Field Corrective Action Reference: **FCA-EIAB-0009**

This notice reference: 100-01-301-004

URGENT
IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Wrong Instructions for Use shipped with Leksell Neurosurgical Instruments and Leksell Stereotactic System®

Product: Leksell Stereotactic Neurosurgery

Scope: Leksell Stereotactic System and Leksell Neurosurgical Instruments

Notification Released: February, 2023

UDI Reference: See below

Description of Problem:

Due to a printing error Elekta has shipped out the wrong instructions for use (IFU) when shipping Leksell Stereotactic System (LSS) and Leksell Neurosurgical Instruments (LNI). Instead of the IFU including both LSS and LNI (1007063, Rev 04), Elekta has shipped an IFU only including the LSS (1007063, Rev 05). The incorrect IFU does not contain any information on the LNI. Customers have therefore been left without an IFU for the delivered instruments.

Details:

The wrong IFU has been shipped to a limited number of customers who have purchased any of the following products:

Part number	Description	UDI-DI
A2800-26	Backlund Catheter Insertion Needle Kit III	07340048301305
A2800-15	Backlund Catheter Insertion Needle Kit I	07340048300285
A2600-01	Backlund Haematoma Evacuator Kit	07340048301220
A2200-01	Salcman Twist Drill Kit I	07340048301145
907801	Insertion Cannula Kit	07340048300315
50398-01	Catheter Insertion Needle for Catheter 1,5 mm	07340048308618
307165	Insertion Cannula 190 mm	07340048308632
60377-02	Twist Drill 3.2 mm	07340048308571
60377-01	Twist Drill 2.1 mm	07340048308564
50376-01	SALCMAN TWIST DRILL COMPLETE	07340048308601
14001050	Catheter Insertion Needle / 2.6 mm	07340048308625
1002248	Frame G w Straight/Curved Front	07340048306348

Clinical Impact:

Elekta Instrument AB | Box 7593 | SE-103 93
Stockholm | Sweden
Tel: +46 8 587 254 00 | Fax: +46 8 587 255 00 |
www.elekta.com | Reg No. 556492-0949

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The instruction for use includes important information related to the safe use of the products. If the user of the device does not read the IFU there is a risk that the product is used incorrectly.

Recommended User Action:
The correct IFU (1007063, Rev 04) will be shipped to all affected customers. It is important that the users of the device read the instruction for use before using neurosurgical equipment from Elekta.

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, e.g. Instructions for Use, until this action is closed.
- Advise the appropriate personnel, working with this product, on the content of this letter.

Elekta Corrective Actions:
Elekta will provide customers with correct IFU and Elekta will take the necessary actions to prevent this from happening again in the future.

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:	100-01-301-004
Description	Wrong Instructions for Use shipped with Leksell Neurosurgical Instruments and Leksell Stereotactic System®		

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:

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