

- **Not for discussion with customers**
- **May be discussed with customers depending on (local) strategy and regulatory requirements**
- **May be discussed freely**

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● Purpose

This product update document is intended to be used for sales, distributors and other personnel in the need to help Elekta customers identify which MRI coil interfaces that are available for Leksell® Vantage™ Stereotactic System. This document is not replacing the Leksell Vantage Stereotactic System instructions for use or the information provided by the MR imaging providers.

● Product Description

Leksell® Vantage™ Stereotactic System components used for stereotactic MRI imaging are designed to fit in MRI head coils with a minimum of 250 mm in diameter.



- **Leksell Vantage Head Frame**

Material: Glassfiber reinforced epoxy

- **FirmFix disposable pins and inserts**

Material: PEEK (Polyether ether ketone) plastic with Al. tip



- **Leksell Vantage MRI Fiducial box**

Material: Glassfiber laminate, Pom plastic, PMMA (plexi), Glass fiber reinforced polyamide pins, Nylon screws

The Leksell Vantage MRI fiducial box has two side fiducial plates with channels that are filled with CuSO₄ solution to apply fiducial markers to the MR images of the brain to position the patient's brain in the stereotactic coordinate system. Then, it is possible to obtain stereotactic target coordinates in the Leksell Coordinate System and send the MR images to compatible treatment planning software.

There are four different coil adapters which support the patient's head within the frame inside the MR head coil. These adapters prevent movement, see Figure 3.88. The coil adapter is attached to the back of the frame.

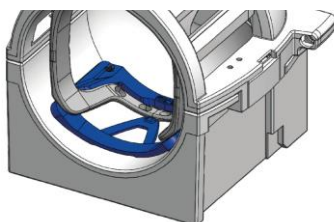


Figure 3.88 The four coil adapters

(1) Coil adapter, posterior
(2) Coil adapter, upper strip
(3) Coil adapter, lower strip
(4) Coil adapter, longer

- **MRI Coil Adapters**




Material: Pom plastic, Rubber feet








Leksell® Vantage™ in stereotactic MRI

● MR labeling

Always refer to the information in the latest instructions for Use (IFU) but at the time of the issuing of this Neuro Product update this is the MR labeling the Leksell Vantage. Each Leksell® Vantage™ Stereotactic System component is classified into MR Safe, two MR condition options, MR unsafe or as not intended for MR environment see below table per IFU June 2020 with document ID 1547039 Rev.02 (English):

MR safety class	Symbol	Definition
MR Safe		An item that poses no known hazards in all MR environments.
MR Conditional		An item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.
MR Unsafe		An item that is known to pose hazards in all MR environments.





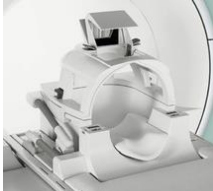










Product	MRI Safety Information
FirmFix™ Ruler Leksell® Vantage™ Frame Holder Leksell® Vantage™ Head Frame Leksell® Vantage™ Head Frame Positioning Band Leksell® Vantage™ MRI Fiducial Box MRI Head Coil Adapter	 MR Safe
FirmFix™ 1, 2, 3, 4, 5	 MR Conditional

Product	MRI Safety Information
	<ul style="list-style-type: none"> Static magnetic field of 1.5 Tesla and 3.0 Tesla Maximum spatial field gradient of 13000 Gauss/cm (130 T/m) Maximum MR system reported whole body averaged specific absorption rate (SAR) of 4.0 W/kg (First Level Controlled Mode), <3 °C after 15 minutes of continuous scanning.
Leksell® Vantage™ Arc System Starburst Adapter with Starburst Screw Starburst Radiolucent Adapter with Starburst Screw Allen Key 6 mm titanium	 MR Conditional <ul style="list-style-type: none"> Static magnetic field of 1.5 Tesla and 3.0 Tesla These components are restricted to a gauss line of 0.8 T (8000 G). An attractive force may be felt when near the entrance to the MR system.
Leksell® Vantage™ Key Leksell® Vantage™ Cross-Hairs	 MR Conditional <ul style="list-style-type: none"> Static magnetic field of 1.5 Tesla and 3.0 Tesla These components are restricted to a gauss line of 0.5 mT (5 G). An attractive force may be felt when near the entrance to the MR system.
Filling needle Leksell® Vantage™ Arc Tray	 MR Unsafe
Allen Key 5 mm stainless steel CT Clamp Type Table Fixation CT Head End Table Fixation CT Universal Table Fixation Leksell® Vantage™ CT Fiducial Box Leksell® Vantage™ CT Frame Holder extension Leksell® Vantage™ CT Interface MRI Box Screwdriver MRI Copper Sulfate Filling Screwdriver	Not intended for MRI environment but can be used in an environment of less than 0.5 mT (5 G).

MRI scanners head coils

Always check with Elekta or the MRI manufacturer for the latest status as this listing will be updated on a regular basis.


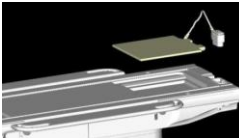






- **Leksell® Vantage™ compatibility chart with MRI head coils below:**

GE head coils	<i>Leksell Vantage coil adapter recommended</i>	Philips Head coils	<i>Leksell Vantage coil adapter recommended</i>	Siemens Head coils	<i>Leksell Vantage coil adapter recommended</i>
Quadrature Head coil 	Part No. 1098530 MRI Coil Adapter Large 	dStream T/R Head coil 	Part No: 1098534 MRI Coil Adapter upper stop 	Head Matrix coil (12 or 20 channels) https://www.healthcare.siemens.com/magnetic-resonance-imaging/options-and-upgrades/coils/head-matrix-coil 	Part No: 1098532 MRI Coil Adapter lower stop 
450/750 and HD split head coil Finns på NKS 	Part No. 1098530 MRI Coil Adapter Large 	dStream Hed 32ch coil 	<i>Potentially but no coil adapter fits, please secure no pressuring on side plates</i>	TxRx CP Head coil 	Part No. 1098530 MRI Coil Adapter Large 
		Transmit Receive Head Coil 	Part No: 1098534 MRI Coil Adapter upper stop 	CP Head Array Coil 	Part No. 1098530 MRI Coil Adapter Large 

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Most MRI providers also have Flex coil solutions that can be utilized, below are examples. Contact Elekta or the MRI provider for more details if needed.

Please ensure to never press the MR fiducial box side plates during scanning if using Velcro bands or similar to hold the flex coils together.

GE	<i>Leksell Vantage coil adapter recommended</i>	Philips	<i>Leksell Vantage coil adapter recommended</i>	Siemens	<i>Leksell Vantage coil adapter recommended</i>
Open RT GEM Array with the 6 channel flex coils Or without the elements in the MR table insert.  	Part No. 1098530 MRI Coil Adapter Large  And a pillow under the patient head	Philips Large, Medium and Small flexcoils 	Part No. 1098530 MRI Coil Adapter Large  And a pillow under the patient head	Siemens Flex Coils  	Part No. 1098530 MRI Coil Adapter Large  And a pillow under the patient head

Please contact your local Elekta representative for latest information.