To : Whom it may concern

From : [local affiliate]

Telephone : :local affiliate

Telefax : :local affiliate

Date : 21-Feb-2023

Subject: Amicus Separator Therapeutic Disposable Kit (Mononuclear Cell Collection (MNC) and Exchange (Therapeutic Plasma Exchange (TPE)/Red Blood Cell Exchange (RBCx)) Disposable kits Field Safety Notice

Field Safety Notice affects the following products:

Product name	Article number	Batch number
AMICUS EXCHANGE KIT	**R6R2339**	FA22G27044
AMICUS MONONUCLEAR CELL KIT	**R6R2326**	FA22F27129
		FA22G26053
		FA22H22126
AMICUS EXCHANGE KIT W/ CC	**R6R2339C**	FA22K22063
AMICUS (ECP) APHERESIS KIT-DOUBLE NEEDLE	**R6R2347**	FA22E24151
AMICUS (ECP) APHERESIS KIT-DOUBLE NEEDLE W/ CC	**R6R2347C**	FA22F20207
AMICUS MONONUCLEAR CELL KIT	**X6R2326**	FA22G25121
		FA22H22134
		FA22I26141
		FA22J25225
		FA22J31074
		FA22K23046
AMICUS EXCHANGE KIT	**X6R2339**	FA22H23132
		FA22I27149
		FA22K22055
AMICUS EXCHANGE KIT - THERAPEUTICS	**X6R2349**	FA22E23138
		FA22F28168
		FA22G28018
		FA22H22225
		FA22J28062
		FA22K21065

Dear Healthcare Provider,

Fresenius Kabi is issuing this Field Safety Notice for certain lots of Amicus MNC Apheresis kits and Amicus Exchange kits (Therapeutic Kits). This product notification details the issue and the required steps for you to perform.

Issue:

Fresenius Kabi has identified the potential for centrifuge packs to develop a stress leak near the end of the procedure for certain lots of Amicus MNC Apheresis kit and Amicus Exchange kit (Therapeutic Kits) on the Amicus Separator.

Under certain circumstances, there may be a defect as follows: a blood leak develops during apheresis procedure in the channel on the separation chamber of the centrifuge pack (see Figure 1).

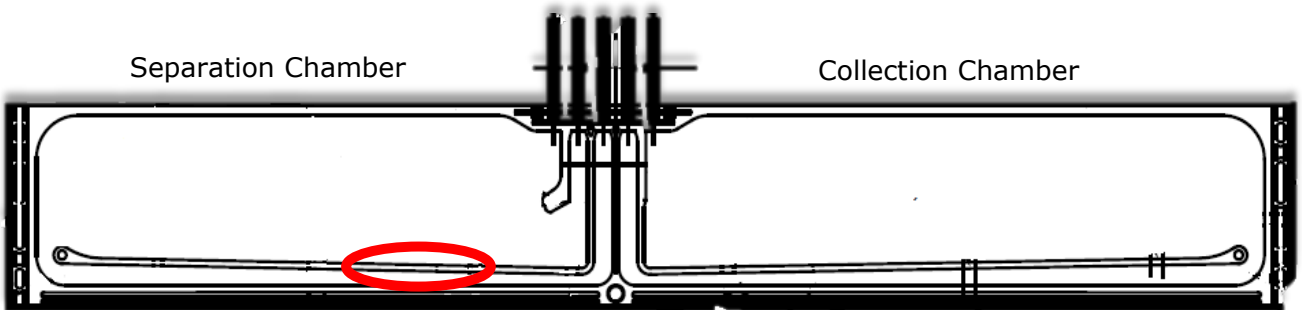

Figure 1: Centrifuge Pack identifying potential leak locations (at the red circle)

Fresenius Kabi will work on inventory replacement upon request by the customer and within the confines of our production capacity.

Continued Use Due to Medical Necessity

Customers may be in a position that no alternate device and/or kits are available and therefore choose to continue with the use of the affected Amicus MNC Apheresis kits or Amicus Exchange kits (Therapeutics kits) out of medical necessity.

For such cases:

a. Ensure the kit is installed correctly on the Amicus Separator per the Operator's Manual.

b. The stress leaks appear to be occurring near the end of the procedure, so shortening the duration of use for any particular kit may decrease the probability of a leak occurring.

c. If a stress leak is detected in the kit at any time during an MNC collection procedure, the disposition of the collected MNC product should be determined by a physician based on medical necessity. The disposal of plasma collected during a TPE procedure in which a kit leak occurs can be handled according to standard procedures, since this plasma is not intended for further processing or transfusion.

d. Discontinue use of the affected kit batches once alternate replacement batches become available.

Potential Risk:

Based on the root cause investigation and health hazard evaluation, the probability of centrifuge pack blood leaks leading to a hazardous situation that may result in a serious adverse health outcome is judged to be improbable.

Occasionally, this defect and resulting hazards may cause a medically reversible or transient adverse health consequence. For example, if a stress leak occurs, sufficient product may not be collected and/or blood within the Amicus device will not be able to be returned to the patient/ donor. In such cases an additional apheresis procedure may be required.

When the Amicus Separator detects a leak in the centrifuge chamber, an unrecoverable alarm is triggered, stopping the procedure. When this happens, clamps are engaged, isolating the donor/patient as well as MNC product (if applicable) from the area with a leak.

To date, Fresenius Kabi has not received any reports of patient related adverse events but has received customer complaints of stress leaks in the centrifuge pack near the end of procedures. Fresenius Kabi has initiated this Field Safety Notice as a precautionary measure.

NOTE: If a Therapeutic Kit in the affected batches did not develop a leak during use, then there is no evidence to suggest that its safety or performance are otherwise impacted.

Affected Product:
Our records indicate that you have received some of the affected products, which were manufactured and/or distributed between May 2022 and December 2022. The affected product codes and batch numbers are provided below:

Product Code/Product Name

	product code here Amicus Exchange Kit Therapeutics	**product code here** Amicus Mononuclear Cell Kit
Batch	X	X
	X	X
	X	X
	X	X

Required Actions for Users:
Given reports that this defect is not occurring within the early phases of TPE or MNC procedures, but rather near the end of the procedures, it is most likely that this defect will have no measurable impact on patient outcome or management. Based on inventory replacement stock at Fresenius Kabi along with balancing the importance of continuing to treat patients, the following is recommended:

1) Evaluate inventory at your facility. Evaluate the option of shortening the duration of use to decrease the probability of a leak occurring and/or need for continued use based on medical necessity.

2) Inform potential users of the product in your organization of this notification. **If your facility further distributes or transfers products amongst satellite sites or other locations, please disseminate this information accordingly.**

3) Based on the options listed below, complete the attached response form and return it to Fresenius Kabi

   Option A: You have no remaining inventory of the affected product

   Option B: You have affected product in inventory but will continue to use based on the assessment of patient demand (medical necessity) and the timing for replacement inventory, once available.

   Option C: You have affected product in inventory which will not be utilized and are requesting to destroy or return the product while awaiting replacement inventory, once available.

Follow-up Actions by Fresenius Kabi:
Fresenius Kabi has implemented corrective actions to improve supply continuation of Amicus MNC Apheresis kits and Amicus Exchange kits (Therapeutic Kits).

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

PLEASE COMPLETE THE ENCLOSED "URGENT FSN RESPONSE FORM" AND SEND IT BACK TO US IMMEDIATELY AT:
E-mail: <local affiliate>
Fax: <local affiliate>

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: local product manager.

Sincerely,

Signature

<name local affiliate>
<function>

FRESENIUS KABI

URGENT FSN response form

Amicus MNC Apheresis Kit – Double Needle
Amicus Exchange Kit Therapeutics
Article number: xxx & xxx
Batch number: xxx

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

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

☐ We have no remaining inventory of the affected product

☐ We haveaffected product in inventory but will continue to use based on the assessment of patient demand (medical necessity) and the timing for replacement inventory, once available.

☐ We have affected product in inventory which will not be utilized and are requesting to destroy or return the product while awaiting replacement inventory, once available.

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 21 Feb2023 and have informed all relevant persons about the FSN and the described procedure.

Date: …… **Signature:** ……