Rehab Impulse™ Promoting Independent Lifestyle

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Transtibial Alignment Kit for Long Stump, Adult

Instructions for Use

Please read this document carefully and follow the safety instructions.

Functions and benefits

The Rehab'Impulse Transtibial Alignment Kit for Long Stump, Adult permits prosthetic fitting for more distal levels of amputation of the lower extremities. The transtibial alignment kit consists of a set of components allowing different alignment configurations.

Intended use

This product is intended for prosthetic fitting of adults. This product is not intended for excessive physical activities.

Approved for a body weight of up to 80 kg (P4)

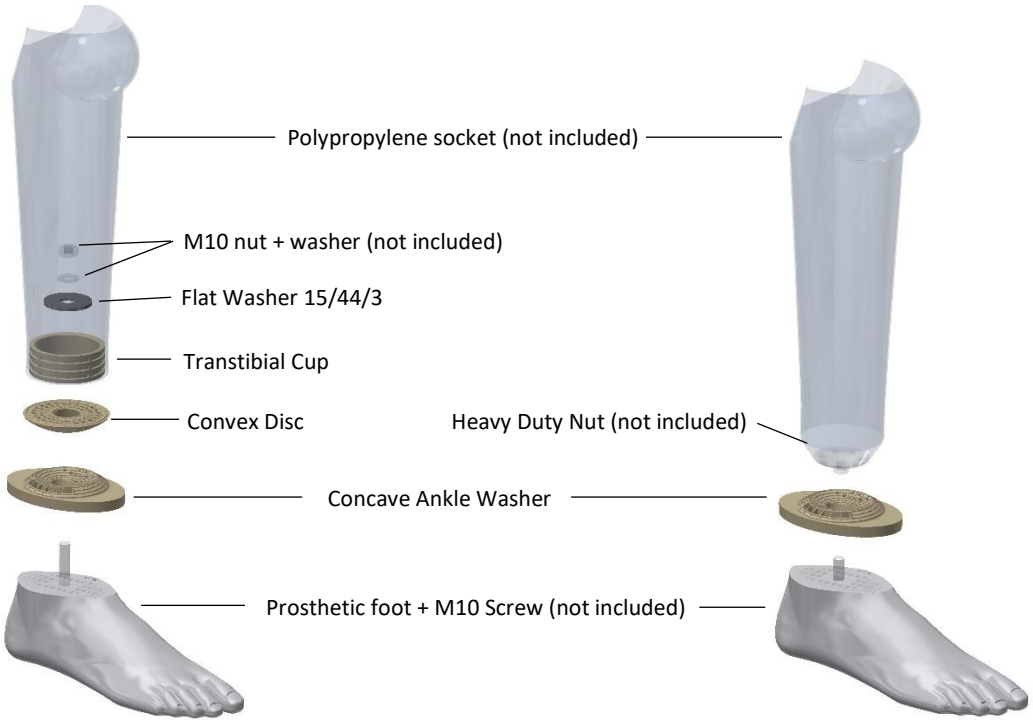
Residual risks, contraindications

n/a

Device specifications

Configuration 1:M10 nut + washer

Configuration 2: Heavy Duty Nut, Adult



Please note that either the M10 Nut + washer (SKU 74-00021 + 74-00030) or the Heavy Duty Nut, Adult (SKU 74-00296) have to be ordered separately depending on the required configuration type.

Training

Please follow the ICRC manufacturing guidelines for transtibial prosthesis:
https://www.icrc.org/en/doc/assets/files/other/eng-transtibial.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 Transtibial Cup (TTA/TTC/TFC/LS)
- 1x Convex disc
- 1x Concave ankle washer, adult
- 1x Flat washer, SS, 15/44/3

Device manufacturing and setup guidelines

Socket manufacturing

2 configurations can be used depending on stump length and preferences.

Configuration 1:

The Transtibial Cup is used as a reinforcement and connection between the socket and the alignment system during the manufacturing of the transtibial socket as indicated in the manufacturing guidelines. It is important to place and align the cup correctly before proceeding with the manufacturing of the socket.

The Transtibial Cup is held in place with plaster at the distal end of the soft socket, with the positive cast in initial flexion, abduction or adduction according to the alignment of the assessed residual limb.

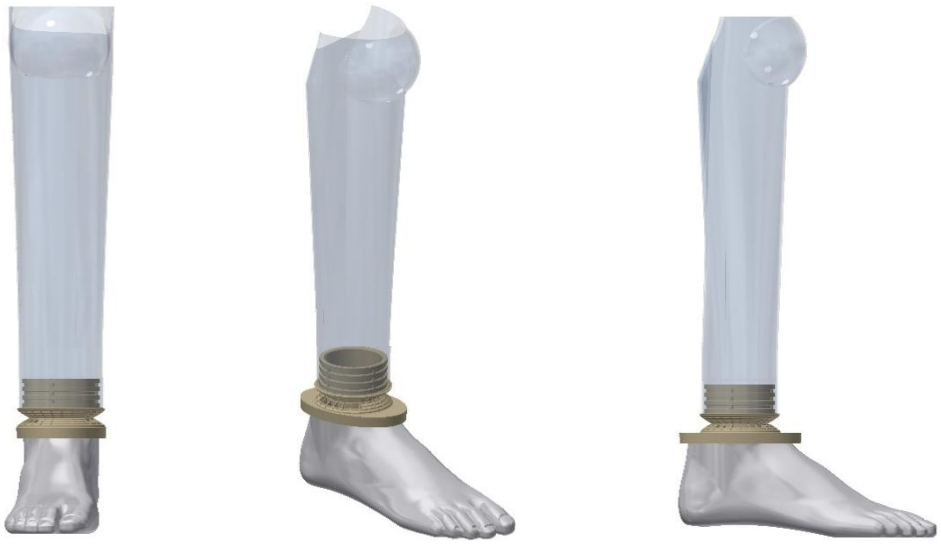
Configuration 2:

This configuration is the most compact one and allows for accommodating the longest residual limbs. The Heavy Duty Nut, Adult is used during the manufacturing of the transtibial socket as indicated in the manufacturing guidelines. It is important to place and align the nut correctly before proceeding with the manufacturing of the socket.

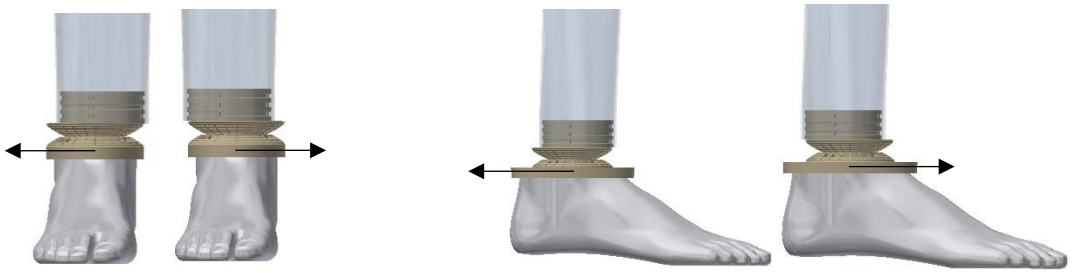
Bench alignment

The socket and the prosthetic foot are assembled with the remaining parts of the kit using the correct tools depending on the chosen configuration.

Configuration 1:

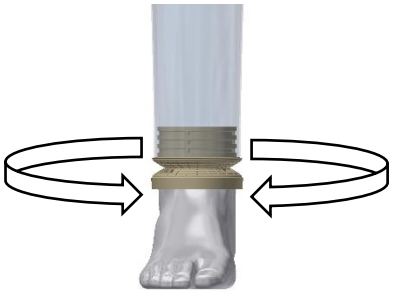


1) Medial-lateral and anterior-posterior translation



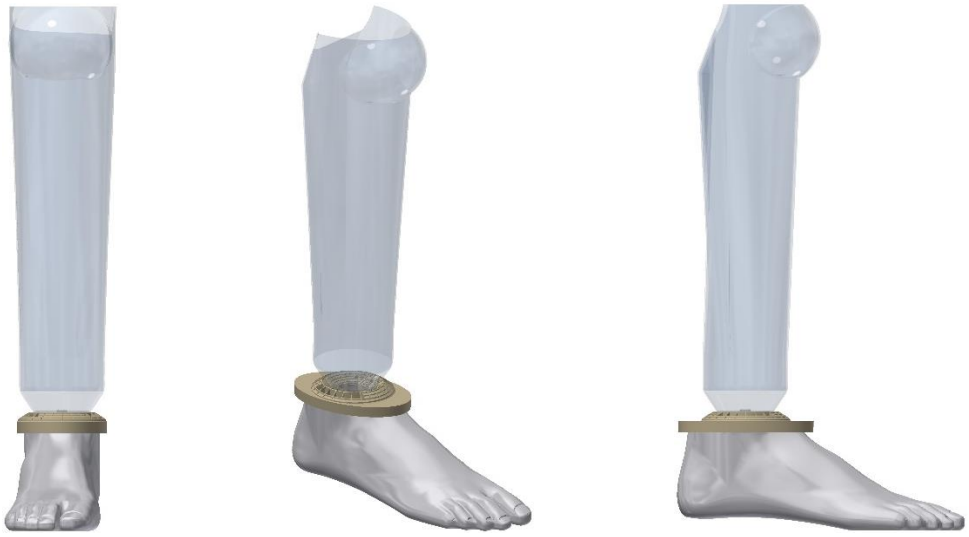
2) Inversion-eversion, plantar flexion-dorsiflexion

3) Rotation

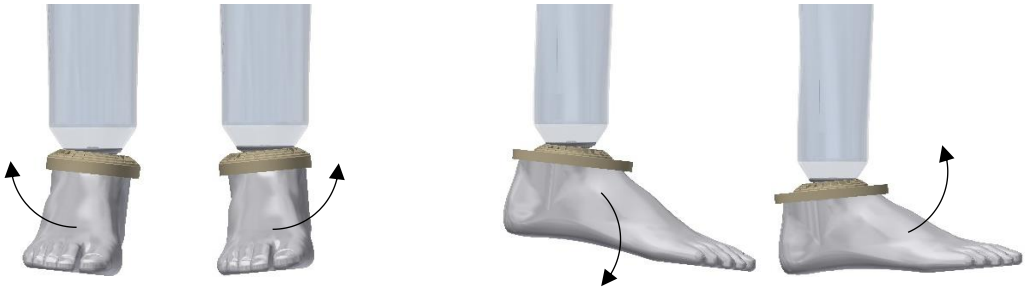


The sytem allows for a total freedom in rotation.

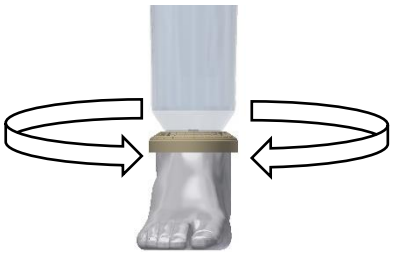
Configuration 2:



1) Inversion-eversion, plantar flexion-dorsiflexion



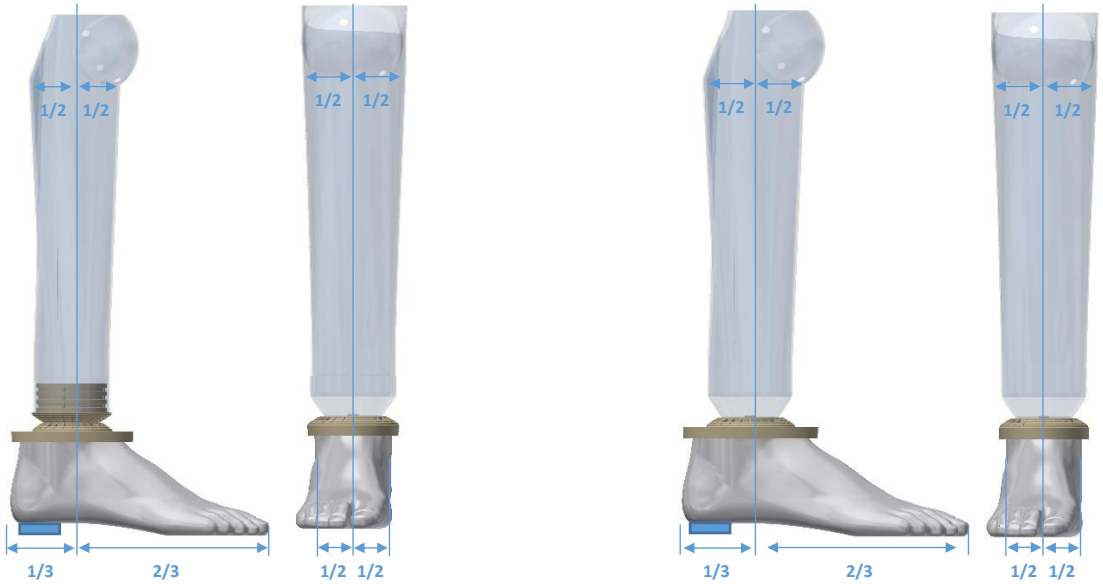
1) Rotation



The system allows for a total freedom in rotation.

IMPORTANT: The Bench alignment should be done according to the user's shoes before fitting.

The aim is to align the socket so the mid-point at the level of the patella tendon is inline with the posterior 1/3 of the foot in the sagittal plane and the center of the foot in the frontal plane. The alignment can be adjusted for heel heights between 0mm and 20mm, but a heel height of 10 mm 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/her 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

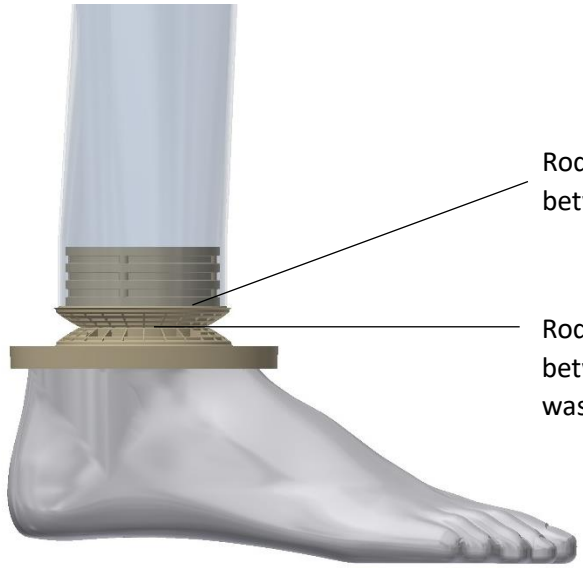
Observe the user's gait between parallel bars. Check for a smooth transition from heel strike to toe-off. Make sure that the socket flexion is accurate to allow physiological full knee extension.

Final welding before polypropylene cosmetic cover manufacturing

IMPORTANT: Welding the polypropylene components ensures proper performance over the lifetime of the prosthetic leg and is a mandatory step before proceeding with the polypropylene **cosmetic cover manufacturing.**

For the final welding of polypropylene parts refer to the manufacturing guidelines.

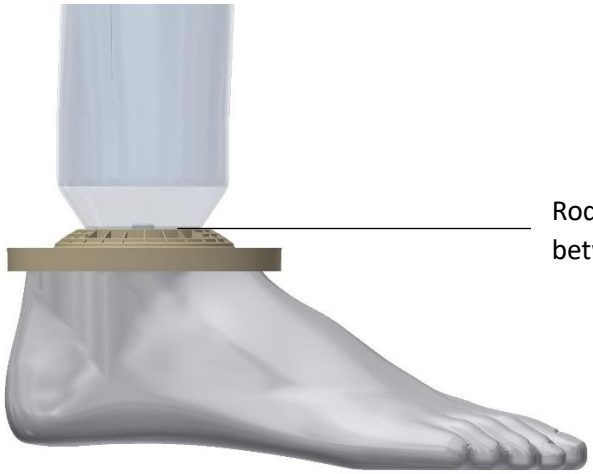
Configuration 1:



Rod welding (whole circumference) on the interface between the socket and the convex disc.

Rod welding (whole circumference) on the interface between the convex disc and the concave ankle washer.

Configuration 2:



Rod welding (whole circumference) on the interface between the socket and the concave ankle washer.

IMPORTANT: the polypropylene cosmetic cover is part of the prosthetic leg and ensures proper performance; the components must not be used without it.

Below is an example of a final product including the polypropylene cosmetic cover.

For the polypropylene cosmetic cover manufacturing refer to the manufacturing guidelines.

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.

Polypropylene is a recyclable polymer, dispose accordingly.

Reusability

This device is intended for single use only.

Compatibilities

The Transtibial Alignment Kit for Long Stump, Adult is compatible with the Rehab'Impulse Prosthetic Foot SACH 2.0, Adult – Sizes 22 to 28

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 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 alignment kit has been tested according to the ISO 10328:2016 standard to 3 million load cycles. Please note that the kit has been tested within a complete prosthesis including a hard shell polypropylene cosmetic cover as stipulated in the above mentioned standard.

This kit is approved for a body weight of up to 80 kg (P4)

Depending on the user’s activity level, this corresponds to a service life of three to five 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.

IFU ID and date

IFU-LS-EN-V1.0 – 27.05.2024

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Provided by

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