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URGENT MEDICAL DEVICE CORRECTION

Mitigating Potential Cardiac Surgery Infection Risks

Availability of New 3T Heater-Cooler System Operating Instructions and Reminder about Design Upgrade

February 24, 2020

Dear Valued Customer:

Purpose of this Letter

The purpose of this letter is to advise you that LivaNova Deutschland GmbH ("LivaNova" or "the Company") is executing a voluntary medical device correction for the 3T Heater-Cooler Systems ("3T Systems"). This letter describes immediate action to be taken by you.

Reason for this Medical Device Correction

The purpose of this medical device correction is to:

1) Provide a copy of the cleared 3T Heater Cooler System Operating Instructions (Version CP_IFU_16-XX-XX_USA_021) for your immediate use (**Attachment 1**). This new version supersedes all previous versions, which should be discarded or destroyed.
2) Advise that all 3T Systems in use at your facility should be upgraded with the 3T Aerosol Collection Set (vacuum canister and internal sealing) to further reduce the risk of potential aerosol emission from the 3T System.

In this correction, LivaNova is:

1) Providing you with the new Operating Instructions (Version CP_IFU_16-XX-XX_USA_021) that were recently cleared in K191402 and include validated instructions for cleaning and disinfecting the external surfaces, connectors, fittings, and water circuits;
2) Advising you that older versions of the Operating Instructions should be discarded or destroyed; and
3) Informing you that LivaNova will contact any facilities who have not already had upgrades to the 3T Aerosol Collection Set pursuant to Medical Device Correction Z-0220-2020 to schedule those upgrades. Facilities that have not already received the upgrade may contact LivaNova at 3T.US@livanova.com to schedule the upgrade.

These corrections apply to all 3T Systems currently in distribution, which includes upgrading any loaners that were previously distributed or that are pending distribution following the receipt of requests for loaners.

Risk to Health

Although the water in the 3T System heater-cooler unit does not come into direct contact with the patient, users should be mindful that aerosols are potentially emitted when the 3T System is used, primarily during the patient warming phase and at the end of a procedure, when water is returned to the tanks. Depending on the characteristics and concentration of nontuberculous mycobacteria (NTM) in the water in the tanks, these aerosols may carry NTM into the operating room

environment. Another risk of contamination for the patient is a direct contact transfer of water/solution droplets containing NTM into the surgical field, and if they come in contact with the patient, could lead to cardiovascular infection including endocarditis or other surgical-site infections.

Actions to be Taken by the Customer/User

Use the Validated Operating Instructions Provided with this Customer Letter

- The FDA cleared Operating Instructions are found in **Attachment 1** as well as at Product Resources on www.livanova.com.
  - Please read and follow the instructions carefully.
  - Section 2.1.5 “Integrating the HC3T into your facility” provides guidance on the use of the 3T System in your facility, highlighting critical tasks that users had the most difficulty with during human factors testing.
  - Section 6 “Maintaining the heater-cooler” provides guidance on the maintenance of the 3T System including the validated cleaning and disinfection instructions.
  - Section 7.1.4 “General performance data” describes performance testing results that emphasize the importance of following the cleaning and disinfection instructions and consistently using the 3T Aerosol Collection Set during surgeries. Specifically, these results describe how (1) the disinfection and water maintenance process maintains water quality and (2) the 3T Aerosol Collection Set design change reduces the potential for aerosolization.

Contact LivaNova to Obtain the 3T System Design Upgrade

- LivaNova has developed a 3T Aerosol Collection Set design change that is intended to further mitigate the risk of airborne transmission of NTM from the 3T System device.
- LivaNova has previously contacted all facilities to schedule upgrades pursuant to Medical Device Correction Z-0220-2020. If any 3T Systems at your facility have not been upgraded, contact LivaNova at 3T.US@livanova.com to schedule upgrades.

Affected Product

Product Code	Product Description	Affected Serial Number range
16-02-80	Heater-Cooler 3T, 230V	16S10027 – 16S16874
16-02-81	Heater-Cooler 3T, 240V	16S10743 – 16S11708
16-02-82	Heater-Cooler 3T, 208V	16S10772 – 16S16840
16-02-83	Heater-Cooler 3T, 127V	16S11455 – 16S16509
16-02-85	Heater-Cooler 3T, 120V	16S10958 – 16S16847
16-02-95	Heater-Cooler 3T, 200V	16S12004 – 16S16818

Note: This Medical Device Correction includes all 3T Systems sold in the United States and currently in your possession.

Transmission of this Medical Device Correction

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Please immediately complete and return the attached Customer Response Form (see Attachment 2) 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 System to a third party, please communicate this information to them and inform the LivaNova Quality Assurance Team at USFSN@livanova.com. Please maintain awareness of this notice and the resulting action until completion of the 3T Aerosol Collection Set design upgrade at your facility.

Contact Reference Person

You can find further information about this issue at Product Resources on www.livanova.com. 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 U.S. Food and Drug Administration (FDA), who is aware of this correction. Adverse reactions or quality problems experienced with the use of this product should 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: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program
Fax: (800) FDA-0178
Phone: (800) FDA-1088

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

Sincerely,

Bryan Olin

Bryan Olin, Ph.D.
Senior Vice President, Clinical, Quality & Regulatory Affairs

Enclosed:
Attachment 1: Operating Instructions
Attachment 2: Customer Response Form

ATTACHMENT 1
Operating Instructions

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ATTACHMENT 2
Customer Response Form

MEDICAL DEVICE CORRECTION
Mitigating Potential Cardiac Surgery Infection Risks
Availability of FDA Cleared Heater-Cooler 3T Systems with Updated Operating Instructions and 3T Aerosol Collection Set Design Upgrade

[February, 2020]

According to our records you received one or more 3T System devices.

Customer Name: _____

Address: _____
_____
_____
_____

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

   a. We have received the new Operating Instructions and have discarded or destroyed any old ones.
   □ Yes □ No

   b. Select which of the following applies to the 3T Systems at your facility:
   □ 3T Systems have been upgraded;
   □ We would like LivaNova to upgrade one or more of our 3T Systems;
   □ The 3T System(s) have been transferred to a third party. Please specify: _____or
   □ Our 3T Systems are no longer used, have been removed from service, and need no upgrade.

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

If "no" was chosen as a response to Question #1, or "yes" to 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 at your earliest convenience.
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.