FRESENIUS KABI

Field Safety Corrective Action CompoStop

To	: Customers and Health professionals
From	: [local affiliate]
Subject:	Leakage of Fresenius Kabi CompoStop Platelet Storage Products

Contact person:

Telephone : local affiliate

Telefax : local affiliate

Email:

Date : 20-March-2019

Field Safety Corrective Action for CompoStop Platelet Storage Systems

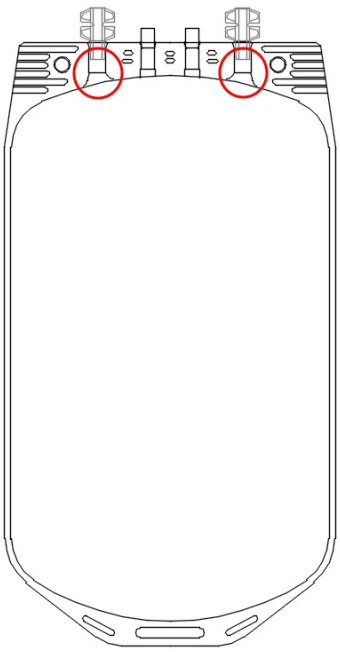
Dear Customer / Health Professional,

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: <local affiliate>
Fax: <local affiliate>

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: local product manager.

Sincerely,

Signature

<name local affiliate>
<function>

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

Product Name	Article Number	Batch Number
CompoStop® FlowFlex 3F T&B - PLT Pooling - processing and leuko reduction system	C5000	41LD01GA00
		41LE17GA00
		41LF26GA00
		41LF30GA00
		41LG25GA00
		41LG28GA00
		41MA15GA00
		41MB19GA00
		41MB07GA00
		41MC28GA00
		41MC27GA00
		41MD16GA00
		41ME04GA00
		41ME22GA00
		41MI09GA00
		41MI08GA00
		41MK23GA00
		41ML06GA00
CompoStop® Flow-Flex 3F T&B - 100/600/1300 - 6-PLT Pooling system	CT52600	41LD13GA00
		41LF27GA00
		41LH06GA00
		41LK04GA00
		41LK25GA00
		41MC02GA00
		41ME03GA00
		41MI07GA00
CompoStop® Flex 2F - PLT processing and leuko reduction system 100/1300	PD51600	41LD18GA00
		41LF18GA00
		41LG26GA00
		41LI11GA00
		41LK16GA00
		41LL06GA00
		41LL07GA00
		41MA06GA00
		41MA12GA00
		41MB14GA00

Product Name	Article Number	Batch Number
		41MC12GA00
		41MD05GA00
		41MD11GA00
		41ME01GA00
		41ME14GA00
		41MH01GA00
		41MI19GA00
		41MI30GA00
		41MK06GA00
		41ML07GA00
		41MK31GA00
		41ML08GA00
		41ML14GA00
		41ML18GA00
		41ML22GA00
		41MM07GA00
		85MK11QF00
		85NA13CA00
CompoStop® Flex 3F T&B - 100/600/1300 - 7-PLT Pooling system	PT52600	41LD08GA00
		41LE23GA00
		41LE25QA00
		41LH03QA00
		41LH07GA00
		41LI03GA00
		41LK10GA00
		41LK24GA00
		41LL14QA00
		41LL28GA00
		41LM11GA00
		41MA23GA00
		41MB15GA00
		41MB20GA00
		41MC04GA00
		41MD06GA00
		41MF13GA00
		41MF12GA00
		41MH06GA00
		41MI12GA00

Product Name	Article Number	Batch Number
		41MK01GA00
		41MK08GA00
		41ML29GA00
		85MA19QC00
		85MK11QE00
CompoStop® Flex 3F T&B - 100/600/1300 - PLT Pooling - processing and leuko reduction system	T5000	41LD03GA00
CompoStop® Flex CS 3F T&B – PLT pooling - processing - leuko reduction system	T5002	41MA30GA00
CompoStop® Flex 3F - 100/600/1300 - PLT processing and leuko reduction system	T5003	41LD02GA00
		41LF11GA00
		41MB05GA00

URGENT FSCA RESPONSE FORM

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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:	

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:	