FRESENIUS KABI

Fresenius Kabi Deutschland GmbH, 61346 Bad Homburg

Important Safety Information to Field Safety Corrective Action

IT 2078315

Fresenius Kabi Deutschland GmbH

Else-Kröner-Straße 1
61352 Bad Homburg
Deutschland
T +49 6172 686-0
www.fresenius-kabi.de

Datum
08.05.2023

Recall of Product Injectomat Syringe 50 ml I IT 2078315

Dear Healthcare Provider,

We would like to inform you about an update of the voluntary field safety corrective action (FSCA) by Fresenius Kabi on 05 December 2022 related to the product Injectomat Syringe 50 ml.

After reviewing additional raw production data, it was determined that the scope of potentially affected batches was expanded. These article codes and batches have been added to this FSCA. Please find below the affected product and batch:

Article Name	Article Code	Batch No.
Injectomat Syringe 50 ml, without cannula	M93000010	**32414362**

Fresenius Kabi has determined production disturbances for affected batch related to the printing process of the scale on the Injectomat syringes. In individual cases, this resulted in traces of ink residues on or in the cone (Luer-Lock connection).

Fresenius Kabi did not receive any report of a potentially serious incident related to this observation.

Based on the available information/data, Fresenius Kabi has decided to recall the affected batch of Injectomat Syringes 50 ml.

We kindly ask you to check any stocks of the listed batches in your facility and not to continue using them.

Please make these products available for collection by Fresenius Kabi.

In addition, we ask you to note the following information:

1. **Clinical Use**
   If affected items are stored in your facility, please stop further internal distribution immediately.

2. **Non-clinical use (trade)**
   Please stop selling the corresponding items to your customers immediately. If partial quantities of the affected items have already been shipped from your inventory, please immediately inform your customers about this product field safety corrective action and ask them to return the products to you.

3. **Response form**
   Please complete the attached response form (Attachment 1) and return it to us within the next 7 days.
   Please note the information in the response form (attachment 1).

Please ensure in your organization that all users of the above products and all other persons to be informed are made aware of this FSCA letter and the procedure.

Fresenius Kabi as the legal manufacturer apologizes for the inconvenience this has caused you and thanks in advance for your support and understanding!

Sincerely,

Fresenius Kabi Deutschland GmbH

Attachments
Response form to Recall

FRESENIUS KABI

URGENT FSCA response form

Injectomat Syringe 50 ml
Article number: M93000010
Batch number: 32414362

We kindly ask you to fill out this form completely and tick the appropriate boxes.

Please send the completed form to Fresenius Kabi

☐ **no** remaining stock of the product concerned.

☐ **following remaining stock available**

Article Code	Batch No.	Stock in pcs.

Please do not return any goods to us unsolicited.

Name of the hospital / institution / client:	
Customer number: Delivery note number:	
Address of the hospital / institution / client:	
Contact person: Function:	
Phone number:	

☐ I have read the information dated 08 May 2023 and have informed all relevant persons about the FSCA and the described procedure.

Date: …… **Signature:** ……