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URGENT – TYPE II Medical Device Recall

Amicus MNC Apheresis/Exchange Disposable Kits

February 24, 2023

Subject: Amicus Separator Therapeutic Disposable Kit for Mononuclear Cell Collection (MNC) and Exchange (Therapeutic Plasma Exchange (TPE)/Red Blood Cell Exchange (RBCx)) Recall

Affected Devices:

Product Code	Lot #	Product Name
X6R2349	FA22E23138	AMICUS EXCHANGE KIT - THERAPEUTICS
X6R2326	FA22J25225	AMICUS - DISPOSABLE APHERESIS KITS

Dear Healthcare Provider,

Fresenius Kabi is issuing this recall for the above listed lots of Amicus Apheresis kits MNC/TPE. 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 Apheresis kits MNC/TPE 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 which leads to an alarm indicative of a leak (see Figures 1-3).

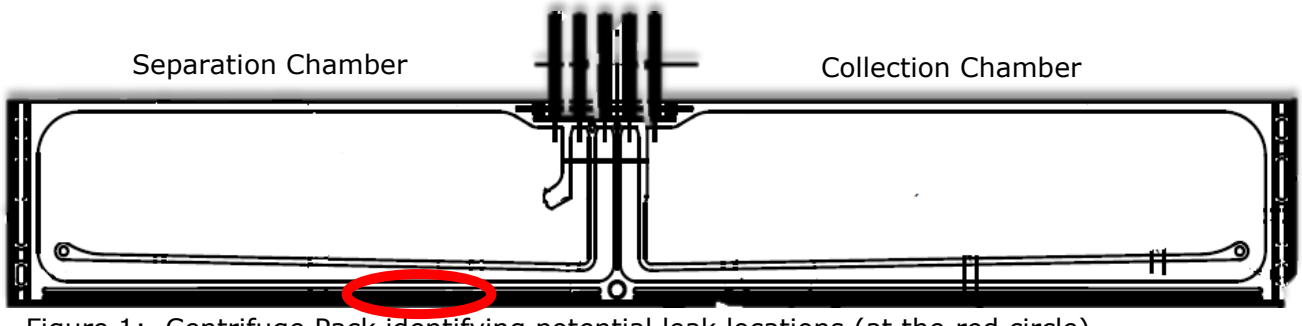


Figure 1: Centrifuge Pack identifying potential leak locations (at the red circle)

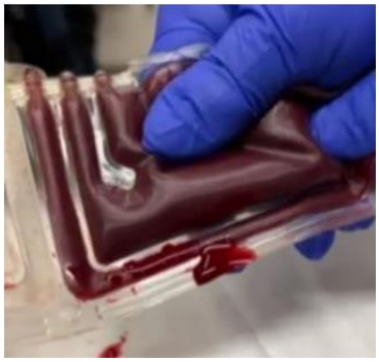


Figure 2: Centrifuge Pack showing blood leak

Alarm Title	Alarm Type	Alarm Trigger	Information/Actions
Leak Detector Failure	Warning	At least one of the two leak detectors has failed.	The procedure will end without reinfusion when the *end procedure button* is touched. Inspect the leak detector for tears or damage. Do not begin another procedure. Contact a qualified service representative for assistance.
Leak in Centrifuge	Warning	Fluid has been detected in the centrifuge compartment.	The procedure will end without reinfusion when the *end procedure button* is touched. During a single needle procedure, clamp the red cell container, or its contents may empty into the centrifuge. All products should be discarded. Clean and dry the surface of the centrifuge compartment and the leak detector before beginning another procedure. For instructions on cleaning the centrifuge compartment, refer to Volume 1 – Chapter 4.

Figure 3: Leak Alarms Page 231 of 346 Operators Manual SW 6.1 Vol 2 Platelets

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 Apheresis kits MNC/TPE out of medical necessity.

For such cases:

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

b. Consider shortening the duration of use for any particular kit as that 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 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. No complaints have been received in Canada. Fresenius Kabi has initiated this recall as a precautionary measure.

NOTE: If a TPE 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 impacted products as listed above, which were distributed between December 2022 and January 2023 to your facility.

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) Send Fresenius Kabi the following, if not already done:

   i. Information about known or suspected blood leaks in your facility
   ii. Adverse events that may have occurred due to this issue
   iii. Unexpected adverse events during or after apheresis, regardless if a blood leak was detected

4) Based on the options listed below, complete the attached response form and return via the email address listed.

   Option A: If you have no remaining inventory of the affected product – complete the response form and return it to Fresenius Kabi Canada.

   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.

Contact Fresenius Kabi Canada Customer Service at 1-877-821-7724 and request to return the affected product. They will assist you with returning the product and placing a replacement order at that time.

Affected units should be returned to the following site:
Fresenius Kabi Canada Ltd.
c/o Accuristix
109 Summerlea Road
Brampton, ON L6T 4P6

For pick-up of product to be returned, please contact ATS at 1-877-694-4454 (ext.7321) and utilize Account Number 4005154 and RGA # provided by Customer Service for return of the product using no ambient service. If a waybill is required, please request one from ATS.

Follow-up Actions by Fresenius Kabi:

Fresenius Kabi has implemented corrective actions to improve supply continuation of Amicus Apheresis kits MNC/TPE).

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

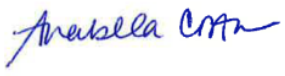
Please ensure within your organization that every user of the concerned products and all other relevant persons or entities where the concerned products have been transferred are informed about this letter and the actions as described herein.

If you experience an incident, please contact Fresenius Kabi Canada Customer Service at 1-877-821-7724 and identify the device and lot associated with the incident. Adverse reactions or quality problems experienced with the use of this product should be reported to Fresenius Kabi Canada at 1-877-821-7724.

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.

Please fill out the Customer Reply Form attached to this letter to acknowledge receipt of this notification and return it to the Fresenius Kabi Canada email address stated on the Form. If you have any questions or require additional information, please contact Fresenius Kabi Canada at 1-877-821-7724.

Sincerely,



Anabela Costa
Sr Director, Quality and Vigilance
Fresenius Kabi Canada

Enclosures: Customer Reply Form