

PIPDriver®

Instructions for Use
Body-driven, Class 1 Prosthetic Device

BPF 201 | 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

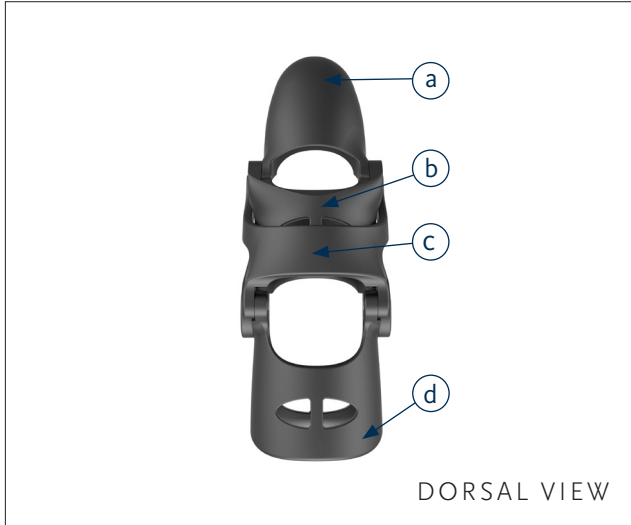


Figure 2

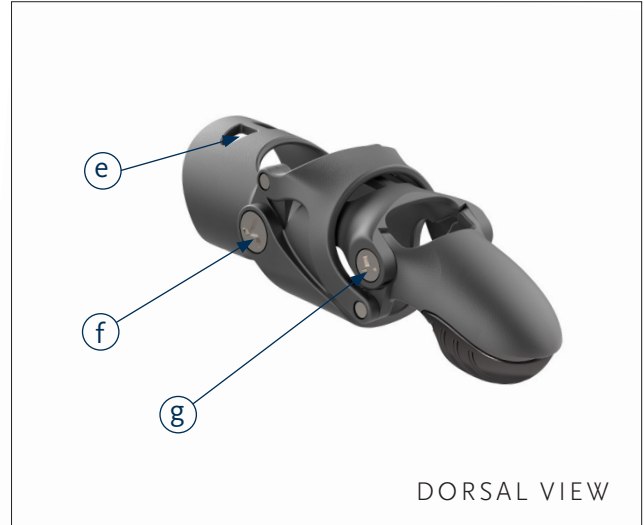


Figure 3



Figure 4



LIST OF PARTS

- | | | | |
|------------|--------------------------|--------------------------|---|
| a. Tip | d. Ring | g. Small Fastener | j. Palmar Ring Shim Hole |
| b. Cage | e. Dorsal Ring Shim Hole | h. Silicone Tip Pad | k. Dorsal Cage Shim Hole |
| c. Tendon* | f. Large Fastener* | i. Palmar Cage Shim Hole | * not present in Static PIPDrivers |

PRODUCT DESCRIPTION

The device is a body-driven mechanical finger prosthesis consisting of a frame made of nylon and titanium that is donned over the residual finger.

Indications for Use:

The PIPDriver is designed for a partial-finger limb difference distal to the proximal interphalangeal (PIP) joint with some joint range of motion and enough residual digit to engage the cage section of the device. For people who do not have the physical presentation to articulate a PIPDriver, a static option may be indicated.

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.

NOTE: If periodic volume change is experienced, shims may be added or removed as necessary.

Device Application

1. Place the device on the appropriate digit. Reference the inside of the ring for a digit identifier.
 - Align the Large Fastener (*Figure 2f*) with, or slightly proximal to, the PIP joint of the finger.
2. Check initial fit.
 - Ring (*Figure 1d*) should fit closely to the shape of the digit.
 - if the fit is loose, install any combination of silicone shims in the ring section to achieve a snug fit
 - change hand position several times to confirm the device remains on the finger
 - if gapping in the cage section of the device is noted, add shims
3. Check dynamic fit.
 - Articulate the device several times, evaluate 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 PIPDriver 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 over fit or function should be addressed by 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

- Silicone Shims (Standard Set and/or Mini Set) – If the device is capacitive, capacitive shims* (Standard Set and/or Mini Set) are supplied. Capacitive shims will feature a lightning bolt.

NOTE: **For capacitive PIPDriver wearers who are experiencing volume fluctuations and need to use shims, they must use capacitive shims to maintain touch screen compatibility.*

Device Maintenance

- The PIPDriver is designed for minimal maintenance and does not require lubrication.
- The PIPDriver is water-, dirt-, chemical- and heat-resistant.
- Contact your prosthetist to facilitate servicing or replacement components.

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

Care & Cleaning

- Prolonged exposure to strong solvents or degreasers may damage surfaces.
- 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.

Warranty

Naked Prosthetics includes a standard 2-year warranty (from ship date) on the mechanical function of the **PIPDriver**. 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
- 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 **PIPDriver** is designed such that any force the patient can generate at the PIP joint can be transmitted by the device. Force output is dependent on the patient's strength. The **PIPDriver** has the potential to output the same force as an intact finger.

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