

Medical Device Alert

Ref: MDA/2011/105 Issued: 03 November 2011 at 15:00

Device

Rollators: model number WA007.

Manufactured by Drive Medical Ltd.

Serial numbers from AJ09080301 to AJ09080530 inclusive.



Problem

Risk of detachment of front castor fork during use.

The manufacturer issued a [Field Safety Notice \(FSN\)](#) – dated 26 August 2011 – for this device but has not had confirmation from a significant number of users that they have received and acted on this information.

A copy of the FSN is in the appendix of this alert, and it is also available on the MHRA website.

This alert has been issued in support of the manufacturer's actions.

Action by

All those involved in maintenance and use of these rollators. In particular: equipment store managers, occupational therapists, maintenance staff and contractors.

CAS deadlines

Action underway: 24 November 2011

Action complete: 03 February 2012

Action

- Ensure that relevant members of staff are aware of the problem.
- Carry out the actions described in the manufacturer's FSN, including sending confirmation requests.

Contact

Manufacturer

Mr Paul Kendall, Drive Medical Ltd

Tel: 0142 231 4488

Fax: 0142 231 4481

Email: technical@drivemedical.co.uk

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care 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:

- Equipment stores
- Occupational therapists
- Physiotherapists
- Rehabilitation engineers
- Supplies managers
- Risk managers

Primary care trusts

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

- Equipment libraries and stores
- Maintenance staff
- Occupational health departments
- Occupational therapists
- Physiotherapists

Social services

Liaison officers for onward distribution to all relevant staff including:

- Adult day centres
- Disability equipment stores
- Equipment stores
- Equipment supplies managers
- Loan store managers
- Loaned equipment store managers
- Occupational health departments
- Occupational therapists

Independent distribution

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

- Hospices and 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.

Contacts

Manufacturer

Paul Kendall
Drive Medical Ltd
Ainley's Industrial Estate
Elland
West Yorkshire
HX5 9JP

Tel: 0142 231 4488

Fax: 0142 231 4481

Email: technical@drivemedical.co.uk

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/105** or **2010/008/012/291/012**

Technical aspects

Emma Rooke and Sara Vincent
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 6609 / 7169

Fax: 020 8754 3965

Email: emma.rooke@mhra.gsi.gov.uk
sara.vincent@mhra.gsi.gov.uk

Clinical aspects

Dr Nicola Lennard
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7126

Fax: 020 8754 3965

Email: nicola.lennard@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

<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

Health Facilities Scotland

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

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

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

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

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Addressees may take copies for distribution within their own organisations

Appendix

Urgent Field Safety Notice

Drive WA007 Rollators
FSCA 001
Type of action : Device Modification



Date: 26 August 2011

Attention: Drive Medical Stockists

Details on affected devices:

*WA007 rollators from batch 5770 and 5862 (supplied after 20 October 2009)
From serial numbers AJ09080301 to AJ09080530 (the serial number is located underneath the seat)*

Description of the problem:

*There is a risk that the front castor fork may become detached during use.
This is due to a fastener becoming unscrewed.*

Advise on action to be taken by the user:

The user or stockist should initially check the front castors for any sign of looseness. The end user or stockist should also contact Drive Medical to arrange for a replacement set of WA007 front castor forks for each of the units they have sold, and supply them to the end users. The castor forks can be replaced without tools by an end user. Full instructions are supplied with replacement castors.

Dealers in receipt of this Field Safety Notice should contact the end users to whom they supplied the rollator for them to arrange the actions above.

Transmission of this Field Safety Notice: (if appropriate)

Distributed to Drive Medical Stockists who have purchased the rollators.

Contact reference person:

Paul Kendall
Drive Medical Ltd,
Ainley's Industrial Estate,
Elland, West Yorkshire HX5 9JP.

The undersign confirms that this notice has been notified the appropriate Regulatory Agency

P Kendall

Please fill in the information below and return immediately to Drive Medical by:

Post: DRIVE MEDICAL LTD, Ainley's Industrial Estate, Elland, West Yorkshire HX5 9JP

Fax: 01422 314481

Email: technical@drivemedical.co.uk

We acknowledge receipt of the field safety notice and require _____ pairs of castors to be sent below:

Name			
Address			
Town		Postcode	
Telephone			
Email			
Serial Numbers of Affected Rollators:			
