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ÖSSUR®
LIFE WITHOUT LIMITATIONS

Össur Legs: Optimising Mobility Outcomes with Complete Solutions

Sarah Mulroy-Lang – Senior Clinical Specialist

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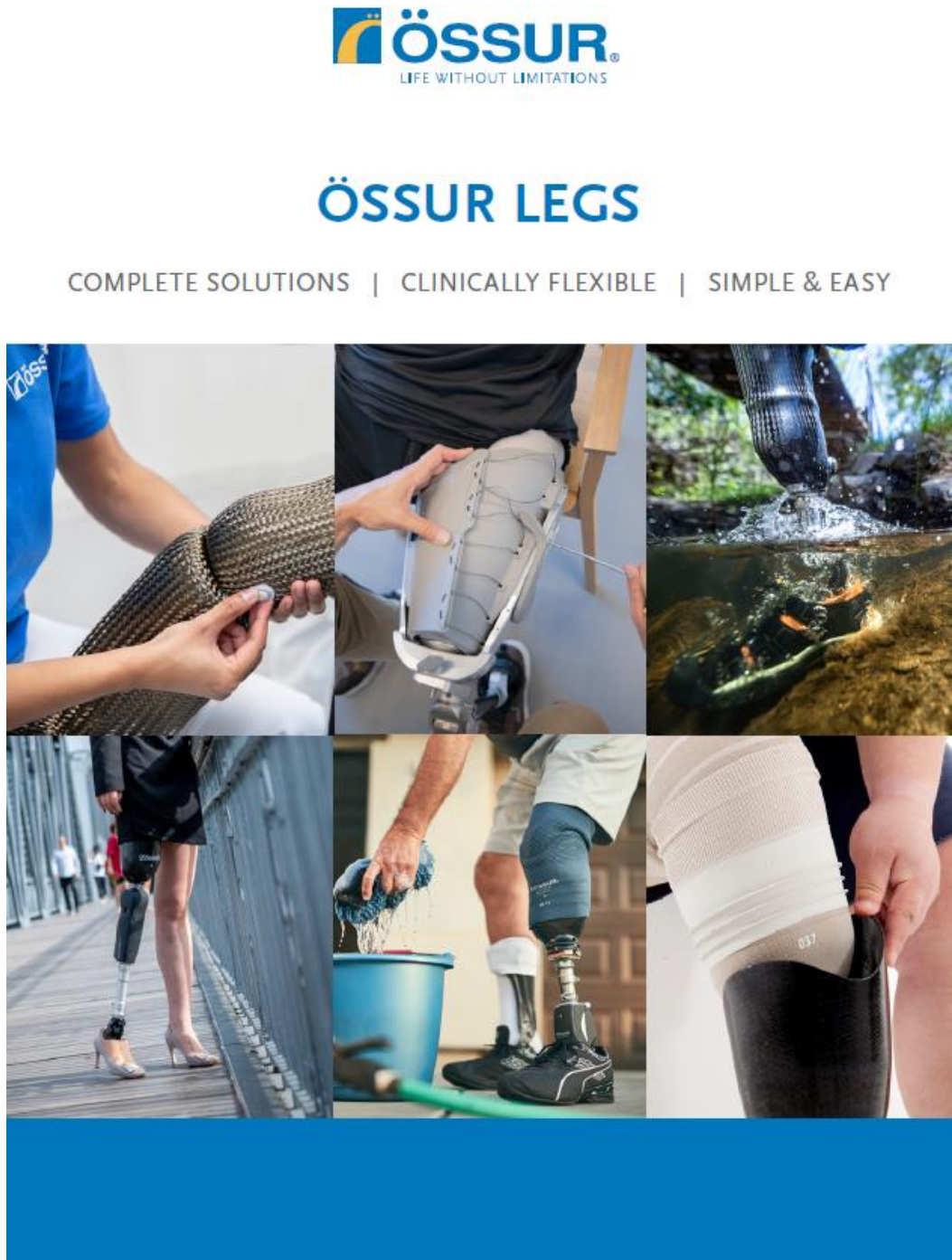
Össur Legs - Complete Solutions

- Commencing in January 2022 we will be launching the Össur legs program
- Össur legs program allows you to quick and easily configure a complete and clinically appropriate solution to meet your clients needs
- Össur Legs program incorporates all of Össur's Mechanical and Bionic products, including Direct Socket and Connect TF socket solutions
- It features digital order forms for a fast and efficient ordering service



Why Össur Legs?: Complete solutions addressing the needs of clients and clinicians

TRANSTIBIAL LEG SOLUTIONS

- Complete range of complementary solutions
- Uncompromised quality
- Expedited fitting capability
- Flexible and fast ordering & service processes

TRANSFEMORAL LEG SOLUTIONS

For Clients

For Clinicians & Workshops

Complete Solutions: Impact Levels

IMPACT LEVELS

LOW
Daily activities involving gentle, steady walking with the use of a walking aid.

Example: Moving around at home, modest walking in the community.

MODERATE
Daily activities involving average walking with the ability to vary speed or walking pattern.

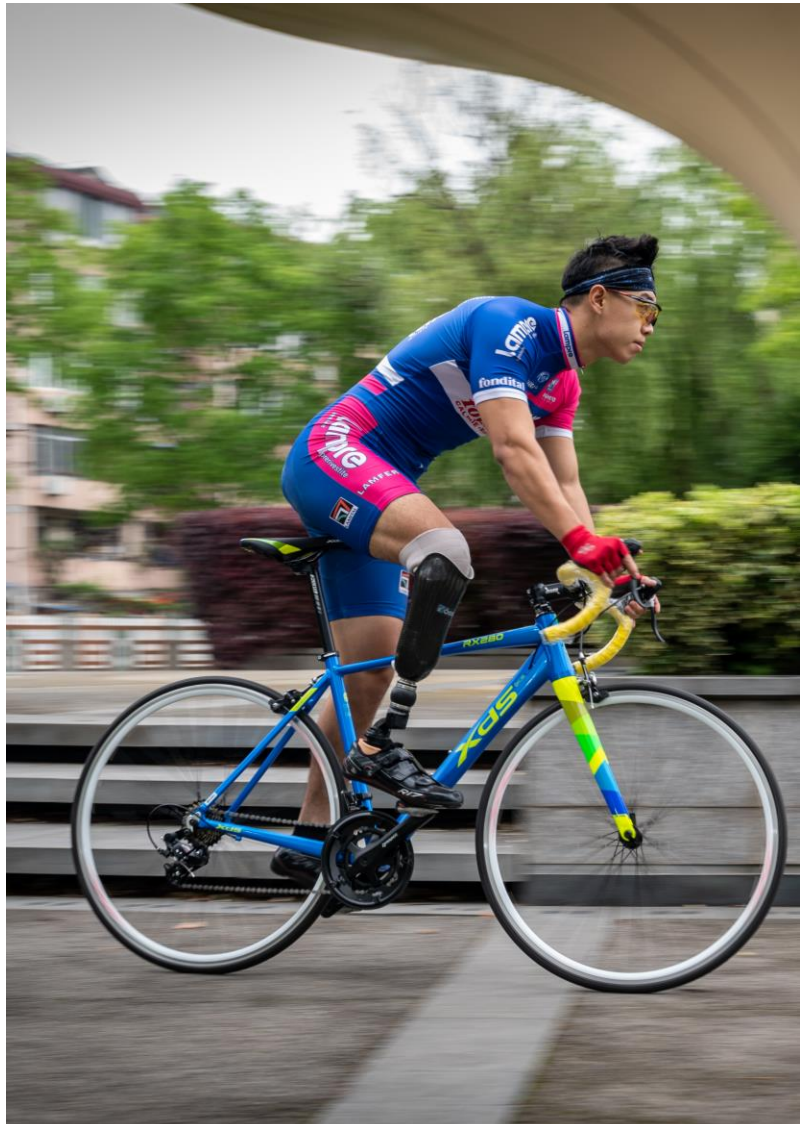
Example: Going to the shops, confident outdoor walking.

HIGH
Daily activities involving fast walking, jogging and climbing stairs.

Example: Heavy-lifting, manual labor, recreational sports.

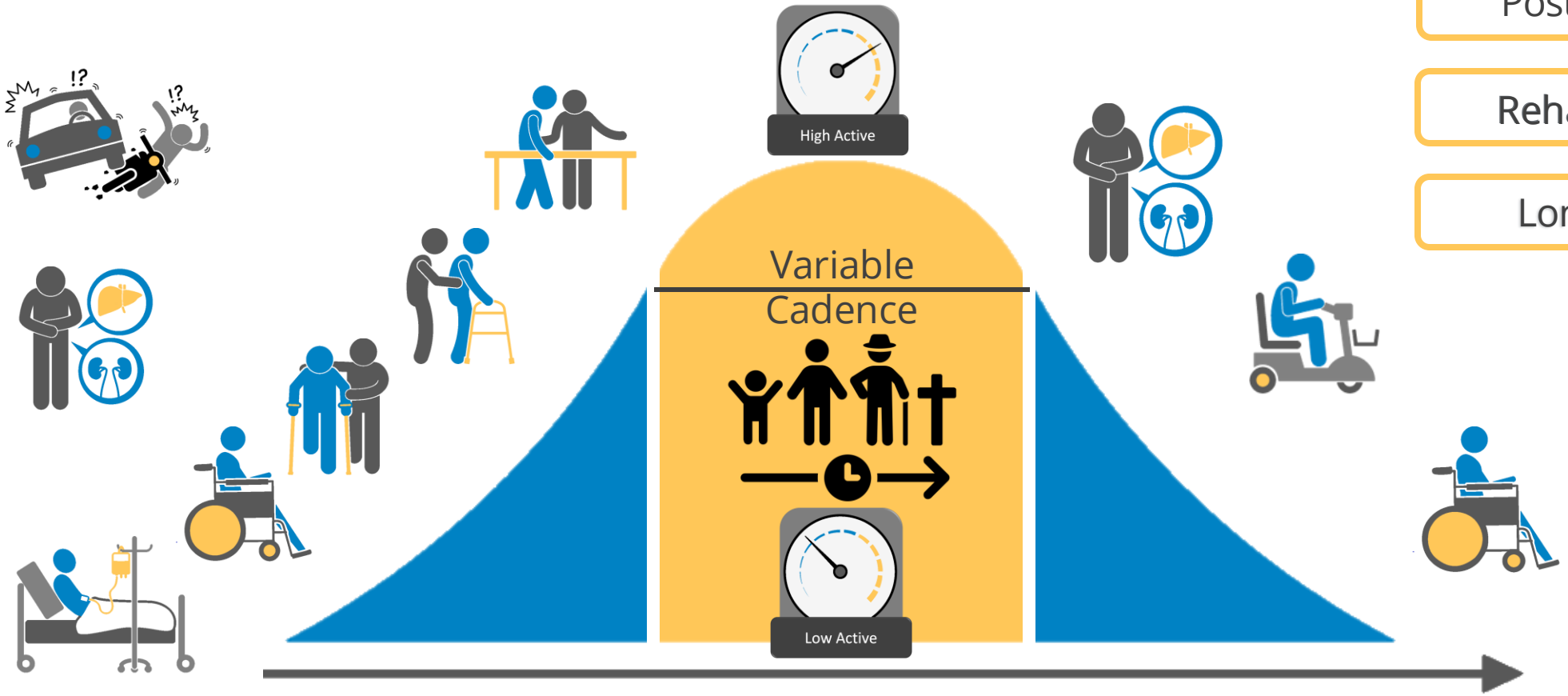
EXTREME
Activities involving running, track and field, sprinting, and long-distance running.

Example: Track and field sports.



Complete Solutions – The Journey

Aim: Improve clinical outcomes, increase efficiency, and patient satisfaction



Post-Op Care

Rehabilitation

Long-Term

Low Active User Profile

Low active prosthetic users have different needs and wants from their prosthesis compared to the active amputee

Comfort

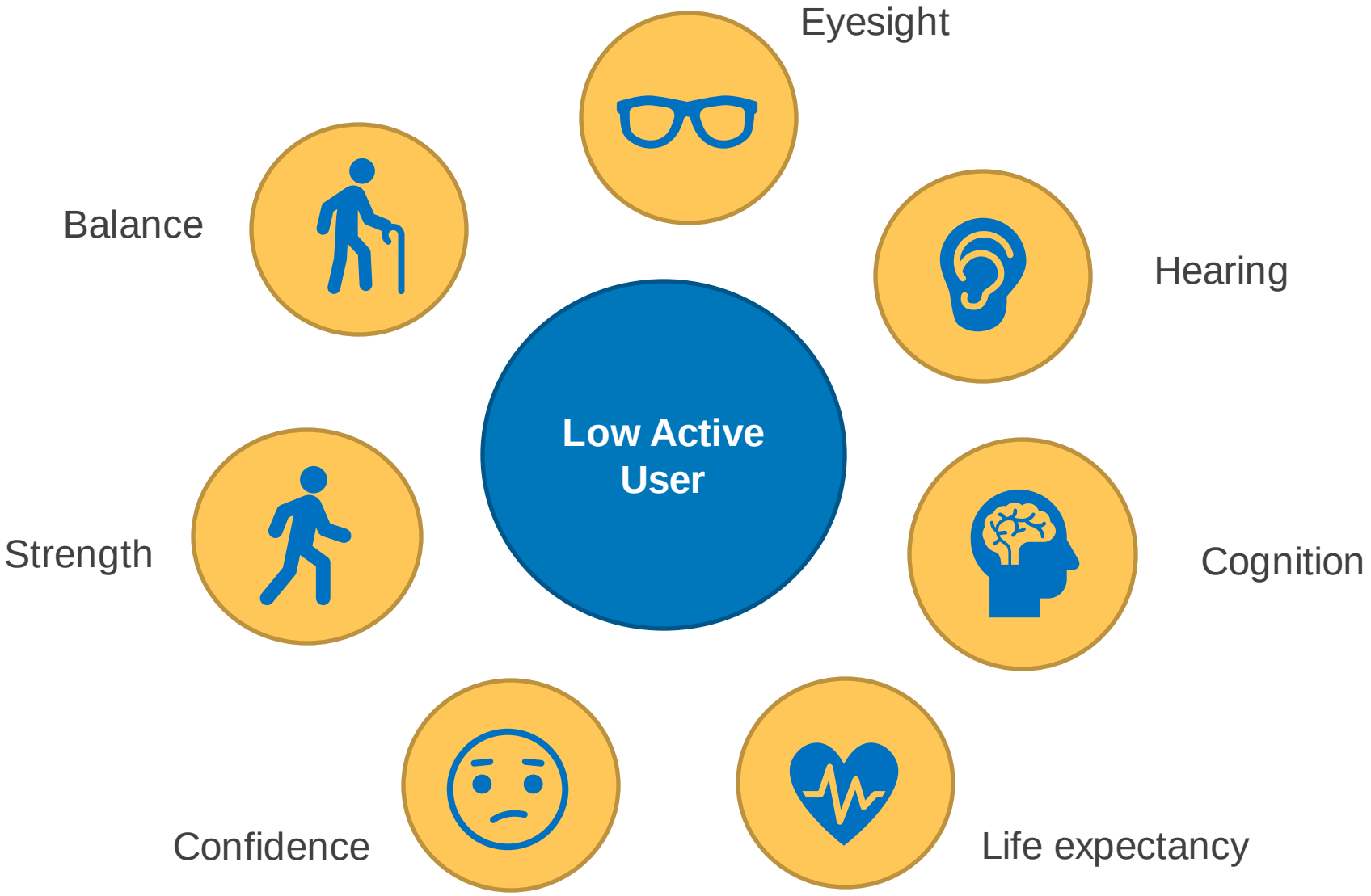
Safety

Mobility

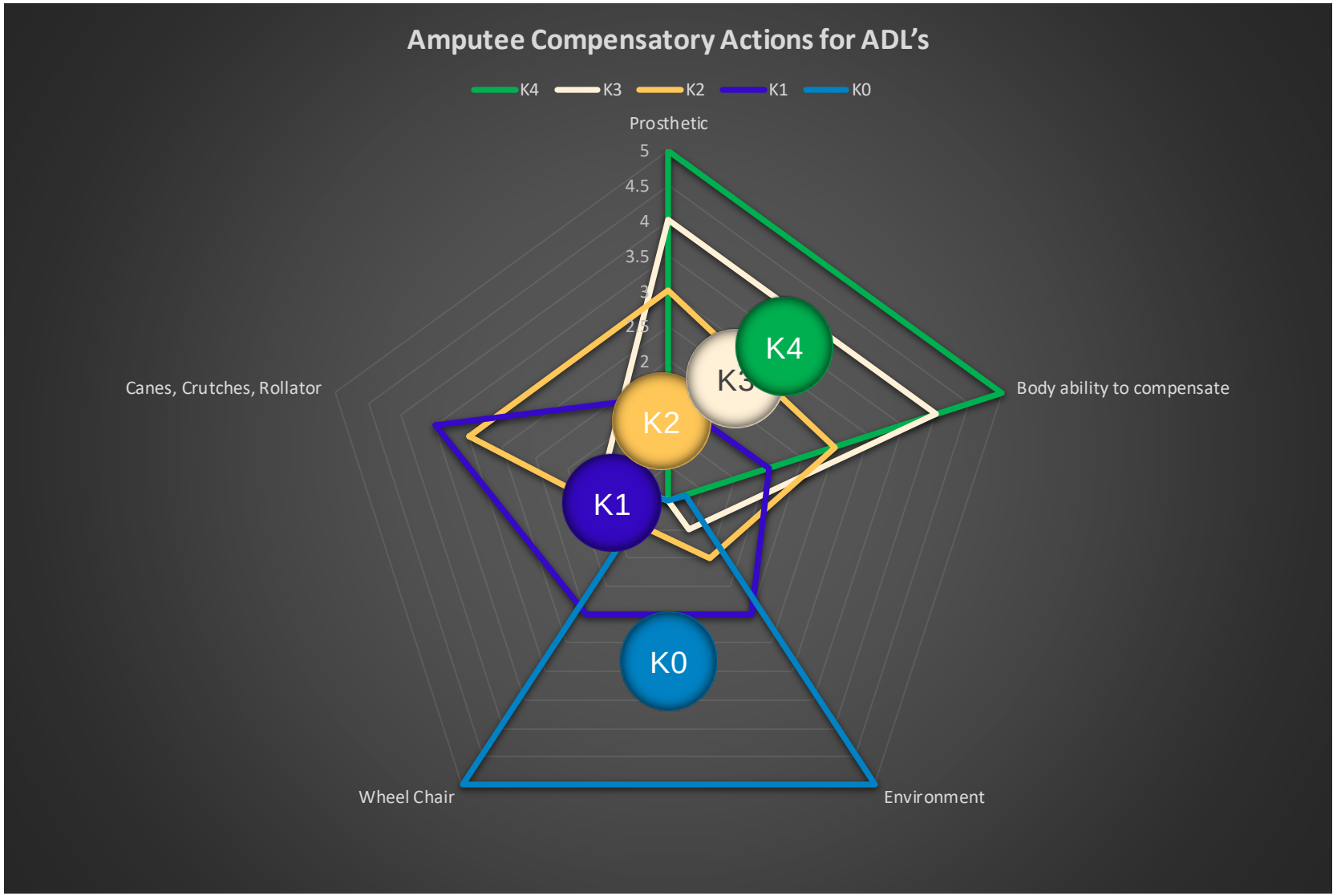
- They also have a different set of mobility goals

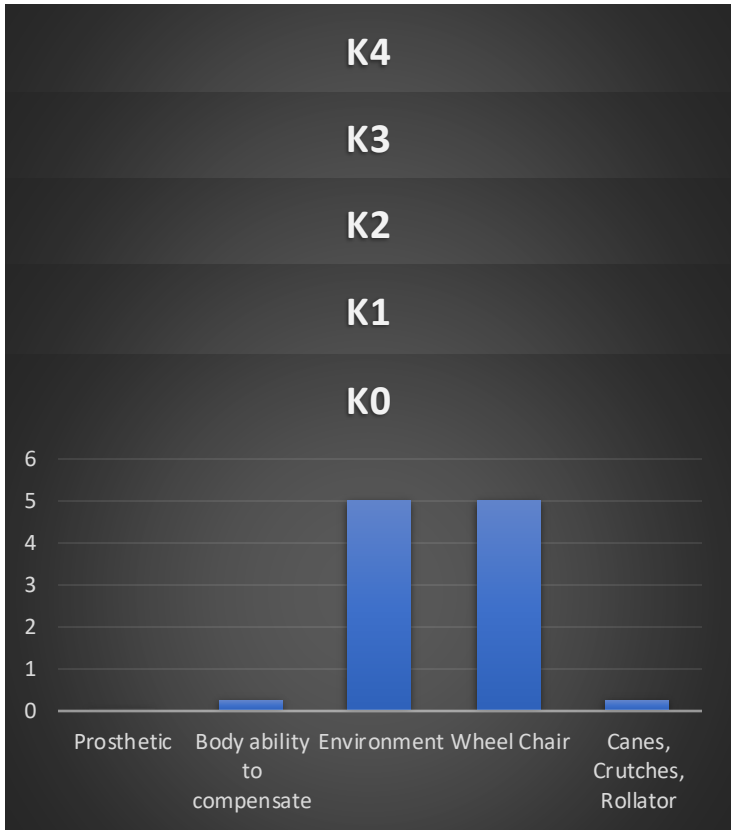
- Getting that balance right can mean
  - greater independence
  - increased confidence
  - increase in both the frequency & safety of transfers and ambulation

Low Active User – Challenges



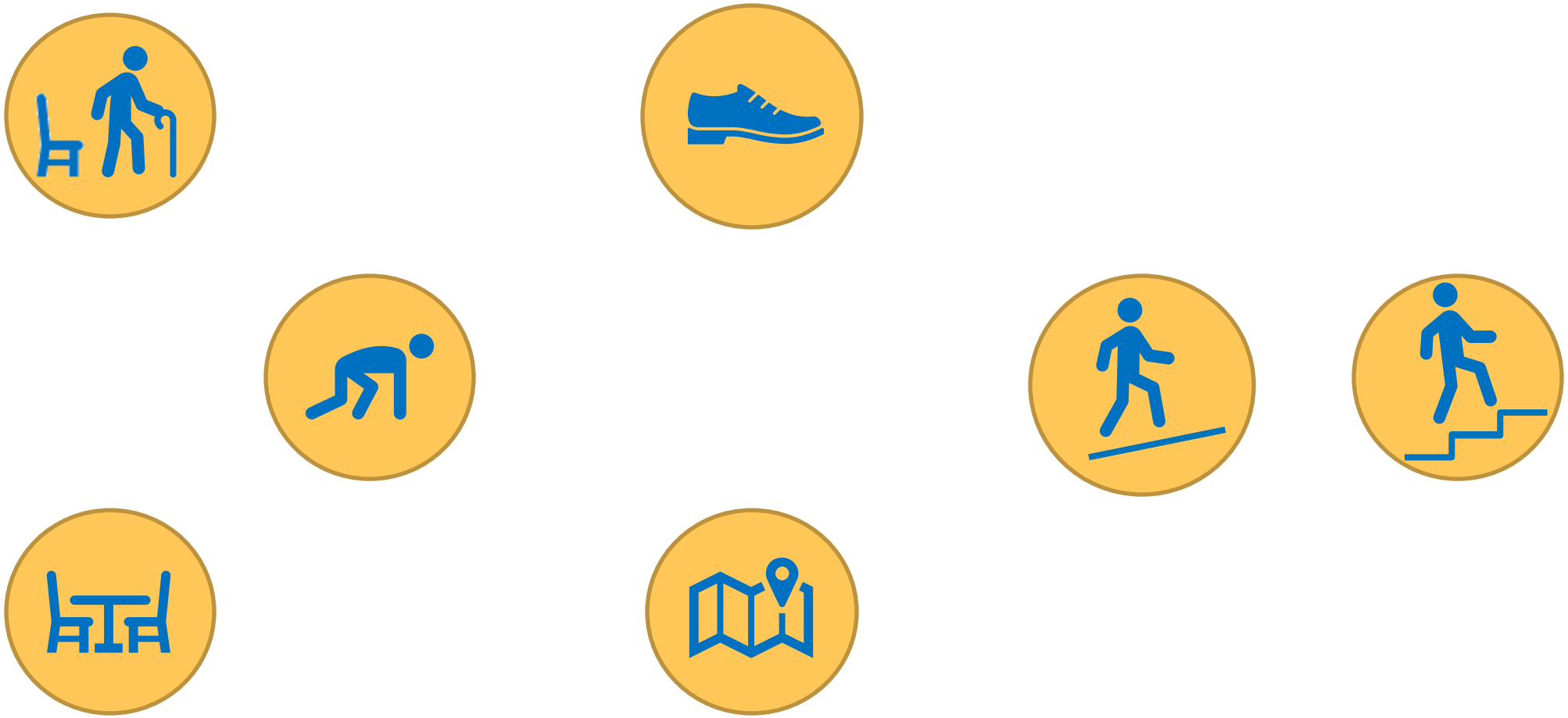
Medical Necessity – Internal Research





Low Active User - Challenges

Low Active User - Challenges



Low activity user

Moderate activity user

Low Activity Solutions - Transtibial

Dave has type 2 diabetes and has spent the last 2 years hoping that the ulcer on his foot would heal, but the wound persisted.

He's been using a wheelchair for the past 8 months since a partial foot amputation which also refused to heal, and his fitness has declined

Dave recently underwent a transtibial amputation

Low Activity Solutions - Transtibial

- 54 year old male
- Diabetic Ulcer
- Fishing, gardening, outdoor bowling, active fundraiser
- Former military, very eager, ulcer and pain in sound foot,
- Goals: Reduce his wheelchair use, get back to bowling, K2-K3 potential

Low Activity Solutions – Direct Socket

Direct Socket is a **standardised**, **efficient** and **repeatable** socket solution for TT amputees

- Reduces patient visits
- Reduces labour hours
- Ability to use **all suspension options**
- Suitable for all **activity levels**
- Rated to **166kg**

Low Activity Solutions – Direct Socket

Basalt, Glass and Carbon options

- Fabricate in under 2 hours
- **Accurate anatomical fitting** utilising Icecast
- Consistent and repeatable results between clinicians
- User is seated when manufactured
  - **Safe & efficient process** done directly on client.
  - Fit same day possible – ideal for patients with volume fluctuations
- Compatible with, Locking, Cushion, Seal –In and Unity Elevated Vacuum

Low Activity Solutions – Iceross Dermo Locking

Iceross Dermo Locking Liner

- Softest durometer of silicone
- Ideal for vascular users or those with sensitive skin
- Features:
  - Active Skin care
  - Silken Inner surface
  - Conforms well to complex shapes
  - Ultra-Elastic textile for improved fit

Low Activity Solutions – Icelock 214

Icelock 214

- Attach to the Direct Socket
- Clutch mechanism provide easy and secure wind-down donning and easy release
- Can be donned in sitting
- Durable and strong, tested to tolerate at least 300kg of pull

Low Activity Solutions – Balance Foot S Torsion

Balance Foot S Torsion

C-Shaped Glass Fibre Foot

Cushioning heel foam

Smooth Roll Over

Gentle energy return

Balance and Stability

WATERPROOF

Waterproof design

Low Active Solutions – Balance Foot S Torsion

Torsion version provides shock absorption and rotation → Reduces shear forces and stress on residual limb

PERMITTED ROTATION AND SHOCK MOVEMENTS REDUCE SHEAR STRESS

- Twiste M. Transverse rotation and longitudinal translation during prosthetic gait – A literature review. Journal of Rehabilitation, 2003; 40: 9-18

LOWER SHEAR STRESSES → REDUCED DISCOMFORT

- Segal AD, et al. Transtibial amputee joint rotation moments during straight-line walking and a common turning task with and without a torsion adapter. Journal of Rehabilitation R&D. 2009 46:375-384

SELF PERCEIVED PAIN REDUCTION

- Segal AD, et al. Does a Torsion Adapter Improve Functional Mobility, Pain and Fatigue in Patients with Transtibial Amputation? Clin Orthop Relat Res 2014 472:3085–3092

REDUCED SHEAR STRESS

- Heitzmann D, et al. Functional effects of a prosthetic torsion adapter in transtibial amputees during unplanned spin and step turns. Prosthet Orthot Int 2015; 1-8.

Low Activity Solutions - Summary

- Direct Socket provides TSB socket and manufactured quickly
- Iceross Dermo locking liner provides cushioning and protection
- Icelock 214 provides secure mechanical lock
- Balance Foot S Torsion combines stability, shock and rotation and a smooth roll over, providing balance and safety for the low active user

Low Activity Solutions: Alternative Prescription

- Iceross Dermo Cushion Liner
  - Provides cushioning and protection for sensitive residual limbs
- Iceform sleeve
  - Easy Donning for users with compromised hand dexterity
- Can be used with Direct Socket, with 511 or 544 expulsion valves

- Suitable for interim use, simple to manage volume changes with socks

Low Activity Solutions: Alternative Prescription

C-Shaped Glass Fibre Foot

+

Cushioning heel foam

↓

Smooth Roll Over

↓

Gentle energy return

↓

Balance and Stability

WATERPROOF

Waterproof design

Alternative Foot Considerations: Low Activity Solutions

Balance Foot

- Balance Foot is lightweight, multi-axial foot for low activity users
- Provides balance comfort and stability
- Single, slow speed walking, with step to gait

DP Flexion

- Hydraulic ankle with adjustable resistance to plantar and dorsiflexion.
- Range of 18°, for adaptability on uneven terrain
- Provides 4° swing dorsiflexion for clearance in swing, increasing toe clearance to reduce trips and falls

Balance Foot J

- J shaped Carbon keel provides good roll over characteristics
- Polyurethane cushioned heel strike benefits users struggling with heel strike and getting into midstance
- New amputees and slow speed walkers

Flex-Foot Assure

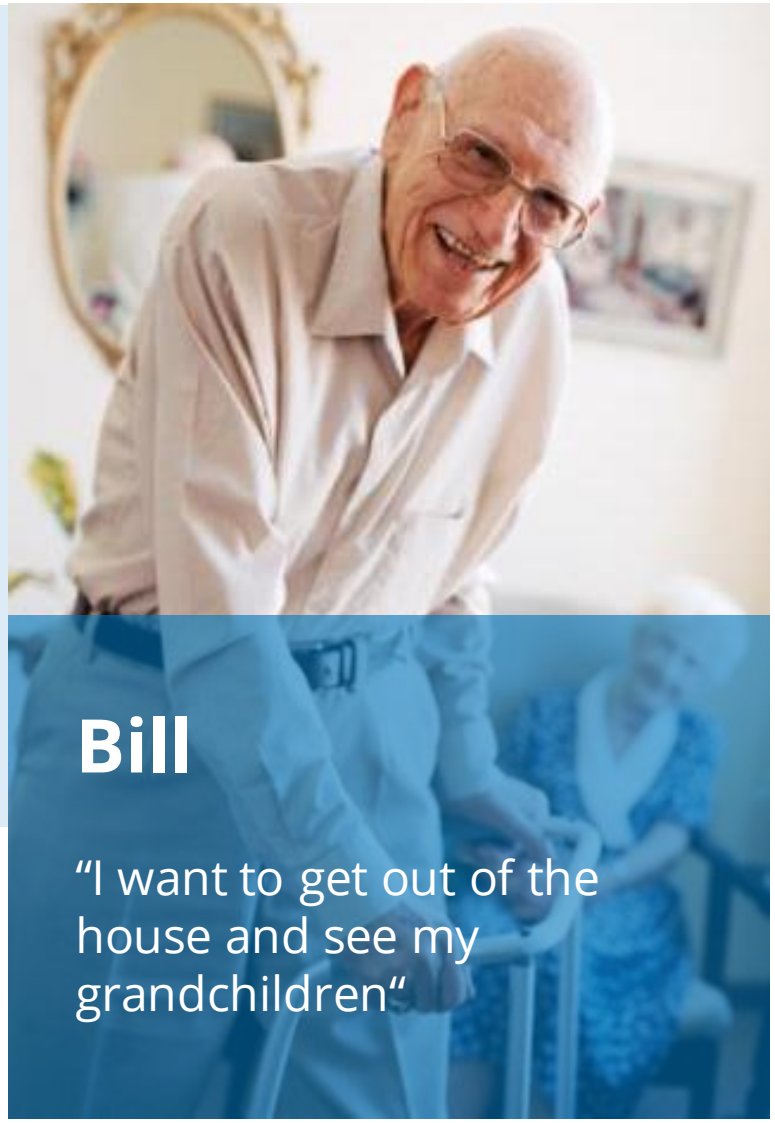
- J Shaped Carbon keel provides full length toe lever
- Active Carbon heel for shock absorption
- Heel wedge enables a slower energy return to accommodate slower walking speeds

Low Activity Solutions - Transfemoral

Bill has been unwell for a while and has recently undergone a transfemoral amputation due to PVD

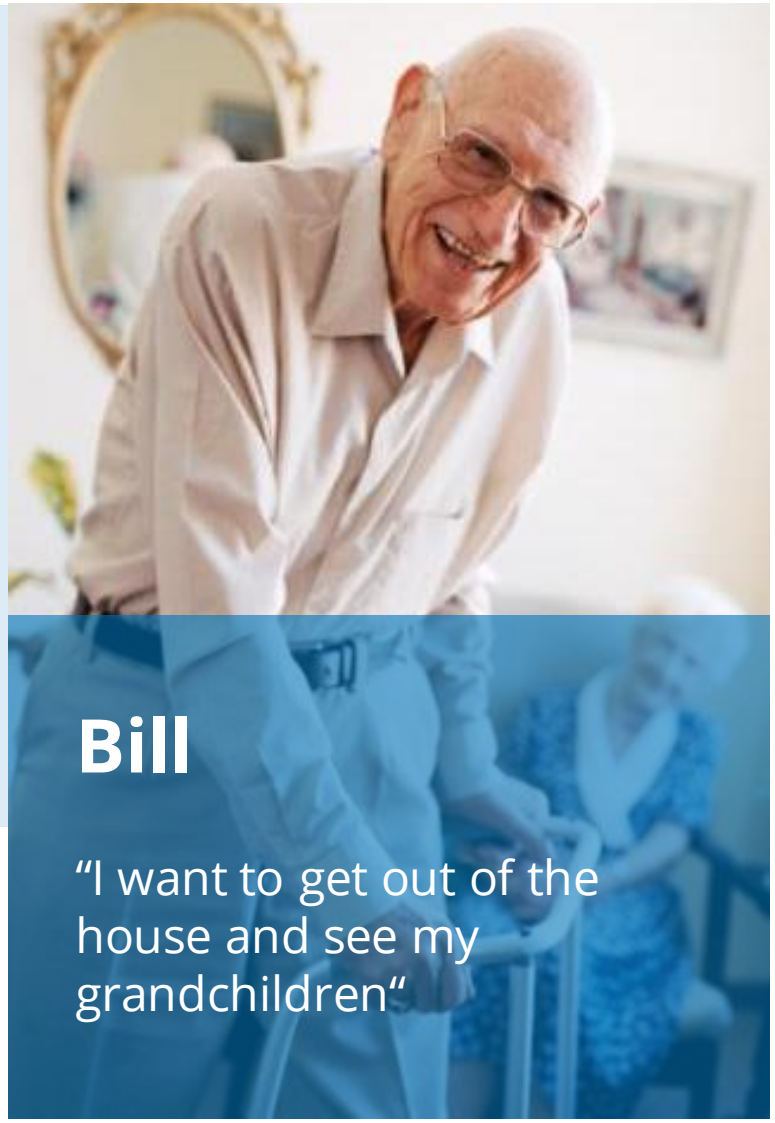
His wife, Kathryn is his main carer and helps Bill with most daily tasks since his recent amputation.

Bill wants to be able to make Kathryn cups of tea and slow dance again



Low Activity Solutions - Transfemoral

- 78 year old male
- Vascular Disease
- Meeting friends at the RSL, Community outings
- Lacks confidence, low energy
- Goals: Limited ambulation, play with grandchildren, K2



Low Activity Solutions – Connect TF

Connect TF

- Adjustable prosthetic socket solution
- Can be custom fit in a single session
- Height and volume adjustable
- Can be donned and doffed in sitting
- Designed to be comfortable whilst sitting and standing

Low Activity Solutions – Connect TF

Connect TF

Safety

- Don in sitting
- Mechanical clutch lock suspension

Comfortable

- Flexible socket brim
- Very comfortable when sitting
- Tension handle can be released in sitting

Ease of Use

- Easy for user of carer to don prosthesis
- Easy to clean - waterproof

Low Activity Solutions – Connect TF

Connect TF – Benefits:

- Beneficial for use in early rehab
  - Can be adjusted to accommodate changes in volume
- K1 users who may not be considered suitable for a prosthesis
  - Can be fit with a Connect TF socket whilst in sitting
  - Can try a comfortable socket solution and assess prosthetic suitability

Low Activity Solutions – Iceross TF Locking Liner

- **Iceross TF Locking Liner**
- Provides firm suspension and soft tissue stabilisation
- Durable fabric cover allows for radial stretch and comfortable elasticity
- Recommended for use with Connect TF or Icelock 200 series

Low Activity Solutions – Balance Knee OFM1

- **Balance Knee OFM1**
  - K-Level 1 and 2
  - Maximum user weight 136Kg
  - 4 bar geometry for stance phase stability
  - Mid-swing shortening for toe clearance
  - Optional locking mechanism

Indications:

- Household ambulators
- Limited community ambulators
- Users in transition between these levels
- Long residual limbs
- Benefit from shock absorption from optional Stance Flexion adapter

Low Activity Solutions – Balance Knee OFM1

- **Balance Knee OFM1**

- Optional locking mechanism-
  - users with low voluntary control or use in early rehab
- Adjustable integrated extension spring
  - Optimise extension speed for the user
  - Adjustable axis friction setting

Contraindications:

- Users capable of varying their walking speeds
- Unable to fully extend the knee

Low Activity Solutions – Balance Foot S

C-Shaped Glass Fibre Foot

+

Cushioning heel foam

↓

Smooth Roll Over

↓

Gentle energy return

↓

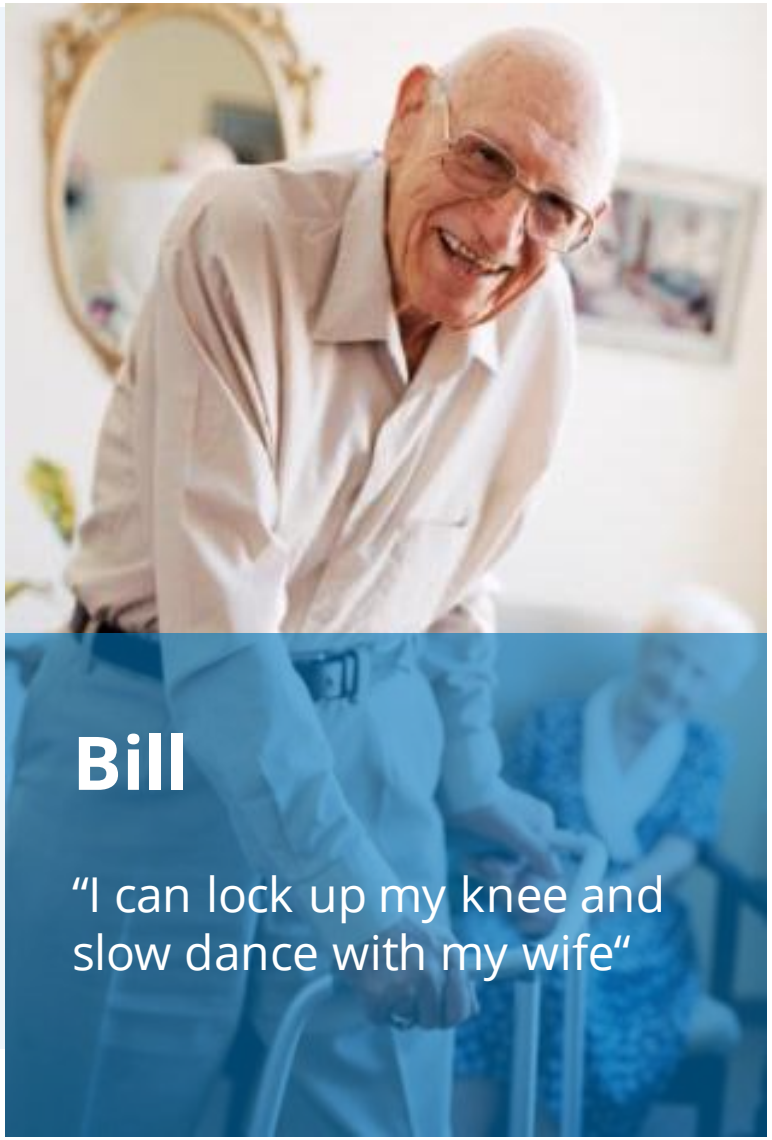
Balance and Stability

WATERPROOF

Waterproof design

Low Activity Solutions - Transfemoral

- Connect TF is adjustable, can be donned in sitting and provides a comfortable socket solution
- Iceross TF Locking liner provides soft tissue stabilisation and secure suspension
- Balance Knee OFM1 provides geometric stability in stance, mid swing shortening for toe clearance and an optional lock for use in early rehab
- Balance Foot S combines stability, and a smooth roll over, providing balance and safety for the low active user



Low Activity Solutions – Alternative Prescription

Balance Knee OFM2

- Features:
  - Adjustable weight activated brake
  - Individual adjustable stance safety
  - Knee will remain stiff even when loading a flexed knee
  - Once fully unloaded the brake mechanism is released and the knee will swing freely
  - Optional locking mechanism for use in early rehab

- Brake sensitivity adjustment (B)
  - Clockwise (-): Decrease sensitivity
  - Anti-clockwise (+): Increase sensitivity

- (P) Brake play screw

Low Activity Solutions – Alternative Prescription

Balance Knee OFM2

Indications:

- Users with low voluntary control
- Elderly/Weak/Co-morbidities
- Low activity user utilising gait aids
- New amputees (interim use)
- Single, slow speed ambulators

Alternative Knee Considerations: Low Activity Solutions

Locking Knee

- K1 level users requiring highest level of stance control
- Single speed slow walkers
- Transfers
- Elderly/weak users unable to utilise a polycentric or friction brake knee

Balance Knee OM8

- K2 Level
- 4 bar geometry for stance phase stability
- Adjustable centroid for to fine tune stance release
- Mid-swing shortening for toe clearance
- Household and limited community ambulators
- Manual lock not required

OP4

- K2-K3 Level
- Adjustable weight activated friction brake knee
- Pneumatic swing phase control for users capable of variable cadence
- Don't require a manual lock, but require stance phase stability from weight activated friction brake

Total Knee 1900

- K2-K3 Level
- Enhanced stability from Geometric Lock
- Mid-swing shortening for toe clearance
- Incorporates adjustable stance flexion for shock absorption
- Polymer friction for variable cadence
- Low build height

Moderate Activity Solutions - Transtibial

Stewart is a family man, who underwent a traumatic transtibial amputation 1 year ago following an accident at work

He loves to bushwalk and go fishing with his family however he is still on his interim prosthesis and has issues with socket discomfort, which limits how long he can wear his prosthesis

Moderate Activity Solutions - Transtibial

- 41 year old male
- Accident at work, lead to traumatic amputation
- Young family, bush walking, fishing
- 1 year post amputation, motivated, active
- Goals: Walk without discomfort, fishing K3

Moderate Activity Solutions – Direct Socket

- Moderate active users can benefit from a total surface bearing socket
- Accurate anatomical fit utilising Icecast
- Manufactured quickly
- Can easily change components to try different suspension methods
- Rated to **166kg**

User experience– Direct Socket

- '… from fabrication through to completion of my new legs, the process was simple and exceptionally quick'
- 'The major benefit I found was knowing how my new sockets would feel on using the pressure test. This allowed me to identify any pressure areas or discomfort prior to the resin setting stage'
- 'The fit is perfect and they're so light and comfortable that I don't feel like I'm wearing anything compared to my previous prosthetics'
- 'The Direct Socket System provides the custom comfort, support, and sense of freedom I never had in my previous sockets'
- 'I can walk longer distances and even jog without any pain or discomfort. They also look so awesome that I'm more confident and happier to show them off. I love my legs!'

Moderate Activity Solutions – Seal-In X Locking

Seal-In X Locking Liner

- Dual suspension silicone liner
- Provides mechanical suspension in combination with Seal-In or elevated vacuum
- Minimises pistoning and rotation within the socket
- Choice of Seal Rings, Classic, Grip or Volume
- Provides confidence and security for the user

Moderate Activity Solutions – Icelock 562 Hybrid Lock

Icelock 562 Hybrid Lock

Provides mechanical suspension in combination with Seal-In or elevated vacuum

- Unity elevated vacuum provides:
  - Very firm suspension
  - Manages volume fluctuations
  - Reduces pistoning and movement providing increased comfort
- 562 Hybrid Lock Features:
  - Low build height
  - Waterproof
  - Rated to 166Kg
  - Unity and Direct Socket compatible

*Must be used in combination with Seal-In X Locking

Unity Elevated Vacuum: Benefits

Advantages of Vacuum Suspension

- Very firm suspension providing excellent security and improved **proprioception** and **balance**[1]
- Elevated vacuum manage limb volume fluctuation[2]. A **constant limb volume**, decreases the need for sock management
- Elevated vacuum **assists with wound healing** by improving circulation through the residual limb[3]
- Provides good distal comfort for bony and sensitive distal ends; as long as the socket fits properly with good **volume and length matching**
- The combination of **reduced pistoning** and maintenance of volume is thought to account for the **more symmetrical gait** observed with vacuum[1,4]

Moderate Activity Solutions – Pro-Flex Pivot

Unique pivot technology

+

Interaction of 3 carbon fibre blades

↓

ROM of 27 degrees

↓

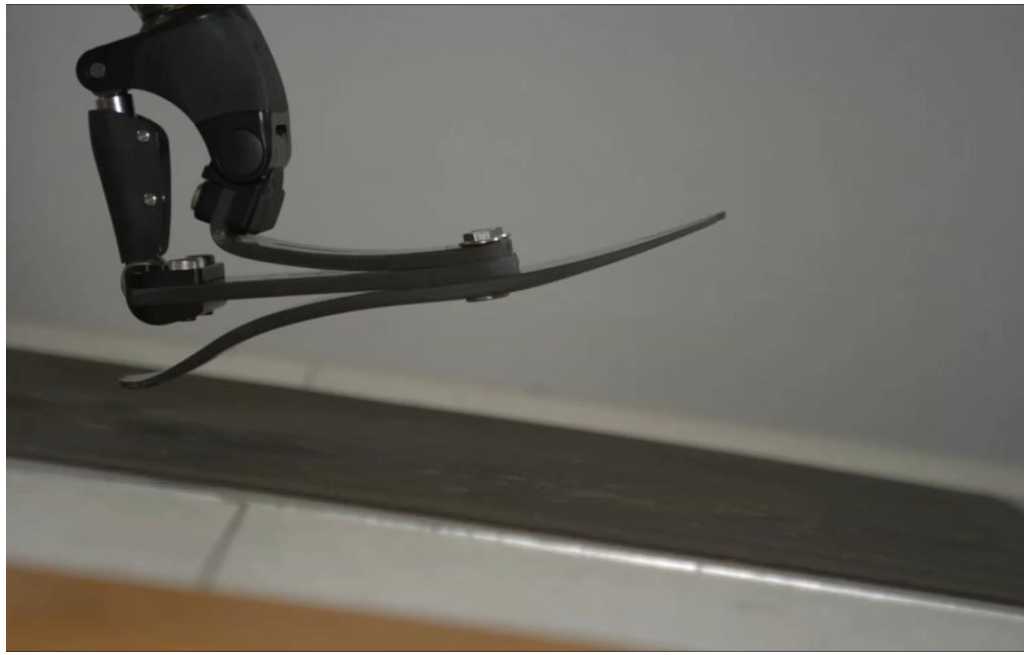
Powerful push off

↓

Physiological progression of COP

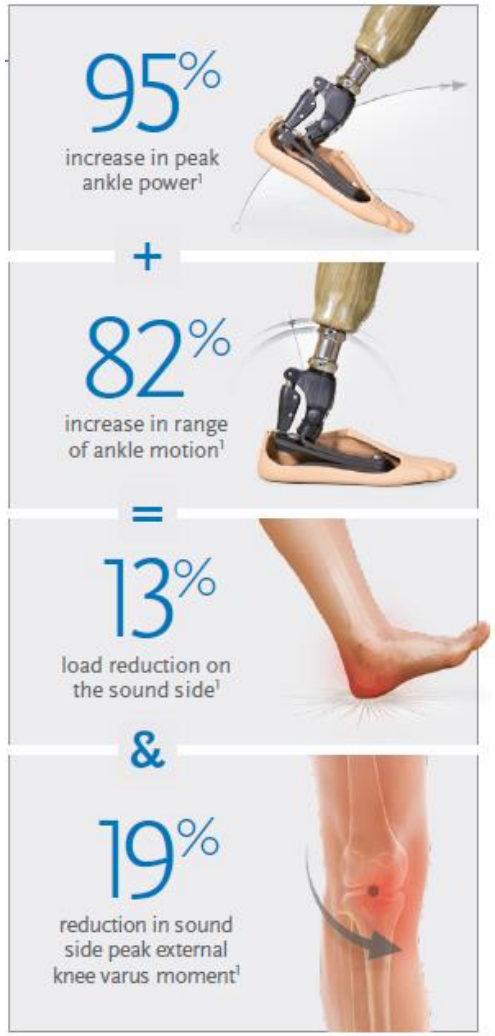
Weatherproof

Moderate Activity Solutions – Pro-Flex Pivot



- Pro-Flex Pivot adapts very well on uneven ground, suitable for:
  - Bush walking
  - Farms environment
  - Slopes/Ramps
  - Stairs
  - Active users that do a lot of walking

Moderate Activity Solutions – Pro-Flex Pivot



- Pro-Flex Pivot delivers functional improvements and benefits to users
- This combination of functional features delivers overall medical benefit:
- Reduced impact of 13% on the sound side
- Reduced varus moment of 19% on the sound side
- Reimbursement Document available

* Data compared to Vari-Flex foot

Moderate Activity Solutions – Pro-Flex Pivot

MODERATE ACTIVITY

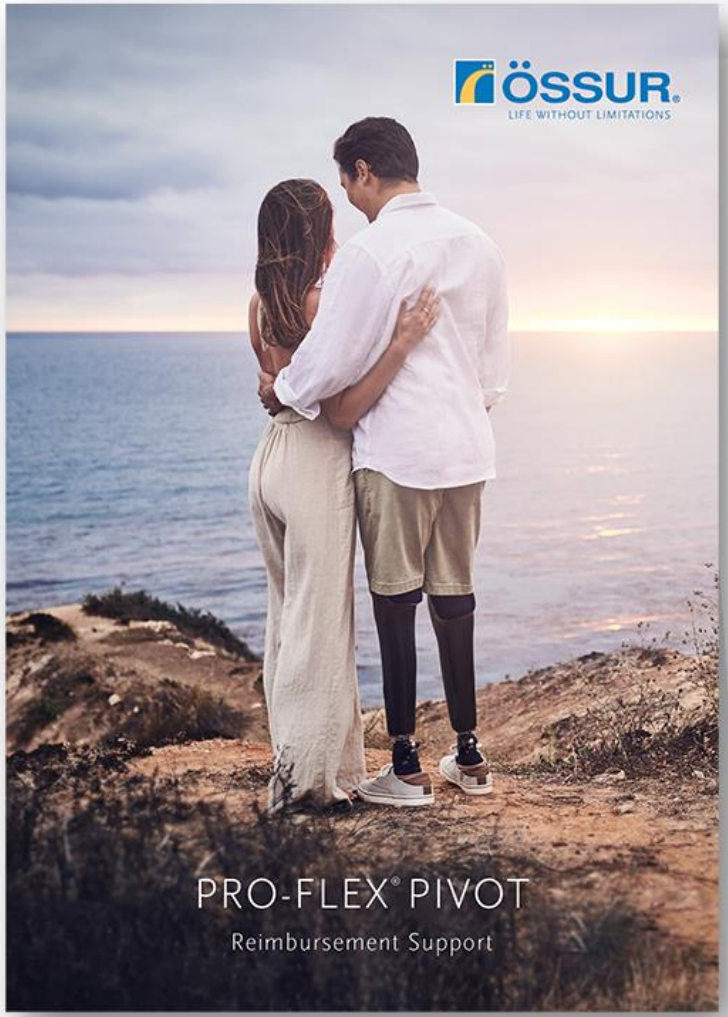
ADAPTABLE | STABLE | COMFORTABLE

DIRECT SOCKET TT

ICEROSS SEAL-IN® X LOCKING

ICELOCK® 562 HYBRID LOCK

PRO-FLEX® PIVOT



INTRODUCTION - PRODUCT FEATURES

The Pro-Flex Pivot features Pivot Technology delivering 27° ankle motion without comprising ankle joint moment and progressive stiffness for a more physiological gait1. Immediate adaptation to ramps, stairs and uneven surfaces increases walking ease, comfort, and stability for daily activities.

95% increase in peak ankle power[2]

+

82% increase in range of ankle motion[2]

=

13% load reduction on the sound side[2]

&

19% reduction in sound side peak external knee varus moment[2]

THE CASE FOR PRO-FLEX PIVOT

The risk of developing osteoarthritis (OA) of the knee is 17 times higher for transtibial amputees than it is for non-disabled people. This shocking statistic regarding the sound leg stems mainly from two key factors: asymmetrical gait and increased impact. The latter is partly a consequence of asymmetrical walking movements, which result in an increased amount of time being spent on the sound side, in comparison with the prosthetic side.[2]

Knee OA is 17 times more likely to develop in below-knee amputees than in non-disabled people.

In addition to increased pain and diminishing mobility for the individual, the financial costs associated with knee OA have risen by 66% over the last 10 years, and are predicted to rise a further 50% in the next two decades.

Responding to this challenge, Össur developed Pro-Flex Pivot. By enhancing gait symmetry and reducing vertical ground reaction forces by 13% and knee varus moment by 19%[2], it has features that may be beneficial to lower the risk of developing OA.

THE LINK BETWEEN LIMB-LOSS AND OA

Osteoarthritis (OA) of the hip and knee joints is one of the world's leading causes of chronic disability. At present, there are more than 700,000 people with lower-limb loss living in the US, and that number is growing by some 50-60,000 each year[3] potentially doubling by the year 2050[4]. As well as suffering with reduced levels of mobility[5,6,7] lower-limb amputees have been shown to experience increased loading, and therefore impact on the sound limb. This contributes to a high incidence of joint pain and degeneration, and the eventual development of osteoarthritis[8,9,2].

Transtibial amputees are known to load their sound limb to a greater extent than their prosthetic limb during gait[10], and the difference between their two limbs in terms of knee pain and degeneration suggests that mechanical loading is a contributory factor. Minor compensatory movements, as well as asymmetrical gait, can increase stress on the sound limb and potentially predispose the long-term prosthetic user to premature degenerative arthritis[11].

The increased risk of hip and knee OA has prompted rising concern about the condition amongst amputees[2]. This type of comorbidity often goes hand-in-hand with limb loss, as does pain[12], with both being capable of diminishing people's mobility further still.[2]

User Experience – Pro-Flex Pivot

… 'the Pro-Flex Pivot allows my gait to be as natural as possible'

…'Everyone comments on how natural my gait is'

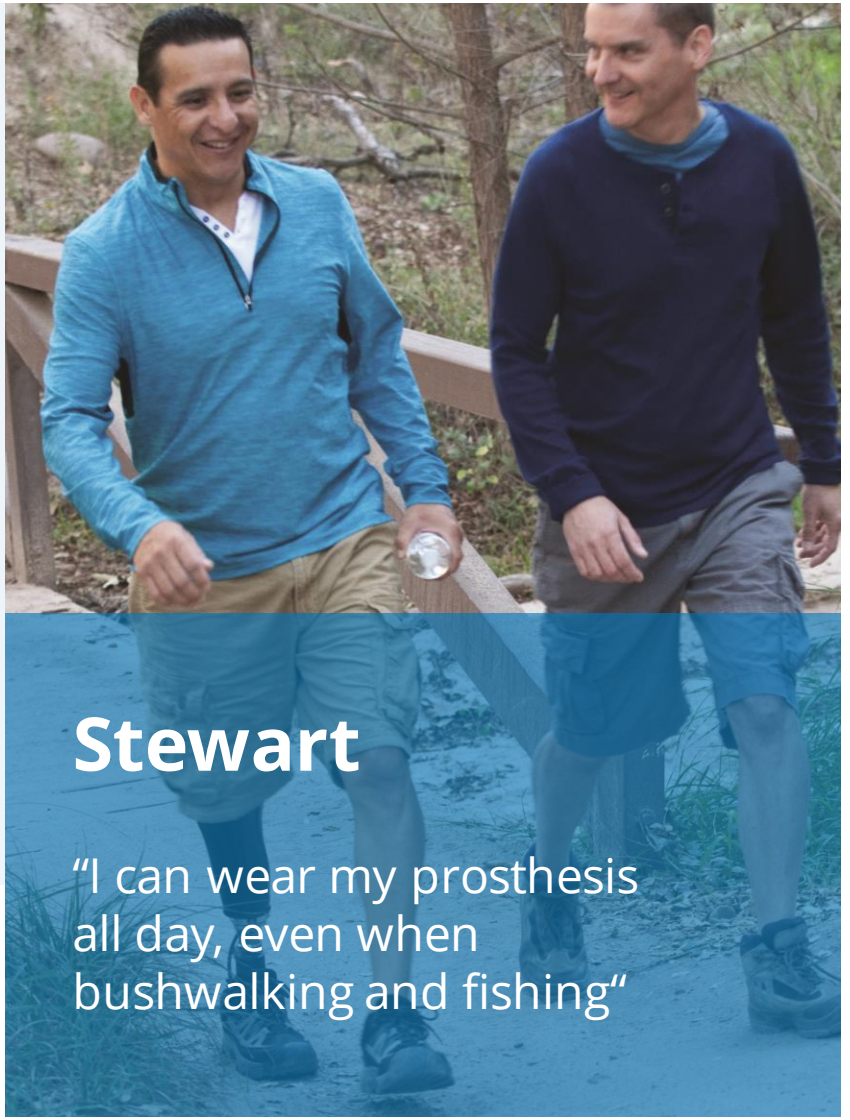
'Gives me practical movement that allows me to perform movements that amputees usually struggle with, balance particularly!'

… 'Prior to Pro-Flex Pivot, I would be fatigued by the afternoon. Now nothing stops me!'

https://www.ossur.com/en-au/prosthetics/client-experiences

Moderate Activity Solutions

- Direct Socket provides TSB socket
- Iceross Seal-In X Locking provides dual suspension for security and confidence
- Icelock 562 hybrid lock provides secure mechanical lock with Unity and Seal-In options
- Pro-Flex Pivot combines a large ROM, anatomical roll over and powerful push off, helping to reduce the impact on the sound limb



Stewart

"I can wear my prosthesis all day, even when bushwalking and fishing"

Moderate Activity Solution: Alternative Prescription

Weatherproof

Integrated battery:
18 - 36 hours battery life
depending on usage

Össur Logic connectivity

33º ROM

Terrain adaptation and
4º mid-swing dorsiflexion

Excellent stance dynamics from
Pro-Flex LP foot blade

Moderate Activity Solution: PROPRIO FOOT

Core functions:

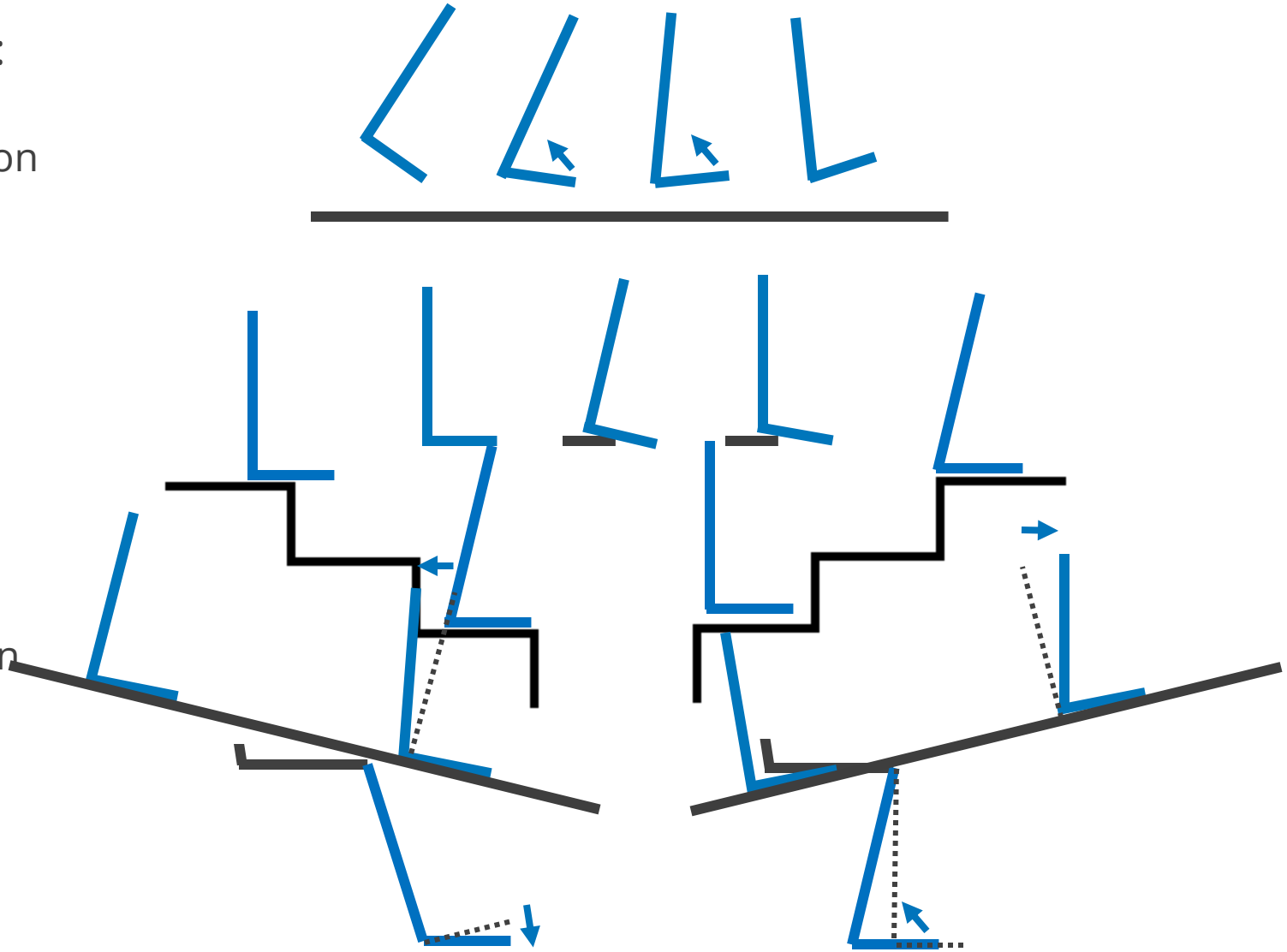
Swing dorsiflexion

Ankle alignment

Stair adaptation

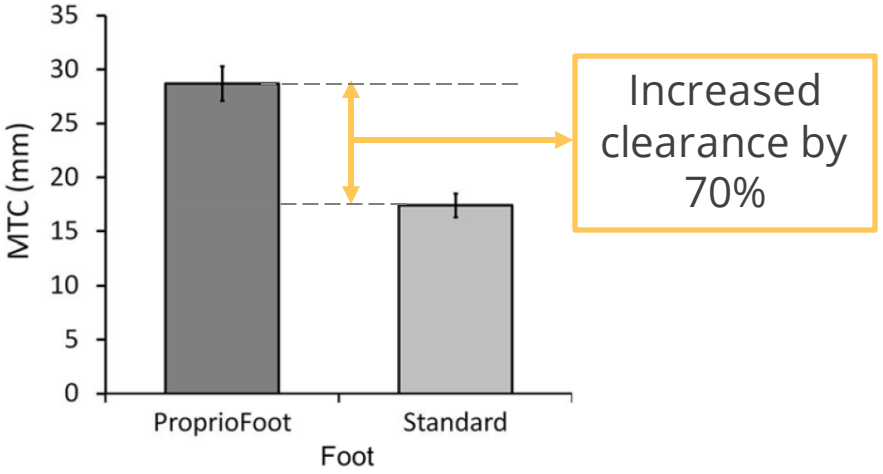
Ramp adaptation

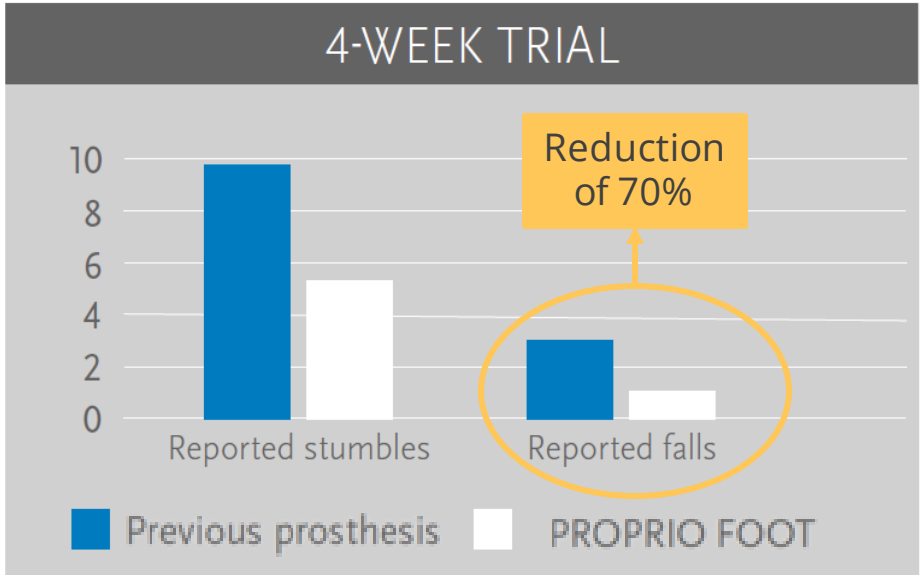
Relax/Chair exit



PROPRIO FOOT - Medical Necessity

- Amputees are more at risk of falling than their peers
- Reduction to Minimum Toe Clearance (MTC) from amputation could increase the incidence of trips and falls





PROPRIO FOOT provides toe clearance

- Reduces risk of trips and falls
- Increases safety

PROPRIO FOOT: Medical Necessity

- 16 TTA + 16 non-amputees
- Neutral ankle angle vs. 4 degree adaptation

Knee flexion is restricted because of limited (ankle) dorsal flexion

Both stair ascent and descent improvements of knee kinematics and kinetics

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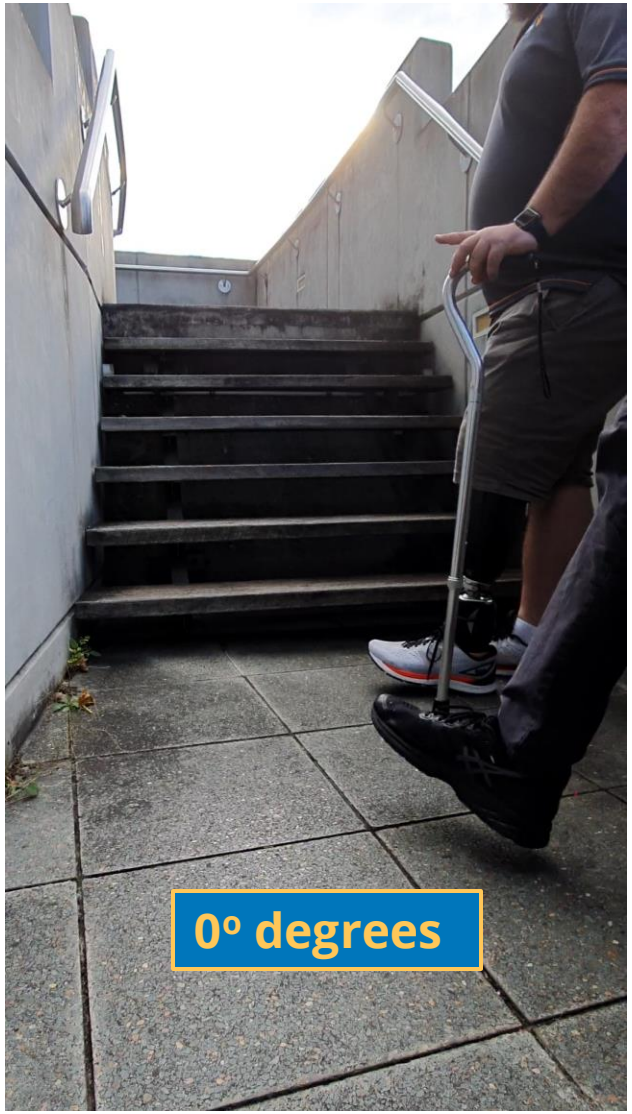
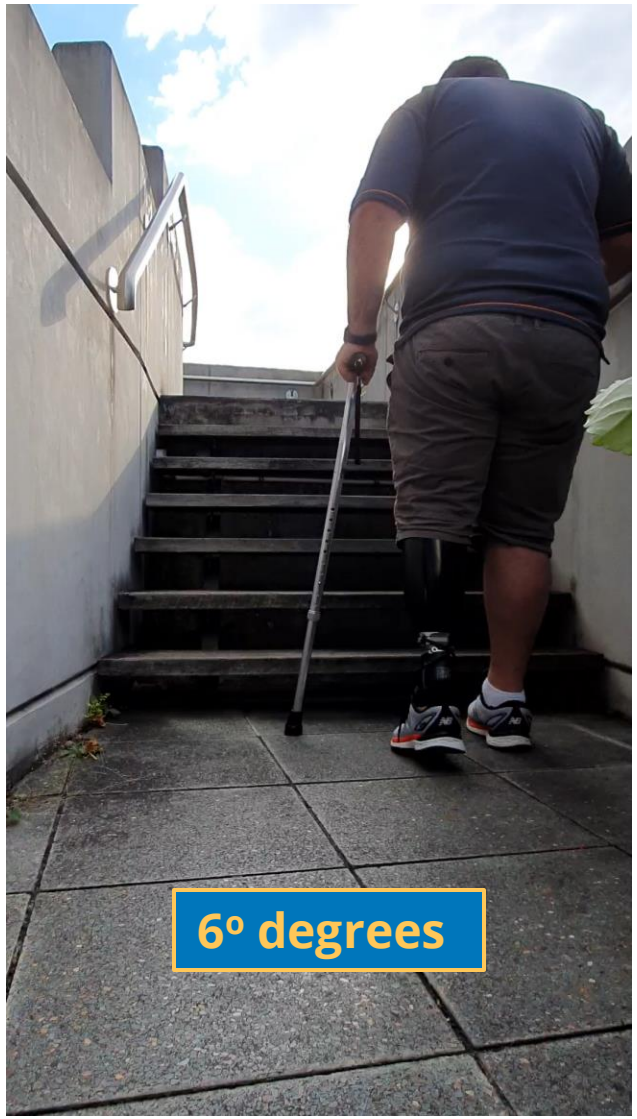
Increased knee flexion and increased knee moment

↓

More physiological knee flexion during stair ascent and descent

PROPRIO FOOT: Medical Necessity

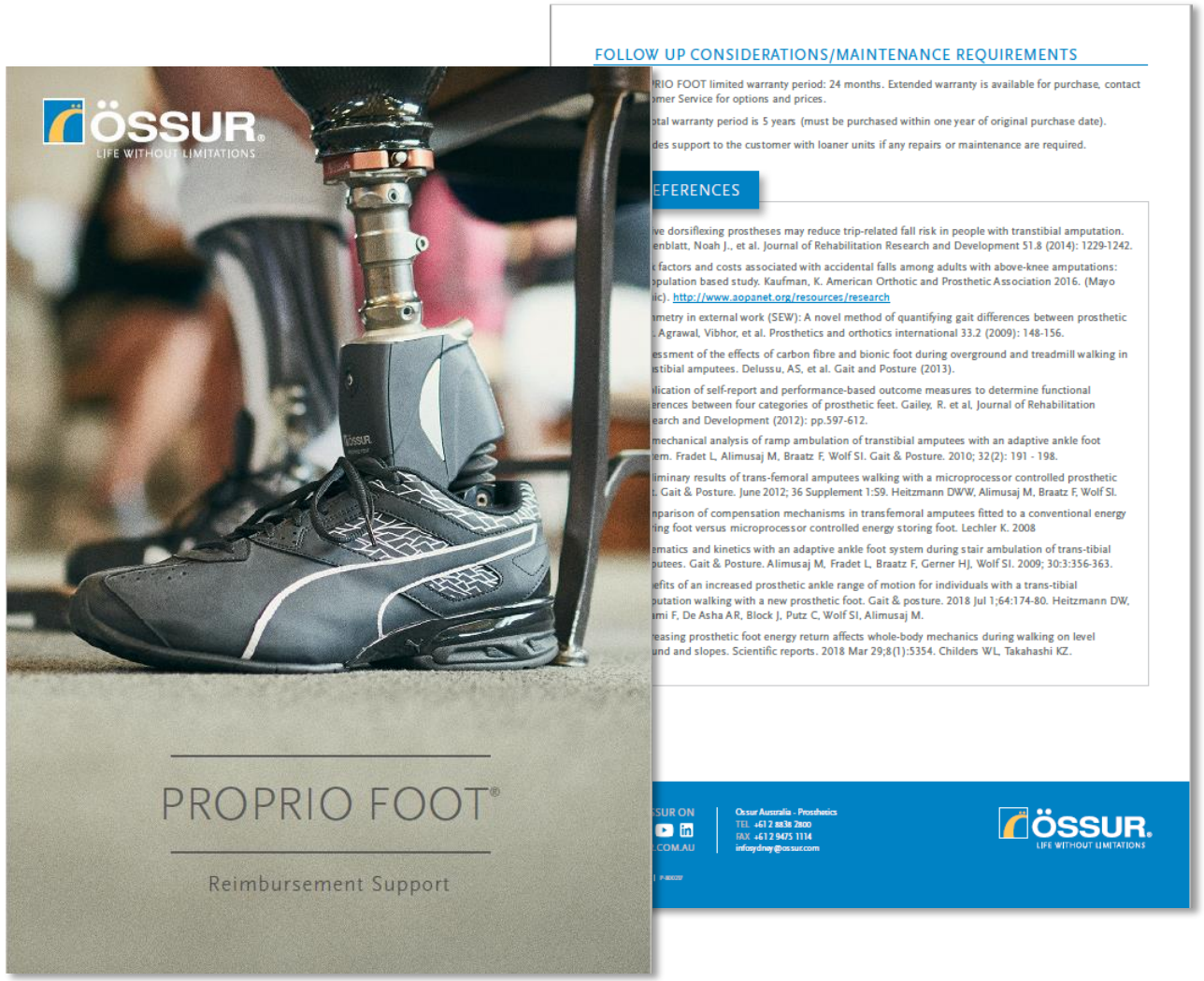




User Experience - PROPRIO FOOT

- 'The PROPRIO FOOT is very reliable, and I find I'm less tired throughout the day'
- 'I feel more confident now I'm using the PROPRIO FOOT due to the ankle being used in combination with a great energy storing carbon fibre foot'
- 'The PROPRIO FOOT has improved my comfort by enabling me to walk more naturally'
- 'I find it easier to navigate uneven surfaces such as building sites and mine sites. This makes me feel more comfortable in my socket and I'm able to walk further than before'
- 'I find I'm less fatigued on slopes and ramps as this foot adjusts to accommodate the surface angles and makes it more comfortable for me to walk on'
- 'The PROPRIO FOOT has positively impacted my life, giving me more flexibility at work and at home to utilise the prosthesis for longer periods'

Moderate Activity Solution: PROPRIO FOOT



[Download Here]

Alternative Foot Considerations: Moderate Activity Solutions

Vari-Flex

- Offers very high energy return in a lightweight design
- Forward tibial progression to assist in propelling the body forward
- Shock absorption at heel strike
- Full-length toe lever
- Split heel and keel to accommodate uneven terrain

Talux

- Ideal for community ambulator, for effortless walking and moderate impact recreational sports
- Multi-axial core providing inversion/eversion compliance on uneven ground
- Features Sandal toe

Pro-Flex LP

- K2-K4 Level
- Greater ankle range of motion than other low profile feet
- Anatomical sole blade and multiaxial compliance
- Smooth Roll over for everyday use
- Great solution when space is compromised

Moderate Activity Solutions - Transfemoral

Sue works in marketing, and loves socialising with friends and trying new restaurants

Sue underwent a transfemoral amputation 7 years ago, due to Osteosarcoma, and has been getting by as best she can, however she sometimes utilises a walking aid when outdoors, for security.

Moderate Activity Solutions - Transfemoral

- 28 year old female
- Osteosarcoma, resulting in TF Amputation
- Foodie, socialising, marketing role
- 7 years post amputation, motivated, active
- Goals: Walk without discomfort, K3

Moderate Activity Solutions – Direct Socket TF

Direct Socket is a **standardised**, **efficient** and **repeatable** socket solution for TF amputees

- Össur Brim

- Direct Socket Material Kit

Moderate Activity Solutions – Direct Socket TF

Direct Socket TF

- Easy to Donn & Doff as compared to traditional socket
- Superior Functional Outcomes
  - Improved ROM/Suspension/Stability in all planes & Superior femur control
- Superior Comfort
  - Sitting, standing & walking
- Ultra-Lightweight & Low-Profile
- True Total Contact

Direct Socket TF: Clinical Study

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RESEARCH ARTICLE

Canadian Prosthetics & Orthotics Journal

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Marable W.R, Smith C, Sigurjónsson B.Þ, Atlason I.F, Johannesson G.A. Transfemoral socket fabrication method using direct casting: outcomes regarding patient satisfaction with device and services. Canadian Prosthetics & Orthotics Journal. 2020;Volume 3, Issue 2, No.6. https://doi.org/10.33137/cpoj.v3i2.34672

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Volume 3, Issue 2, Article No.6. 2020

RICATION METHOD USING DIRECT CASTING: OUTCOMES
CTION WITH DEVICE AND SERVICES

n B.Þ[2], Atlason I.F[3], Johannesson G.A[2,4*]

al (DS-TF) prosthetic user is a novel method of fabricating
t requires different training, production method and service
liar with. This method and model may improve patient
nd delivery in one visit.

n regarding DS-TF interface versus the prosthetic users'
and the clinic service model.

rom July 2018 to April 2020), the DS-TF was implemented
es. Certified prosthetists (CP) and assistants were trained
participated, both those in need of a new socket and those
otics and Prosthetics Users' Survey (OPUS), involving
ice and Services, was used to evaluate each DS-TF user
osthesis that was replaced was the interface, except in 2

ated, fit and delivered in a single clinic visit. At 6-months
29.8% increase in satisfaction with their new interface
e in satisfaction with the services they received from the
eir original prosthesis. The main outcome increases were
follow-up and remained consistent after 6 months. This
e user needed a new socket for clinical reasons or not.

a standardized training and implementation, the DS-TF
mproves the user's satisfaction with their prosthetic device

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KEYWORDS

Transfemoral amputation, Amputee, Prosthesis, Socket, Interface, Outcome measure, Satisfaction, Direct casting

E-mail: ajohannesson@teamolmed.se
ORCID: https://orcid.org/0000-0001-8729-458X

functional prosthesis, especially the interface (i.e. the socket, the liner and its suspension) to enable the amputee to regain as much of their previous mobility as possible.[5,6] TF amputation is also associated with longer amputee rehabilitation time compared with transtibial (TT) amputation and more need of assistance, especially in elderly patients.[7] TF amputees report their general health related quality of life to be lower than that of non-amputees or TT amputees. Furthermore, specific problems have been related to the use of TF prostheses, including limited hip joint range of motion that restricts users comfort or ability to perform daily activities such as sitting, walking, picking

Marable et al. 2020

TRANSFEMORAL SOCKET FABRICATION METHOD USING DIRECT CASTING

function is presumed to be lacking the term "sub-ischial socket" has been used.[26]

LIST OF ABBREVIATIONS

- **CP:** Certified Prosthetist
- **CSD:** Client Satisfaction with Device
- **CSS:** Client Satisfaction with Services
- **DS-TF:** Direct Socket for transfemoral
- **DS-TT:** Direct Socket for transtibial
- **ISO:** International Organization for Standardization
- **ISO/TC:** 168 Prosthetic and Orthotics working group within ISO
- **ISPO:** International Society for Prosthetics and Orthotics
- **OPUS:** Orthotics and Prosthetics User's Survey
- **O&P:** Orthotics and Prosthetic
- **TF:** transfemoral
- **TT:** transtibial
- **6WFU:** six-weeks follow-up
- **6MFU:** six-month follow-up

The problem with this "definition" is that a transtibial or toe prosthesis could also be referred to as sub-ischial socket. This lack of detail and consistency in definitions prevents objective comparison.[27] In an effort to provide detail and resolve the inconsistency, ISO standard 13405-2:2015 contains recommendations on how to systematically describe an interface and provides a base for comparison between different interface design and function.[23]

A method of fabricating a finished laminated TT interface directly on the patient's residual limb has been on the market since 1996. First introduced as ICEX by Össur HF of Iceland, ICEX was based on the inventor's philosophy of pressure casting[28] and was included in a variety of studies related to user satisfaction, cost and function.[29–32] Since then ICEX was improved to Modular Socket System (MSS) in 2005,[31] and finally to Direct Socket in 2018.[33] This system enables a prosthetist to fabricate a custom-made interface directly on the TT residual limb in a single visit. The lesson learned from the use of DS-TT in Scandinavia for over two decades and the finding related to the process, e.g. shorter rehabilitation time, demanded a solution for TF level.[33]

A TF version of Direct Socket (DS-TF) began testing in 2016 in select Scandinavian clinics.[30,31] The proximal portion of a DS-TF interface design differs significantly from the proximal portion of sockets typically called Ischial Containment or Inter Ramus Containment sockets, as the proximal part of the DS-TF includes a size-specific silicone brim. The method of fabricating directly on the residual limb requires a different approach to prosthetist training and fabrication compared to the socket fabrication process most prosthetists apply today.[33]

The primary aim of this study was to collect data on prosthetic users satisfaction regarding DS-TF interface in terms of both interface function and the clinic service model (i.e. one patient visit to the clinic for fabrication of custom TF interface, prosthesis assembly, alignment, gait analysis, and delivery).

Marable et al. 2020

TRANSFEMORAL SOCKET FABRICATION METHOD USING DIRECT CASTING

creating axial and transverse stabilization. During the rest of the gait (pre-, initial-, mid-, and late swing) the brim is only following the hip movement.

The selection criteria for study principle investigators included a Certified Prosthetist (CP) with more than 5-years clinical experience in serving TF amputees with interest in improving patient outcomes and satisfaction, willingness to follow a defined novel fabrication protocol, and commitment to document outcome measures at defined time intervals. The inclusion criteria (*rationale*) is listed in Table 1.

Figure 1: Direct Socket

Table 1: Amputee inclusion criteria (*rationale*)

Amputee inclusion criteria (*rationale*)
• 50Kg< body weight < 160Kg (*the ISO validated weight limit of the DS-TF*)
• Cognitive ability to understand all instructions and questionnaires in the study
• Patients who have undergone a TF amputation > 1-year post amputation (*this was to avoid postoperative problems and/or adjustments related the initial prosthetic fitting of a new amputee*)
• Older than 18 years
• Willing and able to participate in the study and follow the protocol
• Circular dimension of 40-65 cm at the crotch (*limited to available silicone brim sizes*)
• Residual limb length at least 20 cm from ischium to distal end (*fabrication limitation of the DS-TF*)
• Currently using a prosthetic liner (*this was to avoid potential confounding influence from transitioning an amputee from a skin fitting interface (i.e. without a liner), to an interface with a liner*)
• Willing to use a silicone prosthetic liner as called for in Direct Socket Instructions For Use.[34]

Research - Journal Article 1

Document patient satisfaction of new Direct Socket TF (DS-TF) interface (socket) compared to amputees' current interface (socket) in terms of:

- Comfort & function

- Prosthetic Service

  Including Prosthetist training using a standardized training protocol

n=38	Socket satisfaction (DS TF vs previous)	Service satisfaction (DS TF vs previous)	DS TF Preference (DS TF vs previous)
6 months follow-up	**+29,8%**	**+14,8%**	**93.6%**

Research - Journal Article 2

Investigate patient outcomes of new Direct Socket TF (DS-TF) interface (socket) compared to amputees' current interface (socket) in terms of:

- Quality of Life (QoL)
- Comfort
- Mobility

K Level	Subjects
1	4
2	11
3	21
4	11

- **Subjective**: EQ-5D-5L®, PLUS-M™, CLASS, ABC, (*OPUS-CSD and CSS),
- **Objective**: TUG and AMPPRO

Outcome Measure	EQ-5D-5L®	PLUS-M™	CLASS	ABC	TUG	AMPPRO
Initial	0.75	46	74%	63%	14.7s	38
6 weeks	0.82	54	86%	75%	13.0	40
6 months	0.84	61	86%	78%	12.8s	40

Moderate Activity Solutions – Iceross Seal-In HSM

Iceross Seal-In HSM

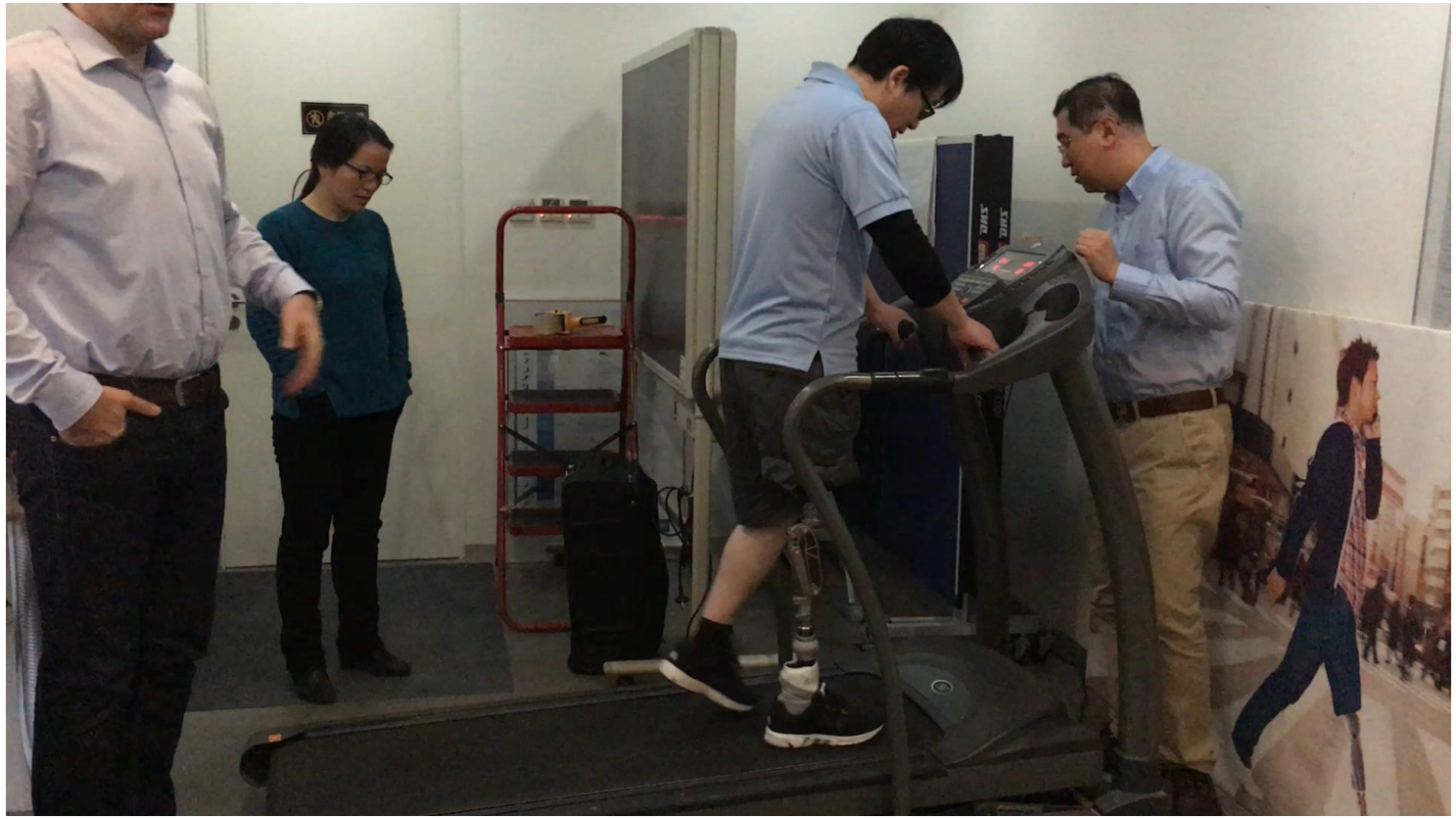
- Features full length matrix for soft tissue stabilisation
- Good compliance with complex limb shapes and bony residual limbs
- Active skin care
- Can be used with Seal-In Socks
  - Maintenance of suspension for volume fluctuations
- Can be used in conjunction with Icelock 544 for seal in and Unity elevated vacuum to provide a firm suspension

Moderate Activity Solutions – PASO Knee

PASO Knee

- Closing Geometry for stability in stance
- **Auto-adaptive swing phase control**
  - No valves to adjust
- Adapts to variable walking speed and smooth and powerful running
- Mid swing shortening (15mm) – helps to prevent trips and falls

Moderate Activity Solutions – PASO Knee



Moderate Activity Solutions – PASO Knee

Moderate Activity Solutions – PASO Knee

Moderate Activity Solutions – PASO Knee

User Experience: PASO KNEE

- 'The PASO Knee maintains the same speed as my natural leg no matter how fast or slow I am walking. This removes the stress of having a prosthetic knee that either won't keep up with me or has too much terminal impact which is uncomfortable for my hip'
- '…I feel more confident and stable'
- '…with the polycentric geometry of the knee and the short build height I find the PASO Knee folds away really well, making sitting on the bus and fitting into an aircraft seat a lot easier than before'
- 'When using the Pro-Flex XC Torsion and PASO Knee I can also run with absolute ease'
- '…I now look forward to walking, no matter how far or how technical the walk is'

Moderate Activity Solutions – Pro-Flex LP Align

Greater ROM than other feet with a low profile design

↓

Functional joint centre is closer to anatomical

↓

Improved physiological gait

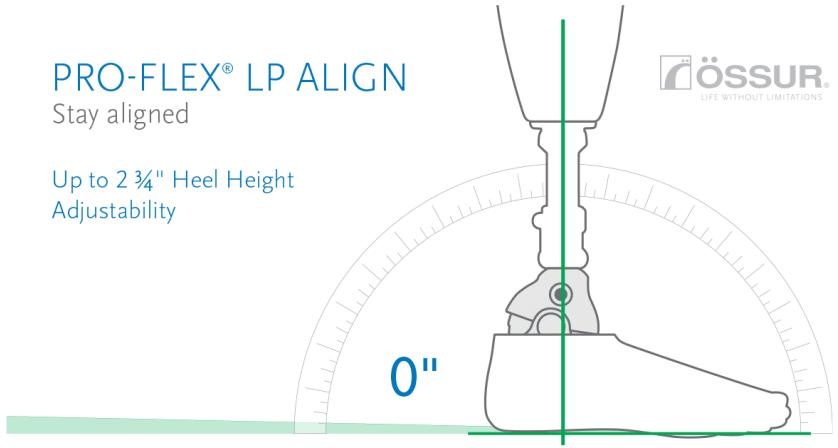
↓

Increased function and user satisfaction

- Hydraulic housing, allows alignment adjustment of the foot to match different heel heights.

0 – 7cm

Moderate Activity Solutions – Pro-Flex LP Align



Malalignment leads to:

Excessive pressures on residual limb:

- Residual limb problems
- Skin breakdown

Disturbed roll-over:

- Asymmetrical gait
- Low back pain

Inefficient gait:

- Higher energy expenditure

Moderate Activity Solutions

- Direct Socket TF provides a total contact, comfortable socket, manufactured in a single appointment
- Iceross Seal-In HSM can be used in conjunction with Icelock 544 for seal in and Unity elevated vacuum to provide a firm suspension
- PASO Knee provides closing geometry for saftey in stance, and automatically adapts to variable walking speeds
- Pro-Flex LP Align combines a wide range of motion, smooth roll over and hydraulic housing, for adjustment of heel height from 0 – 7cm

Alternative Prescription - Moderate Activity Solutions

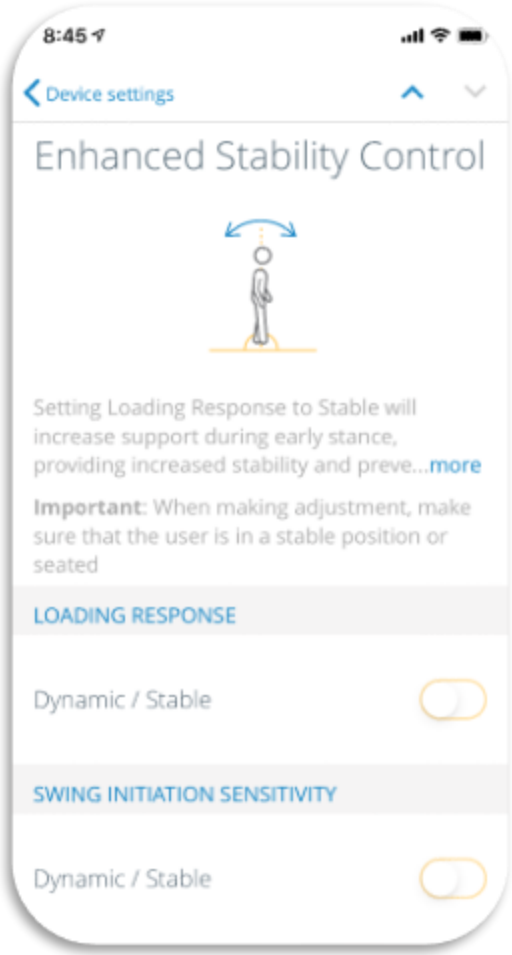
RHEO KNEE

- Stance and Swing controlled MPK, providing adjustable resistance utilising a Magnetorheologic actuator
- Sensors measure angle, load and movement to detect its environment and interaction between the device and the user

Features:

- Kinematic Sensor
  - Creates safer transitions from stance to swing
  - Identifies quiet standing
  - Prevents inadvertent release when backwards walking

Alternative Prescription - Moderate Active Solutions



- Extension Assist
  - Faster extension rate
  - Lowers energy consumption/exertion
- Manual Extension Lock
  - Traversing extreme terrain
  - Exercise related activities
- Enhanced Stability Control Settings
  - **Loading Response**
  - **Swing Initiation**
- Stable options are aimed at insecure, lower active users or primary users

Alternative Prescription - Moderate Activity Solutions

PROPRIO FOOT

- Provides 4° of mid swing dorsiflexion during swing, for toe clearance
  - Beneficial for users who like to bush walk
- Adapts to uneven terrain, and stairs, providing stability, comfort and safety
- Relax and Chair exit mode
- Pro-Flex LP foot blade provides stance dynamics and a smooth roll over

Alternative Knee Considerations: Moderate Activity Solutions

OHP3

- K2 – K3 Level
- Enhanced stability from closing geometry – Provides safety in stance
- High pressure pneumatics for faster speed walkers
- Mid swing shortening for toe clearance in swing, helps to prevent trips and falls
- Optional stance flexion adapter (IKF) for shock absorption

Total Knee 2000

- K3 – K4 Level
- Enhanced stability from Geometric Lock
- Mid-swing shortening for toe clearance
- Incorporates adjustable stance flexion for shock absorption
- 3 phase hydraulic swing phase control for faster speed walking
- Low build height

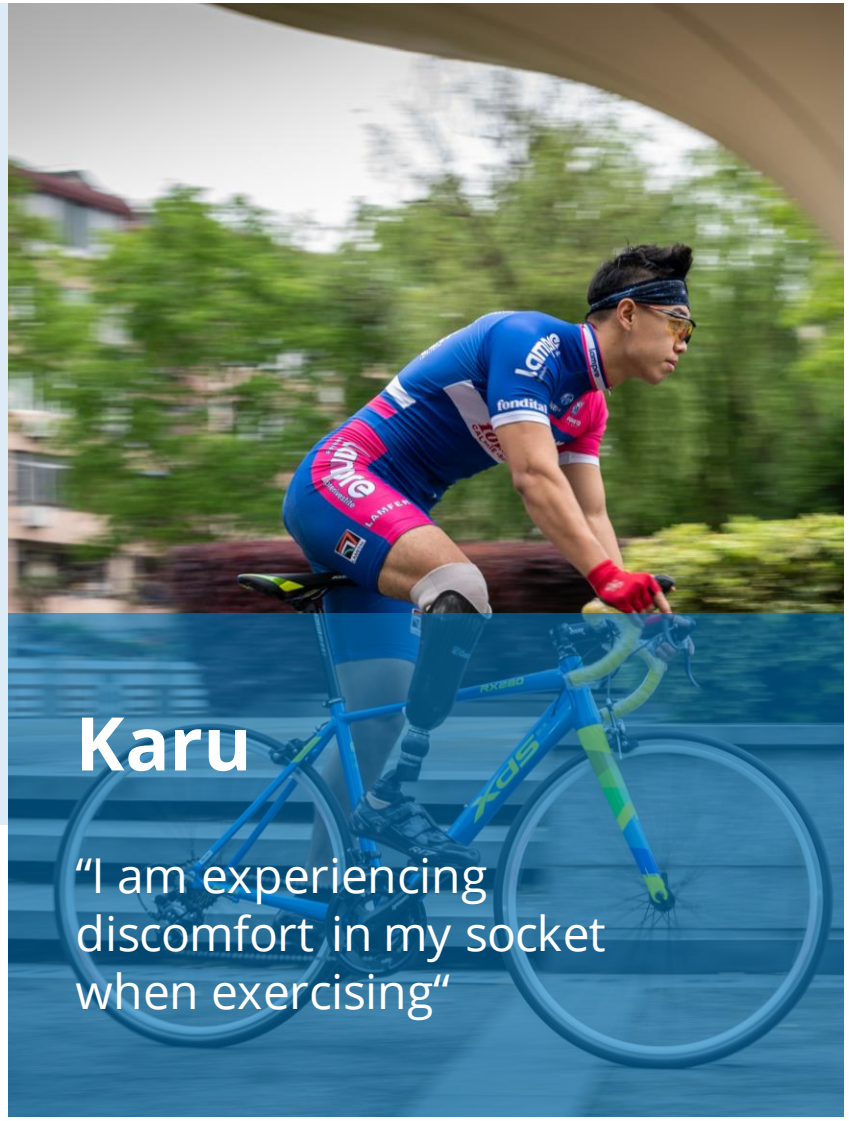
MAUCH Knee

- K3 – 4 Level
- Hydraulic cylinder for control of swing and stance phase
- Hydraulic swing phase control for a wide range of cadence variation, with adjustable flexion and extension resistance
- Hydraulic stance control provides yielding resistance for stair and ramp descent
- Stumble control for safety

High Activity Solutions - Transtibial

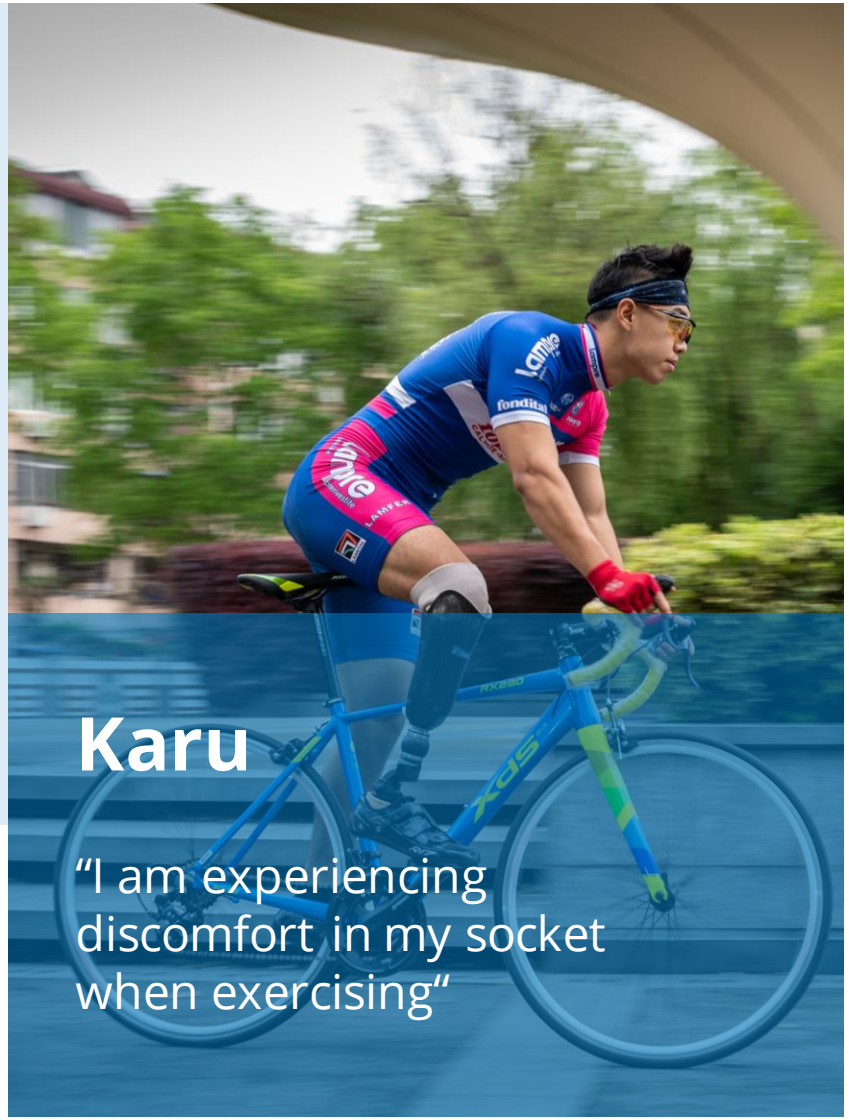
Karu works in finance, however outside of work he very into fitness, participating in cycling and cross fit, and going to the gym daily.

Karu became a transtibial amputee following a motorbike accident, and recently has been experiencing socket discomfort due to volume changes in his residual limb



High Activity Solutions - Transtibial

- 31 year old male
- Motorbike accident
- Cycling, Gym work, Cross Fit
- 3 years post amputation, highly active
- Goals: Cycle and Gym work without limitations



High Activity Solutions – Direct Socket

- High active users can benefit from a total surface bearing socket
- Accurate anatomical fit utilising Icecast
- Can easily change components to try different suspension methods
- Lightweight and strong - rated to **166kg**

High Activity Solutions – Iceross Synergy Cushion

Iceross Synergy Cushion

- Stability, cushioning and impact protection
  - Soft silicone inner layer provides cushioning
  - Firm silicone outer layer provides tissue stabilisation
- Wave feature improves comfort during knee flexion
- Features:
  - Double layer of silicon
  - Active Skin care
  - Silken surface
  - Wave feature available

Iceross sleeve features wave technology for ease of knee flexion, whilst generating firm suction

High Activity Solutions – Icelock 544

Icelock 544 expulsion valve

- For use with cushion liner and sleeve set up, where expulsion only is desired
- Valve sits distal to the socket, protecting it from external damage

High Activity Solutions – Pro-Flex XC

Anatomical sole blade

Smooth roll over

Balance and Stability

Multiaxiality on uneven ground

High Activity Solutions – Pro-Flex XC

Waterproof

C-shaped design provides 10mm vertical compression

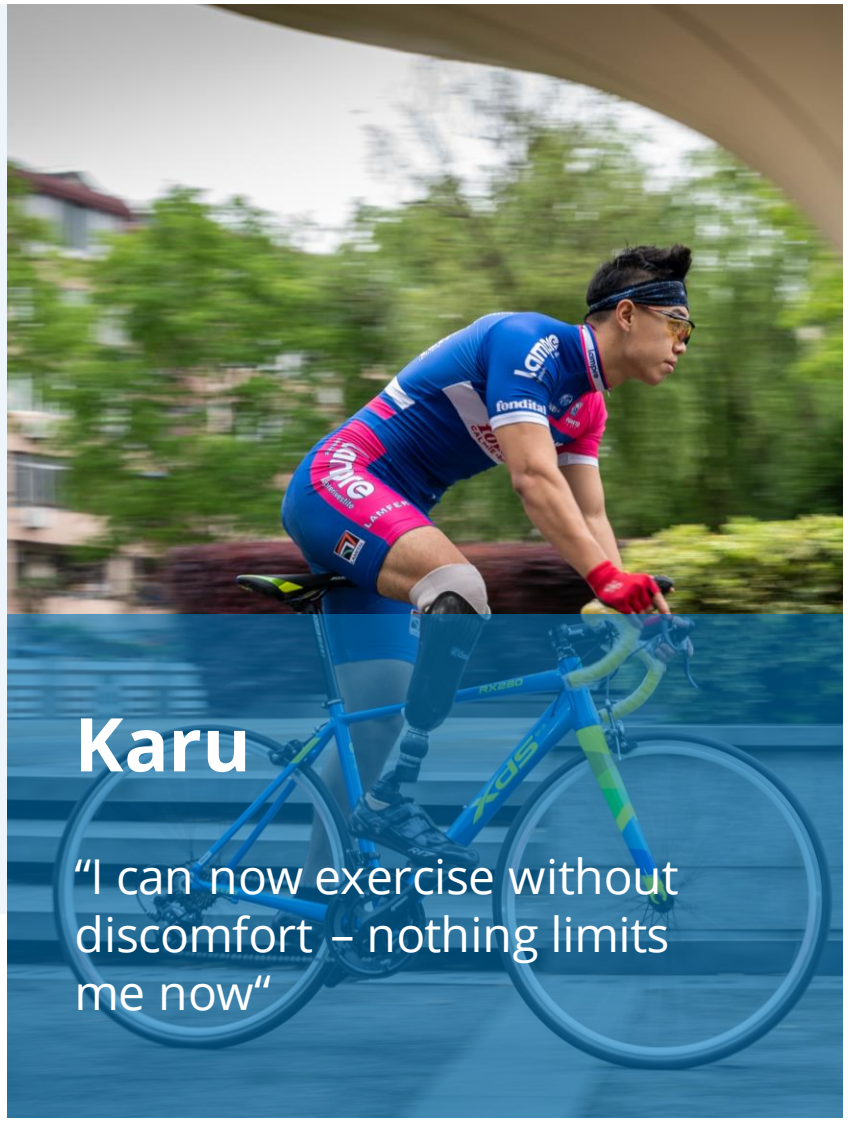
Shock absorption for high impact activities

C-shaped design provides progressive stiffening for a more natural roll over

Great ankle ROM and reduced sound side loading

High Activity Solutions: Summary

- Direct Socket is a lightweight and strong socket (rated to 166kg)
- Iceross Sleeve and Synergy cushion liner provide firm suspension, cushioning and protection
- Icelock 544 Expulsion valve sits distal to the socket, protecting it from external damage
- Pro-Flex XC provides a smooth roll over, shock absorption for high impact activities, and is waterproof (Salt and Chlorine)



High Activity Solutions – Alternative Prescription

- High active user can benefit from the dual suspension Seal-In X Locking liner
- Use combination with the Icelock 562 Hybrid lock with Unity elevated vacuum to minimise movement within the socket during reactional activities
- Pro-Flex XC Torsion provides all the benefits of the Pro-Flex XC, with integrated Torsion Shock
- Compensates for physiological rotation and vertical shock absorption of lost joints
- Benefits users who participate in high impact activities such as basketball or running

Alternative Foot Considerations: High Activity Solutions

Pro-Flex LP Torsion

- Combines the dynamics of the Pro-Flex LP with torsion and shock
- Provides comfort and reduces shear stresses on the residual limb, for co-morbidities, scarring and Osseointegration
- Everyday use and recreational activities
- Rated to 147Kg

Re-Flex Rotate

- K3-K4 Level
- J-Shaped carbon fiber foot
- Integrated torsion shock adapter
- Reduces shear stress on residual limb for high performance individuals
- Available with male or female pyramid options

Re-Flex Shock

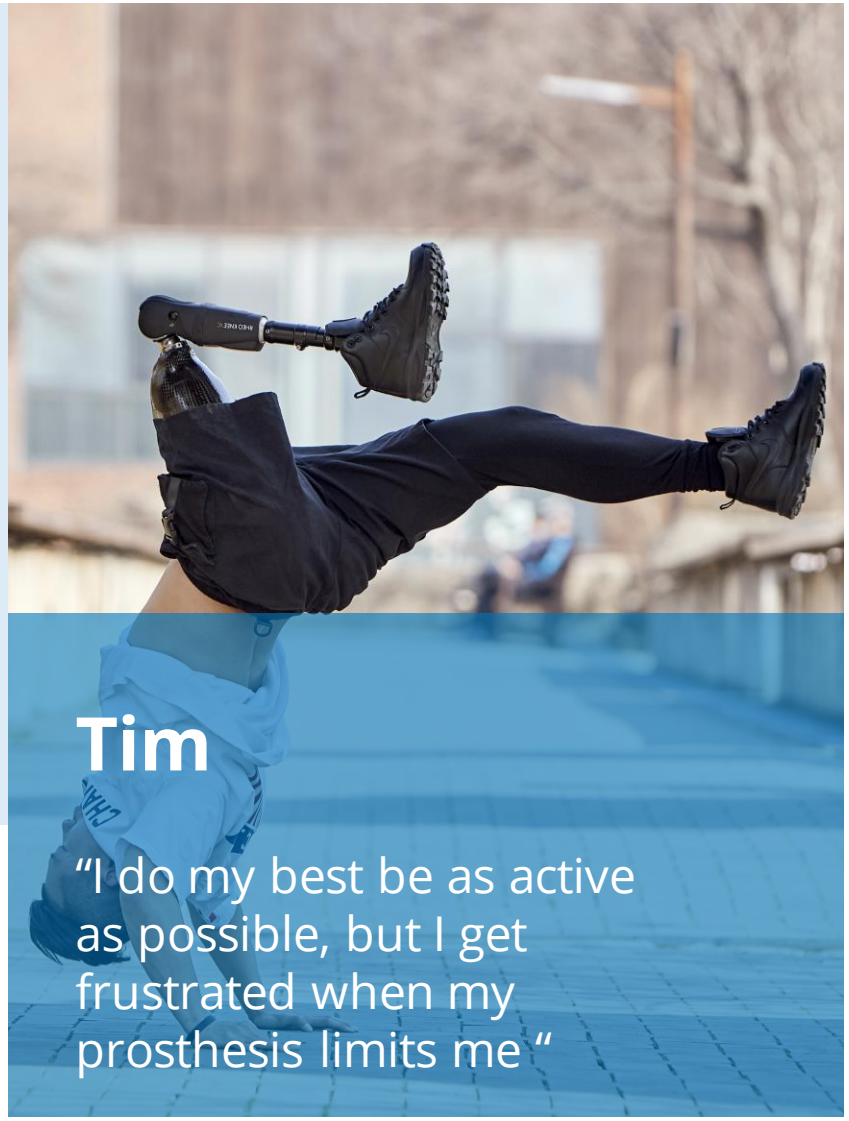
- K3-K4 Level
- J-Shaped Carbon fiber foot
- Integrated shock- absorbing adapter
- Designed for active individuals taking part in sport or high impact manual labour
- Require a foot for everyday use and recreation

High Activity Solutions - Transfemoral

Tim is adventurous, loves to travel, and participates in extreme sports such as snow boarding.

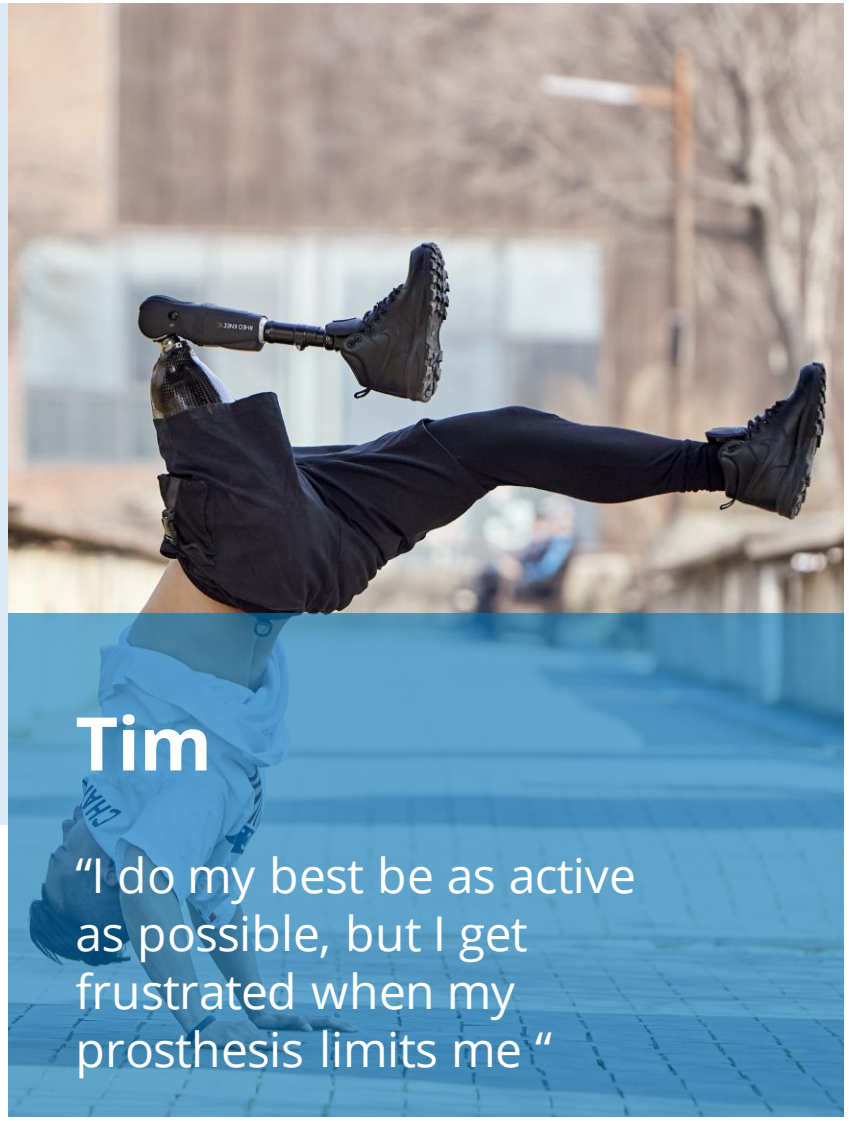
Tim was born with a congenital deficiency which led to a transfemoral amputation at a very early age. He has always lived life to the fullest and doesn't want his amputation to stop him from doing anything.

He has been on a mechanical knee for years and wants to know what other options are available, to keep up with his active lifestyle.



High Activity Solutions - Transfemoral

- 28 year old male
- Congenital – fibular hemimelia
- Travelling, Cycling, Snowboarding, Adventurous
- Highly active, freelance web designer
- Goals: Mobilise without discomfort and perform recreational activities



High Activity Solutions – Direct Socket TF

Direct Socket TF

- Easy to Donn & Doff as compared to traditional socket
- Superior Functional Outcomes
  - Improved ROM/Suspension/Stability in all planes & Superior femur control
- Superior Comfort
  - Sitting, standing & walking
- Ultra-Lightweight & Low-Profile
- True Total Contact

High Activity Solutions – Iceross Seal-In X5

Iceross Seal-In X5

- Features five integrated seals
- Provides security, minimises pistoning and provides enhanced rotational control
- Ideal for active amputees looking for security during recreational activities

High Activity Solutions – RHEO KNEE XC

RHEO KNEE XC

- High active users looking for the increased stability in stance
- Adapts to variable cadence, for fast paced walking and running
- Negotiate ramps/stairs – capable of ascending stairs step over step
- Automatic Cycling recognition – for efficient power transfer to the pedals, allows free movement without resistance

User Experiences: RHEO KNEE XC

'The microprocessor in the RHEO KNEE XC provides safety and prevents falls, and has made the biggest difference to my mobility. '

'...The RHEO KNEE XC features artificial intelligence and is thinking for you the whole time, measuring your speed as you go and constantly adapting for you'

'...My gait and my walking have also improved, and people have commented on how normal my walking looks'

'The RHEO KNEE XC provides resistance which allows me to feel very comfortable and confident going down stairs and down slopes too. I feel you can really get your resistance into the slope and it's quite nice ambling down the hill'

'...I have also enjoyed the cycling function because when you get on the bicycle, the RHEO KNEE XC automatically enters the cycling mode which provides the free resistance that you need for cycling'

High Activity Solutions – Pro-Flex XC Torsion

C-shaped design and Torsion unit provide 16mm vertical compression

↓

Shock absorption for high impact activities

↓

C-shaped design provides progressive stiffening for a more natural roll over

↓

Great ankle ROM and reduced sound side loading

High Active Solutions – Pro-Flex XC Torsion

Torsion version provides shock absorption and rotation → Reduces shear forces and stress on residual limb

PERMITTED ROTATION AND SHOCK MOVEMENTS REDUCE SHEAR STRESS

- Twiste M. Transverse rotation and longitudinal translation during prosthetic gait – A literature review. Journal of Rehabilitation, 2003; 40: 9-18

LOWER SHEAR STRESSES → REDUCED DISCOMFORT

- Segal AD, et al. Transtibial amputee joint rotation moments during straight-line walking and a common turning task with and without a torsion adapter. Journal of Rehabilitation R&D. 2009 46:375-384

SELF PERCEIVED PAIN REDUCTION

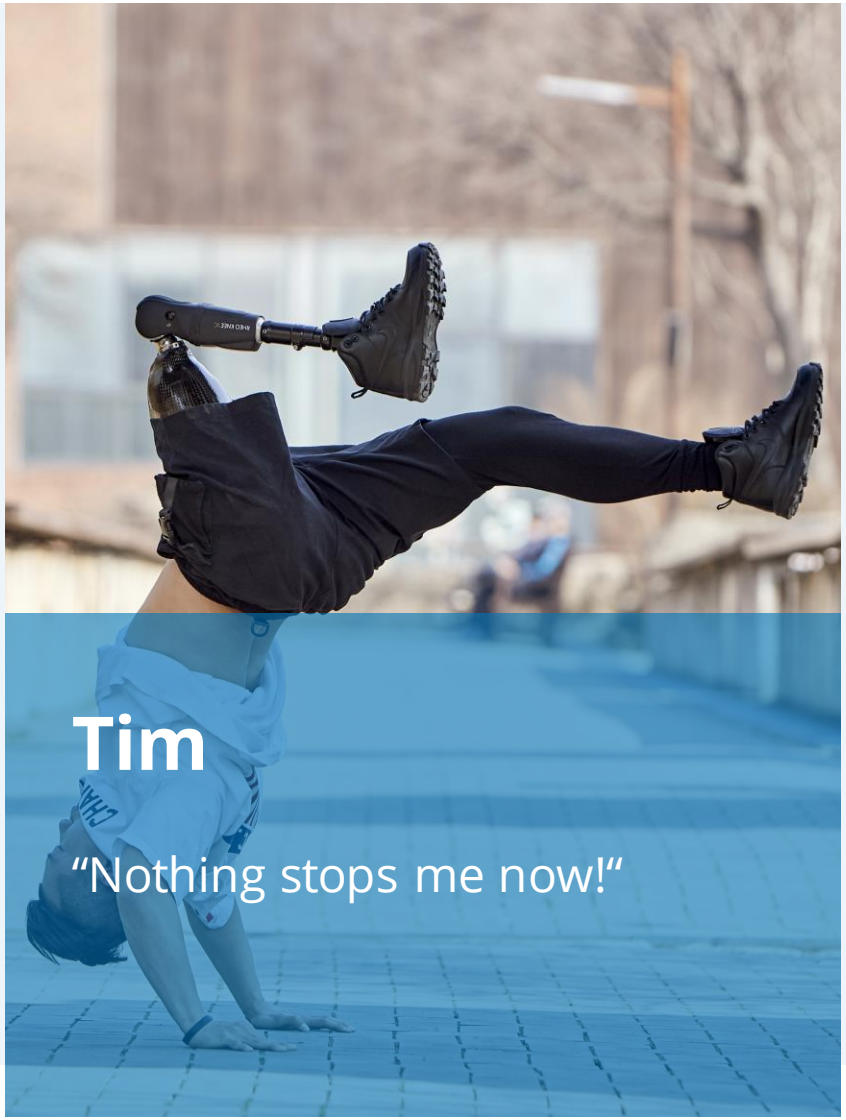
- Segal AD, et al. Does a Torsion Adapter Improve Functional Mobility, Pain and Fatigue in Patients with Transtibial Amputation? Clin Orthop Relat Res 2014 472:3085–3092

REDUCED SHEAR STRESS

- Heitzmann D, et al. Functional effects of a prosthetic torsion adapter in transtibial amputees during unplanned spin and step turns. Prosthet Orthot Int 2015; 1-8.

High Activity Solutions

- Direct Socket TF provides superior comfort in sitting, standing and walking
- Iceross Seal-In X5 provides security during recreational activities
- RHEO KNEE XC provides high level of stability in stance, whilst keeping up with active users, looking to ascend stairs step-over-step, run and cycle
- Pro-Flex XC Torsion provides shock absorption and rotation for users participating in high impact activities and recreational sports



Alternative Prescription - High Active Solutions

Mauch Knee Plus

Features:

- Hydraulic swing control:
  - wide range of cadence variation and independent control of flexion and extension resistance
- Hydraulic stance control:
  - Yielding resistance allows foot over foot stair and ramp descent.
  - Stumble recovery feature improves security
- Hydraulics create a 'yielding' brake for control of knee flexion during stance
  - Stair and ramp descent
  - Sitting
  - Allows for a more natural approach to stairs and sitting

Alternative Prescription - High Active Solutions

Mauch Knee Plus

- Swing Only Mode:
  - Allows for cycling, rowing, or use of various exercise machines.
- Manual Lock Mode:
  - Allows for ultimate security when descending steep or slippery slopes, climbing ladders, or standing for extended periods
- Durable, suitable for high impact activities
  - Weight limit: 166 kg
  - Knee flexion range: 125º
  - 4 hole adapter connections for low build height
  - Heavy duty use
  - Recreational sports

Alternative Knee Considerations: High Activity Solutions

OH7

- K3 – K4 Level – rated to 136Kg
- Enhanced stability from closing geometry – Provides safety in stance
- 3 phase hydraulic swing phase accommodates changes in walking speed
- Capable of fast paced walking and running – up to 10km/hr
- Mid swing shortening for toe clearance in swing, helps to prevent trips and falls

Total Knee 2100

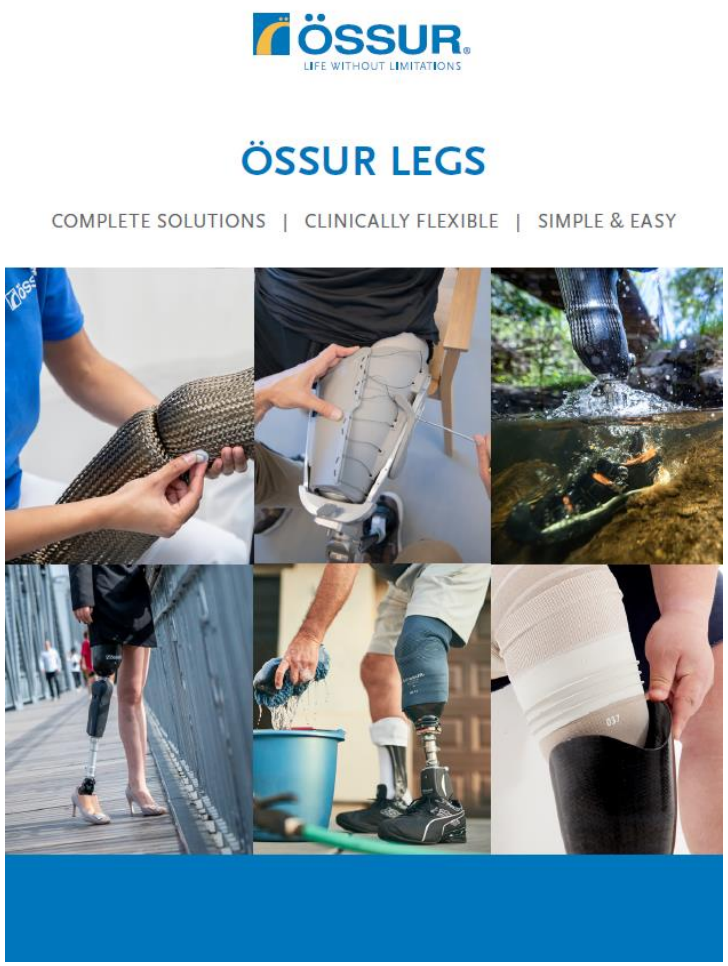
- K3 – K4 Level
- Enhanced stability from Geometric Lock
- Mid-swing shortening for toe clearance
- Incorporates adjustable stance flexion for shock absorption
- 3 phase hydraulic swing phase control for faster speed walking
- Low build height

Cheetah Knee

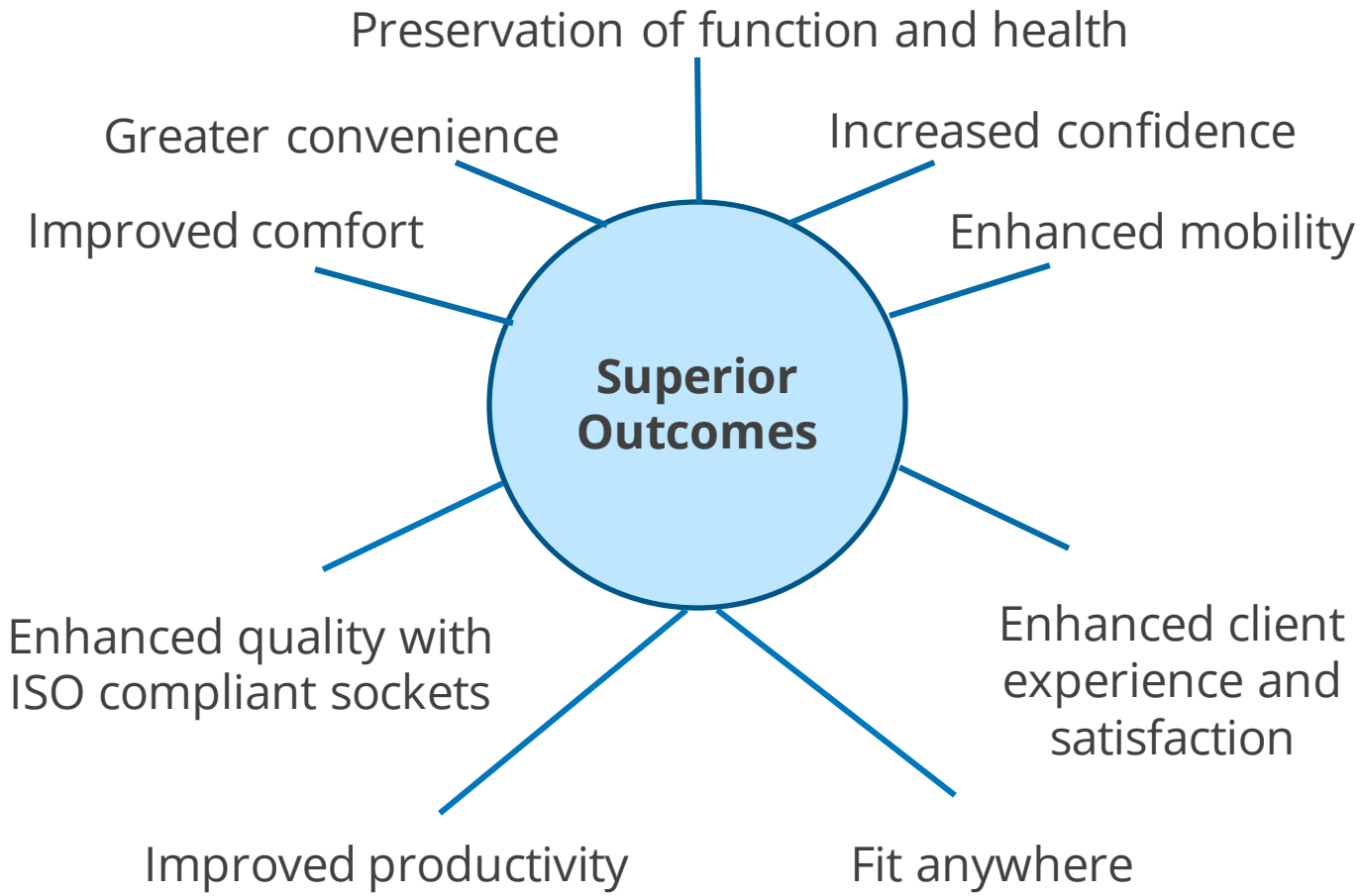
- K3 – 4 Level
- For jogging and distance running
- Enhanced Hydraulics for a faster swing speed
- 4-bar geometry with stable stance control for controlled deceleration
- Extension bumper for softer terminal impact
- Can be combined with the Flex Run for running and jogging

Mechanical Knee Prescription Guide

Össur Legs - Complete Solutions

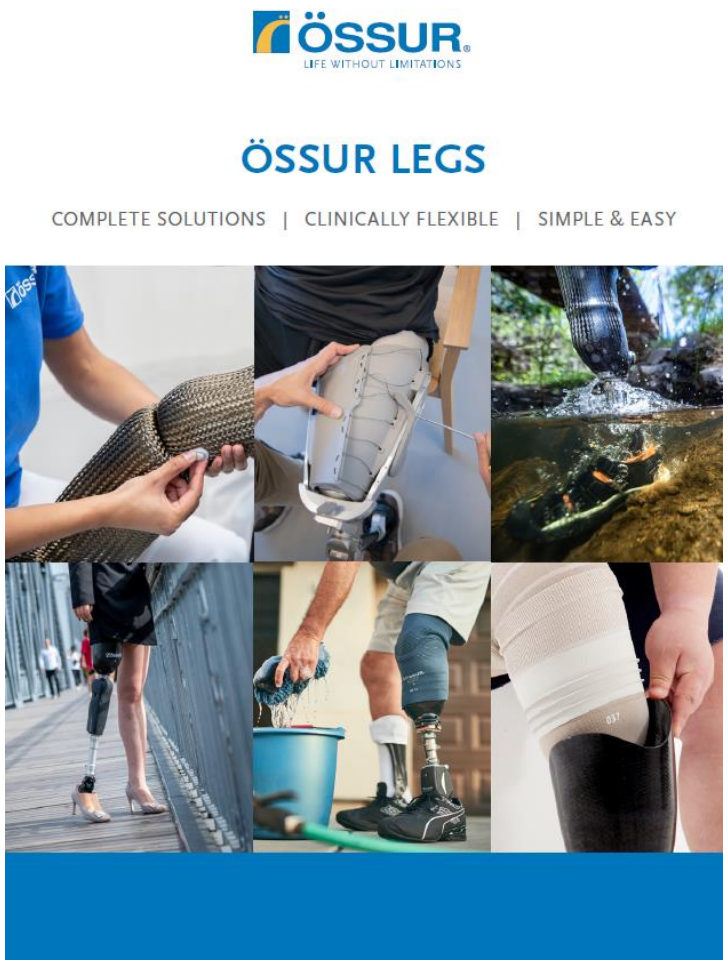


For Clients



For Clinicians & Clinics

Össur Legs - Complete Solutions



- Össur has a complete range of solutions to suit low, moderate, high users
- Commencing in January 2022 we will be launching the Össur legs program
- Please contact your local Össur Clinical Specialist for further information on Össur Legs

Össur Legs – Clinical Specialist Contacts

- Sarah Mulroy-Lang smulroy-lang@ossur.com
- (Senior Clinical Specialist –Prosthetics)
  - Area Manager for VIC, TAS and APC Clinics

- Lizzie Carey ecarey@ossur.com
- (Clinical Specialist- Prosthetics)
  - Area Manager for NZ, NSW and ACT

- Laura Roberts lroberts@ossur.com
- (Clinical Specialist –Prosthetics)
  - Area Manager for QLD, WA, NT and SA

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