

SORIN GROUP DEUTSCHLAND GMBH · Lindberghstr. 25 · D-80939 München

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IMPORTANT INFORMATION
Cardiac Surgery Mycobacterium Risks
Disinfection and Cleaning of Sorin Heater Cooler Devices

Date: 14. July 2014
Reference No: IIS 9611109-07-14-14
Attention: **Hygiene Specialists, Cardiac Surgery Operating Room Responsible, Risk/ Safety Managers, Distributors, Clinicians, Perfusionist and other users of these devices**
Reason: Disinfection and cleaning of Heater Cooler Units

Dear Valued Customer,

We would like to bring to the attention of our customers a newly identified risk for cardiac surgery patients. Some cardiac surgery patients have been infected with a slow growing *Mycobacterium chimaera*. This risk was identified during investigations into these patient infections, root cause investigations are ongoing. Sorin takes the on-going investigations very serious and is participating with Swissmedic, Swiss Federal Office of Public Health, Swissnoso and the hospital where an in depth investigation is actually carried out. This risk is difficult to identify as current practices for monitoring the contamination of a cardiac surgery theatre may not identify the slow growing, chemically resistant organisms involved. *Mycobacteria* organisms are found in water, including tap water sources. Please find additional information on *Mycobacteria* in Attachment 1.

It is important to assure that your staff is aware of the *Mycobacteria* risk and to review your hygiene & surgical practices in the cardiac surgery theatre. This review should include your sampling and monitoring programs for your water sources, solution preparations and systems that use water in the cardiac surgery theatre. Among these water systems, heater cooler device(s) need strict adherence to the cleaning, disinfection and maintenance according to the operating manual (for Sorin devices, see Attachment 2). Without vigilant performance of the disinfection per the *Operating Instructions*, these organisms can multiply in a heater cooler device and potentially form biofilm. As you are aware, the water in the heater cooler devices is not intended to

have direct contact with the patient. One of the highest risks of contamination for the patient is a direct contact transfer of water/solution droplets containing *Mycobacteria* into the surgical field. Another risk that should be reviewed, is the air distribution within the cardiac surgery theatre as this can be a transmission method for *Mycobacteria*. The air conditioning as well as ventilation units including the heater cooler device fans need to be considered in that analysis.

During the investigation work it has been identified that some hospitals heater cooler devices are contaminated. By way of caution and as a safety measure, Sorin reminds its customers using heater cooler devices about the importance of adhering to the correct maintenance of the device at all times and in particular to assure that the cleanliness of the water in the device is maintained. If the water is not properly disinfected and maintained, microbiological growth can occur within the device and over time biofilm may form. We enclose hereto our latest version of the operating instructions for the 3T Heater Cooler Devices giving clear guidance on how the cleanliness of the water in the device is to be maintained. Please note that strict adherence to the instructions is mandatory for the safe use of the device.

You may continue to safely use the heater cooler devices in accordance with the Operator's Manual.

Recommendations:

- Review this information to assure that you are aware of proper water management in your cardiac surgery theatre. Specifically, assure that your team understands *Mycobacteria* and the potential contamination risks for cardiac surgeries. Introductory information is provided in Attachment 1.
- Review your heater cooler operating practices and cardiac surgery theatre water management practices. Also evaluate your heater cooler device(s) for potential contamination.
- Refer to the heater cooler device operator's manual and/or Attachment 2 and review the necessary disinfection practices to assure your practices are aligned with the directions.
- If you are concerned that your vigilance to the operating instructions may be in question, perform microbiological sampling of the water in your heater cooler device, disinfect the device and determine if decontamination is necessary.

Please complete and return the attached Confirmation Form (see Attachment 3) by fax to «Number» or by email to «E-mail Address».

Distribution of this Information:

Please assure this Important Information is distributed to all personnel who needs to be aware of this information. If you have transferred the affected products to a third party, please pass this information to them as well as informing Sorin Group Deutschland GmbH at +49 89 323 01 152 of the transfer.

A copy of this documentation has been provided to the appropriate Regulatory Agencies and they are aware of this measure by Sorin.



Contact reference person:

If you have any further questions please feel free to contact us. We will not fail to inform you in due course once further information particularly with regard the root cause of the observed infections are obtained.

For questions regarding this Important Information, please contact Christian Peis, Director QA, Sorin Group Deutschland GmbH at +49 89 323 01 152, via fax at +49 89 323 01 333 or via e-mail at SGD.fsca@sorin.com.

Thank you for your cooperation in this matter. Sorin Group is committed to provide quality products and service to its customers.

Sincerely,



i.V. Christian Peis
Director Quality Assurance Cardiopulmonary BU
Sorin Group Deutschland GmbH

Enclosures:

Attachment 1: Mycobacterium Data Sheet

Attachment 2: Disinfection Excerpt from the Operating Instructions for 3T Heater Cooler

Attachment 3: Customer Response Form