

# PROPRIO FOOT®

**IOSSUR** 

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Reimbursement Support

# PROPRIO FOOT<sup>®</sup> PRODUCT FEATURES

The PROPRIO FOOT has been redesigned to enhance the safety and stability features of the original design. It features a Pro-Flex<sup>®</sup> 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<sup>1</sup>.

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%.<sup>2</sup>

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        | <ol> <li>Active dorsiflexing prostheses may reduce trip-related fall risk in people with<br/>transtibial amputation. Rosenblatt, Noah J., et al. Journal of Rehabilitation<br/>Research and Development 51.8 (2014): 1229-1242.</li> </ol> |  |  |

| Product feature  | Microprocessor Controlled Plantarflexion and Dorsiflexion  |  |  |  |
|------------------|--|--|--|--|
| Mobility benefit | Promotes a more symmetrical gait, decreasing energy expenditure resulting from gait<br>deviations. Significant reductions in energy cost have been shown when walking after<br>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<br>Predictor, alongside an increase in walking speed when using the PROPRIO FOOT in<br>the non-vascular population.   |  |  |
| Reference        | <ol> <li>Application of self-report and performance-based outcome measures to detern<br/>functional differences between four categories of prosthetic feet. Gailey, R. et a<br/>Journal of Rehabilitation Research and Development (2012): pp.597-612.</li> </ol> |  |  |

| Product feature  | Terrain Adaptation  |  |  |
|------------------|---|--|--|
| Mobility benefit | During stance, stability is affected by the ability of a prosthetic foot to adapt to underlyi terrain. PROPRIO FOOT adapts automatically to changes in terrain, providing an ankle position the matches the underlying slope angle, resulting in improved symmetry. |  |  |
| 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.   |  |  |

| Product feature  | Terrain adaptation: Microprocessor Controlled Plantarflexion   |  |  |
|------------------|--|--|--|
| Mobility benefit | When descending inclines, the foot adjusts to the surface angle, promoting a more<br>natural gait pattern by helping to limit premature knee flexion. Users reported that the<br>felt safer and had better support during roll over with reduced stress at the knee joint. |  |  |
| Reference        | 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.  |  |  |



# 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        | <ol> <li>Preliminary results of trans-femoral amputees walking with a microprocessor<br/>controlled prosthetic foot. Gait &amp; Posture. June 2012; 36 Supplement 1:S9.<br/>Heitzmann DWW, Alimusaj M, Braatz F, Wolf SI.</li> </ol> |  |  |  |
|                  | 8. 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        | <ol> <li>Kinematics and kinetics with an adaptive ankle foot system during stair ambulation<br/>of trans-tibial amputees. Gait &amp; Posture. Alimusaj M, Fradet L, Braatz F, Gerner<br/>HJ, Wolf SI. 2009; 30:3:356-363.</li> </ol> |  |  |  |

| Product feature  | Terrain Adaptation   |  |  |
|------------------|--|--|--|
| Mobility benefit | Users reported increased perception of safety in ramp descent due to foot adapting to the surface angle.   |  |  |
| Reference        | 3. 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   |  |  |
| Mobility benefit | Individually selected pre-positioned dorsiflexion angle allowing greater foot contact<br>on the step and more natural kinetics and kinematics on the prosthetic side. This<br>reduces compensatory movements and increases comfort and stability for the user. |  |  |
| Reference        | <ol> <li>Kinematics and kinetics with an adaptive ankle foot system during stair ambulation<br/>of trans-tibial amputees. Alimusaj M, Fradet L, Braatz F, Gerner HJ, Wolf SI. Gait<br/>&amp; Posture. 2009; 30:3:356-363.</li> </ol>                           |  |  |



# 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       | <ol> <li>Benefits of an increased prosthetic ankle range of motion for individuals with a trans-tibial amputation walking with a new prosthetic foot. Gait &amp; posture. 2018 Jul 1;64:174-80. Heitzmann DW, Salami F, De Asha AR, Block J, Putz C, Wolf SI, Alimusaj M.</li> <li>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.</li> </ol> |  |  |
| 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  |  |  |
|                 | · · · · · · · · · · · · · · · · · · ·  |  |  |

# 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<br>socket forces caused by a misaligned ankle unit when footwear is changed.<br>Provides users with an increased choice of footwear to allow for a wide variety of<br>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<br>Oxygen Intake Correlation Between Field and Treadmill<br>Testing. JAMA. 1968;203(3):201-204.   |
| Amputee Mobility<br>Predictor | Amputee Function                        | Gailey RS, et al. The Amputee Mobility Predictor: an<br>instrument to assess determinants of the lower-limb<br>amputee ability to ambulate. Arch Phys Med Rehabil<br>2002;83:613-27.  |
| АВС                           | Balance/Confidence                      | Powell LE, Myers AM. The Activities-Specific Balance<br>Confidence (ABC) Scale. The Journals of gerontology. Series<br>A, Biological sciences and medical sciences. 1995; 50A<br>(1):M28-34.  |
| PEQ-MS                        | Prosthetic Function<br>and Satisfaction | Franchignoni, et al. Measuring mobility in people with lower<br>limb amputation: Rasch analysis of the mobility section of<br>the prosthesis evaluation questionnaire. J Rehabil Med 2007:<br>39(2):138-144.                            |
| TAPES-R                       | Prosthetic Function<br>and Satisfaction | Gallagher et al. Trinity amputation and prosthesis experience<br>scales: a psychometric assessment using classical test theory<br>and rasch analysis. American Journal of Physical Medicine<br>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:<br>measurement properties of a modified version of the timed<br>up and go test designed for people with<br>lower-limb amputations.   |



#### OUTCOME MEASURES

| Outcome Measures             | Use               | Reference  |
|------------------------------|-------------------|--|
| LCI                          | Prosthetic Use    | Grise MC. Gauthier-Gagnon C. Prosthetic profile of people<br>with lower extremity amputation: concept of a follow up<br>questionnaire. Arch Phys Med Rehabil 1993: 74(8):862-70. |
| Oswestry Disability<br>Index | Lower Back Pain   | Fairbank JCT, Pynsent PB. The Oswestry Disability Index.<br>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<br>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: <u>https://assets.ossur.com/library/40128/PROPRIO%20FOOT%20Instructions%20for%20use%20-%20IFU.pdf</u>

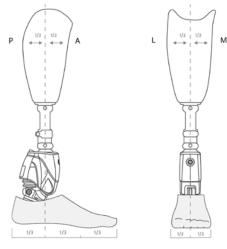
# RECOMMENDED TREATMENT PATHWAY AND ESSENTIAL STEPS

Trial units may be requested by the clinical facility and utilised with clients for up to 3 weeks.

Clinicians are instructed to contact Customer Service for availability and details.

Please see also the AOPA accredited course for the PROPRIO FOOT: https://www.aopa.org.au/events/event/ossur-proprio-foot-course

# RECOMMENDED FITTING SEQUENCE FOR PROPRIO FOOT



**ÖSSUR**®

- 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). <u>http://www.aopanet.org/resources/research</u>
- **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).
- 5. 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.
- 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 SI.
- 8. Comparison of compensation mechanisms in transfemoral amputees fitted to a conventional energy storing foot versus microprocessor controlled energy storing foot. Lechler K. 2008
- 9. 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.
- 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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