

Urgent!
Field Safety Corrective Action (FSCA)

19th December 2015

FSCA Number:	FSCA-2015-12-19
FSCA Title:	Use of Hydrogen Peroxide in Heater-Cooler Systems with Maquet Oxygenators
Affected Product:	All Maquet Oxygenators (and cardioplegia heat exchangers)
Unique Device Identification (UDI Code):	Not Assigned
Affected product details:	N/A
Description of the problem:	<p>Update of Maquet letter concerning the Subject for The Use of Maquet Oxygenators with Sorin 3T heater-cooler systems containing hydrogen peroxide as additive was published on August 19, 2015.</p> <p>Toxicology referred in that letter was based upon estimated diffusion rates of hydrogen peroxide resulting in amounts of diffused hydrogen peroxide below the computed allowable limit (the largest amount of a leachable substance that is deemed acceptable on a daily basis) for the intraoperative exposure ≥ 1 hour and ≤ 6 hours.</p> <p>Additional testing has been performed to determine the diffusion rate of hydrogen peroxide through Maquet oxygenator heat exchangers after the release of the August 19, 2015 letter. These test results indicate that hydrogen peroxide diffuses through the TPU heat exchanger fiber for the period of 6 hours exceeds the computed daily allowable limits (AL):</p> <ul style="list-style-type: none">▪ AL for adults (60 kg body weight): 12.60 mg/day▪ AL for neonates (3 kg body weight): 0.63 mg/day <p>Maquet has not received any reports of incidents related to hydrogen peroxide and Maquet oxygenators.</p>

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

1. Do not use Hydrogen Peroxide in heater-cooler systems as a bactericidal agent in the tank water with Maquet oxygenators.
2. User should follow the Instructions for Use for Maquet oxygenators.

Note: Maquet's oxygenators, like others, incorporate heat exchangers made of polyurethane (TPU) hollow fibers.

**Referenced
documents/attachments:**

Acknowledgement Form

Transmission of the Field Safety Notice:

- This notice is directed to all those who received the “Individual Revised Cleaning/Decontamination Procedures for each affected system” – “Disinfection Procedures” and FSN dated 30. November 2015 of FSCA 2015-11-30.
- Please transfer this notice to other organizations that this action impacts.
- Please maintain awareness of this notice and resulting actions 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,



Gerhard Mayer

Chief Financial Officer

Peter Stein

Safety Officer

Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY

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MAQUET
GETINGE GROUP

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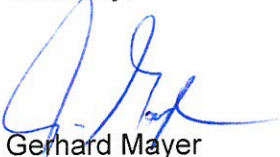
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