

IMPORTANT USER NOTICE

We are providing the information in this Notice to notify you of an important issue that may exist on your equipment, and to inform you of any actions needed to safeguard both your staff and your patients. We ask that you please read and understand the content of this notice and implement any recommendations provided.

We also need you to acknowledge and accept this Notice by signing and returning the statement on the Acknowledgement page.

We advise you to insert this Notice in the applicable copy of the User Manual.

Potentially incorrect mounting of frame adapter

Product: Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™

Reference number (Field Change Order, FCO): 100-03-202-027

Field Corrective Action (FCA) number (if applicable): FCA-EIAB-0004

Scope:	All Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™
Description:	Potentially incorrect mounting of frame adapter to coordinate frame The latches of the frame adapter can be locked even if the locating pins of the frame adapter is not inserted into the corresponding holes in the coordinate frame.
Clinical impact:	If the frame adapter is mounted incorrectly to the coordinate frame and this is not noticed by the user before treatment is started, dose will be delivered in wrong place.
Solution:	Please note that the frame adapter is safe to use provided that the Instructions for use are followed and conducted by a trained professional. It is of the highest importance that the frame adapter is mounted to the coordinate frame as described in the applicable Instruction for Use. The locating pins of the frame adapter shall be inserted into the corresponding holes in the coordinate frame before the three latches are locked. Also make sure that only trained personnel are involved in mounting the frame adapter. A field safety corrective action will be implemented to facilitate a correct mounting of the frame adapter.
Technical Reference:	CAPA 02150105
Contact:	If you have any queries about this Notice, please contact your local Elekta office.

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1 References

The following warnings and cautions are associated with this notice:

N/A

IMPORTANT USER NOTICE ACKNOWLEDGEMENT

Please complete the details below and sign the appropriate acknowledgement section:

- Existing installations; Acknowledgement by the customer
- New installations: New installation confirmation by the installing Elekta or Representative employee

Please return this report to your local Elekta Office or Representative, as soon as possible and within 30 days at the latest.

***The information in this Notice has been provided to address an issue and therefore the customer is expected to acknowledge and accept the recommendations given, and ensure they are implemented. By refusing to implement the recommendations, the customer assumes full responsibility and liability for all matters (including costs, losses, claims, and expenses) resulting, whether directly or indirectly from not implementing such recommendations. Further the customer will hold Elekta harmless from all matters (including costs, losses, claims and expenses) resulting, whether directly or indirectly from not implementing such recommendations.**

Failure to sign and return the acknowledgement may affect any follow-up actions necessary for us to take.

Classification:	Important User Notice	FCO Ref:	100-03-202-027
Description:	Potentially incorrect mounting of frame adapter to coordinate frame		
Scope:	All Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™		
Hospital:			
Device Serial No(s): (e.g. linac - if applicable)		Location or Site No:	
Acknowledgement to be signed by customer*: I acknowledge that I have read and understood this Notice and accept implementation of any given recommendations: Name: _____ Title: _____ Signature: _____ Date: _____			
New installation confirmation to be signed only by the installing Elekta or Representative employee: I acknowledge that the customer is informed on content of this notice and has been inserted in the applicable copy of the User Manual: Name: _____ Title: _____ Signature: _____ Date: _____			