

2R67, 4R39, 4R40, 4R85, 4R86



EN Instructions for use (qualified personnel) ..... 5



**Order your  
free printed copy**



**order-ifu@ottobock.com**

Document: 647G23 Version: 23

<https://product-documents.ottobock.com/IFU/INT/2R67/647G23/23/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).

- NO** | Instruer brukeren i sikker bruk av produktet.  
Flere språk for denne bruksanvisningen er tilgjengelige på nett, eller de kan bestilles som utskrevet eksemplar (se side 2).
- FI** | Perehdytä käyttäjä tuotteen turvalliseen käyttöön.  
Tämän käyttöohjeen muut kielet ovat saatavilla online tai niitä voi tilata maksutta painettuna versiona (katso sivu 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).
- SK** | Používateľa zaučte do bezpečného zaobchádzania s výrobkom.  
Ďalšie jazykové mutácie tohto návodu na použitie sú dostupné online alebo si možno bezplatne objednať ich tlačенú verziu (pozri strana 2).
- 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 güvenle kullanımı konusunda kullanıcıyı bilgilendirin.  
Bu kullanım kılavuzundaki diğer diller online olarak mevcuttur veya ücretsiz basılı kopya olarak sipariş verilebilir (bkz. sayfa 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）。

Basic UDI-DI:

2R67\*: 406441100000000002R67JM

4R39: 406441100000000004R39JW

4R85: 406441100000000004R85K5

4R86: 406441100000000004R86K7



## INFORMATION

Date of last update: 2024-01-17

- ▶ Please read this document carefully before using the product and observe the safety notices.
- ▶ 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.

In the following, the "4R39, 4R40, 4R85, 4R86 torsion adapter" / "2R67 tube adapter with torsion unit" is called the product/adapter/torsion adapter/tube adapter.

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

Instruct the patient in the proper use and care of the product. The product may not be transferred to the patient without prior instruction.

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

## 2 Product description

### 2.1 Construction and Function

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

The torsion adapters optimise the function of the modular lower limb prostheses through elastic rotation ( $\pm 20^\circ$ ). Five different versions are available, with the same functionality and housing dimensions, the only difference being the connection:



2R67 tube adapter with torsion unit,  $\varnothing$  34 mm

4R39 torsion adapter with tube,  $\varnothing$  30 mm

4R40 torsion adapter with 4-hole connection

4R85 torsion adapter with tube clamp adapter,  $\varnothing$  30 mm

4R86 torsion adapter with tube clamp adapter,  $\varnothing$  34 mm

The torsion movement of the adapters occurs in the horizontal plane. In the spring housing, these movements are transferred to the vertical by a deflection system.

### 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.

## 3 Intended use

### 3.1 Indications for use

The product is intended exclusively for lower limb exoprosthetic fittings.

### 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.).

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.

#### 4R85



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 **100 kg max.**

#### 4R86



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 **110 kg max.**

#### 2R67, 4R39, 4R40



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 **125 kg max.**

### 3.3 Contraindications



- All conditions which contradict or go beyond the specifications listed in the sections on "Safety" and "Intended use" or "Indications for use" in the documents included in the delivery.

### 3.4 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

 <b>CAUTION</b>	Warning regarding possible risks of accident or injury.
 <b>NOTICE</b>	Warning regarding possible technical damage.

## 4.2 Structure of the safety instructions

### CAUTION

#### **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 case of failure to observe the hazard
- > E.g.: Consequence 2 in case 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

### CAUTION

#### **Non-observance of safety instructions**

Personal injury/damage to the product due to using the product in certain situations.

- ▶ Observe the safety instructions and the stated precautions in this accompanying document.

### 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 tube adapter must be secured with adhesive before they are tightened to the specified torque.
- ▶ The screws in the clamp bracket must not be secured but only tightened to the specified torque.

### 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 the patient's 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. If necessary, forward the product to an authorised Ottobock Service Centre.

### CAUTION

#### **Remaining in areas outside the allowable temperature range**

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

- ▶ Avoid remaining in areas with temperatures outside of the permissible range (see page 11).

### 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).

**⚠ CAUTION**

**Improper use**

Injury due to faulty operation or malfunction of the product.

- ▶ Instruct the patient in the proper use of the product.

**⚠ CAUTION**

**Penetration of dirt and humidity into the product**

- > Falling due to unexpected product behaviour as the result of malfunction.
- > Falling due to breakage of load-bearing components.
- ▶ Ensure that neither solid particles, foreign objects nor liquids penetrate into the product.
- ▶ Should the product come into contact with liquids, allow the product to dry. The product must be inspected by an authorised Ottobock Service Centre.
- ▶ Should the product come into contact with salt water, immediately clean it with a cloth moistened with fresh water and let it dry. The product must be inspected by an authorised Ottobock Service Centre.

**⚠ CAUTION**

**Mechanical overload**

Falling due to breakage of load-bearing components.

- ▶ Do not subject the system components to mechanical vibration or impacts.
- ▶ Check the product for visible damage before each use.

**⚠ CAUTION**

**Incorrect setting of the torsion moments in the torsion unit**

Falling due to unexpected behaviour of the product.

- ▶ The marking on the Allen head screw may not be turned as far as the red area or beyond the red area (see fig. 1).

## 5 Scope of delivery

- 1 pc. Instructions for use (qualified personnel)
- 1 pc. 4R39/4R40/4R85/4R86 torsion adapter / 2R67 tube adapter with torsion unit

## 6 Preparing the product for use

**⚠ CAUTION**

**Incorrect alignment or assembly**

Falling due to damage to the prosthesis components.

- ▶ Observe the alignment and assembly instructions.

**⚠ 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 11).
- ▶ Observe the instructions for securing the screw connections and the use of the correct length.



## 6.1 Required tools

- 719R2 tube cutter
- 718R1 tube deburrer
- 710D4 torque wrench (up to 30 Nm)
- 710D12 torque wrench (up to 12 Nm)
- 636K13 adhesive (Loctite 241)

## 6.2 Adapting the 4R39 torsion adapter or 2R67 tube adapter with torsion unit

### CAUTION

#### **Improper processing of the tube**

Falling due to damage to the tube.

- ▶ Do not clamp the tube into a vice.
- ▶ Only shorten the tube with the prescribed tools.

- 1) Shorten the tube with the tube cutter if needed.

**INFORMATION: Make sure that the cut edge is at right angles to the longitudinal axis of the tube.**

- 2) Deburr the inside and outside of the cut edge with the tube deburrer.

## 6.3 Mounting the adapter

### 6.3.1 Mounting the torsion adapter (4R39) or tube adapter with torsion unit (2R67)

- ▶ Fully insert the 2R67, 4R39 tube adapter into the tube clamp adapter up to the stop.

### 6.3.2 Mounting the torsion adapter (4R40)

- 1) Remove the screws on the socket attachment block or modular adapter.
- 2) Screw the torsion adapter to the socket attachment block or modular adapter.
- 3) Tighten the screws.

### 6.3.3 Mounting the torsion adapter (4R85/4R86)

### **INFORMATION**

When using the 3R15 and 3R49 knee joints with friction brake, the supplied longer extension assist cable has to be installed.

- 1) On the tube clamp adapter, loosen the tube clamp cap screw by 2 turns.
- 2) Fully insert the tube adapter into the torsion adapter (4R85/4R86) up to the stop.
- 3) Tighten the tube clamp cap screw (installation torque: 5 Nm).

## 6.4 Connecting the pyramid adapter and pyramid receiver

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

### **Fitting:**

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

### **Definitive mounting:**

- 1) Secure the set screws with the adhesive.
- 2) Pre-tighten the set screws with the torque wrench to **10 Nm** and then tighten to **12 Nm**.

## 6.5 Adjusting the torsion moment

### CAUTION

#### **Incorrect setting of the torsion moments in the torsion unit**

Falling due to unexpected behaviour of the product.

- ▶ The marking on the Allen head screw may not be turned as far as the red area or beyond the red area (see fig. 1).

The torsion moment can be adjusted with the Allen head screw in the centre of the adapter (see fig. 1).

**Increasing the torsion moment:**

- ▶ Turn the mark in the centre of the torsion unit clockwise.

**Decreasing the torsion moment:**

- ▶ Turn the mark in the centre of the torsion unit counterclockwise.

## 7 Handling

### 7.1 Adjusting adapter

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

### 7.2 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

**⚠ 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 tube adapter must be secured with adhesive before they are tightened to the specified torque.
- ▶ The screws in the clamp bracket must not be secured but only tightened to the specified torque.

Replace any set screws that are protruding or recessed too much with suitable ones (see selection table).

Selection table for set screws	
Length [mm]	Article number
12 mm	506G3=M8x12-V
14 mm	506G3=M8x14
16 mm	506G3=M8x16

## 8 Cleaning

- 1) Clean the product with a damp, soft cloth.
- 2) Dry the product with a soft cloth.
- 3) Allow to air dry in order to remove residual moisture.

## 9 Maintenance

- ▶ A visual inspection and functional test of the prosthetic components should be performed after the first 30 days of use.
- ▶ Inspect the entire prosthesis for wear during normal consultations.
- ▶ Conduct annual safety inspections.

## 10 Legal information

### 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 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.

### 10.3 CE conformity

Otto Bock Healthcare Products GmbH hereby declares that the product is in compliance with 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>

## 11 Technical data

Environmental conditions	
Storage and transport in original packaging	-10°C/14°F to 60°C/140°F
Storage and transport without packaging	-10°C/14°F to 60°C/140°F Max. 90% relative humidity, non-condensing
Operation	-10°C/14°F to 60°C/140°F Max. 90% relative humidity, non-condensing

Article number	2R67	4R39	4R40	4R85	4R86
Weight [g]	520	500	340	350	340
System height [mm]	Min.: 117 Max.: 322	Min.: 113 Max.: 476	58	68	68
Material	Aluminium/titanium	Stainless steel	Stainless steel	Stainless steel	Titanium
Max. body weight [kg]	125	125	125	100	110
Service life	3 million load cycles (3 – 5 years)				

## 12 Appendices

### 12.1 Symbols Used



Declaration of conformity according to the applicable European directives

**LOT**

Lot number (PPPP YYYY WW)

PPPP – plant

YYYY – year of manufacture

WW – week of manufacture



Manufacturer



Medical device

---









Otto Bock Healthcare Products GmbH  
Brehmstraße 16 · 1110 Wien · Austria  
T +43-1 523 37 86 · F +43-1 523 22 64  
info.austria@ottobock.com · www.ottobock.com