

**Field Safety Notice concerning a
Field Safety Corrective Action (Recall)**

To : Whom it may concern
 From : [local affiliate]

 Subject : Recall Ambix Intrastick® Safe 20G x 20mm

Telephone : [local affiliate]
 Telefax : [local affiliate]
 Date : [local affiliate]

Recall affects the following product:

Product Name	Article number	Batch Number
Ambix Intrastick® Safe 20G x 20mm	8081281	32511189

Dear Customer / Health Professional,

Fresenius Kabi AG is initiating this voluntary recall for the above-mentioned batch of Ambix Intrastick® Safe 20G x 20mm.

The Ambix Intrastick® Safe is a safety port cannula system for puncturing implanted port membranes.

Fresenius Kabi would like to inform you that there is one batch of Ambix Intrastick® Safe 20G x 20mm on the market, that could potentially contain also products with 20G x 14mm.

In case it is discovered that the needle is too short before usage of the Ambix Intrastick Safe, this results in a slight delay of therapy, because the cannula has to be exchanged. If the wrong needle length is not detected and is used, the needle might not puncture the port, and therefore the drug might not be delivered into the vein. This can only occur if the user is not checking the aspiration of blood prior to administering the drug as both are normal practice and described in the instructions for use. In case that happens, this could cause Underdose and Extravasation.

Fresenius Kabi has not received any reports of incidents associated with this failure. However, to mitigate possible risks, Fresenius Kabi has decided to recall batch 32511189 as a voluntary precautionary action.

Actions taken by Fresenius Kabi

- Ambix Intrastick® Safe 20G x 20mm will be exchanged free of charge in alignment with your Fresenius Kabi contact
- Fresenius Kabi has already identified corrective actions to prevent such failure in the future

PLEASE COMPLETE THE ENCLOSED "URGENT PRODUCT RECALL RESPONSE FORM" AND SEND IT BACK TO US IMMEDIATELY AT:

E-mail: <local affiliate>

Fax: <local affiliate>

Kindly 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.

The relevant competent authority has been informed about that Field Safety Corrective Action according to the MEDDEV Guideline.

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 FSN please contact: local product manager.

Sincerely,

Signature

<name local affiliate>

<function>

URGENT PRODUCT RECALL RESPONSE FORM
Ambix Intrastick® Safe 20G x 20mm

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);