

Urgent Field Safety Notice

To : Whom it may concern

Telephone : 01928 533 775

From : Fresenius Kabi

Telefax : 01928 533 420

Date : 08 Jan 2016

Subject : Leakage or component breakage at
ENFit Universal Giving Sets

Field Safety Notice affects the following product:

Product Name	Article Number
Amika Pump Set EasyBag, ENFit universal	7751907
Amika Pump Set Bag, ENFit univ.	7751908
Amika Pump Set VarioLine, ENFit univ.	7751909
Amika Pump Set TwoLine Easybag, ENFit un	7751910
Amika Pump Set VL Comfort, ENFit univ.	7751998
Amika EasyBag mobile, ENFit univ.	7751999
Amika Pump Set Bag mobile, ENFit univ.	7751913
Amika Pump Set Bag, ENFit universal, UK	7751715T
Amika PS Bag mobile, ENFit univ, UK	7752046T
Amika PS EasyBag mobile, ENFit univ UK	7752087T
Amika Pump Set EasyBag, ENFit univ, UK	7752085T
Amika PS EasyBag non med port, ENF UK	7752086T
Amika Pump Set Varioline, ENFit univ UK	7752088T
Amika PS TwoLine EasyBag, ENFit univ UK	7752089T
Applix Pump Set EasyBag, ENFit univ.	7751943
Applix PS EasyBag with cover, ENFit univ	7751944
Applix Pump Set Bag, ENFit, univ.	7751945
Applix Pump Set Varioline, ENFit, univ.	7751946
Applix PS TwoLine EasyBag, ENFit univ	7751947
Applix Pump Set VL Comfort, ENFit univ.	7751948
APPLIX EasyBag mobil, ENFit univ.	7751949
Applix Pump Set Bag mobile, ENFit univ.	7751950
Applix Pump Set EasyBag, ENFit univ. UK	7752102T
Applix PS EasyBag non med por ENF uni UK	7752103T
Applix PS EasyBag mobile, ENFit univ UK	7752104T
Applix Pump Set Varioline, ENFit univ UK	7752105T
Applix Pump Set Bag, ENFit universal, UK	7751714T
Applix PS Bag mobile, ENFit univ, UK	7752045T
Applix PS TwoLine EasyBag, ENFit univ U	7752106T
GraviSet EasyBag, ENFit universal	7751952
GraviSet Varioline, ENFit universal	7751953
GraviSet Bag, ENFit univ.	7751954
GraviSet EasyBag with cover, ENFit univ.	7751955
Freka Transition Adapter LL, ENFit, bulk	7981365
Freka Connect Transition Adapter LL, ENFit, bulk	7981366
ENFit adaptor for Gastrotube, bulk	7981367

Dear Customer / Health Professional,

This letter is to notify you of a voluntary Field Safety Notice by Fresenius Kabi AG for the above-mentioned products.

ENFit, the new enteral connector to avoid misconnections, will soon become an industry safety standard. Several providers, including Fresenius Kabi, have commenced the launch process in Europe.

The company has been informed of events involving female ENFit connectors of Enteral Giving Sets. The products listed above include the same connector.

Internal investigations have shown that a breakage of components could appear in combination with high MCT oil and/ or Amino acids concentrations together with mechanical stress. This breakage might be the root cause for leakages occurring during use.

This issue may have clinical consequences such as:

- failure to properly feed the patient due to leakages

and/or

- wound contamination due to spillage of nutrition on open wounds

Healthcare Professionals or carers are reminded to pay special attention during the enteral feeding process to patients with significant risk of hypoglycaemia, critically ill patients, and patients with open wounds near the distal end of the administration sets, babies or children.

Action to be taken by the customer:

The risk for component defects depends on the composition of the enteral nutrition, medication or supplements which are administered through the giving set and the mechanical stress applied. Please find some more details on the Fresenius Kabi portfolio and further advice in the sections below.

Enteral Nutrition

Tests with Fresenius Kabi enteral nutrition that have high MCT oil and/ or Amino acids concentrations (tube feed and sip feed table 1) showed no negative impact on the connectors. The company will continue to monitor the wider Fresenius Kabi range of products for any impact on the connectors. Enteral nutrition from other manufacturers might be suitable as well, when containing similar concentration of the mentioned substances below.

Product	MCT concentration	Amino acids
Fresubin HP Energy	3,3 g MCT-Oil/100ml	-
Fresubin HP Energy Vanille	3,3 g MCT-Oil/100ml	-
Fresubin 2kcal HP/ fibre	2,6 g MCT-Oil/100ml	-
Supportan	2,3 g MCT-Oil/100ml	-
Fresubin renal Vanille	-	-
Diben 1,5 kcal HP	-	-
5 kcal Shot Lemon or Neutral	13,9 g MCT-Oil/ 100ml	-
Survimed OPD HN	-	6,7 g Whey protein hydrolysate (Free amino acid thereof: 1%) per 100 ml
Reconvan	-	Wheat Protein Hydrolysate, Arginin, Glutamin Peptide
Intestamin	-	Glutamin Dipeptid

Table 1: Fresenius Kabi enteral nutrition

Please be aware that other nutrition containing higher concentrations of amino acids and/or MCT oil may result in component leakage or cracking.

Supplements/ Medication

Special care must be taken by administering nutritional supplements or medications. Such products might contain high amounts of substances which are not compatible with the affected components and should **not** be administered via the giving set. Fresenius Kabi strongly recommends applying such fluids by a syringe directly into the feeding tube. Afterwards the tube should be flushed carefully.

MCT-oil

MCT-oil is used sometimes during placement of a feeding tube. As described above such a contamination of parts of the giving set should be avoided. Lubrication can be achieved with water or saline solution instead.

Mechanical Stress

Further, please avoid mechanical stress and high forces by screwing the connectors too tight.

If there are signs of leakages please change the respective transition adapter, which are also available separately or the complete set for a new one.

When following the above instructions the risk of cracks and leakages can be considerably reduced. In all cases we recommend to check the connectors for any leakage. Should any continuous leakages or breakages occur, please contact your local Fresenius Kabi representative.

Actions taken by Fresenius Kabi

Fresenius Kabi has already started investigations to optimise the design and material. The company will make every effort to provide an improved connector as soon as possible. Post Market Surveillance and complaints will continue to be closely monitored to assess the effectiveness of this Field Safety Notice.

PLEASE COMPLETE THE ENCLOSED "URGENT FSN RESPONSE FORM" AND RETURN IT BACK TO US IMMEDIATELY AT:

E-mail: FK.Complaints-UK@fresenius-kabi.com
Fax: +44 (0) 1928 533 420

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: the local product manager for ENFit Universal Giving Sets.

Sincerely,

Head of Quality

**URGENT FSN RESPONSE FORM
ENFit Connector**

SECTION A

Hospital / Facility Details

Please fill out the information below and send the completed form to Fresenius Kabi at:
E-mail: FK.Complaints-UK@fresenius-kabi.com or Fax: +44 (0) 1928 533 420

Name of Hospital / Facility:	
Hospital / Facility Address:	
Telephone Number:	
Signature:	
Date:	

SECTION B

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