SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

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

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

FIELD SAFETY NOTICE

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

Affected Devices:	Sorin Group perfusion system – Heater Cooler 1T and Heater Cooler 3T devices (refer to Attachment 1 for affected catalog and serial numbers)
Date:	03. June 2015
Reference No:	9611109-06/03/15-002-C
Attention:	Hygiene Specialists, Cardiac Surgery Operating Room Responsible, Risk/ Safety Managers, Distributors, Clinicians, Perfusionist and other users of these devices
Reason:	Sorin has become aware that the actual disinfection practices and the water maintenance that some users have been performing are not always conducted according to our Instructions for Use. Without vigilant performance of the disinfection and maintenance procedures per the Instructions for Use, organisms can multiply in a heater cooler device and potentially form biofilm. The biofilm provides an opportunity for bacteria, including Mycobacteria, to colonize within the device. Once colonized, there is a possibility that bacteria can become aerosolized when the heater cooler device is operated and serve as a source for contamination. Although water from the heater cooler device is not intended to contact the patient directly, fluid leakage from the device or aerosolization generated by a contaminated water circuit during device operation may create conditions in which the organisms could potentially contact the patient and subsequently contaminate the surgical site. Sorin Group is providing this notification to: (1) remind you of the importance of following the company's disinfection and maintenance procedures; (2) inform you that there is a possibility that bacteria can become aerosolized when the heater cooler device is operated and serve as a source for contamination; and (3) provide you with updated Instructions for Use regarding disinfection and maintenance procedures.

Dear Valued Customer:

The purpose of this letter is to advise you that Sorin Group Deutschland GmbH ("Sorin") is executing a voluntary field safety correction for the Heater Cooler 1T and the Heater Cooler 3T devices ("heater cooler devices"). This field safety notice describes below, immediate action to be taken by you.

- If your heater cooler device has been strictly maintained according to the Instructions for Use, please strictly adhere to the new Instructions for Use provided in **Attachment 1** of this letter.
- If your heater cooler device has **not** been strictly maintained according to the Instructions for Use, please perform the steps included in the *Immediate Customer Action* section of this letter.

Description of Issue

Sorin has become aware of cases of non-tuberculous mycobacteria endocarditis or deep infection following cardiac surgery during which the heater cooler device was used. There is a risk that surgical patients may experience invasive cardiovascular infection, including endocarditis, or other deep-surgical-site infections due to non-tuberculous mycobacteria, such as Mycobacterium chimaera. Because the symptoms may be slow to manifest, it is possible that many months may pass after completion of the surgical procedure before a surgical patient presents with an infection. In some cases, it is possible that infection could lead to death. Sorin's investigation into these cases is ongoing. To date, the investigation has not determined a causal connection between the heater cooler device and these cases. In some instances there has been a suggestion of such a link; however, infection following cardiac surgical procedures can be caused by numerous, other sources.

The heater cooler device which is provided non-sterile may develop highly contaminated water due to the failure to follow the Instructions for Use for water maintenance and water circuit disinfection. If contaminated water is used in the device **and** the user performs inadequate maintenance and/or fails to strictly adhere to the user instructions for cleaning of the heater cooler device, the device could become a source for contaminating the surgical environment. This condition can occur where there has been a build-up of biofilm within the water circuit of the device. Although water from the heater cooler device is not intended to contact the patient directly, fluid leakage from the device or aerosolization generated by a contaminated water circuit during device operation may create conditions in which the organisms could potentially contact the patient and subsequently contaminate the surgical site.

Contamination of heater cooler units with other waterborne pathogens, like *Mycobacterium abscessus* and non-fermenting gram-negative bacteria, has also been detected in the water of certain heater cooler units. However, no cases of patient infection have been determined to be caused by heater cooler devices. Further, Sorin's investigations into the potential association of heater cooler units with infections by *Mycobacterium chimaera* and other pathogens are ongoing.

If there is a need for further communication based on the investigation results, we will provide you the information.

SORIN GROUP
DEUTSCHLAND GMBH
Lindberghstr. 25 · D-80939 München
T.: +49-(0)89-323 01 0
F.: +49-(0)89-323 01 100
www.sorin.com

Geschäftsführer:
Alexander H. J. Neumann
Giulio Cordano

Amtsgericht München
HRB 100852
USt-IdNr. (VAT) DE 129304291
Steuer-Nummer: 143/181/70429

Immediate Customer Action

- ✓ Sorin reminds its customers using heater cooler devices about the importance of adhering to correct maintenance of the device at all times and, in particular, to assure that the cleanliness of the water is maintained. **Attachment 1** of this notification includes the new Instructions for Use for the cleaning and disinfection of the Sorin heater cooler devices. Please discard the existing IFU and follow this new IFU which includes updated cleaning and disinfection instructions.
    - o Assure that your team understands Mycobacteria and the potential contamination risks for cardiac surgical procedures, for example, that Mycobacterium is widely distributed in the ecosystem including chlorinated drinking water from the tap, it is inherently resistant to chemical disinfectants and antibiotics, and under the right conditions, it has a propensity to form biofilm and it can also be aerosolized.

- ✓ Healthcare providers involved in the care of patients who have undergone open heart surgery should be vigilant for cases of endocarditis or other cardiovascular infection of unidentified origin with specific testing for slow-growing non-tuberculous Mycobacteria such as *Mycobacterium chimaera* performed as indicated.

- ✓ Verify that this letter has reached your local team and that the recommended monitoring has been considered for your cardiac surgery operating rooms and area. This includes the monitoring of the area water not only for typical microorganisms, but also for slow growing non-tuberculosis Mycobacteria that requires special monitoring practices.

Actions to be taken by the user on the device

- ✓ Review your inventory and identify any heater cooler devices per the attached list, **Attachment 2**.

- ✓ For each unit, determine if the device has been maintained according to the Instructions for Use. If yes, strictly adhere to the new Instructions for Use provided in **Attachment 1** of this notification.

  Note: It is recommended to implement a microbiological monitoring of the water quality (by heterotrophic plate count (HPC) measurement), including monitoring for non-tuberculous Mycobacteria on a monthly basis (Coliform bacteria, P. aeruginosa and non-tuberculous mycobacteria should not be detectable in 100ml). The water in the device should meet microbiological drinking-water quality according to national drinking-water standards.

SORIN GROUP
DEUTSCHLAND GMBH
Lindberghstr. 25 · D-80939 München
T.: +49-(0)89-323 01 0
F.: +49-(0)89-323 01 100
www.sorin.com

Geschäftsführer:
Alexander H. J. Neumann
Giulio Cordano

Amtsgericht München
HRB 100852
USt-IdNr. (VAT) DE 129304291
Steuer-Nummer: 143/181/70429

- ✓ If the device has not been maintained according to the Instructions for Use, follow instructions in the table below:
  Note: Please consult your Infection Control Manager for executing the following steps.

Step 1 / Submission of Test Sample
✓ Take two 100ml or greater water samples from one of the drain valves at the back of the device **prior to** the disinfection step: (1) for heterotrophic plate count measurement; and (2) for non-tuberculous mycobacteria analysis. ✓ Submit samples (1 & 2) to a microbiological lab for heterotrophic plate count measurement of the water and to determine if non-tuberculous mycobacteria are detectable. ✓ Perform disinfection of the water circuit of the heater cooler device(s) according to the new instructions for use provided in **Attachment 1** of this notification. ✓ Replace any accessories and products that are used in conjunction with the heater cooler device which may be potentially contaminated (e.g. tubing and connectors, graduated beaker, warming blanket) by new or re-processed parts. ✓ While awaiting test results from the microbiological lab, operate the heater cooler device outside of the operating room, if structurally possible, and proceed to **Step 2.** Note: For technical support regarding the installation outside the OR (max. distance, routing) please contact your local service representative. ✓ If it is not possible to move the heater cooler device outside the operating room, take the device out of service or proceed to **Step 3**.
Step 2 / Interim Process (If heater cooler device can be operated outside the operating room)
✓ Perform the water maintenance and disinfection of the water circuit of the device(s) according to the new instructions for use provided in **Attachment 1** of this notification. ✓ Implement a bi-weekly microbiological monitoring of the water quality (by heterotrophic plate count (HPC) measurement), including monitoring for non-tuberculous mycobacteria. The samples shall be taken prior disinfection. ✓ When you receive the results from the lab go to **Step 4**

SORIN GROUP
DEUTSCHLAND GMBH
Lindberghstr. 25 · D-80939 München
T.: +49-(0)89-323 01 0
F.: +49-(0)89-323 01 100
www.sorin.com

Geschäftsführer:
Alexander H. J. Neumann
Giulio Cordano

Amtsgericht München
HRB 100852
USt-IdNr. (VAT) DE 129304291
Steuer-Nummer: 143/181/70429

Step 3 / Heater Cooler operated in operating room
✓ Place the heater cooler in a way that the flow conditions of the surgical side are not disturbed by the heater cooler device fans. o Maintain maximum distance from surgical field; o Position heater cooler such that the fan exhausts of the device are directed away from the surgical field; o Position heater cooler fan exhausts close to the suction exhaust (outtake) of the operating room. ✓ The water in the tank must be changed **every day**. ✓ In order to prevent microbial growth and to avoid biofilm build-up, add medical grade 3% hydrogen peroxide solution to the tank contents (follow instructions provided in the new IFU, which direct 150 ml for the heater cooler 3T or 50 ml for the heater cooler 1T). ✓ Perform a **weekly** disinfection as described in the new IFU to kill the waterborne pathogens such as non-tuberculous mycobacteria. ✓ Implement a bi-weekly microbiological monitoring of the water quality (by heterotrophic plate count (HPC) measurement), including monitoring for non-tuberculous mycobacteria. The samples shall be taken prior to disinfection. ✓ Take microbiological air samples for non-tuberculous mycobacteria in the operating room when the heater cooler is running on a bi-weekly basis. ✓ When you receive the results from the lab go to **Step 4**
Step 4 / Review of Lab Analysis and Action
✓ If the microbial counts are within the specified limits (meet microbiological drinking-water quality and Coliform bacteria, P. aeruginosa and non-tuberculous mycobacteria are not detected in 100ml), the device can be placed back into the operating room. Continue to use and maintain the device according to the new IFU, **Attachment 1** ✓ Implement a microbiological monitoring of the water quality, including monitoring for non-tuberculous Mycobacteria on a monthly basis. ✓ If you find microbial counts in the water are greater than the limits specified above, contact your infection control manager to determine appropriate actions and immediately contact your service representative for support. ✓ If non-tuberculous mycobacteria are found in the air of the operating room, when the heater cooler is operated, remove the heater cooler from service and immediately contact your service representative for support. o For emergency surgeries please consult your infection control manager to determine appropriate actions.

For technical support please contact your local service representative.

SORIN GROUP
DEUTSCHLAND GMBH
Lindberghstr. 25 · D-80939 München
T.: +49-(0)89-323 01 0
F.: +49-(0)89-323 01 100
www.sorin.com

Geschäftsführer:
Alexander H. J. Neumann
Giulio Cordano

Amtsgericht München
HRB 100852
USt-IdNr. (VAT) DE 129304291
Steuer-Nummer: 143/181/70429

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

Transmission of this Field Safety Notice

Please assure within your organization that this notice is communicated to all personnel who need to be aware of this Field Safety Notice. In case you have transferred products to a third party please communicate this information to them and also inform the below mentioned contact person.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person

For questions regarding this Field Safety Notice, 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

A copy of this Field Safety Notice has been provided to the appropriate Regulatory Agencies who are aware of these actions.

Thank you for your cooperation in this matter. Sorin Group is committed to provide quality products and service to its customers and we apologize for any inconvenience this situation may have caused.

Sincerely,

i.V. Christian Peis
Director Quality Assurance

Enclosures:

Attachment 1: New Instructions for Use

Attachment 2: Affected Product List

Attachment 3: Customer Response Form

SORIN GROUP
DEUTSCHLAND GMBH
Lindberghstr. 25 · D-80939 München
T.: +49-(0)89-323 01 0
F.: +49-(0)89-323 01 100
www.sorin.com

Geschäftsführer:
Alexander H. J. Neumann
Giulio Cordano

Amtsgericht München
HRB 100852
USt-IdNr. (VAT) DE 129304291
Steuer-Nummer: 143/181/70429

Attachment 2
Affected Product List

FIELD SAFETY NOTICE

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

Reference # 9611109-06/03/15-002-C

Product Code	Product description	Affected Serial Number range
16-02-50	Heater-cooler 1T, 230V	16S00808 - 16S02268
16-02-80	Heater-cooler 3T, 230V	16S10027 - 16S15641
16-02-81	Heater-cooler 3T, 240V	16S10743 - 16S11708
16-02-82	Heater-cooler 3T, 208V	16S10772 - 16S15523
16-02-83	Heater-cooler 3T, 127V	16S11455 - 16S15190
16-02-85	Heater-cooler 3T, 120V	16S10958 - 16S15634
16-02-95	Heater-cooler 3T, 200V	16S12004 - 16S15385

Please refer to Attachment 3 for affected Systems at your site.

SORIN GROUP
DEUTSCHLAND GMBH
Lindberghstr. 25 · D-80939 München
T.: +49-(0)89-323 01 0
F.: +49-(0)89-323 01 100
www.sorin.com

Geschäftsführer:
Alexander H. J. Neumann
Giulio Cordano

Amtsgericht München
HRB 100852
USt-IdNr. (VAT) DE 129304291
Steuer-Nummer: 143/181/70429

Attachment 3 -
Customer Response Form

FIELD SAFETY NOTICE

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

Reference # 9611109-06/03/15-002-C

According to our records you have the following affected products:

<Fill in the customer related codes and serial numbers only- Use Attachment 4_Product trace list (Excel File)>

Product Code	Product description	Affected Serial Number

Please correct any inaccurate information above.

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 Field Safety Notice □ yes □ no
2. We DO NOT understand the attached Field Safety Notice and request more information □ yes □ no
3. WE HAVE discarded the old instruction for use □ yes □ no

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 …...../……...../……..