Field Safety Corrective Action

To : Whom it may concern

From : [local affiliate]

Telephone : :local affiliate

Telefax : :local affiliate

Date : 04-May-2015

Subject : Recall Freka Intestinal Tube ENLock

Field Safety Corrective Action affects the following products:

Product name	Article number
Freka Y Connector for Freka PEG FR 20/9, ENLock	7751412
Freka EasyIn, FR 16/8, 270 cm, ENLock	7755012
Freka Intestinal Tube FR 9 ENLock	7901193
Freka Intestinal Tube FR 12, ENLock	7901352
Freka Click Adaptor FR 9 for Freka PEG, ENLock	7981380
Freka Y Connector for Freka PEG FR 15/9, ENLock	7981393
Freka Click Adaptor FR 12 for Freka PEG, ENLock	7989942
Freka Y Connector for Freka PEG FR 20/12, ENLock	7990012

Dear Customer / Health Professional,

Fresenius Kabi initiated in December 2013 a Field Safety Notice to inform about the risk of an incomplete screwing of the "anti-opening secure function" at our product Freka Intestinal Tube ENLock. At that time we announced that we will improve the "anti-opening secure function" in the future.

The results of the further development of the "anti-opening secure function" was non-satisfying and with the background of the upcoming standard ENFit Fresenius Kabi decided to recall all Freka Intestinal Tubes with ENLock and will switch back to Freka Intestinal Tubes with Luer-Lock as interim solution, till ENFit is available.

So Fresenius Kabi is recalling all unused Freka Intestinal Tubes. They will be replaced by Luer-Lock versions.

It is the position of Fresenius Kabi that also the Freka Intestinal Tubes which are current in used should be updated to the Luer-Lock version. It is up to the Health Professional if he wants to follow this position. In such case you will find attached to this Field Safety Corrective Action guidance how you can exchange the Y-Adapter without changing the whole product. In such case a separate article is available to provide the proper parts to the Health Professional to be able to act according to our guidance.

PLEASE COMPLETE THE ENCLOSED "URGENT FSCA RESPONSE FORM" AND SEND IT BACK TO US IMMEDIATELY AT:
E-mail: <local affiliate>
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.

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: local product manager.

Sincerely,

Signature

<name local affiliate>
<function>

URGENT FSCA RESPONSE FORM

Freka Intestinal Tube ENLock

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);