

4R11 Quickchange

[EN] Instructions for use	
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1

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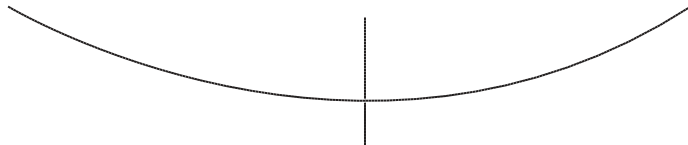


4R11=ST-1-1

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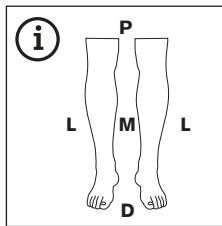
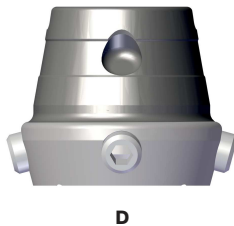
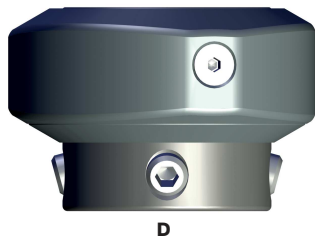
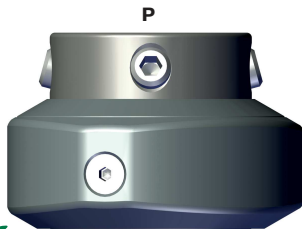
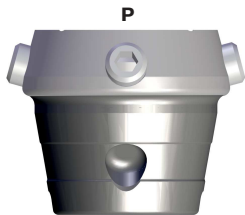


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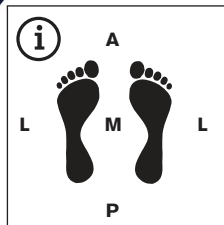
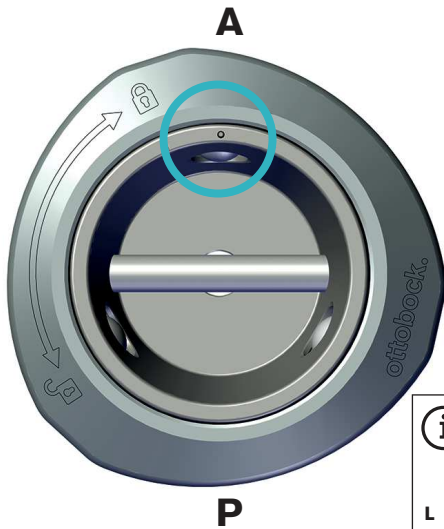


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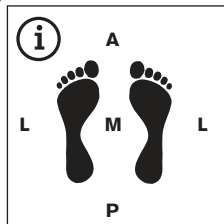
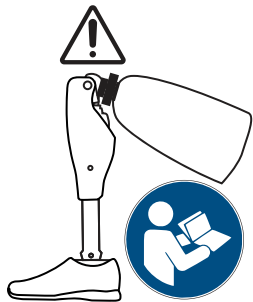
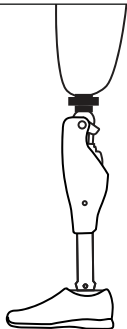
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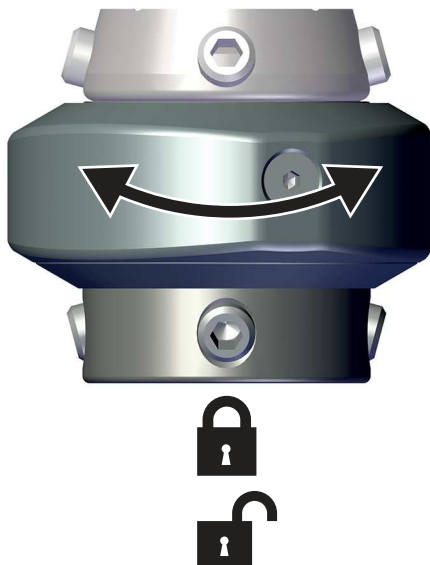


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1 Product description

English

INFORMATION

Date of last update: 2023-07-04

- ▶ Please read this document carefully before using the product and observe the safety notices.
- ▶ Instruct the user in the safe use of the product.
- ▶ Please contact the manufacturer if you have questions about the product or in case of problems.
- ▶ Report each serious incident related to the product to the manufacturer and to the relevant authority in your country. This is particularly important when there is a decline in the health state.
- ▶ Please keep this document for your records.

1.1 Construction and Function

The 4R11 Quickchange adapter makes it possible to quickly change prosthetic components without tools. The adapter consists of a base and various connectors that are plugged together and locked into place.

1.2 Combination possibilities

This prosthetic component is compatible with Ottobock's system of modular connectors. Functionality with components of other manufacturers that have compatible modular connectors has not been tested.

Limited combination options

- **Connect to a pyramid of the modular system for children:** Insert reducer 4X907=1 into the pyramid receiver of the Quickchange adapter base.
- **Combination with the foot adapter 2R40=1:** Do not connect the Quickchange adapter directly to the foot adapter.

2 Intended use

2.1 Indications for use

The product is intended exclusively for lower limb exoprosthetic fittings.

2.2 Area of application

Product approved for max. body weight

- The maximum approved body weight is specified in the technical data (see page 11).

2.3 Environmental conditions

Storage and transport

Storage temperature: -20 °C to +60 °C, relative humidity: 20 % to 90 %, no mechanical vibrations or impacts

Allowable environmental conditions

Temperature during use: -10 °C to +45 °C

Chemicals/liquids: Fresh water, salt water, perspiration, urine, soapsuds, chlorine water

Moisture: Submersion: max. 1 h in 3 m depth, relative humidity: no restrictions

Solids: Dust, occasional contact with sand

Clean the product after contact with humidity/chemicals/solids, in order to avoid increased wear and tear and damage (see page 10).

Prohibited environmental conditions

Solids: Highly liquid-binding particles (e.g. talcum), continuous contact with sand

Chemicals/liquids: Acids, continuous use in liquid media

2.4 Lifetime

This product was tested by the manufacturer with 3 million load cycles. Depending on the user's activity level, this corresponds to a maximum lifetime of 5 years.

Recreational sports: The maximum lifetime is 3 years.

Competitive sports: The lifetime is 1 year.

3 General safety instructions

CAUTION! Risk of injury and risk of product damage

- ▶ To prevent mechanical damage, use caution when working with the product.
- ▶ Note the combination possibilities/combination exclusions in the instructions for use of the products.
- ▶ Observe the maximum lifetime of the product.
- ▶ Check the product for damage and readiness for use prior to each use.
- ▶ Do not expose the product to excessive strain (section: "Area of application" see page 7) or to prohibited environmental conditions (see page 7).
- ▶ Do not use the product if it is damaged or in a questionable condition. Take suitable measures (e.g. cleaning, repair, replacement, inspection by the manufacturer or a specialist workshop).
- ▶ Keep the product away from devices and items that are sensitive to magnetic fields. (e.g. pacemakers, electronic devices, swipe cards). The magnets in the product may affect or damage other devices and objects.
- ▶ Pay attention to any information of the manufacturer regarding magnetic fields (e.g. for a medical implant).

Signs of changes in or loss of functionality during use

Among other factors, changes in functionality can be indicated by an altered gait pattern, a change in the positioning of the prosthetic components relative to each other and by the development of noises.

4 Scope of delivery

Quantity	Designation	Reference number
1	Instructions for use	–
1	Quickchange – base with locking ring	4R11=R-3-2
4	Set screw	506G3=M8x14

Spare parts/accessories	
Designation	Reference number
Quickchange connection: Pyramid	4R11=P-1-1
Quickchange connection: Pyramid receiver	4R11=R-1-1
Quickchange connection: Threaded connector, modular system	4R11=ST-1-1
Quickchange connection: Threaded connector, modular system for children	4R11=ST-2-1
Pyramid receiver reduction	4X907=1
Set screw – 12 mm	506G3=M8X12-V
Set screw – 14 mm	506G3=M8X14
Set screw – 16 mm	506G3=M8X16

5 Preparing the product for use

⚠ CAUTION

Incorrect alignment or assembly

Risk of injury due to damaged prosthetic components

- ▶ Observe the alignment and assembly instructions.

⚠ CAUTION

Improper assembly of the screw connections

Risk of injury due to breakage or loosening of the screw connections

- ▶ Clean the threads before every installation.
- ▶ Apply the specified torque values.
- ▶ Follow the instructions regarding the length of the screws and about how to secure the screws.

INFORMATION

Observe the alignment of the prosthesis for all combinations.

- ▶ Position the adapter in the prosthesis in a way that makes it easy to adjust the structural height (e.g. close to the socket).
- ▶ Perform the "basic configuration," "static alignment" and "dynamic optimisation" steps for each prosthetic component combination.

Aligning the adapter

The adapter connections can be aligned proximally or distally as required (see fig. 2). The anterior or posterior alignment of the adapter is dependent upon its build height in the prosthesis. During this process, the three balls of the locking mechanism are aligned in different directions.

> **Prerequisite:** The adapter is connected and locked into place.

- 1) Carry out proximal/distal alignment of the adapter connections.
- 2) **INFORMATION: A point on the base indicates the position of each sphere.**

Carry out anterior/posterior alignment of the adapter according to the build height in the prosthesis:

- **Below the knee joint:** Align two of the balls in the posterior, align one ball (with the point) in the **anterior** (see fig. 3).
 - **Above a prosthetic knee joint:** Align two balls in the anterior, align one ball (with the point) in the **posterior** (see fig. 4).
- 3) Carry out the prosthetic alignment.
 - 4) **For assembly above a prosthetic knee joint:** Flex the prosthetic knee joint and check whether the adapter is touching the joint. Take appropriate measures if they are touching, for example:
 - Increase the distance between the adapter and prosthetic knee joint.
 - Insert a flexion stop.

Connecting the pyramid adapter and pyramid receiver

The pyramid adapter is fixed with the set screws of the pyramid receiver.

> **Required materials:** Torque wrench (e.g. 710D20), Loctite 241 636K13

- 1) **When a component of the modular system for children is connected:** Insert reducer **4X907=1** into the pyramid receiver of the Quickchange adapter.
- 2) **Do not use Loctite during the fitting.**
Fitting: Screw in and tighten the set screws.
Modular system for children: **9 Nm**
Modular system: **10 Nm**
- 3) **Final assembly:** Secure the set screws with Loctite and tighten them.
Modular system for children: **9 Nm**
Modular system: Pull forward **10 Nm**, then tighten **15 Nm**
- 4) Replace set screws that are protruding or have been screwed in too far (see page 8).

Adjustment

The set screws of the pyramid receiver can be used to adjust the alignment of the prosthesis.

Replacement and disassembly

To keep the position that was set using the set screws: Only unscrew the two adjacent set screws that are screwed in the furthest.

6 Use

Both parts of the adapter can be pulled apart after they are unlocked. After the prosthetic components are changed, the adapter is locked once more.

INFORMATION

Sometimes the two parts of the adapter cannot be easily pulled apart after unlocking. This can happen, for example, if you have not unlocked the adapter for a long time; however, it can be easily corrected:

- ▶ Stand in a place where you can hold on tightly.

► Unlock the adapter. Lift the prosthetic leg slightly to the side and then tap the floor with the inside of the prosthetic foot until the adapter loosens.

- > **Prerequisite:** The user is sitting or the prosthesis is not being worn.
 - > **Prerequisite:** The adapter's parts are clean and free of dust or sand.
- 1) Rotate the locking ring to unlock the adapter (see fig. 5).
 - 2) Pull apart both parts of the adapter.
 - 3) Use a dry cloth to remove any soiling.
 - 4) Make the change and plug the adapter back together.
 - 5) **INFORMATION: Help children to lock the adapter.** Rotate the locking ring to lock the adapter (see fig. 5).
 - 6) Retighten the locking ring slightly while the prosthesis is under load.

7 Cleaning

CAUTION

Use of unsuitable cleaning agents or disinfectants

Impairment of functionality and damage due to incorrect cleaning agents or disinfectants

- Clean the product only according to the instructions given in this section.
- For the prosthesis, observe the cleaning instructions for all prosthetic components.

Solids such as dust or sand can prevent the two parts of the adapter from connecting and locking together. As a result, special attention must be paid when removing dust and sand during cleaning.

Cleaning with water

- 1) Unlock the adapter and pull apart.
- 2) Either rinse both parts of the adapter with clean water or clean with a damp cloth.

- 3) Dry the parts with a soft cloth and leave to air dry.

Cleaning with compressed air

Oil-free compressed air can be used for in-depth cleaning, for example while checking the prosthesis.

- Blow out the adapter with oil-free compressed air.

8 Maintenance

- A visual inspection and functional test of the prosthetic components should be performed after the first 30 days of use.

NOTICE! The individual components of the Quickchange adapter show signs of wear differently depending on frequency and intensity of use. Always bring all of the components that can be connected to each other for inspection.

- During regular inspection: Inspect the prosthesis for signs of wear and check its function.
- Conduct annual safety inspections.

9 Disposal

Do not dispose of the product with unsorted household waste. Improper disposal can be harmful to health and the environment. Observe the information provided by the responsible authorities in your country regarding return, collection and disposal procedures.

10 Legal information

All legal conditions are subject to the respective national laws of the country of use and may vary accordingly.

10.1 Liability

The manufacturer will only assume liability if the product is used in accordance with the descriptions and instructions provided in this document. The manufacturer will not assume liability for damage caused by disregarding the information in this document, particularly due to improper use or unauthorised modification of the product.

10.2 CE conformity

The product meets the requirements of Regulation (EU) 2017/745 on medical devices. The CE declaration of conformity can be downloaded from the manufacturer's website.

11 Technical data

System height and build height together with 4R11=R-3-2		
	System height [mm]	Build height [mm]
4R11=P-1-1	44	44
4R11=R-1-1	91	55
4R11=ST-1-1	62	41
4R11=ST-2-1 (with 4X907=1)	62 (64)	41 (43)

	Weight [g]	Max. body weight [kg]
4R11=R-3-2	220	150
4R11=P-1-1	150	150
4R11=R-1-1	150	150
4R11=ST-1-1	110	150
4R11=ST-2-1	105	45

4R11=R-3-2, 4R11=P-1-1, 4R11=R-1-1, 4R11=ST-1-1: For use in a sport prosthesis, the maximum body weight is 125 kg

	Material
4R11=R-3-2	Titanium/stainless steel
All connections	Stainless steel

4R11=P-1-1, 4R11=R-1-1, 4R11=R-3-2, 4R11=ST-1-1

ISO 10328 – P7 – 150 kg*)

*) Body mass limit not to be exceeded!

For further details see manufacturer's written instructions on intended use!



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