

Prosthetic Systems for Lower-Limb Amputees Above-Knee & Below- Knee Solutions

Clinical-grade performance.
Engineered for demanding environments.



1. Executive Summary

Circleg AG develops high-quality, modular mechanical prosthetic systems for above- and below-knee amputees, purpose-built for demanding environments. Circleg systems deliver clinical outcomes comparable to premium imported components at a fraction of the cost – combining CE marked products, ISO 13485 quality management, and a unique modular design that reduces clinic stocking requirements by up to 80% and prosthetic fitting time by up to 70%.

This report summarises the clinical, performance, and operational evidence supporting the Circleg prosthetic system as a procurement decision for orthopaedic clinics, ministries of health, and public hospital management.

K1–K3

Activity Levels Covered

>85%

Foot Energy Return Rate

0

Structural Failures in 3+ Years Field Use

IP5KX Dust Resistance

Whole system independently tested

2M+

Foot Load Cycles (ISO 10328)

3M+

Knee Load Cycles (ISO 10328)

–80%

Clinic Stocking Needs Reduced

2. Quality Assurance & Regulatory Compliance

All Circleg components are developed and maintained under a comprehensive Quality Management System certified to ISO 13485. This oversight extends across the entire supply chain, ensuring product efficacy and patient safety at every stage.



Figure 1. Official Stamp by Swiss Safety Center

Certifications & Standards

CE Marking

All components bear the CE mark, confirming conformity with EU Medical Device Regulation (EU MDR) requirements for safety and performance.

ISO 13485

Quality Management System certified across design, development, manufacturing, distribution, sales, servicing, and training for prosthetic devices.

ISO 10328

Structural testing standard for prosthetic components – both knee and foot have passed cyclic load testing without failure.

IP5KX Dust Resistance

The whole Circleg One system independently tested in a dust chamber per ISO 20653 protocol; functionality unaffected by extensive dust exposure.

3. Knee Joint Clinical & Technical Evidence

The Circleg polycentric knee joint is a mechanical prosthetic joint designed to balance robust stance-phase stability with natural swing-phase dynamics. It is clinically indicated for K1-K3 activity levels and engineered for high performance in highly demanding settings.



Figure 2-6. Circleg One prosthetic knee joint

Clinical Performance

K1–K3 Activity Range

Designed to support users across a wide range of mobility levels—from basic household ambulation to active community walking—the joint combines reliable stance-phase stability with efficient swing-phase performance. Its broad applicability has been proven through successful fittings across the full K1–K3 activity spectrum in real-world clinical and market settings.

Validated Gait Kinematics

A gait analysis study conducted in collaboration with ETH Zurich confirmed that Circleg knee kinematics are equally performing to those of more sophisticated, high-cost components. Joint trajectory mimics natural movement patterns, reducing compensatory motion and enhancing user comfort.

Swing Phase Control

Integrated damper and spring mechanisms provide smooth stance-to-swing transitions and predictable response as cadence increases – supporting an energy-efficient, natural-appearing gait.

Adjustability without Complexity

Perceived stability can be adjusted by rotating the knee joint in the sagittal plane, accommodating the vast majority of users without requiring multiple adjustment mechanisms that would compromise service life.

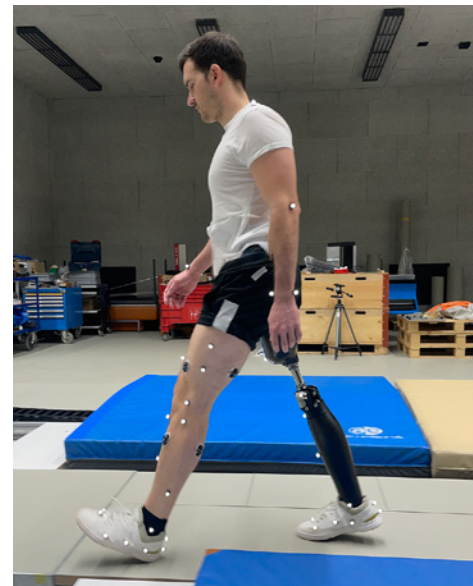


Figure 7. ETH Zurich gait laboratory: instrumented motion capture of Circleg user.

Gait Kinematics Graph

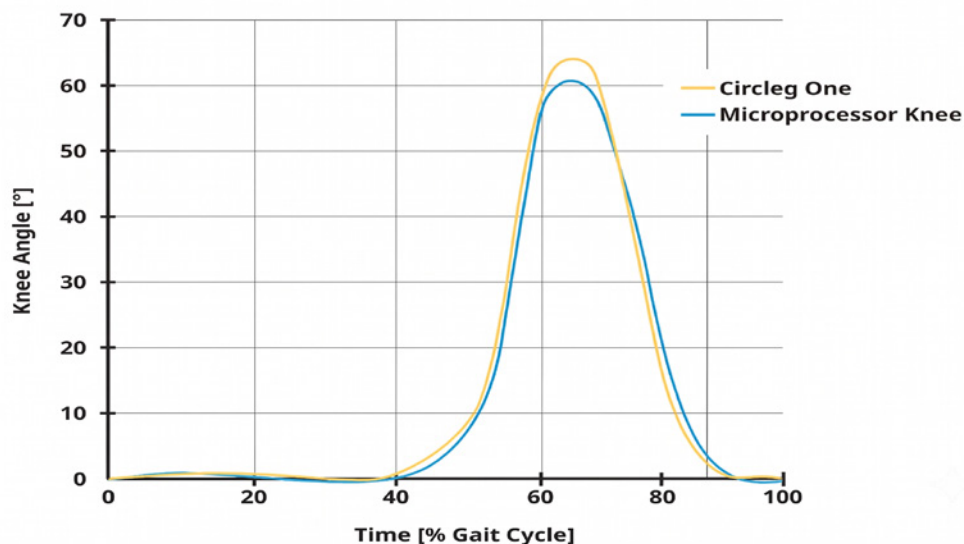


Figure 8. Knee flexion angle throughout the gait cycle. Measured during gait analysis at ETH Zurich. The graph is demonstrating that the Circleg knee closely replicates natural gait patterns and performs comparably to advanced, higher-cost prosthetic knee components.

Durability & Safety Evidence

Test / Indicator	Result	Clinical Significance
ISO 10328 cyclic loading	3,000,000 cycles; no structural failure	Equivalent to several years of daily use
ISO 10328 static testing	>400kg; mechanical integrity maintained	Safe under unexpected high-stress events (e.g. stumbling)
Field reliability	Zero structural failures across 3+ years of market use	Laboratory results validated in real-world conditions
Dust resistance	Passed IP5KX (ISO 20653)	Functional in dusty environments
Maintenance requirement	No scheduled maintenance required (basic cleaning only)	Lower total cost of ownership vs. hydraulic/electronic knees

Environmental Resilience

The mechanical architecture avoids complex electronics, ensuring operational integrity in harsh conditions including dust, water, high humidity, and uneven terrain. Every component is individually replaceable, extending total service life in contexts with limited supply chains.

Figure 9. Circleg prosthesis during environmental dust testing. The prosthesis was exposed to controlled dust conditions to assess resistance to particulate ingress and continued functionality in harsh operating environments.

Figure 10. Dust exposure test setup used for environmental resilience assessment. Test chamber employed to evaluate the performance and operational integrity of the Circleg prosthetic system under conditions of elevated dust exposure.



Figure 9

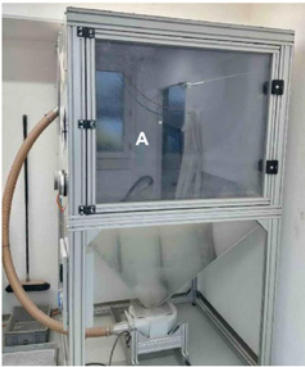


Figure 10

4. Prosthetic Foot — Clinical & Technical Evidence

The Circleg prosthetic foot provides a stable foundation and efficient energy dynamics for daily ambulation. Its size-adjustable design reduces stocking requirements by up to 80%, directly lowering the capital and logistics burden on clinics and public health facilities.



Figure 11-15. Circleg One Dynamic Foot

Clinical Performance

Energy Return

Engineered for an energy return rate exceeding 85%, efficiently releasing stored energy at toe-off to support a functional, assistive gait pattern.

Stability & Ground Confidence

Foot geometry is optimised for consistent ground contact and predictable weight shifting, directly reducing stumble risk and supporting safe ambulation across varied terrain.

Bilateral Compatibility

Each foot size can be used for both right and left limb amputations, further reducing stocking requirements without compromising fit quality.

Figure 16. Energy return performance of the Circleg prosthetic foot. Testing demonstrated an energy return rate exceeding 85%, supporting efficient gait progression.

Figure 17. Bilateral compatibility across foot sizes. The bilateral design enables use on either limb, supporting inventory optimization without compromising clinical application.

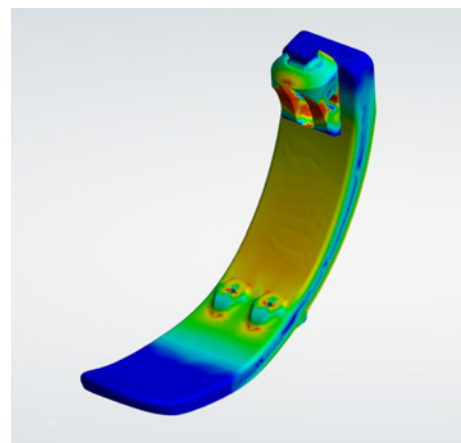


Figure 16

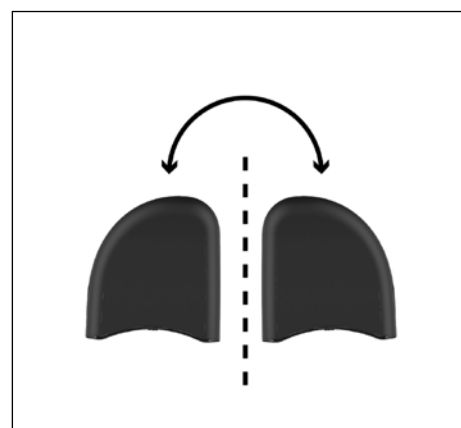


Figure 17

Efficient Sizing Model

Only three foot sizes are required to cover the sizes from 21-30 cm. Each size can be further adjusted to the individual patient, ensuring precise fit and optimal alignment without an extensive or costly inventory.

Sizing Feature	Detail	Benefit for Clinics
Total sizes to stock	3 sizes covers all adult patients	Up to 80% reduction in stocking needs
Left/right compatibility	Same foot used for both limbs	Further halves stocking requirement per size
Individual adjustability	Each size adjustable to individual user	Precise fit without bespoke components
Cover replaceability	Polyurethane outer cover field-replaceable	Extended service life; no full component replacement needed

Durability & Safety Evidence

Test / Indicator	Result	Clinical Significance
ISO 10328	2,000,000 cycles; no structural failure	Validated for several years of daily use
ISO 10328	> 400kg; structural integrity maintained	Safe under unexpected high-force scenarios
Field reliability	Zero structural failures across 3+ years of market use	Laboratory results confirmed in field conditions
Core material	Polypropylene (reinforced); used in structural automotive parts	High-grade, proven material in demanding applications

5. Operational Benefits for Healthcare Facilities

The Circleg system's modular design translates directly into measurable operational and financial benefits for the facilities that adopt it. These advantages are relevant to clinic management, procurement officers, and health ministry planners.

For Orthopaedic Clinics

Reduced Stocking Requirements

Up to 80% reduction in prosthetic components that need to be held in stock, freeing up capital and reducing waste from unused inventory.

Faster Fitting & Finishing

Clinics report up to 70% reduction in prosthetic finishing time per patient, increasing throughput and improving patient access.

Simplified Training

Mechanical simplicity reduces the learning curve for prosthetists, supporting consistent clinical outcomes across different staff experience levels.

Warranty

The Circleg knee is backed by a 2-year warranty. This coverage reflects confidence in the product's durability and provides users, clinics, and payers with greater long-term reliability and peace of mind.

For Ministries of Health & Public Hospital Management

Cost Competitiveness

Circleg systems deliver clinical performance comparable to high-cost imported components at significantly lower procurement cost – improving equity of access at scale.

Supply Chain Simplicity

Three foot sizes cover all adult patients. Reduced number of components simplify national or regional procurement and reduce the risk of stockouts.

Durability in Resource-Limited Settings

CE-marked, ISO-tested components with zero structural failures across three-plus years of field use, including active use in sub-Saharan Africa and Latin America.

No Electronic Maintenance

Mechanical design eliminates the need for specialist servicing, external calibration tools, or proprietary software – critical for settings with limited technical infrastructure.

Regulatory Readiness

CE marked products and EU MDR compliance provide a solid regulatory foundation for national registration processes across multiple markets.

6. About Circleg AG

Circleg AG is a Swiss social enterprise founded with the mission of increasing access to exceptional prosthetic care for the majority of amputees worldwide. The majority of the world's 40+ million lower-limb amputees live in low- and middle-income countries (LMICs), where prosthetic access is severely constrained by cost, supply chain limitations, and lack of qualified clinicians.

Circleg's prosthetic systems are designed from the ground up for these settings – combining clinical-grade performance, proven durability, and an operational model that enables clinics to serve more patients with fewer resources.

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DISCLAIMER

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