



January 2016

## Dear Valued Customer,

The purpose of this letter is to inform you about changes in the availability of the 3T Heater-Cooler System ("3T") in the United States resulting from a Warning Letter issued by the U.S. Food and Drug Administration ("FDA" or "the agency") dated December 29, 2015. The Warning Letter alleged certain violations of FDA regulations applicable to medical device manufacturers at its Munich, Germany and Arvada, Colorado facilities, to which LivaNova intends to respond in a timely manner.

The Warning Letter did not request that existing users cease using the 3T Heater Cooler device. Customers may continue to use the 3T device in accordance with our current Operating Instructions. To this end, we refer you to the Field Safety Notice regarding the Heater-Cooler 3T Devices (Reference #9611109-06/03/15-002-C, dated June 15, 2015 and updated August 6, 2015). Please continue to perform regular maintenance and disinfection of your 3T devices according to the latest Operating Instructions, which can be found at <a href="http://www.livanova.sorin.com/3T">http://www.livanova.sorin.com/3T</a>.

As a result of these issues, FDA has decided to limit the importation of the 3T device into the United States. The Company is working constructively with FDA to reduce the impact of this decision on you, and the Company will promptly communicate to you any updates agreed upon with FDA in this regard. Manufacturing and shipment of all of the Company's products other than the 3T Heater-Cooler are unaffected by this limitation at the present time and will continue as normal.

We are working diligently and in communication with FDA to resolve these issues as quickly as possible. We are committed to providing the highest quality products and service to our customers. We are also collaborating with U.S. medical societies to ensure that we properly and effectively communicate updates related to the adequate disinfection of our 3T Heater-Cooler devices. We will continue this practice of rapid and full disclosure in the future.





## **Contact Information:**

Please contact your LivaNova account representative if you have any questions. If further assistance is required, please contact:

Email: <u>3T.US@LivaNova.com</u>

Technical Services Hotline: 1-800-221-7943, Ext: 6355

3T Voicemail Box: 1-303-467-6601

Thank you for your continued support and cooperation in this matter. We apologize for any inconvenience this situation may have caused for you and your teams.

Sincerely,

Sean M. McNerney

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Country Leader

Vice President, US Sales & Marketing

Sorin Group USA, Inc.

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