

(Customer Name)
(Address Line 1)
(Address Line 2)
(Address Line 3)
(Address Line 4)
(Post Code)

Kimal plc: URGENT VOLUNTARY FIELD SAFETY NOTICE
PRODUCT RECALL

IMMEDIATE ACTION REQUIRED

VAXCEL PICC WITH PASV VALVE TECHNOLOGY/KITS
XCELA PICC TRIPLE LUMEN WITH PASV VALVE TECHNOLOGY/KITS
BIOFLO PICC TRIPLE LUMEN WITH ENDEXO AND PASV VALVE TECHNOLOGY/KITS

Dear Customer,

This letter is to inform you that Kimal Plc has received an urgent medical device recall notice from our supplier, AngioDynamics. The manufacturer of Vaxcel PICC with PASV, Xcela PICC triple lumen with PASV and Bioflo PICC triple lumen with Endexo and PASV is conducting a medical device recall on specific lots of these devices.

AngioDynamics is conducting a medical device recall on PICC catheters that contain valve(s) manufactured prior to July 15, 2014. Valves manufactured after this date incorporate a manufacturing specification change that reduces the incidence of haemolysis during blood sampling through the catheter. Use of the PICC catheters that are subject to this recall may result in an increased incidence of haemolysed blood samples which may require additional peripheral access or replacement of the PICC catheter.

Please see the table below stating product codes and lot numbers sent to your organisation: -

Product Description:	Product Code:	Lot Number:	Quantity Delivered:
3fr x 60cm Single Lumen Picc Cath	45-436	4731137	56
		4895232	10
		4912062	25
		4933353	6
4fr x 60cm Single Lumen PASV Picc	45-455	4772713	158
		4786763	129
		4790018	247
		4817452	184
5frx60cm Single Lumen PASV Picc MST	45-464	4721239	24
5fr x 60cm Dual Lumen PASV Picc	45-470	4725793	132
		4745367	47
		4748673	115
		4756297	125
		4765394	219
		4773295	148
		4784468	172
		4788536	181
4845665	73		
5fr x 60cm Dual Lumen PASV Picc MST	45-474	4724950	50
6fr x 60cm Dual Lumen PASV Picc MST	45-479	4734253	15
BIO STABLE 6F TL-55CM CATHETER KIT VALVED PG WIRE SS	45-841	4814218	15
		4835795	6
		4842658	12

Our records indicate that Kimal has shipped the abovementioned product(s) to your facility as a 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 product codes are attached 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 Mr. Ben Albutt , Device Vigilance department on +44 (0)1527 579 936 or email to ben.albutt@kimal.co.uk
5. Please contact Mr Ben Albutt in our Device Vigilance department who will arrange for an alternative replacement product meeting the correct specification or credit for your returned product. Contact details ben.albutt@kimal.co.uk or +44(0)1527 572314

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:

Vigilance / Compliance: Ben Albutt

Yours Sincerely,

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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

<u>Kimal plc: URGENT FIELD SAFETY NOTICE</u> <u>IMMEDIATE ACTION REQUIRED</u> VAXCEL PICC WITH PASV VALVE TECHNOLOGY/KITS XCELA PICC TRIPLE LUMEN WITH PASV VALVE TECHNOLOGY/KITS BIOFLO PICC TRIPLE LUMEN WITH ENDEXO AND PASV VALVE TECHNOLOGY/KITS <u>Type of Action: Product Recall</u>
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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. Fax: +44 (0) 1527 579 936 Email: Ben.Albutt@kimal.co.uk

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
IMMEDIATE ACTION REQUIRED
VAXCEL PICC WITH PASV VALVE TECHNOLOGY/KITS
XCELA PICC TRIPLE LUMEN WITH PASV VALVE TECHNOLOGY/KITS
BIOFLO PICC TRIPLE LUMEN WITH ENDEXO AND PASV VALVE TECHNOLOGY/KITS
Type of Action: Product Recall

Description of issue:

Kimal's supplier, AngioDynamics is conducting a medical device recall on PICC catheters that contain valve(s) manufactured prior to July 15, 2014. Valves manufactured after this date incorporate a manufacturing specification change that reduces the incidence of haemolysis during blood sampling through the catheter. Use of the PICC catheters that are subject to this recall may result in an increased incidence of haemolysed blood samples which may require additional peripheral access or replacement of the PICC catheter.

Action to be taken by the user:

- Please check your stock for the specified product code(s) and lot number(s) of PICC catheters.
- Please discontinue use, isolate, label and quarantine any stock to prevent continued use.
- 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 an alternative replacement product meeting the correct specification, or credit for your returned product.

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:

Mr Ben Albutt
Compliance / Vigilance Co-ordinator
Kimal plc
Sherwood Road
Aston Fields
Bromsgrove
B60 3DR
United Kingdom

Email: ben.albutt@kimal.co.uk
Phone: +44(0)1527 572314
Fax: +44(0)1527 579936