices have been shipped worldwide. Because tracking is not required, AGA Medical can only estimate the number of ASO devices implanted. AGA Medical's current estimate of implanted devices is approximately 80,000 worldwide. AGA Medical tracks ASO implantation based on the number of implant registration cards (IRF) being returned to the company. IRFs are included in each ASO package. Physicians are strongly encouraged to return the IRF for each implanted ASO to AGA Medical so that a permanent patient ID card can be issued and the patient information logged in the company's registry.

Of the more than 97,000 ASO devices shipped, AGA Medical is able to confirm that approximately 35,000 have been implanted (number of IRFs returned to AGA to date). A total of 37 cases of Hemodynamic Compromise have been reported to date, 18 from overseas markets. The worldwide rate of Hemodynamic Compromise is therefore 0.11% or approximately 1 out of 1,000 confirmed ASO implants.

To date, there have been four reported deaths associated with the use of the ASO device and Hemodynamic Compromise. Each death has been thoroughly reviewed by our panel of experts and adjudicated as device or non device related. Device related deaths include one patient who went into cardiac arrest post ASO closure in the presence of gross device oversizing; a second patient experienced cardiac tamponade but access to the cath lab was compromised and the equipment needed to treat the patient was unavailable. Non- device related deaths include one sudden death patient and one patient who developed a cardiac tamponade post ASD closure attributed (during autopsy) to a wire perforation during cardiac catheterization

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<sup>1</sup> Hemodynamic Compromise is defined as any report of hemopericardium, cardiac tamponade, erosion, fistulae, puncture, hole, laceration, pleural effusion, tear, edema, pinhole, pericardial effusion, and fissure.

<sup>2</sup> Review Board members: Zahid Amin, M.D., University of Nebraska/Creighton University, John L. Bass, M.D., University of Minnesota, John P. Cheatham, M.D., Ohio State University, William L. Hellenbrand, M.D., Columbia University College of Physicians and Surgeons, Ziyad M. Hijazi, M.D., University of Chicago, and Charles S. Kleinman, M.D., Columbia University College of Physicians and Surgeons

## **Trends (US Data)**

Since its introduction in the United States in December 2001, AGA Medical has received 15,900 IRFs (confirmed implants) and 19 cases of Hemodynamic Compromise have been reported. The Review Board has adjudicated 14 cases as device related, 1 as non device related and 4 as unknown.

The US rate of Hemodynamic Compromise is therefore 0.12% or approximately 1 out of 1,000 confirmed ASO implants.

AGA Medical has determined that the incidence of Hemodynamic Compromise due to device erosion is related to device oversizing. The practice of device oversizing is strongly discouraged. The following data compares the mean diameters of implanted ASO devices during the US clinical trial versus those implanted after market release that have resulted in Hemodynamic Compromise.

	<b>ASD Diameter</b>	<b>Stretched Diameter</b>	<b>Device Size Implanted</b>	<b>Ratio</b>
<b>Clinical Trial</b>	<b>12.8 mm</b>	<b>17.2 mm</b>	<b>17.7 mm</b>	<b>1.38</b>
<b>Hemodynamic Compromise</b>	<b>12.7 mm</b>	<b>20.9 mm</b>	<b>22.3 mm</b>	<b>1.76</b>

Although the data shows identical mean native ASD diameters, the balloon stretched diameter in the hemodynamic compromise series is almost 4mm larger and the ratio between native ASD size and device selection is 1.76 (or approximately 30%) larger than during the US controlled trial.

Prior to the Amin, et al article being published, AGA Medical sponsored physicians to speak at various meetings and AGA symposiums on the risk of oversizing. Since the Amin, et al article was published the reported incidence of Hemodynamic Compromise has decreased significantly.

### **Reports of Hemodynamic Compromise reported in the US**

Year	Number of Implants	Reports of HC*	Rate
1998-2001	1,063	1	.10%
12-05-2001 (FDA approval)	199	0	-
2002	2,993	7	.23%
2003	3,815	9	.24%
2004	3,973	1	.02%
2005	3,857	1	.02%
<b>Total</b>	<b>15,900</b>	<b>19</b>	<b>.12%</b>

\*Reported the year the device was implanted, not the year the reported event occurred.

With proper adherence to our panel recommendation, we are hopeful that this very serious complication will be mitigated.

## Steps to Mitigate Risk of Erosion

### AGA Medical recommends changes to physician practice which have been incorporated into the ASO Instructions for Use as follows:

#### 1. Defect/Device Sizing

- The use of echocardiographic imaging is required. Do not inflate the balloon beyond the cessation of the shunt (i.e., stop flow) or the visualization of a small waist in the balloon. DO NOT OVERINFLATE.
- Do not select a device size >1.5 times the ASD diameter as determined by echocardiographic imaging prior to balloon sizing.

#### 2. Patient Selection

Certain patients may be at higher risk for complications such as tissue erosion and device embolization. If higher risk patients have devices implanted, closer follow-up is warranted. Higher risk patients include the following:

- Patients with deformation of the device at the aortic root.
- Patients with high defects (minimal aortic and superior rims).
- Patients with IVC rim deficiency (risk of device embolization).

#### 3. Follow-up

- All patients should be kept overnight for observation. A transthoracic echocardiogram (TTE) should be performed prior to discharge.
- Patients with any observed small pericardial effusion following device implantation should be closely monitored with serial echocardiograms performed until resolution of the pericardial effusion.
- Higher risk patients should be followed more closely, including clinical follow-up with echocardiogram one (1) week following device implantation.

#### 4. Patient Education:

Educate patients about the risk and need for echocardiography with symptoms (i.e., chest pain or shortness of breath). Patients should be instructed to go to the emergency room if they experience symptoms.

Please contact your US Field Clinical Specialist or distributor should you have any questions on this Tech Note.

Sincerely,

Franck Gougeon  
President/CEO

Enclosure