

Prosthetic Foot SACH 2.0

Instructions for Use

Please read this document carefully and follow the safety instructions.

Item codes: see bottom of document



Functions and benefits

The Rehab'Impulse Prosthetic Foot SACH 2.0 (Solid-Ankle Cushion-Heel) is made of soft thermoplastic polyurethane foam moulded over a polyoxymethylene core. It is designed to provide the user with a cushioned heel and a slightly flexible keel that offers a smooth rolling action during stance phase. The cosmetic toe allows wearing of sandals and gives the foot a natural appearance.

Intended use

This product is intended for prosthetic fitting on adults and children with activity levels K1 (household ambulator) and K2 (limited community ambulator).

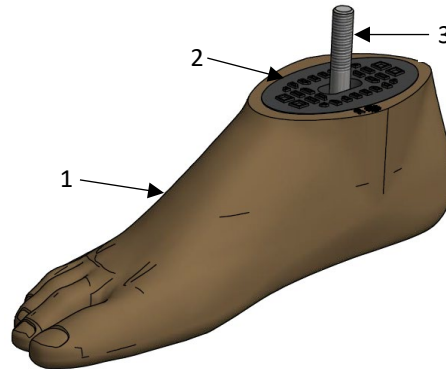
Sizes 14 to 17 (child): Approved for a body weight up to 45kg (P2)
Sizes 18 to 21 (child): Approved for a body weight up to 60kg (P3)
Sizes 22 to 27 (adult): Approved for a body weight up to 80kg (P4)
Size 28 (adult): Approved for a body weight up to 100kg (P5)

Residual risks, contraindications

n/a

Device specifications

1. Foot Shell (TPU foam)
2. Keel
3. Screw and Washer



Training

Please follow the ICRC manufacturing guidelines for transtibial or trans-femoral prosthesis:

<https://www.icrc.org/en/doc/assets/files/other/eng-transtibial.pdf>

<https://www.icrc.org/en/doc/assets/files/other/eng-transfemoral.pdf>

Storage/handling

- Store product in dry conditions
- Store at room temperature (ideally between 15°C and 25°C)
- Keep out of direct sunlight or other sources of light with a high UV content
- Take precautionary measures against sparking and fire

Environmental conditions

Recommended environmental conditions:

- Temperature range for use : -10°C to 60°C (14°F to 140°F)
- Relative humidity 0% to 90%, no condensing situation
- Avoid exposure to dust, sand, salt water, acids and urine

Included in delivery

- 1x Foot SACH 2.0
- Adult: 1x Socket head cap screw, stainless steel, M10x80mm
- Child: 1x Socket head cap screw, stainless steel, M8x80mm
- Adult: 1x Ribbed lock washer M10
- Child: 1x Ribbed lock washer M8

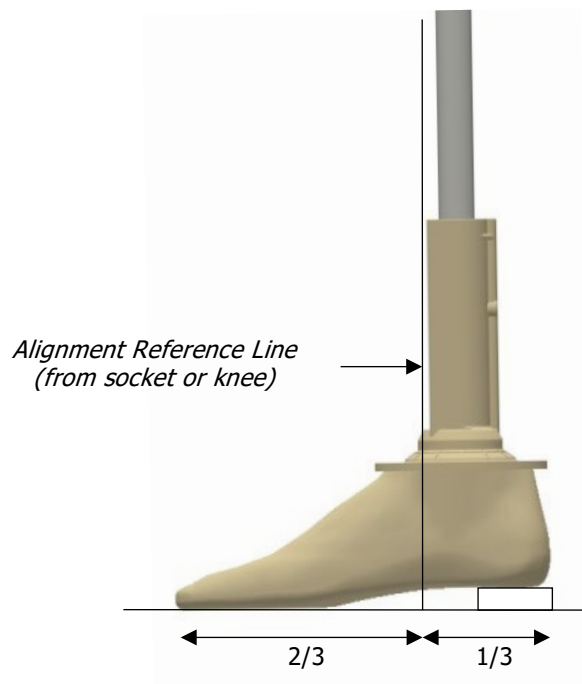
Bench alignment

The ankle alignment system allows dorsal and plantar flexion and rotational alignment so that the prosthesis can be adjusted to the user's anatomy.

All alignment should be done with the user's shoe fitted on the prosthetic foot. Alternatively, use a spacer under the heel of the prosthetic foot representing the effective heel height of the shoe.

The alignment can be adjusted for heel heights between 0mm and 20mm on adult sizes, but a heel height of 10 mm is recommended.

- It is recommended to position the alignment reference line from the socket at 1/3 of the foot length starting from the heel
- An external rotation of 5 to 7° is recommended



Static Alignment

Static alignment should be verified with the user standing in upright position, with both shoes flat on the floor and with his weight equally distributed on both legs. For more security, alignment verification is recommended to be done with the user standing between parallel bars.

Dynamic alignment

Observe the user's gait between parallel bars. Check for a smooth transition from heel strike to toe-off. When standing upright, make sure the user's heel and toes are both touching the floor and that they are evenly loaded.

In the case of transtibial amputees, make sure that the physiological knee flexion is achieved in stance phase.

Maintenance

This device is designed for low maintenance. The prosthetic component should be inspected after the first 30 days of use. After this period it is recommended to inspect the device at least every six months for signs of unusual wear. If the device is used in a corrosive environment or subjected to excessive moisture, this period shall be shortened.

Cleaning and care

This device can be cleaned using mild soap or solvent followed by rinsing with water. Allow device to dry completely before use. Avoid strong acid (pH=4 or less) and oxidizing agents.

This device has been engineered for a service life of 2-3 years depending on user's activity level. Scheduling of regular maintenance lies within the discretion of the service provider. The user shall discontinue use and report to the service provider in the event of any breakage, failure, change in function, or any unusual wear.

Disposal

Users are advised to return defective or worn out products to their clinician.

Please note that disposal of this product with regular domestic waste may not be permitted in all countries of use. Not following the disposal regulations of the responsible authorities may have a detrimental impact on health and environment.

Reusability

This device is intended for single-use only.

Compatibilities

The prosthetic foot SACH 2.0 is compatible with the Rehab'Impulse modular system.

Sizes 14-21:

- 74-00223 Module System, Transfemoral, Child
- 74-00221 Module System, Transtibial, Child
- 74-00404 Module System, Long Stump, Child

Sizes 22-28:

- 74-00134 Module System, Transfemoral, Adult
- 74-00137 Module System, Transtibial, Adult
- 74-00229 Module System, Long Stump, Adult
- 74-00227 Module System, M10 Connector, Child

Spare parts

Please contact manufacturer.

Warnings, precautions

Using the product without following these instructions for use may cause injury or harm to the user and/or damage the product. This device shall be fitted by trained prosthetists only. Ensure that the approved service life of 2 million cycles is not exceeded. Do not expose the product to environmental conditions other than the one specified in this instruction. If damage is apparent or in case of doubt, do not continue using the product. Take suitable measures as required (e.g. cleaning, repair, replacement by trained P&O personal). In case of contact with salt water, acid, abrasive substances or any substance identified above, promptly clean the product in accordance with the chapter "Cleaning and Care".

Compliance

This device has been tested according to the ISO 10328 standard to 2 million load cycles.

Sizes 14 to 17 (child): Approved for a body weight up to 45kg (P2)

Sizes 18 to 21 (child): Approved for a body weight up to 60kg (P3)

Sizes 22 to 27 (adult): Approved for a body weight up to 80kg (P4)

Size 28 (adult): Approved for a body weight up to 100kg (P5)

Depending on the user's activity level, this corresponds to a service life of two to four years. It is recommended to carry out regular safety checks.

CE Conformity

This product meets the requirements of the EU MDR 2017-745 guidelines for medical products. It has been classified as a Class I product according to the classification criteria outlined in Appendix VIII of the guidelines.

Item codes

REF	Description English
74-00157	Foot, SACH 2.0, Size 14, Left, Olive
74-00161	Foot, SACH 2.0, Size 14, Left, Terra
74-00159	Foot, SACH 2.0, Size 14, Right, Olive
74-00163	Foot, SACH 2.0, Size 14, Right, Terra
74-00165	Foot, SACH 2.0, Size 15, Left, Olive
74-00169	Foot, SACH 2.0, Size 15, Left, Terra
74-00167	Foot, SACH 2.0, Size 15, Right, Olive
74-00171	Foot, SACH 2.0, Size 15, Right, Terra
74-00173	Foot, SACH 2.0, Size 16, Left, Olive
74-00177	Foot, SACH 2.0, Size 16, Left, Terra
74-00175	Foot, SACH 2.0, Size 16, Right, Olive
74-00179	Foot, SACH 2.0, Size 16, Right, Terra
74-00181	Foot, SACH 2.0, Size 17, Left, Olive
74-00185	Foot, SACH 2.0, Size 17, Left, Terra
74-00183	Foot, SACH 2.0, Size 17, Right, Olive
74-00187	Foot, SACH 2.0, Size 17, Right, Terra
74-00189	Foot, SACH 2.0, Size 18, Left, Olive
74-00193	Foot, SACH 2.0, Size 18, Left, Terra
74-00191	Foot, SACH 2.0, Size 18, Right, Olive
74-00195	Foot, SACH 2.0, Size 18, Right, Terra
74-00197	Foot, SACH 2.0, Size 19, Left, Olive
74-00201	Foot, SACH 2.0, Size 19, Left, Terra
74-00199	Foot, SACH 2.0, Size 19, Right, Olive
74-00203	Foot, SACH 2.0, Size 19, Right, Terra
74-00205	Foot, SACH 2.0, Size 20, Left, Olive
74-00209	Foot, SACH 2.0, Size 20, Left, Terra
74-00207	Foot, SACH 2.0, Size 20, Right, Olive
74-00211	Foot, SACH 2.0, Size 20, Right, Terra
74-00213	Foot, SACH 2.0, Size 21, Left, Olive
74-00217	Foot, SACH 2.0, Size 21, Left, Terra

REF	Description English
74-00215	Foot, SACH 2.0, Size 21, Right, Olive
74-00219	Foot, SACH 2.0, Size 21, Right, Terra
74-00139	Foot, SACH 2.0, Size 22, Left, Olive
74-00143	Foot, SACH 2.0, Size 22, Left, Terra
74-00141	Foot, SACH 2.0, Size 22, Right, Olive
74-00145	Foot, SACH 2.0, Size 22, Right, Terra
74-00147	Foot, SACH 2.0, Size 23, Left, Olive
74-00151	Foot, SACH 2.0, Size 23, Left, Terra
74-00149	Foot, SACH 2.0, Size 23, Right, Olive
74-00153	Foot, SACH 2.0, Size 23, Right, Terra
74-00087	Foot, SACH 2.0, Size 24, Left, Olive
74-00091	Foot, SACH 2.0, Size 24, Left, Terra
74-00089	Foot, SACH 2.0, Size 24, Right, Olive
74-00093	Foot, SACH 2.0, Size 24, Right, Terra
74-00095	Foot, SACH 2.0, Size 25, Left, Olive
74-00099	Foot, SACH 2.0, Size 25, Left, Terra
74-00097	Foot, SACH 2.0, Size 25, Right, Olive
74-00101	Foot, SACH 2.0, Size 25, Right, Terra
74-00103	Foot, SACH 2.0, Size 26, Left, Olive
74-00108	Foot, SACH 2.0, Size 26, Left, Terra
74-00106	Foot, SACH 2.0, Size 26, Right, Olive
74-00110	Foot, SACH 2.0, Size 26, Right, Terra
74-00112	Foot, SACH 2.0, Size 27, Left, Olive
74-00116	Foot, SACH 2.0, Size 27, Left, Terra
74-00114	Foot, SACH 2.0, Size 27, Right, Olive
74-00118	Foot, SACH 2.0, Size 27, Right, Terra
74-00120	Foot, SACH 2.0, Size 28, Left, Olive
74-00124	Foot, SACH 2.0, Size 28, Left, Terra
74-00122	Foot, SACH 2.0, Size 28, Right, Olive
74-00126	Foot, SACH 2.0, Size 28, Right, Terra

IFU ID and date

IFU-Foot-SACH2.0-EN-V3.0 – 10.03.2021



alfaset
Rue des Terreaux 48
CH-2300 La-Chaux-de-Fonds
Switzerland
+41 32 967 96 50
www.alfaset.ch
contact@alfaset.ch

