FIELD SAFETY NOTICE: MERIVAARA Q-FLOW SURGICAL LIGHT

FSN type: New 31/03/2026 (First version issued)

Manufacturer:
Merivaara Corporation (SRN: FI-MF-000001175)

The product covered by the notice:
Q-FLOW SOLO, Q-FLOW DUO, Q-FLOW TRIO, Q-FLOW QUAD, Q-FLOW MOBILE

For attention of:
Healthcare organization using the product, hospital, organization servicing the device

Distributor:
Merivaara Corporation
Tarmontie 2–4, FI-15860 Hollola
Email: merivaara@merivaara.com
Tel: +358 3 3394611

This Field Safety Notice concerns **the above listed Merivaara Q-Flow lights manufactured before June 2023**. The manufacturer and model of the surgical light can be checked from the type plate attached to the device, see Figure below.

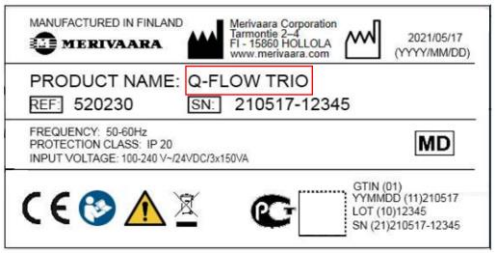

Figure 1. Example of the device's type plate

In post-market surveillance, Merivaara Corporation has become aware that due to an assembly error, the device's support yokes can become loose from their fixings. In the worst case, if these fixing screws become completely loose, the **luminaire may fall off its fixture. This creates a serious risk of injury for the patient and as well as for the user.**

Based on post-market feedback, the probability of the luminaire completely detaching and falling is very low. However, as a responsible manufacturer, Merivaara wants to inform users about this matter and instruct those who service the device to carry out corrective actions to manage the risk.

Note: This corrective action campaign must be carried out even if the device has already undergone the procedures specified in the previously published corrective action campaign 151397. The actions required by this campaign are performed on the joints of the yoke structure that were not subject to the measures specified in campaign 151397. If the actions specified in campaign 151397 have not yet been performed on the device, the actions in this corrective action campaign can be combined with those in campaign 151397. For more information contact service@merivaara.com.

This campaign includes **an inspection or repair of the fixing of the luminaire's support yoke/yokes during the next annual maintenance.** The inspection includes checking the tightness of the screws on one joint (single yoke model) or two joints (double yoke model) and, if necessary, replacing these screws with new ones and adding a screw lock during installation. Depending on the luminaire model, there are 1–3 support yokes to be repaired under a one product name. The repair procedures must be carried out in accordance with the separate instructions provided as attachment to this notice (Annex 1).

In addition to these measures, the manufacturer will provide an updated annual maintenance checklist regarding the functional inspection of the luminaire. The following annual maintenance tasks must be performed in accordance with this checklist for the devices covered by this notice. The updated checklist is provided with this notice (Annex 2).

Furthermore, Merivaara recommends that the user follows the instructions for use and inspects the luminaire daily when cleaning and pays attention to the joints of the support yokes shown in Figure 2. **If looseness is found at these joints during the daily inspection, the luminaire should be taken out of use and repaired by a qualified service technician according to the repair instructions.**

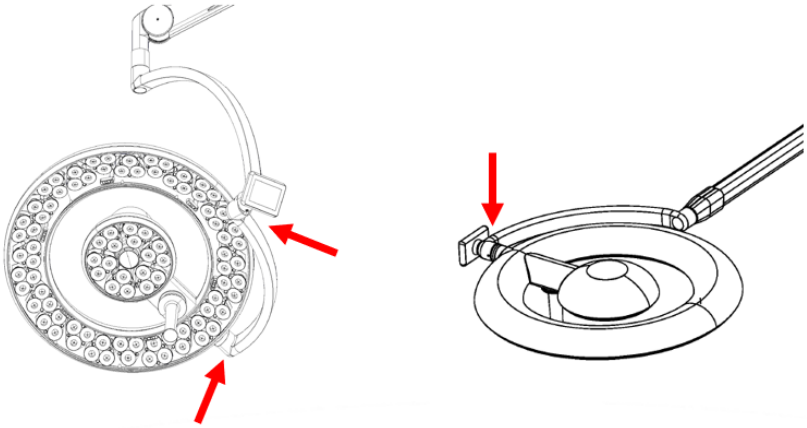

Figure 2. Double yoke model and single yoke model. Joints concerning this Field Safety Notice are marked with an arrow

When following these instructions, it is acceptable and safe to continue using the devices. **Merivaara asks the healthcare organization to inform the users of the device and the organizations servicing the device about this Field Safety Notice and to pay attention to the safety matters mentioned in it.** A copy of this Field Safety Notice should be stored with the user instructions of each device covered by the notice.

This Field Safety Notice should be provided to all people in your organization who need to be aware of it. If the ownership of the device has been transferred to another organization, this notice must be provided to the organization that currently owns the device.

For devices for which the corrective actions required by this Field Safety Notice have already been carried out and recorded in the maintenance history, it is not necessary to repeat the corrective actions.

The manufacturer asks the user to reply to this notice using the Customer reply form at latest by 15/04/2026. The form will be sent with this notice.

Attachments:
FSN_Merivaara Q-Flow surgical light_Repair guidance_698414_Annex 1.pdf
FSN_Merivaara Q-Flow surgical light_Annual maintenance _698414_Annex 2.pdf
FSN_Merivaara Q-Flow surgical light_Field_Safety_Notice_Customer_reply_form_698414.pdf

For questions concerning this notice, please reply to the delivery email or regulatory@lojer.com.

The Competent Medical Device Authority has been informed about this communication to customers. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority, as this provides important feedback regarding device safety.

On behalf of Merivaara Corporation,

Juha Korva
Regulatory Affairs Manager
Lojer Group

Eero Kaaja
Quality- and Sustainability Director
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