



Urgent Field Safety Notice – Ref. MEY-2012-01

Prismaflex/Prisma ST Sets Recall
- Field safety corrective action / Lot specific -

2012-04-03

Dear Customer,

Gambro has learned of a small number of internal blood leaks occurring during treatment with certain Prismaflex® ST 100/150 sets. A similar problem might also occur with one lot of Prisma® ST 100 sets. This situation may be caused by one or more damaged fibers in the filter which allow minute amounts of blood to pass into the effluent. When this happens, the Prismaflex or Prisma monitor will automatically trigger a “Warning: Blood Leak Detected” alarm and will stop all the pumps. In response, the user should change the set and, whenever possible, return the blood from the set to the patient according to the Instructions For Use for the sets, thereby avoiding any blood loss.

Gambro takes its responsibilities to its customers and their patients very seriously and requests that you take the following actions:

Potentially Affected Lots

Gambro has determined that the following lots of Prismaflex ST 100/150 and/or Prisma ST 100 sets may be affected:

Product	Lot
PRISMAFLEX ST 150 SET	12A2404G
PRISMAFLEX ST 100 SET	12A2504
PRISMAFLEX ST 100 SET	12A2505
PRISMAFLEX ST 150 SET	12A3006G
PRISMAFLEX ST 150 SET	12A3104
PRISMAFLEX ST 100 SET	12B0105
PRISMAFLEX ST 150 SET	12B0608G
PRISMAFLEX ST 100 SET	12B0703G
PRISMAFLEX ST 150 SET	12B1305G
PRISMAFLEX ST 150 SET	12B1405
PRISMAFLEX ST 100 SET	12B1406
PRISMAFLEX ST 150 SET	12B2104G
PRISMA ST 100 PRE	12A2403

Actions to be taken

- ❖ If you have any remaining units of Prismaflex ST or Prisma ST sets from the above mentioned lots, please remove them from inventory and place them in quarantine for collection and replacement; please do not use them in any treatment
- ❖ Provide the requested information in the attached Customer Reply Form and return it to your Gambro sales office

- ❖ Bring this notice to the attention of all who need to know or be aware of it within your facility, and to any third party to which any products from the affected lots may have been transferred
- ❖ Maintain awareness of this notice internally until all actions have been completed within your facility

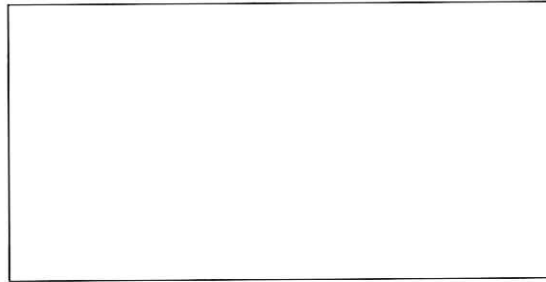
Attachment

- ❖ Customer Reply Form

If you take the actions recommended in this notice, there is absolutely no risk of any harm to the patient.

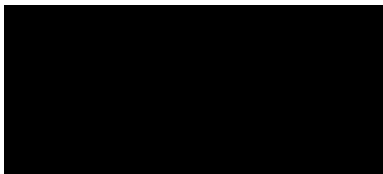
A Gambro representative will contact you to discuss the replacement of product from the affected lots. Gambro sincerely apologizes for any inconvenience this may cause you and your patients.

Should you have any questions or require any further assistance, please contact your Gambro sales office:

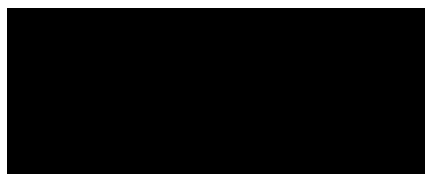


Sincerely yours

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General Manager



Director QA/QC