

FIELD SAFETY NOTICE UPDATE

Cardiac Surgery Mycobacterium Risks

Retrofit of Sorin Heater Cooler Devices

Affected Devices: Sorin Group perfusion system – Heater Cooler 3T devices

Date: May 3rd, 2017

Reference: 9611109-05/05/17-004-C

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

Reason: LivaNova is issuing an updated Field Safety Notice to inform users about the retrofit of their Heater Cooler 3T devices

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.

In June 2015, Sorin Group Deutschland GmbH, now LivaNova Deutschland GmbH², issued a Field Safety Notice regarding “Cardiac Surgery Mycobacterium Risks; Disinfection and Cleaning of Sorin Heater Cooler Devices” (**Attachment 1**) to mitigate a potential risk of patient infection by non-tuberculous mycobacteria released from the Heater-cooler 3T.

In October 2016, following several communications related to nontuberculous mycobacterial (NTM) infections associated with the use of heater-cooler devices issued by the United States Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), LivaNova distributed a second FSN (**Attachment 2**) reiterating and supplementing some of the recommendations contained in the June 2015 FSN. Additionally, the October 2016 communication indicated that, LivaNova continued to develop solutions that further mitigate the potential risk of *M. chimaera* contamination, working closely with the regulatory authorities to obtain approval.

LivaNova has now completed the development of and obtained CE mark for a solution that mitigates against contamination by preventing dispersion of aerosols produced by the heater-cooler in the

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.

² LivaNova Deutschland GmbH and Sorin Group Italia srl are wholly-owned subsidiaries of LivaNova PLC that is a U.K. holding company. In the present document, the brand name LivaNova is also used to refer to either Sorin Group Deutschland GmbH or Sorin Group Italia srl



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operating room. This solution will be implemented in manufacturing, and units currently in use in the field will undergo a field upgrade on-site by LivaNova service personnel or local agent. Although this solution is less necessary when the 3T device's water system is maintained according to the IFU, the field upgrade will mitigate against the reasonably foreseeable hazard of accidental contamination and poor maintenance practices.

LivaNova is initiating this corrective action after having informed the regulatory authorities of your country and having obtained the relevant approvals, if so required.

Action to be taken by the user:

No actions by the user are required at this time, other than to continue to follow the guidance provided in LivaNova's 2015 FSN and 2016 FSN Update. LivaNova will deploy this upgrade to units currently in use at your facility. A LivaNova representative or local agent will contact you to plan the upgrade.

Transmission of this Field Safety Notice:

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

Contact reference person:

For questions regarding this Field Safety Notice, please contact Christian Peis, Director QA, LivaNova 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 Agency who are aware of these actions.

Thank you for your cooperation in this matter. LivaNova is committed to provide quality products.

Sincerely,

A handwritten signature in blue ink, appearing to read 'C. Peis'.

Enclosures:

Attachment 1: 2015 Field Safety Notice

Attachment 2: 2016 Field Safety Notice Update



Attachment 1

LivaNova 2015 FSN



Attachment 2

LivaNova 2016 FSN