Rehab Impulse™ Promoting Independent Lifestyle

Provided by

fondation alfaset

Transfemoral Alignment Kit, Adult

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 Transfemoral Alignment Kit, Adult permits prosthetic fitting for various levels of transfemoral amputation. The Transfemoral alignment kit consists of a set of components allowing four 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

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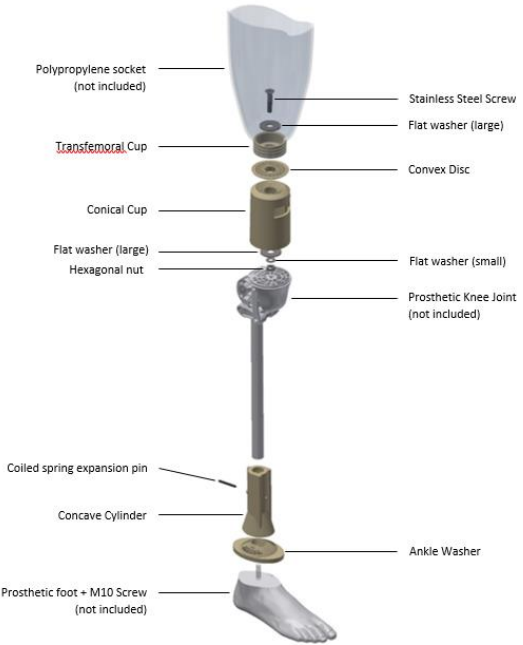
Device specifications



Training

Please follow the ICRC manufacturing guidelines for transtibial prosthesis:
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 Cup, transfemoral adult
- 1x Convex disc
- 1x Conical cup, transfemoral, adult
- 1x Concave cylinder, M10, adult
- 1x Convex ankle washer, adult

- 1x Screw, countersunk head, stainless steel, M10x50
- 2x Flat washer, stainless steel, 15/55/3
- 1x Flat washer, stainless steel, 10.5/25/1.5
- 1x Hexagonal nut, stainless steel, M10
- 1x Coiled spring expansion pin, stainless steel, 5x45

Device manufacturing and setup guidelines

Socket manufacturing

The Transfemoral Cup is used during the manufacturing of the Transfemoral 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 Transfemoral 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. This Transfemoral Cup is used as a reinforcement and connection between the socket and the alignment system.

Knee joint cutting to length and insertion of the concave cylinder

Cut the tube of the knee joint to the required length. Check that the cut is perpendicular to the vertical axis of the tube to allow for straight alignment with the concave cylinder. Determine the tube length by referring to the knee IFU (two adult knee types available in the Rehab'Impulse catalog); remember to take into consideration the ankle washer thickness, the foot height, and the heel clearance.

Insert the concave cylinder on the tube using either the dedicated inserting vice or a nylon mallet. Pay attention to the

orientation of the concave cylinders in the sagittal plane (see illustration below).
Once the cylinder is inerted and correctly orientated, it must be secured against rotation by using the dedicated coiled spring extension pin after drilling the knee pipe with a 5 mm drill.

Socket-to-knee assembly

Depending on the height of the amputation, different assembly types are possible to connect the socket to the prosthetic knee joint.

Important: Pay attention to the orientation of the conical cup in the sagittal plane (see illustrations below).

1) Mid-length and long amputations

Cut the conical cup to the required length (minding the total hip-to-knee segment), remembering to allow an additional 5 mm for the material exuded in the welding process. Check that the cut is perpendicular to the vertical axis of the conical cup to allow for straight alignment of the shank assembly.

The conical cup and the upper knee platform are welded together using a mirror welder. Make sure that the two parts are well aligned during the welding and cooling stages to obtain a perfectly straight assembly.

The conical cup is then assembled to the socket using the convex disc and the dedicated screw, washers and nut.

Alternatively, the conical cup can be turned upside down and welded to the socket (socket manufacturing without transfemoral cup) for a "total contact" configuration. It is further assembled to the knee joint (there is a threaded insert in Rehab'Impulse knees) using the convex disc, the screw and washers.

2) Long amputation (closer to the knee)

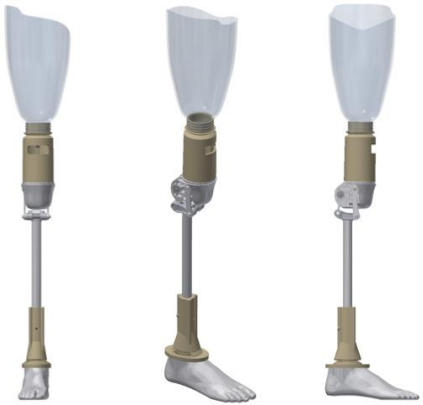
The procedure is the same as in 1) but a shorter conical cup is used.

3) Short amputation (closer to the hip) – **needs 2x Transfemoral Alignment Kit, Adult**

Cut to length and mirror-weld together 2 conical cups, use the convex, discs, screws and nut to assemble all the parts.

Bench alignment

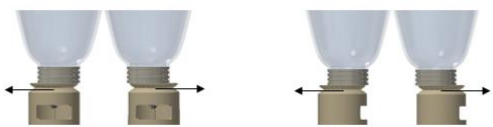
The already assembled parts, the ankle washer, and the prosthetic foot are assembled together using the correct tools.



Alignment changes can be applied to the proximal and/or to the distal end of the assembly:

Socket assembly (Transfemoral Cup, Convex Disc, Conical Cup):

<u>medial-lateral and anterior-posterior translation</u>



The system allows a translation of maximum 10 mm in all directions.

Adduction-abduction and flexion-extension

The system allows a tilting angle of maximum 10° in all directions.

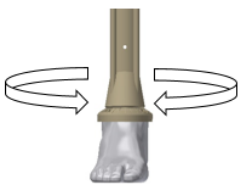
Rotation

The system allows for a total freedom in rotation.

Ankle assembly (Foot, Ankle Washer, Concave Cylinder) which allows:

Plantar flexion-dorsiflexion, inversion-eversion

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 pylon vertically. 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

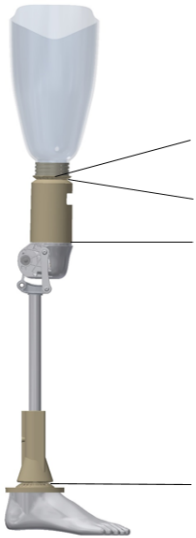
Observe the users gait between parallel bars. Check for a smooth transition from heel strike to toe-off. Make sure that the socket flexion is accurate to allow physiological full knee extension.

The M10x50 screw must be tightened with a 30Nm torque once the bench alignment is done.

Final welding before polypropylene cosmetic cover manufacturing

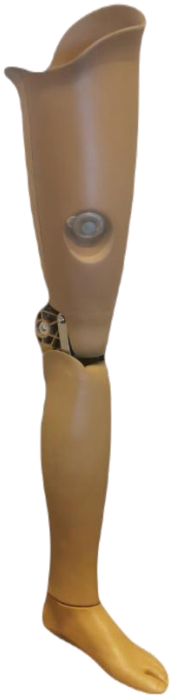
IMPORTANT: Welding the polypropylene components ensures proper performance over the lifetime of the prosthetic leg and is a mandatory step before proceeding with the polypropylene **cosmetic cover manufacturing.**

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



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 Transfemoral Alignment Kit, Adult is compatible with:

- Rehab'Impulse Foot SACH 2.0, Adult – Sizes 22 to 28
- Rehab'impulse Monocentric Knee Joint, Adult
- Rehab'impulse Polycentric Knee Joint, Adult

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.

Item codes

REF	Description English
74-00134	Transfemoral Alignment Kit, Child

IFU ID and date

IFU-Transfemoral-Alignment-Kit-Adult-EN-V1.0 – 14.12.23

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