Field Safety Corrective Action

To : Customers and Health Professionals

From : Fresenius Kabi Danmark

Subject: Leakage of Fresenius Kabi Amicus Therapeutic Kits (EC202101)

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Date : 19 marts 2021

Field Safety Corrective Action for Fresenius Kabi Amicus Therapeutic Kits

Affected products:

Product name	Article number	Batch number
AMICUS MONONUCLEAR CELL KIT	**R6R2326**	FA20H24272
		FA20I21144

Dear Customer / Health Professional,

Based on routine post-market surveillance Fresenius Kabi has identified the potential for certain lots of MNC and Exchange kits (Therapeutic Kits) to have leaking centrifuge packs during a procedure on the Amicus System using therapeutic protocols only. The defect is a blood leak at the boot, elbow, or in the channel on the separation side of the centrifuge pack (see Figure 1).

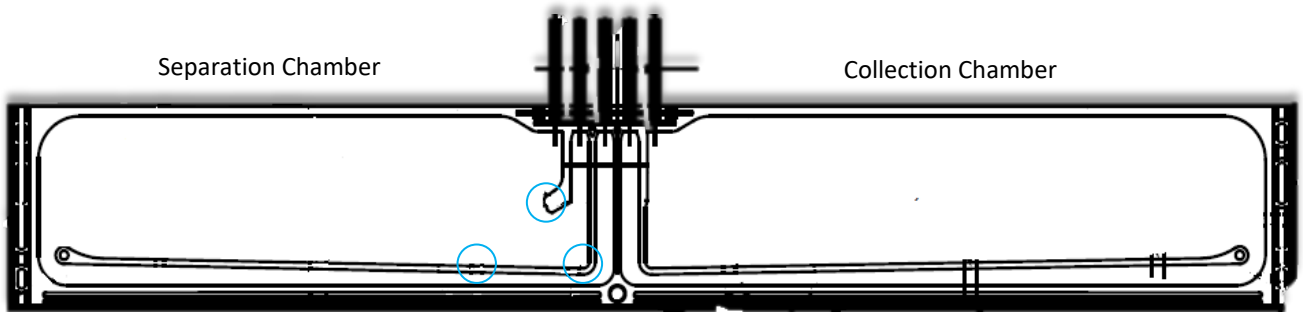

Figure 1: Centrifuge Pack identifying potential leak locations (at the blue circles)

In some instances, the Therapeutic kits may have the potential of a centrifuge pack leak (in the separation chamber side) during an Amicus therapeutic procedure. Centrifuge pack blood leaks could cause donor/patient blood loss, the transfusion of non-sterile blood products to MNC product recipients, blood-borne pathogen exposure to the operator/bystander, and/or failure to complete the MNC/Exchange collection or therapeutic procedure. Based on the root cause investigation and health hazard evaluation, there is moderate health risk to donors and/or patients if a leaking centrifuge pack is further processed.

Amicus platelet kits or photopheresis (ECP) kits have not been affected by this issue.

To date, Fresenius Kabi has not received any reports of adverse events related to this issue.

Regardless, Fresenius Kabi has decided to initiate a Field Safety Corrective Action as a precautionary measure.

Fresenius Kabi has implemented additional control measures and corrective actions to assure supply continuation of Amicus Therapeutic Kits. Fresenius Kabi will work to replace products as requested by the customer.

Field Safety Corrective Action

1. Please discontinue the use of the affected products immediately by checking your inventory and quarantining all affected product at your facility. There is no need to recall collected cells when the collection process was completed without interruption.

2. NOTE: Customers may be in a position that no alternate Device is available and therefore choose to continue with the use of the affected Amicus Therapeutics Kits. For such cases, the following actions should be put in place until replacement products are available:

    a. Ensure the Therapeutics Kit is installed correctly on the Amicus System per the Operator's Manual.

    b. If a leak is detected in the Therapeutics Kit at any time, the disposition of the product should be determined by a physician.

PLEASE COMPLETE THE ENCLOSED "URGENT FSCA RESPONSE FORM" AND SEND IT BACK TO US IMMEDIATELY AT:
E-mail: info-dk@fresenius-kabi.com
Fax: 33181614

Please ensure within your organization that every user of the concerned products and all other relevant persons or entities where the concerned products have been transferred are informed about this letter and the actions as described herein.

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 FSCA please contact: Sales Manager Denmark & Nordics, Transfusion Medicine & Cell Therapies Division, Martin Jørgensen at 29398934.

Sincerely,

Christine Barslev
QA/RA manager and NSO
Fresenius Kabi Danmark

URGENT FSCA RESPONSE FORM

Leakage of Fresenius Kabi Amicus Therapeutic Kits (EC202101)

SECTION A
Hospital / Facility Details
Please fill out the information below and send the completed form to Fresenius Kabi at:
E-mail: info-dk@fresenius-kabi.com or Fax: 33181614

Name of Hospital / Facility:	
Hospital / Facility Address:	
Telephone Number:	

SECTION B

☐ I have read and understand the instructions provided in the FSCA letter.

☐ Our facility has decided to continue use of the affected products.

☐ I have checked my stock and have quarantined inventory, which includes an indication of the disposition of the affected products.

Batch Number	Units used	Units returned	Units destroyed

Print Name: **Signature:**	
Date:	