

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

[INSERT CUSTOMER NAME, ADDRESS]

FIELD SAFETY NOTICE UPDATE

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

Affected Devices: Sorin Group perfusion system – Heater Cooler 3T devices
Date: October 13, 2016
Attention: Hygiene Specialists, Cardiac Surgery Operating Room Responsible, Risk/ Safety Managers, Distributors, Clinicians, Perfusionists and other users of these devices
Reason: In response to the Centers for Disease Control and Prevention’s (“CDC”) Health Alert Network (“HAN”) and Morbidity and Mortality Weekly Report (“MMWR”) communications, and the related FDA Safety Communication, LivaNova has issued an updated Field Safety Notice to conduct customer outreach under which the company will proactively contact facilities to help implement the recommendations contained in the CDC HAN communication, the FDA Safety Communication, and the company’s previous recommendations.

Dear Customer,

Over the past two years, LivaNova¹ and the broader cardiac surgery community has learned a great deal about a newly-identified infection risk to open-heart surgery patients called Nontuberculous Mycobacterium (“NTM”). NTM are widespread in nature and are commonly found in the soil, natural water, drinking water distribution systems, and household and building plumbing, especially in recirculating hot water systems in hospitals and apartment buildings. NTM are typically not harmful, but in rare cases may cause infections in very ill patients or individuals with compromised immune systems.

As the market leader for heater-cooler devices, LivaNova is committed to patient safety and supporting the clinical community who use our devices. We take seriously the rare but concerning potential risk of NTM infections and the related issues raised by FDA and CDC. We are committed to ensuring clinician confidence in our heater-cooler devices, which are a critical part of cardiac surgery procedures. In this regard, we would like to provide you with a further update on this important industry issue.

The Centers for Disease Control and Prevention (“CDC”) has today released a publication in the Morbidity and Mortality Weekly Report (“MMWR”) describing the results of tests conducted by CDC and National Jewish Hospital. According to the CDC’s report, these tests indicate that there appears to be genetic similarity between both patient and heater cooler strains of the NTM bacteria *M. chimaera* isolated in Iowa and Pennsylvania. Given the geographic separation between the two hospitals performing the investigation, there may be a shared point source for the isolated NTM. The company is

¹ LivaNova PLC is a U.K. holding company with a number of wholly-owned subsidiaries, including Sorin Group Deutschland GmbH and Sorin Group USA, Inc. In this document, we refer to all entities using the brand name LivaNova.

continuing to analyze the data referenced in the CDC MMWR. A copy of that publication is attached to this Communication as **Attachment 1**.

In conjunction with the MMWR report, CDC has also issued a Health Advisory on its Health Alert Network (“HAN”) that assesses certain risks associated with heater-cooler devices and provides guidance for providers and patients. This has been included as **Attachment 2**. We also attach as **Attachment 3** a copy of a Safety Communication released today by the FDA concerning the CDC publication.

Consistent with these communications, LivaNova and its representatives will proactively and voluntarily contact facilities to facilitate implementation of the CDC and FDA recommendations that:

1. Heater-cooler devices known or suspected to be contaminated with NTM, based on the facility’s testing program or other information known to the hospital, should be removed from service.
2. Heater-cooler devices manufactured before September 2014 (refer to **Attachment 4** for the affected catalogue and serial numbers) should only be used as directed by the FDA Safety Communication.
3. Heater-cooler devices that are not known or suspected to be contaminated and manufactured during or after September 2014 should be used in accordance with the Operating Instructions and take into account additional precautions specified in the FDA Safety Communication.
 - a. Following the Operating Instructions for heater-cooler devices and specifically those relating to cleaning and disinfecting. We continue to believe that following these operating instructions is essential to mitigating the potential risk posed by using these non-sterile devices. The FDA Safety Communication confirms the importance of following the applicable operating instructions.
 - b. Conducting water quality monitoring per LivaNova’s June 2015 3T Field Safety Notice “Cardiac Surgery Mycobacterium Risks.”²

During the contacts with facilities, LivaNova will also seek to understand your facility’s cleaning and disinfection practices and to obtain results of water quality monitoring.

LivaNova continues to work closely with FDA to develop solutions to further mitigate the potential risk of NTM contamination.

Should you require further information on this important issue, FDA has released a summary of a recent meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee held to discuss NTM infections associated with heater-cooler devices during cardiothoracic surgery. This Advisory Committee meeting took place in early June 2016, with full participation by LivaNova representatives. This summary contains a general overview of the discussion and general recommendations arising out of the Advisory Committee. Together with all of the Advisory Committee materials, this summary can be found on the FDA website at <http://www.fda.gov/AdvisoryCommittees/>

² See the 3T Heater-Cooler section of the LivaNova website at <http://www.livanova.sorin.com/products/cardiac-surgery/perfusion/hlm/3t>



Health innovation that matters

[CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevi
cesPanel/ucm485091.htm](http://www.livanova.com/committees/meeting-materials/medical-devices/medical-devices-advisory-committee/circulatory-system-devices-panel/ucm485091.htm).

In order to help answer questions related to today's communications from CDC and FDA, we have also created a brief FAQ which is available, along with other relevant information, on the 3T Heater-Cooler section of the LivaNova website at <http://www.livanova.sorin.com/products/cardiac-surgery/perfusion/hlm/3t>.

Please complete the Customer Response Form provided in **Attachment 5** and return it as instructed on the form. We thank you for your continued support and cooperation in this matter.

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 1

MMWR

Attachment 2

CDC Health Alert Network Health Advisory

Attachment 3

FDA Safety Communication

Attachment 4

List of Devices Manufactured before September 2014

FIELD SAFETY NOTICE UPDATE

Cardiac Surgery Mycobacterium Risks

Disinfection and Cleaning of Sorin Heater Cooler Devices

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

Product Code	Product description	Affected Serial Number range
16-02-85	Heater Cooler 3T, 120V	Serial Numbers smaller than 16S14911 and 16S14923, 16S14937, 16S14938, 16S14939, 16S14953, 16S14961, 16S14964, 16S14974, 16S14975
16-02-82	Heater Cooler 3T, 208V	Serial numbers smaller than 16S14916
16-02-81	Heater Cooler 3T, 240V	All Serial Numbers

Attachment 5

Customer Response Form

FIELD SAFETY NOTICE UPDATE

Cardiac Surgery Mycobacterium Risks

Disinfection and Cleaning of Sorin Heater Cooler Devices

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

Please list the serial numbers for all Sorin Heater-Cooler device(s) in use at your facility:

Product Code	Product description	Affected Serial Number

Section 1 - Please Complete:

We HAVE reviewed and understand the attached Field Safety Notice Yes No

We DO NOT understand the attached Field Safety Notice and request more information Yes No

We confirm that the list above includes ALL of the Sorin 3T devices in use at our facility Yes No

Customer Name: _____

Contact Name: _____

E-mail: _____

Fax No: _____

Phone Number: _____

Submitted by: _____

Signature: _____ Date: ____/____/____

Please fax or email the completed form within 48 hours to:

Fax: **1-888-276-6166.**

Email: **sorin6564@stericycle.com**

For questions regarding this notice, please contact LivaNova at 1-888-570-1653

(Monday to Friday 8AM to 5PM MT)