MAQUET
GETINGE GROUP

FIELD SAFETY NOTICE
2013-09-13

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

Product: **Pediatric arterial cannula**
Model Numbers: **161408**
Affected Lot Numbers: 92078145

Dear Customer,

This letter is to inform you that Maquet Cardiopulmonary has initiated a product recall
involving the Pediatric arterial cannula Model Number 161408 Lot 92078145.

Intended Use of Device:

The Pediatric arterial cannula are used to introduce blood and sterile solutions into the
systemic circulation during extracorporeal circulation procedures.

Maquet CardioPulmonary AG is recalling the devices due to a possibility that the
indication on the label may not be correct as it pertains to the size of the cannula
adapter. This may create a higher risk of vessel-damaging or the need of replacement of
the cannula during surgical intervention.

Corrective Actions:

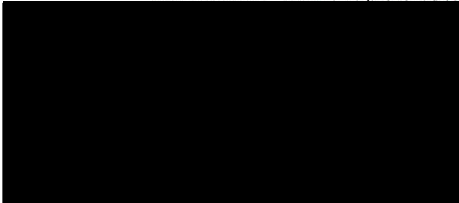Please take the following corrective actions immediately:

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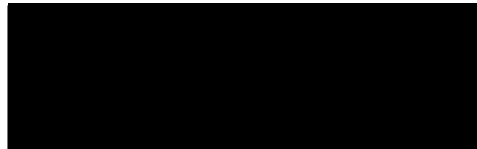
We apologize for any inconvenience this may cause. If you have questions or require additional information, please contact your local MAQUET representative or MAQUET Customer Service.

Yours sincerely

MAQUET Cardiopulmonary AG

President

Safety Officer Medical Devices

Attachment:
- Letter of Acknowledgement Customer
- List of affected products