

Kimal plc: URGENT FIELD SAFETY NOTICE
Field Safety Corrective Action

IMMEDIATE ACTION REQUIRED

**Procedure packs containing specific introducers (with and without guidewires),
 peelaway sheaths and peelaway dilators.**

Dear Customer,

Kimal plc is initiating a Field Safety Notice (FSN) in regards to some of our procedure packs with specific components included. We are initiating a voluntary removal of product due to the potential harm associated with this issue.

Specific introducers (with and without guidewires), peelaway sheaths and peelaway dilators supplied to us by Galt Medical Corp are the components affected by this Field Safety Notice.

Description of issue:

Due to a supplier manufacturing issue for specific components of these packs, the products listed might contain unsafe levels of bacterial endotoxins (Pyrogens) that were introduced during a manufacturing step. Bacterial Endotoxins also called pyrogenic bacteria can activate the inflammatory process and produce fever, chills, and hypotension in a patient.

We have attached the Field Safety Notice and FAQ provided by the supplier to this document for further information and clarification of the reason behind this action.

Timeframe:

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

Products affected:

REF	LOT
DE-K34763	18A0383
DE-K45957	18A0389
CLFKITTP	18B0474
	18C0706
EU-CPP-7F	18C0161
EU-CLF-KITAC-TP	18C0159
K63/0512W	S18016057
	S18106396
K63/0712W	S18080265

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

03 May 2018

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

Yours Sincerely,

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Rebekah Vine
Group Quality & Regulatory Manager
Kimal Plc

Attachments
Appendix 1) Confirmation of Receipt of Field Safety Notice

Appendix 1

Confirmation of Receipt of Field Safety Notice

<p align="center"><u>Kimal plc: URGENT FIELD SAFETY NOTICE</u></p> <p align="center">Procedure packs containing specific introducers (with and without guidewires), peelaway sheaths and peelaway dilators.</p> <p align="center"><u>Type of Action: Field Safety Corrective Action</u></p>
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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 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.

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

For stock identified in Table 1 - please complete the table below:

TABLE 1 Affected Stock		
Product Code:	Lot Number:	Quantity (pcs):
DE-K34763	18A0383	
DE-K45957	18A0389	
CLFKITTP	18B0474	
	18C0706	
EU-CPP-7F	18C0161	
EU-CLF-KITAC-TP	18C0159	
K63/0512W	S18016057	
	S18106396	
K63/0712W	S18080265	