



Health innovation that matters

January 21<sup>st</sup>, 2016

## **INTRODUCTION**

LivaNova PLC (Sorin Group Deutschland GmbH)<sup>1</sup> (“Livanova” or the “Company”) is providing this communication to inform you about changes in the availability of the 3T Heater-Cooler System in the United States resulting from a Warning Letter issued by the Food and Drug Administration (“FDA” or “the agency”) dated December 29, 2015.

### **This communication provides instructions for continuing to receive product support for 3T Heater-Cooler Systems.**

We apologize for any inconvenience that this may cause you and your staff. Your LivaNova sales representative is available to assist with any issues that may arise during the period that additional 3T devices are subject to limited availability.

FDA has agreed that, under a medical necessity program, a Certificate of Medical Necessity (CMN) can be used by a medical facility or institution to request service of an existing device at a foreign service facility or to obtain additional new 3T Heater-Cooler Systems under limited circumstances.

Device users are reminded that reports of adverse events experienced with medical devices should be reported to both LivaNova and FDA’s MedWatch Adverse Event Reporting program. Reports to FDA may be made online, by fax, or by mail. Information regarding the MedWatch program and reporting instructions are available on FDA’s website at <http://www.fda.gov/Safety/MedWatch/>.

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<sup>1</sup> On October 19, 2015, Sorin S.p.A. and Cyberonics, Inc. combined to become LivaNova.



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## **BACKGROUND**

On December 31, 2015, LivaNova received a Warning Letter dated December 29, 2015, from FDA alleging certain violations of agency regulations applicable to medical device manufacturers at its Munich, Germany and Arvada, Colorado facilities.

The Warning Letter states that the 3T Heater Cooler devices are subject to refusal of admission into the United States until resolution of the issues set forth in the Warning Letter. The Warning Letter did not request that existing customers cease using the 3T Heater Cooler device.

As explained in 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), without vigilant performance of the disinfection and maintenance procedures per the Instructions for Use, organisms can multiply in a heater cooler device and potentially form biofilm. The biofilm provides an opportunity for bacteria, including Non Tuberculous Mycobacteria ("NTM"), to colonize within the device. Once colonized, there is a possibility that bacteria can become aerosolized when the heater cooler device is operated and serve as a source for contamination. Although water from the heater cooler device is not intended to contact the patient directly, aerosolization generated by a contaminated water circuit during device operation may create conditions in which the organisms could potentially contaminate a patient's surgical site.

FDA raised concerns in the Warning Letter with respect to the adequacy of the IFU disinfection procedures and certain disinfection processes in production. LivaNova maintains that its disinfection processes are adequate to prevent contamination of water within the 3T device. Importantly, customers can objectively assess their devices for contamination of the water that may pose a risk to patients, in accordance with the detailed instructions provided in 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). We refer you to the Field Safety Notice, available here:

<http://www.livanova.sorin.com/products/cardiac-surgery/perfusion/hlm/3t>



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## **PRODUCT**

This notice affects only the 3T Heater-Cooler System.

## **PRODUCT RESTRICTIONS**

Under the terms of the Warning Letter, and upon further discussion with FDA, LivaNova must restrict the availability of the 3T Heater-Cooler System as follows:

- The Import Alert prohibits LivaNova from importing new units of the 3T Heater-Cooler System to customers in the United States until the issues in the Warning Letter are resolved to the satisfaction of FDA.
- FDA is permitting LivaNova to:
  - Replace existing 3T devices as needed, including when an existing device (1) has reached its useful life; (2) experiences irreparable failure; (3) is suspected of being contaminated or is taken out of service by the customer pursuant to a directive from a state or local public health or other authority; or (4) is subject to complaint investigation requiring the provision of a loaner device to the customer;
  - Deep-disinfect or service existing 3T devices as needed at a foreign service facility and re-import that device to existing U.S. customers; and
  - Provide existing customers with new 3T devices to meet the needs of customers who have reasonably expanded their existing capacity with the desire to maintain uniformity in product vendors.



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LivaNova may continue to import the 3T device to support only existing U.S. customers, as outlined above, provided that the authorized representatives of the existing U.S. customers have signed the attached CMN form provided in **Attachment A** certifying that, after learning of the FDA findings at the Munich, Germany and Arvada, Colorado facilities and evaluating the relevant risks and benefits, they have deemed the 3T device to be an immediate and continuing medical necessity for use in cardiac surgery and that the rationale for the support request indicated above accurately reflects the reason that the device(s) is or are being requested.

The company will continue to provide service and repair of existing 3T devices in the United States without a CMN being necessary.

Until further notice, users should continue to use the most updated Instructions for Use, available on the website for the device here: <http://www.livanova.sorin.com/products/cardiac-surgery/perfusion/hlm/3t>

For our U.S. users, LivaNova Customer Service is available to answer any questions at 1-800-221-7943, extension 6355. The 3T device website can be found at <http://www.livanova.sorin.com/products/cardiac-surgery/perfusion/hlm/3t> and will be updated with new information as it becomes available.

**Attachment A  
Certificate of Medical Necessity (CMN) Form for Existing U.S.  
Customers**

**Date:** \_\_\_\_\_

**User Name (Institution or Hospital):** \_\_\_\_\_

**Address:** \_\_\_\_\_

**City:** \_\_\_\_\_ **State:** \_\_\_\_\_ **Zip:** \_\_\_\_\_

**Serial Number for Device Subject to Request (if applicable):** \_\_\_\_\_

**Model Number (if applicable):** \_\_\_\_\_

**Rationale for Support Request**

- Replace existing 3T device because device has reached end of useful life
- Replace existing 3T device because device has experienced irreparable failure
- Replace existing 3T device because device is suspected of being contaminated
- Replace existing 3T device because device is subject to complaint investigation requiring the provision of a loaner device
- Replace existing 3T device taken out of service by the customer pursuant to a directive from a state or local public health or other authority
- Service existing 3T device requiring repair at an international service facility
- Service existing 3T device requiring deep disinfection at an international service facility
- Provide new 3T device(s) to meet the needs of customers who have reasonably expanded their existing capacity
- Other (provide reasoning)

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**Attachment A**  
**Certificate of Medical Necessity (CMN) Form for Existing U.S. Customers**

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On behalf of the above named institution/medical facility, I certify that:

- After reading the information provided in the LivaNova communication dated January 21st, 2016, I understand the clinical risks but can confirm that I consider the risks of using the device to be outweighed by the benefits of the device.
- All users of the 3T Heater-Cooler System are aware of the risks and benefits outlined in the January 21st, 2016 LivaNova communication.
- This institution/medical facility requires the use of the 3T device due to medical necessity.
- The rationale for support request indicated above accurately reflects the reason that I am requesting the device.

The CMN form must be signed by one of the following individuals: Chief Executive Officer, President, Chief Medical Officer, Chief Operating Officer, Director of the Operating Room, Chief Perfusionist, Hospital Administrator, or authorized individual responsible for risk management.

Name of Authorized Signatory: \_\_\_\_\_

Position: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Telephone: \_\_\_\_\_ Email: \_\_\_\_\_

Return Form to: **3T.US@LivaNova.com.**