

Circleg One

Pylon Kit



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**Published**

2025-03-13

Document Name

IFU-PS1PL1-EN V04 REV00



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Welcome to the Circleg Instructions for Use!

This manual provides comprehensive instructions for certified Prosthetists on the proper use of the Circleg prosthetic components.

Please follow these **Instructions for Use** carefully to ensure optimal functionality and patient satisfaction.

- Prior to utilizing the Circleg prosthetic components, please **review** this document carefully and take heed of all safety instructions provided herein.
- Ensure that the amputee (prosthetic user, patient) receives comprehensive **training** on the safe and proper usage of the product.
- In the event of any serious **incidents** related to the product, it is imperative that you promptly inform the service provider, Circleg and the relevant regulatory authority in your country. Especially if there is a noticeable deterioration in the prosthetic user's health. Your cooperation in this regard is essential to improve product safety.
- It is advised to **retain** this document for your own records. It contains key information that may prove valuable in the future.
- For further clarification or assistance, do not hesitate to **contact** our support team.

1 Circleg product introduction

1.1 General product description

The Circleg prosthesis is a mechanical device for lower limb replacement, consisting of modular components (Polycentric Knee, Pylon, Cosmetic Cover, and Dynamic Foot) that can be used together or individually. These components connect to a custom-fitted socket (not provided by Circleg) via a standard pyramid adapter.

1.2 Intended purpose

The intended purpose of the Circleg prosthesis, designed for both transtibial and transfemoral amputees, is to restore functional mobility by replicating the mechanical movements of a natural limb. This prosthetic device aims to enable amputees to perform daily activities with increased stability, control, and comfort.

1.3 Intended user

Amputees: The Circleg prosthesis shall be used by amputees (prosthetic user, patient) with sufficient physical and mental health to perform daily activities. It accommodates prosthetic users with heights ranging from 150cm to 190cm and weights from 40kg to 110kg.

Certified Prosthetists: The Circleg prosthesis will be customized, fitted, and maintained according to individual patient needs by certified healthcare professionals and Prosthetists.

1.4 Activity levels

The Circleg prosthesis is intended for prosthetic users with activity level K1 (limited and unlimited household ambulator), K2 (limited community ambulator) and K3 (unrestricted outdoor walker). The contraindicated activities must be taken into consideration during the usage (as outlined in section 2).

1.5 Service life

The Circleg prosthesis has an approved service life of 2 million cycles corresponding to 2 to 3 years of use, depending on the prosthetic user's level of activity. It is recommended to carry out regular safety checks (as outlined in section 4).

1.6 Allowable conditions for storage and use

The product shall be stored and used under the following conditions:

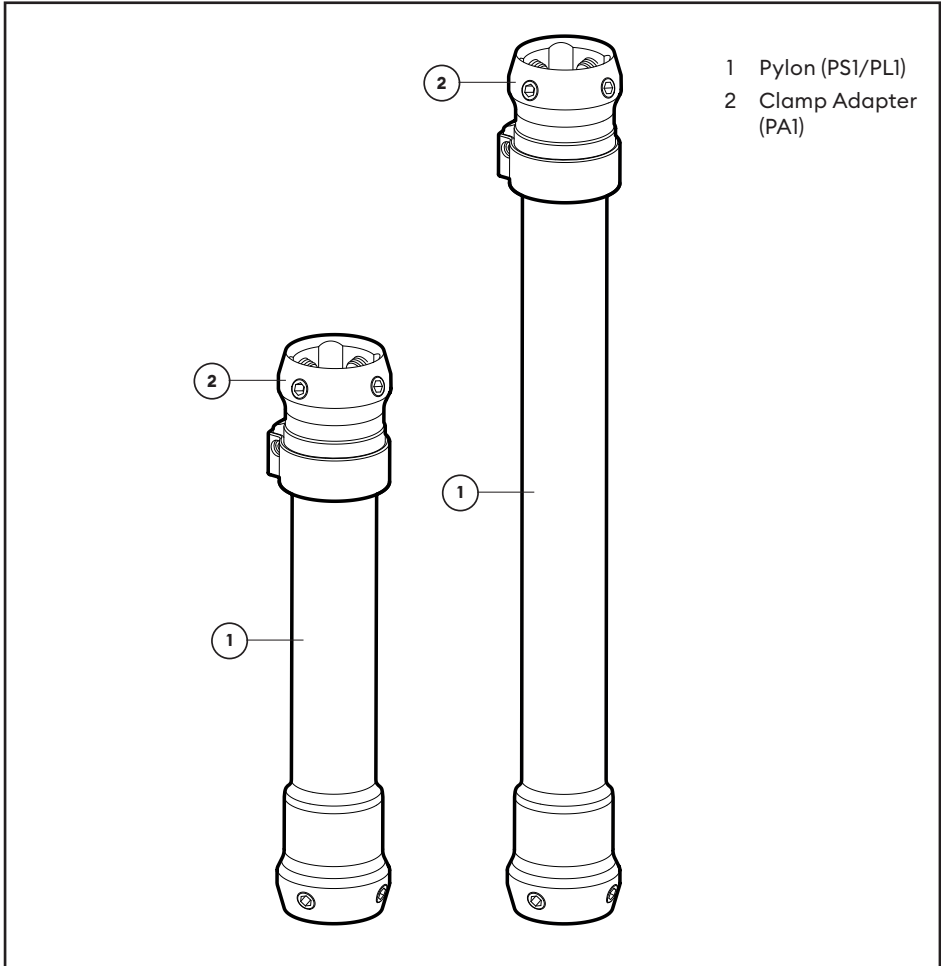
- Environments where the temperature ranges from 0°C to +50°C.
- Conditions where the relative humidity is between 20-90%.
- Weatherproof design allows use in wet or humid environments; tolerates splashes of fresh water (e.g., rain).

1.7 Unallowable conditions for storage and use

The product shall not be exposed to the following conditions:

- Environments involving continuous or prolonged contact with sun, dust and sand.
- Continuous exposure to liquid media, including fresh water.
- Exposure to salt water, acids, and urine.

1.8 Overview of component



The Pylon Kit consists of an aluminium tube with a fixed stainless steel clamp adapter (PS1/PL1) and a screw-on Clamp Adapter (PA1) that allows 360° rotation. They connect the dynamic foot to the proximal components. The Pylon Kit allows for controlled angle and length adaptation in the sagittal and frontal plane and inward and outward rotation adjustment. The Pylon Kit comes in 250 mm and 400 mm sizes and is intended for a maximum body weight of 110 kg.

Article Number	PS1-KIT	PL1-KIT
Component Length	250 mm	400 mm
Component Diameter	30 mm	30 mm
Maximal Body Weight	P5 - 110 kg	P5 - 110 kg

2 General safety instructions

Follow the safety instructions below when using Circleg prosthetics and inform the prosthetic user of the potential consequences. Using the product without following these instructions may cause injury or harm to the prosthetic user and/or damage the product:



Trained Prosthetist requirement

Circleg prosthetic components shall be fitted by trained and certified Prosthetists only.



Contraindicated activities

Do not use Circleg components for activities outside their scope or contraindications, such as:

- Pediatric prosthetic users
- Prosthetic users shorter than 150cm or taller than 190cm
- Prosthetic users weighing less than 40 kg or more than 110kg
- Prosthetic users with foot sizes smaller than 21cm or larger than 30cm
- Sports activities
- Kneeling or squatting



Combination with third-party components

Functionality with components from other manufacturers that feature compatible modular connectors has not been tested. Therefore, using Circleg components with third-party parts is not recommended, except for the socket connected to the residual limb. The selection of an appropriate socket solution should consider factors such as amputation level, activity level, and personal preferences of the prosthetic user. It is the responsibility of the service provider and the certified Prosthetist to assess and determine the most suitable solution.



Counterfeit, beyond end-of-life, or reused components

Do not use counterfeit or reused Circleg components. Always inspect components before use, ensuring they are within their defined lifespan, and instruct prosthetic users not to use components beyond their end-of-life (as outlined in section 1.4 and 1.5). Take suitable measures as outlined in section 4 (e.g. cleaning, repair, replacement by trained and certified Prosthetists).



Unallowable conditions

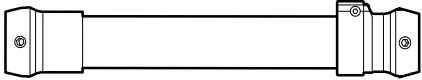
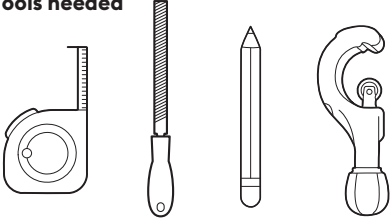
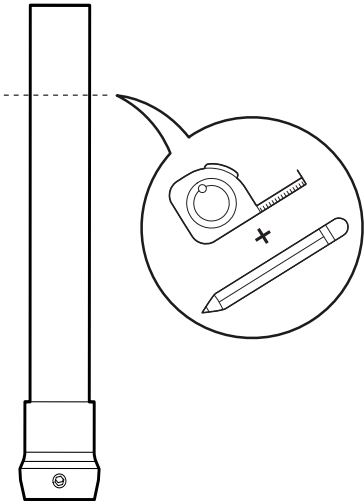
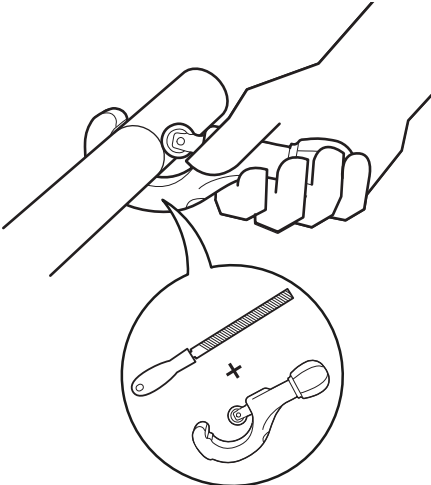
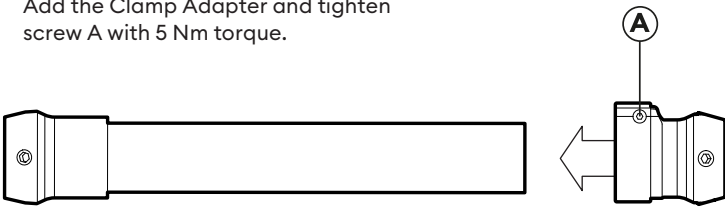
Do not use or expose Circleg components to environmental conditions other than those specified in this instruction (as outlined in section 1.6 and 1.7).



Fire safety

Circleg components meet the flame resistance requirements outlined in FMVSS 302 / DIN 75200. However, they may still ignite if exposed to improper or negligent fire handling. To ensure safety, keep them away from all ignition sources, including open flames and lit cigarettes.

3 Adjustment guideline

 <p>PS1-KIT PL1-KIT</p>	<p>Tools needed</p>  <p>Tape measure Hand rasp Pen Pipe cutter</p>
<p>1 Measure and mark the desired length of the Pylon.</p> 	<p>2 Cut the Pylon according to the measurements with a pipe cutter and smoothen the burrs.</p> 
<p>3 Add the Clamp Adapter and tighten screw A with 5 Nm torque.</p> 	

4 Maintenance

The Circleg components are designed for low maintenance. It is recommended to visually inspect the component after the initial 30 days of use, and subsequently at intervals of every 6 months. This proactive approach helps to identify and prevent any signs of unusual wear or potential issues that may arise over time. Scheduling of regular maintenance lies within the discretion of the service provider. The prosthetic user shall discontinue use and report to the service provider in the event of any breakage, failure, change in function, or any unusual wear

4.1 Cleaning and care

Clean the Circleg components with fresh water and a microfiber cloth only. Dry with a soft towel thoroughly and allow the component to air dry to remove any remaining moisture. Repeat this procedure regularly - especially after exposure to substances other than fresh water. Avoid strong acids or any other chemical cleaning agents (pH=4 or less) on the component. These substances can be harmful and may cause damage to the Circleg components.

5 Product complaints

In the event of any serious incidents related to the product, it is imperative that you promptly inform the service provider, Circleg and the relevant regulatory authority in your country. Especially if there is a noticeable deterioration in the prosthetic user's health. Your cooperation in this regard is essential to improve product safety.

6 Liability

Circleg will only accept responsibility if the product is used in strict accordance with the descriptions and instructions outlined in this document. Circleg will not be held responsible for any damages resulting from the disregard of the information contained in this document, especially in cases of improper usage or unauthorized modifications to the product.

7 Warranty
















The warranty for this product is subject to Circleg's General Terms and Conditions in effect at the time of sale. Details regarding the scope, duration, and conditions of the warranty can be found in the applicable General Terms and Conditions, available upon request or on the Circleg website: www.circleg.world

8 Disposal

Prosthetic users are advised to return defective or worn-out products to their service provider. Please note that disposal of this product with regular domestic waste may not be permitted in all countries of use. Not following the disposal regulations of the responsible authorities may have a detrimental impact on health and environment.

9 Appendices

9.1 Symbols Used

	Manufacturer		Temperature limits
	Date of manufacture		Keep away from sunlight
	Importer		Humidity limits
	Distributor		
	Packaging unit		
	Caution		
	Operator's manual; operating instructions		
	Declaration of conformity according to the applicable European regulation		
	Serial number (SYWCW-REF-NNN-X) S - Series YY - Year CW - Calendar week REF - Catalogue number NNN - Sequential number X - Material ID (where applicable)		
			
	Article number		
	Medical device		
	Local representative		

**Contact us in case of any assistance
needed at support@circleg.world**