

Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/61

Issued: 13 December 2004

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION REQUEST	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
Medical Device/Equipment: Endovascular delivery and exchange systems for Amplatzer [®] cardiac occluders (ASD, VSD, PFO, PDA).	▶ ①
Problem: Recall of product due to the presence of residues on the inside of the delivery sheaths.	▶ ②
Action by: Interventional cardiologists, interventional radiologists and cathlab managers.	▶ ③
Action: <ul style="list-style-type: none"> • Immediately remove from use all Amplatzer[®] cardiac delivery and exchange systems already supplied for planned cardiac closure procedures. • Check the availability of new or replacement stock with the supplier. • Consider rescheduling procedures or using alternative cardiac occluder systems, if unaffected product is unavailable. • Consider consultation with patients who have received affected devices. 	▶ ④
Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers For onward distribution see Section 5	▶ ⑤
Contacts Details of manufacturer/supplier contacts, NIAIC contacts for technical aspects.	▶ ⑥
Feedback Requirements to NIAIC	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Endovascular delivery and exchange systems for Amplatzer® cardiac occluders for use in cardiac defects such as atrial septal defects (ASD), ventricular septal defects (VSD), patent foramen ovale (PFO) and patent ductus arteriosus (PDA).

2. PROBLEM:

AGA Medical Corporation has initiated a recall of the above devices because some delivery sheaths were found to contain an oily particulate residue, coating the inside of the delivery tube. It is possible that this residue may be pushed out of the delivery sheath during deployment of an Amplatzer® occluder device.

The precise characteristics of the residue are still under investigation. Although the risk associated with exposure to the residue is unknown, initial testing by the manufacturer has identified that it may present a toxic hazard. To date, MHRA has not received any reports of adverse clinical reactions. Meanwhile, as a precautionary measure, all affected delivery and exchange systems are being recalled. If significant additional information on the risk associated with exposure to the residue becomes available, MHRA will issue further advice.

These devices are only supplied to order and hospitals do not hold long-term supplies. The manufacturer has undertaken only to supply new or replacement stock that can be verified to be unaffected by this problem.

There is no indication that any intervention is required in respect of Amplatzer® occluder devices already implanted. The supplier can advise on whether devices already implanted were supplied with affected delivery systems. Cardiologists will wish to consider informing patients or their families affected by this issue. In such cases, the following information may be useful:

The product has been recalled because a residue has been found inside tubes used to hold the occluder before and during the implantation procedure. The manufacturer has been unable to identify the residue or establish how harmful it is. Although preliminary tests showed that a high concentration of the residue may be toxic we do not know how much would be transferred to the patient during the procedure. Any residue would be diluted by the blood and no adverse effects have been reported to date in implanted patients. At present there is no indication that exposure to the residue will lead to health problems but, without further information on the identity of the residue or the nature of its toxicity, the actual risk to human health cannot be determined. If additional information comes to light that alters this assessment, MHRA will issue further advice.

3. ACTION BY:

Interventional cardiologists, interventional radiologists and cathlab managers.

4. ACTION:

- Immediately remove from use all Amplatzer® cardiac delivery and exchange systems already supplied for planned cardiac closure procedures.
- Check the availability of new or replacement stock with the supplier.
- Consider rescheduling procedures or using alternative cardiac occluder systems, if unaffected product is unavailable.
- Consider consultation with patients who have received affected devices.

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:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Supplies Staff (RSS)
- Nurse Directors
- Operating Theatre Managers
- Coronary Care – Cardiovascular Surgeons
- Interventional Cardiologists
- Interventional Radiologists
- Medical Directors
- Independent Health and Social Care Providers – Private Clinics through HSS Board R&I Units

6. CONTACTS:

Enquiries to the manufacturer/supplier should be addressed to:

Manufacturer:

AGA Medical Corporation
682 Mendelssohn Avenue
Golden Valley
MN 55427, USA

Tel: 001 763 513 9227

Fax : 001 763 513 9226

E-mail: jraus@amplatz.com

Supplier:

BVM Medical
Trinity Lane
Hinckley
Leicestershire
LE10 0BL

Tel: 01455 614555

Fax: 01455 614546

E-mail: hitesh@bvmmedical.com

Enquires to NIAIC should quote reference number MDEA(NI)2004/61 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

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)2004/01. 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

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