

Point Thumb

Instructions for Use



point designs

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

Refer to www.pointdesignsllc.com/resources to ensure you have the latest copy of this document.



point designs
1216 Commerce Ct., Ste 3
Lafayette, CO 80026
(720) 600-4753
www.pointdesignsllc.com
info@pointdesignsllc.com



mdi Europa GmbH
Langenhagener Str. 71
30855 Langenhagen
Germany

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 Thumb

INSTRUCTIONS FOR USE

V1.0

JULY 5, 2021

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

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

The installation of any Point Thumb should be performed exclusively by a licensed prosthetist or technician. Point Thumbs are intended to be operated by a prosthesis user following installation and setup. Any unauthorized handling or installation of a Point Thumb 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 Thumb

Intended Use

The Point Thumb system is to be used exclusively for external prosthetic fittings of the upper limbs. It is intended to provide flexion and extension at the metacarpal phalangeal (MCP) joint of the thumb in order to generate stable hand grasps.

Indications

Users of the Point Thumb system will achieve the best clinical outcome if they have thumb amputation at or near the MCP joint (slightly distal or proximal of the MCP joint is acceptable).

Intended Patient Population

The Point Thumb is intended to be fit on people with thumb amputations at or near the metacarpal phalangeal (MCP) joint.

Intended Users

The Point Thumb is to be installed into a prosthetic socket by a trained prosthetist, and used by partial hand amputees. The Point Thumb 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 Thumb

Point Thumb

Lateral Grip pads



Alcohol Wipe



Grip Band



Lamination Spacer



Alignment Tool



Mounting Bracket



Fingertip Pad



Mounting Hardware



Torx Tool®



Fingertip Pad Installation Tool



Alignment Transfer Post



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

The **Point Thumb** is a passive (i.e. not powered) mechanical thumb for people with thumb amputations. It features a ratcheting mechanism that enables one-handed use and 11 distinct locking positions. The **Point Thumb** features integrated compliant touchscreen compatible* fingertip pads for enhanced grip. The **Point Thumb** 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 Thumb

The **Point Thumb** 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.).

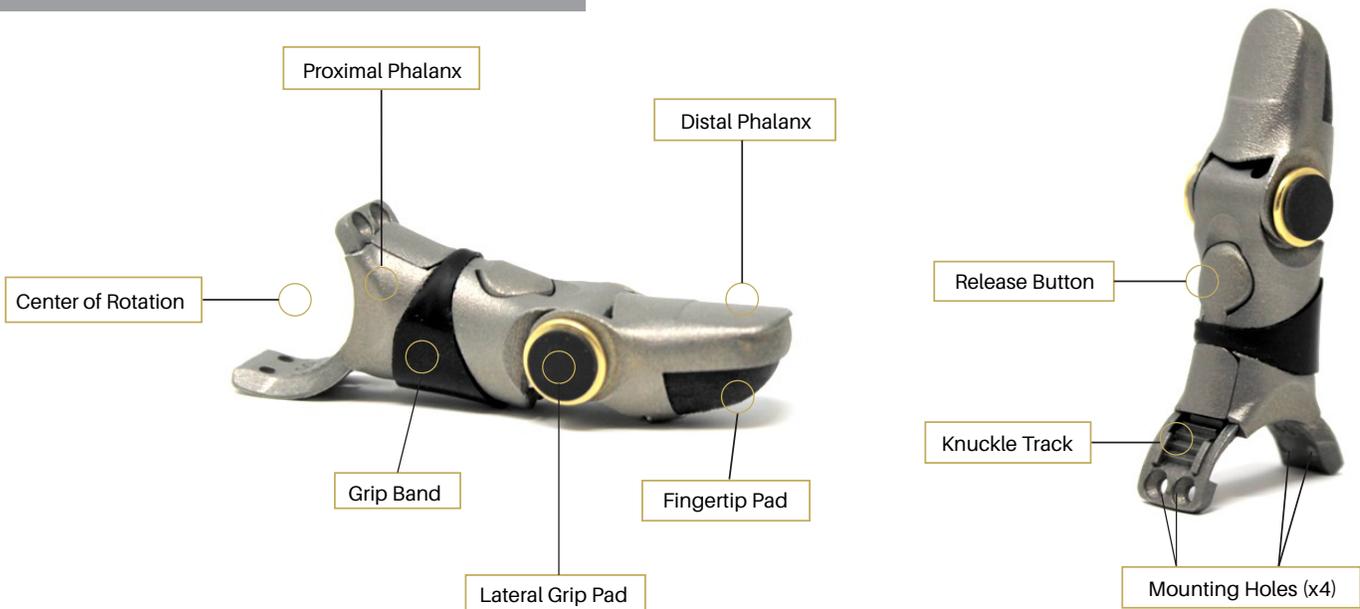
The **Point Thumb** can be extended in one of two ways:

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

A single **Point Thumb** 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

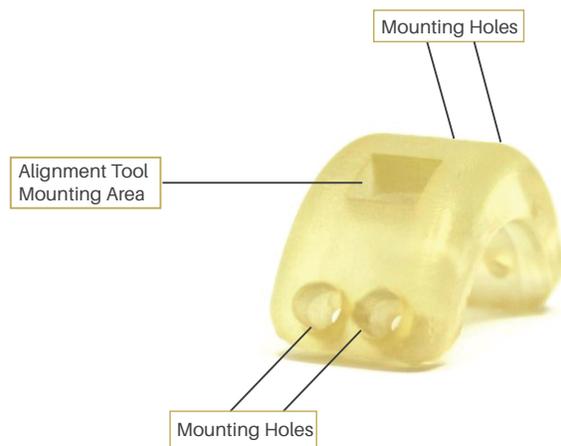
THE POINT THUMB



The **Point Thumb** comes assembled as one unit. The **Point Thumb** is comprised of a curved knuckle track, proximal phalanx, distal phalanx, a release button, grip band, 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.



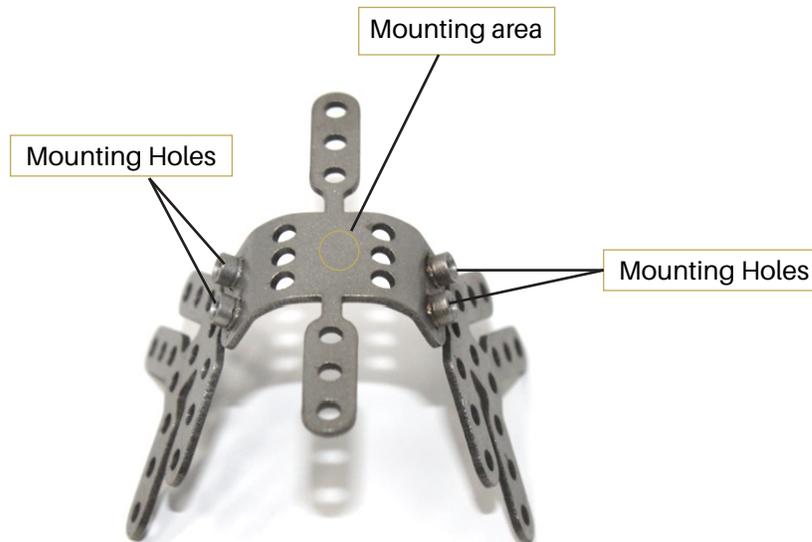
MOUNTING SCREWS

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 thumb to the bracket. 8 screws are supplied with each *Point Thumb*.



Component description

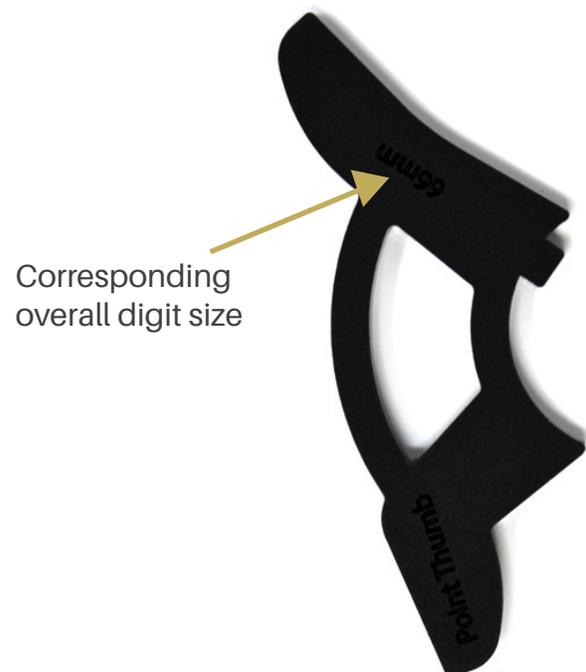
MOUNTING BRACKET



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 Thumb** 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 Thumb** throughout its entire range of motion. While initial alignment can be performed using the alignment tool, it is always recommended to attach the **Point Thumb** 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 Thumb** 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 jig (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 jig, remove the diagnostic socket from the mold, and replace with the initial layup of the definitive socket. Lower the vertical alignment transfer jig, 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 Thumb** 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



Lamination Spacer



Mounting
Hardware



Alignment Tool



Mounting Bracket

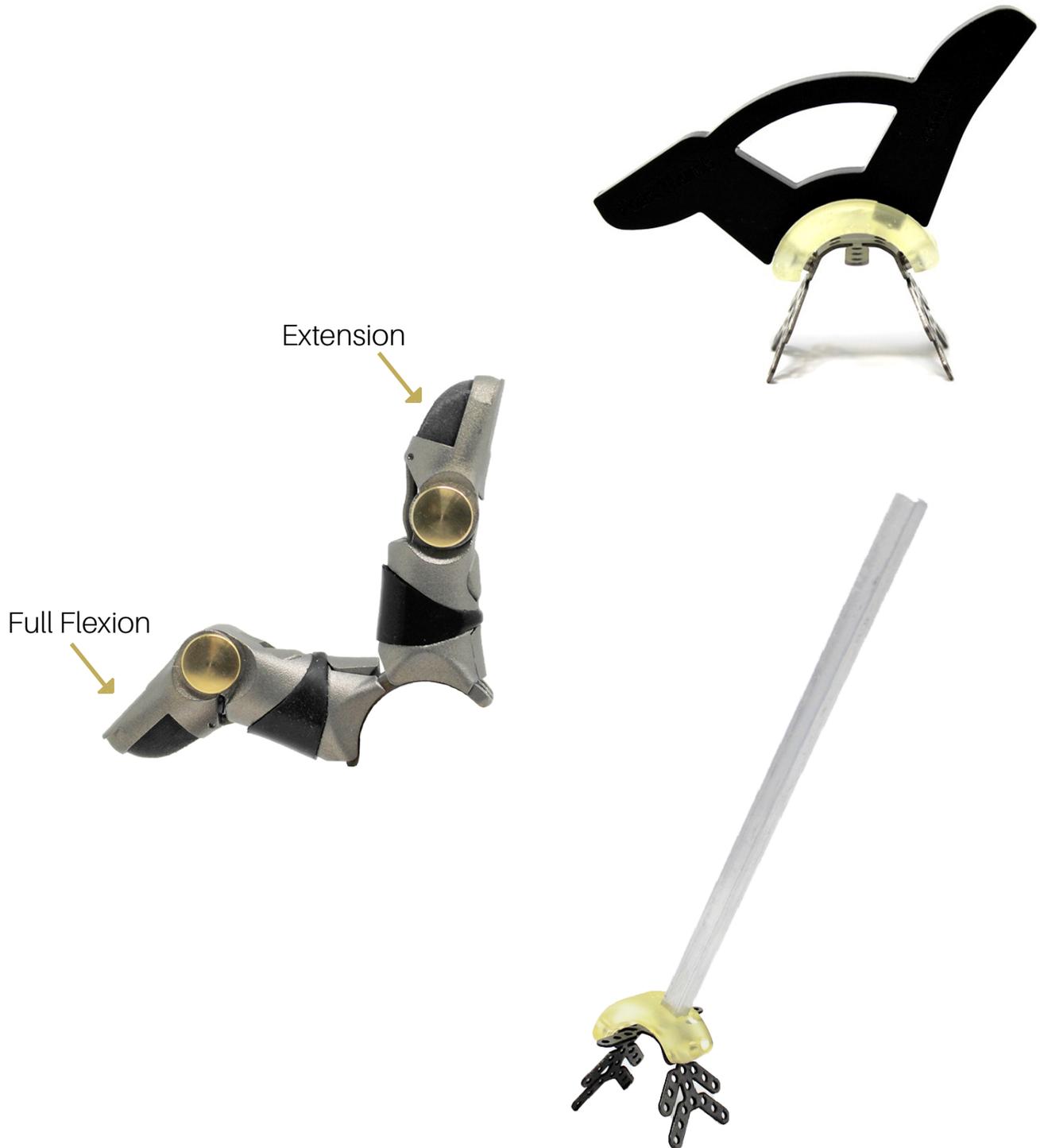


Lamination spacer mounted
onto bracket



Component description

ALIGNMENT TRANSFER



Component description

FINGERTIP PADS

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

LATERAL GRIP PADS

The **Point Thumb** comes with lateral grip pads to be installed after socket fabrication and final digit mounting. The lateral grip pads are intended for contact with the index finger joints to improve lateral grip. Ten lateral grip pads and a surface preparatory wipe are included with each order.

GRIP BAND

The **Point Thumb** comes with a grip band installed. The grip band is intended for contact with the surface of an object to improve grip. Five grip extra grip bands are included with each **Point Thumb**.



*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)

Specifications

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

Installation

FINGERTIP PAD INSTALLATION

The Fingertip Pad will have either 2 holes (for 73mm thumb) or 1 hole (for 59mm and 66mm thumb), and the distal phalange of the Point Thumb will have a corresponding number of posts.

Point Thumb



Installation Tool



Fingertip Pad



1. Press the pad down onto the post(s) so that it seats into the hole(s) in the pad. Start by pressing on the distal end of the pad and work your way proximal. 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(s), 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 the thumb adjacent to the 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.



GRIP BAND INSTALLATION

The Grip Band comes pre-installed on the Point Thumb. Five replacement Grip Bands are included with each Point Thumb.

Point Thumb



Installation Tool



Grip Band



1. Insert the Grip Band over the distal phalanx. Make sure the smaller width on the Grip Band is over the top side of the distal phalanx.



2. With the Point Thumb in extension, roll the Grip Band down the length of the digit.



GRIP BAND INSTALLATION

3. Continue to roll down the length of the digit until the Grip Band reaches the Grip Band cutout.



4. Use the installation tool to position the Grip Band into the Grip Band cutout.



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.

GRIP BAND REMOVAL

1. With the digit in extension, use the installation tool to push the Grip Band out of the cutout section.



2. Roll the Grip Band out through the length of the digit.



Using The Point Thumb

POSITIONING / FLEXION

Push on thumb
to desired
degree of flexion

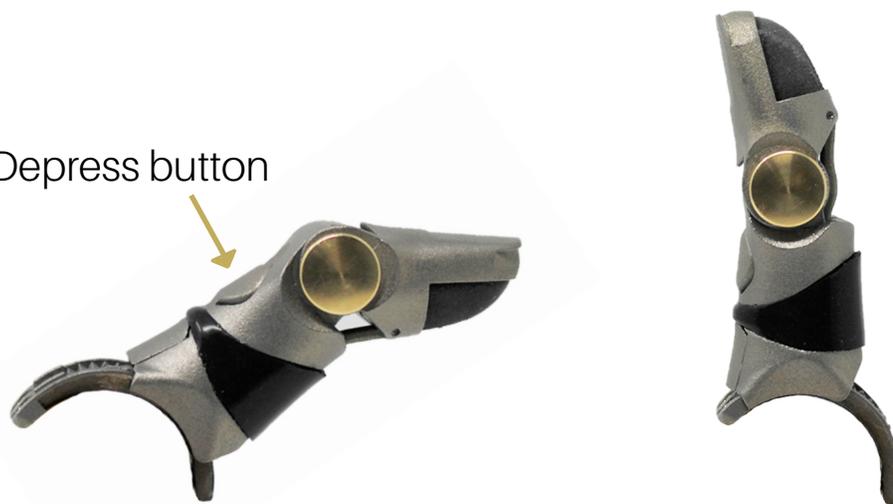


RELEASE / EXTENSION

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

Depress button



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 Thumb.

We have included a few possible issues with solutions below. If your issue is not addressed, email us for support at support@pointdesignsllc.com.

The Point Thumb moves freely and does not lock into position

OR

Cannot press Point Thumb 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 thumb “clicks”, resetting the ratchet mechanism.

Point Thumb 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 Thumb 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 Thumb 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 Thumb 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
- FDA via MAUDE (for cases in the US)
- The competent authority of the Member State in which they are established in the EU/EEA (for cases in the EU/EEA)

Maintaining Point Thumbs

PREVENTATIVE INSPECTION

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

MAINTENANCE

The **Point Thumb** 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 Thumb** 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 Thumb** should not be thrown away with common household waste. Dispose of the **Point Thumb(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 regarding repairs and returns. The **Point Thumb** comes with a 1-year manufacturer's defect warranty.

Details of the warranty are in separate documentation available at www.pointdesignsllc.com/resources

Safety and Warnings



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



WARNING: The Point Thumb 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 Thumb should not be used around high voltage/current.



WARNING: The Point Thumb 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 Thumb should be kept away from hot objects. If a Point Thumb becomes hot, it should be allowed to cool before skin contact.



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



WARNING: The Point Thumb 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 Thumb.



WARNING: The **Point Thumb** 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 Thumb** away from self and others during spring-back.



WARNING: Any unauthorized modification to a **Point Thumb** 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 Thumb** that can trap moisture is not advised due to the likelihood of accelerated corrosion.



WARNING: Care should be taken when grasping objects to ensure a secure grip.

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

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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info@pointdesignsllc.com

(720) 600-4753