

Transfemoral Prosthesis with Synthetic / Lamination Resin Socket

- Custom-made device -

EN Instructions for Use (Patient)



Table of contents

1	Foreword	4
2	Description of the Design and Individual Components	4
3	Areas of Application and Usage Restrictions.....	4
4	Medical and Therapeutic Aspects	4
5	Safety	5
5.1	Explanation of Warning Symbols	5
5.2	General Safety Instructions.....	5
6	Handling	6
6.1	Shoe Selection	6
6.2	Check.....	6
6.3	Donning the Prosthesis	7
6.4	Wearing of the Prosthesis	7
6.5	Doffing of the Prosthesis	8
7	Cleaning and Care.....	8
8	Maintenance	8
9	Disposal.....	9
10	CE Conformity	9
11	Notes.....	10

1 Foreword

INFORMATION

Date of the last update: 2013-05-07

- ▶ Please read this document carefully.
- ▶ Follow the safety instructions.

INFORMATION

Please observe the specific information and safety instructions provided by your prosthetist with regard to your prosthesis.

You have received a custom-made prosthesis from Ottobock, which has been adapted to your personal needs. The Ottobock team has informed you about the correct use of your prosthesis. Please read these Instructions for Use carefully. The Instructions for Use contain detailed information regarding the correct use of your prosthesis as well as important safety instructions.

2 Description of the Design and Individual Components

Your prosthesis mainly consists of a custom prosthetic socket to embed your residual limb, the knee joint, connection adapters and the prosthetic foot. The exterior appearance may be formed by a cosmetic foam cover. The static alignment has been adapted to your individual needs and takes the heel height of your shoe into account.

A consistently good fit of your prosthetic socket can only be maintained if the volume of your residual limb remains constant. Further information is found under volume fluctuations in Section 4 "Medical and Therapeutic Aspects".

In accordance with your indications and personal requirements, you have received a prosthesis of the following design:

Prosthetic socket: In your case, the connection between the residual limb and the prosthesis is provided by a prosthetic socket made of plastic or lamination resin. The Ottobock team has selected the socket design and material combination best suited to you and your specific needs. The prosthetic socket has been adapted so that your residual limb muscles establish a correct connection without constricting you excessively. The prosthetic socket is worn directly on the skin without a residual limb sock. The valve promotes adhesion and is removed to doff the prosthesis.

Prosthesis components: Different knee joints and prosthetic feet are available for a transfemoral prosthesis. The Ottobock team has selected the prosthetic components best suited for you, adapted them to your mobility grade and adjusted them to comply with your individual requirements.

3 Areas of Application and Usage Restrictions

Your prosthesis serves as a functional and cosmetic replacement for the amputated limb and enables you to sit, stand, and walk.

The use of your prosthesis and the performance you will be able to achieve depends on your individual diagnosis, the residual limb conditions and your mobility grade. Please consult your doctor regarding the daily duration of use and potential therapeutic measures (e.g. occupational therapy or physical therapy) to improve your performance.

In general, you should not experience too much discomfort when wearing your prosthesis. Excessive pressure can lead to complications.

4 Medical and Therapeutic Aspects

As a general rule, physiotherapy is recommended in order to maintain and improve the functionality of the residual limb. Please discuss all measures for maintaining and improving residual limb functionality as well as residual limb treatment and hygiene with your doctor. Depending on your

specific indications, complications can occur in individual cases. This may restrict your ability to wear the prosthesis.

Residual Limb Treatment and Hygiene

Caring for your residual limb on a daily basis is essential. Washing your residual limb with skin-friendly soap can prevent skin problems. Use special care products such as Derma Prevent, Derma Repair and Derma Clean.

Volume Fluctuations

As a prosthesis wearer, you should pay special attention to your weight since any fluctuations will have a direct impact on the fit of your prosthesis. Minor volume fluctuations over the course of the day are normal and can be balanced with residual limb socks. To avoid major swelling of your residual limb, it is advisable to dress the residual limb with compression material when you are not wearing a prosthesis (e.g. compression shrinker sock, standard liner, or elastic bandages). To avoid swelling of your residual limb when you are not wearing the prosthesis, it is important to compress the residual limb by applying a compression sock, standard liner or residual limb bandages.

If you have additional questions regarding volume fluctuations, please consult your doctor or prosthetist.

5 Safety

5.1 Explanation of Warning Symbols

 WARNING	Warnings regarding possible risks of severe accident or injury.
 CAUTION	Warnings regarding possible risks of accident or injury.
NOTICE	Warnings regarding possible technical damage.

5.2 General Safety Instructions

 CAUTION
Using the product without following the instructions for use Deteriorating health condition and damage to the product because of failure to follow the safety information ► Observe the safety information in these instructions for use.
 CAUTION
Contact with heat, embers or fire Injuries (e.g. burns) caused by melting of the material ► Keep the product away from open flame, embers and other sources of heat.
 CAUTION
Reaching into the area of the joint mechanism Pinching of limbs (e.g. fingers) and the skin due to uncontrolled joint movement ► Do not reach into the joint mechanism during daily use.
NOTICE
Use of the product under incorrect environmental conditions Damage, brittleness or destruction due to improper use

- ▶ Do not expose the product to environments that may cause components to corrode, such as fresh water, salt water or acids.
- ▶ Avoid using the orthosis in conditions of high relative humidity.
- ▶ Avoid contact with sand and dust.
- ▶ Do not expose the product to temperatures below -10°C or above +60°C (e.g. sauna, excessive sunlight, drying on a radiator).

NOTICE

Mechanical overload

Impaired functionality due to mechanical damage

- ▶ Check the product for damage prior to each use.
- ▶ Do not use the product if its functionality has been impaired.
- ▶ Take any necessary measures (e.g. repair, replacement, inspection by the manufacturer's customer service, etc.).

NOTICE

Improper use and changes

Change in or loss of functionality as well as damage to the product

- ▶ Only use this product carefully and for its intended purpose.
- ▶ Do not make any improper changes to the product.

6 Handling

6.1 Shoe Selection

⚠ CAUTION

Incorrect effective heel height

Falling injuries due to loss of functionality

- ▶ When buying new shoes, be sure to observe the predetermined effective heel height.

Effective Heel Height

The effective heel height of the prosthesis is determined during the construction of the prosthesis. The heel height of the prosthesis cannot be altered and is calculated by the heel height minus the forefoot height.

Calculation of the effective heel height:



The effective heel height (a - b) of your prosthesis is:

.....

Do not use your prosthesis without a shoe that correctly balances the heel height of the prosthetic foot. Otherwise, extension loading of your knee joint and a risk of slipping may result.

6.2 Check

⚠ CAUTION

Use of a worn or damaged prosthesis

Restricted support or injuries due to changes in or loss of functionality

- ▶ Before each use, check the prosthesis for functional reliability and for possible wear or damage.
- ▶ If the prosthesis or a component of the prosthesis shows any signs of wear (e.g. tears, deformations, poor fit) or damage, the prosthesis should no longer be used.

CAUTION

Volume fluctuations of the affected limb or problems with the fit (e.g. caused by growth)

Injuries, friction, pressure sores, circulatory disorders and paralytic symptoms caused by problems with the fit

- ▶ If the product is fitted during the growing phase, it must be adjusted according to changing body dimensions.
- ▶ Check the skin daily for damage and sensitivity disturbances (visually and by palpating).
- ▶ Please consult your doctor or prosthetist in case of any signs of skin damage, even if they are only minor.

Please verify that your prosthesis is undamaged and functional prior to each use.

Every time you put on your prosthesis, verify that the prosthesis is firmly in place by pulling on it.

First-time users in particular have to learn how to handle the prosthesis. Donning and doffing, sitting, standing, and walking, as well as possible falling must be practised. Your doctor, physiotherapist or prosthetist can provide you with additional advice on prosthesis training.

Special attention was paid to the materials used for your prosthesis. They were tested for skin tolerance. If skin changes develop on your residual limb, please consult your doctor in a timely manner.

6.3 Donning the Prosthesis

Your Ottobock team instructed you in how to don the prosthesis. The following donning technique is well proven:

- 1) Apply the donning assist (e.g. elastic bandage/elastic sock/EasyProth donning assist) over your residual limb up to the crotch. Include all soft tissue.
- 2) Push the free end of the donning assist to the outside through the valve opening.
- 3) Slide your residual limb into the prosthetic socket.
- 4) Draw the donning assist to the outside. Slide your residual limb into the prosthetic socket.
- 5) Gradually draw out the donning assist. Ensure that all soft tissue remains in the prosthetic socket.
- 6) Insert the valve and allow the air to escape.

Remove the prosthesis if it does not fit properly. Try donning the prosthesis again. Contact your prosthetist in case of any problems.

6.4 Wearing of the Prosthesis

WARNING

Operation of motor vehicles

Risk of accidents due to restricted body function

- ▶ Observe the applicable legal and insurance regulations for the operation of motor vehicles and have your driving ability examined and certified by an authorised agency.

CAUTION

Excessive strain on load-bearing components

Injuries due to breakage of load-bearing components

- ▶ Sports activities are only permitted after consultation with your doctor or orthotist.

- ▶ If the product has been exposed to extreme strain (e.g. due to falling), take any necessary measures (e.g. repair, replacement, inspection by the manufacturer's customer service etc.).

An energy-saving and natural gait requires a functional prosthesis. Please consult your prosthetist if you experience any problems despite correct handling.

6.5 Doffing of the Prosthesis

- 1) Remove the valve.
- 2) Push the prosthesis down by the socket brim.

7 Cleaning and Care

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.

Your prosthesis, especially the inner socket, requires regular cleaning.

Prosthesis

Cleaning with a damp cloth will generally be sufficient. Ottobock recommends Derma Clean to disinfect the prosthesis. Clean any plastic surfaces with water and skin-friendly soap. Dry the cleaned areas thoroughly. Do not place the prosthesis on a radiator or other heat source. Ensure that no soap residue is left on the prosthesis, since this could cause skin irritation on the residual limb.

Please consult your doctor if you have any questions on skin diseases or disinfection methods.

8 Maintenance

CAUTION

Lack of or insufficient maintenance

Injuries due to changes in or loss of functionality

- ▶ Observe the specified maintenance intervals.

INFORMATION

Failure to observe the specified maintenance intervals will limit liability in cases of damage or may even make the warranty null and void.

Liability is limited exclusively to the product in the form supplied by Ottobock. Liability only extends to services provided by the Ottobock team.

In the interest of your own safety, you should observe the check-up dates established with your prosthetist in order to avoid any damage to your prosthesis.

The Ottobock team recommends a
maintenance interval of:

In addition, please pay attention to any changes that may become evident in the material of your prosthesis.

Please contact your prosthetist immediately if any changes occur.

9 Disposal

In accordance with our activities to protect the environment and also in your best interest, we offer you the option of returning your prosthesis to an Ottobock centre for disposal.

10 CE Conformity

Your custom-fabricated product is a risk class I medical device and, in accordance with appendix VIII of the EU guidelines for medical devices, meets the fundamental requirements of the Council Directive 93/42/EEC of June 14, 1993. The product does not bear the CE mark since it is a custom fabrication.

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