BRAINLAB

KNEE

Instrument User Guide
Revision 1.1

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TABLE OF CONTENTS

1 GENERAL INFORMATION

1.1 Contact Data and Legal Information

1.1.1 Contact Data

Support

If you cannot find information you need in this guide, or if you have questions or problems, contact Brainlab support:

Region	Telephone and Fax	Email
United States, Canada, Central and South America	Tel: +1 (800) 597-5911 Fax: +1 (708) 409-1619	us.support@brainlab.com
Brazil	Tel: (0800) 892-1217	brazil.support@brainlab.com
UK	Tel: +44 1223 755 333	support@brainlab.com
Spain	Tel: +34 (900) 649 115	
France and French-speaking regions	Tel: +33 800 676 030	
Africa, Asia, Australia, Europe	Tel: +49 89 991568-44 Fax: +49 89 991568-811	
Japan	Tel: +81 3 3769 6900 Fax: +81 3 3769 6901	

Expected Service Life

Unless specifically stated otherwise, there is no defined service life for instruments. The end of service life depends on wear and damage during use. Repeated reprocessing has minimal effect on the service life time.

Feedback

Despite careful review, this manual may contain errors.

Please contact us at igs.manuals@brainlab.com if you have suggestions as to how we can improve this manual.

Manufacturer

Brainlab AG
Kapellenstr. 12
85622 Feldkirchen
Germany

1.1.2 Legal Information

Copyright

This guide contains proprietary information protected by copyright. No part of this guide may be reproduced or translated without the express written permission of Brainlab.

Trademarks

PFC® is a registered trademark of DePuy.

CE Label

CE 0123

- The CE label shows that the Brainlab product complies with the essential requirements of the Medical Device Directive (MDD).
- According to the MDD (Council Device Directive 93/42/EEC), the classification of the Brainlab product is defined in the corresponding **Software User Guide**.

NOTE: The validity of the CE label can only be confirmed for products manufactured by Brainlab.

Disposal Instructions

When a surgical instrument reaches the end of its functional life, clean the instrument of all biomaterial/biohazards and safely dispose of the instrument in accordance with applicable laws and regulations.

Only dispose of electrical and electronic equipment in accordance with statutory regulations. For information regarding the WEEE (Waste Electrical and Electronic Equipment) directive, visit:

http://www.brainlab.com/en/sustainability

Sales in the US

US federal law restricts this device to sale by or on the order of a physician.

1.2 Symbols

1.2.1 Symbols Used in this Guide

Warnings

Warnings are indicated by triangular warning symbols. They contain safety-critical information regarding possible injury, death or other serious consequences associated with equipment misuse.

Cautions

Cautions are indicated by circular caution symbols. They contain safety-critical information regarding possible problems with the device. Such problems include device malfunctions, device failure, damage to device or damage to property.

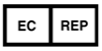
Notes

NOTE: Notes are formatted in italic type and indicate additional useful hints.

1.2.2 Hardware Symbols

Symbols on Hardware Components

Symbol	Explanation
	Caution
	Do not reuse
	Non-Sterile
	Do not resterilize
	Sterilized with ethylene oxide
	Do not use if packaging is damaged
	Keep away from sunlight
	Keep dry
	Storage conditions for relative humidity non-condensing: The specified humidity range is shown on each label
	Storage conditions for air pressure: The specified air pressure range is shown on each label
	Storage conditions for temperature: The specified temperature range is shown on each label
	Quantity of products in packaging
	Batch number
	Serial number
	Article number
	Use by month YYYY

Symbol	Explanation
	Date of manufacture
	Manufacturer
	Authorized representative in the European Community
IPXY	Ingress Protection according to IEC 60529 • X = Protection against ingress of solid objects • Y = Protection against ingress of liquid
	Rx only: U.S. federal law restricts this device to sale by or on the order of a physician
	Consult the operating instructions
	Attention! Consult accompanying documents

1.3 Intended Use

1.3.1 Device Handling

Place of Use

The medical devices in this user guide are to be used in the operating room.

Careful Hardware Handling

Only trained medical personnel may operate system components and accessory instrumentation.

System components and accessory instrumentation comprise precise mechanical parts. Handle them carefully.

Plausibility Review

Before patient treatment, review the plausibility of all information input to and output from the system.

1.4 Training and Documentation

1.4.1 Training

Brainlab Training

To ensure safe and appropriate use, before using the system all users should participate in a training program held by a Brainlab representative.

Supervised Support

Before using the system for surgical procedures where computer-aided navigation is considered critical, perform a sufficient number of complete procedures with a Brainlab representative present to provide guidance where necessary.

Responsibility

This system solely provides assistance to the surgeon and does not substitute or replace the surgeon’s experience and/or responsibility during its use.

1.4.2 Documentation

Intended Audience

This user guide is intended for surgeons and their staff.

Reading User Guides

The user guides describe complex medical devices and software that must be used with care.
It is important that all users of system, instruments and software:

- Read the user guides carefully before handling the equipment
- Have access to the relevant user guides at all times

Available User Guides

User Guide	Contents
Software User Guides	• Overview of treatment planning and image-guided navigation • Description of OR system setup • Detailed software instructions
Instrument User Guides	Detailed instructions on instrument handling
Cleaning, Disinfection and Sterilization Guide	Details on cleaning, disinfecting and sterilizing instrumentation
System User Guides	Comprehensive information on system setup
Technical User Guide	Detailed technical information on the system, including specifications and compliances

2 INSTRUMENTATION OVERVIEW

2.1 Instrument Handling

2.1.1 Safety Critical Information

Correct Handling

The instruments described in this manual are highly accurate and sensitive medical devices and must be handled with extreme care. If you drop or otherwise damage an instrument, contact Brainlab immediately for advice on how to proceed. Failure to do so may lead to serious injury to the patient.

Do not use damaged or corroded instruments.

Plan the OR setup prior to surgery. The camera must have an unobstructed view of all marker spheres, otherwise registration and navigation inaccuracies may occur.

Creutzfeldt-Jakob Contamination

Do not use Brainlab instrumentation on patients suspected of having Creutzfeldt-Jakob disease (CJD or vCJD).

MR Safety

Unless otherwise noted, the instruments are MR unsafe.

Sterilization

Unless otherwise indicated, instruments must be sterilized before use. Details are provided in the Cleaning, Disinfection and Sterilization Guide.

If a sterile instrument is inadvertently removed from the sterile field, it must be sterilized again.

2.1.2 Using Fixation Pins

General Information

The placement of a fixation pin in bone structures is a standard minimally-invasive and low-risk surgical procedure that is required in order to provide a stable basis for attaching reference arrays and performing navigation.

However, as an incision is required, please read the following information carefully before continuing.

Risks

Because placement of a fixation pin requires an incision, one or more of the following complications may occur: infection, local pain, bleeding, lesion of blood vessels or nerves, bone fracture or thrombosis.

Precautions

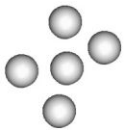
In some cases, fixation pins may be placed using an automatic drill, however, use only the lowest drilling speed to maintain maximum control over the drilling depth.

Use only a threaded fixation pin with the specified diameter. Using a fixation pin with the incorrect diameter could result in unstable attachment.

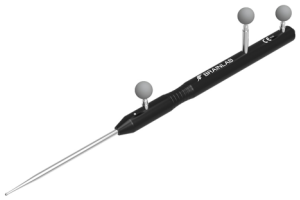
To ensure stable attachment, the fixation pin should be positioned bicortically where possible.

2.1.3 Available Instruments

General Instrumentation

Illustration	Name	See
	**Disposable Reflective Marker Spheres**	Page 23
	**Disposable Schanz Screws**	Page 26
	**Disposable Clip-on Remote Control**	Page 27
	**Footswitch (USB)**	Page 38

Pointers

Illustration	Name	See
	**Pointer Straight for Knee**	Page 41
	**Pointer Angled for Hip and Knee**	Page 41

Reference Arrays

Illustration	Name	See
	**Reference Array T-Geometry X-Press**	Page 44

Illustration	Name	See
	**Reference Array Y-Geometry X-Press**	Page 44
	**Bone Fixator “2-Pin”, Flip-Flop, X-Press**	Page 51
	**Bone Fixator “1-Pin”, X-Press, Size-S/M/L**	Page 48
	**1-Pin Wrench X-Press/ Spine Clamps**	Page 48

Plane Tools

Illustration	Name	See
	**Knee Plane Tool Kit** • **Knee Plane Tool - Tracking Array** • **Knee Plane Tool - Cutting Block Adapter** • **Knee Plane Tool - Bone Verification Plate - Spiked** • **Knee Plane Tool - Bone Verification Plate - Flat**	Page 60

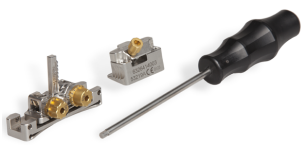
4 in 1 Cutting Block Template

Illustration	Name	See
	**4 in 1 Cutting Block Template**	Page 63

Femoral and Tibial Cutting Block Adapters - Knee

Illustration	Name	See
	**Femoral and Tibial Cutting Block Adapter “Universal”**	Page 66

Adjustable Cutting Blocks

Illustration	Name	See
	**Adjustable Cutting Block - Femur Kit** **• Adjustment Unit** **• Cutting Slot Femur 1.19/1.27/1.37 mm** **• Femoral Alignment Guide** **• Femoral Base Plate** **• Reference Y-Geometry** **• Screwdriver (3.5 mm)** **• Sterilization Tray**	Page 70
	**Adjustable Cutting Block - Basic Femur Kit** **• Adjustment Unit** **• Cutting Slot Femur 1.19/1.27/1.37 mm** **• Femoral Base Plate Small** **• Screwdriver (3.5 mm)**	Page 89

ClearLens Instruments

Illustration	Name	See
	**ClearLens Knee Plane Tool - Interface**	Page 98
	**ClearLens Pointer Handle - Knee**	Page 97
	**ClearLens Bone Fixator 2-pin**	Page 96
	**ClearLens Tracking Array Femur**	Page 96
	**ClearLens Tracking Array Tibia**	Page 96
	**ClearLens Tracking Array Pointer**	Page 97

Illustration	Name	See
	**ClearLens Tracking Array Plane Tool**	Page 98

3 GENERAL INSTRUMENTATION

3.1 Disposable Reflective Marker Spheres

3.1.1 Overview

General Information

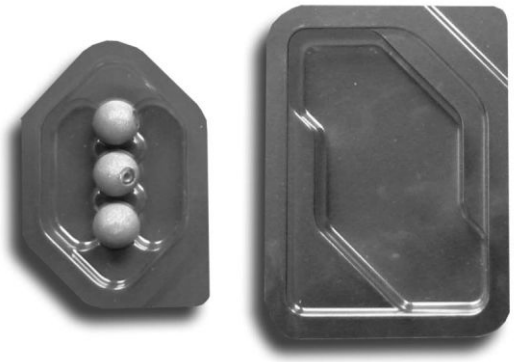


Figure 1

Product	Pieces	Article No.	Available from
Disposable Reflective Marker Spheres	90 (30 x 3)	41773	Brainlab and NDI
	270 (90 x 3)	41774	

Disposable Reflective Marker Spheres are attached to reference arrays and instruments, thus enabling the system to detect the position of the patient and instruments in the surgical field.

Brainlab navigation systems can only be used with the above marker spheres. The use of other marker spheres could affect navigation accuracy, posing a risk to the patient.

When to Attach Marker Spheres

Attach marker spheres to instruments and arrays before calibration or use in surgery.

Ensuring Sterility

Schanz screws are delivered un-sterile and need to be sterilized before use. They cannot be resterilized and must be disposed of after use.

Do not resterilize disposable reflective marker spheres as this reduces their accuracy, posing a risk to the patient. The reflective marker spheres are single use only.

3.1.2 Using Marker Spheres

Ensuring Navigation Accuracy

Navigation accuracy critically depends on the condition of the marker spheres used.

Verify prior to use that the reflective surface of all marker spheres is in good condition, and not peeling.

Disposable Reflective Marker Spheres are highly sensitive medical devices and should be handled with care.

Only use clean and dry marker spheres. Wet or soiled marker spheres must either be cleaned and dried before further use, or replaced.

Do not use defective or deformed marker spheres as this negatively affects navigation, potentially harming the patient.

Set up the OR prior to surgery to ensure the camera has an unobstructed view of all marker spheres on the instrument adapters and reference arrays. Do not mask or cover any marker spheres, otherwise navigation is not possible or may be inaccurate.

How to Attach Marker Spheres

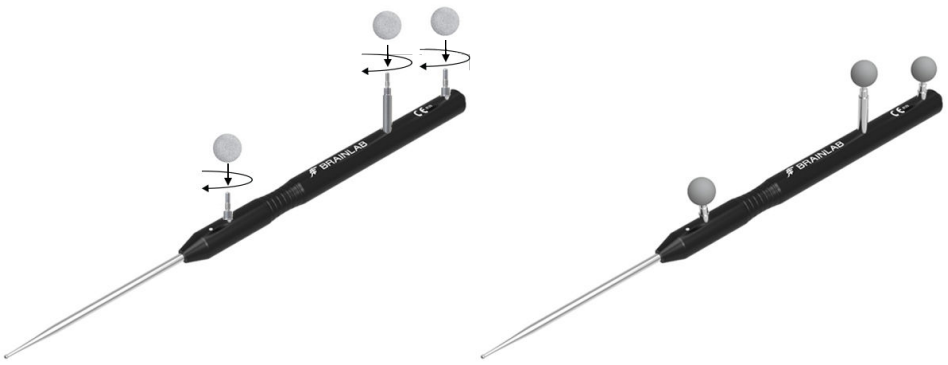


Figure 2

Step
Tightly screw marker sphere by hand onto each attachment pin of the instrument.

Ensuring Secure Attachment

Ensure that marker spheres can be screwed onto the pin until there is no gap between the sphere and the base of the pin. Do not use a marker sphere if it is not securely attached in this position.

If excessive force is needed to screw a marker sphere onto its pin, dispose of the marker sphere and use a new one.

If you use marker spheres on, or in the vicinity of, oscillating or vibrating instruments, check the marker spheres at regular intervals to ensure that they remain securely attached.

Cleaning Marker Spheres

Only use a soft cloth moistened with sterile water to clean the surface of soiled marker spheres. Ensure that the cleaned marker sphere is absolutely dry before use.

If you clean or replace a marker sphere on an instrument or reference array, verify navigation accuracy before continuing.

3.2 Disposable Schanz Screws

3.2.1 Overview

General Information

Figure 3

Product	Type	Article No.
Disposable Schanz Screws	3.2 mm x 100 mm (10 pieces)	54922
	(AO) 4 mm x 125 mm (10 pieces)	54908
	(AO) 5 mm x 175 mm (10 pieces)	54909
	3 mm / 100 mm (10 pieces)	54900
	4 mm / 130 mm (10 pieces)	54901
	5 mm / 150 mm (10 pieces)	54902
	5 mm / 200 mm (10 pieces)	54903

Disposable Schanz Screws are used to attach e.g., bone fixators or cutting blocks directly to the bone of the patient.

Only attach Schanz screws to bone structures, never to tissue or parts of the nervous system.

Only use Brainlab Schanz screws.

Sterility

Schanz screws are delivered un-sterile and need to be sterilized before use. They must be disposed of after use.

Do not resterilize or reuse disposable Schanz screws on another patient as this poses a risk to the patient.

3.3 Disposable Clip-on Remote Control (53153)

3.3.1 Overview

General Information

Figure 4

The **Disposable Clip-on Remote Control** enables active patient registration and software control in combination with existing Brainlab pointers.

The **Disposable Clip-on Remote Control** is an active, non-invasive, single-use device and is delivered sterile in sterile packaging.

Supported Pointers

The **Disposable Clip-on Remote Control** can be used with the following pointers:

- **Pointer Straight for Knee**
- **Pointer Angled for Hip and Knee**

3.3.2 Attaching the Disposable Clip-on Remote Control

Device Overview

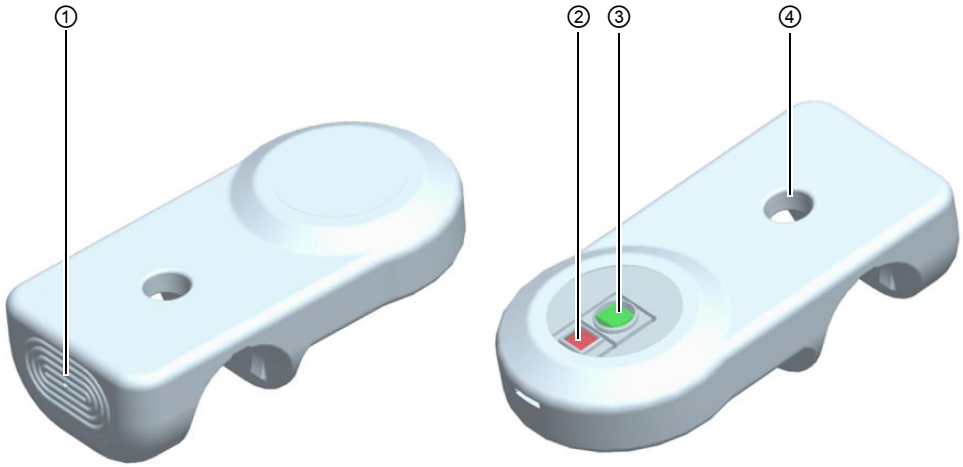


Figure 5

No.	Component	Function
①	Control button	Activates infrared LED
②	Infrared LED	Detected by camera, but not visible to naked eye
③	Green status LED	Indicates battery status and functionality
④	Center opening	Attachment interface to pointer

Before Use

Steps	
1.	Remove the **Disposable Clip-on Remote Control** from its sterile package.
2.	Perform a functionality check by pressing the control button ① and ensuring that: • The status LED ③ is on • The infrared LED ② is displayed as a colored flash on the camera display of the navigation screen

Verify prior to opening the sterile packaging that the expiration date has not lapsed and the package is not damaged. If the expiration date has lapsed or if damage is present, do not use the Disposable Clip-on Remote Control, and dispose of it immediately.

If battery leakage is visible inside the sterile packaging, do not open and dispose of the Disposable Clip-on Remote Control immediately.

Do not use if the packaging is broken.

Ensuring Sterility

The Disposable Clip-on Remote Control is delivered sterile. If any of the sterile components come into contact with an unsterile environment during unpacking or clinical use, dispose of the device immediately.

How to Attach the Disposable Clip-on Remote Control to the Pointer

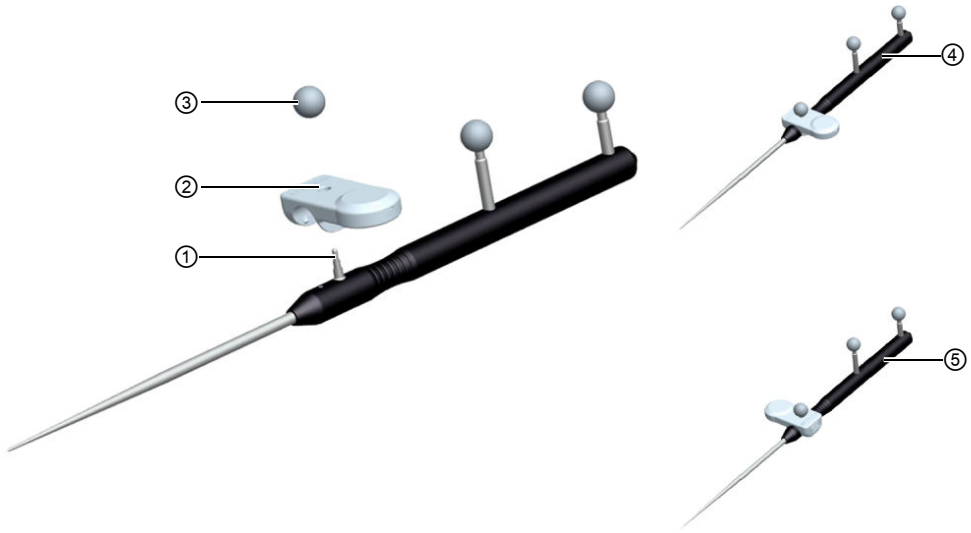


Figure 6

Steps	
1.	Attach the **Disposable Clip-on Remote Control** by placing the center opening ② over the indicated attachment pin ① on the pointer handle. *NOTE: Before attaching, consider the position depending on whether the user is ④ left-handed or right-handed ⑤.*
2.	Snap the **Disposable Clip-on Remote Control** fully onto the pointer handle.
3.	Attach marker spheres ③ to the pointer (see page 23).

*NOTE: When using the pointer, we recommend holding the pointer with the **Disposable Clip-on Remote Control** between the thumb and middle finger, pressing the control button with the index finger.*

Ensuring Correct Attachment

Plan the position of the Disposable Clip-on Remote Control accordingly for a left- or right-handed user, as well as the OR setup prior to surgery. The camera must have an unobstructed view of the reflective marker spheres and infrared LED.

Make sure to properly attach the Disposable Clip-on Remote Control to the attachment pin on the pointer, and to completely screw the Disposable Reflective Marker Sphere until there is no gap between the sphere and the base of the pin.

3.3.3 Using the Disposable Clip-on Remote Control

General Information

When you press the control button, the infrared LED is activated and can be tracked by the camera on the navigation system.

The infrared LED is displayed as a colored flash in the camera display on the navigation screen. Depending on the software application, the infrared LED signal can be used for various functions, for example, acquisition of surface points during registration.

NOTE: During use, make sure that the infrared LED is visible to the camera, and that it is not contaminated, e.g., with blood.

Verify the functionality of infrared LED prior to use by checking the status LED on the Disposable Clip-on Remote Control and the camera display on the navigation screen.

Further Information

Refer to your corresponding **Software User Guide** for more information on using the **Disposable Clip-on Remote Control** in combination with the software.

Correct Instrument Handling

During point acquisition, always make sure that the pointer tip has contact with the patient or bone when activating the Disposable Clip-on Remote Control.

Do not press on the housing of the Disposable Clip-on Remote Control where LEDs are located.

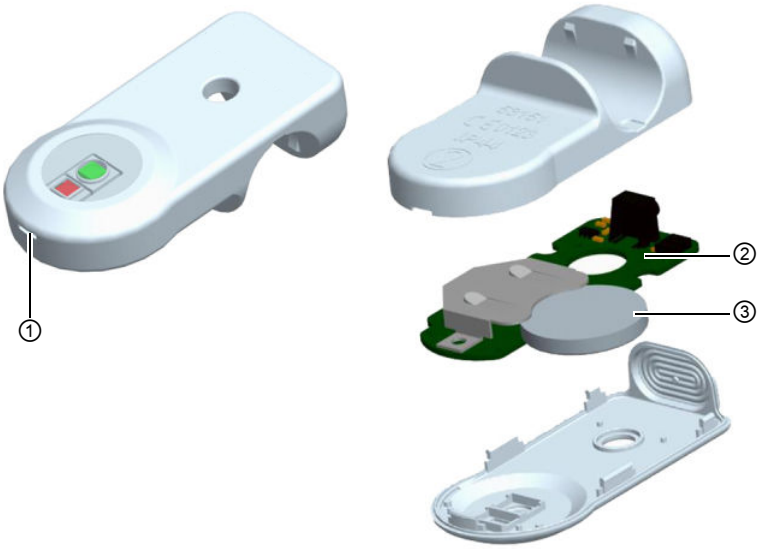
Safety Consideration

Do not look directly into infrared LED of Disposable Clip-on Remote Control at a close distance when the control button is activated.

3.3.4 After Use

Detaching and Disposing of the Disposable Clip-on Remote Control

The Disposable Clip-on Remote Control is a single-use device and cannot be sterilized. Remove it from the pointer and dispose of after use.

Steps	
1.	Following use, remove the **Disposable Clip-on Remote Control** from the pointer.
2.	Prior to disposal, clean all surfaces with a surface disinfectant.
3.	 If required, open the housing at the notch ① with a small sharp tool and remove the battery ③ and electronics ② for separate disposal.

Correct Handling During Disposal

Do not re-use or replace battery and do not autoclave the Disposable Clip-on Remote Control after use. This will destroy the device and might lead to severe damage of autoclaving equipment or injury to patient and user.

No modification of the device is allowed.

Do not completely immerse Disposable Clip-on Remote Control into any liquids.

The Disposable Clip-on Remote Control contains a primary lithium cell. Consider disinfecting device after use and disposing of it separately. For disposal of the contained electronics and primary lithium cell, check with your local environmental protection and waste agency for special disposal restrictions.

3.3.5 Technical Specifications

Dimensions and Weight

Dimension	Value
Height	17.3 mm
Length	53.9 mm
Width	27.0 mm
Weight	12 g

Electrical

Specification	Description
Power Supply	3 V primary lithium cell CR2032
Power Consumption	max. 36 mW
Current	12 mA, direct current (DC)
Electrical Safety	Compliance with IEC 60601-1

LEDs

Specification	Infrared LED	Status LED
Wavelength	870 nm	570 nm
Viewing Angle at 50% Intensity	120°	120°
Photobiological Safety	Compliance with IEC 62471	Compliance with IEC 62471

Housing

Specification	Description
IP Classification	IP44 according to IEC 60529 (protected against particles > 1 mm and against splashing liquids)
Materials	Polyamide 12

Environmental Specifications

	Storage Conditions	Operating Conditions
Temperature	0°C to 35°C (32°F to 95°F)	10°C to 40°C (50°F to 104°F)
Humidity	15% to 80% non-condensing	20% to 80% non condensing
Pressure	700 hPa to 1060 hPa	700 hPa to 1060 hPa
Disposal	According to local environmental waste regulations	

Sterility and Usability

Specification	Description
Sterility Status	Sterile
Method	Ethylene-oxide
Shelf Life	Three years
Usability	Single use

3.3.6 Electromagnetic Compatibility and Emissions

Electromagnetic Compatibility: Declaration

For medical electrical devices, special safety measures with respect to electromagnetic compatibility must be considered. Devices can only be installed and used in accordance with corresponding electromagnetic compatibility guidelines as described in this user guide.

Portable or mobile RF communication devices may influence the intended functionality of medical electrical equipment.

Electromagnetic Environment

The **Disposable Clip-on Remote Control** is intended for use in the electromagnetic environment specified in the tables provided in this section.

The customer or the user should assure that the **Disposable Clip-on Remote Control** is used in such an environment.

RF Emissions Interferences

The **Disposable Clip-on Remote Control** only uses RF energy for internal functions.

For this reason, the RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Declaration

Guidance and manufacturer’s declaration regarding electromagnetic emissions:

Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1 Class B	The **Disposable Clip-on Remote Control** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

3.3.7 Electromagnetic Immunity

Electromagnetic Environment

The **Disposable Clip-on Remote Control** is intended for use in the electromagnetic environment specified in the tables provided in this section.

The customer or the user should assure that the **Disposable Clip-on Remote Control** is used in such an environment.

Electromagnetic Immunity Declaration

The tables in the following sections provide the guidance and manufacturer's declaration regarding electromagnetic immunity.

IEC 61000-4-2, IEC 61000-4-8

Immunity Test	IEC 60601 Test Level and Compliance Level	Electromagnetic Environment- Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

IEC 61000-4-6,IEC 61000-4-3

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the **Disposable Clip-on Remote Control**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	3 Veff 150 kHz to 80 MHz	3 V	1.2 * √P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	1.2 * √P (80 MHz to 800 MHz)
			2.3 * √P (800 MHz to 2.5 GHz)
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with this symbol. 			

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
NOTE: At 80 MHz and 800 MHz, the higher frequency range applies. *NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular /cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **Disposable Clip-on Remote Control** is used exceeds the applicable RF compliance level above, the **Disposable Clip-on Remote Control** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocation the **Disposable Clip-on Remote Control**. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.			

3.3.8 RF Communications Equipment

Effects on the Device

Portable and mobile RF communications equipment can affect the **Disposable Clip-on Remote Control**.

Electromagnetic Environment

The **Disposable Clip-on Remote Control** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.

The customer or the user of the **Disposable Clip-on Remote Control** can help prevent electromagnetic interference.

This is accomplished by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Disposable Clip-on Remote Control** as recommended below, according to the maximum output power of the communications equipment.

Separation Distances

Separation distances between portable and mobile RF communications equipment and the **Disposable Clip-on Remote Control**:

Rated Maximum Output Power of Transmitter	**Separation Distance According to Frequency of Transmitter m**		
W	150 kHz to 80 MHz 1.2 * √P	80 MHz to 800 MHz 1.2 * √P	800 MHz to 2.5 GHz 2.3 * √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12.00	12.00	23.00
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. *NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.* *NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*			

3.4 Footswitch (USB) (18460)

3.4.1 Overview

General Information

Figure 7

The **Footswitch (USB)** enables patient registration to be performed with reduced touchscreen interaction.

The **Footswitch (USB)** uses the USB connection to the navigation system, e.g., **Curve** or **Kick**.

NOTE: The footswitch activates automatically when plugged-in.

Footswitch Pedal Functions

Pedal	Function
Blue	Register landmarks or selects element marked in blue.
Yellow	Selects element marked in yellow.
Black	Cycles through controllable elements in navigation and planning.

How to Use a Footswitch

Refer to your corresponding **Software User Guide** for more information on using the **Footswitch (USB)** in combination with the software.

4 POINTERS

4.1 Using Pointers

4.1.1 Handling Pointers

Pointer Functionality

Pointers are used:

- To perform pointer-based patient registration
- To verify that registration accuracy is maintained

Detailed instructions for use of pointers is provided in your **Software User Guide**.

NOTE: Pointers are precalibrated. They can be used without any further calibration.

Correct Handling of Pointers

The marker spheres of the active pointer must be visible to the camera at all times during registration and navigation.

If a pointer is indicated by the software for a registration step, use that pointer.

4.1.2 Maintaining Pointer Accuracy

Storage

Each pointer comes with a gauge, that serves to prevent pointer damage and ensure maximum accuracy.

Always sterilize pointers and store them in their designated inserts in the pointer gauge.

Checking Pointer Accuracy Using the Pointer Gauge

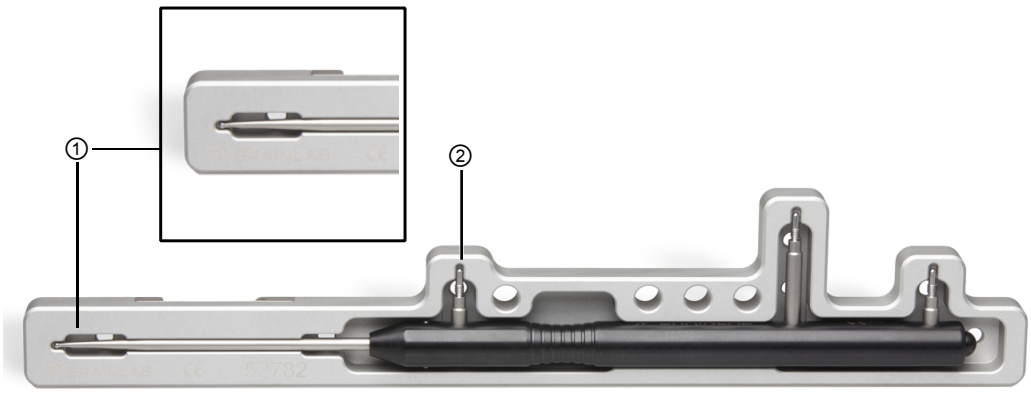


Figure 8

If a pointer is undamaged, its tip ① aligns with the corresponding counterpart of the gauge ②.

Check pointer accuracy before each use. Ensure that the pointer tip aligns with the counterpart on the pointer gauge.

Checking Accuracy Using the Pointer Gauge

The underside of the pointer gauge contains a tool used for checking the accuracy of e.g., the **Knee Plane Tool - Cutting Block Adapter** (see page 61).

4.2 Types of Pointers

Overview

The tips of the pointers are rounded off as a partial sphere, preventing the pointer tips from catching on bone or soft tissue and allowing smoother movement along the bone surface during registration and planning procedures.

NOTE: For easier identification, each pointer has a different color indicator on the end of the handle.

*NOTE: The **Pointer Straight for Knee** and **Pointer Angled for Hip and Knee** all share the same instrument geometry.*

Pointer Straight for Knee (53109)

The **Pointer Straight for Knee** is used to acquire landmarks for registration, for planning, or to verify accuracy. It has a black color indicator.

Pointer Angled for Hip and Knee (53101)

Figure 9

The **Pointer Angled for Hip and Knee** facilitates point acquisition in deeper anatomical areas. It has a downward-curved tip, to enable camera tracking when acquiring registration landmarks at difficult angles. It has a black color indicator.

5 REFERENCE ARRAYS, X-PRESS

5.1 Instrument Overview

5.1.1 Introduction

General Information

The **Reference Arrays, X-Press** are reference array attachment systems that have:

- An adjustment joint to orient the reference array optimally for the camera field of view.
- A quick fastener mechanism to remove the **Reference Array**, **X-Press** during surgery whenever it is not actively needed for navigation, and replace it in the same orientation so that no registration information is lost.

A complete functional **Reference Array, X-Press** comprises the following:

- A reference array (Y or T geometry) that enables tracking of the patient's bone
- A bone fixator (1-pin or 2-pin) that provides the interface between the reference array and the bone
- One or two Schanz screws

Assembled Reference Arrays, X-Press

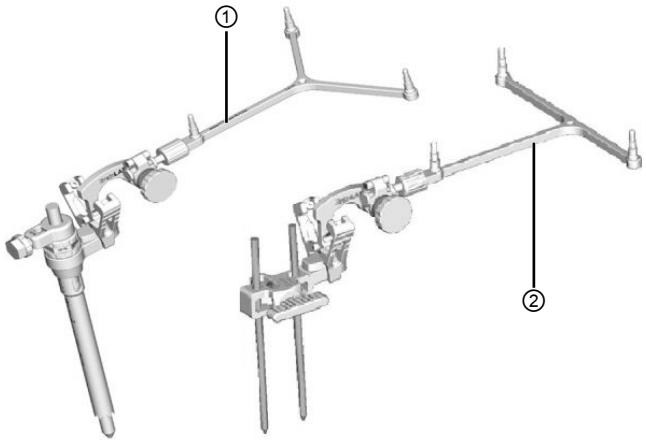


Figure 10

No.	Reference Array X-Press
①	Y geometry, attached to a 1-pin bone fixator
②	T geometry, attached to a 2-pin bone fixator

*NOTE: Either reference array can be used in combination with either the **Bone Fixator "1-Pin", X-Press** or the **Bone Fixator "2-Pin", Flip-Flop, X-Press**.*

5.1.2 Reference Array, X-Press Kits

About Kits

Reference Array, X-Press components can be ordered separately or as part of an application-specific kit.

The exact components of an **Reference Array, X-Press** kit depend on the intended surgical procedure.

Reference Array Kit, X-Press Components

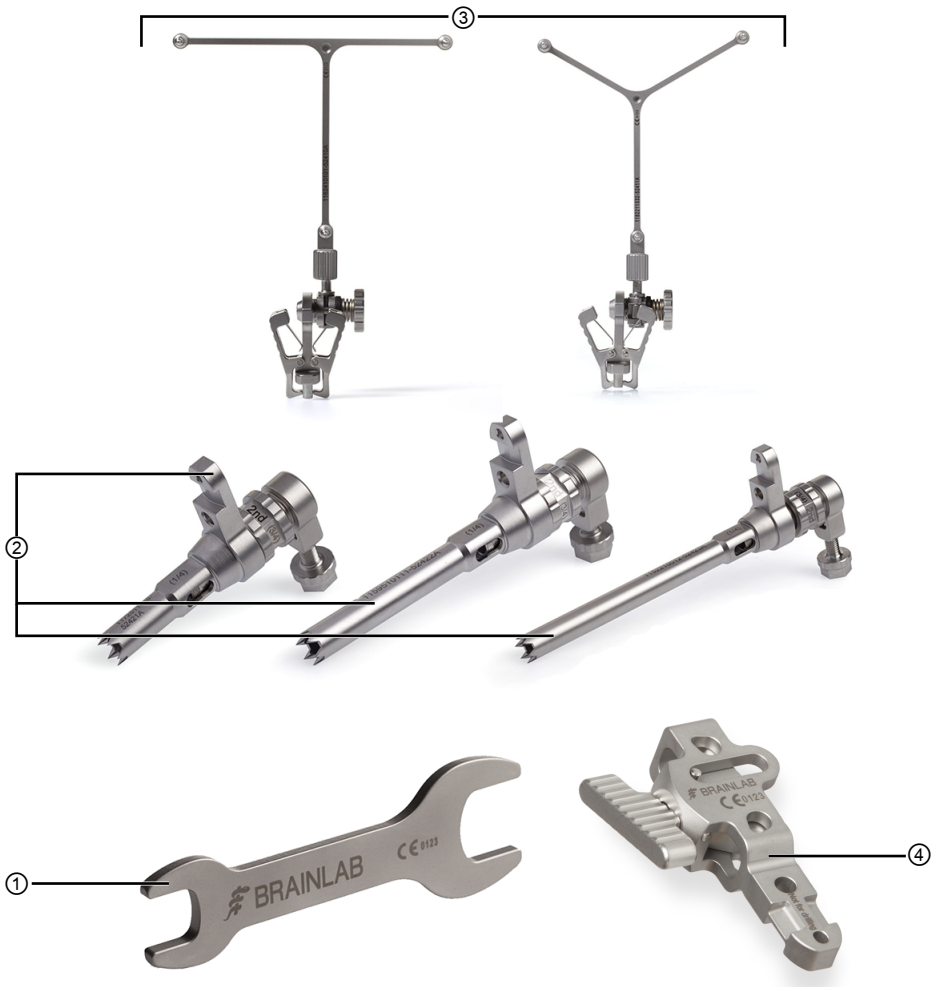


Figure 11

No.	Component
①	**“1-Pin” Wrench, X-Press** (52424)
②	**Bone Fixator “1-Pin”, X-Press**: S (52421), M (52422), and L (52423) (see page 45)
③	**Reference Array T Geometry** (52410) and **Reference Array Y Geometry** (52411) (see page 54)
④	**Bone Fixator “2-Pin”, Flip-Flop, X-Press** (52429) (see page 51)

5.2 Bone Fixators, X-Press

5.2.1 Overview

General Information

Bone fixators provide the interface between X-Press reference arrays and bone. They are affixed to bone via Schanz screws.

The Bone Fixator “1-Pin” or “2-Pin”, Flip-Flop, X-Press must be used with an X-Press reference array.

Place bone fixators so that the alignment of the reference array will not hinder the use of any other instrumentation, such as attachment of a cutting block and its adapter.

Available Bone Fixators

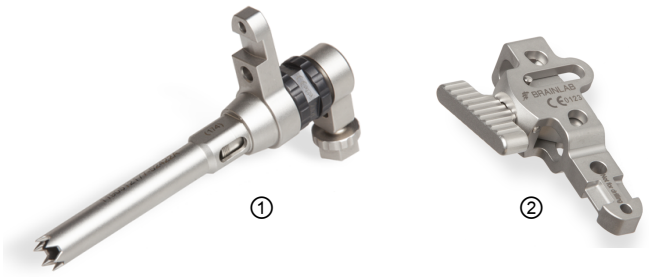


Figure 12

No.	Bone Fixator
①	**“1-Pin”, X-Press**
②	**“2-Pin”, Flip-Flop, X-Press**

5.2.2 Using Schanz Screws with Bone Fixators

Before Using

Read the section referring to the use of fixation pins on page 16.

Rotation of Bone Fixators on Schanz Screws

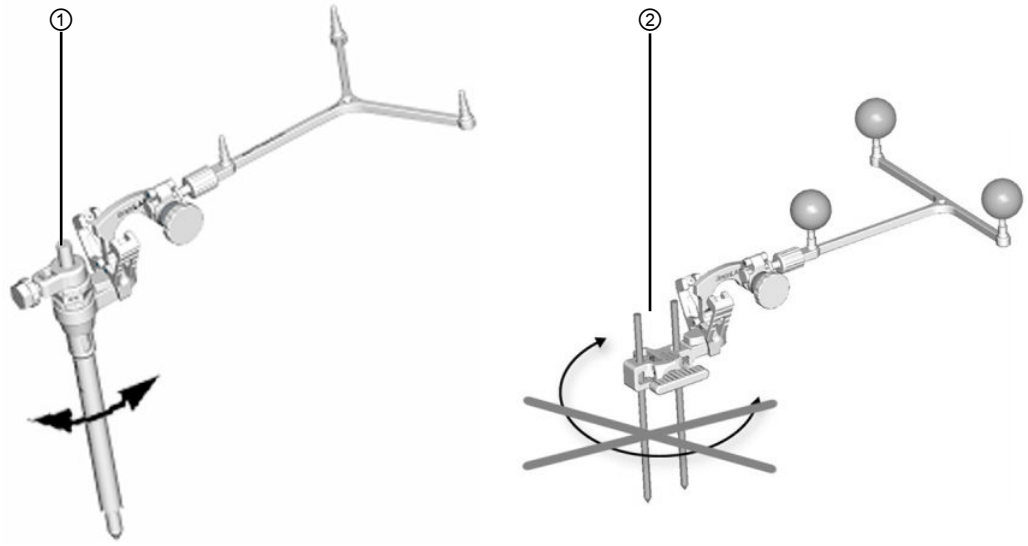


Figure 13

No.	Bone Fixator	Rotation possible?
①	**“1-Pin”, X-Press**	Yes, before fixation
②	**“2-Pin”, Flip-Flop, X-Press**	No

Only attach Schanz screws to bone structures, never to tissue or parts of the nervous system.

The Bone Fixator “2-Pin”, Flip-Flop, X-Press does not support rotation around the Schanz screw. Therefore, consider the orientation of the bone fixator and reference array prior to inserting the Schanz screws into the bone, to ensure marker spheres are visible to the camera.

Because the Bone Fixator “1-Pin”, X-Press can be rotated around the Schanz screw axis, place the spike tube directly on the surface of the bone without penetrating soft tissue. Consider this when making the incision, prior to Schanz screw fixation.

Required Schanz Screw Size

Bone Fixator	Required Schanz screw diameter and Article Number
“1-Pin”, X-Press	5 mm (54902 / 54903 / 54909)
“2-Pin”, Flip-Flop, X-Press	• 3 mm (54900) • 3.2 mm (54922) - **Pin driver Adapter for AO coupling** (54932) • 4 mm (54901 / 54908) A combination using these screw types is also possible.

Only use bone fixators with threaded Schanz screws with the diameters specified above. The length of the thread must allow bicortical fixation.

Unicortical fixation, or using Schanz screws thinner than specified, may result in unstable attachment or cause the Schanz screw to be inadvertently pulled from the bone when the bone fixator is tightened.

Do not use Schanz screws longer or thinner than specified, as they may bend or warp, leading to inaccurate navigation and potential injury to the patient.

Avoid multiple drilling attempts when placing Schanz screws, this weakens the bone and may increase the risk of post-operative stress fracture. Stop drilling the Schanz screw when the opposite cortical bone is reached.

5.2.3 Using the Bone Fixator “1-Pin”, X-Press

Components

The **Bone Fixator “1-Pin”, X-Press** comes in three sizes: S (52421), M (52422), and L (52423). Make sure that you select the appropriate size for the procedure.

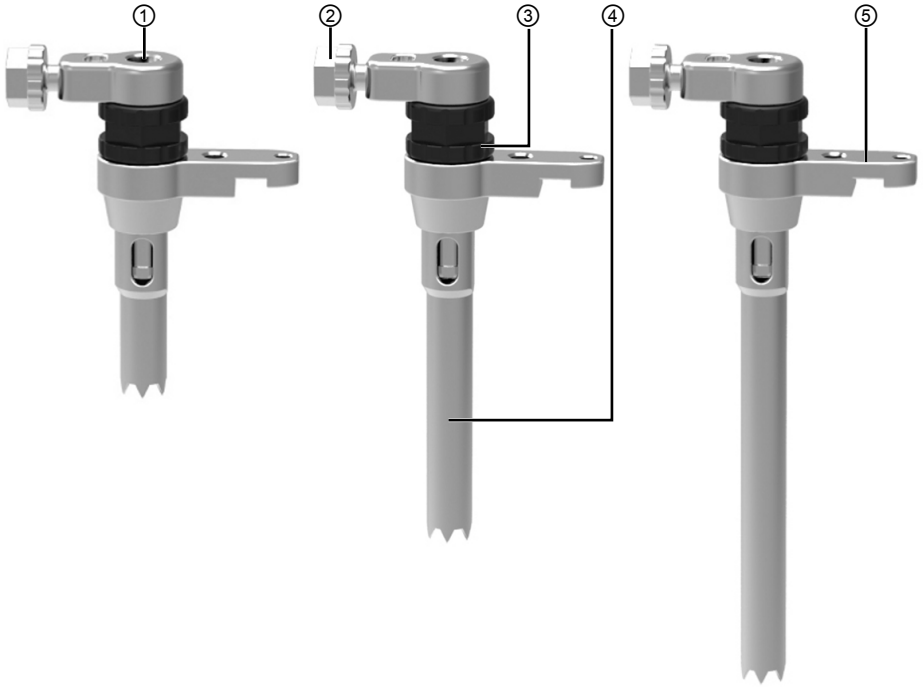


Figure 14

No.	Component
①	Inlay
②	Fixation screw *NOTE: The fixation screw is available as a spare part, and should be replaced if it does not operate smoothly.*
③	Traction nut
④	Spike tube
⑤	Interface plate

How to Assemble the Bone Fixator

Bone fixators should only be disassembled for cleaning. Reassemble them for sterilization and store them assembled in their sterilization tray.

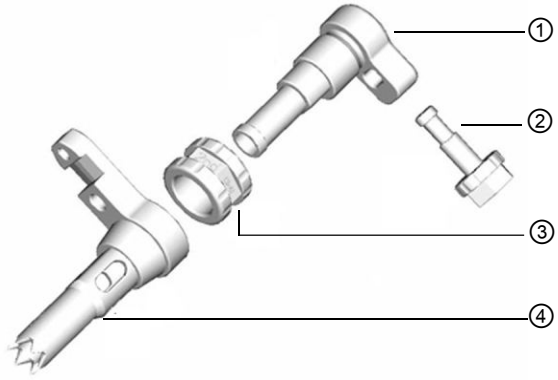


Figure 15

Steps	
1.	Screw the fixation screw ② into the inlay ①.
2.	Screw the traction nut ③ onto the inlay ①.
3.	Screw ①,② and ③ into the spike tube ④.

NOTE: Each part is engraved with a part number for easy identification.

How to Attach the Bone Fixator

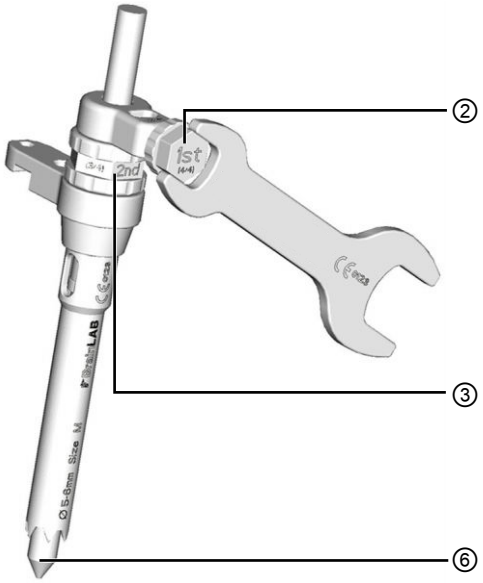


Figure 16

Steps	
1.	Slide assembled bone fixator over Schanz screw ⑥.

Steps	
2.	Attach reference array to the bone fixator. Ensure that there is no space between traction nut ③ and the inlay. Ensure that the necessary reference array orientation is possible from the bone fixator's current position.
3.	Secure bone fixator by tightening fixation screw ② with the wrench.
4.	Tighten traction nut ③ with the wrench.

NOTE: Always use the wrench provided for fastening all screw connections.

Safe Attachment

If you make a small incision in the bone for attachment of the fixator, place the Schanz screw into the incision first. You can then slide the bone fixator over the Schanz screw down onto the surface of the bone. This prevents the spike tube from causing unnecessary abrasion of surrounding soft tissue.

Securing 1-Pin Bone Fixator

Before tightening the Bone Fixator "1-Pin", X-Press to the Schanz screw, attach the Reference Array, X-Press and adjust it to ensure the camera has full view of the reference array.

Never unscrew the Schanz screw if the Bone Fixator "1-Pin", X-Press is still attached, as this will cause extreme abrasion of the corticalis. Only consider doing so if the device cannot be removed using the standard procedure.

Ensure that all screw connections are securely tightened before beginning patient registration. Any movement of the bone fixator during or after patient registration will result in inaccurate navigation.

If the Bone Fixator "1-Pin", X-Press, Size S cannot be tightly attached on the bone through the main incision, make a second incision in an area with less tissue covering the bone. Tightly affixing the Bone Fixator to the treated bone is imperative to achieve high navigation accuracy.

5.2.4 Bone Fixator “2-Pin”, Flip-Flop, X-Press (52429)

General Information

The **Bone Fixator “2-Pin”, Flip-Flop, X-Press** has:

- A wedge-shaped clamping device that allows you to secure it tightly to two Schanz screws inserted in the bone
- A double-sided interface plate for attachment of an X-Press Reference Array

Components

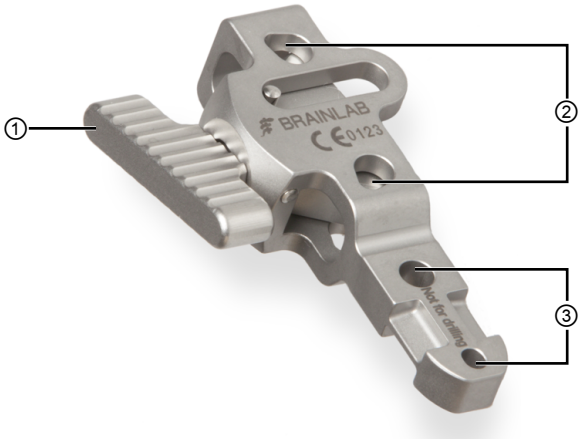


Figure 17

No.	Component
①	Fix knob
②	Holes for attachment to Schanz screws
③	Interface plate

Schanz Screw Placement

Do not use the interface plate ③ on the bone fixator as a template for Schanz screw placement. Otherwise wear will lead to inaccurate navigation, resulting in patient injury.

Make sure to place the Schanz screws the correct distance apart when using the Bone Fixator “2-Pin”, Flip-Flop, X-Press. You can use the holes of the bone fixator to estimate the correct placement. If the Schanz screws are too close together or too far apart, this can cause the screws to stretch during attachment of the fixator, irreparably damaging them.

5.2.5 Attaching the Bone Fixator “2-Pin”, Flip-Flop, X-Press

How to Attach the Bone Fixator

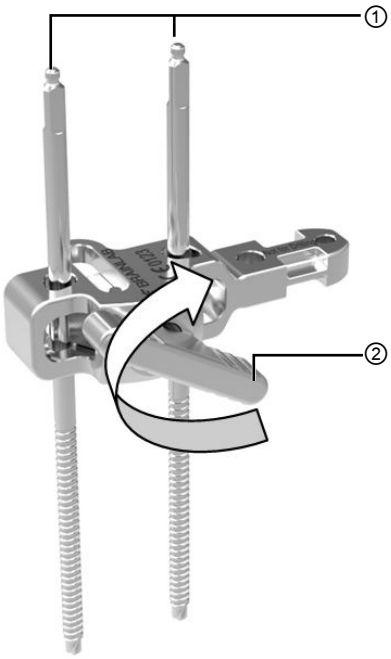


Figure 18

Steps	
1.	Slide the assembled fixator over the Schanz screws ①. *NOTE: If necessary, the fixator can be flipped over, as the reference interface can be used on both sides.*
2.	Verify that the necessary reference array orientation is possible with the bone fixator in its current position.
3.	Tighten the fix knob ② by hand.

The Bone Fixator “2-Pin”, Flip-Flop, X-Press can be sufficiently tightened by hand.

To avoid damaging the Schanz screws, make sure that the fix knob is open when drilling the Schanz screws directly through the respective holes of the Bone Fixator “2-Pin”, Flip-Flop, X-Press.

Safe Attachment

The Bone Fixator “2-Pin”, Flip-Flop, X-Press should be attached to Schanz screws affixed to bony structures covered with thin tissue. Use only Schanz screws from Brainlab. If the screws are too short, the overlying tissue may be too thick to allow stable fixation.

Do not attach the Bone Fixator “2-Pin”, Flip-Flop, X-Press to bone areas covered by strong muscle. Avoid piercing muscle tissue when attaching the bone fixator. Extensive muscle movement may cause the pin to bend. This can irreparably damage the Schanz screw and reduce navigation accuracy.

Securing 2-Pin Bone Fixator

Attach Bone Fixator “2-Pin”, Flip-Flop, X-Press as close as possible to the bone or tissue surface for optimum stability.

Tightly fasten fix knob before patient registration.

If the Bone Fixator “1-Pin”, X-Press, Size S cannot be tightly attached on the bone through the main incision, make a second incision in an area with less tissue covering the bone. Tightly affixing the Bone Fixator to the treated bone is imperative to achieve high navigation accuracy.

When using Schanz screws with a special quick coupling interface e.g., AO quick coupling, do not use the drill template as the screw end is bigger than the drill template holes, making it impossible to remove the drill template after drilling.

To achieve a stable connection and to avoid damage to the bone fixator, only attach it to parts of Schanz screws that have a circular cross section.

Safe Removal

If the bone fixator cannot be lifted off of the Schanz screws for any reason, the screws can be cut below the fixator and unscrewed separately.

5.3 Reference Arrays, X-Press

5.3.1 Reference Array, X-Press Overview

Assembled Reference Arrays

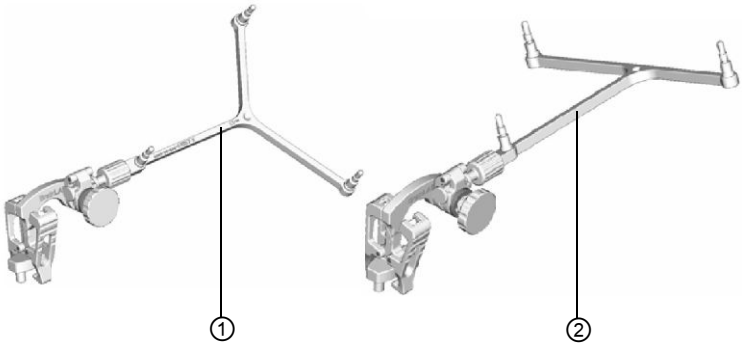


Figure 19

No.	Reference Array
①	Y geometry (52411)
②	T geometry (52410)

How to Assemble the Reference Array, X-Press

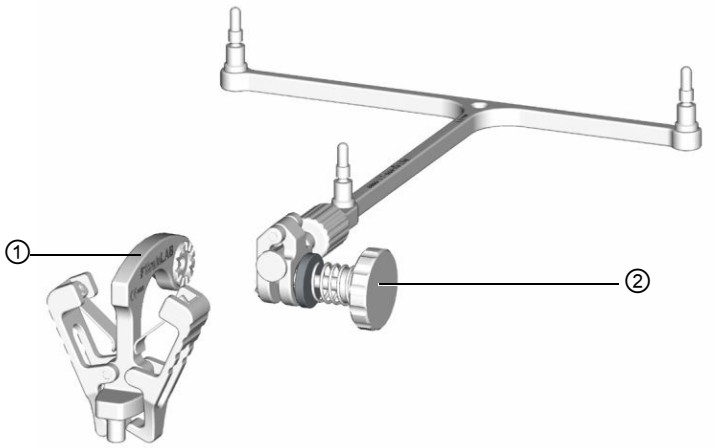


Figure 20

Step
Screw clamp screw ② into quick fastener ①.

5.3.2 Attaching and Detaching the Reference Array

How to Attach a Reference Array to a Bone Fixator

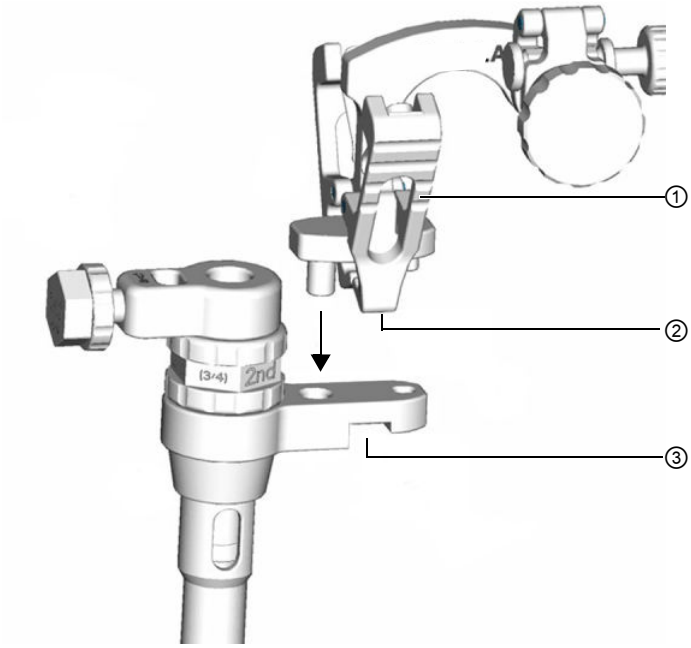


Figure 21

Steps	
1.	Pinch the sides of quick fastener clamp ① to open clamp jaws.
2.	Insert stem pins of the quick fastener into corresponding holes on the interface plate of the bone fixator (arrow).
3.	Release quick fastener clamp and ensure that fixation hooks ② are seated securely in corresponding notches ③ on the interface plate.

If you cannot insert the pins of the array completely into the interface plate, contact Brainlab immediately for advice on how to proceed. Using damaged equipment could severely injure the patient.

After Attachment

Do not apply any force or torque to the bone fixators or reference arrays once they have been attached to the patient.

Detaching the Reference Array

To detach the array, pinch open the clamp jaws and lift the array straight up out of the interface plate.

When removing the reference array during surgery, only use the quick fastener. Do not loosen the screw nut on the bone fixator.

Reference arrays can be removed during sawing, minimizing movement risk.

Handle the Reference Array, X-Press with extreme care if it is detached for any reason during surgery. Damage to the marker sphere pins could lead to inaccurate navigation and patient injury.

Applying excess force on the screw (e.g., using pliers) could cause it to break.

5.3.3 Preparation for Registration

Optimizing Array Visibility

The system recognizes a reference array by the geometrical arrangement of its marker spheres. The angle for best detection of the array is perpendicular to the plane through the centers of all marker spheres in the array. Take this into account when attaching a reference array to the patient or adjusting its angle to the camera for use.

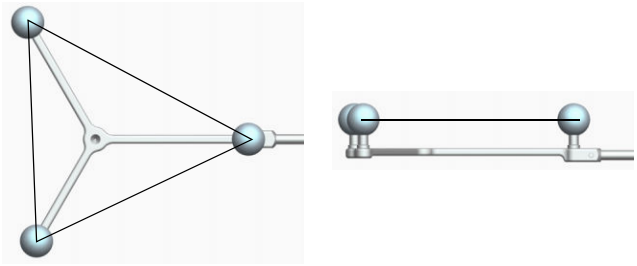


Figure 22

The camera's ability to recognize an array is highest when the plane through the marker spheres on the array is perpendicular to the viewing direction of the camera.

How to Adjust Array Orientation

Use the adjustment joint of the **Reference Array, X-Press** to orient array so that the camera has the best view of the array for tracking purposes.

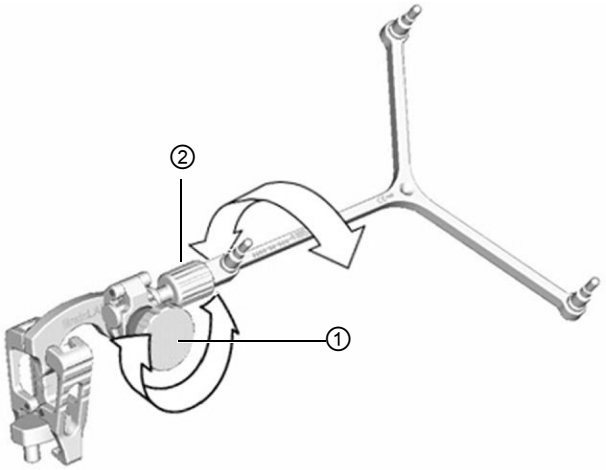


Figure 23

Steps	
1.	Loosen quick fastener clamp screw ①.
2.	Adjust reference array pitch by lifting or lowering array around quick fastener clamp joint.
3.	Adjust reference array side-to-side, tilt by rotating it around its shaft.
4.	Tighten quick fastener clamp screw by hand. Make sure that the joint teeth are positioned within the grooves.

The adjustable joint can be sufficiently secured by tightening the locking screw by hand. Do not use tools, as this may damage the components.

Avoiding Teeth-on-Teeth Alignment

To ensure a secure connection, make sure that the teeth on the adjustable joints of the reference array are in the corresponding grooves, not on other teeth.

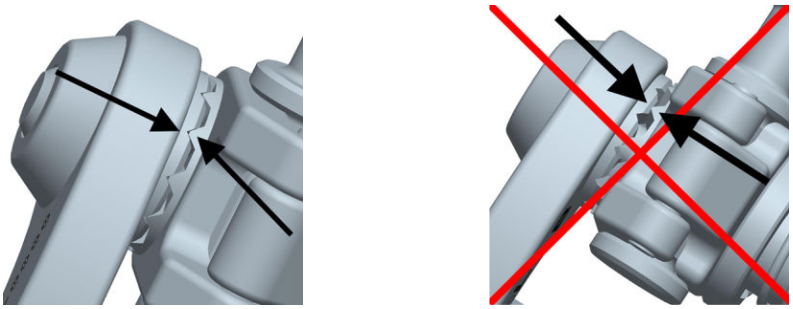


Figure 24

Avoiding Unstable Joint Alignment

An audible click indicates that the second joint is in the correct stable position ①.

Do not position or tighten the second joint in an unstable position ②.

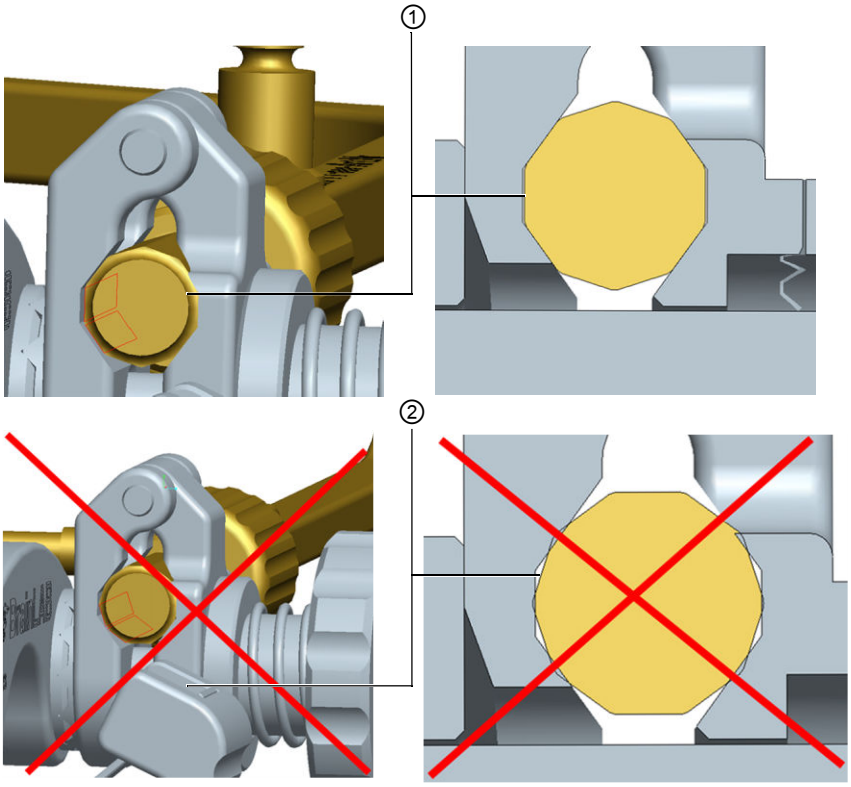


Figure 25

Before Registration

Attach marker spheres to the reference array. For further information, see page 24.

Check regularly that marker spheres remain tightly attached to reference array.

Tighten screws of the adjustable joints before patient registration. Movement of the Reference Array, X-Press during or after patient registration will result in inaccurate navigation.

Before registration, check that the range of motion is sufficient and the bone fixator does not encounter any heavy tissue. If tissue collision is likely to occur, enlarge the incision to reduce tension on the bone fixator. Failure to do so may bend or loosen the bone fixator, causing navigation to be inaccurate.

5.4 Knee Plane Tool Kit

5.4.1 Overview

General Information

The **Knee Plane Tool Kit** is used for navigating distal and femoral cutting blocks as well as verifying resected bone surfaces.

It can be used with cutting blocks with a slot thickness of 1.0 - 1.8 mm with a minimum width of 22 mm.

The **Knee Plane Tool Kit** contains the following:

Component	Function
Knee Plane Tool - Bone Verification Plate - Small	Registering the post cut alignment during the pinless workflow.
Knee Plane Tool - Bone Verification Plate	
Knee Plane Tool - Cutting Block Adapter	Registering points before the resection is made during the pinless workflow.
Knee Plane Tool - Tracking Array	Camera tracking during verification workflow pages.

Component Overview

Figure 26

No.	Component	Article No.
①	**Knee Plane Tool - Bone Verification Plate - Small**	53204
②	**Knee Plane Tool - Bone Verification Plate**	53203
③	**Knee Plane Tool - Cutting Block Adapter**	53202
④	**Knee Plane Tool - Tracking Array**	53201

How to Use the Knee Plane Tool

The **Tracking Array** ④ can be used for registration and verification while using the pinless knee workflows. You can attach the **Tracking Array** to the **Cutting Block Adapter** ③ (in several camera orientations) and to the **Bone Verification Plate** ① or ② (in left and right orientation).

Steps	
1.	Press on the lever on the **Tracking Array** ④ to attach the **Cutting Block Adapter** ③ or the **Bone Verification Plate** ① or ②, then release the lever.
2.	Ensure that the attached adapter/verification plate is in an engaged position.
3.	Always ensure the marker spheres remain visible to the camera.

Verifying Accuracy

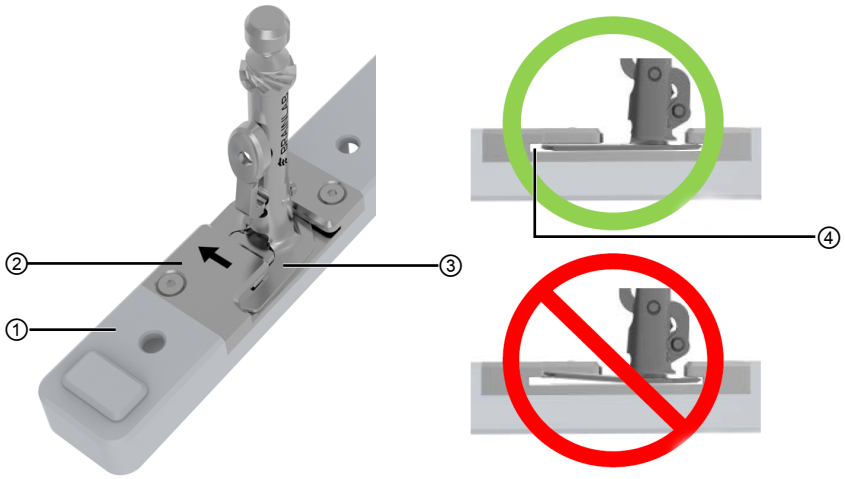


Figure 27

Pointer Straight for Knee gauge ① provides a tool on its underside ②, to check the accuracy of the **Knee Plane Tool - Cutting Block Adapter** ③. The **Knee Plane Tool - Cutting Block Adapter** is considered accurate if it moves smoothly through the profile ④.

Precautions

Ensure that the Cutting Block Adapter fits snugly into the cutting block. Ensure the base plate is not damaged, bent, or worn. If any of the above is apparent, contact Brainlab immediately for advice on how to proceed. The use of damaged equipment could result in severe patient injury.

Do not use the attached Cutting Block Adapter to manipulate the position or orientation of the cutting block, as this could cause the plate to bend and therefore might cause inaccurate navigation. Never hold onto the Cutting Block Adapter with the cutting block still attached.

Rotation of the Knee Plane Tool in the Cutting Block Adapter after registration can cause inaccuracies.

6 CUTTING BLOCKS, ADAPTERS AND TEMPLATES

6.1 4 in 1 Cutting Block Templates

6.1.1 Overview

Precautions

Be aware that the cutting slot has to be identical with the slot used for inserting the Cutting Block Adapter for navigation (if the cutting block has more than one slot for the intended cut).

Ensure that the base plate of the Cutting Block Adapter is completely inserted into the cutting slot prior to attaching the cutting block. During the pinning of the cutting block to the bone, the Cutting Block Adapter might move out of the slot. Regularly check and ensure that the Cutting Block Adapter is still completely inserted to avoid an unstable attachment and inaccurate navigation.

Check the stability of the Cutting Block Adapter ensuring it is correctly inserted into cutting blocks with large openings.

During verification make sure you use the specified Cutting Block Adapter and prevent changing/influencing its position after starting registration as this leads to inaccurate navigation results. A special adapter can be used to mount the Cutting Block Adapter array onto the resected bone.

Use

Figure 28

The **4 in 1 Cutting Block Template** is used to position the 4 in 1 cutting block after the distal resection has been performed. It comes in different varieties to match the implant product line.

Adaptation to Product Lines

A **4 in 1 Cutting Block Template** is available for the product lines below and labeled accordingly:

Implant Manufacturer	Article Number	Implant Product Line
DePuy	41867	PFC® *NOTE: The **4 in 1 Cutting Block Template "DePuy PFC"** is also known as the **4 in 1 Cutting Block Template "DePuy PFC Specialist 2"**.*

Correct Template Selection

Check the label of the 4 in 1 Cutting Block Template before use in order to ensure that the correct product has been selected.

Only use cutting blocks specified by Brainlab. Otherwise, undesired shifting can occur as the result of a loose fit.

If there is significant space between the drill and the burr hole when using a new drill template for the selected product line, the Cutting Block Template must be replaced by a new one.

How to Use the 4 in 1 Cutting Block Template

Steps	
1.	Place the **4 in 1 Cutting Block Template** flush against the resected area and match it to the pre-planned position using the navigation screen.
2.	Once the correct position has been found, drill the necessary holes. *NOTE: After drilling the first hole, leave a pin/drill in place while drilling the second hole.*
3.	Remove the template.
4.	Position the 4 in 1 cutting block.

Correct Instrument Positioning

Any movement of the 4 in 1 Cutting Block Template during drilling will result in incorrect placement, which is hazardous to the patient.

During drilling, check that the position of the Cutting Block Template is correct by comparing with the planned position from the navigation system.

6.1.2 Femoral and Tibial Cutting Block Adapter “Universal” (41866-77)

Overview

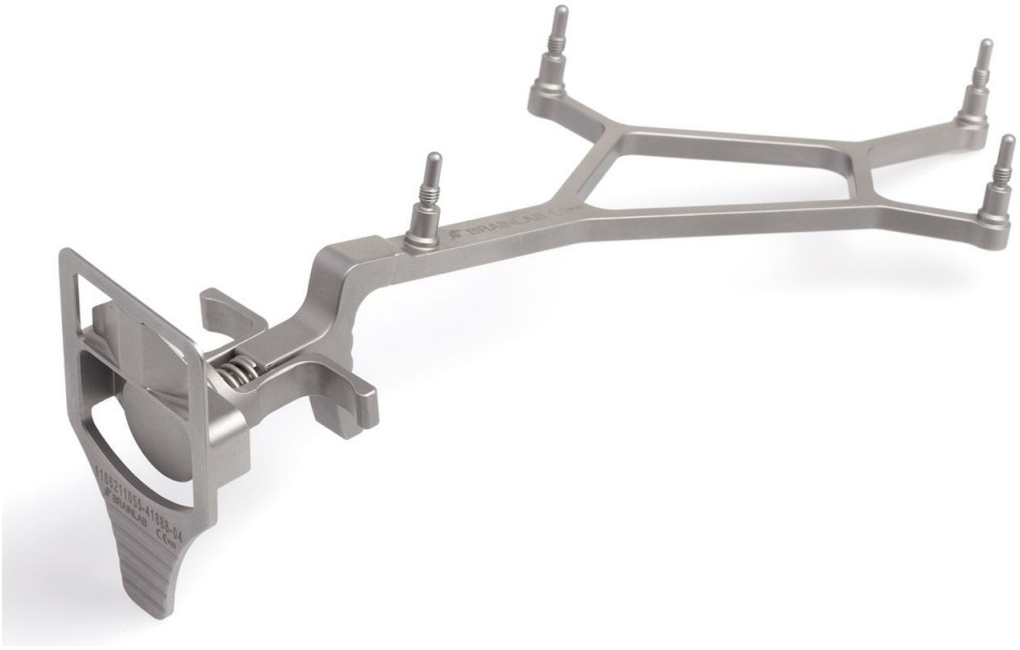


Figure 29

The **Femoral and Tibial Cutting Block Adapter “Universal”** allows the system to track the cutting block during navigation of the cutting block to the planned resection plane.

It is self-adapting to cutting blocks with a slot thickness of 1.0 - 1.8 mm.

Do not attach the Femoral and Tibial Cutting Block Adapter “Universal” to cutting blocks with a slot thickness larger than 1.8 mm as this will result in unstable attachment and lead to inaccurate navigation.

Some instrument sets may have cutting blocks with slots too narrow to enable a stable attachment of the Femoral and Tibial Cutting Block Adapter “Universal”. Prior to surgery, check that the Femoral and Tibial Cutting Block Adapter “Universal” can be completely inserted into the slot of the cutting blocks to be used.

How to Assemble the Adapter

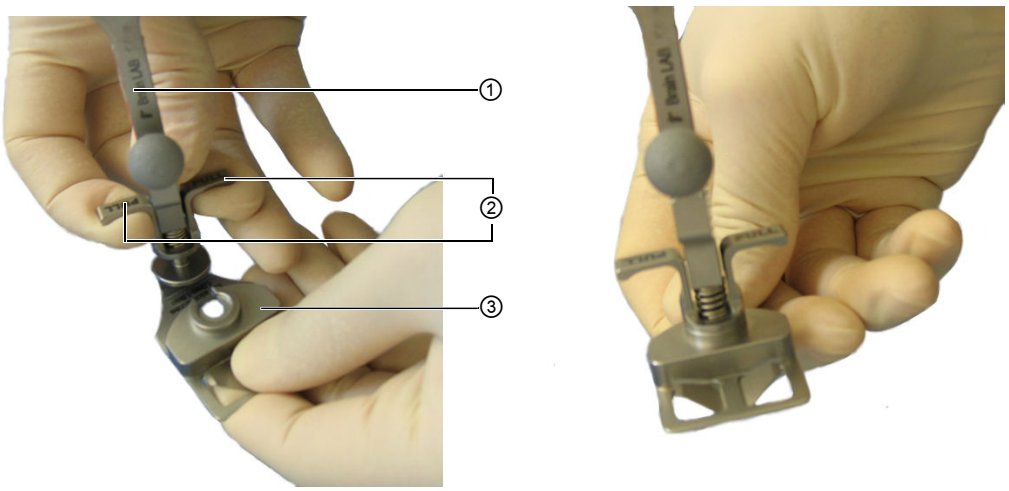


Figure 30

Steps	
1.	Pull up the handles ② on the tracking array ①.
2.	While continuing to hold the handles, insert the array into the base plate ③.

How to Disassemble the Adapter

Steps	
1.	Pull up the handles ② on the tracking array.
2.	While holding the handles up, remove the tracking array from the base plate ③.

How to Attach the Cutting Block Adapter to the Cutting Block

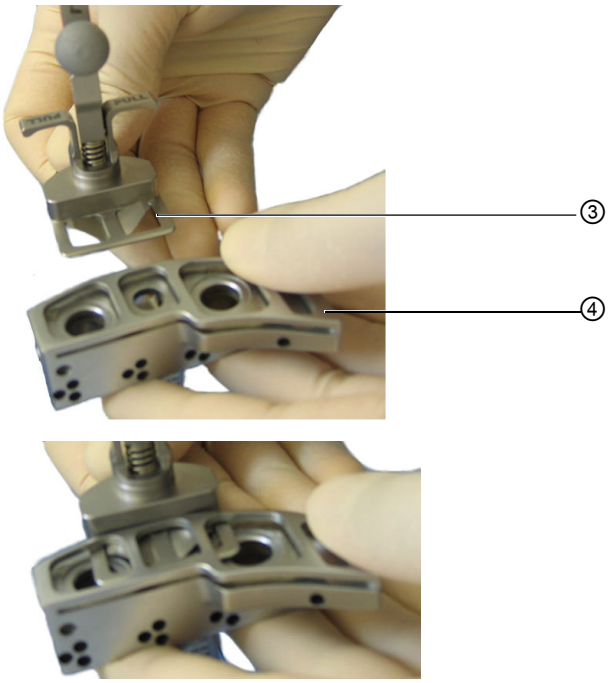


Figure 31

Step
Insert the base plate ③ fully into the slot of the cutting block ④.

Make sure that the base plate of the Femoral and Tibial Cutting Block Adapter “Universal” is completely inserted into the cutting slot prior to placing the cutting block on the bone.

Cutting Block Stability During Positioning and Drilling

To ensure stability during positioning and drilling, hold the device as shown below. Do not hold the assembled device by the tracking array.

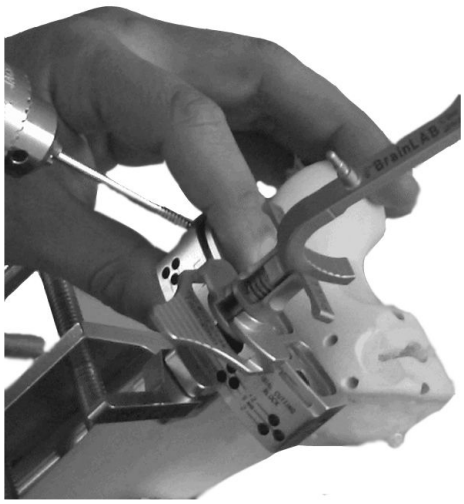


Figure 32

During the pinning of the cutting block to the bone, the Femoral and Tibial Cutting Block Adapter “Universal” might move out of the slot. Regularly check and ensure that the Femoral and Tibial Cutting Block Adapter “Universal” remains completely inserted. Not doing so may lead to an unstable attachment and result in inaccurate navigation.

Do not use the Femoral and Tibial Cutting Block Adapter “Universal” as a handle to manipulate the position or orientation of the cutting block. This could cause the plate to bend resulting in navigation inaccuracies. Do not hold onto the Femoral and Tibial Cutting Block Adapter “Universal” with the cutting block still attached.

Correct Instrument Handling

If the base plate cannot be fully inserted into the cutting slot, the cutting slot might not be compatible with the base plate or the base plate might be damaged. In the latter case, contact Brainlab immediately for advice on how to proceed. The use of damaged equipment could result in severe patient injury.

Make sure that the Femoral and Tibial Cutting Block Adapter “Universal” adapter array does not touch other instruments, reference arrays, the patient’s body or the surgeon’s hand during positioning and attachment of the cutting block to the bone as this will lead to inaccurate navigation of the resection plane.

6.2 Adjustable Cutting Block - Femur Kit

6.2.1 Overview

General Information

The **Adjustable Cutting Block** is used for navigating the distal femoral resection when the distal cut is performed first. The cutting block is pinned close to its desired position with the help of an alignment guide. Fine-adjustments of varus/valgus, flexion/extension and resection height can then be made according to the values displayed by the navigation system.
The **Adjustable Cutting Block** can be used as follows:

- The **Reference Array Y-Geometry** attached to the **Femoral Base Plate** of the cutting block (see page 79)
- A separate array attached to the bone (see page 88)

Before Using

Before using the Adjustable Cutting Block, ensure that all components are available and all movable parts are functioning properly.

Components

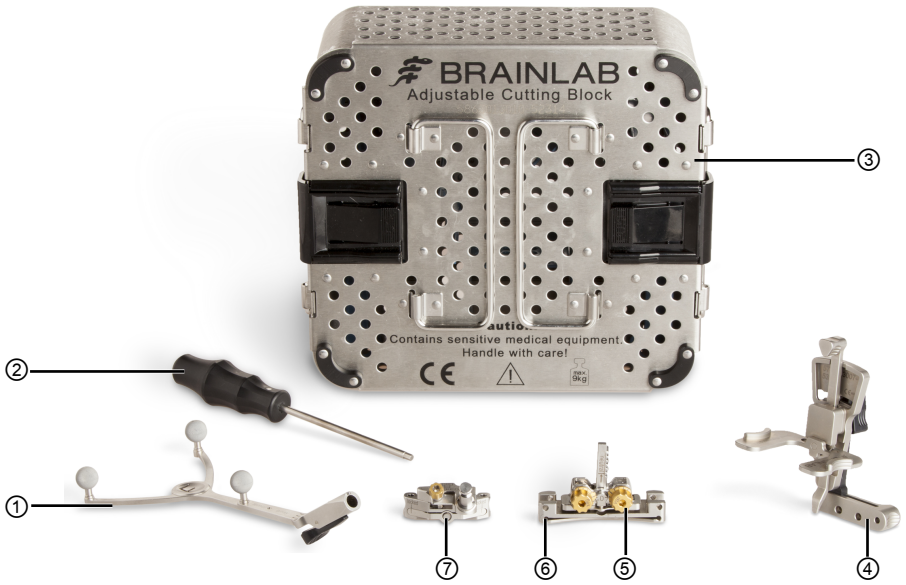


Figure 33

The **Adjustable Cutting Block - Femur Kit** consists of:

No.	Component	Article No.	See
①	**Reference Array Y-Geometry**	53211	Page 74
②	**Screwdriver (3.5 mm)**	53218	N/A
③	**Sterilization Tray**	52314	N/A
④	**Femur Alignment Guide**	53212	Page 72
⑤	**Adjustment Unit**	53210	Page 73

No.	Component	Article No.	See
⑥	**Cutting Slot Femur**	• 53220 (1.19 mm) • 53221 (1.27 mm) • 53222 (1.37 mm)	Page 73
⑦	**Femoral Base Plate**	53213	Page 74

Additional Compatible Components

Description	Article No.
Disposable Schanz Screws 3.2 mm	54922
Pindriver Adapter for AO Coupling	54932

6.2.2 Femur Alignment Guide

Components

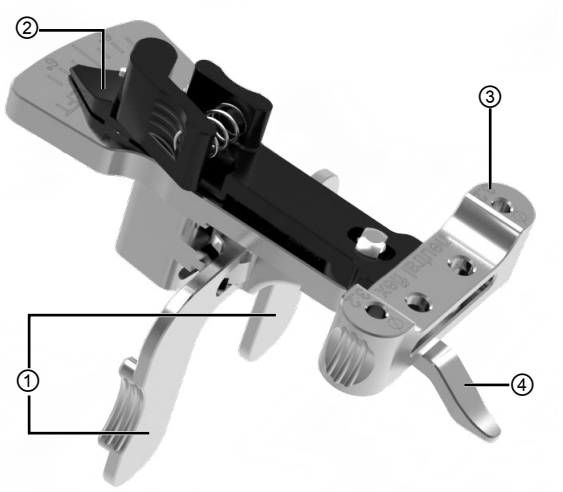


Figure 34

No.	Component
①	Contact surface for distal condyle alignment
②	Angle adjustment unit with clamp
③	Drill template
④	Anterior femoral alignment stylus

6.2.3 Adjustable Cutting Block

General Information

The **Adjustable Cutting Block** consists of:

- **Cutting Slot Femur**
- **Adjustment Unit**
- **Femoral Base Plate**
- **Reference Array Y-Geometry**

Wear and Tear

The Adjustable Cutting Block is subject to wear on both the adjustment mechanism and the slot. If you notice significant wear, the parts must be replaced.

Cutting Slot Femur

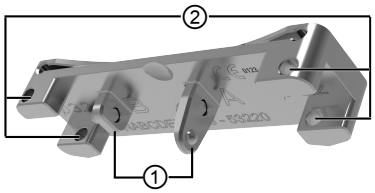


Figure 35

No.	Component
①	Pegs (labeled A and B) for cutting slot attachment
②	Oblique holes for fixation of the cutting slot

The cutting slot must be fixated using at least one 3.2 mm Schanz screw to ensure stability while cutting. Keep in mind that the holes are oblique.

Adjustment Unit

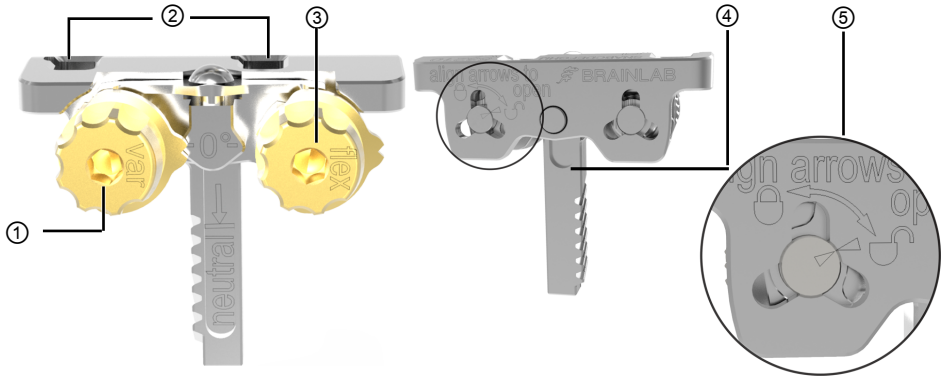


Figure 36

No.	Component
①	Varus/valgus (**var**) adjustment knob
②	Entry points (A and B) for the cutting slot

No.	Component
③	Flexion/extension (**flex**) adjustment knob
④	Height adjustment guide bar
⑤	Unlock label for the cutting slot

Femoral Base Plate

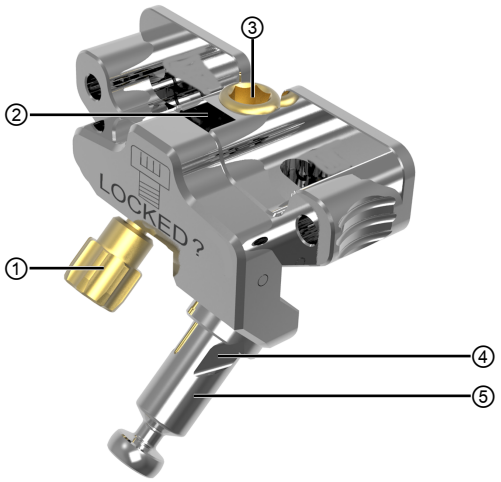


Figure 37

No.	Component
①	Resection height adjustment knob
②	Receiving slot for height adjustment guide bar
③	Base clamping screw
④	Interface alignment markings
⑤	Interface for reference array

Reference Array Y-Geometry

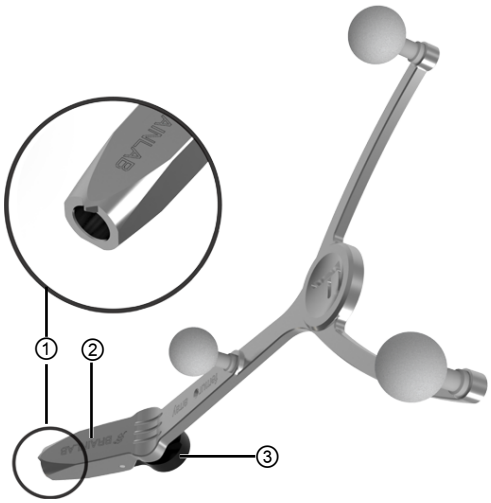
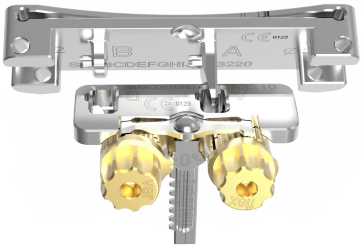
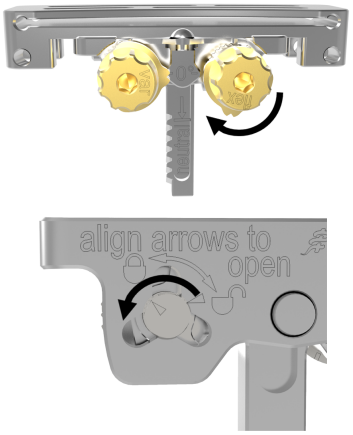


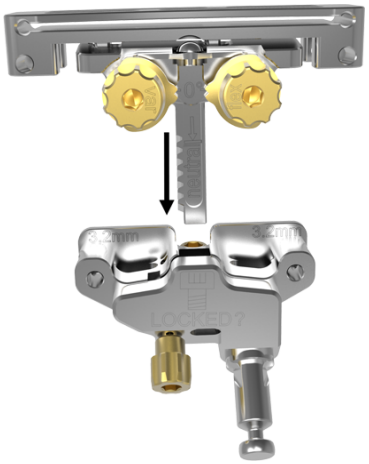
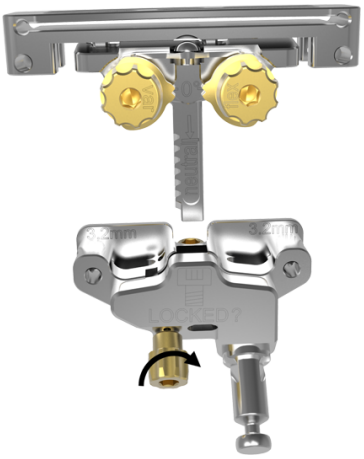
Figure 38

No.	Component
①	Interface for the base
②	Tooth for interface alignment
③	Release lever

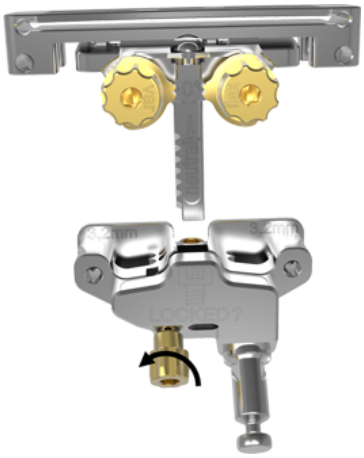
6.2.4 Assembling and Disassembling the Adjustable Cutting Block

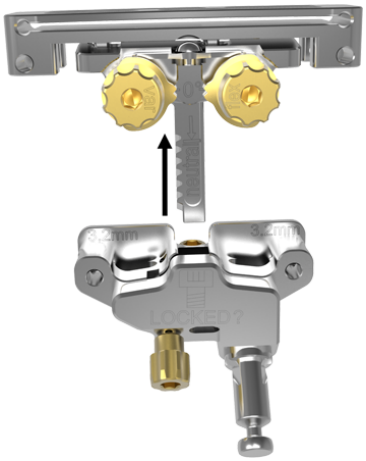
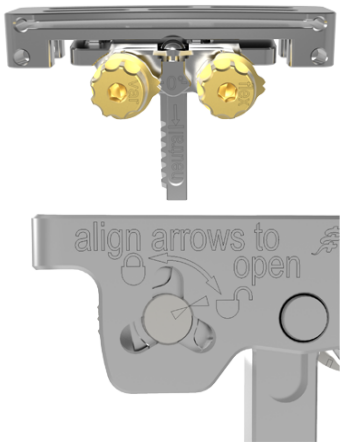
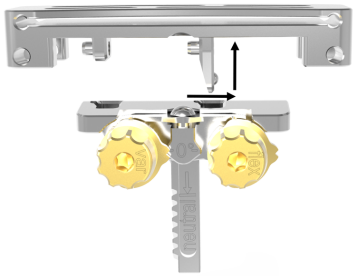
How to Assemble

Steps	
1. Bring the knob marked **flex** into the unlocked position (see label on the back). Turn the knob marked **var** to 0°. *NOTE: There is a threshold mechanism that prevents the unit from being unlocked unintentionally during normal use. Continue to turn the knob marked **flex** until it is unlocked.*	
2. Insert the **A** and **B** pegs of the cutting slot femur into the corresponding entry points of the **Adjustment Unit**.	
3. Bring the knob marked **flex** into the locked position by turning clockwise in order to secure the mechanism. *NOTE: In order to lock the assembly, tilt the **Cutting Slot Femur** slightly forward.*	

Steps	
4. Insert the height adjustment guide bar of the **Adjustment Unit** into the corresponding receiving slot of the **Femoral Base Plate**.	
5. Turn the resection height adjustment knob clockwise to further feed the guide bar into the base.	

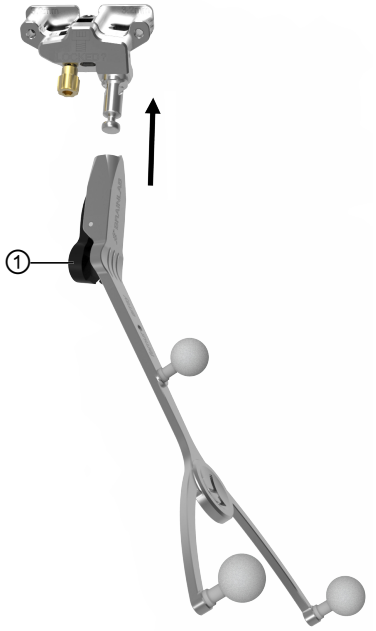
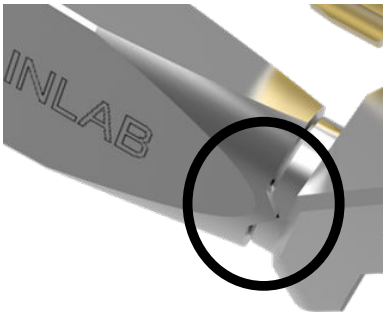
How to Disassemble

Steps	
1. Turn the resection height adjustment knob counterclockwise until the height adjustment guide bar is released.	

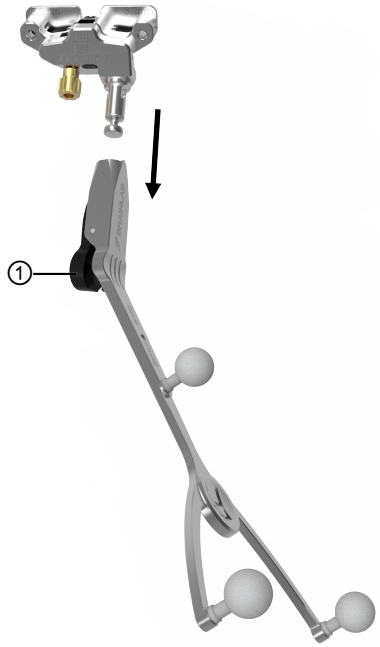
Steps	
2. Remove the **Adjustment Unit** from the **Femoral Base Plate**.	
Bring the knob marked **flex** into the unlocked position (see label on the back). Turn the knob marked **var** to 0°. 3. *NOTE: There is a threshold mechanism that prevents the unit from being unlocked unintentionally during normal use. Continue to turn the knob marked **flex** until it is unlocked.*	
4. Remove the cutting slot femur from the **Adjustment Unit**.	

6.2.5 Assembling and Disassembling the Femur Reference Array and Femoral Base Plate

How to Assemble

Steps	
1. Press on the **Reference Array Y-Geometry** release lever ① and slide the interface of the array onto the **Femoral Base Plate** interface.	
2. Ensure the tooth on the reference array interface snaps into place with the interface on the **Femoral Base Plate**. *NOTE: Choose the right or left indent depending on the camera position.*	

How to Disassemble

Step
Press on the release lever ① and remove the **Reference Array Y-Geometry**. 

6.2.6 Working with the Array on the Base

General Information

When working with the **Reference Array Y-Geometry** on the **Femoral Base Plate** of the **Adjustable Cutting Block**, the base must be attached to the bone before registration can start. It is not possible to navigate the base to the approximate target position. Using the **Femur Alignment Guide** ensures that the base is positioned within the target area.

The Adjustable Cutting Block has a limited adjustment range of ± 8° for both varus/valgus and flexion/extension adjustment and ± 6 mm for height adjustment. The Femur Alignment Guide ensures the initial placement of the base reaches the target cutting plane. It is compulsory to use the Femur Alignment Guide.

Fixation Precautions

Consider patient's bone size. The distance between the two base fixation Schanz screws is 40 mm. They are placed 30-35 mm proximal of the distal condyles. Before inserting the first screw through the template, make sure there is sufficient space in the bone for the second screw.

For fixation of the cutting block, use threaded Schanz screws with a diameter of 3.2 mm. Fixation with screws smaller than 3.2 mm may make the base attachment unstable, leading to an incorrect bone cut or misplacement of the implant. Fixation with screws larger than 3.2 mm may damage the cutting block.

After Schanz screw insertion, ensure the screws are correctly fixed to the bone. It is recommended to insert the screws bicortically if possible. Regularly check the stability of the base and the array on the bone, especially before starting registration or navigation.

The Schanz screws for the Adjustable Cutting Block must only be attached to bony structures, never to tissue or parts of the nervous system.

*NOTE: When using the **Adjustable Cutting Block**, the **Femoral Base Plate** should be attached to the bone in a way that still allows you to easily access the target resection.*

6.2.7 Using the Femur Alignment Guide

Determine the Femur Anatomical Angle

Determine the femur anatomical angle (the angle between the anatomical and mechanical femur axes in the frontal plane) prior to surgery (e.g., via an X-ray image).

NOTE: On average, this angle is 6°.

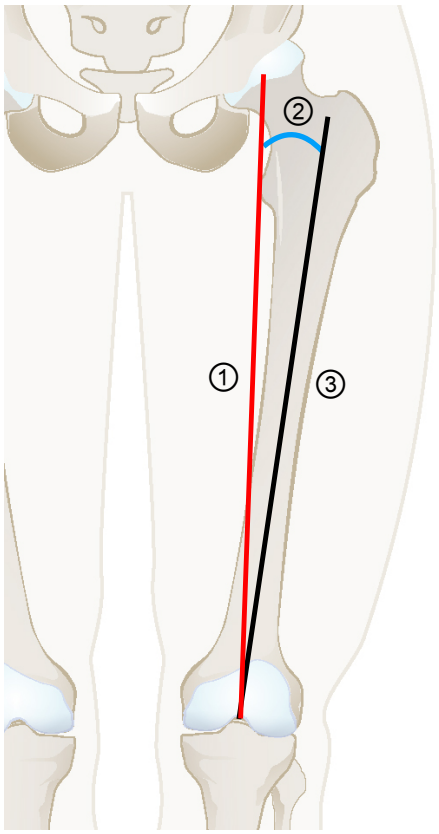
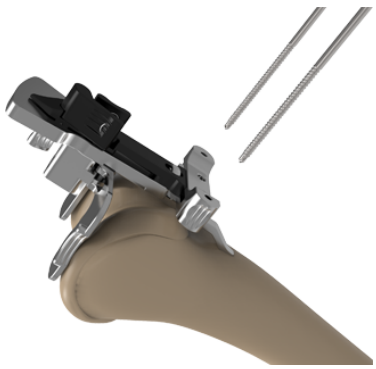
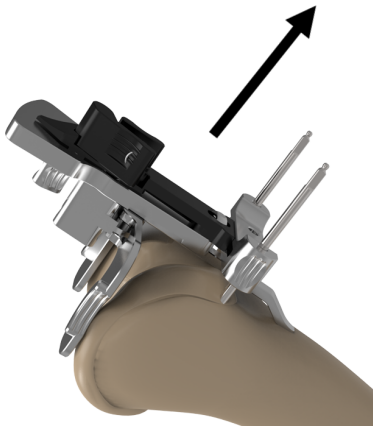


Figure 39

No.	Component
①	Femoral mechanical axis
②	Femur anatomical angle
③	Femoral anatomical axis

How to Insert the Schanz Screws using the Femur Alignment Guide

Steps		
1.	Use the angle adjustment unit on the **Femur Alignment Guide** to adjust the femur's anatomical angle according to preoperative planning or a typical anatomical value.	
2.	Adjust the angle by pressing the clamp on the angle adjustment unit and aligning the tip with the angle mark appropriate for the treatment side.	
3.	Place the **Femur Alignment Guide** on the distal femur, so that the contact surface for distal condyle alignment rests centered on the distal femoral condyles.	
4.	Align the **Femur Alignment Guide** using the anterior femoral alignment stylus. Ensure the stylus is centered on the femoral anterior cortex and points in the direction of the femoral shaft axis (anatomical femur axis). Adapt the flexion angle of the **Femur Alignment Guide** by ensuring that the stylus is centered and in contact with the anterior bone cortex. *NOTE: Make sure that the stylus is in contact with the bone surface.*	
5.	Center the drill template over the anterior bone cortex and drill two threaded Schanz screws with a diameter of 3.2 mm through the holes of the drill template.	

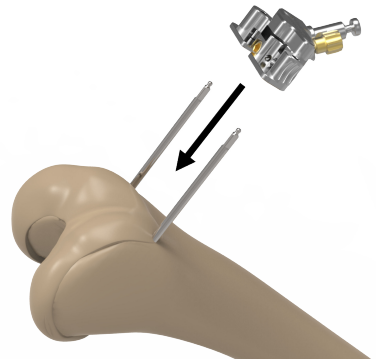
Steps	
6. Remove the **Femur Alignment Guide** from the Schanz screws.	

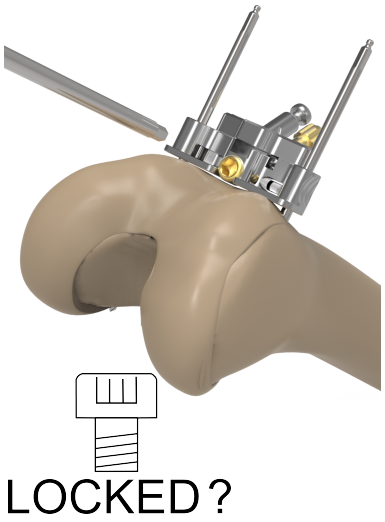
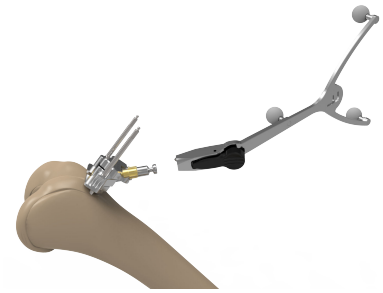
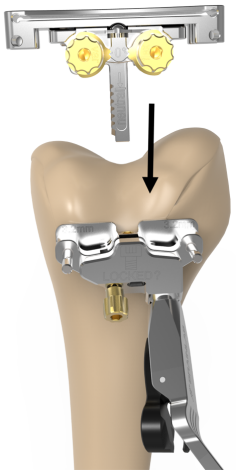
How to Attach the Femoral Base Plate to the Schanz Screws

The base must be unlocked before sliding it onto the screws. If the base is locked, unlock it using the base clamping screw.

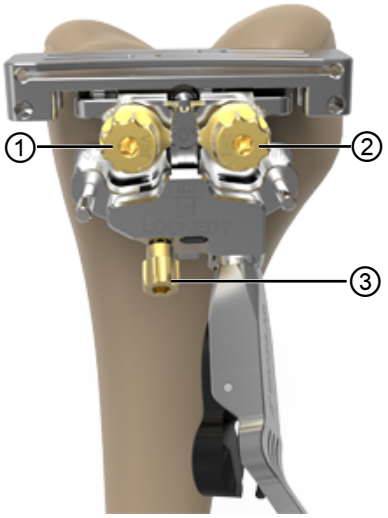
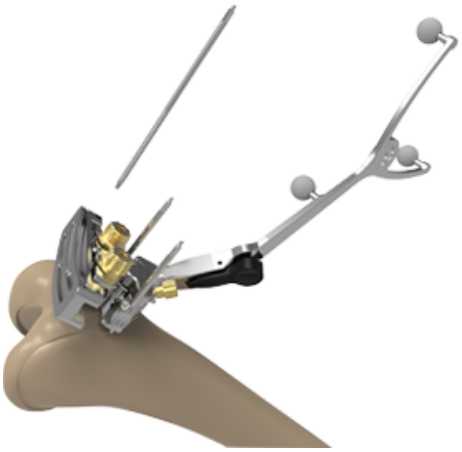
Ensure the Femoral Base Plate is correctly locked before starting registration as the Reference Array Y-Geometry may become loose and the registration inaccurate.

Before starting registration or navigation, check that the Femoral Base Plate and the Reference Array Y-Geometry are still stable.

Steps	
Slide the **Femoral Base Plate** onto the Schanz screws. 1. *NOTE: The base must be unlocked before sliding it onto the screws. If the base is locked, unlock it using the base clamping screw.*	

Steps	
2. Fix the **Femoral Base Plate** onto the Schanz screws by tightening the base clamping screw, using a 3.5 mm hex driver. *NOTE: The **Femoral Base Plate** is marked **LOCKED?** on its top surface.*	
3. Attach the **Reference Array Y-Geometry** to the **Femoral Base Plate** as shown (see page 79).	
4. Insert the **Adjustment Unit** with the cutting slot into the **Femoral Base Plate** (see page 76).	

How to Adjust the Cutting Slot Femur

Steps	
1. Turn the corresponding knobs on the **Adjustment Unit** and **Femoral Base Plate** to adjust the cutting slot: • Varus/valgus ① • Flexion/extension ② • Resection height ③ *NOTE: For optimal results, adjust the knobs in the order above.*	
2. Fixate the cutting slot by inserting a third Schanz screw into the bone through one of the oblique holes.	

Do not turn the adjustment knobs any further if force is needed. You may have reached the limits of the adjustment range.

Do not manipulate the position of the Adjustable Cutting Block by bending the Schanz screws. Only adjust the cutting slot by using the adjustment mechanism.

Do not try to adjust the cutting block when the slot is already pinned with a Schanz screw. This may lead to deformation of the base and an incorrect reference, resulting in an incorrect cut and misplaced implant.

Always check the final stability of the cutting slot before sawing.

Remove the array before sawing or any action causing vibrations.

Safe Disassembly

Remove the Femoral Base Plate before removing the Schanz screws from the bone.

Navigating with the 4 in 1 Cutting Block

When using the 4 in 1 Cutting Block, its orientation pins or the saw blade could collide with the Schanz screws of the Adjustable Cutting Block.

6.2.8 Working with a Separate Reference Array on the Bone

General Information

When working with a **Reference Array Y-Geometry** on the bone, the registration is already complete when the block is attached to the bone. Thus, it is possible to navigate the base to the approximate target position (using a cutting block adapter in the cutting slot). Alternatively, the **Femur Alignment Guide** can be used to place the Schanz screws.

If a separate reference array is used for navigation, position it proximally to allow sufficient space for the Femur Alignment Guide and Femoral Base Plate.

If Schanz screws are placed using the Femoral Base Plate instead of the Femur Alignment Guide, make sure that the base fixation mechanism is unlocked before drilling.

Set all adjustment knobs on the cutting block to the 0° position and the resection height to the neutral position prior to use. Labels on the Adjustment Unit indicate the 0° position. Otherwise the adjustment range may be insufficient to reach the target resection plane.

6.3 Adjustable Cutting Block - Basic Femur Kit

6.3.1 Overview

General Information

The **Adjustable Cutting Block - Basic Femur Kit** is used for navigating the distal femoral resection when the distal cut is first performed. The cutting block is pinned close to its desired position. A reference array is added to the femur to allow navigation. Adjustments of varus/valgus, flexion/extension and resection height can then be made according to the values displayed by the navigation system.

Before Using

Before using the Adjustable Cutting Block - Basic Femur Kit, ensure that all components are available and all movable parts are functioning properly.

Components

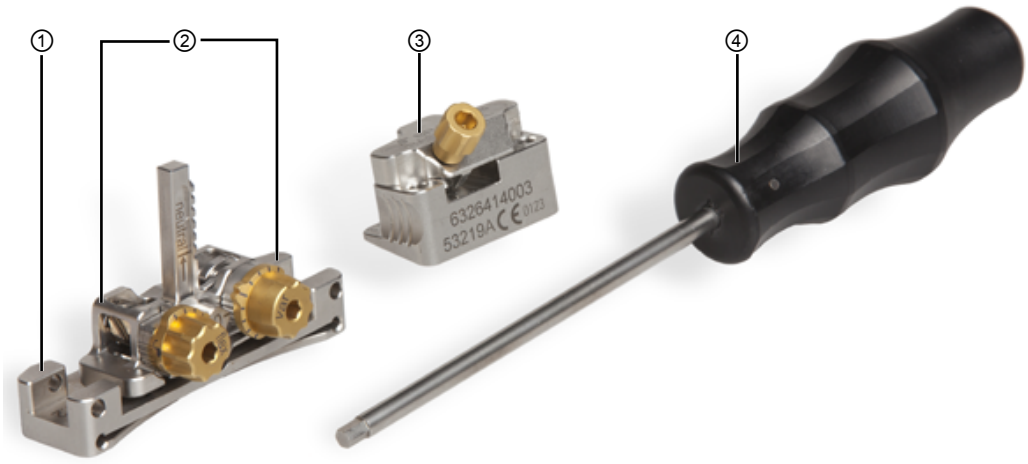
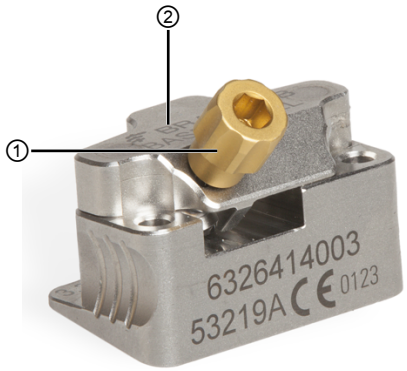


Figure 40

The **Adjustable Cutting Block - Basic Femur Kit** consists of:

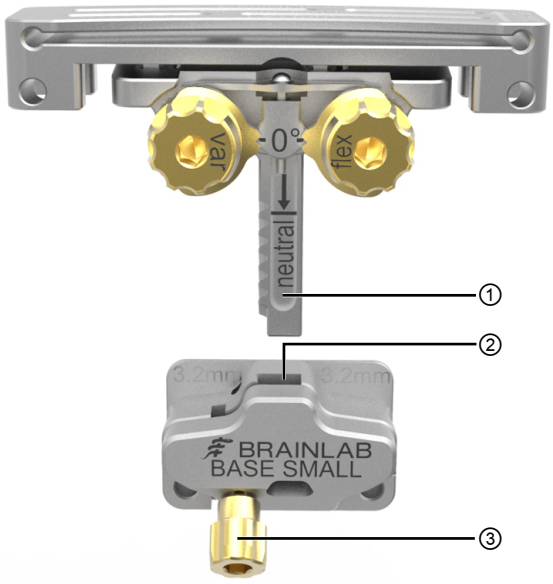
No.	Component	Article No.
①	**Cutting Slot Femur** (1.19 mm/1.27 mm/1.37 mm)	53220/21/22
②	**Adjustment Unit**	53210
③	**Femoral Base Plate Small**	53219
④	**Screwdriver (3.5 mm)**	53218

Femoral Base Plate Small



No.	Component
①	Resection height adjustment knob
②	Receiving slot for height adjustment guide bar

How to Assemble the Femoral Base Plate Small with the Cutting Block



Steps	
1.	Insert the height adjustment guide bar of the adjustment unit ① into the corresponding receiving slot ② of the **Femoral Base Plate Small**.
2.	Turn the height adjustment knob ③ clockwise to further feed the guide bar into the base until the marked “neutral” position is reached.

How to Disassemble the Femoral Base Plate Small and Cutting Block

Step
Turn the height adjustment knob ③ counterclockwise until the height adjustment guide bar is released.

Fixation Precautions

Consider patient's bone size. The distance between the two base fixation Schanz screws is 26 mm. They are placed 40-45 mm proximal of the distal condyles. Before inserting the first screw through the template, make sure there is sufficient space in the bone for the second screw.

For fixation of the cutting block, use threaded Schanz screws with a diameter of 3.2 mm. Fixation with screws smaller than 3.2 mm may make the base attachment unstable, leading to an incorrect bone cut or misplacement of the implant. Fixation with screws larger than 3.2 mm may damage the cutting block.

The Schanz screws for the Adjustable Cutting Block must only be attached to bony structures, never to tissue or parts of the nervous system.

If a separate reference array is used for navigation, position it proximally to allow sufficient space for the Femoral Base Plate Small.

Adjustment Precautions

Set all adjustment knobs on the cutting block to the 0° position and the resection height to the neutral position prior to use. Labels on the Adjustment Unit indicate the 0° position. Otherwise the adjustment range may be insufficient to reach the target resection plane.

Do not turn the adjustment knobs any further if force is needed. You may have reached the limits of the adjustment range.

Always check the final stability of the cutting slot before sawing.

Wear and Tear

The Adjustable Cutting Block is subject to wear on both the adjustment mechanism and the slot. If you notice significant wear, the parts must be replaced.

How to Attach the Femoral Base Plate Small

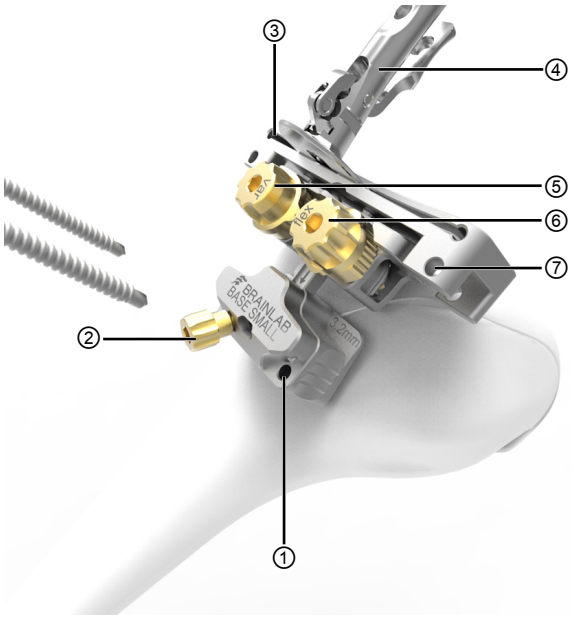


Figure 41

After registration, proceed as follows:

Steps	
1.	Insert a cutting block adapter ④ into the cutting slot ③. This facilitates navigating the cutting block with the **Femoral Base Plate Small** to the approximate target position.
2.	Place the **Femoral Base Plate Small** on the bone and drill two threaded Schanz screws (or threaded pins) with a diameter of 3.2 mm through the holes ①.
3.	Turn the knobs on the adjustment unit and femoral base plate to adjust the cutting slot: • Varus/valgus ⑤ • Flexion/extension ⑥ • Resection height ② *NOTE: For optimal results, adjust the knobs in the order above.*
4.	Fixate the cutting slot by inserting a third Schanz screw into the bone through one of the oblique holes ⑦.

7 CLEARLENS INSTRUMENTS

7.1 Instrument Overview

7.1.1 Introduction

General Information

ClearLens Instruments are used for computer aided surgery performed using **Knee**. The instruments consist of a reusable metal part and a disposable plastic array with pre-attached markers. The parts are connected prior to surgery using a specific interface.

Instrument Types

The following components define the **ClearLens Instruments**:

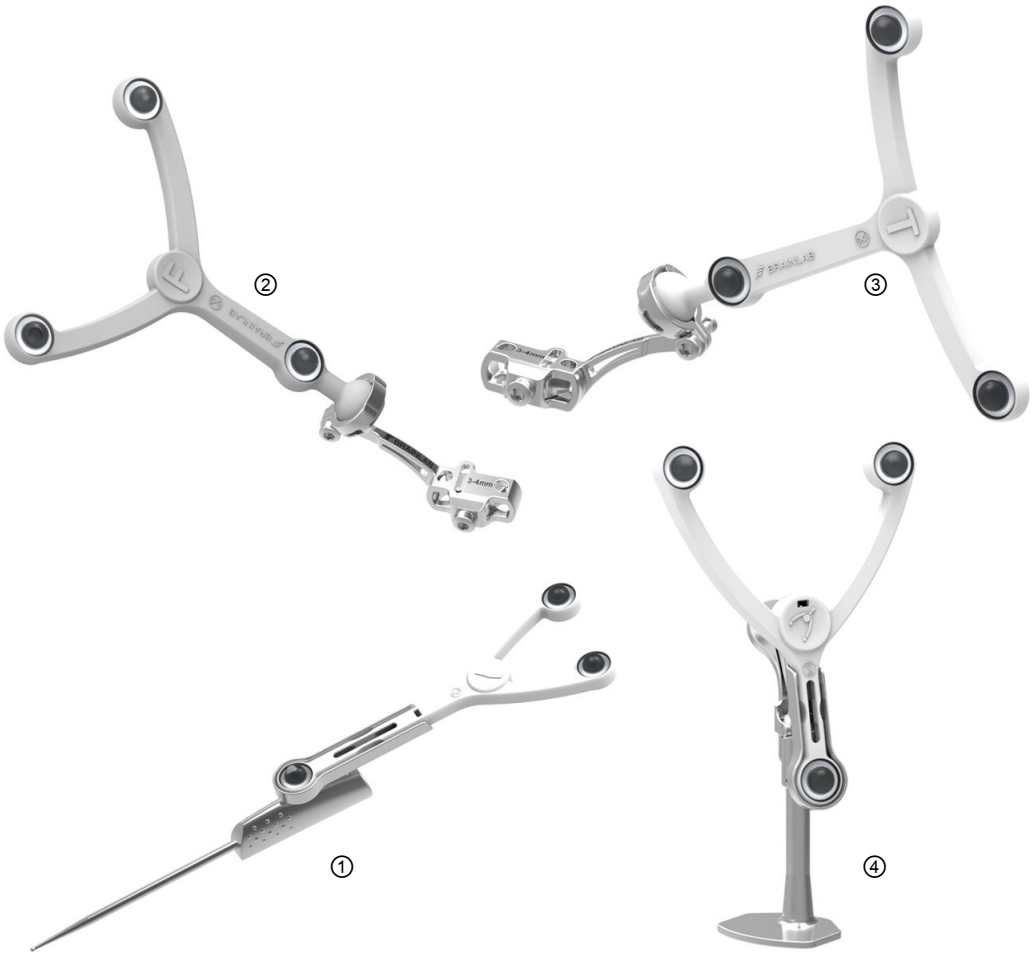


Figure 42

No.	Instrument
①	**ClearLens Pointer**
②	**ClearLens Bone Reference Femur**
③	**ClearLens Bone Reference Tibia**
④	**ClearLens Plane Tool**

Before Use

The arrays are designed for single use only and must be disposed of after use. Reprocessing may damage the device and lead to serious patient injury.

Before opening the sterile packaging, verify that the expiration date has not passed and that the packaging is undamaged. If the expiration date has passed or the packaging is damaged or broken, do not use the arrays.

Ensuring Sterility

The arrays are delivered sterile. If they come into contact with an unsterile environment during unpacking or clinical use, dispose of the array immediately.

During Use

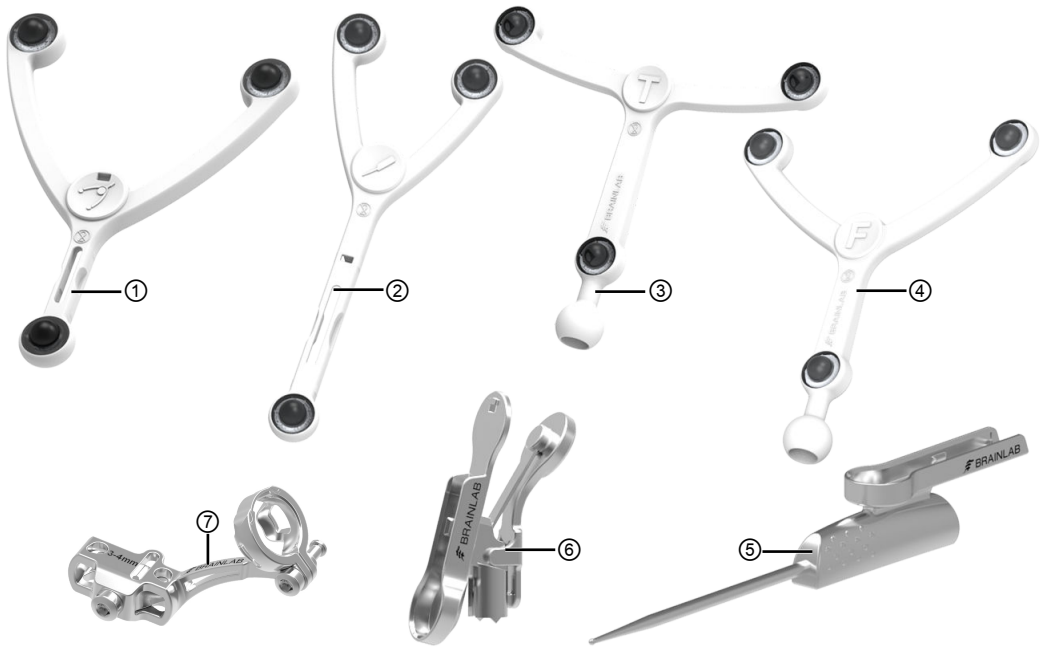
The plastic femur and tibia arrays have a maximum stress (bending/torque) of 15 N/1.5 kg. Exceeding that leads to plastic deformation and potential inaccuracies.

Disposable arrays cannot be resterilized or reused.

Ensure that the reference array is correctly positioned to achieve ideal visibility without interfering with other instruments and to avoid potential inaccuracies.

The markers must be wiped clean when contaminated with blood, fat or tissue.

Component Overview



No.	Component
①	ClearLens Tracking Array Plane Tool
②	ClearLens Tracking Array Pointer
③	ClearLens Tracking Array Tibia
④	ClearLens Tracking Array Femur
⑤	ClearLens Pointer Handle – Knee
⑥	ClearLens Knee Plane Tool – Interface
⑦	ClearLens Bone Fixator 2-Pin

7.1.2 Assembling ClearLens Instruments

How to Assemble ClearLens Bone Reference Femur/Tibia

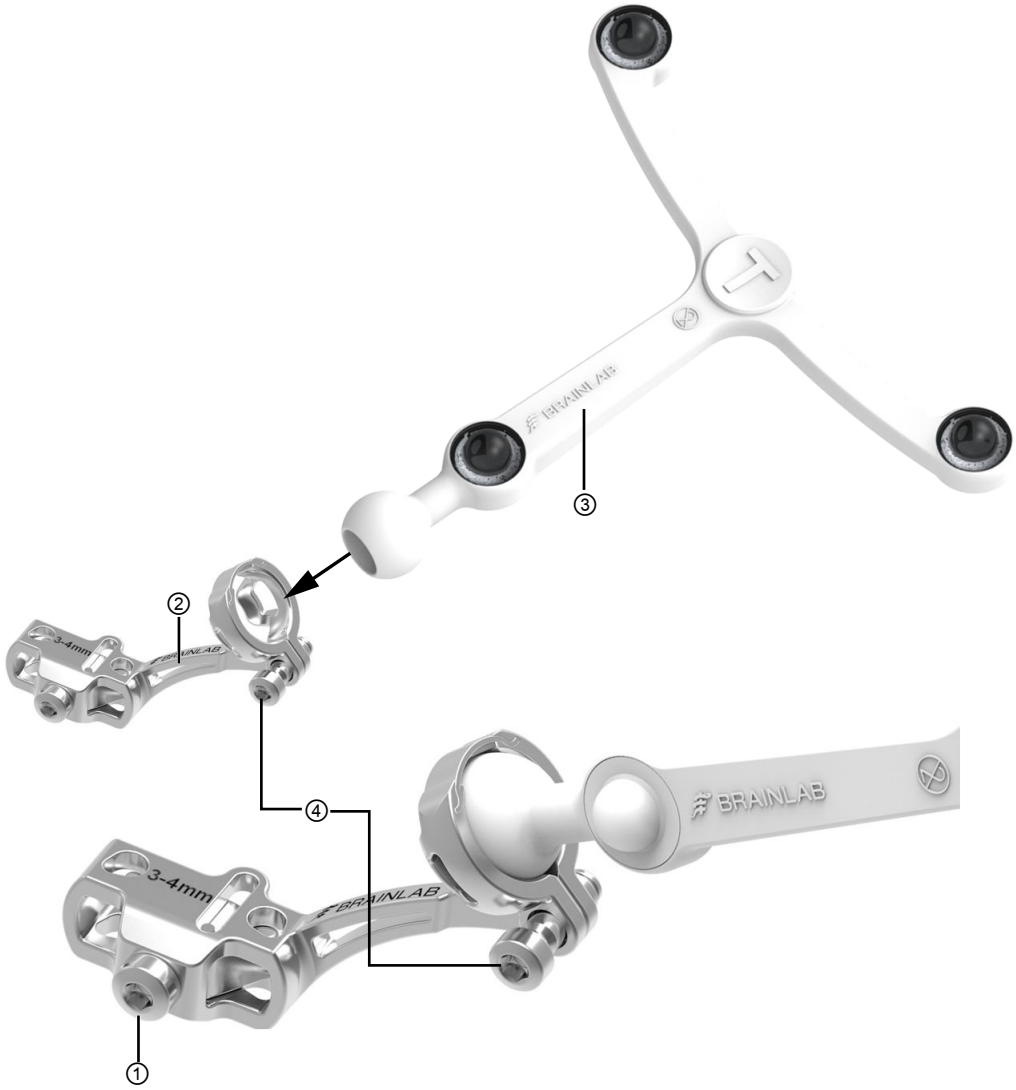


Figure 43

Steps	
1.	Ensure that the array fixator screw ④ is fully open and clip **ClearLens Tracking Array Tibia/Femur** ③ into **ClearLens Bone Fixator 2-Pin** ②.
2.	Fix **ClearLens Bone Fixator 2-Pin** ② onto the Schanz screws and tighten screw ①.
3.	Check visibility and the flexion and extension alignment using e.g., the **Camera App**. Then, fix the array in position by tightening the array fixator screw ④.

Always ensure that the array's ball joint is securely fastened after alignment prior to registration and surgery. Loosening the array causes navigation inaccuracies, possibly requiring re-registration.

How to Assemble ClearLens Pointer

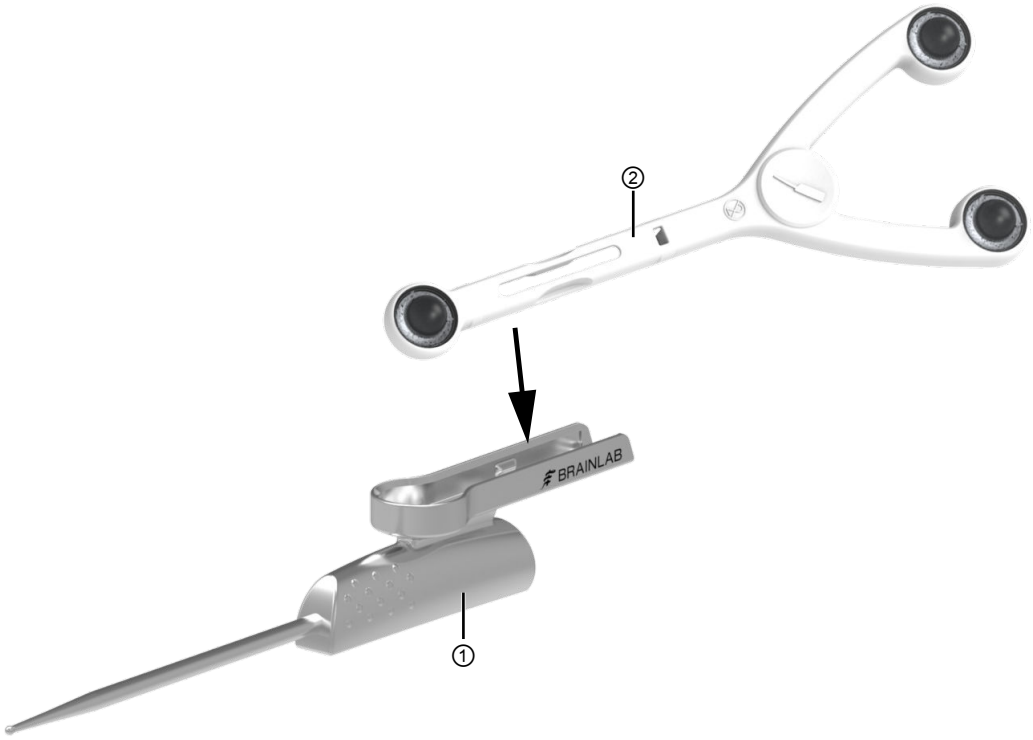


Figure 44

Steps	
1.	Clip **ClearLens Tracking Array Pointer** ② into **ClearLens Pointer Handle - Knee** ①.
2.	Visually verify that the array is fully seated within the interface.

How to Assemble ClearLens Plane Tool

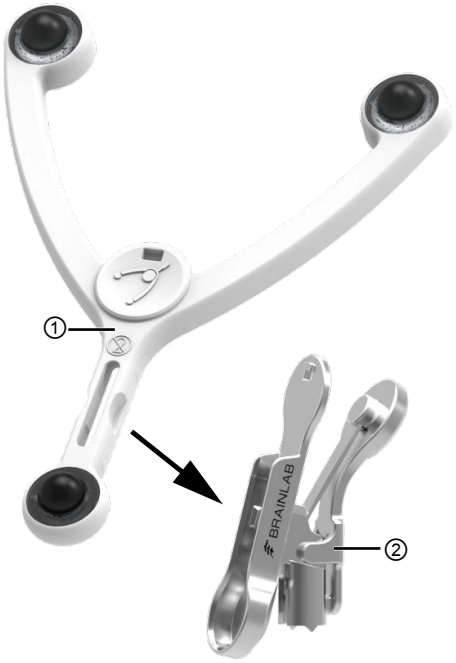


Figure 45

Steps	
1.	Clip **ClearLens Tracking Array Plane Tool** ① into **ClearLens Knee Plane Tool** ②.
2.	Visually verify that the array is fully seated within the interface.

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