

Field Safety Notice

To : Whom it may concern

Telephone : [local affiliate]

From : [local affiliate]

Telefax : [local affiliate]

Date : XX-Jun-2015

Subject : Leaks at Fresenius Kabi Blood Bags

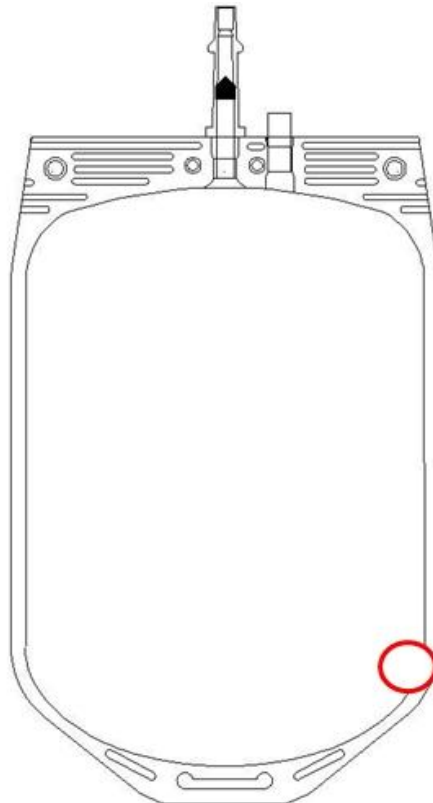
Field Safety Notice affects the following product:

Product Name	Article Number	Batch Number
CompoFlow® 3F T&B 63 ml CPD/100 ml SAG-M - PDS-V+L	C2750	41IC05AA00
		41IC13AA00
CompoFlow® 4F T&B 70 ml CPD/110ml PAGGS-M - RCC + PDS-M	C4010	41IB11FA00
CompoFlow® 4F 63 ml CPD/100 ml SAGM - WB + PDS-V	CQ31450	41IB20FA00
CompoFlow® 4F 63ml CPD/100ml SAG-M - WB + PDS-V	CQ31451	41IB02FA00
		41IC12FA00
CompoFlow® 4F T&B 63 ml CPD/100 ml SAGM - RCC - PDS-V	CQ32250	41IB03FA00
		41IB04FA00
		41IB12FA00
		41IB13FA00
		41IB18FA00
		41IB26FA00
		41IB27FA00
		41IB27FA00
		41IC14FA00
		41IC17FA00
CompoFlow® 4F T&B - 66.5 ml CPD/105 ml SAG-M - RCC - PDS-V	CQ32260	41IB10FA00
		41IC01FA00
		41IC15FA00
CompoFlow® 4F T&B 63 ml CPD/100 ml SAG-M - RCC/PLASMA + PDS-V	CQ32350	41IC05FA00
CompoFlow® 4F 70 ml CPD/110 ml PAGGS-M - WB + PDS-V	CQ41470	41IC02FA00
CompoFlow® 3F T&B 63 ml CPD/100ml SAG-M - PDS-V	CT32150	41IB07AA00
		41IC08AA00
Compoflex® 4F 63 ml CPD/100 ml SAGM - PDS-V	PQ31150	41IB01AA00
Composelect® 4F 63 ml CPD/100 ml SAG-M - WB + PDS-V	PQ31450	41IC06FA00
Compoflex® 4F T&B - 63ml CPD/100ml SAGM - PDS-V	PQ32150	41IB02AA00
		41IB03AA00
		41IB06AA00
		41IB13AA00
		41IB14AA00
		41IB27AA00

		41IC19AA00
Composelect® 4F T&B - 63 ml CPD/100 ml SAG-M - RCC - PDS-V	PQ32250	41IA25FA00
		41IB05FA00
		41IB19FA00
		41IC07FA00
		41IC08FA00
		41IC16FA00
Composelect® 4F 70 ml CPD/110 ml PAGGS-M - WB + PDS-V	PQ41470	41IB23FA00
		41IC03FA00
Composelect® 4F T&B 70 ml CPD/110 ml PAGGS-M - RCC - PDS-V	PQ42271	41IB08FA00
		41IB09FA00
		41IB15FA00
		41IB16FA00
		41IB25FA00
		41IC03FB00
		41IC04FA00
Compoflex® 3F T&B 63 ml CPD/100 ml SAG-M - PDS-V	PT32150	41IB15AA00
		41IC16AA00
Composelect® 4F - 63 ml CPD/100 ml PAGGSM - WB + PDS-V	T2943	41IB17FA00
Composelect® 4F T&B 70 ml CPD/110 ml PAGGS-M - WB + PDS-M	T3902	41IB24FA00
		41IC11FA00
Composelect® 4F 63CPD/100 ml SAG-M - RCC + PDS-V	T3965	41IC06FB00
Composelect® 5F T&B 63 ml CPD/100 ml SAG-M - RCC + PDS-V	T3974	41IB22FA00
Composelect® 4F T&B - 63ml CPD/100 ml SAG-M - WB + PDS-M	T3986	41IB14FA00
Composelect® 4F T&B 70 ml CPD/110ml PAGGS-M - RCC + PDS-M	T4010	41IB17FB00
Composelect® 4F 63 ml CPD/100 ml SAGM - WB + PDSV	T4910	41IC11FB00

Dear Customer / Health Professional,

Through routine post-market surveillance Fresenius Kabi has identified a slight increase in the number of leaks affecting products listed above. These leaks are apparent after centrifugation of the product and can be clearly identified by the user.



Location of the leak

Up to now Fresenius Kabi has received no incidents reported for this failure.

Internal investigation has identified the root cause for the increase in the number of affected products and controls have been immediately implemented to correct this issue. The root cause existed for a period of approximately 2 months, and affected the 60 batches listed above. This is a complete list of all products that may potentially have been affected.

An analysis of the complaints, coupled with internal testing shows us the rate of occurrence of the failure remains within our risk assumptions. However due to the previously low number of defects regarding this type of failure on the product our customers may notice a slight increase in the number of failures.

This information is provided to our customers to make them aware of the situation and to inform them that; at this time, Fresenius Kabi regards the product as safe and effective and advises continued use of the product, but would urge customers to perform an inspection of the bags after centrifugation as indicated in the IFU and discard if necessary.

Fresenius Kabi will continue to monitor the situation closely, ensuring there is no elevation from the currently acceptable level of risk.

Batches which are **not** listed above are not affected by this Field Safety Notice.

PLEASE COMPLETE THE ENCLOSED "URGENT FSN RESPONSE FORM" AND SEND IT BACK TO US IMMEDIATELY AT:

E-mail: <local affiliate>

Fax: <local affiliate>

Please assure 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.

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>

URGENT FSN RESPONSE FORM

SECTION A

Hospital / Facility Details

Please fill out the information below and send the completed form to Fresenius Kabi at:

E-mail: <local affiliate> or Fax: <local affiliate>

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

SECTION B

I have read and understand the FSN instructions provided in the letter.