

Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/49

Issued: 10 August 2006

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
Medical Device/Equipment: Anaesthetic conserving device: Sedana Medical AnaConDa.	▶ ①
Problem: Risk of anaesthetic overdose.	▶ ②
Action by: Anaesthetists and intensivists.	▶ ③
Action: Check that there are procedures in place to ensure that the AnaConDa device is only used: <ul style="list-style-type: none"> • according to the current version of the instructions for use (At the time of publishing this Alert the current version is number 7 691 300-R001, issued in July 2005). • by clinicians specifically trained in the use of anaesthetic drugs. • with the correct level of monitoring and respiratory support, as recommended by the AAGBI (Recommendations for standards of monitoring during anaesthesia and recovery, 3rd edition, 2000). • 	▶ 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	▶ ⑤
Contacts Details of supplier contacts and 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:

The AnaConDa is a novel anaesthetic conserving device that can be used for administration and recirculation of Isoflurane and Sevoflurane. The AnaConDa must be used with a ventilator, a syringe pump, an anaesthetic gas monitor and a gas scavenging system.

2. PROBLEM:

The MHRA is aware of an adverse incident that occurred during the use of an AnaConDa. It is believed that the adverse event was caused by a combination of user error and inconsistencies in the instructions for use. Sedana Medical have taken over as the manufacturer of the AnaConDa and corrected these inconsistencies. The current version of the instructions for use is IFU 7 691 300-R001, published in July 2005 (available at www.sedanamedical.com).

Sedana Medical is implementing changes to the design of the system to eliminate the Luer connection between the syringe and the Anaconda and is making additional changes to the instructions for use. Sedana Medical estimates that these changes will be introduced on new products at the end of 2006.

3. ACTION BY:

Anaesthetists and Intensivists.

4. ACTION:

Check that there are procedures in place to ensure that the AnaConDa device is only used:

- according to the current version number of the instructions for use (At the time of publishing this Alert the current version is number 7 691 300-R001, issued in July 2005).
- by clinicians specifically trained in the use of anaesthetic drugs.
- with the correct level of monitoring and respiratory support, as recommended by the AAGBI (Recommendations for standards of monitoring during anaesthesia and recovery, 3rd edition, 2000).

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
- Adult & Paediatric Intensive Care Units
- Anaesthetists
- Clinical Directors
- Directors of Anaesthetics
- Health & Safety Managers
- Intensive Care Units
- Intensivists
- Independent Health and Social Care Providers – Private Hospitals and Clinics Through RQIA
- Medical Directors
- Nurse Executive Directors
- Risk Managers
- Safety Officers
- Special Care Baby Units
- Theatre Managers

6. CONTACTS:

Enquiries to the UK supplier should be addressed to:

Bill Quick
Anmedic UK
PO Box 114
Hayling Island
Hampshire
PO11 9QN

Tel: 02392 463 791

Fax: 02392 350 731

E-mail: bill.quick@anmedic.co.uk

Enquires to NIAIC should quote reference number MDEA(NI)2006/49 and be addressed to:

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

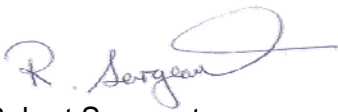
Tel: 028 9052 3868

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)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

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