


MCPDriver®

Instructions for Use
Body-driven, Class 1 Prosthetic Device
BPF 202 | 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 1850 675 1944">EC</td><td data-bbox="675 1850 797 1944">REP</td></tr></table> <p>EMERGO EUROPE Westervoortsediik 60 6827 AT Arnhem The Netherlands</p>	EC	REP
EC	REP		



Medical Device

Figure 1

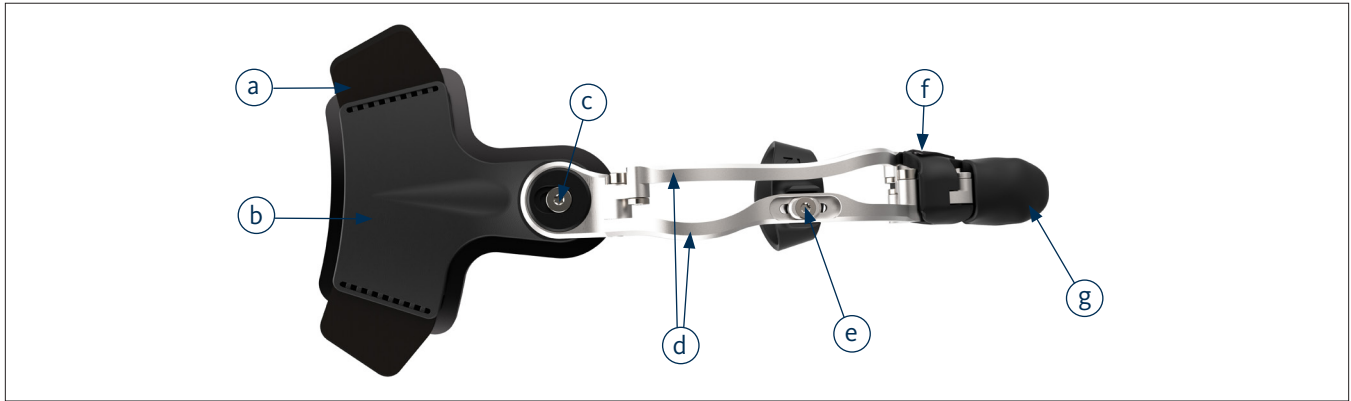
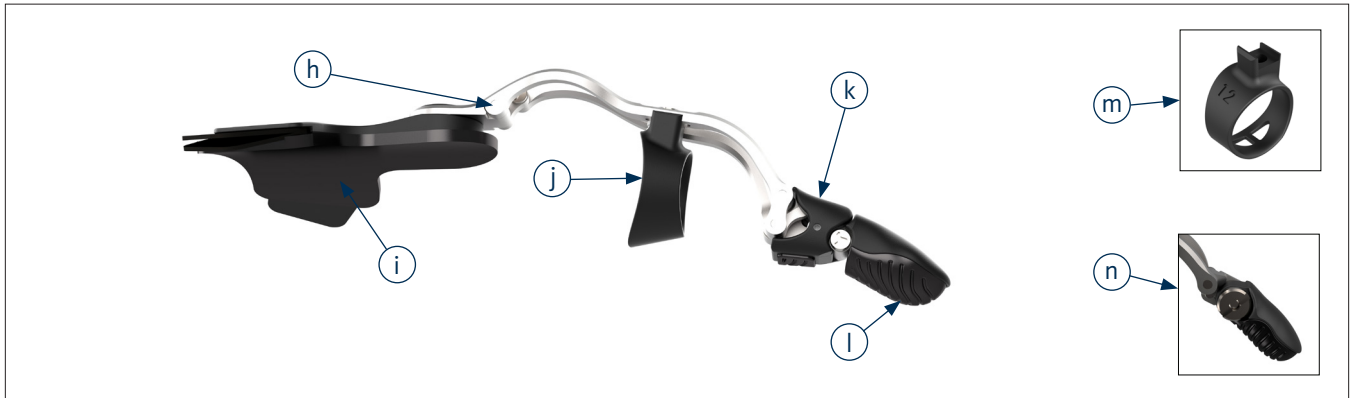


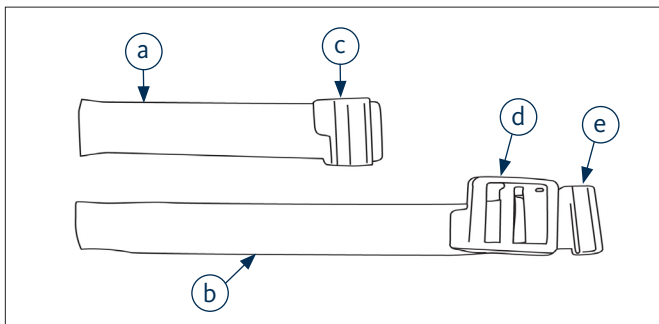
Figure 2



LIST OF PARTS

- | | | |
|-----------------------------------|--------------------|---|
| a. Wrist Alligator Tabs | f. P2 Silicone Pad | k. P2 Fairing * |
| b. Backplate | g. Device Tip | l. Silicone Tip Pad |
| c. Abduction/Adduction Screw | h. Hinge Joint | m. Shim Holes (optional) |
| d. Metal Linkages | i. Backplate Pad | n. Single Articulating Tip (optional) |
| e. Ring Adjustment Screw & Slider | j. Suspension Ring | * not present in Single Articulating Tips |

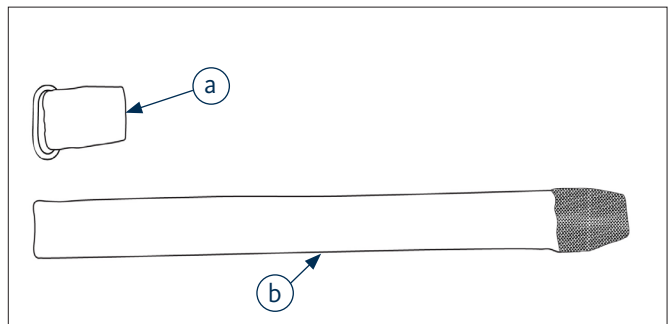
Figure 3 | Click Strap:



Click Strap Parts

- | | |
|----------------|------------------------|
| a. Clasp Strap | d. Cinch Plate |
| b. Cinch Strap | e. Strap Retainer Clip |
| c. Clasp Plate | |

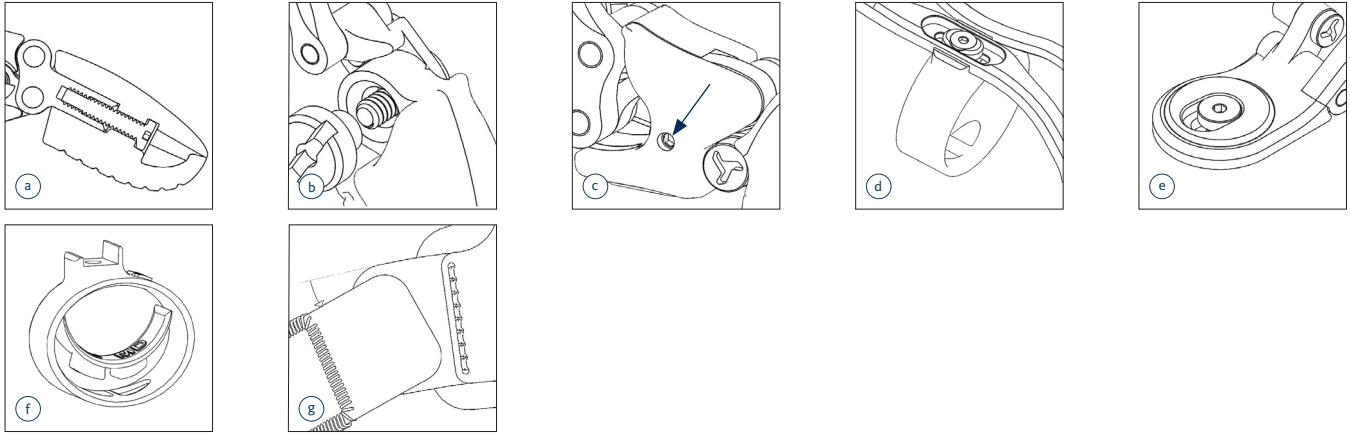
Figure 4 | Classic Strap:



Classic Strap Parts

- | |
|-----------------|
| a. Wrist O-Ring |
| b. Wrist Strap |

Figure 5 | Components Adjustable by a Certified Prosthetist



PRODUCT DESCRIPTION

The device is a body-driven mechanical prosthesis made of titanium linkages, a nylon backplate and finger fairings with a silicone interface. It is anchored to the dorsal surface of the hand and is attached with a wrist strap and nylon ring on the residual finger(s).

Indications for Use

The **MCPDriver** is designed for a partial-finger limb difference distal to the metacarpophalangeal (MCP) joint when there is digit length to engage the Suspension Ring (*Figure 2j*). The **MCPDriver** is designed to be used in conjunction with a provided Backplate system or a custom socket fabricated by a Certified Prosthetist. **MCPDrivers** with Single Articulating Tip (SAT) design are used to compensate for excess digit length or limited range of motion at the MCP joint.

Intended Use

The device is a prosthesis that aims to restore hand function to patients with partial-finger limb difference. The device is intended to be fit by a certified prosthetist.

Contraindications for Use

The residual digit must be properly healed before using device. Do not use device if open wounds or lesions are present.

Device Application

1. Place the device on the hand by adding the ring to the appropriate finger(s) and positioning the backplate on the back of hand.
 - Align the Hinge Joint (*Figure 2h*) directly above, or slightly proximal to the MCP joint of the patient's hand.
 - The Abduction/Adduction Screw (*Figure 1c*) should be $\frac{1}{2}$ " – $\frac{3}{4}$ " proximal to the center of the MCP joint.
2. Check articulation of device.
 - The Suspension Ring (*Figure 2j*) should fit loosely, allowing the ring to slide along the digit(s) during active range of motion.
 - Shorter residual fingers may benefit from a smaller sized ring or silicone shim to help capture range of motion.
 - The suspension ring should never bind on the tissue of the treated digit.
 - If volume change is experienced, use shims to achieve optimal fit.
3. Select appropriate strap option for the wearer.
 - Determine length of strap required by measuring the wrist circumference between the alligator tabs
 - Position the Clasp Plate (*Figure 3c*) or O-Ring (*Figure 4a*) at a comfortable position on the wrist and trim ends of the strap to length. Ensure to only cut the loose ends of the straps. The classic strap O-Ring can be positioned on either side for ease of donning.
 - Re-install the strap into the alligator tabs (*Figure 1a*).
 - For Click Strap Only: Determine a comfortable position for the Strap Retainer Clip (*Figure 3e*). if you need to remove length, do not the cut the retainer clip but remove excess length from the loose end.

Device Application (Continuation)

4. Fasten the strap at the base of the hand.
 - The strap should be distal to the wrist crease in a position which does not block wrist motion.
 - If the **MCPDriver** migrates proximally or significantly impedes wrist extension, reposition the backplate distally on the dorsum of the hand and reattach the strap at an angled or offset position (*Figure 5g*).
5. (For MCPDrivers with an SAT "4 only)
 - Adjust the tip angle. A flexed tip may be used for smaller items or to compensate for lack of range of motion.

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 **MCPDriver** 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 regarding fit or function should be addressed by a prosthetist.

IMPORTANT NOTE: *No part of the metal should touch or cause pressure on the skin of the hand or digit, nor should the device make contact with the distal end of the residual digit at any position – if either occurs, immediately stop usage of the device and contact 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

- Additional Wrist Strap and Palmar Strap (if requested)
- Alternative Suspension Ring Sizes
- Silicone Shims (Small, Medium, and Large)
- (1) Torx 8-Wing Driver
- (1) .050" Hex Wrench

Device Maintenance

- The **MCPDriver** is water-, 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.
- Contact your prosthetist to facilitate servicing or replacement components.

Replacement Components Available Separately:

- Device Tip
- Strap
- P2 Fairing
- Suspension Ring

Instructions:

- To replace the Device Tip, use a 0.050" Hex Wrench. Access the screw through the hidden port between the Silicone Tip Pad and Device Tip at the tip leading-edge centerline (*Figure 5a*).
- To replace **MCPDrivers** with an SAT design, use a flat-head screw driver to loosen and remove the knurled nut. Remove and replace the tip. Re-tighten the new Device Tip until the teeth embed into the plastic (*Figure 5b*).
- To replace the P2 Fairing, use a 0.050" Hex Wrench. Access the screw through the side port (*Figure 5c*).
CAUTION: Do not over-tighten. Doing so will increase stiffness of the device.
- Rings and Backplates can be replaced using a Torx 8-Wing Driver (*Figures 5d and 5e*).
- Shims can be added or removed by inserting them into or pulling them out of the shim holes (*Figure 5f*).
- Straps can be replaced by attaching the new strap to the Wrist Alligator Tabs using the Velcro closure (*Figure 5g*).

Device Maintenance (Continuation)

NOTE: LOCTITE® 243 should be applied each time the ring adjustment and abduction/adduction screws are removed. Ensure that the Loctite has appropriate setting time each use (*Figures 5d and 5e*); refer to Loctite usage instructions.

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

WARNING: *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.
- 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.

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

Warranty

Naked Prosthetics includes a standard 2-year warranty (from ship date) on the mechanical function of the **MCPDriver**. 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

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
- Titanium

Chemical Resistance

- Bleach
- Ammonia
- Acetone
- Rubbing Alcohol (Isopropanol)

Operational Temperature

- 0 – 120° F (-17 – 48° C)

Expected Service Life

- 3 years

Force Output

The **MCPDriver** is designed such that any force the patient can generate at the MCP joint can be transmitted by the devices. Force output is dependent on the patient's strength.

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