

PROPRIO FOOT®

IOSSUR

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Reimbursement Support

PROPRIO FOOT[®] PRODUCT FEATURES

The PROPRIO FOOT has been redesigned to enhance the safety and stability features of the original design. It features a Pro-Flex[®] LP foot module which provides increased range of motion and a higher peak ankle power of 44% from the previous model. The Microprocessor ankle unit adapts to varied terrain 60% faster than the previous, helping users to walk naturally and comfortably on a variety of everyday terrain, including stairs and ramps. It also features 4 degrees of active swing phase dorsiflexion, contributing to a 70% reduction in falls'.

The PROPRIO FOOT is recommended for K2-K3 low to moderate activity users with the following presentations:

- Unilateral transtibial amputation
- Bilateral transtibial amputation
- Unilateral transfemoral amputation

A case by case assessment is recommended for bi-lateral transfemoral amputees and users with limited residual limb control.

SUMMARY OF FEATURES

- Weatherproof for use in wet/humid environments. Rated: IP34
- Mechanical range of ankle motion of 33° (19° Dorsiflexion, 14° Plantarflexion)
- Mid-swing dorsiflexion for improved ground clearance
- Automatic terrain adaptation on level-ground and ramps/inclines
- Stair adaptation
- Faster terrain adaptation than previous model
- Heel height adjustability up to 5cm
- Relax mode for comfortable sitting
- Chair Exit adaptation for easier sit to stand transfers
- Standby mode- disables all motor movements, e.g. for use when driving
- Cycling detection- motor movement disabled automatically when cycling
- Integrated battery
- Össur Logic connectivity (CPO and User versions)
- Activity report generation
- 18-36 hours of battery life depending on use
- Initial PROPRIO FOOT limited warranty period: 24 months. Extended warranty is available for purchase. Maximum total warranty period is 5 years (must be purchased within one year of original purchase date)

THE LINK BETWEEN LIMB-LOSS AND FALLS

A study review on amputees' falls shows that up to 40% of their falls result in an injury and every other fall necessitates medical attention. This is higher than the incidence for the non-amputated elderly, which is estimated to be 30%.²

In light of the increased incidence of falls among amputees it is important to consider the overall efficacy of available prosthetic solutions. Prosthetic technology that can decrease fall rate is worth considering both from quality of life and the long-term healthcare cost perspective.

For further information please follow the link below:

https://assets.ossur.com/library/40319/PROPRIO%20FOOT%20Brochure%20-%20White%20paper.pdf



MOBILITY BENEFITS

Product feature	Mid-swing Dorsiflexion	
Mobility benefit	Provides significantly greater toe clearance than fixed ankle-foot systems, decreasing the likelihood of trips and falls.	
Reference	 Active dorsiflexing prostheses may reduce trip-related fall risk in people with transtibia amputation. Rosenblatt, Noah J., et al. Journal of Rehabilitation Research and Development 51.8 (2014): 1229-1242. 	

Product feature	Microprocessor Controlled Plantarflexion and Dorsiflexion		
Mobility benefit	Promotes a more symmetrical gait, decreasing energy expenditure resulting from gait deviations. Significant reductions in energy cost have been shown when walking after 90 days with PROPRIO FOOT vs dynamic carbon feet on flat ground and inclines.		
Reference	3. Symmetry in external work (SEW): A novel method of quantifying gait differences between prosthetic feet. Agrawal, Vibhor, et al. Prosthetics and orthotics international 33.2 (2009): 148-156.		
	4. Assessment of the effects of carbon fibre and bionic foot during overground and treadmill walking in transtibial amputees. Delussu, AS, et al. Gait and Posture (2013).		

Product feature	Microprocessor Controlled Plantarflexion and Dorsiflexion		
Mobility benefit	Improvements in function were shown from the increase in the Amputee Mobility Predictor, alongside an increase in walking speed when using the PROPRIO FOOT in the non-vascular population.		
Reference	 Application of self-report and performance-based outcome measures to determine functional differences between four categories of prosthetic feet. Gailey, R. et al, Journal of Rehabilitation Research and Development (2012): pp.597-612. 		

Product feature	Terrain Adaptation	
Mobility benefit	During stance, stability is affected by the ability of a prosthetic foot to adapt to underlying terrain. PROPRIO FOOT adapts automatically to changes in terrain, providing an ankle position the matches the underlying slope angle, resulting in improved symmetry.	
Reference	 Symmetry in external work (SEW): A novel method of quantifying gait differences between prosthetic feet. Agrawal, Vibhor, et al. Prosthetics and orthotics international 33.2 (2009): 148-156. 	

Product feature	Terrain adaptation: Microprocessor Controlled Plantarflexion	
Mobility benefit	When descending inclines, the foot adjusts to the surface angle, promoting a more natural gait pattern by helping to limit premature knee flexion. Users reported that they felt safer and had better support during roll over with reduced stress at the knee joint.	
Reference	 Biomechanical analysis of ramp ambulation of transtibial amputees with an adaptive ankle foot system. Fradet L, Alimusaj M, Braatz F, Wolf SI. Gait & Posture. 2010; 32(2): 191 - 198. 	



MOBILITY BENEFITS

Product feature	Terrain adaptation: Microprocessor Controlled Dorsiflexion			
Mobility benefit	Increased toe clearance when walking up inclines reduces the need for compensatory gait strategies (e.g. hip hiking, vaulting, circumduction).			
Reference	 Preliminary results of trans-femoral amputees walking with a microprocessor controlled prosthetic foot. Gait & Posture. June 2012; 36 Supplement 1:S9. Heitzmann DWW, Alimusaj M, Braatz F, Wolf SI. Comparison of compensation mechanisms in transfemoral amputees fitted to a conventional energy storing foot versus microprocessor controlled energy storing foot. Lechler K. 2008. 			
Product feature	Terrain Adaptation: Inclines			
Mobility benefit	More physiological knee and hip movement on inclines, providing the user with a more natural gait and reduced socket interface pressures for more comfortable ambulation.			
Reference	 Kinematics and kinetics with an adaptive ankle foot system during stair ambulation of trans-tibial amputees. Gait & Posture. Alimusaj M, Fradet L, Braatz F, Gerner HJ, Wolf SI. 2009; 30:3:356-363. 			

Product feature	Terrain Adaptation		
Mobility benefit	Users reported increased perception of safety in ramp descent due to foot adapting to the surface angle.		
Reference	 Biomechanical analysis of ramp ambulation of transtibial amputees with an adaptive ankle foot system. Fradet L, Alimusaj M, Braatz F, Wolf SI. Gait & Posture. 2010; 32(2 191 - 198. 		
Product feature	Stair Adaptation		

	Stair Adaptation		
Mobility benefit	Individually selected pre-positioned dorsiflexion angle allowing greater foot contact on the step and more natural kinetics and kinematics on the prosthetic side. This reduces compensatory movements and increases comfort and stability for the user.		
Reference	 Kinematics and kinetics with an adaptive ankle foot system during stair ambulation of trans-tibial amputees. Alimusaj M, Fradet L, Braatz F, Gerner HJ, Wolf SI. Gait & Posture. 2009; 30:3:356-363. 		



HEALTH BENEFITS

Product feature	3 blade carbon fibre foot plate design with mid-tapered blade		
Health benefit	Higher peak ankle power for reduced sound side loading compared to the previous PROPRIO FOOT.		
Reference	 Benefits of an increased prosthetic ankle range of motion for individuals with a transtibial amputation walking with a new prosthetic foot. Gait & posture. 2018 Jul 1;64:174-80. Heitzmann DW, Salami F, De Asha AR, Block J, Putz C, Wolf SI, Alimusaj M. Increasing prosthetic foot energy return affects whole-body mechanics during walking on level ground and slopes. Scientific reports. 2018 Mar 29;8(1):5354. Childers WL, Takahashi KZ. 		
Product feature	Relax Mode		
Health benefit	PROPRIO FOOT moves into full plantarflexion when sitting, for improved symmetry and socket comfort (for Transtibial users).		
Product feature	Chair Exit Mode		
Health benefit	PROPRIO FOOT moves into dorsiflexion when exiting a chair, easing the process of standing up and increasing symmetry, reducing the load on the sound side.		

LIFESTYLE BENEFITS

Product feature	Weatherproof, IP34 rated. Fresh water splashing from all angles		
Lifestyle benefit	Patient works/lives in a wet environment: PROPRIO FOOT can withstand splashing of fresh water from all angles, permitting the user to utilise it in a wider range of conditions/ weather/humidity.		
Reference	IFU		
Product feature	Heel height adjustability of up to 5cm		
Lifestyle benefit	Users can change footwear without compromising their alignment, reducing socket forces caused by a misaligned ankle unit when footwear is changed. Provides users with an increased choice of footwear to allow for a wide variety of activities of daily living.		
Product feature	Standby Mode		
Lifestyle benefit	Increases safety when driving by preventing unwanted ankle movements with Standby Mode.		



LIFESTYLE BENEFITS

Product feature	Automatic Cycling Recognition	
Mobility benefit	Allows for safety and stability when cycling by detecting the cyclic movement of the pedals and disabling motor movements.	

OUTCOME MEASURES

Outcome measures are used by health care professionals to help determine the patient's baseline function and progression throughout rehabilitation and beyond. They are an important tool to utilise to provide credible and reliable justification for treatment and reimbursement.

This table outlines examples of validated outcome measures used in practice to objectively determine function, progress and treatment efficacy.

Outcome Measures	Use	Reference
6 Minute Walk Test	General Mobility	Kenneth H. Cooper, MC. A Means of Assessing Maximal Oxygen Intake Correlation Between Field and Treadmill Testing. JAMA. 1968;203(3):201-204.
Amputee Mobility Predictor	Amputee Function	Gailey RS, et al. The Amputee Mobility Predictor: an instrument to assess determinants of the lower-limb amputee ability to ambulate. Arch Phys Med Rehabil 2002;83:613-27.
ABC	Balance/Confidence	Powell LE, Myers AM. The Activities-Specific Balance Confidence (ABC) Scale. The Journals of gerontology. Series A, Biological sciences and medical sciences. 1995; 50A (1):M28-34.
PEQ-MS	Prosthetic Function and Satisfaction	Franchignoni, et al. Measuring mobility in people with lower limb amputation: Rasch analysis of the mobility section of the prosthesis evaluation questionnaire. J Rehabil Med 2007: 39(2):138-144.
TAPES-R	Prosthetic Function and Satisfaction	Gallagher et al. Trinity amputation and prosthesis experience scales: a psychometric assessment using classical test theory and rasch analysis. American Journal of Physical Medicine and Rehabilitation. 2010; 89(6): 487-96.
Timed Up and Go	Fall Risk	Podsiadlo S. Richardson S. The timed "Up & Go": a test of basic functional mobility for frail elderly persons. Journal of the American Geriatrics Society. 1991; 39(2):142-148.
L-Test	Fall Risk	Deathe AB, Miller WC. The L test of functional mobility: measurement properties of a modified version of the timed up and go test designed for people with lower-limb amputations.



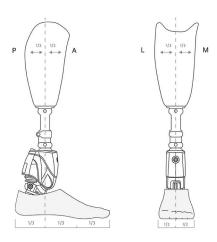
OUTCOME MEASURES

Outcome Measures	Use	Reference
LCI	Prosthetic Use	Grise MC. Gauthier-Gagnon C. Prosthetic profile of people with lower extremity amputation: concept of a follow up questionnaire. Arch Phys Med Rehabil 1993: 74(8):862-70.
Oswestry Disability Index	Lower Back Pain	Fairbank JCT, Pynsent PB. The Oswestry Disability Index. 2000; Spine, 25(22); 2940-2953.
wwWOMAC	OA in Hip or Knee	Western Ontario and McMaster Osteoarthritis Index.
SFCS	Socket Fit	Hanspal RS, Fischer K, Nieveen R. Prosthetic Socket Fit Comfort Score Disability Rehabilitation 2003: 25(22):1278-80.
PLUS-M	Mobility	Morgan, Sara J., et al. "Use of cognitive interviews in the development of the PLUS-M item bank." Quality of Life Research 23.6 (2014): 1767-1775.

PRODUCT INFORMATION

- PROPRIO FOOT Brochure: https://assets.ossur.com/library/40394/PROPRIO%20FOOT%20Brochure%20-%20.pdf
- PROPRIO FOOT White Paper: <u>https://assets.ossur.com/library/40319/PROPRIO%20FOOT%20Brochure%20-%20White%20paper.pdf</u>
- Instructions for Use: https://assets.ossur.com/library/40128/PROPRIO%20FOOT%20Instructions%20for%20use%20-%20IFU.pdf

RECOMMENDED FITTING SEQUENCE FOR PROPRIO FOOT



- 1. Turn ON
- 2. Establish connection with Össur Logic
- 3. Ankle alignment (with shoe)
- 4. Bench alignment
- 5. Static alignment
- 6. Dynamic alignment
- 7. Auto-Adjustment
- 8. Relax / Chair exit mode
- 9. Stair adaptation
- **10.** Ramp adaptation
- 11. Standby

FOLLOW UP CONSIDERATIONS/MAINTENANCE REQUIREMENTS

Initial PROPRIO FOOT limited warranty period: 24 months. Extended warranty is available for purchase, contact Össur Customer Service for options and prices.

Maximum total warranty period is 5 years (must be purchased within one year of original purchase date).

Össur provides support to the customer with loaner units if any repairs or maintenance are required.

REFERENCES

- 1. Active dorsiflexing prostheses may reduce trip-related fall risk in people with transtibial amputation. Rosenblatt, Noah J., et al. Journal of Rehabilitation Research and Development 51.8 (2014): 1229-1242.
- Risk factors and costs associated with accidental falls among adults with above-knee amputations: a
 population based study. Kaufman, K. American Orthotic and Prosthetic Association 2016. (Mayo Clinic).
 http://www.aopanet.org/resources/research
- **3.** Symmetry in external work (SEW): A novel method of quantifying gait differences between prosthetic feet. Agrawal, Vibhor, et al. Prosthetics and orthotics international 33.2 (2009): 148-156.
- 4. Assessment of the effects of carbon fibre and bionic foot during overground and treadmill walking in transtibial amputees. Delussu, AS, et al. Gait and Posture (2013).
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- 6. Biomechanical analysis of ramp ambulation of transtibial amputees with an adaptive ankle foot system. Fradet L, Alimusaj M, Braatz F, Wolf SI. Gait & Posture. 2010; 32(2): 191 - 198.
- 7. Preliminary results of trans-femoral amputees walking with a microprocessor controlled prosthetic foot. Gait & Posture. June 2012; 36 Supplement 1:S9. Heitzmann DWW, Alimusaj M, Braatz F, Wolf Sl.
- 8. Comparison of compensation mechanisms in transfemoral amputees fitted to a conventional energy storing foot versus microprocessor controlled energy storing foot. Lechler K. 2008
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- Benefits of an increased prosthetic ankle range of motion for individuals with a trans-tibial amputation walking with a new prosthetic foot. Gait & posture. 2018 Jul 1;64:174-80. Heitzmann DW, Salami F, De Asha AR, Block J, Putz C, Wolf SI, Alimusaj M.
- 11. Increasing prosthetic foot energy return affects whole-body mechanics during walking on level ground and slopes. Scientific reports. 2018 Mar 29;8(1):5354. Childers WL, Takahashi KZ.



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