

FIELD SAFETY NOTICE

CompoStop™ Platelet Storage Systems

Date: March 26, 2025

Subject: Leakage of Sample Bag of Fresenius Kabi CompoStop™ Platelet Storage Products

Affected Products: Compostop™ Platelet Storage Systems
Article Codes: FD51600, FD516AB, FT52600, GT52600, GT526NL

Dear Customer / Health Professional,

As part of its ongoing market surveillance, Fresenius Kabi has identified for certain CompoStop™ Platelet Storage Systems the possibility of a visible leak on the sample bag. The leakage occurs near the tube ports. This type of defect is recognizable by the user under .

Fresenius Kabi has not received any complaints related to microbiological contamination of platelet concentrates produced and stored in systems from the affected batches nor complaints on potentially associated patient injury.

Potentially affected articles and batches are listed in Annex 1.

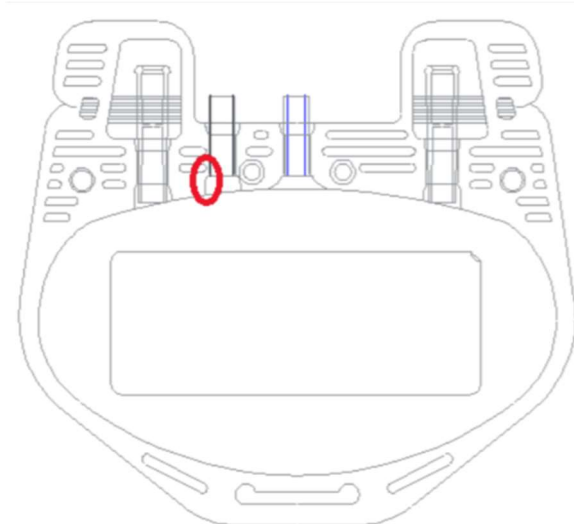


Figure 1 Location of the leak at the sample bag

Fresenius Kabi recognizes its responsibility and therefore has decided to initiate a Field Safety Notice as a precautionary measure.

As marked in Figure 1, the observed location of the leakage is in the area of the tube port welded in the sample bag.

In Chapter 3, the Instruction for Use of the CompoStop™ products points out the correct sample collection as well as the handling of the sample bag. The sample bag should be disconnected from the platelet concentrate by sealing the tubing.

3. Sample collection

- After carefully mixing the platelet concentrate, open the clamp and press remaining air and part of the platelet concentrate to the sample bag.
- Disconnect the sample bag from the platelet concentrate by sealing the tubing between sample and storage bag. For bacterial contamination tests, the sample bag is provided with a needle and in-line break away. Always take these samples before any other sample for analysis (samples should be taken under Laminar Airflow Conditions).

Figur 2: Excerpt of Chapter 3 of the Instruction for Use for CompoStop™ Systems

Any backflow of liquid from the sample bag to the storage bag must be prevented and avoided.

If a leak occurs in the sample bag, it should be discarded in accordance with local disposal instructions and regulations. A new sample for laboratory analysis can be collected by sterile connecting of a separate sample kit (P4206 - CompoFlex 1F 100ml sample system) to the platelet storage bag.

Fresenius Kabi has implemented additional control measures and corrective actions following the production process to ensure the continued and reliable supply of CompoStop™ products.

Field Safety Corrective Action

1. When working with the CompoStop™ products it is inevitable to strictly follow the instruction for use.
2. Prevent any backflow from the sample bag to the storage bag by closing the blue clamp between sample bag and concentrate.
3. In case of visible damage do not use the product.
4. Use a sample kit (P4206 - CompoFlex 1F 100ml sample system) to collect a new sample in case of a leak of the sample bag.

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

PLEASE COMPLETE THE ENCLOSED FSCA RESPONSE FORM AND SEND IT BACK TO US IMMEDIATELY AT:

E-mail: info-dk@fresenius-kabi.com

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 FSCA please contact: Mattias Afzelius, Business Unit Director Medtech.

Sincerely,



Christine Barslev

QA/RA Manager and NSO

Fresenius Kabi Denmark

Product Name	Article Number	Batch Number
CompoStop™ Flex 2F - PLT processing and leuko reduction system	FD51600	41WD15GA00
		41WD29GA00
		41WE09GA00
		41WF13GA00
		41WG22GA00
		41WH06GA00
		41WH07GA00
		41WH21GA00
		41WH30GA00
		41WH31GA00
		41WI15GA00
		41WI28GA00
		41WI17GA00
		41WI30GA00
		41WK10GA00
		41WK26GA00
		41WL15GA00
		41WL11GA00
		41WL19GA00
		41WL21GA00
41WM10GA00		
41WM15GA00		

FIELD SAFETY NOTICE RESPONSE FORM

CompoStop™ Platelet Storage Systems

SECTION A: Hospital / Facility Details

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

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

SECTION B

I have read and understand the information provided in the letter.

Signature:	
Date:	