

4R57



4R57=ST



4R57, 4R57=ST

EN Instructions for use (qualified personnel) 4



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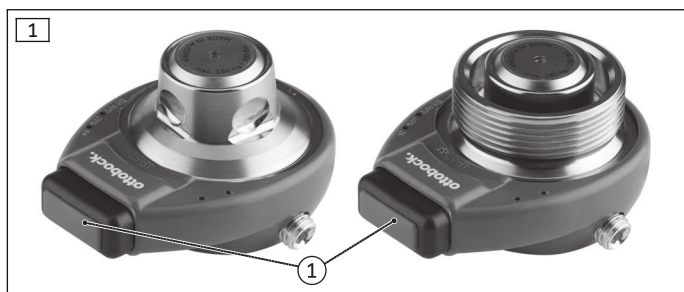
Document: 647G258 Version: 16

<https://product-documents.ottobock.com/IFU/INT/4R57/647G258/16/O/S/F>

- DE** | Weisen Sie den Benutzer in den sicheren Gebrauch des Produkts ein.
Weitere Sprachen dieser Gebrauchsanweisung sind online verfügbar oder können kostenlos als gedrucktes Exemplar bestellt werden (siehe Seite 2).
- EN** | Instruct the user how to use the product safely.
These instructions for use are available in additional languages online or can be ordered as a printed copy free of charge (see page 2).
- FR** | Apprendre à l'utilisateur comment utiliser le produit en toute sécurité.
D'autres langues de cette notice d'utilisation sont disponibles en ligne ou peuvent être commandées gratuitement en format papier (voir page 2).
- IT** | Istruire l'utente sull'uso sicuro del prodotto.
Altre lingue delle presenti istruzioni per l'uso sono disponibili online o possono essere ordinate gratuitamente su supporto cartaceo (vedere pagina 2).
- ES** | Explique al usuario cómo utilizar el producto de forma segura.
Encontrará estas instrucciones de uso en otros idiomas en línea. También puede solicitarlo gratuitamente como ejemplar impreso (véase la página 2).
- PT** | Instrua o usuário sobre a utilização segura do produto.
Outros idiomas destas instruções de uso estão disponíveis online ou podem ser solicitados gratuitamente como um exemplar impresso (veja a página 2).
- NL** | Leer de gebruiker hoe hij/zij veilig met het product moet omgaan.
Andere talen van deze gebruiksaanwijzing zijn online beschikbaar of kunnen gratis in gedrukte vorm worden besteld (zie pagina 2).
- SV** | Instruera användaren i hur produkten används på ett säkert sätt.
Den här bruksanvisningen finns tillgänglig på andra språk online och kan beställas kostnadsfritt i tryckt form (se sidan 2).
- DA** | Instruér brugeren i, hvordan man produktet anvendes på sikker vis.
Denne brugsanvisning er tilgængelig på yderligere sprog online eller kan bestilles gratis som et trykt eksemplar (se side 2).

- PL** | Poinstruować użytkownika na temat bezpiecznego używania produktu.
Niniejszą instrukcję używania w innych językach można przeczytać online lub zamówić bezpłatnie w wersji drukowanej (patrz strona 2).
- HU** | Oktassa ki a felhasználót a termék biztonságos használatáról.
A használati útmutató további nyelvi változatai az interneten elérhetők, vagy nyomtatott példányként ingyenesen megrendelhetők (lásd a 2. oldalt).
- HR** | Podučite korisnika o sigurnoj uporabi proizvoda.
Ostali jezici za ove upute za uporabu dostupni su na internetu ili se mogu besplatno naručiti u tiskanom obliku (vidi 2. stranicu).
- CS** | Poučte uživatele ohledně bezpečného používání produktu.
Další jazykové verze tohoto návodu k použití jsou k dispozici online nebo je lze zdarma objednat v tištěné podobě (viz str. 2).
- TR** | Ürünün güvenli kullanımı konusunda kullanıcıyı bilgilendirin.
Bu kullanım kılavuzundaki diğer diller online olarak mevcuttur veya ücretsiz basılı kopya olarak sipariş verilebilir (bkz. sayfa 2).
- EL** | Ενημερώνετε τον χρήστη για την ασφαλή χρήση του προϊόντος.
Οι οδηγίες χρήσης διατίθενται online και σε άλλες γλώσσες ή μπορείτε να παραγγείλετε δωρεάν ένα εκτυπωμένο αντίτυπο (βλ. σελίδα 2).
- RU** | Проинструктируйте пользователя на предмет безопасного применения изделия.
Текст настоящего руководства по применению на других языках доступен онлайн или может быть заказан бесплатно в печатном виде (см. стр. 2).
- JA** | 使用者には、本製品の安全な取り扱い方法を説明してください。
本取扱説明書のその他言語は、オンラインで入手可能ですが、印刷版も無料で注文できます（P2を参照）。
- ZH** | 就产品的安全使用给予用户指导。
使用说明书的其他语言版本可在线获取，也可免费订购印刷版（参见第 2 页）。

Basic UDI-DI: 40644110000000004R57JY



INFORMATION

Date of last update: 2024-01-03

- ▶ 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.

The product "4R57/4R57=ST rotation adapter" is referred to simply as the product/adapter/rotation adapter below.

These instructions for use provide you with important information on the use, adaptation and handling of the product.

Only put the product into use in accordance with the information contained in the accompanying documents supplied.

2 Product description

2.1 Function

The product is used as a component for modular lower limb prostheses.

By incorporating the rotation adapter above the knee joint, the lower leg may be rotated medially or laterally relative to the socket with the knee flexed.

This makes everyday activities such as putting on shoes and changing socks much easier and allows the user to sit comfortably. The sitting position can be varied up to sitting cross-legged.

The rotation mechanism is activated by pressing the release button (see fig. 1, (1)). Upon reaching the initial position, the rotation movement is locked automatically.

2.2 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.

Prohibited combination possibilities

The rotation adapter **cannot be combined** with the following Ottobock components:

- 2R49, 2R50, 4R22, 4R37, 4R51, 4R55, 4R69, 4R72=32, 4R95, 4R98

3 Intended use

3.1 Indications for use

The product is to be used **solely** for lower limb exoprosthetic fittings above the prosthetic knee joint.

3.2 Conditions of use

The product was developed for everyday use and must not be used for unusual activities. These unusual activities include, for example, extreme sports (free climbing, parachuting, paragliding, etc.).

Permissible ambient conditions are described in the technical data (see page 10).

Our components perform optimally when paired with appropriate components based upon weight and mobility grades identifiable by our MOBIS classification information and which have appropriate modular connectors.



The product is recommended for mobility grade 1 (indoor walker), mobility grade 2 (restricted outdoor walker), mobility grade 3 (unrestricted outdoor walker) and mobility grade 4 (unrestricted outdoor walker with particularly high demands). Approved for a body weight of **max. 150 kg**.

3.3 Indications

- For patients with a transfemoral amputation, hip disarticulation
- For unilateral or bilateral amputation

3.4 Contraindications




- All conditions which contradict or go beyond the specifications listed in the section on "Safety" and "Indications for use".

3.5 Qualification


The fitting of a patient with the product may only be carried out by an O&P professional.

4 Safety




4.1 Explanation of warning symbols

 WARNING	Warning regarding possible serious risks of accident or injury.
 CAUTION	Warning regarding possible risks of accident or injury.
 NOTICE	Warning regarding possible technical damage.

4.2 Structure of the safety instructions

 WARNING
The heading describes the source and/or the type of hazard The introduction describes the consequences in case of failure to observe the safety instructions. Consequences are presented as follows if more than one consequence is possible: > E.g.: Consequence 1 in the event of failure to observe the hazard > E.g.: Consequence 2 in the event of failure to observe the hazard ▶ This symbol identifies activities/actions that must be observed/carried out in order to avert the hazard.

4.3 General safety instructions

 WARNING
Non-observance of safety notices Personal injury/damage to the product due to using the product in certain situations. ▶ Observe the safety notices and the stated precautions in this accompanying document.
 WARNING
Fitting in the presence of children Injury due to swallowing small parts. ▶ Never leave children unattended during the fitting.
 CAUTION
Independent manipulation of the product Falling due to breakage of load-bearing components or malfunction of the product.

- ▶ Manipulations to the product other than the tasks described in these instructions for use are not permitted.
- ▶ Only Ottobock Service Centres may open the product or replace damaged components.

4.4 Information on Alignment/Adjustment

CAUTION

Incorrect alignment or assembly

Falling due to damage to the prosthesis components.

- ▶ Observe the alignment and assembly instructions.

CAUTION

Collision of the rotation adapter with the components (hydraulic unit, frame) of the knee joint

- > Falling due to unexpected behaviour of the knee joint as the result of malfunction.
- > Falling due to breakage of load-bearing components.
- ▶ In case of contact between the rotation adapter and the hydraulic unit and/or frame of the knee joint at maximum flexion, check whether the contact was caused by extreme tilting of the rotation adapter. In this case install the rotation adapter without tilting.
- ▶ If contact between the rotation adapter and the hydraulic unit and/or frame of the knee joint occurs anyway, the knee joint has to be equipped with a flexion stop or the existing flexion stop has to be replaced (see the instructions for use of the knee joint).

CAUTION

Failure to observe the torque values of the screw connections

Falling due to breakage of load-bearing components caused by screw connections coming loose.

- ▶ Observing the specified tightening torques is essential for safe operation.
- ▶ The specified tightening torques **must not** be exceeded.

CAUTION

Incorrectly secured screws

Falling due to breakage of load-bearing components caused by screw connections coming loose.

- ▶ After completing all settings, the set screws in the rotation adapter must be secured with adhesive before they are tightened to the specified torque.

CAUTION

Use of unsuitable prosthetic components

Falling due to unexpected behaviour of the product or breakage of load-bearing components.

- ▶ Use the product only in combination with components approved by Ottobock (see instructions for use and catalogues).
- ▶ Note the prohibited combination possibilities in the section "Combination possibilities".
- ▶ If the product is to be used in water, verify that each prosthetic component is waterproof.

CAUTION

Improper assembly of the screw connections

Falling due to breakage or loosening of the screw connections.

- ▶ Clean the threads before every installation.

- ▶ Apply the specified tightening torque values for installation (see the section "Technical data" see page 10).
- ▶ Observe the instructions for securing the screw connections and the use of the correct length.

4.5 Patient information

CAUTION

Penetration of dirt and moisture into the product

Falling due to unexpected product behaviour as the result of a malfunction.

- ▶ Ensure that neither solid particles nor liquids can penetrate into the product.

CAUTION

Overloading due to unusual activities

Falling due to breakage of load-bearing components.

- ▶ The product was developed for everyday use and must not be used for unusual activities. These unusual activities include, for example, extreme sports (free climbing, paragliding, etc.).
- ▶ Careful handling of the product and its components not only increases their service life but, above all, ensures your personal safety!
- ▶ If the product and its components have been subjected to extreme loads (e.g. due to a fall, etc.), then the product must be inspected for damage immediately by an O&P professional. If necessary, he or she will forward the product to an authorised Ottobock Service Centre.

CAUTION

Accidental activation of the release button

Falling due to twisting of the prosthesis under load.

- ▶ Activate the release button of the rotation adapter only deliberately and with due consideration of the respective situation.

CAUTION

Use with the rotation adapter unlocked

Falling due to twisting of the prosthesis under load.

- ▶ Before loading the prosthesis, check whether the rotation adapter is correctly locked in the initial position.
- ▶ If correct locking is no longer possible, continued use of the rotation adapter is prohibited. The rotation adapter must be inspected by an authorised Ottobock Service Centre. The O&P professional is your contact person.

NOTICE

Improper product care

Damage to the product due to the use of incorrect cleaning agents and/or disinfectants.

- ▶ Only clean the product with a damp cloth and mild soap (e.g. 453H10=1 Ottobock DermaClean).
- ▶ Disinfect the product with 634A58 isopropyl alcohol when needed.
- ▶ Do not use disinfectants based on hydrogen peroxide and silver salt to disinfect the product.
- ▶ Only use fresh water with a temperature of no more than 65°C for cleaning.
- ▶ If dirt cannot be removed, the product has to be sent to an authorised Ottobock Service Centre.

5 Scope of Delivery and Accessories

5.1 Scope of delivery

- 1 pc. 4R57 Rotation adapter or
1 pc. 4R57=ST Rotation adapter
- 1 pc. Instructions for use (qualified personnel)

5.2 Accessories

The following components are not included in the scope of delivery and must be ordered separately:

- 4X46=ST lamination dummy (for 4R57*=ST)

5.3 Spare parts

- 4X69=1 Release button cover, grey

6 Preparing the product for use

6.1 Required tools

- 710D4 torque wrench (up to 30 Nm)
- 636K13 adhesive (Loctite 241)

6.2 Mounting the adapter

6.2.1 Rotation adapter with pyramid adapter

The pyramid adapter of the rotation adapter is fixed to the pyramid receiver with the set screws of the proximal prosthetic component. All four set screws of the rotation adapter have to be unscrewed for replacement or disassembly. The adjustment possibilities for static corrections in this area are minor.

INFORMATION

Deviating from the specification in the corresponding instructions for use of the proximal prosthetic component, the **set screws** of the prosthetic component must be tightened to a **maximum of 10 Nm**.

The following points have to be observed during assembly:

- The alignment of the release button must be medial.
- After activating the release button, it must be possible to rotate the housing of the rotation adapter 360° without touching the socket and/or components of the knee joint (such as the frame or hydraulic unit).
- A collision with the frame or hydraulic unit at maximum flexion of the knee joint must be prevented. If necessary, flexion stops have to be installed or a tilt of the rotation adapter has to be eliminated.

Fitting:

- ▶ Use the torque wrench to tighten the set screws of the pyramid receiver to **10 Nm**.

Definitive mounting:

- 1) Secure the set screws of the pyramid receiver with adhesive.
- 2) Use the torque wrench to tighten the set screws to **10 Nm**.

6.2.2 Rotation adapter with threaded connector

CAUTION

Insufficient screw-in depth in the lamination anchor

Falling due to breakage of load-bearing components.

- ▶ After fully screwing the rotation adapter into the lamination anchor, unscrew the rotation adapter **out of the thread by no more than 3/4 turn**.

INFORMATION

4X46=ST lamination dummy for lamination process

In order to properly screw the rotation adapter with threaded connector into the lamination anchor, the 4X46=ST lamination dummy must be used for laminating. It must be ordered separately.

- 1) Screw the rotation adapter completely into the thread of the lamination anchor.
- 2) Unscrew the rotation adapter out of the thread by **no more than a 3/4 turn**.
 - The alignment of the release button must be medial.
 - After activating the release button, it must be possible to rotate the housing of the rotation adapter by 360° without touching the lamination anchor.
- 3) Secure the cap screw of the threaded clamping of the lamination anchor using adhesive and tighten using the torque wrench (**10 Nm**).

6.3 Installing prosthetic components

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

Fitting:

- Use the torque wrench to tighten the set screws of the pyramid receiver to **10 Nm**.

Definitive assembly:

- 1) Secure the set screws with the adhesive.
- 2) Using the torque wrench, pre-tighten the set screws to **10 Nm** and then tighten to **15 Nm**.

Alignment

The set screws in the pyramid receiver can be used to make static adjustments during alignment, trial fittings and after the prosthesis is finished.

Replacement and disassembly

The set position of the prosthetic component can be maintained during replacement or disassembly. In order to do this, unscrew the two set screws that are screwed in the furthest but are not opposite each other.

Replacing set screws

Replace any set screws that are protruding or recessed too much with suitable ones. For approved set screws, see the section "Technical data" (see page 10).

7 Handling

- 1) To release, press the release button on the side (see fig. 1 (1)) and rotate the prosthesis.
 - The prosthesis can then be rotated from the initial position without holding the button.
- 2) Upon reaching the initial position, the rotation movement is locked automatically.

8 Maintenance

Annual safety inspections are recommended in the interest of the patient's safety and in order to maintain operational safety.

9 Cleaning

- 1) Clean the product with a damp cloth and soap.
- 2) Rinse the product with clean, fresh water.
- 3) Dry the product with a soft cloth.
- 4) **NOTICE! Do not store the product while moist.**
 - Allow to air dry in order to remove residual moisture.

10 Disposal



In some jurisdictions it is not permissible to dispose of these products with unsorted household waste. Disposal that is not in accordance with the regulations of your country may have a detrimental impact on health and the environment. Please observe the instructions of your national authority pertaining to return and collection.

11 Legal information

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

11.1 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.

11.2 Trademarks

All product names mentioned in this document are subject without restriction to the respective applicable trademark laws and are the property of the respective owners.

All brands, trade names or company names may be registered trademarks and are the property of the respective owners.

Should trademarks used in this document fail to be explicitly identified as such, this does not justify the conclusion that the denotation in question is free of third-party rights.

11.3 CE conformity

Otto Bock Healthcare Products GmbH hereby declares that the product is in compliance with applicable European requirements for medical devices.

The full text of the regulations and requirements is available at the following Internet address: <http://www.ottobock.com/conformity>

12 Technical data

Environmental conditions	
Storage and transport in original packaging	-25 °C/-13 °F to +70 °C/+158 °F
Storage and transport without packaging	-25 °C/-13 °F to +70 °C/+158 °F Max. 93% relative humidity, non-condensing
Operation	-10 °C/+14 °F to +60 °C/+140 °F 15% to 93% relative humidity, non-condensing

Product	4R57	4R57-ST
Weight [g]	170	185
Proximal connection	Pyramid	Thread
Tightening torque for the set screws/clamping screw of the proximal connection [Nm]	10	
Distal connection	Pyramid receiver	
Max. body weight [kg]	150	
System height [mm]	22	42
Build height [mm]	22	24
Material	Stainless steel	

Product	4R57	4R57=ST
Rotation range [°]	360	
Lifetime [years]	5	

Approved set screws	506G3=M8x1-0	506G3=M8x1-2-V	506G3=M8x1-4	506G3=M8x1-6	506G3=M8x2-0-V
Length [mm]	10	12	14	16	20
Quantity [pieces]	3				1
Maximum tightening torque [Nm]	15				



A 20 mm long set screw has to be used in the position marked in the figure.

Torque values of the screw connections

Using a torque wrench, tighten the corresponding screws alternately in several cycles until the specified tightening torque is reached.

Screw connection	Tightening torque
Proximal prosthesis components with threaded connector	10 Nm / 89 lbf. in.
Proximal prosthesis components with pyramid	10 Nm / 89 lbf. in.
Pyramid receiver of the rotation adapter	15 Nm / 133 lbf. in.

13 Appendices

13.1 Symbols Used



Declaration of conformity according to the applicable European directives



Medical device



Lot number (PPPP YYYY WW)
 PPPP – plant
 YYYY – year of manufacture
 WW – week of manufacture



Manufacturer



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