

Update to Field Safety Notice

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

Date: January **XX**th, 2020

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,

In April 2019 Fresenius Medical Care issued an Urgent Field Safety Notice regarding undissolved residue remaining in the DIAMIX barrels after the preparation process with the Granumix *plus* 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.

As a measure to reduce the patient risk it was decided to provide a DMA 35 density meter to all Granumix *plus* / DIAMIX users to confirm the correct composition of the concentrate before usage for treatment. Attached to the Field Safety Notice was an IFU addendum, that provided additional guidance on the sampling and evaluation of the composition measurement results.

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

Investigations undertaken since the initial Field Safety Notice was issued, did not elucidate a clear root cause for the incomplete dissolution of the concentrate by the Granumix *plus* / DIAMIX system. Fresenius Medical Care therefore decided to

keep the density measurements as a robust tool to ensure the quality of the prepared concentrate. Based on this decision, the information from the initial IFU addendum will remain in effect.

Per our records you are using a Granumix *plus* / DIAMIX system for acid concentrate preparation. Due to the above considerations affected devices can only continued to be operated after the prepared acid concentrate has been verified by a density measurement. If it is not possible to comply with these instructions, we recommend to immediately stop using the affected Granumix *plus* / DIAMIX system for acid concentrate preparation.

Please forward this update to the 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,