MDA/2018/004(Wales)

Medical Device Alert

15th February 2018

Parc Cathays
Caerdydd CF10 3NQ

Llywodraeth Cymru
Welsh Government

Cathays Park
Cardiff CF10 3NQ

Recall of specific lots of RUSCH sensor (series 400) silicone and non-sterile rectal/ pharyngeal temperature sensors

- Identify affected products listed in the manufacturer's Field Safety Notice (FSN).
- Stop using the devices immediately.
- Follow the instructions in the manufacturer's FSN to return affected devices.

Sent to:
NHS Wales Shared Services Partnership
Directors of Public Health,
Chief Executives, NHS Trusts
Chief Executives, LHBs
Medical Directors, NHS Trusts
Nurse Directors, LHBs
Executive Nurses, NHS Trusts
NHS Direct
CSSIW
Social Services
HIW

A list of people who need to have early sight of this information is given in the Notice.
This Notice has been endorsed by the Welsh Government as being relevant to NHS Wales.

Points of particular importance in Wales:

Healthcare Quality Division
Welsh Government
Cathays Park
Cardiff CF10 3NQ

This document is available online at:
https://www2.nphs.wales.nhs.uk/contacts.nsf

Ffôn/Tel: 029 2082 3624/029 2082 5510
Ebost/Email: Haz-Aic@wales.gsi.gov.uk

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2018/004 Issued: 14 February 2018 at 14:00 Valid until: February 2019

Recall of specific lots of RUSCH sensor (series 400) silicone and non-sterile rectal/ pharyngeal temperature sensors

Summary

Manufactured by Teleflex – risk of misdiagnosis and delivery of inappropriate treatment as sensors may give an inaccurate temperature reading.

Action

- Identify affected products listed in the manufacturer's Field Safety Notice (FSN).
- Stop using the devices immediately.
- Follow the instructions in the manufacturer's FSN to return affected devices.

Action by
Healthcare professionals

Deadlines for actions
Actions underway: 21 February 2018
Actions complete: 07 March 2018

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

Department of Health
An Roinn Sláinte
Mànnystrie O Poustie
www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Device details

Devices affected are:

Teleflex code	NHS Supply Chain code	GS1/UDI
179361-000120	FUS029	24026700000000
179361-000140	FUS030	24026700000000
179361-000160	FUS031	24026700000000
179361-000180	FUS032	24026700000000
179360-000120	n/a	24026700000000
179360-000140	n/a	24026700000000
179360-000160	n/a	24026700000000
179360-000180	n/a	24026700000000
1016	n/a	24026700000000

Manufacturer contacts

Teleflex UK customer service
Tel: 01494 532 761
Email: orders.uk@teleflex.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 NICAS liaison officers for onward distribution to all relevant staff including:

- Adult intensive care units
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Cardiothoracic departments
- Cardiothoracic surgeons
- Coronary care departments
- Coronary care nurses
- General surgeons
- General surgery
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Operating department practitioners
- Paediatric surgeons
- Paediatric surgery, directors of
- Purchasing managers
- Supplies managers

- Theatre managers
- Theatre nurses
- Theatres
- Urological surgeons
- Urology departments

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
- 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 and requesting this facility.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2018/004** or **2017/011/024/228/008**

Technical aspects
Jenifer Hannon or Leanne Simpson, MHRA
Tel: 020 3080 7153 or 020 3080 7143
Email: jenifer.hannon@mhra.gov.uk or leanne.simpson@mhra.gov.uk

Clinical aspects
Devices Clinical Team, MHRA
Tel: 020 3080 7274
Email: dct@mhra.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 NICAS 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
Email: niaic@health-ni.gov.uk
https://www.health-ni.gov.uk/niaic

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

Email: nss.iric@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: 02920 823 624 / 02920 825 510

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).