

# Point Thumb - OI

*Instructions for Use*

**For Clinicians**



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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.*

The *Point Thumb - OI* by Point Designs is a mechanical prosthetic thumb designed for use by patients who have undergone osseointegration of the thumb. Its mechanism of operation is through a ratcheting function that locks the prosthesis into various positions for grasping.

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

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# Point Thumb - OI

## Intended Use

The *Point Thumb - OI* is a prosthetic thumb intended to be used for grasping.

## Indications

The *Point Thumb - OI* is indicated for use with patients who:

- Have amputations or congenital limb differences of the metacarpophalangeal (MCP) joint of the thumb
- Have undergone osseointegration surgery
- And have been cleared for prosthetic fitting

The *Point Thumb - OI* is indicated for light-duty use.

## Contraindications

The *Point Thumb - OI* is contraindicated for use in heavy-duty, wet, or dirty environments. It is contraindicated for use with patients who have an amputation or limb difference distal to the MCP joint with an osseointegrated implant in the proximal phalanx of the thumb.

## Conditions of Use

The *Point Thumb - OI* is designed for home use environments. It is intended for use by one patient. Installation and fitting of this component should be performed exclusively by a certified prosthetist. Any unauthorized handling or installation could void the warranty.

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# What's in the Box



1. *Point Thumb - OI* with integrated grip covers
2. Adapter for *Point Thumb - OI*, specific to the patient's osseointegrated abutment\*
3. 2.5mm hex driver
4. Extra clamping screw

\*Note: adapter is already assembled into the *Point Thumb - OI*.

## Specifications

<b>Length</b>	3 sizes: 60mm, 65mm, 70mm
<b>Weight</b>	24.5g
<b>Materials</b>	Titanium, stainless steel, elastomeric polyurethane
<b>Load Rating</b>	80N (18 lbf)
<b>Max Clamping Torque</b>	0.25 Nm (2.2 in-lbf)
<b>Service Life</b>	3 years

# Compatibility

The *Point Thumb - OI* is compatible with osseointegration implants/abutments from the following manufacturers:

- Integrum
- Southern Implants

Contact Point Designs if your patient has a different implant/abutment or requires a variation of the standard adapter for the compatible implants.

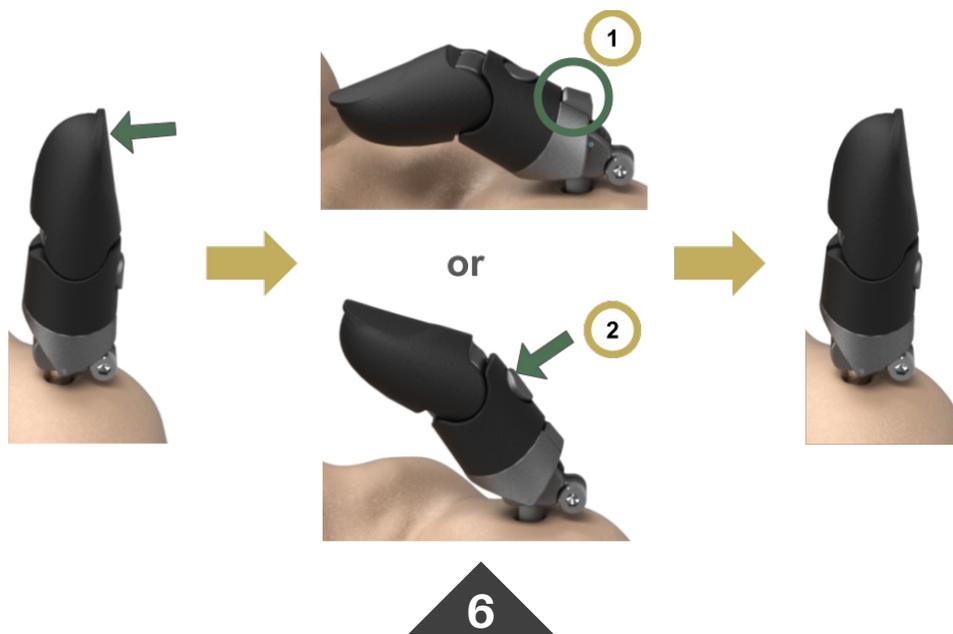


The appropriate adapter for each abutment comes pre-installed into the *Point Thumb - OI*. *Point Thumb - OI* assemblies are not interchangeable.

# Component Operation

The *Point Thumb - OI* is designed with an internal ratcheting mechanism that locks the device into five different flexion positions. The flexion position can be adjusted by applying pressure to the dorsal side of the component. There are two options to release the *Point Thumb - OI* back into extension:

1. Flex the thumb into full flexion until the release lever is propped up. The auto-spring function will return it to full extension.
2. Press the button on the back of the thumb to allow the *Point Thumb - OI* to extend in increments



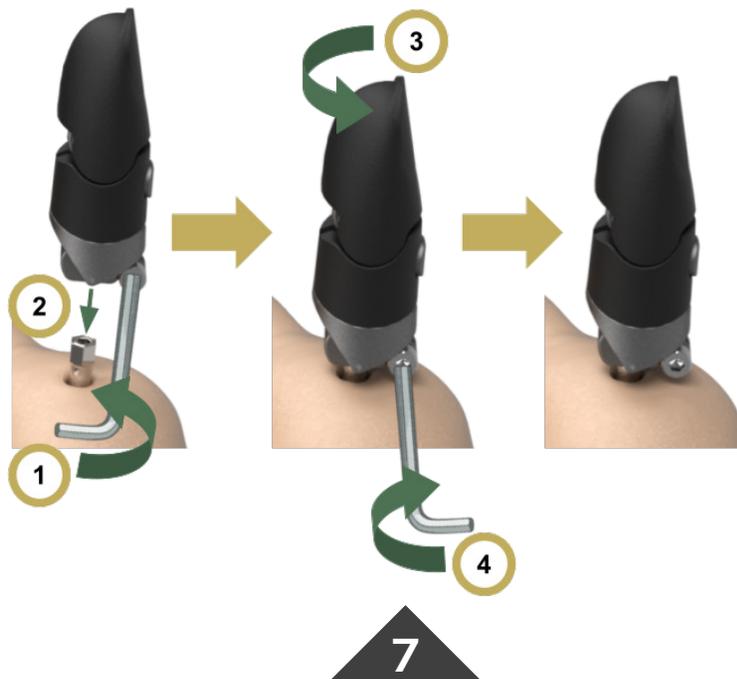
The position of the thumb can be adjusted using the other hand, fingers on the same hand, or nearby surfaces.

Once installed, the *Point Thumb - OI* can be rotated relative to the abutment to increase the number of achievable grasps. To rotate the thumb, loosen the clamping screw with the provided 2.5mm hex driver (1), grab the thumb and rotate it in the desired direction (2), and then tighten the clamping screw (3).



## Installation

To attach the *Point Thumb - OI*, loosen the clamping screw (1) and place the thumb onto the abutment (2). Rotate it to a position that is functional for the patient's desired activities of daily living (3). Use the 2.5 mm hex driver provided to tighten the screw by hand in the direction shown until snug (4). The thumb should not wobble on the abutment and should not pull off of the abutment when gently tugged. Confirm that the device is functioning by grasping a variety of objects.





Tighten gently up to a torque of 0.25Nm. Do not overtighten.

To remove the *Point Thumb - OI*, loosen the screw in the direction shown. Note that the screw does NOT need to be removed completely and should stay inserted in the thumb base.

## Cleaning and Maintenance

### CLEANING

The *Point Thumb - OI* can be cleaned using the methods below. Remove the prosthesis before cleaning.

- To remove dust or small particles, gently blow forced air over the area.
- Rinse the prosthesis with fresh water, especially after exposure to salt water or other harsh environments.
- If needed, clean with mild hand soap that is free of harsh detergents, strong fragrances, or high-pH ingredients.
- Dry thoroughly after washing.

For cleaning the abutment and surgery site, follow the instructions from your surgical care team and the implant manufacturer.

### MAINTENANCE

The *Point Thumb - OI* does not require regular maintenance. If it is damaged or stops working, contact Point Designs to initiate a repair request.

Regularly inspect the *Point Thumb - OI* for dirt and grime, and clean as needed according to cleaning instructions.

If a tear is found on the grip covering, contact Point Designs for a replacement.

The *Point Thumb - OI* includes one extra screw to secure the adapter to the abutment.

### DISPOSAL

A *Point Thumb - OI* should not be thrown away with common household waste. Dispose of the *Point Thumb - OI* 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@pointdesigns.com](mailto:support@pointdesigns.com) regarding repairs and returns. The *Point Thumb - OI* comes with a 2-year manufacturer's defect warranty.

Details of the warranty are available at [www.pointdesigns.com](http://www.pointdesigns.com).

## Safety and Warnings



**WARNING:** The *Point Thumb - OI* is not designed to operate continuously in wet environments. The *Point Thumb - OI* may get wet occasionally, but prolonged exposure to liquid may cause corrosion.



**WARNING:** The *Point Thumb - OI* is electrically conductive and presents a potential electric shock hazard if it contacts a voltage difference and skin simultaneously. The *Point Thumb - OI* should not be used around exposed circuits.



**WARNING:** The *Point Thumb - OI* is thermally conductive and presents a potential burn hazard if it contacts a heat source and skin subsequently. The *Point Thumb - OI* should be kept away from hot objects. If an *OI Thumb* becomes hot, it should be allowed to cool before skin contact.



**WARNING:** The *Point Thumb - OI* contains ferrous materials, and can therefore interact with magnetic fields. Care should be taken when using an *Point Thumb - OI* around magnets, such as MRI machines.



**WARNING:** The *Point Thumb - OI* moving parts present a minor pinching hazard. The user should take care to keep loose skin, clothing, etc. from the moving parts of the *Point Thumb - OI*.



**WARNING:** The *Point Thumb - OI* contains internal springs under tension which cause the thumb to extend rapidly presenting a minor hazard. The user should take care to keep the *Point Thumb - OI* away from themselves and others during springback.



**WARNING:** Any unauthorized modification to a *Point Thumb - OI* 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:** Care should be taken when grasping objects to ensure a secure grip.



**WARNING:** The *Point Thumb - OI* can safely support 80N (18lbf), but the total limit also depends on the abutment and surgical implant. Contact the implant manufacturer for details.



**WARNING:** Failure to remove the *Point Thumb - OI* before heavy or strenuous activities, such as lifting, pushing, or pulling with force, can result in damage to the implant or *Point Thumb - OI*.

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

The warnings listed here are specifically for the *Point Thumb - OI* and related components. For warnings and information related to the surgical implant and abutment, contact the implant manufacturer.

## Annex I

### DESCRIPTION OF SYMBOLS FROM PRODUCT LABEL

	CATALOG/PART NUMBER
	CAUTION
	DATE OF MANUFACTURE
	REFER TO INSTRUCTIONS FOR USE
	LOT NUMBER/BATCH CODE
	MANUFACTURER
	MEDICAL DEVICE
	SERIAL NUMBER



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