SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

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

«Name1»
«Name2»
«Name3»
«Address»
«Address»

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

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HRB 100852
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Attachment 1
Mycobacterium Data Sheet:
IMPORTANT INFORMATION

Sorin Heater Cooler Devices - Mycobacterium

Reference # IIS 9611109-07-14-14

FOR GENERAL HEALTHCARE STAFF - INTRODUCTION

- Mycobacteria are widely distributed in the ecosystem, are present in water, and even survive in chlorinated drinking water. Some species are classic human pathogens, for example *M. tuberculosis* that causes TB. However, most mycobacteria are not considered harmful to humans. These environmental mycobacteria are termed nontuberculous mycobacteria (NTM). These do occasionally cause opportunistic infections. (Van Ingen, J Med Microbiol, September 2012 vol. 61 no. Pt 9, 1234-1239).
- For example, *M. chimaera* was identified as the causative agent of a respiratory tract infection in patients with cystic fibrosis. (Cohen-Bacrie et al. Journal of Medical Case Reports 2011, 5:473).
- The various NTM species have greatly differing microbiological culture requirements and infective characteristics. Special methods must be employed to determine presence or absence and to obtain accurate identification.
- In order to control these organisms in medical environments and equipment, it is critical to identify effective chemicals against NTM and follow Instructions for Use provided by the manufacturer of disinfectants and medical equipment/devices.
- Particular attention **must** be paid to the use of water in critical health care situations because water that is not sterilized, for example by filtration, often carries these kinds of bacteria.

MYCOBACTERIA ARE INHERENTLY RESISTANT TO CHEMICAL DISINFECTANTS AND ANTIBIOTICS

- Mycobacteria have a natural resistance to many disinfectants. All mycobacteria share a characteristic cell wall, which is thicker than in most bacteria, which is hydrophobic, waxy, and rich in mycolic acids. This cell wall makes a substantial contribution to the environmental and chemical tolerance of this group. http://www.cdc.gov/hicpac/Disinfection_Sterilization/4_0efficacyDS.html

FOR TECHNICAL & MEDICAL STAFF - MYCOBACTERIA REQUIRE SPECIALIZED MICROBIOLOGY

- Mycobacteria require specialized growth media and techniques for successful culture. Therefore, they may be present in the samples and not detected due to the inadequate culture media or incubation periods. Extension of incubation for up to 60 days or more may be required to recover these types of isolates.
- Sampling for these organisms can be made challenging by their highly hydrophobic nature. For sampling surfaces directly, or via a liquid medium, swabbing vigorously to recover these organisms may be needed. Also, using a surfactant (e.g. Tween) can assist in recovering during sampling and manipulation during culture/testing.
- It is likely that the presence of these NTM can be overlooked by routine medical microbiological and environmental testing.
- Sampling of the environment (air and surfaces), equipment, and clinical specimens, should be considered whenever mycobacterial infection is a risk. This can include water filled equipment in health care settings. For general mycobacteriology see: http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdi3001-pdf-cnt.htm/$FILE/cdi3001f.pdf For detailed on NTM information see: https://www.thoracic.org/statements/resources/mtpi/nontuberculous-mycobacterial-diseases.pdf

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Attachment 2
Operating Instructions Excerpt:

Cleaning and Disinfection of the Heater Cooler Device

IMPORTANT INFORMATION

Sorin Heater Cooler Devices - Mycobacterium

Reference # IIS 9611109-07-14-14

The following chapters are attached from the current Operating Manual GA-16-XX-XX ENG (rev 11) of the 3T heater cooler device.

5.2 Filling the water tanks

6.2 Cleaning and disinfection of the housing

6.2.1 Disinfection of the water circuits

6.2.2 Protecting the water circuits from microbial growth

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Attachment 3
Customer Response Form

IMPORTANT INFORMATION

Sorin Heater Cooler Devices - Mycobacterium

Reference # IIS 9611109-07-14-14

According to our records you have the following impacted products:

<< Fill in the customer related codes and serial numbers only- Use Product Trace list (Excel File)>>

Product Code	Product description	Serial Number

Please return this completed form to:

Sorin Site/ Distributor Name: <<Print Your Company name here>>
Country: <<Print Your Country here>>
Contact Name: << Print Your Contact Name here>>
E-mail: <<Print Your E-mail address here>>
Fax No.: <<Print Your Fax No. here>>
Phone Number: <<Print Your Phone No. here>>

Section 1 - Please Complete:

1. We HAVE reviewed and understand the attached Important Information ☐
2. Yes- We do have the listed affected products and we will follow the instruction ☐
3. We DO NOT understand the attached Important Information and request more information ☐

Please contact us:
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

Customer Name: <<Print Your Company name here>>
Country: <<Print Your Country here>>
Contact Name: << Print Your Contact Name here>>
E-mail: <<Print Your E-mail address here>>
Fax No.: <<Print Your Fax No. here>>
Phone Number: <<Print Your Phone No. here>>

Submitted by ……..
Signature ……..
Date …...../……...../……..

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