

Safety Notice

Medical Devices

MiniMed™ Mio™ Advance Infusion Sets

**Priority 1 – For Immediate
 Action**



HPRA Safety Notice: SN2019(02)

Issue Date: 23rd January 2019

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Unomedical A/S / Medtronic	V38338

ISSUE
<p>The HPRA is issuing this Safety Notice to raise awareness of an important update to the package insert for MiniMed Mio™ Advance Infusion Sets.</p> <p>The user guide currently recommends filling 6mm and 9mm soft cannulas with 0.9U (0.009 ml) of insulin after inserting a new set. Unomedical a/s has determined that the correct fill cannula volume is 0.6U for <u>both</u> 6mm and 9mm soft cannulas.</p> <p>The MiniMed™ Mio™ Advance infusion set is used with all major insulin pump brands with luer-lock or MiniMed™ connections including Medtronic, Roche and Animas insulin infusion pumps. Only Medtronic MiniMed™ Mio™ Advance infusion sets are affected by this FSN</p> <p>Further information is provided in the accompanying field safety notice (FSN) and pump user letter.</p>

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

BACKGROUND

Unomedical a/s has updated the user guide to recommend that 6mm and 9mm soft cannulae be filled with 0.6U (0.006 ml) of insulin. Reducing the soft cannula insulin fill volume to 0.6U (0.006 ml) will reduce the risk of potential hypoglycaemic events, particularly among paediatric patients.

Users are advised to fill the MiniMed™ Mio™ Advance infusion set soft cannula with insulin as follows:

- 6mm: 0.6U (0.006 ml)
- 9mm: 0.6U (0.006 ml)

Please refer to the accompanying FSN and pump user letter for further details.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

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

Unomedical a/s
Aaholmvej 1-3, Osted
Lejre, 4320
Denmark

Telephone: +45-48-167000
E-mail: FSCA-ID@convatec.com
Website:

Enquiries to the **distributor** 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

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