

LivaNova Receives FDA Clearance for 3T Heater-Cooler Device Modification

London, February 25, 2020 – LivaNova PLC (NASDAQ:LIVN), a market-leading medical technology and innovation company, today announced it received U.S. Food and Drug Administration (FDA) 510(k) clearance for a device modification to its 3T Heater-Cooler® devices. The modification includes the installation of a 3T Aerosol Collection Set, as well as testing that demonstrates the effectiveness of its operating instructions. This modification has been implemented at no cost to customers on devices that have already been distributed and is being implemented on new units being prepared for distribution. Collectively, these modifications further reduce the potential risk of possible dispersion of aerosols in hospital operating rooms when used in accordance with Operating Instructions. Devices manufactured in accordance with this newly cleared 510(k) will not be subject to the current FDA import alert.

Through past and present field actions, LivaNova has been implementing the design modification on devices in the field throughout the U.S since October 2018. In connection with a product remediation plan that was announced in early 2017, the Company continues to make available to U.S. customers its 3T device loaner program, as well as a no-charge deep cleaning service for any 3T device with confirmed *M. chimaera* contamination. In other locations around the world, the Company has been successfully cleaning 3T Heater-Cooler devices and implementing the modification since receiving CE Mark in 2017.

“FDA clearance allows us to implement a permanent design solution for 3T Heater-Cooler devices used in the U.S. that further mitigates the potential risk of aerosolization,” said Bryan Olin, LivaNova Senior Vice President for Clinical, Quality and Regulatory Affairs. “Heater-coolers are critical pieces of equipment for open-heart surgery, and LivaNova wants to ensure continued access to these important devices for the ongoing treatment of patients around the world.”

The [3T Heater-Cooler Operating Instructions](#) can be found on the LivaNova website.

More [information and safety communications from the FDA regarding the 3T Heater-Cooler](#) is available on the FDA website.

About LivaNova

LivaNova PLC is a global medical technology and innovation company built on nearly five decades of experience and a relentless commitment to provide hope for patients and their families through innovative medical technologies, delivering life-changing improvements for both the Head and Heart. Headquartered in London, LivaNova employs approximately 4,000 employees and has a presence in more than 100 countries for the benefit of patients, healthcare professionals and healthcare systems worldwide. LivaNova operates as two businesses: Cardiovascular and Neuromodulation, with operating headquarters in Mirandola (Italy) and Houston (U.S.), respectively.

For more information, please visit www.livanova.com.

Safe Harbor Statement

This news release contains “forward-looking statements” concerning our goals, beliefs, expectations, strategies, objectives, plans and underlying assumptions and other statements that are not necessarily based on historical facts. These statements include, but are not limited to, statements regarding 3T Heater-Cooler devices. Actual results may differ materially from those indicated in our forward-looking statements as a result of various factors, including those factors set forth in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2018, as supplemented by any risk factors contained in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. We undertake no obligation to update the information contained in this press release to reflect subsequently occurring events or circumstances.

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