

URGENT

IMPORTANT FIELD SAFETY NOTIFICATION

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|-------------------------------|---|
| Subject: | Leksell® Neurosurgical Instruments |
| Product: | Disposable Biopsy Needle (911933) |
| Scope: | Batch/Lot number 873874875R |
| Notification Released: | September 2024 |
| UDI Reference: | Package including 6 needles: (01)0 7340048 30034 6 (17) 260401 (10) 873874875R (240) 911933 |
| | Package including 1 needle: (01)0 7340048 30800 7 (17) 260301 (10) 873874875R (240) 911761 |
| | Inner sterile bag including 1 needle: (01)0 7340048 30801 4 (17) 260301 (10) 873874875R (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.

Elektta has become aware that Disposable Biopsy Needles (911933) from the above-mentioned batch (873874875R) 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.

Details:

Investigations together with our supplier confirm 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 the above-mentioned batch should be removed from clinical use and disposed. Please contact your local Elektta representative for alternative solutions.

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



Field Corrective Action Reference: FCA-EIAB-0011

This notice reference: 100-01-301-010

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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.

Qms0433

FCO: 100-01-301-010, VID: 01

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Elekta Care™ Community

QMS0433EN-08



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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.

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|-----------------|--|-----------------------|----------------|
| Classification: | Important Field Safety Notification | FCO Reference Number: | 100-01-301-010 |
| Description | Leksell® Neurosurgical Instruments, batch (873874875R) of Disposable Biopsy Needles can contain stainless steel debris inside the needles. Affected batch shall be disposed. | | |

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|---------------------|-------------------|
| Hospital: | |
| Device batch No(s): | 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: |