



Fresenius Medical Care

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Field Safety Notice concerning 4008 Paediatric Bloodlines:

AV-SET FMC PAED S (6014611)

Lot no.: QDE143, QEE025, QEE283, QGE096, QHE108, QHE269, QIE196, QIE197, QKE309, QKE313, QME108, QME234, RBE167, RBE172, RFE201, RGE309

Dear Customer,

During the continuous monitoring of our bloodlines on the market, we have become aware of single cases of leakage between the arterial bubble catcher and the connecting tubes of the bloodline. Results of our investigations have indicated an insufficient gluing between the arterial bubble catcher and the connecting tubes of the bloodline (see picture 1).

In most reported cases the leakage was detected during priming, in the preparation phase. However, there might be a potential risk for the patient if defect bloodlines are used. To our knowledge up to now no patient has been affected.

Fresenius Medical care is committed to offering quality products and superior customer service. Therefore we have decided to inform all our customers and to replace the involved lot numbers distributed in the market as soon as new batches are available.

In the meantime **we strongly recommend that you examine the bloodlines carefully before use and do not use any lines which are defective.**

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Defective bloodlines can be identified by means of visual inspection as follows:

Take the bloodline out of the blister and check the proper connection of the arterial bubble catcher and the attached tubes (see picture 1).

- a. If the highlighted area is transparent, the bloodline can be used safely and effectively (see picture 2).
- b. If the highlighted area is dull, the bloodline is defective and must not be used (see picture 3).

We are working intensively to solve the problem in order to ensure highest quality standards for our customers. You will be contacted by your local Fresenius Medical Care representative to organize the replacement of the affected bloodlines.

Please make sure that all users of the above mentioned bloodlines in your organization and other concerned persons are informed about this Field Safety Notice.

We sincerely apologize for the inconvenience. In case of any further questions do not hesitate to contact your local Fresenius representative:

Name: Mr Tony Newsham, Director of Regulatory Affairs

Telephone: 01623 445 171

E-mail: tony.newsham@fmc-ag.com

Yours sincerely

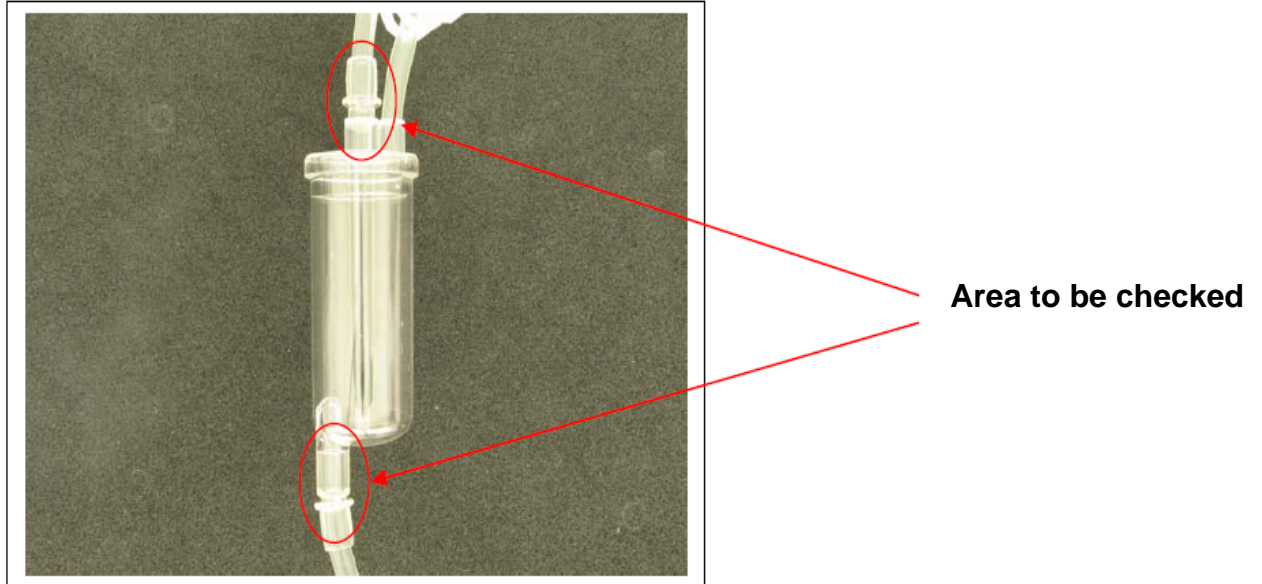
Tony Newsham
Director of Regulatory Affairs

Fresenius Medical Care (UK) Limited

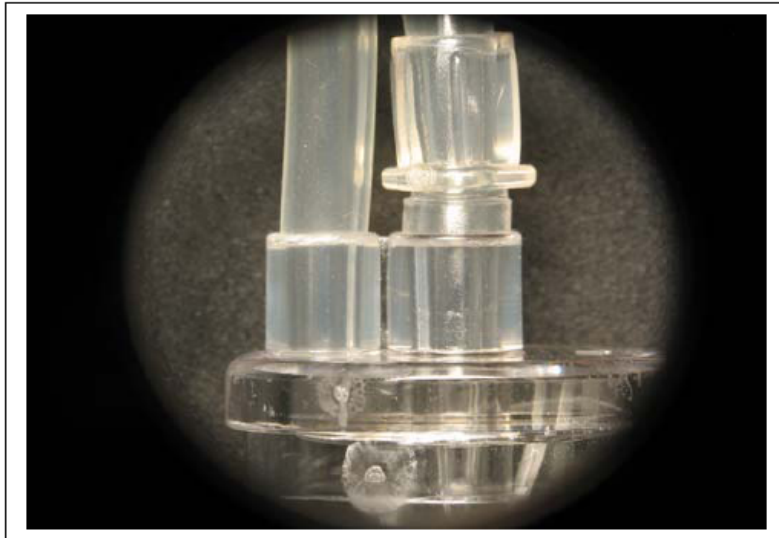


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Picture 1: Arterial bubble catcher



Picture 2: Safe connection (transparent)

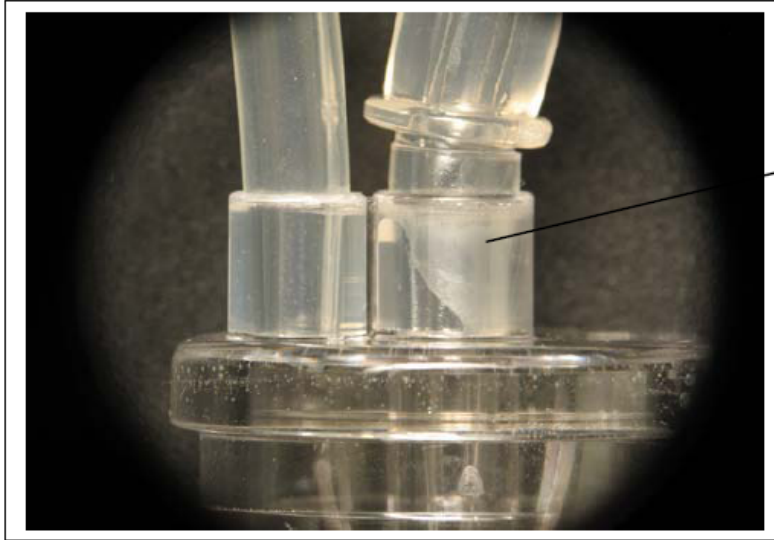


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Picture 3: Defective gluing (dull)



Dull area

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Code	Description	Affected lots
6014611	AV-Set FMC Paed S	QDE143
6014611	AV-Set FMC Paed S	QEE025
6014611	AV-Set FMC Paed S	QEE283
6014611	AV-Set FMC Paed S	QGE096
6014611	AV-Set FMC Paed S	QHE108
6014611	AV-Set FMC Paed S	QHE269
6014611	AV-Set FMC Paed S	QIE196
6014611	AV-Set FMC Paed S	QIE197
6014611	AV-Set FMC Paed S	QKE309
6014611	AV-Set FMC Paed S	QKE313
6014611	AV-Set FMC Paed S	QME108
6014611	AV-Set FMC Paed S	QME234
6014611	AV-Set FMC Paed S	RBE167
6014611	AV-Set FMC Paed S	RBE172
6014611	AV-Set FMC Paed S	RFE201
6014611	AV-Set FMC Paed S	RGE309
6014621	AV-Set FMC BVM/BTM Paed S	QDE148
6014621	AV-Set FMC BVM/BTM Paed S	QEE027
6014621	AV-Set FMC BVM/BTM Paed S	QFE262
6014621	AV-Set FMC BVM/BTM Paed S	QGE097
6014701	AV-SN-Set FMC Paed/Baby S	QME236
6014701	AV-SN-Set FMC Paed/Baby S	RBE176
6014711	AV-SN-Set FMC Paed S	QEE031
6014711	AV-SN-Set FMC Paed S	QEE033
6014711	AV-SN-Set FMC Paed S	QHE103
6014711	AV-SN-Set FMC Paed S	QHE104