Instructions for use

AR-1741
TRIMANO FORTIS adapter
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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

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN</td>
<td>European standard</td>
</tr>
<tr>
<td>IEC</td>
<td>International Electrotechnical Commission</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
</tr>
<tr>
<td>SFC</td>
<td>Soft Foam Core (special foam core)</td>
</tr>
<tr>
<td>SN</td>
<td>Serial no.</td>
</tr>
</tbody>
</table>

1.1.2 Symbols and formatting

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Instructions to follow / list with numbered steps</td>
</tr>
<tr>
<td>2.</td>
<td>Instructions to follow / list with numbered steps</td>
</tr>
<tr>
<td>✔️</td>
<td>Result of an action</td>
</tr>
<tr>
<td>•</td>
<td>Numbered steps / List entry / precondition</td>
</tr>
<tr>
<td>▶️</td>
<td>Reference to other pages within this document</td>
</tr>
<tr>
<td>[...]</td>
<td>Key / Module / Mode</td>
</tr>
<tr>
<td><strong>bold</strong></td>
<td>Menu / on-screen button</td>
</tr>
<tr>
<td><em>italics</em></td>
<td>Field to be filled in</td>
</tr>
<tr>
<td>1122.33XX</td>
<td>Order number with different variants (XX)</td>
</tr>
</tbody>
</table>

Tab. 1: Symbols and formatting
1.1.2.1 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

<table>
<thead>
<tr>
<th>Pictogram</th>
<th>Descriptor</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Exclamation Mark" /></td>
<td>DANGER!</td>
<td>Identifies an immediate danger to people, which may result in death or serious injuries.</td>
</tr>
<tr>
<td><img src="image2.png" alt="Exclamation Mark" /></td>
<td>WARNING!</td>
<td>Identifies a potential danger to people or property, which may result in damage to health or serious property damages.</td>
</tr>
<tr>
<td><img src="image3.png" alt="Exclamation Mark" /></td>
<td>CAUTION!</td>
<td>Identifies a potential danger to property, which may result in property damages.</td>
</tr>
</tbody>
</table>

Tab. 2: Design of safety notes

1.1.3.2 Structure of notes

<table>
<thead>
<tr>
<th>Pictogram</th>
<th>Descriptor</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image4.png" alt="Information Symbol" /></td>
<td>NOTE</td>
<td>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.</td>
</tr>
</tbody>
</table>

Tab. 3: 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.

<table>
<thead>
<tr>
<th>Symbols</th>
<th>Labelling</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="CE" /></td>
<td>Labelling of products developed and marketed in accordance with relevant European legal provisions.</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Labelling in accordance with the standard ISO 15223-1. Symbol for &quot;Name and address of the manufacturer&quot;. The date of manufacturing can be combined with this symbol.</td>
</tr>
<tr>
<td><img src="image" alt="SN" /></td>
<td>Labelling in accordance with the ISO 15223-1 standard. Symbol for &quot;Serial number&quot;.</td>
</tr>
<tr>
<td><img src="image" alt="REF" /></td>
<td>Labelling in accordance with the standard ISO 15223-1. Symbol for &quot;Catalogue number / product number&quot;.</td>
</tr>
<tr>
<td><img src="image" alt="MD" /></td>
<td>Symbol for the labelling of medical devices</td>
</tr>
<tr>
<td><img src="image" alt="LOT" /></td>
<td>Marking according to the standard ISO 15223-1. Symbol for &quot;Name of batch&quot;.</td>
</tr>
<tr>
<td><img src="image" alt="Labelling" /></td>
<td>Labelling in accordance with the ISO 15223-1 standard. Symbol for &quot;Usable until&quot;.</td>
</tr>
<tr>
<td><img src="image" alt="Labelling" /></td>
<td>Labelling in accordance with the ISO 15223-1 standard. Symbol for &quot;Do not use if packaging is damaged&quot;.</td>
</tr>
<tr>
<td><img src="image" alt="Labelling" /></td>
<td>Labelling in accordance with the ISO 15223-1 standard. Symbol for &quot;Not for re-use&quot;.</td>
</tr>
<tr>
<td><img src="image" alt="Labelling" /></td>
<td>Labelling in accordance with the ISO 15223-1 standard. Symbol for &quot;Do not re-sterilize&quot;.</td>
</tr>
</tbody>
</table>

Tab. 4: Symbols
<table>
<thead>
<tr>
<th>Symbols</th>
<th>Labelling</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="STERILE_EQ" /></td>
<td>Labelling in accordance with the standard ISO 15223-1. Symbol for “Sterilisation with ethylene oxide”.</td>
</tr>
<tr>
<td><img src="image" alt="store_protected_from_sunlight" /></td>
<td>Labelling in accordance with the ISO 15223-1 standard. Symbol for &quot;Store protected from sunlight&quot;.</td>
</tr>
<tr>
<td><img src="image" alt="follow_instructions_for_use" /></td>
<td>Labelling in accordance with the IEC 60601-1 standard. Symbol for &quot;Follow Instructions for use&quot;.</td>
</tr>
<tr>
<td><img src="image" alt="consult_instructions_for_use" /></td>
<td>Labelling in accordance with the ISO 15223-1 standard. Symbol für &quot;Consult instructions for use&quot;.</td>
</tr>
<tr>
<td><img src="image" alt="134_deg_C" /></td>
<td>Label for products that can be sterilised at up to 134 °C.</td>
</tr>
<tr>
<td><img src="image" alt="latex_free" /></td>
<td>Labelling in accordance with the ISO 15223-1 standard. Symbol for &quot;Latex-free&quot;.</td>
</tr>
<tr>
<td><img src="image" alt="keep_dry" /></td>
<td>Labelling in accordance with the ISO 15223-1 standard. Labelling of packaging materials. Symbol for &quot;Keep dry&quot;.</td>
</tr>
<tr>
<td><img src="image" alt="fragile_handle_with_care" /></td>
<td>Labelling in accordance with the ISO 15223-1 standard. Symbol for &quot;Fragile! Handle with care&quot;.</td>
</tr>
<tr>
<td><img src="image" alt="top" /></td>
<td>Labelling in accordance with the ISO 7000 standard. Symbol for &quot;Top&quot;.</td>
</tr>
<tr>
<td><img src="image" alt="temperature_limit" /></td>
<td>Labelling in accordance with the ISO 15223-1 standard. Symbol for &quot;Temperature limit&quot;.</td>
</tr>
</tbody>
</table>

Tab. 4: Symbols
### Labelling

<table>
<thead>
<tr>
<th>Symbols</th>
<th>Labelling</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Symbol for &quot;Humidity limitation&quot;" /></td>
<td>Labelling in accordance with the ISO 15223-1 standard. Symbol for &quot;Humidity limitation&quot;.</td>
</tr>
<tr>
<td><img src="image" alt="Symbol for &quot;Atmospheric pressure limitation&quot;" /></td>
<td>Labelling in accordance with the ISO 15223-1 standard. Symbol for &quot;Atmospheric pressure limitation&quot;.</td>
</tr>
</tbody>
</table>

**Tab. 4: Symbols**
1.3 **Disposal**

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

Used products or parts thereof may be contaminated. In order to prevent a potential infection, the product must be cleaned and disinfected prior to its return/disposal.

The national regulations and disposal regulations must be observed for all disposal measures.

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 **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)

![Diagram of TRIMANO FORTIS adapter]

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>TRIMANO FORTIS Adapter</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>Lower release buttons</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>Upper release buttons</td>
<td>3</td>
</tr>
</tbody>
</table>

Fig. 2: TRIMANO FORTIS Adapter

1.4.2 Accessories for TRIMANO FORTIS adapter

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

![Diagram of accessories]

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>TRIMANO Wrist Positioner (AR-1647)</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>TRIMANO Synergy UHD4 Camera Head Holder (AR-3210-0011) / TRIMANO Synergy Camera Head Holder (AR-3210-0010)</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>TRIMANO Drape for Wrist Positioner or Camera Head Holder (AR-1648)</td>
<td>3</td>
</tr>
</tbody>
</table>

Fig. 3: Accessories for TRIMANO FORTIS adapter
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 medical device.
The product is designed solely for the purpose of human medicine.
The patient may only be placed and positioned under medical supervision.

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 meets the basic safety and performance requirements in accordance with the local applicable legal specifications for medical devices.

1.5.3 Intended purpose
The TRIMANO FORTIS Adapter (AR-1741 / 1002.31R0) is designed for placement and positioning of the patient's arm / patient's leg / patient's hand in conjunction with Trimano Fortis (AR-1740 / 1002.30R0) and specific accessories for the TRIMANO system or for attaching other products directly before, during, and after surgical interventions as well as for examination and treatment.
Depending on the specific accessories used, the TRIMANO FORTIS Adapter may only be used along with the sterile covers (AR-1648 / 1002.53F0).
The maximum load that may be placed on the product is 21kg. This corresponds to a proportional arm weight of a 250kg patient. This furthermore corresponds to a proportional leg weight of a 180kg 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.

1.5.4 Mounting Points
The TRIMANO FORTIS adapter may be mounted to the following products:
• TRIMANO FORTIS Arthrex 3D support arm (1002.30R0 / AR-1740)

1.5.5 Variants
The product is available in the following versions:
• AR-1741 / 1002.31R0
  Arthrex adapter for TRIMANO FORTIS
1.5.6 **Product features**

1.5.6.1 **Key performance characteristics**

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

- Placement of the patient (or the patient's body parts) without unwanted movement in case of an initial error.

1.5.6.2 **Latex-free materials**

All used materials (e.g. materials for pads and straps) are latex free.

1.5.7 **Reportable event**

Any serious incident involving this product must be reported to MAQUET GmbH and, if necessary, to the local competent authority.
2 Safety notes

2.1 General safety notes

<table>
<thead>
<tr>
<th>DANGER!</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potentially fatal!</td>
</tr>
<tr>
<td>Risk caused by unauthorised modifications.</td>
</tr>
<tr>
<td>Modifications at the product are not permitted.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DANGER!</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potentially fatal!</td>
</tr>
<tr>
<td>Danger resulting from improper handling.</td>
</tr>
<tr>
<td>Always observe the instructions for use for the OR table.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DANGER!</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potentially fatal!</td>
</tr>
<tr>
<td>Risk posed to the patient's vital functions due to incorrect positioning.</td>
</tr>
<tr>
<td>Position the patient correctly and keep under permanent observation.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WARNING!</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of injury!</td>
</tr>
<tr>
<td>Improper patient positioning may cause health damage (e. g. decubitus).</td>
</tr>
<tr>
<td>Position the patient correctly and keep under constant observation.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WARNING!</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of injury!</td>
</tr>
<tr>
<td>Faulty or defective products may result in injuries.</td>
</tr>
<tr>
<td>• Before use, check the proper working order and fully functional state of the product.</td>
</tr>
<tr>
<td>• Stop using faulty or defective products.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WARNING!</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of injury!</td>
</tr>
<tr>
<td>When adjusting and moving the OR table, the transporter, the table top or the accessories, as well as when carrying out a table top transfer, collisions may occur between the patient and individual products or parts that are pointing downwards.</td>
</tr>
<tr>
<td>During adjustments, observe the OR table, the transporter, the table top and accessories constantly and avoid collisions. Ensure that tubes, cables and drapes are not trapped.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WARNING!</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of burns!</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>Avoid any contact between the patient and metal components; never use damp or wet surgical drapes.</td>
</tr>
<tr>
<td>Be absolutely sure to comply with the manufacturers instructions for use!</td>
</tr>
</tbody>
</table>
**WARNING!**
Risk of injury!
Products / accessories not attached properly may loosen and cause injuries. Although products / accessories are mounted correctly and that the securing elements (handle screws, catches, levers, etc.) are closed and firmly tightened, also ensure that moving parts are correctly secured.

**WARNING!**
Risk of injury!
If locking elements (eccentric levers, handle screws, locks etc.) are open, the product/accessory can be moved.
Before opening the locking elements, hold the individual items firmly. 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

**WARNING!**
Risk of injury due to material failure!
The maximum load that may be placed on the product is 21 kg.

**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.

**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!
If the patient is not secured, particularly when adjusting/moving, the patient and/or their extremities may slip in an uncontrolled manner.
Always secure the patient using suitable aids (e.g. straps) and maintain continuous observation.

**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.

1. Put TRIMANO in the mounting position.
2. Fully unscrew the fixation screw 1 of the clamp 2.
3. Place the clamp on the side rail.
   - The fixation screw points upwards.
4. Tighten the fixation screw.
   - The TRIMANO is adapted to the side rail of the OR table.
5. Check proper seating.

Fig. 6: Mounting TRIMANO
3.3 Mounting / removing the TRIMANO adapter with sterile sheath

**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.

**Separating the closed side**
1. Separate the closed side [1] of the sterile sheath at the perforations [2].

![Fig. 7: Separating the closed side](image-url)
Sticking the sterile sheath to the TRIMANO adapter

1. Insert the TRIMANO adapter 1 into the sterile sheath. When aligning the TRIMANO adapter, ensure that the directional arrow on the TRIMANO adapter points down.

2. Tape the initial piece of the sterile sheath 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 tape fully encloses the TRIMANO adapter.
   - Fluids cannot ingress.

3. Make sure that the adhesive tape is properly attached.

Mounting the TRIMANO adapter

1. Fit the TRIMANO 1 adapter to the pins 3 of the TRIMANO retaining arm A in the direction of the arrow 2 and turn B. Ensure that the sterile sheath does not become stuck.
   - 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.

2. Check proper seating.
Mounting / removing the TRIMANO adapter with sterile sheath

Fitting the sterile sheath
This action is not carried out under sterile conditions!

Prerequisites:
- The TRIMANO is in a neutral position (in extended condition).

1. Hold the sterile sheath [1] at the designated markings [2] and slide fully over the TRIMANO until it reaches the side rail.
   - The TRIMANO is protected from spray water.

2. 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.

Fig. 10: Fitting the sterile sheath
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

1. Push the two lower release buttons 1 of the TRIMANO adapter in simultaneously.
   - The TRIMANO adapter is unlocked.
2. Removing the TRIMANO 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.

**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.
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.

1. Fit the pins \(1\) of the arm rest into the TRIMANO adapter \(2\) \(A\) and move gently back and forth \(B\).
   - The locking device engages with an audible click.
   - The arm rest is adapted to the TRIMANO adapter.

2. Check the firm seat of the arm rest.

Fig. 12: Mounting the arm rest
Positioning and securing the patient’s arm in the BEACH CHAIR

1. Adjusting the TRIMANO support arm for positioning the arm of the patient.
2. Position the arm of the patient on the single-use arm rest [1].
3. Ensure that the patient's fingers are closed around the grip [2] of the single-use arm rest.
4. Fold in the single-use arm rest and secure using the hook and loop closures.
5. Wrap the patient's arm fully in the single-use arm rest (hand/fingers included) with the long tensioning strap [3].
6. 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.
7. 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

1. Simultaneously press the two upper release buttons [T] on the TRIMANO Adapter.
   - The arm rest is unlocked.
2. Remove the arm rest from the TRIMANO adapter.
6  Preparation
The product must be cleaned, disinfected and sterilised after each use.
The product is classified as a critical medical device with increased reprocessing requirements.

6.1  General information

**DANGER!**
Risk due to mishandling of cleaning agents and disinfectants!
- The entire cleaning process may only be completed by qualified technicians.
- For information on concentration, temperature and contact and drying times, refer to the instructions of the detergent and disinfectant manufacturer.
- Observe current national and international regulations for hygiene in the medical field.
- Observe the cleaning and hygiene regulations of the hospital.

**DANGER!**
Risk of infection!
Residues on the product (e.g. blood, secretions etc.) can prevent proper disinfection.
- Remove coarse impurities from the product immediately with suitable non-fixing agents.
- Adjust the cleaning agent to the disinfectant (using a combination agent if necessary) in order to avoid interactions.

**DANGER!**
Risk of infection!
Product may be contaminated.
- Always wear gloves when cleaning / disinfecting.
- If necessary, take further protective measures.

**DANGER!**
Risk of explosion!
Agents containing alcohol can form explosive vapour mixtures and ignite where high-frequency equipment is being used. The cleaning and disinfecting agents must be dried before use.
Ensure that there are no alcoholic residues on the product during high frequency use.

**WARNING!**
Risk of injury!
If unsuitable cleaning agents and disinfectants are used, the antistatic property and electrical conductivity of the product may be lost, which are required to prevent electrostatic charges as required by the standard.
Only use detergents and disinfectants of the specified active ingredient groups.
**CAUTION!**
Improper cleaning and disinfection can cause property damage!
- Observe the manufacturer's instructions for concentrations of cleaning agents and disinfectants
- Perform visual and functional inspections after each cleaning and disinfection process.

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

**NOTE**
The TRIMANO adapter cannot be disassembled and is cleaned, disinfected and sterilised while assembled.

**NOTE**
The TRIMANO adapter must be cleaned, disinfected and sterilised after each use. The TRIMANO adapter may only be used in a sterile state.
6.2 Cleaning agents and disinfectants

6.2.1 Suitable cleaning agents

The cleaning agents must be compatible with the disinfectants used. The use of fixing agents in the cleaning process such as alcohols or aldehydes should be avoided. Cleaners with the following properties may be used:

- Slightly alkaline
- Surfactants and phosphates as active cleaning components

The following cleaning agents are recommended:

- Dr. Weigert neodisher® MediClean
- Dr. Weigert neodisher® MediZym
- Getinge Clean Universal Detergent

6.2.2 Suitable disinfectants

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

<table>
<thead>
<tr>
<th>Ingredient group</th>
<th>Active ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aldehydes</td>
<td>2-ethyl-1-hexanal, formaldehyde, glutaraldehyde, glyoxal, octahaldehyde, succinaldehyde</td>
</tr>
<tr>
<td>Guanidine derivatives</td>
<td>Alkyl-biguanide, chlorhexidine-digluconate, cocospolyene-diamine guanidinium diacetate, oligomeric biguanide, polyhexamethylene biguanide hydrochloride (oligo-dimino imido-carbonyl iminohexamethylene, polyhexamidine)</td>
</tr>
<tr>
<td>Quaternary ammonium compounds</td>
<td>Alkyl-didecyl-polyoxethyl ammonium propionate, alkyl-dimethyl-alkylbenzyl ammonium chloride, alkyl-dimethyl-ethyl ammonium chloride, alkyl-dimethyl-ethylbenzyl ammonium chloride, benzalkonium propionate, benzalkonium chloride (alkyl-dimethyl-benzyl ammonium chloride, coco-dimethyl-benzyl ammonium chloride, lauryl-dimethyl-benzyl ammonium chloride, myristyl-dimethyl-benzyl ammonium chloride), benzethonium chloride, benzyl-dihydroxyethyl-coco-alkyl ammonium chloride, dialkyl-dimethyl ammonium chloride (didecyl-dimethyl ammonium chloride), didecyl-methyl-oxethyl ammonium propionate, mecotronium-ethyl sulfate, methyl-benzethonium chloride, n-octyl-dimethyl-benzyl ammonium chloride</td>
</tr>
</tbody>
</table>

Tab. 5: Active ingredients of disinfectants
6.2.3 Non-usable products / substances

The following products/substances must not be used for cleaning and disinfection:

- Alcohol-based agents (e.g. hand and skin disinfectants)
- Halogenides (e.g. fluorides, chlorides, bromides, iodides)
- Dehalogenating compounds (e.g. fluorine, chlorine, bromine, iodine)
- Products that scratch the surface (e.g. scouring agents, wire brushes, steel wool, cleaning sponges containing iron)
- Standard commercial solvents (e.g. benzene, thinner)
- Water containing particles of iron
- Products containing acid (e.g. hydrochloric acid)
- Saline solutions
6.3 Reconditioning procedure

DANGER!
Risk of infection!
Insufficient preparation.
Always mechanically prepare the product, and do not use the product if it is not sterile. If the product is heavily contaminated, it can be pre-cleaned manually.

DANGER!
Risk of injury due to hot surfaces!
The product becomes hot during the preparation process and may cause burns.
Allow the product to cool off following mechanical preparation.

NOTE
Remove all glue residue from the product before mechanical preparation.

NOTE
If not otherwise described, the water used for the preparation process must be tap water in drinking water quality.
6.3.1 Manual pre-cleaning and disinfection

6.3.1.1 Pre-clean the product

Manual cleaning of the product was tested and validated under the following conditions with the cleaning agent Dr. Weigert neodisher® MediClean:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration</td>
<td>1 %</td>
</tr>
<tr>
<td>Temperature</td>
<td>28°C – 40 °C</td>
</tr>
<tr>
<td>Duration (ultrasound bath)</td>
<td>5 minutes / frequency 35 kHz</td>
</tr>
</tbody>
</table>

Tab. 6: Cleaning solution parameters

1. Place components in an ultrasound bath with a weakly alkaline cleaning agent solution.
2. Remove all visible residue on the surface using a soft, non-metallic nylon brush under flowing tap water. Make sure to remove residue from hard to reach areas.
3. All sliding surfaces, cut-outs and 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.
4. Rinse each channel using a single use syringe and 200 ml of tap water.
5. Then rinse all accessible points with demineralised water for at least 10 seconds.
6. Dry all surfaces with a soft, lint-free cloth.

6.3.1.2 Disinfect the product

The product can be manually disinfected before mechanical preparation. Dr. Weigert neodisher® SeptoMED can be used for manual disinfection, for instance.

6.3.1.3 Inspections

1. Carry out visual and functional inspections.
6.3.2 Mechanical cleaning and disinfection

The manufacturer recommends using a cleaning and disinfection device in accordance with the requirements of ISO 15883. Mechanical preparation of the product was tested and validated under the following conditions in a cleaning and disinfection device type Uniclean PL-II15-2 EL (MMM) with the cleaning agent Dr. Weigert neodisher® MediClean:

6.3.2.1 Prepare the product mechanically

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration</td>
<td>0.5 %</td>
</tr>
<tr>
<td>Temperature</td>
<td>55 °C</td>
</tr>
<tr>
<td>Period</td>
<td>10 minutes</td>
</tr>
</tbody>
</table>

Tab. 7: Cleaning solution parameters

1. Connect every flushing channel of the components with an injector.
2. Rinse with cold tap water (1 minute) and empty.
3. Clean with a cleaning agent solution (10 minutes) and empty
4. Neutralise with cold tap water (2 minutes) and empty.
5. Rinse with cold tap water (1 minute) and empty.

6.3.2.2 Disinfect the product

1. Complete thermal disinfection at 93 °C with demineralised water (5 minutes).*
   * This corresponds to an $A_0$ value > 3000.

6.3.2.3 Inspections

1. Carry out visual and functional inspections.
2. Oil the release buttons if necessary [Page 37].
6.3.3 Sterilisation

**CAUTION!**
Property damage!
For preparation, the product can go through 200 sterilisation cycles with proper hot steam sterilisation.
Document sterilisation cycles using serial numbers and perform visual and functional tests before each application.

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

The manufacturer recommends using a sterilisation process involving moist heat fulfilling the requirements of standard series 17665.
Sterilisation of the product was tested and validated in a steam steriliser type Selectomat HP 666-1 HR (MMM). The following minimum requirements are approved for steam sterilisation:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Minimum requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevacuum phase</td>
<td>3×</td>
</tr>
<tr>
<td>Sterilisation temperature</td>
<td>132 °C</td>
</tr>
<tr>
<td>Dwell time</td>
<td>3 minutes</td>
</tr>
</tbody>
</table>

Tab. 8: Sterilisation parameter
6.3.4 Oiling the release buttons

**NOTE**
If the release buttons become stiff, they can be oiled after preparation. Do so before sterilising them.

**Prerequisites:**
- Product is dry.

1. Oil each locking mechanism [1] with a drop of maintenance oil designed for use with surgical instruments.

Fig. 16: Oiling the release buttons
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 recommend and should include the date and signature of the person who performed the inspections. The following table may be used as a template.

Suggestion:

<table>
<thead>
<tr>
<th>No.</th>
<th>Inspection</th>
<th>Defects are present</th>
<th>No defects</th>
</tr>
</thead>
</table>
| 1   | Has the product not been cleaned and disinfected in accordance with hygiene regulations? | □ 1. Do not continue to use the product.  
2. Clean and disinfect the product in accordance with hygiene regulations. | □          |
|     | Comment:                                                                  |                                                                                     |            |
| 2   | Are there damages to mechanical parts?                                    | □ 1. Do not continue to use the product.  
2. Notify Getinge authorised service.                                          | □          |
|     | Comment:                                                                  |                                                                                     |            |
| 3   | Is it not possible to complete all adjustments on the product?            | □ 1. Do not continue to use the product.  
2. Notify Getinge authorised service.                                          | □          |
|     | Comment:                                                                  |                                                                                     |            |
| 4   | (Space for other tests)                                                   | □ 1.                                                                                 | □          |
|     | Comment:                                                                  |                                                                                     |            |

Tab. 9: 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. [➔ Page 39]

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 Contact

<table>
<thead>
<tr>
<th>Contact</th>
<th>North America</th>
<th>South America</th>
<th>Europe and other countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone</td>
<td>1-866-267-9138</td>
<td>001 954-447-6815</td>
<td>+49 89 9090005-0</td>
</tr>
<tr>
<td></td>
<td>1-239-643-5553 external</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax</td>
<td>1-239-591-6943</td>
<td>001 954-447-6814</td>
<td>+49 89 9090005-2801</td>
</tr>
</tbody>
</table>

Tab. 10: Contact
7.5 **Type plate**

![Type plate diagram]

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 ±5 %, if no other tolerance is specified.

8.1 Ambient conditions

<table>
<thead>
<tr>
<th>Conditions</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature: Transportation</td>
<td>-20 °C to +50 °C</td>
</tr>
<tr>
<td>Temperature: Storage</td>
<td>-20 °C to +30 °C</td>
</tr>
<tr>
<td>Temperature: Operation</td>
<td>+10 °C to +40 °C</td>
</tr>
<tr>
<td>Relative humidity: Shipping / storage</td>
<td>10 % to 95 %</td>
</tr>
<tr>
<td>Relative humidity: Operation</td>
<td>30 % to 75 % (non-condensing)</td>
</tr>
<tr>
<td>Atmospheric pressure: Shipping / storage</td>
<td>500 hPa to 1060 hPa</td>
</tr>
<tr>
<td>Atmospheric pressure: Operation</td>
<td>700 hPa to 1060 hPa</td>
</tr>
</tbody>
</table>

8.2 Dimensions

<table>
<thead>
<tr>
<th>Measurements</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length</td>
<td>65 mm</td>
</tr>
<tr>
<td>Diameter</td>
<td>Ø 80 mm</td>
</tr>
</tbody>
</table>

8.3 Weight

<table>
<thead>
<tr>
<th>Weight</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net weight</td>
<td>0.5 kg</td>
</tr>
</tbody>
</table>
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).

<table>
<thead>
<tr>
<th>AR-1640</th>
<th>Arthrex TRIMANO positioning aid</th>
</tr>
</thead>
<tbody>
<tr>
<td>AR-1641</td>
<td>Arthrex TRIMANO adapter</td>
</tr>
<tr>
<td>AR-1644</td>
<td>Arthrex TRIMANO Beach Chair Kit</td>
</tr>
</tbody>
</table>

Tab. 11: Example of compatible TRIMANO accessories

9.2 Accessories for TRIMANO FORTIS system

<table>
<thead>
<tr>
<th>AR-1740</th>
<th>Arthrex TRIMANO FORTIS 3D support arm</th>
</tr>
</thead>
<tbody>
<tr>
<td>AR-1741</td>
<td>Arthrex TRIMANO FORTIS adapter</td>
</tr>
<tr>
<td>AR-1642</td>
<td>Arthrex TRIMANO arm rest for lateral position</td>
</tr>
<tr>
<td>AR-1643</td>
<td>Arthrex TRIMANO arm rest Beach Chair</td>
</tr>
<tr>
<td>AR-1647</td>
<td>Arthrex TRIMANO Wrist Positioner</td>
</tr>
<tr>
<td>AR-3210-00 11</td>
<td>Arthrex TRIMANO 4K Synergy UHD4 camera head holder</td>
</tr>
<tr>
<td>AR-3210-00 10</td>
<td>Arthrex TRIMANO Synergy camera head holder</td>
</tr>
</tbody>
</table>

Tab. 12: Accessories for TRIMANO FORTIS system
9.3 Sterile sets/drapes for the TRIMANO FORTIS system

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AR-1644</td>
<td>Arthrex TRIMANO Beach Chair Kit</td>
</tr>
<tr>
<td>AR-1648</td>
<td>Sterile drape TRIMANO for (AR-1640) and (AR-1740)</td>
</tr>
<tr>
<td>AR-1646</td>
<td>Arthrex TRIMANO Elbow Kit</td>
</tr>
<tr>
<td>AR-1645</td>
<td>TRIMANO Application Set Shoulder (for AR-1642 / AR-1643)</td>
</tr>
</tbody>
</table>

Tab. 13: Sterile sets/drapes for the TRIMANO FORTIS system
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<table>
<thead>
<tr>
<th>Manufacturer:</th>
<th>Manufactured for:</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAQUET GmbH</td>
<td>Arthrex Inc.</td>
</tr>
<tr>
<td>Kehler Strasse 31</td>
<td>1370 Creekside Blvd</td>
</tr>
<tr>
<td>76437 Rastatt</td>
<td>Naples, FL 34108-1945, USA</td>
</tr>
<tr>
<td>Germany</td>
<td>I-(800) 934-4404</td>
</tr>
</tbody>
</table>

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

For local contact:
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www.arthrex.com