

Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/65

Issued: 22 December 2004



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	✓
INFORMATION REQUEST	

	Section
Medical Device/Equipment: Endovascular delivery and exchange systems for Amplatzer® cardiac occluders (ASD, VSD, PFO, PDA).	▶ ①
Problem: Extension of recall due to the detection of residues on the inside of dilators packaged with Amplatzer® Occluder Systems.	▶ ②
Action by: Interventional cardiologists, interventional radiologists and cathlab managers.	▶ ③
Action: <ul style="list-style-type: none"> Do not use any Amplatzer® cardiac occluder systems. Immediately return all product received to date (21 December 2004) to the supplier. Consider rescheduling procedures or using alternative cardiac occluder systems. Contact the supplier regarding future availability of replacement product. Follow advice on patient management in MDA/2004/054 issued on 9 December 2004. Report any incidence of device failure to the manufacturer/supplier and NIAIC. 	▶ ④
Distributed by NIAIC to: <ul style="list-style-type: none"> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers 	▶ ⑤
Contacts Details of manufacturer/supplier contacts, NIAIC contacts for technical aspects.	▶ ⑥
Feedback Requirements to NIAIC None required	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Endovascular delivery and exchange systems supplied with 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:

Further to NIAIC's Medical Device Alert MDEA(NI)2004/61 issued 13 December 2004, AGA Medical Corporation has extended the scope of the recall to include all dilators supplied within packs of the Amplatzer® delivery and exchange systems distributed to date (21 December 2004). The manufacturer has identified that some dilators may also contain the oily particulate residue previously identified within delivery sheaths. This affects delivery and exchange systems that were unaffected by the initial recall implemented on 22 November 2004.

The manufacturer is continuing to investigate the precise characteristics of the residue. Initial testing found that in high concentrations the residue may be a toxic hazard, but the risk of exposure to the residue remains unknown. Information on the nature of the risk and on appropriate clinical action contained in MDEA(NI)2004/61 remains valid.

AGA Medical is applying corrective measures to ensure future product meets manufacturing specifications. The distributor will have information on replacement devices in the near future.

3. ACTION BY:

Interventional cardiologists, interventional radiologists and cathlab managers.

4. ACTION:

- Do not use any Amplatzer® cardiac occluder systems.
- Immediately return all product received to date (21 December 2004) to the supplier.
- Consider rescheduling procedures or using alternative cardiac occluder systems.
- Contact the supplier regarding future availability of replacement product.
- Follow advice on patient management in MDEA(NI)2004/61 issued on 13 December 2004.
- Report any incidence of device failure to the manufacturer/supplier and NIAIC.

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:

Manufacture

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 614 555

Fax: 01455 614 546

E-mail: hitesh@bvmmedical.com

Enquires to NIAIC should quote reference number MDEA(NI)2004/65 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