

MEDICAL DEVICE CORRECTION

Mitigating Cardiac Surgery Mycobacterium Risks

US Availability of Deep-Cleaning Service for 3T LivaNova Heater-Cooler Devices

April 20, 2018

Dear Valued Customer:

Purpose of this Letter

The purpose of this letter is to provide you with an update regarding the US availability of a Deep-Cleaning Service to clean LivaNova's 3T Heater-Cooler Devices that are suspected of contamination and/or contain visible biofilm.

US Availability of Deep-Cleaning Service

In January 2018, LivaNova completed development of a special "deep-cleaning" servicing process for its 3T Heater-Cooler Devices (the "Deep-Cleaning Service"). The Deep-Cleaning Service allows hospital facilities to return eligible heater-cooler units for full cleaning, disinfection, and replacement of connectors and tubing. The deep-cleaning process will remove visible biofilm and reduce microbial levels to ≤ 100 CFU per 1 ml of water (heterotrophic plate count, HPC) and < 1 CFU per 100ml (nontuberculosis mycobacteria, NTM) in the 3T Heater-Cooler Devices. The Deep-Cleaning Service will be performed at no charge to the device owner.

The Deep-Cleaning Service will be available for all 3T devices less than 10 years old (the expected device lifetime) and LivaNova will prioritize the availability of the Deep-Cleaning Service according to the following criteria:

1. 3T Heater-Cooler Devices known or suspected to be contaminated with NTM, based on your facility's testing program or other information known to you;
2. 3T Heater-Cooler Devices manufactured before September 2014; then
3. 3T Heater-Cooler Devices manufactured after September 2014 and not known or suspected to be contaminated with NTM.

Older devices will not be subject to the deep-cleaning process and will continue to be handled through the company's medical necessity and ongoing loaner programs.

Product that successfully completes the deep-cleaning process will be returned to you. Product that does not successfully complete the process will not be returned to you and you will be notified.

Action to be taken by the Customer

For directions on how to return your devices for the Deep-Cleaning Service, please visit the LivaNova website at www.livanova.sorin.com/3T.

Continue to maintain the 3T according to the Operating Instructions and June 2015 Field Safety Notice, specifically the sections relating to cleaning and disinfecting. Both documents are available on the LivaNova website mentioned above.

Transmission of this Medical Device Correction



Health innovation that matters

Please complete and return the attached Customer Response Form (see Attachment 1) by fax to (303) 467-6502 or by email to USFSN@livanova.com.

Please ensure that this Medical Device Correction is communicated to all personnel within your organization who need to be aware of it. If you have transferred a 3T to a third party, please communicate this information to them and inform the LivaNova Quality Assurance Team at USFSN@livanova.com. Please maintain awareness on this notice and the resulting action for an appropriate period of time to ensure effectiveness of the corrective action.

Contact reference person

You can find further information about the Deep-Cleaning Service, together with all other information related to the investigation on this industry issue, on the LivaNova website at www.livanova.sorin.com/3T.

For questions regarding this Medical Device Correction, please contact (800) 986-4702 or e-mail USFSN@livanova.com. A copy of this letter has been provided to the Food and Drug Administration (FDA), who is aware of these actions. Adverse reactions or quality problems experienced with the use of this product may be reported to LivaNova at customerquality@livanova.com or the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Online: www.fda.gov/MedWatch/report.htm

Regular Mail: use postage-paid FDA form 3500 available at www.fda.gov/MedWatch/get_forms.htm and mail to MedWatch, 5600 Fishers Lane, Rockville, Maryland, 20852-9787

Fax: (800) FDA-0178

Phone: (800) FDA-1088

Thank you for your cooperation in this matter. LivaNova is committed to provide quality products and service to its customers and we apologize for any inconvenience this situation may have caused.

Sincerely,

Joan Ceasar
Director, Customer Quality and Safety

Enclosed:

Attachment 1: Customer Response Form

LivaNova PLC is a U.K. holding company with a number of wholly-owned subsidiaries, including LivaNova Deutschland GmbH and LivaNova USA, Inc. In this document, we refer to all entities using the brand name LivaNova.

ATTACHMENT 1 Customer Response Form

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According to our records you received one or more 3T Heater-Cooler devices.



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Customer Name: _____

Address: _____

1. We have reviewed and understand the attached Medical Device Correction Yes No

2. We DO NOT understand the Medical Device Correction and request more information Yes No

If “no” was indicated in the statement above Question #1, or “yes” indicated in Question #2, please explain:

Other questions:

Name (Print)

Title

Signature

Date

Thank you for your cooperation in completing this Customer Response Form.
Please return to USFSN@livanova.com or fax to (303) 467-6502 **no later than May 30, 2018.**

Adverse reactions or quality problems experienced with the use of this product may be reported to LivaNova at customerquality@livanova.com or the FDA’s MedWatch Adverse Event Reporting program either online (www.fda.gov/MedWatch/report.htm), by regular mail or by fax to (800) FDA-0178.