Field Corrective Action Reference: **FCA-EIAB-0008**

This notice reference: 100-01-301-003

URGENT
IMPORTANT FIELD SAFETY NOTIFICATION

Subject:	Leksell® Vantage™ Stereotactic System: Instrument Carrier
Products:	Instrument Carrier, part of Leksell® Vantage™ Arc (1053958)
Scope:	Instrument Carrier, see Fig.3 for list of serial numbers
Notification Released:	June, 2020

This document contains important information for the continued safe 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.

Summary

You are receiving this Important Field Safety Notification because your hospital is in possession of one or more Leksell Vantage Stereotactic Systems including Instrument Carriers. Elekta has found that the design of the Instrument Carrier is not optimal which may cause the locking mechanism at the interface of the Instrument Carrier and the Leksell® Vantage™ Arc to not function properly. This may potentially cause insecure locking. Elekta has improved the design by removing the spring of the Instrument Carrier. By removing the spring the Instrument Carrier is again fully functional and can be used in clinical care. Removal of the spring can be carried out according to instructions below or via the assistance of an Elekta representative. Instrument Carriers must not be used until the spring of the Instrument Carrier has been removed.

Description of Products in scope

Leksell® Vantage™ Stereotactic System is designed to allow a clinician to set pre-planned target coordinates and trajectory angles and thereafter guide an instrument to the target during neurosurgical procedures. It allows a clinician to accurately localize and treat or diagnose the intended area with high accuracy in a minimal invasive fashion.

Instrument Carrier is part of Leksell® Vantage™ Stereotactic System and more specifically part of the Leksell® Vantage™ Arc. The Instrument Carrier attaches to the Arc and holds and secures the surgical instrument at the desired trajectory angle on the Arc (Figure 1).

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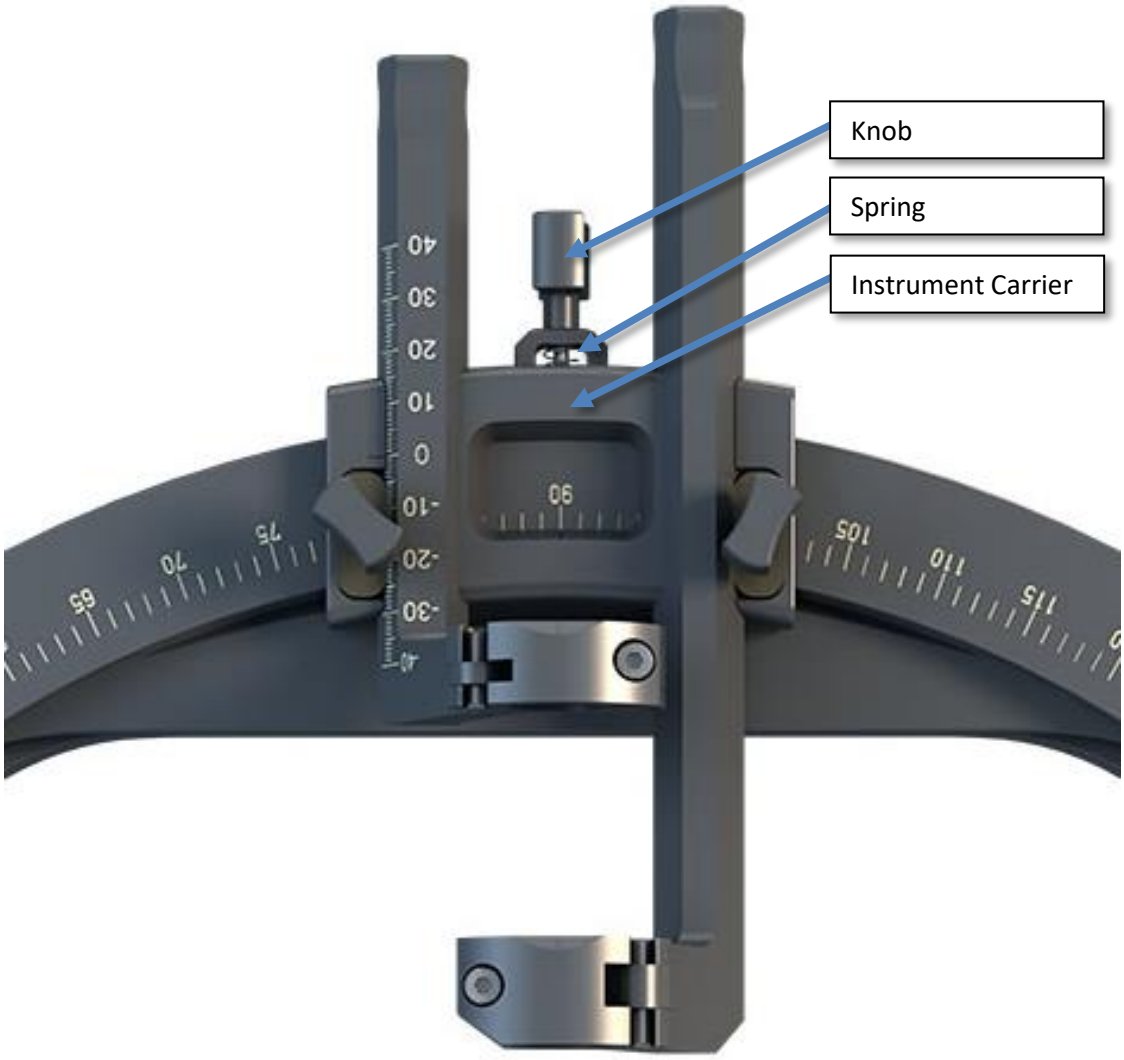

Figure 1. Instrument Carrier including Knob and Spring attached to Leksell® Vantage™ Arc.

Description of Problem

Your hospital is in possession of one or more Instrument Carriers. Elekta has observed that the design of the Instrument Carrier is not optimal where the locking mechanism at the interface of the Instrument Carrier and the Arc may not function properly. Internal testing showed that there is a risk that the spring of the Instrument Carrier can get jammed resulting in insufficient locking (Figure 2). This affects the Instrument Carrier resistance to side forces and the Instrument Carrier may in some occasions not fulfill the requirement of locking force (25 N) it was designed for. Thus, despite tightening the knob firmly there is a risk that the Instrument Carrier may still slide along the Arc when a force is applied from either side.

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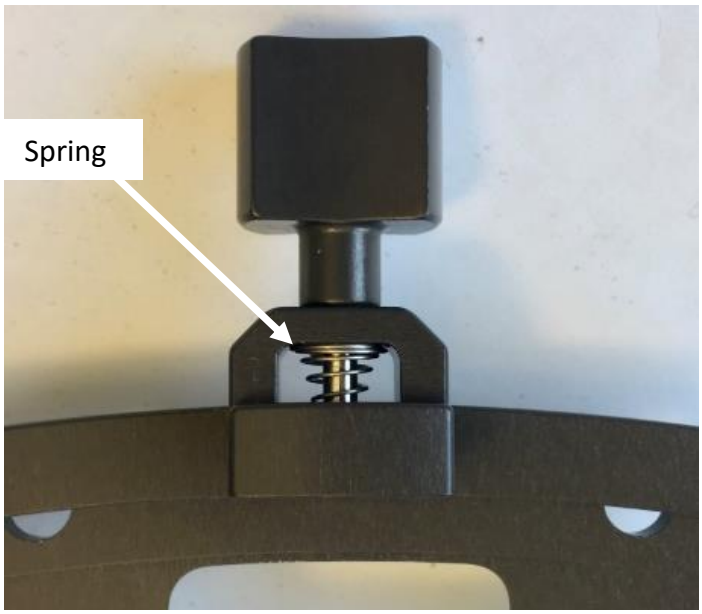

Figure 2. Spring of Instrument Carrier for Leksell® Vantage™ Stereotactic System.

Clinical Impact

Insufficient locking of the Instrument Carrier could result in movement of the Instrument Carrier and the attached neurosurgical instrument during surgery. Such movement may cause clinical mistreatment, or serious injury.

Affected Serial Number on Instrument Carrier

SH00026	SH00049	SH00061	SH00082	SH00092	SH00111
SH00028	SH00050	SH00072	SH00084	SH00094	SH00118
SH00029	SH00052	SH00073	SH00085	SH00095	SH00121
SH00030	SH00054	SH00074	SH00086	SH00097	SH00123
SH00032	SH00055	SH00077	SH00087	SH00099	SH00127
SH00033	SH00057	SH00078	SH00088	SH00100	SH00162
SH00041	SH00058	SH00079	SH00089	SH00102	
SH00044	SH00059	SH00080	SH00090	SH00105	
SH00045	SH00060	SH00081	SH00091	SH00108	

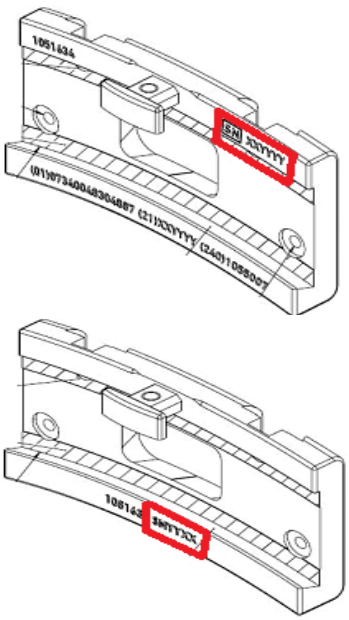

Figure 3. Left) Serial number list of affected Instrument Carriers. Right) Drawings of two different Instrument Carriers where the location of the serial number is marked with a red box.

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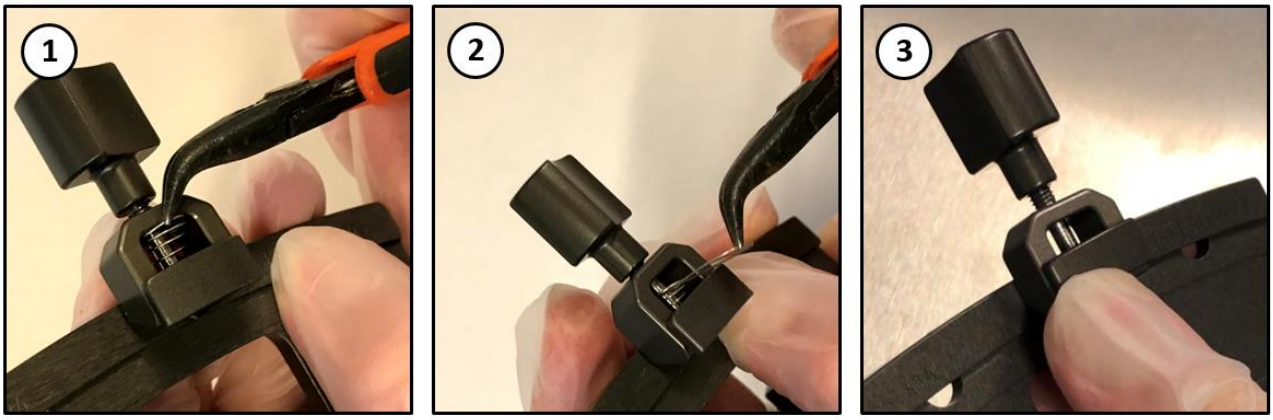
Recommended User Actions

Instrument Carriers must not be used until the spring of the Instrument Carrier has been removed. By removing the spring the product is again fully functional and may be used in clinical care. Removal of the spring will not induce any new risks to the product. Its only function is to lift the locking mechanism to facilitate easy attachment of the Instrument Carrier onto the Arc. After removal of the spring the user will have to manually lift the locking piece when mounting the Instrument Carrier on the Arc. Removal of the spring can be carried out locally by trained Hospital personnel or by an Elekta representative.

Removal of Spring at Hospital

Instructions

1) Grip firmly anywhere on the spring of the Instrument Carrier with an appropriate plier.
2) Gently pull out the spring. Only little force is needed.
3) Check that the spring is fully removed.



Removal of spring by assistance by an Elekta representative

In case you need assistance from an Elekta representative to carry out the removal of the spring, please contact Elekta at Neurosupport@elekta.com.

Elekta Corrective Actions

Elekta is not aware of any cases where the locking mechanism of the Instrument Carrier has not functioned properly in clinical practice. However, Elekta has decided to take this action as a preventative measure. This notice has been submitted to the appropriate Regulatory Authorities.

We sincerely apologize for any inconvenience this 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. You may choose to email or fax the signed acknowledgement form.

Classification:	Important Field Safety Notification	FCO Reference Number:	100-01-301-003
Description	Leksell® Vantage™ Stereotactic System: Instrument Carrier		

Hospital:	
Instrument Carrier Serial No(s):	Location or Site:

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

Please note below the action taken by the hospital.

☐ Spring was removed locally by Hospital personnel

☐ We need assistance by an Elekta representative to remove the spring

Name: Title:

Customer Signature: Date:

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