UPDATE: Reduce the Risk of Cardiac Surgery Infection While Using the LivaNova Heater-Cooler System 3T: FDA Safety Communication

Date Issued: February 25, 2020

The U.S. Food and Drug Administration (FDA) is reminding health care providers and staff of ways to reduce the risk of cardiac surgery infection when using the LivaNova Heater-Cooler System 3T. This is an update to our safety communication issued in October 2018. (/medical-devices/safety-communications/updated-information-reduce-potential-cardiac-surgery-infection-risks-associated-livanova-3t-heater)

As noted in the October 2018 safety communication, LivaNova issued a Medical Device Correction letter to health care facilities to:

- Provide updated instructions to monitor the concentration of hydrogen peroxide in the water circuit to verify that enough concentration of hydrogen peroxide is present to limit microbial growth and to adjust the concentration of hydrogen peroxide if it drops below 100 ppm.
- Announce the availability of a design upgrade, called the 3T Aerosol Collection Set (vacuum canister and internal sealing), to reduce (but not eliminate) the risk of potential emission of aerosols from the 3T System.

In addition, the FDA cleared a new version (https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191402.pdf) of the LivaNova Heater-Cooler System 3T on February 25, 2020 with changes to help reduce the risk of patient infections including updated labeling (Version 21) with validated cleaning and disinfection instructions and the 3T Aerosol Collection Set.

If you use a 3T system that is not the new version, health care providers and staff should immediately start using the updated labeling and follow recommendations in the February 25, 2020 LivaNova Medical Device Correction Letter (https://livanovamediaprod.azureedge.net/livanova-media/livanova-public/media/resources01/sorin-3t-customer-letter-clearance-and-ifu-final-version.pdf?ext=.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer), and continue to follow recommendations in the April 20, 2018 (https://livanovamediaprod.azureedge.net/livanova-media/livanova-public/media/resources01/im-01609-a-deep-cleaning-customer-letter_final-version_april-2018-(2).pdf?ext=.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

and October 18, 2018 (https://livanovamediaprod.azureedge.net/livanova-media/livanova-public/media/resources02/hydrogen-peroxide-monitoring-and-design-upgrade-customer-letter-r1.pdf?ext=.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) LivaNova Medical Device Correction letters regarding a design upgrade and deep cleaning service.

Learn more about cardiac surgery infection associated with heater-cooler devices

Recommendations for Health Care Providers and Staff Using the LivaNova Heater-Cooler System 3T

- Strictly adhere to the updated 3T Operating Instructions (https://livanovamediaprod.azureedge.net/livanova-media/livanova-public/media/resources01/cp_ifu_16-xx-xx_usa_021.pdf?ext=.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (Version 21) to reduce the risk of infection. Be aware of LivaNova's February 25, 2020 Medical Device Correction Letter (https://livanovamediaprod.azureedge.net/livanova-media/livanova-public/media/resources01/sorin-3t-customer-letter-clearance-and-ifu-final-version.pdf?ext=.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).
- Use new accessories, tubing, and connectors to prevent contamination when using a different heater-cooler device.
- Direct and channel the heater-cooler exhaust away from the patient, for example, to the operating room exhaust vent.
- Be aware that device contamination may also occur from other sources such as environmental contamination or device contact with contaminated accessories.
- Be sure to clean and disinfect any accessories connected to the heater cooler according to accessories' manufacturers' instructions for use.
- Be aware that more frequent cleaning and using higher disinfection concentrations can damage the device.

If using a LivaNova Heater-Cooler System 3T that is not the new version (i.e. has a serial number beginning with 16S):

- Be aware of LivaNova's previous Urgent Medical Device Correction letter (https://livanovamediaprod.azureedge.net/livanova-media/livanova-public/media/resources02/hydrogen-peroxide-monitoring-and-design-upgrade-customer-letter-r1.pdf?ext=.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).
- Be aware of the 3T Aerosol Collection Set.

  - LivaNova has developed a vacuum canister and internal sealing design change called the 3T Aerosol Collection Set that is intended to further reduce, but does not eliminate, the risk of airborne transmission of non-tuberculosis mycobacterium (NTM) from the 3T device.
  - A LivaNova representative or local agent will contact customers to plan the upgrade of the affected products.
  - 3T devices that are at the deep cleaning facility will be upgraded while there.
- Be aware of the availability of the deep cleaning service. The "deep-cleaning" service is available for all 3T devices less than 10 years old (the expected device lifetime).
- If your device was manufactured **prior to September 2014**, you should strongly consider transitioning away from the use of these devices for open-cardiac surgery unless your device has been deep cleaned specifically by LivaNova.

If your 3T device is known or suspected to be contaminated, you should:

- Immediately remove from service any heater-cooler devices, accessories, tubing, and connectors that have tested positive for *M. chimaera* or have been associated with known *M. chimaera* patient infections at your facility.
- Consider contacting LivaNova for additional information about the deep-cleaning servicing of your 3T.
- Be aware, if your device is successfully deep cleaned, following the routine cleaning and disinfection procedures found in the most recent Instructions for Use is necessary to help reduce the risk of recontamination.
- Review the FDA's earlier recommendations (/medical-devices/what-heater-cooler-device/recommendations-use-any-heater-cooler-device) provided to help reduce the risk to patients.

Device Description

Heater-cooler devices (/medical-devices/cardiovascular-devices/what-heater-cooler-device) are commonly used to warm or cool a patient to improve medical care and patient outcomes. The LivaNova Heater-Cooler System 3T (formerly Stöckert 3T Heater-Cooler System), manufactured by LivaNova PLC (formerly Sorin Group Deutschland GmbH), is intended to provide temperature-controlled water to:

- Oxygenator heat exchangers
- Cardioplegia (paralysis of the heart) heat exchangers

- Warming/cooling blankets to warm or cool a patient during cardiopulmonary bypass procedures lasting six hours or less.

Cardiac Surgery Infection Associated with Heater-Cooler Devices

In appropriately selected patients, the benefits of temperature control during open chest cardiothoracic procedures (cardiac surgery) generally outweigh the risk of infection transmission associated with the use of heater-cooler devices.
All heater-cooler devices that have water tanks provide temperature-controlled water to external heat exchangers or warming/cooling blankets through closed circuits. Although the water in the circuits does not come into direct contact with the patient, there is the potential for contaminated water to enter other parts of the device and aerosolize. This could send non-tuberculosis mycobacteria (NTM) through the air and through the device's exhaust vent or other unsealed pathways, the environment, and to the patient.

For LivaNova heater-cooler devices, follow the recommendations above.

For more information about other heater-cooler devices see:

- FDA's webpage on What is a Heater-Cooler? (/medical-devices/cardiovascular-devices/what-heater-cooler-device)

FDA Actions

The FDA continues to engage with manufacturers, health care facilities, and the Centers for Disease Control and Prevention (CDC) in evaluating risk and mitigation measures. The FDA will provide updates, as appropriate, as new information becomes available.

For a complete list of actions the FDA has taken on this issue, see FDA's Ongoing Evaluation and Continued Monitoring of Reports of Nontuberculous Mycobacteria Infections Associated with Heater-Cooler Devices (/medical-devices/what-heater-cooler-device/fdas-ongoing-evaluation-and-continued-monitoring-reports-nontuberculous-mycobacteria-infections).

Reporting Problems with Your Device

The FDA encourages you to report device problems, including device contamination and patient infections, using the MedWatch Voluntary Reporting Form (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home).

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Questions?

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV) or call 800-638-2041 or 301-796-7100.