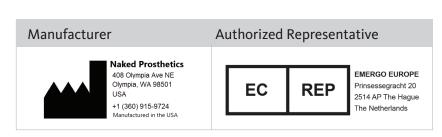


PIPDriver...

Instruction for Use Body-driven, Class 1 Prosthetic Device BPF 201 | Second Generation





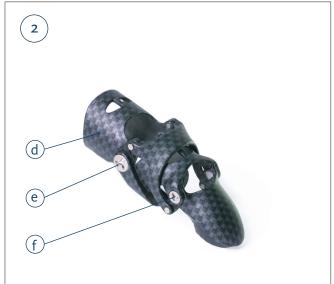
ENGLISH















LIST OF PARTS

- a. Nail Style (Organic pictured)
- **b.** Dorsal Cage Shim Hole
- c. Dorsal Ring Shim Hole
- d. Ring
- e. Large Fastener
- f. Small Fastener

- g. Silicone Tip
- h. Tendon
- i. Palmar Cage Shim Hole
- j. Palmar Ring Shim Hole
- k. Cage (Dorsal and Palmer)



PRODUCT DESCRIPTION

The PIPDriver is a body-driven mechanical prosthesis that aims to restore hand function to patients with partial finger amputations. Each device is customized for a specific patient's size, length, and range of motion. Restoring dexterity, power, and length of the affected finger, it also helps to protect the amputation site, and resists hyperextension in the digit. The PIPDriver... makes use of the user's residual digit strength and motion to articulate an artificial distal phalanx for the restoration of a functional finger.

Device Application

- 1. Place the device on the affected finger. A digit identifying sticker is adhered to the inside of the ring for easy identification.
- 2. Align the large fastener (item e) with or slightly behind the PIP joint (middle knuckle) of the finger
- 3. Check initial fit
 - Ring (item d) should fit intimately like a wedding ring
 - Gently shake your hand upside down to assure the device remains on the finger
 - If the device is loose, install any combination of silicone shims in the four locations (items b, c, i, and j)
 - If gaping around the residual finger is noted, add shims as necessary
- 4. Articulate the device several times, checking for proper flexion and extension
 - If the device does not extend fully, increase shim size in the dorsal cage shim location (item b)

Usage Recommendations

- When using the PIPDriver 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 PIPDriver 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.

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



^{*} NOTE: if you experience periodic volume change, you may add or remove the shims in any location as necessary.



Device Maintenance

- The PIPDriver is designed for minimum maintenance and care.
- The PIPDriver does not require lubrication.
- The PIPDriver is waterproof, dirt, chemical and heat resistant, and built for use.
- Contact your prosthetist to facilitate servicing or for additional silicone shims.
- * 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.

Device Accessories (Included)

In addition to the PIPDriver, a full set of shims is included to help optimize the fit of the device:

- Small shim SM
- Medium shim MD
- · Large shim LG

Warranty

Naked Prosthetics offers a standard 1-year warranty (from ship date) on the mechanical function of the PIPDriver. Please contact Naked Prosthetics Devices 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

