
# INSTRUCTIONS FOR USE

FREEDOM INNOVATIONS

Product Name: Plié3 MPC Knee

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## 1. Important Information

The Plié® 3 MPC Knee is a single axis prosthetic knee joint system providing microprocessor control of both the swing and stance phases of gait. The microprocessor monitors an embedded load sensor and an angle sensor to precisely control the transitions between the stance and swing phases of gait. Three manual settings allow the hydraulic cylinder to provide adjustable resistance for Stance Flexion, Swing Flexion, and Swing Extension. The hydraulic cylinder also provides non-adjustable stance extension resistance. The Plié Control software allows the knee function to be optimized for each individual user's gait, including the stumble recovery parameters. The Gait Lab software provides the prosthetist with access to recorded data files of the microprocessor for analysis and documentation.

### 1.1 Indications

The Plié® 3 MPC Knee is intended for use as a component in a prosthetic leg for individuals with lower-limb loss including:

- transfemoral amputees
- knee disarticulation amputees
- hip disarticulation amputees
- individuals with congenital lower-limb abnormalities

The Plié 3 MPC Knee is appropriate for users who would benefit from the safety inherent in the stability of a microprocessor controlled knee. These users should also have the ability or have the potential to:

- negotiate obstacles in the community or workplace
- exert sufficient hip joint or pelvic voluntary muscle control
- ambulate with variable cadence
- descend stairs and ramps

**1.2 Contraindications** – Do not use Plié 3 MPC Knee on users with

- insufficient hip joint or pelvic voluntary muscle control
- insufficient cognitive ability to charge the batteries and care for the device
- body weight exceeding 125 kg (260 lbs.) for moderate activity
- body weight exceeding 100 kg (220 lbs.) for high activity

## 2. Symbols Used

| | |
|---|---|
| CE | CE MARK (European conformity) |
| ⚠ | Caution Symbol! Failure to adhere to this warning may result in user injury, knee damage, or limit the device the function. |
| | Type BF Applied Part used on device |
| FC | Federal Communications Commission (USA conformity) used on device |
| | A device should not be disposed of in regular wastes at the end of its usable life under WEEE Directive on waste electrical and electronic equipment guidelines. Used on device. |

## 3. Safety Precautions

⚠ Failure to follow the safety precautions can result in device malfunctioning and risk injury to the user.

### 3.1 Battery and Battery Cap

**3.1.1** Follow the Plié 3 owner Guide on battery handling and charging.

**3.1.2** If power is lost from the Plié 3 knee, it will default to the *Stance Flexion* resistance setting and will not release into swing.

**3.1.3** Insert a charged battery when the Plié 3 MPC Knee low battery indicator is visible (symbolized by red blinking light visible on the left side of the knee viewed from posterior) prior to complete power loss to prevent potential personal injury.

**3.1.4** Use ONLY compatible Plié 3 MPC Knee batteries and charger.

**3.1.5** Store spare battery in the battery case to avoid the risk of battery short circuit.

**3.1.6** Use a lint free cloth with or without isopropyl alcohol to wipe the battery compartment area and gasket on the bottom side of the cap (see pictures below). These areas need to be debris and lint free.


**Battery Compartment Area**

**Gasket on Bottom Side of Cap**

### 3.1.7 Battery Cap Opening & Closing

To open the battery cap, press down latch, this will cause the cap will spring open. To close the battery cap, press firmly on entire cap until latch engages. Do not submerse the knee in water when the battery cap is open at any time.

**Cap is Closed, Locked and Watertight**

**Cap is Unlocked and Opened**

**3.1.8** The following pictures show the proper steps to open and close the battery cap.

**Steps to Open or Close the Cap**

To Open: Press down latch. (The cap will spring open).
To Close: Press firmly on entire cap until latch engages.

## 4. Alignment and Setup

Follow the Prosthetist Setup Guide to properly align and adjust the device. Two installation programs, Plié Control and Plié Gait Lab, are provided to optimize the computer settings for each patient. Verify the computer system minimum requirements before software installation (Microsoft Windows 7 or later operating system, 1.0 MHz Processor, 256K RAM and USB Port).

### 4.1 Alignment

Careful attention to the alignment of the socket in relation to the Plié® 3 MPC Knee and the prosthetic foot is essential for a successful user outcome. The prosthesis alignment should account for the range of motion (ROM), voluntary control, and balance of individual users. Proper alignment and user voluntary control are essential to the optimal function of the prosthesis.

Prior to assembly of the prosthesis, the prosthetist should measure the patient's hip joint range of motion (ROM) on the prosthetic side to determine if the user has a hip flexion contracture (Figure 1). If present, the user's hip flexion contracture should be accommodated by attaching the socket to the prosthesis with an appropriate amount of flexion (Figure 2). Failure to sufficiently accommodate a hip flexion contracture can compromise the patient's function during standing and ambulation (Figures 3 and 4).

| | |
|---|---|
|  | During standing, an unaccommodated hip flexion contracture may prevent the patient from standing straight, compromising the patient's balance (Figure 5). Additionally, an unaccommodated hip flexion contracture can cause excessive lumbar lordosis, compromising the structural integrity of the patient's spinal column (Figure 4). |
|  | During ambulation, an unaccommodated hip flexion contracture can cause an excessively asymmetrical gait pattern. |

## 4.2 Bench Alignment

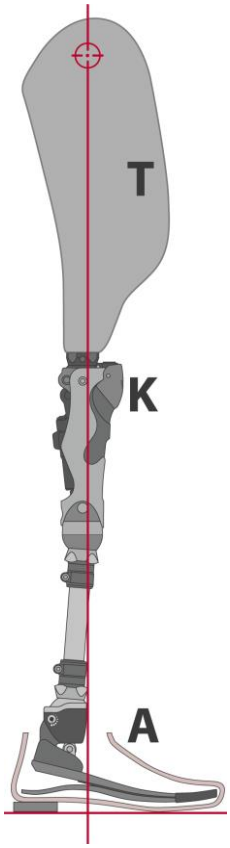


*Figure 1*

The Plié® 3 MPC Knee should be in a fully extended position during stance phase for level ground ambulation. An inherently stable trochanter-knee-ankle (TKA) alignment is essential to a successful user outcome with the Plié MPC Knee. The referenced trochanter on the lateral socket should be placed on or up to 5mm anterior to the knee joint axis (Figure 1).

| | |
|---|---|
| ⚠ | An inherently unstable trochanter-knee-ankle (TKA) alignment can cause a rapid extension moment at the knee joint after mid stance. The non-adjustable stance extension resistance could be insufficient to dampen the extension moment if the user does not exert sufficient voluntary control and/or if the alignment recommendations are not implemented. |
| ⚠ | The recommended inherently stable alignment of the Plié 3 MPC Knee may differ from other knee joints. Consequently, if a new socket is not fabricated for use with a Plié 3 MPC Knee, the socket attachment component may require re-lamination to the socket to achieve the recommended alignment |

## 4.3 Static Alignment

**4.3.1** Instruct the user to stand between parallel bars.

**4.3.2** With equal weight on each limb, adjust the height of the prosthesis as necessary.

**4.3.3** Ensure the trochanter-knee-ankle (TKA) alignment follows the recommendations of inherent stability.

**4.3.4** Ensure the transverse rotation of the knee and foot is appropriate.

**4.3.5** Instruct the user to sit in a chair. Adjust the height of the knee joint axis to match the contralateral limb as closely as possible.

| | |
|---|---|
| ⚠ | To prevent risk of injury to the user, perform the static alignment, dynamic alignment, and set-up between parallel bars. |

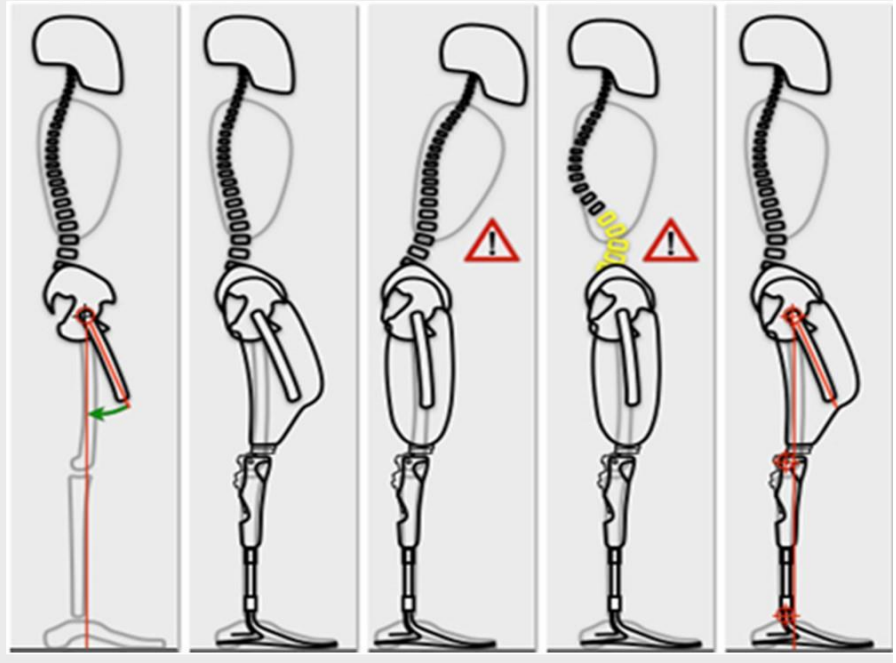

***Figure 2*** ***Figure 3*** ***Figure 4*** ***Figure 5*** ***Figure 6***

### 4.4 Dynamic Alignment

**4.4.1** Instruct the user to take a lunge step with the prosthesis. The lunge motion will allow the user to feel the *Stance Flexion* resistance and develop confidence. Repeat as necessary.

**4.4.2** Instruct the user to carefully ambulate. Teach the user to flex the ipsilateral hip extensor muscles at initial contact to stabilize the knee joint.

**4.4.3** Train the user to load the prosthetic toe to initiate the swing phase transition.

**4.4.4** Train the user to take steps of equal length.

**4.4.5** Adjust the alignment in the transverse, coronal and sagittal planes as necessary.

### 4.5 Plié Control 6

The Plié Control 6 software is required to program a Plié 3 MPC Knee. Download software from the CD provided with the knee or from the Freedom Innovations website to install the program at https://www.pliesupport.com/download.

### 4.6 Plié 3 Setup

Thoroughly read and follow the instructions as stated in the Prosthetist Setup Guide and Plié Setup Wizard to set up and program the knee. Utilize the “Help” function in the Plié Control software to assist any issues that may arise.

### 4.7 Finishing Options

**4.7.1** A discontinuous, two-piece cover is recommended for cosmetic finishing. Care should be taken to ensure that the battery compartment and manual adjustments are accessible. See catalog for Cosmetic Cover Kit.

### 4.8 Technical Support

For Technical Support, please contact Freedom Innovations at +31(0)53-20 30 300.

## 5. Warranty and Service

The Plié® 3 MPC Knee purchase includes a 36 month warranty covering all manufacturer defects effective only if the product is used according to manufacturer recommendations. The batteries, battery charger, and accessories are provided with a 12 month warranty. An extended warranty is available. See product catalog for details.

### 5.1 Service and Repair

For the warranty to remain in effect, the knee must be serviced 12 and 24 months after purchase. For knee service or repair, please contact Freedom Innovations at +31(0)53-20 30 300. A loaner knee will be provided upon request. For service and/or repair, please ship the knee in the provided shipping case to the following address:

Freedom Innovations Europe B.V.
Jaargetijdenweg 4
7532 SX Enschede
The Netherlands

## 6. Technical Specifications

### 6.1 Device Information

| | |
|---|---|
| Product weight (pyramid top): | Approximately 1235 g or 2.7 lbs. |
| Product weight (threaded top): | Approximately 1243 g or 2.74 lbs. |
| Build clearance (pyramid top): | Approximately 9.25” or 235mm |
| Build clearance (threaded top): | Approximately 8.75” or 223mm |
| Maximum flexion angle: | 125° (pyramid top) and 117° (threaded top) |

## 6.2 Battery Information

| | |
|---|---|
| Operating voltage: | 3.6 – 4.2 VDC |
| Charger input voltage: | 12 VDC |
| AC power adapter input voltage: | 100-240 VAC, 50/60 Hz |
| Battery life: | Approximately 24 hours depending on use |
| Air Valve: | Exchangeable |

## 6.3 Environmental Conditions

| | |
|---|---|
| Battery temperature range for charging: | 8° C to 38° C (46° F to 100° F) |
| Storage and shipping temperature range: | -20° C to 80° C (-4° F to 176° F) |
| Operating temperature range: | -5° C to 45° C (23° F to 113° F) |
| Storage and operating relative humidity range: | 0% to 100%, including condensation |
| Storage and operating pressure range: | 500 hPa to 1060 hPa (7.3 psi to 15.4 psi) |
| Water and Dust Resistance: | IP67, Totally protected against dust (6) and Protected against the effect of immersion between 15cm and 1m (7) |

## 6.4 CE Conformity

The electronic of Plié 3 MPC Knee System is tested and certified to comply with the MDD 93/42/EEC (EN 55011 Class B and EN60601-1 and EN60601-1-2), STSI EN 300-328 under R&TTE Directive 1999/5/EC and, ISO10328. The device complies with Part 15 of the FCC Rules and carries the CE mark

## 6.5 Authorized Representative

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