

Merge™ MID

Instructions for Use

For Clinicians



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Refer to www.pointdesigns.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.*

The *Merge MID* by Point Designs is a custom, body-powered prosthesis for use by patients with amputations of digits 2-5 through the middle phalanx. It uses the remaining proximal interphalangeal (PIP) joint motion to drive distal interphalangeal (DIP) joint motion.

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

(720) 600-4753

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Merge™ MID

Intended Use

The *Merge MID* is a custom body-powered prosthesis intended to restore active grasping for patients with amputations through the middle phalanx of digits 2-5.

Indications

The *Merge MID* is indicated for patients who:

- Have amputations of the middle phalanx of digits 2-5
- Have sufficient length of the residual middle phalanx (at least 15-20mm or ~40% of the middle phalanx remaining)
- Have sufficient range of motion (ROM) of the intact PIP joint (at least 45°)

Contraindications

The *Merge MID* is contraindicated for patients with amputations distal to the DIP joint or at or proximal to the PIP joint.

Conditions of Use

The *Merge MID* is designed for use in home environments and for light- to medium-duty activities. It is intended for use by a single patient. Installation and fitting must be performed by a certified prosthetist. Unauthorized handling or installation may void the warranty.

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What's in the Box



A) 1 *Merge MID* device

B) 1 extra fingertip pad*

C) 5 extra proximal elastic bands

D) 5 extra distal elastic bands

E) 1 mini hook tool for installing and removing elastic bands

*Fingertip pad is touchscreen compatible

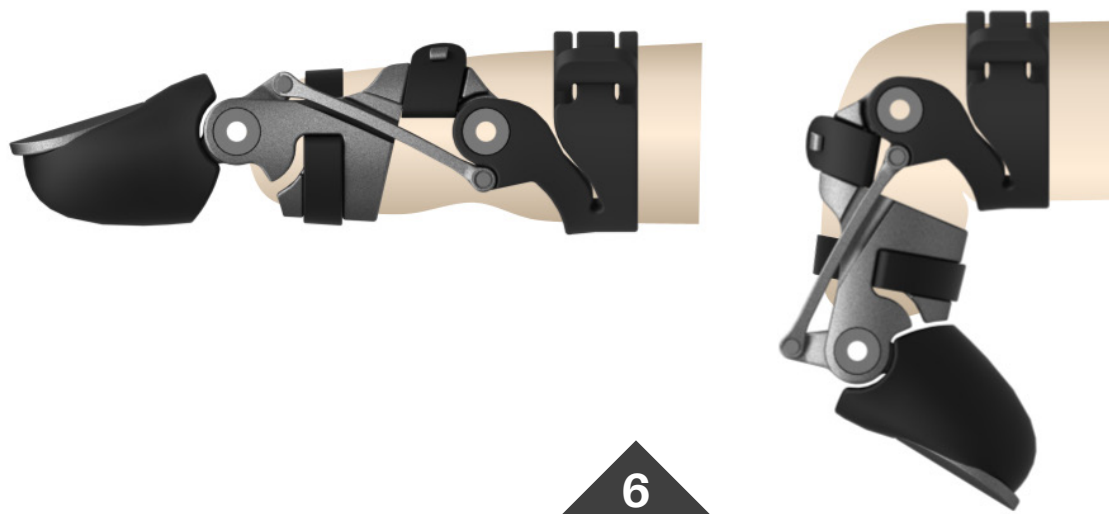
Specifications

Length	<i>Custom, based on clinician-provided measurements and photographs</i>
Weight	<i>12-22g</i>
Materials	<i>Titanium, zinc-coated steel, stainless steel, silicone, nylon</i>
Recommended Min. Residual Length of Middle Phalanx*	<i>15-20 mm (depending on overall finger length)</i>
Recommended Max. Residual Length of Middle Phalanx*	<i>35 mm</i>
Recommended Min. PIP ROM*	<i>45°</i>
Load Rating	<i>60 N (13.5 lbf)</i>
Service Life	<i>3 years</i>

*Length and ROM values are guidelines for optimal functionality; functionality may be reduced if these conditions are not met.

Component Operation

Flex and extend the residual finger at the PIP joint to articulate the prosthesis through its available ROM.

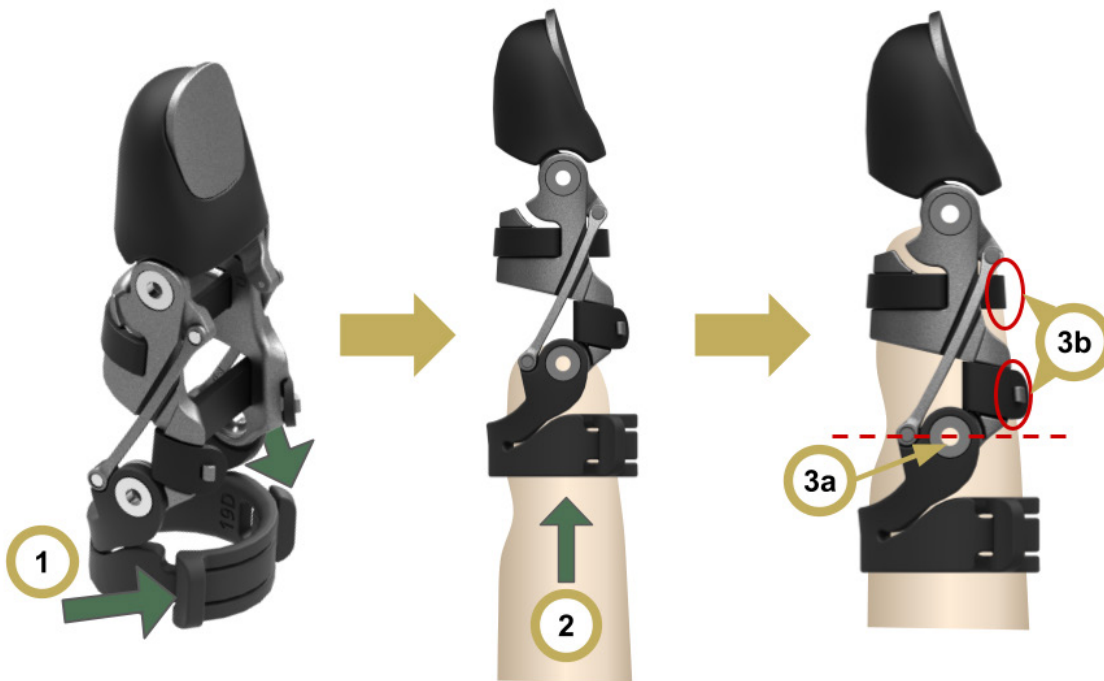


Installation

Instruct your patient to inspect skin for redness, blisters, or irritation before, during, and after each use.

DONNING

1. Squeeze paddles to open the *FlexRing*.
2. Slide finger into device.
3. Align the prosthesis:
 - a. Align the device's PIP joint with the intact PIP joint.
 - b. Ensure both elastic bands are on the dorsal aspect of the finger.
4. Release paddles to close the *FlexRing*.
 - a. Ensure a snug fit with no twisting or sliding. Bend and straighten the finger to confirm full movement.



DOFFING

1. Gently pull device off finger.
2. If needed, squeeze paddles to open the *FlexRing*.

Cleaning and Maintenance

CLEANING

Remove the *Merge MID* before cleaning. Use one of the methods below.

- To remove dust or small particles, gently blow with forced air.
- Rinse with fresh water, especially after exposure to salt water or harsh environments.
- If needed, clean with mild hand soap free of harsh detergents, strong fragrances, or high-pH ingredients. Alcohol wipes may also be used.
- Dry thoroughly after cleaning.

MAINTENANCE

The *Merge MID* does not require regular maintenance. Lubrication with oil/WD-40 is not necessary, but is not harmful. Instruct your patient to inspect the device before and after each use. If damaged or not working properly, contact Point Designs for repair.

Extra fingertip pads and elastic suspension bands are included and can be replaced if worn or damaged (see Replacement Parts).

DISPOSAL

The *Merge MID* should not be thrown away with common household waste. Dispose of the *Merge MID* 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 regarding repairs and returns. The *Merge MID* comes with a 2-year manufacturer's defect warranty.

Details of the warranty are available at www.pointdesigns.com.

Replacement Parts

Instruct your patient to check the elastic bands and fingertip pad for damage before each use. If needed, follow the instructions below to replace the fingertip pad or elastic bands.

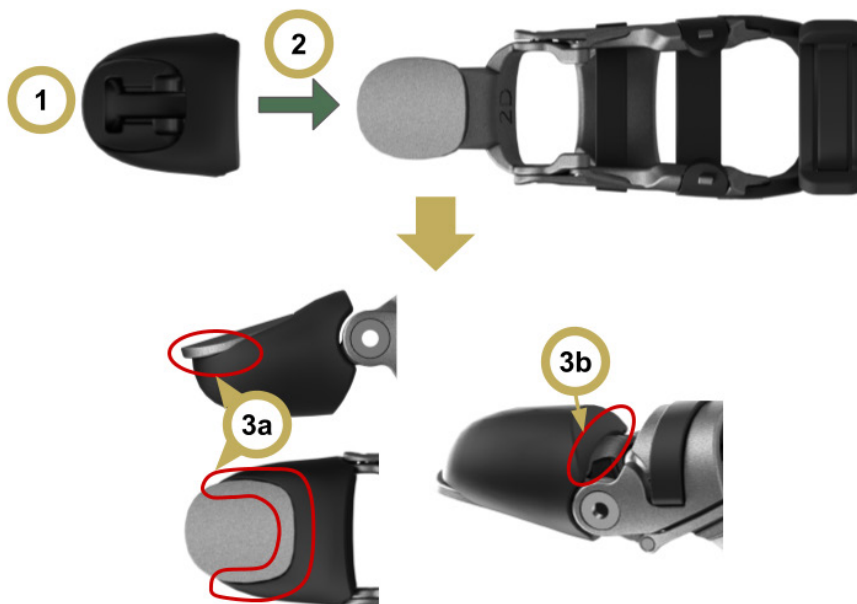
FINGERTIP PAD

Installation

1. Hold fingertip pad with fingernail opening facing up; align T-shaped slot with prosthetic fingertip.
2. Insert prosthetic fingernail into slot; gently wiggle and push pad into place.
3. Check fit:
 - a. Ensure the pad is flush around the fingernail.
 - b. Ensure the proximal palmar end is fully wrapped around the titanium section and fingernail extends slightly past the tip.



If not fully wrapped, squeeze the palmar section of the pad until lip of pad wraps around the titanium.



Removal

1. Slowly peel and slide pad off prosthetic finger.
2. **If damaged:** Carefully cut through pad with snippers, then pull off finger.

PROXIMAL ELASTIC BAND

Installation

1. Hold prosthetic finger with fingernail facing up and push one end of band through side opening in between the link bar and the middle segment.
2. Loop outside end over hook; hold in place with thumb.
3. Use hook tool to pull band through opposite side (passing through the opposite side opening); stretch over opposite hook.
4. Ensure band ends are fully seated on the posts, stretched equally, and the band lies flat.

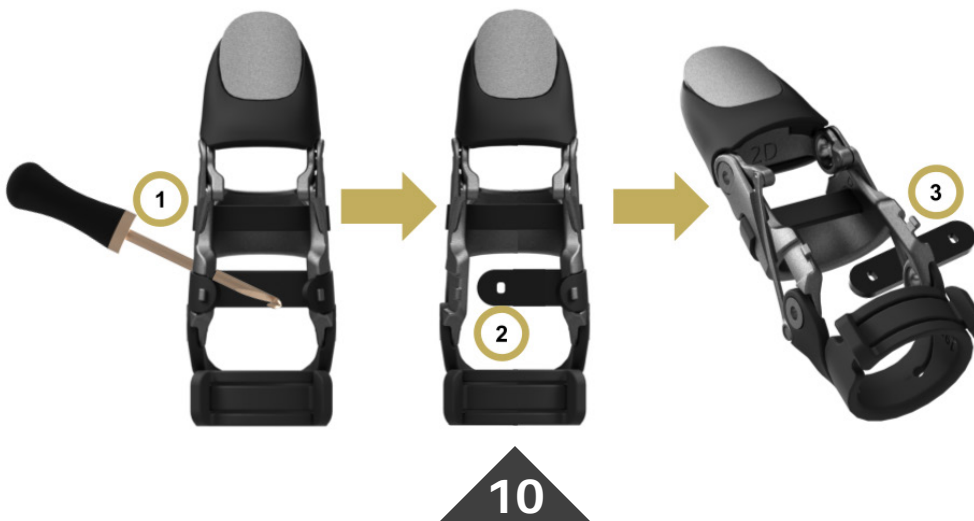


Removal

The device can be used without the proximal band and only with the distal band, if desired.

If damaged: Simply cut, grab each side, and remove from the hook. Otherwise:

1. Hook elastic band inside opening on one post.
2. Pull band off of first post.
3. Pull band through prosthetic finger and off opposite hook.



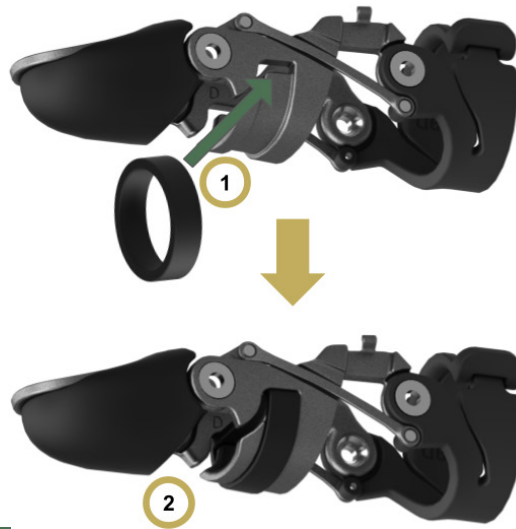
DISTAL ELASTIC BAND

Installation

1. Press one side of band into groove until fully seated.
2. Using fingers or hook tool, stretch band across prosthetic finger and press into opposite groove.
3. Ensure band is fully seated in both grooves and lies flat.



For smaller fingers, the band will have a bulge on the dorsal aspect. This is normal and allows the residuum to slide under it more easily.



Removal

The device can be used without the distal band and only with the proximal band, if desired.

1. Using fingers or hook tool, pull or push band out of grooves.

Safety and Warnings



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



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



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



WARNING: The *Merge MID* contains ferrous materials, and can therefore interact with magnetic fields. Care should be taken when using a *Merge MID* around magnets, such as MRI machines.



WARNING: The *Merge MID* contains moving parts which present a minor pinching hazard. The user should take care to keep loose skin, clothing, etc. away from the moving parts of the *Merge MID*.



WARNING: Any unauthorized modification to a *Merge MID* 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 *Merge MID* can safely support 60 N (13.5 lbf).



WARNING: Remove the *Merge MID* before heavy or strenuous activities, such as forceful lifting, pushing, or pulling.

Warnings in this section are residual risks associated with use of the *Merge MID*. The warnings listed here are specifically for the *Merge MID* and related components.



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

- Point Designs at support@pointdesigns.com
- FDA via MAUDE (for cases in the US)
- Competent Authority of the Member State in which they are established in EU/EEA (for cases in the EU/EEA)

Annex I

DESCRIPTION OF SYMBOLS FROM PRODUCT LABEL

REF	CATALOG/PART NUMBER		MANUFACTURER
EC REP	EU AUTHORIZED REPRESENTATIVE	MD	MEDICAL DEVICE
	DATE OF MANUFACTURE	SN	SERIAL NUMBER
	REFER TO INSTRUCTIONS FOR USE	CE	CE MARK
LOT	LOT NUMBER/BATCH CODE		CAUTION
UDI	UNIQUE DEVICE IDENTIFICATION		SINGLE USE DEVICE



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