

MCPDriver™

Instruction for Use
Body-driven, Class 1 Prosthetic Device
BPF 202 | Second Generation

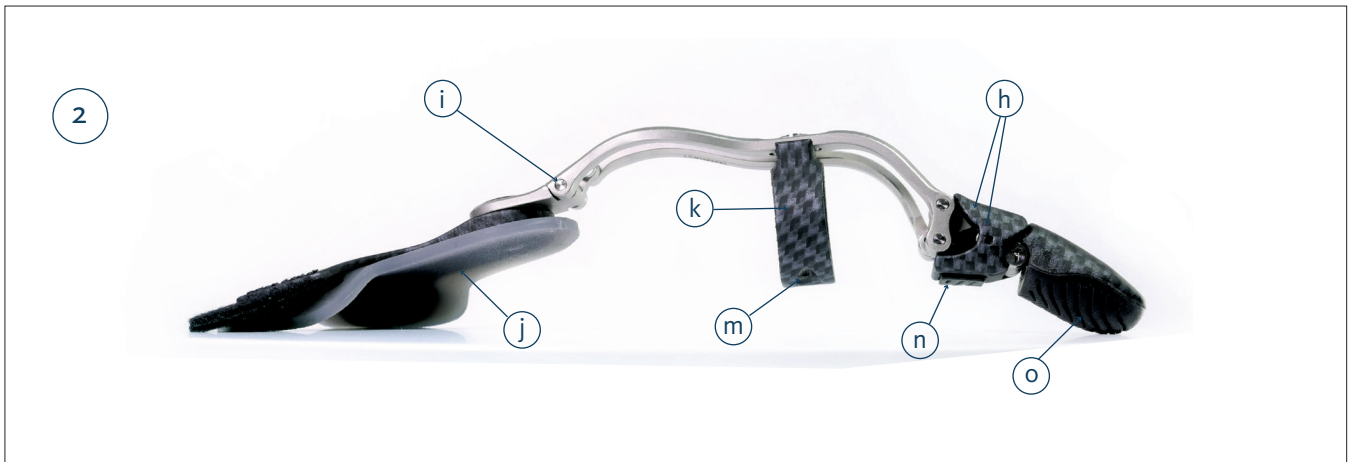
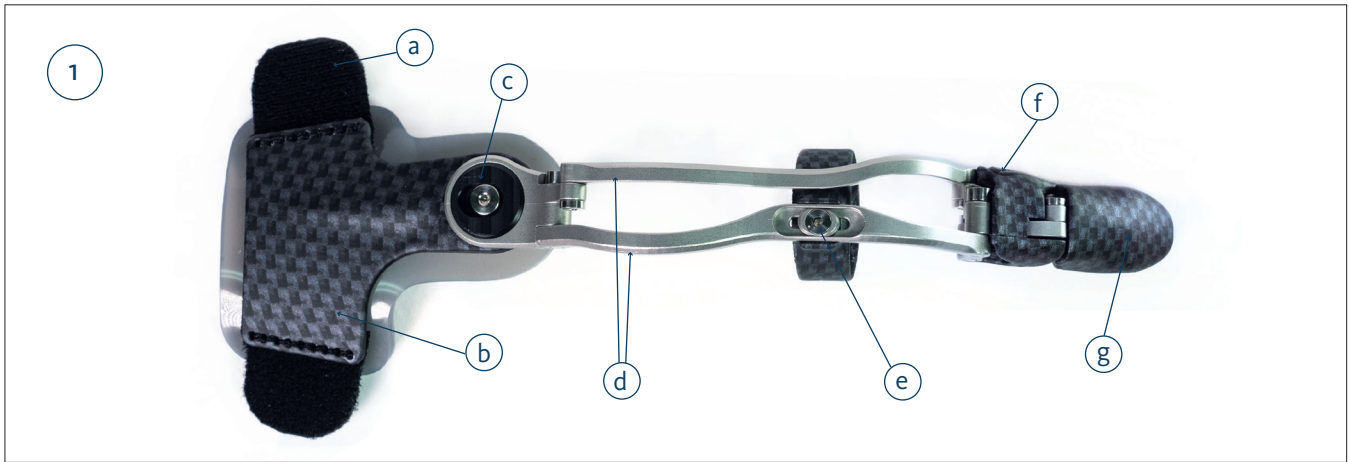


Manufacturer	Authorized Representative		
 <p>Naked Prosthetics 408 Olympia Ave NE Olympia, WA 98501 USA +1 (360) 915-9724 Manufactured in the USA</p>	<table border="1"><tr><td data-bbox="558 1850 678 1946">EC</td><td data-bbox="678 1850 805 1946">REP</td></tr></table> <p>EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands</p>	EC	REP
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ENGLISH



Medical Device



LIST OF PARTS

- | | |
|-------------------------------|------------------------------|
| a. Strap Attachments | h. P2 Fairing |
| b. Custom Backplate | i. Hinge Joint |
| c. Abduction/Adduction Washer | j. Dorsal Silicone Interface |
| d. Custom Metal Linkages | k. Suspension Ring |
| e. Ring Adjustments Screw | m. Ring Shim Hole |
| f. P2 Lateral Pad | n. Silicone Pad |
| g. Device Tip | o. Silicone Tip |

PRODUCT DESCRIPTION

The MCPDriver is a body-driven mechanical prosthesis that aims to restore hand function to patients with partial finger amputations. Restoring dexterity, power, and length of the affected finger, it also follows the natural abduction of the finger, helps to protect the amputation site, and resists hyperextension in the digit. The MCPDriver makes use of the user’s residual digit strength and motion to articulate two artificial distal phalanges for the restoration of a functional finger.

Device Application

1. Open the MCP Backplate strap and place the device on the affected hand and finger.
 - Align the hinge joint (*item i*) directly above or slightly behind the MCP joint (*knuckle*).
 - The abduction/adduction washer (*item c*) should be ½” – ¾” behind (i.e. closer to the wrist) the center of the anatomic MCP joint.
2. Place the installed suspension ring (*item k*) on the residual finger and check initial fit.
 - Suspension ring should fit loosely, allowing the ring to slide along the residual finger during flexion and extension.
 - Shorter residual fingers may benefit from a snugger fit or silicone shim to help capture range of motion.
 - NOTE: *The suspension ring should never “choke” the residual finger.*
3. Fasten the strap at the base of the hand.
 - This should fit closer to the fingers than a watch strap would sit.

* NOTE: *if you experience periodic volume changes, you may add or remove the shims or change your ring size as necessary.*

Usage Recommendations

- When using the MCPDriver, it is recommended to gradually build up to full-time use. This will help prevent overuse injuries in muscles that may have been underutilized until this point.
- Occupational, rehabilitation, or hand therapy is recommended after receiving your device for muscle strengthening and optimal function of the device.

Caution

- For patients with sensitivity, it is recommended to use the MCPDriver as tolerated.
- If redness appears on your skin, decrease usage of your device.
- If redness persists or discomfort arises, stop usage of the device immediately and contact your Prosthetist.

***IMPORTANT NOTE:** *No part of the metal should ever be impinging on your skin, nor should the device be crashing into the end of your limb at any point – if either occurs, stop usage of the device immediately and contact your Prosthetist.*

Serious incidents should be reported to Naked Prosthetics and appropriate government authorities in which the user and/or patient is established.

Device Maintenance

- The MCPDriver is waterproof, dirt, chemical and heat resistant, and built for use.
- Working regularly with degreasers may strip lubrication from hinges. If necessary, apply a food-safe light mineral oil to the hinge locations.
- Contact your Prosthetist to facilitate servicing or replacement components.

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

Care & Cleaning

- Prolonged exposure to strong solvents may damage painted surfaces and remove hinge lubrication.
- Rinse with fresh water after use in salt water.
- Clean device with warm water and mild detergent as necessary. Pat- or air-dry.
- Clean dirt or grime from the device using an old toothbrush or compressed air if desired.
- **Do NOT machine wash; Do NOT place in dryer.**

* **NOTE:** *Strap components will absorb water and take longer to dry than the rest of the device or system.*

Device Accessories (Included)

In addition to the MCPDriver, the following is included to help optimize the fit of the device:

- Additional wrist strap
 - Suspension ring sized larger than initially sized
 - Suspension ring sized smaller than initially sized
 - Small shim – SM
 - Medium shim – MD
 - Large shim – LG
 - One (1) 1/16" hex key
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Warranty

Naked Prosthetics offers a standard 1-year warranty (from ship date) on the mechanical function of the MCPDriver. Please contact Naked Prosthetics for additional, extended warranty options.

Report of Serious Incident

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

Disposal

The device and packaging must be disposed of in accordance with respective local or national environmental regulations.

Liability

Naked Prosthetics does not assume liability for the following:

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

For more information: visit npdevices.com