

Field Safety Corrective Action

To : Whom it may concern

Telephone : [local affiliate]

From : [local affiliate]

Telefax : [local affiliate]

Date : 21-July-2016

Subject : Recall HERMANN GASTROSTOMY
DRESSING SET

Recall affects the following products:

Product name	Article number	Batch number
HERMANN GASTROSTOMY DRESSING SET	7901081	32101266

Dear Customer / Health Professional,

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

Fresenius Kabi were informed by its supplier about a possibility of metal needles present in the wound dressing which is part of the above mentioned product.

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

Investigation showed that this failure could be limited to one batch. Corrective and preventive actions are implemented.

Fresenius Kabi has not received any reports from the field 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 Recall HERMANN GASTROSTOMY DRESSING SET

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);