

12th June 2013

Hospital name.....
 Department.....



Urgent Field Safety Notice
Kimal Procedure Packs containing
Becton, Dickinson UK Limited: BD Plastipak™ 50ml LuerLok Syringe

Dear Customer,

This letter is to inform you that Kimal Plc have received a Field Safety Notice from Becton, Dickinson UK Limited regarding their BD Plastipak 50ml LuerLok syringe. Kimal is performing this recall as one of the affected three codes within their notice was included in some of our procedure packs. Only the below product codes and lot numbers are affected by this Field Safety Notice.

Product code	Batch / Lot numbers affected					
K20343	11A0501	11C0352				
K20128	10A0522	10G0536	10K0466	10L0375	11B0309	11C0470
	11F0204	11H0249	11J0162	11K0248	12D0061	
K2386	11E0509	11H0362	11K0079	12A0015		
K26318	11D0098	12D0479	10E0234	10F0224	10G0443	10G0593
	10J0611	11B0184	11B0512	11C0155	11D0098	11E0391
	11F0164	11G0248	11J0113	11J0435	11K0253	11L0060
	11M0163	12B0240	12D0078			
K36297	11D0508	11G0616	11K0158	12A0172	12C0091	
K33221	10M0465	11J0411	12B0700			
K2257/7	10E0250	10F0634	10H0122	10J0789	10L0558	11A0391
	11C0488	11F0383	11H0250	11K0323	12A0601	12C0536
BR/QUEST/1292/1	10B0560	10F0687	10K0168	11E0097	11G0585	11L0403
	11L0455	11M0094	11M0339	12B0504	12D0347	
K20343	10F0535	10G0543	10H0656	10K0070	10K0605	10L0121
	10L0634	10M0286	11A0501	11C0352	11D0399	11E0387
	11F0677	11G0443	11K0475	11M0039	12A0155	12C0084
	12D0205					
K20435	10B0354	10F0558	10G0554	10H0624	10K0593	10L0550
	11A0040	11A0374	11B0371	11C0110	11D0011	11F0009
	11G0051	11H0381	11J0166	11K0154	11K0564	12A0045
	12A0471	12A0620	12B0355	12D0326	12E0044	
KH205/1	10H0648	10L0545	11C0408	11G0169	11K0452	11M0267
KH205/215/LV	10K0013					
IE-K20304	10A0538	10B0380	11B0660	11F0626		
IE-K20305	10E0373	10F0368				
IE-K4514	10C0095	10L0654	11C0226	11J0204	11M0084	12A0650
DE-K30131	10A0605					
NO-K2700/3	10B0470	10C0076	10G0506	10J0009	10L0054	
NO-K2703	10G0147					
SE-K33570	10D0094	10H0018	10H0082	11B0517	11E0091	11H0077
	11J0145	11J0727	12A0529			
SE-K33573	10G0208					
DK-K31897	10A0468	11F0658				

12th June 2013

Our records indicate that Kimal has shipped the abovementioned product/lot numbers to your facility as a Kimal finished pack.

We draw your attention to the following instructions.

- Please review the specific instructions within the attached Field Safety Corrective Action.
- Details of affected Kimal product codes by customer are included for your convenience in Appendix 3.
- Please complete the attached Confirmation Form 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
- 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.
- Please discontinue use, isolate, label and quarantine any stock to prevent continued use.
- Please contact Mr Ben Albutt in our Device Vigilance department who will arrange for free of charge replacement stock unaffected by this problem. 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 they 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) Kimal plc Urgent Field Safety Notice - 8911

Appendix 3) List of affected Kimal product by Customer

Appendix 1 - Confirmation of Receipt of Field Safety Notice

Urgent Field Safety Notice Kimal Procedure Packs containing Becton, Dickinson UK Limited: BD Plastipak™ 50ml LuerLok Syringe

Please complete this form and return a copy either by FAX or EMAIL immediately to confirm that you have received this confirmation.
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 replacement product or credit where necessary:

Product Code:	Lot Number:	Quantity (pcs):

Appendix 2

<p align="center">Urgent Field Safety Corrective Action Kimal Procedure Packs containing BD Plastipak™ 50ml LuerLok Syringe Type of Action: Product Recall</p>

Description of problem:

Kimal plc is issuing this Field Safety Corrective Action following receipt of a field safety notice from Becton Dickinson UK Limited (BD) dated 11 April 2013.

BD launched a new syringe stopper design in April 2012. Syringes with the new stopper design may exhibit higher plunger forces when used in pumps.

The higher pump forces may increase the likelihood of triggering a false occlusion alarm for the current setting of occlusion level for some pumps.

While most of the products in the distribution chain have the new design stopper, there may be limited inventory of syringes with the previous design stopper. If syringes with the previous design stopper are used in syringe pumps that have been adjusted for the new stopper, there may be a delay in initiating an occlusion alarm. In order to minimise the potential for this occurrence BD is recalling syringes with the previous design stopper.

Kimal purchases only one of the three BD codes being recalled and therefore has identified a number of affected syringes were included in our procedure packs.

Action to be taken by the user:

- Discontinue use
- Identify, isolate, label and quarantine affected stock
- Kimal will arrange the return of any product affected after receipt of the confirmation form or credits where necessary

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