

**UPDATED FIELD SAFETY NOTICE
MARCH 04, 2013**

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

Subject: MAQUET Oxygenators – Blood outlet connector

Products affected:

All sizes and membrane types of QUADROX-i oxygenators, (excluded HLS oxygenators)

i.e. QUADROX-i(D) Adult, Small Adult, Pediatric and Neonatal with SOFTLINE and BIOLINE Coating

- PLS-i gas exchanger in PLS Sets**
- PLS-i gas exchanger in HIT PLS Sets**
- QUADROX-iR with SOFTLINE and BIOLINE Coating**

Dear Customer,

In May 2012, MAQUET announced a field corrective action regarding the blood outlet connector on the above referenced Maquet oxygenators. At that time, we reported that in some rare cases, the blood outlet connector may detach from the oxygenator housing. Following implementation of improvements in the manufacturing and as a result of the field corrective action in May 2012, the event occurrence has changed from less than 0,01% (1:10.000) to less 0.001% (1:100,000) of units shipped.

Please be aware that MAQUET was recently notified of an event in which the patient expired following an apparent detachment of the oxygenator connector after approximately 5 days of use. Based upon the information available to us at that time, the reported failure may be related to the scenario described in the May 2012 communication.

MAQUET is implementing both a short term and long term corrective actions to address the issue. MAQUET will be providing users with a stainless steel retainer clamp. The clamp is intended to hold the oxygenator's outlet and inlet ports in place and is an additional protective measure against the possible failure mode. The clamp will be provided to all oxygenator customers following validation. We anticipate the availability in March 2013.

Longer term we are developing a mechanical fitting to replace the current glue joint. The availability of the permanent mechanical fitting solution is expected to be implemented late this year.

Until such time as the clamp is validated and available for clinical use, MAQUET wishes to emphasize that all oxygenator users maintain a high degree of vigilance during use. Also, as previously noted in our earlier communication, MAQUET recommends that

users confirm the integrity of the connector prior use by manually attempting to manipulate the connector in the housing. If the connector is secure in the housing, use the device in accordance with the Instructions for Use. If the connector feels loose or appears to be cracked, please set it aside in favor of another unit. Maquet will immediately replace any suspect oxygenators which you identify.

Please note that there is a brief video available which illustrates a clinician confirming the integrity of an oxygenator (<http://www.maquet.com/quadroxjune2012>).

Please do not hesitate to contact your local MAQUET representative should you have any questions.

Please return the Letter of Acknowledgement latest by April 12, 2013 to your local Maquet representative or by emailing to quality.assurance.cp@maquet.com, or returning the completed form via fax at +49-7478-9218222.

Please do not hesitate to contact your local MAQUET representative in the case of any questions.

Yours sincerely
MAQUET Cardiopulmonary AG



Dr. Wolfgang Rencken
President



Arne Briest
Director
Quality Assurance

Attachment:
Letter of Acknowledgement Customer