

Medical Device Alert

MDA/2015/025

Issued: 06 July 2015 at 14:30

1. TransWarmer infant transport mattress
 2. NovaPlus TransWarmer infant heat therapy mattress with WarmGel
 3. Infant heel warmer
- Manufactured by CooperSurgical under different brand names

Summary

Recall due to risk of serious burn if device is used past its expiry date. Devices manufactured before May 2013 don't have expiry dates or lot numbers on their packaging.

Action

- Identify and quarantine all product that does not have a lot or expiry date on the packaging (check the transport mattress [FSN](#) and heel warmer [FSN](#) to see where the expiry date should be).
- Discard or return affected product to your supplier.
- Return the relevant acknowledgement and receipt form to the manufacturer.

Action by

- All staff who use these devices

Deadlines for actions

Actions underway: 20 July 2015

Actions complete: 03 August 2015

Device details

Mattresses

Package label	Part	Product description
CooperSurgical	20421	TransWarmer® infant transport mattress
NovaPlus	V6390	NovaPlus TransWarmer® infant heat therapy mattress with WarmGel®

Heel warmers

Package label	Part	Product description
CooperSurgical	20418	WarmGel infant heel warmer
CooperSurgical	24401	Liquid infant heel warmer
Fisher Brand	24647	FISHERBRAND gel infant heel warmer
Fisher Brand	24646	FISHERBRAND liquid infant - heel warmer
MediChoice	24649	MEDICHOICE warmgel infant heel warmer
MediChoice	24648	MEDICHOICE liquid infant - heel warmer
NovaPlus	V6391	WARMGEL infant heel warmer - NOVAPLUS
NovaPlus	V6393	Liquid infant heel warmer - NOVAPLUS

Manufacturer contacts

CooperSurgical
Attn: Product Surveillance
75 Corporate Dr
Trumbull CT 06611, USA
USA phone: +1 203-601-5200 ext. 3414
USA fax: +1 203-601-9870
Email: Productsurveillance@coopersurgical.com

European Authorised Representative – Emergo Europe
Tel: +31 70 346 7299
Email: vigilance@emergogroup.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

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

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- All departments
- Ambulance services directors
- Community children's nurses
- Community hospitals
- Community midwives
- Community nurses
- District nurses
- Gynaecologists
- Gynaecology departments
- Gynaecology nurses
- Health visitors
- Hospital at home units
- Immunisation co-ordinators
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Maternity units
- Midwifery departments
- Midwifery staff
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors

- Obstetrics departments
- Obstetrics nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Paramedics
- Patient transport managers
- Phlebotomists
- Point of care testing co-ordinators
- Purchasing managers
- Special care baby units
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

NHS England area teams

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

- General practice managers
- General practice nurses
- General practitioners

Independent distribution

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

- Clinics
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- 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 and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2015/025** or **2015/004/027/291/014**

Technical aspects

Elke Kerwick or Andy Marsden, MHRA

Tel: 020 3080 6826 / 7205

Email: elke.kerwick@mhra.gsi.gov.uk or andy.marsden@mhra.gsi.gov.uk

Clinical aspects

Mark Grumbridge, MHRA

Tel: 020 3080 7128

Email: mark.grumbridge@mhra.gsi.gov.uk

Reporting adverse incidents in England

Through Yellow Card <https://yellowcard.mhra.gov.uk/>

Northern Ireland

Alerts in Northern Ireland are distributed via the [NI SABS system](#).

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

Northern Ireland Adverse Incident Centre, CMO Group,
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868 Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

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

Reporting adverse incidents in Northern Ireland

Please report directly to NIAIC using the [forms on our website](#).

Scotland

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

Incident Reporting and Investigation Centre, Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575 Fax: 0131 314 0722

Email: nss.irc@nhs.net

Reporting adverse incidents in Scotland

NHS Boards and Local Authorities in Scotland – [report to Health Facilities Scotland](#).

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – [report to Health Facilities Scotland](#).

Private facilities providing care to private clients report to the [Care Inspectorate](#) and [MHRA](#).

Wales

Enquiries in Wales should be addressed to:

Healthcare Quality Division, Welsh Government

Tel: 01267 225278 / 02920 825510

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

Reporting adverse incidents in Wales

Report to MHRA through Yellow Card <https://yellowcard.mhra.gov.uk/> and follow specific advice for reporting in Wales in [MDA/2004/054 \(Wales\)](#).