

Levitate Blade

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 Blade is a prosthetic foot designed to accommodate adaptive athletes. The device is perfect for long distance running and sprinting. The device stores and returns energy for optimal running.

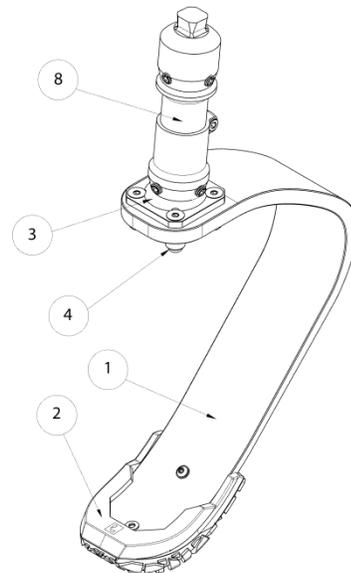
- Please read these instructions prior to fitting to ensure the proper integration of the Levitate Forever into the user's prosthetic system.
- The stiffness of the foot depends on the user's weight and activity level. To ensure that the correct foot is selected, please provide accurate user information.

Components

The Levitate Blade includes all necessary components to mount on existing sockets. Height adjustable adapters can be purchased separately to suit people with different socket clearances.

The device embodies the below mentioned components:

	Description	Included / sold separately
1	Levitate running blade	Included
2	Replaceable sole	Included
3	Flat male adapter	Included
4	Bolts and nuts	Included
5	Tools for mounting	Sold separately
6	Replaceable sole	Sold separately
7	Torque wrench	Sold separately
8	Additional adapters	Sold separately



Product specifications

- Build height*: (10.6 inches / 27 cm, 8.3 inches / 21 cm)
- Rated for users up to 130 kg
- Weight*: 700g
- Moderate to very high active levels
- Material: Fiberglass

*Specifications refer to Levitate Blade 10" weight range 60-70kg with gravel sole and male pyramid adapter

Intended use and general safety

Intended use

The Levitate Blade 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.

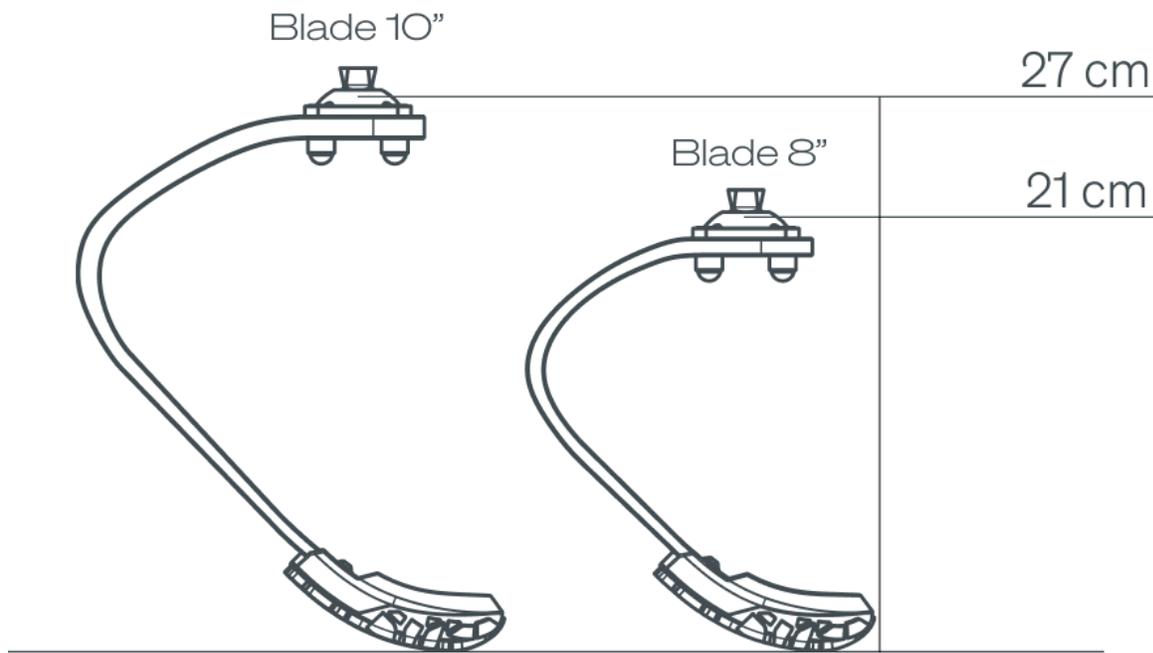
General safety

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, clearance and type of amputation. Note: bi-laterals might need to go up one category. The Levitate Blade is available in two heights.



Category table

Each Levitate Blade has a corresponding weight category table. Please look at the information below to ensure that the correct product is selected.

Blade 8"

Body weight		Activity level	
kg	lbs	Low	High
0-15	0-33	Category 1	Category 2
15-30	33-66	Category 2	Category 3
30-45	66-99	Category 3	Category 4
45-60	99-132	Category 4	Category 5
60-75	132-165	Category 5	Category 6
75-90	165-198	Category 6	N/A

Blade 10"

Body weight		Activity level	
kg	lbs	Low	High
30-40	66-88	Category 2	Category 2.5
40-50	89-110	Category 2.5	Category 3
50-60	111-132	Category 3	Category 3.5
60-70	133-154	Category 3.5	Category 4
70-80	155-176	Category 4	Category 4.5
80-90	177-198	Category 4.5	Category 5
90-100	199-220	Category 5	Category 5.5
100-110	221-242	Category 5.5	Category 6
110-130	243-286	Category 6	N/A

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.

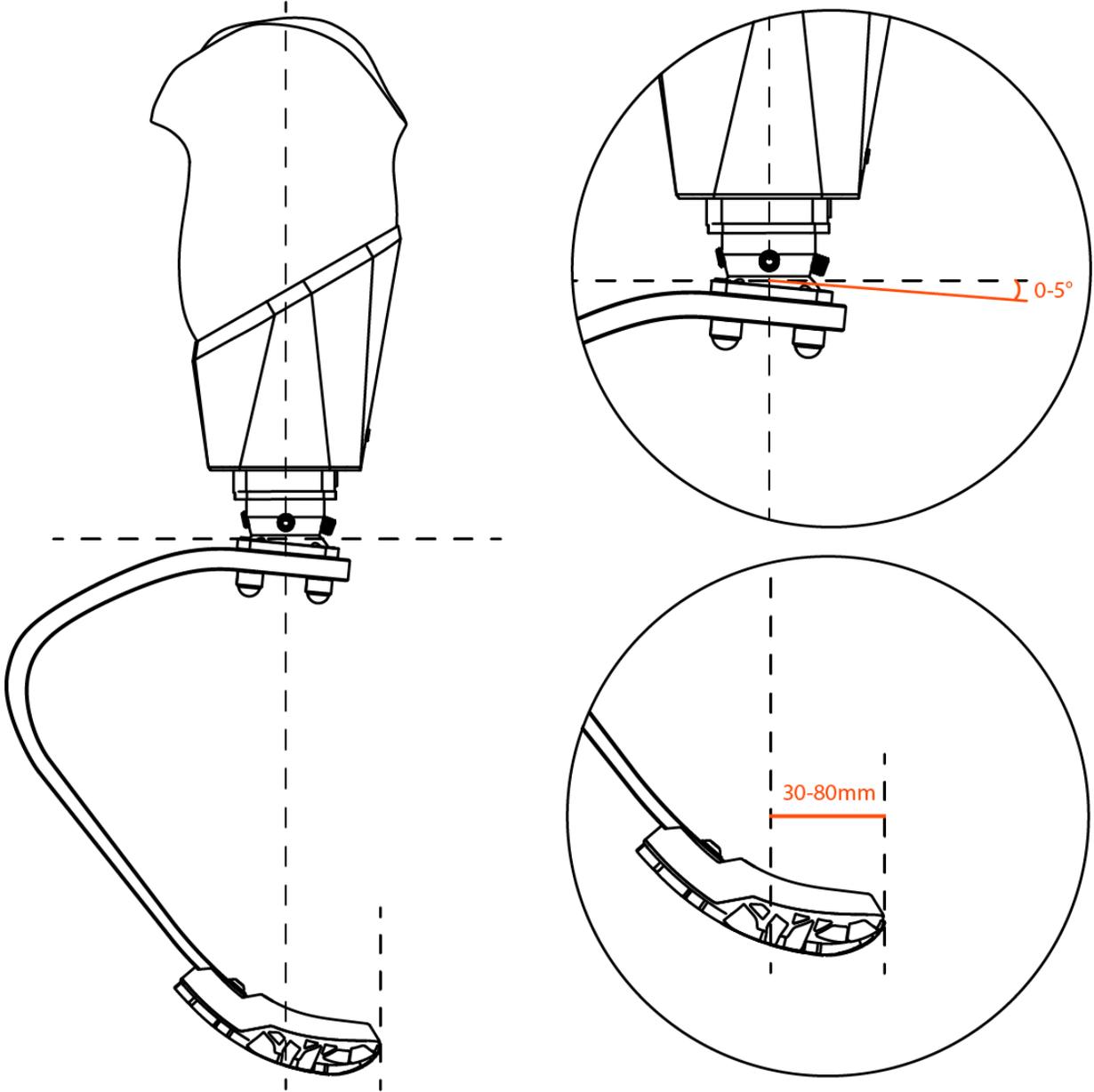


Figure 1 - Sagittal plane alignment

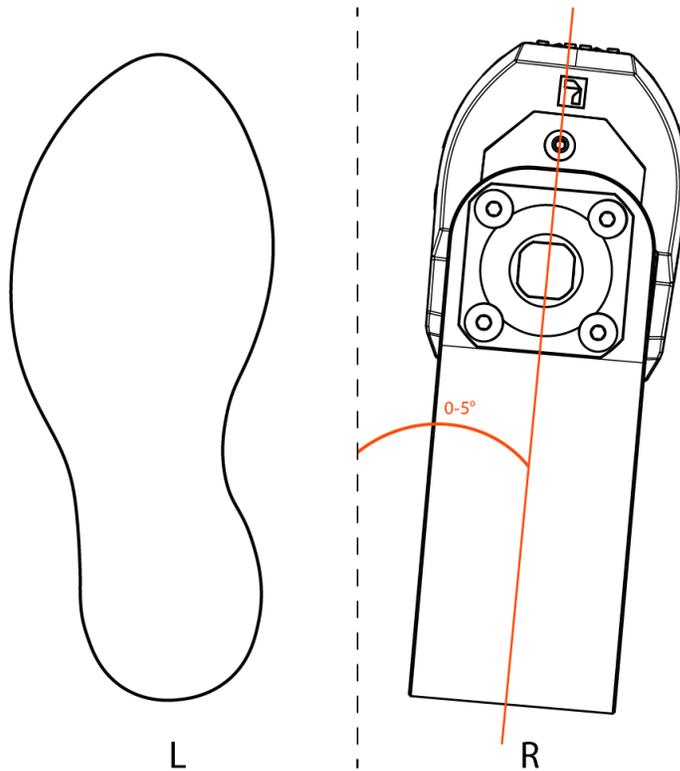


Figure 2 - Transverse plane alignment

Basic installation setup

When applicable, the basic setup is carried out wearing running shoes. Take a look at the figures above before initiating the installation process. Note that the running blade alignment is highly dependent on the user's socket mounting point and structure meaning that these illustrations are not strict guidelines but rather recommendations.

Loosen all four set screws on the female adapter. Place the Levitate Blade into the adapter linked to your socket. Carefully tighten all four set screws at the same time until the foot is oriented in such a way that the socket load line aligns with the Levitate Blade. Note: the torque applied on the set screws must not exceed 12Nm if using the Levitate Female Adapter.

The Levitate Blade can be adjusted according to the user's personal preferences as shown in **Figure 1** and **Figure 2**. Note: the degree range refers to the minimum and maximum tolerances.

When selecting the correct Levitate Blade size and necessary adapters an additional 10-50mm should be added to the user's clearance to adjust hip alignment. The height of the prosthetic should reflect the height of the same when the blade is fully compressed during running.

Changing the Levitate Sole

The Levitate Blade is delivered with the sole on the prosthetic. Below you will find a guide on how to remove and change the sole.

Follow these steps:

1. Unscrew the sole screws with the help of a M4 allen key.
2. Remove the sole and clean the Levitate Blade with a damp cloth if needed. Make sure to let it dry before applying the new sole.
3. Place the sole in the running blade and screw the M4 bolts. Note: do not assemble the bolts without the washers.

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

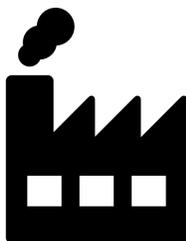
The device has been tested according to ISO 10328. If the product has been used and taken care of as described in these instructions the service life of the product may correspond to 2-3 years of use. This is highly dependent on the activity level.

The Levitate Blade has a 36 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.

Regulatory information

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



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