

FIELD SAFETY NOTICE: BE-ECLS 2.8 SET
2013-06-24

PLEASE FORWARD THIS INFORMATION TO ALL USERS AND BIOMEDICAL STAFF CONCERNED.

Product: BE-ECLS Set
Model Number: BE-ECLS 2.8 set
Affected Lot Numbers: 70084465, 70088588 and 70091932

Dear Customer,

This letter is to inform you that Maquet Cardiopulmonary AG has initiated a product recall involving the BE-ECLS 2.8 set. The affected lot numbers are 70084465, 70088588 and 70091932.

Intended Use of Device:

The BE-ECLS 2.8 set is intended for use as an extracorporeal pulmonary support or a cardiovascular support or as a simultaneous cardiovascular and pulmonary support.

Maquet Cardiopulmonary AG is recalling the devices due to a possibility that the male quick coupling connected to the red arterial line and the female quick coupling connected to the blue venous line of the priming bag may be interchanged. This failure makes the connection of the priming bag to the red and to the blue line of the main circuit for the priming procedure impossible.

Corrective Actions:

Please take the following corrective actions immediately:

- Review your current stock and identify if you have any devices from the affected lots remaining in your inventory.
- Should you have any of this product in your stock, please do not use it and instead, remove the product from clinical use.
- Complete and return the enclosed Letter of Acknowledgment and the list of affected products and lot numbers to your local MAQUET representative to acknowledge receipt and understanding of this notification and to document the current status of devices shipped to your facility; i.e., the number of devices remaining in your inventory.

Your MAQUET sales representative will contact you regarding return and replacement of product remaining in your inventory.

We apologize for any inconvenience this may cause. If you have questions or require additional information, please contact your local MAQUET representative or MAQUET Customer Service.

Yours sincerely

MAQUET Cardiopulmonary AG



Dr. Wolfgang Rencken
President



Arne Briest
Safety Officer Medical Devices

Attachment:

- Letter of Acknowledgement Customer
- List of affected products