

Field Safety Corrective Action

To : Whom it may concern

Telephone : [local affiliate]

From : [local affiliate]

Telefax : [local affiliate]

Date : 11-Mar-2015

Subject : Recall ACD-A bags

Recall affects the following products:

Product name	Article number	Batch number
ACD-A/600 ml - LLW - ICS	TS14001	40HI30KB00 40HK21KA00 40HL20KA00
ACD-A/1000 ml - LLW - ICS	TS14002	40HM09KA00

Dear Customer / Health Professional,

This letter is to notify you of a voluntary recall for the above-mentioned products by Fresenius Kabi AG.

Fresenius Kabi received complaints regarding leakages of the ACD-A bags. Root cause was a variation in the welding process.

Therefore Fresenius Kabi has decided to take this voluntary precautionary action.

Investigation showed that this failure could be limited to the mentioned batches.

Fresenius Kabi has not received any reports of incidents associated with this failure.

You are kindly requested to discontinue the use of the concerned batch and to return all products to Fresenius Kabi.

Please note the following:

1. If you are a health professional and have the affected batch on stock, immediately stop distributing or using the products and return all units to your local or regional Fresenius Kabi organization.
2. If you are a distributor, immediately notify your customers of this recall and direct them to stop distributing and/or using the affected batches. Please help them in preparing to return the products to the local or regional Fresenius Kabi organization.
3. PLEASE COMPLETE THE ENCLOSED "URGENT PRODUCT RECALL RESPONSE FORM" AND SEND IT BACK TO US IMMEDIATELY AT:
 - a. E-mail: [local affiliate]
 - b. Fax [local affiliate]

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.

We apologize for any inconvenience.

If you have any further questions concerning the recall please contact: **local product manager**

Sincerely,

Signature

**<name local affiliate>
<function>**

URGENT PRODUCT Recall RESPONSE FORM

Recall ACD-A bags

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:	
Signature:	
Date:	

SECTION B

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

- I have checked my stock and have quarantined inventory consisting of _____ <units >. Indicate disposition of recalled product:
 - Used (specify quantity and date);
 - Returned (specify quantity, date and method);
 - Destroyed (specify quantity, date and method);