

Medical Device Alert

Ref: MDA/2011/072 Issued: 22 June 2011 at 11:00

Device

Caretex Urinals (PHURI046)
 manufactured by PH Medisavers.
 Lot no. 1011294
 NHS Supply Chain no. FWV042



OMS GROUP

Problem

The manufacturer issued a Field Safety Notice (FSN) on 14 June 2011 recalling this batch of the device but has not had sufficient confirmation from users that they have received and acted on this information.

A copy of the FSN is in the appendix of this alert, and it is also available on the MHRA website.

This alert has been issued in support of the manufacturer's actions.

Action by

All nursing and stores staff.

Action

- Ensure that relevant members of staff are aware of the problem.
- Carry out the actions described in the manufacturer's FSN, including sending any confirmation requests.

CAS deadlines

Action underway: 29 June 2011

Action complete: 22 July 2011

Contact

Manufacturer

Karen Gunning
 PH Medisavers Ltd

Tel: 020 8335 5213

Fax: 020 8335 5252

Email: karen@ph-healthcare.co.uk

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Primary care trusts in England (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- All clinical departments
- All wards
- Nursing executive directors
- Risk managers
- Supplies managers

Primary care trusts

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

- Community hospitals
- Community nurses
- District nurses
- NHS walk-in centres
- Risk managers
- Supplies managers

Contacts

Manufacturer

Karen Gunning
QA and Regulatory Affairs Manager
PH Medisavers Ltd
Colwood House
158 Garth Road
Morden
Surrey
SM4 4LZ

Tel: 020 8335 5213

Fax: 020 8335 5252

Email: Karen@ph-healthcare.co.uk

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/072** or **2011/002/017/401/009**

Brian Mather or David Small
Medicines & Healthcare products Regulatory Agency
Centre for Assistive Technology
241 Bristol Avenue
Bispham
Blackpool FY2 0BR

Tel: 01253 596 000

Fax: 01253 596 177

Email: bav@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>

Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

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Addressees may take copies for distribution within their own organisations

Appendix



URGENT

Field Safety Notice

PH Medisavers, Colwood House, 158 Garth Road, Morden, Surrey, SM4 4LZ, United Kingdom

14 June 2011

Dear Customer,

PH Medisavers Ltd is issuing an urgent device recall notice for Male Bulbous Urinals. A manufacturing anomaly has been detected in the lot below; this has resulted in a seam weakness that has the potential to fail and may result in the bottle leaking in use.

Summary:

Product: Caretex Urinals (PHURI046)
Defect: Leaking
Lot Number: 1011294

Background

An intermittent fault was detected during the manufacturing process that has resulted in a seam weakness at the base of the bottle. As the fault did not occur consistently and will have affected a small percentage of the bottles produced throughout the lot, PH Medisavers Ltd has taken the decision to recall the whole batch.

Identification:

Please note that this recall is specific only to PHURI046, lot number 1011294, manufactured between December 2010 and March 2011.

Please check all stocks immediately and quarantine all cases from the above lot number. The affected stock will require return to PH Medisavers in accordance with the instructions detailed below.

This product must not be used as the integrity of the bottle may have been compromised by the fault.

Issued: 22 June 2011 at 11:00

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Product Return Instructions:

Please report the amount of bulbous urinal cases in your inventory, on the enclosed form and fax the form back to us on 020 8335 0300.

PH Medisavers Ltd will arrange for collection or disposal of the goods, based on the quantity held in quarantine.

Should you have any queries regarding the recall of PHURI046 : lot 1011294 then please contact the customer service department, details below:

Customer Service Department:

Telephone: 020 8335 5213

Fax: 020 8335 5252

E-mail: customerservices@phmedisavers.co.uk

Mr. Andrew Blewett Office Manager

Mrs. Karen Gunning QA and Regulatory Affairs Manager

PH Medisavers Ltd should like to apologise for any inconvenience caused by this recall. All affected stock will be collected and replaced.

The Medicines and Healthcare products Regulatory Agency are aware of this recall.

Yours sincerely,

Karen Gunning
QA and Regulatory Affairs Manager

PH Medisavers
Office: +44 (0) 1733 205284
Mobile: +44 (0) 7733 304284
E-mail: karen@ph-healthcare.co.uk



URGENT FIELD SAFETY NOTICE
Medical Device Recall

PH Medisavers, Colwood House, 158 Garth Road, Morden, Surrey, SM4 4LZ, United Kingdom

T: 0044 (0) 20 8335 5213

F: 0044 (0) 20 8335 5252

27 April 2011

Dear Customer,

PH Medisavers is issuing an urgent device recall notice for Male Bulbous Urinals (PHURI046). A manufacturing anomaly has been detected in the lot below; this has resulted in a seam weakness that has the potential to fail and may result in the bottle leaking in use.

Please would you check all stocks of Male Bulbous Urinals PHURI046, then complete and return the form to the Customer Service department on fax number **020 8335 5252**. Your prompt assistance is appreciated and is necessary to support the recall.

Caretex Male Urinals – PHURI046	Lot Number: 1011294
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Customer Contact Name:	
Customer Contact Telephone Number:	
Business Name:	
Business Address:	
Total Number of Cases of 1011294 in Stock:	

Thank you for your time and support.

Karen Gunning
QA and Regulatory Affairs Manager