
Urgent - Field Safety Notice

Flocare transition giving sets

Type of action: Device modification, advice regarding the use of the device

---

Nutricia Medical Devices BV
Schiphol Boulevard 261
1118BH Schiphol Airport
The Netherlands

Date: 7 January 2016

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

Dear Customer,

We have received a number of complaints regarding the ENFit™ transition adaptor as included in the Flocare Transition Giving Sets.

Description of the problem
Users have experienced issues with leakage and/or breakage with the (white) transition adaptor. Leakage could occur immediately after connection and initiation of the feeding regime, as well as over time.

Part	*Batch information*	*Marketed as of*
	All	September 2015

This transition adaptor, called 'TRANSITION CONNECTOR TO LUER TUBE' is included in the NPSA transition giving sets and is attached at the distal end of the giving set as to enable a connection between the ENFit design giving set and the (old) Luer feeding tubes.

Details on affected devices
The above transition adaptor is included in the follow enteral giving sets supplied in IE:
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

Advise on action to be taken by the user
We appreciate your continued vigilance in checking giving set adaptors for any minor defects, monitoring for leakage and ensuring that connectors are not over-tightened. Furthermore, as a precautionary measure, we advise that you and patients/parents/carers check for any leakages after initial connection and again after approximately 2 hours. If there are signs of leakage please change the set for a new one.

Further practical advice on what can be done to minimise this potential issue can be received through your local Nutricia Nurse on our specific support line on **0800 231 5485**, **(ROI) 1800 22 1800, (NI) 0800 169 5173**, which is manned by Nutricia Nurses.

Important Notice
Patient safety is of the highest priority for Nutricia. Accordingly, we have accelerated the necessary modifications wherever possible to ensure updated products are available in the market as soon as possible.

Corrective and preventive action taken
When a complaint is registered, a clinical call is made by a Nutricia Nurse to the patient/carer to provide bespoke advice and support. If needed this will be followed up with a home visit by the Nurse.

The two following ameliorative modifications of the adaptor are identified to overcome the reported issues:

- Modification of the design of the involved part in order to increase the resistance to break due to the mechanical stress i) apply a full thread design instead of the current thread lug design and ii) increase the Luer barrel diameter
- Change the raw material used for the involved parts in order to increase the resistance against fatty acids included in the various enteral formula.

Nutricia is committed to implement these changes as soon as possible, respecting appropriate validations and regulatory necessities (CE marking). At current, timelines for validation of these changes and actual time-to-market are not set yet, though it anticipated that improved adaptors will be available in the market as of March 2016.

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.

Yours faithfully,

Contact reference person

Unitied Kingdom, Ireland
Nutricia Ltd
Ms Michelle Forster
White Horse Business Park
BA14 0XQ
Trowbridge, Wiltshire
United Kingdom
michelle.forster@danone.com

EU/ non-UK Territory
Nutricia Medical Devices BV
Mr Michel Lombaerts
Schiphol Boulevard 261
1118 BH Schiphol Airport
The Netherlands
michel.lombaerts@danone.com

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

Mr. ME Lombaerts – RA Manager Nutricia Medical Devices