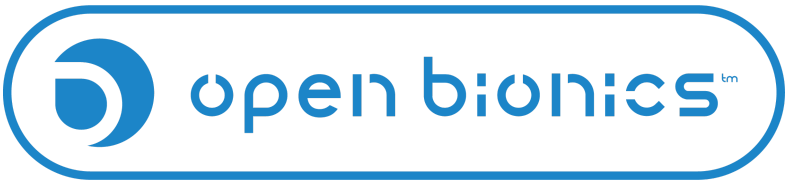


HERO FLEX™

User Manual

Version 01.00

Contents

Introduction

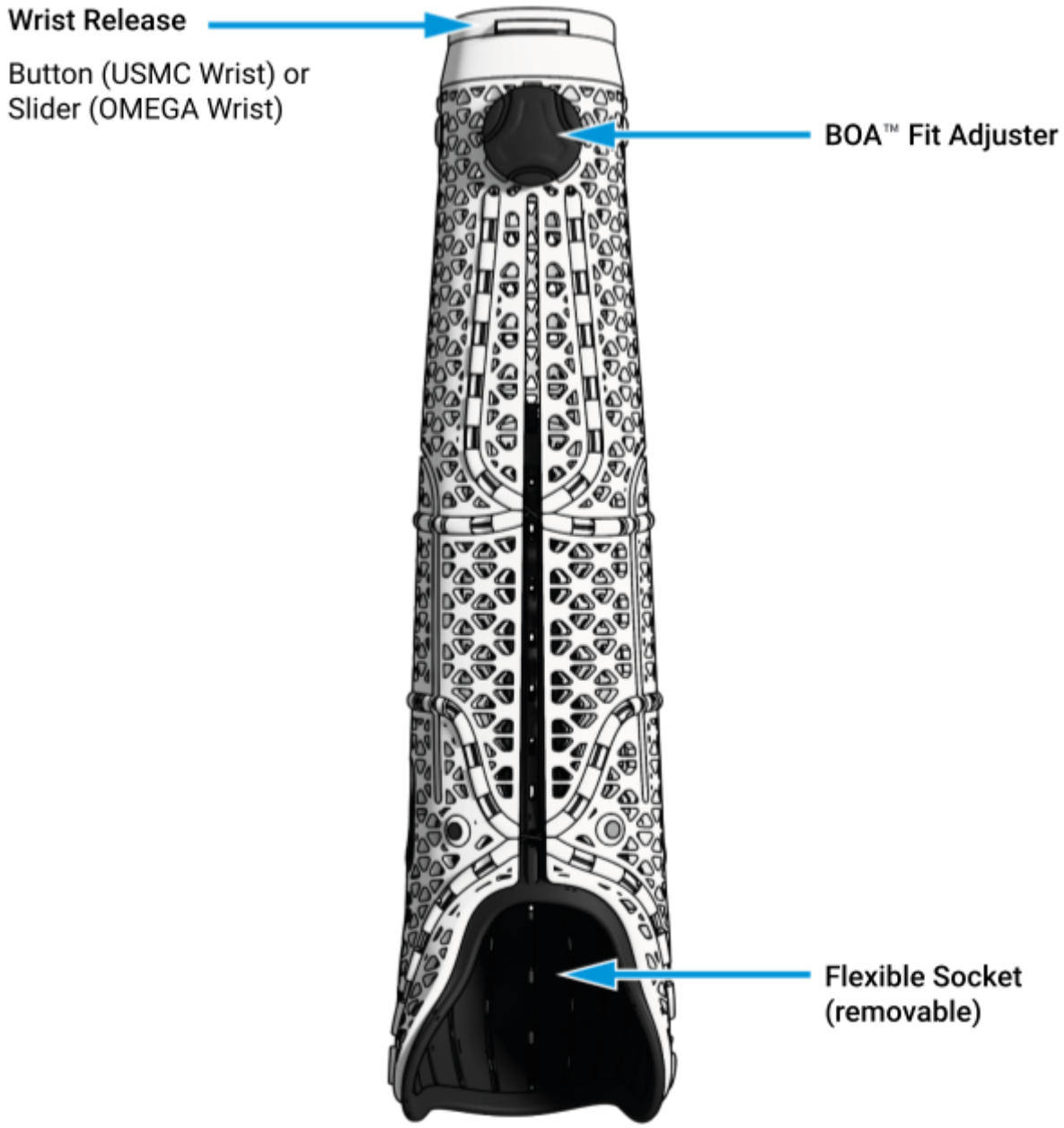
The Hero Flex is an all purpose activity arm, which is bespoke and perfectly formed to the individual's needs. With a breathable design allowing for ventilation and ease of cleaning.

The Hero Flex is designed to work with either USMC or OMEGA wrist connections allowing the individual to adapt the Hero Flex to whatever activities they wish to participate in through the use of specially designed terminal devices.

This manual will give the user an overview of how to use and look after your Hero Flex, and the important safety considerations to take.

Hero Flex Overview

Note: Your Hero Flex may look slightly different from the version pictured.



What's in the Box

1 x Hero Flex
1 x Removable Socket
1 x Quick Start Guide

Configurations

Each Hero Flex is tailor built for every individual. As a result, you may see some differences between your Hero Flex and the diagrams in this manual.

Every socket is designed and 3D printed for each individual based on a 3D scan of their residual limb.

The standard configuration of the Hero Flex includes the USMC wrist attachment. The OMEGA wrist is only supplied (at an extra cost) for users owning devices which already have the OMEGA connection system.

Getting Started

Before putting on your Hero Flex for the first time, please familiarise yourself with this user manual.

When to Use Your Hero Flex

The Hero Flex is intended to be used for activities where activity-specific terminal devices can be attached to the Hero Flex giving the user the ability to participate in activities which may have previously been limited such as:

- Holding objects such as weights, pool cues, drum sticks
- Performing operations such as skiing, kayaking etc.

Precautions and Warnings

The Hero Flex is not intended for use in activities that may result in injury or death to the user or others as a result of it failing to perform the activity as intended. As such, activities which are specifically prohibited include:

- Driving any form of motor vehicle, aircraft or boat,
- the use of firearms, or
- use while partaking in the weight lifting activities with the use of free weights

If the consequence of using the Hero Flex for any of the above activities is injury or death to yourself or anyone else, the Hero Flex must not be used. In the case of using the Hero Flex to return to work, you should discuss the above points with your Health and Safety representative and conduct a formal risk assessment.

The design of the Hero Flex means that there are very little limitations in regards to temperature, pressure, humidity or altitude. The Hero Flex can be safely used in all conditions and temperature ranges in which you would expose yourself, without fear of harm..

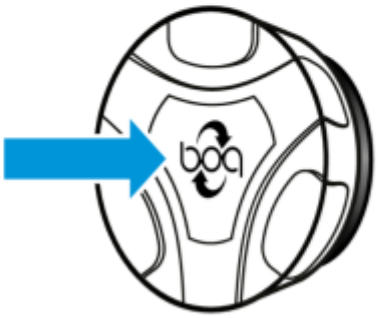
Putting on your Hero Flex

Your Hero Flex has been designed to perfectly fit your arm, and comes with an adjustable BOA Fit System™ to reach the perfect balance of comfort and secure fit.

To tighten, rotate clockwise

To loosen, rotate anticlockwise

To quick-release, pull outwards



To return to rotary mode, push inwards

You can easily adjust the fit of your Hero Flex throughout the day without removing it, simply by adjusting the BOA Dial.

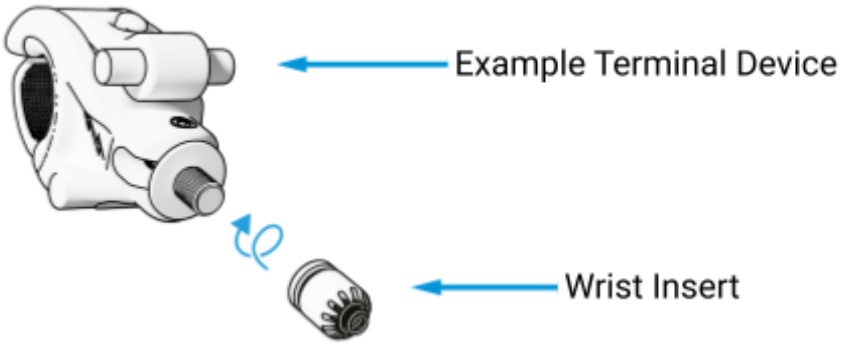
How to Use Your Hero Flex

Wrists and Attachments

The method of attaching your terminal device will depend on which wrist you have chosen:

USMC Wrist (Standard) or **OMEGA Wrist** (Optional Upgrade at the time of order)

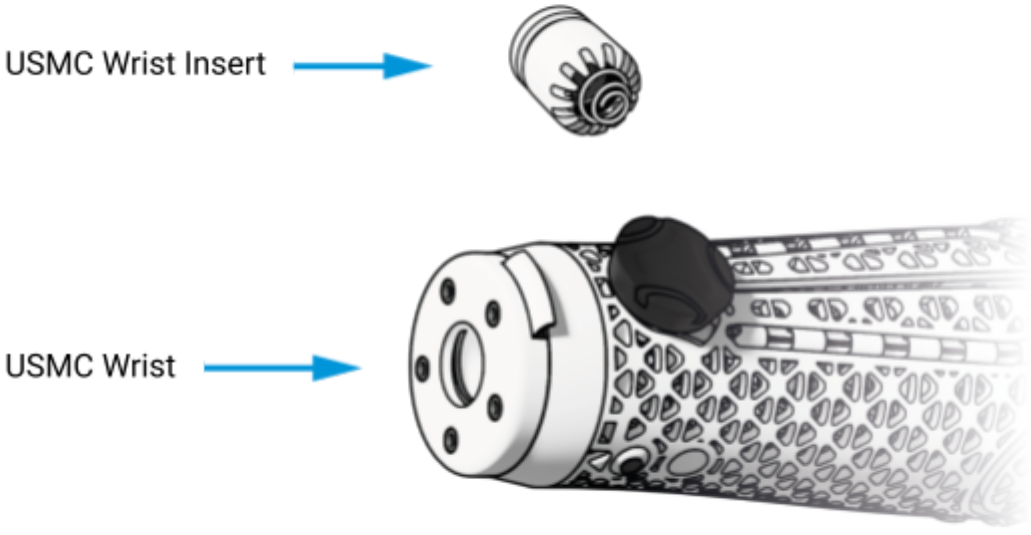
Both types of wrist come with an “Insert” which screws onto the Terminal Devices you will use for each activity:



We recommend that you purchase an extra insert for each additional Terminal Device you plan to use, as this will make swapping devices quicker and easier.

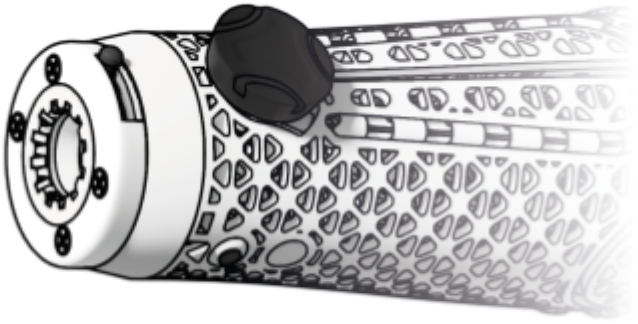
**Inserts can be purchased through Open Bionics or directly from your chosen terminal device supplier*

Check your Hero Flex to see which wrist type you have on your arm, and the corresponding type of insert:



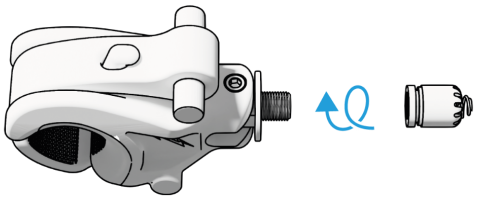
OMEGA Wrist Insert

OMEGA Wrist

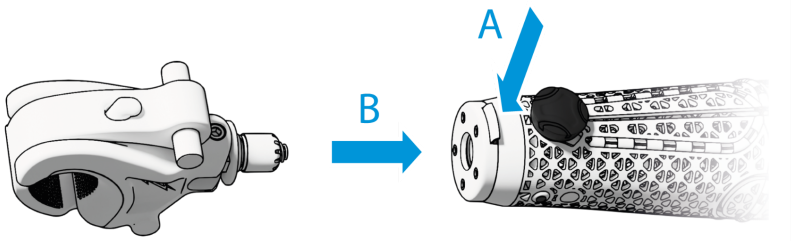


USMC Wrist Instructions:

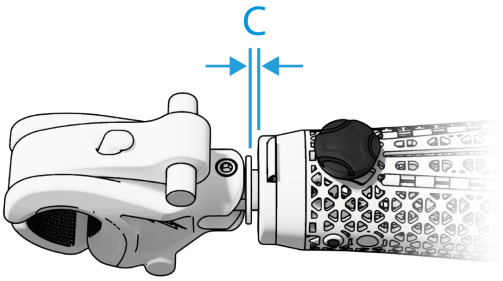
First, hand tighten the insert onto your Terminal Device:



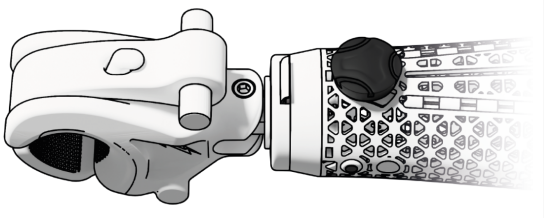
To attach the device to your Hero Flex, press the wrist button (**A**) and, at the same time, push the terminal device into the opening in the wrist (**B**):



At the first click, the device will be held so that it can't pull out, but it will be free to rotate. At this position, there is still a small gap (**C**) between the device and the wrist:



At the second click (fully inserted), the device will be held so that it can't pull out, and so that it can't rotate either. This is the Fully Locked mode. In this mode, the insert can be tightened further or unscrewed by twisting the terminal device.

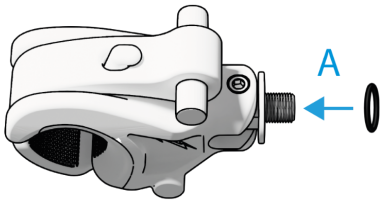


To remove the terminal device, click the wrist button again and it will pop out.

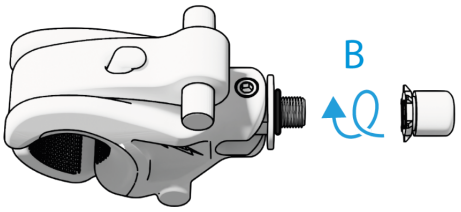
OMEGA Wrist Instructions:

A video demonstration of the OMEGA wrist is available to view here: https://www.youtube.com/watch?v=Zdr3SJRRjMA

First, place the rubber O-ring onto the threaded end of your Terminal Device (**A**):

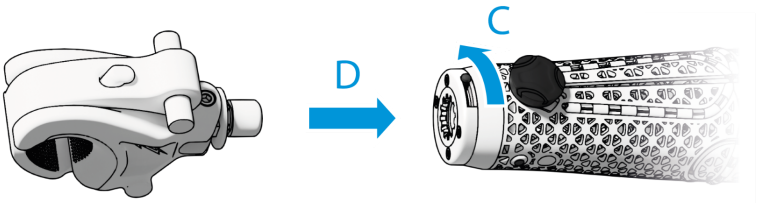


Then screw the insert into place (**B**):

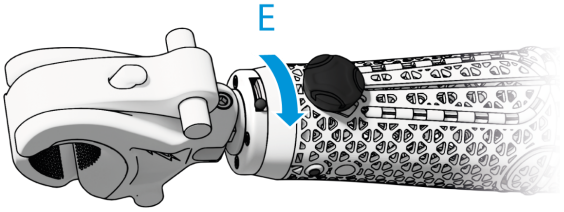


By adjusting how tightly the insert is screwed in, you can adjust how easily the tool will rotate in the wrist. If you don't compress the O-ring at all, the device will "freewheel". If the O-ring is very compressed, the tool will stay in place until you manually rotate it.

To attach the device to your Hero Flex, slide the wrist button slider to the "Open" position (**C**). Then push the terminal device into the opening in the wrist (**D**).



Then slide the wrist button slider to the "Locked" position (**E**).



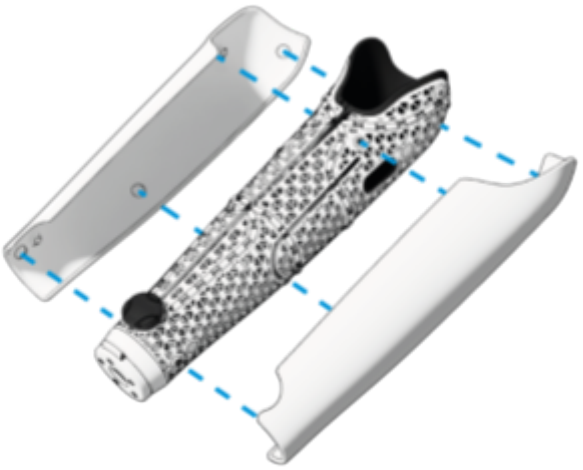
To remove the terminal device, slide the wrist button slider back to the "Open" position and then pull out the device.

Covers

The Hero Flex comes with a 3D Print file for customisable covers and metal disks to attach to the covers.

Covers can be printed at home or through 3rd Party 3D Printing service suppliers. If required, Open Bionics can advise of services local to you.

To attach the covers, line up the metal disks in the covers to the magnets in the arm and they should click into place. To remove, gently pull the cover free from the arm.



*The magnets within the Hero Flex are nickel plated. People with a nickel allergy should avoid direct contact with the magnets

For more cover options go to https://shop.openbionics.com/

Looking After Your Hero Flex

Safety

Although the Hero Flex has been engineered to be strong and robust, you should treat it as if it were your own limb - please read this section of the manual for general safety information and guidance on how to care for your arm.

Avoid subjecting your arm to excessive loads or impacts - your physical safety should not rely on the Hero Flex at any time.

The Hero Flex is designed to enable you to participate in activities and sports through the use of specific terminal devices designed for those activities and sports, we recommend you discuss your requirements fully with your prosthetist when choosing your terminal devices.

The Hero Flex doesn't include any electronics, therefore it can withstand water, dirt and muck, however we do recommend that you clean the Hero Flex after participating in any activity.

Do not expose the Hero Flex to a naked flame or subject it to excessive heat.

Storage

The Hero Flex can be stored between -25°C and +70°C.

Maintenance

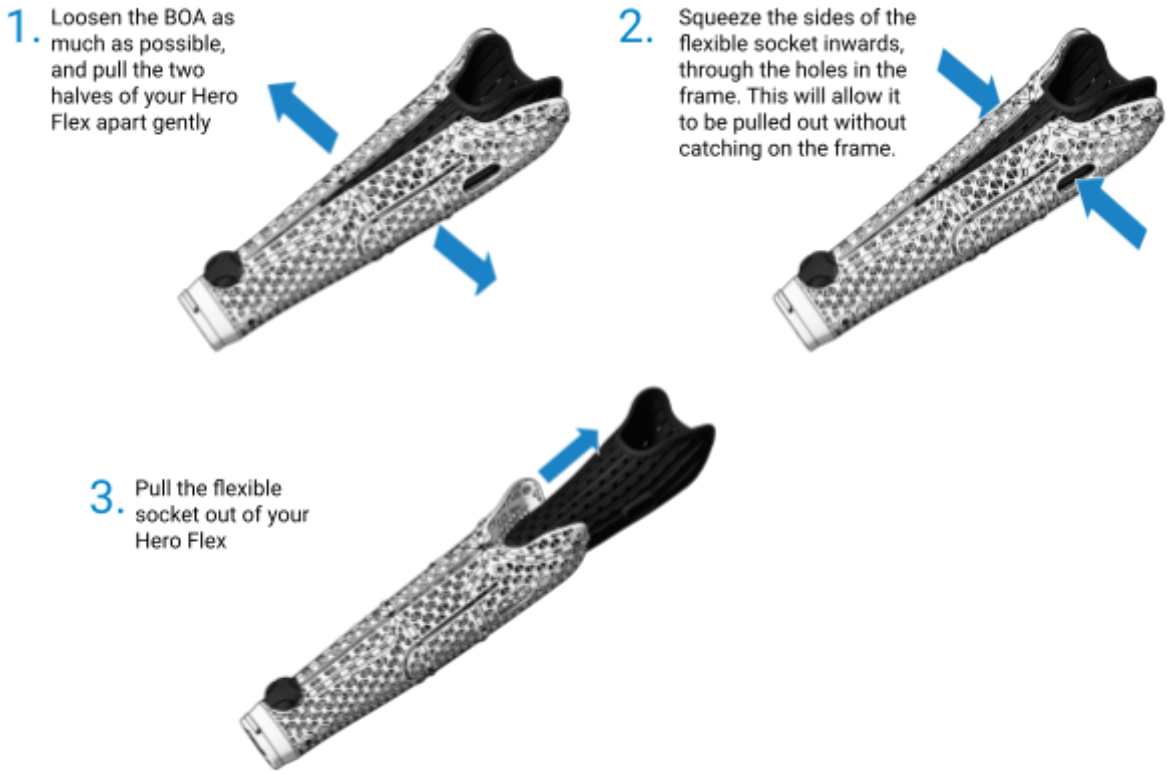
Do not attempt any maintenance or modification of your Hero Flex. If you think your arm has been damaged or is not functioning as it should, you can contact Open Bionics through support@openbionics.com or your prosthetist to arrange for repair or replacement.

It is recommended that you arrange with your Prosthesis or directly with Open Bionics through the support channel support@openbionics.com for an annual review of your Hero Flex. This allows us to keep your Hero Flex in top condition throughout its service life.

Cleaning

The Hero Flex can be cleaned using alcohol-free antibacterial wipes. In addition, the flexible internal socket is easily removable from the frame of your Hero Flex to make

cleaning easy. You should clean the flexible socket using warm, soapy water on a regular basis.



Ensure the socket is thoroughly rinsed after washing, and never use anything marked as irritant to clean the socket (such as bleach), to prevent irritation from residue.

The socket should be thoroughly dried before the next use, the best method for this is leaving it to air dry overnight.

We recommend you clean your socket daily, and the rest of the device as needed. If you find that you struggle to clean part of your Hero Arm, discuss the matter with your prosthetist.

Growing Out of Your Hero Flex

If you are still growing, your Hero Flex may eventually become too small. While the BOA Fit System™ allows you to adjust the tightness of your socket, the length is not adjustable. This means that when your arm grows in length, you may find that it becomes difficult to put your Hero Flex on.

If you think that you have outgrown your Hero Flex, speak to your prosthetist who can advise you about a re-fit.

Troubleshooting

If you experience any issues with your Hero Flex, please try the following solutions. If you are unable to solve the problem, please contact your prosthetic provider, or Open Bionics at support@openbionics.com

Problem	Solutions
Difficulty removing the inner socket.	Squeeze the rear sides of the socket inwards and pull so the two locking features clear the inside of the frame

Indications

The Hero Flex is indicated to replace some of the function of a hand for transradial or wrist-disarticulation amputees. The device can be used by those with congenital or acquired amputations. The device is suitable for bilateral amputees.

Contraindications

The Hero Flex is non-invasive and is not designed to be in contact with damaged or irritated skin. Some transradial amputees may be unsuitable due to the shape of their residual limb. For detailed information on this, please discuss further with your Prosthetist or directly with Open Bionics through support@openbionics.com. The user should be free of comorbidities that could interfere with function of the prosthesis.

Service Life & Shelf Life

The Hero Flex has a 5 year service life. The Hero Flex is custom built specifically for each user so is not intended to sit in storage. As such the Shelf Life is the same 5 year span as the Service Life.

Warranty & Returns

Hero Flex is supplied with a 36 month warranty once purchased directly from Open Bionics. The warranty begins from the day of the Delivery to the end-user. Any fit support required outside of our 8 week Fit Guarantee terms will incur a cost. This guarantees against any manufacturing defects or defects with your Hero Flex which arise out of normal use.

If you think there is a problem with your Hero Flex, please first carefully read through this manual in case any of your issues are addressed, before contacting support@openbionics.com or your prosthetic provider.

The warranty does not apply to any components that have been subject to misuse, excessive loads, deliberate damage or modification by uncertified persons unless otherwise permitted in this user manual or given written permission from Open Bionics Ltd.

Please quote the serial number for your Hero Flex when requesting any warranty repairs or returns. This can be found on the reverse of the Quick Start Guide supplied

with your Hero Flex or above the elbow on the inside of the frame. When returning your Hero Flex to us, please ensure you package it appropriately.

⚠ Warnings

There's a lot to take in in this document, so we've pulled out all the warnings throughout this document and listed them below for your convenience:

- The Hero Flex is not intended for use in activities that may result in injury or death to the user or others as a result of it failing to perform the activity as intended.
- Do not expose the Hero Flex to a naked flame. The device won't catch fire, but it will be burned and disfigured. Plastic fumes should not be inhaled.
- Maintenance or modifications to the Hero Flex should only be conducted by Open Bionics or a qualified Prosthetist (that doesn't include the covers, customise away!)
- The Hero Flex should be cleaned with alcohol-free antibacterial wipes on a regular basis. The flexible socket can be removed and washed with soapy water.
- The Hero Flex should not be used for weight lifting activities with the use of free weights

EU & UK Regulatory Compliance

The Hero Flex meets the appropriate European Union and United Kingdom standards for design, manufacture and supply of prosthetic products.

Open Bionics is accredited to ISO 13485 and certified by UL.

The Hero Flex and accompanying documentation are CE marked indicating that it is compliant with the requirements of EU Regulation MDR 2017/745 (MDR) and UK statutory instrument SI 2002 No 618 - amended (UK MDR 2002)

The Hero Flex and accompanying documentation are UKCA marked indicating that it is compliant with the requirements of Medical Device Regulations 2002 - subsequently amended by: The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019, The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020

For full national compliance information please refer to the UK, EU and US signed declarations of conformity available on request from Open Bionics.

Symbols

CE mark

CE

This mark indicates the product conforms with the essential requirements and provisions of Regulation MDR 2017/745.

UKCA mark

UKCA

This mark indicates the product conforms with the essential requirements and provisions of UK statutory instrument SI 2002 No 618, as amended (UK MDR 2002)

Caution

Indicates the need for the user to consult the instructions for use for important information such as warnings and cautions

Manufacturer (adjacent to company name)

This mark indicates the manufacturer

Refer to instruction manual

Indicates the user must refer to the instruction manual before operating the device.

Serial Number

Indicates the serial number that uniquely identifies the device

Date of Manufacture

Indicates the date the medical device was manufactured

Use-by-date

Indicates the date after which the device is not to be used

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