

Point Endo

Instructions for Use



point designs

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

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 Endo

INSTRUCTIONS FOR USE

V1.0

MARCH 23, 2022

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

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

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

Intended Use

The **Point Endo** system is a finger prosthetic 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 and is intended to be used with a custom cosmetic covering¹. It is intended to provide flexion and extension at the metacarpal phalangeal (MCP) and proximal interphalangeal (PIP) joints. The **Point Endo** is intended to be fit on people with amputations of digits 2-5 at or near the metacarpal phalangeal (MCP) 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 Endo** system is used in combination with prosthetic sockets.

Indications

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

Intended Patient Population

The **Point Endo** is intended to be fit on people with amputations of digits 2-5 at or near the metacarpal phalangeal (MCP) 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 Endo** system is used in combination with prosthetic sockets and a custom cosmetic covering¹.

Intended Users

The **Point Endo** is to be installed into a prosthetic socket by a trained prosthetist, and used by partial hand amputees. A custom cosmetic covering¹ is to be worn over the **Point Endos**. The **Point Endo** is compatible with most prosthetics sockets and cosmetic coverings¹, and is installed into the prosthetic socket by a trained prosthetist or technician.

Contraindications

None known.

¹ The cosmetic cover is not manufactured by Point Designs and must be manufactured by the prosthetic clinic fitting the **Point Endo**.

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Introduction to the Point Endo

Point Endo

Torx Tool®

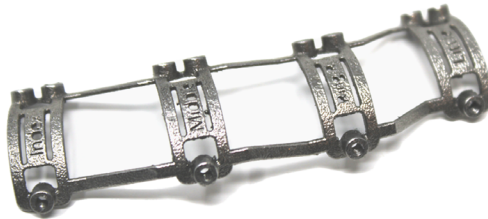


Mounting Bracket

Mounting Hardware



Lamination Spacer



*Images not to scale

The **Point Endo** 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 up to 9 distinct locking positions. The **Point Endo** is made from titanium for ample strength. The **Point Endo** is intended to be used with a custom cosmetic cover¹ over the digit(s).

The **Point Endo** 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 Endo** 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.

Up to 4 **Point Endos** can be integrated into a prosthetic socket using the mounting kit, which includes a mounting bracket, lamination spacers, and mounting hardware.

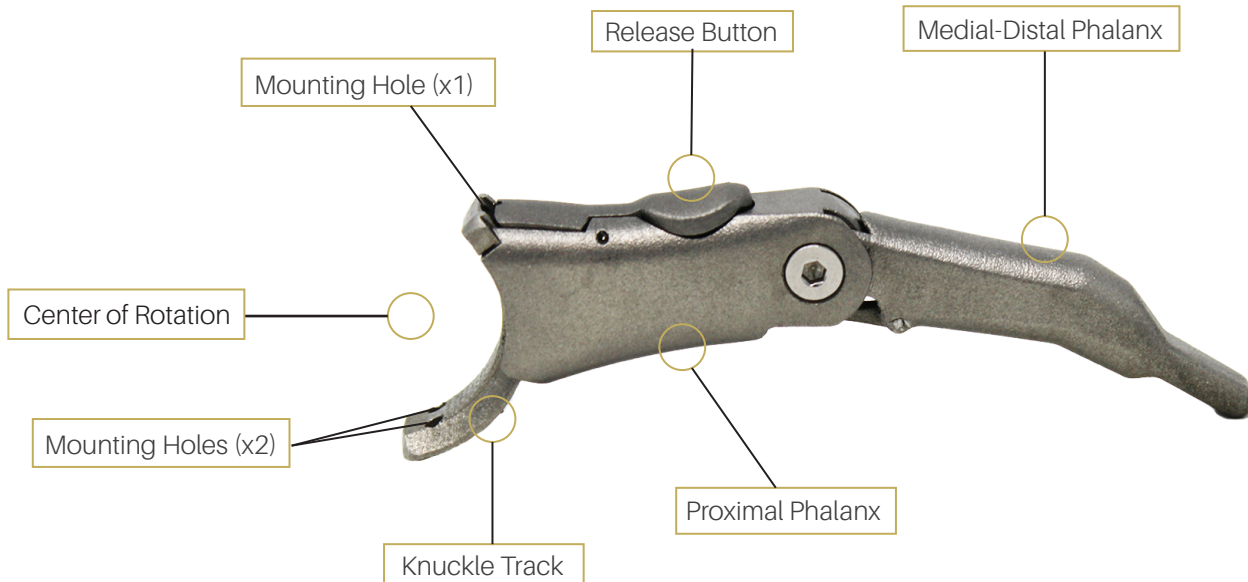
¹ The cosmetic cover is not manufactured by Point Designs and must be manufactured by the prosthetic clinic fitting the Point Endo.

Clinical Benefits of the Point Digit

The **Point Endo** provides patients with several key clinical benefits. First and most importantly, the **Point Endo** allows for one-handed operation, not requiring the contralateral limb to position the finger. In effect, the one-handed operation feature of the **Point Endo** makes it the only clinically sound passive prosthetic finger for people with bilateral partial hand amputations. Second, the strength of the **Point Endo** is the highest reported prosthetic partial finger strength in the field which allows patients to perform high-load activities such as those in industrial or recreational environments. Third, there are 4 standard lengths of the **Point Endo**, accomodating the 1st to 99th percentile male patients and 1st to 100th percentile female patients. Fourth, the **Point Endo** has a virtual center of rotation about the MCP joint which provides for proper anatomical alignment of the finger joints. Fifth, and finally, the **Point Endo** provides up to 9 locking positions to ensure stable grasps of (nearly) any sized object.

Component description

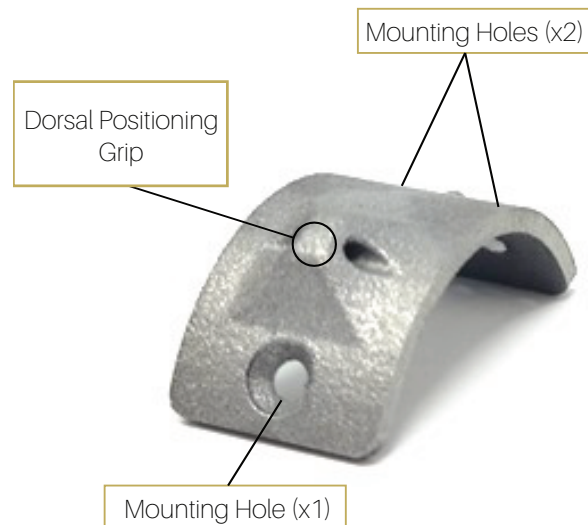
THE POINT ENDO



The **Point Endo** comes assembled as one unit. The **Point Endo** is comprised of a curved knuckle track, proximal phalanx, medial-distal phalanx, a release button, and several other internal parts. The curved knuckle track has 3 mounting holes.

LAMINATION SPACERS

The lamination spacers are curved components with mounting holes and a dorsal positioning grip to help maintain mounting hole alignment and structural rigidity during the lamination process, and prevent resin from seeping into the mounting area or mounting holes.



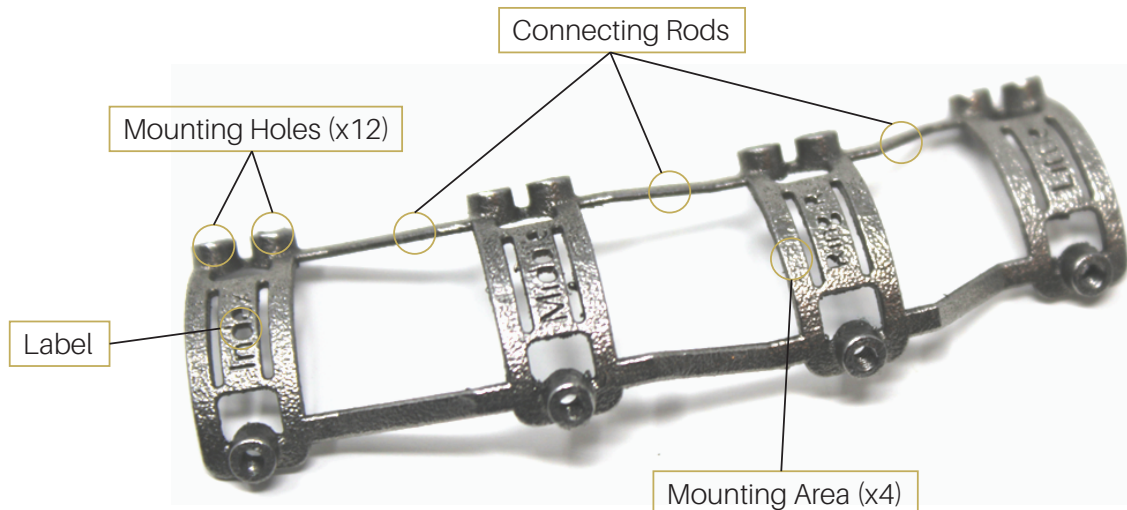
MOUNTING SCREWS

Torx® mounting screws (M2 x 5 mm) are provided for attaching the lamination spacers to the bracket during the lamination process and for mounting the fingers to the bracket. 6 screws per finger are supplied with each **Point Endo**.



Component description

MOUNTING BRACKET



The mounting bracket is a single part comprised of 4 mounting areas with **labels**, 12 mounting holes (3 per mounting area), and **connecting rods** that tie the mounting areas together.

The **labels** denote **Point Endo** locations and are index, middle, ring, and little.

The **connecting rods** are cut prior to installation to retain only the mounting areas needed.

for example for an index and middle finger installation, the connecting rods between the middle and ring mounting areas are cut and filed down to retain only the index and middle mounting areas.

The mounting bracket comes in either a left-handed or a right-handed version denoted by the Ring finger label, i.e., Ring-R (for right) or Ring-L (for left).

Specifications

Material	<i>Titanium</i>
Expected service life²	<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>

² The rated service life as defined is for the Point Endo. It does not apply to the custom cosmetic cover¹. Users should expect to repair or replace the custom cosmetic cover¹ at the expected service rate determined by their prosthetist during the lifetime of the Point Endo.

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**

- ☐ Each **Point Endo** flexes and locks into the 9 distinct levels of flexion.
- ☐ The button on each **Point Endo** can be pressed easily through the cosmetic cover¹.
- ☐ Pressing the button while each **Point Endo** is in a flexed position causes position release and easy extension
- ☐ Full flexion of each **Point Endo** can be achieved
- ☐ Release of each **Point Endo** after full flexion results in spring back to full extension and ratchet mechanism reset.
- All of the above performance specifications are met when a custom cosmetic cover¹ is applied over the **Point Endo**.

¹ The cosmetic cover is not manufactured by Point Designs and must be manufactured by the prosthetic clinic fitting the Point Endo.

Using The Point Digit

POSITIONING / FLEXION

1.



Push on finger to desired degree of flexion.

2.



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

3.



4.



2. SPRING BACK

1. Fully flex finger



2. 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 Endo.

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 Endo moves freely and does not lock into position

OR

Cannot press Point Endo 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 Endo does not flex all of the way

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

Point Endo 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 Endo 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 Endo is corroded.

Contact us for support.

*Ensure the custom cosmetic cover is properly designed such that it does not inhibit or limit the motion of the Point Endo. The Point Endo should be able to overcome minor additional resistance provided by a custom cosmetic cover but if a cover is improperly designed it can provide major additional resistance.



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 Endos

PREVENTATIVE INSPECTION

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

MAINTENANCE

The **Point Endo** can be cleaned with a cleaning solution such as soap + water or detergent + water. Dry the digit with a clean towel or compressed air. Be sure to dry a **Point Endo** 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 Endo** should not be thrown away with common household waste. Dispose of the **Point Endo(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 Endo** 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 Endo** is not designed to operate continuously in wet environments. A **Point Endo** may get wet occasionally, but the user should be advised to thoroughly dry the **Point Endo** after exposure to any liquid. Prolonged exposure to liquid may cause corrosion.



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



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



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



WARNING: The **Point Endo** 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 Endo**.



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



WARNING: Any unauthorized modification to a **Point Endo** 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 Endo** 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 Endo.



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 Endos** and to the fullest extent permitted by law.












PRECAUTION: Only use with approved Point Designs accessories and tooling. An exception to this is the addition of a custom cosmetic cover¹ fabricated and fit by a trained prosthetic clinician or prosthetic technician.



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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