

Levitate Quick - Change

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 Quick Change is a prosthetic adapter designed to accommodate adaptive athletes. The device enables the user to interchange prosthetic feet or knees in mere seconds. It includes all necessary components to mount on your existing socket.

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

Components

The Levitate Quick Change can be sold as a bundle or as separate components.

Female-Male Bundle

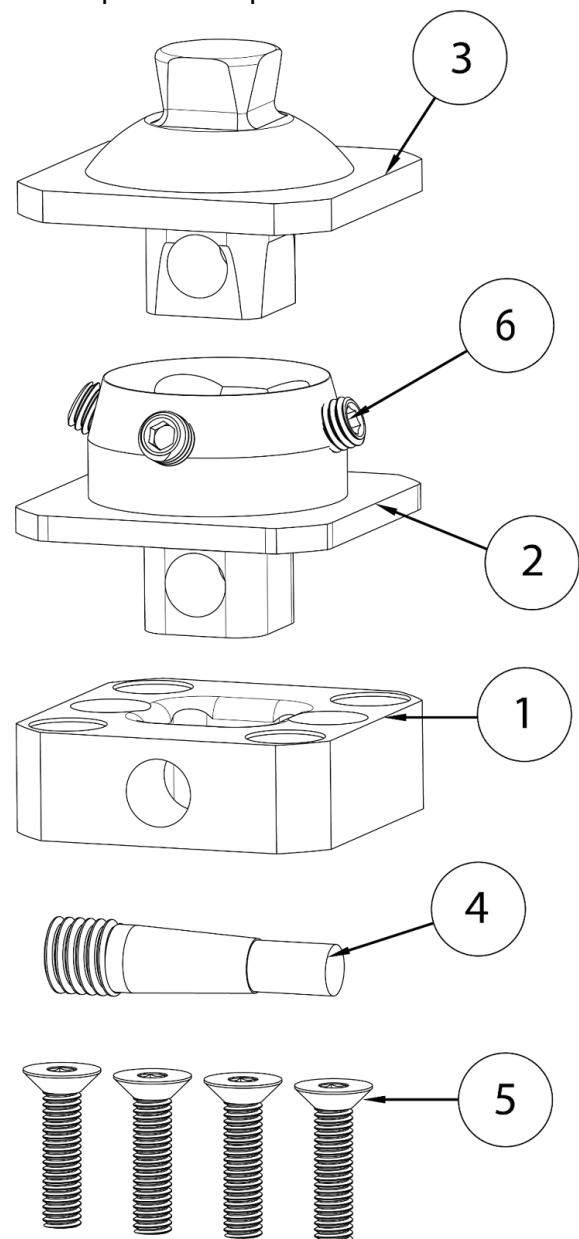
	Description	Amount
1	Quick Change Baseplate	x1
2	Quick Change Female	x1
3	Quick Change Male	x1
4	Quick Change Pin	x1
5	M6 x 25 mm CS Screw	x4
6	M8 x 16 mm Set Screw	x4

Female-Female Bundle

	Description	Included
1	Quick Change Baseplate	x1
2	Quick Change Female	x2
4	Quick Change Pin	x1
5	M6 x 25 mm CS Screw	x4
6	M8 x 16 mm Set Screw	x8

Male-Male Bundle

	Description	Included
1	Quick Change Baseplate	x1
3	Quick Change Male	x2
4	Quick Change Pin	x1
5	M6 x 25 mm CS Screw	x4



Product specifications

The Levitate Quick Change adapter is available in two materials. The maximum patient weight is 100kg when purchasing an aluminum QC and 130kg when purchasing a titanium one.

Components	Material	Weight [g]	Threads
QC Baseplate	Aluminum	85	M12
QC Male	Aluminum	78	-
	Titanium	124	-
QC Female	Aluminum	70	M8
	Titanium	118	M8
QC Pin	Stainless steel	25	M12

Intended use and general safety

Intended use

The Levitate Quick Change is intended exclusively for people who are living with lower limb amputations. 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, a foot and, if deemed necessary, a knee component as well.

General safety


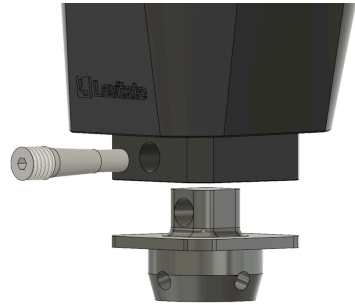

Users of this manual are advised to read it thoroughly and ensure they fully understand its contents to operate the device safely. If the reader should have any questions in regards to the product, please do not hesitate to contact the manufacturer.


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.

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.

To mount and configure your new Levitate Quick Change adapter please follow the steps as described in this section. If in doubt of anything in regards to the installation, please do not hesitate to contact the manufacturer of this product.

Step 1 - Assemble the base plate to your socket	
<ol style="list-style-type: none"> 1. Remove the prosthetic socket from your affected leg. 2. Orient the QC baseplate such that the M12 thread hole is placed in the front. 3. Assemble the QC baseplate to your socket with the help of the M6 x 25mm CS screws. <p>NB!: The Quick Change adapter is only compatible with sockets that have the universal mounting solution. i.e.: 36mm spacing between the M8 threaded holes.</p>	
Step 2 - Assemble the QC male or female on your prosthetic foot	
<ol style="list-style-type: none"> 1. Assemble the QC male/female on the QC baseplate with the help of the M12 pin screw. The maximum torque is limited to 12Nm. <p>NB!: Ensure that the QC male/female is oriented such that the largest hole is placed in the front.</p>	
Step 3 - Assembling the prosthetic foot	
<ol style="list-style-type: none"> 1. Assemble your prosthetic foot with the help of the set screws 2. Align your prosthetic according to your needs. 	

Step 4 - Swap prosthetic feet	
<ol style="list-style-type: none"> 1. To swap between feet, unscrew the M12 pin screw 2. Replace your prosthetic foot with any other prosthetic product. For example, you can switch around the Levitate Running Blade and the Levitate Forever Foot. 	

The Quick change adapter allows the user to align the prosthetic feet with the help of the male-female adapter interface like any other prosthetic device. Please refer to your prosthetic device alignment guideline for this step. Else, refer to the Levitate Running Blade or Levitate Forever Foot IFU manual.

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 it to be utilized in wet or humid environments. It can withstand submersion in water for a maximum duration of 1 hour. It exhibits tolerance towards contact with various substances, including salt water, chlorinated water, sweat, urine, and mild soaps. Furthermore, it can handle occasional exposure to sand, dust, and dirt. While it can withstand brief exposure to sand, dust, and dirt, prolonged contact with these elements is not recommended.

After coming into contact with fresh water or humidity, it is advisable to dry the device using a cloth. This maintenance practice ensures the proper functioning and durability of the device. In instances where the device has encountered other liquids, chemicals, sand, dust, or dirt, it should be cleaned with fresh water, followed by drying with a cloth. By following these guidelines, the device can be effectively maintained and kept in optimal condition for extended 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

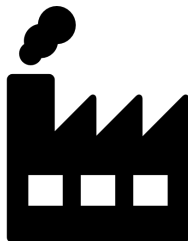
The device has been tested according to ISO 10328. If the product has been used and taken care of as described in these instructions the service life of the product may correspond to 2-3 years of use. This is highly dependent on the activity level.

The Levitate Quick Change 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.



Levitate Technology ApS
Marielundvej 28
2730 Herlev
Denmark
support@letslevitate.com
+45 31629011

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