

FIELD SAFETY NOTICE

2014-07-22

(UPDATE TO FSN 2014-01-27 AND FSN 2014-03-07)

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

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 previously notified you of a functional discrepancy with the PLEGIOX Cardioplegia Heat Exchanger (PLEGIOX) is used in conjunction with a heater/cooler unit. This was based on 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.

We have now been able to produce defect-free products and are requesting that you block all remaining inventory that you may have of the products shown in the attached list and return them to your local MAQUET office. You can also order replacement supplies from your local MAQUET representative.


We apologize for any inconvenience these action may have caused. 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
Managing Director, CEO



Michael Campbell
Safety Officer Medical Devices

Attachment:

- Letter of Acknowledgement Customer
- List of affected products