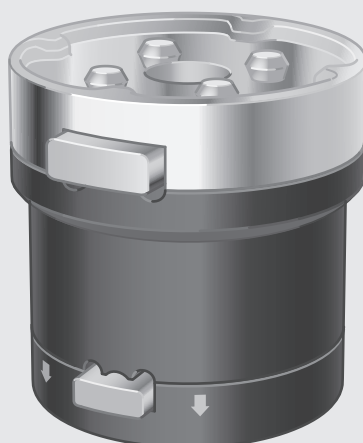


INSTRUCTIONS FOR USE
AR-1741
TRIMANO FORTIS adapter



SOURCE CONTROLLED DOCUMENT

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| Approved as <u>REF-02094</u> | Rev <u>X2</u> |
| Page <u>1</u> of <u>44</u> | CR# <u>ECO-12743</u> |
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| Date: _____ | |
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| Component Nr. <u>REF-02094-02</u> | Rev. <u>X2</u> |



GA AR-1741 EN 03

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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.

V03 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 "»»".

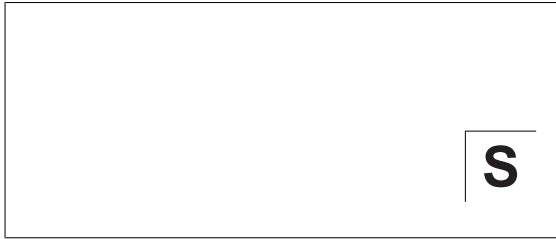
1.1.2.3 Action and reaction

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 accordance with the ISO 15223-1 standard. Symbol for "Batch name". |
|  | Labelling in accordance with the ISO 15223-1 standard. Symbol for "Expiry date". |
|  | 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 accordance with the ISO 15223-1 standard. Symbol for "Not to be reused". |

Tab. 3: Symbols

| Symbols | Identification |
|---|--|
|  | Labelling in compliance with the ISO 15223 -1 standard. Symbol for "Do not sterilise again". |
|  | Labelling in compliance with the ISO 15223 -1 standard. Symbol for "Sterilisation with ethylene oxide". |
|  | 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". |
|  | 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". |

Tab. 3: Symbols

| Symbols | Identification |
|---|---|
|  | Designates products which can be sterilised in the autoclave at up to 134 °C. |

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 adapter (AR-1741)

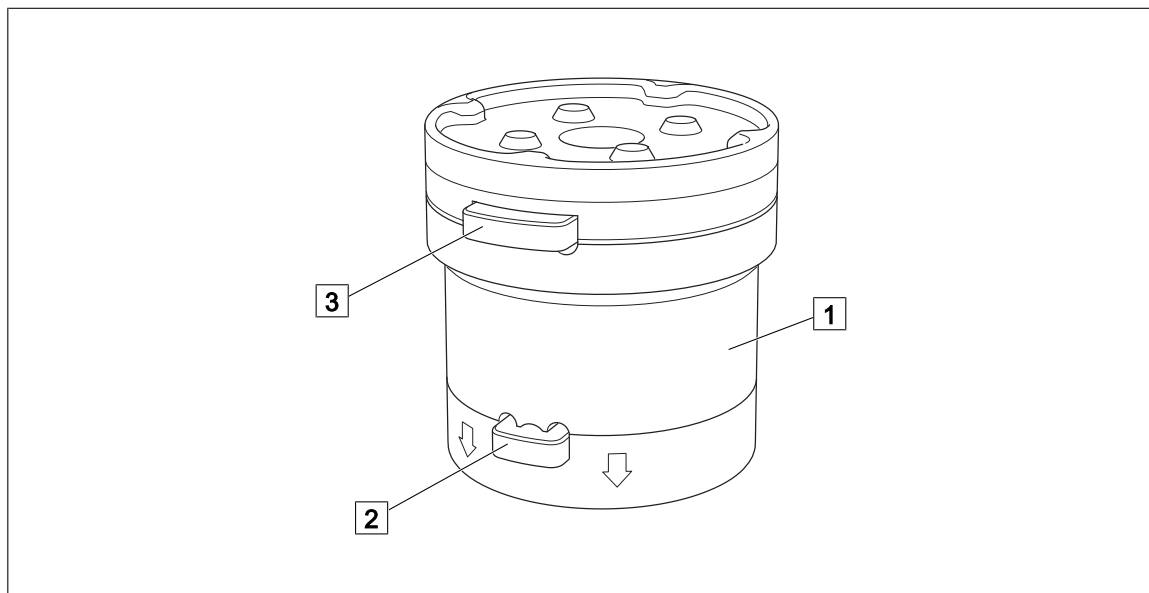


Fig. 2: TRIMANO FORTIS adapter

1 TRIMANO FORTIS adapter

2 Lower release buttons

3 Upper release buttons

1.4.2 Accessories for TRIMANO FORTIS adapter

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

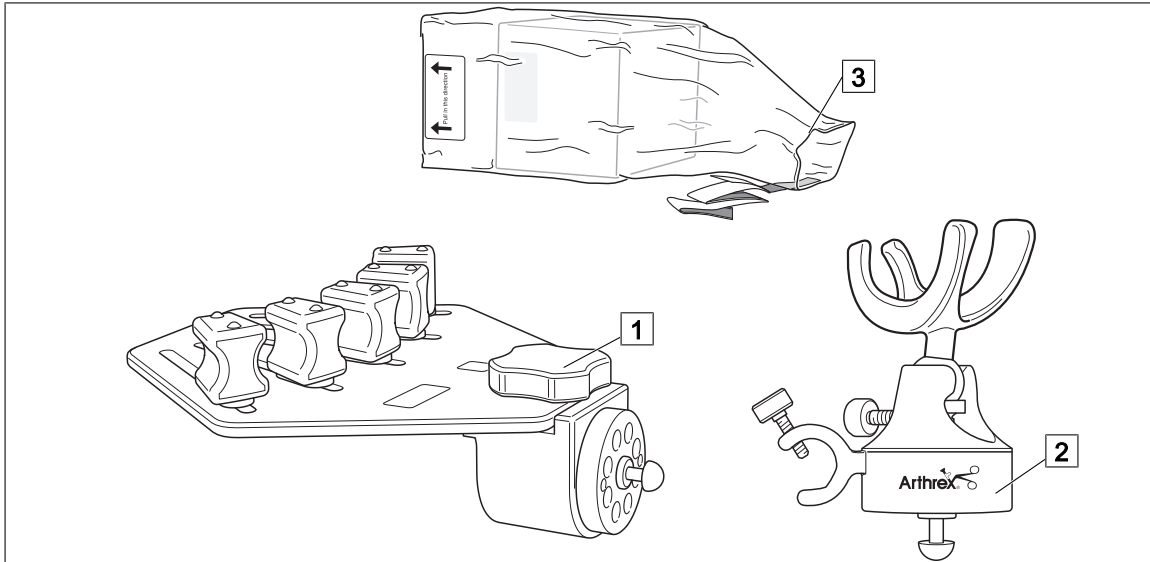


Fig. 3: Accessories for TRIMANO FORTIS adapter

1 TRIMANO Wrist Positioner (AR-1647)

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

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

1.4.3 Sterile sets / Sterile drapes

1.4.3.1 Sterile sets/drapes for the shoulder

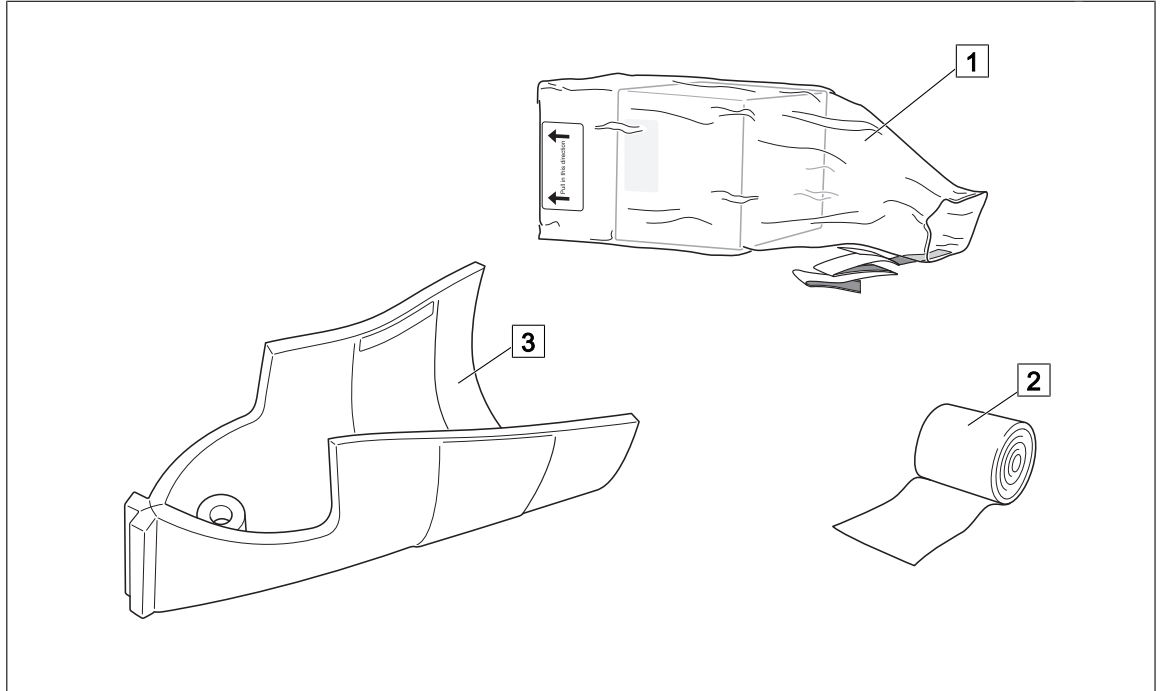


Fig. 4: Arthrex TRIMANO Beach Chair-Kit (AR-1644)

- 1 TRIMANO Drape
- 2 Long stretch strap

3 Disposable arm rest

1.4.3.2 Sterile sets/drapes for the elbow

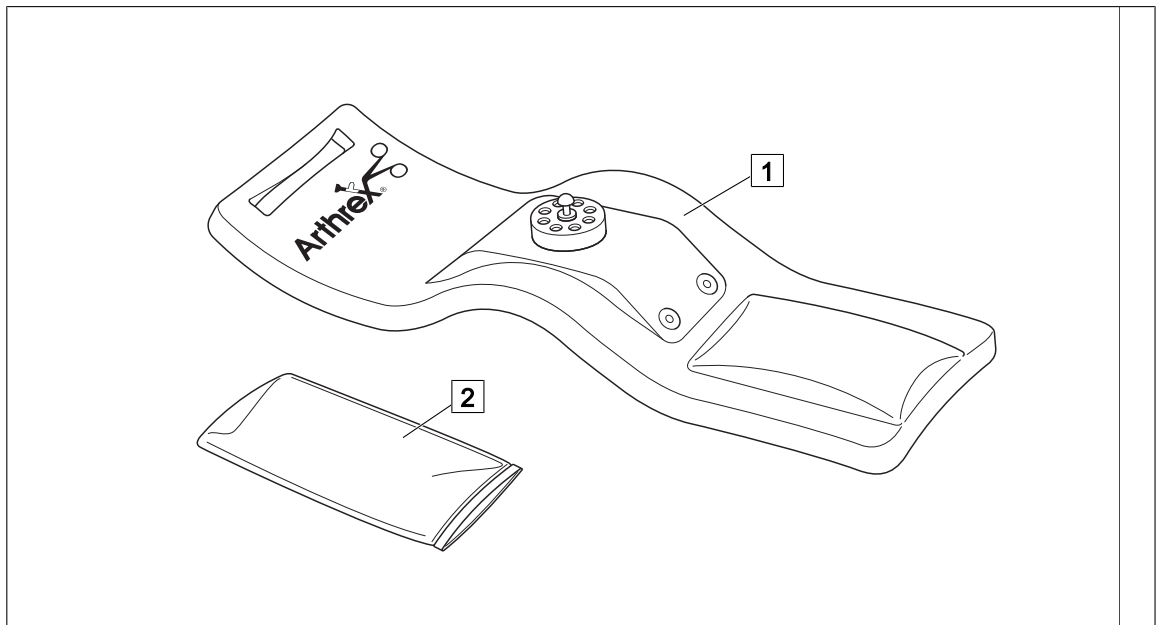


Fig. 5: Arthrex TRIMANO Elbow Kit (AR-1646)

- 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 adapter (AR-1741 / 1002.31X0) 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.

Depending on the specific accessories being used, the TRIMANO FORTIS adapter may only be used with the sterile drapes (AR-1648 / 1002.53F0).

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.

The product may only be used by personnel with the appropriate training.

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 adapter is simply referred to as the TRIMANO adapter, and the TRIMANO FORTIS 3D support arm is also simply referred to as TRIMANO.

1.5.3.1 Mounting point

The TRIMANO FORTIS adapter may only be used on the TRIMANO FORTIS 3D support arm Arthrex (AR-1740 / 1002.30X0).

1.5.3.2 Variants

The product is available in the following versions:

- AR-1741 / 1002.31R0
Arthrex adapter for TRIMANO FORTIS

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

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!
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 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 General



NOTE

Always observe the usage notes for the sterile set as included in the instructions for use of the TRIMANO support arm.

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.

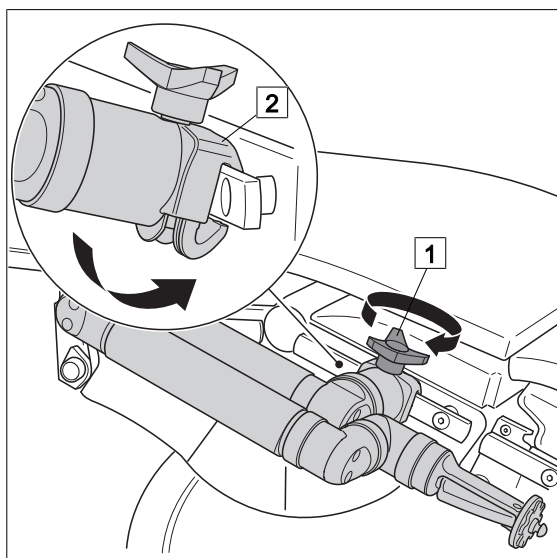


Fig. 6: Mounting TRIMANO

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.

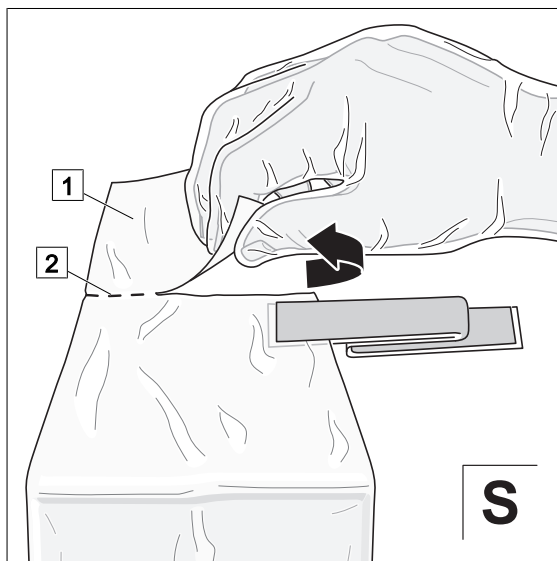


Fig. 7: Separating the closed side

Separating the closed side

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

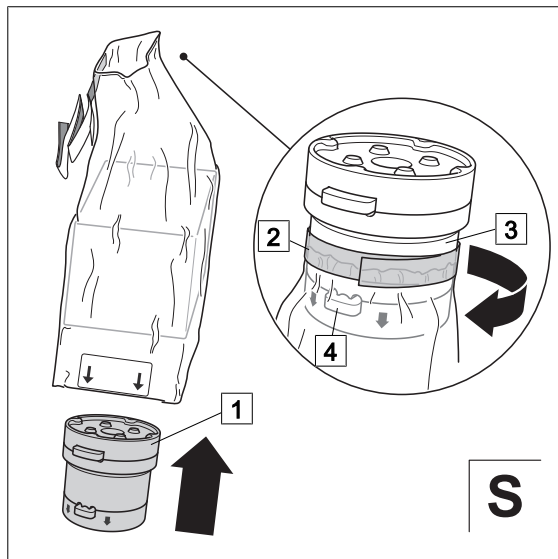


Fig. 8: Sticking the sterile drape to the TRIMANO adapter

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.

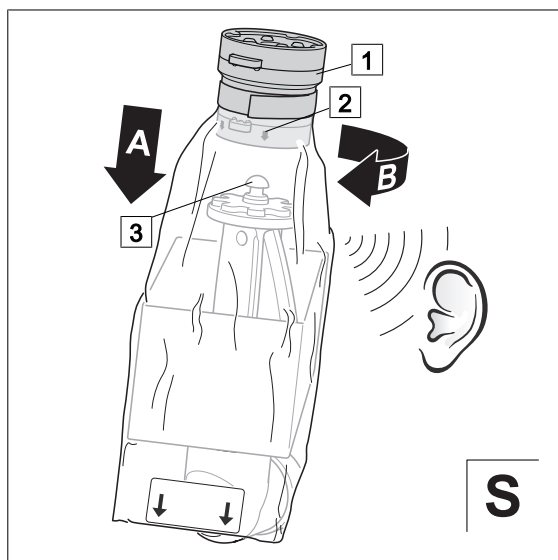


Fig. 9: Mounting the TRIMANO adapter

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.

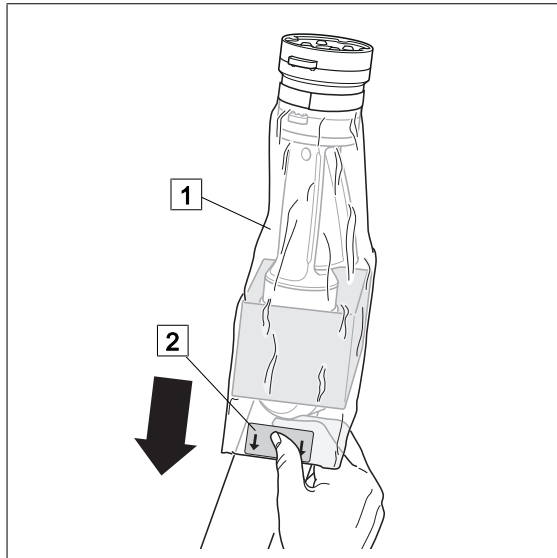


Fig. 10: Fitting the sterile drape

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

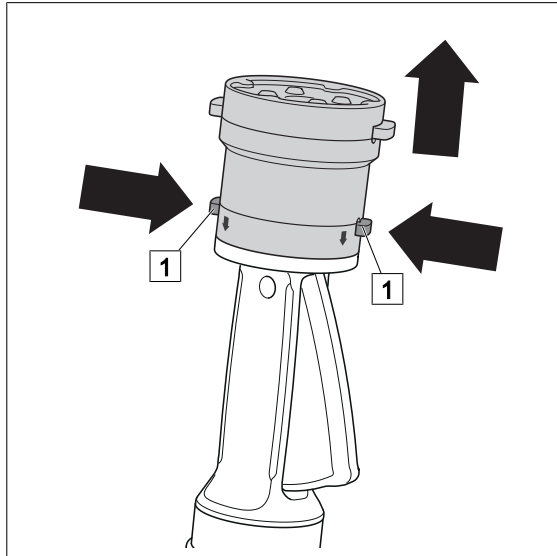


Fig. 11: Removing the TRIMANO adapter

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.

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.

**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.



NOTE

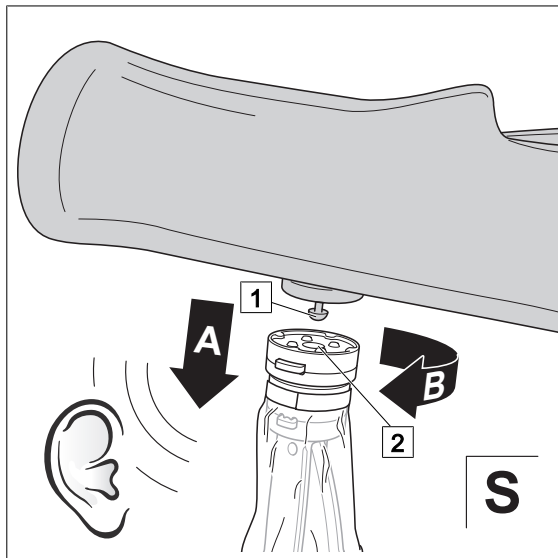
The product may only be used in a sterile condition!
 The product is supplied in a non-sterile condition and must be cleaned and sterilised before the first use.

5.2 Mounting accessories to/removing accessories from the TRIMANO adapter

The Arthrex TRIMANO Beach Chair Kit (AR-1644) is used as an example for mounting accessories to the TRIMANO adapter.

5.2.1 Mounting the BEACH CHAIR arm rest to the TRIMANO

The mounting of the single-use Beach Chair arm rest (AR1644) as well as positioning and securing of the patient's arm is shown.



- Insert the pins (1) of the arm rest into the mount (2) of the TRIMANO adapter (A) and gently move it back and forth (B).
- ✓ The locking device engages with an audible click.
- ✓ The arm rest is fitted to the TRIMANO adapter.
- Check the firm seat of the arm rest.

Fig. 12: Mounting the arm rest

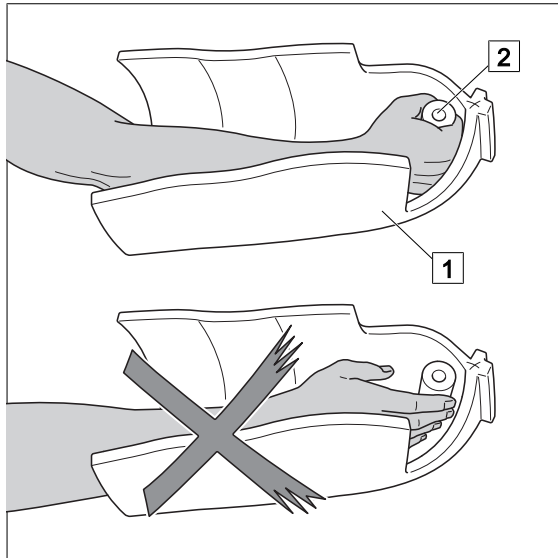


Fig. 13: Positioning the arm of the patient on the arm rest

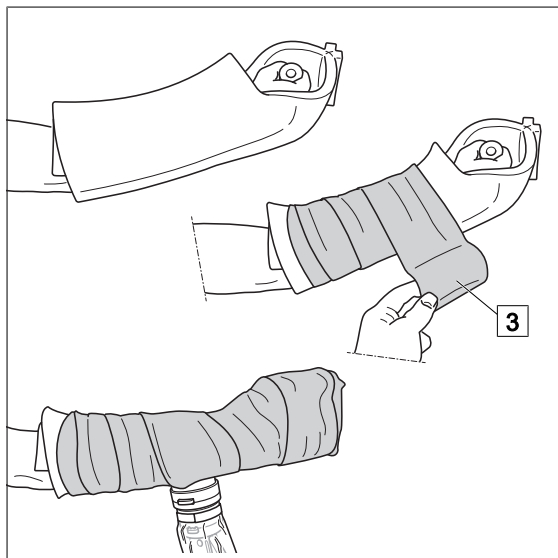


Fig. 14: Securing the arm of the patient to the arm rest

Positioning and securing the patient's arm in the BEACH CHAIR

- ☒ Adjusting the TRIMANO support arm for positioning the arm of the patient.
- ☒ Position the arm of the patient on the single-use arm rest (1).
- ☒ Ensure that the fingers of the patient are closed around the grip (2) of the single-use arm rest.
- ☒ Fold in the single-use arm rest and secure using the hook and loop closures.
- ☒ Wrap the arm of the patient fully in the single-use arm rest (hand/fingers included) with the long tensioning strap (3).
- ☒ Make sure that the upper release buttons of the TRIMANO adapter are easily reached to ensure that the BEACH CHAIR arm rest can be removed from the TRIMANO adapter during the operation.
- ☒ Ensure that the patient's arm is properly seated.

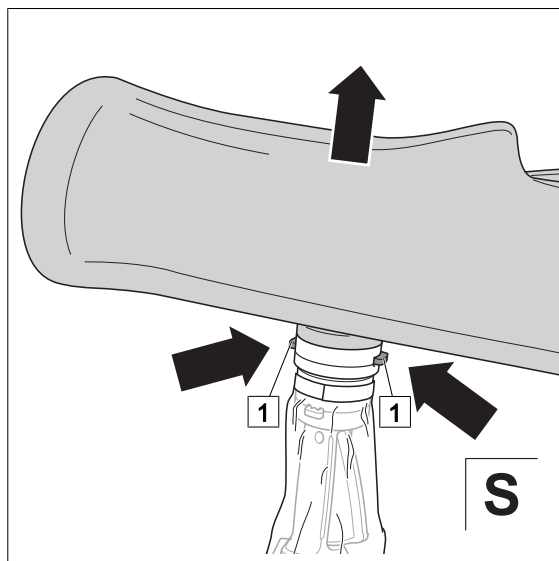
5.2.2 Removing the BEACH CHAIR arm rest from the TRIMANO



NOTE

When removing the arm rest, make sure to press the upper release buttons. If the lower release buttons are pressed, this eliminates the connection between the TRIMANO adapter and the TRIMANO support arm.

The arm rest can be removed from the TRIMANO adapter during the operation and re-mounted while maintaining the sterile state. This enables free movement of the arm without the TRIMANO support arm.



Removing the arm rest

- Simultaneously press the two upper release buttons (1) on the TRIMANO adapter.
- ✓ The arm rest is unlocked.
- Removing the arm rest from the TRIMANO adapter

Fig. 15: Removing the BEACH CHAIR TRIMANO arm rest

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!**

Danger to incorrect cleaning, disinfection, and sterilisation!

The entire cleaning process may only be completed by qualified technicians.

**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

Product-specific notes



WARNING!

Risk of injury due to heated components!

The components are heated after disinfection / sterilisation. Allow the product to cool down in the sterile packing paper and only use in a cooled state.



NOTE

They will be supplied in a non-sterile condition.
Clean, disinfect and sterilise the products before initial use.



NOTE

The TRIMANO adapter must be mechanically cleaned, disinfected **and** sterilised after every use. The TRIMANO adapter may only be used in a sterile condition! Adhesive residue from the sterile drape must be removed fully.



NOTE

The TRIMANO adapter may be cleaned, disinfected and sterilised in an assembled state. The TRIMANO adapter must not be disassembled to clean, disinfect and sterilise.

6.1.3

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.



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 multi-purpose detergent and clean water corresponding to the degree of surface contamination and in accordance with the instructions of the detergent manufacturer.
- Thoroughly wipe the product with a soft cloth dipped in a multi-purpose detergent 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 detergent residues.
- Dry product with a dry, absorbent and lint free cloth.
 - ✓ This will help to reduce pathogen growth on the product's surface.
- Wipe or spray disinfect the product after every cleaning process.

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

Use only surface disinfectants with the following active ingredient bases for disinfection:

- Quaternary ammonium compounds
- Guanidine derivatives

6.3.3 Disinfection procedure

- After each cleaning process, wipe or spray disinfect the product in accordance with the instructions of the disinfectant manufacturer.
- Ensure that the product is free of disinfectant residue.
- Perform visual and functional inspections.

6.4 Cleaning and disinfection procedures

Different cleaning and disinfection procedures may be used for the various components, depending on the properties of the materials.

6.4.1 Manually cleaning and disinfecting the TRIMANO adapter



NOTE

In the event of heavily contaminated surfaces of the product, manual cleaning and disinfection is recommended prior to mechanical cleaning and disinfection.

| Components | Cleaning | Disinfection |
|-----------------|---|---|
| TRIMANO adapter | <ul style="list-style-type: none"> ☒ Place the components in an ultrasound bath (5 minutes, frequency 35 kHz) in a lightly alkaline cleaning agent solution (e. g. Dr. Weigert MediClean 1 % (v/v) in tap water*). ☒ Completely clean the surfaces of the component with a soft, non-metallic brush (e. g. medium-hardness toothbrush) to remove visible residue, under flowing tap water* (at least 1 minute), pay special attention to difficult to reach parts (metal parts). ☒ All sliding surfaces, cut-outs and, in particular, openings in the middle of the metal sides should be rinsed for at least 45 seconds per side under running tap water*. All moving parts should be moved during this process. ☒ Using a single use syringe (e. g. 60 ml) and 200 ml of tap water* rinse each channel. ☒ Then rinse all accessible points with demineralised water for at least 10 seconds. ☒ Dry all surfaces with a lint-free cloth. | <ul style="list-style-type: none"> ☒ Rinse each channel with a single use syringe (e. g. 60 ml) and 200 ml disinfectant solution (e.g. neodisher® SeptoMED, Dr. Weigert, 2% (v/v) at 20 °C ±2 °C in tap water*). ☒ Immerse components in demineralised water (30 minutes). Move all moving parts at the start by hand for a least 10 seconds whilst in the solution to remove any air bubbles. ☒ Immerse components in cold, demineralised water (1 minute). |

*Tap water: minimum quality requirements: drinking water, temperature 30 °C (±3 °C)

Tab. 4: Cleaning and disinfection procedures

6.4.2 Mechanical cleaning and disinfecting the TRIMANO adapter

| Components | Cleaning | Disinfection |
|--|--|--|
| TRIMANO adapter | <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Connect every flushing channel of the components with an injector. <input checked="" type="checkbox"/> Rinse with cold tap water* (1 minute). <input checked="" type="checkbox"/> Clean at 55 °C (-0 °C, +3 °C, 5 minutes) with cleaning agent, e.g. neodisher MediClean (0.5% v/v). <input checked="" type="checkbox"/> Neutralise with cold tap water* (2 minutes). <input checked="" type="checkbox"/> Rinse with cold tap water* (1 minute). | Thermal disinfection at 93 °C (+ 5 °C, -0 °C, 5 minutes) with demineralised water. |
| *Tap water: minimum quality requirements: drinking water | | |

Tab. 5: Cleaning and disinfection procedures

6.5 Sterilisation procedure

6.5.1 Sterilising the TRIMANO adapter



CAUTION!

Property damage!
Using non-colour-fast drapes can cause discolouration of surfaces.
Only use colour-fast drapes.



CAUTION!

Property damage due to heated steam!
The natural ageing of plastics will be accelerated by autoclaving using hot steam.
Perform visual and functional inspections after every autoclaving.



CAUTION!

Property damage!
For preparation purposes, the TRIMANO adapter may go through around 200 sterilisation cycles if autoclaved correctly.
Document the sterilisation cycles using the serial numbers and perform visual and functional inspections before every use.



NOTE

Inspect all components for proper functionality before use.

| Components | Superheated steam sterilisation |
|--|---|
| TRIMANO adapter | Superheated steam temperature: 134 °C, 3× fractionated pre-vacuum; sterilisation (at least 4 minutes) |
| *Tap water: minimum quality requirements: drinking water, temperature 30° C (± 3 °C) | |

Tab. 6: Cleaning and disinfection procedures

6.6 After cleaning / disinfection

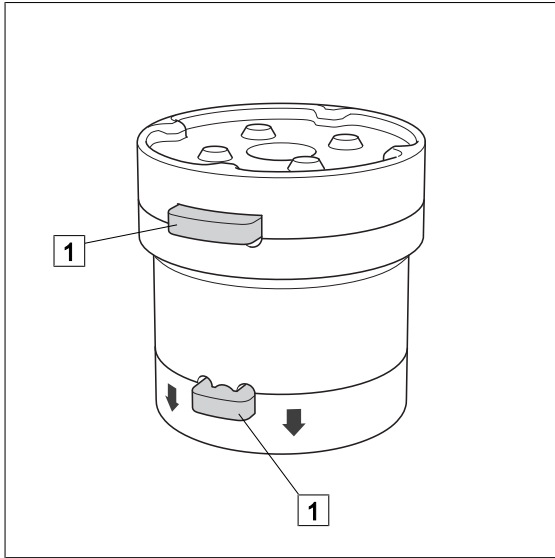


Fig. 16: Oiling the TRIMANO adapter

- ☒ Oil each locking mechanism (1) with a drop of maintenance oil designed for use with surgical instruments.

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. 7: Visual and functional inspections

7.2 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.

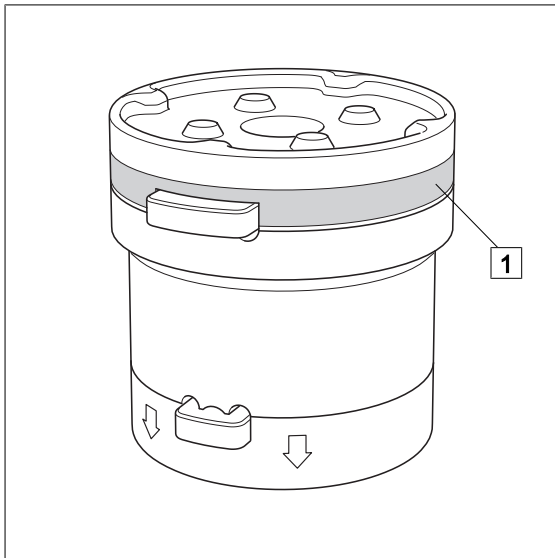
Note the defects and the model number detailed on the type plate, and inform the relevant Arthrex representative. [►► Tab. 8]

7.3 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. 8: Contact

7.4 Type plate



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

Fig. 17: Type plate

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 | 65 mm |
| Diameter | ∅ 80 mm |

8.4 Weight

| | |
|------------|--------|
| Net weight | 0.5 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. 9: 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. 10: 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. 11: 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

