

Vicare Medical A/S  
 Kongevej 150b  
 Birkerød  
 Dk 3460  
 Denmark

**Kimal plc: URGENT FIELD SAFETY NOTICE**  
**Type of Action: Field Safety Notice**

**Kimal plc – STERILE INTRODUCER NEEDLE 18G**

Product Code	Product Description	Lot Number Affected
K6/1	INTRODUCER NEEDLE 18G	15L0164

Dear Customer,

Kimal is initiating a Field Safety Notice in regards to the above mentioned product and lot number of our sterile 18G introducer needle.

**Description of issue:**

Kimal have received one customer complaint, that the product above has a discrepancy with the seal of the pouch. We have identified internally after inspecting retained samples that there may be some cases where the pouch has failed to seal at the peel corner, meaning the product is no longer sterile.

We kindly ask you to inspect your stock of the above mentioned product and lot number. Should you identify that the pouch is not sealed, remove from your inventory, and dispose of the affected product. Please inform Kimal on the quantity disposed of and free of charge, unaffected product will be provided to compensate. The photographs below show a defective seal and an acceptable seal:



Our records indicate that Kimal has shipped the abovementioned product to your facility as a Kimal finished product. Therefore we draw your attention to the following instructions:

1. Please review the specific instructions within the field safety notice.
2. Details of affected Kimal finished codes are above for your convenience.
3. Please forward this Field Safety Notice to any health care professionals within your organisation that needs to be aware of this notice and to any third party where the product may have been used. Please provide Kimal plc with details of any devices that have been distributed to any third party organisations.
4. Please complete the attached Confirmation Form (Appendix 1) and either fax it back to Kimal Plc for the attention of Mrs. Rebekah Vine , Device Vigilance department on +44 (0)1527 579 936 or email to [Rebekah.vine@kimal.co.uk](mailto:Rebekah.vine@kimal.co.uk)
5. Please contact Mrs Rebekah Vine in our Device Vigilance department who will arrange for free of charge replacement product meeting the correct specification. Contact details [Rebekah.vine@kimal.co.uk](mailto:Rebekah.vine@kimal.co.uk) or +44(0)1527 572398

We regret any inconvenience this action may have caused and would appreciate your understanding as we have taken this action in the interest of patient safety. If you have any questions or would like further assistance with this Field Safety Notice please contact the following:

Regulatory Manager: Rebekah Vine

Yours Sincerely,

.....  
Device Vigilance Team  
Kimal Plc

Attachments

Appendix 1) Confirmation of Receipt of Field Safety Notice  
Appendix 2) Description and Actions to be taken.

**Appendix 1**  
**Confirmation of Receipt of Field Safety Notice**

<p><b><u>Kimal plc: URGENT FIELD SAFETY NOTICE</u></b>  <b><u>Type of Action: Field Safety Notice</u></b></p> <p><b><u>Kimal plc – STERILE INTRODUCER NEEDLE 18G</u></b></p>
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<p>Please complete this form and return a copy either by FAX or email to confirm that you have received this confirmation, once all information has been gained.</p> <p><b>Fax: +44 (0) 1527 579 936</b>  <b>Email: <a href="mailto:Rebekah.Vine@kimal.co.uk">Rebekah.Vine@kimal.co.uk</a></b></p>
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Customer Name and Address: (Please Print)	
Reply confirmation completed by: (Please Print Name)	
Title: (Please Print)	
Telephone Number :	
Email :	

We confirm:

- We have read the Field Safety Corrective Action notice as per appendix 2.
- We have communicated the information to staff and other services / departments / units / facilities who need to know.
- We have none of the affected stock

We have the following product that requires replacements:

Product Code:	Lot Number:	Quantity (pcs):

## Appendix 2

**Kimal plc: URGENT FIELD SAFETY NOTICE****Type of Action: Field Safety Notice****Kimal plc – STERILE INTRODUCER NEEDLE 18G****Description of issue:**

Kimal have received one customer complaint, that the product above has a discrepancy with the seal of the pouch. We have identified internally after inspecting retained samples that there may be some cases where the pouch has failed to seal at the peel corner, meaning the product is no longer sterile.

We kindly ask you to inspect your stock of the above mentioned product and lot number. Should you identify that the pouch is not sealed, remove from your inventory, and dispose of the affected product. Please inform Kimal on the quantity disposed of and free of charge, unaffected product will be provided to compensate.

**Action to be taken by the user:**

- Please check your stock for the specified product and lot numbers in page 1 of this Field Safety Notice.
- Should you identify that the pouch is not sealed, remove from your inventory, and dispose of the affected product.
- Complete Appendix 1 of the Field Safety Notice and return to the contact reference person at Kimal, with quantities where replacements are required.
- Kimal will arrange for the replacement product to be sent to your organisation, after receipt of the confirmation form.

Since this issue became known, appropriate measures have been introduced to prevent recurrence. We apologise for the inconvenience caused by this action, taken to safeguard your patients and users.

**Transmission of this Field Safety Notice:**

This notice needs to be communicated immediately to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

**Contact reference person:**

Mrs Rebekah Vine  
Regulatory Manager  
Kimal plc  
Sherwood Road  
Aston Fields  
Bromsgrove  
B60 3DR  
United Kingdom

Email: [Rebekah.vine@kimal.co.uk](mailto:Rebekah.vine@kimal.co.uk)  
Phone: +44(0)1527 572398  
Fax: +44(0)1527 579936