

# Point Partial

*Instructions for Use*



point designs

This document provides information for the prosthetists who will be installing the Point Partial.

Refer to [www.pointdesignsllc.com/resources](http://www.pointdesignsllc.com/resources) to ensure you have the latest copy of this document.



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**Rx ONLY**

**Caution:** Federal law restricts this device to sale by or on the order of a prosthetist.



*This symbol is used throughout the guide to indicate important cautionary information. Text following this symbol should be read carefully.*

# Point Partial

*INSTRUCTIONS FOR USE*

*V2.0*

*DECEMBER 8, 2021*

**Thank you for choosing the Point Partial and providing your client with an effective and robust prosthetic finger solution.**

Whether you are retrofitting the Point Partial into an existing prosthetic socket or you are building a new prosthesis from the ground up, this guide will familiarize you with the Point Partial's functionality and installation.

The installation of any Point Partial should be performed exclusively by a licensed prosthetist or technician. Point Partials are intended to be operated by a prosthesis user following installation and setup. Any unauthorized handling or installation of a Point Partial could void their warranty.

Any questions? We are always happy to help.  
Call us or send us an e-mail.

**(720) 600-4753**

**support@pointdesignsllc.com**

# Point Partial

## Intended Use

The Point Partial system is to be used exclusively for external prosthetic fittings of the upper limbs. In particular, it is intended to be used for patients with partial finger amputations of digits 2-5 near the proximal interphalangeal (PIP) joint.

## Indications

Users of the Point Partial system will achieve the best clinical outcome if they have partial amputation of digits 2-5 near the PIP joint (slightly distal or proximal of the PIP joint is acceptable).

## Intended Patient Population

The Point Partial is intended to be fit to adults with amputations of digits 2-5 at or near the proximal interphalangeal (PIP) joint.

## Intended Users

The Point Partial is to be installed into a prosthetic socket by a trained prosthetist, and used by partial hand amputees. The Point Partial system is compatible with most prosthetic sockets, and is installed into the prosthetic socket by a trained prosthetist or technician.

## Contraindications

None known.

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# Introduction to the Point Partial

## Point Partial

Lateral Grip pads



Alcohol Wipe



Alignment Tool



Alignment Transfer Post



Tox Tool®



Fingertip Pad



Fingertip Pad Installation Tool



Lamination Spacer



Mounting Hardware



Mounting Bracket



\*Images not to scale, lateral grip pads are not preinstalled

The **Point Partial** is a passive (i.e. not powered) mechanical finger for people with partial hand amputation. It features a ratcheting mechanism that enables one-handed use and 7 distinct locking positions. The **Point Partial** features integrated compliant touchscreen compatible\* fingertip pads for enhanced grip. The **Point Partial** is made from titanium for ample strength.

*\*Touchscreen compatibility is not guaranteed, but has been tested on common iOS, Android, and Windows devices using standard socket material (silicone inner liner with carbon fiber outer shell)*

# Introduction to the Point Partial

The **Point Partial** can be flexed and locked by applying a force to the dorsal side of the fingertip. This force can be applied by the contralateral limb or by an opposing surface (e.g., leg, table, desk, wall, chair, etc.).

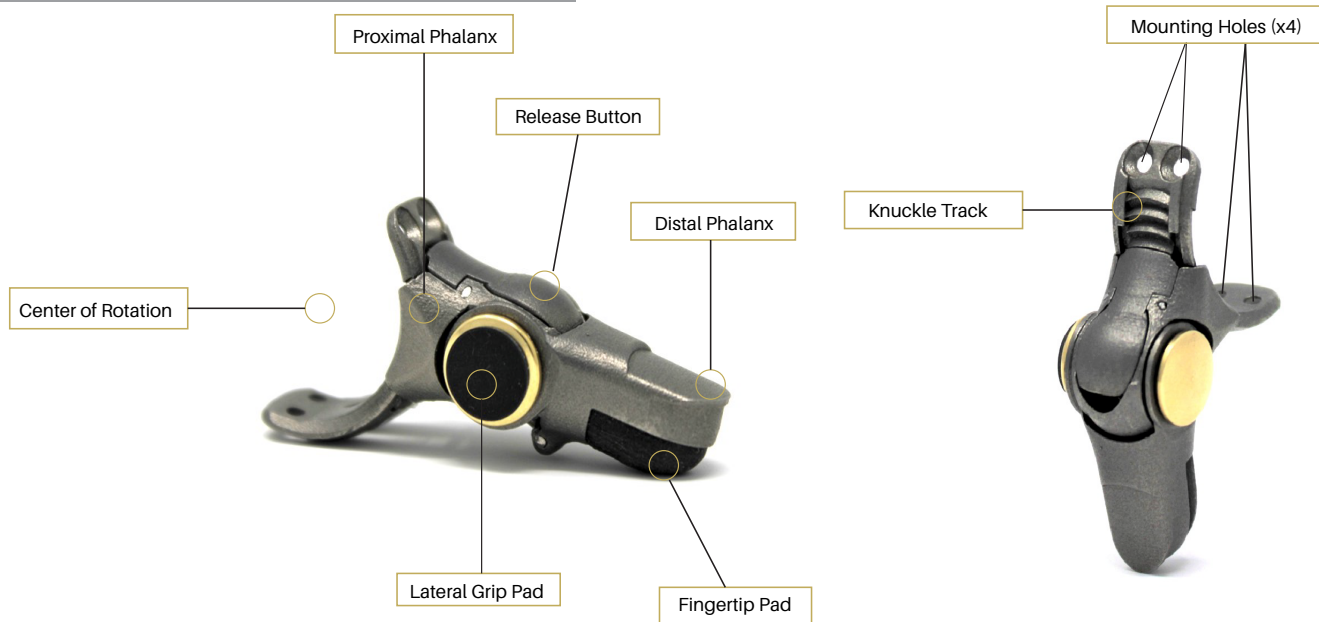
The **Point Partial** can be extended in one of two ways:

- 1) depressing the push button, or
- 2) fully flexing the finger to engage the auto spring-back feature.

A single **Point Partial** can be integrated into a prosthetic socket using the mounting kit, which includes a mounting bracket, lamination spacer, alignment tool, alignment transfer post, and mounting screws.

# Component description

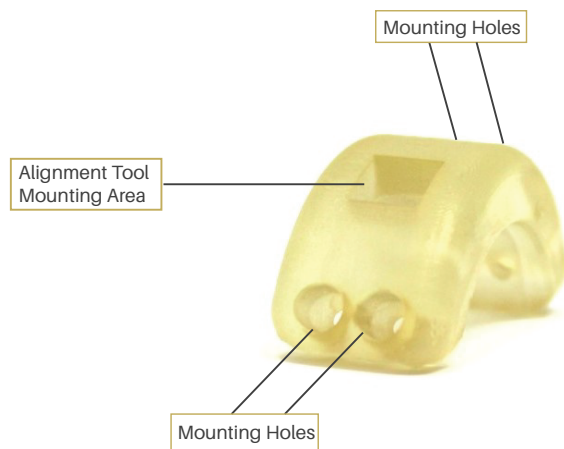
## THE POINT PARTIAL



The **Point Partial** comes assembled as one unit. The **Point Partial** is comprised of a curved knuckle track, proximal phalanx, distal phalanx, a release button, fingertip pad, lateral grip pad, and several other internal parts. The curved knuckle track has 4 mounting holes.

## LAMINATION SPACER

The lamination spacer is a curved component with mounting holes and a square alignment tool mounting area for use during the lamination process.



## MOUNTING SCREWS

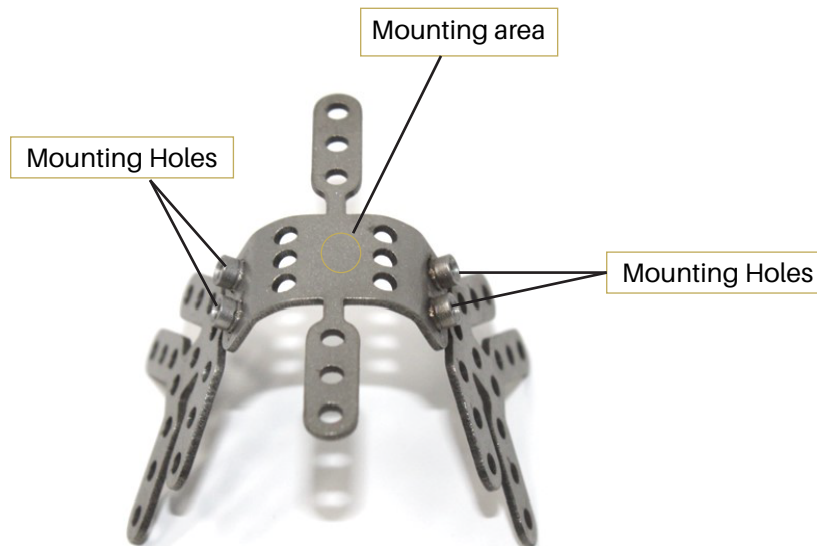
Torx® mounting screws (M2 x 5 mm) are provided for attaching the lamination spacer to the bracket during the lamination process and for mounting the finger to the bracket. 8 screws per finger are supplied with each **Point Partial**.





# Component description

## MOUNTING BRACKET



The mounting bracket is a single part comprised of a mounting area and 4 mounting holes. The mounting bracket is designed to be symmetric for bilateral use, i.e. it can be mounted on both a left and right hand in the same orientation.

## ALIGNMENT TOOL

The alignment tool is an accessory designed to aid in the alignment of a **Point Partial** during fabrication. The alignment tool should be used in combination with the lamination spacer. When inserted into the square mounting hole on top of the lamination spacer and then bolted onto the mounting bracket, the alignment tool represents the position of the **Point Partial** throughout its entire range of motion. While initial alignment can be performed using the alignment tool, it is always recommended to attach the **Point Partial** to the bracket prior to definitive fabrication to verify alignment and function.



# Component description

## ALIGNMENT TRANSFER POST

The alignment transfer post is an accessory designed to aid in the transfer of a **Point Partial** from a diagnostic socket to a definitive socket while maintaining alignment. The alignment transfer post should be used in combination with the lamination spacer. The alignment transfer post is made from 1/4" square aluminum with an M2 threaded hole on one end. To use, insert the end with the threaded hole into the square mounting hole on the lamination spacer. Secure the alignment transfer post to the lamination spacer by inserting an M2x5mm screw from the underside of the lamination spacer. Once alignment of the bracket is achieved on the diagnostic socket, bolt the alignment transfer post/lamination spacer assembly to the bracket. Place the diagnostic socket assembly into a vertical alignment transfer fixture (not provided), and plant the alignment transfer post into a container (e.g. cup, bowl, bucket, etc.) of plaster. Be sure to secure the plaster container so that it does not move. Once the plaster has hardened, separate the bracket from the diagnostic socket, raise the vertical alignment fixture, remove the diagnostic socket from the mold, and replace with the initial layup of the definitive socket. Lower the vertical alignment transfer fixture, and then tack the bracket to the definitive socket. At this point, the alignment should be transferred, and final lamination can be performed.

The alignment transfer post should be used when fabricating both a diagnostic and definitive socket, where transfer of the **Point Partial** while maintaining alignment is necessary. This accessory is not needed if performing a direct to definitive fabrication, where alignment is performed on the definitive socket.



# Component description

## ALIGNMENT TRANSFER

Alignment  
Transfer Post



Mounting Bracket



Lamination Spacer



Alignment Tool



Mounting  
Hardware



Lamination spacer mounted  
onto bracket



# Component description

## ALIGNMENT TRANSFER



# Component description

## FINGERTIP PADS

The Point Partial features integrated compliant touchscreen compatible\* fingertip pads for enhanced grip. Each Point Partial comes with one preinstalled fingertip pad, 5 replacement pads, and an installation tool. Additional replacement pads can be acquired by contacting [support@pointdesignsllc.com](mailto:support@pointdesignsllc.com)



## LATERAL GRIP PADS

The Point Partial comes with lateral grip pads to be installed after socket fabrication and final digit mounting. The lateral grip pads are intended for the index finger joints to improve lateral grip, but can be applied to any digit. Ten lateral grip pads and a surface preparatory wipe are included with each order.



# Specifications

|                                  |                         |
|----------------------------------|-------------------------|
| <b>Material</b>                  | <i>Titanium</i>         |
| <b>Expected service life</b>     | <i>3 years</i>          |
| <b>Rated pinch grip strength</b> | <i>667 N (150 lbf)</i>  |
| <b>Rated hook grip strength</b>  | <i>667 N (150 lbf)</i>  |
| <b>Rated tear out strength</b>   | <i>1334 N (300 lbf)</i> |

\*Touchscreen compatibility is not guaranteed, but has been tested on common iOS, Android, and Windows devices using standard socket material (silicone inner liner with carbon fiber outer shell)

# Installation

## BEFORE YOU BEGIN

### Included in the package:

- Up to four (4) **Point Partial**(s)
- Up to four (4) mounting bracket(s) [one (1) per **Point Partial**]
- Up to four (4) lamination spacer(s) [one (1) per **Point Partial**]
- Up to thirty-two (32) mounting screws [four (4) per **Point Partial** and four (4) spare per digit]
- Up to four (4) alignment tool(s) [one (1) per **Point Partial**]
- Up to four (4) alignment transfer post(s) [one (1) per **Point Partial**]
- Up to twenty-four (24) fingertip pads, [one (1) per **Point Partial** and five (5) spare per digit]
- Fingertip Installation Tool (2)
- Ten (10) lateral grip pads, uninstalled
- Surface preparatory alcohol wipe
- Torx® tool size T6

### What you will need:

- Vertical Alignment Transfer Fixture
- Lamination supplies (e.g., carbon fiber, lamination resin, adhesive, silicone, etc.)
- Lamination tools (Dremel®, files, PVA sheet/bag, vacuum, etc.)
- Blue thread locker (Loctite® Blue 242®) or Red thread locker (Loctite® Red 271®)



These fabrication instructions follow a carbon fiber wet lamination process to install the **Point Partial** system.

# Installation

## INTRODUCTION TO FABRICATION

This section describes how to fabricate a definitive socket, mount the **Point Partial** to the socket, and check that the **Point Partial** is functioning properly once it is mounted to the socket. These instructions assume that a plaster model of the amputated hand, a check socket, and silicone socket have been prepared beforehand. Alignment transfer on the check socket should also be completed prior to these steps. Refer to the “Alignment Transfer Post” section for instructions on how to use the provided alignment tools for the Alignment transfer process.

The “Initial Layup” section describes the fabrication process for the initial layers of carbon fiber.

The “Alignment Transfer” section describes alignment transfer to the definitive socket prior to the final lamination steps.

The “Final Lamination” section describes the fabrication process for the final layer of carbon fiber which integrates the mounting bracket into the socket.

## INITIAL LAYUP

1. Mount plaster model onto a mandrel. Place the mandrel onto a lamination fixture.
2. Cut a section of nylon and place over the plaster model.
3. Wet a sheet of PVA and wrap it over the plaster model with the dull side of the PVA facing out. Make sure the PVA is wrapped tight around the plaster model and that there are no wrinkles. Turn on vacuum to seal in the PVA.

Step 1



## INITIAL LAYUP

4. Lay carbon fiber over the PVA layer.



Any seams or excess carbon fiber material should lay on the outside of the socket for the first layer so that the surface on the inner side remains smooth.

Step 4



5. Place nylon over the carbon fiber layer.  
[Alternative, apply adhesive spray to carbon fiber to hold it in place.]
6. Place a PVA bag over the model.

Step 6



7. Mix the resin and pour over the model through the PVA bag. Saturate the carbon fiber with resin and smooth out any wrinkles over the PVA bag.
8. Seal the PVA bag and maintain vacuum for the recommended resin cure time.



## INITIAL LAYUP

9. Once resin has fully cured, remove the PVA bag. The initial layup is complete. Sand to remove excess cured resin or carbon fiber material.



Initial layup attached to a mandrel

## ALIGNMENT TRANSFER

This image shows the final result from performing the alignment transfer process previously on the check socket using a vertical alignment transfer fixture. Alignment transfer to the definitive socket will follow from here.



1. First, trim excess material from the initial layup socket.

## ALIGNMENT TRANSFER

2. Mount the initial layup into the vertical alignment transfer fixture.

Step 2



3. Lower the initial layup until it is in contact with the bracket.
4. Perform alignment transfer to the initial layup of the definitive socket (reference "Alignment Transfer Post" section). Attach the bracket to the initial layup.

Step 3 & 4



5. Adhere the bracket to the initial layup and unscrew the mounting bracket from the lamination spacer on the alignment transfer setup. Bend the tabs on the bracket to conform to the shape of the socket and remove tabs that are not needed.

## FINAL LAMINATION

1. Fill in any gap between the initial layup socket and bracket with clay or putty.

Step 1



2. Sand the surface of the initial layup to support bonding of the final lamination

3. Lay carbon fiber over the socket and bracket. Make sure the mounting holes on the socket are not obscured by carbon fiber.
4. Cut a section of nylon and place over the carbon fiber layer. Make sure the mounting holes are not obscured by the nylon by cutting around the holes.

Step 3

Mounting holes



## FINAL LAMINATION

5. Install a lamination spacer over the mounting bracket using the supplied mounting screws.



Coat the lamination spacer with release agent for easier removal after lamination.

6. Cover the mounting locations with clay or putty to avoid getting resin over the mounting screws.

Step 5



7. Place a PVA bag over the socket. Turn on vacuum to seal the PVA.
8. Mix the resin and pour over the model through the PVA bag. Saturate the carbon fiber with resin and smooth out any wrinkles over the PVA bag.
9. Seal the PVA bag and maintain vacuum for the recommended resin cure time.
10. Once the resin has fully cured, final lamination is complete. Remove the PVA bag and dismount the lamination spacer.

## FINAL LAMINATION

10. Mount the Point Partial(s) onto the socket using the supplied mounting screws and Torx® Tool. Assemble the definitive socket with the silicone socket. Inspect the Point Partial(s) for proper function.



Apply threadlocker to each mounting screw when satisfied with function.

*\*Mounting screw torque spec: 0.75 - 0.9 Nm*



## PRE-FITTING FUNCTION CHECKLIST

The prosthetist should ensure that all the following functions are checked prior to fitting the user with the prosthesis.

If any of the functions are not working properly, please either review the installation instructions and/or contact [support@pointdesignsllc.com](mailto:support@pointdesignsllc.com)

- Each **Point Partial** flexes and locks into 7 distinct levels of flexion (including full extension).
- The button on each **Point Partial** can be pressed easily
- The button rebounds to a flush position when released
- Pressing the button while each **Point Partial** is in a flexed position causes position release and easy extension
- Full flexion of each **Point Partial** can be achieved
- Release of each **Point Partial** after full flexion results in spring back to full extension and ratchet mechanism reset.

# Installation

## FINGERTIP PAD INSTALLATION

The Fingertip Pad will have 1 hole and the distal phalange of the **Point Partial** will have a corresponding post.

Point Partial



Installation Tool



Fingertip Pad



**1.** Press the pad down onto the post so that it seats into the hole in the pad. Start by pressing on the proximal end of the pad and work your way distal. Maintain pressure on top of the pad as you move to Step 2.



# Installation

## FINGERTIP PAD INSTALLATION

**2.** With the pad mostly seated onto the post, use the Installation Tool to press the edges of the pad under the lip of the distal phalange. Start this process at the proximal end and then work your way distal. Make sure to maintain pressure on the top of the pad during this process.



**3.** With the edges pressed in, apply pressure to the top of the pad and rock back and forth gently to help make sure the pad is fully seated. If the pad looks to be bulging out still, repeat Step 2.





## LATERAL GRIP PAD INSTALLATION

The Lateral Grip Pads come in a pack of 10 adhered to a polymer liner. Only 1 pad is needed as it is only installed on the lateral side of an index finger.



**1.** Clean the brass Chicago Bolt with the alcohol wipe (included).



**2.** Remove the Lateral Grip Pad from the backing

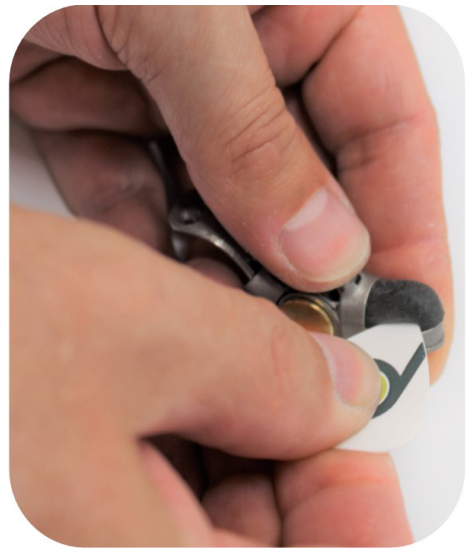


**3.** Center over the joint, then press on to the Chicago Bolt and hold pressure for at least 10-20 seconds. Clamping the pad down for 72hrs will yield optimal results, but is not necessary.



## FINGERTIP PAD REMOVAL

**1.** Use the Installation Tool (or any similar tool such as a flat head screwdriver) to slide between the pad and wall of the distal phalange and pry the pad up.



**2.** With the pad partially pried up, use your fingers to grab the pad and pull it the rest of the way out.



## LATERAL GRIP PAD REMOVAL

**1.** Peel the pad off of the Chicago Bolt using your fingernail or any appropriate tool.

# Using The Point Partial

## POSITIONING / FLEXION



Push on finger to desired degree of flexion



## RELEASE / EXTENSION

There are two methods for extending the finger from a locked flexion position, 1) the manual release button, and 2) the auto spring-back function.

### 1. Manual Release



## 2. Spring Back

Fully flex finger



Button should be propped up in full flexion



Release



If button doesn't reset, apply force in extension

# Troubleshooting

*In case of a problem, this section is intended to help you troubleshoot the operation of the Point Partial.*

*We have included a few possible issues with solutions below. If your issue is not addressed, email us for support at [support@pointdesignsllc.com](mailto:support@pointdesignsllc.com).*

## **The Point Partial moves freely and does not lock into position**

OR

## **Cannot press Point Partial button or button is stuck in depressed position**

Most likely, the ratcheting mechanism has not been reset after the auto spring-back feature was activated. To resolve this issue, apply a force to the fingertip in extension until the finger “clicks”, resetting the ratchet mechanism.

## **Point Partial does not flex all of the way**

Clean curved knuckle track of debris using a clean cloth, mild detergent, or compressed air. If problem persists, contact us for support.

## **Point Partial resets prior to reaching full extension**

The button lever did not reset properly in extension. Ensure that the digit reaches full flexion and the button is propped up in full flexion.

## **Point Partial is loose or came off mounting bracket**

Make sure thread locker has been applied to Torx screws, and then tighten them. If Torx screws are unable to be tightened, contact us for additional support.

## **Point Partial is corroded**

Contact us for support.



Users and/or patients should report any serious incident that has occurred in relation to the device to:

- Point Designs at [support@pointdesignsllc.com](mailto:support@pointdesignsllc.com)
- FDA via MAUDE (for cases in the US)
- The competent authority of the Member States in which they are established in EU/EEA (for cases in the EU/EEA)

# Maintaining the Point Partial

## PREVENTATIVE INSPECTION

All **Point Partial** systems undergo extensive quality assurance inspections prior to shipping. Regularly inspect **Point Partials** for dirt/grime in the joints, ratchet teeth, and sliding track. Clean **Point Partials** (see MAINTENANCE section below) if decreased performance occurs.

## MAINTENANCE

The **Point Partial** can be cleaned with a cleaning solution such as soap + water or mild detergent + water. Dry the digit with a clean towel or compressed air. Be sure to dry a **Point Partial** completely after getting wet, especially when the liquid is likely to accelerate corrosion (e.g., salt water, sweat, etc.).

Lubrication (e.g., WD-40, graphite, etc.) may be applied to the joints and track after cleaning if increased resistance occurs.

No regular care is needed for the fingertip pads, but they can be cleaned with isopropyl alcohol if needed.

For any abnormal issues, discontinue use and contact Point Designs for support.

## DISPOSAL



A **Point Partial** should not be thrown away with common household waste. Dispose of the **Point Partial(s)** by either returning the unit(s) to Point Designs or taking the unit(s) to your nearest metal recycling center.

## REPAIRS, RETURNS + WARRANTY

Please contact Point Designs at [support@pointdesignsllc.com](mailto:support@pointdesignsllc.com) regarding repairs and returns. The **Point Partial** comes with a 1-year manufacturer's defect warranty.

Details of the warranty are in separate documentation available at [www.pointdesignsllc.com/resources](http://www.pointdesignsllc.com/resources)

# Safety and Warnings



**WARNING:** The Point Partial is not designed to operate continuously in wet environments. A Point Partial may get wet occasionally, but the user should be advised to thoroughly dry the Point Partial after exposure to any liquid. Prolonged exposure to liquid may cause corrosion.



**WARNING:** The Point Partial is electrically conductive and thus presents a potential electric shock hazard if it contacts a voltage difference and the user's (or someone else's) skin simultaneously. The Point Partial should not be used around high voltage/current.



**WARNING:** The Point Partial is thermally conductive and thus presents a potential burn hazard if it contacts a heat source and then the user's (or someone else's) skin subsequently. The Point Partial should be kept away from hot objects. If a Point Partial becomes hot, it should be allowed to cool before skin contact.



**WARNING:** The Point Partial contains ferrous material, and can therefore interact with magnetic fields. Care should be taken when using a Point Partial around magnets to avoid accidental attraction. For example, *keep away from MRI machines.*



**WARNING:** The Point Partial contains moving parts (e.g., linkages, springs, ratcheting mechanisms, etc.), and thus presents a minor pinching hazard. The user should take care to keep loose skin, clothing, etc. from the moving parts of the Point Partial.



**WARNING:** The Point Partial contains internal springs under tension. The spring-back mechanism causes the finger to extend rapidly presenting a minor hazard. The user should take care to keep the Point Partial away from self and others during spring-back.



**WARNING:** Any unauthorized modification to a Point Partial System can pose a safety risk to the user and will void the warranty. Changes or modifications not expressly approved by Point Designs could void the user's authority to operate the device.



**WARNING:** Adding material (e.g., coverings, etc.) to a Point Partial that can trap moisture is not advised due to the likelihood of accelerated corrosion.



**WARNING:** The end user is the intended operator of the device and is responsible for its use.



**WARNING:** The Point Partial does not provide sensation; heat and moisture cannot be felt.





**WARNING:** Do not disassemble componentry or modify in any way.



**WARNING:** Do not service or perform maintenance when in use.



**WARNING:** Do not carry objects using only the tips of the digits. Carry objects by evenly distributing weight across the digits, as close to the knuckles and palm of the hand.



**WARNING:** Do not use with machinery with moving parts that may cause personal injury or damage.



**WARNING:** Do not use for extreme activities that may cause injury to a natural hand.



**WARNING:** Do not expose to excessive or high forces, particularly on the fingertips and on the side of the digits.



**WARNING:** Do not expose to excessive moisture, liquids, dust, high temperatures, or shock.



**WARNING:** Do not use in hazardous environments.



**WARNING:** Do not expose to high temperatures.



**WARNING:** Do not expose to flames.



**WARNING:** Do not use in or expose to explosive atmospheres.

\*Warnings covered in this section are residual risks associated with use of the Point Partial.



**PRECAUTION:** Users must comply with local regulations on the operation of automobiles, aircraft, sailing vessels of any kind and any other motorized vehicle or device. It is entirely the user's responsibility to seek confirmation that they are physically and legally able to drive using the Point Partials and to the fullest extent permitted by law.












**PRECAUTION:** Only use with approved Point Designs accessories and tooling.



**PRECAUTION:** Maintenance, repairs, and upgrades may only be performed by qualified Point Designs technicians and technical partners. Point Designs will provide, upon request, information to assist service personnel in repair of a device.

# Annex I

## DESCRIPTION OF SYMBOLS FROM PRODUCT LABEL

| Symbol  | Description                        |
|---|------------------------------------|
|    | CATALOG/PART NUMBER                |
|    | CAUTION                            |
|    | DATE OF MANUFACTURE                |
|   | EUROPEAN AUTHORIZED REPRESENTATIVE |
|  | REFER TO INSTRUCTIONS FOR USE      |
|  | LOT NUMBER/BATCH CODE              |
|  | MANUFACTURER                       |
|  | MEDICAL DEVICE                     |
|  | SERIAL NUMBER                      |

# NOTES

# NOTES



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