

Medical Device/Equipment ALERT

Ref. MDEA(NI)2005/89

Issued: 7/12/2005

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
<p>Medical Device/Equipment: Gambro Prisma Haemodialysis Sets:</p> <ul style="list-style-type: none"> • Prisma M100 Pre Set lot numbers: 05F1574, 05F2387G, 05G1366G • Prisma HF1000 Pre Set lot number: 05F0864P 	▶ ①
<p>Problem: During disconnection of the Prisma set from the Prisma haemodialysis system, blood can spurt out from the access pressure pod.</p>	▶ ②
<p>Action by: All those who use this device (haemodialysis units and intensive care units); and Managers of Supplies departments</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> • Locate and quarantine any products from affected lots. • Immediately cease use of the affected lots. • Ensure that the manufacturer is contacted to arrange collection and replacement of affected stock. <p>If only product from affected lots is available, follow the instructions for pre-use checks and disconnection described overleaf.</p>	▶ ④
<p>Distributed by NIAIC to:</p> <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 <p>For onward distribution see Section 5</p>	▶ ⑤
<p>Contacts Details of manufacturer/supplier contacts, 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:

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

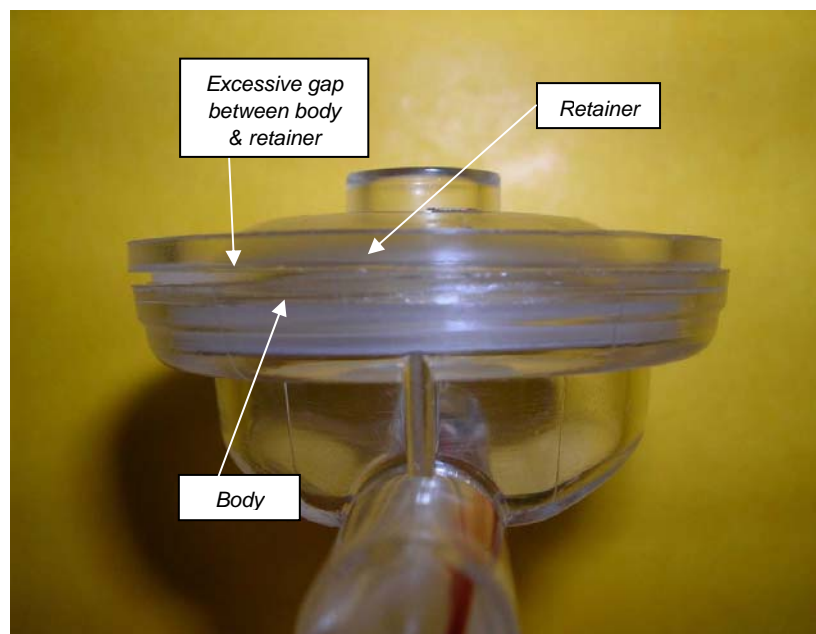
The lots distributed in the UK are:

- Prisma M100 Pre Set lot numbers: 05F1574, 05F2387G, 05G1366G.
- Prisma HF1000 Pre Set lot number: 05F0864P.

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 safety hazard to the patient, but there is a risk of operator exposure to blood whilst unloading the set from the machine. This problem is a result 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

Figure 1 - Picture of a Defective Pod



3. ACTION BY:

All those who use this device (haemodialysis units and intensive care units); 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):

1) BEFORE USE:

Prior to use, perform a visual inspection of the access pressure pod. If you discover a pod which shows an uneven gap between header and housing as illustrated in the picture (see Figure 1), **DO NOT USE**, instead quarantine the defective pod.

2) BEFORE DISCONNECTION OF SET (from affected batch which passed visual inspection and was used):

Reduce the pressure in the access line by following the specific unloading procedure:

After disconnecting the patient from the set:

- 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 used/contaminated sets and bags that were in use during the procedure.

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
- Renal physicians
- Renal units and satellites
- Regional Supplies (RSS)
- Local Supplies Departments

6. CONTACTS:

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

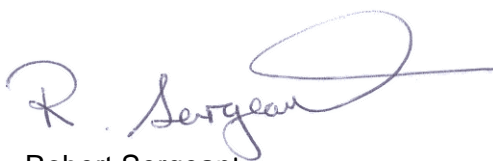
Enquires to NIAIC should quote reference number MDEA(NI)2005/89 and be addressed to:

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)2005/01. 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