IRISH MEDICINES BOARD

Notice Information: - Advisory
21 August 2012

Part 1. Product Information

a)	Title:	Neria Steel Cannula Infusion sets manufactured by Unomedical
b)	Product Name/Type:	Neria Steel Cannula Infusion sets manufactured by Unomedical
c)	Reference:	SN2012(12)
d)	Manufacturer/Supplier:	Unomedical a/s

Part 2. Target Audience

a)	Target Audience:	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.

Part 3. Problem/Issue

a)	Problem/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.

Part 4. Background Information

a)	Background Information:	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.

Part 5. Action to be taken

a)	Action to be taken:	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.

Part 6. Enquiries

a)	All enquiries should be made to:	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 Please click here to view a PDF version of this Safety Notice Please click here to view the Field Safety Notice

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