

Prosthetic Foot SACH 2.0

Instructions for Use

Please read this document carefully and follow the safety instructions.

Item codes: see bottom of document



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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).

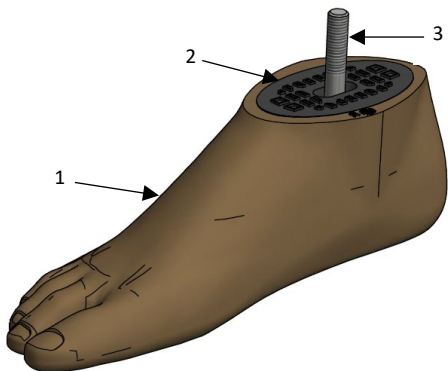
- Sizes 14 to 17 (child): Approved for a body weight up to 45kg (P2)
- Sizes 18 to 21 (child): Approved for a body weight up to 60kg(P3)
- Sizes 22 to 25 (adult): Approved for a body weight up to 80kg (P4)
- Sizes 26 to 28 (adult): Approved for a body weight up to 100kg (P5)

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
- Keep in original packaging before use

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

Assembly instructions

- Place ankle washer on foot
- Ensure that foot pattern engages in recesses of ankle washer
- Place ribbed lock washer on screw
- Insert screw through foot and ankle washer and engage in thread of ankle component
- Align the foot according to users anatomy (see alignment section below)
- Tighten screw applying a tightening torque of 30Nm on adult sizes and 20Nm on children sizes
- Verify alignment

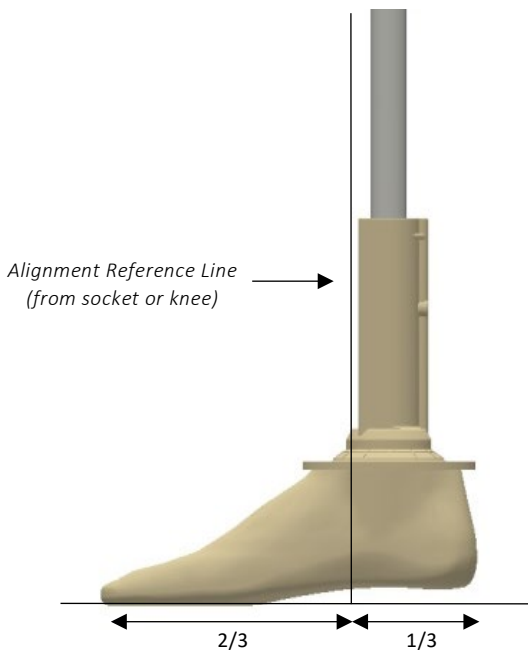
Bench alignment

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 Transfemoral Alignment Kit, Child
- 74-00221 Transtibial Alignment Kit, Child
- 74-00404 Transtibial Alignment Kit, Child,
Long Stump

Sizes 22-28:

- 74-00134 Transfemoral Alignment Kit, Adult
- 74-00137 Transtibial Alignment Kit, Adult
- 74-00229 Transtibial Alignment Kit, Adult,
Long Stump
- 74-00227 Transfemoral Alignment Kit, Child,
Connector for Adult Foot

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 25 (adult): Approved for a body weight up to 80kg (P4)
- Sizes 26 to 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, Olive, Size 14 (Child), Left
74-00159	Foot SACH 2.0, Olive, Size 14 (Child), Right
74-00165	Foot SACH 2.0, Olive, Size 15 (Child), Left
74-00167	Foot SACH 2.0, Olive, Size 15 (Child), Right
74-00173	Foot SACH 2.0, Olive, Size 16 (Child), Left
74-00175	Foot SACH 2.0, Olive, Size 16 (Child), Right
74-00181	Foot SACH 2.0, Olive, Size 17 (Child), Left
74-00183	Foot SACH 2.0, Olive, Size 17 (Child), Right
74-00189	Foot SACH 2.0, Olive, Size 18 (Child), Left
74-00191	Foot SACH 2.0, Olive, Size 18 (Child), Right
74-00197	Foot SACH 2.0, Olive, Size 19 (Child), Left
74-00199	Foot SACH 2.0, Olive, Size 19 (Child), Right
74-00205	Foot SACH 2.0, Olive, Size 20 (Child), Left
74-00207	Foot SACH 2.0, Olive, Size 20 (Child), Right
74-00213	Foot SACH 2.0, Olive, Size 21 (Child), Left
74-00215	Foot SACH 2.0, Olive, Size 21 (Child), Right
74-00139	Foot SACH 2.0, Olive, Size 22 (Adult), Left
74-00141	Foot SACH 2.0, Olive, Size 22 (Adult), Right
74-00147	Foot SACH 2.0, Olive, Size 23 (Adult), Left
74-00149	Foot SACH 2.0, Olive, Size 23 (Adult), Right
74-00087	Foot SACH 2.0, Olive, Size 24 (Adult), Left
74-00089	Foot SACH 2.0, Olive, Size 24 (Adult), Right
74-00095	Foot SACH 2.0, Olive, Size 25 (Adult), Left
74-00097	Foot SACH 2.0, Olive, Size 25 (Adult), Right
74-00103	Foot SACH 2.0, Olive, Size 26 (Adult), Left
74-00106	Foot SACH 2.0, Olive, Size 26 (Adult), Right
74-00112	Foot SACH 2.0, Olive, Size 27 (Adult), Left

74-00114	Foot SACH 2.0, Olive, Size 27 (Adult), Right
74-00120	Foot SACH 2.0, Olive, Size 28 (Adult), Left
74-00122	Foot SACH 2.0, Olive, Size 28 (Adult), Right
74-00161	Foot SACH 2.0, Terra, Size 14 (Child), Left
74-00163	Foot SACH 2.0, Terra, Size 14 (Child), Right
74-00169	Foot SACH 2.0, Terra, Size 15 (Child), Left
74-00171	Foot SACH 2.0, Terra, Size 15 (Child), Right
74-00177	Foot SACH 2.0, Terra, Size 16 (Child), Left
74-00179	Foot SACH 2.0, Terra, Size 16 (Child), Right
74-00185	Foot SACH 2.0, Terra, Size 17 (Child), Left
74-00187	Foot SACH 2.0, Terra, Size 17 (Child), Right
74-00193	Foot SACH 2.0, Terra, Size 18 (Child), Left
74-00195	Foot SACH 2.0, Terra, Size 18 (Child), Right
74-00201	Foot SACH 2.0, Terra, Size 19 (Child), Left
74-00203	Foot SACH 2.0, Terra, Size 19 (Child), Right
74-00209	Foot SACH 2.0, Terra, Size 20 (Child), Left
74-00211	Foot SACH 2.0, Terra, Size 20 (Child), Right
74-00217	Foot SACH 2.0, Terra, Size 21 (Child), Left
74-00219	Foot SACH 2.0, Terra, Size 21 (Child), Right
74-00143	Foot SACH 2.0, Terra, Size 22 (Adult), Left
74-00145	Foot SACH 2.0, Terra, Size 22 (Adult), Right
74-00151	Foot SACH 2.0, Terra, Size 23 (Adult), Left
74-00153	Foot SACH 2.0, Terra, Size 23 (Adult), Right
74-00091	Foot SACH 2.0, Terra, Size 24 (Adult), Left
74-00093	Foot SACH 2.0, Terra, Size 24 (Adult), Right
74-00099	Foot SACH 2.0, Terra, Size 25 (Adult), Left
74-00101	Foot SACH 2.0, Terra, Size 25 (Adult), Right
74-00108	Foot SACH 2.0, Terra, Size 26 (Adult), Left
74-00110	Foot SACH 2.0, Terra, Size 26 (Adult), Right

74-00116	Foot SACH 2.0, Terra, Size 27 (Adult), Left
74-00118	Foot SACH 2.0, Terra, Size 27 (Adult), Right
74-00124	Foot SACH 2.0, Terra, Size 28 (Adult), Left
74-00126	Foot SACH 2.0, Terra, Size 28 (Adult), Right

IFU ID and date

74-02069-IFU-Foot-SACH2.0-EN-V6.0 – 20.04.2023



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