

Medical Device/Equipment ALERT

Ref.

MDEA(NI)2006/26

Issued: 28th April 2006



HEALTH ESTATES

creating healing environments

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	✓
INFORMATION	

	Section
<p>Medical Device/Equipment: Gambro Prisma haemodialysis sets:</p> <ul style="list-style-type: none"> M60 Pre Set, M60 Set, M100 Pre Set, M100 Set, HF1000 Pre Set <p>Manufactured before the end of October 2005.</p>	▶ ①
<p>Problem: During disconnection of the Prisma set from the Prisma haemodialysis system, blood can leak (under pressure) from the access pressure pod due to a manufacturing defect.</p>	▶ ②
<p>Action by: Renal physicians, intensive care consultants and managers of supplies departments.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Immediately cease use of the affected lots, unless no alternative is available. Locate and quarantine any products from affected lots if possible. If only product from affected lots is available, follow the instructions for pre-use checks and disconnection described overleaf. Ensure that the manufacturer is contacted to arrange collection and replacement of affected stock. 	▶ ④
<p>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</p>	▶ ⑤
<p>Contacts Details of manufacturer contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC None required</p>	▶ ⑦

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

1. DEVICE/EQUIPMENT:

The Prisma haemodialysis sets are single-use devices and are used with the Gambro Prisma Continuous Renal Replacement System. These devices are distributed worldwide.

The affected devices which are available in the UK are:

- Prisma M60 Pre Set
- Prisma M60 Set
- Prisma M100 Pre Set
- Prisma M100 Set
- Prisma HF1000 Pre Set

This recall is for all lots produced prior to the end of October 2005 with the exception of the following lot numbers:

05J2796P to 05J2799X

05J28XXX

05J29XXX

05J30XXX

05J31XXX

Where **X** can be any letter or number.

2. PROBLEM:

The manufacturer has notified the MHRA of a number of incidents where blood has escaped from access pressure pods during the unloading of single-use Prisma sets from the Prisma System. This poses no hazard to the patient but there is a risk of operator exposure to blood whilst unloading the set from the machine. This problem arises because of a welding error, resulting in a large gap between body and retainer (see Figure 1).

The manufacturer has undertaken corrective actions to prevent future occurrences, and this corrective action was implemented at the end of October 2005. The initial recall detailed in MDEA(NI)2005/89 was restricted to certain lots. This has now been expanded to cover all lots produced before the corrective action. Any Prisma sets produced prior to the implementation of the corrective action should be considered to be potentially defective.

3. ACTION BY:

Renal physicians, intensive care consultants and managers of supplies departments.

4. ACTION:

If only sets from an affected batch are available and use of the Prisma system is essential, follow the instructions below, (which have been provided and approved by Gambro) until such time as replacements are available.

1) Before use

Perform a visual inspection of the access pressure pod. If you discover a pod which shows an uneven gap between body and retainer as illustrated in Figure 1, **DO NOT USE**. Quarantine the defective set.

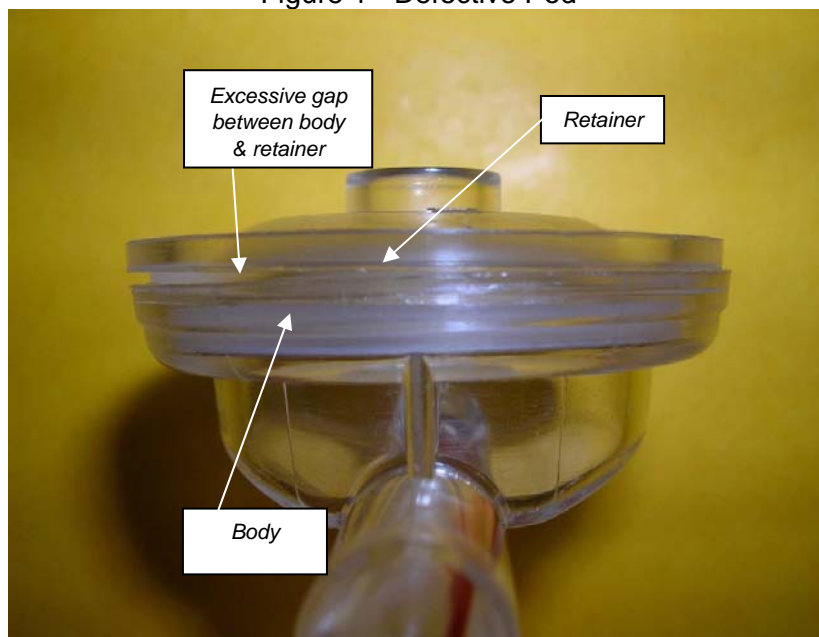
2) Before disconnection of set (from affected batch which passed visual inspection and was used).

After disconnecting patient from set, reduce the pressure in the access line by following the specific unloading procedure:

- i Disconnect the anticoagulant line from the syringe
- ii Connect access line to anticoagulant line
- iii Unclamp access and anticoagulant lines
- iv Press 'UNLOAD'. **DO NOT** remove pressure pods at this point
- v **Wait at least 2 seconds to allow for pressure reduction within the system**
- vi Detach the pressure pods from the machine and remove set

3) Dispose of any used/contaminated sets and bags that were in use during the procedure.

Figure 1 - Defective Pod



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
- Medical Directors
- Clinical Directors
- Nurse Directors
- Independent Health and Social Care Providers – Private Clinics through HSSRIA
- Sterile Services Departments
- Intensive Care
- Home Therapy Units
- Renal Physicians
- Renal Units and Satellites
- Regional Supplies (RSS)
- Local Supplies Departments

6. CONTACTS:

Enquires to NIAIC should quote reference number MDEA(NI)2006/26 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

Enquiries to the manufacturer/supplier should be addressed to:

Mr Jean-Philippe Bret
QA Department
Gambro Industries
7 Avenue Lionel Terray
B.P. 126
69883 Meyzieu Cedex
France

Tel: + 33 4 72 45 25 15

Fax: + 33 4 72 45 24 24

E-mail: jean-philippe.bret@gambro.com

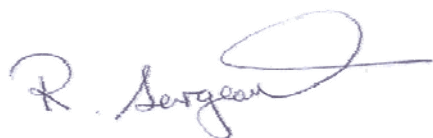
Ms Jenny Shaw
Intensive Care Business Manager
Gambro Hospital Ltd
Ermine Business Park
Huntingdon
PE29 6XX

Tel: 07970 217 974

E-mail: jenny.shaw@gambro.com

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