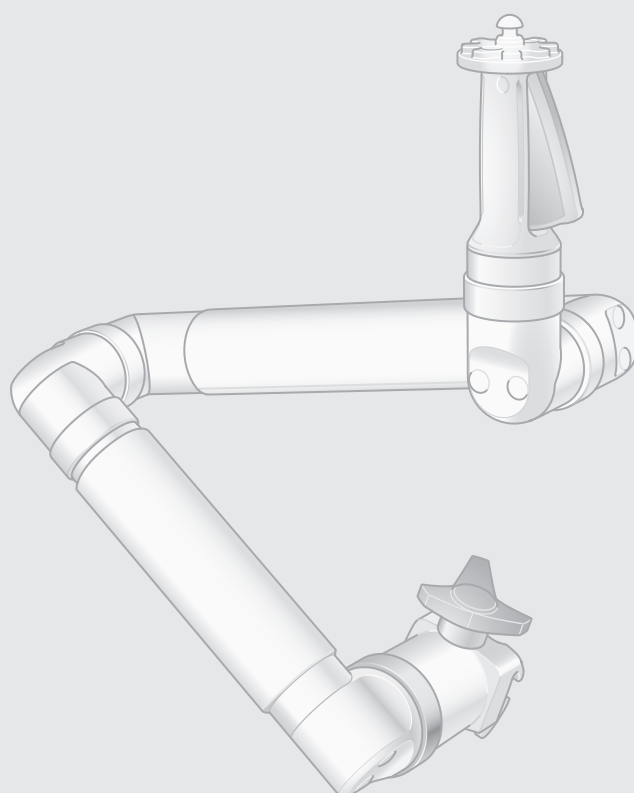


INSTRUCTIONS FOR USE
AR-1740
TRIMANO FORTIS



SOURCE CONTROLLED DOCUMENT

| Arthrex | |
|----------------------------------|----------------------|
| Approved as <u>REF-02093</u> | Rev <u>X2</u> |
| Page <u>1</u> of <u>40</u> | CR# <u>ECO-12743</u> |
| Inspection: <u>MAD-8.2.4.2-6</u> | |
| Date: _____ | |
| Signature: _____ | |
| Component Nr. | Rev. |
| <u>REF-02093-02</u> | <u>X2</u> |



GA AR-1740 EN 02

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Subject to technical modification!

Due to further development of the product, the figures used and technical specifications given in these Instructions for Use may slightly differ from the current state of the product.

V02 02 21-12-2017



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1 Introduction

1.1 How to use these operating instructions

These operating instructions are provided to familiarise you with the features of this product. The operating instructions are divided into separate chapters.

Please note:

- Read these operating instructions through carefully and completely before using the product for the first time.
- Always proceed in accordance with the information provided in these operating instructions.
- Store these operating instructions in the vicinity of the product.

1.1.1 Abbreviations

| | |
|-----|---|
| EC | European Community |
| EN | European standard |
| EEC | European Economic Community |
| IEC | International Electrotechnical Commission |
| ISO | International Standardisation Organisation |
| PUR | Polyurethane integral foam |
| SFC | Soft Foam Core (special foam core) |
| SN | Serial no. |
| VDE | Verband der Elektrotechnik Elektronik Informationstechnik |

1.1.2 Symbols

1.1.2.1 Order number

An "X" in the order number (e.g. 1122.33X4) is a placeholder for a number of variants.

1.1.2.2 References

References to other pages in this manual are identified with a double arrow symbol "»»".

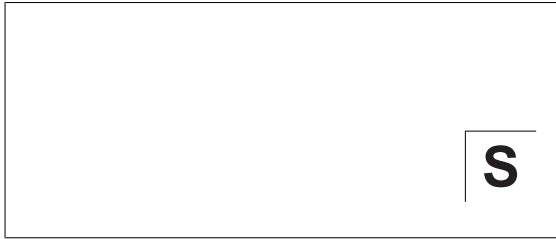
1.1.2.3 Action and reaction

The symbol "☒" identifies an action taken by the user, whereas the "✓" symbol identifies the reaction which this will induce in the system.

Example:

- ☒ Turn on the light switch.
 - ✓ Lamp lights up.

1.1.2.4 Sterile processes






The "S" in graphics identifies an act carried out by the user that must be executed under sterile conditions.

Fig. 1: Example for the labelling of a sterile process

1.1.3 Definitions


1.1.3.1 Design of safety notes

| Pictogram | Descriptor | Text |
|---|--|--|
|  | DANGER! Indicates a direct and immediate risk to persons, which may be fatal or result in most serious injury. | The text for the safety note describes the type of risk and how to prevent it. |
|  | WARNING! Indicates a potential risk to persons or property which may result in health hazard or grave property damage. | |
|  | CAUTION! Indicates a potential risk to property which may result in property damage. | |

Tab. 1: Design of safety notes

1.1.3.2 Structure of notes

Notes not referring to personal injury or property damage are structured as follows:

| Pictogram | Descriptor | Text |
|---|-------------|--|
|  | NOTE | Supplementary assistance or further useful information which does not indicate a risk of injury to persons or a risk of property damage are described in the text of the note. |










Tab. 2: Structure of notes

1.1.3.3 Definition of maximum permitted weight load









The maximum permitted weight load is calculated using the proportional load of the weight of the patient, plus the additional load posed by side rail accessories, mounted accessories and/or OR personnel.

1.2 Graphical symbols used

Symbols are attached to products, type plates and packaging.

| Symbols | Identification |
|---|---|
|  | Labelling of products of Class I that have been developed and distributed in accordance with directive 93/42/EEC regarding medical products. |
|  | Designation in accordance with the ISO 15223-1 standard. Symbol for "Name and address of the manufacturer as well as date of manufacture". |
|  | Labelling in accordance with the ISO 15223-1 standard. Symbol for "Serial number". |
|  | Labelling in compliance with the ISO 15223-1 standard. Symbol for "Product number". |
|  | Labelling in compliance with the ISO 15223 -1 standard. Symbol for "Do not use when packing is damaged". |
|  | Packaging label. Symbol for "Keep dry". |
|  | Labelling in compliance with the ISO 15223 -1 standard. Symbol for "Keep away from direct sunlight". |
|  | Symbol for "Follow Instructions for use" |
|  | Labelling in accordance with the ISO 15223-1 standard. Symbol für "Observe the instructions for use". |

Tab. 3: Symbols

| Symbols | Identification |
|---|---|
|  | Labelling of packaging material. Symbol for "Breakable! Handle with care". |
|  | Packaging label. Symbol for "Top". |
|  | Labelling in accordance with the ISO 15223-1 standard. Symbol for "Temperature limitations". |
|  | Labelling in accordance with the ISO 15223-1 standard. Symbol for "Relative humidity". |
|  | Labelling in accordance with the ISO 15223-1 standard. Symbol for "Atmospheric pressure". |
|  | Symbol for "Not suitable for steam sterilisation". |
|  | Symbol for "Keep dry". |
|  | Labelling based on the ISO 15223-1 standard. Symbol for "latex-free". |

Tab. 3: Symbols

1.3 Disposal

1.3.1 General

Used products or parts thereof may be contaminated. To prevent potential infection, please clean and disinfect the product prior to return/disposal.

1.3.2 Packaging

Packaging materials are made up of environmentally friendly materials and can be disposed of via the household waste in accordance with national requirements.

1.3.3 Products

Arthrex will take back used products or those which are no longer in service. For further information, please contact your personal Arthrex representative.

1.3.4 Disposable product

Disposable products must be handled and disposed of pursuant to national regulations.

1.4 Overview

1.4.1 TRIMANO FORTIS (AR-1740)

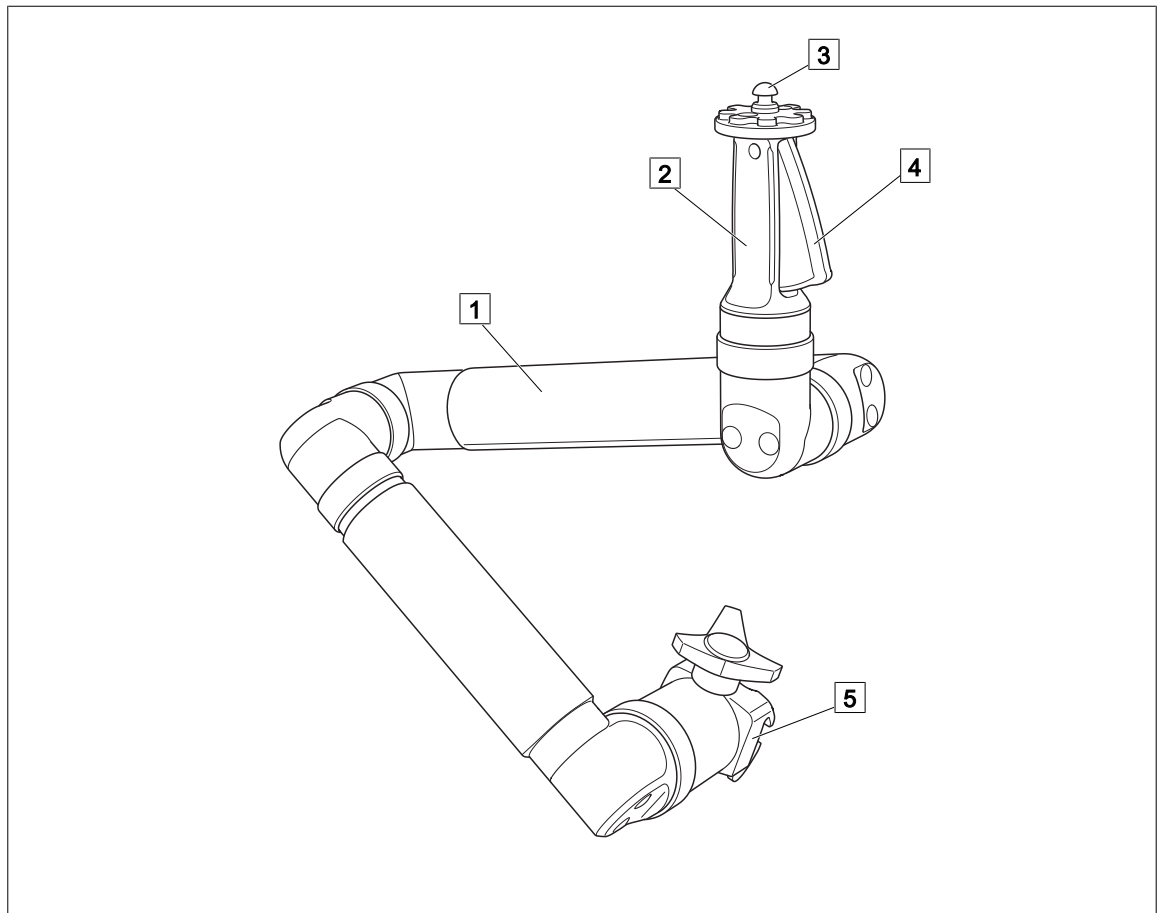


Fig. 2: TRIMANO FORTIS

- 1 TRIMANO FORTIS
- 2 Release handle
- 3 Pin mounting point

- 4 Release button
- 5 Clamp

1.4.2 Accessories for TRIMANO FORTIS

Accessories are not supplied and must be ordered separately. Please observe the operating instructions of the accessories!

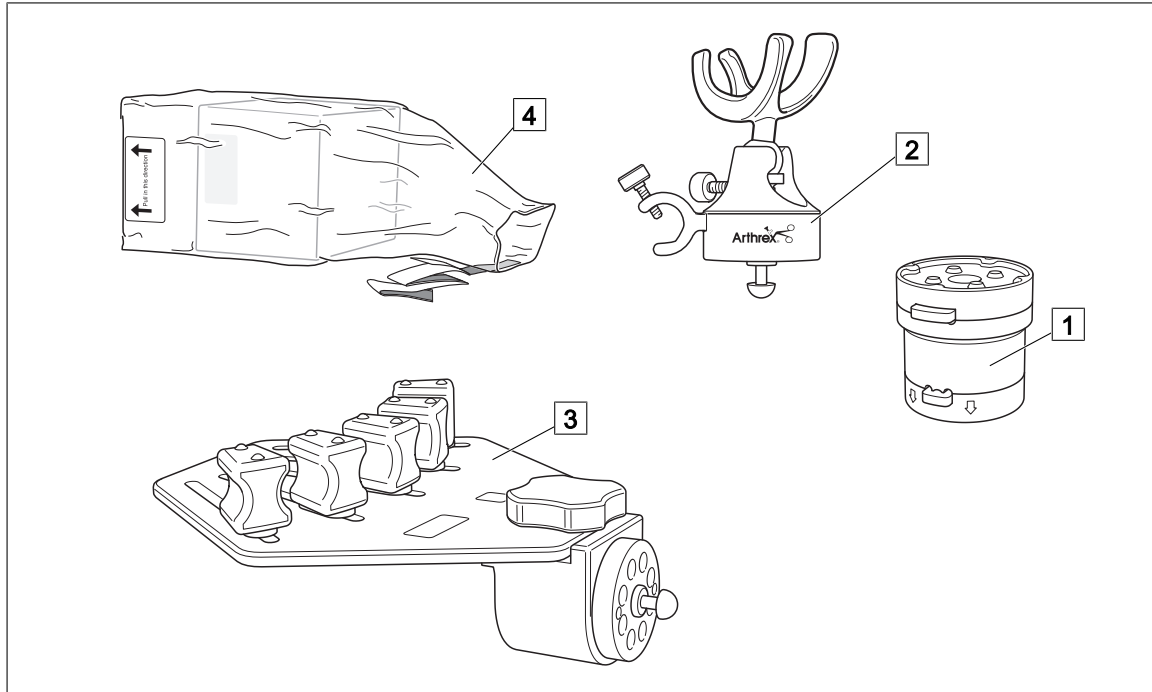


Fig. 3: Accessories for TRIMANO FORTIS

1 TRIMANO FORTIS Adapter (AR-1741)

2 TRIMANO Synergy UHD4 camera head holder (AR-3210-0011) / TRIMANO Synergy camera head holder (AR-3210-0010)

3 TRIMANO Wrist Positioner (AR-1647)

4 TRIMANO drape for Wrist Positioner or camera head holder (AR-1648)

1.4.3 Sterile sets / Sterile drapes

1.4.3.1 Sterile sets/drapes for the shoulder

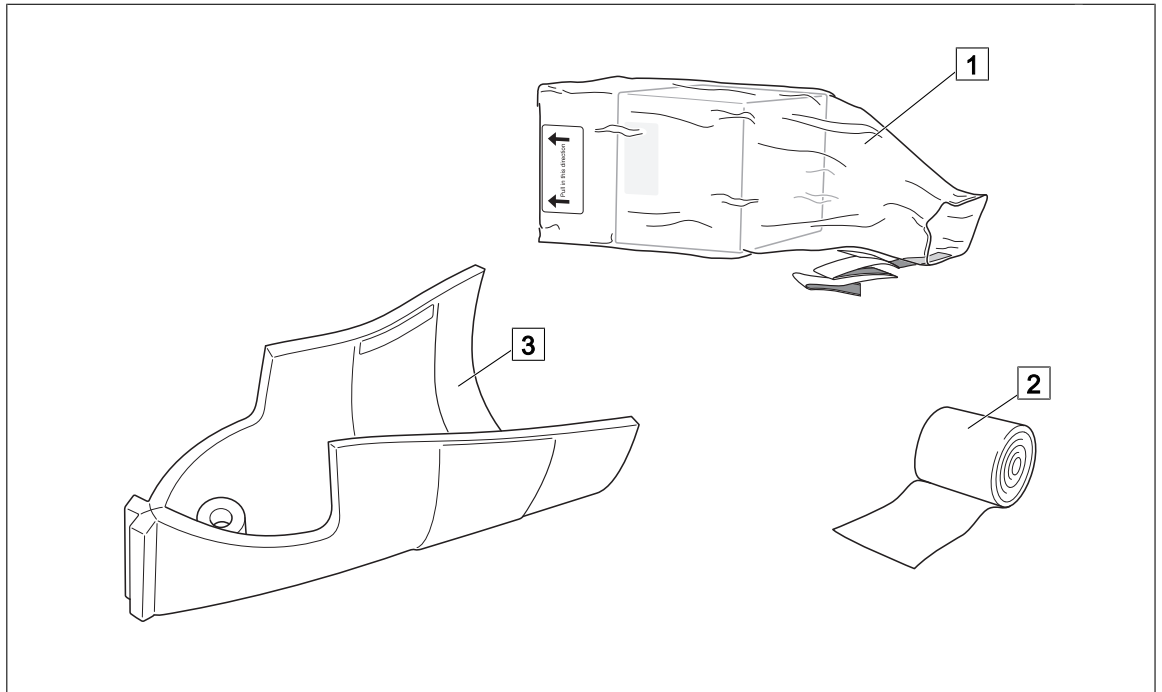


Fig. 4: Arthrex TRIMANO Beach Chair-Kit (AR-1644)

- 1 TRIMANO Drape
- 2 Long stretch strap

3 Disposable arm rest

1.4.3.2 Sterile sets/drapes for the elbow

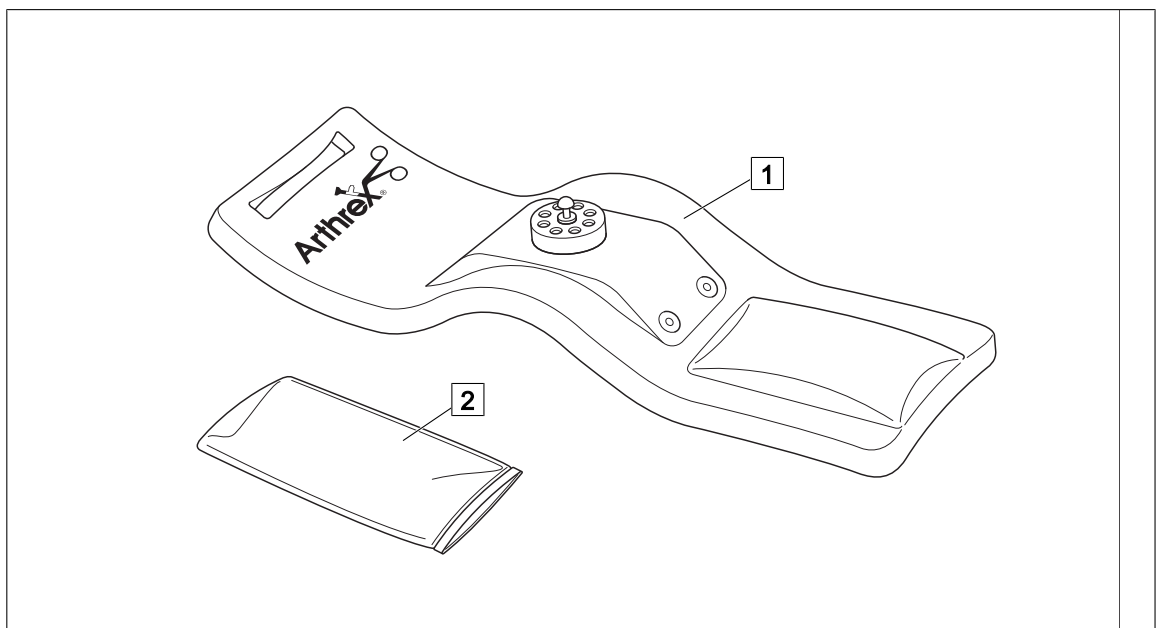


Fig. 5: Arthrex TRIMANO Elbow Kit (AR-1646)

- 1 Disposable elbow rest

2 Drape for elbow kit (supplied)

1.5 Basic requirements

1.5.1 Use in accordance with the intended purpose

This product is a Class I medical device according to the Medical Device Directive 93/42/EEC.

This product is to be used exclusively in human medicine.

Patients may be placed on the device and brought into position only under the supervision of medical personnel.

Accessories

Accessories or combinations of accessories may only be used as and when indicated in these instructions for use.

Other accessories, combinations of accessories or consumables may only be used if they are designed specifically for the use in question and will not adversely affect either performance features or safety requirements.

1.5.2 Applicable standards

The product satisfies the basic requirements set forth in Annex I of the 93/42/EEC Directive as drafted by the Medical Devices Council (Medical Devices Directive) as well as the applicable national (German) codes and the Medical Devices Act in Germany. This has also been demonstrated through the application of the corresponding standards, which have been harmonised with the 93/42/EEC Directive.

1.5.3 Intended purpose

The TRIMANO FORTIS 3D support arm (AR-1740 / 1002.30R0) is designed for mounting specific TRIMANO system accessories for the purpose of placement and positioning of the patient's arm / patient's hand or for the purpose of accommodating other products such as a wound retractor immediately prior to, during and after surgical interventions, as well as for examination and treatment.

The TRIMANO FORTIS is equipped with six rotating joints which enables it to be very flexibly adjusted. The set position of the TRIMANO FORTIS can quickly be secured and released manually using a control element. Only sterile sheaths approved by Maquet may be used.

The maximum load placed on the product may not exceed the appropriate proportional weight of a 250 kg patient. The product may be loaded with an additional 21 kg to support the patient.

The product may only be operated by medically trained staff within the OR environment.

Any use other than those described above is deemed not to be in compliance with the intended purpose.

In the following section, the TRIMANO FORTIS is simply referred to as the TRIMANO.

The product may **not** be used for the following purposes, or under the following conditions:

- For applications to the central nervous system
- For direct cardiac application
- For applications to the head

1.5.3.1 Mounting points

The TRIMANO FORTIS 3D support arm may be mounted to all lateral Maquet side rails as well as to all side rails with the following specifications:

- Height: 24.72-38.10 mm
- Width: 6.35-10.20 mm
- Edge shape: Radius of 0.3-1.5 mm or chamfer 45° of 0.3-0.5 mm

1.5.3.2 Variants

The product is available in the following versions:

- AR-1740 / 1002.30R0
Arthrex TRIMANO FORTIS 3D support arm

1.5.4 Product features

1.5.4.1 Key performance characteristics

The product corresponds to IEC 60601-1 and its collateral standards with the following key performance characteristics:

- Accommodation of the patient's weight and / or weight of a patient's body part without unwanted movement, even in initial fault instance

1.5.4.2 Latex-free materials

All used materials (e.g. materials for SFX and PUR pads, gel pads, straps, transport strap, etc.) are latex free.

2 Safety notes

2.1 General safety notes

**DANGER!**

Potentially fatal!
Hazard caused by unauthorized modifications.
Modifications at the product are not permitted.

**DANGER!**

Potentially fatal!
Danger resulting from improper handling.
Always observe the instructions for use for the OR table.

**DANGER!**

Potentially fatal!
Risk posed to the patient's vital functions due to incorrect positioning.
Position the patient correctly and keep under permanent observation.

**WARNING!**

Risk of injury!
Improper patient positioning may cause health damage (e. g. decubitus).
Position the patient correctly and keep under constant observation.

**WARNING!**

Risk of injury!
Products may only be used in a fully functional state.
Before use, ensure the proper working order and fully functional state of the product.

**WARNING!**

Risk of injury!
If the product is mounted to the OR tables of other manufacturers, there is a risk of tipping or of material breakage if the specifications regarding the side rail interface are not observed.

Always observe the manufacturer's specifications for the OR table.

**WARNING!**

Risk of injury!
When the O.R. Table, the transporter, the table top, or a piece of accessories are moved or adjusted as well as during the take-over procedure of the table top, collisions with the patient, with the involved products, or downward positioned parts may occur.

During the movement always watch the O.R. Table, the transporter, the table top, and the accessories to avoid collisions. Ensure that no hoses, cables, or blankets are squeezed or sheared by moving parts.



WARNING!

Risk of burns!

The use of high-frequency devices, defibrillators and defibrillator monitors exposes the patient to burn risks due to contact with the metal components in the product or accessories and/or as a result of resting on wet drapes or electrically conductive padding.

Avoid any contact between the patient and metal components; never use damp or wet surgical drapes.

Be absolutely sure to comply with the manufacturers instructions for use!



WARNING!

Risk of injury!

A product or accessory part that is not fixed properly may become loose and lead to injury.

Ensure that the product / accessory is mounted correctly and the locking devices (handle screws, locking elements, levers etc.) are closed and tightened properly, ensure that moving parts are fixed correctly.



WARNING!

Risk of injury!

If locking devices (Eccentric levers, handle screws, locking elements etc.) are released the product / accessory is able to move.

Secure movable parts before releasing the locking elements. After every adjustment procedure ensure that all locking elements are closed.



WARNING!

Risk of injury!

When adjusting, moving or storing the OR table / table top, the staff, the patient and the accessories are exposed to pinching and shearing hazards, particularly in the area around the joints at the head rest, back and leg plates.

Always ensure that no one can be subjected to pinching or shearing action or injured in any other way and that the accessories do not collide with any nearby objects.

2.2 Safety notes for the product

**DANGER!**

Potentially fatal!

The maximum load that may be placed on the product is 21 kg. This corresponds to a proportional arm weight of a 250 kg patient. Restrictions arise as a result of the permitted overall load, including the side rails, when using OR tables with a low maximum load capability. Always observe the instructions for use of the OR table used.

**DANGER!**

Risk of explosion!

The product has no explosion protection and is not suitable for use in AP-M areas prone to explosion. When using disinfectants that contain alcohol, cleaning agents or flammable anaesthesia mixtures that are mixed with air, oxygen or nitrous oxide, explosions may result.

If the product is used in an AP-M area, do not use disinfectants that contain alcohol, cleaning agents or flammable anaesthesia mixtures that are mixed with air, oxygen or nitrous oxide.

**DANGER!**

Hazard of infection!

If the packaging of the sterile parts set is damaged the set is no longer permitted to be used.

**WARNING!**

Risk of injury!

Whenever the product is mounted and adjusted, there is a danger of pinching and shearing to the staff, patient and accessories.

Always ensure that no one can be subjected to pinching or shearing action or injured in any other way and that the accessories do not collide with any nearby objects.

**WARNING!**

Risk of injury!

Loose or loosened securing elements may cause injuries.

When mounting, and after every adjustment, tighten all of the locking elements (handle screw, locks, levers, etc.) of the product.

Check the firm seating of the locking elements.

**WARNING!**

Risk of OR table tipping!

The product influences the centre of gravity of mobile operating tables and mobile/independently manoeuvrable columns of operating table systems.

When positioning the patient, observe the instructions for use of the operating table used.

**CAUTION!**

Property damage!

The joints of the TRIMANO may be neither lubricated nor oiled. It may lead to irreparable damage to the functioning of the unit.



CAUTION!

Property damage!
 High temperatures, moisture and humidity can damage the product.
 Protect the product against moisture and humidity, clean by wipe disinfection only.
 Do not store close to radiators and protect from high solar radiation.



CAUTION!

Property damage!
 The product may only be used with accessories designed specifically for this purpose. Do not mount any other accessories to the product.

2.3 Safety notes regarding the use of accessories



DANGER!

Potentially fatal!
 Patient may be endangered as a result of incorrect use.
 Follow the instructions for use for all accessories.



WARNING!

Risk of injury!
 Accessories not approved for this product and accessories by other manufacturers may cause injuries.
 Only use accessories that have been approved for use with the product.
 Accessories made by other manufacturers may only be used after obtaining written permission.

3 Mounting

3.1 Mounting position / neutral position

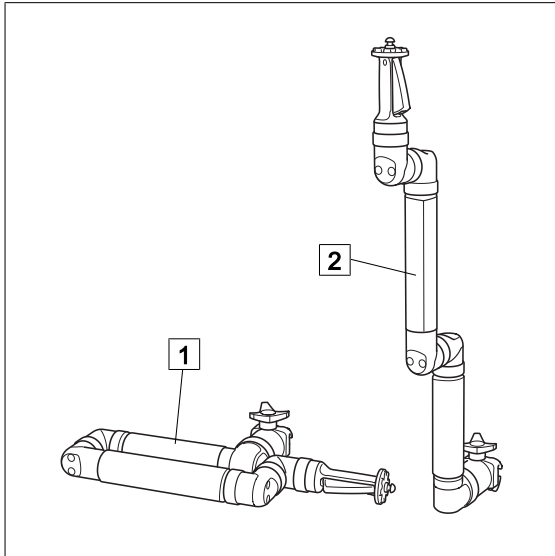


Fig. 6: Mounting position / neutral position

1 Mounting position

Position for the mounting/removal of the TRIMANO

2 Neutral position

Position for applying the drape
Adjusting the TRIMANO [► Page 22].

3.2 Mounting the TRIMANO to the OR table



WARNING!

Risk of injury resulting from collision!

Position the mounted TRIMANO close to the body when transporting a positioned patient.



CAUTION!

Property damage!

The clamp of the TRIMANO may be damaged when removing the patient cover.

Do not attach the TRIMANO to a patient cover. Mount the TRIMANO directly to the side rail of the OR table.



NOTE

For applications on arm and shoulder, attach the TRIMANO in the vicinity of the seat plate between hip and knee.

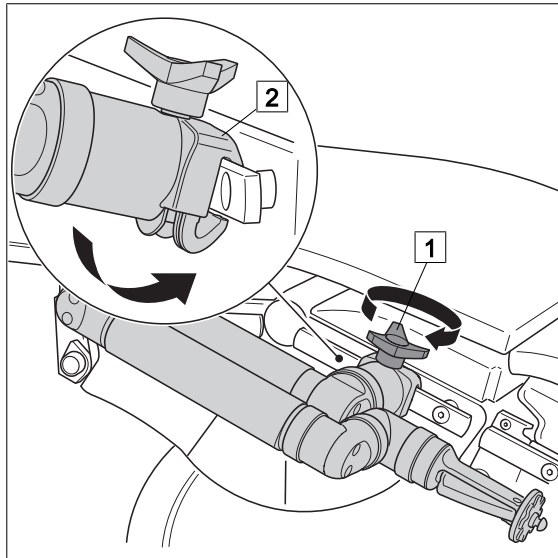


Fig. 7: Mounting TRIMANO

Mounting TRIMANO

- ☒ Put TRIMANO in the mounting position.
- ☒ Open the fixation screw (1) of the clamp (2) completely.
- ☒ Place the clamp on the side rail.
 - ✓ The fixation screw points upwards.
- ☒ Tighten the fixation screw.
 - ✓ The TRIMANO is adapted to the side rail of the OR table.
- ☒ Check proper seating.

3.3

Mounting / removing the TRIMANO adapter with sterile drape



DANGER!

Risk of infection!

Do not use the sterile sheath if the packaging/sterile sheath has been damaged or the use-by date has passed.



DANGER!

Risk of infection!

Apply the adhesive strips of the sterile sheath to a cleaned, sterilised and dried TRIMANO adapter only. Pay attention to ensure that no tensioning forces are acting on the seams of the sterile sheath and the sheath is positioned loosely around the TRIMANO.



NOTE

After having mounted the sterile sheath, check the complete and sterile cover of non-sterile areas.

The sterile drape is mounted to the TRIMANO adapter (AR-1741). It is suitable for sterile covering of the TRIMANO support arm and also acts as protection from ingressing fluids. For this reason, protect the TRIMANO support arm using the sterile drape even for non-sterile applications. The sterile drape (AR-1648) is used as an example to describe how to mount the sterile drape.

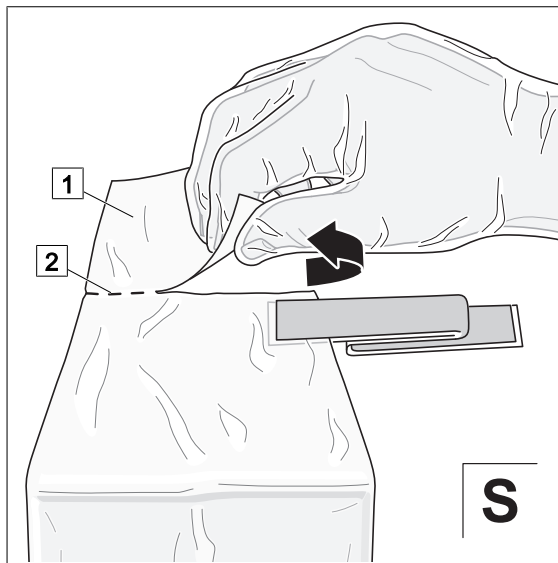


Fig. 8: Separating the closed side

Separating the closed side

- ☒ Separate the closed side (1) of the sterile sheath at the perforation (2).

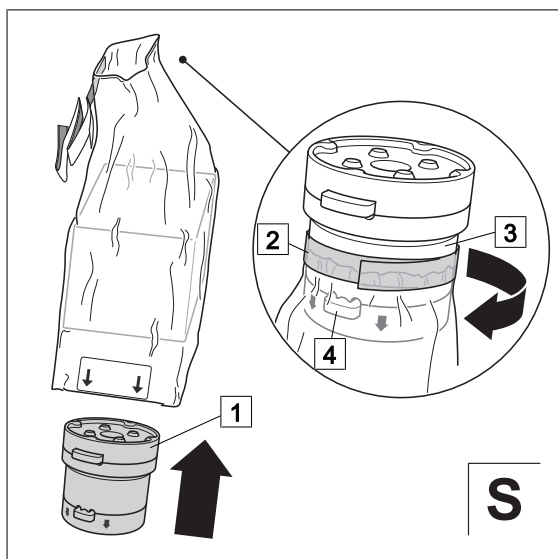


Fig. 9: Sticking the sterile drape to the TRIMANO adapter

Sticking the sterile drape to the TRIMANO adapter

- ☒ Insert the TRIMANO adapter (1) into the sterile drape. When aligning the TRIMANO adapter note that the direction arrow on the TRIMANO adapter points down.
- ☒ Tape the beginning of the sterile drape to the centre area (3) of the TRIMANO adapter using the adhesive tape (2).
 - ✓ The release buttons (4) may not be covered by the adhesive tape.
 - ✓ The adhesive tapes enclose the TRIMANO adapter fully.
 - ✓ Fluids cannot ingress.
- ☒ Make sure that the adhesive tape is properly attached.

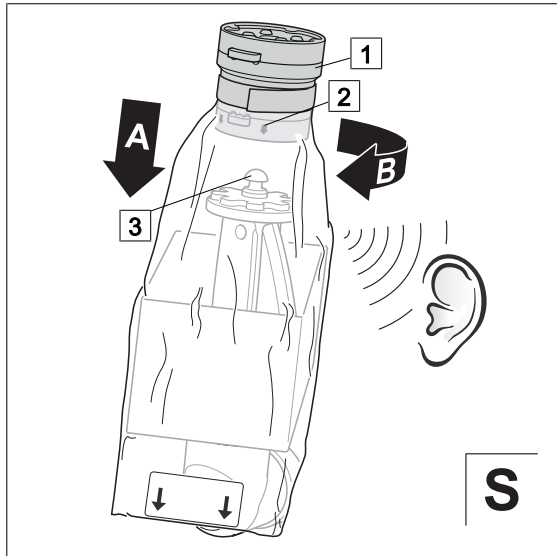


Fig. 10: Mounting the TRIMANO adapter

Mounting the TRIMANO adapter

- Fit the TRIMANO adapter (1) in the direction of the arrow (2) to the pins (3) of the TRIMANO support arm (A) and turn (B). Pay attention to ensure that the sterile drape is not trapped.
 - ✓ The locking device engages with an audible click.
 - ✓ Both release buttons protrude at least 2 mm.
 - ✓ The TRIMANO adapter is adapted to the TRIMANO support arm.
- Check proper seating.

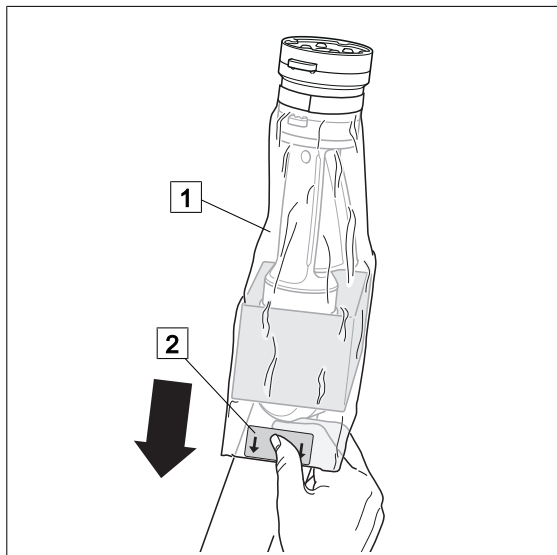


Fig. 11: Fitting the sterile drape

Fitting the sterile sheath

This action is not carried out under sterile conditions!

Prerequisites:

- The TRIMANO is in a neutral position (in extended condition).
- Hold the sterile sheath (1) at the designated markings (2) and slide fully over the TRIMANO until the side rail is reached.
 - ✓ The TRIMANO is protected from spray water.
- Ensure that the non-sterile area is completely covered by the sterile sheath. Cover the non-sterile end of the sterile sheath on the side rail in a sterile way.

4 Disassembly

4.1 Removing the TRIMANO adapter from the TRIMANO support arm

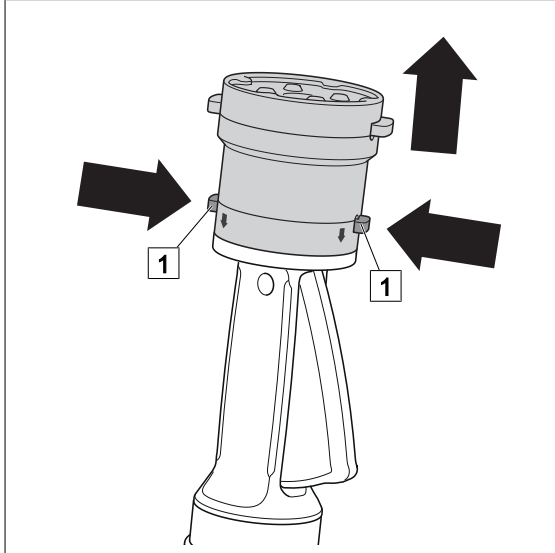


Fig. 12: Removing the TRIMANO adapter

This action is not carried out under sterile conditions!

Prerequisites:

- The sterile drape has been removed.

Removing the TRIMANO adapter

- Push the two lower release buttons (1) of the TRIMANO adapter in simultaneously.
- ✓ The TRIMANO adapter is unlocked.
- Removing the TRIMANO adapter from the TRIMANO support arm.

4.2 Detaching TRIMANO

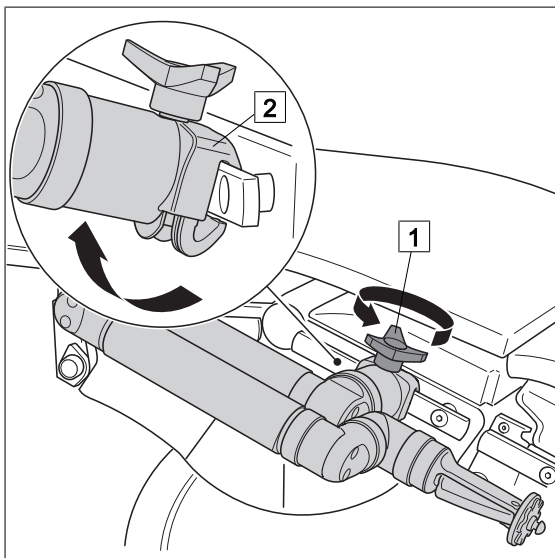


Fig. 13: Detaching TRIMANO

Detaching TRIMANO

- Put TRIMANO in the mounting position.
- Open the fixation screw (1) of the clamp (2) completely.
- Remove the TRIMANO from the side rail.

5 Operation and use

5.1 General



DANGER!

Risk of infection!

Every application requires a special drape. The drapes are disposables. The applications are only approved with the intended drapes!



WARNING!

Risk of infection!

If the TRIMANO system is used in areas with varying hygienic requirements, there is a risk of infection.

Ensure that the TRIMANO system is always in the sterile area when it is in use.



WARNING!

Risk of injury due to overloading!

The permitted load of the product depends on the combination of accessories used.

The product with the lowest permissible load determines the maximum load in the event that it is combined with other accessories.

Refer to the instructions for use of each accessory for the permissible load.



WARNING!

Risk of injury!

Loose or loosened securing elements may cause injuries.

When mounting, and after every adjustment, tighten all of the locking elements (handle screw, locks, levers, etc.) of the product.

Check the firm seating of the locking elements.



WARNING!

Risk of injury resulting from collision!

Position the mounted TRIMANO close to the body when transporting a positioned patient.



CAUTION!

Property damage!

Do not expose the product to large impacts and vibrations, the product is not designed for impulse loads.



CAUTION!

Property damage!

The sterile drape for the TRIMANO support arm also acts as protection from ingress of fluids. For this reason, protect the TRIMANO using the sterile drape even for non-sterile applications.

Always cover the TRIMANO with a sterile drape.

**CAUTION!**

Property damage!

No additional forces, e.g. caused by leaning on or use as support, may act upon the TRIMANO and the accessories mounted to it.

5.2

Adjusting the TRIMANO**WARNING!**

Risk of injury due to unintended movements downwards!

If the release handle is undone, the clamps at the rotating joint are released and the TRIMANO can be moved. Due to its net weight and the patient load, it will swivel downwards.

Before pressing the release handle hold the TRIMANO firmly. After every adjustment procedure, ensure that the release handle of the TRIMANO is correctly locked and no foreign bodies are trapped within.

**WARNING!**

Risk of injury!

The positioning and securing of the body part to be positioned must be carried out with great care. Then check the correct position and securing.

**CAUTION!**

Property damage!

The release handle may be jammed if foreign bodies are included when pushing.

When pushing the release handle closed, ensure that no foreign bodies (e. g. sterile drapes, glove) are trapped.

**CAUTION!**

Property damage!

When adjusting the TRIMANO, if the release handle is not pushed as far as it will go the TRIMANO may be damaged.

To adjust the TRIMANO, push the release handle as far as it will go.

**NOTE**

Always press the release handle with the ball of the hand so that the set position of the TRIMANO is not accidentally changed if the release handle is released before it has been locked.

The TRIMANO has six rotating joints enabling it to be adjusted and secured in a wide variety of positions.

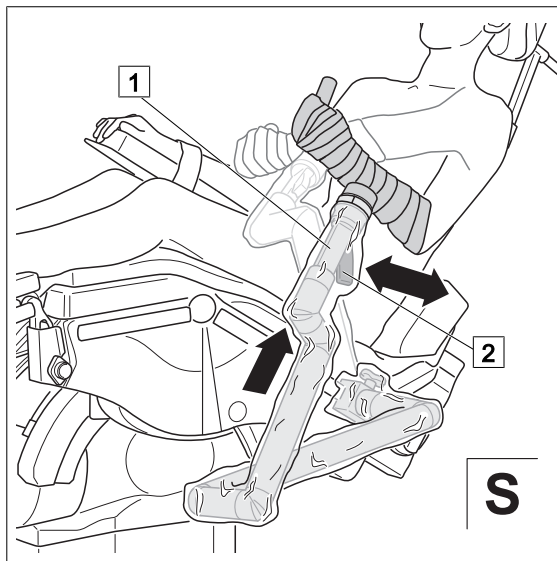


Fig. 14: Adjusting the TRIMANO

Adjusting the TRIMANO

- ☒ Relieve the load on the TRIMANO in an upwards direction.
 - ✓ Easy unlocking is possible.
 - ✓ After releasing, the TRIMANO does not fall back unintentionally.
- ☒ Hold the TRIMANO (1), push the release handle (2) with the ball of the hand and hold.
 - ✓ The locking devices of the swivel joints are released.
- ☒ Swivel the TRIMANO to the required position.
- ☒ Release the release handle.
 - ✓ Swivel joints of the TRIMANO are locked.
 - ✓ The TRIMANO is locked in the required position.

6 Cleaning and disinfection

6.1 General

The product must be cleaned as well as wipe disinfected after every use.

6.1.1 Basic notes



DANGER!

Risk due to mishandling of detergents and disinfectants!

It is strictly advised to observe the manufacturer instructions on how to use the detergents and disinfectants as well as the valid hospital hygiene rules.



DANGER!

Risk of explosion!

Agents containing alcohol can form explosive vapour mixtures and ignite where high-frequency equipment is being used.

Do not use agents containing alcohol where high-frequency equipment is being used.



DANGER!

Risk of infection!

Particles of grime may become encapsulated and may cause the product not to reach the desired germ-reduction after disinfection.

Before disinfection, the product must be cleaned thoroughly of contaminations and encapsulated particles of grime.



DANGER!

Risk of infection!

Product may be contaminated.

Always wear gloves when cleaning / disinfecting.



CAUTION!

Improper cleaning and disinfection can cause property damage!

Perform visual and functional inspections after each cleaning and disinfection process.



CAUTION!

Improper cleaning and disinfection can cause property damage!

Do **not** use the following products for cleaning and disinfection:

- Products containing alcohol (e. g. hand disinfectant)
- Halogenides (e. g. fluorides, chlorides, bromides, iodides)
- Dehalogenating compounds (e. g. fluorine, chlorine, bromine, iodine)
- Products that may scratch surfaces (e. g. scourers, wire brushes, steel wool)
- Standard commercial solvents (e. g. benzene, thinner)
- Water containing particles of iron
- Cleaning sponges containing iron
- Products containing hydrochloric acid

To clean the product, use a soft, lint free cloth or a soft nylon brush.



CAUTION!

Improper cleaning and disinfection can cause property damage!
Use only as much detergent and disinfectant as is required.

6.1.2 No mechanical decontamination



CAUTION!

Property damage!
Do not use any mechanical cleaning or disinfection processes.

6.1.3 No sterilisation



CAUTION!

Property damage due to sterilisation!
Do not sterilise the product.

6.1.4 Stainless steel surfaces



NOTE

If the metal surfaces corrode despite regular cleaning and disinfection, they may be cleaned with special detergents, such as Perr active or Helotil.

6.2 Cleaning

6.2.1 General



CAUTION!

Improper cleaning can cause property damage!
Residues of physiological saline solutions (e. g. sodium chloride) may attack the surfaces of the product.

Remove residues of physiological saline solutions with a cloth dipped in clean water. Then dry the product with a dry, lint free cloth.



CAUTION!

Improper cleaning can cause property damage!
Cleaning agent may **not** ingress into joints or cracks. Do not use pressure washers **nor** submerge the TRIMANO in liquid for cleaning! The TRIMANO may not be soaked. Only wipe off with a damp cloth!

**NOTE**

Use only all-purpose cleaners which are slightly alkaline (soap solution) and which contain tensides or phosphates as active cleaning ingredients.

In the event of heavily contaminated surfaces, use concentrated multi-purpose detergent.

6.2.2 Cleaning procedure

- Use correct dose of all-purpose cleaning agent and clean water corresponding to the degree of surface contamination and in accordance with the instructions of the cleaning agent manufacturer.
- Thoroughly wipe the product with a soft cloth dipped in an all-purpose agent solution.
- Ensure that the product is free from contamination and encapsulated particles of grime.
- Thoroughly wipe the product with a soft cloth dipped in clean water.
- Ensure that the product is free of cleaning agent residues.
- Dry product with a dry, absorbent and lint free cloth.
 - ✓ This will help to reduce pathogen growth on the product's surface.
- Wipe the product with disinfectant after each cleaning.

6.3 Disinfection**6.3.1 General****CAUTION!**

Material damage due to excess exposure times!
Exceeding the given exposure time of the disinfectant may damage the surfaces.

Observe the specified exposure time of the disinfectant manufacturer.

**NOTE**

In the event of product surfaces that are very dirty, carry out an additional cleaning procedure before disinfecting the product.

6.3.2 Suitable disinfectants

Only surface disinfectants based on the following combinations of active ingredients may be used for disinfection:

- Aldehydes
- Quaternary ammonium compounds
- Guanidine derivatives

6.3.3 Disinfection procedure

- Wipe disinfect the product in accordance with the instructions of the disinfectant manufacturer after every cleaning process.
- Ensure that the product is free of disinfectant residue.
- Perform visual and functional inspections.

6.4 Detaching the release handle for cleaning and disinfection

The release handle may be removed to clean/disinfect.



NOTE

If mounted incorrectly, the joints of the TRIMANO cannot be released by pressing the release handle. In this case, remove the release handle and re-mount.

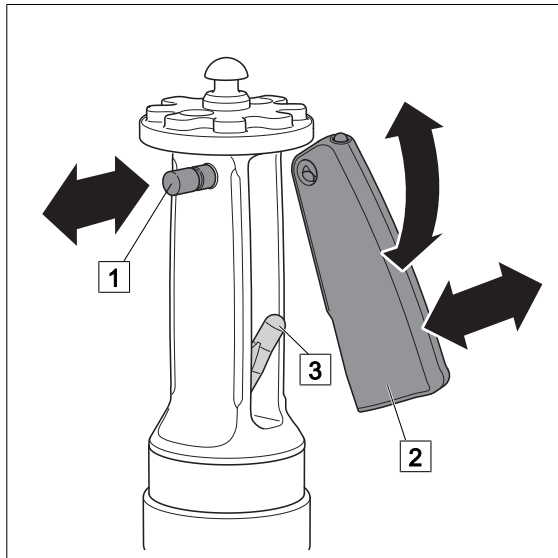


Fig. 15: Detaching / mounting the release handle

Detaching the release handle for cleaning and disinfection

- Push the locking pin (1) with a thin object, e. g. cannula cover out of the drilled hole.
 - ✓ The release button (2) is unlocked.
- Remove the release button from the release handle.
- Clean and disinfect the release handle and button.

Mounting the release handle

- Place the release button (2) on the force transfer pin (3) and push into the release handle.
- Push the locking pin (1) fully into the drilled hole.
 - ✓ The release button is secured to the release handle.
- Check the firm seat of the release button.

7 Maintenance

7.1 Visual and functional inspections

To ensure correct operation, it is necessary to have visual and functional inspections performed by a trained person prior to each use.

Documentation of the results of the visual and functional inspections is recommended and should include the date and signature of the person who performed the inspections. The following table may be used as a template.

Suggestion:

| No. | Inspection | Defects are present | | No defects |
|-----------------|--|--------------------------|--|--------------------------|
| 1 | Has the product not been cleaned and disinfected in accordance with hygiene regulations? | <input type="checkbox"/> | <input checked="" type="checkbox"/> Do not continue to use the product. <input checked="" type="checkbox"/> Clean and disinfect the product in accordance with hygiene regulations. | <input type="checkbox"/> |
| Comment: | | | | |
| 2 | Are there damages to mechanical parts? | <input type="checkbox"/> | <input checked="" type="checkbox"/> Do not continue to use the product. <input checked="" type="checkbox"/> Inform service personnel. | <input type="checkbox"/> |
| Comment: | | | | |
| 3 | Is it not possible to operate all adjustment functions for the product? | <input type="checkbox"/> | <input checked="" type="checkbox"/> Do not continue to use the product. <input checked="" type="checkbox"/> Inform service personnel. | <input type="checkbox"/> |
| Comment: | | | | |
| 4 | (Space for other tests) | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Comment: | | | | |

Tab. 4: Visual and functional inspections

7.2 Faults and troubleshooting

| Appearance / Inspection | Activity / Rectification / Measure |
|--|---|
| The TRIMANO cannot be unlocked, or the joints of the TRIMANO are jammed/blocked. | Prerequisite: The TRIMANO is mounted to the side rail. <input checked="" type="checkbox"/> Take the load off the TRIMANO (if required, remove accessories). <input checked="" type="checkbox"/> Push the release handle with increased force until pressed in fully, hold pressed and simultaneously jiggle the TRIMANO to open the joints. |

Tab. 5: Faults and troubleshooting

7.3 Repair

A damaged product may not be used and you may not repair it yourself. Please have the following information at hand for your Arthrex representative:

- Description of the defect
- Product number (see type plate)
- If available: Serial number (see type plate)
- Construction year (see type plate)

Hotline for Germany +49 89 909005-0

Hotlines for other countries can be found at www.arthrex.com.

7.4 Maintenance

This product is maintenance-free. Wear caused by use and age may influence the safety-relevant functions of the product.

Check the state of the product prior to each use.

If defects are discovered, the product may no longer be used.

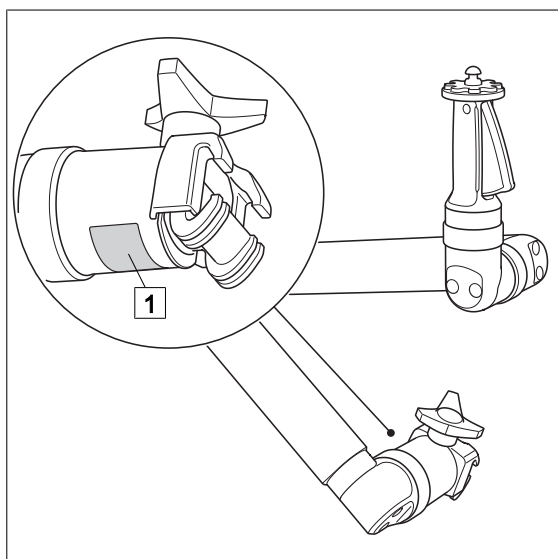
Note the defects and the model number detailed on the type plate, and inform the relevant Arthrex representative. [►► Tab. 6]

7.5 Contact

| Contact | North America | South America | Europe and other countries |
|------------------|--|------------------|----------------------------|
| Telephone | 1-866-267-9138 1-239-643-5553 external -5603 | 001 954-447-6815 | +49 89 9090005-0 |
| Fax | 1-239-591-6943 | 001 954-447-6814 | +49 89 9090005-2801 |

Tab. 6: Contact

7.6 Type plate



Position of the type plate (1) on the product.

Fig. 16: Type plate of TRIMANO support arm

8 Technical specifications



NOTE

For dimensions, adjustment ranges and weight specifications, there is a tolerance of $\pm 5\%$, if no other tolerance is specified.

8.1 General specifications

| | |
|--|---------|
| Classification as per Appendix IX of the 93/42/EEC Directive | Class I |
|--|---------|

8.2 Ambient conditions

| | |
|--|---------------------|
| Temperature: Transportation | -20 °C to +50 °C |
| Temperature: Storage | -20 °C to +30 °C |
| Temperature: Operation | +10 °C to +40 °C |
| Relative humidity: Shipping / storage | 10 % to 95 % |
| Relative humidity: Operation | 30 % to 75 % |
| Atmospheric pressure: Shipping / storage | 500 hPa to 1060 hPa |
| Atmospheric pressure: Operation | 700 hPa to 1060 hPa |

8.3 Dimensions

| | |
|--------|--------|
| Length | 900 mm |
| Width | 320 mm |
| Height | 100 mm |

8.4 Weight

| | |
|------------|--------|
| Net weight | 6.4 kg |
|------------|--------|

9 Approved accessories



DANGER!

Potentially fatal!
Patient may be endangered as a result of incorrect use.
Follow the instructions for use for all accessories.



WARNING!

Risk of injury due to overloading!
The permitted load of the product depends on the combination of accessories used.
The product with the lowest permissible load determines the maximum load in the event that it is combined with other accessories.
Refer to the instructions for use of each accessory for the permissible load.

Only accessories listed in this chapter may be mounted to this product.

9.1 Table structure

The TRIMANO system products/accessories listed in the following table are compatible with one another. This means that the products may be combined regardless of the distributor. The table of compatible accessories is structured. Indented products may be applied to the products above them (multiple possible) which are indented by one column less.

Example: The TRIMANO (AR-1640) is secured to the side rail. The Arthrex TRIMANO adapter (AR-1641) can be fitted to the product. The Arthrex TRIMANO Beach Chair Kit (AR-1644) can be mounted to the Arthrex TRIMANO adapter (AR-1641).

| | | |
|---------|---------------------------------|---|
| AR-1640 | Arthrex TRIMANO positioning aid | |
| | AR-1641 | Arthrex TRIMANO adapter |
| | | AR-1644 Arthrex TRIMANO Beach Chair Kit |

Tab. 7: Example of compatible TRIMANO accessories

9.2 Accessories for TRIMANO FORTIS system

| | | |
|---------|---------------------------------------|---|
| AR-1740 | Arthrex TRIMANO FORTIS 3D support arm | |
| | AR-1741 | Arthrex TRIMANO FORTIS adapter |
| | | AR-1642 Arthrex TRIMANO arm rest for lateral position |
| | | AR-1643 Arthrex TRIMANO arm rest Beach Chair |
| | | AR-1647 Arthrex TRIMANO Wrist Positioner |
| | AR-3210-00 11 | Arthrex TRIMANO 4K Synergy UHD4 camera head holder |
| | AR-3210-00 10 | Arthrex TRIMANO Synergy camera head holder |

Tab. 8: Accessories for TRIMANO FORTIS system

9.3 Sterile sets/drapes for the TRIMANO FORTIS system

| | |
|---------|--|
| AR-1644 | Arthrex TRIMANO Beach Chair Kit |
| AR-1648 | Sterile drape TRIMANO for (AR-1640) and (AR-1740) |
| AR-1646 | Arthrex TRIMANO Elbow Kit |
| AR-1645 | TRIMANO Application Set Shoulder (for AR-1642 / AR-1643) |

Tab. 9: Sterile sets/drapes for the TRIMANO FORTIS system

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Notes

Manufacturer:

MAQUET GmbH
Kehler Strasse 31
76437 Rastatt
Germany

Manufactured for:

Arthrex Inc.
1370 Creekside Blvd
Naples, FL 34108-1945, USA
1-(800) 934-4404

Arthrex GmbH
Erwin-Hielscher-Strasse 9
81249 München/Munich, Germany
+49 89 909005-0

For local contact:
Please visit our Website
www.arthrex.com

