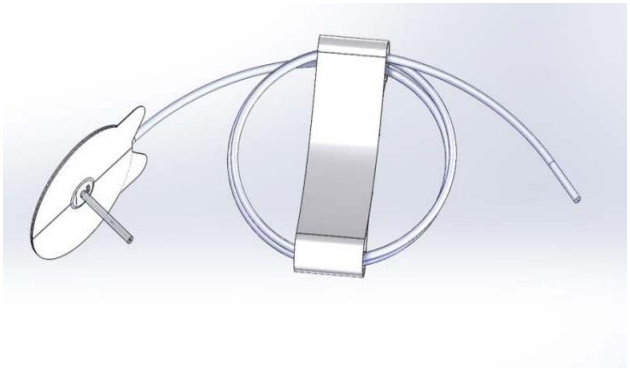
HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

SURE-T, SURE-T Paradigm, Contact Detach, Contact, Sub Q, Neria, Neria Detach, Neria Multi, Thalaset



Priority 2 – Warning

HPRA Safety Notice: SN2015(24) **Issue Date: 24 August 2015**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Unomedical a/s, A Convatec Company	V24336

ISSUE
The Health Products Regulatory Authority (HPRA) has been advised by Unomedical of important safety information relating to the use of SURE-T, SURE-T Paradigm, Contact Detach, Contact, Sub Q, Neria, Neria Detach, Neria Multi, Thalaset Steel cannula infusion sets. Unomedical want to inform users that the steel needle can break during use and result in leakage of medication and the needle may require surgical removal.

ACTION OR RECOMMENDATIONS

The HPRA advise users:

1 To carefully remove the needle guard before inserting the infusion set.

2 Not to bend the needle prior to insertion and not to use the infusion set if the needle is bent or has been damaged.

3 To carefully remove the infusion set after use to avoid mechanical stress on the needle.

4 To ensure that the needle is present on the used infusion set before discarding it.

5 To contact the health care provider if there is suspicion that a needle has broken off and remained under the skin.

6 To forward this safety notice to all relevant users in accordance with your procedures.

7 To report all incidents encountered with the use of these medical devices to the device manufacturer and also to the HPRA.

TARGET GROUPS

All Hospital staff
All Nursing Home staff
Carers
Diabetic Clinics/ outpatients
Diabetic nurse specialists
Diabetic departments
Endocrinology units
Endocrinology Consultants Risk Managers
General Practitioners
Healthcare professionals who use these devices
Hospital Pharmacists
Healthcare professionals managing patients who use these devices
Nursing Managers
Paediatric wards
Pharmacists
Palliative care teams
Parkinson's nurse specialists
Purchasing / Procurement / Material Managers
Risk Managers
General practice nurses
General practitioners
Care at home staff
Care management team managers
Community care staff
In-house residential care homes

BACKGROUND

The manufacturer has issued a Field Safety Notice (FSN) advising of the issue – see attached. This FSN is being sent to all healthcare professionals looking after patients using these devices.

The distributors for these devices are Animas Corporation, Baxter Healthcare Ireland and Medtronic Ireland Ltd., (see details below). The HPRA was informed that this communication was sent by these distributors to centers/ hospitals affected by this issue with further details on the devices/lots involved.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

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

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

Telephone: +45-21195450
Fax: + 45-46427880
E-mail: FSCA-ID@convatec.com
Website: www.infusion-set.com

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

Animas Corporation,
50-100 Holmers Farm Way
High Wycombe
Bucks HP 12 4DP
United Kingdom

Telephone: 1800 812 715
E-mail: AnimasUK@its.jnj.com
Website: www.animas.com

Baxter Healthcare Ireland
Unit 7 Deansgrange Business Park
Blackrock
Co. Dublin
Ireland

Telephone: +353-1-206 5500
Fax: +353-1-206 5577
E-mail: qa_dublin@baxter.com
Website: www.baxterhealthcare.ie

Medtronic Ireland Ltd.
Unit GA,
Swords Business Campus,
Balheary Road, Swords
Co. Dublin
Ireland

Telephone: +353-15111400
Fax: +353-18722077
E-mail: vigilance.eu@medtronic.com
Website: www.medtronic.co.uk

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