



December 2, 2016

As many of you are well aware, we are currently faced with a complex situation surrounding the use of LivaNova's<sup>1</sup> 3T Heater-Cooler devices and the newly identified risk of infections from Nontuberculous Mycobacterium (NTM). For detailed background, please see our recent [Field Safety Notice Update](#) dated October 13, 2016. This Notice includes the latest written communication, also dated October 13, 2016, on this matter from Food and Drug Administration ("FDA") and Centers for Disease Control and Prevention ("CDC"). Additionally, FDA hosted a conference call with healthcare providers on November 1, 2016. Based on recent developments, we want to offer our continued assistance and clarify a few points.

As the leading supplier of cardiopulmonary equipment, LivaNova is committed to patients and clinicians who benefit from the use of our devices. Our products are used in the majority of cardiac operating rooms worldwide. Therefore, we recognize this is a challenging situation for hospitals as they strive to implement the CDC and FDA recommendations for 3T Heater-Cooler devices without interruption to life-sustaining cardiac surgeries.

We know you are eager for answers and further direction, and we are working closely with regulators, clinicians, and all relevant parties to resolve this important industry-wide issue. Specifically, we are actively engaged with FDA on the development of strategies to help further mitigate the risk of NTM infections.

As LivaNova works toward a broad-scale solution, we will keep you informed of our progress. Until then, please note that during its November 1, 2016 conference call, FDA recommended that hospitals should "review their infection control procedures, along with FDA's Safety Communication, to determine, on a case-by-case basis, if the benefits of using the 3T Heater-Cooler device, in a particular situation, outweighs the risk."

For further details, we strongly encourage you to review the FDA's specific recommendations from the November 1, 2016 conference call and the FDA's October 13, 2016 Safety

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<sup>1</sup> \*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 letter, we refer to all entities collectively using the brand name LivaNova.

Communication. A replay of the November 1, 2016 FDA conference call is available as a recording by dialing 1-800-677-9149 (United States and Canada) or 1-203-369-3408 (International Callers) with passcode HCD. Although these resources will not answer all of your questions, these items provide the FDA's most recent guidance on the use of the 3T device.

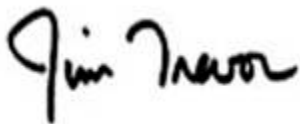
Further, as an interim strategy, LivaNova has implemented a program in the U.S. to provide loaner devices at no charge to support clinicians and their patients during this transition period. The deadline to submit a request for a loaner was October 31, 2016, and we will begin approving and prioritizing loaner devices to be allocated over the coming weeks. At this time, current supply is extremely limited, but as availability increases we will continue to allocate these additional devices according to a prioritization process that is consistent with FDA and CDC recommendations. We anticipate that this prioritization process will continue until we are able to address customer needs either through the loaner program or by implementation of one or more of the risk mitigation strategies currently under review.

For facilities in the U.S. interested in purchasing a new 3T Heater-Cooler device, please be aware that 100% of our U.S. supply is currently allocated to the loaner program.

We stand behind our products and believe the 3T Heater-Cooler is an effective device, which plays a vital role in more than 200,000 U.S. surgeries every year. At LivaNova, we remain committed to the highest quality of service and care, delivering health innovation that matters.

We welcome your questions as we all work together to advance cardiac surgery and provide the best outcomes for every patient. Health care providers and facilities may contact us at 1-888-570-1653 or [3T.US@livanova.com](mailto:3T.US@livanova.com). Past and current communications about this topic are available for download from our [website](#). We encourage patients with questions to speak with their physicians directly.

Sincerely,

A handwritten signature in black ink that reads "Jim Trevor". The signature is written in a cursive, slightly slanted style.

Jim Trevor

LivaNova PLC  
General Manager  
Cardiac Surgery