Kinnex Summary of Evidence (Full Version)

1. **Introduction**

This document establishes the benefit of microprocessor controlled prosthetic ankle components for persons who use a lower limb prosthesis. The Kinnex™ Microprocessor Controlled (MPC) Ankle/Foot System has been available since 2016, and microprocessor ankles have been evaluated in research literature since 2009. Twenty-one different publications were reviewed and established evidence that the Kinnex™ MPC Ankle/Foot System provides benefits over fixed ankle prosthetic systems. These benefits are broken down into the following six areas: level ground ambulation, socket comfort, uneven terrain ambulation, sit to stand, ramp ambulation, and stair ambulation.

Freedom Innovations, LLC developed the Kinnex™ microprocessor controlled hydraulic ankle to address limitations of fixed ankle prosthetic systems. The Kinnex™ is comprised of a graphite foot module, electronic sensors, and a hydraulic single-axis ankle with microprocessor control. A joint rotation sensor, a combined load/torque sensor, an inertial measurement unit (IMU) with integral accelerometers and gyroscopes provide the input to the microprocessor. A linear hydraulic piston provides ankle damping with 10° dorsiflexion and 20° plantar flexion for a combined 30° ankle range of motion (ROM). Mechanical and hydraulic stops have been included in the design to limit the ROM when desired. For specific functional tasks and safety, the Kinnex™ has a mechanical lock to prevent ankle ROM. The Kinnex™ is programmed and adjusted via iOS and Android software interfaces (apps). Additionally, with the microprocessor, it is able to adapt to the slope of the terrain. This feature is intended to improve the user's ability to walk on uneven terrain. The Kinnex™ is also designed to adapt to shoes of varying heel heights so heel height will not affect walking performance of the user.

A recent pilot study compared the Kinnex™ microprocessor controlled ankle against fixed ankle prosthetic foot systems. The pilot study results supported benefits of the Kinnex™ on slope ambulation and during standing on a slope. These results from a small sample size have motivated a larger research study which has enrolled more participants. The results from the larger study are expected in mid-year 2017.

The following six sections explain how the Kinnex™ benefits persons who use a lower limb prosthesis and why it is necessary when compared to a fixed ankle prosthetic ankle system. The up-to-date research evidence further supports this necessity of the Kinnex™ MPC Ankle/Foot System.

2. **Benefits on Level Ground Ambulation**

While ambulating over level ground, a person with lower limb amputation experiences adverse effects and diminished ambulatory capacity due to the shortcomings of a fixed ankle prosthesis in replicating the functions of the anatomical ankle. A microprocessor controlled prosthetic ankle, such as the Kinnex™, provides the ankle dorsiflexion and plantar flexion range of motion necessary to allow persons with lower limb amputation to ambulate on level ground with less impact loads, increased forward progression, and ankle stiffness which matches walking speed.

Microprocessor controlled prosthetic ankles can address shortcomings of fixed ankle prostheses during level ground ambulation in persons with lower limb amputation. In replacing the function of the human anatomical ankle during level ground ambulation, a fixed ankle prosthesis does not provide the shock absorption during the first rocker stance phase[1] (Perry 1997). The heel mechanism of a fixed ankle prosthesis attempts to provide the shock absorption by using a cushion, bumper, or carbon fiber lever in the heel. However, these mechanical structures do not replicate the controlled eccentric plantar flexion of the anatomical ankle during loading response and the first rocker of stance phase. When the mechanical structures compress, the prosthetic foot is delayed in achieving foot flat and leads to an unstable heel only contact[1] (Perry 1997). This disrupts the forward progression of the center of pressure[2] (DeAsha 2013a), the patient's residual limb is exposed to reaction forces and pressures from the socket, and body weight acceptance of the amputated limb and walking speed are negatively affected[2] (DeAsha 2013a).

The Kinnex™ MPC Ankle/Foot System provides controlled hydraulic dampened plantar flexion range of motion in the ankle to replicate shock absorption in loading response during the first rocker of stance phase of gait. The plantar flexion resistance in the Kinnex™ can provide the energy absorption to replace the eccentric plantar flexion of the anatomical ankle. This benefit leads to a more continuous forward progression of the center of pressure and a reduction in the external reaction forces and pressures in the prosthetic socket forcing the residual knee into flexion.

Fixed ankle prostheses cannot react to a change in walking speed, step cadence and associated increase in body weight loading into the prosthesis. This makes it difficult for persons with lower limb amputation to ambulate at more than one walking speed. Fixed ankle carbon fiber energy storing prosthetic feet are currently reserved for patients that have the capacity to walk with variable step cadence[3] (Noridian LCD). These and other fixed ankle prostheses provide no change in function when walking speed and step cadence are increased or decreased [4](DeAsha 2013b). This inherent structural limitation of fixed ankle prostheses can cause persons with lower limb amputation to experience a prosthetic ankle stiffness that is not attuned to the walking speed (e.g. too stiff at slower walking speeds or too flexible at higher walking speeds).

The Kinnex™ microprocessor controlled prosthetic ankle regulates the resistance in the ankle throughout the gait cycle and reacts to changes in walking speed and step cadence. With every step, the microprocessor adjusts the ankle joint stiffness to optimize the function of the hydraulic cylinder and carbon fiber heel and keel levers. This creates an ankle joint stiffness which is automatically varied to match the walking cadence.

[1] Perry, Jacquelin, et al. "Prosthetic weight acceptance mechanics in transtibial amputees wearing the Single Axis, Seattle Lite, and Flex Foot." *IEEE transactions on rehabilitation engineering* 5.4 (1997): 283-289.
[2] De Asha, Alan R., et al. "Attenuation of centre-of-pressure trajectory fluctuations under the prosthetic foot when using an articulating hydraulic ankle attachment compared to fixed attachment." Clinical Biomechanics 28.2 (2013): 218-224.
[3] Noridian Healthcare Solutions, Local coverage determination (LCD) for lower limb prostheses (L33787). 2016, American Medical Association.
[4] De Asha, Alan R., et al. "Walking speed related joint kinetic alterations in trans-tibial amputees: impact of hydraulic'ankle'damping." Journal of neuroengineering and rehabilitation 10.1 (2013): 107.

3. **Benefits to Socket Comfort**

When surveyed, persons who use a lower limb prosthesis rate socket comfort as the most important factor of their prosthetic experience[5] (Legro 1999). Socket discomfort and pressure related skin complications are also frequent problems which limit use of a prosthesis[6] (Gauthier-Fiagnon 1998). A fixed ankle prosthesis exposes the residual limb to higher pressures when ambulating on stairs and slopes [7](Wolf 2009) and uneven terrain[8] (Dou 2006). When walking on level ground, the residual limb experiences peak stresses in the socket at the beginning and end of stance phase[7] (Wolf 2009). The high pressures experienced by the residual limb in these conditions are caused by the lack of motion and angle accommodation in a fixed ankle prosthesis.

Microprocessor controlled prosthetic ankles have been shown to reduce socket pressure during slope and stair ambulation[7] (Wolf 2009). The Kinnex™ allows the ankle to accommodate up to 10° of incline slope and 20° of decline slope during ambulation. By accommodating the uneven surfaces and allowing controlled ankle dorsiflexion and plantar flexion range of motion, a microprocessor ankle reduces the reaction forces and pressures at the socket interface[7] (Wolf 2009), making walking on slopes feel more like walking on level ground. This is not possible with a fixed ankle prosthesis, and the Kinnex™ provides this benefit through the hydraulically dampened plantar flexion and dorsiflexion in the ankle. The resistance in the ankle can be increased or decreased during the programming of the Kinnex™ or through the user software interface (app) in order to reduce the reaction forces and pressures at the socket interface. With this feature, the Kinnex™ allows persons with lower limb amputation to wear their prosthesis longer and ambulate over more environmental barriers without exposing their residual limb to increased pressure and discomfort.

4. **Benefits on Uneven Terrain Ambulation**

Uneven terrain restricts mobility and balance for persons who use a lower limb prosthesis due to the variability in the slope of the ground and the reaction forces and pressures this inflicts upon the residual limb. Fixed ankle prostheses are designed to support ambulation on flat level surfaces. Patients with lower limb amputation are unable to detect the step-to-step change in slope of the ground when walking over uneven terrain, and a fixed ankle prosthesis is unable to react to the change in slope. As a result, the residual limb is exposed to different loads on every step making it difficult for patients to maintain balance. On a simulated uneven walkway, patients using a fixed ankle lower limb prosthesis

[5] Legro, Marcia W., et al. "Issues of importance reported by persons with lower limb amputations and protheses." *Journal of rehabilitation research and development* 36.3 (1999): 155.
[6] Gauthier-fiagnon, Christiane, Marie-Claude Grise, and Diane Potvin. "Predisposing Factors Related to Prosthetic Use by People with a Transtibial and Transfemoral Amputation." *JPO: Journal of Prosthetics and Orthotics* 10.4 (1998): 99-109.
[7] Wolf, Sebastian I., et al. "Pressure characteristics at the stump/socket interface in transtibial amputees using an adaptive prosthetic foot." Clinical Biomechanics 24.10 (2009): 860-865.
[8] Dou, Peng, et al. "Pressure distribution at the stump/socket interface in transtibial amputees during walking on stairs, slope and non-flat road." *Clinical Biomechanics* 21.10 (2006): 1067-1073.

exhibited a destabilized gait pattern[9] (Smith 2015). Additionally, walking with a fixed ankle prosthesis on a non-flat road causes increased pressure on the residual limb from the prosthetic socket[8] (Dou 2006).

The benefits the Kinnex™ MPC Ankle/Foot System provides can improve mobility on uneven terrain and lessen the burden of this environmental barrier. The Kinnex™ provides ankle dorsiflexion and plantar flexion range of motion and controlled hydraulic dampening necessary for persons with lower limb amputation to ambulate over uneven terrain. The step-to-step change in ground slope is accommodated through this ankle range of motion without causing reaction forces and pressures on the residual limb. For example, when a patient steps on a rock or uneven sidewalk surface, the Kinnex™ ankle is designed to move rapidly into foot flat to accommodate the angle of the terrain. With the Kinnex™, the patient can load the prosthesis with full body weight on every step without losing his or her balance or experiencing excessive socket pressures on the residual limb.

5. **Benefits in Sit to Stand**

Standing from a seated position is difficult for persons with a lower limb amputation using a fixed ankle prosthesis. Microprocessor controlled prosthetic ankles provide ankle dorsiflexion range of motion to assist patients ascending from a seated position.

With a fixed ankle prosthesis, persons with lower limb amputation must put most of their weight through the sound limb[10] (Agrawal 2011). Without dorsiflexion range of motion a fixed ankle prosthesis causes patients to hold their limb more anterior, away from the seat and their center of mass. In this position the hip and knee musculature in the residual limb cannot assist in standing from ascent initiation. Ankle dorsiflexion range of motion from the Kinnex™ allows the patient to position the prosthesis further posterior underneath the seat. This moves the prosthetic foot closer to the center of mass and enables the patient to engage the hip and knee extensor musculature of their residual limb to contribute to ascent initiation when standing from a chair.

6. **Benefits on Ramp Ambulation**

Patients with lower limb amputation who use a fixed ankle prosthesis frequently encounter sloped surfaces which cause compensatory movements, expose the residual limb to excessive pressure, and pose a serious environmental barrier. A microprocessor controlled ankle prosthesis addresses these shortcomings by accommodating for the sloped surface through controlled plantar flexion and dorsiflexion ankle range of motion.

With a fixed ankle, the prosthesis cannot accommodate the slope or achieve foot-flat in a normal manner, resulting in an unstable heel-only support when transferring weight onto the prosthesis[1] (Perry 1997). Descending a slope, the patient has been found to experience increased pressures through the socket[7] (Wolf 2009) and a knee flexion moment[11](Vickers 2008). The combination of torque and pressure from the prosthetic socket become too much for patients to tolerate on their residual limbs. To

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[9] Smith, A. M. S., et al. "Prosthetic Feet with Multi-Axial Features Being Used on Uneven Terrain: A Patient-Centered Investigation." Journal of the Proceedings of the 41st Academy Annual Meeting & Scientific Symposium (2015)

[10] Agrawal, Vibhor, et al. "Weight distribution symmetry during the sit-to-stand movement of unilateral transtibial amputees." *Ergonomics* 54.7 (2011): 656-664.

[11] Vickers, D.R., Palk, C.,McIntosh, A.S., Beatty, K.T., 2008. Elderly unilateral transtibial amputee gait on an inclined walkway: a biomechanical analysis. Gait Posture 27, 518–529.

compensate, patients are forced to rapidly flex their knee and fall forward with a short prosthetic side step duration and asymmetrical step length[11] (Vickers 2008). Due to the lack of slope accommodation in a fixed ankle prosthesis, the sound limb experiences more loads and is left to control the lowering of the body through increased negative work required of the sound side knee and hip[12] (Fradet 2010).

A microprocessor controlled ankle improves walking down a slope by accommodating the angle and performing negative work at the ankle through controlled plantar flexion and dorsiflexion[13] (Struchkov 2016). This has been shown to reduce the compensatory movements while walking down slopes[13] (Struchkov 2016). Unlike a fixed ankle, the Kinnex™ microprocessor controlled ankle provides ankle plantar flexion during loading of the limb for an earlier foot flat with the ground. A microprocessor controlled prosthetic ankle provides faster foot flat, and a faster foot flat increases the stability of the prosthetic limb during weight transfer[1] (Perry 1997). This also reduces the excessive socket pressures on the residual limb[7] (Wolf 2009) and allows a more extended and stable knee alignment while loading the prosthetic limb[13] (Struchkov 2016). The Kinnex™ microprocessor controlled ankle allows the patient to lower his or her body while still maintaining forward momentum through controlled hydraulic dampening in the ankle and deflection of the carbon fiber heel of the foot. To provide this function, the stiffness of the hydraulic dampening is optimized with the carbon fiber heel deflection during the programming of the Kinnex™ or through the user software interface (app). Then, the stiffness is adjusted by the microprocessor on every step to match the walking speed. This combination of hydraulic dampening and carbon fiber heel deflection is not possible with fixed ankle prostheses or hydraulic ankles not controlled by a microprocessor. The biomechanical advantages of microprocessor controlled ankles have contributed to patients reporting feeling safer when descending slopes[12] (Fradet 2010).

In the pilot study, which compared the Kinnex™ against fixed ankle prostheses, patients showed improved function descending a sloped ramp on the Hill Assessment Index (HAI) test in addition to a more extended prosthetic side knee angle at mid-stance of gait during ramp ascent when using the Kinnex™. The benefits of the Kinnex™ over fixed ankle prostheses on ramp descent have been confirmed in the pilot study.

Ascending a slope can be just as difficult for a patient using a fixed ankle prosthesis. The lack of angle accommodation in a fixed ankle causes knee hyperextension of the residual limb[12] (Fradet 2010) and increased socket pressures[7] (Wolf 2009). The knee hyperextension and pressures become intolerable to the patient's residual limb and patients compensate by taking short step lengths and decreasing the duration of time spent on the prosthesis along with other gait deviations[14] (Vrieling 2008). The patient's sound side is then required to perform more work in elevating the body up the slope, leading to increased loading and strain on the sound side limb. To avoid the knee hyperextension on the residual limb, some patients will adopt the compensatory strategy of walking up slopes with a toe-only support during stance phase and a relatively flexed knee position on the side with the prosthesis. The patient is less balanced with toe-only support and limited contact with the ground. Holding a flexed knee position against the hyperextension torque from the slope requires a considerable amount of knee flexion

[12] Fradet, Laetitia, et al. "Biomechanical analysis of ramp ambulation of transtibial amputees with an adaptive ankle foot system." Gait & posture 32.2 (2010): 191-198.
[13] Struchkov, Vasily, and John G. Buckley. "Biomechanics of ramp descent in unilateral trans-tibial amputees: Comparison of a microprocessor controlled foot with conventional ankle–foot mechanisms." Clinical Biomechanics 32 (2016): 164-170.
[14] Vrieling, A. H., et al. "Uphill and downhill walking in unilateral lower limb amputees." Gait & posture 28.2 (2008): 235-242.

strength, increases the energy cost of ascending a slope, and exposes the residual limb to high socket pressures. For these reasons, an uphill slope can pose a serious environmental barrier to a person using a lower limb prosthesis.

The Kinnex™ MPC Ankle/Foot System can accommodate the slope angle through controlled dorsiflexion range of motion. This dorsiflexion range of motion of a microprocessor controlled ankle has been shown to reduce the knee hyperextension of the residual limb and reduce the demand on the sound side limb to lift the body up the slope[12] (Fradet 2010). The pressures experienced in the socket are also reduced when the microprocessor controlled ankle accommodates the slope[7] (Wolf 2009). Patients are more stable with the prosthetic foot flat on the ground which allows them to load more body weight during stance phase on the prosthesis[12] (Fradet 2010). To accommodate a slope when ascending an incline, the Kinnex™ has an available 10° of ankle dorsiflexion. The microprocessor controls the hydraulic stop mechanism in the Kinnex™ to allow the ankle to dorsiflex past neutral and allow 10° of ankle dorsiflexion. The hydraulic resistance maintains the Kinnex™ in a dorsiflexed position during swing phase for toe clearance and accommodating the slope in subsequent steps while ascending an incline. By accommodating the slope angle through controlled ankle dorsiflexion and plantar flexion, the Kinnex™ reduces gait compensations, socket pressures, and knee hyperextension of the residual limb and allows the patient to use the prosthetic side more when ambulating up a slope. These benefits can reduce the limitations which sloped surfaces pose for persons with a lower limb amputation.

In the pilot study, which compared the Kinnex™ against fixed ankle prostheses, patients exhibited a more dorsiflexed prosthetic side ankle angle at mid-stance of gait during ramp ascent when using the Kinnex™. The benefits of the Kinnex™ over fixed ankle prostheses on ramp descent have been confirmed in the pilot study.

7. **Benefits on Stair Ambulation**

A fixed ankle prosthesis limits function on stair ambulation and requires compensatory strategies by persons with lower limb amputation. A prosthesis with a microprocessor controlled ankle allowing controlled plantar flexion and dorsiflexion range of motion provides improved function on stair ambulation.

Without a microprocessor controlled ankle, a patient’s body center of mass remains further posterior when ascending stairs. This requires the patient to reach further with the intact limb and use more involved side hip extensors. These compensatory requirements from a fixed ankle prosthesis can be addressed with a microprocessor controlled prosthetic ankle. Ankle angle adaptation and range of motion on stairs results in improved knee kinematic and kinetics on stair ascent and descent, which more closely mimics natural human locomotion[15] (Alimusaj 2009). During stair ascent, a prosthesis with a Kinnex™ MPC Ankle/Foot System allows ankle dorsiflexion in terminal stance phase of gait compared to a fixed ankle prosthesis. This allows users of a microprocessor controlled ankle to bring the center of mass more anterior on the step for proper foot placement of the intact side foot and to use the involved side knee extensors more and rely less on the involved side hip extensors[15] (Alimusaj 2009). Finally, the increased ankle dorsiflexion range of motion in a microprocessor controlled prosthetic ankle allows

[15] Alimusaj, Merkur, et al. "Kinematics and kinetics with an adaptive ankle foot system during stair ambulation of transtibial amputees." *Gait & posture* 30.3 (2009): 356-363.

more symmetrical work done by the involved limb and intact limb[16] (Agrawal 2013) because the involved limb is able to tolerate more body weight[16] (Agrawal 2013).

The compensatory gait deviations from a fixed ankle prosthesis can be reduced with a Kinnex™ microprocessor controlled prosthetic ankle. In stair descent, the microprocessor controlled ankle allows a more anterior position of the body's center of mass from an increased ankle dorsiflexion range of motion. This position allows users to lower their body weight onto the next step in a controlled manner. Without this ankle range of motion a fixed ankle prosthesis requires a compensatory strategy, for example, reaching down for the next step with the intact side limb and dropping rapidly down onto the step rather than lowering in a controlled manner.

[16] Agrawal, Vibhor et al. "Comparison between microprocessor-controlled ankle/foot and conventional prosthetic feet during stair negotiation in people with unilateral transtibial amputation." *Journal of rehabilitation research and development* 50.7 (2013): 941.