To : Whom it may concern

From : [local affiliate]

Telephone : local affiliate

Telefax : local affiliate

Date :21-Apr-2023

Subject : Field Safety Corrective Action
PLASMACELL-C Disposable Set

Field Safety Corrective Action (FSCA) of PLASMACELL-C Disposable Set:

Dear Healthcare Provider,

Fresenius Kabi is issuing a Field Safety Corrective Action for certain batches of PLASMACELL-C Disposable Set. This product notification details the issue and the required steps for you to perform.

Affected Product:

Our records indicate that you have received some of the affected products. The affected article numbers and batch numbers are provided below:

Article	Article Number	Batch Number
PLASMACELL-C Disposable Set	**4R2256**	**FA22K01380** **FA22K01398** **FA22K01406** **FA22K02388** **FA22K02396** **FA22K02404** **FA22K17386**
PLASMACELL-C Disposable Set	**6R2264**	**FA22K02354**
PLASMACELL-C Disposable Set	**6R2600**	**FA22K01364** **FA22K01372** **FA22K02370** **FA22K03378** **FA22K11363** **FA22K11371** **FA22K14375** **FA22K17360**
PLASMACELL-C Disposable Set	**K6R2256**	**FA22K01356**

Issue:

Fresenius Kabi received complaints of plastic tubing that appeared harder and/or stiffer than normal for several batches of the Aurora Xi Disposable Sets. Complaints indicated that this harder and/or stiffer tubing could be more difficult to install on that particular Plasmapheresis System Instrument and could cause a variety of installation check alerts.

Based on the investigation and traceability of raw materials, it appears that the harder and/or stiffer tubing was due to an incorrect plasticizer being used to formulate the plastic tubing. A plasticizer is a chemical added to plastic material to make it softer and more flexible and to increase its plasticity during its handling, manufacturing and use. The tubing in the Aurora

Disposable Sets is formulated with a DEHP plasticizer. However, tubing material identified in the returned Aurora Xi Disposable Set(s) associated with the hard tubing complaints contained DEHT plasticizer, which is not an approved configuration for either the Aurora or Aurora Xi Disposable Sets.

Aurora Xi uses a thick--walled tubing throughout the set, but this tubing is also used in Aurora in key places such as the Plasma Line, the Device Short Line, and Donor Short Line. Harder/stiffer tubing in these three sections of the Aurora kit would not have generated any alarms during use.

Potential Risk:

To date, Fresenius Kabi has not received any Aurora Disposable Set complaints related to harder/stiffer tubing, nor have there been any reports of patient or donor-related adverse events associated with this issue. Based on the traceability of raw materials, Fresenius Kabi has initiated this FSCA out of an abundance of caution as the Aurora Disposable Set has not been validated for use with DEHT-containing plastic tubing.

Based on the Health Hazard Evaluation conducted for Aurora Xi Disposable Sets, if the device malfunctions because of the plastic tubing formulation, there is a low risk to a donor of increased plasma free hemoglobin or air embolization. There is a remote possibility of serious harm to a plasma donor or a recipient of products derived from donated plasma. The potential for increased C3a complement activation has not been fully ruled out, which could potentially cause hypotension and/or anaphylactic reactions. It appears very unlikely that any of these materials might impact the plasma fractionation process, however, without detailed understanding of the ingredients involved, it is difficult to make a definitive conclusion. Furthermore, an experimental assessment of potential harm(s) due to leachable substances has not been completed. Although the risk of the DEHT material is low based on the biocompatibility testing performed to-date, experience Fresenius Kabi has with this plasticizer, as well as information from our supplier that all raw materials used in the formulation are medical grade and already in use in other commercial formulations for medical applications, Fresenius Kabi cannot state the risk is zero. Therefore, Fresenius Kabi has decided to voluntarily recall these batches for precautionary reasons.

Required Actions for Users:

- 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.
- 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.
- 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).

Follow-up Actions by Fresenius Kabi:

Fresenius Kabi has implemented corrective and preventive actions to ensure the proper DEHP plasticizer is used in the manufacturing of Aurora Disposable Sets.

For further inquiries, including product replacement options which are or will be available shortly, please contact Fresenius Kabi using the information provided below.

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

If you have any further questions, please do not hesitate to contact Ms./Mr. [to be filled locally] or your contact person in the field.

You can reach Ms./Mr. [to be filled locally] as follows:
[tobefilledlocally]@fresenius-kabi.com
Phone: T +[to be filled locally]

Sincerely,
Fresenius Kabi

URGENT FSCA response form

PLASMACELL-C Disposable Set
Article number: 4R2256, 6R2264, 6R2600, K6R2256
Batch number: **[to be filled locally]**

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

Please send the completed form to Fresenius Kabi at: [tobefilledlocally]@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:	
Customer number: Delivery note number:	
Address of the hospital / institution / client:	
Contact person: Function:	
Phone number:	

☐ I have read the information dated [to be filled locally] April 2023 and have informed all relevant persons about the FSCA and the described procedure.

Date: ..... **Signature:** .....