HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Medtronic MiniMed Infusion Sets

Priority 1 – For Immediate Action

HPRA Safety Notice: SN2017(31) **Issue Date: 14th September 2017**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Medtronic	V33136

ISSUE

Medtronic is recalling specific lots of certain infusion sets that are used with Medtronic insulin pumps. The affected sets are:-

- Medtronic MiniMed Quick-set
- Medtronic MiniMed Silhouette
- Medtronic MiniMed Sure-T
- Medtronic MiniMed Mio
- Medtronic MiniMed Mio 30

A field safety notice (FSN) has been issued advising customers of the appropriate actions to take. Customers can determine whether they have affected sets in their possession by following prompts at http://www.mmc.medtronic-diabetes.com/look. A list of affected lots that have been distributed in Ireland has also been included at the end of the accompanying document.

Please refer to the accompanying FSN and associated documentation for further details.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1 Refer to the accompanying pump user letter and follow the instructions provided by the manufacturer.
2 Report any concerns regarding these devices to the manufacturer and the HPRA as soon as possible.
3 Contact your healthcare professional with any concerns

The HPRA advises that healthcare professionals:

4 Refer to the accompanying FSN and follow the instructions provided by the manufacturer.
5 Inform all pump users of this recall using the accompanying pump user letter.
6 Forward a copy of this Safety Notice and the FSN to all relevant personnel within your organisation or to any other organisations/persons to which/whom these devices have been transferred.
7 Report any adverse events/incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

Carers	Nursing homes
Clinical engineers	Outpatient clinics
Community care managers	Paediatricians
Community nurses	Pharmacists
Diabetes clinics	Practice nurses
Diabetes nurse specialists	Private medical practitioners
Endocrinologists	Private hospitals
Endocrinology units	Risk managers
General practitioners	School nurses
Hospital managers / CEOs	Supplies managers
Medical directors	

BACKGROUND

Medtronic has become aware of an issue whereby there is a potential for over-delivery of insulin caused by fluid blocking the infusion set membrane during the priming/fill-tubing process when using specific lots of certain infusion sets with Medtronic insulin pumps. The recall is only related to the infusion sets listed above and does not include insulin pumps or glucose sensors.

Medtronic advised that a membrane blocked by fluid most likely occurs if insulin, alcohol, or water is spilled on the top of the insulin reservoir which then could prevent the infusion set from working properly.

Medtronic advised the HPRA that as well as the potential for hypoglycaemia from over-delivery of insulin, there is also a potential for hyperglycaemia from under-delivery of insulin. Under-delivery of insulin could occur if a user waits for insulin dripping that is caused by a blocked infusion set membrane to end and then inserts the infusion set. Medtronic advised that hypoglycaemia would be more clinically critical than hyperglycaemia and that for this reason Medtronic's FSN has focused on the potential for over-delivery/hypoglycaemia.

Medtronic has advised that infusion sets which are unaffected by this issue are available. Infusion sets currently being shipped by Medtronic contain an enhanced membrane material that significantly reduces the identified risk.

Please refer to the accompanying FSN for further details.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Medtronic Limited,
Building 9,
Hatters Lane,
Croxley Park,
Watford,
United Kingdom

Telephone: +353- 1-5111444
E-mail: vigilance.eu@medtronic.com

Enquiries to the **distributor** should be addressed to:

Pharmed Ltd,
Unit 3,
Clonmore Business Park,
Mullingar,
Co. Westmeath

Telephone: +353-44-9334602
Fax: +353-44-9390140
E-mail: caroline.daly@pharmed-group.com
Website: http://pharmed.ie/

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie