03 maggio 2018

Kimal plc: AVVISO URGENTE PER LA SICUREZZA SUL CAMPO
Azione correttiva per la sicurezza sul campo

RICHIESTA DI INTERVENTO IMMEDIATO

Pacchetti per procedura contenenti specifici introduttori (con e senza cavo guida), guaine peel away e dilatatori peel away.

Gentile Cliente,

Kimal plc sta diffondendo un Avviso per la sicurezza sul campo relativo ad alcuni dei nostri pacchetti per procedura contenenti specifici componenti. Stiamo procedendo a un ritiro volontario del prodotto per prevenire potenziali danni associati a questo problema.

I componenti interessati dal presente Avviso per la sicurezza sul campo sono specifici introduttori (con e senza cavo guida), guaine peel away e dilatatori peel away fornitici da Galt Medical Corp.

Descrizione del problema:
A causa di un problema del fornitore nella fabbricazione di specifici componenti inseriti in questi pacchetti, i prodotti elencati potrebbero contenere livelli non sicuri di endotossine batteriche (Pirogeni), che sono state introdotte durante una fase produttiva. Le Endotossine batteriche, chiamate anche batteri pirogeni, sono in grado di attivare il processo infiammatorio e causare febbre, brividi e ipotensione nei pazienti.

Abbiamo allegato al presente documento l'Avviso per la sicurezza sul campo e le Domande frequenti inviati dal fornitore, per ulteriori informazioni e chiarimenti sulla motivazione della presente azione.

Tempistiche:
Kimal plc ha previsto un intervallo di 90 giorni per completare il presente Avviso per la sicurezza sul campo.

Prodotti interessati:

RIF	LOTTO
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

In base ai dati in nostro possesso, Kimal plc ha spedito i suddetti prodotti alla Sua struttura; richiamiamo quindi la Sua attenzione sulle seguenti istruzioni:

1. **La invitiamo a esaminare il contenuto del presente Avviso per la sicurezza sul campo.**
2. **Le presenti informazioni devono essere trasmesse immediatamente a tutti coloro che devono esserne messi a conoscenza all'interno della Sua struttura o di eventuali strutture cui siano stati trasferiti i dispositivi potenzialmente interessati.**
3. **La preghiamo di controllare se nel Suo magazzino sono presenti i codici prodotto e i numeri di lotto interessati, elencati sopra.**
4. **La invitiamo a individuare e mettere da parte tutti i materiali interessati.**

5. **Le chiediamo di compilare l'Appendice 1 e di rispedirla a Kimal, indicando, all'interno delle tabelle, i quantitativi dei materiali interessati in Suo possesso con i rispettivi numeri di lotto.**
6. **Kimal plc agirà in base alla Sua risposta.**

L'autorità competente di coordinamento (MHRA) è a conoscenza della presente azione e sono state avvisate altre autorità di regolamentazione interessate.

Ci scusiamo per eventuali inconvenienti che quest'azione possa aver causato e La ringraziamo per la comprensione, dato che abbiamo intrapreso quest'azione nell'interesse della sicurezza dei pazienti. Se avesse domande o avesse bisogno di ulteriore assistenza relativa al presente Avviso per la sicurezza sul campo, contatti:

Direttore Vigilanza/Compliance: Sig. Paul Beard
vigilance@kimal.co.uk
Riferimento: FSCA 19258

Cordiali saluti,

……..
Rebekah Vine
Responsabile Qualità & Regolamentazione Gruppo
Kimal Plc

Allegati
Allegato 1) Conferma di ricezione dell'Avviso per la sicurezza sul campo

03 maggio 2018

Allegato 1

Conferma di ricezione dell'Avviso per la sicurezza sul campo

Kimal plc: AVVISO URGENTE PER LA SICUREZZA SUL CAMPO
Pacchetti per procedura contenenti specifici introduttori (con e senza cavo guida), guaine peel away e dilatatori peel away.

Tipo di azione: Azione correttiva per la sicurezza sul campo

La preghiamo di compilare questo modulo e d'inviarne una copia via fax o e-mail per confermare la ricezione della presente comunicazione, dopo aver raccolto tutte le informazioni.
Fax: 08454379541
E-mail: vigilance@kimal.co.uk

Nome e indirizzo cliente: (in stampatello)	
Conferma di risposta compilata da: (nome in stampatello)	
Qualifica: (in stampatello)	
Numero di telefono:	
E-mail:	

Confermiamo:

- ☐ Di aver letto e compreso l'Avviso per la sicurezza sul campo.
- ☐ Di aver comunicato le informazioni al personale e ad altri servizi/uffici/unità/strutture che devono esserne messe al corrente.
- ☐ Di non essere in possesso dei prodotti in questione.
- ☐ Di aver distribuito i prodotti interessati a un'azienda terza e d'impegnarci a fornire a Kimal plc tali dati.

03 maggio 2018

Siamo in possesso del seguente prodotto, che richiede la restituzione e l'accredito:

Per i materiali di cui alla Tabella 1, si prega di compilare la seguente tabella:

TABELLA 1 Materiali interessati		
Codice prodotto:	Numero lotto:	Quantità (pz):
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	

Allegato 2

Lettera di richiamo di Galt Medical Corp (ESCLUSIVAMENTE A FINI INFORMATIVI, NON RISPONDERE DIRETTAMENTE A GALT)

02 May 2018

Kimal Plc
Sherwood Road
Aston Fields
Bromsgrove, Worcs. B60 3DR
United Kingdom
RMA: Galt_1032

URGENT: MEDICAL DEVICE RECALL

Attention: Quality/Regulatory Affairs Department:

GALT MEDICAL CORP. has initiated a recall of the products listed in Appendix A. Please direct this notice to the appropriate personnel in the Quality/Regulatory Affairs, or to those responsible for inventory management of the affected product.

Scope of Recall:
The product being recalled is listed in Appendix A and no other products are affected.

Reason for Recall:
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.

Status of Product:
We have identified the lots listed in Appendix A as the only affected products that were distributed to you. The problem has been investigated, and we have taken steps to assure this problem does not recur.

Action to be Taken:
GALT MEDICAL CORP is voluntarily initiating this product recall and requesting the return of products in inventory. The following steps should be taken:

1. Reach out to your customers to whom you have distributed any of this product to determine if they have inventory in stock for return. Please ensure you notify your customers within 48 hours of receipt of this notification.

2. Identify and segregate the recalled lot(s) that are in your possession.

3. Complete the enclosed Recall Reply Form and email or fax it to the attention of the Recall Coordinator at quality@galtneedletech.com or 214-778-1433. The form lists the product number, lot number and quantity our records indicate your facility has received.

1649395-05-02-2018-001-R
Galt Medical Corp| 2220 Merritt Drive, Garland, TX 75040| P: 972-271-5177 F: 214-778-1433

It is important that even if you do not have any product remaining in your possession that you fill out the attached form noting zero quantity to be returned and fax the form to GALT MEDICAL CORP.

3. Ship the recalled product to GALT MEDCIAL CORP. using Galt's carrier account information listed on the form.

4. Reference Return Authorization Number RMA# Galt_1032 on the outside of the shipping box and include a copy of the Recall Reply Form with your shipment.

5. Once the completed Recall Reply Form has been received and processed, Galt will issue a credit to you for the product returned and enter a PO for new products, using your original PO number so your new invoice will pair with your credit.
    a. New inventory for bulk, non-sterile product is estimated to ship in 4-5 weeks, while sterile product is scheduled to ship in 6-7 weeks. Some products will be available to ship sooner, if available upon receipt of the returned product.

GALT MEDICAL CORP. appreciates your understanding and cooperation with this matter and regrets any inconvenience this has caused you. If you have any additional questions or concerns or need more detailed instruction on how to comply with this notice, please do not hesitate to contact your local sales representative or Recall Coordinator at 214-778-1306. You may also e-mail your questions to quality@galtneedletech.com.

Sincerely,

Galt Medical Corp.

David Derrick
Director Quality and Regulatory Affairs.
Galt Medical Corp.

1649395-05-02-2018-001-R
Galt Medical Corp| 2220 Merritt Drive, Garland, TX 75040| P: 972-271-5177 F: 214-778-1433

Galt Medical Corp.

Medical Device Recall Reply Form

Kimal Plc
Sherwood Road
Aston Fields
Bromsgrove, Worcs. B60 3DR
United Kingdom
RMA: Galt_1032

1. Our records indicate you have received the product listed on Appendix A.

Appendix A.

Galt Part	Customer Part#	Lot	PO NO	Ship Date	Original Qty Shipped	UOM	Qty Used	Quantity to be Returned
DSS-005-11	6118	17352818	113914	3/29/18	100	Each		
KCL-212-055	6385/GALT	17363374	110705	12/29/17	300	Each		
KCL-212-055	6385/GALT	18116090	113914	4/5/18	400	Each		
CLI-212-07	6387/GALT	18019455	112398K	2/16/18	1,000	Each		
CLI-212-07	6387/GALT	18019456	112398K	2/16/18	1,000	Each		
CLI-212-07	6387/GALT	18019458	112398K	2/22/18	1,000	Each		
CLI-212-07	6387/GALT	18019460	112398K	2/22/18	1,000	Each		
CLI-212-07	6387/GALT	18019457	112398K	2/22/18	1,000	Each		
CLI-212-07	6387/GALT	18047462	112398K	3/7/18	1,000	Each		
CLI-212-07	6387/GALT	18047463	112398K	3/7/18	1,000	Each		
CLI-212-07	6387/GALT	18047461	112398K	3/7/18	1,000	Each		
DSS-010-05	77328	18005018	111912	1/19/18	173	Each		
DSS-010-05	77328	18026953	111912	2/21/18	327	Each		
KCL-102-05	K63/0512W	S18016057	111366	2/5/18	10	Box		
KCL-102-05	K63/0512W	S18106396	113497	3/29/18	9	Box		
KCL-102-07	K63/0712W	S18080265	112809	3/29/18	10	Box		

2. Check your inventory and enter the quantity of the affected products you have in your possession in the "Quantity to be Returned" column. **Enter a "0" in the "Quantity to be Returned" column if you no longer have any of the listed product.** If there is a discrepancy between the product you have and the identity and quantity of product listed above, please explain in the comment area below or on an attached note.

   ALL PRODUCT WITHIN THE SCOPE OF THE RECALL SHOULD BE RETURNED

3. **Sign and date this form. Email it back to Quality@GaltNeedletech.com or it may be faxed to 214-778-1433.**

1649395-05-02-2018-001-R
Galt Medical Corp| 2220 Merritt Drive, Garland, TX 75040| P: 972-271-5177 F: 214-778-1433

KIMAL
delivering healthcare innovation

Allegato 3

Domande frequenti di Galt Medical Corp

GALT

Galt Medical Corp.

Recall FAQ's

Q: **What product is being recalled, catalog number and specific batch number?**

A: The product being recalled is listed in Appendix A of the notification. Products not listed in the recall notification are not affected.

Q: **What exactly is the problem?**

A: The products listed might contain unsafe levels of bacterial endotoxins (Pyrogens) that was 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

Q: **I haven't had any problems with the Galt Medical product. Can the recalled product still be used?**

A: The recalled product should not be used. The recalled product should be segregated and returned to Galt Medical Corp.

Q: **How was the problem discovered?**

A: During a routine incoming inspection by one of Galt Medical customers, an unacceptable level of bacterial endotoxin (Pyrogen) was observed. A subsequent investigation by Galt Medical's quality department confirmed the findings of bacterial endotoxin (Pyrogen). The root cause was determined to be an equipment malfunction resulting in the introduction of bacterial endotoxins into a manufacturing step for the product covered under this recall.

Q: **Is there a likely chance of patient injury?**

A: Although no complaints have been received involving patient injury, the use of this device could increase the risk of pyrogenic response, which can activate the inflammatory process and produce fever, chills, and hypotension in a patient.

Q: **Why is the product being recalled?**

A: Galt Medical Corps primary concerns are patient safety and customer satisfaction. Although the likelihood of patient injury is considered low, we have implemented this voluntary recall.

Q: **When will replacement product be available?**

A: Corrective actions have been implemented and new product is being manufactured. At this time we do not have a definitive timeline for delivery of replacement product, but we will keep customers informed as we make progress.

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Q: **Who do I contact to report a complaint on the recalled product?**

A: If you experienced a problem, malfunction, or complication attributable to the use of the recalled product, please contact Galt Medical Corp Complaint Department, Quality@GaltNeedleTech.com Diyar Medhat (214) 778-1312 or David Derrick (214) 778-1306.

Q: **Who can I contact to obtain additional information on specific details of the recall?**

A: Technical questions, or questions regarding shipment of returned product and return authorization numbers should be directed to David Derrick, Galt Medical Corp., at (214) 778-1306 or Quality@GaltNeedleTech.com.

Q: **What should I do if I erroneously received a recall letter, but I never purchased or received a sample of the product?**

A: Fax or email the recall response form to Galt Medical Corp at (214) 778-1433, Quality@GaltNeedleTech.com indicating you have zero products to return and make a notation on the page stating that you did not receive the product listed in the letter. We will investigate our shipping records to determine the reason for the error.

Q: **I purchased or received a sample of the product, but I did not receive a recall letter. I heard about the recall from another source. What should I do?**

A: Contact David Derrick, Galt Medical Corp. at (214) 778-1306 he will research your account to determine whether a letter was sent to your hospital. If the letter was lost or misdirected, you will be sent a recall response form that must be completed and faxed back to Galt Medical Corp. If you have product to return, you will be issued a return authorization number and provided instructions on how to ship the product.

Q: **The quantities or model numbers listed on the recall response form are incorrect. What should I do?**

A: Draw a line through the incorrect model numbers and/or quantities and write the correct information on the recall response form. Fax the form to Galt Medical Corp at (214) 778-1433. We will investigate our shipping records to determine the reason for the error.

Q: **Can I return other Galt Medical Corp. products with the recalled product?**

A: Please do not send back excess or obsolete inventory, expired product, or product shipped to you in error in conjunction with the recalled product recall. Receipt of products other than the recalled product will delay the processing of your return and credit. The Galt shipping account numbers cannot be used to return products other than recalled product.

Q: **Can I place an order for the replacement product?**

A: Yes, Galt Medical will be accepting new orders for all product .

Q: **When will credits be issued?**

A: Credits will be only issued by request and only for returned product that is within the scope of the recall.