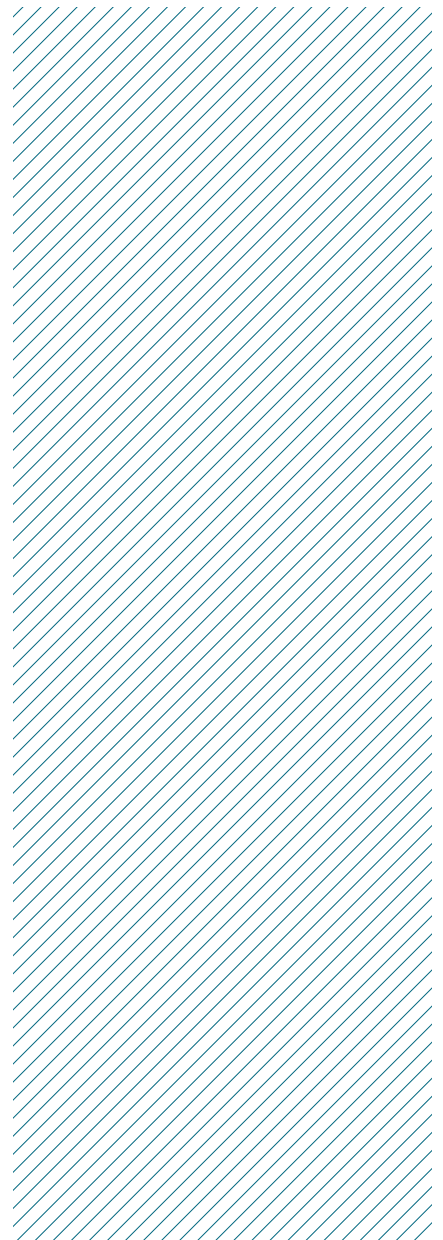
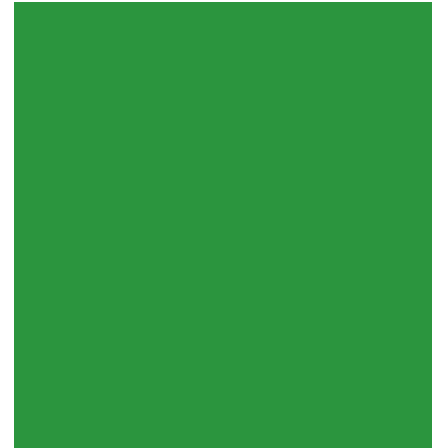


White Paper

# Leksell<sup>®</sup> Vantage<sup>™</sup> Stereotactic System Head Frame Fixation



# Introduction

Elekta released the Leksell® Vantage™ Stereotactic System in 2017. It has a design concept based on the well-established Leksell Stereotactic System®, acknowledged for its ease of use, high accuracy and precision within the clinical application area of stereotactic neurosurgery.

This white paper focuses on the specific head frame fixation characteristics of the Leksell® Vantage™ Head Frame concerning material, design, fixation concept and torque.

(Always read the latest Leksell Vantage Instructions for Use for thorough guidance on usage, assembly, disassembly, maintenance and warnings.)

## Material

The Leksell Vantage Head Frame is manufactured in a glass fiber reinforced epoxy. The FirmFix™ pins used for head frame fixation to the patient's skull are manufactured in a PEEK plastic material (polyether ether ketone), which is a high-performing thermoplastic polymer, with a small aluminum tip that secures the head frame and Leksell® Coordinate System to the patient.

The material composition of head frame and fixation pins are carefully engineered to withstand required forces and maintain stability for the duration of the clinical procedure as well as to enhance capabilities within stereotactic neuroimaging.



**Figure 1.0**  
Leksell Vantage  
Head Frame with  
FirmFix fixation pins

## Design

The Leksell Vantage Head Frame has an open-face design that allows space for intubation of the patient if needed for asleep procedures or in an emergency. In instances when the patient is awake with the head frame mounted, the open-face design allows the patient to read, gives free access to the nose and mouth and enables clinicians to observe patient facial expressions during neurological tests in awake procedures.

The head frame is designed for head sizes 49–62 cm in circumference—the same

head size requirement as its predecessor, the Leksell® Coordinate Frame G.

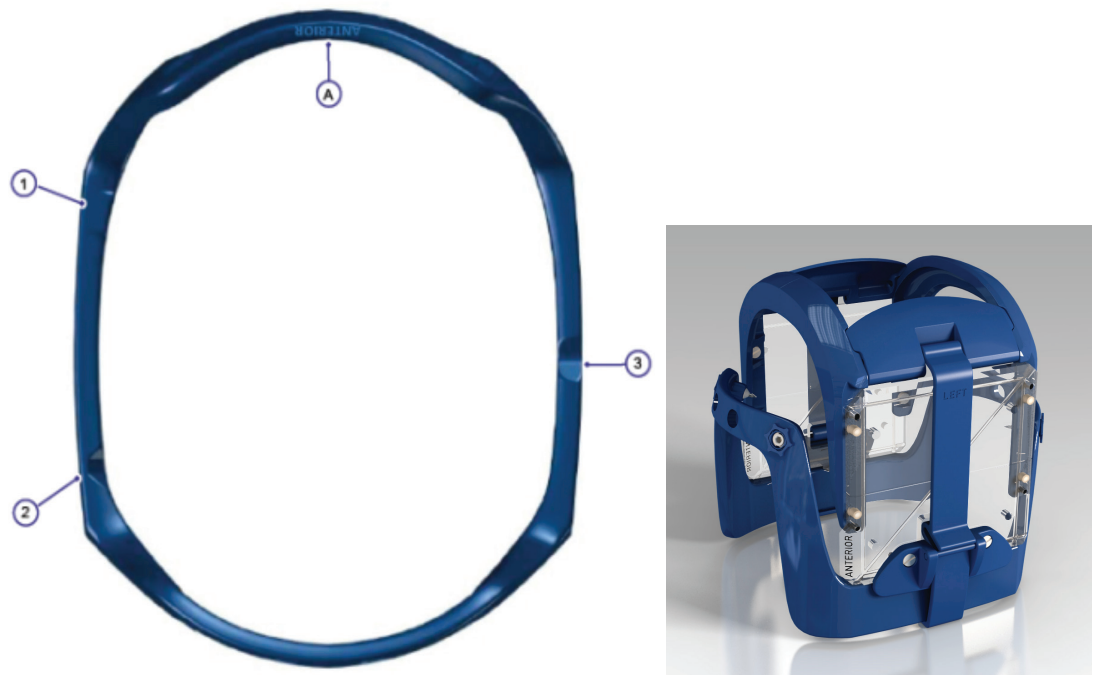
The Leksell Vantage Head Frame is suitable for patient skull widths ranging 134–175 mm and a 167–215 mm skull front-to-back range.

The Leksell Coordinate System origin ( $x = 0$ ,  $y = 0$ ,  $z = 0$ ) is located at patient posterior, superior, right and  $x = 100$  is at the head frame midline fold. The Leksell Vantage Head Frame lateral side bar is designed in a straight line to enable head frame alignment to certain brain anatomy.



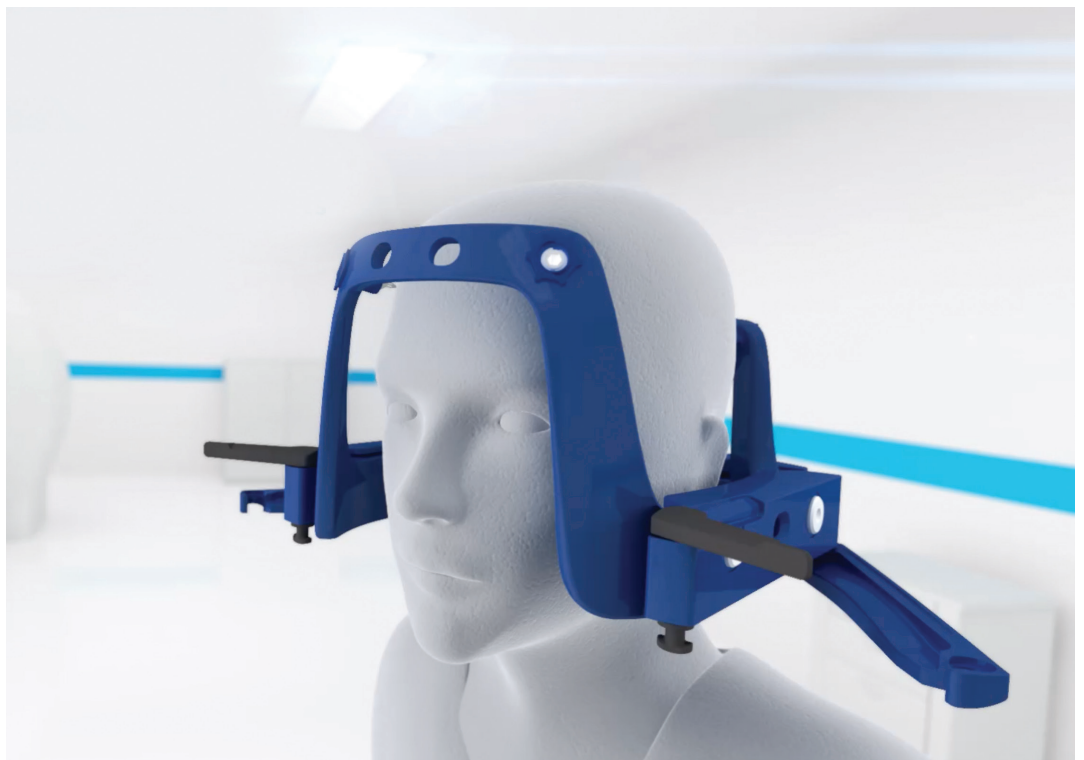
**Figure 2.**  
Leksell Coordinate  
System applied in Leksell  
Vantage Head Frame

The frame has three interface areas (Figure 3) that connect the frame with interface frame holders used to dock the patient to treatment tables and CT scanner tables. In MRI, the head frame interface areas connect directly with the MRI fiducial box.



**Figure 3.**  
Leksell Vantage  
Head Frame

1, 2 and 3 interfaces  
with Frame Holders  
and the Leksell  
Vantage MRI fiducial  
box (A is at the  
anterior position)



## Head Frame fixation concept

Leksell Vantage Head Frame attachment applies the coordinate system to the brain of the patient, enabling precise target coordinate calculation and secured docking to stereotactic neurosurgical treatment devices. The head frame is quickly attached to the patient's skull with four FirmFix fixation pins in combination with local anesthetics or similar. The biocompatible Velcro band may be attached on the head frame and used as a support when applying the FirmFix pins.

The head frame is designed in one piece to fit many head shapes and sizes, so there's no preassembly. In a product surveillance<sup>3</sup> of Leksell Vantage Stereotactic System, four out of four users taking part in the surveillance experienced quicker assembly of the Leksell Vantage Head Frame than the Leksell G Frame.

FirmFix is available in five different lengths to cover a majority of head and skull shapes. Normal fixation uses four FirmFix pins—one in each corner, anterior and posterior, of the frame—but variation can be used for previous craniotomy patients or when pin fixation areas are limited for other medical reasons. Three fixation pins may be used if two pins are used in the posterior part of the head.

The FirmFix ruler is used to select the proper fixation pin length for the patient by introducing it into the intended frame hole. Introducing the ruler all the way to the fixation site on the patient's skull and reading the scale outside the frame guides FirmFix pin selection for optimal fixation. The FirmFix pins are presterilized and labeled with a color and number for proper selection.

FirmFix #3 (green) was used in most of the cases, followed by FirmFix #4 (blue) in the product surveillance feedback reported to Elekta after initial usage.<sup>3</sup>



**Figure 4.**  
FirmFix 1-5, the FirmFix ruler and the frame positioning band

Tightening of FirmFix pins is optimally done diametrically opposite to each other, to distribute the load of the fixation pins evenly against the patient's head. Use sufficient force for a rigid fixation,

but there is no need to overtighten. It's important to ensure that the head frame is rigidly fixated to the skull before continuing with stereotactic imaging and treatment.



**Figure 5.**  
Leksell Vantage  
head frame  
diagonal fixation

All four centers that participated as Elekta product surveillance centers found the rigidity of the fixation to the patient skull satisfactory when using Leksell Vantage Head Frame.<sup>3</sup>



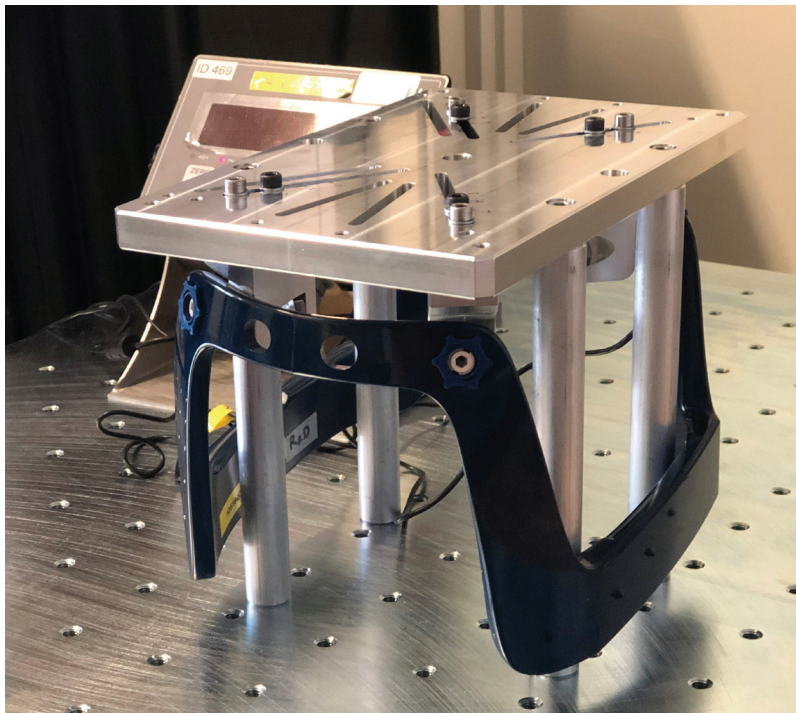


## Fixation torque

Guidance from Elekta on how much torque to use when fixating the Leksell Vantage head frame follows.

### Method

To determine the torque, it's necessary to understand the force the FirmFix pin will transfer to the skull—therefore, a special tool (Figure 6) was used with force sensors behind each attachment area for the pins. The attachment areas could be moved inward/outward to simulate different head sizes and FirmFix sizes.



**Figure 6.**  
Leksell Vantage  
head frame  
torque/force tool

Two torque wrenches set to 0.4, 0.5, 0.6, 0.7 and 0.8 Nm were used to tighten the screws diagonally, and the tool was set to S, M, and L skull sizes. Table 1 shows the set skull size in relation to the FirmFix size. Only normal positions were used—i.e. the four outer holes in the frame.

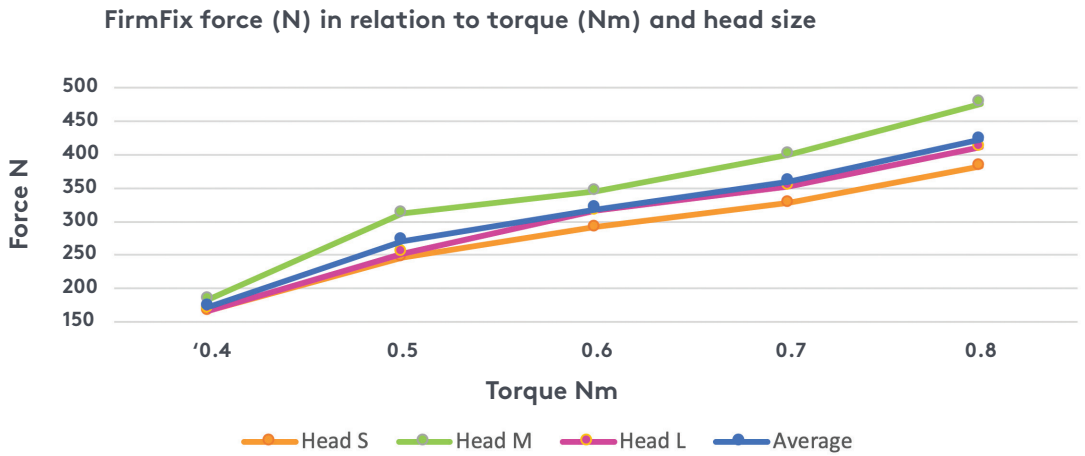
Skull size	Anterior left	Anterior right	Posterior left	Posterior right
<b>S</b>	FirmFix 5	FirmFix 5	FirmFix 4	FirmFix 4
<b>M</b>	FirmFix 4	FirmFix 4	FirmFix 3	FirmFix 3
<b>L</b>	FirmFix 2	FirmFix 2	FirmFix 2	FirmFix 2

**Table 1.**  
FirmFix selected  
for the different  
skull sizes



## Results

Graph 1 shows results regarding the force noted for each skull size and FirmFix position.

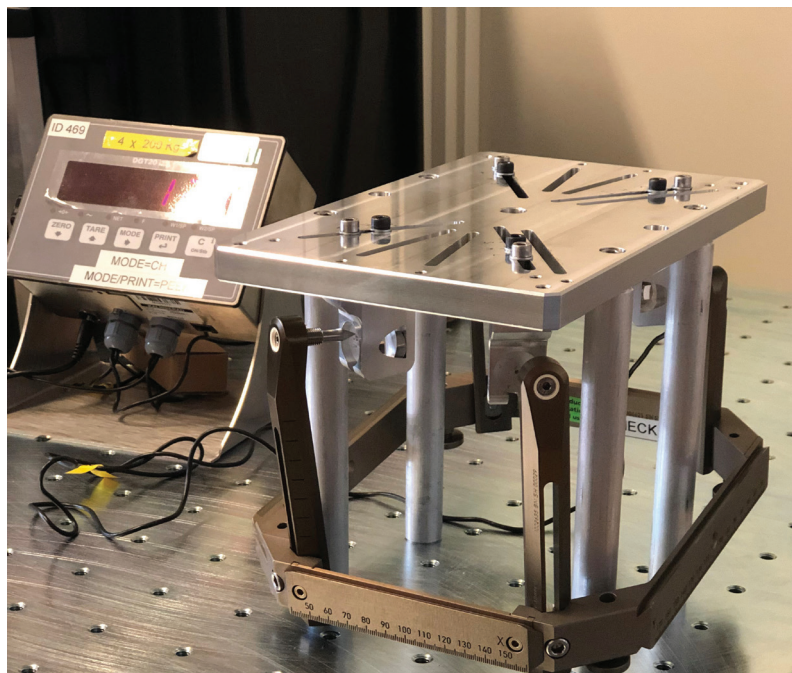


**Graph 1.**  
FirmFix force in relation to torque and head size

The torque required to reach the same force for the different skull sizes varies about  $\pm 0,15$  Nm. When the same torque is used, the force achieved is  $\pm 50$ N compared to average force for all skull sizes, where the small skull gets the least force.

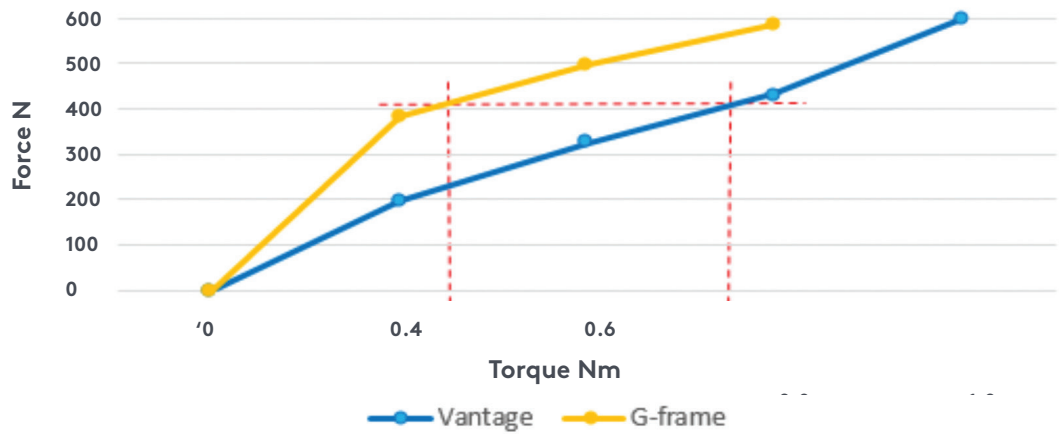
A comparison with the Leksell Coordinate Frame G was done, including simulation of different head sizes. The post screw position was set at the same height as

the Leksell Vantage Head Frame pin position (Figure 7). Disposable inserts were used together with reusable fixation pins in al and titanium fixation pins to see the difference. The al pins gave a slightly higher force in this test, but since cleaning, etc. affects the reached force, the average data for both are included in Graph 2, which is in comparison with the average data for FirmFix.



**Figure 7.**  
Frame G test in the torque/force tool

FirmFix™ and G-frame pin force (N) in relation to torque (Nm)



**Graph 2.**  
FirmFix and  
Frame G pin force in  
relation to torque

The results shown indicate that FirmFix reaches less pin force than the fixation pins for the Leksell G Frame using the same torque. Feedback from users of the Leksell Frame G indicates a torque of 0.45 Nm is often used. This would result in a force of just above 400 N, which for FirmFix is reached with a torque of 0.75 Nm (see Graph 2 dotted red line). In-house verification of the Leksell Vantage Stereotactic System has shown that a torque of 0.6 Nm or more fixated to a PMMA phantom functions well and for a small skull, too. Since a skull gives way to the force with time, it's probable that a higher torque can be used clinically. For the Leksell Frame G, a torque of 1 Nm or above is not possible to use, because the screw for the post can move. Therefore, 0.8 Nm is estimated to be the highest torque used clinically for the Frame G. That would correspond to a highest torque of 1 Nm for FirmFix to reach maximum force as for the Frame G (Graph 2).

Other Leksell Frame G/Leksell Vantage Stereotactic System differences affecting fixation include Frame G posts, which bend out much more than the Vantage Head Frame does, and different pin size and pitch—so, even if a higher torque needs to be used for the Leksell Vantage Stereotactic System to reach the same force toward the skull, the force is reached faster with the Vantage system. This is due to the larger diameter of the pin, higher pitch and less spring effect of the frame, requiring fewer turns with the key to reach the recommended torque with the Leksell Vantage Head Frame.

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## Summary and conclusion

The new design implemented in the Leksell Vantage Head Frame allows greater access to the patient's nose, eyes and mouth—useful for asleep and awake patients. The Leksell Coordinate System used with the frame is based on the same principles as the previous Leksell Coordinate Frame G, with the origin at patient posterior, superior, and right. A dedicated ruler provides a new method for selecting which FirmFix pin length to use for skull fixation. The FirmFix pins are supplied presterilized in five lengths, covering the same head sizes as the Leksell Coordinate Frame G.

To find the force towards the skull in relation to torque, a special in-house tool was used to enable checking. Three different skull sizes were

used, comparing Leksell Vantage with FirmFix and the Leksell Coordinate Frame G fixation pins. The reached force for FirmFix was lower than for the Leksell Frame G when the same torque was used, but it was reached faster—i.e. fewer turns with the screwdriver.

Recommended torque for FirmFix is from 0.6 Nm up to 1 Nm, which will give a force towards the skull of 300–600 N. This is based on the results from verification of the Leksell Vantage Stereotactic System at Elekta and experience from clinically used torque with the Leksell Frame G, which through this document has been translated into FirmFix force.

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## References

- [1] 1540965 Leksell Vantage Stereotactic System Instructions for Use (Eng.) Rev 02
- [2] ASTM F2503-13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.
- [3] Pd201\_10006414 Leksell Vantage Stereotactic System Product Surveillance



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