Urgent Field Safety Notice
LifePort Kidney Transporter 1.1
23 JUN 2023

Manufacturer	Organ Recovery Systems, Inc.		
Single Registration Number	US-MF-000035170		
Item Number	LKT101PNG	Basic UDI	00815045020155
Impacted Serial Numbers	B2123101, B2123102, B2129306, B2131301, B2131303, B2133301, B2133302, B2200403, B2200404, B2200405, B2203101, B2203102, B2203103, B2203104, B2203105, B2203106, B2203107, B2203108, B2212406, B2222406, B2223001, B2223002, B2223003, B2226401, B2226403, B2226404, B2226601, B2226602, B2226603, B2226604, B2227901, B2227902, B2227903, B2227904, B2230408, B2230409, B2230410, B2230411, B2230412, B2231407, B2231408, B2231410, B2231411, B2305205, B2305206, B2305207, B2305208, B2305209, B2305210		

Organ Recovery Systems, Inc. is initiating a Field Safety Corrective Action to address a model number discrepancy between LifePort Kidney Transporters Version 1.1 that contain a Global Positioning System (GPS) module and those that do not. This action impacts 49 devices sold under catalog number LKT101PNG.

These LifePort Kidney Transporters serial numbers were built without the GPS module, in accordance to the BOM and work instructions, and a "NG" suffix was added to the "LKT101P" base item number to differentiate the device. However, the LKT101PNG item number is not included on the Organ Recovery Systems, Inc. CE Mark Certificate, and therefore labeling of that item should not contain a CE Mark icon.

The LKT101P and LKT101PNG devices are identical in all ways except for the labeling and the presence of the GPS module. There is no risk to user or organs associated with the discrepancy. However, Organ Recovery Systems, Inc. will begin tracking the LifePort Kidney Transporter device design options via serial number rather than the labeled item number. To implement this change, all devices currently displaying "LKT101PNG" will be relabeled to show the base item number "LKT101P" only. There are no changes to the device hardware, software or specifications associated with this Field Safety Corrective Action. Customers will have the option of having the relabeling performed at their site or sending the devices to Organ Recovery Systems for the relabeling.

Please contact our Customer Service Desk to arrange for the device to be relabeled. All visits or return shipment costs will be fully covered by Organ Recovery Systems. If you have questions about this notice, please contact Stan Harris at 847-824-2600.

We highly value our relationship with your organization and thank you for your prompt attention to this request.

Sincerely,

[redacted]
Vice President, Regulatory, Quality and Clinical Affairs
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