

# Medical Device Alert

Ref: MDA/2014/043 Issued: 25 November 2014 at 15:00

## Device

Neonatal and paediatric support devices. All batches of:  
Gel-E Donut part numbers: 92025-A, 92025-B, 92025-C and  
Squishon 2 part number 91033-2.  
Manufactured by Philips Healthcare (Children's Medical Ventures)

## Problem

Risk of infection, breathing difficulties and allergic reactions.

Philips Healthcare (Children's Medical Ventures) is aware of mould growth on these neonatal and paediatric support devices. The mould has been identified as *Cladosporium* and *Penicillium* fungi.

The manufacturer has issued a revised [Field Safety Notice \(FSN\)](#) dated 10 October 2014.

## Action

- Stop using **all** these devices, even if you can't see any mould on them.
- Dispose of all the devices according to your local environmental guidelines.
- Fill in the customer reply form attached to the [FSN](#) and return it to your distributor.
- This MDA replaces MDA/2014/038 (issued 30 September 2014).

## Action by

All staff who use or handle these devices, particularly supplies and neonatal/paediatric departments.

## CAS deadlines

Action underway: 02 December 2014

Action complete: 29 December 2014

**Note: These deadlines are for disposal of the affected devices.**

## Contact

### Manufacturer

Phillips Healthcare UK

Philips UK Customer Care Service Centre

Tel: 0870 532 9741

Email: [michelle.norman@philips.com](mailto:michelle.norman@philips.com)

## Device

These gel-filled products are used in hospitals, under the supervision of a caregiver, to support and cradle an infant's head and/or body.

The part number is printed on the product itself.

## Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams for information
- NHS trusts in England (chief executives)
- Special health authorities for information

### 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:

- Clinical governance leads
- Community children's nurses
- Equipment stores
- Equipment libraries and stores
- Health and safety managers
- Infection control departments
- Infection control nurses
- Infection prevention and control directors
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (paediatric)
- Intensive care, directors of
- Maternity units
- Medical directors
- Midwifery departments
- Midwifery staff
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics departments
- Obstetrics nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Purchasing managers
- Risk managers
- Special care baby units
- Supplies managers

### Independent distribution

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

This alert should be read by:

- Hospitals in the independent sector

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

Phillips Healthcare UK  
The Phillips Centre  
Guildford Business Park  
Guildford  
GU2 8XH

Tel: 0870 532 9741

Email: [michelle.norman@philips.com](mailto:michelle.norman@philips.com)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/043** or **2014/006/013/081/023**

### Technical aspects

Andy Marsden or Ian Knott  
Medicines & Healthcare Products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 7205 / 6522

Fax: 020 8754 3965

Email: [andy.marsden@mhra.gsi.gov.uk](mailto:andy.marsden@mhra.gsi.gov.uk)  
[ian.knott@mhra.gsi.gov.uk](mailto:ian.knott@mhra.gsi.gov.uk)

### Clinical aspects

Mark Grumbridge  
Medicines & Healthcare Products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ

Tel: 020 3080 7128

Fax: 020 8754 3965

Email: [mark.grumbridge@mhra.gsi.gov.uk](mailto:mark.grumbridge@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

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

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:

Improving Patient Safety Team

Medical Directorate

Welsh Government

Cathays Park

Cardiff CF10 3NQ

Email: [improvingpatientsafety@wales.gsi.gov.uk](mailto:improvingpatientsafety@wales.gsi.gov.uk)

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