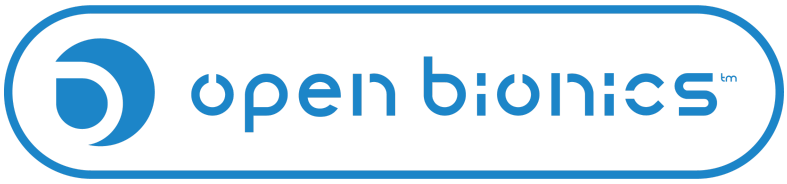


TRIAL KIT

Prosthetist User Manual

Version 3.0

CONTENTS

1 Introduction

The Trial Kit is a device which aids clinical assessment, while also allowing the user to experience some of the Hero Arms functionality.

Please Note: When 'you' is referred to within this user manual, it is referring to trained Prosthetists that have undergone the necessary Open Bionics clinical training needed to use the Trial Kit correctly and safely. When we refer to 'patient' we are referring to the wearer of the device.

The Trial Kit is designed to allow you to fit a prospective user with a Hero hand without any custom design. The Trial Kit will give a user an idea of the function and weight they can expect if they were to purchase a Hero arm. It will allow you to select appropriate EMG sites and decide whether the Hero Arm would be suitable for the patient and assess their ability to trigger the EMG's consistently. In addition the Trial Kit will allow you to check the suspension of the check socket with the approximate weight of the Hero Arm.

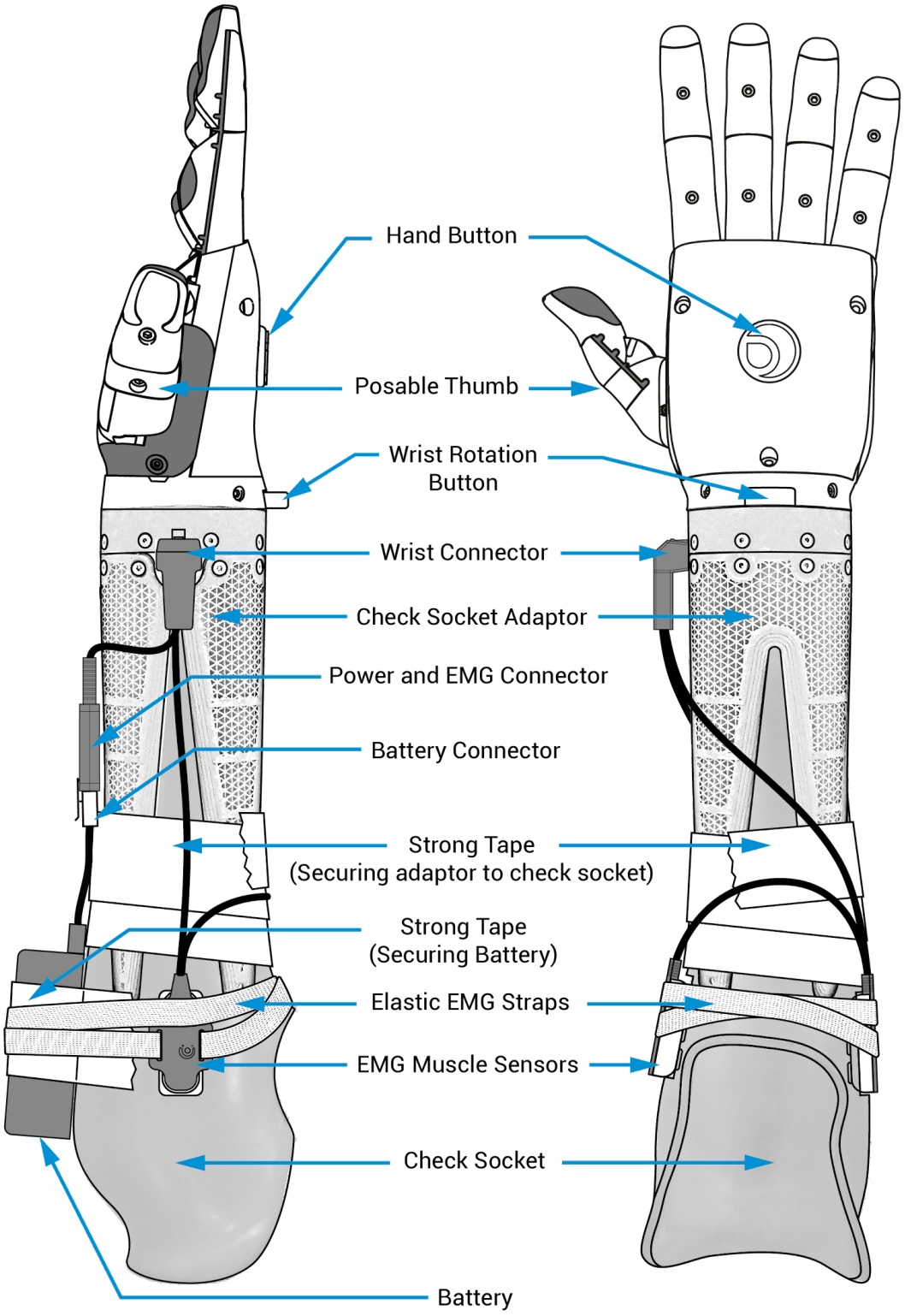
The Trial Kit enables patients to trial product features and characteristics of the Hero Arm, within the clinic and under the supervision of a trained prosthetist **ONLY**. It gives the patient the opportunity to get a feel for whether the Hero Arm would meet their needs and expectations.

All contraindications are the same as the Hero Arm.

To search for a specific word or phrase, hit Ctrl + F (on Windows) or ⌘ Cmd + F (on Mac).

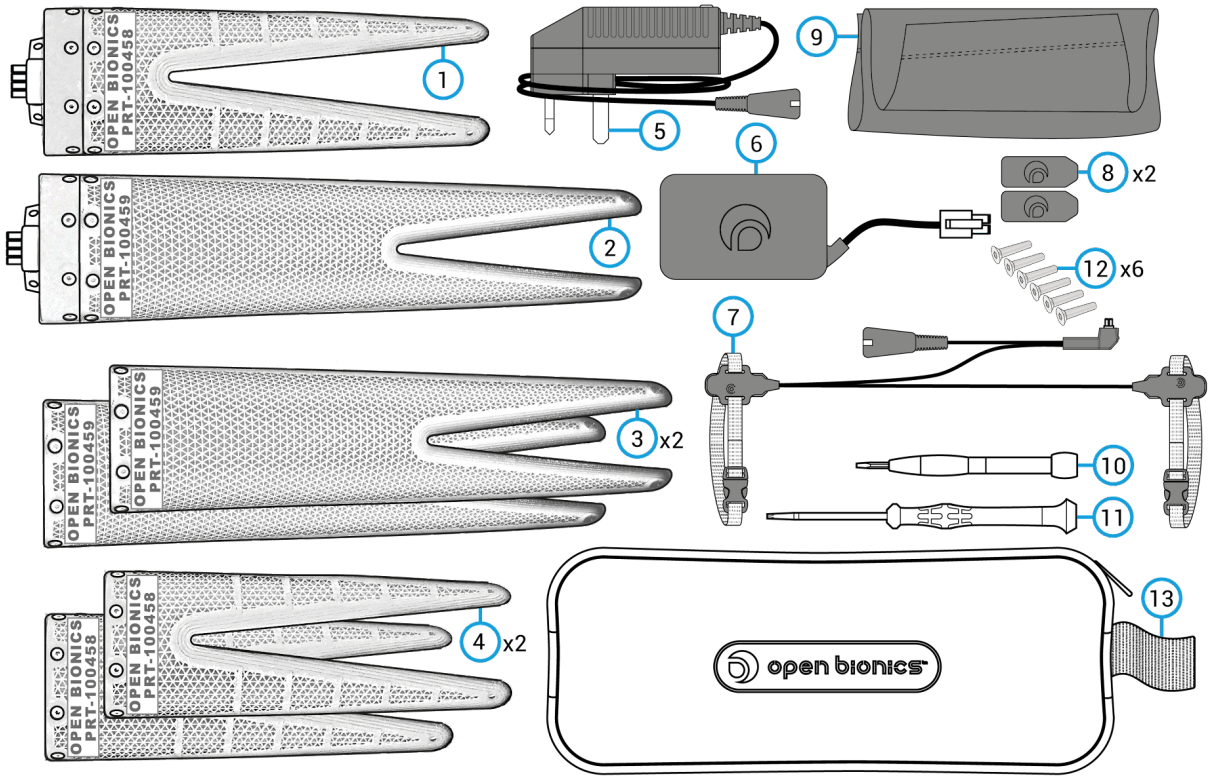
2 Trial Kit Overview

Note: Your Trial Kit may look slightly different from the version pictured.



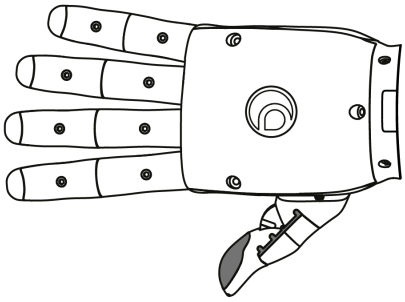
2.1 What's in the Box?

Please Note: If you are missing anything from what is listed below, please don't hesitate to get in touch.



1. Check Socket Adaptor (Short)
2. Check Socket Adaptor (Long)
3. Spare Wings (Short)
4. Spare Wings (Long)
5. Battery Charger
6. Battery
7. EMG Sensors
8. Cut Guides
9. Textile Sleeve
10. Yueran Screwdriver - EMG Sensitivity Adjustment
11. Wera Screwdriver - Removing / Replacing Wings
12. M2 x 8mm Spare Screws
13. Tool Case

Please Note: The Trial Kit is only compatible with the Hero hand. The Hero hand is **not** sold or loaned separately.

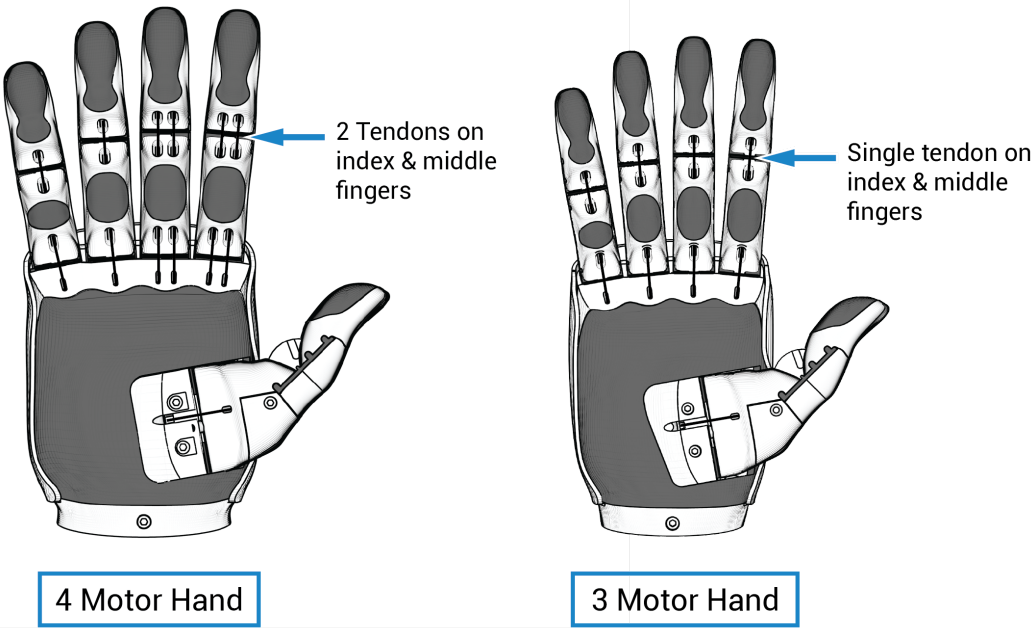


Please note: Hand information (size and side) will be requested at the time of purchase of the Trial Kit.

2.2 Configurations

Each Trial Kit is assembled to best represent the end product, this being the Hero Arm. The Trial Kit comes with 2 different lengths of Check Socket Adaptors. The appropriate size of Check Socket Adaptor should be chosen based upon the patient's arm length. The chosen adaptor is then secured to the check socket (check socket supplied by the prosthetist) and positioned relative to the patient's sound side. If the patient is a bilateral amputee, the desired arm length will be down to your discretion.

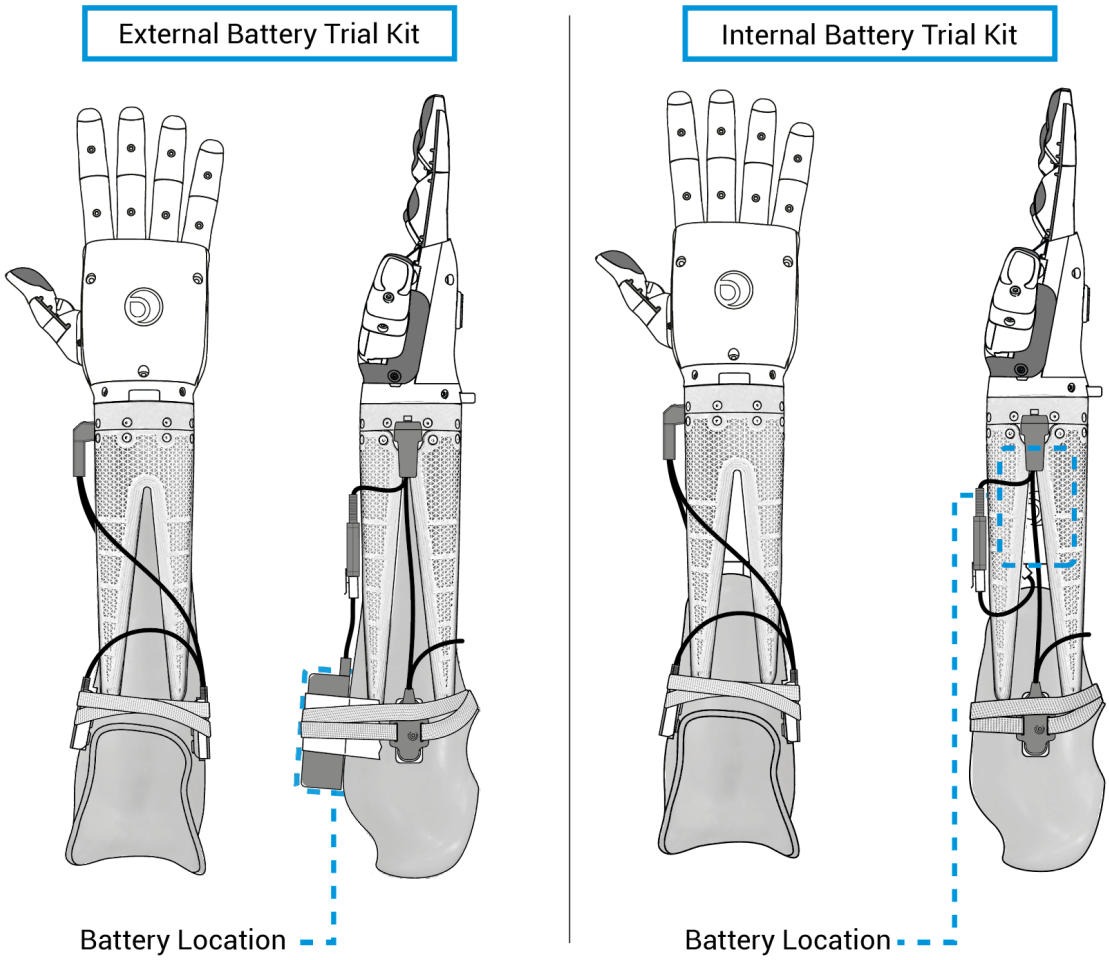
All hands sizes and chiralities are available on a loan period from Open Bionics. If you require a loan hand please don't hesitate to contact **support@openbionics.com**.



The Trial Kit is compatible with any hand size (Small, S92, Medium, S96 and Large, S99). The 4 Motor versions (Medium and Large hands - S96 and S99) have 2 tendons on both the index & middle fingers, which allows them to move independently of each other. On the 3 Motor version (Small hand - S92), the index & middle fingers will always move together.

Hero hand measurements are available in the **Clinician Design Guidelines** booklet page 13. This guide may be used to aid hand-size selection prior to ordering a loan hand.

The Trial Kit can be set up in two different layouts: internal or external battery. These use the same equipment but have a different battery location. The functionality of both layouts are exactly the same, but they have some noticeable cosmetic differences as shown below.



2.3 Sidekick App

Our App is here to assist throughout your journey you can download it for both Android or iOS for free. If you are a Clinician take full advantage of the muscle graph feature which will help you locate the optimal EMG location on the patient.

GET THE APP

3 Getting Started

Before using the Trial Kit for the first time, please familiarise yourself with this User Manual and the **Hero Arm User Manual.**

3.1 Trial Kit - Use Conditions

The Trial Kit is intended to be used within a clinical environment under the supervision of a prosthetist that has undergone all the relevant clinical training for this device. The Trial Kit is a device which aids clinical assessment, while also allowing the user to experience some of the Hero Arms functionality. Such activities include:

- Triggering the EMGs to control hand function
- Pick and place tasks (objects no heavier that 1kg)
- Cycling through grip modes

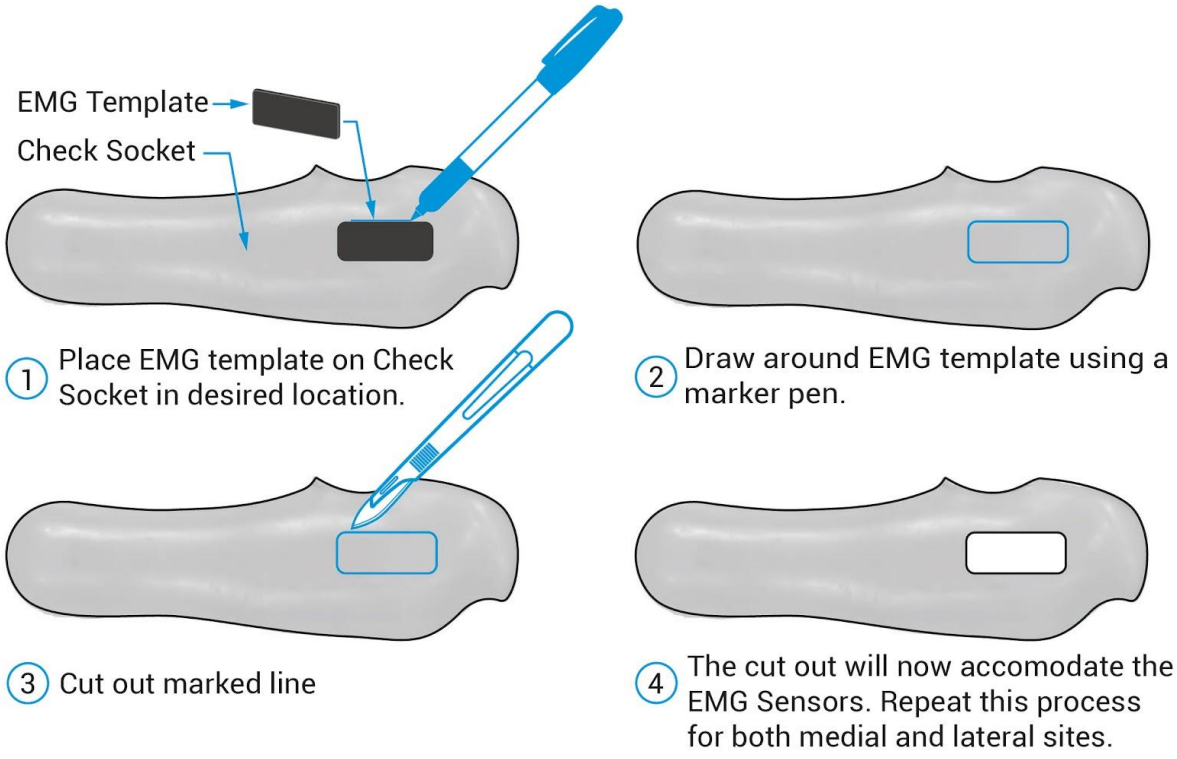
The Trial Kit **MUST NOT** be used outside of the clinic, the product is designed for in clinic use **ONLY, do NOT send home with patients**. The Trial Kit must not be exposed to water other than what is specified in this manual (Thermoforming/Cleaning).

Note: You can use your Hero Arm above -5 °C (23 °F) and below +50 °C (122 °F). You can use it at pressures equivalent to altitudes of up to 4000 m (16,400 ft), making it safe to use in the cabin of a commercial airliner.

4 Fitting the Trial Kit

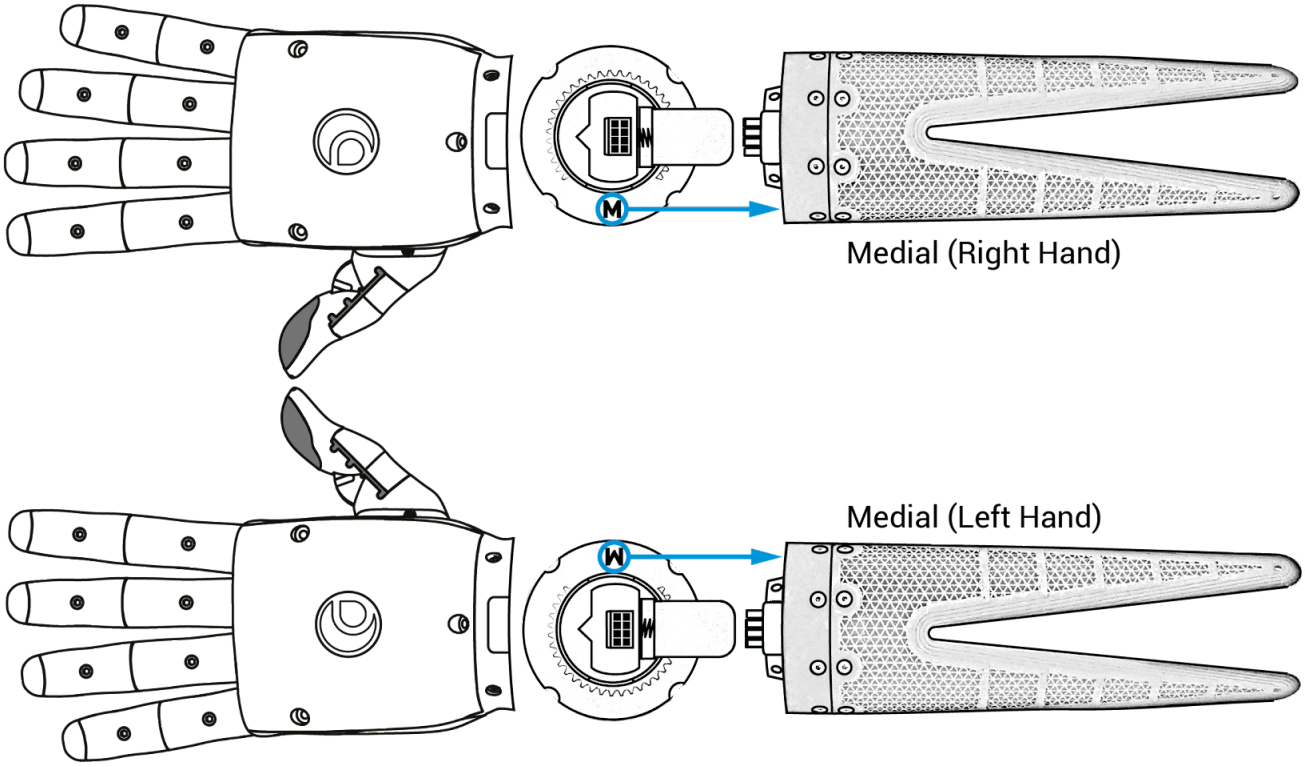
4.1 Marking out EMG sites

The Trial Kit is to be used with a check socket (details on how to secure the Check Socket Adaptor to the Check Socket is shown here). Prior to securing the check socket to the Check Socket Adaptor, EMG sites need to be marked. EMG templates are provided in the Trial Kit to mark the EMG sites on the patient.

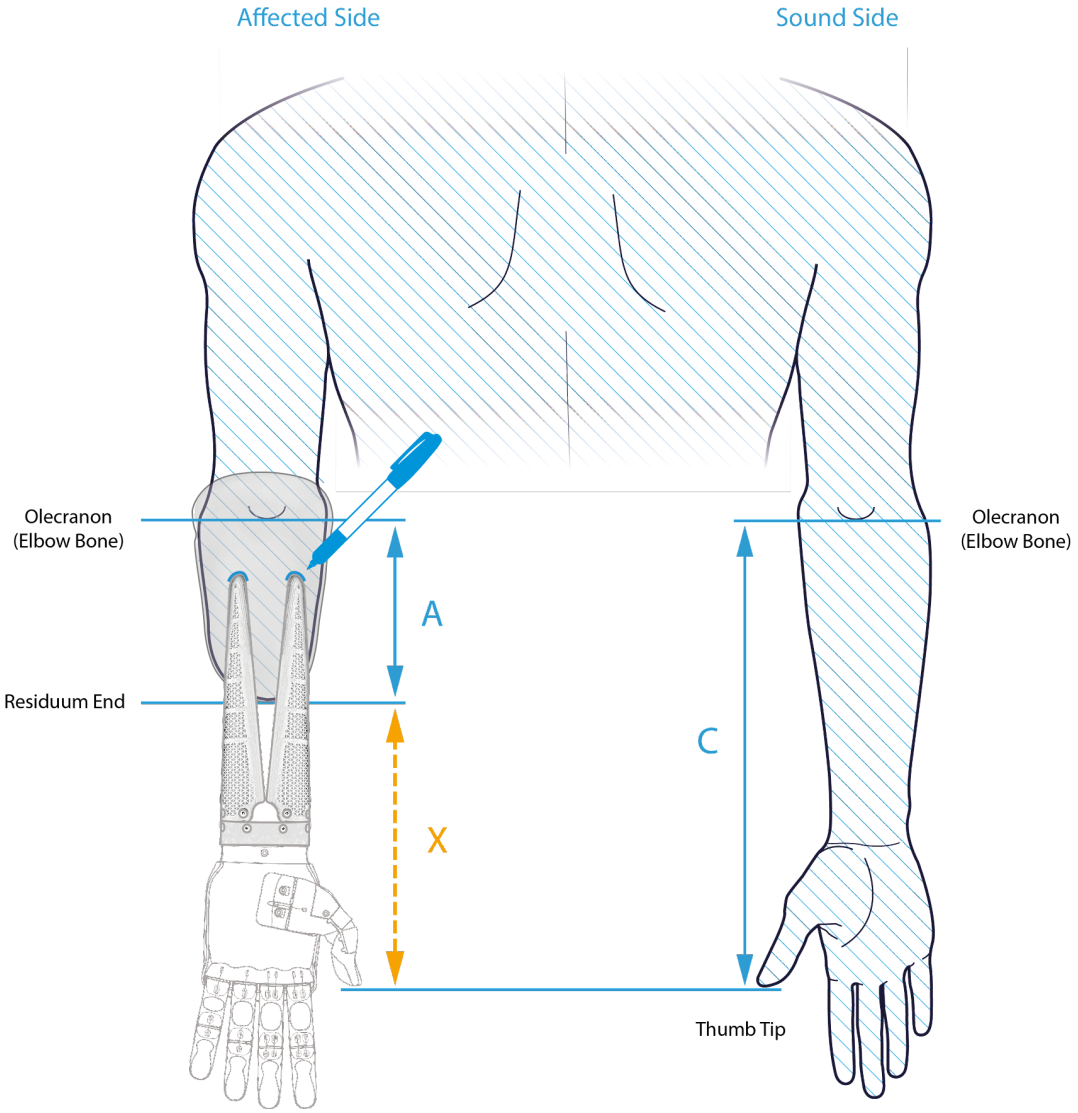


4.2 Check Socket Adaptor Orientation

The Trial Kit is labeled with an ‘M’ for Medial on the flat face of the wrist (see illustration below). This should always be positioned on the Medial side of the arm to ensure the correct rotation of the hand. Ensure this is correct before securing the hand.



4.3 Internal or External Battery



$$(C - A) = X$$

If X = 21cm or greater:

→ Customer can have either an Internal or External Battery Hero Arm

If X = less than 21cm:

→ Customer is only suitable for the External Battery Hero Arm

Please consider the following when assigning a user an internal or external battery version of the Hero Arm.

The distance from the residuum end to thumb tip determines whether a customer is eligible for an internal or external battery version of the Hero Arm.

Measurements **(A)** and **(C)** should be taken from the olecranon (elbow bone), and used to calculate distance **(X)**.

Internal Battery Hero Arm - 21cm is the minimum distance from the thumb tip to the end of the residuum for an internal battery version. A user with an **(X)** distance of 21cm or greater is eligible for either an internal or external battery arm.

External Battery Hero Arm - A user with an **(X)** distance less than 21cm is only eligible for an external battery version.

NOTE: If the plaster cast undergoes **ANY** rectification in length then the Olecranon to rectified residual length should be deducted from **(C)** rather than the **(A)** distance.

The measurements provided on step 5 of the Prosthetist Clinic order form will distinguish whether the user is suitable for an internal or external battery version of the Hero Arm.

You may decide that an eligible internal battery user would be more suited to an externally situated battery due to weight concerns, this will be down to the prosthetists discretion as to what is appropriate. If you would like to discuss or have discussed a different option with the customer, please write the alternative in the notes section on the Clinic order form.

4.4 Arm Configuration

Please note within manufacture all Hero Arms are shortened by a length of 1.5cm, unless specified otherwise by the clinician, from your measurements (with exception to very long residuals where this reduction may not be feasible), to offer a more natural look. If further shortening is required to allow for better weight distribution please provide this information in the order notes when completing an order on the Clinic order form.

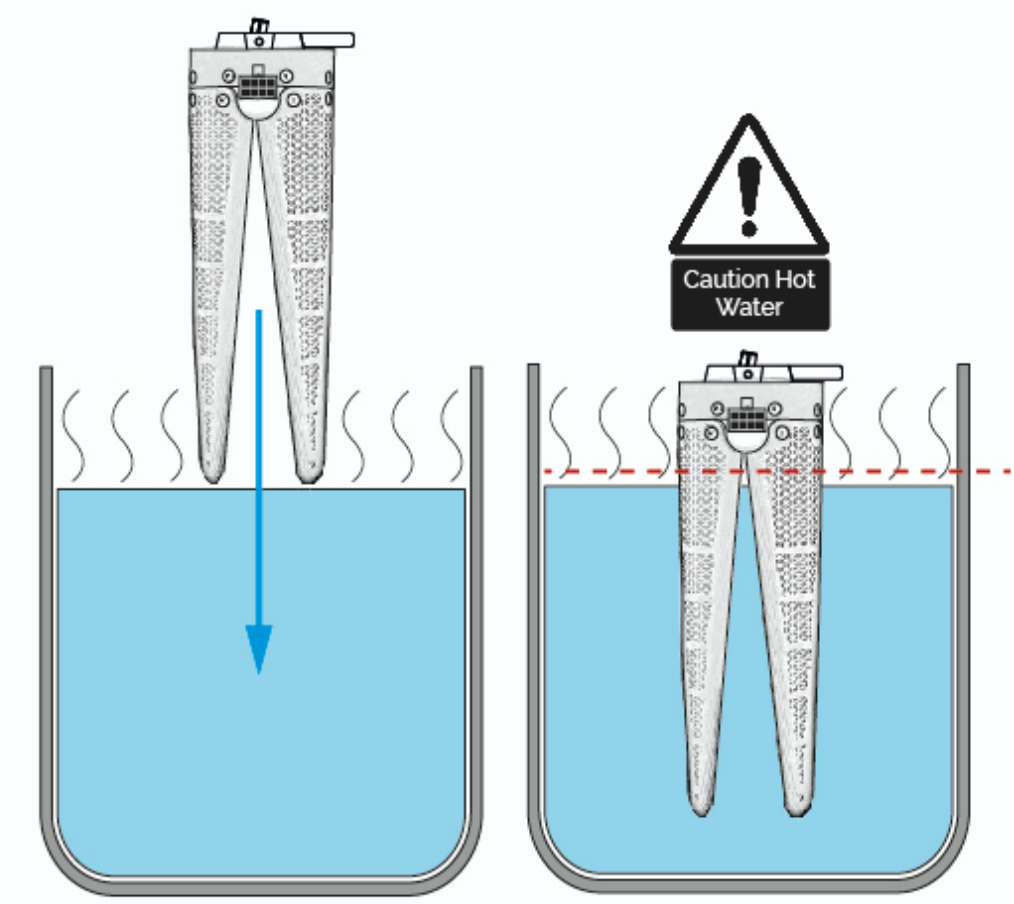
NOTE: All adjustments (trimline height, shape, suspension, etc.) to the check socket must be replicated in the cast/scan data prior to sending.

4.5 Bilateral Amputee

Open Bionics have fitted bilateral users and are aware that this type of amputation affects how measurements are taken for fitting the Hero Arm. We ask that the prosthetist uses their judgement as to an appropriate arm length for the user. Please don't hesitate to contact us for additional support if necessary.

4.6 Thermoforming (Optional)

To achieve a more secure fit between the check socket and adapter, you can thermoform the wings of the adapter, using hot water (Please note: when thermoforming, be sure not to submerge the electronics in the wrist). If you wish to apply heat to a more localized area, use a heat gun on a medium heat. The adapters can also be attached to the test socket using sticky back hook and loop Velcro.



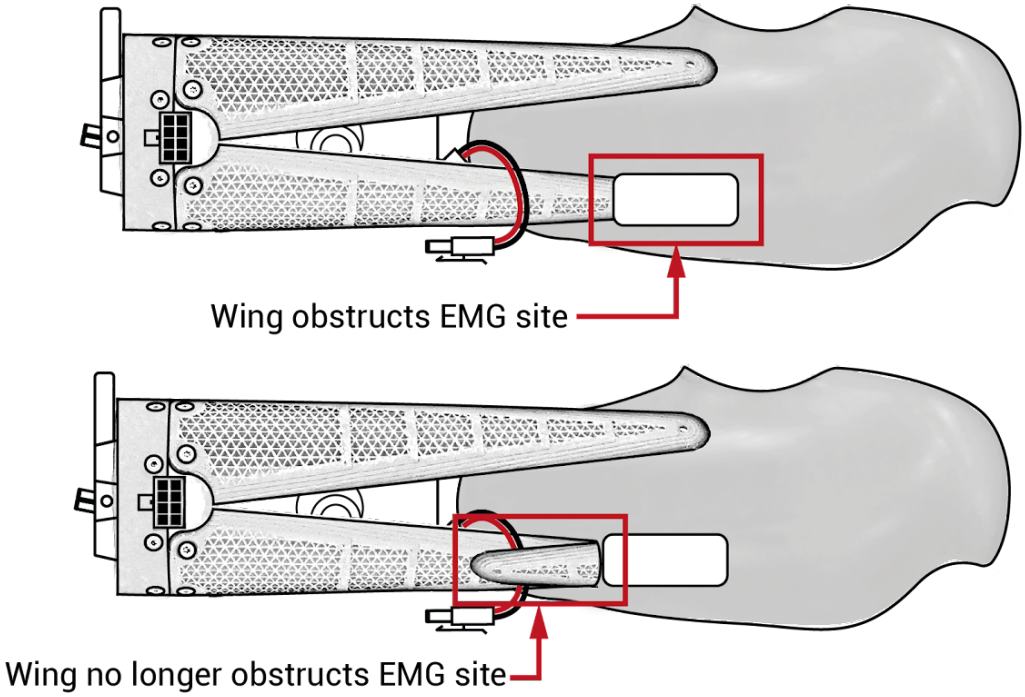
PLEASE NOTE: When thermoforming the wings in hot water, be sure not to submerge the electronics in the wrist or exceed the dashed red line seen in the diagram above.

4.7 Trimming Check Socket Adaptor

When positioning the Trial Kit Check Socket Adaptor you may find the wings on the adaptor interfere with the EMG Sensors or other features on the check socket. If this problem does occur, the wing or wings that are interfering can be heated (using the thermoforming process) and folded back on themselves to shorten the wing to the desired length. Alternatively the wings can be cut to the desired length; however this is irreversible and may result in the Check Socket Adaptor becoming unsuitable for future patients.

If you run out of wings for the test socket process please contact open bionics and we can provide you with new sets.

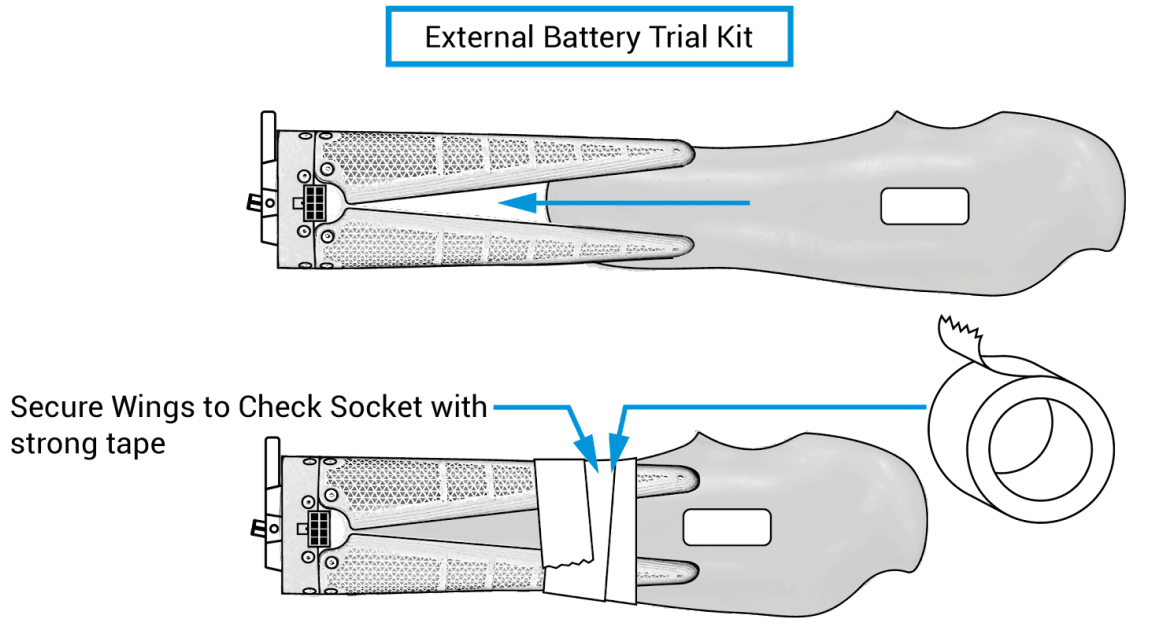
Please Note: Cutting the wings may result in sharp edges, we advise these are capped with tape.

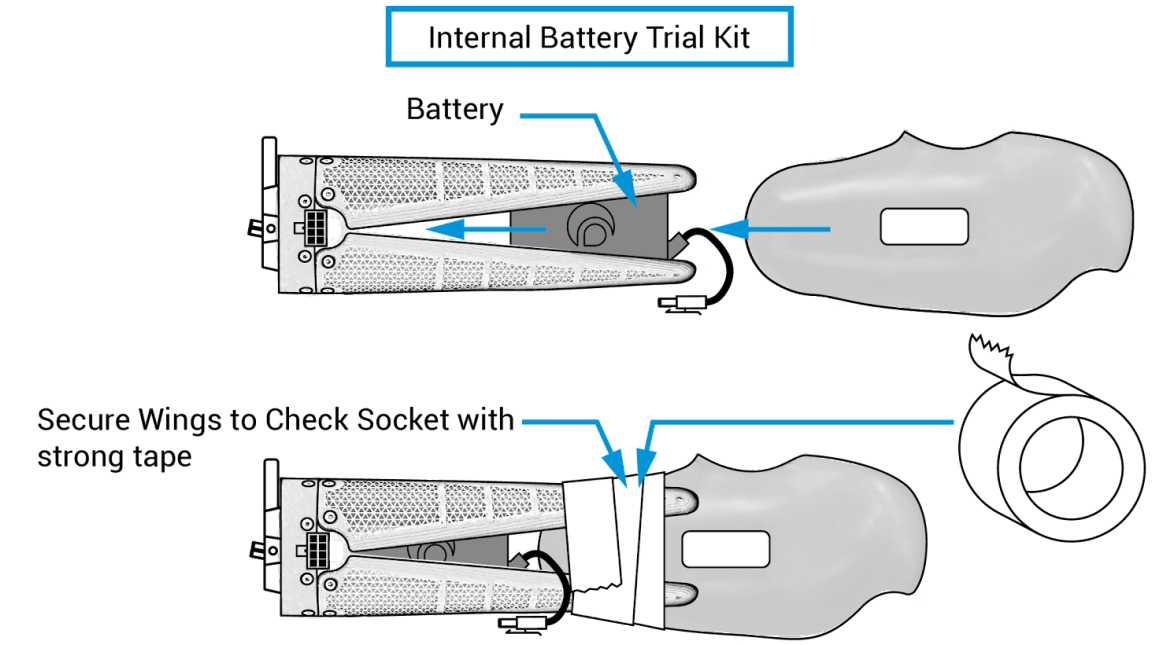


NOTE: The wing has been folded back on itself using the thermoforming process. Please refer to the 'Thermoforming' section of the guide for further information.

4.8 Securing the Check Socket Adaptor

After the appropriate check socket adapter is selected (short or long wings), and the arm length established, it can be fixed to the check socket via strong tape. Please ensure the tape does not come into contact with the patient's skin. If the patient requires an Internal Battery arm, be sure to insert the battery into the adaptor prior to taping.



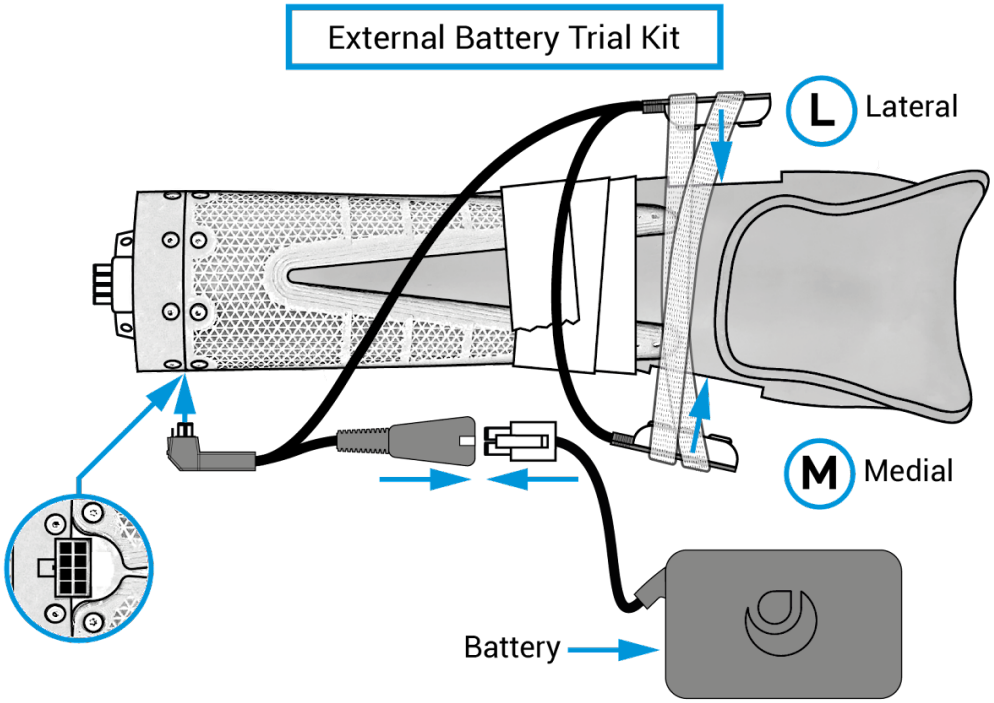


4.9 Wiring Layout

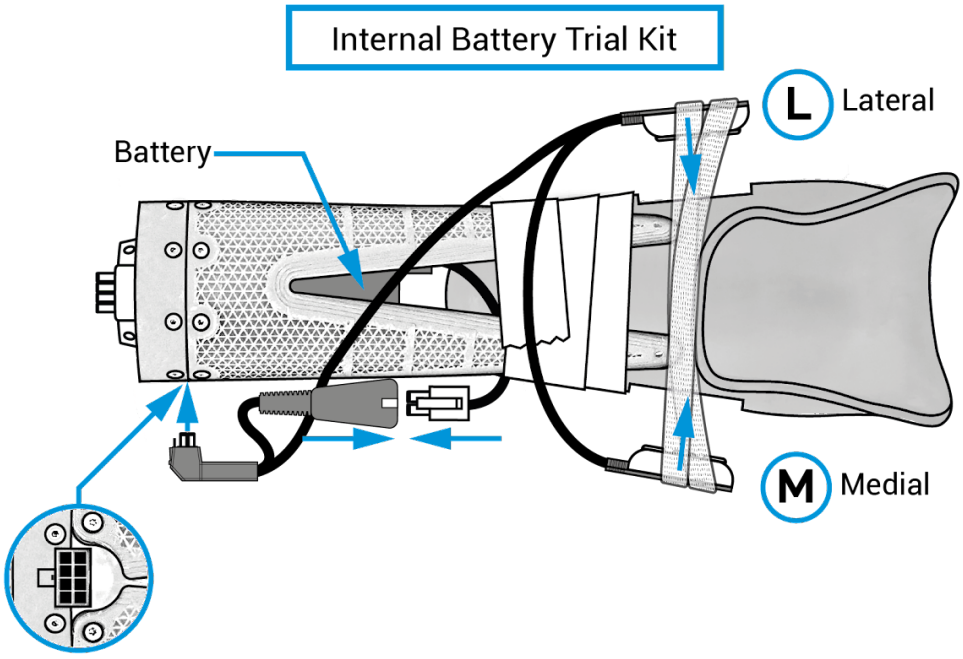
Once the Check Socket Adaptor is secured to the check socket, identify the Medial and Lateral EMG sensors which are labelled with an ‘M’ and an ‘L’. The EMG Sensors must be orientated so the ‘M’ and ‘L’ are pointing away from the wrist, and on the correct sides of the patient’s arm. Once positioned correctly, connect the EMG

Sensors to the Battery and into the Wrist. The diagram below illustrates the wiring layout for the Trial Kit.

For



the

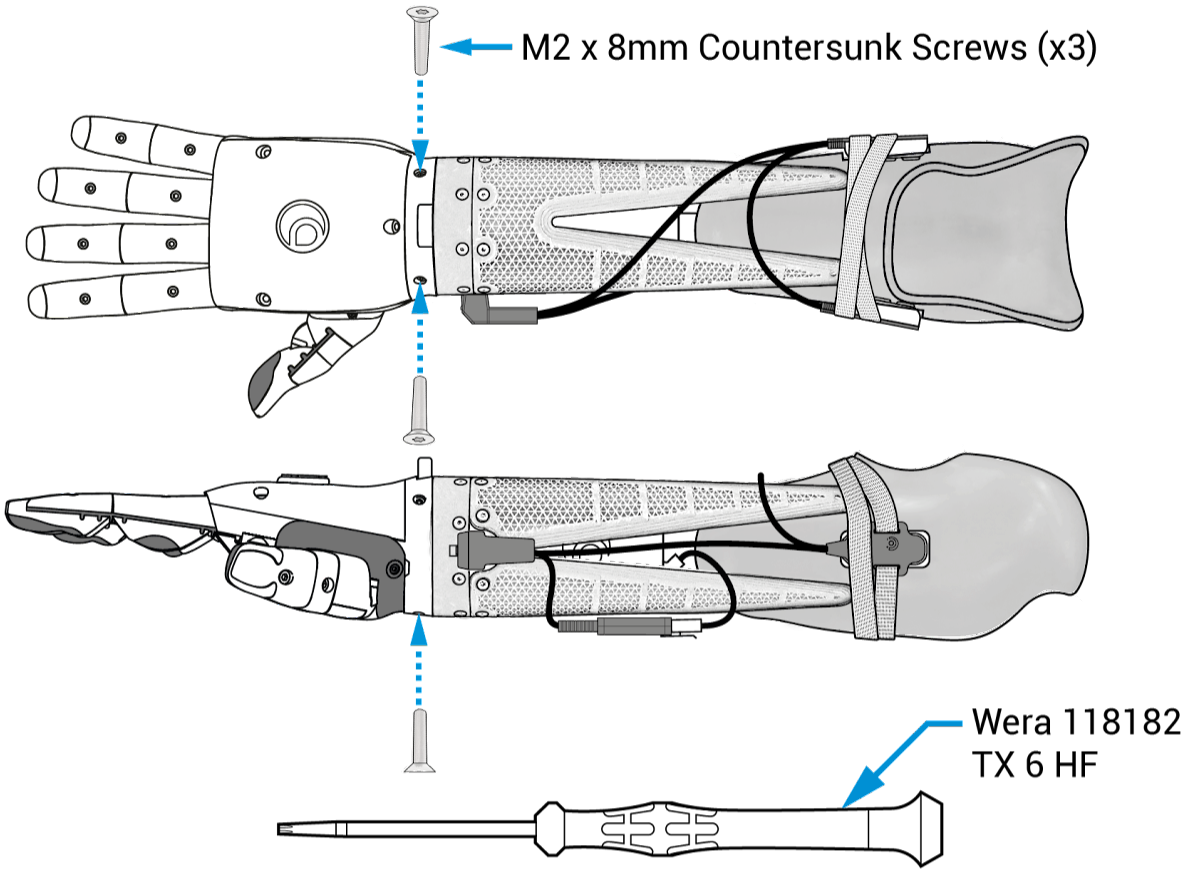


external battery setup, the battery may now be taped to the check socket underneath the arm. The tape should only touch the black sleeve surrounding the battery, and not the wiring, to ensure the battery is not damaged. Refer to the **Battery** Section for more details. Please also avoid putting tape directly onto the EMG's during this process.

Once the wiring is all connected, the supplied lycra sleeve may be slipped over the entire assembly. This helps to keep the system neat and prevent the wires from being snagged or disconnected during the trial.

4.10 Attaching the Hand

The hand may now be attached onto the Trial Kit. This is done via three M2 x 8mm Torx Countersunk Screws that drop into the wrist of the Hand and fix into the wrist of the Trial Kit. These are supplied in a small bag within the box, spares are available upon request.



5 Trial Kit In Use Guidelines

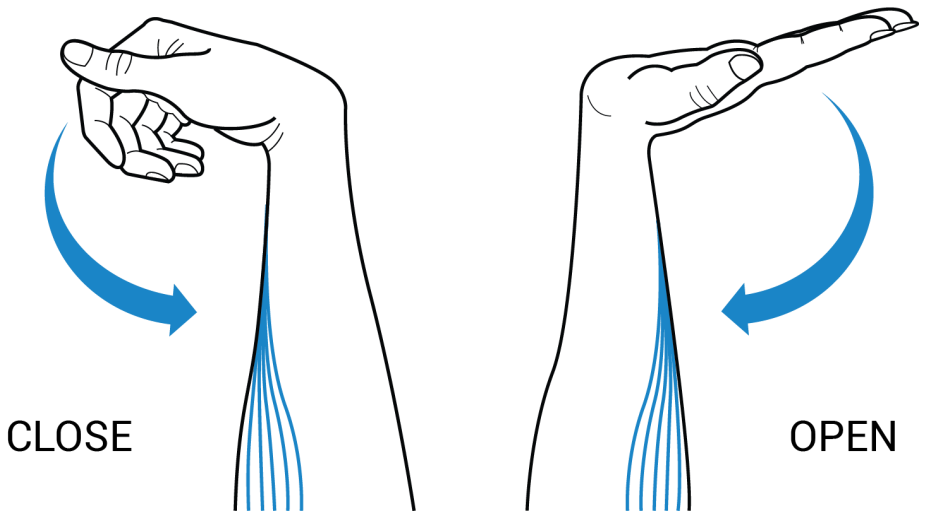
Once the Trial Kit is set up for an individual you may wish to run through a variety of pick and place tasks to give the patient a feel for the product. We do not recommend picking up heavy objects (exceeding 1KG) or objects that may cause damage to the patient or product if dropped.

5.1 Controlling the Hand

The Trial Kit operates a Hero Hand, an advanced myoelectric, multigrip bionic hand. The EMG Sensors that come with the kit detect muscle movements, and the hand responds intuitively.

When fitting a Trial Kit, care must be taken to ensure the EMG Sensors are positioned in the correct orientation. Each sensor is labelled with an 'L' or 'M' indicating whether it should be located medially or laterally on the arm. The bionic hand is controlled by tensing the same muscles which are used to open and close a biological hand. To close the Hero Arm's hand, and perform the selected grip, imagine flexing the wrist inwards while pulling the fingers into the heel of the hand.

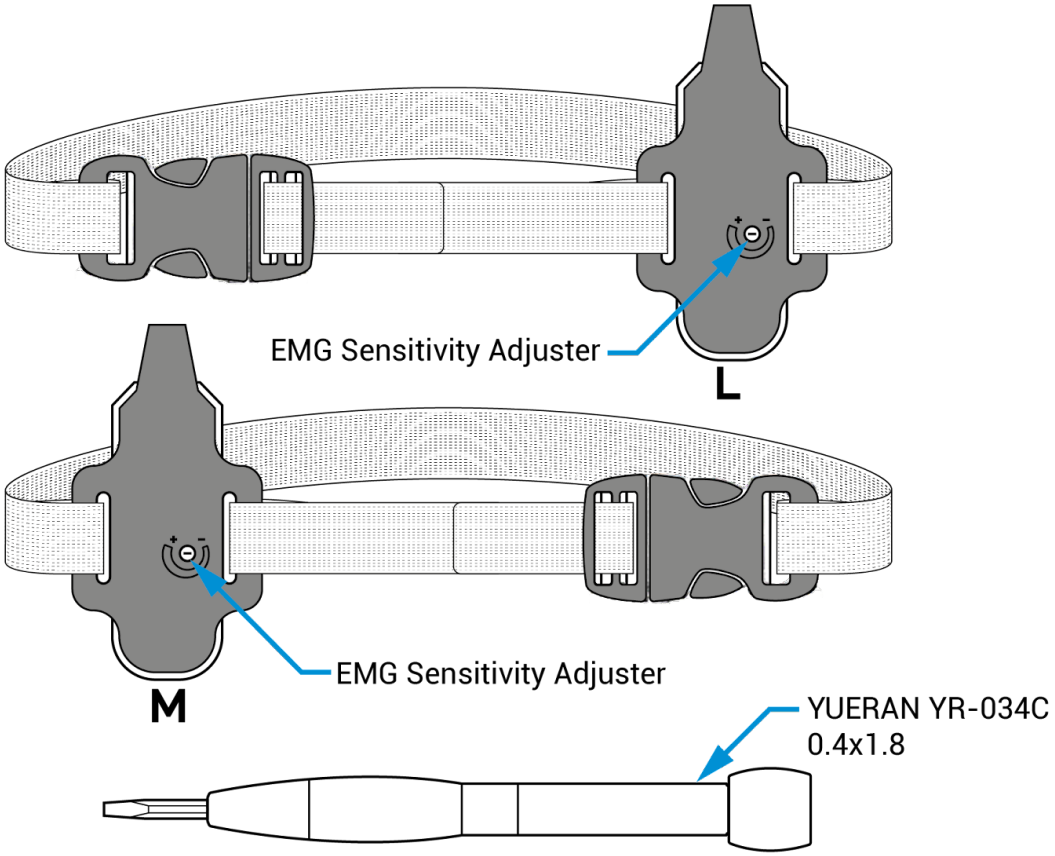
To open the hand, imagine extending the wrist with an outstretched palm.



If you are having trouble getting the hand to respond, please see the **Troubleshooting** section.

5.2 EMG Sensitivity

EMG sensitivity can be adjusted by rotating the dial clockwise to increase sensitivity, and anticlockwise to reduce sensitivity. The correct sensitivity is at your discretion, ensuring the patient can operate the device comfortably. Please note: The dial should only be adjusted using the appropriate tool (supplied in your Open Bionics tool kit) to ensure no damage is caused to the dial.



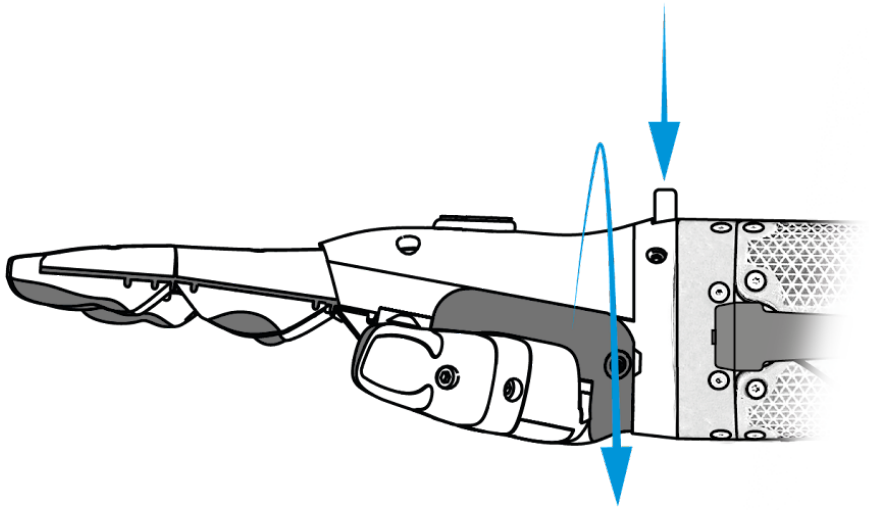
Please Note: Only the tool specified here is to be used to adjust EMG Sensitivity Dials

5.3 Speed Control

The hand will move slower when the user's muscles are tensed gently, and will move quickly with a firmer tense. This control can be useful for manipulating small or delicate objects.

5.4 Wrist Rotation

You can adjust the rotation of the wrist through 180°. To do this, press the Wrist Button at the base of the wrist (on the back of the hand), and rotate to the desired angle. Release the button to lock the wrist in the new position.



5.5 Calibration

When you power on your Trial Kit for the very first time, the hand may perform a calibration routine - this will involve closing each of the fingers and the thumb in order to check everything is working correctly. It is important that the fingers are not obstructed during calibration, as this could cause the calibration to fail. The Hand Button will pulse purple to indicate the hand is calibrating. A successful calibration is indicated by the Hand Button turning white once the movement of the hand has stopped.

If the calibration is unsuccessful for some reason, such as an obstruction preventing the full movement of any of the fingers, the hand will repeat the calibration a second time - ensure any obstruction is cleared before the process repeats. If any finger fails calibration, it will remain in the open position and will not respond to muscle inputs.
If you disconnect the battery before powering off the hand, it will need to recalibrate the next time you power it on. You should therefore always switch off the hand, if it is working correctly, by holding down the Hand Button, before disconnecting the battery.

There may be some situations when you want to force the hand to calibrate, such as if a finger is no longer closing or opening fully - in this scenario it is then acceptable to disconnect the battery with the hand powered on in order to initiate a calibration. If the hand repeatedly fails to calibrate, please see the **Troubleshooting** section of this manual.

6 Notifications/Status

6.1 Switching On

To switch on your Trial Kit, press the Hand Button for 1 second. The Hand Button will pulse purple while calibrating. Once it is ready to use, the Hand Button pulses white.

6.2 Checking the Battery Status

To check the status of the battery, with your Trial Kit switched on, hold the Hand Button down for 1 second. The battery life is indicated by the colour of the Hand Button:

Battery Level Indicator	
Hand Button Colour	**Battery Level**
 **Green**	40%-100%
 **Amber**	20%-39%
 **Red**	2%-19%
 **Red Flashing**	Under 2%

6.3 Charging the Battery

Your Trial Kit comes with a battery and Smart Charger. The battery life of the Trial Kit will vary depending on how heavily you use it, but we recommend charging it before every trial.

You must remove the battery from the arm before charging. For safety reasons, only ever charge your battery using the Smart Charger provided with your Trial Kit.

Follow the steps below to charge your Trial Kit battery:

1. Switch off the Trial Kit by holding down the Hand Button for 3 seconds

2. Once switched off, unplug the battery, by pressing the latch on the male connector and pulling on the white connector.
3. Remove the battery from the arm by removing the securing tape
4. Plug the battery into the supplied Smart Charger
5. Plug the charger into a mains power outlet
6. The status of the Smart Charger light will flash to indicate that the battery is charging.
7. When the battery is fully charged, the status of the Smart Charger light will stop flashing and turn solid green.
8. You can now disconnect the battery from the Smart Charger and reconnect it to the Trial Kit.

6.4 The Hand Button

The multi-function button on the back of the hand can be used to control a variety of functions of the Trial Kit:

- Hand On/Off
  - To switch **on** the Trial Kit, press the button for 1 second
  - To switch **off** the Trial Kit, press the button for 3 seconds

- Change Grip Group
  - Your Trial Kit has multiple grip groups, to change between these, press the Hand Button for 0.5s. See '**Grip Modes**' in the **Hero Arm User Manual** for more information on grips

- Freeze Mode
  - To come out of freeze mode press the hand button for 0.5s the light will change from blue to white and the hand will reverse back to function as normal. Or you can also exit freeze mode by holding the close signal for 3s.

- Check Battery Status
  - Press the Hand Button for 1s, and its color will change to indicate the battery level.

- Calibration
  - Double tap the Hand Button, the hand will flash Blue and go through all the motions to clear any errors.

The Trial Kit will notify you of a variety of status changes through the Hand Button colour, vibration, and beeper. These are summarised below (in addition to the battery level indicators listed in 'Checking the Battery Status'):

 - Indicates a vibration of the EMG Sensors

Hand Button Colour	Notification
Purple (pulsing)	Initialising / Calibrating
White (pulsing)	Normal operation
Green (flash)	Grip change (number of flashes indicates grip number)
Purple (flash)	Grip group change (number of flashes indicates group number)
Purple (solid)	Shutting down
Blue (pulsing)	Freeze Mode active
Orange (pulsing)	Low battery warning
Red (pulsing)	Battery too low (followed by automatically powering off)
Yellow Blue (pulsing)	Hero Arm is getting too hot
Yellow Red (pulsing)	Hero Arm has reached maximum temperature (followed by automatically powering off)
Red (solid)	EMG communication failure

7 Looking after your Trial Kit

7.1 Safety

The Trial Kit provides the patient the opportunity to get a feel for whether the Hero Arm would meet their needs and expectations, it is not designed for prolonged use and should be used in a clinical environment only. Please read this section of the manual for general safety information and guidance on how to care for the Trial Kit.

The patient should not attempt to lift or carry heavy objects exceeding 1KG and avoid subjecting the Trial Kit to excessive impact - the patients safety should not rely on the arm at any time.

Your Trial Kit assembled is not waterproof. Water can only come into contact with the wings as explained in the **Thermoforming** section of this guide. If any water reaches the internal components of the hand, EMG sensors or Wrist they are likely to cause damage and eventual failure. Water damage is not covered by the Trial Kit warranty.

Do not expose it to a naked flame or subject it to excessive heat. If the hand temperature reaches 50°C, the hand will warn you by flashing the Hand Button yellow and blue. At 55°C, the Hand Button will flash yellow and red, and you will be notified with a beep before the hand shuts itself off. The hand will not turn back on until the internal temperature has dropped, please allow time to cool before continuing use.

7.2 Storage

When not using the Trial Kit, you should store it carefully, between -5°C and 30°C, out of direct sunlight.

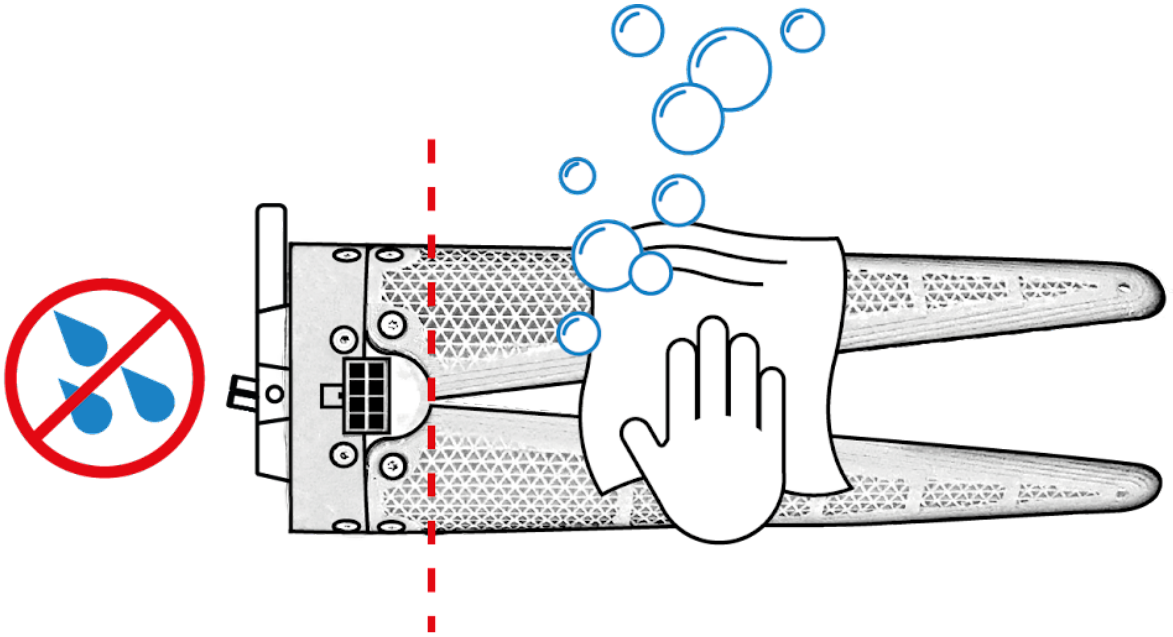
7.3 Maintenance

If the Trial Kit is not functioning as you think, has been damaged, or if you require replacement parts, please contact **support@openbionics.com**.

7.4 Cleaning

The Trial Kit should be cleaned using antibacterial wipes between patients. In addition, the wings can be washed in cool soapy water. If washing the wings in soapy water, be

sure to avoid any water getting on the connectors in the wrist (please refer to diagram below).



The EMGs should also be cleaned between uses. An antibacterial wipe should be used to clean the surfaces that come into contact with the users skin.

8 Troubleshooting

If you experience any issues with your Trial Kit, 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
Fingers are not moving/responding to my signals	Check to make sure the Hand Button is pulsing white to show the hand is on and ready Press gently on the back of the EMG sensors, to make a better skin contact Check the battery is fully charged and plugged in correctly
Fingers are not closing/opening fully	Try calibrating the the Hero Hand by disconnecting the battery with the power still ON (see the **Calibration** section)
There is a loose tendon attached to one of the fingers	A tendon has become damaged from excessive wear or load, please discuss with the Open Bionics team to arrange for your Hero Arm to be repaired.
One finger stays open whilst the other fingers/thumb move normally	The finger that remains open has likely failed calibration. Try calibrating the Hero Hand by disconnecting the battery with the power still ON (see the **Calibration** section). If this issue continues, contact support at: **support@openbionics.com**
The button is not responding to presses but the arm is on	Try disconnecting and reconnecting the battery
The grip patterns are not performing normally	Try calibrating the the Hero Hand by disconnecting the battery with the power still ON (see the **Calibration** section)
Fingers are moving erratically	Try cleaning the EMG pads with an alcohol wipe, remove and reattach the Trial Kit.

Fingers are responding intermittently to signals	Try cleaning the EMG pads with an alcohol wipe, remove and reattach the Trial Kit.
Hand Button is flashing different colours	Please see the 'Notifications/Status' table in the '**Hero Arm User Guide**' for information on what the Hand Button colours mean
The Trial Kit has got wet	Immediately disconnect and remove the battery. Dry off any visible water. Leave the hand to dry completely before trying to switch on again

9 Battery

Your Trial Kit comes with a Li-Ion 7.5V 2600mAh battery, encased within a protective sleeve. **Please Note**: When securing the battery with tape, ensure the protective sleeve is on the battery at all times. This prevents any damage being caused.

Only use the battery issued with your Trial Kit, or another purchased from Open Bionics. Only charge the battery according to the guidance provided in the '**Charging the Battery**' section of this manual, using the provided charger.

Do not expose the battery to water, or leave it in an extremely hot environment such as in a hot car, or exposed to direct sunlight.

Battery performance is dependent on how you use the Trial Kit, but also on the environment - battery performance may decrease in cold temperatures.

9.1 How to store the Battery

If you are not planning on using your Trial Kit or its battery for a long period of time, we recommend you fully charge the battery before storing it in a cool dry place. To maintain the battery's function, you should fully run down and recharge the battery at least once a year.

9.2 Battery Life

Batteries have a limited life, and will lose capacity over time the more they are used. If your battery life seems significantly shorter than it used to, you may need to purchase a new one.

9.3 For more information on:

- Checking the Battery Status
- Hand Notifications/Status
- Grip Modes
- Hand Calibration

Please visit the Hero Arm User Manual (Link Below) for more information on the areas listed: **https://openbionics.com/hero-arm/manual/**

If your hand repeatedly fails to calibrate, please see the **Troubleshooting** section of this manual.

9.4 Disposal


This symbol on the battery indicates that it is not to be treated as household waste. By disposing of the battery correctly, you'll be helping minimise any negative consequences for the environment. Please contact your local authority for information on where you can recycle the battery.

9.5 Safety

Please follow these guidelines in regards to the battery for your Trial Kit

- Do not bend or crush the battery
- Do not pierce the battery
- Do not try and disassemble the battery in any way
- Do not expose to excessive heat or leave in a vehicle
- Do not leave in direct sunlight
- Do not attempt to modify the connector or wiring of the battery in any way
- Do not use a damaged charger with the battery
- Do not use any charger other than the one provided
- Do not attempt to use the battery with any device other than your Trial Kit
- Do not dispose of the battery in regular waste - you must recycle it

WARNING:

If you observe any leaking from your battery, or it has swollen in any way, you must:

- Immediately disconnect it from the Trial Kit or Smart Charger
- Move the battery to a safe place and keep a minimum distance for 30 minutes
- Do not attempt to reuse the battery - you must dispose of it
- Contact Open Bionics and inform them of the situation

10 Warranty & Returns

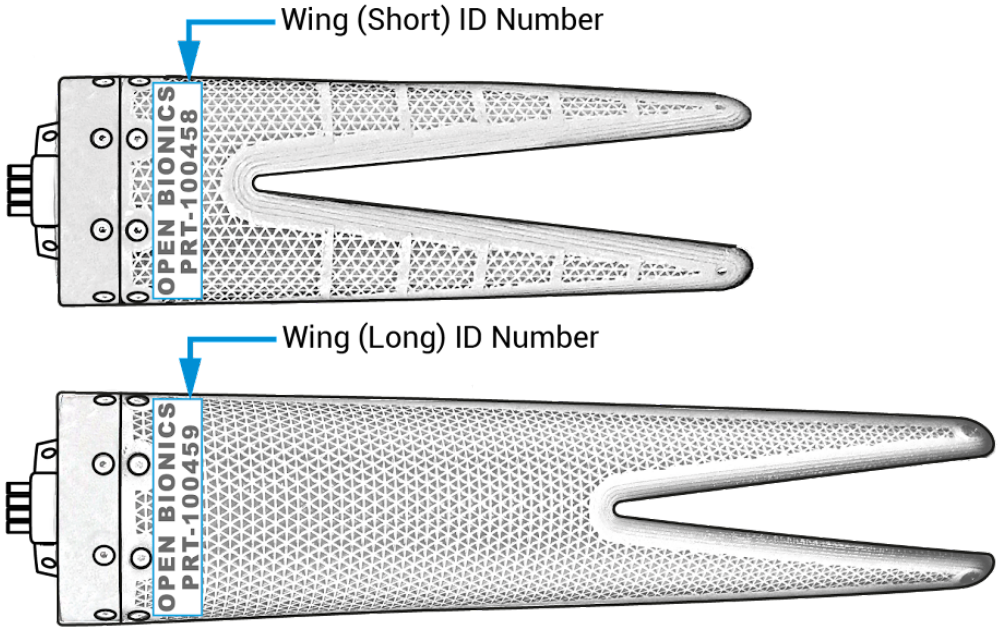
The Trial Kit is covered by a limited warranty. This guarantees against any manufacturing defects, or defects with your Trial Kit which arise out of normal use.

If you think there is a problem with your Trial Kit, please first carefully read through this manual and the '**Hero Arm User Manual**' in case any of your issues are addressed. In the case that they aren't please contact **support@openbionics.com**.

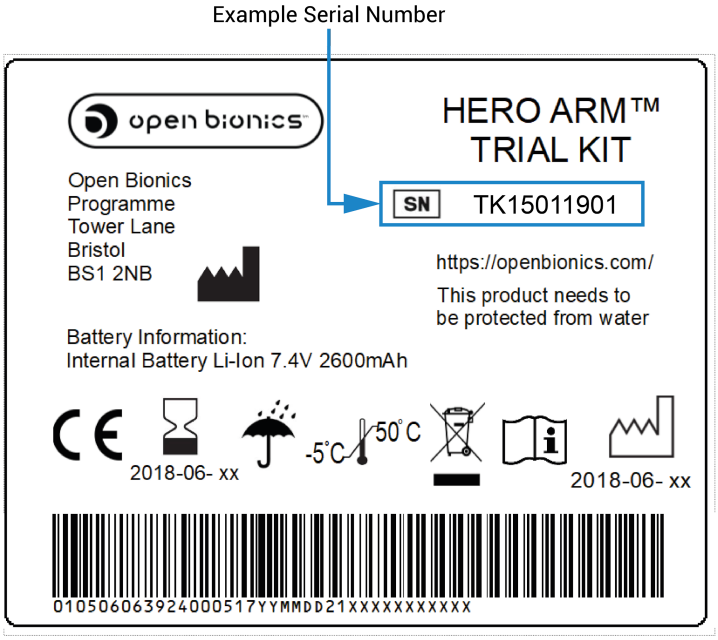
The short and long Check Socket Adaptors come as part of the Trial Kit with one set of spares for each of the two sizes. If necessary these can be modified using the thermoform process, or by shortening the wings to better accommodate the Check Socket. As a result this component may need replacing after a number of uses, due to repeated forming and trimming of wings. If you require replacement parts please contact Open Bionics and we can arrange this.

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

When requesting replacement wings please contact support and reference the **'Wing ID Number'** (See image below). There are different ID numbers for long and short Check Socket Adaptor Wings.



Please quote the serial number for your Trial Kit when requesting any warranty repairs or returns. This can be found on the side of the box that your Trial Kit comes in. When returning your Trial Kit or Trial Kit componentry, please ensure you package it appropriately - the original packaging you received your Trial Kit is great for this purpose.



11 Regulatory Compliance

Open Bionics declare that they meet applicable standards for design, manufacture and supply of prosthetic products and user software.

Continued compliance with the standard is monitored by a programme of internal and external audits.

All individual products are marked indicating that they comply with the requirements of the Medical Devices Directive 93/42/EEC (MDD) and FDA.

The CE mark may be applied on packaging, accompanying literature or an enclosure, rather than the product itself.

The Trial Kit and its associated components listed in this document are covered by test certificates for:

Applicable standards
IEC 60601-1
IEC 60601-1-2
IEC 60601-1-6
BS EN ISO 14971
IEC 62366
Medical Devices Directive 93/42/EEC
RoHS Directive 2011/65/EU

12 Applied Parts

The only applied parts in the Trial Kit are the EMG electrodes, they are type BF.

13 Symbols

A full list of all symbols located on the labels are available on request.

13.1 CE mark

CE

This mark indicates the product conforms with the essential requirements and provisions of Council Directive 93/42/EEC.

13.2 Type BF applied part

To identify a type BF applied part complying with IEC 60601-1.

13.3 Refer to operating instructions

This mark indicates the user should read the operating instructions before use.

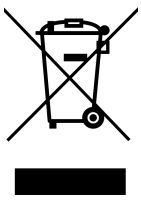
13.4 Manufacturer (adjacent to company name)

This mark indicates the manufacturer

13.5 Date of Manufacture

This mark indicates the date the device was manufactured

13.6 Wheelie Bin (WEEE) mark



This mark indicates that the product falls under the WEEE Directive (2012/19/EU).

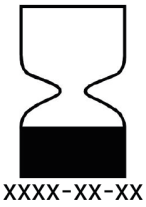
13.7 Protect from water

This symbol indicates the product should be protected from water

13.8 Temperature Range

This symbol indicates the products temperature range

13.9 Use By



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

13.10 Serial Number

To identify the manufacturer's serial number, for example on a medical device or its packaging. The serial number shall be placed adjacent to the symbol.

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