

Urgent!

Field Safety Corrective Action (FSCA)

30 November 2015

FSCA Number: FSCA-2015-11-30

FSCA Title: Revised decontamination procedures for Heater and Heater/Cooler Systems

Affected Product: HU35, HCU20, HCU30, HCU40 Systems

Unique Device Identification (UDI Code): Not Assigned

Affected product details: The FSCA affects all models and all serial numbers of the above referenced devices

Description of the problem: Maquet Cardiopulmonary as well as the National Competent Authorities in multiple countries have received reports confirming the presence of Mycobacterial contamination (and other bacterial contaminants) in the system water of Heater and Heater/Cooler devices. This system water is used in the direct patient warming and or in heat exchangers used to warm the patient blood during surgical procedures (cardiac bypass procedures). Maquet Cardiopulmonary has confirmed that Maquet systems used in these procedures are contaminated with various strains of bacteria that also include Mycobacteria species. The exact source of this contamination is unknown.

Our internal investigations have confirmed that the current published cleaning and or decontamination procedure (in the Instructions for Use) is not sufficient and may not completely remove the contamination and or resulting Biofilm that may accumulate over time in contaminated systems.

Although there is a specific risk that the contamination can be transferred to patients, Maquet Cardiopulmonary has received no reports that this contamination has been confirmed in a patient treated with one of the above listed devices. Maquet have not received any reports of patient injury or death associated with this issue.

Corrective Action: The current published Instruction for Use for these devices should be replaced with the attached updated procedure which outlines a new procedure for the routine cleaning and or decontamination for these systems. All staff involved in the operation and or maintenance of these systems should be informed to incorporate this revised instruction into their internal operating and or hygiene control procedures as relates

to these systems.

**Advice on action to be taken
by the user:**

Complete and return the enclosed Acknowledgement Form as soon as possible to your local Maquet representative.

Incorporate this revised procedure into your operating processes

Conduct any training necessary for the revisions

Continue to monitor the hygiene (contamination levels) in accordance with your internal practices

Immediately report any contamination finds to your local Maquet representative.

**Referenced
documents/attachments:**

Acknowledgement Form

Individual Revised Cleaning/Decontamination Procedures for each affected system

Transmission of the Field Safety Notice:

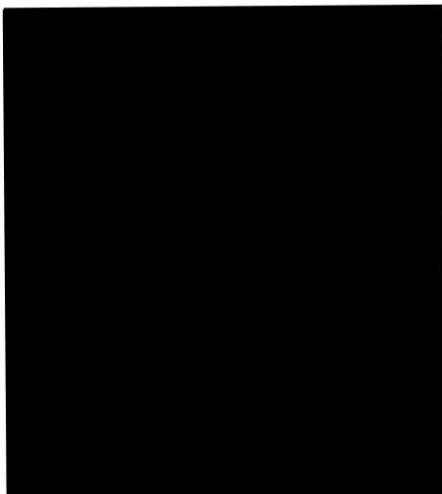
- This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- Please transfer this notice to other organizations on which the action has an impact.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

We apologize for any inconvenience this may cause you and we will do our utmost to carry through this action as swiftly as possible.

As required, we have provided this notification to the necessary Regulatory Agencies.

Should you have questions or require additional information, please contact your local MAQUET representative.

Sincerely,



Maquet Cardiopulmonary AG
Kehler Str. 31
76437 Rastatt
GERMANY