

**FIELD SAFETY NOTICE**  
**2012-05-25**

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, 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**
- **HLS module 5.0 and 7.0 in HLS Sets**
- **HLS module 5.0 and 7.0 in HIT HLS Sets**

Dear valued Customer,

It has come to our attention that, in some rare cases, the blood outlet connector on the Maquet oxygenators referenced above may detach from the oxygenator. This event has occurred in about 0.01% (1:10.000) of units shipped.

Based upon the results of our investigation to date, we have concluded that in an extremely small number of cases the blood outlet connector adhesive has not maintained its bonding properties, and thus the connector came loose from the oxygenator housing.

We realize that you may currently have Maquet oxygenators in inventory, and that you prefer the Maquet oxygenator as your product of choice. Therefore, we recommend that *prior to use*, you confirm the integrity of the blood outlet connector (clearly protected by the red protection cap) by manually attempting to manipulate it 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 in the unlikely event that the connector detaches from the oxygenator during use, replacement of the oxygenator is required.

Pending the results of our final investigation, we will provide a follow up communication.

Please complete and return the Letter of Acknowledgement Customer latest 8<sup>th</sup> June 2012 to your local Maquet representative.

We apologize for any inconvenience that this may cause. If you have any questions, please do not hesitate to contact your local MAQUET representative.

Yours sincerely  
MAQUET Cardiopulmonary AG



Dr. Wolfgang Rencken  
President



Andreas Maurer  
Director  
Quality Assurance & Regulatory Affairs

Attachment:  
Letter of Acknowledgement Customer