Triton® smart ankle
Microprocessor Ankle Foot System

Reimbursement Reference Guide
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Triton® smart ankle
The Triton smart ankle is designed for transtibial and transfemoral prosthetic users, both limited and full community ambulators. The Triton smart ankle is especially suitable for users who need to navigate long inclines or declines, frequently change walking speed, cover long distances, work in a seated position, wear various shoe heights, or need large battery capacity.

HCPCS Code\(^1,2\)
L5973 Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source.

FDA Status
Under FDA’s regulations, Triton smart ankle is a Class I medical device and exempt from the premarket notification [510(k)] requirements. Given the low risk of Class I medical devices, FDA determined that General Controls are sufficient to provide reasonable assurance of the device’s safety and effectiveness; therefore, safety and effectiveness research is not required for this device. Triton smart ankle has met all the General Control requirements which include Establishment Registration (21CFR 807), Medical Device Listing (21 CFR part 807), Quality System Regulation (21 CFR part 820), Labeling (21 CFR part 801), and Medical Device Reporting (21 CFR Part 803). Triton smart ankle is listed under External Limb Prosthetic Component; Product Code ISH; Listing Number E253230

Warranty
Triton smart ankle comes with a three-year manufacturer warranty. During the warranty period, repair costs are covered except for those associated with damages resulting from improper use.

\(^1\)The product/device “Supplier” (defined as an O&P Practitioner or O&P patient care facility) assumes full responsibility for accurate billing of Ottobock products. It is the Supplier’s responsibility to determine medical necessity; ensure coverage criteria is met; and submit appropriate HCPCS codes, modifiers, and charges for services/products delivered. It is also recommended that Supplier’s contact insurance payer(s) for coding and coverage guidance prior to submitting claims. Ottobock Coding Suggestions and Reimbursement Guides are based on reasonable judgment and are not recommended to replace the Supplier’s judgment. These recommendations may be subject to revision based on additional information or alpha-numeric system changes.

\(^2\) Medicare covers L5973 for Medicare Functional Classification Level - K3 and K4 only.
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Microprocessor Controlled Hydraulics
The Triton smart ankle adapts incrementally to changes in the ankle position during stance phase. The maximum ROM/position is up to 17° dorsiflexion and 17° plantar flexion.

Safety Issue: Patient trips, stumbles, or falls frequently
Findings: Increased minimal toe clearance, and reduction in risk of tripping over an unseen obstacle in below-knee amputees

Given the mechanical constraints imposed by a prosthesis, people with amputation tend to be at increased risk of falling compared with age-matched nondisabled individuals [1, 2]. People with amputation have been shown to have a reduced minimal toe clearance (MTC) on the prosthetic limb compared with the intact limb when walking over level ground [3, 4], with interlimb differences increasing when walking on an uneven surface [4]. The reduced MTC on the prosthetic side is likely to be at least partly due to the prosthetic foot’s inability to actively dorsiflex during swing, and this may explain the greater falls risk in people with amputation. Most clinically available prosthetic feet have either a rigid, non-articulating attachment or an "ankle" device that allows elastically controlled articulation, for example, by incorporation of a rubber snubber at the point of attachment. Such elastically controlled devices have an inherent tendency to return to the neutral position once unloaded. Therefore, once the prosthetic foot leaves the ground the ankle angle returns to neutral and remains so throughout swing. This could partly explain why MTC has been shown to be reduced on the prosthetic compared with intact side [4].

Minimal toe clearance in below-knee amputees has been demonstrated to significantly increase when using a foot with hydraulic ankle (5, 6), especially with microprocessor (MP) control (6). Compared to standard ESR feet, walking with an hydraulic ankle that provides 3° of dorsiflexion during swing significantly increased mean MTC on the prosthetic side by 18% (p=.03) and on the sound side by 7% (5). The lowest MTC measured in all trials with the hydraulic ankle was 4 mm, whereas with the standard ESR feet quite a few MTC values of less than only 2 mm were seen. The increase in MTC also allowed for a significantly faster self-selected walking speed (p<.001) (5).

In a study with an MP controlled hydraulic ankle that can produce up to 10° of dorsiflexion, even bigger improvements of MTC were found in level and incline walking that increased with faster walking velocity. At 80%, 100%, and 120% of self-selected walking speed, mean MTC on the prosthetic side significantly (p<.001 each) increased during level walking by 28%, 74%, and 65%, respectively, and on a 5° incline by 53%, 72%, and 100%, respectively (6). The risk of tripping over an unseen obstacle of 5 mm height decreased from 1 in 166 steps with standard ESR feet to 1 in 3,169 steps with the MP controlled hydraulic ankle (6). As the Triton Smart Ankle is able to provide up to 17° and thus 70% more dorsiflexion than the MP controlled ankle studied (6), it can be expected to increase mean MTC and decrease the risk of tripping to an even greater amount.

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Deep soft tissue injuries: Patient experiences pain, pressure sores, and bruises at the skin and soft tissues of the residual limb, especially local pain while walking on non-level surfaces.

Findings: Reduction of soft tissue loading and pressure during walking, especially while walking on slopes, uneven terrain, and stairs.

Deep soft tissue injury (DTI) may occur in soft tissues situated between a bony prominence and a support surface [1-5]. In below-knee amputees, the soft tissues in danger are the gastrocnemius muscle and fat tissues, compressed between the truncated tibia and fibula bones and the hard prosthetic socket. The soft tissues situated at the distal tibial end were clinically observed to be one of the most common areas of tissue damage due to high pressure generation, leading to restriction of blood flow and reduced oxygenation. The resulting tissue breakdown is the main cause of severe pain followed by high incidence of rejection of the prosthesis [6]. While healthy traumatic amputees naturally detect pain when their residual limb is under excessive or prolonged pressure, diabetic or vascular amputees who suffer from neuropathy may not respond to normal biological nerve signals due to their comorbidity, therefore subjecting their residuum to potential DTI [8].

In prosthetic feet with a rigid ankle, especially walking on slopes, uneven terrain, and stairs is associated with relative movements (tilt) between the socket and the residual limb in the sagittal plane, resulting in high peak pressures in the anterior (uphill and on stairs) and posterior regions (downhill) as well as the distal end of the residual limb [7]. Thus, it can be expected that the socket tilt and the resulting peak pressures may be diminished by prosthetic feet with hydraulic ankles that allow for dorsiflexion and plantarflexion. In a study with a hydraulic ankle that provides up to 3° of dorsiflexion and plantarflexion each, the residual limb loading rate and internal stresses were reduced by up two thirds in level and uneven terrain walking, slope and stair ascent and descent compared to standard ESR feet, attaining statistical significance in paved floor walking (p<.03) and stair ascent (p<.01) [8].

In a study with an MP controlled hydraulic ankle that provides up to 10° of dorsiflexion and up to 18° of plantarflexion, peak pressures and pressure time integrals inside the socket measured during slope and stair negotiation were significantly reduced [p<.05 to p<.001, depending on sensor position), more even, and much closer to those in level walking as compared to the rigid ankle condition [9].

In conclusion, both studies suggest that using a foot with a hydraulic ankle may protect the residual limb soft tissues in below-knee amputees from high stresses, therefore preventing pressure related injury. As the Triton Smart Ankle provides even up to 17° of dorsiflexion, it can be expected to diminish anterior peak pressures even more than the two feet studied.

References
2) Oomens CW, Loerakker S, Bader DL. The importance of internal strain as opposed to interface pressure in the prevention of pressure related deep tissue injury. J Tissue Viability 2010;19:35–42.
8) Portnoy S, Kristal A, Gefen A, Siev-Ner I. Outdoor dynamic subject-specific evaluation of internal stresses in...
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the residual limb: Hydraulic energy-stored prosthetic foot compared to conventional energy-stored feet. Gait Posture 2012; 35:121-125.


Level Walking: Patient experiences difficulty increasing walking speed and/or walking longer distances.

Findings: Reduction of braking forces during level walking; reduction of the perception to have to “climb over the foot” at loading response; significant increase in self-selected walking speed in both below- and above-knee

Level walking – ability to walk fast and longer distances

During normal able-bodied gait, the center of pressure (CoP) progresses throughout stance along the plantar surface of the foot from the heel forwards to the toes. Such progression reflects how the forward progression of the whole body center of mass is controlled [1]. In amputee gait, CoP forward progression will be governed by the compliance of the prosthetic foot device [2] and in particular its ability to simulate ankle function to provide 1st and 2nd rocker phases of gait. Many current so-called energy-storing and return (ESR) prosthetic feet have no articulating components, and instead deformation of the foot’s flexible heel spring provides simulated plantarflexion and deformation of the forefoot spring simulates dorsiflexion about an undefined axis. In lower-limb amputees, the CoP has been found to remain in the hindfoot area under the prosthetic foot significantly longer than in both the intact or able-bodied control limbs [1], and at times even move backwards towards the heel during early to mid-stance [1, 3]. This phenomenon is caused by an inappropriate recoil of the heel spring at about 20% of stance phase, resulting in an early heel rise or “bouncing” or unstable sensation [4], often perceived by patients as “having to climb over the foot”, “stuttering” or “dead spot”[5]. During mid- to late stance, loading of the forefoot spring results in increased energy-return from the foot into the shank, creating braking forces with a deceleration of the forward shank rotation [6]. These braking forces in early and late stance increase with faster walking speed and have to be overcome by additional work of the intact limb [1, 3, 6], resulting in restrictions to willingly increase walking speed and walk longer distances.

Studies have demonstrated that a prosthetic foot with a hydraulic ankle can significantly reduce or even eliminate the posterior displacement of the CoP in early to mid-stance and significantly increase the mean forward shank rotational velocity during weight transfer onto the prosthesis [5, 7, 8]. As a result of this significant reduction in braking forces, self-selected walking speed increased significantly in both below- and above-knee amputees [5, 7] with a concurrent reduction in speed-dependent compensatory kinetic adaptations and work of the sound limb [8]. These findings show that a hydraulic ankle allows for smoother and less faltering transfer of the bodyweight onto the prosthetic limb. Consequently, study participants reported the perception of having to ‘climb over’ their prosthesis was no longer present [5, 7], allowing them to increase walking speed and walk longer distances than with standard ESR feet.

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Slopes: Patient has difficulty negotiating slopes, and/or experiences considerable compensatory movements when walking on slopes.

Findings: More symmetrical and physiological movement patterns with reduction of compensatory movements and loading of the sound side in below-knee amputees.

Conventional rigid prosthetic ankles lack dorsi- and plantarflexion which induces locomotion difficulties, especially when walking on slopes [1, 2]. The very limited ankle range of motion and power generation as well as reduced proprioception and tolerance of force compromise the stability of the residual limb during stance, demonstrated by shorter single support and smaller moments and powers measured in transtibial amputees compared to able-bodied subjects. These adaptations result in a slower walking speed on slopes with reduced knee and hip range of motion and hip moments, but greater amplitude and time of muscle activity in both limbs [1]. A study on slope ambulation demonstrated that the use of an MP controlled hydraulic ankle with up to 10° of dorsiflexion during slope ascent resulted in significant improvements in ankle kinematics (dorsiflexion) and knee and hip kinematics (range of motion) and kinetics (moments = loading) on both the prosthetic and the sound side. During slope descent, the MP controlled hydraulic ankle with up to 18° of plantarflexion improved plantarflexion and hip kinematics (range of motion) on the prosthetic side and hip kinetics (moments = loading) in the sound limb [3]. Subjectively, the patients reported that slope ambulation was easier [4] and safer [3] when walking in the adapted mode with increased dorsi- and plantarflexion, suggesting that the self-reported improvements are not fully reflected by the changes in kinematics and kinetics [3]. This may have been caused by the only partial adaptation of the studied foot to the tested inclines [3]. As the Triton Smart Ankle allows for 17° of dorsi- and plantarflexion each with faster (2° per step) and greater adaptation to inclines, it can be expected to even better facilitate slope negotiation than the studied MP controlled foot.

References

Stairs: Patient has difficulty negotiating stairs and/or experiences considerable compensatory movements when walking on stairs.

Findings: More symmetrical and physiological movement patterns with reduction of compensatory movements and loading of the sound side in below-knee amputees.

Stair ambulation increases the kinetic demand compared with level walking [1-4] and emphasizes motor deficits. For amputees who usually suffer from restrictions of muscle strength and joint mobility, balance, or proprioception, stair ambulation becomes specifically challenging [5-8]. Thus, amputees negotiate stairs considerably slower and with greater stance asymmetry and increased muscular effort than able-bodied controls [5, 7].

During stair ascent, below-knee amputees use a particular compensation mechanism that could be a result of a strategy favoring knee stability on the prosthetic side [9]. They generate a strong hip moment...
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to elevate the body during stance on their prosthetic side, conversely to able-bodied subjects who mainly utilize a knee moment [6, 9]. The preparation of the next foot contact is also a challenge on both sides [6]. When preparing step contact for the sound limb, the missing active plantarflexion of the prosthetic foot leads to an insufficient vertical position of the body’s center of mass (CoM). When preparing step contact for the prosthetic limb, the missing dorsiflexion of the foot reduces toe clearance directly prior to the support phase. Both challenges are compensated for by the sound limb through an increased knee flexion during late swing and an increased plantarflexion during late stance [6]. A study with an MP controlled hydraulic ankle with up to 10° of dorsiflexion demonstrated that the increased dorsiflexion had the tendency to diminish the “hip strategy” of power generation and to result in a generally more physiological gait pattern on the prosthetic side. This was reflected by the fact that the differences to able-bodied subjects in kinematics (range of motion) and kinetics (moments = loading) of stair ascent were significantly smaller than when walking with the rigid ankle. With the adapted ankle, knee flexion during loading response and mid-stance was favored and reduced the need for hip flexion at initial contact.

During stair descent, amputees adopt a specific landing strategy on their prosthetic side, with the CoM positioned directly over the landing limb at initial contact. It probably ensures that the ground reaction force is positioned anterior to the knee joint center to ensure knee extension and stability [11]. At loading response, knee flexion is also restricted, possibly as a result of the reduced or missing dorsiflexion [10]. On the sound side, ground contact is initiated with increased plantarflexion, probably to compensate for the lack of dorsiflexion of the prosthetic foot, which causes the amputees to “fall” onto their sound limb. According to these findings, stair ambulation is always challenging to below-knee amputees due to the shortcomings of standard prosthetic feet with rigid ankles in neutral position [10]. When the MP controlled hydraulic ankle with up to 10° of dorsiflexion and up to 18° of plantarflexion, kinematics (range of motion) and kinetics (moments = loading) of the prosthetic side during stair descent were significantly closer to physiologic patterns of hip angle, moment, and power, as well as knee moment. Knee flexion on the prosthetic limb was more pronounced during mid-stance, which results in a greater knee extension moment and power absorption to control the bodyweight acceptance in early stance phase [10]. Both during stair ascent and descent, the most noticeable improvements provided by the increased dorsiflexion of the MP controlled hydraulic ankle were related to more physiologic knee flexion kinematics (range of motion) and kinetics (moments = loading) on the prosthetic side during stance [10]. This may diminish potential joint and muscle overuse and pain. As the Triton Smart Ankle allows for 17° of dorsi- and plantarflexion each, it can be expected to even better facilitate stair negotiation than the studied MP controlled foot.

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Heel Height Adjustment
Using the Galileo™ Smartphone App, the user may adjust for different footwear on a daily basis up to 2 inches (50mm) or even walk barefoot, without affecting the overall status of the prosthesis.

Relief Function
By unloading the foot for 2 seconds, the user can move the foot into a natural position when sitting, standing or kneeling. Once the foot is loaded, the Relief Function is deactivated.

• Foot moves into full ground contact when sitting.
• Foot moves into natural position when kneeling.
• Foot moves into natural position when standing on uneven ground or certain working positions, thus avoiding balancing on heel or toes.
• May provide relief to the residual limb, especially in confined spaces.

Perceived Toe Stiffness
With the Galileo™ Smartphone App, the user can adjust the Home Position of the Triton smart ankle by a small degree. This adjustment translates to the user as a change in the perceived Toe Stiffness, which allows for more relaxed or dynamic walking modes and improved response of the foot to the desired walking style.

Free Ankle Motion
With the Galileo™ Smartphone App the user may initiate the Free Ankle Motion Function, where the valve of the hydraulic opens for 15 seconds during which time the foot can be moved into a desired position. This allows for easier donning or doffing of pants and shoes.

Ankle Lock
Using a movement pattern, the ankle can be locked in a fixed position (e.g. for certain exercises or activities such as driving).

Battery Capacity
The Triton smart ankle stays charged for 2-3 days.

Microprocessor-Controlled Prosthetic Ankle/Foot Clinical Studies


