BRAINLAB

# HIP

## Instrument User Guide
## Revision 1.1

# 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<br>Fax: +1 708 409 1619 | us.support@brainlab.com |
| Brazil | Tel: (0800) 892 1217 | |
| 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<br>Fax: +49 89 991568 811 | |
| Japan | Tel: +81 3 3769 6900<br>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



### Trademarks

Precimed® is a registered trademark of Precimed.

### 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.**

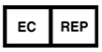
**Notes**

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

### 1.2.2 Hardware Symbols

**Symbols on Hardware Components**

| Symbol | Explanation |
|---|---|
|  | Type B Applied Part according to IEC 60601-1 |
|  | Type BF Applied Part according to IEC 60601-1 |
|  | Caution |
|  | Potential equalization point |
|   | MR Safe |
|   | MR Unsafe |
|   | MR Conditional: The number shown on each label specifies the MR environment in which the device can be used with 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 |

| Symbol | Explanation |
|---|---|
|  | 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 |
|  | Date of manufacture |
|  | Manufacturer |
|  | Authorized representative in the European Community |
| IPXY | Ingress Protection according to IEC 60529<br>• X = Protection against ingress of solid objects<br>• Y = Protection against ingress of liquid |
|  | Direct current |
|  | Acoustic power output of integrated ultrasound probes complies with FDA Track 3 and IEC 60601-2-37 |
|  | On/off switch |
|  | Standby switch to bring the device into standby mode |
|  | Consult the operating instructions |
|  | Attention! Consult accompanying documents |

# 1.3 Intended Use

## 1.3.1 Hardware 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<br>• Description of OR system setup<br>• 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. Placement of a fixation pin in the acetabulum may also cause lesions of the viscera.**

**Precautions**

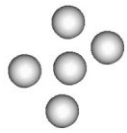
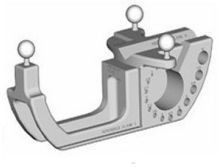
**In some cases, fixation pins may be placed using an automatic drill, however, use only the lowest drilling speed to maintain maximum control over the drilling depth.**

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

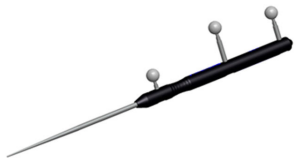
**To ensure stable attachment, the fixation pin should be positioned bicortically where possible.**

### 2.1.3 Available Instruments

**General Instrumentation**

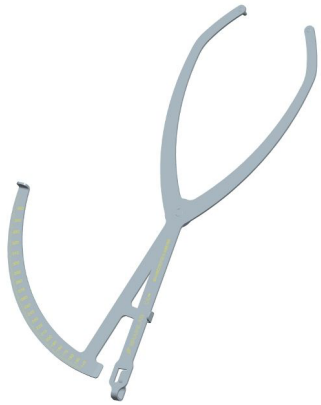
| Illustration | Name | See |
|---|---|---|
|  | **Disposable Reflective Marker Spheres** | Page 21 |
|  | **Disposable Schanz Screws** | Page 24 |
|  | **Instrument Calibration Matrix (Rev. 4) - ICM4** | Page 25 |

**Pointers**

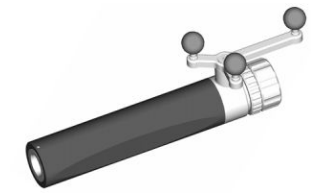
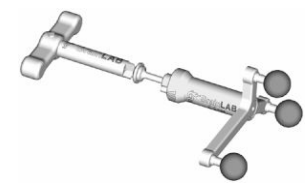
| Illustration | Name | See |
|---|---|---|
|  | **Pointer Straight Extended** | Page 29 |
|  | **Pointer Angled for Hip and Knee** | Page 29 |
|  | **Extended Pointer Sharp Tip** | Page 30 |
|  | **Disposable Clip-on Remote Control** | Page 31 |

## Reference Arrays

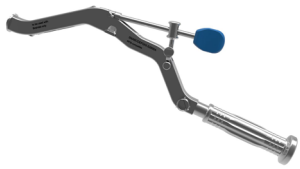
| Illustration | Name | See |
|---|---|---|
|  | **Reference Array T-Geometry X-Press** | Page 46 |
|  | **Reference Array Y-Geometry X-Press** | Page 46 |
|  | **Bone Fixator “1-Pin”, X-Press, Size-S/M/L** | Page 50 |
|  | **1-Pin Wrench X-Press/ Spine Clamps** | Page 51 |
|  | **Bone Fixator “2-Pin”, Flip-Flop, X-Press** | Page 53 |

| Illustration | Name | See |
|---|---|---|
|  | **Pinless Femur Reference Array** | Page 65 |
|  | **Hip Caliper** | Page 43 |

**Instrument Adapters - Hip**

| Illustration | Name | See |
|---|---|---|
|  | **Instrument Adapter, StarLock Interface** | Page 70 |
|  | **Adapter for Cup Inserter** | Page 72 |
|  | **Cup Reamer Adapter** | Page 75 |
|  | **Femoral Broach Adapter “DePuy”** | Page 78 |

## Cup Impactors

| Illustration | Name | See |
|---|---|---|
|  | **Straight Cup Impactor Universal** | Page 91 |
|  | **Offset Cup Impactor Universal** | Page 83 |
|  | **Insert For Cup Impactor Universal** | Page 101 |

## Surgical Instruments

| Illustration | Name | See |
|---|---|---|
|  | **Stem Position Verification Tools** | Page 81 |
|  | **Drill Guide** | Page 103 |

## Footswitch

| Illustration | Name | See |
|---|---|---|
|  | **Footswitch (USB)** | Page 42 |

# 3 GENERAL INSTRUMENTATION

## 3.1 Disposable Reflective Marker Spheres

### 3.1.1 Overview

**General Information**

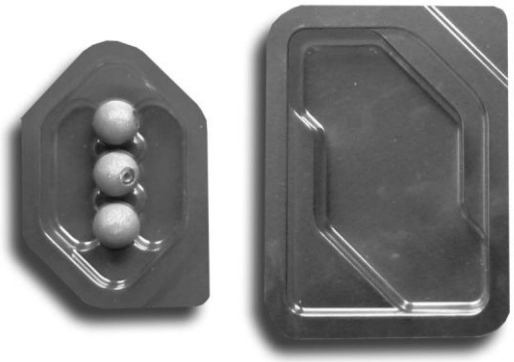


Figure 1

| 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**

Marker spheres are delivered sterile. 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.**

**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**

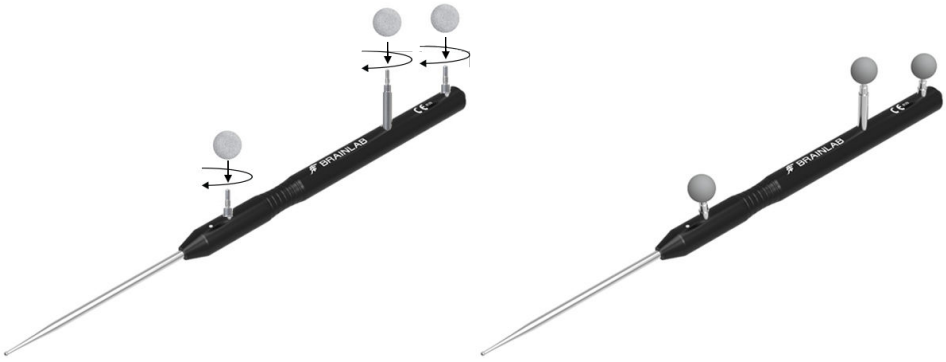



Figure 2

| 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 cannot be resterilized and must be disposed of after use.

**Do not resterilize disposable Schanz screws as this poses a risk to the patient.**

# 3.3 Instrument Calibration Matrix (Rev. 4) - ICM4 (41874)

## 3.3.1 ICM Features

### General Information

The **ICM4** is used:

- To calibrate the axis (and vector), diameter, planes and tips of non-precalibrated instruments so that they can be accurately navigated by the **Brainlab** software
- To verify and validate the calibration accuracy of precalibrated instruments

The **ICM4** can only be used with Brainlab navigation software. Instructions on calibrating instruments using the **ICM4** are in your **Software User Guide**.

### ICM4 Features

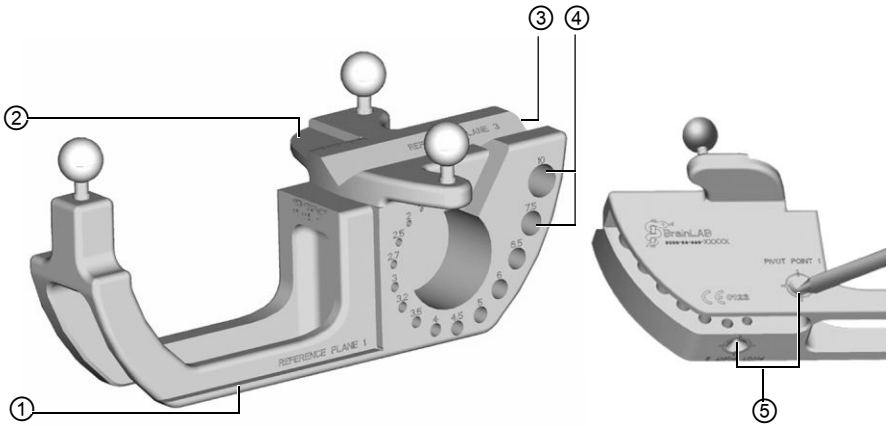



Figure 4

| No. | Component |
|---|---|
| ① | Reference planes (examples) |
| ② | |
| ③ | V-inset |
| ④ | Calibration receptacles (examples) |
| ⑤ | Pivot points |

### Activation

When the system detects the **ICM4** in the camera field of view, the navigation software guides you through instrument calibration, validation, and /or verification. See your **Software User Guide** for more details.

## V-Inset

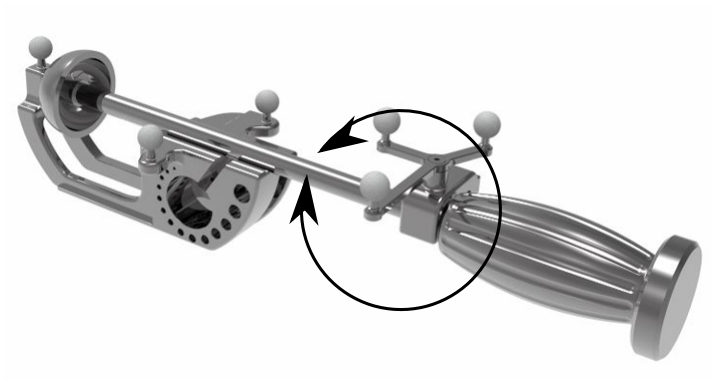


Figure 5

The V-insert is used to calibrate the long axis and vector of the instrument shaft. Calibration performed in the V-inset can be refined, if necessary, using the pivot holes or reference planes.

**Do not calibrate conical instruments using the V-inset. This results in the incorrect display of the instrument axis.**

## Reference Planes

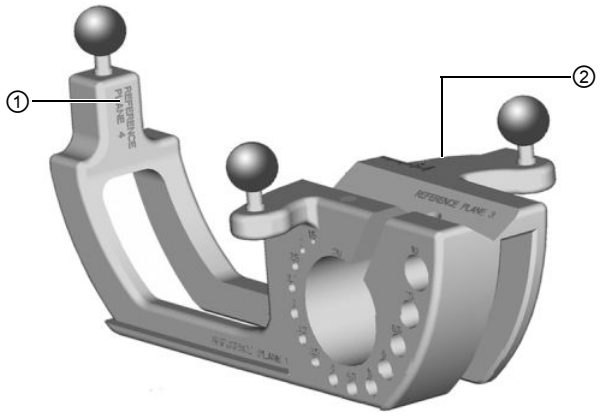



Figure 6

| No. | Plane | Use |
|---|---|---|
| ① | 4 | Reference for tip distance of instruments calibrated in the V-inset |
| ② | 3 | Reference for shaft diameter of instruments calibrated in the V-inset |

# 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
- To verify the accuracy of acquired fluoroscopic images

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.**

**Software Compatibility**

Your **Software User Guide** lists the pointers supported by your Brainlab navigation software.

### 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**

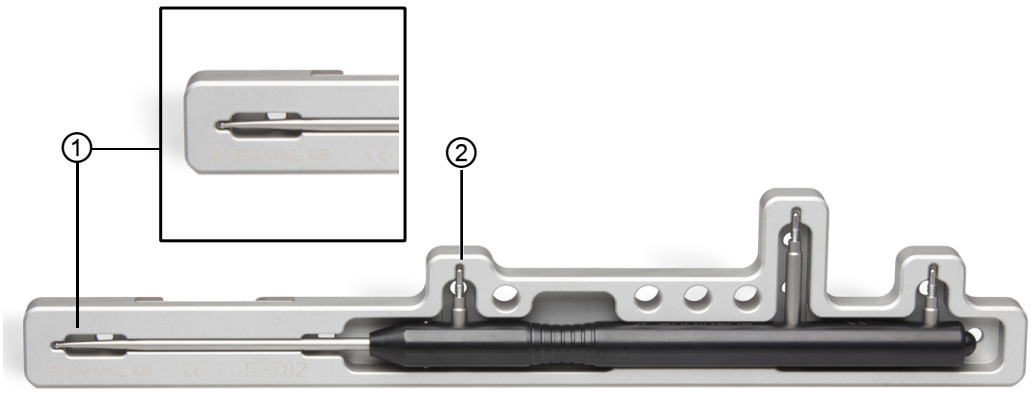



Figure 7

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.**

# 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 Extended for Hip** and **Pointer Angled for Hip and Knee** share the same instrument geometry.*

**Pointer Extended for Hip (53108)**

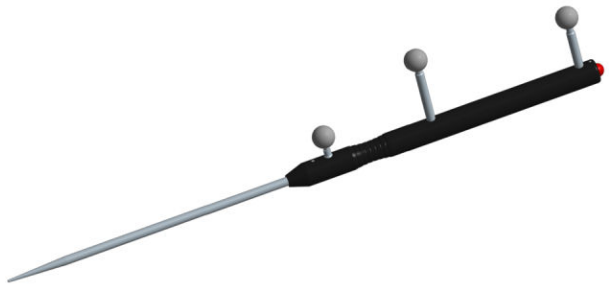


Figure 8

The **Pointer Extended for Hip** is a straight pointer with a longer stem. It enables easier point acquisition on larger patients and of deeper areas, such as the base of the acetabulum, during the registration process. It has a red 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.

**Extended Pointer Sharp Tip (53102)**

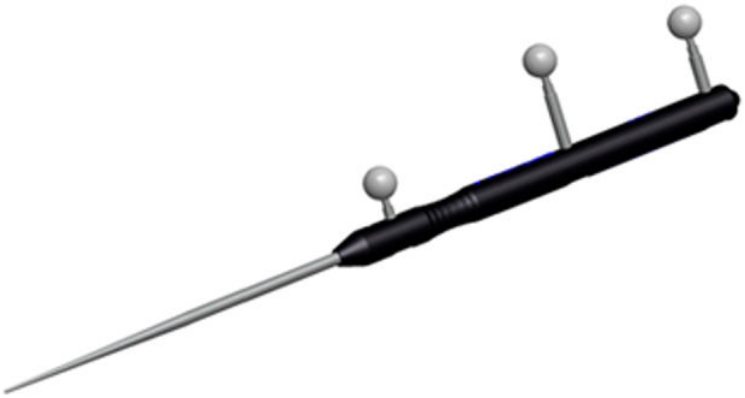


Figure 10

The **Extended Pointer Sharp Tip** facilitates point acquisition in deeper anatomical areas. It also facilitates registration and navigation on larger patients.

# 4.3 Disposable Clip-on Remote Control (53153)

## 4.3.1 Overview

**General Information**

Figure 11

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 Extended for Hip**
- **Pointer Angled for Hip and Knee**
- **Extended Pointer Sharp Tip**

### 4.3.2 Attaching the Disposable Clip-on Remote Control

**Device Overview**

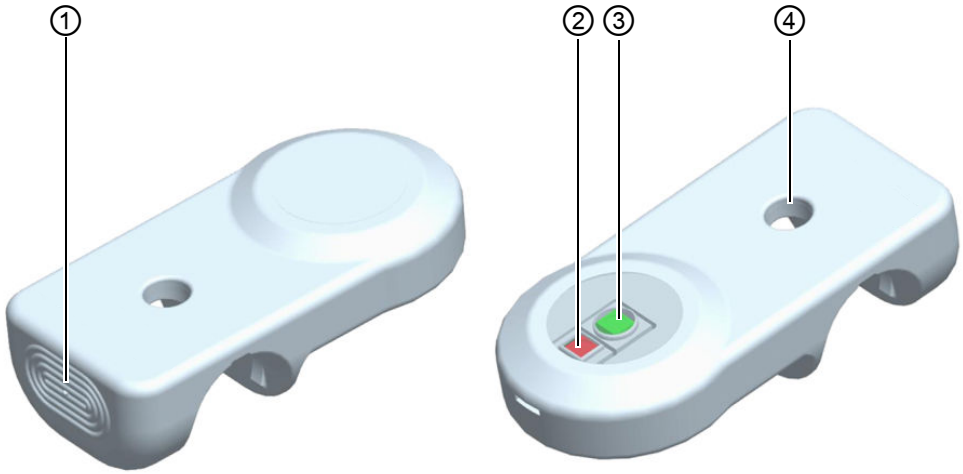



Figure 12

| 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:<br>• The status LED ③ is on<br>• 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

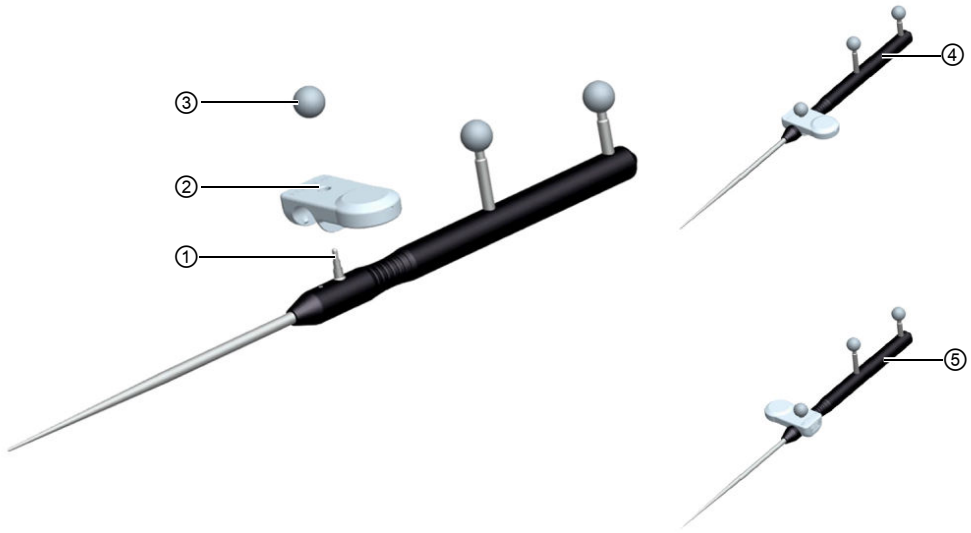



Figure 13

| 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.<br>*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 21). |

*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.**

### 4.3.3 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.**

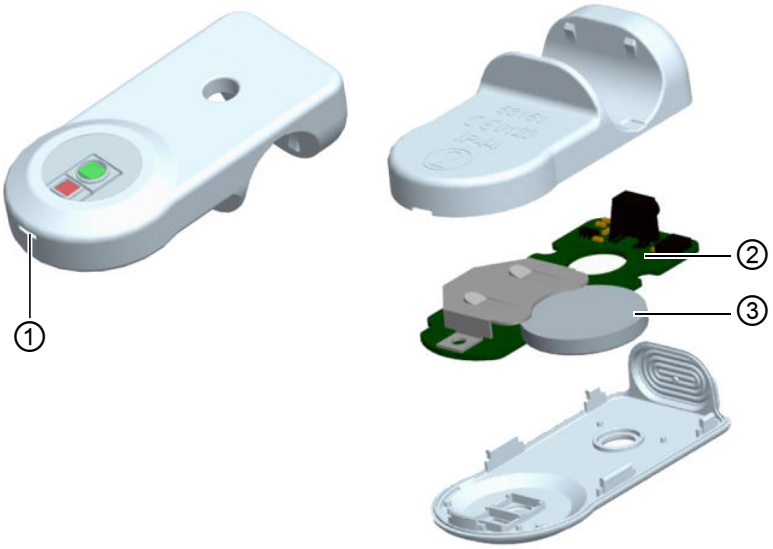
**Safety Consideration**

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

### 4.3.4 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. |  <br>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.**

### 4.3.5 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 |

### 4.3.6 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 | |

### 4.3.7 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<br>+/- 8 kV air | Floors should be wood, concrete or ceramic tile.<br>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 metres (m).[b]<br>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]<br>Interference may occur in the vicinity of equipment marked with this symbol.<br>  | | | |

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment - Guidance |
|---|---|---|---|
| *NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.*<br><br>*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**.<br>[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m. | | | |

### 4.3.8 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<br>1.2 * √P | 80 MHz to 800 MHz<br>1.2 * √P | 800 MHz to 2.5 GHz<br>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 metres (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.<br>*NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*<br><br>*NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.* | | | |

# 4.4 Footswitch (USB) (18460)

## 4.4.1 Overview

### General Information

Figure 14

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.

# 5 HIP CALIPER

## 5.1 Hip Caliper (52876)

### 5.1.1 Using the Hip Caliper

**General Information**

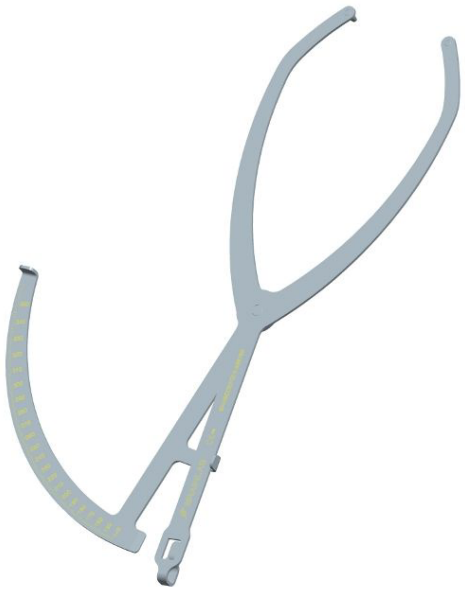


Figure 15

The Brainlab **Hip Caliper** is used to define the distance on distinctive ASIS points for navigated hip surgery using a Brainlab navigation system. This information is required for pelvis definition and navigation of hip implants.

The **Hip Caliper** is intended to be used prior to surgery on intact skin. The degree of accuracy of the device is determined to be +/- 1 mm.

The **Hip Caliper** is not intended for use with any other application or measurements.

**The device shall only be used on intact skin. Sterilize the device if it comes in contact with blood.**

**How to Use the Hip Caliper**

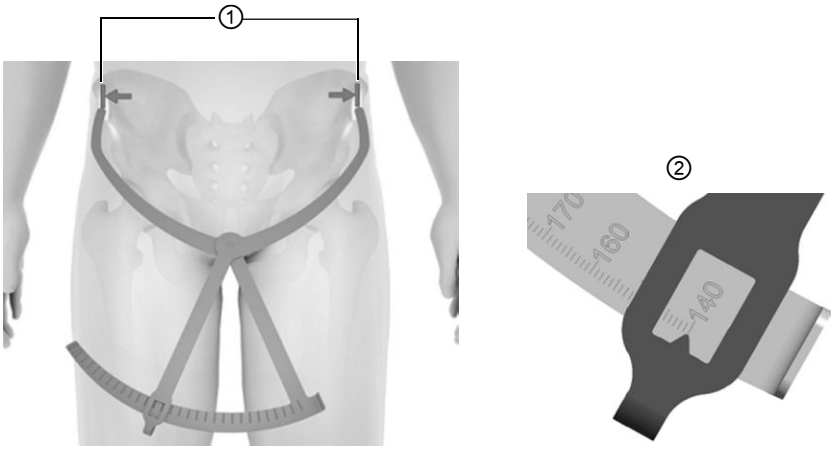



Figure 16

| Steps | |
|---|---|
| 1. | Define two distinctive ASIS landmarks ①.<br>*NOTE: The one on the treated patient side is relocated during subsequent patient registration.* |
| 2. | Place the center of the **Hip Caliper** markers on top of these points ①. |
| 3. | Note the value displayed in the inspection window ②. |

**The Hip Caliper is a highly accurate and sensitive device. To maintain calibration precision, it must be handled with extreme care. If it is dropped or damaged, contact Brainlab immediately for advice on how to proceed.**

# 6 REFERENCE ARRAYS, X-PRESS

## 6.1 Instrument Overview

### 6.1.1 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**

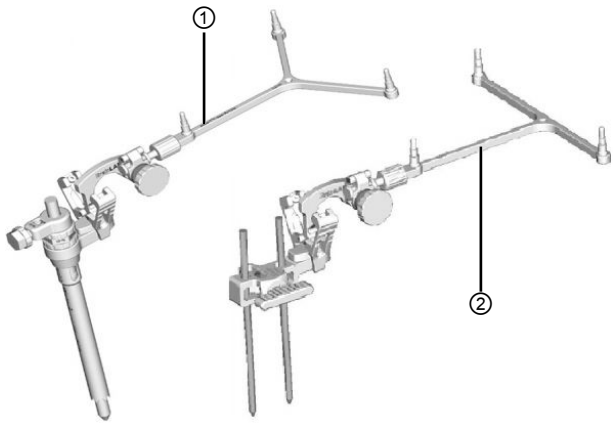



Figure 17

| 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**.*

## 6.1.2 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

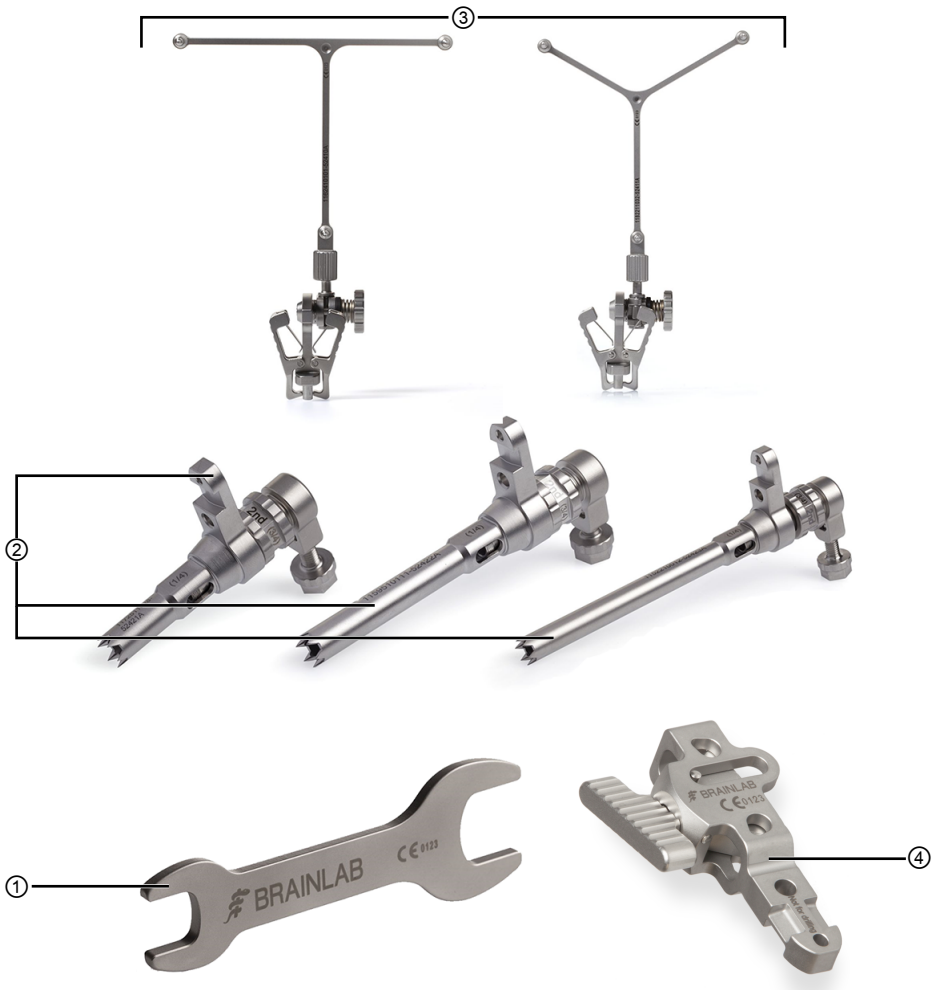



Figure 18

| 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 50) |
| ③ | **Reference Array T Geometry** (52410) and **Reference Array Y Geometry** (52411) (see page 56) |
| ④ | **Bone Fixator “2-Pin”, Flip-Flop, X-Press** (52429) (see page 53) |

# 6.2 Bone Fixators, X-Press

## 6.2.1 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.**

**Always take the size of the implant components into account when placing the Schanz screw of the reference array. If there is a collision during implantation, the arrays have to be removed. Always leave sufficient space to enable incision, implant positioning and cup reaming or drilling without moving the reference arrays.**

**Available Bone Fixators**

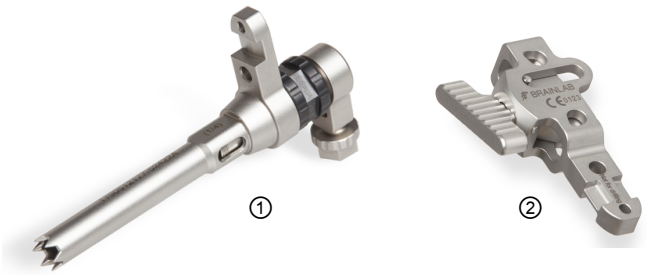



Figure 19

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

## 6.2.2 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**

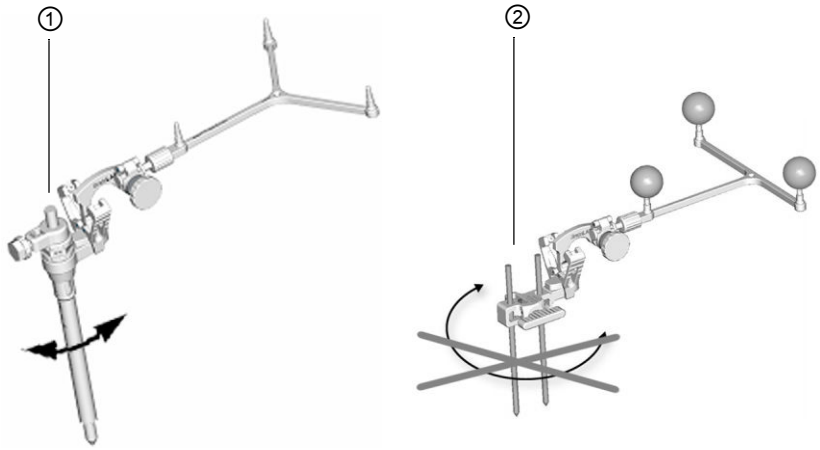



Figure 20

| 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)<br>• 3.2 mm (54922)<br>- **Pin driver Adapter for AO coupling** (54932)<br>• 4 mm (54901 / 54908)<br>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.**

## 6.2.3 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.

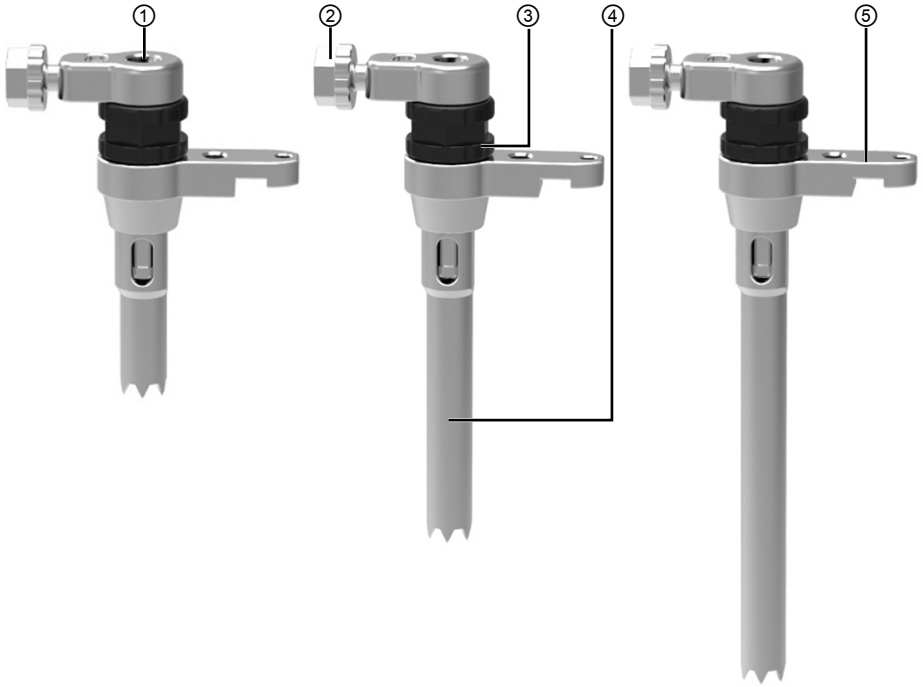



Figure 21

| No. | Component |
|---|---|
| ① | Inlay |
| ② | Fixation screw<br>*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.

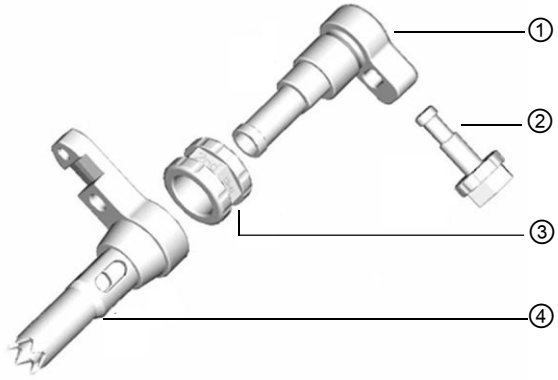



Figure 22

| 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**

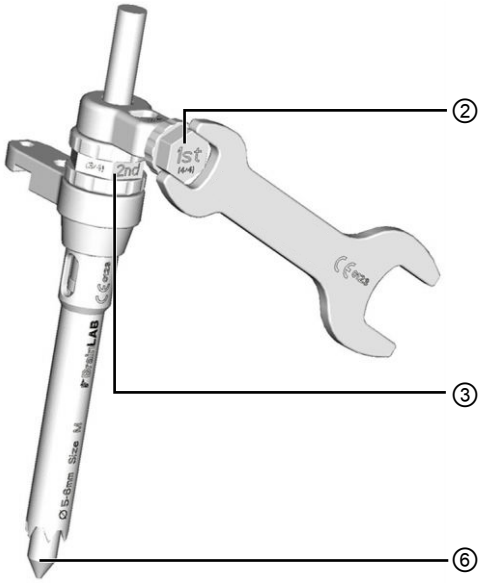



Figure 23

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

| Steps | |
|---|---|
| 2. | Attach reference array to the bone fixator.<br>Ensure that there is no space between traction nut ③ and the inlay.<br>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. |

**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 the 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.**

## 6.2.4 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

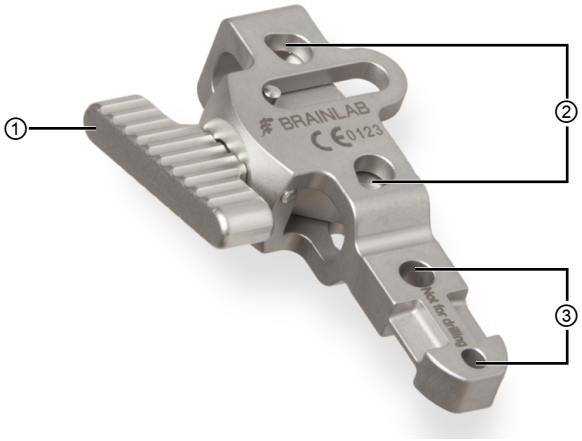



Figure 24

| 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.**

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

**How to Attach the Bone Fixator**

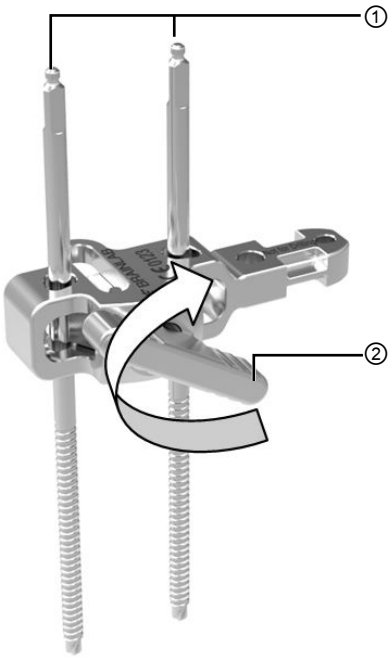



Figure 25

| Steps | |
|---|---|
| 1. | Slide the assembled fixator over the Schanz screws ①.<br>*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 the 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.**

**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.**

# 6.3 Reference Arrays, X-Press

## 6.3.1 Reference Array, X-Press Overview

**Assembled Reference Arrays**

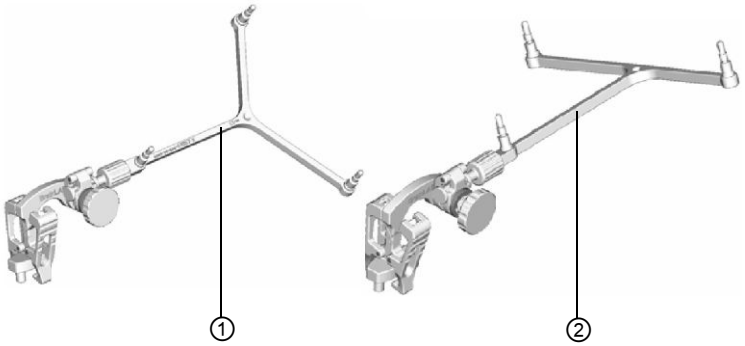



Figure 26

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

**Ensure that the T-geometry and Y-geometry are placed correctly. The T-geometry is pelvis only, and the Y-geometry is femur only.**

**How to Assemble the Reference Array, X-Press**

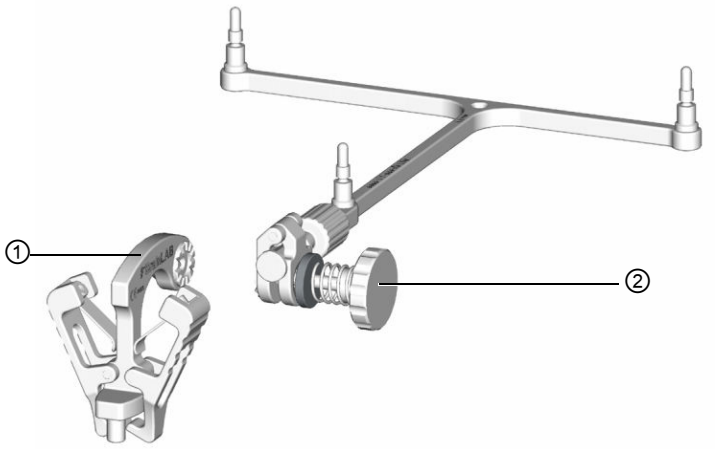



Figure 27

| Step |
|---|
| Screw clamp screw ② into quick fastener ①. |

## 6.3.2 Array Extension (52417)

**General Information**

The **Array Extension** provides an optional extension for the **Reference Array, X-Press**, and is used in combination with the **Bone Fixator “1-Pin”, X-Press,** size small.

**Only use the Array Extension with the size small Bone Fixator “1-Pin”, X-Press. Attaching the Array Extension to a medium or large bone fixator increases the risk of unintentional bending resulting in less accurate navigation.**

**Illustration**


Figure 28

## Attachment Overview

The **Array Extension** is connected between the quick fastener on the **Reference Array, X-Press** and the array itself.

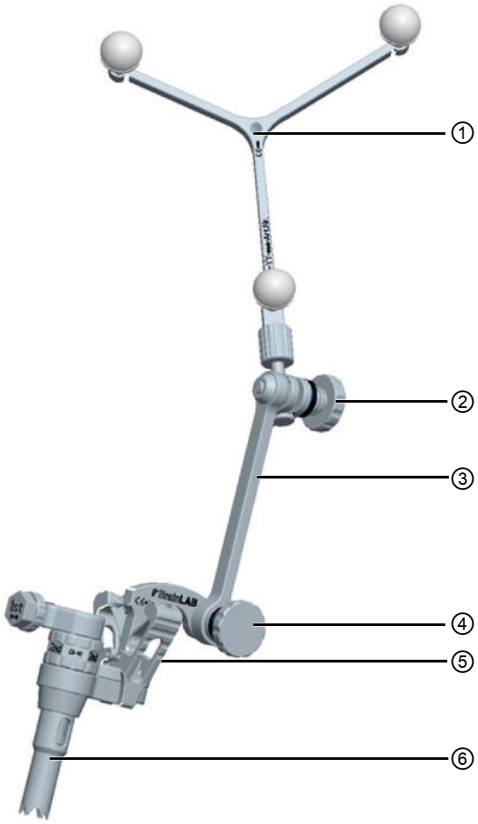



Figure 29

| No. | Component |
|---|---|
| ① | Reference array |
| ② | Clamp screw |
| ③ | Array Extension |
| ④ | Extension screw |
| ⑤ | Quick fastener on the reference array |
| ⑥ | Bone Fixator “1-Pin”, X-Press |

## How to Attach the Array Extension

| Steps | |
|---|---|
| 1. | Screw clamp screw ② into Array Extension ③. |
| 2. | Screw extension screw ④ into quick fastener ⑤. |

**Do not use more than one Array Extension with the reference array as the use of more than one extension would reduce navigation accuracy.**

**If the Bone Fixator “1-Pin”, X-Press size small cannot be securely attached to the bone through the main incision, make a second incision in an area with less tissue covering the**

**bone. Secure fixation of the bone fixator to the bone is critical to ensure accurate navigation.**

---

**During Surgery**

**When using a reference array with the Array Extension, avoid heavy impacts to the patient or to the navigated bone as this may cause unintended bending of the array. Ideally, you should remove the reference array using the quick fastener mechanism (see page 60) for any steps that require impact to the patient or bone. The reference array can be reattached without losing registration information.**

### 6.3.3 Attaching and Detaching the Reference Array

**How to Attach a Reference Array to a Bone Fixator**

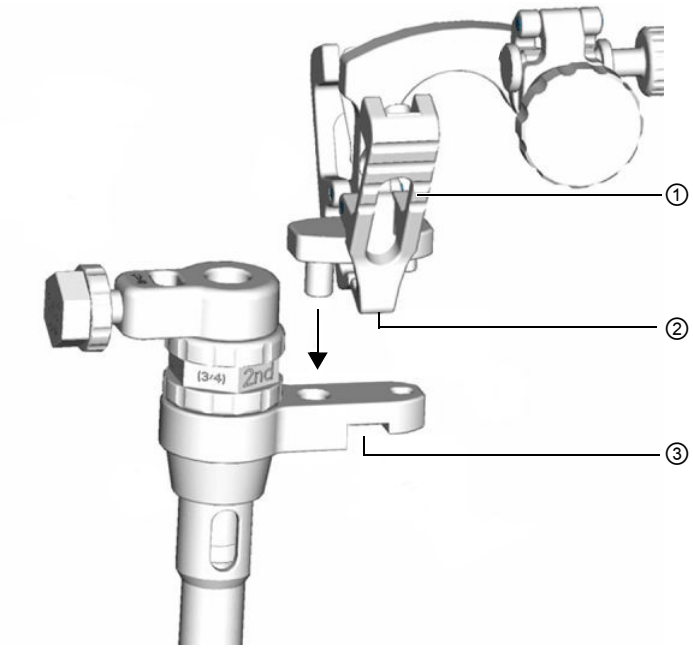



Figure 30

| 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.**

**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.**

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

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

### 6.3.4 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.

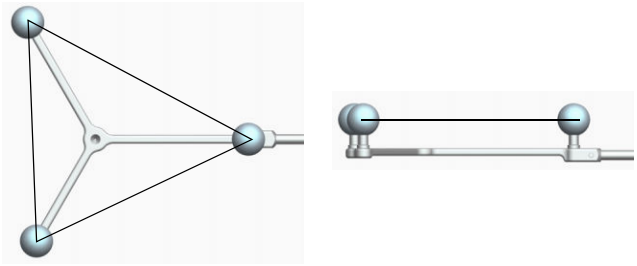


Figure 31

**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.

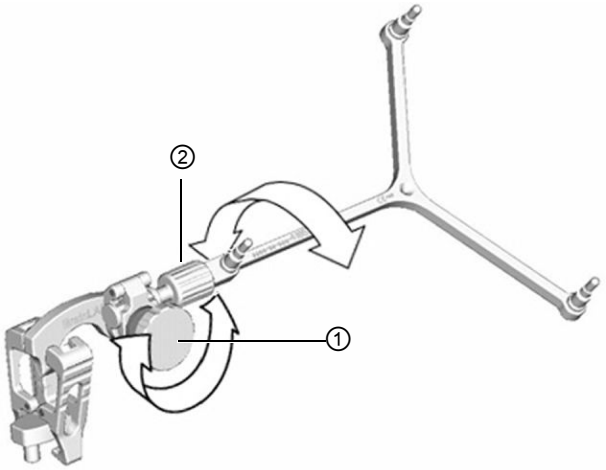



Figure 32

| 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.

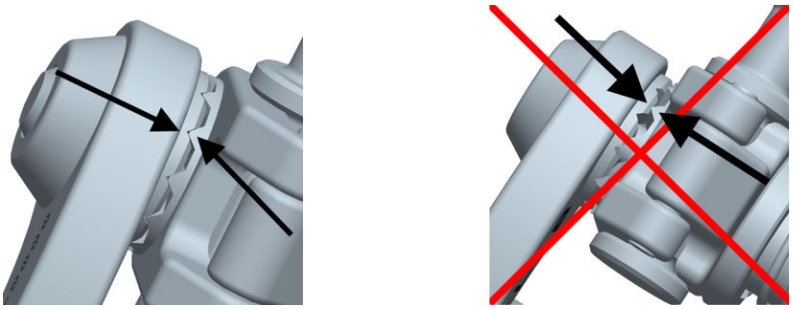


Figure 33

### 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.

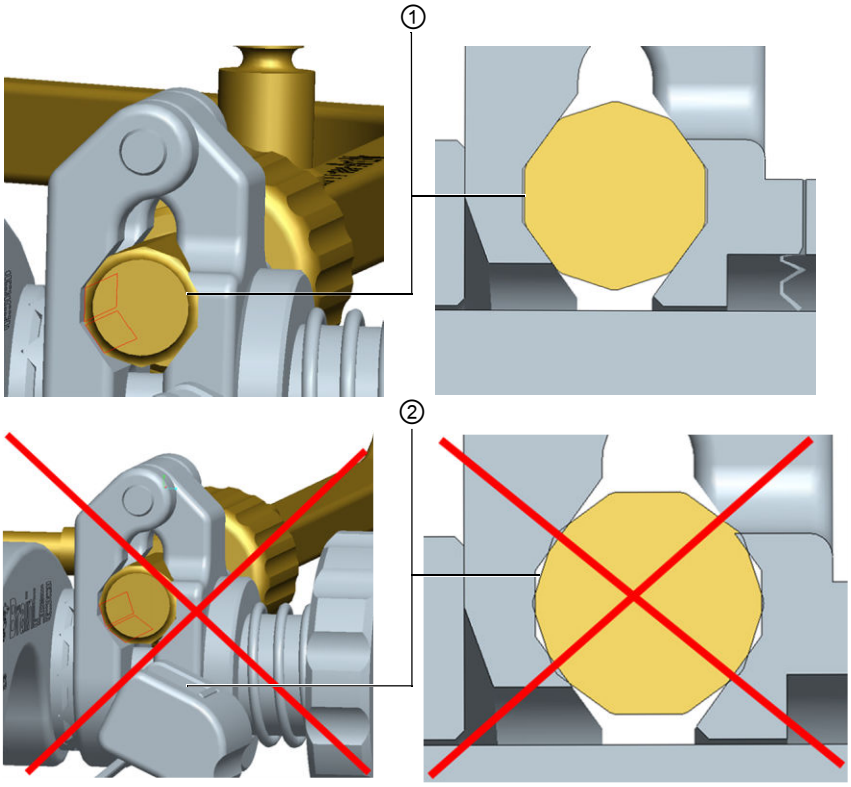



Figure 34

### Before Registration

Attach marker spheres to reference array. For further information, see page 22

**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.**

# 7 PINLESS FEMUR REFERENCE ARRAY

## 7.1 Instrument Overview

### 7.1.1 Introduction

**About the Array**

The **Pinless Femur Reference Array** allows the leg length of the treated femur to be determined during surgery for comparison purposes. These measurements are acquired without additional pins or incisions.

**Pinless Femur Reference Array (52400)**

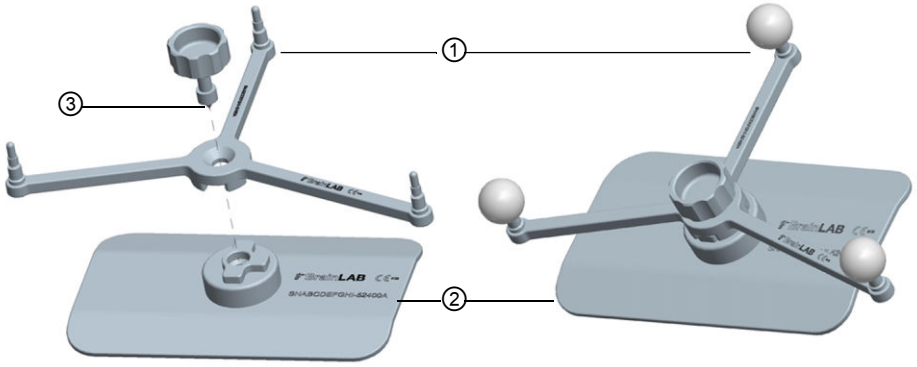



Figure 35

| No. | Component | Explanation |
|---|---|---|
| ① | Reference array | Enables patient tracking. |
| ② | Base plate | Provides base to attach the array to the leg. |
| ③ | Fixation screw with pointed tip | Punctures through the sterile drape and fastens the array to the base plate |

## 7.1.2 Attaching the Base Plate and Reference Array

### Preparation

Before attaching the **Pinless Femur Reference Array**, prepare the patient for surgery and position the patient appropriately in the operating room.

When planning the reference array orientation, bear in mind that the reflective marker spheres must be visible to the camera at all times.

### Marker Sphere Attachment

If not already attached, tightly screw reflective marker spheres onto the attachment pins of the reference array. For further information see page 22.

### Base Plate Positioning

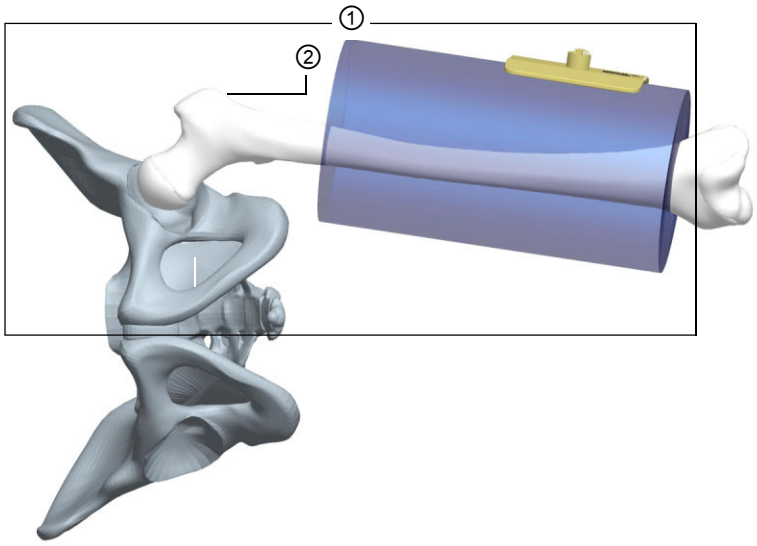



Figure 36

| No. | Component |
|---|---|
| ① | Sterile environment after pelvis registration |
| ② | Side to be treated |

## How to Attach the Pinless Femur Reference Array

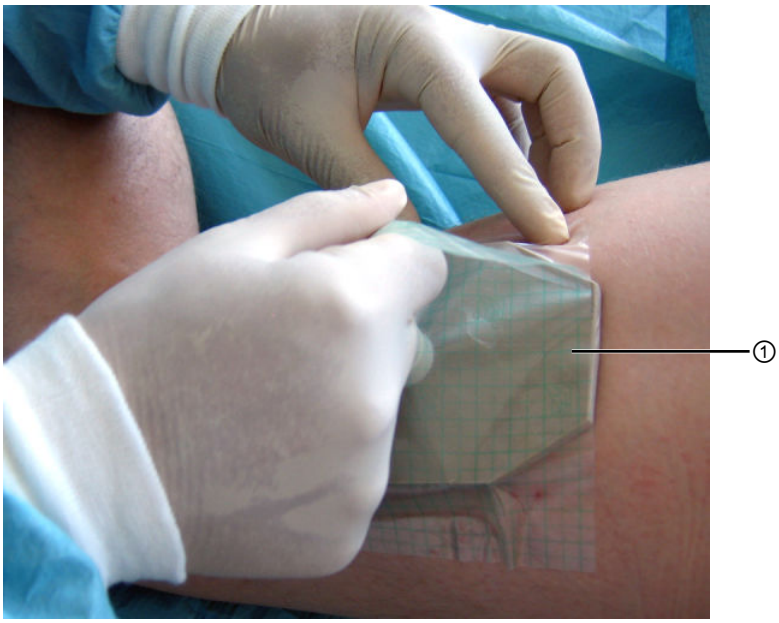



Figure 37

| Steps | |
|---|---|
| 1. | Create a sterile environment on the patients pelvis area and on the femur on the treatment side. |
| 2. | Place the base plate onto the distal femur on the treatment side to enable the reference array to be attached as distally as possible. |
| 3. | Use the sterile self-adhesive drape ① to fix the base plate to the femur. |
| 4. | Wrap the drape around the leg until the base plate is securely fixed to the femur. |
| 5. | Puncture the drape with the pointed tip of the fixation screw and secure the array with the screw.<br>*NOTE: Puncture the drape near the threading of the base plate. Because the base plate is sterile, sterility is not influenced.* |

## Use of Self-Adhesive Drape

The base plate is initially fixed to the patient with strips of adhesive tape. For final fixation, the leg drape can be pulled over the base plate.

The self-adhesive drape is not intended to create a sterile environment, but to affix the base plate to the femur of the patient.

## Ensuring the Reference Array Attachment

**The base plate must be securely fixed to the patient to prevent it from tilting. Tilting could cause inaccurate navigation.**

**Avoid bedsores near the area where the device is attached to the patient's femur by not tightening the drape too tightly.**

# 8 INSTRUMENT ADAPTERS

## 8.1 Using Adapters

### 8.1.1 Overview

**Optimizing Array Angle for Tracking**

The system recognizes an instrument by the geometrical arrangement of the marker spheres on its tracking array.

For the system to identify an instrument, the camera must have a clear view of its marker spheres. The camera viewing angle for best recognition of the array is perpendicular to the plane through the centers of all marker spheres in the array.

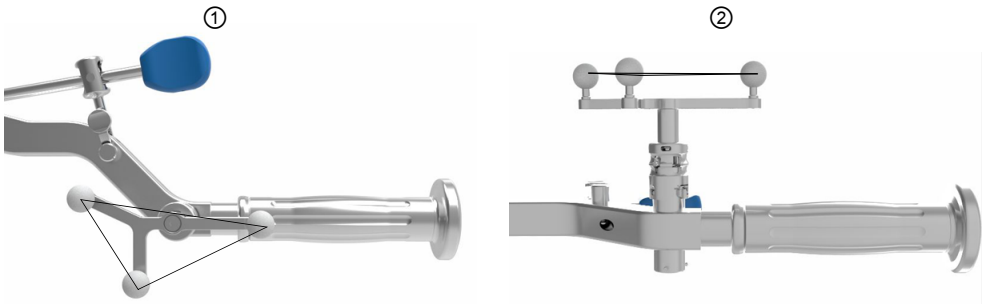



Figure 38

You can optimize the visibility of instruments by:

- Optimally positioning the camera in the operating room (see the **Software User Guide**)
- Orienting arrays on instruments so that during navigation their full geometry is visible to the camera

| No. | Component |
|---|---|
| ① | Optimal viewing angle |
| ② | Least effective viewing angle |

**Attachment Position**

**Attach the tracking array so that the longest arm of the array at 90° to the instrument axis.**

**Calibration**

Attach reflective marker spheres to the array before calibrating the instrument.

**Ensure that all instrument adapter screws and knobs are securely tightened.**

# 8.2 Instrument Adapter, StarLock Interface (55080, 55085)

## 8.2.1 Overview

### General

The **StarLock Instrument Adapter** uses a bayonet-style connector to enable rapid attachment and removal of a tracking array.

It is compatible with precalibrated instruments or 3rd-party instruments to which a **StarLock Adapter Base** has been attached.

### StarLock Adapter

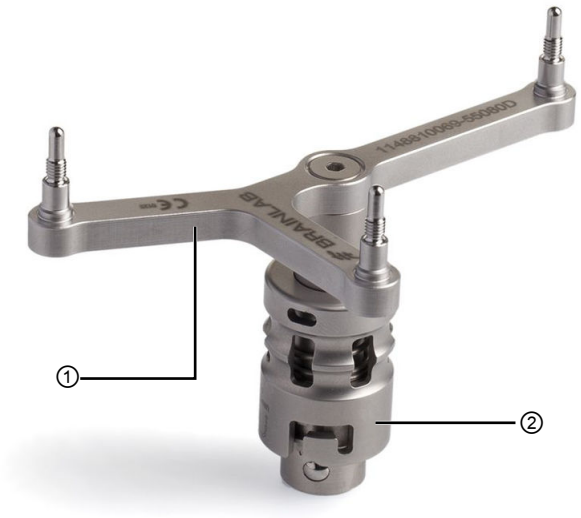



Figure 39

| No. | Component |
|---|---|
| ① | Tracking array |
| ② | Locking sleeve |

### 8.2.2 Attaching the StarLock

**How to Attach the StarLock**

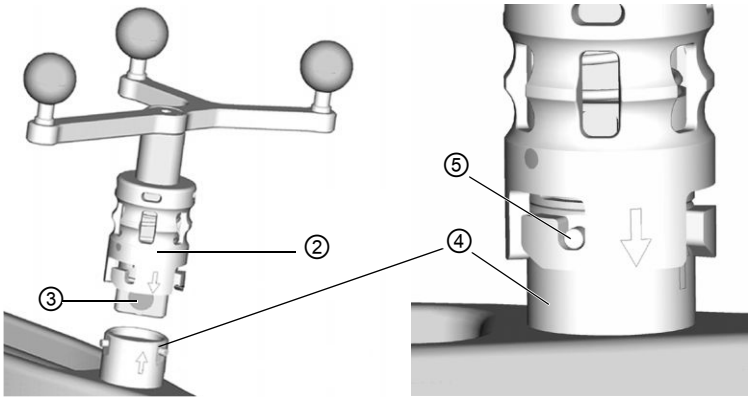



Figure 40

| Steps | |
|---|---|
| 1. | Insert the stem of the StarLock adapter ③ into the base ④, making sure that the engraved arrows are aligned. |
| 2. | Push down the locking sleeve ②, turn it clockwise, and release it so that the locking pins are in the bayonet slots ⑤. |
| 3. | Verify that there is no gap visible between instrument and adapter. |

**The StarLock adapter base should not be soiled with blood or cell tissue.**

# 8.3 Adapter for Cup Inserter (41851)

## 8.3.1 Overview

### General Information

The **Adapter for Cup Inserter** allows you to navigate the axial direction and depth of cup inserters.

### Adapter for Cup Inserter

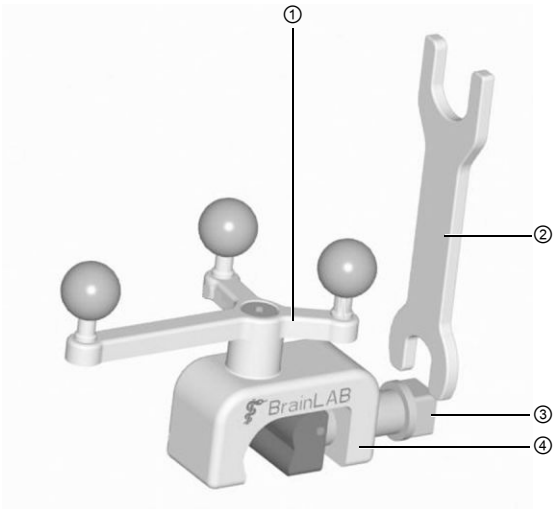



Figure 41

| No. | Component |
|---|---|
| ① | Tracking array |
| ② | Wrench |
| ③ | Clamp bolt |
| ④ | Instrument clamp |

### Instrument Compatibility

The **Adapter for Cup Inserter** has been approved for use with any cup inserter having a straight, cylindrical shaft with a diameter between 6.5 - 17.7 mm. Do not use the adapter with inserters that have a curved shaft.

For more information on compatibility, see the **Software User Guide**.

**If the Adapter for Cup Inserter is used on instruments with a diameter outside the specified diameter parameters, proper fixation cannot be guaranteed, especially in the case of vibrations.**

**Using the instrument adapter with a curved cup inserter may result in inaccurate instrument tracking, which could be hazardous to the patient.**

**Using a cup inserter other than that specified by the implant manufacturer may lead to miscalibration of the cup inserter.**

## 8.3.2 Attaching the Adapter for Cup Inserter

**Where to Attach the Adapter for Cup Inserter**

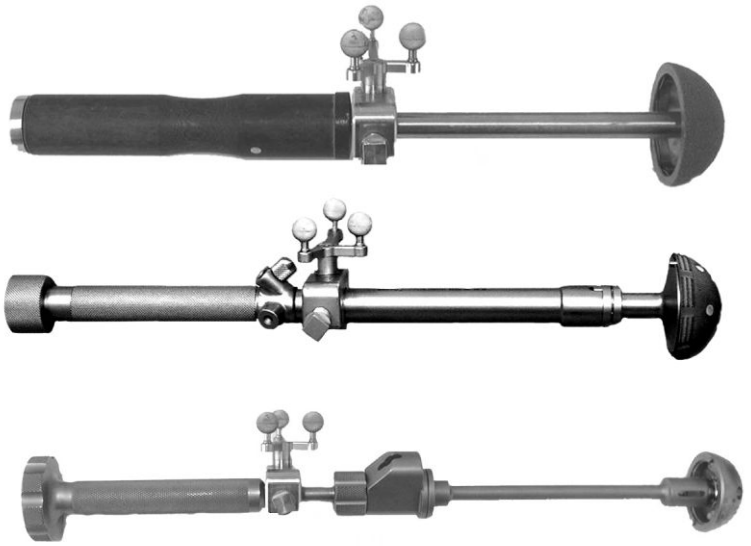


Figure 42

- Position the adapter so that it will not come into contact with patient tissue while the instrument is in use.
- Attach the **Adapter for Cup Inserter** as close to the handle of the cup inserter as possible.

**How to Mount the Adapter for Cup Inserter**

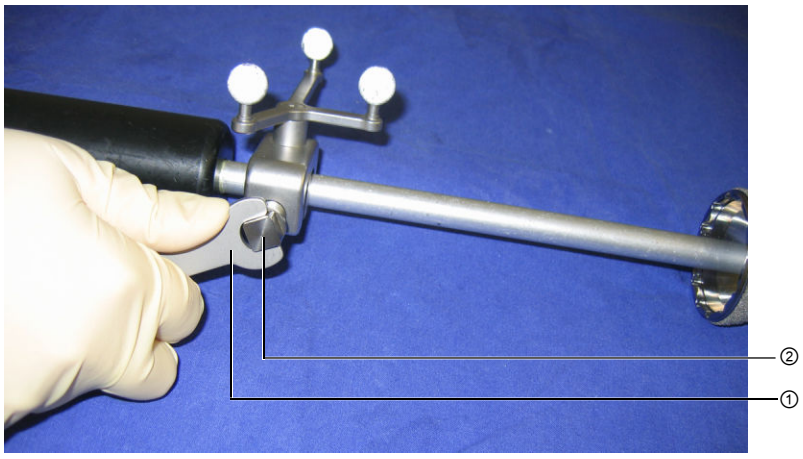



Figure 43

| Steps | |
|---|---|
| 1. | Mount the adapter onto the inserter shaft as close to the handle as possible. |
| 2. | Adjust the position of the adapter so that it will not interfere with the surgeon's work during surgery. |
| 3. | Tighten the clamp bolt ② using the supplied wrench ①.<br>*NOTE: Further adjustments are not possible after tightening the clamp bolt.* |
| 4. | Calibrate the instrument using the **ICM4** after mounting the adapter to the cup inserter. |

**Use the supplied wrench to tighten the clamp bolt to prevent the adapter from moving.**

**Mount the Adapter for Cup Inserter onto the inserter shaft as close to the handle as possible.**

# 8.4 Cup Reamer Adapter (41879)

## 8.4.1 Overview

### General Information

The **Cup Reamer Adapter** may only be used with the compatible cup reamer handles. For more information on compatibility, see the **Software User Guide**.

**The Cup Reamer Adapter may only be used in combination with specified instruments. Brainlab does not assume liability if the Cup Reamer Adapter is used in combination with non-approved instruments.**

### Cup Reamer Adapter Components

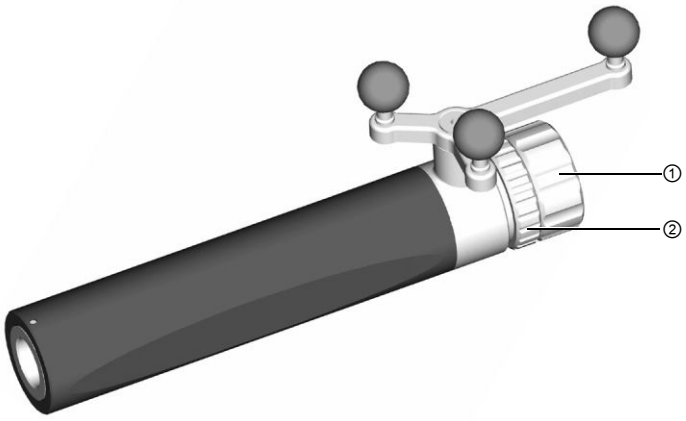



Figure 44

| No. | Component |
|---|---|
| ① | Adjustment nut |
| ② | Counter nut |

### How to Assemble

| Step |
|---|
| Screw the counter nut ② and adjustment nut ① onto the **Cup Reamer Adapter**. |

## 8.4.2 Attaching the Cup Reamer Adapter

**Before You Begin**

Note the specific instructions for each manufacturer.

| Options |
|---|
| If you are using a Precimed EZ-Clean reamer handle, attach the ring and sleeve before attaching the adapter to the instrument. |
| If you are using a cup reamer from any other manufacturer, attach the adapter directly to the handle. |

**How To Attach the Ring and Sleeve (Precimed Only)**

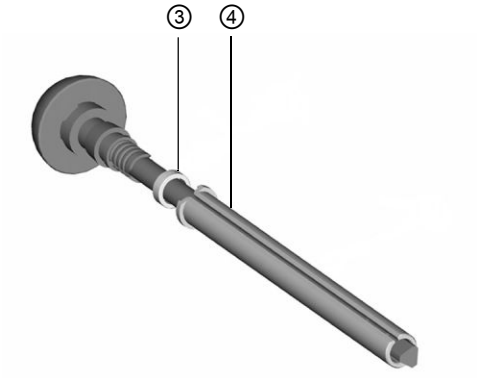



Figure 45

| Steps | |
|---|---|
| 1. | Before attaching the **Cup Reamer Adapter**, slide the ring ③ over the reamer shaft. |
| 2. | Slide the sleeve ④ over the reamer shaft. |

**How To Attach the Cup Reamer Adapter**

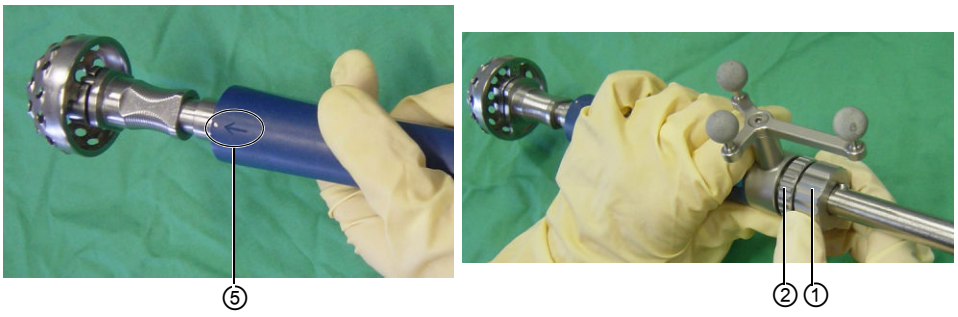



Figure 46

| Steps | |
|---|---|
| 1. | If you are using a Precimed EZ-Clean cup reamer handle, attach the ring. |
| 2. | Slide the adapter over the reamer shaft (or the sleeve, in the case of Precimed). |
| 3. | Make sure that the arrow ⑤ on the **Cup Reamer Adapter** points toward the head of the cup reamer handle. |
| 4. | Tighten the adjustment nut ①. |

| Steps | |
|---|---|
| 5. | Tighten the counter nut ②. Make sure that the reamer can still be easily rotated. Tight attachment ensures accurate reamer navigation. |

**The Cup Reamer Adapter may only be attached to the reamer handle with the arrow pointing towards the head of the cup reamer handle.**

**Make sure that both the counter and adjustment nuts are properly tightened before navigation.**

**Always use the Cup Reamer Adapter, with it pushed forward as close as possible towards the head of the reamer handle. This ensures maximum accuracy.**

### Attaching the Clip

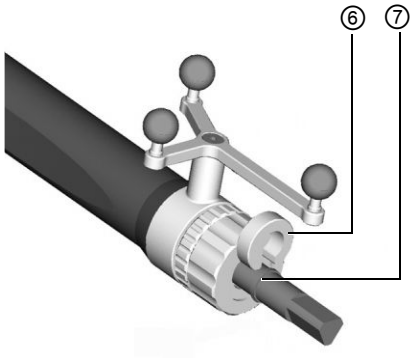



Figure 47

| Step |
|---|
| If you are using a Precimed or Zimmer Full Hemisphere reamer handles, attach the clip ⑥ between the **Cup Reamer Adapter** and the notch ⑦ on the reamer shaft. |

*NOTE: If you are using a cup reamer from any other manufacturer, it is not necessary to attach a clip.*

### Correct Instrument Handling

**Do not use the Cup Reamer Adapter if you notice critical inaccuracies or loose attachment, even after tightening. In such cases, contact Brainlab immediately for advice on how to proceed.**

# 8.5 Femoral Broach Adapter “DePuy” (41852)

## 8.5.1 Overview

**General Information**

The **Femoral Broach Adapter “DePuy”** may only be used in combination with selected DePuy broaches.

**Femoral Broach Adapter “DePuy”**

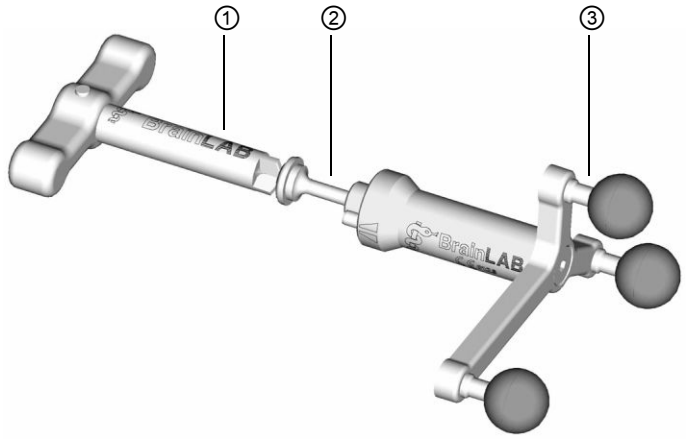



Figure 48

| No. | Component |
|---|---|
| ① | Screwdriver |
| ② | Screw |
| ③ | Tracking array |

**Correct Instrument Handling**

**Using a hammer to insert the broach may cause the marker spheres to loosen. Check the marker spheres at regular intervals to make sure that they remain securely attached.**

**The Femoral Broach Adapter “DePuy” may only be used with specially-modified broach handles.**

## 8.5.2 Attaching the Femoral Broach Adapter “DePuy”

**How to Attach the Femoral Broach Adapter “DePuy”**

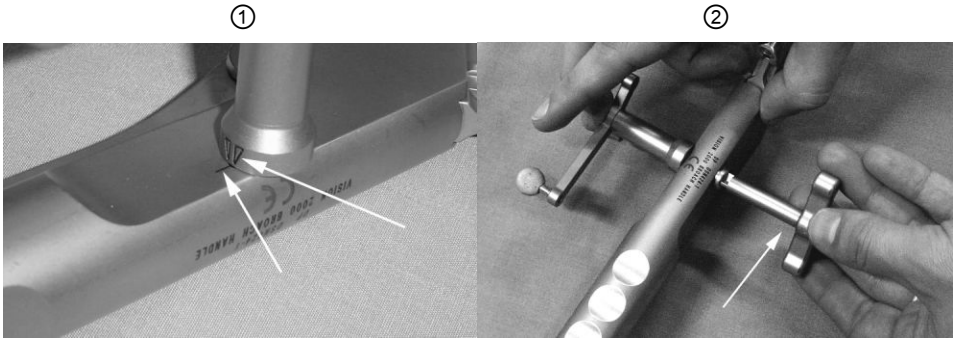



Figure 49

| Steps | |
|---|---|
| 1. | Insert the adapter into the insertion hole on the broach handle. |
| 2. | Make sure that the engraving on the adapter is aligned with the marking on the broach ①. |
| 3. | Tighten the adapter. The supplied screw was specially developed to withstand sustained impact. Only use this screw and the supplied screwdriver to tighten or adjust the screw ②. |

**Correct Handling**

**Only use the wrench provided by Brainlab to tighten the adapter. This protects the screw and ensures a stable connection.**

**To ensure that the adapter is properly aligned, it must be inserted into the designated opening on the modified broach handle, and aligned using the arrow on the adapter and the marking on the broach handle.**

# 9 SURGICAL INSTRUMENTS

## 9.1 Stem Position Verification Tools

### 9.1.1 Overview

**Use**

The Brainlab **Stem Position Verification Tools** are attached to an inserted stem implant to verify stem placement.

| Instrument | Article Number |
|---|---|
| Stem Position Verification Tool Extended | 52873 |

**Compatibility**

These tools can only be used with specified stem implant systems. At the time of this manual revision, the **Stem Position Verification Tools** can be used with:

- DePuy AML Stems (Plus/ LG/ SM)
- Corail AMT Stems
- G2 Stems
- Proxima Stems
- Replica A Stems
- S-ROM Stems (11/13, 12/14, 9/10)
- Summit Stems
- Trilock BPS Stems
- Zimmer Alloclassic SL/SL HAC/ SLL/ SLO/ SLV, CLS stems (145°, 135°, 125°)
- Smith & Nephew Anthology stems

*NOTE: **Stem Position Verification Tools** can also be used for verification of the DePuy 11/13 SROM, DePuy 12/14 Corail AMT, and Smith & Nephew integrated 12/14 trial implants.*

**Only use a Stem Position Verification Tool with its specified stem implants.**

## Stem Position Verification Tools


Figure 50

| No. | Component | |
|---|---|---|
| ① | Stem Position Verification Tool Extended | |
| ② | Exchangeable attachment | Black: for use with DePuy stem implants |
| ③ | | Blue: for use with Zimmer stem implants |
| ④ | | Green: for use with Smith & Nephew stem implants |

## Correct Use

**Use the Stem Position Verification Tools only for verification of stem position – they are not designed to navigate stem placement.**

**If the orientation of the Stem Position Verification Tool changes after a point has been acquired on the stem, verification of the stem's position is no longer valid, e.g., if the connection between the stem or the tracking array is altered in relation to the Stem Position Verification Tool.**

# 9.2 Offset Cup Impactor Universal (52856)

## 9.2.1 Overview

**General Information**


Figure 51

The **Offset Cup Impactor Universal** enables navigated positioning of an acetabular cup implant through a small incision. Its offset design allows minimally-invasive transmission of impaction force directly to the acetabulum.

The **Offset Cup Impactor Universal** comes with exchangeable threaded tips and nosepieces to adapt it for use with different types of cup implants.

For more information check the interface compatibility on page 101.

It has a stem mount for attachment of the **StarLock Instrument Adapter** to enable tracking of the instrument during computer-aided surgery.

## Components

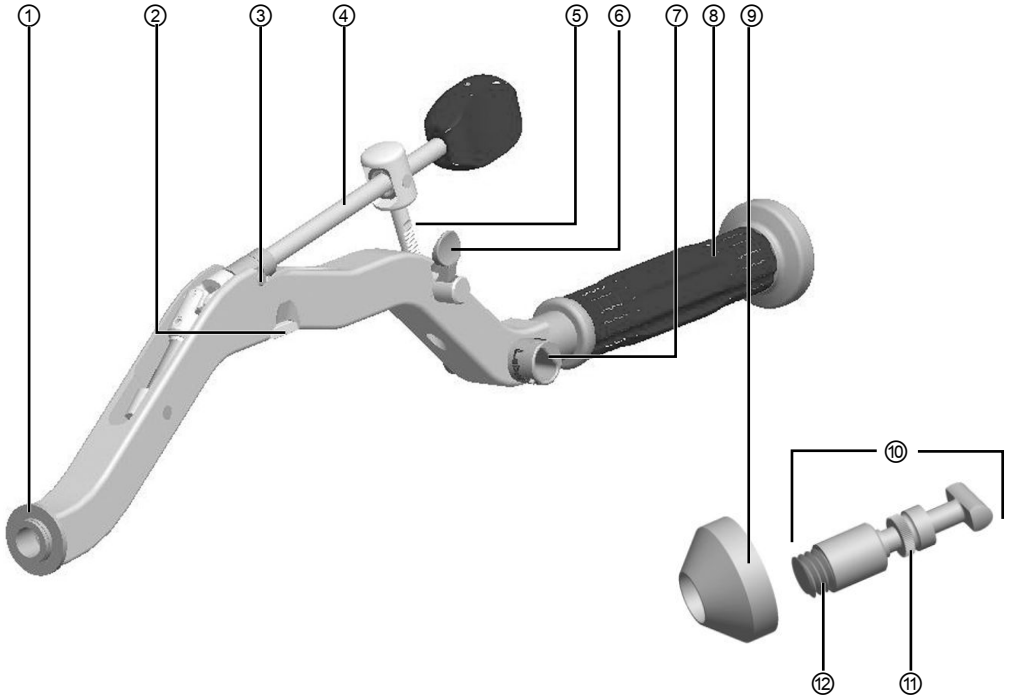



Figure 52

| No. | Component |
|---|---|
| ① | Nose: Insertion point for implant specific nosepieces |
| ② | Release lever for tip driveshaft |
| ③ | Notch for tip driveshaft alignment pins |
| ④ | Tip driveshaft with ergonomic knob (blue) |
| ⑤ | Ratchet |
| ⑥ | Release lever for ratchet |
| ⑦ | Mounting base for the **StarLock Instrument Adapter** |
| ⑧ | Handle (blue) |
| ⑨ | Nosepiece |
| ⑩ | Threaded tip |
| ⑪ | Locking nut |
| ⑫ | Thread |

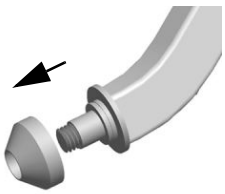
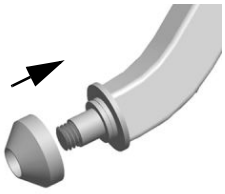
## 9.2.2 Removing and Replacing the Impactor Nosepiece

**General Information**

The **Offset Cup Impactor Universal** nosepieces and threaded tips adapt the impactor for use with various implant types.

Before using the impactor, attach the correct tip and nosepiece for the implant you intend to use.

**How to Remove and Replace the Nosepiece**

| Steps | |
|---|---|
|  | To remove the nosepiece, gently pry it off the nose of the impactor. |
|  | To replace the nosepiece press it onto the nose of the impactor until you hear a click. |

## 9.2.3 Changing the Threaded Tip

### General Use

The exchangeable threaded tips of the **Offset Cup Impactor Universal** are designed for use with specific implants.

Make sure that the implant-compatible threaded tip is attached to the impactor.

**Be certain to attach the correct threaded tip and nosepiece for the implant. Using an incompatible threaded tip or nosepiece may result in the implant not coming free of the impactor.**

### Overview

The procedure for changing the threaded tip entails the steps outlined in the table below and described in more detail on the following pages.

| Steps | See |
|---|---|
| Remove the nosepiece | Page 85 |
| Release the ratchet | Page 86 |
| Release the driveshaft | Page 87 |
| Change the threaded tip | Page 87 |
| Re-insert the tip into the impactor | Page 87 |

### How to Release the Ratchet

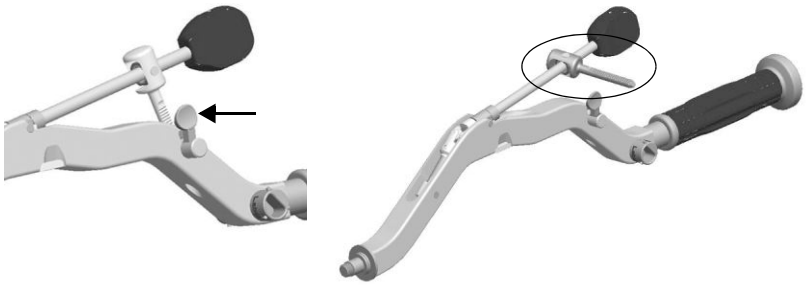


Figure 53

| Steps | |
|---|---|
| 1. | Press the ratchet release lever and lift the tip driveshaft to free the ratchet from the shaft. |
| 2. | Slide the barrel of the ratchet toward the blue knob of the driveshaft until the ratchet is free and able to move freely up and down the driveshaft. |

**How to Release the Driveshaft**

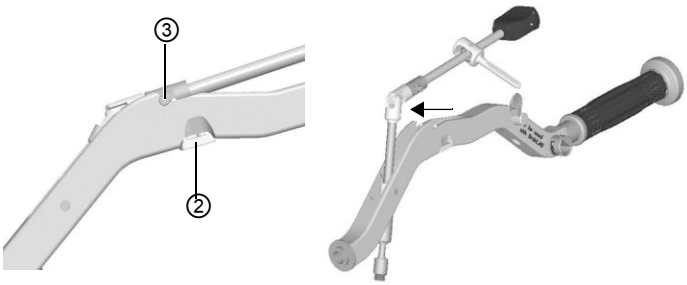



Figure 54

| Steps | |
|---|---|
| 1. | While holding down the driveshaft release lever ②, pull the driveshaft back (toward the impactor handle) and upward to free the alignment pins from the notches ③. |
| 2. | Lift the driveshaft upwards and bend it at its first joint (arrow) to disengage the tip from the nose and free the driveshaft from the impactor body. The tip should now hang free of the nose. |

**How to Remove and Replace the Threaded Tip**

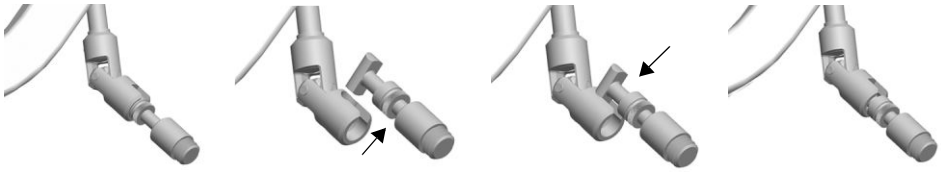


Figure 55

| Steps | |
|---|---|
| 1. | Unscrew the locking nut of the threaded tip. |
| 2. | Slide the old tip out of the driveshaft end joint. |
| 3. | Introduce the new tip into the driveshaft end joint. |
| 4. | Once the tip is fully inserted, tighten the locking nut finger-tight. |

**How to Re-insert the Tip into the Impactor**

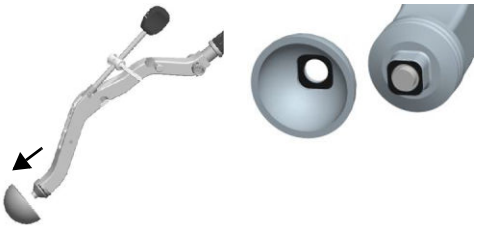
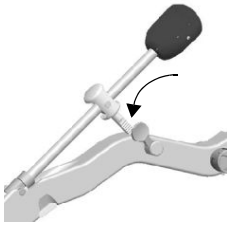
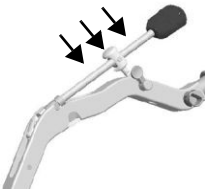
| Steps | |
|---|---|
| 1. | Bend the driveshaft at both joints and insert the tip into the impactor nose. |
| 2. | Straighten the driveshaft and press it down toward the shaft of the impactor until the locking pins click into place in the alignment notches.<br>The tip should now project from the nose of the impactor. |
| 3. | Attach the implant-specific nosepiece by pressing it onto the nose of the impactor until you hear it click in place.<br>The impactor is now ready for you to affix the implant. |

### 9.2.4 Affixing and Locking the Implant on the Impactor

**How to Affix the Implant**

**Some implants and their corresponding nosepiece tips have a squared or hexagonal interface. Make sure to correctly orient the interface of both components when introducing the nosepiece tip of the impactor into the implant.**

**Do not overtighten. Overtightening can destroy the thread of the impactor tip and may make it difficult to release the implant.**

| Steps | |
|---|---|
| 1. | If the ratchet is not released, release the ratchet (see page 86). |
| 2. | Introduce the impactor tip into the center (threaded) hole of the implant.<br>  |
| 3. | Screw the impactor tip into the implant by turning the blue knob on the end of the tip driveshaft clockwise. |
| 4. |  <br>With the implant on the impactor tip, re-introduce the ratchet into the matching hole. |
| 5. | Press down gently on the driveshaft to engage the ratchet. You should hear three clicks.<br>  <br>After three clicks, the implant should still be free to rotate when the blue driveshaft knob is turned. |

### 9.2.5 Steps Prior to Impaction

**Before Impaction**

The order of your next steps depends on the type of implant you are using.

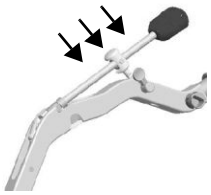
| Options |
| --- |
| If you do not need to be able to turn the implant for alignment, your next steps are:<br>• Lock the implant down onto the impactor<br>• Attach the **StarLock Instrument Adapter** to the impactor<br>• Introduce the implant into the patient<br>• Perform impaction |
| If you are using an implant with screw holes, and will need to be able to turn the implant to align it, your next steps are:<br>• Attach the **StarLock Instrument Adapter** to the impactor<br>• Introduce the implant into the patient and align the screw holes as needed by turning the blue knob clockwise<br>• Lock the implant down onto the impactor<br>• Perform impaction |

**If you encounter any difficulties screwing the implant onto the impactor, continue the procedure using your standard impactor (non-navigation), and inform Brainlab immediately.**

**Locking the Implant onto the Impactor**

Locking the implant down onto the impactor takes the pressure off the implant threads so that they are not stripped during impaction.

**Be sure to lock the implant to the impactor prior to impaction. If you fail to do so, the force of impaction may destroy the threads of the impactor or the implant, making it difficult or even impossible to remove the implant from the impactor.**

| Step |
| --- |
|  To lock the implant down onto the impactor, press the driveshaft firmly toward the impactor body until you can no longer rotate the implant by turning the blue knob.<br>Once the implant is locked, you can perform impaction. |

**Using the StarLock Instrument Adapter**

To enable computer-aided tracking of the impactor during surgery, you must attach the **StarLock Instrument Adapter** (see page 70).

**All reflective marker spheres on the StarLock Instrument Adapter must be visible to the camera while the instrument is being navigated.**

**Before beginning navigation, make sure that the StarLock Instrument Adapter is correctly attached to the impactor and that the reflective marker spheres can be detected by both camera lenses.**

### 9.2.6 Releasing the Implant after Impaction

**How to Release the Implant**

| Steps | |
|---|---|
| 1. | Press the ratchet release lever. The ratchet mechanism releases. |
| 2. | Unscrew the impactor tip completely from the implant by turning the blue knob on the drive-shaft counter-clockwise. |
| 3. | Pull the impactor out. |

# 9.3 Straight Cup Impactor Universal (52858)

## 9.3.1 Overview

**General Information**

Figure 56

The **Straight Cup Impactor Universal** enables navigated positioning of a multiple acetabular cup implants through an incision. It allows minimally-invasive transmission of impaction force directly to the acetabulum.

The **Straight Cup Impactor Universal** comes with exchangeable threaded tips and nosepieces to adapt it for use with different types of cup implants.

For more information check the interface compatibility on page 101.

It has a detachable mounting base to connect to the **StarLock Instrument Adapter** to enable tracking of the instrument during computer-aided surgery.

**Instrument Handling**

**If the Straight Cup Impactor Universal has been damaged or dropped on the floor, it should no longer be used. Contact Brainlab immediately for advice on how to proceed.**

## Components

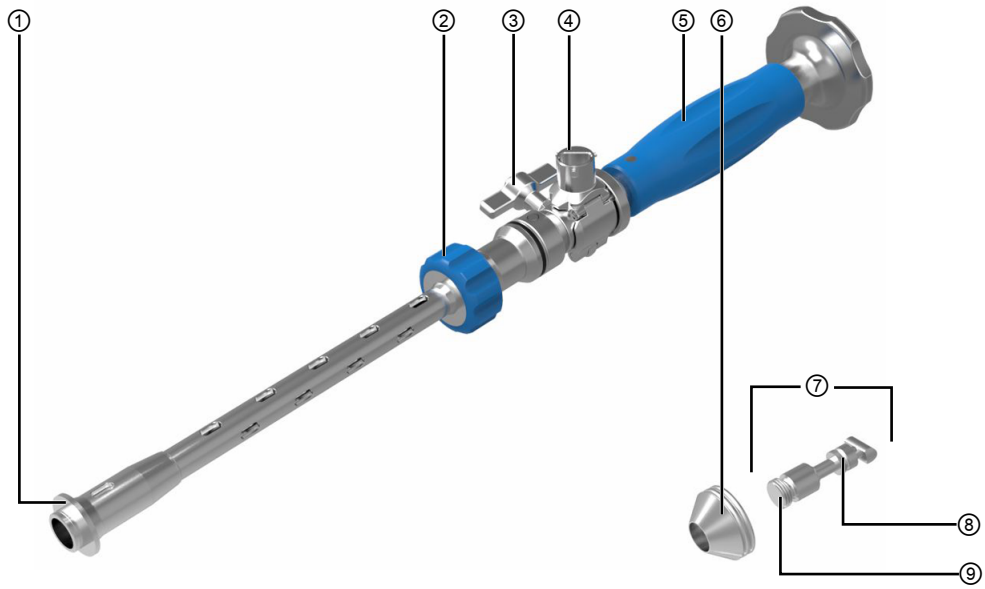
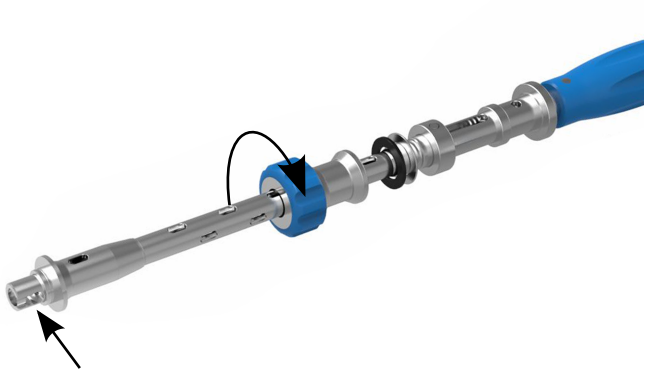
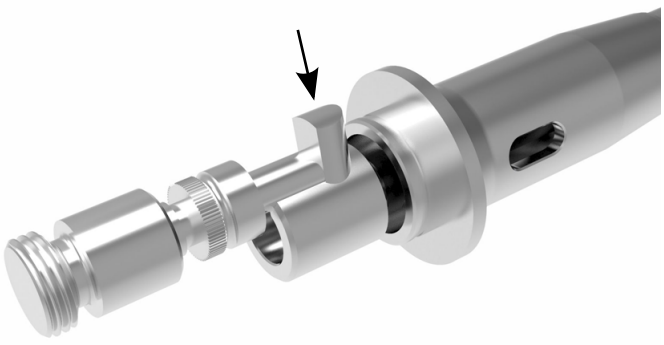
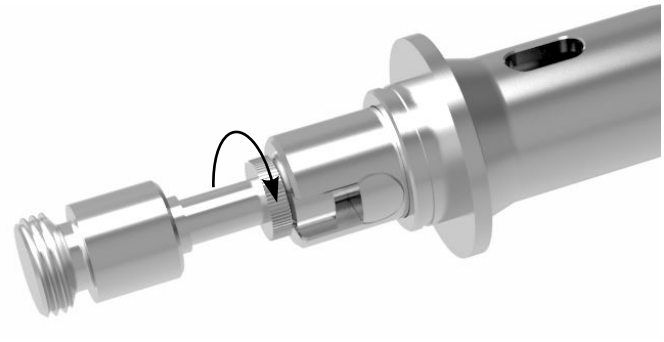


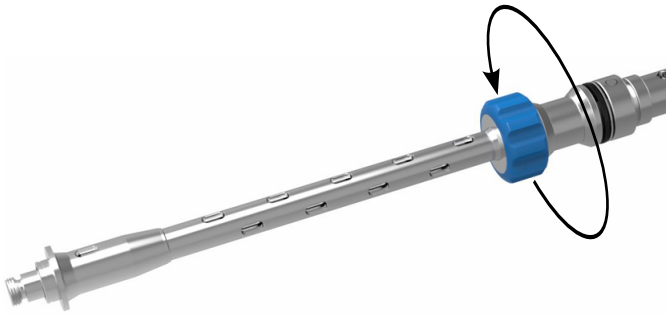
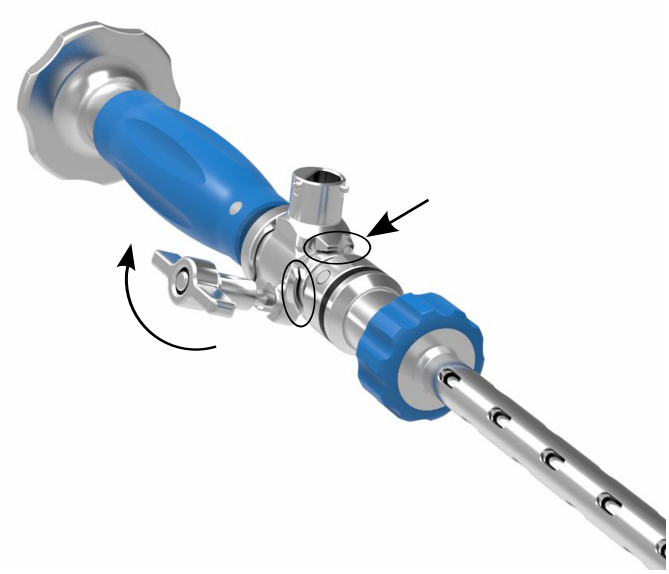

Figure 57

| No. | Component |
|---|---|
| ① | Nose-insertion point for implant-specific nosepieces |
| ② | Handling nut (blue) |
| ③ | Wingscrew |
| ④ | Mounting base for the **StarLock Instrument Adapter** |
| ⑤ | Handle (blue) |
| ⑥ | Nosepiece |
| ⑦ | Threaded tip |
| ⑧ | Locking nut |
| ⑨ | Thread |

## 9.3.2 Assembling the Straight Cup Impactor

**How to Assemble the Straight Cup Impactor**

| Steps |
| --- |
| 1.  Release the handling nut completely by turning it counter-clockwise and sliding the drive-shaft until the end is completely visible. |
| 2.  Introduce the implant-specific threaded tip into the driveshaft end joint. |
| 3.  Once the tip is fully inserted into the end joint, tighten the locking nut hand-tight to secure the tip. |

| Steps |
| --- |
| 4.  Screw the blue handling nut clockwise a few turns onto the thread. |
| 5.  Attach the implant-specific nosepiece by pressing it onto the impactor until you hear a click (symmetrical nosepieces only). |
| 6.  Position the mounting base for the **Straight Cup Impactor Universal** in the correct orientation and lock the wingscrew. |

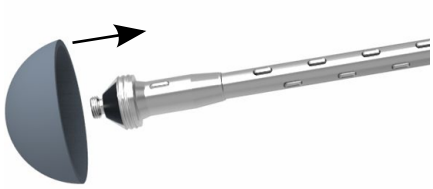
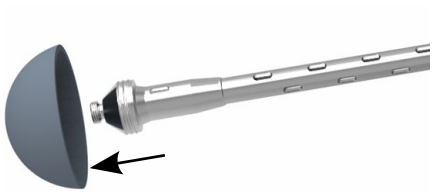
## 9.3.3 Adding and Removing the Impactor Nosepiece

**General Information**

The **Straight Cup Impactor Universal** nosepieces and threaded tips adapt the impactor for use with various implant types.

Before using the impactor, attach the correct tip and nosepiece for the implant you intend to use.

**How to Add and Remove the Nosepiece**

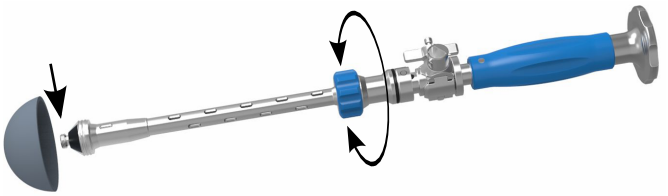
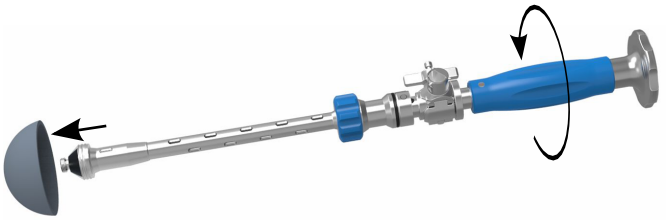
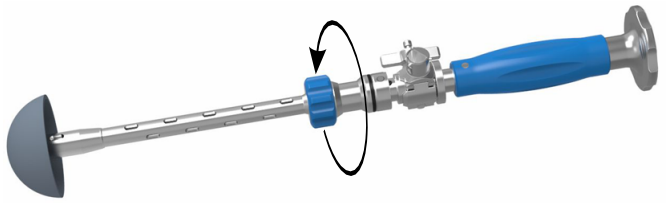
| Steps | |
|---|---|
|  | Attach the implant-specific nosepiece by pressing it onto the impactor until you hear a click (symmetrical nosepieces only). |
|  | To remove the nosepiece, gently pry it off the nose of the impactor. |

### 9.3.4 Affixing and Locking the Implant on the Impactor (Symmetrical Nosepiece)

**How to Affix the Implant**

**Some implants and their corresponding nosepiece tips have a squared or hexagonal interface. Make sure to correctly orient the interface of both components when introducing the nosepiece tip of the impactor into the implant.**

**Do not overtighten. Overtightening can destroy the thread of the impactor tip and may make it difficult to release the implant.**

| Steps |
|---|
| 1.  Ensure that the thread of the threaded tip is completely visible by adjusting the handling nut. |
| 2.  Insert the impactor tip into the center (threaded) hole of the implant. |
| 3.  With the implant on the impactor tip, lock the implant down by screwing the handling nut clockwise. |

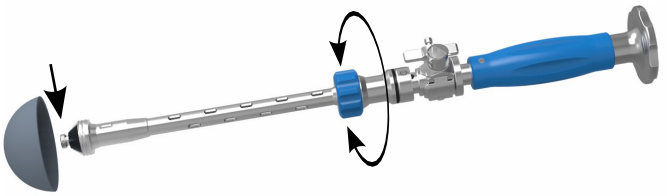
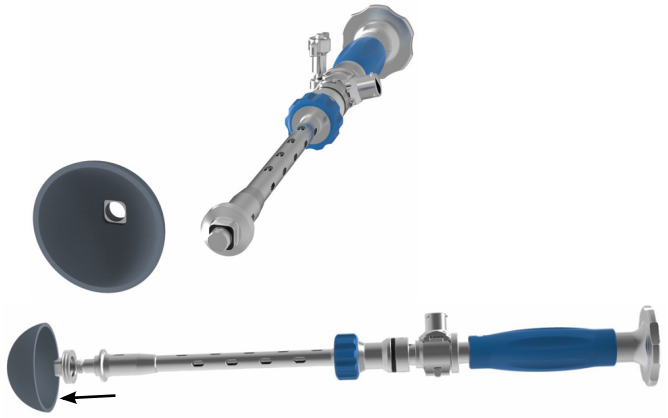
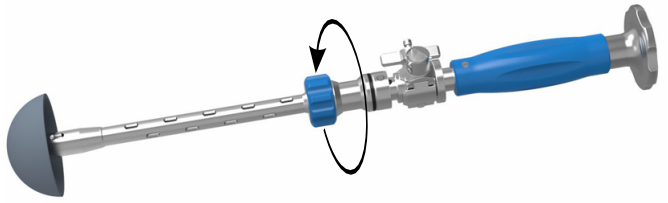
## 9.3.5 Affixing and Locking the Implant on the Impactor (Form Fit Nosepiece)

**How to Affix the Implant**

Some implants have a squared or hexagonal interface (see the interface compatibility list on page 101). When using those implants, fixation and locking the implant differs from the procedure listed above.

**Some implants and their corresponding nosepiece tips have a squared or hexagonal interface. Make sure to correctly orient the interface of both components when introducing the nosepiece tip of the impactor into the implant.**

**Do not overtighten. Overtightening can destroy the thread of the impactor tip and may make it difficult to release the implant.**

| Steps | |
|---|---|
| 1. |  Ensure that the thread of the threaded tip is completely visible by adjusting the handling nut. |
| 2. |  Align the interface of the respective nosepiece into the implant. Then insert the impactor into the nose and the center (threaded) hole of the implant. Screw the implant onto the threaded tip by turning the handle. |
| 3. |  With the implant on the impactor tip, lock the implant down by screwing the handling nut clockwise. |

### 9.3.6 Steps Prior to Impaction

**Before Impaction**

The order of your next steps depends on the type of implant you are using.

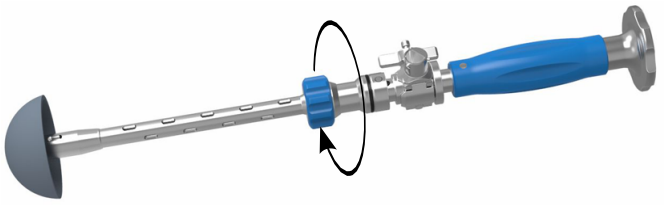
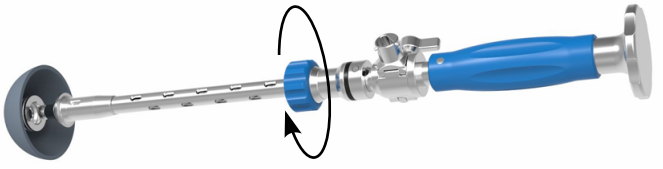
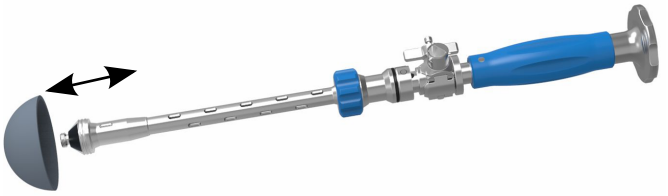
| Steps | |
|---|---|
| 1. | Attach the **StarLock Instrument Adapter** to the mounting base of the impactor. |
| 2. | Insert the implant into the patient. |
| 3. | Align the screw holes of the implant as needed by turning the impactor accordingly. |
| 4. | If the **StarLock Instrument Adapter** is not visible to the cameras, slightly loosen the wingscrew, turn the mounting base with the Starlock Instrument to improve visibility, then tighten the wingscrew again. |
| 5. | Perform impaction. |

**Lock the implant to the impactor prior to impaction. Otherwise the force of impaction may destroy the threads of the impactor or the implant, making it difficult or impossible to remove the implant from the impactor.**

**If you encounter any difficulties screwing the implant onto the impactor, continue the procedure using your standard impactor (non-navigation), and inform Brainlab immediately.**

**How to Release the Implant after Impaction**

**Verify prior to impaction that the handling nut is completely tightened. If you do not lock the instrument, navigation accuracy decreases.**

| Steps | |
|---|---|
| 1. |  <br>Unlock the implant by screwing the handling nut counter-clockwise. |
| 2. |  <br>Unscrew the impactor tip completely from the implant by turning the inserter counter-clockwise. |
| 3. |  <br>Pull out the impactor. |

**Using the StarLock Instrument Adapter**

To enable computer-aided tracking of the impactor during surgery, you must attach the **StarLock Instrument Adapter** (see page 70).

**All reflective marker spheres on the StarLock Instrument Adapter must be visible to the camera while the instrument is being navigated.**

**Before beginning navigation, make sure that the StarLock Instrument Adapter is correctly attached to the impactor and that the reflective marker spheres can be detected by both camera lenses.**

### 9.3.7 Releasing the Implant after Impaction

**How to Release the Implant**

| Steps | |
|---|---|
| 1. | Press the ratchet release lever. The ratchet mechanism releases. |
| 2. | Unscrew the impactor tip completely from the implant by turning the blue knob on the driveshaft counter-clockwise. |
| 3. | Pull the impactor out. |

# 9.4 Insert For Universal Cup Impactor (52855)

## 9.4.1 Overview

**General Information**

Figure 58

An **Insert For Universal Cup Impactor** is an exchangeable insert for use with **Straight Cup Impactor Universal** and **Offset Cup Impactor Universal** to be used with specific cups depending on the manufacturer.

**Interface Compatibility**

| Medical Device/ Manufacturer | Brainlab Article Number | Thread/Nosepiece |
|---|---|---|
| Aesculap: | 52855-08 | |
| • Plasmacup | 52855-38/<br>52855-63 | M8X1/<br>Hexagonal |
| Biomet: | 52855-07 | |
| • Mallory-Head Acetabular Shells USA<br>• Exceed Shells<br>• Universal Acetabular Shells USA<br>• Mallory-Head Acetabular Shells<br>• BiHAPro Shells<br>• BiomEX Shells<br>• Full Hemisphere Acetabular Shells USA | 52855-37/<br>52855-62 | 1/4-28UNF/<br>Squared |
| Corin: | 52855-11 | |
| • Trinity | 52855-41<br>52855-66 | M10/Conical 13.5 mm |
| Depuy: | 52855-03 | |
| • Duraloc<br>• Lagoon<br>• Pinnacle | 52855-33/<br>52855-61 | 7/16-20UNF/<br>Conical12 mm |
| Kyocera AMS: | 52855-01 | |

| Medical Device/ Manufacturer | Brainlab Article Number | Thread/Nosepiece |
|---|---|---|
| | 52855-31/<br>52855-61 | 3/8-24UNF/<br>Conical 12 mm |
| Kyocera KMAX QPOC: | 52855-02 | |
| | 52855-32/<br>52855-61 | M8/<br>Conical 12 mm |
| Mathys: | | |
| • seleXys TPS<br>• seleXys TH<br>• seleXys PC<br>• seleXys revision (TPS-R) | 52855-39/<br>52855-64 | M10x1/<br>Conical 15 mm |
| Smith & Nephew: | 52855-04 | |
| • Reflection<br>• Interfit<br>• R3 | 52855-34/<br>52855-65 | 3/8-16UNC/<br>Hemispherical PPSU |
| • EP-FIT | 52855-40<br>52855-65 | M6/Hemispherical PPSU |
| Stryker: | 52855-10 | |
| • Trident<br>• Titanium | 52855-31/<br>52855-61 | 3/8-24UNF/<br>Conical 12 mm |
| Zimmer: | 52855-05 | |
| • Allofit<br>• Trilogy | 52855-35/<br>52855-60 | 5/16-24UNF/<br>Hemisperical |

### Ensuring Compatibility

If you are using trial cups in combination with the standard cup impactor, use these trials to verify compatibility of the threaded tip and nose with the corresponding implant.

**Before using the impactor, you must attach the correct tip and nosepiece for the implant you intend to use.**

**To ensure compatibility of threaded tips and nosepieces with new implants, contact Brainlab if you receive a new standard inserter (and new implants).**

# 9.5 Drill Guide (41839)

## 9.5.1 Overview

**Use**

The **Drill Guide** is used for navigating drill bits and K-wires.

**Basic Components**

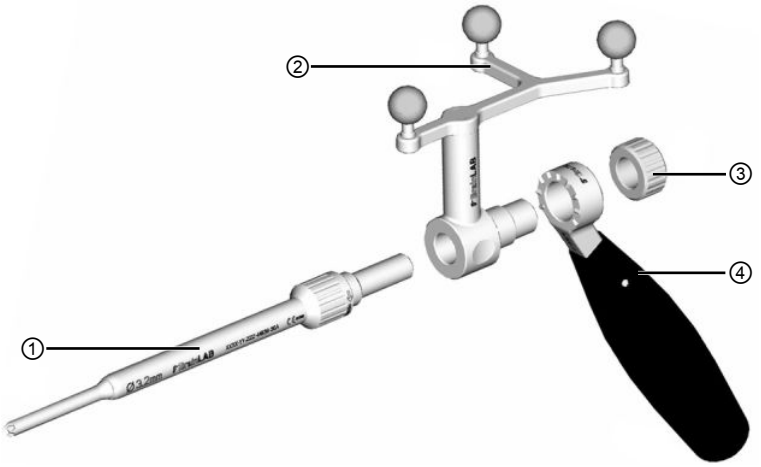



Figure 59

| No. | Component | Comment |
|---|---|---|
| ① | Drill guide tube | • Available in various diameters<br>• The diameter is engraved on the outer surface |
| ② | Precalibrated tracking array | Enables instrument tracking |
| ③ | Fixation nut | Secures the drill guide handle to the tracking array |
| ④ | Drill guide handle | Can be rotated so that surgery is not obstructed and the tracking array remains visible to the camera throughout use. |

| Drill Guide Tube Measurements | Article Number |
|---|---|
| 2.5 x 45 mm | 41839-24 |
| 3.0 x 45 mm | 41839-25 |
| 3.2 x 45 mm | 41839-26 |
| 3.0 x 150 mm | 41839-20 |
| 3.2 x 150 mm | 41839-30 |
| 1.8 x 180 mm | 41839-70 |
| 2.5 x 150 mm | 41839-80 |

## 9.5.2 Assembling the Drill Guide

**Before You Begin**

Use the appropriate tube for the intended application. For example, use a 3.0 mm tube for navigating 3 mm K-wires and a 3.2 mm tube for 3.2 mm drill bits.

**The diameter of the drill guide tube must match that of the drill bit or K-wire to be used. Otherwise navigation could be inaccurate, and the patient could be endangered.**

**How to Assemble**

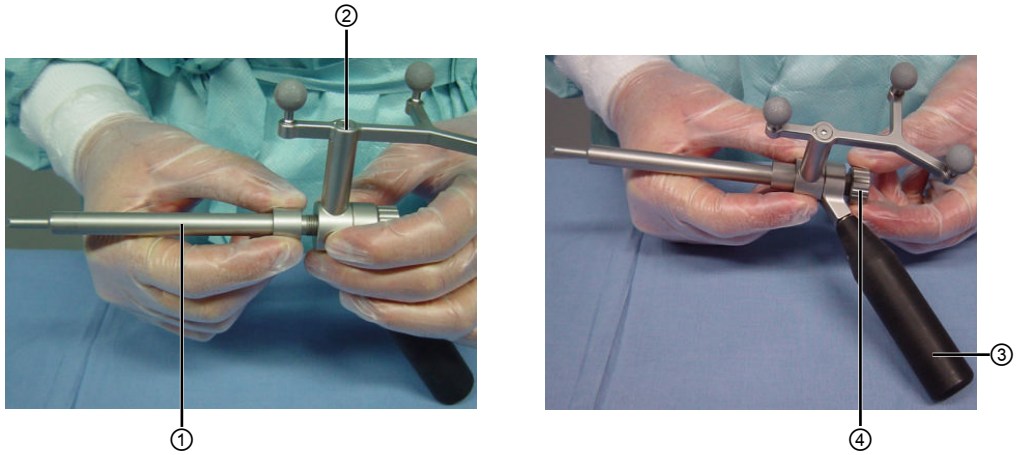



Figure 60

| Steps | |
|---|---|
| 1. | Insert tube ① through the base of the tracking array without canting ②. |
| 2. | Screw the tube counterclockwise to tighten it. |
| 3. | Adjust handle to the most suitable angle, ensuring that the teeth of the handle interface lock correctly into place ③. |
| 4. | Secure handle using fixation nut ④. |
| 5. | Tightly screw reflective marker spheres by hand onto attachment pins of the tracking array. |

**Precautions**

**Tighten the tube securely, and do not, under any circumstances, loosen it during use. This would result in navigational inaccuracies.**

**Once the handle has been adjusted to the required position, properly secure the fixation nut.**

### 9.5.3 Navigation

**Drill Bits and K-wires**

**The Drill Guide should only be used with drill bits and K-wires specified by Brainlab. Brainlab does not assume liability if other drill bits or K-wires are used.**

**Ensure that the drill bits or K-wires are not bent.**

**How to Navigate the Drill Guide**

| Steps | |
|---|---|
| 1. | Match Drill Guide angle and position to the planned trajectory shown on the screen. |
| 2. | Select a drill bit or K-wire with the same diameter as that of the tube selected. |
| 3. | To navigate a drill bit or K-wire of a different diameter, exchange the drill guide tube accordingly before continuing. |

**To ensure accurate navigation of the planned axis, place the spikes of the drill guide tube directly on the bone surface.**

**Do not change the orientation of the Drill Guide while drilling. This could cause the drill bit to fracture and break off in the bone.**

**In the event of accuracy deviations with the navigated drill bit or drill guide tube, do not use the device. Validate it again or contact Brainlab for advice on how to proceed.**

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