

ThumbDriver™

Instructions For Use
Body-driven, Class 1 Prosthetic Device
BPF203 | Second Generation

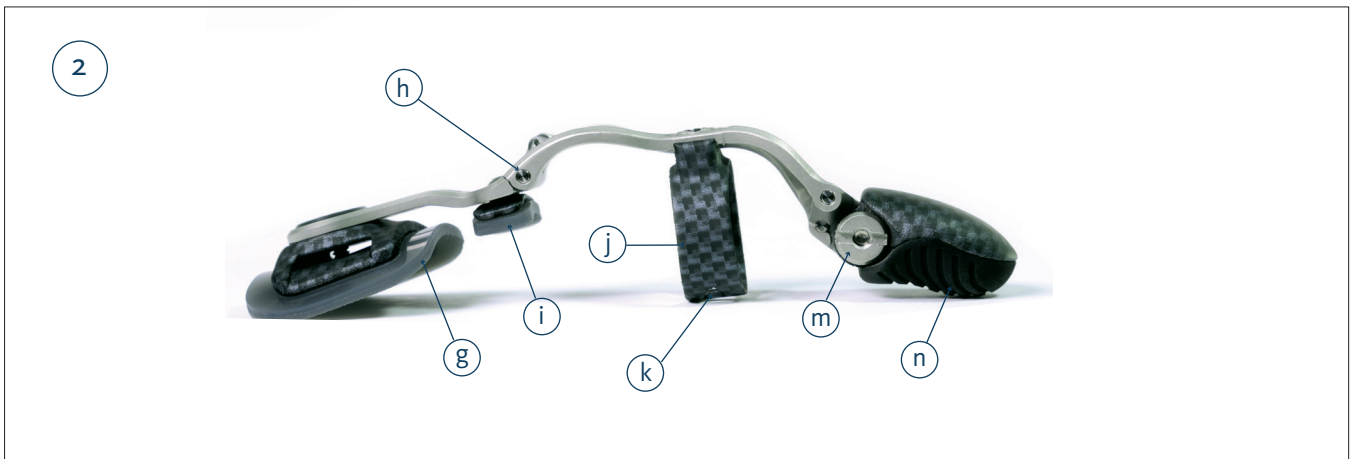
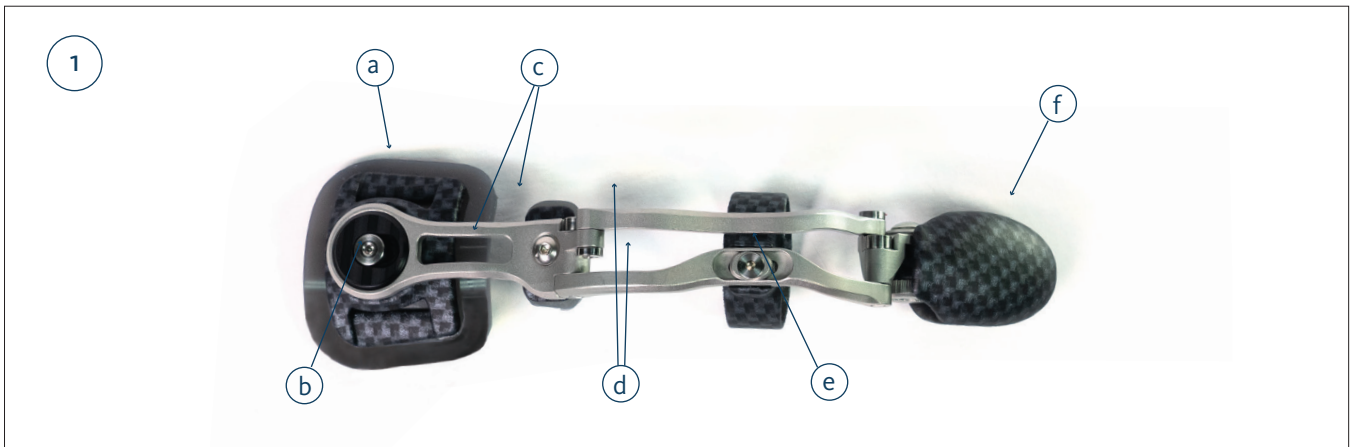


Manufacturer	Authorized Representative		
 <p>Naked Prosthetics 408 Olympia Ave NE Olympia, WA 98501 USA +1 (360) 915-9724 Manufactured in the USA</p>	<table border="1"><tr><td data-bbox="558 1850 680 1946">EC</td><td data-bbox="680 1850 802 1946">REP</td></tr></table> <p>EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands</p>	EC	REP
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ENGLISH



Medical Device



LIST OF PARTS

- | | |
|-------------------------------|-------------------------------|
| a. Anchor Plate | h. Hinge Joint |
| b. Abduction/Adduction Washer | i. Metacarpal Knuckle Pad |
| c. Thumb Anchor | j. Suspension Ring |
| d. Custom Metal Linkages | k. Ring Shim Hole |
| e. Ring Adjustment Screw | m. Tip Angle Adjustment Screw |
| f. Device Tip | n. Silicone Tip |
| g. Dorsal Silicone Interface | |

PRODUCT DESCRIPTION

The ThumbDriver is a body-driven mechanical prosthesis that aims to restore hand function to patients with partial thumb amputations. Restoring dexterity, power, and length of the affected thumb, it also tracks with the natural motion of the thumb, helps to protect the amputation site, and resists hyperextension in the digit. The ThumbDriver makes use of the user's residual digit strength and motion to articulate an artificial distal phalanx and provide robust opposition for the restoration of a functional thumb.

Device Application

1. **Open the ThumbDriver strap and place the device on the affected hand and thumb.**
 - Align the anchor plate (*item a*) directly above the intact CMC joint.
 - Align the hinge joint (*item h*) directly above or slightly behind the MCP joint (knuckle).
2. **Place the installed suspension ring (*item j*) on residual thumb and check initial fit.**
 - Suspension ring should fit loosely, allowing the ring to slide along the residual thumb during flexion and extension.
 - Shorter residual thumbs may benefit for 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 change, you may add or remove the shims or change your ring size as necessary.*

Usage Recommendations

- The tip pre-flex angle may be adjusted per your needs. To do this, use a flat-head screwdriver or coin to loosen the tip angle adjustment screw (*item m*) and adjust to desired angle. Re-tighten until the teeth embed into the plastic.
- When using the ThumbDriver 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 ThumbDriver 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 ThumbDriver 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.
- 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 ThumbDriver, 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 ThumbDriver. 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