ottobock 1C40 C-Walk Feet with Dynamic Behavior Instruction Manual

Contents

ottobock 1C40 C-Walk Feet with Dynamic Behavior

Product description

INFORMATION
Date of last update: 2021-06-30

- 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.

Construction and Function
The 1C40 C-Walk prosthetic foot is suitable for walking on various surfaces and for a large range of speeds. The functional properties of the prosthetic foot are achieved through the carbon spring elements. The prosthetic foot permits perceptible plantar flexion at heel strike and a natural rollover movement. Stored energy is released by the spring elements.

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.

Intended use

Indications for use
The product is intended exclusively for lower limb exoprosthetic fittings.

Area of application
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. m° kg The product is recommended for mobility grade 3 (unrestricted outdoor walker) and mobility grade 4 (unrestricted outdoor walker with particularly high demands).

Size [cm]	24 to 25	26 to 30
Max. body weight [kg]	75	100

Environmental conditions

Storage and transport
Temperature range –20 °C to +60 °C (–4 °F to +140 °F), relative humidity 20 % to 90 %, no mechanical vibrations or impacts.

Allowable environmental conditions

Temperature range: –10 °C to +45 °C (14 °F to 113 °F)
Moisture: relative humidity: 20% to 90%, non-condensing
Chemicals/liquids: fresh water as dripping water, occasional contact with salty air (e.g. near the ocean)
Solids: dust

Prohibited environmental conditions

Chemicals/moisture: salt water, perspiration, urine, acids, soapsuds, chlorine water
Solids: dust in high concentrations (e.g. construction site), sand, highly hygroscopic particles (e.g. talcum)

Lifetime

Prosthetic foot
The product was tested by the manufacturer with 2 million load cycles. Depending on the user's activity level, this corresponds to a maximum lifetime of 3 years.

Footshell, protective sock
The product is a wear part, which means it is subject to normal wear and tear.

Safety

Explanation of warning symbols

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

General safety instructions
CAUTION!
Risk of injury and risk of product damage

- To avoid the risk of injury and product damage, do not use the product beyond the tested lifetime.
- To avoid the risk of injury and product damage, only use the product for a single patient.
- Comply with the product's field of application and do not expose it to excessive strain (see page 11).
- Note the combination possibilities/combination exclusions in the instructions for use of the products.
- To avoid a risk of injury due to a lack of surface grip or loss of functionality of the prosthetic foot, always use the prosthetic foot with a footshell.

NOTICE!

Risk of product damage and limited functionality

- To prevent mechanical damage, use caution when working with the product.
- If you suspect the product is damaged, check it for proper function and readiness for 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).
- Do not expose the product to prohibited environmental conditions.
- 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).

Signs of changes in or loss of functionality during use
Decreased forefoot resistance or changes in roll-over behaviour are noticeable indications of loss of functionality.

Scope of delivery

Quantity	Designation
1	Instructions for use
1	Prosthetic foot

Spare parts/accessories (not included in the scope of delivery)	
Designation	**Reference number**
Footshell	2C4*
Connection cap	2C11*

Preparing the product for use

CAUTION
Incorrect alignment or assembly
Risk of injury due to damaged prosthetic components. Observe the alignment and assembly instructions.

CAUTION
Use of talcum
Risk of injury, damage to the product due to lack of lubrication. Do not use talcum on the product or other prosthesis components.

NOTICE
Grinding the prosthetic foot or footshell
Premature wear resulting from damage to the product. BDo not grind the prosthetic foot or footshell.

Alignment
INFORMATION
There is a plastic protector on the product’s pyramid. It protects the connecting section from scratches during the alignment and fitting of the prosthesis. Remove the protector before the patient leaves the workshop/fitting area.

Applying/removing the footshell

- Recommended tools: 2C100 changing device
    1. Slide the prosthetic foot into the footshell.
    2. Press the heel of the prosthetic foot into the footshell until it engages.
- Recommended tools: 2C100 changing device
    1. Push the lock of the footshell to the rear and pull up the heel of the prosthetic foot.
    2. Remove the prosthetic foot from the footshell.

Bench Alignment

TT bench alignment

Bench alignment process	
Required materials: 662M4 goniometer, 743S12 heel height measuring apparatus, 743A80 50:50 gauge, alignment apparatus (e.g. 743L200 L.A.S.A.R. Assembly or 743A200 PROS.A. Assembly)	
Perform the assembly and alignment of the prosthetic components in the alignment apparatus according to the following specifications:	
Sagittal plane	
	Heel height: **Effective heel height** (shoe heel height **–** sole thickness of fore foot) **+ 5 mm**
	Exterior foot rotation: **approx. 5°**
	Anterior placement, middle of the prosthetic foot to the alignment reference line: **30 mm**
	Connect the prosthetic foot and prosthetic socket using the chosen adapters. The instructions for use of the adapters must be observed.
	Determine the centre of the prosthetic socket with the 50:50 gauge. Align the prosthetic socket centrally to the alignment reference line. Socket flexion: **Individual residual limb flexion + 5°**
Frontal plane	
	Alignment reference line of prosthetic foot: **between big toe and second toe**

Bench alignment process	
	Alignment reference line of prosthetic socket: **along the lateral patella edge**
	Observe the abduction or adduction position.

TF bench alignment
► Observe the information in the prosthetic knee joint instructions for use.

Static Alignment

- Ottobock recommends checking the alignment of the prosthesis using the L.A.S.A.R. Posture and adapting it as needed.
- If necessary, the alignment recommendations (TF modular leg prostheses: 646F219*, TT modular leg prostheses: 646F336*) may be requested from Ottobock.

Dynamic Trial Fitting

- Adapt the alignment of the prosthesis in the frontal plane and the sagittal plane (e.g. by making angle or slide adjustments) to ensure an optimum gait pattern.
- **TT fittings:** Make sure that physiological knee movement in the sagittal and frontal plane is achieved when the leg begins to bear weight after the heel strike. Avoid medial movement of the knee joint. If the knee joint moves in the medial direction in the first half of the stance phase, move the prosthetic foot in the medial direction. If the medial movement occurs in the second half of the stance phase, reduce the exterior rotation of the prosthetic foot.
- Remove the plastic protector from the pyramid after completing the dynamic fitting and the walking exercises.

Optional: Installing the foam cover
The foam cover sits between the prosthetic socket and prosthetic foot. It is cut longer in order to compensate for the movements of the prosthetic foot and prosthetic knee joint. During flexion of the prosthetic knee joint, the foam cover undergoes posterior compression and anterior elongation. The foam cover should be stretched as little as possible in order to increase its service life. There is a connecting element (such as a connection plate, connection cap or connection cover) on the prosthetic foot.

Required materials: degreasing cleaner (e.g. 634A58 isopropyl alcohol), 636N9 contact adhesive or 636W17 plastic adhesive

1. Measure the length of the foam cover on the prosthesis and add the length allowance.
   TT prostheses: Distal allowance for movement of the prosthetic foot.
   TF prostheses: Allowance proximal of the knee rotation point for flexion of the prosthetic knee joint and distal allowance for movement of the prosthetic foot.
2. Cut the pre-shaped foam cover to length and fit it in the proximal area on the prosthetic socket.
3. Pull the foam cover over the prosthesis.

4. Set the connecting element onto the footshell or prosthetic foot. Depending on the version, the connecting element engages in the edge or rests on the foot adapter.
5. Install the prosthetic foot on the prosthesis.
6. Mark the outer contour of the connecting element on the distal face of the foam cover.
7. Disassemble the prosthetic foot and remove the connecting element.
8. Clean the connecting element using a degreasing cleaner.
9. Glue the connecting element onto the distal face of the foam cover according to the marked outer contour.
10. Let the glue dry (approx. 10 minutes).
11. Install the prosthetic foot and adapt the exterior cosmetic shape. Take into account compression caused by cosmetic stockings or SuperSkin.

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.

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.

Disposal
In some jurisdictions it is not permissible to dispose of the product with unsorted household waste. Improper disposal can be harmful to health and the environment. Observe the information provided by the responsible authorities in your country regarding return, collection and disposal procedures.

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

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.

CE conformity
The product meets the requirements of Regulation (EU) 2017/745 on medical devices. The CE declaration of conformity can be downloaded from the manufacturer’s website.

Technical data

Sizes [cm]	24	25	26	27	28	29	30
Heel height [mm]	10 ±5						
System height [mm]	71	71	81	81	81	87	87
Build height [mm]	89	89	99	99	99	105	105
Product weight without foots hell [g]	405	420	480	490	505	605	630
Max. body weight [kg]	75		100				
Mobility grade	3 + 4						

Documents / Resources

	ottobock 1C40 C-Walk Feet with Dynamic Behavior [pdf] Instruction Manual 1C40 C-Walk, Feet with Dynamic Behavior, 1C40, C-Walk Feet with Dynamic Behavior, 1C40 C -Walk Feet with Dynamic Behavior

References

- We help people maintain or regain their freedom of movement.