

## Field Safety Corrective Action

To : Whom it may concern

Telephone : [local affiliate]

From : [local affiliate]

Telefax : [local affiliate]

Date : XX-Apr-2015

Subject : FSN Freka Connect 60ml ENLock

### Field Safety Notice affects the following product:

Product Name	Article Number	Batch Number
Freka Connect ENLock 60ml	9000763	1600020912 1601071025 1601071214 1601071224 1601071284 1601071294 1601071304 1601071314 1601071334 1601071344 1601071364 1601071374 1601071384 1601071414 1601071424 1601071434 1601071444 1601071454 1601071494 1601071504 1601071514 6000204132 6000204133 6000209134 6000209135 6000216134 6000216135 6000220132 6000245125 6000245126 6000245127 6000246123 6000251124 6000251125
	9000763S	1601081354 1601081364 1601081373 1601081453 1601081454 1601081474 1601081483 6000230134

Dear Customer / Health Professional,

During internal tests Fresenius Kabi identified the possibility that during transport the primary packaging could be damaged and thereby the sterility can be compromised.

Up to now Fresenius Kabi has not received any complaints or incidents reported for this failure.

Holes in the primary package of an EN Syringe could lead to a contamination of the product rendering it unsterile. In an extreme worst case a microbiological contamination could lead to a primarily enteral infection.

However several studies have shown that the risk of contamination is related to the manipulation of the system and the system design and that non-sterile syringes do not impact the risk of contamination during usage<sup>1,2</sup>.

According to the information stated above it is the position of Fresenius Kabi that the Freka Connect ENLock 60ml which are currently in the market could be used further with the assumption to use them as unsterile EN syringes.

Batches which are **not** listed above are not affected by this Field Safety Notice.

PLEASE COMPLETE THE ENCLOSED "URGENT FSN 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 FSN please contact: **local product manager.**

Sincerely,

**Signature**

<name local affiliate>

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<sup>1</sup> Gottlieb K, Leya J, Kruss DM, Mobarhan S, Iber FL. Intraluminal fungal colonization of gastrostomy tubes. *Gastrointestinal Endoscopy*. 1993;39(3):413-415. [PubMed: 8514078]

<sup>2</sup> Drain PK, Ralaivao JS, Rakotonandrasana A, Carnell MA. Introducing auto-disable syringes to the national immunization programme in Madagascar. *Bulletin of the World Health Organization*. Ethiopia. 2003;81(8):553-560. [PMC free article: PMC2572525] [PubMed: 14576886]

**URGENT FSN RESPONSE FORM**  
**Freka Connect 60ml 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>

<b>Name of Hospital / Facility:</b>	
<b>Hospital / Facility Address:</b>	
<b>Telephone Number:</b>	
<b>Signature:</b>	
<b>Date:</b>	

**SECTION B**

I have read and understand the FSN instructions provided in the letter.