ottobock.

1C68 Triton side flex

CE

1

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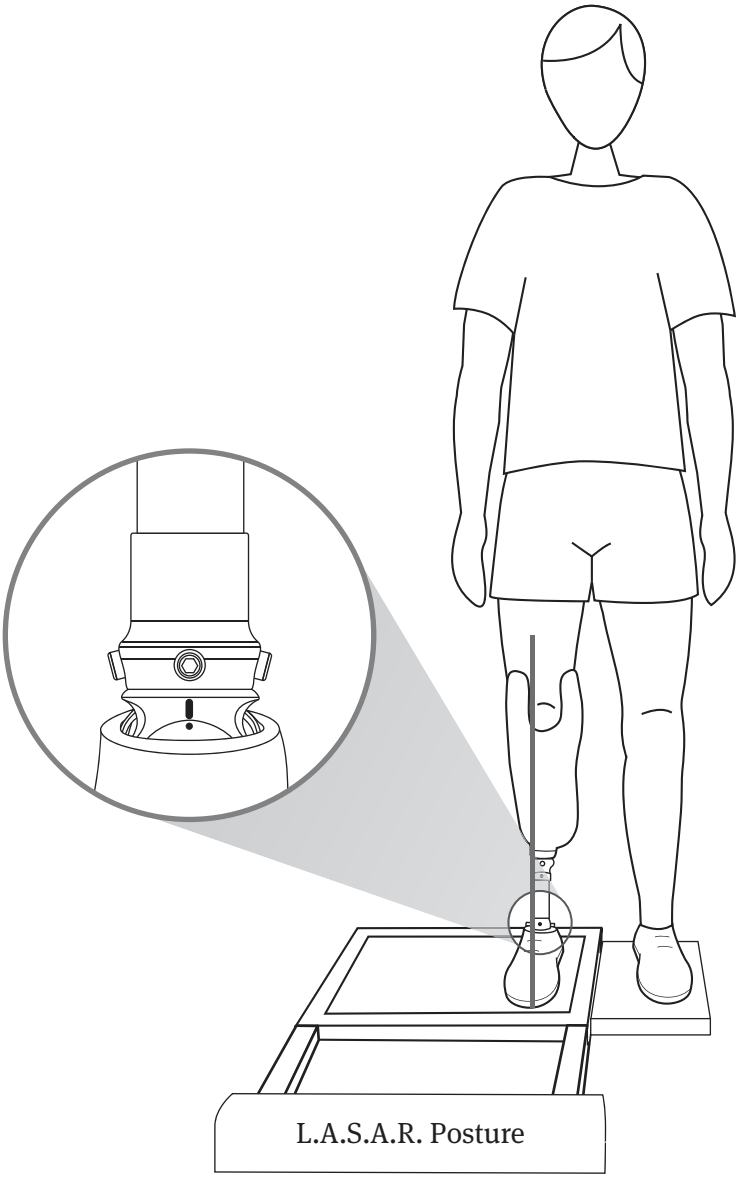
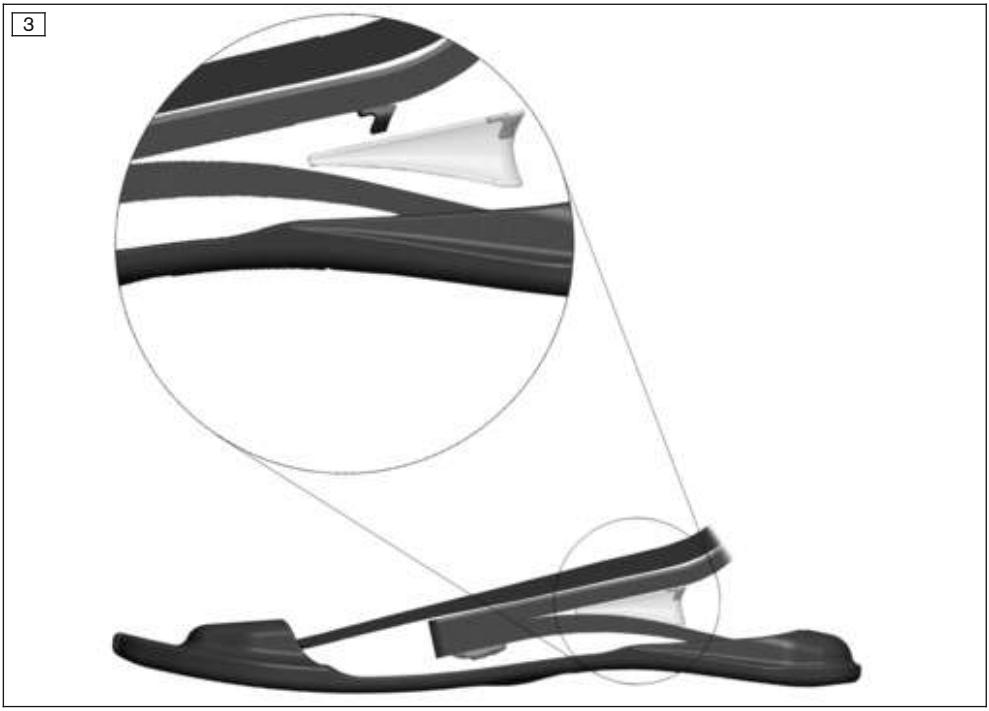


L.A.S.A.R. Posture

3



1 Product description

INFORMATION

Date of last update: 2021-02-12

- ► 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 in connection with the product, in particular a worsening of the state of health, to the manufacturer and to the relevant authority in your country.
- ► Please keep this document for your records.

1.1 Construction and Function

The 1C68 Triton side flex prosthetic foot adapts to uneven surfaces and enables full-surface ground contact even when the foot is not set down straight. It has an m-l unit (medial-lateral) with a titanium torsion bar spring that allows the foot to tilt sideways (inversion and eversion) by up to 10°. Additional buffers gently dampen the stop. Much lower moments of tilt and lateral compression forces are transferred to the residual limb thanks to this flexibility. This results in stabilisation, improved comfort and more natural adaptation to the ground.

Carbon and polymer spring elements permit perceptible plantar flexion at heel strike, a natural rollover movement and high energy return.

1.2 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.

Prohibited combination possibilities

- 3C60, 3C86, 3C96, 3C86-1, 3C96-1, 3C88, 3C98, 3C88-1, 3C98-1, 3C88-2, 3C98-2, 4R88

Limited combination options for Ottobock components

The prosthetic foot generates high moments in the ankle area. Use structural components with higher weight limits:

Body weight [kg]	up to 55	up to 75		up to 100		up to 125
Foot size [cm]	up to 26	up to 28	from 29	up to 28	from 29	up to 30
Structural component weight limit [kg]	**≥75**	**≥100**	**≥125**	**≥125**	**≥150**	**≥150**

Combination with mechatronic prosthetic knee joints	
For spring stiffness 4 from size 27	Contact Ottobock Customer Service before making a combination with a mechatronic prosthetic knee joint.

2 Intended use

2.1 Indications for use

The product is intended exclusively for lower limb exoprosthetic fittings.

2.2 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.

The product is recommended for mobility grade 3 (unrestricted outdoor walker) and mobility grade 4 (unrestricted outdoor walker with particularly high demands).

The table that follows shows the suitable spring stiffness of the prosthetic foot, matching the patient's body weight and the size of the prosthetic foot.

Spring stiffness									
Body weight [kg]	**Foot size [cm]**								
	22	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**
up to 55	1					–			
56 to 75	2								
76 to 100	3								
101 to 125	–		4						

2.3 Environmental conditions

Allowable environmental conditions
Temperature range: –10 °C to +45 °C (14 °F to 113 °F)
Chemicals/liquids: fresh water, salt water, perspiration, urine, soapsuds, chlorine water
Moisture: Submersion: max. 1 h in 3 m depth, relative humidity: no restrictions
Solids: Dust, occasional contact with sand
Clean the product after contact with humidity/chemicals/solids, in order to avoid increased wear and damage (see page 10**).**

Unallowable environmental conditions
Solids: Highly hygroscopic particles (e.g. talcum), continuous contact with sand
Chemicals/liquids: Acids, continuous use in liquid media

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

2.4 Service life

Prosthetic foot
Depending on the patient's level of activity, the service life of the product is 2 to 3 years.

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

3 Safety

3.1 Explanation of warning symbols

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

3.2 General safety instructions

⚠ CAUTION

Unallowable combination of prosthetic components
Risk of injury due to breakage or deformation of the product

- ► Only combine the product with prosthetic components that are approved for that purpose.
- ► Based on the instructions for use of the prosthetic components, verify that they may be combined with each other.

⚠ CAUTION

Excessive strain on the product

Risk of injury due to breakage of load-bearing components

- ► Use the product according to the specified area of application (see page 5).

⚠ CAUTION

Exceeding the service life and reuse on another patient

Risk of injury due to loss of functionality as well as damage to the product

- ► Ensure that the approved service life is not exceeded.
- ► Only use the product on a single patient.

⚠ CAUTION

Mechanical damage to the product

Risk of injury due to change in or loss of functionality

- ► Use caution when working with the product.
- ► If the product is damaged, check it for proper function and readiness for use.
- ► In case of changes in or loss of functionality, do not continue using the product (see "Signs of changes in or loss of functionality during use" in this section).
- ► Take any necessary measures (e.g. repair, replacement, inspection by the manufacturer's customer service, etc.).

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

Use under unallowable environmental conditions

Damage to product due to unallowable environmental conditions

- ► Do not expose the product to unallowable environmental conditions.
- ► If the product has been exposed to unallowable environmental conditions, check it for damage.
- ► If damage is apparent or in case of doubt, do not continue using the product.
- ► Take suitable measures if required (e.g. cleaning, repair, replacement, inspection by the manufacturer or a specialist workshop, etc.).

Signs of changes in or loss of functionality during use

Reduced spring effect (e.g. decreased forefoot resistance or changed rollover behaviour) or delamination of the carbon spring are indications of loss of functionality. Unusual noises can indicate a loss of functionality.

4 Scope of delivery

Quantity	Designation	Reference number
1	Instructions for use	–
1	Prosthetic foot	–
1	Protective sock (black)	SL=Spectra-Sock-7
1	Heel wedge kit (soft, hard)	2F60*

Spare parts/accessories (not included in the scope of delivery)	
Designation	**Reference number**
Footshell	2C6*
Connection cap	2C19*, 2C20*
Protective sock (white)	SL=Spectra-Sock

5 Preparing the product for use

⚠ CAUTION

Incorrect alignment, assembly or adjustment
Injuries due to incorrectly installed or adjusted as well as damaged prosthetic components
► Observe the alignment, assembly and adjustment instructions.

NOTICE

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

5.1 Alignment

INFORMATION

There is a plastic adapter cover on the proximal connection of the prosthetic foot. This protects the connecting section from scratches during the alignment and trial fitting.
► Remove the adapter cover before the patient leaves the workshop/fitting area.

INFORMATION

The resistance of the m-l unit is permanently set and cannot be changed. Do not remove the cover from the m-l unit.

5.1.1 Applying/removing the footshell

INFORMATION

► Pull the protective sock over the prosthetic foot to prevent noises in the footshell.
► Always use the prosthetic foot with the footshell.

► Apply or remove the footshell as described in the footshell instructions for use.

5.1.2 Bench Alignment

TT bench alignment

Bench alignment process
Required materials: 662M4 goniometer, 743S12 heel height measuring device, 743A80 50:50 gauge, alignment tool (e. g. 743L200 L.A.S.A.R. Assembly or 743A200 PROS.A. Assembly)

Bench alignment process		
Perform the assembly and alignment of the prosthetic components in the alignment tool according to the following specifications:		
Sagittal plane		
❶	Heel height: **Effective heel height** (shoe heel height **–** sole thickness of forefoot) **+ 5 mm**	
❷	Exterior foot rotation should not exceed **5°**. Otherwise the inversion/eversion of the prosthetic foot could influence the rollover behaviour and the frontal knee stability in the stance phase.	
❸	a–p positioning, middle of the prosthetic foot to the alignment reference line:	
	Foot size [cm]:	**Anterior placement, middle of foot to alignment reference line [mm]:**
	22 to 25	25
	26 to 28	30
	29 to 30	35
❹	Connect the prosthetic foot and prosthetic socket to the chosen adapters. The instructions for use of the adapters must be observed.	
❺	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		
❻	Alignment reference line of prosthetic foot: **between big toe and second toe** Alignment reference line of prosthetic socket: **along the lateral patella edge**	
❼	Observe the abduction or adduction position.	

TF bench alignment

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

5.1.3 Static Alignment

INFORMATION

Frontal plane, hip width stance: Align the prosthesis so that the m-l unit is in the neutral position (see fig. 2). Thus the entire available movement range can be used for inversion and eversion.

- 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.

5.1.4 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 adapter cover from the prosthetic foot after completion of the dynamic trial fitting and gait training exercises.

5.1.4.1 Optimising the heel characteristics

The heel characteristics are optimised by using heel wedges. In case the heel strike or heel contact is too soft during the mid-stance phase, the heel can be stiffened by means of a heel wedge. Two heel wedges are available (transparent=soft, black=hard). Ottobock recommends starting with the transparent heel wedge.

1) Align the recesses in the heel wedge, in the proximal and posterior directions.

2) Slide the heel wedge into position between the attachment spring and heel spring until it engages (see fig. 3).
3) To remove the heel wedge, push it out to the side.

5.2 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.

6 Cleaning

> **Allowable cleaning agent:** pH neutral soap (e.g. 453H10 Derma Clean)

1) **NOTICE! To avoid product damage, only use the allowable cleaning agents.**
   Clean the product with clear fresh water and a pH neutral soap.
2) Rinse the soap away with clear fresh water. In doing so, rinse the footshell until all dirt has been removed.
3) Dry the product with a soft cloth.
4) Allow to air dry in order to remove residual moisture.

7 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.

8 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.

9 Legal information

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

9.1 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.

9.2 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.

10 Technical data

1C68 Triton side flex										
Sizes [cm]		**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**
With slim footshell	**Heel height [mm]**	15 ± 5						–		
	System height [mm]	57	57	58	63	63	68	–		
	Weight [g]	620	690	720	770	785	835	–		
With normal footshell	**Heel height [mm]**	–		10 ± 5						
	System height [mm]	–		64	66	68	72	72	75	78
	Weight [g]	–		730	780	805	845	870	990	1025
Max. body weight [kg]		100		125						
Mobility grade		3 and 4								

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