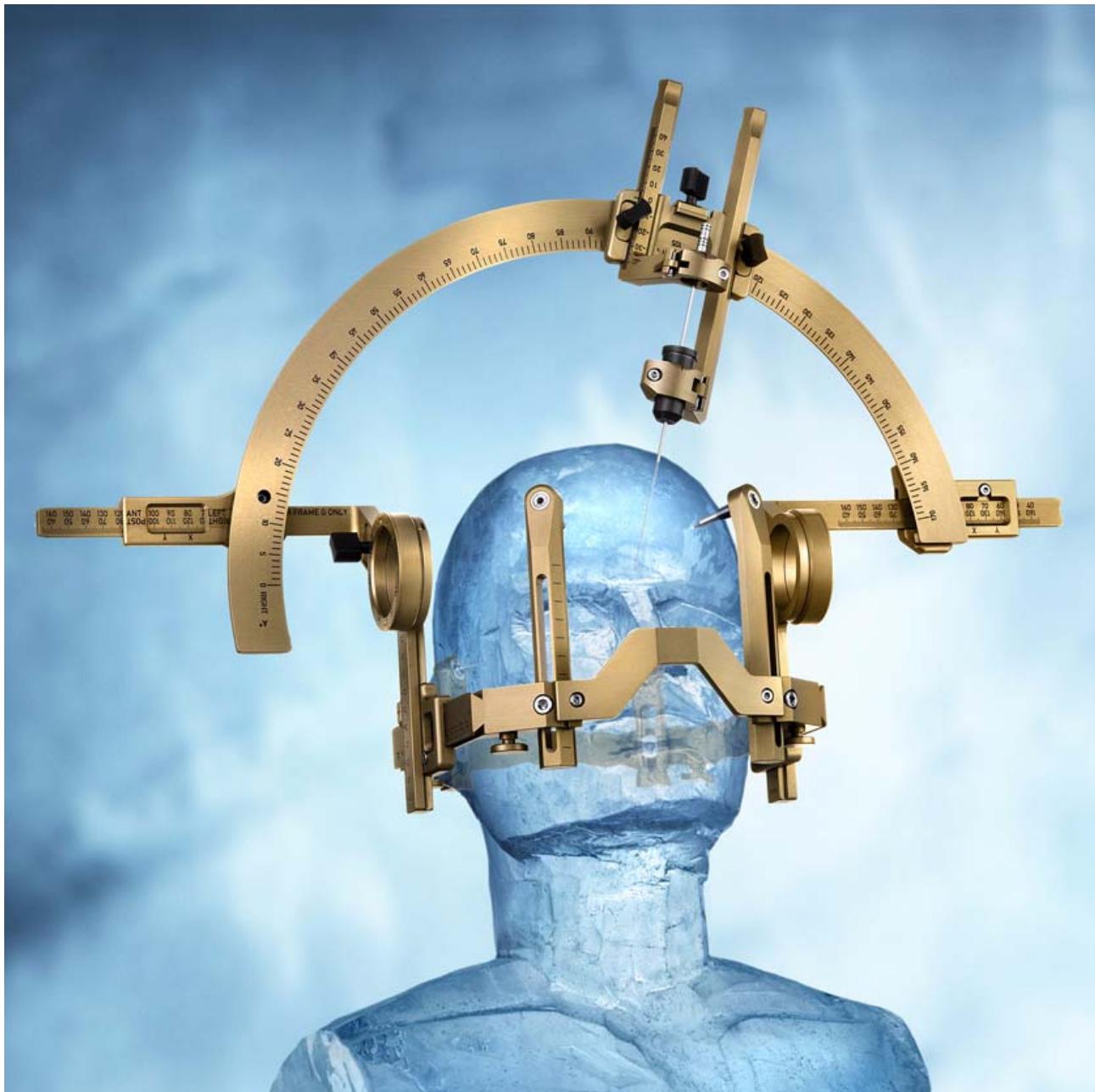


Leksell Stereotactic System®

Instructions for Use



Article number: 1007063 Rev. 04 (2015-05)

Language: English



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Referenced documents

Not all documents referred to in this document are part of the scope of delivery for the equipment. Elekta reserves the right to determine which documents are delivered with a product.

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TECHNICAL SUPPORT

Contact your local Elekta representative for technical support

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1 Introduction

1.1 About this manual

This manual is intended to assist users in the safe and effective operation and maintenance of the equipment described. The user includes the body with authority over the equipment and those persons who actually handle the equipment.

Before attempting to work with this equipment the user must thoroughly read and completely understand this manual.

The most extensive configuration is described within this manual, including the maximum number of options and accessories. Not every function, option or equipment accessory described may have been purchased or licensed by the user.

This manual must be kept with the equipment for easy reference.

1.1.1 Intended audience

This manual is written for trained users of the Leksell Stereotactic System®, for service personnel, and for personnel involved in care and maintenance procedures.

1.1.2 Disclaimer

Elekta assumes no liability for use of this document if any unauthorized changes to the content or format have been made.

Every care has been taken to ensure the accuracy of the information in this document. However, Elekta assumes no responsibility or liability for errors, inaccuracies, or omissions that may appear in this document.

Elekta reserves the right to change the product without further notice to improve reliability, function or design.

This document is provided without warranty of any kind, either implied or expressed, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

1.1.3 Illustrations

Illustrations in this manual display the equipment as present. Differences may occur compared to previous models and versions of the equipment. Such differences in the illustrations are of aesthetic character and not functional.

1.1.4

Warnings, cautions and notes

The following are samples of how warnings, cautions and notes appear throughout this manual. The text within the samples explains their meaning.



WARNING 1.1

Warnings are directions which, if ignored, could constitute a health hazard, cause fatal or serious injury, or lead to clinical mistreatment.



CAUTION 1.1

Cautions are directions which, if ignored, could cause damage to the equipment described in this manual, and/or any other equipment or goods, and/or could cause environmental damage.

Note:

Notes provide advice and highlight unusual points. A note can also be part of an instruction.

1.1.5

Short names

The following are short names for products referenced in this manual. Other short names may occur in each section of the manual and are explained where applicable.

Term	Definition
coordinate frame	Leksell® Coordinate Frame G
stereotactic arc	Leksell® Multi Purpose Stereotactic Arc

1.1.6

Abbreviations

The following abbreviations may be found in this manual.

Abbreviation	Definition
CE	Conformité Européenne
CT	Computerized Tomography
MR	Magnetic Resonance
MRI	Magnetic Resonance Imaging
PET	Positron Emission Tomography
RF	Radio Frequency
SAR	Specific Absorption Rate

1.2

About Leksell Stereotactic System®

1.2.1

Intended use

Leksell Stereotactic System® is intended for localization and diagnosis of intracranial disorders and their surgical treatment including radiosurgery and stereotactic radiation therapy.

WARNING 1.2



Side effects of stereotactic neurosurgery are generally associated with effects on critical structures or blood vessels that are within or nearby the treatment target or the trajectory. These may include effects that can be temporary or permanent. These effects can lead to intracranial bleeding, infection, vascular emboli and neurological symptoms depending on the brain location.

Particular effects depend on the actual region at risk by virtue of proximity to the target and other clinical factors such as age, medical condition, the disorder treated, previous treatment history, and other prior interventions both medical and surgical.

1.2.2

Compliance

Leksell Stereotactic System® is designed to comply with the requirements of the Medical Device Directive 93/42/EEC. The system comprises of separately CE marked devices combined according to Article 12.

1.2.3

Compatibility

Equipment described in this manual shall only be used in combination with other equipment or components if these are expressly recognized by Elekta as compatible. Consult Elekta for advice on compatibility with the Leksell Stereotactic System® before using any equipment not supplied by Elekta.

Changes and/or additions to the equipment shall only be carried out by persons expressly authorized to do so by Elekta. Such changes shall comply with best engineering practice and all applicable laws and regulations that have the force of law within the jurisdiction.

WARNING 1.3



Changes, additions or maintenance to the equipment carried out by persons without appropriate qualifications and training and/or using unapproved spare parts may lead to serious risk of injury and/or damage to the equipment as well as making the warranty void.

1.2.4 MR safety information

1.2.4.1 MR safety classification and symbols

The products included in the Leksell Stereotactic System® are classified into one of three classes, see [Table 1.1](#).

Table 1.1 MR safety classifications and symbols

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.

Alterations performed by the site on MR Safe or MR Conditional equipment may alter the MR compatibility properties of the equipment.

1.2.4.2 Leksell Stereotactic System® and usage in MR environment

Leksell Stereotactic System® is MR Conditional according to the definitions in the ASTM standard F2503-13 “Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment”.

1.2.4.3 Conditions for use in MR environment

By use of a plastic insert, the Insulated Fixation Posts effectively insulates the fixation screws from the fixation posts thus reducing the energy transfer and provide a sterile, single use interface between the patient and the coordinate frame.

Conditions for use of Leksell Stereotactic System® in the MR environment:

- Only for use in 1.5 T or 3 T with RF transmit head or body coil.
- Always use the insulated fixation posts. Otherwise there is a risk of temperature increase at the tip of the fixation screws.
- Non-insulated fixation posts are contraindicated (MR Unsafe).

Note:

All other fixation posts than the “Insulated Fixation Posts” are defined as non-insulated.

1.2.5

Use of the equipment

Leksell Stereotactic System® is intended to be installed and used only in accordance with the safety procedures given within this manual for the purpose for which it was designed. Nothing stated in this manual reduces the user's professional responsibilities for sound judgement and best practice.

Installation and use of this equipment is subject to the law in the jurisdictions in which the equipment is being used. Users shall only install and use the equipment in such ways that do not conflict with applicable laws or regulations which have the force of law.

Use of the equipment for purposes other than those intended and expressly stated by the manufacturer, as well as incorrect use or operation, may relieve the manufacturer or his agent from all or some of the responsibility for resultant non-compliance, damage or injury.

The product shall only be used as described in this manual.

Note:

In the United States, Federal law restricts this device to sale, distribution, and use by or on order of a licensed physician.

1.2.5.1

Training

Users of Leksell Stereotactic System® shall have received adequate training on its safe and effective use before attempting to work with it.

Training requirements may vary from country to country. The user shall ensure that training is received in accordance with local laws or regulations that have the force of law. Information on training is available from Elekta or your local Elekta® representative.

1.2.6

Important safety instructions

Elekta® products are designed to meet stringent safety standards. Every reasonable precaution has been taken during manufacture to safeguard the health and safety of patients and persons who will operate this equipment.

It is vital that the user read, understand, and where applicable strictly observe all safety directions, warnings, cautions, notes and safety markings within this manual and on the equipment.

1.2.6.1

Maintenance and faults

Do not use Leksell Stereotactic System® for any application until you are sure that the procedures for care and maintenance have been satisfactorily completed.



WARNING 1.4

If any part of the equipment is known or suspected to be defective or incorrectly adjusted, DO NOT USE the equipment until a repair has been made by Elekta. Use with defective or incorrectly adjusted components or systems could expose the users and/or the patient to radiation and other safety hazards. This could lead to injury or to clinical mistreatment.

1.2.6.2

Warning symbols

The following warning symbols can be found on the package or equipment:

A blue circular symbol showing a stylized person reading a book.	Instructs the user to refer to the product documentation.
A yellow triangular warning symbol with a black exclamation mark in the center.	Indicates a specific warning if displayed in conjunction with warning text. Instructs the user to refer to the product documentation if displayed without warning text.
A white square symbol with a black 'X' over a trash bin icon.	Indicates never to dispose of the product or component into the domestic waste stream.

For MR safety classifications and symbols see [Section 1.2.4 on page 8](#).

1.2.6.3

Other symbols

The following symbols can be found on the package or equipment:

	Symbol for “Caution”
	U.S. Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
	Do not use if package is damaged
	Non-sterile (The product is delivered non-sterile)
	Do not reuse (Use only once)
	Catalog number
	Batch code
	Serial number
	Sterilized using ethylene oxide
	Sterilized using irradiation
	Use by
	Date of manufacture
	Manufacturer
	CE symbol with number from the notified body

See also [Section 9.7 on page 288](#).

For MR safety classifications and symbols see [Section 1.2.4 on page 8](#).

1.2.7

Final disposal

The term final disposal means disposal of the equipment, or any part of the equipment, in such a way that the equipment or part can no longer be used for its intended purpose(s).

Never dispose of Elekta® products in the domestic waste stream.

Disposal must always be executed in an environmentally sensitive manner that complies with all local and international regulations and laws. Materials hazardous to human health and the environment must be separately removed and disposed of through competent, licensed facilities. The remaining material may be recycled where facilities and local regulations permit.

2

Leksell® Stereotactic Neurosurgery

Leksell® Stereotactic Neurosurgery is an integrated solution for minimally invasive neurosurgery for localization and treatment of targets within the brain.

The neurosurgery solution consists of three major products and their accessories:

- Leksell Stereotactic System® – described in this manual – for diagnostic as well as therapeutic procedures, such as biopsies of deep-seated targets and treatment of functional disorders.
- Leksell SurgiPlan® – for pre-operative planning and post-operative evaluation.
- Leksell® Neuro Generator – for functional procedures such as macro stimulation and stereotactic brain lesioning.

The three major products and their accessories constitutes one integrated system, where all components are designed to work together in an efficient, smooth manner.

The products are easy to use, easy to learn and have an optimized design in a sophisticated, yet simple way. The versatility is demonstrated both by the wide range of supported applications and the freedom of choice that it offers the neurosurgeon.

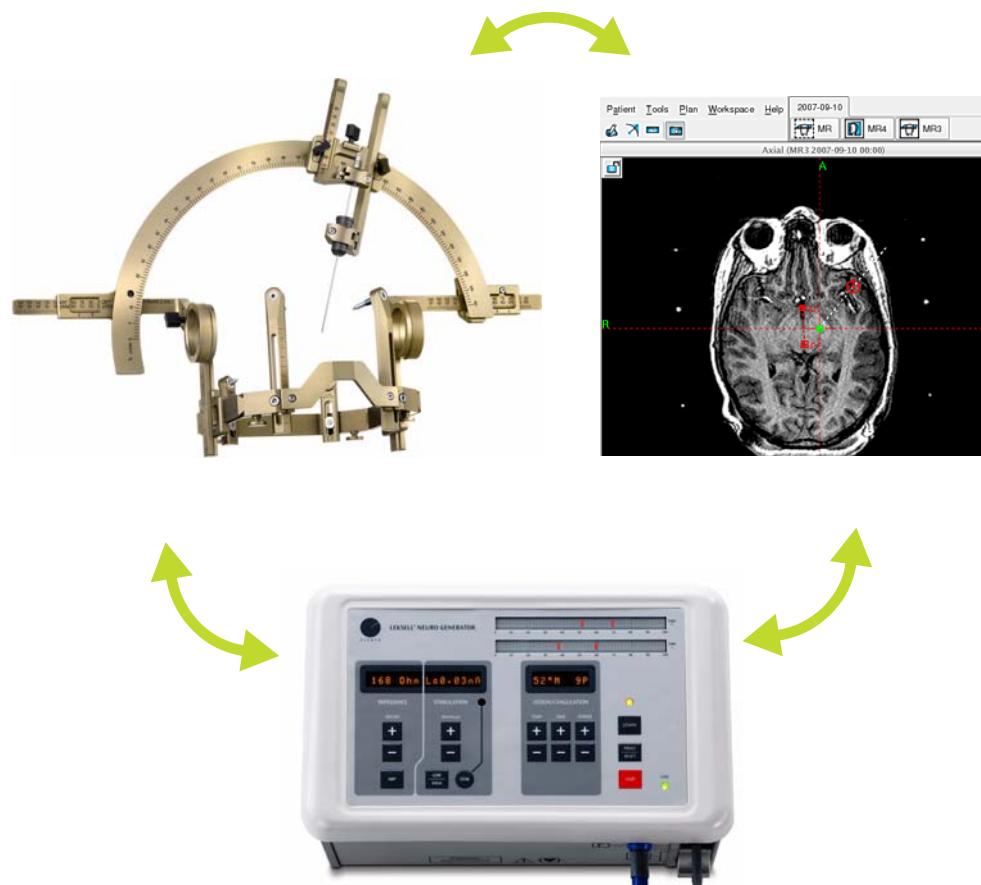


Figure 2.1 The major products of the Leksell® Stereotactic Neurosurgery solution.

Leksell Stereotactic System® – the core system

Leksell Stereotactic System® is the highly reliable and accurate foundation for the neurosurgery solution area. It is a three-dimensional reference system, based on Leksell® Coordinate Frame, a semicircular arc and the center-of-arc principle. The high quality standards and the continuous development of the system have made it an indispensable and user friendly tool for the neurosurgeon.

It provides, as well, the foundation for late professor Lars Leksell's development of Leksell Gamma Knife® and radiosurgery as an effective treatment option.

The system is further described in [Section 2.1 on page 17](#).

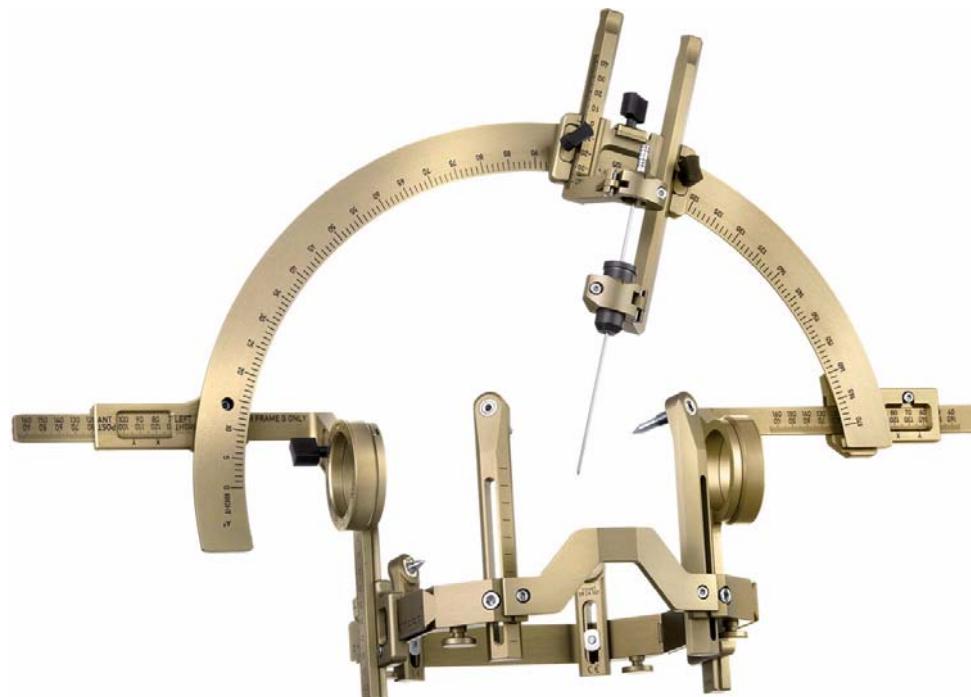


Figure 2.2 The basic components of Leksell Stereotactic System® are the coordinate frame and the stereotactic arc.

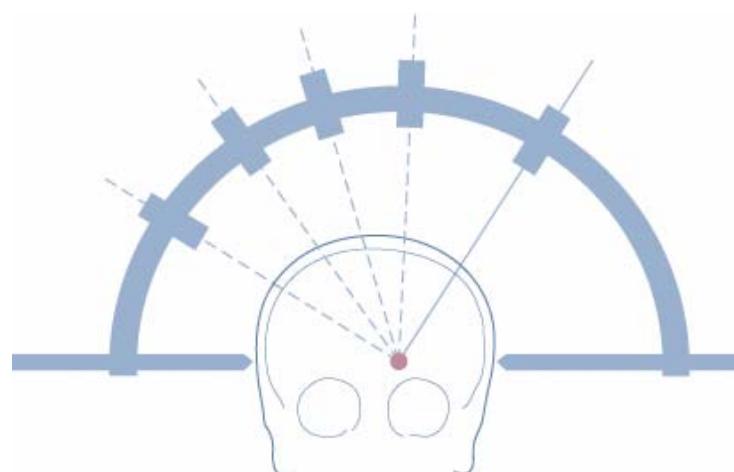


Figure 2.3 Center-of-arc principle: the target is always at the precise center of the stereotactic arc.

Leksell SurgiPlan®

Leksell SurgiPlan® is an advanced image-based neurosurgical planning software, designed for Leksell Stereotactic System®. Its unique image handling capabilities allow the physician to visualize and analyze a wide range of patient images. Targets and surgical paths can be outlined and manipulated across different image views with immediate visual feedback.

Leksell SurgiPlan® provides powerful functions for localizing and defining targets. It also enables precise planning and evaluation of a number of different surgical approaches. The unique tools for functional neurosurgery further increase precision and confidence. Functional targets can be localized using AC-PC line based formulas, which generate the corresponding stereotactic coordinates. The following modules are available:

- **AtlasSpace®**, a stereotactic brain atlas (Schaltenbrand and Wahrendorf) offers sophisticated 3-D matching, contour overlay on patient images and advanced target verification.
- **ImageMerge™** provides co-registration of stereotactic and non-stereotactic images from CT, MR and PET scanners, either automatically or by using landmarks.
- **Pre-Planning** - the surgical planning can be done prior to the day of surgery which increases freedom of choice for the neurosurgeon and enables more efficient scheduling. Localization can be performed on image sets taken without the coordinate frame and only a co-registration with frame-based image study – CT Registration – is done on the day of surgery.

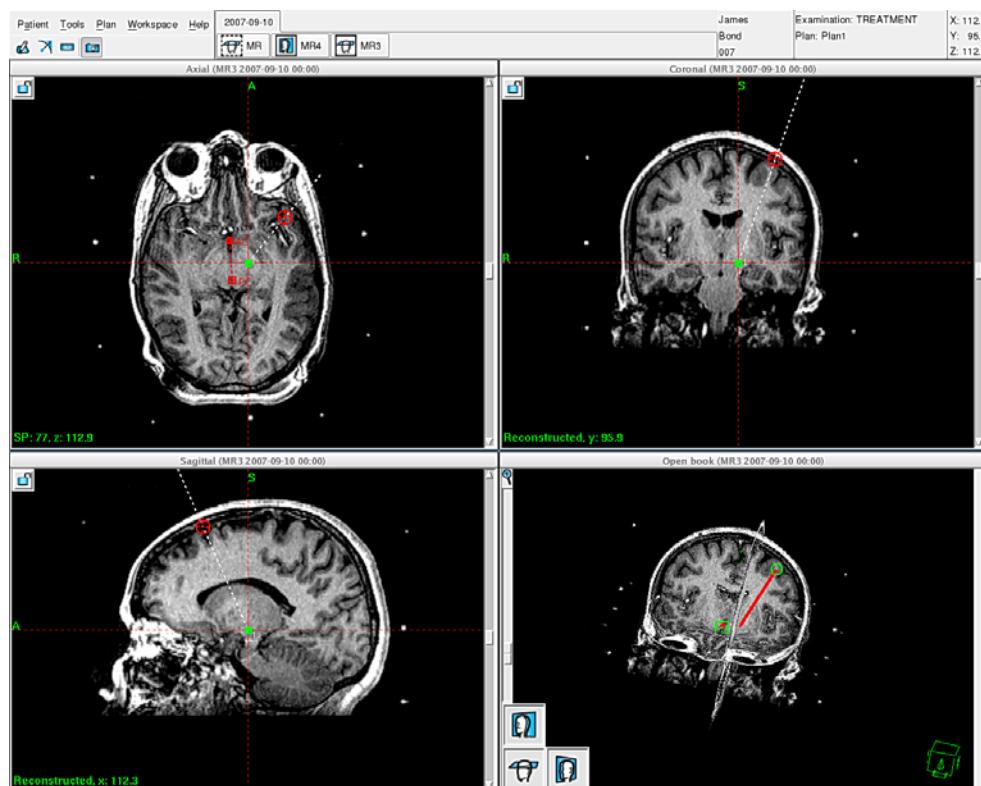


Figure 2.4 Leksell SurgiPlan® – workspaces.

Leksell® Neuro Generator

Leksell® Neuro Generator is a complete system designed for a wide range of treatment techniques and therapies, including:

- Impedance measurement
- Macro stimulation
- Stereotactic brain lesioning
- Bipolar coagulation



Figure 2.5 *Leksell® Neuro Generator*

Leksell® Neuro Generator can be safely and effectively operated while fully draped under full sterility conditions. It is the only neuro generator to be fully integrated with Leksell Stereotactic System®.

Leksell® Neuro Generator is characterized by its easy-to-use graphical user interface with multifunctional keys, compact size and remotely controlled features, allowing the practitioner to work closer to the patient. All stimulation parameters are continuously monitored and adjustable, while the temperature bar graph shows both set and current temperature as well as rate-of-change.

A wide range of specially designed monopolar and bipolar electrodes are available for different applications. The electrodes have integrated thermocouple controlled sensors, to accurately control temperature. All electrodes are autoclavable.

2.1

System description: Leksell Stereotactic System®

Simplicity, versatility and accuracy are the key advantages of Leksell Stereotactic System®. The system is based on the center-of-arc principle and the basic components are the coordinate frame and a stereotactic arc. The word “system” emphasizes the fact that all existing components are fully integrated and compatible with each other.

Ever since Professor Lars Leksell introduced his first stereotactic instrument in 1949, Leksell Stereotactic System® has been at the forefront by continuously setting the standard. All based on vast clinical experience and innovative development that strives to meet new needs and to be at the forefront of stereotaxy and radiosurgery with tools “adapted to the task”.

The modular design of the system, unique components and a range of optional accessories offers an optimal operative system. The lightness of the components is an invaluable feature when performing pediatric surgery.

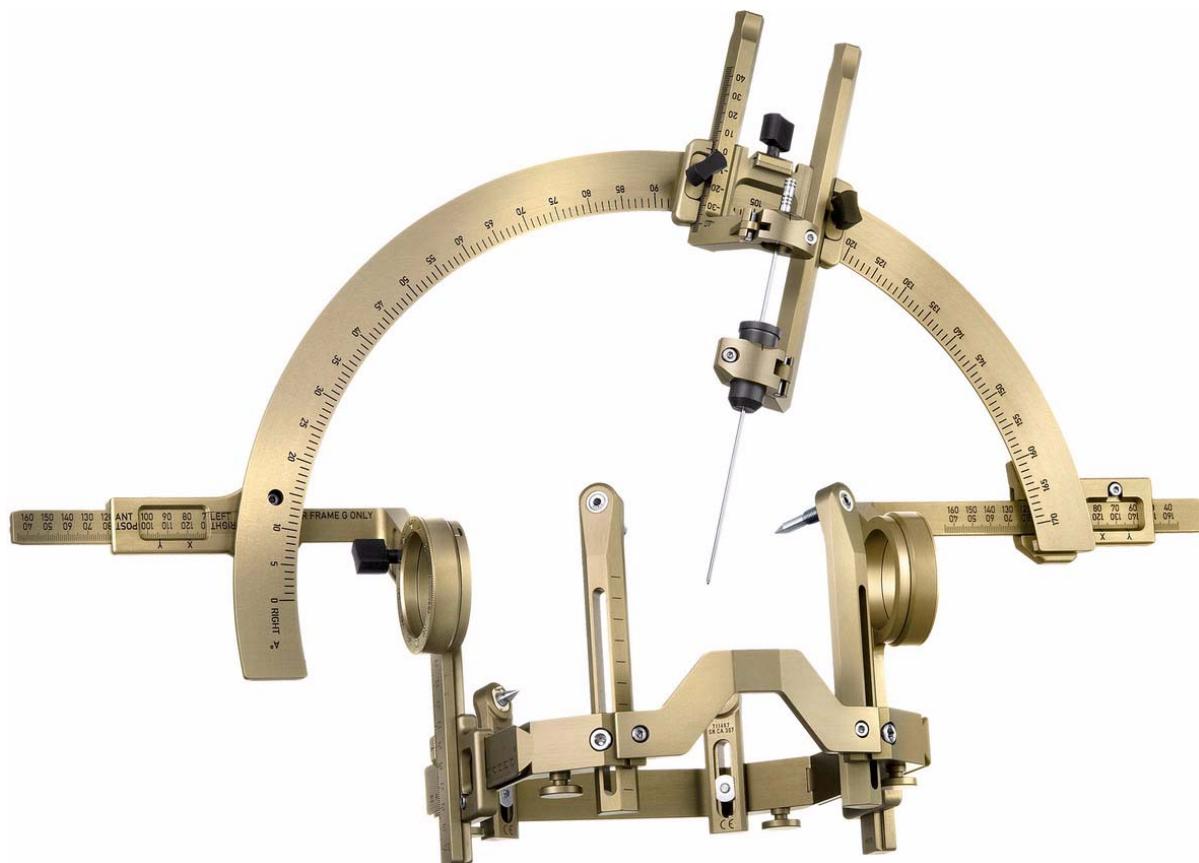


Figure 2.6 The basic components of Leksell Stereotactic System® are the coordinate frame and the stereotactic arc - here with mounted biopsy needle.

Leksell Stereotactic System® is compatible with all types of imaging modalities and CT, MR or X-ray localization may be performed with the same coordinate frame in any sequence.

The system allows the surgeon to very accurately localize and treat the pathological area with highest accuracy. It is used for diagnostic and therapeutic procedures, such as functional interventions, minimal invasive neurosurgical procedures or Gamma Knife® Surgery.

The center-of-arc principle

The center-of-arc principle, with the target in the center of the stereotactic arc, permits full flexibility in terms of access to all intracranial areas. It provides complete freedom of choice in trajectory and entry point selection.

Posterior fossa, transphenoidal and full lateral approaches are possible, in addition to all other approaches.

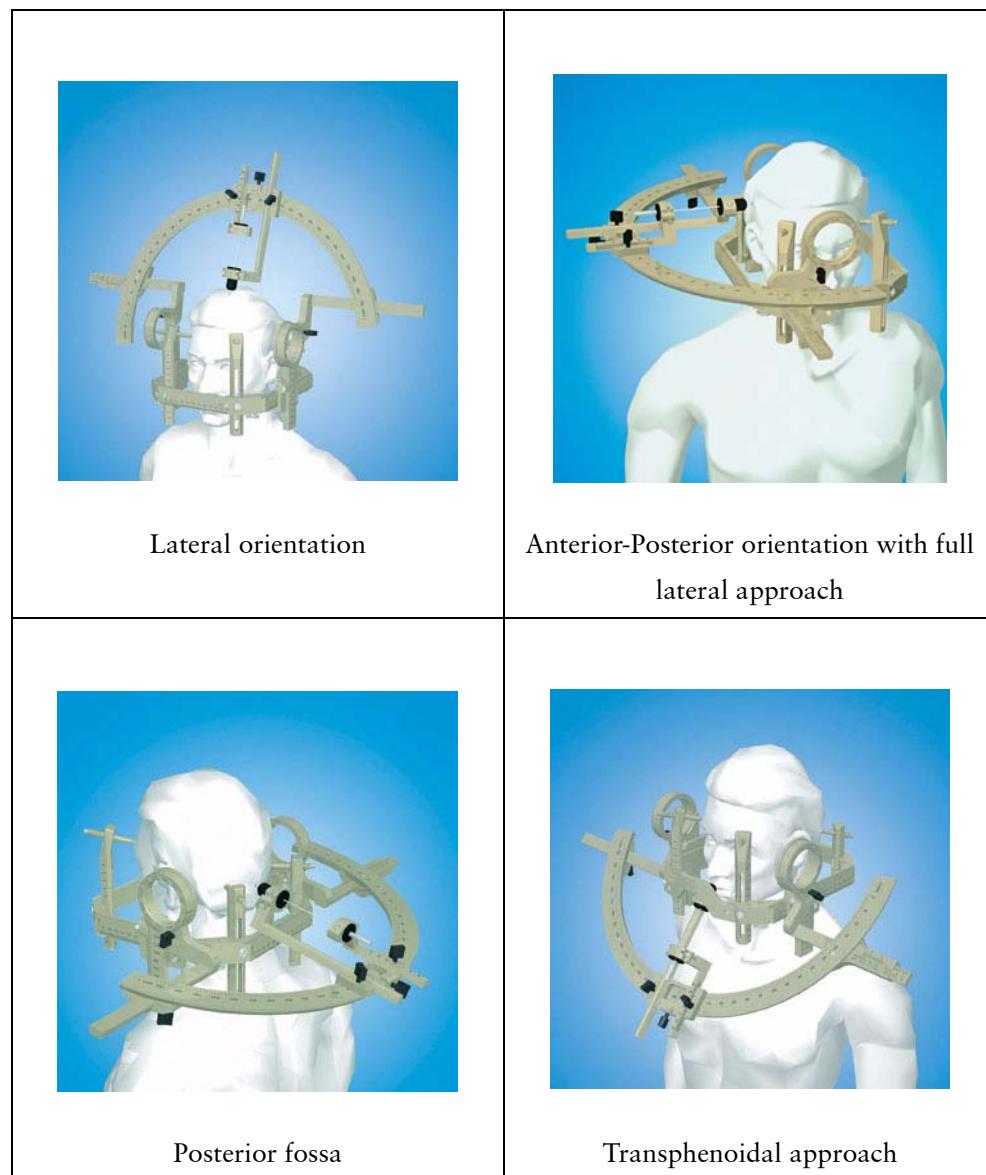


Figure 2.7 *The center-of-arc principle in different orientations.*

2.1.1

Workflow

In day-to-day use the frame-based stereotactic system has been shown to provide significant advantages over other fixation solutions. Accuracy and ease-of-use are two key attributes of Leksell Stereotactic System®, and the documented advantages also include less anesthetic resources, less operating room time and shorter patient hospital stays.

The basic patient treatment workflow is outlined in the following 5 steps, see [Figure 2.8](#):



Figure 2.8 The basic patient treatment workflow

Step 1: Fixation of the coordinate frame

Fixation of the coordinate frame to the patient's head is easily achieved with adjustable fixation posts and self-tapping screws. A variety of exchangeable front pieces provide maximum flexibility – both with regard to access to the patient's nose and mouth and in terms of positioning. The coordinate frame is versatile enough to be fixed in an angled or shifted position to obtain optimal access to the selected target.

Step 2: Imaging

Once the coordinate frame is in position, imaging can take place.

The coordinate frame adapter, provided for most MR and CT scanners, ensures parallel equidistant images and prevents movement distortion during scanning. This greatly simplifies pre-operative planning and allows easy comparison with stereotactic atlases. The compact design of the coordinate frame fits most MR scanner head coils.

Insulated fixation posts must be used to minimize the occurrence of radio frequency generated heating during MR imaging.

Step 3: Target localization and coordinate determination

Elekta simplifies the whole process of localizing and determining target coordinates with a choice of accurate target calculation systems to suit the neurosurgeon's preference.

Systems range from manual methods or use of the scanner console, to Elekta's sophisticated computer-based planning system, Leksell SurgiPlan®. The powerful functionality of this advanced planning software increases confidence and eases the workload in identifying the target and in planning and evaluating different surgical approaches.

Step 4: Coordinate setting

With localization complete, the system is prepared for surgery by attaching the stereotactic arc to the coordinate frame.

The stereotactic arc is positioned according to the X, Y and Z coordinates determined for the target so that the center-of-arc coincides with the selected cerebral target. Because of the complete freedom of choice for the entry point, the target can be reached along any trajectory without the need for any additional computer calculations or phantom simulations – thus shortening the time to treatment and ensuring the highest accuracy.

To facilitate the operative procedure the frame is secured to the operating table by means of adapted fixation components.

Step 5: Treatment

The coordinate frame and the stereotactic arc with its integrated instrument carrier provide a stable and reliable treatment platform with proven sub-millimeter accuracy.

Subsequent procedures usually require minimal preparation and operating time, while the small burr hole reduces the level of trauma. A wide range of fully integrated instruments such as Elekta MicroDrive™ and biopsy instrumentation help maximize the efficiency and accuracy of procedures. The separate guide of the instrument carrier ensures stable, accurate positioning of instruments close to the skull.

2.1.1.1

Optional workflow with Leksell SurgiPlan® Pre-Planning module

When having Leksell SurgiPlan® with optional **Pre-Planning** module the surgical planning can be done prior to the day of surgery. Pre-planning increases freedom of choice for the neurosurgeon and enables more efficient scheduling. In this case the localization and treatment planning can be performed on image studies taken without the coordinate frame and only a co-registration with one frame-based image study – CT Registration – is required on the day of surgery.

Performing pre-planning introduces a 6th step and partly changes the order of the basic patient treatment workflow as outlined in [Figure 2.9](#):

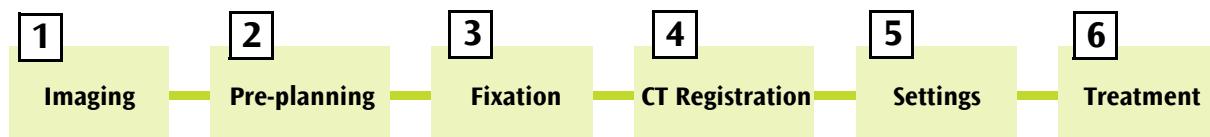


Figure 2.9 Pre-planning workflow: Imaging and Pre-planning are done before the day of surgery.

2.1.2

Verification tools

Elekta offers optional verification tools for Leksell Stereotactic System®. With the unique Target Simulator and Needle Tester tools, you will always have confidence in the accuracy of your system.

- The **Target Simulator** tool is used for mechanical accuracy check by visual inspection.

The solid targets of the tool represent test targets as well as known functional targets.

The easily performed verification procedure can be carried out on a regular basis, if the system have been subject to mishandling or when components have been exchanged.

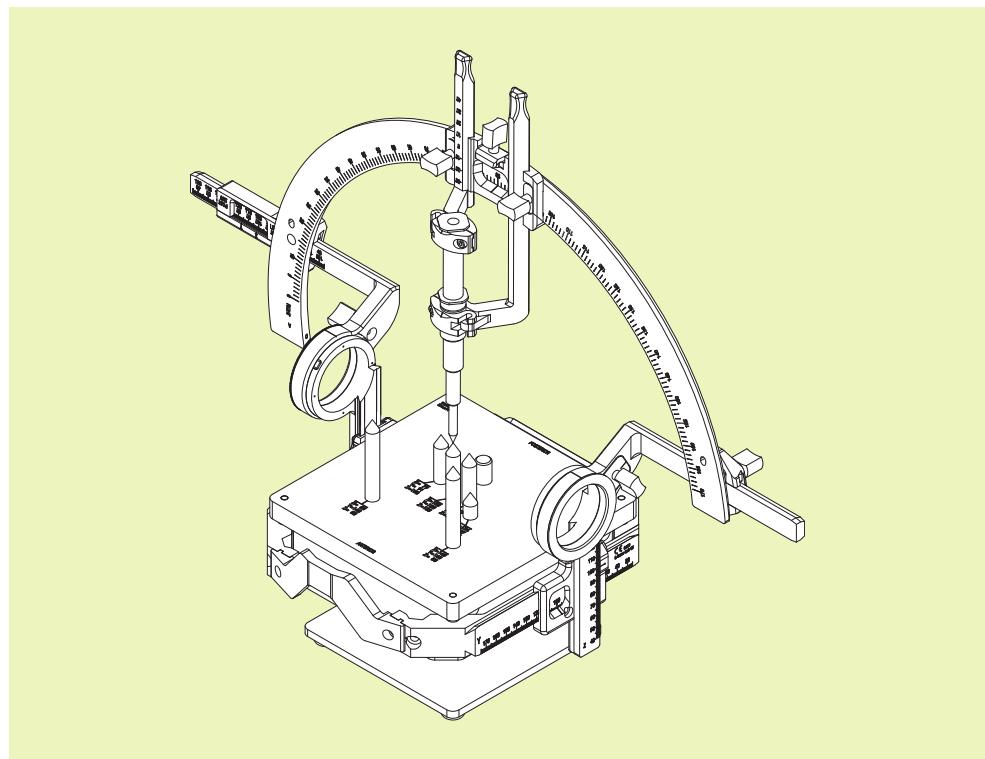


Figure 2.10 Target Simulator tests the accuracy of both the coordinate frame and stereotactic arc.

- The **Needle Tester** tool is used for visual control of the straightness of needles.

The straightness of a needle is checked in the tool by comparing the needle tip position with engraved alignment lines while rotating the needle. The tool can be used in sterile or non-sterile conditions.

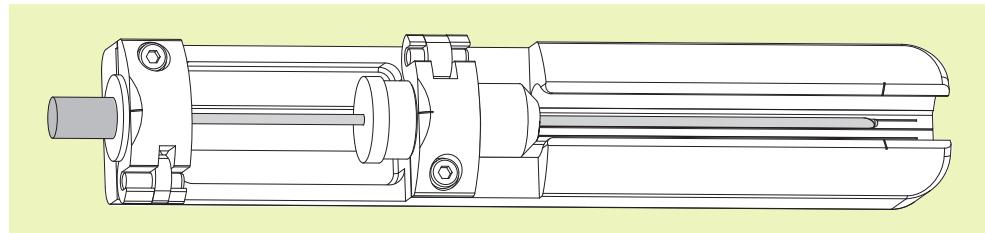


Figure 2.11 Needle Tester device.

2.2

Elekta Services

Elekta Services is more than simply an after-sales service and support program. It is Elekta's commitment to optimize the entire continuum of care by improving clinical effectiveness, ensuring staff competence and smoothing patient flow.

By reducing unnecessary downtime and delivering consistent treatment quality, more patients can be treated throughout each working day. A wide range of service and support programs can be tailored to meet this goal.

A customized package of inspections and verifications is available which will help ensure that the stereotactic frame stays accurate over time and can be upgraded when necessary, providing added confidence and reassurance for the user. The certified accuracy of the inspection service may also be used to help the customer with his own Quality & Assurance programs.

Elekta Services offers education and application training courses for stereotactic neurosurgery.

2.3

Reference list

Other accessories are available as part of the Leksell® Stereotactic Neurosurgery product portfolio. Contact Elekta or your local Elekta® representative for more information.

The following Leksell Stereotactic System® products are described in this manual:

Product	See
Leksell® Coordinate Frame G with accessories <ul style="list-style-type: none"> • Leksell® Coordinate Frame G • Slotted Front Piece • Insulated Fixation Posts • Non-insulated Fixation Posts • Reusable Fixation Screws • Titanium Fixation Screws • Quick Fixation Screws • Disposable Fixation Screws • Frame Fixation • Leksell Stereotactic System® Clamp • Fork and Clamp Type Adapters 	Chapter 3 on page 25 Section 3.2 on page 28 Section 3.3 on page 46 Section 3.4.1 on page 52 Section 3.4.3 on page 55 Section 3.5 on page 58 Section 3.6 on page 60 Section 3.7 on page 62 Section 3.8 on page 64 Section 3.9 on page 66 Section 3.10 on page 73 Section 3.11 on page 79
Leksell® Multi Purpose Stereotactic Arc with accessories <ul style="list-style-type: none"> • Leksell® Multi Purpose Stereotactic Arc • Cross-Hairs Kit and A-P Cross-Hairs Holder • Leksell® Endoscope Adapter 	Chapter 4 on page 87 Section 4.2 on page 89 Section 4.3 on page 110 Section 4.4 on page 119

Product	See
Neurosurgical instruments <ul style="list-style-type: none"> • Salzman Twist Drill Kit • Biopsy instruments <ul style="list-style-type: none"> - Sedan Side-Cutting Biopsy Needle Kit I • Injection/aspiration/evacuation/insertion instruments <ul style="list-style-type: none"> - Backlund Catheter Insertion Kit - Backlund Haematoma Evacuator Kit - Insertion Cannula Kit 	Chapter 5 on page 125 Section 5.3 on page 128 Section 5.4 on page 135 Section 5.5 on page 142 Section 5.6 on page 151 Section 5.7 on page 157
Localization accessories for CT, MR and X-Ray <ul style="list-style-type: none"> • CT indicators with accessories <ul style="list-style-type: none"> - Open CT Indicator - CT Adapter and Table Fixations • MR indicators with accessories <ul style="list-style-type: none"> - MR Indicator - Open MR Indicator - MR Adapters - MR Phantom • X-Ray indicators with accessories <ul style="list-style-type: none"> - X-Ray Indicator with Markers - X-Ray Indicator with Rulers - X-Ray Table Fixations 	Chapter 6 on page 163 Section 6.2 on page 165 Section 6.3 on page 173 Section 6.4 on page 191 Section 6.5 on page 204 Section 6.6 on page 213 Section 6.7 on page 225 Section 6.8 on page 233 Section 6.9 on page 242 Section 6.10 on page 249

3**Leksell® Coordinate Frame G
– with accessories**

This chapter describes the following products:

- Leksell® Coordinate Frame G, [Section 3.2 on page 28](#)
(including preparation and attachment to the patient's skull)
- Slotted Front Piece, [Section 3.3 on page 46](#)
- Insulated Fixation Posts, [Section 3.4.1 on page 52](#)
- Non-insulated Fixation Posts, [Section 3.4.3 on page 55](#)
- Reusable Fixation Screws, [Section 3.5 on page 58](#)
- Titanium Fixation Screws, [Section 3.6 on page 60](#)
- Quick Fixation Screws, [Section 3.7 on page 62](#)
- Disposable Fixation Screws, [Section 3.8 on page 64](#)
- Frame Fixation, [Section 3.9 on page 66](#)
- Leksell Stereotactic System® Clamp, [Section 3.10 on page 73](#)
- Fork and Clamp Type Adapters, [Section 3.11 on page 79](#)

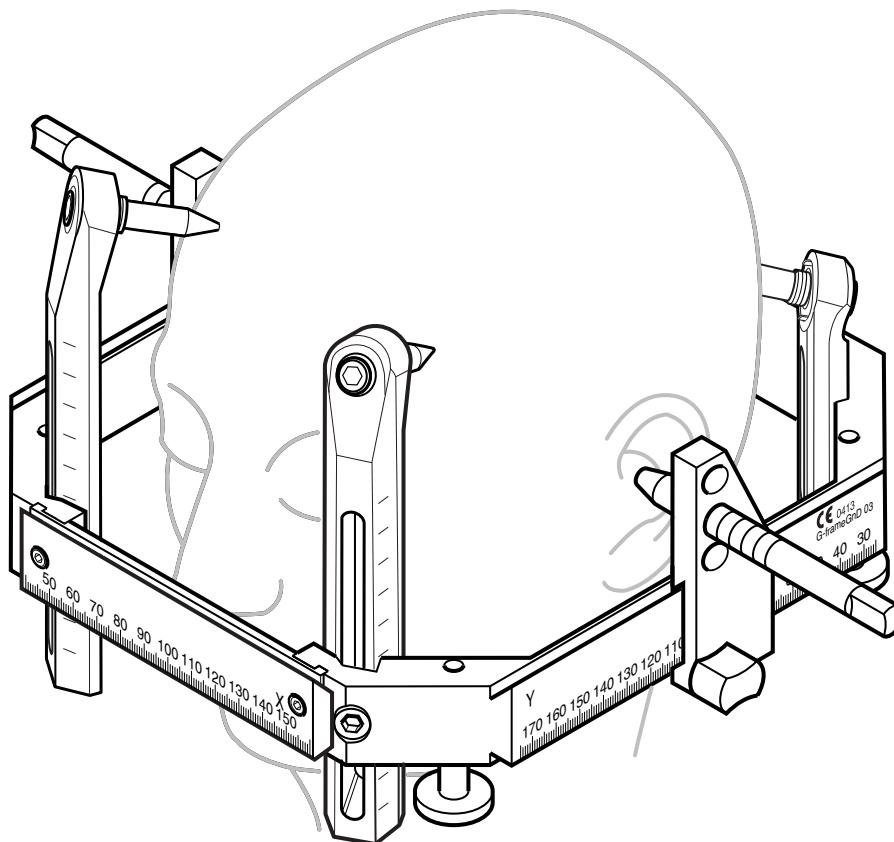


Figure 3.1 Leksell® Coordinate Frame G with some of the accessories

3.1

General warnings and notes

These warnings apply to the usage of all products included in this chapter.

WARNING 3.1



The equipment must only be used with Leksell Stereotactic System® or specified instruments. Usage with other systems can cause inaccurate treatment and patient injury.

WARNING 3.2



Handle all Elekta equipment with care. Any damage, however slight, can reduce treatment safety and accuracy. Inspect the equipment before clinical use. If you suspect that any part is damaged, contact Elekta immediately. Do not use damaged equipment for any purpose until authorized to do so by Elekta.

WARNING 3.3



The equipment must be set up in accordance with the treatment protocol. Otherwise wrong treatment can result and the patient can be injured.

WARNING 3.4



Do not use the coordinate frame with MR scanner frequencies lower than 40 MHz. Otherwise the images can be distorted.

WARNING 3.5



Unless otherwise stated, the equipment is delivered unsterile and must be sterilized before use. Otherwise the patient can be infected.

WARNING 3.6



To avoid excessive force on the screws, use only the intended tools provided with the product. Otherwise the patient can be injured.

WARNING 3.7



Do not use excessive force when tightening locking screws/knobs. Otherwise parts can be damaged and not permit secure fixation. Non-secure fixation can cause incorrect treatment.

WARNING 3.8



Handle equipment with sharp edges or points with care. Otherwise surgical gloves can become damaged and the patient and/or the surgeon can be infected.

WARNING 3.9



Inspect all threads regarding wear and tear before use. Damaged threads can cause unsafe fixation of the coordinate frame.

WARNING 3.10

Exercise extreme caution at all times to ensure that the coordinate frame does not move on the patient's skull. If the coordinate frame is displaced, all treatment planning based on the coordinate frame position is invalid.

WARNING 3.11

Ensure that the patient skull is rigid enough (due to patient age, bone flap, osteoporosis etc) to withstand the fixation force needed for a safe fixation.

WARNING 3.12**Conditions for use in MRI:**

- Only for use in 1.5 T or 3 T with RF transmit head or body coil.
- Always use the insulated fixation posts. Otherwise there is a risk of temperature increase at the tip of the fixation screws.
- Non-insulated fixation posts are contraindicated (MR Unsafe).

Note:

All other fixation posts than the "Insulated Fixation Posts" are defined as non-insulated.

3.2 Leksell® Coordinate Frame G

3.2.1 Product overview

Leksell® Coordinate Frame G (coordinate frame) is the basic component of Leksell Stereotactic System®.

To permit accurate positioning, the coordinate frame is engraved with a rectilinear coordinate scale. The origo of Leksell® Coordinate System (where X, Y and Z are numerically zero) is located outside the coordinate frame at a point that is superior, lateral and posterior to the coordinate frame on the patient's right side. See **Figure 3.2**, which also shows the **left (L)**, **right (R)**, **posterior (P)**, and **anterior (A)** sides of the coordinate frame.

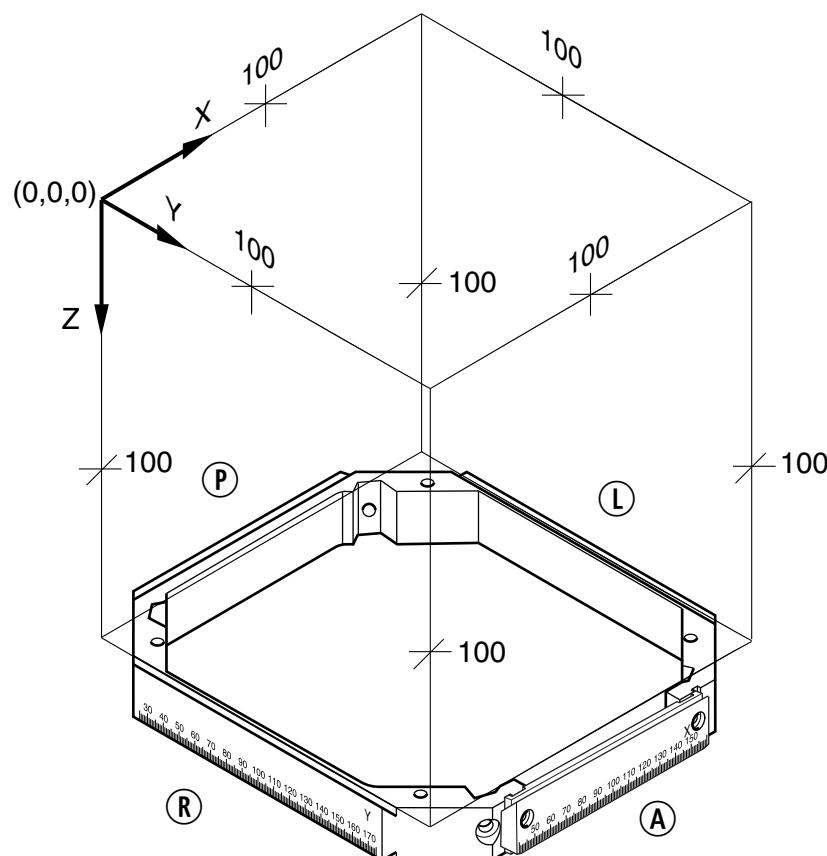


Figure 3.2 Leksell® Coordinate System

The coordinate scale is graduated in millimeters and conforms with the X, Y and Z directions used in CT, MR and X-ray scanning. The X, Y and Z coordinate settings are obtained from the patient's treatment protocol after target localization.

3.2.2

Main parts

All components of the coordinate frame are made of aluminum unless otherwise stated.

Please refer to [Figure 3.3](#).

The **coordinate frame base** ① consists of posterior, left side and right side bars which are permanently connected and cannot be disassembled. The external face of each bar is engraved with a rectilinear coordinate scale. The superior and inferior edges of the bars are shaped with grooves that permit the rapid attachment of other components of Leksell Stereotactic System®.

A fixation post can be fitted into a groove at each internal corner of the coordinate frame base. A threaded hole on the underside of each corner permits the attachment of connection feet.

The anterior bar of the coordinate frame is exchangeable so that differently-shaped **front pieces** (e.g. ⑨ and ⑩) can be used.

Note:

The coordinate frame must not be used without a front piece, otherwise it is unstable.

Insulated fixation posts ② with **disposable inserts** ⑬, **locking screws** ③ and **locking pieces** ④ are used to position the coordinate frame on the patient's head.

One surface of each fixation post is engraved with a scale to facilitate vertical placement of the coordinate frame. A fixation post is fixed at each of the internal corners of the coordinate frame base by means of a 5 × 19 mm titanium locking screw passing through a height adjustment slot in the center of the fixation post and secured with a locking piece.

This arrangement allows adjustment of the height of the coordinate frame in relation to the patient's head.

Fixation screws ⑤ are used to secure the coordinate frame to the patient's skull through threaded holes at the top of each fixation post. A set of fixation screws of different lengths is provided with each coordinate frame. Additional fixation screws are available in sets of different lengths, see [Section 9.6 on page 280](#), so as to accommodate any patient head size up to 62 cm and locate the coordinate frame at any required position on the patient's skull.

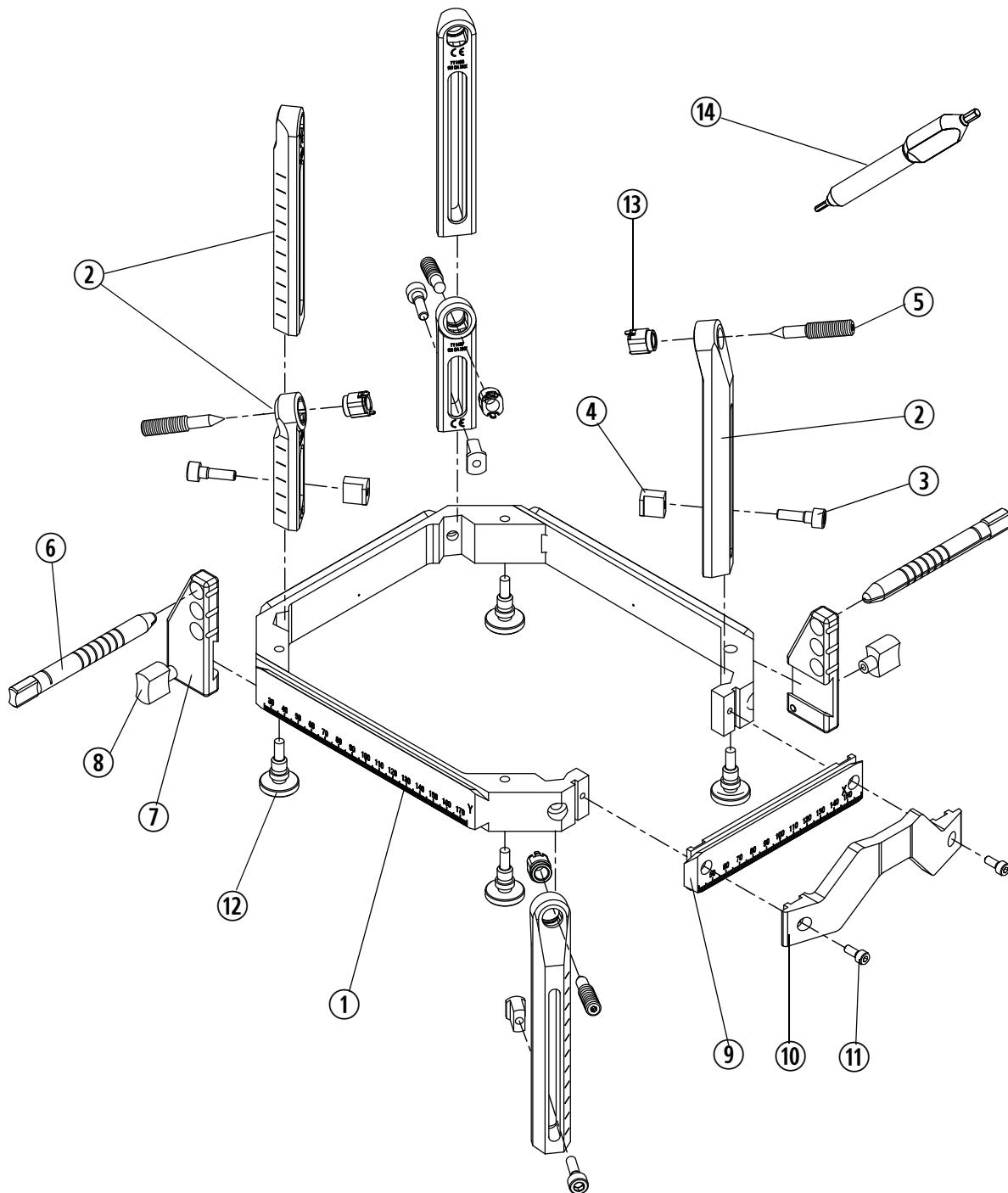
Note:

The different fixation posts and fixation screws are described in more detail in sections 3.4 to 3.8. The description in this section shows the insulated fixation posts.

Ear plugs ⑥ and **ear plug holders** ⑦ can be fitted to the side bars to facilitate alignment and temporarily position the coordinate frame on the patient's head before it is secured in place. The ear plug holder is locked in position by a **knob** ⑧.

An ear plug fits into the ear plug holder through one of its three holes. The hole that yields the required coordinate frame height with respect to the skull is used.

Scales on the shaft of each plug assist in determining the correct depth of insertion of the plug into the auditory canal.



- | | | |
|----------------------------|------------------------|--------------------------|
| ① Coordinate frame base | ⑥ Ear plugs | ⑪ Securing screws |
| ② Insulated fixation posts | ⑦ Ear plug holders | ⑫ Connection feet |
| ③ Locking screws | ⑧ Knob | ⑬ Disposable insert |
| ④ Locking pieces | ⑨ Straight front piece | ⑭ Instrument screwdriver |
| ⑤ Fixation screws | ⑩ Curved front piece | |

Figure 3.3 Main parts of Leksell® Coordinate Frame G

Straight front piece ⑨, curved front piece ⑩, securing screws ⑪ and slotted front piece (not shown, optional) are removable, and the type of front piece in use depends upon surgical requirements.

- The straight front piece is engraved with coordinate graduations (X axis).
- The curved front piece provides access to the patient's airways. It can be fitted with the curve in the inferior or superior orientation.
- The slotted front piece, engraved with coordinate graduations (X axis), is an optional accessory (see [Section 3.3 on page 46](#)). It permits the use of only one of the two anterior fixation posts, thereby obtaining three-point fixation of the coordinate frame. This arrangement extends the area of surgical access.

Connection feet ⑫ permit rapid, simple attachment to other components of Leksell Stereotactic System®. The connection feets (4 pcs) are threaded in one end and are screwed into each of the four corner holes on the underside of the coordinate frame base.

The base of each foot is specially shaped to locate into corresponding holders on the CT, MR and X-ray adapters and to the Frame Fixation.

The coordinate frame is supplied with special double-ended **instrument screwdriver ⑭**.

A sterilization tray (not shown) is provided to house the coordinate frame during sterilization and for storage.

This equipment, except for the instrument screwdriver, is MR Conditional. See [Section 1.2.4 on page 8](#) for detailed information.



Note:

The instrument screwdriver is MR Unsafe.



3.2.2.1 Labels

Some parts have engraved labels. See [Table 3.1](#) for details, and [Section 9.7 on page 288](#) for general label information.

Table 3.1 Labelled parts on the coordinate frame

Part	Labels
① Coordinate frame base	X, Y, CE 0413
⑨ Straight front piece	X, Y

3.2.2.2

Version modified for use in Leksell Gamma Knife®, versions C, 4 and 4C

Please refer to [Figure 3.4](#).

The coordinate frame is available in a version modified for use in radiosurgery with Leksell Gamma Knife®, versions C, 4 and 4C. The coordinate frame base has one **hole** ① in each side bar for fixation of the coordinate frame in the Automatic Positioning System™. Furthermore the coordinate frame base has a **slot** ② in one corner used to line up with the correct gamma angle pin of the Automatic Positioning System™. All other parts of the coordinate frame are the same as for the non-modified version.

The use of the modified coordinate frame in Gamma Knife® Surgery is described in the applicable Leksell Gamma Knife® manual.

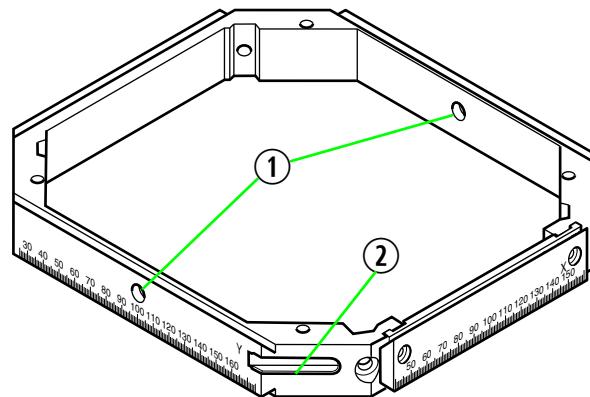


Figure 3.4 Coordinate frame modified for use in Leksell Gamma Knife®, versions C, 4 and 4C.

3.2.3

Using Leksell® Coordinate Frame G

Considerations for use in MR environment:

- always use the Insulated Fixation Post.

Considerations for use in CT environment: The coordinate frame and it's components can cause artifacts in the CT images. To reduce the artifacts;

- Use Reusable Fixation Screws or Disposable Fixation Screws.
- Locate the tips of the fixation screws in a plane away from the anatomical area of interest.
- Reduce the scan slice thickness (for example to 3 mm or less).

Note: In this section the item numbering 1-14 refers to the numbering in [Figure 3.3 on page 30](#).

3.2.3.1

Assembly instructions

A. Preparation

- Inspect all components regarding functionality before use.
- Check that all components to be used are clean, sterilized and at hand.

B. Fitting a front piece

If using the Slotted Front Piece, see [Section 3.3.3 on page 48](#).

- 1 Position the coordinate frame base on a clean horizontal surface.
- 2 Set the selected front piece in place at the anterior of the coordinate frame base.

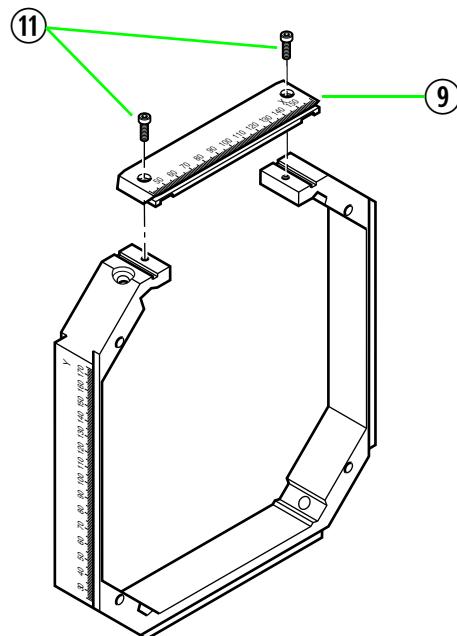


Figure 3.5 Fitting the straight front piece.

- The straight front piece must be fitted with the coordinate scale facing the inferior position, as shown in [Figure 3.5](#).
- The curved front piece can be fitted in inferior or superior orientation.

- To ensure correct fitting, locate the grooves on the inner surface of the front piece into the complementary grooves on the outer surfaces of side bars of the coordinate frame base.

**WARNING 3.13**

**Do not use excessive force when tightening locking screws/knobs.
Otherwise parts can be damaged and not permit secure fixation.
Non-secure fixation can cause incorrect treatment.**

Note:

The front piece of the coordinate frame can be exchanged to meet surgical requirements. If so, this must be done before the coordinate frame is attached to the patient's head.

- Use the instrument screwdriver ⑩ to secure the front piece to the coordinate frame base with the securing screws ⑪ (4 × 10 mm titanium screws).
 - Tighten the crews carefully until secure. Do not employ excessive force.

Note:

Ensure that the front piece is mounted with the correct titanium screws. If screws of steel are used, it will affect the MR imaging properties.

C. Fitting the connection feet

- Position the coordinate frame so that the corner holes on the underside of the coordinate frame base are accessible.
- Insert one connection foot ⑫ into each of the four corner holes and turn until firmly attached.

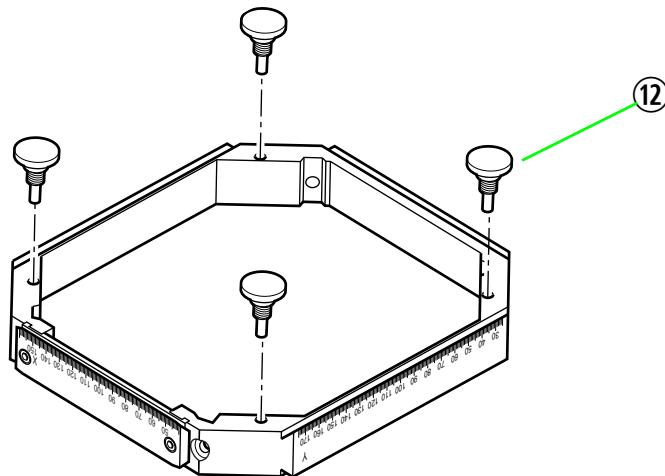


Figure 3.6 Fitting the connection feet.

Note:

Ensure that the connection feet are firmly attached, otherwise the coordinate frame may not be firmly secured in CT and MR adapters.

D. Fitting the fixation posts

The coordinate frame can be used with different fixation posts as suitable for the actual procedure to be performed. For more detailed description of each fixation posts type see:

- Insulated Fixation Posts, see [Section 3.4.1 on page 52](#)
- Non-insulated Fixation Posts, [Section 3.4.3 on page 55](#)

Note: *Do not mix insulated and non-insulated fixation posts in the same setup.*

Note: *In this section, the usage of Insulated Fixation Posts is shown. The term “fixation posts” refer to the actual fixation post type used.*

Assembling the insulated fixation posts and disposable inserts

The disposable inserts can be mounted into the insulated fixation posts before or after attaching the fixation posts to the coordinate frame.

- 6 Before mounting the disposable inserts, always check that the sterile package is unbroken.



WARNING 3.14

Do not use the disposable inserts if the sterile package is broken. Otherwise the patient can be infected.

- 7 Position the circular end of the disposable insert ⑬ into the rectangular insert hole of the fixation post.

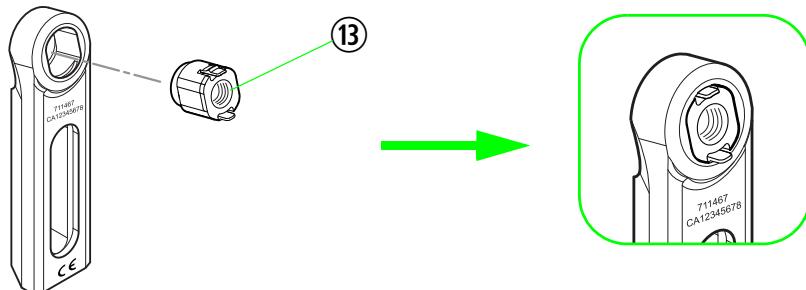


Figure 3.7 Inserting the disposable insert into the fixation post

- 8 Press the disposable insert firmly into the hole until it clicks into position. It shall be aligned with the edge of the insulated fixation post on both sides.
- 9 Place a disposable insert into each fixation post to be used as described above.

Fitting the fixation posts to the coordinate frame

If fitting curved fixation post in the anterior position, see [Fitting the curved fixation posts, page 37](#).

The fixation posts can be fitted in any order - the steps 10 to 15. For example:

- 10 Position a posterior fixation post at a posterior corner of the coordinate frame.
 - The fixation post must be seated in the internal corner slot of the coordinate frame.
- 11 From the internal side of the coordinate frame, insert a locking piece ④ into the height adjustment slot of the fixation post.

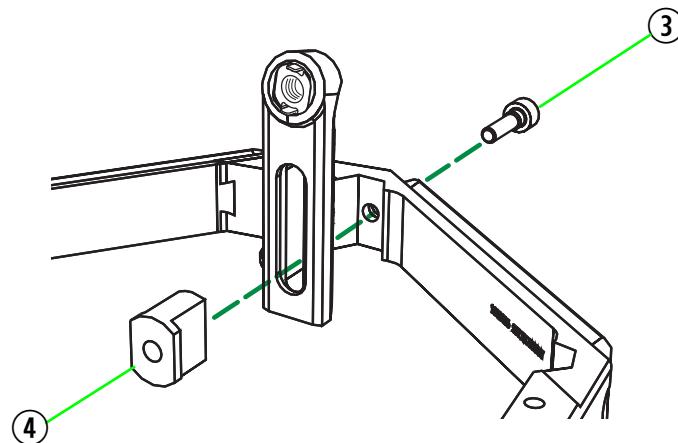


Figure 3.8 Fitting the fixation posts

- 12 From the external side of the coordinate frame, insert a locking screw ③ through the hole in the corner and into the height adjustment slot of the fixation post.
 - Gently tighten the screw into the locking piece.
- 13 Slide the fixation post up or down until it is located at the desired position.
- 14 Use the instrument screwdriver ⑭ to tighten the locking screw until the fixation post is fixed.
 - Do not employ excessive force.

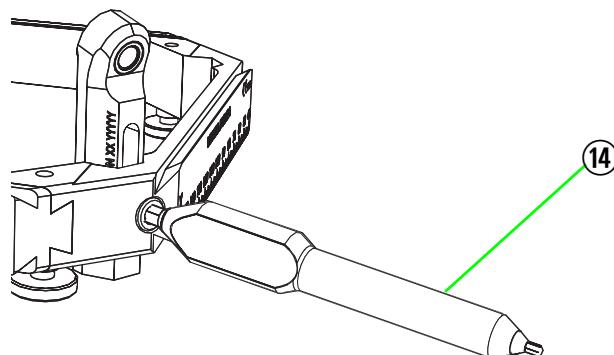


Figure 3.9 Securing the fixation post

- 15 Fit the other fixation posts as described in steps 10 to 14.

Note:

Use the anterior fixation posts in the anterior position, and the posterior fixation posts in the posterior position.

Fitting the curved fixation posts

The curved fixation posts are to be used *only at the anterior position* of the coordinate frame.

- 16 If using the curved insulated fixation posts, mount the disposable insert. See [Assembling the insulated fixation posts and disposable inserts, page 35](#).
- 17 Position a curved fixation post at an anterior corner of the coordinate frame, from the inside of the coordinate frame.
 - Select which of the numbered holes ⑯ of the curved fixation post to use for the fixation.
- 18 From the external side of the coordinate frame corner, insert a locking screw ⑬ in the threaded hole of the curved fixation post.
 - Using the instrument screwdriver, tighten the locking screw until the curved fixation post is securely fixed.
 - Do not employ excessive force when tightening the locking screw.

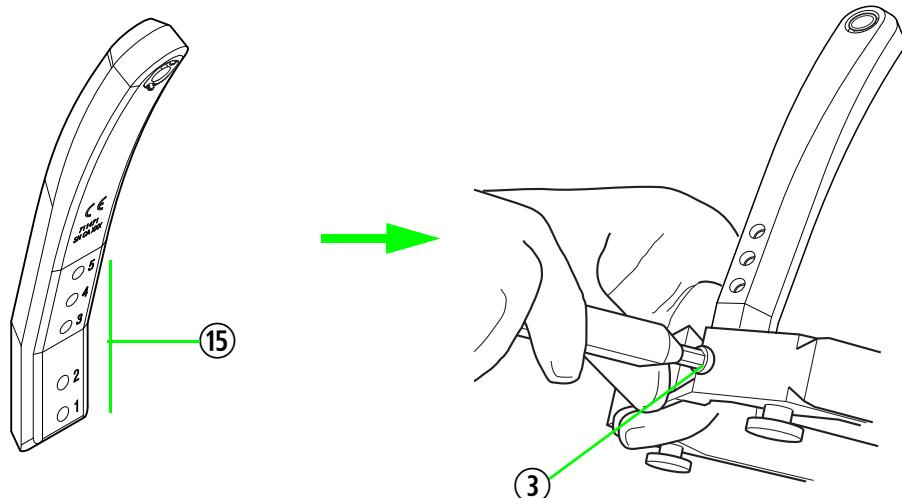


Figure 3.10 Fitting the curved fixation posts in the anterior position.
(The figure shows the insulated fixation post.)

- 19 Fit the other curved fixation post as described in the above steps 16 and 18.

E. Fitting ear plug holders

Ear plugs can be used to aid the correct positioning of the coordinate frame. If you intend to use ear plugs, fit the ear plug holders:

- 20 Slide an ear plug holder ⑥ over the locating grooves on the appropriate side bar. The holder can be fitted from the front or rear of the coordinate frame base.

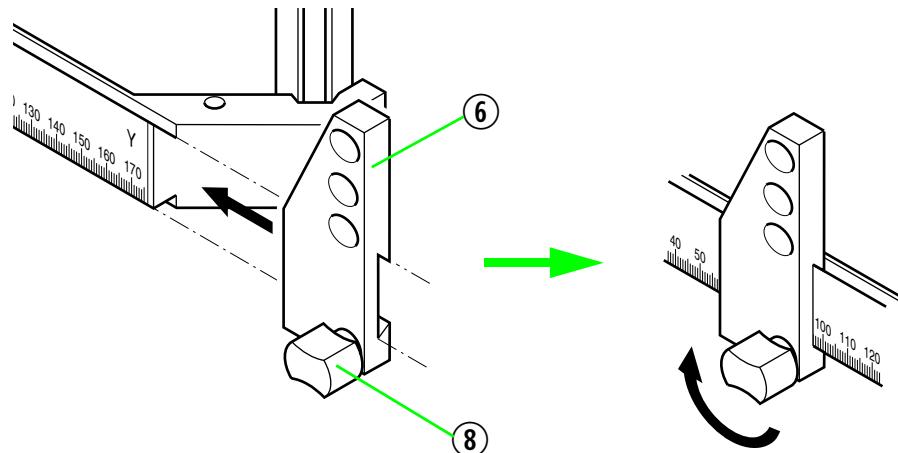


Figure 3.11 Fitting the ear plug holders

- 21 When the ear plug holder is at the desired position, turn its knob ⑧ until the holder is secure.
- 22 Fit the other ear plug holder as described in steps 20 and 21.
- 23 Check that the ear plug holders are correctly and symmetrically attached to the coordinate frame base and securely locked.

The coordinate frame can now be attached to the patient's head.

3.2.3.2

Attaching the coordinate frame to the patient's skull

The appropriate method of attaching the coordinate frame should be planned in advance of application in accordance with treatment requirements.

Usually, local anesthesia is used during coordinate frame application unless special circumstances necessitate general anesthesia.



WARNING 3.15

**Do not position fixation screw tips at the same level as the target.
Otherwise imaging artifacts can cause erroneous treatment planning.**



WARNING 3.16

Do not attach the coordinate frame to the skull in level with the intended target. Otherwise the CT Adapter can cause imaging artifacts.



WARNING 3.17

Do not bring any tools (ferromagnetic objects) into the MRI area since these could be attracted by the magnet and become projectiles and injure the patient or operator.

Preparing the patient

- 1 Ensure that all the necessary components are readily at hand:
 - assembled coordinate frame
 - selected fixation screws
 - ear plugs, if required
 - instrument screwdrivers.
- 2 Position the patient to allow access to all aspects of the head, preferably in a comfortable sitting position.
If a sitting position is not practicable, lie the patient on an operating table with the back raised as high as possible. Position the patient so that the head protrudes over the upper edge of the table. An assistant should support the patient's head if necessary.
- 3 Prepare the patient's head in accordance with local hospital practice.

Positioning the coordinate frame

WARNING 3.18



Always attach the front piece before mounting the coordinate frame on the patient's head. Without the front piece the coordinate frame is not safe for treatment and the patient can be injured.

WARNING 3.19



Always attach the coordinate frame with the front piece at the patient's anterior. Otherwise there is a risk of misunderstanding the Leksell Coordinate System® and wrong target can be treated.

- 4 Position the coordinate frame about the patient's head. The front piece of the coordinate frame must be at the patient's anterior and the threaded holes of the fixation posts must be uppermost.

If ear plugs will be used, continue with steps 5 through 8, otherwise proceed with section *Securing the coordinate frame to the patient's skull*" on page 41.

Note:

The ear plugs must be removed before any imaging or surgical procedure.

- 5 Insert the rounded end of an ear plug into the appropriate hole in each ear plug holder.
- 6 To achieve the desired position of the coordinate frame about the head, push each ear plug in turn into the outer auditory canal to the required depth.

WARNING 3.20



Do not insert the ear plugs too far into the auditory canal. Otherwise the patient can be injured.

- 7 Rotate each ear plug gently to lock it into position.

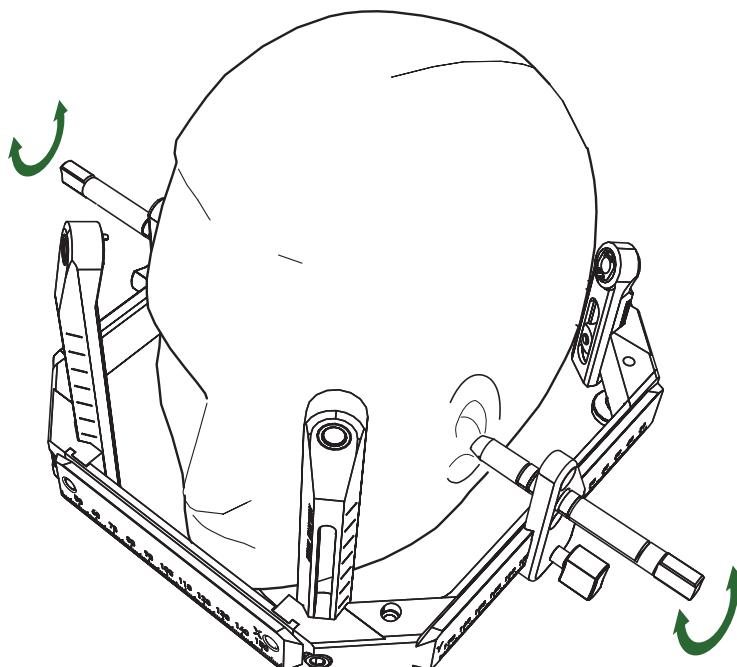


Figure 3.12 Inserting the ear plugs

- 8 The coordinate frame is now supported by the ear plugs. It can be gently swivelled about the plugs to achieve the required relationship of the coordinate frame with respect to the orbitomeatal plane.

Note: *To reduce patient discomfort, avoid pushing or pulling the coordinate frame unnecessarily while the coordinate frame is supported by the ear plugs.*

Securing the coordinate frame to the patient's skull



WARNING 3.21

Mount the coordinate frame in a way that facilitates intubation. Emergency removal of the front piece can injure the patient if a surgical instrument has been inserted.

Note: *Do not position the coordinate frame too low on the patient's skull and ensure that the indicator box will fit.*

The coordinate frame can be used with different fixation screw as suitable for the actual procedure to be performed. For more detailed description of each fixation screw type see:

- Reusable Fixation Screws, see [Section 3.5.2 on page 59](#)
- Titanium Fixation Screws, see [Section 3.6.2 on page 61](#)
- Quick Fixation Screws, see [Section 3.7.2 on page 63](#)
- Disposable Fixation Screws, see [Section 3.8.2 on page 65](#).

In this section, the usage of Titanium Fixation Screws and ear plugs is shown.

Note: *When positioning the coordinate frame on the patient's skull, do not tilt or rotate the coordinate frame excessively. Otherwise it may be difficult to position the patient's head so that the coordinate frame achieves the vertical position required for CT or MR scanning.*

Note: *In patients presenting with a short neck and/or a prominent thoracic kyphosis, the positioning of the head/coordinate frame in the CT or MR adapter may be difficult. Therefore, it is advised that in such patients the coordinate frame should be placed as far posterior as possible and relatively high on the skull. Note that the coordinate frame should not be too close to the anatomic region of interest.*

- 9 If necessary, adjust the fixation posts vertically to achieve the desired position for the intended fixation screws.
- 10 Select the fixation screws you intend to use for each fixation post.
 - To facilitate MR scanning and treatment using Leksell Gamma Knife®, the threads of the fixation screws should not protrude from the fixation posts. Carefully select the length of each fixation screw to minimize protrusion.

Note: To discover damage and/or wear, visually inspect the tip and socket of each fixation screw before use.



WARNING 3.22

Inspect all threads regarding wear and tear before use. Damaged threads can cause unsafe fixation of the coordinate frame.



WARNING 3.23

Ensure that the fixation screw tip is not blunt and that there is no damage to the fixation screw tip and socket. Blunt or damaged fixation screws can cause loose fixation and could reduce treatment safety.

- 11 Apply local anesthetic to the sites where the fixation screws will penetrate the patient's scalp.
- 12 Insert a fixation screw through the threaded hole of each fixation post.

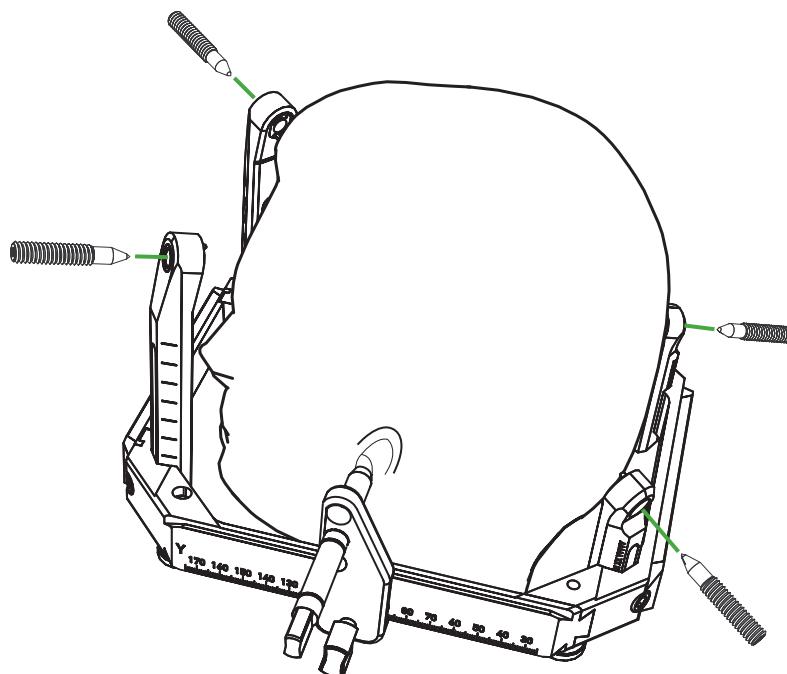


Figure 3.13 Inserting the fixation screws

- 13 In turn, carefully advance each fixation screw by hand until its tip rests gently against the patient's scalp.



WARNING 3.24

Do not apply pressure when inserting fixation screws through the disposable inserts. Otherwise the insert can be pushed out and the fixation screws can injure the patient.

- 14 The four fixation screws must now be advanced into the patient's scalp;
- Let an assistant support the coordinate frame.
 - Fit an instrument screwdriver to each head of two diagonally opposing fixation screws.

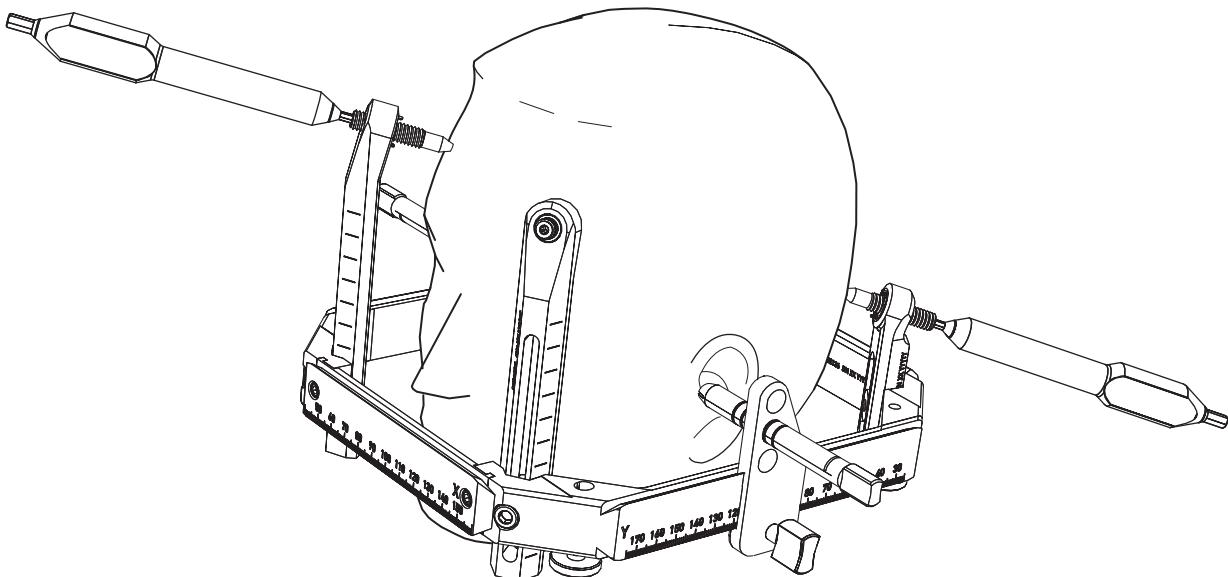


Figure 3.14 Tightening the fixation screws

Note:

If the ear plugs are used, ensure to loosen the ear plugs when tightening the fixation screws to avoid patient discomfort.

- 15 Carefully tighten the two fixation screws simultaneously by turning the instrument screwdrivers one quarter of a turn.

WARNING 3.25



Avoid excessive force when tightening the fixation screws. Otherwise wrong target can be treated due to bent fixation posts or damaged fixation screws, or treatment can be cancelled.

Note:

Ensure to always tighten the fixation screws diagonally, and do not overtighten.

- 16 Move the instrument screwdrivers to the other diagonal pair of fixation screws and turn one quarter of a turn.
- 17 To reduce coordinate frame movement, tighten the two pairs of diagonally opposed fixation screws alternately, one quarter of a turn at a time, until all four fixation screws have entered into the skull bone to a sufficient level.
- 18 Verify that all four fixation screws are securely holding the coordinate frame in place.
- 19 Carefully remove the ear plugs from the patient's ears.
- 20 Remove the ear plug holders from the coordinate frame.

- 21 Check firm attachment of the coordinate frame by grasping the coordinate frame and gently lifting it.

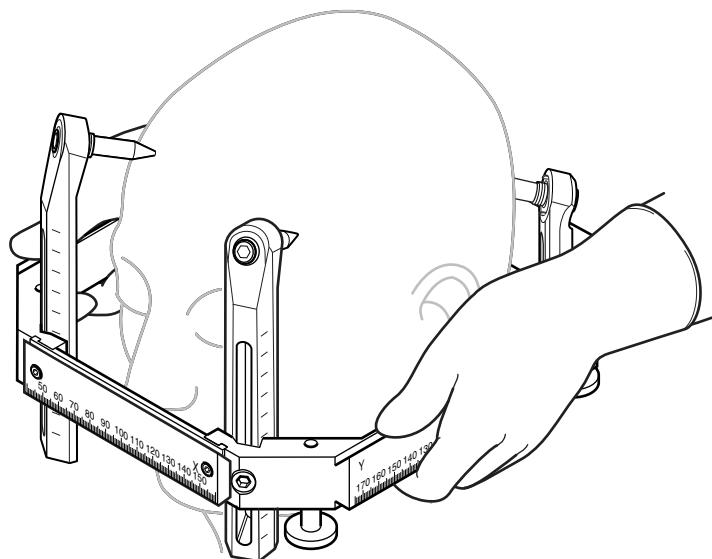


Figure 3.15 Checking the coordinate frame attachment



WARNING 3.26

Before surgery, ensure that the coordinate frame is secured to the patient skull. Otherwise the patient may be injured.



WARNING 3.27

Do not continue surgery if the front piece of the coordinate frame has been removed. The stereotactic procedure must be re-done, starting with imaging. Otherwise the treatment can be inaccurate and the patient can be injured.

3.2.3.3

Removal and disassembly

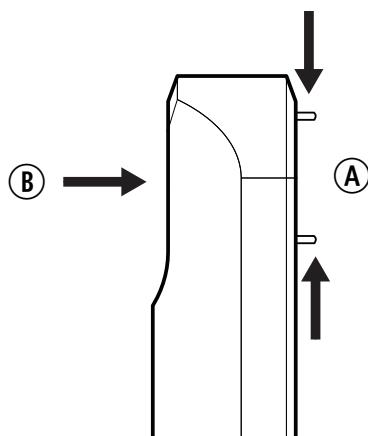
The procedure for removing the coordinate frame from the patient is the reverse of the procedure given in [Section 3.2.3.2 on page 39](#).

The procedure for disassembling the coordinate frame is the reverse of the procedure given in [Section 3.2.3.1 on page 33](#).

Removal of the disposable inserts

To remove the disposable insert from the insulated fixation post:

- 1 Pinch the two clips of the disposable insert by using two fingers **A**.



- 2 With your other hand, gently push the insert with a finger **B** and remove the disposable insert from the insulated fixation post.

Note:

Dispose the inserts in accordance with local regulations.



WARNING 3.28

**The disposable inserts are single use products and must not be re-used.
Re-use can be hazardous for the patient.**

3.3 Slotted Front Piece

3.3.1 Product overview

The slotted front piece enables a three-point fixation of the Leksell® Coordinate Frame G. The three-point fixation allows the surgeon to provide better access for a frontal approach, while still keeping the coordinate frame in a fixed position.

By exchanging the standard front piece of the coordinate frame for the slotted front piece, one anterior fixation post can be moved closer to the midline and the other dispensed with completely.

The slotted front piece is an alternative way of coordinate frame fixation during Leksell Gamma Knife® treatment, if the anterior fixation posts interfere with the collimator helmet/collimator cap.

Note: *The slotted front piece cannot be used with the stereotactic arc in the anterior-posterior orientation.*

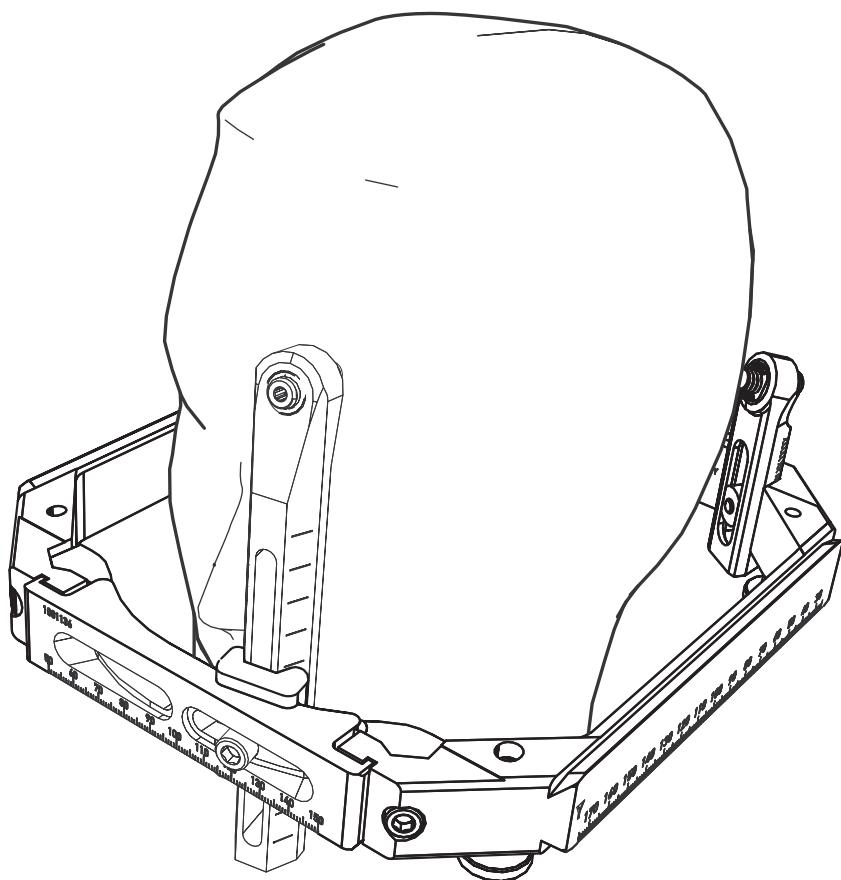


Figure 3.16 Attachment of the slotted front piece

3.3.2

Main parts

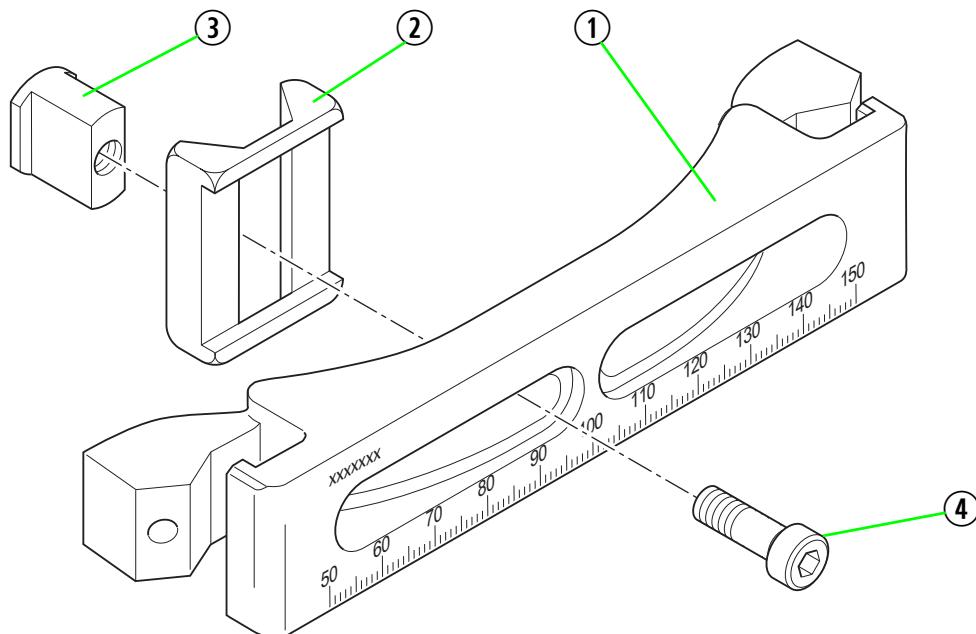
[Figure 3.17](#) shows the main components of the Slotted Front Piece kit.

The **slotted front piece** ① attaches to the coordinate frame using the holes and titanium screws normally used for the anterior fixation posts. The slots in the slotted front piece are slightly curved to match the curvature of the skull. The slotted front piece is made of aluminum and its anterior side is engraved with coordinate graduations (X scale).

The **support** ②, **locking piece** ③ and **locking screw** ④ are used to attach one of the anterior fixation posts to the slotted front piece.

The support allows the fixation post to slide along the slotted front piece until the titanium locking screw (5×19 mm) is tightened into the locking piece. The support and locking piece are made of aluminum and the locking screw is made of titanium.

This equipment is MR Conditional. See [Section 1.2.4 on page 8](#) for detailed information.



- ① Slotted front piece
- ② Support
- ③ Locking piece
- ④ Locking screw

[Figure 3.17 Main parts of the Slotted Front Piece kit](#)

3.3.2.1

Labels

Some parts can have engraved labels. See [Section 9.7 on page 288](#) for general label information.

3.3.3 Using the slotted front piece



WARNING 3.29

When using the slotted front piece, three-point fixation reduces the stability of the fixation to the skull and can cause incorrect treatment.

3.3.3.1 Fitting instructions

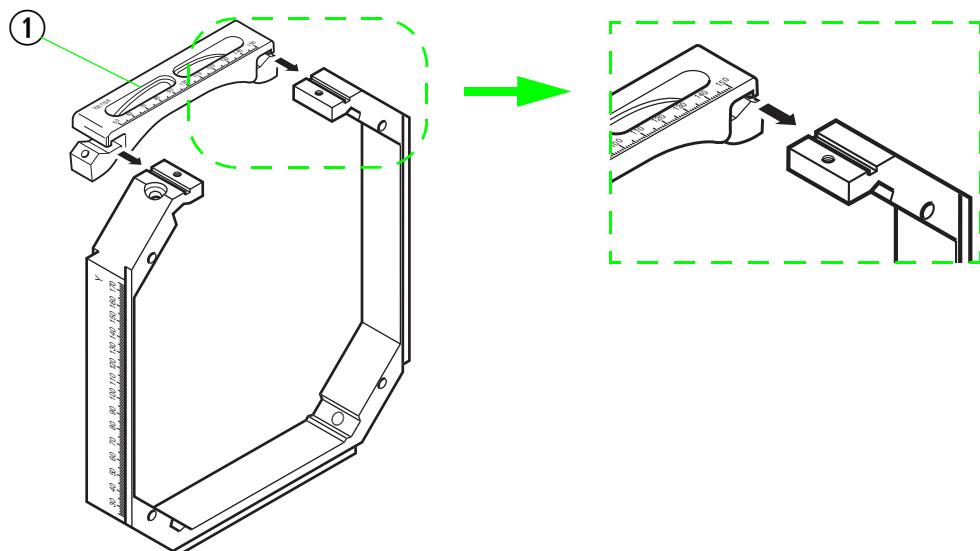
Preparation

Inspect all components regarding functionality before use.

Check that all components of Leksell® Coordinate Frame G (see [Figure 3.3](#)) and the Slotted Front Piece kit (see [Figure 3.17](#)) are clean, sterilized and at hand prior to use.

Fitting the slotted front piece to the coordinate frame

- 1 Position the coordinate frame base on a clean horizontal surface. Rest the coordinate frame base on its posterior bar with the open anterior uppermost.
- 2 Fit the slotted front piece ① in place at the anterior of the coordinate frame base.
 - The slotted front piece must be fitted with the coordinate scaling facing the inferior position, as shown in the figure.
 - To ensure correct fitting, place the grooves on the inner surface of the slotted front piece into the corresponding grooves on the outer surfaces of the side bars of the coordinate frame base.

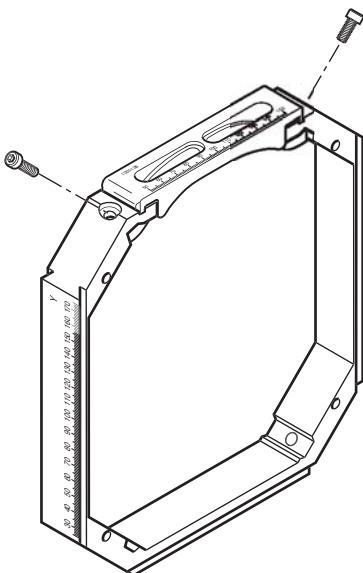


Note: The front piece of the coordinate frame can be exchanged to meet surgical requirements. If so, this must be done before the coordinate frame is attached to the patient's head.

WARNING 3.30

Always ensure that the slotted front piece is inserted in the correct orientation. If the slotted front piece is inserted upside down, the X-coordinate scale will be incorrect. Any treatment based on an incorrect scale could result in injury to the patient.

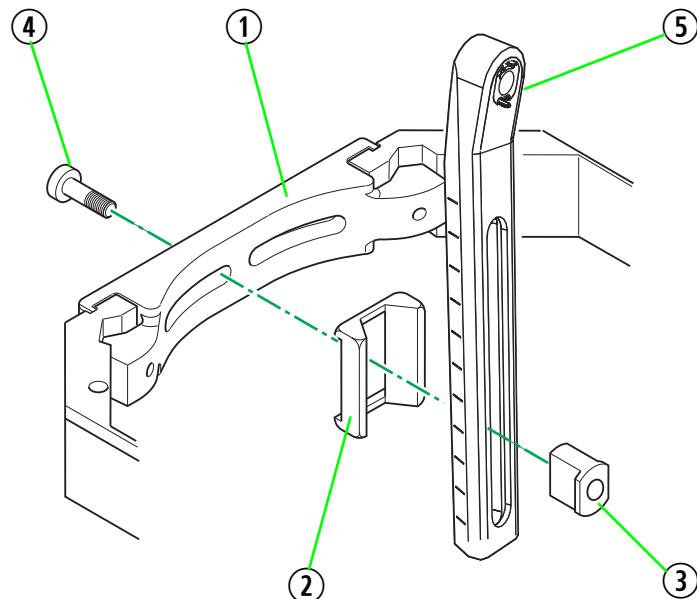
- 3 Use the instrument screwdriver to secure the slotted front piece ① to the coordinate frame base with the two locking screws normally used to secure the anterior fixation posts to the coordinate frame (item “③ Locking screws” in [Figure 3.3](#)).
 - Tighten the screws carefully until secure. Do not employ excessive force.



Slotted Front Piece

Fitting the fixation post to the slotted front piece

- 4 From the internal side of the coordinate frame, position the support ② onto the slotted front piece ① over the slot to be used.
- 5 Place the anterior fixation post ⑤ in the support ②.
- 6 From the internal side of the coordinate frame, insert the locking piece ③ into the height adjustment slot of the fixation post.



- 7 From the external side of the coordinate frame, insert the locking screw ④ through the slot and support ② and into the height adjustment slot of the fixation post.
 - Gently tighten the locking screw in the locking piece ③.
- 8 Slide the fixation post up or down until it is located at the desired position.
- 9 Use the instrument screwdriver to tighten the locking screw until the fixation post is fixed.
 - Do not employ excessive force.
- 10 Fit the rest of the coordinate frame and fixation posts according to [Section 3.2.3 on page 33](#).

3.3.3.2**Removal and disassembly**

The procedure for removing the fixation fixation post from the slotted front piece, and the slotted front piece from the coordinate frame, is the reverse of the attachment procedure.

3.4

Fixation Posts

Safe and secure fixation of the Leksell® Coordinate Frame G is one of the most important factors for achieving the best possible clinical outcome, since it is the reference base for accurate target localization. Fixation of the frame should be quick and easy to perform – but it should also ensure firm attachment and minimize any potential discomfort to the patient.

This section presents the different options for fixation posts. Each type of fixation post in the range has been purposely designed to meet the specific needs of different stereotactic neurosurgical treatments. To ensure maximum versatility and ease-of-use, all fixation post designs are available in a number of different lengths and shapes.

The different type of fixation posts are:

- Insulated Fixation Posts, see [Section 3.4.1 on page 52](#)
- Non-insulated Fixation Posts, see [Section 3.4.3 on page 55](#)

The fixation posts are available both in different configurations as well as pairs, see [Section 9.6.7 on page 282](#).

Note:

In this section, the term “fixation post” refers to the applicable type as described in each sub-section.

3.4.1**Insulated Fixation Posts: product overview**

The Insulated Fixation Posts are designed for both MR and CT scanning.

By use of a plastic insert, the insulated fixation posts effectively insulates the fixation screws from the fixation post thus reducing the energy transfer and provide a sterile, single use interface between the patient and the coordinate frame.

The risk of persistent cross-contamination is reduced when the insulated fixation posts are used together with Disposable Fixation Screws since the insert provides a single use interface between the patient and the coordinate frame.

A further benefit of the plastic inserts is the smooth thread interface of the fixation screw. This helps increase the lifetime of the fixation screws and posts and makes for a smoother procedure when attaching the stereotactic frame.

Common to all insulated fixation posts is the rounded, slim-topped profile that helps optimize the treatable volume for Gamma Knife® surgery and allow for more space in tight MRI head coils.

The medium insulated fixation posts enable low coordinate frame fixation without collision with the patient's shoulders.

The curved insulated fixation posts are mainly intended for use in Gamma Knife® surgery allowing an increased treatable volume as well as increased stability due to the use of shorter fixation screws.

The following items are available, see [Figure 3.18](#):

- **Short** ①, **medium** ② and **long** ③ pair of insulated fixation posts are positioned at the posterior position on the coordinate frame.
- **Anterior** ④ and **curved** ⑤ pair of insulated fixation posts are positioned at the anterior position on the coordinate frame.
- **Disposable inserts** ⑥, to be placed into the insert hole of the insulated fixation post.
- **Locking screws** (of titanium) and **locking pieces** (of aluminum) are used for securing the fixation posts to the coordinate frame, see [Figure 3.19](#).

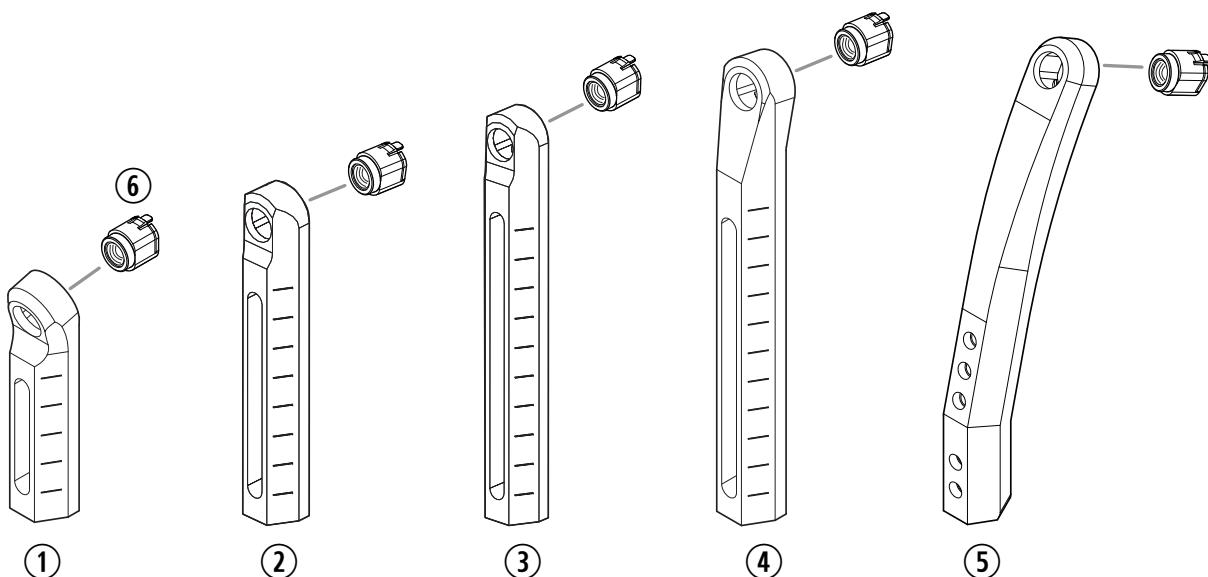


Figure 3.18 The insulated fixation posts

3.4.1.1

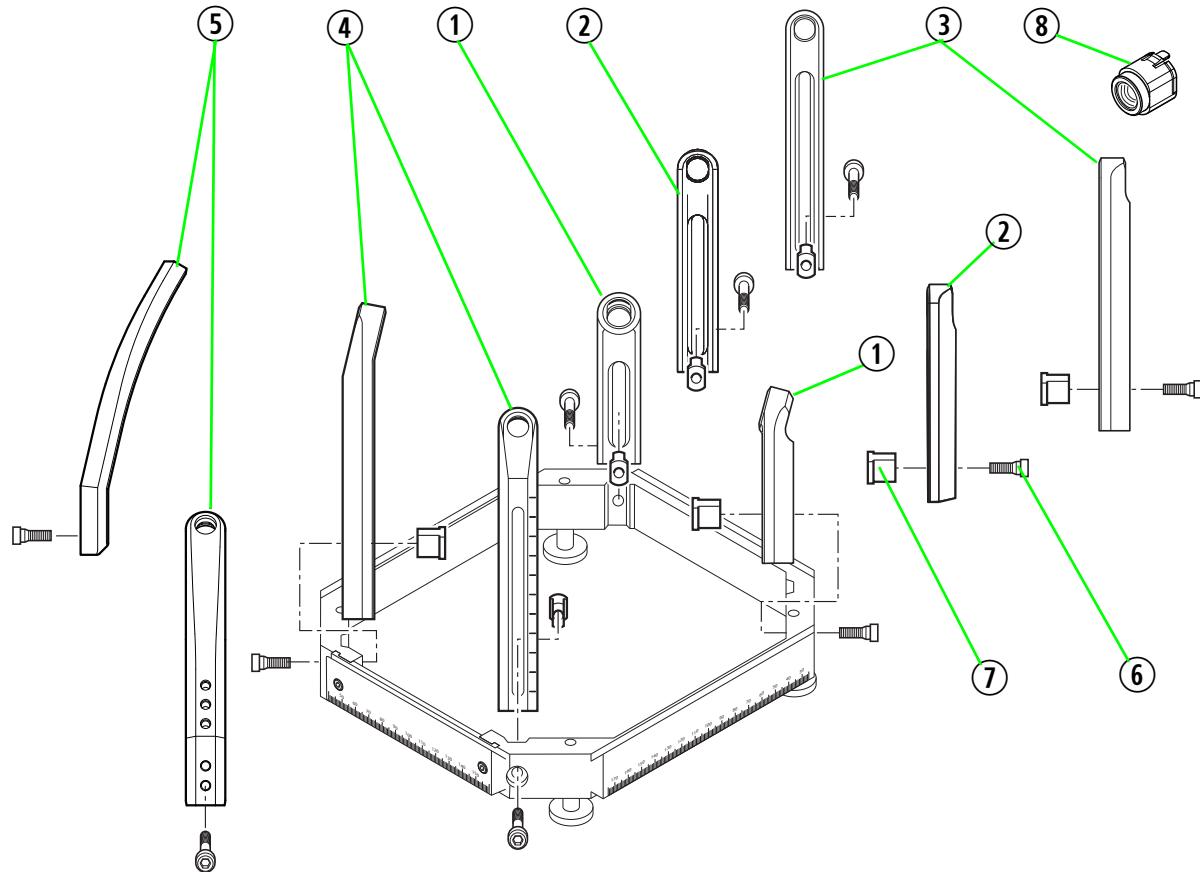
Main parts

Refer to [Figure 3.19](#).



All components except the locking screws and the disposable inserts are made of aluminum.

This equipment is MR Conditional. See [Section 1.2.4 on page 8](#) for detailed information.



- ① Insulated fixation posts, short posterior
- ② Insulated fixation posts, medium posterior
- ③ Insulated fixation posts, long posterior
- ④ Insulated fixation posts, anterior

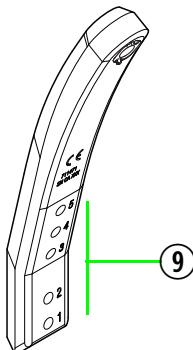
- ⑤ Insulated fixation posts, curved
- ⑥ Locking screws
- ⑦ Locking pieces
- ⑧ Disposable insert

*Figure 3.19 Main parts of the Insulated Fixation Posts.
(Leksell® Coordinate Frame is shown as positional reference only.)*

One surface of the insulated fixation post is engraved with a scale to facilitate positioning on the coordinate frame.

At the top end of the insulated fixation post is an insert hole into which the disposable insert is placed.

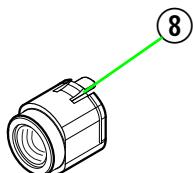
The insulated fixation post is fixed at the internal corners of the coordinate frame by means of a locking screw passing through the height adjustment slot in the center of the insulated fixation post and secured with the locking piece. This arrangement allows adjustment of the height of the coordinate frame in relation to the patient's head.

Fixation Posts**Curved insulated fixation posts**

The curved insulated fixation posts have five mounting holes ⑨ that are used to adjust the height of the coordinate frame in relation to the patient's head. The mounting holes are marked on the face of the curved insulated fixation posts with number 1, 2, 3, 4 and 5.

At the top end of the curved insulated fixation post is an insert hole into which the disposable insert is placed.

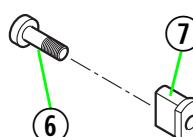
The curved insulated fixation post is fixed at each of the internal anterior corners of the coordinate frame by means of a locking screw.

Disposable inserts

The disposable inserts ⑧, made of plastic, are to be placed into the insulated fixation post.

The disposable inserts are delivered in a sterile package of four and are for single use only.

One end of the insert is circular and the other has flat sides to avoid erroneous fitting into the insulated fixation post. The insert hole of the insulated fixation posts is correspondingly shaped circular in one end and has flat sides in the other.



Note:

For the curved insulated fixation posts only the locking screw is needed.

3.4.1.2**Labels**

Some parts have engraved labels. See [Table 3.2](#) for details, and [Section 9.7 on page 288](#) for general label information.

Table 3.2 Labelled parts on the Insulated Fixation Posts

Part	Labels
⑤ Curved insulated fixation post	1, 2, 3, 4, 5

3.4.2**Using the Insulated Fixation Posts**

Refer to [D. Fitting the fixation posts, page 35](#).

3.4.2.1**Attaching the coordinate frame to the patient**

Refer to [3.2.3.2 Attaching the coordinate frame to the patient's skull, page 39](#).

3.4.2.2**Removal and disassembly**

The procedure for removing the insulated fixation posts from the coordinate frame is the reverse of the fitting, see [D. Fitting the fixation posts, page 35](#).

3.4.3

Non-insulated Fixation Posts: product overview

The Non-insulated Fixation Posts fulfill the common requirements for performing different stereotactic procedures. They are designed for use in CT scanners in conjunction with Reusable Fixation Screws or Disposable Fixation Screws.

Common to the fixation posts is the rounded, slim-topped profile that helps optimize the treatable volume for Gamma Knife® surgery.

The medium fixation posts enable low coordinate frame fixation without collision with the patient's shoulders.

The curved fixation posts are mainly intended for use in Gamma Knife® surgery allowing an increased treatable volume as well as increased stability due to the use of shorter fixation screws.

The following items are available, see [Figure 3.20](#):

- **Short** ①, **medium** ② and **long** ③ pair of fixation posts are positioned at the posterior position on the coordinate frame.
- **Anterior** ④ and **curved** ⑤ pair of fixation posts are positioned at the anterior position on the coordinate frame.
- **Locking screws** (of titanium) and **locking pieces** (of aluminum) are used for securing the fixation posts to the coordinate frame, see [Figure 3.21](#).

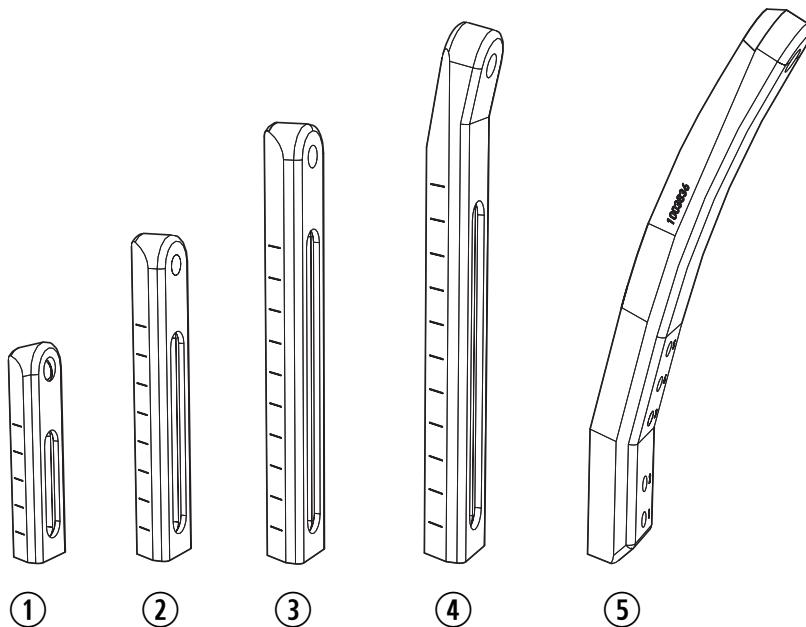


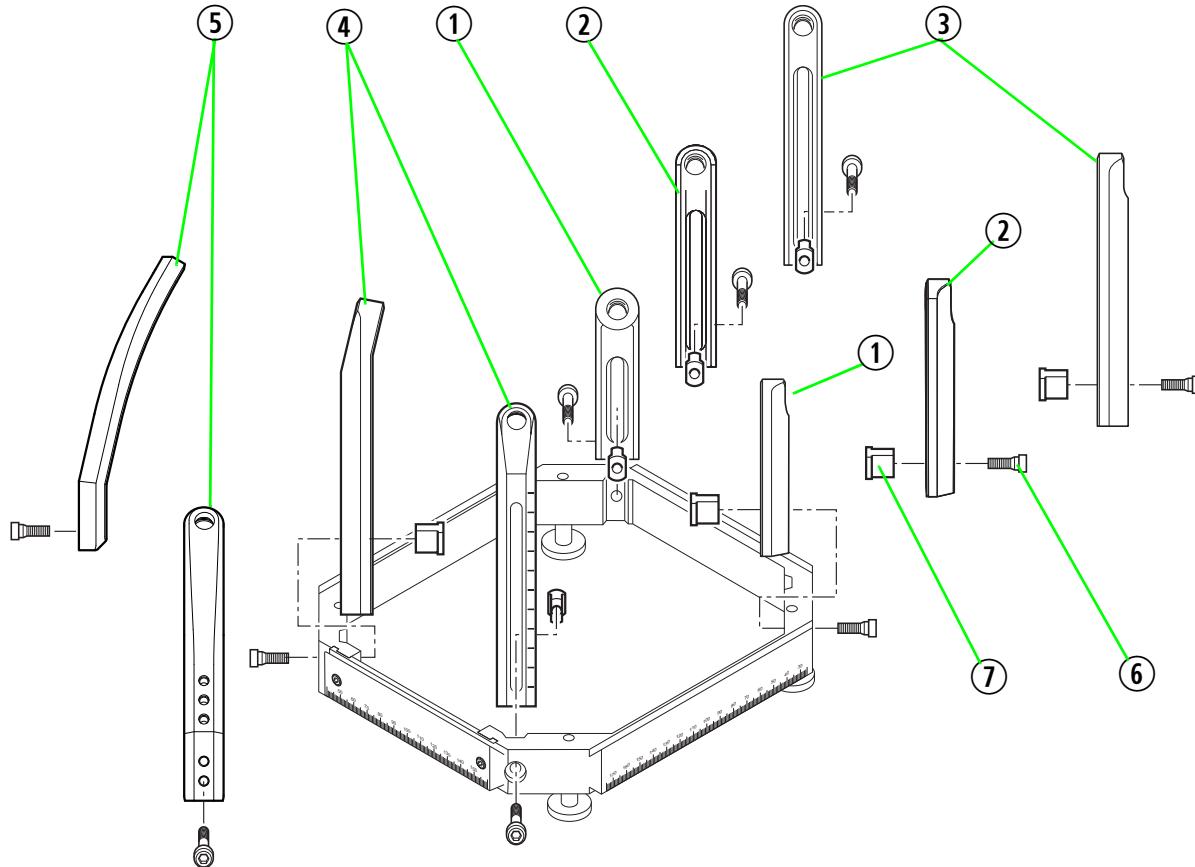
Figure 3.20 The non-insulated fixation posts

3.4.3.1**Main parts**

Refer to [Figure 3.21](#).

All components except the locking screws are made of aluminum.

This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.

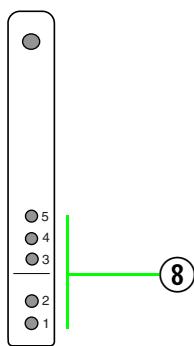


- | | |
|--|--|
| ① Non-insulated fixation posts, short posterior | ⑤ Non-insulated fixation posts, curved |
| ② Non-insulated fixation posts, medium posterior | ⑥ Locking screws |
| ③ Non-insulated fixation posts, long posterior | ⑦ Locking pieces |
| ④ Non-insulated fixation posts, anterior | |

*Figure 3.21 Main parts of the Non-insulated Fixation Posts
(Leksell® Coordinate Frame is shown as positional reference only.)*

One surface of the fixation post is engraved with a scale to facilitate positioning on the coordinate frame.

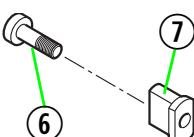
The fixation post is fixed at the internal corners of the coordinate frame by means of a locking screw passing through the height adjustment slot in the center of the fixation post and secured with the locking piece. This arrangement allows adjustment of the height of the coordinate frame in relation to the patient's head.



Curved fixation posts

The curved non-insulated fixation posts have five mounting holes ⑧ that are used to adjust the height of the coordinate frame in relation to the patient's head. The mounting holes are marked on the face of the curved fixation posts with number 1, 2, 3, 4 and 5.

The curved non-insulated fixation post is fixed at each of the internal anterior corners of the coordinate frame by means of a locking screw.



Locking pieces and locking screws

The locking screw ⑥ and locking piece ⑦ is used to secure the fixation post to the coordinate frame. The locking screw, 5 × 19 mm, is made of titanium.

Note:

For the curved fixation posts only the locking screw is needed.

3.4.3.2 Labels

Some parts have engraved labels. See [Table 3.3](#) for details, and [Section 9.7 on page 288](#) for general label information.

Table 3.3 Labelled parts on the fixation posts

Part	Labels
⑤ Non-insulated fixation post, curved	1, 2, 3, 4, 5

3.4.4 Using the Non-insulated Fixation Posts

Refer to [Fitting the fixation posts to the coordinate frame, page 36](#).

3.4.4.1 Attaching the coordinate frame to the patient

Refer to [3.2.3.2 Attaching the coordinate frame to the patient's skull, page 39](#).

3.4.4.2 Removal

The procedure for removing the fixation posts from the coordinate frame is the reverse of the fitting, see [D. Fitting the fixation posts, page 35](#).

3.5 Reusable Fixation Screws

3.5.1 Product overview

The Reusable Fixation Screws are used to affix the coordinate frame firmly to the patient's skull with minimal inconvenience to the patient.

Note: *In this section, the term "fixation screw" refers to a Reusable Fixation Screw.*

The fixation screws are made of coated hard aluminum. The low density and non-magnetic properties makes them the optimum choice in scanning procedures such as MR and CT.

The fixation screws have a hexagon socket with hexagonal key fitting to minimize the portion of the fixation screw protruding at the distal end. This is particularly advantageous in tight-fitting MR headcoils and for optimizing the treatable volume in Leksell Gamma Knife®.

Each fixation screw is inserted through a threaded hole of the fixation post. Using the instrument screwdrivers supplied with Leksell Stereotactic System®, the fixation screws are tightened so that the coordinate frame is held firmly in place. It is necessary to use two instrument screwdrivers when tightening the fixation screws, and to tighten the fixation screw pairs diagonally.

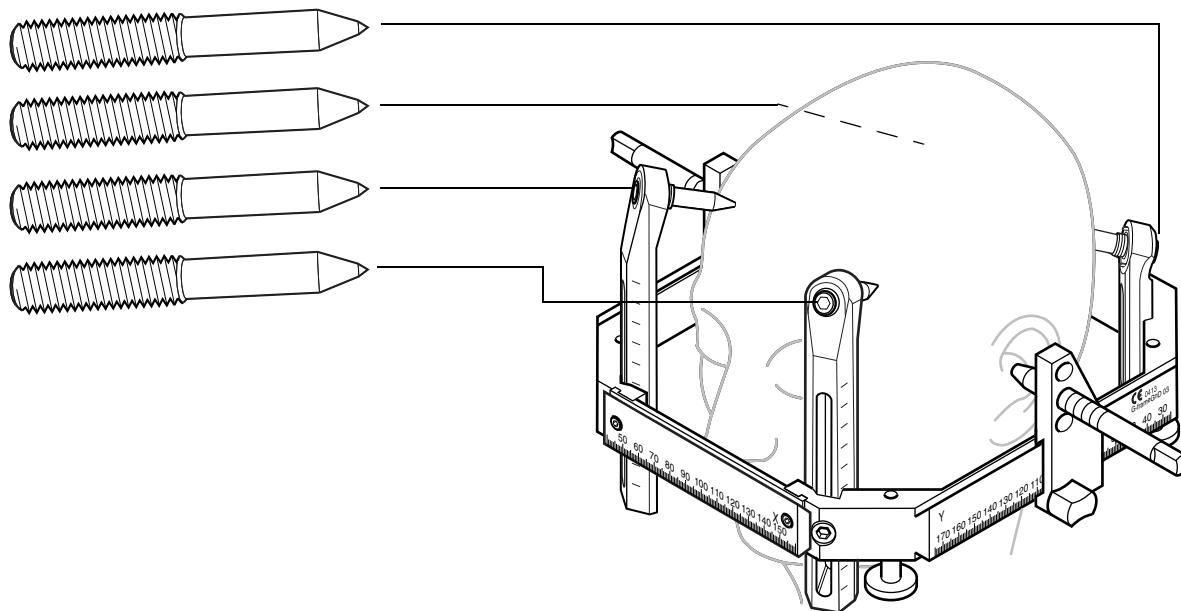


Figure 3.22 Principle of the Reusable Fixation Screws

The fixation screws are supplied according to [Section 9.6.8 on page 283](#). Screws are available in different lengths so as to accommodate any patient head size up to 62 cm and locate the coordinate frame at any required position on a patient's skull.

This equipment is MR Conditional. See [Section 1.2.4 on page 8](#) for detailed information.



3.5.1.1

Labels

Some parts can have engraved labels. See [Section 9.7 on page 288](#) for general label information.

3.5.2

Using the Reusable Fixation Screws

3.5.2.1

Fitting instructions

Preparation

Inspect all components regarding functionality before use.

The fitting instructions assume that:

- The coordinate frame has been correctly assembled before it is fitted to the patient's skull.
- For instructions on preparing the coordinate frame and the patient, refer to [Section 3.2.3](#).
- The fixation screws are clean, sterilized, and at hand.

Check of the fixation screw tip

The tip of each fixation screws must be checked prior to use. Do not use if damaged or blunt.

Fitting the Reusable Fixation Screws

Refer to [Securing the coordinate frame to the patient's skull on page 41](#), for information on how to fit the fixation screws.

3.5.2.2

Removal

The procedure for removing the fixation screws from the coordinate frame and patient is the reverse of the fitting procedure.

3.6 Titanium Fixation Screws

3.6.1 Product overview

The Titanium Fixation Screws are used to affix the coordinate frame firmly to the patient's skull with minimal inconvenience to the patient.

Note: *In this section, the term “fixation screw” refers to a Titanium Fixation Screw.*

The fixation screw are made of titanium and designed to minimize the generation of artifacts on CT and MR images.

The fixation screws are long lasting and durable with a female hex design which enables an expanded treatment volume in Leksell Gamma Knife® and increased ease-of-use in tight MR head coils.

Each fixation screw is inserted through a threaded hole of the fixation post. Using the instrument screwdriver supplied with Leksell Stereotactic System®, the fixation screws are tightened so that the coordinate frame is held firmly in place. It is necessary to use two instrument screwdrivers when tightening the fixation screws, and to tighten the fixation screw pairs diagonally.

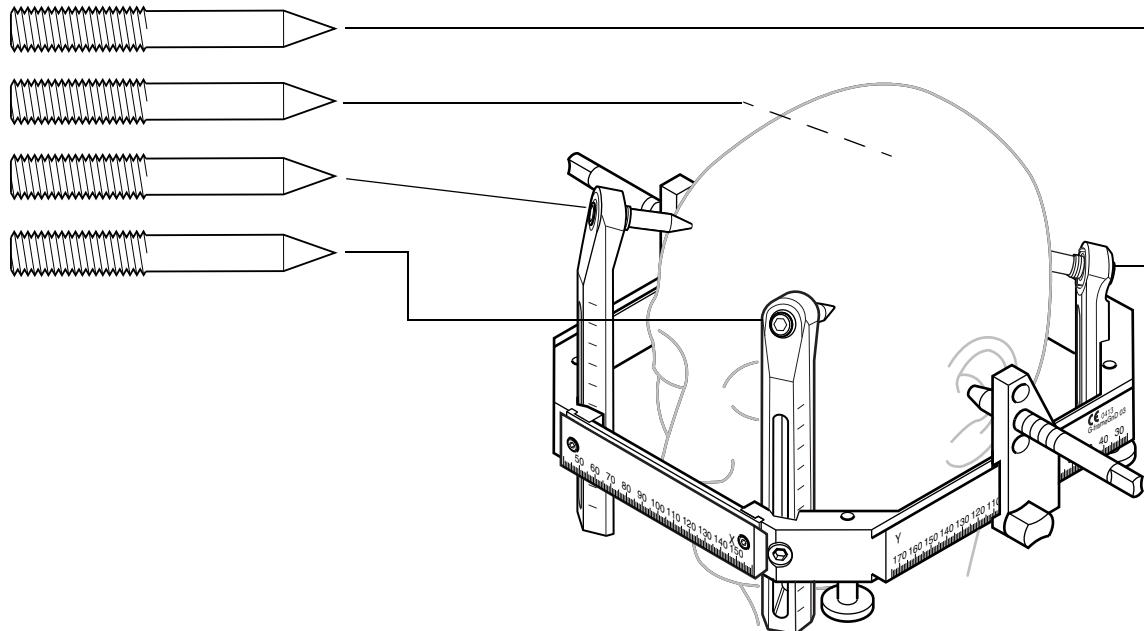


Figure 3.23 Principle of the Titanium Fixation Screws

The fixation screws are supplied according to [Section 9.6.8 on page 283](#). Screws are available in different lengths so as to accommodate any patient head size up to 62 cm and locate the coordinate frame at any required position on a patient's skull.

This equipment is MR Conditional. See [Section 1.2.4 on page 8](#) for detailed information.



3.6.1.1 Labels

Some parts can have engraved labels. See [Section 9.7 on page 288](#) for general label information.

3.6.2 Using the Titanium Fixation Screws



WARNING 3.31

The Titanium Fixation Screws can cause artifacts in MR images.

3.6.2.1 Fitting instructions

Preparation

Inspect all components regarding functionality before use.

The fitting instructions assume that:

- The coordinate frame has been correctly assembled before it is fitted to the patient's skull.
- For instructions on preparing the coordinate frame and the patient, refer to [Section 3.2.3](#).
- The fixation screws are clean, sterilized, and at hand.

Check of the fixation screw tip

The tip of each fixation screws must be checked prior to use. Do not use if damaged or blunt.

Fitting the Titanium Fixation Screws

Refer to [Securing the coordinate frame to the patient's skull on page 41](#), for information on how to fit the fixation screws.

3.6.2.2 Removal

The procedure for removing the fixation screws from the coordinate frame is the reverse of the fitting procedure.

3.7

Quick Fixation Screws

3.7.1

Product overview

The Quick Fixation Screws are used to affix the coordinate frame firmly to the patient's skull with minimal inconvenience to the patient.

Note: *In this section, the term "fixation screw" refers to a Quick Fixation Screw.*

The fixation screws are made of aluminum with a hard metal tip made of tungsten carbide.

Each fixation screw is inserted through a threaded hole of the fixation post. Using the socket wrenches the fixation screws are tightened so that the coordinate frame is held firmly in place. It is necessary to use two socket wrenches when tightening the fixation screws, and to tighten the fixation screw pairs diagonally.

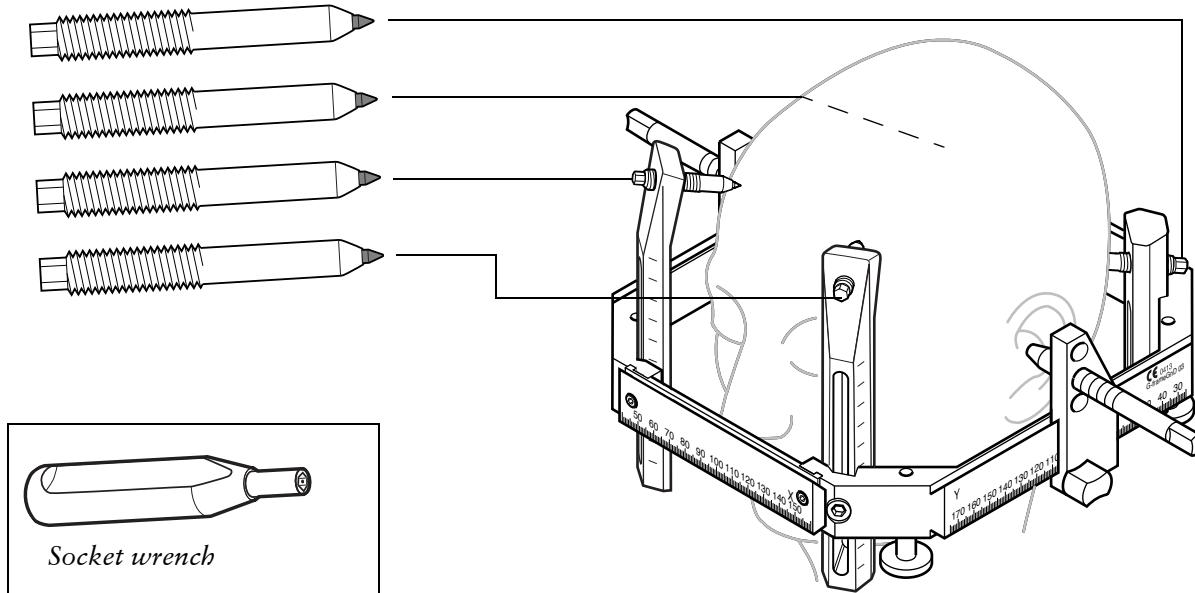


Figure 3.24 Principle of the Quick Fixation Screws

The fixation screws are supplied according to [Section 9.6.8 on page 283](#). Screws are available in different lengths so as to accommodate any patient head size up to 62 cm and locate the coordinate frame at any required position on a patient's skull.

The fixation screws are tested for biocompatibility for 24 hours according to ISO 10993.

This equipment is MR Conditional. See [Section 1.2.4 on page 8](#) for detailed information.



3.7.1.1

Labels

Some parts can have engraved labels. See [Section 9.7 on page 288](#) for general label information.

3.7.2 Using the Quick Fixation Screws

3.7.2.1 Fitting instructions

Preparation

Inspect all components regarding functionality before use.

The fitting instructions assume that:

- The coordinate frame has been correctly assembled before it is fitted to the patient's skull.
- For instructions on preparing the coordinate frame and the patient, refer to [Section 3.2.3](#).
- The fixation screws are clean, sterilized, and at hand.

WARNING 3.32



Prior to use, inspect the fixation screws to find any damage during shipment or storage or out-of-box defects that can increase the risk of fragmentation during use.

Fitting the Quick Fixation Screws

Refer to [Securing the coordinate frame to the patient's skull on page 41](#), for information on how to fit the fixation screws.

- Use socket wrenches to tighten the fixation screws.

3.7.2.2 Removal

The procedure for removing the fixation screws from the coordinate frame is the reverse of the fitting procedure.

WARNING 3.33



Inspect the fixation screw tip for any signs of breakage or fragmentation immediately upon removal from the patient.

If any part of the fixation screw tip has sheared off, ensure that the part is removed from the patient.

3.8 Disposable Fixation Screws

3.8.1 Product overview

The Disposable Fixation Screws are used to affix the coordinate frame firmly to the patient's skull with minimal inconvenience to the patient.

Note: *In this section, the term "fixation screw" refers to a Disposable Fixation Screw.*

The fixation screws are made of aluminum and must only be used once. They are designed to minimize the generation of artifacts on CT and MR images.

Each fixation screw is inserted through a threaded hole of the fixation post. Using the socket wrenches, the fixation screws are tightened so that the coordinate frame is held firmly in place. It is necessary to use two socket wrenches when tightening the fixation screws, and to tighten the fixation screw pairs diagonally.

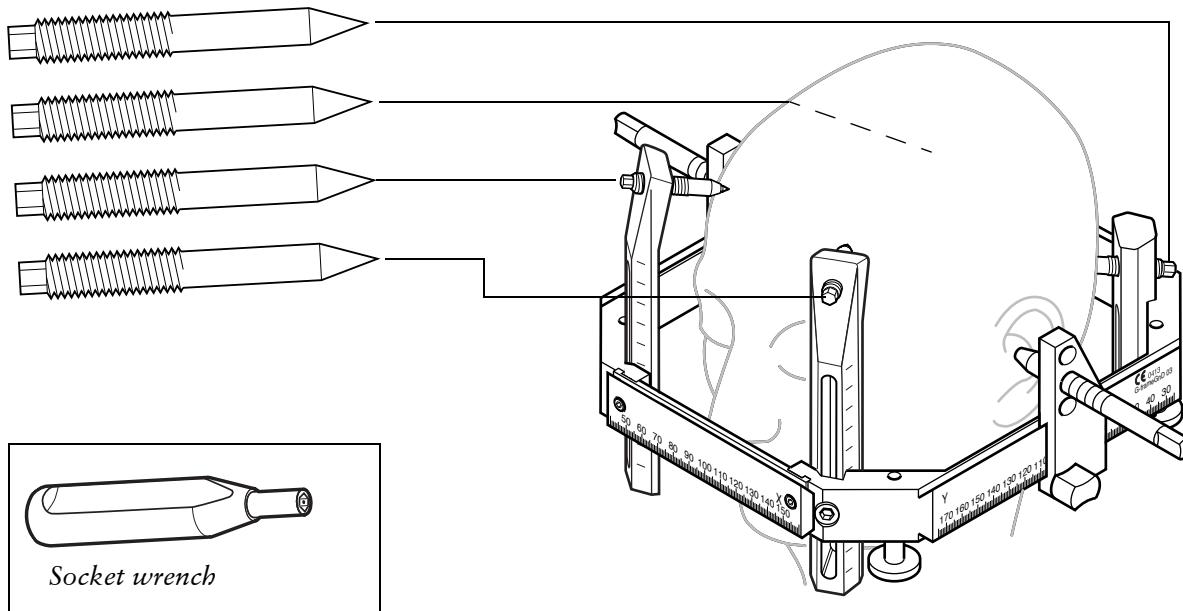


Figure 3.25 Principle of the Disposable Fixation Screws

The fixation screws are supplied according to [Section 9.6.8 on page 283](#). Screws are available in different lengths so as to accommodate any patient head size up to 62 cm and locate the coordinate frame at any required position on a patient's skull.

This equipment is MR Conditional. See [Section 1.2.4 on page 8](#) for detailed information.



3.8.1.1 Labels

Some parts can have engraved labels. See [Section 9.7 on page 288](#) for general label information.

3.8.2 Using the Disposable Fixation Screws

3.8.2.1 Fitting instructions

Preparation

Inspect all components regarding functionality before use.

The fitting instructions assume that:

- The coordinate frame has been correctly assembled before it is fitted to the patient's skull.
- For instructions on preparing the coordinate frame and the patient, refer to [Section 3.2.3](#).
- The fixation screws are clean, sterilized, and at hand.



WARNING 3.34

The Disposable Fixation Screws are single use products and must not be re-used. Re-use can be hazardous for the patient.

Fitting the Disposable Fixation Screws

Refer to [Securing the coordinate frame to the patient's skull on page 41](#), for information on how to fit the fixation screws.

- Use socket wrenches to tighten the fixation screws.

Note:

If a fixation screw have to be untightened during the procedure, check the tip carefully for any signs of damage. In the event of any damage the fixation screw must be exchanged for a new one.

3.8.2.2 Removal

The procedure for removing the fixation screws from the coordinate frame is the reverse of the fitting procedure.

3.9 Frame Fixation

3.9.1 Product overview

The Frame Fixation is a 3-point operating table fixation used to obtain a rigid and accurate fixation of Leksell® Coordinate Frame G in the operating room. The Frame Fixation is designed to attach directly to the feet of the coordinate frame. The rigid 3-point fixation is especially suitable for surgery on patients with tremor. By using the Frame Fixation during surgery, the fixation will be similar to that used during imaging and thus allows an increased accuracy of the treatment.

When the patient has been positioned on the operating table, the Frame Fixation secures the coordinate frame to the operating table via a Mayfield® headrest or a headrest with the same interface.

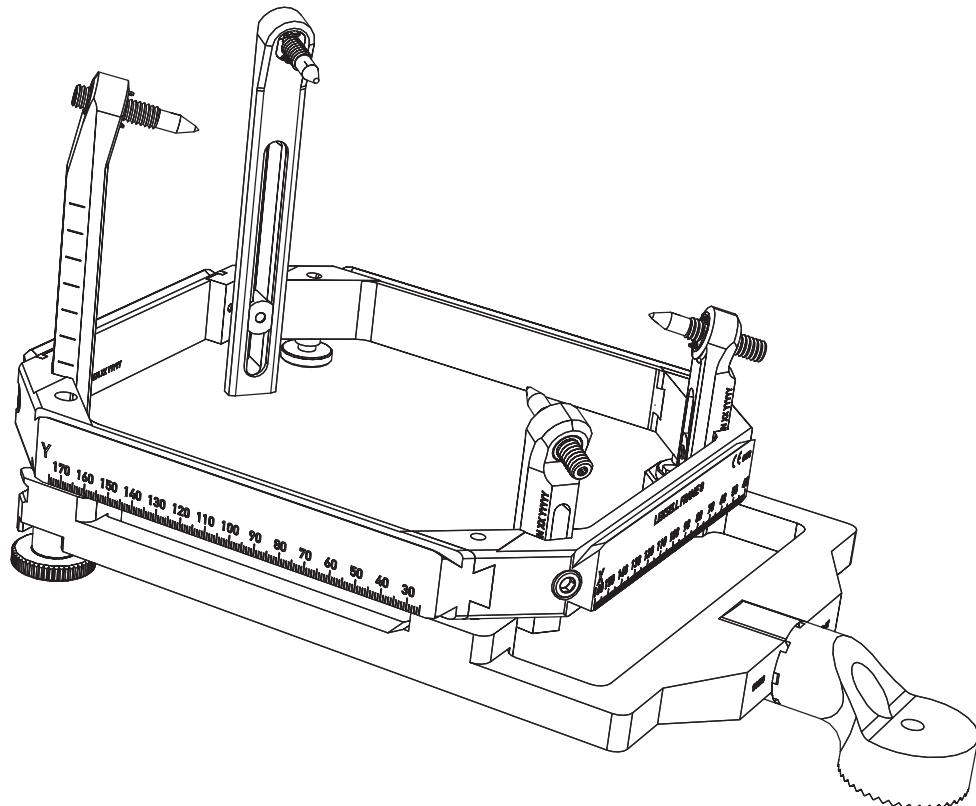


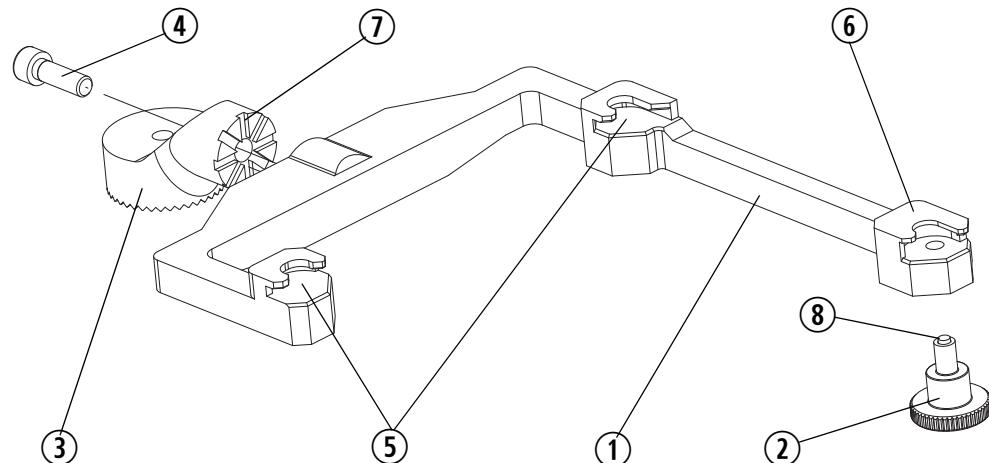
Figure 3.26 The Frame Fixation with an attached Leksell® Coordinate Frame G

3.9.2

Main parts

Refer to [Figure 3.27](#)

The Frame Fixation consists of a **yoke** ①, a **fixing knob** ② with pin, a **headrest support** ③ and a **fixing screw** ④. The yoke has two inner **frame fixation sockets** ⑤ and one outer **frame fixation socket** ⑥ which accommodate the feet of the coordinate frame. The fixing knob secures the coordinate frame in position. The pin on the fixing knob protects the coordinate frame foot from damage.



- | | |
|--------------------|----------------------------|
| ① Yoke | ⑤, ⑥ Frame fixation socket |
| ② Fixing knob | ⑦ Grooves |
| ③ Headrest support | ⑧ Pin |
| ④ Fixing screw | |

Figure 3.27 Main parts of the Frame Fixation

One end of the headrest support has a geometric arrangement of **grooves** ⑦ which can be fitted to the yoke in any one of eight positions. The other end of the headrest support has a serrated pattern which mates with the attachment of the operating table headrest and can be set to any predetermined angle.

All the components of the Frame Fixation are made of aluminum, except the fixing knob and fixing screw (stainless steel) and the pin (plastic).

The Frame Fixation is supplied with a 6 mm hexagonal key for assembly/disassembly purposes.

There is an optional sterilization tray that can be used for the Frame Fixation, see [Section 7.3.1 on page 270](#).

This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.



3.9.2.1

Labels

Some parts can have engraved labels. See [Section 9.7 on page 288](#) for general label information.

3.9.3 Using the Frame Fixation

3.9.3.1 Assembly instructions

Preparation

Inspect all components regarding functionality before use.

The following instructions assume that:

- The coordinate frame has been assembled and attached to the patient's skull in accordance with [Section 3.2 on page 28](#).
- All components of the Frame Fixation are clean, sterilized, and at hand.
- The surgical accessories have been cleaned and sterilized in accordance with the manufacturer's instructions.
- An operating table headrest, for example a Mayfield® headrest, has been fitted to the operating table.

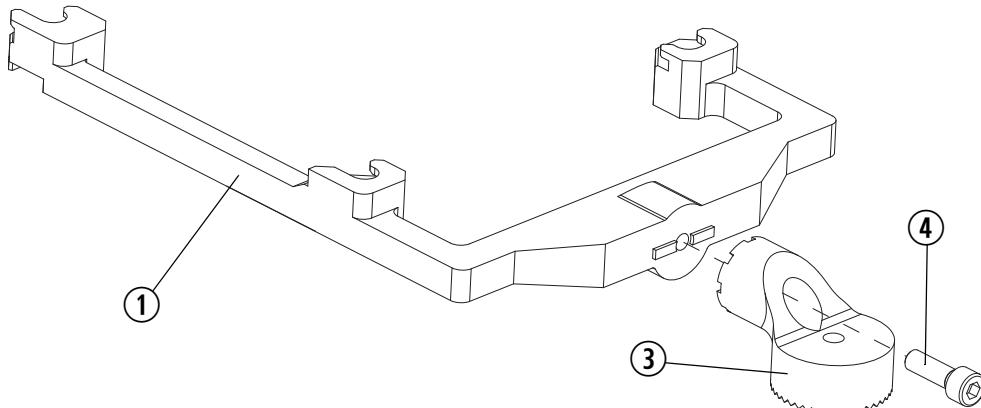


WARNING 3.35

Inspect all threads regarding wear and tear before use. Damaged threads can cause unsafe fixation of the coordinate frame.

Assembling the Frame Fixation

- 1 Mount the headrest support ③ to the yoke ① in the required angle and fix it with the fixing screw ④.



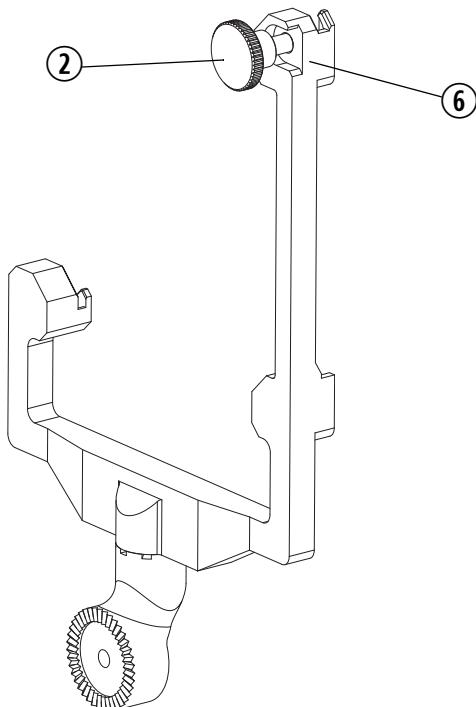
Note: The headrest support and yoke can be fitted together in any one of eight positions.



WARNING 3.36

**Do not use excessive force when tightening locking screws/knobs.
Otherwise parts can be damaged and not permit secure fixation.
Non-secure fixation can cause incorrect treatment.**

- 2 Screw the fixing knob ② slightly into the hole of the outer frame fixation socket ⑥.



3.9.3.2 Positioning the patient



WARNING 3.37

Support the patient's head at all times when fitting the coordinate frame to, and removing it from, any other equipment. Otherwise the patient can be injured.

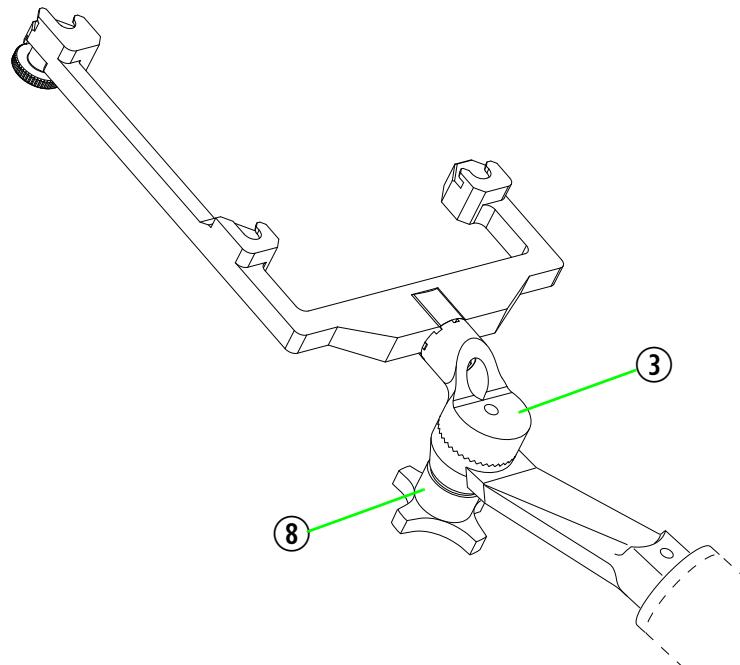
It is possible to position the coordinate frame in two directions in the Frame Fixation:

- For supine surgery:
the anterior side of the coordinate frame is fixed in the outer frame fixation socket.
- For prone surgery:
the posterior side of the coordinate frame is fixed in the outer frame fixation socket.

Frame Fixation

To position the patient:

- 1 Attach the headrest support ③ of the assembled Frame Fixation to the operating table headrest ⑧. Use the attachment screws supplied with the operating table headrest.



Note:

Ensure that the Frame Fixation is securely fixed to the operating table.



WARNING 3.38

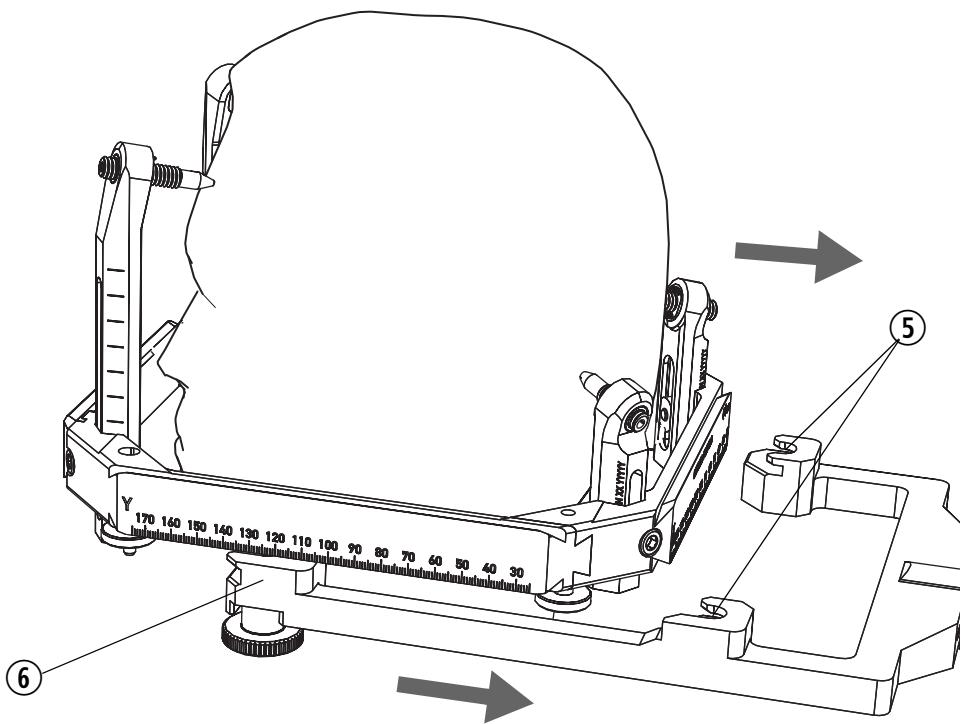
**Ensure that the equipment is properly assembled and securely fixed.
Otherwise the patient can be injured.**

- 2 Position the patient on the operating table so that the coordinate frame will engage with the Frame Fixation when the patient is moved into position.

Note:

If necessary for patient comfort, adjust the Frame Fixation angle by changing the headrest angle or the eight possible angles between the headrest support and the yoke.

- 3 While carefully supporting the patient's head, move the coordinate frame in the following way:
 - For supine surgery:
move the coordinate frame until the posterior feet and the anterior left foot of the coordinate frame slide into the frame fixation sockets ⑤ and ⑥,
or
 - For prone surgery:
move the coordinate frame until the anterior feet and the posterior right foot of the coordinate frame slide into the frame fixation sockets ⑤ and ⑥.

**Note:**

It is recommended to start inserting the two coordinate frame feet into the inner frame fixation sockets ⑤ before inserting the coordinate frame foot into the outer frame fixation socket ⑥.

- 4 Check that the coordinate frame is fully engaged in the Frame Fixation, i.e. that the feet of the coordinate frame are located at the bottom of the frame fixation sockets.
- 5 Tighten the fixing knob by hand to secure the coordinate frame to the Frame Fixation.

The stereotactic arc can now be mounted on the coordinate frame.

**WARNING 3.39**

**Ensure that the equipment is properly assembled and securely fixed.
Otherwise the patient can be injured.**

**WARNING 3.40**

**Ensure that the patient can easily be released in case of emergency.
Otherwise the patient can be injured.**

3.9.3.3

Mounting the stereotactic arc

For information of mounting the stereotactic arc to the coordinate frame, see [Section 4.2.3 on page 94](#).

If the stereotactic arc interferes with the Frame Fixation, examine if switching sides of the arc supports placement will allow the correct X coordinate to be set.

3.9.3.4

Removal and disassembly

The procedure for removing the patient from the Frame Fixation is the reverse of the procedure described in steps 2 to 5 in [Section 3.9.3.2 on page 69](#).

The procedure for removing the Frame Fixation from the operating table is the reverse of the procedure given in step 1 in [Section 3.9.3.2 on page 69](#).

The procedure for disassembling the Frame Fixation is the reverse of the procedure given in [Section 3.9.3.1 on page 68](#).

Quick release of the patient

If a quick release of the patient is needed, **fully** unscrew the fixing knob and lift out the coordinate frame and patient.

Note:

If the fixing knob is not fully unscrewed, a catch on the outer frame fixation socket may stop the removal of the coordinate frame.

3.10 Leksell Stereotactic System[®] Clamp

3.10.1 Product overview

Leksell Stereotactic System[®] Clamp is used to obtain an adjustable, rigid fixation of Leksell[®] Coordinate Frame G during surgical operation. This facilitates the operative procedure by positioning the patient in a proper position. The Leksell Stereotactic System[®] Clamp is designed to attach directly to the bars of the coordinate frame for use in stereotactically guided surgery.

Note: In this section, the term “LSS clamp” refers to Leksell Stereotactic System[®] Clamp.

When the patient has been positioned on the operating table, the LSS Clamp secures the coordinate frame to the standard Mayfield[®] attachment or a headrest with the same interface. It can be used to hold any side (right or left) or posterior bar of the coordinate frame, and can be adjusted to any desired position.

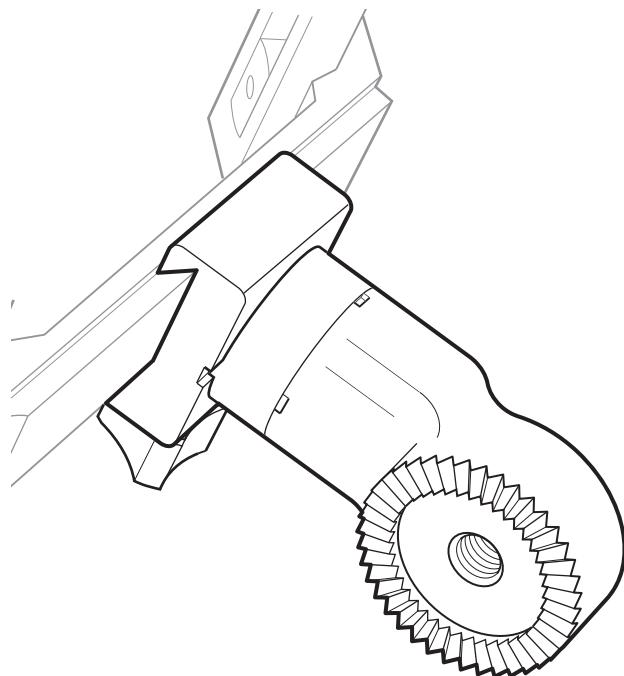


Figure 3.28 Leksell Stereotactic System[®] Clamp attached to the coordinate frame

3.10.2

Main parts

Refer to [Figure 3.29](#).

The **headrest support** ① and the **spacer piece** ② have a geometric arrangement of grooves in their mating faces which allow them to be fitted together in any one of eight positions. The other end of the headrest support mates with the clamp attachment on a headrest attached to the operating table and can be set to any predetermined angle.

The mating faces of the **frame support** ③ and the spacer piece contain a geometric arrangement of grooves which allow them to be fitted together in either of two positions. The frame support is shaped to attach to a bar of the coordinate frame and is in two parts, one fixed and one movable. A **threaded pin** ④ protrudes from the fixed part and passes through a hole in the movable part.

The **knob** ⑤ screws onto the threaded pin of the frame support and clamps the frame support to the coordinate frame.

The **fixing screw** ⑥ passes through the headrest support and spacer piece before terminating in the frame support. This secures the three items together in the required orientation.

The **hexagonal key** ⑦ is provided to adjust the fixing screw.

The parts of the LSS Clamp are made of steel and aluminum.

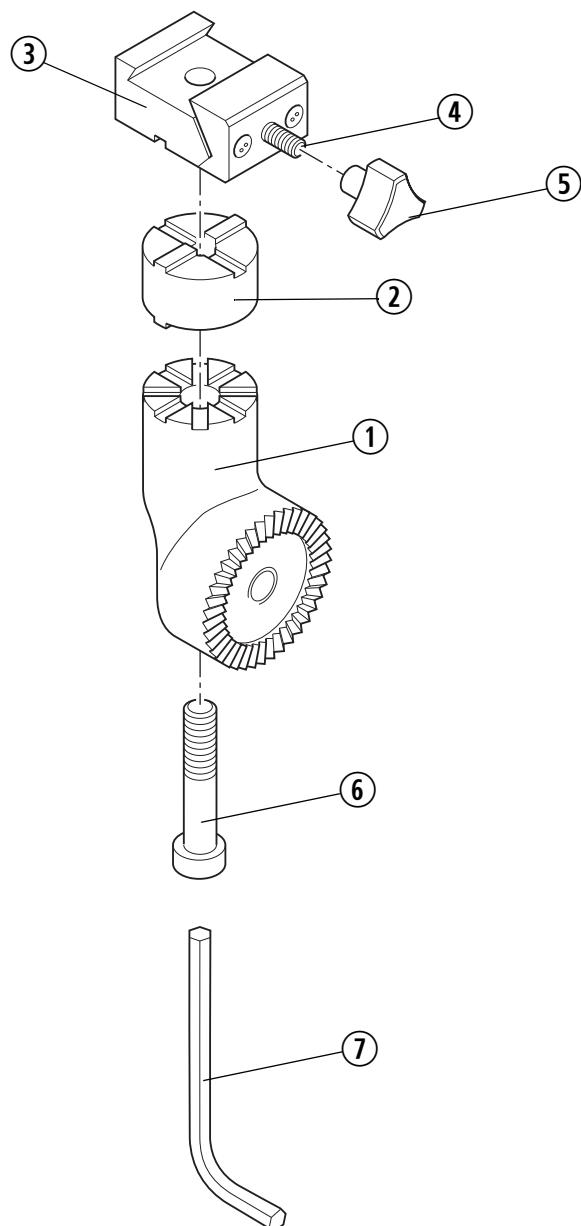
This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.



3.10.2.1

Labels

Some parts can have engraved labels. See [Section 9.7 on page 288](#) for general label information.



- | | |
|--------------------|-----------------|
| ① Headrest support | ⑤ Knob |
| ② Spacer piece | ⑥ Fixing screw |
| ③ Frame support | ⑦ Hexagonal key |
| ④ Threaded pin | |

Figure 3.29 Main parts of Leksell Stereotactic System® Clamp

3.10.3 Using Leksell Stereotactic System® Clamp

3.10.3.1 Assembly instructions



WARNING 3.41

Inspect all threads regarding wear and tear before use. Damaged threads can cause unsafe fixation of the coordinate frame.



WARNING 3.42

Handle equipment with sharp edges or points with care. Otherwise surgical gloves can become damaged and the patient and/or the surgeon can be infected.

Preparation

Inspect all components regarding functionality before use.

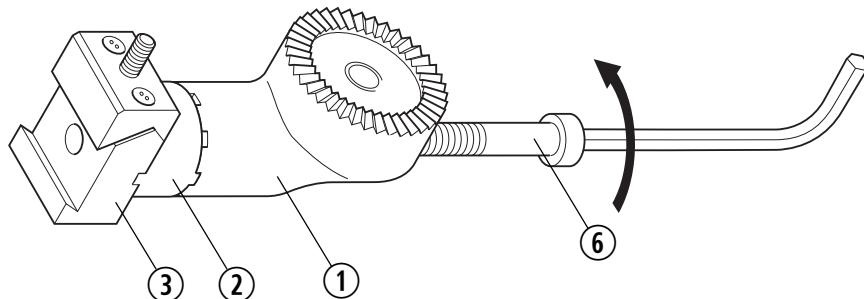
The following instructions assume that:

- The coordinate frame has been assembled and attached to the patient's skull in accordance with [Section 3.2 on page 28](#).
- A Mayfield® headrest (or a headrest with the same interface) with its top end removed has been fitted to the operating table.
- All components of the LSS Clamp are clean, sterilized, and at hand.

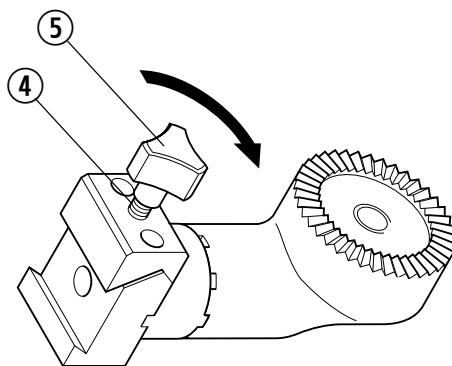
Assembling the LSS Clamp

The LSS Clamp is delivered assembled. If the LSS Clamp has been disassembled, do as follows:

- 1 Assemble the headrest support ①, the spacer piece ② and the frame support ③ and secure them together with the fixing screw ⑥. Use the hexagonal key to tighten the fixing screw until the three parts are held securely.



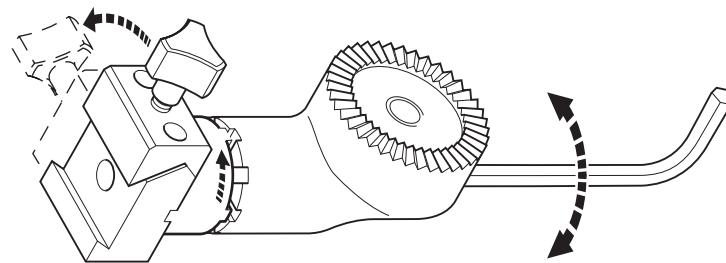
- 2 Screw the knob ⑤ slightly onto the threaded pin ④. Do not tighten the knob yet.



Adjusting the position

The spacer piece with the frame support can be set in one of eight positions. To change the position:

- 3 Loosen the fixing screw slightly.
- 4 Lift and turn the spacer piece until it fits into the appropriate groove of the headrest support.
- 5 Tighten the fixing screw firmly.



3.10.3.2

Attaching the LSS Clamp to the coordinate frame



WARNING 3.43

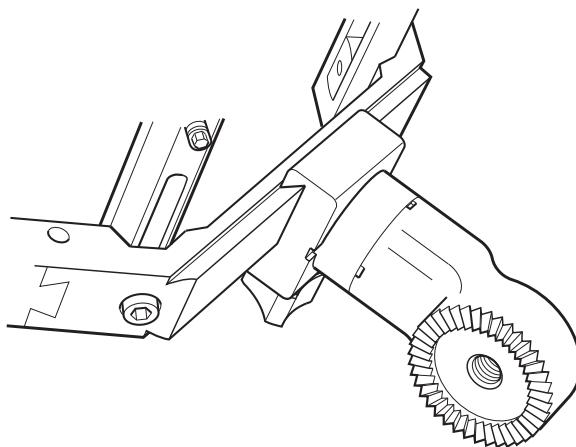
Do not attach the equipment to the anterior bar of the coordinate frame. Otherwise the bar can break from the coordinate frame and the patient can be injured.



WARNING 3.44

Support the patient's head at all times when fitting the coordinate frame to, and removing it from, any other equipment. Otherwise the patient can be injured.

- 1 Slide the frame support over the locating grooves of one side bar or the posterior bar of the coordinate frame.



- 2 Move the frame support along the bar until the LSS Clamp is at the required position.

- 3 Secure the LSS Clamp in place by tightening the knob firmly.

The LSS Clamp can now be secured to the operating table headrest. Use the attachment screw supplied with the headrest.

Note:

Ensure that the LSS Clamp is securely fixed to the operating table.



WARNING 3.45

**Ensure that the equipment is properly assembled and securely fixed.
Otherwise the patient can be injured.**



WARNING 3.46

**Ensure that the patient can easily be released in case of emergency.
Otherwise the patient can be injured.**

3.10.3.3 Removal and disassembly

The procedure for removing the LSS Clamp from the coordinate frame is the reverse of the assembly procedure described in [Section 3.10.3.1 on page 76](#).

The procedure for disassembling the LSS Clamp is the reverse of the assembly procedure described in [Section 3.10.3.1 on page 76](#).

3.11 Fork Type and Clamp Type Adapters

3.11.1 Product overview

The adapters provides an adjustable, rigid fixation for surgical accessories to the Leksell® Coordinate Frame G. This facilitates operative procedures by allowing flexible patient positioning for the desired surgical approach (prone, supine, lateral). The adapters are designed to attach directly to the bars of the coordinate frame for use in stereotactically guided surgery.

When the patient has been positioned on the table and the coordinate frame secured in place using, for example, the Frame Fixation or Leksell Stereotactic System® Clamp, the adapter can be attached to either of the side bars or the posterior bar of the coordinate frame.

A typical application of the Fork Type Adapter with a flexible arm and spatula kit is shown in [Figure 3.30](#).

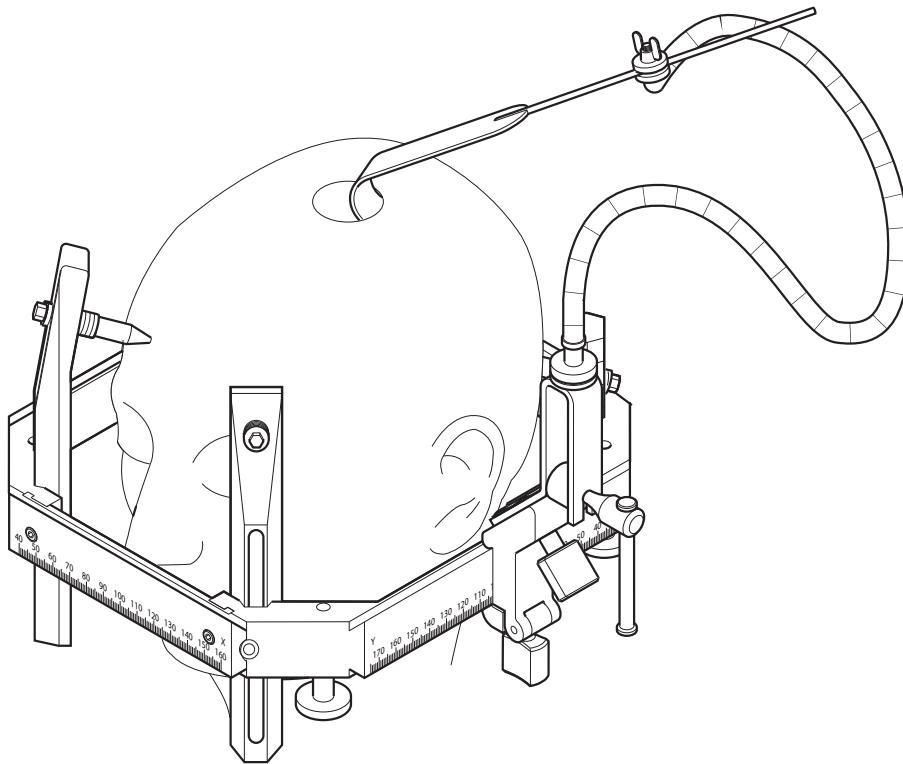


Figure 3.30 Typical application of the Fork Type Adapter

For Fork Type Adapter, see [Section 3.11.2 on page 80](#).

For Clamp Type Adapter, see [Section 3.11.4 on page 83](#).

3.11.1.1 Labels

Some parts can have engraved labels. See [Section 9.7 on page 288](#) for general label information.

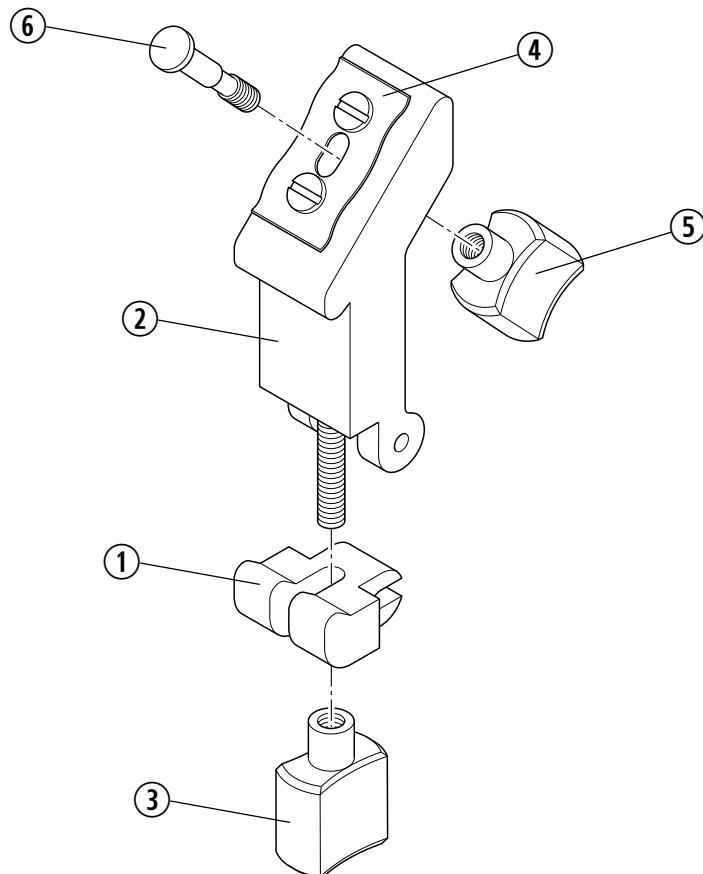
3.11.2**Main parts – Fork Type Adapter**

Refer to [Figure 3.31](#).

The Fork Type Adapter is attached to the coordinate frame by a clamp comprising a **hinged jaw** ① and a **fixed jaw** ②. A **knob** ③ is used to secure the lower jaw to the coordinate frame.

The fork attachment on the surgical instrument is inserted under the **clip** ④ and secured by means of the **knob** ⑤ and **clip bolt** ⑥.

This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.



① Hinged jaw

② Fixed jaw

③, ⑤ Knob

④ Clip

⑥ Clip bolt

Figure 3.31 Main parts of the Fork Type Adapter

3.11.3 Using the Fork Type Adapter

3.11.3.1 Assembly and attachment instructions

Preparation

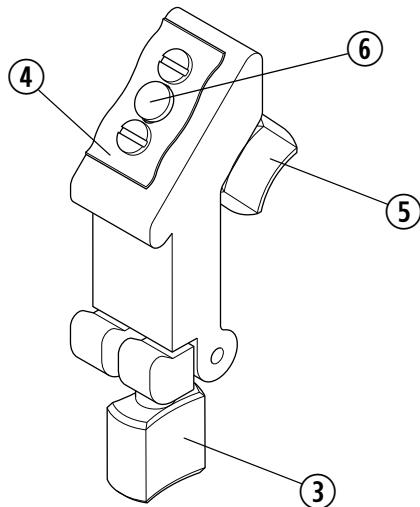
Inspect all components regarding functionality before use.

The following instructions assume that:

- The coordinate frame has been assembled and attached to the patient's skull in accordance with [Section 3.2.3 on page 33](#).
- All components of the Fork Type Adapter are clean, sterilized, and at hand (see [Figure 3.31](#)).
- The surgical accessories have been cleaned and sterilized in accordance with the manufacturer's instructions.

Assembly and attachment – Fork Type Adapter

- 1 Secure the clip ④ to the main body of the adapter using the two screws and their spacers. To tighten the screws, using a flat bladed screwdriver. Make sure that the clip is the right way up.



- 2 Insert the clip bolt ⑥ through the slot in the clip and the hole in the main body of the adapter. The screw must be threaded completely through the thread in the fixed jaw.
- 3 Attach the knob ⑤ to the threaded end of the clip screw by turning it clockwise. There is no need to tighten the knob at this point.

WARNING 3.47

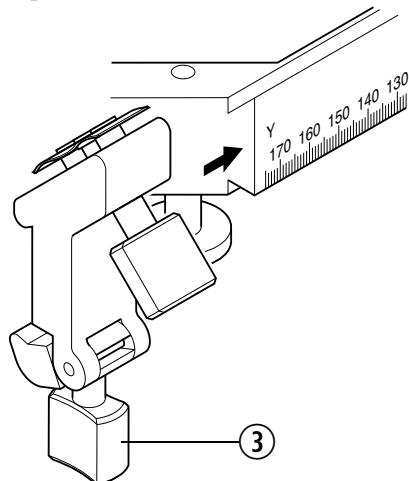


Do not attach the equipment to the anterior bar of the coordinate frame. Otherwise the bar can break from the coordinate frame and the patient can be injured.

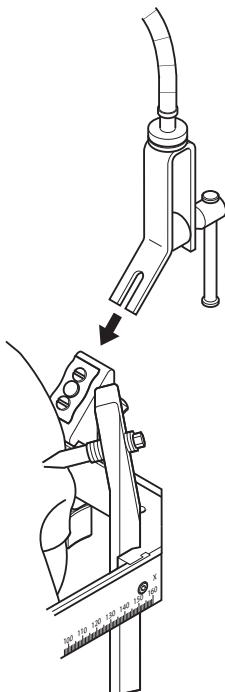
- 4 Loosen but do not remove the knob ③ securing the hinged clamp on the adapter.
- 5 Place the fixed jaw of the adapter over the top edge of the bar of the coordinate frame to which the adapter is to be attached.

Fork Type and Clamp Type Adapters

- 6 Place the hinged jaw of the adapter under the lower edge of the bar of the coordinate frame to which the adapter is to be attached.
- 7 Slide the adapter along the bar to the point necessary to meet the surgical requirements.



- 8 Secure the adapter in place by turning the knob ③. Do not overtighten the knob.
- 9 To attach accessories to the Fork Type Adapter, slide the prongs of the fork attachment on the accessory beneath the clip on the adapter and on either side of the clip screw.
- 10 Turn the knob to tighten the clip and hold the accessory firmly in place.



WARNING 3.48



**Check the screws for wear and that the knobs are securely tightened.
Movement of the clamp or the attached surgical instrument can injure the patient.**

3.11.3.2

Removal and disassembly

The procedure for removing the Fork Type Adapter from the coordinate frame is the reverse of the attachment procedure.

The procedure for disassembling the Fork Type Adapter is the reverse of the assembly procedure.

3.11.4

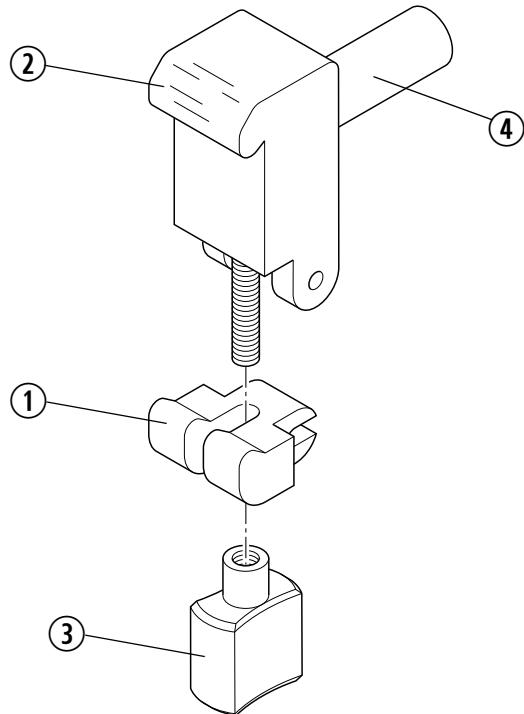
Main parts - Clamp Type Adapter

Refer to [Figure 3.32](#).

The Clamp Type Adapter is attached to the coordinate frame by a clamp comprising a **hinged jaw** ① and a **fixed jaw** ②. A **knob** ③ is used to secure the lower jaw to the coordinate frame.

A **support arm** ④ projects from the fixed jaw for the attachment of instruments with clamp type fixations.

This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.



① Hinged jaw

② Fixed jaw

③ Knob

④ Support arm

Figure 3.32 Main parts of the Clamp Type Adapter

3.11.5 Using the Clamp Type Adapters

3.11.5.1 Assembly and attachment instructions

Preparation

Inspect all components regarding functionality before use.

The following instructions assume that:

- The coordinate frame has been assembled and attached to the patient's skull in accordance with [Section 3.2.3 on page 33](#).
- All components of the Clamp Type Adapter are clean, sterilized, and at hand (see [Figure 3.32](#)).
- The surgical accessories have been cleaned and sterilized in accordance with the manufacturer's instructions.

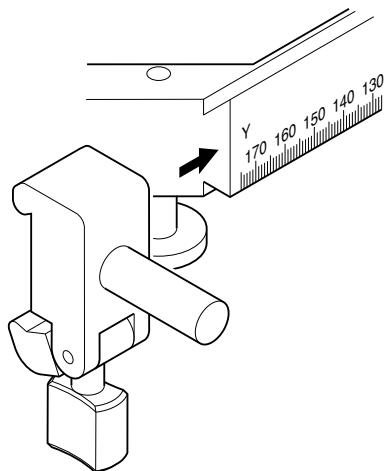
Assembly and attachment - Clamp Type Adapter



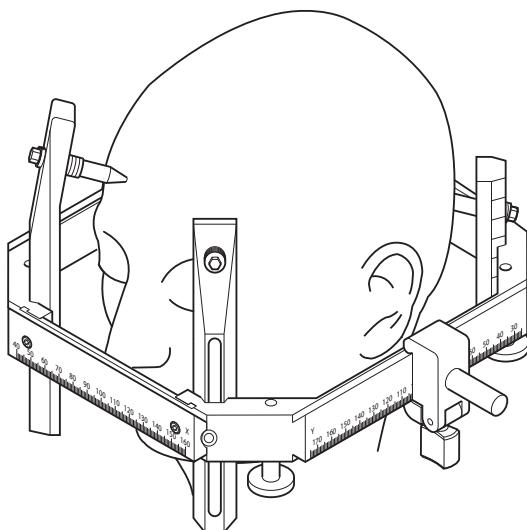
WARNING 3.49

Do not attach the equipment to the anterior bar of the coordinate frame. Otherwise the bar can break from the coordinate frame and the patient can be injured.

- 1 Loosen but do not remove the knob securing the hinged jaw on the adapter.
- 2 Place the fixed jaw of the adapter over the top edge of the bar of the coordinate frame to which the adapter is to be attached.
- 3 Place the hinged jaw of the adapter under the lower edge of the bar of the coordinate frame to which the adapter is to be attached.



- 4 Slide the adapter along the bar to the point necessary to meet the surgical requirements.



- 5 Secure the adapter in place by turning the knob. Do not overtighten the knob.

**WARNING 3.50**

**Check the screws for wear and that the knobs are securely tightened.
Movement of the clamp or the attached surgical instrument can injure the patient.**

- 6 Attach the accessory to the support arm.

3.11.5.2**Removal and disassembly**

The procedure for removing the Clamp Type Adapter from the coordinate frame is the reverse of the attachment procedure.

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4

Leksell® Multi Purpose Stereotactic Arc – with counter scale and accessories

This chapter describes the following products:

- Leksell® Multi Purpose Stereotactic Arc with counter scale, [Section 4.2 on page 89](#)
- Cross-Hairs Kit and A-P Cross-Hairs Holder, [Section 4.3 on page 110](#)
- Leksell® Endoscope Adapter, [Section 4.4 on page 119](#)

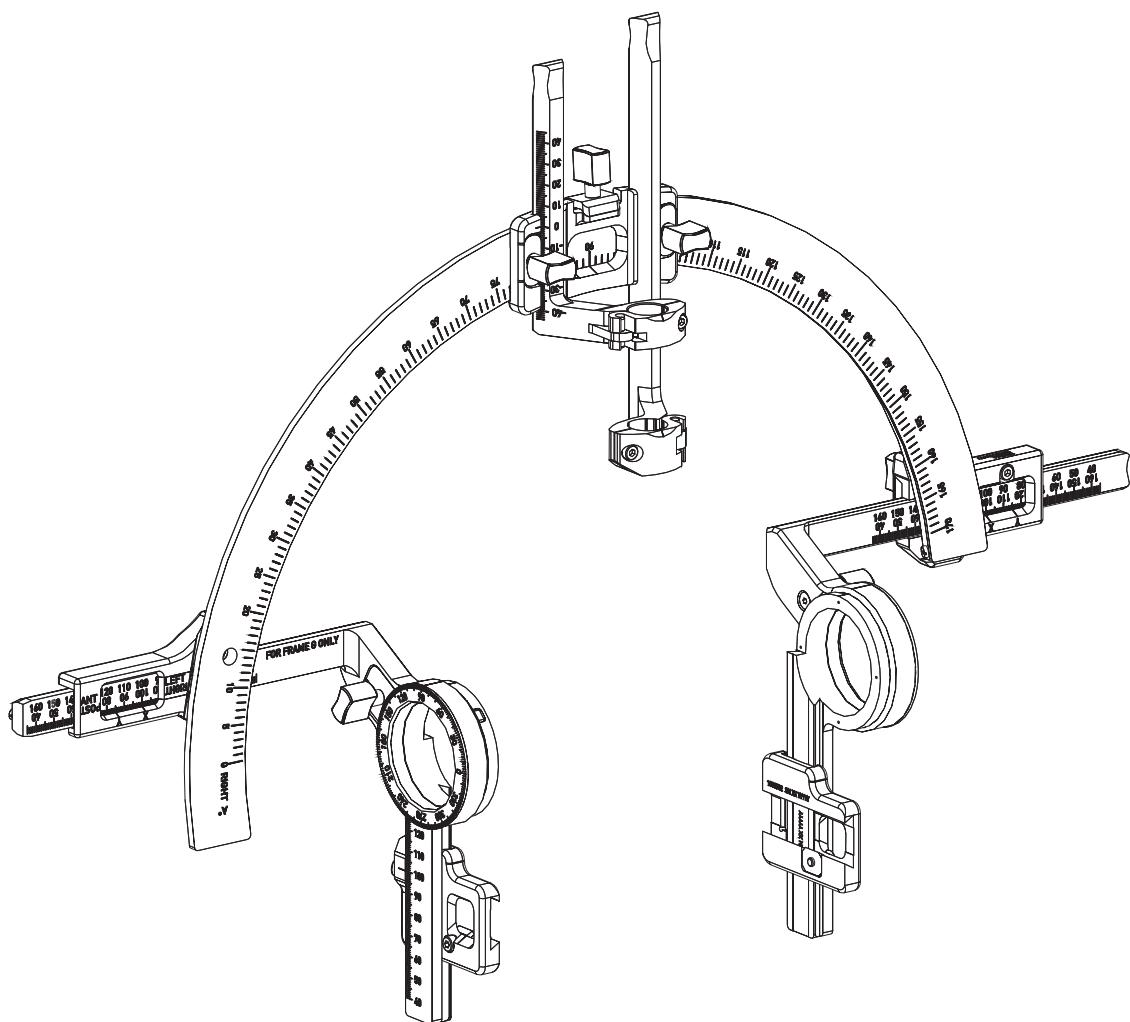


Figure 4.1 Leksell® Multi Purpose Stereotactic Arc with counter scale

4.1

General warnings and notes

These warnings apply to the usage of all products included in this chapter.

WARNING 4.1



The equipment must only be used with Leksell Stereotactic System® or specified instruments. Usage with other systems can cause inaccurate treatment and patient injury.

WARNING 4.2



Handle all Elekta equipment with care. Any damage, however slight, can reduce treatment safety and accuracy. Inspect the equipment before clinical use. If you suspect that any part is damaged, contact Elekta immediately. Do not use damaged equipment for any purpose until authorized to do so by Elekta.

WARNING 4.3



Unless otherwise stated, the equipment is delivered unsterile and must be sterilized before use. Otherwise the patient can be infected.

WARNING 4.4



Exercise extreme caution at all times to ensure that the coordinate frame does not move on the patient's skull. If the coordinate frame is displaced, all treatment planning based on the coordinate frame position is invalid.

WARNING 4.5



The equipment must be set up in accordance with the treatment protocol. Otherwise wrong treatment can result and the patient can be injured.

WARNING 4.6



If loose paint flakes are found on the operation gloves or on the equipment, all parts with engravings must be wiped thoroughly before mounting the equipment in the operating room. Otherwise, loose paint flakes can enter the surgical area.

WARNING 4.7



Do not use excessive force when tightening locking screws/knobs. Otherwise parts can be damaged and not permit secure fixation. Non-secure fixation can cause incorrect treatment.

WARNING 4.8



Handle equipment with sharp edges or points with care. Otherwise surgical gloves can become damaged and the patient and/or the surgeon can be infected.

4.2

Leksell® Multi Purpose Stereotactic Arc

4.2.1

Product overview

Leksell® Multi Purpose Stereotactic Arc permits positioning of surgical instruments with great accuracy at a precise cranial target, when used in conjunction with Leksell® Coordinate Frame G and its accessories.

Note:

In this manual, the term “stereotactic arc” refers to Leksell® Multi Purpose Stereotactic Arc with counter scale.

The stereotactic arc is designed to ensure that when a surgical instrument of standard Leksell® length (190 mm) is correctly fitted, the active point of the instrument is always at the precise center of the stereotactic arc. The entire assembly can be rapidly and accurately adjusted so that the center of the stereotactic arc exactly coincides with the cranial target.

The X, Y and Z coordinates are obtained from the patient’s treatment protocol after target localization. The setting of the coordinates depend upon the desired stereotactic arc orientation. The coordinates may be determined by using treatment planning software such as Leksell SurgiPlan® or obtained by manual calculation on the MR or CT console.

The stereotactic arc allows you to position the burr hole at any desired point on the patient’s skull. More than one instrument carrier with stop holder, guide holder and surgical instrument can be fitted to the stereotactic arc. All such instruments obey the Leksell® center-of-arc principle, offering the unique opportunity to simultaneously reach the same target through two or more trajectories.

This manual describes the version of Leksell® Multi Purpose Stereotactic Arc with counter scale.

4.2.1.1

Main parts



All major components of the stereotactic arc are made of aluminum unless otherwise stated.

This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.

Refer to [Figure 4.2](#).

Semicircular arc ① permits accurate positioning of the instrument carrier at any point along its curve. One face is engraved with the scale 0° to 170° from the **RIGHT** mark. These angles originate at the center of the stereotactic arc, thus implementing the Leksell® center-of-arc principle.

Instrument carrier ② secures the surgical instrument at the required angle on the semicircular arc. To set the stereotactic arc angle, the index mark in the carrier window must be aligned with the desired value on the scale of the stereotactic arc.

Instrument stop holder ③ secures the surgical instrument at the required depth. The stop holder is engraved with a scale from -44 mm to +45 mm. With the horizontal index mark on the instrument carrier at the 0 mm setting, the active point of a surgical instrument of standard Leksell® length (190 mm) is placed exactly at the target. Depth of penetration can also be accurately adjusted from 44 mm above the target to 45 mm below it, for example during sampling for biopsy.

Instrument guide holder ④ ensures that the surgical instrument is accurately maintained at the correct trajectory.

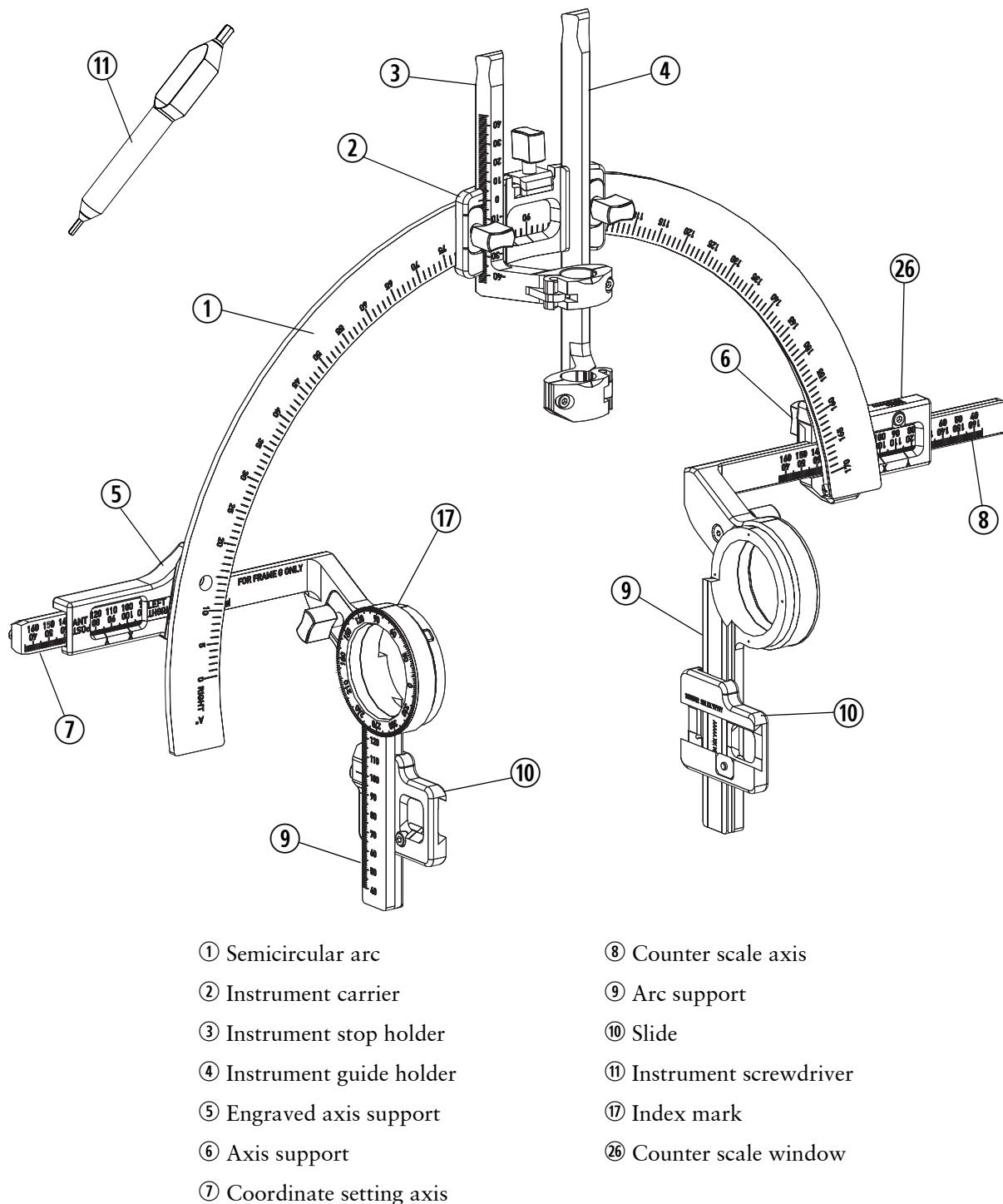


Figure 4.2 Main parts of Leksell® Multi Purpose Stereotactic Arc

Axis supports ⑤ and ⑥ secure the arc axes at the required position. One axis support ⑤ is engraved with X and Y index marks and ANT, POST, LEFT and RIGHT labels, and is therefore referred to as the *engraved axis support*. It is used to set the X coordinate in lateral orientations and the Y coordinate in A-P (Anterior-Posterior) orientations. The other support ⑥ is unmarked.

In lateral stereotactic arc orientations the arc axes are used to set the X coordinate of the arc center. In A-P stereotactic arc orientations they are used to set the Y coordinate. Both axes are engraved with a scale from 40 mm to 160 mm. The axis with the engraved text **FOR FRAME G ONLY** is referred to as the **coordinate setting axis** ⑦. The other axis is referred to as the **counter scale axis** ⑧.

To set the X or Y coordinate, the **X** or **Y** index mark on the engraved axis support must be aligned to the desired value on the coordinate setting axis.

The **counter scale window** ⑯ is fitted on the counter scale axis and set to the same value as on the coordinate setting side to ensure correct mounting of the stereotactic arc.

Each arc axis terminates in a ring at right angles to the stem, which mates with a ring on the corresponding arc support. Each arc axis has a loose inner ring that can rotate freely inside the axis ring when unlocked.

The inner ring of the coordinate setting axis is engraved with a scale 0° to 360°. This scale is used to set the ring angle by aligning the index mark ⑩ on the ring of the coordinate setting axis to the desired value on the engraved inner ring. The inner ring of the other arc axis is not engraved with a scale.

Arc supports ⑨ are used to set the Z coordinate for lateral and A-P stereotactic arc orientations. Each arc support has a ring at the upper end which mates with the ring on the corresponding arc axis. For the Z coordinate, the arc supports are engraved with a scale from 40 mm to 155 mm.

Slides ⑩. In A-P stereotactic arc orientations the slides are used to set the X coordinate. In lateral orientations they set the Y coordinate.

The arc supports and slides can be fitted on either side of the coordinate frame in any stereotactic arc/coordinate frame configuration. Observe that, each arc support must be combined with the correct slide, see [Section on page 94](#).

Each slide is engraved with two index marks. To set the X or Y coordinate the index mark in the slide window must be aligned to the required value on the coordinate frame. To set the Z coordinate the index mark adjacent to the arc support must be aligned to the required value on the arc support.

A special **instrument screwdriver** ⑪ is supplied for assembly and adjustments.

A sterilization tray (not shown) is available to house the stereotactic arc during sterilization and for storage.

4.2.1.2

Labels

Some parts have engraved labels. See [Table 4.1](#) for details, and [Section 9.7 on page 288](#) for general label information.

Table 4.1 Labelled parts on the stereotactic arc

Part	Labels
⑤ Engraved axis support	LEFT, RIGHT, ANT, POST, X ,Y (See also Section 4.2.2 on page 92 .)
⑦ Coordinate setting axis	FOR FRAME G ONLY
⑯ Counter scale window	X, Y

4.2.2

Stereotactic arc orientations

The stereotactic arc must be oriented with respect to the coordinate frame in one of four basic orientations: two lateral and two A-P (Anterior-Posterior). See the descriptions on the following pages.

In all orientations, the terms **left** (L), **right** (R), **anterior** (A) and **posterior** (P) are used as described on [page 28](#).

4.2.2.1

Lateral orientation right

The coordinate setting axis is on the patient's right side and the engraved surface of the stereotactic arc faces the anterior. The X coordinate is set by using the **X** index mark on the **RIGHT** scale.

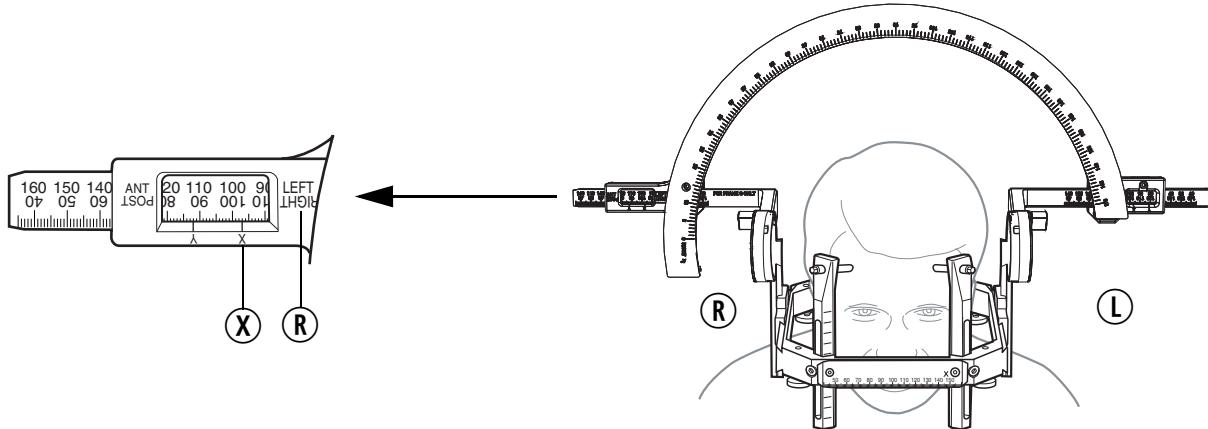


Figure 4.3 Lateral orientation right with enlarged scale and index of the coordinate setting axis

4.2.2.2

Lateral orientation left

The coordinate setting axis is on the patient's left side and the engraved surface of the stereotactic arc faces the posterior. The X coordinate is set by using the **X** index mark on the **LEFT** scale.

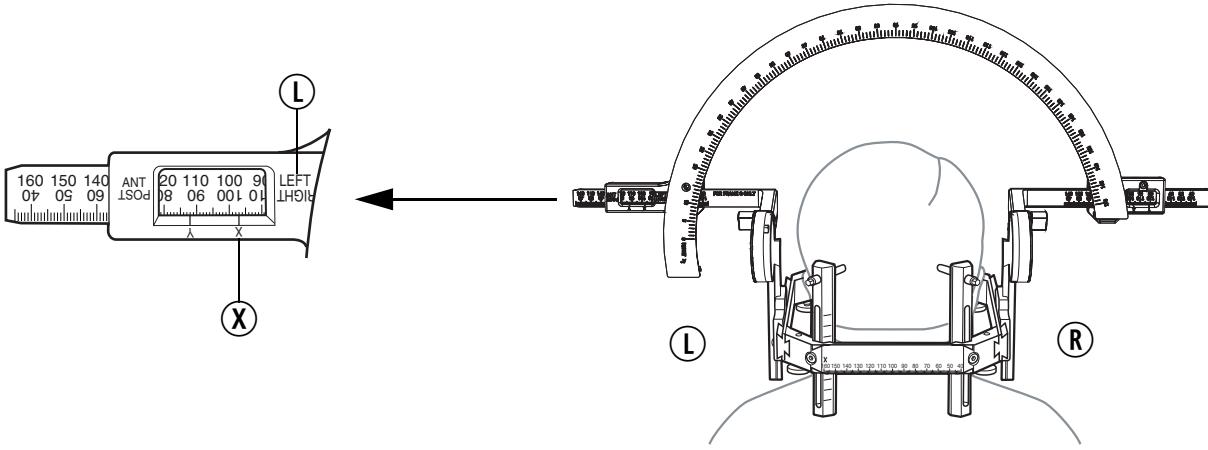


Figure 4.4 Lateral orientation left with enlarged scale and index of the coordinate setting axis

4.2.2.3**A-P (Anterior-Posterior) orientation, posterior**

The coordinate setting axis is at the patient's posterior and the engraved surface of the stereotactic arc faces the patient's right side. The Y coordinate is set by using the **Y** index mark on the **POST** scale.

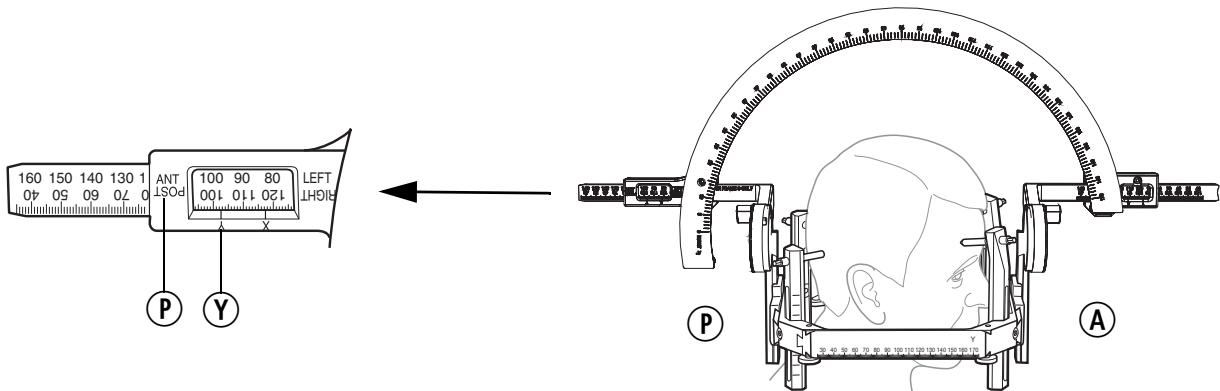


Figure 4.5 A-P orientation, posterior with enlarged scale and index of the coordinate setting axis

4.2.2.4**A-P (Anterior-Posterior) orientation, anterior**

The coordinate setting axis is at the patient's anterior and the engraved surface of the stereotactic arc faces the patient's left side. The Y coordinate is set by using the **Y** index mark on the **ANT** scale.

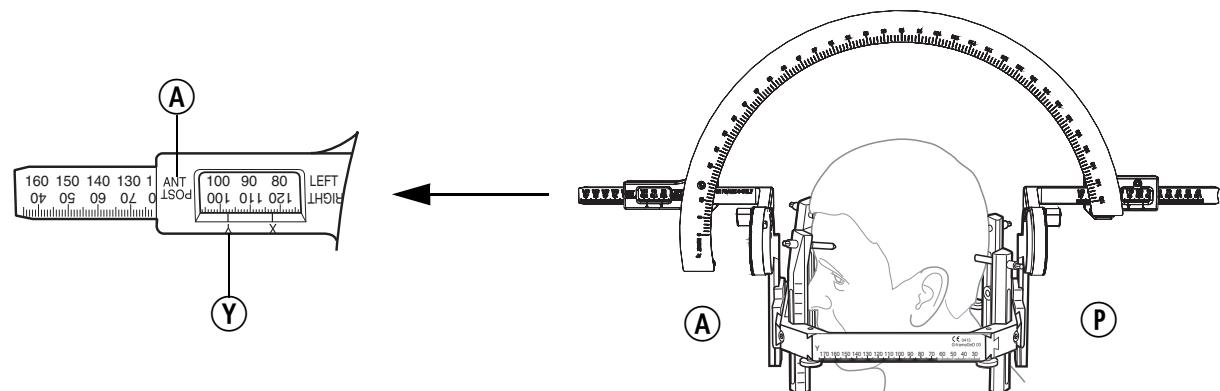


Figure 4.6 A-P orientation, anterior with enlarged scale and index of the coordinate setting axis

4.2.3 Assembling Leksell® Multi Purpose Stereotactic Arc

WARNING 4.9



Use only the screws supplied with the stereotactic arc and ensure to position the screws correctly. Erroneous position of screws can reduce treatment accuracy and cause misplacement of surgical instruments.

Preparation

Inspect all components regarding functionality before use.

Check that all components of the stereotactic arc are at hand (see [Figure 4.2](#)), clean and sterilized prior to use.

The following instructions assume that the coordinate frame has been correctly assembled and fitted to the patient. Please refer to [Section 3.2 on page 28](#) for more information.

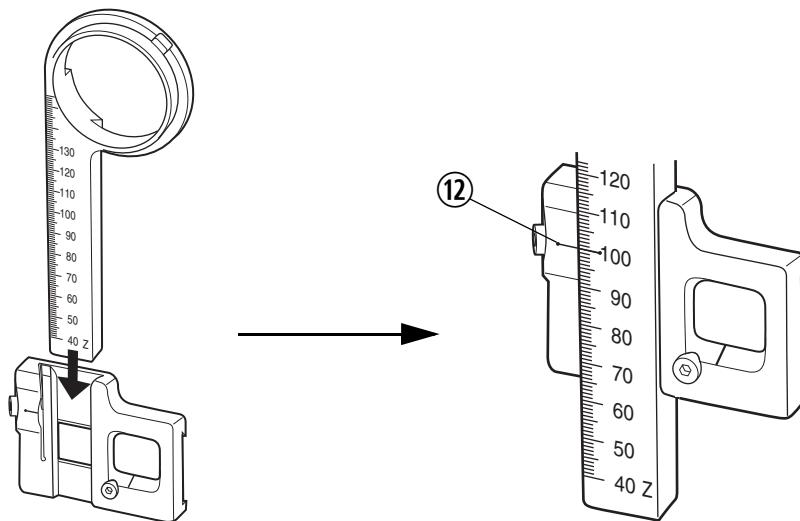
4.2.3.1

Assembling the stereotactic arc for lateral orientations

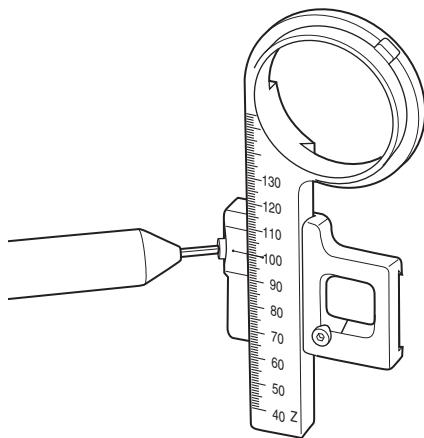
The following instructions apply to the two lateral stereotactic arc orientations. For anterior-posterior stereotactic arc orientations, see [Section 4.2.3.2 on page 102](#).

Fitting the arc supports and setting the Z coordinate

- 1 Insert an arc support into a slide from above.
Ensure that the engraved scale on the support is facing the index mark ⑫ on the slide.
- 2 Move the support in the slide until the required Z coordinate on the support is exactly aligned with the index mark ⑫ on the slide.



- 3 Using the instrument screwdriver, secure the arc support at the required Z coordinate.



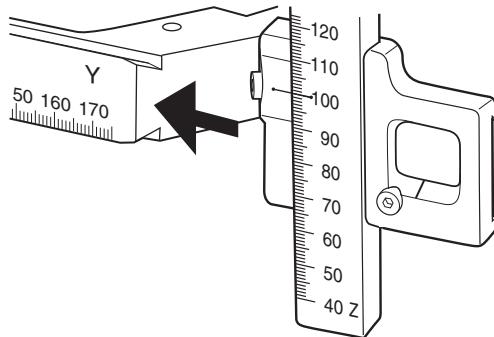
Note: *Do not overtighten the screw to secure the Z coordinate, or it may be difficult to move the slide and arc support along the coordinate frame.*

- 4 Fit and secure the other arc support at the required Z coordinate in the other slide as described in steps 1 to 3 above.

Note: *Usually it is easier to fit the arc supports to the slides and then attach the slides to the coordinate frame. However, if preferred, you can fit the slides first (as described in next section) and then fit the arc supports to the slides.*

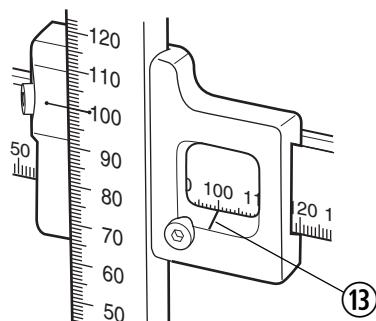
Fitting the slides and setting the Y coordinate

- 5 Insert a slide (with arc support) over the groove of a side bar on the coordinate frame. The slides may be mounted in two orientations: with the Z scale facing either posterior or anterior depending on user preference. Ensure that the slide is correctly oriented with the alignment marks in view.

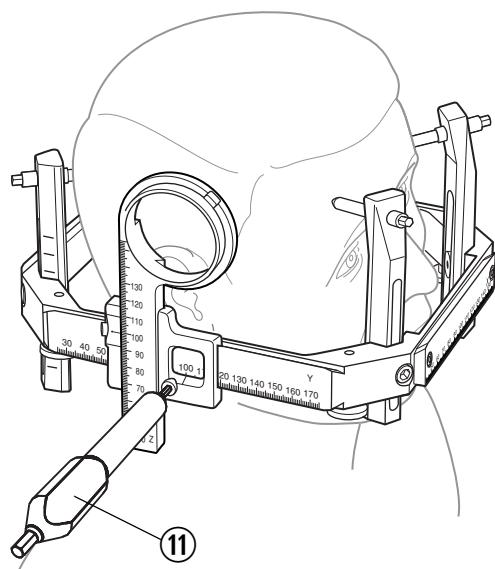


Note: *If it is difficult to insert the slide, temporarily loosen the screw that secures the Z coordinate. Ensure that the Z coordinate is correct and tighten the screw when the slide has been moved to the correct Y position.*

- 6 Move the slide along the side bar until the required Y coordinate on the bar is exactly aligned with the vertical index mark ⑬ on the slide.



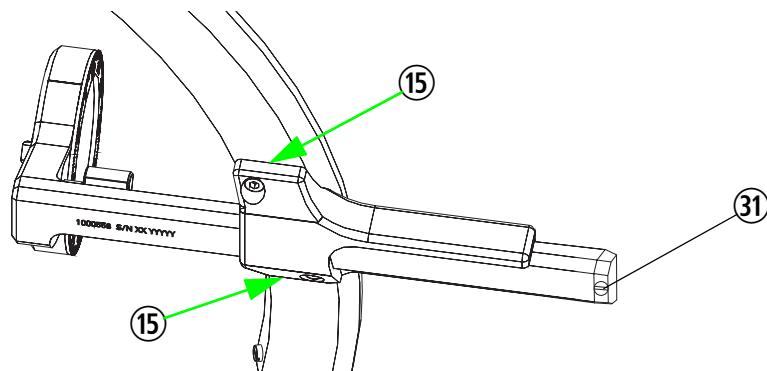
- 7 Using the instrument screwdriver ⑪, secure the slide at the required Y coordinate.



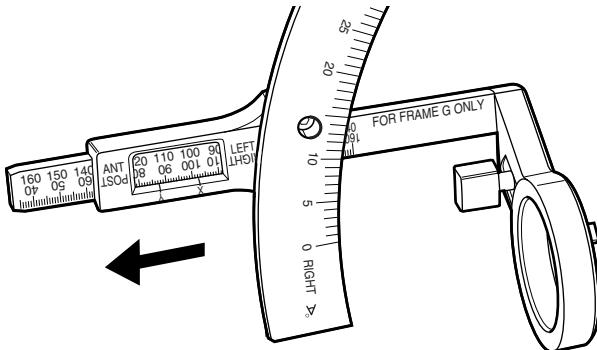
- 8 Fit and secure the other slide (with arc support) at the required Y coordinate on the opposite side bar as described in steps 5 to 7 above.

Fitting the arc axes and setting the X coordinate

- 9 If the axis supports have been disassembled, ensure that both axis supports are fitted tightly to the stereotactic arc. There must be no slit between the axis supports and the back surface of the semicircular arc ⑯.

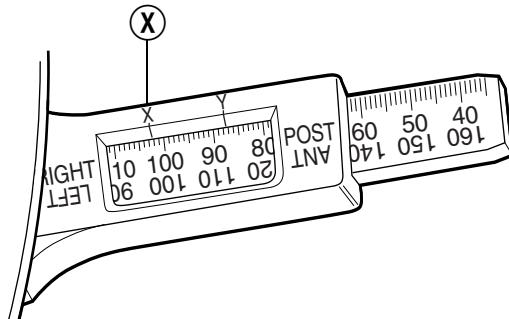


- 10 If the stereotactic arc has been disassembled, insert the stem of the coordinate setting axis into the engraved axis support on the stereotactic arc. If the rings of the arc axis have been disassembled, mount the engraved inner ring to the coordinate setting axis. Ensure that the axis is inserted on the correct side.

**Note:**

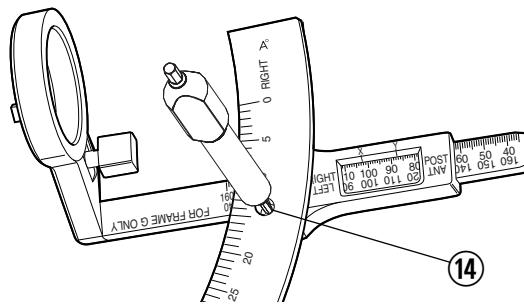
The nylon stop screw ⑪ (see step 9 on page 96) must be removed from the end of the arc axis for the axis to be inserted. Screw it back in again when the axis has been inserted.

- 11 Move the coordinate setting axis within the engraved axis support until the required X coordinate on the correct scale (**LEFT** or **RIGHT**) is exactly aligned with the **X** index mark on the support.

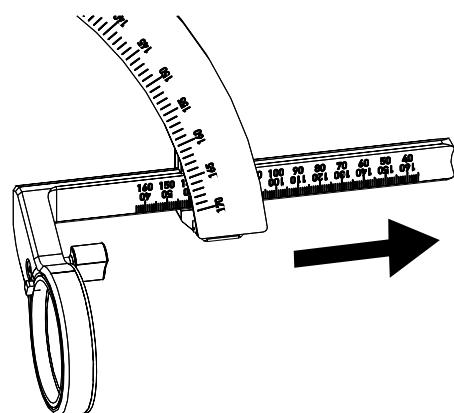
**WARNING 4.10**

Ensure that the correct scale and index mark is used. Otherwise wrong target can be treated.

- 12 Using the instrument screwdriver, tighten the screw ⑭ on the engraved face of the stereotactic arc to secure the arc axis at the required X coordinate.



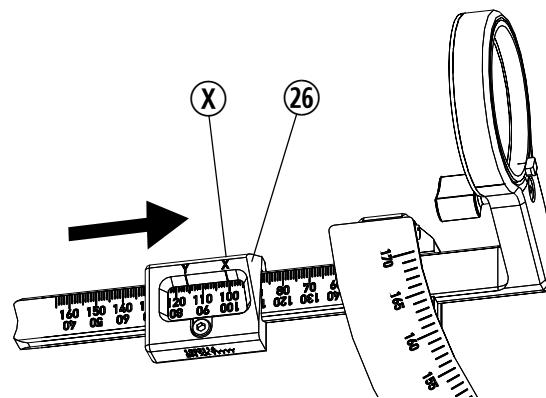
- 13 If the stereotactic arc has been disassembled, insert the stem of the counter scale axis into the unmarked axis support on the stereotactic arc.



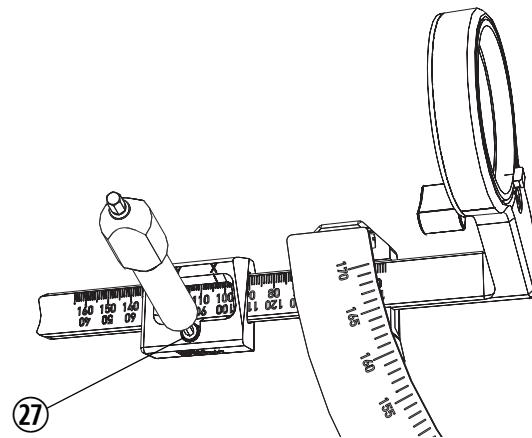
Note:

The nylon stop screw must be removed from the end of the arc axis for the axis to be inserted. Screw it back in again when the axis has been inserted.

- 14 Slide the counter scale window ⑯ onto the counter scale axis and move it until the X index mark on the counter scale window is exactly aligned with the same X coordinate as on the coordinate setting axis.



- 15 Using the instrument screwdriver, tighten the screw ⑰ on the counter scale window at the required X coordinate.



Fitting the stereotactic arc to the arc supports and setting the ring angle

WARNING 4.11



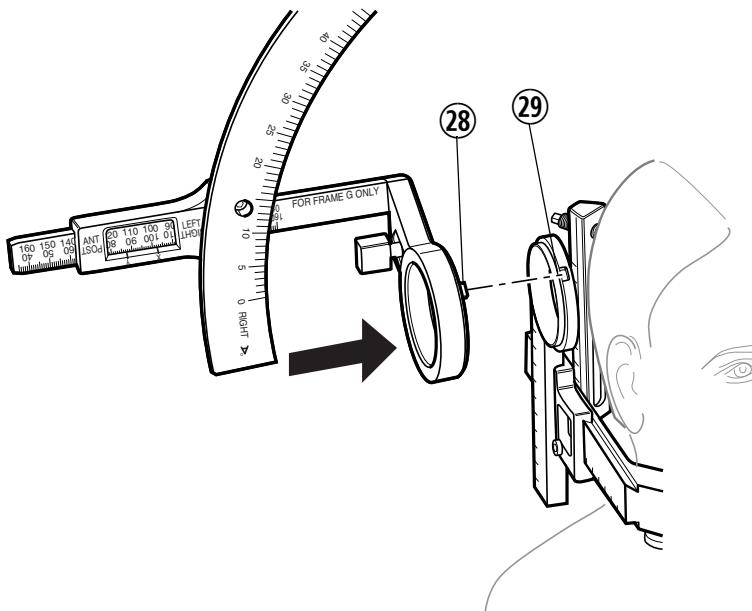
Before attaching the stereotactic arc to the arc support, ensure that the axis support is fitted flush against the stereotactic arc. No opening is permitted between the axis support and the stereotactic arc. An opening will reduce treatment accuracy and can cause misplacement of surgical instruments.

WARNING 4.12



If Leksell SurgiPlan® has been used for the target path planning, ensure that the stereotactic arc orientation used for surgery is the set orientation for the target path planning. Otherwise the patient can be injured.

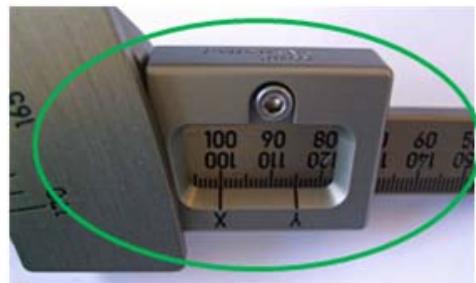
- 16 Align the stereotactic arc correctly with the coordinate frame:
 - For the Lateral orientation *Right*, the ring of the coordinate setting axis must mate with the arc support ring on the patient's right side.
 - For the Lateral orientation *Left*, the ring of the coordinate setting axis must mate with the arc support ring on the patient's left side.
- 17 Introduce the ring of the coordinate setting axis into the annulus of the engraved ring on the arc support.
 - Ensure that the small protruding tab ②⁸ fits into the corresponding indent ②⁹ of the arc support.
 - Ensure that the ring surfaces are flush against each other and the groove between the rings is even all the way around.



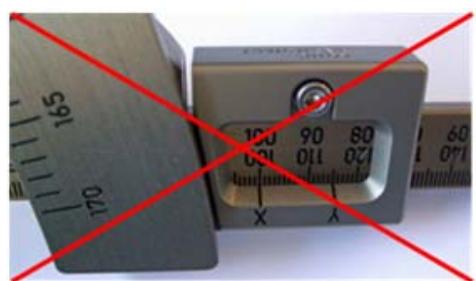
- 18 Align the ring of the counter scale axis with the ring of the other arc support.
 - Ensure that the small protruding tab fits into the corresponding indent of the arc support.
 - Ensure that the ring surfaces are flush against each other and the groove between the rings is even all the way around.

Note: If the protruding tab does not fit into the corresponding indent, release the knob at the ring and rotate it into position.

- Ensure that the counter-scale window is mounted flush against the arc.



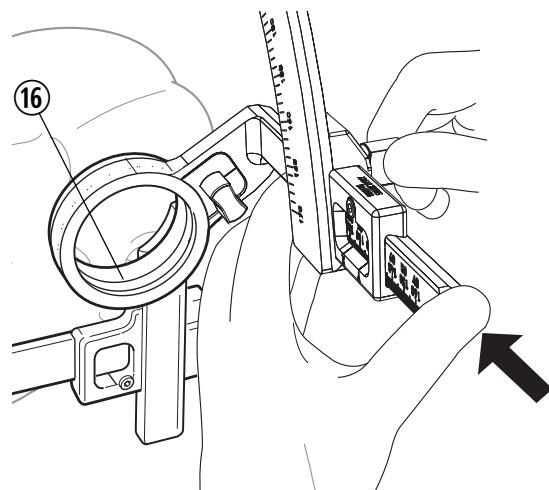
Counter scale mounted flush
– **correct!**



Counter scale mounted with a gap
– **incorrect!**

- 19 With the left hand, carefully push the counter scale axis inwards until the counter scale window is stopped and rests against the side surface of the axis support. Firmly hold it in position. Then, with the right hand, tighten the knob at the rear of the axis support to secure the counter scale axis in place.

The two ring surfaces must be flush against each other and the groove ⑯ between the rings must be even all the way round.

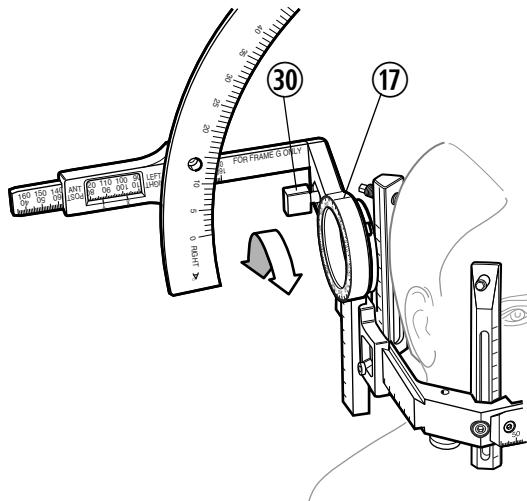


WARNING 4.13



When attaching the stereotactic arc to the arc support, ensure that the two ring surfaces are flush against each other. The groove between the rings must be even all the way around. An uneven groove will reduce treatment accuracy and can cause misplacement of surgical instruments.

- 20 Check that the coordinates on both arc axes are identical.
- 21 Release the knob ⑩ at the ring on each arc axis. Move the stereotactic arc until the index mark ⑯ on the ring of the coordinate setting axis is exactly aligned with the required ring angle, if predetermined, on the engraved inner ring.



- 22 Tighten the knobs on both arc axes to secure the stereotactic arc at the required ring angle.

Note:

The weight of any instrument mounted on the stereotactic arc is held by the rings of the arc supports. It is very important that the two knobs are properly tightened.

**WARNING 4.14**

Ensure that the coordinate and instrument carrier settings are securely locked. Movement of the stereotactic arc or the instrument carrier when a surgical instrument is inserted into the brain can injure the patient.

Continue with the instructions in [Section 4.2.4.1 on page 107](#). (The instructions on the following pages apply to anterior-posterior stereotactic arc orientations.)

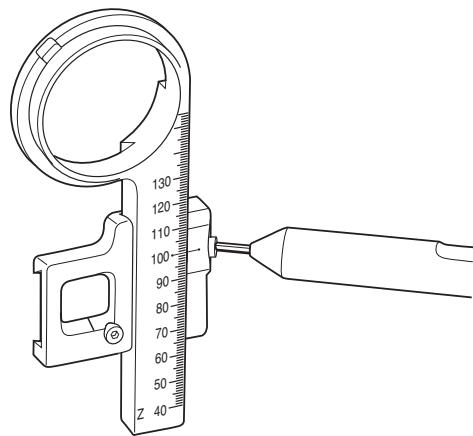
4.2.3.2**Assembling the stereotactic arc for A-P (Anterior-Posterior) orientations**

The following instructions apply to the two A-P stereotactic arc orientations. For lateral stereotactic arc orientations, see [Section 4.2.3.1 on page 94](#).

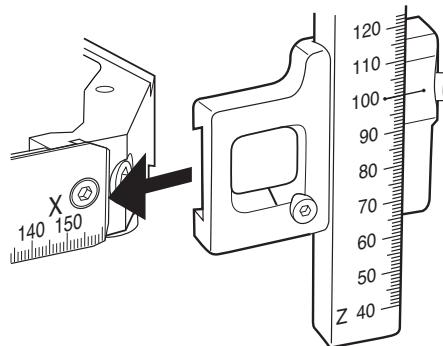
Note: *For A-P orientations, a straight front piece must be mounted on the coordinate frame. A curved or slotted front piece cannot be used.*

Fitting the arc supports and setting the Z coordinate

- 1 Insert the two arc supports into the corresponding slides and set the Z coordinate of each arc support as described in step 1 to 4 on [page 94](#) to [95](#).

**Fitting the slides and setting the X coordinate**

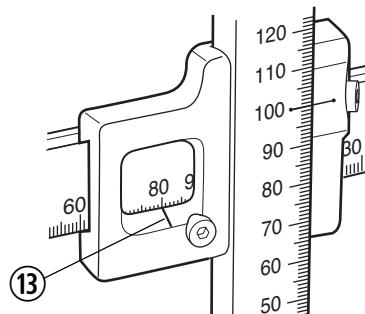
- 2 Insert a slide (with arc support) over the groove of the front piece on the coordinate frame. The slides may be mounted in two orientations: with the Z scale either facing posterior or anterior depending on user preference. Ensure that the slide is correctly oriented with the alignment marks in view.



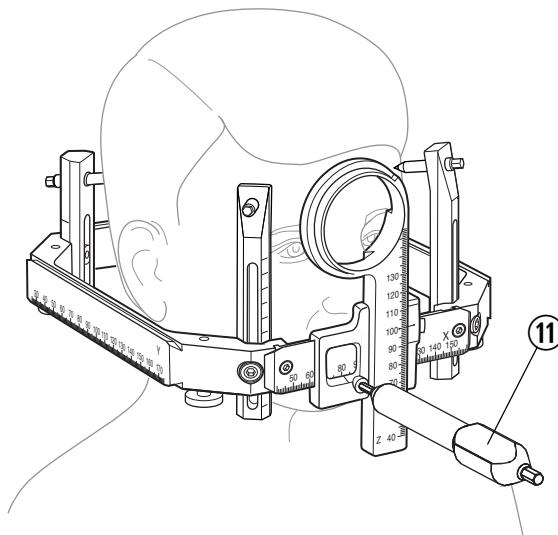
Note:

If it is difficult to insert the slide, temporarily loosen the screw that secures the Z coordinate. Ensure that the Z coordinate is correct and tighten the screw when the slide has been moved to the correct X position.

- 3 Move the slide along the coordinate frame until the required X coordinate on the coordinate frame is exactly aligned with the vertical index mark ⑬ on the slide.



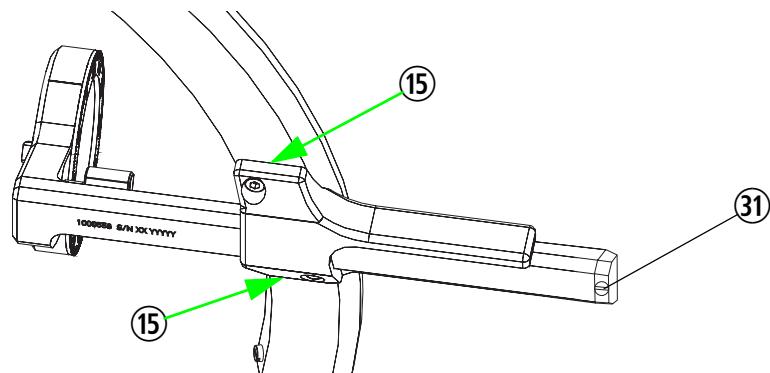
- 4 Using the instrument screwdriver ⑪, secure the slide at the required X coordinate.



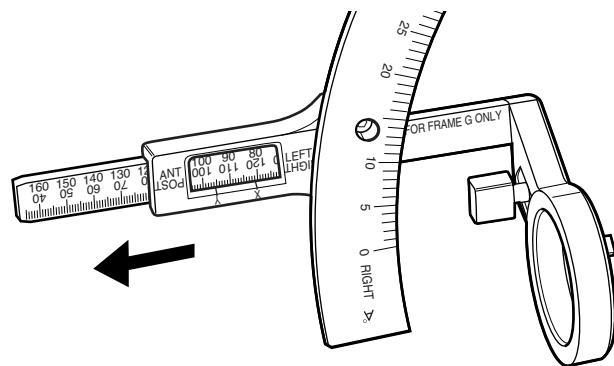
- 5 Fit and secure the other slide (with arc support) at the required X coordinate on the posterior bar of the coordinate frame as described in steps 2 to 4 above.

Fitting the arc axes and setting the Y coordinate

- 6 If the axis supports have been disassembled, ensure that both axis supports are fitted tightly to the stereotactic arc. No narrow opening is allowed between the axis supports and the back surface of the semicircular arc ⑯.

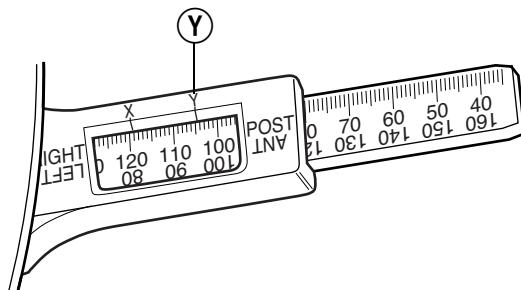


- 7 If the stereotactic arc has been disassembled, insert the stem of the coordinate setting axis into the engraved axis support on the stereotactic arc. If the rings of the arc axis have been disassembled, mount the engraved inner ring to the coordinate setting axis. Ensure that the axis is inserted on the correct side.

**Note:**

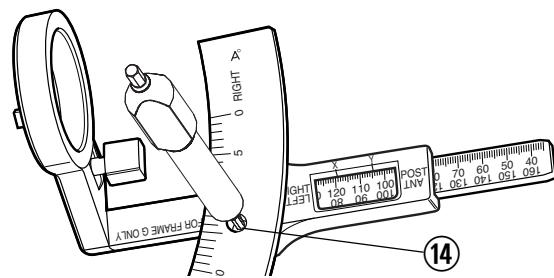
The nylon stop screw ⑪ (see step 6 on page 103) must be removed from the end of the arc axis for the axis to be inserted. Screw it back in again when the axis has been inserted.

- 8 Move the coordinate setting axis within the engraved axis support until the required Y coordinate on the correct scale (**ANT** or **POST**) is exactly aligned with the **Y** index mark on the support.

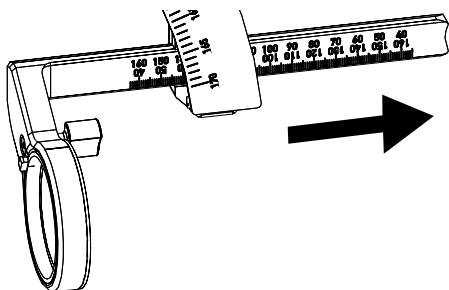
**WARNING 4.15**

Ensure that the correct scale and index mark is used. Otherwise wrong target can be treated.

- 9 Using the instrument screwdriver, tighten the screw ⑭ on the engraved face of the stereotactic arc to secure the arc axis at the required Y coordinate.

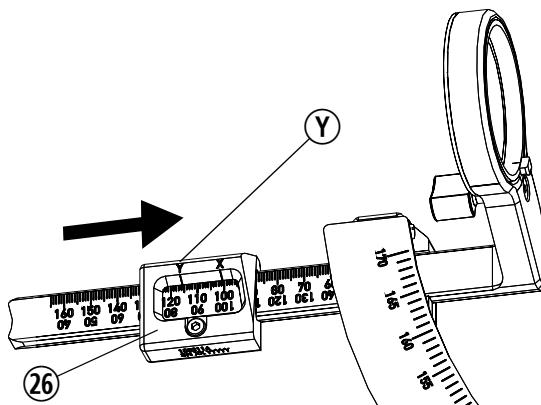


- 10 If the stereotactic arc has been disassembled, insert the stem of the counter scale axis into the unmarked axis support on the stereotactic arc.

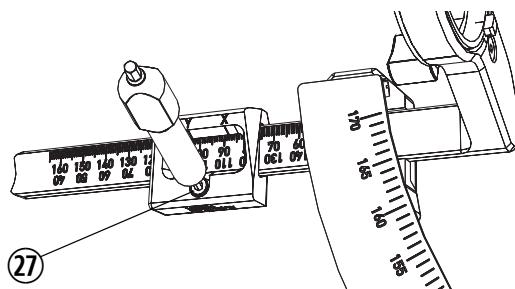
**Note:**

The nylon stop screw must be removed from the end of the arc axis for the axis to be inserted. Screw it back in again when the axis has been inserted.

- 11 Slide the counter scale window ②6 onto the arc axis and move it until the Y index mark on the counter scale window is exactly aligned with the same Y coordinate as on the coordinate setting axis.



- 12 Using the instrument screwdriver, tighten the screw ②7 on the counter scale window at the required Y coordinate.



Fitting the stereotactic arc and setting the ring angle

- 13 Align the stereotactic arc correctly with the coordinate frame:
 - For the A-P orientation **Posterior**, the ring of the coordinate setting axis must mate with the ring of the posterior arc support.
 - For the A-P orientation **Anterior**, the ring of the coordinate setting axis must mate with the ring of the anterior arc support.
- 14 Continue with *Fitting the stereotactic arc to the arc supports and setting the ring angle* on [page 99](#). Observe that the images in that section show lateral orientation.

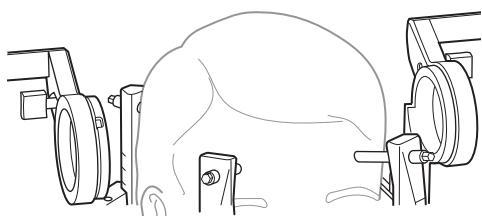
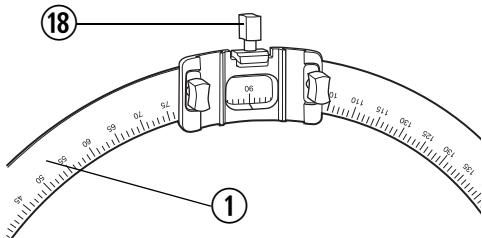
4.2.4

Using Leksell® Multi Purpose Stereotactic Arc

4.2.4.1

Fitting the instrument carrier and setting the stereotactic arc angle

- 1 Release the locking knob ⑯ of the instrument carrier and attach the carrier to the semicircular arc ①. Ensure that the instrument carrier is correctly oriented so that the index mark is visible at the engraved face of the semicircular arc.



WARNING 4.16



Ensure that the screws securing the instrument guide and stop holder do not protrude from the back of the instrument carrier. If they protrude, the instrument carrier must be serviced. Otherwise the instrument carrier will get misplaced and the patient can be injured.

- 2 Move the instrument carrier along the semicircular arc until the required stereotactic arc angle, if predetermined, is exactly aligned with the index mark in the window of the carrier.
- 3 Tighten the knob ⑯ of the instrument carrier to secure the carrier in place at the desired ring angle.

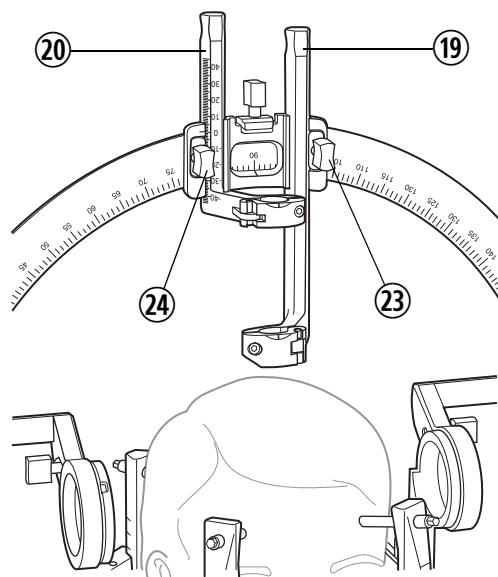
4.2.4.2

Fitting the instrument guide and stop holders

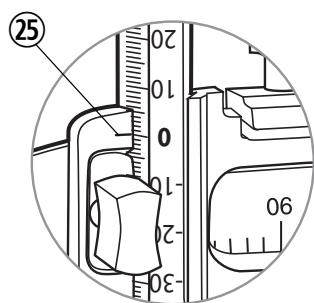
Note:

Ensure that the nylon stop screws on the guide holder and the stop holder are mounted and undamaged.

- From above, insert the stem of the instrument guide holder ⑯ into the slot in the instrument carrier, with the collar of the guide holder nearest to the patient's skull and facing forward.



- Move the instrument guide holder within the instrument carrier. There should be enough room both above and below the collar of the guide holder for the guide insert of the surgical instrument to be inserted and held in place.
- Tighten the knob ㉔ on the instrument carrier to secure the guide holder in place.
- From above, insert the stem of the instrument stop holder ㉐ into the slot in the instrument carrier, with the collar of the stop holder nearest to the patient's skull and facing forward.
- Move the instrument stop holder within the instrument carrier until the horizontal index mark ㉕ on the carrier is exactly aligned with the desired mark on the scale of the stop holder.

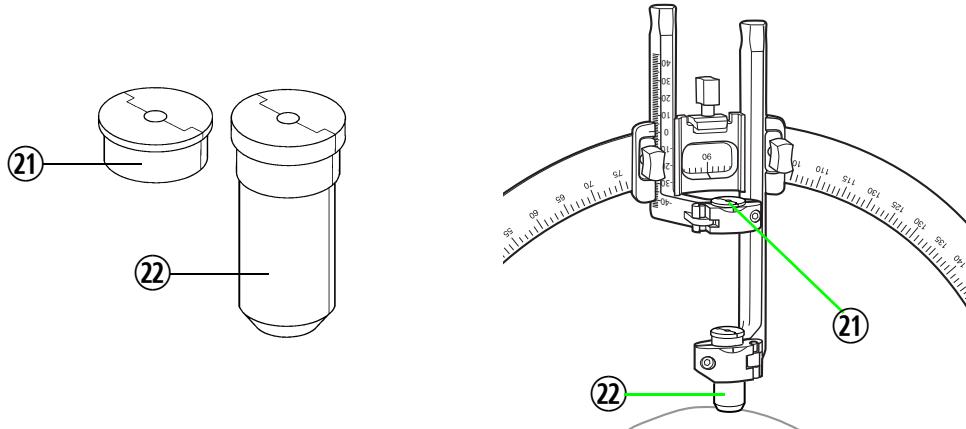
**Note:**

If the **0** mark on the instrument stop holder is aligned with the index mark ㉕ on the instrument carrier, the active point of an instrument of standard Leksell® length (190 mm) will be at the center of the stereotactic arc, when the stop insert of the instrument has been inserted.

- Tighten the knob ㉔ on the instrument carrier to secure the stop holder in place.

Surgical instruments

All Leksell® surgical instruments for use with the stereotactic arc are supplied complete with stop inserts ②1 and guide inserts ②2 of the correct diameter for the instrument. These inserts fit into the collars of the instrument stop and guide holders, respectively.



When the instrument stop holder has been positioned, the stereotactic arc is fully assembled and set to the required coordinates and angles.

WARNING 4.17



If using surgical instruments with a working length different than 190 mm, the setting of the instrument stop holder must compensate for the difference. Otherwise an erroneous treatment depth can be reached and the patient can be injured.

WARNING 4.18



Always check that the instrument stop holder is set to the appropriate position before performing any surgical procedure to avoid injury to the patient or incorrect treatment.

WARNING 4.19



Ensure that the coordinate and instrument carrier settings are securely locked. Movement of the stereotactic arc or the instrument carrier when a surgical instrument is inserted into the brain can injure the patient.

The stop insert and guide insert of the surgical instrument can now be inserted into the collars of the instrument stop and guide holders.

For detailed instructions, see the section for the surgical instrument used.

Note:

Elekta recommends using the Needle Tester to check the straightness of needles.

4.2.4.3

Removal and disassembly

The procedure for removing the stereotactic arc from the coordinate frame, and for disassembling the stereotactic arc, is the reverse of the assembly procedure described in [Section 4.2.3.1 on page 94](#) or [Section 4.2.3.2 on page 102](#).

The procedure for removing the instrument guide and stop holders, and for removing the instrument carrier, is the reverse of the fitting procedures described in [Section 4.2.4.1 on page 107](#) and [Section 4.2.4.2 on page 107](#).

4.3 Cross-Hairs Kit and A-P Cross-Hairs Holder

4.3.1 Product overview

This section describes two separate but related products: the Cross-Hairs Kit and the A-P Cross-Hairs Holder (A-P Holder). Both products are optional parts of Leksell Stereotactic System® and are used in conjunction with Leksell® Coordinate Frame G and Leksell® Multi Purpose Stereotactic Arc.

Note: In this section, the term “A-P Holder” refers to A-P Cross-Hairs Holder.

Both products are used for easy intra-operative X-ray verification of the position of inserted electrodes, catheters, etc. in relation to the pre-determined target point. The Cross-Hairs Kit verifies the position in Y and Z direction (see the left part of [Figure 4.7](#)). The A-P Holder together with the Cross-Hairs Kit verify the position in X direction, i.e. anterior-posterior (see the right part of [Figure 4.7](#)).

The verification is performed by taking an X-ray image of the patient’s head with the Cross-Hairs Kit attached either to the rings of the arc axes of the stereotactic arc, or the rings of the A-P Holder (which is attached to the stereotactic arc). The stereotactic arc is mounted on the coordinate frame.

The center of the Cross-Hairs Kit, alone and together with the A-P Holder, coincides with the center point of the stereotactic arc. This point is the stereotactic target point if the instrument stop is at the zero position and the working length of the instrument used is 190 mm.

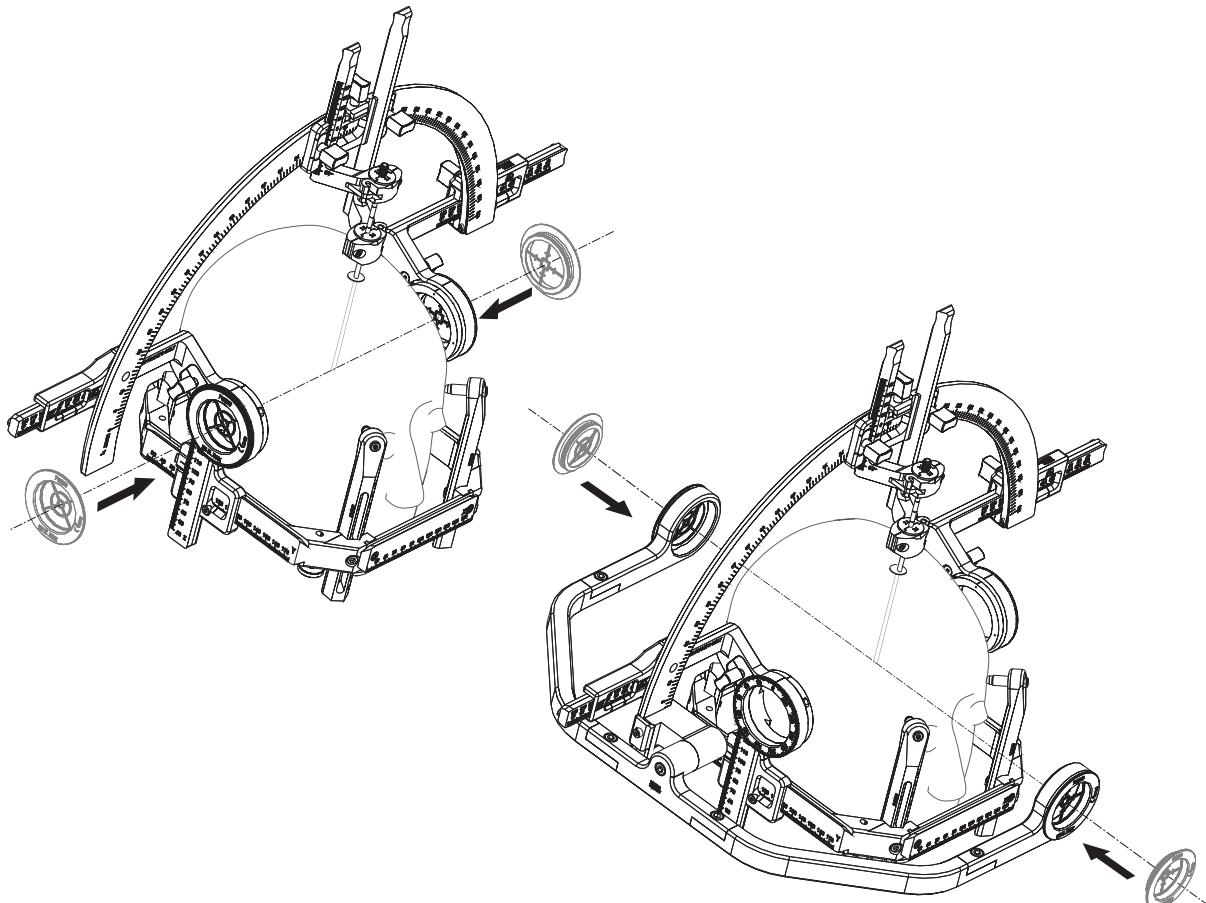


Figure 4.7 Principle of the Cross-Hairs Kit and A-P Cross-Hairs Holder

4.3.2

Main parts

Labels

Some parts have engraved labels. See [Section 9.7 on page 288](#) for general label information.

4.3.2.1

Cross-Hairs Kit

Refer to [Figure 4.8](#).

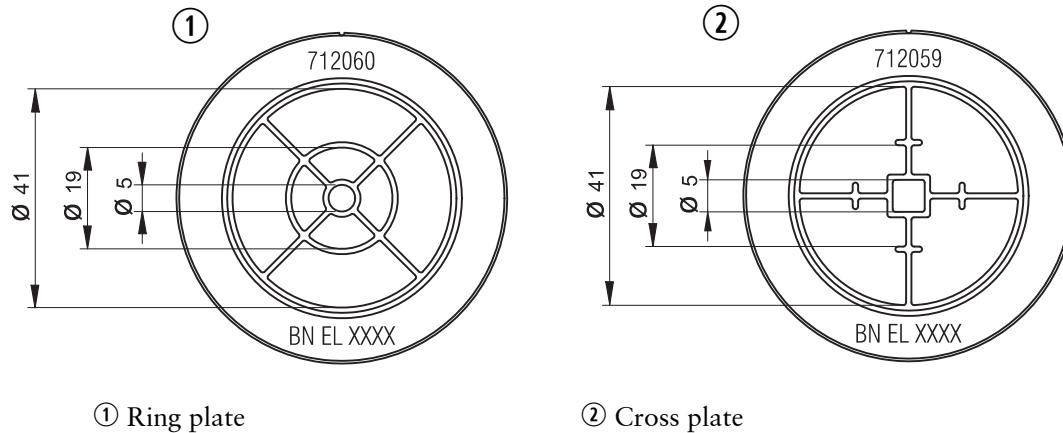
The Cross-Hairs Kit consists of two round plates made entirely of stainless steel. The plates are placed facing each other at opposite sides of the patient's head, using the stereotactic arc.

The **ring plate** ① has a thin pattern of concentric rings. The **cross plate** ② has a thin pattern of a cross. This difference makes it easy to determine the line of sight in the X-ray images.

The ring plate and the cross plate are equipped with rubber O-rings that ensure safe attachment to the rings of the arc axes. Each plate has a notch that facilitates removal of the O-rings.

The plates are fitted into the rings of the arc axes. The diameter of the plates is slightly less than the diameter of the rings, allowing the engraved scale on the ring to be seen.

This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.



① Ring plate

② Cross plate

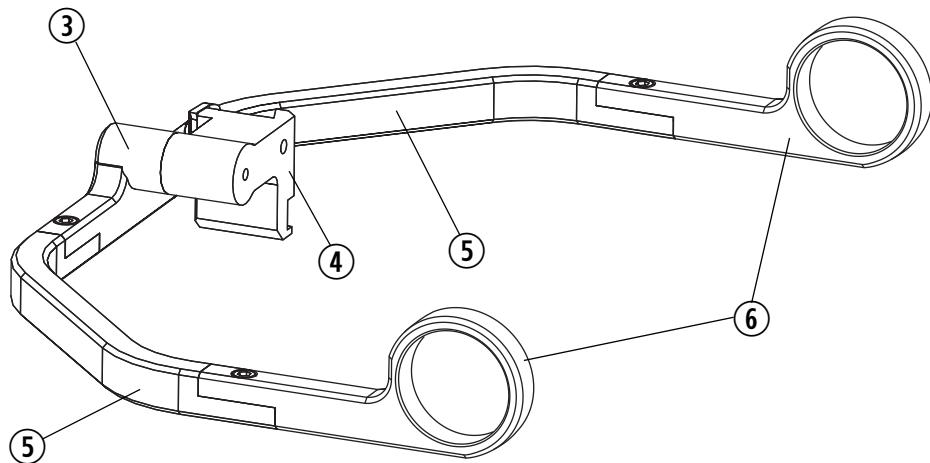
Figure 4.8 Main parts of the Cross-Hairs Kit, dimensions in mm

4.3.2.2

A-P Cross-Hairs Holder

Refer to [Figure 4.9](#).

The A-P Cross-Hairs Holder consists of one carrier and two holder arms consisting of five parts: one **carrier base** ③ with the **carrier** ④, and two holder arms divided into two **arm sections** ⑤ and two **ring holders** ⑥. The A-P Holder is attached to the stereotactic arc via the carrier, and the plates of the Cross-Hairs Kit are fitted into the rings of the two ring holders. The plates then face each other at opposite sides of the patient's head, in anterior-posterior orientation.



③ Carrier base

⑤ Arm section

④ Carrier

⑥ Ring holder

Figure 4.9 Main parts of the A-P holder

The screws and pins (not shown above) are made of stainless steel, the carrier is made of plastic, and the rest of the parts are made of aluminum.

This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.



4.3.3

Using the Cross-Hairs Kit and A-P Cross-Hairs Holder

4.3.3.1

Assembly instructions

Preparation

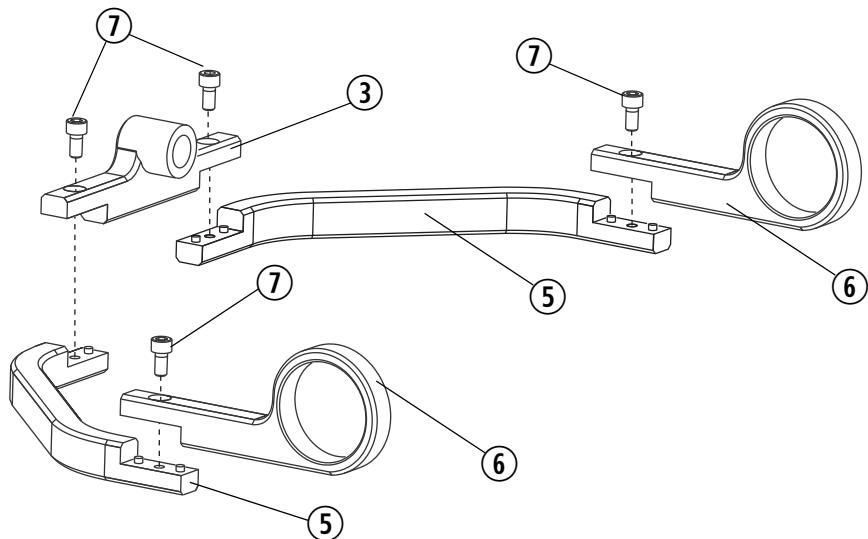
The following instructions assume that:

- The coordinate frame has been assembled and attached to the patient's skull in accordance with [Section 3.2 on page 28](#).
- The stereotactic arc is fitted to the coordinate frame and the X, Y and Z coordinates have been set on the stereotactic arc according to the patient's treatment protocol after preoperative examination and target localization.
- The surgical accessories, whose position are to be verified, have been inserted at the pre-determined target point.
- The rubber O-rings have been attached to the ring and cross plates of the Cross-Hairs Kit.
- All components of the Cross-Hairs Kit and, if required, the A-P Holder are clean, sterilized, and at hand (see [Figure 4.8](#) and [Figure 4.9](#)). Inspect all components regarding functionality before each use in operation.

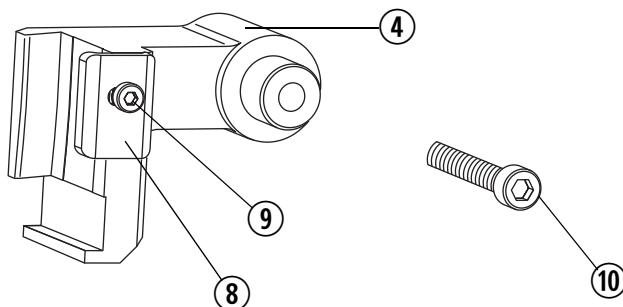
Refer to [Section 4.2 on page 89](#), for more information on the attachment and setting procedures.

Assembling the A-P holder

- Fit the two arm sections ⑤ to the carrier base ③ and secure them with the screws ⑦ using the instrument screwdriver.



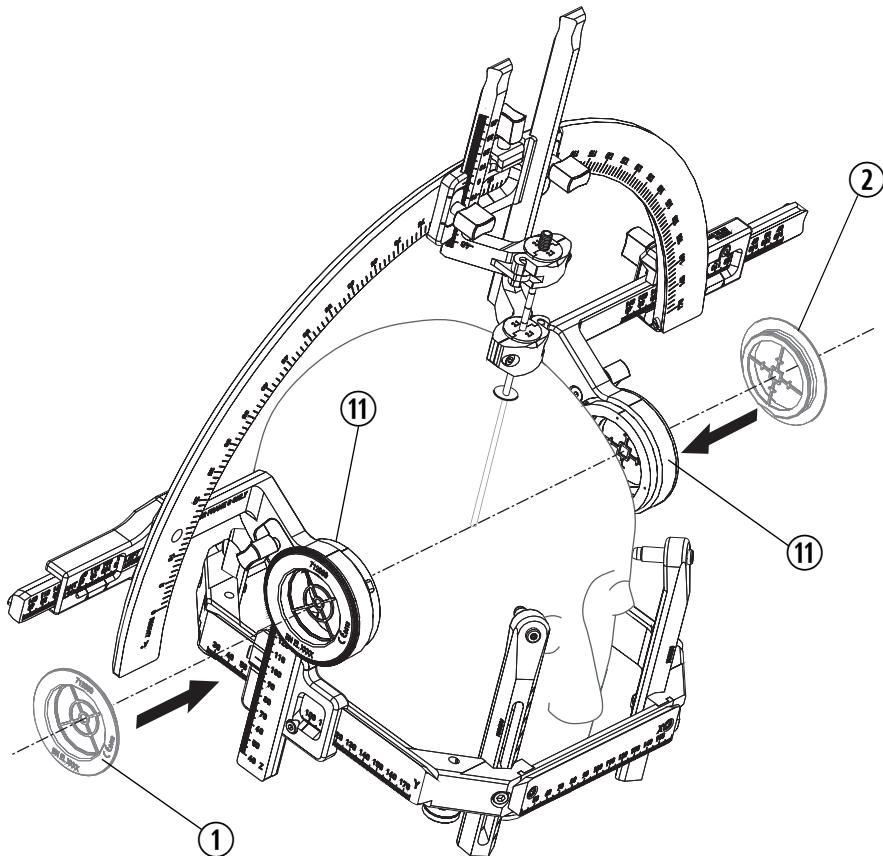
- Fit the ring holders ⑥ to the arm sections and secure them with the screws ⑦.
- Ensure that the attachment clip ⑧ with screw ⑨ is mounted on the carrier ④ and that the carrier screw ⑩ is available.



The A-P holder is now ready to be fitted to the stereotactic arc on the patient.

4.3.3.2**Fitting the Cross-Hairs Kit**

According to the illustration below, fit both the ring plate ① and the cross plate ② into the rings of the arc axes ⑪ from the outside. Do not press the center of the plates as that might damage the patterns.

**WARNING 4.20**

The patterns in the center of the ring and cross plates have sharp edges. Handle the equipment with care. Otherwise surgical gloves can become damaged and the patient and/or the surgeon can be infected.

CAUTION 4.1

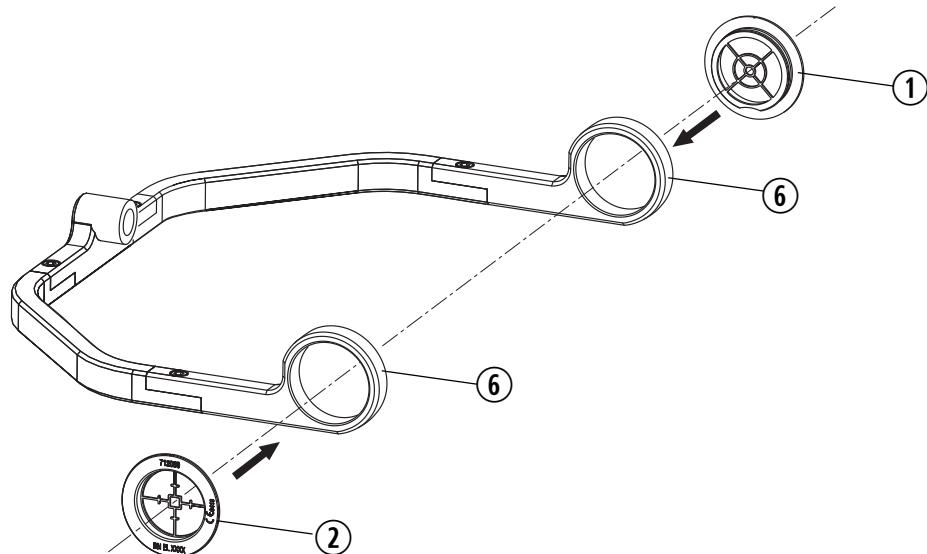
Do not subject the patterns in the center of the ring and cross plates to load or high pressure. This may deform the plates or destroy the patterns. Any damage reduces the precision of the instrument.

The X-ray verification in Y and Z direction can now be performed. Ensure that the central beam of the X-ray unit is directed so that the center of the ring and cross plate coincide, i.e. parallel with the bars of the coordinate frame.

4.3.3.3

Fitting the A-P Cross-Hairs Holder and Cross-Hairs Kit

- 1 Fit the ring plate ① and the cross plate ② into the ring holders ⑥ from the outside. Hold a hand on the inside of the ring holder while inserting the plate. Do not press the center of the plates as that might damage the patterns.

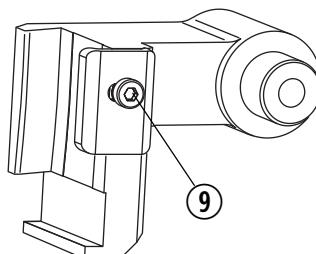


CAUTION 4.2

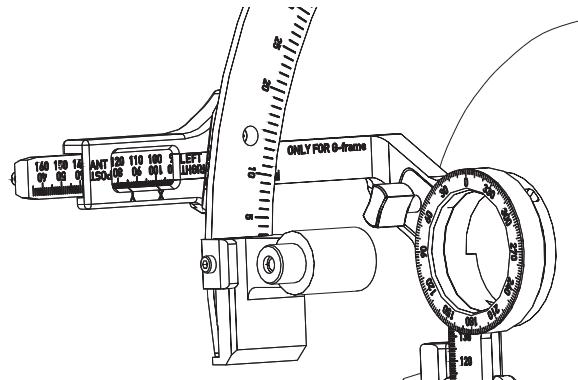


Do not subject the patterns in the center of the ring and cross plates to load or high pressure. This may deform the plates or destroy the patterns. Any damage reduces the precision of the instrument.

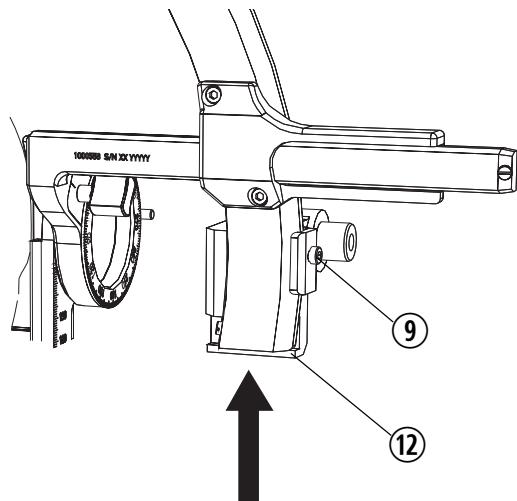
- 2** Release the screw ⑨ on the attachment clip.



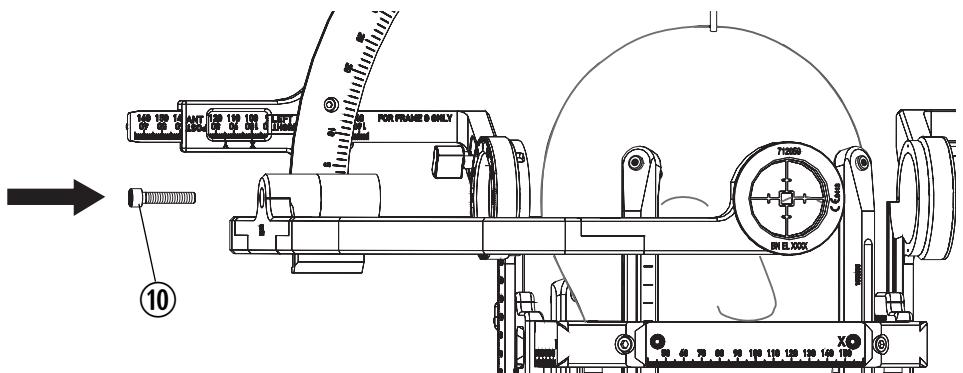
- 3** Fit the carrier on the end of the stereotactic arc where the arc position 0° is engraved.



- 4 Press the flange ⑫ of the carrier towards the end of the stereotactic arc and secure the carrier position by tightening the screw ⑨.



- 5 Fit the A-P holder to the carrier and tighten the carrier screw ⑩ slightly, using the instrument screwdriver provided with the coordinate frame.



- 6 Secure the angle position by tightening the carrier screw ⑩.

Note:

Use the A-P Holder together with the Cross-Hairs Kit only to verify the position in the X direction.

The X-ray verification in the X direction can now be performed. Ensure that the central beam of the X-ray unit is directed so that the center of the ring and cross plate coincide, i.e. parallel with the bars of the coordinate frame.

4.3.3.4 Removal and disassembly

Removing the Cross-Hairs Kit

To remove the Cross-Hairs Kit, pull out the ring plate and the cross plate by gripping the circumference of the plate.



CAUTION 4.3

Do not subject the patterns in the center of the ring and cross plates to load or high pressure. This can deform the plates or destroy the patterns. Any damage reduces the precision of the instrument.

Detach the O-rings from the plates prior to cleaning.

Removing the A-P holder

To remove the A-P holder from the stereotactic arc:

- 1 Hold the A-P holder and release the screw on the attachment clip.
- 2 Lift off the complete A-P holder from the stereotactic arc.

Disassembling the A-P holder

To disassemble the A-P holder:

- 1 Remove the Cross-Hairs Kit from the A-P holder (see above).
- 2 Remove the carrier screw and then the carrier from the arm section.
- 3 If required to fit into the sterilization equipment, disassemble the A-P holder further by reversing the procedure given in step 1 to 3 on [page 114](#).

4.4 Leksell® Endoscope Adapter

4.4.1 Product overview

Leksell® Endoscope Adapter is designed to permit the rapid and accurate positioning of an endoscope when supported by a stereotactic arc. The adapter can be used with most types of endoscopes together with Leksell® Multi Purpose Stereotactic Arc.

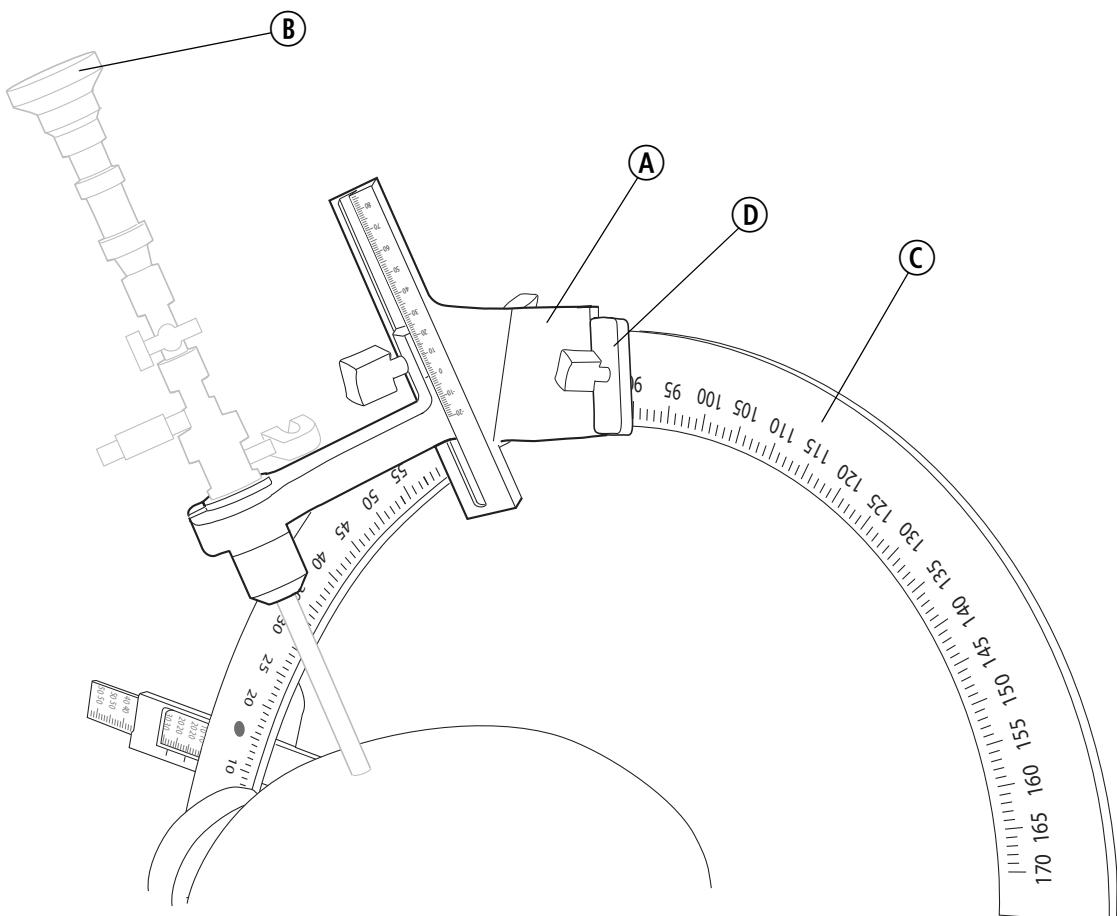


Figure 4.10 Leksell® Endoscope Adapter (A) (with an endoscope (B) inserted) attached to the stereotactic arc (C) via the instrument carrier (D)

4.4.2

Main parts

Refer to [Figure 4.11](#).

The Endoscope Adapter consists of three parts: a **V-shaped arc connector** ①, an **arm** ② and a **knob** ③.

The V-shaped arc connector ① secures the entire adapter to the instrument carrier of the stereotactic arc. One end is shaped as a dovetail ⑤ which mates the slot used for the instrument guide in the instrument carrier of the stereotactic arc. At the top of the dovetail there is a stop ⑥ which ensures correct fitting to the instrument carrier.

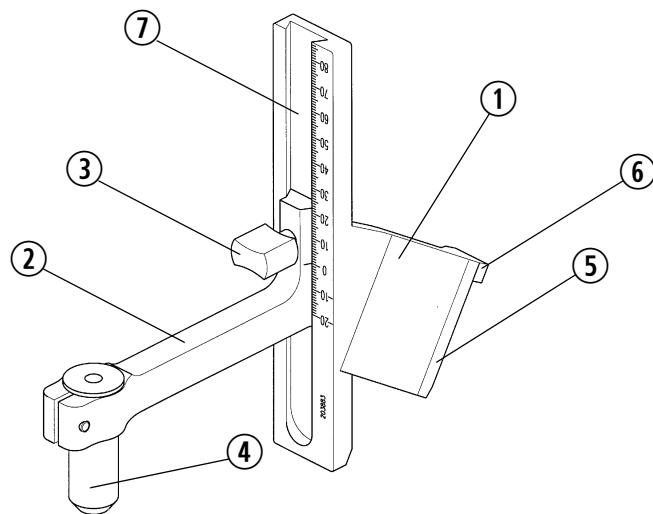
At the other end of the arc connector there is a slot ⑦ to accommodate the arm ②. The face of the slot is engraved with a scale from -20 mm to +85 mm. With the index mark on the arm at the 0 mm setting, the operative part of an endoscope of standard Leksell® length (190 mm) is placed at the target. For endoscopes of other lengths, compensation can be applied by adjusting the position of the arm in the slot of the arc connector.

The arm ② supports the endoscope and adjusts its position away from the stereotactic arc, enabling free rotation of the endoscope and its connecting tubes. The position of the arm with respect to the V-shaped arc connector can be adjusted to accommodate endoscopes of different lengths.

The arm is secured at the required position in the connector by tightening the knob ③.

The **endoscope guide** ④ fits into the forked collar at the end of the arm, thereby securing the endoscope and maintaining it at the required trajectory.

This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.



- | | |
|--------------------------|-----------------|
| ① V-shaped arc connector | ⑤ Dovetail end |
| ② Arm | ⑥ Dovetail stop |
| ③ Knob | ⑦ Slot |
| ④ Endoscope guide | |

Figure 4.11 Main parts of Leksell® Endoscope Adapter

4.4.2.1

Labels

Some parts have engraved labels. See [Section 9.7 on page 288](#) for general label information.

4.4.3

Using Leksell® Endoscope Adapter

4.4.3.1

Assembly instructions



WARNING 4.21

Plan the trajectory to avoid inserting the surgical instrument into regions where it can cause injury.

Preparation

Inspect all components regarding functionality before use.

The following instructions assume that:

- The coordinate frame is attached to the patient's head.
- The stereotactic arc is fitted to the coordinate frame and the X, Y and Z coordinates have been set on the stereotactic arc according to the patient's treatment protocol after preoperative examination and target localization.



WARNING 4.22

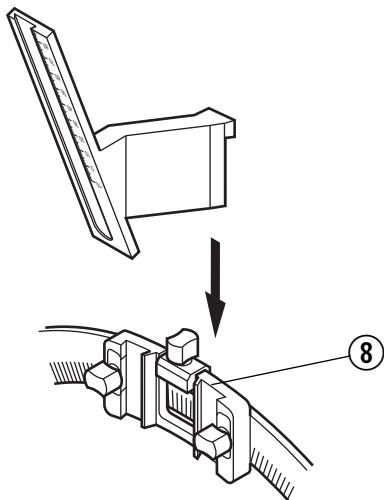
The angle of the V-shaped arc connector is 30°. When using the Leksell® Endoscope Adapter, the correct angle of the endoscope trajectory is obtained by subtracting 30° from the ring angle of the stereotactic arc. You must consider this 30° compensation factor otherwise the angle of the Leksell® Endoscope Adapter will be incorrect.

- The instrument guide and instrument stop have been removed from the instrument carrier.
- Leksell® Endoscope Adapter is clean, sterilized and at hand.

Refer to [Section 4.2 on page 89](#) for more information on the attachment and setting procedures.

4.4.3.2**Fitting Leksell® Endoscope Adapter**

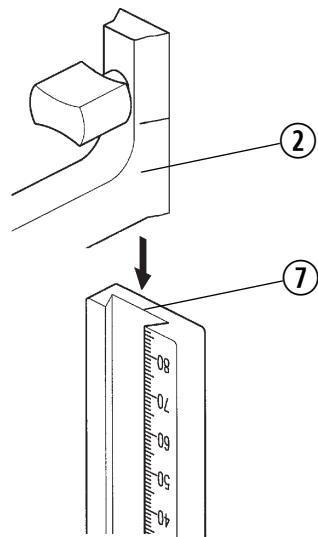
- At the instrument carrier on the stereotactic arc, insert the shaped dovetail of the V-shaped arc connector into the slot ⑧ of the instrument carrier otherwise used for the instrument guide holder. Do not use the slot that would otherwise contain the instrument stop holder.

**WARNING 4.23**

The V-shaped arc connector must be inserted into the correct slot until the stop of the dovetail rests on the surface of the instrument carrier. Otherwise the surgical instrument will not reach the correct depth.

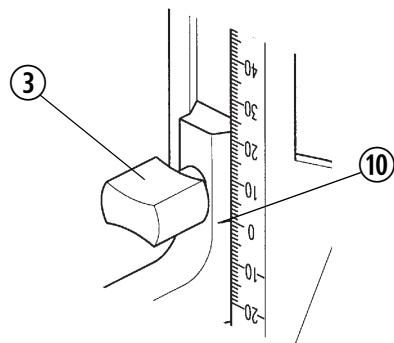
fully insert the arc connector in the slot until the stop at the top of the dovetail is firmly in contact with the upper edge of the instrument carrier. Tighten the knob on the instrument carrier to secure the V-shaped arc connector in place.

- Insert the arm ② into the slot ⑦ on the engraved face of the V-shaped arc connector.

**Note:**

To enable secure locking, the arm must be fully inserted into the slot.

- 3 If an endoscope of standard Leksell® length (190 mm) is to be used, align the index mark ⑩ on the locking piece of the arm with the 0 mark on the face of the V-shaped arc connector.



Tighten the knob ③ on the locking piece to secure the V-shaped arc connector in place.

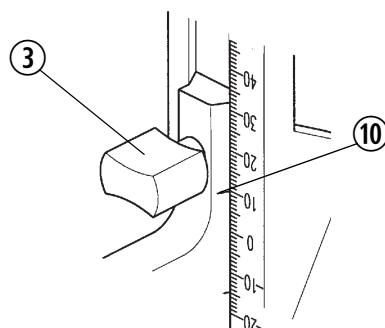
- 4 If an endoscope that is *not* of standard Leksell® length is to be used, compensate for the difference between 190 mm and the length of the endoscope in use.

WARNING 4.24



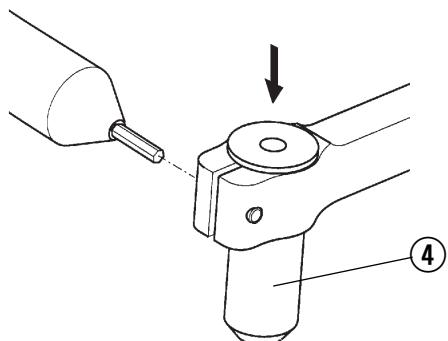
Compensate for the difference between 190 mm and the length of the endoscope in use. Otherwise the surgical instrument will not reach the correct depth.

For example, if an endoscope with a working length of 200 mm is in use, align the index mark ⑩ on the locking piece of the arm with the +10 mm mark on the face of the V-shaped arc connector.



Tighten the knob ③ on the locking piece to secure the V-shaped arc connector in place.

- 5 Insert the endoscope guide ④ into the collar at the free end of the arm. Using the instrument screwdriver supplied with the coordinate frame, tighten the hexagonal screw at the end of the arm to secure the guide.



WARNING 4.25



The endoscope guide must be inserted to its full length, i.e. until its edge is stopped by the collar at the free end of the arm. Otherwise the surgical instrument will not reach the correct depth.

WARNING 4.26



Always use the appropriate guide insert corresponding to the diameter of the surgical instrument. Otherwise the patient can be injured and the surgical instruments can be damaged.

The endoscope can now be inserted into the endoscope guide.

4.4.3.3

Roval and disassembly

The procedure for disassembling the Leksell® Endoscope Adapter is the reverse of the fitting procedure described in [Section 4.4.3.2 on page 122](#).

5

Neurosurgical instruments

This chapter describes the following products:

Drills

- Salcman Twist Drill Kit, [Section 5.3 on page 128](#)

Biopsy instruments

- Sedan Side-Cutting Biopsy Needle Kit I, [Section 5.4 on page 135](#)

Injection/aspiration/evacuation/insertion instruments

- Backlund Catheter Insertion Needle Kit, [Section 5.5 on page 142](#)
- Backlund Haematoma Evacuator Kit, [Section 5.6 on page 151](#)
- Insertion Cannula Kit, [Section 5.7 on page 157](#)

5.1

General warnings and notes

These warnings apply to the usage of all products included in this chapter.

WARNING 5.1



Handle all Elekta equipment with care. Any damage, however slight, can reduce treatment safety and accuracy. Inspect the equipment before clinical use. If you suspect that any part is damaged, contact Elekta immediately. Do not use damaged equipment for any purpose until authorized to do so by Elekta.

WARNING 5.2



The equipment must be set up in accordance with the treatment protocol. Otherwise wrong treatment can result and the patient can be injured.

WARNING 5.3



The equipment must only be used with Leksell Stereotactic System[®] or specified instruments. Usage with other systems can cause inaccurate treatment and patient injury.

WARNING 5.4



Exercise extreme caution at all times to ensure that the coordinate frame does not move on the patient's skull. If the coordinate frame is displaced, all treatment planning based on the coordinate frame position is invalid.

WARNING 5.5



Unless otherwise stated, the equipment is delivered unsterile and must be sterilized before use. Otherwise the patient can be infected.

WARNING 5.6



Always remove the surgical instrument from the brain before changing any stereotactic settings. Otherwise the patient can be injured.

WARNING 5.7



Always check that the instrument stop holder is set to the appropriate position before performing any surgical procedure to avoid injury to the patient or incorrect treatment.

WARNING 5.8



Handle equipment with sharp edges or points with care. Otherwise surgical gloves can become damaged and the patient and/or the surgeon can be infected.

WARNING 5.9



Plan the trajectory to avoid inserting the surgical instrument into regions where it can cause injury.

WARNING 5.10



Insert the surgical instrument slowly and carefully to avoid damage to blood vessels and other sensitive areas. Otherwise the patient can be injured.

WARNING 5.11



The patient's brain may move slightly when the skull is punctured due to the release of fluid pressure. The patient's brain may therefore be in a slightly different position relative to the skull during the operation compared to when the images were acquired. The accuracy of the treatment may be affected.

WARNING 5.12



Do not bring any MR Unsafe products into the MRI area since it may be affected by the magnetic field or cause artifacts in the images.

Note:

Elekta recommends using the Needle Tester to check the straightness of needles.

5.1.1

Labels

Some parts can have engraved labels. See [Section 9.7 on page 288](#) for general label information.

5.1.2

Neurosurgical instruments and MR compatibility

Note that all the listed neurosurgical instruments are **MR Unsafe**. See description of each instrument.



5.2

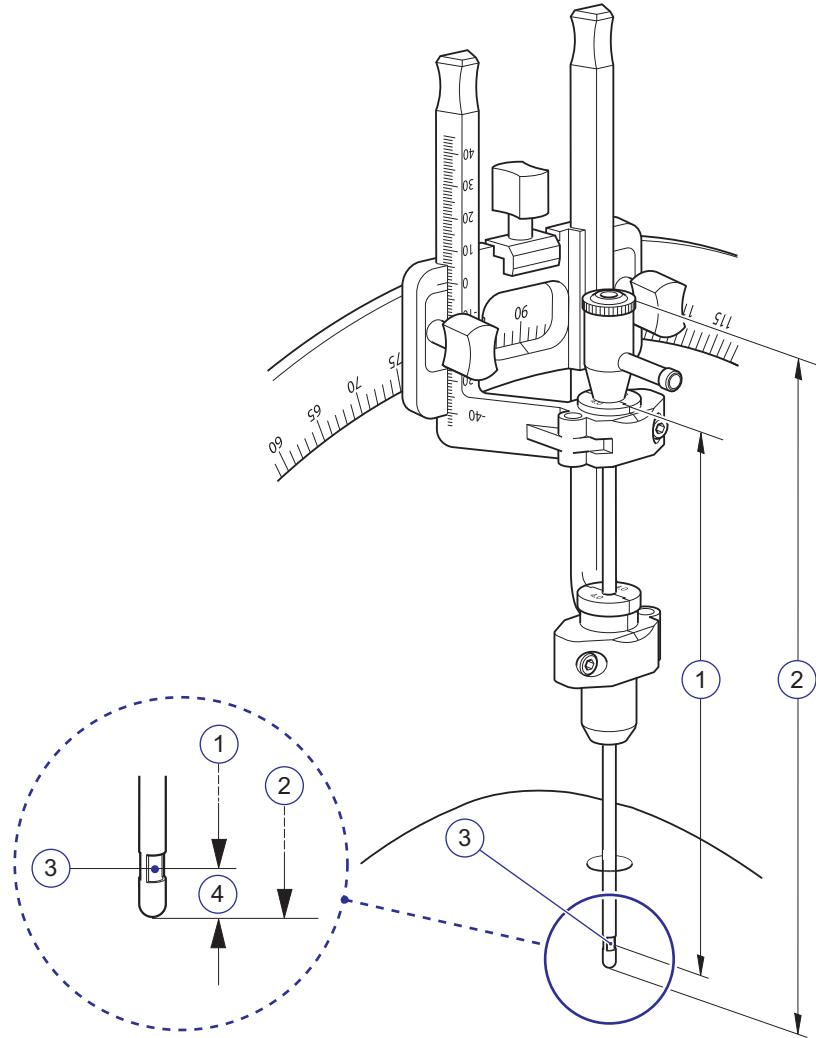
Working length

All Elekta neurosurgical instruments have a standard working length ① of 190 mm, see [Figure 5.1](#).

When a neurosurgical instrument is correctly fitted (as described in this chapter), the working length standard ensure that the center of the active part of the instrument is at the precise center of the stereotactic arc and thus at the target ③.

The tip of the instrument protrudes below the target as indicated by (4). The length of the protruding tip is specific for each instrument.

The total length ② differs from the working length. For dimensions see the product specifications.



- ① Working length = 190 mm
- ② Total length
- ③ Target
- ④ Tip protruding below target

Figure 5.1 Illustration of working length versus total length of a neurosurgical instrument

5.3 Salcman Twist Drill Kit

5.3.1 Product overview

The Salcman Twist Drill Kit consists of a set of neurosurgical instruments designed to allow the surgeon to place a hole with suitable diameter at a predetermined place on the patient's skull.

The surgeon may then, for example, take biopsies, implant electrodes, or evacuate cysts.

The instruments(s) are positioned manually in accordance with the patient's treatment protocol using the stereotactic arc.

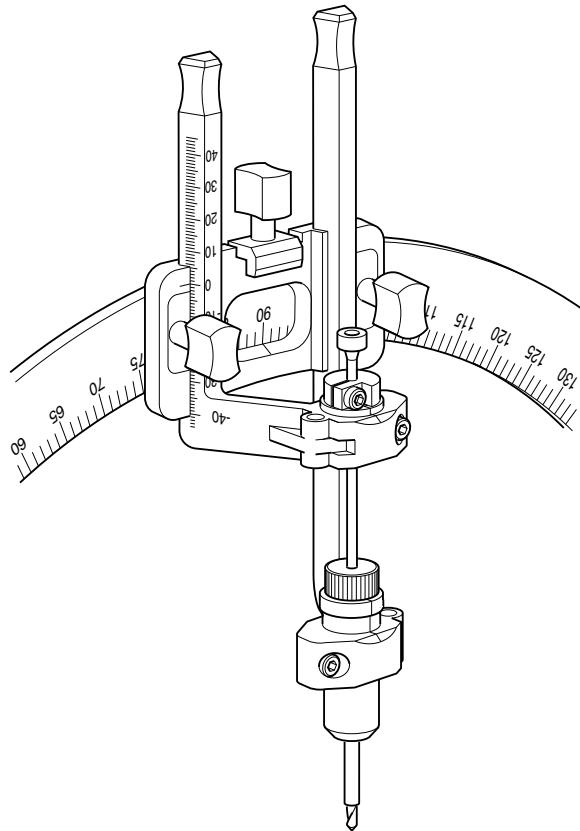


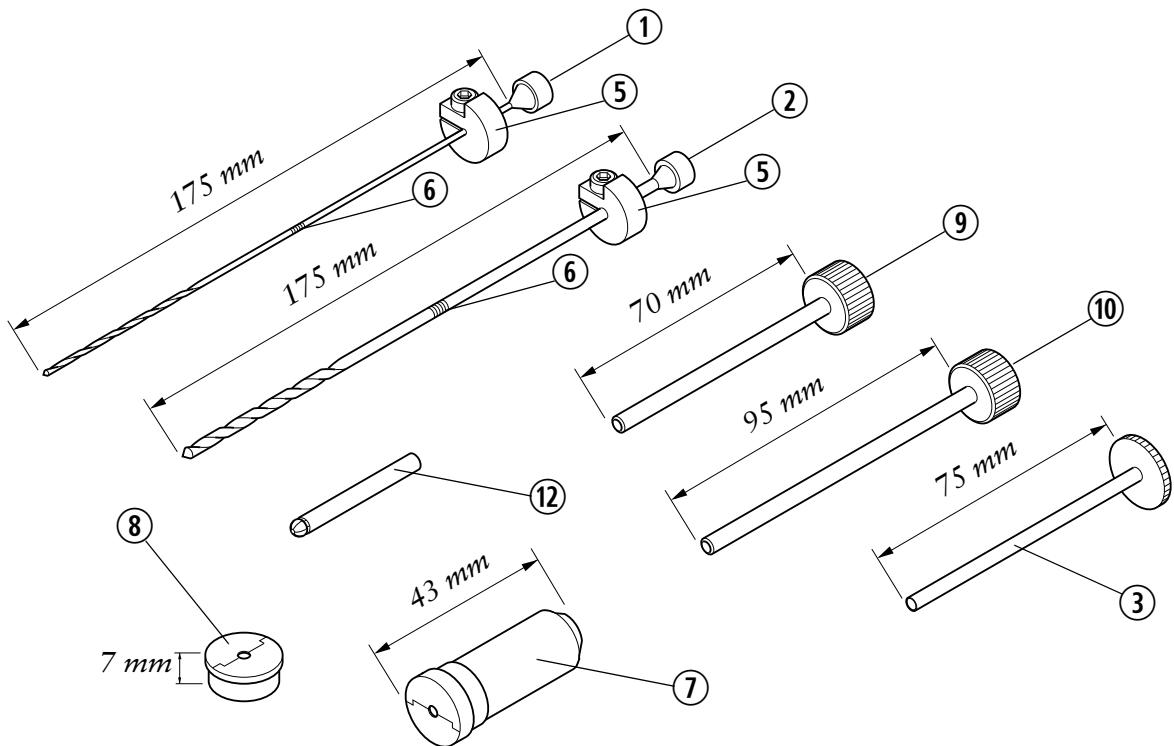
Figure 5.2 Salcman Twist Drill Kit mounted on the stereotactic arc

5.3.2 Main parts

Refer to [Figure 5.3](#).

The kit contains two **twist drills** ① and ② with different diameters (2.1 and 3.2 mm). Drill ① is always used with a **reducing tube** ③.

The **adjustable stop** ⑤ on each drill is used to determine the depth of the hole to be drilled. To visualize current drilling depth during the drilling, there are six **millimeter markings** ⑥ on each drill.



- | | |
|-----------------------|--------------------------------|
| ① Twist drill, 2.1 mm | ⑦ Guide insert (marking “4.0”) |
| ② Twist drill, 3.2 mm | ⑧ Stop insert (marking “4.0”) |
| ③ Reducing tube | ⑨ Sleeve, 70 mm |
| ⑤ Adjustable stop | ⑩ Sleeve, 95 mm |
| ⑥ Millimeter markings | ⑫ Drill driver |

Figure 5.3 Main parts of the Salcman Twist Drill Kit

The **guide insert** ⑦ and **stop insert** ⑧ are fitted onto the stereotactic arc to guide the surgical instrument to the target position. The stop insert sets the limit of instrument insertion to the appropriate depth of the twist drill hole. The guide insert ensures that the instrument follows a straight trajectory to the predetermined location of the twist drill hole. Both inserts are separable into two pieces and drilled with one hole. Each insert is specific to one instrument size and can be identified by the engraved marking on the top surface.

Two **sleeves** ⑨ and ⑩ of different lengths (70 and 95 mm) are included. The sleeve fits into the guide insert and is used to cut a hole through the scalp and also to stabilize the drill during the drilling. The appropriate drill is inserted through the stop insert and then through the sleeve. If the smaller diameter drill ① is to be used, the reducing tube ③ should be inserted into the sleeve before the drill is inserted.

The **drill driver** ⑫ should be inserted into the chuck of an appropriate drilling tool.

All the components are made of stainless steel, with the exception of the guide and stop inserts which are plastic.

A sterilization tray (not shown) is provided to house the kit during sterilization and for storage.

This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.



5.3.3 Using the Salcman Twist Drill Kit

5.3.3.1 Fitting instructions

Preparation

Inspect all components regarding functionality before use.

The following instructions assume that:

- The coordinate frame is attached to the patient's head.
- The stereotactic arc is fitted to the coordinate frame and the X, Y and Z coordinates have been set on the stereotactic arc according to the patient's treatment protocol after preoperative examination and target localization.
- The Salcman Twist Drill Kit is clean, sterilized, and at hand.

Refer to [Section 4.2 on page 89](#) for more information on the attachment and setting procedures.

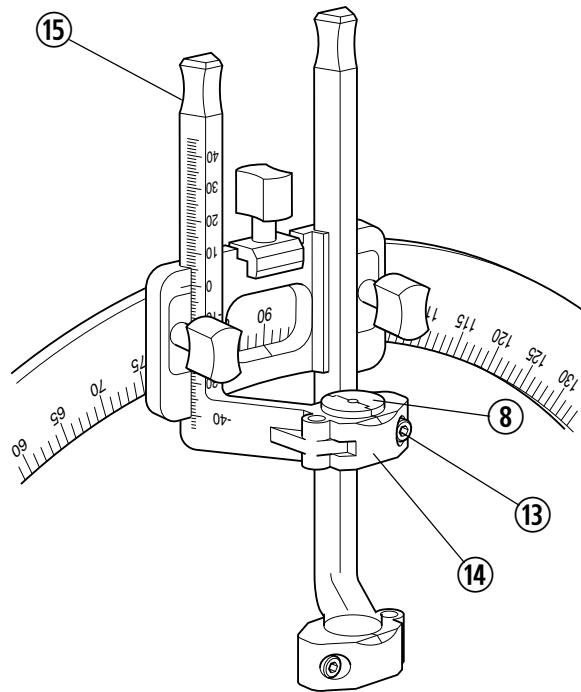
Fitting the stop and guide inserts



WARNING 5.13

Always use the appropriate stop and guide inserts corresponding to the diameter of the surgical instrument. Otherwise the patient can be injured and the surgical instruments can be damaged.

- 1 Using the instrument screwdriver, release the securing screw ⑬ and open the collar ⑭ of the instrument stop holder ⑮.



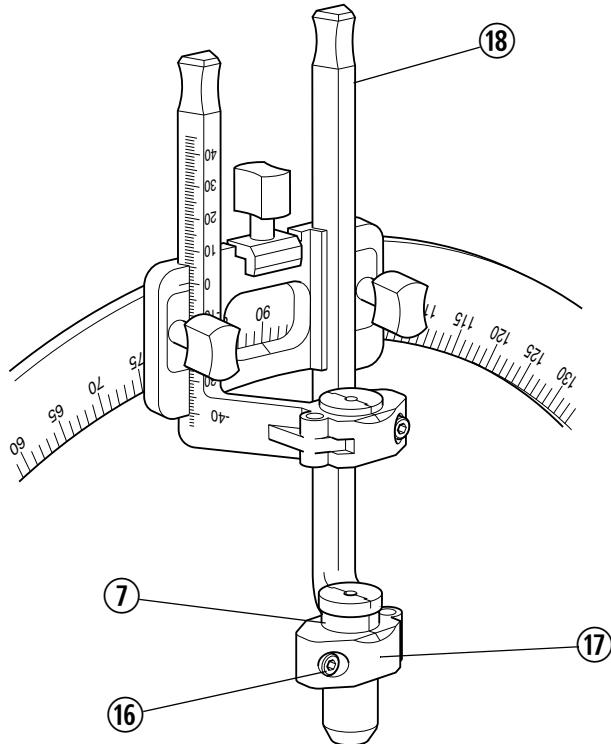
- 2 Position the stop insert ⑧ within the collar of the instrument stop holder, i.e. until its edge is in contact with the instrument stop holder.



WARNING 5.14

The stop insert must be inserted to its full length, i.e. until its edge is stopped by the instrument stop holder. Otherwise the surgical instrument will not reach the correct depth.

- 3 Close the collar and tighten the securing screw ⑬.
- 4 Using the instrument screwdriver, release the securing screw ⑯ and open the collar ⑰ of the instrument guide holder ⑱.



- 5 Position the guide insert ⑦ within the collar of the instrument guide holder.
- 6 Close the collar and tighten the securing screw ⑯.

5.3.3.2 Operating procedure

Mounting the drill on the stereotactic arc

WARNING 5.15



Always check that the instrument stop holder is set to the appropriate position before performing any surgical procedure to avoid injury to the patient or incorrect treatment.

WARNING 5.16



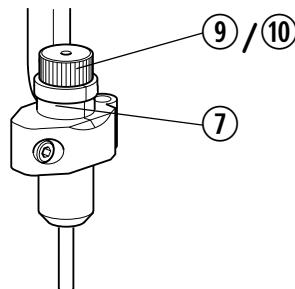
The tip of the drill and the sleeve must be checked for deformation prior to each use. A deformed drill or sleeve can injure the patient.

WARNING 5.17



Always handle the drills with care. Avoid contact between the drills, otherwise they can become damaged and injure the patient during clinical use.

- 1 Set the stereotactic arc and instrument carrier so that the guide insert rests over the desired point of skull penetration.
- 2 Insert the appropriate sleeve ⑨ or ⑩ into the guide insert ⑦.

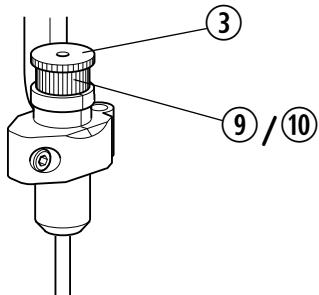


WARNING 5.18

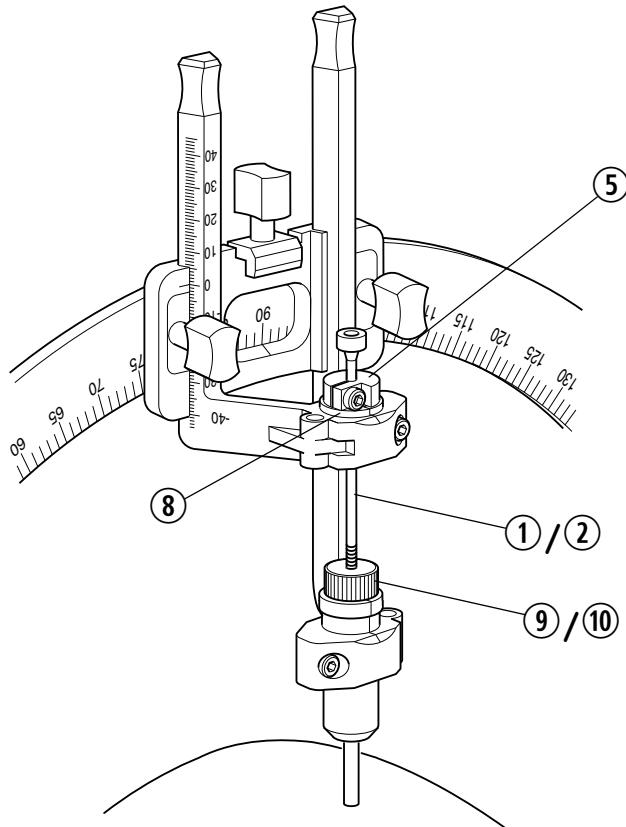


The sleeve must be used and inserted into the guide insert. Otherwise the depth of drilling can be incorrect and the patient can be injured.

- 3 Advance the sleeve through the scalp with a repeated twisting motion until it rests firmly against the skull. Remove the piece of scalp from the sleeve.
- 4 Insert the reducing tube ③ into the sleeve ⑨ or ⑩.



- 5 Insert the selected drill ① or ② with its adjustable stop ⑤ (unlocked) through the stop insert ⑧ and the sleeve ⑨ or ⑩. The tip of the drill now rests against the outer table of the skull.



Drill procedure



WARNING 5.19

In the starting position the tip of the drill must rest against the skull, and the instrument stop holder must be set to 0 (zero). Otherwise the depth of penetration will be unpredictable and the patient can be injured.



WARNING 5.20

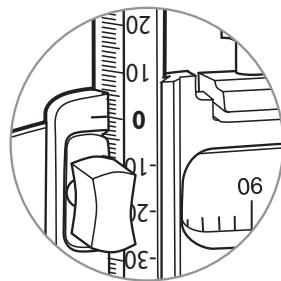
Before drilling, make sure that the drill's adjustable stop is correctly adjusted and properly secured to the drill. Otherwise the depth of penetration will be unpredictable and the patient can be injured.



WARNING 5.21

Ensure the depth of the hole does not exceed the thickness of the skull estimated by the surgeon. Otherwise the patient can be injured.

-
- 6 Set the instrument stop holder is set to 0 (zero). If using sleeve ⑨, all six millimeter markings ⑥ should now be visible above the sleeve.



- 7 Bring the drill's adjustable stop ⑤ all the way down to the stop insert ⑧ and lock it securely in this position with the instrument screwdriver. This is the starting position for the drilling procedure.
- 8 Assess the thickness of the skull at the selected point of the skull penetration and lower the instrument stop holder by an equal number of millimeters.
- 9 Lock the instrument stop holder securely.
- 10 Using the supplied drill driver, connect the proximal end of the drill to a hand or battery operated drill. The drilling may now commence.
- During drilling, when using sleeve ⑨, the depth of the drill hole is indicated by the number of millimeter markings ⑥ hidden by the sleeve, e.g. if 4 of the 6 markings are visible, the depth of the drill hole is 2 mm.
- When the adjustable stop ⑤ on the drill reaches the stop insert ⑧, the tip of the drill has penetrated the bone to a depth equal to the number of millimeters set on the instrument stop holder.
- 11 If further drilling is needed to penetrate the whole thickness of the skull, lower the instrument stop holder and repeat the procedure.

Note:

For some lateral approaches (through the rings of the arc supports) the length of the sleeve may not be sufficient to efficiently penetrate the scalp. An extra sleeve with extended length is included in the kit for these cases.

5.3.3.3 Removal

To remove the drill and sleeve from the stereotactic arc and the patient:

- 1 Remove the drill with adjustable stop from the patient's skull.
- 2 Remove the sleeve (and reducing tube if used) from the guide insert.

The procedure for removing the guide and stop inserts is the reverse of the procedure given in [Fitting the stop and guide inserts](#) on page 130.

5.4 Sedan Side-Cutting Biopsy Needle Kit I

5.4.1 Product overview

The Sedan Side-Cutting Biopsy Needle Kits I consists of a set of neurosurgical instruments designed to take multiple biopsies from one or more targets in one trajectory. The sample is obtained by applying a vacuum.

The cutting window of the needle is 10 mm in length and is useful for a large specimen.

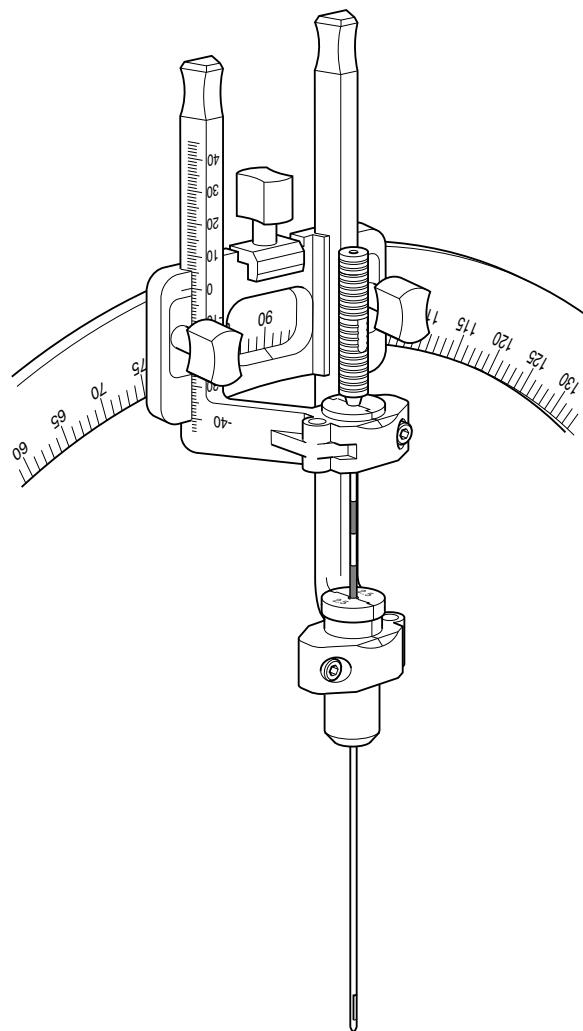


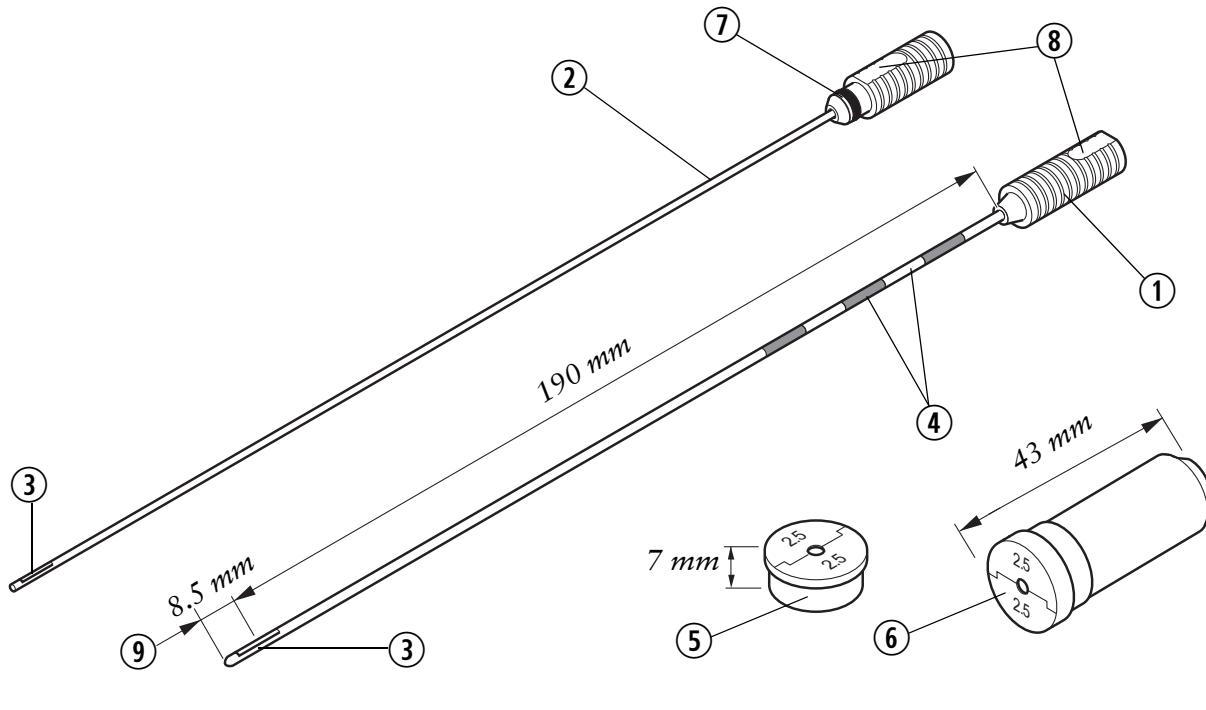
Figure 5.4 Sedan Side-Cutting Biopsy Needle Kit I mounted on the stereotactic arc

Note: If the patient is diagnosed as suffering from Creutzfeldt-Jakob Disease, we recommend using the Disposable Biopsy Needle Kit instead of this equipment.

5.4.2**Main parts**

Refer to [Figure 5.5](#).

The Sedan Side-Cutting Biopsy Needle kit contains a side-cutting needle comprising an **outer cannula** ① and an **inner cannula** ② each with a **lateral cutting window** ③. The outer cannula has **centimeter markings** ④ to indicate the insertion depth.



- | | |
|--|---|
| ① Outer cannula | ⑤ Stop insert (marking “ 2.5 ”) |
| ② Inner cannula | ⑥ Guide insert (marking “ 2.5 ”) |
| ③ Lateral cutting window | ⑦ O-ring |
| ④ Centimeter markings | ⑧ Alignment marks |
| ⑨ Tip protruding below target = 8.5 mm | |

Figure 5.5 Main parts of the Sedan Side-Cutting Biopsy Needle Kit.

The distance from the bottom of the knob on the outer cannula to the center of the cutting window is the standard Leksell Stereotactic System® working length of 190 mm. The total length of the assembled needle is 247 mm.

The tip of the instrument protrudes 8.5 mm below the target. See [Figure 5.6](#) and refer to [Section 5.2](#).

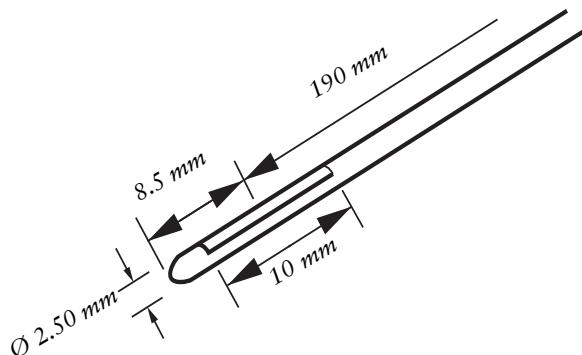


Figure 5.6 Enlargement view and dimensions of the Sedan Side-Cutting Biopsy Needle tip

The outer cannula is inserted through the **stop insert** ⑤ and the **guide insert** ⑥ which are fitted onto the stereotactic arc to guide the surgical instrument to the target position. The stop insert sets the limit of instrument insertion to the appropriate target depth. The guide insert ensures that the instrument follows a straight trajectory to the target. Both inserts are separable into two pieces. Each insert is specific to one surgical size and can be identified by the engraved marking on the top surface.

The inner cannula is inserted into the outer cannula. A **O-ring** ⑦ on the inner cannula provides an air-tight seal with the outer cannula. As the inner cannula is rotated so that the **alignment marks** ⑧ on the inner cannula and outer cannula are adjacent (a), the cutting windows at the distal end of the cannulas align, allowing the specimen to be obtained.

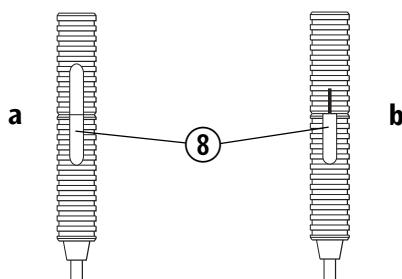


Figure 5.7 Alignment marks for cutting window open (a) and cutting window closed (b)

Both cannulas are made of stainless steel. The stop and guide insert are made of plastic. The O-ring is made of rubber.

A sterilization tray (not shown) is provided to house the kit during sterilization and for storage.

This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.



5.4.3 Using the Sedan Side-Cutting Biopsy Needle Kit I

5.4.3.1 Fitting instructions

Preparation

Inspect all components regarding functionality before use.

The following instructions assume that:

- The coordinate frame is attached to the patient's head.
- The stereotactic arc is fitted to the coordinate frame and the X,Y and Z coordinates have been set on the stereotactic arc according to the patient's treatment protocol after preoperative examination and target localization.
- The burr hole has been prepared.
- The Sedan Side-Cutting Biopsy Needle Kit is clean, sterilized, and at hand.

Refer to [Section 4.2 on page 89](#) for more information on attachment and setting procedures.

Fitting the stop and guide inserts

Fit the stop and guide inserts as described on [page 130](#).

WARNING 5.22



Always use the appropriate stop and guide inserts corresponding to the diameter of the surgical instrument. Before operation, check and make sure that the surgical instrument fits the stop and guide inserts. Otherwise the patient can be injured and the surgical instruments can be damaged.

5.4.3.2 Operating procedure

WARNING 5.23



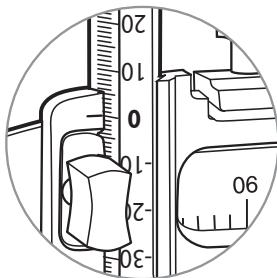
Always check that the instrument stop holder is set to the appropriate position before performing any surgical procedure to avoid injury to the patient or incorrect treatment.

WARNING 5.24



Ensure that the O-ring on the inner cannula is lubricated and in good condition, providing an adequate seal with the outer cannula. Otherwise no specimen will be obtained.

- 1 Ensure that the instrument stop holder is set to the appropriate position.
Setting the instrument stop holder to the zero position makes the center of the cutting window at the distal end of the outer cannula reach the target area.



Note: When performing serial biopsies, it is important to start at the proximal periphery of the lesion and work downwards; the opposite approach will yield scant or less representative specimens.



WARNING 5.25

The tip of the cannula must be checked for deformation prior to each use. A deformed tip can injure the patient.

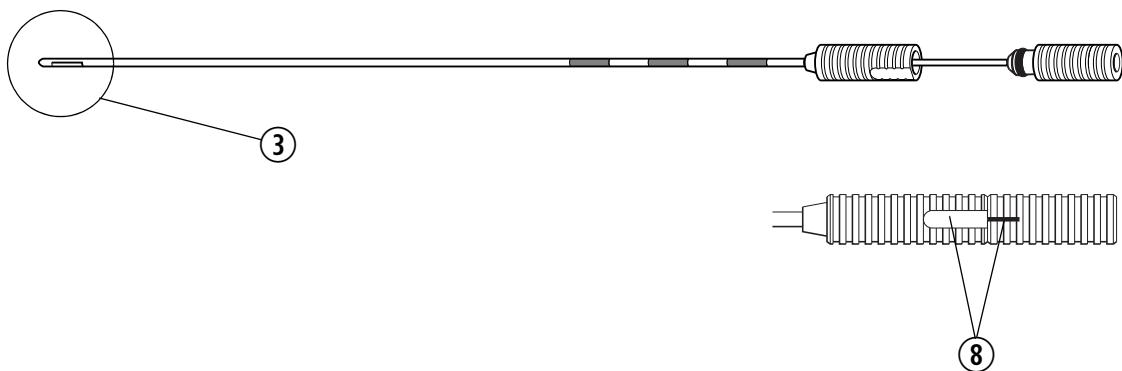


WARNING 5.26

The open slot along the slotted outer cannula must be checked for deformation prior to each use. Deformation of the slot on the slotted outer cannula can injure the patient.

- 2 Fully insert the inner cannula into the outer cannula, ensuring that the alignment marks ⑧ of the cannulas are on *opposite* sides.

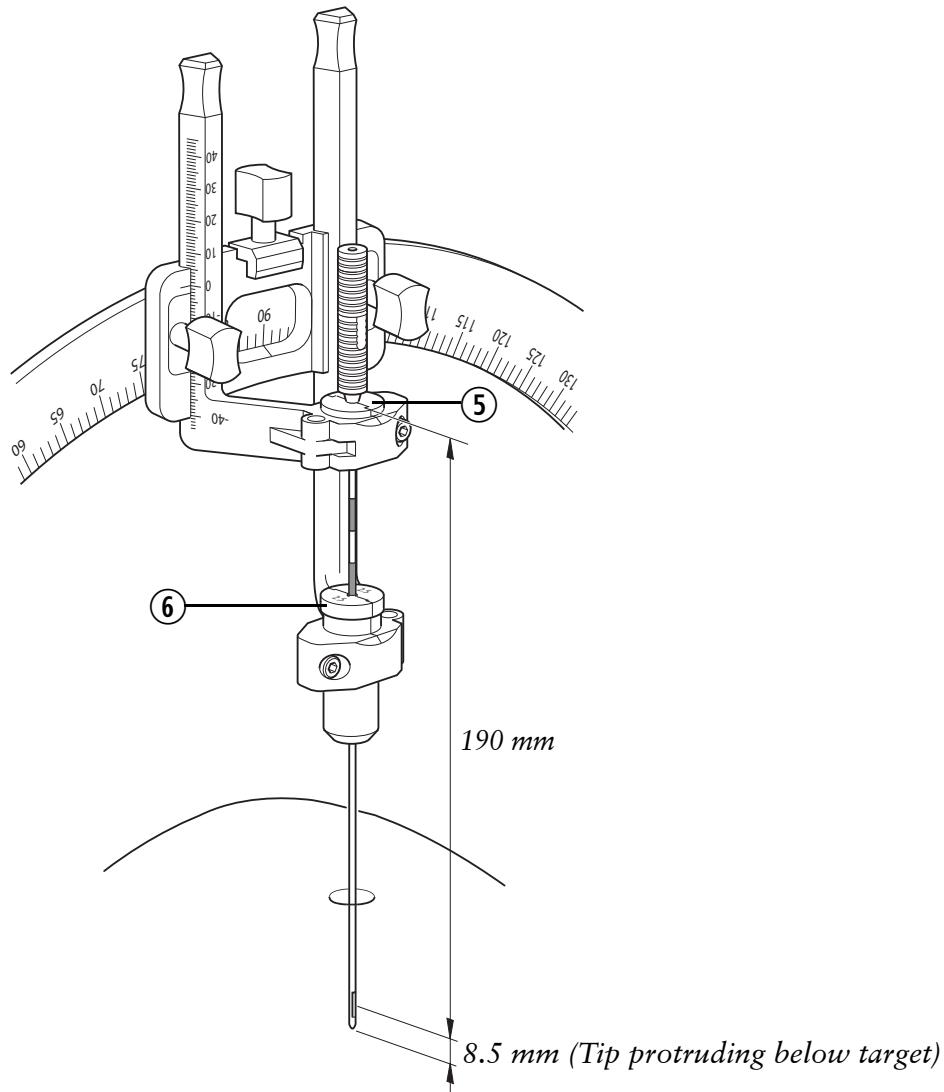
This ensures that the cutting window ③ is closed during the insertion of the instrument.



WARNING 5.27

When inserting or removing the surgical instrument into/from the patient's brain, the inner cannula must be fully inserted into the outer cannula and the cutting window must be closed. Otherwise the patient can be injured.

- 3 Insert the assembled needle through the stop insert ⑤ and guide insert ⑥ and into the patient's brain until it is arrested by the stop insert. This places the center of the cutting window at the selected target.



- The working length of the instrument is 190 mm, i.e. the target position is at the center of the cutting window.
- The tip of the instrument protrudes 8.5 mm below the target.

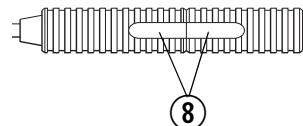


WARNING 5.28

When planning a treatment beware that the surgical instrument protrudes 8.5 mm below the target. Otherwise the patient can be injured.

The centimeter markings on the outer cannula assist in estimating the remaining distance to the target area.

- 4 Open the cutting window by turning the inner cannula 180° so that the marks ⑧ on the proximal ends of the cannulas are aligned.



- 5 Connect a 10 ml syringe to the inner cannula and apply vacuum to the system by suction.



WARNING 5.29

Suction must be performed by hand. Do not connect a suction apparatus to the cannula. Otherwise the patient can be injured.

Note: *The amount of tissue obtained will depend on the amount of vacuum applied to the inner cannula. This will vary according to the surgeon's preference and to the density of the tissue.*

- 6 During continued suction, turn the inner cannula through 180° to close the cutting window around the specimen.



WARNING 5.30

The outer cannula must not be rotated unless the inner cannula is inserted and the cutting window is closed. Otherwise the patient can be injured.

- 7 Discontinue suction with the syringe.
- 8 Remove the inner cannula from the outer cannula, the latter being kept in position in the brain.
- 9 Remove the specimen from the inner cannula.

Note: *The specimen can be ejected from the inner cannula by injecting a few milliliters of air or saline into the cannula.*

- 10 If anatomically possible, another specimen may be taken at a lower level. Lower the instrument stop holder and repeat steps 3 to 9 to obtain another specimen.
- 11 When a satisfactory specimen has been retrieved, reinsert the inner cannula into the outer cannula and rotate the inner cannula so that the cutting window is closed. Then remove the cannulas together through the stop and guide inserts.



WARNING 5.31

When inserting or removing the surgical instrument into/from the patient's brain, the inner cannula must be fully inserted into the outer cannula and the cutting window must be closed. Otherwise the patient can be injured.

- 12 When the biopsy procedure is completed, immediately rinse the kit in cold water to prevent any remaining blood or tissue drying inside the cannulas.

5.4.3.3 Removal

The procedure for removing the guide and stop inserts is the reverse of the procedure given in [Fitting the stop and guide inserts](#) on page 130.

5.5

Backlund Catheter Insertion Needle Kit

5.5.1

Product overview

The Backlund Catheter Insertion Needle Kit consist of neurosurgical instruments which are used to obtain standardized and safe routines for puncturing intracranial cavities using stereotactic technique.

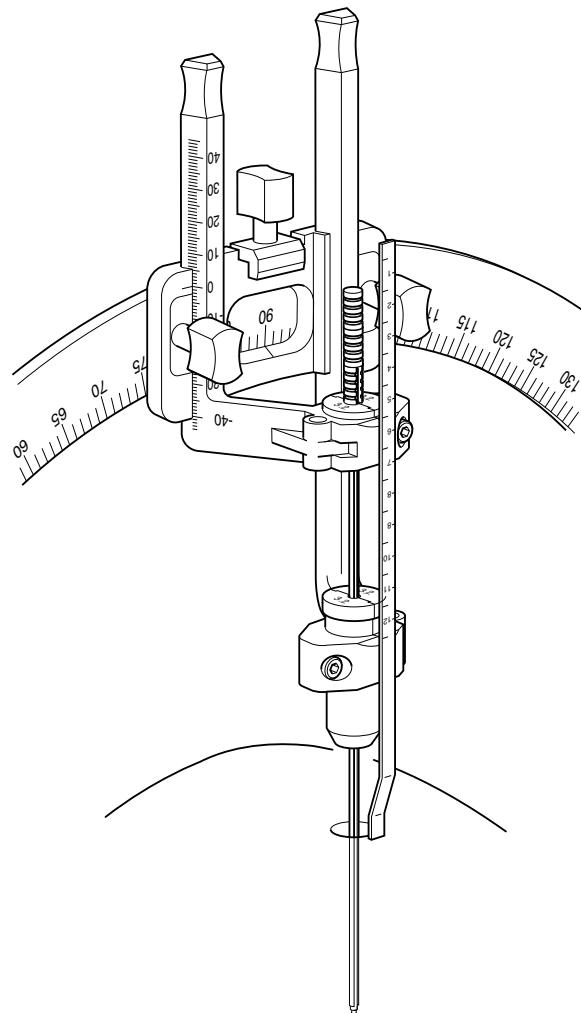


Figure 5.8 A Backlund Catheter Insertion Needle Kit mounted on the stereotactic arc

Two Backlund Catheter Insertion Needle Kits are available to accommodate catheter outer diameters of 1.5 mm (Kit I) and 2.6 mm (Kit III). The kits are referred to as Kit I and Kit III.

The Backlund Catheter Insertion Needle Kits can be used for the following procedures:

- Ventricular shunting/drainage when the width of the ventricles does not allow a completely safe freehand approach.
- Introduction of guides, in conjunction with stereotactic biopsy, to establish the most direct approach route into deeply located structures.
- Abscess drainage.

5.5.2

Main parts

Refer to [Figure 5.9](#).

The **slotted outer cannula** ① has an open slot along its length which allows it to be withdrawn after insertion of the catheter. The **inner cannula** ② fits into the slotted outer cannula and allows fluid to be drained from the target area when appropriate. With the cannulas ① and ② combined, the working length is 190 mm, as indicated in [Figure 5.9](#). The knob of the inner cannula is equipped with a **Luer type conical fitting** ③ to facilitate aspiration. The **stylet** ④ is used to seal the inner cannula during insertion into the patient's brain.

The **ruler** ⑤ is used to measure the depth of insertion of the instrument into the patient's skull, in order to determine the length of the catheter required. It is engraved with a scale graduated at 1 mm intervals. The end of the ruler which rests on the patient's skull is offset so as to clear the edges of the wound.

The **guide insert** ⑥ and **stop insert** ⑦ are fitted onto the stereotactic arc to guide the surgical instrument to the target position. The stop insert sets the limit of instrument insertion to the appropriate target depth. The guide insert ensures that the instrument follows a straight trajectory to the target. Both inserts are separable into two pieces. Each insert is specific to one instrument size and can be identified by the diameter marking engraved on the top surface;

- **Kit I:** the marking is “**2.1**”.
- **Kit III:** the marking is “**3.5**”.

The working length of the instrument is 190 mm. The tip of the instrument protrudes below the target, see [Figure 5.9](#) and refer to [Section 5.2](#);

- Kit I: the tip protrudes 1 mm below the target.
- Kit III: the tip protrudes 1.5 mm below the target.

All the components of the Backlund Catheter Insertion Needle Kits are made of stainless steel, except the stop and guide inserts which are plastic and the ruler which is aluminum.

A sterilization tray (not shown) is provided to house the kit during sterilization and for storage.

This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.



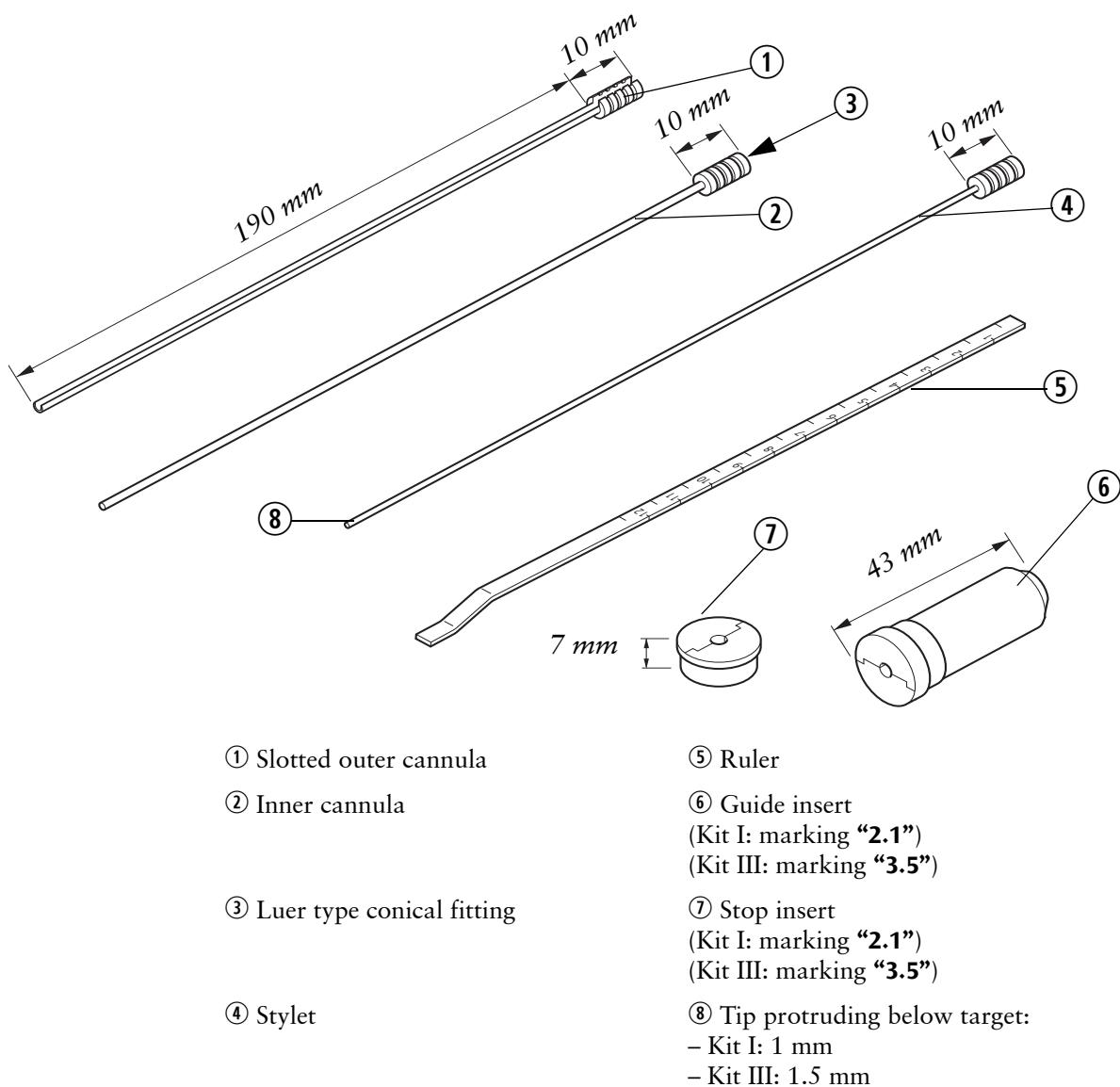


Figure 5.9 Main parts of a Backlund Catheter Insertion Needle Kit

5.5.3 Using the Backlund Catheter Insertion Needle Kit

5.5.3.1 Fitting instructions

Preparation

Inspect all components regarding functionality before use.

The following instructions assume that:

- The coordinate frame is attached to the patient's head.
- The stereotactic arc is fitted to the coordinate frame and the X, Y and Z coordinates have been set on the stereotactic arc according to the patient's treatment protocol after preoperative examination and target localization
- The burr hole has been prepared.
- The Backlund Catheter Insertion Needle Kit is clean, sterilized, and at hand.

Refer to [Section 4.2 on page 89](#) for more information on the attachment and setting procedures.

Fitting the stop and guide inserts

Fit the stop and guide inserts as described on [page 130](#).

WARNING 5.32



Always use the appropriate stop and guide inserts corresponding to the diameter of the surgical instrument. Before operation, check and make sure that the surgical instrument fits the stop and guide inserts. Otherwise the patient can be injured and the surgical instruments can be damaged.

5.5.3.2 Operating procedure

WARNING 5.33



Always check that the instrument stop holder is set to the appropriate position before performing any surgical procedure to avoid injury to the patient or incorrect treatment.

WARNING 5.34



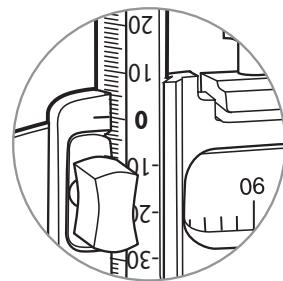
The open slot along the slotted outer cannula must be checked for deformation prior to each use. Deformation of the slot on the slotted outer cannula can injure the patient.

WARNING 5.35

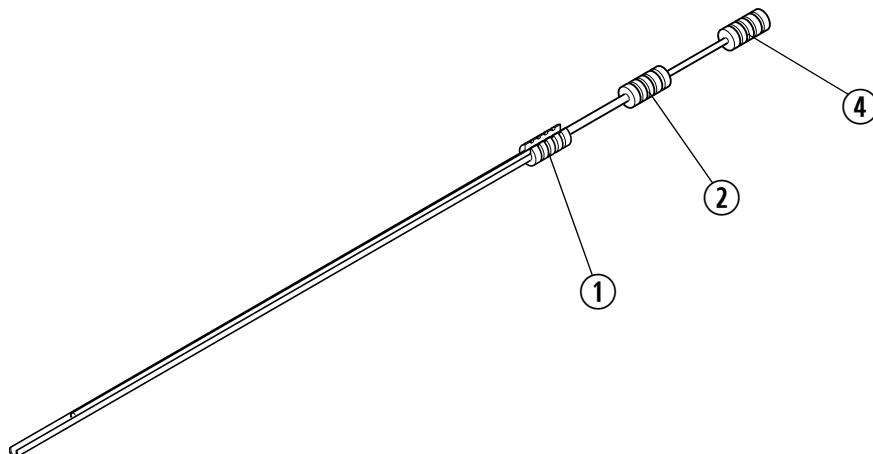


The tip of the cannula must be checked for deformation prior to each use. A deformed tip can injure the patient.

- 1 Ensure that the instrument stop holder is set to the appropriate position.
Setting the instrument stop holder to the zero position makes the tip of the inner cannula reach the target area.



- 2 Insert the inner cannula ② into the slotted outer cannula ①.
- 3 Insert the stylet ④ into the inner cannula ②.

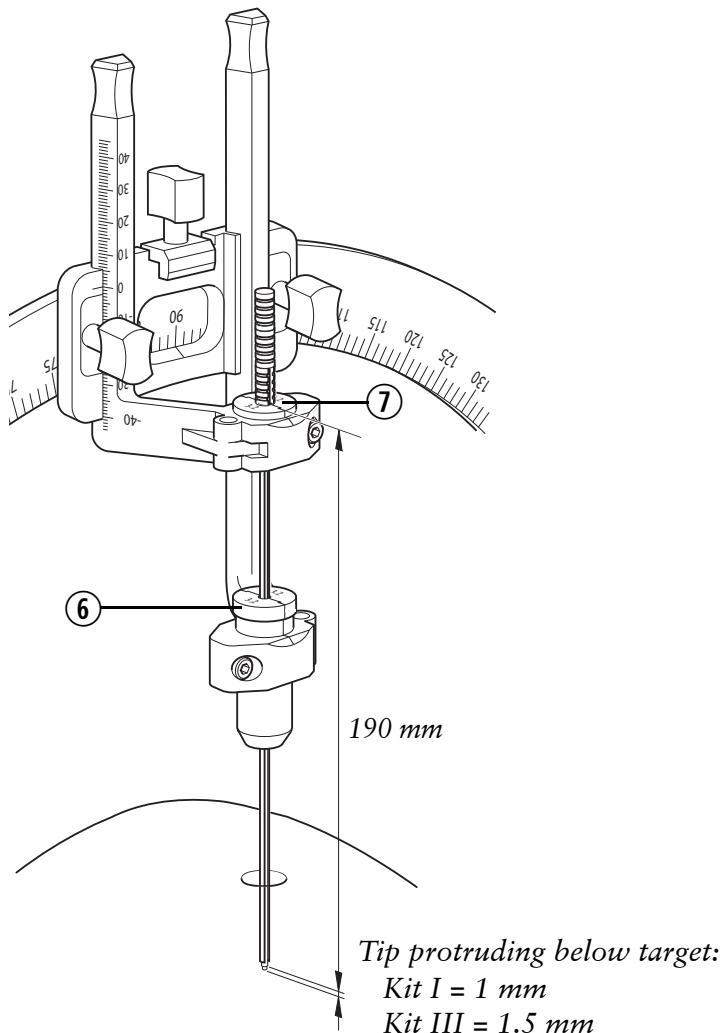


WARNING 5.36



The stylet and inner cannula must be inserted into the outer cannula before the slotted outer cannula is inserted into the patient's brain. Otherwise the patient can be injured.

- 4 Insert the assembled instrument through the stop insert ⑦ and guide insert ⑥ and into the patient's brain until it is arrested by the stop insert. The tip of the inner cannula is now at the selected target.



- The working length of the instrument is 190 mm.
- The tip of the instrument protrudes below the target:
 - Kit I = 1 mm
 - Kit III = 1.5 mm



WARNING 5.37

The slotted outer cannula must not be rotated while positioned in the patient's brain. Otherwise the patient can be injured.

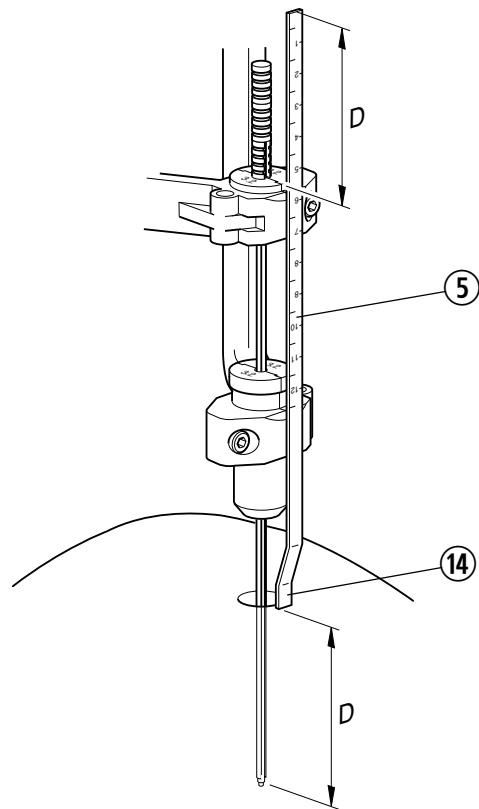


WARNING 5.38

When planning a treatment beware that the surgical instrument protrudes 1 mm below the target in Kit I, and 1.5 mm below the target in Kit III. Otherwise the patient can be injured.

5 Use the ruler ⑤ to measure the depth of insertion (D) into the patient's brain:

- Place the offset end ⑯ of the ruler on the surface of the skull adjacent to the burr hole so that the body of the ruler is close to and parallel with the instrument.
- The reading at the top surface of the stop insert equals to D.

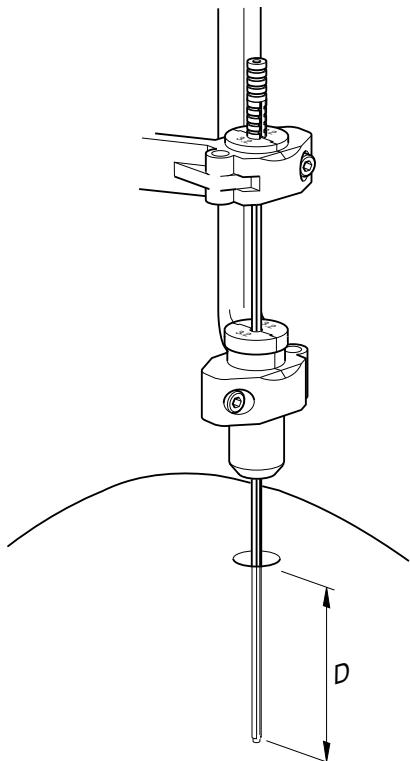


On the following pages two examples of the use of the Backlund Catheter Insertion Needle Kits are given.

Inserting a drainage into an abscess cavity

In this example the aim is to have the outer end of the catheter open for irrigation.

- 1 Prepare the catheter by cutting it to the length (D) measured in step 5 on [page 148](#).
- 2 Withdraw the stylet from the inner cannula to allow flow of the abscess contents through the inner cannula verifying that the abscess cavity has been safely reached.



- 3 Remove the inner cannula and exchange it with the pre-cut catheter without delay.

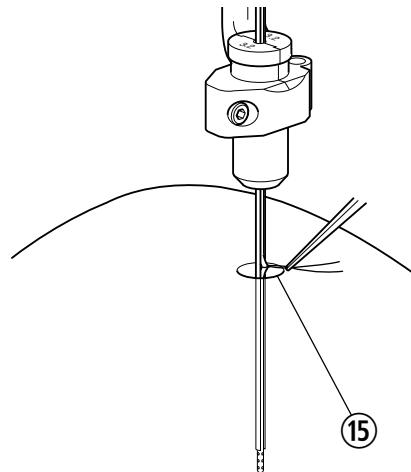
To avoid unnecessary escape of pus and thus collapse of the abscess before the drain is introduced, the inner cannula must be exchanged for the pre-cut catheter without delay.

- 4 Insert the pre-cut catheter into the slotted outer cannula until its proximal end is level with the skin surface.
- 5 Hold the catheter in position close to the burr hole using a small hook or other appropriate instrument. While holding the catheter in position, withdraw the slotted outer cannula. The slot allows this maneuver to be performed without changing the position of the catheter.

Ventricular shunting/drainage

During shunt procedures or when a ventricular drain is installed, a catheter of greater length than the instrument may be required.

- 1 Prepare the catheter by tying on a ligature ⑯ at the length measured in step 5 on [page 148](#).
- 2 Withdraw the stylet and inner cannula as described in steps 2 to 3 on [page 149](#).
- 3 Insert the catheter into the slotted outer cannula until the ligature ⑯ is level with the skin surface.
- 4 Use the ligature ⑯ to hold the catheter in position while withdrawing the slotted outer cannula.



5.5.3.3 Removal

The procedure for removing the guide and stop inserts is the reverse of the procedure given in [Fitting the stop and guide inserts](#) on [page 130](#).

5.6

Backlund Haematoma Evacuator Kit

5.6.1

Product overview

The Backlund Haematoma Evacuator Kit consists of a neurosurgical instrument which allow the evacuation of haematomas through a single burr hole using stereotactic techniques.

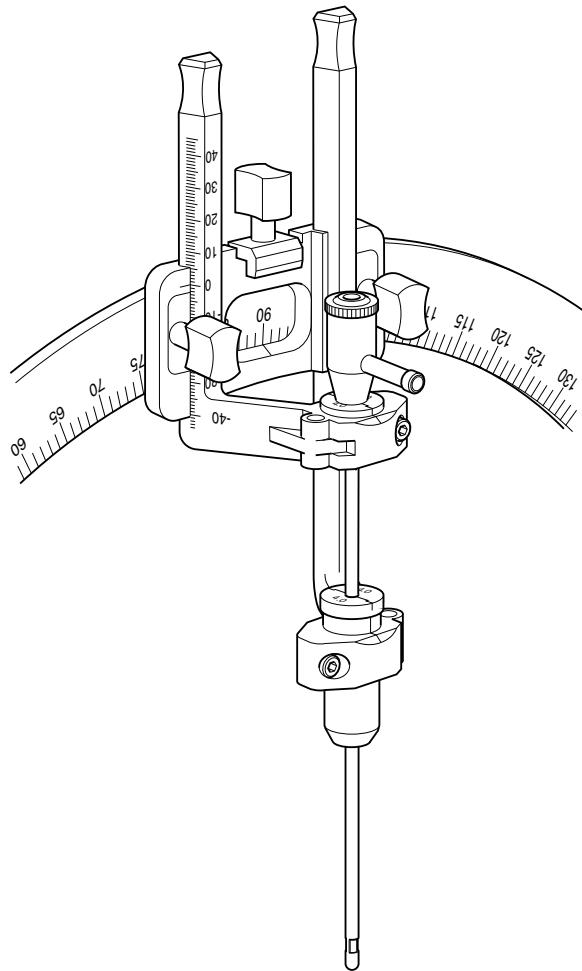


Figure 5.10 The Backlund Haematoma Evacuator Kit mounted on the stereotactic arc

5.6.2

Main parts

Refer to [Figure 5.11](#).

The **cannula** ① encloses an archimedian type **feed screw** ② (not shown). The feed screw is secured in place in the cannula by a **nut** ③. Close to the tip of the cannula there are two **openings** ④, 4 mm long, which allow collection of material from the target site.

The **drill driver** ⑤ is used to manually rotate the feed screw. It connects to the feed screw through a **hole** ⑥ (not shown) in the top of the cannula where a water/airtight seal, comprising an O-ring and washer, maintains any vacuum applied to the instrument. The **branching tube** ⑦ allows suction to be applied by means of a hand operated syringe. Material is moved up the cannula by a combination of rotation of the feed screw's spiral screw and the application of suction.

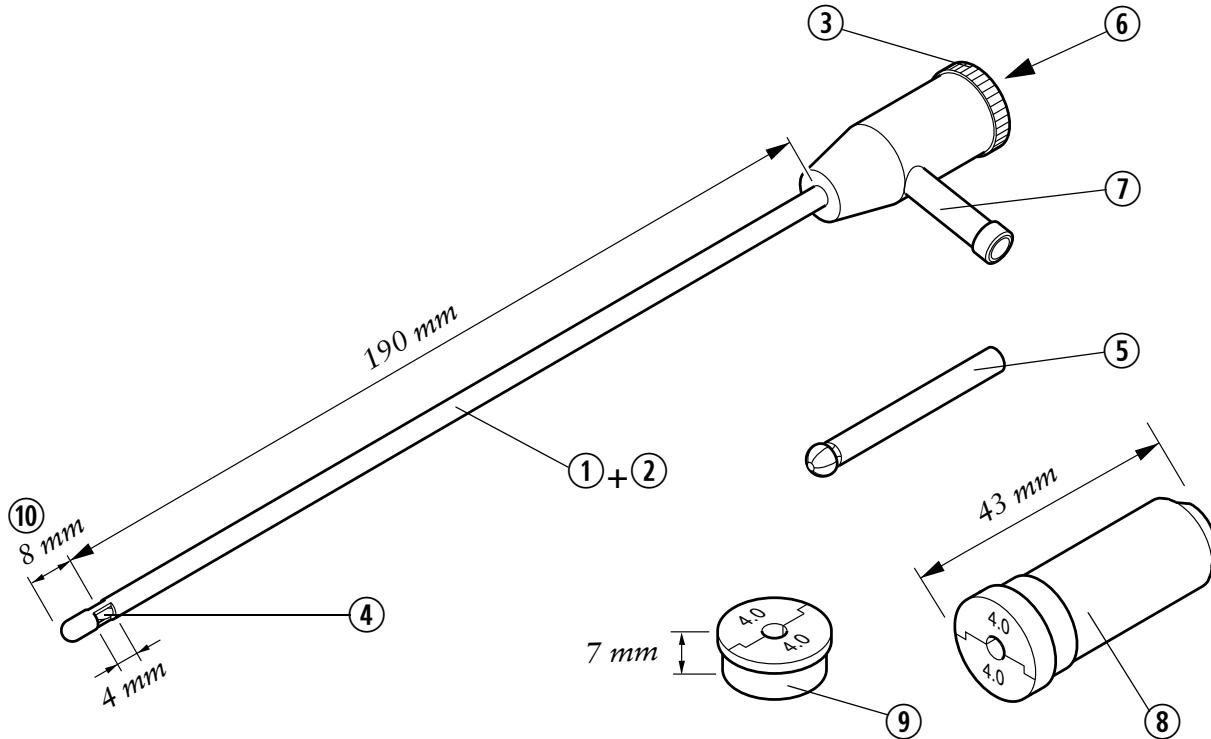
The **guide insert** ⑧ and **stop insert** ⑨ are fitted onto the stereotactic arc to guide the surgical instrument to the target position. The stop insert sets the limit of instrument insertion to the appropriate target depth. The guide insert ensures that the instrument follows a straight trajectory to the target. Both inserts are separable into two pieces. Each insert is specific to one instrument size and can be identified by the engraved marking on the top surface.

The working length of the instrument is 190 mm. The tip of the instrument protrudes 8 mm below the target. See [Figure 5.11](#) and refer to [Section 5.2](#).

A sterilization tray (not shown) is provided to house the evacuator kit during sterilization and for storage.

The stop and guide inserts are made of plastic. The O-ring is made of rubber and the washer from plastic. All other parts are made of stainless steel.

This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.



- | | |
|----------------|--------------------------------------|
| ① Cannula | ⑥ Hole |
| ② Feed screw | ⑦ Branching tube |
| ③ Nut | ⑧ Guide insert (marking “4.0”) |
| ④ Openings | ⑨ Stop insert (marking “4.0”) |
| ⑤ Drill driver | ⑩ Tip protruding below target = 8 mm |

Figure 5.11 Main parts of the Backlund Haematoma Evacuator Kit

5.6.3 Using the Backlund Haematoma Evacuator Kit

5.6.3.1 Fitting instructions

Preparation

Inspect all components regarding functionality before use.

The following instructions assume that:

- The coordinate frame is attached to the patient's head.
- The stereotactic arc is fitted to the coordinate frame and the X, Y and Z coordinates have been set on the stereotactic arc according to the patient's treatment protocol after preoperative examination and target localization.
- The burr hole has been prepared.
- The Backlund Haematoma Evacuator Kit is clean, sterilized, and at hand.

Refer to [Section 4.2 on page 89](#) for more information on the attachment and setting procedures.

Fitting the stop and guide inserts

Fit the stop and guide inserts as described on [page 130](#).

WARNING 5.39



Always use the appropriate stop and guide inserts corresponding to the diameter of the surgical instrument. Before operation, check and make sure that the surgical instrument fits the stop and guide inserts. Otherwise the patient can be injured and the surgical instruments can be damaged.

5.6.3.2 Operating procedure

WARNING 5.40



When planning a treatment beware that the surgical instrument protrudes 8 mm below the target. Otherwise the patient can be injured.

WARNING 5.41



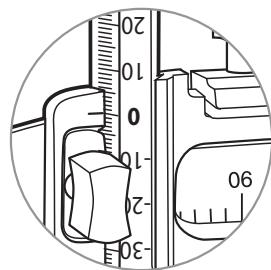
Always check that the instrument stop holder is set to the appropriate position before performing any surgical procedure to avoid injury to the patient or incorrect treatment.

WARNING 5.42

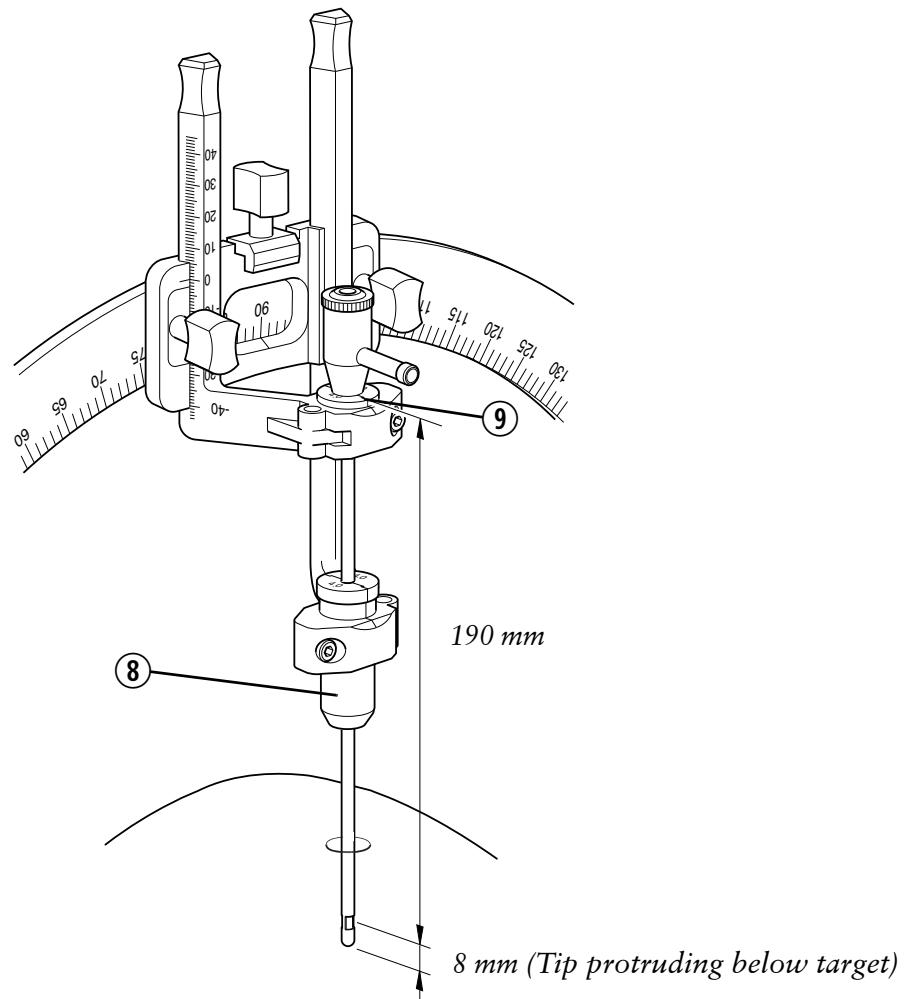


The tip of the cannula must be checked for deformation prior to each use. A deformed tip can injure the patient.

- 1 Ensure that the instrument stop holder is set to the appropriate position.
Setting the instrument stop holder to the zero position makes the openings of the cannula reach the target area.



- 2 Insert the feed screw ② into the cannula ① and secure it in position by tightening the nut ③ by hand.
- 3 Attach the drill driver ⑤ to the chuck of any hand drill device. Check that the drill driver can rotate the feed screw correctly.
- 4 Insert the assembled instrument through the stop insert ⑨ and guide insert ⑧ and into the patient's brain until it is arrested by the stop insert.

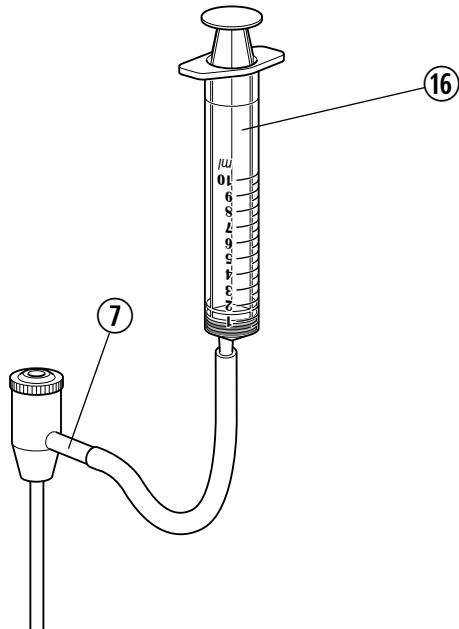


- The working length of the instrument is 190 mm, i.e. the target position is at the center of the openings.
- The tip of the instrument protrudes 8 mm below the target.

**WARNING 5.43**

When planning a treatment beware that the surgical instrument protrudes 8 mm below the target. Otherwise the patient can be injured.

- 5 Apply suction to the instrument by means of a 10 ml capacity syringe ⑯. Connect the syringe to the branching tube ⑦ on the instrument using suitable tubing.

**WARNING 5.44**

Suction must be performed by hand. Do not connect a suction apparatus to the cannula. Otherwise the patient can be injured.

- 6 Aspire the haematomaous mass by rotating the feed screw while an assistant applies suction with the syringe ⑯.
- 7 After aspiration is completed, remove the nut ③ from the proximal end of the instrument and withdraw the feed screw ②.
- 8 Leave the cannula ① in position for a period to allow observation of any further bleeding.

5.6.3.3

Removal and disassembly

To remove the evacuator kit, remove the cannula from the patient's brain.

The procedure for removing the guide and stop inserts from the stereotactic arc is the reverse of the procedure given in *Fitting the stop and guide inserts* on page 130.

Disassembly for cleaning and sterilization

To ensure that the evacuator kit is cleaned and sterilized correctly, it must be dismantled in the following order and placed in the sterilization tray.

- 1 Remove the drill driver ⑤ from the evacuator kit.
- 2 Unscrew the nut ③.
- 3 Withdraw the feed screw ② from the cannula ①.
- 4 Remove the washer.

5.7 Insertion Cannula Kit

5.7.1 Product overview

The Insertion Cannula Kit L=190 / D=1.6 mm kit consists of neurosurgical instruments which are used to obtain safe guidance of implants, e.g. electrodes or catheters using stereotactic technique.

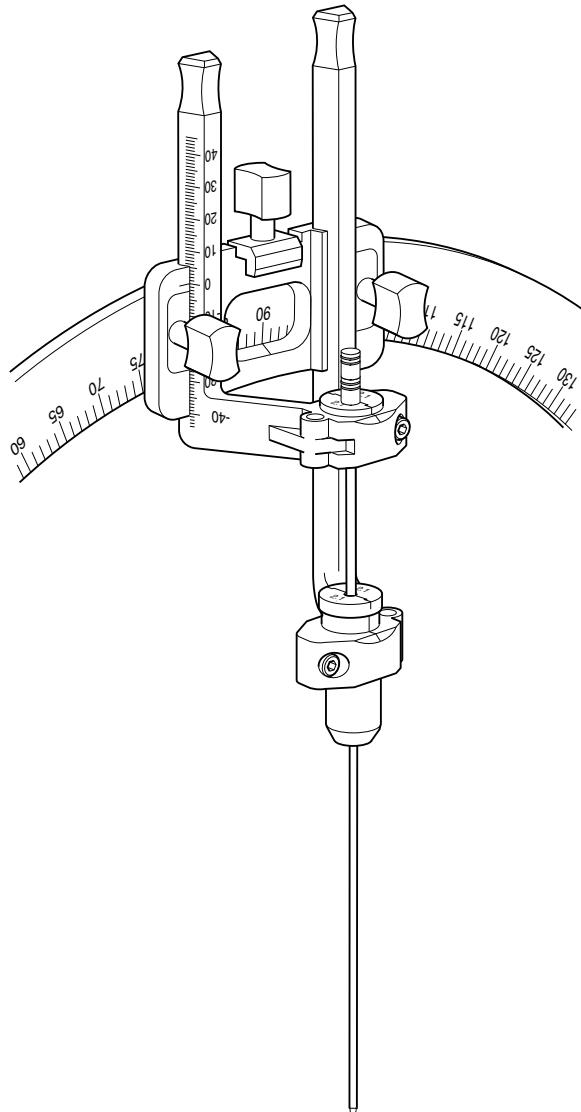


Figure 5.12 The Insertion Cannula Kit mounted on the stereotactic arc

5.7.2**Main parts**

Refer to [Figure 5.13](#).

The **cannula** ① and the **stylet** ② has a working length of 190 mm. Both the cannula and the stylet have a flat surface on the side of the knob (with engravings). The stylet is used to seal the cannula during insertion into the patient's brain. For easy identification, both the cannula and the stylet are marked with the working length and the inner diameter of the cannula, i.e. 190/1.6 (mm).

The **guide insert** ③ and **stop insert** ④ are fitted onto the stereotactic arc to guide the surgical instrument to the target position. The stop insert sets the limit of instrument insertion to the appropriate target depth. The guide insert ensures that the instrument follows a straight trajectory to the target. Both inserts are separable into two pieces. Each insert is specific to one instrument size and can be identified by the engraved marking on the top surface.

The working length of the instrument is 190 mm. The tip of the instrument protrudes 1.5 mm below the target. See [Figure 5.13](#) and refer to [Section 5.2](#).

The components of the kit are made of stainless steel, except the stop and guide inserts which are plastic.

A sterilization tray (not shown) is provided to house the kit during sterilization and for storage.

This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.

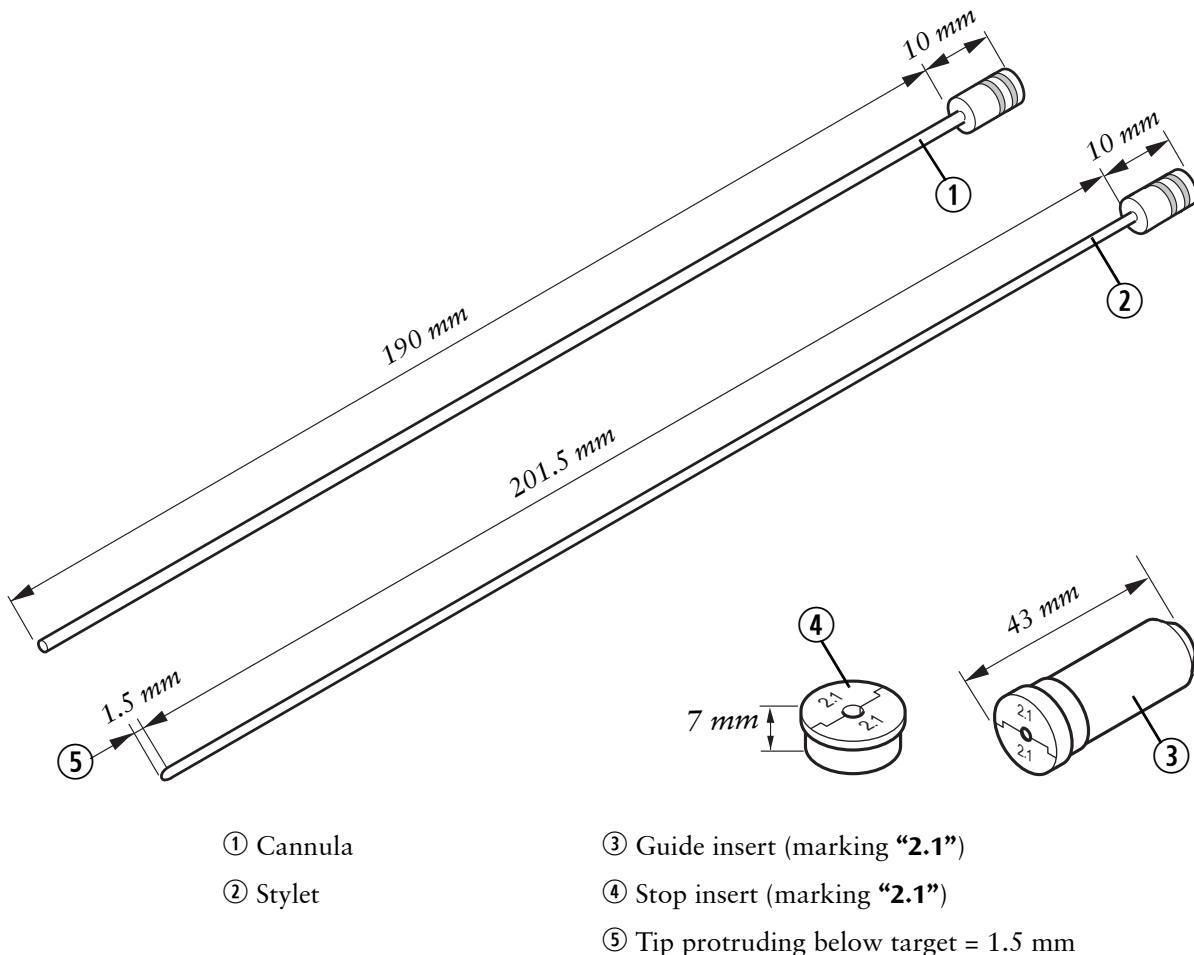


Figure 5.13 Main parts of the Insertion Cannula Kit

5.7.3 Using the Insertion Cannula Kit

5.7.3.1 Fitting instructions

Preparation

Inspect all components regarding functionality before use.

The following instructions assume that:

- The coordinate frame is attached to the patient's head.
- The stereotactic arc is fitted to the coordinate frame and the X, Y and Z coordinates have been set on the stereotactic arc according to the patient's treatment protocol after preoperative examination and target localization.
- The burr hole has been prepared.
- The Insertion Cannula Kit is clean, sterilized, and at hand.

Refer to [Section 4.2 on page 89](#) for more information on the attachment and setting procedures.

Fitting the stop and guide inserts

Fit the stop and guide inserts as described on [page 130](#).

WARNING 5.45



Always use the appropriate stop and guide inserts corresponding to the diameter of the surgical instrument. Before operation, check and make sure that the surgical instrument fits the stop and guide inserts. Otherwise the patient can be injured and the surgical instruments can be damaged.

5.7.3.2 Operating procedure

WARNING 5.46



Always check that the instrument stop holder is set to the appropriate position before performing any surgical procedure to avoid injury to the patient or incorrect treatment.

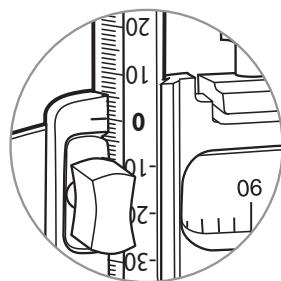
WARNING 5.47



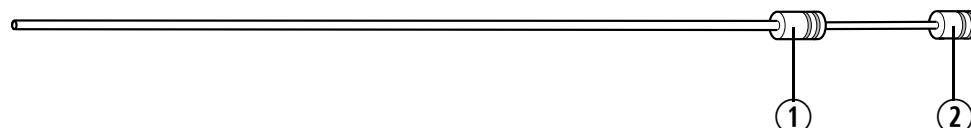
The tip of the cannula must be checked for deformation prior to each use. A deformed tip can injure the patient.

Insertion Cannula Kit

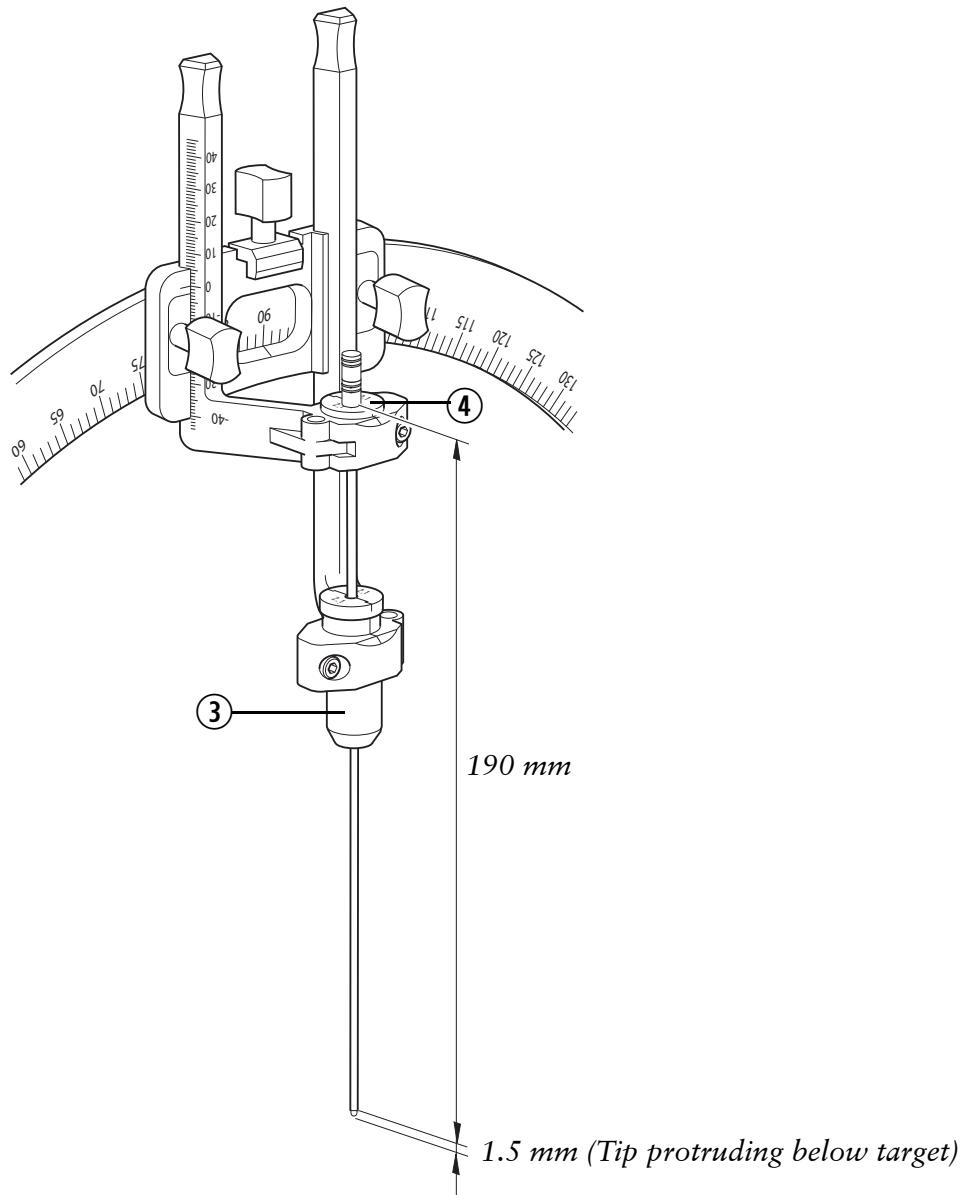
- 1 Ensure that the instrument stop holder is set to the appropriate position.
Setting the instrument stop holder to the zero position makes the tip of the cannula reach the target area.



- 2 Insert the stylet ② into the cannula ①.



- 3 Insert the assembled instrument (①+②) through the stop insert ④ and guide insert ③ and into the patient's brain until it is arrested by the stop insert.



- The working length of the instrument is 190 mm.
- The tip of the instrument protrudes 1.5 mm below the target.



WARNING 5.48

The stylet must be inserted into the cannula before the cannula is inserted into the patient's brain. Otherwise the patient can be injured.



WARNING 5.49

When planning a treatment beware that the surgical instrument protrudes 1.5 mm below the target. Otherwise the patient can be injured.

- 4 Remove the stylet ② and insert the catheter, electrode or other device through the cannula ①.

5.7.3.3

Removal

To remove the kit, remove the cannula from the patient's head.

The procedure for removing the guide and stop inserts is the reverse of the procedure given in *Fitting the stop and guide inserts* on page 130.

6

Localization accessories for CT, MR and X-Ray

This chapter describes the following products:

CT accessories

- Open CT Indicator, [Section 6.2 on page 165](#)
- CT Adapter and Table Fixations, [Section 6.3 on page 173](#)

MR accessories

- MR Indicator, [Section 6.4 on page 191](#)
- Open MR Indicator, [Section 6.5 on page 204](#)
- MR Adapters, [Section 6.6 on page 213](#)
- MR Phantom, [Section 6.7 on page 225](#)

X-Ray accessories

- X-Ray Indicator with Markers, [Section 6.8 on page 233](#)
- X-Ray Indicator with Rulers, [Section 6.9 on page 242](#)
- X-Ray Table Fixations, [Section 6.10 on page 249](#)

6.1

General warnings and notes

These warnings apply to the usage of all products included in this chapter.

WARNING 6.1



The equipment must only be used with Leksell Stereotactic System® or specified instruments. Usage with other systems can cause inaccurate treatment and patient injury.

WARNING 6.2



Handle all Elekta equipment with care. Any damage, however slight, can reduce treatment safety and accuracy. Inspect the equipment before clinical use. If you suspect that any part is damaged, contact Elekta immediately. Do not use damaged equipment for any purpose until authorized to do so by Elekta.

WARNING 6.3



Exercise extreme caution at all times to ensure that the coordinate frame does not move on the patient's skull. If the coordinate frame is displaced, all treatment planning based on the coordinate frame position is invalid.

WARNING 6.4



Do not sterilize the equipment. If sterilized, it can be damaged.

WARNING 6.5



**Do not use excessive force when tightening locking screws/knobs.
Otherwise parts can be damaged and not permit secure fixation.
Non-secure fixation can cause incorrect treatment.**

WARNING 6.6



Conditions for use in MRI:

- Only for use in 1.5 T or 3 T with RF transmit head or body coil.**
- Always use the insulated fixation posts. Otherwise there is a risk of temperature increase at the tip of the fixation screws.**
- Non-insulated fixation posts are contraindicated (MR Unsafe).**

Note:

All other fixation posts than the “Insulated Fixation Posts” are defined as non-insulated.

WARNING 6.7



Do not bring any tools (ferromagnetic objects) into the MRI area since these could be attracted by the magnet and become projectiles and injure the patient or operator.

WARNING 6.8



Do not bring any MR Unsafe products into the MRI area since it may be affected by the magnetic field or cause artifacts in the images.

6.2 Open CT Indicator

6.2.1 Product overview

The Open CT Indicator is an accessory for target localization in stereotactic neurosurgery, stereotactic radiosurgery, and stereotactic radiation therapy. It is used in conjunction with Leksell® Coordinate Frame G and the CT Adapter. It can also be used with the Elekta Esarte™ Frame.

Note: In this section, the term “indicator” refers to the Open CT Indicator.

The purpose of the indicator is to impose fiducials on images of the patient acquired during CT scanning. The fiducials are used for determining target coordinates and for slice alignment by treatment planning software.

The indicator has a marker system designed to ensure that fiducials are visible on the CT images. Usually three sets of fiducials are imposed, with three separate fiducials in each set. The locations of the fiducial sets on an image show the relative position of the patient’s skull in stereotactic space. The distance between the center fiducial and the other two fiducials in each set is indicative of the image slice position.

The principle is illustrated in [Figure 6.1](#), which shows typical fiducials resulting from an axial scan.

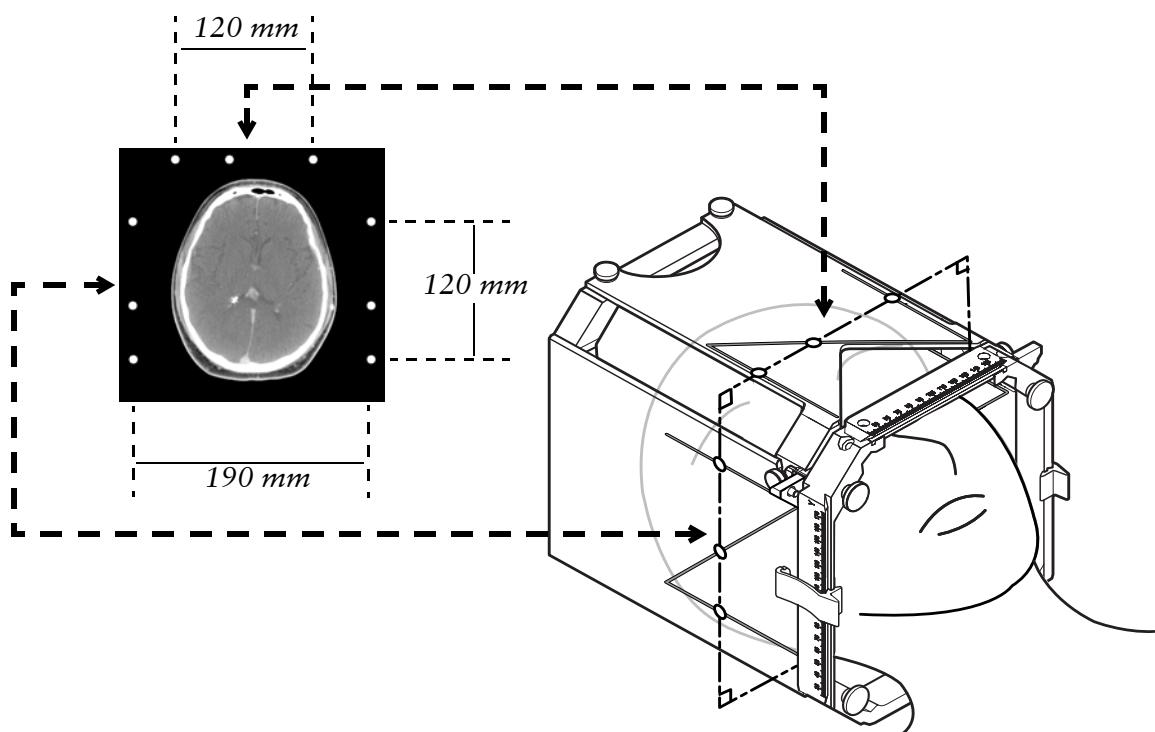


Figure 6.1 Principle of the Open CT Indicator.

6.2.2

Main parts

Refer to [Figure 6.2](#).

The indicator consists of three panels and a top, all made of plastic (PMMA – Polymethyl methacrylate):

- **Side panels right** ① and **left** ②, labelled **RIGHT** and **LEFT**. They mirror each other in appearance.
- The **anterior panel** ③, labelled **ANTERIOR**.
- The **indicator top** ④ holding the three panels together.

The anterior and side panels have embedded **linear markers** ⑤ of X-ray dense material. The lines form an N-shape, which imposes the fiducials on the images during the CT scan.

These panels also have **horizontal grooves** ⑥ corresponding to the midplane of Leksell Coordinate System®. The grooves are used for perpendicular alignment of the indicator in the CT scanner.

The function of the indicator top is to hold the anterior and side panels rigidly when assembled. There are pins on the inside of the left and right side panels. When assembling the indicator these pins fit into corresponding holes in the indicator top.

Screws ⑦ secure the side panels to the indicator top. There are four screws for each side panel. The anterior edges of the side panels have open-ended, countersunk slots for attachment of the anterior panel.

The lateral edges of the anterior panel and the anterior side of the indicator top have threaded holes for the four **fixing screws** ⑧ that secure the anterior panel to the side panels and the indicator top. The superior edge of the anterior panel has open-ended, countersunk slots for attachment to the indicator top. The anterior panel has a cutaway to permit access to the patient's airways.

At each inferior corner of both side panels there are right-angled brackets, from which **locating pins** ⑨, ⑩ and ⑪ protrude. When fitting the indicator to Leksell® Coordinate Frame G, the locating pins ⑨ and ⑩ locate into corresponding holes in the corners of the coordinate frame. To prevent incorrect fitting, the left anterior locating pin ⑩ is of a larger diameter than the other three locating pins ⑨. Locating pin ⑪ is only used when fitting the indicator to the Elekta Esarte™ Frame.

Two **attachment clips** ⑫ secure the assembled indicator to the coordinate frame.

This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.



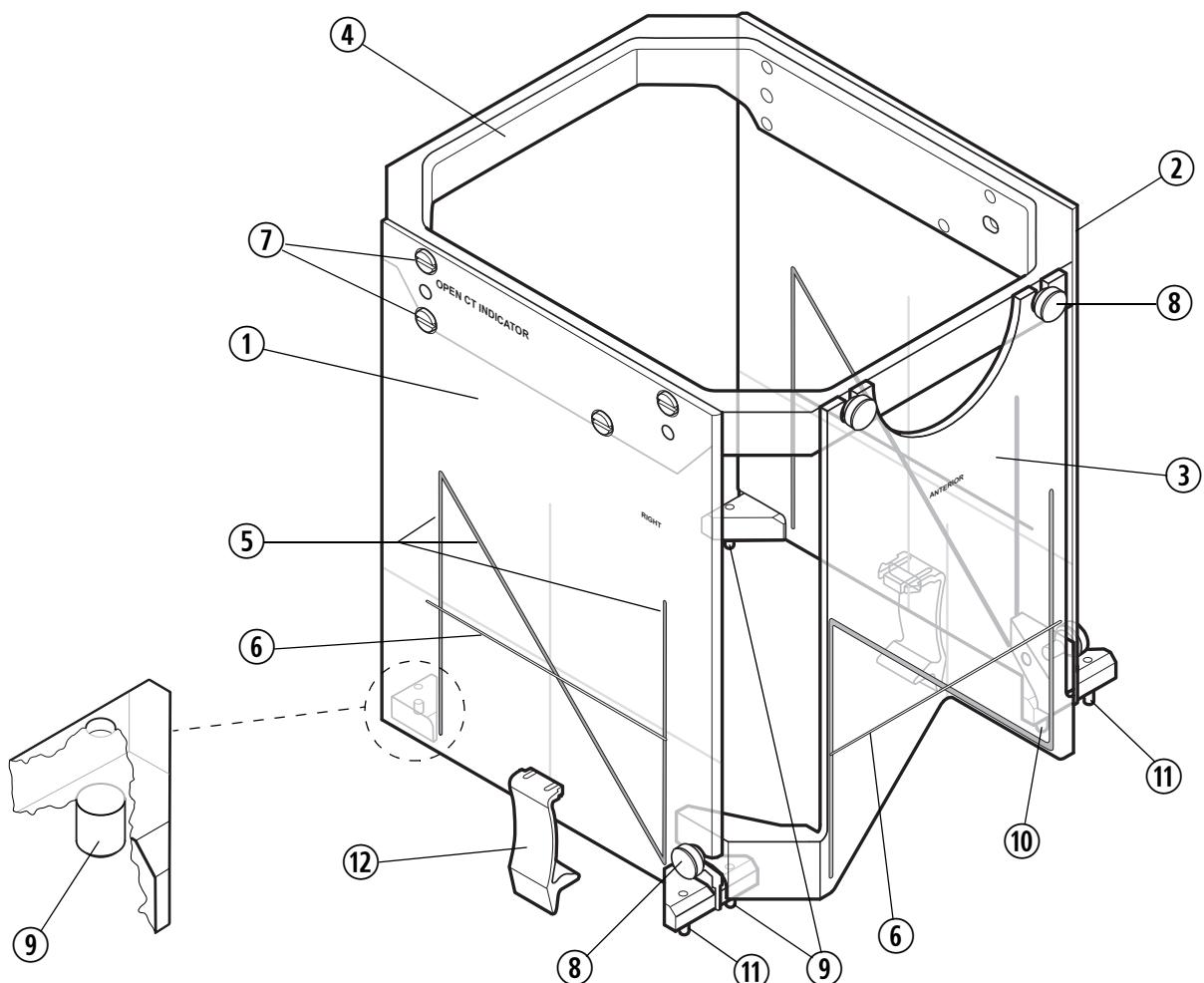
6.2.2.1

Labels

Some parts have engraved labels. See [Table 6.1](#) for details, and [Section 9.7 on page 288](#) for general label information.

Table 6.1 Labelled parts on the Open CT Indicator

Part	Labels
① Side panel, right	RIGHT
② Side panel, left	LEFT
③ Anterior panel	ANTERIOR



- | | |
|----------------------|-------------------------------|
| ① Side panel, right | ⑦ Screws |
| ② Side panel, left | ⑧ Fixing screws |
| ③ Anterior panel | ⑨ Locating pins |
| ④ Indicator top | ⑩ Locating pin, left anterior |
| ⑤ Linear markers | ⑪ Locating pins |
| ⑥ Horizontal grooves | ⑫ Attachment clips |

Figure 6.2 Main parts of the Open CT Indicator

6.2.3 Using the Open CT Indicator

6.2.3.1 Assembly instructions

Preparation

The indicator is usually attached to the coordinate frame after the coordinate frame has been positioned on the patient. For instructions on preparing the coordinate frame, refer to [Section 3.2 on page 28](#).

Check that all components of the indicator are at hand (see [Figure 6.2](#)) and clean prior to use.

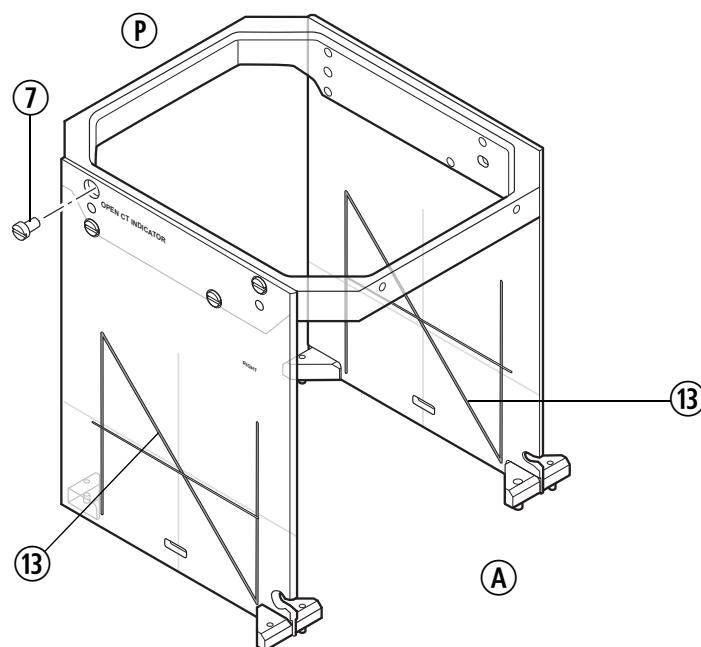
Inspect all components regarding functionality before use.

Assembling the Open CT Indicator

- Using four of the screws ⑦, attach the top edge of one side panel to the corresponding side of the indicator top.

The side panel must be oriented so that the **diagonal marker** ⑩ runs downwards from posterior ⑨ to anterior ⑧. All four screw holes must be aligned to the corresponding holes in the indicator top.

Ensure that the pins protruding from the side panel are correctly inserted into the corresponding holes in the indicator top. Using a screwdriver, tighten the four screws until the side panel is secure.



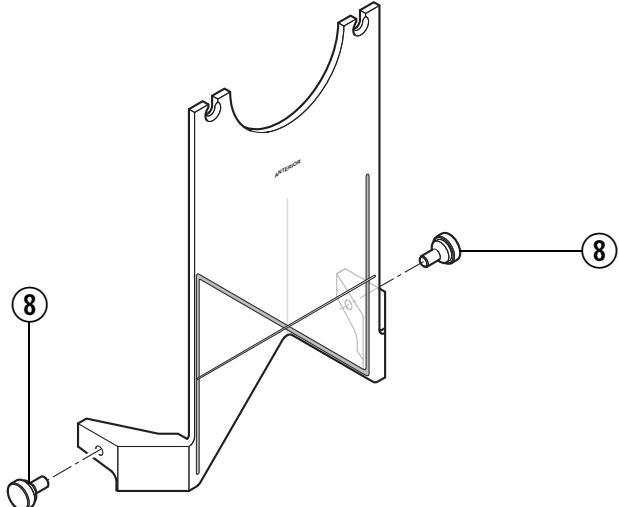
WARNING 6.9



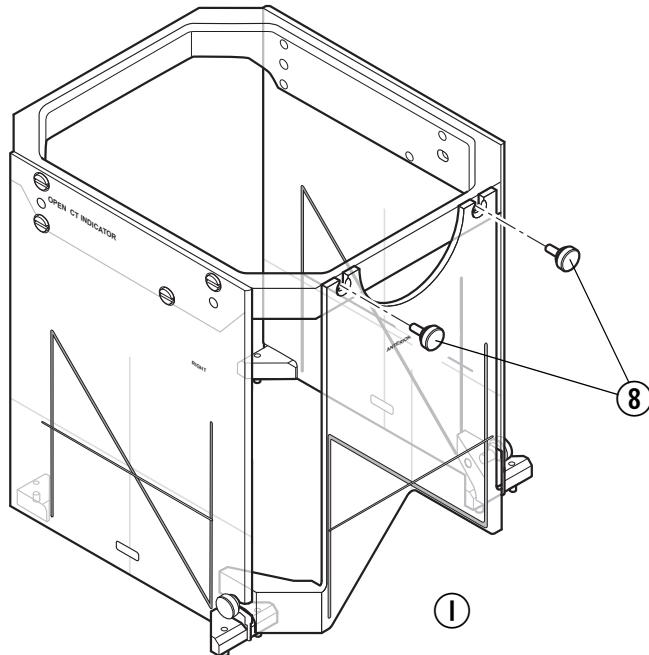
**Do not use excessive force when tightening locking screws/knobs.
Otherwise parts can be damaged and not permit secure fixation.
Non-secure fixation can cause incorrect treatment.**

- Fit the other side panel to the indicator top as described in step 1.

- 3 Loosely insert a fixing screw ⑧ into the hole in each angled bracket of the anterior panel.



- 4 Insert the anterior panel between the side panels. The anterior panel must face outwards, with the angled brackets at the inferior position ①. The two fixing screws must be properly inserted into the countersunk slots of the side panels.
- 5 Insert the two remaining fixing screws ⑧ through the slots at the superior edge of the anterior panel into the holes of the indicator top. The screws must be properly inserted into the countersunk slots.



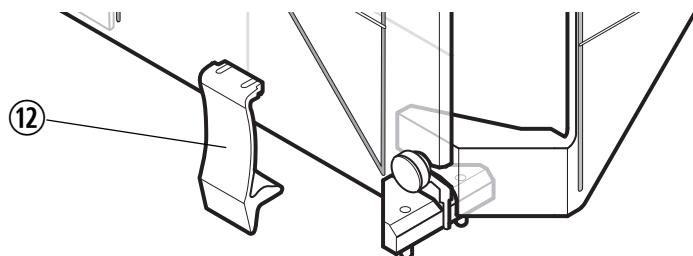
- 6 Secure the anterior panel to the side panels and the indicator top by tightening the four fixing screws. Ensure that the conical portion of each fixing screw is properly seated in the countersunk slot.

Note:

If preferred, the anterior panel can be fitted after the indicator has been fitted to the coordinate frame.

Open CT Indicator

- 7 Insert an attachment clip ⑫ through the slot of each side panel.



The indicator is now ready for attachment to the coordinate frame.

6.2.3.2 Fitting the Open CT Indicator to Leksell® Coordinate Frame G



WARNING 6.10

Support the patient's head at all times when fitting the coordinate frame to, and removing it from, any other equipment. Otherwise the patient can be injured.



WARNING 6.11

The weight of the patient's head must not be supported by the indicator, otherwise the patient can be injured or the indicator can be damaged.



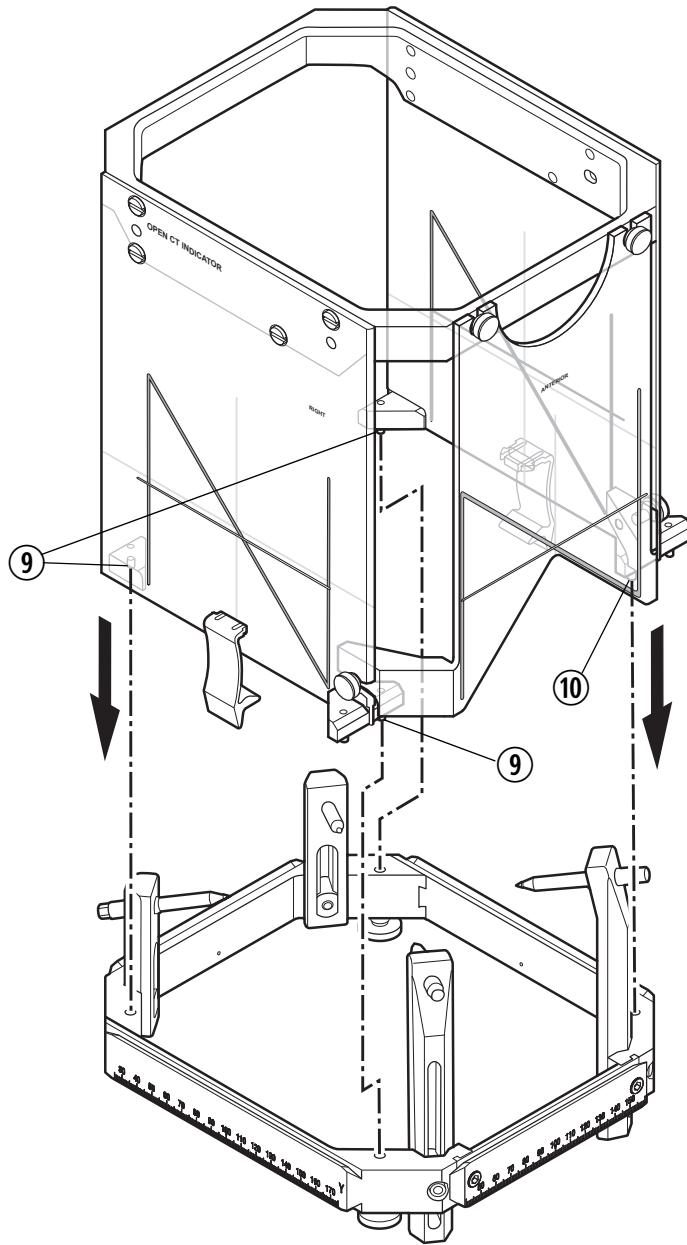
WARNING 6.12

When fitting the indicator to the coordinate frame, ensure that the side panel marked LEFT is on the patient's left side and the side panel marked RIGHT is on the patient's right side.

The indicator can be fitted to Leksell® Coordinate Frame G before or after the coordinate frame has been attached to the patient, although the latter is preferable. The following instructions assume that the coordinate frame has been correctly assembled.

- 1 Align the indicator with the coordinate frame so that the panel labelled **ANTERIOR** is placed above the front piece of the coordinate frame.

- 2 Place the indicator on the coordinate frame by properly inserting the locating pins ⑨ and ⑩ of the indicator into the corresponding holes of the coordinate frame. Ensure that the locating pins are completely inserted into the holes.



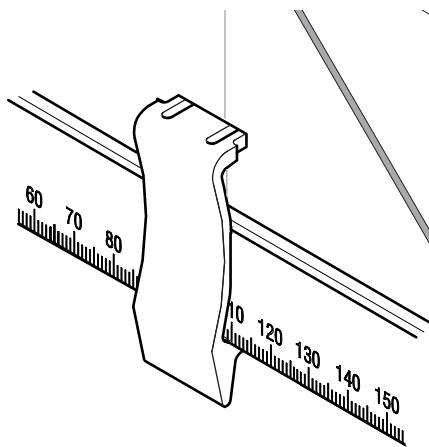
Note: The left anterior pin ⑩ and the corresponding hole in the coordinate frame are of larger diameter to prevent incorrect fitting.



WARNING 6.13

Make sure that the indicator is correctly mounted onto the coordinate frame. Otherwise there is a risk for inaccurate treatment planning.

- 3 While supporting the indicator with both hands, snap both attachment clips into place under the edges of the coordinate frame. This secures the indicator to the coordinate frame.



WARNING 6.14



Verify that the image orientation is correct when preparing a treatment plan. Otherwise wrong target can be treated.

WARNING 6.15



If performing manual treatment planning, ensure to add 40 mm to the measured Z length. Otherwise the Z coordinate will be erroneous and wrong target will be treated.

6.2.3.3 Removal and Disassembly

The procedure for removing the indicator from the coordinate frame is the reverse of the attachment procedure given in [Section 6.2.3.2](#).

The procedure for disassembling the indicator is the reverse of the assembly procedure given in [Section 6.2.3.1](#).

6.3 CT Adapter and CT Table Fixations

6.3.1 Product overview

The CT Adapter and CT Table Fixations are used in conjunction with Leksell® Coordinate Frame G and the corresponding CT Indicator.

Note: In this section, the following abbreviations are used:

adapter = CT Adapter

indicator = CT Indicator

table fixation = CT Table Fixation.

The purpose of the adapter and table fixations is to locate and secure the indicator in the correct position and orientation within the CT scanner. They also ensure that the position and orientation can be accurately reproduced in subsequent images.

The principle of the adapter and table fixation is shown in [Figure 6.3](#).

A table fixation ① is fitted to the scanner table ②, usually in place of the headrest, and the adapter ③ is fitted to the table fixation. The adapter is specifically designed to hold the coordinate frame ④, the indicator ⑤, and the skull of the patient firmly in place.

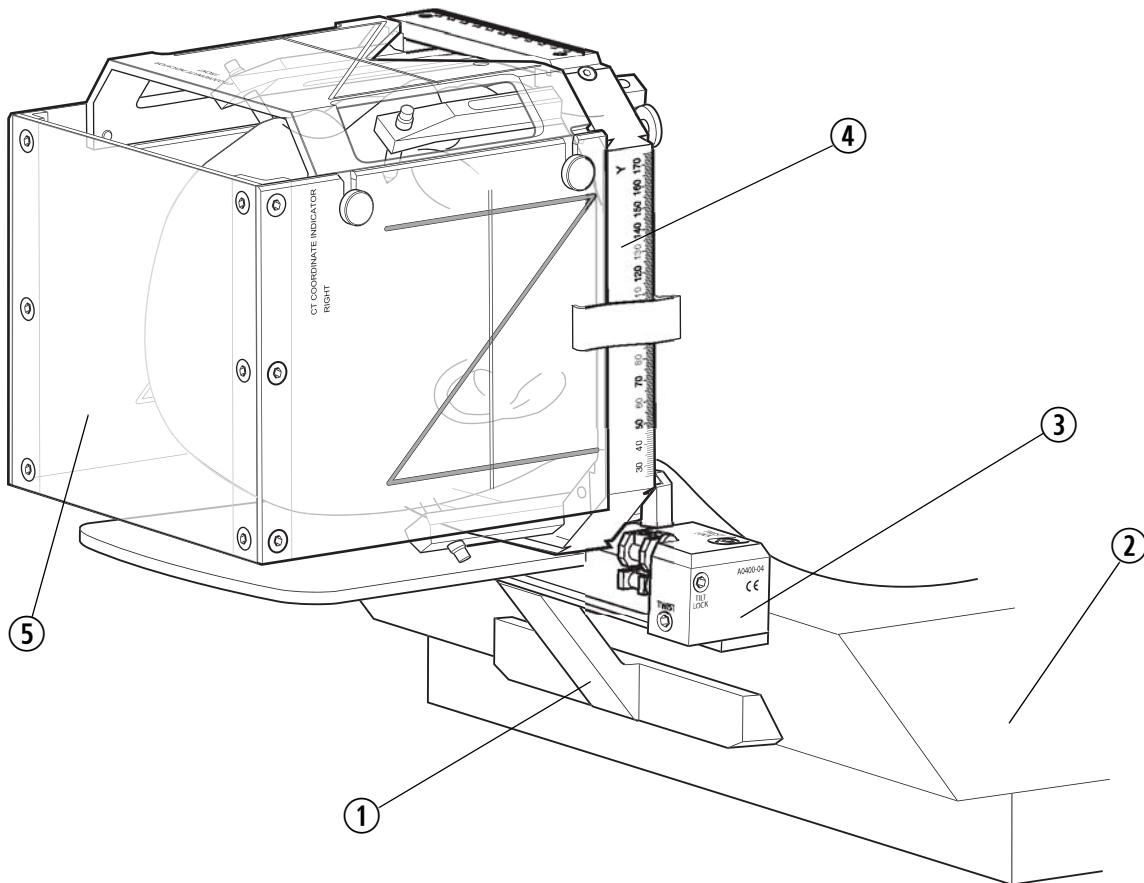


Figure 6.3 Principle of the CT Adapter and a CT Table Fixation

In the event of emergency, the adapter allows the coordinate frame to be detached. If for this or any other reason the scan is interrupted, the arrangement of coordinate frame, adapter and table fixation allows the patient to be reinstalled correctly.

When the coordinate frame is fitted into the adapter, it can be adjusted to an exactly perpendicular position to the gantry of the scanner, so that captured CT images are parallel to the plane of the coordinate frame.

This optimizes the precision of the fiducial markers which are imposed on the CT images. It also ensures repeatability, so that scans can be superimposed on each other and images can be compared in the scan study.

A range of table fixations to suit different designs of CT scanner tables is available from Elekta®. For this reason the instructions and illustrations which follow may vary slightly in detail.

This manual describes three types of table fixations:

- **Head end table fixations**, attaching to the head end of the scanner table, using the headrest attachment points.
- **Clamp type table fixations**, that are clamped around flat or curved scanner tables.
- **Universal table fixation**, for use with scanner tables with no suitable attachment points.

For further details on which table fixation is required for your scanner, contact Elekta® or check the Elekta® product catalog.

6.3.2 Main parts — CT Adapter

Refer to [Figure 6.4](#).

The **base** ⑥ is attached to the table fixation on the scanner table by means of two **screws** ⑦ (delivered with the table fixation). It provides a rigid platform for the **frame supports** ⑧ and ⑨.

The **frame fixation sockets** ⑩, ⑪ and ⑫ hold the coordinate frame in place. Each of the three sockets accommodates one foot of the coordinate frame.

The transparent **plate** ⑬ can be used to support the occiput of the patient if the inflatable rubber cushion is used. The plate is held in place by the **plate clamp** ⑭ and three **plate clamp screws** ⑮. The plate can be removed if desired.

The fiducial markers on the panels of the indicator can be aligned with the scanner's alignment lasers by means of four screws in the base of the adapter. The twist (horizontal rotation) of the adapter can be adjusted by means of the **twist screw** ⑯ and is secured by the **twist lock screw** ⑰. The tilt (vertical rotation) of the adapter can be adjusted by means of the **tilt screw** ⑱ and is secured by the **tilt lock screw** ⑲.

A 5 mm **hexagonal wrench** ⑳ and a 2.5 mm **hexagonal key** ㉑ are supplied with the adapter for adjustment and assembly/disassembly purposes.

This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.

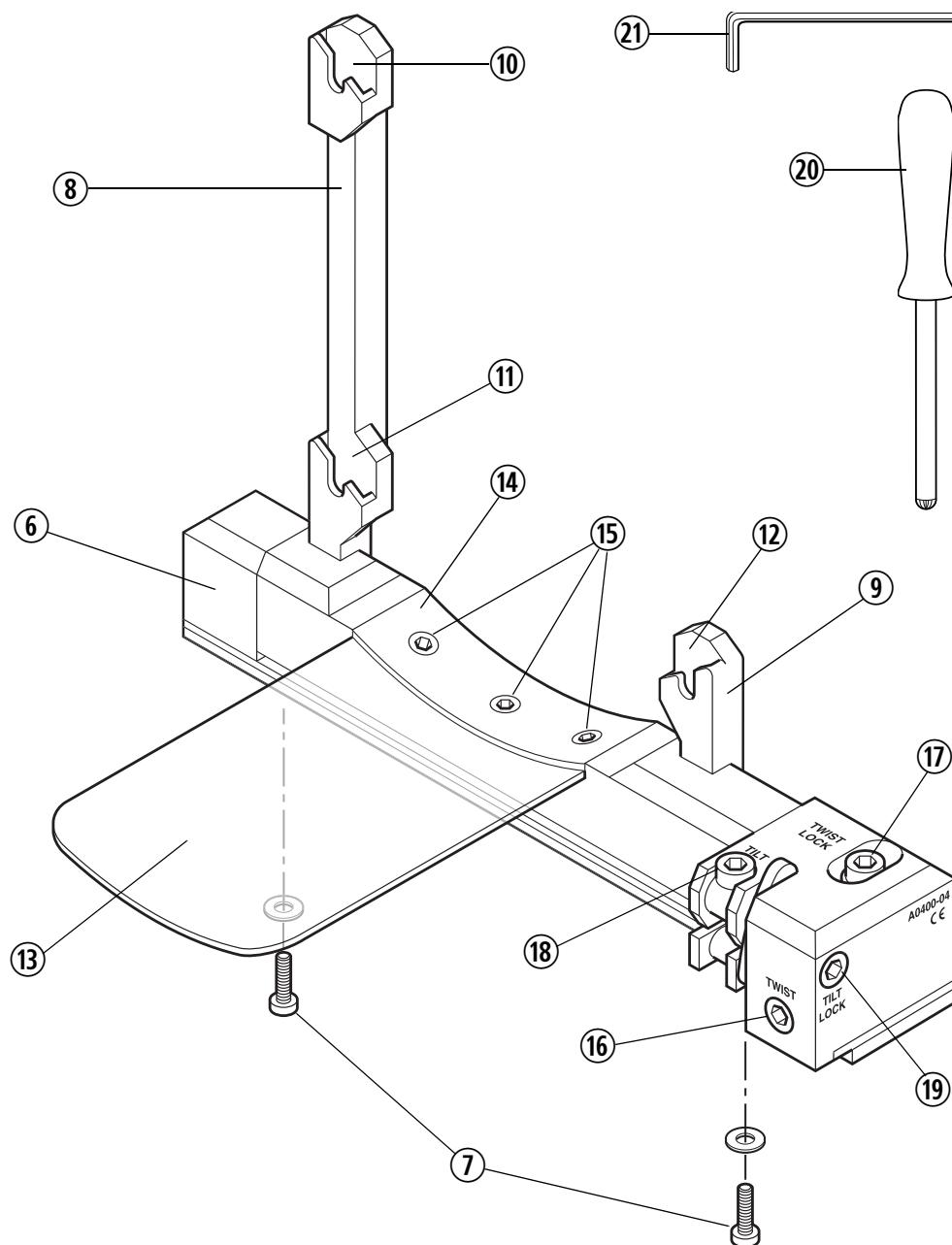


Labels

Some parts have engraved labels. See [Table 6.2](#) for details, and [Section 9.7 on page 288](#) for general label information.

Table 6.2 Labelled parts for the CT Adapter

Part	Labels
⑥ Base	TWIST, TWIST LOCK, TILT, TILT LOCK



- | | |
|--------------------------------|--------------------|
| ⑥ Base | ⑯ Twist screw |
| ⑦ Screws | ⑰ Twist lock screw |
| ⑧, ⑨ Frame supports | ⑱ Tilt screw |
| ⑩, ⑪, ⑫ Frame fixation sockets | ⑲ Tilt lock screw |
| ⑬ Plate | ⑳ Hexagonal wrench |
| ⑭ Plate clamp | ㉑ Hexagonal key |
| ⑮ Plate clamp screws | |

Figure 6.4 Main parts of the CT Adapter

6.3.3



Main parts — CT Table Fixations

The main parts of the table fixations are made of aluminum.

All table fixations are delivered with a hexagonal key (as ②1 in [Figure 6.4](#)).

This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.

Labels

Some parts can have engraved labels. See [Section 9.7 on page 288](#).

Head end table fixations

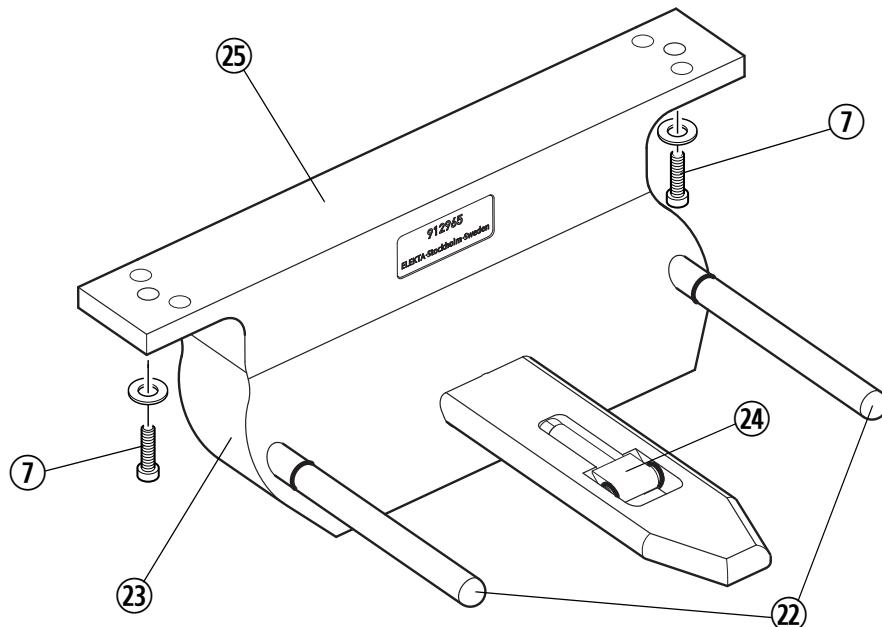
A head end table fixation is fitted to the head rest attachment points of the CT scanner table. The attachment points can be pins, a tongue, a dovetail, or other fitting.

The table fixation is secured by a lock screw or draw-latch, or by a device attached to the scanner table.

[Figure 6.5](#) shows a table fixation for GE Metalless table tops.

This table fixation has **attachment points** ②2 of pin type which protrude from the **fixation body** ②3. It is held in place by a **securing device** ②4 in the form of a clip lock. A knob (not shown) on the back of the fixation body is used to tighten the lock.

The adapter is fixed to the **flat horizontal surface** ②5. Two **screws** ⑦ with washers pass through holes in the table fixation underside and into threaded holes in the adapter.



⑦ Screws

②4 Securing device

②2 Attachment points

②5 Flat horizontal surface

②3 Fixation body

Figure 6.5 Typical head end table fixation (GE Metalless)

Figure 6.6 shows a table fixation for Siemens Somatom table tops.

This table fixation has a single **attachment point** ② with a **securing device** ④ in the form of a lock screw. The attachment point is fitted into a slot in the table top, used for fitting the original headrest.

The adapter is fixed to the **flat horizontal surface** ⑤. Two **screws** ⑦ with washers pass through holes in the table fixation underside and into threaded holes in the adapter.

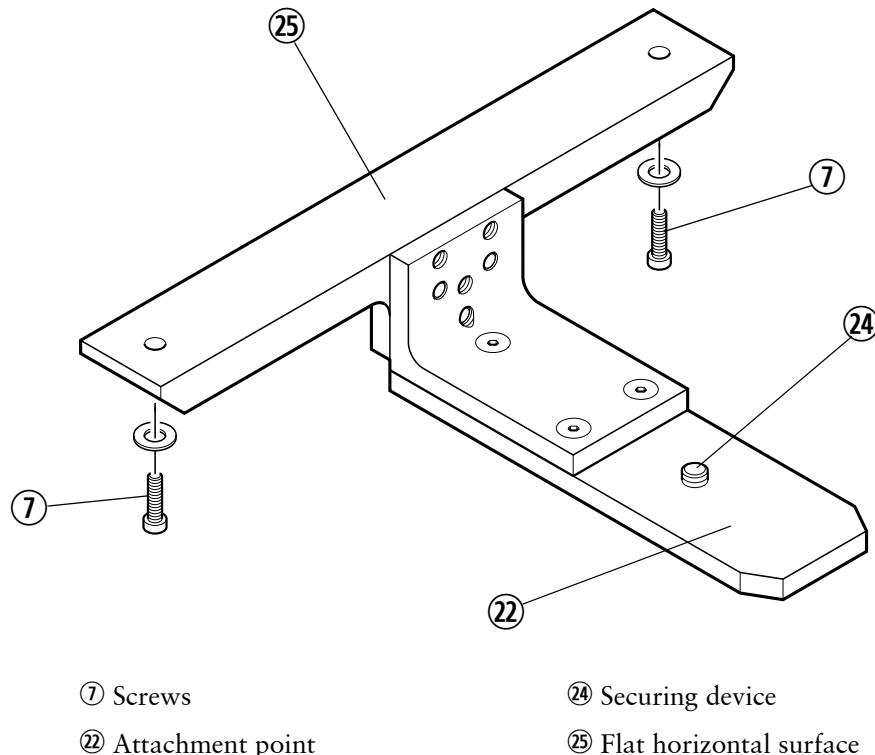


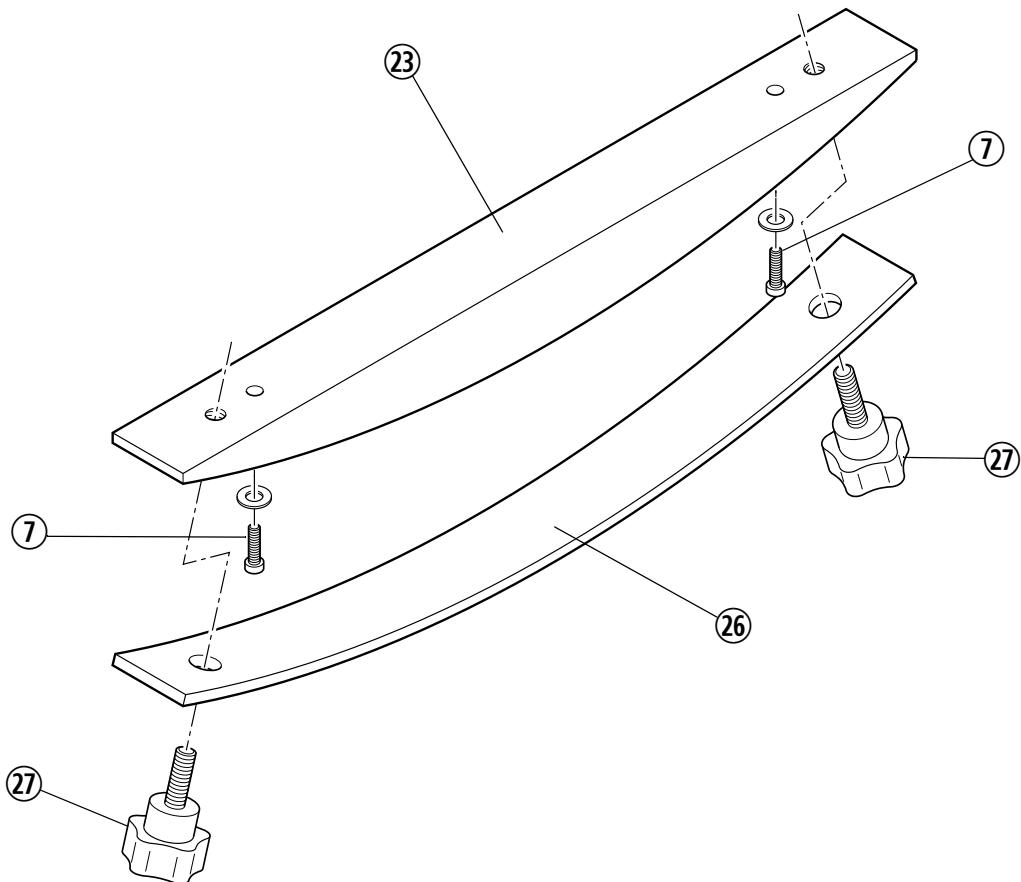
Figure 6.6 Typical head end table fixation (Siemens Somatom)

Clamp type table fixations

Refer to [Figure 6.7](#).

The **fixation body** ⑬ has an underside which fits onto the CT scanner table. The adapter is attached to the upper surface of the fixation body by means of two **screws** ⑦ with washers which pass through two unthreaded vertical holes in the fixation body.

The **clamping plate** ⑯ passes underneath the scanner table and is attached to the fixation body by means of two **threaded fixing knobs** ⑰. The knobs pass through the unthreaded holes of the clamping plate and screw into threaded holes in the fixation body.



⑦ Screws

⑯ Clamping plate

⑬ Fixation body

⑰ Threaded fixing knobs

Figure 6.7 Typical clamp type table fixation

Universal table fixation

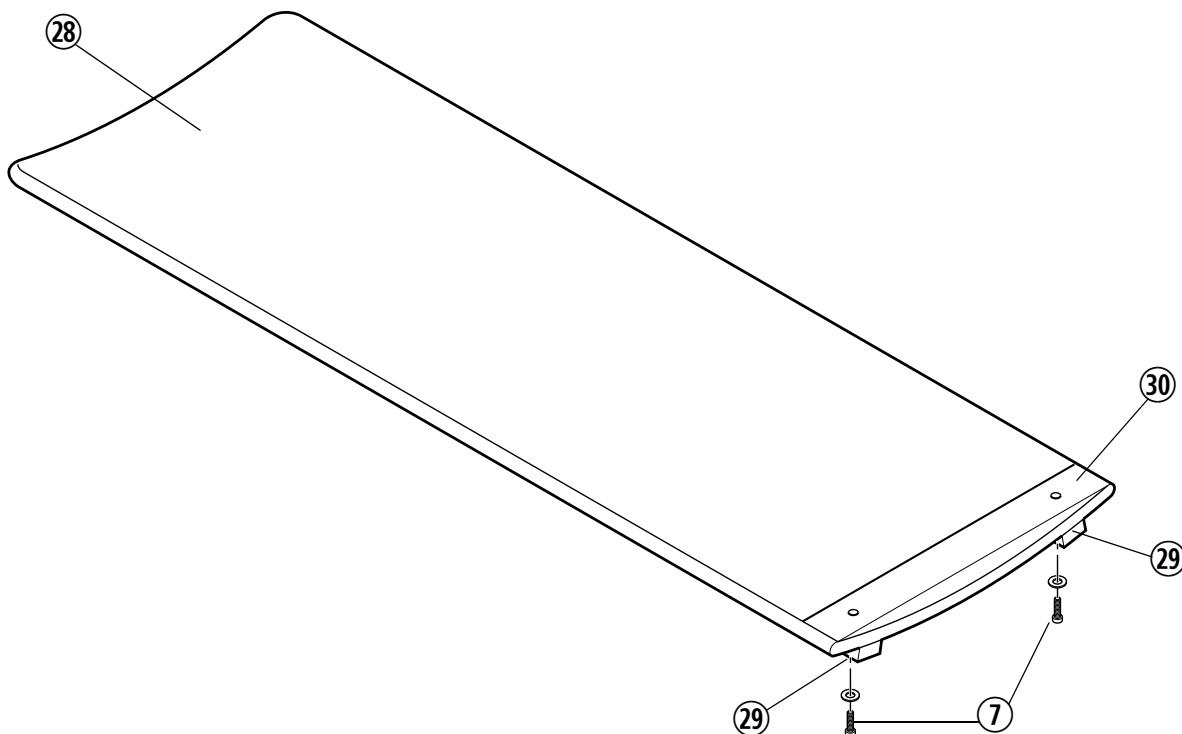
Refer to [Figure 6.8](#).

The universal table fixation is used when the design of the CT scanner table does not permit the attachment of a conventional table fixation.

The **board** ②⁸ is made of laminated plywood and is slightly curved.

Two **wooden strips** ⑨ with ridged rubber strips run along the underside of the board, parallel to the long edges, providing firm and stable contact with the scanner table.

The **end piece** ⑩, made of solid wood, is attached to the end of the board. Its upper edge provides a flat surface to which the adapter is attached. It is drilled with two holes, through which two **screws** ⑦ with washers pass to fix the adapter to the table fixation.



⑦ Screws

⑨ Wooden strips

⑧ Board

⑩ End piece

Figure 6.8 Typical universal table fixation

6.3.4 Using the CT Adapter and CT Table Fixations

6.3.4.1 Assembly instructions

Preparation

Inspect all components regarding functionality before use.

The following instructions assume that:

- The coordinate frame has been assembled and attached to the patient's skull in accordance with [Section 3.2 on page 28](#).
- The indicator has been assembled and fitted to the coordinate frame (see [Section on page 164](#)).
- All components of the adapter and table fixations are clean and at hand.

WARNING 6.16



**Do not position fixation screw tips at the same level as the target.
Otherwise imaging artifacts can cause erroneous treatment planning.**

The coordinate frame and its components can cause artifacts in the CT images. To reduce the artifacts;

- Reduce the scan slice thickness (for example to 3 mm or less).
- Locate the tips of the fixation screws in a plane away from the anatomical area of interest.
- Use Reusable Fixation Screws or Disposable Fixation Screws.

WARNING 6.17



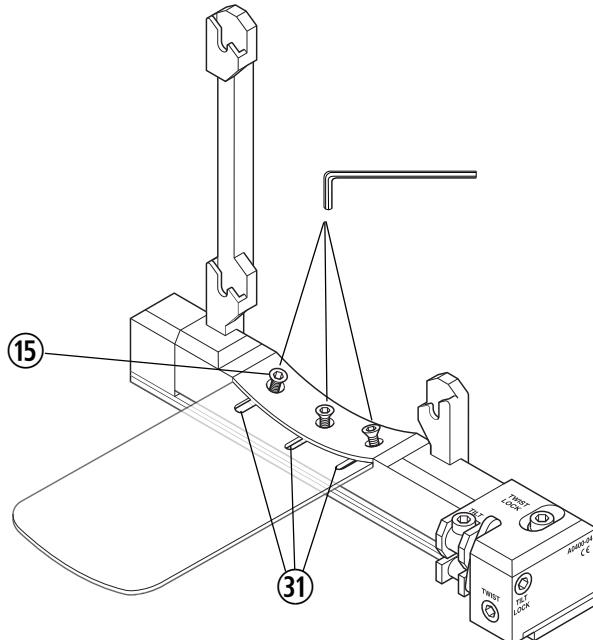
Do not attach the coordinate frame to the skull in level with the intended target. Otherwise the CT Adapter can cause imaging artifacts.

Assembling the CT Adapter

The transparent plate may have been removed.

To attach the plate to the adapter:

- 1 Using the hexagonal key, loosen the plate clamp screws ⑯ until the plate can be slid under the plate clamp. There is no need to withdraw the screws completely.

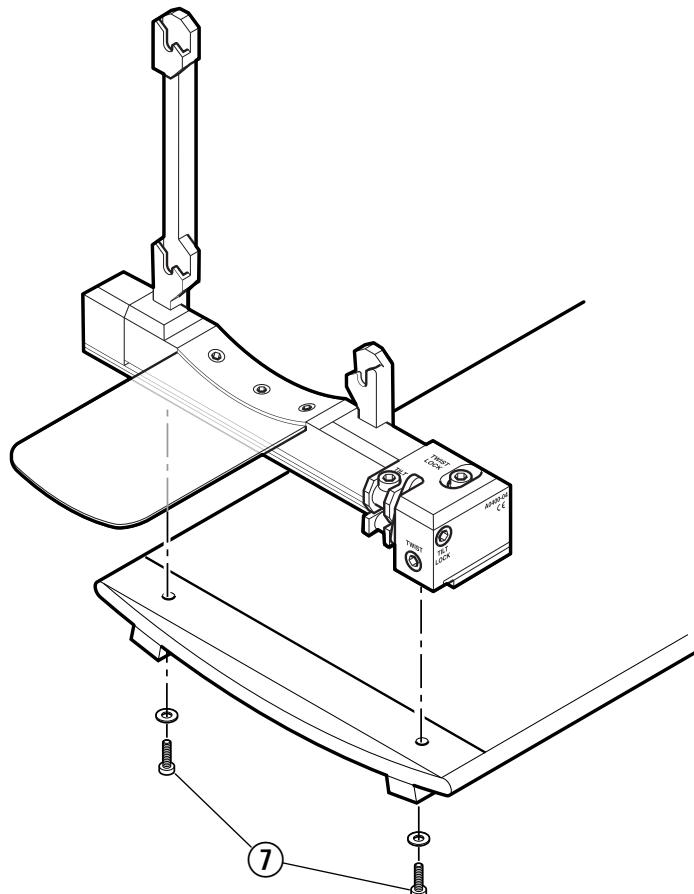


- 2 Push the plate fully in place under the plate clamp, ensuring that the clamp screws slide into the slots ⑯.
- 3 Using the hexagonal key, tighten the clamp screws until the plate is secured.

6.3.4.2**Fitting the CT Adapter to the table fixation**

Attach the adapter to the table fixation before installing the table fixation.

- 1 Position the adapter over the table fixation so that the threaded screw holes in the underside of the adapter align with the holes in the table fixation. Ensure the transparent plate of the adapter will be towards the head end of the table.
- 2 Insert the two screws ⑦ with washers (delivered with the table fixation) through the holes of the table fixation. Using finger pressure, tighten the screws so that they enter the threaded holes in the adapter.



- 3 Using the hexagonal wrench, tighten the screws until the adapter is securely attached to the table fixation.

Note:

Ensure that the CT Adapter is securely fixed to the table fixation.

- 4 Attach the assembled unit to the table top of the scanner (see instructions supplied with the table fixation).
- 5 Check that the entire adapter is secured rigidly to the bed of the scanner via the table fixation.

**WARNING 6.18**

**Ensure that the equipment is properly assembled and securely fixed.
Otherwise the patient can be injured.**

6.3.4.3**Installing the CT Table Fixation**

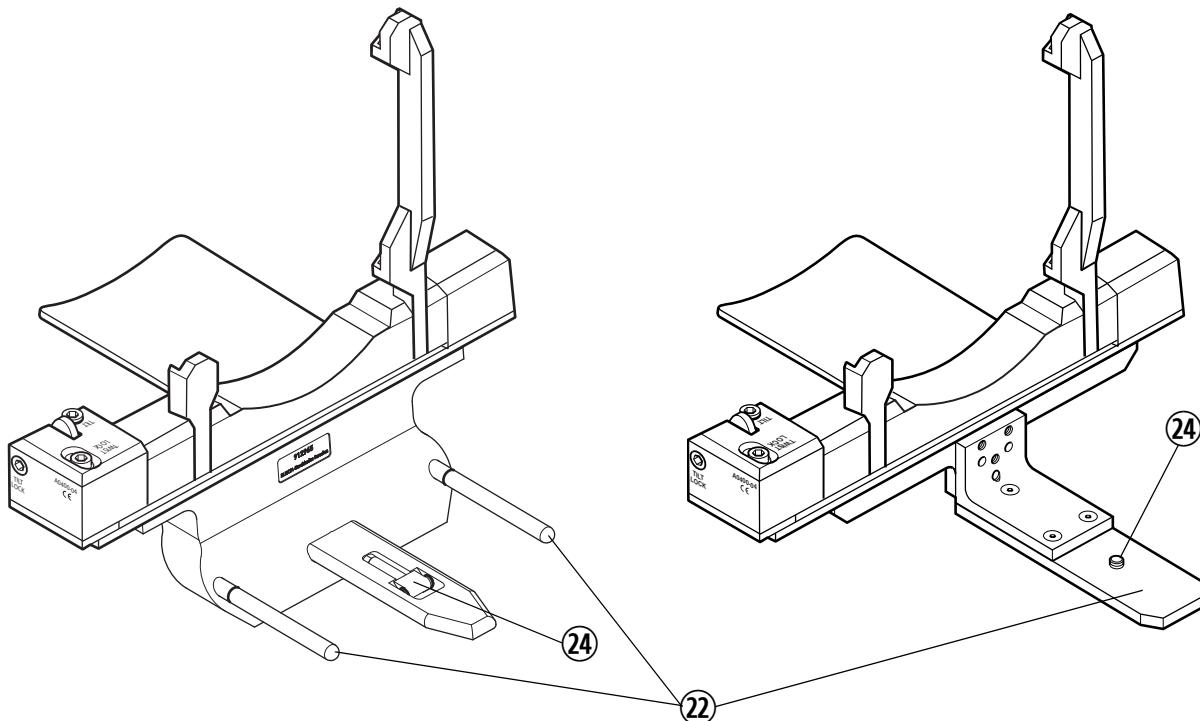
The procedure for installing the table fixation to the CT scanner table depends on the type of table fixation used.

Installing a head end table fixation

- 1 Remove the headrest from the CT scanner table.
- 2 Insert the attachment point(s) ② of the table fixation into the hole(s), slot or similar left by the headrest.
- 3 Fix the table fixation in place by using the lock screw(s), draw-latch or other securing device ④, depending on which model of table fixation is used.

Note:

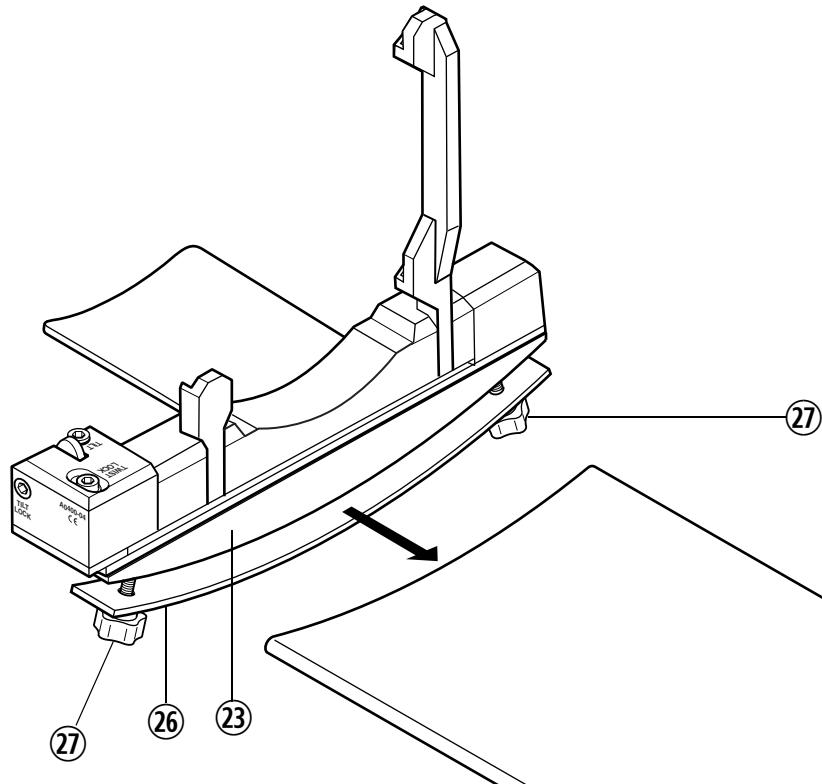
Ensure that the CT Table Fixation is securely fixed to the scanner table.

**WARNING 6.19**

**Ensure that the equipment is properly assembled and securely fixed.
Otherwise the patient can be injured.**

Installing a clamp type table fixation

- 1 Remove any cushions or mattresses from the headrest part of the CT scanner table.
- 2 Loosen the fixing knobs ⑦ holding the clamping plate ⑥ **without** disconnecting them from the fixation body ③.



- 3 Slide the table fixation over the end of the scanner table to a desired position. Gently tighten the fixing knobs.
- 4 Using a spirit level, check that the adapter is not rotated around the curvature of the scanner table. It must be properly centered over the table.
- 5 Once the fixation body is correctly aligned tighten the fixing knobs firmly.

Note:

Ensure that the CT Table Fixation is securely fixed to the scanner table.



WARNING 6.20

**Ensure that the equipment is properly assembled and securely fixed.
Otherwise the patient can be injured.**

Installing the universal table fixation

- 1 Remove any cushions and headrests from the CT scanner table.
- 2 Place the universal table fixation, with the rubber strips on the underside, onto the scanner table.
- 3 Adjust the position of the table fixation so that its edges are parallel to the edges of the scanner table, and the end piece ⑩ is protruding slightly over the end of the table. Use a spirit level to ensure the board is in a horizontal position.

Note:

Ensure that the CT Table Fixation is securely fixed to the scanner table.



WARNING 6.21

**Ensure that the equipment is properly assembled and securely fixed.
Otherwise the patient can be injured.**

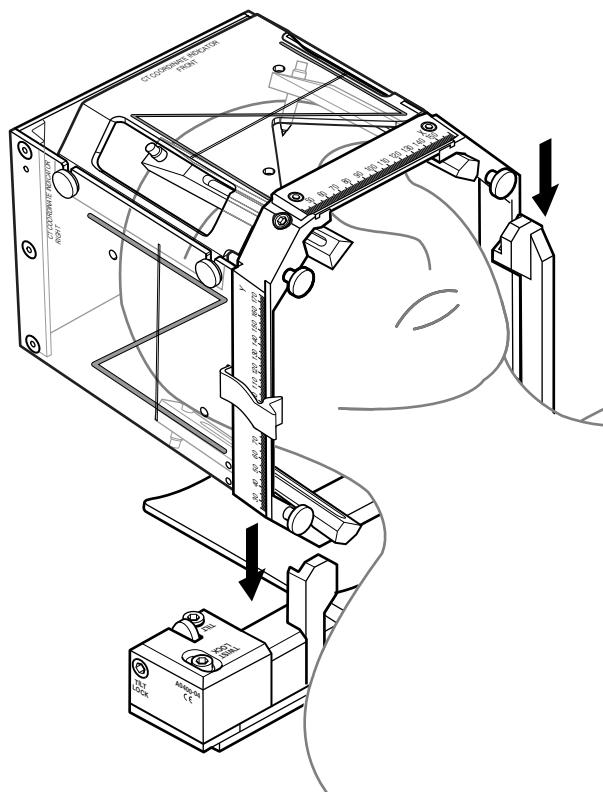
6.3.4.4 Positioning the patient

WARNING 6.22



Support the patient's head at all times when fitting the coordinate frame to, and removing it from, any other equipment. Otherwise the patient can be injured.

- 1 Position the patient on the scanner table so that the coordinate frame will engage with the adapter when the patient's head is lowered to the scanning position.



- 2 While carefully supporting the patient's head, lower the coordinate frame until the posterior feet and the anterior left foot of the coordinate frame slide into the frame fixation sockets.
- 3 Check that the coordinate frame is fully engaged in the adapter, i.e. the feet of the coordinate frame are located at the bottom of the frame fixation sockets. Once the feet are in place, further horizontal movement is prevented.

If desired, use an inflatable cushion or other support between the transparent plate and the patient's neck for increased patient comfort.

WARNING 6.23



Ensure that the equipment is properly assembled and securely fixed. Otherwise the patient can be injured.

WARNING 6.24



The adapter does not have a locking device. The patient can unintentionally get out of the fixation.

**WARNING 6.25**

**Ensure that the patient can easily be released in case of emergency.
Otherwise the patient can be injured.**

**WARNING 6.26**

If a rubber cushion is used to support the patient, ensure that it is not over inflated. Otherwise the coordinate frame can be disconnected from the adapter and the patient can be injured.

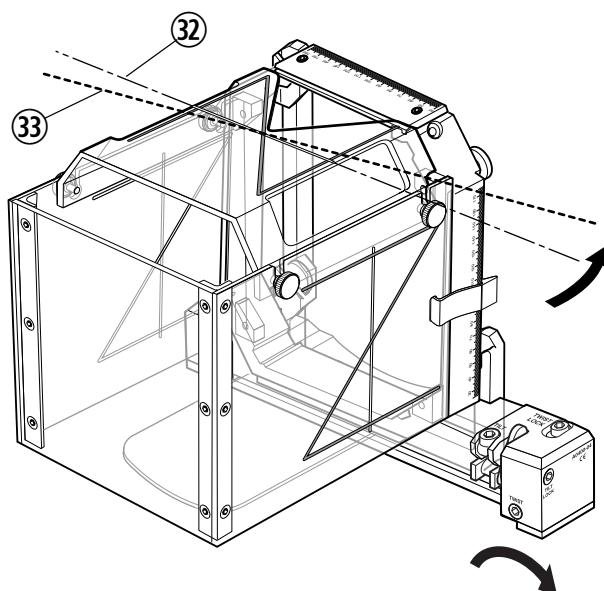
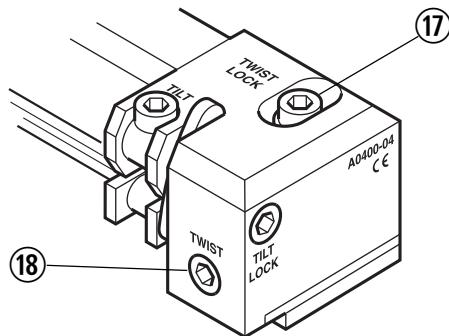
6.3.4.5 Aligning the CT Adapter to the scanner


WARNING 6.27

Ensure that the indicator is correctly aligned during imaging. Otherwise inaccurate treatment can result.

Before the CT scan is performed, the position of the adapter must be adjusted so that the indicator is parallel to the plane of the scan. Use the twist setting for adjusting to the left and right, and the tilt setting for adjusting up and down, as described in the following.

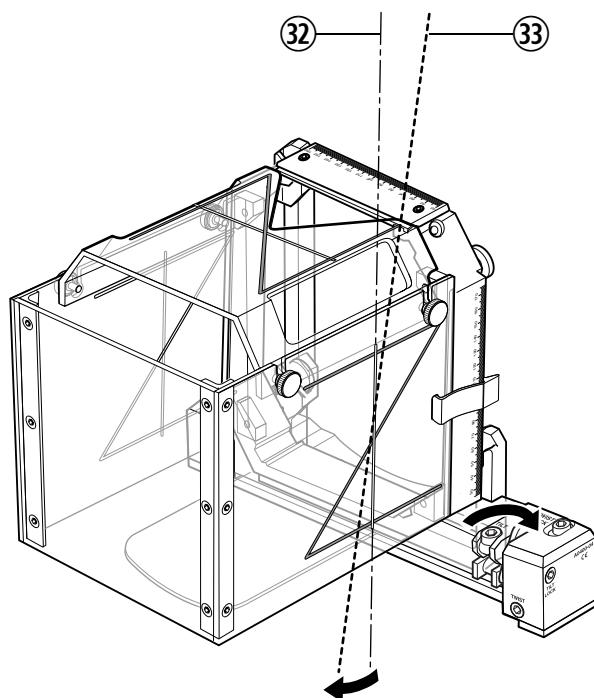
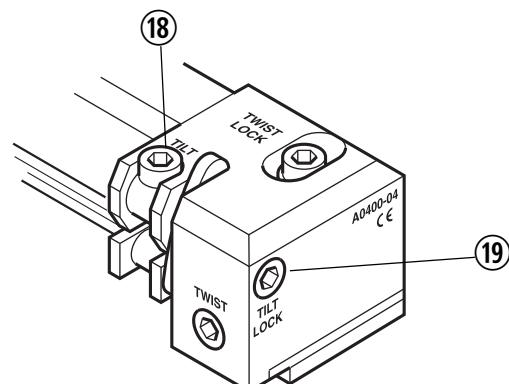
- 1 Switch on the scanner's alignment lasers and observe their positions relative to the reference lines on the indicator.
- 2 Adjust the twist setting of the adapter as follows:
 - (a) Using the hexagonal wrench, release the twist lock screw ⑯.
 - (b) Adjust the twist setting by means of the twist screw ⑰ until the horizontal grooves ⑲ of the front panel of the indicator are aligned with the laser beam ⑳. Turn this screw clockwise to rotate the coordinate frame counter-clockwise as viewed from above.



- (c) When the twist setting is correct, tighten the twist lock screw.

3 Adjust the tilt setting of the adapter as follows:

- (a) Using the hexagonal wrench, release the tilt lock screw ⑯.
- (b) Adjust the tilt setting by means of the tilt screw ⑮ until the vertical grooves ㉑ of the side panels of the indicator are aligned with the laser beam ㉒. Turn this screw clockwise to tilt the coordinate frame forwards.



- (c) When the tilt setting is correct, tighten the tilt lock screw.

- 4** Check the twist setting again, you may have to make a small readjustment.
- 5** Check the tilt setting again.

Alternative adjustment of the tilt setting

If the laser beams are not properly adjusted, a spirit level (not supplied by Elekta®) can be used to adjust the tilt setting. Place the spirit level on the front panel of the indicator and adjust the tilt to a horizontal position. When the setting is correct tighten the tilt lock screw.

6.3.4.6

Removal and disassembly

The procedure for removing the patient from the adapter is the reverse of the installation procedure given in [Section 6.3.4.4 on page 186](#).

The procedure for removing the table fixation from the scanner bed is the reverse of the installation procedure given in [Section 6.3.4.3 on page 183](#).

The procedure for removing the adapter from the table fixation is the reverse of the installation procedure given in [Section 6.3.4.2 on page 182](#).

The procedure for removing the transparent plate from the adapter is the reverse of the assembly procedure given in [page 181](#).



CAUTION 6.1

Except for removal of the transparent plate for cleaning, the adapter should not be disassembled by the user.

6.4 MR Indicator

6.4.1 Product overview

The MR Indicator is an accessory for target localization in stereotactic neurosurgery and radiosurgery. It is used in conjunction with Leksell® Coordinate Frame G and the MR Adapters.

Note: In this section, the term “indicator” refers to the MR Indicator.

The purpose of the indicator is to impose fiducials on images of the patient acquired during MR imaging. The fiducials are used for determining target coordinates and for slice alignment by treatment planning software.

The indicator has a marker system designed to ensure that fiducials are visible on the MR images. The system consists of N-shaped marker channels in each panel of the indicator. The channels are filled with a copper sulfate solution, which imposes the fiducials on to the images during the MR scan.

Usually four sets of fiducials are imposed, with three separate fiducials in each set. The locations of the fiducial sets on an image show the relative position of the patient’s skull in the stereotactic space. The position of the center fiducial in relation to the other two fiducials in each set is indicative of the image slice position.

The principle is illustrated in [Figure 6.9](#), which shows typical fiducials resulting from an axial scan.

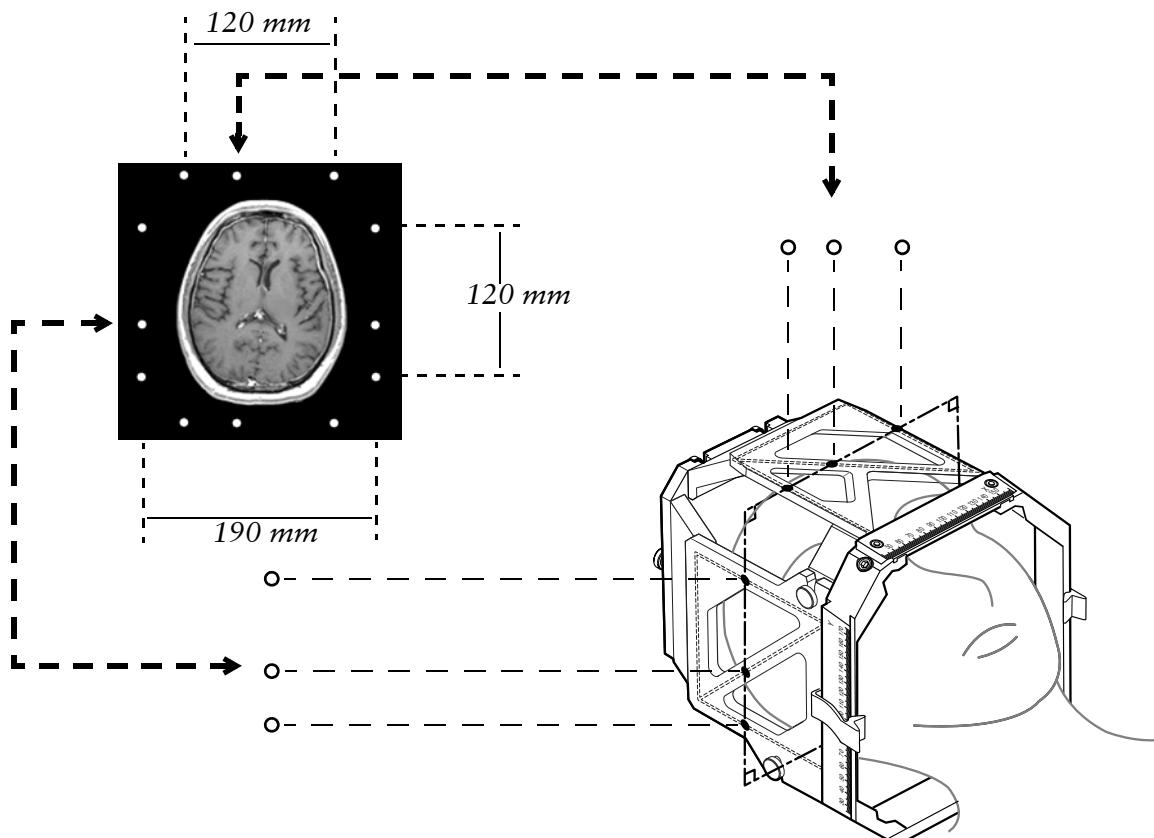


Figure 6.9 Principle of the MR Indicator

6.4.2

Main parts

Refer to [Figure 6.10](#).

The indicator consists of five panels:

- **Side panels right** ① and **left** ②, labelled **MR COORDINATE INDICATOR ANT RIGHT** and **MR COORDINATE INDICATOR ANT LEFT**. They mirror each other in appearance.
- The **anterior panel** ③, labelled **MR COORDINATE INDICATOR ANT**.
- The **posterior panel** ④, labelled **MR COORDINATE INDICATOR POST**.
- The **top panel** ⑤, labelled **MR COORDINATE INDICATOR TOP**.

Each panel is basically square in shape, with segments cut away to reduce weight and allow the indicator to fit into MR scanners with small head coils. The superior edges of the anterior, posterior and side panels have an angled framework that connects to the top panel.

All panels have embedded **marker channels** ⑪ filled with copper sulfate solution. The channels form an N-shape or a square with a diagonal, which imposes the fiducials on the images during the MR scan.

Sealing screws ⑨ and **O-Rings** ⑩ seal the marker channels and permit replenishment of the solution.

The anterior, posterior and side panels have a **horizontal line** ⑫ engraved that bisects the marker channels at the midplane of Leksell Coordinate System®. The lines are used for perpendicular alignment of the indicator in the MR scanner.

There are locating pins on the underside of the left and right sides of the top panel. When assembling the indicator, these locating pins fit into corresponding holes in the angled framework of the side panels.

Two white **locking screws** ⑥ secure the top panel to the side panels.

The anterior and posterior edges of the top and side panels have open-ended, countersunk slots for attachment of the anterior and posterior panels.

Eight black **fixing screws** ⑦ attach the anterior and posterior panels to the top and side panels.

The anterior panel has a cutaway to permit access to the patient's airways. The anterior panel is attached to the side panels by means of angled brackets that project rearwards from the inferior lateral edges.

The posterior panel is attached to the side panels by means of angled brackets that project forwards from the lateral edges.

At each inferior corner of both side panels there is a right-angled bracket, from which a **locating pin** ⑬ ⑭ protrudes.

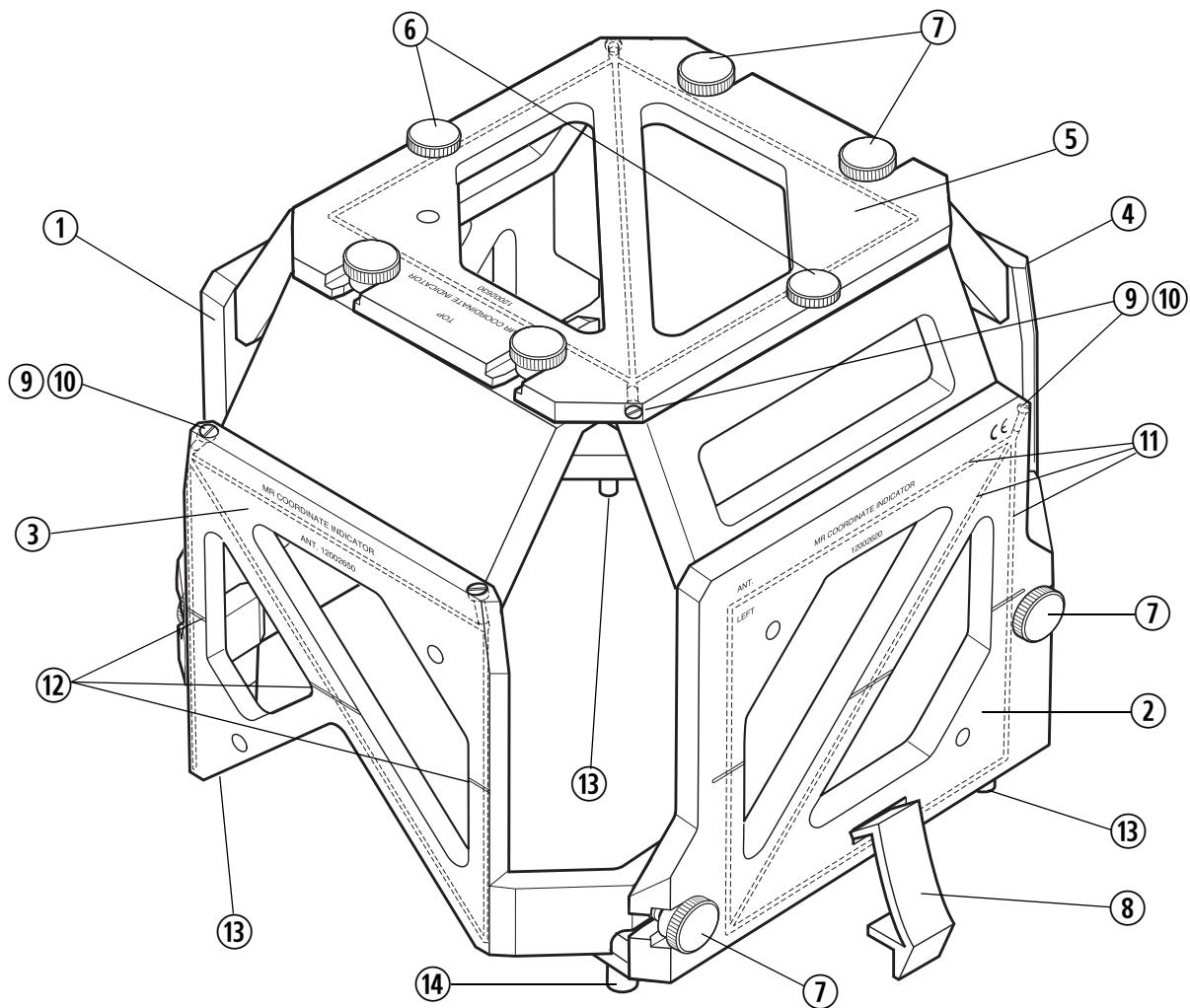
When fitting the indicator to the coordinate frame, these locating pins fit into corresponding holes in the corners of the coordinate frame. To prevent incorrect fitting, the left anterior locating pin ⑭ is of a larger diameter than the other three locating pins ⑬.

Two **attachment clips** ⑧ secure the assembled indicator to the coordinate frame.

A special screwdriver is supplied for the sealing screws ⑨.

This equipment is MR Safe. See [Section 1.2.4 on page 8](#) for detailed information.





- | | |
|---------------------|-------------------------------|
| ① Side panel, right | ⑧ Attachment clips |
| ② Side panel, left | ⑨ Sealing screws |
| ③ Anterior panel | ⑩ O-Rings |
| ④ Posterior panel | ⑪ Marker channels |
| ⑤ Top panel | ⑫ Horizontal line |
| ⑥ Locking screws | ⑬ Locating pins |
| ⑦ Fixing screws | ⑭ Locating pin, left anterior |

Figure 6.10 Main parts of the MR indicator

6.4.2.1 Labels

Some parts have engraved labels. See [Table 6.3](#) for details, and [Section 9.7 on page 288](#) for general label information.

Table 6.3 Labelled parts on the MR Indicator

Part	Labels
① Side panel, right	MR COORDINATE INDICATOR ANT RIGHT
② Side panel, left	MR COORDINATE INDICATOR ANT LEFT
③ Anterior panel	MR COORDINATE INDICATOR ANT
④ Posterior panel	MR COORDINATE INDICATOR POST
⑤ Top panel	MR COORDINATE INDICATOR TOP

6.4.3 Using the MR Indicator



WARNING 6.28

If performing manual treatment planning, ensure to add 40 mm to the measured Z length. Otherwise the Z coordinate will be erroneous and wrong target will be treated.

6.4.3.1 Assembly instructions

Preparation

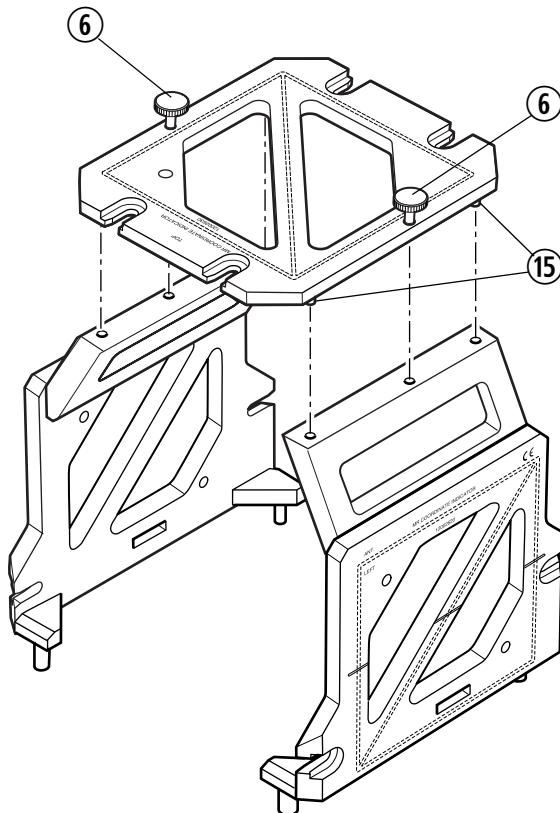
The indicator is usually attached to the coordinate frame after the coordinate frame has been positioned on the patient. For instructions on preparing the coordinate frame, refer to [Section 3.2 on page 28](#).

Inspect all components regarding functionality before use.

- 1 Check that all components of the indicator are at hand (see [Figure 6.10](#)) and clean prior to use.
- 2 Air bubbles may occasionally appear in the marker channels. Inspect the instrument carefully before use and, if any air bubbles are present, replenish the affected channel with copper sulfate solution. See [Section 6.4.4 on page 201](#) for replenishment instructions.

Assembling the MR Indicator

- 1 Loosely insert the two white locking screws ⑥ in the top panel. Attach the top panel to the side panels by using the locking screws. Ensure that the locating pins ⑯ in the top panel are correctly inserted into the corresponding holes of the side panels. Tighten the locking screws by hand until the top panel is secure.



Note:

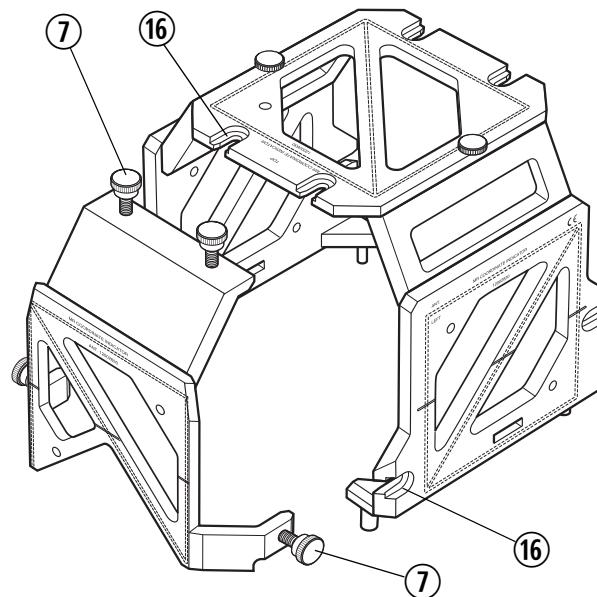
The top panel must be fitted with the label **MR COORDINATE INDICATOR TOP** uppermost. The labelled side can be anterior or posterior.

WARNING 6.29

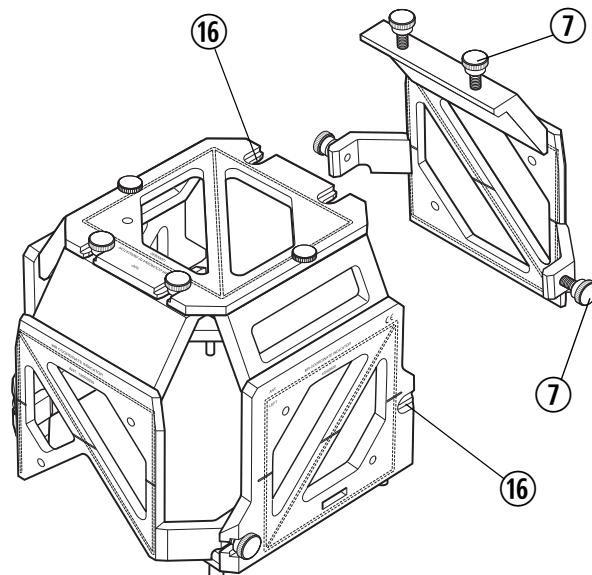


**Do not use excessive force when tightening locking screws/knobs.
Otherwise parts can be damaged and not permit secure fixation.
Non-secure fixation can cause incorrect treatment.**

- 2 Loosely insert black fixing screws ⑦ into the holes in the angled bracket at each inferior corner of the anterior panel, and into the two holes on the top of the anterior panel.



- 3 Insert the anterior panel between the side panels. The anterior panel must face outwards, with the angled brackets at the inferior position. The four fixing screws must be properly inserted into the countersunk slots ⑯ in the anterior edge of each side panel and the top panel.
- 4 Secure the anterior panel to the top and side panels by tightening the four fixing screws by hand. Ensure that the conical portion of each fixing screw is properly seated in the countersunk slot.
- 5 Loosely insert black fixing screws ⑦ into the hole in the angled bracket at each inferior corner of the posterior panel, and into the two holes on the top of the posterior panel.

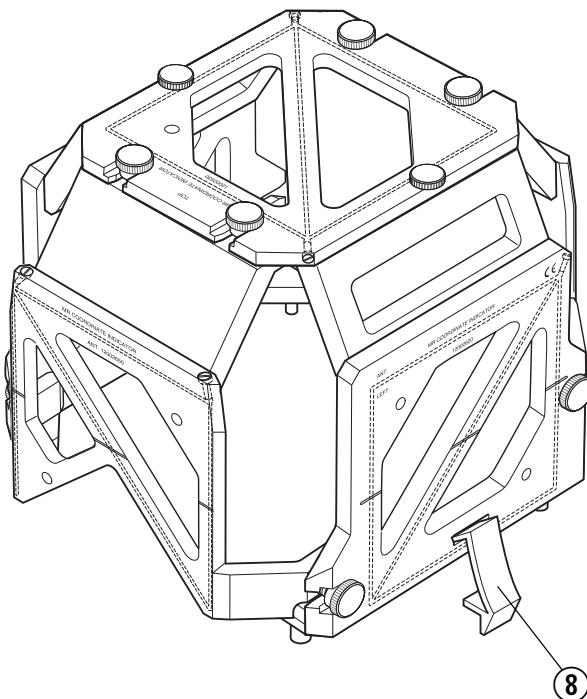


- 6 Insert the posterior panel between the side panels. The posterior panel must face outwards, with a fixing screw properly inserted into the countersunk slots ⑯ in the posterior edge of each side panel and the top panel.

Note: *If long posterior fixation posts are used for the coordinate frame fixation, the fixation posts or the fixation screw ends may obstruct the angled brackets of the posterior panel. This is avoided by positioning the long fixation posts either so that only one mark on the fixation post is visible, or so that at least five marks are visible.*

Note: *If the long fixation posts interfere with the indicator, it is possible to remove the posterior panel from the indicator.*

- 7 Secure the posterior panel to the top and side panels by tightening the four fixing screws by hand. Ensure that the conical portion of each fixing screw is properly seated in the countersunk slot.
- 8 Insert an attachment clip ⑧ through the slot of each side panel.



The indicator is now ready for attachment to the coordinate frame.

6.4.3.2**Fitting the MR Indicator to the coordinate frame**

The indicator can be fitted to the coordinate frame before or after the coordinate frame has been fitted to the patient, although the latter is preferable. The following instructions assume that the coordinate frame has been correctly assembled.

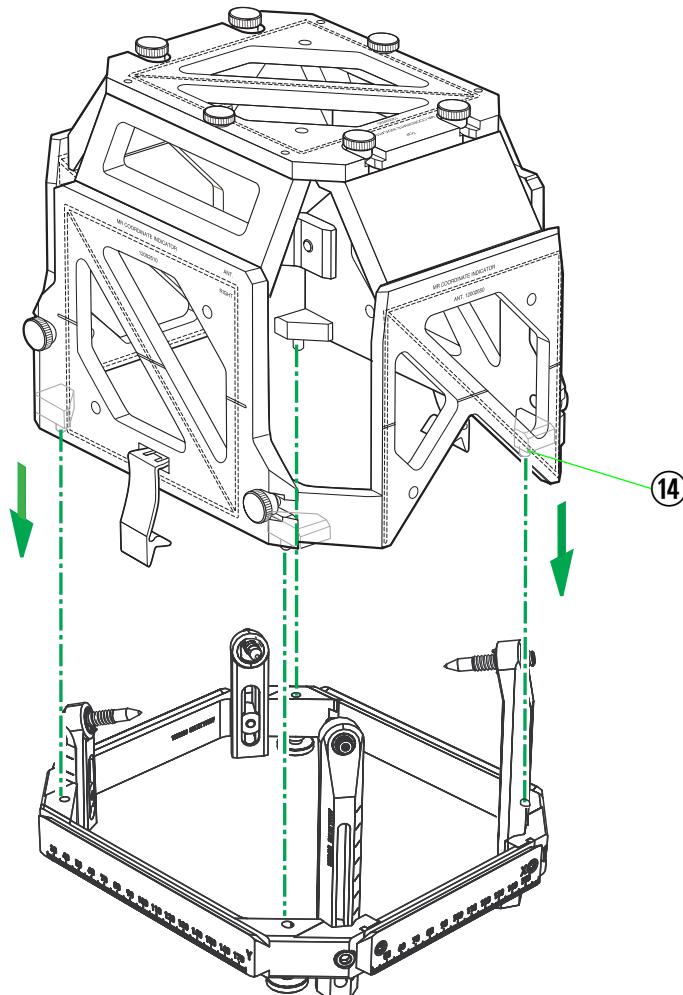
**WARNING 6.30**

Support the patient's head at all times when fitting the coordinate frame to, and removing it from, any other equipment. Otherwise the patient can be injured.

**WARNING 6.31**

The weight of the patient's head must not be supported by the indicator, otherwise the patient can be injured or the indicator can be damaged.

- 1 Align the indicator with the coordinate frame so that the panel labelled **MR COORDINATE INDICATOR ANT** is placed above the front piece of the coordinate frame.
- 2 Place the indicator on the coordinate frame by properly inserting the locating pins of the indicator into the corresponding holes of the coordinate frame. Ensure that the locating pins are completely inserted into the holes.



Note:

The left anterior locating pin ⑯ and the corresponding hole in the coordinate frame are of larger diameter to prevent incorrect fitting.

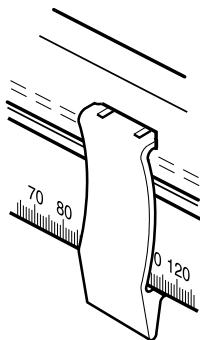
WARNING 6.32

When fitting the indicator to the coordinate frame, ensure that the side panel marked LEFT is on the patient's left side and the side panel marked RIGHT is on the patient's right side.

WARNING 6.33

Make sure that the indicator is correctly mounted onto the coordinate frame. Otherwise there is a risk for inaccurate treatment planning.

- 3 While supporting the indicator with both hands, snap both attachment clips into place under the edges of the coordinate frame. This secures the indicator to the coordinate frame.



6.4.3.3**Scanning images and planning treatment**

The indicator supports the acquisition of axial and coronal image slices. Based on the image information in the axial or coronal image study acquisition, coronal and sagittal images, or axial and sagittal images respectively, are reconstructed in the Elekta treatment planning software.

Elekta recommend using Leksell SurgiPlan® or Leksell GammaPlan® for treatment planning. For manual determination of coordinates for the treatment, it is crucial to acquire perfectly orthogonal images.

Align the horizontal lines ⑫ on the indicator with the laser beam from the MR scanner. For additional information on positioning the patient and aligning the indicator in the MR scanner, refer to [Section 6.6 on page 213](#).

**WARNING 6.34**

Verify that the image orientation is correct when preparing a treatment plan. Otherwise wrong target can be treated.

**WARNING 6.35**

Ensure that the indicator is correctly aligned during imaging. Otherwise inaccurate treatment can result.

6.4.3.4**Removal and disassembly**

The procedure for removing the indicator from the coordinate frame is the reverse of the procedure given in [Section 6.4.3.2 on page 198](#).

The procedure for disassembling the indicator is the reverse of the procedure given in [Section 6.4.3.1 on page 194](#).

6.4.4

Replenishing the marker channels

The following instructions describe a complete replenishment of empty marker channels in the panels of the indicator. If you only need to replenish parts of nearly filled marker channels, adapt the replenishment according to the level of the existing copper sulfate solution in the channels.

- Carefully fill a syringe of suitable size with copper sulfate (CuSO_4) solution, room tempered or warmer, from the bottle provided. Ensure that there are no air bubbles in the syringe.

Note:

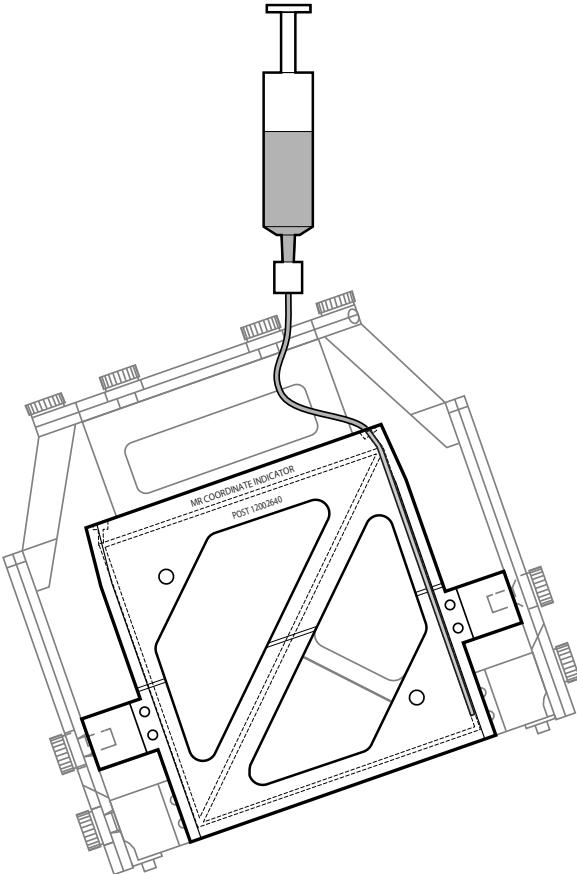
The copper sulfate solution should be stored in room temperature to prevent the formation of air bubbles.

- Connect the tube provided to the syringe. Ensure that there are no air bubbles in the tube.

6.4.4.1

Filling the channels in the posterior panel

- Using the special screwdriver, carefully remove the sealing screw and O-ring seal from the filling hole of the right marker channel in the posterior panel.
- Insert the end of the tube into the filling hole and push the tube all the way into the right channel until the tube reaches the bottom of the channel.



- Tilt the panel to the left as shown in the illustration, with the filling hole uppermost.
- Inject the solution into the right channel. While injecting the solution, slowly withdraw the tube to follow the level of the liquid.

- 5 Continue to inject the solution until the liquid reaches the thread of the filling hole. The liquid will flow into all channels of the panel. Make sure all channels are completely filled when the tube is fully withdrawn.
- 6 Carefully refit the O-ring seal and sealing screw into the filling hole.
- 7 Hold the panel upright with the filling hole upwards and check that no air bubbles remain in the channels. If bubbles are present, repeat steps 1 to 6 above until the channels are clear of air.

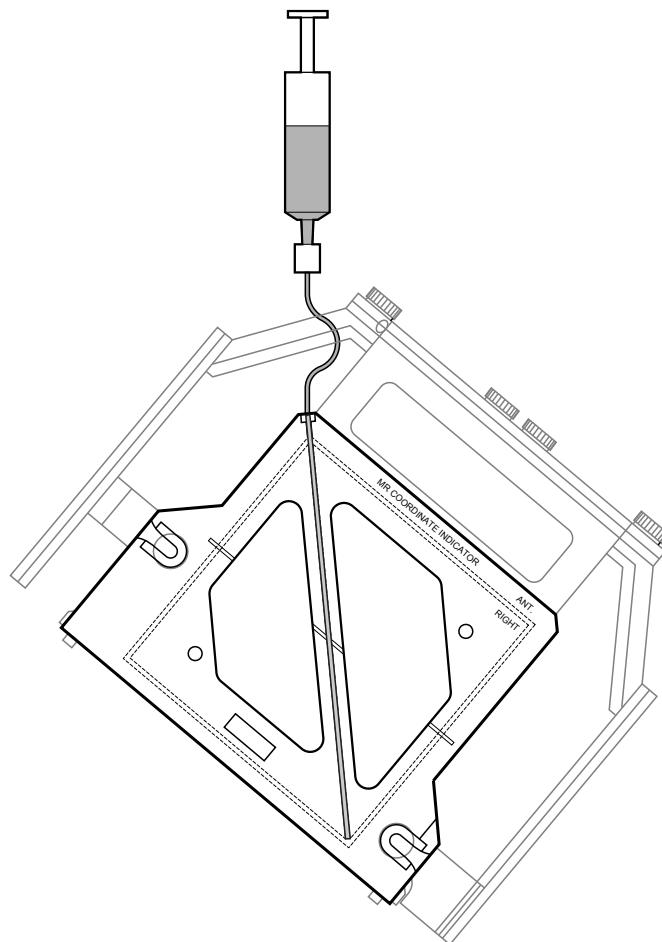
Note:

You do not need to use the filling hole of the left marker channel in the posterior panel when completely replenishing empty channels. You may use the left filling hole if you only need to replenish parts of nearly filled marker channels.

6.4.4.2**Filling the channels in the top and side panels**

The procedure for the top and side panels is the same as for the posterior panel.

- Follow steps 1 to 7 for the posterior panel above, but use the diagonal channel of the top and side panels, as shown in the illustration below. Tilt the panel to one side and make sure to hold the panel upright.

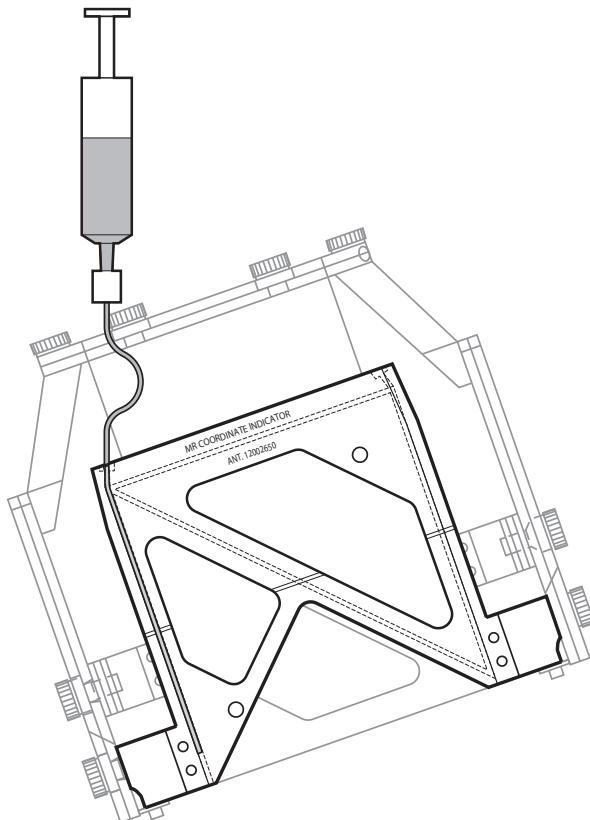


6.4.4.3

Filling the channels in the anterior panel

The procedure for the anterior panel is different from the other panels. Both filling holes of the anterior panel need to be used.

- 1 Start with the left marker channel. Follow steps **1** to **3** for the posterior panel above to insert the tube and tilt the panel, as shown in the illustration.



- 2 Inject the solution into the left channel. While injecting the solution, slowly withdraw the tube to follow the level of the liquid. Continue to inject the solution until the liquid is level with the top of the left channel. Do not fill the diagonal channel from the left filling hole.
- 3 Remove the tube from the left channel. Carefully refit the O-ring seal and sealing screw into the filling hole.
- 4 Continue with the right marker channel. Follow steps **1** to **7** for the posterior panel above. When the right channel is filled, the liquid will flow into the diagonal and top channels.

6.5 Open MR Indicator

6.5.1 Product overview

The Open MR Indicator is an accessory for target localization in stereotactic neurosurgery and radiosurgery. It is used in conjunction with Leksell® Coordinate Frame G and the MR Adapters.

Note: *In this section, the term “indicator” refers to the Open MR Indicator.*

The purpose of the indicator is to impose fiducial points on patient images during MR image acquisition. The fiducial points are used to determine target coordinates in Leksell® coordinate system by the treatment planning software Leksell SurgiPlan® and Leksell GammaPlan®, or by manual coordinate determination.

The indicator fiducial system forms a square with a diagonal in both indicator panels. The fiducial system channels are filled with a copper sulfate solution, which imposes the fiducial points on the images during the MR image acquisition.

Two sets of fiducial points are imposed, with three separate fiducial points in each set. The specific locations of the fiducial sets on an image show the relative position of the patient’s skull in the stereotactic space. The position of the center fiducial point in relation to the other two fiducial points in each set is indicative of the image slice position in Z direction.

The principle is illustrated in [Figure 6.11](#), which shows typical fiducial points resulting from an axial scan.

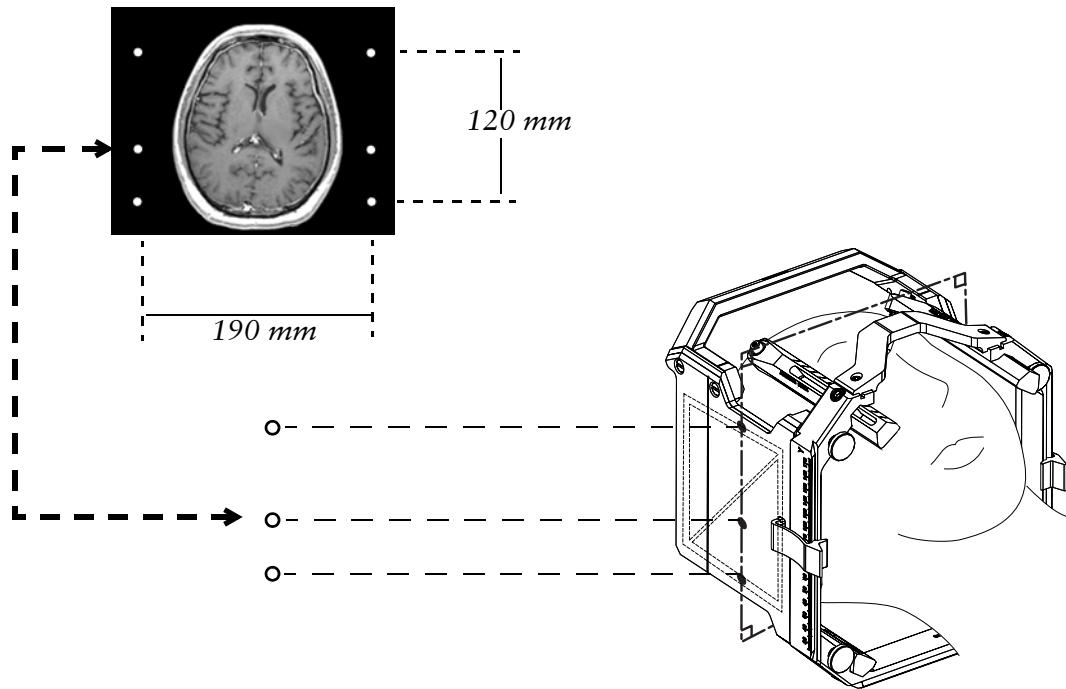


Figure 6.11 Principle of the Open MR Indicator

6.5.2

Main parts

Refer to [Figure 6.12](#).

The indicator consists of two **panels**, labelled **LEFT** ① and **RIGHT** ②, and a **plate holder** ③ labelled **ANTERIOR**. Four **locking screws** ④ secure the panels to the plate holder.

The panels mirror each other in appearance. Both panels have embedded **marker channels** ⑤ filled with copper sulfate solution. The channels form a square with a diagonal, which imposes the fiducial points on the images during the MR image acquisition.

One **sealing screw** ⑥ per panel seal the marker channels and permit replenishment of the copper sulfate solution. The panels and the plate holder have **reference lines** ⑦ engraved. The lines are used for perpendicular alignment of the indicator in the MR scanner.

At each inferior corner of both panels a **locating pin** ⑧ or ⑨ protrudes. When fitting the indicator to the coordinate frame, these locating pins fit into corresponding holes in the corners of the coordinate frame. To ensure correct fitting, the left anterior locating pin ⑨ is of a larger diameter than the other three locating pins ⑧.

Two **attachment clips** ⑩ secure the assembled indicator to the coordinate frame.

The indicator is made of plastic (PMMA – Polymethyl methacrylate).

A screwdriver is supplied with the indicator for assembly and disassembly purposes.

This equipment is MR Safe. See [Section 1.2.4 on page 8](#) for detailed information.



Note:

The instrument screwdriver is MR Unsafe. 

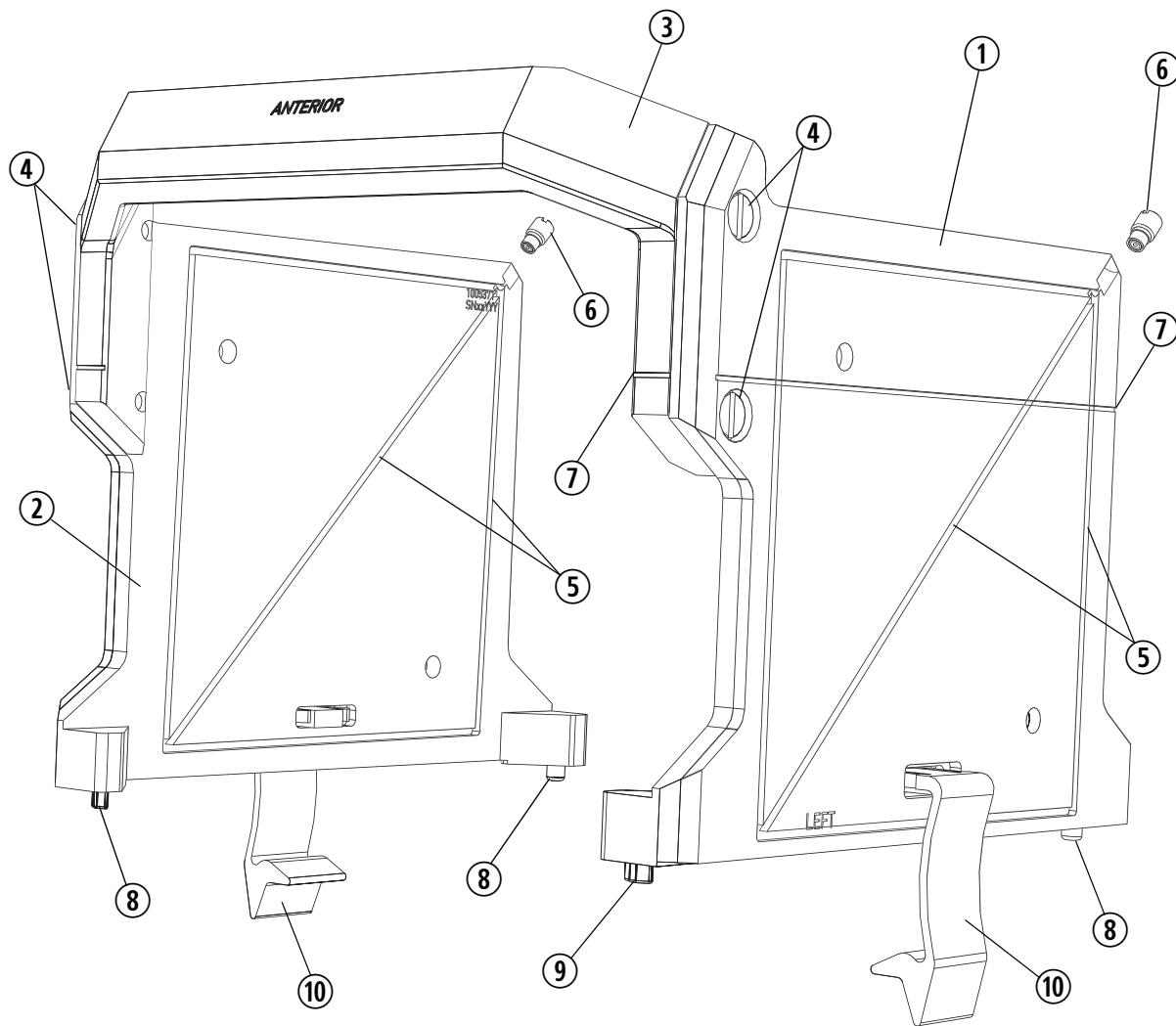
6.5.2.1

Labels

Some parts have engraved labels. See [Table 6.4](#) for details, and [Section 9.7 on page 288](#) for general label information.

Table 6.4 Labelled parts on the Open MR Indicator

Part	Labels
① Panel, left	LEFT
② Panel, right	RIGHT
③ Plate holder	ANTERIOR, PMMA



- ① Panel, left
- ② Panel, right
- ③ Plate holder
- ④ Locking screws
- ⑤ Marker channels

- ⑥ Sealing screw
- ⑦ Reference lines
- ⑧ Locating pin
- ⑨ Locating pin, left anterior
- ⑩ Attachment clips

Figure 6.12 Main parts of the Open MR Indicator

6.5.3 Using the Open MR Indicator



WARNING 6.36

If performing manual treatment planning, ensure to add 40 mm to the measured Z length. Otherwise the Z coordinate will be erroneous and wrong target will be treated.

6.5.3.1 Assembly instructions

Preparation

The indicator is usually attached to the coordinate frame after the coordinate frame has been positioned on the patient. For instructions on preparing the coordinate frame, refer to [Section 3.2 on page 28](#).

Inspect all components regarding functionality before use.

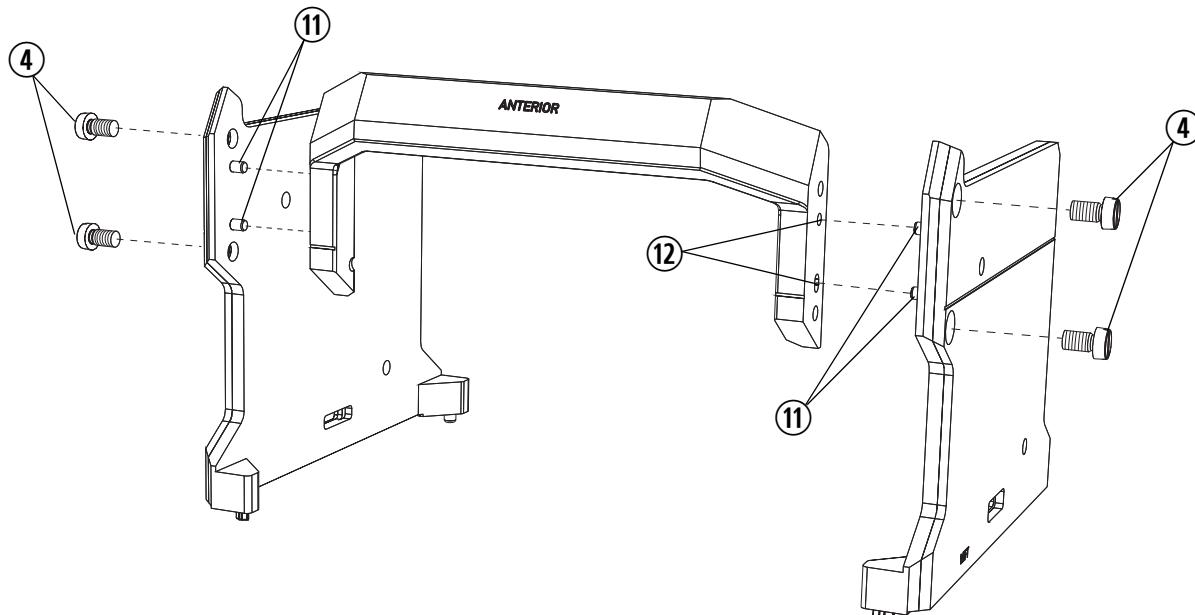
Check that all components of the indicator are at hand (see [Figure 6.12](#)) and clean prior to use.

Check that there are no air bubbles in the marker channels. See [Section 6.5.3.5 on page 211](#) for instructions on how to replenish the marker channels.

Assembling the Open MR Indicator before first use

The indicator must be assembled before first use. It is not recommended to disassemble the indicator afterwards.

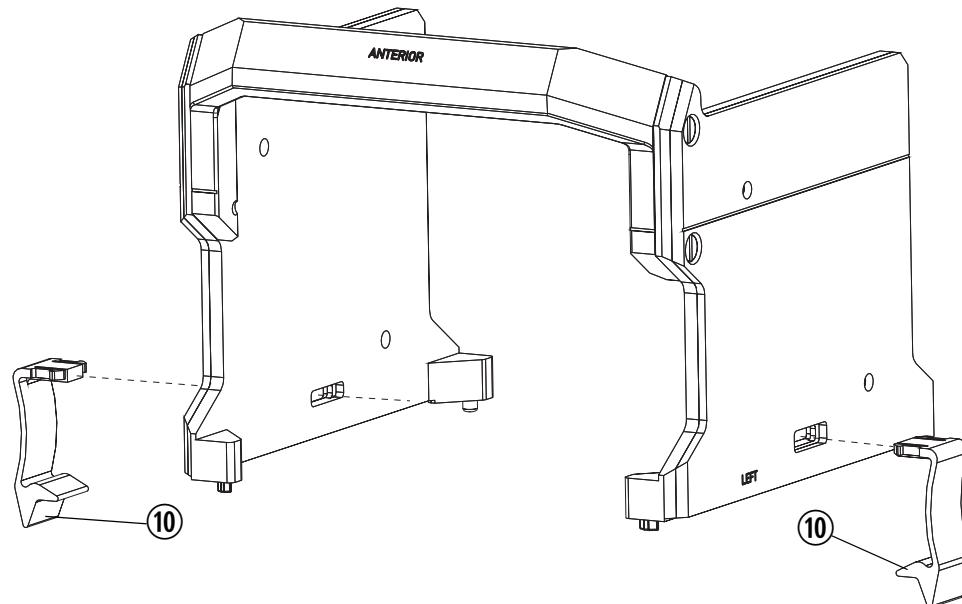
- 1 Attach the panels to the plate holder by fitting the pins ⑪ to the holes ⑫. Secure the plates by inserting and tightening the four screws ⑭ using the screwdriver provided with the product.



WARNING 6.37

Do not use excessive force when tightening locking screws/knobs. Otherwise parts can be damaged and not permit secure fixation. Non-secure fixation can cause incorrect treatment.

- 2 Insert an attachment clip ⑩ through the slot of each panel.



6.5.3.2 Fitting the Open MR Indicator to the coordinate frame



WARNING 6.38

Support the patient's head at all times when fitting the coordinate frame to, and removing it from, any other equipment. Otherwise the patient can be injured.

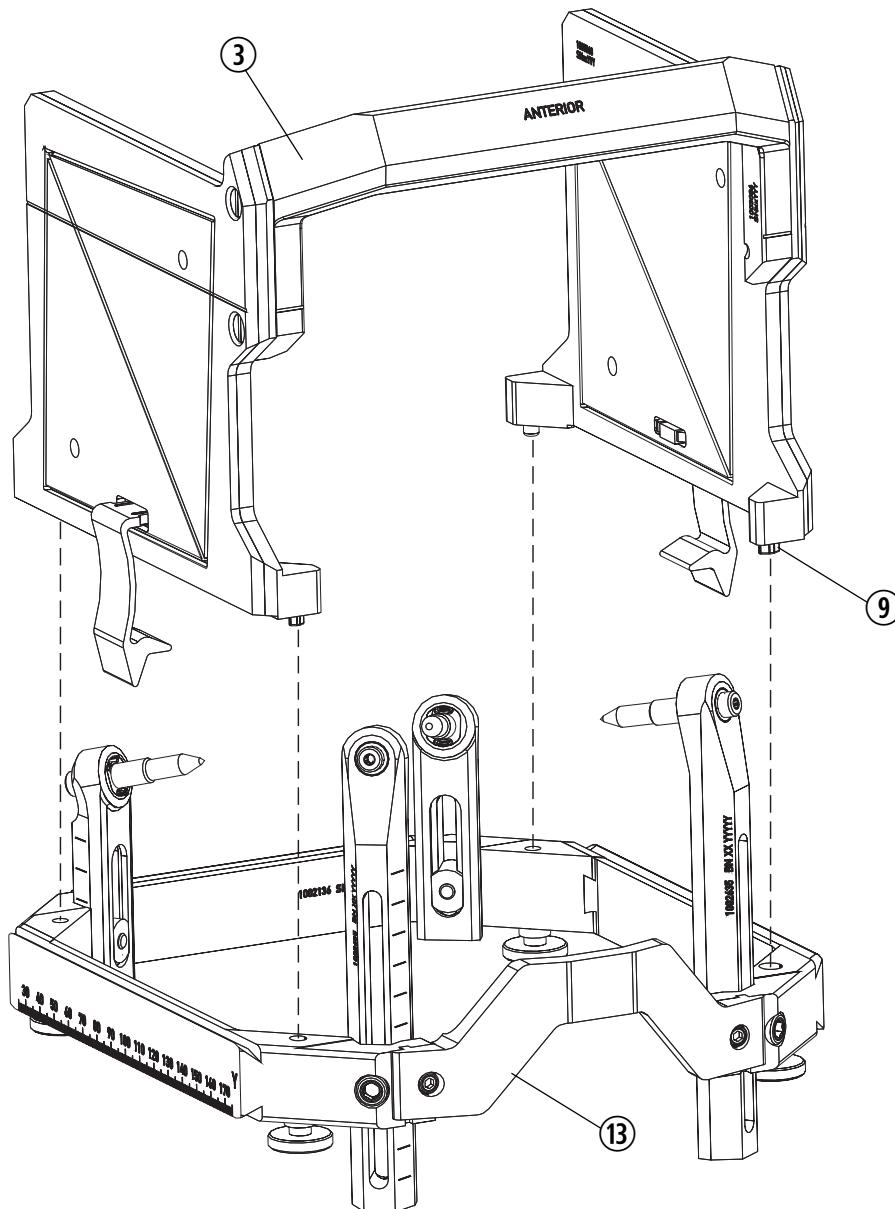


WARNING 6.39

The weight of the patient's head must not be supported by the indicator, otherwise the patient can be injured or the indicator can be damaged.

The indicator can be fitted to the coordinate frame before or after the coordinate frame has been fitted to the patient, although the latter is preferable. The following instructions assume that the coordinate frame has been correctly assembled.

- Fit the indicator to the coordinate frame, so that the plate holder ③, labelled **ANTERIOR**, is placed above the front piece ⑬ of the coordinate frame, and insert the locating pins of the indicator into the corresponding holes of the coordinate frame.

**Note:**

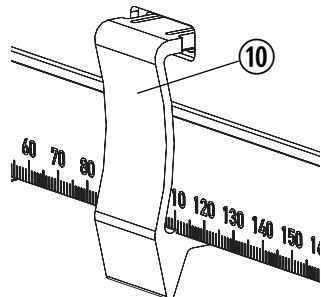
The left anterior locating pin ⑨ and the corresponding hole in the coordinate frame are of larger diameter to ensure correct fitting.

WARNING 6.40

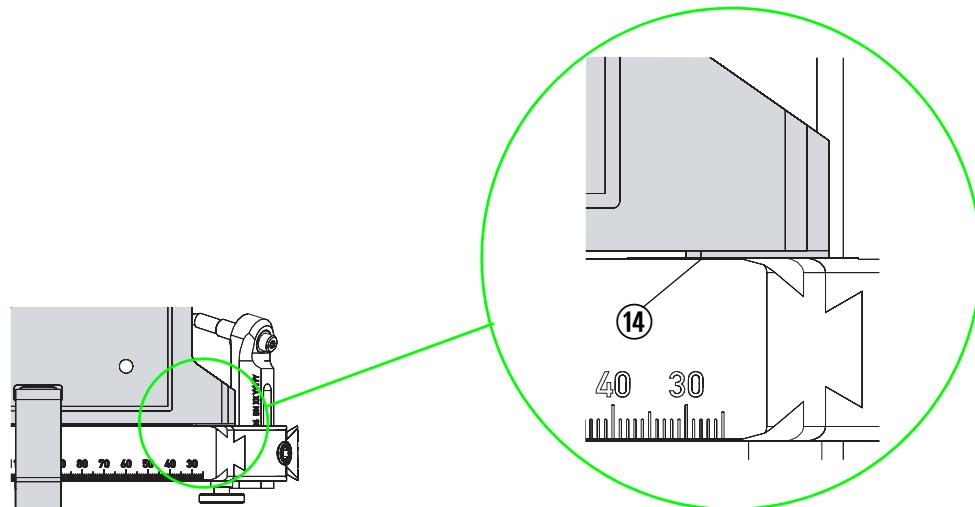
When fitting the Open MR Indicator to the coordinate frame, ensure that the panel marked LEFT is on the patient's left side and that the plate holder, marked ANTERIOR, is placed above the front piece of the coordinate frame.

Open MR Indicator

- 2 Ensure that the locating pins are completely inserted into the holes of the coordinate frame.
- 3 While supporting the indicator with both hands, snap both attachment clips ⑩ into place under the edges of the coordinate frame. This secures the indicator to the coordinate frame.



- 4 Ensure that there is no gap between the coordinate frame and the indicator corners ⑭ at the locating pins.



WARNING 6.41

Make sure that the indicator is correctly mounted onto the coordinate frame. Otherwise there is a risk for inaccurate treatment planning.

6.5.3.3

Scanning images and planning treatment

The indicator supports the acquisition of axial and coronal image slices. Based on the image information in the axial or coronal image study acquisition, coronal and sagittal images, or axial and sagittal images respectively, are reconstructed in the Elekta treatment planning software.

Elekta recommend using Leksell SurgiPlan® or Leksell GammaPlan® for treatment planning. For manual determination of coordinates for the treatment, it is crucial to acquire perfectly orthogonal images.

Align the reference lines ⑦ on the indicator with the laser beam from the MR scanner. For additional information on positioning the patient and aligning the indicator in the MR scanner, see [Section 6.6 on page 213](#).



WARNING 6.42

Verify that the image orientation is correct when preparing a treatment plan. Otherwise wrong target can be treated.



WARNING 6.43

Ensure that the indicator is correctly aligned during imaging. Otherwise inaccurate treatment can result.

6.5.3.4

Removal and disassembly

The procedure for removing the indicator from the coordinate frame is the reverse of the procedure given in [Section 6.5.3.2 on page 208](#).

It is not recommended to disassemble the indicator. If required, the procedure for disassembling the indicator is the reverse of the procedure given in [Section 6.5.3.1 on page 207](#).

6.5.3.5

Replenishing the marker channels

The following instructions describe a complete replenishment of empty marker channels in the panels of the indicator. If you only need to replenish parts of nearly filled marker channels, adapt the replenishment according to the level of the existing copper sulfate solution in the channels.

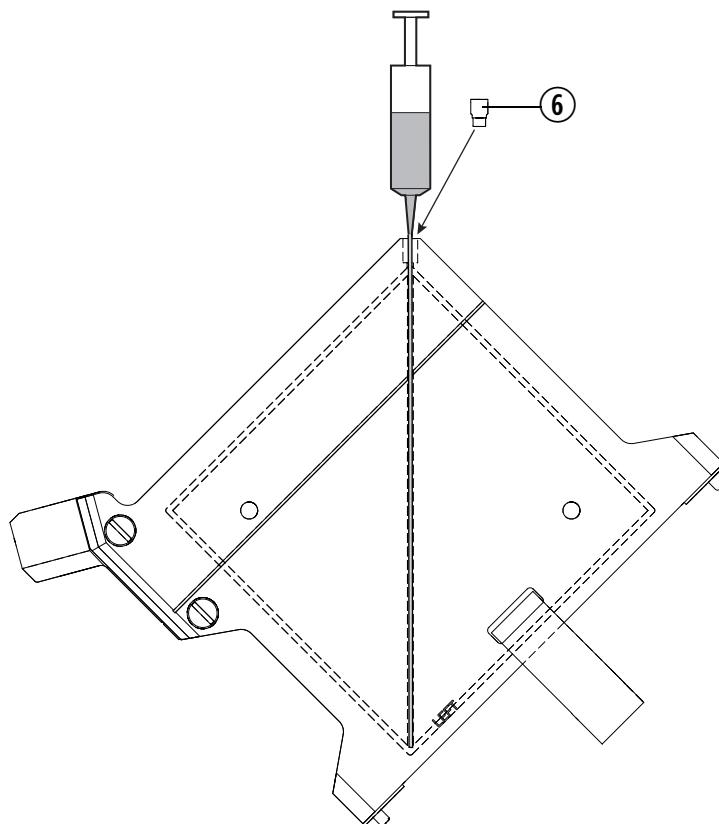
- 1 Carefully fill a syringe of suitable size with copper sulfate (CuSO_4) solution, room tempered or warmer, from the bottle provided.
 - Ensure that there are no air bubbles in the syringe.

Note:

The copper sulfate solution should be stored in room temperature to prevent the formation of air bubbles.

- 2 Connect the syringe to the supplied filling needle and fill the needle with the solution.
 - Ensure that there are no air bubbles in the needle.
- 3 Carefully remove the sealing screw ⑥ from the filling hole in one of the panels.
- 4 Insert the needle all the way to the bottom of the diagonal channel.

- 5 Tilt the panel 45° as shown in the illustration, with the filling hole uppermost to allow the air to move out from the channels during the filling.



- 6 Inject the solution into the diagonal channel. While injecting the solution, slowly withdraw the filling needle to follow the level of the liquid.
- 7 Continue to inject the solution until the liquid reaches the thread of the filling hole. The liquid will flow into all channels of the panel.
- 8 Make sure all channels are completely filled when the needle is fully withdrawn.
- 9 Carefully refit the sealing screw ⑥ into the filling hole.
- 10 Hold the panel upright with the filling hole upwards and check that no air bubbles remain in the channels.
If bubbles are present, repeat steps 3 to 9 above until all the channels are clear of air.

6.6 MR Adapters

6.6.1 Product overview

MR Adapters are used in conjunction with Leksell® Coordinate Frame G and the MR Indicator.

Note: *In this section, the term “adapter” refers to the MR Adapter.*

The purpose of the adapters is to locate and secure the indicator at the correct position in the MR scanner, and to ensure that this position is accurately repeatable in subsequent scans. The adapters also provide comfortable support for the patient’s head throughout the scanning procedure.

A number of adapters are available, each designed to fit a particular type of MR scanner. This manual describes the components and procedures common to all models of adapters. For further details of the appropriate adapter for your scanner, contact Elekta® or check the Elekta® product catalog.

An adapter with indicator and coordinate frame will fit into most MR scanners which have a head coil system with an inner diameter of 268 mm or more. If the inner diameter is less than 268 mm, the body coil of the MR scanner may have to be used.

The adapter is fitted to the table of the scanner in place of the headrest, or fitted directly to the head coil. The coordinate frame is fitted into the adapter and must then be adjusted, so that it becomes exactly perpendicular to the gantry of the scanner. Captured MR images are thus parallel to the plane of the coordinate frame.

This optimizes the precision of the fiducial markers which are imposed on the MR images. It also ensures repeatability, so that scans can be superimposed on each other and images compared with those of a brain atlas.

The adapter is specifically designed to hold the coordinate frame, and thus the skull of the patient, firmly in place. If the scan is interrupted, the adapter permits the coordinate frame to be relocated in the same position.

Table 6.5 list the presently available MR adapters.

Table 6.5 List of available MR adapters

MR Adapter Universal (long)	This MR adapter can be an option for certain MR scanners when no other dedicated MR adapter is suitable. This is a universal MR adapter of a long design.	
MR Adapter Universal (short)	This MR adapter can be an option for certain MR scanners when no other dedicated MR adapter is suitable. This is a universal MR adapter of a short design.	

MR Adapters

Table 6.5 List of available MR adapters

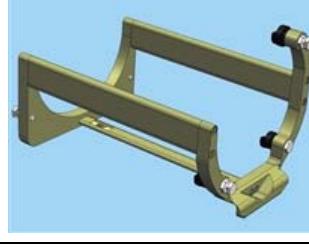
MR Adapter for Philips 3 T QHC T/R	This MR adapter is designed for Philips 3 T Quadrature Headcoil with length 28 cm. Coil inner diameter of 275 mm.	
MR Adapter for Philips Quadrature Headcoil (1.5 T)	This MR adapter is designed for Philips 1.5 T Quadrature Headcoil with length 30.5 cm. Coil diameter is 275 mm.	
MR Adapter for GE Quadrature Headcoil	This MR adapter is designed for GE Quadrature Headcoil with an inner diameter of 275 mm.	
MR Adapter for GE Split Headcoil	The adapter is designed for GE 450/750 Split Headcoil and GE HD Split head coil with inner diameter of 281 mm and a length of 424 and 414 mm respectively.	
MR Adapter for Siemens TxRx CP	MR Adapter for Tx/Rx CP Head Array coil. Inner diameter of 270 mm.	
MR Adapter for Siemens TxRx Headcoil	This MR adapter is designed for Siemens TxRx Headcoil both 1.5 T and 3 T, mainly used with Trio. Inner diameter of 270 mm.	

Table 6.5 List of available MR adapters

MR Adapter for Siemens CP Head Array	Designed for Siemens CP Head Array coils. Inner Diameter 268 mm.	
MR Adapter for Siemens Conical Headcoil	This MR adapter is designed for Siemens Magnetom with circular polarized conical headcoil, shell type opening. Inner diameter of 268 mm.	
MR Adapter for Toshiba QD Headcoil	Designed for Toshiba QD Headcoil.	
MR Adapter for Toshiba	This MR adapter is designed for Toshiba previous scanner models.	

Figure 6.13 shows an **adapter** ① assembled with the coordinate frame and the **indicator** ②, the **reference lines** ③ for scanner light alignment, and the **marker channels** ④ filled with copper sulfate (CuSO_4) solution to create fiducials on MR images.

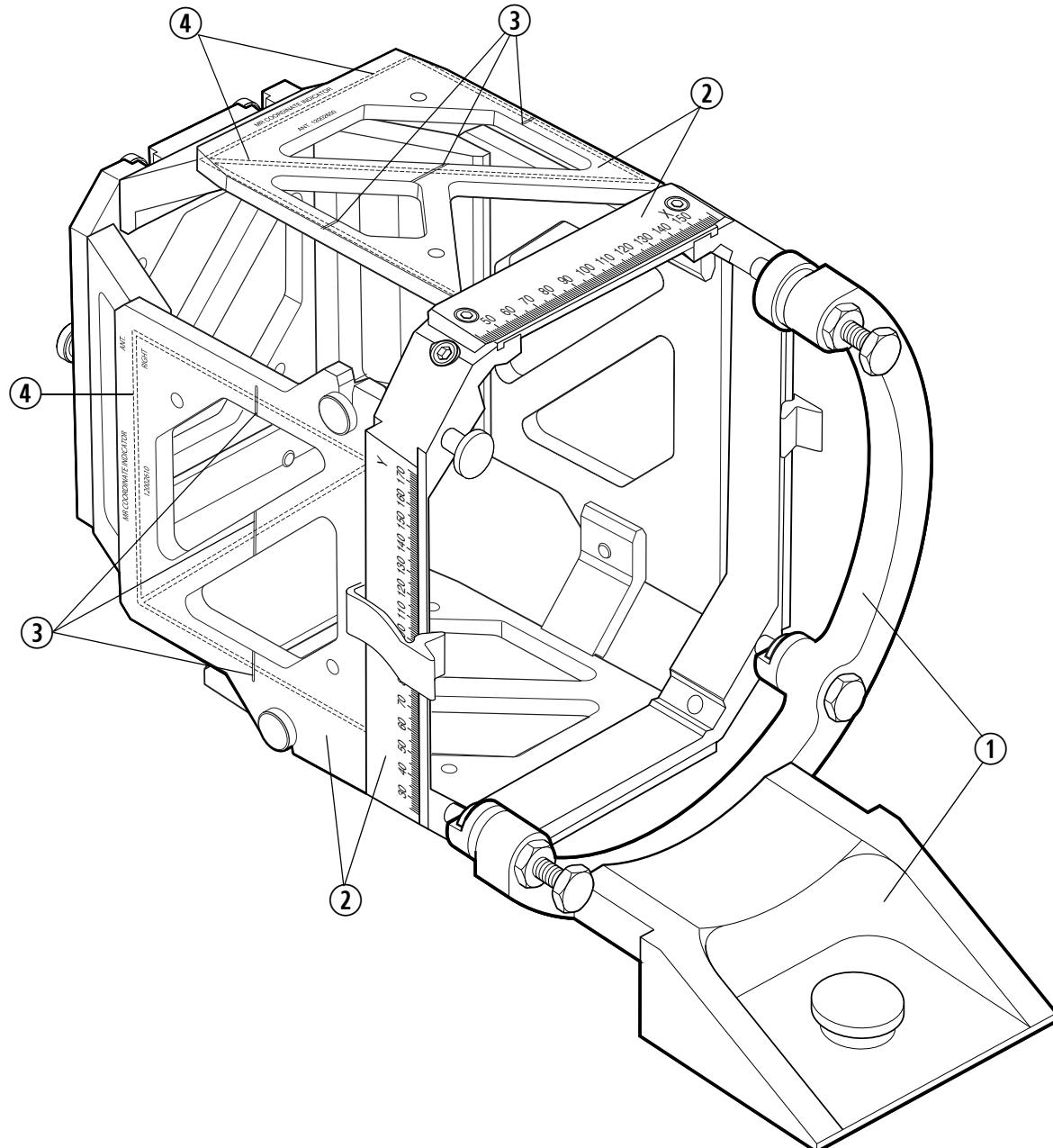


Figure 6.13 *MR Indicator and coordinate frame mounted on an MR Adapter*

6.6.2

Main parts

Refer to [Figure 6.14](#).

The adapters are made of a non-magnetic material. The exact appearance of the adapter and the means by which it is attached to the scanner table vary according to the type of scanner. Some adapters have a **fastening screw** **X** to fasten the adapter to the scanner table.

Each adapter comprises a **base** **⑤** which attaches to the scanner table or head coil, and provides a rigid platform for the **frame support** **⑥**.

The **frame fixation sockets** **⑦**, **⑧** and **⑨** hold the coordinate frame in place. Each socket accommodates one foot of the coordinate frame.

The position of the indicator relative to the plane of the scan is adjusted by means of two screws in the frame supports of the adapter and by reference to the scanner's alignment lasers.

The twist (horizontal rotation) of the adapter is adjusted by means of the **twist screw** **⑩** and is secured by the **twist lock nut** **⑪**. The tilt (vertical rotation) of the adapter is adjusted by means of the **tilt screw** **⑫** and is secured by the **tilt lock nut** **⑬**.

The socket **⑦** is equipped with a **security ring** **⑭** that can be used to prevent accidental detachment of the coordinate frame from the adapter.

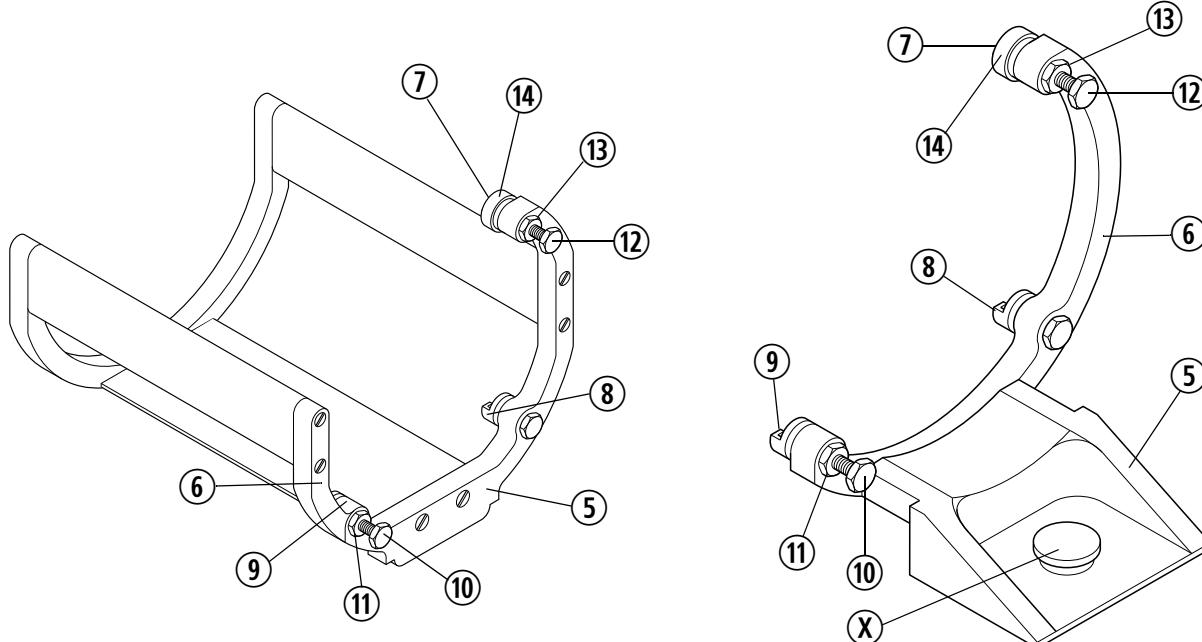
Older adapters are supplied with a wrench and a hexagonal key for adjustment. Newer models are supplied with two non-metallic wrenches.

This equipment is MR Safe. See [Section 1.2.4 on page 8](#) for detailed information.



Note:

The wrench and hexagonal key are MR Unsafe.



⑤ Base

⑩ Twist screw

⑬ Tilt lock nut

⑥ Frame support

⑪ Twist lock nut

⑭ Security ring

⑦, ⑧, ⑨ Frame fixation sockets

⑫ Tilt screw

⑮ Fastening screw

[Figure 6.14 Common parts of MR Adapters](#)

6.6.2.1 Labels

Some parts can have engraved labels. See [Section 9.7 on page 288](#).

6.6.3 Using the MR Adapter**WARNING 6.44**

Do not use the coordinate frame with MR scanner frequencies lower than 40 MHz. Otherwise the images can be distorted.

6.6.3.1 Fitting instructions**Preparation**

Inspect all components regarding functionality before use.

The following instructions assume that:

- The coordinate frame has been assembled and attached to the patient's skull in accordance with [Section 3.2 on page 28](#).
- The indicator has been assembled and fitted to the coordinate frame (see [Section 6.4 on page 191](#) or [Section 6.5 on page 204](#)).
- All components of the adapter are clean and at hand.

6.6.3.2 Fitting the MR Adapter to the scanner

- 1 Remove the headrest (if fitted) from the scanner table/headcoil.
 - Refer to the manual provided with your scanner for the correct procedure and tools required.
- 2 Install the adapter in place of the headrest and fasten it to the scanner table.
 - If there is no headrest, position the adapter in the head coil of the scanner.
- 3 Depending on the adapter model, proceed as instructed in [Table 6.6](#):

Table 6.6 Adjustment instructions for specific adapters

MR Adapter Universal (long) Universal MR adapter of a long design to be used when no other dedicated adapter is suitable.	1. Position the board on the scanner table so that the head coil can be pulled over the coordinate frame and indicator.	
MR Adapter Universal (short) Universal MR adapter of a short design to be used when no other dedicated adapter is suitable.	1. Position the board on the scanner table so that the head coil can be pulled over the coordinate frame and indicator.	

Table 6.6 Adjustment instructions for specific adapters

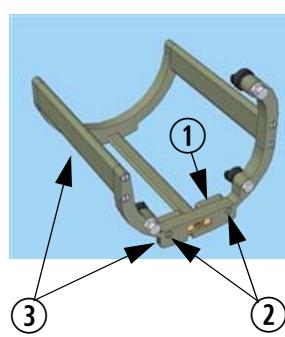
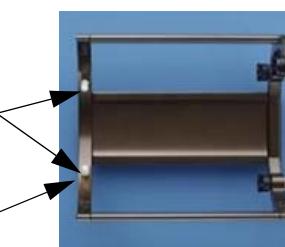
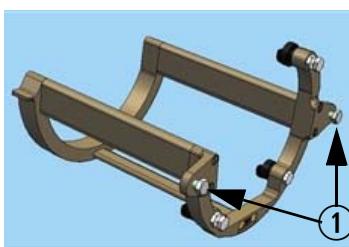
MR Adapter for Philips 3 T Quadrature Headcoil T/R Headcoil length: 28 cm Coil inner diameter: 275 mm.	1. Remove the headrest from the headcoil. 2. Attach the adapter to the headrest fitting points.	
MR Adapter for Philips Quadrature Headcoil (1.5 T) Headcoil length: 30.5 cm Coil inner diameter: 275 mm.	1. To remove the bracket (1) loosen the two screws(2). 2. Mount the bracket in correct position to fit the headcoil lip of 15 mm or 10 mm. 3. Adjust the lateral play with the screw (3). 4. Fasten the bracket with the screws (2). 5. Remove the headrest from the headcoil. 6. Attach the adapter to the headrest fitting points.	
MR Adapter for GE Quadrature Headcoil	1. Adjust the level of the adapter with the screws (1). 2. Lock the screw with the locking nut (2).	
MR Adapter for GE Split Headcoil	1. Attach the adapter to the bottom shell of the headcoil. 2. Tighten the screws (1) to minimize the play.	
MR Adapter for Siemens TxRx CP	1. Attach the adapter to the bottom shell of the headcoil. 2. Tighten the screws (1) to minimize the play.	

Table 6.6 Adjustment instructions for specific adapters

MR Adapter for Siemens TxRx Headcoil	1. Attach the adapter to the bottom shell of the headcoil. 2. Tighten the screws (1) to minimize the play.	
MR Adapter for Siemens CP Head Array	1. Attach the adapter to the cutout in the bottom shell of the headcoil. 2. Adjust the lateral play with the screw (1). 3. Tighten the lever (2) to fit the adapter.	
MR Adapter for Siemens Conical Headcoil	1. Attach the adapter to the cutout in the bottom shell of the headcoil. 2. Adjust the lateral play with the screw (1). 3. Tighten the level (2) to fit the adapter.	
MR Adapter for Toshiba QD Headcoil	1. Attach the adapter to the bottom shell of the headcoil. 2. Level the adater by adjusting the bracket (1). 3. Tighten the screw (2).	
MR Adapter for Toshiba	1. Remove the headrest from the headcoil. 2. Attach the adapter to the headrest slot in the table top.	

Note:

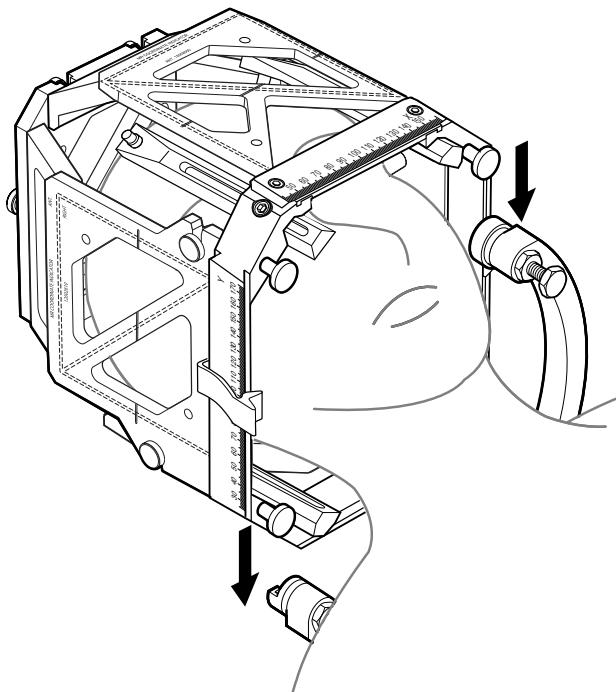
Ensure that the MR Adapter is securely fixed to the scanner table.**WARNING 6.45**

**Ensure that the equipment is properly assembled and securely fixed.
Otherwise the patient can be injured.**

6.6.3.3**Positioning the patient****WARNING 6.46**

Support the patient's head at all times when fitting the coordinate frame to, and removing it from, any other equipment. Otherwise the patient can be injured.

- 1 Position the patient on the scanner table so that he coordinate frame will engage with the adapter when the patient's head is lowered to the scanning position.



- 2 While carefully supporting the patient's head, lower the coordinate frame until the posterior feet and the anterior left foot of the coordinate frame slide into the frame fixation sockets.
- 3 Check that the coordinate frame is fully engaged with the adapter, i.e. the feet of the coordinate frame are located at the bottom of the frame fixation sockets. Once the feet are in place, further horizontal movement is prevented.
- 4 Pull the security ring over the anterior foot of the coordinate frame.
- 5 If desired, use a cushion or other support between the table and the patient's neck for increased patient comfort.

**WARNING 6.47**

Ensure that the equipment is properly assembled and securely fixed. Otherwise the patient can be injured.

**WARNING 6.48**

Ensure that the patient can easily be released in case of emergency. Otherwise the patient can be injured.

6.6.3.4 Aligning the MR Adapter to the scanner

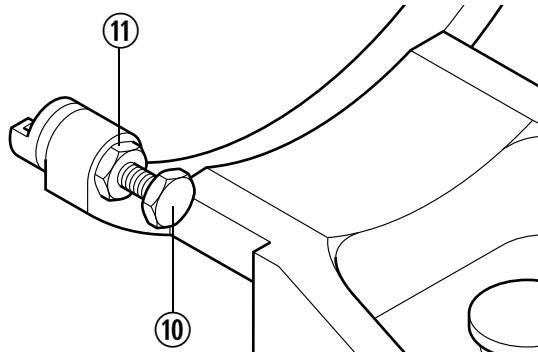

WARNING 6.49

Ensure that the indicator is correctly aligned during imaging. Otherwise inaccurate treatment can result.

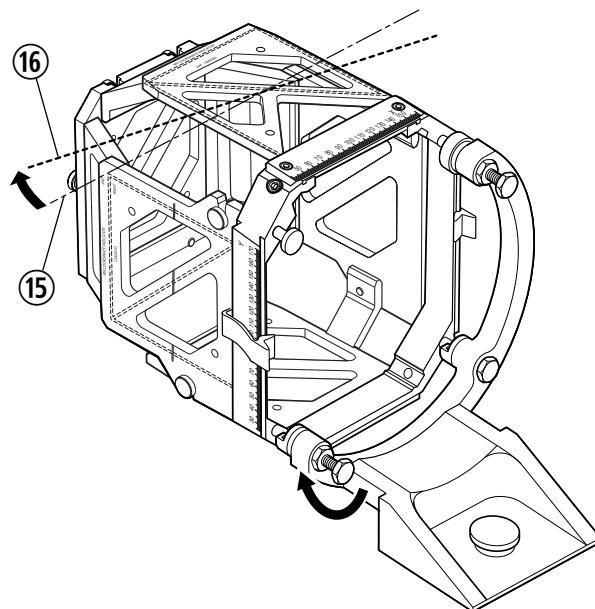
Before the MR scan is performed the position of the adapter must be adjusted so that the indicator is parallel to the plane of the scan. Use the twist setting for adjusting to the left and right, and the tilt setting for adjusting up and down, as described in the following.

- 1 Switch on the scanner's alignment lights and observe their positions relative to the reference lines on the indicator.
- 2 Adjust the twist setting of the adapter as follows:

- (a) Using the wrench, release the twist lock nut ⑪.



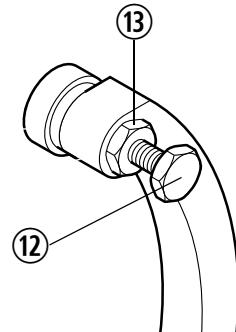
- (b) Adjust the twist setting by means of the twist screw ⑩ until the reference line ⑯ of the anterior panel of the indicator is aligned with the laser beam ⑯. Turn this screw clockwise using the wrench to rotate the coordinate frame clockwise as viewed from above.



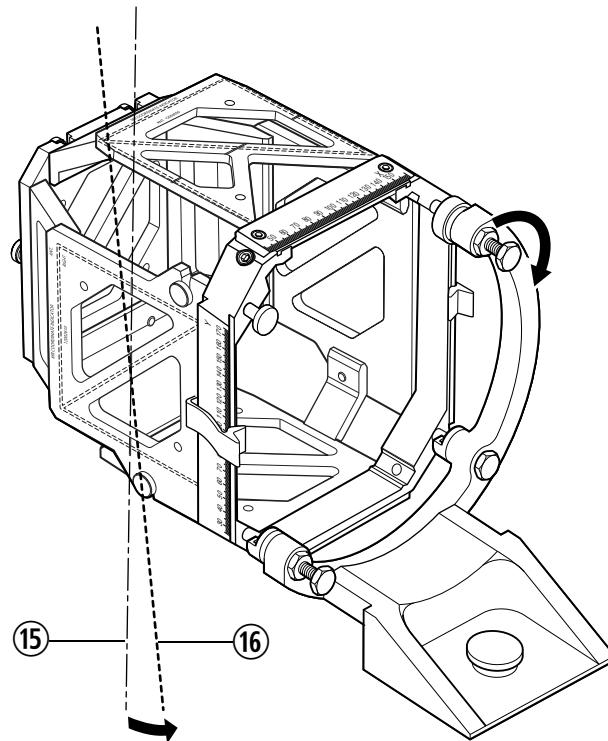
- (c) When the twist setting is correct, tighten the twist lock nut ⑪.

3 Adjust the tilt setting of the adapter as follows:

(a) Using the wrench, release the tilt lock nut ⑬.



(b) Adjust the tilt setting by means of the tilt screw ⑫ until the reference lines ⑮ of the side panels of the indicator are aligned with the laser beam ⑯. Turn this screw clockwise to tilt the coordinate frame counter-clockwise when facing the panel labelled **RIGHT**.



(c) When the tilt setting is correct, tighten the tilt lock nut ⑬.

- 4 Check the twist setting again, you may have to make a small readjustment.
- 5 Check the tilt setting again.

6.6.3.5 Removal and disassembly

The procedure for removing the patient from the adapter and the scanner table is the reverse of the procedure given in [Section 6.6.3.3 on page 221](#).

The procedure for removing the adapter from the scanner table is the reverse of the procedure given in [Section 6.6.3.2 on page 218](#).



CAUTION 6.2

The adapter should not be disassembled by the user.

6.7 MR Phantom

6.7.1 Product overview

The MR Phantom is used to check for the presence of distortions when Leksell® Coordinate Frame G is used in an MR scanner. The phantom consists of a container which simulates the head of the patient, within which two types of grids can be placed to evaluate axial or coronal scanning directions respectively.

Note: In this section, the term “phantom” refers to the MR Phantom.

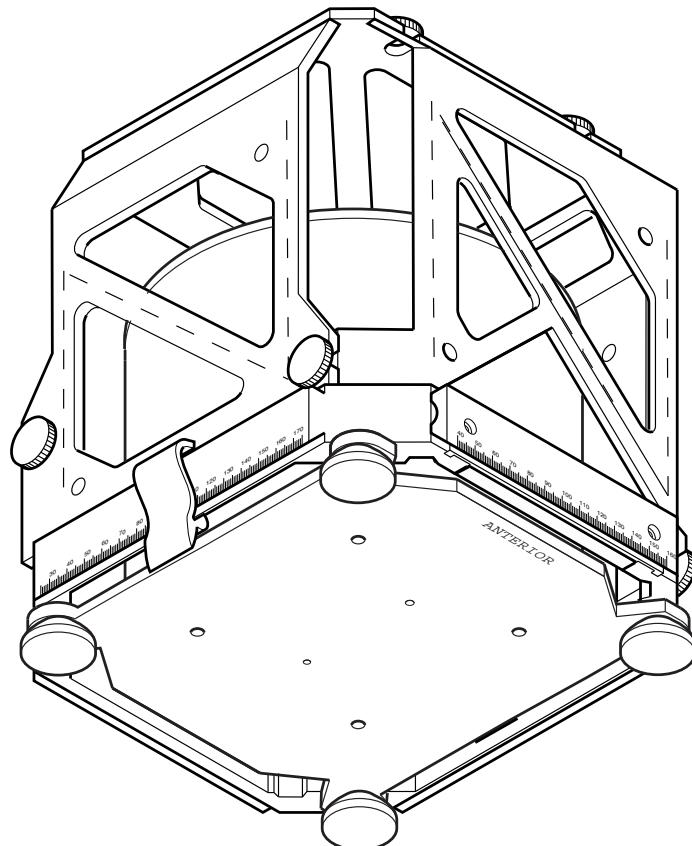


Figure 6.15 Principle of the MR Phantom

6.7.2

Main parts

Refer to [Figure 6.16](#).

The **container** ① is produced from plastic. It has a tapped hole in the center of the base where the locking screw locates. There are two locating holes of different diameters in the underside of the base for installation of (mounting) the grid and four small tapped holes for assembly. The container houses two types of grids:

- **Axial Grid** ② is used for axial slices and has vertical rods fixed to two circular plates. Refer to [Figure 6.17](#).
- **Coronal Grid** ③ is used for coronal slices and has horizontal rods fixed through a series of vertical walls. Refer to [Figure 6.18](#).

The hole in the top plate of the grid is larger to aid removal of the grid. The underside of the lower plate has two locating holes which correspond to the locating pins fitted in the container base.

The **cover** ④ contains three holes. The middle hole is for the locking screw to pass through. The two outer holes are tapped to accommodate the refilling and ventilation screws.

The **base plate** ⑤ has four inner holes for fixing screws to secure the base plate to the container. On the upper side of the base plate, two different sized diameter locating pins are fitted to locate into corresponding holes in underside plate of the container. The different sized pins and corresponding holes act as an aid to the correct orientation of the parts during assembly. The underside of the base plate is marked **ANTERIOR**. The outer holes are for installation of the phantom.

When the phantom is attached to the MR Adapter without using the coordinate frame the four **nuts** ⑫ secure the feet of the coordinate frame to the base plate.

The **locking screw** ⑥ secures the cover to the container.

The **ventilation/filling screws** ⑦ and ⑧ are located in the tapped holes in the cover. The ventilation screw is removed to release trapped air during the filling of the container with liquid, and also to relieve any vacuum acting inside the container when removing the cover. The filling screw is removed to fill the container with liquid.

The **large O-ring** ⑨ provides an air-tight seal between the container and the cover.

The three **O-rings** ⑩ provide an air-tight seal for each screw on the cover.

The four **fixing screws** ⑪ secure the base plate to the container.

This equipment is MR Safe. See [Section 1.2.4 on page 8](#) for detailed information.



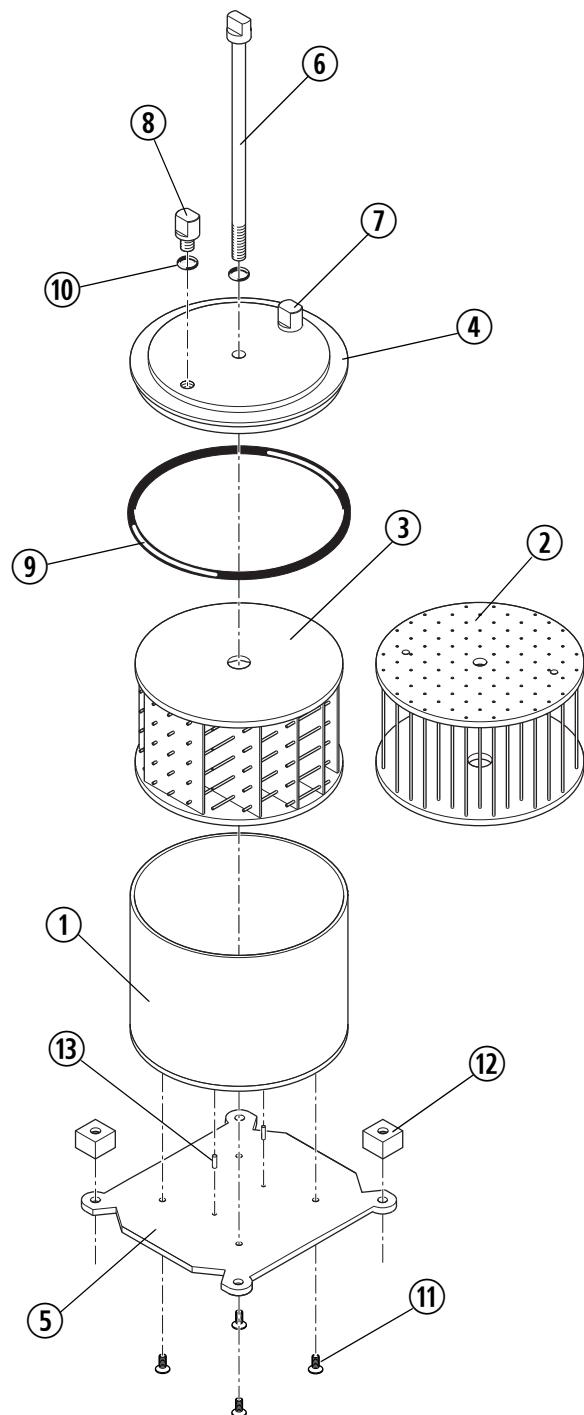
6.7.2.1

Labels

Some parts have engraved labels. See [Table 6.7](#) for details, and [Section 9.7 on page 288](#) for general label information.

Table 6.7 Labelled parts on the MR Phantom

Part	Labels
⑤ Base plate	ANTERIOR



- | | |
|-----------------|---------------------------------|
| ① Container | ⑦, ⑧ Ventilation/filling screws |
| ② Axial grid | ⑨ Large O-ring |
| ③ Coronal grid | ⑩ O-rings |
| ④ Cover | ⑪ Fixing screws |
| ⑤ Base plate | ⑫ Nuts |
| ⑥ Locking screw | ⑬ Locating pins |

Figure 6.16 Main parts of the MR Phantom

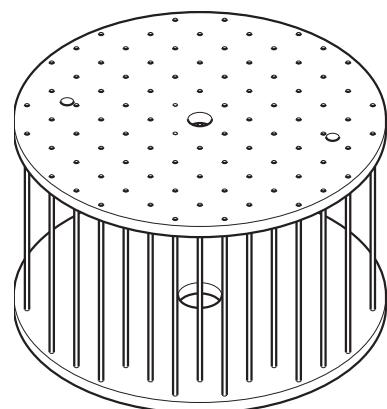


Figure 6.17 Axial Grid ② (underside view)

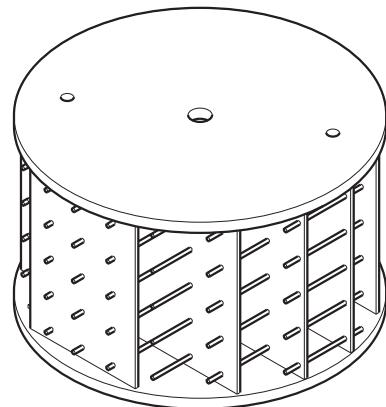


Figure 6.18 Coronal Grid ③ (underside view)

6.7.3 Using the MR Phantom

6.7.3.1 Measurements

The MR images obtained using the phantom consist of a grid with dots corresponding to a slice through the rods. The dots are equidistant. [Figure 6.19](#) shows the axial grid where the distance between two dots is 16 mm. [Figure 6.20](#) shows the coronal grid where the distance between two dots is 20 mm in both horizontal and vertical directions. Any linear distortions can be checked on the MR image by measuring the distances between the dots and comparing them against the geometrically correct values. Check both the center and the boundary of the image.

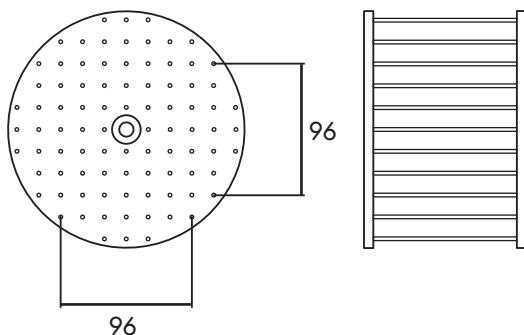


Figure 6.19 Axial Grid

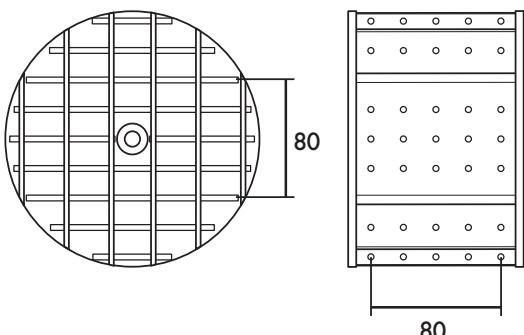


Figure 6.20 Coronal Grid

6.7.3.2 Non-linear Distortions

Non-linear distortions are present if the dots in the phantom are not aligned vertically and horizontally to each other. If non-linear distortions are present, there must be some degree of inhomogeneity in the main magnetic field, or non-linearities in the magnetic field gradients. If there are any distortions present, remove the coordinate frame from the phantom and make new images to ensure that the distortions have not been generated by the coordinate frame. To attach the phantom without the coordinate frame use the nuts as shown in [Figure 6.16](#).



WARNING 6.50

The phantom can only show distortions caused by Leksell® Coordinate Frame. Other distortions cannot be determined with the phantom.

6.7.3.3 Assembly instructions

Preparation

Inspect all components regarding functionality before use.

Check that all components of the phantom are at hand ([Figure 6.16](#)) and clean prior to use.



CAUTION 6.3

Ensure that the large O-ring is in good condition. Otherwise the verification can be incorrect.



CAUTION 6.4

Do not wash the equipment with alcoholic solutions.

The following instructions assume that the coordinate frame has been correctly assembled. Refer to [Section 3.2 on page 28](#), for more information.

Assembling the MR Phantom

- 1 Attach the container to the base plate. When the container is correctly mounted tighten the four fixing screws on the underside of the base plate.
- 2 Lower the grid into the container. Ensure that the locating pins in the bottom of the container are correctly located in the corresponding holes in the underside of the lower grid plate.

Note:

Check that the grid has been correctly mounted.

- 3 Fill the container with copper sulfate dissolved in deionized water (CuSO_4 , 0.002 mol/l).



CAUTION 6.5

Check that the container is filled with liquid before use.

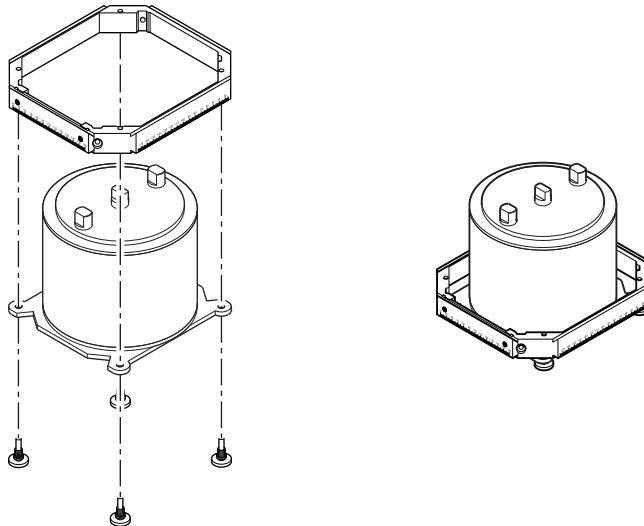
- 4 Place the O-ring seal around the shouldered diameter on the underside of the cover.

- 5 Place the cover on top of the container. Insert and tighten the locking screw.

The phantom is now ready for attachment to the coordinate frame.

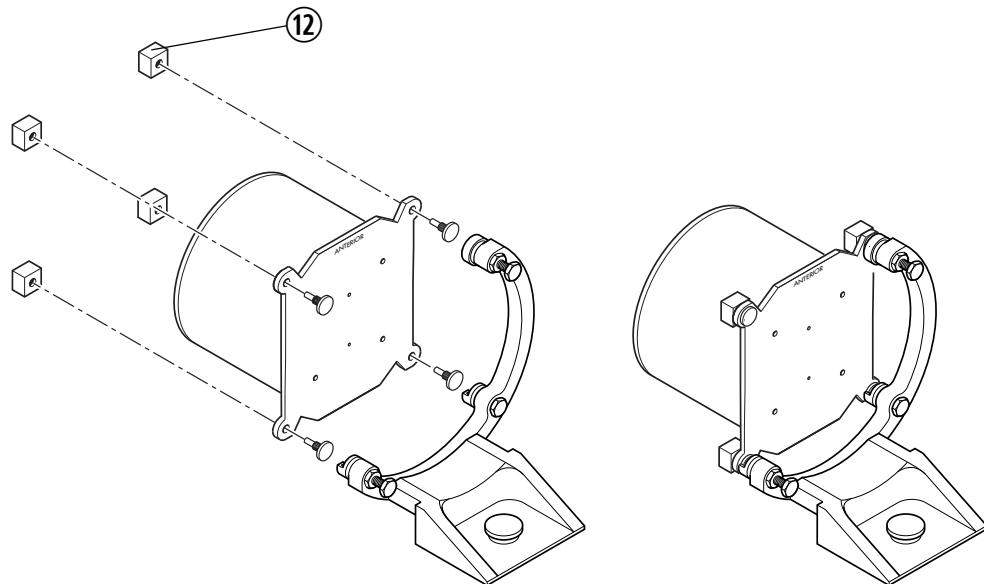
6.7.3.4**Fitting the MR Phantom to the coordinate frame**

Lower the coordinate frame over the phantom and secure the phantom to the coordinate frame by the four threaded connection feet.

**6.7.3.5****Attaching the MR Adapter**

Attach the coordinate frame or the phantom to the MR Adapter as described in [Section 6.6 on page 213](#).

If the phantom is being directly mounted to the MR Adapter, the four nuts ⑫ are used to secure the feet of the coordinate frame to the base plate.



6.7.3.6**Attaching the MR Indicator to the coordinate frame**

- 1 Attach the MR Indicator as described in [Section 6.4 on page 191](#).
- 2 With the MR indicator also fixed to the coordinate frame, the perpendicular alignment of the phantom can be performed with the engraved lines on the front and side panels.
- 3 Place the MR Adapter with coordinate frame (if fitted), phantom and MR Indicator in the MR Coil and adjust the coordinate frame/phantom (if the coordinate frame is not fitted) to be perpendicular to the scanner.

6.7.3.7**Exchanging grids**

- 1 To relieve the vacuum, release the ventilation/filling screws slightly. These screws can then be utilized as grips to aid the removal of the cover.

Note:

The cover can sometimes be difficult to remove due to the large O-ring becoming stuck on the mating surfaces, and/or by a vacuum acting inside the container.

- 2 Release the locking screw and remove the cover.
- 3 Empty the liquid from the container before removing the grid.

**CAUTION 6.6**

Be careful when handling the grids as they are extremely sensitive to external forces.

- 4 Insert a finger into the hole in the center of the upper plate and lift out the grid.
- 5 Lower the new grid into the container. See step [2 on page 230](#).
- 6 Fill the container with copper sulfate diluted in water (CuSO_4 , 0.002 mol/l).

**CAUTION 6.7**

Check that the container is filled with liquid before use.

- 7 Put the cover back and tighten the locking screw.
- 8 Tighten the ventilation/filling screws.

6.7.3.8**Removal and disassembly**

The procedure for removing the phantom from the coordinate frame is the reverse of the attachment procedure.

The procedure for disassembling the phantom is the reverse of the assembly procedure.

6.8 X-Ray Indicator with Markers

6.8.1 Product overview

The X-Ray Indicator with Markers is an accessory for target localization in stereotactic neurosurgery and radiosurgery. It is used in conjunction with Leksell® Coordinate Frame G.

Note: In this section, the term “indicator” refers to the X-Ray Indicator with Marker.

The purpose of the indicator is to impose fiducials on X-ray films of the patient. The fiducials are used for target localization, and for image alignment in treatment planning software.

The indicator ① (shown only in principle) has an integral fiducial system ② designed to ensure that fiducials are visible on X-ray. Two different sets of fiducials are imposed on the film ③; one set represents the coordinate frame plane nearest the X-ray source ④ and the other set represents the coordinate frame plane furthest from the source.

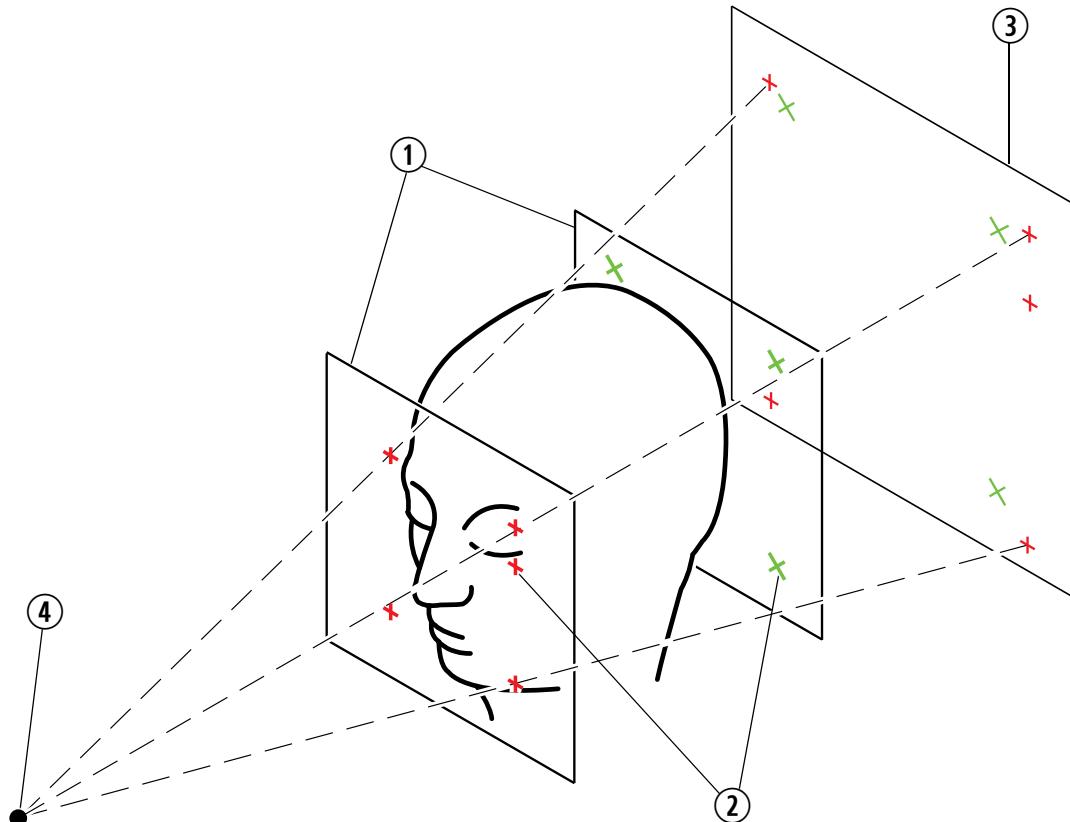


Figure 6.21 Principle of the X-Ray Indicator with Markers

6.8.2

Main parts

Refer to [Figure 6.22](#).

The indicator consists of five panels made of plastic:

- **Side panels right** ⑤ and **left** ⑥, labelled **X-RAY COORDINATE INDICATOR RIGHT** and **X-RAY COORDINATE INDICATOR LEFT**.
- The **anterior panel** ⑦, labelled **X-RAY COORDINATE INDICATOR ANT.**
- The **posterior panel** ⑧, labelled **X-RAY COORDINATE INDICATOR POST.**
- The **top panel** ⑨, labelled **X-RAY COORDINATE INDICATOR TOP**.

The side panels mirror each other in appearance but have different fiducial markers. On the left side panel the fiducial system consists of five upright crosses (+). Four are placed at the corners of a square and the fifth cross indicates the patient's anterior on the X-ray film.

On the right side panel there are four diagonal crosses (x), one at each corner of a square. This arrangement ensures that different fiducials are imposed as lateral-left and lateral-right projections with respect to the X-ray source.

Similar to the side panels, the anterior panel has five upright crosses (+), and the posterior panel has four diagonal crosses (x). One upright cross indicates the patient's left side on the X-ray film. This arrangement ensures that different fiducials are imposed as anterior-posterior and posterior-anterior projections with respect to the X-ray source.

The function of the top panel is to hold the side panels rigidly when assembled. There are pins on the underside of the left and right sides of the top panel. When assembling the indicator these pins fit into corresponding holes in the angle brackets.

Angle brackets ⑩ and **screws** ⑪ secure the top and side panels together. There are two brackets, with six screws for each bracket.

The anterior and posterior edges of the side panels have open-ended, countersunk slots for attachment of the anterior and posterior panels.

The lateral edges of the anterior and posterior panels have threaded holes for the eight **fixing screws** ⑫ that secure them to the side panels. The anterior panel has a cutaway to permit access to the patient's airways.

At each inferior corner of both side panels there is a right-angled bracket, from which a **locating pin** ⑯ protrudes.

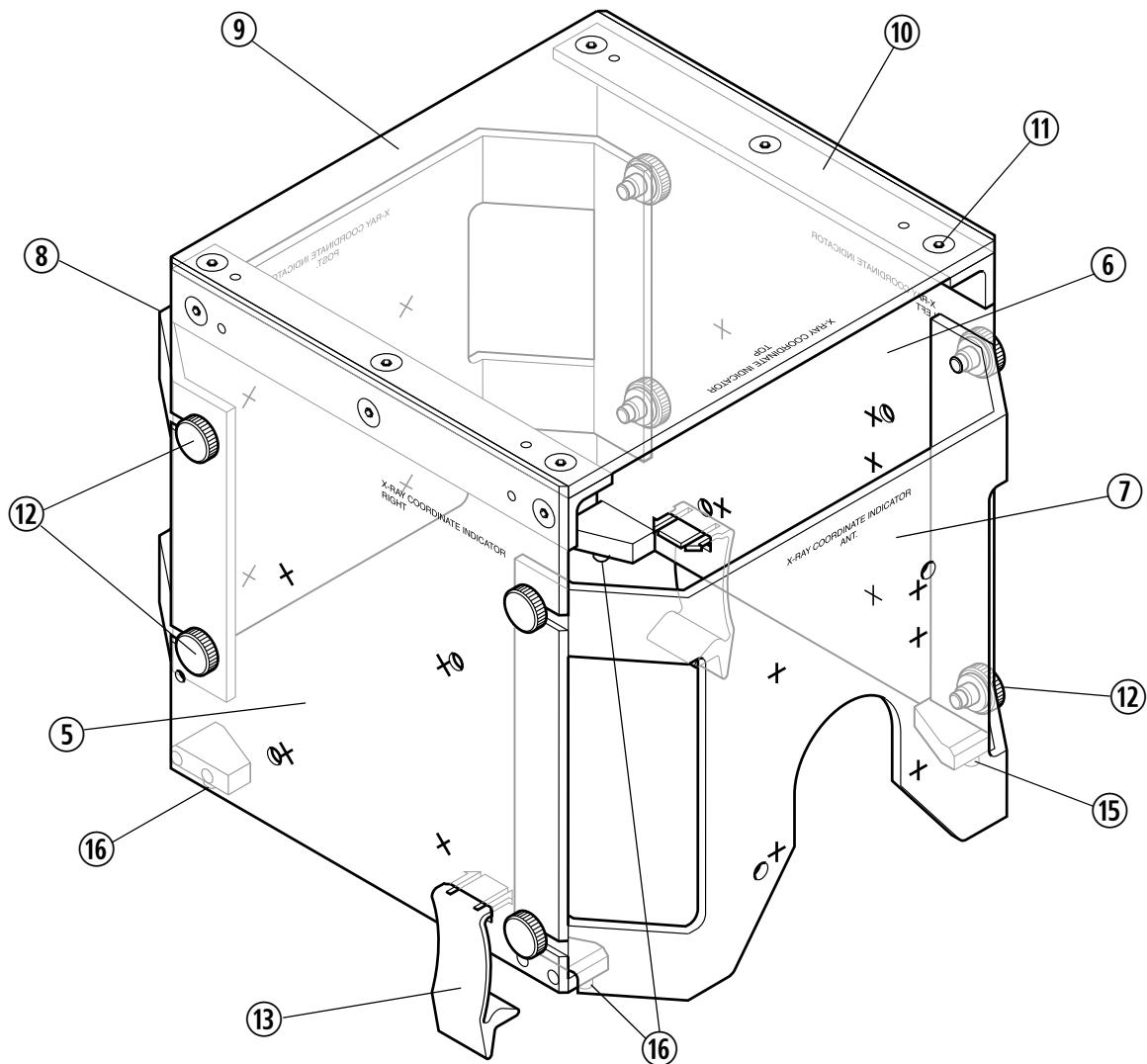
When fitting the indicator to the coordinate frame, these locating pins fit into corresponding holes in the corners of the coordinate frame. To prevent incorrect fitting, the left anterior locating pin ⑯ is of a larger diameter than the other three locating pins ⑯.

Two **attachment clips** ⑬ secure the assembled indicator to the coordinate frame.

The indicator is supplied with a 3 mm hexagonal key for assembly/disassembly purposes.

This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.





- ⑤ Side panel, right
- ⑥ Side panel, left
- ⑦ Anterior panel
- ⑧ Posterior panel
- ⑨ Top panel
- ⑩ Angle brackets
- ⑯ Locating pin

- ⑪ Screws
- ⑫ Fixing screws
- ⑬ Attachment clips
- ⑮ Locating pin, left anterior
- ⑯ Locating pin

Figure 6.22 Main parts of the X-Ray Indicator with Markers

6.8.2.1**Labels**

Some parts have engraved labels. See [Table 6.8](#) for details, and [Section 9.7 on page 288](#) for general label information.

Table 6.8 Labelled parts for the X-Ray Indicator with Markers

Part	Labels
⑤ Side panel, right	X-RAY COORDINATE INDICATOR RIGHT
⑥ Side panel, left	X-RAY COORDINATE INDICATOR LEFT
⑦ Anterior panel	X-RAY COORDINATE INDICATOR ANT
⑧ Posterior panel	X-RAY COORDINATE INDICATOR POST
⑨ Top panel	X-RAY COORDINATE INDICATOR TOP

6.8.3**Using the X-Ray Indicator with Markers****6.8.3.1****Assembly instructions****Preparation**

The indicator is usually attached to the coordinate frame after the coordinate frame has been positioned on the patient. For instructions on preparing the coordinate frame, refer to [Section 3.2 on page 28](#).

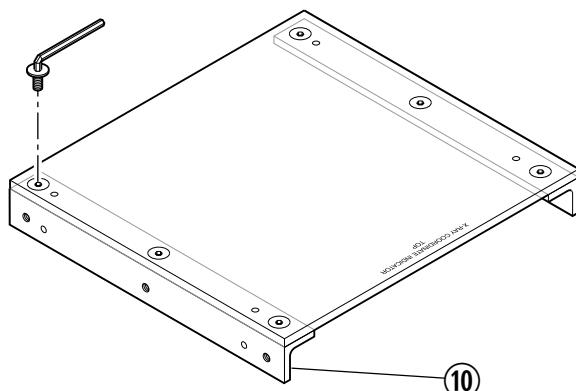
Inspect all components regarding functionality before use.

Check that all components of the indicator are at hand (see [Figure 6.22](#)) and clean prior to use.

Assembling the indicator

- 1 The top panel is pre-assembled on delivery from Elekta®. If the top panel has been disassembled, do as follows:

- (a) Fit an angle bracket ⑩ to the underside of the top panel with three of the screws provided. Ensure that the locating pins protruding from the top panel are correctly inserted into the corresponding holes in the angle bracket. Using the hexagonal key, tighten the screws until the bracket is secure.

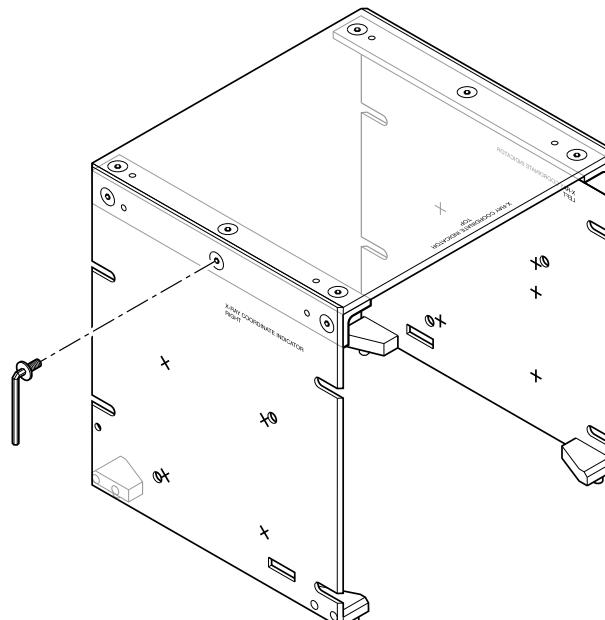


WARNING 6.51



**Do not use excessive force when tightening locking screws/knobs.
Otherwise parts can be damaged and not permit secure fixation.
Non-secure fixation can cause incorrect treatment.**

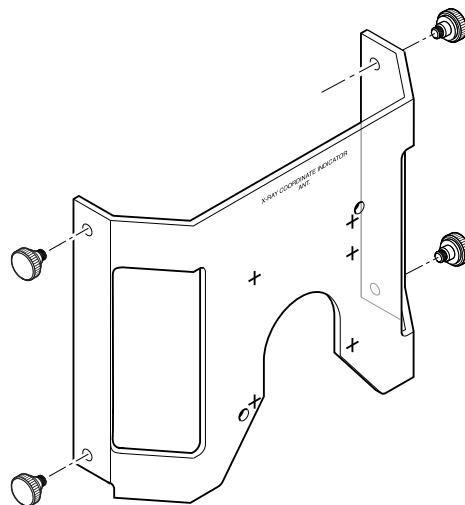
- (b) Fit the other angle bracket to the top panel as described in step (a).
- 2 Using three of the screws, attach the top edge of one side panel to the bracket on the corresponding side of the top panel.
- Ensure that the locating pins protruding from the side panel are correctly inserted into the corresponding holes in the angle bracket. Using the hexagonal key, tighten the screws until the side panel is secure.



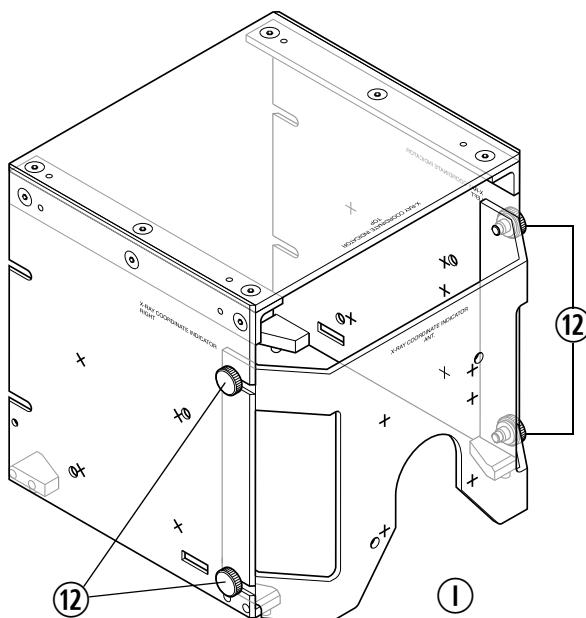
- 3 Fit the other side panel to the top panel as described in step 2.

X-Ray Indicator with Markers

- 4 Loosely insert a fixing screw into the hole in the angled bracket at each corner of the anterior panel. There are four fixing screws in all.



- 5 Insert the anterior panel between the side panels. The anterior panel must face outwards, with the cutaway at the inferior position ① and the fixing screws ⑫ properly inserted into the countersunk slots.

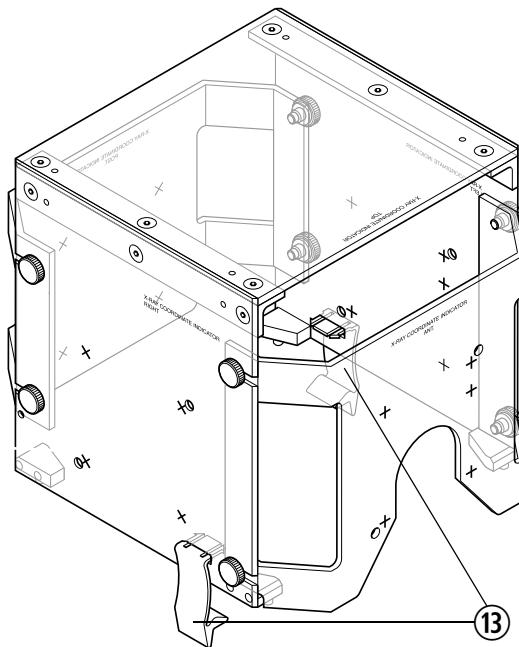


- 6 Secure the anterior panel to the side panels by tightening the four fixing screws ⑫. Ensure that the conical portion of each fixing screw is properly seated in the countersunk slot.
- 7 Secure the posterior panel to the side panels using the same procedure as for the anterior panel, described in steps 4 to 6.

Note:

If preferred, the anterior or posterior panel can be fitted after the indicator has been fitted to the coordinate frame.

- 8 Insert an attachment clip ⑬ through the slot of each side panel.



The indicator is now ready for attachment to the coordinate frame.

6.8.3.2 Fitting the indicator to the coordinate frame

The indicator can be fitted to the coordinate frame before or after the coordinate frame has been attached to the patient, although the latter is preferable. The following instructions assume that the coordinate frame has been correctly assembled.



WARNING 6.52

Support the patient's head at all times when fitting the coordinate frame to, and removing it from, any other equipment. Otherwise the patient can be injured.



WARNING 6.53

When fitting the indicator to the coordinate frame, ensure that the side panel marked LEFT is on the patient's left side and the side panel marked RIGHT is on the patient's right side.



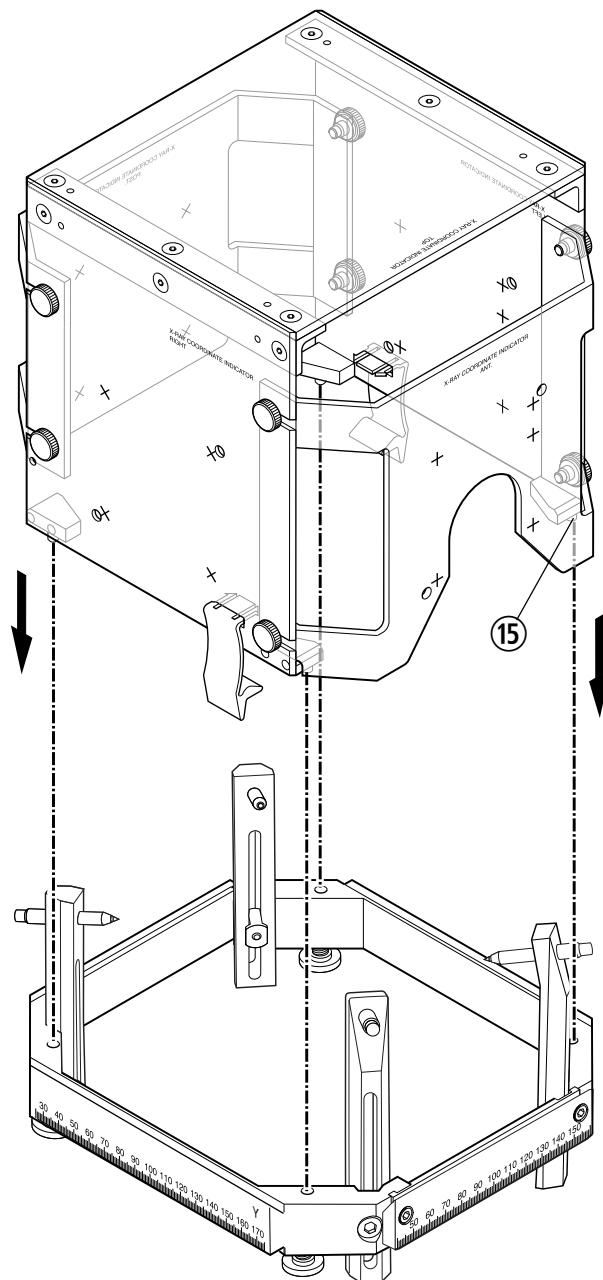
WARNING 6.54

The weight of the patient's head must not be supported by the indicator, otherwise the patient can be injured or the indicator can be damaged.

- 1 Align the indicator with the coordinate frame so that the panel labelled **X-RAY COORDINATE INDICATOR ANT** is placed above the front piece of the coordinate frame.

X-Ray Indicator with Markers

- 2 Place the indicator on the coordinate frame by properly inserting the locating pins of the indicator into the corresponding holes of the coordinate frame. Ensure that the locating pins are completely inserted into the holes.



Note:

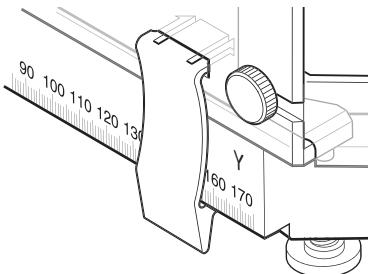
The left anterior locating pin ⑯ and the corresponding hole in the coordinate frame are of larger diameter to prevent incorrect fitting.



WARNING 6.55

Make sure that the indicator is correctly mounted onto the coordinate frame. Otherwise there is a risk for inaccurate treatment planning.

- 3 While supporting the indicator with both hands, snap both attachment clips into place under the edges of the coordinate frame. This secures the indicator to the coordinate frame.

**WARNING 6.56**

Verify that the image orientation is correct when preparing a treatment plan. Otherwise wrong target can be treated.

6.8.3.3 Removal and disassembly

The procedure for removing the indicator from the coordinate frame is the reverse of the attachment procedure given in [Section 6.8.3.2 on page 239](#).

The procedure for disassembling the indicator is the reverse of the assembly procedure given in [Section 6.8.3.1 on page 236](#).

6.9 X-Ray Indicator with Rulers

6.9.1 Product overview

The X-Ray Indicator with Rulers is an accessory for target localization in stereotactic neurosurgery. It is used in conjunction with Leksell® Coordinate Frame G.

Note: In this section, the term “indicator” refers to the X-Ray Indicator with Rulers.

The purpose of the indicator is to impose coordinate scales on X-ray films of the patient. The scales are used for determining the target coordinates.

The indicator ① (shown only in principle) has integral coordinate scales ② designed to ensure that scales are visible on X-ray. Two different sets of scales are imposed on the film ③; one set represents the coordinate frame plane nearest the X-ray source ④ and the other set represents the coordinate frame plane furthest from the source.

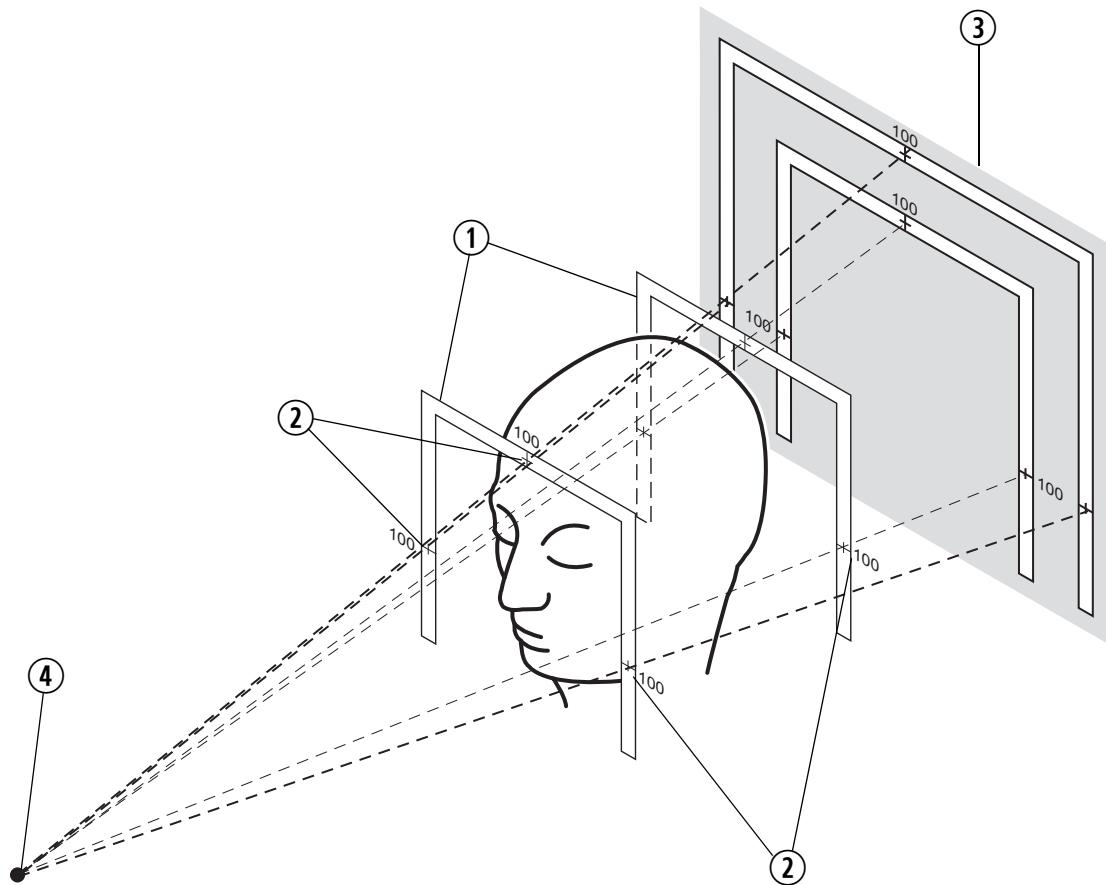


Figure 6.23 Principle of the X-Ray Indicator with Rulers

6.9.2

Main parts

Refer to [Figure 6.24](#).

The indicator consists of three panels:

- The **top panel** ①, labelled **X-RAY COORDINATE INDICATOR TOP**.
- **Side panels right** ② and **left** ③, labelled **X-RAY COORDINATE INDICATOR RIGHT** and **X-RAY COORDINATE INDICATOR LEFT**. They mirror each other in appearance.

The top panel consists of a square frame of plastic with four aluminum bars. The bars are engraved with coordinate scales.

The anterior face is scaled 30 to 170 mm from right to left. The posterior face is engraved with the letter **X** at the right end ⑩ and the scale mirrors the scale on the anterior face. The side bars are engraved 30 to 170 mm from posterior to anterior. The right side bar is also engraved with the letter **Y** at the anterior end ⑪.

Each side panel consists of a square frame of plastic with two aluminum columns.

The columns are engraved with coordinate scales with a range from top to bottom of 40 to 160 mm. The word **RIGHT** is engraved on the lateral face of the anterior column ⑫. The letter **Z** is engraved on each of the posterior columns ⑬.

All engravings on the bars and columns facing right and posterior are laterally inverted to obtain correctly faced letters in the X-ray images.

A hole in each corner of the top panel accepts a **fixing screw** ⑭ for securing the panel to the side panels. A threaded hole at the top of each column accommodates the screw.

Locating pins project from the top and bottom of each column. The top pins locate into corresponding holes of the top panel when the indicator is correctly assembled. The bottom locating pins fit into corresponding holes in the corners of the coordinate frame.



To prevent incorrect fitting of the indicator to the coordinate frame, the left anterior **locating pin** ⑮ is of a larger diameter than the other three **locating pins** ⑯.

Two **attachment clips** ⑰ secure the assembled indicator to the coordinate frame.

This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.

6.9.2.1

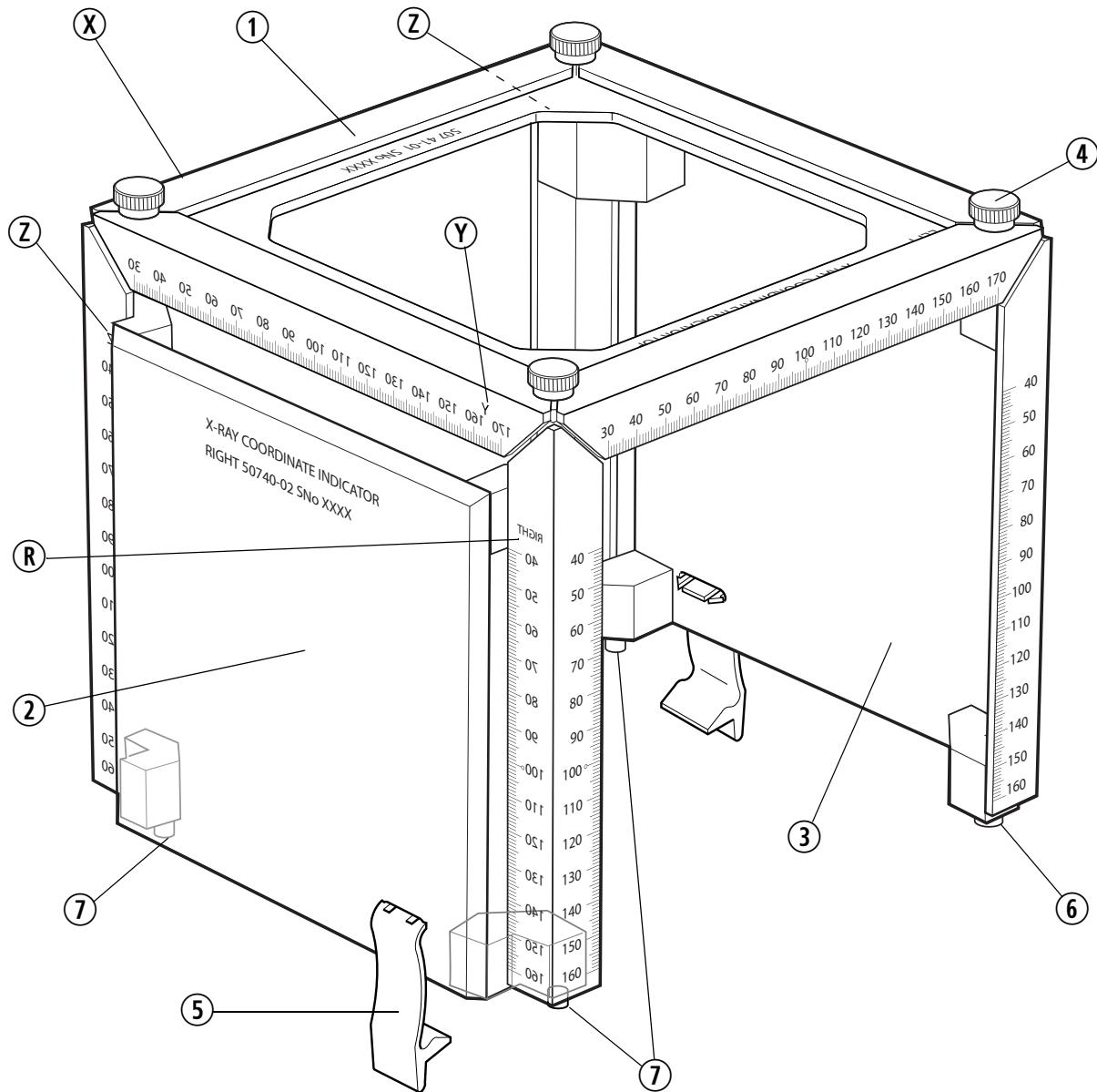
Labels

Some parts have engraved labels. See [Table 6.9](#) for details, and [Section 9.7 on page 288](#) for general label information.

Table 6.9 Labelled parts for the X-Ray Indicator with Rulers

Part	Labels
① Top panel	X-RAY COORDINATE INDICATOR TOP
② Side panel, right	X-RAY COORDINATE INDICATOR ANT RIGHT
③ Side panel, left	X-RAY COORDINATE INDICATOR ANT LEFT

X-Ray Indicator with Rulers



- | | |
|-------------------------------|-------------------|
| ① Top panel | ⑦ Locating pins |
| ② Side panel, right | ⑧ X engraving |
| ③ Side panel, left | ⑨ Y engraving |
| ④ Fixing screw | ⑩ Z engraving |
| ⑤ Attachment clips | ⑪ Anterior column |
| ⑥ Locating pin, left anterior | |

Figure 6.24 Main parts of the X-Ray Indicator with Rulers

6.9.3 Using the X-Ray Indicator with Rulers

6.9.3.1 Assembly instructions

Preparation

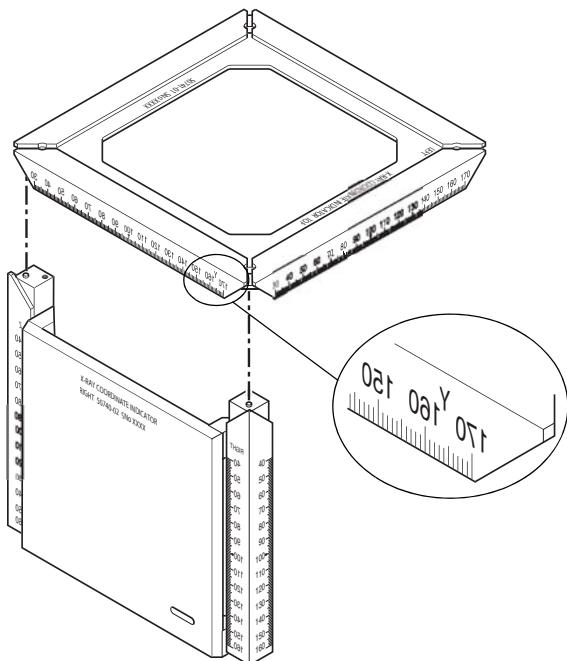
The indicator is usually attached to the coordinate frame after the coordinate frame has been positioned on the patient. For instructions on preparing the coordinate frame, refer to [Section 3.2 on page 28](#).

Inspect all components regarding functionality before use.

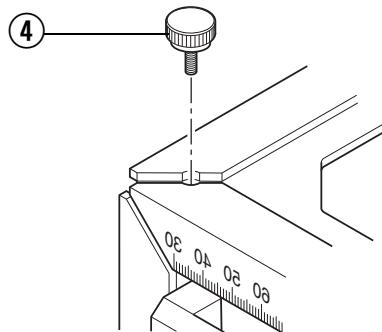
Check that all components of the indicator are at hand (see [Figure 6.24](#)) and clean prior to use.

Assembling the indicator

- 1 Insert the locating pins at the top of the columns of the right side panel into the locating holes in the underside of the right side of the top panel. The right side of the top panel can be identified by the letter Y engraved on the scale.



- 2 Secure the side panel to the top panel with two of the fixing screws ④.



WARNING 6.57

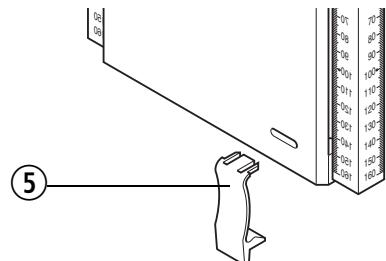


**Do not use excessive force when tightening locking screws/knobs.
Otherwise parts can be damaged and not permit secure fixation.
Non-secure fixation can cause incorrect treatment.**

- 3 Repeat steps 1 and 2 above to secure the left side panel to the opposite side of the top panel.

The anterior locating pin on the left side panel and the corresponding hole in the top plate are larger in diameter to prevent incorrect mounting of the side panels.

- 4 Insert an attachment clip ⑤ through the slot of each side panel.



The indicator is now ready for attachment to the coordinate frame.

6.9.3.2

Fitting the indicator to the coordinate frame

The indicator can be fitted to the coordinate frame before or after the coordinate frame has been attached to the patient, although the latter is preferable. The following instructions assume that the coordinate frame has been correctly assembled.

WARNING 6.58



Support the patient's head at all times when fitting the coordinate frame to, and removing it from, any other equipment. Otherwise the patient can be injured.

WARNING 6.59

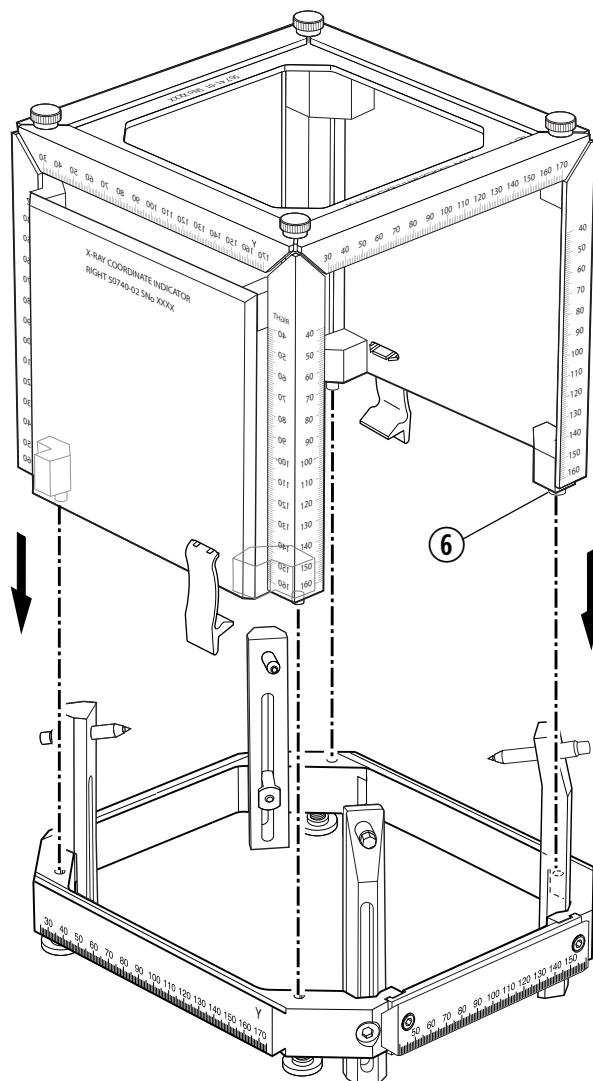


When fitting the indicator to the coordinate frame, ensure that the side panel marked LEFT is on the patient's left side and the side panel marked RIGHT is on the patient's right side.

**WARNING 6.60**

The weight of the patient's head must not be supported by the indicator, otherwise the patient can be injured or the indicator can be damaged.

- 1 Align the indicator with the coordinate frame so that:
 - The panel labelled **X-RAY COORDINATE INDICATOR LEFT** is placed above the left side bar of the coordinate frame.
 - The panel labelled **X-RAY COORDINATE INDICATOR RIGHT** is placed above the right side bar of the coordinate frame.
- 2 Place the indicator on the coordinate frame by properly inserting the locating pins of the indicator into the corresponding holes of the coordinate frame. Ensure that the locating pins are completely inserted into the holes.



Note: *The fitting of the indicator on the coordinate frame can be double-checked by ensuring that the scales on the top plate and on the coordinate frame are aligned.*

The left anterior locating pin ⑥ and the corresponding hole in the coordinate frame are of larger diameter to prevent incorrect fitting.



WARNING 6.61

Make sure that the indicator is correctly mounted onto the coordinate frame. Otherwise there is a risk for inaccurate treatment planning.

- 3 While supporting the indicator with both hands, snap both attachment clips into place under the edges of the coordinate frame. This secures the indicator to the coordinate frame.



WARNING 6.62

Verify that the image orientation is correct when preparing a treatment plan. Otherwise wrong target can be treated.

6.9.3.3 Removal and disassembly

The procedure for removing the indicator from the coordinate frame is the reverse of the attachment procedure given in [Section 6.9.3.2 on page 246](#).

The procedure for disassembling the indicator is the reverse of the assembly procedure given in [Section 6.9.3.1 on page 245](#).

6.10 X-Ray Table Fixations

6.10.1 Product overview

X-Ray Table Fixations are used with Leksell® Coordinate Frame G and the X-Ray Indicator with Markers or the X-Ray Indicator with Rulers.

Note: In this section, the term “table fixation” refers to the X-Ray Table Fixation.

A table fixation ① is fitted to the X-ray patient table ②. The table fixation is designed to hold the coordinate frame ③, the X-Ray Indicator ④, and the skull of the patient firmly and to ensure that position and orientation can be reproduced in subsequent images.

If the patient must be removed from the table for any reason, the arrangement of coordinate frame, X-Ray Indicator and table fixation allows the patient to be reinstalled correctly.

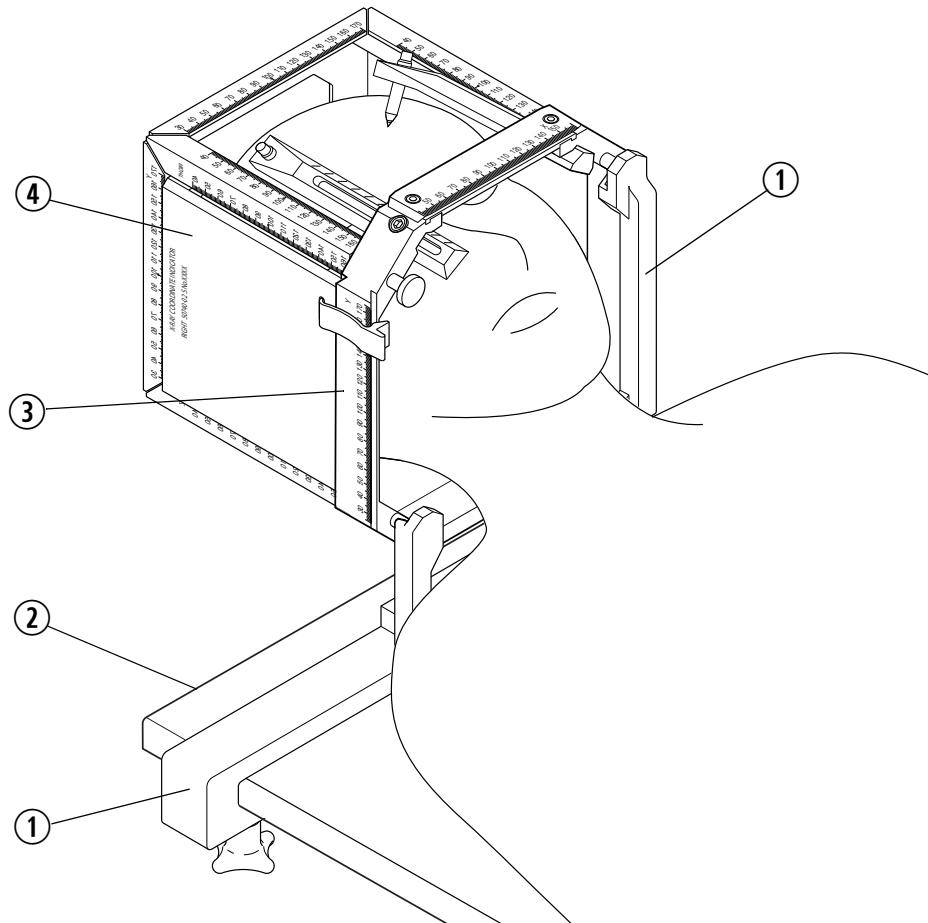


Figure 6.25 Principle of X-Ray Table Fixations

A range of table fixations to suit different designs of X-ray tables is available from Elekta®. For this reason the instructions and illustrations which follow may vary in detail.

This manual describes four basic types of table fixations:

- Table fixation for flat tables.
- Table fixation for curved tables.
- Table fixation for flat, wide tables.
- Table fixation for tables with rails.

For further details on which table fixation is required for your table, contact Elekta® or check the Elekta® product catalog.

6.10.2

Main parts and usage of the X-Ray Table Fixations

All parts of the table fixations are made of aluminum, except knobs, which are plastic.

All table fixations are delivered with a hexagonal key (not shown in the figures).

6.10.2.1

Labels

Some parts can have engraved labels. See [Section 9.7 on page 288](#).

6.10.2.2

Preparation

Inspect all components regarding functionality before use.

The following instructions assume that:

- The coordinate frame has been assembled and attached to the patient's skull in accordance with [Section 3.2 on page 28](#).
- The appropriate X-Ray Indicator has been assembled and fitted to the coordinate frame (see [Section 6.8 on page 233](#) for the X-Ray Indicator with Rulers or [Section 6.9 on page 242](#) for the X-Ray Indicator with Markers).
- All components are clean and at hand.
- Mattresses, pillows and headrests have been removed, whenever applicable.

6.10.2.3**Main parts and assembly of table fixation for flat tables**

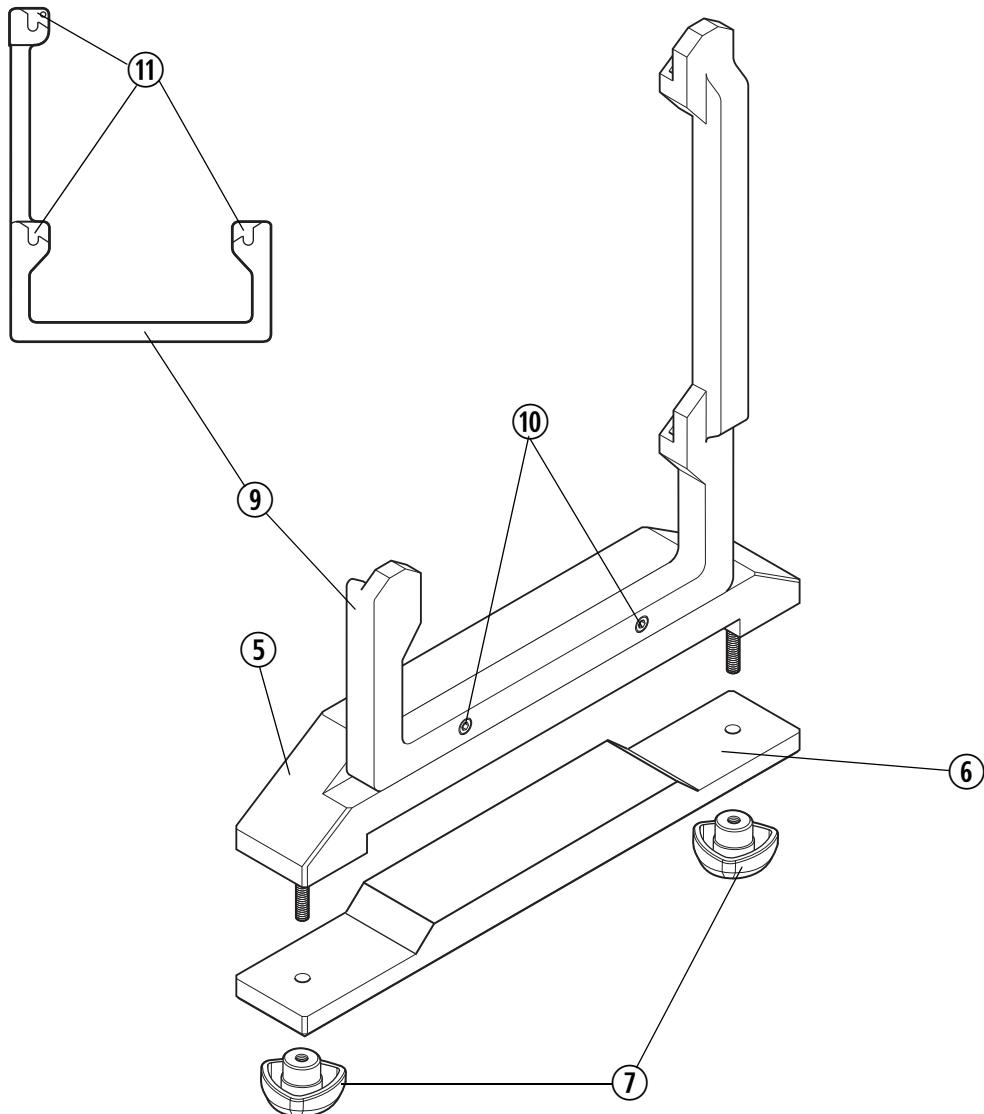
Refer to [Figure 6.26](#). The **fixation body** ⑤ sits on the table top.

The **clamping bar** ⑥ is fitted underneath the table and has unthreaded holes at its ends. It is held in place by two **fixing knobs** ⑦ which attach to captive screws in the fixation body. The clamping bar can be positioned with either side up, as required by the thickness of the table.



A **frame support** ⑨ is attached to the fixation body with two **screws** ⑩. The support has three **frame fixation sockets** ⑪ which accommodate the feet of the coordinate frame.

This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.



⑤ Fixation body

⑥ Clamping bar

⑦ Fixing knobs

⑨ Frame support

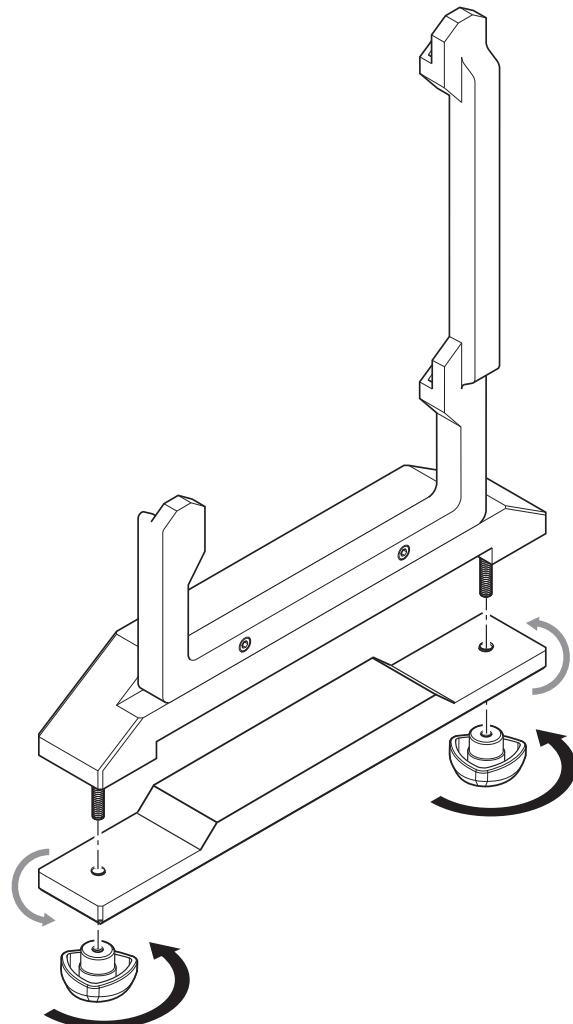
⑩ Screws

⑪ Frame fixation sockets

Figure 6.26 Typical table fixation for flat tables

To assemble the table fixation:

- 1 Attach the clamping bar loosely to the fixation body using the fixing knobs. Turn the knobs a couple of turns to achieve a loose fit.
 - The clamping bar is reversible – turn the required side up to fit the table thickness.



- 2 Slide the table fixation over the table from the head end, so that the table top is positioned between the fixation body and clamping bar. Ensure that the frame fixation sockets of the frame support are facing the head end of the table.
- 3 When the table fixation is at the required position on the table, secure it in place by tightening the two fixing knobs.

Note:

Ensure that the table fixation is securely fixed to the table.

**WARNING 6.63**

**Ensure that the equipment is properly assembled and securely fixed.
Otherwise the patient can be injured.**

- 4 Proceed to [Section 6.10.2.7 on page 259](#).

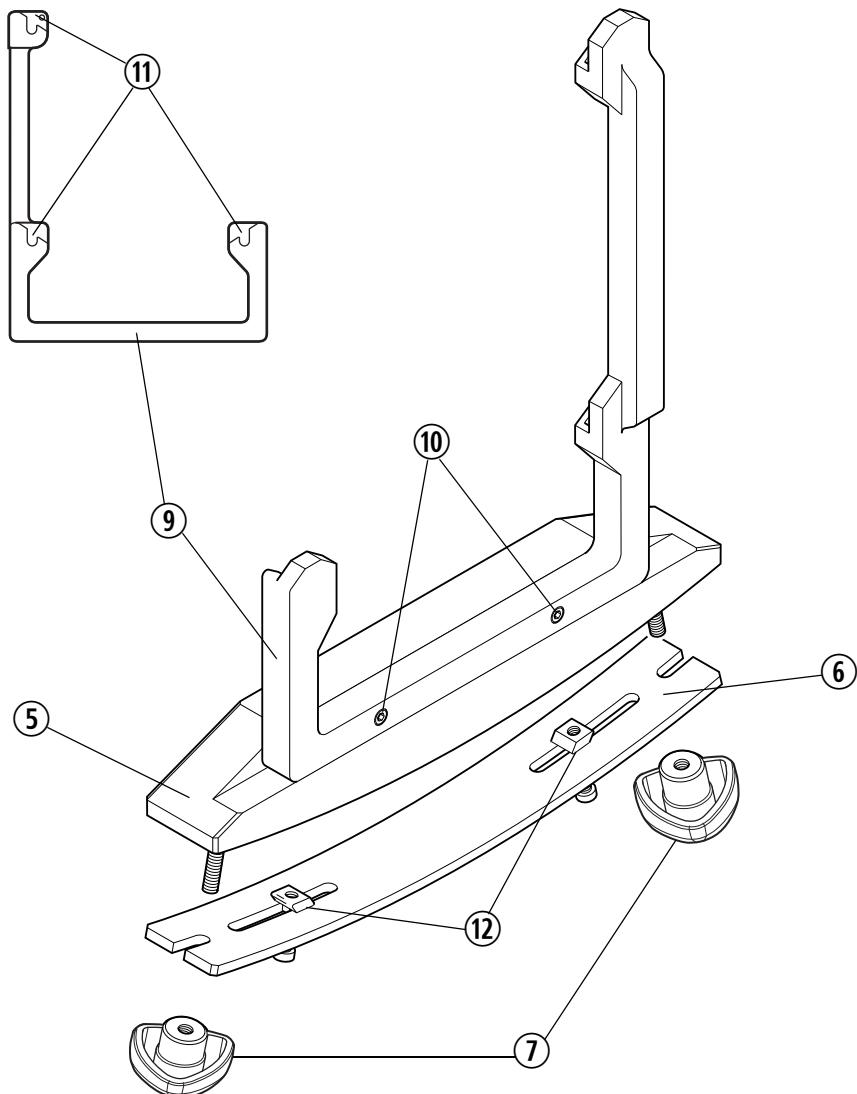
6.10.2.4**Main parts and assembly of table fixation for curved tables**

Refer to [Figure 6.27](#). The **fixation body** ⑤ sits on the table top.

The **clamping bar** ⑥ is fitted to the underside of the table and held in place by two **fixing knobs** ⑦. The knobs attach to captive screws in the fixation body which pass through slots in the clamping bar.

The **nut blocks** ⑫ can be adjusted as appropriate to the table width by loosening the screws and sliding the blocks along the slots. A **frame support** ⑨ is attached to the fixation body with two **screws** ⑩. The support has three **frame fixation sockets** ⑪ which accommodate the feet of the coordinate frame.

This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.



⑤ Fixation body

⑥ Clamping bar

⑦ Fixing knobs

⑨ Frame support

⑩ Screws

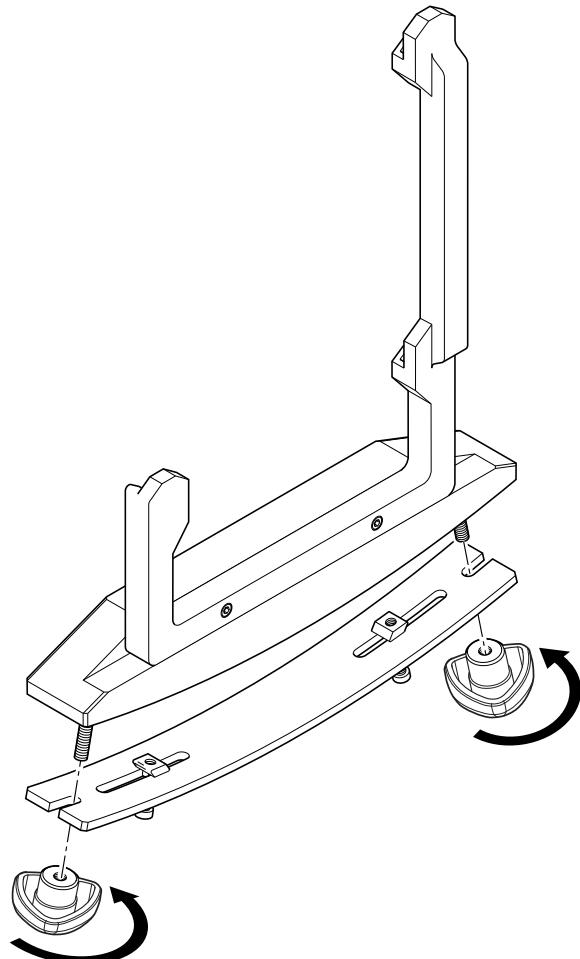
⑪ Frame fixation sockets

⑫ Nut blocks

Figure 6.27 Typical table fixation for curved tables

To assemble the table fixation:

- 1 Attach the clamping bar loosely to the fixation body using the fixing knobs. Turn the knobs a couple of turns to achieve a loose fit.



- 2 Slide the table fixation over the table from the head end, so that the table top is positioned between the fixation body and clamping bar. Ensure that the frame fixation sockets of the frame support are facing the head end of the table.
- 3 Loosen the nut blocks by turning the screws. Adjust the distance between the nut blocks as appropriate to the width of the table. Secure the nut blocks.
- 4 When the table fixation is at the required position on the table secure it in place by tightening the two fixing knobs.

Note:

Ensure that the table fixation is securely fixed to the table.

**WARNING 6.64**

**Ensure that the equipment is properly assembled and securely fixed.
Otherwise the patient can be injured.**

- 5 Proceed to [Section 6.10.2.7 on page 259](#).

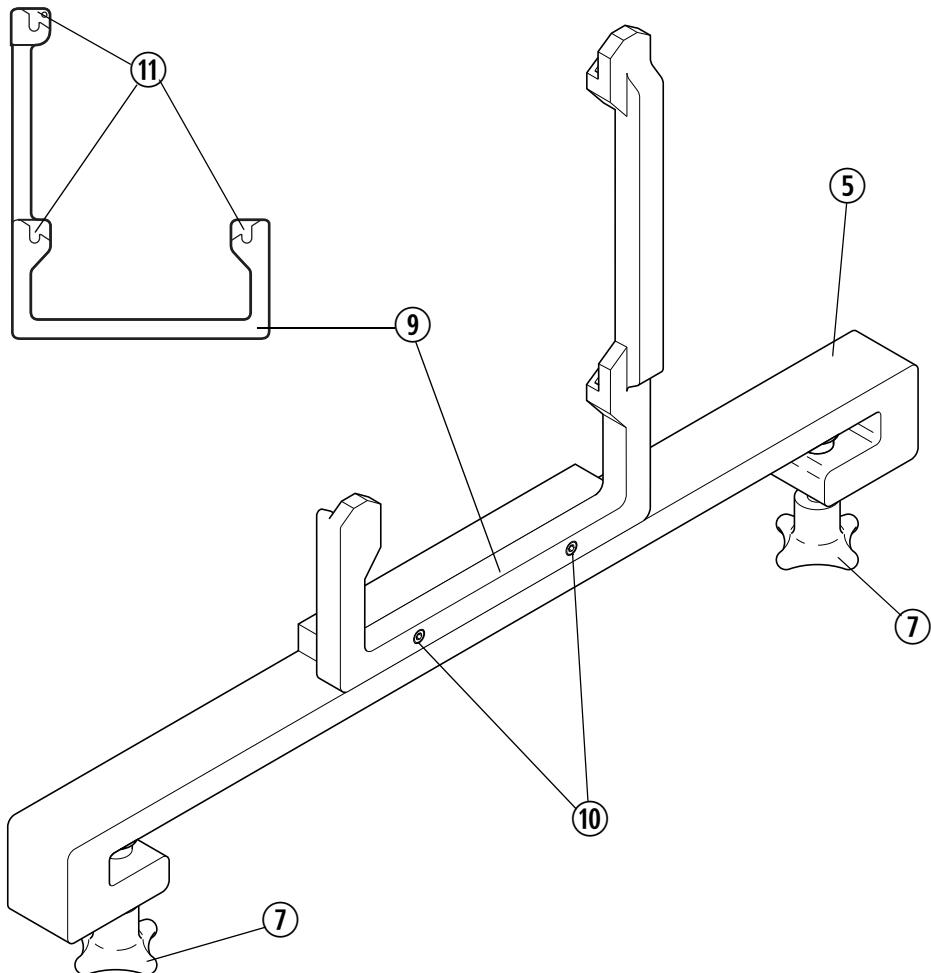
6.10.2.5**Main parts and assembly of table fixation for flat, wide tables**

Refer to [Figure 6.28](#). The **fixation body** ⑤ is C-shaped and slots onto the table top. At either end of the fixation body, on the underside, there is a **fixing knob** ⑦ which is used to clamp the table fixation in position.



A **frame support** ⑨ is attached to the fixation body with two **screws** ⑩. The support has three **frame fixation sockets** ⑪ which accommodate the feet of the coordinate frame.

This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.



⑤ Fixation body

⑩ Screws

⑦ Fixing knobs

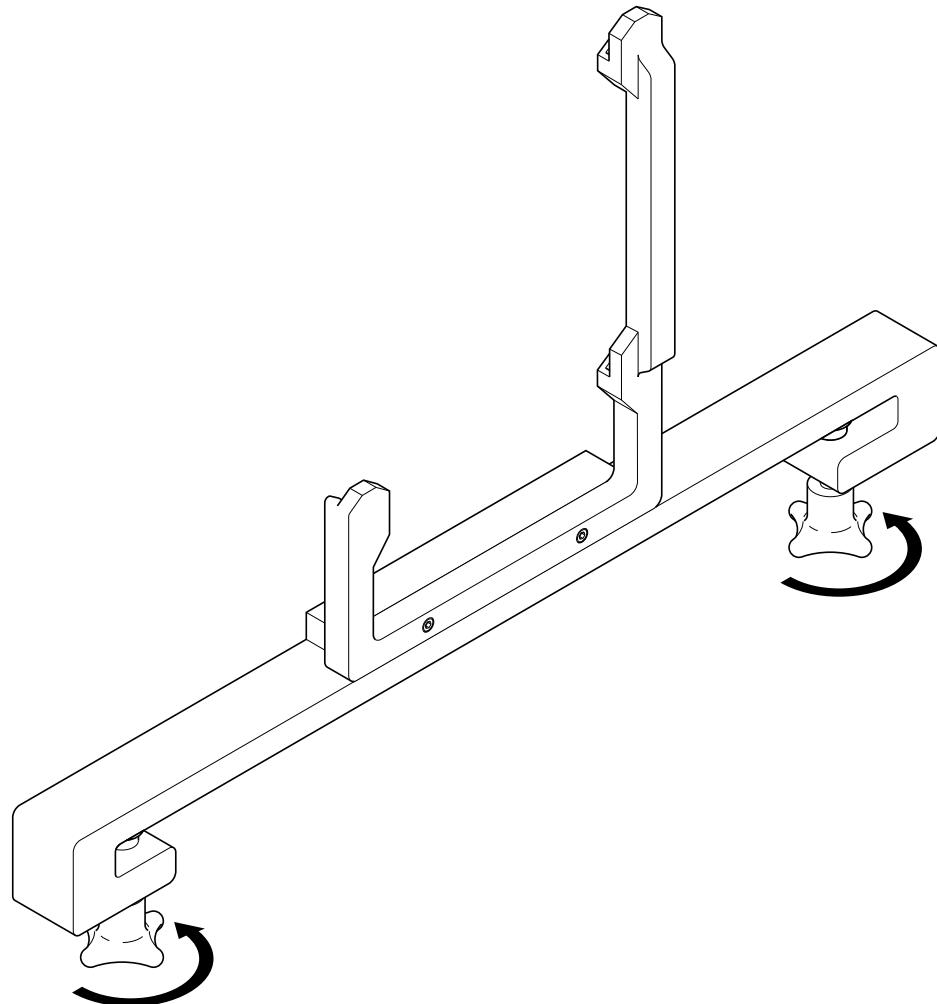
⑪ Frame fixation sockets

⑨ Frame support

Figure 6.28 Typical table fixation for flat, wide tables

To assemble the table fixation:

- 1 Slot the table fixation onto the table. Ensure that the frame fixation sockets of the frame support are facing the head end of the table.



- 2 Adjust the position of the table fixation as desired and fix the table fixation in place by turning the fixing knobs.

Note:

Ensure that the table fixation is securely fixed to the table.



WARNING 6.65

**Ensure that the equipment is properly assembled and securely fixed.
Otherwise the patient can be injured.**

- 3 Proceed to [Section 6.10.2.7 on page 259](#).

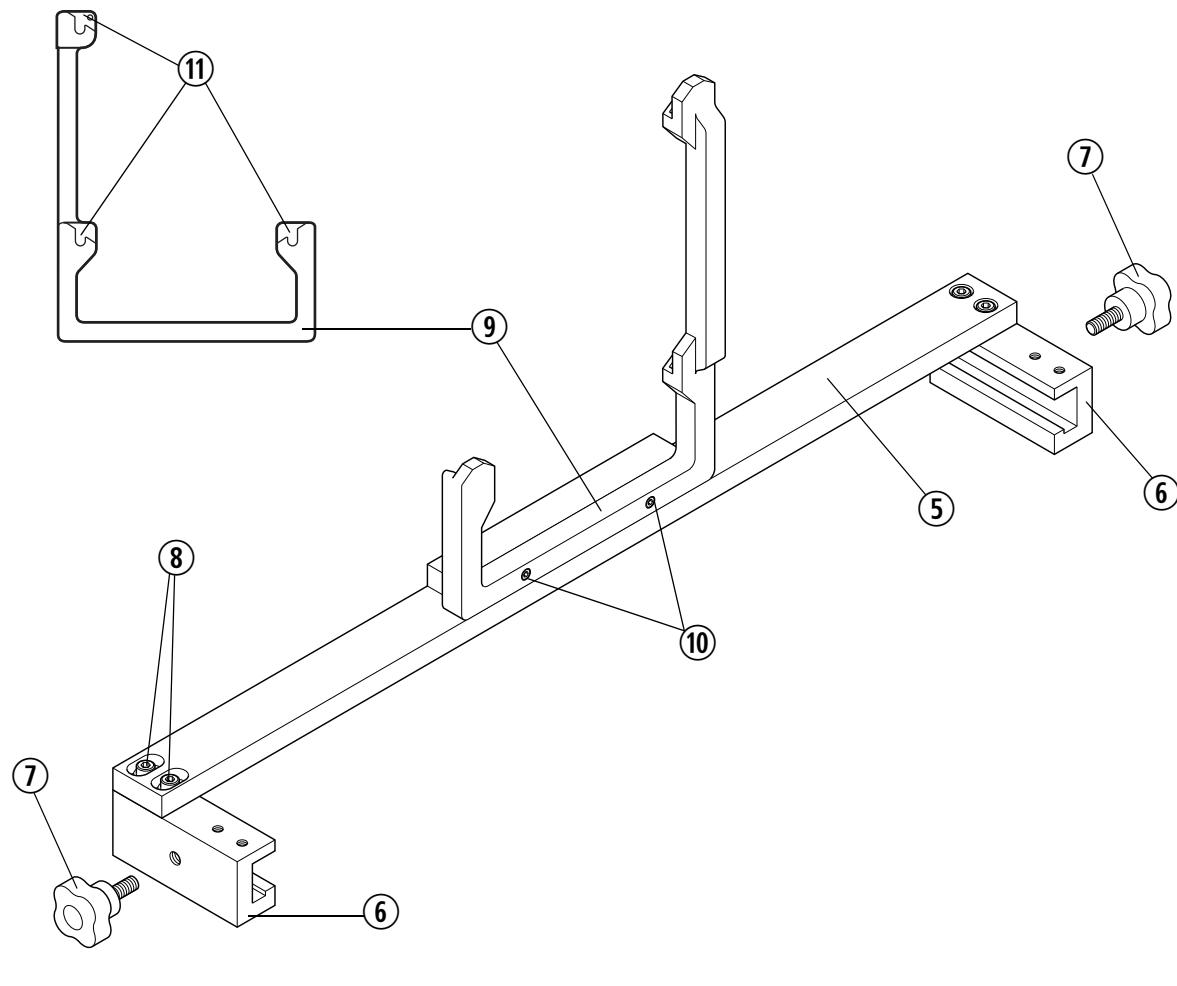
6.10.2.6**Main parts and assembly of table fixation for tables with rails**

Refer to [Figure 6.29](#). The **fixation body** ⑤ consists of a long bar with a **clamp** ⑥ at either end. Each clamp is drilled with a threaded hole through which a **fixing knob** ⑦ passes, which is used to lock the table fixation to the rails.

The distance between the clamps can be adjusted as appropriate to the width of the table by means of the width **adjustment screws and slots** ⑧.

A **frame support** ⑨ is attached to the fixation body with two **screws** ⑩. The support has three **frame fixation sockets** ⑪ which accommodate the feet of the coordinate frame.

This equipment is MR Unsafe. See [Section 1.2.4 on page 8](#) for detailed information.



⑤ Fixation body

⑥ Clamp

⑦ Fixing knob

⑧ Adjustment screws and slots

⑨ Frame support

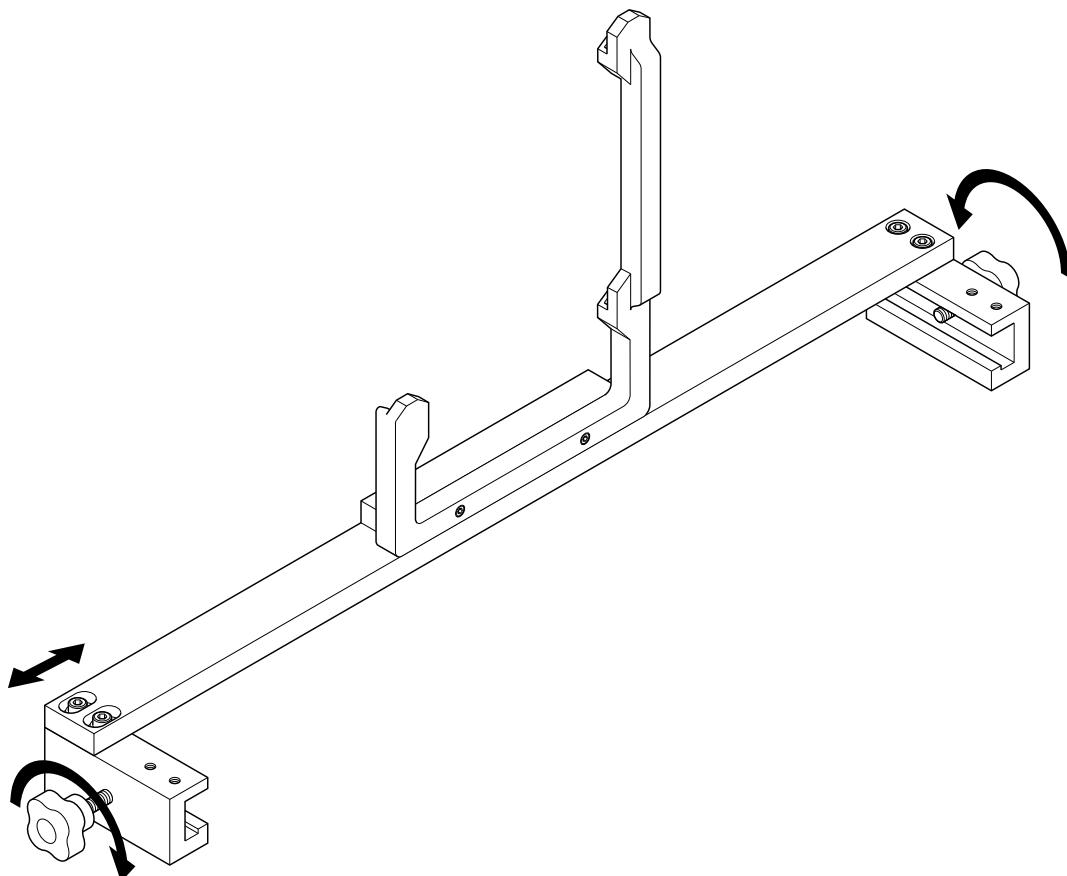
⑩ Screws

⑪ Frame fixation sockets

Figure 6.29 Table fixation for tables with rails

To assemble the table fixation:

- 1 Slot the table fixation onto the table, ensuring the table's rails fit into the clamps. The frame fixation sockets of the frame support should be facing the head end of the table.



- 2 Loosen the width adjustment screws. Adjust the distance between the slots as appropriate to the width of the table, and tighten the screws.
- 3 Adjust the position of the table fixation along the table as desired and fix the table fixation in place by turning the fixing knobs.

Note: *Ensure that the table fixation is securely fixed to the table.*

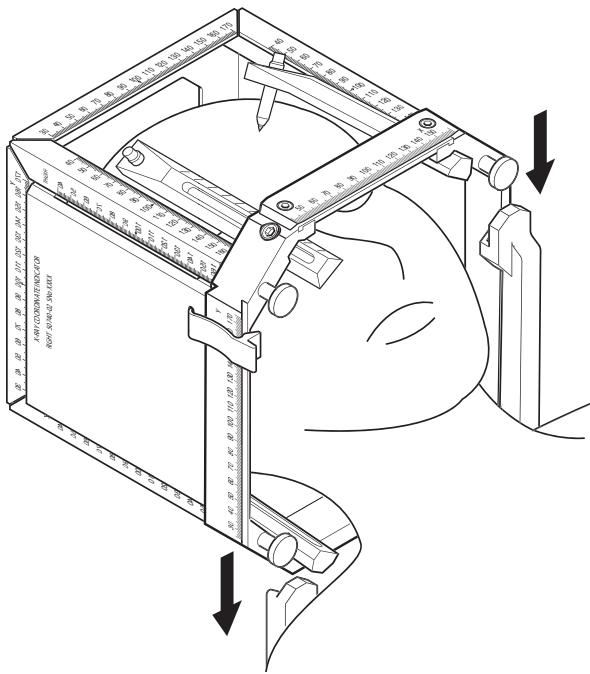
**WARNING 6.66**

**Ensure that the equipment is properly assembled and securely fixed.
Otherwise the patient can be injured.**

- 4 Proceed to [Section 6.10.2.7 on page 259](#).

6.10.2.7**Positioning the patient**

- 1 Position the patient on the X-ray table so that the coordinate frame will engage with the frame support when the patient is lowered to a horizontal position.
- 2 While carefully supporting the patient's head, lower the coordinate frame until the posterior feet and the anterior left foot of the coordinate frame slide into the frame fixation sockets.

**WARNING 6.67**

Support the patient's head at all times when fitting the coordinate frame to, and removing it from, any other equipment. Otherwise the patient can be injured.

- 3 Check that the coordinate frame is fully engaged in the table fixation, i.e. that the feet of the coordinate frame are located at the bottom of the frame fixation sockets. Once the feet are in place, further horizontal movement is prevented.

WARNING 6.68

Ensure that the equipment is properly assembled and securely fixed. Otherwise the patient can be injured.

WARNING 6.69

Ensure that the patient can easily be released in case of emergency. Otherwise the patient can be injured.

WARNING 6.70

The adapter does not have a locking device. The patient can unintentionally get out of the fixation.

If desired, use an inflatable cushion or other support between the table and the patient's neck for increased patient comfort.



WARNING 6.71

If a rubber cushion is used to support the patient, ensure that it is not over inflated. Otherwise the coordinate frame can be disconnected from the adapter and the patient can be injured.



WARNING 6.72

Ensure that the indicator is correctly aligned during imaging. Otherwise inaccurate treatment can result.

6.10.2.8

Removal and disassembly

The procedure for removing the patient from the table fixation is the reverse of the procedure described in [Section 6.10.2.7 on page 259](#).

The procedure for removing the table fixation from the table is the reverse of the procedure for attaching it to the table. Refer to [Section 6.10.2.3 on page 251](#), [Section 6.10.2.4 on page 253](#), [Section 6.10.2.5 on page 255](#) or [Section 6.10.2.6 on page 257](#).

7

Cleaning and sterilization

Leksell Stereotactic System® consists of precision instruments that must be handled with care.

Note: *The products must be cleaned, sterilized (unless otherwise stated) and inspected regarding functionality before use in each operation.*

WARNING 7.1



Handle all Elekta equipment with care. Any damage, however slight, can reduce treatment safety and accuracy. Inspect the equipment before clinical use. If you suspect that any part is damaged, contact Elekta immediately. Do not use damaged equipment for any purpose until authorized to do so by Elekta.

WARNING 7.2



Elekta recommended methods for disassembling, cleaning and sterilization must be followed. Otherwise the equipment can be damaged and the treatment safety reduced.

WARNING 7.3



In case of using this device on a patient infected by Creutzfeldt-Jakob disease and/or when contamination with high risk tissues/organs is suspected, components are recommended to be disposed (single used), since there are no cleaning or sterilization methods proven to be effective against the Creutzfeldt-Jakob disease prions. Risks related for re-use of parts, contaminated with high risk tissues/organs, have to be judged by user when cleaned and sterilized according to applicable national recommendations or WHO's report "Infection Control Guidelines for Transmissible Spongiform Encephalopathy's" (within Elekta's recommended cleaning and sterilization parameters).

Ref: WHO "Infection Control Guidelines for Transmissible Spongiform Encephalopathies", Report of a WHO consultation - WHO/CDS/CSR/APH/2000.3.

Note: *Surgical instruments exposed to Creutzfeldt-Jakob Disease must be disposed in accordance with local regulations.*

7.1**Cleaning and sterilization overview**

Table 7.1 shows the recommended cleaning and proven sterilization methods for the products included in this manual. Details on different methods are found in later sections. For drying and wrapping recommendations, see [Section 7.3 on page 269](#).

Table 7.1 Recommended cleaning and proven sterilization methods

Product	Cleaning method	EtO	Autoclaving	STERRAD® (a)
Coordinate frame and stereotactic arc, including optional parts				
A-P Cross-Hairs Holder				
Cross-Hairs Kit, stainless steel				
Fork and Clamp Type Adapters				
Frame Fixation (b)				
Leksell® Coordinate Frame G	3	•	•	•
Leksell® Endoscope Adapter (c)				
Leksell® Multi Purpose Stereotactic Arc (c)				
Leksell Stereotactic System® Clamp				
Slotted Front Piece				
Fixation posts				
Insulated Fixation Posts (d)				
Non-insulated Fixation Post	3	•	•	•
Locking piece and locking screw				
Fixation screws				
Disposable Fixation Screws (e)				
Quick Fixation Screws	3	•	•	•
Reusable Fixation Screws				
Titanium Fixation Screws				
Imaging adapters and table fixations				
CT Adapter				
CT Table Fixations	1			
MR Adapters				
X-Ray Table Fixations				
Indicators, including optional parts				
Open CT Indicator				
MR Indicator				
MR Phantom	2			
Open MR Indicator				
X-Ray Indicator with Markers				
X-Ray Indicator with Rulers				

Table 7.1 Recommended cleaning and proven sterilization methods

Product	Cleaning method	EtO	Autoclaving	STERRAD® (a)
Neurosurgical instruments				
Backlund Catheter Insertion Needle Kit				
Insertion Cannula Kit	4	•	•	B
Sedan Side-Cutting Biopsy Needle Kit				
Backlund Haematoma Evacuator Kit	4	•	•	•
Salcman Twist Drill Kit				

(a) STERRAD® 100S, 50 and 200.

(b) See also [Section 7.3.1 on page 270](#).(c) See also [Section 7.2.4.3 on page 267](#).

(d) The disposable inserts are for single use only.

(e) Disposable Fixation Screws are for single use only.

Table 7.2 Definitions of symbols used in **Table 7.1**

Symbol	Definition	More information in
1–4	Number of the recommended cleaning method for the product.	Section 7.2 on page 264
•	The method is approved for the product.	Section 7.4 on page 271
B	Always use the STERRAD® booster/adaptor equipment (not required for the stop and guide inserts or the ruler). Always check with the recommendations by the manufacturer of STERRAD® equipment.	Section 7.4.3 on page 273

7.2

Cleaning recommendations

There are 4 different cleaning methods available.

- Make sure to use the correct cleaning method for the specific equipment.
- Make sure to follow the instructions from the detergent supplier regarding the concentration of the detergent.
- Decontamination procedures with highly aggressive agents (i.e. sodium hydroxide, NaOH, and sodium hypochlorite, NaClO, are **not recommended** as material degradation may occur.
- Equipment cleaned with method 3 and 4 must be sterilized, see [Section 7.3](#) and [Section 7.4](#).

7.2.1

Washing detergents that are not approved for use with Leksell Stereotactic System®

The following detergents have shown to affect the stereotactic parts negatively and shall not be used. Note that the detergents may be sold locally under other brands.

- Alkaline from ECOLAB (above pH 10)
- Belizym 203 from BODE (above pH 8.5)
- Dismoclean twin basic / Dismoclean twin zyme from BODE (above pH 9)
- Korsolex AF from BODE (above pH 9)
- Mucocit-T from MERZ Hygiene GmbH (above pH 9)
- Sekusept Aktiv from ECOLAB (above pH 10)
- Sekusept PLUS from ECOLAB (above pH 10)
- Prolystica Enzymatic Presoak from STERIS
- S&N Labor from SCHÜLKE (above pH 10)

7.2.2

Cleaning method 1

Heavy contamination of the product with blood or body tissues should be removed in the operating room at once using soft cloths.

- The transparent plate can be removed from the CT Adapter for cleaning. The plate can be cleaned by wiping with a damp cloth and dried with a clean, soft, lint-free cloth prior to reassembly.
- The CT Table Fixation and the main body of the CT Adapter and MR Adapter should be cleaned by wiping with a clean, soft, lint-free cloth.

Note:

Do not soak any part of the equipment.



WARNING 7.4

Do not sterilize the equipment. If sterilized, it can be damaged.

7.2.3

Cleaning method 2

Heavy contamination of the product with blood or body tissues should be removed at once using soft cloths.

To allow a proper cleaning process, make sure to minimize the time before starting to clean the equipment.

- 1 Disassemble the product into its components according to the disassembly instructions.
- 2 Hand wash all components thoroughly in a mild detergent with a recommended pH of 6 to 8.
- 3 Rinse several times in deionized water to remove all traces of detergent.
- 4 With the exception of the grids of the MR Phantom, dry the components with a clean, soft, lint-free cloth.

The grids of the MR Phantom must be allowed to drip dry.



CAUTION 7.1

For the MR Phantom: Do not wash the equipment with alcoholic solutions.



CAUTION 7.2

Do not leave the MR Phantom with water inside. Otherwise it can be damaged.



WARNING 7.5

Do not sterilize the equipment. If sterilized, it can be damaged.

7.2.4

Cleaning method 3

After the cleaning, the equipment must be dried and sterilized, see [Section 7.3](#) and [Section 7.4](#).

Heavy contamination of the product with blood or body tissues should be removed in the operating room at once using soft cloths.

For not approved detergents see [Section 7.2.1](#).

To allow a proper cleaning process, make sure to minimize the time before starting to clean the equipment.

- 1 Disassemble the product into its components according to the disassembly instructions.
-

Note:

For the Insulated Fixation Posts, dispose the inserts in accordance with local regulations.

- 2 Continue with either machine washing (recommended), see [Section 7.2.4.1](#), or hand washing, see [Section 7.2.4.2](#).
 - Machine washing is recommended as the processes are possible to reproduce and therefore are more reliable.
 - 3 Dry the components, see [Section 7.3](#).
-

Note:

It is important to ensure that all bioburden are removed from the components before sterilization.

7.2.4.1

Machine washing

All machine washing must be performed in a validated cleaning process in accordance to EN ISO 15883:2009, or harmonized standard.

Machine wash all components in a standard program without an ultrasonic cycle in a washer-disinfector.

- Place the components so that they do not collide during machine wash.
- Follow the instructions from the manufacturer of the washer-disinfector.
- Use deionized water in the thermal disinfection and final rinse to avoid damage of the equipment.

Machine washing using a detergent with pH 6 to 8

It is recommended to use a machine wash cycle including pre-washing with cold water (temperature less than 30 °C (86 °F)), cleaning with a suitable neutral detergent (pH of 6 to 8), and completed without detergent at 90 °C (194 °F) for 5 minutes for thermal disinfection and final rinsing. Dry the equipment in the washer-disinfector at 99 °C (210 °F) for 35 minutes.

- An enzymebased detergent specially made for washing proteins and to be used for machine wash is recommended.

Machine washing using a detergent with pH above 10

It is recommended to use a machine wash cycle including pre-washing with cold water (temperature less than 30 °C (86 °F)), cleaning with recommended detergent at a temperature of 55 °C (131 °F) for 5-10 minutes, and completed without detergent at 90 °C (194 °F) for 5 minutes for thermal disinfection and final rinsing. Dry the equipment in the washer-disinfector at 99 °C (210 °F) for 35 minutes.

- Recommended washing detergents⁽¹⁾, validated by Elekta are:
 - Sekumatic® ProClean and Sekumatic® MultiClean from ECOLAB®
 - Neodisher® MediClean forte from DR. WEIGERT®

Note: *Other detergents than listed above may perform equally in conjunction with the equipment being used. Suitability of new cleaning agents should be checked by reference to supplier information and/or physical testing.*

7.2.4.2

Hand washing

- 1 Hand wash all components with a soft dish brush using an instrument disinfectant with a recommended pH of 6 to 8 and cold water (temperature less than 30 °C (86 °F)).
- 2 Rinse the components thoroughly in deionized water to remove all traces of detergent.

7.2.4.3

Cleaning engravings

Cleaning of engravings can be needed for Leksell® Multi Purpose Stereotactic Arc and Leksell® Endoscope Adapter.

WARNING 7.6



If loose paint flakes are found on the operation gloves or on the equipment, all parts with engravings must be wiped thoroughly before mounting the equipment in the operating room. Otherwise, loose paint flakes can enter the surgical area.

Ensure that no loose paint flakes remain in the engravings.

If loose paint flakes are found wipe all engraved parts thoroughly. Use a soft lint free cloth dampened with alcohol or distilled water, both along the part and in the direction of the engravings.

If any paint flakes are discovered on the cloth, the parts must be wiped again until no paint flakes are found.

After cleaning it is important to check that no paint flakes remain on the gloves of the person who has wiped the parts.

(1) Due to local legislation the recommended detergents may not be available in all countries.

7.2.5

Cleaning method 4

After the cleaning, the equipment must be dried and sterilized, see [Section 7.3](#) and [Section 7.4](#).

Note:

Surgical instruments exposed to Creutzfeldt-Jakob Disease must be disposed in accordance with local regulations.



WARNING 7.7

For Salzman Twist Drill Kit: Always handle the drills with care. Avoid contact between the drills, otherwise they can become damaged and injure the patient during clinical use.

Heavy contamination of the product with blood or body tissues should be removed in the operating room at once using soft cloths.

For not approved detergents see [Section 7.2.1](#).

To allow a proper cleaning process, make sure to minimize the time before starting to clean the equipment.

- 1 Disassemble the product into its components according to the disassembly instructions.
- 2 Continue with machine washing, see [Section 7.2.5.1](#).
- 3 Dry the components, see [Section 7.3](#).

Note:

It is important to ensure that all bioburden are removed from the components before sterilization.

7.2.5.1

Machine washing

All machine washing must be performed in a validated cleaning process in accordance to EN ISO 15883:2009, or harmonized standard.

Machine wash all components in a standard program without an ultrasonic cycle in a washer-disinfector.

- Place the components so that they do not collide during machine wash.
- Fixate all luminal components firmly to allow the cleaning and rinsing fluids to fill the inside completely with the necessary pressure.
 - The machine used must have the necessary equipment to allow sufficient and reliable internal rinsing.
- Follow the instructions from the manufacturer of the washer-disinfector.
- Use deionized water in the thermal disinfection and final rinse to avoid damage of the equipment.

Machine washing using a detergent with pH 6 to 8

It is recommended to use a machine wash cycle including pre-washing with cold water (temperature less than 30 °C (86 °F)), cleaning with a suitable neutral detergent (pH of 6 to 8), and completed without detergent at 90 °C (194 °F) for 5 minutes for thermal disinfection and final rinsing. Dry the equipment in the washer-disinfector at 99 °C (210 °F) for 35 minutes.

- An enzymebased detergent specially made for washing proteins and to be used for machine wash is recommended.

Machine washing using a detergent with pH above 10

It is recommended to use a machine wash cycle including pre-washing with cold water (temperature less than 30 °C (86 °F)), cleaning with recommended detergent at a temperature of 55 °C (131 °F) for 5-10 minutes, and completed without detergent at 90 °C (194 °F) for 5 minutes for thermal disinfection and final rinsing. Dry the equipment in the washer-disinfector at 99°C (210°F) for 35 minutes.

- Recommended washing detergents⁽¹⁾, validated by Elekta are:
 - Sekumatic® ProClean and Sekumatic® MultiClean from ECOLAB®
 - Neodisher® MediClean forte from DR. WEIGERT®

Note:

Other detergents than listed above may perform equally in conjunction with the equipment being used. Suitability of new cleaning agents should be checked by reference to supplier information and/or physical testing.

7.3 Drying and wrapping recommendations

For all products that can be sterilized:

- 1 Ensure that all components are completely dry before sterilization. If drying is not performed by the washer-disinfector, it is recommended to use soft dry cloths or compressed air for drying.
- 2 Moving parts should be tested to check correct operation, and sparingly lubricated with a light silicone spray, if required. See [Table 8.1](#) on [page 275](#).
- 3 Inspect all parts for visible soil or corrosion.
- 4 If a sterilization tray
 - is delivered with the product, it is recommended to use that tray. If required, assemble the parts necessary to fit the components into the sterilization tray, and wrap the sterilization tray in cloths intended for the chosen sterilization procedure prior to sterilization.
 - is not used, wrap the components in cloths intended for the chosen sterilization procedure, or for smaller components, pack them in sealed pouches intended for sterilization according to applicable standards (in Europe: EN 868-1 and EN 868-2).

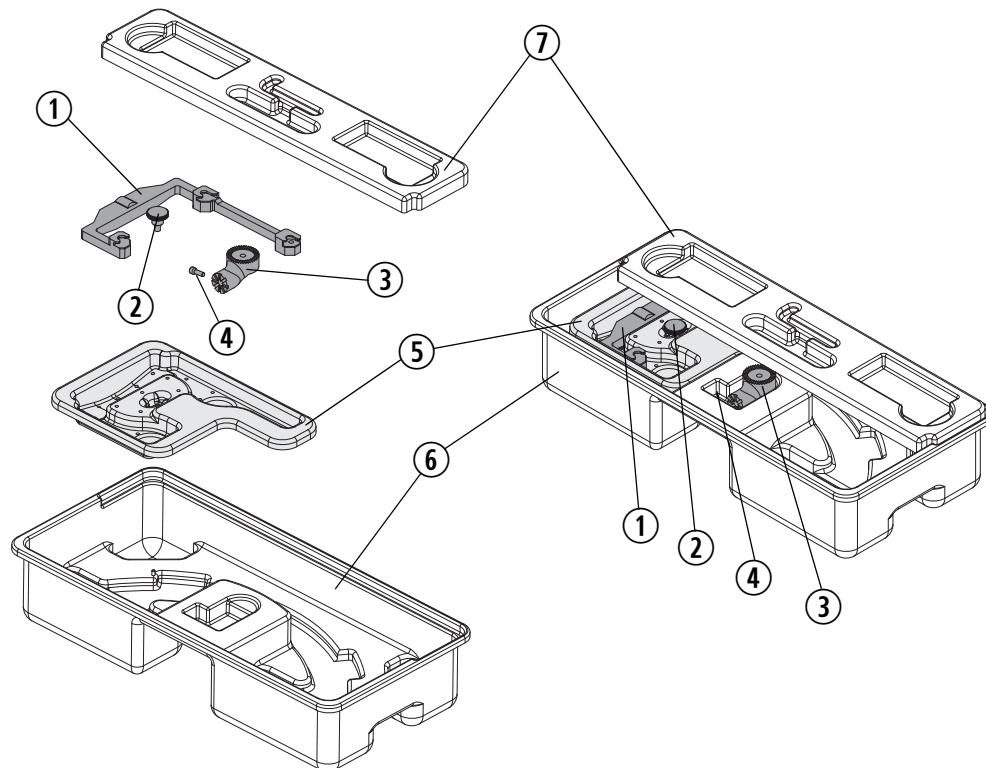
(1) Due to local legislation the recommended detergents may not be available in all countries.

7.3.1**Using the optional sterilization tray for the Frame Fixation**

A dedicated sterilization tray is available for the Frame Fixation, see [Figure 7.1](#). The tray ⑤ is to be stored inside the two-piece sterilizing tray ⑤ and ⑥ for the Leksell® Multi Purpose Stereotactic Arc.

For simultaneous sterilization of the Frame Fixation and stereotactic arc place the components as shown in [Figure 7.1](#):

- Place the headrest support ③ and the fixing screw ④ in the center of the large sterilization tray ⑥.
- Place the yoke ① and the fixing knob ② in the sterilization tray ⑤ for the Frame Fixation.
- Place the sterilization tray ⑤ inside the large sterilization tray ⑥.
- Place the small sterilization tray ⑦, for stereotactic arc components, in the large tray ⑥.



*Figure 7.1 Sterilization trays and the Frame Fixation.
To the left: separate components; to the right: assembled components.*

7.4

Sterilization

For products that are to be sterilized, either of the following sterilization methods can be used (see [Table 7.1 on page 262](#)).

WARNING 7.8



In case of using this device on a patient infected by Creutzfeldt-Jakob disease and/or when contamination with high risk tissues/organs is suspected, components are recommended to be disposed (single used), since there are no cleaning or sterilization methods proven to be effective against the Creutzfeldt-Jakob disease prions. Risks related for re-use of parts, contaminated with high risk tissues/organs, have to be judged by user when cleaned and sterilized according to applicable national recommendations or WHO's report "Infection Control Guidelines for Transmissible Spongiform Encephalopathy's" (within Elekta's recommended cleaning and sterilization parameters).

Ref: WHO "Infection Control Guidelines for Transmissible Spongiform Encephalopathies", Report of a WHO consultation - WHO/CDS/CSR/APH/2000.3.

All sterilization must be performed using a validated sterilization procedure in accordance to applicable standard; EN ISO 17665-1:2006 (Moist heat) and EN ISO 11135-1:2007 (Ethylene oxide), see [Section 7.6 on page 273](#).

The instructions for cleaning and sterilization provided by Elekta have been validated as being capable of preparing the products for re-use considering sterility and also maintaining functionality and accuracy during the product lifetime.

It still remains the responsibility of the executor/processor to ensure that the processing performed in the hospital achieves the desired result, with respect to used equipment, materials and personnel in the processing facility. This requires validation and routine monitoring by the executor/processor to evaluate the effectiveness of the process.

Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

7.4.1**Autoclaving**

For products that may be autoclaved, the following cycle parameters are recommended:

Table 7.3 Steam sterilization

Sterilization method	Cycle parameters			
	Wrapping	Holding (exposure) temperature	Holding (exposure) time¹⁾	Drying time²⁾ (minimum, in chamber)
Prevacuum steam – moist heat	Wrapped	132 °C (270 °F)	10 minutes	30 minutes
Prevacuum or intermittent vacuum steam – moist heat	Wrapped	134 °C (273 °F)	5 minutes	30 minutes
Prevacuum or intermittent vacuum steam – moist heat	Wrapped	134 °C (273 °F)	18 minutes ³⁾	30 minutes
Gravity displacement steam – moist heat	Wrapped	132 °C (270 °F)	25 minutes	30 minutes
Gravity displacement steam – moist heat	Unwrapped	132 °C (270 °F)	5 minutes	30 minutes

(1) **Holding (exposure) time:** The time period for which the load and entire chamber is maintained at the sterilization temperature.

(2) **Drying time:** The time period during which steam is removed from the chamber and the chamber pressure is reduced to permit the evaporation of condensate from the load. The drying time varies due to the load configuration, the wrapping method and the material. It is the user's responsibility to validate the appropriate drying time with the sterilization equipment used.

(3) **18 minutes:** This holding (exposure) time period can be used to comply with the recommendation from the World Health Organization (WHO). The medical devices are able to sustain such sterilization cycle.

7.4.1.1**Flash autoclaving**

Flash autoclaving is not recommended and should be used only in carefully selected clinical situations.

7.4.2**Ethylene oxide sterilization – EtO**

For products that may be sterilized in ethylene oxide, the following cycle parameters are recommended.

Table 7.4 Ethylene oxide sterilization

Sterilization method	Cycle parameters				
	Gas exposure time¹⁾	Holding (exposure) temperature	Pressure	Humidity	Aeration
Ethylene Oxide (or equivalent Oxyfume 2002)	4 hours	50 °C (122 °F)	550 hPa (8 psig)	55% RH	Minimum of 8 hours forced air at 52 °C (126 °F)

(1) **Gas exposure time:** The time period for which the load and entire chamber is maintained at the sterilization temperature.

7.4.3

Gas plasma sterilization – STERRAD®

For products that may be sterilized by gas plasma sterilization using STERRAD® equipment (STERRAD® 100S, 50 or 200 (see [Table 7.1 on page 262](#))):

- Always use sterilization trays and/or other accessories from the manufacturer of the sterilizing equipment.
- Always follow the instructions and guidelines accompanying the STERRAD® equipment.
- Always use the STERRAD® booster/adapter equipment (not required for the stop and guide inserts) for the following products:
 - Backlund Catheter Insertion Needle Kit
 - Insertion Cannula Kit
 - Sedan Side-Cutting Biopsy Needle Kit.

Note:

The use of the STERRAD® booster/adapter equipment is not approved by FDA (Food and Drug Administration) at the time of issue of this manual.

7.5

Storage conditions for sterilized equipment

The sterilized equipment shall be stored in a sterilization package (and in the sterilization tray if used) in a dry and dust-free place. A maximum shelf life for sterilized medical devices should be defined by the health care facility.

7.6

Applicable sterilization standards

The applicable sterilization standards for Leksell Stereotactic System® are:

- SS-EN ISO 17665-1:2006; Sterilization of health-care products – Moist heat.
- SS-EN ISO 11135-1:2007; Sterilization of health-care products – Ethylene oxide.
- SS-EN ISO 15883-1 and -2:2009; Washer-disinfectors – General requirements, terms and definitions and tests for surgical instruments.
- EN 868-1 and EN 868-2:2009 (Europe); Packaging for terminally sterilized medical devices.

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8 Maintenance

8.1 Overview

The Leksell Stereotactic System® consists of precision instruments that must be handled with care.

WARNING 8.1



Handle all Elekta equipment with care. Any damage, however slight, can reduce treatment safety and accuracy. Inspect the equipment before clinical use. If you suspect that any part is damaged, contact Elekta immediately. Do not use damaged equipment for any purpose until authorized to do so by Elekta.

- Regular inspection of components and exchange of worn parts must be performed.
- [Table 8.1](#) shows the required maintenance for the products included in this manual.

Table 8.1 Required maintenance per product.

Lubrication unless otherwise stated: a light, silicone spray lubricant.

(X) = Beyond regular inspection and exchange of worn parts, no further maintenance is required.

Product	Maintenance
A-P Cross-Hairs Holder	(X)
Backlund Catheter Insertion Needle Kit	Do regular visual inspection of the straightness of the needles with the Needle Tester.
Backlund Haematoma Evacuator Kit	Exchange the O-ring and washer if worn or damaged. Do regular visual inspection of the straightness of the needles with the Needle Tester.
Cross-Hairs Kit, stainless steel	Exchange the O-ring if worn or damaged.
CT Adapter	(X)
CT Table Fixations	(X)
Curved Posts Kit	Lubricate the threads regularly.
Disposable Fixation Screws	Single use only.
Fork and Clamp Type Adapters	Lubricate all parts regularly.
Frame Fixation	(X)
Insertion Cannula Kit	Do regular visual inspection of the straightness of the needles with the Needle Tester.
Insulated Fixation Posts	Lubricate the threads regularly.
Leksell® Coordinate Frame G	Lubricate all parts regularly.
Leksell® Endoscope Adapter	Lubricate all moving parts regularly.

Table 8.1

*Required maintenance per product.**Lubrication unless otherwise stated: a light, silicone spray lubricant.**(X) = Beyond regular inspection and exchange of worn parts, no further maintenance is required.*

Product	Maintenance
Leksell® Multi Purpose Stereotactic Arc	<p>Lubricate all parts regularly.</p> <p>To ensure smooth and secure tightening of the five knobs, lubricate the holes of the knobs at regular intervals.</p> <ol style="list-style-type: none"> 1 Unscrew the knobs completely. 2 Spray lubrication into the threaded holes. 3 Screw the knobs in and out a few times to lubricate all threads. <p>Exchange the plastic screws if worn or damaged.</p> <p>If the engravings have become so worn over time that they are difficult to read or if loose paint flakes become a problem (see Section 7.2.4.3 on page 267), contact Elekta® or your local Elekta® representative for service.</p>
Leksell Stereotactic System® Clamp	Lubricate the threads regularly.
MR Adapters	(X)
MR Indicator	See Section 6.4.4 on page 201 .
MR Phantom	Exchange the O-rings if worn or damaged.
Non-insulated Fixation Posts	Lubricate the threads regularly.
Open CT Indicator	(X)
Open MR Indicator	See Section 6.5.3.5 on page 211 .
Quick Fixation Screws	<p>Lubricate the threads regularly.</p> <p>To discover damage and/or wear, visually inspect each fixation screw regularly with a magnifying glass or microscope.</p>
Reusable Fixation Screws	<p>Lubricate the threads regularly.</p> <p>To discover damage and/or wear, visually inspect each fixation screw regularly with a magnifying glass or microscope.</p>
Salcman Twist Drill Kit	(X)
Sedan Side-Cutting Biopsy Needle Kit	<p>Lubricate the O-ring on the inner cannula regularly. Exchange the O-ring if worn or damaged.</p> <p>Recommended lubricant: Dow Corning 260 Fluid Dimethicone NF.</p> <p>Do regular visual inspection of the straightness of the needles with the Needle Tester.</p>
Slotted Front Piece	Lubricate all parts regularly.

Table 8.1

Required maintenance per product.

Lubrication unless otherwise stated: a light, silicone spray lubricant.

(X) = Beyond regular inspection and exchange of worn parts, no further maintenance is required.

Product	Maintenance
Titanium Fixation Screws	Lubricate the threads regularly. To discover damage and/or wear, visually inspect each fixation screw regularly with a magnifying glass or microscope.
X-Ray Indicator with Markers	(X)
X-Ray Indicator with Rulers	(X)
X-Ray Table Fixations	(X)

8.2 Calibration

Except for the products described below, the products in this manual does not require calibration.

Leksell® Coordinate Frame G and Leksell® Multi Purpose Stereotactic Arc

The coordinate frame and stereotactic arc cannot be calibrated in the field. It is recommended that you return the coordinate frame to Elekta for calibration at least once a year.

CT Adapter

The CT Adapter shall be aligned to the scanner as described in [Section 6.3.4.5 on page 188](#).

MR Adapter

The MR Adapter shall be aligned to the scanner as described in [Section 6.6.3.4 on page 222](#).

8.3 Malfunction and repair

The products cannot be repaired in the field. If any component malfunctions or is damaged, contact Elekta or your local Elekta® representative.

The Disposable Fixation Screws must be used once only. In the event of malfunction, contact Elekta or your local Elekta® representative.

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9

Product specifications

9.1

System accuracy

The total mechanical accuracy of Leksell Stereotactic System® is better than 0.90 mm that includes the entire system from the indicator plates to the tip of the surgical instrument. It does not include inaccuracies derived from imaging, anatomical (like brain shift), planning software or human setting errors.

9.2

Environmental conditions

The equipment shall be used and stored in a room temperature between +10 °C (50 °F) and +40 °C (104 °F), room humidity 30–70% RH and atmospheric pressure 700–1060 hPa (10.1–15.4 psi).

9.3

Product lifetime

Elekta guarantee support of Leksell Stereotactic System® for 5 years from the day of acceptance of the specific part of the system with the following exception:

- Reusable Fixation Screws — 1 year

9.4

Spare parts

Spare parts for the products can be obtained from Elekta or your local Elekta® representative.

9.5

Optional parts

Optional sterilization trays for several products can be obtained from Elekta or your local Elekta® representative.

9.6**Product details**

Specifications for the products, in alphabetical order, are listed in this section.

9.6.1**A-P Cross-Hairs Holder**

Weight of assembled A-P Cross-Hairs Holder, without the Cross-Hairs Kit	800 g
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9.6.2**Backlund Catheter Insertion Needle Kit**

Article	Outer diameter (mm)	Inner diameter (mm)
Backlund Catheter Insertion Needle Kit I	—	—
Catheter insertion needle, including:	—	—
• Slotted outer cannula	2.1	1.6
• Inner cannula	1.5	1.0
• Stylet	0.9	—
Stop insert	—	2.1
Guide insert	—	2.1
Suitable catheter diameter	1.5	—
Backlund Catheter Insertion Needle Kit III	—	—
Catheter insertion needle, including:	—	—
• Slotted outer cannula	3.5	2.7
• Inner cannula	2.6	2.0
• Stylet	1.9	—
Stop insert	—	3.5
Guide insert	—	3.5
Suitable catheter dimension	2.6	—
<i>Included in all kits above:</i>		
Ruler	—	—
Sterilization Tray	—	—

For instrument lengths and material, see [Section 5.5.2 on page 143](#).

9.6.3**Backlund Haematoma Evacuator Kit**

Article	Outer diameter (mm)	Inner diameter (mm)
Haematoma evacuator	4.0	3.3
Stop insert	—	4.0
Guide insert	—	4.0
Drill Driver	4.5	—

For instrument lengths and material, see [Section 5.6.2 on page 151](#).

9.6.4**Cross-Hairs Kit**

The Cross-Hairs Kit consists of a ring plate, a cross plate, and a set of four O-rings. The plates and O-rings can also be ordered separately.

Outer diameter of plates	62 mm
Weight of ring and cross plate together, each with an O-ring	80 g

9.6.5**CT Adapter**

Width (fully assembled)	335 mm
Depth (fully assembled)	185 mm
Height (fully assembled)	270 mm
Weight	2030 g

9.6.6**CT Table Fixations**

Contact Elekta® for details of the range of table fixations available, or check the Elekta® product catalog.

9.6.7**Fixation posts**

The following fixation posts and accessories are available.

Insulated fixation posts

- Insulated Fixation Posts, short posterior
- Insulated Fixation Posts, medium posterior
- Insulated Fixation Posts, long posterior
- Insulated Fixation Posts, anterior
- Insulated Curved Posts

Non-insulated fixation posts

- Non-insulated Fixation Posts, short posterior
- Non-insulated Fixation Posts, medium posterior
- Non-insulated Fixation Posts, long posterior
- Non-insulated Fixation Posts, anterior
- Non-insulated Curved Posts

Fixation post accessories

- Locking screws
- Locking pieces
- Disposable inserts

Specifications for individual fixation posts

Fixation post type	Post	Weight (g)	Length (mm)
Insulated Fixation Post	Short posterior	35	79
	Medium posterior	50	110
	Long posterior	57	137.5
	Anterior	68	156
	Curved	91	149
Non-insulated Fixation Posts	Short posterior	39	80
	Medium posterior	50	110
	Long posterior	60	137.5
	Anterior	71	156
	Curved	107	152

9.6.8 Fixation screws

9.6.8.1 Disposable Fixation Screws

The following individual parts can be ordered separately:

- Socket wrench
- Disposable Fixation Screws, available in the following lengths:

25 mm	30 mm	35 mm	40 mm	45 mm
50 mm	55 mm	60 mm	65 mm	70 mm
75 mm	80 mm	90 mm		

Note: *Two socket wrenches are needed when tightening the Disposable Fixation Screws. See Section 3.8 on page 64.*

9.6.8.2 Quick Fixation Screws; Reusable Fixation Screws; Titanium Fixation Screws

The following individual parts can be ordered separately:

- Sterilization tray
- Instrument screwdriver, for use with Reusable Fixation Screws and Titanium Fixation Screws
- Socket wrench, for use with Quick Fixation Screws
- Quick Fixation Screws, Reusable Fixation Screws and Titanium Fixation Screws, available in the following lengths:

20 mm	22.5 mm	25 mm	27.5 mm	30 mm
32.5 mm	35 mm	37.5 mm	40 mm	42.5 mm
45 mm	50 mm	55 mm	60 mm	65 mm
70 mm	75 mm	80 mm	90 mm	110 mm

Note: *Two instrument screwdrivers or socket wrenches are needed when tightening the fixation screws. See Section 3.2 on page 28.*

9.6.9**Fork and Clamp Type Adapters**

	Fork Type Adapter	Clamp Type Adapter
Dimensions	90 × 20 × 45 mm	62 × 20 × 52 mm
Weight	60 g	50 g

9.6.10**Frame Fixation**

Weight	750 g
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9.6.11**Insertion Cannula Kit**

Article	Outer diameter (mm)	Inner diameter (mm)
• Insertion cannula	2.1	1.6
• Stylet	1.5	—
Stop insert	—	2.1
Guide insert	—	2.1

For instrument lengths and material, see [Section 5.7.2 on page 158](#).

9.6.12**Leksell® Coordinate Frame G**

Height	35 mm
Length	236 mm
Width	206 mm
Weight (coordinate frame assembled with straight front piece and connection feet)	650 g

9.6.13**Leksell® Endoscope Adapter**

Height	165 mm
Reach, using a 190 mm endoscope	70 mm above the target 20 mm below the target
Weight	200 g

9.6.14**Leksell® Multi Purpose Stereotactic Arc**

Maximum reach in lateral orientation	X: +/- 55 mm, Y: +/- 70 mm, Z: +55 / -60 mm from center of coordinate frame. (X = 45–155, Y = 30–170, Z = 40–155)
Maximum reach in anterior-posterior orientation	X: +/- 55 mm, Y: +/- 45 mm, Z: +55 / -60 mm from center of coordinate frame. (X = 45–155, Y = 55–145, Z = 40–155)
Weight	1500 g approx.

9.6.15**Leksell Stereotactic System® Clamp**

Width (fully assembled)	45 mm
Length (fully assembled)	105 mm
Height (fully assembled)	70 mm
Weight	250 g

9.6.16**MR Adapters**

The specification of the adapter depends on the type of scanner it is designed to fit. Contact Elekta® for details of the range of adapters available, or check the Elekta® product catalog.

9.6.17**MR Indicator**

Width (fully assembled)	210 mm
Depth (fully assembled)	240 mm
Height (fully assembled), - without attachment clips - with attachment clips	195 mm 235 mm
Weight	940 g

9.6.18**MR Phantom**

Width (fully assembled)	190 mm
Depth (fully assembled)	190 mm
Height (fully assembled)	186 mm
Weight (empty)	2 kg
Weight (filled)	4.5 kg

9.6.19 Open CT Indicator

Width (fully assembled)	240 mm
Depth (fully assembled)	240 mm
Height (fully assembled), - without attachment clips - with attachment clips	240 mm 270 mm
Weight	850 g

9.6.20 Open MR Indicator

Width (fully assembled)	200 mm
Depth (fully assembled)	200 mm
Height (fully assembled), - without attachment clips - with attachment clips	170 mm 200 mm
Weight	500 g

9.6.21 Salcman Twist Drill Kit

Article	Outer diameter (mm)	Inner diameter (mm)
Twist drill 2.1	2.1	—
Twist drill 3.2	3.2	—
Sleeve 70	4.0	3.3
Sleeve 95	4.0	3.3
Reducing tube	3.2	2.2
Stop insert	—	4.0
Guide insert	—	4.0
Drill driver	4.5	—
Adjustable stop 2.1	—	2.1
Adjustable stop 3.2	—	3.2

For instrument lengths and material, see [Section 5.3.2 on page 128](#).

9.6.22**Sedan Side-Cutting Biopsy Needle Kit I**

Article	Outer diameter (mm)	Inner diameter (mm)	Cutting window length (mm)
Outer cannula	2.5	2.0	11
Inner cannula	1.9	1.4	10
Stop insert	—	2.5	—
Guide insert	—	2.5	—

For instrument lengths and material see [Section 5.4.2 on page 136](#).

9.6.23**Slotted Front Piece**

Height	24 mm
Length	140 mm
Width	30 mm
Weight	110 g

9.6.24**X-Ray Indicator with Markers**

Width (fully assembled)	210 mm
Depth (fully assembled)	239 mm
Height (fully assembled), without attachment clips	205 mm
Weight	980 g

9.6.25**X-Ray Indicator with Rulers**

Width (fully assembled)	210 mm
Depth (fully assembled)	180 mm
Height (fully assembled), without attachment clips	181 mm
Weight	650 g

9.6.26**X-Ray Table Fixations**

Contact Elekta® for details of the range of table fixations available, or check the Elekta® product catalog.

9.7 Labels

Engraved labels of different types are found on many of the products in Leksell Stereotactic System®. Regarding symbols used on the equipments see sections [1.2.6.2 Warning symbols - page 10](#) and [1.2.6.3 Other symbols - page 11](#).

- Batch numbers can be marked with BN.
- Serial numbers can be marked with SN.
- Other manufacturing numbers can appear on different parts.
- On disposable products the label **Single use only** can be found on the package.

[Figure 9.1](#) and [Figure 9.2](#) show some examples of engraved labels.

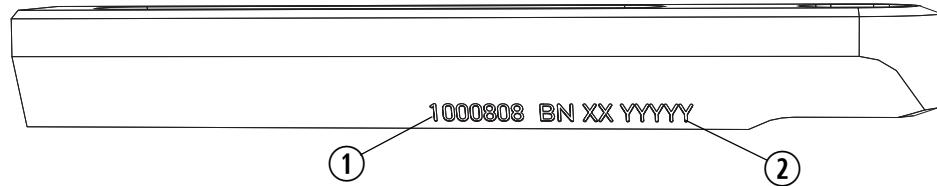


Figure 9.1 Example of engraved article number ① and batch number ② on an Insulated Fixation Post

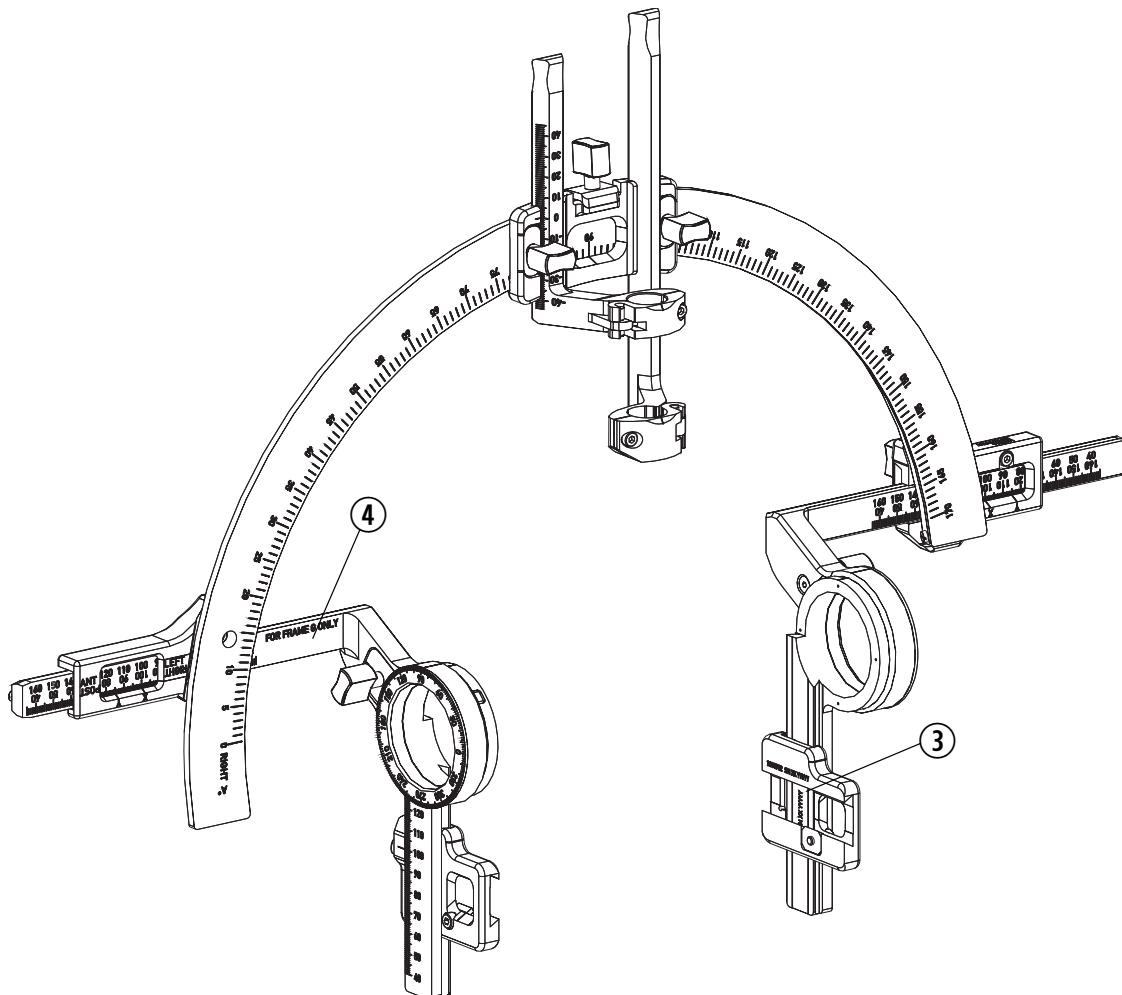


Figure 9.2 Examples of engraved labels on Leksell® Multi Purpose Stereotactic Arc: serial number ③, and text ④

List of warnings and cautions

WARNING 1.1	6
	Warnings are directions which, if ignored, could constitute a health hazard, cause fatal or serious injury, or lead to clinical mistreatment.
CAUTION 1.1	6
	Cautions are directions which, if ignored, could cause damage to the equipment described in this manual, and/or any other equipment or goods, and/or could cause environmental damage.
WARNING 1.2	7
	Side effects of stereotactic neurosurgery are generally associated with effects on critical structures or blood vessels that are within or nearby the treatment target or the trajectory. These may include effects that can be temporary or permanent. These effects can lead to intracranial bleeding, infection, vascular emboli and neurological symptoms depending on the brain location. Particular effects depend on the actual region at risk by virtue of proximity to the target and other clinical factors such as age, medical condition, the disorder treated, previous treatment history, and other prior interventions both medical and surgical.
WARNING 1.3	7
	Changes, additions or maintenance to the equipment carried out by persons without appropriate qualifications and training and/or using unapproved spare parts may lead to serious risk of injury and/or damage to the equipment as well as making the warranty void.
WARNING 1.4	10
	If any part of the equipment is known or suspected to be defective or incorrectly adjusted, DO NOT USE the equipment until a repair has been made by Elekta. Use with defective or incorrectly adjusted components or systems could expose the users and/or the patient to radiation and other safety hazards. This could lead to injury or to clinical mistreatment.
WARNING 3.1	26
	The equipment must only be used with Leksell Stereotactic System® or specified instruments. Usage with other systems can cause inaccurate treatment and patient injury.
WARNING 3.2	26
	Handle all Elekta equipment with care. Any damage, however slight, can reduce treatment safety and accuracy. Inspect the equipment before clinical use. If you suspect that any part is damaged, contact Elekta immediately. Do not use damaged equipment for any purpose until authorized to do so by Elekta.
WARNING 3.3	26
	The equipment must be set up in accordance with the treatment protocol. Otherwise wrong treatment can result and the patient can be injured.
WARNING 3.4	26
	Do not use the coordinate frame with MR scanner frequencies lower than 40 MHz. Otherwise the images can be distorted.
WARNING 3.5	26
	Unless otherwise stated, the equipment is delivered unsterile and must be sterilized before use. Otherwise the patient can be infected.

WARNING 3.6	26
	To avoid excessive force on the screws, use only the intended tools provided with the product. Otherwise the patient can be injured.	
WARNING 3.7	26
	Do not use excessive force when tightening locking screws/knobs. Otherwise parts can be damaged and not permit secure fixation. Non-secure fixation can cause incorrect treatment.	
WARNING 3.8	26
	Handle equipment with sharp edges or points with care. Otherwise surgical gloves can become damaged and the patient and/or the surgeon can be infected.	
WARNING 3.9	26
	Inspect all threads regarding wear and tear before use. Damaged threads can cause unsafe fixation of the coordinate frame.	
WARNING 3.10	27
	Exercise extreme caution at all times to ensure that the coordinate frame does not move on the patient's skull. If the coordinate frame is displaced, all treatment planning based on the coordinate frame position is invalid.	
WARNING 3.11	27
	Ensure that the patient skull is rigid enough (due to patient age, bone flap, osteoporosis etc) to withstand the fixation force needed for a safe fixation.	
WARNING 3.12	27
	Conditions for use in MRI: • Only for use in 1.5 T or 3 T with RF transmit head or body coil. • Always use the insulated fixation posts. Otherwise there is a risk of temperature increase at the tip of the fixation screws. • Non-insulated fixation posts are contraindicated (MR Unsafe).	
WARNING 3.13	34
	Do not use excessive force when tightening locking screws/knobs. Otherwise parts can be damaged and not permit secure fixation. Non-secure fixation can cause incorrect treatment.	
WARNING 3.14	35
	Do not use the disposable inserts if the sterile package is broken. Otherwise the patient can be infected.	
WARNING 3.15	39
	Do not position fixation screw tips at the same level as the target. Otherwise imaging artifacts can cause erroneous treatment planning.	
WARNING 3.16	39
	Do not attach the coordinate frame to the skull in level with the intended target. Otherwise the CT Adapter can cause imaging artifacts.	
WARNING 3.17	39
	Do not bring any tools (ferromagnetic objects) into the MRI area since these could be attracted by the magnet and become projectiles and injure the patient or operator.	
WARNING 3.18	40
	Always attach the front piece before mounting the coordinate frame on the patient's head. Without the front piece the coordinate frame is not safe for treatment and the patient can be injured.	

WARNING 3.19	40
	Always attach the coordinate frame with the front piece at the patient's anterior. Otherwise there is a risk of misunderstanding the Leksell Coordinate System® and wrong target can be treated.	
WARNING 3.20	40
	Do not insert the ear plugs too far into the auditory canal. Otherwise the patient can be injured.	
WARNING 3.21	41
	Mount the coordinate frame in a way that facilitates intubation. Emergency removal of the front piece can injure the patient if a surgical instrument has been inserted.	
WARNING 3.22	42
	Inspect all threads regarding wear and tear before use. Damaged threads can cause unsafe fixation of the coordinate frame.	
WARNING 3.23	42
	Ensure that the fixation screw tip is not blunt and that there is no damage to the fixation screw tip and socket. Blunt or damaged fixation screws can cause loose fixation and could reduce treatment safety.	
WARNING 3.24	42
	Do not apply pressure when inserting fixation screws through the disposable inserts. Otherwise the insert can be pushed out and the fixation screws can injure the patient.	
WARNING 3.25	43
	Avoid excessive force when tightening the fixation screws. Otherwise wrong target can be treated due to bent fixation posts or damaged fixation screws, or treatment can be cancelled.	
WARNING 3.26	44
	Before surgery, ensure that the coordinate frame is secured to the patient skull. Otherwise the patient may be injured.	
WARNING 3.27	44
	Do not continue surgery if the front piece of the coordinate frame has been removed. The stereotactic procedure must be re-done, starting with imaging. Otherwise the treatment can be inaccurate and the patient can be injured.	
WARNING 3.28	45
	The disposable inserts are single use products and must not be re-used. Re-use can be hazardous for the patient.	
WARNING 3.29	48
	When using the slotted front piece, three-point fixation reduces the stability of the fixation to the skull and can cause incorrect treatment.	
WARNING 3.30	49
	Always ensure that the slotted front piece is inserted in the correct orientation. If the slotted front piece is inserted upside down, the X-coordinate scale will be incorrect. Any treatment based on an incorrect scale could result in injury to the patient.	
WARNING 3.31	61
	The Titanium Fixation Screws can cause artifacts in MR images.	

List of warnings and cautions

WARNING 3.32	63
	Prior to use, inspect the fixation screws to find any damage during shipment or storage or out-of-box defects that can increase the risk of fragmentation during use.	
WARNING 3.33	63
	Inspect the fixation screw tip for any signs of breakage or fragmentation immediately upon removal from the patient.	
WARNING 3.34	65
	The Disposable Fixation Screws are single use products and must not be re-used. Re-use can be hazardous for the patient.	
WARNING 3.35	68
	Inspect all threads regarding wear and tear before use. Damaged threads can cause unsafe fixation of the coordinate frame.	
WARNING 3.36	68
	Do not use excessive force when tightening locking screws/knobs. Otherwise parts can be damaged and not permit secure fixation. Non-secure fixation can cause incorrect treatment.	
WARNING 3.37	69
	Support the patient's head at all times when fitting the coordinate frame to, and removing it from, any other equipment. Otherwise the patient can be injured.	
WARNING 3.38	70
	Ensure that the equipment is properly assembled and securely fixed. Otherwise the patient can be injured.	
WARNING 3.39	71
	Ensure that the equipment is properly assembled and securely fixed. Otherwise the patient can be injured.	
WARNING 3.40	71
	Ensure that the patient can easily be released in case of emergency. Otherwise the patient can be injured.	
WARNING 3.41	76
	Inspect all threads regarding wear and tear before use. Damaged threads can cause unsafe fixation of the coordinate frame.	
WARNING 3.42	76
	Handle equipment with sharp edges or points with care. Otherwise surgical gloves can become damaged and the patient and/or the surgeon can be infected.	
WARNING 3.43	77
	Do not attach the equipment to the anterior bar of the coordinate frame. Otherwise the bar can break from the coordinate frame and the patient can be injured.	
WARNING 3.44	77
	Support the patient's head at all times when fitting the coordinate frame to, and removing it from, any other equipment. Otherwise the patient can be injured.	
WARNING 3.45	78
	Ensure that the equipment is properly assembled and securely fixed. Otherwise the patient can be injured.	

WARNING 3.46	78
	Ensure that the patient can easily be released in case of emergency. Otherwise the patient can be injured.	
WARNING 3.47	81
	Do not attach the equipment to the anterior bar of the coordinate frame. Otherwise the bar can break from the coordinate frame and the patient can be injured.	
WARNING 3.48	82
	Check the screws for wear and that the knobs are securely tightened. Movement of the clamp or the attached surgical instrument can injure the patient.	
WARNING 3.49	84
	Do not attach the equipment to the anterior bar of the coordinate frame. Otherwise the bar can break from the coordinate frame and the patient can be injured.	
WARNING 3.50	85
	Check the screws for wear and that the knobs are securely tightened. Movement of the clamp or the attached surgical instrument can injure the patient.	
WARNING 4.1	88
	The equipment must only be used with Leksell Stereotactic System® or specified instruments. Usage with other systems can cause inaccurate treatment and patient injury.	
WARNING 4.2	88
	Handle all Elekta equipment with care. Any damage, however slight, can reduce treatment safety and accuracy. Inspect the equipment before clinical use. If you suspect that any part is damaged, contact Elekta immediately. Do not use damaged equipment for any purpose until authorized to do so by Elekta.	
WARNING 4.3	88
	Unless otherwise stated, the equipment is delivered unsterile and must be sterilized before use. Otherwise the patient can be infected.	
WARNING 4.4	88
	Exercise extreme caution at all times to ensure that the coordinate frame does not move on the patient's skull. If the coordinate frame is displaced, all treatment planning based on the coordinate frame position is invalid.	
WARNING 4.5	88
	The equipment must be set up in accordance with the treatment protocol. Otherwise wrong treatment can result and the patient can be injured.	
WARNING 4.6	88
	If loose paint flakes are found on the operation gloves or on the equipment, all parts with engravings must be wiped thoroughly before mounting the equipment in the operating room. Otherwise, loose paint flakes can enter the surgical area.	
WARNING 4.7	88
	Do not use excessive force when tightening locking screws/knobs. Otherwise parts can be damaged and not permit secure fixation. Non-secure fixation can cause incorrect treatment.	
WARNING 4.8	88
	Handle equipment with sharp edges or points with care. Otherwise surgical gloves can become damaged and the patient and/or the surgeon can be infected.	

WARNING 4.9	94
	Use only the screws supplied with the stereotactic arc and ensure to position the screws correctly. Erroneous position of screws can reduce treatment accuracy and cause misplacement of surgical instruments.	
WARNING 4.10	97
	Ensure that the correct scale and index mark is used. Otherwise wrong target can be treated.	
WARNING 4.11	99
	Before attaching the stereotactic arc to the arc support, ensure that the axis support is fitted flush against the stereotactic arc. No opening is permitted between the axis support and the stereotactic arc. An opening will reduce treatment accuracy and can cause misplacement of surgical instruments.	
WARNING 4.12	99
	If Leksell SurgiPlan® has been used for the target path planning, ensure that the stereotactic arc orientation used for surgery is the set orientation for the target path planning. Otherwise the patient can be injured.	
WARNING 4.13	100
	When attaching the stereotactic arc to the arc support, ensure that the two ring surfaces are flush against each other. The groove between the rings must be even all the way around. An uneven groove will reduce treatment accuracy and can cause misplacement of surgical instruments.	
WARNING 4.14	101
	Ensure that the coordinate and instrument carrier settings are securely locked. Movement of the stereotactic arc or the instrument carrier when a surgical instrument is inserted into the brain can injure the patient.	
WARNING 4.15	104
	Ensure that the correct scale and index mark is used. Otherwise wrong target can be treated.	
WARNING 4.16	107
	Ensure that the screws securing the instrument guide and stop holder do not protrude from the back of the instrument carrier. If they protrude, the instrument carrier must be serviced. Otherwise the instrument carrier will get misplaced and the patient can be injured.	
WARNING 4.17	109
	If using surgical instruments with a working length different than 190 mm, the setting of the instrument stop holder must compensate for the difference. Otherwise an erroneous treatment depth can be reached and the patient can be injured.	
WARNING 4.18	109
	Always check that the instrument stop holder is set to the appropriate position before performing any surgical procedure to avoid injury to the patient or incorrect treatment.	
WARNING 4.19	109
	Ensure that the coordinate and instrument carrier settings are securely locked. Movement of the stereotactic arc or the instrument carrier when a surgical instrument is inserted into the brain can injure the patient.	

WARNING 4.20	115
	The patterns in the center of the ring and cross plates have sharp edges. Handle the equipment with care. Otherwise surgical gloves can become damaged and the patient and/or the surgeon can be infected.	
CAUTION 4.1	115
	Do not subject the patterns in the center of the ring and cross plates to load or high pressure. This may deform the plates or destroy the patterns. Any damage reduces the precision of the instrument.	
CAUTION 4.2	116
	Do not subject the patterns in the center of the ring and cross plates to load or high pressure. This may deform the plates or destroy the patterns. Any damage reduces the precision of the instrument.	
CAUTION 4.3	118
	Do not subject the patterns in the center of the ring and cross plates to load or high pressure. This can deform the plates or destroy the patterns. Any damage reduces the precision of the instrument.	
WARNING 4.21	121
	Plan the trajectory to avoid inserting the surgical instrument into regions where it can cause injury.	
WARNING 4.22	121
	The angle of the V-shaped arc connector is 30°. When using the Leksell® Endoscope Adapter, the correct angle of the endoscope trajectory is obtained by subtracting 30° from the ring angle of the stereotactic arc. You must consider this 30° compensation factor otherwise the angle of the Leksell® Endoscope Adapter will be incorrect.	
WARNING 4.23	122
	The V-shaped arc connector must be inserted into the correct slot until the stop of the dovetail rests on the surface of the instrument carrier. Otherwise the surgical instrument will not reach the correct depth.	
WARNING 4.24	123
	Compensate for the difference between 190 mm and the length of the endoscope in use. Otherwise the surgical instrument will not reach the correct depth.	
WARNING 4.25	124
	The endoscope guide must be inserted to its full length, i.e. until its edge is stopped by the collar at the free end of the arm. Otherwise the surgical instrument will not reach the correct depth.	
WARNING 4.26	124
	Always use the appropriate guide insert corresponding to the diameter of the surgical instrument. Otherwise the patient can be injured and the surgical instruments can be damaged.	
WARNING 5.1	125
	Handle all Elekta equipment with care. Any damage, however slight, can reduce treatment safety and accuracy. Inspect the equipment before clinical use. If you suspect that any part is damaged, contact Elekta immediately. Do not use damaged equipment for any purpose until authorized to do so by Elekta.	
WARNING 5.2	125
	The equipment must be set up in accordance with the treatment protocol. Otherwise wrong treatment can result and the patient can be injured.	

WARNING 5.3	125
	The equipment must only be used with Leksell Stereotactic System® or specified instruments. Usage with other systems can cause inaccurate treatment and patient injury.	
WARNING 5.4	125
	Exercise extreme caution at all times to ensure that the coordinate frame does not move on the patient's skull. If the coordinate frame is displaced, all treatment planning based on the coordinate frame position is invalid.	
WARNING 5.5	125
	Unless otherwise stated, the equipment is delivered unsterile and must be sterilized before use. Otherwise the patient can be infected.	
WARNING 5.6	125
	Always remove the surgical instrument from the brain before changing any stereotactic settings. Otherwise the patient can be injured.	
WARNING 5.7	126
	Always check that the instrument stop holder is set to the appropriate position before performing any surgical procedure to avoid injury to the patient or incorrect treatment.	
WARNING 5.8	126
	Handle equipment with sharp edges or points with care. Otherwise surgical gloves can become damaged and the patient and/or the surgeon can be infected.	
WARNING 5.9	126
	Plan the trajectory to avoid inserting the surgical instrument into regions where it can cause injury.	
WARNING 5.10	126
	Insert the surgical instrument slowly and carefully to avoid damage to blood vessels and other sensitive areas. Otherwise the patient can be injured.	
WARNING 5.11	126
	The patient's brain may move slightly when the skull is punctured due to the release of fluid pressure. The patient's brain may therefore be in a slightly different position relative to the skull during the operation compared to when the images were acquired. The accuracy of the treatment may be affected.	
WARNING 5.12	126
	Do not bring any MR Unsafe products into the MRI area since it may be affected by the magnetic field or cause artifacts in the images.	
WARNING 5.13	130
	Always use the appropriate stop and guide inserts corresponding to the diameter of the surgical instrument. Otherwise the patient can be injured and the surgical instruments can be damaged.	
WARNING 5.14	131
	The stop insert must be inserted to its full length, i.e. until its edge is stopped by the instrument stop holder. Otherwise the surgical instrument will not reach the correct depth.	
WARNING 5.15	132
	Always check that the instrument stop holder is set to the appropriate position before performing any surgical procedure to avoid injury to the patient or incorrect treatment.	

WARNING 5.16	132
	The tip of the drill and the sleeve must be checked for deformation prior to each use. A deformed drill or sleeve can injure the patient.	
WARNING 5.17	132
	Always handle the drills with care. Avoid contact between the drills, otherwise they can become damaged and injure the patient during clinical use.	
WARNING 5.18	132
	The sleeve must be used and inserted into the guide insert. Otherwise the depth of drilling can be incorrect and the patient can be injured.	
WARNING 5.19	133
	In the starting position the tip of the drill must rest against the skull, and the instrument stop holder must be set to 0 (zero). Otherwise the depth of penetration will be unpredictable and the patient can be injured.	
WARNING 5.20	133
	Before drilling, make sure that the drill's adjustable stop is correctly adjusted and properly secured to the drill. Otherwise the depth of penetration will be unpredictable and the patient can be injured.	
WARNING 5.21	133
	Ensure the depth of the hole does not exceed the thickness of the skull estimated by the surgeon. Otherwise the patient can be injured.	
WARNING 5.22	138
	Always use the appropriate stop and guide inserts corresponding to the diameter of the surgical instrument. Before operation, check and make sure that the surgical instrument fits the stop and guide inserts. Otherwise the patient can be injured and the surgical instruments can be damaged.	
WARNING 5.23	138
	Always check that the instrument stop holder is set to the appropriate position before performing any surgical procedure to avoid injury to the patient or incorrect treatment.	
WARNING 5.24	138
	Ensure that the O-ring on the inner cannula is lubricated and in good condition, providing an adequate seal with the outer cannula. Otherwise no specimen will be obtained.	
WARNING 5.25	139
	The tip of the cannula must be checked for deformation prior to each use. A deformed tip can injure the patient.	
WARNING 5.26	139
	The open slot along the slotted outer cannula must be checked for deformation prior to each use. Deformation of the slot on the slotted outer cannula can injure the patient.	
WARNING 5.27	139
	When inserting or removing the surgical instrument into/from the patient's brain, the inner cannula must be fully inserted into the outer cannula and the cutting window must be closed. Otherwise the patient can be injured.	
WARNING 5.28	140
	When planning a treatment beware that the surgical instrument protrudes 8.5 mm below the target. Otherwise the patient can be injured.	

WARNING 5.29	141
	Suction must be performed by hand. Do not connect a suction apparatus to the cannula. Otherwise the patient can be injured.	
WARNING 5.30	141
	The outer cannula must not be rotated unless the inner cannula is inserted and the cutting window is closed. Otherwise the patient can be injured.	
WARNING 5.31	141
	When inserting or removing the surgical instrument into/from the patient's brain, the inner cannula must be fully inserted into the outer cannula and the cutting window must be closed. Otherwise the patient can be injured.	
WARNING 5.32	145
	Always use the appropriate stop and guide inserts corresponding to the diameter of the surgical instrument. Before operation, check and make sure that the surgical instrument fits the stop and guide inserts. Otherwise the patient can be injured and the surgical instruments can be damaged.	
WARNING 5.33	145
	Always check that the instrument stop holder is set to the appropriate position before performing any surgical procedure to avoid injury to the patient or incorrect treatment.	
WARNING 5.34	145
	The open slot along the slotted outer cannula must be checked for deformation prior to each use. Deformation of the slot on the slotted outer cannula can injure the patient.	
WARNING 5.35	145
	The tip of the cannula must be checked for deformation prior to each use. A deformed tip can injure the patient.	
WARNING 5.36	146
	The stylet and inner cannula must be inserted into the outer cannula before the slotted outer cannula is inserted into the patient's brain. Otherwise the patient can be injured.	
WARNING 5.37	147
	The slotted outer cannula must not be rotated while positioned in the patient's brain. Otherwise the patient can be injured.	
WARNING 5.38	147
	When planning a treatment beware that the surgical instrument protrudes 1 mm below the target in Kit I, and 1.5 mm below the target in Kit III. Otherwise the patient can be injured.	
WARNING 5.39	153
	Always use the appropriate stop and guide inserts corresponding to the diameter of the surgical instrument. Before operation, check and make sure that the surgical instrument fits the stop and guide inserts. Otherwise the patient can be injured and the surgical instruments can be damaged.	
WARNING 5.40	153
	When planning a treatment beware that the surgical instrument protrudes 8 mm below the target. Otherwise the patient can be injured.	
WARNING 5.41	153
	Always check that the instrument stop holder is set to the appropriate position before performing any surgical procedure to avoid injury to the patient or incorrect treatment.	

WARNING 5.42	153
	The tip of the cannula must be checked for deformation prior to each use. A deformed tip can injure the patient.	
WARNING 5.43	155
	When planning a treatment beware that the surgical instrument protrudes 8 mm below the target. Otherwise the patient can be injured.	
WARNING 5.44	155
	Suction must be performed by hand. Do not connect a suction apparatus to the cannula. Otherwise the patient can be injured.	
WARNING 5.45	159
	Always use the appropriate stop and guide inserts corresponding to the diameter of the surgical instrument. Before operation, check and make sure that the surgical instrument fits the stop and guide inserts. Otherwise the patient can be injured and the surgical instruments can be damaged.	
WARNING 5.46	159
	Always check that the instrument stop holder is set to the appropriate position before performing any surgical procedure to avoid injury to the patient or incorrect treatment.	
WARNING 5.47	159
	The tip of the cannula must be checked for deformation prior to each use. A deformed tip can injure the patient.	
WARNING 5.48	161
	The stylet must be inserted into the cannula before the cannula is inserted into the patient's brain. Otherwise the patient can be injured.	
WARNING 5.49	161
	When planning a treatment beware that the surgical instrument protrudes 1.5 mm below the target. Otherwise the patient can be injured.	
WARNING 6.1	163
	The equipment must only be used with Leksell Stereotactic System® or specified instruments. Usage with other systems can cause inaccurate treatment and patient injury.	
WARNING 6.2	163
	Handle all Elekta equipment with care. Any damage, however slight, can reduce treatment safety and accuracy. Inspect the equipment before clinical use. If you suspect that any part is damaged, contact Elekta immediately. Do not use damaged equipment for any purpose until authorized to do so by Elekta.	
WARNING 6.3	163
	Exercise extreme caution at all times to ensure that the coordinate frame does not move on the patient's skull. If the coordinate frame is displaced, all treatment planning based on the coordinate frame position is invalid.	
WARNING 6.4	163
	Do not sterilize the equipment. If sterilized, it can be damaged.	
WARNING 6.5	164
	Do not use excessive force when tightening locking screws/knobs. Otherwise parts can be damaged and not permit secure fixation. Non-secure fixation can cause incorrect treatment.	

WARNING 6.6	164
Conditions for use in MRI:		
• Only for use in 1.5 T or 3 T with RF transmit head or body coil.		
• Always use the insulated fixation posts. Otherwise there is a risk of temperature increase at the tip of the fixation screws.		
• Non-insulated fixation posts are contraindicated (MR Unsafe).		
WARNING 6.7	164
Do not bring any tools (ferromagnetic objects) into the MRI area since these could be attracted by the magnet and become projectiles and injure the patient or operator.		
WARNING 6.8	164
Do not bring any MR Unsafe products into the MRI area since it may be affected by the magnetic field or cause artifacts in the images.		
WARNING 6.9	168
Do not use excessive force when tightening locking screws/knobs. Otherwise parts can be damaged and not permit secure fixation. Non-secure fixation can cause incorrect treatment.		
WARNING 6.10	170
Support the patient's head at all times when fitting the coordinate frame to, and removing it from, any other equipment. Otherwise the patient can be injured.		
WARNING 6.11	170
The weight of the patient's head must not be supported by the indicator, otherwise the patient can be injured or the indicator can be damaged.		
WARNING 6.12	170
When fitting the indicator to the coordinate frame, ensure that the side panel marked LEFT is on the patient's left side and the side panel marked RIGHT is on the patient's right side.		
WARNING 6.13	171
Make sure that the indicator is correctly mounted onto the coordinate frame. Otherwise there is a risk for inaccurate treatment planning.		
WARNING 6.14	172
Verify that the image orientation is correct when preparing a treatment plan. Otherwise wrong target can be treated.		
WARNING 6.15	172
If performing manual treatment planning, ensure to add 40 mm to the measured Z length. Otherwise the Z coordinate will be erroneous and wrong target will be treated.		
WARNING 6.16	180
Do not position fixation screw tips at the same level as the target. Otherwise imaging artifacts can cause erroneous treatment planning.		
WARNING 6.17	180
Do not attach the coordinate frame to the skull in level with the intended target. Otherwise the CT Adapter can cause imaging artifacts.		
WARNING 6.18	182
Ensure that the equipment is properly assembled and securely fixed. Otherwise the patient can be injured.		

WARNING 6.19	183
	Ensure that the equipment is properly assembled and securely fixed. Otherwise the patient can be injured.	
WARNING 6.20	184
	Ensure that the equipment is properly assembled and securely fixed. Otherwise the patient can be injured.	
WARNING 6.21	185
	Ensure that the equipment is properly assembled and securely fixed. Otherwise the patient can be injured.	
WARNING 6.22	186
	Support the patient's head at all times when fitting the coordinate frame to, and removing it from, any other equipment. Otherwise the patient can be injured.	
WARNING 6.23	186
	Ensure that the equipment is properly assembled and securely fixed. Otherwise the patient can be injured.	
WARNING 6.24	186
	The adapter does not have a locking device. The patient can unintentionally get out of the fixation.	
WARNING 6.25	187
	Ensure that the patient can easily be released in case of emergency. Otherwise the patient can be injured.	
WARNING 6.26	187
	If a rubber cushion is used to support the patient, ensure that it is not over inflated. Otherwise the coordinate frame can be disconnected from the adapter and the patient can be injured.	
WARNING 6.27	188
	Ensure that the indicator is correctly aligned during imaging. Otherwise inaccurate treatment can result.	
CAUTION 6.1	190
	Except for removal of the transparent plate for cleaning, the adapter should not be disassembled by the user.	
WARNING 6.28	194
	If performing manual treatment planning, ensure to add 40 mm to the measured Z length. Otherwise the Z coordinate will be erroneous and wrong target will be treated.	
WARNING 6.29	195
	Do not use excessive force when tightening locking screws/knobs. Otherwise parts can be damaged and not permit secure fixation. Non-secure fixation can cause incorrect treatment.	
WARNING 6.30	198
	Support the patient's head at all times when fitting the coordinate frame to, and removing it from, any other equipment. Otherwise the patient can be injured.	
WARNING 6.31	198
	The weight of the patient's head must not be supported by the indicator, otherwise the patient can be injured or the indicator can be damaged.	

WARNING 6.32	199
	When fitting the indicator to the coordinate frame, ensure that the side panel marked LEFT is on the patient's left side and the side panel marked RIGHT is on the patient's right side.
WARNING 6.33	199
	Make sure that the indicator is correctly mounted onto the coordinate frame. Otherwise there is a risk for inaccurate treatment planning.
WARNING 6.34	200
	Verify that the image orientation is correct when preparing a treatment plan. Otherwise wrong target can be treated.
WARNING 6.35	200
	Ensure that the indicator is correctly aligned during imaging. Otherwise inaccurate treatment can result.
WARNING 6.36	207
	If performing manual treatment planning, ensure to add 40 mm to the measured Z length. Otherwise the Z coordinate will be erroneous and wrong target will be treated.
WARNING 6.37	207
	Do not use excessive force when tightening locking screws/knobs. Otherwise parts can be damaged and not permit secure fixation. Non-secure fixation can cause incorrect treatment.
WARNING 6.38	208
	Support the patient's head at all times when fitting the coordinate frame to, and removing it from, any other equipment. Otherwise the patient can be injured.
WARNING 6.39	208
	The weight of the patient's head must not be supported by the indicator, otherwise the patient can be injured or the indicator can be damaged.
WARNING 6.40	209
	When fitting the Open MR Indicator to the coordinate frame, ensure that the panel marked LEFT is on the patient's left side and that the plate holder, marked ANTERIOR, is placed above the front piece of the coordinate frame.
WARNING 6.41	210
	Make sure that the indicator is correctly mounted onto the coordinate frame. Otherwise there is a risk for inaccurate treatment planning.
WARNING 6.42	211
	Verify that the image orientation is correct when preparing a treatment plan. Otherwise wrong target can be treated.
WARNING 6.43	211
	Ensure that the indicator is correctly aligned during imaging. Otherwise inaccurate treatment can result.
WARNING 6.44	218
	Do not use the coordinate frame with MR scanner frequencies lower than 40 MHz. Otherwise the images can be distorted.
WARNING 6.45	220
	Ensure that the equipment is properly assembled and securely fixed. Otherwise the patient can be injured.

WARNING 6.46	221
	Support the patient's head at all times when fitting the coordinate frame to, and removing it from, any other equipment. Otherwise the patient can be injured.	
WARNING 6.47	221
	Ensure that the equipment is properly assembled and securely fixed. Otherwise the patient can be injured.	
WARNING 6.48	221
	Ensure that the patient can easily be released in case of emergency. Otherwise the patient can be injured.	
WARNING 6.49	222
	Ensure that the indicator is correctly aligned during imaging. Otherwise inaccurate treatment can result.	
CAUTION 6.2	224
	The adapter should not be disassembled by the user.	
WARNING 6.50	229
	The phantom can only show distortions caused by Leksell® Coordinate Frame. Other distortions cannot be determined with the phantom.	
CAUTION 6.3	230
	Ensure that the large O-ring is in good condition. Otherwise the verification can be incorrect.	
CAUTION 6.4	230
	Do not wash the equipment with alcoholic solutions.	
CAUTION 6.5	230
	Check that the container is filled with liquid before use.	
CAUTION 6.6	232
	Be careful when handling the grids as they are extremely sensitive to external forces.	
CAUTION 6.7	232
	Check that the container is filled with liquid before use.	
WARNING 6.51	237
	Do not use excessive force when tightening locking screws/knobs. Otherwise parts can be damaged and not permit secure fixation. Non-secure fixation can cause incorrect treatment.	
WARNING 6.52	239
	Support the patient's head at all times when fitting the coordinate frame to, and removing it from, any other equipment. Otherwise the patient can be injured.	
WARNING 6.53	239
	When fitting the indicator to the coordinate frame, ensure that the side panel marked LEFT is on the patient's left side and the side panel marked RIGHT is on the patient's right side.	
WARNING 6.54	239
	The weight of the patient's head must not be supported by the indicator, otherwise the patient can be injured or the indicator can be damaged.	

WARNING 6.55	240
	Make sure that the indicator is correctly mounted onto the coordinate frame. Otherwise there is a risk for inaccurate treatment planning.	
WARNING 6.56	241
	Verify that the image orientation is correct when preparing a treatment plan. Otherwise wrong target can be treated.	
WARNING 6.57	246
	Do not use excessive force when tightening locking screws/knobs. Otherwise parts can be damaged and not permit secure fixation. Non-secure fixation can cause incorrect treatment.	
WARNING 6.58	246
	Support the patient's head at all times when fitting the coordinate frame to, and removing it from, any other equipment. Otherwise the patient can be injured.	
WARNING 6.59	246
	When fitting the indicator to the coordinate frame, ensure that the side panel marked LEFT is on the patient's left side and the side panel marked RIGHT is on the patient's right side.	
WARNING 6.60	247
	The weight of the patient's head must not be supported by the indicator, otherwise the patient can be injured or the indicator can be damaged.	
WARNING 6.61	248
	Make sure that the indicator is correctly mounted onto the coordinate frame. Otherwise there is a risk for inaccurate treatment planning.	
WARNING 6.62	248
	Verify that the image orientation is correct when preparing a treatment plan. Otherwise wrong target can be treated.	
WARNING 6.63	252
	Ensure that the equipment is properly assembled and securely fixed. Otherwise the patient can be injured.	
WARNING 6.64	254
	Ensure that the equipment is properly assembled and securely fixed. Otherwise the patient can be injured.	
WARNING 6.65	256
	Ensure that the equipment is properly assembled and securely fixed. Otherwise the patient can be injured.	
WARNING 6.66	258
	Ensure that the equipment is properly assembled and securely fixed. Otherwise the patient can be injured.	
WARNING 6.67	259
	Support the patient's head at all times when fitting the coordinate frame to, and removing it from, any other equipment. Otherwise the patient can be injured.	
WARNING 6.68	259
	Ensure that the equipment is properly assembled and securely fixed. Otherwise the patient can be injured.	

WARNING 6.69	259
	Ensure that the patient can easily be released in case of emergency. Otherwise the patient can be injured.	
WARNING 6.70	259
	The adapter does not have a locking device. The patient can unintentionally get out of the fixation.	
WARNING 6.71	260
	If a rubber cushion is used to support the patient, ensure that it is not over inflated. Otherwise the coordinate frame can be disconnected from the adapter and the patient can be injured.	
WARNING 6.72	260
	Ensure that the indicator is correctly aligned during imaging. Otherwise inaccurate treatment can result.	
WARNING 7.1	261
	Handle all Elekta equipment with care. Any damage, however slight, can reduce treatment safety and accuracy. Inspect the equipment before clinical use. If you suspect that any part is damaged, contact Elekta immediately. Do not use damaged equipment for any purpose until authorized to do so by Elekta.	
WARNING 7.2	261
	Elekta recommended methods for disassembling, cleaning and sterilization must be followed. Otherwise the equipment can be damaged and the treatment safety reduced.	
WARNING 7.3	261
	In case of using this device on a patient infected by Creutzfeldt-Jakob disease and/or when contamination with high risk tissues/organs is suspected, components are recommended to be disposed (single used), since there are no cleaning or sterilization methods proven to be effective against the Creutzfeldt-Jakob disease prions. Risks related for re-use of parts, contaminated with high risk tissues/organs, have to be judged by user when cleaned and sterilized according to applicable national recommendations or WHO's report "Infection Control Guidelines for Transmissible Spongiform Encephalopathy's" (within Elekta's recommended cleaning and sterilization parameters). Ref: WHO "Infection Control Guidelines for Transmissible Spongiform Encephalopathies", Report of a WHO consultation - WHO/CDS/CSR/APH/2000.3.	
WARNING 7.4	264
	Do not sterilize the equipment. If sterilized, it can be damaged.	
CAUTION 7.1	265
	For the MR Phantom: Do not wash the equipment with alcoholic solutions.	
CAUTION 7.2	265
	Do not leave the MR Phantom with water inside. Otherwise it can be damaged.	
WARNING 7.5	265
	Do not sterilize the equipment. If sterilized, it can be damaged.	
WARNING 7.6	267
	If loose paint flakes are found on the operation gloves or on the equipment, all parts with engravings must be wiped thoroughly before mounting the equipment in the operating room. Otherwise, loose paint flakes can enter the surgical area.	

WARNING 7.7 268

For Salcman Twist Drill Kit: Always handle the drills with care. Avoid contact between the drills, otherwise they can become damaged and injure the patient during clinical use.

WARNING 7.8 271

In case of using this device on a patient infected by Creutzfeldt-Jakob disease and/or when contamination with high risk tissues/organs is suspected, components are recommended to be disposed (single used), since there are no cleaning or sterilization methods proven to be effective against the Creutzfeldt-Jakob disease prions. Risks related for re-use of parts, contaminated with high risk tissues/organs, have to be judged by user when cleaned and sterilized according to applicable national recommendations or WHO's report "Infection Control Guidelines for Transmissible Spongiform Encephalopathy's" (within Elekta's recommended cleaning and sterilization parameters).

Ref: WHO "Infection Control Guidelines for Transmissible Spongiform Encephalopathies", Report of a WHO consultation - WHO/CDS/CSR/APH/2000.3.

WARNING 8.1 275

Handle all Elekta equipment with care. Any damage, however slight, can reduce treatment safety and accuracy. Inspect the equipment before clinical use. If you suspect that any part is damaged, contact Elekta immediately. Do not use damaged equipment for any purpose until authorized to do so by Elekta.

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