

URGENT – Field Safety Notice

Date : 17 August 2023

To all users of the AmiCORE Apheresis Kits

RE: AmiCORE Apheresis Kits with possibly incorrect assembly between the saline line and the return line (ECMD202319)

Dear Customer,

This letter is to inform you of a potential issue concerning AmiCORE Apheresis Kits. Our records indicate that your facility has received this impacted product.

Product name	Batch number
AmiCORE Apheresis Kit – Single Needle with Two Platelet Containers	FA23C27075

Issue:

As part of our post market surveillance, it was discovered that two AmiCORE Apheresis Kits were assembled incorrectly. The saline and return lines were swapped at the connection to the AmiCORE Cassette as shown in Figure 1 and 3 below.

Potential Risk:

Incorrectly assembled saline and return lines cause the return line to not pass through the instrument's air detector. If this defect occurs and air is present in the return line, the air detector would not be triggered, and the system would pump the air into the donor's veins. This could potentially cause a serious adverse event (air embolism). Fresenius Kabi has initiated this Field Safety Notice as a precautionary measure.

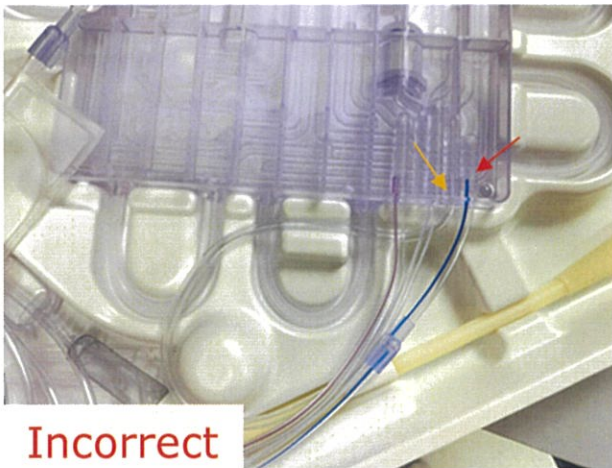
Precautions:

For all batches manufactured before 01-Jun-2023, a visual check is required to be performed by an operator trained on the use of AmiCORE before operation.

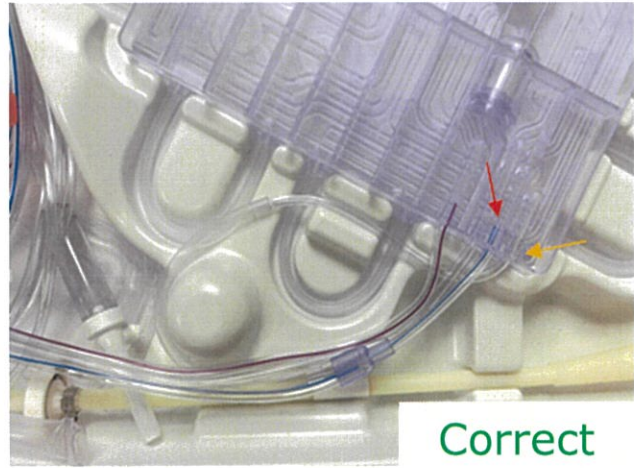
When the saline line and the return line are assembled incorrectly / swapped at the connection to the AmiCORE Cassette, the AmiCORE Apheresis Kit **must not** be used (see Figure 1 and 3 below) and a new, correctly assembled AmiCORE Apheresis Kit must be used. If an AmiCORE Apheresis Kit is suspected of mis-assembly, please retain the kit and contact your local Fresenius Kabi representative for further investigation.

When the saline line and the return line are assembled correctly at the connection to the AmiCORE Cassette, the AmiCORE Apheresis Kit can be used in accordance with the instructions for use (see Figure 2 and 4 below).

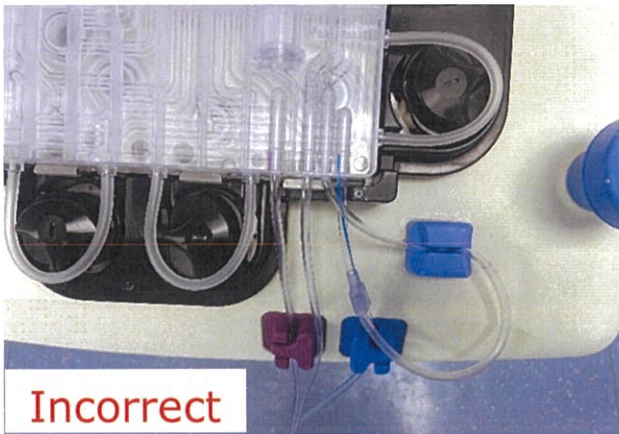
(Figure 1 - Incorrect) Clear tube connected to 3rd port on the right side (orange arrow)
Blue strip line tube connected to the 4th port on the right side (red arrow)



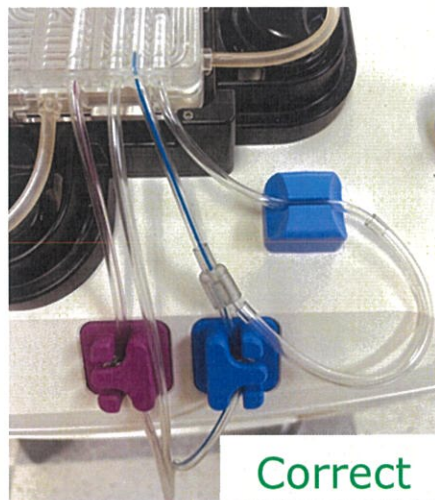
(Figure 2 - Correct) Clear tube connected to the 4th port on the right side (orange arrow)
Blue strip line tube connected to the 3rd port (red arrow)



(Figure 3 - Incorrect Set installed into AmiCORE) Clear tube connected to 3rd port on the right side
Blue strip line tube connected to the 4th port on the right side



(Figure 4 - Correct Set installed into AmiCORE) Clear tube connected to the 4th port on the right side
Blue strip line tube connected to the 3rd port



Corrective Action:

The root cause is related to the operator inadvertently not performing the assembly operation as described in the work instructions. Due to this reason the mis-assembly occurred between the return line and the saline line. The assembled products are checked at the end of the assembly line, but the issue was not detected at the inspection station.

Fresenius Kabi has identified the root cause of the issue and has already implemented corrective measures.

All AmiCORE Apheresis Kits manufactured on or after 01-Jun-2023 have corrective actions implemented to prevent this defect.

Distribution:

Kindly ensure within your organization that every user of the concerned products and all other relevant persons are informed about this letter and the actions as described.

In addition, we ask you to please complete the enclosed "urgent FSN response form" and send it back to us immediately at:

E-mail: hsiaoying.poey@fresenius-kabi.com

Fax: +603 - 7957 3734

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: Poey Hsiao Ying (+6016 - 630 8081).

Sincerely,

Signature:



Foo Ai Lin
Fresenius Kabi Malaysia Sdn. Bhd.
Associate Director, Scientific & Regulatory Affairs

URGENT FSN response form

AmiCORE Apheresis Kits
Article number: P6R8882
Batch number: FA23C27075

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

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

- We have no remaining inventory of the affected product
- We 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.
- 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 17 Aug. 2023 and have informed all relevant persons about the FSN and the described procedure.

Date:

Signature: