Fresenius Kabi
Else-Kröner-Str. 1
F-61352 Bad Homburg (Germany)

Date: September 24, 2025

Field Safety Notice (ECMD202520)

Leakage at printed tube of Compoflow systems

Affected Product:

Product Name	Article No.	Batch No.
COMPOFLOW 4F T&B 63CPD/SAG-M RCC PDS-V	CQ32250	41XC01FA00
CompoFlow 4F T&B 70CPD/110SAG-M RCC PDSV	C4008	41XC01FB00
CompoFlow 4F T&B 70CPD/110SAG-M RCC PDSV	C4008	41XC04FA00

Dear Sir or Madam,

We are writing to inform you of a voluntary recall by Fresenius Kabi of three batches of Compoflow systems (see Product name, Article number and Batch in table above) due to leakages at the printed tube.

As part of its ongoing market surveillance, Fresenius Kabi has determined that individual units were damaged during an automatic assembly step, potentially causing holes in the tube. The size of the holes can lead to leaks, causing blood to escape or air to be sucked into the system. The defect is detectable during priming or filtering. Fresenius Kabi has assessed the potential risk. As a conservative measure and to mitigate the theoretical risk of an infection to user, sepsis, blood stream infection, loss of unit (autologous) whole blood and also to avoid a delay of therapy due to the need to replace the set Fresenius Kabi decided to voluntary recall these three affected batches.

Fresenius Kabi has not received any report of an incident where a patient had an injury or a serious deterioration in the state of health.

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We therefore ask you to check any stocks of the listed batches in your organization and to stop using them.

Please make these products available for collection by Fresenius Kabi.

Please note the following information:

- Clinical use: If affected articles are stored in your organization, please stop further internal distribution immediately.

- Non-clinical Use (trade): Please stop selling the relevant items to your customers immediately. If partial quantities of the affected articles have already been delivered from your stock, please inform your customers immediately about this product recall and ask them to return the products to you.

- Reply Form: Please complete the attached response form (Appendix 1) and return it to us within the next 7 days. Please note the information in the response form (Annex 1).

Please ensure in your organization that all users of the above-mentioned products and all other persons to be informed are notified of this recall letter and the procedure.

Fresenius Kabi as legal manufacturer apologizes for any inconvenience caused and thanks you in advance for your support and understanding!

If you have any further questions, please do not hesitate to contact our customer service team or your sales representative.

Fresenius Kabi
Else-Kröner-Str. 1
F-61352 Bad Homburg (Germany)

You can reach the customer service team as follows:

kundenservice@fresenius-kabi.com

Sincerely,
Fresenius Kabi

Annexes
Annex 1 Response Form

Fresenius Kabi
Else-Kröner-Str. 1
F-61352 Bad Homburg (Germany)

FIELD SAFETY NOTICE (Annex 1)

Response Form to Field Safety Notice (ECMD202520) from 24.09.2025

to Leakage at printed tube of Compoflow systems

Respond per mail to kundenservice@fresenius-kabi.com

Please fill out this form completely and check the appropriate boxes. Please send us the reply form even if you no longer have any of the listed products in stock.

☐ **no** Remaining stock of the product concerned available.

☐ **following stock available**
(A return of the remaining stock and an invoice correction/credit note will be carried out by us after your feedback).

Article No.	Batch No.	Stock
CQ32250	41XC01FA00	
C4008	41XC01FB00	
C4008	41XC04FA00	

Please do not send any goods back to us unsolicited.

If the supply chain has been extended by you, we require feedback from you in order to be able to carry out a clear reconciliation as required by the authorities.

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Name of the hospital / Institute / Customer:	
Customer No.: Delivery note number:	
Address of the hospital / Institute / Customer:	
Contact person: Function:	
Phone No.:	

☐ I have read and understood the safety information dated 24.09.2025 and have informed all relevant persons about the safety information (ECMD202520) and the procedure described.

Name/Date: ……. **Signature:** …….