BRAINLAB

CLEANING, DISINFECTION AND STERILIZATION GUIDE

Revision 5.2

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1 GENERAL INFORMATION

1.1 Contact Data and Legal Information

1.1.1 Contact Data

Support

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

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

Expected Service Life

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

Feedback

Despite careful review, this manual may contain errors.

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

Manufacturer

Brainlab AG
Kapellenstr. 12
85622 Feldkirchen
Germany

1.1.2 Legal Information

Copyright

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- **Softouch**® is a registered trademark of Brainlab in Germany and/or the US.
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- **Z-touch**® is a registered trademark of Brainlab in Germany and/or the US.

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- DORO® is a registered trademark of pro med instruments GmbH in Germany, the US and/or other countries.
- Mayfield® is a registered trademark of OMI, Inc.
- neodisher® is a trademark of Chemische Fabrik Dr. Weigert GmbH & Co. KG.
- Dismoclean® is a trademark of BODE Chemie GmbH.
- CIDEX®, CIDEZYME® and STERRAD® and are trademarks of Advanced Sterilization Products (ASP), a Division of Medos International Sàrl.

CE Label

CE 0123

- The CE label shows that the Brainlab product complies with the essential requirements of Medical Device Directive (MDD).
- According to MDD, Council Device Directive 93/42/EEC, 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/

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.

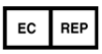
Notes

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

1.2.2 Hardware Symbols

Symbols and Abbreviations on Hardware Components

Symbol	Explanation
	Type B Applied Part according to IEC 60601-1
	Type BF Applied Part according to IEC 60601-1
	Caution
	Warning, laser radiation
	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
	Product manufactured with components that do not contain natural rubber latex
	Fragile, handle with care
	Do not use if packaging is damaged
	Keep away from sunlight

Symbol	Explanation
	Keep dry
	Storage conditions for temperature: The specified temperature range is shown on each label.
	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.
	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 • X = Protection against ingress of solid objects • Y = Protection against ingress of liquid
	On/off switch
	Standby switch to bring the device into standby mode
	Acoustic power output of integrated ultrasound probes complies with FDA Track 3 and IEC 60601-2-37
	Consult the operating instructions

Symbol	Explanation
	Follow the instructions for use

1.3 Hardware

1.3.1 Using the Hardware

Careful Hardware Handling

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

As Brainlab navigation instruments are precalibrated, handle all parts with extreme care.

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

1.4 Documentation

1.4.1 User Guides

Reading User Guides

The user guides describe complex medical devices and surgical navigation 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 user guides at all times

Available User Guides

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

2 REPROCESSING

2.1 Initial Use and Re-Use of Instruments

2.1.1 Fundamental Notes

Responsibility

- Use only approved devices (washer-disinfector, sterilizer) and validated product-specific procedures
- Apply the validated parameters in each re-use cycle
- Pay close attention to your hospital's hygiene guidelines

The reprocessing personnel are responsible for ensuring that reprocessing achieves the desired result. This normally requires validation and routine monitoring of process, equipment and materials.

Any deviation by the reprocessing personnel from the instructions should be evaluated for effectiveness and potential adverse effects. If processes are altered, the desired effect may not be achieved. Brainlab excludes any liability in this case.

Only use reprocessing procedures described in this guide. Other procedures could result in material damage, corrosion, fatigue, breakage, or decrease the weight bearing capability of the instrument.

NOTE: All transparent packaging and other packaging, protective caps and foils etc. must be removed before using the products.

Disassembling Instruments

Disassemble/reassemble/unscrew instruments as described in the corresponding sections.

Disposables

Figure 1

Disposable products are for single-use only. Do not attempt to reprocess any disposables.

Disposable Reflective Marker Spheres

Reflective marker spheres are for single-use only. Do not re-sterilize them, as sterilization may lead to reduced accuracy and endanger patient safety.

Unscrew reflective marker spheres from all instrument components and dispose of them prior to component reprocessing.

Reprocessing Instruments

Effective cleaning and disinfection is essential for effective instrumentation sterilization.

Follow the instructions for each individual instrument, as each instrument may be processed differently.

Ensure that all components (threads, guidances, etc.) are thoroughly cleaned, disinfected and sterilized, according to the following table and its respective instrument section:

Step	Procedure	See
1.	Pretreatment	Page 18
2.	Automated or manual cleaning and disinfection	Page 19
3.	Post-drying	Page 23
4.	Instrument usability check	Page 23
5.	Packaging	Page 26
6.	Steam (preferred) or LTP sterilization	Page 26

All components are delivered unsterile, unless specifically stated otherwise. Follow the reprocessing instructions prior to initial use and each subsequent use.

Neutralization

If instrument neutralization is required, use phosphoric solution, citric solutions or sodium hypochlorite solutions (2%) as described by the solution manufacturer. Alkaline solutions lead to severe corrosion of aluminium instruments.

Creutzfeldt-Jakob Contamination

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

Contact with the Central Nervous System

Standard reprocessing methods are not fully effective for endotoxic contaminated instruments. Endotoxic contamination can only be removed using aggressive treatments, e.g., very high temperatures. Such parameters have not been validated for Brainlab instruments.

2.2 Cleaning and Disinfection

2.2.1 Basics

Authorization

Cleaning and disinfection of Brainlab components may only be performed by trained reprocessing personnel.

Do not clean or disinfect instruments within the Sterilization Tray, as this may result in insufficient cleaning or disinfection.

When to Clean and Disinfect

Dried-in residues following surgery can make cleaning difficult or ineffective and lead to corrosion.

Perform cleaning and disinfection directly (no later than 2 hours) after use.

Applicability

Not all procedures can be applied to all instruments. This is noted in the descriptions of the individual instruments.

Recommended Water

In accordance with ISO standard 17664 and European Pharmacopeia (PharmEur) and US Pharmacopeia (USP) directives, deionized water is recommended for final rinse and was used for Brainlab instrument validation. In order to avoid re-contamination of instruments it is recommend to use highly purified water (HPW).

Effective Cleaning and Disinfection

Effective cleaning and disinfection is an absolute pre-condition for effective sterilization.

Do not use fixating pre-cleaning temperatures or fixating disinfecting agents.

Pay particular attention during cleaning to long narrow cannulations, threads and blind holes.

2.2.2 Pretreatment

Procedural Note

Correct pretreatment increases process efficiency, helping to reduce instrument damage and improve instrument turnaround time. It cannot replace mandatory disinfection or be omitted from the full cleaning, disinfection and sterilization procedure.

Cleaning Detergent

Cleaning detergent requirements:

- Approved for instrument cleaning
- Aldehyde-free (otherwise fixation of blood impurities occurs)
- Officially approved regarding efficiency, for example:
  - FDA clearance
  - CE marking
  - Listed by DGHM/VAH/ÖGHMP
- Compatible with instruments to be cleaned

How to Pretreat

Steps	
1.	Unscrew and dispose of reflective marker spheres or other disposable devices e.g., **Disposable Clip-on Remote Control**.
2.	Remove coarse impurities from instruments directly after use (within a maximum of 2 hours) using running water (20-30°C) or a cleaning-disinfectant solution.
3.	Using a brush, apply detergent solution to all surfaces, threads, cannulations and holes, ensuring that all parts are cleaned. • To manually remove impurities, use only a soft brush or a clean soft tissue • Do not use metal brushes or steel wool
4.	Ultrasonic cleaning may be used to enhance initial cleaning. Make sure that: • The ultrasound bath is large enough for complete immersion of instruments • Instruments do not collide • Blind holes are filled
5.	Rinse under clean running water for at least 3 minutes, ensuring that: • Running water passes through cannulations • Blind holes are repeatedly filled and emptied
6.	Check all parts and holes for contamination residue. If residue is still visible, repeat steps.

Full Cleaning and Disinfection

Perform additional full cleaning and disinfection subsequently.

2.2.3 Automatic Cleaning and Disinfection

General Information

Where possible, perform automatic cleaning and disinfection in favor of manual cleaning and disinfection.

How to Clean and Disinfect

Steps	
1.	Unscrew and dispose of reflective marker spheres or other disposable devices e.g., **Disposable Clip-on Remote Control**.
2.	Transfer instruments to washer-disinfector. Use baskets for small instruments.
3.	Start program.
4.	After program has finished, let instruments dry and then remove them.

NOTE: Drying can be accelerated using medical grade compressed air or a clean, lint-free wipe.

Cleaning Detergent

Requirements for cleaning detergent:

- Approved for instrument cleaning
- Used at the concentration recommended by manufacturer
- Officially approved regarding efficiency, for example:
  - FDA clearance
  - CE marking
  - Listed by DGHM/VAH/ÖGHMP
- Compatible with instruments to be cleaned

Due to the potential danger of remnants staying present, the application of rinsing aids is not recommended.

Cleaning Devices

Only use washer-disinfectors according to EN 15883.

Arrange medical devices so that cannulations do not lie horizontally and ensure that blind holes point downwards to assist drainage.

All sections of each device must be accessible for ease of cleaning and penetration of cleaning agents.

Ensure medical devices are arranged in such a way as to avoid causing collision or damage.

Thermo Disinfector

- Ensure that the thermo disinfector has regulatory clearance in the jurisdiction in which it is being used, for example:

  - FDA clearance
  - CE marking
  - Listed by DGHM/ÖGHMP
- Use only a cleaning and disinfection program with sufficient rinsing and drying steps and filtered air
- Use deionized water or HPW for post-rinsing (using rinse aid is not recommended).

Validation Parameters

The fundamental suitability of instruments for effective automatic cleaning and disinfection was validated by an independent test laboratory in accordance with following parameters:

Cleaning Detergents	Manufacturer	Parameters	Disinfection
neodisher MediZym neodisher MediClean forte	Dr. Weigert	According to manufacturer's specifications	Thermal at 90°C (194°F) for 5 minutes. Thermal at 93°C (199.4°F) for 10 minutes.

Other Procedures

If procedures other than those described above are used (for example: chemical disinfectant), the fundamental suitability and efficiency must be validated.

Chemical disinfectants may lead to corrosion and abrasion of aluminum anodized instruments. To extend component's service life, use enzymatic cleaning solvents.

Incompatible Solutions

- Organic/inorganic, or oxidizing acids (pH < 4)
- Strong alkalines (pH>12)
- Aldehyde-releasing solutions
- Phenol-releasing solutions
- Chlorine-releasing solutions
- Iodine-releasing solutions
- NaOH and NaOCl-releasing solutions
- Fluorine-releasing solutions

To prevent damage to the devices, do not use incompatible solutions.

NOTE: Consider instrument sections for specific incompatible solutions.

2.2.4 Manual Cleaning and Disinfection

Validation

Manual cleaning and disinfection procedures have only been validated for instruments where automatic methods do not apply. This is explicitly stated in the descriptions of the individual instruments.

How to Clean

Steps	
1.	Unscrew and dispose of reflective marker spheres or other disposable devices e.g., **Disposable Clip-on Remote Control**.
2.	Fill a basin with a cleaning solution. Ensure that the cleaning detergent concentration is as according to the information provided by the detergent manufacturer. Full submersion of instruments must be possible.
3.	Transfer the instrument to the basin.
4.	Clean accessible surfaces of instruments with a soft brush.
5.	Remove the instrument from the basin no earlier than the minimum soaking time recommended by the manufacturer of the cleaning detergent.
6.	Rinse the instrument according to the information provided by the detergent manufacturer, using deionized water or HPW (fill lumen, blind holes).
7.	Dry instrument twice with filter-forced air.

How to Disinfect

Steps	
1.	Fill a basin with a disinfection solution. Full submersion of instruments must be possible.
2.	Transfer the instrument to the basin.
3.	Immerse instrument completely in the solution, filling all lumens and eliminating air pockets.
4.	Remove the instrument from the basin no earlier than the minimum soaking time recommended by the disinfectant manufacturer.

All sections of each device must be accessible for ease of cleaning and penetration of cleaning and disinfection agents.

Ensure medical devices are arranged in such a way as to avoid causing collision or damage.

Cleaning Detergent

Requirements for cleaning and disinfection detergent:

- Officially approved regarding efficiency, for example:
  - FDA clearance
  - CE marking
  - Listed by DGHM/VAH/ÖGHMP
- Compatible with instruments to be cleaned

- Used at the concentration and soaking time recommended by manufacturer

NOTE: Only use freshly-prepared solutions. Prevent detergent solutions from foaming.

Validated Detergents

The fundamental suitability of instruments for effective manual cleaning and disinfection was validated by an independent test laboratory using the following detergents:

	Manual cleaning	**Manual disinfection**
Detergent	CIDEZYME®	CIDEX® OPA
Manufacturer	Johnson & Johnson	
Parameters	See manufacturer's instructions.	

Other Procedures

If procedures other than those described are used, the fundamental efficiency must be validated.

2.2.5 Usability Check

Reusable Components

Apart from disposable components labeled “single-use”, instruments are reusable.

Examination and Further Use

After cleaning and disinfection, ensure that each instrument is clean and undamaged.
Check the functionality and check for corrosion.
Mechanisms to be lubricated according to the instrument specific sections.
If you are not sure of an instrument’s suitability for use, contact Brainlab support.

Replace damaged or corroded instruments immediately.

Always repeat cleaning and disinfection for instruments still covered with blood or tissue until they successfully pass as optically clean.

2.3 Sterilization

2.3.1 Basics

Authorization and Responsibility

Sterilization of Brainlab components may only be performed by trained reprocessing personnel.

If steam sterilization or LTP sterilization is indicated, only use the method recommended. Other sterilization methods may harm the instrument.

Suitability for Sterilization

Only sterilize parts for which a sterilization method is specified. All other parts may not be sterilized. Brainlab is not liable for any damage to any parts due to improper sterilization.

Cool-Down Period

After sterilization, wait until instruments are room temperature before use. Using hot instruments could injure the patient or damage non-heat resistant materials.

Sterilization Devices

For steam sterilization only use devices according to EN 285 (for big devices) and EN 13060 (for small devices). For LTP sterilization only use devices according to EN ISO 14937.

Ensure that the maximum load capacity of the steam sterilizer is not exceeded when sterilizing multiple instrument trays at the same time.

2.3.2 Prior to Sterilization

Cleaning and Disinfection

All instruments must be cleaned, disinfected and dried.

Packaging

Transfer instruments to **Sterilization Trays**.

2.3.3 Steam Sterilization

Applicable Technology

Only use the Prevac fractionated vacuum sterilization procedure (with at least 3 vacuum phases), which has been validated in accordance with EN ISO 17665 or AAMI TIR 12-2004.

The use of other sterilization procedures may require longer sterilization times and must be validated. This is the responsibility of the user.

Sterilization Tray

It is mandatory to use a **Sterilization Tray**.

Individual packaging is not recommended, as some instruments have sharp edges and may damage the pouches.

Sterile Packaging

We recommend using a steri container (provided by Brainlab) with the **Sterilization Tray**. Brainlab **Sterilization Trays** are compatible with standard sterilization containers. This ensures safe and reliable sterilization, as sterility is still assured if sharp instruments penetrate the perforation of the **Sterilization Tray**.

Alternatively:

Steps	
1.	Wrap **Sterilization Tray** in a standard pouch made from paper/foil in accordance with AAMI/ISO 11607.
2.	Ensure that pouch is large enough to hold the **Sterilization Tray** without stressing the seals.

Validation

The fundamental suitability of instruments for effective prevac steam sterilization was validated by independent test laboratories.

Sterilization Parameters

The following sterilization parameters have been validated for Prevac procedures as being capable of sterilizing medical devices:

Parameter	**Value**
Sterilization temperature	132°C (270°F)
Sterilization time	At least 5 minutes
Drying time	At least 10 minutes

Sterilization Parameters, UK

The following sterilization parameters have been validated for Prevac procedures required in the UK.

Parameter	**Value**
Sterilization temperature	134°C (273°F)
Sterilization time	At least 3.1 minutes
Drying time	At least 10 minutes

Deviations

Sterilization temperature must not drop below the specified minimum temperature.

The stated sterilization time is the minimum validated sterilization time required to achieve a 10^{-6} sterility assurance level (SAL), and requires complete attention to the instructions on pretreatment, cleaning and disinfection, as well as post-drying and check of the instruments.

Any deviation from the validated parameters could result in patient infection.

Flash Sterilization

There are no validated parameters for emergency situations where flash sterilization is necessary. Validation and execution of such a procedure is the user's responsibility.

Storage

Ensure that sterilized products are completely dry prior to storage.

Sterile, packed products should be stored in a designated area, limited in access but well ventilated. It should provide protection from dust, moisture, insects, vermin and temperature and humidity extremes.

2.3.4 Low Temperature Plasma Sterilization (LTP Sterilization)

Abbreviation

“Low temperature plasma” sterilization is abbreviated as LTP sterilization.

Applicable Technology

Use only LTP sterilization and sterilizers that conform to requirements of EN ISO 14937.

The selected sterilization procedure must be validated in accordance with EN ISO 14937.

Observe underlying restrictions pertaining to LTP sterilization procedure in your country.

In general Brainlab recommends the use of LTP only when primary methods of validated sterilization (e.g., steam sterilization) are not available.

Brainlab specifies LTP sterilization only when other methods may harm the instrument. Refer to the instrument description for validated sterilization methods.

Sterilization Tray

It is mandatory to use an **LTP Sterilization Tray** (Brainlab **Sterilization Tray** suitable for LTP sterilization).

Individual packaging is not recommended, as some instruments have sharp edges and may penetrate the pouches.

Packaging

Use container systems tested and cleared for use in STERRAD sterilizers or wrap the sterilization tray as defined by ASP Instrument Processing Guidelines.

Validation

The fundamental suitability of instruments for effective LTP sterilization was validated by an independent test laboratory using the long cycle of STERRAD 100S sterilizer manufactured by Johnson & Johnson GmbH, Norderstedt, Germany.

Sterilization Parameters

The following sterilization parameters have been validated for LTP procedures:

Parameter	Value
Long cycle	72 minutes
Sterilizer	STERRAD 100S, sterilization system; ASP, Johnson & Johnson

Deviations

Any deviation from the validated parameters could result in patient infection.

2.3.5 Sterilization Trays for Steam Sterilization

Use for Brainlab Instruments

Most Brainlab instruments can only be sterilized in a suitable Brainlab **Sterilization Tray**.
Depending on application-specific instruments, various **Sterilization Trays** are available.
Do not place used instruments back in **Sterilization Trays**.

The metallic Sterilization Trays for steam sterilization are not suitable for LTP sterilization.

Always sterilize and store instruments in the Sterilization Trays, to protect instruments from any damage which could alter their geometry.

Remove and replace any damaged Sterilization Trays.

Illustration

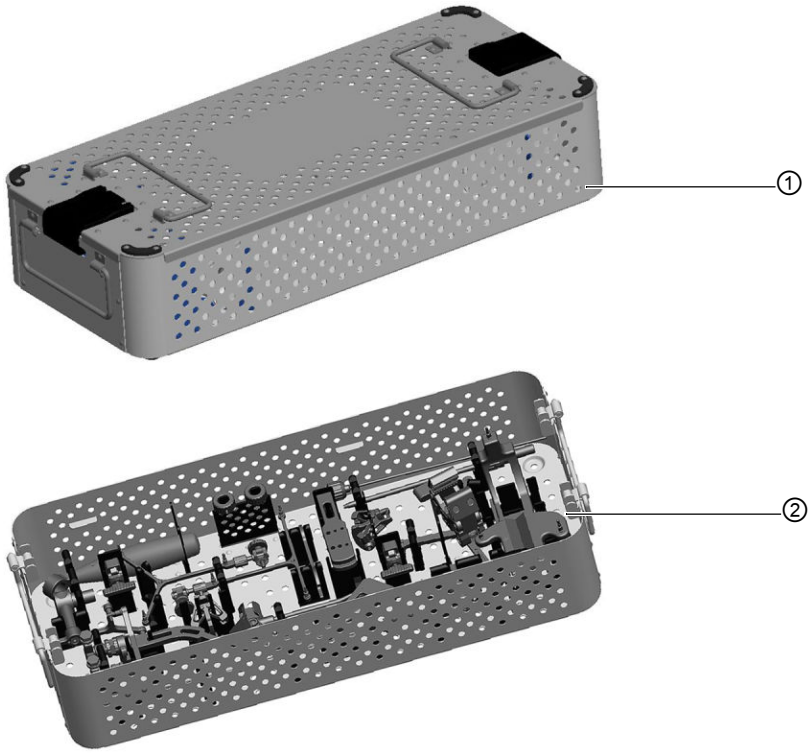


Figure 2

No.	Component	Appearance
①	Outer Design	Always the same, but varying tray sizes
②	Inner Design	Depends on the instruments (image shows the inner design for trauma/ACL instruments)

How to Insert Instruments

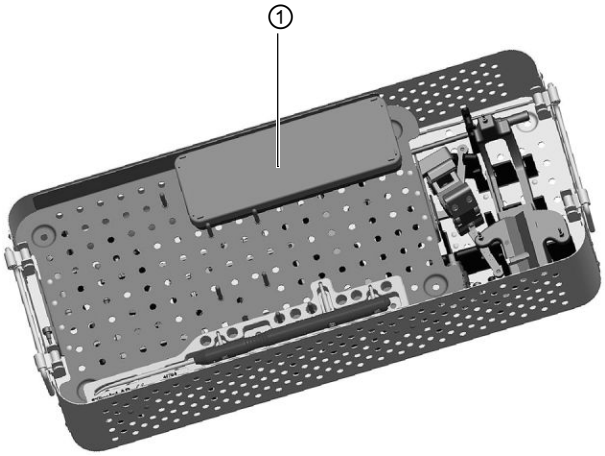


Figure 3

Steps	
1.	Insert instruments directly over engravings on insert tray.
2.	Securely place instruments in corresponding cutouts in silicone bars or metal brackets.
3.	Place small parts (such as screws, pins, tools) inside the microtray ①.

*NOTE: Total weight of a loaded **Sterilization Tray** should not exceed 9 kg.*

How to Open/Close

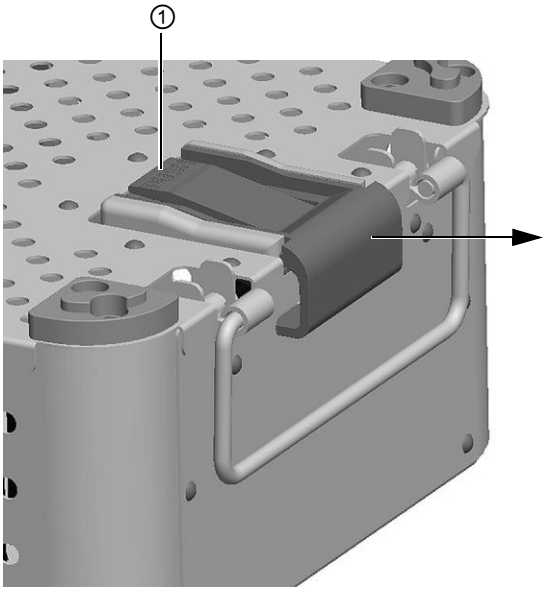


Figure 4

Options
To open the **Sterilization Tray**, press down on the plastic lever ①, and slide fastener outward (arrow).
To close the **Sterilization Tray**, slide fasteners back until a click is heard and they lock into place.

Make sure that the fasteners are securely closed.

How to Stack

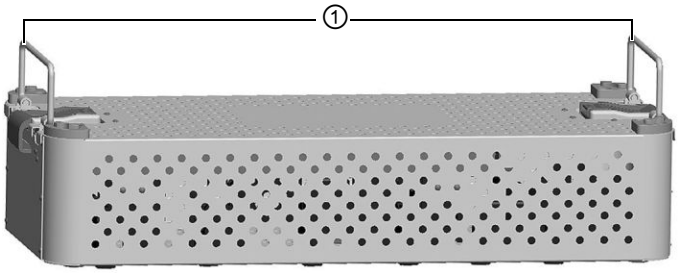


Figure 5

Steps	
1.	Always grip the handles ① on both sides.
2.	Do not stack more than two **Sterilization Trays** on top of each other if instruments are loaded in the **Sterilization Tray**.

*NOTE: The maximum weight loaded onto a **Sterilization Tray** should not exceed 18 kg.*

To avoid injuring your hands, grip handles on both sides when stacking Sterilization Trays.

Do not attempt to carry more than two Sterilization Trays at the same time.

2.3.6 Sterilization Trays for LTP and Steam Sterilization

Use for Brainlab Instruments

Some Brainlab instruments may only be sterilized in an **LTP Sterilization Tray** (Brainlab **Sterilization Tray** suitable for LTP sterilization).

LTP Sterilization Trays suitable for LTP sterilization are explicitly labeled by engravings on the top of the **Sterilization Tray**.

Do not place used instruments back in **LTP Sterilization Trays**.

For LTP sterilization always use the LTP Sterilization Tray which is labeled “Suitable for Low Temperature Plasma Sterilization”.

Remove and replace any damaged Sterilization Trays.

Illustrations

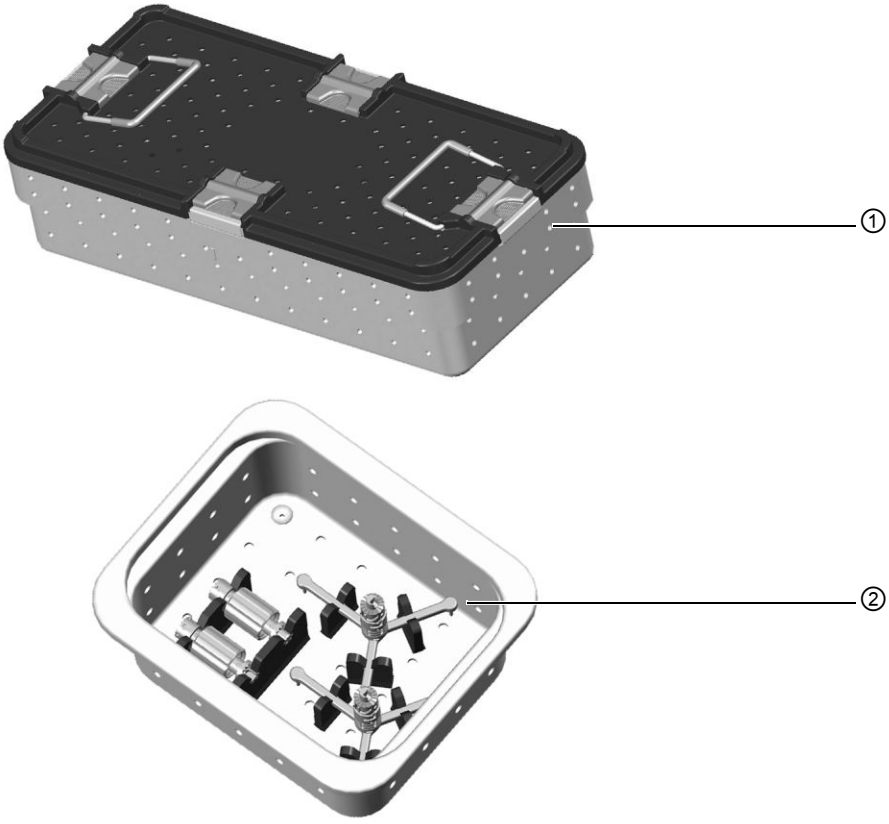


Figure 6

No.	Component	Appearance	Image Shows Tray for
①	Outer Design	Size depends on instruments	Registration matrix
②	Inner Design	Depends on the instruments	Reference array

How to Insert Instruments

Steps	
1.	Insert instruments directly over engravings on insert tray.

Steps	
2.	Securely place instruments in corresponding cutouts in silicone bars.

*NOTE: Total weight of a loaded **Sterilization Tray** should not exceed 9 kg.*

How to Open/Close

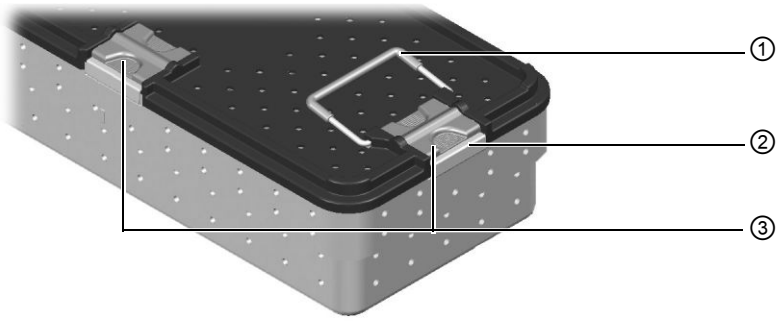


Figure 7

Options
To open the **Sterilization Tray**, release fasteners ② and lift handles ① and sliders ③ outwards.
To close the **Sterilization Tray**, move handles ① inwards to close fasteners ② and move sliders ③ inwards to secure fasteners ②.

Make sure that sliders and fasteners are securely closed.

How to Stack

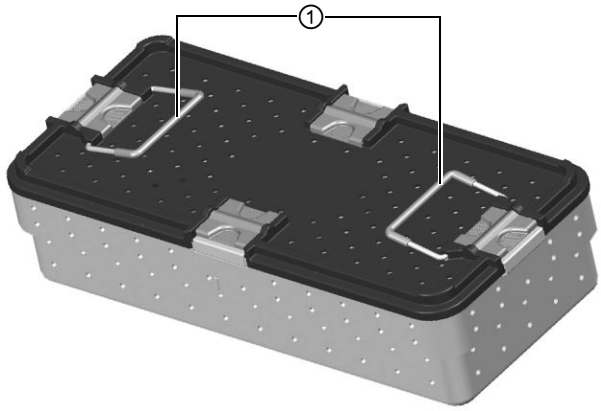


Figure 8

Steps	
1.	Always grip the handles ① on both sides.
2.	Do not stack more than four **Sterilization Trays** on top of each other if instruments are loaded in the **Sterilization Tray**.

*NOTE: The maximum weight loaded onto a **LTP Sterilization Tray** should not exceed 45 kg.*

To avoid injuring your hands, grip handles on both sides when stacking Sterilization Trays.

Do not attempt to carry more than two Sterilization Trays at the same time.

2.4 Reusability

2.4.1 Instrument Stability

Effect of Reprocessing

Repeated reprocessing has minimal effect on instruments, provided that reprocessing is performed as described in this manual.

The end of component service life is normally determined by wear and damage due to use. If there is a specified product life time it is listed in its respective instrument section.

Reprocessing may cause discoloration of some parts. This does not indicate any restriction on usability.

The maximum number of applications possible for reusable medical device depends on factors such as method and duration of each use, and handling between uses.

Damaged Instruments

Closely inspect all parts. Do not use any parts with traces of corrosion, damaged surfaces or impurities. Exchange them immediately.

Do not use damaged or corroded instruments.

3 BRAINLAB IGS INSTRUMENTATION

3.1 General Instrumentation

3.1.1 Instrument Calibration Matrix, Rev. 4 (ICM4) (41874)

Illustration

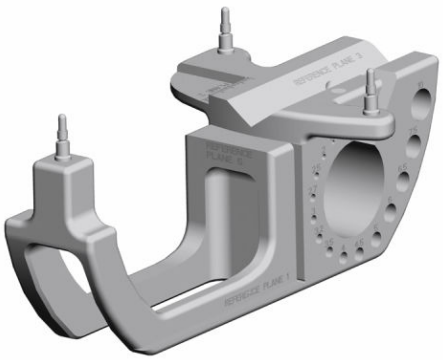


Figure 9

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.1.2 Instrument Adapter Kits (55050, 55060, 55065)

Illustration

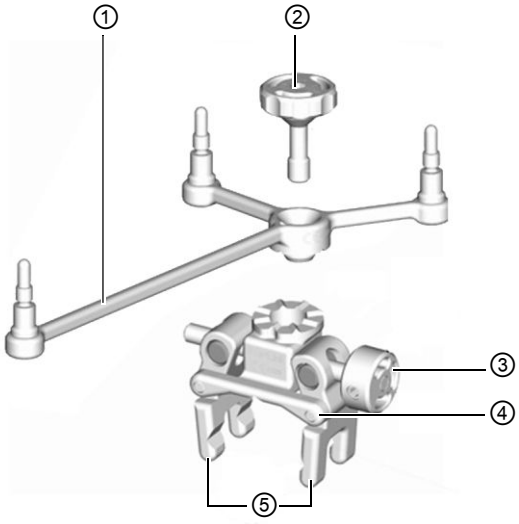


Figure 10

No.	Component
①	Tracking array (41798, 41799, 41801, 41802)
②	Fixation screw
③	Locking screw
④	Adapter clamp (55101, 55102, 55103, 55104)
⑤	Jaws

How to Disassemble

Steps	
1.	If an **Instrument Adapter Offset** (page 39) is used, unscrew it.
2.	Unscrew fixation screw ② so that you can remove tracking array ① from adapter clamp ④.
3.	Loosen locking screw ③ until there is a gap between the jaws ⑤ so that jaws can be easily rinsed out.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.1.3 Instrument Adapter Offset (55013)

Illustration

Figure 11

How to Disassemble

Step
Unscrew fixation screw ① and remove it from **Instrument Adapter Offset** ②.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.1.4 Reference Array, X-Press (52410, 52411)

Illustration

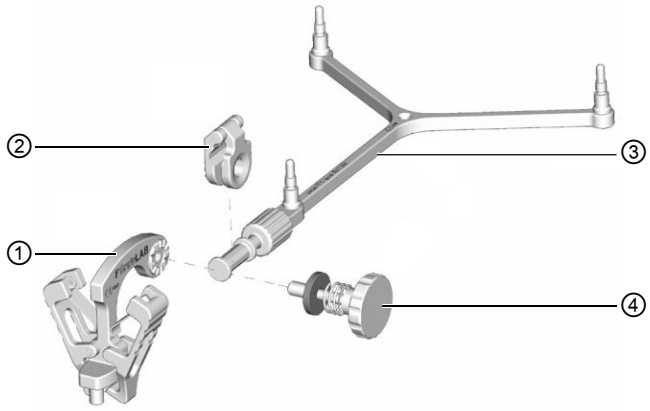


Figure 12

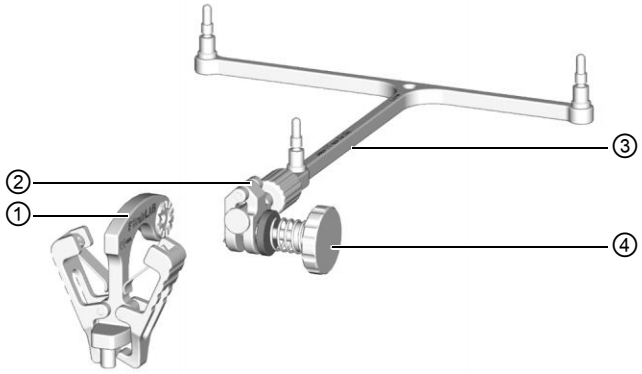
No.	Component
①	Clamp
②	Reference array clamp
③	Reference array
④	Screw unit

How to Disassemble

Steps	
1.	Unscrew screw unit ④ to remove reference array ③ from clamp ①.
2.	Remove array clamp ② from reference array ③. Do not disassemble clamp ① or array clamp ②.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.

Steps	
3.	Reassemble reference array ③ and reference array clamp ② using screw unit ④. 
4.	Make sure that the coil spring of screw unit ④ is relaxed.
5.	Steam sterilization.

3.1.5 Bone Fixator “1-Pin”, X-Press (Size S (52421), M (52422) and L (52423))

Illustration

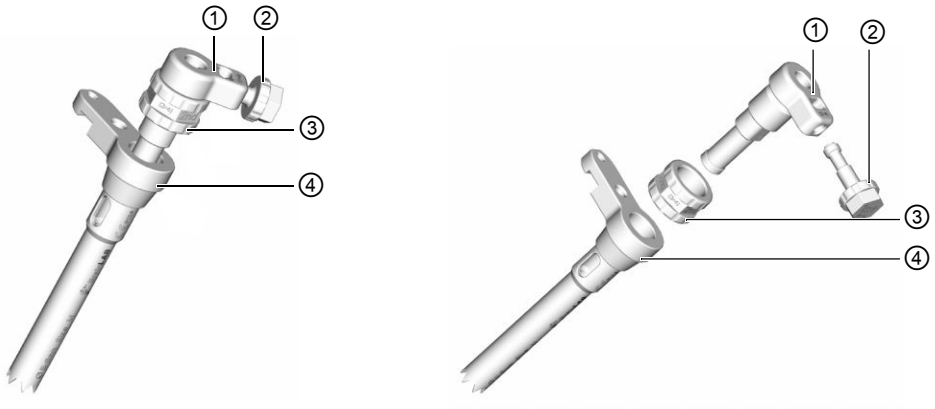


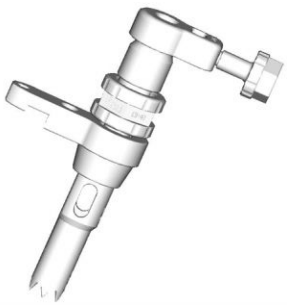
Figure 13

No.	Component
①	Inlay
②	Screw
③	Nut
④	Tube

How to Disassemble

Steps	
1.	Pull out components ①, ② and ③ as far as they will go.
2.	Unscrew unit ①, ② and ③ from tube ④.
3.	Unscrew nut ③ from inlay ①.
4.	Unscrew screw ② from inlay ①.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Reassemble instrument ensuring that threads are disengaged. 

Steps
4. Steam sterilization.

3.1.6 “1-Pin” Wrench, X-Press (52424)

Illustration

Figure 14

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.1.7 Bone Fixator “2-Pin”, X-Press (52420)

Illustration

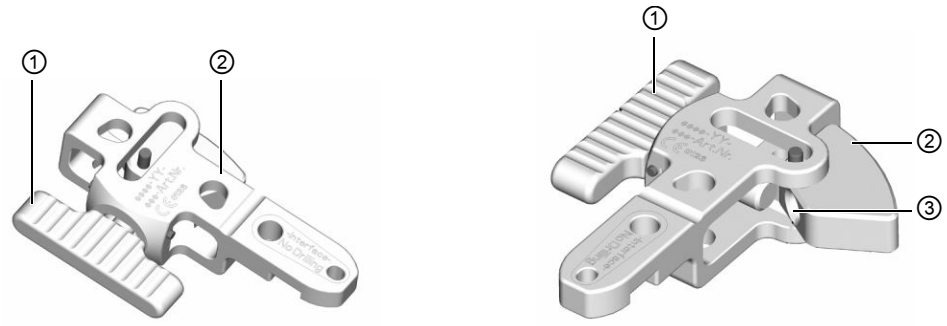


Figure 15

No.	Component
①	Wing screw
②	Wedge
③	Inner thread

How to Disassemble

Steps	
1.	Completely open wing screw ①.
2.	Pivot wedge ② so that inner thread ③ can be cleaned and disinfected.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.1.8 “2-Pin” Drill Template, X-Press (52425)

Illustration

Figure 16

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.1.9 Instrument Adapter - StarLock Interface (55080, 55085)

Illustration

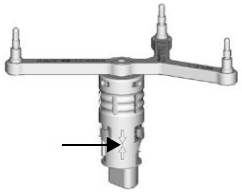
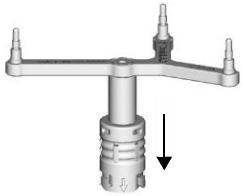
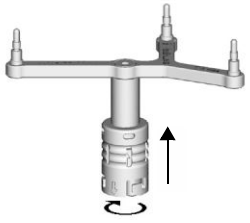
Figure 17

How to Disassemble

Steps	
1.	Pull locking sleeve ① down and keep holding it down while turning it counter-clockwise.
2.	Release locking sleeve.

Detach any instruments from the StarLock interface prior to reprocessing.

How to Reprocess

Steps		
1.	Pretreatment.	
2.	Automatic cleaning and disinfection.	
3.	Adjust locking sleeve so that arrow on sleeve and arrow on stem are correctly aligned.	
4.	Pull locking sleeve down and keep holding it down while turning locking sleeve clockwise.	
5.	Release locking sleeve.	
6.	Steam sterilization.	

3.1.10 Drill Guide Standard

Illustration

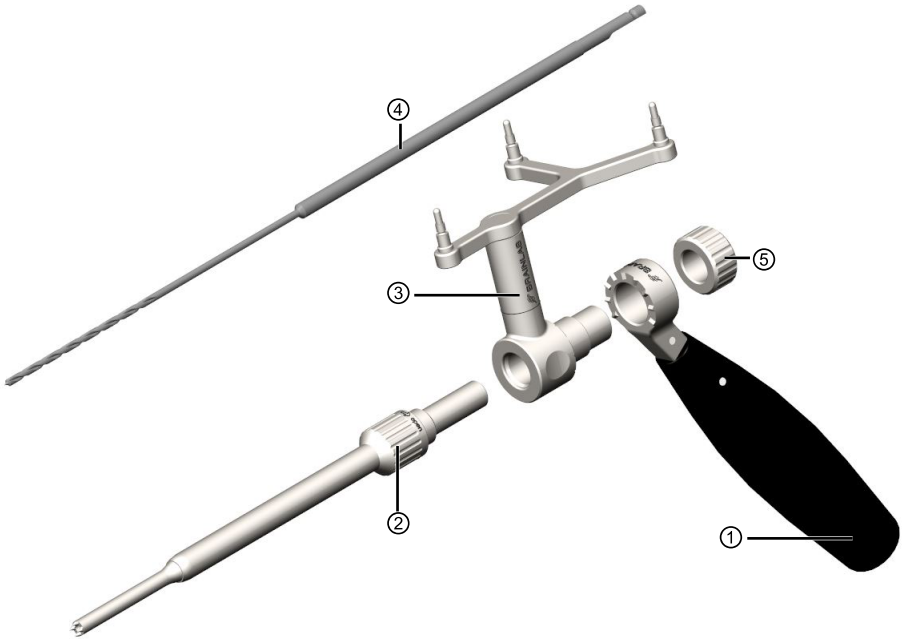


Figure 18

No.	Component	Article No.
①	Handle	41839, 55839
②	Drill guide tube	41839-xx, 55839-xx
③	Tracking array	48139, 55839
④	Drill bit	41839-xx
⑤	Nut	41839-15

How to Disassemble

Steps	
1.	Remove drill guide tube ② from tracking array ③ by turning drill guide tube clockwise.
2.	Unscrew nut ⑤ from tracking array ③.
3.	Remove handle ①.

How to Reprocess

Reprocess all parts separately.

Steps	
1.	Pretreatment.
2.	Attach appropriate flexible flushing tubes to proximal end of drill guide tube ②.
3.	Automatic cleaning and disinfection.
4.	Steam sterilization.

3.1.11 Drill Guide Depth Control (41839-50)

Illustration

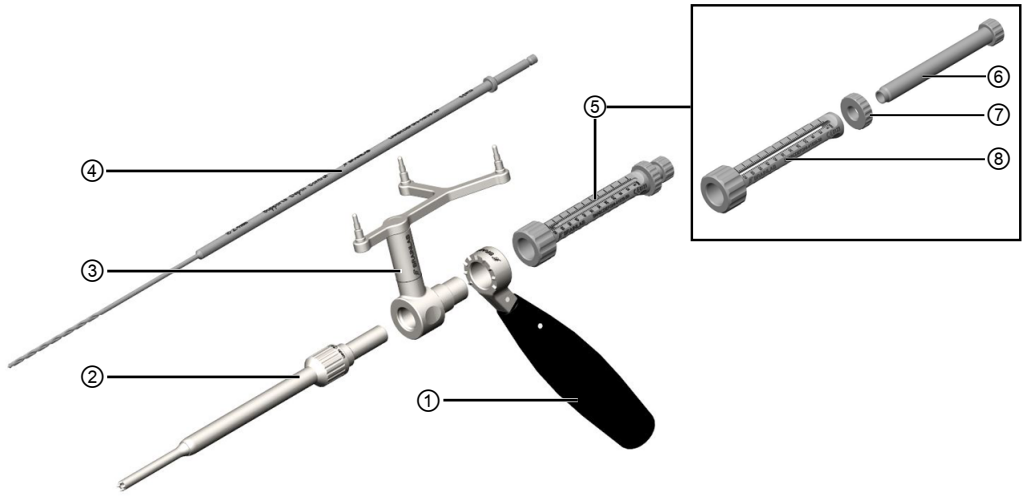


Figure 19

No.	Component
①	Handle
②	Drill guide tube
③	Tracking array
④	Drill bit (41839-xx)
⑤	Depth control
⑥	Inner tube (41839-50)
⑦	Nut (41839-53)
⑧	Scale (41839-50)

How to Disassemble

Steps	
1.	Remove drill guide tube ② from tracking array ③ by turning drill guide tube clockwise.
2.	Unscrew depth control ⑤ from tracking array ③.
3.	Remove handle ①.
4.	Completely unscrew and disassemble scale, nut and inner tube (⑥, ⑦, ⑧) of depth control ⑤.

How to Reprocess

Reprocess all parts separately.

Steps	
1.	Pretreatment.

Steps	
2.	Attach appropriate flexible flushing tubes to proximal end of drill guide tube ②.
3.	Automatic cleaning and disinfection.
4.	Steam sterilization.

3.1.12 Sharp Trocar for Drill Guide Tube 1.8 mm (41839-75)

Illustration

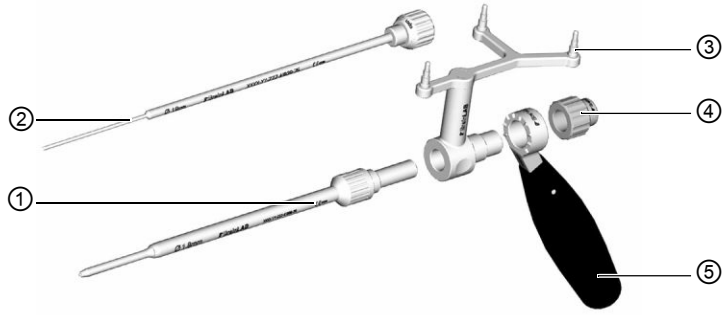


Figure 20

No.	Component
①	Drill guide tube
②	Trocar needle
③	Tracking array
④	Nut (41839-78)
⑤	Handle

How to Disassemble

Steps	
1.	Remove trocar needle ② from drill guide tube ①.
2.	Remove drill guide tube ① from tracking array ③ by turning drill guide tube clockwise.
3.	Unscrew nut ④ from tracking array ③.
4.	Remove handle ⑤ from tracking array ③.

How to Reprocess

Reprocess all parts separately.

Steps	
1.	Pretreatment.
2.	Attach appropriate flexible flushing tubes to proximal end of drill guide tube ①.
3.	Automatic cleaning and disinfection.
4.	Steam sterilization.

3.1.13 Drill Guide Kit - Trocar and Tissue Protection Sleeve (55839-xx)

Illustration

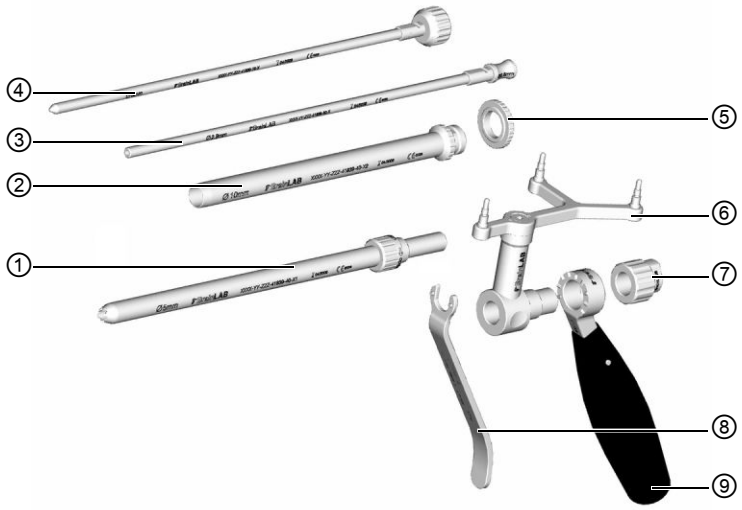


Figure 21

No.	Component	Article No.
①	Drill guide tube	55839-10
②	Tissue protection sleeve	55839-40
③	Drill guide reduction sleeve	55839-20, -28, -32
④	Trocar insert	55839-50
⑤	Nut	55839-40
⑥	Tracking array	
⑦	Nut	55839-60
⑧	Handle for tissue protection sleeve	55839-45
⑨	Handle	

How to Disassemble

Steps	
1.	Remove trocar insert ④ or drill guide reduction sleeve ③ from drill guide tube ①.
2.	Remove tissue protection sleeve ② from drill guide tube ①.
3.	Unscrew nut ⑤ and remove handle for tissue protection sleeve ⑧ from tissue protection sleeve ②.
4.	Remove drill guide tube ① from tracking array ⑥ by turning drill guide tube clockwise.
5.	Unscrew nut ⑦ from tracking array ⑥.
6.	Remove handle ⑨ from tracking array ⑥.

How to Reprocess

Reprocess all parts separately.

Steps	
1.	Pretreatment.
2.	Attach appropriate flexible flushing tubes to proximal end of drill guide tube ① and reduction sleeve insert ③.
3.	Automatic cleaning and disinfection.
4.	Steam sterilization.

3.1.14 Camera Handle Sleeve (18652-01)

Illustration

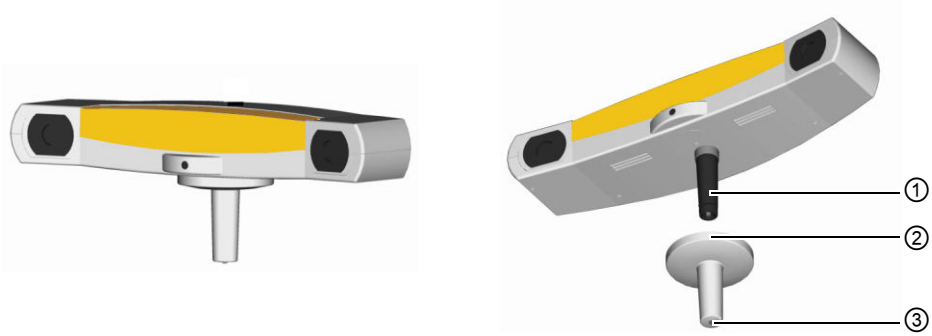


Figure 22

How to Remove

Step
Press release button ③ and remove sleeve ② from camera handle ①.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Use neutral enzymatic (pH4 - pH9) cleaning and disinfection solutions.
3.	Automatic cleaning and disinfection.
4.	Place camera handle sleeve in autoclave with open side pointing downward.
5.	Ensure that camera handle sleeve is neither obstructed nor weighted by other instruments.
6.	Steam sterilization, fractionated vacuum procedure • At 121°C: 1.3 bar, 20 minutes, or • At 134°C: 2.3 bar, 4 minutes

A maximum number of 100 sterilization cycles may be achieved.

Do Not Use

- Active chlorine
- Alcohol
- Gas sterilization
- Ultrasonic cleaners

To prevent damage to the device, only use solutions and procedures approved by Brainlab.

3.1.15 Sterilization Tray for Steam Sterilization (523xx)

Illustration

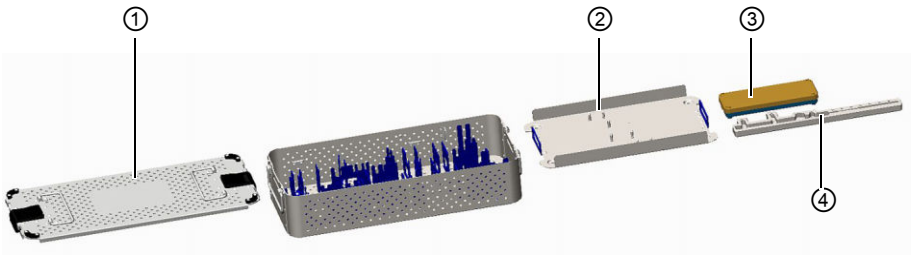


Figure 23

How to Disassemble

Step
Unlatch cover ① and remove cover ①, upper level ②, MicroTray ③, and pointer gauge ④ from **Sterilization Tray**.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

Incompatible Solutions

- Strong alkalines (pH > 9)

For other incompatible solutions see page 20.

To prevent damage to the device, do not use incompatible solutions.

3.1.16 Sterilization Tray for LTP Sterilization

Article Numbers

Component	Article No.
LTP Sterilization Trays	18099-18
	19105
	19112
	19130-03
	19131-01A
	19142-05
	19145-03
	19146-02
	19152-05

Illustration

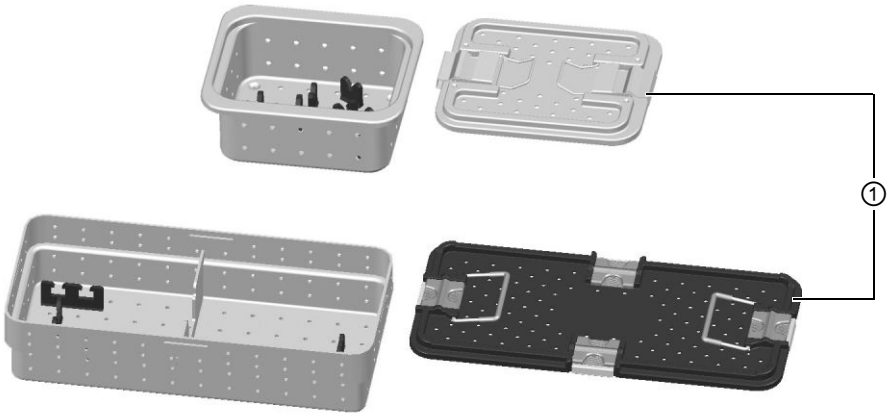


Figure 24

How to Disassemble

Step
Unlatch cover ① and remove it from the **Sterilization Tray**.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	LTP Sterilization.

Incompatible Solutions

- Aldehyde-releasing solutions

- Phenol-releasing solutions
- Chlorine-releasing solutions
- NaOH and NaOCL-releasing solutions
- Iodine-releasing solutions
- Strong alkalines (pH > 9)
- Strong acids (pH < 4)

To prevent damage to the device, do not use incompatible solutions.

3.1.17 Brainlab Pointers

Pointer with Sharp Tip (53105)

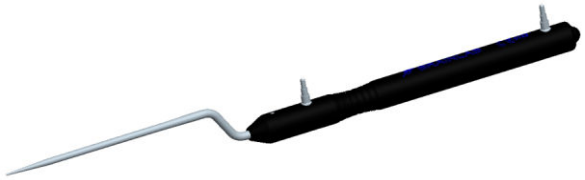


Figure 25

Pointer with Blunt Tip (53106)

Figure 26

Pointer Extended with Sharp Tip (53103)

Figure 27

Pointer Straight Extended (53108)

Figure 28

Pointer Angled (53101)

Figure 29

Pointer Reverse Angled (53104)

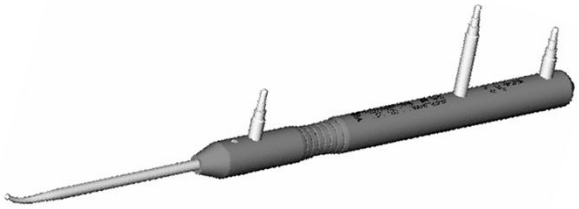


Figure 30

Pointer Square Angled (53100)

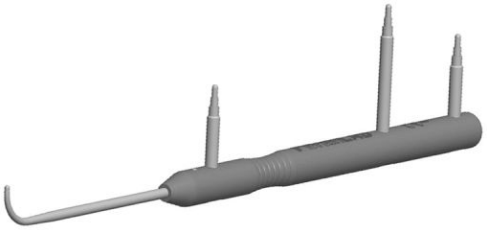


Figure 31

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.1.18 Multiple-Tip-Pointer and Paint Pointer Tip Set

Article Numbers

Component	Article No.
Pointer Tips	55791-01
	55791-02
	55791-03
	55791-04
	55791-05
	55791-34
Handle for Multiple Tip Pointer	55791
Paint Pointer Tip Set	41783

Illustration

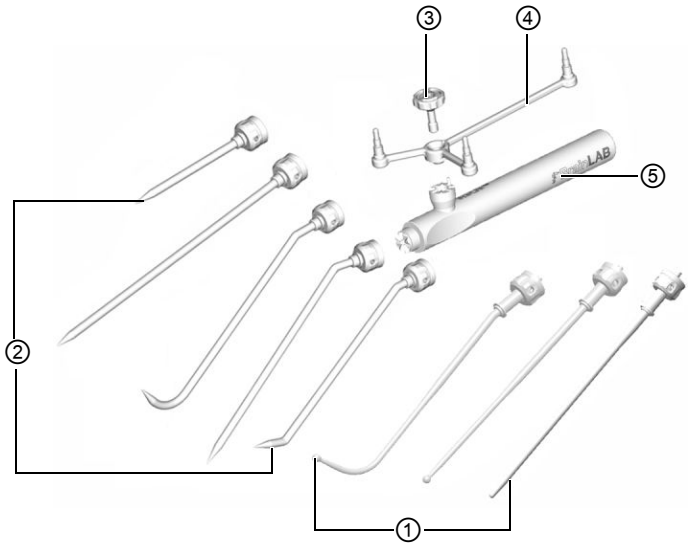


Figure 32

How to Disassemble

Steps	
1.	Unscrew pointer tip ① or ② from pointer handle ⑤.
2.	Open fixation screw ③ to remove tracking array ④ from pointer handle ⑤.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.2 Cranial and ENT Instrumentation

3.2.1 Reference Clamp Universal (41734) and Standard Cranial Reference Array (41725, 41728, 41735)

Illustration

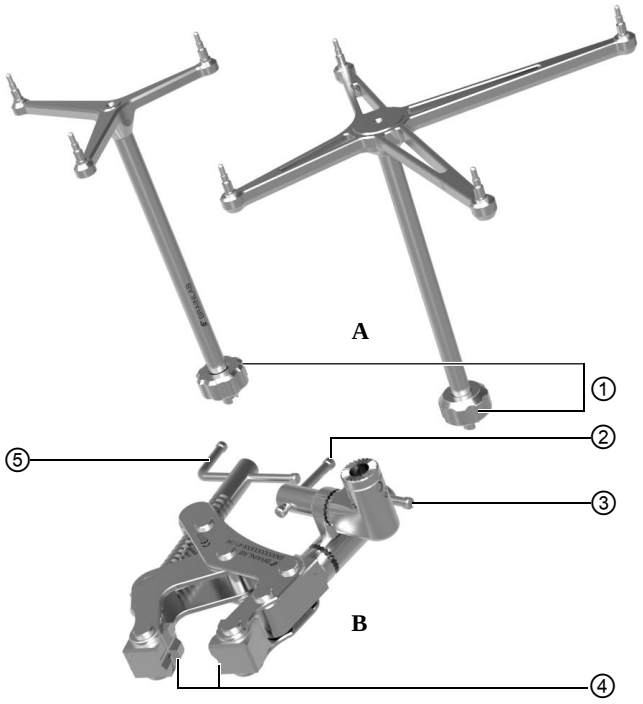


Figure 33

No.	Component	Part
①	Reference array screw	**A**- **Standard Cranial Reference Array** (41725, 41728, 41735)
②	Screw	**B** - **Reference Clamp Universal** (41734)
③	Screw	
④	Jaws	
⑤	Screw	

How to Disassemble

Steps	
1.	Unscrew reference array screw ① to disassemble **Standard Cranial Reference Array** (**A**) and **Reference Clamp Universal** (**B**).
2.	Loosen screw ⑤ so that a gap between jaws ④ is visible.
3.	Loosen screws ② and ③.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.2.2 Vario Reference Arm for Mayfield Headholder (52001)

Illustration

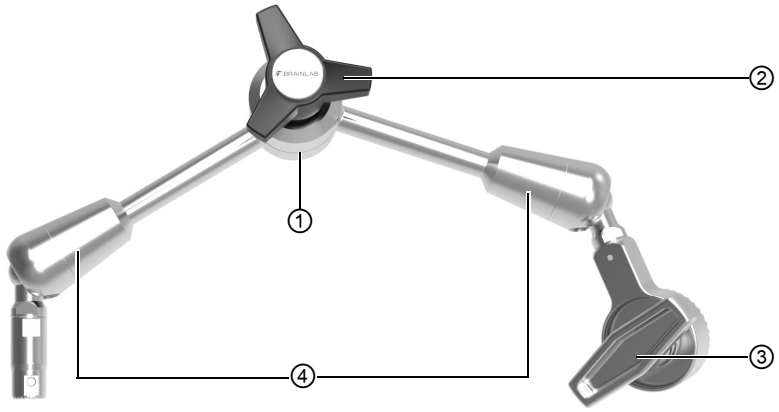


Figure 34

How to Disassemble

Steps	
1.	If a **Standard Cranial Reference Array** is mounted to the **Vario Reference Arm for Mayfield Headholder**, unscrew it.
2.	Unscrew screw ③ to remove any components mounted to the **Vario Reference Arm for Mayfield Headholder**. It is not necessary to remove screw ③ from the arm.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Keep the central tension handle ② tightened during cleaning and disinfection so that central joint ① and ball joints ④ cannot move. This insulates the inner mechanism against liquids and contamination.
3.	Use pretreatment, ensuring that central joint ① and ball joints ④ are not immersed.
4.	Open up the central tension handle ② to ensure that central joint ① and ball joints ④ can move.
5.	Move and rotate central joint ① and ball joints ④.
6.	Check central joint ① and ball joints ④ for residue. If residue is still visible, repeat steps 1-4.
7.	Close central tension handle ②.
8.	Automatic cleaning and disinfection.
9.	Open central tension handle ②.
10.	Steam sterilization.

No flash sterilization.

Incompatible Solutions

- Organic/inorganic, or oxidizing acids (pH < 4)
- Strong alkalines (pH > 11)
- Solvents (such as alcohol, benzene, acetone)
- Phenol
- Chlorine, bromine, iodine
- Chlorine salts (in particular ammonium chloride compounds), chlorinated/halogenated hydrocarbons
- Oxidizing agents, peroxide, hypochlorite

To prevent damage to the device, do not use incompatible solutions.

Ingress of Fluids

As the inner construction of the instrument cannot be accessed, fluids or other materials must be prevented from entering. Critical entry points are ball joints and central joint. If ball joints or central joint are contaminated, clean them before re-positioning the instrument.

Do not use an ultrasonic bath.

Lubrication

Do not lubricate central joint and ball joints. Friction is necessary to ensure safe load bearing and to prevent unwanted movement of the arm.

3.2.3 VarioGuide (55950)

Illustration

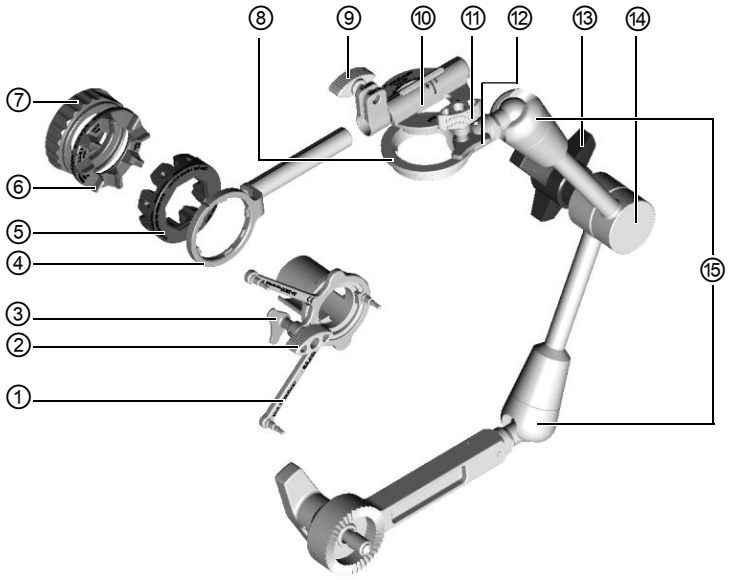


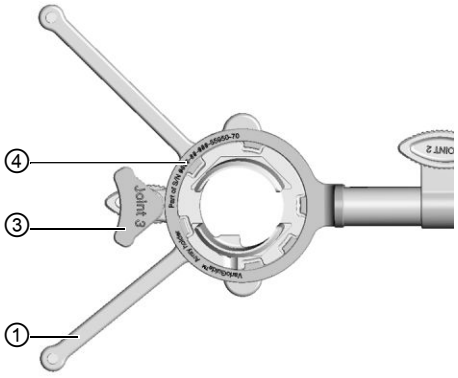
Figure 35

No.	Component
①	Reference array (55950-40)
②	Joint 3 nut (55950-99)
③	Joint 3 lock (55950-99)
④	Reference array holder
⑤	Disc set: inner disc
⑥	Disc set: outer disc
⑦	Disc set: lock ring
⑧	Joint 1
⑨	Joint 2 screw
⑩	Disc joint
⑪	Joint 1 nut (55950-99)
⑫	Joint 1 lock (55950-99)
⑬	Central tension handle
⑭	Central joint
⑮	Ball joints

How to Disassemble Disc Set

Steps	
1.	Unscrew lock ring ⑦ to remove it together with outer disc ⑥ (lock ring and outer disc are pinned together).
2.	Remove lock ring ⑦ from outer disc ⑥.
3.	Remove inner disc ⑤ from reference array ①.

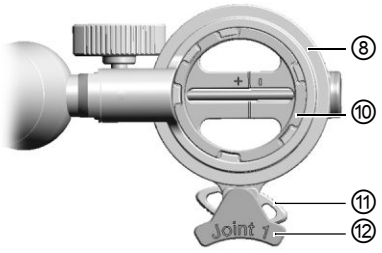
How to Disassemble Reference Array

Steps	
1.	Loosen joint 3 nut ②.
2.	 Turn reference array ① to initial position so that its indentations match the teeth of the reference array holder ④. All six teeth should be visible. Make sure that joint 3 lock ③ has been turned as shown. Otherwise, the reference array can not be removed.
3.	Remove reference array ① from reference array holder ④.

How to Remove Reference Array Holder from Disc Joint

Steps	
1.	Loosen joint 2 screw ⑨.
2.	Withdraw reference array holder ④ as far as it will go.
3.	Completely unscrew reference array holder ④.

How to Remove Disc Joint from Arm

Steps	
1.	Loosen joint 1 nut ⑪.
2.	Orientate component so that joint 1 nut ⑪ points in a downward direction.
3.	 Turn disc joint ⑩ backwards in direction of the arm so that its teeth match the indentations of joint 1 ⑧. All six teeth should be visible. Make sure that joint 1 lock ⑫ has been turned as shown. Otherwise, disc joint ⑩ cannot be removed.
4.	Withdraw disc joint ⑩.

How to Reprocess

Steps	
1.	Keep the central tension handle ⑬ tightened during cleaning and disinfection so that central joint ⑭ and ball joints ⑮ cannot move. This insulates the inner mechanism against liquids and contamination.
2.	Pretreat, ensuring central joint ⑭ and ball joints ⑮ are not immersed.
3.	Open up central tension handle ⑬ to ensure that central joint ⑭ and ball joints ⑮ can move.
4.	Move and rotate central joint ⑭ and ball joints ⑮.
5.	Check central joint ⑭ and ball joints ⑮ for residue. If residue is still visible, repeat steps 1-4.
6.	Close central tension handle ⑬.
7.	Automatic cleaning and disinfection.
8.	Open central tension handle ⑬.
9.	Steam sterilization.

No flash sterilization.

Incompatible Solutions

- Organic/inorganic, or oxidizing acids (pH < 4)
- Strong alkalines (pH > 11)
- Solvents (such as alcohol, benzene, acetone)
- Phenol
- Chlorine, bromine, iodine
- Chlorine salts (in particular ammonium chloride compounds), chlorinated/halogenated hydrocarbons
- Oxidizing agents, peroxide, hypochlorite

To prevent damage to the device, do not use incompatible solutions.

Ingress of Fluids

As the inner construction of the instrument cannot be accessed, fluids or other materials must be prevented from entering. Critical entry points are ball joints and central joint. If ball joints or central joint are contaminated, clean them before re-positioning the instrument.

Do not use an ultrasonic bath.

Lubrication

Do not lubricate central joint and ball joints. Friction is necessary to ensure safe load bearing and to prevent unwanted movement of the arm.

3.2.4 Frameless Biopsy System (55940)

Illustration

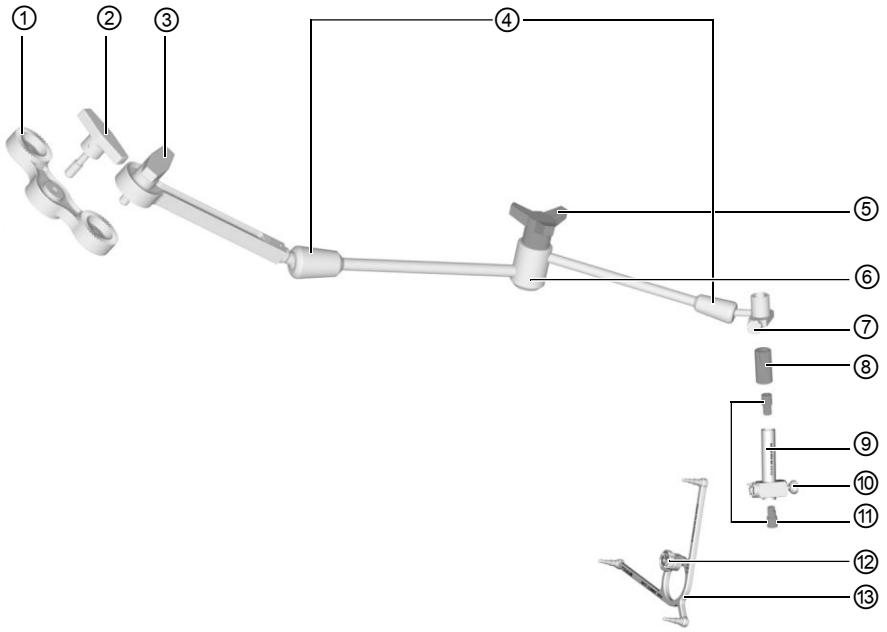


Figure 36

No.	Component
①	V-connector (52003 (Mayfield), 52005 (IMRIS))
②	Screw
③	Screw
④	Ball joints
⑤	Central tension handle
⑥	Central joint
⑦	Screw
⑧	Sleeve
⑨	Biopsy tube
⑩	Screw
⑪	Inserts (2)
⑫	Screw
⑬	Biopsy alignment array (55972)

How to Disassemble

Steps	
1.	Tighten the central tension handle ⑤, so that ball joints ④ and central joint ⑥ cannot move.
2.	Unscrew screw ⑫ to remove biopsy alignment array ⑬ from biopsy tube ⑨.
3.	Unscrew screw ⑦ until biopsy tube ⑨ including the inserts ⑪ can be removed. This screw cannot completely be unscrewed, as it has a stopper.

Steps	
4.	Remove sleeve ⑧.
5.	Loosen screw ⑩. This screw cannot completely be unscrewed, as it has a stopper.
6.	Manually unscrew inserts ⑪. Do not use tools.
7.	Unscrew screw ③ to remove V-connector ①.
8.	Tighten screw ⑦ clockwise and then loosen it half a turn.
9.	Loosen screw ⑩ until it does not grip in the thread any longer, but it is freely moveable.
10.	Place inserts ⑪ and sleeve ⑧ in a fine mesh basket.

How to Reprocess

Steps	
1.	Keep the central tension handle ⑤ tightened during cleaning and disinfection so that ball joints ④ and central joint ⑥ cannot move. This insulates the inner mechanism against liquids and contamination.
2.	Pretreat, ensuring that ball joints ④ and central joint ⑥ are not immersed.
3.	Open up the central tension handle ⑤ so that ball joints ④ and central joint ⑥ can move.
4.	Move and rotate ball joints ④ and central joint ⑥.
5.	Check central joint ⑥ and ball joints ④ for residue. If residue is still visible, repeat steps 1-4.
6.	Close central tension handle ⑤.
7.	Automatic cleaning and disinfection.
8.	Open central tension handle ⑤.
9.	Steam sterilization.

No flash sterilization.

Incompatible Solutions

- Organic/inorganic, or oxidizing acids (pH < 4)
- Strong alkalines (pH > 11)
- Solvents (such as alcohol, benzene, acetone)
- Phenol
- Chlorine, bromine, iodine
- Chlorine salts (in particular ammonium chloride compounds), chlorinated/halogenated hydrocarbons
- Oxidizing agents, peroxide, hypochlorite

To prevent damage to the device, do not use incompatible solutions.

Ingress of Fluids

As the inner construction of the instrument cannot be accessed, fluids or other materials must be prevented from entering. Critical entry points are ball joints and central joint. If ball joints or central joint are contaminated, clean them before re-positioning the instrument.

Do not use an ultrasonic bath.

Lubrication

Do not lubricate central joint and ball joints, as friction is necessary to ensure safe load bearing and to prevent unwanted movement of the arm.

3.2.5 Skull Reference Set

Article Numbers

Component	Article No.
Skull Reference Base	52129
Skull Reference Array	52122
Adjustment Nut	52125
Tube	
Tube Fixation Nut	

Illustration

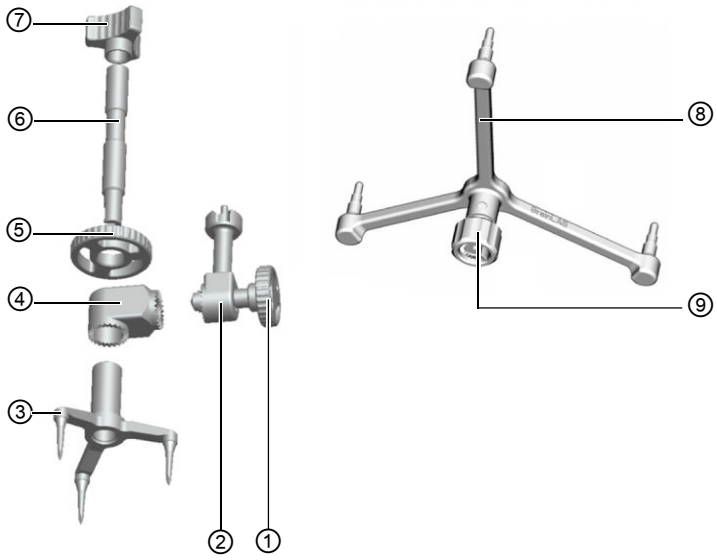


Figure 37

How to Disassemble

Steps	
1.	Unscrew nuts ⑤ and ⑦.
2.	Remove tube ⑥.
3.	Remove base connector ④ from base ③.
4.	Loosen screw ① to remove reference array connector ② from base connector ④.
5.	Loosen nut ⑨ to remove skull reference array ⑧.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.2.6 Screwdriver, Drill and Handle for Skull Reference Set

Screwdriver Blade (52171)

Figure 38

Drill Bit

Figure 39

Handle (52127)

Figure 40

How to Disassemble

Steps	
1.	Pull back front sleeve of the handle.
2.	Remove screwdriver blade/drill bit.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.2.7 Reference Headband Star (41877)

Illustration

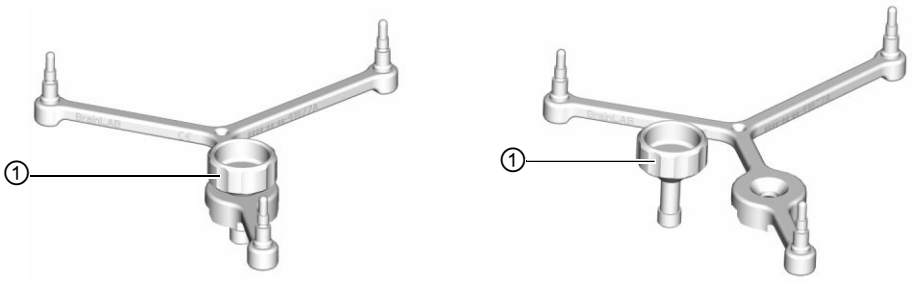


Figure 41

How to Disassemble

Step
Unscrew screw ① from the **Reference Headband Star**.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.2.8 Z-touch Rev. 2 (18370-10)

Illustration

Figure 42

How to Clean and Disinfect

Steps	
1.	Ensure that battery cover ① is closed.
2.	Remove dirt stains using a soft tissue moistened with a surface disinfectant.

Do not clean the laser beam opening with coarse material.

Z-touch is not waterproof. Do not spill any liquids onto Z-touch or immerse Z-touch in any liquids.

Do not use automatic cleaning and disinfection procedures.

Do not sterilize. Sterilization destroys the device and could damage sterilization equipment.

Compatible Disinfectants

Only use the following types of surface disinfectants on **Z-touch**:

Disinfectant Type	Example
Alcohol-based	Meliseptol, Mikrozid AF Liquid
Alkylamine-based	Incidin Plus 2%

Disinfectant Type	Example
Active oxygen-based	Perform
Aldehyde/chloride-based	Antiseptica Kombi - Flächendesinfektion

NOTE: Use only surface disinfectants released in your specific market.

NOTE: Surface disinfectants may leave a residue. This can be easily removed using a dry cloth.

Always closely follow the directions of the disinfectant manufacturer.

Using cleaning fluids, disinfection wipes or cleaning procedures other than those specified may damage equipment. It is suggested to only use disinfectants verified by Brainlab to avoid damaging Z-touch.

3.2.9 Z-touch Rev. 1 (41985)

Illustration

Figure 43

How to Clean and Disinfect

Steps	
1.	Turn off **Z-touch**.
2.	Remove dirt stains using a soft tissue moistened with isopropanol.

Do not clean the laser beam opening with coarse material.

No sterilization.

Do Not Use

- Acid solvents ph < 6
- Caustic or basic solvents ph > 9
- Active chlorine

Only use solutions approved by Brainlab.

3.2.10 Softouch (18390-10A)

Illustration

Figure 44

How to Clean and Disinfect

Steps	
1.	Pretreatment. Thoroughly clean gap ①, diode holder ② and other slots using a soft tissue moistened with neutral (pH6 - pH9) cleaning solvent.
2.	Check gap ①, diode holder ② and other slots for residue. If residue is still visible, repeat step 1.
3.	Use neutral (pH6 - pH9) surface disinfectants such as Meliseptol. Follow disinfectant manufacturer’s recommendations.

Do not sterilize Softouch. Sterilization will destroy the device and may lead to severe damage of sterilization equipment or injury to the patient or user.

Use manual surface disinfection only. Softouch is not resistant to thermo-disinfection in an automatic washing machine.

Do not completely immerse Softouch in any liquid.

Do Not Use

- Acid solvents pH < 6
- Caustic or basic solvents pH > 9
- Solvents that are not suited for polycarbonate (PC) and acrylonitrile-butadiene-styrol-copolymer (ABS) plastics.

Only use solutions approved by Brainlab.

Softouch Gauge

Generally, the **Softouch** gauge does not need to be cleaned. However, if cleaning becomes necessary, use a soft moistened tissue with enzymatic cleaning solvent to wipe it clean and dry it thoroughly.

3.2.11 Adapter for Rectangular Instruments (55105)

Illustration

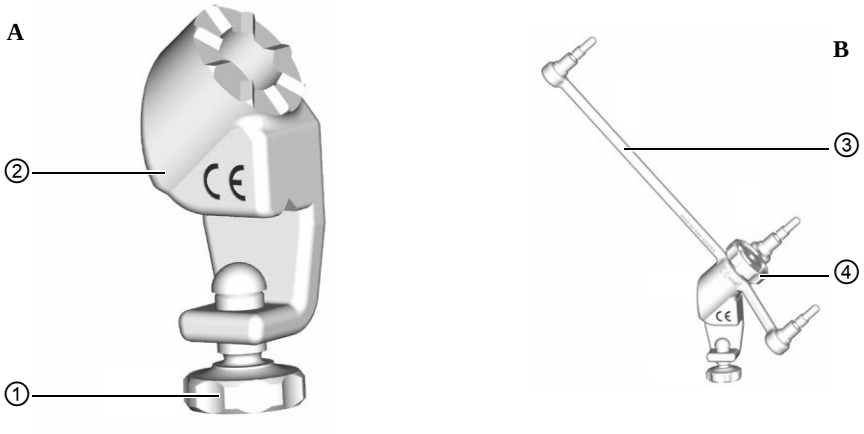


Figure 45

No.	Component	Part
①	Screw	**A** - **Adapter for Rectangular Instruments**
②	**Adapter for Rectangular Instruments**	
③	Tracking array	**B** - Tracking Array
④	Screw	

How to Disassemble

Steps	
1.	Unscrew screw ④ to remove tracking array ③ from **Adapter for Rectangular Instruments** ②.
2.	Loosen screw ① until there is a gap between **Adapter for Rectangular Instruments** ② and screw ① so that all surfaces and threads can be easily rinsed.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.2.12 Adapter for Cylindrical Instruments (55110)

Illustration

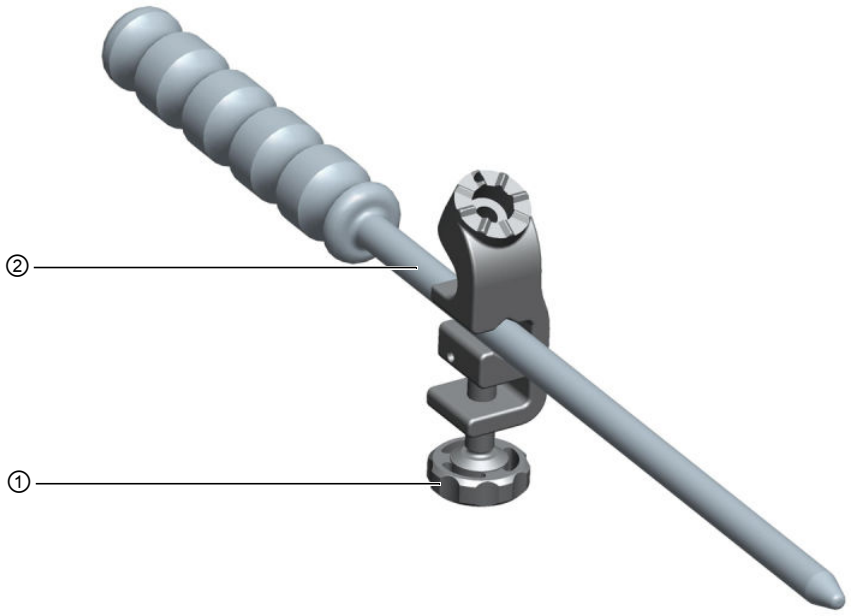


Figure 46

No.	Component
①	Screw
②	Cylindrical instrument (example)

How to Disassemble

Step
Unscrew screw ① to remove the cylindrical instrument ②.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.2.13 Suction Tube - StarLink Interface (55790-xx)

Illustration

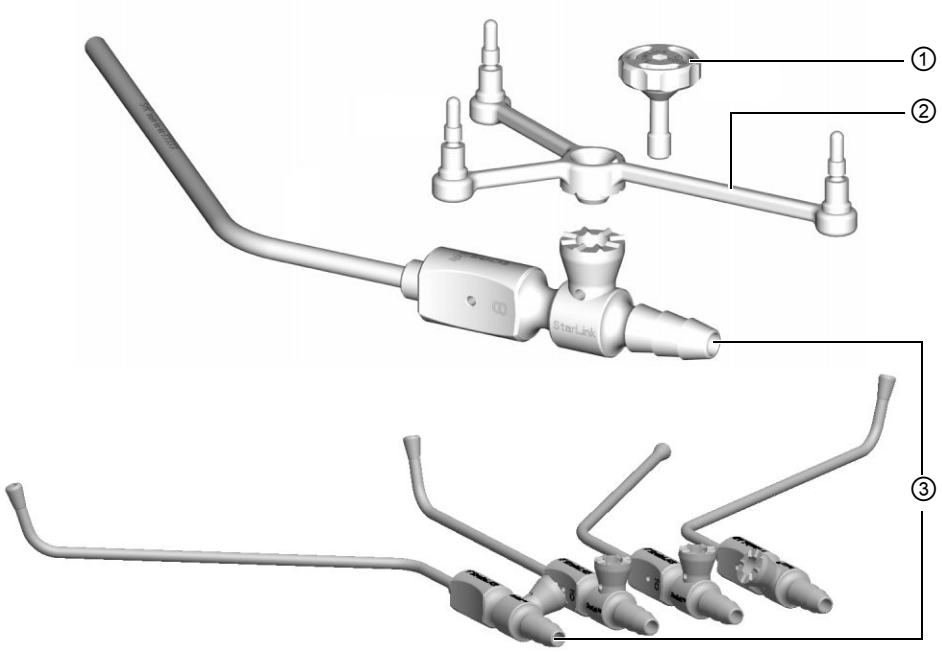


Figure 47

No.	Component
①	Screw
②	Tracking array
③	Suctions

How to Disassemble

Step
Unscrew screw ① to remove tracking array ②.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.2.14 Microscope Adapter Sets (41767-xx)

Illustration, Example

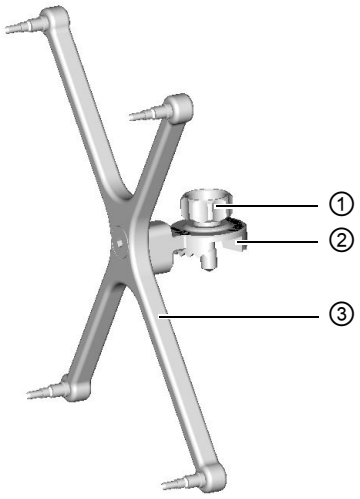


Figure 48

No.	Component
①	Screw
②	Array body *NOTE: Array body geometry depends on the microscope being used.*
③	Tracking array

How to Disassemble

Steps	
1.	Loosen screw ①.
2.	Remove microscope tracking array from the microscope adapter.
3.	Ensure that there is a gap between array body ② and screw ①.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.2.15 Ultrasound Adapter with Latch Lock

Illustration

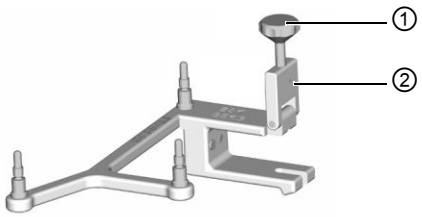


Figure 49

How to Disassemble

Step
Loosen screw ① to open hinge ②.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.2.16 Ultrasound Adapter with Special Clamp Lock

Illustration

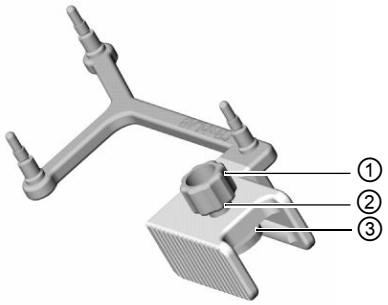


Figure 50

How to Disassemble

Steps	
1.	Loosen screw ①.
2.	Ensure that there are gaps between: • Head of bolt and adapter body ② • Stop disc and adapter body ③

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.2.17 Ultrasound Adapter with Ring Lock

Illustration

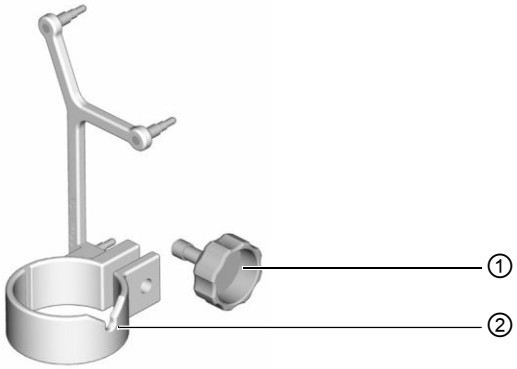


Figure 51

How to Disassemble

Step
Unscrew screw ① from adapter body ②.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.2.18 Ultrasound Adapter with Jaw Lock

Illustration

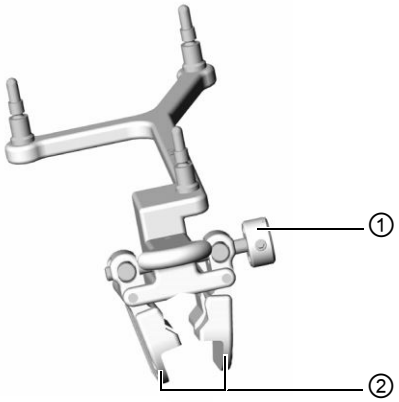


Figure 52

How to Disassemble

Steps	
1.	Loosen screw ①.
2.	Ensure that jaws ② do not touch each other.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.2.19 Ultrasound Adapter with Vise Lock

Illustration

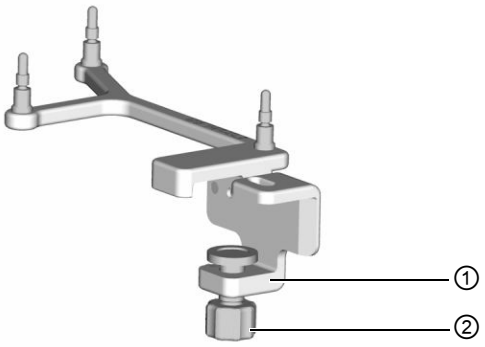


Figure 53

How to Disassemble

Steps	
1.	Loosen screw ②.
2.	Ensure that there are gaps between screw head and adapter body ①.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.2.20 Ultrasound Registration Phantom (22630)

Illustration

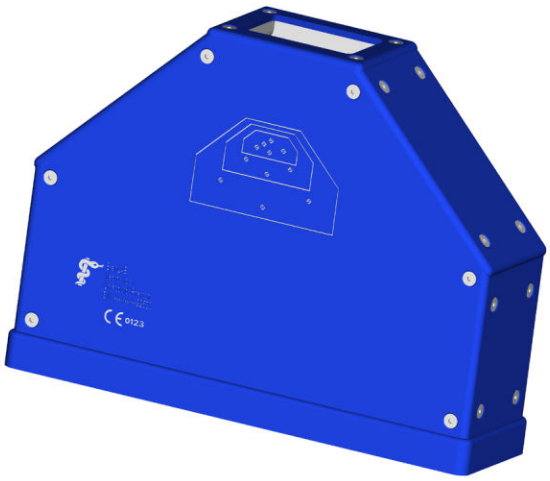


Figure 54

How to Clean

Step
Clean with a damp cloth.

*NOTE: As the **Ultrasound Registration Phantom** is draped using the sterile **Ultrasound Registration Phantom Drape**, complete reprocessing is not necessary.*

No disinfection.

No sterilization.

Do Not Use

- Acid solvents
- Alcohol
- Ultrasonic cleaners

Only use solutions approved by Brainlab.

3.2.21 IGSonic Adapter Base (41860-5D, 41860-35A)

How to Disassemble

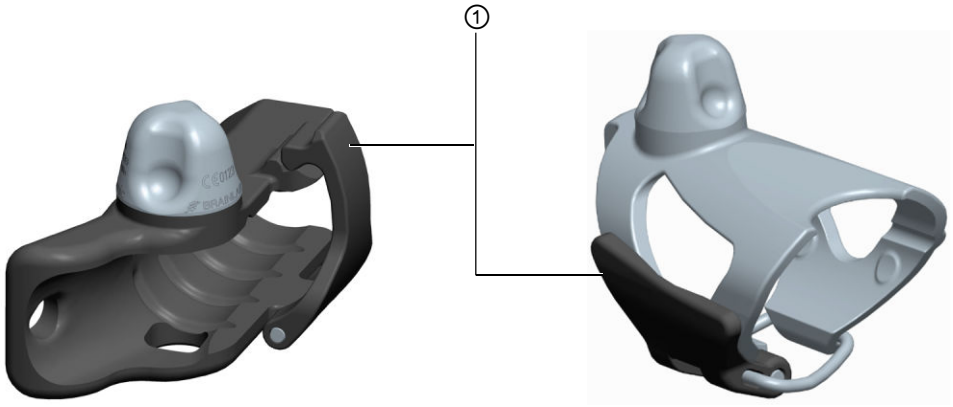


Figure 55

Step
Open clip ① of adapter base.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.2.22 IGSonic Adapter Array (22595)

Illustration

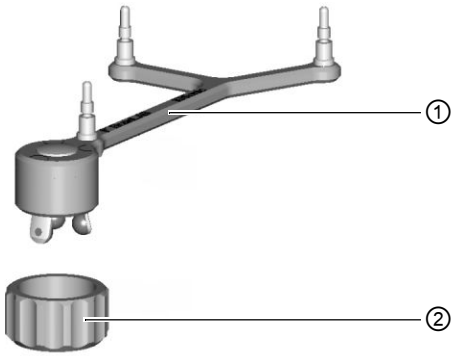
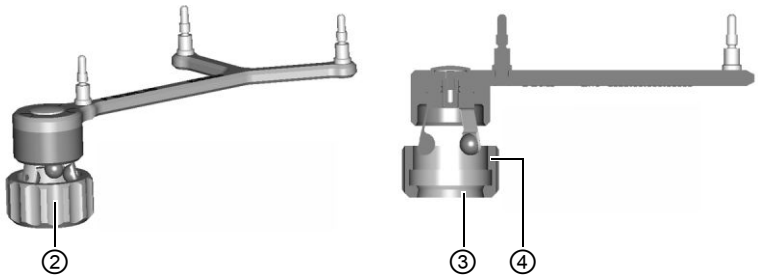


Figure 56

How to Disassemble

Step
Unscrew the round nut ② from tracking array ①.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Remount round nut ② so that it cannot be lost.  As the bottom part ③ of the inner design of the round nut is smaller than the upper part ④, it can only be mounted with the screw thread pointing towards the tracking array ①.
4.	Tighten round nut ② as far as it will go. Slight resistance during tightening is normal.
5.	Loosen round nut ② by turning one full rotation.
6.	Steam sterilization.

3.3 Fluoroscopic and Trauma/ACL Instrumentation

3.3.1 Fluoro 3D/2D Registration Kit (55720)

Illustration

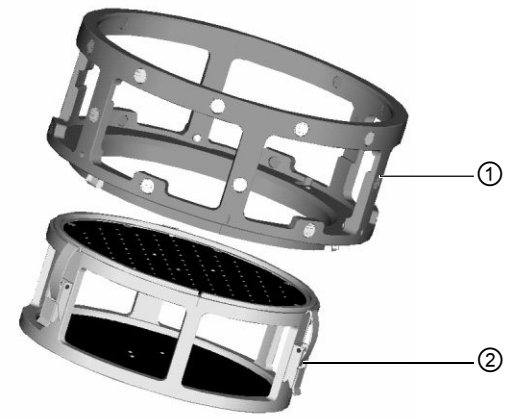


Figure 57

No.	Component	Article No.
①	**Fluoro 3D Registration Ring**	55715-10
②	**Fluoro 2D Registration Ring**	55715-20

How to Clean and Disinfect

The **Fluoro 3D/2D Registration Kit** and corresponding C-arms are sterilely draped.

Do not sterilize the registration kit. Only surface cleaning and surface disinfection is necessary.

Steps	
1.	Clean surfaces using a surface disinfectant such as Meliseptol. Dry surface afterwards.
2.	Use neutral (pH6 - pH9) surface disinfectants. Follow disinfectant manufacturer’s recommendations.

No ultrasonic cleaners.

Draping

The **Fluoro Registration Kit** and the corresponding C-arm are always used sterilely draped. Only surface cleaning and surface disinfection is necessary.

Your **Instrument User Guide** lists the compatible sterile drapes, which are provided by the C-arm manufacturer.

3.3.2 Fluoro Registration Kit, Rev. 2 (55705)

Illustration

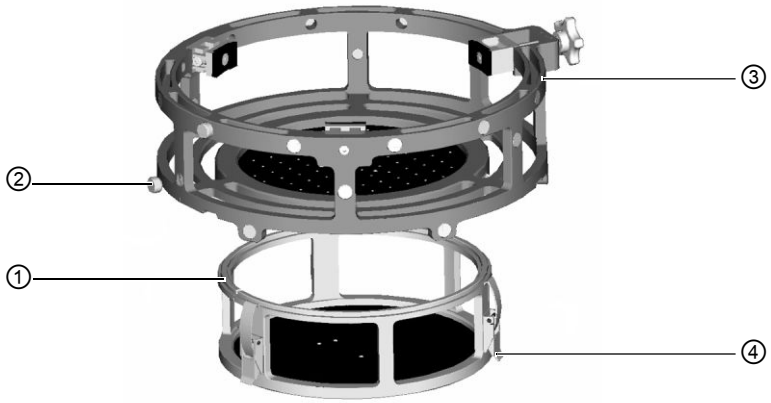


Figure 58

No.	Component
①	Removable plate
②	Reflective disks (for **Fluoro Registration Kit, Rev. 2)**
③	Upper ring
④	Quick fasteners

How to Disassemble

Steps	
1.	Open the three quick-fasteners ④ to detach removable plate ① from **Fluoro Registration Kit, Rev. 2**.
2.	Remove clipable reflective disks ② from **Fluoro Registration Kit, Rev. 2**.
3.	Reprocess upper ring ③ and removable plate ① separately.

Remove reflective disks from Fluoro Registration Kit, Rev. 2 prior to reprocessing.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection. *NOTE: Only use neutral enzymatic cleaners (pH6 - pH9).*
3.	Steam sterilization.

No ultrasonic cleaners.

3.3.3 Fluoro Registration Kit, Rev. 1 (41705)

Illustration

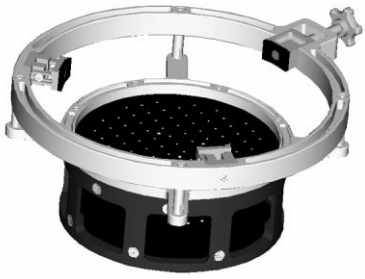


Figure 59

How to Disassemble

Remove reflective disks from Fluoro Registration Kit, Rev. 1 prior to reprocessing.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection. *NOTE: Only use neutral enzymatic cleaners (pH6 - pH9).*
3.	Steam sterilization.

No ultrasonic cleaners.

3.3.4 Reflective Disks (55775)

Illustration

Figure 60

Reflective Disks

Reprocessing reduces reflectiveness of reflective disks. As a result, some reflective disks may not be detected by the system.

NOTE: Experience shows that 15 cycles of use may typically be achieved, however, a specific number of cycles cannot be recommended, as loss of reflectiveness depends on the specific application and re-use processes.

Verify that the surface of the reflective disks is in good condition. Replace reflective disks if reflective surface is dulled, darkened or peeled off.

Before You Begin

Remove reflective disks from Fluoro Registration Kit, Rev. 2 prior to reprocessing.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection. *NOTE: Only use neutral enzymatic cleaners (pH6 - pH9).*
3.	Steam sterilization.

No ultrasonic cleaners.

The reflective foil of the disks should not come into contact with anything during sterilization.

3.3.5 Reflective Disks (for Fluoro Registration Kit, Rev. 1) (41775)

Illustration

Figure 61

Reflective Disks

Reprocessing reduces reflectiveness of reflective disks. As a result, some reflective disks may not be detected by the system.

NOTE: Experience shows that 15 cycles of use may typically be achieved, however, a specific number of cycles cannot be recommended, as loss of reflectiveness depends on the specific application and re-use processes.

Verify that the surface of the reflective disks is in good condition. Replace reflective disks if reflective surface is dulled, darkened or peeled off.

Before You Begin

Remove reflective disks from Fluoro Registration Kit, Rev. 1 prior to reprocessing.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection. *NOTE: Only use neutral enzymatic cleaners (pH6 - pH9).*
3.	Steam sterilization.

No ultrasonic cleaners.

The reflective foil of the disks should not come into contact with anything during sterilization.

3.3.6 Fluoro Registration Kit for Ziehm Vision FD Vario 3D C-arm (55730)

Illustration

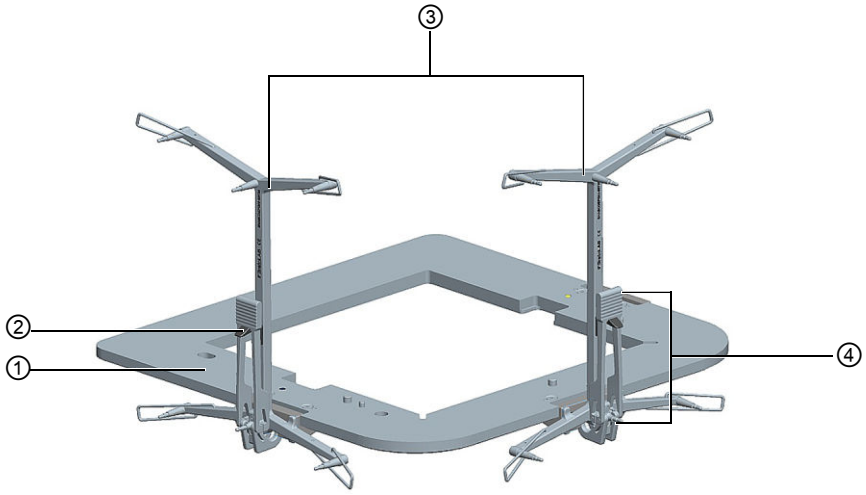


Figure 62

How to Disassemble

Steps	
1.	Push back the safety clip ②.
2.	Open the attachment lever ④.
3.	Remove **Fluorostars** ③ from the frame ①.

How to Clean and Disinfect

Steps	
1.	Clean surfaces using a moistened cloth. Dry surface afterwards.
2.	Use neutral (pH6 - pH9) surface disinfectants. Follow disinfectant manufacturer's recommendations.

Ensure that the attachment pins of the shifting markers (located at the end of the attachment lever ④) are thoroughly cleaned to avoid inaccurate navigation and patient injury.

No sterilization.

No ultrasonic cleaners.

Draping

The **Fluoro Registration Kit for Ziehm Vision FD Vario 3D C-arm** and the corresponding C-arm are always used sterilely draped. Only surface cleaning and surface disinfection is necessary.

Your **Instrument User Guide** lists the compatible sterile drapes, which are provided by the C-arm manufacturer.

3.3.7 xSpot

Illustration

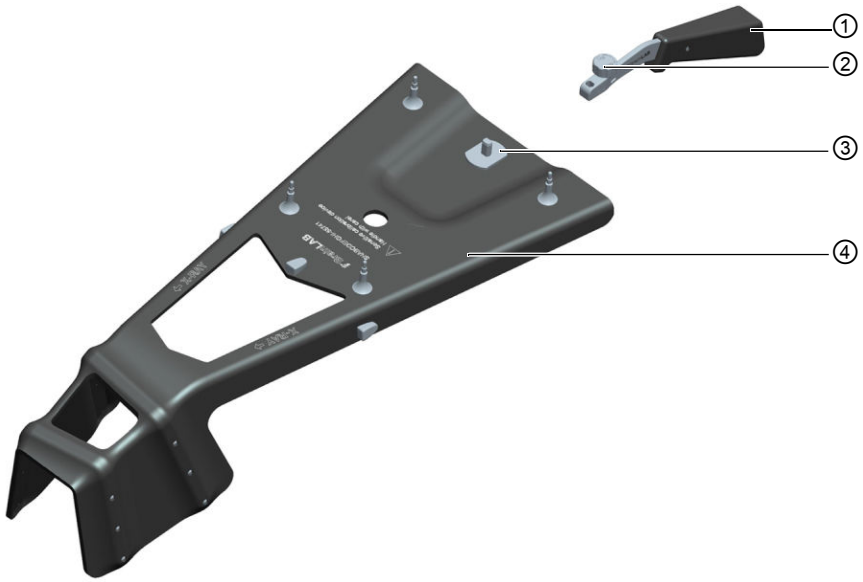


Figure 63

No.	Component
①	Handle (55742)
②	Screw
③	Interface
④	**xSpot** (55741)

How to Disassemble

Step
Loosen screw ② a half turn to remove handle ① from interface ③.

How to Reprocess

Steps	
1.	Pretreatment. Thoroughly clean interface ③ between **xSpot** ④ and handhold ①.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

Incompatible Solutions

- Strong alkalines (pH > 11)

For other incompatible solutions see page 20.

To prevent damage to the device, do not use incompatible solutions.

3.3.8 xSpot Correction Plate and Accessories

Illustration

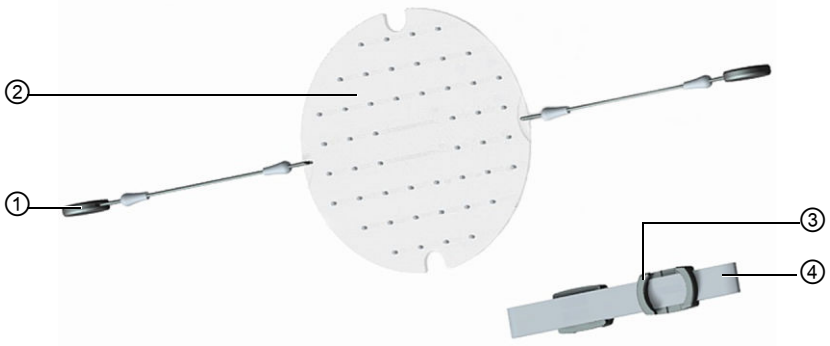


Figure 64

No.	Component
①	Attachment clip
②	**Correction Plate** (55744, 55745)
③	Plastic receptacle
④	Rubber band (55746)

How to Clean and Disinfect

The **Correction Plate**, accessories and corresponding C-arm are sterilely draped. Only surface cleaning and surface disinfection is necessary.

Steps	
1.	Clean **Correction Plate** ① and rubber band with isopropanol.
2.	Pretreatment.
3.	Check for residue. If residue is still visible, repeat step 2.

Do not sterilize the Correction Plate or other accessories. Temperatures above 35°C (95°F) are not approved for these items.

3.3.9 Reference Array for Trauma Implants (53500)

Illustration

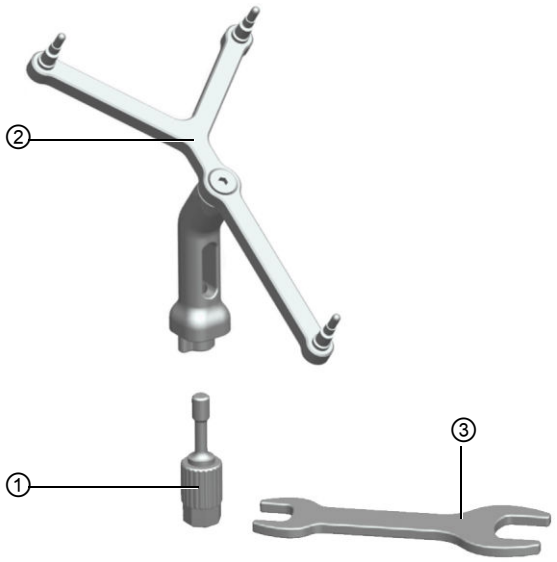


Figure 65

No.	Component	Article No.
①	Fixation screw	53505
②	Reference array	53500
③	Wrench	52424

How to Disassemble

Steps	
1.	Unscrew fixation screw ① using the wrench ③.
2.	Detach reference array ② from implant insertion instrument.
3.	Reprocess all parts separately.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.3.10 Calibration Insert for Synthes LISS/LCP (53510)

Illustration

Figure 66

How to Disassemble

Step
Remove **Calibration Insert for Synthes LISS/LCP** from **ICM4**.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.3.11 Calibration Insert for Synthes LFN 9-11 mm (53511) and 12-16 mm (53512)

Illustration

Figure 67

How to Disassemble

Step
Remove **Calibration Insert for Synthes LFN** from **ICM4**.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.3.12 ACL Tibial Drill Guide (52475) and ICM4 Validation Insert (52476)

Illustration

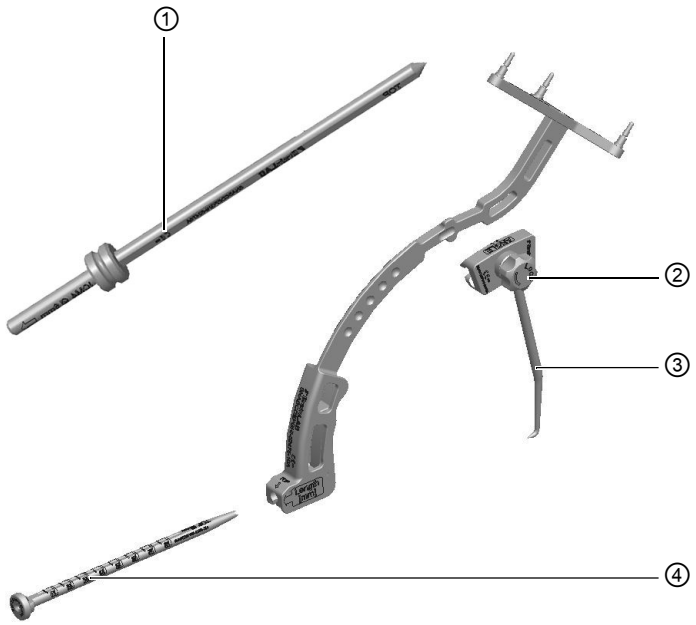


Figure 68

No.	Component
①	ICM4 validation insert
②	Lock knob
③	Target arm (52475-20)
④	Drill guide sleeve (52475-25)

How to Disassemble

Steps	
1.	Loosen lock knob ② and slide target arm to position labeled **Assemble/Disassemble**. *NOTE: The laser arrows on both parts must be aligned for disassembly.*
2.	Remove target arm ③.
3.	Pull release trigger and remove drill guide sleeve ④ from **ACL Tibial Drill Guide**.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Check instrument functionality.
4.	Steam sterilization.

3.4 Hip Instrumentation

3.4.1 Hip Caliper (52876)

Illustration

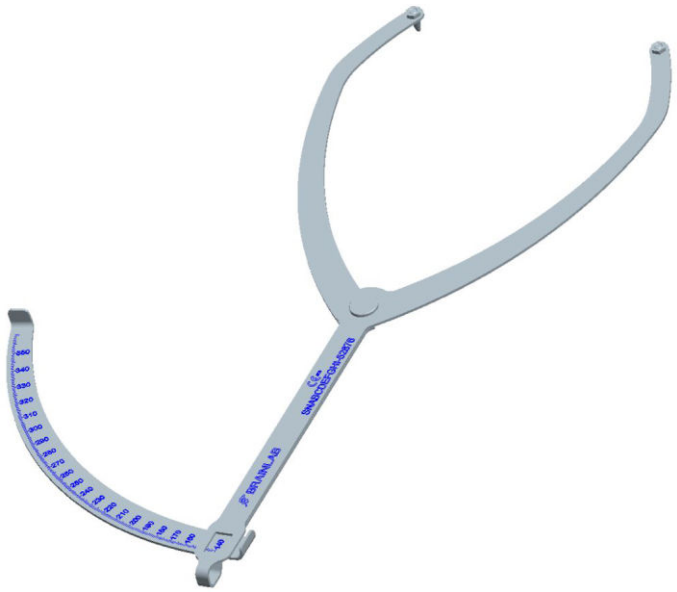


Figure 69

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	*Optional:* Steam sterilization.

The Hip Caliper is intended for use on intact skin only. If the device comes in contact with blood, steam sterilization must be applied.

3.4.2 Pinless Femur Reference Array (52400)

Illustration

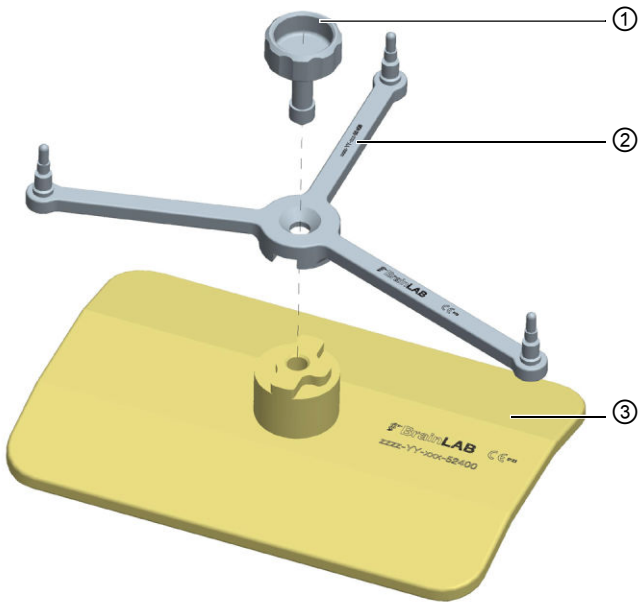


Figure 70

How to Disassemble

Steps	
1.	Unscrew screw ① to remove reference array ② from interface ③.
2.	Remove the self-adhesive tape used for fixation from the patient.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.4.3 Adapter for Surgical Motor System (41840)

Illustration

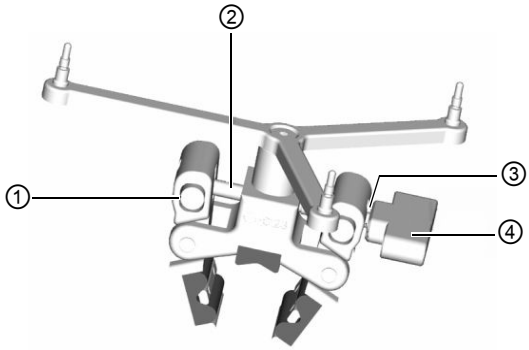


Figure 71

No.	Component
①	Connector
②	Shaft
③	Jaw
④	Screw

How to Disassemble

Steps	
1.	Loosen screw ④.
2.	Ensure that there is a gap between screw ④ and jaw ③.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	After approximately 10 uses, lubricate the shaft ②. Use a biocompatible, non-toxic medicinal lubricant (e.g., based on aliphatic hydro-carbons) which does not negatively impair sterilization and use the minimum necessary to ensure instrument functionality.
4.	After 10 uses only: Turn screw ④ back and forth several times to evenly disperse oil on shaft ② and connector ①.
5.	Steam sterilization.

Only use biocompatible, non-toxic medicinal lubricants that will not endanger the patient.

3.4.4 Cup Reamer Adapter (41879-02, -03, -04)

Illustration

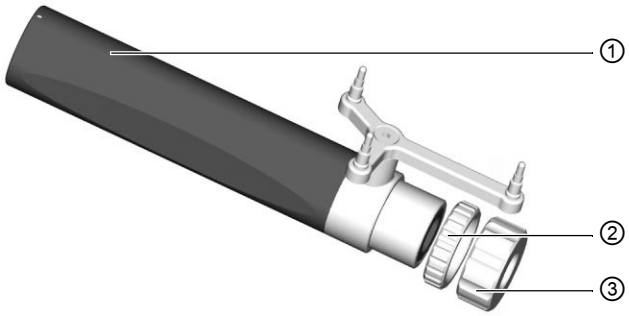


Figure 72

How to Disassemble

Step
Unscrew adjustment nut ③ and counter nut ② from cup reamer adapter ①.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

Incompatible Solutions

- Strong alkalines (pH>9)

For other incompatible solutions see page 20.

To prevent damage to the device, do not use incompatible solutions.

3.4.5 Adapter for Cup Inserter (41851)

Illustration

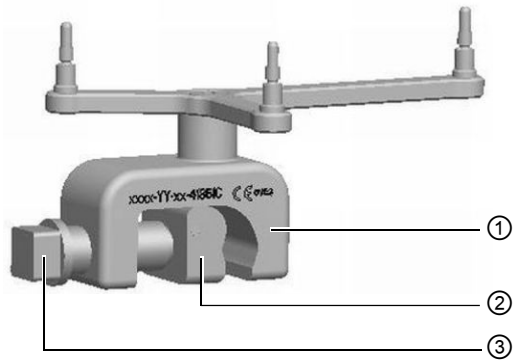


Figure 73

No.	Component
①	Frame
②	Jaw
③	Screw

How to Disassemble

Steps	
1.	Without applying excessive force, loosen screw ③ as far as it will go.
2.	Ensure that jaw ② does not touch frame ①.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	After approximately 10 uses, lubricate the shaft ②. Use a biocompatible, non-toxic medicinal lubricant (e.g., based on aliphatic hydro-carbons) which does not negatively impair sterilization and use the minimum necessary to ensure instrument functionality.
4.	After 10 uses only: Turn screw ③ back and forth several times to evenly disperse oil on the screw and threads of the frame.
5.	Steam sterilization.

Only use biocompatible, non-toxic medicinal lubricants that will not endanger the patient.

3.4.6 Femoral Broach Adapter “DePuy” (41852-01)

Illustration

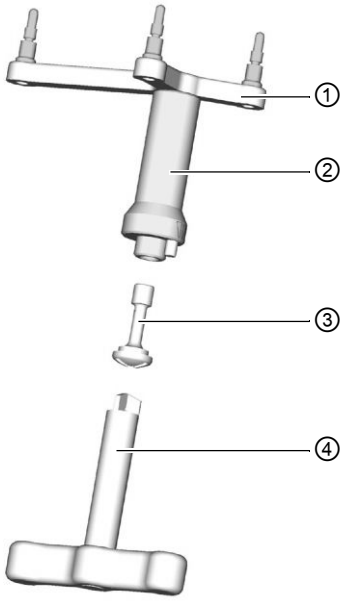


Figure 74

How to Disassemble

Steps	
1.	Unscrew connecting screw ③ to remove adapter ② from the T-shaped handle ④.
2.	Do not remove tracking array ① from adapter ② as it is pre-calibrated.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.4.7 Stem Position Verification Tool (52872, 52873)

Illustration

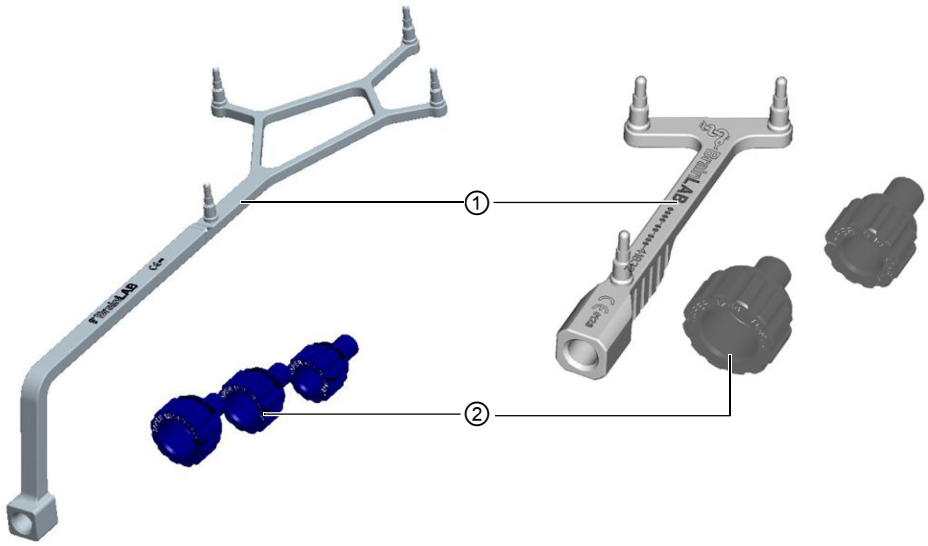


Figure 75

How to Disassemble

Step
Unscrew stem sleeve ② from tracking array ①.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.4.8 Brainlab Offset Reamer Handle (52481-xx)

Cup Reamer Handle, Overview

Figure 76

Removing Interior Tube from Handle

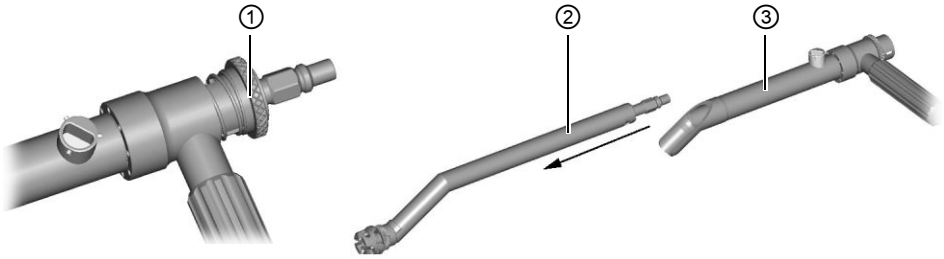


Figure 77

Opening the Halves

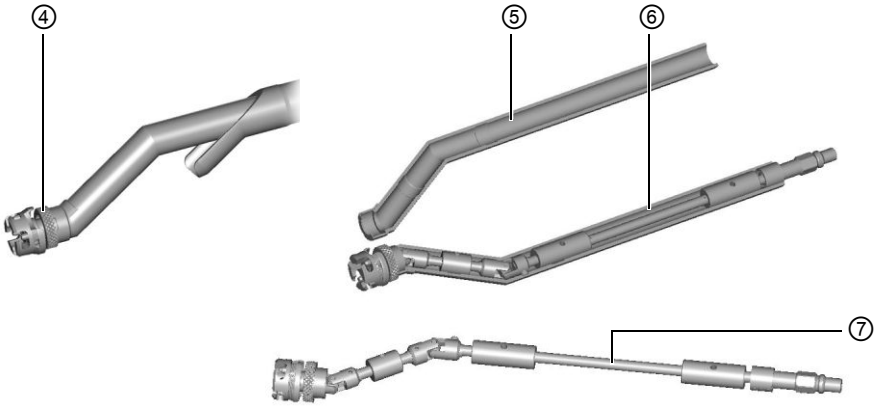


Figure 78

Components

No.	Component
①	Nut
②	Interior tube
③	Handle
④	Nut
⑤	Tube half
⑥	Tube half

No.	Component
⑦	Shaft

How to Disassemble

Steps	
1.	Unscrew nut ① to remove interior tube ② from handle ③.
2.	Unscrew nut ④ to open the two tube halves ⑤ and ⑥.
3.	Remove ⑦ shaft from the two tube halves ⑤ and ⑥.

How to Reprocess

Steps	
1.	Pretreatment
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

Incompatible Solutions

For complete device:

- Fluoride-based solutions
- Chloride-based solutions
- Oil-based solutions

For synthetic (plastic) components of device:

- Bases
- Acid solutions (pH < 4)
- Organic solvents
- Ammonia-based solvents
- Oxidizing chemicals

To prevent damage to the device, do not use incompatible solutions.

3.4.9 Brainlab Offset Cup Impactor Universal (52856, 52855-xx)

Illustration

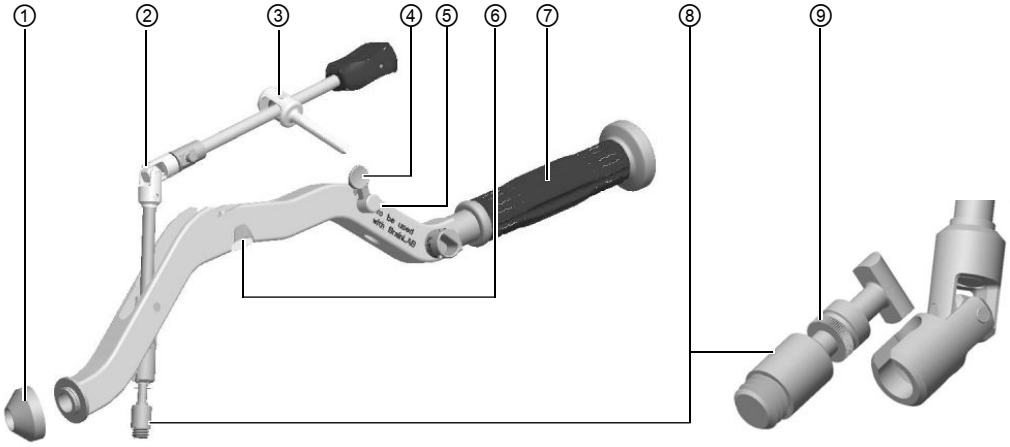


Figure 79

No.	Component	Article No.
①	Nosepiece	52855-xx
②	Tip driveshaft	
③	Ratchet	
④	Release lever (for ratchet)	
⑤	Instrument body	52856
⑥	Release lever (for tip driveshaft)	
⑦	Handle • Blue plastic (illustrated) • Metal	
⑧	Threaded tip	52855-xx
⑨	Locking nut	

How to Disassemble

Steps	
1.	Pull off the nosepiece ①.
2.	Press the release lever (for ratchet) ④ and pull out the ratchet ③.
3.	Push down the release lever (for the tip driveshaft) ⑥ and release the tip driveshaft ②.
4.	Unscrew the locking nut ⑨.
5.	Slide the threaded tip ⑧ out of the end joint of the tip driveshaft ②.
6.	Remove the threaded tip ⑧ from the impactor.

How to Reprocess

Brainlab Offset Cup Impactor Universal is available in two types:

- Impactor with a blue plastic handle
- Impactor with a metal handle

The steam sterilization parameters depend on which type is used. See below for the correct parameters for your Impactor:

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	  Impactor (blue handle): • Steam sterilization using the following prevacuum parameters: - At 134°C (274°F): - Sterilization time, minimum 18 minutes - Drying time, minimum 30 minutes - At 135°C (275°F): - Sterilization time, minimum 3 minutes - Drying time, minimum 60 minutes Impactor (metal handle): • Steam sterilization (see page 26)

Any deviation from the validated parameters could result in patient infection.

3.4.10 Brainlab Straight Cup Impactor “Universal” (52858)

Illustration

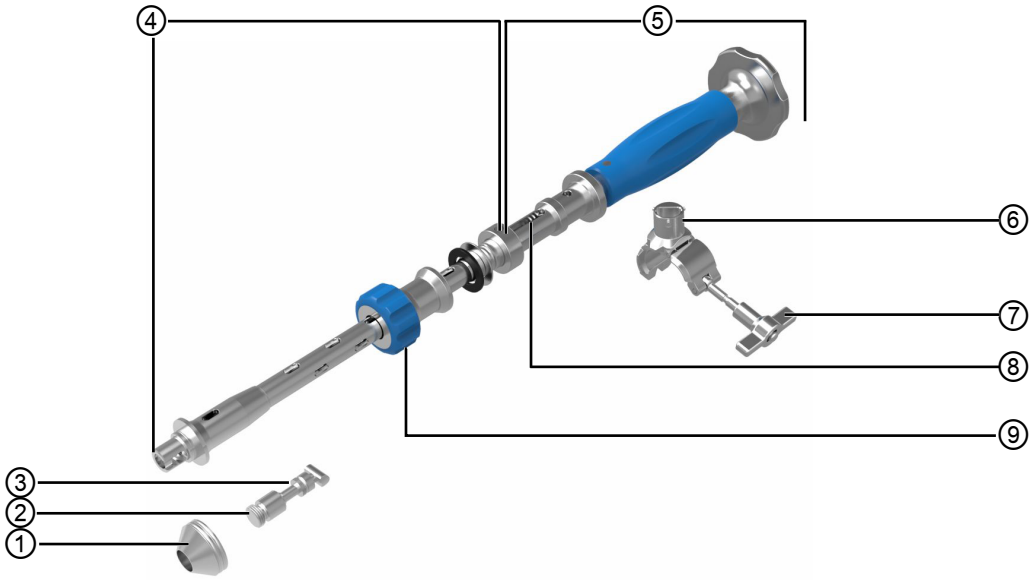


Figure 80

No.	Component	Article No.
①	Nosepiece	52855-xx
②	Threaded tip	52855-xx
③	Locking nut	
④	Driveshaft	
⑤	Instrument Body	52858-01
⑥	StarLock Interface	52858-02
⑦	Wing screw	52858-02
⑧	Spring	
⑨	Blue handling nut	

How to Disassemble

Steps	
1.	Remove the mounting base for the StarLock Interface ⑥ by releasing the wing screw ⑦. Ensure that the wing screw is completely unscrewed.
2.	Gently pry off and remove the nosepiece ①.
3.	Completely unscrew the blue handling nut ⑨ counter-clockwise.
4.	Slide the driveshaft inner rod ④ forward until the threaded tip ② is completely visible.
5.	Unscrew the locking nut ③ off the threaded tip.
6.	Slide threaded tip ② out of the driveshaft ④.
7.	Ensure that the spring ⑧ moves freely.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.5 Knee Instrumentation

3.5.1 4 in 1 Cutting Block Template (Manufacturer Specific)

Illustration, Example

Figure 81

Article Numbers

Implant Manufacturer	Article No.
DePuy	41867
Biomet	41868, 52464, 52472
Exactech	52473
Mathys	52482
Smith & Nephew	41838, 41871
Wright	52465, 52462
Zimmer	52555

How to Reprocess

Steps
1. Pretreatment.
2. Automatic cleaning and disinfection.
3. Steam sterilization.

3.5.2 5 in 1 Cutting Block Adapter “Zimmer NexGen” (41848)

Illustration

Figure 82

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.5.3 CAS Cutting Block Kit “Universal” (52480)

Components

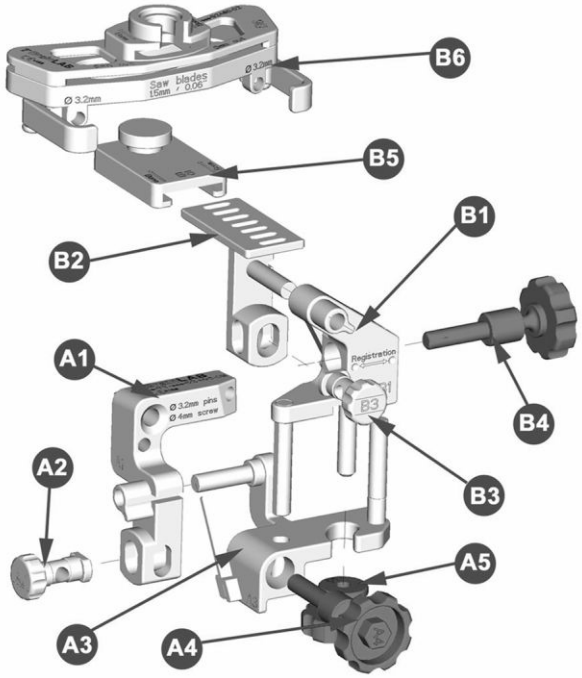
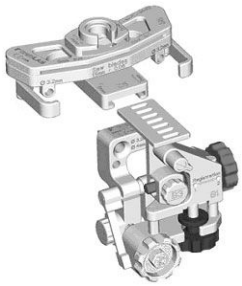


Figure 83

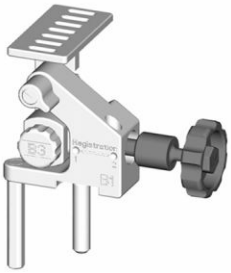
No.	Component
A1	Bone fixation bracket
A2	Slope adjustment bushing
A3	Mainframe
A4	Slope adjustment screw (yellow on the device)
A5	Adjust height knob (blue on the device)
B1	Translation frame
B2	Varus/valgus lever
B3	Varus/valgus adjustment bushing
B4	Adjust varus/valgus screw (red on device)
B5	Slot guide
B6	Cutting Slot “Standard”

NOTE: Component numbers (A1 - B6) are engraved on components.

Disassembling Group B from Group A

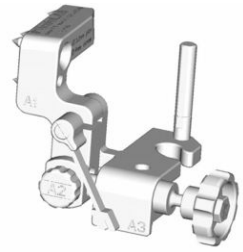
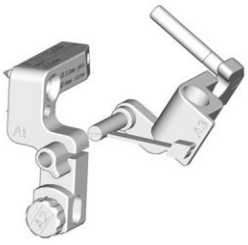
Steps		
1.		Slide **B5** and **B6** off adjustment mechanism.
2.		Turn **B5** so that it is parallel to **B6**. Move knob on **B5** to round hole of **B6**, and pull **B5** out of **B6**.
3.		Remove group **B** from group **A** while unscrewing **A5**.

Disassembling Group B

Steps		
1.		Screw **B4** out of **B3** and remove it from **B1**.
2.		Turn **B3** so that it fits through slot of **B2**, and then remove it from **B2**.

Steps		
3.		Turn **B2** until leaf spring fits through slot of **B1**, and then remove **B2** from **B1**.

Disassembling Group A

Steps		
1.		Remove **A5** from slot of **A3**. If **A4** is in the way, turn **A4** or proceed to next step.
2.		Screw **A4** out of **A2** and remove it from **A3**.
3.		Turn **A3** until leaf spring fits through slot of **A1**, then remove **A3** from **A1**.
4.		Turn **A2** to fit through slot of **A1**, then remove it from **A1**.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.5.4 Femoral and Tibial Cutting Block Adapter Kit “Universal II” (41888)

Illustration

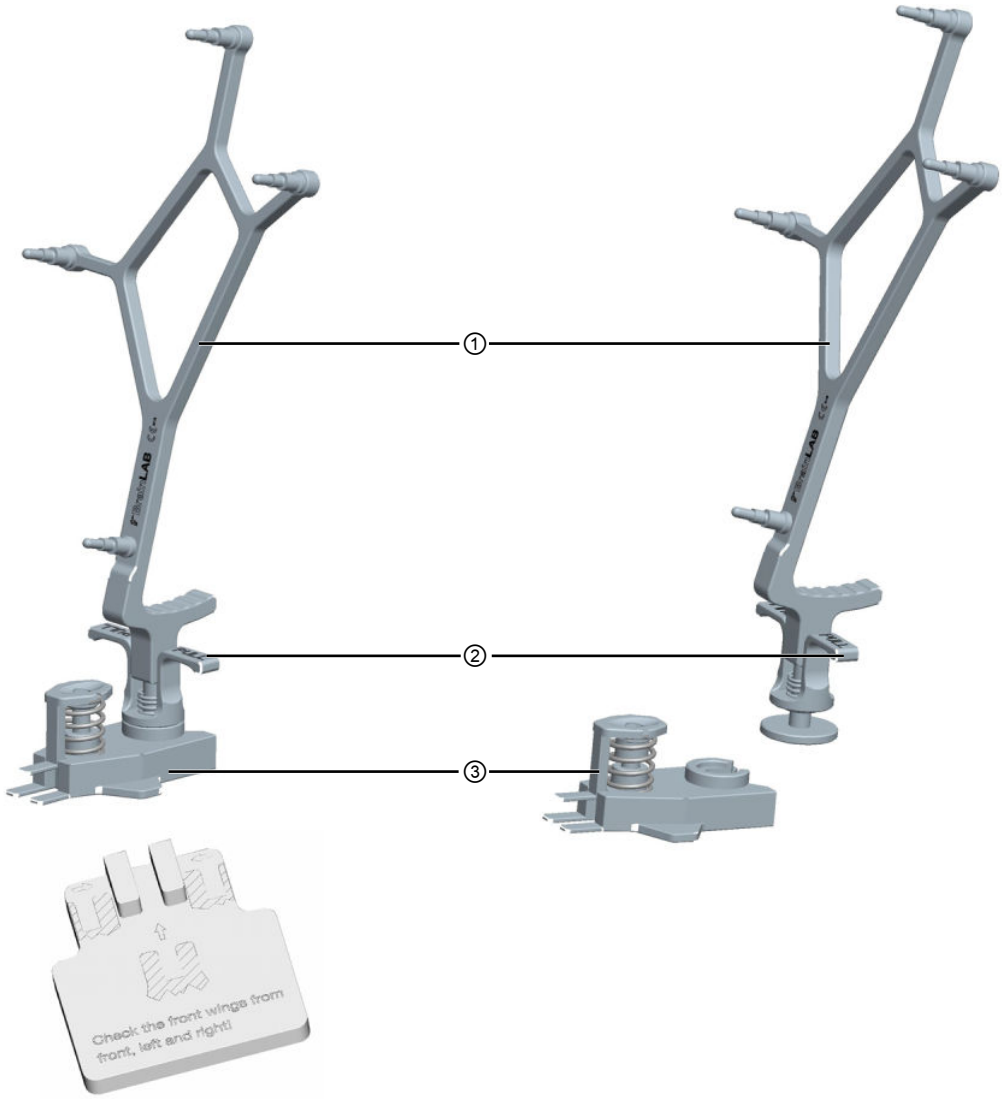


Figure 84

How to Disassemble

Steps	
1.	Pull handles ② upwards.
2.	Remove reference array ① from base plate ③.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

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

Illustration

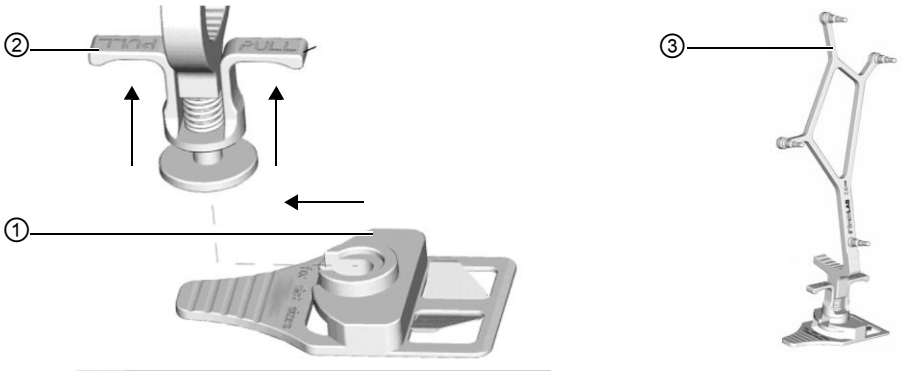


Figure 85

How to Disassemble

Steps	
1.	Pull handles ② upwards.
2.	Remove tracking array ③ from base plate ①.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.5.6 Femoral Cutting Block Adapter “ENDOPLUS” (52463)

Illustration

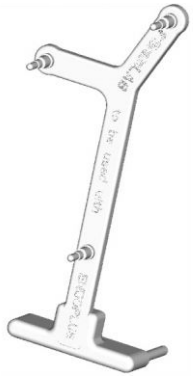


Figure 86

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.5.7 Femoral and Tibial Cutting Block Adapter “Smith & Nephew Genesis UNI” (41838)

Illustration

Figure 87

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.5.8 Patella Tracking Array (52466)

Illustration

Figure 88

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.5.9 Tibial Cutting Block Adapter “Biomet Oxford” (52854)

Illustration

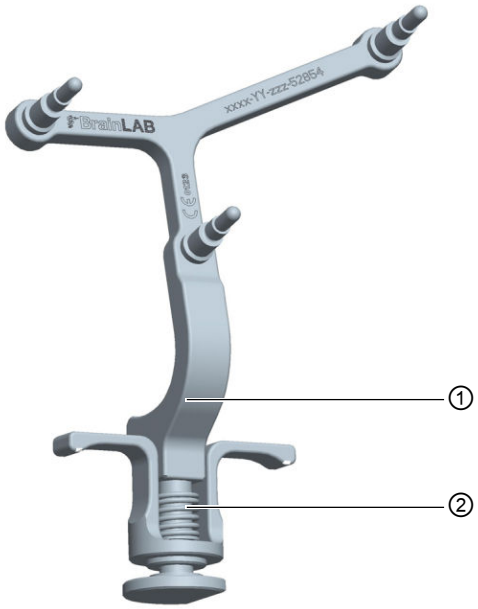


Figure 89

How to Reprocess

Steps	
1.	Pretreatment. *NOTE: As long as no other component is attached, the coil ② is relaxed, and can be moved to gain access to surfaces of coil ② and tracking array ①.*
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.5.10 Cut Verification Tool “Biomet Oxford” (52853)

Illustration

Figure 90

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.5.11 Tibial Cutting Block Adapter “ENDOPLUS” (41866-71)

Illustration

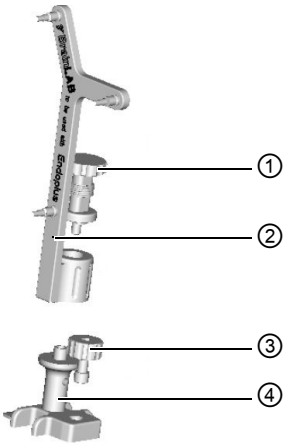


Figure 91

How to Disassemble

Steps	
1.	Completely unscrew screw unit ①.
2.	Remove tracking array ② from cutting block adapter ④.
3.	Completely unscrew screw ③ from cutting block adapter ④.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.5.12 Fine-Adjustable Cutting Block - Femur Kit

Illustration

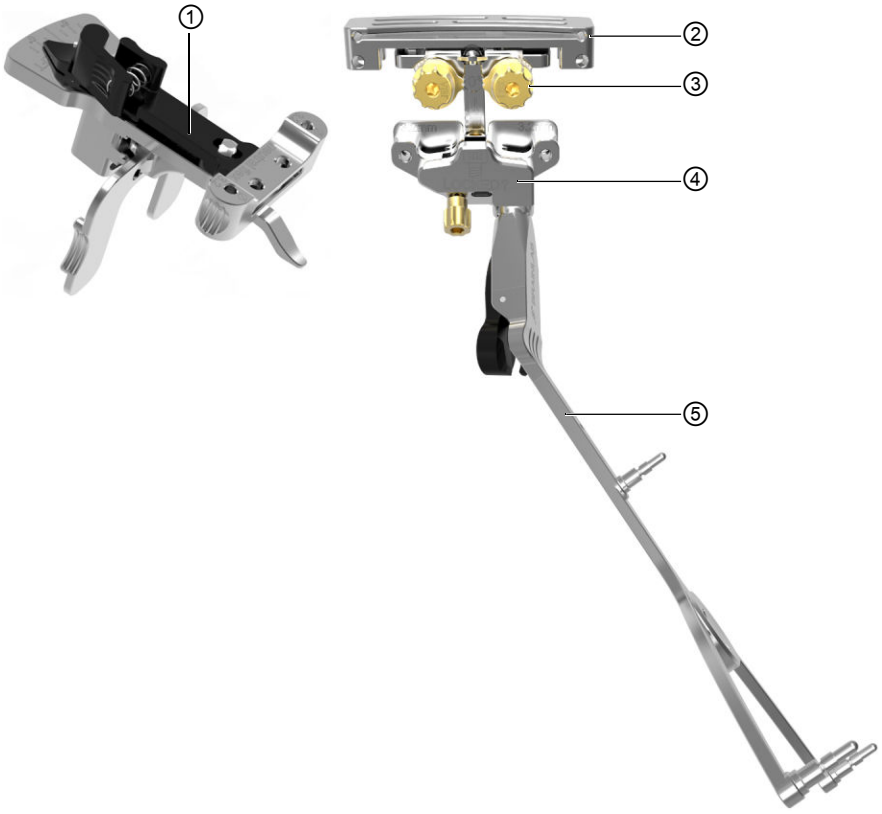


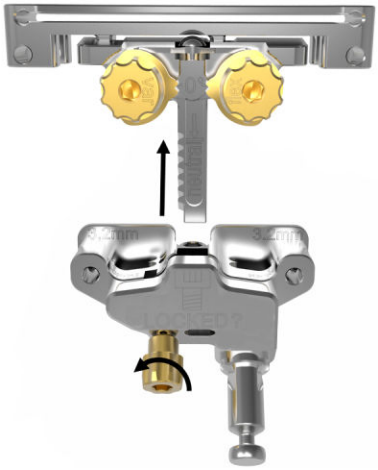
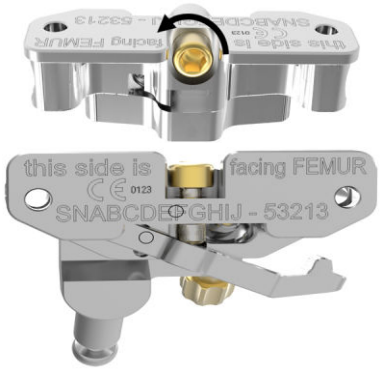
Figure 92

No.	Component	Article No.
①	Femur Alignment Guide	53212
②	Cutting Slot Femur	53220 (1.19 mm), 53221 (1.27 mm), 53222 (1.37 mm)
③	Adjustment Unit	53210
④	Femur Base	53213, 53219 (Femur Base Small)
⑤	Femur Reference Array	53211

How to Reprocess Femur Alignment Guide

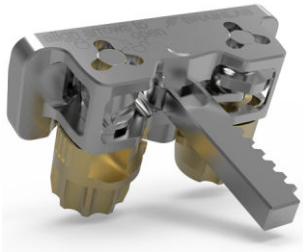
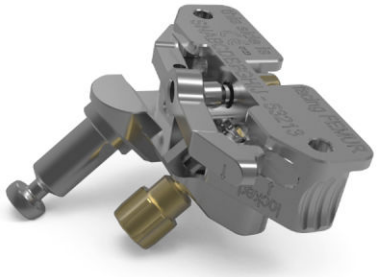
Steps	
1. Press the clamp and turn the black pointer to cleaning position, then perform pretreatment.	
2. Check all cannulations and holes for residue. If residue is still visible, repeat step 1.	
3. Automatic cleaning and disinfection. *NOTE: Position the device as illustrated here.*	
4. Bring black pointer back into guidance groove before sterilization.	
5. Steam sterilization.	

How to Disassemble Cutting Block

Steps	
1. Turn the resection height adjustment knob counter-clockwise, then remove the adjustment unit from the femur base.	
2. Loosen the base fixation screw until the wedge is released.	
3. Bring the **flex** knob into the unlocked position (see label on the back). Turn the **var** knob to **0°**. *NOTE: There is a threshold mechanism that prevents the unit from being unlocked unintentionally during normal use. Continue to turn the **flex** knob until it is unlocked.*	

Steps	
4.	Remove the cutting slot from the adjustment unit. 

How to Clean Cutting Block

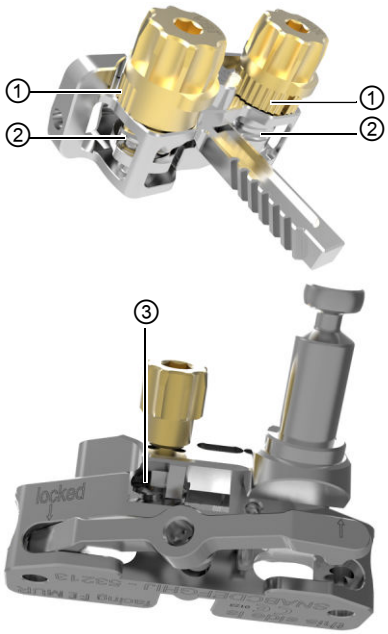
Steps	
1.	Pretreatment.
2.	Check all cannulations and holes for residue. If residue is still visible, repeat step 1.
3.	Bring the **flex** knob into the unlocked position and turn the **var** knob to **0°**. 
4.	Automatic cleaning and disinfection. *NOTE: Position the components as illustrated here.*   

How to Lubricate Cutting Block

Only use biocompatible, non-toxic medicinal lubricants that will not endanger the patient.

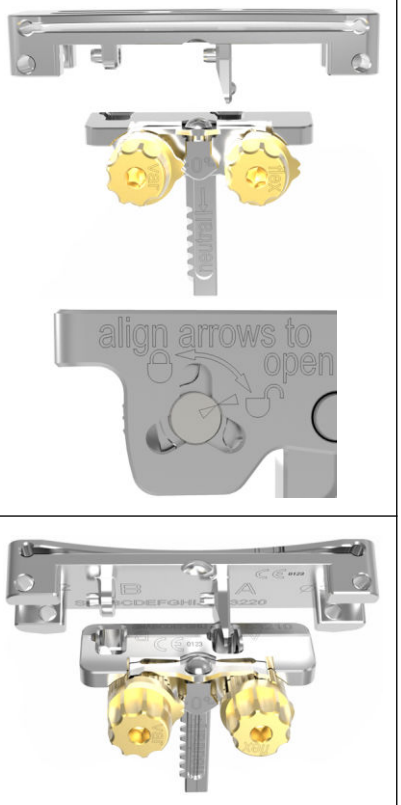
After cleaning, but before sterilization, all moving parts must be lubricated.

Steps	
1.	Lubricate all moving parts including: • The teeth of the adjustment knobs ① • The interior of the adjustment mechanisms ② • The interior of the height adjustment mechanism ③
2.	After lubrication, turn the mechanisms several times to evenly disperse the lubricant and clean all lubricant residue.



How to Sterilize the Cutting Block

Steps	
1.	With the **flex** knob of the adjustment unit in the unlock position and the **var** knob turned to 0°, assemble the cutting slot and the adjustment unit.
2.	Insert the **A** and **B** pegs of the cutting slot into their corresponding holes of the adjustment unit.



Steps	
3. Turn the **flex** knob clockwise to bring it into the locked position. *NOTE: In order to lock the assembly, tilt the cutting slot slightly forward.*	
4. Bring the **var** and **flex** knobs to 0°.	
5. Steam sterilization.	

How to Disassemble the Femur Reference Array

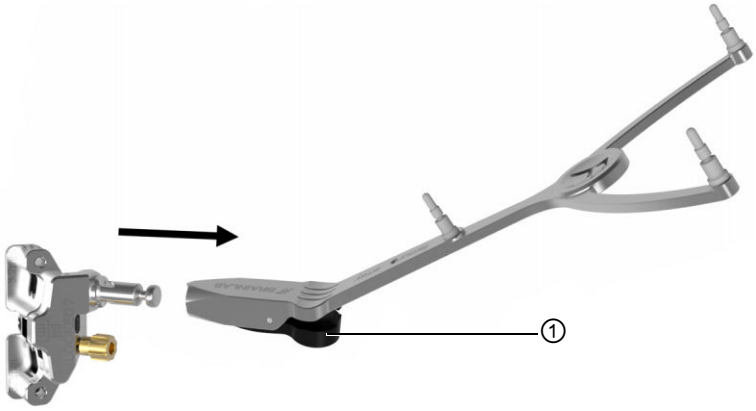


Figure 93

Step
Press the release clamp ①, then pull the reference array off of the base.

How to Reprocess Femur Reference Array

Steps	
1.	Pretreatment.

Steps	
Automatic cleaning and disinfection. 2. *NOTE: Position the reference array as illustrated here.*	
3. Steam sterilization.	

3.5.13 Knee Plane Tool Kit

Illustration

Figure 94

How to Disassemble

Steps	
1.	Press the lever on the tracking array ④.
2.	Detach the **Cutting Block Adapter** ③ or the **Bone Verification Plate** ① or ②, then release the lever.

How to Reprocess

Steps	
1.	Disassemble the tracking array from the adapter.
2.	Automatic cleaning and disinfection.
3.	Neutral steam sterilization.

3.5.14 ClearLens Bone Fixator 2-Pin (53239/53240)

Illustration

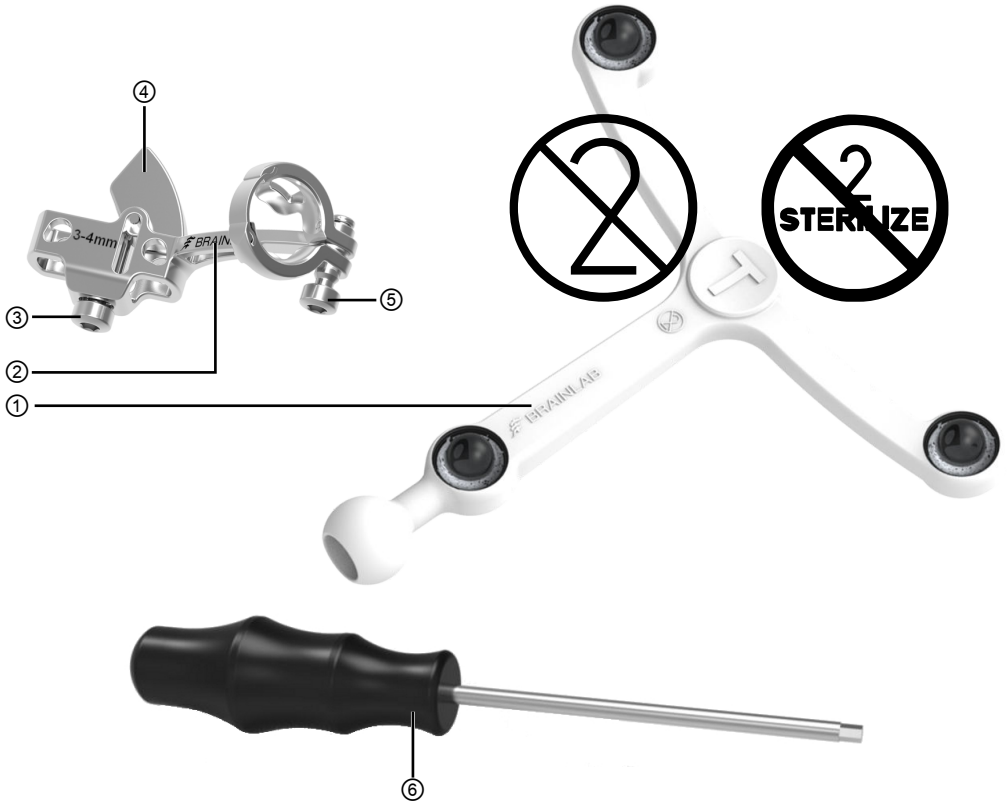


Figure 95

No.	Component
①	**ClearLens Tracking Array**
②	**ClearLens Bone Fixator 2-Pin**
③	Schanz screw fixation screw
④	Wedge
⑤	Array fixation screw
⑥	Screwdriver

How to Disassemble

Steps	
1.	Fully open screws ③ and ⑤.
2.	Remove the **ClearLens Tracking Array** ① and dispose of it.
3.	Pivot the wedge ④ so that the inner thread can be cleaned and disinfected.

How to Reprocess

Steps	
1.	Disassemble

Steps	
2.	Pretreatment
3.	Automatic cleaning and disinfection
4.	Steam sterilization

3.5.15 ClearLens Pointer Handle - Knee (53237)

Illustration

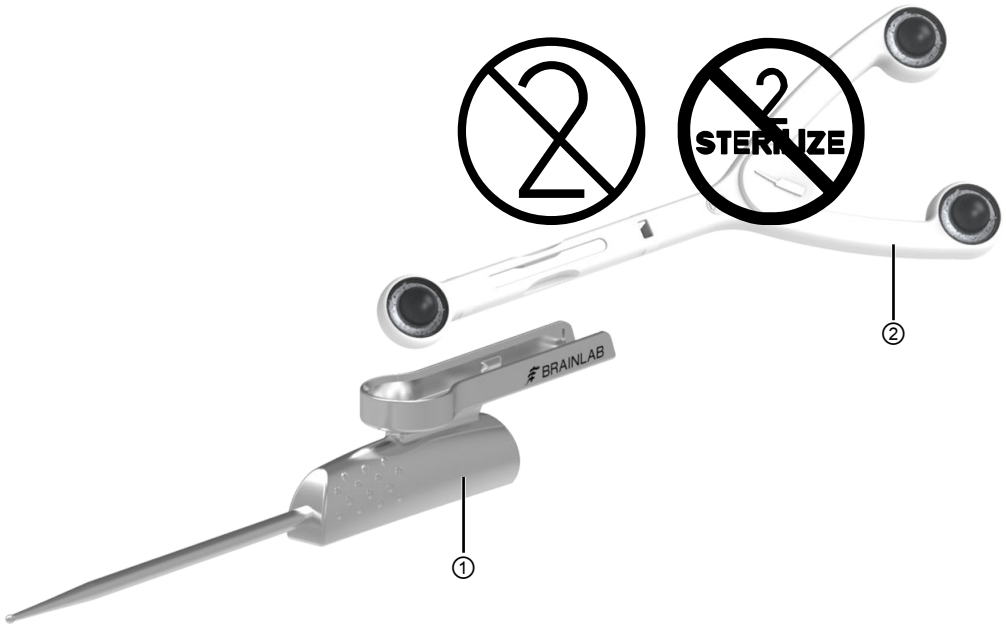


Figure 96

No.	Component
①	**ClearLens Pointer Handle**
②	**ClearLens Tracking Array Pointer**

How to Disassemble

Steps
Remove the **ClearLens Tracking Array Pointer** and dispose of it ②.

How to Reprocess

Steps	
1.	Disassemble
2.	Pretreatment
3.	Automatic cleaning and disinfection
4.	Steam sterilization

3.5.16 ClearLens Knee Plane Tool - Interface (53238)

Illustration

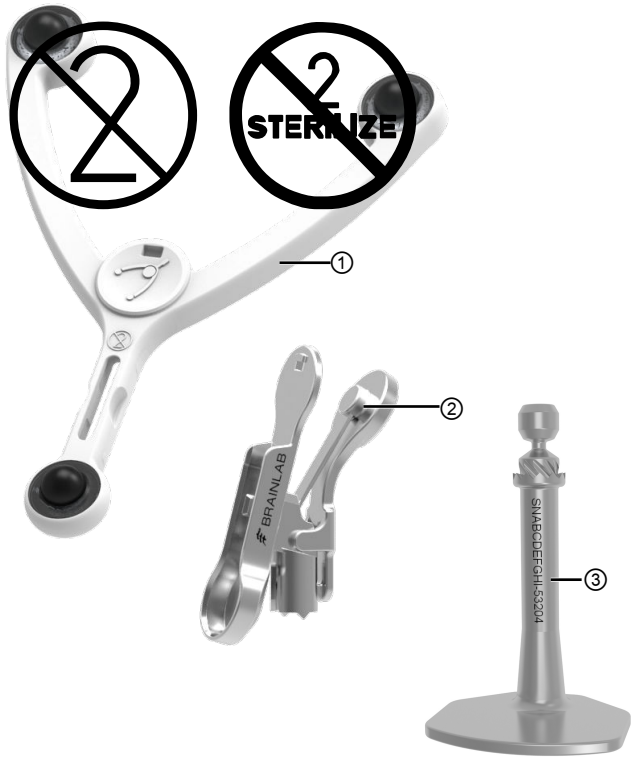


Figure 97

No.	Component
①	**ClearLens Tracking Array Plane Tool**
②	**ClearLens Knee Plane Tool - Interface** with lever
③	**Bone Verification Plate**

How to Disassemble

Steps	
1.	Remove the **ClearLens Tracking Array Plane Tool** and dispose of it ①.
2.	Press on the interface lever ② and detach the **Bone Verification Plate** ③ or the **Cutting Block Adapter**.

How to Reprocess

Steps	
1.	Disassemble
2.	Pretreatment
3.	Automatic cleaning and disinfection
4.	Steam sterilization

3.6 Spinal Instrumentation

3.6.1 Calibration Inserts 3.6 mm and 6.3 mm (53520, 53521)

Illustration

Figure 98

How to Disassemble

Step
Remove calibration insert from **ICM4**.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.6.2 Spine Reference X-Clamp (Size S (55751) and L (55752))

Illustration

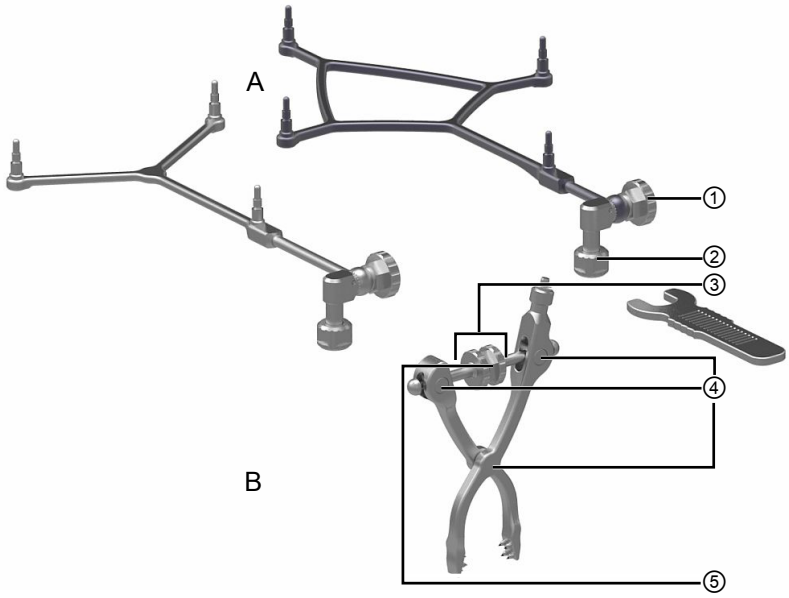


Figure 99

No.	Component	Part
①	Screw	**A** - Reference arrays (55753, 55759)
②	Nut	
③	Threads	**B** - X-Clamp
④	Joints	
⑤	Adjustment wheel	

How to Disassemble

Steps	
1.	Unscrew nut ② to remove reference array (**A**) from X-Clamp (**B**).
2.	Loosen screw ① until there is a gap between reference array and screw head. *NOTE: Screw ① cannot be completely unscrewed. Trying this could damage or break the screw.*
3.	Unscrew the adjustment wheel ⑤ until the clamp is completely opened. Ensure that threads ③ lie open.
4.	Reprocess all parts (**A** and **B**) of the **Spine Reference X-Clamp** separately.

How to Reprocess

Steps	
1.	Pretreatment. Thoroughly clean the adjustment wheel ⑤ and the gaps at joints ④.
2.	Check for residue, especially the adjustment wheel ⑤ and the gaps at joint ④.

Steps	
3.	Automatic cleaning and disinfection.
4.	Steam sterilization.

3.6.3 Radiolucent Spine Reference Clamp (55756)

Illustration

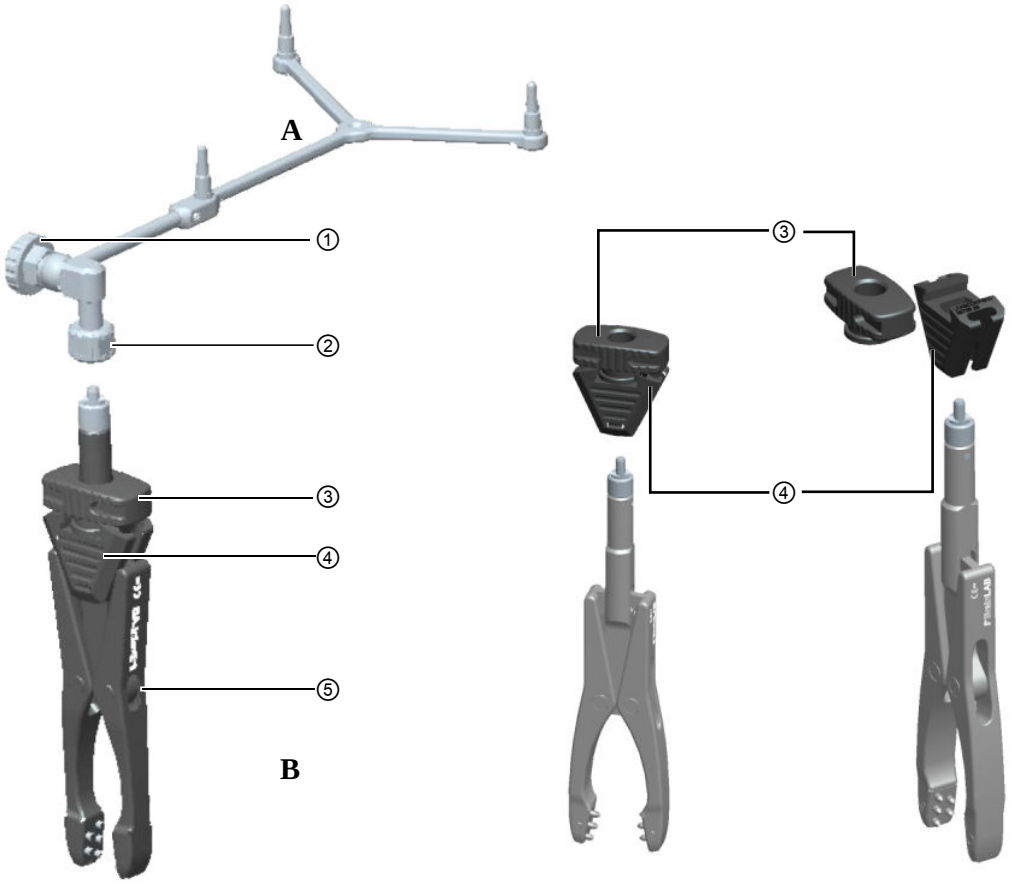


Figure 100

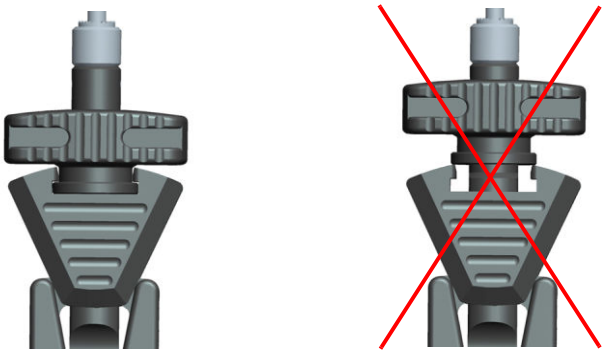
No.	Component	Part
①	Screw	**A** - Reference array (55753)
②	Nut	
③	Wheel	**B** - Clamp
④	Wedge	
⑤	Joints	

How to Disassemble

Steps	
1.	Unscrew nut ② to remove reference array (**A**) from clamp (**B**).
2.	Loosen screw ① until there is a gap between reference array and screw head. *NOTE: Screw ① cannot be completely unscrewed. Trying this could damage or break the screw.*
3.	Unscrew wheel ③ from clamp (**B**). Remove wheel ③ together with wedge ④.
4.	Slide wheel ③ out of wedge ④.

How to Reprocess

Clean and disinfect all parts separately.

Steps	
1.	Pretreatment. Thoroughly clean joints ⑤.
2.	Automatic cleaning and disinfection.
3.	Slide wheel ③ into wedge ④ and onto clamp (**B**).
4.	Turn wheel ③ a few turns clockwise.
5.	Ensure that the instrument is correctly assembled: 
6.	Steam sterilization.

3.6.4 Spine Reference Kit, Anterior/Lateral/Oblique (55070-xx)

Illustration

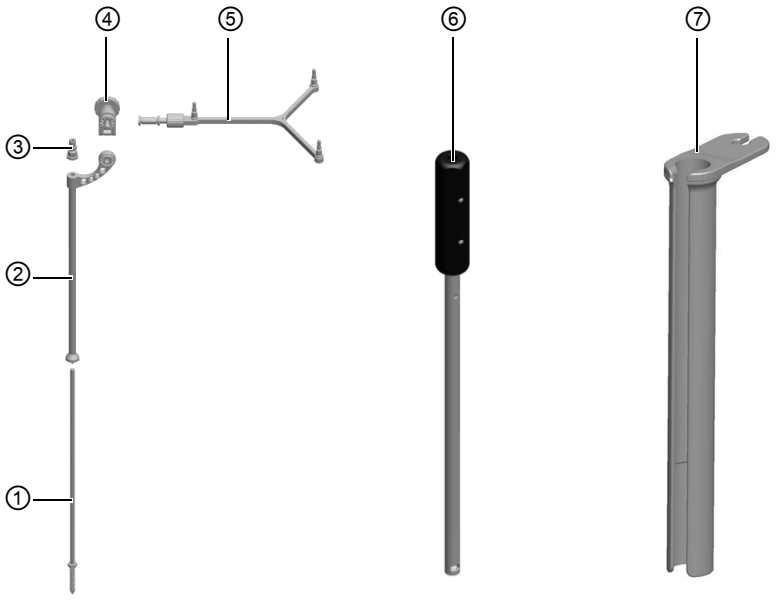


Figure 101

No.	Component
①	Lumbar Fixation pin
②	Connector tube
③	Fastening nut
④	Fastening unit with tightening knob
⑤	Reference array
⑥	Inserter
⑦	Protection sleeve

How to Disassemble

Steps	
1.	If a fixation pin ① is still in connector tube ②: Remove fastening nut ③ and pull out fixation pin ① from connector tube ②.
2.	Completely open tightening knob on fastening unit ④.
3.	Detach fastening unit ④ from connector tube ②.
4.	Remove reference array ⑤ from fastening unit ④.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

The Lumbar Fixation Pin, short and Lumbar Fixation Pin, long can only be sterilized and used two times. Using Lumbar Fixation Pins more than two times risks patient safety, in which case Brainlab does not accept any responsibility.

3.6.5 Spinal IGS Instruments (55830-xx)

Illustration, Example

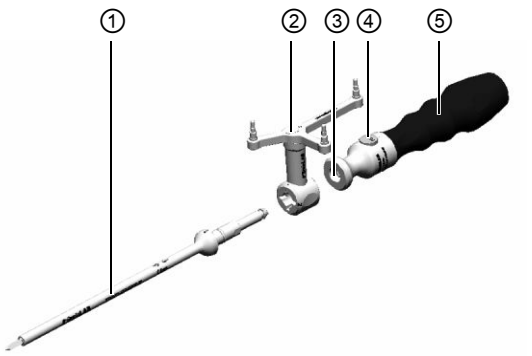


Figure 102

No.	Component	Article No.
①	Instrument tip	55830-30, -35, -40, -43, -45, -50, -55, -60, -64, -65, -66
②	Tracking array	55830-20, -25, -27, -29
③	Inner hole of handle coupling	
④	Press knob	
⑤	Handle	55830-10, -15

How to Disassemble

Steps	
1.	Detach handle ⑤ from instrument tip ①.
2.	Remove tracking array ②.

How to Reprocess

Steps	
1.	Pretreatment: • Thoroughly clean gaps and hole of handle coupling ③. • Push press knob ④ several times during this process.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

3.6.6 Pedicle Access Needle (55843)

Illustration

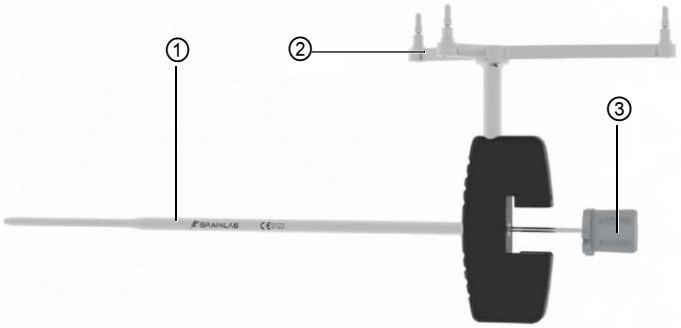


Figure 103

No.	Component	
①	Guide tube	Reprocessable
②	Tracking array	
③	Trocar insert	Single-use

How to Disassemble

Steps
Remove trocar insert ③ from the guide tube ①.

Trocar insert must be removed before sterilization of the guide tube.

How to Process Trocar Insert (Non-Sterile Version)

The trocar insert is for single use, but might be delivered as a non-sterile version. Before using the trocar insert, it must be processed as follows:

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

The trocar insert is single-use only. Dispose of after use.

How to Reprocess Guide Tube and Tracking Array

Steps	
1.	Pretreatment.
2.	Attach appropriate flexible flushing tubes to distal end of guide tube.
3.	Automatic cleaning and disinfection.
4.	Steam sterilization.

4 EM TRACKING INSTRUMENTS

4.1 Pointers

4.1.1 EM Pointer (18099-02A, 18099-02B, 18099-02C)

Illustration

Figure 104

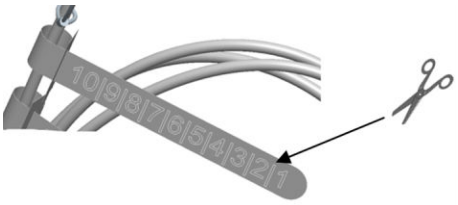
No.	Component
①	Tip
②	Handle
③	Cable
④	Sterilization counter tag
⑤	Checkered area
⑥	Plug

How to Disassemble

Step
Lightly pull the checkered area ⑤ of the plug to remove cable from **Base Station**.

How to Reprocess

Steps	
1.	Remove coarse impurities from **EM Pointer** directly after use (within a maximum of two hours) using running water (20-30°C) or a cleaning-disinfectant solution.
2.	Using a brush, apply detergent solution to all surfaces, ensuring that all parts are cleaned. • To manually remove impurities, use only a soft brush or a clean soft tissue. • Do not use metal brushes or steel wool.

Steps	
3.	Cut off the next number from the sterilization counter tag.  *NOTE: Dispose of the **EM Pointer** when it has been reprocessed 20 times (i.e., all numbers are cut off).*
4.	Automatic cleaning and disinfection.
5.	Steam sterilization. Prevac procedure: • Between 132°C (269.6°F) - 134°C (273.2°F) • Five minutes • At least ten minutes drying time • Use **EM Pointer Sterilization Tray** (18099-08) or **EM Basic Instruments Sterilization Tray** (18099-08A). *NOTE: The holding time for the sterilization temperature should not exceed five minutes, as this can shorten the life of the **EM Pointer**.*

EM Validation Parameters

Brainlab has tested the compatibility of the **EM Pointer** with the following detergents:

Cleaning Detergents	Manufacturer	Parameters	Disinfection
neodisher MediClean forte	Dr. Weigert	According to manufacturer's specifications	Thermal at 90°C (194°F) for 5 minutes. Thermal at 93°C (199.4°F) for 10 minutes.
neodisher SeptoClean			
Dismoclean 28 alka med	Bode		

4.1.2 EM Unsterile Registration Pointer (18099-23)

Illustration

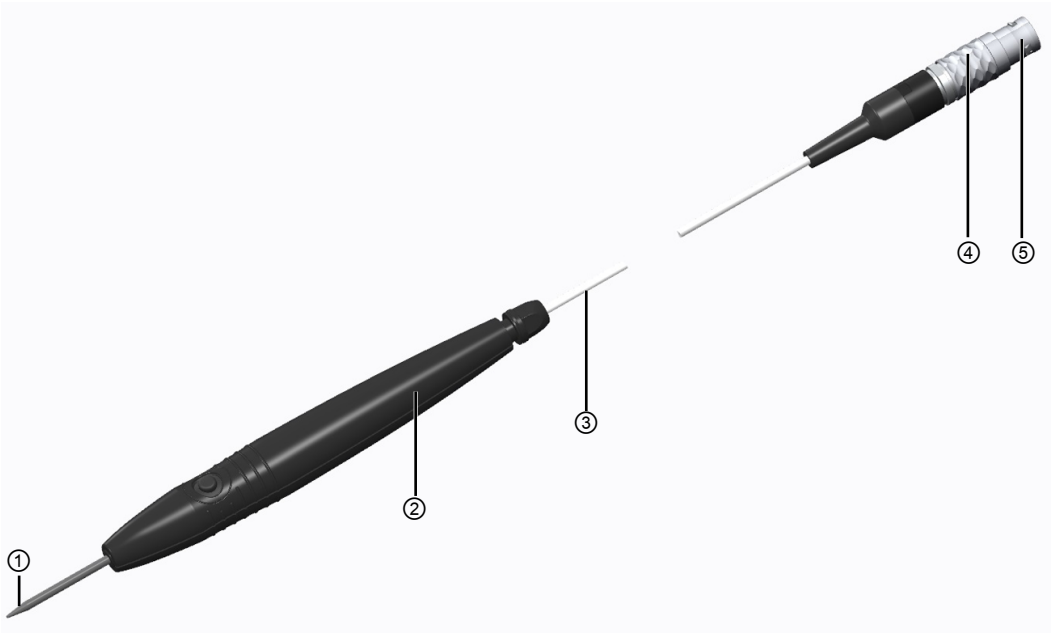


Figure 105

No.	Component
①	Tip
②	Handle
③	Cable
④	Checkered area
⑤	Plug

How to Disassemble

Step
Lightly pull the checkered area ④ of the plug to remove cable from **Base Station**.

How to Reprocess

Step
Remove dirt stains from all surfaces and gaps using a soft tissue moistened with surface disinfectants. Use a neutral (pH6-pH9) surface disinfectant e.g., Meliseptol. Follow the disinfectant manufacturer’s recommendations.

Do Not Use

- Acid solvents
- Caustic solvents

Do not use steam sterilization.

Do not clean in an automatic washer/disinfector. Sterilization and automatic cleaning/ disinfection will shorten the lifetime of the device and may lead to injury to the patient or user.

4.2 References

4.2.1 EM Instrument Reference (18099-05)

Illustration

Figure 106

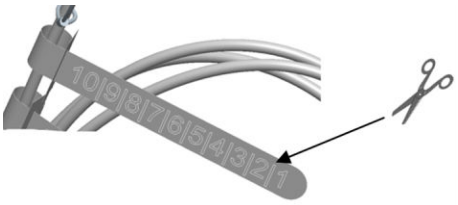
No.	Component
①	Screw
②	Plug
③	Checkered area
④	Cable

How to Disassemble

Step
Lightly pull the checkered area ③ of the plug to remove the cable from **Base Station**.

How to Reprocess

Steps	
1.	Remove coarse impurities from **EM Instrument Reference** directly after use (within a maximum of two hours) using running water (20-30°C) or a cleaning-disinfectant solution.
2.	Using a brush, apply detergent solution to all surfaces and holes, ensuring that all parts are cleaned. • To manually remove impurities, use only a soft brush or a clean soft tissue. • Do not use metal brushes or steel wool.

Steps	
3.	Cut off the next number from the sterilization counter tag.  *NOTE: Dispose of the **EM Instrument Reference** when it has been reprocessed 20 times (i.e., all numbers are cut off).*
4.	Automatic cleaning and disinfection.
5.	Steam sterilization. Prevac procedure: • Between 132°C (269.6°F) - 134°C (273.2°F) • Five minutes • At least ten minutes drying time • Use **EM Cranial/ENT Instruments Sterilization Tray** only (18099-07A). *NOTE: The holding time for the sterilization temperature should not exceed five minutes, as this can shorten the life of the **EM Instrument Reference**.*

4.2.2 EM Patient Reference (18099-04)

Illustration

Figure 107

No.	Component
①	Reference
②	Plug
③	Checkered area
④	Cable

How to Disassemble

Step
Lightly pull the checkered area ③ of the plug to remove cable from **Base Station**.

How to Reprocess

Step
Remove dirt stains using a soft tissue moistened with isopropanol.

Do Not Use

- Acid solvents
- Caustic solvents

Only use solutions approved by Brainlab.

4.2.3 EM Patient Reference (18099-24)

Illustration

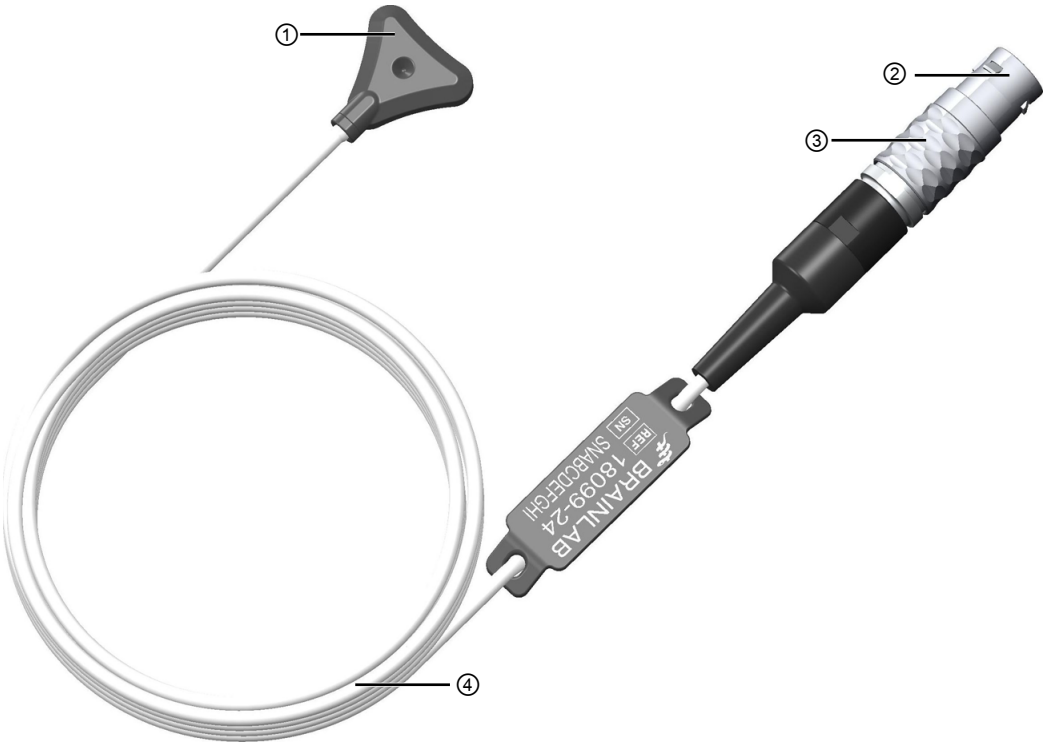


Figure 108

No.	Component
①	Reference
②	Plug
③	Checkered area
④	Cable

How to Disassemble

Step
Lightly pull the checkered area ③ of the plug to remove cable from **Base Station**.

How to Clean

Steps	
1.	Remove dirt stains and adhesive residues using a soft tissue moistened with alcohol (≤ 70% alcohol, e.g., Microzid AF liquid).
2.	Manual cleaning. Fill a basin with cleaning solution. Use cleaning agents suitable for: • Plastics (reference body material is made of PEEK plastic) • Silicone (cable material)
3.	Immerse the **EM Patient Reference** body including the cable in the cleaning solution. Do not immerse the plug.

Steps	
4.	Perform cleaning according to the instructions of the cleaning agent manufacturer. Use a soft brush to clean the surfaces while immersed in the cleaning solution. Repeat until the device and the connection between the cable and reference body is visually clean.
5.	Remove the reference from the basin after the minimum soaking time recommended by the cleaning agent manufacturer.
6.	Thoroughly rinse the reference at least three times under running deionized water or HPW through all channels to remove traces of the cleaning agent. Each rinse should be at least one minute in duration.
7.	Dry reference twice with filter-forced air.

Do Not Use

- Acid solvents
- Caustic solvents

How to Disinfect

Steps	
1.	Fill a basin with disinfection solution.
2.	Immerse the **EM Patient Reference** body including the cable in the cleaning solution filling all lumens and eliminating air pockets. Do not immerse the plug.
3.	Remove the reference from the basin after the minimum soaking time recommended by the cleaning agent manufacturer.
4.	Paying attention to the detergent manufacturer’s instructions, rinse the instrument a minimum of three times by immersing it completely in a large volume of water (e.g., 7-8 liters). Use fresh water for each rinse. Each rinse should be at least one minute in duration.
5.	Manually flush all areas and channels with large volumes (at least 100 ml) of rinse water using deionized water or HPW (fill lumen, blind holes).
6.	Dry reference twice with filter-forced air.

Do not sterilize the EM Patient Reference as this may damage the device.

Validated Detergents

Brainlab has validated cleaning and disinfection with the following detergents:

- CIDEZYME
- CIDEX OPA

4.2.4 EM Skull Reference Set

EM Skull Reference Base Components

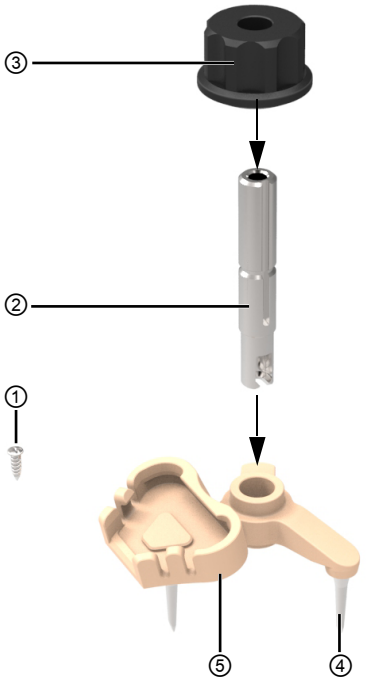


Figure 109

No.	Component
①	Drill-free screw
②	Tube
③	Tube fixation nut
④	Pins
⑤	Base

How to Disassemble

Steps	
1.	Unscrew tube fixation nut ③.
2.	Remove tube ②.

How to Process Drill-free Screws

The drill-free screws are for single use and require sterilization before use.

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

Sterilize drill-free screws prior to use and dispose of after use.

How to Reprocess EM Skull Reference Base Components

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization. Use **EM Cranial/ENT Instruments Sterilization Tray** (18099-07A).

NOTE: For more information on reprocessing the screwdriver see page 72.

4.3 EM Sterilization Trays

4.3.1 Sterilization Trays for Steam Sterilization (18099-07, 18099-08, 18099-08A)

Illustration

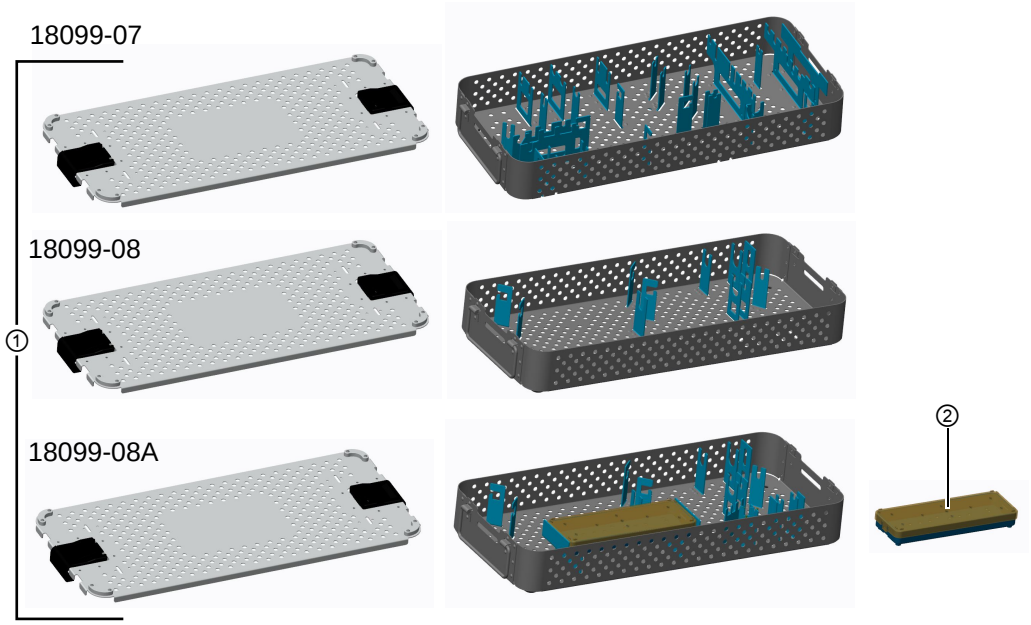


Figure 110

How to Disassemble

Step
Sterilization Tray EM ENT/Cranial Instruments (18099-07): Unlatch and remove cover ① from the sterilization tray. **Sterilization Tray EM Pointer** (18099-08): Unlatch and remove cover ① from the sterilization tray. **Sterilization Tray EM Basic Instruments** (18099-08A): Unlatch and remove cover ① and MicroTray ② from the sterilization tray.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

Incompatible Solutions

- Strong alkalines (pH > 9)

For other incompatible solutions see page 20.

To prevent damage to the device, do not use incompatible solutions.

5 INTRAOPERATIVE IMAGING INSTRUMENTS

5.1 Automatic Image Registration System for GE

5.1.1 iMRI Registration Matrix for GE Head Holder (19202)

Illustration

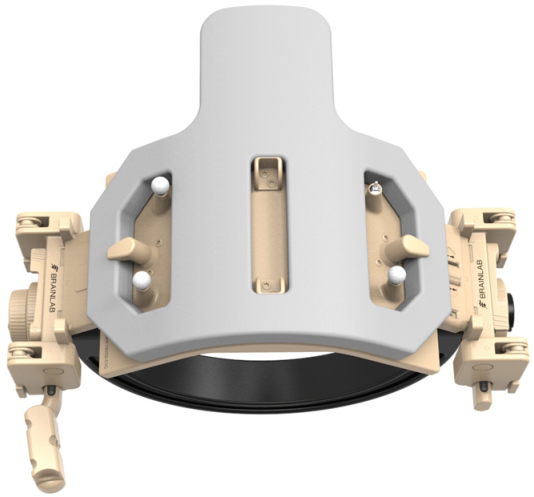


Figure 111

How to Dissassemble

Step
Remove flex coil and rails from the matrix.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Manual cleaning and disinfection. Place components in such a way that they do not collide.
3.	Wipe all surfaces and areas with a moistened cloth or with a wipe. Use a slightly moistened cloth and, if required, add mild neutral enzymatic cleaner solution (pH4 - pH9).
4.	Verify that all organic material and soil has been removed and that all parts are clean.

Steps	
5.	Rinse using HPW or WFI.
6.	Dry twice with filter-forced air.

The temperature of the disinfectant solution should not exceed +50°C (+122°F). Immersion time should not exceed 30 minutes.

Do Not Use

- Automatic cleaning and disinfection, as this may damage the device
- Metal brushes or sponges for debris removal
- Undiluted disinfectants unless specified in the manufacturer instructions
- Ultrasonic cleaners

To prevent damage to the device, only use procedures approved by Brainlab.

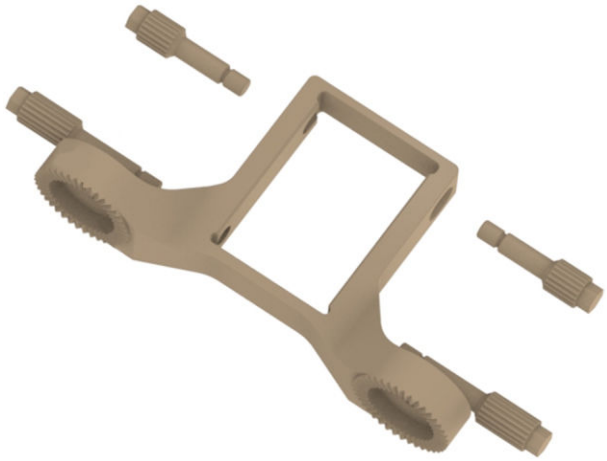
Incompatible Solutions

- Aldehyde-releasing solutions
- Phenol-releasing solutions
- Chlorine-releasing solutions
- NaOH and NaOCL-releasing solutions
- Iodine-releasing solutions
- Bromine-releasing solutions
- Fluorine-releasing solutions
- Strong alkalines (pH > 9)
- Strong acids (pH < 4)

To prevent damage to the device, do not use incompatible solutions.

5.1.2 V-Inset for GE Head Holder (52006)

Illustration



How to Reprocess

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.
3.	Steam sterilization.

5.2 iMRI Registration Matrix for Noras Head Holder (19102)

5.2.1 Component Overview and Disassembling

Terminology

The **iMRI Registration Matrix for Noras Head Holder** is referred to as iMRI reference system in the following.

Illustration

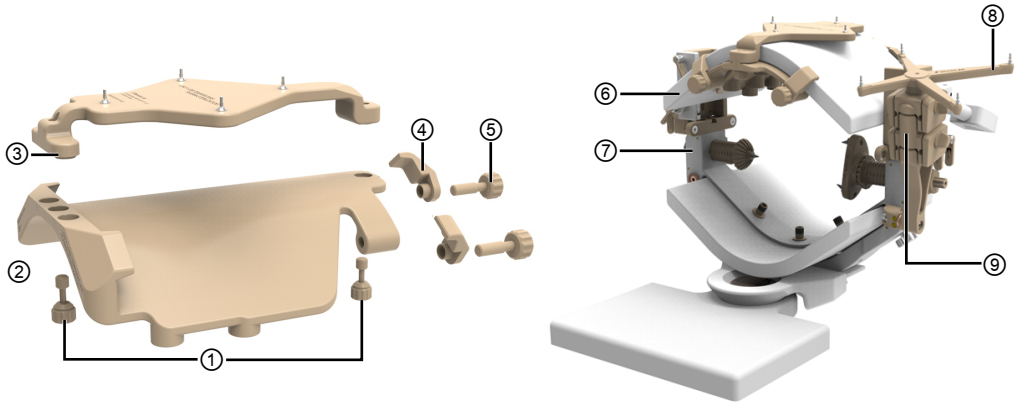


Figure 112

No.	Component	Part	Manufacturer
①	IR (infrared) marker holder fixation screw	Registration matrix	Brainlab
②	MR (magnetic resonance) marker holder		
③	IR marker holder		
④	Coil fixation bracket		
⑤	Coil fixation screw		
⑥	Noras coil	Siemens OR equipment	Siemens
⑦	Noras head holder		
⑧	Reference array	Reference array	Brainlab
⑨	Interconnector (or Interconnector, angled (not pictured))		

How to Disassemble

Steps	
1.	Unscrew IR marker holder fixation screw ① from MR marker holder ② to remove IR marker holder ③.
2.	Unscrew and loosen coil fixation screws ⑤ together with coil fixation bracket ④ from MR marker holder ②.
3.	Remove MR marker holder ② from Siemens coil ⑥.
4.	Remove interconnector ⑨ from Siemens head holder ⑦.

Steps
5. Remove reference array ⑧ from interconnector ⑨.

Reprocessing Siemens Components

For reprocessing the Siemens components, see respective Siemens instructions.

5.2.2 iMRI Registration Matrix for Noras Head Holder (19102)

Illustration

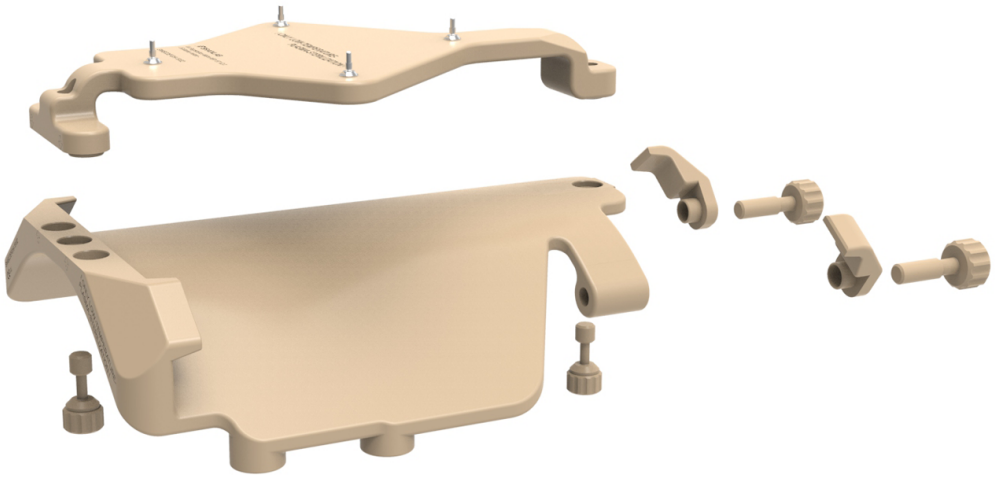


Figure 113

How to Clean and Disinfect

Steps	
1.	Ensure that the registration matrix has been removed from the iMRI reference system.
2.	Pretreatment.
3.	Manual cleaning and disinfection.
4.	Wipe all surfaces and areas with a moistened cloth or with a wipe. Use a slightly moistened cloth and, if required, add mild neutral enzymatic cleaner solution (pH4 - pH9).
5.	Verify that all organic material and soil has been removed and that all parts are clean.
6.	Rinse using HPW or WFI.
7.	Dry twice with filter-forced air.

The temperature of the disinfectant solution should not exceed +50°C (+122°F). Immersion time should not exceed 30 minutes.

Do Not Use

- Automatic cleaning and disinfection
- Metal brushes or sponges for debris removal
- Undiluted disinfectants unless specified in the manufacturer instructions
- Ultrasonic cleaners

To prevent damage to the device, always follow procedures approved by Brainlab.

Incompatible Solutions

- Aldehyde-releasing solutions
- Phenol-releasing solutions

- Chlorine-releasing solutions
- NaOH and NaOCL-releasing solutions
- Iodine-releasing solutions
- Bromine-releasing solutions
- Fluorine-releasing solutions
- Strong alkalines (pH > 9)
- Strong acids (pH < 4)

To prevent damage to the device, do not use incompatible solutions.

How to Sterilize

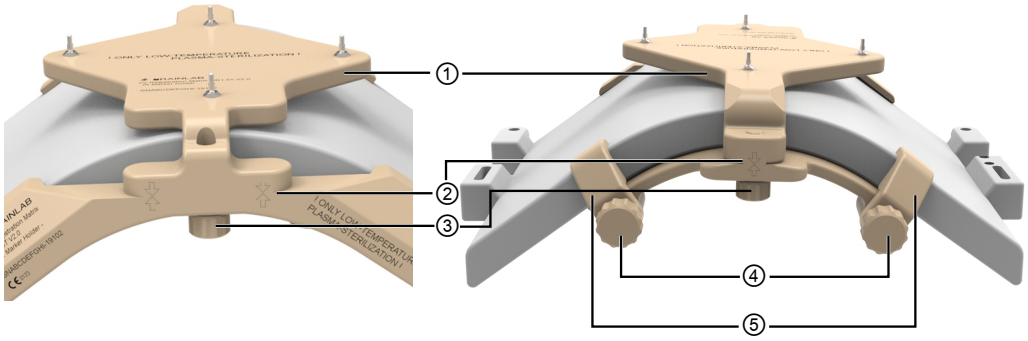


Figure 114

Steps	
1.	Check surfaces and lumen areas for debris, soil and corrosion.
2.	Check mating parts for proper assembly.
3.	Mount IR marker holder ① and MR marker holder ② with IR marker holder fixation screw ③. Verify that arrows ② are exactly aligned.
4.	Verify that coil fixation brackets ⑤ and coil fixation screw ④ can be mounted easily.
5.	Verify that coil fixation brackets ⑤ can be rotated easily within MR marker holder ②.
6.	Dismantle all parts.
7.	LTP sterilization.

5.3 iCT and iMRI Reference Equipment

5.3.1 Cranial Reference Unit DrapeLink (19152)

Illustration

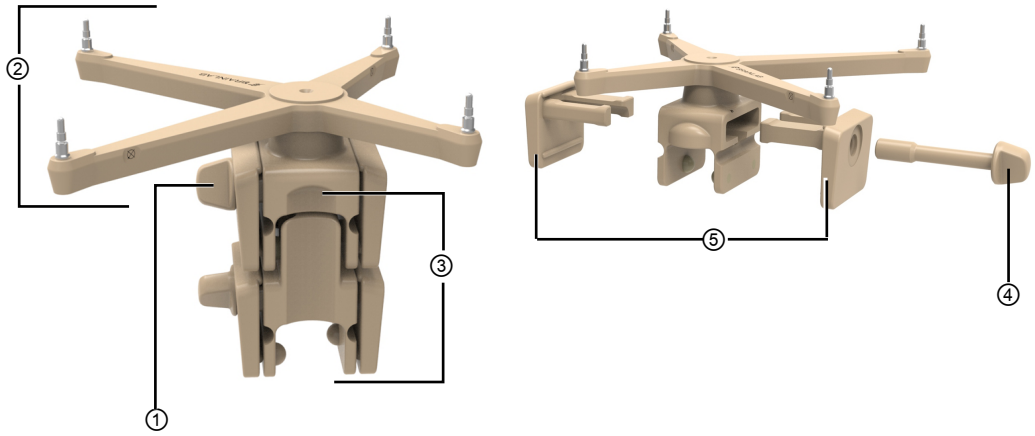


Figure 115

How to Disassemble

Ensure that the reference array has been removed from the rest of the **Cranial Reference Unit DrapeLink** reference package.

Steps	
1.	Loosen the locking screw ④, then disconnect the reference array ② from the interconnector ③.
2.	Unscrew both locking screws (① and ④) completely, then remove the side plates ⑤ from the components.

How to Reprocess

Steps	
1.	Pretreatment.
2.	Reassemble the side plates so that the locking screws are on the same side as the double rounded node on the inside of the base.
3.	Automatic cleaning and disinfection.
4.	Steam sterilization.

5.3.2 Radiolucent Adapter for DORO Skull Clamp (19153-02)

Illustration

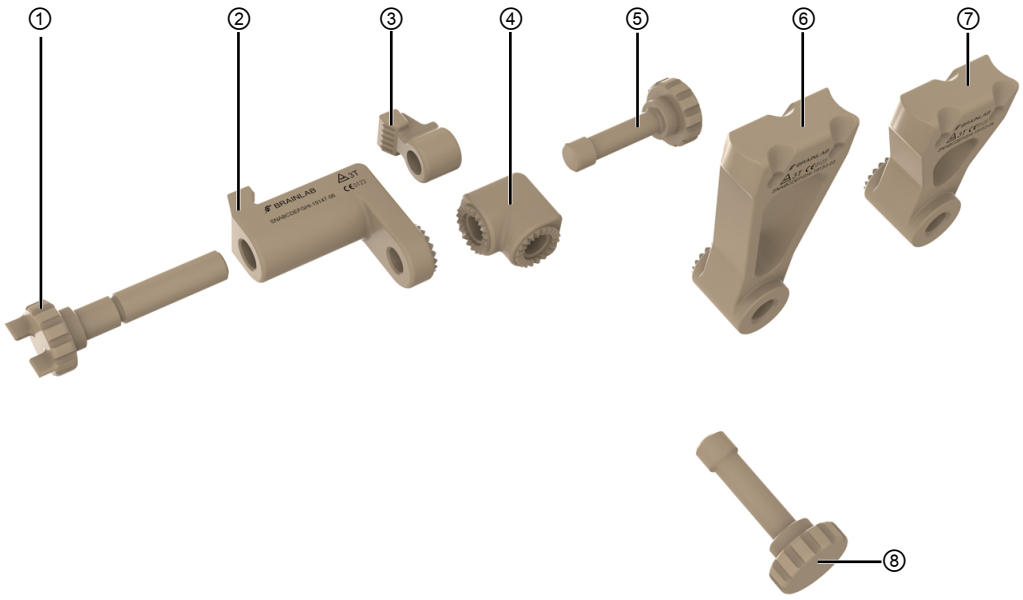


Figure 116

No.	Component
①	Adjustment screw for skull clamp Interface
②	Skull clamp interface
③	Movable Jaw
④	Elbow
⑤	Adjustment screw
⑥	**Base Long for DrapeLink**
⑦	**Base Short for DrapeLink**
⑧	Adjustment screw

How to Disassemble

Steps	
1.	Unscrew screw ① and remove jaw ③.
2.	Remove screw ⑥ to separate clamp ② from elbow ④.

How to Clean and Disinfect

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.

No sterilization.

5.3.3 Radiolucent Adapter for Mayfield Skull Clamp (19153-01)

Illustration

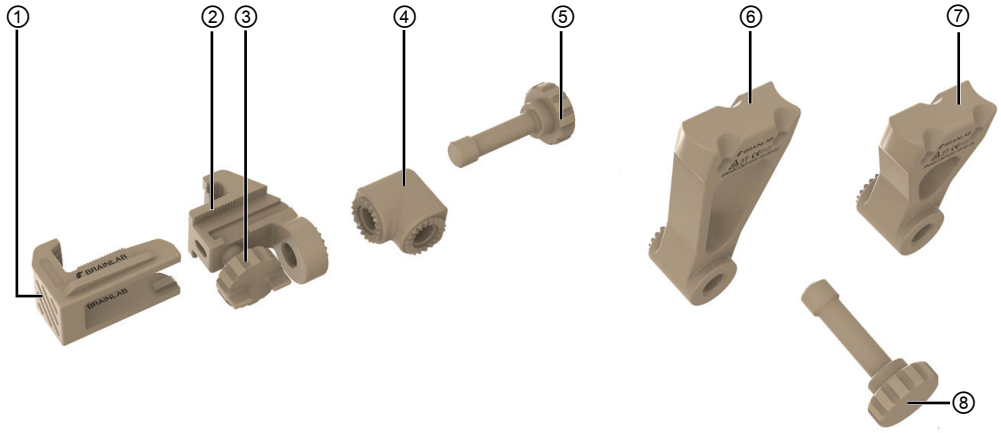


Figure 117

No.	Component
①	Movable jaw
②	Skull clamp interface
③	Adjustment screw for skull clamp Interface
④	Elbow
⑤	Adjustment screw
⑥	**Base Long for DrapeLink**
⑦	**Base Short for DrapeLink**
⑧	Adjustment screw

How to Disassemble

Steps	
1.	Slide jaw ① off the clamp ②.
2.	Remove screw ⑦ to separate from the elbow ③.

How to Clean and Disinfect

Steps	
1.	Pretreatment.
2.	Automatic cleaning and disinfection.

No sterilization.

5.4 Scanner References

5.4.1 Scanner Reference Hardware for NeuroLogica BodyTom (19134)

Illustration

Figure 118

How to Disassemble

Step
Remove reflective marker disks.

How to Reprocess

As the **Scanner Reference Hardware for NeuroLogica BodyTom** is used non-sterilely with a draped patient, only surface cleaning and disinfection is necessary.

Steps	
1.	Clean surfaces using a moistened cloth. Dry surface afterwards.
2.	Use neutral (pH6 - pH9) surface disinfectants. Follow disinfectant manufacturer’s recommendations.

5.4.2 Adhesive Flat Markers iCT (19141)

Illustration

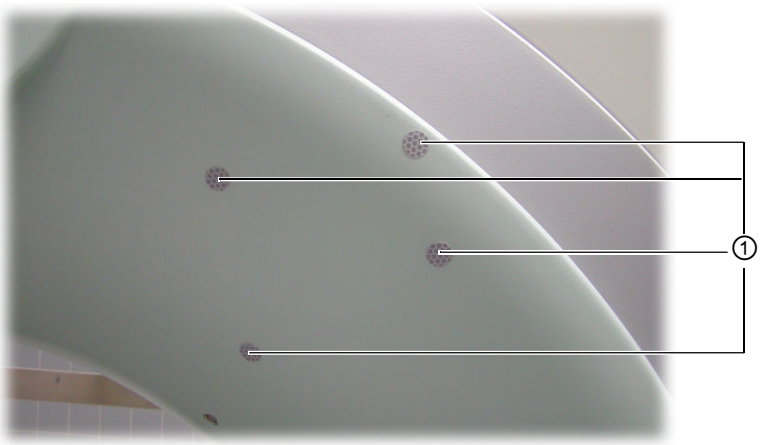


Figure 119

How to Clean and Disinfect

Steps	
1.	Clean using a cloth moistened with water.
2.	Disinfect using a cloth moistened with an aldehyde or amphoteric surfactant-based surface disinfectant. Follow disinfectant manufacturer’s recommendations.

Do not spray disinfectant directly on Adhesive Flat Markers iCT ①.

Only use a moist cloth for cleaning and disinfection. Using an abrasive brush or sponge may damage the markers.

No sterilization.

5.4.3 Adhesive Flat Markers for Scanners (19143, 19144)

Illustration

Figure 120

How to Clean and Disinfect

Steps	
1.	Clean using a cloth moistened with water.
2.	Disinfect using a cloth moistened with an aldehyde or amphoteric surfactant-based surface disinfectant. Follow disinfectant manufacturer’s recommendations.

Only use a moist cloth for cleaning and disinfection. Using an abrasive brush or sponge may damage the markers.

No sterilization.

Incompatible Solutions

- Alcohol-based solutions
- Phenol-based solutions
- Chlorine-releasing solutions
- Virex TB
- Terralin

To prevent damage, do not use incompatible solutions.

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