

FIELD SAFETY NOTICE - UPDATE

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

FSCA identifier: 9611109-11/11/16-008-C

Affected Devices: Sorin Group perfusion system – Heater-cooler 1T, Heater-cooler 3T and FlexTherm devices (catalog number: 16-02-50, 16-02-80, 16-02-81, 16-02-82, 16-02-83, 16-02-85, 16-02-95, 16-70-00)

Date: November 11, 2016

Attention: Hygiene Specialists, Cardiac Surgery Operating Room Responsible, Risk/ Safety Managers, Distributors, Clinicians, Perfusionists and other users of these devices

Reason: LivaNova has issued an updated Field Safety Notice based on recent information released by the United States.

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. 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.

As you may be aware, on October 13, 2016, the United States Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) issued several communications related to nontuberculous mycobacterial (NTM) infections associated with the use of heater-cooler devices. The CDC Morbidity and Mortality Weekly Report (“MMWR”) article describes the results of a genomic analysis of samples obtained from patients with NTM infections caused by Mycobacterium chimaera (**Attachment 1**). As the MMWR article acknowledges, the data presented therein is not new data; rather it appears to corroborate the conclusions previously presented in an April 2016 EuroSurveillance article by Haller, et. al. (**Attachment 2**).

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.

However, based on the data presented in this recent publication, LivaNova wishes to proactively convey LivaNova's recommendations for actions in your country, in which there are options that are unavailable in the United States. These recommendations are as follows.

1. Heater-cooler devices known or suspected to be contaminated with *M. chimaera*, based on the facility's testing program or other information known to the hospital, should be removed from the operating room or, if feasible, from service as soon as is practicable. We recommend contacting your LivaNova representative to arrange to have a deep-disinfection service performed prior to further use.
2. For facilities who have devices that are not known to be contaminated with *M. chimaera*, we recommend the following actions:
 - 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.
 - b. If appropriate for your operating room, direct or channel the heater-cooler exhaust away from the patient, e.g., to the operating room exhaust vent per the Field Safety Notice "Cardiac Surgery Mycobacterium Risks (**Attachment 3**)".
 - c. Conducting water quality monitoring per the Field Safety Notice "Cardiac Surgery Mycobacterium Risks (**Attachment 3**)".
 - d. Using new accessories, tubing, and connectors to prevent recontamination when using a different heater-cooler device. Be aware that device contamination also may occur from other sources such as environmental contamination or device contact with contaminated accessories

LivaNova continues to work closely with the regulatory authorities in your country to develop solutions to further mitigate the potential risk of *M. chimaera* contamination.

Please complete the Customer Response Form provided in **Attachment 4** and return it as instructed on the form. We thank you for your continued support and cooperation in this matter.

Sincerely



Thierry Dupoux
Vice President Quality Assurance
LivaNova

Attachment 1

MMWR

Attachment 2

EuroSurveillance

Attachment 3

LivaNova 2015 FSN

Attachment 4

Customer Response Form

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 Reference # 9611109-11/11/16-008-C

Please complete and return this completed form within two working days

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**

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

Product Code	Product description	Affected Serial Number

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 Number:	<<Print Your Fax No. here>>	
Phone Number:	<<Print Your Phone No. here>>	
SUBMITTED BY	SIGNATURE	DATE
...../...../.....

To return the form or if you have any questions regarding this Field Safety Notice or deep-disinfection service, please contact us at:

E-mail:	sorin.fsn@stericycle.com
Fax Number:	+44 – 2080806540 (international)
Phone Number:	<<Print Your Phone Number here>>