MAQUET
GETINGE GROUP

September 27, 2016 via FEDEX

URGENT MEDICAL DEVICE RECALL
FIELD SAFETY NOTICE
HEATER-COOLER UNIT (HCU 30)
DECONTAMINATION PROCEDURE FOR HEATER-COOLER UNITS

All Product Distributed Since December 30, 2004

PLEASE FORWARD THIS INFORMATION TO ALL USERS, PERFUSIONISTS, AND STAFF WHO MAY USE AND/OR MAINTAIN MAQUET HEATER-COOLER UNITS.

Dear Risk Manager,

The purpose of this letter is to advise our customers that Maquet Cardiopulmonary ("MCP") as well as European Health Authorities have received reports confirming the presence of Mycobacterial contamination (and other bacterial contamination) in the system water of Heater-Cooler devices, used to warm or cool a patient during short-duration cardiopulmonary bypass procedures.

Although the water in the Heater-Cooler Unit circuits does not come into direct contact with the patient, there is the potential for contaminated water to enter other parts of the device or transmit bacteria through the air (aerosolize) via the device's exhaust vent into the environment and to the patient.

MCP has confirmed that Maquet Heater Cooler Units may become contaminated with various strains of bacteria that also include Mycobacteria species. However, there have been no reported adverse events, diseases or illnesses associated with Mycobacteria contaminations. Maquet has not received any reports of patient Mycobacteria infections resulting from surgery involving Heater Cooler Units.

Reason for the Field Safety Notice:

MCP has determined that Maquet Heater-Cooler Units may possess the potential for bacterial contamination to occur. You are being contacted because you have been identified as a device user of one or more Maquet Heater Cooler Units.

Actions to be taken by the Device User:

In case of suspected bacterial contamination of the HCU 30 unit, we recommend taking the unit out of operation at the earliest opportunity, emptying the system water and performing the recommended cleaning per the cleaning instructions in the User's Manual.

Preventative measures within the framework of common and recommended hospital hygiene reduce significantly the risks of bacterial transmission after contact with contaminated system water. The measures include the following:

- use of gloves,
- use of sterile filter for filling the units,
- regular water changes,
- cleaning of the units, and
- continuing to monitor the hygiene (contamination level) in accordance with your internal practices.

Users should continue to follow the User's Manual provided with the Heater-Cooler Unit.

Maquet Cardiopulmonary is currently developing new hygiene protocols for its Heater-Cooler units. These new protocols include preventative measures, routine disinfections as well as high level disinfections and biofilm reductions - also effective against atypical Mycobacteria in the water systems. The newly developed disinfection procedures will take a holistic approach based on validated methods.

It is important to note that the product is **not** being removed from the field.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form
- **Fax**: 1-800-FDA-0178

If you are a distributor who has shipped any affected products to customers, please forward this document to their attention for appropriate action.

Please acknowledge receipt of the Urgent Recall Medical Device Notice by completing and returning the enclosed response form. Please either fax the completed form to 1-973-629-1518 or send via email to HCU30@maquet.com.

We apologize for any inconvenience that this may cause to you or your patients. For any questions, please contact your Maquet sales representative or Maquet Customer Service at 1-888-627-8383 (press option 2, followed by option 2) Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. EST.

Thank you for your cooperation and immediate assistance.

Sincerely,

Karen LeFevere

Karen LeFevere
Director Regulatory Affairs and Quality Compliance Field Actions
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