



# ThumbDriver®

Instructions For Use  
Body-driven, Class 1 Prosthetic Device

BPF203 | 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><b>EMERGO EUROPE</b> Westervoortsediik 60 6827 AT Arnhem The Netherlands</p>	EC	REP
EC	REP		



Medical Device

Figure 1

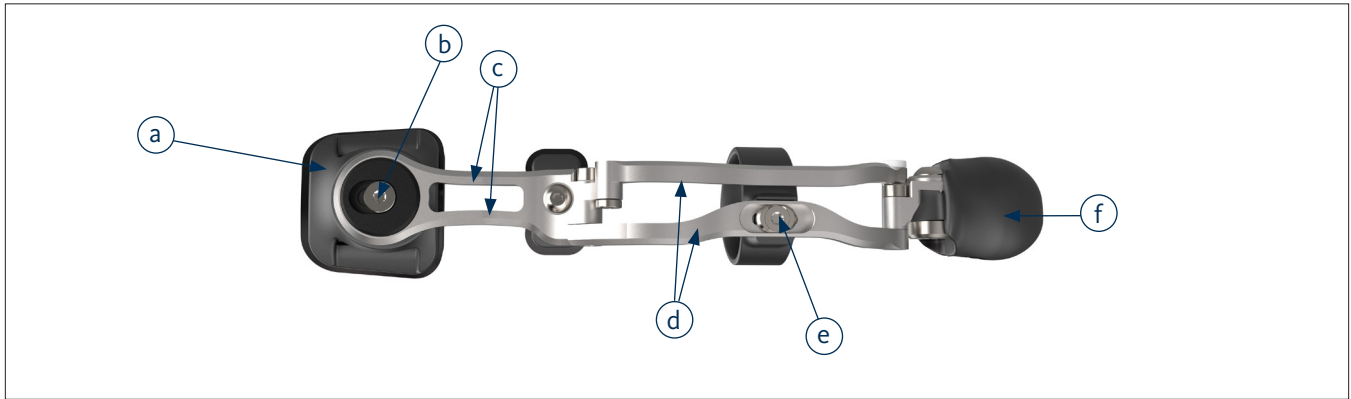
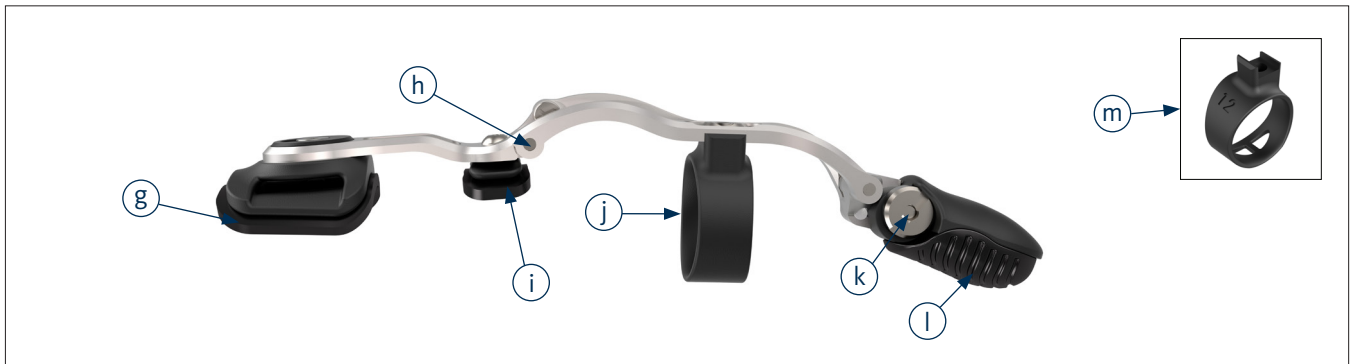


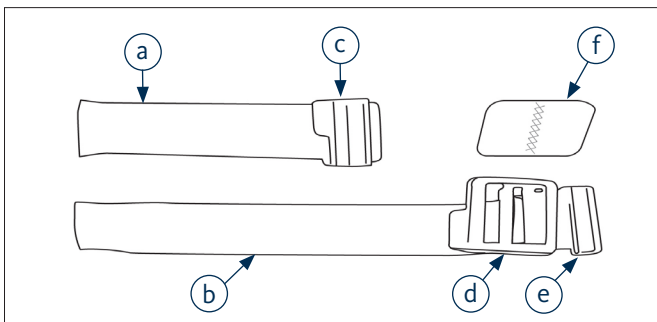
Figure 2



**LIST OF PARTS**

- |                                   |                     |                               |
|-----------------------------------|---------------------|-------------------------------|
| a. Anchor Plate                   | f. Device Tip       | k. Tip Angle Adjustment Screw |
| b. Abduction/Adduction Screw      | g. Anchor Plate Pad | l. Silicone Tip Pad           |
| c. Thumb Anchor                   | h. Hinge Joint      | m. Shim Holes (optional)      |
| d. Metal Linkages                 | i. Knuckle Pad      |                               |
| e. Ring Adjustment Screw & Slider | j. Suspension Ring  |                               |

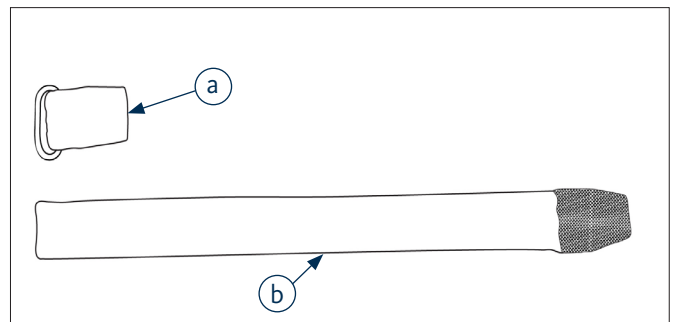
Figure 3 | Click Strap:



**Click Strap Parts**

- |                |                         |
|----------------|-------------------------|
| a. Clasp Strap | d. Cinch Plate          |
| b. Cinch Strap | e. Strap Retainer Clip  |
| c. Clasp Plate | f. Dual-Ended Alligator |

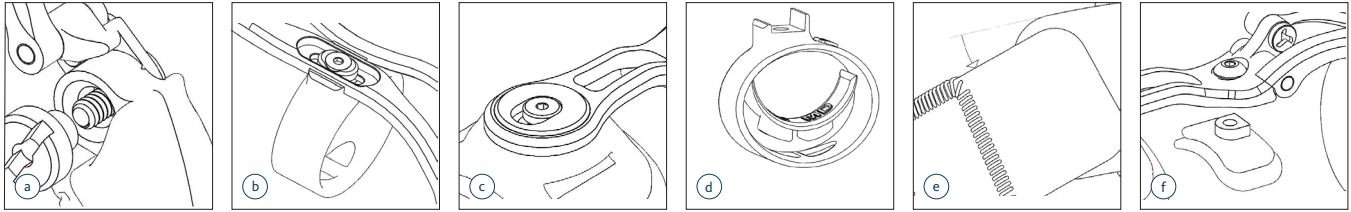
Figure 4 | Classic Strap:



**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). The device allows for user adjustment of thumb tip flexion or extension.

## Indications for Use

The **ThumbDriver** is designed for a partial-finger limb difference distal at the MP joint or phalanges of the thumb when there is digit length to engage the Suspension Ring (*Figure 2j*) and motion at the CMC joint. The **ThumbDriver** is driven off two joints: the metacarpophalangeal (MP) and the carpometacarpal (CMC) joints of the thumb.

**NOTE:** *The device will only achieve active articulation if the MP joint is intact and functional. However, the device will provide most of its functional opposition via CMC tracking, therefore full ROM at the MP joint is not required for successful device fitting.*

## 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 thumb.**
  - Align the Hinge Joint (*Figure 2h*) directly above or slightly proximal to the MCP joint.
  - Align the Anchor Plate (*Figure 1a*) directly above the intact CMC joint.
2. **Check articulation of device.**
  - The Suspension Ring (*Figure 2j*) should fit loosely, allowing the ring to slide along the thumb during active range of motion.
  - Shorter residual thumbs 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 accounting for the anchor plate.
  - Position the Clasp Plate (*Figure 3c*) or O-Ring (*Figure 4a*) at a comfortable position on the wrist. Remove the Dual-Ended Alligator Tab and trim the loose ends as required.
  - Re-install the strap into the Dual-Ended Alligator (*Figure 3f*).
  - For Click Strap Only: Determine a comfortable position for the Strap Retainer Clip (*Figure 3e*). If you need to remove length, do not cut the retainer clip but remove excess length from the loose end.
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 **ThumbDriver** migrates proximally or significantly impedes wrist extension, reposition the Anchor Plate distally on the dorsum of the hand and reattach the strap at an angled or offset position.

## 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 **ThumbDriver** as recommended by a healthcare provider.
- If redness appears on the skin, decrease usage of the device until skin status returns to normal.
- If there is persistent redness or discomfort, 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
- Alternative Suspension Ring Sizes
- Silicone Shims (Small, Medium, and Large)
- (1) Torx 8-Wing Driver
- (1) .050" Hex Wrench

## Device Maintenance

- The **ThumbDriver** 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
- Twisted Tip (optional)
- Knuckle Pad
- Suspension Ring

## Instructions:

- To replace the Device Tip, use a flat-head screw driver to loosen and remove the Tip Angle Adjustment Screw. Remove and replace the tip. Re-tighten the new Device Tip until the teeth embed into the plastic (*Figure 3a*).  
**CAUTION: Do not over-tighten.**
- Rings, Anchor Plates, and Knuckle Pads can be replaced using a torx 8-wing driver (*Figures 3b, 3c, and 3f*).
- Shims can be added or removed by inserting them into or pulling them out of the shim holes (*Figure 3d*).
- Straps can be replaced by attaching new strap to the Wrist Alligator Tabs using the Velcro closure (*Figure 3e*).

**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 3b and 3c); 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 **ThumbDriver**. 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.

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## PRODUCT TECHNICAL SPECIFICATIONS

### Materials

- Nylon
- Silicone
- Stainless Steel
- Titanium

### Chemical Resistance

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

### Operational Temperature

- 0 – 120° F (-17 – 48° C)

### Expected Service Life

- 3 years

## Force Output

The **ThumbDriver** is designed such that any force the patient can generate at the MP and/or CMC 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](http://npdevices.com)