



114S1=* MyFit TT

EN Instructions for use 4

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4Y424=M6x30



Use 4R415 only



**Use 501S128=M6x25
or 501S41=M6x25**

Loctite 241, 10 Nm
Start on posterior screws



1 Product description

INFORMATION

Date of last update: 2022-11-01

- ▶ 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.

1.1 Construction and Function

The MyFit TT prosthetic socket is custom fabricated using the 3D printing process based on the patient's data. The definitive prosthetic socket has an integrated four-hole connector for connection to the modular system and can be used for passive and active vacuum prostheses.

Product	Fabrication process	Material
114S1-1-*	Selective laser sintering	Polyamide 11 (PA11)
114S1-5-*	Multi Jet Fusion	Polyamide 12 (PA12)

Variants

The MyFit TT prosthetic socket is available in several variants:

- **Outlet valve, pre-assembled:** The prosthetic socket was ordered with a specific valve. It has a recess and the valve has already been glued in.
- **Outlet valve included:** The prosthetic socket was ordered with a specific valve. It has a recess and a hole to match the valve. The valve is included.
- **Recess for outlet valve present:** The prosthetic socket was ordered for use with a valve. It has a recess but there is no hole. The material may be drilled through in the recess to mount a valve. A socket connector may also be installed above the contour of the prosthetic socket.
- **No recess:** The prosthetic socket has no recess. A valve or socket connector can only be installed above the contour of the prosthetic socket.

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.

- **Liner without textile coating:** Pull a thin residual limb sock over the liner.
- Always use the prosthetic socket with a liner.

Limited combination options for Ottobock components

Thigh sleeve	Not allowed
Modular system for children	Not compatible

Socket adapter

4R51, 4R54, 4R55, 4R77	Only with 501S128 stainless steel screws
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Prosthetic feet

1E90, 1E91, 1E92, 1E93	Not allowed
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Recommended combinations

Socket adapter

4R22, 4R23, 4R37, 4R51, 4R54, 4R55, 4R73=A, 4R73=D, 4R74=AL, 4R77, 4R95

2 Intended use

2.1 Indications for use

The product is intended exclusively for exoprosthetic fittings after a transtibial amputation.

2.2 Contraindications

Indications must be determined by the physician.

2.2.1 Absolute Contraindications

- Postoperative oedema
- Ultra-short residual limb with a length of less than 10 cm from the medial tibial plateau to the end of the residual limb
- Ultra-long residual limb with a length greater than 3/4 of the distance from the medial tibial plateau to the centre of the medial malleolus on the contralateral side

2.2.2 Relative Contraindications

The following accompanying symptoms require consultation with a physician: skin diseases and injuries, especially in case of inflammatory changes, prominent scars with swelling, reddening and hyperthermia in the area treated; lymphatic flow disorders, including unclear soft tissue swelling; sensory and circulatory disorders.

2.3 Area of application

The MOBIS classification describes the mobility grade and body weight, and makes it easy to identify compatible components.



The product is recommended for mobility grade 1 (indoor walker), mobility grade 2 (restricted outdoor walker), mobility grade 3 (unrestricted outdoor walker) and mobility grade 4 (unrestricted outdoor walker with particularly high demands).

- **With 501S128 stainless steel screws:** Approved for a body weight up to **max. 100 kg**.
- **With 501S41 steel screws:** Approved for a body weight up to **max. 125 kg**.

2.4 Environmental conditions

Allowable environmental conditions

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

Temperature range (Use): -10 °C to +45 °C

Moisture: relative humidity: 20% to 90%, non-condensing

Prohibited environmental conditions

Chemicals/liquids: salt water, perspiration, urine, acids, soapsuds, chlorine water

Solids: sand, highly hygroscopic particles (e.g. talcum)

Contact: heat, embers or fire; oils, ointments or lotions containing oils or acids

Other environmental conditions

UV light Not resistant

Hydrolysis Not resistant

With 501S41 steel screws

Prohibited environmental conditions
Chemicals/liquids: fresh water
Solids: dust

With 501S128 stainless steel screws




Allowable environmental conditions
Chemicals/liquids: fresh water as dripping water, occasional contact with salty air (e.g. near the ocean)
Solids: dust
Prohibited environmental conditions
Solids: dust in high concentrations (e.g. construction site)

2.5 Lifetime

This product was tested by the manufacturer with 3 million load cycles. Depending on the user's activity level, this corresponds to a maximum lifetime of 5 years.

3 Safety

3.1 Explanation of warning symbols

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

3.2 General safety instructions



Risk of injury and risk of product damage

- ▶ Note the combination possibilities/combination exclusions in the instructions for use of the products.
- ▶ Observe the maximum lifetime of the product.
- ▶ 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).
- ▶ 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).
- ▶ Follow the maintenance instructions (see page 9).

Skin irritation, formation of eczema or infections due to contamination with germs

- ▶ Clean the product regularly according to the cleaning instructions.
- ▶ Use the product for a single patient only.

4 Scope of delivery

Quantity	Designation	Reference number
1	Instructions for use	–

Quantity	Designation	Reference number
1	Prosthetic socket	-
1	Spacer plate (pre-assembled)	4R415
4	Cross dowels (pre-assembled)	4Y424=M6x30
4	Countersunk screws, stainless steel (pre-assembled)	501S128=M6x25
4	Countersunk screws	501S41=M6x25

5 Preparing the product for use

⚠ CAUTION

Modifying the product

Risk of injury due to reduced strength, stability and incorrect forming

- ▶ Do not modify the product (e.g. by sanding, heating, deforming).

INFORMATION

Gluing in padding materials for volume management

- ▶ Use Ottobock 636N9 contact adhesive to glue in pads.

5.1 Mounting the adapter

Countersunk screws and a pressure plate that must be used for assembling a socket adapter are included with the prosthetic socket.

- > **Required materials:** 710D20 torque wrench, 636K13 Loctite 241, **4R415** spacer plate and **501S128=M6x25** or **501S41=M6x25** countersunk screws of the prosthetic socket
- > **CAUTION! Use only the countersunk screws included with the prosthetic socket. The countersunk screws of the socket adapter are too short; risk of injury.**
 - 1) Unscrew the countersunk screws from the cross dowels of the prosthetic socket.
 - 2) Position the spacer plate on the connecting section
 - 3) **If a pressure plate is part of the socket adapter:** Set the pressure plate of the adapter **aside** and ignore it.
 - 4) Set the adapter onto the spacer plate.
 - 5) **Optional:** Align the pyramid receiver or the pyramid.
 - 6) **NOTICE! To prevent damage, do not apply Loctite to plastic parts.**
Apply Loctite to the threads of the screws.
 - 7) Screw in the 2 posterior screws and tighten them (tightening torque: **10 Nm**).
 - 8) Screw in the 2 anterior screws and tighten them (tightening torque: **10 Nm**).

5.2 Optional: Installing the valve or socket connector

The prosthetic socket may be used for active and passive vacuum prostheses. If the prosthetic socket was not supplied with a preinstalled valve or socket connector, assembly can be carried out as follows:

- 1) **If there is a hole in the prosthetic socket:** Use the hole to install the appropriate valve/socket connector.
- 2) **If there is no hole:** Drill a hole in the recess for the valve. If there is no recess, drill above the contour line.
- 3) Mount the valve or socket connector according to the information in its instructions for use.

5.3 Alignment

Align the prosthetic socket in the prosthesis.

Sagittal

- 1) **TIP: Apply masking tape to the prosthetic socket and mark on it. The masking tape with the markings can be easily removed.**
Determine the centre of the prosthetic socket proximal and distal with the 50:50 gauge and mark the centre line.
- 2) Mark the socket reference point on the centre line: **at the height of the centre of the patella.**
→ The alignment reference line runs vertically through the socket reference point.
- 3) Adjust the socket flexion by rotating around the socket reference point: **individual residual limb flexion + 5°**

Frontal

- 1) Position the prosthetic foot in the frontal plane so that the alignment reference line runs between the big toe and second toe.
- 2) Position the prosthetic socket so that the alignment reference line runs along the lateral patella edge.
- 3) Observe the abduction or adduction position.

5.4 Installing the reduction plates

The volume of the prosthetic socket can be changed by inserting reduction plates. The reduction plates are custom fabricated and fitted perfectly into the prosthetic socket.

- > **Required materials:** degreasing cleaner (e.g. isopropyl alcohol), 633D5=50 double-sided adhesive tape
- 1) Clean the outwardly curved side of the reduction plate and the inside of the prosthetic socket using a degreasing cleaner.
 - 2) Apply a piece of double-sided adhesive tape to the reduction plate.
 - 3) Insert the reduction plate into the prosthetic socket, position it correctly and press it into place (see fig. 2).

6 Use

6.1 Donning the prosthesis

CAUTION

Incorrect application to the body

Falling due to incorrect application

- ▶ Ensure that the product is applied properly.

- > **Prerequisite:** The sealing sleeve is attached to the prosthetic socket and folded downwards over the socket brim.
 - > **Prerequisite:** The liner (and, if necessary, a residual limb sock) has been applied.
- 1) **If a gaiter is being used:** Wrap the gaiter down over the socket brim.
 - 2) Slide the residual limb into the prosthetic socket.
 - 3) **If a gaiter is being used:** Roll the gaiter over the residual limb without wrinkles, air pockets or shifting the soft tissue.
 - 4) Roll the sealing sleeve onto the thigh without wrinkles, air pockets and shifting the soft tissue.

6.2 Doffing the prosthesis

- 1) Roll the sealing sleeve and gaiter from the thigh down over the socket brim.
- 2) Pull the residual limb out of the prosthetic socket.

7 Cleaning and Care

NOTICE

Use of improper cleaning agents

Damage to the product due to use of improper cleaning agents

- ▶ Only clean the product with the approved cleaning agents.

- 1) Clean the inside and outside of the prosthetic socket with a damp cloth and mild soap (e.g. 453H10=1 Ottobock Derma Clean).
- 2) Dry the prosthetic socket with a lint-free cloth and allow it to air dry fully.

8 Maintenance

- ▶ A visual inspection and functional test of the prosthetic components should be performed after the first 30 days of use.
- ▶ During regular inspection: Inspect the prosthesis for signs of wear and check its function.
- ▶ Conduct annual safety inspections.

9 Disposal

Do not 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.

10 Legal information

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

10.1 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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