Medical Device Alert

Ref: MDA/2013/070 Issued: 28 August 2013 at 15:30

Device

Insulin infusion sets and reservoirs used with Paradigm ambulatory insulin pumps (manufactured by Medtronic):
1) Paradigm infusion sets (all MMT models, all lot numbers).
2) Paradigm insulin reservoirs (MMT models - 326A and 332A, specific lots).
See below for details of model and lot numbers for both products.

Problem

Risk of under- or over-delivery of insulin, which may lead to hypoglycaemia or hyperglycaemia, with a consequent loss of consciousness or death, in extreme cases.

The root causes are:

1) Spillage from the insulin reservoir may block connector vents, preventing correct priming of the pump. Medtronic have issued advice on the correct technique for filling the reservoir.

2) The insulin reservoir may leak, due to a manufacturing defect, which may result in under delivery of insulin and failure of the pump's occlusion alarm. Medtronic have initiated a recall of affected reservoirs.

Action by

Diabetes departments.
Those involved in the supply and use of these devices.

Action

Identify affected infusion sets and reservoirs.

Ensure that all relevant staff and patients receive the appropriate copy of Medtronic's Field Safety Notices and are aware of the recommendations. In particular:

- Ensure staff and patients follow the manufacturer's recommendations to avoid spillage from the insulin reservoir.
- Discard unused, affected reservoirs immediately and request replacements.
- Return Field safety Action sheet to manufacturer.

CAS deadlines

Action underway: 18 September 2013

Action complete: 02 October 2013

Note: These deadlines are for staff and patients to follow the recommendations in the FSNs and to ensure that affected reservoirs are removed from use.

Contact

Manufacturer
Lisa Stanley
Medtronic Ltd
Tel: 01923 212 213
Email: Lisa.stanley@medtronic.com

Device

Models of Paradigm infusion sets affected (all lots):

MMT-317	MMT-318	MMT-324	MMT-325
MMT-312S	MMT-312L	MMT-386	MMT-387
MMT-394	MMT-396	MMT-397	MMT-398
MMT-399	MMT-377	MMT-378	MMT-381
MMT-382	MMT-383	MMT-384	MMT-368
MMT-862	MMT-864	MMT-866	MMT-874
MMT-876	MMT-884	MMT-886	MMT-921
MMT-923	MMT-925	MMT-941	MMT-943
MMT-945	MMT-961	MMT-963	MMT-965
MMT-975			

Lot numbers of recalled MMT-326A and MMT-332A reservoirs:

H8416432	H8461538	H8489386	H8512826
H8420977	H8463297	H8491921	H8515317
H8422490	H8464121	H8492449	H8517079
H8424676	H8467888	H8494645	H8521052
H8437486	H8469703	H8496561	H8539013
H8441420	H8471745	H8500423	H8541843
H8442973	H8473106	H8500472	H8584244
H8451531	H8473271	H8503372	H8627745
H8452933	H8476270	H8503728	H8603292
H8455959	H8478398	H8509305	H8604958
H8457716	H8485398	H8510440	H8635301
H8459557	H8486688	H8512566	

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- 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
- NHS trusts in England (chief executives)
- Social services in England (directors)

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
- Clinical governance leads
- Community children's nurses
- Community diabetes specialist nurses
- Community hospitals
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- Diabetologists

- EBME departments
- Equipment stores
- Hospital pharmacies
- Medical directors
- Medical libraries
- Nursing executive directors
- Paediatric nurse specialists
- Paediatricians
- Risk managers
- Supplies managers

NHS England area teams
CAS liaison officers for onward distribution to all relevant staff including:
- Community pharmacists
- District nurses
- General practitioners

Social services
Liaison officers for onward distribution to all relevant staff including:
- Care at home staff
- Care management team managers
- Community care staff

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
This alert should be read by:
- Clinics
- 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 and requesting this facility.

Contacts

Manufacturer
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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/070** or **2013/006/013/291/041**

Technical aspects
Enitan Taiwo and Claire Dunne
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

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Clinical aspects
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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

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
NHS National Services Scotland, Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB

Tel: 0131 275 7575 Fax: 0131 314 0722 Email: nss.iric@nhs.net

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

Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team
Medical Directorate, Welsh Government, Cathays Park, Cardiff CF10 3NQ

Tel: 029 2082 3922 Email: Haz-Aic@wales.gsi.gov.uk