



OPERATING INSTRUCTIONS

These operating instructions contain important information to enable you to operate the Arthrex TRIMANO Wrist Positioner (AR-1647) safely, including its accessories. Read the operating instructions carefully before using the system and keep them where they can be easily accessed by all the operating personnel. Familiarize yourself with all warning and cautionary notices and ensure you follow them.



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Subject to technical modification

Illustrations and technical specifications may vary slightly from those in these Operating Instructions as a result of ongoing product development.

AR-1647



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AR-1648



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1 Introduction

Environmental protection

Packaging

The packaging is made of materials compatible with the environment. Arthrex will dispose of the packaging materials upon request.

Arthrex products

Arthrex will take back used products or those which are no longer in service. Please contact your Arthrex Distribution for more detailed information.

Disposables

Disposables must be handled and disposed of pursuant to national regulations.

How to use these operating instructions

General

These operating instructions are provided to familiarize you with the features of this product. They are subdivided into several chapters.

Please note:

- Please read these operating instructions carefully and completely before using the product for the first time.
- Always proceed in accordance with the information contained herein.
- Store these operating instructions in a location near the product.

Symbols

Action and responses

The " \boxtimes " symbol identifies an action taken by the user while the " \checkmark " symbol identifies the reaction that this will induce in the system.

Example:

Turn on the light switch.

✓ Lamp lights up.

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Definitions

Design of safety notes

Pictogram	Descriptor	Text	
	D A N G E R ! Indicates a direct and immediate risk to persons, which may be fatal or result in most serious injury.		
	W A R N I N G ! Indicates a potential risk to persons or property which may result in health hazard or grave property damage.	The text for the safety note describes the type of risk and how to avert it.	
	C A U T I O N ! Indicates a potential risk to property which may result in property damage.		

Fig. 1: Design of safety notes

Design of other notes

Pictogram	Descriptor	Text	
1	ΝΟΤΕ	Supplementary assistance or further useful information without potential injury to persons or property damage is described in the text of the note.	

Fig. 2: Design of other notes

Symbols used

Pictogram	Identification	Pictogram	Identification
(6	Labeling for Class I products, developed and marketed in compliance with Medical Device Directive 93/42/EU.	C E 0 4 8 1	Labeling for products which were developed and are marketed in compliance with the 93/42/EEC Medial products Directive. Class Is, Im, IIa, IIb and III products are also marked with the identifying number for the notified body.
134°C \$\$\$	Designates products which can be sterilized in the autoclave at up to 134 °C.		Designation in compliance with the EN 980 standard. Symbol for "Manufacturer".
$\sim \sim$	Labeling in compliance with the EN 980 standard. Symbol for "Manufacturing date".	2	Marking in accordance with the EN 980 standard. Symbol for "Not to be reused".
LOT	Marking in accordance with the EN 980 standard. Symbol for "Lot identifier"	Ť	Packaging label. Symbol for "Keep dry".
SN	Labeling in compliance with the EN 980 standard. Symbol for "Serial number".	REF	Labeling as per EN 980 standard. Symbol for "Order number".
STERNIZE	Labeling in compliance with the EN 980 standard. Symbol for "Do not sterilize again".		Marking in compliance with the EN 980 standard. Symbol for "Can be used until".
STERILE EU	Labeling in compliance with the EN 980 standard. Symbol for "Sterilization with ethylene oxide".		Labeling in compliance with the EN 980 standard.Symbol for "Do not use when packaging is damaged".
(Symbol for "Observe operating instructions".		Labeling in compliance with the EN 980 standard. Symbol for "Keep away from direct sunlight".

Fig. 3: Symbols

Basic requirements

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 put in position only under the supervision of medical personnel.

Accessories

Accessories or combinations of accessories may be utilized only when and as indicated in these operating instructions. Use other accessories, combinations and parts subject to wear only if these are intended expressly for the application and will not adversely affect performance features or safety requirements.

Applicable standards

The product satisfies the basic requirements set forth in Annex I to the 93/42/EU Directive drafted by the Medical Products Council (Medical Device Directive) as well as the applicable national codes and the Medical Products Act in Germany. This is certified by compliance with harmonized standards such as IEC 60601-1 and related standards and the respective special sections.

Intended purposes

Wrist Positioner (AR-1647)

The Wrist Positioner (AR-1647) is used in combination with the quick change coupling (AR-1641) and the TRIMANO 3D support arm (AR-1640). The product is used to fix the finger in place as well as to simultaneously position the patient's lower arm. The field of application ranges from arthroscopy of the wrist to fractures in the lower arm area. The system is covered with the sterile set (AR-1648) during surgery. The system may be mounted to the lateral side rails of operating tables. 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.

Sterile sheath (AR-1648)

The sterile sheath is used as a sterile covering for the support arm. The sterile sheath is a disposable product. It is only intended for single use.

2 Safety Notes

General safety notes



DANGER! Potentially fatal!

Hazard resulting from improper handling. Be absolutely sure to follow he operating instructions for your mobile operating table or operating table system.



DANGER!

Potentially fatal! Vital functions can be impaired through incorrect positioning. Position the patient correctly and maintain continuous observation.



WARNING!

Risk of injury! Improper positioning can be detrimental to patient health. Always position the patient correctly and maintain continuous observation



WARNING!

Risk of injury! A worn or damaged product/accessory can cause injuries. Only use products/accessories which are in perfect condition.



DANGER!

Potentially fatal!

The maximum load placed on the product may not exceed the appropriate proportion of a patient weighing 180 kg. Restrictions result from the permissible overall load, among other things, of accessory rails when using operating tables with a low maximum load capacity. Be absolutely sure to follow the operating instructions for your mobile operating table or operating table system.



WARNING!

Risk of injury! patient may be endangered as a result of incorrect use. Follow the operating instructions for all accessories.



WARNING!

Risk of injury!

Accessories which are improperly mounted may come loose and cause injuries. Use Arthrex accessories exclusively and be sure to affix them correctly. Use accessories made by other manufacturers only after obtaining written permission from Arthrex.



WARNING!

Risk of injury!

Collisions between accessories, the operating table, the table top and the patient can occur when adjusting or moving the operating table or table top or when transferring to the table top. Observe the adjustment procedure and avoid collisions.



WARNING!

Risk of burning!

Using high-frequency devices, defibrillators and defibrillator monitors exposes t patient to burn hazard due to contact with metal components in the device or accessories and/or if resting on wet drapes or electrically conductive padding. Avoid any contact between the patient and metallic components; never use moist or wet surgical drapes. Be absolutely sure to comply with the manufacturers operating instructions!



WARNING!

Risk of injury!

Products/accessories not attached properly may loosen and cause injuries. Always ensure that all locking elements (offset lever, setting clamps, catches etc.) of the product/accessory are closed and movable parts are fixed properly. Check locking after every adjustment procedure.



WARNING!

Risk of injury!

If locking elements (offset levers, handle screws, locking mechanisms etc.) are opened, the clamps are released and the product can be moved. Before opening the locking elements, hold the individual parts securely. Make sure that all locking elements are closed after each adjustment procedure.



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 mobile operating table tipping over! The product affects the center of gravity of the mobile operating table. When positioning the patient, observe the operating instructions of the mobile operating table.



DANGER!

Risk of infection! Do not use the sterile set when the packaging of the sterile set is damaged.

3 Operation and use

General



WARNING! Risk of injury!

Danger due to improper handling. Please strictly observe the operating instructions of the support arm TRIMANO (AR-1640) and the quick change coupling (AR-1641).



NOTE

The sterile sheath (AR-1648) requires adhesive tapes for use. The sterile sheath is a disposable product. The application is only approved with the designated sterile sheath.



NOTE

All components to be used are latex-free.



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 sterilized before the first use.

Pictorial guide



Fig. 4: Overview of the Wrist Positioner (AR-1647)

- 1. Adapter
- 2. Small clamping blocks (movable)
- 3. Screw
- 4. Fan plate



Fig. 5: Overview of sterile sheath (AR-1648)

- 1. Sterile sheath
- 2. Adhesive tapes

Sterile sheath (AR-1648)

The sterile sheath (AR-1648) is mounted to the quick change coupling (AR-1641) and is used as a sterile covering of the support arm.



DANGER!

Risk of infection! If the packaging or the sterile sheath itself is damaged, the sterile sheath must

not be used. Store the sterile sheath under the following conditions:

- out of direct light (UV radiation),
- free of dust and dirt,
- dry,
- relative humidity 45 55 %,
- in the original packaging,
- far from heat sources and extreme temperatures,
- free of vermin,
- protected against mechanical load,
- in closed storage rooms,
- temperature range between -20° and +30 °C.



DANGER!

Infection hazard due to damaged sterile sheath! Ensure that no tensile forces act on the seams of the sterile sheath. Fit the sterile sheath in such a way that the sterile sheath is loosely draped round the support arm.



NOTE

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



NOTE

Perform the disassembly in reverse order.



NOTE

Ensure that the release buttons are not covered by adhesive tape.



Fig. 6: Sticking the sterile sheath to the quick change coupling

Sticking the sterile sheath to the quick change coupling

☑ Tape the initial part of the sterile sheath to the center of the black, protruding area of the quick change coupling using the adhesive tape (1).

Mounting options for the Wrist Positioner

The Wrist Positioner may be mounted in a number of ways. The letters "A" and "B" on the adapter indicate the side which is mounted to the fan plate.



Fig. 7 & 8: Mounting options for the Wrist Positioner

Mounting option 1:

The side with the letter "B" is mounted on the fan plate.

Application:

e.g. for the supine position in combination with the hand operating table for radius fractures.



Mounting option 2:

the side with the letter "A" is mounted on the fan plate.

Application: e.g. for arthroscopy of the wrist.

Mounting the Wrist Positioner

Select the mounting option which suits your needs. An example is used to describe the mounting / detaching procedure.



Mounting the Wrist Positioner

- ☑ Place the adapter (1) on the fan plate (2) and fix it with the screw (3).
 - ✓ Make sure that it is properly attached.

Fig. 9: Mounting the Wrist Positioner

Mounting the Wrist Positioner



Fig. 10: Mounting the Wrist Positioner

Prerequisites

- The TRIMANO is mounted on the operating table,
- the quick change coupling is mounted on the TRIMANO,
- the sterile sheath is mounted and all nonsterile areas are covered completely,
- the Wrist Positioner is mounted.

Mounting the Wrist Positioner

- ☑ Fit the Wrist Positioner (1) to the locking mechanism (2) of the quick change coupling and turn slightly back and forth.
 - \checkmark The locking device engages with an audible click.
 - ✓ Both release buttons (3) protrude at least 2 mm.
 - ✓ The Wrist Positioner is mounted to the quick change coupling.
- \boxtimes Make sure that it is properly attached.

Fixing and releasing the patient's hand



WARNING!

Decubitus / Impairment of the circulation!

The higher the tensile force, the more firmly the patient's hand is fixed. Apply only as much tensile force, as is required for the application. The maximum permissible traction is 5 kg.



WARNING!

Risk of injury!

TRIMANO can be positioned with the patient's hand fixed. For positioning, observe the anatomy of the patient's hand and the patient's arm. If required, use several persons to position the patient. Check the correct fixation of the patient's hand after every new position has been achieved.



WARNING!

Risk of injury! If there are liquids on the Wrist Positioner, safe fixation of the patient's hand is not guaranteed. Avoid liquids on the Wrist Positioner.



NOTE

For detaching the Wrist Positioner, press the top release buttons of the quick change coupling. When positioning, ensure proper accessibility to the release buttons.



Fig. 11: Fixing the patient's hand

Removing the Wrist Positioner



Fig. 12: Removing the Wrist Positioner

Removing the Wrist Positioner

- Remove the Wrist Positioner (2) from the quick change coupling.

Fixing the patient's hand

- Slide the small clamping blocks (1) towards the adapter (2).
- ☑ Position the center of the metacarpal bone above the lower edge of the fan plate.
- ☑ Position the fingers centrally on the bars between the small clamping blocks.
- \boxtimes Move the small clamping blocks backwards.
 - \checkmark Tensile force is exerted to fix the patient's hand.

Releasing the patient's hand

- ☑ Move the patient's hand with the small clamping blocks (1) to the center of the fan plate (2).
 ✓ The fixation is released.
- ☑ Move only the small clamping blocks to the center of the fan plate.
- \boxtimes Remove the patient's hand from the fan plate.

Detaching the Wrist Positioner



Fig. 13: Detaching the Wrist Positioner

Detaching the Wrist Positioner

- \boxtimes Open the screw (1).
- \boxtimes Remove the screw and adapter (2) from the fan plate (3).



NOTE

Press the upper release buttons to remove the product. If the bottom release buttons are pressed, the connection between the quick change coupling and the retaining arm is unlocked.

4 Cleaning and disinfection

General



DANGER!

Risk of infection! The product must be cleaned mechanically, disinfected and sterilized after every use. A purely mechanical cleaning and disinfection is not sufficient. The product may only be used in a sterile condition!



DANGER!

Risk of infection! Detach the Wrist Positioner for cleaning, disinfection and sterilization. The small clamping blocks do not need to be detached.





WARNING!

Risk of injury due to heated components! The components are heated after disinfection / sterilization. Let the product cool down in the sterile packaging before reuse.



NOTE

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



Basic instructions



DANGER!

Risk due to incorrect use of detergents and disinfectants!

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



WARNING!

Risk of infection!

Particles of grime may become encapsulated and lead to the product not reaching the desired germreduction after disinfection. Before disinfection, the product must be cleaned thoroughly of contamination and encapsulated particles of grime and then be dried.



WARNING!

Risk of infection!

Product may be contaminated. Always wear gloves for cleaning and disinfection.



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 disinfectants)
- Halogenides (e. g. fluorites, chlorides, bromides, iodides)
- Dehalogenating compounds (e. g. fluorine, chlorine, bromine, iodine)
- · Products that may scratch the surface (e. g. scouring agents, wire brushes, wire wool)
- Standard commercial solvents (e. g. benzene, thinner)
- Water containing iron particles
- · Cleaning sponges containing iron
- Products containing hydrochloric acid

Use approved detergents and disinfectants only. Use a soft, lint free cloth or a soft nylon brush to clean the product.



CAUTION!

Improper cleaning and disinfection can cause property damage! Use only as much detergent and disinfectant as required. Thoroughly wipe off any excess detergent and disinfectant with a damp, soft cloth. Avoid surface drying of excess detergents and disinfectants.



CAUTION!

Improper cleaning and disinfection can cause property damage! Perform visual and functional inspections after each cleaning and disinfection process.

Cleaning

General



DANGER!

Risk of infection! A purely mechanical cleaning and disinfection is not sufficient. We recommend manual precleaning in case of strong contamination.



NOTE

Use only all-purpose cleaners which are slightly alkaline (soap solution) and contain tensides and phosphates as the active cleaning agents. In the event of heavily contaminated surfaces, use concentrated multi-purpose detergent.



CAUTION!

Improper cleaning can cause property damage! Residues of physiological saline solutions (e. g. sodium chloride) can 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! Do not splash detergents directly into gaps or openings and do not use pressure washers! Do not immerse TRIMANO in liquid for cleaning!

Cleaning procedure

- ☑ Use the correct dose of multi-purpose detergent with water for the degree of surface contamination and in accordance with the instructions of the detergent manufacturer.
- ☑ Thoroughly wipe off the product with a soft cloth slightly wetted in a multi-purpose detergent solution.
- Ensure that the product is free of contamination and encapsulated particles of grime.
- ☑ Thoroughly wipe off the product with a soft cloth dipped in clean water.
- \boxtimes 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 to disinfect the product after every cleaning.

Stainless steel surfaces



NOTE

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

Cleaning and disinfection procedures

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

Mechanical cleaning and disinfection procedures

Components	Cleaning	Disinfection		
Wrist Positioner (AR-1647)Rinse with cold tap water* (1 minute). Clean at 55 °C (- 0 °C, + 3 °C, 5 minutes) with detergents, e. g. neodisher MediClean (0.5% v/v).Neutralization with cold tap water* (2 minutes). Rinse with cold tap water* (1 minute).		Thermal disinfection at 93 °C (+ 5 °C, - 0 °C, 5 minutes) with demineralized water.		
Sterile sheath (AR-1648) Disposable product. Only intended for a single use.				
*Tap water: minimum quality requirements: drinking water				

Fig. 14: Cleaning and disinfection procedures

Sterilisation

Components	Sterilisation with live steam		
Wrist Positioner (AR-1647)	Live steam temperature: 134 °C; 3 x fractionated pre- vacuum; sterilization (at least 4 minutes).		
	Hot steam temperature: 132 °C; 3 x fractionated pre- vacuum; sterilization (at least 6.5 minutes).		
Sterile sheath (AR-1648)	erile sheath (AR-1648) Disposable product. Only intended for a single use.		
*Tap water: minimum quality requirements: drinking water, temperature 30° C (± 3° C)			

Fig. 15: Cleaning and disinfection procedures

5 Maintenance

Visual and functional inspections

For correct operation it is necessary to have visual and functional inspections performed by a trained person each time before using the operating table, at least once a day. The result of the visual and functional inspections has to be documented and must include the date and signature of the person who performed the inspections. The following table can be used as a model.

Suggestion:

No.	Inspection	Defe	Defects are present	
1	Has the product been cleaned and disinfected according to the hygiene guideline?	-	 Do not use the product any longer. Clean and disinfect the product according to the guideline. 	
	Comment:			
2	Is there damage to mechanical parts?		☑ Do not use the product any longer.	
			☑ Inform service personnel.	
	Comment:			
3	Is it possible to operate all adjustment features of the product?		☑ Do not use the product any longer.	
	adjustment reatures of the product:		☑ Inform service personnel.	
	Comment:			
4	(Space for other tests)		\boxtimes	
	Comment:			

Fig. 16: Visual and functional inspections

Maintenance

This product is maintenance-free. Wear caused by use and ageing can impair functions of the product which are relevant to safety. Check the condition of the product each time before using it. If defects are detected, the product should not continue to be used. Note down the defects and the model number which can be found on the type plate and inform the local Arthrex representative. Inform the appropriate foreign representative outside Germany.

Repair



Fig. 17: Type plate

A defective product may not be used and may not be repaired by yourself. Inform the responsible Arthrex representative about:

- Defect
- Product number (see type plate)
- If available, serial number (see type plate)
- Construction year (see type plate)

Position of the type plate (1).



6 Technical specifications and spare parts

General

Classification as per Medical Products Directive 93/42/EEC

Class I

Ambient conditions

Temperature	-20° to +50 °C (during shipping)
	+10° to +40 °C (in operation)
	-20° to +30 °C (storage)
Relative humidity	10 % to 95 % (during shipping)
	30 % to 75 % (in operation)
Atmospheric pressure	500 hPa to 1060 hPa (during shipping)
	700 hPa to 1060 hPa (in operation)

Dimensions and weight

Dimensions (L x W x H)	Approximately 244 x 196 x 72 mm
Weight:	Approximately 1.3 kg

Accessories

AR-1648 Sterile sheath TRIMANO (12 units)

Fig. 18: Accessories

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