Field Corrective Action Reference: FCA-EIAB-0010

This notice reference: 100-01-301-007

URGENT
IMPORTANT FIELD SAFETY NOTIFICATION

Subject:	Leksell® Neurosurgical Instruments
Product:	**Disposable Biopsy Needle (911933)**
Scope:	Batch/Lot number 837838839
Notification Released:	March 2024
UDI-PI Reference:	Package including 6 needles: (01)0 7340048 30034 6, (17)250401 (10) 837838839 (240) 911933 Package including 1 needle: (01)0 7340048 30800 7, (17)250401 (10) 837838839 (240) 911761 Inner sterile bag including 1 needle: (01)0 7340048 30801 4, (17)250401 (10) 837838839 (240) 912465

Description of Problem:
Disposable biopsy needles are used together with Leksell® Stereotactic System and Leksell® Vantage™ Stereotactic System to take intracranial biopsies using stereotactic technique.

Elekta has become aware that Disposable Biopsy Needles (911933) from one batch (837838839) can contain some microscopic debris on the inside of the biopsy needle. The material in the debris is stainless steel, same material as the biopsy needle. No debris has been found on the outer parts of the biopsy needles. The sterility of the biopsy needles has not been affected. This issue has been reported from one site.

Details:
Investigations suggest that the debris originates from the manufacturing process.

Clinical Impact:
There is a risk that debris can come loose and appear in the biopsy sample. Debris in the biopsy sample may interfere with the slicing of the biopsy sample and delay or make examination difficult.

There is also a potential risk that debris is deposited in the brain. This risk is considered very low since debris have only been reported on the inside of the biopsy needle.

Recommended User Action:
Due to the clinical impact of this issue, all Disposable Biopsy Needles (911933) from batch 837838839 should be removed from clinical use and disposed. Please contact your local Elekta representative for ordering replacement needle kits.

This document contains important information for the continued safe and proper use of your equipment.

- Please post this notice in a place accessible to all users until this action is closed.

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- Advise the appropriate personnel, working with this product, on the content of this letter.

Elekta Corrective Actions:
Elekta is issuing this letter to make users aware of this problem and notifying users to dispose potentially defective products from use. Elekta is investigating necessary actions to prevent the recurrence of this issue.

This notice has been submitted to the appropriate Regulatory Authorities.

We sincerely apologize for any inconvenience this action may cause and thank you in advance for your cooperation.

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Acknowledgement Form

In order to meet regulatory requirements, you are required to either acknowledge receipt of this notification via the Elekta Care™ Community or complete this form and return it to Elekta immediately upon receipt, but no later than within 30 days.

Classification:	Important Field Safety Notification	FCO Reference Number:	100-01-301-007
Description	Leksell® Neurosurgical Instruments: One batch (837838839) of Disposable Biopsy Needles can contain stainless steel debris inside the needles. Affected batch shall be thrown away.		

Hospital:	
Device Serial No(s): (if applicable)	Location or Site:

I acknowledge that I have read and understood this Notice and accept the implementation of any given recommendation.

Name: Title:

Customer Signature: Date:

New installation confirmation to be signed by the installing Elekta engineer or a Representative employee, when the installed product has a physical IFU/manual:

I acknowledge that the customer has been informed on the content of this notice and that it has been inserted into the applicable copy of the User Manual, or added on record with the applicable User Manual:

Name: Title:

Signature: Date: