Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2020/007 Issued: 25 February 2020 at 12:00

All T34 and T34L (T60) ambulatory syringe pumps – check pumps before each use due to risk of under-infusion and no alarm

Summary

Manufactured by CME (a BD company) – updated advice to address 'wear and tear' of the syringe pump motor block which may lead to under-infusion.

Action

- Healthcare users should be aware of the updated Directions for Use (DFU) and actions in the manufacturer's Field Safety Notice (MMS-19-1572) published in February 2020. This includes:
  - instructions to inspect the pump **before each use**
  - if you see white plastic debris on the lead screw, immediately **stop using** the pump and send it to BD or your chosen service provider for repair
  - a reminder that it's vital to regularly check that an infusion is running as expected.
- Technical staff should be aware of updated service manual advice for pump maintenance. Contact BD to obtain it if required.
- Complete the customer acknowledgement form and send it to BDUKFieldAction@bd.com to confirm receipt of the FSN.
- Report suspected or actual adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to manufacturers if your local or national systems do not.

Action by
All technical staff responsible for servicing these pumps and healthcare staff who use the pumps.

Deadlines for actions
Actions underway: 17 March 2020
Actions complete: 31 March 2020

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
Männystrie O Poustie
www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Problem/Background

Clarification for the UK:
The Field Safety Notice also states “Do not use the pump in case an alternative infusion pump is available”. However, MHRA understands that in the UK this is not feasible/practical due to the unusually high dependence on this device and the lack of suitable alternatives.

BD/CME is in the process of releasing a new design of lead screw. Once the new lead screw design is released, the lead screw component will be replaced for all pumps on the market. In the interim, any customer identifying white debris should contact BD/service provider to arrange repair.

Note: BD/CME published an FSN (MMS-20-1907) on the T34 (3rd edition) pump in December 2019 relating to the availability of the software and the release of updated DFU, which includes the revised instructions for pump set-up. The version 3 pumps were released in 2019.

MHRA is working with the manufacturer on these issues.

Manufacturer contacts

Becton Dickinson UK Ltd.
Customer service line: Tel: 0800 090 2460
Email: BDUKFieldAction@bd.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:

- Clinical governance leads
- Community nurses
- District nurses
- EBME departments
- Equipment stores
- Equipment libraries and stores
- In-house maintenance staff
- Medical directors
- Nursing executive directors
- Palliative care teams
- Purchasing managers
- Risk managers

GP Practices registered with CAS
This Medical Device Alert is being sent to GPs for information only, in circumstances where patients may seek advice about the contents of this notice. GPs need take no further action on receipt of this alert.

NHS England area teams
CAS liaison officers for onward distribution to all relevant staff including:

- GP practices not yet registered with CAS (for information only)

This Medical Device Alert is being sent to GPs for information only, in circumstances where patients may seek advice about the contents of this notice. GPs need take no further action on receipt of this alert.

Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Care management team managers
- Equipment stores
- Equipment supplies managers
- In-house residential care homes
- Loan store managers
- Loaned equipment store managers

Independent distribution

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

- Adult placement
- Care homes providing nursing care (adults)
- Hospices
- Hospitals in the independent sector
- 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 Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number MDA/2020/007 or 2020/001/016/487/009.

Technical aspects

Enitan Taiwo or Roopa Prabhakar, MHRA

Tel: 020 3080 6000

Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health (Northern Ireland)

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

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

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales

Population Healthcare Division, Welsh Government

Tel: 03000 255278 or 03000 255510

Email: Haz-Aic@gov.wales

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).