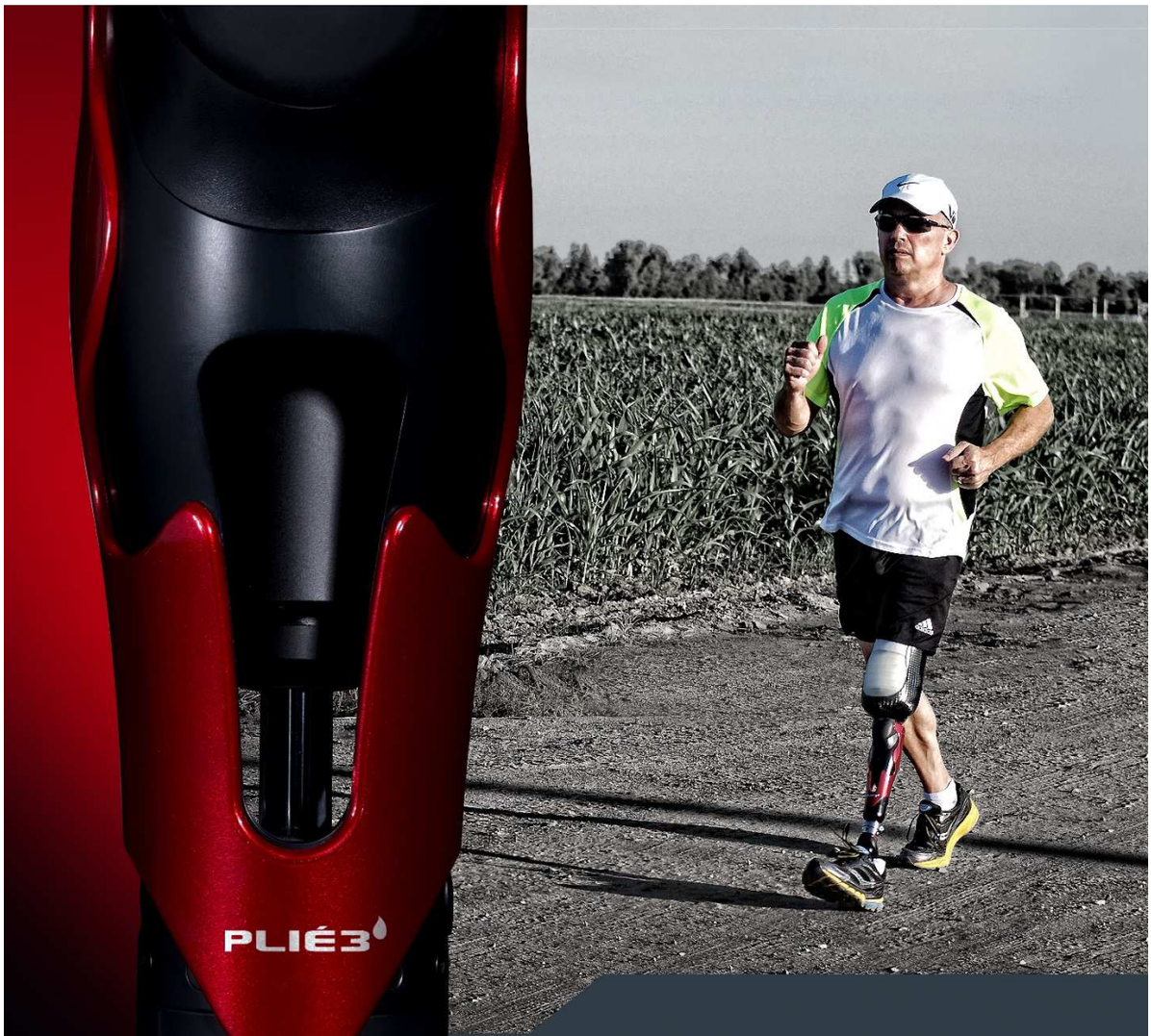
AR ZH JA UK RU HR SK CS PL FI SV NO DA NL PT ES IT DE EN FR



FREEEDOM

PLIÉ3

MICROPROCESSOR KNEE

FR	Notice d'Utilisation
EN	Instruction for use
DE	Gebrauchsanweisung
IT	Istruzioni per l'uso
ES	Instrucciones de uso
PT	Instruções de utilização
NL	Gebruikershandleiding
DA	Brugervejledning
NO	Brukerveiledning
SV	Bruksanvisning
FI	Käyttöohjeet
PL	Instrukcja użytkowania
CS	Návod k použití
SK	Návod na používanie
HR	Upute za uporabu
RU	Инструкция по использованию
UK	Інструкція з використання
JA	取扱説明書
ZH	使用说明
AR	تعليمات الاستخدام

PROTEOR

CE 2006	**Plié® 3 MPC Knee** *Instructions For Use* ***Read before use***	IFU-03-001 Rev C

EN

Provide and explain § 3, 7, 8, and 9 to the Patient.

1. INCLUDED ITEMS

#	Part Description	Part Number	Included/Sold Separately
1	Pyramid Top Plie Knee with Black Cover or Threaded Top Plie Knee with Black Cover	KS3-00-KNEE1-00 or KD3-00-KNEE2-00	Included
2	Wireless USB Adapter	KS1-00-BLUE1-00	Included
3	Lithium Ion Battery (2 pc)	KS1-00-BATT2-00	Included
4	Battery Charger	OTS0401	Included
5	Air Pump with Hose Adapter	KS1-00-AIRP1-00	Included
6	Smooth Hose Adapter for Air Pump	SGK0213	Included

2. DESCRIPTION AND PROPERTIES

A. Description

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.

B. Properties

Device Information

Version	Pyramid Top	Threaded Top
Weight	1235 g / 2.7 lb	1243 g / 2.74 lb
Build Height	235mm / 9.25"	223mm / 8.75"
Maximum Flexion Angle	125°	117°

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

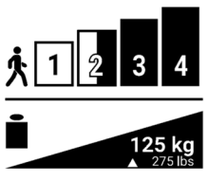
Expected Lifetime

The expected lifetime of the Plié 3 MPC Knee is defined by the warranty period and contingent on adherence to the service plan.

3. INTENDED USE/INDICATIONS

The Plié 3 MPC Knee is appropriate for users who would benefit from the safety inherent in the stability of a microprocessor-controlled knee. This medical device is supplied to healthcare professionals (prosthetists) who will train the patient in its use. The prescription is made by a doctor together with the prosthetist, who assess the patient's ability to use it.

⚠ This device is for **SINGLE PATIENT** use. It should not be reused on another patient.



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

It is recommended specifically for patients with medium activity level (2.5) to high activity patients (4):Maximum weight (load carrying included):

- for moderate activity: 125 kg / 275 lbs.
- for high activity: 100 kg / 220 lbs.

4. CLINICAL BENEFITS

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

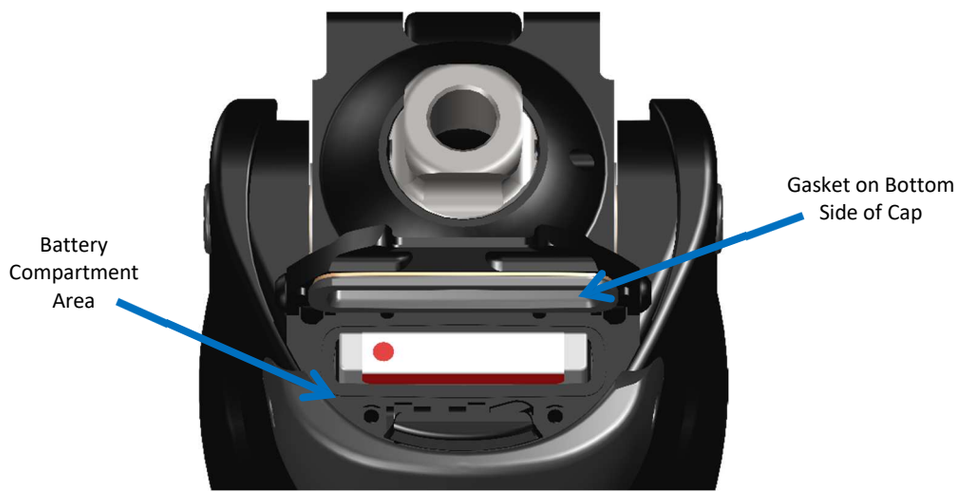
5. ACCESSORIES AND COMPATIBILITIES

The device incorporates a male pyramid link that allows it to be used with female pyramid connectors for the Pyramid Top version and a M36 x 1.5 thread for the Threaded Top version.

6. ASSEMBLY AND PATIENT FITTING

A. Battery and Battery Cap

- Follow the Plié 3 Owner's Guide on battery handling and charging.
- If power is lost from the Plié 3 knee, it will default to the *Stance Flexion* resistance setting and will not release into swing.
- 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.
- Use ONLY compatible Plié 3 MPC Knee batteries and charger.
- Store spare battery in the battery bag to avoid the risk of battery short circuit.
- 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.



B. Battery Cap Opening & Closing

To open the battery cap, press down latch, this will cause the cap to 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

The following picture show the proper steps to open and close the battery cap.

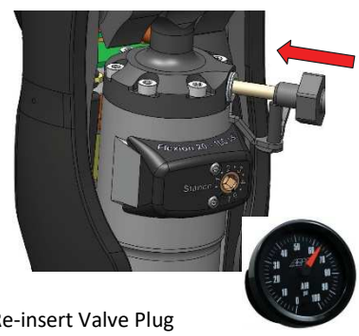
Steps to Open or Close the Cap

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

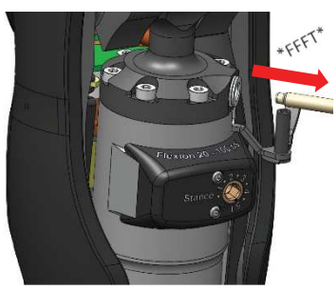
The following pictures shows the proper steps to utilizing the air pump.

1. Remove the Valve Plug

2. Insert Pump Tube and Pump Air



3. Remove the Pump Tube



4. Re-insert Valve Plug

FFFT sound is residual air escaping the pump hose. This is normal - no air is lost from the Knee.

- Pump tip must be clean and free of debris and lint before inserting.
- Knee must be fully extended when adjusting air pressure.
- After re-attachment, gauge reads about half of the pressure in the knee.

C. 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).

D. 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.

E. Bench Alignment

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. A plumbline dropped from the trochanter reference point on the lateral socket should fall at or up to 5mm anterior to the knee joint axis

⚠ (Figure 5). Align the foot as recommended by the foot manufacturer.

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

F. Static Alignment

- Instruct the user to stand between parallel bars.
- With equal weight on each limb, adjust the height of the prosthesis as necessary.
- Ensure the trochanter-knee-ankle (TKA) alignment follows the recommendations of inherent stability.
- 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.

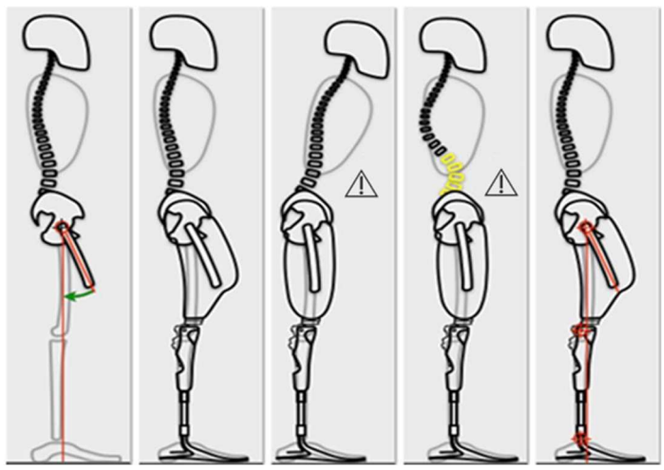


Figure 1 Figure 2 Figure 3 Figure 4 Figure 5

- Ensure the transverse rotation of the knee and foot is appropriate.

G. Dynamic Alignment

- 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.
- Instruct the user to carefully ambulate. Teach the user to flex the ipsilateral hip extensor muscles at initial contact to stabilize the knee joint.
- Train the user to load the prosthetic toe to initiate the swing phase transition.
- Train the user to take steps of equal length.
- Adjust the alignment in the transverse, coronal and sagittal planes as necessary.

H. Plié Control 6

The Plié Control 6 software is required to program a Plié 3 MPC Knee. Download software from the following website to install the program at https://www.pliesupport.com/download. This software is for use by prosthetists to program the knee. This software should not be used by the patient.

I. 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 with issues that may arise.

J. Finishing Options

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.

7. DETECTION OF MALFUNCTIONS

⚠ If you notice any abnormal behavior or feel any changes in the characteristics of the device, or if the device has received a severe impact, consult your prosthetist.

8. WARNINGS, CONTRAINDICATIONS, AND SIDE EFFECTS

A. Warnings

⚠ Inappropriate use of the device, in relation to the recommendations of your prosthetist, can cause the degradation of parts of the device (carrying heavy loads for example, excessive stress, exceeding the service life, etc.).

⚠ Never attempt to loosen the bolts affixing the pyramid connector.

⚠ If unusual movement or product wear is detected in a structural part of a prosthesis at any time, immediately discontinue use of the device and consult a clinical specialist.

⚠ **Water resistant: The device is safe for occasional submersion in fresh water up to 1 m (3 ft) for up to 30 minutes.**

⚠ The device should not be used for bathing and should not be immersed in salt water or chlorinated water as these may cause corrosion.

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

B. Contraindications

⚠ The device is inappropriate for users with:

- insufficient hip joint or pelvic voluntary muscle control
- insufficient cognitive ability to charge the batteries and care for the device

⚠ This device is not intended for activities where there is a risk of severe impact or excessive overload.

C. Side effects

There are no known negative side effects.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority.

9. MAINTENANCE, STORAGE, DISPOSAL, AND DURABILITY

A. Maintenance / Cleaning

⚠ No maintenance operation such as lubrication, work on the screws, or other parts is required.

⚠ Inspect the device every six months. If the user is more active, more frequent inspection may be necessary. Service as necessary.

After use in water:

- Dry the knee with a towel once out of the water

⚠ If the device is sprayed by, or accidentally submerged in, salt water or chlorinated water immediately rinse with fresh water and allow to dry.

The device may be cleaned with mild soap and warm water.

B. Storage

Battery temperature range for charging:	0°C to 45°C (32°F to 113°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:	Rated to IP67 per IEC 60529 (Protected against dust and the effect of submersion in water up to 1m for 30 minutes)

C. Disposal

The different items of the device are special wastes and must be handled according to local laws.

D. Technical Support

For Technical Support in the USA, please contact PROTEOR USA toll-free at 1-855-450-7300. For Technical Support in the EU, please contact PROTEOR France at +33 3 80 78 42 08.

E. 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.

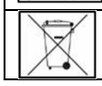
F. Service and Repair

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 PROTEOR.
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:

PROTEOR USA
425 East 400 North (PO Box 50)
Gunnison, UT 84634
USA
Toll-free: 1-855-450-7300
support@proteorusa.com

PROTEOR France
Rue du Cheffin
21250 Seurre
France
+33 3 80 78 42 08
cs@proteor.com

10. DESCRIPTION OF SYMBOLS

	**Manufacturer**
	**Warning**
	**CE marking and year of 1st declaration**
	**Type BF Applied Part**
	**FCC Declaration of Conformity**
	**WEEE Directive on waste electrical and electronic equipment, which should not be disposed of in regular wastes at the end of its usable life**

11. REGULATORY INFORMATION

This product is tested and certified to comply with the MDR 2017/745 (EN 55011 Class B and EN60601-1 and EN60601-1-2), STSI EN 300-328 under R&TTE Directive 1999/5/EC and, ISO 10328 - P6 - 125 kg.
The device complies with Part 15 of the FCC Rules and carries the CE mark

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