Risk Assessment / Corrective Action Plan

Date of Report	February 2026
Subject:	Locking adapter/s to the Leksell Gamma Knife®
Product:	Leksell Gamma Knife®
Manufacturer:	Elekta Solutions AB
Elekta Reference #:	FCA-ESAB-0011

Details of the defect or deficiency

When treating patients with the Leksell Gamma Knife®, the patient is attached to the device via an adapter. The adapter is the interface between the Leksell Gamma Knife® and the immobilization system used for the treatment. The Leksell Gamma Knife® has three types of adapters for patient fixation, the G-frame adapter, the Vantage adapter, and the Mask adapter. Elekta has become aware that a Quality Assurance (QA) procedure was initiated while the adapter was not properly locked to the Patient Positioning System of the Leksell Gamma Knife® As a result, the QA check failed.

Potential Failure mode (Clinical Impact)

In the event that docking misalignment is not detected and treatment proceeds, the dose may be delivered to an unintended location in the patient.

The likelihood of docking misalignment decreases when docking with a patient, as the patient's weight provides increased downward force on the left and right docking blocks. This additional load improves the mechanical seating of the frame adapter into the docking block indentations. Therefore, the probability of the above clinical impact is considered very low.

Failure rate

Failure rate = 0%

**Failure rate has been determined based on patient injury, not on device failure as the action to lock the frame in place is a manual action and was concluded to be use error.*

How the defect was identified

Elekta became aware of this issue on 18 July 2025 from a complaint in the field. Internal reference CLM 03784061.

Any reported patient injuries

Elekta have not received any patient injury reports

Severity and probability of occurrence

Severity has been assessed as *Critical*. *Probability* has been assessed as *Improbable*.

Potential root causes

The root cause has been identified as use error during the docking process of the frame adapter to the patient positioning system. Specifically, the if the operator does not verify that the frame adapter is fully and securely locked into the Gamma Knife system prior to use.

Stock affected

All Leksell Gamma Knife® Perfexion™ devices, All Leksell Gamma Knife® ICON™ devices, All Leksell Gamma Knife® Elekta Esprit™ devices.

Proposed Actions by Manufacturer

Corrective Action #1: Release of Important Field Safety Notice

Elekta will send an Important Field Safety Notice 100-01-202-030 to all affected customers 18 FEB-26. The notice informs users of the specific product and version numbers affected by the issue, and any work around that can be used to avoid the issue.

- Sites affected will be Customers with Leksell Gamma Knife Perfexion devices, All Gamma Knife ICON devices and all Elekta Esprit Devices.

Corrective Action #2: Updates to Instructions for Use (IFU)

Elekta will revise the Instructions for Use (IFU) to incorporate a warning related to this issue. As communicated in the Field Safety Notice (100-01-202-030), existing customers are instructed to print the warning and retain it alongside their current IFU. Newly installed systems will be supplied with an IFU that includes the updated warning.

Estimated completion for this action is April 2026.

_____ 04-FEB-2026

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