

Field Safety Corrective Action CompoStop

To : Customers and Health professionals

From : [local affiliate]

Subject: Leakage of Fresenius Kabi CompoStop Platelet Storage Products (EC202005)

Contact person:

Telephone: local affiliate

Telefax : local affiliate

Email:

Date : xx-March 2020

Field Safety Corrective Action for CompoStop Platelet Storage Systems

Affected products:

Product name	Article number	Batch number
CompoStop® Flex 3F T&B - 100/600/1300 - 7-PLT Pooling system	PT52600	41NK23GA00
CompoStop® Flow-Flex 3F T&B - 100/600/1300 - 6-PLT Pooling system	CT52600	41OA28GA00

Dear Customer / Health Professional,

Based on routine post-market surveillance Fresenius Kabi has identified a slight trend of complaints for visible leakage of the platelet storage bag in CompoStop products. Such leakage predominantly occurs in the upper area next to the 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.

The observed location of the leakage is in the area of the tube ports weld in platelet storage bags.

Observed location of the leak



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 classified as affected it is requested to send remaining CompoStop products back to Fresenius Kabi.

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>

URGENT FSCA RESPONSE FORM

Leakage of Fresenius Kabi CompoStop Platelet Storage Products (EC202005)

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, which includes an indication of the disposition of the recalled product.

Batch Number	Units used	Units returned	Units destroyed

Signature:	
Date:	