26 March 2018

KIMAL
delivering healthcare innovation

Kimal plc: URGENT FIELD SAFETY NOTICE
Field Safety Corrective Action

IMMEDIATE ACTION REQUIRED

Multi-lumen Altius Central Venous Catheter kit (codes beginning with K2CS / K2CV, 3 through 7 lumen), lots 0016008 and above

Dear Customer,

Kimal plc is initiating a Field Safety Notice (FSN) in regards to specific lots of our Altius range of Central Venous Catheter (CVC) products. The affected products have been circulated as individual catheter kits and within procedure packs as listed below. We are initiating a voluntary removal of product due to the potential harm associated with this issue.

The catheter is the component affected by this Field Safety Notice.

Description of issue:
Through investigation of recent device experience reports, we have identified an increased trend in the occurrence of wall breaches in catheters with three or more lumens, leading to the potential for the interruption in delivery of critical medications, infection or, extremely rarely, the aspiration of air through the breach, potentially leading to air embolism.

We kindly ask you to review the instructions carefully within this FSN, inspect your stock for the affected products and lot numbers, advise us on the quantities in your inventory and return affected stock to receive a credit note.

Where devices are currently in use with no signs of malfunction, it is unlikely that a breach will spontaneously develop, however we recommend that heightened surveillance of catheters to ensure that patient safety is assured. Decision to remove the device must be made on the basis of a clinical risk/ benefit assessment. Further information regarding safe use is given within the DFU provided with each device.

Timeframe:
Kimal plc have assigned a timeframe of 90 days to complete this FSN.

Products affected:

Catheter kits:
We have identified that all Kimal plc 3, 4, 5, 6 and 7 lumen Altius CVCs (with product codes beginning K2CV or K2CS), with LOT references of 0016008, 0016009, 0016011, 0016012, 0017001, 0017002, 0017003, 0017005, 0017006, 0017007, 0017009, 0017010, 0017011 are affected. There are no affected products with Lot numbers 00160010, 0017004, 0017008

Altius Central Venous Catheter Kit Procedure Packs:
Quantities of the above mentioned lots have also been circulated as part of a Procedure Pack. The procedure packs affected as listed below:

KIMAL
delivering healthcare innovation

REF	LOT
UK-ALT1905P-51145/P1	17E0384
	17H0259
	17H0642
	18A0200
	18A0755
UK-ALT2905P-51226/P1	17D0415
	17E0546
	17E0546
	17J0623
	17L0581
	18A0318
UK-ALT2855-51244/P1	17G0234
	17H0371
	17D0414
	17E0545
	17E0636
	17K0133
	18A0286

Catheters contained within the above procedure packs will also be individually labelled with a lot number as referenced previously as affected.

Our records indicate that Kimal plc has shipped a number of affected product(s) to your facility; therefore we draw your attention to the following instructions:

1. **Please review the content of this Field Safety Notice.**
2. **Communicate immediately to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.**
3. **Please check your stock for the affected product code(s) and lot number(s) listed above.**
4. **Please identify and quarantine all affected stock.**
5. **Please complete Appendix 1 and return to Kimal indicating quantities of stock with lot codes per quantity on the tables shown.**
6. **Kimal plc will action your response**

The co-ordinating competent authority (MHRA) is aware of this action and other regulatory authorities concerned have also been alerted.

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 designated person.

Vigilance / Compliance Executive: Mr. Paul Beard
vigilance@kimal.co.uk
Reference: FSCA 19258

[redacted]

Kimal Plc

Attachments
Appendix 1) Confirmation of Receipt of Field Safety Notice

26 March 2018

KIMAL
delivering healthcare innovation

Appendix 1

Confirmation of Receipt of Field Safety Notice

Kimal plc: URGENT FIELD SAFETY NOTICE
Multi-lumen 3-7 lumen Altius Central Venous Catheter kit (codes beginning with K2CS / K2CV, 3 through 7 lumen), lots 0016008 and above

Type of Action: Field Safety Corrective Action

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 obtained.
Fax: 0845 4379541
Email: vigilance@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 and understood the Field Safety Notice.
- ☐ 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 distributed the affected products to a third party organisation and will provide Kimal plc with these details.

26 March 2018

KIMAL
delivering healthcare innovation

We have the following product that requires return and credit action:

For stock identified in Table 1 - Altius Central Venous Catheter Kit Codes please complete the table below:

TABLE 1 Affected Stock		
Product Code:	Lot Number:	Quantity (pcs):

For stock identified in Table 2 - Altius Central Venous Catheter Kit Procedure Packs please complete the table(s) below depending on procedure pack received:

TABLE 2 Affected Procedure pack Stock		
Product Code:	Lot Number:	Quantity (pcs):