



Unomedical

A ConvaTec Company

Name
Address
Address
Address
Town
Postcode

Field Safety Notice

Regarding

neria steel cannula infusion sets

12 June 2012

Dear Customer,

We would like to provide you with some important information regarding the safe use of the following infusion sets:

<u>REF #</u>	<u>PRODUCT DESCRIPTION</u>
78-060-2738	neria 27G 60cm tube, 8mm needle
78-060-2931	neria 29G 60cm tube, 10mm needle
78-060-2938	neria 29G 60cm tube, 8mm needle
78-110-2731	neria 27G 110cm tube, 10mm needle
78-110-2736	neria 27G 110cm tube, 6mm needle
78-110-2738	neria 27G 110cm tube, 8mm needle
78-110-2931	neria 29G 110cm tube, 10mm needle
78-110-2936	neria 29G 110cm tube, 6mm needle
78-110-2938	neria 29G 110cm tube, 8mm needle

These infusion sets are manufactured by Unomedical a/s and are used for subcutaneous infusion of medication.

You are receiving this letter because you have purchased one or more of these codes during the period 1 May 2011 to 31 May 2012. We kindly ask you to present this information to the end users of these products

Unomedical has through its continuous quality management processes 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. Unomedical has executed the required actions immediately to secure this issue.

By following the advice mentioned below and the instructions for use accompanying the devices you can continue to use your infusion sets safely:

- Carefully remove the needle guard before inserting the infusion set.
- Do not bend the needle prior to insertion and do not use the infusion set if the needle is bent or has been damaged.
- Carefully remove the infusion set after use to avoid mechanical stress on the needle.
- Please ensure that the needle is present on the used infusion set before discarding it.
- Please contact your health care provider if you suspect that a needle has broken off and remained under the skin

Please note that neria infusion sets that expire after January 2017 do not carry an increased risk of needle breakage.

We sincerely apologize for any inconvenience this may have caused. For any questions you may have, please contact the ConvaTec Clinical Support Line on Freephone 0800 289 738 (or from the Republic of Ireland 1800 946 938)

Best Regards



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