



HERO GAUNTLET™

User Manual

Version 02.00

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Introduction

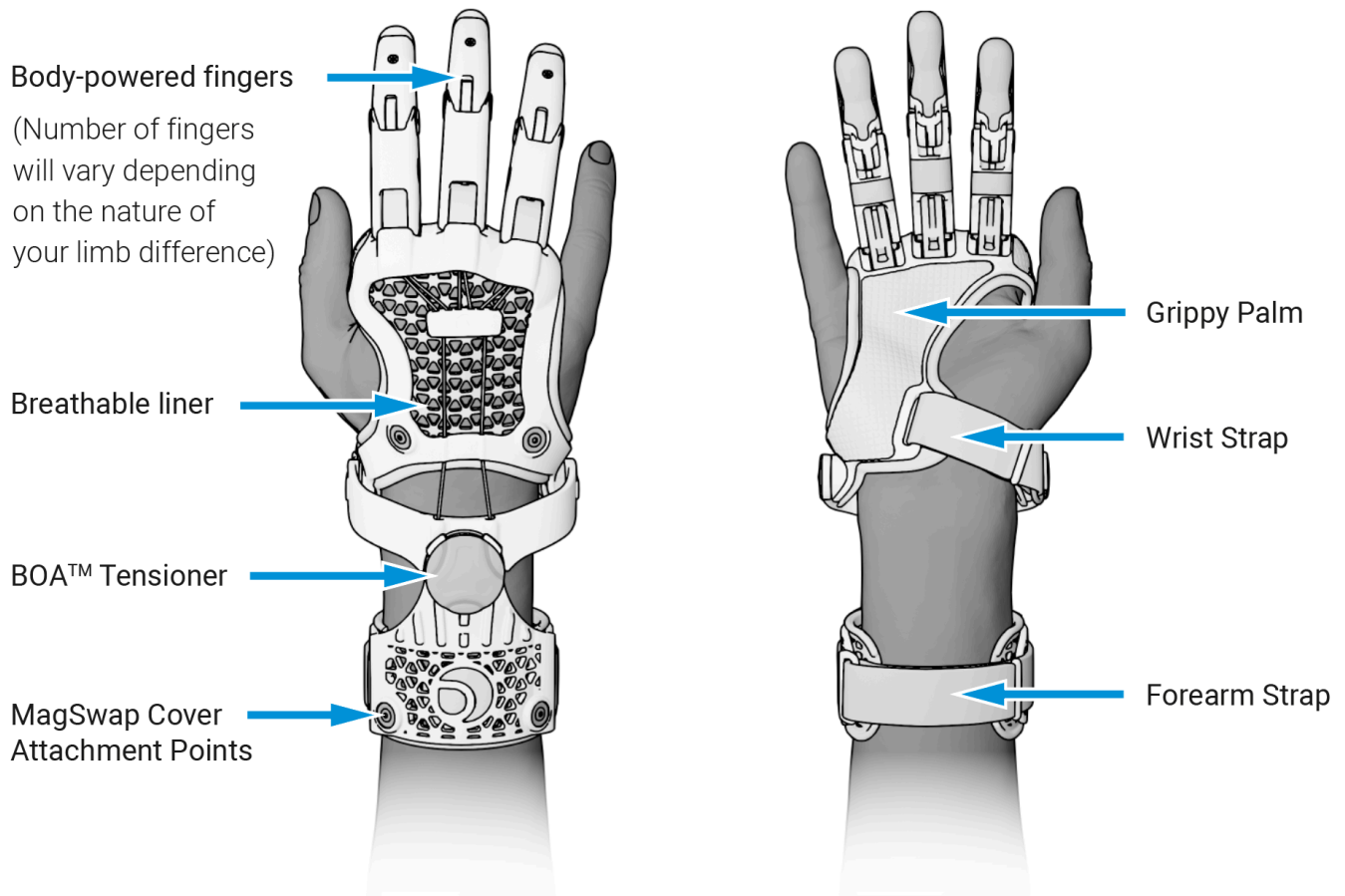
The Hero Gauntlet™ is a body powered partial hand solution, which is bespoke and perfectly formed to the individual's needs. With a breathable design allowing for ventilation and ease of cleaning.

The Hero Gauntlet™ is designed to enable the user to gain or regain their ability to Grip and optimise their hand functionality.

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

Hero Gauntlet™ Overview

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



What's in the Box

- 1 x Hero Gauntlet™
- 1 x Hand and forearm Cover
- 1 x Quick Start Guide

Configurations

Each Hero Gauntlet™ is tailored for every individual. As a result, you may see some differences between your Hero Gauntlet™ 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.

Getting Started

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

When to Use Your Hero Gauntlet™

The Hero Gauntlet™ is intended to be used for activities from your day-to-day life like holding multiple shaped objects, turning switches, carrying shopping bags, etc.

Precautions and Warnings

The Hero Gauntlet™ 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

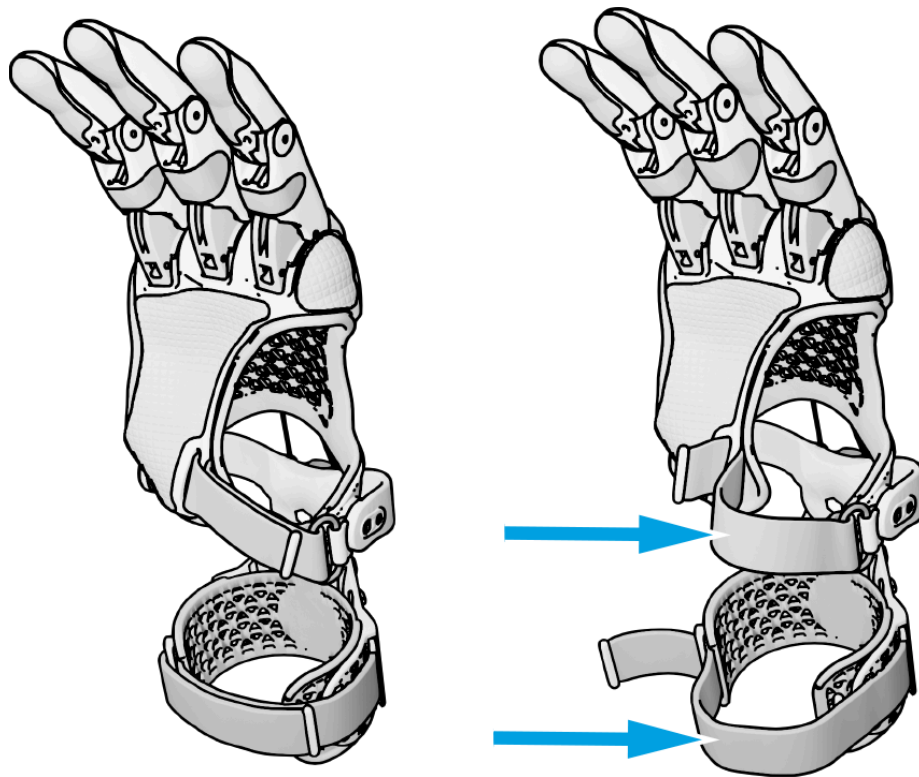
If the consequence of using the Hero Gauntlet™ for any of the above activities is injury or death to yourself or anyone else, the Hero Gauntlet™ must not be used. In the case of using the Hero Gauntlet™ to return to work, you should discuss the above points with your Health and Safety representative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

The Hero Gauntlet™ design means there are very few limitations regarding temperature, pressure, humidity or altitude. The Hero Gauntlet™ can be safely used in all conditions and temperature ranges in which you would expose yourself, without fear of harm.

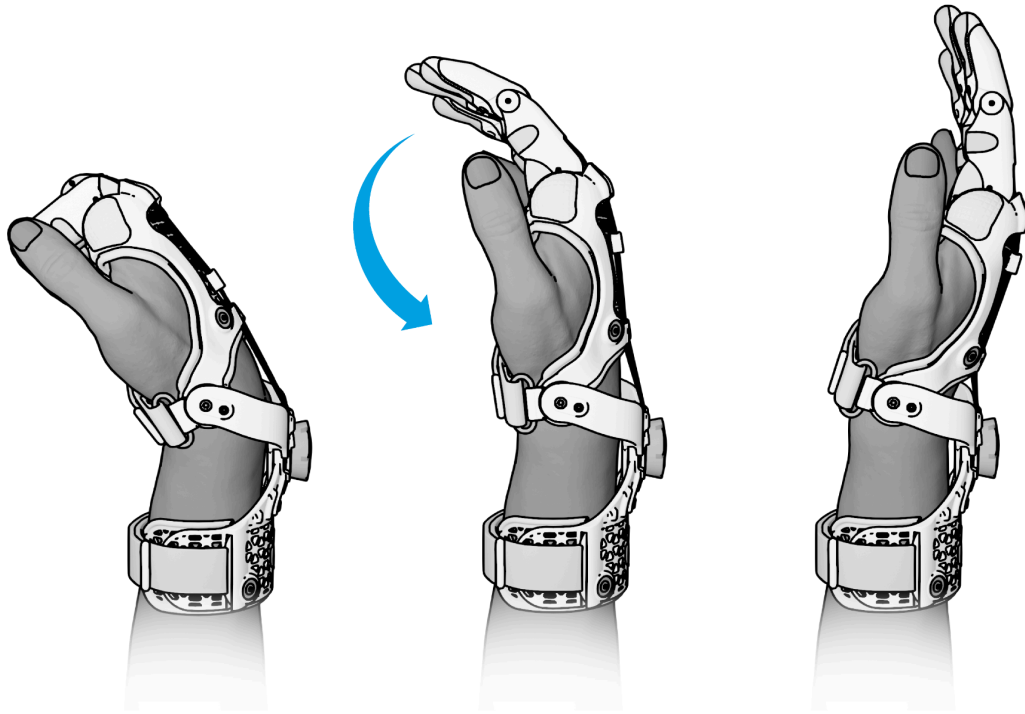
Putting on your Hero Gauntlet™

Your Hero Gauntlet™ has been designed to perfectly fit your arm. It comes with 2 straps, one to adjust around your forearm and another to adjust on the lateral side of your thumb.

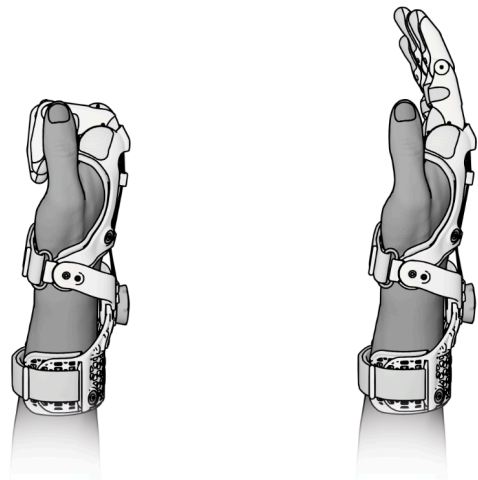
Open the straps to get your hand on your Hero Gauntlet™ and then adjust them to a position where you feel a secure and comfortable fit.



How to Use Your Hero Gauntlet™



Your wrist operates the Hero Gauntlet™. When you flex your wrist, the fingers will close against the grippy palm of the device. Extend your wrist and they will open back up.



Fully Tightened:
Fingers are closed

Fully Loosened:
Fingers are open

Adjust the Boa™ dial to adjust the tension on the strings. The more you tighten the Boa System™ the less wrist movement you will be required to do in order to close the fingers.

For example, if you want the fingers to stay closed without having to keep your wrist flexed, you would tighten it fully.



To tighten, rotate
clockwise



To loosen, rotate
anticlockwise



To quick-release, pull
outwards



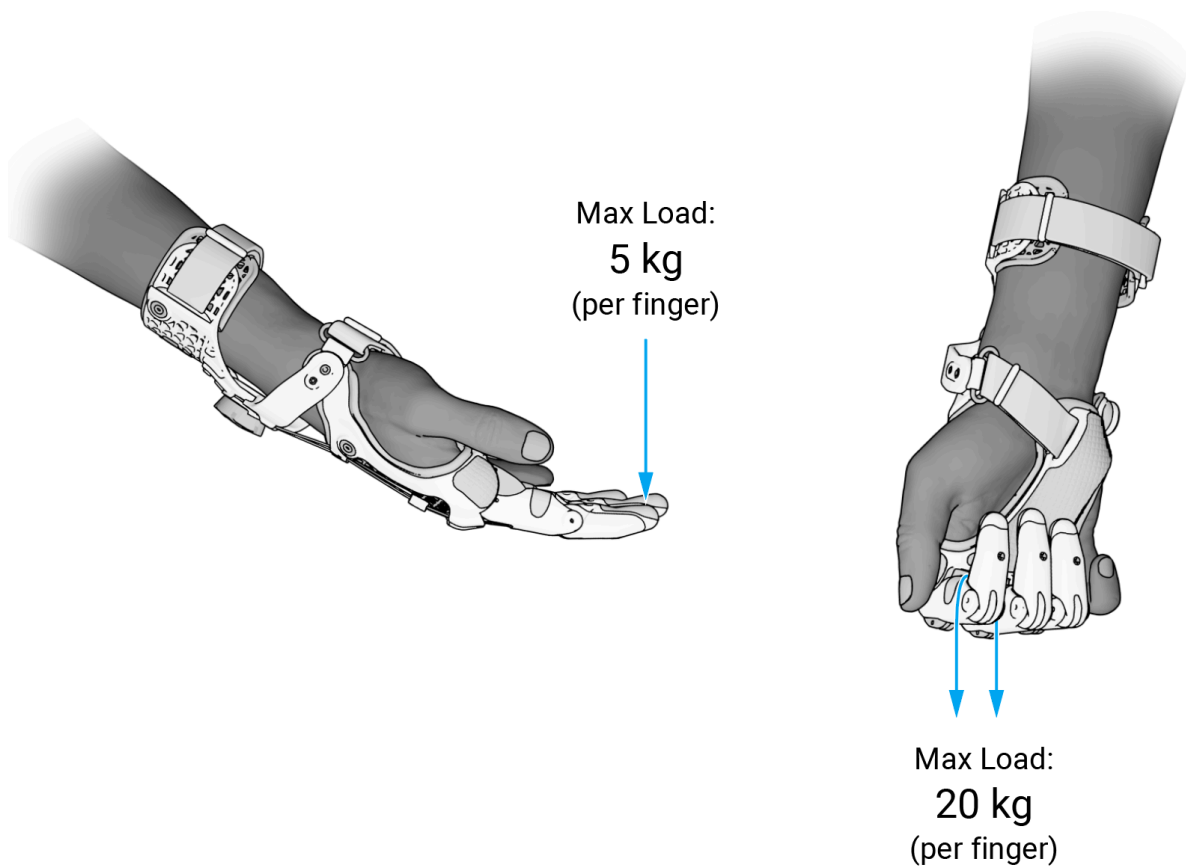
To return to rotary mode,
push inwards

The Boa system™ is located on top of the pivot point that allows radial and ulnar deviation of your wrist so that your movements are never restricted.

The forearm strap comes in a variety of styles so you can tailor your Hero Gauntlet to your liking and express yourself through your device!

Load Limits

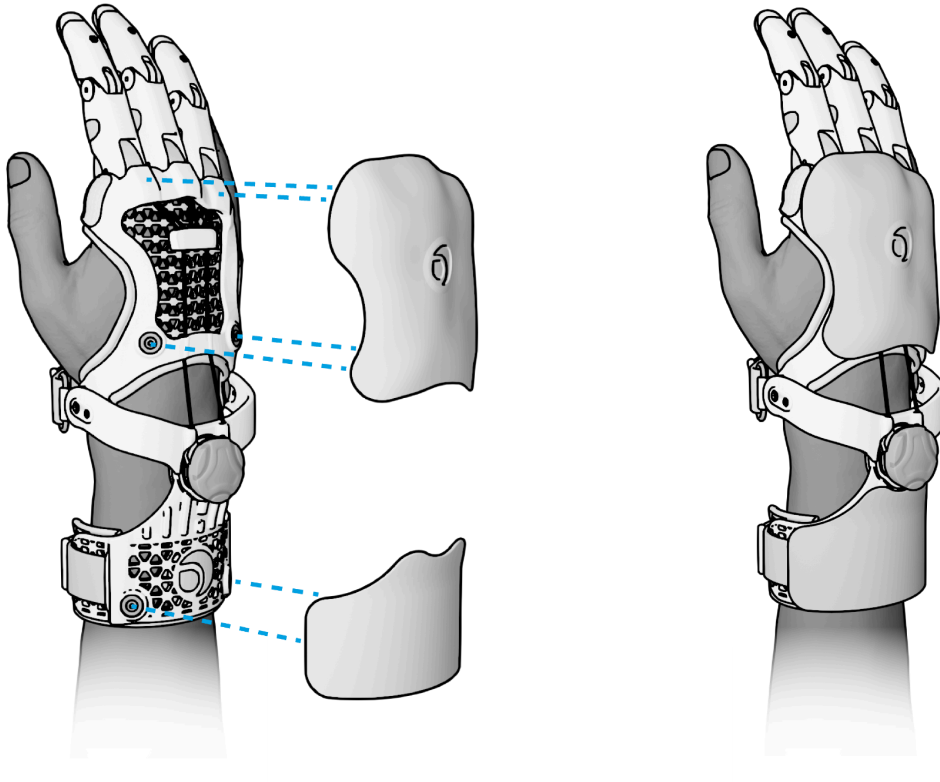
The images below illustrate the maximum loads that the Hero Gauntlet™ can safely be subjected to. To avoid damage to the device, you should avoid exceeding these limits.



Covers

The Hero Gauntlet™ comes with a set of Regenerate magnetic covers in black.

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



*The magnets within the HeroGauntlet™ 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 Gauntlet™

Safety

Although the Hero Gauntlet™ 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 prosthesis.

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

The Hero Gauntlet™ is designed to support you throughout your daily activities. We recommend you discuss your requirements fully with your prosthetist when considering this prosthetic option.

Your Prosthetist will also advise you on the safe load limits for your customised Hero Gauntlet™.

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

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

Storage

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

Maintenance

Do not attempt any maintenance or modification of your Hero Gauntlet™. If you think your prosthesis 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 Gauntlet™. This allows us to keep your Hero Gauntlet™ in top condition throughout its service life.

Cleaning

The Hero Gauntlet™ can be cleaned using alcohol-free antibacterial wipes. In addition you should clean the flexible socket using warm, soapy water on a regular basis to avoid risks of skin irritation.

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 Gauntlet™, discuss the matter with your prosthetist.

Growing Out of Your Hero Gauntlet™

If you are still growing, your Hero Gauntlet™ may eventually become too small. This means that when your hand grows you may find that it becomes difficult to put your Hero Gauntlet™ on.

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

Troubleshooting

If you experience any issues with your Hero Gauntlet™, 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
More effort than normal to operate the Hero Gauntlet™.	Tighten forearm strap this will decrease the amount of energy loss to operate the prosthesis

Indications

The Hero Gauntlet™ is indicated to gain or regain the hand function to a degree.

The device can be used by those with congenital or acquired amputations/malformations. The device is suitable for bilateral amputees.

Contraindications

The Hero Gauntlet™ is non-invasive and is not designed to be in contact with damaged or irritated skin. Some partial hand presentations 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 Gauntlet™ has a 3 year service life. The Hero Gauntlet™ is custom built specifically for each user so is not intended to sit in storage. As such the Shelf Life is the same 3 year span as the Service Life.

Warranty & Returns

The Hero Gauntlet™ 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 Gauntlet™ which arise out of normal use.

If you think there is a problem with your Hero Gauntlet™, 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 device number for your Hero Gauntlet™ when requesting any warranty repairs or returns. This can be found on the reverse of the hand cover and between the hand frames and socket on the hand section of the device. When returning your Hero Gauntlet™ 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 Gauntlet™ 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 Gauntlet™ 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 Gauntlet™ should only be conducted by Open Bionics or a qualified Prosthetist (that doesn't include the covers, customise away!)
- The Hero Gauntlet™ should be cleaned with alcohol-free antibacterial wipes on a regular basis.
- The Hero Gauntlet™ should not be used for weightlifting using free weights .

EU & UK Regulatory Compliance

The Hero Gauntlet™ 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 Gauntlet™ 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 Gauntlet™ 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



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

UKCA mark



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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