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Date : 25-March-2019

Field Safety Corrective Action CompoStop

To: Customers and Health Professionals

From: Fresenius Kabi (Schweiz) AG

Aawasserstrasse 2

6370 Oberdorf

Subject: Leakage of Fresenius Kabi CompoStop Platelet Storage Products

Field Safety Corrective Action for CompoStop Platelet Storage Systems

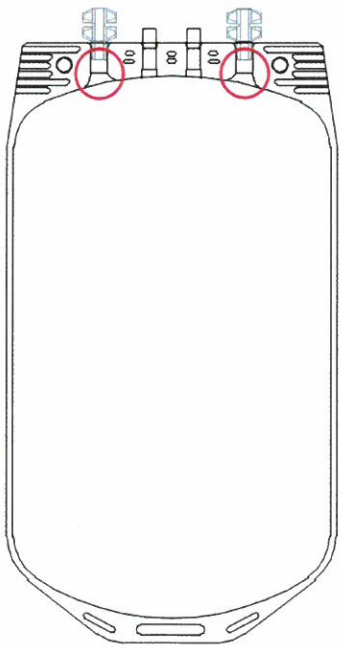
Dear Customer / Health Professional,

Based on routine post-market surveillance Fresenius Kabi has identified an increased number of complaints for visible leakage of the platelet storage bag in CompoStop products. Such leakage predominantly occurs near the twist-off ports and has become apparent during processing of platelets in the storage bag. This type of defect has been identified by the user under routine handling conditions.

Fresenius Kabi has not received any complaints related to microbiological contamination of these platelet storage bags, nor complaints on potentially associated patient injury.

Potentially affected articles and batches are listed in Annex 1.

Observed location of the leak



The observed location of the leakage is in the area of the twist-off port weld in platelet storage bags.

The instruction for use of CompoStop products indicates that if a visible damage or defect to the product is noticed and represents a risk to the integrity of the system, the product should not be used.

In the unlikely event of not detecting the leakage, the defect could potentially lead to a microbiological contamination of the platelet concentrate.

Accordingly, 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 CompoStop products. Fresenius Kabi will work to replace products as requested by the customer.

Field Safety Corrective Action

1. If platelets are already collected and/or CompoStop products in stock are needed for medical treatment, it is recommended to perform a detailed visual inspection for leakage of the processed platelet bag during the de-aeration process of the product and/or perform any additional applicable control measures.
2. For all batches referenced in Annex 1 it is requested to send remaining CompoStop products back to Fresenius Kabi.

Batches which are not listed in Appendix 1 are not affected by this Field Safety Corrective Action.

PLEASE COMPLETE THE ENCLOSED "URGENT FSCA RESPONSE FORM" AND SEND IT BACK TO US IMMEDIATELY AT:
E-mail: pascal.agerter@fresenius-kabi.com
Fax: 041 619 50 80

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: Pascal Aegerter, Tel.-Nr. 079 435 83 45.

Sincerely,

Fresenius Kabi (Schweiz) AG

Pascal Aegerter
Leiter Sales & Marketing TCT

Eva-Maria Süssmeier
Leiterin Regulatory Affairs & Quality Management

FRESENIUS KABI

Annex 1: List of batches affected by the Field Safety Corrective Action

Product Name	Article Number	Batch Number
CompoStop® Flex 2F - PLT processing and leuko reduction system 100/1300	PD51600	41LD18GA00
		41LF18GA00
		41LI11GA00
		41LL06GA00
		41LL07GA00
		41MB14GA00
		41MC12GA00
		41MD05GA00
		41ME01GA00
		41MI19GA00
		41MK06GA00
CompoStop® Flex 3F T&B - 100/600/1300 - 7-PLT Pooling system	PT52600	41MK01GA00
		41MF13GA00

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URGENT FSCA RESPONSE FORM

SECTION A
Hospital / Facility Details
Please fill out the information below and send the completed form to Fresenius Kabi at:
E-mail: pascal.agerter@fresenius-kabi.com or Fax: 041 619 50 80

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

SECTION B

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

☐ Due to product shortage, we decided to continue using the affected products.

☐ I have checked my stock and have quarantined inventory according to the next page, which includes an indication of the disposition of the recalled product.

Batch Number	Units used	Units returned	Units destroyed

Signature:	
Date:	