

LIVANOVA DEUTSCHLAND GMBH · Lindberghstr. 25 · D-80939 München

CUSTOMER INFORMATION

Mitigating Cardiac Surgery Mycobacterium Risks

Vacuum & Sealing Upgrade and Aerosol Collection Kit for 3T Sorin Heater-Cooler Devices

Munich, 25 May 2017

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 re-circulating 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. Recently in Europe and the U.S., NTM infections caused by *Mycobacterium chimaera* (*M. chimaera*) have been identified in patients who have previously undergone cardiothoracic surgery.

As the market leader for heater-cooler devices, LivaNova is committed to patient safety and supporting the clinical community who use our devices. Since the company became aware of this industry issue in 2014, LivaNova has conducted an intensive investigation into how this might occur, essentially creating new knowledge to understand how NTM might become aerosolized and dispersed. The company has invested enormous efforts and resources in the last three years, implementing a significant amount of actions in its investigation and response. Among others, from mid-2014, the following actions have been rolled out:

- **Device Manufacturing and Design Changes²:** changes in heater-cooler device (HCD) manufacturing processes to supplement pre-existing cleaning and disinfection process in the field and design changes for devices in manufacturing to mitigate the risk of infection caused by NTM emitted from the HCD.
- **Device services²:** creation of a deep-disinfection service to allow customers to return HCDs for a full cleaning, disinfection and replacement of connectors and tubing.
- **Device labeling²:** LivaNova issued Field Safety Notices in June 2015³ and November 2016⁴ informing all customers on a worldwide basis about the newly identified NTM infection risk in cardiac surgery, and providing instructions to detect and handle contaminated HCDs..

During this time, LivaNova has continued to work in close collaboration with government regulatory agencies and Competent Authorities, aiming to develop a broad-scale solution to further mitigate the already low risk of NTM transmission. LivaNova has now achieved a key milestone in this remediation program, obtaining **CE mark** for a **design change** of its 3T HCDs, the “**3T Vacuum and Sealing Upgrade,**” which is **intended to be a permanent design modification to address the issue caused by aerosolization**. The 3T Vacuum and Sealing Upgrade is a modification to the design of the 3T HCD, which is capable of isolating any potential contaminated aerosol from the 3T HCD and preventing it from entering into the sterile field.

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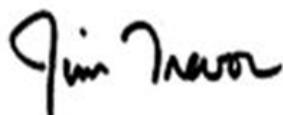
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We are committed to ensuring clinician confidence in our heater-cooler devices, which are a critical part of cardiac surgery procedures. **The company will soon start the roll-out of these design upgrades on a global basis as** we obtain approval by local regulatory agencies in each country. The installation of the design modifications described above will be performed by the company at no cost to our customers.

This modification of the 3T HCD design is part of the three-part device remediation plan related to the 3T HCD publically announced by LivaNova on March 1, 2017. In addition to the vacuum and sealing design modification, the remediation plan also includes the loaner program that began in the U.S. and has now been extended globally according to prioritization criteria, and the deep disinfection program, available outside of the U.S. at no charge for 3T HCD users who have reported *M. chimaera* mycobacterium contamination.

You can find this information, together with all other information related to the investigation on this industry issue, on the LivaNova website at <http://www.livanova.sorin.com/3T-out-us>

Sincerely



Jim Trevor
Senior Vice President, Cardiac Surgery
LivaNova

References

1. LivaNova PLC is a U.K. holding company with a number of wholly-owned subsidiaries, including LivaNova Deutschland GmbH and Sorin Group USA, Inc. In this document, we refer to all entities using the brand name LivaNova.
2. November 2016 - "EU FAQ for 3T Field Safety Notice Update"
3. June 2015 - "Cardiac Surgery Mycobacterium Risks Disinfection and Cleaning of Sorin Heater Cooler devices" – Field Safety Notice
4. November 2016 – "Field Safety Notice Update - Cardiac Surgery Mycobacterium Risks Disinfection and Cleaning of Sorin Heater-Cooler Devices"

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