MAQUET
GETINGE GROUP

URGENT DEVICE RECALL
AUGUST 2, 2013

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

Subject: **MAQUET Oxygenators**

Products affected:

Adult version for the following product:

QUADROX-i oxygenators,-

QUADROX-iD (SOFTLINE and BIOLINE coating)

QUADROX-iR (SOFTLINE and BIOLINE coating)

PLS module (SOFTLINE and BIOLINE coating)

Lot Numbers: See Attachment I for Part Number Details

Dear Customer,

As you know, MAQUET has on ongoing Field Safety Notification regarding its oxygenators which includes use of a reusable mechanical clamp to provide a protective safeguard against the possible failure mode associated with the oxygenator's inlet and outlet ports not remaining in place. This letter is to inform you that MAQUET Cardiopulmonary (MCP) is now initiating a product recall involving specific lots of its oxygenators (see attached list for details).

Internal testing conducted by MCP has indicated that specific oxygenator lots manufactured between July 16, 2012 and August 8, 2012 may not meet product specifications. Specifically, internal testing conducted by MCP indicates that the outlet or/and inlet connector port of the unit may dislodge and separate from the main body of the oxygenator.

Please note that this recall pertains to specific lots of oxygenators. Users need to continue to use the reusable mechanical clamp provided by MAQUET with all remaining MAQUET QUADROX oxygenators currently in distribution. The specific lots within this recall may have an increased tendency for separation as indicated in the internal testing results.

A review of our records indicates that you may have purchased and currently have a MAQUET oxygenator affected by this recall in your inventory.

Corrective Actions:
Please take the following corrective actions immediately:

- Please review your current inventory and determine whether you have any devices from the affected lots remaining in your inventory.

- If you determine that you have any of this product in your inventory, please do not use the oxygenator and instead, remove the product from any potential clinical use.

- Please complete the enclosed Letter of Acknowledgment Form acknowledging receipt and understanding of this notification and documenting the affected oxygenators remaining in your inventory. Please return the completed Letter of Acknowledgment by sending a scanned copy to your local MAQUET Sales office.

Your MAQUET Sales Representative will contact you shortly to assist with the return of any unused oxygenators and the associated issuance of a credit.

Yours sincerely
MAQUET Cardiopulmonary AG

Dr. Wolfgang Rencken
President

Arne Briest
Director
QA & QM

Attachment:
Letter of Acknowledgement Customer
Attachment 1