Urgent Field Safety Notice

Granumix *plus* / DIAMIX system – Prepared acid concentrate out of specification

Date: March 25th, 2019

Affected article numbers:

F00003333	Granumix *plus*	in combination with:	
8002571	Diamix ACF 213/4 (193 l)	8009571	Diamix A2 3 25 52 (193 l)
8001571	Diamix ACF 219/1 (193 l)	F00001840	Diamix A2 4 25 52
8004571	Diamix ACF 313/1 (193 l)	F00004888	Diamix ACF 313/5 (193 l)
8003571	Diamix ACF 313/2 (193 l)	F00003372	Diamix ACF 219/1 (193 l)
8006571	Diamix ACF 413/1 (193 l)	F00003384	Diamix ACF 213/4 (193 l)
8005571	Diamix ACF 419 (193 l)	F00003386	Diamix ACF 313/1 (193 l)
8008571	Diamix A2 2 25 52 (193 l)		

To whom it may concern,

During the continuous monitoring of our Granumix *plus* / DIAMIX acid concentrate preparation systems on the market, Fresenius Medical Care has become aware of occasionally incorrectly mixed acid concentrate preparations. In some cases an undissolved residue remained in the DIAMIX barrel after the preparation process has been completed. This led to a wrong composition of the acid concentrate, which in turn resulted in conductivity alerts on the connected hemodialysis machines. The root cause for this failure is still under investigation.

According to our internal assessments, there is a potential risk that serious electrolyte and/or pH disorders may occur in treated patients if incorrectly composed acid concentrate is used for hemodialysis treatments. In most cases a wrongly composed acid concentrate will be detected by the dialysis machine. As a measure to further reduce patient risk, Fresenius Medical Care will provide a DMA 35 density meter to all Granumix *plus* / DIAMIX users to confirm the correct composition of the concentrate before usage for treatment.

Until now, no incidents with serious patient harm have been reported to Fresenius Medical Care.

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General Partner: Fresenius Medical Care Management AG, Registered Office and Commercial Register: Hof an der Saale, HRB 3894
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Per our records you are currently using a Granumix *plus* / DIAMIX system for acid concentrate preparation. Affected devices can be continued to be operated per the below instructions:

- In case the prepared concentrate is used together with a hemodialysis machine with **conductivity**-controlled-proportioning, it is mandatory to confirm the correct composition of the acid concentrate by a density measurement with a provided DMA 35 density meter or by laboratory test.

- If the prepared concentrate is used together with a hemodialysis machine with **volume**-controlled-proportioning, the probability for the detection of an incorrectly composed concentrate is increased. Nevertheless, the DMA 35 density meter or a laboratory test should be used to verify acid concentrate preparations before usage.
  The following Fresenius Medical Care hemodialysis machines use volume-controlled-proportioning:

4008 B	5008
4008 H	5008S
4008 S	6008

If it is not possible to comply with these above mentioned instructions, we recommend to immediately stop using the affected Granumix *plus* / DIAMIX system for acid concentrate preparation.

In case it is not clear which type of concentrate proportioning your hemodialysis machine is using, please consult with the manufacturer.

Attached to this Field Safety Notice you will receive an IFU addendum that provides additional guidance on the sampling and evaluation of the composition measurement results.

Please excuse the inconvenience caused by this matter. A Fresenius Medical Care representative will proactively contact you to provide you with a density meter and the necessary instructions for use.

Please forward this Urgent Field Safety Notice to those in your organization who require this information.

Should you have any questions, please feel free to get in touch with us:

Name: xxx
Telephone: xxx
E-mail: xxx

Sincerely yours,