

# Medical Device Alert

Ref: MDA/2011/053 Issued: 20 May 2011 at 14:00

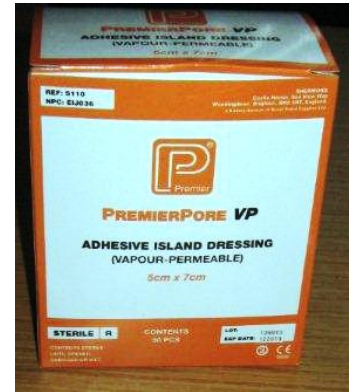
## Device

Wound dressing.

PremierPore vapour permeable island dressing.

Manufactured by Shermond.

Specific lot numbers.



## Problem

The manufacturer issued a Field Safety Notice (FSN) for this device on 16 March 2011, 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 users, suppliers and distributors of these dressings.

## CAS deadlines

Action underway: 07 June 2011

Action complete: 21 June 2011

## 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.

## Contact

### Manufacturer

Michael Bennett  
Shermond

Tel: 0161 848 4028

Fax: 0845 082 0180

Email: [mike.bennett@bunzl.co.uk](mailto:mike.bennett@bunzl.co.uk)

## Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (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 wards and clinical departments
- Day surgery units
- Hospital at home units
- Nursing executive directors
- Outpatient clinics
- Outpatient theatre managers
- Paramedics
- Purchasing managers
- Risk managers
- Supplies managers
- Theatres
- Tissue viability nurses

### Primary care trusts

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

- Community children's nurses
- Community nurses
- Community pharmacists
- District nurses
- General practitioners
- Minor injury units
- NHS walk-in centres
- Practice managers
- Practice nurses
- School nurses
- Tissue viability nurses
- Walk-in centres

### Independent distribution

#### Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Care homes
- Clinics
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: [safetyalerts@dh.gsi.gov.uk](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## Contacts

### Manufacturer

Michael Bennett  
Shermond  
Boundary House  
Interlink Way East  
Interlink Business Park  
Bardon  
Coalville  
Leicestershire  
LE67 1LA

Tel: 0161 848 4028

Fax: 0845 082 0180

Email: [mike.bennett@bunzl.co.uk](mailto:mike.bennett@bunzl.co.uk)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/053** or **2011/003/017/291/005**

### Technical aspects

Sally Mounter  
Medicines & Healthcare products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 7168

Fax: 020 8754 3965

Email: [sally.mounter@mhra.gsi.gov.uk](mailto:sally.mounter@mhra.gsi.gov.uk)

### Clinical aspects

Jonathan Plumb  
Medicines & Healthcare products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 7128

Fax: 020 8754 3965

Email: [jonathan.plumb@mhra.gsi.gov.uk](mailto:jonathan.plumb@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>

## Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre

Health Estates Investment Group

Room 17

Annex 6

Castle Buildings

Stormont Estate

Dundonald BT4 3SQ

Tel: 02890 523 704

Fax: 02890 523 900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

### How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

## Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

Health Facilities Scotland

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

## 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](mailto:Haz-Aic@wales.gsi.gov.uk)

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Addressees may take copies for distribution within their own organisations

## Appendix



Boundary House  
Interlink Way East  
Interlink Business Park  
Bardon, Coalville  
Leicestershire  
LE67 1LA

### Urgent Field Safety Notice

**Product: PremierPore VP Island Dressing**

**Type of Action: Recall**

16 March 2011

Attention: All Users of PremierPore VP Island Dressings

**Affected devices: PremierPore VP Island Dressings**

**Product References: 5110, 5111, 5112, 5113, 5114, 5115, 5116**

**Description of problem:**

**Specific lots are missing the vapour permeable polyurethane film**

The Premierpore VP Island Dressing is a vapour permeable dressing coated with a polyurethane film that is intended to stop the wound drying out or becoming saturated. Through our vigorous QC conformance procedures we have become aware that some of the lots that have not had the polyurethane film applied which may result in the dressing becoming saturated and detached exposing the wound. As a result we are recalling stock from the following product references and Lot numbers

Shermond Reference	NHS Supply Chain Code	Description	Lot Numbers
5110	EIJ036	5cm x 7cm	125896, 126187, 126528, 126698, 126913
5111	EIJ037	10cm x 10cm	125896, 126187, 126352, 126697, 126698, 126913
5112	EIJ044	10cm x 15cm	125896, 126187, 126697, 126698, 126913
5113	EIJ045	10cm x 25cm	126352, 126698, 126913
5114	EIJ047	10cm x 20cm	125710, 125896, 126697, 126698, 126913
5115	EIJ046	10cm x 30cm	125929, 126697, 126698, 126913
5116	N/A	10cm x 35cm	126501, 126528, 126698, 126913





Boundary House  
Interlink Way East  
Interlink Business Park  
Bardon, Coalville  
Leicestershire  
LE67 1LA

As a matter of urgency can you please:

- 1) Identify if you have any of the potentially affected devices
- 2) Quarantine the devices
- 3) Contact our Customer Service Team on for replacement stock. We are only requesting the return of complete boxes. We will not require any incomplete boxes
- 4) Complete the acknowledgement and return to:

Debbie Black, Customer Services Manager at the details on the acknowledgement form below

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Should you have any questions relating to this recall please contact:

Michael Bennett  
Quality & Technical Manager

The MHRA is aware of this Field Safety Notice





Boundary House  
Interlink Way East  
Interlink Business Park  
Bardon, Coalville  
Leicestershire  
LE67 1LA

**Recall Notice**

**Confirmation of Receipt**

I/We confirm receipt of the recall notice relating to Shermond PremierPore VP Island Dressing:

**Product Refs: 5110, 5111, 5112, 5113, 5114, 5115, 5116**

I/We will ensure that all necessary personnel will be made aware of the notice.

Name of Organisation: \_\_\_\_\_

Department: \_\_\_\_\_

Name and Title: \_\_\_\_\_

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

Number of complete boxes to be returned	Number of dressings from Incomplete boxes to be replaced	Lot number of stock to be returned/replaced

- **Please return to Customer Support Services**

**Fax: 0845 082 0180  
or email**

**Email: [sales@shermond.com](mailto:sales@shermond.com)**

**By 8 April 2011**

**If you require any further information please contact**

**Michael Bennett**





Boundary House  
Interlink Way East  
Interlink Business Park  
Bardon, Coalville  
Leicestershire  
LE67 1LA

**Quality Assurance**  
**Telephone: 0161 8484028**  
**Email: [mike.bennett@bunzl.co.uk](mailto:mike.bennett@bunzl.co.uk)**

