

**Kimal plc: Urgent Field Safety Notice****KS837/838PS Bloodline Set For Braun Dialog,**

Dear Customer,

This letter is to inform you that Kimal Plc have issued a Field Safety Notice regarding our Bloodline sets for Braun Dialog. Kimal plc have received complaints that air aspiration has been noticed via both, the arterial connection and venous connection points, where the connectors are attached to the patient.

The product codes and affected lot numbers are listed below:

<b>Kimal Product Code:</b>	<b>Lot Number:</b>
KS837/838PS	B140001
KS837/838PS	B140002
KS837/838PS	B140009
KS837/838PS	B140034
KS837/838PS	B140053
KS837/838PS	B140088
KS837/838PS	B140171

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 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](mailto:ben.albutt@kimal.co.uk)
5. Please contact Mr Ben Albutt in our Device Vigilance department who will arrange for free of charge replacement product meeting the correct specification. Contact details [ben.albutt@kimal.co.uk](mailto: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) Description and Actions to be taken.