



GripLock Finger[®]

Instructions For Use
Class 1 Prosthetic Device

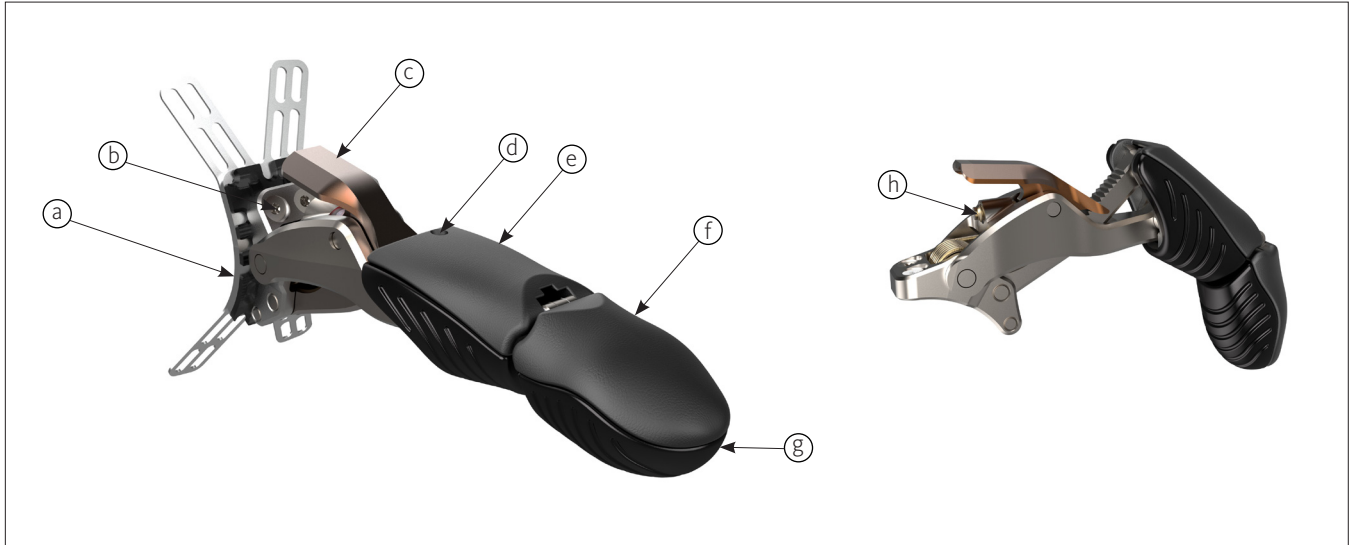
PPF101 | Gen 3

Manufacturer	Authorized Representative		
 <p>Naked Prosthetics 408 Olympia Ave NE Olympia, WA 98501 USA +1 (888) 977-6693 Manufactured in the USA</p>	<table border="1"><tr><td data-bbox="553 1854 675 1948">EC</td><td data-bbox="675 1854 797 1948">REP</td></tr></table> <p>EMERGO EUROPE Westervoortsediik 60 6827 AT Arnhem The Netherlands</p>	EC	REP
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Medical Device

Figure 1



LIST OF PARTS

- | | | | |
|-----------------------------|-----------------------------|---------------|-----------------------------|
| a. Anchor Subbase Assembly | c. Pawl | e. P2 Fairing | g. Silicone Tip Pad |
| b. Anchor Attachment Screws | d. Fairing Attachment Screw | f. Device Tip | h. Ball-Nose Spring Plunger |

Figures 2 -5

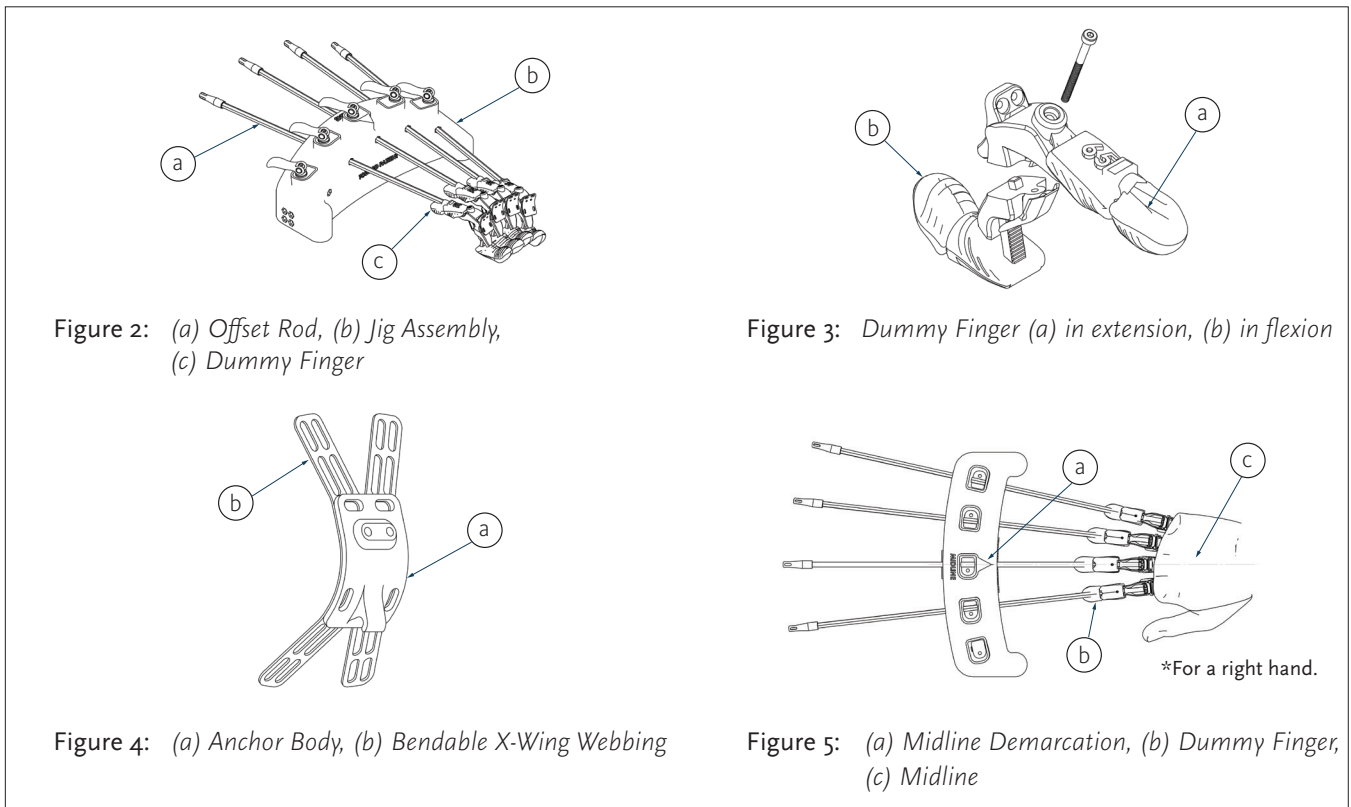


Figure 2: (a) Offset Rod, (b) Jig Assembly, (c) Dummy Finger

Figure 3: Dummy Finger (a) in extension, (b) in flexion

Figure 4: (a) Anchor Body, (b) Bendable X-Wing Webbing

Figure 5: (a) Midline Demarcation, (b) Dummy Finger, (c) Midline

Figures 6 - 10

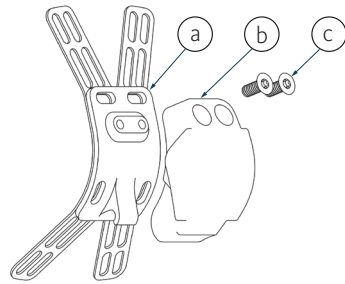


Figure 6: (a) Anchor, (b) Lamination Dummy, (c) T6 Torx Head Screws

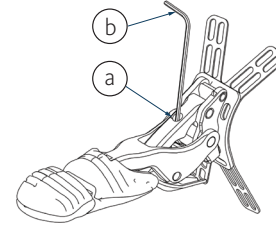


Figure 7: (a) Adjustable Flexion Release Screw, (b) 0.89mm Hex Wrench

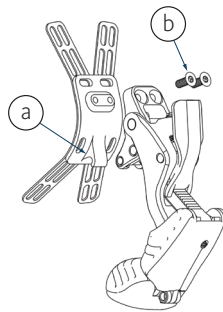


Figure 8: (a) Anchor Hook, (b) T6 Torx Head Screw

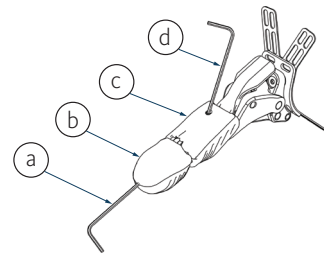


Figure 9: (a) 1.5 mm Hex Wrench, (b) Device Tip, (c) P2 Fairing, (d) 0.89 mm Hex Wrench

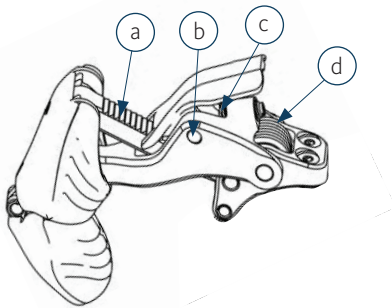


Figure 10: (a) Teeth, (b) Pawl Hinge, (c) Pawl Interface, (d) Spring

PRODUCT DESCRIPTION

The **GripLock Finger** works as a positionable, locking, mechanical finger via a ratcheting element. Once flexed, there are two methods of returning it to its extended position: (1) by depressing the Pawl (**Figure 1c**) located at the dorsal side of the **GripLock Finger** or (2) by fully flexing the **GripLock Finger** until the flexion release point is reached, and then allowing it to release.

Indications for Use

The **GripLock Finger** is designed for use with metacarpophalangeal disarticulations or transmetacarpal amputations, ray resections, or comparable congenital presentations.

Intended Use

The **GripLock Finger** is a passive, locking, mechanical prosthesis for patients with partial-hand limb difference. The **GripLock Finger** intended to be used as part of a prosthetic system, fabricated and fit by a certified prosthetist.

Contraindications for Use

The anatomical area where the socket comes into contact with the skin must be properly healed before using device. Do not use device if open wounds or lesions are present.

Alignment and Adjustment

GripLock Fingers are designed for use in conjunction with a partial-hand socket. Considerations should be given to prosthetic fitting factors which include, but are not limited to, skin/socket interface, material selection, suspension type, and donning/doffing methods.

There are size indicators displayed on the Silicon and Tip Fairings. Use the Jig Assembly (*Figure 2b*) to align each Dummy Finger (*Figure 2c*) on to the test socket. The Dummy Fingers show the full locking position of the **GripLock Finger** in both flexion and extension (*Figure 3*). To use, attach the provided Anchor Body (*Figure 4a*) using the T6 Torx Head Screws to each applicable Dummy Finger. Next, attach each Dummy Finger to the Offset Rods (*Figure 2a*) using the magnetic connection. Identify the Midline Demarcation (*Figure 5a*) on the Jig Assembly and use this to establish midline (*Figure 5c*) of the hand.

As a general rule, midline is located approximately in line with the third metacarpal. Slide the Offset Rods toward or away from the hand until you have achieved the most appropriate transverse metacarpal arch. Suggested placement of the **GripLock Fingers** is in a comfortable neutral position while ensuring no collision with the palm in full flexion to allow for the device to reset into full extension position. If **GripLock Finger** is installed next to a **PIPDriver**®, **MCPDriver**®, and/or **ThumbDriver**®, ensure the digits do not collide at end range flexion.

Once proper finger alignment is achieved, use the Bendable X-Wing Webbing (*Figure 4b*) to match the contour of the socket and attach to the socket using epoxy or alternative adhesives. Before final lamination, remove the Dummy Finger and install the Lamination Dummy (*Figure 6b*) to protect the Anchor Body. Once the resin has cured, remove the Lamination Dummy and discard.

NOTE: The X-Wings are not intended for the sole strength of the final product. The holes in the anchor body must be fully encapsulated in the lamination to achieve full strength of the system.

Once the socket fabrication is completed, slide the **GripLock Finger** into the embedded Anchor Body to engage the Anchor Hook (*Figure 8a*). Flex the device to expose attachment screw locations and install with T6 Torx Head Screws (*Figure 8b*).

Check function by flexing and releasing the **GripLock Finger** through its full range of motion. It is important to ensure that the **GripLock Finger** does not collide with the palm while fully flexed and that it releases into extension at the end range. If the end range flexion needs to be altered, this can be done by adjusting Adjustable Flexion Release Screw (*Figure 7a*).

Usage Recommendations

- Occupational or physical therapy is highly recommended to optimize functional use after receiving this device.
- Follow a healthcare provider's direction regarding length of time and use, particularly during the adoption phase.

Caution

- For device wearers with sensitive skin conditions, use the **GripLock Finger** as recommended by a healthcare provider.
- If redness appears on the skin, decrease usage of the device until skin status returns to normal.
- If redness persists or discomfort arises, stop usage of the device immediately and contact a healthcare provider.
- Any concerns over fit or function should be addressed by a prosthetist.

Serious incidents should be reported to Naked Prosthetics and appropriate government authorities in which the device wearer is established.

WARNING: Do not use device in environments or situations that would cause harm to a natural hand.

Included With The Device

- (1) Anchor Assembly for alignment
- (1) Anchor Assembly for final lamination
- (1) Corresponding Dummy Finger per size
- (1) Torx 6-Wing Driver
- (1) 0.89mm Hex Wrench
- (1) 1.5mm Hex Wrench

Device Maintenance

- The **GripLock Finger** is waterproof; dirt, chemical and heat resistant.
- Working regularly with degreasers may strip lubrication from hinges. If necessary, apply a food-safe mineral oil to the hinge locations (**Figure 1o**).
- Contact your Prosthetist to facilitate servicing or replacement components.

Replacement Components Available Separately:

- Device Tip
- P2 Fairing

Instructions:

- To replace the Device Tip, use a 1.5mm Hex Wrench. Access the screw through the hidden port between the Silicone Tip Pad and Device Tip at the tip leading-edge line (*Figures 9a and 9b*).
- To replace the P2 Fairing use a 0.89 mm Hex Wrench. Access the screw through on the dorsal side of the finger (*Figures 9c and 9d*).
- After replacement, tighten carefully into the Nylon threads while checking flexion for stiffness.

NOTE: *For safety reasons, hinges should only be disassembled by the device manufacturer.*

WARNING: *Do not make adjustments to the Ball-Nose Spring Plunger (Figure 1h). Do not modify device in any way or attempt maintenance other than intended by the manufacturer. Unintended modifications or maintenance may cause device failure.*

Care & Cleaning

- Prolonged exposure to strong solvents and degreasers may damage surfaces and remove hinge lubrication. If necessary, apply a food-safe mineral oil to the hinge locations.
- Rinse with fresh water after exposure to salt water.
- Clean device with warm water and mild detergent as necessary; pat- or air-dry.
- Scrub dirt or grime using a soft bristle brush, remove dust with compressed air if necessary.
- Do **NOT** machine wash; Do **NOT** place in dryer.

Warranty

Naked Prosthetics includes a standard 2-year warranty (from ship date) on the mechanical function of the **GripLock Finger**. Please contact Naked Prosthetics for additional, extended warranty options.

Change in Performance

In the event of change in performance of a device, always cease using device and contact your clinic.



Warning: Do not use device if contact between device and patient's skin is causing pain, excessive abrasion, or bleeding.

Report of Serious Incident

Any serious incident in relation to the device must be reported to the manufacturer and relevant authorities.

Liability

For socket-related concerns, please contact a prothetist. Naked Prosthetics does not assume liability for the following:

- Device not maintained as instructed by the instructions for use.
- Device disassembled or amended with components from other manufacturers.
- Device used outside of recommended use condition, application, or environment.

PRODUCT TECHNICAL SPECIFICATIONS

Materials

- Nylon
- Silicone
- Stainless Steel
- Anodized Aluminum

Chemical Resistance

- Bleach
- Ammonia
- Acetone
- Rubbing Alcohol (Isopropanol)
- Gasoline
- Antifreeze
- Ethanol

Operational Temperature

- 0 – 120° F (-17 – 48° C)

Load Capacity

- 215 lbs. (~97 kg)

Expected Service Life

3 years (300,000 cycles with regular oiling using a food-safe mineral oil)

Force Output

The **GripLock Finger** is a passive-locking and positionable prosthetic finger, designed to be laminated into a custom, partial-hand socket. It is an off-the-shelf product available in six lengths. It is designed to support up to 215 lbs. in hook grasp.

Silicone

Silicone will absorb gasoline or diesel if exposed and will experience a volume change. It will return to a normal shape if cleaned after exposure.

For more information: visit npdevices.com