MAQUET
GETINGE GROUP

# FIELD SAFETY NOTICE
# 2014-01-27

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

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| **Product:** | **PLEGIOX Cardioplegia Heat Exchanger** |
| **Model Numbers:** | **see attached list** |
| **Affected Lot Numbers:** | **see attached list** |

Dear Customer ,

The MAQUET post-marketing vigilance program has identified a discrepancy that the desired cardioplegia temperature may not be obtained when the PLEGIOX Cardioplegia Heat Exchanger (PLEGIOX) is used in conjunction with a heater/cooler unit. Isolated field reports have indicated that a user could not reach a desired low cooling temperature of cardioplegic solution, as the measured value of the cardioplegia temperature by the probe on the PLEGIOX did not match the set temperature on the heater/cooler unit. This variation has been attributed to the position of the temperature probe at the port on the PLEGIOX, which may lead to temperature readings differing to a varying degree from the real temperature of the cardioplegic solution. We are notifying all customers who have received the affected PLEGIOX lot numbers listed in the attachment.

Issue Description:

The PLEGIOX Cardioplegia Heat Exchanger is used as part of a cardioplegia system to set and maintain temperature (for given flow rates and within the given temperature range) of blood cardioplegic and crystalloid cardioplegic solutions during extracorporal circulation. The discrepancy between cardioplegia temperature measured at the probe of the PLEGIOX and set water temperature on the heater/cooler unit may appear greater than typical during clinical use of the heater/cooler system. This excess temperature difference is attributed to the positioning of the temperature probe within the fluid path to measure the temperature of the solution outflow from the heat exchanger.

Based upon the results of our investigation to date, we have determined that selected lots of the PLEGIOX units manufactured between April 2013 and January 2014 (see attached list) may be affected. The root cause was determined to be a change to a molded component that may restrict the depth the external temperature probe can be inserted into the unit.

In house testing has determined that the difference between the real solution temperature and the measured solution temperature may be up to 3 degrees Celsius at a flow rate of up to 500 ml/min.

This action is being taken to notify PLEGIOX Cardioplegia Heat Exchanger users that a temperature misreading may exist but that the performance of the PLEGIOX Heat Exchanger is unaffected and has not changed. Clinicians are also advised not to solely rely on the measured temperature at the probe on the PLEGIOX Cardioplegia Heat Exchanger, and utilize other available measurements or clinical observations to determine desired clinical endpoints for the lots indicated in this Field Safety Notice. It must be emphasized that no adverse patient consequences related to this discrepancy have been

reported at present and all appropriate regulatory agencies have been notified of this issue.

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

Hartmut Schmidt
President

Arne Briest
Safety Officer Medical Devices

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