Walkasins is a prescribed wearable sensory neuroprosthesis enabling patients with Sensory Peripheral Neuropathy to improve walking balance and subsequently decrease risk of falls.

Sensory Peripheral Neuropathy and Balance

Sensory Peripheral Neuropathy (SPN) is a type of nerve damage that frequently affects sensory nerves in the soles of the feet that are responsible for signaling sense of touch, pressure and vibration, information that is crucial for our sense of balance. SPN is a common form of polyneuropathy, seen in up to 50 percent of people with diabetes and in a majority of cancer patients receiving neurotoxic anti-cancer drugs that cause chemotherapy-induced peripheral neuropathies. SPN may also be idiopathic, especially in the older population. SPN is well documented to be associated with gait and balance impairments and a higher prevalence of falls in these categories of patients.

In individuals with SPN and gait and balance impairments, Walkasins replaces lost nerve function and restores important sensory information of foot contact with the ground to the central nervous system.

Physiology of the Balance System

When a normally functioning adult human stands, walks, or performs balance activities, the central nervous system (CNS) relies on three principle sources of sensory information to perform movements and maintain balance in a safe and coordinated manner:

- **Somatosensory System**
  Signals position and touch information including critical pressure sensation from the soles of the feet.

- **Vestibular System (Inner Ear)**
  Signals how the head is oriented in space with respect to gravity to help with balance.

- **Visual System (Sight)**
  Helps maintain orientation and upright balance related to the environment.

Contributions to balance control from these three channels of sensory information are not “weighted” equally and may change with environmental circumstances. When standing on a firm base of support in a well-lit environment, healthy individuals typically rely about 70% on somatosensory system information, 20% on vestibular system information, and 10% on visual system information. The CNS integrates these sources of afferent information to ensure activation of relevant muscles to maintain upright balance and avoid falling.

In normal balance control, the detection of plantar pressure occurs through cutaneous mechanoreceptors in the glabrous skin of the soles of the feet. This pressure information is signaled through cutaneous afferents to the spinal cord, brainstem, thalamic relay nuclei and onto the somatosensory cortex of the brain. An appropriate response is computed in the CNS and signaled through the body’s efferent pathways to activate appropriate muscles to control balance and avoid falling.

While normal balance function naturally declines with age, various balance abnormalities also result from diseases, conditions, or side effects from prescribed therapies. In individuals with SPN, the ability to accurately sense, measure and communicate plantar pressure information is compromised due to afferent nerve damage, often resulting in poor or staggered gait, which increases the risk of falls with the potential for serious injury. Although these patients commonly have intact efferent pathways and motor function, the inability of their afferent nerves to sense and signal plantar pressure leaves the CNS unaware of essential information for optimal balance control.

The principle focus for the design and development of Walkasins Sensory Neuroprosthesis technology is on the somatosensory system and the need to replace plantar pressure sensation in patients with SPN, thereby helping to improve their balance.
Sensory Peripheral Neuropathy and Balance Impairment Research

The role of plantar cutaneous sensory afferent information for balance has been studied for more than two decades and is well-established in the peer-reviewed study literature. Lars Oddsson, Ph.D., a scientist and widely published investigator in topics related to balance, co-invented Walkasins® with PhD student Peter Meyer during his tenure at Boston University’s Neuromuscular Research Center. Their early work on plantar cutaneous sensation for balance control, combined with promising pilot data, led to the NIH-funded development of Walkasins for appropriately diagnosed patients presenting with gait and balance impairments and SPN.

A randomized cross-over study of short-term, in-clinic effects of Walkasins use conducted at the Minneapolis Veterans Affairs Medical Center (VAMC) and recently published in PLOS ONE, found clinically meaningful and statistically significant improvements in gait speed and functional balance in patients with SPN using Walkasins. The authors’ findings suggest new sensory balance cues provided to the lower limb can modulate the activity of relevant nerve afferents and become integrated into sensorimotor control of balance and gait.

An ongoing multi-site clinical trial of long-term use effects of Walkasins (walk2Wellness, ClinicalTrials.org #NCT03538756) is being conducted at the Minneapolis Veterans Affairs Health Care System, M Health Fairview, Baylor College of Medicine, Hebrew SeniorLife (a Harvard Medical School Affiliate), and Johns Hopkins Medical Center. To date, more than 50 subjects have been enrolled, accumulating over 8,000 Walkasins use days.

Interim study data reported to the Peripheral Nerve Society, the American Congress of Rehabilitation Medicine, and the American Assembly of Physical Medicine and Rehabilitation essentially confirm previous in-clinic findings, including sustained improvements in Functional Gait Assessment (FGA) and gait speed, as well as a substantial decrease in self-reported fall rates.

Walkasins® Lower Limb Sensory Prosthesis: How it Works

The Walkasins System is designed to serve as a prosthesis for the lost sensory nerve function from the plantar surface of the foot.

Walkasins Foot Pads detect plantar pressure which is analyzed and interpreted in real-time through a sophisticated proprietary software algorithm in the microprocessor within the Walkasins Leg Unit. The Leg Unit, worn on the lower leg just above the ankle, provides gentle tactile balance stimuli administered by four tactile stimulators embedded in the Leg Unit. Walkasins replaces lost plantar sensation with tactile balance stimuli that modulate cutaneous mechanoreceptors above the ankle where sensation remains sufficiently intact. These new balance stimuli replace lost somatosensory information necessary for the CNS to complete the sensorimotor circuit for balance control.

Minimal instruction is required for patients to benefit from this new sensory information. Following a brief 10-minute in-clinic orientation session, a majority of patients showed meaningful improvements in clinical outcomes.

Lost foot sensation due to peripheral neuropathy causes unsteady walking, often leading to falls.

Walkasins evaluates balance and delivers gentle sensory signals to functioning nerves around the lower leg.

This new sensory information is integrated by the brain to help replace lost foot sensation.

Balance and gait are improved, restoring mobility and confidence.
Care Plans for SPN Patients Susceptible to Falls

Healthcare providers are encouraged to adopt and implement clinical practice guidelines for fall prevention, such as the STEADI initiative developed by the Centers for Disease Control (CDC), which consists of three core elements:

**Screen**
Regular screening of patient-reported fall history and fear of falling is an important step in identifying patients at risk of falls.

**Assess**
Specific fall risk factors, including SPN, along with evaluations of gait and balance may suggest a Falls Plan of Care be developed and interventions implemented.

**Intervene**
Interventions, devices, and treatments to address the identified risk factors should be implemented to help mitigate high fall risk and improve safety.
- Strength and balance training with physical therapy.
- Medication adjustments.
- Home safety modifications.

**Walkasins Sensory Neuroprosthesis** is a newly-available, evidence-based intervention which aligns with the STEADI initiative.

**Assessment for Walkasins**
Prescribers can complete an assessment for gait and balance impairments through commonly used clinical measures, including:
- Functional Gait Assessment (FGA)
- Gait speed
- 4 stage Balance
- Timed Up and Go (TUG)

The FGA has recently been established as the recommended “walking balance assessment” by the American Physical Therapy Association for patients with neurologic conditions who are undergoing rehabilitation and want to improve balance while walking. The FGA has also been shown to be effective in classifying fall risk in community-dwelling older adults as well as identified as a reliable and valid tool.

In the research evaluating Walkasins use on individuals with peripheral neuropathy, the FGA has been used as both a criteria for study inclusion and as a primary outcome measure of gait and balance improvement.

In addition to identifying an individual as being at risk for falls, a sensory test must be completed with the Walkasins Leg Unit to ensure the individual has sufficient sensation to benefit from the technology. Tactile stimuli from the Leg Unit have different sensory characteristics than clinical sensory tests such as monofilament and tuning fork vibration. Patients who are unable to feel monofilament and vibration tuning fork above the ankle, may likely still be able to feel the stimuli from the Walkasins Leg Unit.
Lars Oddsson, PhD
RxFunction Co-Founder and Walkasins Co-Inventor

Lars Oddsson, PhD, is a scientist, an inventor, a visionary leader and an entrepreneur. Dr. Oddsson has studied the physiology and science of balance for over three decades and is widely cited in the peer-reviewed scientific literature with an h-index of 38xviii. Oddsson teaches in the M.S. in Medical Device Innovation program at the Technological Leadership Institute at the University of Minnesota, where he also holds a position as Adjunct Professor in the Division of Rehabilitation Science. He is Visiting Professor at Recanati School of Community Health, Ben-Gurion University, Israel. Oddsson is also Co-investigator at NASA’s Johnson Space Center on projects related to the development of sensorimotor countermeasures to long-term space flight. Oddsson received engineering training at Linköping University, his doctorate in Medical Sciences at the Karolinska Institute, both in Sweden, and post-doctoral training in biomedical engineering at Boston University. He has held academic appointments at Karolinska Institute, Boston University, MIT and Harvard Medical School. He is also Chief Technology Officer and co-inventor of Walkasins, a wearable sensory prosthesis for balance.

Caution: Please review the Instructions for Use for a complete listing of indications, contraindications, warnings, and precautions prior to using this device. There are potential risks and complications with using this product including but not limited to: patients should not rely solely on Walkasins to maintain balance, this product cannot prevent falls; potential skin breakdown or injury; long-term effects of persistent low-intensity vibrations to the skin are unknown; over-tightening the strap of the Leg Unit can reduce blood flow and cause injury.

Indications for Use
Walkasins is an external lower limb sensory prosthesis intended to replace the nerve function used for detection and signaling of foot pressure sensation.

Walkasins is indicated for patients with lower limb sensory peripheral neuropathy who present with gait and balance impairments. Walkasins is indicated for patients who can feel the tactile stimuli from the Leg Unit on the lower leg.

Contraindications for Use
Walkasins is contraindicated for:

- Untreated lymphedema;
- Untreated lesion of any kind, swelling, infection, inflamed area of skin or eruptions on the lower leg near product use;
- Acute thrombophlebitis including deep vein thrombosis;
- Untreated fractures in the foot and ankle;
- Severe peripheral vascular disease.

Patient Selection Criteria

- Age: Any, as long as the Foot Pad and Leg Unit fit properly.
- Health: Must be able to walk without severe impairment even when using assistive devices.
- Education: Must be able to read and understand Instructions for Use.

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