

January 4th 2016

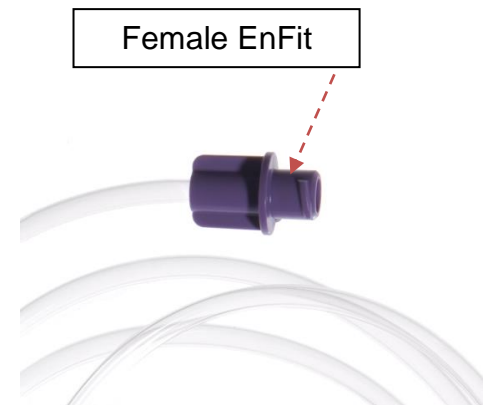
FIELD SAFETY NOTICE (FSN)

Dear Nestlé Health Science Customers,

Nestlé Health Science is issuing this notification to provide you with important information regarding a voluntary Field Safety Notice (FSN) for all Compat Go Enteral Feeding Sets with ENFit™ connectors listed in the table below.

We have been informed of field incidents involving female ENFit™ connectors on Enteral Feeding Sets. These incidents did not involve products distributed by Nestlé Health Science in Europe, however, Compat Go Enteral Feeding Sets distributed in Europe by Nestlé Health Science do include the same connector.

<u>Reference</u>	<u>Product Name</u>
12267461	Compat Go® Pump Combiset 1.5L ENFit
12267449	Compat Go® Pump Portable Set ENFit
12267443	Compat Go® Pump Spike Set ENFit
12267460	Compat Go® Pump Universal Set ENFit



Issue Description

Use of the female ENFit™ distal end may result in product leakage and/or component breakage.

After investigation, it appears that a combination of

- a) amino acids and/or MCT oil in the enteral nutrition products
- b) mechanical stress in the connection and
- c) component material and method of manufacturing.

may lead to the observed issues

Hazard Description

This issue may have clinical consequences such as:

- a failure to properly feed the patient (leakage may lead to under-delivery of the nutrition, especially to patients who need to be fed continuously),

and/or

- contamination of an open wound (due to spillage of nutrition on open wound)

Actions to be taken by Healthcare Professionals or Carers:

Nestlé Health Science advises you to take the following actions:

- 1) Healthcare Professionals or Carers should not leave any patients receiving amino acid-based formulae unattended for more than 2 hours while being fed, in order to check the continued proper functioning of the enteral feeding process. If there are signs of leakage, please exchange the set for a new one.
- 2) Healthcare Professionals or Carers are reminded to pay attention to those patients considered vulnerable (such as those with a significant risk of hypoglycemia, critically ill patients, patients with open wounds near the administration set distal end, babies and small children).
- 3) Healthcare Professionals should complete the FSN Acknowledgement Form and return it to your local Nestlé Health Science representative.

Actions Taken by Nestlé Health Science

- Nestlé Health Science has started investigations with suppliers to evaluate the root cause and options in order to optimize the female ENFit™ connector performance and remove the potential for failure.
- Administration sets with this optimized female ENFit™ connector will be introduced once the appropriate validations have been completed (expected April 2016).
- Potential complaints will be closely monitored to assess the effectiveness of this Field Safety Corrective Action.

Transmission of this Field Safety Notice

- This Field Safety Notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- If you are a dealer, wholesaler, or distributor/reseller that distributed any product to other facilities, please notify your customers of this communication in accordance with your customary procedures.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

Nestlé Health Science confirms that the relevant Competent Authorities have been informed of this Field Safety Corrective Action.

Please be assured that maintaining a high level of safety and quality is our highest priority. We apologize for any inconvenience this may cause to you and your staff. Should you have any concerns or if you require further clarification, please contact your Nestlé Health Science Local Representative.

Signature



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FSN Acknowledgement Form

Nestlé Enteral Feeding Sets including ENfit connectors

Please complete and return one copy of this form to your local Nestlé Health Science representative within 15 days.

Healthcare Professionals or Carers Information	
Facility Name	
Street Address	
Postcode & City	
Country	
Name	
Function	
Phone number	
E-mail address	

We hereby confirm that we have received the above-mentioned Field Safety Notice and we commit to perform the requested actions to be taken.

Date

Signature