

# Medical Device Alert

Ref: MDA/2014/033 Issued: 20 August 2014 at 15:00

## Device

Insulin syringe 1ml safety syringe 27G (for professional use).

Product code: RN01/27i.

All batches.

Manufactured by Medicina Ltd.

## Problem

The affected devices are unable to deliver fewer than 7 units of insulin.

In addition, the safety and performance of these devices has not been properly evaluated and so the CE marking of all of these devices is invalid.

Medicina issued a [Field Safety Notice](#) in June 2014 but has not had sufficient confirmation that customers have received and acted on these notices.

## Action by

All healthcare workers who use these devices.

Personnel involved in the purchase, supply and distribution of these devices.

## Action

Do not use affected devices.

Quarantine them and contact Medicina Ltd to arrange for their collection.

Return the email / fax back form in the FSN to the manufacturer.

## CAS deadlines

Action underway: 04 September 2014

Action complete: 18 September 2014

**Note: These deadlines are for systems to be in place.**

## Contact

### Manufacturer

Carol Cole  
Medicina Ltd

Tel: 01204 695 050

Email: [carol@medicina.co.uk](mailto:carol@medicina.co.uk)

## Device

If relevant to you, the NHS Supply Chain Code is as follows:

Medicina product code	NPC	Product description
RN01/27i	FWD150	Syringe hypodermic safety product with needle attached 1ml syringe with 27G automatically retractable needle insulin

## 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)
- Special health authorities for information

### 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:

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units
- All departments
- All staff
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Chief pharmacists
- Community children's nurses
- Community diabetes specialist nurses
- Community hospitals
- Community nurses
- Day surgery units
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- District nurses
- Equipment stores
- Health and safety managers
- Hospital at home units
- Hospital pharmacies
- Hospital pharmacists
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- NHS walk-in centres
- Nursing executive directors

- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Palliative care teams
- Paramedics
- Pharmaceutical advisors
- Pharmacists
- Point of care testing co-ordinators
- Purchasing managers
- Supplies managers
- Walk-in centres
- Wheelchair service managers

### **NHS England area teams**

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

- Community pharmacists
- General practitioners
- Nutritional nurse specialists
- Occupational health departments
- Practice managers
- Practice nurses

### **Independent distribution**

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

This alert should be read by:

- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Hospices
- 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](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## **Contacts**

### **Manufacturer/Supplier**

Carol Cole

Medicina Ltd

Unit 2, Rivington View Business Park, Station Road, Blackrod, Bolton, BL6 5BN

Tel: 01204 6950505 Fax: 01204 697755 Email: [carol@medicina.co.uk](mailto:carol@medicina.co.uk)

## **England**

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/033** or **2014/005/029/601/003**

### **Technical aspects**

Sonal Vara or Bina Mackenzie

Medicines & Healthcare Products Regulatory Agency

Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 7710/7229

Fax: 020 8754 3965

Email: [sonal.vara@mhra.gsi.gov.uk](mailto:sonal.vara@mhra.gsi.gov.uk)  
[bina.mackenzie@mhra.gsi.gov.uk](mailto:bina.mackenzie@mhra.gsi.gov.uk)

### **Clinical aspects**

Dr Camilla Fleetcroft  
Medicines & Healthcare Products Regulatory Agency  
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ  
Tel: 020 3080 6097  
Email: [camilla.fleetcroft@mhra.gsi.gov.uk](mailto:camilla.fleetcroft@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](mailto: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**

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other 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.irc@nhs.net](mailto: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:

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

Email: [improvingpatientsafety@wales.gsi.gov.uk](mailto:improvingpatientsafety@wales.gsi.gov.uk)