



Organ Recovery
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LKT-200 Service Bulletin and Customer Update

April 3, 2020

Organ Recovery Systems (ORS) continues to closely monitor the COVID-19 developments, including information and guidance published by healthcare and government authorities in the domestic and global markets that we serve.

We are headquartered in the state of Illinois and have been designated as an “Essential Business” under the Illinois Stay-in Place Order. Accordingly, we have permission to travel on mission-critical matters, remain fully staffed, and are open for business worldwide.

We continue to take all necessary measures to mitigate COVID-19 risk and maintain compliance with applicable regulations and guidelines. The COVID-19 situation has not affected Organ Recovery Systems’ ability to produce and deliver products and services, including our ability to staff our 24/7 Perfusion Helpline (Helpline).

As shared with you in our prior notice, several weeks ago we activated business continuity measures to ensure that operations are maintained during this sensitive period, which includes creating an incident management leadership team responsible for overseeing our response to the evolving situation. We also continue to closely monitor our supply chain with respect to vendor preparedness and product availability. This process includes maintaining regular communications with key manufacturing partners, component and logistic services suppliers.

We will continue to do all that we are able to maintain an uninterrupted supply of product and timely technical assistance in support of your life-saving work. Should conditions change, we will promptly notify our clients.

The following provides an update on the status of several ongoing projects at Organ Recovery Systems.

Regarding the voluntary removal by ORS of certain LifePort Kidney Transporter Perfusion Circuit (LKT-200) Lots on January 30th, our investigation is near completion. We have identified a production line leak-test issue at our contract manufacturer and this issue has been corrected.

Also, many of you have asked about the status of ongoing product development programs at ORS regarding our LifePort Kidney Transporter (LifePort).

We have recently completed building machine tools for the injection molding for the enclosure components that will improve robustness/strength of the outer shell of the LifePort Kidney Transporter. Validations and testing are ongoing. LifePorts with the new enclosure are presently expected to be available sometime early in the fourth quarter of

Chicago | One Pierce Place, Suite 475W, Itasca, IL 60143, USA | **T** +1.847.824.2600 | **F** +1.847.824.0234

São Paulo | 170 Moema Avenue, Suite 11 & 12, São Paulo, SP 04077-020, Brazil | **T** +55.11.3586.6259 | **F** +55.11.3586.4944

Brussels | Da Vincilaan 2, Box 6, 1831 Diegem, Belgium | **T** +32.2.715.0000 | **F** +32.2.715.0009

www.organ-recovery.com



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2020. We also completed several LKT-200 modifications to reduce the potential for leakage. These are also in the process of final testing and validation. Presently we are anticipating product availability within June of 2020.

We also want to take this opportunity to provide a **Service Bulletin**.

As always, please employ LifePort and use of its single-use disposables per their Instructions for Use and supplemental training received from ORS. LifePort and the LKT-200 should only be used by a trained healthcare professional.

Specifically, when removing the LKT-200 from LifePort, please inspect the Ice Container for evidence of a potential leak from the LKT-200. We recently received a report of a leak from this location (to be clear, this is not related to the leak observations involved with the prior Lot removal). We recommend that this inspection be conducted out of an abundance of caution.

While in use, it is our recommendation that LifePort should be operated under the direct supervision of properly trained perfusion staff, and actively monitored periodically as prescribed in the Instructions for Use. Please contact the Helpline with any LifePort-related questions or concerns.

If you observe a concern and decide not to use a particular LKT-200 unit, please set the unit aside (do not discard) and contact the Helpline for instructions on the return and replacement of the LKT-200 in question. Proceed with machine preservation using another LKT-200 unit. Importantly, please do not attempt to perform in-house testing or repairs of any kind on an LKT-200; doing so interferes with our investigation and causal analysis.

Our mission is providing medical devices and services in support of the worldwide donation and transplant community's life-saving work. We are deeply honored and grateful for this opportunity and for our long-standing relationship with you. As always, should you have any questions about this service bulletin, please don't hesitate to contact us here: <https://www.organ-recovery.com/contact-us/>.