



Prosthesis - lower limb

 Instructions for use (user)

INFORMATION

Date of last update: 2023-08-18

- ▶ Please read this document carefully before using the product and observe the safety notices.
- ▶ Obtain instruction from the qualified personnel in the safe use of the product.
- ▶ Please contact the qualified personnel 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

Your prosthesis is a custom-made medical device. It was built and adapted to meet your personal needs and indications.

- Information regarding the components used in your prosthesis can be found in the enclosed document: "Patient solution statement"

Do not modify or repair your prosthesis yourself. Attempting this can damage the prosthesis or impair its functionality. Contact your O&P professional if you have questions or in case of problems.

2 Intended use

2.1 Indications for use

The product is intended exclusively for lower limb exoprosthetic fittings.

2.2 Area of application

Your personal situation (e.g. training level, amputation conditions) determines your performance when using your prosthesis. The technically possible area of application depends on the components used for your prosthesis; see the document "Patient solution statement."

3 General safety instructions

CAUTION! Risk of injury and risk of product damage

- ▶ To avoid the risk of pinching, do not reach into the joint mechanism.
- ▶ Keep the product away from open flames, embers and other sources of heat.

NOTICE! Danger of product damage and restricted functionality

- ▶ Do not expose the product to prohibited environmental conditions (see instructions for use of the individual components).
- ▶ Check the product for damage if it has been exposed to prohibited environmental conditions.
- ▶ 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).
- ▶ Use the product carefully and as intended.
- ▶ Do not make any changes to the product.
- ▶ Check the product for damage and readiness for use prior to each use.
- ▶ Do not use the product if its functionality is restricted. Take suitable measures (e.g. cleaning, repair, replacement, inspection by the manufacturer or a specialist workshop).

4 Use

WARNING

Operation of motor vehicles

Risk of accident due to limited body function

- ▶ The product has not been approved by the manufacturer for the operation of motor vehicles.
- ▶ Observe the applicable legal regulations for the operation of motor vehicles and have your driving ability examined by an authorised test centre.

4.1 Information for use

This section contains information on the use of your prosthesis. The optimum benefit can only be obtained through only error-free handling of a prosthesis with a good fit and function. Please contact your O&P professional if you have any questions or problems.

Discuss the following topics with your doctor

- ▶ The daily duration of use for the product.
- ▶ The design of accompanying therapeutic measures (e.g. physiotherapy, occupational therapy) that are recommended for achieving optimal performance.
- ▶ Measures required to maintain or improve the functionality of your amputation area.
- ▶ The required hygiene in the amputation area.

4.2 Putting on and taking off

Putting on

- 1) **CAUTION! Do not use the prosthesis if it exhibits signs of damage or wear and tear (e.g. cracks, deformations, noises, poor fit).**
Check the prosthesis for visible damage and proper functioning before putting it on.
- 2) Put on the prosthesis as instructed by your O&P professional and verify the firm fit of the prosthesis. Please contact your O&P professional if you have any questions or problems.

Taking off

- 1) Take off the prosthesis just as your O&P professional has shown you.
- 2) Clean and care for your skin after removing the prosthesis (see page 3).
- 3) Clean your prosthesis (see page 3).

4.3 Volume fluctuations

Minor volume fluctuations may be part of normal everyday life. They influence the fit of the prosthesis and must be compensated by compression therapy (compression agents and therapeutic measures). Skin damage or other injuries may occur if the prosthesis no longer fits properly.

If you have any questions or problems, please contact your doctor or O&P professional.

- Use appropriate compression agents (e.g. residual limb compression socks, wrapping the amputation area with elastic bandages, adjustable prosthesis closures) to compensate for minor volume fluctuations.
- Avoid swelling of the residual limb after taking off your prosthesis. Use liners or residual limb compression socks for this purpose or, for example, wrap the residual limb with elastic bandages.
- Ensure that the body weight remains as constant as possible. Changes in your body weight have a direct impact on the fit of the prosthesis.
- If injuries or changes (e.g. sensory disorders) occur, contact your doctor or O&P professional.

4.4 Cleaning and Care

Skin cleaning and care

- 1) Wash the skin with pH-neutral soap.
- 2) Dry the skin thoroughly.

- 3) Check (look and feel) the skin for changes and damage such as sensory disorders. Use a mirror if you can't see everywhere.
- 4) **Optional:** Use a nourishing cream/lotion.

Cleaning the prosthesis

CAUTION

Use of unsuitable cleaning agents or disinfectants

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

- Only clean the product with the approved cleaning agents.
- Only disinfect the product with the approved disinfectants.
- Observe the instructions for cleaning and care.

The precise way in which the prosthesis may be cleaned depends on the components used. In general, the following steps are possible:

- 1) Wipe the outside of the prosthesis with a damp cloth.
- 2) Clean the inside of the prosthetic socket with a cloth and pH-neutral soap.
- 3) Remove soap residue with a damp cloth. Soap residue can cause skin irritation.
- 4) Allow the prosthesis to air dry.

4.5 Selecting shoes

Your prosthesis was built for the effective heel height of your preferred shoes; see the document "Patient solution statement." If you want to use your prosthesis with other shoes, the effective heel height of the shoes must be the same. Otherwise, the alignment of the prosthesis may need to be adjusted.

INFORMATION: Bathing prostheses are usually constructed for use without footwear.



Determining the effective heel height

- Measure the sole thickness of the heel (**a**) and forefoot (**b**)
- **Effective heel height = a - b**

- 1) Do not use the prosthesis barefoot or with shoes that have an incorrect effective heel height.
- 2) Talk to your O&P professional if you want to use your prosthesis with different shoes.

5 Maintenance

In order to avoid damage to the product, adhere to the inspection intervals recommended by your O&P professional.

6 Disposal

Return the product to the O&P professional for disposal.

7 Legal information

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

7.1 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.

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A series of horizontal lines for writing, spanning the width of the page. There are 20 lines in total, evenly spaced.

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