

MEDICAL DEVICE ALERT

Issued: **03 December 2007 at 14:00** Ref: **MDA/2007/090**

<input type="checkbox"/>	Immediate action
<input checked="" type="checkbox"/>	Action
<input type="checkbox"/>	Update
<input type="checkbox"/>	Information request

Device: Anaesthetic Gas Scavenging System (AGSS) receiver, manufactured by Draeger Medical.	▶ Page 2
Problem: There have been reports of anaesthetic scavenging hoses being misconnected to the blanked-off port of the Draeger AGSS receiver (see appendix). This prevents gases from leaving the anaesthetic breathing system, creating excessive airway pressures, which if undetected could result in serious lung injury.	▶ Page 2
Action by: Anaesthetists, operating department practitioners, anaesthetic nurses and servicing engineers.	
Action: <ul style="list-style-type: none"> • Ensure that all anaesthetic staff using this device are aware of this potential misconnection. • AGSS connections must be included in the pre-use checks of the anaesthetic breathing system to ensure the scavenging hose is connected to the open port of the AGSS receiver. 	
Distributed to: NHS trusts in England Healthcare Commission (CHAI) <ul style="list-style-type: none"> – Chief Executives* – Headquarters <p style="text-align: right;">* via CE Bulletin</p>	▶ Page 2
Contacts: Details of manufacturer contacts and MHRA contacts for technical and clinical aspects. Change of address or removal from address list for Healthcare Commission.	▶ Pages 2-3
Appendix: Diagrams showing how the problem could occur.	▶ Pages 4-5

Action deadlines for the Safety Alert Broadcast System (SABS)

Deadline (action underway): 17/12/2007

Deadline (action complete): 31/12/2007

This notice is also on our website: <http://www.mhra.gov.uk>

Device:

The Draeger AGSS receiver is supplied with Draeger anaesthetic machines. It is designed to take waste gases from the anaesthetic breathing system and has two 30 mm female ports for the attachment of scavenging hoses. However as only one inlet is usually required the second port is sealed off with a Draeger metal blanking plug. The Draeger AGSS inlets are the standard size for gas scavenging fittings in the UK, in compliance with the British, European and International Standard BS EN ISO 5356-1:2004, Part 1, Cones and sockets.

Problem:

When the Draeger metal blanking plug is in place, it is not possible to insert Draeger AGSS connectors. However non-Draeger thin walled plastic male connectors of the same 30 mm size can be fitted into the blanked-off inlet port. Such a misconnection of the scavenging hose prevents any gases from leaving the breathing system, leading to excessive airway pressures. Draeger recommend that only their connectors are used with their AGSS receivers.

Distribution:

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

Trusts to:

SABS liaison officers for onward distribution to all relevant staff including:

- Anaesthesia, directors of
- Anaesthetic nursing staff
- Anaesthetists
- Biomedical engineering staff
- Day surgery units
- EBME departments
- Health and safety manager
- In-house maintenance staff
- Operating department practitioners
- Outpatient theatre managers
- Risk managers
- Theatre managers
- Theatres

Healthcare Commission (CHAI) to:

Headquarters for onward distribution to:

- Acute hospitals in the independent sector
- Independent Treatment centres

Contacts:

Enquiries to the manufacturer should be addressed to:

Mr Doug Sims
Draeger Medical UK Ltd.
The Willows
Mark Road
Hemel Hempstead HP2 7BW

Tel: 01442 213 542

Fax: 01442 259 770

E-mail: Doug.Sims@draeger.com

Enquiries to the MHRA should quote reference number **2007/007/002/401/004** and be addressed to:

Technical aspects:

Doug Mcivor or Louise Mulroy
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3193/3344

Fax: 020 7084 3209

E-mail: douglas.mcivor@mhra.gsi.gov.uk
louise.mulroy@mhra.gsi.gov.uk

Clinical aspects:

Jonathan Plumb
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3128

Fax: 020 7084 3111

E-mail: jonathan.plumb@mhra.gsi.gov.uk

Contacts (continued):

Change of address or removal from address list for CSCI and Healthcare Commission:

Healthcare Commission
Finsbury Tower
103-105 Bunhill Row
London
EC1Y 8TG

Tel: 020 7448 0842

E-mail: contacts@healthcarecommission.org.uk

How to report adverse incidents

Incidents relating to medical devices must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as soon as possible.

Further information about reporting incidents; on-line incident reporting facilities; and downloadable report forms are available from MHRA's website (<http://www.mhra.gov.uk>).

Alternatively, further information and printed incident report forms are available from:

MHRA Adverse Incident Centre
Medicines and Healthcare products Regulatory Agency
Market Towers, 1 Nine Elms Lane, London SW8 5NQ
Telephone 020 7084 3080 or Fax 020 7084 3109
or e-mail: aic@mhra.gsi.gov.uk

(An answerphone service operates outside normal office hours)

Medical Device Alerts are available in full text on the MHRA website: <http://www.mhra.gov.uk>

Further information about **SABS** can be found at www.info.doh.gov.uk/sar2/cmopatie.nsf

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Draeger AGSS receiver with blanked-off inlet port.

Blanked-off inlet port



A gas scavenging hose misconnected to the blanked-off inlet port of the Draeger AGSS receiver.

A scavenging hose can be inserted into a blanked-off port.

