IRISH MEDICINES BOARD
SAFETY NOTICE

SAFETY NOTICE

Neria Steel Cannula Infusion sets manufactured by Unomedical

IMB Safety Notice: SN2012(12)
Circulation Date: 21 August 2012

MANUFACTURER/SUPPLIER
Unomedical a/s

TARGET GROUPS
Hospital
Hospital CEOs
Hospital Risk Managers
Medical Nursing Staff
Paramedics
Palliative Care Units
Intensive Care Units
Haematologists
Haematology nurse specialist
Anaesthetic Officers
General Practitioners
Practice Nurses
Clinical Engineers
Hospices
Nursing Homes
Community Care Managers
Community Therapists
Carers
Pharmacists

Please bring this safety notice to the attention of all who need to be aware of it.

ISSUE
There is a risk that the needle of the neria steel cannula infusion set may break during use leading to leakage of medication and the potential need for surgical intervention to remove the needle.

SAFETY NOTICE

BACKGROUND

Unomedical has found that in rare cases the steel needle can break during use. This can lead to leakage of medication and the needle may require surgical removal. Through their investigation, the manufacturer has confirmed that this issue may occur on certain device models for sets with expiry dates up to and including January 2017. The expiration date is shown on the packaging as yyyy-mm.

The manufacturer has distributed the attached Field Safety Notice (FSN) to its customers providing information to identify potentially affected devices and to provide advice for using the infusion sets safely.

Unomedical has informed the Irish Medicines Board (IMB) that all users that were supplied with the affected devices may not have received a copy of the FSN. The IMB is issuing this Safety Notice to ensure all users of the potentially affected devices are aware of the issue.

ACTION OR RECOMMENDATIONS

1. Ensure that the relevant personnel in your organisation are made aware of this issue.

2. Determine whether you have purchased a device that could be affected by this issue by reviewing the attached FSN.

3. Ensure that all users of these devices are aware of the information supplied by the manufacturer in the attached FSN to ensure safe use of the devices.

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Cindie Vandfeldt
Unomedical a/s
Infusion Devices
Aaholmvej 1-3, Osted
DK - 4320 Lejre
Denmark
Email: Buid.complaints@convatec.com

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

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

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