
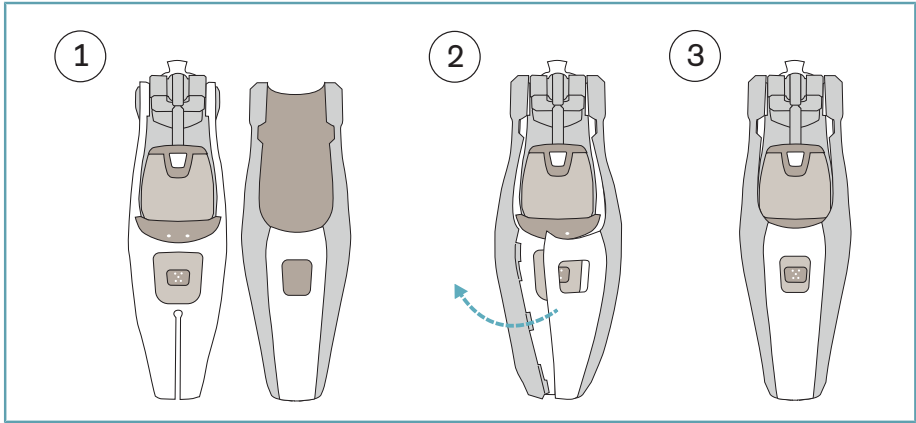


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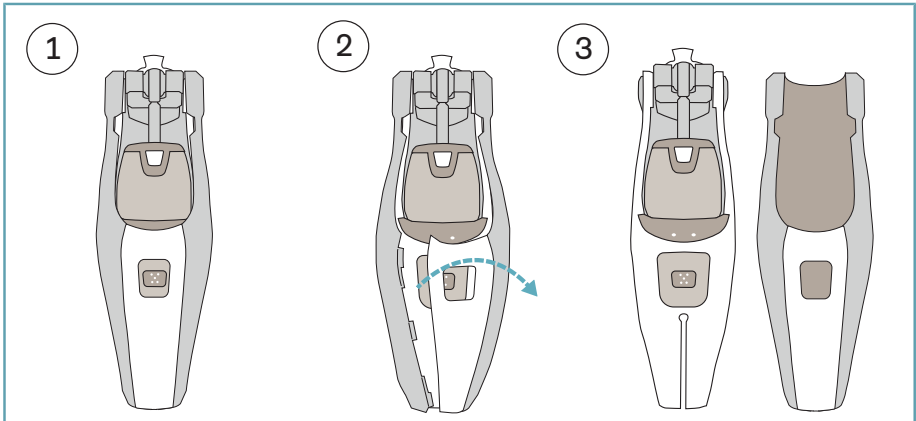
4P100=7

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 6.1



 6.3



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1 Foreword

INFORMATION

Date of last update: 2023-08-16

- ▶ 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 any serious incident related to the product, in particular any deterioration of health, to the manufacturer and the competent authority in your country.

The product “4P100=7 Genium X4 Protective Cover, short” is referred to as the Protective Cover/product below.

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

Only put the Protective Cover into use in accordance with the information provided in the accompanying documents supplied.

2 Product description

2.1 Combination possibilities

Prosthetic components that are suited for combination with the product are listed below.

Knee Joint Combination Possibilities

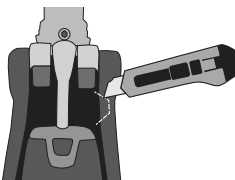
- 3B5-4=P Genium X4 (with pyramid) or 3B5-4=ST Genium X4 (with threaded connector)

Prosthetic Foot Combination Possibilities

- All Ottobock prosthetic feet approved for combination with the 3B5-4=P or 3B5-4=ST knee joints.

Limited use of the 4R57* rotation adapter

A check must be carried out to verify whether rotation is possible over the entire flexion angle range when this rotation adapter is used. Collisions between the rotation adapter and the knee joint have to be ruled out by tilting and/or using suitable flexion stops.



If the **release button** of the rotation adapter **comes into contact with the Protective Cover** at full flexion, the Protective Cover can be cut out in this area along the specified contour.

If the **release button** of the rotation adapter **comes into contact with the knee joint** at full flexion, a larger flexion stop has to be used in accordance with the alignment recommendations for the knee joint.

3 Intended use

3.1 Indications for use

The product is to be used **solely** for lower limb exoprosthetic fittings.

The Protective Cover provides a means of enclosing the mechatronic knee joints Genium X4 3B5-4=P or Genium X4 3B5-4=ST to enhance the appearance and function. The Protective Cover protects the housing of the knee joint against external influences such as scratches or surface

contamination. The Protective Cover is not required for the knee joint to function properly and safely.

3.2 Conditions of use

The product is intended exclusively for wearers of the 3B5-4=P Genium X4 or 3B5-4=ST Genium X4 prosthetic knee joints.

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

3.3 Contraindications

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

3.4 Qualification

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

4 Safety

Ottobock developed this product according to applicable standards and rules and tested it multiple times. In order for you to enjoy the product, we need your help. Only by complying with the following instructions can we guarantee safe treatment and operation.

4.1 Meaning of warning levels

CAUTION! Failure to follow the instructions can lead to accidents and injuries.

NOTICE! Failure to follow the instructions can result in technical damage.

4.2 During treatment

CAUTION! Possibility of falling

- ▶ Observe the alignment and assembly instructions.
- ▶ Only combine the product with the components mentioned in the chapter on possible combinations.
- ▶ Check that the user can hear the operating state signals and set the corresponding volume.
- ▶ Warnings/error signals are always emitted at the highest volume. The volume of the warnings/error signals cannot be changed.

5 Scope of delivery, spare parts

5.1 Scope of delivery

- 1 pc. 4P100=7 Protective Cover, short
- 1 pc. Instructions for use (qualified personnel)
- 1 pc. Instructions for use (user)

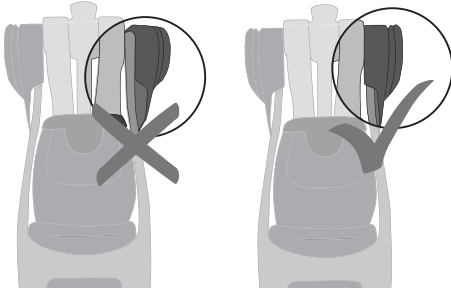
5.2 Spare parts

- 4P101=1 Closure for Protective Cover, short

6 Preparing the product for use

6.1 Putting on the Protective Cover

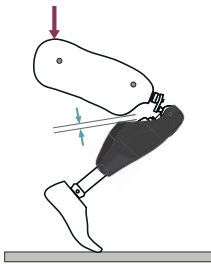
- 1) Open the closure.
- 2) Spread open the Protective Cover.



- 3) Put the Protective Cover onto the frame of the knee joint.
Ensure that the Protective Cover fits flush on the knee joint. The retainers have to engage exactly in the frame.
- 4) Fasten the closure.

6.2 Checking the clearance between the prosthetic socket and knee joint

After assembly of the Protective Cover, verify that the distance from the prosthetic socket to the knee joint is not less than the minimum under load at maximum flexion. Damage to the hydraulics, frame, electronics housing etc. may occur if the distance from the socket to the knee joint is insufficient.



- 1) Place the prosthesis with assembled Protective Cover on the workbench and flex the knee joint.
- 2) Check the available distance between the Protective Cover and socket.
- 3) The distance should be at least 3 mm.
- 4) Then grasp the upper front area of the socket with both hands and put a substantial load on the socket.
- 5) Check the available distance between the Protective Cover and socket again.
→ The distance under this load should still be at least 3 mm.

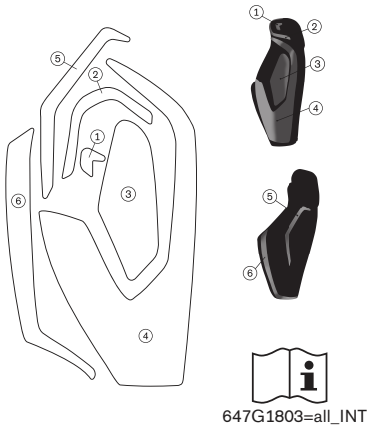
INFORMATION: If the value falls short of this distance, a flexion stop has to be installed or an existing flexion stop has to be replaced with a larger flexion stop. If the largest flexion stop is already installed, please contact Ottobock Customer Service.

6.3 Taking off the Protective Cover

- 1) Open the closure.
- 2) Spread open the Protective Cover and remove it from the knee joint.
- 3) Fasten the closure after taking off the Protective Cover.

7 Customising the Protective Cover

7.1 Laminating the Protective Cover



- 1) Select the corresponding template from the 647G1803=all_INT supplement.
- 2) Transfer the pattern to any adhesive film. Note that the supplement only shows the cuts for the right side. For the left side, the cutting part must be turned over before transferring.
- 3) Cut out the adhesive film.
- 4) Clean the Protective Cover.
- 5) Apply the adhesive film to the Protective Cover.

NOTICE! Do not use a hot air gun.

7.2 Painting the Protective Cover

CAUTION! Possible injury due to skin, eye and respiratory tract irritation.

► Read the corresponding safety data sheets/processing instructions prior to processing with substances for priming the surface and for painting.

► Wear appropriate protective equipment during processing.

Complete the following steps to varnish the Protective Cover:

- 1) Clean and degrease the Protective Cover (e.g. with Hesse-Lignal NV 395)
- 2) Pre-treat the outer surface of the Protective Cover with a bonding agent for TPU/polyurethanes (e.g. Hesse-Lignal TG 5250 adhesive primer) according to the processing instructions for the bonding agent.

The bonding agent being used specifies which paint can be used for painting.

INFORMATION: Follow the processing instructions for the chosen paint to obtain optimal painting results.

INFORMATION: Use paint for elastic materials to obtain the most long-lasting results possible.

8 Maintenance

► During the standard inspection of the prosthesis components, also inspect the product.

9 Cleaning and Care

INFORMATION

Take the product off for drying.

INFORMATION

In case of heavy soiling, the product can be rinsed with warm running water and cleaned with a brush.

9.1 Manual cleaning

- 1) Clean with a soft, damp cloth.

- 2) Dry with a soft cloth.
- 3) Allow to air dry in order to remove residual moisture.
- 4) Disinfect by wiping with a surface disinfectant (e.g. DescoSept) and drying.

9.2 Cleaning in the dishwasher

The following points have to be observed for cleaning in the dishwasher:

- Rinse dishes first to remove food scraps and any food residue likely to leave strong stains.
- Place the Protective Cover in the top rack.
- Use a short wash cycle with a water temperature below 60 °C.

10 Disposal

The product must be disposed of properly in accordance with the respective national environmental regulations.

11 Legal information

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 CE conformity

This product complies with the relevant 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>

11.3 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.

12 Technical data

Environmental conditions	
Transport in original packaging	-25 °C/-13 °F to +75 °C/+167 °F Max. 90% relative humidity, non-condensing
Storage in the original packaging (≤3 months)	+5 °C/+41 °F to +40 °C/+104 °F Max. 85% relative humidity, non-condensing
Long-term storage in the original packaging (>3 months)	+5 °C/+41 °F to +20 °C/+68 °F Max. 93% relative humidity, non-condensing
Transport and storage between applications (without packaging)	-25 °C/-13 °F to +70 °C/+158 °F Max. 90% relative humidity, non-condensing
Operation	-5 °C/+23 °F to +45 °C/+113 °F 5% to 90% relative humidity, non-condensing
General	
Reference number	4P100=7

General	
Lifetime	2 years The lifetime decreases or increases depending on the individual level of use. The maximum lifetime – which depends on the level of use – can only be achieved when the instructions for use are observed.
Weight	Approx. 250 g

13 Appendices

13.1 Symbols Used



Declaration of conformity according to the applicable European directives



Manufacturer



Lot number (10)PPPP YYYY WW
PPPP – plant
YYYY – year of manufacture
WW – week of manufacture



Please note the instructions for use



Article number



Medical device



Global Trade Item Number



Unique device identifier



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