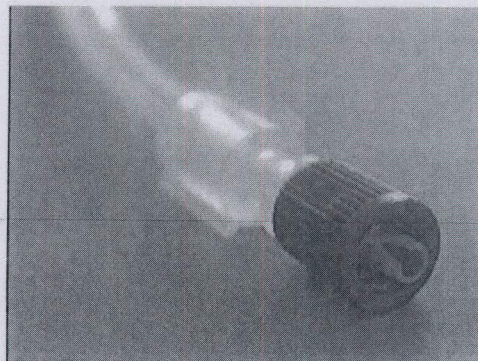


FIELD SAFETY NOTICE**POTENTIAL GAMBRO AK SERIES SINGLE NEEDLE LINE AIR INTAKE****BLD_FSN_01_14_GD****11 March 2014**

Dear Customer,

Gambro is sending you this communication to advise you of a possible defect on certain lots of Gambro Single Needle Bloodlines for AK machines that involves a potential bonding of the venous male luer with the drain bag connector and/or of the arterial male luer with the spike connector.

When this occurs, the cone of the luer may be damaged if the operator forces the disconnection of the bonded luer. In most cases, this condition is identified before or during patient connection, and prior to the start of treatment, thus preventing any risk for the patient.



Performing a treatment with a damaged luer connection could result in an intake of air into the bloodline which could potentially reach the patient and would not pass through the "air in blood" protective system of the dialysis machine.

The present field safety notice is applicable for the following Gambro bloodlines models, for the batch numbers in the table reported below:

Product Name	Product Code	Batch numbers
BL148 SN	114524	From batch number 1317 to 1350
BL 211 B SND	114561	From batch number 1316 to 1401
BL130 PSN	114527	From batch number 1316 to 1321

Gambro has received no reports of serious injury or harm to patients in connection with this issue and has implemented corrective actions to eliminate the defect from occurring.

Due to the potential risk associated with the use of the affected lines, we are requesting that you do not use products from the above lot numbers but, instead, use product from different lots or similar product as available. The affected product will be collected and replaced by Gambro.

If you do not have alternative product on-hand, please immediately contact your Gambro representative to have the product from the above listed lots exchanged with replacement product.

Should you have the urgent need to use products from the above mentioned lots before receipt of replacement product, please check the connection between the venous male luer and the drain bag and the connection between the arterial male luer and the spike for priming bag before using the set. Please discard the sets with bonded connections.

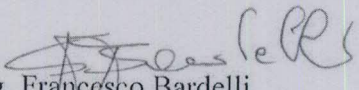
FIELD SAFETY NOTICE**POTENTIAL GAMBRO AK SERIES SINGLE NEEDLE LINE AIR INTAKE**

Gambro is committed to maintaining the continuity of care for patients relying on receiving these lifesaving treatments and to ensuring the safety and effectiveness of its products.

Please return the attached **Customer Reply Form** to Gambro to confirm that you have received this Field Safety Notice and that you and all involved operators have been informed of this potential risk.

We have advised the relevant Competent Authorities of this Field Safety Notice.

We are available to personally answer any questions you may have regarding this issue and the proposed actions. Please contact your local Gambro sales office/distributor.


Ing. Francesco Bardelli
Senior Director QA/RA Disposables Operations