

Point Pivot+

Instructions for Use



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

Refer to 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 Pivot+

INSTRUCTIONS FOR USE

V1.0

NOVEMBER 11, 2022

Thank you for choosing the Point Pivot+ and providing your client with an effective and robust dynamic mounting solution.

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

The installation of any Point Pivot+ should be performed exclusively by a licensed prosthetist or technician. Point Pivot+ is intended to be operated by a prosthesis user following installation and setup. Any unauthorized handling or installation of a Point Pivot+ could void its warranty.

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

(720) 600-4753

support@pointdesignsllc.com

Point Pivot+

Intended Use

The Point Pivot+ is a prosthetic device that is a reusable, non-sterile, non-active, and non-invasive medical device. It is used for long term compensation of a disability. It is used exclusively for external prosthetic fittings of the upper limbs. It is intended to provide thumb adduction/abduction around the carpometacarpal (CMC) joint and rotation of the thumb flexion-extension plane around the metacarpal phalangeal (MP) joint in order to generate stable hand grasps. The Point Pivot+ is intended to be fit on people with amputations of the thumb at or near the CMC joint. The patient population is not specific, and it is used by lay persons and health professionals in clinical, home, working and/or industrial environment. The Point Pivot+ system is used in combination with the Point Thumb and a prosthetic socket.

Indications

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

Intended Patient Population

The Point Pivot+ is intended to be fit on people with amputations of the thumb at or near the carpometacarpal (CMC) joint. The patient population is not specific, and it is used by lay persons and health professionals in clinical, home, working and/or industrial environment. The Point Pivot+ system is used in combination with the Point Thumb and a prosthetic socket.

Intended Users

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

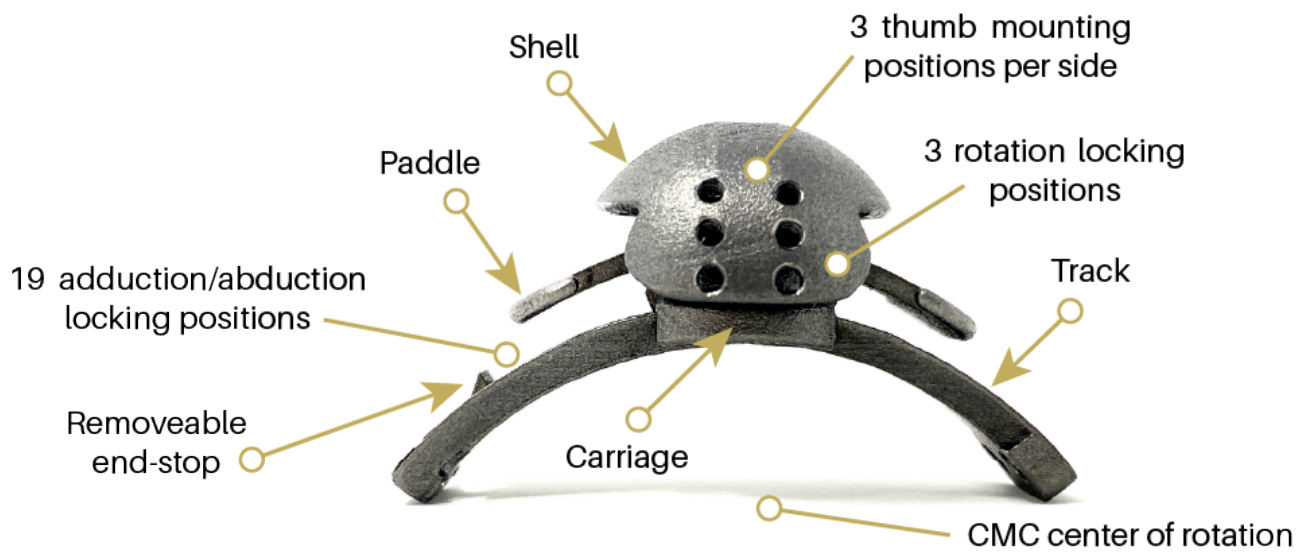
Contraindications

None known.

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Introduction to the Point Pivot+



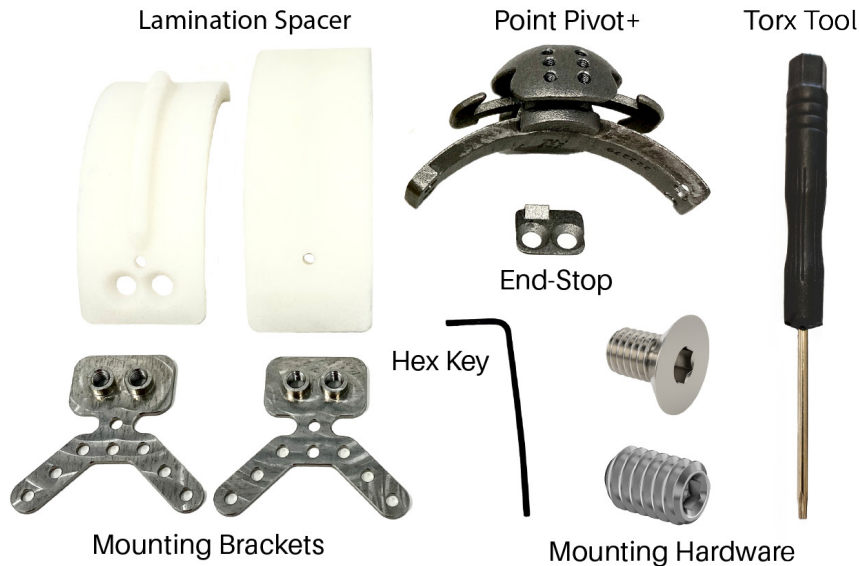
The **Point Pivot+** is a dynamic mounting system that provides additional degrees of freedom to the Point Thumb. As a replacement to the standard mounting for the Point Thumb, the **Point Pivot+** provides many functional benefits to the patient. It allows for the Point Thumb to be moved from an oppositional position to a lateral position with 19 locking levels of adduction/abduction. Additionally, it enables 3 positions of rotation in the plane that the Point Thumb flexes and extends in, allowing for a greater number of achievable hand grasps. The **Point Pivot+** is made from titanium for ample strength.

A Point Thumb attached to a **Point Pivot+** can be adducted or abducted by applying force to the paddles on the **Point Pivot+**. 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 also be rotated by applying a downward force and turning it clockwise or counterclockwise.

A single **Point Pivot+** can be integrated into a prosthetic socket using the mounting kit, which includes mounting brackets, a lamination spacer, and mounting hardware.

Component description

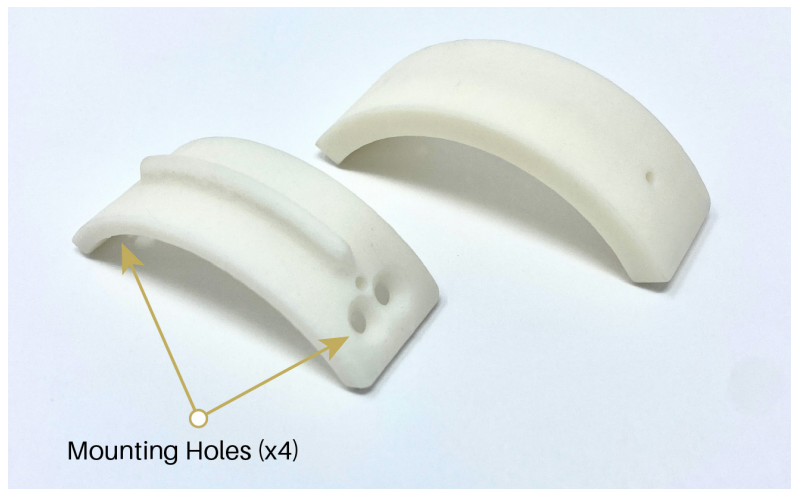
THE POINT PIVOT+



The **Point Pivot+** comes assembled as one unit and is comprised of a curved track, carriage, shell, paddles, and several other internal parts. The curved track has 4 mounting holes. Additionally, an end-stop is included in the mounting kit and becomes part of the final system during the installation process.

LAMINATION SPACER

The lamination spacer is a curved two-part component with mounting holes to help maintain mounting hole alignment and structural rigidity during the lamination process and prevents resin from seeping into the mounting area or mounting holes.



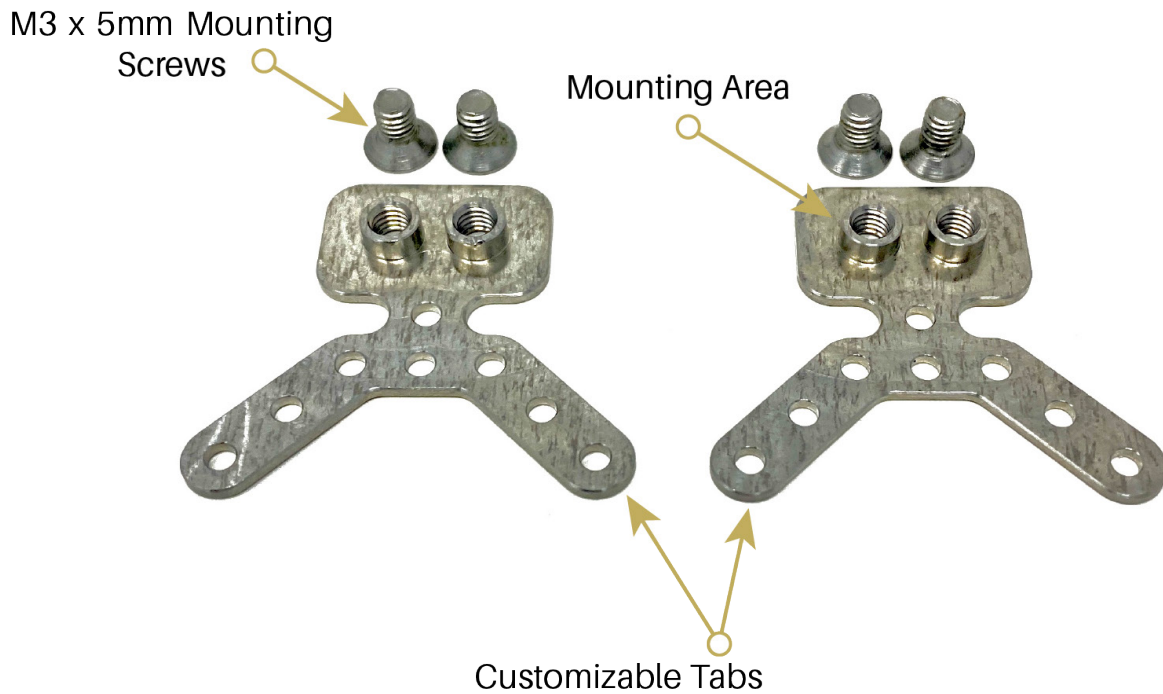
MOUNTING SCREWS

Torx mounting screws (M3 x 5 mm) are provided for attaching the lamination spacer to the brackets during the lamination process and for mounting the track of the **Point Pivot+** to the brackets. 8 screws are supplied with each **Point Pivot+**.



Component description

MOUNTING BRACKET



The mounting bracket is comprised of a mounting area and tabs that can be cut and shaped as desired. 2 mounting brackets are provided in each mounting kit.

Specifications

Material	<i>Titanium</i>
Rated load parallel to the track (in the adduction/abduction direction)	<i>667 N (150 lbf)</i>
Rated load perpendicular to the track	<i>667 N (150 lbf)</i>
Rated torque	<i>8 Nm (5.9 ft-lbf)</i>

Installation

INCLUDED IN THE PACKAGE

- One (1) **Point Pivot+**
- One (1) end-stop
- One (1) Point Thumb (ordered separately)
- Two (2) mounting brackets
- One (1) lamination spacer [bottom component and top component]
- Eight (8) M3 x 5mm mounting screws [four (4) for the **Point Pivot+** and four (4) spare]
- Eight (8) M2 x 3mm set screws [four (4) for disabling the rotation mechanism and four (4) spare]
- Eight (8) M2 x 4mm mounting screws (included with the Point Thumb) [four (4) for the Point Thumb and four (4) spare]
- Torx tool size T10
- Torx tool size T6 (included with the Point Thumb)
- Hex key size 0.9 mm

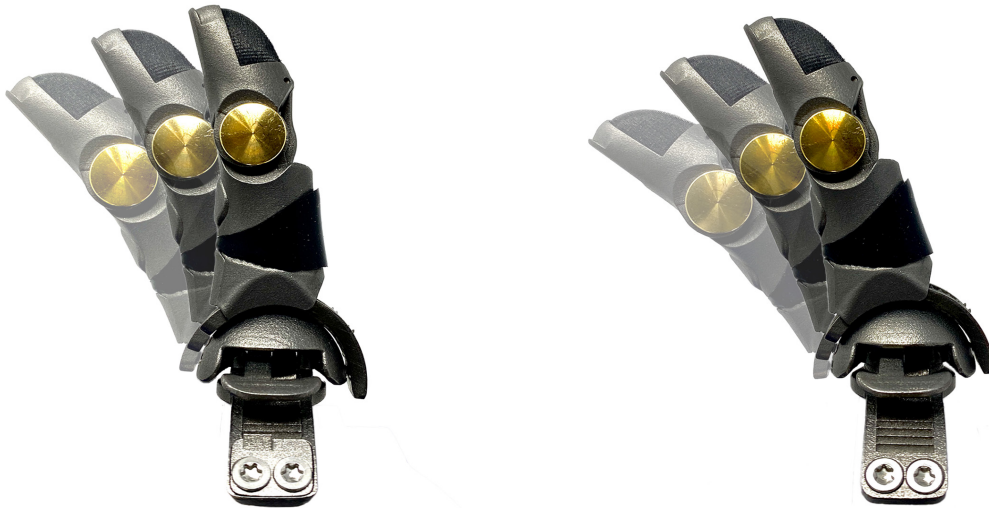
WHAT YOU WILL NEED

- Prefabricated patient socket (e.g., carbon fiber & silicone)
- Lamination supplies (e.g., prepreg carbon fiber, adhesive, silicone, etc.)
- Lamination tools (Dremel, files, PVA bag, etc.)
- Blue thread locker (Loctite Blue 242 or similar)

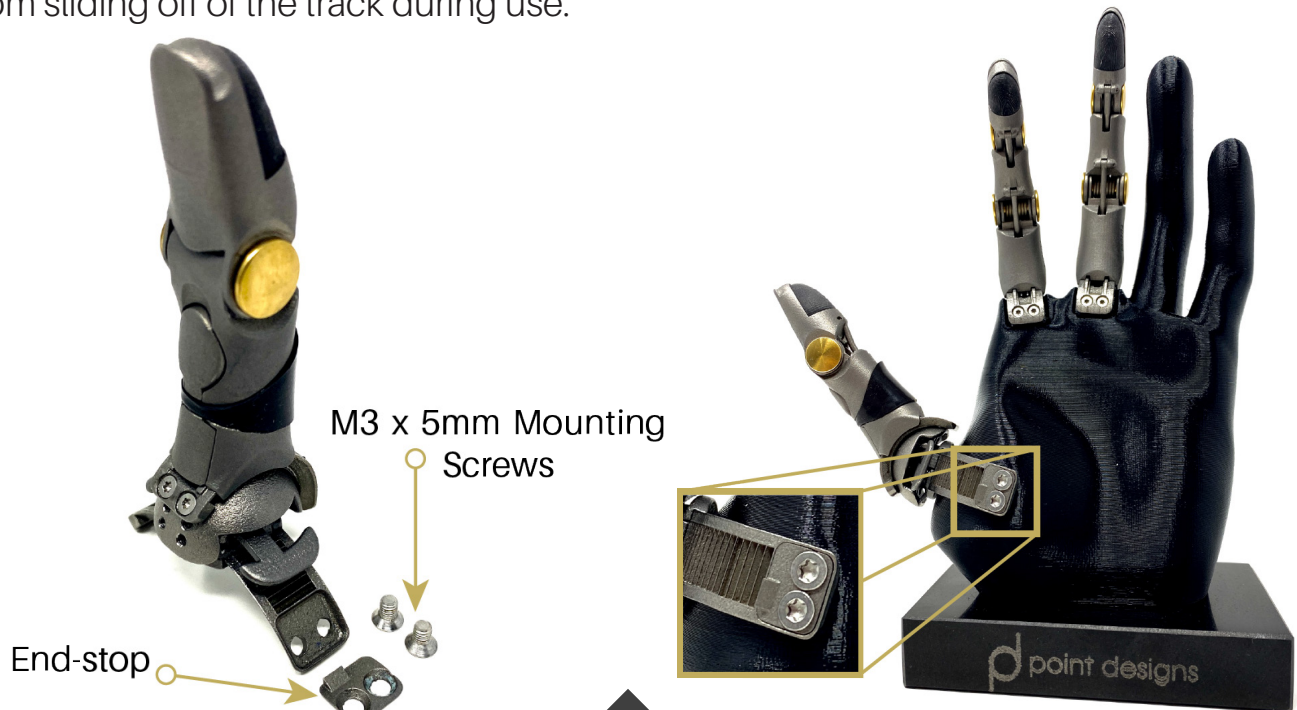
Installation

POSITIONING

1. Mount the Point Thumb to the shell of the Point Pivot+ using the M2 x 4mm mounting screws and T6 Torx tool. Note that you can mount the Point Thumb in 6 possible positions (3 in each direction) depending on the desired alignment.



2. Cut and file down the mounting brackets as desired while retaining the mounting locations needed for installation.
3. Attach the mounting brackets to the Point Pivot+ using the M3 x 5mm screws and T10 Torx tool. Note that you will need to place the end stop into the cavity on the track of the Point Pivot+ before securing the screws. The end stop prevents the carriage from sliding off of the track during use.



Installation

POSITIONING

4. With the mounting brackets attached, align the **Point Pivot+** on the carbon shell as desired.
5. Use your preferred adhesive to tack the mounting bracket into position, then remove the **Point Pivot+** using the Torx tool.
6. Apply additional adhesive to create a secure bond to the mounting brackets.
7. Remount the **Point Pivot+** using the supplied mounting hardware and Torx tool. Inspect the clearance around the **Point Pivot+** mounts, considering there will be some layers of prepreg carbon fiber added later. Remove the device.
8. Check that the **Point Pivot+** carriage can move smoothly and lock into every position, that the Point Thumb can rotate into each position, and that the Point Thumb can reach full flexion. If these functions cannot be achieved, then adjust the position of the **Point Pivot+** on the carbon shell.

Installation

LAMINATION

1. Attach the bottom part of the lamination spacer to the mounting brackets using the supplied mounting hardware and Torx tool.
2. Check the clearance between the lamination spacer and the adhesive.
3. Shape adhesive with dremel (or similar) as needed.
4. Remove the bottom part of the lamination spacer.
5. Pack carbon prepreg under/around the mounting brackets to fill any voids.
6. Add carbon prepreg to fill the area over the brackets up to the height of the thread mounts.
7. Add carbon prepreg over the entire model excluding the threaded mounting faces.
8. Apply a very thin layer of non-curing silicone to the bottom part of the lamination spacer so it will form to the prepreg and apply pressure.
9. Fill the threaded mounting holes with silicone grease to ease later removal of screws by preventing prepreg epoxy from flowing into threads.
10. Reapply the bottom part of the lamination spacer using supplied mounting hardware and the Torx tool.
11. Remove excess silicone that is pressed out during reapplication of the lamination spacer.
12. Apply more silicone putty to blend the bottom part of the lamination spacer to the model.
13. Fill over mounting screw with silicone.
14. Place the top part of the lamination spacer over the bottom part such that the two pieces become flush. This will further protect the mounting screws from being contaminated or damaged.
15. If desired, secure both lamination spacer components to the model with a finishing nail (or other fastener) through the small holes in the top of the lamination spacer.
16. Apply PVA bag under the prepreg shell.
17. Apply second PVA bag over the entire model.
18. Apply vacuum.
19. After curing is complete and the model has cooled, clean the prepreg and remove both parts of the lamination spacer.
20. Mount the **Point Pivot+** using the mounting hardware and the provided Torx tool. Apply threadlocker to mounting hardware. Inspect the **Point Pivot+** for proper function.

Installation

PREFITTING FUNCTION CHECKLIST

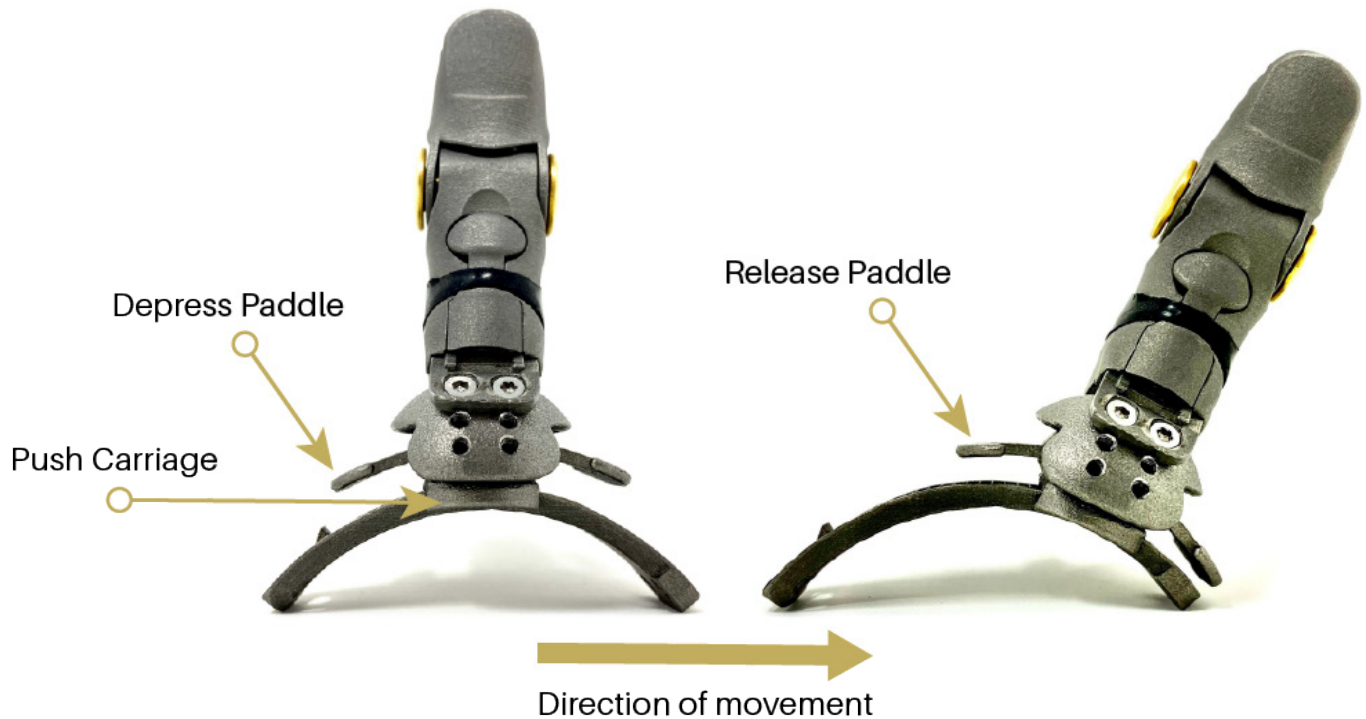
The prosthetist should ensure that all the following functions are checked prior to fitting the user with the prosthesis.

If any of the functions are not working properly, please either review the installation instructions and/or contact **support@pointdesignsllc.com**

- Ensure both paddles can be depressed.
- Ensure the carriage locks into all 19 locking positions.
- Ensure carriage can be moved across the length of the track.
- Ensure the shell can be depressed.
- Ensure that the Point Thumb can reach full flexion and spring back to full extension
- Ensure the shell can be rotated into all 3 positions.
For increased stability of the Point Thumb, the rotation feature can be disabled using the following steps:
 - Dismount Point Thumb
 - Thread set screws into up to four unused mounting holes until head is flush with shell (do not use the 2 sets of mounting holes closest to either edge of the shell as set screws placed there will not interact with the carriage)
 - Remount Point Thumb

Using The Point Pivot+

ADDUCTION/ABDUCTION



Method 1:

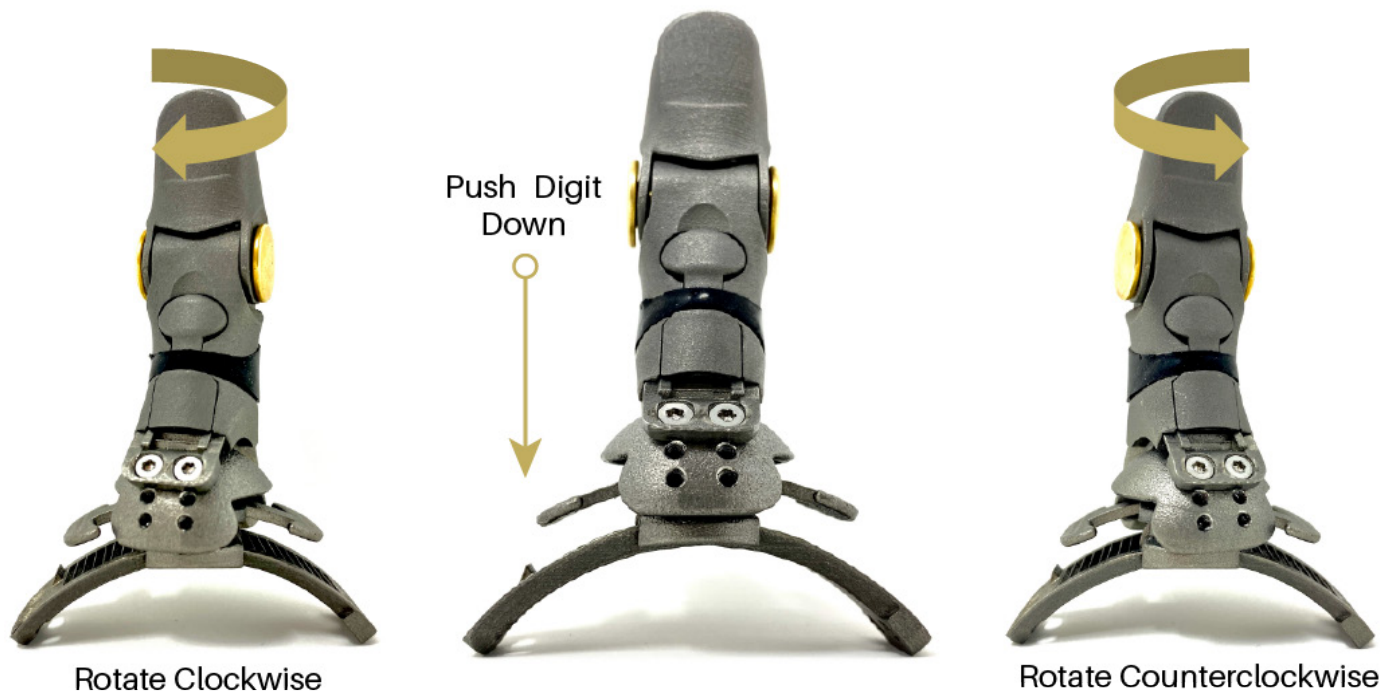
1. Depress the paddle opposite the desired direction of motion and push carriage. When the paddle is released, the device will automatically lock into place.
2. For movement in the other direction, depress the opposite paddle and push the carriage in the opposite direction.

Method 2:

1. Depress both paddles and move the carriage in either direction to the desired position. When the paddles are released, the device automatically locks into place.

Using The Point Pivot+

ROTATION



Rotation:

1. Apply a downward force and rotate the attached digit into one of three locking positions. When the digit is released, the device will automatically lock into place.

Troubleshooting

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

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 Pivot+ carriage moves freely and does not lock into position

OR

The Point Pivot+ is completely locked in position and cannot be moved

The paddles are likely obstructed and cannot engage or disengage properly. Clean the inside of the carriage around the paddles with compressed air to remove any debris.

Point Pivot+ rocks between two locking position or does not completely lock into position

The paddles likely did not fully seat in the track. Push the Point Thumb/carriage slightly until the paddles “click” into the track.

Point Pivot+ does not adduct/abduct all of the way

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

Point Pivot+ shell does not depress to allow for rotation

There is likely debris obstructing the rotation mechanism. Clean the inside of the carriage with compressed air to remove the debris.

Point Pivot+ 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 Pivot+ 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 US)
- The competent authority of the Member States in which they are established in EU/EEA (for cases in the EU/EEA)

Maintaining Point Pivot+

PREVENTATIVE INSPECTION

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

MAINTENANCE

The **Point Pivot+** can be cleaned with a cleaning solution such as soap + water or detergent + water. Dry the device with a clean towel or compressed air. Be sure to dry the device 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.

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

DISPOSAL



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

REPAIRS, RETURNS + WARRANTY

Please contact Point Designs at support@pointdesignsllc.com regarding repairs and returns. The **Point Pivot+** 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 Pivot+ is not designed to operate continuously in wet environments. A Point Pivot+ may get wet occasionally, but the user should be advised to thoroughly dry the Point Pivot+ after exposure to any liquid. Prolonged exposure to liquid may cause corrosion.



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



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



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



WARNING: The Point Pivot+ contains moving parts (e.g., 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 Pivot+.



WARNING: The Point Pivot+ contains internal springs under tension.



WARNING: Any unauthorized modification to a Point Pivot+ 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 equipment.



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



WARNING: The Point Pivot+ 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 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 Pivot+



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 Pivot+** 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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