

Levitate Forever

INSTRUCTIONS FOR USE



General Information

- Read this document carefully before using the product.
- Follow the instructions to avoid injuries or accidents.
- Please follow the mounting and configuration instructions carefully.
- Keep this information safe.

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Description

The Levitate Forever is a prosthetic foot designed to accommodate adaptive athletes. The device is perfect for everyday usage as well as competitive sports like tennis, basketball.

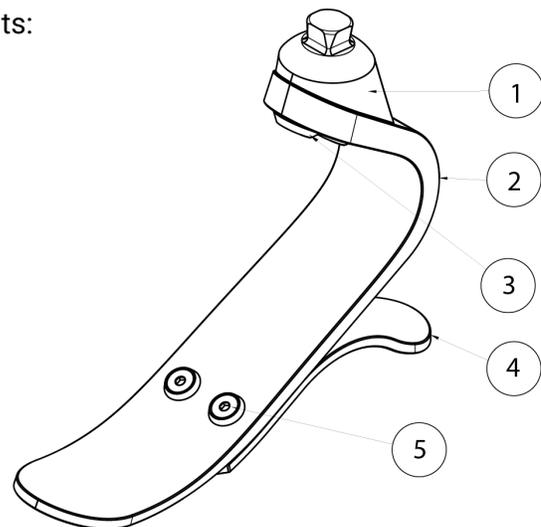
- Please read these instructions prior to fitting to ensure the proper integration of the Levitate Forever into the user's prosthetic system.
- The stiffness of the foot depends on the user's weight and activity level. To ensure that the correct foot is selected, please provide accurate user information.

Components

The Levitate Forever is a prosthetic foot with a pyramid male adapter. It is composed of two fiberglass components.

The device embodies the below mentioned components:

1. Pyramid Male Adapter
2. Top Composite Part
3. M8 Bolts and washers
4. Bottom Composite Part
5. M6 Bolts and washers



Product specifications

- Build height*: (5.9 inches / 15.2 cm, 7.1 inches / 18 cm, 8.7 inches / 22 cm)
- Rated for users up to 125 kg
- Weight*: 600g
- Moderate to very high active levels
- Material: Fiberglass

*Specifications refer to Levitate Forever 9" (II) size 27 weight range 65-80kg

Intended use and general safety

Intended use

The Levitate Forever is engineered to serve as a viable substitute for the ankle mechanism in the absence of a lower limb. It is specifically designed to cater to individuals who have undergone either bilateral or unilateral transfemoral, transtibial, or knee disarticulation amputations. This advanced prosthetic component is an integral part of a comprehensive system including a socket and, if deemed necessary, a knee component as well.

General safety

Users of this manual are advised to read it thoroughly and ensure they fully understand its contents to operate the device safely. If the reader should have any questions in regards to the product, please do not hesitate to contact the manufacturer.

Warning: If there should be any change or loss in functionality of the product, such as cracking sounds or radical changes on the energy return, please stop using the product immediately and contact the manufacturer.

Device Selection

The device is designed in different categories and sizes in order to accommodate various body differences such as weight, foot size and type of amputation.

The Levitate Forever Foot is available in three heights. The product lengths vary from 23 to 29cm including the footshell.



Category table

Weight kg	0-50	50-65	65-80	80-95	95-110	110-125
Weight lbs	0-110	110-143	143-176	176-209	209-243	243-276
Size 23-24	1	1.5	2	2.5	N/A	N/A
Size 25-26	1	1.5	2	2.5	3	3.5
Size 27-30	N/A	N/A	2	2.5	3	3.5

Installation

Warning: Any deviation from the installation instructions or alterations to the foot's design will result in the voiding of the product warranty. Moreover, such actions may lead to product failure and pose a risk of injury to the user. Therefore, it is crucial to strictly adhere to the provided installation guidelines to ensure both product performance and user safety.

Installation Figure references are found in the Appendix.

Basic installation setup

Take a look at **Figure 1** and **Figure 4** before initiating the installation process. Position the foot such that the Load Line (**A**) aligns with the inner third of the foot cover (**B**) - as shown in **Figure 1** simultaneously look at **Figure 4** and align the foot so the load line in the socket is parallel to the load line in the forever foot. If needed, consider an external foot rotation. If possible, the alignment reference Load Line (**A**) should pass through the midpoint of the socket. Use the necessary adapters to connect the Levitate Forever foot to the socket or knee.

Note: When using a prosthetic knee, align it following the provided instructions, and employ suitable adapters to connect the socket to the prosthesis.

Static alignment

Once the Levitate Forever foot is installed in the user's full system check for correct device length. Ensure the patient distributes their weight evenly between both legs. Adjust the height if needed with the use of prosthetic adapters. Check for correct load line alignment and foot abduction/adduction.

Dynamic alignment

It is essential to align the prosthetic device to the users needs and preferences to ensure a smooth rollover. The rollover can be influenced by the shoe characteristics as well as incorrect alignment of the device.

If the heel to toe transition is too fast and the user has minimum control of the device during heel strike, a promptness in the rollover may be present. Take a look at **Figure 2** to increase the dorsiflexion angle of the device and ensure a smooth rollover. If the foot comes flat too fast and feels like the heel is getting compressed too much and has no energy return, a delay in the rollover may be present. Take a look at **Figure 3** to increase the plantar flexion angle of the device and ensure a smooth rollover.

Additional adjustments can be made to improve walking gait. If the user tends to tilt inward while walking or standing on the prosthetic, take a look at **Figure 5** to adjust the device outward. Conversely, if the user is leaning outward over the prosthetic, the device should be aligned inward as shown in **Figure 6**.

Installation and removal of Foot Cover

The Levitate Forever is equipped with a flexible foot cover designed to protect the foot without constraining its smooth rollover. To maintain the appearance and durability of the Levitate Forever always use a foot cover and handle its installation and removal with care.

Note: Always use a smooth edge shoehorn to remove the foot cover to avoid pinching fingers between the cover and the prosthetic foot.

Installation:

1. Put the nylon sock over the Levitate Forever.
2. Insert the front foot as far as possible into the foot cover.
3. Jam a shoe horn between the foot cover heel and the Levitate Forever heel and press downwards to insert the Levitate Forever heel into the foot cover heel lock. Note: ensure that the shoe horn is placed between the foot cover and the nylon sock and not between the nylon sock and the prosthetic device.
4. Ensure that the Levitate Forever heel is placed underneath the foot cover heel lock.

Removal:

1. Jam a shoe horn between the inside of the heel in the foot cover and the back end of the heel plate on the prosthetic device. Note: ensure that the shoe horn is placed between the foot cover and the nylon sock and not between the nylon sock and the prosthetic device.
2. Push the shoehorn away from the heel, until the cover comes off
3. Pull the cover off from the front of the prosthetic
4. Check to see if the nylon sock is intact. If not, change it.
5. Take the new foot cover and follow the Installation steps.

Usage

Cleaning and Maintenance

To ensure proper hygiene and care, clean the device using a damp cloth and a mild soap. After cleaning, it is essential to dry the device thoroughly using a cloth.

Environmental Conditions

The device is engineered to be waterproof, allowing for use in wet or humid environments. When combined with an aluminum adapter, it can withstand submersion in fresh water up to 1 meter deep for a maximum duration of 30 minutes. With the titanium adapter, it can endure submersion in all water types (including salt water) up to 3 meters deep for up to 1 hour. The device is also resistant to various substances, including chlorinated water, sweat, urine, and mild soaps.

After exposure to water or humidity, the device should be rinsed with fresh water and dried with a cloth. This maintenance routine helps ensure the device's performance and durability. It can tolerate occasional contact with sand, dust, and dirt; however, prolonged exposure to these elements is not recommended. In cases of exposure to other liquids, chemicals, sand, dust, or dirt, the device should be cleaned with fresh water and dried thoroughly with a cloth. By following these care guidelines, the device can be effectively maintained and kept in optimal condition for long-term use.

Warnings

- ⚠ This product is not intended for activities that applies an excessive overload to the product, such as jumping from significant heights or using it beyond its service life.
- ⚠ The maximum torque force is of 12Nm for the Levitate Adapter set screws. Do not fasten the bolts more than advised.
- ⚠ Check the device regularly after use for visual flaws and to make sure all bolts and nuts are fastened correctly.
- ⚠ Do not modify the product (Trimming, drilling, sanding, etc.).
- ⚠ Do not expose the device to fire or other heat source.
- ⚠ Never use the product without the provided foot cover.
- ⚠ Do not sell this product as second-hand.

Maintenance

- Check the components regularly.

- In case of any clicking noises please tighten all the screws on the device. In case of continuously clicking noises, please contact the manufacturer.
- In case of any damage or loss of function, please contact the manufacturer.
- In case of loss of functionality, do not try to modify the product or components other than specified in the installation and alignment manual.

Storage

Temperature range -10°C to +60°C

Humidity range 0% to 90%

Disposal

The product should be disposed of in accordance with the local regulations where it is being disposed. Please contact the responsible authorities to make sure to dispose of the product in an environmentally friendly manner.

Service life and warranty

The device has been tested according to ISO 10328. If the product has been used and taken care of as described in these instructions the service life of the product may correspond to 2-3 years of use. This is highly dependent on the activity level.

The Levitate Forever has a 36 months warranty from the date of patient fitting.

The foot cover (sold separately) has a 6 months warranty from the date of patient fitting.

Warning: The device is crafted and tailored to accommodate particular user weights. If the weight guidelines are not adhered to, or if the user engages in activities like heavy lifting, high impact sports, or abusive actions that could potentially harm the natural limb, the warranty may be voided.

Appendix

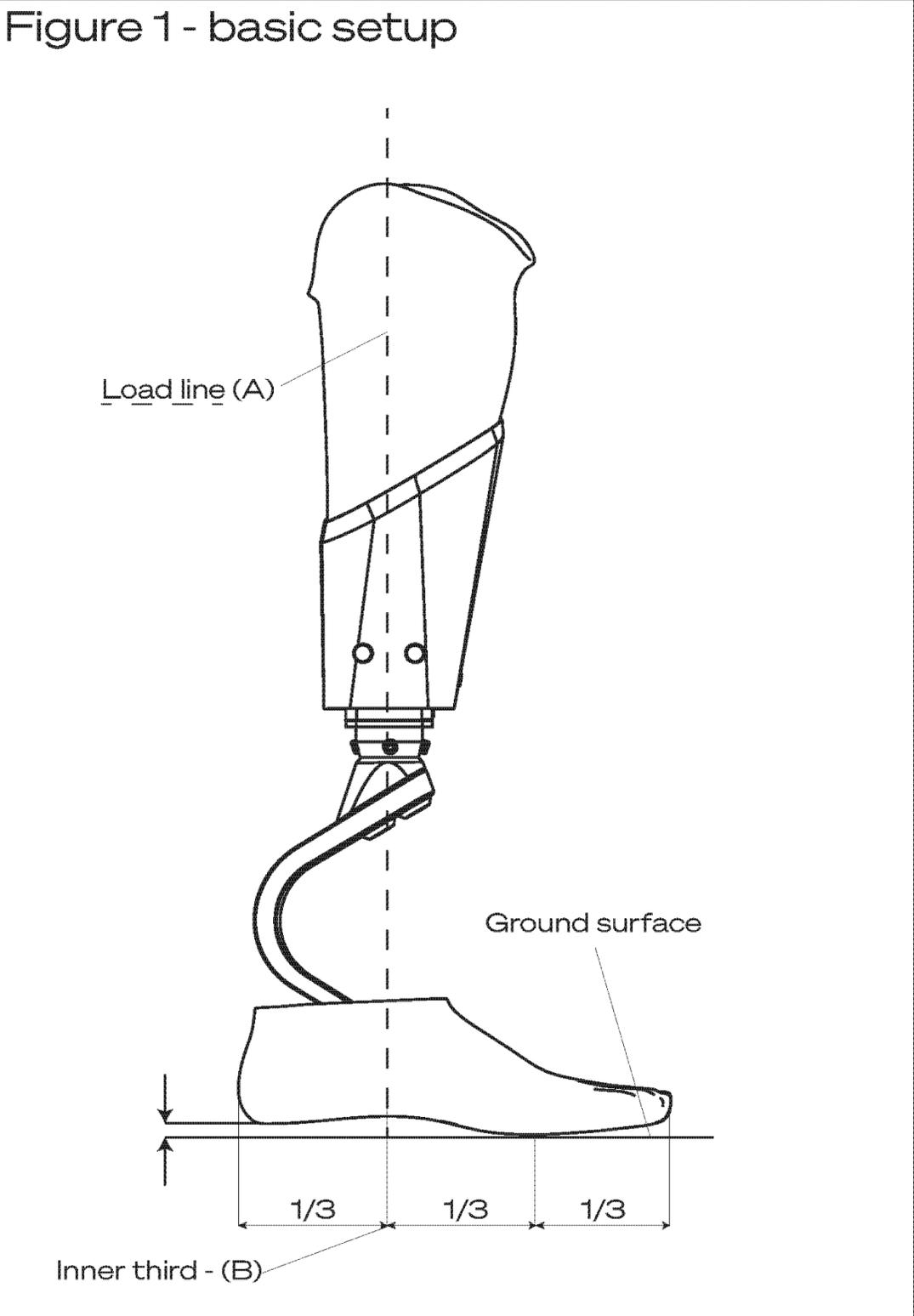


Figure 2 - Raising heel height

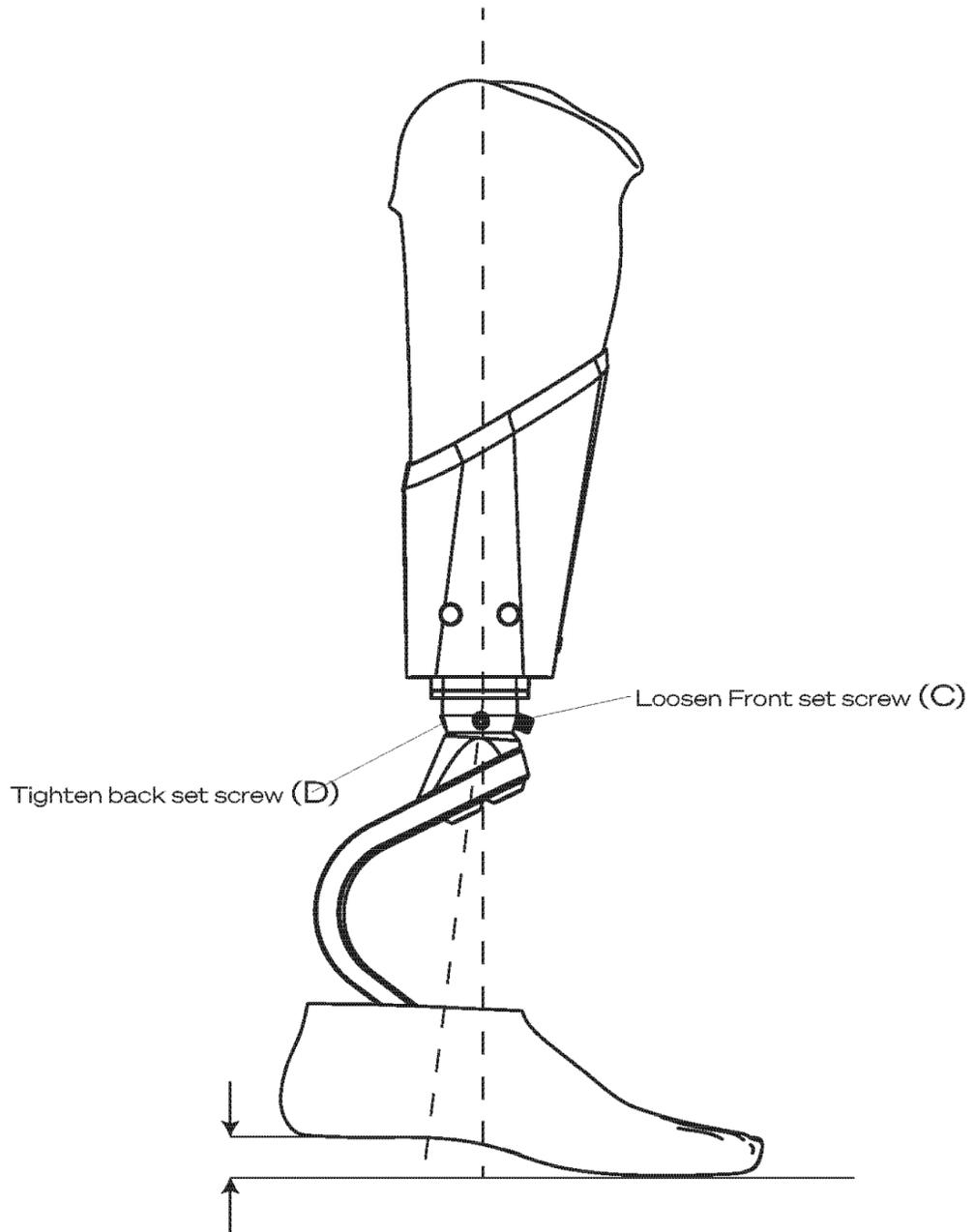


Figure 3 - Lowering heel height

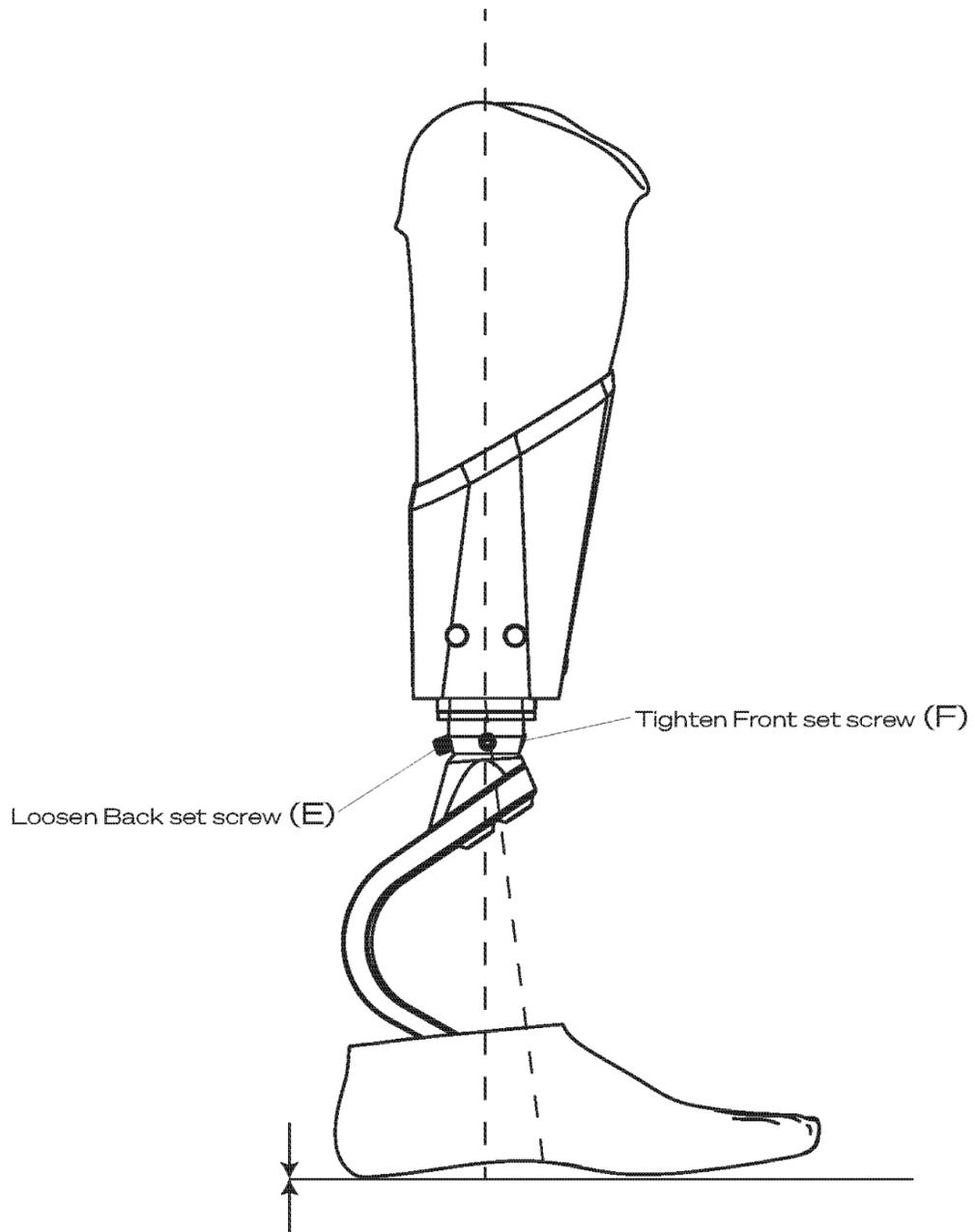


Figure 4 - Basic setup

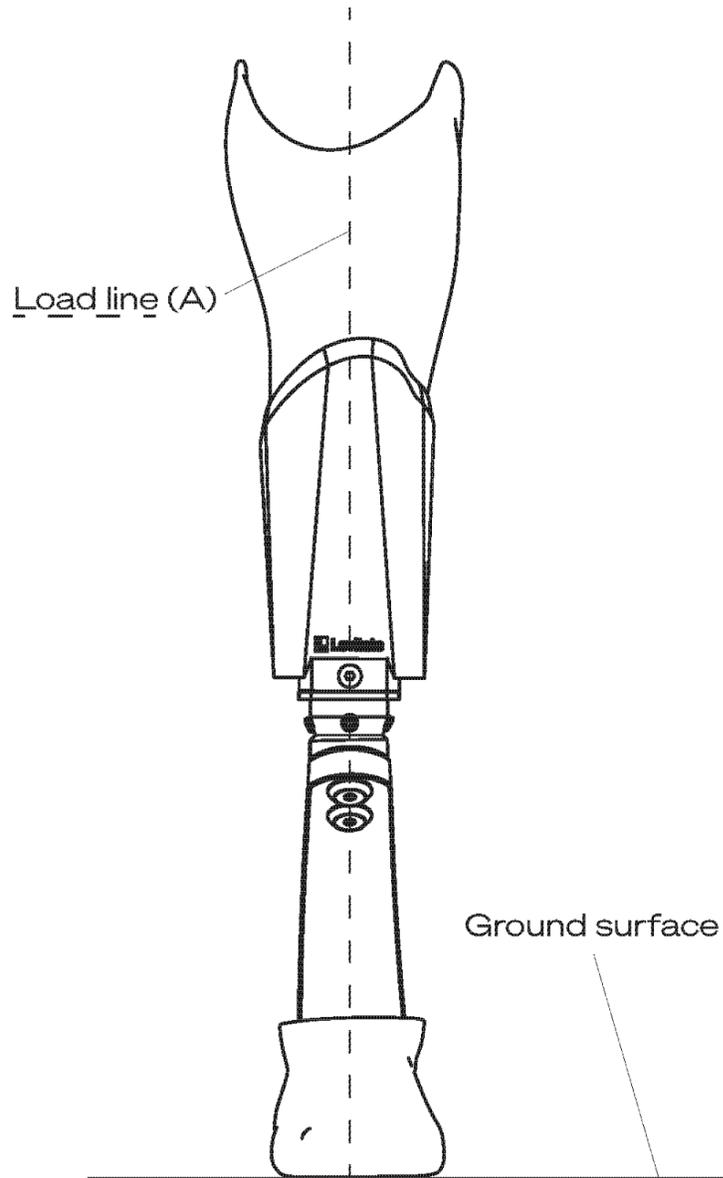


Figure 5 - Adjustment outward

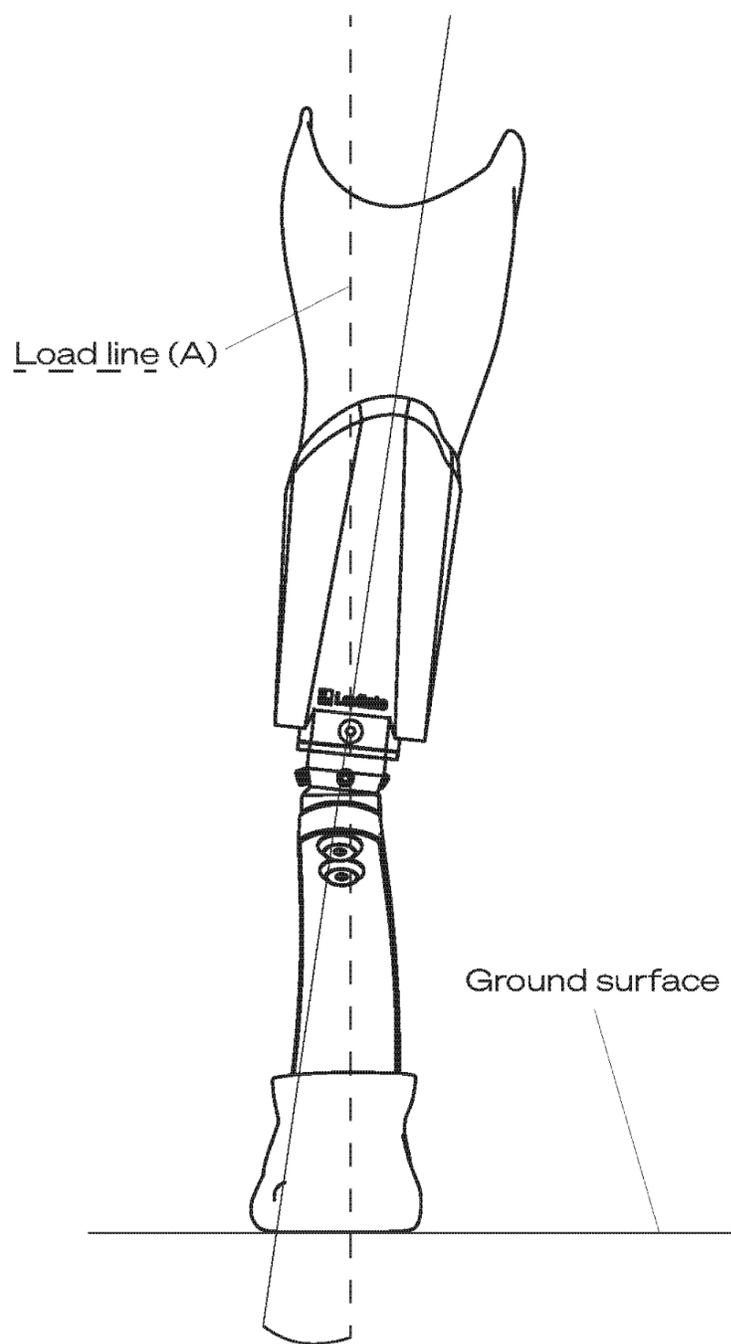
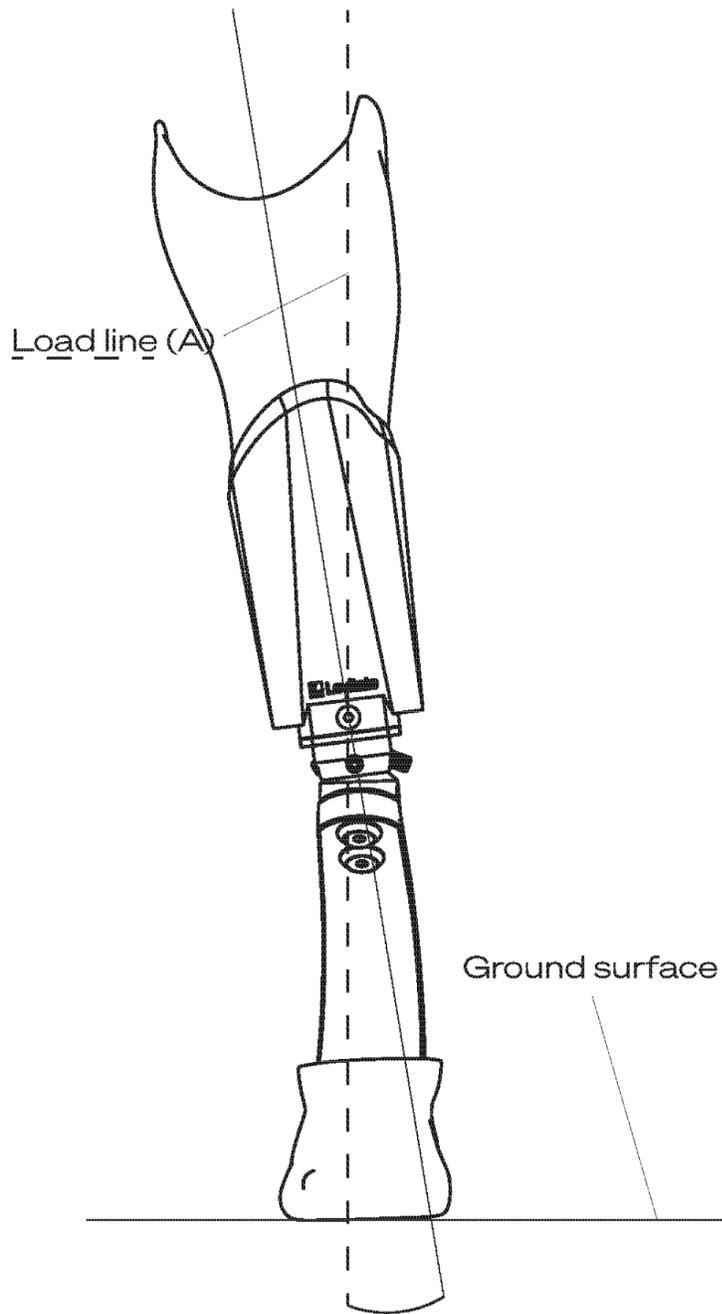
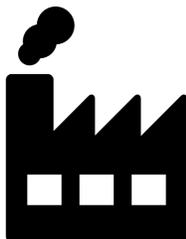


Figure 6 - Adjustment inward



Regulatory information

This product is a medical device and is CE marked in compliance with the Regulation (EU) 2017/745.



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