03. Mai 2018

Kimal plc: WICHTIGE PRODUKTINFORMATION
Sicherheitsrelevante Korrekturmaßnahme

SOFORTIGES HANDELN ERFORDERLICH

Verfahrensverpackungen, die spezielle Einführhilfen (mit und ohne Führungsdrähte), Peel-Away-Schleusen und Peel-Away-Dilatoren enthalten.

Sehr geehrte Kundin, sehr geehrter Kunde,

Kimal plc gibt eine wichtige Produktinformation (FSN) für einige unserer Verfahrensverpackungen heraus, die spezielle Komponenten enthalten. Aufgrund des möglichen Risikos in Verbindung mit diesem Problem rufen wir das Produkt freiwillig zurück.

Bestimmte Einführhilfen (mit und ohne Führungsdrähte), Peel-Away-Schleusen und Peel-Away-Dilatoren, die wir von Galt Medical Corp geliefert bekommen haben, sind die von dieser wichtigen Produktinformation betroffenen Produkte.

Problembeschreibung:
Aufgrund eines Herstellungsfehlers seitens des Lieferanten bei bestimmten Komponenten in diesen Verpackungen könnten die aufgeführten Produkte unsichere Konzentrationen an bakteriellen Endotoxinen (Pyrogenen) enthalten, die während eines Produktionsschritts eingeführt wurden. Bakterielle Endotoxine, auch pyrogene Bakterien genannt, können den Entzündungsprozess aktivieren und Fieber, Schüttelfrost und Hypotonie bei einem Patienten verursachen.

Wir haben diesem Schreiben die wichtige Produktinformation und vom Lieferanten bereitgestellte Fragen und Antworten angefügt, um Ihnen weitere Informationen und Erläuterungen zum Grund für diese Maßnahme zu geben.

Zeitrahmen:
Kimal plc hat einen Zeitrahmen von 90 Tagen angesetzt, um diese wichtige Produktinformation abzuschließen.

Betroffene Produkte:

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

Gemäß unseren Unterlagen hat Kimal plc eine Reihe betroffener Produkte an Ihre Einrichtung geliefert. Aus diesem Grund möchten wir Sie auf die folgenden Anweisungen aufmerksam machen:

1. **Bitte lesen Sie diese wichtige Produktinformation.**
2. **Informieren Sie sofort alle Personen, die in Ihrer Einrichtung benachrichtigt werden müssen, oder alle Organisationen, an die Sie die möglicherweise betroffenen Produkte weitergeleitet haben.**

3. **Bitte prüfen Sie Ihren Bestand auf die betroffenen Produktcodes und Chargennummern, die oben aufgeführt sind.**
4. **Bitte ermitteln und isolieren Sie alle betroffenen Bestände.**
5. **Bitte füllen Sie Anhang 1 aus und schicken Sie diesen an Kimal mit Angabe der Mengen in Ihrem Bestand zusammen mit den Chargennummern pro Menge, die in den Tabellen oben angegeben ist, zurück.**
6. **Kimal plc wird aufgrund Ihrer Antwort Maßnahmen ergreifen**

Die koordinierende zuständige Behörde (MHRA) hat Kenntnis über diese Maßnahme. Auch andere betroffene Aufsichtsbehörden wurden informiert.

Wir entschuldigen uns für alle Unannehmlichkeiten, die Ihnen durch diese Maßnahme möglicherweise entstanden sind, und hoffen auf Ihr Verständnis, da wir diese Maßnahme im Interesse der Patientensicherheit ergreifen. Wenn Sie Fragen haben oder weitere Informationen zu dieser wichtigen Produktinformation benötigen, können Sie sich an den unten genannten Ansprechpartner wenden.

Vigilanz-/Compliance-Beauftragter: Herr Paul Beard
vigilance@kimal.co.uk
Referenz: FSCA 19258

Mit freundlichen Grüßen,

……..
Rebekah Vine
Konzernverantwortliche für Qualität und Rechtsfragen
Kimal Plc

Anlagen
Anhang 1) Bestätigung des Empfangs der wichtigen Produktinformation

03. Mai 2018

Anhang 1

Bestätigung des Empfangs der wichtigen Produktinformation

Kimal plc: WICHTIGE PRODUKTINFORMATION
Verfahrensverpackungen, die spezielle Einführhilfen (mit und ohne Führungsdrähte), Peel-Away-Schleusen und Peel-Away-Dilatoren enthalten.

Art der Maßnahme: Sicherheitsrelevante Korrekturmaßnahme

Bitte füllen Sie dieses Formular aus, nachdem Sie alle Informationen gelesen haben, und schicken Sie eine Kopie entweder per FAX oder E-Mail zurück, um zu bestätigen, dass Sie diese Bestätigung empfangen haben.
Fax: 0845 4379541
E-Mail: vigilance@kimal.co.uk

Name und Anschrift des Kunden: (In Druckbuchstaben)	
Bestätigung ausgefüllt von: (In Druckbuchstaben)	
Position: (In Druckbuchstaben)	
Telefonnummer:	
E-Mail-Adresse:	

Wir bestätigen:

- ☐ die wichtige Produktinformation gelesen und verstanden zu haben.
- ☐ die Informationen an Mitarbeiter und andere Dienste/Abteilungen/Einheiten/Einrichtungen weitergeleitet zu haben, die über diese Informationen verfügen müssen.
- ☐ dass wir keine betroffenen Produkte im Bestand haben.
- ☐ dass wir die betroffenen Produkte an eine Drittorganisation weitergeleitet haben und Kimal plc diese Details zur Verfügung stellen werden.

03. Mai 2018

Wir haben das folgende Produkt, das zurückgesendet und für das eine Gutschrift ausgestellt werden muss:

Für Bestände, die in Tabelle 1 aufgeführt werden - Bitte füllen Sie die folgende Tabelle aus:

TABELLE 1 Betroffener Bestand		
Produktnummer:	Chargennummer:	Menge (Stück):
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	

Anhang 2

Rückrufschreiben von Galt Medical Corp (NUR ZUR INFORMATION. BITTE GALT NICHT DIREKT ANTWORTEN)

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

Anhang 3

Fragen und Antworten von Galt Medical Corp

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.