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IMPORTANT UPDATE

Dear Healthcare Professional,

Nutricia has initiated a Field Safety Notice (FSN) for the Flocare Infinity II enteral feeding pump (“Infinity II Pump”).

This Field Safety Notice is a precautionary measure and there are no known issues with the Infinity II Pump in the UK and Ireland.

However, we wanted to make you aware that we are currently investigating five instances in France where patients using the Infinity II Pump experienced an unexpected, unnoticed disruption in the delivery of their enteral feeding therapy.

Patient safety is always our number one priority. Therefore, as a precaution, we are updating the guidance on using the Infinity II Pump for enterally tube fed patients to include additional points, as summarised below.

Other than to acknowledge the FSN and apply the additional precautions where required, there is no action required.

Full details of the precautions can be found in the FSN document. In summary:

- Please ensure that all mixed or reconstituted nutrition is prepared and dissolved properly. Any nutrition added into the feeding line must be of a homogenous nature, as bigger particles or high viscous foods can result in blockages in the feeding line.
- For volume & nutrient sensitive patients:
 - put additional surveillance in place to verify programmed therapy is delivered as expected
 - set the pump alarm volume to the appropriate level for the environment it is operating in

Please see attached the notice for full details and the required FSN acknowledgment details. Please return the signed acknowledgement to support.ireland@nutricia.com

It is important to reiterate that in the UK and Ireland there are no known issues to date with the Infinity II Pump and there is a robust safety and reporting process for all Flocare Infinity pumps. Training patients and healthcare professionals on all aspects of pump use, along with routine servicing, is a core part of our service and ensuring you are aware of any changes or issues is a part of this.



If you have any questions in the meantime, please contact us support.ireland@nutricia.com

Yours faithfully,

A handwritten signature in black ink that reads "Killian Barry". The signature is written in a cursive style with a large, sweeping "K" and "B".

Killian Barry
Managing Director