Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	Injectomat Syringe 50ml with cannula
Device Model	M93000020
Lot No.	32265622
Manufacturer	Fresenius Vial SAS
Country of Origin	France
Reference	attached
Reason of Recall	NHRA initiates this FSN due 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).
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative General Medical W.L.L at registration.medics@intercol.com to take the necessary action for recall.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh

Recall 2023 0009

15/May/2023

Fresenius Vial S.A.S
Le Grand Chemin
F-38590 Brézins (France)
Tél. : +33 (0)4 76 67 10 10
Fax : +33 (0)4 76 65 56 66
E-mail : contact.vial@fresenius-kabi.com

To	:	**GENERAL MEDICALS W.L.L.**	Contact person: Vincent Leynier
From	:	FRESENIUS VIAL SAS	Telephone: +33 4 76 67 23 59
		Le Grand Chemin - CS 20103	Email: qualite.vigilance@fresenius-kabi.com
		38590 Brézins - FRANCE	Date: 14-April 2023
Subject :		Updated Field Safety Notice Injectomat Syringe 50 ml	

Field safety corrective action of Injectomat Syringe 50 ml:

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 products and batches:

Article Name	Article Code	Batch No.
Injectomat Syringe 50ml light protected with cannula	M93000020	**32265622**

Fresenius Kabi has determined production disturbances for affected batches 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 batches 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.

Fresenius Vial S.A.S
Le Grand Chemin
F-38590 Brézins (France)
Tél. : +33 (0)4 76 67 10 10
Fax : +33 (0)4 76 65 56 66
E-mail : contact.vial@fresenius-kabi.com

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.

PLEASE COMPLETE THE ENCLOSED "URGENT FSN RESPONSE FORM" AND SEND IT BACK TO US IMMEDIATELY AT:
E-mail: qualite.vigilance@fresenius-kabi.com

Fresenius Kabi is committed to providing you with the highest level of service, product quality and reliability. We apologize for any inconvenience.

If you have any further questions concerning the FSN please contact:
qualite.vigilance@fresenius-kabi.com

Sincerely,

Frédéric COUILLAUD
Quality Assurance Director

Fresenius Vial S.A.S
Le Grand Chemin
F-38590 Brézins (France)
Tél. : +33 (0)4 76 67 10 10
Fax : +33 (0)4 76 65 56 66
E-mail : contact.vial@fresenius-kabi.com

URGENT FSCA response form

Injectomat Syringe 50 ml
Article number: M93000020
Batch number: **32265622**

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

Please send the completed form to Fresenius Kabi at:
qualite.vigilance@fresenius-kabi.com

☐ **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:	**GENERAL MEDICALS W.L.L.**
Address of the hospital / institution / client:	
Contact person: Function:	
Phone number:	

☐ I have read the information dated 14th April 2023 and have informed all relevant persons about the FSCA and the described procedure.

Date: …… **Signature:** ……