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**Urgent - Field Safety Notice <update>**

**Flocare transition giving sets**

Type of action: Device modification, advice regarding the use of the device –  
**follow up on FSN dated 7 January 2016**

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Nutricia Medical Devices BV  
Schiphol Boulevard 261  
1118BH Schiphol Airport  
The Netherlands  
Date: 29 February 2016

Attention: All Nursing, Medical and Technical staff using these products.

**Details of affected devices**

595168 FLOCARE INFINITY PACK GIVING SET MLL W/O DC - TRANSITION  
595172 FLOCARE INFINITY BOTTLE GIVING SET - TRANSITION  
595174 FLOCARE INFINITY PACK GIVING SET W/O DC & W/O MP - TRANSITION  
595181 FLOCARE INFINITY PACK MOBILE GIVING SET - TRANSITION  
595182 FLOCARE INFINITY PACK MOBILE GIVING SET W/O MP - TRANSITION

Dear Customer,

Further to our FSN dated 7 January 2016, we would like to provide you with an update on the actions we are taking in response to complaints received concerning the ENFit transition adaptors in our giving sets.

As advised previously, we have received complaints where users have experienced issues with leakage and/breakage with the adaptor. We distribute approximately 130,000 ENFit transition adaptors as included in the ENFit transition feeding sets each week to patients across the UK and Ireland and, for the vast majority of users, these continued to be used safely and effectively. However, we take any concerns of this nature very seriously and have been working with our supplier to enhance the design of the adaptor to overcome potential issues.

**Advise on action to be taken by the user**

The previous actions required by the FSN/customer letter are still in place and we appreciate your continued vigilance in monitoring for any leakage and seek advice from the Nutricia specialist nurse team where required. As a precautionary measure, we advise that you and patients/parents/carers:

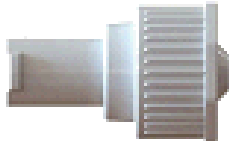

- Check giving set adaptors for any minor defects
- Ensure that connectors are not over-tightened
- Check for any leakages after initial connection and again after approximately 2 hours.
- If there are signs of leakage please change the set or adaptor for a new one

Further practical advice on what can be done to minimise this potential issue can be received through our Patient Care Freephone on (ROI) 1800 221 800 or (NI) 0800 028 3416.

**Corrective and preventive action taken**

Since our last communication the following changes have been made to the design of the adaptor:

- We are changing the material used in the adaptor (note this will result in a color change from white to transparent)
- We are increasing the wall thickness of the Luer barrel part of the adaptor
- We are replacing the partial screw lug thread with a continuous screw thread

<i>Current design</i>	<i>Improved design</i>
	

We committed to doing user testing with patients and hospital staff and can confirm that the results of field tests demonstrated the changes made have improved the strength of the adaptor; as well as making connection and disconnection easier.

**Implementation of improvements**

We expect that all patients and hospitals will start to receive giving sets with new adaptors from June 2016 onwards. This is a little later than we had originally anticipated as we need to scale up the production process following our rigorous period of testing.

We are aware of a small number of patients in their own homes that continue to experience issues with the current adaptors. To ensure we support these specific patients, from March we will supply these patients with the new adaptors as separate items. This distribution will be carefully managed by our Quality Assurance team based on current complaint information. Please understand that we have a limited supply of the new adaptors as a separate item, as all resources are being channelled into making the new adaptors available to all as soon as possible.

**Transmission of this Field Safety Notice** (if appropriate)

This notice needs to be passed on all those who need to be aware within your organization or to any organisation where the potentially affected devices have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please sign and return the attached FSN Acknowledgement Form as soon as possible.

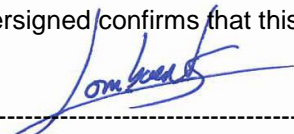
Yours faithfully,

**Contact reference person**

United Kingdom, Ireland  
Nutricia Ltd  
Ms Michelle Forster  
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Trowbridge, Wiltshire  
United Kingdom  
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EU/ non-UK Territory  
Nutricia Medical Devices BV  
Mr Michel Lombaerts  
Schiphol Boulevard 261  
1118 BH Schiphol Airport  
The Netherlands  
michel.lombaerts@nutricia.com

The undersigned confirms that this notice has been notified the appropriate Regulatory Agency



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Mr. ME Lombaerts – RA Manager Nutricia Medical Devices



## Acknowledgement Form

### Field Safety Notice (FSN)

Product name: **Flocare transition giving sets**

Please complete this form and send it back to:

Quality Assurance  
Nutricia Ltd  
White Horse Business Park  
Trowbridge  
Wiltshire  
BA14 0XQ

Email: [qualityassurance@nutricia.com](mailto:qualityassurance@nutricia.com)

Hospital name:	
Address:	
Name:	
Function:	
Phone:	
Email:	

I have read and understood this Field Safety Notice, and circulated it to all staff/departments that use this product.

Signed:

Date: